Replacement of Cardiac Device Carries Risks

BY MITCHEL L. ZOLER

ORLANDO — Replacing the generator and lead from cardiac antiarrhythmia devices carries a substantial risk for causing a major complication, a study of registry data from 713 patients has shown.

Patients who underwent generator replacement for a pacemaker or implantable cardioverter defibrillator (ICD) along with a planned lead addition or revision had a major complication rate of 15% during the 6 months following the procedure, Dr. Jeanne E. Poole said at the annual scientific sessions of the American Heart Association. When combined with minor complications, the total rate of patients having any complication during the 6 months following generator replacement and planned lead addition or revision reached 21%.

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Among the subgroup of patients who underwent a left ventricular lead addition or revision, the major complication rate reached 19%, said Dr. Poole, professor and director of the electrophysiology service at the University of Washington in Seattle, and principal investigator of the registry.

"These prospectively collected data provide comprehensive risk rates for physicians to consider when planning to upgrade pacemaker or ICD systems," Dr. Poole said. The strikingly high major complication rate found in this series contrasts with the 4% major complication rate found for 1,031 patients who underwent pacemaker or ICD generator replacement without a planned lead change in the same registry. An initial report of those data was presented last May at the annual meeting of the Heart Rhythm Society in Boston.

The complication rates reported in the new study are "sobering," said Dr. Alan H. Kadish, professor and director of cardiac electrophysiology at Northwestern University in Chicago. "The findings suggest that for some indications, we should continue to practice as we have, but for other indications we should take a long and hard look before adding or revising a lead, especially when an atrial lead is added for 'soft' indications. A left ventricular lead addition is still quite reasonable for overt congestive heart failure, but prophylactic addition of a left ventricular lead is something that must be carefully thought about in light of the results of this study," he said.

The Implantable Cardiac Pulse Generator Replacement Registry (REPLACE) enrolled 713 patients in the planned lead addition or revision arm of the study at 69 U.S. sites—37 academic centers and 32 private hospitals—during July 2007–November 2008, with follow-up through July 2009.

The average age of the 713 patients in this arm of the registry was 70 years; 24% were women. Heart failure was present in 83%. Pacemakers were implanted in 46%, ICDs in 45%, and cardiac resynchronization devices in 9%. The devices had been in place for an average of 4 years.

The most common procedure was a planned upgrade to a cardiac resynchronization device, in 57%.

The study used a predefined list of major and minor complications. Major complications included 14 items, including death within 30 days as a direct result of the procedure, stroke within 30 days, infection requiring intravenous antibiotics or device removal, deep vein thrombosis, pulmonary embolism, and pneumothorax or hemothorax.

During the first 24 hours after the procedure, 17 patients (2%) had major complications including 5 with cardiac perforations and 4 with pneumothorax. There were no deaths in this perioperative period. During the subsequent 6 months, 100 patients (14%) had major complications, most commonly a malfunction that required reopening the pocket, in 7%, followed by an unplanned lead addition or removal, in 4%.

Eight patients (1%) died. Overall, 109 patients (15%) had one or more major complications during the 6 months following the index intervention.

A reassuring finding was that the infection rate was low. Six patients (0.8%) had a major infection and another two (0.3%) had minor infections.

"All patients received intravenous antibiotics and appropriate skin prep," Dr. Poole said. ■

Disclosures: *The registry was sponsored by Biotronik, a company that markets cardiac pulse generators and leads, but it enrolled patients with any type of commercially available pacemaker or ICD.*

Dr. Poole has received research grants from Biotronik, as well as honoraria from Boston Scientific, Medtronic, and St. Jude Medical.

Dr. Kadish has received grant support from St. Jude Medical and Baird. He also has consulted for and received honoraria from several companies, including Baird, Medtronic, Impulse Dynamics, Lifewatch, and Sanofi.

Two Factors Tied to Complications

Cardiac device type and procedure volume emerged from the REPLACE registry as the only variables significantly linked with complication rates.

In data collected from the first arm of the registry, limited to patients who had a generator replacement for an existing pacemaker or ICD but without a planned lead addition or revision, patients with an ICD were 60% more likely to have a major complication than were patients with a pacemaker, Dr. Theofanie Mela said at the annual scientific sessions of the American Heart Association.

In the same cohort, patients who underwent generator replacement at a center that did 250 or more procedures per year were 45% less likely to have any type of complication, compared with patients who were treated at centers that did fewer procedures each year, said Dr. Mela, director of the pacemaker laboratory at Massachusetts General Hospital in Boston.

Other variables examined that did not have a significant bearing on complication rates included age, gender, number and severity of comorbidities as measured by the Charlson Comorbidity Index, specialty of the physician performing the procedure (electrophysiologist compared with nonelectrophysiologist), and type of practice (academic center compared with private hospital).

The analysis used data from the first arm of REPLACE, in which 1,031 patients were enrolled at 68 U.S. centers (34 academic and 34 private) during July 2007–March 2008, and tallied the number of complications during 6 months' follow-up. The researchers reported a 4% major complication rate, a 7.4% minor complication rate, and an overall complication rate of 10.9% at the annual meeting of the Heart Rhythm Society in Boston last May.

Subsequent analysis examined potential determinants of the complication rate. Patients with a pacemaker had a major complication rate of 2.3%, compared with a rate of 5.8% in patients with an ICD (the registry included roughly equal numbers of patients with each device type). The 68 sites had a median annual procedure volume of 250. High-volume sites had an overall complication rate of 8.6%; low-volume centers had an overall rate of 14.9%.

Dr. Mela said that she has received honoraria from Boston Scientific, Medtronic, and St. Jude Medical.

Ablation Before ICD Surgery Improves Patient Outcomes

BY ROBERT FINN

Patients with ventricular tachycardia or ventricular fibrillation do better if they undergo catheter ablation before receiving an implantable cardioverter defibrillator, according to a study of 107 patients.

Patients in the prospective, randomized controlled Ventricular Tachycardia Ablation in Coronary Heart Disease (VTACH) study were included if they had previous myocardial infarction, stable ventricular tachycardia, and a left ventricular ejection fraction of 50% or less. The investigators, led by Dr. Karl-Heinz Kuck of the Asklepios Klinik St. Georg in Hamburg, Germany, compared 52 patients who underwent catheter ablation before receiving an implantable cardioverter defibrillator (ICD) with 55 patients who received the ICD alone (Lancet 2010;375:31-40).

Patients in the ICD-alone group had a recurrence of ventricular tachycardia or ventricular fibrillation after a median of 6 months, compared with 19 months in patients who underwent ablation before ICD implantation, a significant difference. Also, 47% of patients in the ablation group had no ventricular tachycardia or fibrillation episodes within 2 years of the procedure, compared with 29% of those in the ICD-only group.

In an editorial, Dr. William G. Stevenson and Dr. Usha Tedrow of Brigham and Women's Hospital, Boston, said ablation can be "considered early, in selected patients who are receiving an [ICD] for stable ventricular tachycardia, in whom recurrences of a ventricular tachycardia are likely." They noted, however, that catheter ablation can be risky (Lancet 2010;375:4-6).

Two patients in the ablation group experienced serious complications during the procedure—one experienced transient ischemic ST segment elevation, and another experienced a transient cerebral ischemic event.

"Evidence of a positive effect on survival, subsequent hospital admissions, or quality of life is needed before this strategy can be recommended for routine use," Dr. Stevenson and Dr. Tedrow wrote. ■

Disclosures: *The study was funded by St. Jude Medical, which manufactured and supplied all of the ICDs used in the study. Dr. Kuck acknowledged relationships with Biosense Webster, St. Jude Medical, Boston Scientific, and Medtronic. Several of the coauthors also disclosed relationships with St. Jude Medical, Sanofi-Aventis, and Biosense Webster. The editorial authors reported no relevant conflicts of interest.*