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MAJOR ARTICLE

Safety and Efficacy of Submuscular Implantation With Resterilized Cardiac Implantable Electronic Device in Patients With Device Infection: A Retrospective Observational Study in Taiwan

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Background. Reuse of cardiac implantable electronic devices (CIEDs) can reduce the cost of using these expensive devices. However, whether resterilized CIEDs will increase the risk of reinfection in patients with previous device infection remains unknown. The aim of the present study is to compare the reinfection rates in patients who had initial CIED infection and underwent reimplantation of resterilized CIEDs or new devices.

Methods. Data from patients with initial CIED infection who received debridement of the infected pocket and underwent reimplantation of new or resterilized CIEDs at MacKay Memorial Hospital, Taipei, Taiwan, between January 2014 and June 2019 were retrospectively analyzed. Patient characteristics, relapse rates of infection, and potential contributing factors to the infection risk were examined.

Results. Twenty-seven patients with initial CIED infection and reimplanted new CIEDs (n = 11) or resterilized CIEDs (n = 16) were included. During the 2-year follow-up, there were 1 (9.1%) and 2 (12.5%) infection relapses in the new and resterilized CIED groups, respectively. No relapse occurred for either group if the lead was completely removed or cut short. The median duration between debridement and device reimplantation in patients with infection relapse vs patients without relapse was 97 vs 4.5 days for all included patients, and 97 vs 2 days and 50.5 vs 5.5 days for the new and resterilized CIED groups, respectively.

Conclusions. Subpectoral reimplanting of resterilized CIEDs in patients with previous device infection is safe and efficacious. With delicate debridement and complete extraction of the leads, the CIED pocket infection relapse risk can be greatly decreased.

Keywords. cardiac implantable electronic devices; cardiac implantable electronic device infection; reutilization.

Cardiac implantable electronic devices (CIEDs) can improve quality of life and reduce the risk of sudden cardiac death in patients with abnormal heart rhythm or arrhythmia. The number of patients requiring a CIED has increased worldwide, with about 1.5 million patients receiving a CIED each year [1–3]. In low- or middle-income countries, the challenge with CIEDs, regardless of pacemaker type or the more complicated implantable cardioverter defibrillators (ICDs), is the high cost [4]. For the most basic form of pacemaker, the cost is around US$2500–3000 or higher, and the leads cost US$800–1000 or higher. The cost of ICDs is even higher—at least US$20 000–40 000, and the leads cost >US$10 000 [5]. Because of the high cost of new pacemakers, which may be prohibitive for many patients, reusing the devices when patients cannot afford new ones is being considered.

CIEDs were routinely reused around 30 years ago, and clinical outcomes with the reused devices and new devices were compared. In a meta-analysis of 18 studies and 2270 patients with pacemaker reuse in various countries, the overall rate of adverse effects, particularly infection (1.97%) and device malfunction (0.68%), was low [6]. In a 2014 report, members of the Heart Rhythm Society agreed that resterilization of CIEDs when costs of new devices are prohibitive may be safe and will be ethical if the devices are proven safe, although the major concerns are infection and device malfunction [7]. In another meta-analysis, which identified 172 studies published between 2009 and 2017, the authors concluded

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that CIED resterilization did not significantly increase the risk of infection, malfunction, premature battery depletion, or device-related death [8]. More recently, a retrospective case–control study indicated that ICD reuse is not associated with increased risk of complications [9]. However, despite the satisfactory outcomes and established acceptance with resterilization of CIED, data of repeat infection after reimplantation of resterilized CIED are lacking. In this study, we compared infection relapse rates in patients with previous CIED infection and reimplantation with new vs resterilized CIEDs.

METHODS

This study was approved by the Institutional Review Board of MacKay Memorial Hospital, Taipei, Taiwan (IRB number 21MMHIS037e). The use of resterilized CIEDs in the present study complied with guidelines of reprocessing medical devices regulated by the Ministry of Health and Welfare. For patients who received reimplantation of a CIED, all were well informed of whether a new or resterilized CIED would be used, and written informed consent from all patients was obtained. This study conformed to provisions of the Declaration of Helsinki.

We retrospectively reviewed data from patients with initial CIED infection who received debridement of the infected pocket and underwent reimplantation of a new or resterilized CIED in our hospital between January 2014 and June 2019. Patients who only had removal of the initial CIED without a reimplantation, or whose records were incomplete, were excluded. Resterilized CIEDs were implanted mainly in patients with multiple (≥3) comorbidities (hypertension, diabetes mellitus, dyslipidemia, thalassemia, liver diseases, and malignancy) who were expected to have reduced life expectancy. In addition, a resterilized CIED was considered if the device was implanted within 3 years and still had sufficient electricity as determined by the cardiologist. Patients were followed for at least 6 months and up to 24 months after the reimplantation.

Before being reimplanted, the resterilized CIED had to fulfill conditions, including no sign of device malfunction during initial implantation, no visual signs of physical damage, and estimated remaining running time of the battery greater than two-thirds of the theoretical total running time [9, 10]. Biological residue was thoroughly removed, particularly in the device connector slots, which if still present excluded the device from further use. Reprocessing, sterilization, and validation testing for the resterilized CIEDs was performed based on the procedures proposed by Crawford et al. [10], with some modifications. Briefly, CIEDs were pretreated with Enzymex L9 (Franklab) for at least 10 minutes, then rinsed in deionized water and wiped dry. Afterwards, they went through electrical testing, screw cap and set screw reassembly, brushing, inspection, and sterilization in an ethylene oxide (EO) sterilizer (3M Steri-Vac Sterilizer GS8). EO sterilization was performed in accordance with the manufacturer's instructions. The sterilization cycle consists of 5 stages: preconditioning and humidification, gas introduction, exposure, evacuation, and air washes. Effectiveness of the sterilization was verified, and compliance with accepted standards was ensured. Finally, the resterilized CIEDs were repackaged and sealed.

The initial CIED was implanted in the prepectoral space for all cases. The diagnosis of CIED infection was confirmed by an expert multidisciplinary team that included a cardiologist, a microbiologist, and a plastic surgeon. A representative photo of a patient with pocket infection is shown in Figure 1A. CIED infection was identified if 1 of the following conditions occurred: (1) the implantation incision healed completely, but displayed obvious perifocal fluctuation or erythematous change; (2) the implantation incision had an ulcer, concurrent with CIED exposure and/or pus-like discharge from the ulcer. Before debridement and removal of the CIED and lead, a temporary pacemaker was used for patients needing a permanent pacemaker and who were pacemaker dependent. Relapse of infection was assumed if ulcers recurred after the wound was healed. Samples of the infected pocket and blood were cultured to determine the causative pathogen of infection. For treatment of infection relapse, amoxycillin plus clavulanate potassium (Augmentin) was used, unless specific and individualized therapy was needed per the results of antibiotic susceptibility testing.

The surgical incision used for debridement and subsequent reimplantation of the CIED was made from the same incision of the previous CIED implantation. During debridement of the infected pocket, the lead was completely removed (Figure 1B–G). If the lead adhered to the myocardium or to the inner wall of the blood vessel and could not be completely removed, an attempt was made to cut it short to the side of the subclavian vein, regardless of subsequent reimplantation of new or resterilized CIED.

CIEDs were reimplanted immediately after or several days later following wound debridement. The timing of CIED reimplantation was arbitrarily classified as early (≤30 days) or late (>30 days). Augmentin or specific therapeutic antibiotics (based on the antibiotic susceptibility test results) were used as prophylaxis before reimplantation of the CIEDs. Skin ulcers and fibrotic capsules, which formed in the tissue around the previous CIED, were removed by capsulectomy to ensure complete debridement. For implantation of a resterilized CIED, a sterile subpectoral pocket ipsilateral to, but separate from, the site of previous prepectoral device implantation was made, where the pectoralis major muscle was cut directly to the depth of the submuscular plane to create an optimized-sized and tension-free CIED pocket in the subpectoral space. For implantation of a new CIED, a contralateral subpectoral placement was used.

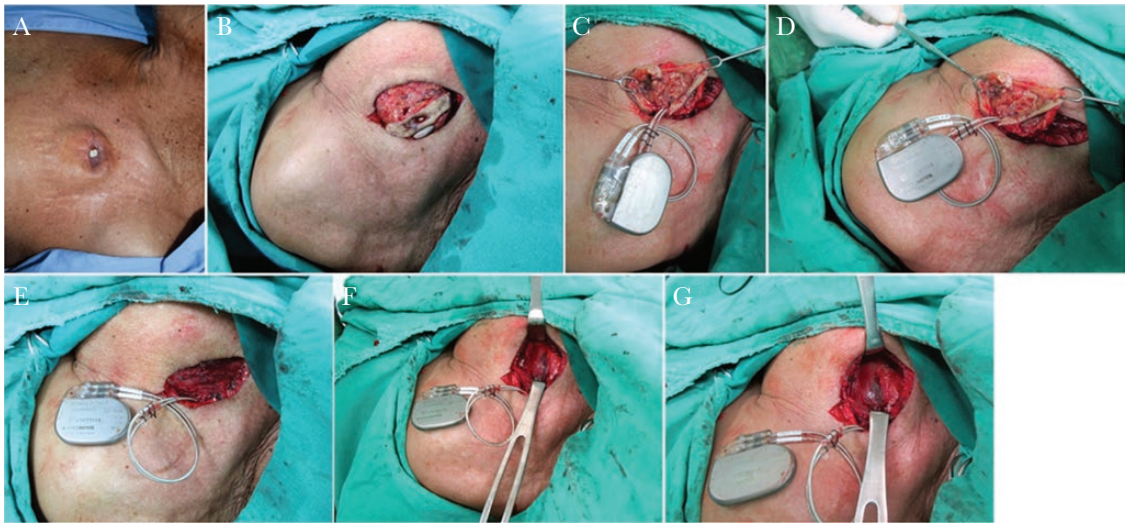

Figure 1. Debridement of infected pocket and extraction of previous CIED and lead. A, Preoperative examination of the infected CIED pocket. Erythematic change and ulcer were noted. B, Same incision of previous CIED implantation was made for debridement. C–G, During the operation, a skin ulcer and fibrotic capsule were removed completely, and the initial CIED and lead were extracted. If reimplantation of the CIED was not going to be performed immediately, the surgical wound would be sewn up first. Abbreviation: CIED, cardiac implantable electronic device.

The extent of the subpectoral pocket was predetermined and marked on the skin. After making a new incision and dissection through the subcutaneous tissue to the submuscular plane of the pectoralis major muscle, a subpectoral space for placing the new CIED was exposed. The cardiac surgeon inserted the leads into the subclavian vein, estimated the location of the device, and determined if the leads would reach the device without tension. After the leads were connected to the device and the device was positioned in the planned subpectoral plane, the device was anchored with an absorbable suture. After the device was fixed at the optimal position, 1 Fr.15 channel drain tube was placed in the subcutaneous pocket. The split pectoralis major muscle and skin were repaired layer by layer with absorbable sutures.

All statistical analyses were performed with SPSS, version 22.0 (IBM Corp., Armonk, NY, USA). The nonparametric Mann-Whitney *U* test was used to compare continuous variables, and the chi-square test was used to compare categorical variables. *P* values <.05 were considered statistically significant.

RESULTS

Twenty-seven patients with initial CIED infection who underwent debridement of the infected pocket and reimplantation of a new CIED (n = 11) or resterilized CIED (n = 16) were included (Figure 2). The baseline characteristics of included patients, grouped according to reimplantation of new CIED or resterilized CIED, are presented in Table 1. The mean age, proportion of elderly patients, sex ratio, renal function, comorbidities, and antiplatelet or anticoagulation therapy were similar between the groups. Impaired renal function, as evidenced by diminished creatinine clearance, was common in both groups without statistically significant differences between them. Comorbidities also were common among all patients, where the major one was hypertension, with 72.7% and 62.5% in the new and resterilized CIED groups, respectively. Significantly more patients in the resterilized CIED group had multiple (≥3) comorbidities (31.3% vs 0%; $P = .044$). Indications for initial CIED implantation included sick sinus syndrome with or without other conditions such as congestive heart failure or ventricular tachycardia arrythmia, high-degree atrioventricular (AV) block (with or without congestive heart failure), and other arrythmia-related conditions. For initial CIED infection, the prevalence of positive wound culture (indicative of local infection) or positive blood culture (indicative of systemic infection) was numerically higher in

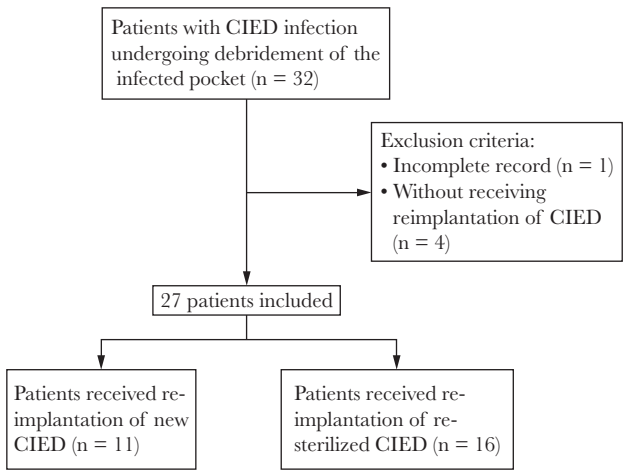

Figure 2. Flowchart of patients' inclusion process.

Table 1. Baseline Clinical Characteristics of Included Patients

	Reimplantation of CIED		
	New CIED (n = 11)	Resterilized CIED (n = 16)	*P* Value
Age, y	68.4 ± 14.8	71.1 ± 10.0	.748
Age ≥65 y	7 (63.6)	11 (68.8)	.782
Males	9 (81.8)	10 (62.5)	.290
Renal function			
Normal (CCr > 85 mL/min)	1 (9.1)	5 (31.3)	.181
Moderate (CCr = 50 mL/min–85 mL/min)	8 (72.7)	6 (37.5)	.078
Severe (CCr < 50 mL/min)	2 (18.2)	5 (31.3)	.454
Comorbidities			
Hypertension	8 (72.7)	10 (62.5)	.588
Diabetes mellitus	3 (27.3)	5 (31.3)	.826
Dyslipidemia	2 (18.2)	5 (31.3)	.454
Thalassemia	0 (0)	1 (6.25)	.407
Liver disease	1 (9.1)	1 (6.3)	.789
Malignancy	1 (9.1)	1 (6.3)	.789
Multiple comorbidities (≥3)	0 (0)	5 (31.3)	**.044**
Experience with antiplatelet or anticoagulation therapy	6 (54.5)	7 (43.8)	.592
Platelet counts (per μL) before debridement operation			
>200 001	5 (45.5)	4 (25)	.276
150 001–200 000	4 (36.4)	7 (43.8)	.706
100 001–150 000	2 (18.2)	3 (18.8)	.969
50 001–100 000	0 (0)	2 (12.5)	.232
Source of previous infection			
Positive wound culture	3 (27.3)[a]	1 (6.3)[b]	.139
Positive blood culture	1 (9.1)[c]	0 (0)	.228
Indications for previous CIED implantation			
SSS, with or without CHF, Vt/other arrythmia, high-degree AV block	5 (45.5)	6 (37.5)	.683
Vt/Vf, with or without CHF	1 (9.1)	1 (6.3)	.789
High-degree AV block, with or without CHF	2 (18.2)	6 (37.5)	.290
Vt/other arrythmia, with or without CHF	3 (27.3)	3 (18.8)	.609
Previous CIED			
Initial implantation	4 (36.4)	13 (81.3)	**.020**
Types of previous CIED before infection occurred			
ICD	2 (18.2)	2 (12.5)	.688
PPM	8 (72.7)	10 (62.5)	.588
CRT-D	0 (0)	3 (18.8)	.134
CRT-P	1 (9.1)	1 (6.3)	.789

Values are mean ± SD or No. (%). Statistical significance: $P < .05$, indicated in bold.

Abbreviations: AV, atrioventricular; CCr, creatinine clearance rate; CHF, congestive heart failure; CIED, cardiac implantable electronic device; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; ICD, implantable cardioverter defibrillators; MSSA, methicillin-susceptible *Staphylococcus aureus*; PPM, permanent pacemakers; SSS, sick sinus syndrome; Vf, ventricular fibrillation; Vt, ventricular tachycardia.

[a]Two patients had *Staphylococcus aureus* (MSSA); 1 patient had *Proteus mirabilis* and *Morganella morganii*.

[b]Yeast.

[c]*Staphylococcus aureus* (MSSA).

patients subsequently receiving reimplantation of new CIEDs vs resterilized CIEDs (27.3% vs 6.3% positive wound cultures and 9.1% vs 0% positive blood cultures; $P > .05$). In the new device group, the major involved pathogen was methicillin-sensitive *Staphylococcus aureus* (MSSA; 2 patients had local infection, and 1 patient had systemic infection). Other infectious agents in the new device group were *Proteus mirabilis* and *Morganella morganii* in a local infection in 1 patient. In the resterilized CIED group, a yeast species was involved in the initial local infection in 1 patient. For other included patients, the infection-causing agents were unidentifiable, as no growth of bacteria was observed in the wound or blood culture. Compared with the new CIED group, significantly more patients in the resterilized CIED group had the previous CIED implanted for the first time (81.3% vs 36.4%; $P = .02$), and the main reason for replacement of the previous CIED was battery depletion. The initially implanted CIED type for both the new and resterilized CIED groups was mainly permanent pacemaker (72.7% and 62.5%, respectively). ICDs, cardiac resynchronization therapy with defibrillator (CRT-D), and cardiac resynchronization therapy with pacemaker (CRT-P) were also used in both groups of patients (Table 1).

Table 2. Lead Extraction Strategy and Infection Relapse Rate

	Reimplantation of CIED	
	New CIED (n = 11)	Resterilized CIED (n = 16)
Lead management during debridement		
Completely removed	8 (72.7)	3 (18.8)
Cut short	1 (9.1)	2 (12.5)
Unremoved	2 (18.2)	11 (68.8)
Infection relapse after CIED reimplantation	1 (9.1)	2 (12.5)
Duration between CIED reimplantation and infection relapse, d	30 (30–30)[a]	377.5 (120–635)[b]

Values are median (range) or No. (%).

Abbreviation: CIED, cardiac implantable electronic device.

[a]Only 1 patient had infection relapse in the new CIED group.

[b]Two patients had infection relapse in the resterilized CIED group.

The duration between debridement and device reimplantation in patients with or without reinfection is represented in Supplementary Table 1. Among all included patients, 3 (2 with resterilized CIEDs and 1 with a new CIED) had infection relapse that occurred at the ipsilateral, original wound area for the previous CIED. The intervals between debridement and device reimplantation for the 3 patients were 0, 97, and 101 days. The 1 patient who had infection relapse in the new CIED group underwent device reimplantation at 97 days after debridement. For the 2 patients who had infection relapse in the resterilized CIED group, 1 underwent device reimplantation on the same day of debridement, but the other underwent device reimplantation at 101 days after debridement. The delayed reimplantation of CIED (>30 days), regardless of new or resterilized device, was due to patients' personal reasons. Notably, the median duration between debridement and device reimplantation was longer, although without statistical significance ($P > .05$), in patients with infection relapse than in patients without infection relapse, regardless of whether a new or resterilized CIED was used.

Table 2 reports the lead extraction strategies for managing initial CIED infection and infection relapse (at the ipsilateral, original wound site) after reimplantation of a CIED. In the group with new CIEDs, 72.7% of patients had the lead completely removed, while in the group with resterilized CIEDs, only 18.8% had complete lead removal, and 12.5% had the leads cut short. Leads were cut short if the lead adhered to the myocardium or the inner wall of the blood vessel, in which case the risk was considered too high for attempted complete removal of the lead. In a few cases, the lead was left intact according to the cardiologist's decision and the patient's situation. Relapse rates of the ipsilateral infection after device reimplantation were low for both groups: 1 (9.1%) and 2 (12.5%) patients in the new and resterilized CIED groups, respectively. The duration between CIED reimplantation and infection relapse was 30 days for the 1 patient (a 60-year-old female) in the group with a new CIED, whereas it was about 21 months and 4 months for the 2 patients (a 70-year-old male and a 63-year-old female, respectively) with resterilized CIEDs. A prospective analysis of infection relapse with patients of varying age (≥65 and <65 years) groups was performed to overcome the associated bias (Supplementary Table 2). Table 3 reports the association of different lead management strategies and the reinfection rates. The rate of relapse was 0% for both the new and resterilized CIED groups if the lead was completely removed or cut short vs 9.1% and 12.5% if the lead was not removed in the new CIED and resterilized CIED groups, respectively.

DISCUSSION

Despite evidence-based support of the safety of using resterilized CIEDs, concerns still exist about possible increased risk of repeat infection in patients who have had previous device infection. In this study, we compared the infection relapse rates in patients who had a history of CIED infection and then received debridement and reimplantation of a new or resterilized CIED. We found that the relapse rate was low for both new and resterilized CIED, and there was no significant difference in the rate of infection with either device. To our knowledge, this study is the first to focus on using resterilized CIEDs in patients with a history of device infection. In addition, we applied an ipsilateral, subpectoral muscular implantation technique, which places the device deep in the submuscular plane rather than using the conventional prepectoral implantation method.

Our results are consistent with those of other studies that compared the clinical outcomes of new vs resterilized CIEDs [4, 9, 11–13]. The combined results provide persuasive evidence of the safety and efficacy of reimplantation of resterilized CIED. A 9.5% rate of complications after CIED implantation has been reported [14], and the risk was higher with reimplantation

Table 3. Lead Management Strategies and Relapse Rate of CIED Infection

	New CIED, No. (%)		Resterilized CIED, No. (%)	
	No Infection Relapse	Infection Relapse	No Infection Relapse	Infection Relapse
Lead completely removed	8 (72.7)	0	3 (18.8)	0
Lead cut short	1 (9.1)	0	2 (12.5)	0
Lead unremoved	1 (9.1)	1 (9.1)	9 (56.3)	2 (12.5)

Abbreviation: CIED, cardiac implantable electronic device.

than with first implantation; however, it is unclear whether any resterilized CIEDs were used in that study.

Several recent studies have reported an infection rate of <5% with resterilized CIEDs, suggesting comparable risk with that of new devices (Supplementary Table 3) [4, 9, 11–13]. In a multinational study that follows the infection outcomes of reused CIEDs that entered the prospective Heart to Heart registry, established in 2003, the rate of device infection at 2 years was 2.0% among the 1051 patients with reused CIEDs and 1.2% among 3153 patients with new devices [11]. In another study, which recruited 887 patients undergoing implantation of new or reused CRT devices or ICDs, a 0.48% (3/627) rate of infection occurred at 6-month follow-up [13]. For patients with previous CIED infection and reimplantation in our study, the infection relapse rates were numerically higher than the reported CIED infection rates regardless of reimplantation with new or resterilized CIEDs. We suggest that in addition to the small sample size that may bias the results, previous device infection may pose a risk of reinfection. The thoroughness of lead extraction may be another important contributing factor. Our results showed that no relapse of infection occurred during 2 years of follow-up among patients with leads completely removed or cut short. Previous studies have suggested that complete device removal is a central pillar of effective treatment [15]. Moreover, in the 2017 Heart Rhythm Society expert consensus [14], extraction of all hardware, including the lead, is a class I recommendation (ie, benefit greatly exceeds risk) in all cases of pocket infection and endocarditis, regardless of whether there is unambiguous evidence of device infection. Extraction of leads is sometimes challenging, and special extraction devices (eg, Cook's Evolution or Spectranetics's laser sheath) may be useful to extract leads that are not easy to extract. However, these special devices have not been introduced to Taiwan or are not widely used in local hospitals. Nevertheless, it is highly recommended that all leads be extracted whenever possible.

The major identifiable agent in initial CIED infection in the new device group in our study was methicillin-susceptible *Staphylococcus aureus* (MSSA), and the agent in the resterilized CIED group was a yeast species. In some patients, the infection-causing agents were unidentifiable, possibly because these cases had been treated with antibiotics for some time in other outpatient clinics before admission to our hospital for surgical intervention. In other studies [11, 16], *Staphylococcus* species have been the predominate causative pathogen in major CIED infection. Major CIED infection is defined as either deep incisional or organ/space surgical site infection meeting the criteria of the Centers for Disease Control and Prevention, independent of time from surgery; superficial cellulitis in the region of the CIED pocket with erosion or wound dehiscence; endocarditis; or persistent bacteremia [17]. Major CIED infection has been associated with higher risk of mortality [17]. In our study, no device-related death occurred during the follow-up period. Nevertheless, as the mortality is high after CIED infection [18–21], caution should be taken to avoid device infection. Recent reports have indicated that use of an antibacterial envelope for CIEDs may reduce device infection [3, 22, 23]. This policy, in addition to sound CIED sterilization techniques, may reduce the risk of infection with reused CIEDs.

Device malfunction has been another major concern about CIED reuse. A meta-analysis reported that about 0.68% of patients encountered device malfunction after receiving reused pacemakers, which was a significantly higher risk of device malfunction than in patients receiving a new device (odds ratio, 5.80; $P = .002$) [6]. However, more recent studies have shown a decreased rate of device malfunction for reused CIED [4, 9, 11–13]. Improvements in device refurbishment or resterilization techniques may be responsible for the decreased rates of device malfunction [10]. On the other hand, the type of CIED may influence the efficacy of reutilization: ICD reuse usually poses a greater challenge than does pacemaker reuse due to the high cost of the electrode and the complexity of dealing with the complications [24]. Nevertheless, according to the study of Jama et al. [4], in which the performance of reused pacemakers and ICDs in patients matched for age, sex, and date of implantation was examined, no device malfunction or early battery depletion was identified, and only 1 (1/12) reused ICD delivered unwanted shocks, which resolved with no harm to the patient. These results suggest that, even with the more complicated ICDs, low rates of device malfunction can be achieved.

The 2017 Heart Rhythm Society expert consensus on transvenous lead extraction recommended that blood cultures be negative for at least 72 hours before CIED reimplantation [14]. Surgeons are even suggested to extend that time to at least 14 days when there is evidence of valvular or lead vegetations. However, as our results suggest, much longer duration (>30 days) between lead removal/debridement and reimplantation of the CIED might increase the risk of infection and earlier relapse of infection. Within the 14-day removal/debridement–reimplantation interval recommended by the Heart Rhythm Society, the wound area for debridement and removal of leads and CIED likely will not have fully healed, and reimplantation along the original dissection plain to reduce soft tissue injury can be performed. However, if this duration is too long, the wound may heal almost completely and be replaced by fibrotic scars. In this situation, the reoperation dissection may increase the risk of soft tissue injury and wound infection. In our cases, the interval was unusually long only because the patients resisted undergoing CIED reimplantation. Nevertheless, because the cases of infection relapse in our study were few, no conclusion can be drawn regarding the safe duration between device removal and reimplantation. Thus, we agree with Boyle et al. [15] that no specific time frame is of especially high or low risk for reimplantation, but the infection relapse rates are low for reimplantation shortly after extraction.

Subpectoral muscle implantation of CIEDs has cosmetic advantages in that it avoids device bulges and protrusion. In this technique, the CIED is placed under a healthy layer of muscle, making it less palpable and almost visually undetectable, and it prevents device migration or torsion. This technique is especially appropriate for patients who have thin skin or indwelling catheters, for whom the conventional prepectoral approach is not feasible [25, 26]. In the present study, we used the subpectoral muscular implantation technique, which has the benefit of preventing skin erosions and ulcerations, better protecting the device, and aesthetic advantages for the reimplantation of CIEDs. Satisfactory results were achieved, as no severe complications were observed at 6 months after the surgery. Nevertheless, longer follow-up is warranted to determine the long-term outcomes with this implantation technique.

The limitations of the present study include the small sample size and nonrandomized assignment of patients, which may have introduced selection bias. However, CIED infection is a rare complication after the implantation surgery, and if the surgery is of good quality, CIED infection is less likely to occur. Another limitation is that patients were about 70 years old and had comorbidities that may be associated with poor clinical outcomes. These limitations may restrict the generalizability of the conclusions. Appropriately designed, multicentered, randomized controlled prospective studies are needed to address these issues.

CONCLUSIONS

Subpectoral reimplantation of ethylene oxide-resterilized CIEDs in patients with previous device infection is safe and efficacious. With delicate debridement and complete extraction of the leads during infection management, the risk of CIED pocket infection relapse can be greatly diminished.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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Author contributions. Chia-Meng Yu, Ying-Hsiang Lee, Feng-Ching Liao, Wen-Chen Huang, Kwang-Yi Tung, and Ming-Feng Tsai made substantial contributions to the conception and study design; Chia-Meng Yu, Chieh-Ming Yu, Wen-Teng Yao, Chih-Yin Chien, and Hung-Wei Liao collected the data; Chieh-Ming Yu, Wen-Teng Yao, Ying-Hsiang Lee, Feng-Ching Liao, Chih-Yin Chien, Sheng-Hsiung Chang, Hung-Wei Liao, Yu-Fan Chen, and Ming-Feng Tsai analyzed the data; Chieh-Ming Yu and Ming-Feng Tsai prepared the manuscript; Wen-Teng Yao, Wen-Chen Huang, and Kwang-Yi Tung contributed to critical revision of the manuscript; all of the authors read and approved the final version for submission.

Patient consent. This study was approved by the Institutional Review Board of MacKay Memorial Hospital, Taipei, Taiwan (IRB number 21MMHIS037e). The use of resterilized CIED in the present study complied with guidelines of reprocessing medical devices regulated by the Ministry of Health and Welfare. For patients who received reimplantation of CIED, all were well informed of whether new or resterilized CIED would be used, and written informed consent from all patients was obtained. This study conformed to the provisions of the Declaration of Helsinki.

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