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Appropriateness of Primary Prevention Implantable Cardioverter-Defibrillators at the Time of Generator Replacement

Are Indications Still Met?

Vinay Kini, MD,* Mohamad Khaled Soufi, MD,† Rajat Deo, MD, MTR,* Andrew E. Epstein, MD,*‡ Rupa Bala, MD,* Michael Riley, MD, PhD,* Peter W. Groeneveld, MD, MS,‡ Alaa Shalaby, MD,† Sanjay Dixit, MD*‡

Philadelphia and Pittsburgh, Pennsylvania

Objectives This study sought to determine how often patients with primary prevention implantable cardioverter-defibrillators (ICDs) meet guideline-derived indications at the time of generator replacement.

Background Professional societies have developed guideline criteria for the appropriate implantation of an ICD for the primary prevention of sudden cardiac death. It is unknown whether patients continue to meet criteria when their devices need replacement for battery depletion.

Methods We performed a retrospective chart review of patients undergoing replacement of primary prevention ICDs at 2 tertiary Veterans Affairs Medical Centers. Indications for continued ICD therapy at the time of generator replacement included a left ventricular ejection fraction (LVEF) ≤35% or receipt of appropriate device therapy.

Results In our cohort of 231 patients, 59 (26%) no longer met guideline-driven indications for an ICD at the time of generator replacement. An additional 79 patients (34%) had not received any appropriate ICD therapies and had not undergone reassessment of their LVEF. Patients with an initial LVEF of 30% to 35% were less likely to meet indications for ICD therapy at the time of replacement (odds ratio: 0.52; 95% confidence interval: 0.30 to 0.88; $p = 0.01$). Patients without ICD indications subsequently received appropriate ICD therapies at a significantly lower rate than patients with indications (2.8% vs. 10.7% annually, $p < 0.001$). If ICD generator explantations were performed instead of replacements in the patients without ICD indications, the cost savings would be $1.6 million.

Conclusions Approximately 25% of patients who receive primary prevention ICDs may no longer meet guideline indications for ICD use at the time of generator replacement, and these patients receive subsequent ICD therapies at a significantly lower rate. (J Am Coll Cardiol 2014;63:2388–94) © 2014 by the American College of Cardiology Foundation

Implantable cardioverter-defibrillators (ICDs) reduce mortality in patients with reduced left ventricular function in the absence of previous sustained ventricular arrhythmias (1–3), a treatment strategy referred to as primary prevention. On the basis of the data from several randomized clinical trials, the American College of Cardiology/American Heart Association/Heart Rhythm Society as well as the Centers for Medicare & Medicaid Services have developed specific guideline criteria that patients are required to fulfill to receive an ICD for the primary prevention of sudden cardiac death (SCD) (4). These guideline criteria do not distinguish between patients receiving initial devices and those undergoing generator replacement for battery depletion.

See page 2395

However, after the initial ICD implantation, the clinical characteristics of patients may change. In particular, many patients who receive primary prevention ICDs may experience improvement or recovery of the left ventricular ejection fraction (LVEF) (5,6), and therefore no longer meet indications for a primary prevention ICD at the time of generator replacement.

From the *Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; †VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania; and the ‡Philadelphia VA Medical Center, Philadelphia, Pennsylvania. Dr. Epstein has received honoraria from Boston Scientific, Medtronic, and St. Jude Medical; and research grants from Biotronik, Boston Scientific, Medtronic, and St. Jude Medical. Dr. Dixit has received a research grant from Medtronic. Dr. Deo has received support from grant number K23DK089118 from the National Institutes of Health. Drs. Epstein, Bala, Riley, Deo, and Dixit have received fellowship support from Boston Scientific, Medtronic, and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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It is possible that patients who experience improvement or recovery of LVEF may have no benefit from continued ICD therapy. Furthermore, multiple studies have shown that device replacement is associated with significant morbidity and even mortality (7–9). Patients with ICDs may also experience inappropriate therapies that have been shown to have detrimental effects including progression of heart failure, impaired psychological well-being, and impaired survival (10,11). Because ~30,000 replacement procedures are performed in the United States annually (12), ICD replacement also has a significant healthcare cost (13,14). For all of these reasons, research examining the appropriateness of ICD replacement is long overdue.

In this study, we sought to determine how often guideline-derived indications for primary prevention ICD therapy are still present when patients undergo elective ICD generator replacement. Additionally, we examined how often patients who no longer have an indication for primary prevention ICD at the time of generator replacement receive ICD therapies compared with patients who meet these indications. Finally, we sought to estimate the differential costs of replacement versus potentially withholding replacement in patients who no longer meet indications for primary prevention ICD at the time of elective generator replacement.

Abbreviations and Acronyms

CPRS = Computerized Patient Records System
CPT = Current Procedural Technology
CRT = cardiac resynchronization therapy
CRT-D = cardiac resynchronization therapy with a defibrillator
CRT-P = cardiac resynchronization therapy without a defibrillator
ICD = implantable cardioverter-defibrillator
ICM = ischemic cardiomyopathy
LVEF = left ventricular ejection fraction
NICM = nonischemic cardiomyopathy
SCD = sudden cardiac death
VA = Veterans Affairs

Methods

Study population. We performed a retrospective chart review of all patients who underwent ICD replacement at the Philadelphia Veterans Affairs (VA) Medical Center and the VA Pittsburgh Healthcare System over a period of 7 years (March 2006 through March 2013) to identify patients who had an ICD initially implanted for primary prevention of SCD on the basis of a low LVEF (≤35%). Within this subgroup, we further identified patients who underwent ICD replacement for battery depletion manifest by achievement of the device elective replacement indicator or end-of-life measure. These patients constituted our study cohort. Patients with any other indication for generator change such as lead malfunction, recall, and upgrade to a dual-chamber or cardiac resynchronization therapy (CRT) device before battery replacement indication were excluded. Patients undergoing their second or more generator change and those who were pacemaker dependent were also excluded. We also excluded patients who received the original device on the basis of MUSTT (Multicenter Unsustained Tachycardia Trial) criteria (i.e., LVEF ≤40% and inducible ventricular tachycardia or fibrillation at electrophysiological study). Clinical records of all veteran patients are maintained in the national VA-wide Computerized Patient Records System (CPRS), and we were able to review the medical records comprehensively for all study patients. The study was approved by the Philadelphia VA Medical Center and VA Pittsburgh Healthcare System Institutional Review Boards.

Data collection and definitions. Data collection included patient characteristics such as age and race, the initial indication for ICD implantation, the type of device implanted (CRT with defibrillator [CRT-D], dual-chamber ICD, or single-chamber ICD), the most recent LVEF, and the presence or absence of comorbid conditions at baseline and at the time of ICD replacement. Comorbid conditions included chronic kidney disease (stage III or greater), dialysis dependence, cognitive impairment, neoplastic disease, atrial fibrillation, hypertension, diabetes, and history of stroke. Pertinent medication use (beta-blockers, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and antiarrhythmic drugs) at baseline and at the time of ICD replacement was reviewed. Data were also collected from device interrogation records, which included delivery of appropriate therapies (shock or antitachycardia pacing for ventricular arrhythmia) and inappropriate therapies (shock or antitachycardia pacing for nonventricular arrhythmia events). Conventional criteria validated in previous ICD trials (3) were used to categorize patients as having ischemic cardiomyopathy (ICM) or non-ICM (NICM).

At the time of the generator replacement, patients were classified into 1 of 3 groups: 1) ICD therapy was considered to be *indicated* for any patient whose LVEF was ≤35% on the basis of assessment within 1 year of undergoing generator replacement or if the patient had received appropriate therapy (shock or antitachycardia pacing) from their ICD after initial implantation regardless of the LVEF; 2) ICD therapy was considered *not indicated* in patients who demonstrated an improvement in their LVEF to ≥40% and had not received any appropriate therapies over the lifetime of the original device; and 3) ICD therapy was considered *unclear* in patients who had not received any appropriate therapies over the lifetime of the original device and had also not had a reassessment of their LVEF within 1 year of undergoing ICD generator replacement. LVEF assessment was on the basis of echocardiographic or nuclear imaging studies.

Cost analysis. Three models were considered for the cost analysis: 1) replace all ICD generators regardless of LVEF; 2) explant generators in the group of patients for whom ICD therapy was considered *not indicated*; and 3) obtain echocardiograms in the group of patients with *unclear* indications for ICD, assume that the percent of patients for whom ICD therapy was not indicated would be the same in this group as in our overall cohort, and additionally explant