Current practice in Transvenous Lead Extraction in Latin-American: Latin-American Heart Rhythm Association Survey

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Abstract

Background: Transvenous lead extraction (TLE) is standard of care for the management of patients with cardiac implantable electronic device infection or lead related complications. Currently, objective data on TLE in Latin America is lacking. Objective: To describe the current practice standards in Latin American centers performing TLE. Methods: An online survey was sent through the mailing list of the Latin American Heart Rhythm Association (LAHRS). Online reminders were sent through the mailing list; duplicate answers were discarded. The survey was available for one month, after which no more answers were accepted. Results: A total of 48 answers were received, from 44 different institutions (39.6% from Colombia, 27,1% from Brazil), with most respondents (83%) being electrophysiologists. Twenty-nine institutions (66%) performed less than 10 lead extractions/year, with 7 (15%) institutions not performing lead extraction. Although most institutions in which lead extraction is performed reported using several tools, mechanical rotating sheaths were cited as the main tool (73%), 13.5% reported the use of mechanical extraction sheaths and only 13.5% reporting the use of laser sheaths. Management of infected leads was performed according to current guidelines. Conclusion: This survey is the first attempt to provide information on TLE procedures in Latin America and could provide useful information for future prospective registries. According to our results, the number of centers performing high volume lead extraction in Latin America is smaller than that reported in other continents, with most interventions performed using mechanical tools. Future prospective registries assessing acute and long-term success are needed.

Introduction

Over the last decades, the number of cardiac implantable electronic devices (CIED) implanted has steadily increased as technological advances have allowed for a greater number of conditions to be treated with CIEDs (1,2). Long-term CIED implants are usually associated with a need to add or replace existing electrodes due to lead failure or need for device upgrade, with many patients having abandoned leads which increase the risk of infection and venous thrombosis. Moreover, implants are being performed in older patients with more comorbidities (3,4). This increase in implants and the use of devices in older, sicker patients have led to a higher number of device related infection and lead related complications (5,6). As such, there is an

increasing need for lead extraction procedures (7,8). Although technological advances have allowed for safer and easier percutaneous lead extraction procedures, access to different tools and the high costs limit in many cases their widespread availability and as such their use varies in different institutions and countries.

Although several centers in Latin America perform lead extraction, objective data on current practice is lacking. In order to obtain information on the current lead extraction practice in Latin America, we performed this survey.

Methods

In this descriptive cross-sectional observational study, physicians working at electrophysiology services in Latin American countries were sent a 16-question online survey (table 1) created using a commercial online platform (Google Forms®) were contacted using the Latin American Heart Rhythm Society (LAHRS) directory. Additional invitations were sent through national cardiology medical associations. Information regarding city and country of origin, hospital center, participation in lead extraction procedures, operator experience, number of procedures per year, available tools and procedural characteristics was collected. If a respondent answered that extractions were not performed in his/her institution, no further questions regarding lead extraction procedures were made. The online survey was available from October 1 to October 31st, 2020. All duplicate answers were eliminated. Results are presented as absolute frequencies and percentages for categorical variables.

Results

The survey was answered by 48 participants from 44 different institutions spanning 8 different countries. Transvenous lead extraction (TLE) was performed in 85% of these institutions. Most respondents were from Colombia (39.6%) and Brazil (27.1%) (figure 1A); 82% of respondents were electrophysiologists (figure 1B) with 71% of respondents having more than 10 years of experience (figure 1C).

Procedural characteristics

Forty-one respondents (85%) performed lead extractions, with most institutions (66%) performing less than 10 procedures per year and only 11% of of them preforming >25 procedures per year (figure 2A). Procedures were generally performed under general anesthesia (97%). As expected, based on the respondent's specialty, electrophysiologists were reported to be in charge of lead extractions in 85% of cases (figure 2B). Out of the 38 institutions in which lead extraction was performed, laser powered sheaths were available in only 5 institutions (13%), while mechanical tools (either mechanical dilators or rotating sheaths) were used by most respondents (figure 2C). Regarding safety measures and intra-procedural monitoring (figure 2D), the BRIDGE balloon (Phillips, San Diego, CA) was used in 5 institutions (13%), with transesophageal echocardiography (TEE) and intracardiac echocardiography (ICE) used in 15 (39%) and 6 (16%) institutions, respectively. Most respondents reported a cardiovascular surgeon was either in the procedure room (46%) or on call within the institution (46%).

Proposed clinical scenarios

Answers to proposed clinical scenarios (including high-risk lead extraction procedures the management CIED pocked infections and malfunctioning leads) were received from the 42 respondents who performed lead extraction. Although the majority of respondents (30, 71%) had no specific clinical scenarios in which lead extraction would be avoided, 10 (24%) respondents reported avoiding lead extraction in patients over 80 years of age (3A). In cases of device related pocket infection, total capsulectomy was performed by 24 (57%), with 9 (24%) reporting not performing capsulectomy (figure 3B). In pacing dependent patients with isolated pocket infection (figure 3C), a new device was implanted only after consultation with the infectious disease specialist by 18 (43%) of respondents, with 5 respondents (12%) reporting implantation of a new device during the same procedure. In patients with malfunctioning pacemaker or ICD leads, lead abandonment within the generator pocket (with implantation of a new lead) was routinely performed by 3 respondents (7%), while 30 (71%) respondents basing their decision on a case-by-case basis after analyzing individual patient characteristics and comorbidities (figure 3D)

Discussion

During the last two decades, the number of CIEDs implanted has increased steadily as technological advances have allowed a wider range of conditions to be treated with implantable devices. Moreover, the number of dual chamber vs single chamber pacemakers, along with the use of cardiac resynchronization devices has also increased (9-12). As such, not only has the number of CIED implantations but also the number of implanted leads has increased. This has led to a higher number of lead related complications, mainly infection, and a greater number of TLE procedures performed.

This is the first Latin American survey on TLE. Although smaller than previous surveys (13-15), answers were received from 48 respondents from 44 different institutions (8 different countries). As such the survey provides valuable information on the current practice of lead extraction in our continent. Importantly, although TLE is performed in several institutions in Latin America, most (66%) report a low procedural volume (i.e., less than 10 procedures per year). This percentage is higher than that reported in the US (in which less than 20% of institutions performed <10 lead extraction procedures per year) and the first European lead extraction survey (in which 40% of institutions performed <10 procedures each year)(15) demonstrating a low use of TLE in the continent. Several possible reasons exist for this finding: high cost of lead extraction tools, a perceived higher risk for complications (as evidenced by a reluctance to perform TLE in patients older than 80 years old in 22% of respondents), and a lack of proper training/knowledge (16). Unfortunately, the number of implant procedures and the infection rate in Latin America is currently unknown but taking into consideration European guidelines which estimate the need of TLE as 1.5 times the infection rate (17), a significantly higher number of lead extraction procedures is expected. Lack of public financing in many Latin American countries has a significant impact on CIED use and waiting times (18), and as such should also impact the use of TLE techniques. Implementation of training programs, along with a reduction in costs associated with TLE tools could have positive impact on the number of lead extraction cases performed. Taking into consideration that low procedural volume (defined in the ELECTRa registry as less than 30 lead extraction procedures per year) is associated with a significant increase in procedural mortality, efforts should be made to increase training and to perform lead extraction procedures only in high volume centers (19).

Although most institutions (73%) used mechanical rotating sheaths (which is similar to what was found in the European survey)(13), 13.5% of institutions reported the use of laser sheaths. This is particularly surprising in latin america, taking into consideration the higher cost of laser sheaths (20), with procedural success rates similar to those reported with current mechanical rotating sheaths (21-23). In fact, in the recently published PROMET study laser sheaths were almost entirely abandoned in favor of mechanical rotating sheaths due to lower costs and similar effectiveness (24). Regarding safety measures, cardiac surgeons were included (either in room or within the institution) by 92% of respondents, similar to what has been described in the ILEEM survey (25) but higher than reported in the US survey (in which a surgeon was not identified in 25% of lead extraction procedures)(14). Importantly, other safety measures including TEE (39%) ICE (16.2%) and the BRIDGE balloon (13.5%) were used in a significant number of institutions.

Regarding the proposed clinical scenarios, the number of respondents who perform complete capsulectomy in CIED related infection is lower than that reported in a recent worldwide survey (57% vs 76%)(26). This is in line with the most recent guidelines, in which capsulectomy is not recommended as routine practice (27). Elderly patients (i.e., those older than 80 years of age) were considered to be at high risk of procedure related complications and 24% of respondents routinely avoided extraction in this patient population. Indeed, extraction procedures in elderly patients have been found to be significantly associated with a higher periprocedural mortality (2.5% in 18–44 years compared to 5.3% in 85+ years, $P < 0.001$) in the US (28). Finally, regarding malfunctioning leads, 71% of respondents would base their decision (i.e., lead abandonment or extraction) on individual patient characteristics. This is similar to what has been described in previous European surveys, in which malfunctioning lead management was strongly determined by patient's age, the presence of damaged leads and lead dwelling time (29).

Recently, the results of the largest prospective lead extraction registry in Latin America were published,

demonstrating the safety and effectiveness of lead extraction in a large volume center (30). Future efforts should thus be focused on increasing the number of centers performing high volume lead extraction, as this study demonstrates results comparable to those published in literature can be achieved.

Limitations

Our results have limitations to be considered. Although the survey was sent using the LAHRS database, it is possible that several practitioners from high volume centers failed to answer the survey. Additionally, since the survey was sent in English, this could have also limited the number of possible physicians willing to answer the survey. This could have reduced the number of answers received. Finally, most answers were received from Colombia and Brazil (66.7% of total answers), and as such other countries may be under-represented even though this type of procedures are known to be performed.

Conclusions

This survey is the first attempt to obtain information on current practices involving TLE in Latin America. According to our results, TLE is performed in select centers in Latin America, with most centers having a low procedural volume (<10 procedures per year). As observed in other surveys, mechanical rotational sheaths are the most frequently tool used, with current management techniques closely resembling what is described in current guidelines. Results from this survey could be used as guidance towards the creation of a future prospective registry which could allow comparison of clinical outcomes using different extraction techniques and the implementation of quality improvement strategies.

Tables and Figures

Name of the institution you most of the time work in (OQ)	In which country do you live in? (MC, SA)	What is your specia

Table 1: Survey questions and type of answer expected. Abbreviations: OQ: open question; MC: Multiple choice; SA: single

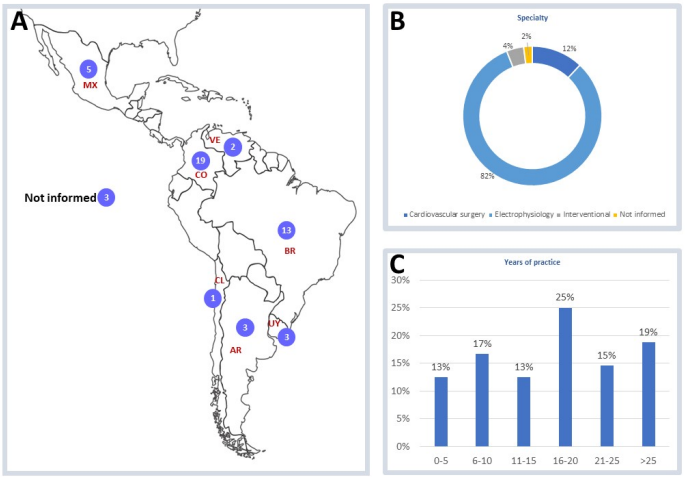

Figure 1. A: Number of respondents per country.Although answers from several countries were received, the majority of respondents were either from Colombia or Brazil. Most respondents were electrophysiologists (B), with 70% having more than 10 years of experience. Abbreviations: MX: Mexico; CO: Colombia; VE: Venezuela; BR: Brazil; CL: Chile; AR; Argentina; UY: Uruguay.

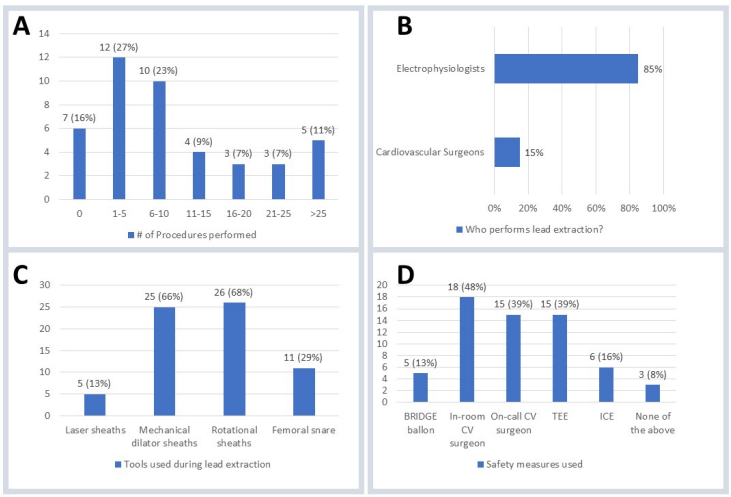

Figure 2. Information from 44 different institutions was obtained. A: Number of procedures performed per institution. B: In most institutions, lead extraction is performed by electrophysiologists. C: Most institutions rely on mechanical lead extraction tools, with only 5 institutions (13%) using laser powered sheaths. D: Safety measures used during lead extraction procedures. Eighty-seven percent of respondents reported cardiovascular surgeons were present either in room or on call within the institution. Abbreviations: CV: cardiovascular; TEE: transesophageal echocardiography; ICE: intracardiac echocardiography.

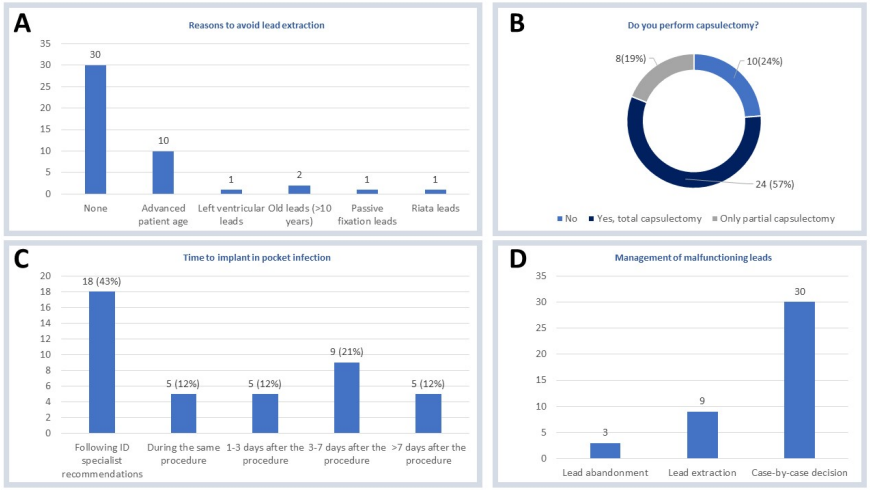

Figure 3. Respondents' answers to proposed clinical scenarios, including reasons to avoid lead extraction (A), use of capsulectomy during lead extraction procedures in device related infections (B), time to reimplantation in pacemaker dependent patients who have isolated CIED pocket infection (i.e., without bacteremia or endocarditis) (C) and approach to patients with malfunctioning pacemaker or ICD leads. Abbreviations: ID: infectious disease; CIED: cardiac implantable electronic device; ICD: implantable cardioverter defibrillator.

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