

S-ICD: CONFIRMING SAFETY AND EFFICACY

This clinical update reviews three individual studies. The [PRAETORIAN trial](#) provides randomised, head-to-head data for the subcutaneous implantable cardioverter-defibrillator (S-ICD) *versus* a transvenous ICD (TV-ICD), and confirms the non-inferiority of S-ICD compared with TV-ICD.¹ Also discussed is the [UNTOUCHED study](#) of primary prevention in patients with low ejection fraction – the population most commonly indicated for ICD therapy – which is the first trial to evaluate S-ICD standardised programming and rhythm discrimination at very high rates (250 bpm) using contemporary electrogram filtering and algorithms.² It also shows a high efficacy for terminating ventricular tachycardias, and a very low inappropriate shock rate using the SMART Pass system, despite a sicker patient population with more comorbidities than previously studied in S-ICD trials.² Finally, post-approval data from [S-ICD Post-Approval Study \(S-ICD PAS\)](#), a large, prospective registry that confirms a high complication-free rate and good efficacy for terminating arrhythmias, are reviewed.³

1. Non-inferiority of S-ICD versus TV-ICD in the first head-to-head, randomised, prospective study

The S-ICD was designed to avoid complications related to the TV-ICD lead by using an entirely extra thoracic placement.^{1,4} Evidence comparing these systems is primarily based on observational studies, and to date shows a good safety profile, with high first and final shock efficacy rates (first efficacy 90.1–92.1%; final efficacy 97.4–98.2%)^{5,6} and low rates of complications and appropriate shocks.^{2,5,7-11}

The PRAETORIAN trial provides the first prospective, randomised, head-to-head data investigating whether the S-ICD is non-inferior to the TV-ICD with regards to short- and long-term device-related complications and

inappropriate shocks.¹ The study enrolled 876 patients with an indication for an ICD, but no indication for pacing, from 39 centres in Europe and the United States.¹ From a total of 849 patients, 426 patients were randomised to the S-ICD group and 423 to the TV-ICD group. The clinical characteristics of the patients at baseline were similar in the two groups.¹ The patients were more representative of a typical ICD cohort than those previously included in S-ICD studies, as patients were older (mean age 63 years), had low ejection fraction (mean left ventricular ejection fraction [LVEF] 30%) and primarily had ischaemic cardiomyopathy.

Table 1: Baseline characteristics of patients in the PRAETORIAN trial.¹

Characteristic	S-ICD (N=426)	TV-ICD (N=423)
Age, Years	63 (54 – 69)	64 (56 – 70)
Diagnosis		
Ischaemic cardiomyopathy	289 (67.8)	298 (70.4)
Non-ischaemic cardiomyopathy	99 (23.2)	98 (23.2)
Genetic arrhythmia syndrome	20 (4.7)	18 (4.3)
Hypertrophic cardiomyopathy	15 (3.5)	7 (1.7)
Idiopathic ventricular fibrillation	11 (2.6)	5 (1.2)
Congenital heart disease	3 (0.7)	3 (0.7)
Other	4 (0.9)	1 (0.2)
LVEF, %	30 (25 – 35)	30 (25 – 35)
Secondary Prevention	80 (18.8)	84 (19.9)
NYHA Class		
I	144/423 (34.0)	134/421 (31.8)
II	205/423 (48.5)	223/421 (53.0)
III or IV	74/423 (17.5)	64/421 (15.2)
Hypertension/use of anti-hypertensive drugs	227/424 (53.5)	240/419 (57.3)
Diabetes	112/426 (26.3)	126/421 (29.9)

Values are ratio of patients: n/N (%) or median (IQR) unless otherwise stated. IQR, interquartile range; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; S-ICD, subcutaneous implantable cardioverter-defibrillator; TV-ICD, transvenous implantable cardioverter defibrillator.

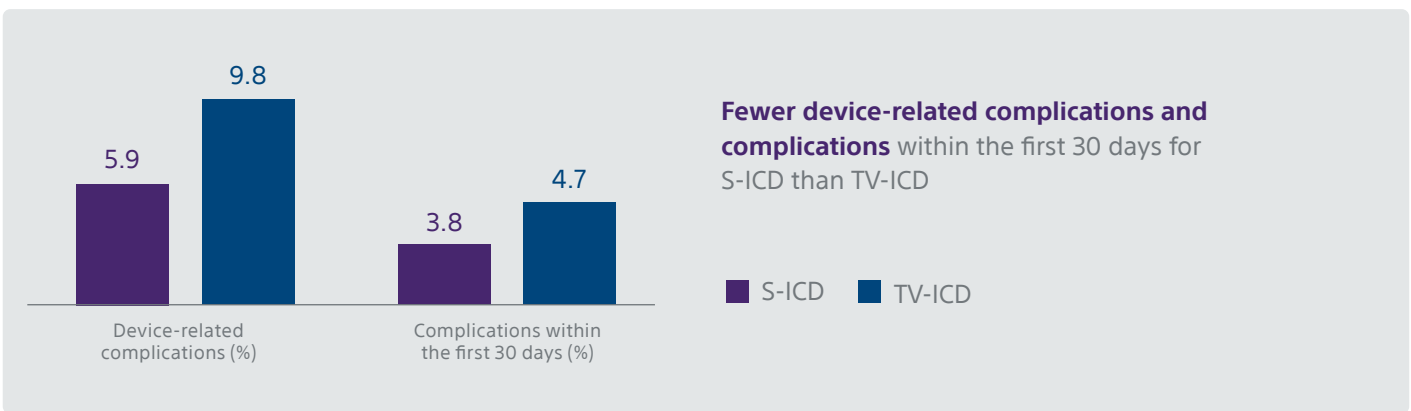
Follow-up was complete in 339 (S-ICD) and 346 (TV-ICD) patients, with median follow-up duration of 48.0 and 50.6 months. The composite primary endpoint of the trial consisted of device-related complications and inappropriate shocks.¹ The primary endpoint

occurred in 68 patients in both groups, giving 48-month Kaplan–Meier estimated cumulative incidences of 15.1% (S-ICD) and 15.7% (TV-ICD), respectively ($p=0.01$ for non-inferiority and 0.95 for superiority).¹

Fewer device-related complications for S-ICD

Device-related complications occurred in 31 patients in the S-ICD group and 44 in the TV-ICD group, with cumulative incidences of 5.9% and 9.8%, respectively.¹ The incidence of complications within the first 30 days was 3.8% in the S-ICD group and 4.7% in the TV-ICD group.¹

COMPARED WITH TV-ICD, THE S-ICD HAD FEWER DEVICE-RELATED COMPLICATIONS (5.9% VERSUS 9.8%) AND FEWER COMPLICATIONS WITHIN THE FIRST 30 DAYS (3.8% VERSUS 4.7%)

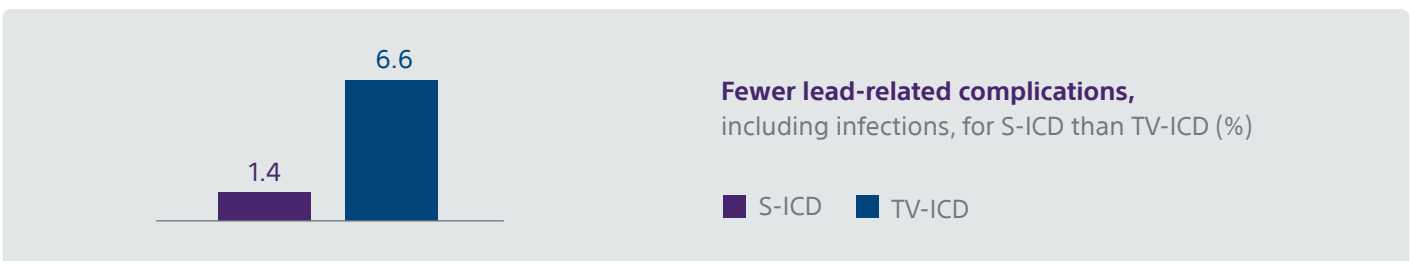


Fewer lead-related complications for S-ICD, including lower infection rates

The incidence of lead-related complications was also lower (with statistical significance) in the S-ICD group than the TV-ICD group: 1.4% versus 6.6%.¹ Fewer lead-related complications, including infection, perforation, lead dislodgement, and lead dysfunction, and subsequent surgical reinterventions, occurred in the S-ICD group than in the TV-ICD group, although pocket haematomas were more frequent with the S-ICD.

In line with the findings on infections, the 2017 guidelines from the American Heart Association (AHA), American College of Cardiology (ACC) and Heart Rhythm Society (HRS) recommend S-ICD in patients who meet criteria for an ICD who are at high risk of infection and in whom pacing for bradycardia or ventricular tachyarrhythmia (VT) termination or as part of cardiac resynchronisation therapy (CRT) is neither needed nor anticipated.¹²

INFECTION RATES ARE LOWER WITH S-ICD THAN TV-ICD, AND GUIDELINES RECOMMEND S-ICD IN PATIENTS AT HIGH RISK OF INFECTION FOR WHOM PACING FOR BRADYCARDIA OR VT TERMINATION OR AS PART OF CRT IS NEITHER NEEDED NOR ANTICIPATED



Low inappropriate shock rate for S-ICD

The inappropriate shock rate was comparable between S-ICD and TV-ICD at 1-year follow-up: 4.8% for S-ICD *versus* 4.1% for TV-ICD.¹ First occurrences of inappropriate shocks with the S-ICD were most frequently caused by cardiac oversensing (58.5% of patients with an inappropriate shock), whereas inappropriate shocks with TV-ICD were more commonly triggered by supraventricular arrhythmias (93.1%).¹

The **SMART Pass filter** was unavailable, or not activated, in most S-ICD patients (78%) during their first inappropriate shock in the PRAETORIAN study (9.7%).¹ Contemporary devices with this sensing filter may improve the inappropriate shock rate for the S-ICD,¹ as evidenced by the findings of the **UNTOUCHED study**, which found an inappropriate shock rate for the S-ICD of just 2.4% in third generation devices with SMART Pass activated,¹³ and a separate study of the SMART Pass filter, which showed that this technology reduced the risk of first inappropriate shock by 50%.¹⁴

SMART Pass technology

Despite the safety and efficacy of the S-ICD system, the main cause of morbidity in S-ICD patients is inappropriate shocks, primarily caused by cardiac oversensing.^{14,8,15} Shocks on supraventricular arrhythmias can generally be managed with device reprogramming or medication, but shocks caused by cardiac or non-cardiac oversensing are less modifiable.¹

An initial update in the morphology-based sensing algorithm in the S-ICD reduced inappropriate charges caused by T-wave oversensing by about 40%. To reduce inappropriate shocks further, a new high-pass filter – the SMART Pass – was developed for the S-ICD system.¹⁴ The SMART Pass filter reduces the amplitude of lower frequency signals, such as T-waves, by applying an additional high-pass filter to reduce inappropriate shocks due to T-wave oversensing.^{2,16} Recent generations of S-ICD, the third-generation being the first, are now fitted with the SMART Pass filter, which is automatically enabled at device implant. The SMART Pass technology resulted in a 50% reduction of first inappropriate shocks in an earlier study.^{1,14}

Evolution of S-ICD¹⁶

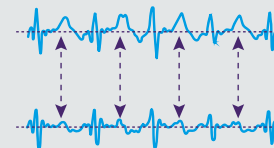
Dual Zone Programming

Conditional zone reduces IAS and unnecessary therapy



SMART Pass

SMART Pass reduces the amplitude of lower frequency signals, such as T-waves, by applying an additional high pass filter.



2012 2013 2014 2015 2016 2017 2018 2019 2020



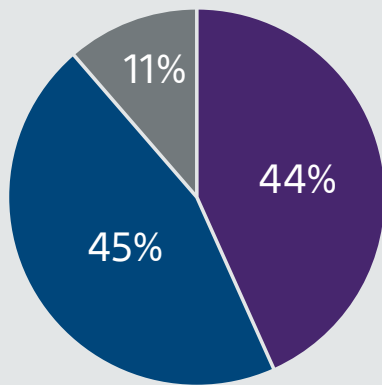
SMR-8

A new double detection algorithm was introduced with SMR-8



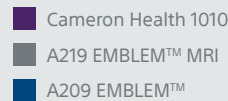
UNTOUCHED Study

The UNTOUCHED study combined prescriptive programming (conditional zone of 200 bpm and a shock zone of 250 bpm) with EMBLEM™ S-ICD technology and a patient cohort representative of those most commonly receiving ICDs (primary prevention, LVEF ≤35%).



Distribution of S-ICD devices by generation in the PRAETORIAN study.¹

Cameron Health 1010: First generation S-ICD; EMBLEM™ A209: Second generation S-ICD; EMBLEM™ A219: Second generation S-ICD with SMART Pass technology



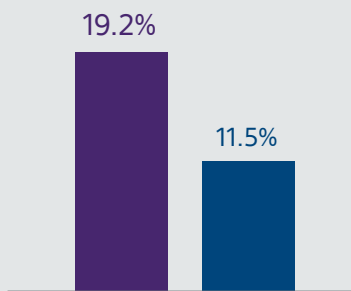
Low appropriate shock rate for S-ICD

Appropriate shock rates were more frequent in the S-ICD group than the TV-ICD group (19.2% vs 11.5%, HR 1.52 [95% CI 1.08 to 2.12]).¹ This included S-ICD shocks due to oversensing of ventricular tachycardia below the programmed therapy zone in 11 patients.¹

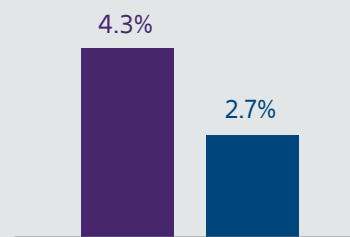
Low crossover rate from S-ICD to TV-ICD

There were no between-group differences in total crossovers (18 [4.3%] S-ICD patients vs 11 [2.7%] TV-ICD patients; HR 1.64 [95% CI 0.77 to 3.47]), although there were numerically more crossovers during follow-up (shortly after the implantation attempt or later in follow-up) from the S-ICD to the TV-ICD (14 patients) than vice versa (5 patients).¹

Low inappropriate shock rates despite older-generation devices without contemporary sensing filters.



Only 5 patients required pacing/ATP (1 crossed over to CRT-D, 3 received concomitant pacemaker, 1 crossed over to TV-ICD)



■ S-ICD ■ TV-ICD

Conclusion

These head-to-head data confirm the non-inferiority of S-ICD compared with TV-ICD in patients with characteristics more typical of previously studied ICD cohorts (older, low ejection fraction, ischaemic cardiomyopathy). With the S-ICD, there were fewer device- and lead-related

complications, and there was a low rate of inappropriate shocks, despite most patients receiving an older-generation device without contemporary algorithms. There was also a low rate of cross-over from S-ICD to TV-ICD over the 4 years of data analysis.

2. UNTOUCHED study combined recent generations of S-ICD devices and prescriptive programming in a typical ICD patient cohort (primary prevention, LVEF ≤35%)

The UNTOUCHED study is the first prospective S-ICD trial to assess modern devices and standardised programming to evaluate rhythm discrimination to very high rates (250 bpm) using contemporary electrogram filtering and algorithms.² It was a multi-national, prospective, non-randomised study in a typical primary prevention ICD cohort, with LVEF ≤35%, undergoing *de novo* implant of an S-ICD, but without a pacing indication for bradycardia or CRT.² Patients were implanted with a second- or third-generation S-ICD that includes prespecified device programming with a conditional zone between 200 and 250 bpm.²

The primary endpoint was inappropriate shock-free rate at 18 months, with a performance goal of 91.6%, which was derived from the inappropriate shock-free rate of 94.6% in Arms B and C of MADIT-RIT.^{2,17} Secondary endpoints were all-cause shock-free rate at 18 months, with a performance goal of 85.8%, and system- and procedure-related complications at 30 days.²

Sicker patient population than previously studied

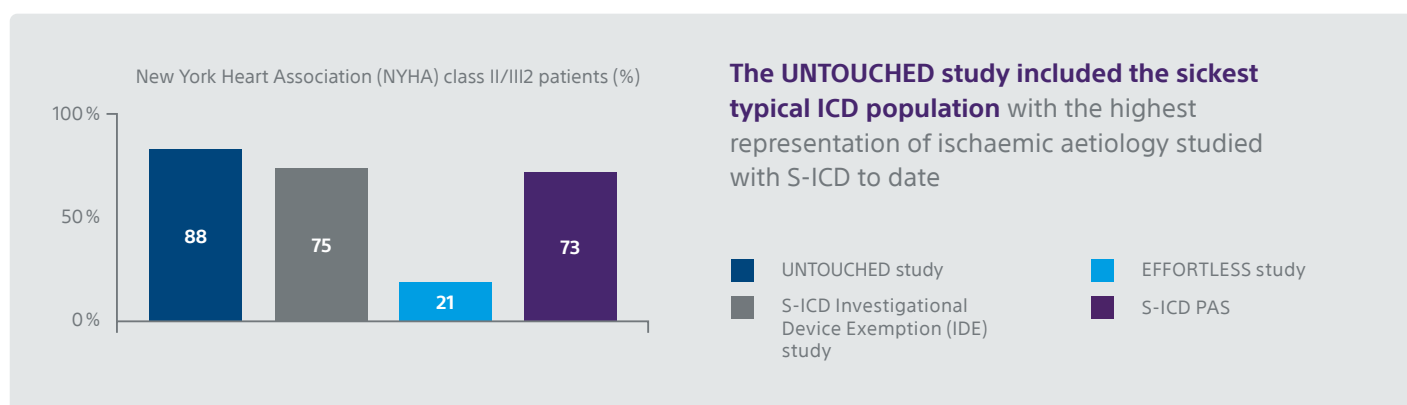
In studies to date showing that the S-ICD reduces lead-related complications compared with TV devices, the cohorts studied were younger with fewer comorbidities and more preserved LVEF, and inappropriate shocks resulting from cardiac oversensing were more frequent than with TV-ICDs.² The 1,111 patients implanted with an S-ICD in the UNTOUCHED study had more severe disease

than in previous S-ICD studies: 87.7% of patients had New York Heart Association (NYHA) class II/III² compared with 75% in the S-ICD Investigational Device Exemption (IDE) study, 21% in the EFFORTLESS study and 73% in S-ICD PAS.^{2,3,6,8,17} Furthermore, more than half of patients (54%) in the UNTOUCHED study had ischaemic aetiology.

Table 2: Baseline characteristics of patients in UNTOUCHED, S-ICD IDE, EFFORTLESS, S-ICD PAS and MADIT-RIT trials.^{2,3,6,8,17}

	UNTOUCHED ²	S-ICD IDE ⁶	EFFORTLESS ICD Registry ⁸	S-ICD PAS ³	MADIT-RIT (TV-ICD only) ¹⁷
Device type	S-ICD	S-ICD	S-ICD	S-ICD	TV-ICD
Age, years	56 ± 12	52 ± 16	48 ± 17	53 ± 15	61 ± 12
LVEF, %	26 ± 6	36 ± 16	43 ± 18	32 ± 15	27 ± 7
NYHA II/III/IV	888/1,013 (88)	202/270 (75)	206/985 (21)	1,358/1,637 (73)	702/729 (96)
Primary prevention	1,116/1,116 (100)	255/321 (79)	638/985 (65)	1,254/1,637 (77)	742/742 (100)
Ischaemic	570/1,065 (54)	73/321 (23)	311/983 (32)	672/1,637 (41)	457/741 (62)
Hypertension	787/1,116 (71)	187/321 (58)	279/985 (28)	1,009/1,637 (62)	500/739 (68)
Diabetes	364/1,116 (33)	90/321 (28)	110/985 (11)	550/1,637 (34)	239/733 (33)

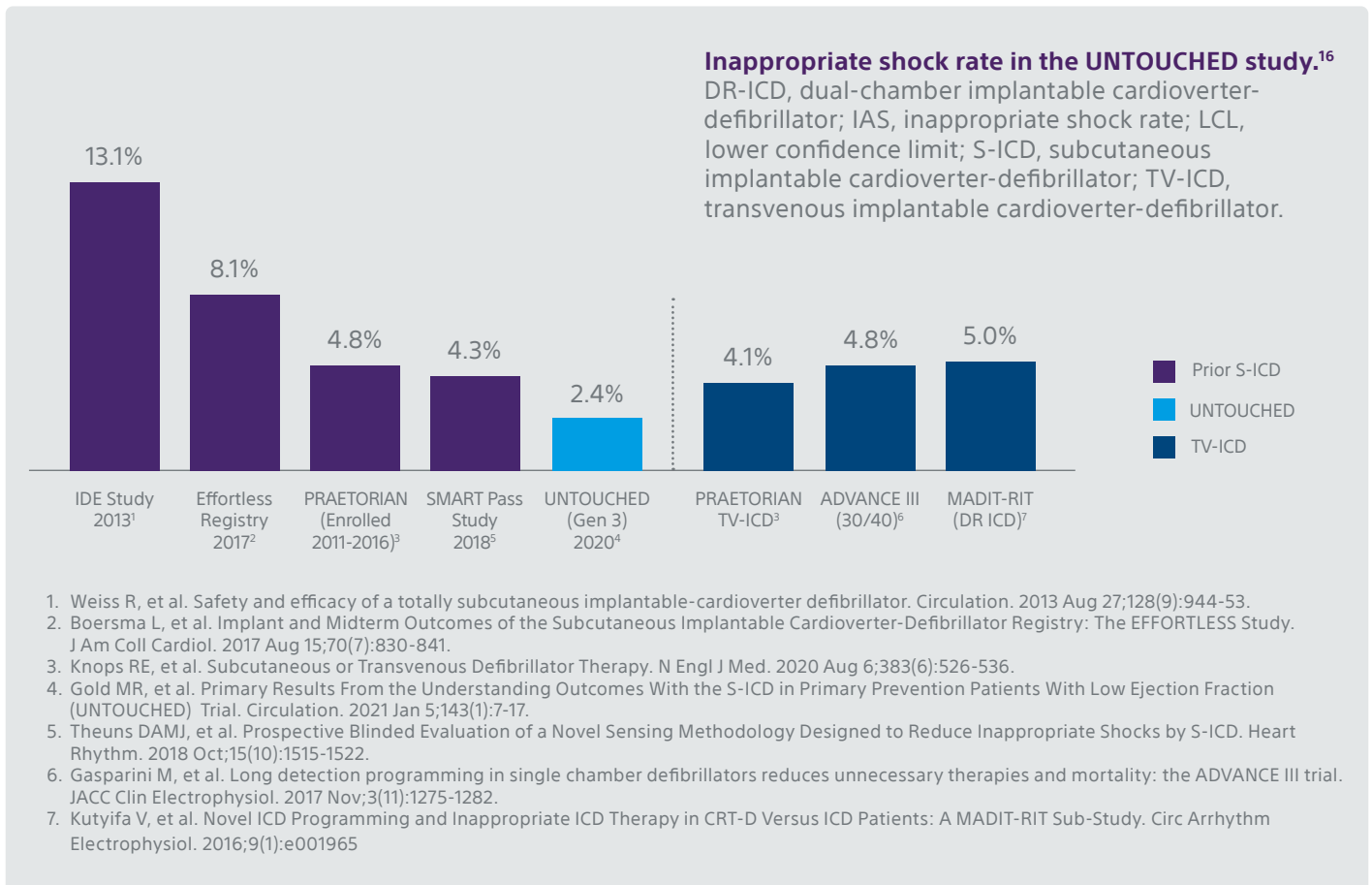
Values are ratio of patients: n/N (%) or mean ± standard deviation unless otherwise stated. AF, atrial fibrillation; BMI, body mass index; LVEF, left ventricular ejection fraction; MADIT-RIT, Multicentre Automatic Defibrillator Implantation Trial: Reduce Inappropriate Therapy; NYHA, New York Heart Association; S-ICD, subcutaneous implantable cardioverter-defibrillator; S-ICD IDE, S-ICD System Investigational Device Exemption; S-ICD PAS, S-ICD Post-Approval Study; SD, standard deviation; TV-ICD, transvenous implantable cardioverter-defibrillator; UNTOUCHED, Understanding Outcomes With The S-ICD In Primary Prevention Patients With Low Ejection Fraction.



Impact of SMART Pass technology on inappropriate shock rate

Overall, 95.9% (95% lower confidence limit 94.8%) of patients, implanted with 2nd and 3rd generations of S-ICD, were free of inappropriate shocks at 18 months, which is well above the performance goal of 91.6% ($p < 0.0001$).² Post-hoc analysis looking at the different S-ICD devices found an inappropriate shock rate at 1 year of 3.1% for all S-ICD and 2.4% for the EMBLEM™ MRI S-ICD device with SMART Pass.² The overall rate of inappropriate shocks and the rate for the EMBLEM™ MRI S-ICD with SMART Pass are the lowest reported for the S-ICD, and lower than for many TV-ICD devices using contemporary programming to reduce inappropriate shocks.¹⁶

IN THE UNTOUCHED STUDY, INAPPROPRIATE SHOCK RATES WITH THE 3rd GENERATION S-ICD DEVICE WITH SMART PASS WERE THE LOWEST REPORTED FOR THE S-ICD



Patients with a history of atrial fibrillation (AF) (paroxysmal, persistent or permanent) and non-ischaemic aetiology had a higher risk of inappropriate shock in the multivariable model ($p=0.0003$ and 0.019).² Overall, 8.5% of patients with a history of AF received an inappropriate shock at 18 months.²

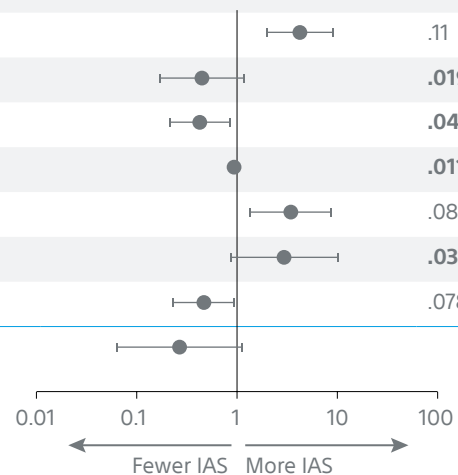
An unexpected finding in the UNTOUCHED study was that the two-incision technique, which is increasingly popular as it shortens procedural time and does not increase implantation complications, was associated with a higher rate of inappropriate shock.² However, the inappropriate shock rate using the two-incision technique was still low enough to meet the study's performance requirement.²

Table 3: Predictors of inappropriate shock in the UNTOUCHED study.²

Variable	Hazard Ratio	P-value
History of AF	4.24 (1.95 – 9.25)	.0003
Black Race	0.45 (0.17 – 1.20)	.11
Ischemic etiology	0.43 (0.21 – 0.87)	.019
LVEF, %	0.94 (0.89 – 1.00)	.042
Two-incision technique	3.47 (1.33 – 9.06)	.011
DFT performed within first 30 days	3.00 (0.88 – 10.23)	.080
Gen 3 device	0.47 (0.24 – 0.93)	.031
Prescribed programming throughout study	0.27 (0.06 – 1.16)	.078

AF, atrial fibrillation; DFT, defibrillation testing; Gen, generation; IAS, inappropriate shock; LVEF, left ventricular ejection fraction.

n=1040



IN THE UNTOUCHED STUDY, USE OF A THIRD-GENERATION S-ICD WITH SMART PASS FILTER PREDICTED A LOWER RATE OF INAPPROPRIATE SHOCKS DESPITE A COHORT WITH MORE LEFT VENTRICULAR DYSFUNCTION AND HEART FAILURE

S-ICD demonstrated high rates of spontaneous episode conversion

Among the 58 patients, with 64 discrete appropriate shock episodes, S-ICD showed a high success rate, with 93.8% of first shocks and 98.4% of final shocks being successful.² One of 64 final shocks failed, but this patient converted spontaneously.² Seven patients experienced 58 episodes in nine storm events, with a final conversion rate of 100% for all storm events.² The appropriate shock rate was low for episodes of VT storm as well as discrete episodes, with a high defibrillation success similar to that reported with TV-ICD trials.^{2,18,19}

The complication-free rate at 18 months was 92.7%.² No lead failures occurred and only 12 infections were observed (1.1%), none of which resulted in bacteraemia; this reinforces a key advantage of the S-ICD over TV-ICDs in this high-risk population.² Ten (0.9%) patients experienced syncope during the trial; only one of these patients experienced syncope associated with a tachyarrhythmia: a monomorphic VT arrhythmia at a rate of ~160 bpm that spontaneously

terminated, with no change in patient management subsequent to the event.² Overall survival was 94.9%, with one-year survival of 96.7%.²

In a cohort in which almost 90% had symptomatic heart failure and more than half had coronary artery disease, replacement of the S-ICD with a TV-ICD for pacing indications was required in just four patients (<0.5%): two for anti-tachycardia pacing (ATP), two for CRT pacing, and none for bradycardia pacing.²

IN THE UNTOUCHED STUDY, REPLACEMENT OF THE S-ICD WITH A TV-ICD FOR PACING INDICATIONS WAS REQUIRED IN JUST FOUR PATIENTS (<0.5%)

Conclusion

In a population of typical ICD patients with low ejection fraction being treated for primary prevention, the UNTOUCHED study demonstrates high efficacy and safety with contemporary S-ICD devices and programming, despite the relatively high incidence of comorbidities in comparison with earlier S-ICD trials.² The inappropriate shock rate (3.1% at one year overall and 2.4% for third-generation devices) is the lowest reported for the S-ICD and lower than many TV-ICD studies using contemporary programming to reduce inappropriate shocks.^{2,16} The

appropriate shock rate of 5.7% was low,² despite the absence of ATP in the S-ICD. Furthermore, although 90% of patients had symptomatic heart failure and more than half had coronary artery disease, only four (<0.5%) patients required replacement of the S-ICD with a TV-ICD for pacing indications.² The S-ICD can be considered in all primary prevention patients without pacing indications regardless of underlying heart disease or left ventricular function.² The device programming used in this study should be adopted routinely to avoid unnecessary shocks.²

3. High complication-free rate and good appropriate shock efficacy

The S-ICD PAS prospective registry includes 1,637 *de novo* patients from 86 US centres who underwent implantation for a primary (76.6%) or secondary prevention indication (23.4%).³ The patient population more closely resembles TV-ICD cohorts than earlier studies, which included many patients with little structural heart disease and few comorbidities.³

A recently published analysis evaluated spontaneous arrhythmias and clinical outcomes in this registry.³ With an inappropriate shock incidence of 6.8% without the use of **SMART Pass technology**, the appropriate shock rate at 1 year was 5.3% in a sicker population than previous S-ICD registries.³ The complication-free rate was 92.5%.³ A total of 395 VT or ventricular fibrillation (VF) episodes were appropriately sensed, with 131 (33.2%) self-terminating, as the dual zone programming allows self-termination of non-sustained episodes.³ First and final shock efficacy (up

to five shocks) for the 127 discrete episodes of appropriate shock were 91.3% and 100%, respectively.³ Eighteen patients experienced a total of 19 storm events with 137 storm episodes, with 84.2% conversion success.³

In the first year after implantation of S-ICD, the predominantly primary prevention population with low ejection fraction in the S-ICD PAS registry had a high complication-free rate and spontaneous-event shock efficacy for monomorphic VT and polymorphic VT/VF arrhythmias at rapid ventricular rates.³ Only nine patients (0.5%) exited the study due to a change in indication or patient condition. The appropriate shock rate was low (5.3%) in the first year after implantation,³ suggesting that the lack of ATP or bradycardia pacing was a minor limitation in properly selected primary and secondary prevention patients.³

S-ICD HAS A HIGH COMPLICATION-FREE RATE AND GOOD APPROPRIATE SHOCK EFFICACY IN A REAL-WORLD POPULATION

High complication-free rate and good appropriate shock efficacy

6.8%

**inappropriate
shock incidence**

92.5%

**complication-
free rate**

Summary

Data from the PRAETORIAN trial – the first prospective, randomised, head-to-head trial – confirmed the non-inferiority of S-ICD compared with TV-ICD, with fewer device- and lead-related complications, a lower infection rate and a low inappropriate shock rate for S-ICD.

The UNTOUCHED study, which included the sickest population studied to date, confirmed a high spontaneous conversion efficacy with S-ICD and low inappropriate shock rate well above the performance goal. Furthermore, use of SMART Pass technology predicted a lower inappropriate shock rate.

Crossover rates from S-ICD to TV-ICD were low in both the PRAETORIAN trial and the UNTOUCHED study.

A large, prospective, post-approval registry confirmed that S-ICD has a high complication-free rate and good appropriate shock efficacy in a real-life setting.

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