Device Therapy - Implantable Cardioverter Defibrillator (ICD)

Five year outcomes of the subcutaneous implantable cardioverter-defibrillator EFFORTLESS (evaluation of factors impacting clinical outcome and cost effectiveness of the S-ICD) registry

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OnBehalf: EFFORTLESS Registry

Introduction: Patients (pts) implanted with transvenous (TV) implantable cardioverter-defibrillator (ICD) experience complications (Cx) associated with TV leads and inappropriate shocks (IAS) for atrial fibrillation (AF) or other supraventricular tachycardias (SVT). The EFFORTLESS S-ICD Registry is a 5-year (yr) follow-up (f/u) study of pts implanted with the subcutaneous ICD (S-ICD).

Purpose: To report on the 5-yr outcomes of pts with a wide range of S-ICD indications implanted with early generation devices.

Methods: Pts were enrolled at 43 centers February 2011-December 2014. Kaplan-Meier Cx, appropriate shock (AS), and IAS rates are reported.

Results: 994 pts (495 retrospective) were enrolled in the EFFORTLESS study and 984 pts (28% female, 48 ± 17 yrs, BMI 27 ± 6 kg/m2, ejection fraction 43 ± 18%) underwent S-ICD implantation. Mean study f/u was 4.4 ± 1.6 yrs. The pt cohort had diverse etiologies: 31% ischemic heart disease, 19% non-ischemic cardiomyopathy, 11% hypertrophic cardiomyopathy, 17% channelopathies, and 20% of pts miscellaneous. Total system- and procedure-related Cx (table) were 9.4% at 5 yrs. AS and IAS rates at 5 yrs were 15.9% and 16.9%, respectively and the IAS rates for AF/SVT and t wave oversensing were 3.1% and 5.8%, respectively. More pts experienced Cx and IAS in the first yr than in yrs 2-5 altogether (8.7 vs 8.2%), the most common as a result of discomfort/erosion (38%), IAS (26%), system infection (9%), and premature battery depletion (9%). Of these late Cx, 74% were experienced by retrospective pts. Spontaneous conversion efficacy for the first shock and final shocks was 89.7% and 97.7%. Of the 91 (9.2%) deaths reported, none were associated with the S-ICD system or procedure. Cause of death was cardiac for 40 pts, non-cardiac for 40 pts, other for 4 pts, and unknown for 7 pts. Only 20 (2.0%) pts had their S-ICD replaced for a TV device for pacing: 4 bradycardia, 7 anti-tachycardia, and 9 for biventricular pacing.

Conclusions: The EFFORTLESS registry provides 5-year follow-up for a diverse, large, multinational S-ICD registry. Complications primarily occurred in the first year but remained low through 5 years. Inappropriate shock rates were typically observed in older generation devices prior to introduction of the SMART Pass filter. Replacement for TV-ICD due to the need for pacing was rare.

Outcome	30 day	1 yr	2 yr	3 yr	4 yr	5yr	Annual
Complications (Kaplan-Meier)	2.0	5.3	6.8	7.6	8.6	9.4	1.9
IAS, overall (Kaplan-Meier)	1.7	8.7	11.6	13.1	14.6	16.9	3.4
IAS, t wave oversensing		3.4				5.8	1.2