UNDERSTANDING OUTCOMES WITH THE S-ICD IN PRIMARY PREVENTION PATIENTS WITH LOW EJECTION FRACTION STUDY (UNTOUCHED)

LATE BREAKING CLINICAL TRIAL RESULTS – HRS 2020

Boston Scientific
Advancing science for life™

Overview

Objective: Compare the inappropriate shock (IAS) rate of modern EMBLEM™ S-ICDs in patients most commonly receiving ICDs (primary prevention, LVEF ≤ 35%) to the IAS rate of TV-ICDs with optimal programming observed in MADIT-RIT.

Hypothesis: The incidence of IAS in primary prevention, LVEF ≤ 35% patients will be non-inferior to the rate in TV-ICD patients with optimal programming observed in MADIT-RIT high rate and long duration arms B and C.[1]

Results: The UNTOUCHED study shows high S-ICD efficacy and safety despite the sickest cohort studied to date (LVEF% 26 ± 6, 54% ischemic, 41% prior MI, 88% NYHA class II/III, 33% diabetes). The IAS rates of **3.1%** at one year for all EMBLEM™ S-ICDs (Gen 2 and Gen 3) and **2.4%** at one year for EMBLEM™ MRI S-ICDs (Gen 3 only), are the lowest reported for S-ICD, and lower than many TV-ICD studies using contemporary programming to reduce IAS, supporting the use of S-ICD as a first line therapy for the traditional cohort of patients in need of an ICD to manage the risk of sudden cardiac death.[2]

Primary and Secondary Endpoints

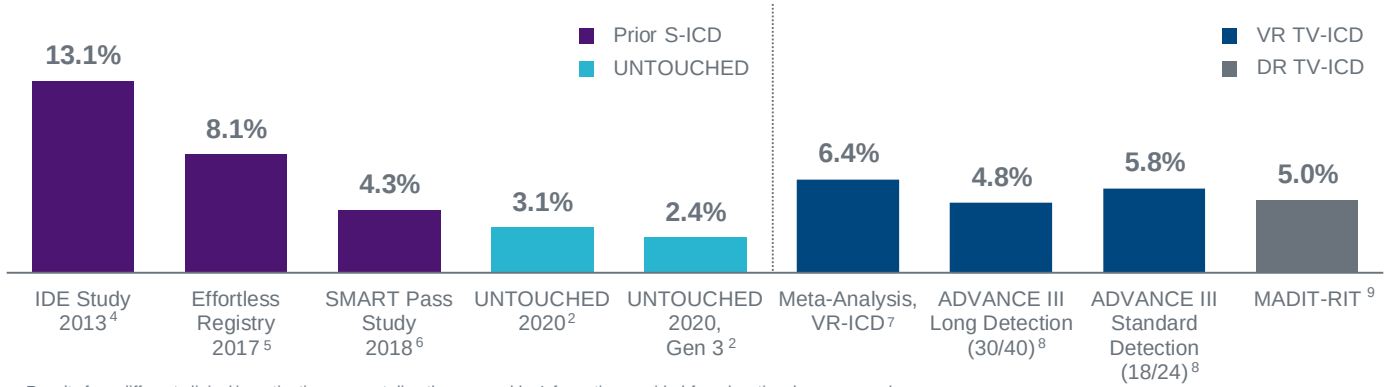
Primary Endpoint: IAS-free rate at 18 months met the performance goal of **91.6% (P<.0001)** derived from MADIT RIT IAS-free rate in Arms B and C

Secondary Endpoint: All cause shock-free rate at 18 months met the performance goal of **85.8% (P<.0001)**

Secondary Endpoint: System and procedure related complications at 30 days met the performance goal of **93.8% (P<.0001)**

One Year Inappropriate Shock Rates for S-ICD and TV-ICD

The one-year IAS rates measured across S-ICD studies have decreased substantially over time due to the implementation of conditional zone programming and technology improvements to minimize T-wave oversensing, including the SMART Pass filter. The 2020 UNTOUCHED study demonstrated IAS rates for S-ICD to be only half the rates for TV-ICDs as demonstrated in major studies, such as ADVANCE III and MADIT-RIT.



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

Discussion

Previous S-ICD trials typically had younger patients with less advanced heart disease and “niche” indications, including channelopathies, hypertrophic cardiomyopathy, previous ICD infection, or congenital heart disease. These groups do not represent patients most commonly receiving ICDs. UNTOUCHED is the first study designed to understand the IAS rate with S-ICD in the more traditional cohort of patients (primary prevention, LVEF ≤ 35%).[1]

UNTOUCHED is also the first study with all contemporary EMBLEM™ or EMBLEM™ MRI devices, and the first study to have prescriptive programming requiring no therapies delivered for rates <200 bpm, activation of the conditional zone for >200 bpm to 250 bpm, and the shock-only zone at ≥ 250 bpm. This programming is consistent with the high rates and long detection durations in MADIT-RIT, which was the study used to establish the performance goal for all shock endpoints in UNTOUCHED.[1]

UNTOUCHED demonstrated lower IAS rates for EMBLEM™ and EMBLEM™ MRI S-ICDs than the IAS rates seen in many TV-ICD studies using contemporary programming to reduce inappropriate shocks.[2] The results support the use of S-ICD as a first line therapy for the traditional cohort of patients in need of an ICD to manage the risk of sudden cardiac death.

1. Gold, M, et al. The Design of the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED). Pacing Clin Electrophysiol 2017;40:1–8.
2. Gold, M, et al. Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED) Trial Primary Results. LBCT HRS 2020.
3. Boersma, L, et al. Understanding Outcomes with the EMBLEM S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED): Clinical Characteristics and Perioperative Results. Heart Rhythm, 2019; 16:1636-1644.
4. Weiss, et al. The Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator. CIRCULATION. Vol. 128, no. 9. (August 2013.): 944-953.
5. Boersma, L, et al. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol 2017;70:830–841.
6. Theuns, et al. Prospective Blinded Evaluation of a Novel Sensing Methodology Designed to Reduce Inappropriate Shocks by S-ICD. Heart Rhythm. 2018;15:1515-1522.
7. Auricchio A, et al. Inappropriate shocks in single-chamber and subcutaneous implantable cardioverter-defibrillators: a systematic review and meta-analysis. Europace. 2017;19(12)
8. Gasparini, et al., Long Detection Programming in Single-Chamber Defibrillators Reduces Unnecessary Therapies and Mortality. JACC: Clinical EP, 2017. 3:1275–82.
9. Kutyifa, V et al., Novel ICD Programming and Inappropriate ICD Therapy in CRT-D Versus ICD Patients: A MADIT-RIT Sub-Study. Circ Arrhythm Electrophysiol, 2016. 9(1): p. e001965.

Boston Scientific
Advancing science for life™

www.bostonscientific.eu

CRM-805806-AA