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Cardiac Implantable Electronic Devices - What We Have Done So Far? A Single-center Experience

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Abstract

Objectives: In this study, we examined the various device treatments that we applied to patients in different scenarios in our clinic and compared the complication rates we encountered with the current literature. This study revised our usual protocols to avoid and treat possible events at an early stage.

Materials and Methods: Between September 2016 and March 2022, 965 consecutive children and adult patients (66.2% men; 66.4±14.0 years) who underwent 1018 cardiac device procedures at our center were analyzed retrospectively. The clinical and electrophysiological characteristics of the study group were evaluated.

Results: The total number of device procedures performed in the electrophysiology laboratory was 1018, including 709 cardiac device implantations, 236 generator replacements, 59 lead revisions, and 14 lead extractions. In the pacemaker group, the study population was older and mostly female [306 patients (48.7% men); 71.1±15.0 years], compared to the implantable cardioverter defibrillators and cardiac resynchronization therapy groups [254 patients (82.2% men); 62.1±13.2 years and 149 patients (75.1% men); 60.1±9.6 years, respectively]. Regarding procedure-related complications, the most common complications were device-related infection (8 patients, 0.8%) and lead-related reintervention (6 patients, 0.6%). Following in order: vascular complications included coronary sinus (6 patients, 0.6%), axillary vein dissection/perforation (3 patients, 0.3%), pneumothorax (4 patients, 0.4%), diaphragmatic stimulation requiring reintervention (2 patients, 0.2%), and cardiac perforation (1 patient, 0.1%) were other complications we encountered. No patient had a device-related hemothorax or brachial plexus injury. The procedure-related mortality rate following the index procedure during the first month was 0.1%.

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Conclusion: In this retrospective study, we present various cardiac implantable electronic device (CIED) procedures performed at our center and their periprocedural results. These data underline the significance of specific methods aimed at reducing CIED complications and improving their management.

Keywords: Electrophysiology, pacemakers, registries

Introduction

In the 21st century, cardiac implantable electronic device (CIED) implantation, consisting of pacemakers (PMs), implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy (CRT) devices, has become increasingly common worldwide. Nonetheless, there is considerable heterogeneity among countries in PM, ICD, and CRT implantation rates; this is due to epidemiological, social, and socio-economic reasons[1-4].

CIED implantation provides definite clinical benefits; however, one in ten patients receiving device therapy experience various possibly severe complications[5]. To manage and prevent complications, it is necessary to evaluate each patient's indications for CIED implantation, the steps of the implantation procedure, and device function.

As a tertiary center, our hospital is a center where cardiac devices are most frequently implanted. Recently, with increasing interest and confidence in device treatments, especially CRT, the number of patients receiving device treatment in our hospital has increased, and the leading role of our hospital has been consolidated. In this study, we examined the various device treatments we applied to patients in different scenarios in our clinic and compared the complication rates we encountered with the current literature. This study revised our usual protocols to avoid and treat possible events at an early stage.

Materials and Methods

This study was a retrospective analysis, and our population consisted of 965 consecutive children and adult patients (66.2% men; 66.4±14.0 years) who underwent 1018 cardiac device procedures between September 2016 and March 2022 at our center. The clinical and electrophysiological characteristics of the study group were evaluated. There were no exclusion criteria for this study. The study protocol was approved by the Clinical Research Ethics Committee of University of Health Sciences Turkey, Gülhane Training and Research Hospital (approval date: May 26, 2022; approval number: 2022-173) and conformed to the principles of the Declaration of Helsinki.

Statistical Analysis

This was a descriptive study, in which categorical variables were represented as absolute numbers and percentages. Continuous variables are presented as the mean ± standard deviation. Statistical analyses were performed using SPSS for Windows version 26.0 (IBM Corp., Armonk, NY, USA).

Results

The total number of device procedures performed in the electrophysiology laboratory was 1018 that consisted of 709 cardiac device implantations, 236 generator replacements, 59 lead revisions, and 14 lead extractions.

The baseline characteristics of the patients who underwent device implantation are shown in Table 1. In the PM group, the study population was older and mostly female [306 patients (48.7% men); 71.1±15.0 years], in contrast to ICD and CRT groups [254 patients (82.2% men); 62.1±13.2 years and 149 patients (75.1% men); 60.1±9.6 years, respectively]. The ejection fraction of ICD and CRT patients was lower (30.1±11.8 and 23.8±6.3, respectively) as expected, and it was in the normal range for PM patients (58.1±8.5). The number of patients with

sinus rhythm (223; 72.9%) was lower in the PM group compared to ICD and CRT groups (225, 88.6%; 128, 86.0%, respectively). The ratio of patients to who device implantation was applied for non-ischaemic etiology and primary prevention were detected more frequently in the CRT group (62 patients; 41.6%, and 133 patients; 89.3%, respectively) in proportion to the ICD group (59 patients; 23.3% and 195 patients 76.8%, respectively). The ICD group was classified according to the specific cardiomyopathy groups are as follows: of the 254 patients, 12 had hypertrophic obstructive cardiomyopathy (4.7%), 2 had arrhythmogenic right ventricular dysplasia (0.8%), 1 had Brugada syndrome (0.8%), 1 had muscular dystrophy (0.8%), and 1 patient had non-compaction cardiomyopathy (0.8%).

The absolute and proportional numbers of ICD, PM, and CRT device types implanted between 2017 and 2021 are presented in Table 2 and Figure 1. While the number of other devices remained relatively constant, the use of CRTs has increased over the last 5-years.

Complications following the device procedures are shown in Table 3. Regarding procedure-related complications, the most common complication was device-related infection (8 patients, 0.8%) (Figure 2) and lead-related re-intervention (6 patients, 0.6%). Following in order: vascular complications, including coronary sinus dissection/perforation (6 patients, 0.6%) and axillary vein dissection/perforation (3 patients, 0.3%), pneumothorax (4 patients, 0.4%) (Figure 3), diaphragmatic stimulation requiring reintervention (2 patients, 0.2%), and cardiac perforation (1 patient, 0.1%) (Figure 4) were other complications encountered. None of the patients had a device-related hemothorax or brachial plexus injury. The procedure-related mortality rate following the index procedure during the first month was 0.1%.

Considering the iatrogenic causes of atrioventricular (AV) node injuries (26 patients, 2.6%), surgical operations (14 patients, 1.4%), transcatheter aortic valve replacement (TAVR) procedures (self-expandable TAVR, 12 patients, 1.2%; balloon-expandable TAVR, 6 patients, 0.6%), AV node ablation procedures for treating atrial fibrillation (3 patients, 0.3%), and inadvertent AV node impairment during anteroseptal accessory pathway ablation (2 patients, 0.2%) were major indications for

Table 1. The baseline patient characteristics

	PM (N=306)	ICD (N=254)	CRT (N=149)
Age, mean (SD), years	71.1 (+15.0)	62.1 (+13.2)	60.1 (+9.6)
Male gender, N (%)	149 (48.7)	209 (82.2)	112 (75.1)
EF, mean (SD), (%)	58.1 (+8.5)	30.1 (+11.8)	23.8 (+6.3)
QRS duration, mean (SD), ms	N/A	N/A	153.1 (+15.0)
Basal rhythm, N (%)			
-Sinus	223 (72.9)	225 (88.6)	128 (86.0)
-AF	33 (10.8)	24 (9.4)	20 (13.4)
-Unknown	50 (16.3)	5 (2.0)	1 (0.6)
Heart failure type, N (%)			
-Ischeamic	N/A	195 (76.8)	87 (58.4)
-Non-ischeamic	N/A	59 (23.2)	62 (41.6)
Primary & secondary prevention, N (%)			
-Primary prevention	N/A	195 (76.8)	133 (89.3)
-Secondary prevention	N/A	59 (23.2)	16 (10.7)

AV: Atrioventricular, CRT: Cardiac resynchronization therapy device, EF: Ejection fraction, ICD: Implantable cardioverter defibrillator, N/A: Not applicable, PM: Pacemaker

cardiac device implantation. CIED requirements after surgical operations occurring following valve surgeries (valve surgery, totally 12 patients, 1.2%; multiple valve surgery, 8 patients, 0.8%; multiple valve surgery involving tricuspid valve repair or replacement, 6 of 8 patients, 0.6%), congenital heart surgery [ventricular septal defect (VSD) repair, 1 patient, 0.1%], and surgical myectomy (1 patient, 0.1%).

Twelve patients underwent CRT implantation at our institution after indirect percutaneous mitral annuloplasty (Carillon Mitral Contour System) to treat functional mitral regurgitation.

Table 2. Distribution of the number of devices implanted by years

Device type	2017	2018	2019	2020	2021
	N (%)	N (%)	N (%)	N (%)	N (%)
ICD					
- SC	0 (0)	3 (27.2)	66 (83.5)	56 (90.3)	65 (86.7)
- DC	9 (100)	8 (72.8)	13 (16.5)	6 (9.7)	10 (13.3)
- Total	9 (100)	11 (100)	79 (100)	62 (100)	75 (100)
PM					
- SC	7 (13.2)	1 (3.4)	15 (18.1)	11 (17.5)	15 (24.2)
- DC	46 (86.8)	28 (96.6)	68 (91.9)	52 (82.5)	47 (75.8)
- Total	53 (100)	29 (100)	83 (100)	63 (100)	62 (100)
CRT					
- CRT-D	20 (100)	19 (100)	28 (100)	34 (100)	41 (100)
- CRT-P	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
- Total	20 (100)	19 (100)	28 (100)	34 (100)	41 (100)

CRT: Cardiac resynchronization therapy device, CRT-D: Cardiac resynchronization therapy defibrillators, CRT-P: Cardiac resynchronization therapy pacemakers, DC: Dual chamber device, ICD: Implantable cardioverter defibrillator, PM: Pacemaker, SC: Single chamber device

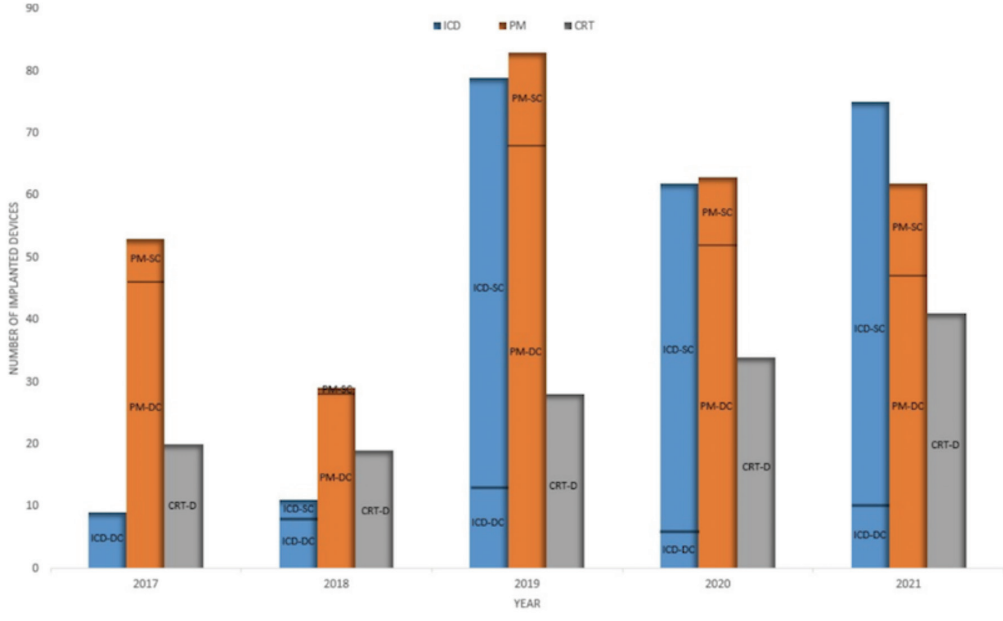

Figure 1. Bar graph showing the types and numbers of cardiac implantable electronic devices by years

Among the 14 lead extraction patients, only one patient had a vascular complication requiring a surgical surgery (Figure 5). The patient was discharged after successful surgery without any disability.

Table 3. Complications of cardiac device procedures

	N (%)
Cardiac device related infection <12 months	7 (0.7)
Cardiac device related infection >12 months	1 (0.1)
Pneumothorax	4 (0.4)
Haemothorax	0 (0)
Coronary sinus dissection/perforation	6 (0.6)
Axillary vein dissection/perforation	3 (0.3)
Diaphragmatic stimulation requiring reintervention	2 (0.2)
Brachial plexus injury	0 (0)
Lead-related reintervention	6 (0.6)
Cardiac perforation	1 (0.1)
Mortality (<30 days)	1 (0.1)

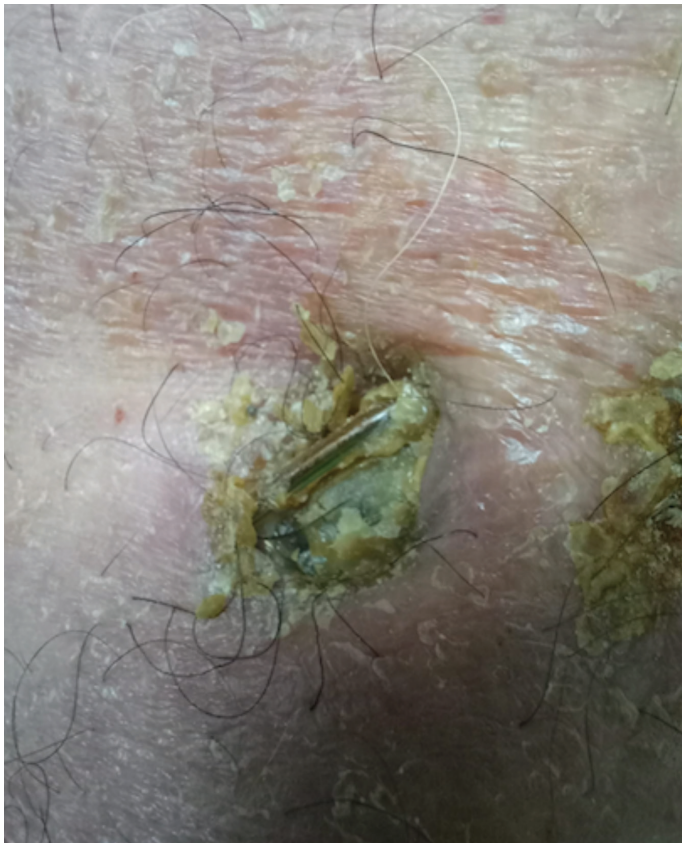

Figure 2. With the seperation of the primary suture line, it is seen that the pacemaker and lead are exposed. Note the infected appearance at the wound site

Discussion

Our national cohort is one of the first registries of CIEDs conducted in Turkey to evaluate CIED patients presenting to our center for device implantation, generator

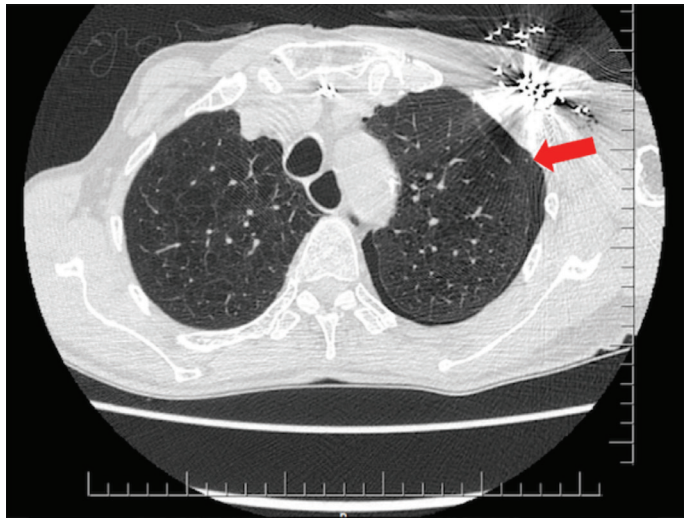

Figure 3. CT scan of the chest (axial view) showing pneumothorax in the left hemithorax after ICD implantation (red arrow)

CT: Computed tomography, ICD: Implantable cardioverter defibrillator

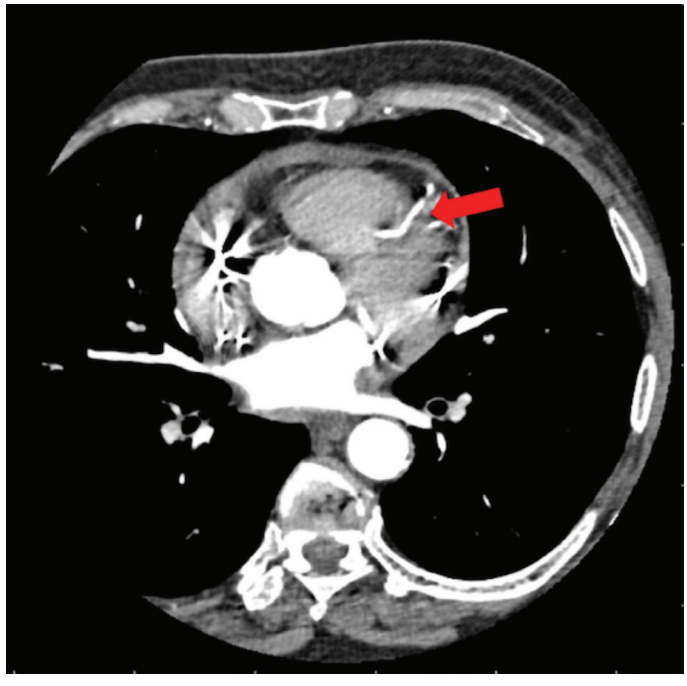

Figure 4. Cardiac CT (axial view) demonstrates a CRT lead that has perforated the right ventricle (red arrow)

CT: Computed tomography, CRT: Cardiac resynchronization therapy

replacement, lead revision, or lead extraction. This article provides key information and first-step guidance on follow-up and treatment for electrophysiologists implanting CIEDs, other cardiologists, and healthcare professionals who follow these patients.

The general descriptive findings from the registry were similar to those in the previously published reports and clinical practice. More male patients than female patients received both ICDs and CRTs compared with patients who received PMs, possibly due to differences in heart failure prevalence and the younger population[6,7]. The reason for the age-related difference between the two groups may be that the device implantation indication in the ICD-CRT groups occurred in the early period due to the primary prevention predominantly, and tachy-brady arrhythmias, as the main indications for device implantation in the PM group, appeared at a later age. AF incidence in the PM group was more prevalent, possibly because the population consisted of a mostly female older population, which is more prone to AF existence. CRT is indicated in patients who have heart failure with reduced EF accompanying AV conduction defects. In this group of patients, degenerative AV node dysfunction may have been a more dominant cause of ischemic etiology. Therefore, CRT device implantation for nonischemic heart failure and/or primary prevention may be seen more often than in the ICD group.

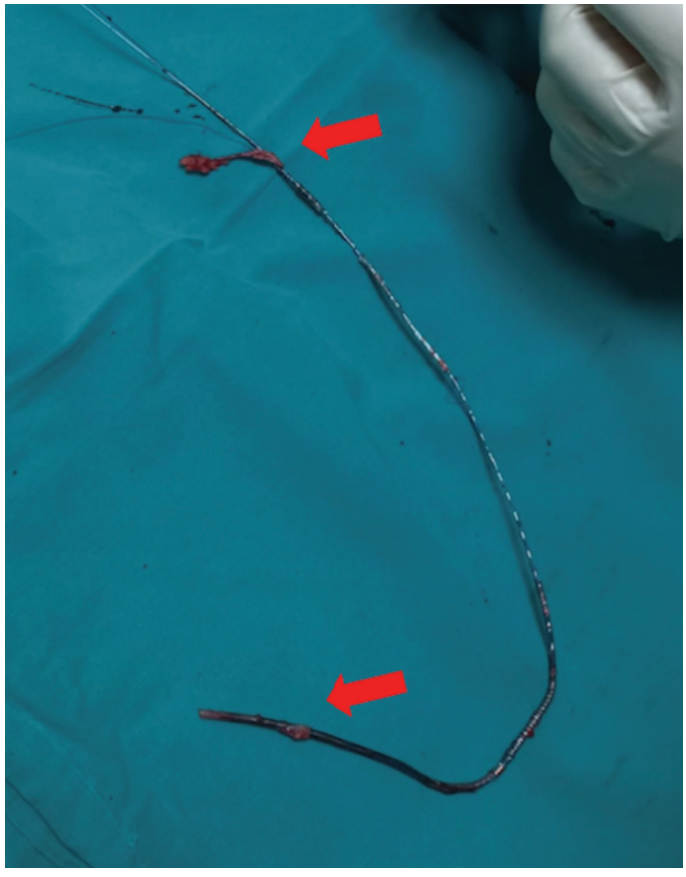

Figure 5. Pieces of tissue detached from the brachiocephalic vein are seen after lead extraction procedure (red arrows)

In our clinic, we have observed an increasing interest in biventricular pacing over time, as is seen worldwide. However, all the CRT devices we implanted were CRT-d due to the reimbursement requirements of the healthcare system, which is exceptionally different in our country.

Device-related infections and lead-related problems were two common urgent complications detected in our study group, consistent with the previous reports (0.3%-4.2% and 1.61%-5.54%, respectively)[8-12]. These complications were associated with high morbidity and substantial financial costs, which caused the device extraction or led to re-intervention[13]. Choosing the most suitable and long-lasting device for the patient and planning the procedure in elective conditions as much as possible will reduce possible lead infections or lead-related problems. In fact, infection rates and lead-related problems were observed at a lower rate in our patients than those in the literature.

Vascular problems, including venous access site complications and coronary sinus complications, emerged as the other common complications encountered in patients treated with CIED at our center, as stated in previous studies[14,15]. Fluoroscopy-guided axillary access was the chosen technique for device implantation in our electrophysiology laboratory because of its convenient calibration and tortuosity compared to subclavian or cephalic access. Coronary sinus dissection and perforation are rare complications in CIED cases. Owing to the low-pressure nature of the cardiac venous system, the conservative approach to venous vascular injuries has generally been successful, and only one patient-required

pericardiocentesis. Since we used the axillary access technique during device implantation at our center, we rarely had pneumothorax complications, and none of the patients developed hemothorax or brachial plexus injury.

Lead-induced right ventricular perforation developed only in a 75-year-old patient 2 weeks after device implantation. In the asymptomatic patient, the incidentally detected perforation on the control chest radiographs consisted of a self-limiting mild pericardial effusion and lead exceeding the cardiac margin. The lead was withdrawn in a controlled and careful fashion in the operating room, and the ventricular lead was re-implanted within 1 week since there were no complications in the follow-up. Considering our patients' advanced age, right ventricular septal (RVS) pacing was preferred for the second time; however, the beneficial effects of RVS pacing compared with right ventricular apical pacing have been shown only in an observational study on the mean risk of perforation[16].

Inadvertent phrenic nerve stimulation (PNS) is common in patients who receive CRT, which has left ventricular (LV) pacing lead[17]. In our population, all PNS procedures except one were moderated using electrical reprogramming, without requiring invasive intervention options for PNS. In the aforementioned patient, the PNS was terminated when the lead was retracted and re-implanted.

The development of iatrogenic AV block after open-heart surgery carries a high risk, especially after multiple valve surgeries involving tricuspid valve repair or replacement, congenital heart surgeries involving VSD, and recurrent surgeries[18]. Our clinic's surgical considerations for device therapy were compatible with those in the previous studies.

The TAVR procedure, which is gradually replacing conventional aortic valve surgeries, can cause transient and sometimes persistent AV block in a target patient group consisting of an elderly patient population, with the massive effect of a bioprosthesis implanted in close proximity to the bundle or left bundle branch within the membranous septum[19]. In a case series of more than 400 patients who underwent TAVR in our clinic, persistent AV block developed in 18 patients, and permanent PMs were implanted in these patients. Consistent with the literature, the rate of development of AV block was higher in patients implanted with a self-expandable valve than in patients implanted with a balloon-expandable valve.

Programmed AV junction ablation in patients AF, by slowing and regularizing the ventricular rate, improves symptoms, quality of life, and cardiac function. In this context, AV node ablation and subsequent PM implantation are appropriate options in cases where drug therapy is insufficient and heart failure cannot be controlled[20]. In our clinic, we performed permanent PM implantation in 3 patients with similar clinical scenarios.

As the risk of developing AV block is higher in the septal pathways, it is necessary to be more careful during the ablation procedure. Cryoablation may be preferred over radiofrequency (RF) ablation to avoid permanent damage[21]. We encountered a persistent AV block complication that required PM implantation after RF ablation[22].

Both CRT and indirect mitral annuloplasty are coronary-based procedures and are indicated for LV systolic function improvement[23]. The presence of CRT lead in the coronary sinus is a contraindication to indirect mitral annuloplasty. Therefore, in the presence of severe functional mitral valve insufficiency, the Carillon mitral contour system (Cardiac Dimensions, Kirkland, WA, USA) was primarily implanted in patients with CRT indications[24]. In this group of patients, we experienced the synergistic effect of the CIED and the Carillon device in the long term.

Infections or lead-related reasons caused us to perform lead extraction in a small portion of our patients. While our lead extraction success rate was better than previous studies established [100% vs. 96.7% (95% CI 96.1%-97.3%)], our all-cause major complication rate was similar to that of low-volume centers [5.8% vs. 4.1% (95% CI 2.7%-6.0%)][25]. Implanting the proper device in

a favorable patient will undoubtedly reduce lead extraction rates.

It is indisputable that device procedures performed at high-volume centers are safer. In this sense, as a high-volume center, we shared the data and experience gained from different CIED procedures applied to different patient groups. We hope that this study will shed light on other multicenter national studies that can be conducted in our country in the future.

Study Limitations

This was a single-center retrospective study in which the epidemiological characteristics of the patients and findings of the device procedures were retrieved from institutional archives. Therefore, the study lacked follow-up data and excluded long-term outcomes.

Conclusion

To the best of our knowledge, this article presents the data on the most comprehensive CIED procedures performed in our country. We investigated patient characteristics, CIED types and requirements for implantation, and peri-procedural results in our study. As a result, our experience as one of the leading centers in our country in terms of the number and diversity of patients was reflected as a low complication rate in our study results.

Ethics

Ethics Committee Approval: The study protocol was approved by the Clinical Research Ethics Committee of University of Health Sciences Turkey, Gülhane Training and Research Hospital (approval date: May 26, 2022; approval number: 2022-173) and conformed to the principles of the Declaration of Helsinki.

Informed Consent: Patient data were collected retrospectively.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Görmel S, Yaşar S, Concept: Görmel S, Design: Görmel S, Data Collection and/or Processing: Görmel S, Analysis of Interpretation: Yaşar S, Literature Search: Yaşar S, Writing: Görmel S, Yaşar S.

Conflict of Interest: No conflict of interest was declared by the authors.

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