Original Article

In-Hospital and Midterm Outcomes of Lead Extraction: A Single-Center Clinical Study

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Abstract

Background: *The rate of lead extraction has steadily increased alongside the extensive use of cardiovascular implantable electronic devices. Data on the complications and safety of this challenging procedure are limited. We investigated in-hospital and midterm outcomes following lead extraction.*

Methods: *Data were retrieved from 51 patients who underwent pacemaker/defibrillator lead extraction procedures at Tehran Heart Center between 2016 and 2021. The procedural success rate, patients' demographic characteristics, and in-hospital and midterm procedure-related complications were investigated.*

Results: *Fifty-one patients were enrolled, including 44 men (86.3%). A total of 109 leads were extracted, with a 90.2% complete procedural success rate. In-hospital death occurred in 4 patients (7.8%): 1 patient (1.9%) died from pneumonia, 1 (1.9%) from septic shock, and 2 (3.9%) from septic shock besides heparin-induced thrombocytopenia. Adverse events in 3 patients (5.8%) were directly related to the procedure: 1 patient (1.9%) suffered lung laceration and hemorrhage, 1 (1.9%) sustained subclavian injury, and 1 (1.9%) developed tamponade. Neither reinfection nor rehospitalization was observed during follow-up.*

Conclusion: *Lead extraction can be considered a highly successful procedure with a low rate of death-related events and complications.*

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Introduction

The implantation of pacemakers and implantable cardioverter-defibrillators (ICDs) has increased significantly during the past years.[1] Despite their life-saving role, pacemakers and ICDs still suffer from major obstacles, such as lead malfunction and device infection, rendering lead extraction inevitable.[2,3]

As a challenging procedure, lead extraction is accompanied by serious complications and life-threatening adverse events, including vascular leakage (due to superior vena cava laceration) and cardiac tear with tamponade.[4,5] However, considering the constantly rising lead extraction rates, many extraction approaches have been devised to achieve successful pacemaker or ICD lead extraction.[6,7]

Although previous studies have offered some insight into the current clinical practice of defibrillator and pacemaker lead extraction,[8-11] data on the complications and safety of this demanding procedure remain limited.

In this study, we aimed to describe in-hospital and midterm outcomes following lead extraction and provide data on major cardiac and vascular complications in patients referred to our center.

Methods

From March 2016 through February 2021, we included all patients with ICDs or cardiac resynchronization therapy-defibrillator (CRT-D) admitted to Tehran Heart Center for lead extraction under the supervision of a single operator. Clinical data were retrieved from patient records and our laboratory database. Definitions employed in this study were as defined in the consensus report from the Heart Rhythm Society in 20097 and EHRA in 2017.[12] The protocol was reviewed and approved by the Research Committee and the Ethics Committee at Tehran University of Medical Sciences (IR.TUMS.THC.REC.1399.093).

Indications for lead extraction were classified as infection and lead dysfunction. Infection was defined as either isolated pocket infection, characterized by local inflammation signs including erythema, pain, and purulent discharge, or infective endocarditis in patients with permanent transvenous leads. Pocket infection associated with lead or valvular vegetation, persistent bacteremia, or sepsis without an attributable source was also considered for lead extraction indications. Lead dysfunction was defined as a lead fracture or mechanical failure resulting in pacing, sensing, or lead impedance.[13] For patients with cardiac implantable electronic devices interfering with the treatment of malignant tumors, prophylactic lead extraction was considered.[7,14]

Extraction was performed by the same operator in the electrophysiology laboratory or the operating room after informed consent was obtained. The procedures were performed with local anesthesia and deep sedation in the electrophysiology laboratory or generalized anesthesia in the operating room under continuous monitoring of arterial blood pressure and oxygen saturation. Intravenous anticoagulation and enoxaparin were interrupted at least 4 and 12 hours before the procedure, respectively. Oral anticoagulants were interrupted a few days before the procedure. Typed and cross-matched blood was reserved. The chest was fully prepped during each procedure. Leads were always removed via the lead insertion site. The superior subclavian approach was chosen as the primary option for lead extraction procedures. Where a subclavian approach failed or was not feasible, open thoracotomy or femoral vein approaches were applied.

Techniques for transvenous lead removal are as follows: (a) simple traction, (b) locking stylets, and (c) femoral snares. After the lead exposition, simple manual traction of the lead with non-locking stylets was the first attempt for transvenous lead extraction. If the traction did not result in successful lead extraction, a locking stylet (VascoExtor, VascoMed, Germany) was advanced to each lead tip. A suture was then tied onto the insulation and the locking stylet. A manual dilator sheath was passed over the lead. All bound tissue was dissected, and when the sheath reached the lead tip, the lead was extracted. If the lead remained immobile in the venous system after a superior approach with locking stylets and manual sheaths, a snare extraction via the femoral vein was carried out. The femoral vein was punctured, and a femoral introducer sheath was advanced over a guidewire into the right atrium to snare the leads in the right atrium. An open surgical approach was performed in the case of procedure failure or complex cases, including lead vegetation and the removal of epicardial lead components.

Complete success was defined as the complete removal of lead material without any procedure-related complications and mortality.[15] The extraction was considered partial if a residual lead fragment ≤4 cm was abandoned in the vascular space. The incomplete removal of all components (>4 cm) of an intravascular lead was considered a clinical failure.[16]

Procedural complications were classified as major or minor according to the Heart Rhythm Society guidelines.[7] Major complications were defined as life-threatening events leading to death, any persistent disability, or unexpected events requiring surgical intervention. All other complications deemed related to the extraction procedure were considered minor. All the patients participated in 2 follow-up visit sessions 1 and 3 months after discharge, respectively.

Categorical variables are presented as frequencies with percentages and continuous variables as mean±standard deviation or medians and interquartile ranges, as appropriate. All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 21.0 (Armonk, TX: IBM Corp).

Results

Fifty-one patients were included in the study. The mean age of our study population was 62.12±16.00 years, and 44 patients (86.3%) were men. The patients' demographic characteristics are presented in Table 1.

Table 1. Demographic characteristics of the study population

Characteristic	n, (%)
Age (y)	62.12±16.00
Sex	
Male	44 (86.3)
Female	7 (13.7)
BMI (kg/m^2)	25.71±5.83
Ejection fraction	33.53±12.14
NYHA Functional Class	
I	12 (23.5)
II	33 (64.7)
III	6 (11.8)
IV	0
Diabetes	20 (39.2)
IHD history	25 (49.0)
Renal failure	24 (47.1)
CVA	8 (15.7)
AF	14 (27.5)
Previous cardiac surgery	17 (33.3)
Previous Noncardiac Surgery	
Brain surgery	3 (5.9)
Cancer	1 (1.9)
Previous lead extraction attempts	4 (7.8)

*Data are presented as mean±SD or frequencies (%).
AF, Atrial fibrillation; BMI, Body mass index; CVA, Cerebrovascular accident; IHD, Ischemic heart disease; NYHA, New York Heart Association

Among the patients, 15 (29.4%) had pacemakers, 25 (49.0%) had ICDs, and 11 (21.6%) had CRT-D. The reason for lead removal was a pocket infection in 32 patients (62.7%), endocarditis in 18 (35.2%), and insulation break in 1 (1.9%). Lead extraction was attempted in 109 leads, with a median for implant duration of 7 years, including 54 ventricular pacing leads (49.5%), 43 atrial pacing leads (39.44%), 11 coronary sinus leads (10.0%), and 1 epicardial lead (1.9%). The procedure characteristics are summarized in Table 2.

Complete and partial procedural success was achieved in 46 (90.2%) and 5 (9.8%) patients, respectively. No intraprocedural death was observed. Four in-hospital deaths (7.8%) were reported, with the causes being pneumonia in 1 patient (1.9%), septic shock in 1 (1.9%), and septic shock accompanied by heparin-induced thrombocytopenia in 2 (3.9%). Major procedural complications were 1 (1.9%) case of subclavian perforation and 1 (1.9%) case of tamponade. Only 1 patient suffered lung laceration and hemorrhage as a minor complication. No reinfection or rehospitalization was reported during the follow-up period. Procedural outcomes and complications are demonstrated in Table 3.

Table 2. Procedural characteristics of the patients*

Characteristic	n (%)
Indications for Device Implantation	
Primary prevention	14 (27.5)
Secondary prevention	20 (39.2)
CHB	11 (21.6)
SSS	3 (5.9)
Brugada syndrome	2 (3.9)
Low-response AF	4 (7.8)
Duration of implantation, y	7 [5-11]
Indications for Lead Extraction	
Pocket infection	32 (62.7)
Endocarditis	18 (35.2)
Insulation break	1 (1.9)
Type of Lead	
RA active	41 (37.6)
RA passive	2 (3.9)
RV active	43 (39.44)
RV passive	11 (10.0)
CS	11 (10.0)
Epicardial	1 (1.9)
Type of Device	
ppm dual-chamber	12 (23.5)
ppm single-chamber	2 (3.9)
ICD DR	17 (33.3)
ICD VR	8 (15.7)
CRT-D	11 (21.6)
CRT-P	1 (1.9)
Preprocedural Findings	
Vegetation in TTE	18 (35.3)
Size of vegetation (mm)	9 [5-13]
Positive blood culture	10 (19.6)
Positive wound culture	27 (52.9)
Duration of antibiotic therapy, d	14 [12-21]
Procedural Room	
Operating room	45 (88.2)
Electrophysiology laboratory	14 (27.5)
Hybrid	8 (15.6)
Anesthesia	
General	39 (76.5)
Local	4 (7.8)
Both	8 (15.7)
Duration of the procedure, h	3 [2.5-4.5]
Hospital stay, d	17 [14-22]
Lead Traction Technique	
Simple traction	17 (15.5)
Locking stylets	76 (69.7)
Femoral snares	5 (4.5)
Surgical extraction	7 (10.0)
Lead Traction Approach	
Femoral	5 (9.8)
Right subclavian vein	13 (25.5)
Left subclavian vein	37 (72.5)

*Data are presented as mean±SD or n (%) or medians (interquartile ranges).
AF, Atrial fibrillation; CHB, Complete heart block; CRT-D, Cardiac resynchronization therapy-defibrillator; CRT-P, Cardiac resynchronization therapy with a pacemaker; CS, Coronary sinus; ICD DR, Dual-chamber implantable cardioverter-defibrillator; ICD VR, Single-chamber implantable cardioverter-defibrillator; ppm, Permanent pacemaker; RA, Right atrium; RV, Right ventricle; SSS, Sick sinus syndrome; TTE, Transthoracic echocardiography

Table 3. Procedural outcome and complications*

Outcomes and Complications	n (%)
Success Rate	
Complete	46 (90.2)
Partial	5 (9.8)
In-hospital death	4 (7.8)
Cause of Death	
Pneumonia	1 (1.9)
Septic shock	1 (1.9)
Septic shock and HIT	2 (3.9)
Procedure-Related Complications	
Lung laceration and hemorrhage	1 (1.9)
Subclavian perforation	1 (1.9)
Tamponade	1 (1.9)
Re-Implantation	
Right subclavian	13 (25.5)
Left subclavian	6 (11.8)

*Data are presented as frequencies (%).
HIT, Heparin-induced thrombocytopenia

Discussion

In this single-center and single-operator study experience, we extracted 109 leads from 51 patients, with a complete success rate of 90.2% and a partial success (residual lead fragment ≤4) rate of 9.8%. (See the Graphical Abstract.) No procedure-associated death was found. In-hospital deaths were due to pneumonia and septic shock. Subclavian perforation and tamponade were the only major intraprocedural complications. No rehospitalization or reinfection occurred during the follow-up. Figure 1 summarizes the salient findings of this study.

Device-related infection continues to be the most common indication for extraction. In agreement with previous studies, pocket infection, and device-related endocarditis were the most common indications for extraction.[16, 17] As the previous studies have reported, mortality following lead extraction is substantially increased with pocket infection or device-related endocarditis.[4, 18] This emphasizes the seriousness of the debridement of the infected pocket tissue and the extraction of leads. Of note, in our study, no reinfection occurred during follow-up, which could be due to adequate antibiotic therapy and immediate lead extraction. According to the latest Heart Rhythm Society statement regarding infection, pocket infection is a class I indication for complete device and lead extraction. Nonetheless, there is a report of a patient with a complicated pocket infection treated conservatively through daily irrigation and dressing, debridement, and broad-spectrum antibiotics.[19]

Additionally, we provided updated data on in-hospital and midterm outcomes. Our high procedural success rate despite using simple manual non-powered tools is an extremely remarkable observation consistent with prior reports.20 However, other studies have demonstrated that powered tools, including electrosurgical-powered sheaths, are more effective.[21] In a trial, Wilkoff et al[22] compared efficacy and safety between laser sheath and conventional lead extraction methods in 301 patients with 465 chronically implanted pacemaker leads. The complete lead extraction rate was significantly higher in the laser group and was reported to be up to 94%. More recently, the ELECTRa study[12] reported the outcomes of lead extraction in 3555 patients. Manual traction without specific tools for extraction was effective only in

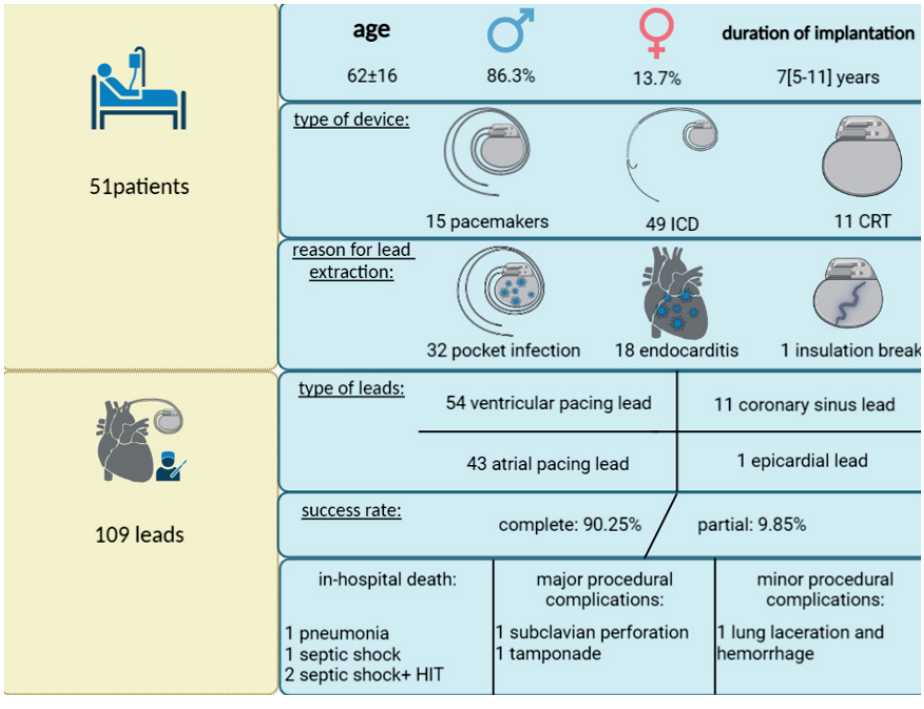

Figure 1. Graphical abstract: 109 leads were extracted from 51 patients, with a complete success rate of 90.2% and a partial success rate of 9.8%.

27.3% of leads, which rose to 99% with the use of locking stylets, dilators, and powered and non-powered sheath cross-over approaches.

Transvenous lead extraction has emerged as a safe and effective procedure, demonstrating a commendable procedural success rate and yielding favorable long-term survival outcomes for patients. Notably, the achievement of procedural success is contingent upon several independent predictors, including a history of hypertension, lengthier time-lapse from implantation, and the expertise of the operator.[23] Additionally, the ongoing development of innovative devices and advancements in procedural techniques hold significant importance in facilitating successful transvenous extraction of leads across diverse patient populations and anatomical variations. In a study by Wazni et al,[4] 1449 consecutive patients underwent laser-assisted lead extraction of 2405 leads with a median implantation duration of 82.1 months, resulting in a 97.7% complete success rate. The investigators revealed that failure to achieve clinical success was associated with the duration of the implanted lead being more than 10 years. In our study, the median time of implantation was 84 months. This lengthier duration of lead implantation might have contributed to a lower success rate in our study.

Despite the promising outcomes and low procedural risk associated with transvenous lead extraction, it remains a procedure demanding precision and expertise. Significant complications related to the procedure consist of cardiac tamponade, pneumothorax, subclavian vein laceration with massive hemothorax, and death. The 3.9% rate of major complications observed in our study is somewhat in accordance with the 4% rate reported by Atallah et al,[9] who reported 3 vascular injuries, 1 moderate tricuspid regurgitation, and 1 not specified complication. Bongiorni et al[12] observed no major complications. However, minor complications occurred in 13 patients (2.4%). The considerably lower complications may partly reflect differences in the characteristics of the study population. Moreover, the lower rate of complication in this study may have contributed to the use of advanced extraction tools, including powered, laser, and electrosurgical dissection sheaths.

Although lead removal procedures have been frequently reported to be safe, they can be complicated by major cardiovascular adverse events and death. Factors associated with increased long-term mortality include cardiac device infection, impaired renal function indications for lead extraction, and patient age and sex.[24] Procedure-related mortality has been reported to range from 0.04% up to 0.28%.[4,25] In our study, no procedure-related deaths occurred in the electrophysiology laboratory and the operating room, while in a previous study, the cardiac tamponade-related intraprocedural mortality rate was reported at about 47%.[26] In our study, most of the patients underwent the procedure in the operating room, with a cardiac surgeon present as a colleague. Further, in 2 patients with tamponade and superior vena cava tears, the chest was immediately opened, and the leakage was repaired. This could properly clear the need to immediately perform pericardiocentesis, followed by a surgical approach, as a rescue. Moreover, it is worth acknowledging that operator expertise and managing complications arising after the procedure remain areas with significant effects on patient survival.

Still, percutaneous extraction of leads is considered a safe procedure. Alternative repositioning or preserving methods are used for patients who refuse surgical intervention.[27-29] Comparative data directly contrasting preserving lead methods with surgical intervention remain limited; however, preserving strategies present several potential advantages, particularly a reduced risk of complications. Although managing device-related complications without extraction is not well supported by conventional surgical practice, accumulating clinical data imply promising results.[29] Initial experience with preserving strategies has yielded encouraging results, but the optimization of long-term outcomes necessitates further exploration through studies.

Our study suffers from some limitations. As a single-center and single-operator study, the results may not apply to a larger population. Another drawback of note is the lack of access to advanced lead extraction tools, such as electrosurgical and laser sheaths. Further, we did not manage to evaluate long-term outcomes. A longer follow-up period would have been valuable in determining the ultimate outcomes. Future analyses should be conducted to investigate the factors influencing the success and complication rate of the procedure besides the type of extraction tool or approach used.

Conclusion

In summary, percutaneous extraction of transvenous permanent pacemaker/defibrillator leads could be considered a highly successful procedure without any death-related events and with a low rate of complications. Further data on risk factors for device-related complications will be helpful with a specific focus on lead-preserving strategies and improving the device technology.

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