Cardiac Implantable Electronic Device Infections: A Single Tertiary Care Center Experience

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ABSTRACT

Objective: The rate of cardiac implantable electronic device (CIED) infections has become prevalent in recent years, and they are related to severe complications, as well as a cost burden. In the present study, we assessed the results of our single tertiary care center experience.

Methods: All patients who underwent CIEDs implantation between 2012 and 2018 with procedural and follow-up data available were included in this study.

Results: Device infection was defined in six of 512 patients aged from 29 to 78 years old. The mean follow-up period was 2.8 ± 1.7 years. They were new implants and system, removal which included a generator, and all transvenous leads were carried out for five cases. Removal of the generator and debridement of the pocket was performed in one case with isolated pocket erosion without local signs of infection and the wound was irrigated with antibiotic solution. A 2-week oral antibiotic therapy was administered to all patients following discharge. After reimplantation, there was no infection recurrence in three patients during 13 ± 6.1 months follow-up period. Baseline characteristics, with the exception of implanted device types, were similar between infected and non-infected patients. Hematoma or pneumothorax was not observed in patients with device infection.

Conclusion: Prevalent risk factors for device infections were not relevant to our patients. Our device infection rates (1.17%) were slightly lower, and there was no serious complication due to the device infection itself or its management.

INTRODUCTION

Cardiac implantable electronic device (CIED) implantation, which has rapidly developed over the last years with increasing indications, is essential in both the treatment of cardiac arrhythmias and management of heart failure. While CIED implantation is related to improved outcomes, CIED infections may lead to the most severe complications causing morbidity and mortality, as well as significant cost burden.^[1,2] The total prevalence of CIED infections ranges from 0.68% to 5.7%.^[3,4] CIED infections may change from superficial pocket infections to systemic manifestations, including the transvenous leads.

The rate of CIED infections is higher in patients with diabetes mellitus, heart and renal failure.^[5] Older age, obstructive pulmonary disease, use of oral anticoagulation, and immunosuppression also constitute risk factors.^[6,7] The procedure-related risk factors are the complexity of CIED, length of hospitalization, periprocedural temporary pacing, and early re-intervention.^[8,9] Low operator experience and center volume are other risk factors.^[10] The effects of device infection on morbidity and mortality, inspite of the growing experience in the management of CIED infection, are still considerable. Prompt and accurate diagnosis is advantageous to the achievement of early management with antibiotic therapy and device removal. Still, prevention is the best strategy. Careful evaluation of the indication and patient status, strict sterile surgical techniques, preoperative antibiotics, and adequate homeostasis are measures to avoid CIED infections.

The aim of this observational study is to present data on CIED infections from a tertiary care center.

MATERIALS AND METHODS

This was a retrospective, single-center study, with the data obtained from medical records of patients who underwent denovo CIEDs (pacemaker (PM), implantable cardioverter-defibrillator (ICD), cardiac resynchronization therapy (CRT)) implantation, generator replacement, system revision or upgrade procedures from 2012 to 2018. All patients undergoing CIEDs implantation with procedural and follow-up data available were involved in this study.

The implantation procedures were carried out in an electrophysiology laboratory. If the patients were on warfarin, the anticoagulant therapy was not interrupted provided the international normalized ratio (INR) was between 2.0 and 2.5. If novel oral anticoagulants (NOACs) were used, they were interrupted a day before. Prophylactic antibiotic therapy (cefazolin) was provided 30 min before surgery. After preoperative skin preparation with 10% povidoneiodine solution, the incision site was infiltrated with 20 ml 1% prilocaine. The subclavian or axillary vein approach was utilized as a venous access method.

The leads and generator were secured with a nonabsorbable silk suture. The skin incision was closed with absorbable sutures following the pocket wash with bacitracin (50.000 U diluted in 50 ml of saline). The blood pressure and oxygen saturation of each patient were monitored throughout the procedure. Posteroanterior and lateral radiographs were taken before discharge. Patients were examined in the outpatient clinic within one week after discharge, and every six months thereafter. Patients were advised to visit the clinic if they had any problem with the wound or device.

All routinely-recorded periprocedural parameters, which included clinical and demographic characteristics of patients, procedure and implanted device types, venous access methods (ultrasound/ fluoroscopy/venography guided), procedure-related complications (e.g., pneumothorax, pocket hematoma), postoperative antibiotic regimens were collected and analysed. CIEDs infection definition was made according to current guidelines.^[11]

Written informed consent was obtained from all patients. This study was approved by the local ethics committee.

RESULTS

A total of 512 patients (35.5% female; mean age 66.8 ± 13.31 years) were included in our study. The mean follow-up period was 2.8 ± 1.7 years. In this study, 45.2% patients had ischemic etiology and 51.7% patients had heart failure. 87.9% of the cases were new implants. Implanted devices included CRT-D in 13.9%, a dual-chamber (DC) ICD in 2.0%; a single-chamber (SC) ICD in 34.4% a dual-chamber PM in 27.3%; a single-chamber PM in 22.5% of the patients. 13.6% of the patients were on anticoagulant therapy; 9.9% of them were on warfarin and 3.7% of them were on NOACs. Other baseline clinical characteristics of the patients and implanted device types are shown in Table 1.

CIEDs infection was defined in six of 512 patients, including one female and five males aged from 29 to 78 years, with a median age 61.6. Five cases were presented to the hospital due to pocket erosion with or without purulent drainage. One case was diagnosed during admission with acute congestive heart failure. All patients were new implants (Four of them SC-ICD; one of them DC-ICD and

one CRT-D). Minimum two sets of blood cultures, including both aerobic and anaerobic bacterial cultures, were obtained from all patients. All of them underwent empiric antibiotic therapy immediately after diagnosis and then broad-spectrum antibiotics following infectious disease specialist approval. Blood cultures were all found negative. Transesophageal echocardiography performed in one suspected case with purulent drainage and small vegetation was found on the lead. The system removal, including generator and all transvenous, leads were applied for five cases, which had pocket erosion with purulent drainage. The generator removal and debridement of the pocket were performed in one case with isolated pocket erosion without local signs of infection, and the wound was irrigated with antibiotic solution. A 2-week oral antibiotic therapy was administered to all patients following their discharge. Baseline characteristics, review of diagnosis and management of patients with CIEDs infection are shown in Table 2. After reimplantation in three patients, there was no infection recurrence during 15±6.1 months follow-up period. Baseline clinical and demographic characteristics,

 Table I.
 Baseline clinical characteristics of the patients, procedure and implanted device types

			F
		n=!	512
	n	%	Mean±SD
Age			66.8±13.31
Female	182	35.5	
Procedure types			
New implant	450	87.9	
Lead revision	21	4.1	
Upgrade procedure	2	0.4	
Generator replacement	39	7.6	
Device types			
SC-PM	115	22.5	
DC-PM	140	27.3	
SC-ICD	176	34.4	
CRT-D	71	13.9	
DC-ICD	10	2.0	
White blood cell (10 ³ /µl)			7.87±2.55
Platelet (10 ³ /µl)			221.2±69.3
Hemoglobin (g/dL)			12.82±1.91
Creatinine (mg/dL)			1.08±0.455
International normalized ratio			0.62±0.68
C-reactive protein (mg/L)			6.45±20.89
Hypertension	307	60.6	
Coronary ertery disease	229	45.2	
Heart failure	262	51.7	
Asetylsalicylic-acide	224	44.2	
Klopidogrel	66	13	
Oral anticoagulant	50	9.9	
NOAC	19	3.7	
NOAC	19	3.7	

SC: Single chamber; ICD: Implantable cardioverter defibrillator; CRT-D: Cardiac resynchronization therapy; DC: Dual chamber; NOAC: Novel oral anticoagulant; SD: Standard deviation. antiplatelet or anticoagulants and implanted device types were not statistically significant between infected and non-infected patients (Table 3).

Six patients experienced a pocket hematoma and pocket revisions for hematoma evacuation were needed in one patient. US-guided axillary venipuncture in 40 patients;

	Age/ gender	Device type	Time after implantation, months	Symptoms	Presentation	Systemic findings	Management	Re-implantation
Ptl	76/male	SC-ICD	38	No	Pocket erosion, purulent drainage	No	AB+ System removal	No, patient refused
Pt2	68/male	SC-ICD	7	Dyspnea, ortopnea	Pocket erosion, purulent drainage	No	AB+System removal	No, exitus
Pt3	60/male	SC-ICD	33	No	Pocket erosion	No	AB+generator removal	Yes, 2 weeks after
Pt4	59/male	CRT-D	7	No	Pocket erosion, purulent drainage		AB+System removal	Yes, 20 days after
Pt5	78/female	SC-ICD	17	No	Pocket erosion, purulent drainage	No	AB+System removal	No, patient refused
Pt6	29/male	DC-ICD	8	No	Pocket erosion, purulent drainage	No	AB+System removal	Yes, 3 months later

 Table 2.
 Baseline characteristics, review of the diagnosis and management of the infected patients

Pt: Patientt; SC: Single chamber; ICD: Implantable cardioverter defibrillator; CRT-D: Cardiac resynchronization therapy; DC: Dual chamber; AB: Antibiotherapy.

Table 3.	Comparison of	f the baseline	characteristics of	f the infecte	d and	non-infected	patients
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	Infected patients	Non-infected patients	p-value
n	6	506	
Age	61.3±18.5	66.8±13.2	0.31
Female, n (%)	I (0.2)	181 (35.4)	0.33
Procedure types, n (%)			
New implant	6 (1.17%)	404 (78.9)	0.841
Lead revision	0	21 (4.1)	
Upgrade procedure	0	2 (0.4)	
Generator replacement	0	39 (7.6)	
Cardiac implantable electronic devices type, n (%)			
SC-PM	0	115 (22.5)	0.02
DC-PM	0	140 (27.3)	
SC-ICD	4 (0.8)	172 (33.6)	
CRT-D	I (0.19)	70 (13.67)	
DC-ICD	I (0.19)	9 (1.76)	
White blood cell (10 ³ /µL), mean±SD	7.38±2.08	7.9±2.57	0.613
Platelet (10³/μL), mean±SD	71.3±29.1	74.9±33.3	0.800
Hemoglobin (g/dL), mean±SD	13.3±1.47	12.8±1.93	0.8
Creatinine (mg/dL), mean±SD	1.03±0.3	1.08±0.45	0.48
International normalized ratio, mean±SD	0.56±0.61	0.61±0.68	0.84
C-reactive protein (mg/L), mean±SD	7.83±15.6	7.15±21.88	0.94
Hypertension	5	303	0.243
Coronary ertery disease	4	229	0.295
Heart failure	4	257	0.439
Asetylsalicylic-acide	3	222	0.764
Klopidogrel	2	63	0.127
Oral anticoagulant	2	49	0.054
Novel oral anticoagulant	1	17	0.079

SC: Single chamber; ICD: Implantable cardioverter defibrillator; CRT-D: Cardiac resynchronization therapy; DC: Dual chamber.

venography guided axillary venipuncture 312 patients and floro-guided axillary /subclavian venepuncture in 160 patients was used as a venous access approach. Seven patients experienced a pneumothorax and chest tube insertion was needed in fife of them. All pneumothorax cases emerged when fluoro or venography guided approach were preferred. Hematoma or pneumothorax did not occur in patients with device infection.

Statistical analysis

Statistical Package for Social Sciences 16.0 (SPSS, Chicago, IL) was used for the statistical analysis of this study. Numerical variables were described as mean ± standard deviation and categorical variables were given as percentage and numbers. Categorical variables were compared by the χ^2 or Fisher exact test. The Mann-Whitney U test was used to assess differences in baseline and clinical findings between infected and non-infected patients. A p-value less than 0.05 was considered as statistically significant.

DISCUSSION

In the present study, we used intraprocedural pocket wash with rifampicin and postoperative one or two day intravenous cefazoline and oral antibiotics at discharge for all patients besides preoperative single dose cefazoline. Only one patient experienced systemic complication (endocarditis) and the rests of them (five patients) had isolated generator pocket erosion and/or infection without bacteremia. There was no severe complication due to device infection itself or its management (e.g., antibiotherapy, extraction).

In a recent large registry, including 97 750 patients, infection rates were found to be higher for ICD's and CRT patients when compared to PMs; and the risk of re-operations also increased more than denovo implantations.^[12] Our results were not fully consistent with this study, although none of our infected patients had pacemaker and all of them were new implants. Clinically significant pocket hematoma also increases long-term risk of device infection.^[13] However, none of our six patients with hematoma developed long-term device infection. Although interrupted suture is considered to be more adventagous than continuous suture to avoid pacemaker pocket infection, wound closure by continuous or interrupted suture technique was stated to have no role in preventing pacemaker pocket infection in a recent study involving 2200 patients.^[14]

Since long stay hospitalization, long term IV antibiotherapy and need for system removal cause high treatment cost, prevention should be a main objective for operators. Single pre-operative infusion of cefazolin which is supported by guidelines is the standard approach for prevention.^[11] However, long-term post-procedural antibiotics, following device placement, are considered to be a standard care by clinical electrophysiologists.^[15] In our centre, our implanters preferred postoperative IV antibiotics (cefazolin) and post-discharge oral antibiotic therapy for five or seven

days. Based on the current literature, we state that our device infection rates (1.17%) were slightly lower. Additional oral and/or IV antibiotic treatments are not supported.^[11] However, approximately 20% of infections are due to organisms resistant to cefazolin. Thus, incremental antibiotic policy would decrease the rate of device infection.^[16] It is demonstrated in the prevention of arrhythmia device infection trial (PADIT) that adding a vancomycin preoperatively along with bacitracin pocket wash and and 2-day post-procedural oral cephalexin did not maintain statistically significant benefit. Still, the authors stated that infection rate was much lower than anticipated.^[17] In a study carried out by Lee et al.,^[18] the patients treated with postoperative antibiotics were found to experience a similar rate of infection as those treated with not. A recent large multicenter study evaluating the strategies commonly used in clinical practice to reduce CIED infections found that prolonged use of antimicrobials after skin closure was not effective. Reducing postprocedural antibiotherapy can also prevent potential harmful consequences, such as kidney injury.[19]

One of the other methods for prevention is intraprocedural pocket irrigation with antibiotic solutions, whereas this practice is supported or discouraged by little clinical data, the usage of antimicrobial agent pocket irrigation for CIED infection prophylaxis is frequently preferred in current practice. The most commonly chosen antibiotics are Bacitracin (48%), vancomycin (39%), and cephalosporin (29%). ^[20] Kang et al.^[21] conducted a metaanalyses, including 10 studies, to investigate the protective effects of pocket irrigation regardless of antibiotics classes. The incidence of pocket infection decreased by about 59% with antibiotic irrigation compared with the use of saline. However, pocket irrigation is not recommended by current guideline due to inconsistent results of the trials.^[11]

Apart from the periprocedural antibiotic strategy, there are certain efforts which are innovative in decreasing infections. Recently, an absorbable, minocycline and rifampin eluting envelope covering CIEDs has been advanced. The envelope elutes antibiotics over a minimum of seven days and the envelope is absorbed in almost nine weeks. The Worldwide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT) compared infection rates in CIED procedures with or without the envelope. At 12 months follow-up period, envelope decreased the incidence of major infections by 40% relative to standard care alone. There was no difference between two groups concerning procedure-related complications.^[22]

Following combined system removal and antibiotherapy, a large number of patients with CIEDs infection could be treated. Vancomycin should be administered as an empirical antibiotic agent until the microbiological etiology is determined since staphylococci are the most prevalent microbe and nearly half of them are methicillin resistant. ^[23–25] In general, following lead extraction, a 2-week antibiotic therapy should be performed for pocket infection, and 10 days is advised for pocket erosion.^[26] Superficial or

incisional infection without device involvement, which is only disseminated to the skin and the subcutaneous tissue of the incision, is not an indication for CIED removal. However, erosion in any part of the CIED is a sign of contamination of the entire system and it requires complete device removal. Patients with superficial incisional infection or hematoma, immediately after CIED intervention, may present with signs of inflammation. These patients could require close follow-up and 7 to 10 days of oral antibiotherapy is advisable.^[26] If an infection does not involve the device, the alternative conservative methods can be considered, especially for superficial or incisional infection at the device pocket, due to the potential risks related to lead extraction and patient preference. Lopez et al.^[27] used a closed irrigation system which included pulse irrigation and suction, using a solution of vancomycin and gentamycin for 72 hours after pocket debridement and washout in patients with isolated pocket infection. There was no recurrence of infection during 19 months. Puri et al.^[28] described a similar closed irrigation system that uses povidone-iodine solution infused four times daily for one week, besides a 2-week course of oral antibiotics. They also reported no recurrent infection over a 2-year followup period. Since there is no clinical predictor of successful salvage of infected devices, patients need to be closely followed for progression to deeper infection, which would require system removal.[29]

Following the extraction, it is essential to redefine the indication for pacing and/or defibrillation. There are no recommendations given in the guidelines regarding the timing and a few recommendations based on expert opinion are available.^[30,31] Re-implantation should be reconsidered using evaluating the initial indication and reversibility of disease.^[32] Especially, in case of inadequate Leadless, PM implant can considered in patients with CIED infection and residual venous anatomy. In two smaller studies, leadless PM's were implanted after system removal and there were no cases of recurrent infection during a mean followup of 16 months and 12 weeks. It was also shown that in patients receiving Micra following extraction due to a device infection, no recurring infections occured in longterm follow-up.^[33-35]

CONCLUSION

Contrary to common knowledge, the use of a more complex device, the second procedure, or the development of hematoma or pneumomothorax did not increase the infection rate in our patients. Although our device infection rates (1.17%) were slightly lower and there was no serious complication, we suggest that a single dose of preoperative antibiotic treatment may be sufficient in accordance with guideline recommendations to reduce the cost and length of hospitalization. On the other hand, we acknowledge that there are still some limitations in this study. It is a single-center and nonrandomized study with a small sample size.

Ethics Committee Approval

Approved by the local ethics committee.

Informed Consent

Retrospective study.

Peer-review

Internally peer-reviewed.

Authorship Contributions

Concept: S.B.; Design: S.B.; Supervision: S.B.; Fundings: T.E.G.; Materials: S.B., T.E.G.; Data: S.B., T.E.G.; Analysis: S.B., T.E.G.; Literature search: S.B.; Writing: S.B.; Critical revision: S.B., T.E.G.

Conflict of Interest

No conflicts of interests to disclose.

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Kardiyak İmplante Edilebilir Cihaz Enfeksiyonu: Tek, Üçüncü Basamak Sağlık Merkezi Deneyimi

Amaç: Kardiyak implante edilebilir elektronik cihaz enfeksiyonlarının görülme oranı yıllar geçtikçe artmakta ve bu durum ciddi komplikasyonlar ve maliyet artışı ile ilişkili olabilmektedir. Bu çalışmada, bizim üçüncü basamak sağlık merkezi deneyim sonuçlarını değerlendirdik.

Gereç ve Yöntem: 2012–2018 yılları arasında, prosedürel ve izlem verileri mevcut olan, tüm kardiyak implante edilebilir elektronik cihaz implantasyonu uygulanan hastalar çalışmaya alındı.

Bulgular: Beş yüz on iki hasta içerisinden, yaşları 29–78 yaş arası değişen altı hastada cihaz enfeksiyonu saptandı. Ortalama takip süresi 2.8±1.7 yıl idi. Hepsi yeni implant olgulardı ve beş olgu için tüm sistemin çıkarılması (jeneratör ve tüm transvenöz lead'ler dahil) işlemi yapıldı. Lokal enfeksiyon belirtileri olmayan izole cep erozyonu olan bir olguda, jeneratör çıkarılması ve debridman işlemleri yapıldı ve yara antibiyotik solüsyonu ile yıkandı. Tüm hastalara taburculuk sonrası iki haftalık oral antibiyotik tedavisi verildi. Üç hastada reimplantasyon sonrası, 13±6.1 ay takip döneminde enfeksiyon tekrarı oluşmadı. İmplante edilmiş cihaz tipleri hariç, enfekte olan ve enfekte olmayan hastalar arasında bazal özellikler açısından farklılık saptanmadı. Cihaz enfeksiyonu olan hastalarda hematom ve pnömotoraks görülmedi.

Sonuç: Cihaz enfeksiyonları için bilinen geleneksel risk faktörleri enfekte hastalarımızla ilişkili olarak saptanmadı. Cihaz enfeksiyon oranımız (%1.17) düşüktü ve hem cihaz enfeksiyonu hem de tedavisi nedeniyle ciddi bir komplikasyon görülmedi.

Anahtar Sözcükler: Enfeksiyon; kardiyak İmplante edilebilir elektronik cihazlar; üçüncü basamak sağlık merkezi.