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THE IMPACT OF SMART PASS ON REDUCING INAPPROPRIATE SHOCKS FOR S-ICD

2018 HRS LATE-BREAKER: ANALYSIS OF REAL WORLD LATITUDE DATA[1]

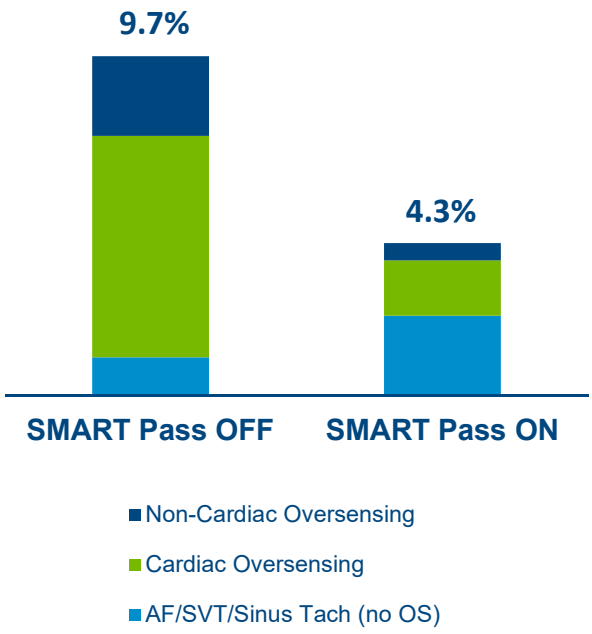
BACKGROUND
The SMART Pass filter aims to reduce cardiac oversensing and was first approved in 2016. The purpose of the study was to evaluate SMART Pass in ambulatory patients with S-ICD.

METHODS
1,984 patients were followed for 1 year. SMART Pass was enabled in 33% and disabled in 67%. Shocks were adjudicated by 3 independent blinded reviewers as appropriate or inappropriate.

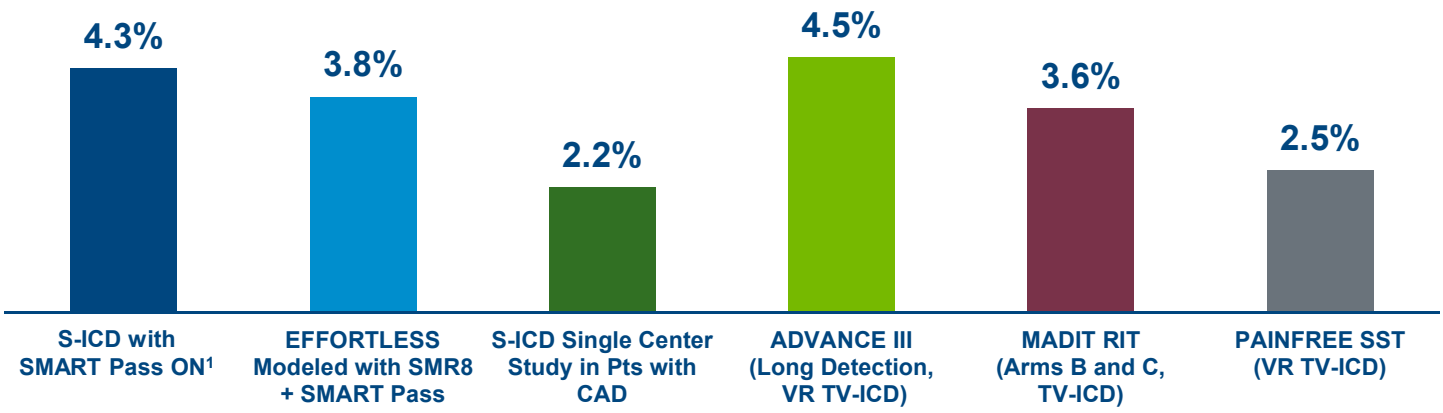
RESULTS
SMART Pass reduced the risk for first inappropriate shock by 50% and the risk for all inappropriate shocks by 68%. Incidence of inappropriate shocks was 4.3% in the SMART Pass enabled arm vs. 9.7% in the disabled arm.

CONCLUSION
This prospective blinded evaluation demonstrated SMART Pass results in a significant reduction of inappropriate shocks.

DISTRIBUTION OF CAUSES OF FIRST INAPPROPRIATE SHOCK

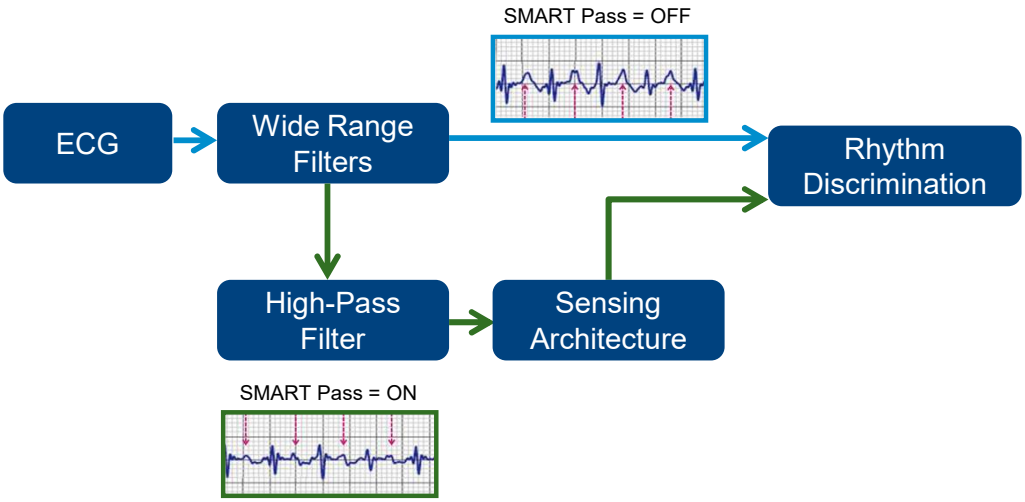


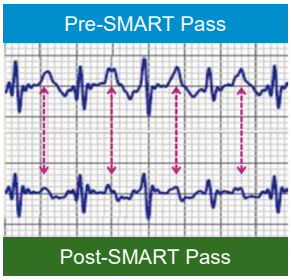
HOW DOES THE S-ICD INAPPROPRIATE SHOCK RATE COMPARE TO TRANSVENOUS ICDS WHEN SMART PASS IS ENABLED?[1-6]



Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

SMART PASS REDUCES OVERSENSING WHILE MAINTAINING APPROPRIATE SENSING MARGIN[1]





The SMART Pass filter reduces the amplitude of lower frequency signals such as T-waves, by applying an additional High Pass filter which lets higher frequencies “pass” through. Higher Frequency signals such as R-waves, VT, and VF amplitudes remain largely unchanged.

1. Theuns, et al. Prospective Blinded Evaluation of a Novel Sensing Methodology Designed to Reduce Inappropriate Shocks by S-ICD. Heart Rhythm. 2018.
2. Theuns, et al. Evaluation of a Novel Algorithm Designed to Reduce Oversensing in the S-ICD. HRS 2016; AB05-01.
3. Willy, et al., Feasibility of entirely subcutaneous ICD systems in patients with coronary artery disease. Clin Res Cardiol, 2019.
4. Gasparini, et al., Long Detection Programming in Single-Chamber Defibrillators Reduces Unnecessary Therapies and Mortality. JACC: Clinical Electrophysiology, 2017.
5. Gold, et al. Design of the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low EF (UNTOUCHED). Pacing Clinical Electrophysiology, 2017.
6. Auricchio, et al., PainFree SST trial primary results. Heart Rhythm, 2015. 12(5): p. 926-936.

The S-ICD™ System

INDICATIONS FOR USE
The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.
CONTRAINDICATIONS
Unipolar stimulation and impedance-based features are contraindicated for use with the S-ICD System.
WARNINGS
Concomitant use of the S-ICD System and implanted electromechanical devices (for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. The S-ICD is intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants over non-lifesaving applications. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death. Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions changes which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.
PRECAUTIONS
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.
POTENTIAL ADVERSE EVENTS
Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmia, adverse reaction to induction testing, allergic/adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hematoma/seroma, hemothorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, injury to or pain in upper extremity, including clavicle, shoulder and arm, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumothorax, post-shock/post-pace discomfort, premature battery depletion, random component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis. Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.
Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev. E) 046774 AI

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