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Cardiac surgeon and electrophysiologist shoulder-to-shoulder approach: Hybrid room, a kingdom for two. A zero mortality transvenous lead extraction single center experience☆

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ABSTRACT

Background: Nowadays, transvenous lead extraction (TLE) is considered an essential technique in lead management strategy. Since 2011, a multidisciplinary approach was undertaken in our centre involving electrophysiologists, cardiac surgeons and anaesthesiologists to improve cross- unit cooperation and minimize complications and mortality. The present paper reports procedural outcomes and complications of our lead extraction experience.
Methods: We retrospectively collected and analysed data from all consecutive patients undergoing cardiac implantable electronic device leads TLE at the IRCCS Centro Cardiologico Monzino between January 2011 and November 2017.
Results: One-hundred fifty patients (111 males, 68 ± 13 years) underwent extraction procedures. The most common extraction indication were infections (86.7%) and TLE was carried out by laser-based approach in 88 (58.6%) patients, by mechanical dilating sheaths in 58 (38.7%) patients and by a combined approach (TLE + open surgical intervention) in 4 (2.7%) patients. Procedural success was obtained in 146 (97.3%) cases with only 3 (2.0%) major complications with 2 cases of structural injury with tamponade requiring emergent median sternotomy. Open surgery extraction was required in 4 patients, after an attempt to TLE, due to leads strict adhesion to cardiac or vascular structures, whereas in 5 (3.3%) cases, the treatment of choice was a combined approach consisting in transvenous leads extraction followed by planned surgery.
Conclusions: TLE is a complex procedure that sometimes leads to fatal complications. In our single center experience, a multidisciplinary approach involving electrophysiologist, cardiac surgeon, anaesthesiologist in an operating room allows a safer approach and major complications treatment.

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1. Introduction

In the last decade, the use of cardiac implantable electronic devices (CIEDs) has been constantly increasing, especially for cardiac resynchronization therapy. Those devices have strongly helped in improving the quality of life and reducing the incidence of sudden cardiac death in selected patient populations [1,2]. However, the dark side of the medal has been a consensual increase in CIED-related complications and need for extraction as well, mainly due to new devices complexity, higher-risk patients and lead malfunctions.

Nowadays indeed, around 30,000 devices extraction are required worldwide, being infection the leading cause shortly followed by lead malfunction. Deshmukh A. et al. reported a rise in infection-related lead extractions from nearly 30% of overall extraction in 2006 to about 50% in 2012, while lead extraction for other causes decreased from 70% to 50% in the same period of time [3].

Since the first procedures in the 1980s the extraction technique has evolved and transvenous lead extraction (TLE) has become the choice treatment in case of CIED-infection or malfunction. Several studies have reported a 95% success rates, but it still remains a challenging

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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procedure with a high rate of procedural risks, generally related to either sudden-onset tamponade or hemothorax [4,5]. Peri-operative mortality has been especially correlated with device infection [6–8]. Since the number of TLE procedures is going to increase, a safer approach has been recommended [9].

The 2017 TLE consensus guidelines strongly highlight the importance of a collaborative and multidisciplinary team approach to properly address the lead extraction management to optimize safety and efficacy [9]. Coordination with cardiac surgeons plays a pivotal role in ensuring that, being most of the peri-procedural deaths related to the lack of an emergency surgical intervention [10].

A survey of Heart Rhythm Society found that 25% of extraction procedures are done without a willing surgeon or an operating room on standby [11].

Since early 2011, a multidisciplinary approach was undertaken in our centre involving electrophysiologists, cardiac surgeons and anaesthesiologists, to improve cross- unit cooperation and minimize complications and mortality. The present paper reports procedural outcomes and complications of our lead extraction experience using this novel multidisciplinary approach.

2. Methods

We retrospectively collected and analysed data from all consecutive patients undergoing CIED leads TLE at the IRCCS Centro Cardiologico Monzino between January 2011 and November 2017.

Patients with recently lead implantation (less than one year), requiring lead removal by simple traction, were excluded from our analysis.

Lead extraction procedure was defined in accordance with the current Heart Rhythm Society (HRS) TLE consensus statements and 2018 European Heart Rhythm Association (EHRA) expert consensus statement [9,12,13]. Complete procedural success was defined as the removal of all lead material from the vascular space with no permanent or disabling complications. Clinical procedural success was determined as the removal of all targeted leads with retention of no more than a small portion of lead material (<4 cm) that does not cause any undesired outcome. Procedural failure was defined as inability to reach either complete procedural or clinical success. Major and minor complications have been defined as 2009, 2017 HRS and 2018 EHRA expert consensus statements [9,12,13].

All patients were well apprised about the technical complexity and risk of life-threatening complications and signed a written informed consent after a thorough discussion about the advantages and risks of the procedure. Demographic, clinical, and procedural data of all our cases were collected after the Institutional Review Board approval of the study.

2.1. Extraction team patient evaluation

Every case was collegially discussed during scheduled meetings by electrophysiologists, cardiac surgeons and anaesthesiologists to establish the most suitable lead removal approach.

Patient's medical history and therapy were reviewed with special consideration for antibiotics and oral anticoagulant therapy. Antero-posterior and latero-lateral chest radiography was examined to assess heart, lungs and lead features. In case of previous cardiac surgery, a computerised axial tomography was used to better study cardiac anatomy. Transthoracic and trans-oesophageal echocardiography were requested in all cases before lead removal; a rule-out evaluation for valvular diseases and endocarditis was performed through those two examinations, recording valvular regurgitation degree and vegetation localization and size. Heart contractility was also assessed through a left ventricle ejection fraction (EF) analysis. In all infection-driven TLE, complete blood analysis and hemocultures were used to identify the pathogen and its antibiotic sensitivity; a consult with an infectious disease specialist was required in all cases to choose the proper antibiotic therapy regimen and duration. A valid type and screen test was done before surgery and packed red blood cells were set available prior to the procedure, in case of complications requiring transfusion.

Then, the Extraction Team classified patients in two categories according to risk factors, comorbidities and clinical picture: *class 1*, patients with indication to a totally percutaneous lead extraction, and *class 2*, patients with indication to a combined procedure which includes TLE and elective cardiac surgery. The workflow process has been reported in Fig. 1. According to this flow chart, an elective open surgical procedure could be considered in case of large endocardial vegetation (>4 cm), severe tricuspid valve regurgitation requiring valve repair or replacement, severe thrombosis or total occlusion of venous access and high risk of superior vena cava injury, and extra-anatomic or damaged leads with cable externalization (i.e. Riata leads) that increase the technical difficulty of the procedure. Moreover, timing and need for the subsequent re-implantation of PM or ICD was decided according with Extraction Team opinion and HRS guidelines [9].

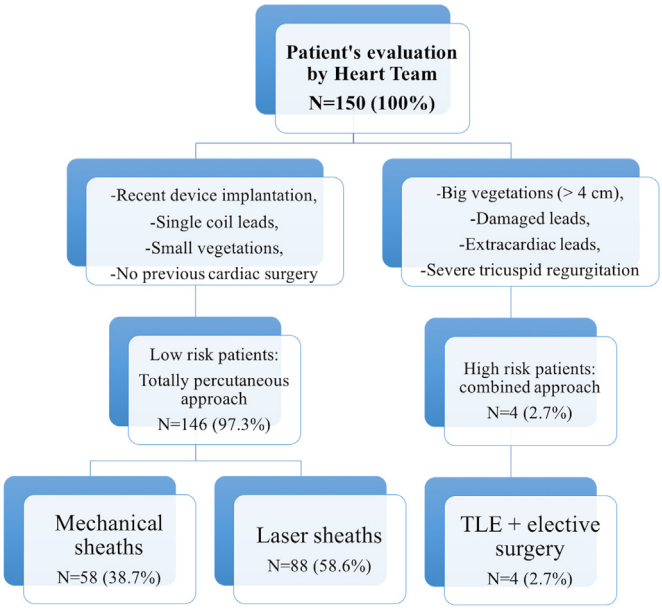

Fig. 1. Patient's evaluation flow chart as performed by our Heart Team. TLE: transvenous lead extraction.

2.2. Intraoperative management

All procedures were performed by Extraction Team members in the hybrid operating room under general anaesthesia. The plans of the hybrid room, staff position and instruments location have been represented in Supp. Fig. 2.

Invasive arterial pressure monitoring was obtained before anaesthesia induction in all cases; central vein catheter was placed by the anaesthesiologist for rapid drug administration, usually through the right internal jugular vein. Patients were prepared and draped to allow the cardiac surgeon to obtain immediate access for median sternotomy incisions, when it needed. A femoral venous sheath was used for temporary pacing, while other two femoral lines, one arterial and one venous, were placed in case of rapid need for extracorporeal circulation. A cardiopulmonary by-pass circuit with a staff perfusionist was also kept available in the room. Advanced monitoring with trans-oesophageal or intracardiac echocardiography (ICE) was used to quickly find out pericardial or pleural effusions and evaluate fractured leads, valvular abnormalities and cardiac anomalies.

All procedures were performed under fluoroscopic guidance.

After induction of general anaesthesia, electrophysiologist and cardiac surgeon together were responsible for device pocket opening, leads preparing for the extraction and for ensuring the correct exposure of the site to guarantee the passage of mechanical dilating sheaths, laser or other extraction tools. Scar tissue from the pocket and part of the device were collected and send to laboratory.

Whenever possible, the electrophysiologist performed the extraction from the implant site with simple traction, using a standard non-locking or locking stylet (Liberator® Locking Stylet Cook Medical Inc., Bloomington, Indiana, USA; or LLD Lead Locking Device Spectranetics Corporation, Colorado Springs). In the event of excessive fibrosis, laser sheath (GlideLight™ laser sheath Spectranetics Corporation, Colorado Springs) was utilized to separate the fibrotic lead from the scarring tissue. In some instances, a femoral approach was used when extraction could not be accomplished through the prior implantation site of the transvenous lead. During the whole percutaneous approach, the cardiac surgeon was physically on site already scrubbed in, ready to start an emergent operation at any needed time.

2.3. Infective management

Pre-operative blood cultures, prosthetic materials (PM/ICD generator and leads), and PM pocket tissue samples were collected and shared with the infectious disease specialist consulting for the Extraction Team. The samples, with the exception of blood cultures, were processed and inoculated on blood agar and chocolate agar plates, schaedler agar and in 7 ml thioglycolate broth (BD Diagnostic Systems). The prosthetic materials were first inoculated in thioglycolate. Blood cultures were processed by BacT/Alert® 3D System (BioMérieux) and blood collected in FA bottles for aerobic, in FN bottles for anaerobic research. Colonies of microorganisms growing on plates were identified and their susceptibility to antibiotics tested, using standard microbiological techniques. Bacterial identification and sensitivity test were performed both with automated and manual instruments. Antibiotics therapy regimen and length was chosen collegially taking the results into account.

2.4. Statistical analysis

Our study had a descriptive purpose, therefore no comparisons or correlations analysis have been run. Descriptive statistics have been analysed by using Statistics version for Macintosh 24.0 (SPSS, Chicago, IL). Categorical data was presented as numbers and percentages, while continuous data was expressed as mean value ± standard deviation (SD).

3. Results

3.1. Baseline population

From January 2011 to November 2017, a total of 216 consecutive patients were included into a dedicated database. Of these, 66 patients requiring simple lead traction were excluded, leading to a final study population of 150. Baseline clinical characteristics and lead extraction indications of the study population are summarized in Table 1. Mean age of our population was 68 ± 13 years and 111 (74.0%) patients were males. A full blown diabetes condition was present in 40 (26.7%) cases and severe renal impairment in 68 (45.3%) cases.

Considering heart structural diseases in patient past medical history, ischemic dilated cardiomyopathy (31.3%) was the most common heart disease, followed by valvular diseases (28.7%) and non-ischemic dilated cardiomyopathy (23.3%).

The most common extraction indication (86.7%) was infections, of which 29.2% were endocarditis.

3.2. Procedural outcomes

Preoperative pacing system information, extracted leads and history of previous device revision are reported in Table 2.

A total of 321 leads were extracted, 129 (40.2%) leads from the atrial chamber, 149 (46.4%) from ventricular chamber and 43 (13.4%) from the coronary sinus. 53 (35.3%) were pacemaker devices, 81.1% of which were dual chamber pacing system. There were also 97 (64.7%) implantable cardiac defibrillation systems, including 45.3% cardiac resynchronization devices. In 22 (14.7%) patients an extraction procedure had already been performed. The mean time from implantation to extraction was 7.3 ± 4.4 years.

The effectiveness of TLE and peri-procedural complications are presented in Table 3.

According to our flow chart, a laser-based approach was chosen in 88 (58.6%) patients, while mechanical dilating sheaths were used in 58 (38.7%) patients and combined approach based on TLE followed by open surgical interventions in 4 (2.7%) patients.

Procedural success was obtained in 146 (97.3%) cases, out of which 3 (2.0%) were clinical procedural success.

Only 3 (2.0%) cases presented major complications, being 2 cases of structural injury with tamponade (1 right atrial tear and 1 left subclavian vein tear), requiring emergent median sternotomy and repair in cardiopulmonary bypass and one case of pericardial effusion requiring pericardiocentesis (Table 3).

After an unsuccessful TLE, open lead extraction was required in 4 (2.7%) patients due to leads strict adhesion to cardiac or vascular structures that could not be released neither with mechanical nor laser sheaths (Table 3). In other 5 (3.3%) cases, the treatment of choice was a planned combined approach consisting in transvenous leads extraction followed by cardiac surgery. In detail, one of those patients required tricuspid annuloplasty, another one tricuspid valve replacement, two patients surgical removal of large endocarditic vegetation (>4 cm) and one patient required ventricular plasty for a known RV lead perforation before the lead extraction (Supp. Fig. 2, Video 1). Despite the high-risk population, procedural and in- hospital mortality rate was zero.

Table 1
Demographic and clinical data of patients admitted for lead extraction (overall population: n = 150).

Variables	
Age, years ± SD	68 ± 13
Male, n (%)	111 (74.0)
Diabetes, n (%)	40 (26.7)
Medical history	
Non-ischemic dilated cardiomyopathy, n (%)	35 (23.3)
Ischemic dilated cardiomyopathy, n (%)	47 (31.3)
Arrhythmogenic cardiomyopathy, n (%)	8 (5.3)
Ischemic cardiomyopathy, n (%)	11 (7.3)
Hypertrophic cardiomyopathy, n (%)	3 (2.0)
Myocarditis, n (%)	1 (0.7)
Brugada syndrome, n (%)	2 (1.3)
Valvular heart disease, n (%)	43 (28.7)
Clinical presentation	
Severe chronic renal failure, n (%)	68 (45.3)
Cerebrovascular disease, n (%)	14 (9.3)
Immunodeficiency disease, n (%)	10 (6.7)
Oral anticoagulation therapy, n (%)	64 (42.7)
Antiplatelet therapy, n (%)	64 (42.7)
Indication for lead extraction	
Infective, n (%)	130 (86.7)
Endocarditis, n (%)	38/130 (29.2)
Lead malfunction, n (%)	19 (12.6)
SVC occlusion, n (%)	1 (0.7)

Abbreviations: SVC, superior vena cava.

Table 2
Lead and device characteristics (total leads: n = 321, overall population: n = 150).

Variables	
Atrial lead, n (%)	129 (40.2)
Ventricular lead, n (%)	149 (46.4)
PM lead, n (%)	58/149 (38.9)
Single-coil ICD lead, n (%)	73/149 (49.0)
Dual-coil ICD lead, n (%)	18/149 (12.1)
Coronary sinus lead, n (%)	43 (13.4)
Extracted lead body dwell time, (y ± SD)	7.3 ± 4.4
Method of fixation	
Active, n (%)	132 (47.5)
Passive, n (%)	146 (52.5)
Recalled leads	
Riata leads, n (%)	5 (1.6)
Sprint fidelis, n (%)	2 (0.6)
Preoperative pacing system	
PM, n (%)	53 (35.3)
PM-V, n (%)	7/53 (13.2)
PM-D, n (%)	43/53 (81.1)
CRT-P, n (%)	3/53 (5.7)
ICD, n (%)	97 (64.7)
ICD-V, n (%)	12/97 (12.4)
ICD-D, n (%)	41/97 (42.3)
CRT-D, n (%)	44/97 (45.3)
Previous device revision	
Generator replacement, n (%)	55 (36.7)
Device upgrading, n (%)	16 (10.7)
Pocket revision, n (%)	51 (34.0)
Previous lead extraction, n (%)	22 (14.7)

Abbreviations: PM, pacemaker; ICD, implantable cardioverter defibrillator; V, ventricular; D, dual chamber; CRT-P, cardiac resynchronization pacemaker; CRT-D, cardiac resynchronization therapy defibrillator.

Table 3
Transvenous lead extraction procedural data and outcomes (overall population: n = 150).

Variables	
TLE techniques	
Laser sheaths, n (%)	88 (58.6)
Mechanical sheaths, n (%)	58 (38.7)
TLE approaches + surgery, n (%)	4 (2.7)
TLE efficacy	
Success, n (%)	146 (97.3)
Complete procedural success, n (%)	144 (96.0)
Clinical procedural success, n (%)	3 (2.0)
Failure, n (%)	4 (2.7)
Complications	
Major complications, n (%)	3 (2.0)
Cardiac avulsion requiring thoracotomy, n (%)	2 (1.3)
Vascular or cardiac avulsion requiring pericardiocentesis, n (%)	1 (0.6)
Death, n (%)	0 (0)
Minor complications, n (%)	7 (4.7)
Pericardial effusion, n (%)	6 (4.0)
Pulmonary embolism, n (%)	1 (0.6)
Cases of surgery	
Bail-out surgery approach	6 (4.0)
Major complications requiring emergent thoracotomy, n (%)	2 (1.3)
Sternotomy after failed removal for tight adhesion to the tissue, n (%)	4 (2.7)
Planned surgery approach	5 (3.3)
Planned thoracotomy to remove big vegetation and repair TV, n (%)	4 (2.7)
Combined approach for known RV lead perforation, n (%)	1 (0.6)

Abbreviations: TLE, transvenous lead extraction; TV, tricuspid valve; RV right ventricle.

4. Discussion

In recent years, CIEDs have become part of the state-of-the-art-procedures used all around the world to increase prognosis and quality of life of patients suffering from many different cardiac conditions. The medical expertise required to properly deal with these devices also includes being able to take on associated complications so this necessity has put TLE technique right in the spotlight. In many cases of device related complications, there is not possibility of conservative approach but only a chance of device extraction (e.g. septic shock, lead/valvular endocarditis); fast and proper removal of the device, leads included, might indeed represent the tip of the balance between life and death of the patient.

To date, TLE technique appears to be the preferred approach for lead management. The sheer amount of TLE procedures performed is already impressive but it is expected to increase in the next future, reaching up to 5000 case/year in Europe and 30.000 cases/year worldwide [14,15].

Despite the development of extraction sheaths and good success rate obtained with transvenous approach, TLE procedures may still result in major cardiovascular complications such as vascular tears, myocardial perforations and death [10,16]. Diemberger et al. have published a meta-analysis of a 15 years lead extraction experience with over 13.000 patients enrolled and have reported 1.7% of major complications and 0.3% of death [17]. Moreover, a non-randomized European multicentre study of excimer laser-assisted lead extractions reported a 5.1% complication rate, including 10 non-fatal vascular and cardiac perforations [18].

Other studies have shown that risks of TLE depend on patient general status and lead characteristics but especially on the physician experience performing the procedure [19,20].

Still, a Heart Rhythm Society survey, performed in 2009 in the United States, found that just 19% of physicians performing TLE have an experience of at least 50 extractions a year, and that 25% of procedures are done in a catheterization laboratory without a surgeon specifically identified or an operation room on standby. Whereas 36% of cases were performed in an operating room [11].

In this paper we describe our single-centre experience, based on a multidisciplinary team approach involving both electrophysiologist and cardiac surgeon as first line operators.

Despite the heterogeneity and the complexity of our study population, we have achieved an overall procedural success of 96.0% with 2.0% of major complications and zero mortality rate.

These results have been achieved through several small but important adjustments introduced in our daily practise.

First of all, a multidisciplinary Extraction Team was assembled: patients in our experience presented multiple comorbidities and various medical conditions requiring an all-around evaluation. All three medical branches (electrophysiologists, cardiac surgeons and anaesthesiologists) were involved since the beginning in the decision making process, in order to risk-stratify patients and cooperatively approach all the clinical issues that the single specialist alone would not be able to solve or, sometimes, even to recognise.

Collegial discussion performed for each case, prior to patient treatment, represented a moment of different knowledge and mind-set integration required to guarantee procedural success and patient safety. Other hospital figures such as nurses, perfusionists and radiologists should also be included in this cross-specialty collaboration in order to obtain a shared knowledge of the whole team.

It is also important to remind that TLE is an invasive procedure and success rate has been mainly associated with operators' experience, coming from a good knowledge of TLE technique [19,20]. TLE should be considered as a specific procedural branch.

An adequate multi-step approach is also needed. Pre-procedural examinations, such as computed tomography and transoesophageal echocardiogram, are fundamental to identify areas of lead adhesions, cardiac perforation or to evaluate big vegetation and tricuspid valve damage to plan the best management choosing between totally percutaneous or combined approach (TLE associated with elective surgery).

Thanks to our experience, we strongly encourage a shoulder-to-shoulder approach between the electrophysiologist and the cardiac surgeon that share the procedure since the beginning, alternating their role being leader operator or support.

In our daily practise, device pocket is initially approached surgically in order to gain a faster and cleaner access to the device and to the leads; then according to pre-operative evaluation a totally percutaneous or a combined approach is performed.

In case of a totally percutaneous TLE, the electrophysiologist proceeds liberating and removing with mechanical or laser extraction sheaths the device leads. In the meanwhile, the cardiac surgeon does not have a passive role but constantly helps the electrophysiologist interpreting fluoroscopy imaging, chest and heart anatomy and assessing the risk of perforation during all the procedure.

Furthermore, performing a standardized procedure in an operating room allows to avoid unnecessary transport, prepping and draping the patient for cardiac surgery, saving time and increasing survival chances in the event of complications.

In our experience, a bail-out surgery approach was used in 6 cases, and in 2 of these the presence of the surgeon proved to be invaluable, containing the vascular complications quickly like in a “damage control trauma surgery”, an idea first introduced by Caniglia-Miller et al. [21] who underling the importance of preoperative preparation, immediate sternotomy, control of haemorrhage, injury definition and careful repair.

Moreover, our experience seems to agree with the study of Gaca et al. [22] who have described a clear improvement in their TLE outcomes when the cardiac surgeon was present in the operating room during laser lead extraction, underling the importance of a surgical team specifically prepared for TLE complications.

4.1. Limitations

This study faces some limitations; first, it is a single-centre and retrospective study and does not provide an overview of TLE safety and efficacy across multiple centres. In addition, despite the relatively small patient sample size due to strict observation of our operating procedure,

our results support the hypothesis that a multidisciplinary technique is safe and should be widely used in most centres. Our study provides an additional resource for the wider introduction of the hybrid operating room for rapid complication management in TLE procedure.

5. Conclusions

Despite new technologies, such as leadless pacemaker and subcutaneous ICD, TLE will still be used for many years to come, especially dealing with old devices. Therefore, mastering this procedure and being able to perform it in the safest and best protected environment will be a cornerstone in the proper management of those situations. TLE requires training and experience to consistently guarantee safe and effective care, and cannot be performed by a single operator but requiring instead a whole team being to work as one. This might require time, therefore simulator training, proctorship and fellow programs are recommended, however the simplest way to increase TLE results is a well- known multidisciplinary approach in an environment with appropriate education of the supporting staff.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.12.074.

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Conflict of interest

The authors declare no relationships with industry.

Ethical approval

The study was approved by the Institutional Review Board of Centro Cardiologico Monzino IRCCS.

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