Cardiac implantable electronic device infection in patients with end-stage renal disease @ @



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INTRODUCTION Cardiac implantable electronic devices (CIED) are increasingly being used in end-stage renal disease (ESRD) patients. These patients have a high risk of device infection.

OBJECTIVES To study the optimal management of device infections in patients with ESRD.

METHOD We used the United States Renal Data System (USRDS) to assess the presence of a CIED and associated comorbidities, risk factors for infection, and mortality following device extraction or medical management in ESRD patients with CIED infection. Univariable, multivariable, and survival analyses were performed using USRDS data from 2005 to 2009.

RESULTS Of 546,769 patients, 6.4% had CIED and 8.0% of those developed CIED infection. The major risk factors for device infection were black race, temporary dialysis catheter, and body mass index > 25. Patients with artificial valves were excluded from the analysis. Only 28.4% of infected CIED were removed. CIED removal was more common in those with congestive heart failure. The

median time to death following diagnosis of a CIED infection was 15.7 months versus 9.2 months for those treated via device extraction versus medical-only therapy (hazard ratio: 0.75; 95% confidence interval: 0.68–0.82).

CONCLUSION Patients with ESRD and infected CIEDs have a poor prognosis. Rates of device extraction are low, but this strategy appears to be associated with modest improvement in survival.

KEYWORDS Pacemaker; Implanted cardioverter-defibrillator; Infection; Device extraction

ABBREVIATIONS aRR = adjusted risk ratio; CAD = coronary artery disease; CHF = congestive heart failure; CI = confidence interval; CIED = cardiac implantable electronic devices; ESRD = end-stage renal disease; HR = crude hazard ratio; LR = likelihood ratio; RR = crude risk ratio; USRDS = United States Renal Data System

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Introduction

Cardiac implantable electronic devices (CIED) are increasingly used to treat bradyarrhythmias, tachyarrhythmias, and congestive heart failure (CHF).^{1,2} Cardiovascular diseases, including arrhythmias and CHF, are the most common cause of death in patients with end-stage renal disease (ESRD).³ Thus, ESRD patients frequently have indications for the use of CIED. Infectious complications of CIED in the general population are relatively uncommon,⁴ but are associated with significant morbidity and mortality.⁵ The management of CIED infections usually includes the administration of antibiotics and removal of the infected hardware.⁶ In the general population with an infected CIED, a survival advantage has been shown for patients treated with antibiotics and device extraction when compared to antibiotic therapy alone.⁷

ESRD patients are at increased risk of bloodstream infection owing to frequent vascular access for hemodialysis or indwelling catheters for temporary hemodialysis or for peritoneal dialysis.^{8,9} Alterations in immune system function and limited inflammatory responses also put them at a higher risk for infection.¹⁰ Current guidelines do not directly address the management of CIED infections in ESRD patients, since these patients have been excluded from nearly

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all clinical trials. To better understand current management practices and outcomes for ESRD patients with CIED infections, we queried the United States Renal Data System (USRDS). In this large cohort we assessed the prevalence of CIED use, risk factors for infection, and mortality following device extraction, or medical management without extraction, in patients with CIED infection.

Methods

Data source

The USRDS is a de-identified database that includes demographic characteristics, hospitalization and physician/ supplier claims, and vital statistics on all ESRD patients in the United States.⁸ We queried USRDS data from 2005 through 2009. Comorbidities were defined by ICD-9 billing codes submitted to Medicare. The latest version of the form CMS-2728 was used to obtain additional comorbidity information. CMS form 2728 is a medical information form used by Medicare to determine eligibility and is a required submission by dialysis units on every patient enrolled.

Outcome variables

There were 3 primary outcome variables in this study: 1) presence of a CIED, 2) CIED infection, and 3) medical versus device extraction and associated survival of an infected CIED (Supplemental Table 1).

Presence of a CIED

The presence of a CIED was defined a priori according to the following ICD-9 codes: V45.01 (cardiac pacemaker), V45.02 (automatic implantable cardiac defibrillator), 996.61 (infection and inflammatory reaction due to cardiac device, implant, and graft), or any CIED extraction code (Supplemental Table 2). Only diagnosis codes defining the presence of a CIED occurring on or after the date of the first ESRD service were included in the analysis. Patients with cardiac valve prostheses were excluded from the analysis.

CIED infection

This analysis was limited to those individuals with evidence of a CIED and the presence of a CIED infection based on ICD-9 code 996.61 (see above). Because this code may indicate either CIED infection or cardiac prosthetic valve endocarditis, patients with prosthetic valves were excluded. This code was considered valid only if it was present after the placement date of a CIED.

Medical treatment versus extraction of an infected CIED, and associated survival

Medical therapy of a CIED infection without hardware removal was inferred by the lack of surgical extraction codes. Device extraction was defined by the presence of at least 1 surgical extraction code (Supplemental Table 1). Surgical extraction codes were considered valid only if they were dated within the 60 days following the diagnosis of a CIED infection. Survival following medical therapy, or device extraction of an infected CIED, was assessed through December 31, 2011. Individuals who had not died during follow-up were also censored on this date. Among patients who died, the cause of death was classified as cardiacrelated, infection-related, or other. Patients with cardiac valve prostheses were also excluded from this analysis.

Covariates

For all analyses, demographic characteristics considered included age at the onset of dialysis, sex, race/ethnicity, initial dialysis type, and year of first dialysis. Age was categorized as 18-39 years, 40-64 years, and greater than 65 years of age. Race was categorized as white, black, or other, or as Hispanic versus non-Hispanic. Demographic variables and date of first dialysis were obtained from the main USRDS patient database. The initial dialysis type was extracted from CMS-2728 version 2005, if available (25% of the study population had this available). For each set of analyses, covariates or potential risk factors as predictors of a given outcome of interest were considered, including several comorbid conditions as predictors for having a CIED or CIED infection. These variables differed in terms of data source and/or time of occurrence relative to the development of a CIED infection, and were divided into 3 general categories.

Category 1

Most comorbid conditions were identified based on the presence of 1 or more primary or secondary ICD-9 codes from hospitalization records that occurred from date of first ESRD service to date of the development of a CIED infection. Comorbid conditions considered specifically related to cardiovascular health were a history of atrial fibrillation or flutter, CHF, or coronary artery bypass graft. Other conditions reported were a history of cancer or sleep apnea. Comorbid conditions diagnosed prior to ESRD, and up to the diagnosis of a CIED infection, were included.

Category 2

For some comorbid conditions, we combined data from CMS-2728 with ICD-9 diagnosis codes to improve case finding. These comorbidities included a history of coronary artery disease (CAD), diabetes, hypertension, and alcohol use/abuse. These conditions may have occurred prior to ESRD or might have been a contributing factor to ESRD, and were included if they were present at or prior to the date of a CIED infection.

Category 3

Comorbid conditions considered as risk factors or conditions potentially requiring device extraction of an infected CIED included bacteremia, bacteremia with sepsis, infectious endocarditis, pulmonary embolism, and stroke. The presence of these conditions was inferred based on the presence of ICD-9 codes in the dataset within 2 days prior to and up to 7 days after the date of CIED infection. Download English Version:

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