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Outcome of Infected Cardiac Device Re-implantation in Erbil Cardiac Center-Iraq

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Abstract

Background & Objectives: Cardiac electronic devices have been in clinical practice for more than 6 decades. Infection is not uncommon with these devices due to their scarcity and exorbitant cost which makes them inaccessible to a significant number of patients. Therefore, the only method to source them is to reimplant used devices. The problem of possible infection as result of reusing these devices has not been previously investigated in Iraq. The objective of the current study was to find the outcomes of the re-implanted infected device.

Methods: Ten patients with infected boxes (complete or partial dehiscence with or without pus discharge) were included in this case-series study, from January 2016 to January 2023 in Erbil cardiac center, All the patients were well informed that their re-sterilized devices will be re-implanted, and verbal informed consents were obtained from all patients.

Results: Ten procedures for ten patients with permanent pacemaker infected boxes had been done. The patients' age ranged from 1.5 to 77 years, and all of them were males. Nine infections had been cured and followed for six months to 7 years. One patient died after 12 months (1.5 years old child with severe heart failure).

Conclusion: Re-implantation of infected box after sterilization had high success rate.

Key words: Infected box, Permanent pacemaker, Re-implantation.

Introduction

The global prevalence of cardiac device implantation has shown a significant rise since Åke Senning performed the first implantation in 1958. Modern systems, such as cardioverter defibrillators (ICD) and cardiac Re-synchronization treatment (CRT), are frequently employed as life-saving interventions. Nonetheless, it is essential to acknowledge that device infections can still occur, becoming a potential risk to the patient's life.[1] The clinical presentation may be associated with the pocket of the device, the leads, or involving the entire cardiovascular system and circulatory system. The prevalence of device infections varies between 0.5% and 2.2% among different patient populations, depending on factors like the type of device and the duration since implantation.[2] Infection creates a substantial clinical challenge due to

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its connection with increased mortality rates (up to 35% at 5 years), morbidity, and a substantial financial burden on healthcare systems. The cost of hospital admissions related to infection is estimated to be $16,500 each hospitalization, with an average total cost of $146,000 per infection case.[3-5] The rapid increase in the infection rate of electronic devices exceeds a related increase in the number of device implantations.[6] The number of implanted boxes experienced a twofold increase (a 95% increase), while the frequency of box infections reached a substantial high of over 200%.[5] A simple pocket infection can be described as an infection that is confined to the box pocket and lacks significant symptoms, clinical evidence of infection, or positive blood cultures.[3, 6] According to previous research, the generator pocket has been identified as the primary location for cardiac device infection.[7] Several hypotheses have been put out to explain the increase in infections connected with electronic cardiac devices. There is a growing trend among elderly patients to receive cardiac devices, and this demographic also experiences higher rates of comorbidity. These comorbidities may contribute to impaired wound healing and immune system.[5,8-10] Moreover, there is an increasing percentage of younger patients receiving cardiac devices, resulting in a larger likelihood of requiring box modifications and lead revisions due to prolonged survival.[11] It is important to note that these procedures are associated with an elevated risk of infection.[12,13] Between the years 1988 and 2015, there was a notable rise in the prevalence of cardiac device infection, with rates increasing from 1.3% to 4.7% per 1,000 person-years.[14] The risk of infection in patients with cardiac devices is a highly concerning complication, with a prevalence ranging from 1% to 3% over the course of their lifetime. Furthermore, the death rate linked to such infections can reach as high as 27.5% within a three-year period[2].The occurrence of an advanced pocket infection can result in several manifestations, including the development of a fluctuating abscess, adhesion of the pocket, drainage of pus from incision sites, formation of fistulas, wound dehiscence, and skin erosion leading to the externalization of the generator or leads. In the present scenario, it is imperative to regard the box as contaminated, regardless of the outcomes derived from microbiology investigations.[15] Nowadays, the primary approach for managing individuals with cardiac device infection is a combination of lead extraction and antibiotic therapy. Nevertheless, it is important to note that incidences of recurrent infections following device extraction continue to be documented.[16] Infections related to cardiovascular-implantable electronic devices (CIEDs) provide significant challenges for both patients and healthcare providers. These conditions are linked to significant morbidity and mortality rates, resulting to increased treatment expenses and extended hospital stays.[17,18] The acknowledgment of the impact and prevalence of these infections has been growing due to the contribution of several extensive prospective studies, which have provided valuable insights into their nature and offered suggestions for their care. Complete device extraction is considered the optimal approach for treatment. The current guideline recommends the extraction of all the system as a Class I recommendation for both pocket infection and endocarditis, regardless of the presence of definitive proof of device involvement.[19] Infections become the primary factors contributing to both death and morbidity in patients with CIEDs. A precise definition and rapid diagnosis facilitate efficient care in terms of device removal, administration of antibiotic, and determining the ideal period for reimplantation. In the present era,

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however, it is imperative to adopt and execute alternative methods and preventive measures in order to alleviate the effect of this problem.[20] The aim of this study was to determine the consequences of reimplanting an infected device.

Patients and methods

Out of 650 cardiac implantable electronic devices in Erbil cardiac center, 10 patients with infected boxes were enrolled in this study was conducted at the cardiac center placed in Erbil, Iraq, spanning from January 2016 to January 2023. The study comprised a cohort of ten individuals who reported with infections in their permanent pacemakers. The diagnosis was determined by evaluating the local indications of inflammation, including erythema, rise of skin temperature, fluctuance, wound dehiscence, soreness, purulent drainage, or erosion of the generator or lead through the skin. A transthoracic echocardiogram was performed on all patients in order to evaluate the presence of vegetation. Inclusion criteria all patient were implanted at time of box absence and patient cannot buy new box. Exclusion criteria-patient refusal. The surgical procedure consisted of making an incision for the purpose of debridement and subsequent re-implantation of the generator. This incision was positioned around 4-5 cm below and 3 to 4 cm medial to the prior incision. The debridement procedure was performed on the infected pocket, and the separation of the new pocket from the contaminated skin was carried out. The procedure involved the full debridement of skin ulcers and fibrotic capsules to assure their removal. In order to perform the implantation of a re-sterilized pacemaker box, a sterile subpectoral pocket was created on the same side but distinct from the location where the prior prepectoral device had been implanted in four patients. For the remaining patients, subcutaneous implantation was carried out. The wound, box and exposed lead was sterilized by washing with chlorohexidine and normal saline. A channel drain tube was inserted into the subcutaneous pocket of five patients. The integumentary system and the pectoralis major muscle were carefully restored using a sequential approach, employing sutures that are capable of being absorbed by the body. The patients were followed up for a duration ranging from 6 months to 7 years. The present investigation was granted approval by the Ethics Committee of the College of Medicine at Hawler Medical University on November 15, 2015.

Results

Out of 650 cardiac implantable electronic devices in Erbil cardiac center, 10 patients with infected boxes were enrolled in this study. All individuals in the group were of the male gender. The average age (standard deviation) of the patients was 59.7 (21.6) years, with a median age of 64.5 years. Three patients' diabetes mellitus, 2 were smoker & 3 from rural area as shown in Table (1).

Table (1): Baseline clinical characteristic of patients

Criteria	No. of patients	% of total
Age SD	59.7(21.6) y	
Sex-male female	10 zero	100% 00
Diabetes	3	30%
smoker	2	20%
Rural Urban	3 7	30% 70%

The age range covered from 1.5 to 77 years. Half of the patients were in the age group ≥ 65 years, four patients were aged 55-64 years, while only one patient was 1.5 years old, Figure (1).

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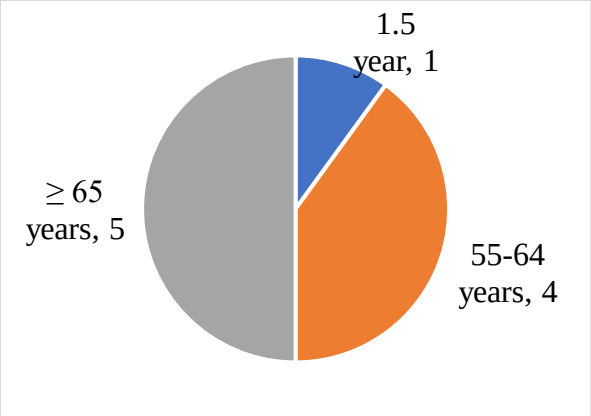

Figure (1): The age distribution of patients.

All of those patients had complete or incomplete device dehiscence Figure (2) with or without pus discharge.

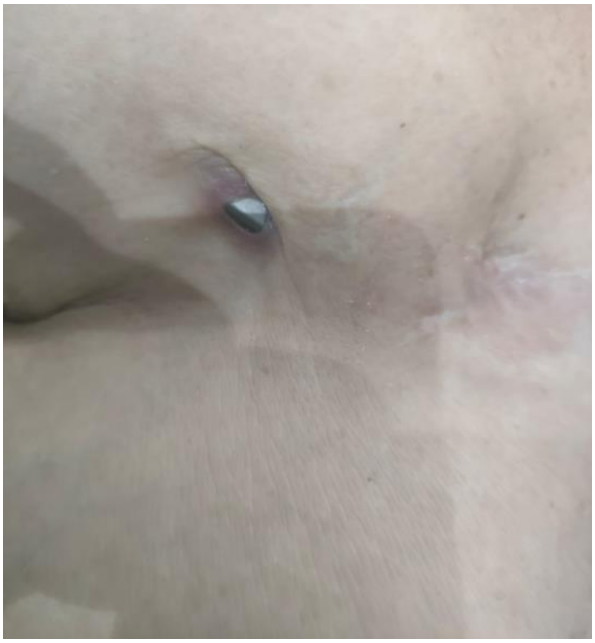

Figure (2): The occurrence box dehiscence

All patients were followed for six months to seven years. Nine patients cured from infection, with antibiotic duration from 14 to 20 days Figure (3,4). The child (1.5 years old) died after one year (due to heart failure). All reimplantation have been done within seven days except one which was done after two months.

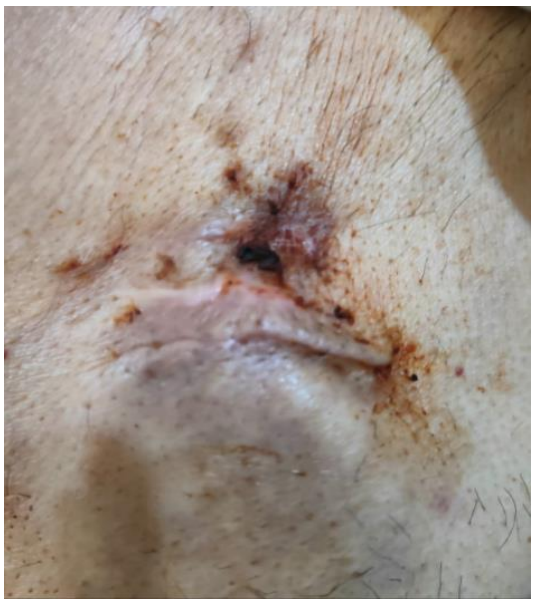

Figure (3): after2 weeks of Reimplantation

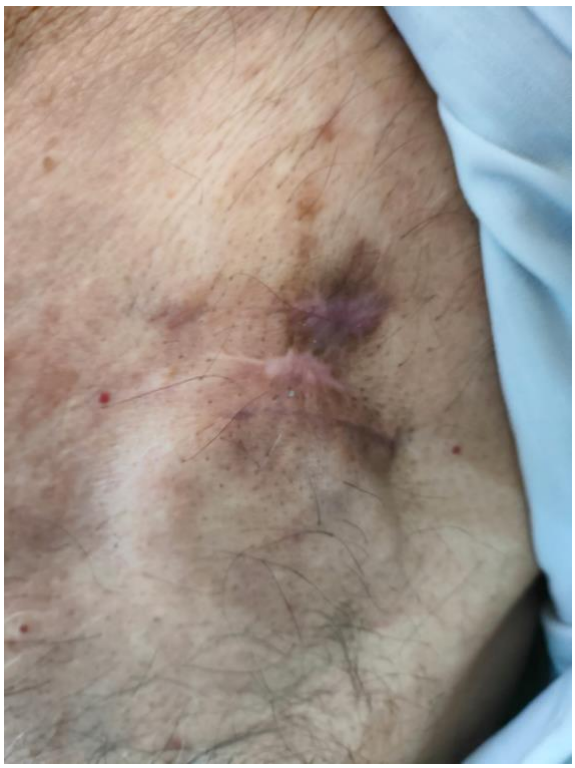

Figure (4): after3 months of Reimplantation

Discussion

As wound infections are common, and because of shortage of permanent pacemakers, the trial for reused infected box was done. In the present study, it was seen

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that all of the patients had box dehiscence, which aligns with the findings of Modi et als` study. In their investigation, which included 23 infected individuals, wound dehiscence was the most often observed presentation, accounting for 95.6% of cases.[21] A patient died due to heart failure, which exhibited similarities to the findings of Jinghaq et als` study. The study identified significant risk factors linked to mortality in CIED infections, including Staphylococcus aureus as the causative agent, as well as the possibility of complications such as heart failure and embolic phenomena. These findings were derived from a combination of ten retrospective and two prospective cohort studies.[22] The current study illustrates a high success rate in the reuse of infected boxes, which aligns with the findings of Baman et al and Sinha et als`. These studies conducted a meta-analysis involving 18 studies and 2270 patients from different countries, revealing a low overall incidence of adverse effects, specifically infection (1.97%) and device malfunction (0.68%).[23] In a separate meta-analysis encompassing a total of 172 papers published from 2009 to 2017, the researchers reached the conclusion that re sterilization of cardiac implantable electronic devices (CIEDs) did not yield a statistically significant increase in the probability of infection, malfunction, early battery depletion, or device-related mortality.[24] In the present study, a reinfection rate of 10% was observed, which matches the findings of Thomas et al, who reported a low rate of recurring infection (1.8%) among those who underwent new box re-implantation , while patients who chose to maintain their original hardware saw a recurrent infection rate of 11.3%.[25] Based to the findings of the current investigation, the re-implantation of infected boxes was determined to be a safe procedure. This conclusion is supported by a study carried out in Taiwan, which examined 27 patients with initial cardiac implantable electronic device (CIED) infections. The study included patients who received either new CIEDs (n = 11) or re-sterilized CIEDs (n = 16), and the safety outcomes were shown to be comparable. During the two-year period of observation, the occurrence of infection relapses was recorded. In the fresh CIED group, there was one relapse, representing 9.1% of the cases. In the re-sterilized CIED group, there were two relapses, accounting for 12.5% of the cases limitation of study-small sample size.[26]

Conclusion

Re-implantation of infected box after a simple sterilization procedure had high success rate with lower cost.

Conflict of interest:

The authors have none to declare.

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