ORIGINAL ARTICLE

FIRST NATIONAL REGISTRY OF TRANSVENOUS LEAD EXTRACTION (RENEDI) PRELIMINARY RESULTS

ABSTRACT

Introduction: RENEDI ("Registro Nacional de Extracción de Dispositivos") is the first inter-societary, prospective, multicenter and observational cohort study for patients undergoing transvenous lead extraction (TLE) performed in Argentina. **Objectives:** To provide realworld data of current practice in our country, characterize the population of patients and personnel involved and analyze, with an interdisciplinary and internstitutional focus, the results obtained. **Methods:** An online database platform active from January 2018 to December 2019 was designed. Data provided by specialists was compiled, verified and reviewed by a Committee. **Results:** A total of 621 leads (325 patients - average age: 59 years; 71%: male) were extracted. The targeted leads included 379 (61%) pacemakers, 174 (28%) implantable cardioverter-defibrillator and 68 (11%) cardiac resynchronization therapy Devices. Two hundred and thirty-three (38%) were atrial leads, 367 (59%) ventricular leads, and 21 (3%) were in the coronary sinus. The average lead dwell time was 105.9 months. The commonest indication for removal was infection (68%). Vascular or cardiovascular surgeons were usually the primary operators (81%). The majority of interventions were performed in standard operating theatre (79%). The presence of stand by was reported in 65% of cases. Percutaneous approach (98%) was predominant. Hybrid approaches were performed in 7 patients (16 leads). A total of 158 (25%) leads were extracted using simple traction (median dwell time: 33.3 months). Additional and specified tools were used in 74% of cases. Overall complications rate were 4% (major: 0.3%; minor: 3.7%). Complete procedural success was 96.3%. Incomplete extraction was obtained in 23 leads. No deaths were reported. **Conclusions:** TLE is a safe and effective procedure associated with a low incidence of complications and high success rate when it is performed in well-trained hands. In our county, few specialists are dedicated to this practice. An extensive training and sufficient prior experience in performing these techniques are essential to minimize the risk of complications and obtain successful outcomes.

Keywords: *multi centre registry, prospective clinical trial, lead extraction, outcomes, training*

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Received: 03/24/2021 Accepted: 03/31/2021

INTRODUCTION

Over the past years, a higher number of pacemakers, cardioverter defibrillators and cardiac resynchronization therapy devices implantation for the treatment of bradyarrhythmias and tachyarrhythmias as well as for the primary prevention of sudden death and cardiac insufficiency has been noted. Similarly, the number of leads extractions (LE) due to several causes such as pocket infection, endocarditis, catheter or electrode dysfunction or up-grade has also been registered. The development of new percutaneous lead extraction systems together with the major experience of the surgical team have lead to wider indications for surgical removal. However, leads extractions remain being a complex procedure related to several complications. Hence, the existence of specialized centers and well-trained operators in performing these techniques are essential to minimize the risk of unnecessary and unexpected events.

The aim of this first national registry of lead extraction is to provide data on our realworld practice, characterize the population of patients and personnel involved and analyze, with an interdisciplinary and interinstitutional focus, the results obtained.

METHODS

A prospective, multi center and observational national cohort study for patients undergoing transvenous lead extraction (TLE) was performed. Data were obtained for 325 patients with lead (pacemaker, cardioverter-defibrillator or cardiac resynchronization therapy Device (CRTD) indication for extraction. An online database platform active from January 2018 to December 2019 was designed. An Executive Committee composed of members from Argentinian College of Cardiovascular Surgeons (CACCV), Argentinian College of Cardiac Electrophysiology (SADEC), Argentinian College of Cardiology (SAC) and Argentinian Federation of Cardiology (FAC) provided the study design. Definitions published in the guidance documents by HRS (2009), EHRA (2012) and EHRA (2018) were used to define procedural approaches, techniques and outcomes[1-3].

Data referred to patients (age, gender), leads (types of devices, leads localization, average implant time, indications for removal, re-implant during the same procedure, complications, success rates) and extraction procedures (facilities, equipment and personnel) were compiled, verified and reviewed by the Committee.

RESULTS

Data were obtained for 325 patients (average age of 59 years, 71% male) and 621 targeted leads (atrial: 38%; n=233; ventricle 59%; n=367; coronary sinus;3%; n=21). The mean dwell time of the targeted leads averaged 105.9 months. Sixty-one percent of the targeted leads were pacemaker leads, 28% implantable cardioverter defibrillator leads and 11% cardiac resynchronization therapy Devices (CRTD). The mean number of leads extracted per device was 1.9.

The commonest indication for TLE was infection informed in 68% (222/325) of patients. Pathogens were identified in only 32% of cases. Bacterial culture data showed that staphylococcal infection was the most frequent (71%).

Leads removal for non-infective indications (32%) included lead dysfunction, abandoned lead dysfunction or other reasons (venous stenosis, access to magnetic resonance imaging, cardiac failure and arrhythmia). Demographic data including details on patients, leads and indications for removal are reported in *Table 1*.

Most procedures were performed by vascular or cardiovascular surgeons (81%) working in the majority of cases in standard operating theatre (79%). The remainder was performed by cardiologists or electrophysiologists, generally working in an electrophysiology laboratory (21%). Procedures performed by a cardiologist or electrophysiology with cardiac surgical stand-by were reported in 65% of cases. In the majority of TLE interventions, general anaesthesia (92%; n=299) was preferred.

Most lead extractions were performed using a percutaneous approach (98%). The majority began via identical route of lead implantation. Superior approach (subclavian/jugular/cephalic) was performed in 315 patients. Only in three cases, combined approaches (superior-femoral or inferior access) with additional snares or baskets were required. Simple traction without the use of specified tools (other than a standard stylet) was sufficient for removing 25% (158/621) of leads with a median dwell time of 33.3 months. For leads that could not be removed using simple traction (75%; n=463), a multistep approach was performed. Locking stylet (Liberator® Beacon® Tip Locking Stylet) was generally used in these steps. Additional equipment preferred by operators were quite variable from dilator sheaths, snares, baskets or mechanical rotational dilator sheaths (Evolution and Evolution RL, Cook Medical, USA) and most of them used in combination with others. A small minority of leads (7 patients=16 leads) were extracted by a simultaneous "hybrid approach" using a minithoracotomy/sternotomy (three patients with active endocarditis) including extracorporeal circulation and perfusionist. No laser extractions were performed.

Re-implant devices (leads + generator) during the same procedure was reported in 57% (185/325) of cases (permanent device: 65%=120/185).

Overall complications rate were 4%. The investigators reported only one major complication (outcome related to the procedure involving disability, life threatening or death) in a patient who suffered a temporary ventricular fibrillation and sudden cardiac arrest with immediate cardiopulmonary resuscitation and recovery at 24 hours. No procedural mortality occurred in our cohort study. Minor complications (outcome which did not limit patient`s function, life threatening or death) were observed in 12 patients (3.7%). Infection was the indication for lead extraction in more than half of these patients. Two patients experienced local haematoma related to lead extraction procedure due to extensive fibrosis. Vascular repair was informed in one patient with lead disruption during extraction and a femoral approach using a snare was required. Only one patient experienced an haemothorax which did not require intervention and an epicardial pacing was re-implanted at 24 hs.

Complete procedural success rates (removal of all targeted leads and material) were achieved for 96.3% (598/621) of leads. Procedural failure rates (inability to achieve a complete procedural) were 3.7%. Twenty-three leads were incompletely extracted and more than half of them were related to infection. The mean dwell time was 134 months. Extensive fibrosis, presence of calcification and venous stenosis or occlusion were commented by investigators. At hospital discharge, lead fragments did not result in any undesired outcomes. No permanent disabling complications or procedure-related death were reported.

COMMENTS

In Argentina, the first TLE was performed in 1993 at the Pirovano Hospital[4,5]. Despite long experience, our country has not had a global and institutional clinical investigation on real-world patients.

RENEDI is the first intersocietary, prospective and observational registry of leads extraction designed in Argentina. Our preliminary results agree with other similar worldwide experiences that TLE

TABLE 1. Demographic data

PATIENTS		
Patient number		325
Age		average 59 years
Gender		
	Male (n=231)	71%
	Female (n=94)	29%
LEADS		
Number of targeted leads		621
		61% (n=379) pacemaker leads 28% (n=174) implantable cardioverter defibrillator leads 11% (n=68) cardiac resynchronization therapy leads
Implant duration		average 105.9 months
Localization of leads		
	Atrium (n=233)	38%
	Ventricule (n=367)	59%
	Coronary sinus (n=21)	3%
Mean lead extracted per device		1,9
INDICATIONS FOR REMOVAL		
Infection		68% (222/325)
Local	71% (n=158)	
Local + systemic	25% (n=55)	
Systemic	4% (n=9)	
Lead dysfunction		26% (84/325)
Abandoned lead dysfunction		3% (11/325)
Other reasons		3% (8/325)

is a safe and effective procedure associated with a low incidence of complications and high success rates when it is performed in well-trained hands[6-14]. Comparisons of TLE complications and success rate in current literature is informed in *Table 2*.

This report describes for the first time the indications, role of the operators, procedures, different operating environments and safety and effectiveness of mechanical extraction including tools and techniques. More than 600 procedures were performed over a mean of two years which represent the reflection of our current practice. The results as detailed above provide an useful resource for research and improvements in care.

Few specialists are dedicated to this practice developing a high quality training and remarkable experience. As for all interventional procedure an appropiate learning curve is essential to become a competent operator, we emphasize the necessity for extended training and sufficient prior experience in performing these techniques in order to minimize the risk of complications and obtain successful outcomes.

ACKNOWLEDGEMENT

The authors thank all patients who participated in this study, as well as all the study investigators and research personnel. The authors thank the following individuals Fraguas, Hugo, MD; Blanco, Rocio, MD; Salvo, Gustavo, MD; Robi, Marcelo, MD; Duval Javier, MD; Reyes Prieto, Gabriela, MD; Talin, Carlos, MD; Picolin, Agustín, MD; Figueroa, Jorge MD; Cronshey, Andrés, MD; Zanuttini, Antonella, MD; Deluso, Daniel, MD; Pérez Salamanca, Cristhian, MD; Perona, Carlos MD and Cotti, César, MD for their contributions to the development of this manuscript.

TABLE 2. Complications and success rate reported in literature

	MAJOR COMPLICATIONS	MINOR COMPLICATIONS	PROCEDURE RELATED-DEATH	COMPLETE PROCEDURAL SUCCESS	CLINICAL PROCEDURAL SUCCESS
RELEASE 2021[6]	2.6%	18%	0	96.3%	98.7%
PROMET 2020[7]	1%	3.1%	0.18%	96.5%	97%
ELECTRA 2017[8]	1.7%	5%	0.5%	95.7%	96.7%
LEXICON 2010[9]	4%	1.8%	1.86%	96.5%	97.7%
CENTELLA ET AL. 2007[10]	2.5%	2.1%	0.5%	96.8%	99.04%

Conflicts of interest

Authors report no disclosures.

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