

Outcomes of Transvenous Lead Extraction for Cardiovascular Implantable Electronic Device Infections in Patients With Prosthetic Heart Valves

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Background—Lead-related or valve-related endocarditis can complicate cardiovascular implantable electronic device (CIED) infection in patients with both CIED and prosthetic valves. The objective of this study was to determine the outcomes of transvenous lead extraction for CIED infection in patients with prosthetic valves.

Methods and Results—We retrospectively screened 794 transvenous lead extraction procedures, between September 1, 2001 and August 31, 2012, at Mayo Clinic to identify patients with prosthetic valves who underwent lead extraction for infection. Demographic, clinical, and follow-up characteristics were analyzed. In total, 51 patients (6%) met the study inclusion criteria, of whom 20 had pocket infection and 31 had lead-related or valve-related, or both, endocarditis or bloodstream infection (mean age, 67 [18] years). Staphylococcal species were the most common pathogens, including *Staphylococcus aureus* in 20 cases (39%) and coagulase-negative staphylococci in 19 cases (37%). Overall, 127 transvenous leads (median lead age, 52 months) were extracted. Of these leads, 123 (97%) were removed completely. The in-hospital mortality rate was 9.8%; no deaths were attributable to the extraction procedure. Ninety-five percent of patients who survived had no evidence of recurrent device-related or valve-related infection.

Conclusions—Transvenous lead extraction seems safe and curative in patients with CIED infection and prosthetic valves. Cure of infection can be achieved in the majority of patients with complete CIED removal and antimicrobial therapy and without valve surgery. (*Circ Arrhythm Electrophysiol.* 2016;9:e004188. DOI: 10.1161/CIRCEP.116.004188.)

Key Words: anti-infective agents ■ cardiovascular infections ■ endocarditis
■ retrospective studies ■ Staphylococcal infections

Infective endocarditis (IE) is not uncommon in recipients of cardiovascular implantable electronic devices (CIEDs) who have an underlying prosthetic valve. An epidemiological study found that 24.4% of recipients of a permanent pacemaker who had definite IE had prosthetic valves.¹ The latest Heart Rhythm Society consensus' statement on transvenous lead extraction recommended complete device removal in all patients with CIED infection (systemic or pocket infection [PI]), valvular endocarditis without definite involvement of CIED, or occult Gram-positive bacteremia (class I; level of evidence, B).² The presence of prosthetic valves complicates CIED infection for at least 2 theoretical reasons: first, CIED infection could serve as a nidus for secondary infection of a prosthetic valve; second, a prosthetic valve is a potential

source of infection relapse after complete CIED removal. The outcomes of transvenous lead extraction for CIED infection in patients with prosthetic heart valves have not been well defined.³ The objective of the present study was to determine the outcomes of lead extraction for CIED infection in patients with prosthetic valves.

Methods

Study Patients

The records of all patients who underwent transvenous lead extraction at Mayo Clinic in Rochester, MN, between September 1, 2001 and August 31, 2012, were searched and screened to identify patients with prosthetic heart valves who underwent transvenous lead extraction for infectious complications. Cases were excluded from the

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WHAT IS KNOWN

- Complete CIED system removal is recommended in patients with CIED infection or valvular endocarditis without definite involvement of CIED. The presence of prosthetic valves complicates CIED infection.
- Transvenous lead extraction has become the preferred method for removal of CIED hardware.

WHAT THE STUDY ADDS

- Transvenous lead extraction permits successful treatment of CIED infection in the presence of prosthetic heart valves.
- Cure of infection can be achieved with transvenous lead extraction and antimicrobial therapy in patients with CIEDs and prosthetic valve endocarditis who are not surgical candidates.

analysis if patients were recommended for prosthetic valve surgery or had undergone surgical valve replacement for IE during the same hospitalization. All patients in this study consented to use of their medical records for research purposes. The study was approved by the Mayo Clinic Institutional Review Board.

Data Collection

The electronic medical records of all identified patients were reviewed. Baseline demographic, clinical, and follow-up characteristics were collected. The IE diagnosis was based on the modified Duke criteria⁴ and related guidelines.^{5,6} The patients were classified into a PI group and an IE group. The PI group included patients who presented with signs of inflammation at the generator pocket but without intracardiac involvement based on transesophageal echocardiography findings. The PI group may or may not have positive blood culture. The IE group contained patients who presented with definite or possible IE (lead-related IE, valve-related IE, or persistent occult bloodstream infection despite appropriate antibiotic therapy) with or without PI manifestation.

Lead Extraction

Transvenous lead extraction was performed in the surgical operating room or the electrophysiology laboratory with transesophageal echocardiography monitoring and cardiovascular surgical backup. A stepwise approach was used for lead extraction, as described previously.^{2,7,8} Briefly, manual lead traction with the aid of a regular stylet or a locket stylet was performed. If simple traction was not successful, a locking stylet and an excimer laser catheter were used. In patients with pacemaker dependency, a new active-fixation right ventricular lead was inserted and connected to an external pacemaker generator before lead extraction.⁹

Postprocedure Care and Follow-Up

After lead extraction procedure, all patients underwent continuous cardiac monitoring. Wound debridement or wound care was undertaken by surgical service. A new CIED reimplantation was performed as per the physician's discretion. Antimicrobial therapy was guided by infectious disease service for all cases. An outpatient follow-up visit at 2 to 4 weeks was recommended.

Statistical Analysis

Continuous variables are expressed as mean (SD) or median (first and third quartiles [Q1–Q3]). Categorical variables are reported as frequency and percentage. Continuous variables were compared with

2-sample *t* test or Wilcoxon Rank-sum test as appropriate. Categorical variables were assessed with χ^2 test or Fisher exact test. Statistical analyses were performed with JMP Pro version 9.0 (SAS Institute Inc). *P* values <0.05 were considered significant.

Results

Baseline Characteristics

Of 794 transvenous lead extraction procedures during the 11-year period, 51 procedures (6.4%) were performed for CIED infection in 51 patients with prosthetic valves. Of these, 20 patients (39%) had CIED PI (PI group); 31 patients (61%) had definite or possible IE (IE group), including 15 patients with lead-related IE (vegetation attached to lead observed with echocardiography), 4 with valve-related IE (involving prosthetic valve in 3 and native valve in 1), 7 with IE involving both lead and valve (prosthetic valve in 6 and native valve in 1), and 5 with occult bloodstream infection (Figure). There was no chronic draining sinus occurring in this study group.

Baseline characteristics of the 2 groups (mean [SD] age, 67 [18] years; men, 65%) are summarized in Table 1. The device type was permanent pacemaker in 25 patients (49%), implantable cardioverter-defibrillator in 10 (20%); and cardiac resynchronization therapy device in 16 (31%). As compared with the IE group, the PI group had more cardiac resynchronization therapy devices (50% versus 16%; *P*=0.01), more often generator replacement (85% versus 35%, *P*<0.001), and a shorter median interval time from the last procedure to lead extraction (3 versus 12 months; *P*<0.001). There was no significant difference in antibiotic duration between the 2 groups before lead extraction. Sixty percent of patients took Coumadin for mechanical valve anticoagulation. Coumadin was discontinued with heparin bridging before and after lead extraction as a standard protocol. The international normalized ratio level was similar in PI and IE groups on the day of extraction (Table 1).

Clinical Features at Presentation

Clinical presentations for both groups are summarized in Table 2. More positive pocket (70% versus 32%, *P*=0.03) and lead tip cultures (65% versus 39%; *P*=0.02) were detected in the PI group than in the IE group. Pathogen distribution was similar between the groups. Staphylococcal species were the most common pathogens, including *Staphylococcus aureus* in 20 (39%) cases and coagulase-negative staphylococci in 19 (37%).

Procedures of Lead Extraction

Procedure details are itemized in Table 3. In total, 127 transvenous leads (median [Q1–Q3] lead age, 52 [12–79] months) were extracted; of these, 79% were active fixation leads and 21% were passive fixation leads. Lead age, location, and type of fixation were similar in both groups. Patients in the PI group required a laser sheath more frequently than those in the IE group (69% versus 45%; *P*=0.008).

A total of 123 (97%) target leads were removed completely. Two leads (1.6%) were partially removed. Lead extraction was abandoned in one other patient with a 6-year-old dual-chamber pacemaker because calcified fibrosis around

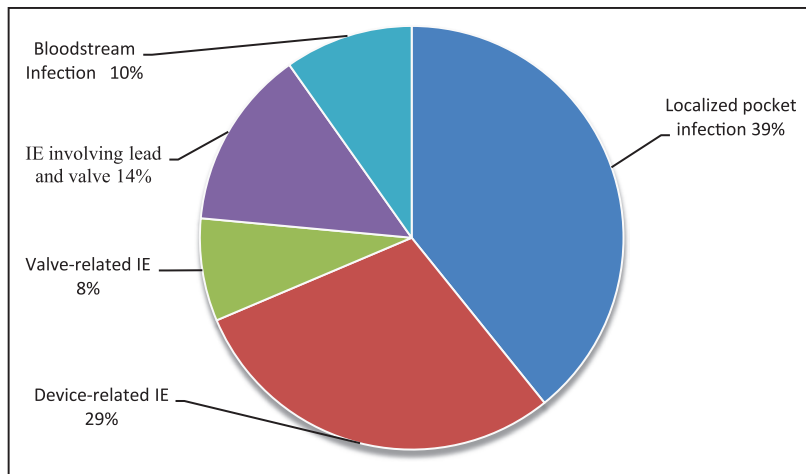


Figure. Infectious complications for lead extraction in the 51 patients with prosthetic heart valves. IE indicates infective endocarditis.

the leads at the junction of subclavian vein and innominate vein prevented laser sheath advancement.

Secondary closure of device pocket wound was required in 33 (65%) of the 51 patients. Median time from lead extraction to secondary closure of pocket was 6 days. A new CIED was implanted in 38 (75%) patients during the same hospitalization (mean [SD] time from extraction to implantation, 10 [4.8] days). No statistically significant differences were demonstrated in the rate and interval time of new device implantation between the groups.

Clinical Outcome

Echocardiography was performed in 34 (67%) of 51 patients after transvenous lead extraction including transthoracic in 12 and transesophageal in 22 patients. Residual mobile masses in the right atrium were found in 6 patients, including 3 with identified vegetations on preoperative echocardiography and 3 without preoperative vegetations. One patient with IE involving both lead and prosthetic mitral valve underwent surgical valve replacement 6 days after lead extraction because of infection progression. None of the other 50 patients underwent open heart surgery during the same hospitalization.

Overall, complications occurred in 11 cases (20%). No difference was found in the complication rate between the 2 groups. Native tricuspid valve injury with associated severe tricuspid regurgitation was found in 4 patients, including a flail tricuspid valve in 3 and markedly increased tricuspid regurgitation in 1. One patient had symptomatic acute thrombus in the left subclavian vein, resulting in medical intervention.

Overall, the in-hospital mortality rate was 9.8% (5 patients). All deaths occurred in the IE group (16% in IE group versus 0% in PI group; $P=0.14$). Deaths were because of IE complicated by multiple-organ failure in 2 patients, peptic ulcer perforation in 1 patient, urosepsis in 1 patient, and arrhythmia in 1 patient. No deaths were attributable directly to an extraction procedure. Median duration of hospitalization was longer in the IE group than in the PI group (20 versus 15.5 days; $P=0.01$).

Follow-up was available for 40 (87%) of the 46 discharged patients, of whom 25 patients were in the IE group and 15 patients in the PI group. The dismissal to first follow-up duration was 71 days. The median (Q1–Q3) last follow-up duration was 19 (5.7–47.0) months. The IE group had longer

median duration of intravenous antibiotic treatment after lead extraction than the PI group (40 versus 14 days; $P<0.001$). Five patients in the IE group received long-term oral antimicrobial suppressive therapy. During follow-up, 1 patient with IE involving native tricuspid valve received surgical treatment at 37 days after lead extraction because of infection progression involving the prosthetic aortic valve with perivalvular abscess. The patient died 8 days after the operation. Another patient with IE involving prosthetic mitral valve had recurrent methicillin-resistant *Staphylococcus aureus* bloodstream infection 24 months after lead extraction. The remaining 38 patients (95%) had no recurrent valve infection. None of the PI group developed IE after lead extraction. Five patients underwent implantation of a new CIED during follow-up.

Discussion

CIED-related infection is a class I indication for complete CIED system removal.² Patients with prosthetic valves often have prominent comorbidities and are at risk for valve infection.¹⁰ Little is known about the outcomes of transvenous lead extraction for infection in patients with prosthetic valves.³ To our knowledge, this series is the largest reported case series to specifically address CIED infection in the presence of prosthetic heart valves. This study had 2 key findings. First, in patients with prosthetic valves and infected CIEDs, percutaneous extraction of the implantable cardioverter-defibrillator or pacemaker permits successful treatment of the infection without the need for concomitant cardiac surgery in the vast majority of patients. The low rate of relapse suggests that prompt and aggressive removal of the CIED permits the removal of foreign, infected material, before cardiac valves are affected. In patients with PI, IE will be prevented if treated timely. None of our PI group developed IE after lead extraction. Second, most PIs in patients with prosthetic valves are related to recent device procedures, most commonly pulse generator replacements. Because this population is at particularly high risk of complications in the event of infection, the use of more aggressive infection-prevention strategies such as antibiotic impregnated pouches and antimicrobial dressing may be particularly attractive. Patients with a PI had shorter median time from the last device procedure to device infection than those with IE. This suggests that a

Table 1. Baseline Characteristics of the 51 Patients With Prosthetic Valves who Underwent Lead Extraction for Infectious Complications

Characteristic*	All Patients (N=51)	PI Group (n=20)	IE Group (n=31)	P Value
Age, mean (SD), y	67 (18)	65 (24)	68 (15)	0.61
Male sex	33 (65)	17 (85)	16 (52)	0.02
BMI, mean (SD)	29 (6)	30 (7)	28 (6)	0.32
Comorbid condition				
Hypertension	29 (57)	9 (45)	20 (65)	0.17
Coronary artery disease	28 (55)	11 (55)	17 (55)	0.72
Prior CABG	18 (35)	9 (45)	9 (29)	0.24
Diabetes mellitus	17 (33)	6 (30)	11 (35)	0.69
Nonischemic cardiomyopathy	14 (27)	8 (40)	6 (19)	0.11
Chronic renal insufficiency	20 (39)	7 (35)	13 (42)	0.62
On hemodialysis	5 (10)	0 (0)	5 (16)	0.14
Rheumatic heart disease	5 (10)	1 (5)	4 (13)	0.64
Congenital heart disease	6 (12)	4 (20)	2 (7)	0.20
Medications				
Antiplatelet agent	30 (59)	12 (60)	18 (58)	0.89
Warfarin	36 (71)	14 (70)	22 (71)	0.94
Antibiotics before extraction, n	35 (70)	12 (60)	23 (74)	0.35
Antibiotics duration before extraction, mean (SD), d	2.3 (2.2)	1.7 (1.0)	3.0 (2.4)	0.12
INR, mean (SD)	1.3 (1.3)	1.0 (1.5)	1.3 (1.2)	0.87
LVEF <35%	11 (22)	4 (20)	7 (23)	>0.99
Device				
PPM	25 (49)	4 (20)	21 (68)	0.001
ICD	11 (22)	6 (30)	5 (16)	0.23
CRT	15 (29)	10 (50)	5 (16)	0.01
Last CIED procedure				
Initial implantation	23 (45)	3 (15)	20 (65)	<0.001
Revision/generator replacement	28 (55)	17 (85)	11 (35)	<0.001
Time from last procedure to lead extraction, median (Q1–Q3), mo	11 (3–42)	3 (1–11.5)	12 (6–57)	<0.001
Prosthetic valve				
Aortic	34 (67)	11 (55)	23 (74)	0.16
Mitral	19 (37)	7 (35)	12 (39)	0.79
Tricuspid	3 (6)	1 (5)	2 (7)	>0.99
Pulmonary	2 (4)	2 (10)	0 (0)	0.16
Mechanical prosthesis	27 (53)	11 (55)	16 (52)	0.81
Bioprosthesis	31 (61)	10 (50)	21 (68)	0.21
Time from valve replacement to lead extraction, median (Q1–Q3), y	6 (1.5–11)	8 (3.5–10.8)	5 (1–11)	0.22

BMI indicates body mass index; CABG, coronary artery bypass grafting; CIED, cardiovascular implantable electronic device; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; IE, infective endocarditis; INR, international normalized ratio; Q1–Q3, first to third quartiles; LVEF, left ventricular ejection fraction; PI, pocket infection; and PPM, permanent pacemaker.

*Values are presented as number and percentage of patients unless specified otherwise.

remote source of infection is an important causative factor in the patients with IE.¹¹ Staphylococcal species were the most common causative organisms in both groups, which is consistent with previous reports of prosthetic valve endocarditis¹² and CIED infections.^{13–15}

All in-hospital deaths (5 cases) occurred in the IE group. This finding supports the consensus that patients with IE are sicker than those with PI.¹³ Interestingly, the rate of positive lead tip cultures in the PI group was higher than the IE group. This phenomenon could be because of contamination of the lead tip while

Table 2. Clinical Characteristics of the 51 patients With Prosthetic Valves who Underwent Lead Extraction for Infectious Complications

Characteristic*	All Patients (N=51)	PI Group (N=20)	IE Group (N=31)	P Value
Presenting symptoms				
Systemic	34 (67)	6 (30)	28 (90)	<0.001
Local pocket	25 (49)	19 (95)	6 (19)	<0.001
Peripheral emboli	2 (4)	0 (0)	2 (7)	0.51
Positive culture				
Blood	30 (59)	9 (45)	21 (68)	0.11
Pocket swab/tissue	24 (47)	14 (70)	10 (32)	0.03
Lead tip	25 (49)	13 (65)	12 (39)	0.02
Microbiological results				
CoNS	19 (37)	8 (40)	11 (35)	0.75
MSSA	13 (25)	6 (30)	7 (23)	0.55
MRSA	7 (14)	2 (10)	5 (16)	0.69
<i>Enterococcus faecalis</i>	3 (6)	0 (0)	3 (10)	0.27
β -Hemolytic <i>Streptococcus</i>	3 (6)	1 (5)	2 (7)	>0.99
<i>Propionibacterium</i> sp	3 (6)	1 (5)	2 (7)	>0.99
<i>Candida albicans</i>	1 (2)	0 (0)	1 (3)	>0.99
Others	8 (16)	5 (25)	3 (10)	0.24
Laboratory abnormalities				
Peripheral leukocytosis†	11 (22)	1 (5)	10 (32)	0.03
Anemia‡	41 (80)	13 (65)	28 (90)	0.04
Creatinine >1.2 mg/dL	26 (51)	10 (50)	16 (52)	0.91

CoNS indicates coagulase-negative Staphylococci; IE, infective endocarditis; MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-sensitive *Staphylococcus aureus*; and PI, pocket infection.

*Values are presented as number and percentage of patients unless specified otherwise.

†Peripheral white blood cell count $>10 \times 10^9/L$.

‡Hemoglobin level <12.0 g/dL in women and <13.0 g/dL in men.

being dragged through the infected pocket at the time of lead extraction.^{16,17} However, given that the diagnosis of PI is based on clinical presentation and negative echocardiographic findings, patients in the PI group might have subclinical lead-related IE. Recently, Le Dolley et al¹⁸ described the residual masses as ghosts of leads and proposed that the presence of ghosts may be included as a new criterion in the diagnosis of lead-related IE. Our results suggest that these casts, unlike CIEDs themselves, are not impervious to host immune mechanisms. Therefore, removal of the CIED system promptly and completely is imperative, even in patients presenting with localized PI.⁶

As newer and more effective lead extraction technologies have emerged, percutaneous lead extraction has become the preferred method for the removal of CIED hardware.⁶ In the present study, the extraction success rate was high and similar to those in previous general lead extraction studies, although our in-hospital mortality rate was higher than that in other studies.^{19–21} Major complications associated with lead extraction were infrequent.² There was no death or surgical resuscitation required for this study group. Pocket hematoma and tricuspid valve injury were the most common complications.

Prosthetic valve endocarditis may be treated with antibiotic therapy alone in selected patients who are hemodynamically

stable without paravalvular complications.^{10,22,23} However, the presence of CIED complicates the management of valvular endocarditis because the CIED could serve as a nidus for relapsing infection.²⁴ Complete CIED removal is recommended in patients with valvular endocarditis even without definite infection of the lead or the device, or both.² Precise estimates of the benefits of lead extraction are not available because of a lack of comparison groups. Only 2 patients required surgical valve replacement because of infection progression after lead extraction. Our results are suggestive that transvenous lead extraction is feasible and effective for patients with prosthetic valve endocarditis who are not surgical candidates or that a redo prosthetic valve operation could be spared from high-risk patients. Prosthetic valve removal was not required in patients without the evidence of valve infection and even in selected patients with the evidence of valve infection.

Study Limitations

A majority of the patients in current series were referred for lead extraction to our medical center; thus, referral bias may have impacted the patient characteristics of our study cohort. Risk of infection relapse is higher in patients with infected CIED who do

Table 3. Procedures and Outcome of Lead Extraction for Infection in 51 Patients With Prosthetic Valves

Procedures and Outcomes*	All Patients (N=51)	PI Group (N=20)	IE Group (N=31)	P Value
Leads, n	127	51	76	...
Lead age, median (Q1–Q3), mo	52 (12–79)	58 (35–73)	52 (11–79)	0.22
Location				
Atrial	46 (36)	16 (31)	30 (39)	0.35
Ventricular	65 (51)	26 (51)	39 (51)	0.97
Coronary sinus	16 (13)	9 (18)	7 (9.2)	0.16
Fixation				
Active	100 (79)	39 (76)	61 (80)	0.61
Passive	27 (21)	12 (24)	15 (20)	0.61
Anesthesia				
General	38 (75)	17 (85)	21 (68)	0.20
Local	13 (25)	3 (15)	10 (32)	...
Techniques of extraction				
Manual traction	58 (46)	16 (31)	42 (55)	0.008
Laser sheath	69 (54)	35 (69)	34 (45)	0.008
Procedural success				
Complete extraction	123 (97)	51 (100)	72 (95)	0.15
Partial extraction	2 (2)	0 (0)	2 (3)	0.52
Failure to remove	2 (2)	0 (0)	2 (3)	0.52
Temporary pacing	29 (57)	11 (55)	18 (58)	0.83
Indwell time of temporary pacemaker, mean (SD), d	10 (5)	10 (5)	10 (5)	0.98
Reimplantation	38 (75)	15 (75)	23 (74)	0.95
Time of reimplantation from extraction, mean (SD), mo	10 (5)	10 (4)	9.8 (5)	0.72
Complications				
Pocket hematoma	4 (8)	2 (10)	2 (7)	0.64
Tricuspid injury	4 (8)	1 (5)	3 (10)	>0.99
Ventricular tachycardia	1(2)	0 (0)	1 (3)	0.42
Thrombosis of implant vein	1 (2)	1 (5)	0 (0)	0.39
Acute renal insufficiency	1 (2)	0 (0)	1 (3)	0.42
Hospital length of stay, median (Q1–Q3), d	18 (12–28)	15.5 (9.3–17.8)	20 (14–29)	0.01

IE indicates infective endocarditis; Q1–Q3, first and third quartiles; and PI, pocket infection.

*Values are presented as number and percentage of patients unless specified otherwise.

not undergo complete device, including leads, extraction.^{14,25–28}

Therefore, all patients in our series were managed with complete device removal. However, as a result, we had no group of patients who did not undergo lead extraction for the comparison of outcomes. Our follow-up echocardiograms immediately after lead extraction and return clinical follow-up are not complete, which may impact on the outcome assessment.

Conclusion

Transvenous lead extraction for CIED infection seems safe and feasible in patients with prosthetic heart valves. Cure of infection can be achieved in the large majority of patients with complete CIED removal and antimicrobial therapy and without valve surgery.

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Department of Cardiovascular Diseases, Mayo Clinic.

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