Prof. Kornej concluded that even in anticoagulated patients all three stroke risk stratification scores are useful in predicting thromboembolic events after catheter ablation and stressed the importance to control the AF recurrences during follow up because of their association with thromboembolic complications.

Low Inappropriate Shock Rate With ICD SmartShock Algorithms

Written by Toni Rizzo

Shocks delivered by implantable cardioverter defibrillators (ICDs) can cause anxiety [Sears SF Jr et al. *Clin Cardiol* 1999], decreased quality of life [Schron EB et al. *Circulation* 2002], and mortality [Daubert JP et al. *J Am Coll Cardiol* 2008]. Although ICDs are intended to deliver a shock when needed, inappropriate shocks comprise 2% to 10% of ICD shocks [Schloss EJ et al. *Heart Rhythm* 2013; Moss AJ et al. *N Engl J Med* 2012; Gasparini M et al. *JAMA* 2013].

Painfree SmartShock Technology (SST) is designed to reduce the number of inappropriate shocks with dual- (DR), triple- (CRT), and single- (VR) chamber ICDs. According to Edward J. Schloss, MD, The Christ Hospital, Cincinnati, Ohio, USA, the Study to Evaluate System Safety and Clinical Performance of the Protecta Implantable Cardioverter Defibrillator (ICD) Plus Cardiac Resynchronization Therapy Defibrillator [Painfree SST; NCT00982397] is the first study to evaluate the SmartShock discrimination algorithms for reducing inappropriate shocks by VR-ICDs.

The SST programming for the study used out-of-the box nominal values in current ICDs. The primary endpoint was inappropriate shock-free rate at 1 year post implant. Dr. Schloss previously presented the results for DR- and CRT-ICDs at the Heart Rhythm Society (HRS) 2013 annual meeting [HRS 2013 (abstr 28-04)]. A total of 757 patients were included in the VR-ICD cohort. Follow-up was ≥1 year in 712 patients and <1 year in 45 patients.

At 1-year follow-up, the inappropriate shock-free rate was 97.6% (95% CI, 96.4 to 98.8; Figure 1).

Of the 757 patients, 15 had experienced 19 inappropriate shocks. The causes of the inappropriate shocks were atrial fibrillation or atrial flutter (10 patients, 14 episodes), other supraventricular tachycardia (2 patients, 2 episodes), and over-sensing (3 patients, 3 episodes). The risk of inappropriate shock was not affected by the ventricular tachycardia (VT) therapy zone. Patients with VT shock enabled were 98.1% inappropriate shock-free compared with 97.1% of patients with VT shock not enabled (p=0.38).

The all-cause shock-free rate at 1 year was 91.6% (95% CI, 89.5 to 93.8; Figure 2). There were 252 shock episodes in 53 patients, with 4.8±11.1 episodes per patient. Of these, 175 episodes in 41 patients were appropriate (4.3±6.9 episodes per patient) and 19 episodes in 15 patients were inappropriate (1.3±0.5 episodes per patient). An electrogram was not available for 58 episodes in 5 patients (11.6±17.8 episodes per patient). For the primary objective, patients were censored at the time of a first shock without an electrogram.

Figure 1. Inappropriate Shock-Free Rate at 1 Year

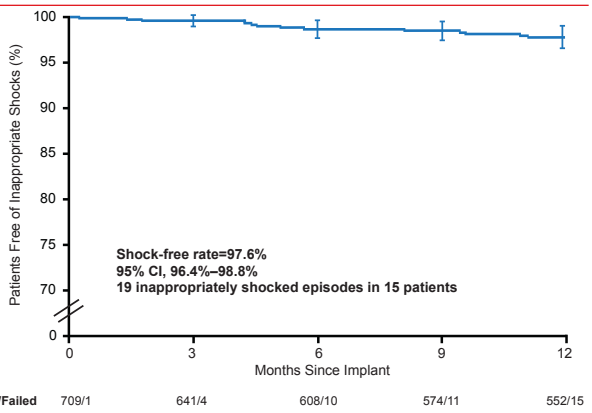

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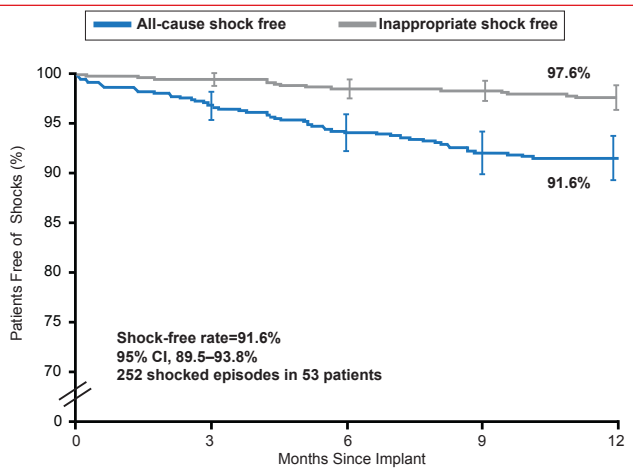
Figure 2. All-Cause Shock-Free Rate at 1 Year



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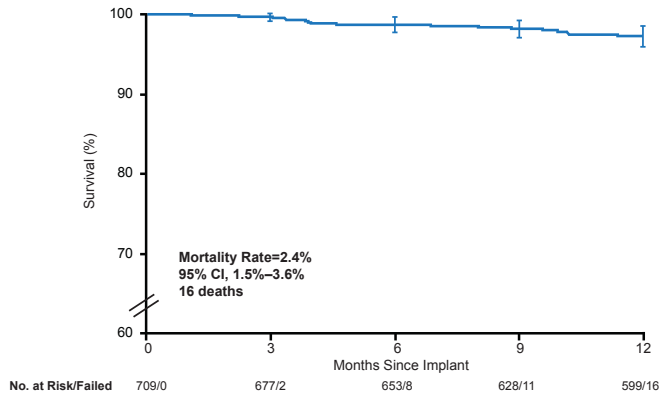
Sixteen patients died during the 12 months following ICD implantation (mortality rate, 2.4%; 95% CI, 1.5% to 3.6%; Figure 3). There were 3 noncardiac deaths, 5 nonsudden cardiac deaths, and 8 deaths with an unknown cause.

Figure 3. Survival at 1 Year



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The 1-year results of the Painfree SST trial demonstrate that using SmartShock algorithms with VR-ICDs is effective for preventing inappropriate shocks. Use of this technology allows for flexibility in heart rate detection interval programming without resulting in a higher rate of inappropriate shocks.

Major CIED Infections Significantly Lower With Use of Antibacterial Envelope

Written by Toni Rizzo

Infections associated with cardiovascular implantable electronic devices (CIEDs) cause substantial morbidity and mortality. Although perioperative intravenous (IV) antibiotic prophylaxis is standard care for CIED procedures, the rate of CIED infections has been increasing. The AIGISRx antibacterial envelope (ABE) for prophylaxis of CIED infections was approved by the Food and Drug Administration (FDA) in 2008 for use with perioperative IV antibiotics. The ABE consists of a polypropylene mesh coated with a resorbable tyrosine polymer impregnated with rifampin and minocycline, which are released for 7 to 10 days.

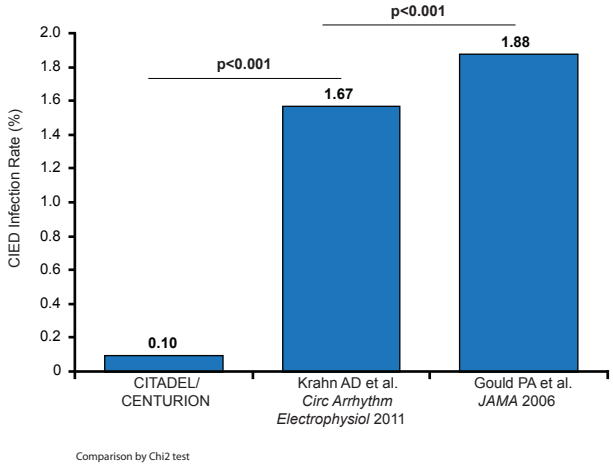
The AIGISRx Envelope for Prevention of Infection Following Replacement With an Implantable Cardioverter-Defibrillator (ICD) [CITADEL; NCT01043861] or Cardiac Resynchronization Therapy Device (CRT) [CENTURION; NCT01043705] trials prospectively evaluated the effectiveness of the ABE in patients implanted with a non-*de novo* single- or dual-chamber ICD (CITADEL) or non-*de novo* CRT (CENTURION) devices. Charles A. Henrikson, MD, Oregon Health Sciences University, Portland, Oregon, USA, presented results of the 3-month interim analysis of these studies.

The study designs planned for ICD implantation in 2300 patients to be compared with published controls (CITADEL) and for CRT implantation in 2000 patients to be compared with a site- and case-matched retrospective control cohort (CENTURION). The endpoints were CIED infection and mechanical complications rates. Eligible patients underwent generator replacement with a single- or dual-chamber ICD or CRT and the ABE, with or without lead revision or addition. Data for the interim analysis were obtained from a total of 1000 patients in the CITADEL (n=403) and CENTURION (n=597) studies at the 3-month follow-up visit.

At 3 months, the major infection rate among all 1000 patients (CITADEL and CENTURION) was 0.10% (95% CI, 0.00 to 0.56), with one major infection in the ICD cohort and none in the CRT cohort. The minor infection rate was 1.00% (95% CI, 0.48 to 1.83), with 4 minor infections in the ICD cohort and 6 in the CRT cohort.

Comparison with published controls showed a significant reduction in infection rates among patients treated with the ABE (0.10%, CITADEL+CENTURION) versus controls 1.67% (p<0.001) [Krahn AD et al. *Circ Arrhythm Electrophysiol* 2011], 1.88% (p<0.001) [Gould PA et al. *JAMA* 2006] (Figure 1).

Figure 1. Comparison of Infection Rates in CITADEL Plus CENTURION Versus Published Controls



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Among the 597 CENTURION patients, 532 had an eligible case-match. Major infections were reported in 0.00% (95% CI, 0.0 to 0.7) of ABE-treated patients versus 1.12% (95% CI, 0.4 to 2.4) in the case-matched controls (p=0.031; Figure 2). There was no significant difference in the rate of mechanical complications between the two groups.

The results of this interim analysis showed that use of the AIGISRx antibacterial envelope in patients undergoing CIED procedures significantly reduced the risk of infections