

Complete Pocket Resection with Regional Flap Closure for Treatment of Cardiac Implantable Device Infections

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Background: Cardiac implantable electronic device infections are associated with substantial morbidity and mortality. There are varied recommendations in the literature about treatment of the wound after extraction of all hardware, but only conservative, time-consuming approaches such as open packing and negative-pressure therapy along with a long interval before reimplanting any hardware have generally been recommended for the treatment.¹⁻⁴

Methods: A retrospective review was performed of 42 patients treated at Jersey Shore University Medical Center for implantable cardioverter defibrillator and permanent pacemaker infections between July 2010 and April 2018 with an aggressive, multidisciplinary approach utilizing an invasive cardiologist and a plastic surgeon. Clinical and demographic data were collected, and a descriptive analysis was conducted.

Results: A total of 42 patients, with a median age of 76 years, were selected for our treatment of pacemaker pocket infection. Patients underwent removal of all hardware followed by debridement and flap closure of the wound soon after extraction. Reimplantation was performed when indicated typically within a week after initial extraction and typically on the contralateral side. There were no reports of reinfection and no mortality in all 42 patients treated.

Conclusion: We found that the aggressive removal of all hardware and excisional debridement of the entire capsule followed by flap coverage and closure of the wound allowed for a shortened interval to reimplantation with no ipsilateral or contralateral infections during the follow-up period. (*Plast Reconstr Surg Glob Open* 2019;7:e2204; doi: 10.1097/GOX.0000000000002204; Published online 3 May 2019.)

INTRODUCTION

The number of cardiac implantable electronic devices (CIEDs) being implanted is increasing at a rapid rate. Unfortunately, there has been a concordant increase in the absolute number and rate of infection in this cohort of patients.⁵⁻⁷ Indeed, a large population study assessing the impact of device complications found device infection to

be the second most common complication and the one with the greatest impact on patient outcome.⁸

Pathogenesis typically involves any of 3 modalities: breach in sterile technique at the time of implant, breakdown of the skin barrier subsequent to placement, and remote systemic infection leading to device infection. Bacteria form an extracellular matrix, known as biofilm, which acts as a protective barrier for microorganisms, preventing treatment with antibiotics alone in the vast majority of cases of CIED infection. Thus device and lead removal is the mainstay of treatment.

Treatment of these CIED infections is largely guided by the American Heart Association scientific statement published in 2009 and updated in 2010 and 2017.⁹⁻¹¹ The most relevant treatment recommendations for CIED infection is summarized in Table 1. Endovascular infections are associated with higher morbidity and mortality compared to pocket limited infections. Options for

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Table 1. CIED Treatment Recommendations by the American Heart Association

Characteristic	Value
Class strength of recommendation	
Class I	Strong
Class IIa	Moderate
Class IIb	Weak
Class III: No benefit	Moderate
Class III: Harm	Strong
Systemic CIED infection	
Valvular endocarditis	Class I: Complete device and lead removal
Lead endocarditis	Class I: Complete device and lead removal
Persistent or recurrent bacteremia	
Class I: Complete device and lead removal	

CIED, cardiac implantable electronic device.

extraction of devices and leads, either mechanical, laser, or surgical assisted, have become more widespread and significantly reduce 1-year mortality rate compared to antimicrobial therapy alone.¹² However, very little guidance is devoted to wound care after extraction.

Standard treatment consists of removal of all hardware and secondary intention healing of the wound, typically using wet-to-dry dressing changes. While this method has the advantage of being simple and does not require the presence of an additional consultant (ie, a plastic surgeon), it also has several disadvantages, including prolonged healing time, necessity of frequent dressing changes, patient discomfort, and a potential significant delay until reimplantation. The typical patient in this clinical scenario is presented to the electrophysiologist, and the “conservative” treatment scenario described above fits neatly into the skill set of the typical invasive cardiologist and likely explains why this treatment scenario is still widely utilized.³ However, there is some evidence in the literature that a more aggressive surgical approach might have several advantages over the conservative methods.¹³ Thus, our institution began an aggressive, interdisciplinary approach to this problem utilizing the electrophysiologist for the hardware removal and the plastic surgeon for the soft tissue and wound management.

Although some uncertainty persists with regards to timing of reimplantation after explantation, there is evidence that in cases of device erosion and isolated infection without systemic involvement, there is a low risk of recurring infection, even after a short interval.¹³ Indeed, one study reported low relapse rate (8%) in a group of 123 patients with implantable cardioverter defibrillator (ICD) infections, in which 63% were reimplanted at a remote anatomic site at a mean interval of 7 days from the date of explantation of all hardware.¹⁴

The purpose of this retrospective, single-center study is to present our data on 42 patients treated with our approach, which included the aggressive extraction of all hardware, complete pocket and capsule extirpation, anti-

septic and antibiotic irrigation, and regional flap coverage of the wound. We hypothesized that if patients with infected CIED pockets were converted from a high risk “infected” status to a lower risk, “contaminated” state through the aggressive extraction of all hardware, complete pocket and capsule extirpation, antiseptic and antibiotic irrigation, and regional flap closure, the risk of local or systemic reinfection would be minimal. To date, we have uncovered little to no literature with specific retrospective or prospective evaluation of postoperative wound care in the setting of CIED pocket infections.

METHODS

Between July 2010 and April 2018, 42 patients (34 men and 8 women) were treated with our method of management of pacemaker pocket infection. The age of patients ranged from 34 to 92 years (median, 76 years). Patients had an average of 2 infection-related risk factors (Table 2). On average, each patient had 2 leads extracted. The infection occurred within 3 months of the generator placement in 13 patients (31%; median, 1 month; range, 1–3 months), whereas in 29 patients, infection occurred within 3 months or more after the generator placement (69%; median, 30 months; range, 4–106 months). In total, 98 leads were explanted (36 atrial and 35 ventricular pace sense leads, 4 coronary sinus leads, and 23 ICD leads). Of the 42 patients, 32 patients were reimplanted with a device on the contralateral side, whereas 1 patient was reimplanted on the ipsilateral side with a subcutaneous ICD system.

Surgical Technique

After identifying a patient with a CIED pocket infection, the patient would be scheduled for the hardware extraction with cardiac surgery standby. A plastic surgeon will be available for debridement and closure of the wound ideally at the time of extraction or less frequently within 24–36 hours after extraction at a subsequent procedure.

Intravenous antibiotics were administered after cultures were taken. A complete extraction of all hardware was done with laser and/or mechanical assistance. After removal of all hardware by the electrophysiologist, the plastic surgeon would then completely debride the capsule, often down to the surface of the pectoralis major muscle. In most cases, this necessitated a caudal extension of the original scar at its lateral limit, resulting in a scar that resembles a number “7.” Hemostasis was meticulously obtained, and careful attention to capsule removal was also given to where the leads pass underneath the clavicle to ensure complete removal, but no effort was made to “chase” the lead capsules under the bone to avoid injury to the subclavian vessels. The superior lateral edge of the pectoralis major muscle was undermined, rotated, and advanced superiorly to fill the dead space and cover the clavicle if exposed (Fig. 1). The wound was irrigated with Irrisept (Irrimax Corp.,

Table 2. Risk Factors Associated with Infection Identified in Patients

	Diabetes Mellitus	Renal Failure	Heart Failure	Generator Replacement	Anticoagulation
No. patients	14	3	19	23	20

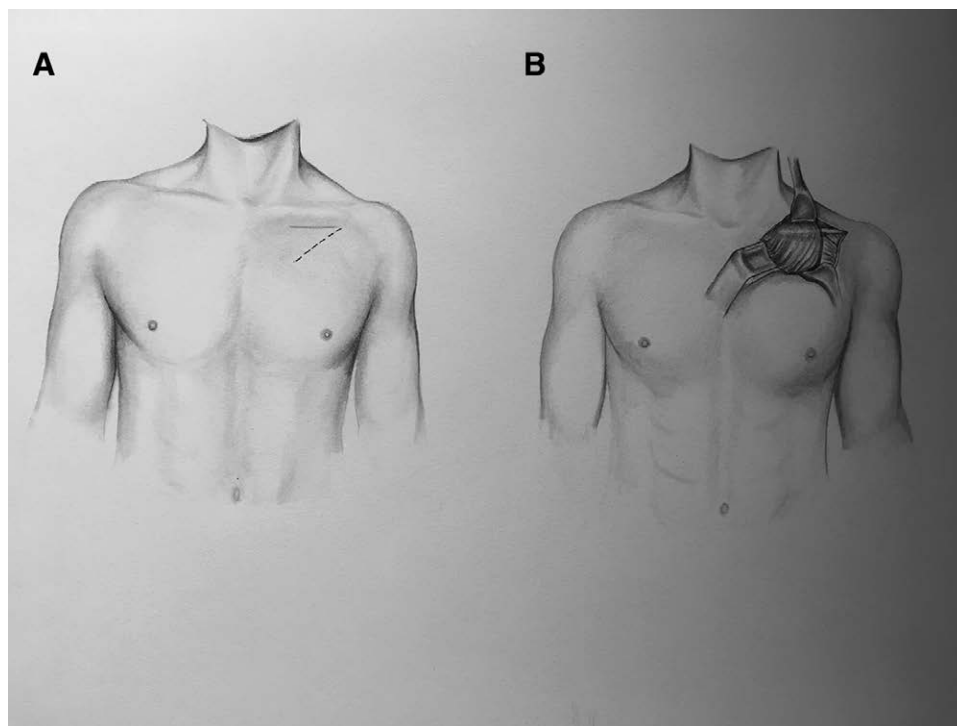


Fig. 1. The result of the surgical technique. A, The scar that resembles the number “7,” which results from the surgery. B, The pectoralis major muscle flap that serves to fill the empty pacemaker pocket.

Gainsville, Fla.) and antibiotic saline solution consisting of 1g Ancef (generic cefazolin, manufacturer GlaxoSmith-Kline, USA), 80mg gentamycin, and 50,000 Units/1 bacitracin before closure over a 7f Flat channel drain (BARD, Medline Industries Inc., USA) and secured with a remote stab incision with 3-0 nylon. The dermal layer of wounds was closed with 3-0 Monocryl (Ethicon/ Johnson & Johnson) sutures and skin was closed with 3-0 nylon sutures in a running fashion. In case of high risk for bleeding, quilting sutures of 2-0 Vicryl (Ethicon/ Johnson & Johnson) were used within the pocket. A pressure dressing was applied, and the drain was placed on suction.

The drain was removed when it was putting out less than 30 ml per day, and contralateral or remote reimplantation was performed typically within 7 days of explantation. Sutures were removed at 2 weeks.

RESULTS

In the short term, at a mean follow-up of 13 days (range, 7–21 days), there were no reports of reinfection. In the long term, throughout the 8-year duration of the study, there is no report of reinfection in our patients.

Demographics and clinical factors of study participants were outlined in Table 3, showing median age of 76 years, and a majority of patients had previously received implantable cardiac defibrillators (67% versus 33% permanent pacemaker). Table 4 presents the causes of infection for all the patients, and Table 5 provides clinical and surgical outcome data. The bulk of leads extracted were less than 9 years old but ranged up to 30 years. Thirty-eight percent of patients represented were diagnosed with congestive

heart failure, and a majority had coronary artery disease. Twenty-nine percent of patients had 3 or more leads removed at the time of extraction.

Debridement and flap closure were most frequently performed on the same day or the day after extraction of all hardware. The mean duration for all patients was 1 day,

Table 3. Demographics and Clinical Characteristics of Patients with CIED Treated Between 2010 and 2016

Characteristic	Value
Age (y), median (range)	76 (34–92)
Gender (male), n (%)	34 (81)
Device extracted, n (%)	
PPM	14 (33)
ICD	28 (67)
No. leads, n (%)	
5	2 (5)
4	3 (7)
3	8 (19)
2	23 (55)
1	6 (14)
Average age of leads (mo)	
0–50	40
50–100	16
100–150	25
150–200	11
200–400	4
Not registered	2
Comorbid conditions, n (%)	
Coronary artery disease	24 (57)
Cardiomyopathy	17 (40)
Congestive heart failure	16 (38)
Diabetes mellitus	15 (36)
Hypertension	29 (69)

CIED, Cardiac implantable electronic device; ICD, implantable cardioverter defibrillator; PPM, permanent pacemaker.

Table 4. Microorganisms Responsible for Device Infection

Cause of Infection	No. Patients
MRSA	4
Bacteremia (not specified)	3
Septicemia	1
<i>Escherichia coli</i>	2
MSSA	1
<i>Pseudomonas</i>	1
<i>Streptococcus</i>	1
<i>Staphylococcus epidermidis</i>	2
Enterobacteria	1
Unspecified/site erosion-related infection	26

MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-sensitive *Staphylococcus aureus*.

Table 5. Clinical and Surgical Data of Patients Treated Between 2010 and 2016

Characteristic	Value, n (%)
Laser-assisted extraction	34 (81)
Time since prior generator surgery (y)	
<1	21 (50)
1–5	14 (33)
6–10	7 (17)
Pacemaker dependency	
Dependent	16 (38)
Not dependent	26 (62)
Postoperative complications	
Reintubation for hypoxemia	1 (2)
Hematoma	1 (2)
Mortality and reinfection	
Mortality	0
Reinfection	0

except the first 2 patients who were treated initially with open packing and were the impetus for instituting the new, more aggressive protocol. The average time for reimplantation of a CIED was 6 days after the initial extraction procedure for all but 5 patients. For these 5 patients, reimplantation occurred 2–3 months after explantation due to the need for prolonged antibiotic administration and multiple comorbidities.

Thirty-four patients had laser-assisted lead extraction with the remainder extracted with mechanical assistance alone. One patient required a brief period of reintubation postprocedure due to hypoxemia, and another patient developed a hematoma within 7 days after extraction, and was subsequently treated with open hematoma evacuation.

In 21 patients, the mean time for extraction of all the hardware was 2 hours and 20 minutes, whereas the mean time for debridement and flap closure was 47 minutes. In 20 patients, both explant and flap closure procedure times were registered together, with a mean time of 1.75 hours.

DISCUSSION

The incidence of CIED infections is increasing, with one US study reporting an increased rate of infection from 1.53% in 2004 to 2.41% in 2008.⁶ The impact of CIED infections is substantial due to morbidity, mortality, and cost.¹⁵ Current treatment guidelines recommend the removal of all hardware, antibiotic therapy, and reimplantation when feasible and appropriate on the contralateral side.^{16–18} However, specific wound care protocols

are scarce and tend to be prolonged secondary healing techniques.³

In addition to the guideline-directed therapy for complete extraction of infected CIED hardware and contralateral reimplant sites when appropriate, our treatment method addresses the uncertainty concerning the wound management of CIED pocket infections. Our results demonstrate that an aggressive protocol of the wound management after removal of all hardware is safe, effective, and allows for reimplantation after a short interval, if necessary.

There were no deaths in our series and no recurrent infections. There were two complications: one patient was reintubated as a result of hypoxemia due to volume overload and another patient underwent hematoma evacuation at the extraction/debridement site.

Compared to extraction alone, our procedure duration was prolonged on average by 47 minutes due to the additional soft tissue work at the time of extraction. We believe that the added procedure time is offset by less postoperative wound management and quicker time to reimplantation. Furthermore, the morbidity of secondary intention healing (pain, scarring, prolonged drainage, and wound care) is reduced with our method.

Our study is limited by the inherent shortcomings of a retrospective study with relatively small numbers. Both extraction and debridement were performed by two clinicians. Patients were not followed up postoperatively long term and could have presented to other hospitals with subsequent complications. Also, although our results are good, we do not present any comparison to other studies with different methods for wound care after CIED extraction. Despite these limitations, there were no reports of reinfection and no deaths in our series. We believe that the described approach is safe and effective, may decrease the length of stay in hospital, may decrease costs of prolonged wound care, and may decrease the time to reimplantation.

CONCLUSIONS

There were no reports of reinfection in 42 patients treated for pacemaker pocket infection.

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