Negative-pressure wound therapy (NPWT) for the treatment of pacemaker pocket infection in patients unable or unwilling to undergo CIED extraction

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Abstract

Purpose The occurrence of cardiac pacemaker pocket infection has markedly increased and has become a new problem facing cardiovascular internists. The aim of our study was to investigate the effectiveness and safety of treating cardiac pacemaker pocket infection using negative-pressure wound therapy (NPWT) in patients who are unwilling or unable to have their cardiac implantable electronic devices (CIEDs) removed.

Methods From March 2013 to April 2019, NPWT was applied to 26 patients with cardiac pacemaker pocket infection who were unwilling or unable to have their CIEDs removed. In the first stage, a negative-pressure drainage system was placed in the pacemaker pocket after debridement. Then, NPWT was used to seal the wound, and the negative pressure (300–400 mmHg) was sustained for 5–7 days. In the second stage, the pacemaker was relocated to the subpectoral layer, and the wound was closed.

Results In all but three of our 26 patients, the wound healed completely without complications and without evidence of residual infection. The average follow-up period was 26.92 ± 9.46 months. Only 3 diabetic patients whose tissue bacterial cultures revealed that methicillin-resistant Staphylococcus epidermidis developed uncontrolled infections. Eventually, the entire original pacemaker systems were removed, and new pacemakers were implanted in the contralateral chest wall.

Conclusions When warranted by strictly selected indications, the method of NPWT without CIED extraction can be considered as a new and effective treatment for patients with pacemaker pocket infection who are unwilling or unable to have the device removed.

Keywords Pacemaker pocket infection • Treatment • NPWT • Retained CIED • Cardiology

1 Introduction

With the aging of the population and the increasing number of cardiac pacemaker implantations per year, the occurrence of cardiac pacemaker pocket infection has markedly increased and has become a new problem facing cardiovascular internists. Completely removing the entire implant system, as currently recommended by guidelines and expert consensus documents, can eradicate infection [1–3]. However, compared with other interventional treatments, transvenous lead extraction is a difficult technique with a high incidence of serious complications and mortality [1, 3, 4]. In addition, after the removal of the entire system, another time for the implantation of a new system must be chosen, which prolongs the patient’s hospital stay and adds significantly to healthcare costs. Although complete system removal represents the ideal management of an infected system, 3–15% of patients either refuse cardiac implantable electronic device (CIED) removal or are not suited for the procedure [5–10]. For such patients, the only other treatment option is to attempt salvage of the device with a course of appropriate antimicrobial therapy [9–11].

Negative-pressure wound therapy (NPWT) is a mature method of wound surface treatment established and developed in the last 20 years. NPWT is now widely used to treat the...
surfaces of acute and chronic wounds, achieving curative effects. NPWT has also been increasingly applied to treat deep wound infections in cardiac surgery and post-cardiac surgery mediastinitis [12–14]. Several reports [15, 16] have demonstrated that NPWT can be used as an effective strategy for patients with infected pacemaker pockets after removing the entire CIED or cutting the lead and retaining only that component. However, these approaches require the entire device or infected generator to be removed first, which still impacts the patient financially and psychologically, and they also face a high risk of complications, as mentioned above [1, 3, 4]. Importantly, we have accumulated rich clinical experience in applying NPWT to treat various serious infections and complex refractory wounds. Here, we present long-term results from 26 patients at our clinic who suffered pacemaker pocket infection but refused to undergo percutaneous lead extraction or cardiac surgery to remove the electrodes, and the final results showed that NPWT was a safe and effective treatment.

2 Methods and materials

2.1 Inclusion criteria

Restriction of the infection to the pacemaker pocket, i.e., uncomplicated generator pocket infection, was confirmed, and the following inclusion criteria were also applied:

- The site showed common signs of swelling, erythema, tenderness of the skin overlying the device, skin ulceration, and pyorrhea.
- Any of the following:
  - The patient, after being fully informed, declined percutaneous CIED extraction.
  - Two specialists determined, based on the patient’s condition, that extraction was too risky or that a CIED was absolutely necessary.
  - Percutaneous removal failed, and open surgical removal was declined.
  - The anatomical structure of the pectoralis major was normal.

2.2 Exclusion criteria

The exclusion criteria for the present study were uncomplicated generator pocket infection and any of the following:

- Systemic signs or symptoms of infection, such as chills, fever (> 39 °C), elevated white blood cell count (> 10.0 × 10^9/L), or a positive blood culture at any time.
- Evidence of lead infection or vegetations on the valves, as confirmed by a transesophageal echocardiogram or 18F-FDG PET/CT.
- More than once pacemaker pocket infection or generator change in the past with severe coagulation dysfunction, including cases that progressed to disseminated intravascular coagulation (DIC) or patients with an estimated life expectancy of less than 1 year.

2.3 Patient characteristics

The baseline and operative characteristics of the patients studied are shown in Table 1. NPWT devices were implanted in 26 patients who showed obvious evidence of a pocket infection at the time of wound opening. The subjects were predominantly male (84.6%) and elderly (61.4 ± 9.6), and their primary basic diseases were diabetes (30.8%), hypertension (38.5%), and congestive heart failure (26.9%). The number of patients with more than two lead types was 6 (23.1%). Procedures were performed on an average of 20.7 ± 18.7 days after the patient’s initial presentation for the infection. All patients had erythema and swelling, increased skin temperature, and tenderness of the skin overlying the pocket. Eleven (42.3%) patients had pocket ulceration, and 12 (46.2%) had pocket pyorrhea. Regarding the wound tissue bacterial cultures, 13 (50.0%) patients had multiple negative tissue bacterial cultures, 5 (19.2%) were culture positive for Staphylococcus epidermidis, 5 (19.2%) were culture positive for methicillin-resistant Staphylococcus epidermidis, and 3 (11.5%) were culture positive for Enterococcus. Three types of CIED were used in the 26 patients, including 1 (3.9%) single-chamber ventricular demand device (VVI, St. Jude Medical, Sylmar, CA, USA), 19 (73.1%) dual-chamber universal devices (DDD, Medtronic, Dublin, Ireland), and 6 (23.1%) cardiac resynchronization therapy devices (CRTDs, Medtronic, Dublin, Ireland). The median duration of lead implants in the patients was 27 months, ranging from 5 months to 19 years.

2.4 Procedure setup

2.4.1 Preoperative disposal

The following routine examinations were performed: a routine blood examination, a hepatic and renal function examination, coagulation function, and electrolyte and electrocardiogram tests. The following special examinations were performed: a transesophageal echocardiogram or 18F-FDG PET/CT, a chest periapical (PA) X-ray, and blood and wound secretion cultures along with a drug allergy assessment. Whether to apply a temporary pacemaker or adjust the working condition of the pacemaker during the operation to guarantee the


2.4.2 Phase I: debridement

After successful local anesthesia, the infected leads and the pulse generator were temporarily removed from the pocket and disinfected by immersion in 0.5% iodophor solution for 30 min. The pocket was extensively debrided to remove all infected tissue, biofilm, foreign material, and pus. We performed a complete capsulectomy until normal tissue was exposed, because the capsule is relatively avascular and is often seeded with bacteria [17]. Then, a sample of the tissue at the junction of the inflammation and the normal tissue around the lead was taken for bacterial culture.

Then, the flap was moderately separated to expand the pocket, the generator and lead were placed in situ, and the polyvinyl alcohol (PVA) foam sponge connected with the flushing and drainage tube was trimmed to be approximately 25% smaller than the wound margins [15]. The purpose of the sponge is to distribute the negative pressure throughout the entire wound bed and to prevent the end of the pressure tubing from becoming occluded. Finally, a standard continuous negative pressure of 300–400 mmHg was applied via the therapy unit, causing the dressing to collapse into the wound, and 500 ml/day of normal saline solution was used to continuously

flush the drainage tube to prevent drainage tube blockage. After treatment for 5–7 days, the phase II operation was arranged according to the characteristics of the rinses and the effusion from the polyurethane foam dressings. If the dressing was clean and the rinses were clear, the phase II operation was considered; if not, the entire negative-pressure device was changed.

2.4.3 Phase II: cardiac pacemaker reimplantation and incision closure

The generator was removed and placed in 0.5% iodophor for 30 min. After the pocket was repeatedly irrigated with 0.5% iodophor, hydrogen peroxide, and normal saline, the pectoralis major was separated along the muscle fiber to form an appropriate cavity gap. Care was taken to ensure complete hemostasis using electrocautery, and the condition of the lead was inspected. Then, the generator and lead were flatly reimplanted in the subpectoral layer without angulation or retraction. A figure-of-eight 4–0 Vicryl suture was placed in the muscle overlying the sites where the lead entered the venous system to fix the electrode lead to prevent movement and retraction. Multiside hole silica gel drainage tubes were separately placed in the subpectoral position and subcutaneous plane and extended from the normal skin above the incision through a separate perforation. After connecting the wound to wall continuous negative-pressure suction, we closed the incision with stratificate saturation.

2.4.4 Postoperative disposal

Patients were treated with intravenous (IV) antibiotics for an average of 2 weeks after debridement. Based on the guideline recommendation, vancomycin was used empirically until the microbial cause was known, at which time it was adjusted to directed (or targeted) antimicrobial regimens. During the phase II operation, the drain tubes were gradually extracted by removing a small length each day until completely removed, which usually took 3 to 5 days. The incision suture was removed 7 days after the operation.

2.5 Statistical analysis

Continuous variables were presented as mean ± standard deviation (SD) if the data were normally distributed, or as median with interquartile range (25th and 75th percentile) otherwise. Categorical variables are presented as numbers and percentages. For continuous variables, parametric analyses were performed using Student’s t test. Categorical variables were compared using Fisher’s exact tests. A P value < 0.05 was regarded as statistically significant. Analyses were performed using SPSS 22.0 (SPSS, Chicago, IL).
3 Results

The average duration of NPWT was 7.7 ± 2.6 days, and the average duration of hospitalization was 21.2 ± 3.9 days. In all but three of our 26 patients, the wound healed completely without complications and without evidence of residual infection. The average follow-up period was 26.9 ± 9.5 months, ranging from 10 to 49 months. Over more than 13 months of follow-up, no reinfections occurred in the successful group. The operating procedures of the successful cases are shown in Fig. 1. We found that a variety of patient characteristics and procedural issues such as male sex, hypertension, congestive heart failure, and pocket skin ulceration were associated with CIED infections but were not the significantly risk factors associated with treatment failure. Three patients who developed a recurrent infection, wound secretion, or tissue bacterial cultures showed methicillin-resistant Staphylococcus, and the patients also had diabetes. The entire cardiac pacemaker device was needed to be removed, and the new device was implanted in the contralateral chest wall (Table 2).

4 Discussion

The rate of CIED infection is increasing even more rapidly than the rate of implantation [2, 18, 19], and pacemaker pocket infection is the major complication of CIED implantation. Given the significant risk of serious complications and mortality of pocket infection, most guidelines currently recommend complete and early (as soon as possible, but not more than 2 weeks after diagnosis) removal of an infected CIED system (generator and all leads) combined with appropriate antimicrobial therapy, which is the most effective, safe, and efficient treatment option, including the lead in the case of a pocket infection. For such patients, the guideline clearly states that “a new system must be implanted in other parts of the noninfected side, avoiding the original pocket” [1, 4, 10]. Therefore, the lower chest wall or shoulder-back region of the patient’s noninfected side can be used for constructing the pocket and connected with the newly implanted electrode lead through a subcutaneous tunnel.

Accumulating evidence [9, 20, 21] indicates that CIED infections are complex to manage because of the presence of intra-cardiac and extra-cardiac components, both of which may become infected, and removal of the device can be major undertaking, with a risk of death or significant complications. Although complete CIED extraction represents the ideal treatment of an infected system, 3–15% of patients were still considered medically unsuitable for this procedure [6, 22], and others may refused CIED extraction, because of either the patient’s wishes, technical difficulties, or a perceived high surgical risk [5, 23, 24]. Specially, there have been reports of patients who refuse CIED extraction or are considered to have excessively high risk for this procedure, who have been successfully treated more conservatively [25]. Similarly, in the present study, 3 (11.5%) patients had undergone two CIED extraction therapies because of recurrent pacemaker infection, which resulted in a great risk for reimplantation of a pacemaker. Moreover, 4 (15.4%) patients were deemed unsuitable for CIED extraction because of their poor physical condition following a comprehensive assessment by two experienced cardiologists. Another 19 (73.1%) patients strongly refused to undergo CIED extraction for personal reasons or financial burden. In view of this, NPWT may be considered as an alternative therapeutic approach for patients who decline or are unsuitable for CIED extraction.

The guidelines categorize CIED infections as early postimplantation inflammation, uncomplicated and complicated generator pocket infections, CIED-infective endocarditis (CIED-IE), and CIED lead infections (CIED LIs) [4, 10]. Among all cardiac device infections, pocket infection is the most challenging diagnosis. Because of a lack of adequate comparison

![Fig. 1 Operating procedure in a typical case. a Preoperative pacemaker pocket infection with skin ulcers. b Phase I: debridement, separation, and removal of the infected capsular sac and inflammatory granulation tissue from the pacemaker pocket. c Complete removal of the infected capsular sac. d Repeated flushing of the operated cavity and placement of a sponge on the surface of the pacemaker. e Installation of the NPWT devices, infection control, and completion of the phase I operation. f Separation of the posterior division of the pectoralis major. g Resetting of the pacemaker device. h Withdrawal of the drain in segments for complete removal. i The incision was well healed after 1.5 years of follow-up](image-url)
groups and substantial heterogeneity among studies, guidelines cannot yet identify the differences in mortality rate between different types of CIED infections [1, 4, 10]. A large international prospective cohort study [26] demonstrated that an infection involving the valve and causing right heart failure and tricuspid regurgitation can significantly increase the risk of death at 6 months, which means that the prognosis of uncomplicated generator pocket infections was better than the other types. Patients with uncomplicated generator pocket infections who decline or are unsuitable for removable or patients with early postimplantation inflammation are most likely to benefit from the new treatment.

Within the past two decades, NPWT has been implemented in a broad spectrum of clinically complicated wound infections with notable curative effects. This method is based on the application of continuous negative pressure on the wound, leading to the removal of secretions and toxic products and to increased blood and lymphatic flow. NPWT systems further reduce the bacterial contamination of the wound and induce the formation of granulation tissue [27]. Negative pressure can be applied over the entire wound bed, minimizing the possibility that pockets of infection will go untreated. There is also evidence that it promotes angiogenesis, the secretion of growth factors, and cell division in granulation tissue [28, 29]. NPWT can also be used to control other implant infections and prevent the need for removal of internal fixation instruments [30] and porous titanium percutaneous devices [31]. It can also be successfully applied to cardiovascular surgical wound infections [32, 33].

However, clinical experience using NPWT to treat CIED pocket infections has been limited. A current small sample study [24, 34, 35] reported that after removing the entire device or infected generator, NPWT was applied to treat cardiac pacemaker pocket infection and preliminarily indicated the safety and effectiveness of this method. Thus, it may provide a new treatment for pacemaker infection. However, the best opportunity for NPWT treatment selection must be carefully considered. The guidelines recommend that the CIED is initially left in situ, while the patient is observed if there is early postimplantation inflammation [4, 10]. Early postimplantation inflammation is characterized by localized cellulitis, swelling, discharge, dehiscence, and pain. Wound inflammation occurring soon after implantation (superficial cellulitis) can be an early sign of pocket infection but can also be caused by non-infective conditions. Oral antibiotic coordination with NPWT treatment can achieve a good therapeutic effect at this stage. The period of this reaction overlaps with that of real pocket infection. During the period of identification, patients should be first given active antibiotics as a conservative treatment, along with the control of high-risk factors for infection (such as blood sugar control) and supportive nutrition. The device should be considered infected once the skin is breached due to erosion. At this stage, active debridement can help quickly remove inflammatory granulation, and further application of NPWT can help control infection and eliminate inflammation. Studies show that [18F] FDG PET/CT has emerged as a new imaging tool in the diagnosis of CIED infections to identify genuine infections associated with CIED or normal acute-phase reactions after implantation (4–8 weeks) [36–38]. It can also identify deep pocket infections and superficial skin infections at the pocket. Therefore, if suspected infected patients’ PET/CT results were positive, NPWT can be used as an adjunctive therapy to block the further development of infection.

Our study aimed to demonstrate the effectiveness and safety of treating cardiac pacemaker pocket infection using NPWT to patients who are unwilling or unable to remove CIEDs. Therefore, we excluded patients with systemic signs or symptoms of infection, any time of a positive blood culture; patients who suffered lead infection or vegetations on the

### Table 2 Differences in baseline characteristics between the successful group and the failure group

| Characteristics                                           | Successful group (n = 22) | Failure group (n = 4) | P value |
|-----------------------------------------------------------|--------------------------|----------------------|---------|
| Male, n (%)                                               | 19 (86.4)                | 3 (75.0)             | 0.51    |
| Age (years), mean ± SD                                    | 61.1 ± 9.8               | 63.0 ± 9.8           | 0.72    |
| Diabetes, n (%)                                           | 5 (22.7)                 | 3 (75.0)             | < 0.05  |
| Hypertension, n (%)                                       | 7 (31.8)                 | 3 (75.0)             | 0.26    |
| Congestive heart failure (NYHA grade > I), n (%)          | 5 (22.7)                 | 2 (50.0)             | 0.29    |
| Lead type (> 2), n (%)                                    | 5 (22.7)                 | 1 (33.3)             | 1.00    |
| Pocket skin ulceration, n (%)                             | 9 (40.9)                 | 2 (50.0)             | 1.00    |
| Pocket pyorrhea, n (%)                                    | 10 (45.5)                | 2 (50.0)             | 1.00    |
| Wound secretion or tissue bacterial cultures of Staphylococcus epidermidis, n (%) | 4 (18.2)                | 1 (25.0)             | 1.00    |
| Wound secretion or tissue bacterial cultures of methicillin-resistant Staphylococcus epidermidis, n (%) | 2 (9.1)                  | 3 (75.0)             | 0.01    |
| Wound secretion or tissue bacterial cultures as Enterococcus, n (%) | 2 (9.1)                  | 1 (25.0)             | 0.41    |
| Infection time (days), mean ± SD                          | 21.6 ± 19.7              | 15.3 ± 11.6          | 0.50    |

### References

[1] [26]...
valves, more than once pacemaker pocket infection or generator change in the past with severe coagulation dysfunction; and patients whose life expectancy may remain less than 1 year. Importantly, the generator and lead were reimplanted in the subpectoral layer instead of the original subcutaneous space. Our results showed that in all but three of our 26 patients, the wound healed completely without complications and without evidence of residual infection. This reminded us that we should be more cautious about using NPWT for patients with diabetes and methicillin-resistant *Staphylococcus aureus* in pathogenic microorganisms. We suggest that this treatment could be used in nondiabetic patients or in diabetic patients whose pathogenic microorganisms are methicillin-resistant *Staphylococcus aureus* with pacemaker pocket infections.

4.1 Limitations

The study was conducted at a single center and had a small sample size because of the limitations on enrollment. Additionally, we did not directly compare NPWT to any other form of wound therapy in a randomized manner, and we did not compare patients who received NPWT with a group of historical controls who did not. Therefore, further research is needed to confirm this conclusion.

5 Conclusions

In conclusion, complete CIED extraction remains the standard therapy for an infected system. However, under strict inclusion and exclusion criteria, NPWT can be considered as an alternative therapeutic approach in patients who are unable or unwilling to undergo CIED extraction.

Code availability

Not applicable.

Authors’ contributions

Conceptualization: Shengwu Zheng and Xiongmei Huang; methodology: Shengwu Zheng; formal analysis and investigation: Yazhou Lin, Xiaohui Chen, Genhui Lin, and Jing Zhuang; writing—original draft preparation: Xiongmei Huang; writing—review and editing: Shengwu Zheng and Xiaohui Chen; resources: Shengwu Zheng and Xiongmei Huang; supervision: Shengwu Zheng.

Data availability

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Compliance with ethical standards

Conflict of interest

The authors declare that they have no conflict of interest.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Fujian Provincial Hospital (No. K2013-02-002).

Consent to participate

Informed consent was obtained from the patients prior to study participation.

Consent for publication

Patients signed informed consent regarding publishing their data and photographs.

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