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Survival of Patients With Biventricular Devices After Device Infection, Extraction, and Reimplantation

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Objectives This study sought to compare outcomes in patients with biventricular device infections who undergo successful treatment including extraction and reimplantation to patients with biventricular devices never known to become infected.

Background Infection of a cardiac implantable electronic device (CIED) is associated with substantial morbidity and mortality. Survival in patients with cardiac resynchronization therapy (CRT) device infections undergoing full system extraction is unknown.

Methods We extracted data on all patients undergoing extraction of a biventricular pacing device for an infectious indication at the Cleveland Clinic between February 16, 2000, and June 30, 2011. Survival of patients who presented with a CRT device infection, extraction, and successful reimplantation was compared to that of a large cohort of consecutive patients undergoing initial CRT implantation without a known history of subsequent device-related infection. In addition, long-term outcomes were compared between patients who were extracted and deemed to be cured with and without successful biventricular device reimplantation.

Results In all, 151 patients underwent biventricular device extraction for infection, of whom 81 were successfully reimplanted. The noninfected cohort consisted of 879 patients. In a multivariate Cox regression model controlling for sex, a history of ischemic cardiomyopathy, creatinine, hemoglobin, beta-blocker use, angiotensin-converting enzyme inhibitor use, and diuretic use, no significant association between subsequent infection with reimplantation and all-cause mortality was noted ($p = 0.21$). There was a trend toward worse outcomes for patients extracted, deemed cured, and not reimplanted compared to patients with successful CRT reimplantation.

Conclusions Patients with a biventricular device infection who are successfully extracted, treated with antibiotics, and reimplanted with a biventricular device have outcomes similar to those of patients with biventricular devices not known to have become infected. (J Am Coll Cardiol HF 2013;1:508–13) © 2013 by the American College of Cardiology Foundation

As a result of multiple recent large clinical trials, the indications for implantation of a cardiac implantable electronic device (CIED) have continued to expand (1–3). Such expansion has led to a significant increase in the incidence of device-related infections, which are well known to be associated with significant morbidity and mortality (4–6). The current therapeutic approach to dealing with CIED infections typically involves aggressive antibiotic therapy, complete system removal, and reimplantation of a new device on the opposing side (7). With complete device extraction, mortality has been reported to range from 7.4% to 18% and from 8.4% to 41% with antibiotic management alone (8,9). Because of the more recent adoption of biventricular devices compared to other types of CIEDs, very little is known with regard to outcomes in patients with biventricular device infections. Patients with biventricular device infections typically have higher comorbidity indices and more advanced cardiomyopathies compared to patients with other types of CIED infections. In addition to the risks

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associated with long-term intravenous antibiotics and the procedural risks of device extraction, patients with biventricular device infections must also cope with the transient loss of biventricular pacing which, for many, had provided significant hemodynamic support. To complicate matters further, the venous site of the original left ventricular lead often becomes occluded, necessitating placement of the lead in potentially less optimal sites (10). Given these factors, we sought to determine the impact of infection on mortality in patients with biventricular device infections successfully treated according to current recommendations with aggressive antibiotic therapy, extraction, and reimplantation.

Methods

We extracted clinical and laboratory data on a cohort of 151 patients who presented for extraction of a biventricular device at the Cleveland Clinic, Cleveland, Ohio, between February 16, 2000, and June 30, 2011. Survival of patients who presented with a cardiac resynchronization therapy (CRT) device infection, extraction, and successful reimplantation were compared to a large cohort of consecutive patients who underwent initial CRT implantation between 2002 and 2008 without a known history of subsequent device-related infection. The US Social Security Death Index was used to determine mortality status. Patients lacking a US social security number were excluded. A comparison was also made between patients who underwent CRT device extraction and were deemed cured with and without successful CRT reimplantation in terms of all-cause mortality.

Biventricular device infection management. Per the protocol in place at the Cleveland Clinic, all patients with a suspected device infection were seen by a dedicated infectious disease service, which focuses on cardiothoracic infections (10). Patients with suspected CIED infections receive a comprehensive physical examination, serial blood cultures, and a pre-extraction transesophageal echocardiogram to evaluate for valve- and lead-associated infective endocarditis. The CIED infection is further broken down into pocket infection or infective endocarditis. A CIED pocket infection is defined as erythema with or without purulent discharge, device erosion, fat necrosis, and/or adherence of the device to the skin, which may be accompanied by pain. Device-related infective endocarditis is defined as persistent bacteremia or sepsis in the absence of another identifiable source or vegetation on the leads or valves in the presence of a CIED. A minimum 2-week course of intravenous antibiotics is prescribed for all CIED infections, and longer depending on the presence of infective endocarditis and bloodstream infection. Antimicrobial selection is based on culture data from blood, pocket, and lead tip cultures. Patients with CIED infections undergo a full system extraction in the electrophysiology laboratory with placement of a transvenous temporary pacing wire in cases of pacer dependency. The time to device reimplantation is a clinical decision based on clearance of the signs and symptoms of active infection. Device reimplantation is usually performed on the contralateral side (or abdominal site) after clearance of the infection.

Abbreviations and Acronyms

CIED = cardiac implantable electronic device

CRT = cardiac resynchronization therapy

Statistical analysis. Continuous variables were presented as a mean ± SD. Categorical variables were presented as absolute numbers with percentages. Comparisons between continuous variables were made using Student *t* test and a 1-way analysis of variance. A chi-square test was used to make comparisons between dichotomous variables. A multivariate Cox regression model was created to determine the relationship between the presence of a successfully treated infection with biventricular device reimplantation and survival. Bootstrapping methods were used to select variables (in addition to the presence of infection, extraction, and reimplantation) independently associated with mortality.

All variables that were statistically significant in addition to the presence of infection remained in the final model. To help deal with the issue of length bias, the presence of subsequent infection, extraction, and reimplantation was entered into the model as time varying covariate. To test the Cox model assumptions, each variable in the final model was tested as a time varying covariate. Kaplan-Meier survival curves were constructed to compare survival out to 2 years in patients with biventricular device extraction and reimplantation starting at the time of reimplantation in the infected group to patients with biventricular devices never known to become infected. Kaplan-Meier survival curves were also constructed to compare survival in patients, extracted and deemed to be cured with and without reimplantation of a biventricular pacing device. All analyses were performed using SAS version 9.3 (SAS Institute, Cary, North Carolina) and SPSS version 21 (SPSS, Chicago, Illinois).

Results

From a cohort of 151 patients undergoing biventricular device extraction for an infectious indication, 81 were deemed cured and successfully reimplanted with a biventricular device on the contra-lateral side. Of the 70 patients not reimplanted, 10 were never deemed to be fully cured of infection and died shortly after extraction. Of the patients who underwent extraction and were deemed cured but not reimplanted with a biventricular device, 21 (13.9%) were deemed to no longer have an indication for CRT and received an implantable cardioverter-defibrillator or nonbiventricular pacemaker, 18 (11.9%) had a failed CRT implantation attempt and received an implantable cardioverter-defibrillator or nonbiventricular pacemaker, 10 (6.6%) were deemed too high risk to undergo device reimplantation, 6 (4.0%) were followed up elsewhere, and 5 (3.3%) refused reimplantation of another device.

JACC: Heart Failure Vol. 1, No. 6, 2013
December 2013:508–13

For patients in the successfully reimplanted, infected group, the median age of the left ventricular leads was 18.4 months (25% to 75% range 4.4 to 42.6 months) at the time of presentation. The median time between device extraction and reimplantation was 8 days (25% to 75% range 4 to 17 days). At the time of extraction, the median number of leads extracted was 3 (minimum of 2 and maximum of 6). A laser-powered sheath was required for extraction of at least 1 of the leads in 85.2% of patients. A laser-powered sheath was used to extract the right ventricular lead in 74.1% of patients, the right atrial lead in 38.2%, and the coronary sinus lead in 17.3%. The use of either manual dissection or a laser-powered sheath within the coronary sinus itself was necessary in 2 patients, and a femoral work station was required in 1 patient. At baseline, the infected and reimplanted cohort was older (71.4 ± 8.9 years vs. 66.5 ± 12.1 years, $p < 0.001$), more commonly male (90.1% vs. 70.2%, $p < 0.001$), had a higher incidence of ischemic cardiomyopathy (72.8% vs. 60.0%, $p = 0.02$), had a lower hemoglobin level (11.6 ± 1.9 g/dl vs. 12.5 ± 2.0 g/dl, $p < 0.001$), and was less likely to be taking a diuretic (61.7% vs. 76.2%, $p < 0.001$) compared to patients not known infected (Table 1). The most common presentation for patients in the infected and reimplanted group was with purulent drainage from the wound site (Table 2). Purulence within the pocket was seen in 74.1% of infected and reimplanted patients at the time of extraction (Table 3), and *Staphylococcus sp.* was the most common pathogen, seen in 64.2% of cases (Table 4). In a multivariate Cox regression model controlling for sex, ischemic cardiomyopathy, creatinine, hemoglobin, angiotensin-enzyme converting inhibitor use, beta-blocker use, and diuretic use, the presence of an infection with extraction and reimplantation of a biventricular device (as a time varying covariate) was not significantly associated with increased mortality ($p = 0.21$) (Fig. 1, Table 4). Of 81 patients with infection and reimplantation, 47 (58.0%) were deemed to have a systemic infection, defined as the presence of bacteremia and/or documented vegetations on a valve or lead. Patients with infection and subsequent reimplantation with and without systemic manifestations had a 2-year survival similar to that of patients never known to become infected (Fig. 2).

Compared to patients with infection who were extracted, deemed to be cured, and successfully reimplanted, patients not undergoing successful biventricular device reimplantation were younger (66.4 ± 13.1 years vs. 71.4 ± 8.9 years, $p = 0.012$), had a higher creatinine (1.80 ± 1.4 mg/dl vs. 1.3 ± 0.4 mg/dl; $p = 0.01$) and incidence of end-stage renal disease on dialysis (16.7% vs. 3.7%, $p = 0.2$), and were more often female (26.7% vs. 9.9%, $p = 0.012$). Lastly, there was a trend toward improved survival among patients successfully reimplanted with a biventricular device (Fig. 3).

Table 1 Baseline Characteristics

	Subsequently Infected, Extracted, Cured, Not Reimplanted (n = 60)	Subsequently Infected, Extracted, Cured, and Reimplanted (n = 81)	Not Known to be Infected (n = 879)	p Value
Age, yrs	66.4 ± 13.1	71.4 ± 8.9	66.5 ± 12.1	0.002
Male	44 (73.3)	73 (90.1)	617 (70.2)	0.001
ICD	52 (86.7)	77 (95.1)	826 (94.0)	0.07
Ischemic cardiomyopathy	36 (60.0)	59 (72.8)	526 (60.0)	0.07
White blood cell count, $\times 10^9$/l	9.0 ± 4.0	8.1 ± 2.6	7.6 ± 2.5	<0.001
Serum hemoglobin, g/dl	11.2 ± 2.2	11.6 ± 1.9	12.5 ± 2.0	<0.001
Serum creatinine, mg/dl	1.8 ± 1.4	1.3 ± 0.4	1.4 ± 0.8	<0.001
Atrial fibrillation	28 (46.7)	43 (53.1)	464 (52.8)	0.65
ESRD on hemodialysis	10 (16.7)	3 (3.7)	20 (2.3)	<0.001
COPD	9 (15.0)	9 (11.1)	136 (15.5)	0.57
Hypertension	31 (51.7)	47 (58.0)	518 (58.9)	0.53
Hyperlipidemia	26 (43.3)	40 (49.4)	477 (54.3)	0.19
History of malignancy	5 (8.3)	8 (9.9)	117 (13.3)	0.38
Diabetes mellitus	29 (48.3)	31 (38.3)	334 (38.0)	0.61
History of CVA or TIA	7 (11.7)	11 (13.6)	108 (12.3)	0.93
Beta-adrenergic blocker	45 (75.0)	63 (77.8)	677 (77.0)	0.40
ACE inhibitor or ARB	41 (68.3)	63 (77.8)	658 (74.9)	0.15
Diuretic	37 (61.7)	50 (61.7)	670 (76.2)	<0.001
Antiarrhythmic medications	21 (35.0)	25 (30.9)	181 (20.6)	0.016
Coumadin	25 (41.7)	37 (45.7)	325 (37.0)	0.48
Clopidogrel	5 (8.3)	13 (16.0)	123 (14.0)	0.36
Nitrates	8 (13.3)	27 (33.3)	230 (26.2)	0.02
Hydralazine	8 (13.3)	8 (9.9)	84 (9.6)	0.72

Values are mean ± SD or n (%).

ACE = angiotensin-converting enzyme inhibitor; ARB = angiotensin-II receptor blocker; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; ESRD = end-stage renal disease; ICD = implantable cardioverter-defibrillator; TIA = transient ischemic attack.

Table 2 Characteristics of Infection in Reimplanted Patients

Pocket presentation	
Purulent drainage from wound	22 (27.2)
Erythema, pain, and swelling	20 (24.7)
Erosion	20 (24.7)
Not-infected appearing	14 (17.3)
Erosion with purulent drainage	3 (3.7)
Hematoma	2 (2.5)
Presentation on extraction	
Pocket purulence noted on extraction	60 (74.1)
Bacteremia	17 (21.0)
Vegetations on lead and/or valves	25 (30.9)

Values are n (%).

Discussion

Complete system extraction with prolonged intravenous antibiotic therapy followed by device reimplantation is the current recommended approach to treating CIED infection (7,11). Although mortality associated with this strategy is certainly lower than using antibiotics alone, the true impact on survival of device infection and implementation of this invasive strategy is unclear (7). Patients with biventricular devices figure to be among the most vulnerable to poor outcomes after device infection. The potential negative impacts of a device extraction procedure utilizing general anesthesia, temporary withdrawal of biventricular pacing, prolonged intravenous antibiotic therapy, and implantation of a new biventricular device often with a coronary sinus lead in a new, potentially suboptimal location in this population is unknown. In the current study, we demonstrate for the first time that despite a high comorbidity burden, patients with advanced heart failure with biventricular device infections who are able to undergo an invasive strategy encompassing full system extraction with antibiotic therapy and system reimplantation have a similar survival at 2 years as patients with similar devices without infection. In addition, patients with biventricular device infections who undergo extraction, are deemed cured, and do not undergo system reimplantation have a trend toward worse outcomes compared to patients who are successfully reimplanted.

The incidence of CIED infection in the United States is rising at a rate out of proportion to the rate of device implantation (4,6). It is speculated that an aging population with increasing comorbidities, improved survival of CIED patients, and improved surveillance methods may be responsible for this increase (4). Given this increase, effective treatment strategies are needed to prevent significant rises in device-related morbidity and mortality. Before the routine use of percutaneous extraction techniques, device infections were commonly managed with antibiotics alone (12). Such a strategy was associated with an extremely high mortality

Table 3 Culture Characteristics of Reimplanted Patients

Bacteria	
MSSE	19 (23.5)
MSSA	12 (14.8)
MRSA	11 (13.6)
MRSE	8 (9.9)
Enterococcus sp.	2 (2.5)
MSSA and MSSE	2 (2.5)
Serratia marcescens	2 (2.5)
Peptostreptococcus sp.	2 (2.5)
Proteus mirabilis	2 (2.5)
Klebsiella sp.	2 (2.5)
Other	8 (9.9)
Negative	11 (13.6)

Values are n (%).

MRSA = methicillin-resistant *Staphylococcus aureus*; MRSE = methicillin-resistant *Staphylococcus epidermidis*; MSSA = methicillin-sensitive *Staphylococcus aureus*; MSSE = methicillin-sensitive *Staphylococcus epidermidis*.

Table 4 Cox Multivariate Model for All-Cause Mortality*

Variable	Hazard Ratio (CI)	p Value
Infection, extraction, reimplantation†	1.27 (0.88–1.83)	0.21
Male	1.44 (1.10–1.90)	0.008
Ischemic cardiomyopathy	1.80 (1.42–2.28)	<0.001
Creatinine, mg/dl	1.42 (1.22–1.60)	<0.001
Hemoglobin, g/dl	0.92 (0.87–0.97)	0.002
ACE inhibitor or ARB†	0.70 (0.55–0.88)	0.003
Diuretic use	2.1 (1.54–2.77)	<0.001

*Analysis stratified by beta-blocker use as this variable was in violation of the Cox model assumptions. †As a time varying covariate accounting for time from left ventricular lead implant to extraction.

CI = confidence interval; other abbreviations as in Table 1.

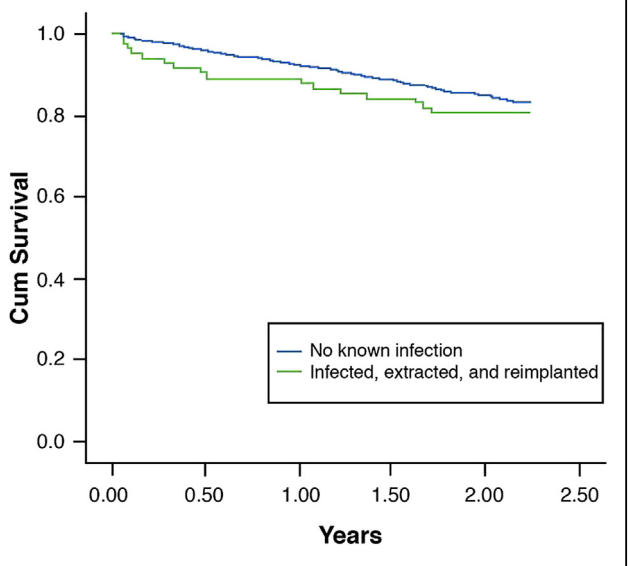

Figure 1 Survival in Patients With Successfully Treated Biventricular Device Infections Compared to a Noninfected Control

Survival measured from initial coronary sinus lead implant in the not-infected group **(blue line)** and the time from extraction in the reimplanted group **(green line)**.

JACC: Heart Failure Vol. 1, No. 6, 2013
December 2013:508–13

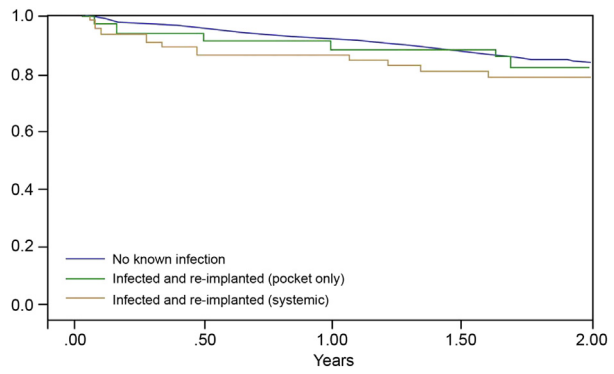

Figure 2 **Survival in Patients With Successfully Treated Biventricular Device Infections Broken Down by Systemic Versus Pocket Infection Only Compared to a Noninfected Control**

Survival measured from initial coronary sinus lead implant in the not-infected group **(blue line)** and the time from extraction in the reimplanted groups—infected and reimplanted, pocket only **(green line)**, and infected and reimplanted, systemic **(red line)**.

rate, forcing physicians to rethink treatment options (7,12). With the adoption of newer extraction techniques, most notably the use of laser-powered sheaths, procedural success rates and safety for extraction procedures have improved remarkably (13–15). While the pursuit of an invasive strategy has lowered the mortality rates of CIED infection, the true impact on survival of device infections treated successfully with an aggressive strategy is not known (16,17).

Patients with biventricular devices comprise the sickest cohort of patients receiving CIEDs and therefore figure to be the most vulnerable to poor outcomes with CIED infection despite aggressive treatment. Patients with biventricular device infections treated with an invasive strategy must undergo an often prolonged extraction procedure under general anesthesia, cessation of biventricular pacing for days to weeks, deleterious temporary right ventricular pacing in those who are pacemaker dependent, long-term intravenous antibiotic therapy with its inherent toxicities, reimplantation of a biventricular device often from the right side where operators have less experience, adding to procedural times, and placement of the coronary sinus lead in a vein often different from and less optimal than the original branch. A combination of 1 or all of these factors could lead to poor outcomes despite ultimate eradication of the infection and successful device reimplantation. Despite coping with these potentially morbid conditions, patients with biventricular device infections who successfully complete an invasive treatment course have a survival at 2 years that is similar to that of patients who were never infected. In addition, survival in the infected group was similar to the never-infected group despite the infected group having a longer duration of heart failure.

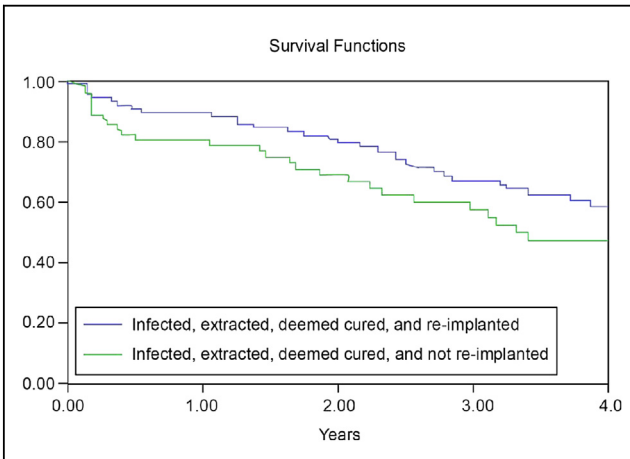

Figure 3 **Survival in Patients With Biventricular Device Infections Who Undergo Extraction and Are Deemed to be Cured With and Without Successful Biventricular Device Reimplantation**

Survival functions: infected, extracted, deemed cured, and reimplanted **(blue line)**; and infected, extracted, deemed cured, and not reimplanted **(green line)**.

In addition, we found that patients with biventricular device infections who are deemed to be cured and undergo successful reimplantation of a biventricular device have a trend toward better outcomes than patients deemed cured and not undergoing successful CRT reimplantation. The reason for this is most likely that the nonreimplanted patients are sicker at baseline (they are noted to have a higher incidence of renal dysfunction); however, the beneficial effects of CRT in the reimplanted group may also have played a role. Taken together, these findings further justify the current treatment guidelines dictating an aggressive and invasive approach to this population.

Study limitations. The retrospective nature of this study is subject to the well-known limitations of this study design. Moreover, patients in our cohort come from a single tertiary care center and therefore may not be representative of patients presenting to other centers. The population of patients with biventricular device infections undergoing extraction with reimplantation is relatively small but constitutes the largest known cohort in the literature to our knowledge. It is our belief that a type II error is unlikely given the nonsignificant results despite the longer duration of heart failure in the infected cohort. In comparing survival between patients with subsequent device infection and reimplantation, length bias exists. In an attempt to account for this, infection with reimplantation was entered into the model as a time varying covariate. In comparing patients who were extracted and deemed cured with and without CRT reimplantation, the nonreimplanted patients were likely somewhat sicker. Therefore, it is unclear whether the improved outcomes in the reimplanted group are the result of the CRT reimplant itself, a healthier status, or a combination of the two.

Conclusions

Patients with biventricular device infections who are able to be treated successfully with complete system extraction, prolonged intravenous antibiotic therapy, and biventricular device reimplantation have mortality similar to that of patients with biventricular devices never known to be infected. Patients successfully reimplanted with a CRT device have better outcomes than patients not reimplanted with a biventricular device. These findings further validate the current guidelines of pursuing an aggressive course toward patients with CIED infection, with the ultimate goal of infection eradication and full system reimplantation.

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