Understanding Outcomes with the EMBLEM S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED): Clinical characteristics and perioperative results

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BACKGROUND The subcutaneous implantable cardioverter-defibrillator (S-ICD) has shown favorable outcomes in large registries with broad inclusion criteria. The cohorts reported had less heart disease and fewer comorbidities than standard ICD populations.

OBJECTIVE The purpose of this study is to characterize acute performance for primary prevention patients with a left ventricular ejection fraction (LVEF) ≤35% (primary prevention ≤35%).

METHODS Primary prevention ≤35% patients with no prior documented sustained ventricular tachycardia (VT), pacing indication, end-stage heart failure, or advanced renal failure were prospectively enrolled. Analyses included descriptive statistics, Kaplan-Meier time to event, and multivariable linear and logistic regression.

RESULTS In 1112 of 1116 patients, an S-ICD was successfully implanted (99.6%). Predictors for longer procedure time included 3-incision technique, higher body mass index (BMI), performing defibrillation testing (DFT), imaging, younger age, black race, and European vs North American centers. Patients undergoing DFT (82%) were successfully converted (99.2%; 93.5% converting at ≤65 J). Higher BMI was predictive of failing DFT at ≤65 J. The rate of 30-day freedom

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from complications was 95.8%. Most complications involved postoperative healing (45%) or interventions after DFT or impedance check (19%).

CONCLUSION The procedural outcome data of UNTOUCHED reinforce that S-ICD therapy has low perioperative complication rates and high conversion efficacy of induced ventricular fibrillation, even in a higher-risk cohort with low LVEF and more comorbidities than previous S-ICD studies. Higher BMI warrants more careful attention to implant technique.

KEYWORDS Arrhythmia; Heart failure; Implantable cardioverter-defibrillator; Primary prevention; Subcutaneous ICD; Sudden cardiac death; Ventricular arrhythmia

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Introduction

The subcutaneous implantable cardioverter-defibrillator (S-ICD) has proven to be a successful option for sudden cardiac death prevention among many patients with high risk of ventricular tachycardia or ventricular fibrillation (VT/VF). Initial registries[1–6] showing low complication rates and high effectiveness of VT/VF conversion included patients with a wide range of indications. Patients with a left ventricular ejection fraction (LVEF) ≤35% and a primary prevention indication (primary prevention ≤35%) were underrepresented in most registries, although the early registries showed equally good performance in this cohort.[1–6]

The UNTOUCHED study was designed specifically to evaluate patients undergoing S-ICD implantation for the most common indication for ICD therapy, primary prevention ≤35%, to compare inappropriate shock rates in this population[7] with those in the MADIT-RIT study.[7,8] With a contemporary version of the S-ICD device and algorithms, the periprocedural performance and safety are presented here.

Methods

Study design

The Understanding Outcomes with the EMBLEM™ S-ICD in Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) study (ClinicalTrials.gov Registration No.: NCT02433379) is a global, multicenter, prospective, nonrandomized study.[7]

Primary prevention ≤35% patients were eligible for the study if they met current guidelines for ICD implantation. Patients with a life expectancy of less than 18 months, a pacing indication, or a history of pace-terminable VT and those in end-stage heart failure or renal disease were excluded. The objective of this report is to describe the procedure and 30-day outcomes for the 1116 patients in 111 centers from North America and Europe in whom implant was attempted.[7]

The patient cohort underwent implantation from June 9, 2015, to April 10, 2018. An S-ICD screening test was required for inclusion.[1,6,9,10] Procedural techniques, including defibrillation testing (DFT), surgical technique, and anesthesia, were left to the operator's discretion. Devices were programmed with conditional and shock zones at 200 beats per minute (bpm) and 250 bpm.

Obtaining and documenting informed consent was done in accordance with the principles of the Declaration of Helsinki, ISO 14155, and all pertinent laws and regulations. Patients were enrolled after providing written informed consent in accordance with all applicable guidelines and laws, and after ethics committee/institutional review board approval. Complications were defined as events resulting in death, serious injury, correction using invasive intervention, or permanent loss of device function and that were caused by, or would not have occurred in the absence of, the S-ICD system.[1,3,4,6] Procedure time was defined as the duration from first incision to wound closure. DFT success was defined as conversion of induced VT/VF at any energy, chosen at the discretion of the implanter, and analyzed for success at ≤65 J and >65 J. The reported results are based on the database snapshot taken in January 2019.

Statistical analysis

Basic characteristics were analyzed using descriptive statistics. Continuous variables were summarized by the number of patients and mean ± standard deviation. Categorical variables were summarized by frequencies and percentages of patients in each category. *P* values for group comparisons were calculated using a pooled *t* test for continuous variables and χ^2 for categorical variables. Kaplan-Meier time-to-event analyses were conducted with censoring of subjects at their last known status. Multivariable generalized linear regression was used to calculate parameter estimates, standard error, least squared means, and *P* values for model predictors of continuous variables; namely, procedure time. Multivariable logistic regression was used to calculate odds ratios (OR), 95% confidence intervals (CI), and *P* values for model predictors of categorical variables; namely, DFT success at ≤65 J vs >65 J and the occurrence of 30-day complications. For multivariable analysis, all variables of interest were entered in the model. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Author Contributions

Drs Boersma, Bongiorni, Knops, Lambiase, Deharo, Gold, Burke, Aasbo, El-Chami, and Russo serve as Steering Committee Members for the UNTOUCHED study and contributed to study design. They, as well as Drs Dinerman, Shaik, and Barr, served as Principal Investigators for their respective centers. Dr Stein contributed to study concept and design. Ursula Appl, Nathan Carter, and Amy Brisben supported data analyses. Nathan Carter performed all statistical analyses. Lucas Boersma wrote the manuscript with assistance from Amy Brisben Revision and final review were done by all the authors.

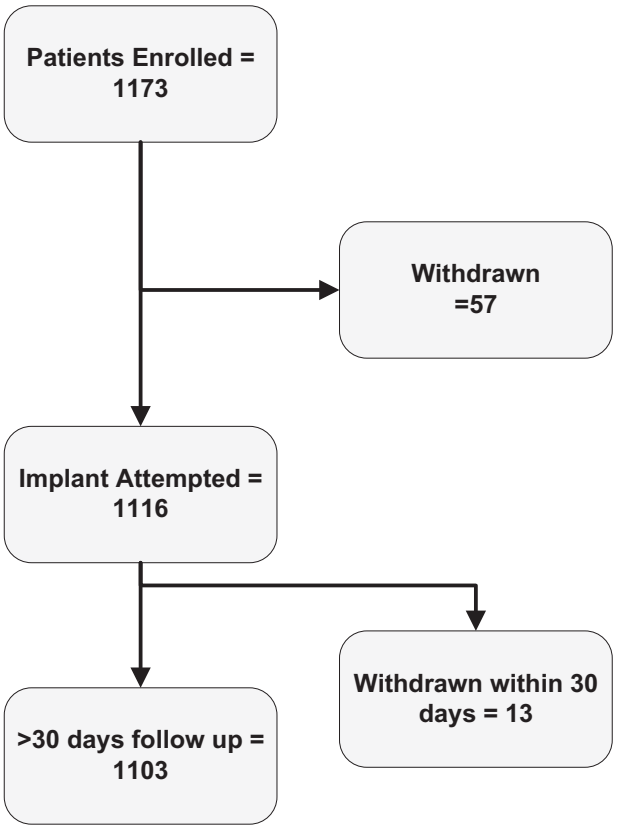


Figure 1 Patient status through 30 days. See Supplemental Table 5 for reasons for study withdrawal.

Results

Patient demographic characteristics

As shown in Figure 1, of the 1173 patients enrolled in the study (enrollment by country is provided in Supplemental Table 1), 57 patients were withdrawn prior to implant. An implant was attempted in 1116 patients, with 1103 patients remaining in the study through 30 days.

Table 1 illustrates the baseline patient characteristics for UNTOUCHED, in comparison with IDE, EFFORTLESS, and PAS S-ICD and MADIT-RIT studies (ICD recipients only). The UNTOUCHED patients are older, have more comorbidities, and are more likely to be NYHA class II/III and of ischemic etiology than the S-ICD patients in prior studies. Compared with the MADIT-RIT cohort, UNTOUCHED patients have similar comorbidities but are younger and less likely to be NYHA class II/III and of ischemic etiology. Patient characteristics indicate that the UNTOUCHED population is closer to the MADIT-RIT ICD cohort than previous S-ICD studies. Patients enrolled in European centers (total 292) were more often male and ischemic in etiology, while the North American centers (total 824) enrolled almost all patients self-identifying as black race (95%; Supplemental Table 2). Patients of black race had more comorbidities, were more likely to be younger and female, had a lower LVEF (25 ± 6), had a higher body mass index (BMI; 33 ± 9), and were more often diagnosed with a nonischemic etiology (71.5%) than the nonblack patients (40.3%).

Table 1 Baseline characteristics of patients in UNTOUCHED and comparison with S-ICD and MADIT-RIT studies

Parameter	UNTOUCHED[††]	IDE[6‡‡]	EFFORTLESS[2‡‡]	PAS[3††,‡‡]	MADIT-RIT[8‡‡] TV-ICD only
Description	Global trial Primary prevention LVEF ≤35%	Premarket safety and efficacy trial	Global postapproval registry, Gen 1	US postapproval registry, Gen 2	Evaluation of IAS with high rate cutoff and/or programming delay Primary prevention LVEF ≤35%
Device type	S-ICD	S-ICD	S-ICD	S-ICD	TV-ICD only
Enroll start date	June 2015	January 2010	October 2010	March 2013	Sep 2009
Age, years	(n = 1116) 56 ± 12	**(n = 321)** **52 ± 16**[§]	**(n = 985)** **48 ± 17**[§]	**(n = 1637)** **53 ± 15**[§]	**(n = 742)** **61 ± 12**[§]
Gender female	286/1116 (26)	83/321 (26)	275/985 (28)	**514/1637 (31)**[‡]	174/742 (23)
LVEF, %	(n = 1116) 26 ± 6[¶]	**(n = 299)** **36 ± 16**[§]	**(n = 789)** **43 ± 18**[§]	**(n = 1593)** **32 ± 15**[§]	**(n = 742)** **27 ± 7**[§,¶]
NYHA II/III/IV	888/1013 (88)[#]	**202/270 (75)**[§]	**206/985 (21)**[§]	**1358/1637 (73)**[§]	**702/729 (96)**[§,#]
Primary prevention	1116/1116 (100)[†]	**255/321 (79)**[§]	**638/985 (65)**[§]	**1254/1637 (77)**[§]	**742/742 (100)**[†]
Ischemic	570/1065 (54)	**73/321 (23)**[§]	**311/983 (32)**[§]	**672/1637 (41)**[§]	**457/741 (62)**[‡]
Hypertension	787/1116 (71)	**187/321 (58)**[§]	**279/985 (28)**[§]	**1009/1637 (62)**[§]	500/739 (68)
Diabetes	364/1116 (33)	90/321 (28)	**110/985 (11)**[§]	550/1637 (34)	239/733 (33)

Unless otherwise noted, values are ratio of patients: n/N (%); or number of patients and mean ± standard deviation.

IAS = inappropriate shock; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; S-ICD = subcutaneous implantable cardioverter-defibrillator; TV-ICD = transvenous implantable cardioverter-defibrillator.

Values in bold differ significantly from the UNTOUCHED study.

[†] $P < .01$.

[‡] $P < .001$.

[§] $P < .0001$.

[¶] LVEF ≤35% per prespecified protocol.

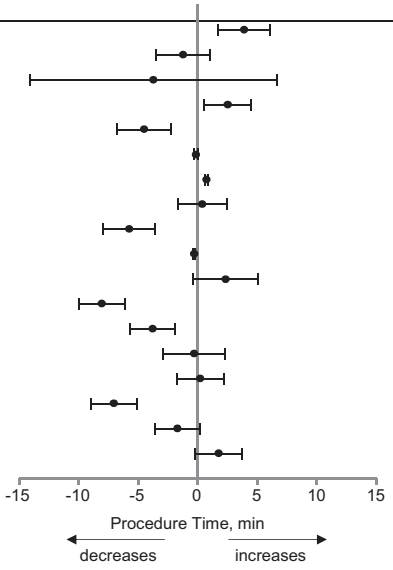
[#] Trial excluded NYHA class IV patients per prespecified protocol.[‡‡] Patient population 100% primary prevention per prespecified protocol.

[††] Patient population 100% primary prevention per prespecified protocol.

[‡‡] Source: Boston Scientific Corporation; data on file.

A

Variable	Unit or Comparison (LS means)	Estimate ± std error	p-value
Antiplatelet Use	yes (55.7) vs. no (59.5)	3.88 +/- 2.21	0.08
Anticoagulants	yes (59.7) vs. no (58.5)	-1.25 +/- 2.23	0.58
Procedure type	replacement (62.4) vs. initial (58.7)	-3.74 +/- 10.39	0.72
History of diabetes	yes (58.5) vs. no (61.2)	2.5 +/- 1.94	0.20
DFT performed	**yes (59.6) vs. no (55.1)**	**-4.52 +/- 2.3**	**0.0498**
LVEF	percent	-0.17 +/- 0.16	0.27
BMI	**kg/m^2**	**0.72 +/- 0.13**	**<.0001**
Sex	male (58.6) vs. female (59.0)	0.36 +/- 2.06	0.86
Race	**black (63.3) vs. non-black (57.6)**	**-5.77 +/- 2.19**	**0.0087**
Age	**year**	**-0.31 +/- 0.07**	**<.0001**
Atrial Fibrillation	yes (56.7) vs. no (59.0)	2.32 +/- 2.76	0.40
Incision Technique	**3 (63.6) vs. 2 incision (55.6)**	**-8.07 +/- 1.92**	**<.0001**
Ischemic Etiology	non-ischemic (60.9) vs. ischemic (57.1)	-3.8 +/- 1.87	0.04
Kidney Disease	yes (59.0) vs. no (58.7)	-0.32 +/- 2.57	0.90
High Blood Pressure	yes (58.7) vs. no (58.9)	0.19 +/- 1.97	0.92
Imaging performed	**yes (61.0) vs. no (54.0)**	**-7.06 +/- 1.91**	**0.0002**
General anesthesia	yes (59.3) vs. no (57.6)	-1.73 +/- 1.9	0.36
Geography	North America (58.2) vs. Europe (60.0)	1.73 +/- 1.98	0.38



B

Variable	Unit or Comparison (LS means)	Estimate ± std error	p-value
Anticoagulants	yes (61.2) vs. no (58.4)	-2.83 ± 2.29	0.22
History of diabetes	yes (58.5) vs. no (61.2)	2.71 ± 2.02	0.18
BMI	**kg/m^2**	**0.65 ± 0.14**	**<.0001**
Age	**year**	**-0.21 ± 0.08**	**0.0061**
Race	**black (62.3) vs. non-black (57.3)**	**-5.08 ± 2.27**	**0.03**
Incision technique	**3 (63.8) vs. 2 incision(55.8)**	**-8.04 ± 1.93**	**<.0001**
Imaging performed	**yes (63.9) vs. no (55.8)**	**-8.12 ± 1.96**	**<.0001**
DFT performed	**yes (63.1) vs. no (56.5)**	**-6.6 ± 2.42**	**0.0065**
Geography	**North America (56.1) vs. Europe (63.6)**	**7.51 ± 2.18**	**0.0006**

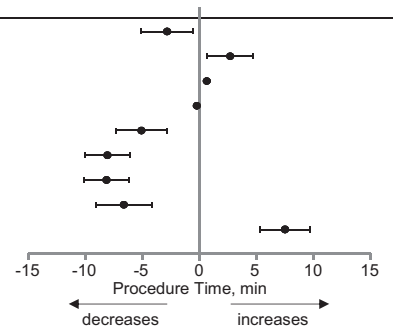


Figure 2 Linear predictor model: factors affecting procedure time. **A:** Univariable model. **B:** Multivariable model. BMI = body mass index; DFT = defibrillation testing; LVEF = left ventricular ejection fraction.

Implant procedure

General anesthesia (GA) was used in 62.3% of implant procedures, whereas conscious sedation was used in 33.4%. Study centers in Europe employed GA less frequently than in North America (53.8% vs 66.6%; $P < .0001$). Procedure time was 58.1 ± 27.5 minutes and medical imaging was used in 67.3% of procedures. The electrodes were placed in the left or midsternal location in 98% of cases. The inferior sternal incision technique (2-incision technique)[11] was used in 68.64% of cases and the inferior/superior sternal in 28.84% (3 incisions); in 2.52% incision technique was not specified. Predictors for a longer procedure (Figure 2) included patient characteristics (greater BMI, younger age, and patients of black race) and procedural factors (3-incision vs 2-incision technique, performing DFT, and performing imaging). Multivariable least square estimates for procedure time demonstrated 7.5 minutes increase in European centers compared to North American centers. There is a higher proportion of female and white subjects in the 3-incision vs 2-incision technique cohort (30.2% vs 23.8% and 76.6% vs 66.0%; Supplemental Table 3), and BMI and cancer rates were greater.

Conversion testing

DFT (Figure 3) was attempted in 82.1% of the patients, with failure to induce VT/VF in 4 subjects. In the remaining 912 patients, induced VT/VF was successfully converted by the device in 99.2% of patients, with 93.5% of patients successfully converted at ≤65 J. Two of these patients originally failed DFT, then underwent a pocket revision and had a successful DFT. Of the 7 patients who had only failed DFT (0.8%), 4 were not implanted and 3 remained implanted without further sequelae through the 30-day window.

Univariable analysis showed that lower BMI was the only predictor of DFT success at ≤65 J (Supplemental Figure 1A), whereas multivariable analysis showed lower BMI (OR 0.94 per kg/m^2 increase, 95% CI 0.9–0.98, $P = .002$) and presence of diabetes (OR 2.4, 95% CI 1.1–5.2, $P = .03$) were predictors of DFT success ≤65 J (Supplemental Figure 1B).

Patients who did not undergo DFT (n = 200) were more likely to be male (81.4% vs 72.9%; $P = .02$), be black (32.0% vs 21.7%; $P = .004$), and have a lower LVEF (25% ± 7% vs 27% ± 6%; $P < .0001$). DFT was less likely to take place without GA (51.3% vs 65.8%, $P < .0001$). Of the 79 centers that had 5 or more attempted implants, 71

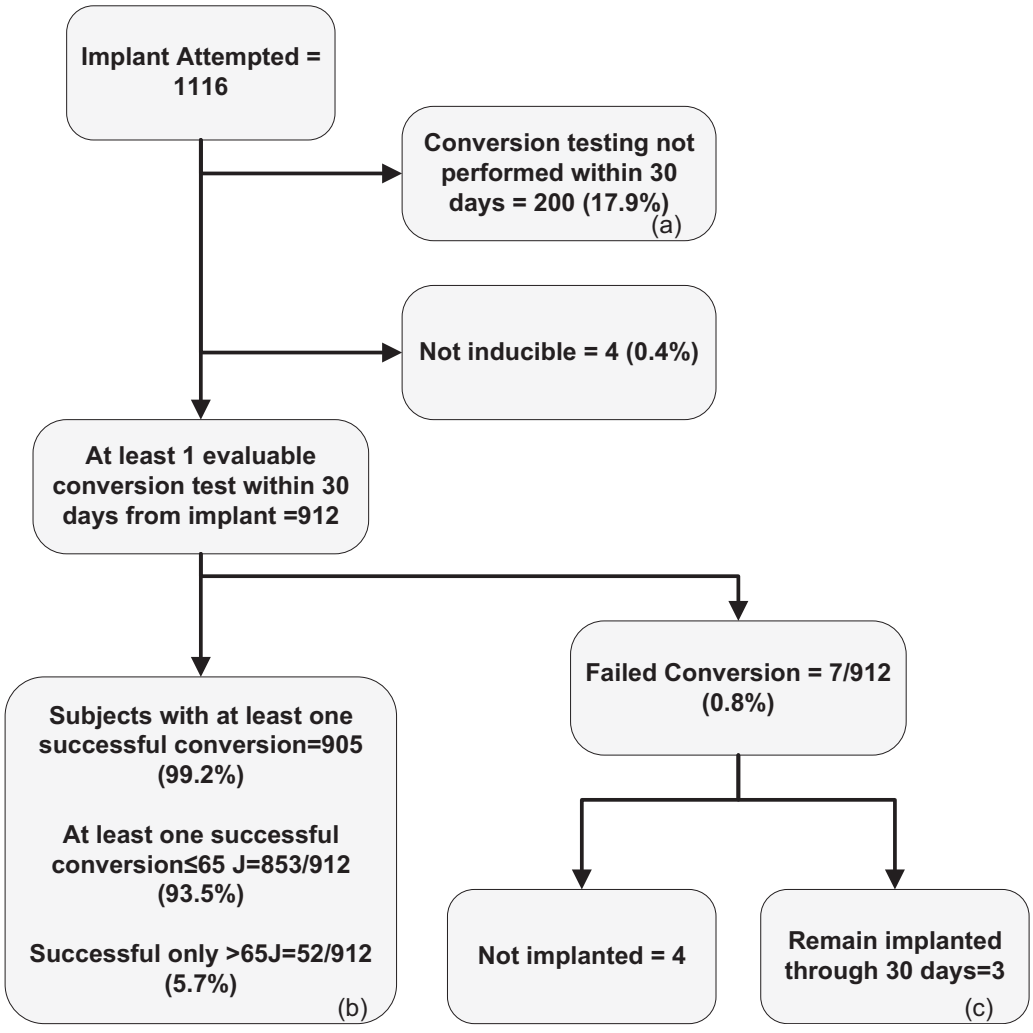


Figure 3 UNTOUCHED defibrillation testing (DFT). Notes: [a]One patient withdrawn, no information on DFT. [b]Two patients were first unsuccessful at 80 J, then pocket revision with subsequently successful DFT. Both patients completed follow-up without spontaneous episodes. [c]One patient: device explanted at day 41. One patient: electrode repositioned 42 days after implant; DFT reperformed and successful; patient has successfully completed study. One patient: completed follow-up without any spontaneous episodes.

centers performed DFT on at least 50% of their patients and 57 centers performed DFT on at least 75% of their patients. DFT was performed in 79.8% of patients in Europe and 82.4% of patients in North America.

Programming summary

Device programming summary is available for all but 28 patients. There was high adherence to the study protocol[7] (98.3%) to program the S-ICD at 200 bpm and 250 bpm. The programmed vector was primary (55.4%) or secondary (33.6%) for most patients, with the alternate vector programmed for 6.8% patients.

In the first 30 days, there were 13 patients with 48 treated spontaneous episodes. Adjudication of episodes for appropriateness will be part of the primary endpoint analysis.

Complications

Freedom from complications at 30 days was 95.8% (Figure 4). The most common causes of complications (Table 2) were related to postoperative healing or pain management (1.9%), miscellaneous procedure-related events (1.0%), and interventions after DFT or impedance check (0.8%). Most complications due to device infection resulted in system explant (6/7). The seventh patient was hospitalized for 6 days, was treated with intravenous medication, and completed the study without any subsequent complications. Bacteremia was not present (0/7).

Univariable predictors of complications (Supplemental Figure 2) are the use of any antiplatelets, a higher BMI, and longer procedure time. Multivariable analysis resulted in no significant predictors.

Nine complications required system electrode or pulse generator (PG) repositioning (Supplemental Table 4 and Table 2). The repositioning rate was 0.81%; 1.75% (5) in female and 0.48% (4) in male patients. Repositioning for female patients was due to electrode migration/movement, suboptimal electrode position, or electrode suture issues. For male patients 3 of 4 were due to DFT failures, 2 of which involved PG repositioning.

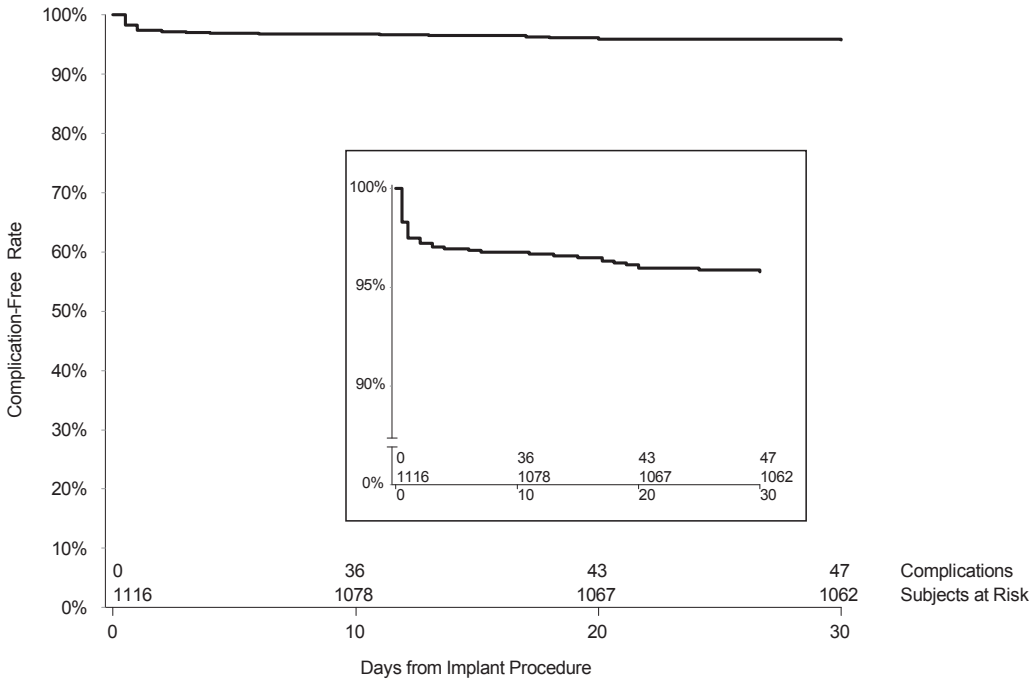


Figure 4 Freedom from complications. Kaplan-Meier analysis for freedom from subcutaneous implantable defibrillator system- or procedure-related complications for the first 30 days postimplant.

Procedural outcomes across S-ICD studies

Procedure time and the percentage of patients undergoing conversion testing were significantly lower than previous S-ICD trials (Table 3). Complications and DFT success rates are like previous S-ICD trials.

Discussion

The UNTOUCHED study is designed to provide outcome data in patients with depressed LVEF indicated for primary prevention of sudden cardiac death—the largest patient population being implanted with an ICD. The current analysis involves the periprocedural outcomes up to 30 days follow-up of 1116 patients with an attempted implant. The data reconfirm S-ICD reliability to convert VT/VF and the low number of periprocedural complications observed in prior S-ICD registries.

Patient demographics

By design, all patients had LVEF $\leq$35%. Compared with prior S-ICD registries, advanced heart failure, ischemic heart disease, hypertension, and diabetes were more common. The present population more closely resembles the MADIT-RIT patient cohort with a transvenous ICD implanted,[8] albeit younger and with fewer ischemic heart disease cases. These differences might reflect a selection bias to avoid elderly patients with a perceived need for pacing either at or soon after implant.

About 25% of patients declared their race as "black," a cohort 95% enrolled in the United States. They were much more likely to be nonischemic and were a generally sicker population. Similar increased comorbidity in primary prevention $\leq$35% black patients was reported in the PROSE-ICD trial.[12] Black patients had longer procedure times but less frequently underwent DFT. Further study is warranted in this population.

Implant procedure

The devices implanted in the UNTOUCHED study were EMBLEM (Boston Scientific, Marlborough, MA) and EMBLEM MRI devices, which have MRI compatibility, the AF detection and SMART PASS algorithms, and longer-lasting battery. Compared to previously studied S-ICD devices, they are also smaller (59.5 cc vs 69 cc) and have 2 suture holes for fixation, potentially influencing procedure time and complications.

Procedure times for implant were shorter than in previous S-ICD registries. The 2-incision technique has become widely adopted worldwide, which shortens procedure time without increasing complications. In the North American cohort procedures were shorter than in the EU cohort, potentially influenced by their more frequent use of GA.

BMI was also observed to influence procedure time. During implant, the S-ICD's proper position and plane ideally should be directly on or between the muscle layers and the parasternal shock coil should be as close as possible to the muscle and rib cage to facilitate low impedance and proper energy transmission to the heart.[13,14] Furthermore, a posterior position of the PG parallel to the cardiac silhouette is important to have an optimal shock vector. This may be more difficult in patients with higher BMI, resulting in longer procedure times.

Table 2 UNTOUCHED study complications

	UNTOUCHED					
	All		Women		Men	
Classification	Events	N (%)	Events	N (%)	Events	N (%)
Sub-optimal position/movement	**5**	**5 (0.4)**	**4**	**4 (1.4)**	**1**	**1 (0.1)**
Suboptimal electrode position	2	2 (0.2)	2	2 (0.7)*		
Electrode migration/revision	2	2 (0.2)	1	1 (0.3)*	1	1 (0.1)*
Electrode movement	1	1 (0.1)	1	1 (0.3)*		
Sensing/device function	**1**	**1 (0.1)**			**1**	**1 (0.1)**
Inappropriate shock/oversensing	1	1 (0.1)			1	1 (0.1)
Conversion test-related	**9**	**9 (0.8)**			**9**	**9 (1.1)**
Out-of-range shock impedance–electrode	1	1 (0.1)			1	1 (0.1)
Unable to convert VT/VF with S-ICD	8	8 (0.7)			8	8 (1.0)†
Postoperative healing / pain management	**21**	**21 (1.9)**	**5**	**5 (1.7)**	**16**	**16 (1.9)**
Electrode suture discomfort	1	1 (0.1)	1	1 (0.3)*		
Postsurgical wound discomfort PG site	4	4 (0.4)	1	1 (0.3)	3	3 (0.3)
Incisional/superficial infection	2	2 (0.2)			2	2 (0.2)
Device system infection	7	7 (0.6)	2	2 (0.7)	5	5 (0.6)
Suspected infection–incisional/superficial	1	1 (0.1)			1	1 (0.1)
Hematoma–PG pocket (≤30 d postimplant)	4	4 (0.4)			4	4 (0.5)
Physical trauma	2	2 (0.2)	1	1 (0.3)	1	1 (0.1)
Other procedure-related	**12**	**11 (1.0)**	4	4 (0.5)	8	7 (0.8)
Adverse reaction–respiratory	1	1 (0.1)			1	1 (0.1)
Adverse reaction–hypotension	3	3 (0.3)	1	1 (0.3)	2	2 (0.2)
Adverse reaction–medication/anaphylactic shock	1	1 (0.1)	1	1 (0.3)		
Adverse reaction–HF symptoms	1	1 (0.1)	1	1 (0.3)		
Acute blood loss	1	1 (0.1)	1	1 (0.3)		
Postoperative urinary retention	1	1 (0.1)			1	1 (0.1)
Hemodynamic instability–DFT	1	1 (0.1)			1	1 (0.1)
Fascial defect closure	1	1 (0.1)			1	1 (0.1)
Suture revision	1	1 (0.1)			1	1 (0.1)
Syncope	1	1 (0.1)			1	1 (0.1)

Text in bold indicate categories of complications and sub-totals of events, N, % for each category.

DFT = defibrillation testing; HF = heart failure; PG = pulse generator; S-ICD = subcutaneous implantable cardioverter-defibrillator; VT/VF = ventricular tachycardia/ventricular fibrillation.

*Patients underwent electrode repositioning.

†One patient underwent electrode repositioning; 2 patients underwent PG repositioning.

Table 3 Procedural outcomes for UNTOUCHED and comparison with other S-ICD studies

Outcome	IDE[6‡‡]	EFFORTLESS[2‡‡]	PAS[3‡‡]	UNTOUCHED
2-incision technique	**0/321 (0.0)**§	N/A	**855/1637 (52.2)**§	764/1113 (68.6)
Procedure time (minutes)¶	N/A	**(n = 985)**	**(n = 1615)**	(n = 1099)
		66.8 ± 28§	**77.3 ± 36.2**§	58.1 ± 40.6
% Patients who underwent DFT	**320/321 (99.7)**§	**861/985 (87.4)**‡	**1412/1637 (86.3)**§	916/1116 (82.1)
DFT success rate	304/304 (100)#	**857/861 (99.5)**†	1394/1412 (98.7)	905/912 (99.2)
DFT success rate ≤65 J	N/A	**789/861 (91.6)**†	**1286/1412 (91.1)**†	853/912 (93.5)
30-day complication rate††	4.4%	4.1%	3.8%	4.2%

Values are ratio of patients: n/N (%), or number of patients and mean ± standard deviation, unless otherwise noted.

Text in bold indicate *P* values < 0.05.

DFT = defibrillation testing; N/A = Not applicable.

†$P < .05$.

‡$P < .001$.

§$P < .0001$.

¶Duration from first incision to wound closure (minutes).

#The IDE study included a rigorous DFT protocol; thus results are not directly comparable.

††Rates derived from Kaplan-Meier analysis.

‡‡Source: Boston Scientific Corporation; data on file.

Conversion testing

BMI did not influence the decision to perform DFT, although it may have significant effects on electrical current transmission through the thorax. Although DFT was successful in 99% of patients, and in 93% at 65 J or less, BMI was a predictor for failed conversion at ≤65 J in multivariable analysis. In the IDE S-ICD study, Amin and colleagues[13] found that BMI, while a predictor of conversion failure, was not a factor in conversion failure for appropriately placed devices. This study as well as recent work by Knops and colleagues[15] suggests that improper anatomical position and fat between the device and the rib cage were associated with DFT failure. The PRAETORIAN scoring system[15] was devised to predict such failure and guide physicians' implant techniques, which will be prospectively studied in the PRAETORIAN DFT trial (ClinicalTrials.gov Registration No. NCT03495297).

DFT was not performed in 17.9% of patients, among them more male subjects and patients with lower LVEF. The choice to not perform DFT appears to be more patient-specific than center-specific during the UNTOUCHED study and potentially influenced by the availability of GA. The perceived risk of certain patient characteristics such as lower LVEF and higher comorbidities may have prompted caution to perform DFT. There seems to be a trend to forgo DFT by implanters worldwide. The findings of the SIMPLE and NORDIC ICD trials showing the noninferiority for avoiding DFT in transvenous ICD patients,[16,17] as well as high conversion efficacy in prior S-ICD registries, may lead physicians to extend this trend to the S-ICD. In the current population there were 2 patients requiring repositioning of PG to have a successful DFT and 4 others deemed unsuitable owing to failed DFT and then implant aborted. Of note, all patients who failed DFT or required repositioning had LVEF ≤25% and were male. Similar additional efforts were required in the NORDIC ICD trial for 25 of 519 patients[16] and in the SIMPLE trial for 37 of 1119 patients[17] in order to obtain successful DFT. Until more prospective studies are performed, it seems prudent to adhere to international guidelines recommending DFT in patients with an S-ICD.[18–20]

Implant and 30-day procedural safety

Overall, the complication rate was as low as in prior S-ICD registries, despite the current population having much lower LVEF, more hypertension, and diabetes. This is reassuring, as sicker patients still do well with this implantation. The need for repositioning the lead and/or PG was low; in men repositioning was owing primarily to DFT failure, whereas in women electrode migration or discomfort were the reasons. It seems that implant techniques have matured such that the appropriate surgical skills are recognized and become standard of care.[21–23] There were no characteristics (e.g., ischemic heart disease, gender, or BMI) observed that predicted procedural complication.

Limitations

Although all data were prospectively collected as part of the UNTOUCHED trial, the current report is a retrospective analysis. The study was not designed to evaluate interactions between race, geography, or characteristics of underlying disease. Comparisons between trials are strictly observational and may contain important confounding variables.

Conclusions

The procedural outcome data of UNTOUCHED reinforce that S-ICD therapy has low perioperative complication rates and high conversion efficacy of induced VT/VF, even in a higher-risk cohort with low LVEF and more comorbidities. Among experienced implant centers, the 2-incision technique has a shorter implant procedure time without impacting safety or efficacy. Higher BMI is not an independent predictor of complications, yet it does warrant more careful attention to implant technique to assure successful conversion.

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Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2019.04.048.

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