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# Management of Cardiac Implantable Electronic Devices removal with cardiopulmonary bypass: A single center experience

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## Abstract

**Backround:** Currently, permanent pacemakers and internal defibrillators are widely used as a result of technological developments. Infection and dysfunction are the most important reasons for removing these devices from patients. Transvenous removal of these devices is the first recommended method. Failure of transvenous methods, presence of endocarditis, large vegetation or thrombus requires the use of surgical methods to remove these devices.

In this study, our purpose is to present our management in surgical removal of cardiac implantable electronic devices (CIED).

**Methods:** Between June 2017 and October 2019, 667 CIED were implanted and 10 patients underwent surgical removal of CIED in our hospital. The demographic data of the patients were obtained from the polyclinic files and the hospital registration system.

**Results:** Eight (80%) patients were male and the mean age was 55.3±16.4 years (22.0-77.0). Complete pacemaker system removal was decided by the heart team in all cases. In 4 patients, permanent pacemaker reimplantation was required intraoperatively.

**Conclusion:** CIED infection is a serious disease associated with high mortality. For this reason, we believe that it should be beneficial to consider the long-term results in determining permanent pacemaker and internal defibrillator indications.

**Keywords:** Cardiac implantable electronic device, cardiopulmonary bypass, cardiac pacemaker

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# Kardiyak İmplante Edilebilir Elektronik Cihazların kardiyopulmoner bypass ile çıkarılmasının yönetimi: Tek merkez deneyimi

**Öz**

**Amaç:** Günümüzde teknolojik gelişmeler sonucunda kalıcı kalp pilleri ve dahili defibrilatörler yaygın olarak kullanılmaktadır. Enfeksiyon ve disfonksiyon bu cihazların hastalardan çıkarılmasının en önemli sebepleridir. Bu cihazların transvenöz olarak çıkarılması önerilen ilk yöntemdir. Transvenöz yöntemlerin başarısız olması, endokardit gelişmesi, vejetasyon veya trombüsün varlığı, bu cihazları çıkarmak için cerrahi yöntemlerin kullanılmasını gerektirir.

Bu çalışmada, kardiyak implante edilebilir elektronik cihazların (CIED) cerrahi olarak çıkarılmasına yönelik tecrübemizi paylaşmayı amaçladık.

**Yöntemler:** Haziran 2017 ile Ekim 2019 arasında hastanemizde 667 CIED implante edildi ve 10 hastada CIED cerrahi olarak çıkarıldı. Hastaların demografik bilgileri poliklinik dosyalarından ve hastane kayıt sisteminden elde edildi.

**Bulgular:** Sekiz (%80) hasta erkekti ve yaş ortalaması 55,3±16,4 (22,0-77,0) idi. Tüm vakalarda kalıcı kalp pili sisteminin tamamen çıkarılmasına kalp konseyi tarafından karar verildi. Hastaların 4'üne intraoperatif olarak kalıcı kalp pili reimplantasyonu gerekti.

**Sonuç:** CIED enfeksiyonu, yüksek mortalite oranları ile ilişkili ciddi bir hastalıktır. Bu nedenle kalıcı kalp pili ve dahili defibrilatör endikasyonları belirlenirken uzun dönem sonuçlarının dikkate alınmasının faydalı olacağı kanaatindeyiz.

**Anahtar kelimeler:** Kardiyak implante edilebilir elektronik cihaz, Kardiyopulmoner bypass, Kardiyak pacemaker.

## INTRODUCTION

In recent years, cardiovascular implantable electronic devices (CIEDs) such as implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) systems have led to a significant reduction in cardiac morbidity and mortality[1-4]. As indications for device implantation expanded, the use of CIEDs has increased significantly. The frequency of CIED infections has also increased with the increase in CIED implantation. Today, the frequency of CIED infection seems to exceed the increase in device implantations[5]. Although the development of CIED-related infections is rare, it has a high mortality. In CIED infections, owing to unsuccessful results of the antimicrobial treatment approach, removal of the infected material is also considered as part of the treatment[6]. CIED infection can be systemic or can only be seen as a local battery pocket infection[7]. Infection and dysfunction are the most common reasons for removing these devices that are implanted in patients[8]; other rare indications are venous thrombosis, suspected migration and perforation[9]. Transvenous methods are recommended firstly in most studies in removing these devices from the patient[10]. However, surgical treatment is still used in the failure of transvenous methods, endocarditis, vegetation in the valve tissue, development of thrombus and removal of some passively fixed electrodes[11,12].

This study aimed to share our experience with surgically removed CIED, the early and late results of patients, to draw attention to questioning the indication requirement for permanent pacemakers, taking into account the increased cost analysis studies and preventive measures related to CIED infection.

## METHOD

Our study, which reflects the experience of single-center, was retrospectively evaluated in 10 patients who were diagnosed with CIED infection, which is a subgroup of infective endocarditis, according to modified Duke criteria[13], and who underwent permanent removal of the pacemaker lead and battery with cardiopulmonary bypass. Ethics committee approval was obtained from our Hospital ethics

committee on 2022/02. These patients were first evaluated in the council consisting of an infectious disease specialist, cardiologist and cardiac surgeon, and it was decided to remove the pacemaker and battery by surgical method. In addition to transthoracic echocardiography (TTE), a transesophageal echocardiography (TEE) was performed on all patients as recommended by the guidelines[14]. TTE was used to evaluate pericardial effusion, ventricular dysfunction and pulmonary vascular pressure, while TEE was used to detect vegetations and size assessment. Patients with isolated battery pocket infections were excluded from the study. Appropriate antibiotherapy was started in all patients since diagnosis by the infectious disease specialist during the preoperative period. In all patients, the right atrium was opened under cardiopulmonary bypass (Figure 1). The superior vena cava, tricuspid valve, right atrium, and endocardium of the ventricle were visualized and the infected permanent pacemaker leads and batteries were removed. In the postoperative period, according to the results of the pacemaker system and blood culture, antibiotic therapy was administered in the period determined by the infectious disease specialist to be completed in at least 6 weeks.

Demographic data of the patients were obtained from the polyclinic files and the hospital registration system. Complete blood count and biochemical data were compared using values taken 1 day before surgery and 1 day after surgery.

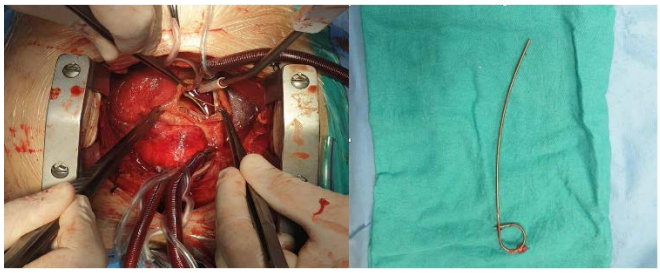

**Figure 1:** The vegetations at right atrium and ventricule leads on cardiopulmonary bypass.

## Statistical Analysis

Analyses were performed using SPSS ver. 22.0 package program for Windows. Results

are expressed as mean ± SD or median (lower and upper limit) for descriptive data. The

normality of the parameters was tested using the Shapiro–Wilk normality test. The Wilcoxon test was was used to compare the change between preoperative and postoperative laboratory results. Values of $p<0.05$ were considered statistically significant.

## RESULTS

Eight of the patients were male (80%) and 2 were female (20%). The mean age was 55.3 ± 16.4 years (22.0-77.0). Four patients had uncontrolled diabetes and two patients had hypertension. Application complaints were fever in 5 patients and discharge in the battery site in 5 patients. Half of the patients had a previous history of cardiac surgery (Figure 2). Three patients had undergone surgical intervention due to infected lead at least once more. The demographic data of the patients are summarized in Table 1.

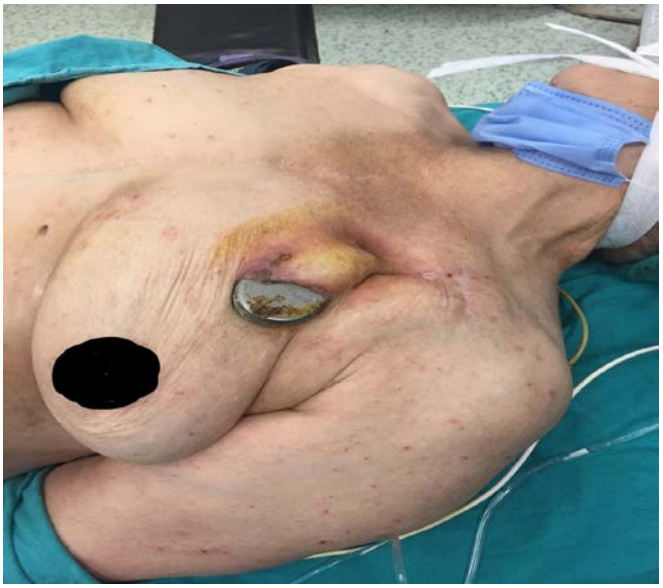

**Figure 2:** A 62 year-old female patient who had a previous cardiac surgery with permanent pacemaker pocket side and lead infection

**Table I:** Characteristics of patients

| | **Patients** ***(n=10)*** |
|---|---|
| Age, years mean±SD (min-max) | 55.3±16.4 (22.0-77.0) |
| Sex, male/female *n (%)* | 8/2 (80.0/20.0) |
| Presence of diabetes mellitus Yes/No *n (%)* | 4/6 (40.0/60.0) |
| Presence of hipertansion Yes/No *n (%)* | 2/8 (20.0/80.0) |
| Presence of previous cardiac surgery Yes/No *n (%)* | 5/5 (50.0/50.0) |
| Presence of previous surgical intervention for infected lead extraction Yes/No *n (%)* | 3/7 (30.0/70.0) |
| Fever Yes/No *n (%)* | 5/5 (50.0/50.0) |
| Discharge of battery Yes/No *n (%)* | 5/5 (50.0/50.0) |
| Operation time (minute) mean±SD (min-max) | 229.0±79.8 (140.0-420.0) |
| Cardiopulmonary bypass time (minute) mean±SD (min-max) | 98.0±53.9 (6.0-187.0) |
| Intensive care unit time (day) mean±SD (min-max) | 2.3±1.7 (1.0-5.0) |
| Hospitalization time (day) mean±SD (min-max) | 42.9±18.3 (21.0-78.0) |

Nine patients underwent sternotomy and one had a thoracotomy procedure. Cardiopulmonary bypass was used in all patients. Operations were performed under cross-clamp in 4 patients. Six patients were operated on the beating heart under cardiopulmonary bypass. Right atriotomy was performed in all cases. Pace leads in atrium and ventricle are released. One patient required ventriculotomy to release the ventricular lead. Four patients required valve resection because the infected lead and vegetation were fixed to the tricuspid valve, one patient underwent tricuspid replacement with a bioprosthetic valve, one patient underwent de vega annuloplasty and two patients underwent ring annuloplasty. The released leads were removed from the battery pocket area by traction. Pace battery was removed with lead in 4 patients. It was observed that 4 patients who had a lead removed need reimplantation while 6 patients did not. In 40% of the patients, the lead and battery were removed, while in 60%, only the lead was removed. No cardiac or vascular complications or endocardial defects were observed during the surgery. At the end of the operation, the patients were taken to intensive care. Three of the patients were in normal sinus rhythm, three were in sinus tachycardia and four were in blocky rhythm. Inotropic support was needed in 4 of the patients, one of them had a blocky rhythm.

Of the five patients who had previous history of cardiac surgery, only the lead was removed in three, and the lead and battery were removed in two. Three patients required postoperative inotropes, and two patients had a blocky rhythm.

Two patients required dialysis in the postoperative period, and one also had a history of cardiac surgery.

The patients who were taken into the service after the intensive care period were discharged when their antibiotherapy was completed. The preoperative hospital stay was determined as 26.1 ± 17.8 days (6.0-64.0 days), and the mean duration of post-op hospital stay was 16.8 ± 9.0 days (5.0-39.0 days). The postoperative hematocrit value was significantly lower than the preoperative hematocrit value (p= 0.02). The postoperative platelet value was significantly higher than the preoperative platelet value (p= 0.02). There was no significant difference in comparison of other blood parameters (p> 0.05) (Table 2).

**Table II:** Comparison the features of the patients preoperation and postoperation

| | ***Preoperative . day*** | **Postoperative .day** | **p** |
|---|---|---|---|
| Ejection fraction % mean±SD<br>Median (25th-75th pers) | 45.5±14.2<br>50.0 (35-55) | 44.5±13.4<br>47.5 (40-50) | 0.68 |
| White blood cell (x10$^3$) mean±SD<br>Median (25th-75th pers) | 12.3±7.8<br>10.9 (8.2-15.8) | 13.3±3.6<br>14.7 (9.4-16.4) | 0.24 |
| Platelet (x10$^3$) mean±SD<br>Median (25th-75th pers) | 188.0±87.9<br>168.0 (148.0-196.0) | 257.7±130.4<br>200.0 (162.0-365.0) | **0.02** |
| Hematocrit % mean±SD<br>Median (25th-75th pers) | 32.6±6.5<br>31.2 (26.6-39.0) | 28.2±3.3<br>26.8 (26.3-30.0) | **0.02** |
| C-reactive protein mg/dL mean±SD<br>Median (25th-75th pers) | 29.4±23.9<br>28.4 (7.3-46.4) | 81.7±94.3<br>33.8 (15.5-161.4) | 0.17 |
| Aspartate aminotransferase (AST) U/L mean±SD,<br>Median (25th-75th pers) | 17.8±3.9<br>18.0 (15.0-20.0) | 23.2±18.9<br>18.0 (12.0-33.0) | 0.61 |
| Alanine aminotransferase (ALT) U/L mean±SD Median<br>(25th-75th pers) | 13.4±7.0<br>12.5 (8.0-20.0) | 14.3±13.5<br>11.0 (6.0-15.0) | 0.78 |
| Serum creatinine mg/dl mean±SD<br>Median (25th-75th pers) | 1.9±2.0<br>1.1 (0.8-2.1) | 1.5±1.5<br>1.1 (0.7-1.4) | 0.14 |

The mortality rate in this study was 0%. In the follow-up, eight patients came to their control without any problem, one case was removed from follow-up as a result of two-year non-follow-up, and one case made their follow-up at another center voluntarily.

## DISCUSSION

In recent years, CIEDs have been increasingly used to treat problems of cardiac electrophysiology[5]. Although rare, CIED infection is associated with high mortality and morbidity[15]. Studies have shown that there is a relationship between the male gender and the risk of CIED infection, but the underlying mechanism is unclear[16,17]. The fact that eight of the cases in our study are male may support this relationship.

The incidence of CIED infection was 1.9 per 1000 device-years, and more common in ICD than permanent pacemakers[15]. Of the cases in our study, seven were patients with pacemakers and three were patients with ICD-induced CIED infection.

The main mechanism of infection is the contamination of the generator pocket during device implantation or at a later time, following skin infection and/or erosion at the pocket site. With this contamination, microorganisms can spread throughout the electrode to the endocardium and the electrode tip. A separate mechanism is that bacteremia in another part of the body holds the electrodes through the blood. Although it is a subgroup of infective endocarditis, this disease is more difficult in terms of diagnosis and treatment strategy. CIED infection can occur in different ways, with fever and local signs of infection being the main stimulants[7]. In half of our cases, clinical manifestation was fever, while in the other half, this was local pocket discharge. Echocardiography and blood cultures are the cornerstone of the diagnosis, as in other findings of infective endocarditis[7]. However, a normal echocardiographic examination does not rule out CIED infection. Transesophageal echocardiography is required for every patient with suspected CIED infection[14]. In order to make a diagnosis in the preoperative period, TEE and TTE were performed in all of our cases. While the rate of development of endocarditis due to CIED infection was reported as 10% in

previous studies[18,19], this rate has been shown to increase up to 25% more recent studies[20,21]. There is no standard diagnostic tool for CIED endocarditis. Today, modified Duke criteria[13] and ESC 2015 criteria[22] used for the diagnosis of infective endocarditis are the only available framework for the diagnosis of CIED endocarditis.

The treatment of CIED infection should include the removal of infected material (generator and electrodes) along with adequate antibiotic therapy[7,17,23]. Staphylococcus bacteria occasionally cause CIED infection[7]. In only three of the ten cases we studied, there was a reproduction in culture. Methicillin-sensitive Staphylococcus was detected in two cases and enterobacter in one case. Preoperative using of antibiotherapy might cause these negative culture results. Serious and fatal complications may develop in the extraction of pacemaker lead and battery. In a 10-year prospective study, major complications developed in two out of five cases (superior vena cava laceration and superior vena cava massive thrombosis)[24]. In a 13-year retrospective study by Sohail et al., major complications (two massive bleeding, one cardiac arrest, one subclavian vein laceration, one ventricular injury) were reported in five of the 19 patients who underwent surgery due to CIED infection[23]. In our study, none of the ten patients developed a major complication.

Given the risks of open surgery, the first choice for removing medical devices is the lead extraction by transvenous means, which poses less risk. It's more difficult to remove ICD from the coronary sinus. Despite the evolution of transvenous lead extraction techniques, there are still risks associated with the process. The main complications include rupture of the tricuspid valve, damage to the myocardium, venous lacerations, cardiac tamponade and pulmonary embolism[14]. If these complications develop, cardiac surgical intervention is required.

In our study, our patients who underwent surgical procedures were taken to intensive care without any problems. Five of our cases were patients with previous cardiac surgery anamnesis. In four cases, permanent pacemaker lead and battery were placed again in the same session, during the operation or evaluations before the operation. Other patients were also taken to intensive care with a temporary pacemaker and there was no need for a permanent pacemaker in a subsequent follow-up. Therefore, surgical removal of the pacemaker system, accompanied by cardiopulmonary bypass, should be considered a safe and applicable method for CIED infection.

In recent years, studies have been carried out to prevent CIED infection which causes significant cost increases, especially in the health sector[25]. It should be determined whether reimplantation is required before the electronic devices are completely removed. In our study, after removing the electronic devices, the CIED reimplantation rate of 40% indicates the importance of determining the requirement in both the initial CIED implantation and the reimplantation process.

**Ethics Committee Approval:** Ethics committee approval was obtained from İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training Research Hospital ethics committee on 2022/02.

**Conflict of interest:** The authors declare that there is no conflict of interest.

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