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 or planned lead addition or revision reached 21%.

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 year, said Dr. Poole.

The analysis used data 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. Theodore M. 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 non-electrophysiologist), 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 had a generator replacement for an existing pacemaker or ICD.

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

Two Factors Tied to Complications

CARDIOVASCULAR MEDICINE

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 ventricular catheter ablation before receiving an implantable cardioverter defibrillator (ICD) with 55 patients who received the ICD alone (Lancet 2010;375:31-40).

In the ICD-alone group there was 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 lykouides 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 the study confirms that ventricular tachycardia is 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 transient cerebral ischemic event,” the editorialists said.

“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.

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