RESEARCH ARTICLE

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Predictors of Percutaneous Lead Extraction Major Complications: A Tertiary Center Experience

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Abstract

Background and Aim: Over the years, transvenous lead extraction (TLE) procedures (TLEP) have been increasing because of factors such as infection, loss of device function, and lead-related complications. This study aimed to evaluate the factors affecting major complications during TLEP.

Materials and Methods: Between January 2011 and May 2023, patients who underwent TLE of cardiac implantable electronic devices were included in the study. The demographic and procedural features of all patients were evaluated according to major complications.

Results: A total of 121 consecutive patients (192 leads) underwent TLEP. The mean age was 63 ± 17.3 years, and 76% were male. Most leads were active fixation leads (67%) and 74 procedures (61%) required an extraction device. The mean lead dwell time was 5.6 ± 5.2 years. Major complications were observed in 16 procedures (13.2%) and 5 of them (4.1%) resulted in exitus. When we compared the groups according to the major complication, the rates of chronic obstructive pulmonary disease (4 vs. 3; $P = 0.020$), existence of passive fixation leads (PFL) (24 vs. 9; $P = 0.013$), and device indication ($P = 0.012$) were higher in the complication group. Multivariate analysis revealed that only the presence of PFL was associated with major complications. (odds ratio 4.486, 95% confidence interval 1.365-14.748; $P = 0.013$)

Conclusion: The present study showed that the presence of a PFL is a predictive factor for major complications.

Keywords: Percutaneous lead extraction, transvenous lead extraction, cardiac implantable electronic devices

INTRODUCTION

Transvenous lead extraction (TLE) is an important part of the management of patients with cardiac implantable electronic devices (CIED). TLE is considered a high-risk procedure because of its mechanical nature and its association with potential mortality.[1] The purpose of TLE is to eliminate lead-related undesirable effects without damaging the surrounding tissue. For example, in the 2023 European Society of Cardiology Guidelines for the management of endocarditis, complete system extraction without delay is recommended with a class 1 indication in the case of infective endocarditis associated with CIED.[2] When the decision is made to remove the device, the primary approach is to perform this procedure percutaneously.[1] With advancements over the years, several methods are available today, from manual traction to excimer laser extraction. While the extraction process can be performed by manual traction if performed shortly after implantation, fibrosis that develops around the lead over time makes this

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procedure difficult. Therefore, it may be necessary to use various special equipment such as locking stylets, rotational mechanical dilators, and excimer lasers. The most lethal complication during percutaneous extraction is vascular or cardiac perforation. Studies have reported life-threatening major complications between 0.4% and 3.5% and mortality rates during the procedure between 0.19% and 1.8%.[3] To mitigate the risk, patient selection and predictive factors should be well evaluated.[4,5] Most studies in the literature related to the procedure consist of single-center experiences. Therefore, sharing experiences is important to increase expertise and prevent complications.

In this study, we aimed to evaluate the factors affecting the major complications experienced during the procedure by evaluating the patients who underwent extraction at our clinic. In this way, it is aimed to contribute to the literature on predictive factors against possible major complications during the procedure in patients who decide to undergo percutaneous extraction.

MATERIALS AND METHODS

Study design and patient population

This study was conducted by retrospectively evaluating consecutive patients who underwent TLE of CIED leads in a tertiary care center between January 2011 and May 2023. Demographic characteristics of the patients (age, gender, patient history), additional clinical factors, CIED information, echocardiographic findings, and events experienced during the procedure were retrospectively scanned from the hospital database. The 30-day and 5-year mortality status of the patients was obtained by scanning the national health registry system. Patients were divided into two groups: Group 1 consisted of patients with major complications and group 2 consisted of patients without major complications.

Patients whose medical records and procedural information could not be accessed were not included in the study.

The study design met the criteria of the Declaration of Helsinki and was approved by the ethics commission of the İzmir Katip Çelebi University Non-Interventional Clinical Studies Institutionel Review Board (decision no: 0579, date: 23.11.2023).

Lead extraction procedure and definitions

All procedures were performed by two cardiologists with cardiac surgery backup. All patients were administered sedation and local anesthesia during procedures with blood pressure monitoring. Patients with bradycardia were implanted with a temporary pacemaker through the femoral vein before the procedure. Transesophageal echocardiography was routinely performed to rule out the presence of vegetation in patients scheduled for extraction due to infection. If vegetation is detected, treatment is planned in accordance with the characteristics and clinic within the current guidelines.

The primary approach was gentle manual traction. The CIED pocket was explored under sterile conditions using blunt dissection. The generator and leads were separated from the tissue. If the leads had active fixation, they were unscrewed from the myocardium. Then, gentle traction was applied. If this was not successful, the fibrous adhesions surrounding the leads were dissected using mechanical systems such as locking stylets and rotational mechanical dilators sheaths (Cook Medical, Bloomington, IN, USA). The excimer laser was not applied. The locking stylet was placed toward the distal implantation site to fix the lead from the distal end. If the lumen's integrity was damaged or locking stylets could not be advanced to the distal portion of the leads, a bulldog system was employed for lead fixation. After lead fixation, a mechanical dilator sheath was advanced over the lead and stylet complex. The distal blades of the mechanical dilator sheath were used to separate the leads from the fibrous tissue. In pacemaker (PM) dependent patients who underwent the TLE procedure (TLEP) due to infection, a new PM was implanted at the contralateral site after having negative blood cultures for 72 h, which were obtained within 24 h of the TLEP.

Device indications are divided into three groups. First, atrioventricular (AV) node blockage includes total AV block, Mobitz type 2 block, and syncope with bifascicular block. Second, tachycardia-related arrhythmias include primary and secondary prophylaxis for ventricular arrhythmias. Third, bradycardia-related arrhythmias include sick sinus syndrome, sinus bradycardia, and slow-response atrial fibrillation. Procedural success was defined as the complete removal of all targeted leads from the vascular space. Major complications were defined as complications that were life threatening, resulted in death or persistent significant disability, or required significant surgical intervention to prevent such outcomes. The indications for lead extraction were infection, generator pocket erosion, lead dysfunction, patient's desire, chronic pain, unclear source of the systemic infection, and interference with other devices.

Statistical analysis

SPSS version 26 was used for statistical analysis. (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as the mean ± standard deviation or median (interquartile range) based on normality distribution, and categorical variables were reported as counts and percentages. Student's t-test and Mann-Whitney U test were used to compare mean and median values between the two groups. The chi-square test was used

to compare categorical variables. Logistic regression analyses, univariate and multivariate analyses, were used to evaluate the factors affecting complications separately and together.

RESULTS

The study included 121 patients from 2011 to 2023, and 192 leads were removed during these extraction procedures (Figure 1). The mean age was 63 ± 17.3 and 76% were male. The median left ventricular ejection fraction was 45% (30-60). Major complications were observed in 16 procedures, 5 of which were exitus (Figure 2). When comparing the groups based on complication status, baseline variables including age, sex, body mass index, hypertension, diabetes mellitus, coronary artery disease, chronic renal failure, previous stroke, heart failure, and history of open heart surgery were similar between the groups. The demographic characteristics of the patients are summarized in Table 1. Most of the leads were active fixation leads (AFL) (67%) and 74 procedures (61%) required an extraction device. The mean lead dwell time was 5.6 ± 5.2 years. All planned leads were extracted. The features of the patients' CIEDs are shown in Table 2. The indications for the procedures were infection (42%), generator pocket erosion (33%), lead dysfunction (26%) and others (6%) (Figure 3). When comparing the groups based on complication status, chronic obstructive pulmonary disease (COPD) (4 vs. 3, P = 0.020), the presence of passive fixation leads (PFL) (24 vs. 9, P = 0.013), and device indication (P = 0.012) were found to be significant (Tables 1, 2). However, multivariate analysis revealed that only the presence of PFL was statistically significant [PFL (odds ratio (OR) 4.486, 95% confidence interval (CI) 1.365-14.748; P = 0.013), COPD (OR: 4.675, 95% CI 0.816-26.791; P = 0.083), device indication (OR: 1.307, 95% CI 0.596-2.866; P = 0.504), Table 3]. When the mortality status of the patients was evaluated from the national health registry system, it was found that the all-cause mortality rate was 5.7% (7) for 30 days and 42.1% (51) for 5 years. The central illustration summarizes the main findings of this study (Figure 4).

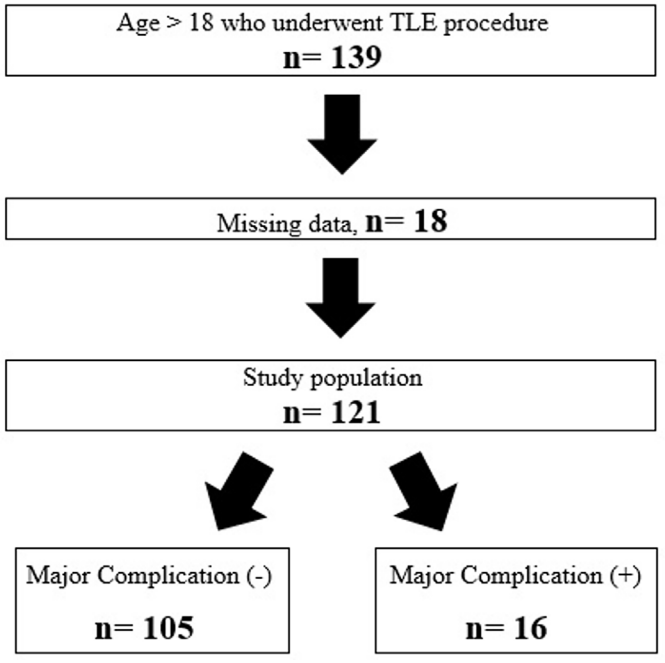

Figure 1: Study population

TLE: Transvenous lead extractionq

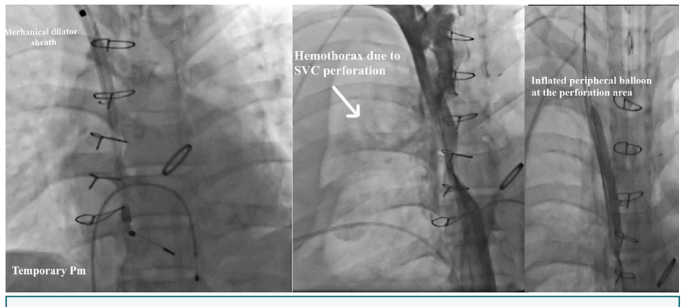

Figure 2: SVC perforation during TLEP

SVC: Superior vena cava, TLEP: Transvenous lead extraction procedure

DISCUSSION

In this study, the causes of complications of TLEP were evaluated. We found that the presence of PFL is an indicator of major complications.

The mechanism of lead fixation is an important factor for TLE procedural difficulty.[6,7] In the literature, there are different opinions about the relationship between lead fixation mechanism and TLE major complications.[8-10] Over the years, fibrous tissue has developed around the electrode, especially at its tip.[11] The shape of the PFL and their mechanical adhesion to the anchor-like tissue increases the contact surface between the lead and the tissue. Studies have shown that PFLs develop stronger adhesions to fibrous tissue.[12,13] In patients with PFL, increased adhesion to fibrous tissue can pose challenges during lead extraction procedures. For this reason, PFLs are more prone to breaking during extraction than AFLs, or they may cause perforation in the tissue.[8] Compared with PFL, AFL can provide an advantage in resolving these adhesions with their ability to activate the tip from outside the heart.[7] Over the years, the use of PFL has decreased, and more AFL have started to be used.[12] Therefore, the dwell time of the PFL is usually longer. Because of this, when deciding to remove the PFL, we decide to intervene in patients who have had a longer time for fibrous tissue and adhesions to develop. In this study, similar to some studies in the literature, it was determined that PFL was a predictor of major complications in our study.[8,10]

Table 1: Demographic characteristics of the patients according to their complication status

Variables	All patients n=121	Complication (-) n=105	Complication (+) n=16	*P*-value
Age (years)	67 (52.5-76)	68 (55-76)	56.5 (37-72.8)	0.090
Gender (male)	92 (76)	77 (73.3)	15 (93.8)	0.075
BMI (<26)	59 (49)	52 (49.5)	7 (43.8)	0.757
Coronary artery disease	50 (41)	46 (43.8)	4 (25)	0.159
Hypertension	58 (48)	53 (50.4)	5 (31.2)	0.152
Diabetes mellitus	31 (26)	28 (26.6)	3 (18.8)	0.487
Chronic renal failure	13 (11)	12 (11.4)	2 (12.5)	0.526
Cerebrovascular disease	8 (7)	8 (7.6)	0 (0)	0.243
COPD	7 (6)	4 (4)	3 (18.75)	0.020
LVEF (%)	45 (30-60)	50 (30-60)	60 (30-60)	0.322
History of OHS	24 (20)	21 (20)	3 (18.8)	0.865
30-day all-cause mortality	7 (6)	2 (1.9)	5 (31.3)	<0.001
5-year all-cause mortality	51 (42.1)	44 (41.9)	6 (37.5)	0.300

BMI: Body mass index, COPD: Chronic obstructive pulmonary disease, LVEF: Left ventricle ejection fraction, OHS: Open heart surgery

Table 2: Procedural characteristics of the patients according to their complication status

Variables	All patients n=121	Complication (-) n= 105	Complication (+) n= 16	*P*-value
Device indication				
AVNB	40 (33.1)	32 (30.47)	8 (50)	0.012
TRA	48 (39.7)	46 (43.81)	2 (12.5)	
BRA	16 (13.2)	11 (10.48)	5 (31.25)	
PM	78 (64.5)	63 (60)	13 (8.13)	0.446
Dual chamber	39 (32.2)	33 (31.4)	6 (37.5)	
Single chamber	38 (29.8)	31 (29.5)	7 (43.8)	
Biventricular	1 (0.8)	1 (1)	0 (0)	
ICD	43 (35.5)	40 (38)	3 (18.8)	0.120
Dual chamber	15 (12.4)	15 (14.3)	0 (0)	
Single chamber	25 (20.7)	22 (20.9)	3 (18.8)	
Biventricular	3 (2.5)	3 (2.8)	0 (0)	
Total lead count	2 (1-2)	2 (1-2)	2 (1-2)	0.844
One lead	56 (46.3)	48 (45.7)	8 (50)	
Two lead	56 (46.3)	49 (46.7)	7 (43.8)	
Three or more	7 (5.7)	5 (4.8)	2 (12.5)	
Dual coil presence	46 (38)	43 (41)	3 (18.8)	0.088
Atrial lead presence	61 (50.4)	53 (50.1)	8 (50)	0.914
Passive fixation lead	33 (27.3)	24 (22.9)	9 (56.3)	0.013
Lead dwell time (years)	4 (1.12-8)	4 (1-8)	5 (2.08-15.5)	0.061
Passive fixation leads	8 (5-14)	5.16 (3.75-7.5)	11 (5-11)	0.049
Active fixation leads	2.12 (0.83-5.25)	2.08 (0.83-5)	2.16 (2-3.5)	0.842
Extraction device usage	74 (61.2)	62 (59)	12 (75)	0.294
Extraction cause				0.372
Infection	51 (42.2)	42 (40)	9 (56.3)	
Generator pocket erosion	33 (27.3)	28 (26.6)	5 (31.3)	
Lead dysfunction	31 (25.6)	29 (27.6)	2 (12.5)	
Others	6 (5)	6 (5.7)	0 (0)	
Operator experience ≥50 cases	14 (11.6)	12 (11.8)	2 (12.5)	0.933

AVNB: AV node blockage, BRA: Bradycardia-related arrhythmias, ICD: Implantable cardioverter-defibrillator, TRA: Tachycardia-related arrhythmias, PM: Pacemaker

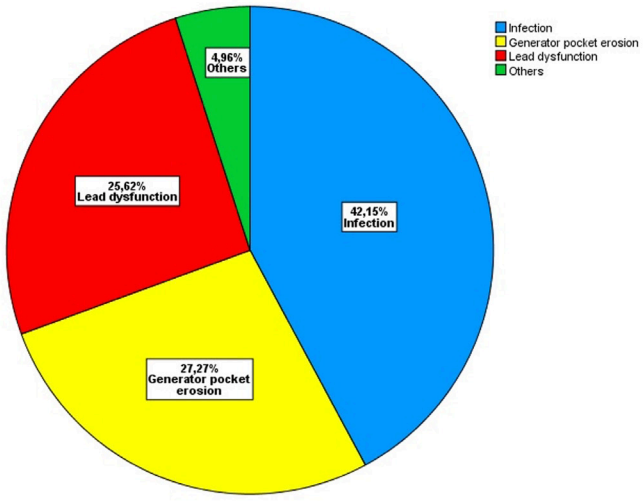

Figure 3: Extraction causes

Table 3: Multivariate predictors of major complications

Variables	Odds ratio	95 %CI lower and upper	*P*-value
Passive fixation lead	4.486	1.365 - 14.748	0.013
COPD	4.675	0.816 - 26.791	0.083
Device indication	1.307	0.596 - 2.866	0.504

CI: Confidence interval, COPD: Chronic obstructive pulmonary disease

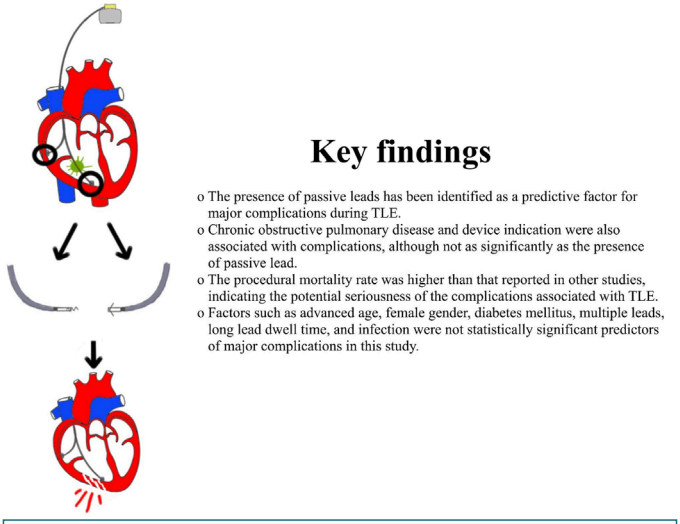

Figure 4: Central illustration of the study
TLE: Transvenous lead extraction

In this study, it was determined that 5 patients (4%) died during the procedure. When the patients who died during the procedure were evaluated, it was determined that three of them had rupture in the superior vena cava during the procedure, one developed tamponade due to right ventricular laceration during the procedure, and one developed tamponade after the procedure. Although pericardiocentesis was performed, the patient could not be saved. Of the patients who died during the procedure, two had dual coils and three had PFL. However, it was not statistically significant. (each $P > 0.05$) Additionally, the lead was broken during the procedure in 4 (3%) patients, and surgical intervention was required in 2 patients. In 2 patients, broken lead was tried to be removed with a snare system. However, because of RV damage and tamponade during the procedure, the patients were transferred to surgical intervention. Even though mortality is the most devastating complication, other major complications that cause morbidity for the patient should not be ignored. In 7 (5%) patients, pleural or pericardial fluid or hematoma requiring intervention was detected.

Previous studies have found advanced age, female gender, diabetes mellitus, multiple leads, long lead dwell time, and infection as common factors contributing to mortality in lead extraction procedures.[3,14] With advancing age, the slowing of the healing process, increased fragility, and vascular calcification may increase the risk of complications related to the intervention. In previous studies, female gender was found to be a risk factor, but the underlying mechanism has not been elucidated. As a general inference, it is thought that the caliber of the vascular structures may play a role.[3,5] As a result of the study conducted by Bashir et al.,[3] diabetes was identified as a new risk factor. Their hypothesis is that diabetes mellitus may play a role in the calcification of leads, similar to atherosclerosis, and this may cause challenges in the removal. As the dwell time of the lead increases and the number of leads planned for removal increases, there may be more adhesion to the tissue and an increase in fibrous tissue, which may make extraction difficult and require the use of more extraction devices. When infection is the indication for extraction, the increased risk of developing sepsis during the intervention process makes this process riskier in terms of mortality. However, in this study, these factors were not significant. TLE is not a simple procedure and has serious complications such as mortality; therefore, there may be bias in patient selection for the TLE procedure, which could affect these findings. While the 30-day mortality rate was 1.6% in Bashir et al.'s [3] study, Bongiorni et al.[5] found that the procedural mortality rate could be up to 2.8%. In this study, the procedural mortality (4%) and major complication rates (13%) were higher than those in other studies in the literature.[3,5] While there are many reasons for this, it may have been due to the fact that lead extraction is often considered a last resort, especially in patients with a high burden of comorbidities, and therefore may have been performed later in the treatment process. In addition, it may have been caused by the persistence to achieve procedural success. In this study, when the experience of the operator who performed the procedure was evaluated, no significant difference was found

between those with more than 50 procedures. This finding may be because of the small size of the study population. When we evaluated long-term mortality according to complication status, we found that TLE complications did not affect 5-year all-cause mortality, similar to the literature.[10]

In conclusion, it should be noted that the procedure carries a risk of complications, including mortality, in patients scheduled for TLE. For this reason, patient selection should be conducted carefully and preferably in a high-volume center with experienced operators.

Study limitations

Our study has several limitations. First, as this was a single-center retrospective study, its findings should be interpreted in light of the common limitations of retrospective studies. In addition, no patients underwent extraction with laser sheaths in this study. Moreover, this study had a small sample size, which may limit the generalizability of the findings.

CONCLUSION

This study showed that the presence of a PFL is a predictive factor for major complications. However, further studies are required to confirm these findings.

Ethics

Ethics Committee Approval: The study design met the criteria of the Declaration of Helsinki and was approved by the ethics commission of the İzmir Katip Çelebi University Non-Interventional Clinical Studies Institutionel Review Board (decision no: 0579, date: 23.11.2023).

Informed Consent: Retrospective study.

Authorship Contributions

Surgical and Medical Practices: V.E., E.Ö., U.K., T.K., M.K., C.N., Concept: M.M.T., V.E., Design: M.M.T., V.E., Data Collection or Processing: M.M.T., V.E., Analysis or Interpretation: M.M.T., V.E., Literature Search: M.M.T., Z.Y.E., Writing: M.M.T., Z.Y.E.

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