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Efficacy and safety of negative pressure wound therapy in the treatment of patients with cardiovascular implantable electronic devices pocket infection

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Abstract

Objectives To evaluate the efficacy of negative-pressure wound therapy (NPWT) for cardiac implantable electronic device (CIED) pocket infection, eliminating the need for CIED and leads extraction.

Methods The NPWT cohort consisted of 42 patients with CIED infection who were treated with NPWT from 2013 to 2023. Among them, 3 patients had a systemic infection and 1 patient had incomplete data. We performed a case-control study in which the NPWT group was compared with the conservative treatment group (40 patients). Main outcomes included failure rate (CIED/lead extraction during the 1-year follow-up, 30-day mortality/chronic infection, or infection-related mortality/recurrence) and infection-free time, with cure defined as absence of failure criteria.

Results A total of 38 patients with pocket infections were treated with NPWT from 2013 to 2023. NPWT was curative in 78.9% ($n=30$ of 38) of patients who remained free of infection [median follow-up 12.63 months, interquartile range (IQR): 12.30–34.10 months]. Compared with patients who were treated conservatively, the two groups demonstrated balanced baseline characteristics. Patients who were treated with NPWT had a significantly higher cure rate (78.9% vs. 55.0%, $n=22$ of 40; $p=0.025$) and a longer mean infection-free time at the 1-year follow-up (338.00 vs. 285.20 days, $p=0.034$).

Conclusion NPWT is an effective alternative for patients with CIED pocket infections who are unsuitable or unwilling to undergo CIED and leads extraction.

Trial registration This study was approved by the Chinese Clinical Trial Registry (Clinicaltrials.gov number: ChiCTR2300073560) on July 07, 2023.

Keywords Negative-pressure wound therapy, Cardiac implantable electronic devices, Prosthesis-related infections, CIED pocket infection

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Background

A cardiac implantable electronic device (CIED) infection is a serious complication and a source of major concern [1]. CIED infections may be local or systemic. A local infection, termed "pocket infection," is the most common type of CIED infection and is defined as an infection limited to the subcutaneous pocket where the device is located [2]. The prevalence of CIED pocket infections varies from 36.75 to 66.13% [2–5]. The impact of a pocket infection is significant, as its management typically involves hospitalization, prolonged antibiotic therapy and often complete removal of the CIED and leads [6]. However, there are risks associated with lead extraction, including massive hemothorax due to venous rupture, cardiac perforation with tamponade, and tricuspid regurgitation [1, 7]. The risk of mortality following lead extraction is 2 to 4 times higher when the indication involves infection [4, 7, 8].

Negative-pressure wound therapy (NPWT) has been used to treat many different types of chronic wounds that exhibit poor healing after primary closure [9–12]. NPWT involves the removal of fluid, exudate and debris from the wound bed. It is also thought to increase blood flow to the wound, reduce the number of bacteria and promote the formation of granulation tissue by stimulating cell proliferation, angiogenesis and the production of growth factors [13].

Since 2013, we have routinely used NPWT to treat CIED pocket infections in an attempt to obviate the need for CIED and leads extraction. Initially, our NPWT program was limited to patients who were unsuitable for CIED and leads extraction due to their high risk of surgical complications. As we noted favorable results in our preliminary research, we decided to extend our NPWT program to patients who were candidates for CIED and leads extraction and preferred a less invasive intervention [14]. We conducted a case-control study comparing NPWT with conservative treatment for CIED pocket infections and reported our 10-year experience in performing NPWT.

Methods

Subjects

A total of 97 patients with pocket infection were treated at Fujian Provincial Hospital during the 10-year period from March 2013 (the first NPWT patient) to June 2023. From the cohort, we retrospectively identified that all 78 patients (80.4%) were unsuitable or unwilling to CIED and leads extraction, including 38 patients treated with NPWT (NPWT group) and 40 patients underwent conservative treatment. All 78 patients had at least 1-year follow-up or until reinfection/death (Fig. 1).

The inclusion criteria were as follows: (1) patients aged 18 years or older, (2) patients with pocket infections (without systemic infections: positive blood cultures at any time during hospitalization, evidence of lead-related infection or valvular vegetations confirmed by transesophageal echocardiography, or metabolic activity suggestive of infection on 18 F-FDG PET/CT), and (3) patients who were unsuitable for or unwilling to undergo CIED extraction, including: (a) patients with refusal of the procedure due to unfavorable risk-benefit ratio or financial constraints; (b) expressing definitive preference for NPWT or conservative treatment as initial therapy strategy; (c) patients deemed ineligible for CIED and leads extraction due to geriatric vulnerability (e.g., advanced age or frailty syndrome) or compounded by pre-existing organ dysfunction (cardiac, pulmonary, or renal), resulting in prohibitive procedural risks.

The exclusion criteria were as follows: (1) patients with a CIED or leads beyond repair or a CIED or leads with a service life less than 12 months, including: (a) leads/generator damage (e.g., insulation breach, erosion) or irreversible dysfunction (e.g., chronic high thresholds > 3.5 V

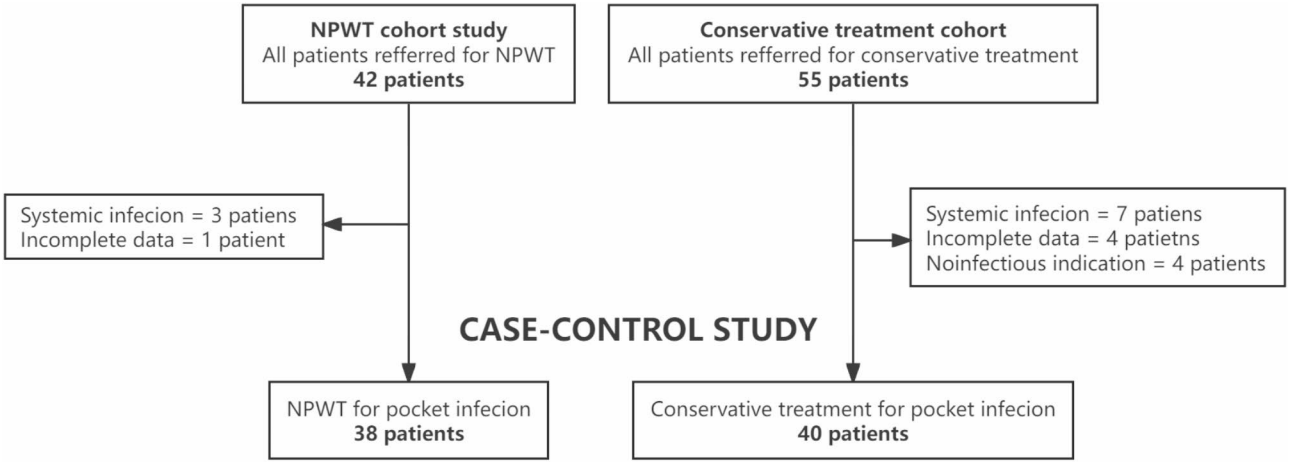

Fig. 1 NPWT cohort and case-control study (NPWT vs. conservative treatment). CIED, cardiac implantable electronic device

unresponsive toreprogramming) confirmed via intraoperative inspection [15]. (b) service life was determined by remote monitoring parameters (battery voltage ≤ 2.6 V, pacing burden > 80%) and manufacturer-provided longevity algorithms (e.g. predictive models). (2) patients with venous occlusion combined with lead-related complications (cardiac perforation, arrhythmia, nonfunctional leads, etc.); (3) patients with anatomic variations, absence or structural incompleteness of the pectoralis major because of surgery, trauma or other reasons; and (4) patients who refused to complete the survey or dropped out.

Negative pressure wound therapy procedure

On admission, bacteriological cultures were obtained from secretions at dehisced wounds. If such cultures were negative, we deferred empiric preoperative antibiotic treatment to enable the attainment of tissue cultures during surgery. If surgical cultures were negative again, we administered an empiric anti-staphylococcal antibiotic.

NPWT was performed under local anesthesia/conscious sedation in the operating room. The edge of the pocket and the fibrous capsule surrounding the device were thoroughly and extensively debrided. The CIED and leads were immersed in 0.5% povidone-iodine for at least 30 min. The pocket was cleansed by alternating 1.5% hydrogen peroxide and 0.5% povidone-iodine. The skin incision was modified, and the CIED and leads were placed in situ in the pocket and then the pocket was packed with a polyvinyl alcohol sponge composite with a porous propylene random copolymer (Guangdong Meiji Biotechnology). The entire wound and sponge were covered with polyurethane occlusive dressing. A double-lumen catheter, with an 8 F inner lumen and a 20 F outer lumen, was inserted percutaneously into the pocket for continuous saline infusion, and a vacuum-sealed irrigation wound therapy kit (MJ-03, Guangdong Meiji Biotechnology Co., Ltd.) was applied. 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 saline solution was used for continuous infusion (Fig. 2A-D). If the dressing and the fluid drained by negative pressure were clear after a period of treatment (5–7 days), we proceeded to the next step. If not, the entire vacuum-sealed irrigation wound therapy kit and sponge were replaced, and NPWT was performed again.

In the next step of the procedure, the CIED and leads were immersed and irrigated as in the previous treatment period. The pectoralis major was separated along the muscle fiber to form an appropriate cavity gap as a new pocket. Then, the CIED and leads were flatly reimplanted in the subpectoral layer, and the leads were fixed with 4–0 Vicryl sutures to prevent movement and retraction. A 16 F drainage tube and a 10 F drainage tube were placed in the subpectoral and subcutaneous layers, respectively. Negative pressure suction was applied to the wound, the drain tube was gradually removed according to the drainage situation, and the sutures were usually removed on postoperative days 10–14 (Fig. 2E-H). All patients received systemic antibiotics for at least 4 weeks after discharge (Fig. 3).

A protocol-defined NPWT approach was mandated for all patients, comprising povidone-iodine immersion, hydrogen peroxide irrigation, subpectoral reimplantation and negative pressure suction of the wound.

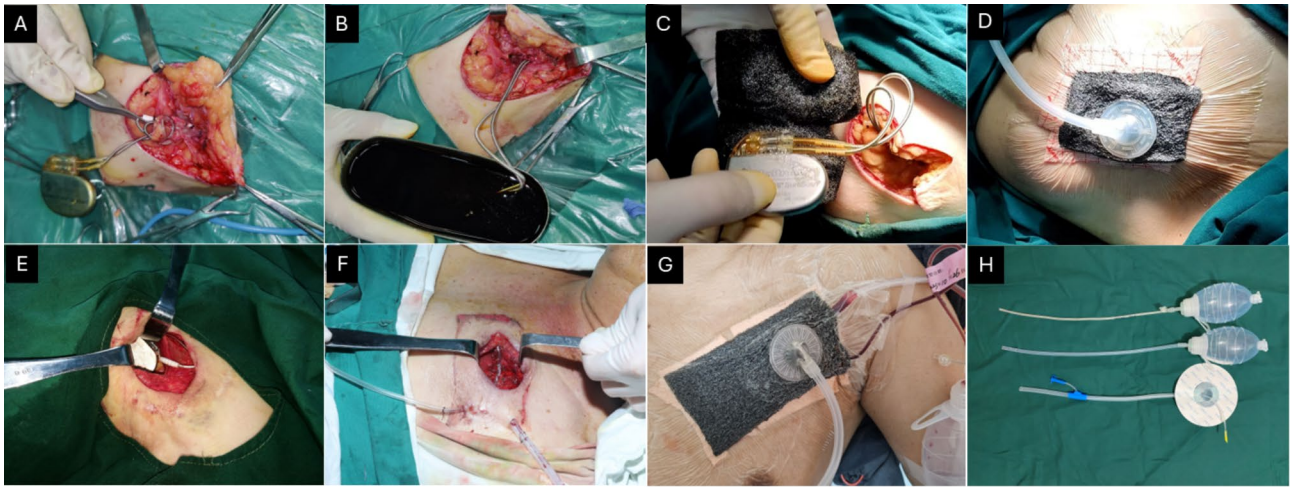

Fig. 2 Procedure of NPWT. **(A)** Debridement of infected capsule. (B) Immersion of CIED and leads in 0.5% povidone-iodine. **(C)** Packed with a sponge. **(D)** Application of vacuum-sealed irrigation wound therapy kit. **(E)** Separation the pectoralis major as a new pocket and CIED and leads were reimplanted in the subpectoral layer. **(G)** Application of negative pressure suction. **(H)** 10 F, 16 F drainage tube and a double-lumen catheter (an 8 F inner and a 20 F outer lumen). NPWT, negative pressure wound therapy; CIED, cardiac implantable electronic device

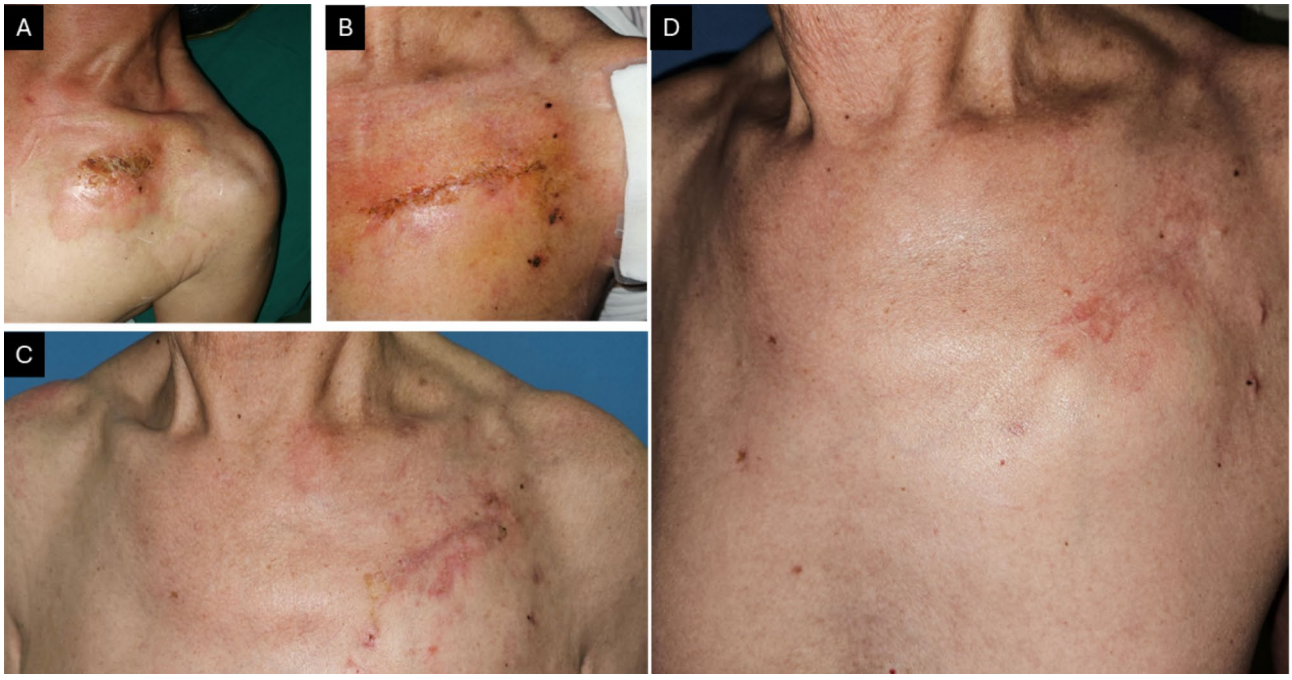

Fig. 3 **(A)** A 74-year-old man with an implanted dual-chamber pacemaker, was referred to our center with pocket infection presenting as skin discoloration and secretions and tissue cultures growing staphylococcus aureus. **(B)** The wound was closed primarily after the entire NPWT procedure. **(C)** Follow-up 3 months. **(D)** Follow-up 12 months later showing complete cure. NPWT, negative-pressure wound therapy

Conservative treatment procedure

All patients with CIED pocket infections received an initial 1-week systemic anti-staphylococcal antibiotic therapy, comprising empirical cefazolin initiation [escalated to vancomycin for high-risk methicillin-resistant staphylococcus aureus (MRSA) cases] or moxifloxacin for biofilm-associated infections, combined with prompt wound debridement/dressing changes upon admission. Most patients underwent debridement under local anesthesia or general anesthesia if necessary. The debridement procedure consisted of opening the pocket capsule, removing all infected and necrotic tissue, cleaning the capsule, and embedding the battery in the subpectoral muscle region after 0.5% povidone-iodine and saline irrigation of the wound. Minor patients underwent only a local dressing change.

On admission, bacteriological cultures were obtained from secretions at dehisced.

wounds. If such cultures were negative, we continued empiric anti-staphylococcal antibiotic treatment. All patients received systemic antibiotics for at least 4 weeks after discharge.

Data collection

All clinical data were extracted from the hospital information system, data of prognostic significance collected for all the patients included population characteristics [age, gender, body mass index (BMI)], past medical history, left ventricular ejection fraction (LVEF), creatinine, estimated glomerular filtration rate (eGFR) (calculated using the Mayo Clinic quadratic equation) and CIED characteristics [16, 17]. Follow-up was performed by telephone or outpatient review at 1 month after discharge and then every 3 months thereafter for 1 year, and the time to event was the time from treatment to reinfection or death. Data was entered into a standardized electronic database (Microsoft Excel).

Main outcome measures

In this case-control study of NPWT vs. conservative treatment, the main outcomes measured were the failure rate and infection-free time. Failure was defined as any of the following: (1) need for CIED and leads extraction at any time during the follow-up period; (2) death or development of a chronic infection from any cause within 30 days after treatment; or (3) death or reinfection related to the original pocket infection at any time during the follow-up period. Otherwise, patients were considered cured.

Infection-free time was defined as the time from treatment to reinfection or death related to the original pocket infection at the 1-year follow-up, irrespective of cause.

Statistical analysis

The $\chi 2$ test or Fisher exact test was used to evaluate associations between categorical variables. Continuous variables were compared using *t* tests or Wilcoxon rank sum tests (Mann–Whitney U tests). The infection-free time

was estimated for the two groups (NPWT and conservative treatment) via Kaplan–Meier analysis, and log-rank tests were used to compare differences by treatment type.

All comparisons were 2-sided, and a p value < 0.05 indicated statistically significant differences. Statistical analyses were performed using IBM SPSS Statistics, version 22.0 (Statistical Package for the Social Sciences, Chicago, IL, USA), GraphPad Prism, version 9.0 (GraphPad Software, San Diego, CA, USA) and Stata, version 15.0 (StataCorp LLC, College Station, TX, USA).

Results

The NPWT cohort

A total of 38 patients with CIED pocket infection underwent salvage attempts with NPWT. The most common bacteriological culture was negative (20/38; 52.6%). Cultures were coagulase-negative staphylococcus for 10 patients (10/38; 26.3%) in the entire cohort (Fig. 4).

Most patients (36/38; 94.7%) received NPWT only once, and 2 patients received it twice. The median time to CIED reimplantation was 7 days [IQR (interquartile range): 6–7 days], and the median length of NPWT was 10 days (IQR: 7.5–11.5 days). If the infection recurred after NPWT during the hospital stay, NPWT was repeated as soon as possible.

According to the predefined cure criteria (absence of treatment failure events during the 12-month follow-up period, including CIED/lead extraction, death or chronic infection within 30 days after treatment, or reinfection/death related to the original infection.), NPWT was curative for 78.9% (30/38) of patients and no patients died during the follow-up period. Of the 8 patients who experienced treatment failure, 3 experienced NPWT failure during the hospital stay, 2 of whom were discharged and transferred to another center for further treatment. The other patient underwent complete extraction of the CIED and leads without reimplementation.

NPWT failed in 5 patients (13.2% of the total cohort) who were alive during the entire follow-up period but required CIED and leads extraction because of septicemia (1 patient) and recurrent pocket infections (4 patients). The median follow-up period was 12.63 months (IQR: 12.30–34.10 months).

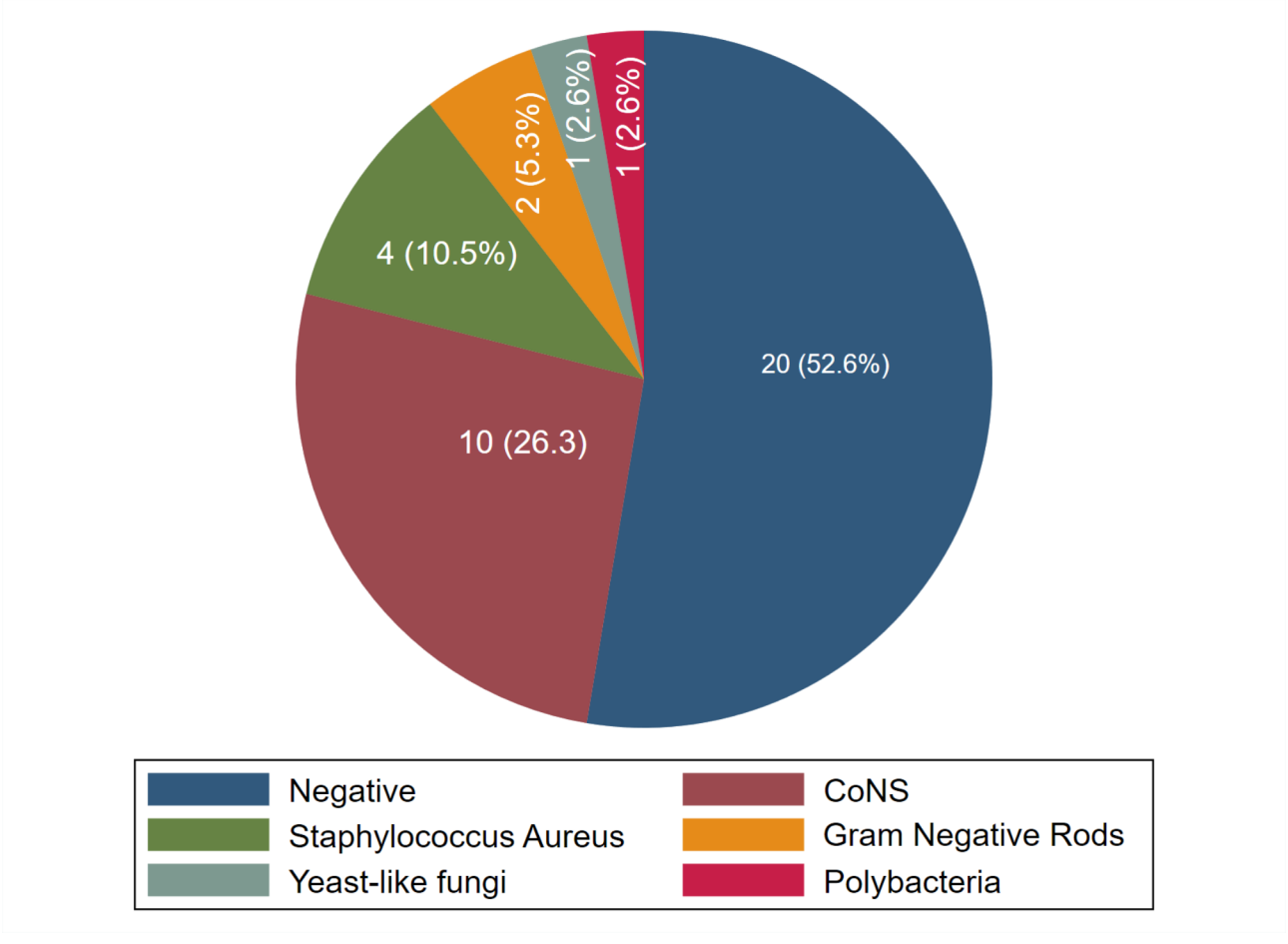

Fig. 4 Distribution of bacteriologic results during pocket infection. CoNS, coagulase-negative staphylococcus

The case-control study of NPWT vs. conservative treatment

The case-control study included 38 patients who underwent NPWT and 40 patients who received conservative treatment as primary therapy for pocket infection (Fig. 1). Significant differences were not detected between the 2 groups in any of the.

characteristics with known prognostic significance (Table 1).

Most patients (29/40; 72.5%) underwent debridement of the pacemaker pocket capsule, and 11 patients underwent only a local dressing change. Conservative treatment was curative for 55.0% ($n = 22$ of 40) of patients who remained free from infection and for only 1 patient who died of a systemic CIED infection during the follow-up period. Of the 18 patients whose treatment failed, 5 experienced conservative treatment failure during the hospital stay. All of them were discharged and transferred to other centers for further treatment. The median follow-up period was 16.40 months (IQR: 3.70–104.33 months).

The rate of failure was significantly higher for conservative treatment than for NPWT (45.0%, 18/40 vs. 21.1%, 8/38; $p = 0.025$). After patients whose treatment failed during the hospital stay were excluded, 37.1% of those who received conservative treatment experienced treatment failure ($n = 13$ of 35), whereas 14.3% of patients who received NPWT experienced treatment failure ($n = 5$ of 35) ($p = 0.029$). Figure 5 shows the 1-year follow-up and reinfection curves for patients who experienced reinfection or cure after either NPWT or conservative treatment. Compared with patients who were treated conservatively, patients who were treated with NPWT had a longer mean infection-free time at the 1-year follow-up (338.00 vs. 285.20 days, $p = 0.034$). (Table 2).

Discussion

Our single-center retrospective case-control study, reflecting a 10-year experience in performing NPWT, compared with conservative treatment, suggests that NPWT may serve as a reasonable alternative of CIED and leads extraction for pocket infection, as it cured most patients.

Although complete removal of the CIED and leads is the best way to manage a pocket infection, leads extraction is a complex procedure that carries its own risks [1]. While more than 95% of leads can be successfully removed by highly experienced surgeons in the event

Table 1 Comparison of patients with pocket infection treated by NPWT vs. conservative treatment

	NPWT ($n = 38$)	Conservative treatment ($n = 40$)	*P*
Age, year	64.21 ± 9.97	68.58 ± 9.74	0.054
Gender			
Male	26(68.4)	29(72.5)	0.693
Female	12(31,6)	11(27.5)	
BMI ≤ 25, kg/m^2	25(65.8)	27(67.5)	0.873
BMI > 25, kg/m^2	13(34.2)	13(32.5)	
Past medical history			
Smoking history	7(18.4)	5(12.5)	0.469
Oral anticoagulant	10(26.3)	12(30.0)	0.718
Diabetes mellitus	8(21.1)	11(27.5)	0.507
Hypertension	20(52.6)	20(50.0)	0.816
Coronary heart disease	4(10.8)	8(20.0)	0.246
Post valve replacement	5(13.2)	3(7.50)	0.653[a]
LVEF, %	56.26 ± 7.84	57.98 ± 7.40	0.324
Creatinine, mg/dL	77.16 ± 14.27	81.30 ± 23.9	0.359
eGFR, mL/min/1.73 m^2	100.17 ± 13.28	93.32 ± 18.07	0.061
CIED characteristics			
Single-chamber PM	5(13.2)	12(30.0)	0.173[a]
Dual-chamber PM	28 (73.6)	25(62.5)	
ICD and CRT	5 (13.2)	3(7.5)	
CIED variables			
Number of leads	1.95 ± 0.46	2.03 ± 0.77	0.588
Age of device	285.00(60.00,1095.00)	150.0(18.00,727.50)	0.174[b]
Post device replacement	15(39.47)	19(47.5)	0.475

Data are presented as No. (%) of patients or median (interquartile range) or mean ± standard deviation

NPWT, negative pressure wound therapy; BMI, body mass index; LVEF, left ventricular ejection fraction; eGFR, estimated glomerular filtration rate; CIED, cardiac implantable electronic device; PM, pacemaker; ICD, implantable cardioverter defibrillator; CRT, cardiac resynchronization therapy

a, Yates's correction for continuity

b, Mann-Whitney U tests

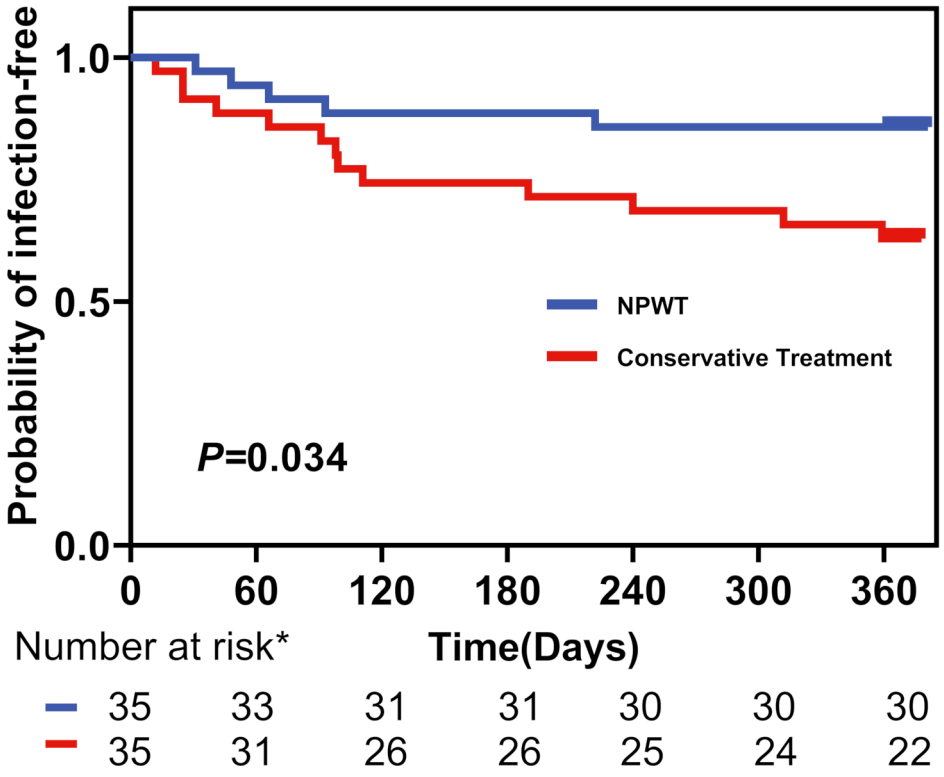

Fig. 5 Infection-free time for 1-year follow-up by different treatment. * Infection-free time was analyzed in 35 NPWT and 35 conservative patients after excluding failures in-hospital (3 experienced NPWT failure and 5 experienced conservative treatment failure during the hospital stay). *P* value by log-rank test. NPWT, negative-pressure wound therapy

Table 2 Summary of post-procedure/after discharge result and main outcomes

	Total (*n* = 78)	**NWPT (*n* = 38)**	**Conservative treatment (*n* = 40)**	***P***
Post-procedure results (days)				
Post-procedure LOS	12.88 ± 8.44	15.34 ± 6.84	10.60 ± 9.32	0.013
NWPT duration	NA	10 (7.5,11.5)	NA	NA
Time to re-implant	NA	7(6,7)	NA	NA
Main outcomes				
Total Failures[a]	26(33.3)	8(21.1)	18(45.0)	0.025
Failures in-hospital	8(10.3)	3(7.9)	5(12.5)	0.712[b]
Failures after discharge				
Reinfection	17(21.8)	5(13.2)	12(30.0)	0.072
Death	1(1.3)	0(0.0)	1(2.5)	1.000[b]
	Total (*n* = 70)	NWPT (*n* = 35)	Conservative treatment (*n* = 35)	*P*
After discharge results (days or months)				
Failures after discharge	18(25.7)	5(14.3)	13(37.1)	0.029
Follow-up time (months)	12.63(9.80,70.25)	12.63(12.30–34.10)	16.40(3.70-104.33)	0.963[c]
Infection-free time	311.91(282.68-341.14)	338.00(303.65-372.35)	285.20(239.65-330.76)	0.034[d]

Data are presented as No. (%) of patients or median (interquartile range) or mean ± standard deviation

NPWT, negative pressure wound therapy; LOS, length of stay; NA, not applicable

a, Failure was defined as any of the following: (1) need for CIED and lead extraction at any time during the follow-up period; (2) death or development of a chronic infection from any cause within 30 days after treatment; or (3) death or reinfection related to the original pocket infection at any time during the follow-up period

b, Fisher exact tests

c, Mann-Whitney U tests

d, Log-rank test and data are presented as mean (95% confidence intervals)

that a pocket infection develops, and the risk of a major complication is less than 2% in such cases, real-world outcomes may be less favorable, particularly in patients who are unsuitable for extraction, including frail elderly patients with multiple comorbidities [3, 18, 19]. In this population, alternatives to leads extraction are necessary, especially in cases of local pocket infection without systemic infection.

Although conservative treatment of a pocket infection often fails and leads to recurrent infection, most treatment techniques involve a combination of local debridement and dressing changes with antibiotic or antiseptic solutions. In the past decade, NPWT has been introduced as a new treatment modality for pocket infections, and numerous studies have revealed its efficacy [20–22]. However, clinical experience and reports of the use of NPWT to treat CIED pocket infections have been limited. *Satsu et al.*. described a small series of patients (4 patients) with local symptoms or purulent collection in the pocket of pacemakers and reported that the infections were eradicated by NPWT with no evidence of recurrent infection for 5–15 months after discharge [20]. Similarly, *Poller et al.* described 5 patients with a local cardiac device infection treated with NPWT (34.6 ± 19.2 months of follow-up), and 1 patient experienced recurrent infection [21]. In another large study, *McGarry et al.* reported their experience in treating 28 patients with NPWT for pocket infections after device and lead extraction (a median follow-up of 49 days, range 10–752 days). Only one patient developed a recurrent infection when NPWT was discontinued prematurely and a new device was implanted at the infected site [22]. In the above studies, most patients received a new CIED on the contralateral side.

However, many of the above studies were single-arm studies without a control group [14, 22]. We therefore performed a case-control study comparing NPWT with conservative treatment to increase comparability, increase statistical power, and present clinical outcomes. In NPWT cohort, most of our patients had positive wounds or tissue cultures, and approximately one-third (14/38; 36.8%) had staphylococcal infections. The only difference was a smaller proportion of patients with gram-negative rods: 10.5% in our study vs. 8.9–20.3% [23–25]. The observation of negative cultures in 52.6% of our patients is expected given the increasing proportion of culture-negative CIED infections reported in large studies [23, 24, 26]. Among patients who underwent CIED implantation without an absorbable antibacterial envelope (the placebo arm) in the WRAP-IT (Worldwide Randomized Antibiotic Envelope Infection Prevention Trial), 35.7% of pocket infections were culture negative [24]. Our finding was consistent with the microbiology of CIED infections reported in previous studies, which demonstrated that staphylococci was predominantly responsible for most CIED infections [2, 23, 27]. Although causative pathogens were identified in only 47.4% of samples, this lower detection rate was not unexpected due to variable practices in sample collection and culturing techniques. Negative culture rates reported in the literature vary widely and are often attributed to the biofilm-associated nature of device infections and prior antibiotic exposure before device extraction [24].

In our case-control study, patients were similar in terms of their clinical profiles, regardless of whether they received NPWT or conservative treatment. Compared with the conservative treatment group, the NPWT group had a lower failure rate (total failure rate and failure rate after discharge) and a longer infection-free time (Table 2; Fig. 5). Compared with conservative treatment, NPWT is safe and effective but prolongs the length of hospital stay after treatment. Most importantly, we found that NPWT is associated with a low risk of recurrent infection. Five of the 38 patients in the NPWT group and 12 of the 40 patients in the conservative treatment group developed recurrent pocket infections after discharge. There are several advantages of NPWT for chronic wounds, including active treatment without the risk of fluid leakage, cost-effectiveness owing to faster wound healing, fewer dressing changes and less resource use [28–30]. In addition to the above advantages, NPWT has the following potential advantages. First, the original CIED worked properly during NPWT, so a temporary or new CIED was not needed, thereby reducing the costs associated with reimplantation [31, 32]. Second, we placed the original CIED in a new pocket below the pectoralis major, which provides better coverage if the subcutaneous tissue is thin or was the site of a previous infection (Fig. 2E-F) [33, 34]. Third, continued NPWT after superficial healing aids deeper tissue recovery for complete healing and maintains the ideal position of the CIED below the pectoralis major (Fig. 2G) [33, 35].

Limitations

Our study has several limitations that should be considered. First, given the case-control design of the study, the results should be interpreted carefully, particularly regarding patients treated conservatively. Despite our NPWT cohort ($n = 38$) being the largest single-center series reported to date, the sample size remains relatively small, and the conservative treatment group ($n = 40$) is similarly limited. Although the difference in failure rates between groups reached statistical significance ($p = 0.025$), the borderline P value (close to the conventional threshold of $p < 0.05$) and limited sample size may reduce statistical power, warranting cautious interpretation of its clinical importance.

Second, a small proportion (27.5%, 11/40) of patients in the conservative treatment group underwent only local dressing changes, which may have contributed to the higher failure rate than that reported in other studies [36, 37]. While a sensitivity analysis excluding these patients could have clarified the robustness of our findings, the limited subgroup size ($n = 11$) rendered such analyses statistically unreliable. A power calculation (Fisher's exact test, $\alpha = 0.05$) estimated < 30% probability of detecting a clinically relevant 20% absolute risk reduction (e.g., 50% vs. 30% failure rates), far below the conventional 80% threshold. This insufficient power elevates the risk of Type II error (false-negative conclusions), potentially obscuring true treatment effects. To address this limitation, future multicenter studies with larger cohorts and protocol-driven conservative therapies are needed to validate subgroup-specific outcomes. Third, transvenous lead extraction (TLE) is difficult at our center, and scar tissue increases over time since implantation is a complicating factor and the main cause of lead removal failure [38, 39]. Many patients whose CIED were salvaged after NPWT or conservative treatment chose to visit high-volume specialized centers, where complication rates from TLE are lower [40, 41]. The homogeneity of the study population may hinder the generalization of the results to patients treated at other centers. Fourth, in our study, we did not directly compare NPWT with CIED or lead extraction (including TLE) to reach definitive conclusions regarding noninferiority. Such comparisons would be necessary before one could conclude that NPWT was superior or inferior, and a greater number of patients would need to be studied to demonstrate a difference. If confirmed in randomized studies, NPWT could become an alternative to CIED and leads extraction for appropriately selected patients.

Conclusions

Our study evaluated the safety and efficacy of NPWT (including full wound revision and capsular debridement). The findings suggest that NPWT might be indicated for patients at high risk for complications or mortality, providing an opportunity for healing and salvage of the CIED.

Abbreviations

CIED	Cardiac implantable electronic device
NPWT	Negative-pressure wound therapy
MRSA	Methicillin-resistant staphylococcus aureus
BMI	Body mass index
LVEF	Left ventricular ejection fraction
eGFR	estimated glomerular filtration rate
IQR	Interquartile range
TLE	Transvenous lead extraction

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions

GMY, XMH and SWZ were involved in the research conception. Study was conceptualized by all 4 authors. GMY, XMH and SWZ were the principal investigators and responsible for the data collection, entry and analysis with RJL, GMY and SWZ for manuscript preparation. All authors read and approve the final manuscript.

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Data availability

This is part of a larger study. The dataset generated and analyzed during the current study is not publicly available but may be obtained from the corresponding author if accompanied by a reasonable request.

Declarations

Ethics approval and consent to participants

This study conformed to the provisions of the Declaration of Helsinki and was approved by the Chinese Clinical Trial Registry (Clinicaltrials.gov number: ChiCTR2300073560; approval date: July 14, 2023) and Fujian Provincial Hospital (approval no. from the ethics committee: K2023-07-005; approval date: July 07, 2023). All participants provided written informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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