Best of the HRS 2009 Scientific Sessions

Highlights From the 30th Annual Heart Rhythm Society Scientific Sessions, May 13-16, 2009, Boston, MA

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The 2009 Heart Rhythm Society Scientific Sessions were held this year in the new convention center in Boston, MA. The meeting was highly attended despite international travel concerns related to the recent swine flu outbreak. This article will summarize a few of the high-impact clinical trials and new practice guidelines that were presented at the meeting.

Thermocool AF Trial

The final results of the Thermocool AF trial were presented early in the meeting. This study compared catheter ablation to antiarrhythmic drug therapy in patients with paroxysmal atrial fibrillation and a left ventricular ejection fraction at or exceeding 40%.[1]

At the conclusion of the study, 63% of catheter ablation patients compared with 17% of antiarrhythmic drug therapy patients were free of recurrent atrial arrhythmias ($P < .0001$), and catheter ablation patients had a significantly higher sustained quality of life ($P < .0001$). Thirty-day major treatment-related adverse events occurred in 4% of catheter ablation patients (no deaths, embolic events, or perforation) and in 9% of antiarrhythmic drug patients, a difference that was not statistically significant.

The ALTITUDE Study

The ALTITUDE study, presented by Leslie A. Saxon, MD, was an observational study of data from the LATITUDE® remote monitoring system (Boston Scientific, Natick, MA) database.[2] It was designed to determine mortality outcomes and the incidence of appropriate and inappropriate shocks in a cohort of 85,999 patients with an implantable cardioverter defibrillator (ICD) (n = 47,032) or a defibrillating cardiac-resynchronization-therapy (CRT-D) (n = 38,967) device. Prior to this study, the 2 largest randomized trials evaluating mortality outcomes had enrolled a total of 4000 patients, and thus the ALTITUDE study is the largest patient cohort reported.

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The 5-year survival was 91.8% for ICD patients and 75.6% for CRT-D patients. There was a survival reduction in patients who received a shock (hazard ratio, 1.60; $P < .0001$), which is consistent with previous findings from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT),[3] the Multicenter Automatic Defibrillator Trial II (MADIT II),[4] and the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial.[5] Overall, the ALTITUDE study showed that patients implanted in a real-life setting with an ICD or CRT-D device (monitored over a network) have excellent survival.

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Multicenter Automatic Defibrillator Trial II

Results of the 8-year follow-up study of MADIT II were also reported.[6] Prior to this study, the longest follow-up in a defibrillator trial had been in the SCD-HeFT trial,[3] which reported results after 5 years of follow-up. The MADIT II trial had enrolled 1232 patients with ischemic heart disease and a left ventricular ejection fraction at or less than 30%. Mean follow-up at 20 months showed a significant survival benefit of ICD implantation.

After 8 years of follow-up, the cumulative probability of all-cause mortality was 45% in the ICD patients and 61% in patients not treated with an ICD. Defibrillator therapy in the 8 years of follow-up led to 1.2 life-years saved; the number of patients needed to treat to save 1 life improved to 6. A significant survival benefit was shown during the extended 4- to 8-year follow-up. This extended mortality benefit was driven by patients who did not experience symptomatic heart failure prior to trial closure in November 2001, whereas patients who had experienced symptomatic heart failure did not have a significant survival benefit in the extended follow-up. The other subgroup of patients that did not derive survival benefit in the extended follow-up were those who were randomized to receive dual-chamber devices programmed DDD with a lower rate limit of 60 to 70 beats per minute and who had greater than 50% right ventricular pacing.

The conclusions of the MADIT II 8-year follow-up are that survival benefit of ICD implantation was sustained over 8 years, but that long-term benefit occurred in patients who did not develop symptomatic heart failure during the study as well as in patients who had limited right ventricular pacing.

New Subcutaneous Implantable Defibrillator

The Clinical Evaluation of the Subcutaneous Implantable Defibrillator (S-ICD®, Cameron Health, San Clemente, CA) reported on the feasibility and efficacy of a completely subcutaneous ICD.[7] The primary objective was to evaluate the detection and conversion efficacy of induced ventricular fibrillation (VF).

Of the 53 patients included in the analysis, the sensitivity of detection was 100% and the conversion efficacy was 98%, with success defined as detection and 2 consecutive successful conversions of VF at 65 J (with a 15-J margin), out of a maximum of 4 attempts. Postimplant lead movement occurred in 4 patients, 2 of whom required repositioning. During the 30-day follow-up period, 1 patient was found to have a loose set screw and another patient experienced T wave oversensing, both of which were corrected. This study shows that the S-ICD® system may be an alternative to existing ICD systems, particularly in patients at high risk for vascular infections or with barriers to vascular access to the heart; however, long-term follow-up data will be needed.

The REPLACE Registry

The Implantable Cardiac Pulse Generator Replacement (REPLACE) registry is the largest prospective, multicenter study of pacemaker and ICD generator replacements, with 1031 patients.[8] The overall 30-day complication rate was 10.9%. The major complication rate was 4.2%, with device malfunction that required reopening of the pocket as the most common major complication. The minor complication rate was 7.3%, with visible swelling the most common. There was more than twice the rate of major complications in ICD generator replacements (6%) than in pacemaker generator replacements (2.5%).

Recommendations From the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines

A new document, Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines, was also presented.[9] It focused on safety and improvement of quality care through remote monitoring linked to clinical databases. This document provides a classification for data on leads removed from service and a framework for defining lead performance, reliability,

and malfunction. It states that manufacturers should provide performance reports at least semiannually and that postings on the manufacturers' Web sites should be timely. It describes methods for postmarket surveillance of leads to identify underperforming products, ensure quality patient care, and evaluate long-term performance/reliability. Recommendations are given for activation of lead advisories and communications after identification of abnormal performance. Furthermore, it characterizes situations that may warrant rapid communication and situations in which premature notifications should be avoided so as not to promote clinical overreaction. To that extent, the task force advised that the Food and Drug Administration should call a public meeting to discuss the implications of the word "recall" and to develop alternative terminology for implanted medical devices.

The document emphasizes recommendations for clinicians, proposes factors by which to determine whether a lead is "new," and discusses when a clinical trial is warranted. It supports an educational campaign to inform the public that the term "recall" is not synonymous with "device explant." It also recommends that leads undergo premarket evaluation and that manufacturers perform bench testing of new leads prior to the first human implant.

More extensive coverage of the presented trials and abstracts can be found in the May 2009 *Heart Rhythm* supplement and at www.hrsonline.org, which also has Web casts from the meeting. ■

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Main Points

- The Thermocool AF trial compared catheter ablation to antiarrhythmic drug therapy in patients with paroxysmal atrial fibrillation and a left ventricular ejection fraction at or exceeding 40%. Recurrent atrial arrhythmias were alleviated in 63% of catheter ablation patients compared with 17% of antiarrhythmic drug therapy patients.
- The ALTITUDE study aimed to determine mortality outcomes and the incidence of appropriate and inappropriate shocks in a cohort of 85,999 patients with an implantable cardioverter defibrillator (ICD) or a defibrillating cardiac-resynchronization-therapy (CRT-D) device. The 5-year survival was 91.8% for ICD patients and 75.6% for CRT-D patients. The study found a survival reduction in patients who received a shock.
- Results of the 8-year follow-up study of the Multicenter Automatic Defibrillator Trial II (MADIT II) showed that the cumulative probability of all-cause mortality was 45% in ICD patients and 61% in patients not treated with an ICD.
- A new, completely subcutaneous ICD may be an alternative to existing ICD systems, particularly in patients at high risk for vascular infections or with barriers to vascular access to the heart.
- In the Implantable Cardiac Pulse Generator Replacement (REPLACE) registry of patients with pacemakers and ICD generator replacements, the overall 30-day complication rate was 10.9%.
- A new document, Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines, provides a classification for data on leads removed from service and a framework for defining lead performance, reliability, and malfunction.