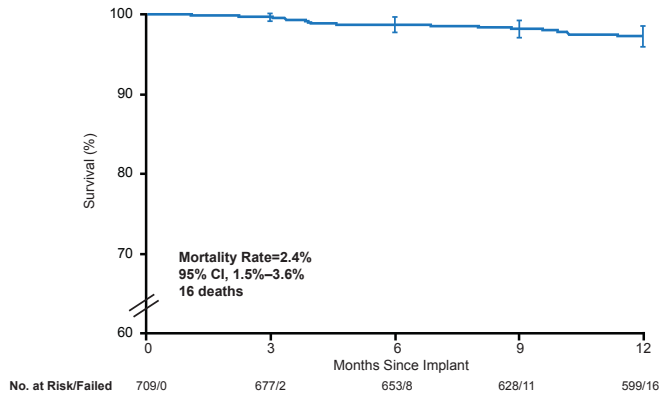
Figure 3. Survival at 1 Year



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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.

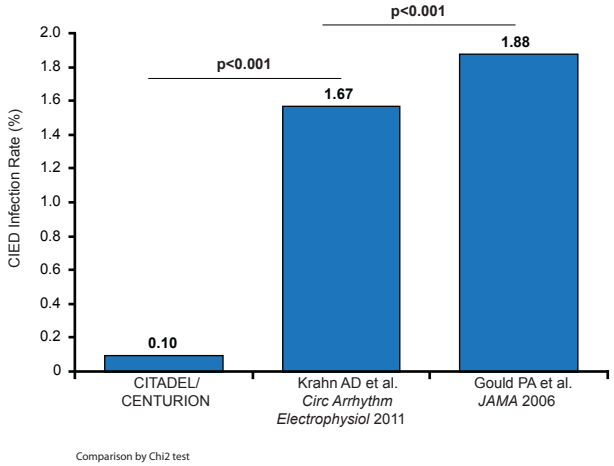
The AIGISRx Envelope for Prevention of Infection Following Replacement With an Implantable Cardioverter-Defibrillator (ICD) [CITADEL; NCT01043861] or Cardiac Resynchronization Therapy Device (CRT) [CENTURION; NCT01043705] trials prospectively evaluated the effectiveness of the ABE in patients implanted 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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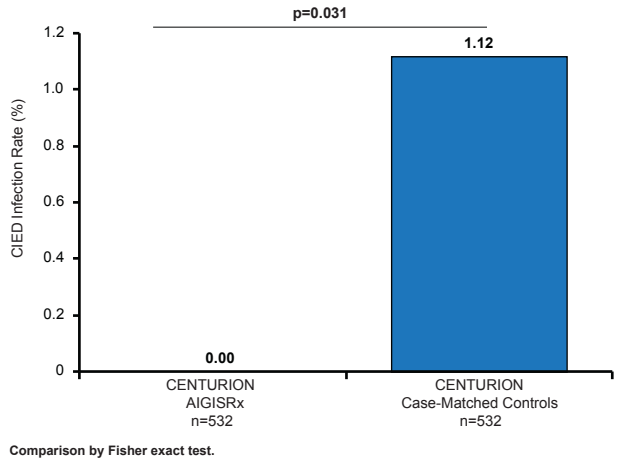
Among the 597 CENTURION patients, 532 had an eligible case-match. Major infections were reported in 0.00% (95% CI, 0.0 to 0.7) of ABE-treated patients versus 1.12% (95% CI, 0.4 to 2.4) in the case-matched controls (p=0.031; Figure 2). There was no significant difference in the rate of mechanical complications 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

when compared with published historical controls and case-matched controls. There was no increase in serious device-related complications among the CITADEL and CENTURION patients treated with the AIGISRx antibacterial envelope compared with controls.

Figure 2. Infection Rates With ABE Versus Case-Matched Controls



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Dual Chamber ICD Therapy Associated With Fewer Inappropriate Shocks

Written by Nicola Parry

Christof Kolb, MD, German Heart Centre/Technische Universität München, Munich, Germany, presented data from an international multicenter study, demonstrating that patients with dual-chamber (DC) implantable cardioverter defibrillators (ICDs) experienced a significantly lower incidence of inappropriate shocks compared with those with single-chamber (SC) devices, with no difference in all-cause mortality between the two groups.

Despite its lifesaving potential, ICD therapy remains complicated by inappropriate therapies and shocks that may result in pain, anxiety, depression, and proarrhythmia. Additionally, controversy still exists as to whether a SC or DC device is the most appropriate to prevent inappropriate shocks.

The Optimal Anti-tachycardia Therapy in ICD Patients Without Pacing Indications study [OPTION; NCT00729703] was designed to test the hypothesis that DC ICD therapy with specific device-based algorithms would reduce the rate of inappropriate shocks without affecting morbidity and mortality by ventricular pacing.

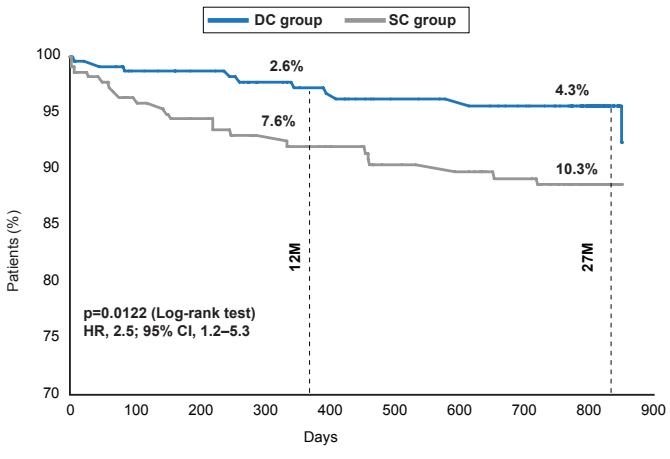
OPTION was a prospective, international multicenter trial that was conducted among 54 centers in nine countries in Europe and North America. It enrolled 462 patients (86% men; mean age 63 years; 77% with ischemic heart disease) for 27 months, from 2006 to 2009. Inclusion criteria were implantation of an ICD according to European Society of Cardiology/European Heart Rhythm Association or American College of Cardiology/American Heart Association guidelines, and left ventricular ejection fraction ≤40%.

The primary endpoints of the study were time to first inappropriate shock and percentage of patients with a combined endpoint of all-cause mortality and hospitalization for specified cardiac reasons. Secondary endpoints included occurrence of appropriate and inappropriate shocks, all-cause mortality, and hospitalizations due to cardiovascular (CV) events.

All subjects were supplied with a DC device (Ovatio DR 6550, Sorin Group) and then randomized to undergo SC therapy (SC tachyarrhythmia detection and ventricular back-up pacing at 40 bpm; n=223) or DC therapy (featuring device-based algorithms to reduce the incidence of inappropriate shocks by DC discrimination and to minimize ventricular pacing; n=230).

At the study end (27 months follow-up) there was a significant difference in time to first occurrence of inappropriate shock between the two groups, with a significantly lower incidence in the DC arm compared with the SC arm (4.3% vs 10.3%; HR, 2.5; 95% CI, 1.2 to 5.3; log-rank p=0.0122; Figure 1). At 12 months, the incidences were 2.6% and 7.6%, respectively.

Figure 1. Time to First Inappropriate Shock



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Considering the safety aspect, there was no significant difference in mortality and CV events between the two groups. Twenty-one and 18 patients died in the DC and