Equivalent arrhythmic risk in patients recently diagnosed with dilated cardiomyopathy compared with patients diagnosed for 9 months or more

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BACKGROUND The Centers for Medicare and Medicaid Services (CMS) recently expanded coverage for implantable cardioverter-defibrillators (ICDs) in patients with left ventricular ejection fraction ≤35% and nonischemic dilated cardiomyopathy for ≥9 months. To investigate the ramifications of these criteria, the ICD registry from Tufts-New England Medical Center was analyzed for arrhythmic events and death in patients with newly diagnosed (<9 months) vs late-diagnosed (≥9 months) nonischemic dilated cardiomyopathy.

OBJECTIVES The purpose of this study was to analyze the arrhythmic risk in patients with recent vs late diagnosis of nonischemic dilated cardiomyopathy.

METHODS One hundred thirty-one patients with nonischemic dilated cardiomyopathy were divided into two cohorts (<9 or ≥9 months of symptoms) and analyzed for any occurrence of treated ventricular arrhythmia, potentially lethal arrhythmias defined as ventricular flutter rates ≥230 bpm, and ventricular fibrillation. Patients with documented sustained ventricular tachycardias (included in prior CMS coverage) were excluded.

RESULTS In the study group, the mean age was 58.1 ± 15 years and ejection fraction 20.6% ± 8%. In a follow-up period of 25.3 ± 24 months, the 52 patients with a recent diagnosis (1.4 ± 2 months) had no difference in the occurrence of ventricular arrhythmias ($P = .49$) and malignant ventricular arrhythmias ($P = .16$) compared with the 79 patients diagnosed ≥9 months (mean 58.1 ± 39 months).

CONCLUSION Patients with nonischemic dilated cardiomyopathy experienced equivalent occurrences of treated and potentially lethal arrhythmias irrespective of diagnosis duration. These findings suggest that the 9-month time qualifier used in the CMS guidelines for ICD reimbursement may not reliably discriminate patients at high risk for sudden cardiac death in this selected population.

KEYWORDS Sudden cardiac death; Heart failure; Implantable cardioverter-defibrillator; Idiopathic dilated cardiomyopathy

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Introduction

Sudden cardiac death (SCD) affects more than 450,000 Americans annually.[1] The majority of cases are attributed to ventricular arrhythmias.[1] Secondary prevention trials have demonstrated the superiority of implantable cardioverter-defibrillators (ICDs) over antiarrhythmic agents.[2–4] Primary prevention or prophylactic ICD placement has also been shown to be beneficial in patients with reduced left ventricular ejection fractions due to coronary artery disease.[5–7] More recently, the DEFINITE (Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation) trial[8] and SCD-HeFT (Sudden Cardiac Death–Heart Failure Trial[9] demonstrated that this survival advantage extends to patients with nonischemic dilated cardiomyopathy. Based on the DEFINITE trial and SCD-HeFT, the Centers for Medicare and Medicaid Services (CMS) have approved expanded coverage of ICDs for Medicare recipients with nonischemic dilated cardiomyopathy but have stated that patients must have nonischemic dilated cardiomyopathy for ≥9 months.[10] This time qualifier was based on small ICD trials[11,12] and the more contemporary ICD trial, SCD-HeFT,

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which enrolled patients with disease durations of at least 3 months (actual range of enrollees 8–59 months).

To investigate the risk of SCD in patients with nonischemic dilated cardiomyopathy and the potential ramifications of current CMS guidelines, we performed an analysis of patients with nonischemic dilated cardiomyopathy <9 months and compared their risk of arrhythmias and death to patients with diagnoses ≥9 months. Our hypothesis in this retrospective study was that the arrhythmic risk and mortality would be similar in patients recently diagnosed with nonischemic dilated cardiomyopathy compared with patients having a longer diagnosis of nonischemic dilated cardiomyopathy in whom an earlier decision (largely independent of time of diagnosis) was made to implant a device.

Methods

Patient population

The enrollment criteria for the analysis included a diagnosis of nonischemic dilated cardiomyopathy, left ventricular ejection fraction (LVEF) ≤35%, and placement of an ICD at Tufts-New England Medical Center during the period from 1995 to June 2004. All patients underwent cardiac evaluation, which included echocardiography, long-term ambulatory monitoring, and stress myocardial imaging with cardiac catheterization when appropriate. Patients were excluded if they had a diagnosis of ischemic cardiomyopathy (defined as any coronary stenosis ≥50% or prior myocardial infarction) or nonischemic dilated cardiomyopathy secondary to valvular, hypertrophic, or congenital cardiomyopathies. Patients with sustained and spontaneous ventricular tachyarrythmias (defined as arrhythmias lasting >30 seconds or requiring termination by cardioversion) prior to ICD placement also were excluded.

Patients were divided into two groups according to the duration of nonischemic dilated cardiomyopathy (<9 months or ≥9 months). The duration of nonischemic dilated cardiomyopathy was assessed by symptom onset of congestive heart failure. The characteristics of each group were compared with respect to ejection fraction, frequency of standard medications, age, gender, ambient arrhythmias, and inducibility of ventricular tachyarrhythmias using electrophysiologic-guided studies.

Follow-up

Patients were scheduled for follow-up at 3-month intervals or when ICD device therapy occurred. During follow-up appointments, the device was interrogated for arrhythmic events, and a clinical assessment was performed to determine their current medical status. All ICDs possessed internal electrogram storage capabilities. Arrhythmic events were characterized by two electrophysiologists, who were blinded with respect to the duration of nonischemic dilated cardiomyopathy. The criteria for diagnosis of ventricular tachyarrhythmias included standard criteria such as morphology of stored electrograms, onset, regularity of arrhythmia, presence of atrioventricular dissociation, and response to therapy.

Endpoints

There were two primary endpoints of the study: ICD treatment of any ventricular arrhythmia, and ICD treatment for potentially life-threatening ventricular arrhythmias. Potentially life-threatening ventricular arrhythmias were defined as ventricular flutter (monomorphic ventricular tachyarrhythmia at rates ≥230 bpm) and ventricular fibrillation. All-cause mortality was used as the secondary endpoint. The numbers of deaths were registered when they were reported by the next of kin or if the event occurred in our institution. At the end of the study, the Social Security death index was queried for all patients. Time at risk for the two primary endpoints was calculated as the number of days elapsed from the date of ICD placement to the date of the first occurrence of the endpoint, mortality date, or last follow-up date, whichever came first.

Statistical analysis

Continuous variables are given as mean ± SD. Variables were compared using the Student's t-test for continuous variables and the Chi-square test for categorical variables. Endpoints were compared using Kaplan-Meier analysis and statistical significance calculated by a log rank statistic. Kaplan-Meier curves were constructed with respect to time of ICD placement. Cox univariate and multivariate regression analysis also were performed. $P \leq .05$ was considered significant.

Results

Baseline characteristics

During the analysis period from 1995 to 2004, 201 patients with nonischemic dilated cardiomyopathy underwent ICD placement. Of these patients, 70 had sustained arrhythmias prior to ICD placement and thus were excluded from analysis. The remaining 131 patients constituted the study patient population. Of these 131 patients, 43 presented with syncope, 25 with presyncope, and 63 had no arrhythmic symptoms. Seventy-nine patients experienced nonsustained ventricular tachycardia during ambulatory monitoring in the initial implant hospitalization. Fifty-two patients composed the <9 months group, and 79 patients were in the ≥9 months group. There was no difference in baseline characteristics with regard to age, LVEF, gender, and presentation with syncope or presyncope (Table 1). Use of angiotensin-