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Single center experience with cardiac device infection: Importance of periprocedural precautions

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Abstract

Aim: Cardiac implantable electronic devices (CIED) have been increasingly used in recent years; consequently, there has been an increment in device-related complications. In this study, we aimed to make a recommendation to the centers that can implant cardiac devices about perioperative measures and to reinforce the role of perioperative measures in preventing cardiac device infection.

Materials and Methods: The retrospective review examined the patients demographic data, medical diagnoses, operation details, echocardiographic findings, anticoagulant/ antiaggregant usement and complications (Table 1), laboratory findings and comorbidities (Table 2). No distinction was made between device types. A 90-day and a 30-day retrospective screening were performed. Patients were scheduled for follow-up visits one week and one month after the procedure. Three-month checks on telecommunication methods were performed.

Results: The study included 169 people. There were 60 (35.5%) emergency department patients admitted. A pacemaker was implanted in 60 patients, an implantable cardioverter-defibrillator (ICD) in 79 patients, and a Cardiac Resynchronization Therapy (CRT) in 30 patients. The procedure time of patients with CRT implantation was significantly longer ($p < 0.001$) when battery replacements were excluded from the analysis (p 0.001). However, no statistical difference was found in infection rates. A battery pocket hematoma was observed in 4 patients, and 1 patient with a possible battery pocket infection.

Conclusion: We think that the low rate of CIED infection in our clinic is a result of strict periprocedural measures and collaboration with infectious diseases.

Introduction

Over the last five decades, the use of cardiac implantable electronic devices (CIEDs) in cardiovascular disease with expanding indications has rapidly increased. Technological developments in the field of interventional cardiology have increased the life expectancy of cardiac patients. Due to the needs of surviving patients, the number of patients who have been implanted with a permanent pacemaker and an implantable cardioverter-defibrillator is increasing on a daily basis [1]. The increase in the number of patients who have had a CIED implanted adds to the complications associated with the procedure. CIED-related infections are increasing at a faster rate than the implanted device infections [2] and infection-related complications are increasing at a 5% annual rate [3]. Although the frequency of CIED infections varies by center, it ranges between 0.5% and 19.9% in patients with permanent pacemakers and between 0.0% and 3.2% for Implantable Cardioverter Defibrillator (ICD)/ Cardiac Resynchronization Therapy (CRT) devices [4-7]. Recent studies have shown that patients undergoing a battery replacement have a higher infection rate than those undergoing a new implantation [8-10]. Individual characteristics of the patient (comorbid diseases, self-care), peri-procedural preparations (repetitive procedures, contamination during the procedure, appropriate preprocedural preparation and use of antimicrobials), environmental and organizational factors (facility cleanliness, quality environmental cleanliness, lack of space to store necessary supplies), and microbial factors (type and virulence of the organism) all play an important role in CIED infections [3]. Patients with comorbidities, such as diabetes mellitus, heart failure, long-term corticosteroid use, anticoagulation, and renal dysfunction are reported to be

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at higher risk of CIED infection. There is no standardized practice in the literature for the use of periprocedural antibiotics to protect against CIED infections [11]. The use of antibiotics in CIED implantations is one of the robust recommendations based on many clinical studies [12]. Although routine surgical measures are taken as periprocedural protection measures in many centers, weaker measures are taken in terms of environmental factors (operating in a catheter laboratory, environmental cleaning, etc.). In this observational study, we aimed to find out the reasons for low single-center CIED infection rates, compare the practices of our center with the literature, and contribute to the literature in terms of periprocedural measures.

Material and Methods

The research was carried out at the Ankara 29 Mayıs State Hospital Cardiology Clinic. The first CIED implantation was performed in our center, a 100-bed city hospital, in November 2019. Patients who had a CIED implanted (initial or revision) between November 2019 and June 2020 was included in this single-center observational study. In the retrospective file review, the demographic data, medical diagnoses, operation details, echocardiographic findings, anticoagulant/antiaggregant use and complications (Table 1), laboratory findings, and comorbidities (Table 2) of the patients were examined. The data on the practices performed for perioperative infection protection (preoperative use of antibiotics, shaving of the operation area, use of disinfectants, operator-related factors) were collected. 1.0 gr Cephazolin solution I/V was administered to patients who had not received antibiotics during hospitalization for any other reason before the procedure. In the event of severe bleeding from the device pocket and the need to continue drainage, antibiotics were continued. The procedure was performed under the antiplatelet and antiaggregant drugs used by the patients. In addition, patients receiving warfarin were processed with INR levels of around 2. In patients using NOACs, the drugs were discontinued 24 hours before, and bridging treatment was not applied in any of the patients. One day of bed rest and two hours of cold and compression therapy were prescribed for all patients. Data on the type of CIED implanted (ICD, pacemaker, or CRT), lead number, replacement/new operation, recurring operation, and operation time were recorded. Although the elevated risk is known for ICD implantation, battery replacement, and complex operations (like resynchronization therapy, complicated cases, or long procedure time), there is insufficient data on the CIED infection rate for each of these procedures [11]. Therefore, no distinction was made between device types. The presence of battery pocket infection was evaluated according to the definition of infection in the Mayo Cardiovascular Infection Study group, and the definition of endocarditis was determined according to the presence of vegetation in the valve or lead and Duke Criteria [13]. In addition, since there is no clear definition of a CIED infection, exclusion criteria were not applied to patients with suspected infection. A 90-day and a 30-day retrospective screening were performed. Patients were called for follow-up visits one week and one month after the procedure. 3-month checks were made over telecommunication methods.

Table 1. Variables

Sex	Male	112 (66.3)
	Female	57 (33.7)
Age	18-65	52 (30.7)
	65-75	75(44.3)
	75-90	42 (24.8)
Smoking	Yes	32(18.9)
	No	137 (81.1)
Ejection fraction	<40	87 (51.6)
	40-49	6 (3.2)
	>50	76 (44.3)
Preoperative antibiotics	Yes	169 (100)
	Sefazolin	158
	Others	11
	No	0 (0)
Indications	Ischemic CMP[1]	71 (42)
	Non-ischemic CMP	13 (7.6)
	AV2[2] block	60 (35.5)
	Syncope	4 (2.5)
	Heart failure resenc. Therapy	11 (6.5)
	Asystoli	1 (1)
	Multi endication	10 (6)
Hair clipping for male patients	Yes	69 (62)
	No	43 (38)
Type of CIED[3]	ICD[4]	79 (46.7)
	Pacemaker	60 (35.5)
	BIV-ICD[5]	30 (17.8)
Number of leads implanted	1	75(44.3)
	2	43 (28.2)
	3	9 (5.6)
Initial/Reimplantation	Initial	114 (67.5)
	Battery replacement	41 (24.3)
	Battery replacement + lead revision	13(7.7)
Processing Time	< 1 hour	118 (69.8)
	1-2 hour	38 (22.4)
	> 2 hour	13 (7.7)
Complications	Hematoma	4
	Pnomothorax	1
	Hemathorax	1
	Infective	1
Type of suture	Aesthetic	158 (93,4)
	Matrix	11 (6,6)

[1]CMP: Cardiomyopathy, [2]AV: Atrioventricular, [3]CIED: Cardiovascular Implantable Electronic Device, [4]ICD: Implantable Cardiac Device, [5]BIV-ICD: Biventricular Implantable Cardiac Device.

Results

One hundred sixty nine people were enrolled in the study. 42 patients (24.8%) were 75 years of age or older, 75 patients (44.3%) were 65-75 years of age, and 52 patients (30.7%) were under 65 years of age. The emer-

Table 2. Comorbidities and laboratory findings.

Atrial fibrillation		42 (25)
Diabetes Mellitus		41(24)
Hypertension		111 (65.7)
Hyperlipidemia		47 (40)
Chronic obstructive lung disease		15 (8.9)
Malignancy		3 (1.8)
Serebrovascular disease		3 (1.8)
Aterosclerotic vascular disease		96 (56.8)
Heart failure		109 (64.5)
Acetylsalicylic acid		82 (48.5)
NOACs		25 (14.8)
Klopidogrel		40 (23.7)
Warfarin		15 (8.9)
Betablocker		108 (63.9)
Angiotensin converting enzyme inhibitor		80 (47.3)
Angiotensin receptor blocker		27 (16)
Statin		79 (46.7)
Spironolactone		69 (40.8)
INR	<2,0	165 (97.6)
	2-3	4 (2.4)
White blood cells	<10000	144 (79.8)
	>10000	25 (20.2)
c- Reactive Protein	<5	99 (68.5)
	5-10	34 (20.1)
	10-25	18 (10.7)
	>25	18 (10.7)
GFR(ml/dak /1.73 m^2)	$\geq$ 90	25 (14.8)
	> 60-89	89 (52.6)
	> 30-60	48 (28.4)
	> 15-29	6 (3.6)
	< 15	1 (6)

GFR: Glomerular Filtration Rate, INR: Internationel normalized ratio, NOACs: Novel Oral Anticoagulants.

gency department admitted 44 (35.5%) patients. A pacemaker was implanted in 60 patients (35.5%), an implantable cardioverter-defibrillator was implanted in 79 patients (46.7%) and a 3-chamber implantable cardioverter-defibrillator was implanted in 30 patients (17.8). CIED implantation was performed for the first time in 114 patients (67.5%), battery replacement in 41 patients (24.3%), and lead implantation and battery replacement in 13 patients (7.7). Aesthetic sutures were used in 93.4% of the patients, while matrix sutures were used in the remaining patients. Subcutaneous sutures of all patients were closed with continuous sutures. In four patients, a submuscular battery pocket was opened, and in others, a pectoral fascia pocket was opened. Tweenty three patients were using dual antiplatelet therapy, 40 patients were using clopidogrel, and 82 patients were using acetylsalicylic acid. 15 patients were using warfarin and 25 patients were using Novel Oral Anticoagulants (NOACs). The number of patients with an Ejection Fraction (EF) of less than 40 was 87 (51.6), the number of patients with an EF of 40-49 was 6 (3.2), and the rest was 50 or over. In the analysis performed by excluding battery replacements, the procedure time of patients with CRT implantation was significantly longer ($p < 0.001$). However, no statistical difference was found in infection rates. A battery pocket hematoma was observed in 4 patients, and a battery pocket infection was suspected in one. No growth was detected in the cultures made. A granulomatous reaction was observed in the pathology. The device was extracted due to purulent discharge. Preoperative fever was observed in 8 patients. Before the procedure, 158(93.4) patients were given cefazolin, and 11(6.6) patients were given other antibiotics.

Discussion

CIED infections are major complications that result in complete removal of the device and have high morbidity and mortality [14]. Although there is no consensus about the methods of infection prevention in CIED infections, different expert opinions, reviews, and some mini guides have been tried and established [10-16]. In this observational study, we aimed to investigate low infection rates and causes in a single-center and to compare individual, procedural, and environmental infection prevention measures with the literature. According to the European Society of Cardiology (ESC) consensus report published in 2019, the CIED infection rate was <0.5% in 44.8% of the centers, in the range of 0.5-1.0% in 16.5%, 1-2% in 17.4%, 2-5% in 13.5%, and >5% in 7.8 [11]. Battery replacement, an increase in co-morbidities, and an increase in complex device implantation (ICD/CRT) are all potential risk factors for CIED infections [11].

Environmental factors / Personnel

According to recent publications on the prevention and management of CIED infections, the operation room is required to be suitable for operating room conditions [16-17]. In our hospital, procedures were carried out in the catheter laboratory by providing appropriate conditions. Although recent publications recommend that the room in which CIED implantation would be performed should have negative pressure [16-17], the catheter laboratory of our hospital is ventilated with a ventilation system that operates with outside air at a rate of 15-20 air changes/hour. The ventilation system in our catheter laboratory meets the basic requirements outlined in the CIED infection guidelines. Some days of the week were designated as CIED implantation days, and coronary events were not accepted unless they were an emergency. We cleaned the catheter laboratory before each procedure. In the event of a CIED, access to the catheter laboratory was restricted, and operating room personnel followed the minimum required surgical precautions.

Preprocedural

On the day of the procedure, if the surgical site was the scalp, it was cleaned with electric clippers (with a single-use head) [16-18]. If the surgery could be performed on a hairless area, shaving was not done as recommended due to the increased risk of infection [23]. Although taking a shower before the procedure was recommended in the British guideline published in 2015, except for emergency patients, elective patients followed this rule [23]. Again, no staphylococcal carriage samples were obtained from any of our patients for staphylococcal carriage prior to the procedure. The use of anticoagulant/antiaggregant is a problem for most patients undergoing CIED implantation. In

patients who have had a CIED implanted, the development of a hematoma in the operation site increases the risk of infection fourfold [18]. It is known that the combination of clopidogrel and acetylsalicylic acid increases the risk of hematoma in patients with CIED implants [19-20]. It was observed that the rate of bleeding and hematoma increased approximately 3 times in patients receiving warfarin who also received heparin bridging therapy [19]. A rise in bleeding complications was not observed in CIED implantations where INR was maintained at around 2 instead of discontinuing warfarin compared to those with an INR <1.5 [19-21]. Considering this information, warfarin use was not interrupted in patients processed [22]. Although there were recommendations for discontinuation regarding the use of antiaggregant, its use was not discontinued in any patient, and the elevated risk of hematoma was not observed in patients using dual antiplatelet observationally. In our study, 4 patients were observed to develop a hematoma. In subgroup analysis, it was observed that 2 patients with hematoma used warfarin and had to use enoxaparin after the procedure because their arrival INR was under 1.5, and 1 patient was from the NOAC group, and one patient was from the group using dual antiplatelets. Although flucloxacillin is recommended in some guidelines for preprocedural antibiotic prophylaxis due to C. difficile infections (16,23%), Cefazolin 2 gr was administered intravenously before the procedure in our hospital, as it is in many high-volume centers around the world [11]. However, no C. difficile infection was detected in the follow-up of the patients. Cefazolin was administered 1 hour before the procedure, as recommended by 10 guidelines supported by meta-analyses [24]. If the patients who were planned for CIED implantation showed signs of sepsis (fever, high C - reactive protein, or leukocytosis), the patients were consulted with infectious diseases and implantation was performed after a fever-free period for a minimum of 2 days following the use of appropriate antibiotics.

Procedural / Postprocedural

The use of a topical antiseptic at the operation site is controversial. In a randomized clinical study by Darouiche et al., it was found that administration of chlorhexidine antisepsis caused a relative 41% lower rate of infection compared to povidone iodine [25]. In another single-center study, no difference was identified between aqueous or alcoholic preparations of povidone iodine and chlorhexidine [26]. All members of the operation team washed their hands with a single-use 4% chlorhexidine impregnated surgical nail brush at least 2 times and for a minimum of 3 minutes. Before the operation, the surgical site was disinfected at least 3 times with a single-use surgical nail brush impregnated with 4% chlorhexidine and a surgical nail brush impregnated with 7.5% povidone iodine with a minimum contact time of at least 30 seconds. The operation table was used by a doctor and a nurse. Operations were performed by a single physician. The operation nurse was not substituted as much as possible. Since hematoma formation would increase the risk of infection [18], particular attention was paid to bleeding control during the procedure. After the procedure, the patients were taken to the intensive care unit with a compressive dressing for bleeding control, and the compressive dressing was applied for 4-6 hours. In the postoperative period, cefazolin was administered twice a day. There is no evidence for post-operative antibiotic administration in preventing CIED infections [11, 16, 17, 22]. Considering that CIED implantations are new in our hospital, as they are in many other centers in Europe [11], we believe that continued use of postoperative antibiotics is effective in high-patient-volume centers in our country. All patients with CIED implantations were discharged as soon as possible. Wound control was performed on the patients at the visit made on the next day of the procedure. First and only antiseptic dressing was done. The patients were advised to re.ove their dressings the next day and to keep the operation area dry and clean for 2-3 days if it was a subcutaneous suture, but to keep it dry and clean until the sutures were removed if it was a matrix suture. Although the first CIED implantation in our hospital was 2 years ago, the main reason for achieving low infection rates was suggested to be a combination of personnel sensitivity and appropriate environmental factors. We would like to state that we found our single-center observational study valuable in terms of guiding centers that are new to CIED implantation.

Conclucion

In our hospital, the rate of CIED infection is low. This, we think, is due to the use of antibiotic prophylaxis in accordance with pre-procedural measures and cooperation with infectious diseases. In CIED prevention, we believe that working as a single team improves efficiency in the implementation of procedural measures.

Limitations

The study had certain limitations. First of all, it was a retrospective cross-sectional and a single-center study. There were only two cardiologists operating the patients, and it is a known fact that bleeding complications vary with experience of the operator. Secondly, the sample size was relatively small, and larger cohort studies are needed to confirm our conclusions.

Ethics approval

Ankara Diskapi Yildirim Beyazit Training and Research Hospital Ethics by the Presidency of the Board on Periprocedural in the Implantation of Cardiac Devices Our study on the Importance of Precautions has been approved (17.05.2021 with the date and number of 111/12).

References

1. Athan E, Chu VH, Tattevin P et al. Clinical characteristics and outcome of infective endocarditis involving implantable cardiac devices. JAMA. 2012; 307:1727-35.
2. Harper MW, Uslan DZ, Greenspon A et al. "Clinical presentation of CIED infection following initial implant versus reoperation for generator change or lead addition." Open heart 5.1 (2018).
3. Branch-Elliman, W. A Roadmap for Reducing Cardiac Device Infections: a Review of Epidemiology, Pathogenesis, and Actionable Risk Factors to Guide the Development of an Infection Prevention Program for the Electrophysiology Laboratory. Curr Infect Dis Rep 19, 34 (2017). https://doi.org/10.1007/s11908-017-0591-8.

4. Romeyer-Bouchard C, Costa A, Dauphinot V et al. Prevalence and risk factors related to infections of cardiac resynchronization therapy devices. Eur Heart J. 2010; 31:203-10.
5. Edelstein S, Yahalom M. Cardiac device-related endocarditis: epidemiology, pathogenesis, diagnosis, and treatment --- a review. Int J Angiol. 2009; 18:167-72.
6. Baddour LM, Epstein AE, Ericksonet CC et al. Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association. Circulation. 2010; 121:458-77.
7. Tarakji KG, Wilkoff BL. How to diagnose and manage patients with cardiac implantable electronic device infections. J Arrhythm. 2013; 6:320-4.
8. Voigt A, Shalaby A, Saba S. Continued rise in rates of cardiovascular implantable electronic device infections in the United States:temporal trends and causative insights. Pacing Clin Electrophysiol 2010; 33:414–9.
9. Rohacek M, Weisser M, Kobza R et al. Bacterial colonization and infection of electrophysiological cardiac devices detected with sonication and swab culture. Circulation 2010; 121:1691–7.
10. Baddour LM, Epstein AE, Erickson CC et al. Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association. Circulation 2010; 121:458–77.
11. Traykov V, Bongiorni MG, Boriani G et al. "Clinical practice and implementation of guidelines for the prevention, diagnosis and management of cardiac implantable electronic device infections: results of a worldwide survey under the auspices of the European Heart Rhythm Association." EP Europace 21.8 (2019): 1270-1279.
12. Rahman R, Saba S, Bazaz R et al. "Infection and readmission rate of cardiac implantable electronic device insertions: an observational single center study." American journal of infection control 44.3 (2016): 278-282.
13. Polyzos KA, Konstantelias AA, Falagas ME. "Risk factors for cardiac implantable electronic device infection: a systematic review and meta-analysis." Ep Europace 17.5 (2015): 767-777.
14. Birnie DH, Wang J, Alings M, Philippon F et al. "Risk factors for infections involving cardiac implanted electronic devices." Journal of the American College of Cardiology 74.23 (2019): 2845-2854.
15. Barbar T, Patel R, Thomas G, Cheung JW. "Strategies to Prevent Cardiac Implantable Electronic Device Infection." The Journal of Innovations in Cardiac Rhythm Management 11.1 (2020): 3949.
16. Sandoe JA, Barlow G, Chambers JB et al. "Guidelines for the diagnosis, prevention and management of implantable cardiac electronic device infection. Report of a joint Working Party project on behalf of the British Society for Antimicrobial Chemotherapy (BSAC, host organization), British Heart Rhythm Society (BHRS), British Cardiovascular Society (BCS), British Heart Valve Society (BHVS) and British Society for Echocardiography (BSE)." Journal of Antimicrobial Chemotherapy 70.2 (2015): 325-359.
17. Harrison JL, Prendergast BD, Sandoe JA. "Guidelines for the diagnosis, management and prevention of implantable cardiac electronic device infection." (2015): 250-252.
18. Uslan DZ, Gleva MJ, Warren DK et al. Cardiovascular implantable electronic device replacement infections and prevention: results from the REPLACE Registry. Pacing Clin Electrophysiol 2012; 35: 81-7.
19. Tompkins C, Cheng A, Dalal D et al. Dual antiplatelet therapy and heparin "bridging" significantly increase the risk of bleeding complications after pacemaker or implantable cardioverter-defibrillator device implantation. J Am Coll Cardiol 2010; 55: 2376–82.
20. Kutinsky IB, Jarandilla R, Jewett M, Haines DE. Risk of hematoma complications after device implant in the clopidogrel era. Circ Arrhythm Electrophysiol 2010; 3: 312–8.
21. Li HK, Chen FC, Rea RF, et al. No increased bleeding events with continuation of oral anticoagulation therapy for patients undergoing cardiac device procedure. Pacing Clin Electrophysiol 2011; 34: 868–74.
22. Ostrowska, B., Gkiouzepas, S., Kurland, S. Et al (2021). Device infections related to cardiac resynchronization therapy in clinical practice-An analysis of its prevalence, risk factors and routine surveillance at a single center university hospital. Clinical cardiology, 44(6), 739–747.
23. Han, H. C., Hawkins, N. M., Pearman et al. (2021). Epidemiology of cardiac implantable electronic device infections: incidence and risk factors. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology, 23(23 Suppl 4), iv3–iv10.
24. Barbar T, Patel R, Thomas G, Cheung JW. "Strategies to Prevent Cardiac Implantable Electronic Device Infection." The Journal of Innovations in Cardiac Rhythm Management 11.1 (2020): 3949.
25. Mangram AJ, Horan TC, Pearson ML et al. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol. 1999;20(4):250–278; quiz 279–280.
26. Darouiche RO, Wall MJ Jr, Itani KM et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. N Engl J Med. 2010;362(1):18–26.
27. Qintar M, Zardkoohi O, Hammadah M et al. The impact of changing antiseptic skin preparation agent used for cardiac implantable electronic device (CIED) procedures on the risk of infection. Pacing Clin Electrophysiol. 2015;38(2):240–246.