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Outcomes Among Older Patients Receiving Implantable Cardioverter-Defibrillators for Secondary Prevention

From the NCDR ICD Registry

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ABSTRACT

BACKGROUND Clinical trials of implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death were conducted nearly 2 decades ago and enrolled few older patients.

OBJECTIVES This study assessed morbidity and mortality of older patients receiving ICDs for secondary prevention in contemporary clinical practice.

METHODS We identified 12,420 Medicare beneficiaries from the National Cardiovascular Data Registry ICD Registry undergoing first-time secondary prevention ICD implantation between 2006 and 2009 in 956 U.S. hospitals. Risks of death, hospitalization, and admission to a skilled nursing facility (SNF) were assessed over 2 years in age strata (65 to 69, 70 to 74, 75 to 79, and ≥80 years of age) using Medicare claims. The adjusted association between age and outcomes was evaluated using multivariable models.

RESULTS The mean age was 75 years at the time of implantation; 25.3% were <70 years of age and 25.7% were ≥80 years of age. Overall, the risk of death at 2 years was 21.8%, ranging from 14.7% among those <70 years of age to 28.9% among those ≥80 years of age (adjusted risk ratio [aRR]: 2.01; 95% confidence interval [CI]: 1.85 to 2.33; p for trend <0.001). The cumulative incidence of hospitalizations was 65.4%, ranging from 60.5% in those <70 years of age to 71.5% in those ≥80 years of age (aRR: 1.27; 95% CI: 1.19 to 1.36; p for trend <0.001). The cumulative incidence of admission to a SNF ranged from 13.1% among those <70 years of age to 31.9% among those ≥80 years of age (aRR: 2.67; 95% CI: 2.37 to 3.01; p for trend <0.001); SNF admission risk was highest in the first 30 days.

CONCLUSIONS Almost 4 in 5 older patients receiving a secondary prevention ICD survives at least 2 years. High hospitalization and SNF admission rates, particularly among the oldest patients, identify substantial care needs after device implantation. (J Am Coll Cardiol 2017;69:265–74) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CI = confidence interval

ICD = implantable cardioverter-defibrillator

NCDR = National Cardiovascular Data Registry

SNF = skilled nursing facility

VT = ventricular tachycardia

Implantable cardioverter-defibrillators (ICDs) were initially used in the early 1980s to treat individuals who had been successfully resuscitated from cardiac arrest (i.e., secondary prevention) (1). Although the indications for ICDs have since expanded to include high-risk individuals who have not experienced lethal ventricular arrhythmias (i.e., primary prevention), patients undergoing secondary prevention ICD implantation still account for approximately one-quarter of all procedures entered in the National Cardiovascular Data Registry (NCDR) (2). Although the outcomes in patients receiving an ICD for primary prevention have been characterized in detail (3), those for patients receiving secondary prevention ICDs are substantially more limited.

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For several reasons, existing clinical trial data on secondary prevention ICDs may not apply to contemporary clinical practice, especially to older patients (4-7). First, the few randomized controlled trials in this context were performed nearly 2 decades ago, and were generally restricted to younger patients with a history of documented ventricular tachycardia (VT) and ventricular fibrillation. Older patients surviving cardiac arrest may have a higher burden of coexisting illnesses that may influence outcomes after ICD implantation. Second, therapies for underlying structural heart disease, including those for left ventricular systolic dysfunction and coronary artery disease, have evolved substantially. Finally, guideline recommendations for secondary prevention ICD therapy expand beyond the enrollment criteria of the randomized trials, and are generally predicated upon the assumption that patients considered for therapy have reasonable prospects for a life expectancy of at least 1 year (8,9). In the 15 years since the publication of these randomized trials, the outcomes of older patients receiving an ICD for secondary prevention in clinical practice have not been well characterized.

Accordingly, we analyzed data from the NCDR ICD Registry to assess rates of death, rehospitalization, and skilled nursing facility (SNF) admission among older persons undergoing secondary prevention ICD implantation. These data are intended to provide patients and clinicians with contemporary, representative estimates of the risks of adverse outcomes after ICD implantation to inform decision making and understand the resource needs of this population to support health policy.

METHODS

DATA SOURCES. Patients assessed in this study were enrolled in the NCDR ICD Registry (10,11). The registry includes data on patients receiving implantable devices in the United States across hospital and payer types. As a condition of reimbursement from the Centers for Medicare and Medicaid Services, all Medicare beneficiaries receiving a primary prevention ICD must be included in the ICD Registry. Although this requirement does not apply to patients receiving an ICD designated as secondary prevention, 91% (1,320 of 1,465) of participating sites have submitted data on patients receiving ICDs for secondary prevention indications. Clinical, demographic, and procedural data are collected using standardized definitions. Data are submitted by participating hospitals using certified software and are examined using a formal Data Quality Reporting and audit process (12). Medicare claims data were used to ascertain outcomes through linkage with NCDR data. Using an established validated method, eligible subjects were matched to Medicare claims data on the basis of indirect identifiers, including age, sex, admission or procedure date, and hospital Medicare provider number (13). Analyses of the NCDR ICD Registry are performed under an institutional review board approval by Yale University, with a waiver of informed consent because of the study design.

STUDY GROUP. Medicare beneficiaries in the NCDR ICD registry ≥65 years of age were included. This study group was limited to those undergoing initial implantation of a secondary prevention ICD between 2006 and 2009. The implanting physician determined the designation of secondary prevention. The cohort was further limited to patients with a prior episode of sudden cardiac arrest, defined as having any of the following: 1) tachycardic arrest; 2) sustained, monomorphic VT; or 3) sustained polymorphic VT. Single-chamber, dual-chamber, and cardiac resynchronization therapy-defibrillator devices were included. Patients meeting the clinical eligibility criteria who could be linked to Medicare data formed the study cohort.

INDEPENDENT VARIABLES. Clinical and demographic information on patients were obtained from the NCDR, including age, sex, and clinical characteristics. The primary predictor variable was age. The study patients were stratified into groups on the basis of age at time of implantation (<70, 70 to 74, 75 to 79, or ≥80 years of age). Other covariates considered included patient, clinician, and hospital