Performance of the subcutaneous implantable cardioverter-defibrillator in patients with a primary prevention indication with and without a reduced ejection fraction versus patients with a secondary prevention indication

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BACKGROUND The subcutaneous implantable defibrillator (S-ICD) provides an alternative to the transvenous ICD for the prevention of sudden cardiac death, but has not been well studied in the most commonly treated transvenous ICD patient population, namely, primary prevention (PP) patients with left ventricular dysfunction.

OBJECTIVE The analyses in the present study were designed to compare clinical outcomes for PP patients with and without a reduced ejection fraction (EF) and secondary prevention (SP) patients implanted with the S-ICD.

METHODS All patients 18 years and older from the S-ICD IDE study and the EFFORTLESS Registry with available data as of November 18, 2013, were included (n = 856; mean follow-up duration 644 days). Outcomes were evaluated in 2 analyses: (1) comparing all PP patients (n = 603, 70.4%) with all SP patients (n = 253, 29.6%) and (2) comparing all PP patients with an EF ≤35% (n = 379) with those with an EF >35% (n = 149, 17.4%).

RESULTS No differences were observed in mortality, complications, inappropriate therapy, or ability to convert ventricular tachyarrhythmias between SP and PP patients. However, SP patients had a higher incidence of appropriate therapy than did PP patients (11.9% vs 5.0%; P = .0004). In the PP subanalysis, the cohort with an EF ≤35% had significantly older patients with more comorbidities and higher mortality (3.0% annually vs 0.0%). Despite these differences, device-related complications, conversion efficacy, and incidence of inappropriate shock therapies were not significantly different between PP subgroups.

CONCLUSION The S-ICD performs well in protecting patients with either PP or SP implant indications from sudden cardiac death. Within PP patients, device performance was independent of EF.

KEYWORDS Subcutaneous ICD; Primary prevention; Secondary prevention; Ejection fraction; Appropriate shock

Introduction The benefit of implantable defibrillator (ICD) therapy in reducing arrhythmic death in patients with either a secondary
has been established through a number of studies over the past 2 decades. As these studies have resulted in an increased number of patients receiving a transvenous ICD (TV-ICD), the incidence of device- and lead-related complications requiring reoperation or explantation has also increased concomitantly.5,6

The subcutaneous implantable defibrillator (S-ICD) was developed as an alternative to the TV-ICD, without the need to implant transvenous or epicardial leads. The safety and effectiveness of the S-ICD has been established,7,8 and the largest S-ICD studies include a wide variety of ICD-indicated patients.9 The S-ICD is often selected for younger patients with inherited diseases and normal ventricular function,10 yet patients with the more common indication of a reduced left ventricular (LV) ejection fraction (EF) remain the largest major subgroup implanted. We sought to understand the device performance and patient outcomes in patients with a PP indication, and specifically those with a reduced EF. We retrospectively evaluated the long-term clinical outcomes of patients implanted with the S-ICD for both primary and secondary indications. A second analysis was performed to compare outcomes for PP patients with an EF cutoff of ≤35% (“PP EF ≤35%”) with those for PP patients with an EF >35% (“PP EF >35%”).

**Methods**

**Patient population**

The patients included in the analysis were those implanted as part of the pivotal S-ICD System Clinical Investigation (“IDE study”) and the initial cohort of the EFFORTLESS S-ICD Registry (“EFFORTLESS Registry”) as previously described.11 In brief, the IDE study was designed to demonstrate the safety and efficacy of the S-ICD system for Food and Drug Administration approval while the EFFORTLESS Registry is an ongoing standard-of-care postmarket evaluation of long-term clinical outcomes in 1000 patients commercially implanted with the S-ICD in countries outside the United States. For the IDE study, the data presented reflect information from all implanted patients (implanted between January 27, 2010, and May 20, 2011), while for the ongoing EFFORTLESS Registry, the data reflect information available as of November 18, 2013 (first implantation on August 20, 2009). Ethical approval was obtained in all centers for the purpose of each study, and all patients provided informed consent according to national and institutional regulations.

For the present analysis, the initial pooled data set consists of 889 enrolled patients: 308 from the IDE study, 568 from the EFFORTLESS Registry, and 13 patients common to the 2 studies. The analysis included patients from 58 clinical centers in 8 countries. Twenty-nine patients were subsequently excluded from the analysis because they were younger than 18 years at the time of implantation, and an additional 4 patients were excluded because of insufficient baseline data to characterize the indication for implantation.

The remaining 856 patients are included in the analysis of SP and PP patients for all-cause mortality and device- and procedure-related complications. Only patients successfully implanted with the S-ICD system (853) are included in the analysis of shock therapy (appropriate and inappropriate).

The analysis of PP patients by EF level included all PP patients with sufficient EF data. EF measurements were recorded as available for patients in the IDE study and EFFORTLESS Registry. Device programming was left to the discretion of the implanting physician in both studies.

**Statistical and data analysis**

All outcomes were evaluated through the latest available follow-up. Two separate analyses were completed. First, clinical outcomes for all patients implanted for SP were compared with patients implanted for PP. Second, a subsequent analysis further subdivided the PP patients on the basis of EF into PP EF >35%, or PP EF ≤35%. The appropriateness of pooling study data, event definitions, and event adjudications have been previously described.8,10

Baseline demographic and clinical characteristics, including medical history, risk factors, comorbidities, and New York Heart Association functional class for heart failure, are presented as available. Continuous variables are summarized as means ± SDs or as medians and ranges, where appropriate. Continuous data were compared using the Student t test. Categorical variables are summarized as frequencies and percentages and compared using the χ2 test. Freedom from complications, mortality, and appropriate shock and inappropriate shock rates are analyzed using the Kaplan-Meier method. All statistical analyses were performed using SAS Enterprise Guide, version 5.1 (SAS 9.3, SAS Institute Inc. NC USA).

**Results**

Of the 856 patients in the primary analysis cohort, 29.6% were SP patients (n = 253) and 70.4% were PP patients (n = 603). Of the 603 PP patients, 379 had an EF ≤35% (62.9%), 149 had an EF >35% (24.7%), and 75 (12.4%) lacked sufficient data to determine baseline LVEF. Missing LVEF values were observed primarily in the EFFORTLESS Registry, predominantly in patients with etiologies that are not characterized by low EF. The mean follow-up duration for all patients was 644 days, with a range of 2–1542 days (median 633 days). There were no significant differences in follow-up duration between any of the groups evaluated (663, 636, 621, and 658 days for SP, PP, PP EF ≤35%, and PP EF >35%, respectively).

**Baseline demographic characteristics**

Patient characteristics and baseline demographic characteristics are summarized in Tables 1 and 2. In general, SP patients had a lower incidence of comorbidities than did PP patients (Table 1). The mean LVEF was significantly higher in SP patients (48%) than in PP patients (36%) (P < .0001). PP patients had a significantly higher incidence of congestive
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