Feasibility and safety of a transvenous lead extraction program implementation in South America: Challenges, early outcomes, and global collaboration—A single-center experience

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BACKGROUND Transvenous lead extraction is the standard of care for cardiac implantable electronic device (CIED) malfunction/infection-related removal. However, data on its performance and results in underdeveloped countries are limited.

OBJECTIVE The purpose of this study was to report the feasibility and efficacy of a lead extraction program in a tertiary hospital in Chile, South America.

METHODS Patients requiring CIED removal at the Electrophysiology Division of the Hospital las Higuera's were retrospectively analyzed. Outcomes including procedure-related mortality, procedural success and failure, and cardiac and vascular complications were reported.

RESULTS A total of 15 patients were analyzed (median age 68 [interquartile range 52–75] years; 80% male). Patients with lead extraction difficulty index >10 represented 33% of patients. Infection was the indication for removal in all patients, with pocket infection (80%). Mechanical rotational tools were used in 66% of cases, and a total of 29 leads were removed. Procedural success was accomplished in 93% of cases. There was 1 (7%) intraprocedural complication and no procedure-related mortality.

CONCLUSIONS The development of a lead management program is feasible, safe, and effective in underdeveloped countries.

KEYWORDS Electrophysiology; Lead complications; Lead extraction; Lead management; South America

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Introduction

Cardiac implantable electronic device (CIED)-related infections are associated with significant morbidity and mortality, and a substantial increase in cost to the health care system.[1] In addition, late detection and treatment are directly associated with poor outcomes. In this context, it is critical to implement strategies to ensure early detection and appropriate treatment of CIED-related complications.[2]

Transvenous lead extraction (TLE) has become the therapeutic strategy of choice for removing malfunctioning or infected CIEDs and has proven to be safe and effective.[3] However, this technique requires highly qualified operators, specifics tools, and the coordination and deployment of significant human and technological resources, thus limiting its widespread implementation, particularly among underdeveloped countries.

The aim of this study is to describe the implementation, challenges, and results of a lead management program in a high-volume tertiary hospital in Chile, South America.

Methods

Patient population

This was a single-center, retrospective cohort study. Consecutive patients undergoing lead removal management at Hospital las Higuera's Electrophysiology Division between 2021 and 2022 were included in the analysis. Patients with ischemic cardiomyopathy (ICM) and nonischemic cardiomyopathy (NICM) were included. The diagnosis of NICM was defined as the presence of left ventricular ejection fraction <50%, the absence of significant coronary artery disease (obstruction >75%), and previous myocardial infarction or primary valvular disease. Right ventricular arrhythmogenic cardiomyopathy was included in the NICM group. The

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KEY FINDINGS

- Infection was the predominant indication for cardiac implantable electronic device removal.
- Transvenous lead extraction is feasible and effective.
- No procedure-related mortality was reported.

diagnosis of ICM was defined as a history of infarction with Q waves, focal wall-motion abnormality on imaging, or fixed perfusion defect correlating with coronary stenosis or previous coronary intervention. The diagnosis of CIED0related infection and the indications for lead removal were in accordance with the current clinical guidelines and classified as infectious (local or systemic) and noninfectious indications.[3] Patients were classified as high risk for complications using the lead extraction difficulty (LED) index score.[4] The data were obtained from the Hospital las Higuera's Electrophysiology Division Registry, all patients signed informed consent, and the study was approved by the Institutional Board on Scientific Conduct and Ethics. The research reported in this paper adhered to the revised 2013 Helsinki Declaration guidelines.

Procedure protocol and equipment

Overall, our procedure technique follows standard descriptions in the literature.[5] The procedures were performed by electrophysiologists in the electrophysiology laboratory with patients under general anesthesia, with an available cardiac surgeon/team on standby. All cardiac surgery equipment, including extracorporeal circulation, were present in the room and ready for immediate use. Patients were monitored by invasive blood pressure monitoring and transesophageal echocardiography during the entire procedure. Along with peripheral venous accesses, central femoral access (8F) was obtained for exclusive use by the anesthesiology team. If backup pacing was necessary, contralateral femoral access was obtained, and a deflectable quadripolar catheter was advanced into the right ventricle.

Because of limited technological availability, a few distinctions were introduced into our practice. First, laser extraction tools (Spectranetics, Colorado Springs, CO) are not commercially available in our country; therefore, for leads that could not be extracted by simple traction, we used mechanical rotational tools (Evolution and Evolution RL, Cook Medical, Bloomington, IN). Second, the Philips Bridge balloon wire (Philips Corp., Amsterdam, The Netherlands) is not commercially available in our country, so patients considered at high risk for complications based on LED index score >10 underwent additional arterial and venous femoral access (5F) that could quickly be upsized during an emergency for insertion of femoral extracorporeal circulation cannulas. Third, procedure-related imaging techniques such as computed tomographic scan, intravascular ultrasound, and intracardiac echocardiography are not widely available. Instead, at operator discretion we performed fluoroscopic venography to identify regions of venous stenosis, occlusion, and vascular adhesion.

Follow-up

Procedural outcomes assessed were procedural success and failure, as defined by the 2017 Heart Rhythm Society consensus statement.[3] Procedural complications related to vascular access, vascular injury, tamponade, emergency cardiac surgery, and intraprocedural death also were recorded. Procedural outcomes were assessed during the index admission.

Statistical analysis

Categorical variables are given as number (percentage). Continuous variables are given as either mean ± SD or median [interquartile range]. Analysis was performed using IBM SPSS Statistics for Macintosh, Version 28.0 (IBM Corp., Armonk, NY).

Results

Patient characteristics

Between 2021 and 2022, a total of 15 patients were referred to our center for lead management and underwent CIED removal procedures. Baseline characteristics are summarized in Table 1. Males comprised 80% of the patients, and median age was 68 [interquartile range 52–75] years. Heart failure with reduced ejection fraction was present in 67%, with a predominance of NICM etiology (80%). Median ejection fraction was 43% [30%–56%]. Pacemakers represented 47% (n = 7) of devices, cardiac resynchronization therapy–defibrillator 33% (n = 5), and defibrillators 20% (n = 3). Of the implantable cardioverter–defibrillator implants, 27% (n = 4) were for primary prevention of sudden cardiac death, and 20% of patients (n = 3) had a superior vena cava coil. In total, 40% (n = 6) of patients had a history of pocket revision and/or generator change.

Procedural characteristics

Procedural characteristics are summarized in Table 2. Patients at high risk for procedural complications based on LED index >10 represented 33% (n = 5) of cases. The indication for device removal was infection in all cases (n = 15). Isolated pocket infection represented 80% (n = 12) of the infectious processes; 3 patients presented with externalization of some device components. Systemic infections represented 20% (n = 3) of cases, all with lead vegetations clearly identifiable on transesophageal echocardiogram. Overall cohort median time from last device intervention to device removal was 35 [12–120] months. For procedures requiring mechanical tools (extractions), median time from device implant to extraction was 96 [36–120] months. For procedures not requiring extraction tools (explants), median time from device implant to explant was 8 [6.5–12] months.

The subclavian approach was performed in all procedures (100%). Mechanical rotational tools were necessary for extraction in 66% (n = 10) of the procedures. Total number

Table 1 Patient characteristics

Characteristics	(N = 15)
Age (y)	68 [52–75]
Sex	
Male	12 (80)
Female	3 (20)
Heart failure with reduced EF	10 (67)
ICM	2 (20)
NICM	8 (80)
Ejection fraction (%)	43 [30–56]
Atrial fibrillation	7 (47)
Hypertension	11 (73)
Diabetes	7 (47)
CKD	1 (7)
Obesity	5 (33)
Type of device	
Single-chamber ICD	2 (13)
Dual-chamber ICD	1 (7)
CRT-D	5 (33)
Single-chamber pacemaker	4 (27)
Dual-chamber pacemaker	3 (20)
ICD indication	
Primary prevention	4 (27)
Secondary prevention	4 (27)
SVC coil	3 (20)
Pacemaker indications	
Complete AVB	4 (27)
High-degree AVB	2 (13)
SSNS	1 (7)
No. of transvenous leads	
1	6 (40)
2	6 (40)
3	2 (13)
4	1 (7)
Previous generator change/revision	6 (40)

Values are given as n (%) or median [interquartile range].

AVB = atrioventricular block; CKD = chronic kidney disease; CRT-D = cardiac resynchronization therapy–defibrillator; EF = ejection fraction; ICD = implantable cardioverter–defibrillator; ICM = ischemic cardiomyopathy; NICM = nonischemic cardiomyopathy; SSNS = sick sinus node syndrome; SVC = superior vena cava.

of targeted leads was 29: 72% (n = 21) pacing leads and 28% (n = 8) implantable cardioverter–defibrillator leads. The most common lead locations were the right ventricle (52%), followed by the right atrium (31%) and coronary sinus tributary (17%). Of the fixation mechanisms, 52% (n = 15) of the leads were active fixation and 21% (n = 6) were passive fixation (Figure 1). Implantation of a contralateral jugular temporary transvenous active fixation lead with an externalized pacemaker was required in 53% (n = 8) of cases.

Procedural outcomes and follow-up

Complete procedural success was achieved in 93% (n = 14) of cases. The only failure was a >4-cm retained lead fragment in the intravascular space at the level of the subclavian vein without further clinical consequences on follow-up. Median procedural time was 100 [80–120] minutes. After the infection was clear, device reimplantation was performed in 64% (n = 9) of patients. Median time to reimplant was 12 [7–23] days. Reasons for not reimplanting the devices were patient preference in 50% (n = 3) and absence of a clear indication in 50% (n = 3).

One intraprocedural complication (7%) was reported: a pneumothorax during implantation of the contralateral temporary active fixation lead. Two remote complications were reported: (1) dislodgment of a temporary transvenous active fixation lead, 4 days postextraction, in a pacemaker-dependent patient requiring urgent repositioning; and (2) after the contralateral reimplantation, 1 patient developed a new pocket infection and underwent epicardial lead placement secondary to lack of vascular access. There was no procedure-related mortality.

Discussion

In this study we report the implementation, challenges, and results of a lead extraction program in a tertiary hospital in Chile, South America. Because of expanded use of CIEDs, lead extraction procedures have become more frequent. However, according to a recent lead extraction survey by the Latin-America Heart Rhythm Society, the technique is not widely available, most likely secondary to high costs, lower operator experience, and/or lack of proper training/knowledge in the techniques necessary to ensure the performance of safe and effective procedures.[6]

Table 2 Procedure characteristics

Characteristics	(N = 15)
Patients with LED index >10	6 (40)
Procedure time (min)	100 [80–120]
Type of infection	
Pocket	12 (80)
Systemic	3 (20)
Implant duration (mo)	36 [12–120]
Use of mechanical rotational tools	10 (67)
Active fixation externalized temporary pacemaker	8 (53)
Complete procedural success	14 (93)
Procedure-related mortality	0 (0)
Intraprocedural complications	1 (7)
Remote complications	2 (13)
Device reimplantation	9 (64)
Time to device reimplantation (d)	12 [7–23]
No. of targeted leads and locations	29
Right atrium	9 (31)
Right ventricle	15 (52)
Coronary sinus tributary	5 (17)
Type of lead	29
Pacing lead	21 (72)
ICD lead	8 (28)
Fixation mechanism	29
Active fixation	15 (52)
Passive fixation	6 (21)
No information	3 (10)

Values are given as n (%) or median [interquartile range].

ICD = implantable cardioverter–defibrillator; LED = lead extraction difficulty.

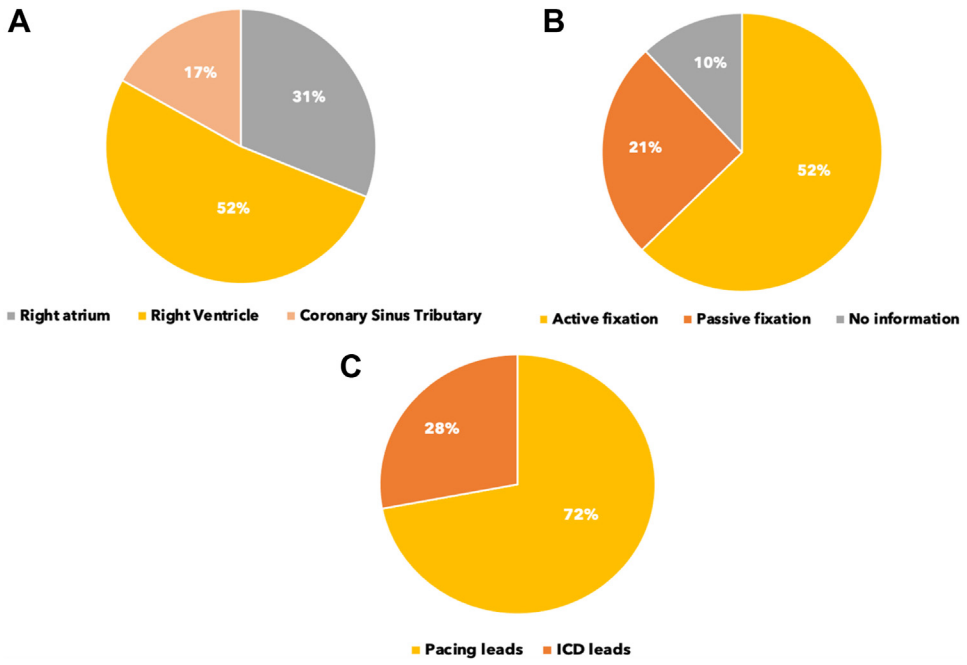

Figure 1 Distribution of removed leads. **A:** Leads removed according to location. **B:** Leads removed according to fixation mechanism. **C:** Leads removed according to type. ICD = implantable cardioverter–defibrillator.

There is a significant lack of data on lead extraction in South America, and the results of our small series seem to be in accordance with previous reports in this region, with infections being the most frequent reason for removal and the use of mechanical tools being the preferred technique.[6-9] Notably, no patients had any lead malfunction as an indication for lead removal. There are many reasons for this observation, including underdiagnosis due to challenges with patient follow-up because many patients returned to their community hospitals, where further resource scarcity may lead to missed diagnoses of lead malfunctions.

Despite the technological challenges, such as the lack of Bridge balloon wires and laser-powered tools, our results seem to be in accordance with international reports.[8,9] Our locally adapted protocol based on mechanical rotational tools proved to be effective and was associated with a low rate of major complications. Our early results suggest that use of laser-powered tools may not be cost-effective in our region, although study of a larger cohort will be necessary to confirm this suggestion.

Las Higuera's Hospital is a government, high-complexity hospital serving more than 1 million patients, and we perform more than 500 CIED procedures per year. In this context, there was a need to develop a lead management program to provide solutions to the growing number of lead-related issues associated with the increasing number of CIED implants. The lead extraction program was formally implemented in 2021. Before the program was implemented, lead abandonment was not unusual. Our current lead extraction team consists of 2 cardiac electrophysiologists with international training (A.P., Madrid, Spain, and Boston, MA, USA; P.S., Chicago, IL, USA), along with electrophysiology and cardiosurgical staff. Our valuable international collaboration allows us to receive advice for procedure planning and troubleshooting. As 2022, we have exceeded the number of procedures performed in all of 2021, and due to our exponentially growing volume of procedures and promising results, we recently have been selected as training center and hope to assist in expanding the use of these technique in our country. We aim to become a national reference center for lead extraction, and we are actively building referral networks to maintain our procedure volume.

The major challenges we routinely encounter are (1) economics (ie, keeping the procedure cost-effective); and (2) setting up cardiac surgical backup. Because there is only 1 surgical team, surgical backup is available only 1day per week, for only 1 procedure. We hope to incorporate more cardiac surgical staff in the future.

Study limitations

The study was a single-center, small sample size, retrospective analysis, which included a population mostly at low risk for complication based on LED index. Therefore, the results should be carefully interpreted before they are extrapolated too broadly. In the future we hope to incorporate new technology to increase safety and incorporate more high-risk patients.

Conclusion

In our experience, the development of a local lead extraction program in underdeveloped countries is feasible, safe, and effective.

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Patient Consent: All patients signed written informed consent.

Ethics Statement: The study was approved by the Institutional Board on Scientific Conduct and Ethics. The research reported in this paper adhered to the revised 2013 Helsinki Declaration guidelines.

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