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Original Article

Long-term survival of implantable cardioverter defibrillator recipients with end-stage renal disease

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ABSTRACT

Background: The efficacy of implantable cardioverter-defibrillators (ICD) for primary prevention of sudden cardiac death (SCD) has not been studied in patients with end-stage renal disease (ESRD) and left ventricular dysfunction. We sought to identify predictors of long-term survival among ICD recipients with and without ESRD.

Methods: Patients implanted with an ICD at our institution from January 2006 to March 2014 were retrospectively identified. Clinical and demographic characteristics were collected. Patients were stratified by the presence of ESRD at the time of ICD implant. Mortality data were collected from the Social Security Death Index (SSDI).

Results: A total of 3453 patients received an ICD at our institution in the pre-specified time period, 184 (5.3%) of whom had ESRD. In general, ESRD patients were sicker and had more comorbidities. Kaplan Meier survival curve showed that ESRD patients had worse survival as compared with non-dialysis patients ($p < 0.001$). Following adjustment for differences in baseline characteristics, patients with ESRD remained at increased long-term mortality in the Cox model. The one-year mortality in the ESRD patients was 18.1%, as compared with 7.7% in the non-dialysis cohort ($p < 0.001$). The three-year mortality in ESRD patients was 43%, as compared with 21% in the non-dialysis cohort ($p < 0.001$).

Conclusion: ESRD patients are at significantly increased risk of mortality as compared with a non-dialysis cohort. While the majority of these patients survive more than one year post-diagnosis, the three-year mortality is high (43%). Randomized studies addressing the benefits of ICDs in ESRD patients are needed to better define their value for primary prevention of SCD.

1. Introduction

Patients with end-stage renal disease (ESRD) are at increased risk of cardiovascular mortality [1], in particular sudden cardiac death (SCD) [2,3]. A subgroup at significant risk of arrhythmic death includes patients with ESRD and left ventricular dysfunction with low ejection fraction (EF) [4,5]. These patients, however, have not been included in any of the known SCD primary prevention trials [6–8], and some data suggest indirectly that these patients may not derive any benefit from implantable cardioverter-defibrillators (ICD) [9]. Furthermore, the competing arrhythmic and non-arrhythmic (cardiac and non-cardiac) causes of death in this population might make the benefit derived from ICDs

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negligible or neutral [1,5,10]. In addition, higher complication rates after implantation of ICDs in ESRD patients might contribute to the lack of observed ICD benefit in this population [5,11].

The proportion of patients with ESRD in the United States is increasing [4], and physicians are increasingly faced with difficult clinical decisions when caring for the subgroup of patients with ESRD and low EF. Current guidelines suggest that patients referred for ICD implantation for primary prevention of SCD have an expected survival of more than one year [12]. In this study, we sought to determine the long-term survival of ICD recipients with ESRD as compared with those not receiving dialysis, and to determine predictors of long-term survival of ICD recipients.

2. Material and methods

We retrospectively reviewed medical records for all patients undergoing de novo ICD implantation at Emory University hospital and Emory University hospital Midtown, two tertiary care hospitals located in metro Atlanta, Ga., from January 2006 to March 2014, and stratified them by the presence of ESRD at the time of implant. ESRD was defined by the need or lack of need for chronic dialysis (either hemodialysis or peritoneal dialysis) at the time of device implant. The decision to implant a defibrillator, along with specific details of the implant procedure and type of device implanted (i.e., single chamber, dual chamber, or cardiac resynchronization therapy defibrillator [CRT-D]) was performed at the discretion of the treating physician. Baseline clinical characteristics and procedural details were ascertained from medical records review.

The primary endpoint for this analysis was all-cause mortality. Vital status was determined via a query of the Social Security Death Index (SSDI). Patients who could not be identified in the SSDI and for whom vital status could not be determined were excluded from this analysis.

The protocol for this study was approved by the Emory University Institutional Review Board in June 2014 (IRB 00075736).

2.1. Statistical analysis

Continuous variables are presented as mean ± standard deviation, and categorical data are summarized as frequencies and percentages. Univariate analysis was performed using the Student's t-test, chi-square test, or Fisher's exact test, as appropriate. The time course of the primary endpoint, stratified by ESRD status, was assessed by Kaplan-Meier estimates and tested with the log-rank test. In order to identify correlations of mortality and assess for confounders, Cox proportional hazards models were performed, and univariate predictors with a p value ≤ 0.1 were included in the multivariate model. A two-tailed p value of < 0.05 was considered significant. All statistical analysis was performed using SPSS® (IBM Corp., Armonk, NY, USA).

3. Results

A total of 3453 ICD implants were identified, of whom 184 (5.3%) had ESRD requiring chronic dialysis at the time of implant. From this group, we were able to determine mortality/survival data on 2554 patients (74%) who served as the final cohort for this analysis. Baseline characteristics, stratified by ESRD status, are presented in Table 1. Across the entire cohort, mean age at the time of implant was 59.6 years, and 66.8% of the patients were male, without significant differences between groups. However, as might be expected, the patients with ESRD were predominately sicker, as evidenced by a higher prevalence of comorbidities including diabetes (49.6% vs. 33.2%, $p < 0.001$), hypertension (88.2% vs. 74.7%, $p < 0.001$) and lower ejection fraction (EF) (22.3% vs. 25.6%, $p = 0.004$). They were also more likely to be implanted

Table 1
Baseline characteristics.

Variable	non-ESRD ($n=2427$)	ESRD ($n=127$)	P
Age (years)	59.6 ± 14.5	59.1 ± 14.9	0.705
Male gender	1615 (66.5)	91 (71.7)	0.234
Left ventricle ejection fraction (%)	25.6 ± 12.5	22.3 ± 9.7	0.004
New York Heart Association class			0.772
I	218 (9.0)	14 (11.0)	
II	946 (39.0)	40 (31.5)	
III	1214 (50.0)	73 (57.5)	
IV	49 (2.0)	0	
Primary prevention ICD indication	2235 (92.1)	107 (84.3)	0.001
Coronary artery disease	1085 (44.7)	59 (46.5)	0.696
Prior CABG	541 (22.3)	36 (28.4)	0.112
Prior PCI	548 (22.6)	22 (17.3)	0.165
Chronic lung disease	314 (12.9)	20 (15.6)	0.358
Diabetes mellitus	805 (33.2)	63 (49.6)	< 0.001
Hypertension	1812 (74.7)	112 (88.2)	< 0.001
QRS duration	121.5 ± 32.3	117.7 ± 28.8	0.196
Medications			
ACE-I/ARB	1743 (71.8)	81 (63.8)	0.051
Beta blockers	2117 (87.2)	108 (85.0)	0.472
Hydralazine	244 (10.1)	29 (22.8)	< 0.001
Oral Nitrates	298 (12.3)	17 (13.4)	0.711
Digoxin	530 (21.9)	23 (18.1)	0.322
Diuretics	1687 (69.5)	68 (53.5)	< 0.001
Aspirin	1715 (70.7)	92 (72.4)	0.667
Clopidogrel	451 (18.6)	24 (18.9)	0.928
Warfarin	626 (25.8)	29 (22.8)	0.459
Statins	1424 (58.7)	78 (61.4)	0.541
Amiodarone	65 (2.7)	3 (2.4)	0.826
Defibrillator type			
Single chamber	1067 (44.0)	61 (48.0)	0.410
Dual chamber	413 (17.0)	17 (13.4)	0.331
Cardiac resynchronization	947 (39.0)	49 (38.6)	1.000

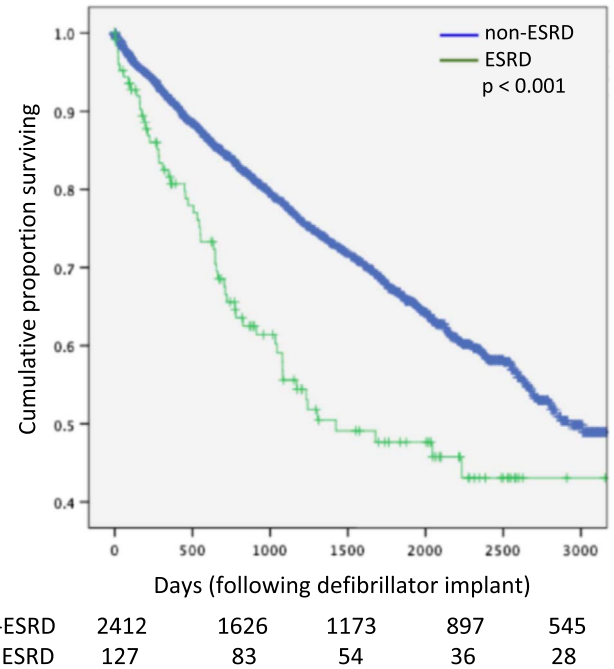

Fig. 1. Kaplan Meier (unadjusted) survival in end-stage renal disease (ESRD) and non-ESRD cohorts.