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SALVAGE OF EXPOSED CARDIAC IMPLANTABLE ELECTRONIC DEVICES, CIEDS : OUR EXPERIENCE AND UPDATE ON LITERATURE

Plastic Surgery

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ABSTRACT

Exposure of cardiac implantable electronic devices (CIEDs) is an uncommon problem in today's era. Traditionally, infected implants were removed and replaced with new implants. However, recent literature suggests the possibility of salvage of exposed implants. This study evaluates a series of cases that presented with exposure of pacemakers and implantable cardiac defibrillator (ICD) devices. Retrospective analysis of hospital records between March 2021 and October 2022 was done. Patients who presented with skin erosion or impending erosion, signs of local infection and exposure of cardiac defibrillator devices were included in the study. All patients with systemic sepsis, and infective endocarditis were excluded from the study. The surgical technique involved wide exposure of the implant site followed by removal of the generator unit and complete debridement of the pre-device capsule. The pocket was irrigated with a solution of 10% povidone-iodine and antibiotics locally. A new sub-pectoral pocket was developed about two centimeters away from the initial implant site and the wound was closed primarily under a closed drainage system. twelve patients (nine males, and three females) were included in the study. The mean follow-up of these patients was 22 months. All twelve patients were treated successfully with no evidence of wound dehiscence or exposure of the generator or leads or recurrence of infection. In conclusion, in the absence of gross infection or the presence of sepsis in the patient, a simple debridement with the creation of a new sub-pectoral pocket for re-implantation of the exposed cardiac pacemaker may be considered a safe and feasible approach to salvage CIEDs.

KEYWORDS

Exposure, Cardiac Pacemaker, Extrusion, Sub-Pectoral Pocket

INTRODUCTION

Exposure of cardiac implantable electronic devices (CIEDs) occurs occasionally in a tertiary centre with a high device implantation rate. The standard treatment for devices that get infected or contaminated as a result of skin erosion has been to remove the device and implant a new one. Recent literature, however, suggests the possibility of salvaging such devices. Debridement and re-implantation of the same device at a new subcutaneous site, and the use of a closed irrigation system with relocation to a new site under the Pectoralis Major muscle were also mentioned. In this study, we have explored the possibility of creation of a sub-pectoral pocket for salvaging such devices.

MATERIALS AND METHODS

Study Design for Case Series

A retrospective review of hospital records was done. This study included patients treated for locally infected or extruded CIEDs over 20 months, from March 2021 to October 2022.

The inclusion criteria included the presence of skin erosion with an exposed device, impending exposure with thinned-out skin, and purulent discharge from the subcutaneous pocket of the CIED site.

In all cases, microbiological cultures were taken from the wound and broad-spectrum parenteral antibiotics were initiated which were later changed according to the results of culture & sensitivity. These antibiotics were continued post-operatively and continued for 14 days. Patients with a diagnosis of systemic infection, septic shock, or overt infective endocarditis, or with a history of vegetation on echocardiography were excluded from this study.

Informed consent was obtained. Patients were informed of the risk of failure of salvage and the requirement for conversion to explantation.

There was no blinding or prospective data collection. All procedures were performed at the Regional Institute of Medical Sciences, Imphal.

Surgical technique

Povidone-iodine was used for skin preparation. The skin surrounding the site of the device exposure along with any area of thinned/eroded skin is excised. This allows the temporary removal of the generator device and lead. The generator device is removed temporarily from the pocket and handed over to the scrub nurse. This is followed by the removal of the fibrous capsule surrounding the generator. All slough or unhealthy granulation tissue surrounding the pocket is removed. Tissue culture from the pocket is obtained intra-operatively. A thorough wash is given with povidone-iodine solution. An antibiotic solution (gentamicin) is instilled into the pocket. The generator device is washed thoroughly with a povidone-iodine solution.

A new pocket is created. The pectoralis major muscle is split at the inferior end and a pocket is created. At this point, the generator device is introduced into the pocket after assessing the adequacy of the pocket size. Haemostasis is secured. The split muscle fibres are reinforced with absorbable sutures. A subcutaneous closed drainage system is introduced. The skin and subcutaneous tissue is closed in layers.

Compressive dressing is given to the operated site. The drain output is monitored and removed when the drainage is < 10 ml over 24 hours. Post-operatively, antibiotics are continued for 2 weeks and skin stitches are removed at the end of 2 weeks.

Statistical Analysis

Data were arranged and analyzed in Microsoft Excel (v16 Redmond, Wash). Descriptive statistics were performed for relevant variables.

Literature Review

A literature search was carried out for the period 2002 to 2022 using the Google search engine (Mountain View, California). Keywords used were as follows: “cardiovascular implantable electronic device,” “cardiac pacemaker,” “implanted cardioverter,” “infection,” “salvage,” “revision,” and “surgery.” All articles involving attempted salvage of CIEDs with surgery were included. Articles involving medical management of infection or exposure alone were excluded. Only English-language articles were included. Cross-referencing identified articles not initially captured in online search; these references were reviewed and either included or excluded based on the above criteria.

RESULTS

Case Series

A total of 12 patients were included in our series. Eight patients had cardiac pacemakers, while the other four had implantable cardiac defibrillators. Nine patients were male, three were female, and their ages ranged from 43 to 78 years (mean age, 60 years). The time from primary CIED placement to exposure ranged from 3 to 151 months (mean, 115 months). Maintenance of drainage ranged from 4 to 10 days (mean, 6.6 days), and postoperative follow-up in this series ranged from 8 to 31 months (mean follow-up, 22 months). 7 patients had negative wound cultures and 5 patients had positive wound cultures (2 patients had methicillin-resistant Staphylococcus aureus)

(Table 1). Seven patients received intravenous first-generation cephalosporin for 14 days, 3 patients received third-generation cephalosporin for 14 days, and 2 patients received vancomycin peri-operatively and for 14 days postoperatively.

Among the 12 patients, none showed any postoperative signs of infection. None of the patients developed any signs of implant exposure or impending rupture. None required surgical explantation of the system.

DISCUSSION

Infection, erosion of the skin and exposure are known complications of CIEDs. Traditional surgical teaching emphasizes the removal of the infected and exposed CIEDs including the generator, all leads, and patches, followed by the replacement of a new device system to a new non-infected site. [8] This method usually results in the complete resolution of infected CIEDs. However, this approach may be associated with major complications like superior vena cava perforation, right ventricular perforation, cardiac valvular injury, cardiac tamponade, and sudden death, with complication rates ranging from 2.4% to 17%. [3,9,10]

There have been various reports of salvage of an infected or exposed CIED. In 1995, Foster [11] reported successful sub-pectoral replacement with a lateral axillary approach. Jensen [12] reported a case of sub-pectoral implantable generator relocation from an abdominal pocket using an axillary tunnelling technique. In 2010, Al-Bataineh et al [13] reported a lateral axillary approach to the sub-pectoral plane in patients with ipsilateral pre-pectoral infection and limited venous access. No recurrence of infection was observed, with only 1 hematoma and 1 pneumothorax in the 16 patients who were treated. More recently, in 2012, Knepp et al [14] described repositioning devices under the pectoralis muscle using an anterior muscle-splitting approach under intravenous sedation with local anaesthesia.

Some authors have described success with CIED replacements using a sub-pectoral pocket under local anaesthesia. However, a considerable number of these patients report suffering from pain for the duration of surgery especially at the moment of sub-pectoral dissection or muscle-splitting.

Another study by Jung et al has documented the creation of a new pocket under local anaesthesia as a certain subset of patients are reluctant to undergo general anaesthesia, without a sub-pectoral dissection or muscle-splitting. The authors also mention that patients suffer from pain at the time of sub-pectoral dissection or muscle splitting.

Studies have compared the primary placement of cardiac devices in the subcutaneous versus sub-pectoral space. [15] No significant differences in complication rates were found. Most cardiac catheter laboratories adopt placement of devices into the subcutaneous space which is simpler and technically less challenging.

Conservative management is also described in the literature. Efforts have been made to reduce the potential risks associated with explantation and replacement of all devices. Taylor et al [16] described the treatment of infected pacemakers with revision and placement of a continuous irrigation system. Hurst et al [6] described similar treatments, with the use of closed antibiotic irrigation for lead preservation. Lee et al [17] described the treatment of infected device pockets with revision followed by the placement of a continuous irrigation system and closed antibiotic irrigation, with successful outcomes. However, these approaches do not move the device into a sterile tissue plane, meaning that the long-term sterility after discontinuation of the antibiotic irrigation systems is questionable.

Yamada et al [18] presented the successful salvage of AV lead systems in 17 of 18 patients, using surgical lead-preserving procedures to place a new generator with a new incision made just below the ipsilateral clavicle.

Baddour et al [19] have suggested an algorithm for treating patients with infected exposed CIEDs who have negative blood cultures with the removal of the entire device A success rate of 74% with pocket debridement, lead preservation, and creation of a new ipsilateral subcutaneous pocket in patients with negative wound cultures was noted by Griffith et al [20] However, these strategies were confined to patients with negative wound cultures, and replacement was performed under general anaesthesia.

Har-Shai et al [21] reported a sub-capsular relocation technique for the generator and lead systems. While this may be an effective salvage method, the potential of infection with the remnant capsule still exists, meaning that long-term sterility is not guaranteed.

A new pocket in the same subcutaneous plane, in our opinion, might fail once again. Long-term salvage was successful in 12 patients, using the same device. We propose that the introduction of a vascularised cover like the Pectoralis major muscle and the elimination of all infected debris lead to the possibility of salvage of such devices. This is critically valuable in a region or country with a low income like India.

Moreover, explantation of the device and implantation on the contralateral side has its own possible antecedent costs and possible surgical and anaesthetic adverse events.

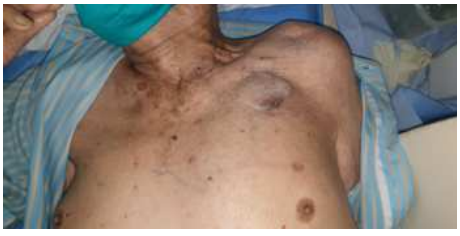

Figure 1: 73-year-old patient presenting with implant exposure

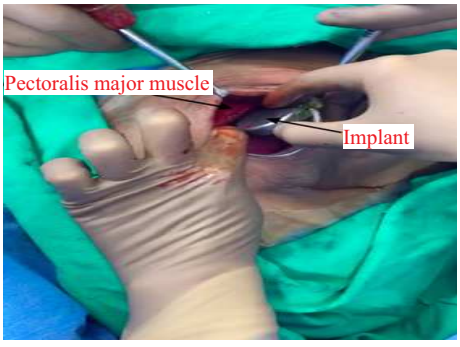

Figure 2 : Creation of sub-pectoral pocket

Figure 3 : Implant placed in sub-pectoral pocket

Figure 4 : Patient on follow-up visit 10 days after surgery

Table 1 Patients undergoing salvage surgery of CIEDs Table						
Sl No	Age	Sex	Device type	Clinical presentation	Culture result	Device age (months)
1	78	F	Pacemaker	Exposure + Pus	CoNS	121
2	48	M	Pacemaker	Skin atrophy	—	54
3	68	M	Pacemaker	Exposure + Pus	S.aureus	53
4	52	M	Pacemaker	Skin atrophy	—	76
5	73	M	Cardioverter	Exposure + Pus	Polymicrobial	151
6	47	F	Pacemaker	Skin atrophy	—	3
7	67	M	Pacemaker	Skin atrophy	—	72
8	71	F	Cardioverter	Exposure + Pus	S.aureus	86
9	55	M	Pacemaker	Exposure + Pus	CoNS	98
10	59	M	Cardioverter	Skin atrophy	—	5
11	43	M	Pacemaker	Exposure	—	37
12	63	M	Cardioverter	Exposure	—	15

CoNS : Coagulase negative Staphylococcus
S.aureus : Staphylococcus aureus

Table 2 Outcomes of Patients undergoing salvage surgery of CIEDs			
Sl No	Surgery	Outcome	Follow up (months)
1	Pocket revision and Subpectoral placement	Successful salvage	22
2	Pocket revision and Subpectoral placement	Successful salvage	14
3	Pocket revision and Subpectoral placement	Successful salvage	8
4	Pocket revision and Subpectoral placement	Successful salvage	3
5	Pocket revision and Subpectoral placement	Successful salvage	11
6	Pocket revision and Subpectoral placement	Successful salvage	7
7	Pocket revision and Subpectoral placement	Successful salvage	13
8	Pocket revision and Subpectoral placement	Successful salvage	15
9	Pocket revision and Subpectoral placement	Successful salvage	17
10	Pocket revision and Subpectoral placement	Successful salvage	19
11	Pocket revision and Subpectoral placement	Successful salvage	9
12	Pocket revision and Subpectoral placement	Successful salvage	23

CONCLUSIONS

Our series concludes that salvage of exposed CIEDs is possible without explantation of the devices in selected patients. Compared to removing the complete device and replacing with a new device, this may be a less invasive alternative technique. However, the decision to proceed with this simplified method must be predicated upon proof that no systemic infection is present.

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