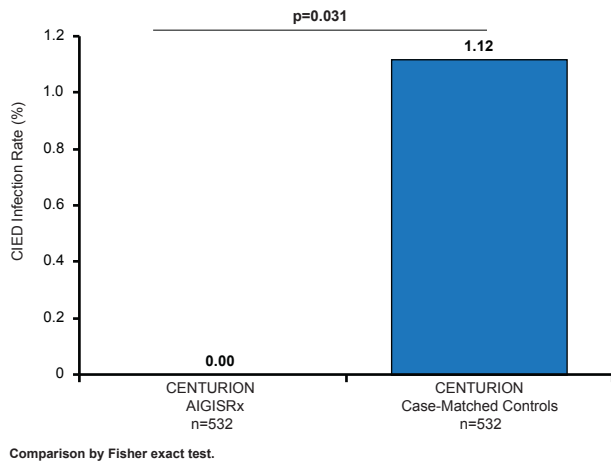


when compared with published historical controls and case-matched controls. There was no increase in serious device-related complications among the CITADEL and CENTURION patients treated with the AIGISRx antibacterial envelope compared with controls.

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.

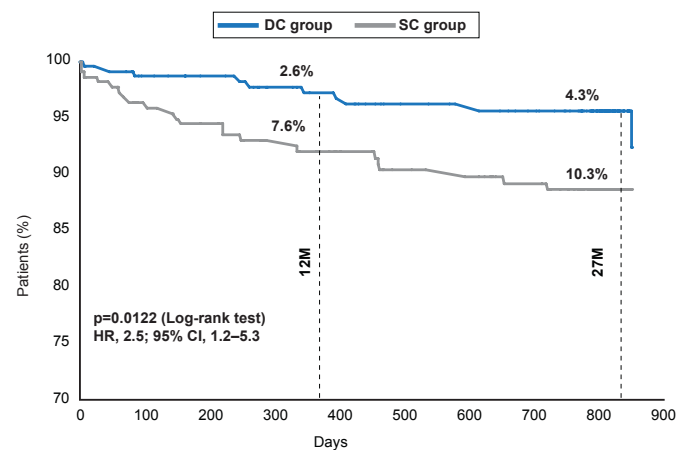
OPTION was a prospective, international multicenter trial that was conducted among 54 centers in nine countries in Europe and North America. It enrolled 462 patients (86% men; mean age 63 years; 77% with ischemic heart disease) for 27 months, from 2006 to 2009. Inclusion criteria were implantation of 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 $\leq 40\%$.

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



CLINICAL TRIAL HIGHLIGHTS

SC groups, respectively, with CV events reported in 33 and 40 patients respectively. Additionally there were relatively few device-related complications overall, with atrial lead complications in 0.9% and 1.8% of patients in the DC and SC groups, respectively.

The investigators concluded that DC ICD therapy resulted in a significantly reduced incidence of inappropriate shocks compared with SC therapy, and similar rates of all-cause mortality and CV events with a low rate of atrial lead complications.

Although further studies may be required to confirm this benefit, the data suggest that when a lower rate of inappropriate shocks is needed, use of a DC ICD is preferable.

Changes in Management of Atrial Fibrillation Since 2010 ESC Guidelines Update

Written by Nicola Parry

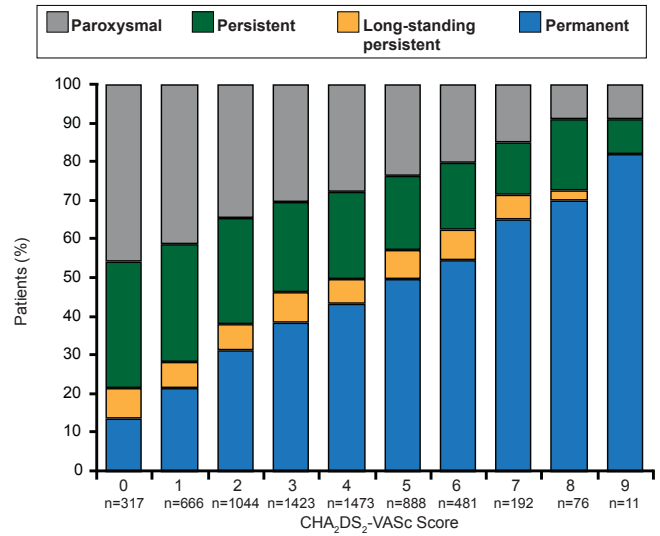
Paulus Kirchhof, MD, University of Birmingham, Birmingham, United Kingdom, presented results from a European study, demonstrating that although the management of patients with atrial fibrillation (AF) has changed based on updated guidelines, many continue to experience symptoms, highlighting the need to improve the management of this patient population.

The Prevention of Thromboembolic Events - European Registry in Atrial Fibrillation [PREFER in AF] is a multicenter study conducted across seven countries in Europe, comprising a prospective, observational disease registry. The study was designed to determine the extent to which publication of the 2010 European Society of Cardiology (ESC) guidelines has affected clinical behavior in Europe.

Inclusion criteria were patient age of at least 18 years; a history of AF documented by some form of recording of electrical activity of the heart within the previous 12 months; and written, informed consent to participate in the study. The registry enrolled 7243 patients (60% men; mean age 71.5 years; 72% with hypertension; 23% with coronary artery disease; 8% with prior stroke; 11% with prior myocardial infarction; and 4% with valvular AF). Patients were evaluated at an initial baseline visit to investigate their symptoms and disease-management strategies, with an emphasis on preventing thromboembolic events. A follow-up visit will occur 12 months after the baseline visit.

At baseline it was demonstrated that as CHA₂DS₂-VASc scores increase, so does the incidence of chronic forms of AF (persistent, long-standing persistent, and permanent). Conversely, the proportion of paroxysmal AF patients is reduced as scores increase (Figure 1).

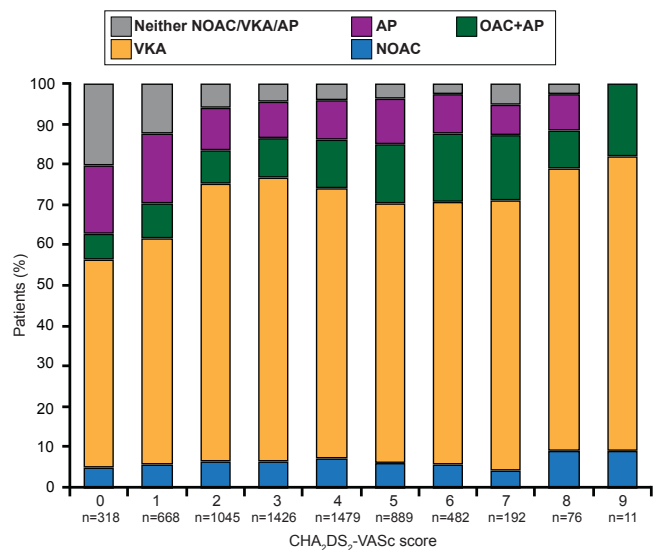
Figure 1. Relationship Between Type of AF and CHA₂DS₂-VASc Score



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It was also shown that, of patients who were clear-cut candidates for oral anticoagulant drugs (OACs), >80% actually received therapy in accordance with recommended guidelines. Most received vitamin K antagonists (VKAs) as monotherapy, although others received antiplatelet (AP) monotherapy, combined OACs and AP, or new OACs (Figure 2).

Figure 2. Type of Antithrombotic Therapy Used



AP=antiplatelet; NOAC=new oral anticoagulant; OAC=oral anticoagulant; VKA=vitamin K antagonists.

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