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Clinical Studies

Alonso P, Osca J, Cano O, Pimenta P, Andres A, Yague J, Millet J, Rueda J, Sancho-Tello MJ. **The Role of Conventional and Right-Sided ECG Screening for Subcutaneous ICD in a Tetralogy of Fallot Population.** *Pacing Clin Electrophysiol.* 2017; 10 (10): 1540-8159.

<http://onlinelibrary.wiley.com/doi/10.1111/pace.13017/epdf>

BACKGROUND: Information regarding suitability for S-ICD implant in Tetralogy of Fallot (ToF) population is scarce and needs to be further explored.

Brouwer TF, Miller MA, Quast AB, Palaniswamy C, Dukkipati SR, Reddy V, Wilde AA, Willner JM, Knops RE.

Implantation of the Subcutaneous Implantable Cardioverter-Defibrillator: An Evaluation of 4 Implantation Techniques. *Circ Arrhythm Electrophysiol.* 2017; 10 (1): e004663.

<http://circep.ahajournals.org/content/circae/10/1/e004663.full.pdf>

Boston Scientific funded. BACKGROUND:

Alternative techniques to the traditional 3-incision subcutaneous implantation of the subcutaneous implantable cardioverter-defibrillator may offer procedural and cosmetic advantages. We evaluate 4 different implant techniques of the subcutaneous implantable cardioverter-defibrillator. METHODS AND RESULTS: Patients implanted with subcutaneous implantable cardioverter-defibrillators from 2 hospitals between 2009 and 2016 were included. Four implantation techniques were used depending on physician preference and patient characteristics. The 2- and 3-incision techniques both place the pulse generator subcutaneously, but the 2-incision technique omits the superior parasternal incision for lead positioning. Submuscular implantation places the pulse generator underneath the serratus anterior muscle and subfascial implantation underneath the fascial layer on the anterior side of the serratus anterior muscle. Reported outcomes include perioperative parameters, defibrillation testing, and clinical follow-up. A total of 246 patients were included with a median age of 47 years and 37% female. Fifty-four patients were implanted with the 3-incision technique, 118 with the 2-incision technique, 38 with submuscular, and 37 with subfascial. Defibrillation test efficacy and shock lead impedance during testing did not differ among the groups; respectively, $P=0.46$ and $P=0.18$. The 2-incision technique resulted in the shortest procedure duration and time-to-hospital discharge compared with the other techniques ($P<0.001$). A total of 18 complications occurred, but there were no significant differences between the groups ($P=0.21$). All infections occurred in subcutaneous implants (3-incision, $n=3$; 2-incision, $n=4$). In the 2-incision group, there were no lead displacements. CONCLUSIONS: The presented implantation techniques are feasible alternatives to the standard 3-incision subcutaneous implantation, and the 2-incision technique resulted in shortest procedure duration.

Gold MR, Knops R, Burke MC, Lambiase PD, Russo AM, Bongiorno MG, Deharo JC, Aasbo J, El Chami MF, Husby M, Carter N, Boersma L. **The Design of the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED).** *Pacing Clin Electrophysiol.* 2017; 40 (1): 1-8.

<http://onlinelibrary.wiley.com/store/10.1111/pace.12994/asset/pace12994.pdf?v=1&t=iz8kx5vh&s=a0582a6848875e948f6aff164799f40d72acbbe7>

BACKGROUND: The UNTOUCHED study will assess the safety and efficacy of the subcutaneous implantable cardioverter defibrillator (S-ICD) in the most common cohort of patients receiving ICDs. The primary goal is to evaluate the inappropriate shock (IAS)-free rate in primary prevention patients with a reduced ejection fraction (EF) and compare with a historical control of transvenous ICD patients with similar programming. METHODS AND RESULTS: The UNTOUCHED study is a global, multicenter, prospective, nonrandomized study of patients undergoing de novo S-ICD implantation for primary prevention of sudden cardiac death with a left ventricular EF \leq 35%. The primary end point of this trial is freedom from IAS at 18 months. The lower 95% confidence bound of the observed incidence will be compared to a performance goal of 91.6%, which was derived from the IAS rate in MADIT-RIT. The secondary end points are all-cause shock-free rate at 18 months, and system- and procedure-related complication-free rate at 1 month and 6 months. Enrollment of a minimum of 1,100 subjects from up to 200 centers worldwide is planned based on power calculations of the primary and principal secondary end points. CONCLUSIONS: This trial will provide important data regarding the rates of inappropriate and appropriate shock therapy in real-world use of the S-ICD in the most common group of patients receiving ICDs.

Ip JE, Wu MS, Kennel PJ, Thomas G, Liu CF, Cheung JW, Markowitz SM, Lerman BB. **Eligibility of Pacemaker Patients for Subcutaneous Implantable Cardioverter Defibrillators.** *J Cardiovasc Electrophysiol.* 2017; 10 (10): 1540-8167. <http://onlinelibrary.wiley.com/doi/10.1111/jce.13182/abstract>

INTRODUCTION: The subcutaneous implantable cardioverter defibrillator (ICD) has emerged as a viable therapeutic option for patients who are deemed high risk for sudden cardiac death. Previous studies have shown that 7-15% of patients are not candidates for the S-ICD based on their intrinsic QRS/T-wave morphology. Presently, it is not known if the S-ICD can be considered as supplementary therapy in patients who are ventricularly paced. We sought to determine the proportion of ventricularly paced patients who would qualify for an S-ICD. METHODS AND RESULTS: We evaluated 100 patients with transvenous pacemakers/ICDs, including 25 biventricular devices to determine S-ICD candidacy during right ventricular (RV) pacing and biventricular pacing based on the recommended QRS:T-wave ratio screening template. 58% of patients qualified for an S-ICD based on their QRS morphology during ventricular pacing. More patients during biventricular pacing met criteria compared to during RV pacing alone (80% versus 46%, $p < 0.01$). Patients that were paced from the RV septum were more likely to qualify compared to those paced from the RV apex (67% versus 37%, respectively, $p < 0.01$). CONCLUSION: While S-ICD implantation may be considered as supplemental therapy in select patients with preexisting transvenous devices, relatively fewer candidates who are paced from the RV apex qualify. QRS morphologies generated from biventricular pacing as well as from septal RV pacing are more likely to screen in based on the recommended S-ICD template. This article is protected by copyright. All rights reserved.

Maurizi N, Tanini I, Olivotto I, Amendola E, Limongelli G, Losi MA, Allocca G, Perego GB, Pieragnoli P, Ricciardi G, De Filippo P, Ferrari P, Quarta G, Viani S, Rapacciuolo A, Bongiorno MG, Cecchi F. **Effectiveness of subcutaneous implantable cardioverter-defibrillator testing in patients with hypertrophic cardiomyopathy.** *Int J Cardiol.* 2017: Epub before print. http://ac.els-cdn.com/S0167527316337068/1-s2.0-S0167527316337068-main.pdf?_tid=c9183448-e8a8-11e6-ac6b-0000aab0f6b&acdnat=1485972410_9d29112b6f357de900624d545590561d

BACKGROUND: Subcutaneous ICD (S-ICD) is a promising option for Hypertrophic Cardiomyopathy (HCM) patients at risk of Sudden Cardiac Death (SCD). However, its effectiveness in terminating ventricular arrhythmias in HCM is yet unresolved. METHODS: Consecutive HCM patients referred for S-ICD implantation were prospectively enrolled. Patients underwent one or two attempts of VF induction by the programmer. Successful conversion was defined as any 65J shock that terminated VF (not requiring rescue shocks). Clinical and instrumental parameters were analyzed to study predictors of conversion failure. RESULTS: Fifty HCM patients (34 males, 40+/-16years) with a mean BMI of 25.2+/-4.4kg/m² were evaluated. Mean ESC SCD risk of was 6.5+/-3.9% and maximal LV wall thickness (LVMWT) was 26+/-6mm. In 2/50 patients no arrhythmias were inducible, while in 7 (14%) only sustained ventricular tachycardia was induced and cardioverted. In the remaining 41 (82%) patients, 73 VF episodes were induced (1 episode in 14 and >1 in 27 patients). Of these, 4 (6%) spontaneously converted. In 68/69 (98%) the S-ICD successfully cardioverted, but failed in 1 (2%) patient, who needed rescue defibrillation. This patient was severely obese (BMI 36) and LVMWT of 25mm. VF was re-induced and successfully converted by the 80J reversed polarity S-ICD. CONCLUSIONS: Acute DT at 65J at the implant showed the effectiveness of S-ICD in the recognition and termination of VT/VF in all HCM patients except one. Extreme LVH did not affect the performance of the device, whereas severe obesity was likely responsible for the single 65J failure.

Mesquita J, Cavaco D, Ferreira A, Lopes N, Santos PG, Carvalho MS, Haas A, Costa F, Carmo P, Morgado F, Adragao P, Mendes M. **Effectiveness of subcutaneous implantable cardioverter-defibrillators and determinants of inappropriate shock delivery.** *Int J Cardiol.* 2017; Epub before print. http://ac.els-cdn.com/S0167527317300657/1-s2.0-S0167527317300657-main.pdf?_tid=cb74de26-e8a8-11e6-92d0-00000aacb361&acdnat=1485972414_b96dd8c54fb61dd61f3e691208a7acf2 *Boston Scientific (S-ICD model 1010; EMBLEM).* **AIMS:** Assess subcutaneous implantable cardioverter-defibrillator (S-ICD) effectiveness in the prevention of sudden cardiac death and the impact of demographics and the initial detection algorithm in the delivery of inappropriate shocks (safety). **METHODS:** Real world prospective registry in which we assessed 54 patients (40+/-17years old, 85% males) who underwent S-ICD implantation for primary or secondary prevention of SCD. Safety and efficacy outcomes were defined as the delivery of inappropriate shocks and the prevention of sudden cardiac death, respectively. Tiered-therapy S-ICD had at least two programmed zones, determined by the longest RR interval. **RESULTS:** During a mean follow-up of 2.6+/-1.9years, 6 patients (11%) died, none due to sudden cardiac death. Six patients (11%) received appropriate therapies, irrespectively of the established detection algorithm (p=0.59). All ventricular tachycardia and fibrillation episodes were adequately treated. Nine patients (17%) had inappropriate shocks: 6 without tiered-therapy vs 3 with previously programmed tiered-therapy (p=0.001). The yearly rate of inappropriate shocks was 17%/year with single zone detection vs 4%/year with tiered-therapy programming (p=0.007). Single-zone detection programming was an independent predictor of inappropriate shock delivery (HR 1.49, IC 95%: 1.05-18.80, p=0.04). **CONCLUSION:** In this selected population of patients, the S-ICDs proved effective in preventing sudden cardiac death. Tiered-therapy was independently associated with a lower rate of inappropriate shock delivery.

Wilson DG, Cronbach PL, Panfilo D, Greenhut SE, Stegemann BP, Morgan JM. **Reconstruction of an 8-lead surface ECG from two subcutaneous ICD vectors.** *Int J Cardiol.* 2017; 27 (27): 1874-754. <http://dx.doi.org/10.1016/j.ijcard.2017.01.117> **INTRODUCTION:** Techniques exist which allow surface ECGs to be reconstructed from reduced lead sets. We aimed to reconstruct an 8-lead ECG from two independent S-ICD sensing electrodes vectors as proof of this principle. **METHODS:** Participants with ICDs (N=61) underwent 3minute ECGs using a TMSi Porti7 multi-channel signal recorder (TMS international, The Netherlands) with electrodes in the standard S-ICD and 12-lead positions. Participants were randomised to either a training (N=31) or validation (N=30) group. The transformation used was a linear combination of the 2 independent S-ICD vectors to each of the 8 independent leads of the 12-lead ECG, with coefficients selected that minimized the root mean square error (RMSE) between recorded and derived ECGs when applied to the training group. The transformation was then applied to the validation group and agreement between the recorded and derived lead pairs was measured by Pearson correlation coefficient (r) and normalised RMSE (NRMSE). **RESULTS:** In total, 27 patients with complete data sets were included in the validation set consisting of 57,888 data points from 216 full lead sets. The distribution of the r and NRMSE were skewed. Mean r=0.770 (SE 0.024), median r=0.925. NRMSE mean=0.233 (SE 0.015) median=0.171. **CONCLUSIONS:** We have demonstrated that the reconstruction of an 8-lead ECG from two S-ICD vectors is possible. If perfected, the ability to generate accurate multi-lead surface ECG data from an S-ICD would potentially allow recording and review of clinical arrhythmias at follow-up.

Arias MA, Pachon M, Akerstrom F, Puchol A, Rodriguez-Padial L. **Two-incision Technique for Subcutaneous Cardioverter-defibrillator Implantation: Method of Choice?** *Rev Esp Cardiol (Engl Ed).* 2016; 69 (4): 445-6. http://pdf.revespcardiol.org/watermark/ctl_servlet?_f=10&pident_articulo=90450759&pident_usuario=0&pcontactid=&pident_revista=255&ty=138&accion=L&origen=cardio&web=www.revespcardiol.org&lan=en&fichero=255v69n04a90450759pdf001.pdf "...The results of our series show that the S-ICD can be appropriately positioned using the 2-incision technique, permitting cardiac signal detection without oversensing or undersensing, providing appropriate defibrillation, and ensuring system stability during follow-up. These results support the adoption of this technique as a first-line approach in S-ICD implantation...".

Aykan HH, Karagoz T, Gulgun M, Ertugrul I, Aypar E, Ozer S, Alehan D, Celiker A, Ozkutlu S. **Midterm results of implantable cardioverter defibrillators in children and young adults from a single center in turkey.** *Pacing Clin Electrophysiol.* 2016; 39 (11): 1225-39. <http://onlinelibrary.wiley.com/doi/10.1111/pace.12954/pdf> *Guidant (battery; ventricular lead); Medtronic (battery; ventricular lead); St Jude Medical (battery; ventricular lead); Boston Scientific (SICD SQ-RX 1010; Q-Trak 3010).* Background Despite concerns about complications with the implantable cardioverter defibrillator (ICD), it is effective for the prevention of sudden cardiac death (SCD). We aimed to analyze our midterm experience with ICD in children and young adults. **Methods** This retrospective study included patients who were implanted with an ICD between 2001 and 2014. Demographic characteristics, clinical information, shock features, and complications for all patients with ICD were analyzed. The study population was divided into two groups: early-era patients implanted before 2008, and late-era patients implanted after 2008. **Results** Sixty-nine patients (median age: 12 years, median follow-up: 52 months) were implanted with an ICD. Diagnostic categories were channelopathy (56.6%), cardiomyopathy (36.2%), congenital

heart disease (5.8%), and other (1.4%). We performed implantation for primary prevention in 66.6% (39.3% in early-era patients and 85.4% in late-era patients). Thirty-one (44.9%) received 139 appropriate shocks (66% of total shocks) while 14 (20.2%) received 71 inappropriate shocks. However, there was no statistically significant difference in the use of appropriate shocks in the primary (66.7%) versus the secondary (72.2%) prevention groups. The incidence of appropriate and inappropriate shock was 66.7% and 33.3% in the primary prevention group, and 72.2% and 27.8% in the secondary prevention group, respectively. Two patients died, although only one death was the result of a lead problem. Conclusions Although lead integrity problems, inappropriate shocks, and infections are significant issues, ICD therapy appears to be a safe, effective, and necessary option for the prevention of SCD in both children and young adults. Table III. Summary of Publications Related to ICD implantation in Pediatric Population.

- Boersma L, Burke MC, Neuzil P, Lambiase P, Friehling T, Theuns DA, Garcia F, Carter N, Stivland T, Weiss R. **Infection and mortality after implantation of a subcutaneous ICD after transvenous ICD extraction.** *Heart Rhythm.* 2016; 13 (1): 157-64. http://ac.els-cdn.com/S1547527115011297/1-s2.0-S1547527115011297-main.pdf?_tid=0a376e2c-cae0-11e5-870a-00000aacb360&acdnat=1454550109_cbc12d8df9ae6d1e2113f8888ffaf5ab Boston Scientific employee (Carter; Stivland). *EFFORTLESS Registry & IDE study, NCDR ICD Registry.* Background The subcutaneous implantable cardioverter-defibrillator (S-ICD) provides an alternative to the transvenous implantable cardioverter-defibrillator (TV-ICD). Patients undergoing TV-ICD explantation may be eligible for reimplantation with an S-ICD; however, information on safety outcomes in this complex population is limited. Objective This analysis was designed to provide outcome and safety data from S-ICD patients who received their device after TV-ICD explantation. Methods Patients in the S-ICD IDE Study and EFFORTLESS Registry with a prior TV-ICD explantation, as well as those with no prior implantable cardioverter-defibrillator (ICD), were included. Patients were divided into 3 groups: those implanted with the S-ICD after TV-ICD extraction for system-related infection (n = 75); those implanted after TV-ICD extraction for reasons other than system-related infection (n = 44); and patients with no prior ICD (de novo implantations, n = 747). Results Mean follow-up duration was 651 days, and all-cause mortality was low (3.2%). Patients previously explanted for TV-ICD infection were older (55.5 ± 14.6 , 47.8 ± 14.3 and 49.9 ± 17.3 years in the infection, noninfection, and de novo cohorts, respectively; $P = .01$), were more likely to have received the ICD for secondary prevention (42.7%, 37.2% and 25.6%; $P < 0.0001$) and had higher percentages of comorbidities, including atrial fibrillation, congestive heart failure, diabetes mellitus, and hypertension, in line with the highest mortality rate (6.7%). Major infection after S-ICD implantation was low in all groups, with no evidence that patients implanted with the S-ICD after TV-ICD explantation for infection were more likely to experience a subsequent reinfection. Conclusion The S-ICD is a suitable alternative for TV-ICD patients whose devices are explanted for any reason. Postimplantation risk of infection remains low even in patients whose devices were explanted for prior TV-ICD infection.
- Botto GL, Forleo GB, Capucci A, Solimene F, Vado A, Bertero G, Palmisano P, Pisano E, Rapacciuolo A, Infusino T, Vicentini A, Viscusi M, Ferrari P, Talarico A, Russo G, Boriani G, Padeletti L, Lovecchio M, Valsecchi S, D'Onofrio A. **The Italian subcutaneous implantable cardioverter-defibrillator survey: S-ICD, why not?** *Europace.* 2016: Epub before print. <https://academic.oup.com/europace/article/2736223/The-Italian-subcutaneous-implantable-cardioverter> AIAC S-ICD Why Not Survey. Boston Scientific employee (Valsecchi; Lovecchio). *AIMS:* A recommendation for a subcutaneous-implantable cardioverter-defibrillator (S-ICD) has been added to recent European Society of Cardiology Guidelines. However, the S-ICD is not ideally suitable for patients who need pacing. The aim of this survey was to analyse the current practice of ICD implantation and to evaluate the actual suitability of S-ICD. **METHODS AND RESULTS:** The survey 'S-ICD Why Not?' was an independent initiative taken by the Italian Heart Rhythm Society (AIAC). Clinical characteristics, selection criteria, and factors guiding the choice of ICD type were collected in consecutive patients who underwent ICD implantation in 33 Italian centres from September to December 2015. A cardiac resynchronization therapy (CRT) device was implanted in 39% (369 of 947) of patients undergoing de novo ICD implantation. An S-ICD was implanted in 12% of patients with no CRT indication (62 of 510 with available data). S-ICD patients were younger than patients who received transvenous ICD, more often had channelopathies, and more frequently received their device for secondary prevention of sudden death. More frequently, the clinical reason for preferring a transvenous ICD over an S-ICD was the need for pacing (45%) or for antitachycardia pacing (36%). Nonetheless, only 7% of patients fulfilled conditions for recommending permanent pacing, and 4% of patients had a history of monomorphic ventricular tachycardia that might have been treatable with antitachycardia pacing. **CONCLUSION:** The vast majority of patients needing ICD therapy are suitable candidates for S-ICD implantation. Nevertheless, it currently seems to be preferentially adopted for secondary prevention of sudden death in young patients with channelopathies.

- Boveda S, Lenarczyk R, Haugaa K, Fumagalli S, Madrid AH, Defaye P, Broadhurst P, Dagres N. **Implantation of subcutaneous implantable cardioverter defibrillators in Europe: results of the European Heart Rhythm**

Association survey. *Europace*. 2016; 18 (9): 1434-9.

<http://europace.oxfordjournals.org/content/europace/18/9/1434.full.pdf> AIMS: The purpose of this European Heart Rhythm Association (EHRA) survey is to provide an overview of the current use of subcutaneous cardioverter defibrillators (S-ICDs) across a broad range of European centres. METHODS AND RESULTS: A questionnaire was sent via the internet to centres participating in the EHRA electrophysiology research network. Questions included standards of care and policies used for patient management, indications, and techniques of implantation of the S-ICDs. In total, 52 centres replied to the questionnaire. More than one-fourth of the responding centres does not implant the S-ICD (n = 14, 27%). The majority reported to have implanted <10 (50%) or 10-29 (23%) S-ICDs during the last 12 months. Lack of reimbursement (25%), non-availability (19%), and cost of the device (25%) seem to limit the use of the S-ICD. The most commonly reported indications for S-ICD implantation are a difficult vascular access (82%), a history of previous complicated transvenous ICD (80%), young age (69%), or an anticipated higher risk of infection (63%). Inappropriate therapies were the most frequently reported major problems (38%), but the majority of respondents (51%) never encountered any issue after an S-ICD implantation. Most of the respondents (83%) anticipate significant increase of S-ICD use within the next 2 years. CONCLUSION: This survey provides a contemporary insight into S-ICD implantation and management in the European electrophysiology centres, showing different approaches, depending on local policies. Cost issues or lack of reimbursement strongly influence the dissemination of the device. However, most respondents retain that S-ICD use will significantly increase in a very short time.

Brouwer TF, Driessen AHG, Olde Nordkamp LRA, Kooiman KM, de Groot JR, Wilde AAM, Knops RE. **Surgical Management of Implantation-Related Complications of the Subcutaneous Implantable Cardioverter-Defibrillator. *JACC: Clinical Electrophysiology*.** 2016; 2 (1): 89-96.

<http://www.sciencedirect.com/science/article/pii/S2405500X1500362X> PRAETORIAN. *ClinicalTrials.gov* ID: NCT01296022. Zoll Medical (*LifeVest*). AbstractObjectives This study assessed outcomes in patients in whom subcutaneous implantable cardioverter-defibrillator (S-ICD) therapy was continued after implantation-related complications, in order to avoid conversion to transvenous ICD therapy. Background Patients at risk for sudden cardiac death benefit from ICD therapy, despite a significant risk for complications. S-ICD has a similar complication rate as transvenous ICD therapy, but the absence of transvenous leads may hold long-term benefits, especially in young ICD patients. Methods In the largest single-center cohort available to date, S-ICD patients implanted between 2009 and 2015 were included. Results There were 123 patients at a median age of 40 years. During a median follow-up of 2 years, 10 patients (9.4%) suffered implant-related complications. There were 5 infections, 3 erosions, and 2 implant failures for which 21 surgical procedures were needed. In 9 of 10 patients, S-ICD therapy could be continued after intervention. In 6 patients, the period between extraction and reimplantation of the S-ICD system was bridged with a wearable cardioverter-defibrillator (WCD). The pulse generator was reimplanted at the original site in 5 patients and in 3 underneath the serratus anterior muscle. One patient was not reimplanted following extraction due to recurrent infections. Conversion to a transvenous ICD was not needed in any patient. Conclusions In most patients with a complication, S-ICD therapy could be continued after intervention, avoiding the need to convert to a transvenous system. Bridging to recovery with a WCD and submuscular implantation of the pulse generator are effective treatment strategies to manage S-ICD complications.

Brouwer TF, Kooiman KM, Olde Nordkamp LR, van Halm VP, Knops RE. **Algorithm-based screening may improve patient selection for the subcutaneous implantable defibrillator. *JACC: Clinical Electrophysiology*.** 2016; 2 (5): 605-14. http://ac.els-cdn.com/S2405500X16300081/1-s2.0-S2405500X16300081-main.pdf?_tid=c3f4e914-ad22-11e6-a65a-00000aabb0f27&acdnat=1479427731_f58b6e9055a0ba16d0e825bc831de229 Cameron

Health (SQ-RX model A1010; Q-TRAK model A3010; Q-Tech programmer). AbstractObjectives The study sought to describe the concept of algorithm-based screening with an external subcutaneous implantable cardioverter-defibrillator (S-ICD) to evaluate sensing using the rhythm discrimination algorithm of the device. Background In a proportion of patients, screening for S-ICD therapy with the dedicated screening tool results in false negative and false positive results. Methods Both patients who failed the standard screening and who passed with abnormal baseline ECGs were screened with an external S-ICD to evaluate sensing at rest and during exercise in all 3 sensing vectors (algorithm-based screening). Patients with adequate sensing were implanted with an S-ICD. Follow-up data regarding (in)appropriate shocks was collected. Results Algorithm-based screening was performed in 15 patients. Group 1 consists of 8 who failed standard screening and Group 2 consists of 7 who passed and had abnormal ECGs. Six of 8 who failed standard screening in all sensing vectors demonstrated adequate sensing with the external S-ICD and were implanted with an S-ICD. Of these 6 implanted patients in Group 1, 1 inappropriate shock was observed duration median of 17 months' follow-up and 2 episodes of ventricular fibrillation were successfully treated. Of the 7 patients in Group 2, who passed standard screening, 2 demonstrated inadequate sensing during additional screening with the external S-ICD. No appropriate or inappropriate shocks were observed in Group 2 during 10 months' follow-up. Conclusions Algorithm-based

screening with the external S-ICD may improve patient selection and reduce the number of false positive and false negative screening results of the standard screening method. .

- Brouwer TF, Yilmaz D, Lindeboom R, Buiten MS, Olde Nordkamp LR, Schalij MJ, Wilde AA, van Erven L, Knops RE. **Long-term clinical outcomes of subcutaneous versus transvenous implantable defibrillator therapy.** *J Am Coll Cardiol.* 2016; 68 (19): 2047-55. http://ac.els-cdn.com/S0735109716351920/1-s2.0-S0735109716351920-main.pdf?_tid=1fd4e924-c0aa-11e6-8e8e-00000aacb362&acdnat=1481574939_7044bc9078f722fc78dcbd345aa7d563 Boston Scientific (SICDs; ICDs); Biotronik (ICDs); Medtronic (ICDs); St Jude Medical (ICDs). **BACKGROUND:** Transvenous implantable cardioverter-defibrillators (TV-ICDs) improve survival in patients at risk for sudden cardiac death, but complications remain an important drawback. The subcutaneous ICD (S-ICD) was developed to overcome lead-related complications. Comparison of clinical outcomes of both device types in previous studies was hampered by dissimilar patient characteristics. **OBJECTIVES:** This retrospective study compares long-term clinical outcomes of S-ICD and TV-ICD therapy in a propensity-matched cohort. **METHODS:** The authors analyzed 1,160 patients who underwent S-ICD or TV-ICD implantation in 2 high-volume hospitals in the Netherlands. Propensity matching for 16 baseline characteristics, including diagnosis, yielded 140 matched pairs. Clinical outcomes were device-related complications requiring surgical intervention, appropriate and inappropriate ICD therapy, and were reported as 5-year Kaplan-Meier rate estimates. **RESULTS:** All 16 baseline characteristics were balanced in the matched cohort of 140 patients with S-ICDs and 140 patients with TV-ICDs (median age 41 years [interquartile range: 30 to 52 years] and 40% women). The complication rate was 13.7% in the S-ICD group versus 18.0% in the TV-ICD group ($p = 0.80$). The infection rate was 4.1% versus 3.6% in the TV-ICD groups ($p = 0.36$). Lead complications were lower in the S-ICD arm compared with the TV-ICD arm, 0.8% versus 11.5%, respectively ($p = 0.03$). S-ICD patients had more nonlead-related complications than TV-ICD patients, 9.9% versus 2.2%, respectively ($p = 0.047$). Appropriate ICD intervention (antitachycardia pacing and shocks) occurred more often in the TV-ICD group (hazard ratio [HR]: 2.42; $p = 0.01$). The incidence of appropriate (TV-ICD HR: 1.46; $p = 0.36$) and inappropriate shocks (TV-ICD HR: 0.85; $p = 0.64$) was similar. **CONCLUSIONS:** The complication rate in patients implanted with an S-ICD or TV-ICD was similar, but their nature differed. The S-ICD reduced lead-related complications significantly, at the cost of nonlead-related complications. Rates of appropriate and inappropriate shocks were similar between the 2 groups.
- D'Souza BA, Epstein AE, Garcia FC, Kim YY, Agarwal SC, Belott PH, Burke MC, Leon AR, Morgan JM, Patton KK, Shah M. **Outcomes in Patients With Congenital Heart Disease Receiving the Subcutaneous Implantable-Cardioverter Defibrillator: Results From a Pooled Analysis From the IDE Study and the EFFORTLESS S-ICD Registry.** *JACC: Clinical Electrophysiology.* 2016; 2 (5): 615-22. http://ac.els-cdn.com/S2405500X16300056/1-s2.0-S2405500X16300056-main.pdf?_tid=efe5b0d0-ad22-11e6-81bc-00000aab0f02&acdnat=1479427804_0c93ece6a364e14d8ff211d95d12033c EFFORTLESS registry. Cameron Health (S-ICD, version 1.59.0 or later). **Abstract Objectives** This study was conceived to determine the safety and efficacy of the subcutaneous implantable cardioverter-defibrillator (S-ICD) in patients with congenital heart disease (CHD). **Background** The S-ICD is a treatment option for patients with CHD in which a transvenous device is contraindicated due to anatomic considerations. However, efficacy in this group has not been determined. **Methods** A pooled analysis of 865 patients in the EFFORTLESS (Evaluation of Factors Affecting the Clinical Outcome and Cost-Effectiveness) registry (an international observational database) and a U.S. Investigational Device Exemption study were reviewed. **Results** Nineteen CHD patients versus 846 non-CHD patients with a median follow-up of 567 days and 639 days, respectively, were included. There were no deaths and no appropriate shocks for ventricular tachycardia/ventricular fibrillation in the CHD cohort, versus 26 deaths (3.1%, $p = 0.42$) and 111 appropriate shocks in 59 patients (7.1%) in the non-CHD cohort ($p = 0.23$). There were similar complication rates for the CHD versus non-CHD groups (10.5 vs. 9.6% [$p = 0.89$]), with inappropriate shocks for T-wave oversensing as the only complication in the CHD group ($n = 2$). The rate of inappropriate shocks was similar for both groups (10.5% vs. 10.9% [$p = 0.96$]). Successful defibrillation testing at 80J was comparable for the CHD versus non-CHD groups (100% vs. 98.5%). **Conclusions** The overall analysis of the CHD cohort from the pooled data of the Investigational Device Exemption study and the EFFORTLESS registry shows that the S-ICD is a safe option in CHD patients deemed to be at high risk for sudden cardiac death who do not have pacing indications. Further research to accurately define sudden cardiac death risk in the diverse anatomic substrates of CHD patients is warranted. ["...the data provided for analysis were provided by Boston Scientific. Statistical analysis was performed by Nathan Carter...."].
- EI-Chami MF, Harbieh B, Levy M, Leon AR, Merchant FM. **Clinical and electrocardiographic predictors of T wave oversensing in patients with subcutaneous ICD.** *J Arrhythm.* 2016; 32 (3): 181-5. http://ac.els-cdn.com/S1880427616000090/1-s2.0-S1880427616000090-main.pdf?_tid=0e9e8fe8-42b5-11e6-be55-00000aab0f6c&acdnat=1467725788_68f3f6d757163efa0c782f44f1583044 Cameron Health (SQ-RX model)

1010; *Subcutaneous lead model 3010*). **BACKGROUND:** T wave oversensing (TWOS) is a major drawback of the subcutaneous implantable cardioverter defibrillator (S-ICD). Data on predictors of TWOS in S-ICD recipients are limited. We sought to investigate predictors of TWOS in a cohort of patients receiving an S-ICD at our institution. **METHODS:** S-ICD recipients at our center were identified retrospectively and stratified based on the presence or absence of TWOS. Clinical and electrocardiographic parameters were collected and compared between the 2 groups. **RESULTS:** Ninety-two patients underwent an S-ICD implantation at our institution between April 2010 and January 2015. Six (6.5%) patients had TWOS. These patients were younger (38.1+/-13.7 vs. 52.3+/-16.1 years, $p=0.04$) and had higher left ventricle ejection fractions (48.5+/-14.9% vs. 28.4+/-12.2%, $p<0.01$) than patients without a history of TWOS. Baseline 12-lead electrocardiogram (ECG) parameters were not different between the 2 groups. Leads I, II, and avF (which mimic the sensing vectors of the S-ICD) were further inspected to identify ECG characteristics that could predict TWOS. The QRS amplitude in ECG lead I was significantly smaller in the TWOS group than in the non-TWOS group (3.7 vs. 7.4 mV, $p=0.02$). **CONCLUSION:** In this study, younger age, higher ejection fraction, and lower QRS amplitude were associated with TWOS. These findings could help identify patients referred for S-ICD at high-risk of TWOS.

Essandoh MK, Otey AJ, Abdel-Rasoul M, Stein EJ, Turner KR, Joseph NC, Daoud EG. **Monitored Anesthesia Care for Subcutaneous Cardioverter-Defibrillator Implantation: A Single-Center Experience.** *J Cardiothorac Vasc Anesth.* 2016; 30 (5): 1228-33. http://ac.els-cdn.com/S1053077016301793/1-s2.0-S1053077016301793-main.pdf?_tid=edf4cf78-8977-11e6-8433-0000aacb360&acdnat=1475506066_2215e084320138909c3279976928898d **BACKGROUND:** To date, general anesthesia has been suggested as the preferred approach for implantation of a subcutaneous implantable cardioverter-defibrillator (S-ICD). The purpose of this study was to assess the use of monitored anesthesia care (MAC) for S-ICD implantation. The goals were to assess adequate sedation and analgesia (efficacy endpoints) and major perioperative airway or hemodynamic compromise (safety endpoints). The authors hypothesized that MAC may provide adequate sedation and analgesia and no major perioperative airway or hemodynamic compromise during S-ICD implantation and multiple defibrillation threshold (DFT) testing. **METHODS:** Prospectively collected data of patients who underwent S-ICD implantation with MAC from 2015 to 2016 were analyzed retrospectively. The efficacy endpoints were the provision of an optimal depth of sedation and analgesia to facilitate S-ICD implantation without intra-procedure patient discomfort or awareness, and the absence of "severe" pain at the lead tunneling and the generator insertion sites post-procedure. The safety endpoints included: (1) peri-procedural hypotension, as defined by a mean arterial pressure (MAP) <60 mmHg refractory to conventional pharmacotherapy, (2) heart rate (HR) <45 bpm requiring pharmacologic support, and (3) sedation-induced airway compromise requiring endotracheal intubation. **MEASUREMENTS:** MAP and HR were recorded during S-ICD implantation and DFT testing. The maximum and minimum infusion rates of propofol, supplemental sedatives, and analgesics, and doses of vasopressor and/or inotropic agents administered intra-procedurally were recorded. Post-procedure pain scores also were noted. **RESULTS:** Ten patients underwent S-ICD implantation with MAC (mean age, 56 years; 50% men; mean left ventricular ejection fraction was 39%). Implantation of the S-ICD system using MAC was successful in all patients without any major adverse events. The mean baseline MAP was 92.8 mmHg, and the mean end-procedure MAP was 88 mmHg ($p = 0.26$). When compared to baseline and end-procedure, the mean lowest intra-procedure MAP was significantly lower (67.4 mmHg; $p = 0.0001$). The mean baseline HR was 65.7 bpm, and the mean end-procedure HR was 70.1 bpm ($p = 0.28$). When compared to baseline and end-procedure, the mean lowest intra-procedure HR was significantly lower (55.8 bpm; $p<0.001$). MAC was not associated with airway compromise in any patient, and post-procedure pain was rated as no greater than "mild". **CONCLUSIONS:** Among a heterogeneous patient population undergoing S-ICD implantation and DFT testing, the use of MAC is efficacious, feasible, and safe.

Essandoh MK, Portillo JG, Weiss R, Otey AJ, Zuleta-Alarcon AN, Humeidan ML, Torres JL, Flores AS, Castellon-Larios K, Abdel-Rasoul M, Andritsos MJ, Perez WJ, Stein EJ, Turner KR, Dimitrova GT, Awad H, Bhandary SP, Tripathi RS, Joseph NC, Hummel JD, Augostini RS, Kalbfleisch SJ, Tyler JD, Houmsse M, Daoud EG. **Anesthesia care for subcutaneous implantable cardioverter/defibrillator placement: a single-center experience.** *J Clin Anesth.* 2016; 31: 53-9. *This article is not in the library's collection.* **BACKGROUND:** The recently approved subcutaneous implantable cardioverter/defibrillator (S-ICD) uses a single extrathoracic subcutaneous lead to treat life-threatening ventricular arrhythmias, such as ventricular tachycardia and ventricular fibrillation. This is different from conventional transvenous ICDs, which are typically implanted under sedation. Currently, there are no reports regarding the anesthetic management of patients undergoing S-ICD implantation. **STUDY OBJECTIVES:** This study describes the anesthetic management and outcomes in patients undergoing S-ICD implantation and defibrillation threshold (DFT) testing. **METHODS:** The study population consists of 73 patients who underwent S-ICD implantation. General anesthesia ($n = 69$, 95%) or conscious/deep sedation ($n = 4$, 5%) was used for device implantation. **MEASUREMENTS:** Systolic blood pressure (SBP) and heart rate were recorded peri-procedurally for S-ICD implantation and DFTs. Major adverse events were SBP <90 mm Hg

refractory to vasopressor agents, significant bradycardia (heart rate <45 beats per minute) requiring pharmacologic intervention and, "severe" pain at the lead tunneling site and the S-ICD generator insertion site based on patient perception. INTERVENTIONS: Of the 73 patients, 39 had SBP <90 mm Hg (53%), and intermittent boluses of vasopressors and inotropes were administered with recovery of SBP. In 2 patients, SBP did not respond, and the patients required vasopressor infusion in the intensive care unit. MAIN RESULTS: Although the S-ICD procedure involved extensive tunneling and a mean of 2.5 +/- 1.7 DFTs per patient, refractory hypotension was a major adverse event in only 2 patients. The mean baseline SBP was 132.5 +/- 22.0 mm Hg, and the mean minimum SBP during the procedure was 97.3 +/- 9.2 mm Hg (P < .01). There was also a mean 13-beats per minute decrease in heart rate (P < .01), but no pharmacologic intervention was required. Eight patients developed "severe" pain at the lead tunneling and generator insertion sites and were adequately managed with intravenous morphine. CONCLUSIONS: Among a heterogeneous population, anesthesiologists can safely manage patients undergoing S-ICD implantation and repeated DFTs without wide swings in SBP and with minimal intermittent pharmacologic support.

Ferrari P, Giofre F, De Filippo P. **Intermuscular pocket for subcutaneous implantable cardioverter defibrillator: Single-center experience.** *J Arrhythm.* 2016; 32 (3): 223-6. http://ac.els-cdn.com/S1880427616000132/1-s2.0-S1880427616000132-main.pdf?_tid=19742efa-42b5-11e6-81d4-00000aab0f02&acdnat=1467725806_de04e2d986f00a5a4582ee9698da8d7d The subcutaneous implantable cardioverter defibrillator (S-ICD) is a novel device now accepted in clinical practice for treating ventricular arrhythmias. In 14 consecutive patients, S-ICD devices were placed in the virtual space between the anterior surface of the serratus anterior muscle and the posterior surface of the latissimus dorsi muscle. During a mean follow up of 9 months, no dislocations, infections, hematoma formations, or skin erosions were observed. Intermuscular implantation of the S-ICD could be a reliable, safe, and appealing alternative to the standard subcutaneous placement.

Friedman DJ, Parzynski CS, Varosy PD, Prutkin JM, Patton KK, Mithani A, Russo AM, Curtis JP, Al-Khatib SM. **Trends and In-Hospital Outcomes Associated With Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States.** *JAMA Cardiol.* 2016: Epub before print. <http://cardiology.jamanetwork.com/data/Journals/CARDIOLOGY/0/hoi160057.pdf> *National Cardiovascular Data Registry ICD Registry. Boston Scientific (S-ICD).* Importance: Trends and in-hospital outcomes associated with early adoption of the subcutaneous implantable cardioverter defibrillator (S-ICD) in the United States have not been described. Objectives: To describe early use of the S-ICD in the United States and to compare in-hospital outcomes among patients undergoing S-ICD vs transvenous (TV)-ICD implantation. Design, Setting, and Participants: A retrospective analysis of 393734 ICD implants reported to the National Cardiovascular Data Registry ICD Registry, a nationally representative US ICD registry, between September 28, 2012 (US Food and Drug Administration S-ICD approval date), and March 31, 2015, was conducted. A 1:1:1 propensity-matched analysis of 5760 patients was performed to compare in-hospital outcomes among patients with S-ICD with those of patients with single-chamber (SC)-ICD and dual-chamber (DC)-ICD. Main Outcomes and Measures: Analysis of trends in S-ICD adoption as a function of total ICD implants and comparison of in-hospital outcomes (death, complications, and defibrillation threshold [DFT] testing) among S-ICD and TV-ICD recipients. Results: Of the 393734 ICD implants evaluated during the study period, 3717 were S-ICDs (0.9%). A total of 109445 (27.8%) of the patients were female; the mean (SD) age was 67.03 (13.10) years. Use of ICDs increased from 0.2% during the fourth quarter of 2012 to 1.9% during the first quarter of 2015. Compared with SC-ICD and DC-ICD recipients, those with S-ICDs were more often younger, female, black, undergoing dialysis, and had experienced prior cardiac arrest. Among 2791 patients with S-ICD who underwent DFT testing, 2588 (92.7%), 2629 (94.2%), 2635 (94.4%), and 2784 (99.7%) were successfully defibrillated (<=65, <=70, <=75, and <=80 J, respectively). In the propensity-matched analysis of 5760 patients, in-hospital complication rates associated with S-ICDs (0.9%) were comparable to those of SC-ICDs (0.6%) (P = .27) and DC-ICD rates (1.5%) (P = .11). Mean (SD) length of stay after S-ICD implantation was comparable to that after SC-ICD implantation (1.1 [1.5] vs 1.0 [1.2] days; P = .77) and less than after DC-ICD implantation (1.1 [1.5] vs 1.2 [1.5] days; P < .001). Conclusions and Relevance: The use of S-ICDs is rapidly increasing in the United States. Early adoption has been associated with low complication rates and high rates of successful DFT testing despite frequent use in patients with a high number of comorbidities.

Frommeyer G, Dechering DG, Kochhauser S, Bettin M, Kobe J, Eckardt L, Reinke F. **Long-time "real-life" performance of the subcutaneous ICD in patients with electrical heart disease or idiopathic ventricular fibrillation.** *J Interv Card Electrophysiol.* 2016: Epub before print. <http://download.springer.com/static/pdf/759/art%253A10.1007%252Fs10840-016-0143-4.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs10840-016-0143-4&token2=exp=1464794665~acl=%2Fstatic%2Fpdf%2F759%2Fart%25253A10.1007%25252Fs10840-016-0143-4>

[4.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs10840-016-0143-4~hmac=8ec4be6e54de588e2a7c4316c1ac3ba2fad7f80aaef3ceaf300015f7135dd41](http://dx.doi.org/10.1007/s10840-016-0143-4) Boston

Scientific (S-ICD). **BACKGROUND:** The totally subcutaneous implantable defibrillator (S-ICD) has been designed as a new alternative to conventional implantable defibrillators. This system is especially attractive for young patients. However, long-term experience is not yet available. To address the question whether the S-ICD system is safe and feasible for young patients with electrical heart disease or idiopathic ventricular fibrillation (VF), the data of a standard of care prospective single center S-ICD registry were evaluated. **METHODS:** In the present study, 24 patients (age 34.2 +/- 11.5 years) with electrical heart disease or idiopathic VF received an S-ICD for primary (n = 8) or secondary prevention (n = 16). The mean follow-up duration was 29.6 +/- 15.1 months. **RESULTS:** Ventricular arrhythmias were adequately detected in four patients (17 %). In three patients (13 %) oversensing was noticed and led to at least one inappropriate shock in two patients (8 %). Further adverse events included surgical revision due to a mobile pulse generator as well as explantation of one system and switch to a transvenous ICD system due to several ineffective shocks. **CONCLUSIONS:** The results of the present study suggest that S-ICD therapy may be an attractive alternative in young patients with electrical heart disease or idiopathic VF. However, episodes of oversensing as well as ineffective shocks may occur.

Frommeyer G, Zumhagen S, Dechering DG, Larbig R, Bettin M, Loher A, Kobe J, Reinke F, Eckardt L. **Intraoperative defibrillation testing of subcutaneous implantable cardioverter-defibrillator systems-a simple issue?** *J Am Heart Assoc.* 2016; 4 (3): e003181 [7 pages]. <http://jaha.ahajournals.org/content/5/3/e003181.full.pdf>

BACKGROUND: The results of the recently published randomized SIMPLE trial question the role of routine intraoperative defibrillation testing. However, testing is still recommended during implantation of the entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) system. To address the question of whether defibrillation testing in S-ICD systems is still necessary, we analyzed the data of a large, standard-of-care prospective single-center S-ICD registry. **METHODS AND RESULTS:** In the present study, 102 consecutive patients received an S-ICD for primary (n=50) or secondary prevention (n=52). Defibrillation testing was performed in all except 4 patients. In 74 (75%; 95% CI 0.66-0.83) of 98 patients, ventricular fibrillation was effectively terminated by the first programmed internal shock. In 24 (25%; 95% CI 0.22-0.44) of 98 patients, the first internal shock was ineffective and further internal or external shock deliveries were required. In these patients, programming to reversed shock polarity (n=14) or repositioning of the sensing lead (n=1) or the pulse generator (n=5) led to successful defibrillation. In 4 patients, a safety margin of <10 J was not attained. Nevertheless, in these 4 patients, ventricular arrhythmias were effectively terminated with an internal 80-J shock. **CONCLUSIONS:** Although it has been shown that defibrillation testing is not necessary in transvenous ICD systems, it seems particular important for S-ICD systems, because in nearly 25% of the cases the primary intraoperative test was not successful. In most cases, a successful defibrillation could be achieved by changing shock polarity or by optimizing the shock vector caused by the pulse generator or lead repositioning.

Grett M, Christ M, Trappe HJ. **Predictors for need of antibradycardia and antitachycardia pacing after ICD implantation : Implications for the subcutaneous ICD [article is in German].** *Herzschrittmacherther Elektrophysiol.* 2016: <http://download.springer.com/static/pdf/797/art%253A10.1007%252Fs00399-016-0460-4.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs00399-016-0460-4&token2=exp=1479250319~acl=%2Fstatic%2Fpdf%2F797%2Fart%25253A10.1007%25252Fs00399-016-0460-4.pdf%3ForiginUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%252Fs00399-016-0460-4~hmac=f815e5ac250dc2617997c72cec52734b7efa63b9da89a60e6953af036fdc7192>

BACKGROUND: Little is known about the incidence and risk factors for progression to pacemaker dependency or the need for cardiac resynchronization in typical patients with an implanted defibrillator with regard to an alternative implantation of a subcutaneous ICD (S-ICD). **STUDY DESIGN AND METHODS:** After retrospective analysis of 291 patients with first implantation of a transvenous single chamber ICD (VVI-ICD) from 2010-2016 and excluding those with an indication for pacemaker or lack of follow-up data, 121 patients were included and investigated with regard to the following endpoints: need for pacemaker stimulation, upgrade for cardiac resynchronization (CRT), and secondary occurrence and effectiveness of antitachycardia pacing (ATP). We compared the results with those of fundamental S-ICD studies and tried to determine risk factors on the basis of medical history and pre-implant data. **RESULTS:** The study population and the rate of endpoints were significantly different to those of fundamental S-ICD studies. Within a 2.2-year follow-up, 14.9 % of the patients developed a need for pacemaker stimulation and 0.8 % the need for cardiac resynchronization. Excluding patients who at implantation were already at high risk for pacemaker dependency, 7.4 % remained with a reached endpoint. We identified atrial fibrillation and bundle-branch-block as risk factors. All episodes of ventricular tachycardia (VT) could be terminated by ATP in 9.9 % of the patients. They more often had ischemic heart disease and a secondary prophylactic indication for an ICD. **CONCLUSION:** The low rate of conversions from S-ICD to a transvenous ICD in case of pacemaker-dependency as stated in fundamental S-ICD studies should not be transferred to other typical collectives of ICD recipients. The latter group is at significantly higher risk for

developing pacemaker-dependency.

Honarbaksh S, Providencia R, Srinivasan N, Ahsan S, Lowe M, Rowland E, Hunter RJ, Finlay M, Segal O, Earley MJ, Chow A, Schilling RJ, Lambiase PD. **A propensity matched case-control study comparing efficacy, safety and costs of the subcutaneous vs. transvenous implantable cardioverter defibrillator.** *Int J Cardiol.* 2016; 228: 280-5. http://ac.els-cdn.com/S0167527316334532/1-s2.0-S0167527316334532-main.pdf?_tid=18f408b0-c0aa-11e6-8ac4-00000aacb360&acdnat=1481574927_a699d9ff224c678c037eda864861dd0f *Boston Scientific (LATITUDE); Medtronic (CareLink); St Jude Medical (Merlin).* **BACKGROUND:** Subcutaneous implantable cardioverter defibrillators (S-ICD) have become more widely available. However, comparisons with conventional transvenous ICDs (TV-ICD) are scarce. **METHODS:** We conducted a propensity matched case-control study including all patients that underwent S-ICD implantation over a five-year period in a single tertiary centre. Controls consisted of all TV-ICD implant patients over a contemporary time period excluding those with pacing indication, biventricular pacemakers and those with sustained monomorphic ventricular tachycardia requiring anti-tachycardia pacing. Data was collected on device-related complications and mortality rates. A cost efficacy analysis was performed. **RESULTS:** Sixty-nine S-ICD cases were propensity matched to 69 TV-ICD controls. During a mean follow-up of 31+/-19 (S-ICD) and 32+/-21 months (TV-ICD; p=0.88) there was a higher rate of device-related complications in the TV-ICD group predominantly accounted for by lead failures (n=20, 29% vs. n=6, 9%; p=0.004). The total mean cost for each group, including the complication-related costs was pound9967+/-4511 (\$13,639+/-6173) and pound12,601+/-1786 (\$17,243+/-2444) in the TV-ICD and S-ICD groups respectively (p=0.0001). Even though more expensive S-ICD was associated with a relative risk reduction of device-related complication of 70% with a HR of 0.30 (95%CI 0.12-0.76; p=0.01) compared to TV-ICDs. **CONCLUSIONS:** TV-ICDs are associated with increased device-related complication rates compared to a propensity matched S-ICD group during a similar follow-up period. Despite the existing significant difference in unit cost of the S-ICD, overall S-ICD costs may be mitigated versus TV-ICDs over a longer follow-up period. .

Huang J, Patton KK, Prutkin JM. **Concomitant Use of the Subcutaneous Implantable Cardioverter Defibrillator and a Permanent Pacemaker.** *Pacing Clin Electrophysiol.* 2016; 39 (11): 1240-5.

<http://onlinelibrary.wiley.com/doi/10.1111/pace.12955/pdf> **Background** The subcutaneous implantable cardioverter defibrillator (S-ICD) is a novel implanted defibrillator for the prevention of sudden cardiac death that avoids intravascular access. Use of this device is limited by its inability to provide backup pacing. Combined use of the S-ICD with a permanent pacemaker may be the optimal choice in certain situations though experience with the use of both devices together remains limited. **Methods** We reviewed our single-center experience with the S-ICD from March 2011 to November 2015. Four patients with concomitant use of the S-ICD and a permanent pacemaker were identified. Clinical indication for device therapy, operative details, and subsequent follow-up was reviewed. During implantation, S-ICD sensing of paced morphologies was evaluated at maximal voltage output. After S-ICD implant, if feasible, the upper rate was adjusted to ≤50% of the S-ICD tachycardia zone to minimize risk of inappropriate shocks. **Results** After a mean follow-up of over 1 year, no adverse events occurred, including no inappropriate shock, lead malfunction, or device infection. One patient had a total of eight appropriate shocks, while another individual had no inappropriate shocks despite having a unipolar pacing lead. **Conclusions** In unique situations, combined use of the S-ICD and a permanent pacemaker may be preferable to alternative options. In our experience, this approach was successful in varying conditions including complex congenital heart disease, recurrent device infection, and limited vascular access.

Knops RE, Brouwer TF, Barr CS, Theuns DA, Boersma L, Weiss R, Neuzil P, Scholten M, Lambiase PD, Leon AR, Hood M, Jones PW, Wold N, Grace AA, Olde Nordkamp LR, Burke MC. **The learning curve associated with the introduction of the subcutaneous implantable defibrillator.** *Europace.* 2016; 18 (7): 1010-5.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4927061/pdf/euv299.pdf> *ClinicalTrials.gov ID: NCT01085435 LEADLESS. ClinicalTrials.gov ID: NCT01065076 IDE Study Boston Scientific employee (jones).* **AIMS:** The subcutaneous implantable cardioverter defibrillator (S-ICD) was introduced to overcome complications related to transvenous leads. Adoption of the S-ICD requires implanters to learn a new implantation technique. The aim of this study was to assess the learning curve for S-ICD implanters with respect to implant-related complications, procedure time, and inappropriate shocks (IASs). **METHODS AND RESULTS:** In a pooled cohort from two clinical S-ICD databases, the IDE Trial and the EFFORTLESS Registry, complications, IASs at 180 days follow-up and implant procedure duration were assessed. Patients were grouped in quartiles based on experience of the implanter and Kaplan-Meier estimates of complication and IAS rates were calculated. A total of 882 patients implanted in 61 centres by 107 implanters with a median of 4 implants (IQR 1,8) were analysed. There were a total of 59 patients with complications and 48 patients with IAS. The complication rate decreased significantly from 9.8% in Quartile 1 (least experience) to 5.4% in Quartile 4 (most experience) (P = 0.02) and non-significantly for IAS from 7.9 to 4.8% (P = 0.10). Multivariable analysis demonstrated a hazard ratio of 0.78 (P = 0.045) for complications and 1.01 (P = 0.958) for IAS. Dual-zone programming increased with experience of the individual

implanter ($P < 0.001$), which reduced IAS significantly in the multivariable model (HR 0.44, $P = 0.01$). Procedure time decreased from 75 to 65 min ($P < 0.001$). The complication rate and procedure time stabilized after Quartile 2 (>13 implants). **CONCLUSION:** There is a short and significant learning curve associated with physicians adopting the S-ICD. Performance stabilizes after 13 implants.

Kobe J, Hucklenbroich K, Geisendorfer N, Bettin M, Frommeyer G, Reinke F, Dechering D, Burgmer M, Eckardt L. **Posttraumatic stress and quality of life with the totally subcutaneous compared to conventional cardioverter-defibrillator systems.** *Clin Res Cardiol.* 2016: Epub before print.

http://download.springer.com/static/pdf/50/art%253A10.1007%252Fs00392-016-1055-0.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%252Fs00392-016-1055-0&token2=exp=1481575945~acl=%2Fstatic%2Fpdf%2F50%2Fart%25253A10.1007%25252Fs00392-016-1055-0.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs00392-016-1055-0*~hmac=7bb967132cf62d85faf196def0f3aa81ab27549e5eb2adc902aa1c20930f33e0

BACKGROUND: For prevention of sudden cardiac death, the transvenously implantable cardioverter-defibrillator therapy (tv-ICD) is well accepted. The subcutaneous system (S-ICD(R)) is promising in terms of reducing ICD complications. Nevertheless, the impact of the novel generator position on patients' quality of life (QoL) is yet unknown. **OBJECTIVE:** This study aimed at comparing QoL and posttraumatic stress with both systems. **METHODS:** 60 S-ICD(R) and 60 case-controlled tv single-chamber ICD patients were asked to respond to three standardized questionnaires. PDS [screening for posttraumatic stress disorders (PTSD)] and PHQ-D (detection of the most predominant psychological disorders) were used to screen for potential mental comorbidities. The SF-12 questionnaire was used to evaluate physical and mental well-being. Groups were compared in terms of QoL and PTSD. **RESULTS:** $n = 42$ (70%) pairs were analyzed ($n = 30$ male, mean age 44.6 ± 12.2 years). Prior appropriate ($p = 0.06$) or inappropriate episodes ($p = 0.24$), ejection fraction ($p = 0.28$), or underlying cardiac disease did not differ significantly between groups. PDS revealed a PTSD in $n = 6$ tv-ICD and $n = 6$ S-ICD(R) patients (14.3%) equally. In the PHQ-D questionnaire, $n = 4$ tv-ICD and $n = 2$ S-ICD(R) patients fulfilled criteria for a major depression ($p = 0.68$). Panic disorders ($n = 2$ tv, $n = 0$ S-ICD(R), $p = 0.5$), and anxiety disorders ($n = 3$ S-ICD(R), $n = 0$ tv-ICD, $p = 0.24$) did not differ between groups. The physical well-being score was 39.9 ± 12.5 in patients with a tv-ICD compared to 46.6 ± 9.9 in S-ICD(R) patients ($p = 0.01$). The mental well-being score was comparable in both groups (tv-ICD 51.8 ± 10.8 vs. S-ICD(R) 51.9 ± 10.4 , $p = 0.95$). **CONCLUSIONS:** Our case-control study revealed equal or even better physical well-being of patients with the S-ICD(R). PTSD occurred in almost 15% of ICD patients irrespective of the type of system.

Koman E, Gupta A, Subzposh F, Saltzman H, Kutalek SP. **Outcomes of subcutaneous implantable cardioverter-defibrillator implantation in patients on hemodialysis.** *J Interv Card Electrophysiol.* 2016; 45 (2): 219-23.

http://download.springer.com/static/pdf/438/art%253A10.1007%252Fs10840-015-0093-2.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%252Fs10840-015-0093-2&token2=exp=1454343129~acl=%2Fstatic%2Fpdf%2F438%2Fart%25253A10.1007%25252Fs10840-015-0093-2.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs10840-015-0093-2*~hmac=1e7db9755e9ebc89b67500f17ca96c064216536d1ae23ebff1aea5a12fc91c35

BACKGROUND: Subcutaneous implantable cardioverter-defibrillator (S-ICD) provides potential benefits in patients on hemodialysis (HD) by reducing the risk of blood stream infection and preserving vascular access sites. We evaluated the safety and efficacy of S-ICD in patients with end-stage renal disease (ESRD) on HD. **METHODS:** All consecutive patients implanted with S-ICD between October 2012 and April 2015 at our high-volume center were included in this retrospective, single-center study. Baseline demographics, procedural details, and short- as well as long-term outcomes were compared between patients on HD and not on HD. **RESULTS:** A total of 86 S-ICDs were implanted at our institution during the study period. Eighteen (21 %) patients were on HD at the time of implant. HD patients were more likely to be implanted for secondary prevention. There was no statistically significant difference in procedural complications between the two groups. HD patients had a longer duration hospital stay after implant (3.6 ± 5.14 vs. 1.69 ± 2.29 days, $p = 0.021$). During a mean follow-up of 205 ± 208 days in the HD cohort and 242 ± 238 days in the non-HD cohort ($p = 0.268$), there was no device or blood stream infection in the HD group, compared with five device infections in the non-HD group. The incidence of inappropriate shocks was similar in both groups. All appropriate shocks were successful in terminating ventricular tachyarrhythmias in both groups. Patients on hemodialysis had worse inpatient as well as long-term mortality after S-ICD implant, compared with non-HD patients. **CONCLUSIONS:** Our study demonstrates the safety and efficacy of S-ICD in patients on HD. Despite representing a sicker patient population, HD patients implanted with S-ICD had similar procedural outcomes and inappropriate shocks. There was no device or blood stream-related infection in HD patients. All appropriate shocks for ventricular arrhythmias in HD patients were successful.

Lambiase PD, Gold MR, Hood M, Boersma L, Theuns DAMJ, Burke MC, Weiss R, Russo AM, Käb S, Knight BP.

Evaluation of subcutaneous ICD early performance in hypertrophic cardiomyopathy from the pooled EFFORTLESS and IDE cohorts. *Heart Rhythm.* 2016; 13 (5): 1066-74. http://ac.els-cdn.com/S1547527116000023/1-s2.0-S1547527116000023-main.pdf?_tid=1497add6-1145-11e6-8ba4-00000aacb35d&acdnat=1462290087_b9a1ff8fc1b5188e305f74518d9cad8a

ClinicalTrials.gov ID: NCT01085435, NCT01064076. Background The subcutaneous implantable cardioverter-defibrillator (S-ICD) is a potential alternative to transvenous systems in hypertrophic cardiomyopathy (HCM) where lead complications are a significant issue. Objectives To compare the S-ICD efficacy of defibrillation threshold (DFT) testing, arrhythmia therapy, and complications in HCM versus non-HCM patients. Methods Outcomes of patients with HCM implanted with S-ICD were compared to non-HCM S-ICD recipients using pooled data from a total of 872 subjects enrolled in the EFFORTLESS Registry and US IDE study. Results The cohort included 99 HCM (75% male) and 773 non-HCM (72% male) patients with a median follow-up of 637 days. The HCM cohort was younger and more likely to receive a primary-prevention S-ICD (88.5% vs 67.5%, $P < .0001$). During implant testing, successful defibrillation at ≤ 80 J was achieved in 98.9% of HCM and 98.5% of non-HCM patients. One year postoperative complication-free rates were similar: 92.7% in HCM (with no lead complications) versus 89.5% in non-HCM. There were 3 appropriate shocks for ventricular tachycardia in 3 HCM patients that were all converted by the first shock. Overall final shock conversion efficacy was 100% in HCM versus 98% in non-HCM ($P = ns$). Inappropriate shocks occurred in 12.5% of HCM patients and 10.3% of non-HCM patients ($P = ns$), being reduced by 47% using dual-zone programming. Conclusion These initial data indicate the S-ICD is safe and effective in patients with HCM who are at high risk of ventricular arrhythmias and pass preimplantation electrocardiogram screening. Inappropriate shocks were mainly due to T-wave oversensing, but there were no lead complications requiring reintervention.

Maurizi N, Olivetto I, Olde Nordkamp LRA, Baldini K, Fumagalli C, Brouwer TF, Knops RE, Cecchi F. **Prevalence of subcutaneous implantable cardioverter-defibrillator candidacy based on template ECG screening in patients with hypertrophic cardiomyopathy.** *Heart Rhythm.* 2016; 13 (2): 457-63. http://ac.els-cdn.com/S1547527115011364/1-s2.0-S1547527115011364-main.pdf?_tid=484e2566-cae0-11e5-8e8a-00000aab0f27&acdnat=1454550213_753b90398333596f08ce3bc00f8f560a

Boston Scientific (Patient Screening Tool). EFFORTLESS S-ICD Registry. Background Subcutaneous implantable cardioverter-defibrillator (S-ICD) is a promising option for patients with hypertrophic cardiomyopathy (HCM). Patients with HCM can present markedly abnormal electrocardiograms (ECGs), and there are no data on what percentage of patients with HCM fail the prerequisite S-ICD vector screening. Objective The purpose of this study was to determine the failure rate of the prerequisite vector screening using 1 or 2 acceptable vectors stratified for risk profile for sudden cardiac death and predictors of failure. Methods ECG recordings from consecutive patients with HCM simulating the S-ICD sensing vectors were analyzed with the S-ICD screening tool. Eligibility was defined by 1 or 2 appropriate vectors. Medical history, ultrasound characteristics, and 12-lead ECG characteristics were analyzed and the individual arrhythmic risk at 5 year was determined to study potential predictors of failure. Results One hundred sixty-five (118 men; mean age 51 ± 16 years) patients were analyzed. Twenty-two patients (13%) had a high risk of sudden cardiac death, 33 (20%) had intermediate to high risk, and 110 (67%) had low risk. Twenty-six patients (16%) had no suitable vector, including 8 of 22 high-risk patients (36%). The primary cause of failure was high T-wave voltages in 25% of the vectors analyzed. T-wave inversions in ≥ 2 leads on the surface 12-lead ECG (odds ratio 15.6; 95% confidence interval 4.9–50.3; $P < .001$) and prior myectomy (odds ratio 8.4; 95% confidence interval 2.1–33.1; $P = .002$) were significantly associated with screening failure in a multivariable model. Conclusion Currently available preimplant screening algorithms recommended by the manufacturer are associated with a significant failure rate in patients with HCM, particularly in the high-risk subgroup.

Migliore F, Allocca G, Calzolari V, Crosato M, Facchin D, Daleffe E, Zecchin M, Fantinel M, Cannas S, Arancio R, Marchese P, Zanon F, Zorzi A, Iliceto S, Bertaglia E. **Intermuscular Two-Incision Technique for Subcutaneous Implantable Cardioverter Defibrillator Implantation: Results from a Multicenter Registry.** *Pacing Clin Electrophysiol.* 2016; 10 (10): 1540-8159. <http://dx.doi.org/10.1111/pace.12987>

BACKGROUND: The traditional technique for subcutaneous implantable cardioverter defibrillator (S-ICD) implantation, which involves three incisions and a subcutaneous pocket, is associated with possible complications, including inappropriate interventions. The aim of this prospective multicenter study was to evaluate the efficacy and safety of an alternative intermuscular two-incision technique for S-ICD implantation. METHODS: The study population included 36 consecutive patients (75% male, mean age 44 ± 12 years [range 20-69]) who underwent S-ICD implantation using the intermuscular two-incision technique. This technique avoids the superior parasternal incision for the lead placement and consists of creating an intermuscular pocket between the anterior surface of the serratus anterior and the posterior surface of the latissimus dorsi muscles instead of a subcutaneous pocket. RESULTS: All patients were successfully implanted in the absence of any procedure-related complications with a successful 65-J standard polarity defibrillation threshold testing, except in one, who received a second successful shock after pocket revision. During a mean follow-up of 10 months (range 3-30), no

complications requiring surgical revision were observed. At device interrogation, stable sensing without interferences was observed in all patients. Two patients (5.5%) experienced appropriate and successful shock on ventricular fibrillation and in four patients (11%), a total of seven nonsustained self-terminated ventricular tachycardias were correctly detected. No inappropriate interventions were observed. **CONCLUSIONS:** Our experience suggests that the two-incision intermuscular technique is a safe and efficacious alternative to the current technique for S-ICD implantation that may help reducing complications including inappropriate interventions and offer a better cosmetic outcome, especially in thin individuals.

Moore JP, Mondesert B, Lloyd MS, Cook SC, Zaidi AN, Pass RH, John AS, Fish FA, Shannon KM, Aboulhosn JA, Khairy P. **Clinical Experience With the Subcutaneous Implantable Cardioverter-Defibrillator in Adults With Congenital Heart Disease.** *Circ Arrhythm Electrophysiol.* 2016; 9 (9): [8 pages].

<http://circep.ahajournals.org/content/9/9/e004338.full.pdf> *Boston Scientific (SQ-RX 1010 pulse generator).*
BACKGROUND: Sudden cardiac death is a major contributor to mortality for adults with congenital heart disease. The subcutaneous implantable cardioverter-defibrillator (ICD) has emerged as a novel tool for prevention of sudden cardiac death, but clinical performance data for adults with congenital heart disease are limited.
METHODS AND RESULTS: A retrospective study involving 7 centers over a 5-year period beginning in 2011 was performed. Twenty-one patients (median 33.9 years) were identified. The most common diagnosis was single ventricle physiology (52%), 9 palliated by Fontan operation and 2 by aortopulmonary shunts: d-transposition of the great arteries after Mustard/Senning (n=2), tetralogy of Fallot (n=2), aortic valve disease (n=2), and other biventricular surgery (n=4). A prior cardiac device had been implanted in 7 (33%). The ICD indication was primary prevention in 67% and secondary in 33% patients. The most common reason for subcutaneous ICD placement was limited transvenous access for ventricular lead placement (n=10) followed by intracardiac right-to-left shunt (n=5). Ventricular arrhythmia was induced in 17 (81%) and was converted with ≤ 80 Joules in all. There was one implant complication related to infection, not requiring device removal. Over a median follow-up of 14 months, 4 patients (21%) received inappropriate and 1 (5%) patient received appropriate shocks. There was one arrhythmic death related to asystole in a single ventricle patient. **CONCLUSIONS:** Subcutaneous ICD implantation is feasible for adults with congenital heart disease patients. Most candidates have single ventricle heart disease and limited transvenous options for ICD placement. Despite variable anatomy, this study demonstrates successful conversion of induced ventricular arrhythmia and reasonable rhythm discrimination during follow-up.

Okamura H, McLeod CJ, DeSimone CD, Webster TL, Bonnicksen CR, Grogan M, Phillips SD, Connolly HM, Ammash NM, Warnes CA, Friedman PA. **Right parasternal lead placement increases eligibility for subcutaneous implantable cardioverter defibrillator therapy in adults with congenital heart disease.** *Circ J.* 2016; 80 (6): 1328-35. https://www.jstage.jst.go.jp/article/circj/80/6/80_CJ-16-0153/_pdf *Boston Scientific (S-ICD).*

BACKGROUND: The subcutaneous implantable cardioverter defibrillator (S-ICD) provides an attractive option for patients with congenital heart disease (CHD) in whom a transvenous defibrillator is contraindicated. Given the unusual cardiac anatomy and repolarization strain, the surface electrocardiogram (ECG) is frequently abnormal, potentially increasing the screen failure rate. **Methods and Results:** We prospectively screened 100 adult CHD patients regardless of the presence of clinical indication for ICD utilizing a standard left sternal lead placement, as well as a right parasternal position. Baseline patient and 12-lead ECG characteristics were examined to assess for predictors of screen failure. Average patient age was 48 \pm 14 years, average QRS duration was 134 \pm 37 ms, and 13 patients were pacemaker dependent. Using the standard left parasternal electrode position, 21 patients failed screening. Of these 21 patients with screen failure, 9 passed screening with the use of right parasternal electrode positioning, reducing screening failure rate from 21% to 12%. QT interval and inverted T wave anywhere in V2-V6 leads were found to be independent predictors of left parasternal screening failure (P=0.01 and P=0.04, respectively). **CONCLUSIONS:** Utilization of both left and right parasternal screening should be used in evaluation of CHD patients for S-ICD eligibility. ECG repolarization characteristics were also identified as novel predictors of screening failure in this group.

Olde Nordkamp LR, Conte G, Rosenmoller BR, Warnars JL, Tan HL, Caputo ML, Regoli F, Moccetti T, Auricchio A, Knops RE, Wilde AA. **Brugada Syndrome and the Subcutaneous Implantable Cardioverter-Defibrillator.** *J Am Coll Cardiol.* 2016; 68 (6): 665-6. http://ac.els-cdn.com/S0735109716334015/1-s2.0-S0735109716334015-main.pdf?_tid=2e631cb6-704d-11e6-8580-0000aacb35f&acdnat=1472738927_35194829133138d9682245283a783cee

"...This is the largest report on potentially inappropriate sensing by the S-ICD in patients with BrS. The morphology analysis failed in 24% of patients upon development of type 1 BrS-ECG during ajmaline testing, although morphology analysis in these patients was appropriate at baseline. These patients are accordingly at risk for inappropriate shocks. We therefore recommend that in the presence of a type-1 Brs-ECG after S-ICD implantation, for example, during fever or during an additional ajmaline test, all 3 sensing vectors should be evaluated, and the best suitable sensing vector should be programmed..."

Pedersen SS, Mastenbroek MH, Carter N, Barr C, Neuzil P, Scholten M, Lambiase PD, Boersma L, Johansen JB, Theuns DA. **A comparison of the quality of life of patients with an entirely subcutaneous implantable defibrillator system versus a transvenous system (from the EFFORTLESS S-ICD Quality of Life Substudy).** *Am J Cardiol.* 2016; 118 (4): 520-6. http://ac.els-cdn.com/S000291491630950X/1-s2.0-S000291491630950X-main.pdf?_tid=58d6e902-a543-11e6-b35f-00000aab0f27&acdnat=1478562115_c7b7a44ec53bc62a21728be5a1e24666 Boston Scientific employee (Carter). *ClinicalTrials.gov ID: NCT01085435.* The first clinical results from the Evaluation of Factors Impacting Clinical Outcome and Cost Effectiveness of the subcutaneous implantable cardioverter defibrillator (EFFORTLESS S-ICD) Registry on the entirely S-ICD system are promising, but the impact of the S-ICD system on patients' quality of life (QoL) is not known. We evaluated the QoL of patients with an S-ICD against an unrelated cohort with a transvenous (TV)-ICD system during 6 months of follow-up. Consecutively implanted patients with an S-ICD system were matched with patients with a TV-ICD system on a priori selected variables including baseline QoL. QoL was measured with the Short-Form Health Survey at baseline, 3, and 6 months after implant and compared using multivariable modeling with repeated measures. Patients with an S-ICD (n = 167) versus a TV-ICD system (n = 167) did not differ significantly on physical (p = 0.8157) and mental QoL scores (p = 0.9080) across baseline, 3, and 6 months after implantation in adjusted analyses. The evolution in physical (p = 0.0503) and mental scores (p = 0.3772) during follow-up was similar for both cohorts, as indicated by the nonsignificant interaction effect for ICD system by time. Both patients with an S-ICD system and a TV-ICD system experienced significant improvements in physical and mental QoL between time of implant and 3 months (both p's <0.0001) and between time of implant and 6 months (both p's <0.0001) but not between 3 and 6 months (both p's >0.05). In conclusion, these first results show that the QoL of patients with an S-ICD versus TV-ICD system is similar and that patients with either system experience improvements in QoL on the short term.

Raatikainen MJ, Arnar DO, Merkely B, Camm AJ, Hindricks G. **Access to and clinical use of cardiac implantable electronic devices and interventional electrophysiological procedures in the European Society of Cardiology Countries: 2016 Report from the European Heart Rhythm Association.** *Europace.* 2016; 18 Suppl 3: iii1-iii79. http://europace.oxfordjournals.org/content/europace/18/suppl_3/iii1.full.pdf AIMS: The aim of this analysis was to provide comprehensive information on the access to and use of cardiac implantable electronic device (CIED) and catheter ablation therapy in the European Society of Cardiology (ESC) area. METHODS AND RESULTS: The European Heart Rhythm Association (EHRA) has been collecting descriptive and quantitative data on invasive arrhythmia therapies since 2008. This year 50 of the 56 ESC member countries provided data for the EHRA White Book. Up-to-date information on procedure rates for the last 5 years together with information on demographics, economy, vital statistics, local healthcare systems, and training activities is presented for each country and the 5 geographical ESC regions. Our analysis indicated that considerable heterogeneity in the access to arrhythmia therapies still exists across the ESC area. In 2015, the CIED implantation rates per million population were highest in the Western followed by the Southern and Northern European countries. The catheter ablation activity was largest in the Western followed by the Northern and Southern areas. Overall, the procedure rates were 3-10 times higher in the European than in the non-European ESC countries. Economic resources were not the only driver for utilization of arrhythmia therapies as in some Eastern European countries with relative low gross domestic product the procedure rates exceeded the average values. CONCLUSION: These data will help the healthcare professionals and stakeholders to identify and to understand in more depth the trends, disparities, and gaps in cardiac arrhythmia care and thereby promote harmonization of cardiac arrhythmias therapies in the ESC area. ["...according to the EHRA White Book survey, a total of 244 leadless PMs were implanted in 9 countries in 2015...the most active countries...France, the Netherlands and Hungary...A total of 1049 S-ICDs were implanted in 13 countries in 2015. No S-ICDs were implanted in 24 countries, and 19 countries reported no data on these devices. The most active countries...were Italy with 561 implantations followed by the UK (196 implantations) and the Netherlands (150 implantations) (Figure 39)..."].

Tachibana M, Nishii N, Morimoto Y, Kawada S, Miyoshi A, Sugiyama H, Nakagawa K, Watanabe A, Nakamura K, Morita H, Ito H. **Complete right bundle branch block and QRS-T discordance can be the initial clue to detect S-ICD ineligibility.** *J Cardiol.* 2016: Epub before print. *This article is not available in the library's collection.* BACKGROUND: In order to minimize inappropriate shocks of subcutaneous implantable cardioverter-defibrillators (S-ICD), it is important to recognize who is suitable for S-ICD indication. This study aimed to clarify what types of cardiac disease are likely to fulfill the S-ICD screening criteria and ineligible factors for S-ICD in the standard 12-lead electrocardiogram (ECG). METHODS: A total of 348 patients with heart disease were enrolled. They were assessed by supine and standing ECG recording to simulate the 3 S-ICD sensing vectors and standard 12-lead ECG, simultaneously. Clinical and ECG characteristics were analyzed to compare the patients who are eligible and ineligible with S-ICD screening ECG indication. RESULTS: The mean age of study patients was 49+/-21

years and 244 (70%) were men. Nineteen percent of patients were unsuitable for S-ICD. There was no significant difference in ineligibility for S-ICD among cardiac diseases ($p=0.48$). Univariate analysis showed complete right bundle branch block (CRBBB), QRS-T discordance in lead II, and QRS-T discordance in 3 leads (I, II, and aVF) were more frequent in patients who were ineligible for S-ICD than in the eligible group. Multivariate regression analysis showed CRBBB and QRS-T discordance in 3 leads were independent predictors for ineligibility of S-ICD. CONCLUSION: There are no differences in eligibility of S-ICD among types of cardiac diseases. CRBBB and QRS-T discordance were independent predictors for ineligibility.

von Gunten S, Schaer BA, Yap SC, Szili-Torok T, Kuhne M, Sticherling C, Osswald S, Theuns DA. **Longevity of implantable cardioverter defibrillators: a comparison among manufacturers and over time.** *Europace*. 2016; 18 (5): 710-7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4880113/pdf/euv296.pdf> *Biotronik; Boston Scientific; Cameron Health; Intermedics; Medtronic; St Jude Medical; Sorin.* AIMS: Longevity of implantable cardioverter defibrillators (ICDs) is crucial for patients and healthcare systems as replacements impact on infection rates and cost-effectiveness. Aim was to determine longevity using very large databases of two teaching hospitals with a high number of replacements and a rather homogeneous distribution among manufacturers. METHODS AND RESULTS: The study population consists of all patients in whom an ICD was inserted in. All ICD manufacturers operating in Switzerland and the Netherlands and all implanted ICDs were included. Implantable cardioverter defibrillator replacements due to normal battery depletion were considered events, and other replacements were censored. Longevity was assessed depending on manufacturers, pacing mode, implant before/after 2006, and all parameters combined. We analysed data from 3436 patients in whom 4881 ICDs [44.2% VVI-ICDs, 27.4% DDD-ICDs, 26.3% cardiac resynchronization therapy (CRT)-ICDs, 2.0% subcutaneous ICDs] were implanted. The four major manufacturers had implant shares between 18.4 and 31.5%. Replacement due to battery depletion (27.4%) was performed for 1339 ICDs. Patient survival at 5 years was 80.1%. Longevity at 5 years improved in contemporary compared with elderly ICDs [63.9-80.6% across all ICDs, of 73.7-92.1% in VVIs, 58.2-76.1% in DDDs, and of 47.1-66.3% in CRT defibrillators, all P value < 0.05]. Remarkable differences were seen among manufacturers, and those with better performance in elderly ICDs were not those with better performance in contemporary ones. CONCLUSION: Implantable cardioverter defibrillator longevity increased in contemporary models independent of manufacturer and pacing mode. Still, significant differences exist among manufacturers. These results might impact on device selection.

Weinstock J, Bader YH, Maron MS, Rowin EJ, Link MS. **Subcutaneous Implantable Cardioverter Defibrillator in Patients With Hypertrophic Cardiomyopathy: An Initial Experience.** *J Am Heart Assoc*. 2016; 5 (2): [7 pages]. <http://jaha.ahajournals.org/content/5/2/e002488.full.pdf+html> *Boston Scientific (S-ICD).* BACKGROUND: The subcutaneous implantable cardioverter defibrillator (S-ICD) has been developed to avert risks associated with transvenous defibrillator leads. The technology is attractive for younger patients, such as those with hypertrophic cardiomyopathy (HCM). However, there are limited data on S-ICD use in HCM. METHODS AND RESULTS: HCM patients identified at risk for sudden death were considered for S-ICD implantation. Patients were screened for potential oversensing by surface electrocardiography (ECG). At implant, defibrillation threshold (DFT) testing was performed at 65, 50, and 35 joules (J). Twenty-seven patients were considered for S-ICD implantation, and after screening, 23 (85%) remained eligible. The presence of a bundle branch block was associated with screening failure, whereas elevated body mass index (BMI) showed a trend toward association. One patient passed screening at rest, but failed with an ECG obtained after exercise. At implant, the S-ICD terminated ventricular fibrillation (VF) with a 65J shock in all 15 implanted patients and a 50J shock was successful in 12 of 15. A 35J shock terminated VF in 10 of 12 patients. DFT failure at 50 J was associated with a higher BMI. There were no appropriate shocks after a median follow-up of 17.5 (3-35) months, and 1 patient received an inappropriate shock attributable to a temporary reduction in QRS amplitude while bending forward, resulting in oversensing, despite successful screening. CONCLUSIONS: In a high-risk HCM cohort without a pacing indication referred for consideration of an ICD, the majority were eligible for S-ICD. The S-ICD is effective at recognizing and terminating VF at implant with a wide safety margin.

Wilson DG, Leventigiannis G, Barr C, Morgan JM. **ECG predictors of T wave oversensing in subcutaneous implantable cardioverter defibrillators.** *Int J Cardiol*. 2016; 220: 27-31. http://ac.els-cdn.com/S0167527316311366/1-s2.0-S0167527316311366-main.pdf?_tid=0b83d458-42b5-11e6-97af-00000aacb35e&acdnat=1467725783_ed82c9d6c3e53fa59a6aa6bc265f7a3a BACKGROUND: T wave oversensing (TWOS) is the commonest cause of inappropriate shocks in subcutaneous implantable cardioverter defibrillators (S-ICDs). We hypothesise that predictors of TWOS can be derived from surface ECG parameters. METHODS: In a cohort of S-ICD recipients in two UK centres, all patients who had TWOS (study group) were compared to all those who had not (control group). The pre-implant screen was scanned and the R wave, T wave amplitudes, QRS interval, time to peak T wave, QT interval and R:T ratio was measured using digital callipers. Logistic regression was performed to identify ECG predictors of TWOS. RESULTS: One hundred one patients

were studied. Six (5.9%) had TWOS. The mean age of the population was 58.6±18years and the median follow-up was 19.5months. By univariate analysis, the predictors of TWOS are QRS duration (140.7±28.7 vs. 105.9±24.6, P=0.007), time to peak T wave (corrected for heart rate, pTc) (403.9±22.6 vs. 347.8±41.4, P=0.006), QTc interval (500.4±41.2 vs. 446.8±49.7, P=0.021), and R:T ratio (3.5±1.1 vs. 9.5±13.2, P=0.034). By multivariate analysis, time to pTc is the most predictive of TWOS. A time to pTc of 390ms cut-off point provided a sensitivity 38.5%, a specificity of 98.9%, a positive predictive value for TWOS of 83.3%, and a negative predictive value of 91.6% (AUC=0.687). **CONCLUSION:** In this study, time to pTc is the most powerful ECG predictor of TWOS.

Wilson DG, Zeb M, Veldtman G, Dimitrov BD, Morgan JM. **Left and Right Parasternal Sensing for the S-ICD in Adult Congenital Heart Disease Patients and Normal Controls.** *Pacing Clin Electrophysiol.* 2016; 39 (3): 282-90. <http://dx.doi.org/10.1111/pace.12802> Background This study investigated the impact of a right parasternal sensing electrode position on the R- and T-wave amplitudes and the R:T ratio in three subcutaneous implantable cardioverter defibrillator (S-ICD) vectors in patients with adult congenital heart disease (ACHD) and normal controls. Methods Conventional left parasternal sensing electrode position and right parasternal sensing electrode positions were used to collect 10-second electrograms, recorded through an 80-electrode body surface mapping technology (Prime ECG™ system, HeartScape Technologies Inc., now Verathon, Columbia, MD, USA). Recordings were made in the supine, prone, left lateral, right lateral, sitting, and standing positions in using both the standard electrode vector position and the right parasternal positions. Results Forty patients were recruited and 37 patients were used for analysis. Twenty-seven (73%) had complex ACHD; 10 patients had normal hearts and acted as controls. A total of 3,708 data points were analyzed. There were no significant differences in the R:T ratio when measured in ACHD patients in the right compared to the left parasternal lead position. In contrast, there were important differences in the magnitude of the R:T ratio when measured in control patients in the right compared to the left parasternal lead position; in the primary vector, the R:T ratio was greater in right than left by 2.99 (P = 0.0002; 95% confidence interval [CI]: 1.48–4.50) and in the secondary vector, the R:T ratio was smaller in the right than in the left by 0.77 (P = 0.004; 95% CI: –1.58–0.05). Conclusion In selected patients, a right parasternal lead position may provide a useful alternative sensing configuration for the S-ICD.

Winter J, Siekiera M, Shin DI, Meyer C, Kropil P, Clahsen H, O'Connor S. **Intermuscular technique for implantation of the subcutaneous implantable cardioverter defibrillator: long-term performance and complications.** *Europace.* 2016: Epub before print. <https://academic.oup.com/europace/article/2732189/Intermuscular-technique-for-implantation-of-the> Cameron Health. former Boston Scientific employee (O'Connor). **AIMS:** The subcutaneous cardioverter defibrillator was designed to overcome electrode complications of transvenous defibrillation systems. While largely achieved, pocket complications have increased. Subcutaneous implantation of the pulse generator leaves it prone to erosion, extrusion, discomfort, and poor cosmesis. **METHODS AND RESULTS:** We use a demonstration electrode and pulse generator with fluoroscopy, prior to prepping and draping, to maximize the left ventricular mass between them. We adapted a submuscular abdominal ICD technique to implant the S-ICD intermuscularly between the anterior surface of serratus anterior and the posterior surface of latissimus dorsi. Surgery in our patients beyond the subcutaneous tissue was bloodless, as muscle layers were carefully separated but not incised, which also protected the long thoracic nerve. Two layers of muscle protect the pulse generator. We have implanted 82 consecutive patients with this technique, taking approximately 65 min. All patients were converted with 65 J standard polarity shock during induced arrhythmia conversion testing, with six (7.3%) patients requiring a repositioning of the pulse generator prior to successful conversion. Seven spontaneous episodes of ventricular fibrillation were detected in three (3.6%) patients, all successfully converted back to sinus rhythm. Long-term patient outcomes have been good with low complication rates over the mean ± standard deviation 3.6 ± 1.2 years. **CONCLUSION:** Our intermuscular technique and implant methodology is successful for placement of the subcutaneous defibrillator pulse generator. Our technique leads to an excellent cosmetic result and high levels of patient satisfaction. Rates of first shock conversion during defibrillation testing, inappropriate shocks, and complications during follow-up compare favourably with previous published case series. There were no left arm movement limitations post-operatively.

Ziacchi M, Corzani A, Diemberger I, Martignani C, Marziali A, Mazzotti A, Massaro G, Rapezzi C, Biffi M, Boriani G. **Electrocardiographic Eligibility for Subcutaneous Implantable Cardioverter Defibrillator: Evaluation during Bicycle Exercise.** *Heart Lung Circ.* 2016; 25 (5): 476-83. *This article is not in the library's collection.* **BACKGROUND:** The subcutaneous implantable cardioverter-defibrillator (S-ICD) is used in patients at risk of sudden death. Our aim was to assess clinical predictors of electrocardiographic ineligibility for S-ICD, and the impact of exercise on S-ICD eligibility in an unselected series of patients requiring ICD therapy. **METHODS:** 102 patients at risk of sudden death were evaluated at rest and during exercise. Electrocardiograph screening using limb lead electrodes (to simulate the S-ICD sensing vectors) was performed at rest and during bicycle ergometer exercise. **RESULTS:** R wave amplitude in lead D3 during exercise >16mV, baseline QTc and the sum

of amplitudes of the R waves at supine >30mV were predictors of ineligibility for S-ICD. Eligibility increased from 90% to 100% of patients when evaluated with an "any of the three leads" criterion compared to current recommendations. A more restrictive criterion based on two of three ECG leads caused an eligibility drop at 66%, that further decreased to 56% during exercise; these figures improved to 79% and 81%, respectively, when an "any 2 of 3 leads" criterion was used. CONCLUSIONS: Huge ECG amplitude and QTc duration are associated with ineligibility in the current S-ICD release. By performing exercise testing, lead suitability changes in one patient out of 14 (7% of tested patients) and eligibility is decreased by use of a more stringent criterion for eligibility (ECG criteria satisfied in two of three leads). A dynamic selection of sensing vectors aiming at situation-specific suitability (any of three leads) would increase S-ICD eligibility to 100% of patients.

Ziegelhoeffer T, Siebel A, Markewitz A, Doll N, Barsch V, Reinartz M, Oswald B, Bimmel D, Meyer A, Weimar T, Walther T, Burger H. **Intraoperative Defibrillation Testing Should Not Be Generally Abandoned for All ICD Procedures-A Multicenter Study on 4,572 Consecutive Patients.** *Thorac Cardiovasc Surg.* 2016; 64 (8): 679-87. <https://www.thieme-connect.com/products/ejournals/pdf/10.1055/s-0036-1583767.pdf> Background The ongoing technical advances in development of new implantable cardioverter defibrillator (ICD) systems led some investigators to question the routine use of intraoperative defibrillation testing (DT). Therefore, we evaluated retrospectively in a multicenter study effectiveness, safety, and usefulness of intraoperative DT on unbiased large patient population. Methods Data from 4,572 consecutive patients undergoing any ICD intervention were retrospectively analyzed. Besides efficacy of DT, risk factors for DT failure were identified in a multiple logistic regression analysis. Results Overall 5,483 shock data from 4,532 patients were available. Not tested for medical reasons were 13.5%. DT-associated complications were not noted. Primary DT effectiveness was 95.8%, whereas 4.2% were ineffective. Optimization (51.6% increase of DT energy, 10.1% subcutaneous lead array (SQ array), 2% generator exchange, 4.8% lead reposition, 9.3% lead exchange, and 22.2% change of shock parameters) led to successful DT in 152 patients (96.2%). Subanalyses and logistic regression identified implantation of generator in any other position than left subpectoral, age, body mass index and left ventricular ejection fraction as independent predictors for primary DT failure. Conclusion The number of patients, including those undergoing generator exchange, system upgrade, or system revision, with inappropriate intraoperative testshock is relatively high. The results of recent prospective clinical trials can be extrapolated only on first ICD implantations with high-energy generators. For patients undergoing subcutaneous ICD implantation, right-sided implantation, patients with channelopathies and hypertrophic cardiomyopathy, as well as for procedures on already implanted ICD systems, the intraoperative DT might still be recommended.

Arias MA, Pachon M, Akerstrom F, Puchol A, Giacomani-Hernandez S, Rodriguez-Padial L. **Implantation of the Subcutaneous Implantable Defibrillator S-ICD: Initial Experience in a Single Spanish Center.** *Rev Esp Cardiol (Engl Ed).* 2015: Epub before print. [http://www.revespcardiol.org/en/pdf/S1885-5857\(15\)00123-1/S100/Boston Scientific \(S-ICD SQ-RX 1010\). Mentions EFFORTLESS](http://www.revespcardiol.org/en/pdf/S1885-5857(15)00123-1/S100/Boston%20Scientific%20(S-ICD%20SQ-RX%201010).Mentions%20EFFORTLESS). "...We present an initial experience with subcutaneous ICD implantation in 8 consecutive patients, representing the largest series to date treated with these new devices in Spain..."

Brisben AJ, Burke MC, Knight BP, Hahn SJ, Herrmann KL, Allavattam V, Mahajan D, Sanghera R, Gold MR. **A new algorithm to reduce inappropriate therapy in the s-icd system.** *J Cardiovasc Electrophysiol.* 2015; 26 (4): 417-23. <http://onlinelibrary.wiley.com/doi/10.1111/jce.12612/pdf> Boston Scientific employees (Brisben; Hahn; Herrmann, Allavattam; Mahajan, Sanghera). INTRODUCTION: The subcutaneous ICD system (S-ICD) has been shown to be a safe and effective treatment for patients at risk for sudden cardiac death. This device reliably detects ventricular tachyarrhythmias with a low incidence of inappropriate shocks for supraventricular arrhythmias. However, T-wave over sensing (TWOS) is more common with the S-ICD compared with transvenous systems. We developed a novel discrimination algorithm to reduce TWO without compromising tachyarrhythmia discrimination. METHODS AND RESULTS: The algorithm was developed using a database of recorded episodes, including 244 appropriate therapies for ventricular arrhythmias and 133 episodes with an inappropriate detection due to TWOS, and using a computer model that simulates the S-ICD system. An independent set of data of 161 TWOS episodes, 137 ventricular, and 328 supraventricular episodes were used to validate the algorithm on actual device hardware. The S-ICD performance with the new algorithm was compared with the S-ICD without the new algorithm. Development results showed a decrease in inappropriate charge due to TWOS by 30.7+/-18%. All ventricular arrhythmias were appropriately detected and the time to appropriate charge initiation was not increased. System validation showed that the new algorithm avoided an inappropriate charge due to TWOS by 39.8+/-11.4%. No decrease in ventricular arrhythmia sensitivity and no significant change in supraventricular specificity were observed. CONCLUSIONS: A new algorithm that uses correlation of the existing complex to previous complexes reduced TWOS episodes by approximately 40%. The algorithm has potential for a clinically meaningful decrease in inappropriate shocks. This article is protected by copyright. All rights reserved.

Burke MC, Gold MR, Knight BP, Barr CS, Theuns DA, Boersma LV, Knops RE, Weiss R, Leon AR, Herre JM, Husby M, Stein KM, Lambiase PD. **Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-Year Results From a Pooled Analysis of the IDE Study and EFFORTLESS Registry.** *J Am Coll Cardiol.* 2015; 65 (16): 1605-15. http://ac.els-cdn.com/S0735109715007573/1-s2.0-S0735109715007573-main.pdf?_tid=dfb0402e-f01b-11e4-95f7-00000aabb0f02&acdnat=1430496503_5204979aaa7999b0ef853ff492d4de38 S-ICD IDE study and the EFFORTLESS S-ICD Registry. Boston Scientific employees (Husby, Stein). BACKGROUND: The entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) is the first implantable defibrillator that avoids placing electrodes in or around the heart. Two large prospective studies (IDE [S-ICD System IDE Clinical Investigation] and EFFORTLESS [Boston Scientific Post Market S-ICD Registry]) have reported 6-month to 1-year data on the S-ICD. OBJECTIVES: The objective of this study was to evaluate the safety and efficacy of the S-ICD in a large diverse population. METHODS: Data from the IDE and EFFORTLESS studies were pooled. Shocks were independently adjudicated, and complications were measured with a standardized classification scheme. Enrollment date quartiles were used to assess event rates over time. RESULTS: Eight hundred eighty-two patients who underwent implantation were followed for 651 +/- 345 days. Spontaneous ventricular tachyarrhythmia (VT)/ventricular fibrillation (VF) events (n = 111) were treated in 59 patients; 100 (90.1%) events were terminated with 1 shock, and 109 events (98.2%) were terminated within the 5 available shocks. The estimated 3-year inappropriate shock rate was 13.1%. Estimated 3-year, all-cause mortality was 4.7% (95% confidence interval: 0.9% to 8.5%), with 26 deaths (2.9%). Device-related complications occurred in 11.1% of patients at 3 years. There were no electrode failures, and no S-ICD-related endocarditis or bacteremia occurred. Three devices (0.3%) were replaced for right ventricular pacing. The 6-month complication rate decreased by quartile of enrollment (Q1: 8.9%; Q4: 5.5%), and there was a trend toward a reduction in inappropriate shocks (Q1: 6.9% Q4: 4.5%). CONCLUSIONS: The S-ICD demonstrated high efficacy for VT/VF. Complications and inappropriate shock rates were reduced consistently with strategic programming and as operator experience increased. These data provide further evidence for the safety and efficacy of the S-ICD. (Boston Scientific Post Market S-ICD Registry [EFFORTLESS]; NCT01085435; S-ICD(R) System IDE Clinical Study; NCT01064076). ["...They acknowledge those involved from Cameron Health/ Boston Scientific, including Laura Fischer for episode review, Paul Jones for medical writing assistance, and Nathan Carter for biostatistics support..."].

El-Chami MF, Levy M, Kelli HM, Casey M, Hoskins MH, Goyal A, Langberg JJ, Patel A, Delurgio D, Lloyd MS, Leon AR, Merchant FM. **Outcome of subcutaneous implantable cardioverter defibrillator implantation in patients with end-stage renal disease on dialysis.** *J Cardiovasc Electrophysiol.* 2015; 26 (8): 900-4. <http://onlinelibrary.wiley.com/doi/10.1111/jce.12705/pdf> Boston Scientific (S-ICD). BACKGROUND: Although the subcutaneous ICD (S-ICD(R)) is an attractive alternative in patients with end-stage renal disease (ESRD), data on S-ICD outcomes in dialysis patients is lacking. METHODS: Patients with cardiomyopathy undergoing S-ICD implantation in our center were stratified by need for chronic dialysis at the time of implant. The primary endpoint was incidence of death, heart failure hospitalization or appropriate S-ICD shocks, and secondary endpoints were incidence of inappropriate shocks or implant related complications requiring surgical re-intervention. Mean follow-up was longer in the non-dialysis cohort (514 +/- 495 vs. 227 +/- 233 days, p = 0.006), so all endpoints were analyzed using time-dependent comparisons and reported as annual event rates. RESULTS: Out of 79 S-ICD implants included in this analysis, 27 patients were on dialysis. Dialysis patients were older and more likely to be diabetic. Mean ejection fraction across the entire cohort was 26.9% without significant difference between dialysis and non-dialysis groups. Although not significant, the incidence of the primary endpoint was higher in the dialysis cohort (23.8%/year vs. 10.9%/year, p = 0.317), driven primarily by a higher rate of appropriate shocks. The rate of inappropriate shocks was similar between groups (dialysis 6.0%/year vs. non-dialysis 6.8%/year, p = 0.509). No patients in the dialysis cohort had complications requiring surgical re-intervention versus 6 patients in the non-dialysis cohort (p = 0.086). CONCLUSIONS: Our data suggest that S-ICD implantation in dialysis patients is not associated with an excess risk of implant related complications or inappropriate shocks. This article is protected by copyright. All rights reserved.

Ertugrul I, Karagoz T, Aykan H, Yildirim I, Ozer S, Karagoz H, Yilmaz M. **Subcutaneous defibrillator implantation in pediatric patients.** *Anatol J Cardiol.* 2015: Epub before print. <http://www.anatoljcardiol.com/jvi.aspx?un=AJC-53825> OBJECTIVE: Although sudden cardiac death is rare in children, an intracardiac defibrillator system is indicated in children with various types of cardiomyopathy, primary electrical diseases, and after surgical repair of congenital heart defects. The use of transvenous defibrillator lead systems is limited in pediatric patients because of a small body size and/or limited vascular access. Subcutaneous array leads combined with an abdominally placed generator can enable implantation. METHOD: This is a retrospective study of 13 patients who underwent subcutaneous defibrillator implantation between September 2010 and March 2015. The subcutaneous system was preferred because patients were not amenable to transvenous lead placement. RESULTS: The median patient age was 4.1 years, and the median patient weight was 12.1 kg. Diagnoses of patients were long-QT syndrome in 6, aborted cardiac arrest with left ventricular non-compaction in 3, hypertrophic cardiomyopathy with

sustained ventricular tachycardia in 3, and arrhythmogenic right ventricular cardiomyopathy in 1. Revision of the subcutaneous lead was required in 5 patients 2-26 months after the implantation. Appropriate shocks were observed in three patients. Inappropriate shock and lead fractures were observed in one patient during the follow-up period. The failure of therapy was observed in one patient. There were no perioperative complications and no early or late deaths. **CONCLUSION:** Subcutaneous defibrillator systems are safe and effective in pediatric patients when the transvenous method is risky and contraindicated. Because the high growth rate in this population leads to lead failures, a close follow-up of this population is essential.

- Findikoglu G, Yildiz BS, Sanlialp M, Alihanoglu YI, Kilic ID, Evregul H, Senol H. **Limitation of motion and shoulder disabilities in patients with cardiac implantable electronic devices.** *Int J Rehabil Res.* 2015; 38 (4): 287-93. *This article is not in the KR collection.* The aim of this study is to investigate the presence of limitations in the shoulder range of motion (ROM) or the loss of upper extremity function on the affected side in patients with cardiac implantable electronic devices (CIEDs) with respect to the implantation time. Forty-nine patients (30 men and 19 women), mean age 64.84±11.18 years, who had been living with a CIED for less than 3 months were included in the short-term recipient (STR) group and 127 patients (85 men and 42 women), mean age 64.91±14.70 years, and with the device for longer than 3 months were included in the long-term recipients group. Shoulder ROMs were measured using a digital goniometer. The other arm was used as the control. The Constant-Murler Score, Shoulder Pain Disability Index, and Shoulder Disability Questionnaire were used to assess the functional status. Limitations of ROM for flexion, abduction, and internal rotation were found to be significantly lower in the arm on the side of CIED compared with the control arm. Significant differences in shoulder flexion, abduction, and external rotation in STRs were found compared with long-term recipient ($P<0.05$). However, the functional comparison of groups by the Constant-Murler Score was not significant. A low to moderate amount of shoulder disability measured by Shoulder Pain Disability Index and Shoulder Disability Questionnaire was found in patients with CIEDs, which was more prominent in STRs ($P<0.05$). Pain, association of CIED with pectoral muscles, a possible subtle ongoing capsular pathology, and avoidance behaviors of patients to minimize the risk of lead dislodgement might be related to restriction of motion and function in the shoulder joint in patients with CIEDs.
- Francia P, Adduci C, Palano F, Semprini L, Serdoz A, Montesanti D, Santini D, Musumeci B, Salvati A, Volpe M, Autore C. **Eligibility for the subcutaneous implantable cardioverter-defibrillator in patients with hypertrophic cardiomyopathy.** *J Cardiovasc Electrophysiol.* 2015; 26 (8): 893-9. <http://onlinelibrary.wiley.com/doi/10.1111/jce.12714/pdf> *Boston Scientific (LATITUDE).* **BACKGROUND:** High-risk hypertrophic cardiomyopathy (HCM) patients benefit from the implantable cardioverter defibrillator (ICD). The subcutaneous ICD (S-ICD) may provide comparable protection while avoiding the shortcomings of transvenous (TV) leads. We assessed S-ICD eligibility according to surface ECG screening test in a cohort of high-risk HCM patients. **METHODS AND RESULTS:** 47 HCM patients (3 S-ICD candidates; 41 TV-ICD patients without pacing indication; 3 pacemaker-dependent TV-ICD patients) underwent 4 screening protocols: standard ($n = 44$); exercise ($n = 33$); continuous pacing ($n = 44$); alternating paced/spontaneous QRS ($n = 41$). Of the 44 patients in the standard screening group, 41 (93%) were eligible. Max LV thickness was inversely related to the number of qualifying leads (3 leads: 21±4 mm; 2 leads: 22±6 mm; 1 lead: 25±6 mm; no leads: 28±11 mm; $p = 0.07$). Of the 33 patients in the exercise group, 5 were ineligible (3 after exercise). Of these, 2 became eligible after moving sternal electrodes from the left to the right parasternal line (eligibility rate: 30/33; 91%). Of the 44 patients in the continuous pacing group, 28 (64%) were eligible, 8 of which with right parasternal electrodes. In the paced/spontaneous QRS group ($n = 41$), 21 patients (51%) had at least one eligible lead during pacing and retained compatibility on the same lead during spontaneous rhythm, 5 of which with right parasternal electrodes. **CONCLUSIONS:** S-ICD screening failure is low in HCM, provided that patients with severe hypertrophy are carefully evaluated. Exercise test should be performed and right parasternal leads tested. Pacemaker patients display lower eligibility rate. This article is protected by copyright. All rights reserved.
- Frommeyer G, Dechering DG, Zumhagen S, Loher A, Kobe J, Eckardt L, Reinke F. **Long-term follow-up of subcutaneous ICD systems in patients with hypertrophic cardiomyopathy: a single-center experience.** *Clin Res Cardiol.* 2015: Epub before print. http://download.springer.com/static/pdf/687/art%253A10.1007%252Fs00392-015-0901-9.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs00392-015-0901-9&token2=exp=1443133643~acl=%2Fstatic%2Fpdf%2F687%2Fart%25253A10.1007%25252Fs00392-015-0901-9.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs00392-015-0901-9*~hmac=231631d269d975a6ef21b15147a70cf3fca7064b7b7b9e08f25081be7508fa2c *Boston Scientific (S-ICD).* *Mentions EFFORTLESS.* **BACKGROUND:** The totally subcutaneous implantable defibrillator (S-ICD) was introduced as a new alternative to conventional implantable defibrillators and is employed worldwide. This system is especially attractive for young patients. However, in patients with hypertrophic cardiomyopathy

(HCM), T-wave oversensing may occur. To address the question whether the S-ICD system is suitable for HCM patients, the data of a standard of care prospective single-center S-ICD registry were evaluated. **METHODS AND RESULTS:** In the present study, 18 HCM patients who received an S-ICD for primary (n = 14) or secondary prevention (n = 4) and a minimal follow-up duration of 6 months were analyzed. The mean follow-up duration was 31.7 +/- 15.4 months. Ventricular arrhythmias were adequately detected in 4 patients (22 %). In 7 patients (39 %), T-wave oversensing was noticed and led to at least one inappropriate shock in 4 patients (22 %). Further adverse events included surgical revision due to a mobile sensing electrode and resulting noise detection as well as one case of early battery failure requiring pulse generator change. **CONCLUSION:** Patients with HCM and S-ICD systems have an increased risk of T-wave oversensing and inappropriate shock delivery. Thorough monitoring as well as exercise tests may help to improve device settings and thereby prevent T-wave oversensing.

Hai JJ, Lim ET, Chan CP, Chan YS, Chan KK, Chong D, Ho KL, Tan BY, Teo WS, Ching CK, Tse HF. **First clinical experience of the safety and feasibility of total subcutaneous implantable defibrillator in an Asian population.** *Europace*. 2015; 17 Suppl 2: ii63-ii8.

http://europace.oxfordjournals.org/content/europace/17/suppl_2/ii63.full.pdf Boston Scientific (ECG screening tool). **AIMS:** The safety and feasibility of a subcutaneous implantable cardioverter-defibrillator (S-ICD) has been demonstrated in the treatment of life-threatening ventricular tachyarrhythmias (VT). Nonetheless, its safety and feasibility in an Asian population with smaller body-build is unclear. **METHODS AND RESULTS:** Twenty-one Asian patients who underwent S-ICD from 1 April 2014 to 2 February 2015 in five institutions in Hong Kong and Singapore were retrospectively reviewed. Twenty-one patients with a mean age of 50.0 +/- 14.1 years (range 29-77 years, 82.6% male) were included. Among them, 17 (81.0%) were Chinese, 3 (14.3%) were Malay, and 1 (4.8%) was Indian. Their mean body mass index was 23.0 +/- 4.0 kg/m². An S-ICD was implanted for primary and secondary prevention in 13 (61.9%) and 8 (38.1%) patients, respectively. The indications included Brugada syndrome (n = 6, 28.6%), ischaemic cardiomyopathy (CMP, n = 6, 28.6%), dilated CMP (n = 4, 19.0%), hypertrophic CMP (n = 2, 9.5%), and idiopathic ventricular fibrillation (n = 2, 9.5%). Three patients (14.3%) had prior infected transvenous ICD. There were no acute complications but eight wound complications (persistent wound bleeding requiring intervention = 2; delayed wound healing: upper sternal wound = 3; generator site = 1; local wound infection = 2) were observed in six (28.2%) patients. After a mean follow-up of 107.2 +/- 81.3 days (range of 14-254 days), one patient underwent three successful appropriate shocks for treatment of VTs. No inappropriate therapy was documented. **CONCLUSION:** Our initial experience shows that S-ICD is a feasible treatment for VT among an Asian population with smaller body-build. There was nonetheless a relatively high rate of wound complications.

Keller J, Neuzil P, Vymazal J, Janotka M, Brada J, Zacek R, Vopalka R, Weichet J, Reddy VY. **Magnetic resonance imaging in patients with a subcutaneous implantable cardioverter-defibrillator.** *Europace*. 2015; 17 (5): 761-6. <http://europace.oxfordjournals.org/content/europace/early/2015/02/13/europace.euu377.full.pdf> Boston Scientific (SQRx model 1010; Q-TRAK model 3010); beta-THERM model G22K7MCD8. Mentions Biotronik's MR-compatible ICD (PPro MRI). **AIMS:** Our aim was to evaluate the potential for safely imaging patients with a new type of implantable cardioverter-defibrillator called the subcutaneous implantable cardioverter-defibrillator (S-ICD) in a 1.5 T magnetic resonance imaging (MRI) scanner. With the increasing number of patients with cardiac implantable devices who are indicated for MRI, there is a growing need for establishing MRI compatibility of cardiac implantable devices. **METHODS AND RESULTS:** Patients with implanted S-ICD systems underwent one or more types of anatomical MRI scans. The S-ICD was programmed off and patients were monitored throughout the imaging procedure. Device function was evaluated pre- and post-scan. Patients were asked to report immediately any pain, torqueing movement, or heating sensation in the area of the pocket or electrode. Fifteen patients underwent a total of 22 examinations at 1.5 T. Scans included brain, spine, knee, and heart. Two patients were re-scanned due to complaints of heating over the can during lumbar scans, which was caused by a thermistor probe placed on the skin to measure skin temperature. All the remaining scans occurred without incident. No evidence of device malfunction was observed. **CONCLUSION:** This study is the first to demonstrate the feasibility of exposing S-ICD patients to MRI using the scanning and monitoring protocol described. More data are required to support S-ICD as a MRI conditional device. ["...The authors thank Brendan Koop and Richard Sanders from Boston Scientific for their assistance in the preparation and review of this manuscript and Martina Goldbergova for study coordination."].

Olde Nordkamp LRA, Brouwer TF, Barr C, Theuns DAMJ, Boersma LVA, Johansen JB, Neuzil P, Wilde AAM, Carter N, Husby M, Lambiase PD, Knops RE. **Inappropriate shocks in the subcutaneous ICD: Incidence, predictors and management.** *Int J Cardiol*. 2015; 195: 126-33. http://ac.els-cdn.com/S0167527315011985/1-s2.0-S0167527315011985-main.pdf?_tid=488e56b4-a53b-11e6-946e-00000aacb35e&acdnat=1478558652_ed8b823d18d86cbdf0b038be85da4638 Background The entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) eliminates the need for transvenous leads, and

therefore has the potential to improve lead-longevity and reduce lead-related complications. The S-ICD has a morphology-based sensing algorithm of which inappropriate shocks have been reported. Methods We analyzed the incidence, predictors and management of inappropriate shocks in the EFFORTLESS S-ICD Registry, which collects S-ICD implantation information and follow-up data from clinical centers in Europe and New Zealand. Results During a follow-up of 21 ± 13 months, 48 out of 581 S-ICD patients (71% male, age 49 ± 18 years) experienced 101 inappropriate shocks (8.3%). The most common cause was cardiac signal oversensing (73%), such as T-wave oversensing. Eighteen shocks (18%) were due to supraventricular tachycardias (SVT), of which 15 occurred in the shock-only zone. Cox-proportional hazard modeling using time-dependent covariates demonstrated that patients with a history of atrial fibrillation (HR 2.4) and patients with hypertrophic cardiomyopathy (HR 4.6) had an increased risk for inappropriate shocks, while programming the primary vector for sensing (from xyphoid to V6) reduced the risk. Reprogramming or optimization of SVT treatment after the first clinical event of inappropriate shock was successful in preventing further inappropriate shocks for cardiac oversensing and SVT events. Conclusions Inappropriate shocks, mainly due to cardiac oversensing, occurred in 8.3% of the S-ICD patients. Patients with hypertrophic cardiomyopathy or a history of atrial fibrillation were at increased risk, warranting specific attention for sensing and programming in this population.

Theuns DA, Crozier IG, Barr CS, Hood MA, Cappato R, Knops R, Maass AH, Boersma LV, Jordaens L. **Longevity of the Subcutaneous Implantable Defibrillator: Long-Term Follow-Up of the European Regulatory Trial Cohort.** *Circ Arrhythm Electrophysiol.* 2015; 8 (5): 1159-63.

<http://circep.ahajournals.org/content/circae/8/5/1159.full.pdf> *Subcutaneous Implantable Defibrillator (S-ICD) System - CE Clinical Investigation ClinicalTrials.gov ID: NCT01117792. funded by Boston Scientific.*

BACKGROUND: -The recent advent of subcutaneous implantable cardioverter defibrillators (S-ICDs) has provided investigators with a safe and effective new therapy in patients at risk of sudden cardiac death. At present, no data are available with regard to the longevity of these new devices. This study evaluated the longevity of the S-ICD system. METHODS AND RESULTS: -All patients enrolled in the European Regulatory Trial were included in the analysis. During follow-up, time and causes of device replacement or explantation were assessed and categorized. Device longevity was estimated using Kaplan-Meier analysis. Fifty-five patients were followed for a median of 5.8 years. During follow-up, 26 (47%) patients underwent device replacement and 5 (9%) device explantation. Median time to replacement was 5.0 years (Q1-Q3, 4.4 - 5.6 years). Replacement was caused by battery depletion in 25 patients (92%), of which 5 within 1.5 years due to premature battery depletion, and by infection in 1 patient (2%). Replacement for a transvenous ICD system was required in 4 patients (7%), due to ineffective defibrillation in 1 (0.003 per patient-year), need for resynchronization therapy in 2 (0.01 per patient-year) and for anti-bradycardia pacing in 1 (0.003 per patient-year). At 5 years follow-up, 71% of devices were still in service. CONCLUSIONS: -This study provides the first estimate of S-ICD system longevity since its introduction in clinical practice. Median longevity of the first generation S-ICD system was 5.0 years. The majority of devices were replaced due to battery depletion. Clinical Trial Registration-<http://www.clinicaltrials.gov>. Unique identifier: NCT01117792.

Zeb M, Curzen N, Allavattam V, Wilson D, Yue A, Roberts P, Morgan J. **Sensitivity and specificity of the subcutaneous implantable cardioverter defibrillator pre-implant screening tool.** *Int J Cardiol.* 2015; 195: 205-9.

http://ac.els-cdn.com/S0167527315011390/1-s2.0-S0167527315011390-main.pdf?_tid=3a656bde-2717-11e5-a380-00000aacb35d&acdnat=1436541822_9e34c212cd617f483a509d66077f1e42 *Boston Scientific employee (Allavattam, Wilson). Boston Scientific (Q-Trak lead; SQ-RX pulse generator).*

BACKGROUND: The sensitivity and specificity of the subcutaneous implantable cardioverter defibrillator (S-ICD) pre-implant screening tool required clinical evaluation. METHODS: Bipolar vectors were derived from electrodes positioned at locations similar to those employed for S-ICD sensing and pre-implant screening electrodes, and recordings collected through 80-electrode PRIME(R)-ECGs, in six different postures, from 40 subjects (10 healthy controls, and 30 patients with complex congenital heart disease (CCHD); 10 with Tetralogy of Fallot (TOF), 10 with single ventricle physiology (SVP), and 10 with transposition of great arteries (TGA)). The resulting vectors were analysed using the S-ICD pre-implant screening tool (Boston Scientific) and processed through the sensing algorithm of S-ICD (Boston Scientific). The data were then evaluated using 2x2 contingency tables. Fisher exact and McNemar tests were used for a comparison of the different categories of CCHD, and $p < 0.05$ vs. controls considered to be statistically significant. RESULTS: 57% of patients were male, mean age of 36.3years. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the S-ICD screening tool were 95%, 79%, 59% and 98%, respectively, for controls, and 84%, 79%, 76% and 86%, respectively, in patients with CCHD ($p=0.0001$). CONCLUSION: The S-ICD screening tool was comparatively more sensitive in normal controls but less specific in both CCHD patients and controls; a possible explanation for the reported high incidence of inappropriate S-ICD shocks. Thus, we propose a pre-implant screening device using the S-ICD sensing algorithm to minimise false exclusion and selection, and hence minimise potentially inappropriate shocks.

Zeb M, Curzen N, Veldtman G, Yue A, Roberts P, Wilson D, Morgan J. **Potential eligibility of congenital heart disease patients for subcutaneous implantable cardioverter-defibrillator based on surface electrocardiogram mapping.** *Europace*. 2015; 17 (7): 1059-67.

<http://europace.oxfordjournals.org/content/europace/17/7/1059.1.full.pdf> Boston Scientific (S-ICD); HeartScape Technologies/Verathon (PRIME ECG vests). Funded partially by Medtronic and Boston Scientific. AIMS: The eligibility of complex congenital heart disease (C-CHD) patients for subcutaneous implantable cardioverter-defibrillator (S-ICD) has yet to be determined. The aim of this study was to determine in C-CHD patients: (i) the S-ICD eligibility, (ii) the most effective sensing vector, (iii) the impact of posture change on screening eligibility, and (iv) the impact of using two vs. six postures for screening. Adults with structurally normal hearts were used as controls. METHODS AND RESULTS: The Boston Scientific ECG screening tool was used to determine eligibility for S-ICD in two and six different postures in 30 patients with C-CHD and 10 controls. Statistical significance was determined using Fisher's exact test. In total, 1440 bipolar vectors were collected. The mean age was 36.3 years, 57% subjects were men. Over all 86.7% of C-CHD patients and 100% controls ($P > 0.05$) met S-ICD eligibility. In controls, the primary vector (PV) was the most effective, and the alternate vector (AV) was least effective. In C-CHD patients, the AV was comparable to the PV. Posture change did not significantly affect S-ICD eligibility in C-CHD patients and controls ($P > 0.05$). Screening with six postures vs. two did not significantly affect S-ICD eligibility of C-CHD patients (83% vs. 87%, $P > 0.05$) or controls (90% vs. 100% $P = >0.05$). CONCLUSION: No significant differences were observed between S-ICD eligibility in C-CHD patients and controls. The AV and PV are most suitable in C-CHD patients. No significant impact of postural change was observed for S-ICD eligibility between the two groups. No significant difference was observed in S-ICD eligibility when screening using two or six postures in both groups.

Gold MR, Weiss R, Theuns DAMJ, Smith W, Leon A, Knight BP, Carter N, Husby M, Burke MC. **Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator.** *Heart Rhythm*. 2014; 11 (8): 1352-8. [http://ac.els-cdn.com/S1547527114004044/1-s2.0-S1547527114004044-main.pdf?_tid=1c2292ec-1998-11e4-a4fa-](http://ac.els-cdn.com/S1547527114004044/1-s2.0-S1547527114004044-main.pdf?_tid=1c2292ec-1998-11e4-a4fa-00000aacb35d&acdnat=1406910362_21f5aef05a3d062ed9d57c98f05af813)

[00000aacb35d&acdnat=1406910362_21f5aef05a3d062ed9d57c98f05af813](http://ac.els-cdn.com/S1547527114004044/1-s2.0-S1547527114004044-main.pdf?_tid=1c2292ec-1998-11e4-a4fa-00000aacb35d&acdnat=1406910362_21f5aef05a3d062ed9d57c98f05af813) S-ICD System Clinical Investigation. Boston Scientific (SQ-RX pulse generator). Mentions MADIT RIT, EFFORTLESS registry. Comment in: Poole JE. Novel ICD therapy begets novel ICD detection: First look at the performance of the subcutaneous ICD discrimination algorithm. *Heart Rhythm*. 2014; 11 (8): 1359-60. The subcutaneous implantable cardioverter-defibrillator system (S-ICD) uses a novel detection algorithm previously shown to discriminate induced tachyarrhythmias (ventricular vs supraventricular) effectively. Objective The purpose of this study was to evaluate the role of the S-ICD discrimination algorithm in reducing the incidence of spontaneous inappropriate shocks. Methods A total of 314 subjects underwent implantation with an S-ICD system as part of the S-ICD Clinical Investigation (IDE Trial). Subjects were grouped according to programming at discharge to either a single shock zone or 2 shock zones, with a discrimination algorithm in the lower rate zone. Results This cohort had 226 subjects (72%) with dual zone programming and 88 subjects (28%) with single zone programming. Over a mean follow-up period of 661 ± 174 days, inappropriate shocks occurred in 23 subjects from the dual zone subgroup (10.2%) and 23 subjects from the single zone subgroup (26.1%, $P < .001$), with 2-year inappropriate shock-free rates of 89.7% vs 73.6%;, respectively (hazard ratio 0.38, $P = .001$). Freedom from appropriate shocks did not differ between subgroups (92.2% vs 90.3%, hazard ratio 0.82, $P = .64$). Moreover, mean time to appropriate therapy did not differ between subgroups, and there was only 1 episode of arrhythmic syncope in the cohort. Conclusion The addition of a second shock zone with an active discrimination algorithm was strongly associated with a reduction in inappropriate shocks with the S-ICD system and did not result in prolongation of detection times or increased syncope. These data support the use of dual zone programming as a standard setting for S-ICD patients.

Groh CA, Sharma S, Pelchovitz DJ, Bhavne PD, Rhyner J, Verma N, Arora R, Chicos AB, Kim SS, Lin AC, Passman RS, Knight BP. **Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator.** *Heart Rhythm*. 2014; 11 (8): 1361-6. [http://ac.els-cdn.com/S1547527114004536/1-s2.0-S1547527114004536-main.pdf?_tid=adf01b96-a53b-11e6-b758-](http://ac.els-cdn.com/S1547527114004536/1-s2.0-S1547527114004536-main.pdf?_tid=adf01b96-a53b-11e6-b758-00000aab0f02&acdnat=1478558822_822c649cf384fd6e2b2d98016a2fc748)

[00000aab0f02&acdnat=1478558822_822c649cf384fd6e2b2d98016a2fc748](http://ac.els-cdn.com/S1547527114004536/1-s2.0-S1547527114004536-main.pdf?_tid=adf01b96-a53b-11e6-b758-00000aab0f02&acdnat=1478558822_822c649cf384fd6e2b2d98016a2fc748) Background An electrocardiographic (ECG) screening test has been developed to identify patients being considered for a totally subcutaneous implantable cardioverter-defibrillator (S-ICD) at risk for T-wave oversensing. Objective The purpose of this study was to determine the proportion of potential S-ICD recipients who fail the ECG screening test and to identify predictors of failure. Methods Patients who already have an ICD but are not receiving antibradycardia pacing are representative of patients who might be considered for an S-ICD. One hundred such outpatients were enrolled in the study. Surface rhythm strips were recorded along the sensing vectors of the S-ICD system and the screening template applied. Clinical and standard ECG characteristics of patients who failed the test were compared to those who passed. Results Patients had the following characteristics: 72% male, age 57 ± 16 years,

body mass index 29 ± 6 kg/m², left ventricular ejection fraction $43\% \pm 17\%$, QRS duration 109 ± 23 ms, QTc interval 447 ± 39 ms, 44% had coronary disease, and 55% had heart failure. Among the 100 patients, 8% failed the screening test. There were no differences in patient clinical characteristics and most standard ECG measurements. However, patients with T-wave inversions in standard ECG leads I, II, and aVF had a 45% chance of failing. Conclusion Eight percent of potential S-ICD patients were not eligible for the S-ICD after failing the screening test designed to identify patients susceptible to T-wave oversensing. Patients with T-wave inversions in leads I, II, and aVF on a standard ECG were 23 times more likely to fail. More work is needed in S-ICD sensing algorithms to increase patient eligibility for the S-ICD. © 2014 Heart Rhythm Society. All right reserved.

Kooiman KM, Knops RE, Olde Nordkamp L, Wilde AAM, de Groot JR. **Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: Implications for management.** *Heart Rhythm.* 2014; 11 (3): 426-34. http://ac.els-cdn.com/S1547527113013945/1-s2.0-S1547527113013945-main.pdf?_tid=aa55b21c-a2db-11e3-9467-00000aacb35e&acdnat=1393855189_412bcfef5cb544a9c741a62b9361ce68 Cameron Health (SQ-RX Pulse generator). *EFFORTLESS Registry, ClinicalTrials.gov ID: NCT01085435 PRAETORIAN trial, ClinicalTrials.gov ID: NCT01296022.* BACKGROUND: Inappropriate shocks (IASs) complicate implantable cardioverter-defibrillator (ICD) therapy. The management of IASs in patients with a subcutaneous ICD (S-ICD) differs from that in patients with a conventional ICD because of different sensing algorithms and programming options. OBJECTIVE: To describe the management of IASs in patients with an S-ICD. METHODS: Patients were implanted with an S-ICD between February 2009 and July 2012. The prevalence data and clinical determinants of IASs were prospectively collected. In the case of T-wave oversensing (TWOS), an exercise test was performed, and all possible sensing vectors were screened for TWOS. The absence of TWOS defined a suitable vector. RESULTS: Eleven of 69 patients (54% men; mean age 39 ± 14 years; 73% primary prevention) received IASs after 8.9 ± 10 months of implantation (10.8% annual incidence rate). In 8 cases, TWOS caused IASs. Seven of these IASs occurred during exercise and 1 during atrial fibrillation with a high ventricular rate. To manage TWOS, in 7 of 8 patients the sensing vector was changed and in 5 of 8 patients the (un)conditional zone was changed. Hereafter, IASs recurred in 3 of 8 patients, in 2 because of programming errors. Hence, after reprogramming, we observed no IASs in 87.5% of the patients with TWOS during a follow-up of 14.1 ± 13 months. CONCLUSIONS: IASs due to TWOS in the S-ICD can be managed by reprogramming the sensing vector and/or the therapy zones of the device using a template acquired during exercise. Exercise-optimized programming can reduce future IASs, and standard exercise testing shortly after the implantation of an S-ICD may be considered in patients at an increased risk for TWOS.

Copyright © 2014 Heart Rhythm Society. Published by Elsevier Inc. All rights reserved.

Kuschyk J, Milasinovic G, Kuhlkamp V, Roberts PR, Zabel M, Molin F, Shorofsky S, Stromberg KD, Degroot PJ, Murgatroyd FD. **A multicenter study of shock pathways for subcutaneous implantable defibrillators.** *J Cardiovasc Electrophysiol.* 2014; 25 (1): 29-35. <http://onlinelibrary.wiley.com/doi/10.1111/jce.12281/pdf> SOLO Study. Medtronic (6996SQ). Mentions CREDIT registry. INTRODUCTION: A purely subcutaneous implantable cardioverter defibrillator (ICD) requires higher energy but may be an effective alternative to transvenous ICDs to deliver lifesaving therapies. OBJECTIVE: To identify combinations of anteroposterior subcutaneous shock pathways and waveforms with defibrillation efficacy comparable to transvenous ICDs. METHODS: Defibrillation testing was performed in 141 patients temporarily implanted with an active can emulator and subcutaneous coil electrodes. The patients were subdivided into 5 groups within 2 study phases. In all groups, a posterior electrode was positioned with its tip close to the spine. In the first study phase, 2 different can locations were evaluated: (1) an inframammary pocket (IM-1-750), or (2) a conventional infraclavicular pocket (IC-1-750). In both cases, a 70 J biphasic shock was used (peak voltage 750 V; 270 μ F capacitance). In the second phase, configuration IC-1-750 was enhanced by the addition of a second (parasternal) subcutaneous electrode (IC-2-750). Furthermore, the effects of a different 70 J shock waveform (1,000 V, 160 μ F) were evaluated for configurations IM-1-750 and IC-2-750 (becoming IM-1-1000 and IC-2-1000). RESULTS: The proportion of patients satisfying a defibrillation safety margin test of 2 consecutive successes at ≤ 50 J was 74%, 11%, and 44%, respectively, for the IM-1-750, IC-1-750, and IC-2-750 configurations, and 93% and 86% for the IM-1-1000 and IC-2-1000 configurations. CONCLUSIONS: Defibrillation efficacy comparable to that of a transvenous system was achieved with an anteroposterior subcutaneous ICD configuration, with 160 μ F capacitance, 1,000 V, and 70 J output. An infraclavicular pocket location becomes feasible if a parasternal subcutaneous coil is added.

Lambiase PD, Barr C, Theuns DA, Knops R, Neuzil P, Johansen JB, Hood M, Pedersen S, Kaab S, Murgatroyd F, Reeve HL, Carter N, Boersma L. **Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry.** *Eur Heart J.* 2014; 35 (25): 1657-65. <http://eurheartj.oxfordjournals.org/content/early/2014/03/25/eurheartj.ehu112.full.pdf> Evaluation of FactORs

Impacting Clinical Outcome and Cost Effectiveness of the S-ICD (EFFORTLESS S-ICD) Registry
Clinicaltrials.gov ID: NCT01085435. Boston Scientific (S-ICD system). Mentions Cameron Health IDE study.
AIMS: The totally subcutaneous implantable-defibrillator (S-ICD) is a new alternative to the conventional transvenous ICD system to minimize intravascular lead complications. There are limited data describing the long-term performance of the S-ICD. This paper presents the first large international patient population collected as part of the EFFORTLESS S-ICD Registry. METHODS AND RESULTS: The EFFORTLESS S-ICD Registry is a non-randomized, standard of care, multicentre Registry designed to collect long-term, system-related, clinical, and patient reported outcome data from S-ICD implanted patients since June 2009. Follow-up data are systematically collected over 60-month post-implant including Quality of Life. The study population of 472 patients of which 241 (51%) were enrolled prospectively has a mean follow-up duration of 558 days (range 13-1342 days, median 498 days), 72% male, mean age of 49 +/- 18 years (range 9-88 years), 42% mean left ventricular ejection fraction. Complication-free rates were 97 and 94%, at 30 and 360 days, respectively. Three hundred and seventeen spontaneous episodes were recorded in 85 patients during the follow-up period. Of these episodes, 169 (53%) received therapy, 93 being for Ventricular Tachycardia/Fibrillation (VT/VF). One patient died of recurrent VF and severe bradycardia. Regarding discrete VT/VF episodes, first shock conversion efficacy was 88% with 100% overall successful clinical conversion after a maximum of five shocks. The 360-day inappropriate shock rate was 7% with the vast majority occurring for oversensing (62/73 episodes), primarily of cardiac signals (94% of oversensed episodes). CONCLUSION: The first large cohort of real-world data from an International patient S-ICD population demonstrates appropriate system performance with clinical event rates and inappropriate shock rates comparable with those reported for conventional ICDs. .

Olde Nordkamp LR, Warnars JL, Kooiman KM, JR DEG, Rosenmoller BR, Wilde AA, Knops RE. **Which Patients are Not Suitable for a Subcutaneous ICD: Incidence and Predictors of Failed QRS-T-Wave Morphology Screening.** *J Cardiovasc Electrophysiol.* 2014; 25 (5): 494-9.

<http://onlinelibrary.wiley.com/doi/10.1111/jce.12343/pdf> *Cameron Health (patient screening tool).*

BACKGROUND: The subcutaneous cardioverter-defibrillator (S-ICD) relies on a pre-implantation QRS-T morphology screening (TMS) of the ECG to assure that it reliably detects the QRS-complexes and T-waves. The prevalence and clinical characteristics of the patients who fail this TMS is unknown. METHODS AND RESULTS: QRS-T morphology screening was done in 230 consecutive ICD outpatients (75% male, age 57 +/- 15 years) without an indication for cardiac pacing, using an ECG simulating the three sensing vectors of the S-ICD (TMS-ECG). Patients were defined suitable when at least one sensing vector was considered appropriate in both supine and standing position. In total, 7.4% of patients, who were all male, were considered not suitable for a S-ICD according to the TMS-ECG. Independent predictors for TMS failure were hypertrophic cardiomyopathy (HCM; OR 12.6), a heavy weight (OR 1.5), a prolonged QRS duration (OR 1.5) and a R:T ratio <3 in the lead with the largest T-wave on a standard 12-lead surface ECG (OR 14.6). CONCLUSION: In patients without an indication for pacing, 7.4% would have been not suitable for a S-ICD according to the TMS. HCM, a heavy weight, a prolonged QRS duration and a R:T ratio <3 in the ECG lead with the largest T-wave were independently associated with TMS failure. These data might alert physicians that selection of patients for a S-ICD should be considered with special caution in certain patient groups, because they may not satisfy ECG criteria for adequate sensing. This article is protected by copyright. All rights reserved.

Randles DA, Hawkins NM, Shaw M, Patwala AY, Pettit SJ, Wright DJ. **How many patients fulfil the surface electrocardiogram criteria for subcutaneous implantable cardioverter-defibrillator implantation?** *Europace.* 2014; 16 (7): 1015-21.

<http://europace.oxfordjournals.org/content/early/2013/12/18/europace.eut370.full.pdf> *Cameron Health (S-ICD; SQ-RX pulse generator; Q-TRAK subcutaneous lead).* AIMS: To determine the number of patients with a primary or secondary prevention implantable cardioverter-defibrillator (ICD) indication who are eligible for subcutaneous ICD (S-ICD) implantation according to the S-ICD manufacturer's surface electrocardiogram (ECG) screening template. METHODS AND RESULTS: One hundred and ninety-six ICD patients with a non-paced ventricle were assessed using erect and supine ECG limb lead recordings to simulate the three S-ICD sensing vectors. Each ECG lead was scrutinized by two independent observers. Subcutaneous ICD eligibility required two or more leads to satisfy the S-ICD screening template in both erect and supine positions. Overall, 85.2% of patients [95% confidence interval (CI): 80.2-90.2%] fulfilled surface ECG screening criteria. The proportion of patients with 3, 2, 1, and 0 qualifying leads were 37.2% (95% CI: 30.4-44.0%), 48.0% (95% CI: 41.0-55.0%), 11.2% (95% CI: 6.8-15.6%), and 3.6% (95% CI: 1.0-6.2%). The S-ICD screening template was satisfied more often by Lead III (primary vector, 83.7%, 95% CI: 78.5-88.9%) and Lead II (secondary vector, 82.7%, 95% CI: 77.4-88.0%) compared with Lead I (alternate vector, 52.6%, 95% CI: 45.6-59.6%). A prolonged QRS duration was the only baseline characteristic independently associated with ineligibility for S-ICD implantation. There was 92.9% agreement between the two independent observers in assessment of eligibility using the S-ICD screening template. CONCLUSION: About 85.2% of patients with an indication for a primary or secondary prevention ICD

have a surface ECG that is suitable for S-ICD implantation when assessed with an S-ICD screening template. There is minor inter-observer variation in assessment of eligibility using the S-ICD screening template.

Bongiorni MG, Proclemer A, Dobreanu D, Marinskis G, Pison L, Blomstrom-Lundqvist C. **Preferred tools and techniques for implantation of cardiac electronic devices in Europe: results of the European Heart Rhythm Association survey.** *Europace*. 2013; 15 (11): 1664-8.

<http://europace.oxfordjournals.org/content/15/11/1664.full.pdf> The aim of this European Heart Rhythm Association (EHRA) survey was to assess clinical practice in relation to the tools and techniques used for cardiac implantable electronic devices procedures in the European countries. Responses to the questionnaire were received from 62 members of the EHRA research network. The survey involved high-, medium-, and low-volume implanting centres, performing, respectively, more than 200, 100-199 and under 100 implants per year. The following topics were explored: the side approach for implantation, surgical techniques for pocket incision, first venous access for lead implantation, preference of lead fixation, preferred coil number for implantable cardioverter-defibrillator (ICD) leads, right ventricular pacing site, generator placement site, subcutaneous ICD implantation, specific tools and techniques for cardiac resynchronization therapy (CRT), lead implantation sequence in CRT, coronary sinus cannulation technique, target site for left ventricular lead placement, strategy in left ventricular lead implant failure, mean CRT implantation time, optimization of the atrioventricular (AV) and ventriculo-ventricular intervals, CRT implants in patients with permanent atrial fibrillation, AV node ablation in patients with permanent AF. This panoramic view allows us to find out the operator preferences regarding the techniques and tools for device implantation in Europe. The results showed different practices in all the fields we investigated, nevertheless the survey also outlines a good adherence to the common standards and recommendations. [Figure 1 Centre preferences for right ventricular pacing site (A), first venous access (B), and ICD coils (C); Figure 2 Centre preferences for lead fixation. ICD, implantable cardioverter-defibrillator; PM, pacemaker; Figure 3 Centre preferences for CRT device implantation. "...**Fifty-three percent of the centres declare implanting subcutaneous ICD, with 60% performing the procedure under local anaesthesia, and 40% under general anaesthesia...**"].

Celikyurt U, Agacdiken A, Bozyel S, Argan O, Sade I, Vural A, Ural D. **Assessment of shoulder pain and shoulder disability in patients with implantable cardioverter-defibrillator.** *J Interv Card Electrophysiol*. 2013; 36 (1): 91-4. http://download.springer.com/static/pdf/924/art%253A10.1007%252Fs10840-012-9753-7.pdf?auth66=1354724875_29c7c2d3f7f8cd9b956821e5be4cae6d&ext=.pdf PURPOSE: Shoulder pain and

disability is a common but overlooked disorder in patients with implantable cardioverter-defibrillators (ICD). We aimed to assess chronic shoulder pain and disability in patients with ICD. METHODS: Two hundred fifty-four patients (mean age, 66 +/- 12 years; 156 men) with ICD were included in the study. The Shoulder Pain and Disability Index (SPADI) was used for assessment of shoulder pain and disability. RESULTS: Of the patients, 131 (52 %) have shoulder pain and disability. The total mean SPADI score in patients with shoulder pain and disability was 33 +/- 18 and was significantly higher than in patients without shoulder pain and disability (11 +/- 2; $p < 0.001$). Patients with three-lead ICD have significantly higher SPADI scores than patients with single-lead ICD ($p < 0.001$). Number of leads correlated with pain score ($p = 0.001$, $r = 0.253$), disability score ($p = 0.006$, $r = 0.174$) and total SPADI score ($p = 0.001$, $r = 0.213$). In multivariate analysis, significant associates of shoulder pain and disability were evaluated, adjusting for age, sex, body mass index, procedure time, implantation time interval, limitation of shoulder activity and number of leads. Number of leads was the only predictor of shoulder pain and disability (OR 0.518, 95 % CI, 0.372-0.721; $p < 0.001$). CONCLUSIONS: Patients with ICD implantation frequently have chronic shoulder pain and disability. Patients with three leads suffer more shoulder pain and disability. [Mentions S-ICD"...avoids the need for the placement of electrodes within the heart...may present development of shoulder pain and disability..."].

de Bie MK, Thijssen J, van Rees JB, Putter H, van der Velde ET, Schaliij MJ, van Erven L. **Suitability for subcutaneous defibrillator implantation: results based on data from routine clinical practice.** *Heart*. 2013; 99 (14): 1018-23. <http://heart.bmj.com/content/early/2013/05/22/heartjnl-2012-303349.full.pdf> *Biotronik (ICDs); Boston Scientific (ICDs); Medtronic (ICDs); St Jude Medical (ICDs)*. OBJECTIVE: To assess the proportion of current implantable cardioverter defibrillator (ICD) recipients who would be suitable for a subcutaneous lead ICD (S-ICD). DESIGN: A retrospective cohort study. SETTING: Tertiary care facility in the Netherlands. PATIENTS: All patients who received a single- or dual-chamber ICD in the Leiden University Medical Center between 2002 and 2011. Patients with a pre-existent indication for cardiac pacing were excluded. MAIN OUTCOME MEASURE: Suitability for an S-ICD defined as not reaching one of the following endpoints during follow-up: (1) an atrial and/or right ventricular pacing indication, (2) successful antitachycardia pacing without a subsequent shock or (3) an upgrade to a CRT-D device. RESULTS: During a median follow-up of 3.4 years (IQR 1.7-5.7 years), 463 patients (34% of the total population of 1345 patients) reached an endpoint. The cumulative incidence of ICD recipients suitable for an initial S-ICD implantation was 55.5% (95% CI 52.0% to 59.0%) after 5 years. Significant predictors for the

unsuitability of an S-ICD were: secondary prevention, severe heart failure and prolonged QRS duration.

CONCLUSIONS: After 5 years of follow-up, approximately 55% of the patients would have been suitable for an S-ICD implantation. Several baseline clinical characteristics were demonstrated to be useful in the selection of patients suitable for an S-ICD implantation.

Griksaitis MJ, Rosengarten JA, Gnanapragasam JP, Haw MP, Morgan JM. **Implantable cardioverter defibrillator therapy in paediatric practice: a single-centre UK experience with focus on subcutaneous defibrillation.** *Europace*. 2013; 15 (4): 523-30.

<http://europace.oxfordjournals.org/content/early/2013/01/18/europace.eus388.full.pdf> *Cameron Health (S-ICD, n=3; discrimination algorithm); Medtronic (Subcutaneous coil 6996SQ).* **AIMS:** Sudden cardiac death (SCD) risk can be managed by implantable cardioverter defibrillators (ICD). Defibrillation shocks can be delivered via ICD generator and/or intracardiac or subcutaneous coil configurations. We present our single-centre use of childhood ICDs. **METHODS AND RESULTS:** Twenty-three patients had ICD implantation, with median age and weight of 12.96 years and 41.35 kg. Indications included eight long QT; four hypertrophic cardiomyopathy; three Brugada syndrome; two idiopathic ventricular fibrillation; two post-congenital heart repair; two family history of SCD with abnormal repolarization; one catecholaminergic polymorphic ventricular tachycardia; and one left ventricle non-compaction. Twelve had out of hospital cardiac arrests prior to implantation. Techniques included 13 conventional ICD implants (pre-pectoral device with endocardial leads), 7 with subcutaneous defibrillation coils (sensing via epicardial or endocardial leads tunneled to the ICD), and 3 with exclusive subcutaneous ICD (sensing and defibrillation via the same subcutaneous lead). Satisfactory defibrillation efficacy and ventricular arrhythmia sensing was confirmed at implantation. Follow-up ranged from 0.17 to 11.08 years. One child died with the ICD in situ. Ten children received appropriate shocks; five on more than one occasion. Five received inappropriate shocks (for inappropriate recognition of sinus tachycardia or supraventricular tachycardia). Five children underwent six further interventions; all had intracardiac leads. **CONCLUSION:** Innovative shock delivery systems can be used in children requiring an ICD. The insertion technique and device used need to accommodate the age and weight of the child, and concomitant need for pacing therapy. We have demonstrated effective defibrillation with shocks delivered via configurations employing subcutaneous coils in children. [Figure 1 Pie chart demonstrating the ICD implant indications; Three children had exclusive subcutaneous ICD insertion with S-ICD (Figure 3). [Table 1 Patient characteristics included in this study, **Implant radiology data, Screening time/Exposure dose.**

Jarman JW, Todd DM. **United Kingdom national experience of entirely subcutaneous implantable cardioverter-defibrillator technology: important lessons to learn.** *Europace*. 2013; 15 (8): 1158-65.

<http://europace.oxfordjournals.org/content/early/2013/02/28/europace.eut016.full.pdf> *Cameron Health (S-ICD).* **AIMS:** The aim of this study was to describe the early phase United Kingdom (UK) clinical experience with a novel entirely subcutaneous implantable cardioverter-defibrillator (S-ICD). **METHODS AND RESULTS:** A questionnaire was sent to all UK hospitals implanting S-ICDs. Nineteen of 25 (76%) hospitals responded with the details of 111 implanted patients [median 5/hospital (range 1-18)]. Mean duration of follow-up was 12.7 +/- 7.1 months. Median patient age was 33 years (range 10-87 years). Underlying pathology was primary electrical disease in 43%, congenital heart disease 12%, hypertrophic cardiomyopathy 20%, ischaemic cardiomyopathy 14%, idiopathic dilated cardiomyopathy 5%, and other cardiomyopathies 7% patients. Nineteen (17%) patients required 20 re-operations, including permanent device explantation in 10 (9%). Twenty-four appropriate shocks were delivered in 13 (12%) patients, including 10 for ventricular fibrillation. One patient suffered arrhythmic death, but there were no failures to detect or terminate ventricular arrhythmias above the programmed detection rate. Fifty-one inappropriate shocks were delivered in 17 (15%) patients. Forty-one (80%) were for T-wave over-sensing and 1 (2%) for atrial flutter-wave over-sensing. The 11 patients who received inappropriate shocks due to T-wave over-sensing were significantly younger than patients who did not (24 +/- 10 vs. 37 +/- 19 years; P = 0.02). **CONCLUSION:** The S-ICD is an important innovation in ICD technology. However, these data indicate that adverse event rates are significant during early clinical adoption. Important lessons in patient selection, implant technique, and device programming can be learnt from this experience.

Köbe J, Reinke F, Meyer C, Shin D-I, Martens E, Käab S, Löher A, Amler S, Lichtenberg A, Winter J, Eckardt L. **Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: A multicenter case-control study.** *Heart Rhythm*. 2013; 10 (1): 29-36. http://ac.els-cdn.com/S154752711201185X/1-s2.0-S154752711201185X-main.pdf?_tid=53ea73d2-56a5-11e2-b618-0000aacb35d&acdnat=1357328065_ddc703024e73d68d1976f3c68b688d27

Cameron Health (S-ICD). *Comment in: Dubner S. Implantation and follow-up of totally subcutaneous vs conventional implantable cardioverter-defibrillators: A multicenter case-control study. Heart Rhythm. 2013; 10 (1): 37-8.* . Background The approval of an entirely subcutaneous implantable-cardioverter defibrillator (ICD) system (S-ICD) has raised attention about this promising technology. It was developed to overcome lead failure and infection problems of

conventional transvenous ICD systems. Nevertheless, lead migration of the initial design and inappropriate shock rates have raised concerns regarding its reliability and safety. Objective The purpose of this study was to report the largest multicenter series to date of patients with the new device in comparison with a matched conventional transvenous ICD collective with focus on perioperative complications, conversion of induced ventricular fibrillation (VF), and short-term follow-up. Methods/Results Sixty-nine patients (50 male and 19 female; mean age 45.7±15.7 years) received an S-ICD in three German centers and were randomly assigned to 69 sex- and age-matched conventional ICD patients. The indication was primary prevention in 41 patients (59.4%) without difference between groups (34 control patients; P = .268). The predominant underlying heart disease was ischemic cardiomyopathy in 11 (15.9%), dilated cardiomyopathy in 25 (36.2%), and hypertrophic cardiomyopathy in 10 (14.5%) in the S-ICD group. Mean implantation time was 70.8±27.9 minutes (P = .398). Conversion rates of induced VF were 89.5% for 65 J (15-J safety margin) and 95.5% including reversed shock polarity (15-J safety margin) in the study group. Termination of induced VF was successful in 90.8% (10-J safety margin, device dependent) of the control patients (P = .815). Procedural complications were similar between the 2 groups. Mean follow-up was 217±138 days. During follow-up, 3 patients with S-ICD were appropriately treated for ventricular arrhythmias. Three inappropriate episodes (5.2%) occurred in 3 S-ICD patients due to T-wave oversensing, whereas atrial fibrillation with rapid conduction was the predominant reason for inappropriate therapy in conventional devices (P = .745). Conclusion The novel S-ICD system can be implanted safely with similar perioperative adverse events compared with standard transvenous devices. Our case-control study demonstrates a 10.4% failure of conversion of induced VF with the S-ICD set to standard polarity and 15-J safety margin and comparable inappropriate shock rates during short-term follow-up.

Tan CS, Jie C, Joe J, Irani ZD, Ganguli S, Kalva SP, Wicky S, Wu S. **The impact of transvenous cardiac devices on vascular access patency in hemodialysis patients.** *Semin Dial.* 2013: Epub before print. <http://onlinelibrary.wiley.com/doi/10.1111/sdi.12073/pdf> Creating a vascular access in the presence of a cardiovascular implantable electronic device (CIED) in a patient with or approaching end-stage renal disease can be challenging. In this study, we aimed to evaluate the impact of a CIED on the outcomes of vascular access creation in hemodialysis patients and determine their effects on vascular access patency. This is a single-center retrospective review of hemodialysis patients who underwent vascular access creation after CIED placement. Outcomes of vascular access creation and need for endovascular interventions were compared between patients with vascular access created ipsilateral and contralateral to the site of CIED. Comparing patients with arteriovenous (AV) access created ipsilateral to CIED placement (n = 19) versus the contralateral side (n = 17), the primary failure rate was 78.9% versus 35.3% (p = 0.02). For AV accesses that were matured, the median primary patency durations for AV accesses created ipsilateral to the CIED was 11.2 months compared to 7.8 months for AV accesses created contralateral to the CIED (p = 1.00). AV accesses created ipsilateral to a CIED have a higher primary failure rate compared with the contralateral arm and should be avoided as much as possible. ["...The subcutaneous ICD is an implantable defibrillator in which all of the device components are implanted subcutaneously with no intracardiac or epicardial components (25). It is effective in terminating ventricular arrhythmias, whilst avoiding the need for transvenous leads (24). This in turn avoids the inherent risks associated with transvenous leads and may be potentially beneficial in hemodialysis patients where infection and vascular access patency are the Achilles heels. More studies are needed to confirm its efficacy, especially in patients withCKD....".

Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, Rashtian M, Kremers M, Crozier I, Lee KL, Smith W, Burke MC. **Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator.** *Circulation.* 2013; 128 (9): 944-53. <http://circ.ahajournals.org/content/128/9/944.full.pdf> S-ICD System IDE Clinical Study. *ClinicalTrials.gov ID: NCT01064076. Boston Scientific (S-ICD). Comment in: Saxon LA. The subcutaneous implantable defibrillator: a new technology that raises an existential question for the implantable cardioverter-defibrillator. Circulation.* 2013; 128 (9): 938-40. Mentions MADIT-RIT, PREPARE. BACKGROUND: The most frequent complications associated with implantable cardioverter-defibrillators (ICDs) involve the transvenous leads. A subcutaneous implantable cardioverter-defibrillator (S-ICD) has been developed as an alternative system. This study evaluated the safety and effectiveness of the S-ICD System (Cameron Health/Boston Scientific) for the treatment of life-threatening ventricular arrhythmias (ventricular tachycardia/ventricular fibrillation). METHODS AND RESULTS: This prospective, nonrandomized, multicenter trial included adult patients with a standard indication for an ICD, who neither required pacing nor had documented pace-terminable ventricular tachycardia. The primary safety end point was the 180-day S-ICD System complication-free rate compared with a prespecified performance goal of 79%. The primary effectiveness end point was the induced ventricular fibrillation conversion rate compared with a prespecified performance goal of 88%, with success defined as 2 consecutive ventricular fibrillation conversions of 4 attempts. Detection and conversion of spontaneous episodes were also evaluated. Device implantation was attempted in 321 of 330 enrolled patients, and 314 patients underwent successful implantation. The cohort was followed for a mean duration of 11 months.

The study population was 74% male with a mean age of 52+/-16 years and mean left ventricular ejection fraction of 36+/-16%. A previous transvenous ICD had been implanted in 13%. Both primary end points were met: The 180-day system complication-free rate was 99%, and sensitivity analysis of the acute ventricular fibrillation conversion rate was >90% in the entire cohort. There were 38 discrete spontaneous episodes of ventricular tachycardia/ventricular fibrillation recorded in 21 patients (6.7%), all of which successfully converted. Forty-one patients (13.1%) received an inappropriate shock. **CONCLUSIONS:** The findings support the efficacy and safety of the S-ICD System for the treatment of life-threatening ventricular arrhythmias. .

Aydin A, Hartel F, Schluter M, Butter C, Kobe J, Seifert M, Gosau N, Hoffmann B, Hoffmann M, Vettorazzi E, Wilke I, Wegscheider K, Reichenspurner H, Eckardt L, Steven D, Willems S. **Shock efficacy of subcutaneous implantable cardioverter-defibrillator for prevention of sudden cardiac death: initial multicenter experience.** *Circ Arrhythm Electrophysiol.* 2012; 5 (5): 913-9. <http://circep.ahajournals.org/content/early/2012/08/23/CIRCEP.112.973339.full.pdf> *Cameron Health (S-ICD model SQ-RX 1010; Q-Trak lead model 3010).* **BACKGROUND:** -Recently, the subcutaneous implantable cardioverter-defibrillator (S-ICD) has become available. The aim of our study was to assess the efficacy of the S-ICD in a clinical setting. **METHODS AND RESULTS:** -Between June 2010 and July 2011, 40 consecutive patients (42 +/- 15 years; body mass index 27 +/- 6 kg/m(2); left ventricular ejection fraction 47 +/- 15%; 28 men) received an S-ICD for primary (n=17) or secondary prevention (n=23 [58%]) at three institutions in Germany. Intraoperative defibrillation efficacy testing failed in 1 patient with severely reduced left ventricular ejection fraction; testing was effective in all other patients. All episodes stored in the S-ICD were analyzed for appropriate and/or inappropriate detection as well as effective shock delivery to convert ventricular tachyarrhythmia into sinus rhythm. During a median follow-up of 229 (interquartile range, 116 - 305) days, 4 patients experienced 21 episodes with correct detection of ventricular tachyarrhythmia and subsequent shock therapy. A total of 28 shocks were delivered in these 4 patients. Mixed logistic regression modeling revealed a shock efficacy of 96.4% (95% CI, 12.8% - 100%). The efficacy of first shocks, however, was only 57.9% (95% CI, 35.6% - 77.4%). Four episodes were incorrectly classified as ventricular tachyarrhythmia, which led to inappropriate shock delivery in 2 patients. **CONCLUSIONS:** -Ineffective shock delivery may occur in patients with S-ICD, even after successful intraoperative testing. Multicenter trials are needed with close monitoring of safety and efficacy endpoints to identify patients who may be at risk for shock failure.

Diemberger I, Pegreff F, Mazzotti A, Foschi E, Martignani C, Belli G, Biffi M, Ziacchi M, Branzi A, Grigioni F, Maietta Latessa P, Porcellini G, Tentoni C, Boriani G. **Implantation of cardioverter-defibrillator: Effects on shoulder function.** *Int J Cardiol.* 2012: Epub before print. http://ac.els-cdn.com/S0167527312011771/1-s2.0-S0167527312011771-main.pdf?_tid=125a10be-2444-11e2-b16c-00000aacb35e&acdnat=1351788735_434264366c1559be8e3be5da8c57c12c **BACKGROUND:** Subcutaneous almost substituted subpectoral approach of implantable cardioverter-defibrillator (ICD) implantation as a less invasive surgical technique. However, the impact of this change in placement site on procedure-related shoulder impairment is poorly understood. **METHODS:** Candidates for ICD implantation were prospectively evaluated at baseline, 2-weeks and 3-months after the procedure. Assessment of shoulder function included: Constant Score, Numeric Rating Scale (NRS) for pain and the Disability of the Arm, Shoulder and Hand (DASH) scoring method. The Short Form-36 (SF-36) questionnaire was adopted for quality of life. **RESULTS:** Fifty consecutive patients were enrolled (21 single-chamber, 5 dual-chamber and 24 biventricular ICD). Significant changes in the short term were observed: physical component summary (regarding SF-36) decreased from 44.5+/-9.1 to 41.8+/-11.4 (p=0.016), patients with NRS >1 increased from 14% to 44% (p<0.001), DASH score increased from 1.29 [interquartile range 0.00-10.34] to 30.60 [interquartile range 12.93-46.34] (p<0.001). Notably, only the shoulder ipsilateral to implantation site presented a decrease in Constant Score (76.00 [interquartile range 61.37-86.87] vs. 95.75 [interquartile range 91.37-98.00]; p<0.001). After three months most of the parameters seemed to have recovered, except for range of motion. Procedure-related increase in pain (i.e. NRS increase >=1 point) was the most important independent predictor of shoulder impairment, in terms of Constant Score modification (r=0.570; p<0.001). **CONCLUSIONS:** ICD implantation is frequently associated with ipsilateral shoulder impairment which tends to recover within 3-months. These data positively compare with the subpectoral approach and should be considered for future research regarding impact of ICD implant on physical well-being and quality of life.

Jarman JW, Lascelles K, Wong T, Markides V, Clague JR, Till J. **Clinical experience of entirely subcutaneous implantable cardioverter-defibrillators in children and adults: cause for caution.** *Eur Heart J.* 2012; 33 (11): 1351-9. <http://eurheartj.oxfordjournals.org/content/early/2012/03/08/eurheartj.ehs017.full.pdf> *Cameron Health (S-ICD; SQ-RX 1010 pulse generator; Q-Trak 3010 subcutaneous electrode).* This paper describes our clinical experience of using an entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) in children and adults. Maintaining lead integrity and long-term vascular access are critical challenges of ICD therapy,

especially in younger patients. The S-ICD has considerable theoretical advantages in selected patients without pacing indications, particularly children and young adults. Although sensing in an S-ICD may be influenced by age, pathology, and posture, there are currently few published data on clinical sensing performance outside the setting of intra-operative testing or in younger patients. Methods and results Patients were selected by a multi-disciplinary team on clinical grounds for S-ICD implantation from a broad population at risk of sudden arrhythmic death. Sixteen patients underwent implantation [median age 20 years (range 10-48 years)]. Twelve had primary electrical disease and four had congenital structural heart disease. There were no operative complications, and ventricular fibrillation (VF) induction testing was successful in all cases. During median follow-up of 9 months (range 3-15 months), three children required re-operation. Eighteen clinical shocks were delivered in six patients. Ten shocks in four patients were inappropriate due to T-wave over-sensing. Within the eight shocks for ventricular arrhythmia, three were delivered for VF, among which two had delays in detection with time to therapy of 24 and 27 s. Conclusion The S-ICD is an important new option for some patients. However, these data give cause for caution in light of the limited published data regarding clinical sensing capabilities, particularly among younger patients.

Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, Maass AH, de Groot JR, van Oostrom AJ, Theuns DA, Jordaens LJ, Wilde AA, Knops RE. **The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort.** *J Am Coll Cardiol.* 2012; 60 (19): 1933-9. http://ac.els-cdn.com/S0735109712041101/1-s2.0-S0735109712041101-main.pdf?_tid=63528456-2444-11e2-981e-0000aacb35f&acdnat=1351788871_313631e950f8c5150b3f21142137d117

Cameron Health (S-ICD; SQ-RX Pulse Generator, Q-TRAK Subcutaneous Electrode, Q-TECH Programmer.). mentions Medtronic (Sprint Fidelis). mentions S-ICD® System IDE Clinical Study ClinicalTrials.gov ID: NCT01064076; Prospective, RANdomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy) trial (PRAETORIAN) ClinicalTrials.gov ID: NCT01296022, PAINFREE Rx II. OBJECTIVES: The purpose of the study was to evaluate the efficacy and safety of the entirely subcutaneous implantable cardioverter-defibrillator (S-ICD). BACKGROUND: A new entirely S-ICD has been introduced, that does not require lead placement in or on the heart. The authors report the largest multicenter experience to date with the S-ICD with a minimum of 1-year follow-up in the first 118 Dutch patients who were implanted with this device. METHODS: Patients were selected if they had a class I or IIa indication for primary or secondary prevention of sudden cardiac death. All consecutive patients from 4 high-volume centers in the Netherlands with an S-ICD implanted between December 2008 and April 2011 were included. RESULTS: A total of 118 patients (75% males, mean age 50 years) received the S-ICD. After 18 months of follow-up, 8 patients experienced 45 successful appropriate shocks (98% first shock conversion efficacy). No sudden deaths occurred. Fifteen patients (13%) received inappropriate shocks, mainly due to T-wave oversensing, which was mostly solved by a software upgrade and changing the sensing vector of the S-ICD. Sixteen patients (14%) experienced complications. Adverse events were more frequent in the first 15 implantations per center compared with subsequent implantations (inappropriate shocks 19% vs. 6.7%, $p = 0.03$; complications 17% vs. 10%, $p = 0.10$). CONCLUSIONS: This study demonstrates that the S-ICD is effective in terminating ventricular arrhythmias. There is, however, a considerable percentage of ICD related adverse events, which decreases as the therapy evolves and experience increases.

Olde Nordkamp LR, Knops RE, Bardy GH, Blaauw Y, Boersma LV, Bos JS, Delnoy PP, van Dessel PF, Driessen AH, de Groot JR, Herrman JP, Jordaens LJ, Kooiman KM, Maass AH, Meine M, Mizusawa Y, Molhoek SG, van Opstal J, Tijssen JG, Wilde AA. **Rationale and design of the PRAETORIAN trial: A Prospective, RANdomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy.** *Am Heart J.* 2012; 163 (5): 753-60 e2. http://ac.els-cdn.com/S0002870312000968/1-s2.0-S0002870312000968-main.pdf?_tid=6f4bb95429fc30809f997dc2d2ef5c1c&acdnat=1338566225_3f7460eabb2c2b12248b4c40577e2e82

Cameron Health. ClinicalTrials.gov ID: NCT01296022. Medtronic (ICDs), St Jude Medical (ICDs), Biotronik (ICDs), Boston Scientific (ICDs), Sorin (ICDs). BACKGROUND: Implantable cardioverter-defibrillators (ICDs) are widely used to prevent fatal outcomes associated with life-threatening arrhythmic episodes in a variety of cardiac diseases. These ICDs rely on transvenous leads for cardiac sensing and defibrillation. A new entirely subcutaneous ICD overcomes problems associated with transvenous leads. However, the role of the subcutaneous ICD as an adjunctive or primary therapy in patients at risk for sudden cardiac death is unclear. STUDY DESIGN: The PRAETORIAN trial is an investigator-initiated, randomized, controlled, multicenter, prospective 2-arm trial that outlines the advantages and disadvantages of the subcutaneous ICD. Patients with a class I or IIa indication for ICD therapy without an indication for bradypacing or tachypacing are included. A total of 700 patients are randomized to either the subcutaneous or transvenous ICD (1:1). The study is powered to claim noninferiority of the subcutaneous ICD with respect to the composite primary endpoint of inappropriate shocks and ICD-related complications. After noninferiority is established, statistical analysis is done for potential superiority. Secondary endpoint comparisons of shock efficacy and patient mortality are also made.

CONCLUSION: The PRAETORIAN trial is a randomized trial that aims to gain scientific evidence for the use of the subcutaneous ICD compared with the transvenous ICD in a population of patients with conventional ICD with respect to major ICD-related adverse events. [Appendix A. PRAETORIAN endpoint definitions; Appendix B. Suggested ICD device settings to establish proper time to charge or initiate ATP (derived from PREPARE settings)-Medtronic, St Jude Medical, Biotronik, Boston Scientific, Sorin); .

- Pedersen SS, Lambiase P, Boersma LVA, Murgatroyd F, Johansen JB, Reeve H, Stuart AG, Adragao P, Theuns DAMJ. **Evaluation of FactORs Impacting CLinical Outcome and Cost EffectiveneSS of the S-ICD: Design and Rationale of the EFFORTLESS S-ICD Registry.** *Pacing Clin Electrophysiol.* 2012; 35 (5): 574-9. <http://dx.doi.org/10.1111/j.1540-8159.2012.03337.x> *EFFORTLESS S-ICD Registry. ClinicalTrials.gov ID: NCT01085435. Cameron Health (S-ICD).* Background: Leads in and on the heart of the transvenous implantable cardioverter defibrillator (ICD) form the Achilles' heel of this system due to potential for peri- and postimplant complications. The S-ICD is a newer generation of the ICD that does not require leads on the heart or in the vasculature. We present the rationale and study design of the Evaluation of FactORs Impacting CLinical Outcome and Cost EffectiveneSS of the S-ICD (EFFORTLESS S-ICD) Registry which was designed to evaluate the long-term performance of the S-ICD including patient quality of life and long-term resource utilization. Methods: The Registry is an observational, nonrandomized, standard of care evaluation to be conducted at approximately 50 investigational centers in Europe and New Zealand where the S-ICD is approved for use and distribution. Clinical Registry endpoints include perioperative (30 days postimplant) complication-free rate, 360-day complication-free rate, and percentage of inappropriate shocks for atrial fibrillation and supraventricular ventricular tachyarrhythmia. Other endpoints include patient-reported outcomes (e.g., quality of life) and hospital personnel implant and follow-up experience with the S-ICD system. Conclusions: Results from EFFORTLESS will build on and expand the initial published experience with the S-ICD, which demonstrated that the device successfully and consistently detects and treats episodes of sustained ventricular tachyarrhythmias. The Registry will also evaluate the patients' perspective of how it is to live with an S-ICD as compared to a contemporary transvenous system and track the experience of implanting physicians and personnel performing patient follow-up with a completely subcutaneous system. [Table I. Patient Reported Outcomes and Psychological Factors Assessed in the EFFORTLESS S-ICD Registry; Table II. Observational Data Collected in the EFFORTLESS S-ICD Registry]
- Dabiri Abkenari L, Theuns DA, Valk SD, Van Belle Y, de Groot NM, Haitsma D, Muskens-Heemskerk A, Szili-Torok T, Jordaens L. **Clinical experience with a novel subcutaneous implantable defibrillator system in a single center.** *Clin Res Cardiol.* 2011; 100 (9): 737-44. <http://pubmedcentralcanada.ca/picrender.cgi?accid=PMC3167040&blobtype=pdf> *Cameron Health (SQ-RX 1010; Q-Trak 3010 lead).* BACKGROUND: Implantable cardioverter-defibrillators (ICDs) reduce mortality in both primary and secondary prevention, but are associated with substantial short- and long-term morbidity. A totally subcutaneous ICD (S-ICD) system has been developed. We report the initial clinical experience of the first 31 patients implanted at our hospital. METHODS: All patients had an ICD indication according to the ACC/AHA/ESC guidelines. The first 11 patients were part of the reported CE trial. The implantation was performed without fluoroscopy. The device was implanted subcutaneously in the anterior axillary line, with a parasternal lead tunneled from the xiphoid to the manubrial-sternal junction. Ventricular fibrillation (VF) was induced to assess detection accuracy and defibrillation efficacy using 65 J shocks. RESULTS: Post-implant, 52 sustained episodes of VF were induced. Sensitivity was 100% and induced conversion efficacy was 100% (with standard polarity in 29 patients). Mean time to therapy was 13.9 +/- 2.5 s (range 11-21.6 s). Late procedure-related complications were observed in 2 of the first 11 implantations (lead migration). During follow-up, spontaneous ventricular arrhythmias occurred in four patients, with accurate detection of all episodes. Inappropriate therapy was observed in five patients. Recurrences were prevented with reprogramming. CONCLUSIONS: The S-ICD system can be implanted without the use of fluoroscopy by using anatomical landmarks only. Episodes of VF were accurately detected using subcutaneous signals, and all induced and clinical episodes were successfully converted. The S-ICD system is a viable alternative to conventional ICD systems for selected patients. ["Table 3 Inappropriate shocks, T-wave Oversensing ; Double Counting, Myopotential detection, Noise from lead dislodgement] ["...The implantations were usually done within 100 min (average of 101 ± 33 min) including the DFT (with 3 min between each attempt and up to three attempts before external defibrillation was used).
- Daniels JD, Sun S, Zafereo J, Minhajuddin A, Nguyen C, Obel O, Wu R, Joglar JA. **Preventing shoulder pain after cardiac rhythm management device implantation: a randomized, controlled study.** *Pacing Clin Electrophysiol.* 2011; 34 (6): 672-8. <http://onlinelibrary.wiley.com/store/10.1111/j.1540-8159.2010.03026.x/asset/j.1540-8159.2010.03026.x.pdf?v=1&t=ipyg081h&s=0ba1aa5678e82fe089f83c7fde8b5d4ad9097a7f> Introduction: Shoulder pain and disability ipsilateral to the implant site is a common complication of cardiac rhythm device

implantation, yet very little has been published about this morbidity. We designed a study to assess the potential benefit of a simple exercise protocol in preventing shoulder pain postoperatively. **Methods and Results:** Patients undergoing subcutaneous device implantation were randomized to one of two groups. The control group received standard instructions, whereas the exercise group was instructed on specific exercises aimed at strengthening or stretching the shoulder girdle, to be completed 3 days per week. Groups were postoperatively monitored for the development of shoulder discomfort and shoulder impingement by using physical examination and disability questionnaires. At 1 month, seven of 21 control patients reported developing shoulder pain or discomfort compared to one of 23 in the exercise group ($P = 0.02$). At 6 months, four of 23 control patients still reported worsening shoulder symptoms, compared to none in the exercise group ($P = 0.11$). In the control group, five of 19 patients developed a positive impingement test at 1 month, versus none in the exercise group ($P = 0.01$). Scores for the questionnaires designed to assess shoulder pain and dysfunction were worse in the control group. There were no activity-related complications in either group. **Conclusion:** Shoulder pain and disability occurs often following cardiac rhythm management device implantation. A simple exercise program aimed at strengthening the shoulder girdle is effective at preventing this complication. (PACE 2011; 1-7).

Gold MR, Theuns DA, Knight BP, Sturdivant JL, Sanghera R, Ellenbogen KA, Wood MA, Burke MC. **Head-To-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study.** *J Cardiovasc Electrophysiol.* 2011; 23 (4): 359-66. <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8167.2011.02199.x/abstract;jsessionid=35149BD8A3926C7085C124FBE65E33FC.f01t03>

Subcutaneous versus Transvenous Arrhythmia Recognition Testing (START) study. *ClinicalTrials.gov ID: NCT01161589.* Cameron Health (CHI subcutaneous system); Boston Scientific (Teligen; sustained rate duration (SRD); Rhythm ID); Guidant (ENDOTAK ENDURANCE Rx 0145, ENDOTAK RELIANCE 0147, 0158, ENDOTAK RELIANCE G 0184, 0185); Medtronic (Secura; Virtuoso; Sprint 6942, 6945, Sprint Quattro 6944, Sprint Quattro Secure 6947, Sprint Fidelis 6949; PR Logic algorithm; High Rate Timeout feature; Wavelet); St Jude Medical (Riata 1580, 1581; Atlas II + HF; MD algorithm); Biotronik (Linxx 65 SD). **Arrhythmia Detection with S-ICD Versus Transvenous ICDs.** **Background:** The development of a totally subcutaneous implantable defibrillator (S-ICD) system requires a new approach for arrhythmia detection. To evaluate arrhythmia discrimination of one such system, the Subcutaneous versus Transvenous Arrhythmia Recognition Testing (START) study was designed as a prospective, multicenter trial comparing simulated sensing performances of the S-ICD system with single- (SC-TV) and dual-chamber transvenous (DC-TV) implantable cardioverter-defibrillator (ICD) systems. **Methods:** At ICD implantation, induced ventricular and atrial arrhythmias were recorded simultaneously in transvenous (right ventricular [RV]-->superior vena cava [SVC] + Coil) and cutaneous electrode configurations. Recorded signals of ventricular ($n = 46$) and atrial arrhythmias ($n = 50$) with ventricular rates >170 bpm from 64 patients were used to compare detection performance of the S-ICD system with TV-ICD systems from 3 manufacturers. Appropriate detection of ventricular tachyarrhythmias was assessed with devices programmed in single-zone (rate ≥ 170 bpm) and dual-zone configurations (ventricular fibrillation ≥ 240 bpm; ventricular tachycardia ≥ 170 bpm). S-ICD specificity performance for supraventricular arrhythmias was compared to single- and dual-chamber devices in a dual-zone configuration. **Results:** Appropriate detection of ventricular tachyarrhythmias for subcutaneous and TV devices in single- and dual-zone configurations was 100% and $>99\%$, respectively. Specificity for supraventricular arrhythmias was significantly better for the S-ICD system compared to 2 of 3 TV systems, as well as the composite of TV devices (98.0%[S-ICD] vs 76.7%[SC-TV range: 64.0-92.0%] vs 68.0%[DC-TV range: 32.7-89.8%; $P < 0.001$]). **Conclusion:** Appropriate ventricular arrhythmia detection is excellent for all ICD systems evaluated; however, specificity of supraventricular arrhythmia discrimination by the S-ICD system is better than discrimination by 2 of 3 TV systems. (J Cardiovasc Electrophysiol, Vol. pp. 1-8).

Bardy GH, Smith WM, Hood MA, Crozier IG, Melton IC, Jordaens L, Theuns D, Park RE, Wright DJ, Connelly DT, Fynn SP, Murgatroyd FD, Sperzel J, Neuzner J, Spitzer SG, Ardashev AV, Oduro A, Boersma L, Maass AH, Van Gelder IC, Wilde AA, Van Dessel PF, Knops RE, Barr CS, Lupo P, Cappato R, Grace AA. **An entirely subcutaneous implantable cardioverter-defibrillator.** *N Engl J Med.* 2010; 363 (1): 36-44. <http://www.nejm.org/doi/pdf/10.1056/NEJMoa0909545> **BACKGROUND:** Implantable cardioverter-defibrillators (ICDs) prevent sudden death from cardiac causes in selected patients but require the use of transvenous lead systems. To eliminate the need for venous access, we designed and tested an entirely subcutaneous ICD system. **METHODS:** First, we conducted two short-term clinical trials to identify a suitable device configuration and assess energy requirements. We evaluated four subcutaneous ICD configurations in 78 patients who were candidates for ICD implantation and subsequently tested the best configuration in 49 additional patients to determine the subcutaneous defibrillation threshold in comparison with that of the standard transvenous ICD. Then we evaluated the long-term use of subcutaneous ICDs in a pilot study, involving 6 patients, which was followed by a trial involving 55 patients. **RESULTS:** The best device configuration consisted of a parasternal electrode and a left lateral thoracic pulse generator. This configuration was as effective as a transvenous ICD for

terminating induced ventricular fibrillation, albeit with a significantly higher mean (\pm SD) energy requirement (36.6 ± 19.8 J vs. 11.1 ± 8.5 J). Among patients who received a permanent subcutaneous ICD, ventricular fibrillation was successfully detected in 100% of 137 induced episodes. Induced ventricular fibrillation was converted twice in 58 of 59 patients (98%) with the delivery of 65J shocks in two consecutive tests. Clinically significant adverse events included two pocket infections and four lead revisions. After a mean of 10 ± 1 months, the device had successfully detected and treated all 12 episodes of spontaneous, sustained ventricular tachyarrhythmia. CONCLUSIONS: In small, nonrandomized studies, an entirely subcutaneous ICD consistently detected and converted ventricular fibrillation induced during electrophysiological testing. The device also successfully detected and treated all 12 episodes of spontaneous, sustained ventricular tachyarrhythmia. (ClinicalTrials.gov numbers, NCT00399217 and NCT00853645.). Copyright © 2010 Massachusetts Medical Society.

Lieberman R, Havel WJ, Rashba E, DeGroot PJ, Stromberg K, Shorofsky SR. **Acute defibrillation performance of a novel, non-transvenous shock pathway in adult ICD indicated patients.** *Heart Rhythm.* 2008; 5 (1): 28-34. http://ac.els-cdn.com/S1547527107008971/1-s2.0-S1547527107008971-main.pdf?_tid=dcd55ca0-ed6a-11e2-8066-00000aacb362&acdnat=1373905580_a5e130e671a7604fe344094f69688bc4 *Comment in Heart Rhythm. 2008 Jan;5(1):35-6* OBJECTIVES: The purpose of this study was to evaluate the efficacy of a totally subcutaneous, anteroposterior defibrillation shock pathway using a long time-constant shock waveform that emulates a proposed device having approximately twice the capacitance and thus twice the available energy of traditional transvenous devices. BACKGROUND: A non-transvenous defibrillation system potentially offers advantages over a transvenous system including simplification of the implant procedure and reduction of the impact of device complications by eliminating the need to place a lead within the heart. Previous non-transvenous defibrillation efficacy studies have been reported using anterolateral and anterior-anterior shock vectors. An external anteroposterior shock vector has demonstrated superior efficacy compared to anterolateral shock vectors but a prospective study on an anteroposterior shock vector with implanted electrodes has not been previously reported. METHODS: The non-transvenous shock vector consisted of an anterior low pectorally-placed active can emulator electrode and a posterior subcutaneous coil electrode. The shock waveform was a biphasic with 50% tilt per phase and a time constant of decay of 12 ms. Defibrillation efficacy was characterized using a step-down defibrillation threshold protocol (35 J, 25 J, 15 J). RESULTS: A total of 33 patients with standard ICD indications were enrolled in the study with 32 fully completing the protocol. The patient population was 69% male, with a mean age of 59 ± 12 years. Mean ejection fraction was $27 \pm 12\%$. Of the 32 patients tested, 26 patients (81%) were successfully defibrillated at 35 J or less, 18 patients were defibrillated at 25 J or less and 9 patients were successfully defibrillated at 15 J. CONCLUSIONS: Defibrillation using a long time-constant waveform delivered through an anteroposterior non-transvenous pathway including a pectoral active can emulator electrode and a posterior subcutaneous coil electrode is feasible with over 80% of patients defibrillated successfully using 35 J or less.

Burke M, C., Coman J, A., Cates A, W., Lindstrom C, C., Sandler David A, Kim S, S., Knight B, P. **Defibrillation energy requirements using a left anterior chest cutaneous to subcutaneous shocking vector: implications for a total subcutaneous implantable defibrillator.** *Heart Rhythm.* 2005; 2 (12): 1332-8. http://ac.els-cdn.com/S154752710502031X/1-s2.0-S154752710502031X-main.pdf?_tid=d0bfd990-ed79-11e2-831e-00000aab0f26&acdnat=1373912002_3e83d54ae8e23d86c19a16cd0bf461cc BACKGROUND: Subcutaneous implantable defibrillators (ICDs) are being developed to facilitate ICD implantation. OBJECTIVE: The purpose of this study was to estimate the human defibrillation energy requirement (DER) using a left chest cutaneous (Q) to subcutaneous (SQ) shocking vector. METHODS: Twenty patients undergoing implantation of an indicated ICD were enrolled (15 males, age = 63 ± 12 years; ejection fraction = 0.27 ± 0.14). Defibrillation testing was performed using an investigational system consisting of an external defibrillator and a constructed connector to deliver a shock between a pectoral SQ can and a cardiac apical Q electrode. Two attempts at defibrillation using this configuration were allowed. Stage 1 testing started at 70 J with a step-down/step-up to 50 or 100 J, respectively. Stage 2 testing began at 50 J with a step-down/step-up to 30 or 70 J. RESULTS: During stage 1, a 70-J shock was successful in 7/9 (78%) patients. A second attempt was successful in 7/7 patients using a 50-J shock. In the two remaining patients, a second attempt using a 100-J shock was successful. During stage 2, a 50-J shock was successful in 10/11 (91%) patients. The protocol could not be completed in 2/11 patients. Of the remaining nine patients, a second defibrillation was successful in seven (78%) using a 30-J shock. CONCLUSIONS: The defibrillation energy requirement (DER) of this study vector was 50 J or less in most patients. This low DER supports further investigation of a totally SQ-ICD. However, the DER of 100 J in two patients indicates that further investigation is needed regarding DER variability and safety margins.

Kettering K, Mewis C, Dörnberger V, Vonthein R, Bosch RF, Seipel L, Kühlkamp V. **Long-term experience with subcutaneous ICD leads: A comparison among three different types of subcutaneous leads.** *Pacing Clin Electrophysiol.* 2004; 27 (10): 1355-61. <http://dx.doi.org/10.1111/j.1540-8159.2004.00639.x> ICDs provide

protection against sudden cardiac death in patients with life-threatening arrhythmias. Nevertheless, efficacy of defibrillation remains an important issue to guarantee the future safety of patients who receive an ICD. There is a significant number of patients who need an additional subcutaneous lead to obtain a defibrillation safety margin of at least 10 J between the maximum output of the ICD and the energy needed for ventricular defibrillation. However, few data exists about the long-term performance of different types of subcutaneous leads. Therefore, the aim of this study was to analyze the long-term experience with three different types of subcutaneous leads. The study included 132 patients (109 men, 23 women; mean age 59.8 years [SD \pm 10.7 years]). All of them received a subcutaneous lead in addition to a single chamber or dual chamber ICD between October 1990 and April 2002. Two patients received a second subcutaneous lead after the first lead had been removed so that a total of 134 subcutaneous leads were evaluated. Inclusion criteria for the implantation of an additional subcutaneous lead were (1) unsuccessful ventricular defibrillation at implant without a subcutaneous lead, (2) insufficient safety margin (< 10 J) between the maximum output of the ICD and the energy needed for ventricular defibrillation, or (3) clinical evaluation of a new subcutaneous lead (Medtronic 13014). There were no significant differences between the three study groups with regard to age, sex, underlying cardiac disease, left ventricular ejection fraction, NYHA class assessment and clinical arrhythmia. The results of the DFT testing during follow-up (prehospital discharge test and 1 and 3 years) were compared to the baseline value obtained during the implantation procedure. All lead related complications were analyzed. Eighty-two single element subcutaneous array electrodes (SQ-A1), 31 subcutaneous three-finger electrodes (SQ-A3), and 21 subcutaneous patch electrodes (SQ-P) were implanted during the study period. The median follow-up was 1,499 days (25th percentile: 798 days, 75th percentile: 1,976 days) in the SQ-A1 group, 2,209 days (25th percentile: 1,242 days, 75th percentile: 2,710 days) in the SQ-A3 group, and 1,419 days (25th percentile: 787 days, 75th percentile: 2,838 days) in the SQ-P group. None of the three groups had a significant change of the DFT during follow-up compared to baseline. Major complications occurred in six (7.3%) patients in group SQ-A1 and in two (9.5%) patients in group SQ-P. There were no major complications in group SQ-A3. Kaplan-Meier curves analyzing freedom from subcutaneous lead related complications did not show a significant difference between the three study groups ($P = 0.16$).

Review Articles

Cappato R, Hindricks G, Steffel J. **The Year in Cardiology 2016: arrhythmias and cardiac implantable electronic devices.** *Eur Heart J.* 2017: http://oup.silverchair-cdn.com/oup/backfile/Content_public/Journal/eurheartj/PAP/10.1093_eurheartj_ehw629/2/ehw629.pdf?Expires=1486322738&Signature=MymzVyjoEmNM8n8aH1xY5H4GakwhlUa5Asr8HxtlkLsiRoNCS081kJIsJRZs-sDErfr7MLo4uMYciH56FIB-X0XA90AEnsP-mqSL9RE3iOMpgkhV7f3mb-8COXoYTggaeUHQ4eGDIGNypSbFL4CrEkNxC8ChNRVWCUSiVXZqR8H-lcr4cOp9xMLIngTsvKMf0ulxrWqrVaY-WcJQwJY-NaGoUdnGDYbGULQjwqh6ITcKPEhzCMdUhhq-vvERaYke8DGdznZAcO7c5oNskHvmXIG9yzSMkcf0Y6xk0MTToJnRRsdmPXz701aInXrK4Xy~2M0AGW~NYHjc2ZqWn7EKg_&Key-Pair-Id=APKAIUCZBIA4LVPVW3Q Brief section on Ablation, ICDs, Leadless pacing, S-ICD.

Sideris S, Archontakis S, Gatzoulis KA, Anastasakis A, Sotiropoulos I, Arsenos P, Kasiakogias A, Terentes D, Trachanas K, Paschalidis E, Tousoulis D, Kallikazaros I. **The Subcutaneous ICD as an alternative to the conventional ICD system. Initial experience in Greece and review of the literature.** *Hellenic journal of cardiology.* 2017; 02 (2): 2241-5955. <http://dx.doi.org/10.1016/j.hjc.2017.01.010> The introduction of the implantable cardioverter defibrillator (ICD) in clinical practice has revolutionized our therapeutic approach for sudden cardiac death (SCD) both in the context of primary and secondary prevention, since it has proven to be superior to medical therapy in treating potentially life-threatening ventricular arrhythmias, resulting in reduced mortality rates. However, conventional ICDs' implantation carries a not negligible risk of periprocedural and long-term complications associated with the transvenous ICD leads. The entirely subcutaneous implantable cardioverter defibrillator (S-ICD) has recently emerged as a therapeutic alternative to the conventional ICD for patients with various cardiopathies and a high risk for SCD. The main advantage is the avoidance of vascular access and thus, of the complications associated with transvenous leads. Patients without pacing indications, such as bradycardia, need for antitachycardia pacing or indication for cardiac resynchronization, and those at higher risk of complications from transvenous lead implantation represent the perfect candidates of this novel technology. Subcutaneous ICD has proven to be equally safe and effective when compared to transvenous ICD systems in early clinical trials. Further technical improvement of the system will probably lead to the expansion of indications and a widespread use of this technology. In the present review, we discuss the indications, summarise the early clinical experience and highlight the advantages and disadvantages of this novel technology. In addition, we present the first two cases of a subcutaneous cardioverter defibrillator system implantation in Greece. Copyright © 2017 Hellenic

Cardiological Society. Published by Elsevier B.V. All rights reserved.

Al-Khatib SM, Friedman P, Ellenbogen KA. **Defibrillators: Selecting the right device for the right patient.** *Circulation.* 2016; 134 (18): 1390-404. <http://circ.ahajournals.org/content/circulationaha/134/18/1390.full.pdf> Advances in the field of defibrillation have brought to practice different types of devices that include the transvenous implantable cardioverter-defibrillator (ICD) with or without cardiac resynchronization therapy, the subcutaneous ICD (S-ICD), and the wearable cardioverter-defibrillator. To ensure optimal use of these devices and to achieve best patient outcomes, clinicians need to understand how these devices work, learn the characteristics of patients who qualify them for one type of device versus another, and recognize the remaining gaps in knowledge surrounding these devices. The transvenous ICD has been shown in several randomized clinical trials to improve the survival of patients resuscitated from near-fatal ventricular fibrillation and those with sustained ventricular tachycardia with syncope or systolic heart failure as a result of ischemic or nonischemic cardiomyopathy despite receiving guideline-directed medical therapy. Important gaps in knowledge regarding the transvenous ICD involve the role of the ICD in patient subgroups not included, or not well represented, in clinical trials and the need to refine the selection criteria for the ICD in patients who are indicated for it. S-ICDs were recently introduced into the clinical arena as another option for many patients who have an approved indication for a transvenous ICD. The main advantage of the S-ICD is a lower risk of infection and lead-related complications; however, the S-ICD does not offer bradycardia or antitachycardia pacing. The S-ICD may be ideal for patients with limited vascular access, high infection risk, or some congenital heart diseases. However, more data are needed regarding the efficacy and effectiveness of the S-ICD in comparison to transvenous ICDs, the extent of defibrillation testing required, and the use of the S-ICD with other novel technologies, including leadless pacemakers. Cardiac resynchronization therapy-defibrillators are indicated in patients with a left ventricular ejection fraction $\leq 35\%$, QRS width ≥ 130 ms, and New York Heart Association class II, III, or ambulatory IV symptoms despite treatment with guideline-directed medical therapy. Multiple randomized controlled trials have shown that the cardiac resynchronization therapy-defibrillator improves survival, quality of life, and several echocardiographic measures. One main challenge related to cardiac resynchronization therapy-defibrillators is the 30% nonresponse rate. Many initiatives are underway to address this challenge including improved cardiac resynchronization therapy and imaging technologies and enhanced selection of patients and device programming. table 2. Class I Guideline Recommendations and Cms Reimbursement Criteria for ICDs; table 3. Comparison of transvenous ICDs with S-ICDs.

Bennett M, Parkash R, Nery P, Senechal M, Mondesert B, Birnie D, Sterns LD, Rinne C, Exner D, Philippon F, Campbell D, Cox J, Dorian P, Essebag V, Krahn A, Manlucu J, Molin F, Slawnych M, Talajic M. **Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines.** *Can J Cardiol.* 2016: Epub before print. http://ac.els-cdn.com/S0828282X16310054/1-s2.0-S0828282X16310054-main.pdf?_tid=6c575a2c-d9df-11e6-8247-00000aacb362&acdnat=1484346610_8d98e38f1842a006e3982b3333dfc330 Sudden cardiac death is a major public health issue in Canada. However, despite the overwhelming evidence to support the use of implantable cardioverter defibrillators (ICDs) in the prevention of cardiac death there remains significant variability in implantation rates across Canada. Since the most recent Canadian Cardiovascular Society position statement on ICD use in Canada in 2005, there has been a plethora of new scientific information to assist physicians in their discussions with patients considered for ICD implantation to prevent sudden cardiac death due to ventricular arrhythmias. We have reviewed, critically appraised, and synthesized the pertinent evidence to develop recommendations regarding: (1) ICD implantation in the primary and secondary prevention of sudden cardiac death in patients with and without ischemic heart disease; (2) when it is reasonable to withhold ICD implantation on the basis of comorbidities; (3) ICD implantation in patients listed for heart transplantation; (4) implantation of a single- vs dual-chamber ICD; (5) implantation of single- vs dual-coil ICD leads; (6) the role of subcutaneous ICDs; and (7) ICD implantation infection prevention strategies. We expect that this document, in combination with the companion article that addresses the implementation of these guidelines, will assist all medical professionals with the care of patients who have had or at risk of sudden cardiac death.

Bernard ML. **Pacing Without Wires: Leadless Cardiac Pacing.** *Ochsner J.* 2016; 16 (3): 238-42. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5024804/pdf/i1524-5012-16-3-238.pdf> Medtronic (Micra); St Jude Medical (Nanostim); Boston Scientific (S-ICD). BACKGROUND: Worldwide, more than 700,000 pacemakers are implanted annually with more than 250,000 implanted in the United States. Since the first fully transvenous pacemaker implantations in the early 1960s, great technologic advances have been made in pacing systems. However, the combination of subcutaneous pulse generators and transvenous pacing leads has remained constant for more than 50 years. Leadless pacing systems offer an alternative to traditional pacing systems by eliminating the need for permanent transvenous leads while providing therapy for patients with bradyarrhythmias. METHODS: We discuss the 2 leadless cardiac pacemakers (LCPs), the Nanostim Leadless Pacemaker and

Micra Transcatheter Pacing System, and the 1 ultrasound-powered device, the WiCS-LV, that have been studied in humans. Currently LCPs are restricted to single-chamber pacing, specifically, ventricular pacing. Dual-chamber pacing and multichamber pacing with leadless systems have yet to be studied. RESULTS: LCPs represent the greatest advancement in bradycardia therapy since the first transvenous pacemaker implantation more than 50 years ago. CONCLUSION: Initial studies of both the Nanostim and Micra LCPs show favorable efficacy and safety results compared to transvenous pacemakers. Pending US Food and Drug Administration approval, these devices will transform our ability to provide pacing for patients with bradyarrhythmias. Future developments may allow for completely leadless single-chamber and multichamber pacing, ushering in an era of pacing without wires.

- Chubb H, Rosenthal E. **Implantable cardioverter-defibrillators in congenital heart disease.** *Herzschrittmacherther Elektrophysiol.* 2016; 27 (2): 95-103.
http://download.springer.com/static/pdf/150/art%253A10.1007%252Fs00399-016-0437-3.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs00399-016-0437-3&token2=exp=1467728116~acl=%2Fstatic%2Fpdf%2F150%2Fart%25253A10.1007%25252Fs00399-016-0437-3.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs00399-016-0437-3*~hmac=201b5463232cf9758b6c6dd280b4a41548d78dceddf9e679d0886efb0c6723ad Boston Scientific (Emblem S-ICD; ImageReady); Medtronic (Sprint Fidelis; SureScan); St Jude Medical (Riata; Durata; MRI Ready); Biotronik (Protego; ProMRI); Zoll Medical (LifeVest). Implantable cardioverter-defibrillators (ICD) have an important role in reducing sudden cardiac death in patients with congenital heart disease (CHD); however, the benefit of ICDs needs to be weighed up against both short-term and long-term adverse effects, which are difficult to evaluate in the heterogeneous CHD population. A tailored approach, taking into account risk stratification and patient-specific factors, is needed to select the most appropriate strategy. This review discusses primary and secondary ICD indications, implantation approaches and long-term follow-up. Recent publications have shed light on the concerns of system longevity, lead extractions, inappropriate shocks and impact on the quality of life. All of these factors require consideration prior to commitment to this long-term treatment strategy. Fig. 1 Distribution of congenital heart disease (CHD) implantable cardioverter-defibrillator population byCHDlesion.
- Essandoh M, Daoud EG. **Perioperative considerations for patients with subcutaneous implantable cardioverter-defibrillators undergoing noncardiac surgery.** *J Cardiothorac Vasc Anesth.* 2016; 30 (3): Epub before print. *This article is not in the library's collection.* Boston Scientific (Emblem S-ICD A209; 1010 SQ-RX). The aim of this article is to provide an overview of the S-ICD system and to discuss management of the system in the perioperative period for noncardiac surgery.
- Kondo Y, Ueda M, Kobayashi Y, Schwab JO. **New horizon for infection prevention technology and implantable device.** *J Arrhythm.* 2016; 32 (4): 297-302.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4996843/pdf/main.pdf> St Jude Medical (Nanstim; Merlin Patient Care System); Medtronic (Micra; Tyrx antibacterial envelope); Boston Scientific (Emblem S-ICD); Zoll (LifeVest). There has been a significant increase in the number of patients receiving cardiovascular implantable electronic devices (CIED) over the last two decades. CIED infection represents a serious complication after CIED implantation and is associated with significant morbidity and mortality. Recently, newly advanced technologies have offered attractive and suitable therapeutic alternatives. Notably, the leadless pacemaker and anti-bacterial envelope decrease the potential risk of CIED infection and the resulting mortality, when it does occur. A completely subcutaneous implantable cardioverter defibrillator is also an alternative to the transvenous implantable cardioverter defibrillator (ICD), as it does not require implantation of any transvenous or epicardial leads. Among the patients who require ICD removal and subsequent antibiotics secondary to infection, the wearable cardioverter defibrillator represents an alternative approach to inpatient monitoring for the prevention of sudden cardiac death. In this review paper, we aimed to introduce the advanced technologies and devices for prevention of CIED infection.
- Leung S, Danik S. **Prevention, diagnosis, and treatment of cardiac implantable electronic device infections.** *Curr Cardiol Rep.* 2016; 18 (6): 58 [7 pages].
http://download.springer.com/static/pdf/483/art%253A10.1007%252Fs11886-016-0733-x.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs11886-016-0733-x&token2=exp=1464801415~acl=%2Fstatic%2Fpdf%2F483%2Fart%25253A10.1007%25252Fs11886-016-0733-x.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs11886-016-0733-x*~hmac=72e9d12498887e9907063c22d3631c37143f8636883eebc480c499e5a56d5d88 Boston Scientific (EMBLEM S-ICD); St Jude Medical (Nanstim). Cardiac implantable electronic device (CIED) infections are complex medical problems that are increasingly encountered. They are associated with significant morbidity

and mortality with tremendous economic cost. The current review will emphasize the prevention, diagnosis, and treatment of this clinical entity using the relatively limited evidence that is currently available. Because there is a paucity of high quality evidence regarding prevention, diagnosis, and treatment of CIED infections, this review will attempt to summarize the best evidence as well as to suggest, when possible, paradigms for care. The topic of CIED infections is a dynamic one as the scope of CIED continues to widen. Furthermore, there are promising advancements in CIED technology which may help reduce its occurrence the future. Unfortunately, significant gaps in knowledge remain, and definitive recommendations regarding CIED infections and future studies should be directed at improving our ability to prevent infections. Fig. 2 a The subcutaneous ICD is an extrathoracic device appropriate for patients who do not have a pacing requirement.

Lewis GF, Gold MR. **Safety and efficacy of the subcutaneous implantable defibrillator.** *J Am Coll Cardiol.* 2016; 67 (4): 445-54. http://ac.els-cdn.com/S0735109715074793/1-s2.0-S0735109715074793-main.pdf?_tid=cba6a35c-c8fb-11e5-84d6-00000aab0f01&acdnat=1454342128_4ee8cb3c42772d312e5d97e627287a65 Boston Scientific (S-ICD; EMBLEM). Multiple randomized, multicenter trials have established the role of the implantable cardioverter-defibrillator (ICD) in the treatment and prevention of sudden cardiac death. However, transvenous ICD leads have significant short- and long-term complications, offsetting some of the benefit of this therapy. This has led to the development of the entirely subcutaneous ICD. This system is safe and effective, avoiding the need for intravascular leads. It is best suited for patients at low risk for pacing and increased risk for transvenous lead complications. Ongoing randomized and long-term registries will help identify the optimal role of this device in clinical practice. FIGURE 2 Photograph of Lateral Views of First-Generation S-ICD, Second-Generation (Emblem) S-ICD, and Single-Chamber ICD Pulse Generators Demonstrating Device Thickness.

Mangels D, Frishman WH. **The subcutaneous implantable cardioverter-defibrillator.** *Cardiol Rev.* 2016: Epub before print. <http://www.ncbi.nlm.nih.gov/pubmed/26807549> Boston Scientific (Emblem; Inogen). BSC's sponsored EFFORTLESS. The subcutaneous implantable cardioverter-defibrillator (S-ICD) is a subcutaneous alternative to conventional transvenous ICD (TV-ICD) systems which have previously been shown to treat life-threatening ventricular tachyarrhythmias in cardiac disease patients. A review of the literature reveals that S-ICDs have similar shock efficacy rates for both induced and spontaneous ventricular tachyarrhythmias when compared to TV-ICDs. Further, S-ICDs appear to have a higher specificity for withholding therapy when supraventricular tachycardia is present compared to TV-ICDs. The advantages of the S-ICD system are numerous: fewer vascular complications including thrombosis and hemothorax, avoidance of fluoroscopy, and an easier means of lead replacement. These advantages make the S-ICD system most suitable for younger patients who may require replacements in later life, those with abnormal venous anatomy, and individuals prone to infection and/or central vein thrombosis. However, S-ICDs are not without their complications, and are associated with a higher incidence of inappropriate shocks secondary to T-wave oversensing. S-ICDs also lack anti-tachycardia pacing, making them a suboptimal device in patients with recurrent monomorphic ventricular tachycardia who would otherwise benefit from the anti-tachycardia pacing offered in TV-ICDs. Lastly, the limited number of long-term randomized, head-to-head studies involving direct comparison to TV-ICDs poses a challenge in the implementation of the S-ICD.

Nishii N. **Arrhythmia management after device removal.** *J Arrhythm.* 2016; 32 (4): 287-92. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4996859/pdf/main.pdf> OSYPKA (temporary pacing leads). Arrhythmic management is needed after removal of cardiac implantable electronic devices (CIEDs). Patients completely dependent on CIEDs need temporary device back-up until new CIEDs are implanted. Various methods are available for device back-up, and the appropriate management varies among patients. The duration from CIED removal to implantation of a new CIED also differs among patients. Temporary pacing is needed for patients with bradycardia, a wearable cardioverter defibrillator (WCD) or catheter ablation is needed for patients with tachyarrhythmia, and sequential pacing is needed for patients dependent on cardiac resynchronization therapy. The present review focuses on arrhythmic management after CIED removal. Fig. 5. Totally subcutaneous implantable cardioverter defibrillator.

Rutzen-Lopez H, Silva J, Helm RH. **Leadless cardiac devices-pacemakers and implantable cardioverter-defibrillators.** *Curr Treat Options Cardiovasc Med.* 2016; 18 (8): 49. http://download.springer.com/static/pdf/550/art%253A10.1007%252Fs11936-016-0472-8.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs11936-016-0472-8&token2=exp=1467726796~acl=%2Fstatic%2Fpdf%2F550%2Fart%25253A10.1007%25252Fs11936-016-0472-8.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs11936-016-0472-8*~hmac=1a076b5f7e38687280665e6010dcf15eb6e0608a6622e36d276621e1fec63f1b Boston Scientific (S-ICD); Medtronic (Micra); St Jude Medical (Nanostim); EBR (WiCS-LV). OPINION STATEMENT: Since the initial introduction of pacemakers and defibrillators, the rapid growth in microcircuit and battery technology has increased the longevity demands and exposed the vulnerabilities of transvenous leads. Over a

half of century later, leadless pacemaker and defibrillation systems are just reaching the clinical arena. Despite the remarkable advantages of leadless pacing systems, the data are still quite limited and broad implementation of these technologies need to occur in a cautious and deliberate fashion as the peri-procedural risks remains high. Two of the three systems, Nanostim(TM) (St. Jude Medical) and Micra Transcatheter Pacing System (Medtronic Inc.), have shown the greatest applicability, although they are currently only limited to single chamber pacing and procedural risks are modest. The WiCS(TM)-LV system (EBR Systems, Inc.) is anatomically limited and benefits a small subset of patients. Leadless implantable cardioverter-defibrillator (ICD) therapy, the subcutaneous ICD (S-ICD, Cameron Health/Boston Scientific), has demonstrated encouraging short-term safety and efficacy data supporting its use. Since its introduction, modifications to the implant procedure, pre-screening of patients, and programming of the devices have reduced procedural-related complications and inappropriate shocks. The S-ICD is a promising technology, but it is premature to conclude that it will supplant conventional ICDs. At this current time, the S-ICD may benefit select patients, such as those with recurrent bacteremia, vascular access limitations, and who may be prone to transvenous lead failure.

Trivedi A, Knight BP. **ICD Therapy for Primary Prevention in Hypertrophic Cardiomyopathy.** *Arrhythm Electrophysiol Rev.* 2016; 5 (3): 188-96. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5248664/pdf/aer-05-188.pdf> Hypertrophic cardiomyopathy (HCM) is a common and heterogeneous disorder that increases an individual's risk of sudden cardiac death (SCD). This review article discusses the relevant factors that are involved in the challenge of preventing SCD in patients with HCM. The epidemiology of SCD in patients is reviewed as well as the structural and genetic basis behind ventricular arrhythmias in HCM. The primary prevention of SCD with implantable cardioverter-defibrillator (ICD) therapy is the cornerstone of modern treatment for individuals at high risk of SCD. The focus here is on the current and emerging predictors of SCD as well as risk stratification recommendations from both North American and European guidelines. Issues related to ICD implantation, such as programming, complications and inappropriate therapies, are discussed. The emerging role of the fully subcutaneous ICD and the data regarding its implantation are reviewed.

Wilkoff BL, Fauchier L, Stiles MK, Morillo CA, Al-Khatib SM, Almendral J, Aguinaga L, Berger RD, Cuesta A, Daubert JP, Dubner S, Ellenbogen KA, Estes NA, 3rd, Fenelon G, Garcia FC, Gasparini M, Haines DE, Healey JS, Hurtwitz JL, Keegan R, Kolb C, Kuck KH, Marinskis G, Martinelli M, McGuire M, Molina LG, Okumura K, Proclemer A, Russo AM, Singh JP, Swerdlow CD, Teo WS, Uribe W, Viskin S, Wang CC, Zhang S. **2015 HRS/EHRA/APHS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing.** *J Arrhythm.* 2016; 32 (1): 1-28. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4759125/pdf/main.pdf> PEGASUS CRT; MADIT-CRT; SIMPLE; MODALITY; MADIT-RIT; INTRINSIC RV; EMPIRIC; MADIT II; NORDIC ICD; CREDIT; Ontario DT Registry; Israel DFT Registry; SAFE-ICD; ADEPT; DATAS; PITAGORA ICD; ADVANCE-D; RAPTURE; ALTITUDE REDUCES; MADIT-RIT; RELEVANT; PREPARE; ADVANCE III; PROVIDE; CLEAR; PROSPECT; FREEDOM; DAVID; SAVE PACE; MiniVPACE; PreFER MVP; MINERVA; COMPARE; DANPACE; Medtronic (MVP algorithm); St Jude Medical (QuickOpt); Boston Scientific (LATITUDE); NCDR Registry. "...It is the consensus of the 4 continental electrophysiology societies that there are 4 important clinical issues for which there are sufficient ICD clinical and trial data to provide evidence-based expert guidance. This document systematically describes the greater than 80% (83%–100%, mean 96%) required consensus achieved for each recommendation by official balloting in regard to the programming of (1) bradycardia mode and rate, (2) tachycardia detection, (3) tachycardia therapy, and (4) the intraprocedural testing of defibrillation efficacy..."

Willcox ME, Prutkin JM, Bardy GH. **Recent developments in the subcutaneous ICD.** *Trends Cardiovasc Med.* 2016: Epub before print. http://ac.els-cdn.com/S1050173816000803/1-s2.0-S1050173816000803-main.pdf?_tid=c1a6ba7e-1147-11e6-9dd5-00000aacb35e&acdnat=1462291237_df872e0b561727290fa5ac437fef62a2 Boston Scientific (Emblem S-ICD); St Jude Medical (Riata ICD); Guidant (ENDOTAK Reliance); Medtronic (Sprint Quattro 6947; Sprint Fidelis). The subcutaneous implantable cardioverter-defibrillator (ICD) was developed as a simple device to reduce the morbidity of ICD therapy while providing a comparable reduction in sudden death from ventricular fibrillation. This review highlights the differences compared to the traditional ICD. It includes recent data on safety and efficacy, as well as best practices on screening and programming, and discusses expected future developments. Fig. 1 – Posterior–anterior and lateral chest X-ray demonstrating appropriate S-ICD lead placement; Fig. 3 – Printout of S-ICD interrogation with identifying data blacked out.

Ali H, Lupo P, Cappato R. **The entirely subcutaneous defibrillator - a new generation and future expectations.** *Arrhythm Electrophysiol Rev.* 2015; 4 (2): 116-21. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4711556/pdf/aer-04-116.pdf> Cameron Health (SQ-RX 1010); Boston Scientific (Emblem). Although conventional implantable cardioverter-defibrillators (ICDs) have

proved effective in the prevention of sudden cardiac death (SCD), they still appear to be limited by non-trivial acute and long-term complications. The recent advent of an entirely subcutaneous ICD (S-ICD) represents a further step in the evolution of defibrillation technology towards a less-invasive approach. This review highlights some historical and current issues concerning the S-ICD that may offer a viable therapeutic option in selected patients at high risk of SCD and in whom pacing is not required. After the CE Mark and US Food and Drug Administration (FDA) approvals, the S-ICD is being implanted worldwide with growing clinical data regarding its safety and efficacy (the EFFORTLESS Registry). The recently developed new generation of S-ICD (EMBLEM, Boston Scientific) demonstrates favourable features including a smaller device, longer longevity and remote-monitoring compatibility. Further innovations in the S-ICD system and potential integration with leadless pacing may play an important role in defibrillation therapy and prevention of SCD in the near future.

- Bettin M, Reinke F, Rath B, Kobe J, Eckardt L. **Recent advances in the entirely subcutaneous ICD System. F1000Prime Rep.** 2015; 7: 46 [10 pages]. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4447043/pdf/medrep-07-46.pdf> Boston Scientific (SQ-RX 1010 S-ICD). Mentions EFFORTLESS. The entirely subcutaneous implantable cardioverter defibrillator (S-ICD((R))) is emerging as a widely accepted therapeutic alternative to a conventional implantable cardioverter defibrillator (ICD) for prevention of sudden cardiac death. Essentially, the S-ICD((R)) is promising in terms of reduction of electrode-related complications such as lead failure and infections. The conventional transvenous ICD has proven efficacy in various randomized clinical trials. The first results of S-ICD((R)) studies confirm efficacy and safety in primary and secondary prevention as well. Owing to basic differences between S-ICD((R)) and transvenous ICD-such as limited programming options and lack of pacing-not all patients are eligible for the S-ICD((R)). Concerns exist regarding inappropriate shocks due to T-wave oversensing, dimensions of the device, and shorter battery longevity. However, the S-ICD((R)) should be considered a useful supplementation of ICD therapy in those patients at risk for sudden cardiac death who are not expected to require pacing due to bradycardia or antitachycardic pacing.
- Bordachar P, Marquie C, Pospiech T, Pasquie JL, Jalal Z, Haissaguerre M, Thambo JB. **Subcutaneous implantable cardioverter defibrillators in children, young adults and patients with congenital heart disease. Int J Cardiol.** 2015; 203: 251-8. http://ac.els-cdn.com/S0167527315305246/1-s2.0-S0167527315305246-main.pdf?_tid=4621cc5c-817f-11e5-aa6d-00000aab0f26&acdnat=1446482114_68bc372f9857acd8a3b622ba4f8e18ef Boston Scientific (S-ICD) The demonstration of severe complications in patients implanted with a transvenous implantable cardioverter defibrillator (ICD) has led to the development of devices equipped with a subcutaneous lead. This new technique offers numerous advantages but also certain disadvantages. Various studies or anecdotal clinical cases have specifically been conducted with this subcutaneous defibrillation system in children and/or patients with congenital heart disease. Results of these studies suggest: 1) a high feasibility despite being limited by a selection process that excludes patients requiring permanent pacing and patients declared ineligible during pre-screening; 2) good efficacy of electrical shocks in reducing induced or spontaneous ventricular arrhythmias; 3) in this specific subset of patients, 2 types of complications have been particularly described: a risk of device exteriorization and infection, and a large number of inappropriate therapies primarily related to T-wave oversensing. The subcutaneous ICD could therefore constitute the gold standard for patients with complex congenital heart disease with no venous access to the heart or with a persistent shunt increasing the risk of systemic emboli as well as in young patients with channelopathy or hypertrophic cardiomyopathy not requiring long-term pacing. Technological change (reduction in device size, better differentiation between R- and T-waves, possibility of pacing if device coupled with a leadless pacemaker) could reduce the limitations and complications and thereby increase the indications in this sub-group of patients.
- Garcia-Bolao I, Ruiz-Mateas F, Bazan V, Berruezo A, Alcalde O, Leal Del Ojo J, Acosta J, Martinez Selles M, Mosquera I. **Update in cardiac arrhythmias and pacing. Rev Esp Cardiol (Engl Ed).** 2015; 68 (3): 226-33. <http://www.revespcardiol.org/en/pdf/90387084/S300/> Boston Scientific (WATCHMAN; S-ICD); Amplatzer; EFFORTLESS S-ICD registry, HomeGuide Registry, REFORM, TRUST, REVERSE, MADIT-CRT, NARROW-CRT, EchoCRT, WiSE-CRT, WiCS-LV system, Spanish ICD Registry, . This article discusses the main advances in cardiac arrhythmias and pacing published between 2013 and 2014. Special attention is given to the interventional treatment of atrial fibrillation and ventricular arrhythmias, and on advances in cardiac pacing and implantable cardioverter defibrillators, with particular reference to the elderly patient.

- Lewis GF, Gold MR. **Clinical experience with subcutaneous implantable cardioverter-defibrillators. Nat Rev Cardiol.** 2015: Epub before print. <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=yrovft&AN=01429652-900000000-99052&PDF=y> Boston Scientific (S-ICD). The subcutaneous implantable cardioverter-defibrillator (S-ICD) is a novel technology for the treatment of sudden cardiac death. The system consists of a

pulse generator implanted in the left axillary position and a single subcutaneous lead for detection and delivery of therapy. Initial clinical trials of S-ICDs demonstrated improved safety and efficacy when compared to transvenous ICD systems, leading to their widespread approval. The main advantage of the S-ICD is the avoidance of vascular access and the complications associated with transvenous leads. Owing to limitations of S-ICDs, patients who require pacing support or antitachycardia pacing are not candidates for the device; instead, this system is currently used most commonly in young patients with previous lead malfunction, limited vascular access, or low risk for subsequent bradycardia or antitachycardia pacing. Findings from device trials support S-ICDs as a viable alternative to transvenous ICDs in certain patients, and the current limitations associated with S-ICDs are likely to be addressed in future iterations of the device, extending its indications and target patient populations.

- McLeod CJ, Boersma L, Okamura H, Friedman PA. **The subcutaneous implantable cardioverter defibrillator: state-of-the-art review.** *Eur Heart J.* 2015: Epub before print. <http://eurheartj.oxfordjournals.org/content/ehj/early/2015/10/29/eurheartj.ehv507.full.pdf> Boston Scientific (EMBLEM S-ICD). EFFORTLESS S-ICD, SCD-HeFT, MADIT-RIT, ALTITUDE. The subcutaneous implantable cardioverter defibrillator (ICD) provides therapy for the prevention of sudden cardiac death while avoiding the numerous complications associated with transvenous leads. This relatively novel device employs an innovative approach to sensing and defibrillation from outside of the thoracic cage. Substantial data from cohort studies and registries have accrued and can be used to inform patient eligibility, implant technique, and efficacy compared with the standard transvenous ICD. This review serves to update the clinician as to current evidence and the nuances involved in the optimal utilization of this innovative technology.
- Napp A, Stunder D, Maytin M, Kraus T, Marx N, Driessen S. **Are patients with cardiac implants protected against electromagnetic interference in daily life and occupational environment?** *Eur Heart J.* 2015: Epub before print. <http://eurheartj.oxfordjournals.org/content/ehj/early/2015/04/22/eurheartj.ehv135.full.pdf> Utilization of cardiac implants such as pacemakers and implantable cardioverter defibrillators is now commonplace among heart disease patients. The ever-increasing technological complexity of these devices is matched by the near omnipresent exposure to electric, magnetic, and electromagnetic fields (EMFs), both in everyday life and the occupational environment. Given that electromagnetic interferences (EMIs) are associated with potential risk in device patients, physicians are increasingly confronted with managing device patients with intermittent EMI and chronic occupational exposure. The current review aims to provide a contemporary overview of cardiovascular implantable electronic devices, their function and susceptibility of non-medical EMFs and provide recommendations for physicians caring for cardiac device patients presenting with EMI. Table 1 Theoretical constellation of interference of different device types and their clinical consequences, pacemaker, ICD, S-ICD.
- Priori SG, Blomstrom-Lundqvist C, Mazzanti A, Blom N, Borggrefe M, Camm J, Elliott PM, Fitzsimons D, Hatala R, Hindricks G, Kirchhof P, Kjeldsen K, Kuck KH, Hernandez-Madrid A, Nikolaou N, Norekval TM, Spaulding C, Van Veldhuisen DJ. **2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC) Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC).** *Eur Heart J.* 2015: Epub before print. <http://eurheartj.oxfordjournals.org/content/ehj/early/2015/08/28/eurheartj.ehv316.full.pdf>
- Röger S, Borggrefe M, Kuschyk J. **Heart failure with reduced ejection fraction and a narrow qrs complex: Combination of a subcutaneous defibrillator with cardiac contractility modulation.** *Journal of Atrial Fibrillation.* 2015; 8 (3): 74-8. <http://jafib.com/published.php?type=pdf&id=1081> Boston Scientific (S-ICD); Impulse Dynamics (Optimizer). Cardiac contractility modulation (CCM) is a relatively new electrical therapy for heart failure patients with reduced ejection fraction. The majority of patients eligible for CCM will also need an implantable cardioverter-defibrillator (ICD). To-date, three pacing electrodes are mandatory for CCM therapy because the current CCM signal delivery algorithm requires sequential intracardiac sensing of a p-wave, followed by appropriately timed ventricular activation by the two ventricular septal leads. As there is no device combining CCM with ICD functions, most CCM patients will need multiple intracardiac electrodes, which increase the cumulative risk for complications such as systemic infections, thrombosis of central venous lines, insulation failures or lead fractures. The long-term complications associated with trans-venous ICD leads have led to the development of a totally subcutaneous implantable cardioverter-defibrillator (S-ICD). In this essay the two technologies CCM and S-ICD are reviewed. Additionally, we present their successful combination on the basis of a case report on the first patient receiving both devices.
- Swerdlow CD, Asirvatham SJ, Ellenbogen KA, Friedman PA. **Troubleshooting implantable cardioverter-defibrillator sensing problems II.** *Circ Arrhythm Electrophysiol.* 2015; 8 (1): 212-20. <http://circep.ahajournals.org/content/8/1/212.full.pdf> Mentions EFFORTLESS registry; St Jude Medical

(ICDs); Medtronic (ICDs); Boston Scientific (S-ICD). Figure 3. Signal processing architecture for sensing and detection. A, Conventional implantable cardioverter-defibrillator (ICD) architecture; B, Enhanced ICD architecture; C, S-ICD architecture; Figure 4. Subcutaneous implantable cardioverter-defibrillator (S-ICD) system; Figure 5. Subcutaneous implantable cardioverter-defibrillator (S-ICD) sensing and detection of spontaneous ventricular fibrillation (VF); Figure 6. Subcutaneous implantable cardioverter-defibrillator (S-ICD) postshock undersensing of spontaneous ventricular fibrillation (VF).

Verma N, Rhyner J, Knight BP. **The subcutaneous implantable cardioverter and defibrillator: advantages, limitations and future directions.** *Expert Rev Cardiovasc Ther.* 2015; 13 (9): 989-99. *This article is not in the KR collection.* The totally subcutaneous implantable cardioverter and defibrillator (S-ICD) represents the most innovative development in implantable cardioverter and defibrillator therapy in the last 15 years. Its development arose out of concern for the long-term complications of transvenous devices. Clinical trials have shown that it is a safe and effective device for patients at risk of sudden cardiac death. The lack of transvenous and intracardiac components makes it an attractive choice for young patients, those with limited vascular access and increased infectious risk. Despite these advantages, the current S-ICD system has limitations, including the inability to deliver cardiac pacing. Future programming and technologic advancements have the opportunity to dramatically improve the efficacy and broaden the patient population treated with the S-ICD.

Yousuf O, Chrispin J, Tomaselli GF, Berger RD. **Clinical management and prevention of sudden cardiac death.** *Circ Res.* 2015; 116 (12): 2020-40. <http://circres.ahajournals.org/content/116/12/2020.full.pdf> *Boston Scientific (S-ICD); Zoll (LifeVest) MADIT I & II; MUSTT; CABG-Patch; DINAMIT; DEFINITE; SCD-HeFT; AVID; CIDS; CASH; COMPANION, MADIT-CRT; CARE-HF; EFFORTLESS.* Despite the revolutionary advancements in the past 3 decades in the treatment of ventricular tachyarrhythmias with device-based therapy, sudden cardiac death (SCD) remains an enormous public health burden. Survivors of SCD are generally at high risk for recurrent events. The clinical management of such patients requires a multidisciplinary approach from postresuscitative care to a thorough cardiovascular investigation in an attempt to identify the underlying substrate, with potential to eliminate or modify the triggers through catheter ablation and ultimately an implantable cardioverter-defibrillator (ICD) for prompt treatment of recurrences in those at risk. Early recognition of low left ventricular ejection fraction as a strong predictor of death and association of ventricular arrhythmias with sudden death led to significant investigation with antiarrhythmic drugs. The lack of efficacy and the proarrhythmic effects of drugs catalyzed the development and investigation of the ICD through several major clinical trials that proved the efficacy of ICD as a bedrock tool to detect and promptly treat life-threatening arrhythmias. The ICD therapy is routinely used for primary prevention of SCD in patients with cardiomyopathy and high risk inherited arrhythmic conditions and secondary prevention in survivors of sudden cardiac arrest. This compendium will review the clinical management of those surviving SCD and discuss landmark studies of antiarrhythmic drugs, ICD, and cardiac resynchronization therapy in the primary and secondary prevention of SCD. Table 2. Clinical Trials of Primary and Secondary Prevention ICD; Table 5. ICD Use Recommendations in the Missing Gap Population From Clinical Trials; Table 6. ICD Use Recommendations in the Missing Gap Population From Clinical Trials.

Patel KH, Lambiase PD. **The subcutaneous ICD-current evidence and challenges.** *Cardiovasc Diagn Ther.* 2014; 4 (6): 449-59. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278039/pdf/cdt-04-06-449.pdf> *Boston Scientific (S-ICD; ICDs). Mentions St Jude Medical (ICDs); Medtronic (ICDs). Mentions -PRAETORIAN, EFFORTLESS, S-ICD IDE study.* The subcutaneous implantable cardioverter-defibrillator (S-ICD) represents an exciting development in ICD technology. It has relative advantages over traditional transvenous systems, particularly for young patients in whom the lifetime risk of device-related complications may be deemed to be unacceptably high. While data relating to device longevity and long term safety profile is yet to be accrued, several recent studies have demonstrated good clinical efficacy comparable to transvenous ICDs. Indeed, new techniques have also been developed to simplify the S-ICD implantation procedure and attempts have been made to address challenges pertaining to T-wave oversensing to reduce the delivery of inappropriate shocks. The impact of inappropriate shocks and lack of anti-tachycardia pacing (ATP) function are not only contentious matters, but also have important implications for patients in whom the S-ICD would be suitable. It is envisaged that subsequent models of this device will be less cumbersome, with the possibility that an entirely leadless pacemaker-defibrillator will one day be possible. Although the S-ICD may not completely replace transvenous devices in its current form, evidence suggests that it is a viable alternative particularly in preventing sudden cardiac death in non-pacing dependent patients.

Garratt CJ, Saeed Y. **The Year in Cardiology 2012: arrhythmia and pacing.** *Eur Heart J.* 2013: Epub before print. <http://eurheartj.oxfordjournals.org/content/34/5/333.full.pdf> *St Jude Medical (Riata).* This is a commissioned review for 'A Year in Cardiology 2012', focusing on recent developments in the field of arrhythmias and pacing. [sections on subcutaneous ICD; CRT; Pacing for syncope; Riata leads; device longevity-"...In

general, devices implanted by Medtronic lasted the longest, followed by Guidant, with the shortest longevity in St Jude and Biotronik devices. Early studies of 'piezoelectric energy harvesting' have shown potential to supplement battery power and improve longevity in the future...".

- Mondesert B, Abadir S, Khairy P. **Arrhythmias in adult congenital heart disease: the year in review.** *Curr Opin Cardiol.* 2013; Epub before print. <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=toc&SEARCH=00001573-90000000-00000.kc&LINKTYPE=asBody&LINKPOS=1&D=ovft> *Cameron Health (S-ICD SQ-RXTM 1010; Q-TRAKTM 3010)*. PURPOSE OF REVIEW: Management of arrhythmias is an integral component of care for adults with congenital heart disease (CHD). Our objective was to highlight the important advances from the year 2012 regarding arrhythmias in adult CHD, with a focus on diagnostic considerations, acute management, catheter ablation, and device therapy. RECENT FINDINGS: During the course of 2012, Holter studies suggested that routine screening was helpful in guiding the clinical decisions for certain patient subgroups, such as adults with tetralogy of Fallot. Supportive evidence was provided for the common practice of anticoagulation and/or screening for intracardiac thrombosis by transesophageal echocardiography prior to electrically cardioverting atrial tachyarrhythmias. Advances in catheter ablation, particularly robotic magnetic navigation, offer new hope for patients in whom access to arrhythmia substrates is not feasible by standard means. The subcutaneous defibrillator emerged as an innovative solution of great interest to the patients at risk of sudden death in whom transvenous lead implantation is unachievable or contraindicated. Finally, 2012 ended with a major milestone: the establishment of physician certification in adult CHD by the American Board of Medical Specialties. SUMMARY: The year 2012 witnessed important advances in the diagnosis and management of arrhythmias in adults with CHD. [Holter monitoring, page 1-2, Robotic Catheter Ablation page 3, S-ICD described page 3-4].
- Cappato R, Smith WM, Hood MA, Crozier IG, Jordaens L, Spitzer SG, Ardashev AV, Boersma L, Lupo P, Grace AA, Bardy GH. **Subcutaneous chronic implantable defibrillation systems in humans.** *J Interv Card Electrophysiol.* 2012; 34 (3): 325-32. <http://www.springerlink.com/content/51jv32802730073v/fulltext.pdf> *Cameron Health (S-ICD)*. The recent introduction of subcutaneous implantable cardioverter defibrillator (S-ICD) has raised attention about the potential of this technology for clinical use in daily clinical practice. We review the methods and results of the four studies conducted in humans for approval of this innovative technology for daily practice. Two studies using a temporary S-ICD system (acute human studies) were conducted to search for an appropriate lead configuration and energy requirements. For this purpose, 4 S-ICD configurations were tested in 78 patients at the time of transvenous (TV)-ICD implantation. The optimal configuration was tested in 49 more patients to comparatively assess the subcutaneous defibrillation threshold (S-DFT) versus the standard TV-ICD. Long-term implants were evaluated in 55 patients using an implanted system (chronic human study). The acute human studies led to an optimal S-ICD configuration comprising a parasternal electrode and left anterolateral thoracic pulse generator. Both configurations successfully terminated 98% of induced ventricular fibrillation (VF), but significantly higher energy levels were required with S-ICD than with TV-ICD systems (36.6 +/- 19.8 J vs. 11.1 +/- 8.5 J). In the chronic study, all 137 VF episodes induced at time of implant were detected with a 98% conversion rate. Two pocket infections and four lead revisions were required during 10 +/- 1 months of follow-up. During this period, survival was 98%, and 12 spontaneous ventricular tachyarrhythmias were detected and treated by the device. These data show that the S-ICD systems here consistently detected and converted VF induced at time of implant as well as sustained ventricular tachyarrhythmias occurring during follow-up (248).
- Lupo PP, Pelissero G, Ali H, Sanghera R, Cappato R. **Development of an entirely subcutaneous implantable cardioverter-defibrillator.** *Prog Cardiovasc Dis.* 2012; 54 (6): 493-7. http://ac.els-cdn.com/S0033062012000436/1-s2.0-S0033062012000436-main.pdf?_tid=46f87fab6a67aad3637570877890f85b&acdnat=1341935670_836813c8b5a914c139ed5ffd1ca2c81a *Cameron Health*. The recent advent of an entirely subcutaneous implantable defibrillator (ICD) has provided a relevant contribution to the debate concerning the use of ICD therapy in patients at high risk for death. Although conventional transvenous ICDs have proven very effective during the past 23 years, they still appear to be limited by nontrivial acute and long-term complications. This study delineates some of the historical and current issues characterizing the advent of the subcutaneous ICD system in daily clinical practice. Subcutaneous ICDs have proven effective in more than 1100 patients worldwide and appear to be competitive with transvenous ICD in all clinical conditions not requiring antibradycardia, antitachycardia, or cardiac resynchronization pacing.
- Rowley CP, Gold MR. **Subcutaneous implantable cardioverter defibrillator.** *Circ Arrhythm Electrophysiol.* 2012; 5 (3): 587-93. <http://circep.ahajournals.org/content/5/3/587.full.pdf> *Cameron Health. Subcutaneous versus Transvenous Arrhythmia Recognition Testing (START)*. "...Having demonstrated effective arrhythmia detection, discrimination, and termination, the first purpose built entirely subcutaneous ICD was developed. With appropriate patient selection, the S-ICD is emerging as an effective alternative to transvenous systems for

primary and secondary prevention of sudden cardiac death."

- Rowley CP, Lobodzinski SS, Gold MR. **The Subcutaneous Defibrillator.** *Curr Treat Options Cardiovasc Med.* 2012; 14 (5): 550-7. <http://www.springerlink.com/content/x2j02jr207p45050/fulltext.pdf> *Cameron Health (S-ICD).* OPINION STATEMENT: Prevention of sudden cardiac death (SCD) remains an important clinical problem. Currently, therapeutic goals for SCD prevention include identification of high risk patients and aggressively treating comorbidities underlying. However, many patients remain at increased risk despite optimal medical management (eg, coronary artery disease and cardiomyopathy) whereas others have nonmodifiable risk for sudden death (eg, arrhythmogenic right ventricular dysplasia/cardiomyopathy, Brugada syndrome, long QT syndrome, and hypertrophic cardiomyopathy). In such patients, device therapy with an implantable defibrillator remains the most effective therapy for SCD prevention. However, implantable cardioverter defibrillators (ICDs), which are typically implanted with at least 1 lead placed within the heart, are associated with risks related to device implantation, as well as the presence of chronic endovascular leads. The durability of chronic leads is variable and can require either new leads to be placed or require lead extraction, which is associated with significant morbidity and mortality. The recently developed subcutaneous ICD (S-ICD) does not rely on any component to be placed within the heart or vasculature and therefore may mitigate the risks associated with endovascular leads. Therefore, it may be preferred for patients who are young, have inherited channelopathies, are immunocompromised, have indwelling catheters, or in whom venous access is obstructed or unfavorable due to congenital heart disease. Though long-term data regarding S-ICD performance are not yet available it may prove to be an effective therapeutic option for prevention of SCD.
- Sweeney MO. **The implantable cardioverter-defibrillator minimalist: an approach to patient follow-up and management of implantable defibrillators.** *Circulation.* 2012; 126 (3): 369-77. <http://circ.ahajournals.org/content/126/3/369.full.pdf> *Mentions SCD-HeFT, DAVID I & II, INTRINSIC RV, MVP Trial, MADIT II, DINAMIT, IRIS.* "...The recently emerged shock-only subcutaneous ICD expresses a theme of hardware minimization by eliminating transvenous leads altogether.¹⁹ This arrangement also eliminates the possibility of conventional bradycardia and antitachycardia pacing, although neither are essential to the primary mission of terminating life-threatening VTA..."
- Zitron E, Thomas D, Katus HA, Becker R. **Cardioverter defibrillator therapy in the primary and secondary prevention of sudden cardiac death.** *Appl Cardiopulm Pathophysiol.* 2012; 16 (2): 174-91. <http://www.applied-cardiopulmonary-pathophysiology.com/acp-2-2012.html> Implantable cardioverter defibrillators (ICDs) are the mainstay of modern device-based therapy for ventricular arrhythmias. Originally developed for patients resuscitated from cardiac arrest, the vast majority of today's ICDs are implanted prophylactically in patients with heart failure at increased risk for ventricular arrhythmias. The objective of this review is to provide a concise overview of current ICD indications and device selection criteria. Furthermore, remaining limitations of ICD therapy are discussed and current trends are outlined. [Subcutaneous ICD systems see page 185].
- Crozier I, Smith W. **Modern Device Technologies.** *Heart Lung Circ.* 2011; 21 (6-7): 320-7. *Article is not in the KR Collection.* Implantable cardiac devices for arrhythmias and related conditions are a rapidly evolving field, with a constant stream of technologies being developed. There are a number of novel devices, other than conventional pacemakers and implantable defibrillators, currently being developed that have the potential to greatly improve patient outcomes. This paper reviews the important recent technologies, the subcutaneous defibrillator, cardiac contraction modulation, the HeartPOD and CardioMEMS heart failure monitors, left atrial appendage closure devices and leadless cardiac pacing. The features of these devices, the results to date, and their possible clinical utility are discussed.
- Lobodzinski SS. **Subcutaneous implantable cardioverter-defibrillator (S-ICD).** *Cardiol J.* 2011; 18 (3): 326-31. http://www.cardiologyjournal.org/en/darmowy_pdf.phtml?id=103&indeks_art=1462 *Cameron Health (Q-TRAK lead; SQ-RX implantable pulse generator; Q-Guide lead insertion tool; Q-Tech programmer).* Current state-of-the art implantable cardioverter-defibrillator (ICD) systems have been proven to be safe and effective in treating ventricular arrhythmias leading to cardiac death. ICDs require placement of at least one lead in, or on, the heart. Surgical placement under fluoroscopy and the ongoing presence of the transvenous leads within the patient's heart are associated with a significant proportion of the complications related to this well-established and highly effective therapy. A new ICD has been developed that is implanted entirely subcutaneously (S-ICD), thus eliminating the need for lead placement in or on the heart and simplifying surgery by eliminating the need for imaging equipment. Recent clinical studies suggest that the S-ICD system provides a viable alternative to conventional transvenous devices that may reduce barriers to treatment and lead to the wider adoption of this life-saving therapy.

- Refaat M, Saba S. **Total subcutaneous defibrillators: The current status and future prospect of a new technology.** *Card Electrophysiol Clin.* 2011; 3 (3): 403-8. *This article is not in the KR collection.*
- Gupta A, Al-Ahmad A, Wang P. **Subcutaneous implantable cardioverter-defibrillator technology.** *Card Electrophysiol Rev.* 2009; 1 (1): 147-54. *This article is not in the KR collection.*
- Santini M, Cappato R, Andresen D, Brachmann J, Davies DW, Cleland J, Filippi A, Gronda E, Hauer R, Steinbeck G, Steinhaus D. **Current state of knowledge and experts' perspective on the subcutaneous implantable cardioverter-defibrillator.** *J Interv Card Electrophysiol.* 2009; 25 (1): 83-8.
<http://link.springer.com/content/pdf/10.1007%2Fs10840-008-9360-9.pdf> ICD implantation is today a well-recognized therapy to prevent sudden cardiac death. The available implantable devices at present need the use of permanent endocavitary leads which may cause, in some instances, serious troubles to the patients (lead dislodgement, ventricular perforation, lead infections, etc.). A new implantable defibrillator provided by only a subcutaneous lead is at present under evaluation. Its potential indications, usefulness benefits, and problems represent an interesting field of investigation and discussion. This paper describes the conclusions recently reached by a panel of experts, with regard to the potential role of an implantable subcutaneous defibrillator in the prevention of sudden cardiac death.

Case Reports

- Nishiyama T, Kimura T, Nishiyama N, Aizawa Y, Fukuda K, Takatsuki S. **Discrimination Between QRS and T Waves Using a Right Parasternal Lead for S-ICD in a Patient with a Single Ventricle.** *Pacing Clin Electrophysiol.* 2017; 9 (9): 1540-8159. <http://dx.doi.org/10.1111/pace.13046> The subcutaneous implantable cardioverter-defibrillator (S-ICD) is a useful option for patients with a single ventricle (SV) in which transvenous leads are contraindicated because of intracardiac shunts. We report a case in which a right parasternal lead placement was indicated for an S-ICD in a resuscitated patient with an SV. There were significant changes in the magnitude of R to T waves ratio in the right compared to left parasternal lead position. Screening in the right parasternal position is effective for selecting appropriate patients with CHD for S-ICD implantations. This article is protected by copyright. All rights reserved. This article is protected by copyright. All rights reserved.
- Al-Khatib SM, Belbase S, Sauro D, Brock G, Brink K, Jackson KP. **Inappropriate shocks in a patient with a subcutaneous implantable cardioverter-defibrillator.** *HeartRhythm Case Reports.* 2016; 2 (6): 478-83.
http://ac.els-cdn.com/S2214027116300598/1-s2.0-S2214027116300598-main.pdf?_tid=fd631fc-c098-11e6-afc3-0000aacb35f&acdnat=1481567581_c24b411ed375b6f8cd9a5da7ba96e064 Boston Scientific (SQ-RX; Q-TRAK).
- Amado J, Marques N, Candeias R, Gago P, de Jesus I. **Congenital left ventricular apical aneurysm presenting as ventricular tachycardia.** *Rev Port Cardiol.* 2016; 35 (10): 545 e1-4. http://ac.els-cdn.com/S0870255116301780/1-s2.0-S0870255116301780-main.pdf?_tid=e89e1f48-8977-11e6-9708-0000aacb35e&acdnat=1475506057_90e875cb746b86547c870cbd69cfdcee The authors present the case of a 34-year-old male patient seen in our department due to palpitations. On the electrocardiogram monomorphic ventricular tachycardia (VT) was documented, treated successfully with amiodarone. The subsequent study revealed a normal echocardiogram and an apical aneurysm of the left ventricle on magnetic resonance imaging, confirmed by computed tomography coronary angiography that also excluded coronary disease. He underwent an electrophysiological study to determine the origin of the VT and to perform catheter ablation using electroanatomical mapping. VT was induced and radiofrequency applications were performed in the left ventricular aneurysm area. VT was no longer inducible, with acute success. Despite this it was decided to implant a subcutaneous implantable cardioverter-defibrillator (ICD). Eight months after the ablation the patient was admitted again due to VT, treated by the ICD.
- Angel B, Overcash J, Fischer W, Fontaine JM. **Surgical and electrophysiological considerations in the management of a patient with a subcutaneous implantable cardioverter-defibrillator undergoing coronary artery bypass surgery.** *HeartRhythm Case Reports.* 2016: Epub before print. <http://dx.doi.org/10.1016/j.hrcc.2016.09.002> Boston Scientific employee (Overcash). "...This case report demonstrates that an S-ICD lead can be safely removed and then successfully replaced provided that careful precautions are undertaken regarding the sternal lead field..."
- Arias MA, Pachon M, Akerstrom F, Puchol A, Sanchez-Perez A, Rodriguez-Padial L. **Subcutaneous Defibrillator: Role in the Prevention of Sudden Cardiac Death in the Setting of Mechanical Tricuspid Prosthesis.** *Rev Esp*

Cardiol (Engl Ed). 2016: Epub before print.

http://pdf.revespcardiol.org/watermark/ctl_servlet?_f=10&pident_articulo=90449193&pident_usuario=0&pcontacto_d=&pident_revista=255&ty=111&accion=L&origen=cardio&web=www.revespcardiol.org&lan=en&fichero=255v69n03a90449193pdf001.pdf Boston Scientific (SQ-RX 1010; Q-Trak 3010).

Boyle TA, Cohen J, Carrillo R. **Substernal implantation of a subcutaneous implantable cardioverter-defibrillator in a patient with preexisting Hemodialysis Reliable Outflow graft.** *HeartRhythm Case Reports.* 2016; 2 (5): 412-4. http://ac.els-cdn.com/S2214027116300501/1-s2.0-S2214027116300501-main.pdf?_tid=f08f7028-8975-11e6-aa67-0000aacb35e&acdnat=1475505212_5f14d982f807618f210c4be9f82c61a9 Boston Scientific (S-ICD). "...We present a novel approach for implanting an S-ICD in a patient with end-stage renal disease, central venous stenosis, and precordial hemodialysis graft obstructing the normal subcutaneous implant site..."

Chang PM, Saxon LA, Doshi RN. **The subcutaneous implantable cardioverter-defibrillator as part of dual device therapy in complex congenital heart disease.** *Journal of Innovation in Cardiac Rhythm Management.* 2016; 7 (6): 2395–99. <http://www.innovationsincrm.com/images/pdf/crm-07-06-2395.pdf> We report the case of a 44-year-old with unrepaired complex congenital heart disease (CHD), a pre-existing permanent pacemaker, and a subcutaneous implantable cardioverterdefibrillator (SICD) implanted for secondary prevention. Right parasternal electrode positioning and step-down defibrillation testing were integrated. Application of the SICD for device therapy in CHD patients remains quite limited but can have an expanding role in this population.

Chinitz J, Nadraus P, Darge A, Cacciabauda J, Altman EJ. **Inappropriate Shocks within 24 hours after Implantation of a Subcutaneous Defibrillator with a Two-incision Technique.** *Journal of Innovation in Cardiac Rhythm Management.* 2016; 7 (3): 2295–8. <http://www.innovationsincrm.com/images/pdf/crm-07-03-2295.pdf> Boston Scientific (SICD); Zoll Medical (LifeVest). The subcutaneous implantable cardioverter-defibrillator (S-ICD) has traditionally been implanted using three incisions, but a two-incision technique has emerged involving a subaxillary and single parasternal incision. We present two cases of early inappropriate discharge after S-ICD implant with the two-incision technique. Two patients underwent S-ICD implantation using the two-incision technique. Patient 1 is a 56-year-old male with prior coronary artery bypass graft who underwent transvenous ICD extraction for pocket infection, and was later reimplanted with an S-ICD. Patient 2 is a 73-year-old male with prior mitral valve repair and severe left ventricular dysfunction. In both cases chest X-ray confirmed good lead position without evidence of subcutaneous air, and the patients were discharged the day of implant. Several hours after discharge, both patients experienced a sudden shock, and device interrogation demonstrated a decrease in signal amplitude and abrupt baseline shift, followed by an inappropriate 80-J discharge. The artifact was not reproducible on device testing the next day. No subsequent inappropriate therapy was observed on follow-up. Inappropriate S-ICD shocks are rare in the early post-implant period using traditional implant techniques. The two-incision technique is a simplified implant method, but may predispose to oversensing and inappropriate therapy in the early post-implant period, possibly due to introduction of air along the sternal track as the lead is inserted and sheath is removed.

Droghetti A, Locatelli A, Casiraghi B, Malacrida M, Arupi M, Ragusa M. **Totally submuscular implantation of subcutaneous implantable cardioverter defibrillator: a safe and effective solution for obese or oversized patients.** *Clin Case Rep.* 2016; 4 (10): 1009-11. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5054481/pdf/CCR3-4-1009.pdf> The subcutaneous implantable cardioverter-defibrillator (S-ICD) is a safe alternative to transvenous ICD. We describe a submuscular S-ICD placement technique in a severely obese with an oversized chest. Submuscular configuration allows optimal system positioning and impedance values warranting a safe and effective shock transmission. This technique is safe and improves patients comfort.

Erath JW, Sirat AS, Vamos M, Hohnloser SH. **Epicardial crt-p- and s-icd implantation in a young patient with persistent left superior vena cava.** *Herzschrittmacherther Elektrophysiol.* 2016: Epub before print. http://download.springer.com/static/pdf/968/art%253A10.1007%252Fs00399-016-0451-5.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs00399-016-0451-5&token2=exp=1475507084~acl=%2Fstatic%2Fpdf%2F968%2Fart%25253A10.1007%25252Fs00399-016-0451-5.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs00399-016-0451-5*~hmac=9f3519340855f47864bb27a6725ab2c1bfa0d3d06407134e5bfc5504f494b349 Persistent left superior vena cava is known to be a challenging anatomic abnormality for transvenous cardiac device implantation. In the a case of a young man presenting with dilative cardiomyopathy with severely impaired left ventricular ejection fraction (LVEF) and second-degree atrioventricular block (AV block), cardiac resynchronization therapy (CRT) with defibrillator (CRT-D) implantation was indicated. A transvenous approach was attempted, but placement of the right ventricular lead was not successful due to anatomic abnormalities.

Therefore, epicardial CRT leads were implanted via a left mini-thoracotomy. For primary prevention of sudden death, the patient was also fitted with an additional subcutaneous implantable cardioverter defibrillator (S-ICD). Any cross-talk between the devices was ruled out both intraoperatively and by ergometry prior to discharge. The combination of epicardial CRT-P with S-ICD implantation might be a safe and effective alternative in patients with cardiac anatomic abnormalities.

Gemein C, Haj M, Schmitt J. **Combining an subcutaneous ICD and a pacemaker with abdominal device location and bipolar epicardial left ventricular lead: first-in-man approach.** *Europace*. 2016: Epub before print. <http://europace.oxfordjournals.org/content/europace/early/2016/02/02/europace.euv443.full.pdf>

Ishizuka M, Yamamoto Y, Yamada S, Maemura S, Nakata R, Motozawa Y, Yamamoto K, Takizawa M, Uozumi H, Ikenouchi H. **Bilateral Subclavian Vein Occlusion in a SAPHO Syndrome Patient Who Needed an Implantable Cardioverter Defibrillator.** *Int Heart J*. 2016; 57 (3): 380-2. https://www.jstage.jst.go.jp/article/ihj/57/3/57_15-453/pdf A 79-year-old Asian man was hospitalized because of progressive exertional dyspnea with decreasing left ventricular ejection fraction and frequent non-sustained ventricular tachycardia. Pre-procedure venography for implantable cardioverter defibrillator (ICD) implantation showed occlusion of the bilateral subclavian veins. In consideration of subcutaneous humps in the sterno-clavicular area and palmoplantar pustulosis, we diagnosed him as having synovitis, acne, pustulosis, hyperostosis, osteitis (SAPHO) syndrome and speculated that it induced peri-osteal chronic inflammation in the sterno-clavicular area, resulting in occlusion of the adjacent bilateral subclavian veins. An automatic external defibrillator (AED) was installed in the patient's house and total subcutaneous ICD was considered. Venous thrombosis in SAPHO syndrome is not frequent but has been reported. To the best of our knowledge, this is the first case of bilateral subclavian vein occlusion in a SAPHO syndrome patient who needs ICD implantation.

Ishizuka M, Yamamoto Y, Yamada S, Maemura S, Nakata R, Motozawa Y, Yamamoto K, Takizawa M, Uozumi H, Ikenouchi H. **Bilateral subclavian vein occlusion in a sapho syndrome patient who needed an implantable cardioverter defibrillator: an unusual cause of lead access failure.** *Int Heart J*. 2016; 57 (3): 380-2. https://www.jstage.jst.go.jp/article/ihj/57/3/57_15-453/pdf A 79-year-old Asian man was hospitalized because of progressive exertional dyspnea with decreasing left ventricular ejection fraction and frequent non-sustained ventricular tachycardia. Pre-procedure venography for implantable cardioverter defibrillator (ICD) implantation showed occlusion of the bilateral subclavian veins. In consideration of subcutaneous humps in the sterno-clavicular area and palmoplantar pustulosis, we diagnosed him as having synovitis, acne, pustulosis, hyperostosis, osteitis (SAPHO) syndrome and speculated that it induced peri-osteal chronic inflammation in the sterno-clavicular area, resulting in occlusion of the adjacent bilateral subclavian veins. An automatic external defibrillator (AED) was installed in the patient's house and total **subcutaneous ICD** was considered. Venous thrombosis in SAPHO syndrome is not frequent but has been reported. To the best of our knowledge, this is the first case of bilateral subclavian vein occlusion in a SAPHO syndrome patient who needs ICD implantation. ["...although it has been reported that a home AED did not significantly improve overall survival in patients with anterior-wall myocardial infarction because of the high proportion of unwitnessed events and the underuse of AEDs in emergencies.6) As a result, we concluded an entirely subcutaneous ICD implantation would be a preferable choice because it avoids the use of transvenous leads.7..."].

Kamakura T, Sato T, Wada M, Ishibashi K, Noda T, Kusano K. **T-wave oversensing during drug challenge test after subcutaneous implantable cardioverter-defibrillator implantation in a patient with Brugada syndrome.** *HeartRhythm Case Reports*. 2016; 2 (5): 391-4. http://ac.els-cdn.com/S2214027116300446/1-s2.0-S2214027116300446-main.pdf?_tid=05363066-8976-11e6-a4e3-00000aacb35d&acdnat=1475505246_bd5d03d8f60ab90081104a1d3ad6c930 *Boston Scientific (Emblem)*. "...Drug challenge testing with pilsicainide and isoproterenol unmasked an unsuitable BrS patient formerly thought to be eligible for S-ICD implantation at baseline. Our report demonstrates that the drug challenge test may be useful in evaluating the appropriateness of an indication for S-ICD in patients with BrS."

Kattih B, Duncker D, Konig T, Hohmann S, Oswald H, Veltmann C. **The "Pain wave": Pwave oversensing in subcutaneous ICD.** *Herzschrittmacherther Elektrophysiol*. 2016: Epub before print. http://download.springer.com/static/pdf/521/art%253A10.1007%252Fs00399-016-0423-9.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%252Fs00399-016-0423-9&token2=exp=1462292239~acl=%2Fstatic%2Fpdf%2F521%2Fart%25253A10.1007%25252Fs00399-016-0423-9.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%25252Fs00399-016-0423-9*~hmac=8346922bd290ad4f3ba4da0a84f2d2424e4af7d88dbfcbbaee4c44b4d508b532b *Boston Scientific (SQ-RX model 1010; Q-Trak subQ 3400; INSIGHT algorithm)*. A 46-year old man was implanted with a totally subcutaneous implantable defibrillator, after having a documented episode of cardiac arrest due to

idiopathic ventricular fibrillation. During the 4month follow-up, an episode of inappropriate triple counting due to P and T wave oversensing was detected. Although preoperative screening, high detection rates, and the INSIGHTTM discrimination algorithm have reduced the incidence of oversensing-related implantable cardioverter defibrillator (ICD) shocks, continuous evaluation of appropriate sensing vectors at rest, during positional maneuver, and exercise, seems to be mandatory at each follow-up visit.

- Kaufmann MR, Panna ME, Miles WM, McKillop MS. **Subcutaneous ICD implant complicated by an intraperitoneal lead course and device infection.** *HeartRhythm Case Reports.* 2016; 2 (3): 270-1. http://ac.els-cdn.com/S2214027116000026/1-s2.0-S2214027116000026-main.pdf?_tid=df0f7f4c-7047-11e6-bcf9-00000aab0f6c&acdnat=1472736646_dc234097ec92b8d49ad763498d4e7bcd "...We present a case of extreme lead misplacement that represents how a usually simple implant procedure can result in a serious complication in the hands of an inexperienced implanter..."
- Kempa M, Budrejko S, Raczak G. **Subcutaneous implantable cardioverter-defibrillator (S-ICD) for secondary prevention of sudden cardiac death.** *Arch Med Sci.* 2016; 12 (5): 1179-80. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5016596/pdf/AMS-12-28231.pdf> *Cameron Health (S-ICD SQ-RX model 1010).*
- Levine JD, Ellins C, Winn N, Kim R, Hsu SS, Catanzaro JN. **Failed maximal defibrillation threshold testing in the subcutaneous implantable cardioverter defibrillator.** *Cardiology.* 2016; 136 (1): 29-32. <http://www.karger.com/Article/Pdf/447484> *Cook Medical (Cobra guide catheter); Boston Scientific (S-ICD).* The subcutaneous implantable cardioverter defibrillator (S-ICD) registry included very few patients with a body mass index (BMI) greater than 40. We present a case of a 40-year-old male with a BMI of 44 and ejection fraction of 25% who underwent S-ICD implantation for primary prevention of sudden cardiac death in the setting of a nonischemic cardiomyopathy. Defibrillation threshold (DFT) testing failed at high output. A posterior to anterior radiograph demonstrated migration of the components despite positioning under fluoroscopy. After repositioning, repeat DFT testing showed an inconsistent efficacy. We discuss the probabilistic nature of DFT testing, clinical factors affecting the S-ICD implant in the obese population and offer a novel insight from this specific experience.
- Mondoly P, Cardin C, Rollin A, Duparc A, Maury P. **Use of a subcutaneous ICD in a patient with short QT syndrome.** *Clin Case Rep.* 2016; 4 (1): 35-8. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4706391/pdf/CCR3-4-035.pdf> *Boston Scientific (S-ICD).* Short QT syndrome carries the risk for inappropriate therapies using transvenous ICD because of overdetection of the ample T wave. SQT syndrome may also benefit from subcutaneous ICD, although additional cases are needed to affirm the safety of such device in this setting.
- Montgomery JA, Orton JM, Ellis CR. **Feasibility of defibrillation and pacing without transvenous leads in a combined micra and s-icd system following lead extraction.** *J Cardiovasc Electrophysiol.* 2016: Epub before print. <http://onlinelibrary.wiley.com/doi/10.1111/jce.13111/pdf> *Medtronic (Sprint Quattro ICD lead; CapSure SP Novus lead 5592; Micra); Boston Scientific (S-ICD).* Figure 1. Replacement of a transvenous pacing-ICD system using a system without transvenous leads. A dual-chamber ICD and abandoned 5592 right ventricular pace-sense lead (A) was extracted due to fracture of the right ventricular DF-4 Sprint Quattro ICD lead, including the redundant leads. Immediately after extraction (B), a transcatheter MICRA pacemaker and S-ICD system were implanted simultaneously. .
- Nagra B, Awan MU, Miriyala V, Kantharia BK. **Efficacy and limitations of treatment of ventricular fibrillation/ventricular tachycardia storm by subcutaneous implantable cardioverter defibrillator.** *Int J Cardiol.* 2016; 222: 978-9. http://ac.els-cdn.com/S0167527316318113/1-s2.0-S0167527316318113-main.pdf?_tid=34d02e40-704d-11e6-b610-00000aacb361&acdnat=1472738938_db904bfd58686336e944554e5c7b9e0e *Boston Scientific (S-ICD).*
- Pfeffer TJ, Konig T, Duncker D, Michalski R, Hohmann S, Oswald H, Schmitto JD, Veltmann C. **Subcutaneous Implantable Cardioverter-Defibrillator Shocks After Left Ventricular Assist Device Implantation.** *Circ Arrhythm Electrophysiol.* 2016; 9 (11): <http://circep.ahajournals.org/content/circae/9/11/e004633.full.pdf> *Boston Scientific (EMBLEM S-ICD); Thoratec (HeartMate 3; HeartMate II; HVAD).* "...On the basis of our experience, we recommend deactivation of the antitachycardia therapy of the S-ICD before LVAD implantation. After recovery from surgery and before reactivation of the device, all sensing vectors should be evaluated with respect to adequate sensing and differentiation of R wave and T wave."
- Raman AS, Shabari FR, Kar B, Loyalka P, Hariharan R. **No Electromagnetic Interference Occurred in a Patient with a HeartMate II Left Ventricular Assist System and a Subcutaneous Implantable Cardioverter-Defibrillator.**

Tex Heart Inst J. 2016; 43 (2): 183-5. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4845567/pdf/i0730-2347-43-2-183.pdf> St Jude Medical (HeartMate II); Boston Scientific (SQ-RX model 1010; VITALITY ICD T125); Ventracor (VentrAssist LVAD). The use of subcutaneous implantable cardioverter-defibrillators is a novel option for preventing arrhythmia-mediated cardiac death in patients who are at risk of endovascular-device infection or in whom venous access is difficult. However, the potential for electromagnetic interference between subcutaneous defibrillators and left ventricular assist devices is largely unknown. We report the case of a 24-year-old man in whom we observed no electromagnetic interference between a subcutaneous implanted cardioverter-defibrillator and a HeartMate II Left Ventricular Assist System, at 3 different pump speeds. To our knowledge, this is the first report of such findings in this circumstance.

Saberwal B, Roy A, Lambiase P. **Ineffective shock therapy in a subcutaneous implantable cardioverter-defibrillator patient with hypertrophic cardiomyopathy.** *Journal of Innovation in Cardiac Rhythm Management.* 2016; 7 (3): 2308–10. <http://www.innovationsincrm.com/images/pdf/crm-07-03-2308.pdf> We report the case of an 18-year-old hypertrophic cardiomyopathy female with a subcutaneous implantable cardioverter-defibrillator (S-ICD) for primary prevention who presented with monomorphic ventricular tachycardia and five ineffective 80-J shocks. We have examined the patient case notes, imaging and electrophysiology study data, and traces obtained from S-ICD device interrogation. This is a rare example of device failure in an otherwise safe and effective system as illustrated by EFFORTLESS and IDE data.

Santucci LM, Saputo FA, Verticelli L, Tamburri I, Placidi S, Silvetti MS, Drago F. **Inappropriate Shocks in a Patient with Subcutaneous ICD and Transvenous Pacemaker: Is it as it Seems?** *Pacing Clin Electrophysiol.* 2016; 39 (8): 873-5. <http://onlinelibrary.wiley.com/store/10.1111/pace.12885/asset/pace12885.pdf?v=1&t=iz8k9v4q&s=7b3093b0b126317689986631a10f575339ca690b>

Schaarschmidt C, Kolb C. **Optimisation of subcutaneous defibrillator programming after inappropriate shocks due to new onset of right bundle branch block [article is in German].** *Herzschrittmacherther Elektrophysiol.* 2016; Epub before print. http://download.springer.com/static/pdf/757/art%253A10.1007%252Fs00399-016-0461-3.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs00399-016-0461-3&token2=exp=1479250345~acl=%2Fstatic%2Fpdf%2F757%2Fart%25253A10.1007%25252Fs00399-016-0461-3.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs00399-016-0461-3*~hmac=435a4df5f3298629e373cb0cf47ebcd57726042b64d8a3dc5a637c54243261e1 Boston Scientific (S-ICD model SQ-RX 1010). The subcutaneous implantable defibrillator (S-ICD) has become an established tool for the prevention of sudden cardiac death. Based on its detection properties, the S-ICD is essentially dependent on correct morphology discrimination of the QRS complex and avoidance of potential T-wave sensing. We report on a patient who experienced multiple inappropriate S-ICD shocks due to T-wave oversensing in the setting of new onset of right bundle branch block. Strategies for the optimisation of the device programming are discussed.

Ueshima H, Hara E, Otake H. **Successful cases of S-ICD implantation performed under the serratus plane block.** *J Clin Anesth.* 2016; 33: 147-8. *This article is not in the library's collection.*

Ueshima H, Hiroshi O. **A successful case of subcutaneous implantable cardioverter-defibrillator implantation performed under the transversus thoracic muscle plane block.** *J Clin Anesth.* 2016; 32: 253-4. *This article is not in the library's collection.*

Viani S, Zucchelli G, Paperini L, Soldati E, Segreti L, Di Cori A, Menichetti F, Coluccia G, Andreini D, Branchitta G, Bongiorni MG. **Subcutaneous Implantable Defibrillator in an acromegalic pregnant woman for secondary prevention of sudden cardiac death: When (2) technologies save (2) lives.** *Int J Cardiol.* 2016; 223: 313-5. http://ac.els-cdn.com/S0167527316319568/1-s2.0-S0167527316319568-main.pdf?_tid=22605960-f45f-11e6-86ba-00000aab0f02&acdnat=1487260191_41ff105e3768beec21e5579e930d0a2f

Viani S, Zucchelli G, Paperini L, Soldati E, Segreti L, Di Cori A, Menichetti F, Coluccia G, Andreini D, Branchitta G, Bongiorni MG. **Subcutaneous Implantable Defibrillator in an acromegalic pregnant woman for secondary prevention of sudden cardiac death: When (2) technologies save (2) lives.** *Int J Cardiol.* 2016; 223: 313-5. http://ac.els-cdn.com/S0167527316319568/1-s2.0-S0167527316319568-main.pdf?_tid=5a8bc604-7051-11e6-b168-00000aab0f26&acdnat=1472740719_69a5173e26c14672c122f654ac021e45 Boston Scientific (Emblem A209 S-ICD; subcutaneous lead 3401).

Akin I, Roger S, Borggreffe M, Kuschyk J. **Impeding sudden cardiac death despite subcutaneous implantable**

defibrillator due to fatal crosstalk. *J Cardiovasc Electrophysiol.* 2015: Epub before print. <http://onlinelibrary.wiley.com/doi/10.1111/jce.12871/pdf> Boston Scientific (Emblem S-ICD). We report the case of an 89-year-old patient being admitted electively for implantation of a subcutaneous implantable defibrillator (S-ICD). Previously a dual-chamber pacemaker (DDD-R) was implanted in 1997 for a complete atrio-ventricular (AV-) block and revised in 2005 and 2012 (St. Jude Medical Accent DR). Pacemaker interrogation showed 100% right ventricular stimulation without intrinsic ventricular signals. Venography revealed fully thrombosed left internal jugular vein and thrombosis of the subclavian veins on both sides.

Allocca G, Sitta N, Turiano G. **Inappropriate shocks by subcutaneous defibrillator in a patient with arrhythmogenic right ventricular cardiomyopathy: problem fixed. *Europace.* 2015: Epub before print. <http://europace.oxfordjournals.org/content/europace/early/2015/04/03/europace.euv086.full.pdf> Boston Scientific (S-ICD).**

Bader Y, Weinstock J. **Successful implantation of a subcutaneous cardiac defibrillator in a patient with a preexisting deep brain stimulator. *HeartRhythm Case Reports.* 2015; 1 (4): 241-4. [http://www.heartrhythmcasereports.com/article/S2214-0271\(15\)00074-3/pdf](http://www.heartrhythmcasereports.com/article/S2214-0271(15)00074-3/pdf) Boston Scientific (S-ICD); Medtronic (Activa DBS); Medtronic (Venitex Cadence); ST Jude Medical (Riata).**

Beutler BD, Cohen PR. **Reticular telangiectatic erythema: case report and literature review. *Dermatol Pract Concept.* 2015; 5 (1): 71-5. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4325699/pdf/dp0501a16.pdf>**
BACKGROUND: Reticular telangiectatic erythema is a benign cutaneous reaction that may occur in patients who have received a subcutaneous implantable cardioverter-defibrillator. Reticular telangiectatic erythema is characterized by asymptomatic telangiectasias, blanchable erythematous patches, or both overlying and/or adjacent to the subcutaneous implantable cardioverter-defibrillator. PURPOSE: We describe a man who developed reticular telangiectatic erythema after receiving a subcutaneous implantable cardioverter-defibrillator and review the salient features of this condition. We also summarize the conditions that can mimic reticular telangiectatic erythema. MATERIALS AND METHODS: The features of a man with reticular telangiectatic erythema are presented and the literature on reticular telangiectatic erythema is reviewed. RESULTS: Our patient developed reticular telangiectatic erythema within one month of subcutaneous implantable cardioverter-defibrillator insertion. The subcutaneous manifestations were asymptomatic. The patient concurred to have periodic clinical follow up and his condition will be monitored for any changes. CONCLUSION: Reticular telangiectatic erythema is a benign condition characterized by the development of erythema, telangiectasia, or both following insertion of a subcutaneous implantable cardioverter-defibrillator. Other subcutaneous implantable cardioverter-defibrillator-related side effects, such as pressure dermatitis and contact dermatitis, can mimic the condition. Reticular telangiectatic erythema can also be observed following insertion of other devices or, rarely, in the absence of inserted devices. Local microcirculatory changes and subcutaneous implantable cardioverter-defibrillator-related obstruction of blood flow have been suggested as possible mechanisms of pathogenesis. The diagnosis can usually be established by clinical presentation. Therefore, patch testing can usually be omitted. Reticular telangiectatic erythema is typically asymptomatic and thus removal of the device is not required.

Ceresnak SR, Motonaga KS, Rogers IS, Viswanathan MN. **Right-sided subcutaneous implantable cardioverter-defibrillator placement in a patient with dextrocardia, tetralogy of Fallot, and conduction disease. *HeartRhythm Case Reports.* 2015; 1 (4): 186-9. http://ac.els-cdn.com/S2214027115000299/1-s2.0-S2214027115000299-main.pdf?_tid=a07a1d0a-c09c-11e6-9f2c-00000aab0f02&acdnat=1481569142_80b5354eb0315652fbbb43136c86fa83 Boston Scientific (SQ-RX S-ICD).**

Chan NY, Yuen HC, Mok NS. **Right Parasternal Electrode Configuration Converts a Failed Electrocardiographic Screening to a Pass for Subcutaneous Implantable Cardioverter-Defibrillator Implantation. *Heart Lung Circ.* 2015; 24 (12): Epub before print. *This article is not in the KR collection.* BACKGROUND: Pre-operative electrocardiographic (ECG) screening before subcutaneous implantable cardioverter-defibrillator (SICD) implantation is essential to prevent T-wave oversensing and inappropriate shocks. The failure rate of ECG screening was reported to be up to 8% when only two body positions were tested. METHOD: Three subcutaneous ECG vectors represented by lead I, II and III were obtained in standing, supine, sitting and squatting positions. A patient qualified if the ECG in any same lead passed in all four positions. We report a 31-year-old man with idiopathic ventricular fibrillation who failed ECG screening for SICD implantation with the conventional left parasternal electrode (LPS) configuration in all three subcutaneous ECG vectors. Right parasternal electrode (RPS) configuration with left arm and right arm ECG electrodes positioned 1cm lateral to right sternal border was attempted for screening. RESULT: The amplitude of the QRS complex was significantly larger in the RPS compared to the LPS configuration in lead III and the patient passed the ECG screening in four**

body positions. He underwent successful S-ICD implantation with RPS approach with appropriate sensing both during the procedure and exercise treadmill test four weeks later. Ventricular fibrillation was successfully converted with 65J standard polarity shock during the procedure and no ICD shock was experienced by the patient on six-month follow-up. **CONCLUSION:** RPS configuration may be considered in patients who fail the ECG screening with the conventional LPS approach for S-ICD implantation.

Conte G, Regoli F, Moccetti T, Auricchio A. **Subcutaneous implantable cardioverter-defibrillator and drug-induced Brugada syndrome: the importance of repeat morphology analysis during ajmaline challenge.** *Eur Heart J.* 2015: Epub before print. <http://ehj.prod-oup.highwire.org/content/ehj/early/2015/11/02/eurheartj.ehv572.full.pdf> "...To date, no information is available on S-ICD morphology analysis in patients with Brugada syndrome and normal baseline electrocardiogram. Repeat analysis during ajmaline challenge could be useful in this category of patients to evaluate the appropriateness of S-ICD indication and avoid inappropriate shocks..."

De Maria E. **New skin closure system facilitates wound healing after cardiovascular implantable electronic device surgery.** *World J Clin Cases.* 2015; 3 (8): 675-7.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4539406/pdf/WJCC-3-675.pdf> *Zipline Medical (ZipLine; Zip Surgical Skin Closure)*. The manuscript describes the efficacy of a new skin closure system (ZipLine) for wound closure after pacemaker/implantable cardioverter defibrillator surgery. The system is particularly useful when wound healing is difficult with traditional methods and in patients at high risk for surgical site infections (SSIs). This skin closure option is easy and quick to apply and remove, and produces excellent cosmetic results. Although it is associated with a minimal expense upcharge, the benefits, including the potential for decrease in SSI, make it attractive and worth considering for skin closure in device patients, particularly those at increased risk of complications. {...Here we present two cases of CIED surgery wounds treated with Zip™ system. In the first case the system was placed as first-line option after the replacement of a subcutaneous defibrillator [S-implantable cardioverter defibrillator (ICD)] due to battery depletion...The second patient was an obese diabetic on hemodialysis who had an incomplete wound healing three weeks after a transvenous ICD placement..}.

Frommeyer G, Dechering DG, Zumhagen S, Kobe J, Eckardt L, Reinke F. **Limitations in S-ICD therapy: reasons for system explantation.** *Clin Res Cardiol.* 2015: Epub before print.

http://download.springer.com/static/pdf/596/art%253A10.1007%252Fs00392-015-0880-x.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs00392-015-0880-x&token2=exp=1436542825~acl=%2Fstatic%2Fpdf%2F596%2Fart%25253A10.1007%25252Fs00392-015-0880-x.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs00392-015-0880-x*~hmac=fb55664a6f0b4c76581f1fdc5061c81777476c1455533074d288bed96194c9b3 *Boston Scientific (S-ICD); Zoll Medical (LifeVest)*. Mentions *EFFORTLESS* registry. 6 patients. .

Frommeyer G, Reinke F, Eckardt L, Wasmer K. **Inappropriate shock in a subcutaneous ICD due to interference with a street lantern.** *Int J Cardiol.* 2015; 198: 6-8. http://ac.els-cdn.com/S0167527315300723/1-s2.0-S0167527315300723-main.pdf?_tid=3069f8e8-2717-11e5-812f-00000aab0f6b&acdnt=1436541805_3717afa179ddd192afb79e67d01e69d2

Boston Scientific (S-ICD). "...17 year old patient...He was sitting leaned against a street lantern at a railway station and reported that he stood up immediately after shock delivery. The present case reveals a new potential problem S-ICD recipients may face in daily life. The position of the pulse generator and the subcutaneous location of the sensing electrode may enhance such interference when leaning on electrically powered hardware..." Fig. 2. Subcutaneous EGM of inappropriate shock delivery due to oversensing of external electrical interference.

Gupta A, Subzposh F, Hankins SR, Kutalek SP. **Subcutaneous implantable cardioverter-defibrillator implantation in a patient with a left ventricular assist device already in place.** *Tex Heart Inst J.* 2015; 42 (2): 140-3.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382880/pdf/i0730-2347-42-2-140.pdf> *Boston Scientific (SQ-RX model 1010); Medtronic (Concerto II D274TRK); HeartMate II LVAD)*. A 56-year-old man with ischemic cardiomyopathy, a biventricular implantable cardioverter-defibrillator (ICD), and a left ventricular assist device (LVAD) developed a pocket hematoma and infection after an ICD generator change. The biventricular ICD was extracted, and the patient was given a full course of antibiotics. Because he had no indications for bradycardia pacing or biventricular pacing, he was implanted with a subcutaneous ICD under full anticoagulation. There was no interference in sensing or shock delivery from the ICD. The LVAD readings were unchanged during and after the procedure. The patient had an uneventful postoperative course, and both devices were functioning normally. To our knowledge, this is the first reported case of the implantation of a subcutaneous ICD in the presence of an LVAD. This report illustrates that both devices can be implanted successfully in the same patient. In addition, the subcutaneous ICD minimizes the risk of bloodstream infections, which can be fatal in patients who have life-supporting devices such as an LVAD. [...We acknowledge the technical support provided by Jay Overcash,

CCDS (Boston Scientific Corporation), in this case."].

- Hong PS, Callinan P, Amit G, Healey JS. **Successful Implant of a Subcutaneous ICD System in a Patient with an Ipsilateral Epicardial Pacemaker.** *Indian Pacing Electrophysiol J.* 2015; 15 (1): 62-4. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4380696/pdf/ipej150062-00.pdf> Boston Scientific employee (Callinan). Boston Scientific (S-ICD).
- Infusino T, Valsecchi S, Rigano M, Maselli D. **Perioperative management of a patient with subcutaneous defibrillator undergoing cardiac surgery.** *Springerplus.* 2015; 4: 533 [2 pages]. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4577496/pdf/40064_2015_Article_1315.pdf We describe a case of inappropriate shocks due to temporary epicardial pacing after cardiothoracic surgery in a patient with a subcutaneous ICD. ["...According to our experience, cardiac surgery through median sternotomy is feasible in the setting of a previously implanted S-ICD system, but care must be taken to avoid cautery application to the lead, and placing the metal sternal wires in contact with the lead. If post-operative pacing is required, it is strongly advised to use bipolar wires and to carefully program the pacemaker..."].
- Kaczmarek K, Zwolinski R, Bartczak K, Ptaszynski P, Wranicz JK. **A subcutaneous implantable cardioverter-defibrillator - the first implantation in Poland.** *Kardiol Pol.* 2015; 73 (1): 62. <http://ojs.kardiologiapolska.pl/kp/article/download/KP.2015.0010/7981> Medtronic (tricuspid valve); "...We present the first Polish experience of implantation of a S-ICD system. This modern therapy is an option for those patients who cannot have a standard ICD implanted for any reason, e.g. vascular abnormalities or intravascular infection. This procedure, although it is still not routinely reimbursed by the public health system, has become a new treatment option for Polish patients...".
- Kaczmarek KA, Winter J, Wranicz JK, Ptaszynski PA. **Atypical position of subcutaneous implantable cardioverter-defibrillator as a solution in hypertrophic cardiomyopathy patient with initially negative electrocardiographic screening.** *Eur Heart J.* 2015: Epub before print. <http://eurheartj.oxfordjournals.org/content/ehj/early/2015/06/02/eurheartj.ehv209.full.pdf> Cameron Health.
- Katz JS, Rajper N, Giedd KN. **SPECT attenuation artifact in a patient with a subcutaneous implantable cardioverter-defibrillator.** *J Nucl Cardiol.* 2015: Epub before print. <http://rd.springer.com/article/10.1007%2Fs12350-015-0095-6> Boston Scientific (S-ICD). "...We present the case of a patient with an s-ICD who had an apparent dense attenuation artifact on SPECT MPI caused by the device's pulse generator...".
- Kiamanesh O, O'Neill D, Sivakumaran S, Kimber S. **Inappropriate shocks by subcutaneous implantable cardioverter-defibrillator due to T-wave oversensing in hyperkalemia leading to ventricular fibrillation.** *HeartRhythm Case Reports.* 2015; 1 (4): 257-9. [http://www.heartrhythmcasereports.com/article/S2214-0271\(15\)00090-1/pdf](http://www.heartrhythmcasereports.com/article/S2214-0271(15)00090-1/pdf) Medtronic (Protecta XT); Boston Scientific (SQ-RX model 1010; Q-Trak 3010).
- Lau KC, Shah MJ. **Subcutaneous implantable cardioverter defibrillator device malfunction: first report of a "high current" condition triggering device failure.** *J Interv Card Electrophysiol.* 2015: Epub before print. http://download.springer.com/static/pdf/257/art%253A10.1007%252Fs10840-015-9985-4.pdf?auth66=1425344984_a3c88b04f53faf449d1b0fad400646b5&ext=.pdf Boston Scientific (SQ-RX model 1010; model 3010 electrode). "...This is the first report of a S-ICD failure secondary to a high current condition (Manufacturer and User Facility Device Experience report#MW5038415)...This particular ICD technology also lacks remote monitoring, which could have provided an earlier notification of device inoperability. The duration of time in which our patient was unprotected[^] may thus have been as long as the 6-month time interval between his in-office evaluations. Close surveillance of S-ICD recipients should therefore be maintained due to the unpredictable nature of this problem.".
- Lim TS, Tan BY, Ho KL, Lim CY, Teo WS, Ching CK. **Initial experience of subcutaneous implantable cardioverter defibrillators in Singapore: a case series and review of the literature.** *Singapore Med J.* 2015; 56 (10): 580-5. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4613935/pdf/SMJ-56-580.pdf> Boston Scientific (S-ICD). Transvenous implantable cardioverter defibrillators are a type of implantable cardiac device. They are effective at reducing total and arrhythmic mortality in patients at risk of sudden cardiac death. Subcutaneous implantable cardioverter defibrillators (S-ICDs) are a new alternative that avoids the disadvantages of transvenous lead placement. In this case series, we report on the initial feasibility and safety of S-ICD implantation in Singapore.
- Migliore F, Bottio T, Iliceto S, Bertaglia E. **Submuscular approach for subcutaneous implantable cardioverter defibrillator: A potential alternative technique.** *J Cardiovasc Electrophysiol.* 2015: Epub before print. <http://onlinelibrary.wiley.com/store/10.1111/jce.12642/asset/jce12642.pdf?v=1&t=i6sll2k5&s=0246b75303643a36>

[6a1c629b389d5472c0ea6b3d](#) Cameron Health (SQ-RX 1010). A 46-year-old man with cardiac amyloidosis underwent implantable cardioverter defibrillator (ICD) after an episode of ventricular fibrillation at rest. Because of device infection, lead extraction was performed. Subsequently, we decided to implant a subcutaneous ICD (S-ICD) (SQ-RX 1010, Cameron Health(R)). We developed a submuscular approach to avoid potential pocket complications due to the size of the device. This article is protected by copyright. All rights reserved.

Mondésert B, Dubuc M, Khairy P, Guerra PG, Gosselin G, Thibault B. **Combination of a leadless pacemaker and subcutaneous defibrillator: First in-human report.** *HeartRhythm Case Reports*. 2015; 1 (6): 469-71. http://ac.els-cdn.com/S2214027115001578/1-s2.0-S2214027115001578-main.pdf?_tid=494ee35c-c09d-11e6-9f01-00000aacb35e&acdnat=1481569425_fe1e293d4c370c0c189f6b75a27f91aa Boston Scientific (SQ-RX); St Jude Medical (Nanostim).

Reeves JG, Kim JS, Mitchell MB, McCanta AC. **Implantation of the subcutaneous implantable cardioverter-defibrillator with retroperitoneal generator placement in a child with hypoplastic left heart syndrome.** *HeartRhythm Case Reports*. 2015; 1 (4): 176-9. http://ac.els-cdn.com/S2214027115000226/1-s2.0-S2214027115000226-main.pdf?_tid=94a9fdb0-c09c-11e6-b481-00000aab0f27&acdnat=1481569122_c174762e9c41d21a81f9b8163233eda0 Cameron Health (S-ICD); mentions Boston Scientific (Incepta E160). "...We report a life-threatening ventricular arrhythmia in a 3year-old boy weighing 13.5 kg with HLHS after RV-PA shunt creation, in whom the implantation of the S-ICD was successful with the placement of a retroperitoneal generator..."

Russo CR, Welch TD, Sangha RS, Greenberg ML. **Brugada Syndrome Presenting as Polymorphic Ventricular Tachycardia-Ventricular Fibrillation Lasting 94 Seconds Recorded on an Ambulatory Monitor.** *JAMA Intern Med*. 2015: Epub before print. <http://archinte.jamanetwork.com/data/Journals/INTEMED/0/icr150002.pdf> Importance: Cardiac arrhythmias are common causes of syncope. Brugada syndrome is an uncommon but serious genetic arrhythmia disorder that can be unmasked by medicines causing sodium channel blockade. Observations: This report documents a case of Brugada syndrome and polymorphic ventricular tachycardia-ventricular fibrillation not initially recognized in a patient taking nortriptyline and experiencing syncope. It also illustrates one of the longest episodes of ventricular fibrillation recorded on an ambulatory monitor (94 seconds). Although the baseline electrocardiogram did not demonstrate a typical appearance for Brugada syndrome, provocative testing with flecainide in this patient with documented polymorphic ventricular tachycardia revealed a Brugada electrocardiogram pattern. Conclusions and Relevance: Vigilance should be maintained for arrhythmia substrates such as Brugada syndrome in patients with typical symptoms when they are prescribed membrane-active medicines. Long-term ambulatory rhythm monitors can provide useful information in these cases, especially when symptoms are infrequent. ["...She was diagnosed with Brugada syndrome and received a subcutaneous implantable cardioverter-defibrillator (ICD). Her nortriptyline treatment was discontinued..."]

Santarpia G, Polimeni A, De Rosa S, Sabatino J, Curcio A, Indolfi C. **First case of subcutaneous implantable cardioverter-defibrillator extrusion.** *Int J Cardiol*. 2015; 192: 19-20. http://ac.els-cdn.com/S0167527315010141/1-s2.0-S0167527315010141-main.pdf?_tid=66119b1e-0867-11e5-a5a8-00000aacb361&acdnat=1433167769_46ab85394deb73a51395647ac2631f89 Boston Scientific (SQ model 1010). Fig. 1. Complete extrusion of the S-ICD out of the chest.

Steinberg C, Chakrabarti S, Krahn AD, Bashir J. **Nothing inside the heart – Combining epicardial pacing with the S-ICD.** *HeartRhythm Case Reports*. 2015; 1 (6): 419-23. http://ac.els-cdn.com/S2214027115000846/1-s2.0-S2214027115000846-main.pdf?_tid=6aa91a9a-c09d-11e6-ba7f-00000aab0f6b&acdnat=1481569481_69317a3f668cd1e5059bf394cd9e068b Boston Scientific (SICD; Altrua); Medtronic (Protecta XT; CapSure Epi 4968). "...We report the feasibility and safety of co-implantation of an S-ICD and a permanent epicardial pacemaker. Device programming is challenging because of the complex interaction of 2 separate devices, but this approach does seem feasible..."

Stevenson WG. **MY APPROACH to ventricular tachycardia.** *Trends Cardiovasc Med*. 2015; 25 (6): 565-6. http://ac.els-cdn.com/S1050173815001346/1-s2.0-S1050173815001346-main.pdf?_tid=10f98b62-6629-11e5-93f4-00000aab0f26&acdnat=1443476407_0551740a27de19302021a2da1e67ac53 "...We elected to place a transvenous ICD as a safety net. He asked us if he was a candidate for a subcutaneous ICD. This is a bad option for a patient with known monomorphic VT because there is no possibility of anti-tachycardia pacing; it can only deliver shocks to terminate VT. The ICD was programmed to provide anti-tachycardia pacing if VT recurs..."

van Gelder BM, Bracke FA, Simmers T. **Inappropriate shock because of triple counting in a patient with a subcutaneous implantable cardioverter defibrillator corrected by initiation of dual site left ventricular**

pacing. *Circ Arrhythm Electrophysiol.* 2015; 8 (1): 239-40. <http://circep.ahajournals.org/content/8/1/239.full.pdf> Medtronic (ADAPT ADDR1; Attain OTW lead model 4194); Boston Scientific (S-ICD; Acuity X4 Spiral L4678); St Jude Medical (Allura Quadra CRT-P).

Noheria A, Cha YM, Asirvatham SJ, Friedman PA. **Shoulder joint dislocation as an unusual complication of defibrillation threshold testing following subcutaneous implantable cardioverter-defibrillator implantation. *Indian Pacing Electrophysiol J.* 2014; 14 (6): 297-300.**

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4286953/pdf/ipej140297-00.pdf> Boston Scientific (S-ICD). A 53-year-old man underwent implantation of a totally subcutaneous ICD (S-ICD; Boston Scientific). He was positioned supine, with the left arm abducted, externally rotated (i.e. palm up) and strapped to the arm extender. The generator was placed in the left mid-axillary line along the 5th-6th intercostal spaces and the defibrillation coil was tunneled anterior to the sternum. Defibrillation threshold (DFT) testing with 65 J caused a forceful pectoralis twitch. The patient woke up with a painful anteriorly dislocated left shoulder. Glenohumeral dislocation due to DFT testing has not been previously reported. It is likely that this complication is specific to the S-ICD implantation, and is related to positioning with the arm abducted, externally rotated, and immobilized, and use of greater defibrillation energy with current pathway through the bulk of the pectoralis muscle. Precautions may include extending the arm palm down, strapping the arm loosely, and adduction of the arm for DFT testing.

Kolb C, Lennerz C, Semmler V, Jilek C. **Primary prevention of sudden cardiac death with an entirely subcutaneous defibrillator in a patient with a large right atrial thrombus. *Clin Res Cardiol.* 2013; 102 (2): 169-70.**

http://download.springer.com/static/pdf/940/art%253A10.1007%252Fs00392-012-0514-5.pdf?auth66=1351788708_a5b8e799b3a0a8c972069f3fa78a3bcd&ext=.pdf Cameron Health (SQ RX 1010). "...Due to the lack of thrombus regression during intensified anticoagulation, a wearable cardioverter-defibrillator was not deemed as a suitable solution in terms of "bridge-to-thrombus-regression". Instead, an entirely subcutaneous defibrillator was implanted..."

Mazzone P, Tsiachris D, Della Bella P. **Epicardial management of myocarditis-related ventricular tachycardia. *Eur Heart J.* 2013; 34 (3): 244.**

<http://eurheartj.oxfordjournals.org/content/early/2012/09/24/eurheartj.ehs316.full.pdf> Cameron Health (S-ICD); Biosense Webster (CARTO-3 System; Navistar ThermoCool). "...The patient refused implantation of a transvenous implantable cardioverter-defibrillator (ICD). On the basis of the presence of fast VT and the absence of a bradycardic pacing indication, an entirely subcutaneous ICD (Cameron Health, San Clemente, CA, USA) was implanted..."

Paiva L, Providencia R, Faustino A, Nascimento J. **Subclavian crush syndrome and subcutaneous ICD in primary prevention patients. *J Cardiovasc Med.* 2013: Epub before print.**

<http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=toc&SEARCH=01244665-900000000-00000.kc&LINKTYPE=asBody&LINKPOS=1&D=ovft> Boston Scientific (Teligen 100 F102; ENDOTAK RELIANCE G 0175; FINELINE II lead model 4474); Cameron Health (S-ICD; Q-Trak Subcutaneous Electrode model 3010). Subclavian crush syndrome is a cause of transvenous lead failure resulting from an entrapment of a lead between the clavicle and the first rib. This image case typifies a 'scissor-like' mechanism, which is considered one of the main reasons for subclavian crush syndrome. The multidetector computer tomography images of this complication are rare and due to their three-dimensional nature offer important insights concerning its causes.

Saeed D, Albert A, Westenfeld R, Maxhera B, Gramsch-Zabel H, O'Connor S, Lichtenberg A, Winter J. **Left ventricular assist device in a patient with a concomitant subcutaneous implantable cardioverter defibrillator. *Circ Arrhythm Electrophysiol.* 2013; 6 (3): e32-3.**

<http://circep.ahajournals.org/content/6/3/e32.full.pdf> "...The patient was placed on the heart transplantation list. A subcutaneous-implantable cardioverter/defibrillator (S-ICD; Cameron Health, San Clemente, CA) was electively implanted 1 month later for primary prevention..."

Valk SD, Dabiri-Abkenari L, Theuns DA, Thornton AS, Res JC, Jordaens L. **Ventricular fibrillation and life-threatening ventricular tachycardia in the setting of outflow tract arrhythmias - The place of ICD therapy. *Int J Cardiol.* 2013; 165 (2): 165-7.**

http://ac.els-cdn.com/S0167527312010509/1-s2.0-S0167527312010509-main.pdf?_tid=15935a3c-0bf4-11e2-ae34-00000aacb35e&acdnat=1349115553_25442644751574899eeb33bb00e83c43 7 patients. Table 1 clinical characteristics and arrhythmia. "...Implantation of a defibrillator may seem a step too far for some of these patients; however, high risk patients are entitled to a prophylactic device in our opinion. The absence of a lead in the heart, as possible with a subcutaneous ICD, poses no obstacles for further ablation if necessary..."

Zaki A, Zaidi A, Newman WG, Garratt CJ. **Advantages of a subcutaneous implantable cardioverter-defibrillator in**

lamp2 hypertrophic cardiomyopathy. *J Cardiovasc Electrophysiol.* 2013: Epub before print.
<http://onlinelibrary.wiley.com/doi/10.1111/jce.12142/pdf> *St Jude Medical (Ellipse ICD; Durata lead model 7120Q DF4); Cameron Health (SQ-RX 1010; Q-Trak 3010).* Danon disease is a rare X-linked lysosomal disease causing severe hypertrophic cardiomyopathy (LAMP2 cardiomyopathy) and an extremely poor prognosis in males, with several reported cases of sudden cardiac death despite the use of transvenous implantable cardioverter defibrillators (TV-ICD). We describe a case in which a TV-ICD was unable to defibrillate induced ventricular fibrillation (VF), but a wholly subcutaneous system (S-ICD) was successful in terminating induced VF and spontaneous ventricular tachycardia. These findings have relevance to the selection of device therapy in the management of these individuals and a wider group of young patients with severe hypertrophic cardiomyopathy.

De Maria E, Bonetti L, Patrizi G, Scrivener J, Andraghetti A, Di Gregorio F, Montin A, Zuccon G, Cappelli S. **Implantation of a completely subcutaneous ICD system: case report of a patient with Brugada syndrome and state of the art. *J Interv Card Electrophysiol.* 2012; 34 (1): 105-13.**

<http://www.springerlink.com/content/r65360r523w96685/fulltext.pdf> *Cameron Health (S-ICD).* AIMS: Complications of implantable cardioverter-defibrillator (ICD) therapy are often linked to transvenous lead insertion, lead failure, or infections. An entirely subcutaneous ICD system (S-ICD) avoids the need for the placement of electrodes within the heart and can provide clinical advantages. METHODS AND RESULTS: A 45-year-old patient with Brugada syndrome (spontaneous type 1 Brugada ECG, syncope during fever, family history of sudden death <45 years old) was implanted with an entirely S-ICD. A left lateral incision was made over the sixth rib in the anterior axillary line for pocket formation and pulse generator placement. The subcutaneous electrode was placed subcutaneously, parallel to and 2 cm to the left of the sternal midline, and was connected to the generator. The insertion of the system was guided only by anatomical landmarks, and no fluoroscopy was required. Ventricular fibrillation was induced and terminated by a 65-J shock (15-J safety margin). No complication occurred, and subsequent course was uneventful. CONCLUSIONS: S-ICD is a new system for delivering lifesaving shock therapy in patients at risk of sudden cardiac death, without the need of intracardiac leads. Young patients with inherited arrhythmogenic syndromes could benefit the most from this system. This is the first case of Brugada syndrome implanted with a first-generation S-ICD in Italy.

McLeod KA, McLean A. **Implantation of a Fully Subcutaneous ICD in Children. *Pacing Clin Electrophysiol.* 2012; 35 (1): e20-e3.** <http://dx.doi.org/10.1111/j.1540-8159.2010.02865.x> *Cameron Health (S-ICD; SQ-RX; Q-Trak lead; T-GUIDE tunneling tool).* The subcutaneous implantable cardioverter defibrillator (S-ICD) from Cameron Health (San Clemente, CA, USA) does not require a lead to be placed on or in the heart. Such a device, being subcutaneous, has potential benefits in children who require ICDs where problems largely relate to transvenous or epicardial leads and inappropriate shocks. The S-ICD was approved for use in Europe in June 2009 and recently a study commenced to acquire data in 330 patients in order to submit to the FDA. We shall describe the implantation of the S-ICD in two children aged 10 and 12 years at our institution. ["Figure 1. The subcutaneous ICD (S-ICD) (Cameron Health, San Clemente, CA, USA). The device consists of a generator and a subcutaneous lead, which has two electrodes on either side of the coil.:Figure 2. Chest x-ray the day after implantation of the S-ICD in boy B, showing the generator in the midaxillary pocket and the position of the subcutaneous lead. There is some slack in the lead parasternally and behind the generator, which may help to compensate for growth; Figure 3. Appearance of the chest wall 1week following implantation of the S-ICD in boy B, showing the three scars and the bulk of the generator evident in the left mid-axillary position."].

Peters B, Will A, Berger F, Butter C. **Implantation of a fully subcutaneous ICD in a patient with single ventricle morphology and Eisenmenger physiology. *Acta Cardiol.* 2012; 67 (4): 473-5.** <https://secure.peeters-leuven.be/POJ/purchaseform.php?id=2170692&sid=> *Cameron Health (S-ICD; Q-Trak subcutaneous lead; Q-Guide tunneling tool; Q-TECH programmer model 2020).* Implantable cardioverter-defibrillator (ICD) therapy has been adopted increasingly in congenital heart disease. However, in patients with intracardiac right-to-left shunting the use of standard transvenous ICD lead systems is relatively contraindicated due to the increased risk of systemic thromboembolism. In this constellation, a recently introduced totally subcutaneous ICD system (S-ICD) seems to be a good and minimal invasive alternative to conventional epicardial ICD therapy. Here we describe the first use of this S-ICD in a patient with single ventricle and Eisenmenger physiology. In this unusual cardiac anatomy modification of the standard implantation technique by use of short sequences of fluoroscopy helped to ensure exact electrode and can placement and thus regular function of the S-ICD system.

van Oostrom AJ, Wijffels MC, van Boven WJ, Nicastia D, Boersma LV. **Positron emission tomography in a complex case of cardiac device-related infection. *Europace.* 2012: Epub before print.**
<http://europace.oxfordjournals.org/content/early/2012/05/11/europace.eus108.full.pdf> *Cameron Health (S-ICD); Cook Medical (Dilator sheaths).*

- Van Opstal JM, Blaauw Y, Pison LP. **A completely subcutaneous implantable cardioverter defibrillator in a patient with situs inversus totalis.** *J Cardiovasc Electrophysiol.* 2012; 23 (3): 333. <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8167.2011.02076.x/pdf> *Cameron Health (S-ICD).*
- Yamada T, Robertson Peter G, McElderry HT, Doppalapudi H, Plumb Vance J, Kay GN. **Successful reduction of a high defibrillation threshold by a combined implantation of a subcutaneous array and azygos vein lead.** *Pacing Clin Electrophysiol.* 2012; 35 (6): e173-6. <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8159.2012.03332.x/pdf> A 72-year-old man with nonischemic cardiomyopathy was referred because his implantable cardioverter defibrillator had failed to terminate spontaneous ventricular fibrillation (VF). Defibrillation threshold (DFT) testing confirmed that 830-V shocks failed to defibrillate VF despite optimization of the biphasic waveform and reversal of shock polarity. The placement of a new right ventricular lead and the addition of a subcutaneous array failed to defibrillate VF at 830 V. The combination of a subcutaneous array and azygos vein coil successfully defibrillated VF. The mechanism for successful DFT reduction was likely greater current supplied to the posterior basal left ventricle by the azygos vein lead. (c)2012, The Authors. Journal compilation (c)2012 Wiley Periodicals, Inc.
- Zumhagen S, Grace AA, O'Connor S, LÖHer A, KÖBe J, Eckardt L, Schulze-Bahr E. **Totally Subcutaneous Implantable Cardioverter Defibrillator with an Alternative, Right Parasternal, Electrode Placement.** *Pacing Clin Electrophysiol.* 2012; 35 (9): e254-e7. <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8159.2011.03043.x/pdf> *Cameron Health (S-ICD).* The totally subcutaneous implantable cardioverter-defibrillator (S-ICD) is an entirely novel defibrillation device that avoids the direct contact of device electrodes with the heart and the cardiovascular system. Here, we present a particular case of a young woman with congenital long-QT syndrome in which we implanted the electrode alternatively, right parasternally. This decision was based on the thoracic anatomy of the patient and on findings of a model of S-ICD electrodes in an adult torso. In conclusion, in some patients an alternative subcutaneous electrode position may be carefully considered but should not be taken to outweigh the standard left-sided placement. .
- Mehta PA, Bostock J, Rinaldi CA. **A modified subcutaneous implantable cardioverter-defibrillator implant in a patient with a previous left ventricular epicardial defibrillation patch.** *Europace.* 2011; 14 (1): 149-50. <http://europace.oxfordjournals.org/content/early/2011/08/26/europace.eur262.full.pdf> *Guidant (RV pace/sense leads? and LV epicardial defibrillation patch A76); Cameron Health (SQ RX 1010; S-ICD lead QTRAK 3010).* We describe a case of subcutaneous implantable cardioverter-defibrillator (ICD) implant in a patient with an existing epicardial defibrillation patch. Potential issues with shock vector shielding were overcome by a modification of the generator implant site and poor sensing were successfully managed by programming a sensing vector which excluded the generator.
- Neuzil P, Petru J, Reddy VY. **Subcutaneous icd implantation in the setting of an occluded superior vena cava.** *J Cardiovasc Electrophysiol.* 2011; 22 (4): 475-6. <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8167.2010.01953.x/pdf> *Cameron Health (S-ICD).* Complete ICD system explanted after 2nd pocket infection and replaced with S-ICD.
- van Opstal J, Geskes G, Debie L. **A completely subcutaneous implantable cardioverter defibrillator system functioning simultaneously with an endocardial implantable cardioverter defibrillator programmed as pacemaker.** *Europace.* 2011; 13 (1): 141-2. <http://europace.oxfordjournals.org/content/early/2010/06/28/europace.euq187.full.pdf> *Boston Scientific (ENDOTAK lead model 0181; Teligen F110); Cameron Health (S-ICD).* Because of multiple ventricular lead fractures with inappropriate shocks, a 31-year-old male received a completely subcutaneous implantable cardioverter defibrillator (ICD) system with the already existing 'endocardial' ICD functioning as an atrial pacemaker.
- Baez-Escudero JL, Beshai JF, Burke MC. **Use of a primary prevention totally subcutaneous defibrillator in hypertrophic cardiomyopathy.** *Circ Arrhythm Electrophysiol.* 2010; 3 (5): 560-1. <http://circep.ahajournals.org/content/3/5/560.full.pdf> *Cameron Health ((S-ICD).*
- Sousa PJ, Cavaco D, Neves JP, Adragao P, Brito J, Carmo P, Bouzin M, Bernardo R, Santos KR, Morgado FB, Silva Jose A. **Subcutaneous ICD implantation.** *Rev Port Cardiol.* 2010; 29 (3): 451-7. <http://www.spc.pt/DL/RPC/artigos/1181.pdf> *Medtronic (Sprint Quattro); Cameron Heart (S-ICD SQ-RX).* Mentions START, AVID, MUSTT, CIDS, CASH, MADIT II, SCD-HeFT. An 18-year-old patient, with hypertrophic cardiomyopathy and an implantable cardioverter defibrillator for 6 years, was admitted with inappropriate shocks

as a consequence of a lead fracture (Sprint Quattro, Medtronic). The device was explanted and replaced with a new subcutaneous defibrillator (Cameron SQ-RX), without complications. This was the first time that a subcutaneous cardioverter defibrillator had been used in the Iberian Peninsula. The new implantable defibrillator, with subcutaneous lead and generator, can lower the risk of complications, including lead fracture or infection. Furthermore, this device has good rhythm diagnostic performance and therapeutic efficacy. Following the case report, we present a brief review of the new defibrillator with subcutaneous implantation.

Pai RK, Cadman CS. **Subcutaneous implantable cardioverter-defibrillator lead erosion after weight loss.** *Cardiol Rev.* 2005; 13 (1): 27.
<http://graphics.tx.ovid.com/ovftpdfs/FPDDNCGCODOKOM00/fs047/ovft/live/gv024/00045415/00045415-200501000-00006.pdf>

Editorials

Wiles BM, Roberts PR. **Lead or be led: an update on leadless cardiac devices for general physicians.** *Clin Med.* 2017; 17 (1): 33-6. <http://www.clinmed.rcpjournal.org/content/17/1/33.full.pdf> Implantable cardiac devices have an increasingly important role. Pacemakers remain the only effective treatment for symptomatic bradycardia; cardiac resynchronisation therapy is a proven treatment for heart failure; and implantable cardioverter defibrillators (ICD) are superior to medical therapy in prevention of sudden cardiac death. Our ageing population has led to a rising number of device implants. Physicians in all specialties increasingly encounter patients with cardiac devices and require an understanding of their capabilities and functions. The rising prevalence of implantable devices has been matched by a parallel expanse in device technology. Leadless devices have become a reality and represent the future of device therapy. The absence of a transvenous lead offers a significant clinical advantage because of many well established issues related to lead complications. The leadless pacemaker and subcutaneous ICD are significant new products that are currently not well recognised or understood by general physicians. © Royal College of Physicians 2017. All rights reserved.

Bhakta D, Foreman L. **Editorial Commentary: Keeping it simple: The subcutaneous implantable cardioverter defibrillator.** *Trends Cardiovasc Med.* 2016: Epub before print. http://ac.els-cdn.com/S1050173816300020/1-s2.0-S1050173816300020-main.pdf?_tid=b4983c9a-1147-11e6-8fff-00000aacb35f&acdnat=1462291215_5fd6f95b7ed113cf63db72e8356755ee Comment on: Willcox M, Prutkin J, Bardy G. Recent developments in the subcutaneous ICD. *Trends Cardiovasc Med* 2016 [in press].

Day J. **Highlights from Heart Rhythm 2016.** *Journal of Innovations in Cardiac Rhythm Management.* 2016; 7 (7): 2419–21. <http://www.innovationsincrm.com/images/pdf/crm-07-07-2419.pdf> OASIS Study. Heart Rhythm 2016 in San Francisco, CA was an incredible success by all measures. As other big cardiology meetings are decreasing, Heart Rhythm remains as strong as ever with more than 12,000 in attendance this year. In this article, I share my five biggest takeaways from Heart Rhythm 2016. 1. The subcutaneous ICD works, 2. Leadless pacemakers are the future, 3. Evolving role of VT ablation, 4. Does warfarin cause dementia? 5. The ongoing persistent AF dilemma.

Estes NA, 3rd. **Clinical Outcomes of Patients Who Received the Subcutaneous Implantable Cardioverter Defibrillator.** *JAMA Cardiol.* 2016: Epub before print.
<http://cardiology.jamanetwork.com/data/Journals/CARDIOLOGY/0/hed160016.pdf>

Kidia KK. **Disheartening Disparities.** *N Engl J Med.* 2016; 374 (10): 909-11.
<http://www.nejm.org/doi/pdf/10.1056/NEJMp1512888> "...My family still lives in Zimbabwe, where there are no ICDs or heart surgeons or, in some places, ambulances...The \$40,000 subcutaneous ICD that rubs against my rib cage is a constant reminder of these inequalities..."

Knops RE, Brouwer TF. **Should the subcutaneous implantable defibrillator be the first choice for primary prevention of sudden cardiac death?** *Rev Esp Cardiol (Engl Ed).* 2016: Epub before print.
<http://www.revespcardiol.org/en/should-the-subcutaneous-implantable-defibrillator/avance-resumen/S1885585716303243/> "...The subcutaneous ICD is a radically different design that may offer long-term benefits by reducing lead-related complications. Long-term comparison data are urgently needed to establish its role among the various ICDs that are available today. From a costeffectiveness standpoint, considering the available evidence, it is difficult to argue that the subcutaneous ICD must be the first choice in primary prevention patients. We do believe, however, that the subcutaneous ICD shows strong promise to be superior in the long-term, which would make it the first choice for primary prevention of sudden cardiac death."

- Rinaldi CA. **The future direction of cardiac pacing?** *Trends Cardiovasc Med*. 2016: Epub before print. http://ac.els-cdn.com/S1050173816000694/1-s2.0-S1050173816000694-main.pdf?_tid=748a8386-1194-11e6-97a9-00000aab0f6b&acdnat=1462324179_6489bcac7189271891114cd9ca13ac75 *Comment on: Austin C, Kusumoto F. Innovative pacing: recent advances, emerging technologies and future directions in cardiac pacing by Austin and Kusumoto. Trends Cardiovasc Med 2016: epub before print. MORE CRT MPP.*
- Sharma PS, Ellenbogen KA. **Inside or outside of the heart: Where do we go from here?** *J Am Coll Cardiol*. 2016; 68 (19): 2056-8. http://ac.els-cdn.com/S0735109716351610/1-s2.0-S0735109716351610-main.pdf?_tid=7683a310-c0ae-11e6-9969-00000aab0f02&acdnat=1481576802_807b4b28722ee2b51f02a0c5e4a085b5 "...In summary, this study by Brouwer et al. (9) provides valuable insight into the long-term outcome differences between S- and TV-ICD systems. The possible use of S-ICD as a first-line strategy or as an alternative approach to TV-ICD for specific populations needs further evaluation using large clinical trials and registries, such as the PRAETORIAN (Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplAntable cardioverterdefibrillator therapy) study (11) and the EFFORTLESS S-ICD (Evaluation of FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS of the S-ICD) registry (12) that are currently ongoing."
- Crozier IG, Theuns DA. **Patients with congenital heart disease: how to determine the eligibility for implantation of a subcutaneous implantable defibrillator?** *Europace*. 2015: Epub before print. <http://europace.oxfordjournals.org/content/europace/early/2015/04/02/europace.euv087.full.pdf>
- Kuschyk J, Roger S, Fastner C, Behnes M, Akin I. **Subcutaneous ICD in anatomical challenging cases.** *Eur Rev Med Pharmacol Sci*. 2015; 19 (17): 3140-1. *This article is not in the KR collection.*
- Saeed M. **Subcutaneous implantable cardioverter-defibrillators: expanding the scope of technology.** *Tex Heart Inst J*. 2015; 42 (2): 139. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382879/pdf/i0730-2347-42-2-139.pdf> *HeartMate II.*
- Della Bella P, Vergara P. **The Subcutaneous ICD: A Niche Indication or the Next Contender of the Transvenous ICD?** *J Cardiovasc Electrophysiol*. 2013; 24 (1): 83-5. <http://onlinelibrary.wiley.com/doi/10.1111/jce.12013/pdf> *Comment on: Cappato R, et al: Feasibility of defibrillation and automatic arrhythmia detection using an exclusively subcutaneous defibrillator system in canines. J Cardiovasc Electrophysiol 2012; epub before print. Mentions START study.*
- Demaria AN, Bax JJ, Feld GK, Greenberg BH, Hall JL, Hlatky MA, Lew WY, Lima JA, Mahmud E, Maisel AS, Narayan SM, Nissen SE, Sahn DJ, Tsimikas S. **Highlights of the Year in JACC 2012.** *J Am Coll Cardiol*. 2013; 61 (3): 357-85. http://ac.els-cdn.com/S0735109712058378/1-s2.0-S0735109712058378-main.pdf?_tid=2f1e5f52-6cb5-11e2-8a25-00000aacb360&acdnat=1359753801_5f292f241521ca30080203ec80608de6 *PRELUDE (PRogrammed ELEctrical stimUlation preDictive valuE).* "...Old Nordkamp et al. (92) reported their initial experience using a totally subcutaneous implantable cardioverter defibrillator (SQ-ICD), ushering in a new era in ICD therapy..."
- Dubner S. **Implantation and follow-up of totally subcutaneous vs conventional implantable cardioverter-defibrillators: A multicenter case-control study.** *Heart Rhythm*. 2013; 10 (1): 37-8. http://ac.els-cdn.com/S1547527112012027/1-s2.0-S1547527112012027-main.pdf?_tid=cdca9eda-56a4-11e2-83db-00000aab0f01&acdnat=1357327840_aecff1c8bf7617feb63cb689b52027ea *Comments on: Kobe J, et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators—a multicenter case-control study. Heart Rhythm. 2013; 10: 29–36. "...Just as when the cell phone first appeared, despite the draw of this revolutionary idea, there were many challenges to overcome: large size, high cost, limited battery duration and so on. But the technology improved so fast that we forget that initial rough start, and now wholeheartedly embrace the new technology and all it does for us. Maybe s-ICD will follow a similar trend..."*
- Hauser R, G. **The subcutaneous implantable cardioverter-defibrillator: should patients want one?** *J Am Coll Cardiol*. 2013; 61 (1): 20-2. http://ac.els-cdn.com/S0735109712049182/1-s2.0-S0735109712049182-main.pdf?_tid=b5d67fc6-ed79-11e2-a16e-00000aab0f27&acdnat=1373911957_af5f0b02e7f5dcfb5354ffbbcb5b470 The subcutaneous implantable cardioverter-defibrillator is a novel device that does not require insertion of a transvenous lead; rather, it delivers 80-J transthoracic shocks via a subcutaneous pulse generator implanted in the left lateral chest and a subcutaneous left parasternal lead-electrode. It recently received approval by U.S. Food and Drug Administration panel on the basis of a 180-day study in 330 patients. However, it has not been shown to be non inferior to

current implantable cardioverter-defibrillators, and it does not provide either anti-tachycardia or bradycardia pacing. Thus, is this technology ready for widespread application? Specifically, should a patient want one? Copyright (c) 2013 American College of Cardiology Foundation. Published by Elsevier Inc. All rights reserved.

Sherrid MV. **The implanted cardioverter-defibrillator for children and adolescents with high risk of sudden death from hypertrophic cardiomyopathy.** *J Am Coll Cardiol.* 2013; 61 (14): 1536-8. http://ac.els-cdn.com/S0735109713004774/1-s2.0-S0735109713004774-main.pdf?_tid=ebeb9bec-9ba7-11e2-85fe-00000aab0f27&acdnat=1364915809_44a0e53b3aa2ad70d579e0342409c2c3 Comments on: Maron BJ, et al. *Prevention of sudden cardiac death with implantable cardioverter-defibrillators in children and adolescents with hypertrophic cardiomyopathy.* *J Am Coll Cardiol* 2013;61:1527–35. MADIT-RIT. "...The approval by the U.S. Food and Drug Administration of the completely subcutaneous ICD may offer a choice for patients who do not require ventricular pacing for persistent bradycardia or antitachycardia pacing..."

Denniss AR, Davis LM, Sanders P. **Advances in implantable cardiac electronic devices and cardiac electrophysiology.** *Heart Lung Circ.* 2012; 21 (6 7): 309-10. This article is not in the KR collection.

Foster W, Sopher M. **Developments in implantable cardioverter defibrillator therapy.** *European Cardiology.* 2012; 8 (2): 98-100. <http://www.touchcardiology.com/system/files/private/articles/15964/pdf/foster.pdf> Since the first implantable cardioverter defibrillator (ICD) implant in 1980, advances in the design of the devices, leads, detection algorithms and programming have led to major advances in device implantation, arrhythmia detection, recording and termination. Shocks from ICDs can be life-saving but increase morbidity, particularly when they are unnecessary or inappropriate. Recent evidence-based advances in programming have allowed reliable arrhythmia termination, in many cases without the need for shocks. The development of the subcutaneous ICD has allowed implantation in patients for whom vascular access may be difficult or best avoided. Remote monitoring of ICD patients allows some follow-up visits to be done in the patient's home and increases the diagnostic data available to the ICD centre. (c) Touch Briefings 2012.

Lee J. **Alternative heart therapy: Defibrillator is less invasive, called cost-effective.** *Mod Healthc.* 2012; 42 (44): 12-3. This article is in the KR collection. *Cameron Health (S-ICD).* "...Boston Scientific Corp. is betting that its newly approved subcutaneous implantable heart defibrillator will not only serve as a less invasive alternative, but also will reduce the need for costly follow-up procedures..."

Stambler BS. **ICD arrhythmia detection and discrimination algorithms: whose is best?** *J Cardiovasc Electrophysiol.* 2012; 23 (4): Epub before print <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8167.2011.02213.x/abstract> Comments on: Gold MR, Theuns DA, Knight BP, Sturdivant JL, Sanghera R, Ellenbogen KA, Wood MA, Burke MC: *Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous ICD arrhythmia detection algorithms: the START Study.* *J Cardiovasc Electrophysiol.* 2011: Epub before print. Boston Scientific (ICD algorithm RHYTHM ID), St Jude Medical (ICD algorithm), Medtronic (ICD algorithm). *Cameron Health (subcutaneous ICD).* mentions RIGHT study.

Crozier I. **The subcutaneous defibrillator will replace the transvenous defibrillator.** *J Interv Card Electrophysiol.* 2011; 32 (1): 73-7. <http://www.springerlink.com/content/k303202068305404/fulltext.pdf> *Cameron Health.* Mentions SCD-HeFT, PainFREE Rx II, SCD-HeFT, DINAMIT, DAVID, ENTRUST and MADIT-II trials. 1 The subcutaneous defibrillator is the natural evolution of defibrillator technology; 2 The S-ICD avoids all the risks associated with transvenous leads; 3 The S-ICD is easily implanted; 4 The Cameron S-ICD is the only purpose-built subcutaneous defibrillator with clinical experience; 5 The S-ICD effectively detects and terminates ventricular fibrillation; 6 The S-ICD was specifically designed to deal with the challenges of subcutaneous rhythm discrimination; 7 The S-ICD more closely approaches the ideal model of defibrillation; 8 The S-ICD is not appropriate for patients that have a pacing indication; 9 The S-ICD does not have antitachycardia pacing; 10 The mortality benefit from defibrillators is from shock therapy.

Daubert JP, Schuger C. **Percutaneous intravascular defibrillator: Preliminary data and many questions.** *Heart Rhythm.* 2011; 8 (2): 293-4. <http://www.sciencedirect.com/science/article/pii/S154752711001307X> *InnerPulse (InnerPulse percutaneous intravascular cardioverter defibrillator).* Comments on: Sanders WE Jr, Richey MW, Malkin RA, et al. *Novel intravascular defibrillator: defibrillation thresholds of intravascular cardioverter-defibrillator compared to conventional implantable cardioverter-defibrillator in a canine model* *Heart Rhythm* 2011;8:288–292. [Table 1 Comparison with current transvenous ICD: Subcutaneous ICD, Percutaneous ICD, LifeVest.].

Burke MC. **The infinite value in subcutaneous defibrillation.** *Heart Rhythm.* 2010; 7 (5): 699-700. <http://ac.els->

cdn.com/S1547527110001438/1-s2.0-S1547527110001438-main.pdf?_tid=5ed9dd38-adc5-11e2-af39-00000aab0f6b&acdnat=1366907578_f6c3f6b934b3001e024d74ee13f8dcf1 Comments on: Jolley M, et al. Finite element modeling of subcutaneous implantable defibrillator electrodes in an adult torso. *Heart Rhythm*. 2010; 7 (5): 692-8. *Cameron Health (S-ICD)*.

Spirito P, Boriani G. **Device therapy: A subcutaneous ICD-preliminary results.** *Nat Rev Cardiol*. 2010; 7 (10): 543-4. <http://graphics.tx.ovid.com/ovftpdfs/FPDDNCIBOFMOLH00/fs046/ovft/live/gv023/01429652/01429652-201010000-00010.pdf> *Cameron Health (S-ICD)*. "...Transvenous leads are the most common source of complications associated with the use of implantable cardioverter-defibrillators (ICDs). A preliminary experience with an entirely subcutaneous ICD system, which avoids the need for transvenous leads, has been reported. We discuss these results and the importance of investigations in this new field..."

Toma N. **An entirely subcutaneous implantable cardioverter-defibrillator.** *Maedica*. 2010; 5 (3): 225-6. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3177551/pdf/maed-05-225.pdf> "The authors report the results of two short-term trials of a temporarily inserted subcutaneous ICD electrode system, followed by two trials of long-term subcutaneous ICD implantation of a fully functional system..."

Cleland JG, Coletta AP, Lammiman M, Witte KK, Loh H, Nasir M, Clark AL. **Clinical trials update from the European Society of Cardiology meeting 2005: CARE-HF extension study, ESSENTIAL, CIBIS-III, S-ICD, ISSUE-2, STRIDE-2, SOFA, IMAGINE, PREAMI, SIRIUS-II and ACTIVE.** *Eur J Heart Fail*. 2005; 7 (6): 1070-5. <http://eurjhf.oxfordjournals.org/content/7/6/1070.full.pdf> Discusses S-ICD. Comment in *Eur J Heart Fail*. 2006 Mar;8(2):219-20 PMID 16488368 Comment in *Eur J Heart Fail*. 2006 Mar;8(2):221-2 PMID 16488369. This article provides information and a commentary on trials presented at the European Society of Cardiology meeting held in September 2005, relevant to the pathophysiology, prevention and treatment of heart failure. All reports should be considered as preliminary data, as analyses may change in the final publication. In the CARE-HF extension study, the benefits of cardiac resynchronisation therapy (CRT) observed in the original study were maintained over an increased follow-up period. A study of oral enoximone (25-50 mg t.i.d.) in advanced heart failure (ESSENTIAL) showed limited benefit compared to placebo. The CIBIS-III study showed that heart failure therapy could be safely initiated with bisoprolol followed by the addition of enalapril. A subcutaneous ICD system (S-ICD) showed potential as an alternative to a transvenous ICD. In the ISSUE-2 study, an implantable loop recorder was used to guide therapy in patients with recurrent syncope. The selective endothelin antagonist sitaxsentan improved 6-MWT and functional class in patients with pulmonary arterial hypertension in the STRIDE-2 study. In SOFA, fish oil had no beneficial effect on the incidence of life-threatening arrhythmias in patients with an ICD. In IMAGINE, quinapril showed no benefit when administered to patients following CABG. Perindopril reduced cardiac remodelling in post-MI patients with normal LV function in PREAMI. SIRIUS-II showed encouraging results for the use of intravenous ularitide in symptomatic decompensated chronic heart failure. The ACTIVE W study of warfarin versus aspirin plus clopidogrel in atrial fibrillation has been stopped due to superiority of warfarin.

Saksena S. **The leadless defibrillator or the return of the subcutaneous electrode: episode III in the ICD saga?** *J Interv Card Electrophysiol*. 2005; 13 (3): 179-80. <http://link.springer.com/content/pdf/10.1007%2Fs10840-005-4579-1.pdf> "...This concept has been reduced to practice in a new device developed and recently tested in pilot clinical studies (Cameron Health, San Jose, CA).The attractiveness of this concept stems from several viewpoints..."

Letters

Dhruva SS, Redberg RF. **Sex-Specific Data for the Subcutaneous Implantable Cardioverter-Defibrillator.** *J Am Coll Cardiol*. 2016; 68 (1): 133. http://ac.els-cdn.com/S0735109716328601/1-s2.0-S0735109716328601-main.pdf?_tid=fe1fbeda-42b4-11e6-9aa4-00000aab0f26&acdnat=1467725760_b32ccf00f1f3be1caa829f39ecc3d9d4 *Boston Scientific (S-ICD)*. "...Although the evidence base for S-ICDs is growing, it is still unfinished. Given the underrepresentation of women in S-ICD studies and the inconsistent data on benefits of ICDs for primary prevention in women, there is an urgent need to increase the enrollment of women and consider a female-only study of the S-ICD. Further, sex-specific analyses of outcomes should be required in future reports of the EFFORTLESS (Boston Scientific PostMarket S-ICD) registry..."

Dogan M, Uz O, Isilak Z. **Subcutaneous ICD implantation should be considered when confronting anatomically complex cases.** *Eur Rev Med Pharmacol Sci*. 2015; 19 (17): 3139. <http://www.europeanreview.org/wp/wp-content/uploads/3139-Letter-to-the-Editor.pdf>

Buga L, Tageldien A, Cleland JG. **An entirely subcutaneous implantable cardioverter-defibrillator.** *N Engl J Med.* 2010; 363 (16): 1577; author reply -8. <http://www.nejm.org/doi/pdf/10.1056/NEJMc1008499> *Comments on N Engl J Med.* 2010 Jul 1;363(1):36-44 PMID 20463331.

Kleijn S, van der Veldt A. **An entirely subcutaneous implantable cardioverter-defibrillator.** *N Engl J Med.* 2010; 363 (16): 1577; author reply -8. <http://www.nejm.org/doi/pdf/10.1056/NEJMc1008499> *Comments on N Engl J Med.* 2010 Jul 1;363(1):36-44 PMID 20463331.

Experimental Articles

Tjong FV, Brouwer TF, Kooiman KM, Smeding L, Koop B, Soltis B, Shuros A, Wilde AA, Burke M, Knops RE.

Communicating antitachycardia pacing-enabled leadless pacemaker and subcutaneous implantable defibrillator. *J Am Coll Cardiol.* 2016: Epub before print. http://ac.els-cdn.com/S0735109716008743/1-s2.0-S0735109716008743-main.pdf?_tid=81762910-f82b-11e5-b5df-00000aab0f6c&acdnat=1459530324_01b6e821bdd5e9664aaf2100658e9acc *Boston Scientific (leadless cardiac pacemaker prototype; S-ICD prototype).* "...The combined LCP and S-ICD therapy that was studied is a proof of concept of successful wireless device-device communication in cardiac rhythm management and a first step toward establishing multicomponent device systems that eliminate transvenous leads. We demonstrated appropriate VVI functionality, successful S-ICD to LCP communication, and ATP-delivery by the LCP. The next steps should include larger and chronic studies of independently functioning ATP-enabled LCP and S-ICD systems..."

Tjong FV, Brouwer TF, Smeding L, Kooiman KM, de Groot JR, Ligon D, Sanghera R, Schaliq MJ, Wilde AA, Knops RE.

Combined leadless pacemaker and subcutaneous implantable defibrillator therapy: feasibility, safety, and performance. *Europace.* 2016: Epub before print.

<http://europace.oxfordjournals.org/content/early/2016/03/02/europace.euv457> *St Jude Medical employee (Ligon); Boston Scientific employee (Sanghera). Cameron Health (S-ICD model 1010; Q-Tech Programmer); St Jude Medical (Nanostim; Merlin programmer; Nanostim Link).* **AIMS:** The subcutaneous implantable cardioverter-defibrillator (S-ICD) and leadless pacemaker (LP) are evolving technologies that do not require intracardiac leads. However, interactions between these two devices are unexplored. We investigated the feasibility, safety, and performance of combined LP and S-ICD therapy, considering (i) simultaneous device-programmer communication, (ii) S-ICD rhythm discrimination during LP communication and pacing, and (iii) post-shock LP performance. **METHODS AND RESULTS:** The study consists of two parts. Animal experiments: Two sheep were implanted with both an S-ICD and LP (Nanostim, SJM), and the objectives above were tested. Human experience: Follow-up of one S-ICD patient with bilateral subclavian occlusion who received an LP and two LP (all Nanostim, SJM) patients (without S-ICD) who received electrical cardioversion (ECV) are presented. Animal experiments : Simultaneous device-programmer communication was successful, but LP-programmer communication telemetry was temporarily lost (2 +/- 2 s) during ventricular fibrillation (VF) induction and 4/54 shocks. Leadless pacemaker communication and pacing did not interfere with S-ICD rhythm discrimination. Additionally, all VF episodes (n = 12/12), including during simultaneous LP pacing, were detected and treated by the S-ICD. Post-shock LP performance was unaltered, and no post-shock device resets or dislodgements were observed (24 S-ICD and 30 external shocks). Human experience : The S-ICD/LP patient showed adequate S-ICD sensing during intrinsic rhythm, nominal, and high-output LP pacing. Two LP patients (without S-ICD) received ECV during follow-up. No impact on performance or LP dislodgements were observed. **CONCLUSION:** Combined LP and S-ICD therapy appears feasible in all animal experiments (n = 2) and in one human subject. No interference in sensing and pacing during intrinsic and paced rhythm was noted in both animal and human subjects. However, induced arrhythmia testing was not performed in the patient. Defibrillation therapy did not seem to affect LP function. More data on safety and performance are needed.

Wang S, Lu Z, He W, He B, Xie J, Yu X, Jiang H. **Selective Ablation of the Ligament of Marshall Reduces the Prevalence of Ventricular Arrhythmias Through Autonomic Modulation in a Cesium-Induced Long QT Canine Model.** *JACC: Clinical Electrophysiology.* 2016; 2 (1): 97-106.

<http://www.sciencedirect.com/science/article/pii/S2405500X15003710> *PRAETORIAN.* AbstractObjectives The goal of this study was to investigate the effect of selective ablation of the ligament of Marshall (LOM) on ventricular arrhythmias (VAs). Background Previous studies have shown that selective stimulation of sympathetic elements of the LOM, the distal segment of the ligament of Marshall that extends beyond the left superior pulmonary vein (LOMLSPV), might induce VAs. Methods In protocol 1, the blood pressure and ventricular effective refractory period changes as a response to LOMLSPV stimulation and left stellate ganglion (LSG) stimulation were measured before and after LOMLSPV ablation in 8 anesthetized dogs. In protocol 2, a total of 24

dogs were randomly divided into group 1 (cesium alone, n = 8), group 2 (cesium combined with LSG stimulation, n = 8), and group 3 (cesium combined with LSG stimulation after LOMLSPV ablation, n = 8). Early afterdepolarization amplitude, VA prevalence, and the tachycardia threshold (measured according to the dose of cesium administered) were compared among the groups. Results In protocol 1, both LOMLSPV stimulation and LSG stimulation significantly increased blood pressure and shortened the ventricular effective refractory period, both of which were significantly attenuated by LOMLSPV ablation. In protocol 2, compared with group 1, the prevalence of VAs and the early afterdepolarization amplitudes were significantly augmented in group 2 and were maintained at a comparable level in group 3. Furthermore, the tachycardia threshold in group 2 (0.625 mmol/kg) was significantly lower than that noted in groups 1 and 3 (both 1.000 mmol/kg; $p < 0.05$). Conclusions LOMLSPV ablation reduced the prevalence of the VAs induced by cesium in combination with LSG stimulation, and the antiarrhythmic effect may involve the blockade of the sympathetic conduit between the LSG and the ventricles.

Eggen M, Grubac V, Bonner M. **Design and evaluation of a novel fixation mechanism for a transcatheter pacemaker.** *IEEE Trans Biomed Eng.* 2015: Epub before print.

<http://ieeexplore.ieee.org/ielx7/10/4359967/07132723.pdf?tp=&number=7132723&isnumber=4359967>

Medtronic employee (Grubac; Bonner). Medtronic (Micra; CapSure Sense). GOAL: The purpose of this work was to evaluate a nitinol tine fixation design for a transcatheter pacemaker in order to determine if the tines could be easily deployed and safely removed from the myocardium, enable low, stable pacing thresholds, and minimize the potential for dislodgment. METHODS: The penetration properties of 13 human hearts were compared to the deployment and fixation energy of the tines to determine if the tines could be easily deployed and removed from the myocardium. The safety factor for dislodgement was calculated by comparing the kinetic energy of the device to the fixation energy of the tines. The fixation stability was tested in 113 chronic implants across 89 animals via pacing threshold measurements or evidence of dislodgement at necropsy. RESULTS: Based on the tine fixation and tissue energy analysis, the tines can easily penetrate the heart. The tines can be safely removed from the myocardium based on the increased tine surface area during retraction. There were no dislodgements observed in the animals and the mean pacing threshold at implant was 0.59 +/- 0.21 V and at termination was 0.65 +/- 0.36 V. The safety factor for dislodgement was determined to be 15X during simulated exercise conditions. CONCLUSION: The nitinol tine fixation design enabled the implant of a self-contained pacemaker within the right ventricle and was effective in meeting the design requirements. SIGNIFICANCE: This fixation technology provides a novel solution to enable the attachment of a transcatheter pacemaker directly within the heart.

Noro M, Zhu X, Enomoto Y, Asami M, Ishii R, Toyoda Y, Sahara N, Takagi T, Narabayashi Y, Hashimoto H, Ito N, Kujime S, Oikawa Y, Tatsunami H, Sakai T, Nakamura K, Sakata T, Sugi K. **Efficacy and Myocardial Injury With Subcutaneous Implantable Cardioverter Defibrillators- Computer Simulation of Defibrillation Shock Conduction.** *Circ J.* 2015: Epub before print. https://www.jstage.jst.go.jp/article/circj/advpub/0/advpub_CJ-15-0883/pdf

Boston Scientific employees (Yasushiro Oikawa; Hiroyuki Tatsunami). BACKGROUND: Subcutaneous implantable cardiac defibrillator (S-ICD) systems have a lower invasiveness than traditional ICD systems, and expand the indications of ICD implantations. The S-ICD standard defibrillation shock output energy, however, is approximately 4 times that of the traditional ICD system. This raises concern about the efficacy of the defibrillation and myocardial injury. In this study, we investigated the defibrillation efficacy and myocardial injury with S-ICD systems based on computer simulations. Methods and Results: First, computer simulations were performed based on the S-ICD system configurations proposed in a previous study. Furthermore, simulations were performed by placing the lead at the left or right parasternal margin and the pulse generator in the superior and inferior positions (0-10 cm) of the recommended site. The simulated defibrillation threshold (DFT) for the 4 S-ICD system configurations were 30.1, 41.6, 40.6, and 32.8 J, which were generally similar to the corresponding clinical results of 33.5, 40.4, 40.1, and 34.3 J. CONCLUSIONS: The simulated DFT were generally similar to their clinical counterparts. In the simulation, the S-ICD system had a higher DFT but relatively less severe myocardial injury compared with the traditional ICD system. Further, the lead at the right parasternal margin may correspond to a lower DFT and cause less myocardial injury.

Cappato R, Castelvechio S, Erlinger P, Sanghera R, Scheck D, Ostroff A, Rissmann W, Gropper C, Bardy GH.

Feasibility of Defibrillation and Automatic Arrhythmia Detection Using an Exclusively Subcutaneous Defibrillator System in Canines. *J Cardiovasc Electrophysiol.* 2013; 24 (1): 77-82.

<http://onlinelibrary.wiley.com/doi/10.1111/j.1540-8167.2012.02432.x/abstract>

Cameron Health (S-ICD).

Introduction: This study reports the experimental process leading to development of an automatic totally subcutaneous implantable cardioverter defibrillator (SICD) system engineered for human use. Methods and Results: Two studies were conducted to test defibrillation and detection feasibility of an SICD system located in the left chest. In the first study, 2 pockets were created in 15 canines for placement of an anterior electrode adjacent to the left edge of the sternum and a lateral electrode at the site along the axillary line between the 4th

and 6th intercostal space. Stainless steel flat electrodes with active surface areas of 5, 10, 20, and 25 cm² or rod electrodes were subsequently positioned and the defibrillation threshold (DFT) was measured for multiple combinations. In the second study, the ability to induce, detect, and provide shock delivery in response to ventricular fibrillation (VF) using an SCD system engineered for clinical use was tested in 5 canines. One hundred and three DFT tests with 11 different dual electrode combinations were performed. All combinations terminated VF with a DFT of 35 +/- 16 J (range: 9-79 J). Nineteen VF episodes were induced and recognized by the chronic SCD, leading to automatic capacitor charge and shock delivery in all cases. Conclusions: Subcutaneous defibrillation using different electrode combinations with shock energies less than 80 J terminated all induced VFs. An automatic SCD proved effective in detecting and activating shock delivery in all cases. (J Cardiovasc Electrophysiol, Vol. pp. 1-6).

Jolley M, Stinstra J, Tate J, Pieper S, Macleod R, Chu L, Wang P, Triedman JK. **Finite element modeling of subcutaneous implantable defibrillator electrodes in an adult torso.** *Heart Rhythm.* 2010; 7 (5): 692-8. http://ac.els-cdn.com/S1547527110000615/1-s2.0-S1547527110000615-main.pdf?_tid=6a8e9fba-adc5-11e2-81ca-00000aacb35d&acdnat=1366907598_e523565327cd868cef4b4359ee031f3b *Comment in:* Burke MC. *The infinite value in subcutaneous defibrillation.* *Heart Rhythm.* 2010; 7 (5): 699-700. **BACKGROUND:** Total subcutaneous implantable subcutaneous defibrillators are in development, but optimal electrode configurations are not known. **OBJECTIVE:** We used image-based finite element models (FEM) to predict the myocardial electric field generated during defibrillation shocks (pseudo-DFT) in a wide variety of reported and innovative subcutaneous electrode positions to determine factors affecting optimal lead positions for subcutaneous implantable cardioverter-defibrillators (S-ICD). **METHODS:** An image-based FEM of an adult man was used to predict pseudo-DFTs across a wide range of technically feasible S-ICD electrode placements. Generator location, lead location, length, geometry and orientation, and spatial relation of electrodes to ventricular mass were systematically varied. Best electrode configurations were determined, and spatial factors contributing to low pseudo-DFTs were identified using regression and general linear models. **RESULTS:** A total of 122 single-electrode/array configurations and 28 dual-electrode configurations were simulated. Pseudo-DFTs for single-electrode orientations ranged from 0.60 to 16.0 (mean 2.65 +/- 2.48) times that predicted for the base case, an anterior-posterior configuration recently tested clinically. A total of 32 of 150 tested configurations (21%) had pseudo-DFT ratios <=1, indicating the possibility of multiple novel, efficient, and clinically relevant orientations. Favorable alignment of lead-generator vector with ventricular myocardium and increased lead length were the most important factors correlated with pseudo-DFT, accounting for 70% of the predicted variation (R² = 0.70, each factor P < .05) in a combined general linear model in which parameter estimates were calculated for each factor. **CONCLUSION:** Further exploration of novel and efficient electrode configurations may be of value in the development of the S-ICD technologies and implant procedure. FEM modeling suggests that the choice of configurations that maximize shock vector alignment with the center of myocardial mass and use of longer leads is more likely to result in lower DFT.

Meeting Abstracts

Ali M, Toca FM. **Subcutaneous implantable cardioverter defibrillator use for an unusual clinical case [abstract].** *Ochsner Journal.* 2016; 16 (1): e33. *16th Annual Southern Hospital Medicine Conference New Orleans, LA, United States 2015-10-21 to 2015-10-24.* Case Presentation: A 59-year-old male with a history of ischemic heart disease on medical therapy presented with progressive dyspnea, intermittent dizziness, and near-syncopal episodes. On examination, the patient was alert and fully oriented. His pulse rate was 58 bpm, blood pressure was 125/70 mmHg, respiratory rate was 16 breaths per minute, and oxygen saturation was 98% while breathing ambient air. The patient's breath sounds were normal. Heart sounds were heard with soft systolic murmur at the left sternal border. The remainder of the examination was unremarkable. On the day of admission, he developed cardiac arrest with documented ventricular fibrillation and was successfully resuscitated. Transthoracic echocardiogram revealed a moderately enlarged left ventricle with severely depressed systolic function (left ventricular ejection fraction of 15%). A large protruding fixed thrombus was attached to the left ventricular apex. Thrombus was also seen in the right ventricle apex. Optimal medical therapy was continued for heart failure. Because of the clinical findings, an implantable cardioverter defibrillator (ICD) was indicated. He received a subcutaneous ICD because of the presence of thrombus in the right ventricle. The patient was discharged without any further event. Discussion: An entirely subcutaneous ICD has been demonstrated to be a reliable and effective system for detecting and terminating ventricular arrhythmias and for potentially avoiding many of the complications associated with transvenous ICDs. This case illustrates one of the several advantages of the subcutaneous ICD that may make it a preferred treatment rather than simply an alternative to the transvenous route. In our literature search, we found no report of the use of subcutaneous ICD for right ventricle thrombus. It is well documented that transvenous device leads may result in thromboembolic complications. Placement of a

transvenous defibrillator lead in the presence of a right ventricle thrombus would potentially have deleterious consequences. The subcutaneous ICD has several limitations, principally because of the absence of pacing ability. It cannot be used in patients requiring pacing for bradyarrhythmias, resynchronization therapy for heart failure, and antitachycardia pacing. However, these conditions were not present in this case. Future studies and observations will better define patient target groups and establish the therapeutic potential of the subcutaneous device technology. Conclusion: This case illustrates the preferable use of a subcutaneous ICD in select clinical presentations, one of which is the presence of right ventricle thrombus.

Amado L, Iskos D, Pham Q, Li H. **Welding safety in patients with contemporary implantable cardiac-defibrillators [abstract]. *Heart Rhythm***. 2016; 13 (5 SUPPL. 1): S233-S4. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: Welding Electromagnetic Interference (EMI) is a known cause of noise in the sensing leads, which may lead to inappropriate shocks and erroneous pacing. Traditional instruction after defibrillator (ICD) implantation is to avoid welding for fear of device malfunction. However, published data of welding-related EMI interfering with contemporary ICD function is lacking. We describe two patients who performed wire-feed welding safely after ICD implantation. Methods: Two patients with previous welding experience underwent ICD implantation. One patient had a subcutaneous ICD (Boston Scientific SQ-RX ICD) and the other an intravenous ICD system (Boston Scientific Inogen EL-VR) implanted. Patients returned to work with instructions to wear insulated gloves, use properly grounded equipment and keep a 24 inch distance between the device and the welding equipment. EMI was evaluated at the work place during wire-feed welding. Results: Electromagnetic interference during welding was minimal. No significant sensing noise, inappropriate shocks or pacing occurred during welding (Figure). Conclusions: These cases demonstrate the safety of wire-feed welding in patients with contemporary ICD technology. (Figure presented).

Arts I, Boulaksil M, Westra S, Smeets JLRM. **Co-existence of A572D mutation and H558R polymorphism of SCN5a sodium channel may result in QT prolongation and enhance susceptibility to torsades de pointes arrhythmias [abstract]. *Heart Rhythm***. 2016; 13 (5 SUPPL. 1): S408-S9. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: Here, we report on a transient QT prolongation resulting in a torsade de pointes ventricular tachyarrhythmia. Our patient appeared to be a carrier of a missense mutation and a single nucleotide polymorphism in the sodium channel coding gene. Although it has been suggested in literature that the A572D mutation should not be considered an independent LQT3-susceptibility mutation, we hypothesize that, under the appropriate circumstances, this in vitro aberrant mutation may result in critical QT prolongation. Methods: N/A Results: Case description: A previously healthy 36-year old woman suffering from a hemophagocytic syndrome underwent treatment with Rituximab, an anti-CD20 monoclonal antibody, and Ceftazidim, a cephalosporin antibiotic. The course of our patient was complicated with ventricular fibrillation preceded by long QT interval. No electrolyte plasma abnormalities existed. After successful resuscitation, a cardiac MRI showed a pattern highly suggestive of myocarditis. Genetic analysis revealed a missense mutation (A572D) in the SCN5A gene encoding the alpha subunit of the cardiac sodium channel and a single nucleotide polymorphism (H558R) in the same gene. Subsequently, the patient was given a subcutaneous cardiac defibrillator. Two months later, QT interval was normal. It is known that A572D results in increased late sodium current which prolongs action potential duration (APD) and QT interval. This sensitizes myocardial cells to premature ventricular activity potentially leading to ventricular tachyarrhythmias. In our patient, the single nucleotide polymorphism (SNP) H558R was present as well. This common SNP, because of its neighboring position and invariable linkage, may silence the A572D mutation and normalize APD by stabilizing the fast inactivation of sodium current. Conclusions: Therefore, we postulate that this silencing effect of H558R on the A572D mutation may be canceled under certain circumstances (hemophagocytic syndrome, Rituximab, Ceftazidim, and myocarditis) unmasking sodium channel aberrancy in A572D mutation. This may underlie QT prolongation resulting in the arrhythmic phenotype, like in our patient, with torsades de pointes ventricular arrhythmias.

Audoubert M, Ostiguy G, Nguyen D, Plante M, Dubuc M, Guerra P, Khairy P, Macle L, Mondesert B, Rivard L, Talajic M, Thibault B, Roy D, Dyrda K. **Resistance of the subcutaneous internal cardioverter defibrillator to 60 Hz electric fields [abstract]. *Can J Cardiol***. 2016; 32 (10 Supplement 1): S181. 69th Annual Meeting of the Canadian Cardiovascular Society Montreal, QC, Canada 2016-10-22 to 2016-10-25. BACKGROUND: The technology behind implantable cardioverter defibrillators (ICDs) is constantly evolving. Although improved shielding and other manufacturing features have rendered them more immune to electromagnetic interference (EMI), there remains safety concerns in high-risk exposure situations. Based on the International Standards Organization standard ISO 14117 and the calculations that can be made based on annex F of European norm EN 50-527-2-1 ICDs on the market are presumed immune at least up to ICNIRP's general public exposure limit (4.2 kV/m for 60 Hz electric fields).. The goal of this study was to expose the subcutaneous ICD (S-ICD) to electric

fields up to 20kV/m, so to determine the electric field threshold for interference. Such high electric field levels can be encountered in industrial settings (power utility substations) and in the right of way of high voltage (735 kV) power lines (theoretically up to about 8,5 kV/m at midspan). **METHODS:** The only S-ICD device model currently on the market, manufactured by Boston Scientific, was tested in vitro, in a high voltage laboratory. The device was mounted in a saline tank at human torso height, incrementally tested up to 20 kV/m. The device was set up as a left-sided implant. The three vector configurations were tested. **RESULTS:** When programmed to nominal parameters, the S-ICD sensing in primary vector was immune to interference up to a level of 10 kV/m. These signals noted at 10 kV/m and above were classified as noise by the device (and not signals of cardiac origin) and consequently did not trigger any inappropriate therapy. When programmed to higher sensitivity levels, the interference threshold decreased to 9 kV/m, a level at which noise was detected and identified properly. The SICD sensing nominally in both secondary and alternate (electrode tip to proximal ring) vectors detected and identified noise at a level of 4 kV/m. When programmed to higher sensitivity levels, the interference threshold remained at 4 kV/m. **CONCLUSION:** EMI remains a concern with S-ICD exposure to electric fields although these results are reassuring since noise was properly identified when programmed to nominal parameters or to higher sensitivity levels, no matter the vector chosen. There remains a need for individualized decision making for the safety of employees with S-ICDs in their work environment. For the general safety of the public, no significant concern should arise in individuals with S-ICDs programmed to nominal settings or to higher sensitivity levels, no matter the chosen vector.

Batul SA, Yang F, Greenberg YJ. **R-wave amplitude variation leading to inappropriate S-ICD therapy-another challenge in device management [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S46-S7. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: The subcutaneous ICD (S-ICD) provides protection against SCD without the risks associated with endocardial leads. The safety, efficacy and rate of inappropriate shocks (IAS) of S-ICD is comparable to that of transvenous ICD (TV-ICD). The most common cause of IAS is T-wave over-sensing (TWOS). We report a rare event in a patient with S-ICD receiving IAS due to increased R-wave amplitude after implant despite appropriate initial screening. Methods: N/A Results: A 24-year-old female with familial cardiomyopathy received an S-ICD 5 weeks post-partum. She previously had a TV-ICD implanted at the age of 13 with device malfunction due to lead fracture. Given the patient's age, no pacing indication and unwillingness to proceed with lead extraction, an S-ICD was considered an appropriate choice. The QRS amplitude was large in the S-ICD primary vector but within acceptable limits. Her labs were within normal range. She returned 1 week later with IAS. Her QRS amplitude was noted to have increased since the implant exceeding the device-sensing algorithm, leading to a downward shift in the baseline and predisposing to oversensing (Figure). An alternate vector with the smallest QRS was selected to overcome this problem and exercise testing was performed to optimize device function. Conclusions: Although IAS are more commonly due to TWOS as a result of a relatively low-amplitude R-wave and large T-wave, IAS due to large R-waves has not been reported. No software upgrade is available to resolve this problem in the current generation device. Until a more dynamic range of R-wave amplitude sensing is permitted, selection of an alternate vector with smaller R-waves should resolve this problem. (Figure Presented).

Bhagwandien R, Kik C, Yap SC, Szili-Torok T. **Substernal ICD lead implantation in a patient not suitable for a subcutaneous ICD without venous access [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S237-S8. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: ICD implantation may be challenging in patients with a lack of venous access and who are not suitable for a standard subcutaneous ICD (S-ICD). Methods: N/A Results: A 51-year-old man with dilated cardiomyopathy required an ICD for secondary prevention. The patient was known with superior vena cava syndrome related to a JAK2 mutation. In anticipation of a permanent ICD he received a wearable defibrillator. The patient was not a suitable candidate for a S-ICD due to low-amplitude R waves on his surface ECG. Therefore we implanted a standard ICD in the left mid-axillary line (1) combined with a standard epicardial pace/ sense electrode (2) via a left-sided mini-thoracotomy. Then we implanted a standard SVC coil in a substernal position (3) under guidance of video-assisted thoracoscopy. A standard subcutaneous parasternal position would probably not suffice due to the maximal shock energy (40 J) of a standard ICD. We used the standard tunneling tool from the S-ICD lead with a 11 F peel away sheath. The patient underwent a successful defibrillation safety margin test. The patient had an eventful recovery. The figure shows the position of the ICD at 3 months and a still frame from the thoracoscopy movie (A: ICD lead; B: Sternum). Conclusions: This is the first case report of an ICD implantation using a substernal ICD lead visualized by video-assisted thoracoscopy and an epicardial pace/sense electrode. It presents a good alternative for patients who are not a candidate for a transvenous or a subcutaneous ICD. (Figure presented).

Boersma LVA, Mahajan D, Jones PW, Mittal S. **Performance of a novel atrial fibrillation detection algorithm for use**

in patients with a subcutaneous implantable cardioverter defibrillator [abstract]. *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S11. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: The subcutaneous ICD distinguishes between atrial fibrillation (AF) and ventricular arrhythmias; however, an AF diagnostic is currently not available. We evaluated the performance of a novel AF detection algorithm, which could overcome this limitation. Methods: The algorithm combines ventricular scatter analysis (VSA), a measure of HR variability, with a heart rate (HR) histogram. VSA calculates beat-to-beat RR interval differences, which are categorized into 3 bins: stable, unstable, or unstable and random. In each 192 cycle window, the ratio of beats across the 3 bins differentiates sinus rhythm (SR) from AF. The HR histogram distribution optimizes the algorithm's specificity. The algorithm was developed and separately tested against several publicly available ECG databases. Results: The Validation cohort included 100 patients with and 79 patients without AF. The algorithm correctly excluded AF in all 79 non-AF patients (specificity 100%). Conversely, the AF algorithm correctly identified 94 of the 100 AF patients (sensitivity 94%) AF was not detected when episode were quite short (< 8 minutes; n=4) or associated with a stable ventricular response (n=2). Conclusions: A novel RR based AF algorithm was developed and tested using publicly available ECG databases. The algorithm exhibited very high sensitivity and specificity. If incorporated within existing S ICD systems, it would offer clinicians the ability to monitor for AF without requirement of a transvenous atrial lead. (Figure Presented).

Bordachar P, Christelle M, Pospiech T, Pasquié JL, Jalal Z, Haïssaguerre M, Thambo JB. **Subcutaneous implantable cardioverter defibrillators in children, young adults and patients with congenital heart disease [abstract].** *J Interv Card Electrophysiol.* 2016; 45 (3): 299. 12th Annual Congress of the European Cardiac Arrhythmia Society, ECAS 2016 Paris, France 2016-04-17 to 2016-04-19. The demonstration of severe complications in patients implanted with a transvenous implantable cardioverter defibrillator (ICD) has led to the development of devices equipped with a subcutaneous lead. This new technique offers numerous advantages but also certain disadvantages. Various studies or anecdotal clinical cases have specifically been conducted with this subcutaneous defibrillation system in children and/or patients with congenital heart disease. Results of these studies suggest: 1) a high feasibility despite being limited by a selection process that excludes patients requiring permanent pacing and patients declared ineligible during pre-screening; 2) good efficacy of electrical shocks in reducing induced or spontaneous ventricular arrhythmias; 3) in this specific subset of patients, 2 types of complications have been particularly described: a risk of device exteriorization and infection, and a large number of inappropriate therapies primarily related to T-wave oversensing. The subcutaneous ICD could therefore constitute the gold standard for patients with complex congenital heart disease with no venous access to the heart or with a persistent shunt increasing the risk of systemic emboli as well as in young patients with channelopathy or hypertrophic cardiomyopathy not requiring long-term pacing. Technological change (reduction in device size, better differentiation between R- and T-waves, possibility of pacing if device coupled with a leadless pacemaker) could reduce the limitations and complications and thereby increase the indications in this subgroup of patients.

Brouwer TF, Willner JM, Palaniswamy C, Dukkipati SR, Reddy V, Miller MA, Knops RE. **Evaluation of alternative implant techniques for the subcutaneous implantable cardioverter-defibrillator [abstract].** *Eur Heart J.* 2016; 37 Supplement 1: 103-4. European Society of Cardiology, ESC Congress 2016 Rome, Italy 2016-08-27 to 2016-08-31. Introduction: Alternative techniques to standard three-incision subcutaneous implantation of the subcutaneous implantable cardioverter-defibrillator (S-ICD) have been proposed, which may offer both operative and cosmetic advantages. Purpose: We evaluated four implantation techniques in a large cohort of S-ICD patients for clinical outcomes. Methods: Consecutive patients from two hospitals with ample experience with the S-ICD between 2009 and 2016 were included. Physician preference and patient characteristics determined the implant technique. The two- and three-incision techniques place the pulse generator (PG) subcutaneously, but the two-incision technique omits the superior parasternal incision for lead positioning. Submuscular implantation places the PG underneath the Serratus Anterior muscle. Subfascial implantation positions the PG underneath the fascial layer on the anterior side of the Serratus Anterior muscle. Devices were tested intraoperatively at operator's discretion. Results: 236 patients were included (table 1). First-shock efficacy and shock lead impedance during testing did not differ among the groups. A total 18 complications occurred, of which seven were infections requiring extraction. All infections occurred in subcutaneous implants (three-incision: n=3, two-incision: n=4, submuscular: n=0, subfascial: n=0). Skin erosion occurred in two patients, both implanted subcutaneously (three-incision: n=1, two-incision: n=1, submuscular: n=0, subfascial: n=0). Both appropriate shocks and inappropriate shocks did not differ significantly. Conclusions: The presented implantation techniques are feasible alternatives to the standard three-incision subcutaneous implantation and may reduce the risk of pocket-related complications. (Table Presented).

Brouwer TF, Yilmaz D, Buiten M, Van Erven L, Schaliij MJ, Wilde AA, Knops RE. **A balanced comparison of long-term clinical outcomes of subcutaneous and transvenous implantable defibrillator therapy [abstract].** *Heart*

Rhythm. 2016; 13 (5 SUPPL. 1): S103. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: Comparison of subcutaneous and transvenous implantable cardioverter-defibrillator (S-ICD, TV-ICD) therapy in previous studies is hampered by dissimilar patient characteristics. This study compared long-term clinical outcomes of both ICDs in a balanced cohort. Methods: ICD patients from two tertiary centers in The Netherlands were compared; S-ICDs implanted since 2009 (n=140) and TV-ICDs between 2005-2014 (n=1014). S-ICD patients were 1:1 propensity matched to 140 TV-ICD patients for 16 baseline characteristics including diagnosis. Kaplan Meier estimates for complications requiring surgical intervention were calculated at 5-year follow-up and hazard ratios (HR) for appropriate and inappropriate therapy adjusted for ICD settings. Results: All 16 baseline characteristics were balanced, with median age 41 (30-52) and 40% females. Follow-up was shorter in the S-ICD arm, 3 versus 5 years. All cause complications (figure) were similar and infections occurred in 4% in both arms, p=0.46. Lead complications were lower in the S-ICD group, 1% versus 12% p=0.008. S-ICDs had more non-lead complications (e.g erosion), p=0.02. Appropriate ICD intervention (antitachycardiapacing and shocks) was higher in the TV-ICD group (HR 2.5, p=0.003). Appropriate shocks (S-ICD HR 0.69, p=0.32) and inappropriate shocks (S-ICD HR 1.09 p=0.79) were equal. Patient survival at 5 year was 96% for S-ICD and 95% for TV-ICD, p=0.41. Conclusions: Long-term outcomes in this balanced cohort of S-ICDs and TV-ICDs were equal for complications and shocks. Patients with TV-ICDs had more appropriate interventions and lead complications, but S-ICD patients more non-lead complications. (Figure Presented).

Choi A, Rozen G, Rafael A, Ng CY, Chalhoub F, Koplán BA, Maytin M, Mela T, Milan DJ, Epstein LM. **Institutional experience with the totally subcutaneous implantable cardioverter defibrillator [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S254. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: A subcutaneous ICD system (S-ICD) has been developed as an alternative to the standard transvenous ICD. Data presented by the EFFORTLESS registry demonstrated safety and efficacy of the S-ICD. We sought to describe and compare the experience with the S-ICD system at our institution. Methods: Data from our centers were retrospectively collected from 2012 to 2015. Patient and lead characteristics, indications, and outcomes were analyzed. Composite endpoint included inappropriate therapies, system removal, and failed implant defibrillator threshold testing (DFT) on the day of implant, regardless of subsequent successful testing. Results: We identified 79 patients implanted with the S-ICD. The average follow up time was 400 days. Complication-free survival at 30, 180 and 360 days was 92%, 89%, and 85% respectively. Overall first shock DFT success was 83%. Failed DFT occurred in 6 implants (7.6%). Of these 6 patients, 2 had subsequently successful DFT. Time from implant and indication for explant are reported (Table). Explant rate at our center was 11.4% vs. 3.7% in the EFFORTLESS registry. Conclusions: Our S-ICD experience differs from the EFFORTLESS registry in regard to complications that were driven by failed DFTs. This may be in part due to a difference in the definition of failed DFTs (registries defined failure after 5 failed therapies/event) and patient selection into the EFFORTLESS registry. Consistent with typical practice, no failed DFTs in our experience reached 5 attempts. Our data suggest that DFT at the time of implant remains relevant and continued follow up of registry and institutional data may provide insight in patients who are best suited for S-ICD. (Table Presented).

Choi A, Rozen G, Rafael A, Ng CY, Chalhoub F, Koplán BA, Maytin M, Mela T, Milan DJ, Epstein LM. **A novel cause of inappropriate therapies in the s-ICD: Low amplitude R waves with autogain [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S253. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: Inappropriate therapies (IT) from implanted cardioverter defibrillators (ICD) are a morbid complication. An entirely subcutaneous ICD system (S-ICD) has been developed as an alternative to the standard transvenous ICD system (T-ICD). As this system relies entirely on extrathoracic sensing, appropriate therapies are dependent on the fidelity of sensing. We report a novel cause of oversensing, leading to inappropriate therapies in a series of S-ICD patients. Methods: Data from all patients undergoing S-ICD implant at Massachusetts General Hospital and Brigham and Women's Hospital from November 2012 to May 2015 were collected. Cases of inappropriate therapy were identified and interrogation records reviewed Results: Six patients (7.6%) with inappropriate therapy were identified in our series of 79 patients. Of these, 5 (6.3%) were found to have transient reduction of signal amplitude based on interrogation waveform. Tachycardia detection was deemed inappropriate if this resulted in oversensing of T waves or P waves or noise due to the autogain algorithm of the device. (Figure). In 3 patients (3.4%) with inappropriate therapies programming changes were ineffective and device extraction was required Conclusions: Variability in waveform amplitude detected by the S-ICD can result in oversensing of P waves, T waves and noise due to the autogain algorithm of the device. Our case series represents 6.3% inappropriate therapies that can be attributed to transient low amplitude sensing. Continued monitoring of R wave amplitude, especially soon after implant may help identify patients at risk for IT from their S-ICD. (Figure Presented).

Conte G, Caputo ML, Chiodini A, Ruggiero D, Regoli F, De Asmundis C, Moccetti T, Brugada P, Auricchio A. **Eligibility for subcutaneous cardioverter-defibrillator in patients with Brugada syndrome [abstract].** *Eur Heart J.* 2016; 37 Supplement 1: 104. *European Society of Cardiology, ESC Congress 2016 Rome, Italy 2016-08-27 to 2016-08-31.* Background: Subcutaneous implantable cardioverter-defibrillator (S-ICD) can avoid important complications associated with transvenous leads in subjects who do not need pacing therapy such as patients with Brugada syndrome (BrS). Very little information is available on the S-ICD eligibility of patients with BrS. Aim of this study was to analyze eligibility for S-ICD in a series of patients with BrS, and to compare it with age- and gender-matched patients with other indication to ICD therapy. Methods: ECG screening of consecutive patients was performed by analysis of QRS complex and T wave morphology recorded in standing and supine position. In BrS patients without a diagnostic baseline ECG, S-ICD sensing analysis was repeated during ajmaline challenge. Ajmaline was administered at a dosage of 1 mg/kg over 5 minutes. Eligibility was defined when ≥ 1 sense vector was acceptable in both supine and standing position. Results: A total of 58 patients (37 males; mean age: 54 ± 13 years; mean LVEF $47 \pm 16\%$) underwent S-ICD sensing screening before an ICD implantation procedure. Twenty-four patients (41%) presented with ischemic heart disease and 30 (52%) with a primary electrical disorder (BrS: 23 pts, long-QT syndrome: 2 pts; idiopathic ventricular fibrillation: 5 pts). The remaining 4 subjects (7%) had an inherited myocardial disease. Ten patients with BrS (43%) presented with spontaneous type 1 ECG. In the other 13 patients, type 1 ECG was unmasked by ajmaline. Six out of 10 patients (60%) with spontaneous type 1 ECG failed the sensing screening. All patients with drug-induced BrS had appropriate morphology analysis at baseline. However, in 3 of them (23%), morphology analysis was inappropriate after ajmaline administration. Individuals with BrS had a higher prevalence of S-ICD screening failure as compared with other candidates to ICD therapy (39% vs 8.6%, $p = 0.007$). In all patients with BrS, the reason for sensing inappropriateness was due to the presence of too high T-wave voltages. Conclusions: S-ICD screening failure occurs in up to 40% of patients with BrS. In patients with non-diagnostic baseline ECG, morphology analysis should be repeated after ajmaline challenge, which may unmask sensing issues in 23% of cases previously considered suitable to S-ICD.

Contino C, Drabina-Dombrowski V, Tiwari A, Subzposh FA, Gupta A, Singh D, Koman E, Overcash J, Saltzman HE, Kutalek SP. **Subcutaneous implantable cardioverter-defibrillator implantation on uninterrupted anticoagulation [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S14. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: The safety of implantation of transvenous pacemakers and implantable cardioverter-defibrillators (ICDs) with uninterrupted therapeutic warfarin therapy has been established. Very limited data are available on the safety of subcutaneous ICD (S-ICD) implantation on warfarin and antiplatelet therapies. Methods: We evaluated procedural and post-procedural outcomes in patients undergoing S-ICD implantation from February 2011 to November 2015 at our academic center. Results: One hundred one S-ICDs were implanted at our academic center of which 64 were male. The mean age was 53 years ± 13.9 years. Fifty-five (54.5%) were implanted for primary prevention and 61 (60.4%) were implanted using a three incision technique. Eighteen patients (17.8%) were actively taking warfarin and had an INR of at least 1.60 on the day of the procedure with a mean INR of 2.13 ± 0.51 and range 1.60-3.30. Seven patients were on dual antiplatelet therapy in addition to warfarin, 17 patients were on dual antiplatelet therapy alone, and 29 patients (27.7%) were not taking either. One patient on warfarin had a pocket infection compared to three patients not on warfarin (p value = 0.7). Of the three pocket infections in patients not on warfarin, two required device explant. There were no intra- or postoperative bleeding complications in any patients regardless of warfarin or antiplatelet therapy. Procedure time in patients taking warfarin was 59.9 minutes ± 14.5 minutes and 59.6 minutes ± 14.9 minutes in patients not on warfarin. Conclusions: Patients implanted with S-ICDs on uninterrupted warfarin show no increase in bleeding complications or in postoperative device infections.

Do K, Carlson SK, Konecny T, Chang PM, Doshi RN. **High defibrillation threshold in obese patients receiving S-ICD [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S524. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: Average defibrillation threshold (DFT) values with the S-ICD have been reported as 36.6 J. Formal DFT testing is not currently required following S-ICD implantation. Given the S-ICD's extrathoracic position, DFT may be affected by body mass index (BMI) due to increased thoracic size and adipose tissue in obese patient. Methods: Records of consecutive patients at our institution included in the post-market S-ICD study over the past two years were reviewed. Pertinent clinical risk factors, medications, cardiomyopathy etiology and ICD indications were recorded. Patients underwent full DFT testing and factors associated with elevated DFT were examined. Results: Twenty-one patients underwent S-ICD implantation. Eighteen patients had attempted VF induction; three were deemed unsafe for DFT testing due to hemodynamic instability. The mean age was 50.7 years with average BMI 31.2 kg/m^2 and ejection fraction 33%. The average DFT was 50.7J and the average number of shocks during DFT testing was 4.6. Four patients had DFT of 80J or greater and three patients were non-inducible. Higher BMI was positively correlated with higher DFT values (correlation coefficient 0.46, R-square 0.21, p -value 0.08) (Figure 1).

There was a trend toward markedly higher DFTs in patients with BMI above 30. Conclusions: Obese patients (BMI >30) undergoing S-ICD implant may have DFTs that are higher than published averages. Formal DFT testing should be considered in this population. Further study with large sample size is needed to further characterize risk factors that may predict unacceptably high DFTs. (Figure Presented).

Dookhan C, Ghatak A, Padala S, Alimohammad R, Steckman D, Tan H, O'Brien J, Sidhu M, Tzur A, Mendoza I. **Two incision versus three incision procedure times for implantation of subcutaneous implantable cardioverter defibrillators: A two center experience [abstract].** *J Am Coll Cardiol.* 2016; 67 (13 SUPPL. 1): 823. *65th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.16 Chicago, IL, United States 2016-04-02 to 2016-04-04.* Background: Traditionally, the three incision technique had been used for device and electrode implantation for subcutaneous Implantable Cardioverter Defibrillators (sICDs). The 2 incision technique obviates the superior parasternal incision, which can be a source of discomfort and infection. Currently data on comparison of procedure times between these 2 techniques is lacking. Methods: We retrospectively reviewed the medical records of all consecutive patients at 2 major tertiary centers who had sICD implantation with Class Ia or II indications for ICD without need for pacing from January 2014 to March 2015. Data on age, gender, ejection fraction (EF), procedural times of 2 incision and 3 incision techniques and peri and post procedure complications including death, new onset atrial fibrillation, pocket hematomas, wound dehiscence and superficial wound infection were collected. Results: Thirty seven patients (40.5% females, mean age 52± 16 years, mean EF 30± 15%) had sICDs implanted. The mean procedure time for patients undergoing 2- incision technique (n=8) was significantly lower than that of the 3- incision technique (80.5± 50 mins versus 126.6± 32.8 mins respectively, p<0.007). Complication rates for death, new onset atrial fibrillation, wound dehiscence and wound infection with 2 vs 3 incision technique were not significantly different 0% (0/8) vs 3.44% (1/29), p=0.59 with rates of 0% (0/8) vs 10.3% (3/29), p= 0.34 for pocket hematoma. Conclusions: The 2 incision technique is associated with a shorter procedure time compared with the 3 incision technique for S-ICD implantation.

Edla S, Chandrasekaran J, Neupane S, Shakir A. **Ventricular tachycardia storm on the same day of ICD implantation for primary prevention. What happened? [abstract].** *Cardiology.* 2016; (2016) 134 Supplement 1: 281. *International Academy of Cardiology 21st World Congress on Heart Disease Annual Scientific Sessions 2016 Boston, MA, United States 2016-07-30 to 2016-08-01.* Background: The risk of defibrillator shock after implantable cardiac defibrillator (ICD) implantation for primary prevention is approximately 5% per year. It is very rare for a patient to have an appropriate ICD shock for a ventricular tachycardia (VT) storm on the very day of implant. We present a patient who underwent subcutaneous ICD(s-ICD) placement and had VT storm on the same day of implantation due to severe hyperkalemia. Case: A 35 year old male with a history of nonischemic cardiomyopathy, ejection fraction of 20% and end stage renal disease on hemodialysis was admitted for elective s-ICD placement. His last dialysis was the day before procedure. All serum electrolyte levels the day of the procedure were within normal range. Patient underwent s-ICD implantation without any complications. Later that evening, the patient began complaining of dizziness. He was bradycardic with typical electrocardiogram changes for hyperkalemia. The patient subsequently developed wide complex tachycardia eventually degenerating into a VT storm. The defibrillator delivered multiple appropriate ICD shocks during this rhythm. Decision making: Dialysis associated hyperglycemia is a well-documented but oft forgotten cause of hyperkalemia in hemodialysis patients. Given the heightened concern for possible hyperkalemia from the electrocardiogram the patient was immediately transferred to the cardiac ICU. Serum potassium level was 8.6mEq/L and glucose level was 360mg/dl. The patient underwent emergent hemodialysis with normalization of his potassium levels down to 4.4mEq/l and his glucose levels down to 140mg/dl. He improved clinically back to his baseline. Discussion: ICD shocks are highly unusual on the day of implant. In our case, VT storm was triggered by hyperkalemia and early recognition resulted in successful resuscitation. High index of suspicion for hyperkalemia secondary to dialysis-associated hyperglycemia is warranted in hemodialysis patients. Close monitoring of electrolyte levels, especially post-implantation, may prevent serious arrhythmias.

El Bouazzaoui R, Marquie C, Bertaux G, Chauvin M, Bredy C, Klug D, Massin F, Pasquie JL. **Interest of the totally subcutaneous S-ICD in adults with complex congenital heart diseases and absence of venous access to the heart [abstract].** *Eur Heart J.* 2016; 37 Supplement 1: 574. *European Society of Cardiology, ESC Congress 2016 Rome, Italy 2016-08-27 to 2016-08-31.* Aim of the study: Malignant ventricular arrhythmias are a major cause of mortality in patients with complex congenital heart disease (CHD). Because of anatomic variations, surgical interventions, abnormal systemic venous pathway, ICD implantation can be technically challenging requiring a surgical epicardial approach. The totally subcutaneous S-ICD may be an interesting alternative. Our objective was to assess the feasibility and safety of this device in patients with complex CHD and absence of vascular access to the heart. Methods: In 4 French tertiary centers, complex CHD patients requiring an ICD, with no transvenous access to the ventricle were prospectively included to receive an S-ICD. From 2012

to 2015, 12 patients were included: 9 (75%) were men and 3 (25%) were women. The median age was 27.5 years old IQ [22.8- 44.5]. 5 patients had univentricular heart (4 due to pulmonary atresia and 1 due to tricuspid atresia), 2 had interatrial communication associated with Ebstein's anomaly, 2 Tetralogy of Fallot and 1 Tetralogy of Fallot associated to Ebstein's anomaly, 1 transposition of the great arteries and 1 congenitally corrected transposition. They all had surgical repair of their CHD. The median number of surgery for CHD was 3 IQ [1-4]. They had no transvenous access to the ventricle because of Fontan repair in 6, a tricuspid prosthetic valve in 1, VCS thrombosis in 2, abnormal central venous return in 3. Baseline ECG was in sinus rhythm in 9 and AF in 3. One patient had a pacemaker with epicardial leads and paced QRS complex due to permanent AV block. Median LVEF was 51% IQ [33%-60%]. 8 patients (66.7%) had secondary prevention indication for ICD and 4 (33.3%) had primary prevention indications. Summary of results: The S-ICD implantation was achieved successfully in all patients under general anesthesia. 3 patients had situs inversus requiring right-sided implantation of the lead and the device. At the end of the procedure, induced ventricular fibrillation was successfully detected and treated with a 60 joules-shock in all patients (100%). There was no procedural complication. After 15 months of median follow-up IQ [8-30]; there were no device-related serious events. Survival free of inappropriate therapy or system revision was 75%. 1 patient had an impending extrusion requiring reintervention. 2 patients experienced inappropriate shocks: 1 due to T-wave over sensing (necessitating reprogramming of the detection vector), 1 due to supra ventricular arrhythmia (1/1 atrial flutter). One patient was admitted for heart failure unrelated to device implantation. During follow-up, 1 patient died of heart failure and 1 of accidental drowning. There were no deaths related with ventricular arrhythmia. Conclusion: The S-ICD is a simple procedure appearing as an excellent alternative to a surgical epicardial approach for ICD implantation in CHD patients with no central venous access available.

Ellins C, Garcia E, Levine J, Kim R, Hsu SS, Catanzaro JN. **Failed maximal defibrillation threshold testing in the subcutaneous implantable cardioverter defibrillator [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S45-S6. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: The subcutaneous implantable cardioverter defibrillator (SICD) has emerged as a technological advance to prevent sudden cardiac death in patients who are not pacemaker dependent. The SICD offers the advantage of extracardiac route of implantation and long term lead management options in high risk patients for infection while sustaining non-inferior discrimination of arrhythmia. Methods: N/A. Results: A 42-year-old gentleman with a nonischemic dilated cardiomyopathy (EF=20%) on guideline driven medical therapy for nine months was seen for risk stratification of sudden cardiac death. He had a chronic thromboembolic hematologic disorder and upper extremity deep venous thromboemboli with failed left sided transvenous ICD implantation due to venous occlusion. Given patient preference, implantation indication and consideration of thrombotic potential a SICD was implanted. After successful induction of VF at 50 Hz via the device therapy at 65J and 80J failed to defibrillate the patient warranting external defibrillation which was successful. The shock impedance was 125 ohms demonstrating a tissue interface. The patient received an erect PA radiograph which demonstrated shifting of the shocking coil and can below the diaphragm despite supine positioning via fluoroscopy. The system was revised moving the coil rightward of the sternum to compensate for anatomic shifting and the generator was moved superior above the diaphragm. Defibrillation at 80 J was successful, however upon second attempt this was unsuccessful. Shock impedance was within normal limits on both attempts. Given the probabilistic mechanism of DFTs, a JR4 guide catheter was placed transfemoral and identified a patent right sided venous system. A transvenous dual coil ICD was subsequently implanted with DFTs <or = to 25J. The SICD was explanted and the patient was discharged the next day. Analysis of the device by the manufacturer did not demonstrate defect. Conclusions: This case illustrates the limitations of the SICD and may identify a patient population which can pose challenges in clinical decision making based upon indication of the SICD, patient preference and limitations of current technology.

Flatley EE, Kagan V, Ruedlinger H, Juricek CJ, Uriel N, Moss JD. **Defibrillation threshold testing to guide management in patients with a continuous flow left ventricular assist device [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S1. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: While the utility of defibrillation threshold (DFT) testing at initial ICD implant is debated, placement of a left ventricular assist device (LVAD) may compromise ICD function. We present a series of LVAD patients for whom formal DFT testing was used to guide management. Methods: N/A Results: Patient 1: 47-year-old man with dilated cardiomyopathy (CM), status post HeartMate 2 (HM2) LVAD. Given syncope and documented non-sustained VT, an ICD was implanted post-LVAD. Initial DFT was >35J despite optimal lead placement. A subcutaneous defibrillator coil was implanted, with subsequent DFT<20J (Fig 1a). Patient 2: 56-year-old man with ischemic CM, status post ICD implant and HeartWare HVAD 6 years later. At ICD generator change, DFT testing was deferred. He later presented in VF with ineffective ICD shocks (Fig 1b). After hemodynamic optimization, DFT remained greater than maximum programmable ICD output. He underwent VT ablation and addition of a subcutaneous coil. Post-revision DFT was

< 36J. Patient 3: 72-year-old man with dilated CM, status post BiV-ICD and HM2 LVAD. He presented with ineffective ICD shocks for sustained VT. Echocardiography showed severe LV dilatation, with left ventricular end-diastolic dimension (LVEDD) 8.5 cm. After diuresis and LVAD optimization via hemodynamic ramp study, LVEDD was 6.8 cm (Fig 1c). Subsequent DFT was < 30J, and no device revision was pursued. Conclusions: These cases highlight the need for a multidisciplinary approach to the management of ICDs in LVAD patients. Device reprogramming and/or revision when appropriate may reduce both shock burden and morbidity, and DFT testing can influence clinical decision-making.. (Figure Presented).

Frankel DS, Burke M, Callans DJ, Stivland T, Duffy E, Epstein AE. **Impact of BMI on safety and efficacy of the subcutaneous ICD [abstract]. *Heart Rhythm***. 2016; 13 (5 SUPPL. 1): S12. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07*. Introduction: The subcutaneous ICD (S-ICD) is an established treatment option for patients at high risk for ventricular arrhythmias. Whether efficacy and risk of complications differ by patient (pt) weight remains unknown. Methods: We analyzed data from the 321 pts enrolled in the S-ICD IDE study. Pts underwent implantation followed by defibrillation testing at 65J. They were categorized into 3 body mass index (BMI) groups: <25 (underweight and normal), 25-30 (overweight) and >30 (obese). Three outcomes were compared across groups: 1) Infection-type complications including erosion, prolonged healing, superficial and system infection; 2) Suboptimal generator/lead position including any revision to a malpositioned device; and 3) Failure of the first 65J shock to defibrillate the first induced VF during implant. Results: Mean BMI was 29.7 ± 7.3 . Seventy-nine pts had BMI <25, 105 pts BMI 25-30 and 137 pts BMI >30. There were no significant differences between BMI groups in rates of infection-type complications (5.1% for BMI<25, 2.9% for BMI 25-30 and 2.9% for BMI>30, $p=0.7$) or suboptimal generator/lead positioning (3.8%, 3.8% and 5.1%, respectively, $p=0.9$). Protocol-defined acute conversion success was 100% for 304 evaluable pts. However, the rate of failed first shock at 65J increased across BMI categories (5.2%, 13.3% and 16.5%, respectively, $p=0.02$ for comparison between BMI>30 vs BMI<25). There were 8 underweight (BMI <18.5) pts, none of whom had infection-type complications or failed first shocks. One had suboptimal device positioning. Conclusions: While rates of infection-type complications and suboptimal device positioning do not significantly differ according to patient weight, failed 65J shocks may be more common in obese patients.

Friedman DJ, Parzynski C, Curtis J, Varosy P, Russo A, Prutkin J, Patton K, Mithani A, Al-Khatib S. **Early use of the subcutaneous implantable cardioverter defibrillator in the United States: A report from the national cardiovascular data registry [abstract]. *J Am Coll Cardiol***. 2016; 67 (13 SUPPL. 1): 685. *65th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.16 Chicago, IL, United States 2016-04-02 to 2016-04-04*. Background: The use and in-hospital outcomes of the subcutaneous (S) implantable cardioverter defibrillator (ICD) in the US have not been described. Methods: We studied patients (pts) in the National Cardiovascular Data Registry (NCDR) ICD registry who underwent ICD implant between September 28, 2012 (SICD FDA approval date) and March 31, 2015, to describe trends in early S-ICD use and in-hospital outcomes. Results: SICDs comprised 3,717 of the 393,734 ICD implants reported to the NCDR. SICD use generally increased during the study period (Figure). Implants were often by board certified electrophysiologists (79%) at hospitals that were: >500 beds (52%), teaching institutions (74%), in the Atlantic (45%) and Central (35%) US. SICD pts (vs. single chamber, dual chamber, and biventricular ICD pts, respectively) were more often younger (54 vs 62 vs 66 vs 70 years), female (31 vs 28 vs 26 vs. 29%), black (27 vs 20 vs 13 vs 11%), on dialysis (20 vs 3 vs 2 vs 2%), and post cardiac arrest (20 vs 15 vs 15 vs 6%) ($P<0.001$ for all). Among SICD pts who underwent defibrillation threshold (DFT) testing ($n=2,791$), 92.73%, 94.20%, 94.41%, and 99.75% were successfully defibrillated at $\leq 65j$, $\leq 70j$, $\leq 75j$, and $\leq 80j$, respectively. Periprocedural complications (1.16% total) included hematoma (0.30%), lead dislodgement (0.13%), myocardial infarction (0.08%), cardiac arrest (0.43%), and death (0.35%). Conclusions: SICD use is rapidly increasing in the US and is associated with low complication rates and high rates of successful DFT testing. (Figure Presented).

Gandjbakhch E. **Cardiac rhythm management in heart failure [abstract]. *Eur J Clin Invest***. 2016; 46 SUPPL. 1: 25. *50th Annual Scientific Meeting of the European Society for Clinical Investigation Paris, France 2016-04-27 to 2016-04-29*. In the last 20 years, important advances have been made in the management of rhythm disorders in heart failure. Implantable cardioverter defibrillators have allowed an important reduction of sudden cardiac deaths in patients with cardiomyopathies and low ejection fraction (EF). Cardiac resynchronization therapy has reduced the rate of heart failure-related deaths and hospitalisations in patients with low ejection fraction and wide QRS. In addition, there is a growing place for ablative therapies in the treatment of atrial and ventricular arrhythmias in heart failure, particularly for arrhythmia-induced cardiomyopathies. Earlier detection of arrhythmias and device-related complications is made possible thanks to remote monitoring. The emergence of new technologies, like subcutaneous ICD, wearable defibrillators or left ventricular multielectrode pacing, opens new therapeutic perspectives. However, further studies are needed to improve the stratification of sudden-death risk in heart

failure patients, in particular those with mild ventricular dysfunction.

- Gluer R, Lee A, Denman R, Haqqani H. **Subcutaneous implantable defibrillators: An early experience [abstract].** *Heart Lung and Circulation*. 2016; 25 Supplement 2: S155. 64th Cardiac Society of Australia and New Zealand Annual Scientific Meeting and the International Society for Heart Research Australasian Section Annual Scientific Meeting 2016 Adelaide, SA, Australia 2016-08-04 to 2016-08-07. Subcutaneous defibrillators are recently developed to overcome limitations of transvenous access and complications, including intravascular infection. Drawbacks include shorter battery life, greater device size, insertion under general anaesthetic, cost, post defibrillation pacing only, and T wave oversensing causing inappropriate shocks. Presented is the early device experience in this institution. Eight patients underwent subcutaneous ICD insertion from January 2015 to January 2016. Mean age was 48 years (range 34-66 years). Five were for secondary prevention. Primary prevention devices were for hypertrophic cardiomyopathy, ARVC with syncope, and heart failure with LVEF <35%. All other patients had normal LVEF. Two patients had no transvenous access secondary to complex congenital heart disease. Two patients had previous transvenous ICD infection. The subcutaneous lead was tunnelled medially from the axillary pocket, externalised, then tunnelled to the third intercostal space with suture fixation. Ventricular fibrillation was induced and device tested to confirm adequate defibrillation threshold in the first seven patients. No significant procedural complications occurred. No patient had a defibrillation threshold greater than 65 Joules-VF was unable to be induced in one patient. No ventricular tachycardia or fibrillation was detected on follow-up. One inappropriate shocked secondary to atrial fibrillation at 250bpm occurred. Measured lead impedances were within manufacturer specifications. No shocks secondary to T wave oversensing occurred. No other complications on follow up of 5.2 patient years. Subcutaneous defibrillators are a promising technology for patients requiring defibrillator functionality alone.
- Hai JJ, Tam E, Chan PH, Siu CW, Tse HF. **Ventricular tachyarrhythmias at presentation predicts sudden cardiac death after acute coronary syndrome [abstract].** *Eur Heart J*. 2016; 37 Supplement 1: 85. European Society of Cardiology, ESC Congress 2016 Rome, Italy 2016-08-27 to 2016-08-31. Introduction: Patients suffer from acute coronary syndrome (ACS) are at risk of sudden cardiac death (SCD), and the prognostic implication of the presence of ventricular tachyarrhythmias (VTs) at presentation remains unclear. Current guidelines do not support the use of implantable cardioverter defibrillator (ICD) for prevention of SCD in those patients who develop VTs within 48 hours of presentation. Purpose: We sought to investigate the risk of SCD in patients with and without VTs within 48 hours of ACS. Method: Consecutive patients admitted to our cardiac unit for ACS and received successful coronary intervention from 2010 to 2015 were retrospectively reviewed. Results: A total of 905 patients (age: 65.8±13.4 years, 75.1% male) were included in the analysis. Documented VTs within the first 48 hours of ACS was observed in 106 (11.8%) patients, of which 59 (6.5%) required defibrillation and 47 (5.2%) terminated spontaneously. Compared to those without VTs, patients with VTs were more likely to be male (84.9% vs 73.8%, P=0.01), suffered from STElevated myocardial infarction (75.5% vs 63.7%, P=0.02) and lower left ventricular ejection fraction (LVEF; 39.3±11.8 vs 44.6±11.1, P<0.001), but less likely to have hypertension (40.6% vs 58.6%, P=0.001) or diabetes (22.6% vs 36.0%, P=0.006). However, there was no difference in the site of culprit lesion and peak troponin level between the two groups (P>0.05). After a mean follow-up of 32.4±22.3 months, 195 (21.5%) patients died. After exclusion of those who died within 7 days of ACS, or died of pulseless electrical activity or asystole, 10 (9.4%) patients with VTs and 28 (3.5%) without VTs developed SCD. In the multivariate cox regression analysis, VTs at presentation [Hazard Ratio (HR) 3.90 (95% confidence interval (CI) 1.86-8.20), P<0.001], prior coronary artery disease [HR 2.27 (95% CI 1.11-4.64), P=0.03], LVEF ≤35% [HR 2.32 (95% CI 1.21-4.45), P=0.01] and renal failure [defined by creatinine 200µmol/L; HR 3.08 (95% CI 1.39-6.79), P=0.005] remained independently predictive of SCD. Importantly, the incidences of SCD in ACS patients with VTs were much higher at 8-40 days, 41-120 days, 121- 360 days and 361-720 days of presentation compared to those without VTs. Nevertheless, the risk of SCD reduced and became same in both groups after 2 years. Conclusions: Despite successful coronary intervention, VTs at presentation independently increases the risk of SCD especially within the first 2 years after ACS. Consideration should be given to implant ICD for prevention of SCD in this group of patients regardless of LVEF. Subcutaneous ICD that can be safely removed in those without initial events may be preferred. (Figure Presented).
- Hauser R, Abraham JE, Katsiyiannis W. **ICD lead malfunction due to failure at the device-tissue interface [abstract].** *J Interv Card Electrophysiol*. 2016; 45 (3): 299-300. 12th Annual Congress of the European Cardiac Arrhythmia Society, ECAS 2016 Paris, France 2016-04-17 to 2016-04-19. Background: ICD lead malfunction (MAL) may result in morbidity and surgical revision. While MAL due to conductor and insulation defects are well known, there are little data for MAL caused by failure at the device-tissue interface. Accordingly, we assessed MAL for contemporary ICD leads at our center and compared MAL caused by conductor and insulation defects (ELEC) to MAL due to device-tissue interface failure (DTF). Methods: This is a retrospective single center observational study that includes all Sprint Quattro (SQ), Endotak Reliance (ER), and Durata (DU) leads followed

in our clinic. ELEC were MAL in the presence of electrical failure, mainly impedance and/or noise; DTF were high threshold/exit block and/or undersensing/low R-wave in the presence of electrically intact leads and absence of radiographic lead dislodgement. Kaplan-Meier estimates were calculated to assess lead survivals (SURV). Results: Of 2,268 ICD leads, 29 MAL were due to ELEC and 31 MAL were caused by DTF; the overall mean implant time was 3.8 ± 3.0 SD yrs. The SURV for ELEC vs DTF are shown in the graph (log rank $p = 0.90$). No significant differences in ELEC or DTF MAL were found for SQ ($n = 1706$), ER ($n = 363$) or DU ($n = 199$). Mean time to failure was significantly shorter for DTF (1.9 ± 2.1 SD yrs) than ELEC (4.9 ± 2.6 SD yrs; $p < 0.001$). Conclusions: DTF MAL is as common as ELEC MAL in contemporary ICD leads and they occur much earlier. This observation should encourage leadless ICD development and efforts to improve electrodes, fixation mechanisms, and implant techniques.

Hauser RG, Abdelhadi R, Garberich R, Katsiyannis W. **Icd lead malfunction due to failure at the device-tissue interface [abstract].** *J Am Coll Cardiol.* 2016; 67 (13 SUPPL. 1): 702. *65th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.16 Chicago, IL, United States 2016-04-02 to 2016-04-04.* Background: ICD lead malfunction (MAL) may result in morbidity and surgical revision. While MAL due to conductor and insulation defects are well known, little data exist for MAL caused by failure at the device-tissue interface. Accordingly we assessed MAL for contemporary ICD leads at our center and compared MAL caused by conductor and insulation defects (ELEC) to MAL due to device-tissue interface failure (DTF). Methods: This is a retrospective single center observational study that includes all Sprint Quattro (SQ), Endotak Reliance (ER), and Durata (DU) leads followed in our clinic. ELEC were MAL in the presence of electrical failure, mainly impedance and/or noise; DTF were high threshold/exit block and/or undersensing/low R-wave in the presence of electrically intact leads and absence of radiographic lead dislodgement. Kaplan-Meier estimates were calculated to assess survivals (SURV). Results: Of 2,268 ICD leads, 29 MAL were due to ELEC and 31 MAL were caused by DTF; the overall mean implant time was 3.8 ± 3.0 SD yrs. The SURV for ELEC vs DTF are shown in the graph (log rank $p = 0.90$). No significant differences in ELEC or DTF MAL were found for SQ ($n = 1706$), ER ($n = 363$) or DU ($n = 199$). Mean time to failure was significantly shorter for DTF (1.9 ± 2.1 SD yrs) than ELEC (4.9 ± 2.6 SD yrs; $p < 0.001$). Conclusions: DTF MAL is as common as ELEC MAL in contemporary ICD leads and occur much earlier. This observation should encourage leadless ICD development and efforts to improve electrodes, fixation mechanisms, and implant techniques. (Figure Presented).

Heist EK, Stahl W, Belalcazar A. **Impact of generator location and sub-coil fat on subcutaneous-ICD defibrillation thresholds [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S11-S2. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: Some subcutaneous ICD (S-ICD) patients exhibit unacceptably high defibrillation thresholds (DFT). Implant characteristics associated with high DFTs in S-ICD patients have not previously been described. We sought to determine the impact of S-ICD coil and generator position on DFT based on a computer defibrillation simulation. Methods: A 3.8 million-element computer model built from MRI images of the thorax was used to simulate the electric fields that occur during defibrillation. Each element represents the electrical properties of the respective tissue or organ. Four generator positions were tested, from posterior to anterior, with 4 cm displacements. The left para-sternal coil was tested with 0, 5, and 10 mm of underlying subcutaneous fat. The DFT for the S-ICD was defined conventionally as the delivered energy required to produce an electric field of 4 Volts/cm in at least 95% of the ventricular myocardium. Results: DFTs were 22, 29, 64, and 135 Joules for posterior (-4 cm), standard, mid-anterior (+4 cm), and anterior (+8 cm) generator locations. DFTs were 29, 58, and 95 Joules when tested with 0, 5, and 10 mm of underlying fat. Fat (0-10 mm) under the generator did not substantially impact DFTs. Conclusions: Our model suggests that an S-ICD implant strategy involving (1) posterior generator location and (2) the coil directly over the ribs without underlying fat is likely to markedly lower DFTs with the S-ICD and reduce the number of patients with unacceptably high DFTs.

Hreibee H, Saba S. **Risk of S-ICD shocks to healthcare providers during CPR: A case report [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S235-S6. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: S-ICD is a relatively novel technology with both generator and lead placed subcutaneously. The relatively superficial lead position creates a potential risk of transmitting the shock to people in contact with the patient. More patients are receiving S-ICD for prevention of SCD. The risk of S-ICD shocks for healthcare providers during CPR is unknown. Methods: N/A Results: A 55-year-old male with non-ischemic cardiomyopathy who received an S-ICD was hospitalized with decompensated CHF. During his hospital stay, he suffered a cardiac arrest secondary to VT. CPR was initiated and the two nursing staff providing chest compressions were not using protective barriers. The S-ICD fired appropriately an 80 J successful shock resulting in an electric shock to both nurses. While it was not clear whether the two nursing staff experienced the mechanical jerking or actual electric shock, and in order to test the effect of S-ICD shock on a person in contact with chest, the implanting physician placed his bare hand

over the sternum during DFT testing in a subsequent S-ICD implantation procedure. This resulted in a significant electric shock to the physician with a tingling sensation and numbness in his arm that lasted for several minutes. There were not any observed long-term sequelae. Conclusions: S-ICD shocks can be felt by a person in contact with the patient at the time of shock. These can result in a significantly painful sensation. Utilization of protective gloves is strongly recommended during chest compressions. Further sequelae of the S-ICD shocks remain unknown and need to be investigated in future studies.

- Jain A, Peterson M, McDaniel M, Rothman A, Restrepo H, Thomas VC. **Analysis of screening electrocardiograms in congenital heart disease patients for the subcutaneous implantable defibrillator [abstract].** *Heart Rhythm*. 2016; 13 (5 SUPPL. 1): S178. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07*. Introduction: Candidates for the subcutaneous implantable cardioverter-defibrillator (S-ICD) are screened using an electrocardiogram (S-EKG) tool to measure appropriate detection. We sought to define the S-ICD candidacy of congenital heart disease patients using the S-EKG tool. We also analyzed the reliability of the (S-EKG) tool between measurers in this population. Methods: Patients above the age of 12 and with a diagnosis associated with either a higher incidence of cardiac arrest or vascular access challenges were asked to undergo screening. Patients underwent S-EKG screening in both supine and standing positions. S-EKGs were then analyzed by a pediatric electrophysiologist, an S-ICD device engineer, and an S-ICD clinical representative for candidacy. Results were compared for interobserver variability using a Kappa statistic. S-EKGs were analyzed by t-test to determine variables that differ among passing and failing leads. Results: Thirty-one patients underwent screening with mean age was 34 (range 19-56) years and 16 females. Diagnoses included tetralogy of Fallot (10), post-operative Fontan (9), postoperative atrial switch (4), aortic stenosis (6), and hypertrophic cardiomyopathy (2). Two of the 31 (6.5%) patients failed S-ICD screening, both with diagnoses of tetralogy of Fallot. Two patients with ventricular pacing passed S-EKG screening. Analysis of the screening leads demonstrated the highest passing rates using lead III at a 5 mm/mV amplitude setting with 71% and 62% pass rate in the supine and standing positions, respectively. Interobserver analysis correlated well among the three measurers at 0.739 in the supine and 0.817 in the standing (p-value <0.01). There was a higher amplitude difference in lead III between the QRS and T waves among passing S-EKG, mean 14.9 mV, versus failing S-EKG, mean 7.2 mV (p-value <0.01). Conclusions: Congenital heart disease patients have acceptable passage rates utilizing the S-EKG algorithm. Interobserver measurements were well correlated and this data suggests that the proximal coil to device (lead III) vector would be best utilized in this patient population. A larger difference between QRS and T wave amplitudes was associated with a higher S-EKG passing rate.
- Kandala J, Oommen C, Hamoud N, Ott P. **Chronotropic incompetence in ICD recipients: Implications for device selection [abstract].** *J Am Coll Cardiol*. 2016; 67 (13 SUPPL. 1): 858. *65th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.16 Chicago, IL, United States 2016-04-02 to 2016-04-04*. Background: The current subcutaneous ICD system lacks the capability of cardiac pacing. ICD recipients with chronotropic incompetence (CI) benefit from pacing, however the prevalence of CI is underappreciated in ICD recipients. Analysis of the heart rate histogram (HRH) data, stored in the device log, has been shown to allow clinical diagnosis of CI. Hypothesis: The aim of this study is to assess the prevalence of CI and its predictors in ICD recipients. Methods: This study included 101 ICD recipients (dual chamber and single chamber) with availability of minimum 3 months of usable HRH data, and at least one year follow up in our continuity clinic. According to recently validated data, CI was diagnosed if the percentage of all atrial-paced and sensed events in the lowest heart rate histogram bin >70%. A multivariate logistic regression was performed to identify predictors of CI. P<0.05 was considered significant. Results: Among 101 ICD recipients, 32% female, age 59 ±17 years, ischemic cardiomyopathy [ICM] 41%, non-ischemic cardiomyopathy [NICM] 26%, congenital heart disease [CHD] 10%; ICD implanted for secondary prevention [SCD] 22 %. The overall prevalence of CI was 27 (26%). The prevalence of CI varied as follows: 33% in ICM, 18% in NICM, 30% in CHD, and 22% in SCD. In multivariate logistic regression analysis, age (OR 1.03, p=0.05), use of beta-blockers (OR 0.24, p= 0.04), prior coronary artery bypass grafting (OR 4.5, p= 0.01), and use of antiarrhythmic drugs (OR 3.5, p= 0.018) were independent predictors of CI. Conclusions: CI was present in 26% of ICD recipients. While trans-venous ICD systems allow rate responsive pacing on those patients, the current subcutaneous ICD system lacks this capability. This study underscores the importance of appropriate device selection, which in turn may have implications for patients exercise capacity and quality of life.
- Kawabata M, Goya M, Sasaki T, Maeda S, Shirai Y, Nishimura T, Yoshitake T, Shiohira S, Hirao K. **Surface electrocardiogram screening for subcutaneous implantable cardioverter-defibrillators: The comparison between Brugada syndrome and non-Brugada syndrome [abstract].** *Eur Heart J*. 2016; 37 Supplement 1: 693. *European Society of Cardiology, ESC Congress 2016 Rome, Italy 2016-08-27 to 2016-08-31*. Surface electrocardiogram (ECG) screening for subcutaneous implantable cardioverter-defibrillators (S-ICDs) is essential to prevent inappropriate shocks due to T-wave oversensing. It has been reported that in patients with Brugada

syndrome (BrS) implanted with an ICD, T-wave oversensing is more frequent than those without BrS. We assessed the current ICD recipients who are eligible for S-ICD implantation using the surface ECG screening and compared those with and without BrS. Methods and results: A ECG screening tool was used to determine eligibility for S-ICDs in two different postures (supine and sitting). S-ICD eligibility required at least 1 lead to satisfy the S-ICD screening template in both postures. Patients who needed antibradycardia pacing were excluded. Sixty ICD patients were assessed (age 57.0 years, 90% men, body mass index 23 ± 4 kg/m²), QRS duration 123 ± 44 ms, QTc interval 437 ± 42 , and QRS axis 22 ± 52 degrees). Overall, 9 (15.0%) of patients were considered not suitable for S-ICDs according to the surface ECG screening criteria. There were significantly more unsuitable patients in those with BrS compared to those without ($p=0.016$; 6/18 [33.3%] in BrS vs. 3/42 [7.1%] in non-BrS). There were no differences in the clinical characteristics and standard ECG measurements between those eligible and ineligible. The S-ICD screening template was satisfied more often by Lead III (primary vector, 77.1%) and Lead II (secondary vector, 68.8%) compared with Lead I (alternate vector, 43.8%). Conclusion: Among current ICD patients, there was a considerably high incidence of patients with BrS unsuitable for S-ICDs after the currently available screening test. There were no predictors associated with ineligibility for S-ICD implantations.

Klier I, Beckmann B, Schuhmann C, Clauss S, Sattler S, Siebermaier J, Sinner M, Strewe C, Wakili R, Käab S, Estner H, Fichtner S. **The subcutaneous ICD (S-ICD) during pregnancy and delivery—first experiences [abstract].** *J Interv Card Electrophysiol.* 2016; 45 (3): 298. *12th Annual Congress of the European Cardiac Arrhythmia Society, ECAS 2016 Paris, France 2016-04-17 to 2016-04-19.* Background: Implantable cardioverter defibrillators (ICD) are the gold standard for primary and secondary prevention of sudden cardiac death. Hereditary arrhythmia syndromes often require ICD implantation during adolescence. One of the major problems of transvenous ICDs is the risk of lead complications that requires repeated interventions. The subcutaneous cardioverter defibrillator (S-ICD) is an ICD which is implanted subcutaneous without transvenous leads and might therefore be suitable especially for young patients who wish to become pregnant. Methods: We performed a retrospective analysis by screening all patients with implanted S-ICD who became pregnant. Our standardized follow-up included a regular ICD interrogation and a patient interview regarding any issues with their S-ICD. Results We identified three patients who were provided with an S-ICD before their pregnancy. Indication for S-ICD implantation included Long-QT-Syndrom Type 2 (secondary prevention; heterozygous mutation in KCNH2 (p.Arg1047Leu)), idiopathic ventricular fibrillation (secondary prevention) and an “arrhythmogenic left dominant cardiomyopathy” (primary prevention; family history of SCD and heterozygous mutation in DSP (DSP6502-6505delAGTCfs)). No complications were seen during pregnancy and delivery in all three women. During spontaneous delivery the S-ICD was deactivated and patients were continuously monitored. The newborns were healthy with APGAR scores of 9/10/10 (2/3) and 8/9/10 (1/3). In 2/3 women inadequate ICD shocks occurred before pregnancy. During pregnancy and birth no arrhythmias or shocks were noticed. Conclusion: Patients with hereditary arrhythmia syndromes often need an ICD early in life. In this context the S-ICD might be a suitable alternative to a transvenous ICD. Our retrospective analysis in this small cohort of patients shows that the S-ICD is efficient and safe during pregnancy and birth. Deactivating the S-ICD during delivery is important to prevent inadequate shocks, but requires continuous monitoring.

Knops RE, Brouwer T, Quast AF, Wilde A. **Long-term follow-up of the two-incision implantation technique for the subcutaneous icd [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S344. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: Implantation of subcutaneous implantable cardioverter-defibrillator (S-ICD) requires three incisions. The two-incision technique omits the superior parasternal incision. Short-term results showed safety and efficacious, but no long-term follow up-data is available. We assessed long-term clinical outcomes of the two-incision technique for S-ICD implantation in a larger cohort. Methods: In the largest single center S-ICD cohort, patients implanted between 2009-2015 were included. Between February 2009 and October 2010 patients were implanted with the labeled three-incision technique (N=31) and were compared to those implanted with the two-incision technique after October 2010 (N=110). Outcomes were shock impedance and efficacy. Complications were those requiring intervention. Inappropriate shocks were those not for ventricular tachycardia or fibrillation. Kaplan Meier estimates at 5 year follow-up were calculated. Results: First shock efficacy during defibrillation testing was 100% in the three-incision group versus 96% in the two-incision group ($P=0.57$). Shock impedance during defibrillation testing was higher in the three-incision group, 88 versus 65 ohms ($P<0.001$). First shock success was 80% versus 75% for spontaneous episodes ($P=1.00$), respectively. During follow-up to five years there was one lead dislocation in the three-incision group and none in the two-incision group ($P=0.22$). Complication-free survival at five year follow-up in the three-incision group was estimated at 84% 95%CI (72-98) versus 88% 95%CI(80-97) in the two-incision group ($P=0.40$) and for inappropriate shocks at one year 90% 95%CI(81-100) versus 92% 95%CI(87-98) ($P=0.65$), respectively. Five infections occurred that required device extraction, three in the three-incision group versus two in the two-incision group ($P=0.08$). Erosion occurred in zero patients in the three-incision group versus 3 in the two-incision group ($P=0.29$). Conclusions: Long-term

follow-up in this S-ICD cohort showed safety and effectiveness of the two incision technique. This technique offers physicians a less invasive and more simplified implantation procedure for the S-ICD.

Kondo Y, Kurita T, Ueda M, Miyazawa K, Ishimura M, Nakano M, Kobayashi Y. **Efficacy and cost-effectiveness of wearable cardioverter-defibrillator as a lifesaving-bridge therapy for decision in high risk Japanese patients of sudden arrhythmic death [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S150. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: The wearable cardioverterdefibrillator (WCD) is a promising approach to reducing sudden cardiac death (SCD), but its cost-effectiveness is uncertain. This study was designed to determine the efficacy and cost-effectiveness of the WCD in terminating tachyarrhythmias in patients at high risk for SCD. Methods: This study was conducted on all WCD patients who were at high risk for SCD but did not meet the implantation-eligibility criteria for implantable cardioverter-defibrillator (ICD). We developed a Markov model of the cost, survival, and incremental cost-effectiveness of the WCD compared with usual care among patients at high risk for SCD Results: Sixty-six patients (age 63 (48-75), males 74%, follow-up period 20 (14-31) months) were enrolled. Of those, 24 (36%) were early post-myocardial infarction patients. Thirty-one patients (47%) used a WCD for secondary prevention for SCD. The mean duration of use was 55 (24-85) days. A total of 3 patients (5.0%) were shocked by a WCD. The first-shock success was 4 out of 4 shocks (100%) for unconscious ventricular tachycardia or ventricular fibrillation. No patients experienced an inappropriate treatment and died during the WCD therapy period. An ICD was implanted in 37 patients (56%) and subcutaneous ICD was implanted in only one young patient (1.5%) after the WCD therapies. Of 28 patients (42%), the use of WCD contributed to the prevention of an unnecessary ICD implantations. In terms of the Japanese medical economic impact, WCD therapy was able to save 7122 dollars per patient. After WCD therapy, 2 patients with an ICD died by non-arrhythmic events; however, no death occurred in patients without an ICD. Conclusions: WCD is a safe and beneficial device for patients at high risk for SCD, who are not clear candidates for an ICD, and provides superior cost-effectiveness.

Konrad T, Veltmann C, Sonnenschein S, Mollnau H, Gerhardt S, Bock K, Ocete BQ, Spittler R, Huber C, Schuff A, Theis C, Rostock T. **RANGRF-a gene potentially involved in early repolarization syndrome [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S366. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: Early repolarization syndrome (ER) has been described as an ECG variant that is associated with an increased risk of sudden cardiac death (SCD). There is paucity of data regarding the genetical background of ERS. Methods: A 45-year-old male patient was referred to our institution because of recurrent dizziness and pre-syncope. ECG showed a discrete early repolarization (ER) pattern (notching, horizontal ST-segment) in the infero-lateral leads. Ajmaline-challenge did not induce a Brugada ECG pattern (3rd and 4th intercostal space). Detailed history of the index patient revealed the following cases of SCD: the patients' 19y/o son died suddenly, autopsy did not show any cardio-vascular abnormalities. The patients' father died unexpectedly at an age of 39. Finally, an uncle (paternal line) died suddenly at an age of 49 years. A loop recorder was implanted in the index patient. Recurrent fast polymorphic VTs for up to 20s were documented which were accompanied by the patients' previously reported symptoms. Subsequently, a subcutaneous ICD was implanted. Next-Generation-Sequencing of a Brugada-syndrome Gene-panel revealed the heterozygote mutation p.Glu61*in exon 2 of the RANGRF-gene. This mutation is known to result in a tremendously shortened MOG1-proteine and thereby to a decreased NAV 1.5 current. Although a potential involvement of this mutation in Brugada-syndrome was published, no association with ER has been described thus far. Results: Family screening: The patient has 2 living sons and two brothers (one with 1 daughter + 1 son). All family members were evaluated with ECG, ajmaline-test (negative in all patients) and sequencing of RANGRF. The patients' 24y/o son and his 19y/o cousin showed similar ER ECG-pattern. The ECG was unremarkable in all other family members. In all family members with an ER ECG-pattern, the same p.Glu61*RANGRF-mutation was detected. Of note, this mutation was not found in any of the family members without an ER ECG pattern. Conclusions: In this family with a high incidence of SCD and ER ECG pattern, p.Glu61*mutation in RANGRF-gene was identified. All family members with verified gene-mutation showed an ER pattern. Thus, RANGRF-mutations leading to a decreased NAV 1.5 current could be potentially involved in the ER-syndrome.

Kumar AA, Liang JJ, Maeda S, Supple GE. **Reduction in electrocardiographic lateral precordial voltage after subcutaneous implantable cardioverter-defibrillator implantation [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S584. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: Decreased voltage across the precordial leads may occur in the setting of increased impedence between the heart and the surface electrodes. ECG changes may occur after implantation of a subcutaneous ICD (S-ICD) when surface ECG electrodes are placed over the implant site. Methods: N/A Results: A 31-year old man was diagnosed with apical hypertrophic

cardiomyopathy (HCM) on echocardiogram after a syncopal episode. Cardiac MRI demonstrated delayed enhancement in the inferior septal wall. He was referred for evaluation of a primary prevention ICD. After discussion, it was decided to implant a S-ICD (Boston Scientific). Pre-implant ECG (Figure, A) demonstrated left ventricular hypertrophy (LVH). R-wave amplitude in the lateral precordial leads were consistent with apical HCM. The S-ICD was implanted successfully in the left upper abdomen. Repeat ECG after device implant (Figure, B) demonstrated only minimal criteria for LVH. The R-wave amplitudes in the lateral precordial leads V4-V6 were lower than the pre-implant ECG, while R-wave amplitudes in the lateral limb leads were unchanged. Conclusions: Reduction of precordial voltage on ECG most commonly results from the presence of pericardial/pleural fluid or subcutaneous fat. In patients undergoing implantation of a left-sided S-ICD, it is important to recognize that the placement of the lateral precordial leads over the device may result in reduced voltages on the corresponding leads recorded on the surface ECG.(Figure Presented).

Kuschyk J, Rudic B, Roeger S, Tueluemen E, Liebe V, Borggreffe M. **The subcutaneous implantable cardioverter-defibrillator: First single-center experience with other cardiac implantable electronic devices [abstract].** *Cardiology*. 2016; (2016) 134 Supplement 1: 327. *International Academy of Cardiology 21st World Congress on Heart Disease Annual Scientific Sessions 2016 Boston, MA, United States 2016-07-30 to 2016-08-01*. Background: Subcutaneous implantable cardioverter-defibrillator (S-ICD) is an implantable device for antiarrhythmic therapy with no intravascular leads. Objective: We describe the technical feasibility of combining the S-ICD with other cardiac implantable electronic devices (CIEDs), including pacemakers with trans-venous or epicardial electrodes. We also provide the first experience of combining S-ICD with catheter-based therapies including cardiac contractility modulation (CCM) and vagus nerve stimulation (VNS). Methods: Between 7/2011 and 11/2014 six patients received a CCM device and S-ICD, three patients with a single-chamber pacemaker using either trans-venous or epicardial pacing electrodes received S-ICD, and one patient with an implanted S-ICD received VNS. In all patients intraoperative S-ICD testing, crosstalk tests and postoperative ergo metric testing were performed. Results: In all 10 patients device implantations were successfully performed without complications. S-ICD therapy was shown to be technically feasible with concomitant CIED. Mean follow up was nearly 17 months. S-ICD testing and crosstalk testing before and during exercise enabled device programming across a broad range of test conditions and was associated with no subsequent evidence of adverse device interaction. None of the devices required permanent inactivation or removal and no patient received an inappropriate shock. Conclusion: In suitable patients, combining an S-ICD with CCM or pacemaker may provide an acceptable means to reduce the number of trans-vascular leads. S-ICD appeared safe with CCM over an intermediate follow-up period. Additional prospective randomized controlled trials examining S-ICD in conjunction with CIEDs are warranted.

Latt H, Evans J. **Device implantation conundrum: Optimal management of a patient with mixed phenotype channelopathy [abstract].** *Cardiology*. 2016; (2016) 134 Supplement 1: 332. *International Academy of Cardiology 21st World Congress on Heart Disease Annual Scientific Sessions 2016 Boston, MA, United States 2016-07-30 to 2016-08-01*. Cardiac ion channelopathies are common causes of sudden death with normal cardiac anatomy. Of them, congenital long QT syndrome (LQTS) and Brugada syndrome (BrS) are two major entities. A 48 year old woman presented with ventricular fibrillation cardiac arrest. Electrocardiogram, echocardiogram, coronary angiogram and cardiac MRI were unrevealing. Given ST elevation on telemetry precordial leads, BrS was suspected, but procainamide provocation test was negative. Subcutaneous implantable cardioverter defibrillator (S-ICD) was placed. Unfortunately, the patient had recurrent cardiac arrest four days later. The device interrogation revealed monomorphic ventricular tachycardia (mVT) and torsades de pointes, which remained undetected by S-ICD, and required external shocks. Subsequent twelve-lead EKG showed QTc of 532 msec. A dual-chamber ICD was implanted. No recurrent arrhythmias were reported at three-month follow up. Sustained mVT is common in BrS, but rare in LQTS, the trademark arrhythmia of which is torsades. In our patient, BrS is suggested by mVT and precordial ST elevation, but torsades and prolonged QTc point towards LQTS, raising the possibility of mixed phenotype channelopathy. Additionally, this case challenges the contemporary use of S-ICD as a mainstay of therapy for channelopathy in a young patient, subsequently demanding the use of conventional dual-chamber ICD to potentially pace terminate VT and prevent recurrent cardiac arrests. Despite the advances in knowledge of cardiac channelopathies and sophisticated ICDs, the clinical management is still a challenge. So, not only does the genetic enigma of channelopathies demand further research, but the optimal management of these patients warrants further study.

Marshall MT, Christie MG, Zhang X, Nikolski VP, Olson N. **Pacing and sensing performance of non-contact electrodes in the substernal space in swine [abstract].** *Heart Rhythm*. 2016; 13 (5 SUPPL. 1): S106. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07*. Introduction: Subcutaneous ICDs (S-ICD) provide lifesaving defibrillation therapy while preserving the vascular space or in patients without vascular access. Current S-ICDs lack the

capability of ATP for painless conversion of VT. A novel ICD has been proposed with a defibrillation lead in the mediastinal region between the sternum and the pericardium. This pre-clinical study sought to evaluate lead electrode concepts for electrical performance in swine. Methods: Ten swine were implanted with 9 different electrode concepts in Latin squared order. The lead concepts employed defibrillation coil electrode sections and 2or3 ring electrodes for pacing and sensing functionality. Accessing the substernal space via a subxiphoid incision, leads were tunneled superiorly right of midline and positioned over the cardiac silhouette using a malleable tunneling tool and introducer. Fluoroscopic images were recorded for each lead position and distance of the electrode to epicardial surface estimated. Pacing thresholds, impedance and Rwaves were recorded using a standard pacing system analyzer (max output 10 volts @ 1.5 ms). Results: Pacing was successful in 69% of all attempts and with < 8 volts for 78% of the electrodes within 1 cm of the epicardium. Electrodes positioned between 10-45 cm of the silhouette apex achieve 100% capture with max outputs. Conclusions: Pacing can be achieved in swine with standard pacing outputs. Proximity and location over the heart silhouette are critical factors in pacing success. Implant methods and lead design can aid in achieving pacing therapy.

Mellor G, Cheung C, Steinberg C, Lane C, Lemaitre J, Bennett M, Chakrabarti S, Krahn AD, Bashir J. **The British Columbia provincial experience with a totally subcutaneous implantable defibrillator: A retrospective cohort study [abstract].** *Can J Cardiol.* 2016; 32 (10 Supplement 1): S286. 69th Annual Meeting of the Canadian Cardiovascular Society Montreal, QC, Canada 2016-10-22 to 2016-10-25. BACKGROUND: The subcutaneous internal defibrillator (SICD) is a novel technology aimed at minimizing intravascular defibrillator lead complications. The number of devices implanted across Canada remains small. METHODS AND RESULTS: A retrospective cohort analysis of all patients who received a S-ICD across the province of British Columbia was conducted. All patients met guideline criteria for ICD implant. The decision to implant a S-ICD was agreed by a provincial panel of implanting physicians. All patients underwent ECG screening as per the manufacturer's recommendation (3 screening failures). Implants were performed across 3 sites from April 2014 to April 2016. The implant rate increased over the period of study from 0.9 to 2.3/month. Patient demographics are shown in the accompanying table and were similar to previously published international registries. The majority of patients had normal LV function and a narrow QRS duration. 44% of implants were for primary prevention. The most common indications were ischaemic cardiomyopathy, idiopathic VF and hypertrophic cardiomyopathy. A previous transvenous ICD system had been in place in 11 (31%). This proportion tended to decrease over the course of the study. Rates of co-morbidities were low. There were no procedural complications relating to the S-ICD implant. During defibrillation threshold (DFT) testing, it was not possible to induce VT/VF in 2 (6%) patients and a single patient required an 80J shock after failing to cardiovert at 65J. Over a mean follow-up of 10.3±7.0 months, there were no appropriate or inappropriate therapies delivered. CONCLUSION: S-ICD implant rates are increasing and recipients are similar to those in international registries. Acute complication rates are low and comprise only failed DFT at this time. Longer follow-up is required to identify predictors of appropriate and inappropriate therapy. (Table presented).

Mithani A, Kath H, Eno E, Nathan K, Field J, Hunter K, Ortman M, Andriulli J, Russo A. **Characteristics and clinical outcomes of patients undergoing subcutaneous versus transvenous single chamber ICD placement [abstract].** *J Am Coll Cardiol.* 2016; 67 (13 SUPPL. 1): 860. 65th Annual Scientific Session of the American College of Cardiology and 12 Summit: Innovation in Intervention, ACC.16 Chicago, IL, United States 2016-04-02 to 2016-04-04. Background: In 2012, the first totally Subcutaneous Implantable Cardioverter-Defibrillator (S-ICD) was approved by the Food and Drug Administration (FDA). A potential benefit of this device is that it does not involve placing leads "in" or "on" the heart, potentially reducing complications. Methods: Seventy-one pts underwent S-ICD implantation between 10/22/2012 and 1/22/2015. During this period of time, 71 pts with TV-ICDs were matched to S-ICD pts using NCDR ICD Registry Data based on dialysis status, age, and gender. Intra- and post-operative complications were examined within the first 180 days following implantation.. Results: Pts with S-ICDs had higher creatinine (2.32 vs. 1.20, p <0.05) and were more likely to be on chronic dialysis (22.5% vs. 9.9%, p=0.004) than TV-ICD ps. Three pts in the TV-ICD and 7 pts in the S-ICD group had prior TV device infection requiring explant. Two pts in the TV-ICD and 13 ps in the S-ICD group had a previous CVA/TIA (p=0.007). Five pts experienced 6 complications in TV-ICD group and 2 pts experienced 4 complications in SQ-ICD group, p = 0.453 (See Complications Table). Conclusions: In this retrospective matched single center cohort study, there was no significant difference in implantation complications in pts receiving single chamber TV-ICDs compared to S-ICDs within 6 months following implantation. This occurred despite more severe preexisting illness in the S-ICD group. Further investigation is needed to determine outcomes after longer-term follow-up. (Table Presented).

Modi D, Mangroia H, Overcash J, Arkles J, Gangireddy C, Mirachi N, Patel R, Cooper JM. **Inappropriate shock delivery from subcutaneous implantable cardioverter defibrillator systems due to early reduction in ventricular electrogram amplitude [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S47. 37th Annual Scientific

Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: The subcutaneous ICD (S-ICD) detects ventricular activity using one of 3 sensing vectors from 3 electrodes on the lead and generator. The device employs non-programmable algorithms to detect ventricular rate and discriminate SVT from VT or VF. We present 2 patients who passed the pre-operative ECG screening and had good sensing vectors at S-ICD implantation, but who received inappropriate shocks due to subsequent markedly reduced R wave amplitude and oversensing. Methods: N/A Results: A 47 yo woman with renal failure on dialysis, bifascicular block (QRS 160 ms) and non-ischemic cardiomyopathy (EF 20%) had a VF arrest. Transvenous ICD implantation was not feasible due to R-sided venous occlusion and a L-sided dialysis fistula, so she underwent S-ICD implantation. One week later, she received multiple inappropriate shocks for noise oversensing in the setting of markedly reduced R wave amplitudes, both lying and standing. A 49 yo man with non-ischemic cardiomyopathy (EF 35%) had a VF arrest and underwent S-ICD implantation. One month later, while mopping the floor, he received a shock from his device. Interrogation revealed an inappropriate shock from markedly reduced R wave amplitude and noise oversensing. Small R waves in his optimal sensing vector were reproduced with bending forward. Conclusions: Despite a favorable auto-selected sensing vector at implantation, R wave amplitudes can subsequently drop, leading to undersensing, oversensing, and inappropriate shocks. There are minimal programming options to overcome this problem when it occurs, and reoperation for electrode repositioning or conversion to a standard ICD are the primary available solutions. (Figure Presented).

Modi D, Mangrolia H, Chernuta E, Lark Sr S, Greenberg RM, Cooper JM. **Implantable cardioverter defibrillator lead destruction by a tricuspid bioprosthetic valve [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S323-S4. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: Placement of an RV lead through a bioprosthetic tricuspid valve creates a risk for future valve injury, although this risk is reported to be low. Lead injury has generally not been a concern. Methods: N/A Results: A 46 yo woman underwent bioprosthetic tricuspid valve replacement for endocarditis and heart failure. Her postoperative course was complicated by sinus node dysfunction, intermittent heart block, and a VF arrest. A dual chamber ICD was implanted. Over the subsequent 18 months, the ICD lead pacing impedance declined, and ventricular oversensing of atrial events was also seen. Lead extraction and replacement was scheduled. The lead was removed with steady traction, and gross examination revealed a long, deep, ovoid insulation abrasion just proximal to the RV coil where the lead crossed the bioprosthetic tricuspid valve. This defect involved both outer and inner insulation, exposing the metal conductors. This injury was consistent with chronic friction interaction with the bioprosthetic tricuspid valve. There was concern for similar lead damage if a new lead were placed through the tricuspid valve. Because heart block had completely resolved but sinus node dysfunction remained, an atrial pacemaker was implanted, along with a subcutaneous ICD system for her history of VF arrest. Conclusions: Lead placement across a bioprosthetic valve can result in mechanical interactions that cumulatively damage one or both devices. The degree of interaction is difficult to predict during lead implantation, and alternative solutions should be considered whenever possible, to avoid the potential complication of valve or lead injury over time.

Mollnau H, Konrad T, Sonnenschein S, Theis C, Ocete BQ, Bock K, Rostock T. **Repetitive inappropriate shocks of a subcutaneous ICD during sinus rhythm with QRST triple sensing inducing ventricular fibrillation with fatal outcome in a young patient [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S177. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: The entirely subcutaneous implantable defibrillator (sICD) was developed to offer an alternative device technique devoid of intracardiac leads for the prevention of sudden cardiac death. Previous studies have shown that the sICD is a safe and effective alternative to conventional endovascular ICD systems. However, a few cases have reported inappropriate sICD therapies due to T wave or QRST oversensing. Here, we describe the case of a young patient who received multiple shocks from the sICD during normal sinus rhythm (NSR) that induced ventricular fibrillation (VF), ultimately resulting in fatal outcome. Methods: N/A Results: In a 34-year-old male patient with severely depressed left ventricular function (LVEF 30%) and advanced heart failure due to a history of methamphetamine-induced dilative cardiomyopathy, a sICD was implanted for primary prevention. One month later, the patient survived an electrical storm (five consecutive episodes of VF within 12 hours) due to hypokalemia (1.9 mmol/l). Subsequently, long-term potassium substitution was prescribed. One year later, the patient suddenly received multiple repetitive ICD shocks during a resting and conscious stage while suffering from gastro-enteritis. Within a few minutes after the first sICD discharge, the patient collapsed. First rhythm documentation showed NSR with repetitive ICD therapies and the patient was transferred to a hospital under continuous cardio pulmonary resuscitation. The Initial blood sample revealed hyperkalemia (>7 mmol/l). Despite intensive efforts, the patient died due to electromechanical dissociation. Postmortem interrogation of the sICD showed a significant deviation of the QRS vector morphology as compared to the time of post-implantation treadmill testing. Moreover, hyperkalemia induced T wave doming was identified, resulting in QRST triple sensing (QRST3sens) and subsequent inappropriate ICD therapy. Conclusions: T-wave oversensing and QRST3sens

may cause inappropriate shock therapy in sICD patients with the potential to induce hyperdynamic cardiac arrest with fatal outcome. Further improvements of sICD algorithms and programming are required to prevent oversensing related inappropriate shocks.

Mutha V, Rangasamy K, Healy S, Kotschet E, Adam D, Bittinger L, Krafchek J, Alison J. **Initial Australian experience with sub-cutaneous implantable cardiac defibrillators (S-ICD) [abstract].** *Heart Lung and Circulation.* 2016; 25 Supplement 2: S148. *64th Cardiac Society of Australia and New Zealand Annual Scientific Meeting and the International Society for Heart Research Australasian Section Annual Scientific Meeting 2016 Adelaide, SA, Australia 2016-08-04 to 2016-08-07.* Aim: To report on initial Australian Experience with Subcutaneous ICDs (S-ICD) Background: Several trials have demonstrated mortality benefit for implantable cardiac defibrillators (ICDs). However; there is a significant incidence of trans venous lead related complications. Subcutaneous-ICD(S-ICD) have been now approved for use in Australia; these device consist of a tri-polar parasternal lead (12-French) connected to a pulse generator; thus potentially avoiding deleterious effects of trans-venous lead implantation. Methods: Data was prospectively collected for all S-ICDs implanted by Monash Heart doctors. Patients needing ICD without pacing indication were selected at the discretion of operators. All patients had post implant exercise stress tests (30 day) to evaluate ventricular sensing. Results & Discussion: 11 S-ICDs were implanted by Monash Heart doctors during December 2014-March 2016 with average age of patients being 46 years. Indication was primary prevention (5/11) & secondary prevention (6/11). Primary vector was the most common sensing vector for majority of patients. One patient experienced inappropriate shock with primary vector (sensing related) and his sensing vector was changed to secondary vector. One device failure was seen; with the device not responding to interrogation at one month follow up. This patient got a replacement device and initial reports from manufacturer suggest piezoelectric crystal malfunction. Conclusion: S-ICD is a feasible option for patients requiring implantable cardiac defibrillators without indication for trans-venous pacing.

Palaniswamy C, Miller MA, Willner JM, Koruth JS, Choudry S, Langan MN, Dukkipati S, Reddy VY. **First report of inappropriate shocks from a S-ICD during chest compressions for asystolic cardiac arrest [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S499. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: The subcutaneous implantable cardioverter-defibrillator (S-ICD) uses a morphology-based sensing algorithm for detection of ventricular arrhythmias. Inappropriate therapies remain a significant concern with the S-ICD. We report the first case of multiple inappropriate shocks from S-ICD during chest compressions for asystolic arrest. Methods: N/A Results: A 71 year old male with history of ischemic cardiomyopathy (EF= 30%) underwent implantation of S-ICD for primary prevention. At implantation, defibrillation testing at 65 J was successful, and conditional (200 bpm) and shock-only zones (220 bpm) were programmed. Approximately 11 months after the implant, the patient was admitted for decompensated heart failure. While on continuous telemetry monitoring, the patient had worsening hypoxia resulting in bradycardia followed by asystole. During subsequent chest compressions, the patient was noted to have multiple shocks from the S-ICD. A subsequent interrogation after successful resuscitation demonstrated normal device function, and the device had incorrectly identified chest compressions as a ventricular arrhythmia (figure). Chest radiograph confirmed that the position of the electrodes and the pulse generator were unchanged compared to implant. Although the S-ICD has an algorithm for accurately discriminating noncardiac from cardiac signals, this case highlights the potential for inappropriate shocks due to chest compressions. Conclusions: Despite significant advances in discrimination algorithms, inappropriate shocks can occur from non-cardiac interferences, such as chest compressions, during cardiopulmonary resuscitation. (Figure Presented).

Parsamehr B, Meseeha M, Kolade V. **A case of noncompaction cardiomyopathy [abstract].** *Chest.* 2016; 150 (4 Supplement 1): 90A. *CHEST 2016 Los Angeles, CA, United States 2016-10-22 to 2016-10-26.* INTRODUCTION: Left Ventricular Noncompaction Cardiomyopathy (LVNC) is a rare form of cardiomyopathy with an abnormal thick myocardium and multiple trabeculations of endocardial layer. Clinical manifestation of LVNC includes chest pain, syncope, arrhythmia, sudden cardiac arrest, and thromboembolism. Electrocardiogram in these patients could show different abnormalities such as left or right bundle branch block, fascicular block, atrial fibrillation, and ventricular tachycardia. An association of LVNC with sinus bradycardia or Wolff-Parkinson-White syndrome has been described in some cases [1]. CASE PRESENTATION: A 20 year old African American male had multiple episodes of palpitation and chest pain. Patient did not have any significant past medical history other than hypercholesterolemia. Patient did not have history of smoking, alcohol, or drug abuse. Two years ago he woke up with an episode of palpitations and chest pain that prompted an emergency room visit. He was found to have T wave inversions in pre-cordial leads. A subsequent echocardiogram revealed extensive trabeculations in the apex of the LV with LVEF of 35%. A cardiac MRI was performed which showed increased ratio of noncompacted wall to compacted wall (2.5:1) in addition to global hypokinesis of the left ventricle. Patient started taking Nebivolol and later he switched to metoprolol. Patient also started taking Lisinopril and warfarin for his

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cardiomyopathy. One year later, he came to the ER with an episode of prolonged palpitation. He was found to have an episode of nonsustained ventricular tachycardia and subsequently a subcutaneous defibrillator was placed for him. Two months later he developed Atrial Fibrillation (AF) with rapid ventricular response (RVR). Patient was medically managed with Cardizem infusion. Interrogation of ICD revealed AF with heart rate in 200s. He started taking Sotalol and the next day he converted to sinus rhythm. **DISCUSSION:** Noncompaction cardiomyopathy is a rare type of cardiomyopathy with different manifestations such as heart block, atrial, and ventricular arrhythmia. Genes have been recognized to play a key role in pathogenesis of this condition. Screening of up to 3 generations of affected individuals has been recommended. High index of suspicion is necessary in order to diagnose LVNC. **CONCLUSIONS:** There are common genes involved in pathogenesis of hypertrophic cardiomyopathy and LVNC. Most of the times LVNC is misdiagnosed as hypertrophic cardiomyopathy. Our patient was diagnosed with a rare type of cardiomyopathy at an early stage. Placement of AICD was a good decision for this patient. What we concluded from this case was that a high suspicion for certain disorders in addition to proper diagnostic test is the key in diagnosing and managing the patients.

Quast AFBE, Brouwer TF, Kooiman KM, Van Dessel PFHM, Wilde AAM, Knops RE. **Comparison of complications and shocks in pediatric and young subcutaneous and transvenous implantable cardioverter-defibrillator patients [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S60. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.*

Introduction: Young implantable cardioverter-defibrillator (ICD) patients are prone for complications and inappropriate shocks (IAS). The subcutaneous ICD (S-ICD) may avoid lead related complications. To our knowledge this is the largest cohort to date comparing complications and shocks of S-ICD and transvenous ICD (TV-ICD) in children and young adults. **Methods:** All consecutive de novo single chamber TV-ICD and S-ICD patients <26 years implanted in our center between 2002 and 2015 were retrospectively analyzed. Device complications were defined as complications requiring surgical intervention and IAS as shocks not for VT/VF. Kaplan Meier estimates for complications at 5 year follow-up were calculated with corresponding 95%CI. **Results:** A total of 46 TV-ICD patients (median at implant age 17 years) and 35 S-ICD patients (median age at implant 19 years) were included, median follow-up is 78 and 25 months respectively. All cause complications did not differ significantly, 34% in the TV-ICD arm and 25% in the S-ICD arm ($p=0.64$). However TV-ICD patients had more lead complications 23% (9%-35%) versus 0% ($p=0.02$) (figure) and S-ICD patients had more infections 10% (1%-25%) versus 2% (0%-6%) ($p=0.14$). All infections were local. Appropriate shocks were similar, TV-ICD 22% (8%-36%) versus S-ICD 25% (4%-46%) ($p=0.85$), as was IAS rate 19% (7%-31%) versus 17% (1%-33%) ($p=0.50$). **Conclusions:** All cause complications in this cohort were equal, however TV-ICD patients suffered more lead complications. Appropriate and inappropriate therapy was similar. Our data confirms the expected reduction of lead complications with use of the S-ICD in this high risk population. (Figure Presented).

Saxena A, Shankar S, Chen O, Rehman A, Homel P, Miller A, Pundru N, Acholonu CM, Patel J, Rao O, Greenberg Y, Yang F. **Optimal time for subcutaneous implantable defibrillator screening in patients requiring hemodialysis [abstract].** *J Am Coll Cardiol.* 2016; 67 (13 SUPPL. 1): 703. *65th Annual Scientific Session of the American College of Cardiology and 12 Summit: Innovation in Intervention, ACC.16 Chicago, IL, United States 2016-04-02 to 2016-04-04.* **Background:** Since the subcutaneous implantable defibrillator (S-ICD) does not require venous access, patients on hemodialysis (HD) particularly stand to benefit from it. There is little information with regards to optimal screening windows for these patients due to their exclusion in major studies (e.g., S-ICD IDE). Fluctuations in potassium levels pre- and post-dialysis may alter the ECG and affect S-ICD sensing. **Methods:** Patients on routine HD were screened with tri-channel surface ECG's that mimic the screening vectors of the S-ICD. Patients were screened in supine and seated position (gains=5mv, 10mv and 20mv) in pre- and post-dialysis setting. Screening days were chosen based on largest gap in patient's routine HD (Monday, for Monday-Wednesday-Friday; Tuesday for Tuesday-Thursday-Saturday schedules). Patients were considered passing screening if they satisfied the screening algorithm in supine and standing position in both pre- and immediate post-dialysis setting in the same lead, any gain. **Results:** 44 patients were enrolled to date. 42 patients passed screening in both pre- and post-dialysis setting. One patient failed only in the pre-dialysis setting and one failed in both pre- and post-dialysis setting ($p=1.00$). The one sided 95% CI for the overall rate of failure was 4.5%-9.8%. The patient who failed only at pre-dialysis had a longer interdialytic interval of 4 days after missing a session. He was noted to have a potassium of 6.0 with peaked T-waves on the ECG pre-dialysis. Left ventricular hypertrophy (LVH) as per the Cornell criteria was noted in 8 patients, 7 of whom passed screening. The 1 patient with LVH who failed screening was the same patient who failed in the predialysis setting only due to hyperkalemia. The patient who failed in the pre- and post-dialysis setting had left bundle branch block. **Conclusions:** Despite anticipated fluctuations in potassium levels in dialysis patients, screening for S-ICD candidacy may not need to be performed at a particular time during their dialysis schedule. There is no significant difference in the screening failure rates in the predialysis vs the post-dialysis setting. However, patients not compliant with HD schedules may oversense peaked T waves.

Sholevar D, Tung S, Kuriachan V, Leong-Sit P, Roukoz H, Engel G, Kutalek SP, Akula D, Christie MG, Ostanniy M, Thompson A, Molin F. **Feasibility of extravascular pacing with a novel substernal electrode configuration: Results from the multi-center substernal pacing acute clinical evaluation (SPACE) trial [abstract]. *Heart Rhythm*. 2016; 13 (5 SUPPL. 1): S61-S2. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.** Introduction: Subcutaneous defibrillators offer a viable alternative to intravascular transvenous defibrillators. However, because of extra-thoracic lead placement, this system is limited by high defibrillation thresholds and an inability to deliver anti-tachycardia pacing. The SPACE trial evaluated the feasibility of cardiac pacing from an extra-vascular substernal space. Methods: This prospective feasibility study enrolled adult patients (pts) undergoing midline sternotomy surgery or S-ICD implant. The primary endpoint was to assess the feasibility of pacing through a decapolar EP catheter (Marinr, 7F, Medtronic) temporarily placed via percutaneous subxiphoid access into the mediastinal tissues under the sternum at or adjacent to the midline. Using fluoroscopy and a malleable tunneling tool and introducer, the middle pair of electrodes was centered over the right ventricle. Pacing capture data in 7 vectors (3 bipolar and 4 unipolar) were collected with constant current pacing up to 20 mA and pulse-width (PW) up to 10 ms. Results: Twenty-four pts (19 males, 5 females; age 64.1 ± 10.3 years) were studied at 8 sites in the US and Canada. Parent procedures included one S-ICD implantation and 23 cardiothoracic surgeries. Catheter placement was accomplished in all 24 pts (mean placement time = 13.4 ± 11.0 minutes). Seventeen out of 24 pts had successful, consistent ventricular pacing capture (PC) in ≥ 1 tested vector. The mean pacing thresholds at PW 10 ms, 3 ms, 1 ms were 7.0 ± 4.4 mA (17 pts), 9.0 ± 4.7 mA (13 pts), 11.8 ± 4.5 mA (7 pts), respectively. Failed PC in 7 pts was mostly associated with sub-optimal implant or atrial PC. Among the 17 pts with PC, 11 pts had the best PC in bipolar vs 5 pts in unipolar (no difference in 1 pt). Among the 15 pts with bipolar PC, widely spaced bipolar electrode pairs were consistently associated with the lowest threshold in all pts. For the 15 pts with bipolar PC with electrode spacing 19 mm and 10 ms PW, the median pacing threshold was 2.9 V (IQR: 2.2-8.0 V) or 4.1 mA (IQR: 3.0-10.0 mA). Conclusions: Preliminary data demonstrates that pacing is feasible from this novel extravascular substernal location. A bipolar substernal electrode configuration with wide electrode spacing has the potential to provide pacing in a future extravascular defibrillator.

Singh D, Koman E, Tiwari A, Subzposh FA, Gupta A, Overcash J, Saltzman HE, Kutalek SP. **Safety and efficacy of subcutaneous implantable-cardioverter defibrillator: A review of 100 single center implantations [abstract]. *Heart Rhythm*. 2016; 13 (5 SUPPL. 1): S516. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.** Introduction: Subcutaneous implantable cardioverter defibrillator (S-ICD) is the latest advancement in defibrillation therapy. It is currently approved for patients with indications for ICD implantation, without any pacing indications. Despite initial studies showing safety and efficacy, there are limited data available. We report our single, high-volume academic center experience with S-ICD implantation. Methods: We retrospectively analyzed inpatient and outpatient records of patients implanted with S-ICD at our center between October 2012 and November 2015. Results: S-ICD was implanted in 100 patients, with a mean age of 53 ± 14 years (range 18-86). There were 63% males, 56% African-American and 40% Caucasian. 55% were implanted for primary prevention, 40% had ischemic cardiomyopathy, 39% non-ischemic cardiomyopathy, 19% were on dialysis and 17% had prior transvenous device extraction. The mean ejection fraction was $30 \pm 17\%$. Mean procedure time was 59 ± 14 minutes. The mean procedure time per year decreased from 73.66 minutes in 2012 to 44.89 minutes in 2015. Defibrillation threshold testing (DFT) was performed in 87% of patients. Two patients had unsuccessful DFTs. Repeat testing was successful with reversed polarity in one patient and repositioning of the can in the other patient. Median follow-up was 154 days (1-306 days). A three incision approach was used 60% of the time. There was no procedural mortality. Two patients died prior to discharge- 1 from intractable VT due to non-revascularizable triple vessel CAD and 1 from mesenteric ischemia. Four patients died during follow-up (1 from asystolic arrest and 3 from unknown causes). Four patients had pocket infections, 2 required S-ICD removal. Nineteen patients received shocks- 11 had an appropriate successful shock and 8 had inappropriate shocks (4 from SVT, 2 from noise sensing due to air in the pocket and 2 from T wave oversensing). Conclusions: Our data show that S-ICD implantation can be performed safely and efficiently to treat life threatening ventricular arrhythmias in a large volume single center.

Srinivasan NT, Patel KH, Taylor A, Qamar K, Lambiase PD. **Disease severity and exercise testing reduce s-ICD ECG screening success in hypertrophic cardiomyopathy [abstract]. *Heart Rhythm*. 2016; 13 (5 SUPPL. 1): S173. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.** Introduction: Previous studies indicate up to 16% of patients (pts) with Hypertrophic Cardiomyopathy (HCM) are ineligible for the S-ICD on resting ECG screening alone. We investigated the factors determining the proportion of HCM pts meeting S-ICD ECG screening criteria at rest & on exercise. Methods: 131 HCM pts (age: 50 ± 16 years, 92M/39F) with a 1 risk factor for sudden death (SD)

underwent left sternal ECG screening while supine, standing & during exercise. The European Society of Cardiology (ESC) HCM SD risk score was high in 41%(5-year risk >6%), intermediate in 18% & low in 41%. Patients were deemed eligible for S-ICD if >1 sensing vector passed in all 3 screening positions. Results: 50 patients (38%) were ineligible for the S-ICD due to failure in every lead vector & position- 33 (66%) failed while supine; 12 pts (24%) standing & 5 (10%) on exercise. 31(44%) had 1 vector safety, 16(23%) had 2 vector safety and 24(33%) had 3 vector safety. An increased R:T-wave ratio in the screening ECG ($p<0.001$) & on the 12 lead ECG ($p=0.003$) was associated with a risk of screening failure. Patients with a high ESC risk score were more likely to fail screening (odds ratio 3.15; 95%CI 1.23-8.57; $p = 0.02$). Conclusions: (i) Large amplitude QRS complexes & (ii) High risk of SD result in S-ICD screening failure. Sensing algorithms need to be optimized to enable HCM pts to benefit from S-ICD. (Figure Presented).

Srivathsan K. **Newer implantable devices in heart failure [abstract].** *Cardiology.* 2016; (2016) 134 Supplement 1: 291. *International Academy of Cardiology 21st World Congress on Heart Disease Annual Scientific Sessions 2016 Boston, MA, United States 2016-07-30 to 2016-08-01.* Congestive heart failure due to systolic dysfunction is a frequent cause for hospitalization and not infrequently sudden death. Some of these patients have venous occlusion due to prior central venous access. Non traditional placement of devices has been replaced by entirely subcutaneous defibrillators. Detection and therapeutic algorithm of these devices are different from traditional trans venous implantable devices. Elevated pressures in cardiac chambers and pulmonary venous system precede overt clinical symptoms and weight gain. Implantable device monitoring of such pressures leads to early intervention and prevention of hospitalization. Utility of these devices in improving hospitalization and reducing mortality/morbidity is an important new development in heart failure management.

Steinfurt J, Biermann J, Staudacher D, Duerschmied D, Trolese L, Lang CN, Gressler A, Zehender M, Faber T, Bode C, Odening KE. **Familial early repolarization syndrome in two siblings [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S491. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: Sixteen percent of patients with early repolarization syndrome (ERS) have a family history of unexplained sudden death, indicating that ERS may be inheritable. However, there are no co-segregation data of genetic variants and ERS in affected families. We have identified two siblings with ERS. This study aims to characterize the ERS phenotype in this family and to identify a causative mutation. Methods: Clinical data (history of syncope and sudden cardiac arrest), continuous monitoring tracings, 12-lead- and Holter-ECGs were acquired. ERS diagnosis required an ER pattern in inferior and/or lateral leads and symptoms (sudden cardiac arrest or arrhythmic syncope) and/or documented VF. Sequencing of ERS candidate genes, followed by whole exome sequencing (WES), is performed. Results: After out-of-hospital cardiac arrest, the first patient (23 yr, female) developed electrical storm with cardiogenic shock, requiring Extracorporeal Life Support. Conventional anti-arrhythmic drugs failed and, by slowing heart rate, even increased the number of VF episodes per time. ECG revealed an inferolateral ER pattern with a J peak (Jp) amplitude of 0.25 mV with dynamic, pause-dependent augmentation. Recurrent VF was initiated by a monofocal premature ventricular complex (PVC). Isoproterenol was administered resulting in (1) successful defibrillation, (2) suppression of the ER pattern and the triggering PVC, and (3) suppression of any further VF. After full recovery, an implantable cardioverter-defibrillator (ICD) was implanted. KCNJ8, CACNA1C, CACNB2, CACNA2D1, and SCN5A genes showed no mutation. The patient's brother (25 yr) showed a persistent inferior ER pattern with a high Jp amplitude (0.6 mV in III), and a horizontal ST segment. During Valsalva maneuver, Jp was augmented to 0.9 mV. Due to a high-risk ER pattern, a family history of ERS, and a history of arrhythmic syncope, an S-ICD was implanted. Conclusions: Two siblings show a malignant ERS phenotype with dynamic ER pattern manifesting as arrhythmic syncope, sudden cardiac arrest, and electrical storm. Our findings support an autosomal-dominant inheritance of ERS. WES to determine the genetic defect underlying ERS in this family is ongoing.

Sultan A, Luker J, Halbach M, Fritz T, Van Den Bruck JH, Plenge T, Steven D. **Implantation of a subcutaneous implantable cardioverter defibrillator in a patient with baroreflex activation system: Feasibility and precautions [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S411. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: We report a case of a subcutaneous implantable defibrillator (S-ICD) implantation in a patient with a pre-existing baroreflex activation therapy device (BAT). Interferences caused by BAT stimulation may potentially lead to inappropriate shocks or under-detection of ventricular arrhythmia. Methods: A 32-year old man with dilative cardiomyopathy underwent S-ICD implantation after extraction of an intravenous single chamber ICD system due to lead failure. Intraoperative S-ICD defibrillation testing was successful. No interference between the BAT and the S-ICD was observed at patient's current BAT programming (PW 65 ps, amplitude 9.8 mA). Results: Over time, increasing stimulation output is often necessary in BAT therapy. Therefore, meticulous postoperative S-ICD interrogation was carried out. All 3 S-ICD detection vectors were assessed in seated and prone position while gradually increasing pulse width (PW) and output amplitude of the BAT system. An amplitude of up to

13.5mA did not result in S-ICD sensing disturbance. Increasing the PW to 95/L/S led to noise detection in one vector, possibly withholding ICD shock. At 140/L/S all available vectors exhibited severe noise detection. Noise detection was more pronounced in the seated as compared to the prone position. The maximum tolerated PW before the patient complained of symptoms was 500/L/S. Noise detection may inhibit shock delivery for life threatening arrhythmia. It can occur at an output that is much lower than the patient's threshold for symptoms caused by BAT stimulation. Therefore, determining a noise free output range is crucial to safely combine BAT therapy with an S-ICD. Conclusions: Combining an S-ICD with a BAT device is feasible. Noise caused by BAT stimulation is possible and may lead to potentially fatal S-ICD malfunction. Thorough assessment of crosstalk is essential for a safe combination of both systems.

Theuns DA, Burke M, Allavattam V, Jones PW, Gold MR. **Evaluation of a high pass filter designed to reduce oversensing in the S-ICD [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S10-S1. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: Inappropriate shocks in transvenous ICDs are most often caused by supraventricular tachycardia (SVT), while in the subcutaneous ICD (S-ICD) the most common cause is T-wave oversensing (TWOS). We sought to evaluate the performance of a high-pass filter designed to reduce cardiac oversensing in the S-ICD. Methods: The algorithm was tested on a dataset of 626 adjudicated episodes (161 TWOS, 328 SVT, 137 VT/VF) from 161 patients. Episodes were evaluated for appropriate decision to treat. TWOS episodes were tested with and without a stored normal sinus rhythm reference ECG. Each episode was run through three devices to account for test system variability, for each device generation (9 evaluations per episode). Repeated measures logistic modeling compared odds of inappropriate decision to treat across generations. TWOS episodes were evaluated at nominal settings of dual zone with rate 200/220. VT/ VF and SVT episodes were evaluated at 170/250 for maximal algorithm exposure. Results: Odds of inappropriate decision for SVT (treated) and VT/VF (untreated) remained unchanged across device generations (table). Inappropriate therapy decision for TWOS (treated) was reduced by 82% compared to the previous generation and 71% compared to generation 1. The time to detect treatable arrhythmias was 8.60 ± 3.81 sec in gen 2 and 8.86 ± 3.30 sec in gen 2.5. All episodes of VT/VF undersensed were treated by at least 1 device configuration for each generation. Conclusions: A new S-ICD algorithm demonstrated significant reduction in shocks for TWOS without a reduction in sensitivity to VT/VF. Results: The validation cohort included 100 patients with and 79 patients without AF. The algorithm correctly excluded AF in all 79 non-AF patients (specificity 100%). Conversely, the AF algorithm correctly identified 94 of the 100 AF patients (sensitivity 94%). AF was not detected when episodes were quite short (<8 minutes; n=4) or associated with a stable ventricular response (n=2). Conclusions: A novel RR based AF algorithm was developed and tested using publically available ECG databases. The algorithm exhibited very high sensitivity and specificity. If incorporated within existing S ICD systems, it would offer clinicians the ability to monitor for AF without requirement of a transvenous atrial lead.

Tjong F, Brouwer T, Smeding L, Kooiman K, Shuros A, Soltis B, Koop B, Wilde A, Burke M, Knops R. **The first report on communicating leadless anti-tachycardia pacemaker and subcutaneous implantable defibrillator: The next step in cardiac rhythm management [abstract].** *J Am Coll Cardiol.* 2016; 67 (13 SUPPL. 1): 684. *65th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.16 Chicago, IL, United States 2016-04-02 to 2016-04-04.* Background: With the aim of eliminating lead and pocket related complications, we examine the next step in multi-component leadless cardiac rhythm management (CRM): feasibility of an anti-tachycardia (ATP) leadless cardiac pacemaker (LCP), commanded by an implanted S-ICD through wireless, intra-body, device-device communication. Methods: Two sheep were implanted with ATP-enabled LCP and S-ICD prototypes (Boston Scientific). LCP performance, LCP programmer and LCP-S-ICD communication (both through conductive communication) were tested. ATP-commands from the S-ICD programmer were transmitted by the S-ICD to the LCP and LCP response was evaluated. Results: The LCP and S-ICD were successfully implanted (Panel A). LCP performance was adequate and demonstrated appropriate VVI behavior. Programmer and LCP-S-ICD communication were established without interference. Uni-directional communication between the S-ICD and LCP was successful in all (n=15/15) attempts (Panel B, *) resulting in ATP delivery by the LCP (10 beats at 81% of coupling interval). Acute LCP retrieval was successful. Conclusions: We present the first proof of concept study with the combined implant of an ATP-enabled LCP and S-ICD. We demonstrated appropriate VVI functionality, successful wireless device-device communication and ATP-delivery by the LCP. Further studies on safety and performance are needed. (Figure Presented).

Tjong FVY, Brouwer TF, Kooiman KM, Smeding L, Soltis B, Shuros A, Koop B, Wilde AA, Burke MC, Knops RE. **First report on communicating leadless anti-tachycardia pacemaker and subcutaneous implantable defibrillator [[unsupported character-codename SHY]] [abstract].** *Heart Rhythm.* 2016; 13 (5 SUPPL. 1): S12. *37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07.* Introduction: With the aim of eliminating lead and pocket related

complications, we examine the next step in multi-component leadless cardiac rhythm management (CRM): feasibility of an anti-tachycardia (ATP) leadless cardiac pacemaker (LCP), commanded by an implanted S-ICD through wireless, intra-body, device-device communication. Methods: The first experiments were conducted in sheep (n=2) with implantation of ATP-enabled LCP and S-ICD prototypes (Boston Scientific). LCP performance, LCP-programmer and LCP-S-ICD communication (both through conductive communication) were tested. ATP-commands, initiated via the S-ICD programmer, were transmitted by the S-ICD to the LCP and LCP response was evaluated. Results: The LCP and S-ICD were successfully implanted (Panel A). LCP performance was adequate and demonstrated appropriate VVI behavior. Programmer and LCP-S-ICD communication were established without interference. Unidirectional communication between the S-ICD and LCP was successful in all (n=15) attempts (Panel B) resulting in ATP delivery by the LCP (10 beats at 81% of coupling interval). Acute LCP retrieval was successful. Data on additional experiments with automatic S-ICD initiated ATP-delivery in porcine (n=4), canine (n=8) and ovine (n=6) animal models will be added to this analysis. Conclusions: We present the first proof of concept study with the combined implant of an ATP-enabled LCP and S-ICD. We demonstrated appropriate VVI functionality, successful wireless device-device communication and ATP-delivery by the LCP. Data from 18 animal experiments will be added to this analysis and presented. Further studies on safety and performance are needed. (Figure Presented).

Willner JM, Miller MA, Shimiaie J, Torina P, Sharma D, Palaniswamy C, Bhardwaj R, Balulad SS, Koruth JS, Dukkipati S, Reddy VY. **Feasibility of subfascial implantation of the subcutaneous ICD system [abstract]. *Heart Rhythm***. 2016; 13 (5 SUPPL. 1): S253-S4. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: We previously reported our results on the submuscular implantation (Sm-ICD) of the subcutaneous (S-ICD) as a strategy to reduce the risk of skin erosion and infection. However, that approach could result in more patient discomfort and longer recovery. Subfascial ICD (Sf-ICD) implantation may offer the same operative and cosmetic advantages of Sm-ICD implantation while minimizing patient discomfort. Methods: Physician preference and/or patient characteristics determined implant technique. Subfascial implantation of the generator was performed beneath the fascial layer of the serratus anterior muscle (but above the muscle). At the operator's discretion, devices were tested intra-operatively by induction of VF, and defibrillation was performed at 65J. Results: 78 consecutive patients (Sf-ICD, n = 26; Sm-ICD, n = 29, S-ICD, n =23) were included at a median length of followup of 127 days (IQR 34 - 322). Four patients (S-ICD, n = 2, Sm-ICD, n = 2) received appropriate therapy during follow-up. Of the 48 patients (61.5%) who underwent DFT testing, all were successfully defibrillated at 65J. In followup, two patients (S-ICD = 1, Sm-ICD = 1) received an inappropriate shock. There was one incision site wound infection in the S-ICD group and one device failure (early battery depletion) in the Sm-ICD group. There were no complications in the Sf-ICD group. Conclusions: The Sf-ICD is a feasible alternative to S-ICD and Sm-ICD implantation. Placement of the pulse generator in the subfascial position may offer the same reduced risk of pocket-related complications and improved appearance conferred by submuscular positioning, with a trend towards reducing length of stay. (Table Presented).

Zhang P, Grinberg Y, Nikolski VP, Degroot P, Marshall M, Simha N, Gan W. **Modeling of novel substernal defibrillation coil electrode location shows significant reduction in defibrillation threshold compared to a subcutaneous ICD system [abstract]. *Heart Rhythm***. 2016; 13 (5 SUPPL. 1): S59. 37th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2016 San Francisco, CA, United States 2016-05-04 to 2016-05-07. Introduction: A subcutaneous (SQ) ICD has emerged as an alternative to transvenous (TV) ICD, but with electrodes outside the chest wall they require higher energy to achieve effective defibrillation. A novel extravascular ICD concept which places a coil electrode in the substernal space between sternum and heart may significantly reduce defibrillation thresholds (DFTs) as compared with the present SQ ICD, allowing for smaller device size and greater patient comfort. To verify this assertion, we created human thorax Finite Element Analysis (FEA) models and computed DFTs for various electrode configurations including five configurations from a published SQ ICD clinical trial. Methods: A human thorax model was created based on a CT scan and scaled to represent a median size adult. The Critical Mass Assumption was used to calculate DFTs. Model predictions were compared for a coil placed either in the substernal space at the midline, subcutaneously adjacent to the sternum, and in the RV apex. An ICD Can was modeled on mid-axillary line at the level of the heart for extravascular ICD leads and in a pectoral location for the RV lead. Results: In the figure below, the left panel shows that model DFTs match published clinical DFT data; the right panel shows the DFT for all 3 locations. The substernal coil DFT is significantly lower than for the SQ coil and is about 22% higher than DFT for the RV coil. Conclusions: Results show that a novel substernal coil electrode may significantly reduce defibrillation energy required for an extravascular ICD. (Figure Presented).

Backenkoehler UU. **Patients with compensated relevant heart insufficiency receiving subcutaneous ICD-therapy may be saved from harmful inadequate shock therapies through anatomical selection of implantation site**

[abstract]. Eur J Heart Fail. 2015; 17 SUPPL. 1: 400-1. *Heart Failure 2015 and the 2nd World Congress on Acute Heart Failure Seville, Spain 2015-05-23 to 2015-05-26.* Background: Subcutaneous ICD (S-ICD)-implantation in patients in whom out clinical reasons the deployment of a conventional intracardiac lead system is impossible may be vitally threatened by inadequate ICD-shock therapies potentially resulting in left heart failure. However implantation of a S-ICD-can and subcutaneous lead with a wide field of detection may typically lead to inappropriate myopotential detection and S-ICD-therapy. Myopotentials are mediated by proprioceptive sensory nerve receptors (SNR). Purpose: We searched for number, location and structure of SNR in the adjacent thoracic tissue of the anterior serratus muscle (ASM) in order to identify optimal implantation sites allowing for improvement of postoperative results and to reduce inadequate ICD-therapies. Methods: Topography and ultrastructure of SNR in the anterior serratusmuscle were analyzed in 12 models of adult female NMRI-mice. Three SNR-types were identified using light and electron microscopy: Muscle Spindles (MSP), Lamellated Pacini Corpucles (PC) andGolgi Tendon Organs (GTO). Their location within the skeletal muscle was determined by 3D-image processing of 3 complete thorax section series. Results: Within the relevant structure of the anterior serratus muscle (ASM) a total amount of $n=27 \pm 5$ MSP were found per thorax. The vast majority of SNR of the MSP-type were identified either within the area of tendinous origin ($n=11 \pm 4$) or the fibromuscular tissue of muscle insertion ($n=13 \pm 4$) respectively, in all samples only a very small number ofMSP were located within the central portions of the ASM ($n=3 \pm 1$).GTO ($n=3 \pm 1$) and rare PC were exclusively found within the fibrous tissue of the tendinous muscle insertions Conclusion: To avoid SNR irritation near the tendinous zones of origin and insertion of the ASM that are richly supplied with a large number of MSP as well as GTO and PC, special attention should be paid to the implantation of the S-ICD-can within the anterolateral central muscle region close to the landmark of the anterior axillary line. Thus, the risk of secondary heart failure induced by sequential inadequate S-ICD shock therapies resulting from myopotential detection may be reduced in patients with compensated but relevant heart insufficiency by selecting a neuroanatomically guided implantation site.

Boersma LVA, Barr CS, Burke M, Leon AR, Theuns DA, Herre JM, Weiss R, Rashtian M, Kremers MS, Neuzil P, Husby MP, Carter N, Stivland T, Gold MR. **Performance of the subcutaneous implantable cardioverter defibrillator in primary prevention patients [abstract]. Heart Rhythm.** 2015; 12 (5 SUPPL. 1): S64. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: The subcutaneous implantable cardioverter defibrillator (S-ICD) avoids the need to implant electrodes in or around the heart. This device is often used in patients with relative or absolute contraindications to transvenous ICDs. In contrast, the role of the S-ICD in more conventional indications is less well studied. Accordingly, we evaluated the performance of the S-ICD in the largest patient subset; adults with a primary indication and left ventricular systolic dysfunction. Methods: Data were pooled from the pivotal IDE and ongoing EFFORTLESS S-ICD Registry. Patients were divided into three groups based on indication for implant and ejection fraction (EF). Group A was primary prevention patients with an $EF \leq 35\%$; Group B was primary prevention patients with an $EF >35\%$. Group C was secondary prevention patients. Incidence of device and procedural-related complications, defined as those requiring invasive action, mortality and all-cause therapy, were evaluated. Results: A total of 774 implanted patients were evaluated. Mean follow-up was 1.8 yrs (max. 4.2yrs). Patients in Group A were older ($n=376$, 57 ± 14 yrs; $EF 26 \pm 6\%$) and with a higher incidence of significant comorbidities including heart failure, diabetes, hypertension and myocardial infarction than either Groups B ($n=146$; 40 ± 14 yrs; $EF 60 \pm 11\%$) or C ($n=252$; 50 ± 17 yrs; $EF 48 \pm 15\%$). Three-year complication-free rates were not significantly different between groups (A=91%; B=92% and C=90%) and overall mortality was low (3.2%). The highest number of deaths occurred in Group A ($n=19$; 5.0%) with no deaths in Group B and 6 deaths in Group C (2.4%). All groups had appropriately treated individual episodes of VT/VF during follow-up (A=36 episodes in 22 patients; B=7 episodes in 4 patients and C=61 episodes in 29 patients). All discrete VT/VF episodes converted with a shock or spontaneously. There were no significant differences between average time to first therapy (251; 204 and 234 days for Cohorts A, B and C respectively) or first shock conversion efficacy (89%; 100% and 90%). Conclusions: In this pooled subgroup analysis, performance of the S-ICD is independent of patient indication. As such it should be considered suitable for primary and secondary prevention patients regardless of EF.

Brouwer TF, Knops RE, Barr CS, Theuns DA, Boersma LVA, Weiss R, Neuzil P, Lambiase PD, Leon AR, Hood MA, Jones PW, Grace AA, Carter N, Stivland T, Burke M. **Learning curve associated with implantation of the totally subcutaneous implantable defibrillator: Results from a pooled analysis of 882 patients from the ide study and effortless registry [abstract]. Heart Rhythm.** 2015; 12 (5 SUPPL. 1): S60. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: Performance tends to improve with experience when learning a new procedure. We evaluated the learning curve for implantation of the subcutaneous ICD (S-ICD) per individual implanter. Methods: In a pooled cohort from two clinical S-ICD databases, the IDE Trial and the EFFORTLESS Registry, performance per individual implanter was assessed by the rate of complications at 180 days follow-up. Complications related to the surgical procedure, such as but not limited to infection and erosion, and requiring surgical intervention were

considered. Adjustment was made for implants outside both studies using the manufacturer's device tracking database. Kaplan-Meier estimates of complication rates were calculated for initial (1-4 implants), early (5-20 implants) and late (>20 implants) experience. Results: A total of 882 implants by 107 implanters with a median of 4 implants (IQR 1,8) and a total of 86 complications were analyzed. The complication rate improved significantly from 9.3% (CI 6.3-13.6) to 4.6% (CI 2.7-7.8) in the initial compared to the late experience group ($p=0.03$). The complication rate in the early experience group of 6.4% (CI 4.2-9.6) did not significantly differ from either the initial ($p=0.18$) or late experience ($p=0.34$). Figure 1 shows the progress towards lower complication rate with increasing experience per individual implanter. Conclusions: S-ICD implant performance improves significantly per individual implanter with experience beyond 20 implants. (Figure Presented).

Brouwer TF, Knops RE, Barr CS, Theuns DA, Weiss R, Lambiase PD, Leon AR, Jones P, Carter N, Burke MC. **Learning curve associated with inappropriate shocks of the subcutaneous implantable defibrillator: Results from a pooled analysis of 882 patients from the IDE study and EFFORTLESS Registry [abstract].** *Eur Heart J.* 2015; 36 SUPPL. 1: 719-20. *European Society of Cardiology, ESC Congress 2015 London, United Kingdom 2015-08-29 to 2015-09-02.* Introduction: The subcutaneous ICD (S-ICD) uses a morphology based discrimination algorithm that requires a unique programming strategy. We evaluated the inappropriate shock (IAS) rate of the S-ICD versus increasing center experience, to determine whether a learning curve is present. Methods: In a pooled cohort from two clinical S-ICD databases, the IDE Trial and the EFFORTLESS Registry, the IAS rate was assessed at one-year follow-up. Kaplan-Meier (KM) estimates for freedom of IAS, percentage dual zone programming and zone cut-off rate grouped by implanting center experience as initial (1-4 implants), early (5-20 implants) and late (>20 implants) were calculated. Results: A total of 882 implants in 61 implanting centers with a median of 4 implants (IQR 1-8) and a total of 235 IAS in 94 patients were analyzed between 2009 and 2013. There was a non-significant trend towards higher freedom of IAS from 86.3% (CI 79.5-92.3) to 91.6% (CI 88.4-93.9) with increasing experience ($p=0.12$), and a significant trend in dual zone programming ($p<0.001$). Multivariable adjustment for known confounders (atrial fibrillation and NYHA class III/IV) (Figure presented) for IAS showed that dual zone programming was associated with a hazard ratio of 0.45 for IAS ($P<0.001$), whereas experience and zone cut-off rate were not significant. Figure 1 shows the KM estimates for freedom of IAS at 1 year with increasing center experience, the percentage dual zone programming and the lower zone cut-off rate in beats per minute. Conclusions: There was a non-significant trend from 12.7% to 8.4% towards higher freedom of IAS with increasing center experience. However dual zone programming did increase significantly with increasing experience. Dual zone programming was associated with less IAS adjusted for known confounders.

Brouwer TF, Knops RE, Theuns DA, Boersma LVA, Weiss R, Neuzil P, Lambiase P, Leon AR, Jones PW, Burke M. **Learning curve associated with implantation of the totally subcutaneous implantable defibrillator: Results from a pooled analysis of 882 patients from the IDE study and effortless registry [abstract].** *Europace.* 2015; 17 SUPPL. 3: iii192. *EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24.* Introduction: Performance tends to improve with experience when learning a new procedure. We evaluated the learning curve for implantation of the subcutaneous ICD (S-ICD) per individual implanter. Methods: In a pooled cohort from two clinical S-ICD databases, the IDE Trial and the EFFORTLESS Registry, performance per individual implanter was assessed by the rate of complications at 180 days follow-up. Complications related to the surgical procedure, such as but not limited to infection and erosion, and requiring surgical intervention were considered. Adjustment was made for implants outside both studies using the manufacturer's device tracking database. Kaplan-Meier estimates of complication rates were calculated for initial (1-4 implants), early (5-20 implants) and late (>20 implants) experience. Results: A total of 882 implants by 107 implanters with a median of 4 implants (IQR 1,8) and a total of 86 complications were analyzed. The complication rate improved significantly from 9.3% (CI 6.3-13.6) to 4.6% (CI 2.7-7.8) in the initial compared to the late experience group ($p=0.03$). The complication rate in the early experience group of 6.4% (CI 4.2-9.6) did not significantly differ from either the initial ($p=0.18$) or late experience ($p=0.34$). Figure 1 shows the progress towards lower complication rate with increasing experience per individual implanter. Conclusions: S-ICD implant performance improves significantly per individual implanter with experience beyond 20 implants. (Figure Presented).

Brunner MP, Hussein A, Wazni OM, Martin DO, Saliba WI, Wilkoff BL, Tarakji KG. **Extraction of subcutaneous defibrillator shocking coils, arrays, and patches [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S165. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: Subcutaneous (SQ) implantable cardioverter defibrillator (ICD) systems are being utilized with increased frequency. Data describing the extraction of SQ defibrillator coils, arrays, and patches is lacking. Methods: Consecutive patients that underwent extraction of pacemaker and ICD leads at the Cleveland Clinic between August 1996 and August 2014 were included in the analysis. Lead extraction was defined in accordance with the Heart Rhythm Society (HRS) transvenous lead extraction (TLE) guidelines. Categorical data are presented as number (percentage); continuous as median (25th, 75th percentile). Results:

SQ defibrillator coils (n=12 [63.2%]), arrays (n=4 [21.1%]), or patches (n=3 [15.8%]) were extracted during 19 of 3,576 TLE procedures. There were not any Boston Scientific S-ICDTM systems extracted. Patients had median age 66.4 (51.5, 72.1) years, ejection fraction 25.0% (16.3%, 30.8%) and were predominately male (n=17 [89.5%]). Endovascular and SQ leads were extracted during each procedure. A median of 3.0 (2.0, 3.0) leads were extracted and the sum of the age of the leads extracted was 10.9 (3.2, 25.1) years. The median age of the SQ defibrillator leads was 6.1 (0.6, 7.9) years. Indications for extraction included infection (n=13 [68.4%]), system upgrade or revision (n=3 [15.8%]), SQ coil fracture (n=2 [10.5%]), and need for removal after heart transplant (n=1 [5.3%]). Eighteen (94.7%) of the leads were removed using traction and tissue dissection. Additional incisions were required in 6 (31.6%) cases. A I6F laser sheath was required to remove one of the SQ coils. The leads were completely removed in all cases. Procedural complications were likely unrelated to the extraction of the SQ leads but occurred in 3 (15.8%) patients and included cardiac arrest due to pulseless electrical activity, hemothorax requiring chest tube insertion, and subsequent pocket infection. Conclusions: In our experience SQ defibrillator leads were successfully extracted but additional incisions were often required and a laser sheath in one instance. The frequency of complications during these extractions reflects the complexity of patients in which SQ defibrillation leads were implanted.

Chan NY, Yuen HC, Shing N. **Inclusion of right parasternal configuration may reduce the failure rate of electrocardiographic screening for subcutaneous implantable cardioverter-defibrillator implantation [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S483. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16*. Introduction: Some patients may fail the preoperative electrocardiographic (ECG) screening for subcutaneous cardioverter-defibrillator (SICD) implantation. Whether the inclusion of right parasternal configuration can reduce the failure rate has not been studied. Methods: N/A Results: Six patients (1 female, mean age 52.3±16.2) with diagnoses of idiopathic ventricular fibrillation (VF) (2), Brugada syndrome (1), hypertrophic cardiomyopathy (1), arrhythmogenic right ventricular dysplasia (ARVD) (1) and dilated cardiomyopathy (1) underwent ECG screening for SICD implantation. Two patients with idiopathic VF and ARVD respectively failed the screening. With right parasternal configuration, the patient with idiopathic VF passed the ECG screening and the patient with ARVD had significant reduction in T-wave and preservation of QRS amplitudes. Both patients underwent SICD implantation with electrode placement in the right parasternal region (see figure). VF was induced and appropriately sensed and terminated with 65J shock. Sensing was also appropriate during exercise treadmill. No inappropriate shock was observed during a short follow-up of 2 and 4 months respectively. Conclusions: The failure rate of ECG screening for SICD implantation was high in this small patient cohort. Inclusion of right parasternal configuration may reduce the failure rate. (Figure Presented).

Chik W, Benhayon D, Sadek M, Santangeli P, Maeda S, Pouliopoulos J, Frankel D, Marchlinski F. **Prevention of inappropriate sensing/therapies by subcutaneous ICD in the setting of unipolar pacing from an abdominal epicardial pacemaker in a patient with mustard atrial switch and unrepaired ventricular septal defect [abstract].** *Heart Lung and Circulation*. 2015; 24 SUPPL. 3: S244. *Cardiac Society of Australia and New Zealand Annual Scientific Meeting and the International Society for Heart Research Australasian Section Annual Scientific Meeting 2015 Melbourne, VIC, Australia 2015-08-13 to 2015-08-16*. 49-year-old-man with transposition of the great arteries s/p Mustard atrial switch underwent abdominal epicardial dual chamber pacemaker (PM) with unipolar RA and RV leads for post-operative heart block; conduction subsequently recovered. He had syncope from MMVT (226bpm) warranting 2°prevention ICD. However endovascular system could not be implanted due to unrepaired large VSD with bidirectional flow. CTS felt epicardial ICD could not be readily implanted given prior sternotomy and complex baffling. Subcutaneous ICD (SQ ICD) was implanted. (Fig A) Since AV conduction recovered, PMwasreprogrammedtoVVI40bpm, so that even if pacer spikes were double counted, the total rate would not satisfy VT detection criteria. At sensitivity=4mV, PM EGMs (B) showed VF undersensing, but not long enough to trigger pacing, which could potentially saturate the SQ ICD amplifier and inhibit detection ofVFby theSQICD. At sensitivity=2mV, PM EGMs (C) revealed good VF detection, again with no pacing. On both occasions, the SQ ICD sensed VF and defibrillated the patient with a single 65J shock. Conclusions: In this patient with a unipolar pacemaker and haemodynamically significant VT, we implanted a SQ ICD. By programming the PM, risk of double counting paced beats leading to inappropriate therapy was minimised. Additionally, as the pacemaker was able to sense VF and inhibit pacing, the risk ofPMpacing preventing the SQ ICD from sensing VF is small.

Chik W, Sadek M, Maeda S, Pouliopoulos J, Cooper J, Marchlinski F, Schaller R. **Novel technique to implant a transvenous ICD lead through a totally occluded superior vena cava and left subclavian venous system [abstract].** *Heart Lung and Circulation*. 2015; 24 SUPPL. 3: S241-S2. *Cardiac Society of Australia and New Zealand Annual Scientific Meeting and the International Society for Heart Research Australasian Section Annual Scientific Meeting 2015 Melbourne, VIC, Australia 2015-08-13 to 2015-08-16*. Bilateral peripheral venograms

revealed a totally occluded left-subclavian system in a patient with cardiac sarcoidosis on chronic steroid therapy admitted for implantation of primary prevention ICD (Fig A) and complete SVC occlusion with venous drainage via an Azygous system (B & C). A subcutaneous-ICD was implanted (D) but subsequent pocket infection necessitated system explantation. An Agilis sheath and a 7Fr sheath were advanced to the superior and inferior aspects of the obstruction respectively. Venography revealed a 1.5cm central occlusion (E). 7Fr dilator was advanced through the Agilis (F). The back end of a Glidewire was placed through the Agilis and punctured across the occlusion (G). 4Fr multi-purpose angiography catheter was advanced across the occlusion followed by contrast administration to verify location (H). GlideWire was exchanged for a 0.032 J-tipped wire, which was guided into the right axillary vein (RAV) (I). A right deltopectoral pocket was created and RAV access was obtained. The J-tip wire was secured with a Gooseneck snare (J) and pulled through the pocket (K). A long 8Fr sheath was railed over the wire past the occlusion (L) and a single VDD lead was placed in the RV apex (M). (Figure presented). Conclusions: ICD implantation through complete SVC and left subclavian venous occlusions can be safely performed using a combined femoral and axillary snaring.

Chik WW, Benhayon D, Sadek M, Maeda S, Venugopal D, Liang JJ, Santangeli P, Supple G, Frankel DS. **Strategies to prevent inappropriate sensing/therapies by subcutaneous ICD in the setting of unipolar pacing from an abdominal epicardial pacemaker in a patient with mustard atrial switch and unrepaired ventricular septal defect [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S314-S5. 36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16. Introduction: A 49 year-old-man with transposition of the great arteries s/p Mustard atrial switch underwent an abdominal epicardial dual chamber pacemaker (PM) with unipolar RA and RV leads for post-operative heart block; conduction subsequently recovered. Methods: N/A Results: He suffered syncope from monomorphic VT (226bpm) warranting secondary prevention ICD. However, an endovascular system could not be implanted due to unrepaired, large VSD with bidirectional flow. CT surgery felt an epicardial ICD could not be readily implanted given prior sternotomy and complex baffling. After a thorough discussion of risks and benefits, a subcutaneous ICD (SQ ICD) was implanted. (Fig A) Since his AV conduction recovered, PM was reprogrammed to VVI 40bpm, so that even if pacemaker spikes were double counted, the total rate would not satisfy VT detection criteria by the SQ ICD. At a sensitivity of 4mV, PM EGMs (B) showed VF undersensing, but not for long enough to trigger pacing, which could potentially saturate the SQ ICD amplifier and inhibit detection of VF by the SQ ICD. When sensitivity was decreased to 2mV, PM EGMs (C) revealed good VF detection, again with no pacing. On both occasions, the SQ ICD sensed VF and defibrillated the patient with a single 65J shock. Conclusions: In this patient with a unipolar pacemaker and hemodynamically significant VT, we implanted a SQ ICD. By programming the PM appropriately, the risk of double counting paced beats leading to inappropriate SQ ICD therapy was minimized. Additionally, as the pacemaker was able to sense VF and inhibit pacing, the risk of PM pacing preventing the SQ ICD from sensing VF is small. (Figure Presented).

Corzani A, Ziacchi M, Biffi M, Diemberger I, Martignani C, Marziali A, Mazzotti A, Massaro G, Rapezzi C, Boriani G. **Eligibility to subcutaneous implantable cardioverter-defibrillator: Relationship with ECG suitability in different physiologic conditions [abstract].** *Europace*. 2015; 17 SUPPL. 3: iii193. EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24. Aims: To investigate clinical predictors of ineligibility for S-ICD, and to evaluate the impact of exercise on S-ICD eligibility in an unselected series of patients requiring ICD therapy. Methods: 102 high risk of sudden death patients were evaluated at rest and during exercise. ECG screening using limb lead electrodes (to simulate the S-ICD sensing vectors) was performed at rest and during bicycle ergometer exercise. Results: R wave amplitude in lead D3 during exercise >16 mV, baseline QTc and the sum of amplitudes of the R waves at supine >30 mV were predictors of ineligibility for S-ICD. Eligibility increased from 90% to 100% of patients when evaluated with an "any of the 3 leads" criterion compared to current recommendations. A more restrictive criterion based on 2/3 ECG leads caused an eligibility drop at 66%, that further decreased to 56% during exercise; this eligibility improved to 79% and 81%, respectively, when an "any 2 of 3 leads" criterion was used. Conclusions: Huge ECG amplitude and QTc duration are associated to ineligibility in the current S-ICD release. Exercise testing doesn't affect S-ICD eligibility with current criteria. However, it may significantly enhance rhythm detection when technologically improved S-ICDs will be released for implantation in a broader patient population.

Cronbach PL, Wilson DG, Greenhut SE, Stegemann B, Panfilo D, Morgan JM. **12-lead electrocardiograms can be reconstructed using the 3 electrodes of a subcutaneous implantable cardioverter defibrillator [abstract].** *Circulation*. 2015; 132 SUPPL. 3: American Heart Association's 2015 Scientific Sessions and Resuscitation Science Symposium Orlando, FL, United States 2015-11-07 to 2015-11-11. Background: Data from reduced lead ECG configurations can be transformed to reconstruct a 12-lead ECG. The sensing electrodes of a subcutaneous ICD (S-ICD) could provide a suitable basis for such a system. Reconstruction of a 12-lead ECG from conventional S-ICD vectors has not previously been demonstrated. Hypothesis: A 12-lead ECG signal can

be accurately derived from S-ICD electrode vectors. Methods: Participants with ICDs (N=61) underwent 3 minute ECGs with electrodes in the standard S-ICD and 12-lead positions. Participants were randomised to either a training (N=31) or validation (N=30) group. Two participants and one further lead were subsequently excluded from the validation group due to technical faults. The transformation was a linear combination of the 2 independent S-ICD vectors to each of the 8 independent leads of the 12-lead ECG, with coefficients selected that minimized the root mean square error (RMSE) between recorded and derived ECGs when applied to the training group. The transformation was then applied to the validation group and agreement between the recorded and derived lead pairs was measured by Pearson correlation coefficient (r) and normalised RMSE (NRMSE). Results: In total, 335 lead pairs were compared (figure1). Distribution of r and NRMSE were skewed. Mean r = 0.731 (SE 0.021), Median r = 0.903 (SE 0.015). NRMSE Mean = 0.227 (SE 0.011) Median = 0.167 (SE 0.008). 252/335 (75.2%) of all pairs had an r > 0.7 (indicating very strong positive correlation). Figure 1: Example 12-lead ECG, recorded (blue line) and derived (red line). Participant randomly selected from top 20% by mean Pearson correlation coefficient. Conclusions: We have demonstrated reconstruction of a 12-lead ECG from S-ICD vectors. The agreement between derived and measured signals was generally excellent and comparable with other widely accepted reduced lead systems. If perfected, the ability to generate 12-lead data from an S-ICD could help clinicians to localise and treat arrhythmias.

D'Souza B, Kim YY, Burke M, Morgan JM, Leon AR, Patton KK, Agarwal SC, Belott PH, Epstein AE, Shah MJ. **Prevalence of subcutaneous implantable defibrillator (S-ICD) related complications in patients with congenital heart disease: Results from a pooled analysis from the IDE study and effortless registry [abstract].** *Europace*. 2015; 17 SUPPL. 3: iii74. *EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24*. Introduction: The Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) has potential advantages for pts with congenital heart disease (CHD). However, the prevalence of S-ICD related complications is unknown. Methods: A pooled analysis of 865 pts in the EFFORTLESS Registry (an international observational database) and the US IDE study was used. Results: 19 CHD vs. 846 non-CHD pts with a median follow up of 567 & 639 days, respectively, were included. A total of 71 events (in 66 pts, 7.6 %) were identified. There were similar overall complication rates for both groups (10.5 vs 9.6% [p=0.89], Table) with inappropriate shocks for T-wave oversensing as the only complication in the CHD group (n=2). The rate of inappropriate shocks was similar for both groups (10.5 vs 10.9% [p=0.96]). Conclusion: The cohort of CHD patient with an S-ICD shows complication rates to be comparable to non-CHD patients. (Table Presented).

D'Souza BA, Kim YY, Burke M, Morgan JM, Leon AR, Patton KK, Agarwal SC, Garcia FC, Belott PH, Epstein AE, Shah MJ. **Outcomes in patients with congenital heart disease receiving the subcutaneous implantable defibrillator (S-ICD): Results from a pooled analysis from the IDE study and effortless registry [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S225-S6. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16*. Introduction: The subcutaneous implantable defibrillator (S-ICD) is a treatment option for patients (pts) with congenital heart disease (CHD) in which a transvenous device is contraindicated due to anatomic considerations. However, efficacy in this group has not been determined. Methods: A pooled analysis of 865 pts in the EFFORTLESS Registry (an international observational database) and the US IDE study was used. A subgroup of patients with CHD was separately compared to a non-CHD group. Results: There were 865 total patients included in this study, with 19 CHD pts and 846 non-CHD pts, a median follow-up of 567 days and 639 days, respectively. There were no deaths and no appropriate shocks for ventricular tachyarrhythmias (VT/VF) in the CHD cohort, versus 26 deaths (0 vs 3.1%, p=0.42) and 111 appropriate shocks in 59 patients (0 vs 7.1%, p=0.23) in the non-CHD cohort. There were similar complication rates for the CHD vs. non-CHD groups (10.5 vs 9.6%, p=0.89), with inappropriate shocks for T-wave oversensing as the only complication in the CHD group (n=2). The rate of inappropriate shocks was similar for both groups (10.5 vs 10.9%, p=0.96). Successful defibrillation testing for induced VT/VF at 65J was comparable for the CHD vs. non-CHD groups (88.2 vs 94.6%, p=0.26). Conclusions: Analysis of the cohort of CHD patient with an S-ICD shows complication rates, acute defibrillation success, and rhythm discrimination to be comparable to non-CHD patients. VT/VF event rates were lower in this cohort, suggesting further assessment of risk stratification in this patient population is warranted. (Table Presented).

Franca P, Adduci C, Semprini L, Palano F, Serdoz A, Mastromarino V, Montesanti D, Casenghi M, Salvati A, Musumeci B, Volpe M, Autore C. **Eligibility for the subcutaneous ICD in patients with hypertrophic cardiomyopathy [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S13. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16*. Introduction: High-risk HCM patients benefit from the implantable cardioverter defibrillator (ICD). The subcutaneous ICD (S-ICD) may provide comparable protection while avoiding the shortcomings of transvenous (TV) leads. We assessed S-ICD eligibility in a cohort of HCM patients. Methods: Screening was performed at rest according to standard ECG criteria defined by the S-ICD manufacturer and then enhanced by assessing eligibility during exercise and

ventricular pacing. Results: 47 HCM patients (3 S-ICD candidates without pacing indication, 41 TV-ICD carriers without pacing indication, 3 TVICD carriers with pacing indication) were enrolled. 4 groups were selected: spontaneous QRS (n= 44); exercise (n= 33); full pacing (n= 44); alternating pacing/spontaneous QRS (n= 41). Of the 44 patients in the spontaneous QRS group, 41 (93%) were eligible for S-ICD (50%: 3 qualifying leads, 18%: 2 qualifying leads, 32%: 1 qualifying lead). Max LV thickness was inversely related to the number of qualifying leads (3 leads: 21±4 mm; 2 leads: 22±6 mm; 1 lead: 25±6 mm; no leads: 28±11 mm; p= 0.07). Of the 33 patients who agreed to undergo exercise test, 5 (15%) were ineligible. 2 were already ineligible at rest, and 3 were non-eligible only during exercise. Of these, 2 became eligible after moving chest electrodes from the left to the right parasternal line (final eligibility rate: 30/33; 91%). Of the 44 patients in the full pacing group, 20 (45%) were eligible (80% with 1 qualifying lead). 8 out of 24 non-eligible patients became eligible after moving chest electrodes on the right parasternal line (final eligibility rate: 28/44; 64%). In the alternating pacing/ spontaneous QRS group (n= 41), 16 patients (39%) had at least one eligible lead during pacing and retained compatibility on the same lead on spontaneous rhythm. Out of 25 ineligible patients, 5 passed the screening using right parasternal electrodes (final eligibility rate: 21/41; 51%). Conclusions: Screening failure is low in HCM, provided that patients with severe hypertrophy are carefully evaluated. Exercise test should be performed in HCM patients, and right parasternal leads tested. Pace-maker patients display low eligibility rate, mostly those with alternating spontaneous/paced QRS.

Frommeyer G, Dechering DG, Koebe J, Reinke F, Eckardt L. **Pitfalls in S-ICD therapy: Reasons for system explantation [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S57-S8. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.*

Introduction: The totally subcutaneous implantable defibrillator (S-ICD) was introduced as a new alternative to conventional implantable defibrillators and is employed worldwide. However, reasons for S-ICD failure and explantation as well as subsequent implantation of a conventional transvenous have not yet been sufficiently described. Methods: Between July 2010 and August 2014 93 S-ICD systems were implanted at our institution. Results: 44 patients (47%) were implanted for primary prevention of sudden cardiac death. In 6 patients (7 %), the S-ICD system was explanted for different reasons: in two cases, severe pocket infection led to system explantation and subsequent replacement by a conventional transvenous device. In one patient slow ventricular tachycardia requiring antitachycardia pacing occurred after S-ICD implantation. Therefore, the system was replaced by a transvenous ICD. In another case, the S-ICD was replaced by a transvenous system due to repeated bradycardic syncope. In one patient who initially passed ECG-screening successfully p-wave and T-wave oversensing led to inadequate shock delivery. Finally, in one patient the S-ICD was replaced by a transvenous ICD due to several ineffective shock deliveries in the presence of electrical storm. Conclusions: The S-ICD has demonstrated promising results and may be the preferred ICD system in various clinical situations. However, the reported series clearly emphasizes the need for more prospective data to evaluate the future role of this promising innovation.

Garikipati NV, Torres JL, Okabe T, Kumar S, Amin A, Liu Z, Tyler J, Houmsse M, Augostini RS, Hummel JD, Kalbfleisch SJ, Weiss R, Daoud EG. **Importance of routine treadmill exercise stress testing after subcutaneous implantable cardioverter defibrillator implantation [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S422. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: The basis for appropriate sensing in the subcutaneous implantable cardioverter-defibrillator (SICD) is the QRS-T wave ratio. However, T wave morphology can change based on several common situations, including tachypnea, change in posture, and exercise. Also, a potential cause of inappropriate therapies from a SICD is T-wave oversensing (TWO). The purpose of this prospective study was to assess the usefulness of routine exercise treadmill testing (ETT) completed soon after implantation of a SICD to screen for changes in sensing vector and TWO. Methods: The study population consisted of 37 consecutive patients who underwent successful SICD implantation and had routine symptom-limited modified Bruce protocol ETT soon after device implantation. Study endpoints included the need to change SICD sensing vector based on the ETT results, and TWO detected during ETT. Results: Patient population included 54% males (n=20), mean age was 39 +/- 12 years, 9/37 (24%) had ischemic cardiomyopathy, 16/37 (43%) had non-ischemic cardiomyopathy, 12/37 (33%) were for other etiologies. The mean LVEF 38 +/- 17%, QRS duration was 97 +/- 14 msec and 20/37 (54%) were for primary prevention. At the implantation procedure, the optimal sensing vector was primary 39%, secondary 50% and alternate 11%. After the ETT, the optimal sensing vector was primary 47%, secondary 47%, and alternate 6%. The findings at ETT, therefore, resulted in a change in the optimal sensing vector compared to initial implantation in 4/37 (11%) patients. The reason for reprogramming sensing vector was due to variations in QRS/T ratio; there was no TWO. The alternate vector was reprogrammed significantly more often when compared to the primary vector (p=0.04). Conclusions: Routine ETT after SICD implantation demonstrated important sensing changes in about a tenth of patients and was managed by a change in SICD sensing vector programming, with the majority of change occurring in patients initially programmed to the

alternate vector. These findings suggest that routine ETT should be performed following S-ICD implantation to optimize the sensing vector. Long term follow up for this patient population will be available to address the rate of appropriate and inappropriate therapies and TWO.

Gemein C, Haj M, Chasan R, Weipert KF, Abaci G, Helmig IM, Erkapic D, Boening A, Hamm CW, Schmitt J. **Combining a S-ICD and a pacemaker with abdominal device location and bipolar epicardial LV-lead: First-in-man approach [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S534. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: ICD therapy is established for patients with severe heart failure or survived sudden cardiac death (SCD). Some patients may also present bradycardia and therefore need additional pacing. However, patients with device infection or subclavian vein stenosis might not be eligible for transvenous endocardial lead placement. Methods: N/A Results: We describe a case of a 78-year-old man with survived SCD due to ischemic cardiomyopathy followed by secondary prophylactic ICD implantation in 1998. Between 1998 and 2008 the patient underwent several lead and device replacements via both the right and left subclavian vein due to right ventricular (RV) lead malfunction or device infection. In 2008 a 2-chamber- ICD was implanted. During the last years right ventricular pacing fraction increased to 100% due to complete AV block without escape rhythm while permanent atrial fibrillation emerged and ejection fraction decreased to 35%. In 2014 the patient was admitted to hospital with inadequate ICD shocks due to anew RV lead malfunction. Further transvenous lead revision was not feasible due to right and left subclavian vein stenosis. Therefore, a S-ICD with parasternal placed subcutaneous shock lead but without pacing ability was implanted in combination with a pacemaker in abdominal location with a bipolar epicardial lead positioned on the left ventricle. Placement of both leads in anatomical neighborhood was feasible without lead contact or damage. In the chosen pacemaker and ICD lead positions no interaction between the ICD detection algorithm and bipolar pacing with maximum output (7,5 V/1,5 ms) was observed. Unipolar pacing with maximum output evoked noise in 2 of 3 possible ICD detection vectors, while no interaction was observed using the safety program of the chosen pacemaker (unipolar stimulation at 5 V/0,6 ms in VVI mode). Defibrillation threshold tests were performed with adequate detection and termination of induced ventricular fibrillation by the S-ICD while no interaction with the implanted pacemaker occurred. Conclusions: Combination of a S-ICD and a pacemaker with bipolar leads is feasible and may be an option for patients in need for ventricular pacemaker stimulation and ICD therapy with contraindication for endocardial lead placement.

Gifford J, Thomas C, Larimer K, Brown C, Burke M, Saleem M. **Effects of electrosurgery on subcutaneous ICDs [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S243. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: Electromagnetic interference (EMI) has been reported in cardiac implantable electronic devices (CIED) during electrosurgery. We evaluated the effects of monopolar electrosurgery and harmonic scalpel during thyroidectomy and laparoscopic cholecystectomy in two subjects with the subcutaneous ICD (S-ICD) enrolled in the ICD-ON Registry. Both subjects had been successfully screened for sensing prior to implant using appropriate criteria (pre-operative ECG screening in the supine position and upright position). There are three sensing vectors: primary (xiphoid to generator); secondary (2nd intercostal left parasternum to generator); and alternate (2nd intercostal to xiphoid along left parasternum). The S-ICD implant involves a generator placement in the 4th-6th intercostal space in the mid-posterior axillary line with the lead tunneled to the left parasternum from the xiphoid process superiorly to the 2nd intercostal space. The S-ICD sensing algorithm uses filters to neglect non-physiologic electrical activity thereby avoiding over-sensing such as that seen with electrosurgery. We programmed ICD therapies off during surgery to avoid oversensing of EMI from electrosurgery. External defibrillator pads were applied with continuous ECG monitoring. Grounding pad was placed on the right thigh. The device electrogram data was evaluated for over-sensing of EMI during surgery. Methods: N/A Results: Subject A had a secondary sensing vector and underwent thyroidectomy. Subject B had a primary sensing vector and underwent laparoscopic cholecystectomy. The presence of EMI was evaluated during electrosurgery via the programmer in both cases. In each case, the electrosurgery signal was sensed by the S-ICD vectors programmed, however, the signal amplitude and frequency was correctly identified as non-physiologic and therefore labeled as noise. Conclusions: EMI was sensed on the S-ICD electrograms during thyroidectomy and laparoscopic cholecystectomy. The S-ICD algorithm appropriately discriminated EMI as nonphysiologic avoiding a shock event or charge by the device. There is further need to evaluate electrosurgery in S-ICD patients in a variety of surgical locations with this new device.

Knops R, Brouwer T. **Clinical experience with the subcutaneous implantable cardioverter defibrillator in paediatric patients [abstract].** *Circulation.* 2015; 132 SUPPL. 3: *American Heart Association's 2015 Scientific Sessions and Resuscitation Science Symposium Orlando, FL, United States 2015-11-07 to 2015-11-11.* Introduction: In pediatric patients prevention of Sudden Cardiac Death (SCD) using Implantable Cardioverter Defibrillators (ICD) is associated with a higher risk of complications than in the adult population. Surgical re-

interventions due to infection, lead dislocation or migration and inappropriate shocks on intra and extracardiac oversensing are the most prevalent complications. The Subcutaneous ICD (S-ICD) has been introduced as a less invasive and extravascular alternative to overcome some of these complications. The scientific data that has led to the approval of the S-ICD did not include pediatric patients. Contradicting reports in small cohorts have been published on the effectiveness of S-ICD therapy in the pediatric population. We here report the largest pediatric cohort with the longest follow up to date where the S-ICD has been used for SCD prevention. Hypothesis: The S-ICD is safe and effective for the prevention of SCD in a diverse pediatric population. Methods: We retrospectively studied all consecutive pediatric patients (age < 18 yrs) that were implanted with a S-ICD in our center. Results: Fifteen S-ICDs were implanted in 14 patients (mean age 14, range 8-17), 71% were male, mean BMI was 18.8 (range 17.2-28.8), 57% had a secondary prevention indication, 77% had a genetic arrhythmia diagnosis and the median follow up was 21 months (range 1- 57). The first shock efficacy of induced and spontaneous episodes was 100% (n=13 and n=2 respectively). Inappropriate shocks due to intracardiac oversensing occurred in 3 (21%) patients. No lead failures or dislocations were observed. Two patients (14%) experienced a complication requiring re-intervention: one infection and one pocket erosion. After the pocket erosion the S-ICD has been successfully re-implanted. In one patient the S-ICD was removed after cardiac transplantation. None of the patients died during follow up. Conclusions: The S-ICD is safe and effective in a diverse pediatric populations. There was a very high efficacy of defibrillation therapy (100%) and a relative low and mild occurrence of complications. The S-ICD should be considered as a viable alternative for transvenous ICD's in pediatric patients.

Knops R, Brouwer T. **Long term follow up of the two incision technique for implantation of the subcutaneous implantable cardioverter defibrillator [abstract].** *Circulation.* 2015; 132 SUPPL. 3.: *American Heart Association's 2015 Scientific Sessions and Resuscitation Science Symposium Orlando, FL, United States 2015-11-07 to 2015-11-11.* Introduction: The fully Subcutaneous Implantable Cardioverter Defibrillator (SICD) has been introduced as a less invasive option for the prevention of Sudden Cardiac Death (SCD). According to the labeling, the implantation of the device requires three incisions: one pocket incision for the pulse generator and two parasternal incisions to tunnel the lead. These parasternal incisions are a potential source of discomfort and infection. Also the superior parasternal incision leaves a cosmetically notable scar on the upper chest. A less invasive, two incision, implantation technique has recently been introduced that omits the superior parasternal incision. Short term follow-up in a small patient cohort has shown that it is a safe and efficacious alternative for S-ICD implantation and may help to reduce complications. No long term follow up data is available on this technique. Hypothesis: Long term follow up in a large patient cohort continues to show the safety and effectiveness of the two incision technique for S-ICD implantation. Methods: The two incision technique has been described previously. It makes use of a peelable sheath to avoid the superior parasternal incision. We performed a retrospective analysis of all the patients in our center that have been implanted with this technique. Results: A total of 107 S-ICD patients were implanted with the two incision technique (56% male, mean age 40±16, BMI 25 (16.6-37.3). During a total follow up of 180 years patient years (mean 12 months, range 1-48) no dislocations were observed. One S-ICD system was repositioned due to DFT failure. First shock efficacy during DFT was 96% and 75% (6/8) for spontaneous episodes (100% efficacy with multiple shocks). The 1 year inappropriate shock rate was 7.4%. Device function was normal in all patients, and no inappropriate sensing occurred related to the implantation technique. Four infections occurred of which one originated from the parasternal incision. Conclusions: Long term follow up in a large patient cohort continues to show the safety and effectiveness of the two incision technique for S-ICD implantation. This technique offers physicians a less invasive and simplified implantation procedure for the S-ICD.

Koman E, Gupta A, Subzposh F, Tiwari A, Fontaine J, Kusmirek S, Kutalek S, Saltzman H. **Safety and efficacy of subcutaneous implantable-cardioverter de fibrillator implantation: A single center experience [abstract].** *J Am Coll Cardiol.* 2015; 65 (10 SUPPL. 1): A323. *64th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.15 San Diego, CA, United States 2015-03-14 to 2015-03-16.* Background: Subcutaneous implantable cardioverter defibrillator (S-ICD) is the latest advancement in defibrillation therapy. It is approved for all patients with indications for ICD implantation, without any pacing indications. Despite initial studies showing good safety and efficacy, there are limited real world data available. We report our single, high-volume center experience with S-ICD implantation. Methods: We retrospectively analyzed data regarding demographics, safety, efficacy and long-term follow-up of patients implanted with S-ICD at our center between October 2012 and June 2014. Results: S-ICD was implanted in 61 patients, with a mean age of 54±16 years (range 19-86). There were 57% males, 56% African-American and 41% Caucasian. 57% were implanted for primary prevention, 41% had ischemic cardiomyopathy, 39% non-ischemic cardiomyopathy, 21% were on dialysis and 20% had prior transvenous device extraction. Mean procedure time was 66±14 minutes. Defibrillation threshold testing was performed in 87% of patients. It was initially unsuccessful in 2 patients; repeat testing was successful in one with reversed polarity and one required repositioning of the can. Median follow-up was 160 days (range 1-621). Three patients had peri-procedural complications- bradycardia

requiring temporary pacing, hypercapnic respiratory failure and prolonged hypotension requiring inotropic support. There was no procedural mortality. Two patients died prior to discharge- 1 from intractable ventricular tachycardia due to non-revascularizable triple vessel coronary artery disease and 1 from mesenteric ischemia. Three patients died during follow-up (1 from asystole and 2 from unknown causes). Four patients had pocket infection with 2 requiring system removal. Eleven patients (18%) received shocks- 4 had an appropriate successful shock and 7 had inappropriate shocks (3 from supraventricular tachycardia, 2 from noise sensing due to air in the pocket and 2 from T wave oversensing). Conclusion: Our data confirms the safety and efficacy of the S-ICD in a real world setting. There are some risks associated with S-ICD and careful patient selection is critical to improve long-term success.

Koman E, Gupta A, Subzposh F, Tiwari A, Fontaine J, Kusmirek S, Saltzman H, Kutalek S. **Patients on hemodialysis have worse outcomes compared with non-dialysis patients after subcutaneous implantable-cardioverter de fibrillator implantation [abstract].** *J Am Coll Cardiol.* 2015; 65 (10 SUPPL. 1): A368. 64th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.15 San Diego, CA, United States 2015-03-14 to 2015-03-16. Background: Subcutaneous implantable cardioverter defibrillator (S-ICD) offers potential benefits for hemodialysis (HD) patients by preserving vascular access sites and reducing the risk of blood stream infections. However, HD patients were excluded from initial S-ICD trials and limited data are available regarding outcomes in these patients. Methods: We collected data regarding demographics, safety, efficacy and long-term follow-up of all patients implanted with S-ICD at our center between October 2012 and June 2014. We compared short- and long-term outcomes between HD and non-HD patients. Results: S-ICD was implanted in 61 patients-13 were on HD and 48 were not on HD. There was no significant difference in baseline demographics. HD patients had more S-ICD implants for secondary prevention (p value 0.005). They had more procedural complications (p value 0.007), longer inpatient stay (3.9 vs. 1.4 days, p value 0.001) and increased inpatient mortality (p value 0.006). After a median follow-up of 160 days, HD patients received more appropriate shocks (p value 0.007). HD patients also had increased all-cause mortality during followup (Figure 1). Blood stream infection was not seen in any patient. Pocket infection was seen in 4 patients and none of them were on HD. Conclusion: Patients on HD, who are implanted with S-ICD, have worse short- and long-term outcomes, compared with non-HD patients. However, S-ICD implantation is associated with reduced risk of infection, especially in HD patients. (Figure presented).

Koman E, Gupta A, Subzposh F, Tiwari A, Fontaine JM, S.L K, Saltzman H, Kutalek SP. **Safety and efficacy of subcutaneous implantable cardioverter defibrillator implantation in patients on hemodialysis [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S249. 36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16. Introduction: Subcutaneous implantable cardioverterdefibrillator (S-ICD) offers potential benefits for hemodialysis (HD) patients by preserving vascular access sites and reducing the risk of blood stream infections. However, HD patients were excluded from initial S-ICD trials and limited data are available regarding outcomes in these patients. Methods: We compared short- and long-term outcomes between HD and non-HD patients implanted with S-ICD at a major university center between October 2012 and October 2014. Results: S-ICD was implanted in 74 patients-17 were on HD and 57 were not on HD. HD patients had more implants for secondary prevention (p value 0.005) and also increased incidence of liver disease (p value 0.002). They had more peri-procedural complications (p value 0.01), longer inpatient stay (3.9 vs. 1.4 days, p value 0.001) and increased inpatient mortality (p value 0.006). After a median follow-up of 152 days, HD patients received more appropriate shocks (p value 0.04), and also had increased all-cause mortality (Figure 1). Blood stream infection was not seen in any patient. Pocket infection was seen in 4 patients and none of them were on HD. Conclusions: Patients on HD implanted with S-ICD, have worse short- and long-term outcomes, compared with non-HD patients. However, this is probably related to HD patients representing a sicker patient population with increased incidence of prior VT and liver disease, in addition to being on HD. (Figure Presented).

Kuschyk J, Stach K, Rudic B, Liebe V, Tülümen E, Schimpf R, Borggreffe MM, Roeger S. **The subcutaneous implantable cardioverterdefibrillator: First single-center experience with concomitant implantable pulse generators [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S249-S50. 36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16. Introduction: Subcutaneous implantable cardioverterdefibrillator (S-ICD) is a device for antiarrhythmic therapy with no intravascular leads. The S-ICD does not have pacing functions. We describe the technical feasibility of combining the S-ICD with other implantable pulse generators (IPGs), including pacemakers or resynchronization therapy (CRT). For the first time, we describe how S-ICD can also co-work successfully with cardiac contractility modulation (CCM) and with vagus nerve stimulation (VNS). Methods: Between 7/2011 and 11/2014 six patients had S-ICD in combination with CCM, three patients with abdominal single-chamber pacemakers or CRT-P received S-ICD, and one S-ICD patient received VNS. In all patients intraoperative S-ICD testing, cross talk tests

and postoperative ergometer testing were performed. Results: In all 10 patients device implantations were successfully performed without complications. S-ICD therapy was shown to be technically feasible with concomitant IPGs including CCM, pacemaker, CRT-P and VNS. Mean follow up was nearly 17 months (in CCM 5 cases had up to 35 months of follow-up, mean 20.4 months). S-ICD testing and crosstalk check before and during exercise enable successful programming of the S-ICD for proper functioning with concomitant IPG. None of the devices had to be permanently inactivated and no patient received inadequate shock. Conclusions: In selected patients, S-ICD can be combined with a pacemaker or a CRT-P. Combination of an S-ICD with CCM and with VNS may be practical for reducing the number of trans-vascular leads. S-ICD is safe with CCM over a long follow-up period. Additional reports on S-ICD co-work with IPGs are warranted.

Kuschyk J, Stach K, Tueluemen E, Rudic B, Liebe V, Schimpf R, Borggreffe M, Roeger S. **The subcutaneous implantable cardioverter-defibrillator: First single-center experience with concomitant implantable pulse generators [abstract].** *Eur J Heart Fail.* 2015; 17 SUPPL. 1: 324. *Heart Failure 2015 and the 2nd World Congress on Acute Heart Failure Seville, Spain 2015-05-23 to 2015-05-26.* Background: Subcutaneous implantable cardioverter-defibrillator (S-ICD) is a device for antiarrhythmic therapy with no intravascular leads. The S-ICD does not have pacing functions. We describe the technical feasibility of combining the S-ICD with other implantable pulse generators (IPGs), including pacemakers with trans-venous or epicardial electrodes. For the first time, we describe how S-ICD can also co-work successfully with cardiac contractility modulation (CCM) and with vagus nerve stimulation (VNS). Methods: Between 7/2011 and 11/2014 six patients had S-ICD in combination with CCM, three patients with single-chamber pacemakers with trans-venous or epicardial pacing electrodes received S-ICD, and one S-ICD patient received VNS. In all patients intraoperative S-ICD testing, crosstalk tests and postoperative ergometer testing were performed. Results: In all 10 patients device implantations were successfully performed without complications. S-ICD therapy was shown to be technically feasible with concomitant IPGs including CCM, pacemaker and VNS. Mean follow up was nearly 17 months (in CCM 5 cases had up to 35 months of follow-up, mean 20.4 months). S-ICD testing and crosstalk check before and during exercise enable successful programming of the S-ICD for proper functioning with concomitant IPG. None of the devices had to be permanently inactivated and no patient received inadequate shock. Conclusions: In select patients, S-ICD can be combined with a pacemaker. Combination of a S-ICD with CCM and with VNS may be practical for reducing the number of trans-vascular leads. S-ICD appeared safe with CCM over a long follow-up period. Additional reports on S-ICD co-work with IPGs are warranted.

Kuschyk J, Stach K, Tulumen E, Rudic B, Liebe V, Schimpf R, Borggreffe M, Roeger S. **The subcutaneous implantable cardioverter-defibrillator: First single-center experience with concomitant implantable pulse generators [abstract].** *Europace.* 2015; 17 SUPPL. 3: iii119. *EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24.* Background: Subcutaneous implantable cardioverter-defibrillator (S-ICD) is a device for antiarrhythmic therapy with no intravascular leads. The S-ICD does not have pacing functions. We describe the technical feasibility of combining the S-ICD with other implantable pulse generators (IPGs), including pacemakers with trans-venous or epicardial electrodes. For the first time, we describe how S-ICD can also co-work successfully with cardiac contractility modulation (CCM) and with vagus nerve stimulation (VNS). Methods: Between 7/2011 and 11/2014 six patients had S-ICD in combination with CCM, three patients with single-chamber pacemakers with trans-venous or epicardial pacing electrodes received S-ICD, and one S-ICD patient received VNS. In all patients intraoperative S-ICD testing, crosstalk tests and postoperative ergometer testing were performed. Results: In all 10 patients device implantations were successfully performed without complications. S-ICD therapy was shown to be technically feasible with concomitant IPGs including CCM, pacemaker and VNS. Mean follow up was nearly 17 months (in CCM 5 cases had up to 35 months of follow-up, mean 20.4 months). S-ICD testing and crosstalk check before and during exercise enable successful programming of the S-ICD for proper functioning with concomitant IPG. None of the devices had to be permanently inactivated and no patient received inadequate shock. Conclusions: In select patients, S-ICD can be combined with a pacemaker. Combination of a S-ICD with CCM and with VNS may be practical for reducing the number of trans-vascular leads. S-ICD appeared safe with CCM over a long follow-up period. Additional reports on S-ICD co-work with IPGs are warranted.

Levy M, Merchant F, Casey M, Hoskins M, Lloyd M, Leon A, DeLurgio D, Goyal A, El-Chami M. **Outcomes of subcutaneous implantable cardioverter de fibrillator implant in renal dialysis patients [abstract].** *J Am Coll Cardiol.* 2015; 65 (10 SUPPL. 1): A367. *64th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.15 San Diego, CA, United States 2015-03-14 to 2015-03-16.* Background: Patients with end stage renal disease (ESRD) are at increased risk of complications after trans-venous defibrillators. The subcutaneous ICD (S-ICD®) offers an attractive alternative in this population, however, data on the safety and efficacy of the S-ICD in dialysis patients is lacking. Methods: We reviewed all S-ICD implants at our center and stratified patients based on need for dialysis at the time of implant. The combined

primary endpoint was incidence of device related complications requiring surgical re-intervention and incidence of defibrillator shocks (appropriate & inappropriate). The secondary end point was incidence of death or heart failure (HF) hospitalization. Results: 68 patients underwent S-ICD implantation (18 on dialysis, 50 without dialysis). Dialysis patients were older (60.3 vs 48.0 years, $p = 0.004$), had lower ejection fraction (24.7 vs. 32.5%, $p = 0.042$), more likely diabetic (72 vs. 30%, $p = 0.004$) and less likely to have primary electrical disorders (0 vs. 20%, $p = 0.05$). 75% of the cohort underwent S-ICD implantation for primary prevention and 17% had prior transvenous ICDs, without significant differences between groups. Fewer patients in the dialysis cohort underwent defibrillation threshold (DFT) testing at implant (67 vs. 90%, $p = 0.06$) and among those who were tested, the lowest successful energy was higher in the dialysis cohort (70.0 vs. 65.9 J, $p = 0.011$). The primary endpoint occurred in 10 patients (20%) in the non-dialysis cohort (6 inappropriate shocks, 1 appropriate shock and 3 infections requiring explant) and 1 patient (5.5%) in the dialysis cohort (appropriate shock) ($p = 0.384$). There were no inappropriate shocks and no infections requiring explant in the dialysis cohort. The secondary endpoint occurred in 7 patients in the nondialysis cohort (3 deaths, 4 HF hospitalizations) and 2 patients in the dialysis cohort (1 death, 1 HF hospitalization) ($p = 0.484$). Conclusion: Our data suggest that S-ICD implantation in dialysis patients is not associated with an excess risk of implant related complications or inappropriate shocks. The incidence of other endpoints is also comparable between dialysis and non-dialysis patients.

Maurizi N, Oldenordkamp L, Brouwer TF, Baldini K, Olivotto I, Knops RE, Cecchi F. **Failure rate of prerequisite subcutaneous-ICD vector screening in patients with hypertrophic cardiomyopathy [abstract].** *Eur Heart J.* 2015; 36 SUPPL. 1: 43-4. *European Society of Cardiology, ESC Congress 2015 London, United Kingdom 2015-08-29 to 2015-09-02.* Background: Sudden cardiac death (SCD) can be prevented in high risk hypertrophic cardiomyopathy (HCM) patients by implantable cardioverter defibrillator (ICD). Subcutaneous ICD (S-ICD) is a promising option for HCM patients. However, there are no data regarding failure of the prerequisite S-ICD vector screening in these patients, who often show markedly abnormal electrocardiograms (ECG) and are therefore at risk of inappropriate shocks. Purpose: To determine the failure rate of the prerequisite vector screening using one or two acceptable vectors, stratified for high and low risk profile for SCD. Methods: Consecutive patients from August to December 2012 and March to November 2014 were analyzed, after obtaining informed consent. The individual arrhythmic risk at 5 years was calculated using the ESC HCM-Risk SCD algorithm. High and low-risk patients were defined respectively by a 5-year risk $>6\%$ and $<4\%$. ECG recordings simulating the S-ICD sensing vectors at three different gain settings (5, 10 and 20 mm/mV) were analyzed with the S-ICD screening tool provided by the manufacturer. Successful vector screening at any of the three gain settings in both erect and supine postures was defined in two ways: 1) as one fitting vector ("1 vector method") 2) as two sensing vectors fitting the template ("2 vector method"). Results: We evaluated 165 HCM patients (118 males, mean age 51 ± 16 years). Forty-one patients (24%) had a prior transvenous ICD, 5 (3%) had a history of cardiac arrest and 22 (13%) prior myectomy. Twenty-two patients (13%) were stratified as high-risk (5-year SCD $7.6 \pm 1.7\%$) and 110 (67%) as low risk ($2.5 \pm 1.0\%$). With the current 1 vector method 26 (16%) patients failed, including 14/110 (13%) low risk and 8/22 (36%) high-risk patients. Reasons for failure were: too high T-wave voltages in 50% of cases, too high R-wave voltages in 26% of cases and low QRS complex voltages in the remaining 24% of cases. With the "2 lead method", 72 patients (43.6%) were considered not eligible for S-ICD therapy, including 42/110 (38%) low risk group and 16/22 (73%) of the high-risk group. Conclusions: The 1 vector screening method as recommended by the manufacturer for S-ICD eligibility is associated with a significant failure rate in HCM patients, particularly in the high-risk subgroup. The use of two suitable vectors resulted in an even higher failure rate. Further research is needed to determine the inappropriate shock rate in HCM patients using the 1 versus 2 vector method and how inappropriate discharges can be managed, e.g. by changing the vector in patients with two suitable vectors.

Mendoza I, Healy C, Tzur A, Mendoza IJ, Carrillo R. **Feasibility and safety of a modified two incision technique for subcutaneous defibrillator implantation [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S13-S4. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: Implantable cardiac defibrillators have demonstrated important survival benefit for primary and secondary prevention of sudden cardiac death. New technologies such a totally subcutaneous cardioverter defibrillator (SICD) have recently emerge as an alternative to endovascular defibrillator devices. Standard implantation technique includes 3 incisions that include a lateral thoracic & 2 parasternal incisions. The purpose of this study is to evaluate the safety & feasibility of a modified 2-incision technique that avoids the superior parasternal incision, Methods: We evaluate patients who underwent implantation of a SICD using a 2-incisions technique. All patients were follow 1day, 1 month & 6 months post intervention. The visits include standard device interrogation. A chest X ray was obtained at 1 day & 6 months after implantation Results: Ten patients (10) were included in the present study. Patient had a mean age of 57 ± 13 years, ejection fraction of 25%, males 60%, ischemic cardiomyopathy 60%, prior device extraction 50%, end stage renal disease 30% & prior documented ventricular tachycardia 40%. No complications occurred during the procedure or 6 months post intervention. Conclusions: A modified two-incision technique appears to be feasible & safe for candidates

undergoing implantation of S-ICD, as well as a less invasive & simplified intervention. Further studies are required to validate this implantation technique. (Figure Presented).

Monteforte N, Mazzanti A, Maurizi N, Bloise R, Morini M, Gambelli P, Napolitano C, Priori SG. **The subcutaneous-ICD for patients with Brugada syndrome: A viable option for everybody? [abstract]. *Europace*. 2015; 17 SUPPL. 3: iii6. *EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24*. Purpose: The availability of the subcutaneous implantable cardiac defibrillator (S-ICD) has opened new possibilities for the treatment of life-threatening ventricular arrhythmias. Eligibility to S-ICD implant has to be always assessed to avoid T wave over-sensing and data show that up to 85% of individuals are usually eligible. However, experience in patients with Brugada syndrome (BrS), is very limited. Here, we assessed S-ICD eligibility at baseline and during ajmaline challenge to induce ST-T BrS pattern. Methods: ECG traces were recorded in supine and upright position at baseline, according to the instructions provided by the manufacturer. The same set of recordings was repeated at maximal ST-T change during the infusion of ajmaline (1 mg/kg in 10 minutes). S-ICD eligibility was confirmed when at least 75% of QRS-T complexes of one ECG lead were included within the pre-defined template in both postures at baseline or during ajmaline test. Results: We evaluated 40 subjects (31 males, mean age 41±11y) referred for incidental type 2 or 3 BrS ECG pattern (n =26; 65%), family history of BrS (n = 12; 30%), history of cardiac arrest and/or syncope (n = 2; 5%). Twenty patients had a positive ajmaline challenge: 1 patient was not eligible for S-ICD at baseline; 19 patients passed the baseline screening and all of them maintained eligibility despite ST segment and T wave changes evoked by ajmaline infusion. Conclusions: Our data show that only few BrS patients (approximately 5%) fail the baseline screening for S-ICD. Most importantly, the (drug-induced) transition to a BrS type-1 does not affect S-ICD eligibility. Therefore our data suggest that spontaneous ECG changes in BrS do not significantly affect the risk of T wave over-sensing. S-ICD appears appealing solution for high risk BrS patients. (Figure Presented).**

Neuzil P, Janotka M, Keller J, Vymazal J, Weichet J, Brada J, Mudroch M, Zacek J, Petru J. **Magnetic resonance imaging in patients with a subcutaneous implantable cardioverter-defibrillator (S-ICD) [abstract]. *Eur Heart J*. 2015; 36 SUPPL. 1: 10. *European Society of Cardiology, ESC Congress 2015 London, United Kingdom 2015-08-29 to 2015-09-02*. Background: With the increasing number of patients with cardiac implantable devices who are indicated for MRI, there is a growing need for establishing MRI compatibility of cardiac implantable devices. This is the first publication demonstrating that patients implanted with an S-ICD can be safely scanned with a 1.5T MRI. Methods: Patients with implanted S-ICD systems (minimum 3 months after implantation procedure) underwent one or more types of anatomical MRI scans. The S-ICD was programmed "off" and patient were monitored throughout the imaging procedure (ECG and oxygen saturation). Device function was evaluated pre and post each scan. Patients were asked to report immediately any pain, torqueing movement or heating sensation in the area of the pocket or electrode Results: Fifteen patients underwent a total of 19 examinations at 1.5T. Scans included brain, spine, cardiac and extremities. Two patients were re-scanned due complaints of heating over the can during lumbar scans which was caused by a thermistor probe placed on the skin to measure skin temperature. All the remaining scans occurred without incident. In one patient we properly diagnosed protrusion of the L5 disc and adequate therapy was indicated. No evidence of device malfunction, depletion of batteries, interaction with programmed parameters or tissue injury by potential overheating was observed. Conclusions: MRI scanned of patients with the implanted S-ICD can be performed safely under controlled conditions. (Figure Presented).**

Okamura H, McLeod CJ, Bashir MU, Webster TL, Bonnicksen CR, Grogan M, Phillips SD, Warnes CA, Ammass NM, Connolly HM, Friedman PA. **Right sternal lead placement increases eligibility for subcutaneous defibrillator implantation in adults with congenital heart disease [abstract]. *Circulation*. 2015; 132 SUPPL. 3.: *American Heart Association's 2015 Scientific Sessions and Resuscitation Science Symposium Orlando, FL, United States 2015-11-07 to 2015-11-11*. Introduction: The subcutaneous implantable cardioverter defibrillator (S-ICD) is an attractive option for patients with congenital heart disease (CHD) in whom a transvenous system is contraindicated. However, more than 10% of adult patients with CHD fail S-ICD screening due to a large T- to R-wave ratio. We hypothesized right-sternal electrodes may permit S-ICD placement in patients who fail left-sternal screen. Methods: We prospectively screened 40 patients with CHD for S-ICD using the standard proprietary approach. We also screened with right sternal electrodes (with left can electrode position). Results: The mean age of the cohort was 46±15 years; 24 males were enrolled. CHD anomalies consisted of tetralogy of Fallot (n=11), Ebstein's anomaly (n=7), atrial septal defect (n=6), dextro-looped transposition of the great artery (n=5) and other (n=11). Left side screening ECG failed in 9 patients (23%), five of whom passed with right sternal electrodes, increasing the pass rate from 77% to 90%. Figure shows the screening ECG and chest x-ray of a patient who failed in all three vectors on the left side but passed in the alternative vector on the right side and underwent right sided implantation. Conclusions: The addition of right sternal electrodes during screening increases S-ICD eligibility and may avoid thoracotomy for high risk patients with CHD.**

Pedersen SS, Mastenbroek M, Carter N, Scholten MF, Lambiase PD, Boersma LVA, Johansen JB, Theuns DA. **The patient perspective on the entirely subcutaneous implantable defibrillator system: Early results from the effortless S-ICD quality of life substudy [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S255-S6. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: The first clinical results from the EFFORTLESS S-ICD Registry on the entirely subcutaneous implantable defibrillator (S-ICD) system are promising, but the impact of the S-ICD system on patients' quality of life (QoL) is not known. We compared the QoL of patients with an S-ICD versus a transvenous (TV)-ICD system during 6 months of follow-up. Methods: Consecutively implanted patients with an S-ICD versus a TV-ICD system were matched on a priori selected baseline characteristics and QoL scores. QoL was measured with the Short-Form Health Survey (SF-12) at baseline, 3- and 6 months post implant and was compared using multivariable modelling with repeated measures. Results: Patients with an S-ICD (n=168) versus a TV-ICD system (n=168) did not differ significantly on mean scores of physical (p=0.2005) and mental QoL (p=0.3141) across baseline, 3- and 6 months post implantation in adjusted analyses. The evolution in physical (p=0.1325) and mental QoL scores (p=0.6004) during the follow-up period was similar for both cohorts, as indicated by the non-significant interaction effect for ICD system by time for both domains. Both patients with an S-ICD system and a TV-ICD system experienced significant improvements in physical and mental QoL between time of implant and 3 months (both ps>0.0001) and between time of implant and 6 months (both ps>0.0001) but not between 3 and 6 months (both ps<0.05). Conclusions: These first results show that the QoL of patients with an S-ICD versus TV-ICD system is similar, and that patients with either system experience improvements in QoL on the short-term. (Table Presented).

Sharma D, Miller MA, Palaniswamy C, Koruth JS, Dukkipati S, Reddy VY. **Position related ventricular undersensing of the subcutaneous implantable cardioverter defibrillator [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S498. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: The subcutaneous ICD (S-ICD) employs a transthoracic morphology-based detection algorithm. The sensing vector is selected automatically at implant, and reconfirmed the next day. We sought to determine whether detection is susceptible to errors based on body position. Methods: Ventricular sensing was performed in a consecutive series of S-ICD patients. Patients underwent standardized testing of the 3 sensing vectors (primary, secondary, alternate) in 3 positions (supine, sitting up, flexed forward) during follow-up. Results: The cohort included 15 patients (age 54 ± 19 yrs) with a mean f/u of 339 days. In the flexed forward position, ventricular undersensing with the alternate vector occurred in 26% (n=4). As a result of low amplitude signals in the alternate position while flexed forward (leading to sensing decay to the 80 µV absolute sensing floor), one patient experienced a spontaneous inappropriate shock (due to P and T oversensing). Unlike the alternative vector, position related ventricular undersensing did not occur with the primary or secondary vectors. Conclusions: One quarter of patients experience ventricular undersensing during forward flexion in the alternate sensing vector, a phenomenon not seen in other positions/vectors. This could have significant implications for inappropriate shocks or withholding of appropriate therapy in patients for whom the device chooses the alternate as the optimal sensing vector. In this case, positional testing should be performed and consideration given to manual reprogramming if undersensing occurs. (Table Presented).

Sharma D, Miller MA, Singh A, Koruth JS, Dukkipati S, Reddy VY. **First report of a subcutaneous ICD inappropriate shock due to position related triple counting [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S485. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: The subcutaneous ICD (S-ICD) uses a morphology-based sensing algorithm, which can be vulnerable to oversensing, potentially resulting in inappropriate shocks in 5-10% of patients. One etiology of inappropriate shocks is oversensing because of low-amplitude signal. Herein, we report the first case of position-related low amplitude signals resulting in triple counting (P/QRS/T) and an inappropriate shock. Methods: N/A Results: A 63 year-old man who underwent a secondary prevention S-ICD implantation 7 months prior presented for an ICD shock. The event occurred while bending forward (seated position) to tie his boot (right foot). Device interrogation demonstrated an inappropriate shock due to P and T oversensing (Figure). The programmed sensing configuration was the Alternate vector (conditional shock zone = 170 bpm; shock zone = 240 bpm). Further analysis revealed that a sensing decay to the absolute sensing floor (80 µV), as a direct result of position related reduction in surface QRS amplitude, led to cardiac signal oversensing (P/T). The position related decrease in QRS amplitude was reproducible during device interrogation. The primary and secondary vector did not reveal position related amplitude changes, so device sensing was changed to primary vector. Conclusions: This represents the first report of position related triple counting (P/QRS/T) leading to an inappropriate shock in a patient with an S-ICD. Consideration should be given for post-implant positional screening in patients whose sensing configuration is programmed to alternate vector. (Figure Presented).

- Srinivasan NT, Patel K, Lambiase PD. **Eligibility of hypertrophic cardiomyopathy patients for subcutaneous ICD: Results of postural & exercise ECG screening [abstract].** *Europace.* 2015; 17 SUPPL. 3: iii6. *EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24.* Purpose: Subcutaneous cardioverter defibrillator (S-ICD) implantation requires pre-procedure ECG screening to minimise inappropriate therapy. Initial studies have shown that up to 7.4% patients (pts) are ineligible for S-ICD. We investigated the proportion with HCM pts meeting the ECG criteria for S-ICD & reasons for failure. Methods: 44 pts (70% male, age 51 +/-15 years) with HCM & ≥1 risk factors for sudden cardiac death were screened. Exclusion criteria: inability to exercise, age <20 or >70 years or pacing indication. Results: 18% of patients failed screening for S-ICD. Genders were equivalent, (16%F, 20%M p=0.75). 87% failed at rest & 13% on exercise. Mean EF was 65 ± 10%, Max. wall thickness 16 ± 0.3 mm, 2% had >30mmHg LVOT gradient < 57% had NSVT. 48% of patients had a transvenous ICD, of which 86% passed S-ICD screening. Univariate predictors for screening failure were a prolonged QRS duration (OR 1.03), increased T-wave amplitude (OR 1.4), low R-wave amplitude in lead aVF(OR 0.79) & a reduced R:T ratio in lead aVF(OR 0.63). Conclusion: A greater proportion of HCM pts do not meet criteria for S-ICD than previously reported. Prolonged QRS, increased maximal T wave amplitude, low R-wave amplitude in aVF & reduced R:T ratio in aVF are associated with screening failure. Next generation device algorithms are needed to enable greater device implantation in HCM. (Table Presented).
- Theuns DAMJ, Crozier IG, Barr GS, Hood MA, Cappato R, Knops RE, Maass AH, Boersma LVA, Jordaens L. **Longevity of the subcutaneous implantable defibrillator: Long-term follow-up of the European regulatory trial cohort [abstract].** *Europace.* 2015; 17 SUPPL. 3: iii6. *EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24.* Purpose: The subcutaneous implantable defibrillator (S-ICD) is a safe and viable alternative to conventional ICD therapy in patients at high-risk for arrhythmic death. However to date, no data is available about the longevity of the S-ICD. The purpose of this study was to assess device longevity of the S-ICD. Methods: All patients who participated in the European Regulatory Trial were included in the analysis. During follow-up, reasons for device replacement or explantation were assessed and categorized either as battery depletion or non-battery depletion. Device longevity was estimated using Kaplan-Meier analysis. Results: The study cohort consisted of 55 patients; 80% were male, 67% had ischaemic heart disease and primary prevention indication in 78%. During a median follow-up of 5.8 years, 26 (47%) devices were replaced and 5 (9%) were explanted. The majority of devices (81%) were replaced based on battery depletion. Median time to device replacement was 5.0 years. Replacement for a transvenous ICD system was observed in 7% of patients. At 5 years followup, 71% of devices were still in service. Conclusion: The majority of devices were replaced because of battery depletion. The longevity of the S-ICD is slightly less compared to single- and dual-chamber ICDs, but it should be remembered that the current subcutaneous defibrillator is a first generation device, and as such it has performed well.
- Tjong FVY, Smeding L, Kooiman KM, Olde Nordkamp LRA, De Groot J, Wilde AA, Knops RE. **Combined implantation of a subcutaneous implantable cardioverter-defibrillator (S-ICD) and a leadless cardiac pacemaker: Evaluation of feasibility, safety and performance in an ovine model [abstract].** *Heart Rhythm.* 2015; 12 (5 SUPPL. 1): S64. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: The S-ICD has been designed to overcome lead related complications but cannot deliver brady- or antitachycardia pacing. For patients with an S-ICD who develop a bradycardia pacing indication additional implant of a leadless pacemaker (LP) could be considered. The feasibility and safety of a combination of an S-ICD and LP is unknown. Methods: We implanted a combination of S-ICD (BSCI) and LP (SJM) implant in an ovine model and tested: 1) simultaneous programmer-device communication 2) appropriate VF sensing by the S-ICD 3) post-shock LP function. Results: The S-ICD and LP were successfully implanted in two adult sheep (Panel A). 1) Simultaneous communication between programmers and devices was achieved in both subjects without interference pre- and post-shock, but LP telemetry was temporary lost during VF induction and shocks. 2) LP pacing (up to max output: 6V at 1.5 ms) did not interfere with S-ICD VF sensing (Panel B). In total, 13 episodes of VF were induced; all sensed appropriately by the S-ICD, and in 12/13 episodes S-ICD therapy was delivered. 3) A total of 25 shocks (3@65J; 22@80J) were delivered by the S-ICD and 28 shocks by an external defibrillator (3@200J; 25@360J) in the two subjects (subject 1: 26 shocks, subject 2: 27 shocks). The post-shock LP performance was unaltered in both subjects, pre- and post-shock measurements in sheep 1; resp. sheep 2 were: ΔR-wave (mV): 0; -3 Δimpedance (Ohm): -20; -40; Δthreshold (V@0.4ms): 0; 0. No post-shock device dislodgements were observed. Conclusions: The combined implant of an S-ICD and LP in an ovine animal model is feasible and did not show any safety or performance issues. These data might support future human combined implants. (Figure Presented).
- Viani SM, Zucchelli G, Soldati E, Paperini L, Segreti L, Di Cori A, Boem A, Levorato D, Branchitta G, Bongiorni MG. **The subcutaneous implantable defibrillator: Global experience in a high volume ICD lead extraction centre [abstract].** *Europace.* 2015; 17 SUPPL. 3: iii147. *EHRA EUROPACE CARDIOSTIM 2015 Milan, Italy 2015-06-21 to 2015-06-24.* The S-ICD is a new device developed to treat life-threatening arrhythmias that works

leaving the heart and vascular system completely untouched. Purpose of the Study: To analyse S-ICD global experience at our referral centre for ICD lead extraction. Methods: from April 2011 to December 2014, 25 pts (23 M; 2 F), mean age 43.3±15.3 years underwent S-ICD implantation. 10 pts (40%) received an S-ICD as their first device (Naïve) while the remaining 15 (60%) were implanted after extraction of a trans-venous ICD system due to infection (10), malfunction (4) or symptomatic superior vena cava obstruction (1) (Explanted). Results: S-ICD implantation was successful in all the pts. Induced VF was successfully treated with a 65J shock in 100%. No complications occurred; 1 pt experienced a pocket hematoma before discharge treated conservatively. No arrhythmic or cardiovascular deaths occurred at a mean FU of 13.6 ± 11.3 months. 1 N pt died due to progressively worsening CKD. 1 N pt (10%) and 1 EX pt (6.6%) experienced, respectively, 1 fast VT and 4 VF episodes, all converted by S-ICD first 80 J shock. Inappropriate shocks due to T wave over sensing occurred in 1 N (10%) and 2 EX (13.3%) pts (p=ns) and were treated by reprogramming. No infection occurred both in N and EX group. Conclusions: S-ICD therapy is safe and effective both for naïve and previously explanted ICD pts. For explanted pts, S-ICD is an attractive solution due to the higher risk of reinfection and/or the higher incidence of venous obstruction and should be considered whenever pacing is deemed not necessary. (Table Presented).

Von Wald LN, Chen LY, Adkisson W, Sakaguchi S, Benditt D, Roukoz H. **Adipositas cordis: A rare cause of sudden cardiac arrest [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S1-S2. 36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.

Introduction: Adipositas Cordis (AC) is a very rare cardiomyopathy (CM) characterized by lipomatous infiltration of the myocardium which has generally been considered a benign entity in the obese. Only a few reports exist associating it with arrhythmias and restrictive CM. We report the case of a 29-year-old male with AC presenting after aborted out of hospital VF arrest. To our knowledge, this is the first reported case of AC presenting with aborted sudden cardiac arrest. Methods: N/A Results: A 29-year-old fit male with a medical history of testicular lymphoma, end stage renal disease with previous dialysis now status post kidney transplant, provoked and spontaneous DVTs and PE, was admitted for out of hospital VF arrest defibrillated by EMS. His echocardiogram showed moderate left ventricular hypertrophy with normal EF. A cardiac MRI showed diffuse hyperenhancement throughout the myocardium consistent with lipomatous infiltration of the left ventricle (figure). MRI showed normal RV and LV wall thickness with no wall motion abnormalities. Endomyocardial biopsy demonstrated mild myocyte hypertrophy with minimal fibrosis without other abnormal histopathology. There were no findings suggestive of Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) or Hypertrophic Cardiomyopathy (HCM) on either MRI or pathology. The patient underwent implantation of a subcutaneous ICD to avoid thrombotic complications. Conclusions: This case shows that AC can present with sudden cardiac death. It should be differentiated from HCM and ARVC. (Figure Presented).

Weiss R, Knight B, Kaab S, Neuzil P, Sheridan P, Eckhardt L, Doshi S, Mead H, Hood M. **Worldwide experience with the S-ICD in patients with congenital long QT [abstract].** *Eur Heart J*. 2015; 36 SUPPL. 1: 519.

European Society of Cardiology, ESC Congress 2015 London, United Kingdom 2015-08-29 to 2015-09-02.

Introduction: Long-QT syndrome patients (pts) with an ICD indication are young individuals likely to survive many generator changes. Transvenous (TV) leads carry a risk of complication which increases over time. The subcutaneous implantable cardioverter defibrillator (S-ICD) may be an attractive option for these pts but data are scarce. We report on a worldwide experience of a large cohort with long-term follow-up in this group of pts. Methods: Data from the S-ICD EFFORTLESS multicenter real world registry and IDE studies were pooled (N=882). All patients with a primary indication of Long- QT were included. Results: A total of 27 pts met inclusion criteria. Age 38±13 y/o, 67% male and 13 pts (45%) were implanted for secondary prevention. Seven patients (25.9%) had a previous TV-ICD (5 explanted due to infection and 2 for lead failure) and 1 patient had a concomitant pacemaker implanted prior to the S-ICD. During a mean follow-up of 1.8±0.8 years, there were no deaths. S-ICD revision occurred in 2 pts (7.4%) (1 infection, 1 repositioning). 21 of 22 pts (96%) with complete S-ICD testing at implant converted with ≤65J and all 100% were successful at 80J. Eight ventricular episodes in 4 patients (15%) were converted after a single shock. One patient had a VT storm with all shocks being successful. Cardiac oversensing led to device therapy in 3 (11%) patients all resolve with vector reprogramming. Comparing to the non-LQT indication the rate of inappropriate shocks were not different among groups with a follow up of 1080 days (13% for LQT and 16% for Non-LQT pts) Conclusion: In the Largest cohort of Long-QT patients with the S-ICD followed to date, the S-ICD system was an acceptable alternative to TV-ICD. All ventricular arrhythmias were successfully terminated. Inappropriate shocks were caused by oversensing and were corrected by vector reprogramming in all patients. Rates of inappropriate shocks were equivalent in the 2 patient groups.

Willner JM, Miller MA, Singh A, Sharma D, Palaniswamy C, Dukkipati S, Reddy VY. **Chronic safety and efficacy of submuscular implantation of a subcutaneous ICD system [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S336. 36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16. Introduction: The subcutaneous ICD (S-ICD) is safe and effective for the

treatment of life-threatening ventricular arrhythmias, but has been associated with a moderate risk of skin erosion, wound dehiscence and localized infection. Submuscular ICD (Sm-ICD) implantation may mitigate these complications, but the long-term safety and efficacy of this approach is unknown. Methods: Physician preference and/or patient characteristics determined implant technique. Submuscular implantation of the generator was performed under the serratus anterior muscle. Devices were tested intra-operatively by induction of VF, and defibrillation was performed at 65J. Results: 34 consecutive patients (S-ICD, n = 12; Sm-ICD, n= 22) were included at a median length of follow up of 110 days (IQR 31 - 218). Of the 29 patients who underwent DFT testing, all were successfully sensed and converted out of VF with 65J. Five patients did not receive DFT testing due to subtherapeutic anticoagulation (n = 3), frailty (n = 1), or severe pHTN (n=1). Three patients (S-ICD, n = 2, Sm-ICD, n = 1) received appropriate therapy during follow-up. One patient in each group received an inappropriate shock. There was one incision site wound infection in the SC-ICD group. Conclusions: The Sm-ICD is a safe and feasible alternative to subcutaneous implantation. Placement of the pulse generator in the submuscular position may reduce the risk of pocket-related complications while offering a more desirable cosmetic profile. Though shock impedance was increased in the Sm-ICD group compared to Sc-ICD group, there was no difference in time to therapy or defibrillation capacity. (Table Presented).

Yap SC, Bhagwandien RE, Szili- Torok T, Theuns DA. **Early post-implantation inappropriate shocks due to air entrapment in a patient with a subcutaneous cardioverter defibrillator [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S46. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015 Boston, MA, United States 2015-05-13 to 2015-05-16.* Introduction: The subcutaneous implantable cardiac defibrillator (S-ICD) is an alternative to the conventional transvenous ICD system. The use of subcutaneous electrodes, however, may be associated with specific sensing issues. Methods: N/A Results: A 37-year-old man was admitted after experiencing an out-hospital cardiac arrest due to ventricular fibrillation. He was diagnosed with Brugada syndrome. He received a S-ICD (Cameron Health/Boston Scientific) and the device automatically chose the alternate vector (sensing between distal and proximal electrode) for detection. The evening of the S-ICD implantation he experienced 2 inappropriate shocks due to oversensing of low amplitude signals and artifact. The artifact could be reproduced by manipulation over the proximal electrode. Provocative maneuvers did not produce an artifact in the secondary vector (sensing between distal electrode and can), however, this vector was not suitable due to a low R/T ratio. Chest radiography demonstrated entrapped subcutaneous air surrounding the proximal electrode (Figure A). Four days after implantation there was partial subcutaneous air resolution with no air surrounding the proximal electrode (Figure B). No artifact could be produced with provocative maneuvers. There was complete air resolution 10 days after implantation (Figure C). During mid-term follow-up the patient did not experience any inappropriate shocks. Conclusions: The presence of subcutaneous air may insulate the sensing contact ring causing oversensing and inappropriate shocks. It is important to have good tissue contact of the electrodes by taking care not to introduce air into the subcutaneous tissue. (Figure Presented).

Zabala Diaz L, Romero Roldan J, Abad Vicente J, Perez L, Vinolas X, Martinez JB, Perez F, Garcia E, Alzueta J, Diaz Infante E. **Identifying a population of patients suitable for the implantation of a subcutaneous defibrillator (S-ICD) among patients implanted with a conventional transvenous device (TV-ICD) [abstract].** *Eur Heart J*. 2015; 36 SUPPL. 1: 9. *European Society of Cardiology, ESC Congress 2015 London, United Kingdom 2015-08-29 to 2015-09-02.* Background and objectives: The new S-ICD minimizes the complications associated with the use of intravascular leads in a TV-ICD. However, it have limitations such as the inability to provide pacemaker function or pacing to treat ventricular tachycardia (VT). There are a few trials that analyze the potential candidates for this new device. The aim of our study was to identify patients implanted with TV-ICD who would be potential candidates for S-ICD. Methods: We included patients from UMBRELLA, a prospective study involving ICD patients followed through the Carelink system. We selected patients who underwent a single-chamber ICD first implantation in both primary and secondary prevention, presenting with no monomorphic VT and without indication for pacing at the time of the implant procedure. During the follow-up the emergence of new indication of stimulation was assessed, as well as the appearance of at least one episode of VT successfully ended by antitachycardia pacing (ATP). Results: Among a total of 1652 patients who underwent a first time ICD implantation, 444 met the inclusion criteria (26.9%). During a median follow-up of 31 months, 31 patients (6.9%) needed stimulation, 56 (12.6%) presented episodes of VT terminated by ATP and 76 (17.1%) achieved the combined endpoint. Multivariate analysis indicated the determinants of the unsuitability for an S-ICD (table). Conclusions: Selected candidates for S-ICD implantation depending on the absence of need for stimulation and monomorphic VT episodes at the time of the implant procedure, maintain the suitability for such device throughout the time, especially if they do not present with atrial fibrillation or severe LVEF depression. (Table Presented).

Zeb M, Curzen N, Yue A, Roberts P, Allavatam V, Morgan JM. **Sensitivity and specificity of the subcutaneous implantable cardioverter defibrillator preimplant screening tool [abstract].** *Heart Rhythm*. 2015; 12 (5 SUPPL. 1): S248. *36th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2015*

Boston, MA, United States 2015-05-13 to 2015-05-16. Introduction: The sensitivity and specificity of the subcutaneous implantable cardioverter defibrillator (S-ICD) pre-implant screening tool has yet to be determined. Methods: 80-electrode PRIME-ECGs were collected in 6 postures from 40 subjects [10 normal control and 30 complex congenital heart disease (CCHD) patients (10 tetralogy-of-fallot (TOF), 10 single-ventricle-physiology (SVP), 10 transposition-of-great arteries (TGA)]. Three bipolar vectors were derived from electrodes at locations similar to the S-ICD sensing electrodes and pre-implant screening electrodes placement. These vectors were analysed using the S-ICD pre-implant screening tool (Boston Scientific) and then through the sensing algorithm of S-ICD (Boston Scientific). The data was assessed using 2x2 contingency tables. McNemar test was used for comparison of different categories, $P < 0.05$ was considered significant. Results: The mean age was 36.3 years, 57% were male. The screening tool sensitivity was 86%, specificity was 79%, positive predictive value was 73% and negative predictive value was 89% in all subjects. The sensitivity and specificity of the screening tool was significantly lower in individuals with congenital heart disease (CHD) in comparison to normal control (TOF $p = 0.001$, TGA $p = 0.03$, SVP $p = 0.002$), and in Lead III in comparison to Lead I ($p = 0.004$). However there was no significant difference in Lead II in comparison to Lead III, and six postures (all $p > 0.05$). Conclusions: The screening tool displayed high sensitivity but comparatively lower specificity. Which could explain the high incidence of inappropriate S-ICD shocks reported in the literature. We propose a pre-implant screening device with the S-ICD sensing algorithm to reduce false exclusion and selection and hence possible inappropriate shocks.

Carinci V, Pergolini F, Barbato G, Di Pasquale G. **Monomorphic ventricular tachycardia and brugada syndrome: An unusual association [abstract].** *G Ital Cardiol.* 2014; 15 (4 SUPPL. 2): e33-e4. 45 Congresso Nazionale di Cardiologia dell'ANMCO Firenze, Italy 2014-05-29 to 2014-05-31. A 64-year-old man was referred to our Cardiology department after a resuscitated ventricular fibrillation (OHCA). After discontinuation of hypothermia treatment he showed a complete neurological recover. All cardiological exams (coronary angiography, echocardiogram and MRI) failed to show any cardiopathy. The patient had no family history of sudden death. A subcutaneous defibrillator was implanted. In the follow-up he presented 3 electrical storm: the first one due to 2 episodes of fast ventricular tachycardia (VT) treated with DC shock, the second one due to several episodes of VT (CL 180-200 bpm) responsive to ATP, and the last one due to repetitive VT (160-180 bpm) responsive to ATP (Fig. 1), but causing also DC-shock. On two occasions the patient had fever. Under the suspicion of VT amenable to RF ablation we performed electrophysiological study. No monomorphic tachycardia was inducible. After 0.5 mg/kg of ajmaline a Brugada pattern in inferior leads was induced (Fig. 2). Conclusion. 1) Ventricular monomorphic tachycardia is a rare manifestation of Brugada syndrome, as is the involvement of inferior leads (4.6%). Then this case shows a very atypical form of Brugada syndrome. 2) The follow-up of OHCA is very important to reach a complete diagnosis. (Figure presented).

Carvalho MS, Galvao Santos P, Costa F, Carmo P, Cavaco D, Morgado F, Adragao P. **Implantable cardioverter defibrillator therapy in a young population: Differences between conventional and subcutaneous devices [abstract].** *Eur Heart J.* 2014; 35 SUPPL. 1: 772. European Society of Cardiology, ESC Congress 2014 Barcelona, Spain 2014-08-30 to 2014-09-03. Background: Implantable cardioverter-defibrillators (ICDs) are the most effective therapy for primary and secondary prevention of sudden cardiac death (SCD). Currently, two device options are available: transvenous and subcutaneous (S-ICD). The later has the advantage of avoiding transvenous leads and is becoming widely used in children, young adults and patients for whom venous access may be difficult to achieve. Nevertheless, it is unclear whether the positive aspects of the S-ICD outweigh its disadvantages. Aim: Our aim is to study a population of patients (pts) under 35 years of age, who had a conventional or S-ICD implanted and evaluate the safety and efficacy of the devices. Methods and results: At our institution, about 250 ICDs are implanted each year. All pts under 35 years old who implanted ICDs (either conventional or subcutaneous) from November/2009 to December/2013 were included in this analysis ($n = 44$, 70% men, mean age 25 ± 8 years, youngest patient with 10). Main indications were hypertrophic cardiomyopathy (36%), idiopathic or postmyocarditis cardiomyopathy (16%), left ventricular noncompaction (14%) and Brugada syndrome (11%). 80% of the devices were implanted for primary prevention. 13 pts (29.5%) had appropriate shocks (VF $n = 7$, VT $n = 5$). S-ICDs were implanted in 12 pts [39% of all S-ICDs (31) implanted in this period of time], the remaining had conventional ICDs implanted. Median time of follow-up was 29 [20-42] months. There was no significant difference in the incidence of complications such as infection ($n = 1$, 8.3% in the S-ICD group vs. $n = 2$, 6.3%, $p = n.s.$) or inappropriate shock therapy ($n = 3$, 25.0% in the S-ICD group vs. $n = 7$, 21.9%, $p = n.s.$). There were no undetected fatal arrhythmias. There were no complications related to transvenous lead insertion (pneumothorax or hemothorax and cardiac perforation) and there were no lead dislodgement or fracture in either group. No patient referred discomfort related to the device and no patient was pacemaker-dependent. Conclusion: In our S-ICD candidate population (no pacemaker-dependent patients), no differences were observed on efficacy or safety of subcutaneous versus transvenous devices.

- Gupta A, Subzposh F, Saltzman H, Kutalek SP. **Subcutaneous implantable cardioverter defibrillator implantation in patients after device extraction [abstract].** *Cardiology.* 2014; (2014) 128 SUPPL. 1: 336. *International Academy of Cardiology 19th World Congress on Heart Disease Annual Scientific Sessions 2014 Boston, MA, United States 2014-07-25 to 2014-07-28 CONFERENCE EDITORS Kimchi A.* Objective: We analyzed the safety of subcutaneous implantable cardioverter defibrillator (S-ICD) (Cameron Health/Boston Scientific) implantation after transvenous device extraction. Background: S-ICD is an appealing option for patients after transvenous defibrillator removal due to any cause, especially infection. These patients are at a higher risk for repeat infections and venous occlusion. We report our single-center experience of S-ICD implantation in patients with prior device extraction. Methods: We evaluated the patients implanted with a S-ICD after previous transvenous device extraction at our center between October 2012 and February 2014. Patient information was collected from inpatient and outpatient records. Results: Of the 43 pts implanted with S-ICD at our center, 8 patients had a previous device extraction. Seven were male and seven had ischemic cardiomyopathy. The average age was 60 ±17 years. Seven patients had a pocket or blood stream infection; and one had lead malfunction. Median duration between extraction and implantation of S-ICD was 75 days. Two devices were implanted during the same hospitalization; one of those was done on the same day. Successful defibrillation threshold (DFT) testing was performed in six pts. DFT testing was not performed due to inconsistent anticoagulation in setting of chronic atrial fibrillation in one patient and hypotension during the implantation in the other. There were no procedural complications. There were no infectious complications or inappropriate shocks during a mean follow up of 3 months. Conclusions: Patients undergoing device extraction are at an increased risk for endovascular complications and repeat infections with reimplantation of a transvenous device. S-ICD is a safe and viable option for these patients. It can be safely implanted early after the extraction without any increased risk of complications.
- Gupta A, Subzposh F, Saltzman H, Kutalek SP. **Subcutaneous implantable cardioverter defibrillator implantation in patients with chronic kidney disease [abstract].** *Cardiology.* 2014; (2014) 128 SUPPL. 1: 188. *International Academy of Cardiology 19th World Congress on Heart Disease Annual Scientific Sessions 2014 Boston, MA, United States 2014-07-25 to 2014-07-28 CONFERENCE EDITORS Kimchi A.* Objective: We analyzed the safety and efficacy of subcutaneous implantable cardioverter defibrillator (S-ICD) (Cameron Health/Boston Scientific) implantation in patients with advanced chronic kidney disease (CKD). Background: S-ICD has been approved to provide defibrillation therapy for life threatening ventricular tachyarrhythmias. The safety of S-ICD implantation in patients with advanced CKD is unknown. These patients have significantly increased risk of cardiovascular morbidity and mortality. Also, CKD patients often have vascular access issues and are more prone to bloodstream infections. S-ICD does not require any vascular access. We report our single center experience of S-ICD implantation in these patients. Methods: We evaluated the patients implanted with S-ICD at our center between November 2012 and February 2014 with glomerular filtration rate (GFR) ≤40ml/min. GFR was determined using the Modification of Diet in Renal Disease (MDRD) Study equation. Patient information was collected from inpatient and outpatient records. Results: Of the 43 patients implanted with S-ICD at our center, 11 patients had a GFR ≤40ml/min. Eight patients were already on hemodialysis. Six were female, eight had ischemic cardiomyopathy and nine were African-American. The average age was 56 ±16 years and mean ejection fraction was 26.5%. Seven patients underwent successful defibrillation threshold testing. There were no peri-procedural complications. During a mean follow up of four months, two patients died- one from ischemic bowel and other from PEA arrest. There were no infectious complications and no mortality from ventricular tachyarrhythmias. Conclusions: S-ICD can be safely implanted in patients with advanced CKD, including patients on hemodialysis. Long-term follow-up is needed to determine the efficacy of S-ICD in patients with chronic kidney disease.
- Knopp H, Heine T, Lucas J, Doering M, Hindricks G, Richter S. **Transvenous lead extraction: To reimplant or not to reimplant? [abstract].** *Eur Heart J.* 2014; 35 SUPPL. 1: 691. *European Society of Cardiology, ESC Congress 2014 Barcelona, Spain 2014-08-30 to 2014-09-03.* Purpose: Advanced indications for primary preventive implantable cardioverterdefibrillator (ICD) therapy and cardiac resynchronization therapy (CRT) bear steadily increasing numbers of cardiovascular implantable electronic device (CIED) recipients worldwide. The higher burden of CIED interventions is associated with local and systemic CIED infections and lead-related complications requiring complex transvenous lead extraction (TLE) procedures and careful reassessment of the indication to reimplant a new CIED system. The purpose of the study was to investigate the need and indications for reimplantation in explanted patients (pts). Methods: Prospectively collected data on 150 consecutive CIED pts [123 male (82%), median age 67 years (56-76)] undergoing total TLE at our center between January 2012 and October 2013 were reviewed for indication and type of reimplanted device. Results: TLE was indicated for pocket infection in 48 pts (32.0%), device-related systemic infection in 44 pts (29.3%), and lead-related complications in 58 pts (38.7%). Eight patients (5.3%) died during hospitalization and were excluded from analysis. Thirty-two of the 142 included pts (22.5%) did not receive a new CIED system due to lack of a proper indication according to the current ESC guidelines. Among the 110 reimplanted pts (77.5%), 77 pts (70%) received the same CIED

system, whereas 33 pts (30%) underwent either an upgrade (n=16), downgrade (n=15), or change to a subcutaneous ICD (n=2). In this group 14 pts received a cardiac resynchronization device. Conclusion: Reimplantation of a CIED was not indicated in 22.5% of our TLE study population. Patients with an indication for CIED following TLE need to be reassessed carefully with regard to upgrade or downgrade of the previous system. Almost half of these patients had an indication for CRT therapy. Furthermore novel therapy strategies such as subcutaneous ICD or wireless pacing are gaining in importance in this patient population.

- Koplan BA, Charytan DM, Podoll AS, Reddy V, Roy-Chaudhury P, Tiwari SC, Tumlin J, Williamson DE. **Implantable loop recorder monitoring detects a high incidence of bradycardia leading to pacemaker implant in hemodialysis patients: Preliminary results from the monitoring in dialysis (MiD) study [abstract].** *Circulation*. 2014; 130 SUPPL. 2.: American Heart Association's 2014 Scientific Sessions and Resuscitation Science Symposium Chicago, IL, United States 2014-11-15 to 2014-11-18. Introduction: Hemodialysis (HD) pts have an increased incidence of syncope and sudden death. A greater understanding of the incidence of bradyarrhythmias as a potential risk factor for these events is needed. The MiD study enrolled maintenance HD pts to undergo implantable loop recorder (ILR) placement to determine the arrhythmia incidence in this population. Hypothesis: ILR monitoring will be useful in detecting bradyarrhythmias and guiding treatment in ESRD patients Methods: MiD is a prospective, multi-center study to characterize arrhythmias in HD pts during 12mo of ILR monitoring. All ILR-detected events with stored ECG are visually reviewed for confirmation during the initial 6mo. Clinically significant arrhythmias include bradycardia ≤ 40 bpm for 6sec, asystole ≥ 3 sec, or sustained VT ≥ 130 bpm for ≥ 30 sec. Results: Follow up is available for 45 pts [mean follow-up 6.4mo (0.6-12.0mo), mean age 56 (27-76yrs), 36% female]. Bradycardia events occurred in 16/45 pts (36%) with an incidence of 28.7 (95% CI 10.1-81.7) events per patient month in these 16 pts. Bradycardia was confirmed by visual review in 408 out of 456 ILR-detected brady events with stored ECG occurring during the first 6mo for a positive predictive value (PPV) of 89.5%. An additional 27 of these ILR-detected "brady events" were found to contain either premature ventricular contractions or atrial arrhythmias (PPV for any arrhythmia 95.5%). 4 of 45 subjects (8.9%) have undergone permanent pacemaker implant for bradyarrhythmias or symptomatic tachy-brady syndrome. In comparison, only one patient (2.2%) has been observed to have ventricular tachycardia (VT ≥ 130 bpm for ≥ 30 seconds). There was no association between timing of dialysis and bradyarrhythmias. Conclusions: ILR monitoring detects bradyarrhythmias with high PPV in $> 1/3$ of HD pts and is associated with a high incidence (9%) of permanent pacemaker implant. With improvement in ILR technology with respect to size and wireless capability, clinicians should have a low tolerance to evaluate.
- Kutyifa V, Zareba W, Rosero S, McNitt S, Polonsky B, Moss AJ. **The need for pacing in patients who qualify for an ICD: Clinical implications [abstract].** *Eur Heart J*. 2014; 35 SUPPL. 1: 766. *European Society of Cardiology, ESC Congress 2014 Barcelona, Spain 2014-08-30 to 2014-09-03*. Background: Implantation of subcutaneous implantable cardioverter defibrillator (ICD) is spreading and has been shown to be safe and efficient to terminate life-threatening ventricular tachyarrhythmias, however it does not provide bradypacing. Currently, data on the need for brady-pacing and cardiac resynchronization (CRT) in patients with ICD indication are limited. Methods: The MADIT-II study enrolled post-MI patients with reduced ejection fraction (EF $\leq 30\%$), randomized to either an implantable cardioverter defibrillator (ICD), or conventional medical therapy. Survival analyses and multivariate Coxmodels were performed to assess the incidence and predictors of pacemaker (PM)/CRT implantation in the conventional arm of MADIT-II, after excluding 32 patients (6.5%) with a previously implanted PM. Results: During the median follow-up of 20 months, 24 of 458 patients (5.2%) were implanted with a PM or a CRT (Figure). Five of these patients (21%) received a CRT device. Symptomatic sinus bradycardia was the primary indication for PM implantation (n=9, 37%), followed by AV-block (n=5, 21%), tachy-brady syndrome (n=4, 17%), and carotid sinus hypersensitivity (n=1, 4%). CABG before enrollment (HR=6.88, 95% CI: 1.58-29.84, p=0.01), and baseline PR interval >200 ms (HR=3.07, 95% CI: 1.24-7.57, p=0.02) significantly predicted subsequent PM/CRT implantation. Patients with PM/CRT implantation had a significantly higher risk for subsequent heart failure (HR=2.67, 95% CI=1.38-5.14, p=0.003), but there was no increased risk of all-cause mortality (HR=1.06, 95% CI=0.46-2.46, p=0.89). Conclusion: The need for ventricular pacing or CRT implantation in patients with MADIT-II ICD criteria was low, especially in those with a normal baseline PRinterval, and such patients should do well with a subcutaneous ICD. (Figure presented).
- Olde Nordkamp LRA, Wilde AAM, De Groot JR, Knops RE. **Influence of young age on adverse outcomes of the subcutaneous implantable cardioverter defibrillator [abstract].** *Eur Heart J*. 2014; 35 SUPPL. 1: 868. *European Society of Cardiology, ESC Congress 2014 Barcelona, Spain 2014-08-30 to 2014-09-03*. Purpose: The new subcutaneous implantable cardioverter-defibrillator (S-ICD) eliminates the need for transvenous leads, and therefore has the potential to reduce long-term complications by elongating lead-longevity, which is particularly interesting for younger ICD patients who are at increased risk of ICD-related complications. It is however unknown whether young S-ICD patients are more at risk for short-term complications. Methods: From the largest

S-ICD implanting center worldwide, we compared ICD harm (i.e. inappropriate shocks and/or complications) in patients < and >50 years (yrs) in our S-ICD registry, which collects consecutive S-ICD implantation information plus follow-up data. Results: A total of 82 S-ICD patients were included, of whom 62 were <50 yrs (53% male, age 34±10 yrs) and 20 >50 yrs (50% male, age 58±7 years). During a follow-up of 23±14 months 7 (11%) patients <50 yrs and 2 (10%) patients >50 yrs had inappropriate shocks (p=1.00), of which 5 and 1 were due to T-wave oversensing respectively. Complications occurred in 6 (10%) patients <50 yrs and 2 (10%) patients >50 yrs (p=1.00). The composite endpoint of ICD harm occurred in 12 (19%) patients <50yrs and 3 (15%) patients >50 yrs (p=1.00). The probability of S-ICD harm at 2 years was 22% in patients <50 years and 18% in patients >50 years (figure, log-rank p=0.69). (Figure Presented) Conclusion: In contrast to transvenous ICDs, there is no difference in the probability of short-term ICD-related harm after 2 years in S-ICD patients <50 yrs vs. >50 yrs. Therefore, the potential benefit of the S-ICD to reduce long-term complications for young patients is not overshadowed by a higher rate of short-term complications.

Olde Nordkamp LRA, Wilde AAM, De Groot JR, Knops RE. **Outcomes of the entirely subcutaneous implantable cardioverter defibrillator in patients with inherited cardiac diseases [abstract].** *Eur Heart J.* 2014; 35 SUPPL. 1: 767. *European Society of Cardiology, ESC Congress 2014 Barcelona, Spain 2014-08-30 to 2014-09-03.* Purpose: A new entirely subcutaneous ICD (S-ICD) has been introduced, that does not require lead placement in or on the heart, which therefore has theoretical advantages particularly in young patients with inherited cardiac diseases. We report the largest experience to date in these patients with the S-ICD to evaluate efficacy and safety. Methods: Patients with inherited cardiac diseases were selected if they had a class I or IIa indication for primary or secondary prevention of sudden cardiac death. Patients from our center with a S-ICD implanted between December 2008 and May 2013 were included in this study. Results: A total of 44 patients with inherited cardiac diseases (59% male, mean age 37±12 years, 80% primary prevention) received the S-ICD. After 25 months of follow-up, 2 patients experienced 18 successful appropriate shocks: one patient with Brugada syndrome received 17 appropriate shocks, and 1 patient with hypertrophic cardiomyopathy received 1 appropriate shock. No sudden deaths occurred. Six patients (14%) received a total of 9 inappropriate shocks. Eight inappropriate shock episodes (8/9, 89%) were due to T-wave oversensing, which were mostly (6/8, 75%) solved by optimization of the programming during exercise. In one patient with inappropriate shocks on TWOS during aberrant conduction, the device had to be explanted because reprogramming was not successful in avoiding further inappropriate shocks. Four patients (9%) experienced complications: 3 infections of which 1 was explanted, and 1 defibrillation testing problem in which the device had to be repositioned. Conclusion: The S-ICD is an important new option for young patients with inherited cardiac diseases and is effective in terminating ventricular arrhythmias. There is, however, a considerable percentage of ICD related adverse events, especially inappropriate shocks due to sensing issues during exercise in this young population, which can be solved in most patients by optimized programming during exercise.

Rambhatla T, Kodra A, Levine E, Mountantonakis S, Bhasin K, Skipitaris N. **A case of new supraventricular tachycardia during pregnancy, with the development of post-partum eclampsia, torsades de pointes, and long qt syndrome: Is there a connection? [abstract].** *Circulation.* 2014; 130 SUPPL. 2.: *American Heart Association's 2014 Scientific Sessions and Resuscitation Science Symposium Chicago, IL, United States 2014-11-15 to 2014-11-18.* Background: There is a mechanistic link between QT prolongation and the development of TdP. Women with LQTS have an increased risk of serious cardiac arrhythmias during the postpartum period, however, there is limited data on the effects of pregnancy on those without a prolonged QT prior to delivery. Case Description: The patient is a 22 y/o female with no history of arrhythmia. During pregnancy she had three episodes of SVT, each prompting hospital admissions. ECG showed a heart rate of 148-163bpm, a QTc of 390 to 410ms, and laboratory data a magnesium level of 1.6. On day 3 after a scheduled cesarean section, she suffered a eclamptic seizure and then a Tdp induced cardiac arrest. Magnesium was immediately given. CPR was performed for 31 minutes until return of spontaneous circulation was achieved. The patient had an extended ICU course but was eventually discharged home with her newborn twins, a subcutaneous implantable cardiac defibrillator (S-ICD), multiple postpartum ECGs showing QTc of 493 to 524ms, and a diagnosis of LQTS. Discussion: Pregnancy increases or precipitate cardiac arrhythmias not previously present in otherwise healthy females. In women with LQTS, there have been studies that have shown significant increases in arrhythmias and SCD during the 9 months postpartum. Also recognized are silent forms of congenital LQTS in which patients are arrhythmia free until exposed to a precipitant. 5-10% of patients who develop drug-induced TdP are silent carriers of gene mutations related to LQTS, suggesting a "second hit" can uncover the LQTS phenotype despite a "normal" QTc in the unprovoked state. This emphasizes the importance of other potential 'hits' that can uncover a LQTS, particularly relevant to this case, the postpartum period. To our knowledge, this is the first case of a simultaneously occurring eclamptic seizure and TdP induced cardiac arrest both successfully treated with IV magnesium. This is also the first report, to our knowledge, of multiple episodes of SVT occurring during pregnancy in a patient who subsequently developed postpartum eclampsia, TdP, SVT, and LQTS. Further studies are needed

to identify patients at high risk for postpartum induced LQTS/TdP and if SVT during pregnancy is a risk factor, as well as twin births and Caesarian deliveries.

- Wilke I, Witzel KW, Muench JM, Aydin AA, Patten-Hamel MPH. **High incidence of subclinical atrial fibrillation in patients with hypertrophic cardiomyopathy [abstract].** *Eur Heart J.* 2014; 35 SUPPL. 1: 925. *European Society of Cardiology, ESC Congress 2014 Barcelona, Spain 2014-08-30 to 2014-09-03.* Purpose: In patients with hypertrophic cardiomyopathy (HCM) atrial fibrillation (AF) is an important prognostic parameter and often causes cardiac decompensation. Incidence of subclinical atrial fibrillation in HCM is unknown. Moreover, it remains unclear whether parameters like septal hypertrophy, obstruction of left ventricular outflow tract (LVOT) or diastolic dysfunction contribute to higher incidence of AF. In a single centre study we evaluate the incidence of AF in patients with HCM and de novo implantation of pacemakers and implantable cardioverter defibrillators (ICD). Methods: Over a period of 26 months 44 patients with HCM (25 with LVOT obstruction >30mmHg) received ICDs (4 VVI, 33 DDD, 1 subcutaneous ICD, 30 primary prophylaxis), pacemakers (5 DDD) or event recorder (1). To detect AF device interrogation was performed by analysing atrial high rate episodes. Results: In 30 HCM-patients (68%) AF could be detected. In 13 patients AF was documented already prior to device implantation. During follow up (337±405 days) in a total of 17 patients newly diagnosed AF was detected only by the use of device interrogation in the absence of corresponding clinical symptoms. Neither an increasing septal hypertrophy, nor an obstruction of the LVOT or a higher grade of diastolic dysfunction is associated with the incidence of AF. However, comparable to the general population the incidence of AF in HCM patients increases with age (no AF: mean age + SD 45,1 +14,7 vs. AF: 56,7+ 12,2; p<0.01) and goes along with an increased CHA2DS2 VASc Score (p<0.005). In the AF group 7 patients (23%) suffered from thromboembolic event vs 1 patient without documentation of AF but diagnosed coagulopathy (p<0.01). In 3 ICD patients inadequate shock delivery was seen due to supraventricular tachycardia. None of them had AF before. ICD therapy due to ventricular tachycardia occurred in 6 patients (4 primary prophylaxis), 5 of them had a history of AF. Conclusion: Interrogation of cardiac devices revealed a much higher incidence (68%) of AF in HCM patients as anticipated. According to a high rate of thromboembolic events (23%) in patients with AF early detection and treatment of AF in HCM patients should be addressed more thoroughly.
- Zeb M, Roberts P, Yue A, Morgan J. **Surface electrocardiogram signals variation with posture in normal adults and in adults with congenital heart disease and its clinical implication [abstract].** *Heart.* 2014; 100 SUPPL. 3.: *British Cardiovascular Society Annual Conference 2014 Manchester, United Kingdom 2014-06-02 to 2014-06-04.* Introduction Ambulatory cardiac monitoring devices and the novel subcutaneous ICD (SICD) sensing algorithms are based on the surface electrocardiograms (ECGs) parameters for detection and discrimination of arrhythmias. However the impact of posture, cardiac morphologies (normal and congenital heart diseases), and electrode placement on these parameters are not known. Aim To determine the impact of posture (standing, sitting, supine, left lateral, right lateral) and bipolar electrode location (LI, LII, LIII), cardiac morphologies (normal, TOF, TGA, SVP) and gender on R-wave amplitude, T-wave amplitude, R/T ratio, QRS, QTc, Tpeak-end duration. Method 720 bipolar vectors were collected in a set of three lead (LI, LII, LIII) transcutaneous ECGs at gain 10, at a speed 25mm/sec from three location of SICD sensing arrays in 6 postures from 40 patients including 10 normal controls, 10TOF, 10 SVP, 10 TGA. The ECGs were digitally measured and analysed using repeated-measures ANOVA and Post hoc Helmert contrast pair wise analysis with Bonferroni adjustment. A p value of less than 0.05 was considered significant. Results The mean R-wave amplitude was significantly smaller in LI than LIII (p = 0.025), and right lateral posture in comparison to left lateral posture (p = 0.02). The T-wave amplitude in individuals with TOF was significantly greater than individuals with normal cardiac morphology (p = 0.013) and SVP (p = 0.005). The mean QRS duration in individuals with normal cardiac morphology was significantly smaller than individuals with TOF (p = 0.0001) and SVP (p = 0.006). Also the mean QRS duration in female was significantly smaller than male (p = 0.03). There were no statistically significant differences in the mean R/T ratio, QTc interval, Tpeak-end duration between subgroups, six postures and three lead (p > 0.05). Conclusion Postures, electrodes location and cardiac morphologies have impact on the surface ECG morphological components which may have to be considered while designing sensing algorithm of monitoring devices and specifically SICD.
- Boersma LVA, Neuzil P, Reeve H, Knops R, Theuns D, Nordkamp LO, Johansen JB, Carter N, Lambiase P. **Long term outcome of patients receiving the subcutaneous ICD after transvenous ICD extraction [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S59. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: One-year mortality rates in patients undergoing transvenous ICD (TV ICD) re-implant following lead extraction, are reported to be around 8% with even higher rates in patients indicated for explant for infection. The outcomes of patients receiving a subcutaneous ICD (SICD) as replacement of an extracted, infected TV ICD are unknown. Therefore, we evaluated long term outcome of these patients enrolled in the EFFORTLESS S-ICD Registry Methods: The EFFORTLESS database is an international prospective registry of pts that have received an SICD. Enrollment of up to 1000 pts with a follow-up of 5 yrs will allow evaluation of

effectiveness and safety of the S-ICD in different populations, as well as quality of life. The trial design has been published by Pedersen et al. in PACE 2012. Results: Of the 369 EFFORTLESS Registry patients evaluated at the time of analysis, 55 (15%) had received their S-ICD following explant of a TV-ICD including 34 (or 62% of explants) explanted for documented infection (including endocarditis). Within this group 71% were male with a median age of 60 years (range 19-86). Comorbidities included CAD 53%; CHF 29%; AF 29% and diabetes 24%. The mean ejection fraction was 46+/- 17%. Mean follow-up duration was 398+/- 303days (median 329 days, range 30-1160 days). Of the 34 patients undergoing S-ICD implant after TV-ICD extraction for infection, only two (5.9%) developed a subsequent re-infection. One infection was related to a concomitant pacemaker implanted after the S-ICD (pacemaker was replaced but the S-ICD remains implanted 631 days post original implant). One patient (2.9%) required a repeat procedure with explant of the S-ICD (30 days post implant). One-year mortality rate within this specific population was 2.9% (1 patient died 124 days post implant of pump failure). One additional patient died 706 days post implant of non-cardiac causes. Conclusion: Data from the International EFFORTLESS S-ICD Registry indicates that in patients who received replacement S-ICDs following infection-related TV ICD extractions, the 1-year mortality rate is low with 2.9%. In addition, reported re-infections specific to the S-ICD in this specific population were rare.

Gold MR, Weiss R, Smith W, Leon A, Knight B, Carter N, Husby M, Burke MC. **Inappropriate shock outcomes for subjects programmed to single vs dual zone configuration with the subcutaneous implantable defibrillator [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S59-S60. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: The subcutaneous defibrillator (S-ICD) has a novel algorithm for arrhythmia discrimination that was shown in a head to head comparison of induced SVTs to be superior to transvenous ICDs. We assessed the specificity of this algorithm for spontaneous shocks during the prospective, multicenter S-ICD System IDE Study. Methods: The S-ICD system provides the option of programming a conditional shock zone that uses an SVT discrimination algorithm to determine appropriateness for therapy. Programming of rate cutoffs and zones was at the investigators' discretion. Stepwise logistic regression models were used to evaluate associations between programming a conditional shock zone and the proportion of subjects with an inappropriate shock episode from: 1) any cause; 2) oversensing, and; 3) high-rate SVTs. Results: Of 314 patients with an S-ICD there were 51 inappropriate shocks in 41 (13.1%) subjects. Subjects with a conditional shock zone had a lower tachycardia detection rate compared to subjects programmed with a single zone (191+13 vs 200+13 bpm, $p < 0.001$). However, despite the lower rate threshold, they were significantly less likely to experience an inappropriate shock episode due to any cause (23% vs. 9%; $p < 0.01$) or due to a high-rate SVT (10% vs. 3%; $p = 0.07$) (14% vs 6%; $p = 0.07$). There were no shocks delivered due to discrimination errors within the conditional shock zone. Conclusion: The addition of rhythm discrimination algorithms designed to distinguish fast rhythms due to SVT from VT/VF rhythms reduces the incidence of all-cause inappropriate shocks among patients implanted with the S-ICD System. (Table presented).

Hansky B, Kaymer W, Zu Vilsendorf DM, Strunk-Mueller C, Stellbrink C. **Successful treatment of allergic rejection after ICD implantation [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S48. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: Acute allergic reactions after pacemaker or ICD implantations are extremely rare and often misdiagnosed as pocket infection. Epicutaneous patch testings are used to prove allergic genesis and help to guide the construction of a gold-coated device. We report the case of allergic rejection successfully treated with ePTFE-membrane coating of the ICD device. Methods: A 66 years old patient, suffered from ischemic left ventricular dysfunction (LVEF 25%, coronary bypass grafting in history) received a single chamber ICD system for primary prophylaxis. After two days the system was explanted due to rapid infection. Two months later a new system was implanted from contralateral site. Due to repeated infection this system had to be explanted after 6 days, as well. Epicutaneous testings showed negative results. After exclusion of potential focus, a subcutaneous ICD-system (S-ICD) was implanted three months later. Postoperatively, secretion from the pocket occurred while parasternal wounds showed normal healing process. Under suspicion of allergic rejection systemic treatment with steroids was initiated and the device was coated with a 0.1 mm ePTFE membrane in a re-operation procedure. Results: Postoperative course was normal and device testings demonstrated regular ICD function after 6 weeks. Conclusion: Allergic tissue-device interactions are rare and cannot be ruled out by negative epicutaneous testing at all. In case of early pocket infection and highly unlikely intraoperative contamination device coating with ePTFE membrane may be an option to treat allergic rejection. Porous structure of these membranes prevents electrical insulation of ICD devices and helps to avoid an unnecessary implantation of gold-coated devices.

Johansen JB, Kirkfeldt RE, Nielsen JC, Boersma L, Knops R, Nordekamp LO, Lambiasi P, Neuzil P, Carter N, Reeve H, Theuns D. **Surgical complications in subcutaneous implantable-defibrillator compared to conventional transvenous implants [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S12-S3. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: Subcutaneous implantable-defibrillator

(S-ICD) without the need for a transvenous (TV) lead may be an attractive alternative to conventional TV-ICD in some patients, as TV leads have been linked to significant morbidity. On the other hand, implantation of an S-ICD requires a higher number of incisions and more extensive surgery. However, little is known about the rate of complications in S-ICD implants compared to conventional TV implants. Methods: The rate of surgical complications in S-ICD pts originated from the Cameron Health International Post Market Registry (EFFORTLESS). It was compared to a nationwide cohort of single- and dual-chamber first ICD implantations derived from the Danish ICD Register. Complications (lead-related reintervention, pneumothorax, cardiac perforation, pocket revision, hematoma) were categorized as major, requiring surgical intervention, or minor, without any need for surgery. Results: S-ICD was implanted in 369 patients and TV-ICD in 784 (single-chamber ICD, n=489, dual-chamber ICD, n=295). The median follow-up time was 391 days in the S-ICD and 163 days in the TV-ICD patients. Any complications occurred in 29 (7.9%) S-ICD pts, and 90 (11.5%) TV-ICD pts, $p=.06$, (Chi Square). There were fewer major lead complications (lead re-intervention, pneumothorax, cardiac perforation) in the S-ICD group, $n=5$ (1.4%) vs. $n=37$ (4.7%), $p<0.01$. Major infection was reported more frequently in S-ICD pts, $n=9$ (2.4%), compared to TV-ICD, $n=6$ (0.8%), $p=0.02$, whereas the rate of minor infection only requiring antibiotics did not differ in the two groups. There were also no differences in the rate of pocket revision and hematoma requiring re-intervention. Minor hematoma was more often observed in TV-ICD pts, $n=25$ (3.2%), than in S-ICD pts, $n=2$ (0.5%), $p<0.01$. Conclusion: Lead related complications requiring surgical intervention was less frequent with the totally subcutaneous ICD system compared to a conventional transvenous based ICD. Infections resulting in removal of the system occurred more often with the S-ICD. Overall, there is a trend toward fewer surgical complications with the S-ICD compared to conventional TV-ICD.

Kooiman KM, Knops RE, Nordkamp LRAO, Wilde AAM, De Groot JR. **Management of inappropriate shocks in patients with a subcutaneous implantable cardioverter defibrillator [abstract].** *Heart Rhythm*. 2013; 10 (5, SUPPL. 1): S60. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.*
Introduction: Inappropriate shocks (IAS) are a complication of implantable cardioverter defibrillator (ICD) therapy. IAS can be caused by double counting of the cardiac signal due to T-wave oversensing (TWOS). The management of IAS in patients with a subcutaneous ICD (S-ICD) may be different compared to conventional ICDs because of different sensing algorithms and programming options. Here we describe the management of IAS in patients with an S-ICD. Methods: Sixty nine patients were implanted with an S-ICD in a tertiary referral center between February 2009 and July 2012. The stored electrograms of patients with IAS were analysed. In case of TWOS, an exercise test was performed. All possible sensing vectors were screened on occurrence of TWOS during exercise. Absence of TWOS defined a suitable vector. S-ICD settings were adapted accordingly and patients were followed-up within a month. Results: Eleven patients (16%; 54% male, age 39 ± 14 years, 73% primary prevention) received IAS after 8.9 ± 10 months following implantation. In 8 cases IAS was caused by TWOS. Seven of these IAS occurred during exercise and one during an episode of atrial fibrillation with fast conduction (cycle length 397 ± 78 ms). In these patients a new template was made during exercise. Additionally, in 7 patients the sensing vector and in 5 patients the (un)conditional zone was changed. After this, IAS reoccurred in 3 patients: in one patient the vector was inadvertently changed to the initial setting during an automatic setup on an optimized device, in another patient IAS occurred on new aberrant conduction and in the third patient a second exercise optimization was necessary. After optimization we observed no IAS during a follow-up of 14.1 ± 13 months. Conclusion: Inappropriate shocks due to TWOS in the S-ICD may be managed adequately with reprogramming the sensing vector and/or the (un)conditional zone of the device using a template acquired during exercise. Exercise-optimized programming may reduce future IAS.

Mark GE, Skaf J. **Subcutaneous ICD(S-ICD) shock due to mechanical interaction with sternotomy wires [abstract].** *Heart Rhythm*. 2013; 10 (5, SUPPL. 1): S143-S4. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.*
Introduction: A 72 year old man with a history of CABG and previous ICD infections presented after receiving a shock from a newly implanted S-ICD Methods: N/A Results: The S-ICD lead is composed of a distal and proximal electrode that flank the shocking coil. To optimize both sensing and defibrillation, lead placement is recommended along or adjacent to the sternum. The defibrillator is placed in the left axillary line at the 5th intercostal space. Three sensing vectors are described as primary (ring-can), secondary (tip-can) and alternate (tip-ring). At implant the device automatically selects its optimal sensing vector. Interrogation revealed the programmed sensing vector was secondary, with normal impedance and no evidence of T wave oversensing. Stored electrograms (fig 1) revealed noise markers (N) and tachycardia markers (T) following multiple noise events. T events continued to be noted due to both upward and downward shift of the baseline. Noise was reproduced with motion of the left arm and with contact to the lead tip. CXR showed the distal electrode in contact with a sternal wire. After discussing treatment options including lead repositioning or removal of the sternal wire, the device was reprogrammed. The primary vector was used to avoid sensing from the distal electrode. At follow-up no further noise has been detected. Conclusion: This is the first report of interaction between sternal wires and the S-ICD. Due to baseline shift, a short episode of noise can result in ICD shock. In

patients with prior sternotomy avoidance of noise may require either removal of the sternal wire adjacent to the distal electrode or reprogramming the device to the primary sensing vector. (Figure presented).

Martens E, Siebermair J, Sinner MF, Beckmann BM, Schuessler F, Kaeae S. **Subcutaneous implantable defibrillator - Is a stress test ECG required before implantation? [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S60. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: The sICD system is located entirely subcutaneous, eliminating the need for intravenous or intracardiac lead placement. The sICD can deliver shocks up to 90J. Antitachycardia pacing (ATP) is not possible. Thus the possible need for ATP or bradycardia pacing need to be appropriately excluded. To predict adequate subcutaneous sensing, the manufacturer recommends specific ECG recordings in both supine and sitting positions. In our clinics, we observed individual patients with delivery of inappropriate sICD-shocks under physical stress. Methods: We retrospectively analyzed 18 sICD-patients for the occurrence of inappropriate shocks during rest and physical activity. We then prospectively screened 42 patients potentially suitable for sICD implantation recording resting ECGs in supine and sitting positions as well as under stress. ECGs were recorded according to the figure. Results: Retrospectively analyzed patients (n=18) were more commonly male (65%; mean age 38+/-16). One patient received an inappropriate shocks under physical stress because of t-wave-oversensing. We were able to reproduce t-wave oversensing in a later screening ECG recorded in this patient. The 42 prospectively screened (screening between 4/2012 and 10/2012) were 67% male with a mean age of 36+/-12 years. Six patients were rejected due to t-wave-oversensing at rest caused by RBB or LBB. A standard transvenous ICD was implanted in 29 patients for clinical indications despite successful screening. In 4 patients (12-20 years), we identified t-wave-oversensing during stress test ECG. These patients received an transvenous ICD. We identify 5 of 60 patients with screening failure during physical stress, although the screening by resting ECG was successful. We successfully implanted sICDs in 6 patients without t-wave-oversensing as assessed during rest and under physical stress. Conclusion: In our cohort we identified 8,3% (5 of 60) patients with successful screening ECGs at rest but t-wave-oversensing during stress test. Our data underlines the importance of stress test ECG for sICD screening and hopefully the prevention of inappropriate sICD shock by reasonable screening. Certainly further investigations are necessary to prevent sICD patients of inappropriate therapies.

Nordkamp LRAO, Warnars JL, Wilde AA, Knops RE. **Who is suitable for the subcutaneous ICD: Incidence and predictors of failed T-wave analysis [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S58-S9. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: The entirely subcutaneous implantable cardioverter-defibrillator (S-ICD), recently approved by the US Food and Drug Administration, eliminates the need for transvenous leads, and therefore probably elongates lead-longevity and reduces lead-related complications. The S-ICD relies on a pre-implantation T-wave analysis to assure that it reliably records the QRS-complexes and T-waves. Inappropriate sensing can lead to inappropriate shocks and this has proven to be so far a significant limitation of the S-ICD. Which patients fail the pre-implantation T-wave analysis and are therefore at risk for inappropriate shocks is unknown. Methods: A T-wave analysis was done in consecutive ICD patients visiting the general outpatient clinic using an ECG simulating the three sense vectors of the S-ICD (primary: xyphoid to V6; secondary: sterno-manubrium to V6; alternate: sterno-manubrium to xyphoid). Patients were defined suitable when one sense vector was considered correct in both supine and standing position. All other patients were non-suitable. Results: A total of 182 general ICD patients (76% male, age 60+/-16 years) were included in this analysis. Based on the T-wave analysis 147 (81%) of the ICD recipients would have been suitable for initial S-ICD implantation. The primary sensing vector was most frequently suitable (69%). Important univariate predictors for non-suitability of a S-ICD were dilated cardiomyopathy (OR 3.7; p<0.01), wide QRS complex on 12-lead baseline ECG (OR 1.4 per 10ms; p<0.01), maximum T-wave amplitude on 12-lead baseline ECG (OR 1.3; p<0.01), primary prevention indication (OR 3.0; p=0.01). Conclusion: In the general ICD population 81% was suitable for initial S-ICD implantation based on the T-wave analysis. Patients with dilated cardiomyopathy, a wide QRS complex, large T-waves or a primary prevention indication are more often non-eligible for S-ICD implantation.

Nordkamp LRAO, Wilde AA, Carter N, Lambiasi P, Boersma L, Neuzil P, Theuns D, Johansen JB, Reeve H, Knops RE. **Inappropriate shocks in the subcutaneous ICD population: Incidence, predictors and therapy [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S476-S7. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: The entirely subcutaneous implantable cardioverter-defibrillator (S-ICD), recently approved by the US Food and Drug Administration, eliminates the need for transvenous leads, and therefore has the potential to elongate lead-longevity and reduce lead-related complications. The S-ICD has a morphology-based sensing algorithm due to which inappropriate shocks have been reported. Methods: We analyzed the incidence, predictors and therapy of inappropriate shocks in the EFFORTLESS S-ICD Registry which collects S-ICD implantation information plus 60-month follow-up data from international clinical centres in Europe and New Zealand. Results: A total of 369 S-ICD patients (71% male, age 49+/-18 years) were included in

this analysis. During a follow-up of 15+/-11 months 25 patients (6.8%) experienced a total of 37 inappropriate shocks (16/25 received 1 inappropriate shock). The most common cause of inappropriate therapy was inappropriate sensing (29/37; 78%). All other events were in the shock-only rate zone. Predictors for the occurrence of inappropriate shocks were sex (male OR 4.6, p=0.04) and a non-ischemic diagnosis (OR 3.6, p=0.02). Programming the primary sensing vector (sensing from xyphoid to V6) was associated with fewer inappropriate shocks (OR 0.4 p=0.04). In the majority of cases inappropriate sensing leading to shocks was solved by a change in programming (22/37; 59%), most frequently by changing the sensing vector (10/37; 27%). Conclusion: Inappropriate shocks occur in 6.8% of the S-ICD patients, especially in males and in patients with non-ischemic diseases. Strict sense-vector selection and rate programming can probably reduce the occurrence of inappropriate shocks of the S-ICD.

Peters B, Rosenthal E, Schmitt B, Schoof S, Berger F. **First experience with a new totally subcutaneous ICD (Cameron Health) in five high risk patients with complex congenital heart disease (CHD) [abstract].** *Cardiol Young.* 2013; 23 (, SUPPL. 1): S5. 47th Annual Meeting of the Association for European Paediatric Cardiology, AEPC with Joint Sessions with the Japanese Society of Pediatric Cardiology and Cardiac Surgery and Asia-Pacific Pediatric Cardiac Society. Introduction: Implantable cardioverter-defibrillator (ICD) therapy for prevention of sudden cardiac death has been increasingly adopted in the CHD population. In this group, conventional transvenous systems are often not applicable due to specific anatomic situations. Therefore we describe our preliminary experience with a new totally subcutaneous ICD (S-ICD, Cameron Health, USA) in a high risk patients group. Patients and clinical outcome: In 5 patients (8.9-51.2 years) the S-ICD system (69 cc, 145 gram) was implanted for secondary prevention of sudden death. Patient weights ranged from 34-130 kg. 3 patients with an intracardiac right-to-left-shunt had a contraindication to transvenous lead placement: two with Eisenmenger syndrome and one with pulmonary atresia and VSD. In one patient with Ebstein's anomaly, transvalvular lead passage was not appropriate. In the youngest patient (8.9 y) with severe ventricular dysfunction, transvenous access was limited by a Glenn shunt. No patient had an antibradycardiac pacing indication. 3 procedures were performed with general anaesthesia and two with conscious sedation. In 4 patients the device was submuscular and in one (130 kg) subcutaneous. Post implantation DFT testing showed effective ICD function. Good cosmetic results without patient discomfort were achieved in all. During a median follow up of 11.9 months 4 of the 5 patients did not experience any shocks. In the patient with Ebstein's anomaly with complete right bundle branch block (RBBB), two inappropriate shocks occurred during exercise; this was due to a change of T-wave morphology at higher heart rates leading to 'double counting'. Conclusions: The new S-ICD is a good choice for complex CHD patients, in whom transvenous lead placement is not applicable. The minimally invasive approach avoids epicardial lead placement via thoracotomy - a major advantage in patients with high preoperative risk factors. Unfortunately the S-ICD has no antibradycardiac pacing option, which substantially limits its use in CHD patients. Despite the bulky size of the device, which restricts the use to patients above 30 kg, good cosmetic results can be achieved if the device is placed submuscularly. For pre-implantation ECG screening, exercise testing should be considered to rule out T-wave oversensing at increased heart rates especially with RBBB.

Rantner LJ, Vadakkumpadan F, Crosson JE, Spevak PJ, Trayanova NA. **Prediction of optimal icd placement in a patient- specific model of pediatric congenital heart defect [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S254. 34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013. Introduction: Due to small size and varied anatomies, choosing ICD placement sites in children with congenital heart defects (CHDs) is challenging. Patient-specific heart-torso computer models offer the possibility to determine the optimal ICD placement. Methods: A biophysically-detailed heart-torso model was generated from clinical MRIs of a pediatric patient with tricuspid valve atresia (Fig A), and fiber orientation estimated using published methodology. IKs, Ito, and conductivity heterogeneities were incorporated. Since transvenous access was not possible, 3 subcutaneous (SQ) and 3 epicardial lead placement sites were identified along with 5 ICD can sites (Fig B). VF was induced, and defibrillation shocks were applied from 11 ICD configurations (Fig C) to determine defibrillation thresholds (DFTs). Results: The use of epicardial leads resulted in a lower DFT than SQ leads. Three configurations shared the lowest DFT for SQ leads (12.5% of highest DFT): 1. similar to a commercially available SQ ICD (S-ICD), 2. with two SQ leads, 3. with three SQ leads. In previous studies, extracellular potential (ct>e) gradients > 5 V/cm in > 95% of the ventricles have been used as a surrogate for defibrillation success. However, this was an inadequate predictor here, as defibrillation failed in some instances when 100% of myocardium experienced such gradients. Conclusion: We demonstrated the feasibility of constructing electrophysiological CHD heart-torso models from clinical MRI. For the patient in this study, an S-ICD configuration was the optimal option. ct>e gradients are not sufficient to predict defibrillation success. (Figure presented).

Russo AM, Burke MC, Gold MR, Knight B, Leon A, Smith W, Carter N, Husby M, Weiss R. **The impact of gender on complications associated with subcutaneous implantable cardioverter defibrillators [abstract].** *Heart*

Rhythm. 2013; 10 (5, SUPPL. 1): S12. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: Previous studies demonstrate gender differences in outcome following transvenous ICD implantation, including a higher rate of procedural complications in women, with an increased risk of perforation, tamponade or mechanical complications. As endovascular access is not required for a totally subcutaneous ICD (S-ICD), it was hypothesized that men and women will have similar outcome following S-ICD implantation. Methods: We analyzed the influence of gender on outcome of patients receiving S-ICDs in the Cameron Health (Boston Scientific, Inc) IDE trial. The safety cohort consisted of 321 patients (238 men, 83 women). Complications were defined as any adverse event resolved by an invasive procedure. Multivariate analysis was performed to identify factors predicting complications and shocks. Results: Women comprised 26% of the IDE cohort. Mean follow-up was 10.6 +/-5.0 months. Compared to men, women were younger, had a higher LVEF, and were less likely to have atrial fibrillation, prior MI or PCI. (Table) There were no gender differences in complication rates (10.9% in men and 10.8% in women, p=0.984). Multivariable analysis revealed higher complication rates associated with heart failure NYHA class III-IV (OR 3.367, 95% CI 1.286, 8.820, p=0.014) and younger age (OR 0.963, 95% CI 0.934, 0.994, p=0.019). Conclusion: Contrary to prior data related to gender differences in outcome following transvenous ICD systems, there are no gender differences in complications with S-ICD implantation. Further investigation is needed to determine if women meeting ICD indications might be better served by S-ICDs rather than conventional transvenous systems. (Table presented).

Winner IMW, Rhodes T, Love C, Kamalov G, Torres J, Weiss R, Hamam I. **Exercise treadmill testing is a useful tool for eliminating T wave oversensing in patients with subcutaneous cardioverter defibrillators [abstract].** *Heart Rhythm.* 2013; 10 (5, SUPPL. 1): S295-S6. *34th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2013.* Introduction: Subcutaneous cardioverter defibrillators (S-ICDs) eliminate the need for intravascular leads; however, appropriate sensing without a transvenous lead has been called into question. Patient activity may result in morphological changes in the QRS and T-wave leading to oversensing by the S-ICD. Exercise Treadmill Testing (ETT) may be a useful tool to evaluate these changes. Methods: We performed a retrospective chart review of all pts who received an S-ICD at our institution between 4/10 and 4/11. We analyzed all patients that had detection or therapy for T-Wave oversensing (TWO) by the S-ICD. Results: Forty-one pts had an S-ICD implanted during the study period (47.4 +/-14.9 years; 18 (44%) female). Six (15%) patients received inappropriate shocks for TWO. ETT was performed in 5 of 6 patients. Vector reprogramming was successful in 3 of 5 (60%) patients undergoing ETT. One patient's S-ICD was removed for the lack of appropriate vector programmability and one patient had the S-ICD turned off due to terminal lung cancer. One patient's sensing vector was reprogrammed without the aid of ETT. During a mean follow-up period of 24 months only 1 patient received a shock from T-wave oversensing after reprogramming guided by ETT. Conclusion: TWO is a common cause of inappropriate shocks in patients with an S-ICD. ETT is a helpful tool in the selection of the appropriate sensing vector and elimination of TWO. In a single patient ETT led to S-ICD extraction. (Figure presented).

Knops R, Wilde AA. **An alternative implantation technique for the electrode of the fully Subcutaneous Internal Cardioverter Defibrillator (S-ICD): The sheath facilitated technique [abstract].** *Eur Heart J.* 2012; 33 SUPPL. 1: 543. Abstract P3270. *ESC Congress 2012 Munchen, Germany 2012-08-25 to 2012-08-29.* Introduction: The electrode of the S-ICD is implanted by making three incisions, one lateral pocket incision and two parasternal incisions; the electrode is then tunneled through these incisions to a parasternal position. In our experience these parasternal incisions are a possible risk for infection and a potential source of discomfort. We present an alternative technique of implanting the S-ICD electrode avoiding the distal incision and suture. Methods: In our approach we tunnel the electrode, conform the current technique, with the tunnelling tool from the lateral pocket to the proximal parasternal incision. We now place an 11 F peel-away sheath, for transvenous lead placement, over the tunnelling tool and tunnel this sheath subcutaneously to a distal parasternal position. The electrode is then placed through the sheath to this position. No distal suture is used. After manually confirming correct placement the sheath is peeled away. It is important to firmly fixate the lead with the suture sleeve in the proximal parasternal incision to avoid lead displacement. Results: A total of 39 patients were implanted with this technique without complications. Correct placement of the electrode was verified by chest x-ray at day 1 and 2 months. In all cases there was a correct position of the electrode. No dislocations occurred (follow up 2-14 months). (Figure presented) Conclusions: We introduce an alternative, sheath facilitated, implant technique for the electrode of the S-ICD, which in 39 cases successfully avoided a distal parasternal tunnelling incision.

Lambiase PD, Theuns DAMJ, Barr C, Knopps ER, Murgatroyd F, Johansen JB, Boersma L, Calkins H. **International experience with a subcutaneous ICD: Preliminary results of the effortless S-ICD registry [abstract].** *Heart Rhythm.* 2012; 9 (5, SUPPL. 1): S15. Abstract AB07-2. *33rd Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2012. EFFORTLESS S-ICD Registry.* Introduction: The EFFORTLESS S-ICD Registry is designed to collect subcutaneous implantable cardioverter defibrillator (S-ICD) implant information plus 60 months of system performance and patient clinical outcome follow-up data, including an optional Quality of Life (QOL)

sub-study for prospective patients. Methods: Clinical Centres from 9 countries in Europe and New Zealand are participating in the Registry. Currently 149 patients are enrolled (54 prospective/95 retrospective) and 53/54 (98%) are included in the QOL sub-study. Cumulative follow up duration is 1726 months with a median follow-up of 13 months. Results: Average age is 49+/-19yrs (range 11-86), 77% male and 67% primary prevention (of which 54% are ischemic). Ischemic MADITII and SCD-HeFT indications account for 42% of primary indication patients (30% and 12% respectively). Non ischemic indications include HCM (17%); dilated cardiomyopathy (12%); Brugada (4%); ARVC (4%); CPVT (2%) and other congenital or familial risks (5%). Previously implanted transvenous systems have been documented in 14% of patients (21 patients: 19 ICDs and 2 pacemakers). Mean LVEF is currently 41+/-19% (n=116) and mean QRS duration is 104+/-20ms (n=127). Induced shock conversion efficacy is 98.4% (125/127) with an average time to therapy for the first 65J shock of 16+/-3 seconds (n=38). Of the two patients who failed at initial implant, one required electrode repositioning and the second has planned retesting at the time of submission. Sixteen patients have received ambulatory shock therapy (10.7%; n=53 episodes) of which 9 received appropriate shocks (6%) and 9 (6%) received inappropriate shocks (5 for noise/T wave oversensing and 4 for supraventricular (SVT) arrhythmias with rates above the shock zone cut-off). No patient has received therapy for any SVTs (including atrial fibrillation) within a programmed conditional shock zone. Conclusions: This early clinical evaluation designed to capture the real world performance of the S-ICD, indicates that the S-ICD is functioning appropriately and is emerging as a viable option for a significant proportion of standard ICD patients.

Maass AH, Waterbolk TW, Van Melle JP, Van Gelder IC. **Subcutaneous only ICD on top of a permanent pacemaker in adult congenital heart disease [abstract].** *Heart Rhythm.* 2012; 9 (5 SUPPL. 1): S298. *33rd Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2012 CONFERENCE LOCATION Boston, MA, United States CONFERENCE DATE 2012-05-09 to 2012-05-12 CONFERENCE EDITORS Calkins H.*
Introduction: The subcutaneous only ICD (S-ICD) is an evolving technique for treatment of patients at risk for life threatening arrhythmias. It has been approved for routine use in Europe. Sensing and shock pathways are based on a parasternal subcutaneous lead that is connected to a subaxillary ICD device. It can be used in patients with limited venous access such as patients with complex congenital heart disease. A potential caveat is the lack of pacing capability besides brief post shock pacing. Methods: A 37 year old male patient with Mustard's correction of transposition of the great arteries had been previously implanted with a DDD-pacemaker system for intermittent AV conduction block and had 2 active and 1 abandoned lead via the surgically created tunnel from the right atrium. He had a severely dilated system chamber with reduced contractile function and was at risk of developing ventricular arrhythmias. A transvenous ICD lead through the Mustard tunnel was considered to be associated with high risk for obstruction. The patient was implanted with an S-ICD. Results: Implantation was uneventful. Sensing of QRS was tested at three possible scenarios: spontaneous AV-conduction, fusion pacing, and total ventricular capture. The S-ICD detected all rhythms as normal and no T top oversensing occurred even at higher paced rates. Ventricular fibrillation induction testing was performed with nominal settings of the pacemaker system and with the pacemaker set at DOO mode with high output pacing. Sensing of ventricular fibrillation was successful in both situations and 65J shocks successfully terminated ventricular fibrillation. During 2 year follow up no inadequate ICD shocks occurred. 2 episodes of symptomatic atrial flutter with fast ventricular conduction also did not lead to inadequate shock therapy and were terminated with elective electrocardioversion. Conclusions: 1. The subcutaneous only ICD is an additional therapy option for patients at risk for life-threatening ventricular arrhythmias and limited venous access. 2. This therapy can be used on top of an existing permanent pacemaker with adequate sensing of normal rhythm, fusion beats or full ventricular capture as well as adequate detection and termination of ventricular fibrillation.

Pammer M, Zado ES, Garcia FC, Calkins H. **Subcutaneous defibrillator: Benefits, arrhythmia detection and common pitfalls [abstract].** *Heart Rhythm.* 2012; 9 (5, SUPPL. 1): S366. *33rd Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2012.* Introduction: The subcutaneous implantable defibrillator (S-ICD) is a new device comprised of totally subcutaneous pulse generator and lead system to treat ventricular arrhythmias. Methods: N/A Results: 23 year old male competitive athlete with a strong family history of sudden cardiac death (SCD) and cardiomyopathy. The patient (pt), while asymptomatic, has an LVEF of 35% and the same abnormal ECG pattern as his brother who survived SCD. Given the strong family history and low EF, an ICD was recommended. The S-ICD was chosen because of the known increased incidence of lead problems in young patients with traditional transvenous ICDs. Additionally transvenous leads are difficult to extract because they can adhere to the veins or cardiac structures, another consequence that is avoided with the use of the S-ICD. A month after implant, the patient received 2 ICD shocks. Device interrogation revealed a wide complex tachycardia which narrowed without changing cycle length (CL 240 ms) failing first shock followed by a second successful therapy. (Figure 1) Subsequent EPS excluded AVNRT, AVRT, and VT with aggressive stimulation. Spontaneously occurring non sustained atrial tachycardia with aberrant conduction was seen and matched the intracardiac electrogram. He was treated with Sotalol and ICD detection was increased to 250 bpm. He has had no further shocks. Conclusions: Inappropriate ICD shocks are common problem with traditional ICDs and may

occur with S-ICDs. Treatment is directed towards the primary rhythm abnormality and thoughtful device reprogramming. Figure 1 (Figure presented).

Siebermair J, Beckmann BM, Wakili R, Martens E, Oversohl N, Schussler F, Estner H, Kaab S. **The entirely subcutaneous implantable cardioverter-defibrillator (S-ICD)-an alternative to conventional ICDs in inherited arrhythmia syndromes [abstract].** *J Interv Card Electrophysiol.* 2012; 33 (3): 285-6. 8th Annual Congress of the European Cardiac Arrhythmia Society, ECAS 2012. Introduction: The use of implantable cardioverter-defibrillators (ICDs) is an established therapy for the prevention of death from ventricular tachyarrhythmia. An entirely subcutaneous ICD was recently developed to avoid complications associated with transvenous leads. Due to the impossibility of antibradycardic pacing (except 8-sec post-shock pacing) and antitachycardic overdrive pacing (ATP), these devices seem to be an alternative for patients with inherited arrhythmia syndromes like idiopathic ventricular fibrillation [iVF], Brugada syndrome [BrS] and long QT syndrome (LQTS), respectively. We examined the follow-up (FU) of such patient, collective with conventional ICD in special regard to bradycardic or tachycardic arrhythmias in the long-term FU which would have required modification of an subcutaneous implantable cardioverter-defibrillator (S-ICD) system. Methods and results: We examined the FU of 51 consecutive patients having undergone conventional ICD implantation between 1989 and 2011 (55% men, 41.6+/-17.6 years) with one of the mentioned diagnoses (n=30 iVF, n=15 LQTS, n=6 BrS). A structural heart disease had been previously excluded, the LVEF was preserved in all patients (66.4+/-8.5%). Before device implantation, an indication for antibradycardic pacing had been excluded by an electrophysiologic study (EPS) in 36/51 patients (71%) and in 51/51 patients. (100%) by Holter-ECG, respectively. During the long-term FU of 11.3+/-8.4 years, no patient developed signs of bradycardia as defined by AVB II(de g)-III(deg), SSS or chronotropic incompetence requiring antibradycardic pacing. During the FU, 26/51 patients. (51%) received appropriate therapies (shock and/or ATP), thereof 13/51 patients. (26%) exclusively appropriate shocks (cumulative 69 shocks, 5.3 per patient). 9/51 patients. (18%) suffered ventricular tachycardia (VT) episodes which were terminated by ATP (98 ATPs, 10.9 per patient, mean CL 328+/-35 ms). Inducible non-sustained VTs did not predict the occurrence of ventricular tachycardia accessible to ATP. 19/51 patients. (38%) suffered inappropriate ICD interventions (18 ATPs, 70 shocks, 4.6 therapies per patient). Conclusion: Data from our long-term analysis suggest that Holter-ECG and EPS in patients with VT/VF due to inherited arrhythmia syndromes are able to preclude the occurrence of bradycardic episodes. The high amount of VTs successfully treated with ATP may indicate the limitation of the S-ICD in this collective. Further prospective investigation must examine the need for antitachycardic pacing as well as the advantages and disadvantages, respectively, of the S-ICD in this patient collective.

Thijssen J, De Bie MK, Van Rees JB, Van Der Velde ET, Schalij MJ, Van Erven L. **The subcutaneous implantable cardioverter defibrillator: What proportion of the current device patient population is eligible for such a device? [abstract].** *Heart Rhythm.* 2012; 9 (5 SUPPL. 1): S14-S5. 33rd Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2012 CONFERENCE LOCATION Boston, MA, United States CONFERENCE DATE 2012-05-09 to 2012-05-12 CONFERENCE EDITORS Calkins H. Introduction: Currently, Implantable Cardioverter Defibrillators (ICDs) rely on transvenously implanted leads for cardiac sensing, pacing, and defibrillation. Recently, an ICD with a subcutaneous lead (S-ICD) was developed which may be easier to implant and has fewer device related-complications. Since the S-ICD is incapable of cardiac pacing, it is of interest what proportion of ICD recipients is eligible (i.e. pacing independent) for a S-ICD. Methods: The study cohort consisted of all patients who received a single or dual-chamber ICD in our center between 1996 and 2011. Patients were defined eligible for a S-ICD if they did not reach one of the following end points during follow-up: 1) an atrial and/or right ventricular pacing indication, 2) successful antitachycardia pacing without a subsequent shock, 3) an upgrade to a CRT-D device. Results: 1,971 patients were included in the analysis. During a median follow-up of 47 months, 863 (44%) patients reached an end point. The cumulative incidence of ICD recipients, eligible for an initial S-ICD implantation was 52% (95% CI 49%-55%) after 5 years. Important predictors for the non-eligibility of a S-ICD were: older age, secondary prevention, congenital heart disease, severe heart failure, atrial fibrillation, and a wide QRS. Conclusions: After 5 years of follow-up, more than half of the patients would have been eligible for S-ICD implantation. Several baseline clinical characteristics demonstrated to be useful in the selection of patients eligible for S-ICD implantation. (Figure presented).

Winter J, In Shin D, Siekiera M, Donner B, O'Connor S, Kelm M, Lichtenberg A. **First experiences in children and young adults with a totally subcutaneous implantable cardioverter defibrillator system [abstract].** *Circulation.* 2012; 126 (21): American Heart Association 2012 Scientific Sessions and Resuscitation Science Symposium Los Angeles, CA, United States 2012-11-03 to 2012-11-06. Objectives The risk of transvenous lead failure in young patients remains a major complication, including inappropriate shocks and system failure. We report our experiences with a totally subcutaneous implantable cardioverter defibrillator, S-ICD (Cameron Health, San Clemente, USA). Methods We implanted the S-ICD system in 14 pts with mean +/- standard deviation (SD)

aged of 25 +/- 7.2 years, (range 13 - 35 years), between August 2010 and June 2012. Indications for implantation were ion channelopathies, congenital heart disease, dilated cardiomyopathy and idiopathic ventricular fibrillation in 5, 4, 3 and 2 pts respectively. Mean +/- SD left ventricular ejection fraction was 41 +/- 16%, (range 10-55%). Implantation was for primary prevention in 8 pts and for secondary in 6 pts. All pts were implanted with an S-ICD system sub-muscularly between the anterior and posterior axillary lines via a left sub-mammary incision, under general anaesthesia. The electrode was tunneled subcutaneously from the generator pocket to the xyphoid and then left parasternally towards the manubrial sternal junction. Results 13 of 14 pts were tested intra-operatively and sustained ventricular fibrillation was converted to sinus rhythm with a 65 Joule standard polarity shock. 1 pt was not tested due to thrombus within the heart. There were no procedure related complications. Mean +/- SD follow-up of 313 +/-222 days (range 1-640 days) demonstrated 2 pts with shock therapy. A 13 year old male, Brugada Syndrome, received an inappropriate shock due to T wave over sensing on exercise. This was investigated with an exercise test and the secondary vector, tip to generator, was the only vector of the 3 available which demonstrated the over sensing. The primary vector, ring to generator, was programmed and the boy has been free of further therapy for 10 months. A 17 year old female with Long QT syndrome received 2 appropriate shocks which successfully terminated episodes of torsades-de-pointes within 2 months of implantation. Conclusion The implantation of the S-ICD is safe and feasible in children and young adults. It represents an alternative in pts, who are otherwise at the risk of on-going transvenous lead complications and extractions.

Abkenari LD, Nordkamp LO, Boersma L, Knops RE, Theuns D, Wilde AA, Jordaens L. **The subcutaneous defibrillator: The Dutch experience [abstract].** *Heart Rhythm.* 2011; 8 (5 SUPPL. 1): S2. 32nd Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm CONFERENCE LOCATION San Francisco, CA, United States CONFERENCE DATE 2011-05-04 to 2011-05-07 CONFERENCE EDITORS Gillis A.M. Introduction: Conventional implantable cardiac defibrillators (ICD's) reduce mortality in primary and secondary prevention, but are associated with substantial short- and long-term morbidity. We report the initial clinical experience of three hospitals in the Netherlands with a new subcutaneous ICD system. Methods: ICD's were implanted according to the ACC/AHA/ ESC guidelines. The first 17 patients (18%) were part of the reported CE trial; the remaining 82% were post CE mark. Implantation was without fluoroscopy and the device was entirely subcutaneous. Defibrillation efficacy was tested after implantation using 65 J shocks. Results: A total of 98 patients (78 males, 20 females) with a mean age of 56 years received the S-ICD system. A primary prevention indication was present in 62 patients (63%). Ischemic cardiomyopathy was diagnosed in 40 patients (41%). Other causes of cardiac disease included non ischemic dilated cardiomyopathy (14%), Brugada syndrome (7%), and idiopathic ventricular fibrillation (28%). Three patients had a history of explanted transvenous systems. Sensitivity for induced ventricular fibrillation (VF) and conversion efficacy were 100%. The median follow-up was 9 months (range 1 to 21months). Thirty-four spontaneous ventricular arrhythmias (sustained and non-sustained) were accurately detected in 6 patients. A total of 23 arrhythmic episodes were effectively treated in 3 patients. Inappropriate therapy occurred in 8 (early) patients due to oversensing. A software upgrade improving the detection algorithm, prevented recurrences of inappropriate therapy to date in all cases. Lead migration was observed in 3 early patients, with no recurrence since the use of an additional suture sleeve at the xiphoid incision. The number of adverse events declined after adjusting implant technique and reprogramming the T-wave sensing algorithm. One patient died from an aggressive lung carcinoma. Conclusions: We report the largest cohort to date, with a median follow-up of 9 months, of 98 patients who received the S-ICD system. All episodes of VF were accurately detected, and successfully converted. No sudden death occurred. In our experience, the S-ICD system is a viable alternative to conventional ICD systems for selected patients.

Abkenari LD, Olde Nordkamp L, Boersma L, Knops RE, Theuns DAMJ, Wilde AA, Jordaens L. **Initial clinical experience with a novel subcutaneous implantable defibrillator system in three Dutch centers [abstract].** *Europace.* 2011; 13 (3): EHRA Europace 2011 CONFERENCE LOCATION Madrid, Spain CONFERENCE DATE 2011-06-26 to 2011-06-29. Purpose: Implantable cardioverter-defibrillators (ICDs) have become standard therapy to prevent sudden cardiac death but have recently been associated with serious short and long term morbidity. A totally subcutaneous ICD (S-ICD) system has been developed to address some of these concerns. We report the initial clinical experience with a new subcutaneous ICD system in three hospitals in the Netherlands. Methods: ICDs were implanted according to the ACC/AHA/ESC guidelines. The first 17 patients (18%) were reported in the CE trial; the remaining 82% were post CE mark. Implantation was without fluoroscopy and the device was entirely subcutaneous. Defibrillation efficacy was tested after implantation using 65 J shocks. Results: The S-ICD was implanted in a total of 98 patients (78 males, 20 females) with a mean age of 56 years. A primary prevention indication was present in 62 patients (63%). Ischemic cardiomyopathy was diagnosed in 40 patients (41%). Other causes of cardiac disease included non ischemic dilated cardiomyopathy (14%), Brugada syndrome (7%), and idiopathic ventricular fibrillation (28%). Three patients had a history of explanted transvenous systems. Sensitivity for induced ventricular fibrillation (VF) and conversion efficacy were 100%. The median follow-up was 9 months

(range 1 to 21 months). Thirty-four spontaneous ventricular arrhythmias (sustained and non-sustained) were accurately detected in 6 patients. A total of 23 arrhythmic episodes were effectively treated in 3 patients. Inappropriate therapy occurred in 8 patients due to oversensing. A software upgrade, added just prior to CE mark, improving the detection algorithm has prevented recurrences of inappropriate therapy in all cases, to date. Lead migration was observed in 3 of the first implanted patients, with no recurrence since the use of an additional suture sleeve at the xiphoid incision. The number of adverse events declined after adjusting implant technique and reprogramming the T-wave sensing algorithm. One patient died from an aggressive lung carcinoma. Conclusion: We report the largest cohort to date of 98 patients who received the S-ICD system. The median follow-up was 9 months. The S-ICD system can be implanted without the use of fluoroscopy by using anatomical landmarks only. All episodes of VF were accurately detected and successfully converted.

Choo JTL, Chen CK, Tan TH, Ong KK, Kam R. **Successful use of the subcutaneous lead for ICD implant in a small child with congenital long QT syndrome [abstract].** *Europace*. 2011; 13 SUPPL. 1: i65. *CardioRhythm 2011 CONFERENCE LOCATION Hong Kong, Hong Kong CONFERENCE DATE 2011-02-25 to 2011-02-27.*
Background: ICD implantation in small children is hampered by their small venous capacity and chest surface area. We describe the implantation of an ICD system with a subcutaneous defibrillator lead, epicardial dual-chamber pacing leads, pulse generator in the active can configuration in the abdomen for a child with congenital long QT syndrome. Method: A 6-year-old child, weighing 18 kg, was put under general anaesthesia and put in the right lateral position. The Medtronic Subcutaneous Lead Model 6996SQ (SQL) was inserted through an incision inferior to the left nipple and tunnelled subcutaneously along the 6th intercostal space along the anterolateral chest posteriorly till the edge of the spine, using finger palpation and fluoroscopic guidance. Two bipolar epicardial pacing leads were implanted in the right atrium and right ventricle through a limited median sternotomy. A pocket was created in the left upper abdomen beneath the rectus muscle. The pacing leads and the SQL were tunnelled to the pocket and connected to a pulse generator (Medtronic Maximo DR) placed within the pocket. Results: Pacing thresholds for the atrium and ventricle were 0.3V and 1 V at 0.5 ms, respectively. Atrial and ventricular lead impedances were 640 and 917 ohms, respectively. Defibrillation testing was performed and ventricular fibrillation (VF) was induced twice and successfully defibrillated with 20 and 15 J, respectively. The device was set at AAIR mode, 80 bpm, with managed ventricular pacing (MVP) mode on. Post-implant, the patient developed a pericardial effusion on the 10th postoperative day requiring surgical drainage. The patient is currently 3 months post-ICD implantation. She has been free of any VT/VF episodes. Conclusion: For small children, in whom space is a limitation, the SQL with an active can is an option for those who need ICD therapy.

Eckardt L, Shin DI, Aydin M, Juchem G, Kaab S, Butter C, Kobe J, Willems S, Winter J, Gillis AM. **Initial clinical experience with an entirely subcutaneous implantable cardioverter-defibrillator [abstract].** *Heart Rhythm*. 2011; 8 (5, SUPPL. 1): S12. *32nd Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm.*
Introduction: Whilst lead failure, thrombosis and/or infection remain a major limitation in the use of ICDs, a fully subcutaneous ICD system (S-ICD, Cameron Health, Inc., USA) has been designed. The S-ICD uses subcutaneous rather than intracardiac ECG for discriminating normal rhythms from VT/VF. In this report, we describe the initial experience with the S-ICD in Germany. Methods and Results: Between June 1st and beginning of December 2010, 35 pts (27 (82%) male, mean age 47+/-18 yrs) received a S-ICD in 6 centers in Germany through a left inframammary incision. The electrode was tunnelled subcutaneously from the device pocket to the xyphoid and then 1-2 cm left parasternally towards the sternal-manubrium junction. This was the first ICD implantation in 26 (74%) pts. Indications were both primary (n=18; 51% pts) and secondary prophylaxis (n=17; 49% pts) in 25 (71%) pts with structural heart disease and ion-channelopathies (n=10 (29%)). S-ICD was implanted in the presence of endocarditis and explantation of a previously implanted conventional ICD system in 3 (9%) pts. The mean duration of the procedure including testing was 76+/-32 min. 33 of the 35 pts who received a permanent s-ICD were tested intraoperatively. VF was successfully detected in 100% of 50 induced episodes during electrophysiological testing. Induced VF was converted to sinus rhythm with the first delivery of a 65-J shock in 23 (70%) of the 33 tested pts. Change in device position in 2 (6%) pts and changing polarity in 4 (12%) pts terminated VF in all but one of the 33 pts. Our S-ICD experience has a mean of 61 +/- 47 days and 67 cumulative months of follow up, during which time the device had successfully detected and treated 3 episodes of spontaneous, sustained VT/VF. All pts are alive except one who died of severe heart failure. A single clinically significant adverse event occurred which was a large pocket hematoma requiring re-intervention. Conclusions: The novel S-ICD system designed to avoid electrodes on or in the heart could, in our small experience, be safely implanted and was seen to consistently detect and convert VT/VF both induced during EP testing and spontaneously. It will further simplify defibrillator therapy in patients who do not require pacing and are likely not to require ATP therapy.

Fedorco M. **Subcutaneous defibrillator - Case report [abstract].** *J Cardiovasc Electrophysiol*. 2011; 22 SUPPL. 1: S150. *Venice Arrhythmias 2011 CONFERENCE LOCATION Venice, Italy CONFERENCE DATE 2011-10-09 to*

2011-10-12. Introduction: A complete subcutaneous defibrillator implantation is a new option to secure risk patients in primary and secondary sudden cardiac death prevention (SCD). A contemporary standard is a transvenous defibrillation electrode implantation with a subsequent prepectoral or subpectoral device implantation. The number of complications increases with an increase of transvenous electrode implantations. A frequent complication of transvenous implantation or extraction of defibrillator electrodes is subclavian vein thrombosis preventing repeated electrode implantation. One option in the absence of venous access is a subcutaneous defibrillator (S-ICD) implantation. Methods used: The authors of the case-report present a case of a young patient with repeated implantations and extractions due to infectious complications. The patient developed a complete bilateral occlusion of subclavian veins as a consequence. She refused to undergo cardiosurgical device implantation, thus we decided to implant S-ICD. Implantation was without complications. The device works properly. Conclusions: Our first experience shows feasibility and safety of S-ICD implantation in primary and secondary SCD prevention. S-ICD will possibly remain as an alternative in cases without a possibility of classic transvenous ICD implantation.

Jarman JWE, Clague JR, Till J, Gillis AM. **Totally subcutaneous ICD implantation in children and young adults [abstract]. *Heart Rhythm*. 2011; 8 (5, SUPPL. 1): S13. Abstract AB06-4. 32nd Annual Scientific Sessions of the Heart Rhythm Society, *Heart Rhythm*.** Introduction: Implantable cardioverter-defibrillators (ICDs) have become established as a first-line therapy for children and young adults at high risk of sudden arrhythmic death (SAD). However transvenous and epicardial systems are associated with significant complications in this population, particularly related to lead integrity and the difficulty of maintaining long-term vascular access. A new totally subcutaneous ICD (S-ICD) has been developed and shown to be effective in adults. Its use in children has the potential to ameliorate the problems of long-term lead integrity in this difficult population. Methods: Eight children and young adults at risk of SAD underwent implantation of S-ICDs (median age 15 years (range 10 to 21 years), median weight 51 kg (range 32 to 77 kg)). Three had catecholaminergic polymorphic ventricular tachycardia, two long QT syndrome, one idiopathic primary electrical disease, and two congenital heart disease. Results: S-ICDs were successfully implanted in all patients. An axillary generator position superior to the incision was found to be preferable to the manufacturer's recommended position inferior to the incision due to greater tissue thickness, protection and comfort. VF induction resulted in successful sensing and termination with a single 65 joule shock in all cases. There were no peri-operative complications. During a median follow-up of 5 months (range 1 to 11 months) two children required re-operation (one threatened erosion in a 70 kg 16 year old boy, one following a cycling accident impacting the incision site) - both had inferiorly positioned generators which were then re-positioned to a superior position in the axilla. One child experienced three appropriate shocks for polymorphic VT and one child suffered one inappropriate shock due to T wave over-sensing during frequent ventricular ectopy. Conclusions: The S-ICD is an important new option for treating some children and young adults at risk of SAD, particularly those with difficult vascular access. More experience is required to determine ideal generator positioning and the accuracy of its arrhythmia discrimination in children. An axillary position superior to the incision was preferable in our experience.

Knops RE, Wilde AA. **A new implantation technique for the electrode of the fully subcutaneous internal cardioverter defibrillator (s-icd): the sheath facilitated technique [abstract]. *Europace*. 2011; 13 (3): EHRA *Europace* 2011 CONFERENCE LOCATION Madrid, Spain CONFERENCE DATE 2011-06-26 to 2011-06-29.** Introduction: The S-ICD system is designed to avoid the need for the placement of sensing and therapy electrodes within or on the heart. The electrode of the S-ICD is implanted by making three incisions, one lateral pocket incision and two parasternal incisions; the electrode is then tunnelled through these incisions to a parasternal position. The electrode is fixated with a suture through the distal fixation point and a suture-sleeve at the proximal parasternal incision. In our experience these parasternal incisions are a possible risk for infection and a potential source of discomfort. We present a new technique of implanting the S-ICD electrode avoiding the distal incision and suture. Methods: In our new approach we tunnel the electrode, conform the current technique, with the tunnelling tool from the lateral pocket to the proximal parasternal incision. We now place an 11 F peel away sheath, for transvenous lead placement, over the tunnelling tool and tunnel this sheath subcutaneously to a distal parasternal position. The electrode is then placed through the sheath to this position. No proximal suture is used. After manually confirming correct placement the sheath is peeled away. It is important to firmly fixate the lead with the suture sleeve in the distal parasternal incision to avoid lead displacement. Results: Five patients were implanted without complications with this new technique. In all cases the two-month post procedure chest x-ray showed a correct position of the electrode (figure1). Conclusion: We introduce a new, sheath facilitated, implant technique for the electrode of the S-ICD, which in five cases successfully avoided a distal parasternal tunneling incision.

Mazzotti A, Diemberger I, Pegreff F, Foschi E, Belli G, Martignani C, Biffi M, Gardini B, Massaro G, Ziacchi M, Porcellini G, Tentoni C, Branzi A, Boriani G. **Prospective assessment of the effects of subcutaneous implantation of**

cardioverter-defibrillator on shoulder function [abstract]. *G Ital Cardiol.* 2011; 12 (12, SUPPL. 3): e186. 72 *Congresso Nazionale Della Societa Italiana di Cardiologia.* Background. Subcutaneous implantation of cardioverter-defibrillator (ICD) almost substituted subpectoral approach as a less invasive surgical technique. However, the impact of this change in placement site on procedure-related shoulder impairment is poorly understood. Methods. Candidates for ICD implantation were prospectively evaluated at baseline, 2-weeks and 3-months after the procedure. Assessment of shoulder function included: Constant Score, Numeric Rating Scale (NRS) for pain and the Disability of the Arm, Shoulder and Hand (DASH) scoring method. The short format-36 (SF-36) questionnaire was adopted for quality of life. Results. Fifty consecutive patients were enrolled (21 single-chamber, 5 dual-chamber and 24 biventricular ICD). Significant changes were observed in the short term: Physical Component Summary (regarding SF- 36) decreased from 44.5+/-9.1 to 41.8+/-11.4 ($p=0.016$), patients with NRS >1 increased from 14% to 44% ($p<0.001$), DASH score increased from 1.29 [interquartile range 0.00-10.34] to 30.60 [interquartile range 12.93-46.34] ($p<0.001$). Notably, only the shoulder ipsilateral to implantation site presented a decrease in Constant score (76.00 [interquartile range 61.37- 86.87] vs. 95.75 [interquartile range 91.37-98.00]; $p<0.001$). After three months most of the parameters seemed to have recovered, except for range of motion. Procedure-related increase in pain (i.e. NRS increase ≥ 1 point) was the most important independent predictor of shoulder impairment, in terms of Constant score modification ($r=0.570$; $p<0.001$). Conclusions. ICD implantation is frequently associated with ipsilateral shoulder impairment which tends to recover within 3-months. These data positively compare with the subpectoral approach and should be considered for future research regarding impact of ICD implant on physical wellbeing and quality of life.

McLeod K, Connelly D, McLean A. **Implantation of a totally subcutaneous ICD in children [abstract]. *Heart Lung and Circulation.* 2011; 20 SUPPL. 2: S96. *Cardiac Society of Australia and New Zealand Annual Scientific Meeting and the International Society for Heart Research Australasian Section Annual Scientific Meeting 2011 CONFERENCE LOCATION Perth, WA, Australia CONFERENCE DATE 2011-08-11 to 2011-08-14.* The Cameron Health subcutaneous implantable cardioverter defibrillator (S-ICD) does not require a lead to be in contact with the heart. We describe the use of the SQ-ICD in seven patients under the age of 18 years. (Table Presented). Implantation was carried out under general anaesthetic by a cardiac surgeon. A subcutaneous pocket was made at the level of the fifth intercostal space medial to the midaxillary line. The distal tip of the lead was tunnelled from the pocket to an incision made at the lower left sternum. In the first six patients, the remaining distal tip was tunnelled to an incision made at the upper left sternum but in the seventh patient no upper sternal wound was made. On testing, the S-ICD detected and cardioverted VF appropriately in all patients. Time to therapy ranged from 12 to 22 seconds. All, except patient 7, were discharged home on a beta-blocker. On follow up of 1-16 months there have been no inappropriate shocks. Patient 1 developed VF following anaesthesia for an orthopaedic procedure and the S-ICD delivered a successful shock. Patient 6 required a course of antibiotics for infection in the upper sternal wound. Conclusion: The ICD eliminates many of the problems associated with endocardial leads. The S-ICD can be safely implanted in patients under age 18 years with good early follow-up. The S-ICD is our ICD of choice for patients >30 kg, where there is no indication for brady or antitachycardia pacing.**

Mohammed AA, Bhat PK, Unsorfer K, Costantini O. **Single versus dual chamber implantable cardioverter defibrillators: Are single chamber devices really obsolete? [abstract]. *J Am Coll Cardiol.* 2011; 57 (14, SUPPL. 1): E15. *60th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC. 11.* Background: National registry data shows the majority of implanted cardioverter defibrillators (ICD) are dual chamber devices (D-ICD). While D-ICDs are indicated in patients with concomitant pacing indications, whether to implant D-ICDs for the sole purpose of avoiding inappropriate shocks or a future upgrade procedure is equivocal. Given that D-ICDs may cause deleterious ventricular pacing, and given the problems with lead recalls, we hypothesized that in patients receiving an ICD, without a pacing indication, implanting single chamber defibrillator (S-ICD) will not result in frequent device upgrades and the clinical outcomes will be comparable to D-ICDs. Methods: We conducted a retrospective chart review of patients with ICDs implanted from January 1996 to January 2009 with ≥ 18 months of follow-up. Demographic, clinical, ECG and echocardiographic data were compared between patients with S-ICDs and D-ICDs. Patients were followed until their last office visit. Patients who had an upgrade were censored at that point. Results: Of the 924 patients with an ICD implant, 556 patients met inclusion criteria. 338/556 patients (61%) had S-ICDs. The mean duration of follow-up was 5 years in both groups. Patients with S-ICDs were younger (58 vs. 63 yrs; $p<0.001$), had faster heart rate at implant, (77 vs. 62 bpm; $p=0.01$) and had a shorter QRS duration (110 vs. 126 ms; $p<0.001$). Although the mean ejection fraction (EF) was identical at baseline (0.30 in both groups), on last follow-up, S-ICD patients had a significant improvement in EF compared to D-ICD patients (0.37 vs. 0.31; $P<0.001$). Only 37/338 (10%) patients needed an upgrade, 10 (3%) to a biventricular ICD. Importantly, hospitalization for heart failure were higher in patients with D-ICDs (36% vs. 24%, $p<0.001$), while inappropriate therapy was identical in both groups (17% in S-ICDs vs. 18% in D-ICDs $p=NS$). Conclusions: The majority of patients implanted with S-ICDs do**

not require an upgrade to a D-ICD and have similar rates of inappropriate therapy compared to patients with D-ICDs at a mean follow-up of 5 years. Since D-ICDs may lead to higher rate of hospitalizations for heart failure, S-ICD should be the device of choice in patients without pacing indications.

- Pedi C, Greco E, Bonadonna G, Cusumano S, Fossi C, Chiaranda G. **The subcutaneous implantable defibrillator. a new frontier in arrhythmias. description of a clinical case [abstract].** *J Cardiovasc Electrophysiol.* 2011; 22 SUPPL. 1: S158. *Venice Arrhythmias 2011 CONFERENCE LOCATION Venice, Italy CONFERENCE DATE 2011-10-09 to 2011-10-12.* Introduction: The totally subcutaneous ICD (S-ICD) is a new defibrillation device that avoids some of the possible complications related to traditional transvenous systems. We describe a clinical case of a patient who has received the S-ICD system. We examined a case of a 70-year-old man with dilated cardiomyopathy and severe systolic dysfunction (EF 30%) who has developed infection following a traditional ICD replacement. We chose the S-ICD system to take into account the bacterial endocarditis (later resolved). In addition, the patient did not require antibradycardia pacing. Methods used: The device and electrode are implanted subcutaneously in the left thoracic region. The defibrillation coil is positioned parallel to the sternal midline. During the implant, an automatic procedure driven by a programmer of the system, optimizes the sense electrode configuration. The S-ICD system has been programmed with a shock zone (230 Bpm) and a conditional shock zone (190- 230 Bpm). Results: The implant procedure has been performed without complications (duration of the procedure approximately 90 min). Conclusions: The S-ICD may represent an alternative to traditional ICD in specific patients. In our case it was necessary for severe endocarditis.
- Santos P, Cavaco D, Adragao P, Morgado F, Reis Santos K, Carmo P, Costa F, Mendes M. **Subcutaneous ICD - Initial experience [abstract].** *Eur Heart J.* 2011; 32 SUPPL. 1: 923. *European Society of Cardiology, ESC Congress 2011 CONFERENCE LOCATION Paris, France CONFERENCE DATE 2011-08-27 to 2011-08-31.* Introduction: Most of the complications of ICDs are related to lead dysfunction or vascular access problems. These can be amplified in very young patients due to a very long expected follow-up time. There is the hope that a recently released entirely subcutaneous CDI (SC-ICD) can avoid some of these problems. Population and methods: From 298 ICD implanted in 2010 in our center, in 7 there was an intention to implant a SC-ICD. The indications for implantation were: vascular access problems hindering the placement of conventional ICD (2 patients with chronic renal failure on hemodialysis - secondary prevention; 1 patient - fracture of ICD transvenous lead - primary prevention in hypertrophic cardiomyopathy) and in four young patients, due to a very long expected followup (2 patients with syncope and diagnosis of noncompaction and the other 2 patients with Brugada syndrome). We evaluated the occurrence of complications (implant related or not) and of device therapies. Results: It was possible to implant the device in 6 patients, with an average time of procedure of 80 minutes. One of the patients failed the initial screening (inadequate QRS/T amplitude and duration, in the 3 possible vectors tested). The implant was uneventful. Defibrillation test was performed in all. In one the generator was repositioned to have an acceptable defibrillation threshold. At a mean follow up of 3.5 months, one of the patients had an inappropriate shock (due to T wave oversensing). The problem was corrected with vector sensing reprogramming. Conclusion: The SC-ICD implant can be performed by cardiologists, with high success rate and implant times comparable to those of conventional CDI. The initial experience appears favourable, but further studies are needed with longer follow up periods to evaluate the safety and efficacy of this strategy compared to conventional.
- Scipione P, Luzi M, Bedendi N, Andraghetti A, Capucci A. **Case report: Subcutaneous implantable cardioverter-defibrillator system S-ICD [abstract].** *J Cardiovasc Electrophysiol.* 2011; 22 (, SUPPL. 1): S150. *Venice Arrhythmias 2011.* Introduction: 40 years old female with syncope episode during emotional stress. Sustained ventricular tachycardia at 220 bpm recorded, treated by DC shock. Regular blood tests. No drugs taken by the patient. Methods used: cardiac surgery intervention for Alpacas Syndrome (anomalous origin of left coronary artery from truncus of pulmonary artery). Results: coronary TAC = no signs of lesions on coronary arteries; Ergometric test = negative for reduced coronary reserve; EP study = no arrhythmia induction. Conclusions: S ubcutaneous S-ICD implant as secondary prevention. A left lateral incision was made over the 6 SUP th rib in the anterior axillary line for pocket creation and pulse generator placement. The subcutaneous electrode was placed subcutaneously, parallel to the sternal midline and 2 cm left lateral of the xiphoid midline, and finally connected to the generator. The insertion of the system was guided only by anatomical landmarks and no fluoroscopy was required. Ventricular fibrillation was induced and terminated by a 65-J shock (15-J safety margin). No complication occurred and subsequent course was uneventful.
- Theuns DA, Gold MR, Sanghera R, Burke MC, Bardy GH, Gillis AM. **Detection time of polymorphic ventricular tachyarrhythmias by a totally subcutaneous S-ICD(R) system: Comparison of cutaneous electrode signals with subcutaneous electrode signals [abstract].** *Heart Rhythm.* 2011; 8 (5, SUPPL. 1): S12. Abstract AB06-2. *32nd Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm.* Introduction: The development of a totally subcutaneous implantable defibrillator (S-ICD) system required a new approach for

arrhythmia detection using subcutaneous (SQ) signals. The system is designed to reduce the delivery of unnecessary therapy for ventricular arrhythmias with a propensity for spontaneous termination. The objective of this study was to compare the detection times of the S-ICD system measured from cutaneous recordings of polymorphic ventricular arrhythmias with detection times calculated from implanted systems. Methods: Induced ventricular arrhythmias in the electrophysiology laboratory were recorded using SQ equivalent cutaneous electrode configurations (Primary, Secondary and Alternate vectors). The recorded ventricular arrhythmias with rates > 170 bpm (n=45) were used to assess detection by the S-ICD OFF line. Separately, we evaluated the episodes of induced ventricular fibrillation (n=121) of patients in a trial of permanent S-ICD implantation. Testing in these patients was done with the use of 65-J shocks and the device programmed in single-zone (rate > 170 bpm). Results: Of 121 episodes of induced ventricular fibrillation, 100% were detected by the S-ICD system. The mean time to delivery of a 65-J shock was 14.1 +/- 2.4 seconds. Charge time to 65-J is 7.0 seconds; the mean detection time was 7.1 +/- 2.4 seconds. Of the 45 ventricular episodes for simulation, 100% were detected by the S-ICD system; mean detection time of 7.2 +/- 2.7 sec. The mean detection time was not significantly different between simulated and clinical episodes. Detailed analysis of simulated episodes demonstrated an initial artifactual delay in arrhythmia detection after arrhythmia onset. This delay had a mean duration of 2.9 +/- 2.4 seconds. After adjustment for the artifactual delay, the true mean detection time was 4.4 +/- 0.4 seconds. Conclusions: The S-ICD system successfully detected induced ventricular fibrillation, whether from implanted electrodes or cutaneous electrodes for simulation. Detection of polymorphic ventricular tachyarrhythmias by the S-ICD system requires a longer duration without adversely impacting sensitivity, which may reduce the likelihood of unnecessary therapy delivery for short duration ventricular tachyarrhythmias.

Theuns DAMJ, Gold MR, Burke MC, Bardy GH. **Detection time of ventricular fibrillation by a totally subcutaneous S-ICD system: Comparison of cutaneous electrode signals with subcutaneous electrode signals [abstract].** *Europace*. 2011; 13 (3): *EHRA Europace 2011 CONFERENCE LOCATION Madrid, Spain CONFERENCE DATE 2011-06-26 to 2011-06-29*. Introduction: The development of a totally subcutaneous implantable defibrillator (S-ICD) system required a new approach for arrhythmia detection using subcutaneous (SQ) signals. The system is designed to reduce the delivery of unnecessary therapy for ventricular rhythms with a propensity for spontaneous termination. The objective of this study was to compare the detection times of the S-ICD system measured from cutaneous recordings of ventricular fibrillation with detection times calculated from implanted systems. Methods: Induced ventricular fibrillation in the electrophysiology laboratory were recorded using SQ equivalent cutaneous electrode configurations (Primary, Secondary and Alternate vectors). The recorded ventricular arrhythmias with rates > 170 bpm (n=45) were used to assess detection by the S-ICD off line. Separately, we evaluated the episodes of induced ventricular fibrillation (n=121) of patients in a trial of permanent S-ICD implantation. Testing in these patients was done with the use of 65-J shocks and the device programmed in single-zone (rate > 170 bpm). Results: Of 121 episodes of induced ventricular fibrillation, 100% were detected by the S-ICD system. The mean time to delivery of a 65-J shock was 14.1 (plus or minus) 2.4 seconds. Charge time to 65-J is 7.0 seconds and the mean detection time was 7.1 (plus or minus) 2.4 seconds. Of the 45 ventricular episodes for simulation, 100% were detected by the S-ICD system with a mean detection time of 7.2 (plus or minus) 2.7 sec. Detection time was not significantly different between simulated and clinical episodes. Detailed analysis of cutaneous electrode episodes demonstrated an initial artifactual delay in arrhythmia detection after arrhythmia onset. This delay had a mean duration of 2.9 (plus or minus) 2.4 seconds. After adjustment for the artifactual delay, the true mean detection time was 4.4 (plus or minus) 0.4 seconds. Conclusion: The S-ICD system successfully detected induced ventricular fibrillation, whether from implanted electrodes or cutaneous signals. Detection of ventricular fibrillation by the S-ICD system requires a longer duration without adversely impacting sensitivity, which may reduce the likelihood of unnecessary therapy delivery for short duration ventricular tachyarrhythmias.

Baez-Escudero J, Hamilton A, Walcott G, Killingsworth CR, Burke MC, Lux R. **Are cutaneously derived electrocardiography signals reliable surrogates for subcutaneous sensing algorithm testing? [abstract].** *J Electrocardiol*. 2010; 43 (6): 645. *ISCE 2010 Symposium*. Introduction: A subcutaneous (SQ) defibrillator is a viable alternative to transvenous defibrillators in many patients. In efforts to develop a cutaneous (Q) database to verify and validate an SQ sensing algorithm, we compared the electrocardiography (ECG) characteristics of the SQ and Q signals simultaneously. Methods: Fifteen pigs underwent general anesthesia in the dorsal recumbent position. The SQ pocket for the can was made in the fourth to sixth intercostal space along the left midaxillary line. A small incision left lateral to the xiphoid was created; and using a tool, a multielectrode lead with coil was tunneled from the SQ pocket to this incision. Next, another small incision 8 to 10 cm superior to the xiphoid incision was made along the left sternum. The lead was then tunneled from the xiphoid incision along the parasternum superiorly. The lead body was sutured with a sleeve at the xiphoid position, and the distal tip was sutured to the underlying muscle at the superior parasternum. The lead was attached to the can in the midaxillary pocket, and all incisions were closed. Q conductive adhesive ECG electrodes were placed directly over 3 SQ

electrodes. The Q and SQ electrodes were then connected to a multichannel TEAC digital recording system. Three minutes of sinus rhythm data were obtained, and the QRS complexes were analyzed across 3 left chest bipolar vectors (1-3). Average QRS and T wave amplitude values were generated for each vector by analyzing 10 contiguous cardiac cycles. QRS:T ratios were calculated using the averaged values. Results: The mean QRS:T ratio directly correlated between the Q and SQ space when measured simultaneously in vectors 1 to 3 ($r = 0.674$, $r = 0.951$, and $r = 0.988$, respectively). The measured SQ QRS amplitudes strongly correlated with the Q signal in vectors 1 to 3 ($r = 0.92$, $r = 0.94$, and $r = 0.92$, respectively). There was no significant difference in measured QRS amplitude between Q and SQ signals in any vector. Conclusions: Surface QRS, T wave, and their ratio correlate with the SQ space directly underlying and across various left chest vectors. Cutaneous ECG signals are reliable surrogates for the SQ ECG in the same location and vectors.

Burke MC, Knight BP, Jordaens L, Ellenbogen K, Wood MA, Gold M, Lux R. **First arrhythmia collection of transvenous and simultaneous subcutaneous implantable defibrillator data (FACTS ICD) multicenter study [abstract].** *J Electrocardiol.* 2010; 43 (6): 645-6. *ISCE 2010 Symposium.* A total subcutaneous (SQ) implantable cardioverter defibrillator (ICD) will need to be as sensitive and specific at detecting and treating ventricular arrhythmias as a transvenous ICD. We induced a library of supraventricular and ventricular arrhythmias during ICD implantation that collected simultaneous electrogram data using intracardiac and left chest cutaneous electrodes representing surrogate SQ electrodes and vectors. Methods: A multicenter prospective study registered 143 patients, where 132 patients had usable data for inclusion into the library. Inclusion required a left chest dual-chamber ICD initial or replacement implant with dual-coil high-voltage electrodes. Integrated (INT) and dedicated (DED) bipolar ICD leads were used. Cable connections were attached to all electrodes including intravascular, muscular device pocket tissue, and cutaneous and then were connected to a TEAC digital recorder. At least 4 minutes of baseline rhythm was obtained. Bursts of electrocautery delivered to the pocket were recorded. Programmed stimulation via the atrial and ventricular leads was performed for induction. Induced rhythms were categorized as shockable or nonshockable. An episode inclusion heart rate was greater than 170 beats per minute for at least 20 seconds. Isuprel or atropine were used at the operator's discretion to obtain atrial rates in the target zone. Episodes were divided as RV lead INT, DED, or BOTH. Valid episodes were qualified as equivalent simultaneous SQ and transvenous data. Results: One hundred fourteen episodes in 76 patients met the rate inclusion for nonshockable rhythms, whereas 190 episodes in 110 patients met inclusion for shockable rhythms. Careful analysis found 81 valid nonshockable episodes and 104 valid shockable episodes. The nonshockable valid episodes were distributed as 37 (46%) INT, 3 (4%) DED, and 41 (50%) BOTH. The shockable valid episodes were distributed as 39 (38%) INT, 14 (13%) DED, and 51 (49%) BOTH. Nonshockable episode rates were concentrated between 165 and 190 beats per minute, whereas shockable episode rates were clustered in 3 rate patterns, 180, 240, and 300 beats per minute, with the major concentration at 300 beats per minute. Conclusions: A robust collection of valid shockable and nonshockable episodes were simultaneously and digitally collected from intracardiac and SQ surrogates in an effort to compare the sensitivity and specificity of all available ICD sensing vectors. The sensing algorithm comparative analysis will use the valid episodes of this library.

Killingsworth CR, Litovsky SH, Melnick SB, Vance FL, Ideker RE, Walcott GP, Wilkoff BL. **Shocks delivered via a subcutaneous defibrillation system cause less acute injury than transvenous leads in swine [abstract].** *Heart Rhythm.* 2010; 7 (5, SUPPL. 1): S186. Abstract PO2-47. *31st Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2010.* Introduction: A totally subcutaneous implantable cardioverter defibrillation system (SICD) may be easier to place and could reduce the complications of transvenous ICDs. Defibrillation from the SICD system requires more energy than transvenous ICDs. The goal of this study was to assess cardiac and chest wall damage caused by subcutaneous shocks compared with transvenous shocks. Methods: Anesthetized pigs (38±6 kg) received either a subcutaneous system (SICD, n = 4) and five 80-Joule (J) shocks, or a control transvenous ICD system (CTRL, n=4) and five 35-J shocks. An inactive SICD electrode was also implanted into CTRL pigs to study implant trauma. Post-shock ECG changes were determined. All animals were survived for 24 hours. Troponin I and creatinine kinase muscle isoenzyme (CK-MM) were measured at baseline, 4, and 24 hours as indicators of myocardial and skeletal muscle injury, respectively. Histopathologic injury of heart, lungs, and chest wall was assessed using semi-quantitative scoring. Results: Ectopy and ST segment changes occurred post-shock in CTRL but not in SICD pigs. Histopathology indicated that the myocardium and lungs were normal in both groups. Tissue injury surrounding the subcutaneous electrode was not significantly different between SICD (shocks) and CTRL (no shocks). Conclusions: Although CK-MM suggested more skeletal muscle injury, significant cardiac and chest wall histopathological changes were not detected following 80-J SICD shocks. Troponin I data indicate less cardiac injury from 80-J S-ICD shocks than 35-J transvenous shocks. (Table presented).

Knops RE, Van Dessel PF, Blom NA, Wilde AA, Wilkoff BL. **Paediatric use of the first fully subcutaneous implantable**

cardioverter defibrillator (S-ICD) in a 10 year old girl [abstract]. *Heart Rhythm.* 2010; 7 (5, SUPPL. 1): S48-S9. *31st Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2010.* Introduction: The S-ICD(r) system, including a totally subcutaneous implantable defibrillator and electrode, removes the complexity and long term complications associated with transvenous lead use, making the system potentially ideal for use in the pediatric population. We describe the successful use of the S-ICD system in a 10 year old girl referred to our institution for ICD implantation. Methods: N/A Results: The 10 year old patient was previously diagnosed with dilated cardiomyopathy, likely due to viral infection. Cardiac MRI revealed poor ventricular function with a calculated EF of 11%. There was extensive myocardial fibrosis consistent with that noted from viral myocarditis. The 24-hour holter showed frequent non-sustained VT. Despite a four month HF medication regimen, little improvement in clinical condition was noted; therefore, ICD implantation was deemed necessary. Due to the potential long-term benefits of the subcutaneous approach, we considered the patient for the S-ICD system. ECG screening and anatomical measurements were performed to confirm that the system, primarily developed for adult use, would fit in such a small girl (142cm, 34kg). Thorax geometry was deemed sufficient for electrode placement and the S-ICD system device was planned for left lateral thorax positioning with the long axis of the device in the longitudinal (cranio-caudal) direction. The system was implanted without complication under general anesthesia. The parasternal electrode was placed with a slight curvature to allow for expected sternal growth. Following implantation, VF was twice induced. Both VF episodes were appropriately sensed by the S-ICD system and successful conversion to SR was noted with sub-maximal 65 J shocks (80 J max output). Pre-discharge chest x-rays were collected and the technical performance of the S-ICD system was checked. No complications were noted and the patient was discharged. Conclusions: The first fully subcutaneous ICD system (S-ICD) is a viable alternative to contemporary approaches in the pediatric population and may reduce the long term complications associated with transvenous lead use in young patients.

Lupo PP, Erlinger P, Sanghera R, Scheck D, Bardy G, Cappato R. **Feasibility of defibrillation and arrhythmia detection using an exclusively subcutaneous defibrillator system in canines [abstract].** *J Interv Card Electrophysiol.* 2010; 27 (3): 168. *6th Annual Congress of the European Cardiac Arrhythmia Society, ECAS 2010.* There are no systematic data on the automatic detection and defibrillation requirements for a subcutaneous ICD system entirely located in the thorax. Two canine studies were conducted to test defibrillation and detection feasibility of a fully subcutaneous ICD system located in the left chest. In the first study, two pockets were created in 15 animals for placement of an anterior electrode adjacent to the left edge of the sternum and a lateral electrode at the site along the lateral axillary line between the fourth and sixth intercostals space. Stainless steel flat electrodes with active surface areas of 5, 10, 20, and 25 cm SUP 2 were subsequently positioned and the defibrillation threshold (DFT) was measured for multiple dual-electrode combinations. In the second study, the ability of detecting ventricular fibrillation (VF) and providing automatic defibrillation by a custom-built subcutaneous ICD with electrode-to-can electrode configuration implanted in the left lateral thorax were tested in five canines. Ninety-seven DFT tests with seven different dual electrode combinations were performed. All combinations successfully terminated VF with a DFT of 35+/-16 J (range, 9-79 J). Nineteen induced VF episodes were correctly recognized, leading to automatic ICD charge and shock delivery in all cases. Subcutaneous defibrillation using different dual electrode combinations in the left thorax successfully terminated all induced VFs within 79 J DFT. A custom-built subcutaneous ICD proved effective to detect and shock activate in response to all induced VF episodes, providing the groundwork for human testing.

Spitzer SG, Andresen D, Kuck KH, Seidl K, Eckardt L, Ulbrich M, Brachmann J, Gonska BD, Hoffmann E, Bauer A, Senges J, Ritter P. **Outpatient implantation of ICDs data of the German device quality register [abstract].** *Europace.* 2010; 12 (, SUPPL. 1): i14. *17th World Congress in Cardiac Electrophysiology and Cardiac Techniques, Cardioslim 2010.* Since the beginning of the register on March 1 SUP st, 2007 to February 13 SUP th, 2009 overall 1982 patients were included in the German device quality register, 18.9% of the patients with an outpatient care and 81.1% with hospital treatment. The following table demonstrates selected demographic and clinical data. In Germany approx. 1/5 of ICD implantations were performed in an outpatient setup. Both groups showed similar clinical characteristics as well as ICD indications. Among the outpatient group significant more subcutaneous ICD implantations were found. In selected patients ICD implantation can be performed on an outpatient basis, with equal success rates The 1 year-follow up is on the way; the data with 95% completeness will be presented at the meeting. (Table presented).

Theuns DAMJ, Dabiri L, Jordaens L. **Initial clinical experience with a novel, totally subcutaneous implantable defibrillator (s-icd) system [abstract].** *Eur Heart J.* 2010; 31 (, SUPPL. 1): 929. *European Society of Cardiology, ESC Congress 2010.* Background: The implantable cardioverter-defibrillators (ICD) has become standard therapy to prevent arrhythmic mortality. To avoid short- and longterm morbidity of conventional ICD systems, a total subcutaneous ICD (S-ICD) system has been developed. We report our initial clinical experience of the first 19 patients implanted at our clinic. Methods: All patients had a Class I or II ICD indication according to

the ACC/AHA/HRS guidelines. The implantation was performed by anatomical markers without fluoroscopy. The device was implanted subcutaneously over the 6th rib in the anterior axillary line, with a parasternal lead tunneled from xiphoid to the manubrial-sternal junction. The S-ICD automatically selects the best vector for rhythm detection. After implantation, ventricular fibrillation (VF) was induced to assess detection accuracy, and defibrillation efficacy by using 65J conversion energy. Results: A total of 19 patients (15 males, 4 females) received the S-ICD system. The patient's mean age was 57+/-16 years, and left ventricular ejection fraction 33 +/- 14%. Coronary artery disease was present in 14 patients, and a primary prevention indication was present in 16 patients. Post-implant testing was completed in all patients; 41 sustained episodes of VF were induced. Sensitivity was 100% and induced conversion efficacy was 100% (17 patients had standard polarity, for conversion). Mean time-to-therapy was: 13.9+/-2.5 seconds (range 11 - 21.6 seconds). The secondary sensing vector was automatically selected in the majority of patients (88%). Procedure-related complication was observed in 1 patient (lead migration). During follow-up, spontaneous ventricular arrhythmias occurred in 3 patients, with accurate detection for all episodes. Inappropriate therapy was observed in 2 patients. Conclusions: We report our initial clinical experience with the S-ICD system. The system can be implanted without the use of fluoroscopy by using anatomical landmarks only. Episodes of VF are accurately detected using subcutaneous signals, and all episodes were converted. The S-ICD system is a viable alternative to conventional ICD systems.

Bardy GH, Smith W, Hood M, Grace A, Crozier I, Melton I. **Subcutaneous only implantable cardioverter defibrillators [abstract].** *J Am Coll Cardiol.* 2009; 53 (10): A132. *American College of Cardiology 58th Annual Scientific Session and 12 Summit: Innovation in Intervention.* Background: Transvenous (TV) implantable cardioverter defibrillators (ICDs) prevent sudden death but also cause serious surgical complications. Further, device recalls from TV lead failure can threaten large patient populations and result in enormous costs. This report describes the first human experience with a subcutaneous-only ICD specifically engineered to avoid TV leads. Methods and Results: Six patients with standard ICD indications received a subcutaneous-only ICD system, S-ICD(TM), (Cameron Health, Inc., San Clemente, CA). All patients were provided full disclosure about relative risks and provided informed consent. No patient required anti-bradycardia or anti-tachycardia pacing. The S-ICD consists of a single left parasternal tripolar electrode and an electrically active pulse generator positioned in the left anterior axillary line between the 5 SUP th and 6 SUP th ribs. Only anatomic landmarks were used for the surgical procedure (i.e., no fluoroscopy). VF was induced and terminated twice using 65J shocks to ensure an adequate safety margin; the S-ICD delivers 80J shocks for spontaneous VT/VF. A discrimination zone that uses a waveform analysis and rate detection algorithm can be programmed between 170 - 250 bpm to avoid inappropriate shocks for supraventricular tachycardia, non-sustained VT and double detection. The device has only 4 programmable parameters: post-shock pacing off/on, discrimination zone off/on, and lower and upper rate limits for the discrimination zone. Over 2.5 months of follow-up no spontaneous VF/VT events occurred. Importantly, no false positive shocks occurred after a total of 35 million (M) detected heart beats. Conclusion: This is the first report of a fully subcutaneous-only ICD that can be inserted without fluoroscopy using only anatomic landmarks. In this early clinical experience, the S-ICD has detected and terminated induced VF without difficulty. Equally importantly, it has avoided inappropriate therapies after monitoring more than 35M heartbeats. In this early experience, the S-ICD appears to offer a viable alternative to traditional transvenous ICD systems where protection from cardiac arrest is indicated.

Burke M, Hamilton A, Walcott GP, Killingsworth CR, Knight BP, Packer DL. **Are cutaneously derived electrocardiography signals reliable surrogates for subcutaneous sensing algorithm testing?** *Heart Rhythm.* 2009; 6 (5, SUPPL. 1): S373. *30th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2009.* Introduction: A subcutaneous (SQ) defibrillator as an alternative to transvenous defibrillators is being developed. In efforts to develop a cutaneous (Q) database to verify and validate a SQ sensing algorithm, we compared the electrocardiography (ECG) characteristics of the SQ and Q signals simultaneously. Methods: 15 pigs underwent general anesthesia in the dorsal recumbent position. The SQ pocket for the can was made in the 4th-6th intercostal space along the left mid-axillary line. A small incision, left lateral to the xiphoid was created and, using a tool, a multi-electrode lead with coil was tunneled from the SQ pocket to this incision. Next, another small incision 8-10 cm superior to the xiphoid incision was made along the left sternum. The lead was then tunneled from the xiphoid incision along the parasternum superiorly. The lead body was sutured with a sleeve at the xiphoid position, and the distal tip was sutured to the underlying muscle at the superior parasternum. The lead was attached to the can in the mid-axillary pocket and all incisions were closed. Q conductive adhesive ECG electrodes were placed directly over three SQ electrodes. The Q and SQ electrodes were then connected to a multichannel TEAC digital recording system. Three minutes of sinus rhythm data were obtained and the QRS complexes were analyzed across three left chest bipolar vectors (1-3). Average QRS and T wave amplitude values were generated for each vector by analyzing ten contiguous cardiac cycles. QRS: T ratios were calculated using the averaged values. Results: The mean QRS: T ratio directly correlated between the Q and SQ space when measured simultaneously in each vector 1-3 (r=0.674; r=0.951; r=0.988, respectively). The QRS amplitudes

measured SQ strongly correlated with the Q signal in vectors 1-3 ($r=0.92$; $r=0.94$; $r=0.92$, respectively). There was no significant difference in measured QRS amplitude between Q and SQ signals in any vector. Conclusions: Surface QRS, T wave and their ratio correlate with the SQ space directly underlying and across various left chest vectors. Cutaneous ECG signals are reliable surrogates for the SQ ECG in the same location and vectors.

Burke M, Toff WD, Ludmer PL, Barr CS, Beshai JF, O'Neill PG, Lee MA, Skehan JD, Kim SS, Cho S, Kang S, Lin AC, Knight BP, Packer DL. **Comparisons during multiple postures of resting ECG's (compare) study.** *Heart Rhythm*. 2009; 6 (5, SUPPL. 1): S126. *30th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2009*. Introduction: The S-ICD(R) system, a totally subcutaneous implantable defibrillator, uses surface potentials that are affected by body position changes (BPC). To quantify the requirements for subcutaneous sensing, QRS amplitude (AMP) and QRS:T-wave ratio changes across seven patient postures and three vectors were evaluated. Methods: This multicenter prospective study enrolled 249 pts [mean data: age 68 years; 187 (75%) males; height 173 cm; weight 84 kg; BMI 29]. All patients were previously implanted with cardiac devices [107 (43%) pacemakers; 142 (57%) ICDs]. Five surface electrodes on the chest were used to obtain three simultaneously recorded vectors, plus lead II. Electrode "B" was positioned 1-2 cm to the left of the xyphoid process. Electrode "A" was placed 9 cm superior to the B electrode and 1-2 cm to the left of the sternum. Electrode "C" was placed over the 5th intercostal space along the left mid-axillary line. Signals were collected for two minutes in each of seven anatomic positions (six unique, one posture repeated). Signals from all vectors (AC, BC, AB) were recorded simultaneously. Results: 247 files were completed for all vectors. BPC caused significant variance in AMP. Supine QRS amp (mean +/- SD) were AC: 0.67 +/- 0.49 mV; BC: 0.86 +/- 0.5 mV; AB: 0.55 +/- 0.32 mV. Supine QRS:T-wave ratios (mean +/- SD) were AC: 6.39 +/- 4.6; BC: 7.18 +/- 5.2; AB: 4.78 +/- 3.2. See figure for comparison across the three vectors. Conclusions: The COMPARE data identified variances in QRS and T-wave signal amplitudes that were due to BPC. BPC should be factored into the sensing architecture for system's designed for subcutaneous sensing. (GP.).

Gold MR, Theuns DA, Knight BP, Sturdivant JL, Ellenbogen KA, Wood MA, Burke MC, Packer DL. **Arrhythmia detection by a totally subcutaneous s-ICD(R) system compared to transvenous single-chamber ICD systems with morphology discrimination [abstract].** *Heart Rhythm*. 2009; 6 (5, SUPPL. 1): S34-S5. *30th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2009*. Introduction: The development of a novel, totally subcutaneous implantable defibrillator (S-ICD) system required a new approach for arrhythmia detection using subcutaneous (SQ) signals. The objective of this study was to compare the sensitivity and specificity of the S-ICD system with single-chamber transvenous ICD (TV) systems that use 3 different morphology discrimination algorithms. Methods: Induced ventricular and atrial arrhythmias were recorded simultaneously in transvenous (RA, RV Can+Coil) and SQ equivalent cutaneous electrode configurations (P rimary, Secondary and Alternate vectors). Recorded signals of induced ventricular (n=43) and atrial arrhythmias (n=45) with rates > 170 bpm were used to assess detection by MDT, BSc, SJM and Cameron Health devices. Sensitivity analysis was performed with all devices programmed in single-zone (rate > 170 bpm) as well as dual-zone configurations (VF > 240 bpm; VT > 170 bpm). For specificity analysis, all devices were programmed in a dual-zone configuration (VT zone: 170-240 bpm, VF zone: >240 bpm) with the respective morphology algorithm acting as the sole discriminator. All detection parameters were programmed at nominal settings, except sustained rate timers programmed OFF. Results: Detection of ventricular arrhythmias by the S-ICD system was not different than TV systems. Sensitivity: 100% (S-ICD) vs 99.2% (TV range: 97.7% - 100.0%) in a single-zone configuration; 100% (S-ICD) vs 98.4% (TV range: 95.3% -100.0%) in a dual-zone configuration. Specificity was significantly different for the S-ICD system compared to TV systems (97.8% (S-ICD) vs 65.2% (TV range: 53.3% - 86.7%); $p < 0.001$). The majority of misclassifications were observed during atrial fibrillation. Specificity for atrial fibrillation was 97.2% (S-ICD) vs 64.8% (TV); $p < 0.001$. Conclusions: Arrhythmia detection sensitivity of the S-ICD system using subcutaneous signals is not different than current TV systems. Specificity of arrhythmia detection by the S-ICD system is significantly better than morphology discrimination by TV systems without adversely impacting sensitivity.

Radbill A, Triedman JK, Berul CI, Alexander ME, Walsh EP, Atallah J, Cecchin F, Packer DL. **System survival of non-transvenous ICDS compared to transvenous ICDS in pediatric and congenital heart disease patients [abstract].** *Heart Rhythm*. 2009; 6 (5, SUPPL. 1): S38. *30th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2009*. Introduction: Non-transvenous (pericardial and/or subcutaneous coils) ICD systems are used in select pediatric and congenital heart disease patients. This study compared survival of these non-transvenous (NTV) systems to standard transvenous (TV) systems. Methods: Retrospective single-center study. The TV group was matched to the NTV group 2:1 by type of cardiac disease and implant date. Patients with a subcutaneous array added to a transvenous ICD lead were excluded. Results: There were 37 pts in the NTV group and 74 in the TV group. For the NTV group, coil configurations included subcutaneous (n=6), pericardial (n=22), subcutaneous + pericardial (n=7), and other (n=2). A high intra-procedural defibrillation threshold prompted revision of coil configuration in 24% of patients with NTV systems. In the NTV group, acute

complications occurred in 16% of patients, and both appropriate and inappropriate shocks occurred in 19% of patients with NTV systems. Compared to the TV group, the NTV group was younger (median 7 vs. 20 yrs) with smaller BSA at implant (0.88 vs. 1.76 m²), and patients more frequently received the ICD for secondary prevention (57% vs. 16%) (all p<0.001). Gender, somatic growth and use of recalled Sprint Fidelis leads did not differ significantly between the 2 groups. Median follow-up was 16mo. Unadjusted system survival at 12, 24 and 36 months was 73%, 58% and 52% in the NTV group vs. 94%, 83% and 79% in the TV group (p=0.003, log-rank test). Multivariate Cox proportional hazards model including group and above variables did not identify any independent predictors of system survival. Rate of unanticipated interventions in the NTV group was 19.7 per 1000 person-months vs. 7.3 per 1000 person-months in the TV group. There was 1 patient death in each group. Conclusions: Survival of ICD systems utilizing non-transvenous shocking coils is significantly shorter than transvenous ICD systems. No independent predictors of system survival could be identified. Although NTV systems provide protection for this unique subset of patients, more durable options are needed.

Smith BM, Clark J, Kapil J, Packer DL. **Intermediate follow-up of subcutaneous ICD placement [abstract]. *Heart Rhythm***. 2009; 6 (5, SUPPL. 1): S324. *30th Annual Scientific Sessions of the Heart Rhythm Society, Heart Rhythm 2009*. Introduction: The pediatric population presents a challenge for traditional transvenous ICD systems due to small size, unique cardiovascular anatomy, and risk of venous occlusion. Thus, new, non-traditional methods of ICD coil placement continue to be developed to find acceptable alternatives for the pediatric population. We reviewed the performance of our nontransvenous ICD systems over an intermediate time frame. Methods: Six years of records were reviewed for patients undergoing subcutaneous ICD placement. Eleven patients were identified (n = 11). Indications for ICD placement, device function at implantation and follow-up, and complications were reviewed retrospectively. Device placement consisted of an epicardial pace-sense lead sutured to the right ventricular free wall. The first 3 patients had subcutaneous coils placed, one in each axilla. The next 8 patients had 1 subcutaneous coil placed in the left axilla, and 1 SVC coil sewn to the pericardium adjacent to the RV free wall. In all patients, the generator was positioned abdominally in a midline subrectus location. Results: Patient age ranged 3-27 years (median age = 5 years). Indications for ICD placement were Long QT Syndrome (n = 8), Hypertrophic Cardiomyopathy (n = 1), ventricular tachycardia (n = 1), and complex single ventricle with ventricular tachycardia (n = 1). Follow-up ranged 8-74 months (median follow-up = 33 months). Subcutaneous coil lead impedance at implant ranged 33-96 ohms (median = 74 ohms). Coil impedance at follow-up ranged 26-90 ohms (median = 64 ohms). During follow-up, 3 patients received appropriate shocks. Three patients received spurious shocks, 1 due to T wave over-sense, and 2 due to pace-sense lead fracture. Three lead fractures occurred, and 2 ICD revisions were done due to generator recall. There were no deaths. Conclusions: Subcutaneous ICD placement is a reasonable alternative to traditional transvenous systems. Similar complications of lead fracture, inappropriate shock, and generator recall occur. This approach may be an effective alternative for small patients, those with unique or incompatible venous access, and young patients for whom vascular access should be preserved.

Hood M, Smith W, Grace A, Fynn S, Connelly D, Wright J, Crozier I, Melton I, Ardashev A, Sperzel J, Neuzner J, Spitzer S, Cappato R, Bardy G. **DFT for a subcutaneous implantable defibrillator (S-ICD) system: Experience for the first 150 patients [abstract]. *Heart Rhythm***. 2007; 4 (5 Suppl): S132. Abstract PO1-67. *HRS 2007*.

Smith W, Hood M. **Comfort/tolerability test results for a subcutaneous ICD compared to a standard transvenous ICD [abstract]. *Heart Rhythm***. 2007; 4 (5 Suppl): S210. Abstract PO3-30. *Heart Rhythm Society Scientific Conference 2007*.

Grace AA, Hood MA, Smith WM, Ardashev A, Cappato R, Bardy GH. **Evaluation of four distinct subcutaneous implantable defibrillator (S-ICD[®]) lead systems in humans [abstract]. *Heart Rhythm***. 2006; 3 (5 Suppl): S128-9. Abstract P1-65. 10 patients.

Cappato R, Bardy G. **Sub-cutaneous electrical defibrillation in canines [abstract]. *Eur Heart J***. 2005; 26 (Suppl 1): 270. Abstract P1742.

Grace AA, Smith WM, Hood MA, Connelly DT, Murgatroyd FD, Crozier IG, Melton IC, Wright DJ, Cappato R, Bardy GH. **A prospective, randomized comparison in humans of defibrillation efficacy of a standard transvenous ICD system with a totally subcutaneous ICD system (The S-ICD[®] system) [abstract]. *Heart Rhythm***. 2005; 2 (9): 1036. Abstract AB-6107. *Late Breaker at HRS 2005. Cameron Health*. 41 patients.

Bardy G, Cappato R, WM S, Hood M, Rissmann W, Gropper C, Ostroff A. **The Totally subcutaneous ICD system (S-ICD) [abstract]. *Pacing Clin Electrophysiol***. 2002; 25 (4 Suppl 2): 578. Abstract 222. *Cameron Health (S-ICD)*.

