

# 2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS

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## Keywords

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## Introduction

The number of cardiac implantable electronic device (CIED) implantations has increased over recent years<sup>1,2</sup> as a result of population growth, increasing life expectancy, adoption of guidelines, and better access to healthcare. Transvenous lead extraction (TLE), as a part of an overall lead management strategy, has also been increasing, not only as a consequence of this growth, but also because of increasing rates of infection,<sup>3</sup> lead failure, awareness of indications for lead management, and development of extraction tools. Clinical research is essential for understanding efficacy and risks of TLE, which has important implications regarding decision-making and therapeutic strategies in patients who are candidates for this procedure. Data on TLE have mainly come from retrospective series, with variable reporting of endpoints. Recently, the ELECTRa registry conducted by the European Heart Rhythm Association (EHRA), has reported the largest prospective experience on lead extraction published to date in 3555 patients recruited from 19 European countries.<sup>4</sup> There remain unresolved issues, which is a strong incentive for conducting further specifically-designed clinical trials to answer important questions in this area. In addition to clinical studies, national registries are potentially useful for evaluating epidemiology of TLE as well as for quality control and understanding resource implications. Standardization of definitions and reporting of parameters are paramount in order to analyse, compare, and pool data for scientific purposes. Expert consensus statements on lead extraction have been published by the Heart Rhythm Society (HRS) in 2009<sup>5</sup> and 2017,<sup>6</sup> and by EHRA in 2012.<sup>7</sup> Experience from the ELECTRa registry has been valuable for identifying challenges faced with conducting scientific studies in this field, and provides a framework for future endeavours.

This writing group has been commissioned by EHRA to provide recommendations for designing scientific studies, reports and registries relating to lead extraction.

## Indications for lead extraction

In order to clarify the indications for lead extraction the following definitions are proposed (see *Table 1*).

### Infection

This was the most frequent indication for TLE in the ELECTRa registry amounting to 52.8% (of which approximately two-thirds were local infections).<sup>4</sup> Several entities exist, which should be specified.

#### Isolated pocket infection

This is defined as an infection limited to the generator pocket or along the lead course. It is clinically associated with local signs of inflammation, including erythema, warmth, fluctuance, wound dehiscence, tenderness, or purulent drainage, with negative blood cultures.<sup>8–10</sup> This entity should be differentiated from *superficial incisional Infection*, which involves only skin and subcutaneous tissue without communication with the pocket (and may not require lead extraction).

#### Isolated pocket erosion

This is a chronic process whereby the device and/or lead(s) are exposed through the skin, with or without local signs of infection

(the device should however be considered infected, whatever the mechanism for erosion). Very often the erosion is preceded by the adherence of the skin on the device with a concomitant browning and thinning of the skin. Erosion is usually indicative of infection. Blood cultures are negative, and some of these patients are asymptomatic, while others complain of local pain.

### Bacteraemia

In presence of positive blood cultures with or without systemic infection symptoms and signs.

### Pocket infection with lead/valvular endocarditis

Local signs of pocket infection and positive blood cultures and lead or valvular vegetation(s). The 2015 European Society of Cardiology (ESC) modified Duke Criteria<sup>8</sup> have been used to define endocarditis. It should be noted that these criteria are used to define valvular endocarditis. For CIED-related endocarditis, additional criteria might be

**Table 1** CIED-related infection types

Clinical scenarios	Infection types	Definitions
Superficial incisional infection	Superficial local	Involves only skin and subcutaneous tissue
Isolated pocket infection	Local	Clinically associated with local signs of inflammation at the generator pocket or along the lead course, including erythema, warmth, fluctuance, wound dehiscence, tenderness, or purulent drainage, with negative blood cultures <sup>8–10</sup>
Isolated pocket erosion	Local	Device and/or lead(s) are exposed through the skin (the device should however, be considered infected, whatever the mechanism for erosion)
Bacteraemia	Systemic	Positive blood cultures with or without systemic infection symptoms and signs
Pocket infection (open or closed) with bacteraemia	Systemic	Local signs of pocket infection and positive blood cultures, without lead or valvular vegetation(s)
CIED-related endocarditis without pocket infection	Systemic	Bacteraemia and lead or valvular vegetation(s), without local signs of pocket infection
Pocket infection with lead/valvular endocarditis	Systemic	Local signs of pocket infection and positive blood cultures and lead or valvular vegetation(s)
Occult bacteraemia with probable CIED infection	Systemic	Bacteraemia without an alternative source

CIED, cardiac implantable electronic device.

considered, such as positive cultures of the extracted lead in case of negative blood cultures, presence of lead vegetations, and abnormal metabolic activity around the CIED generator and/or leads detected by  $^{18}\text{F}$ -fluorodeoxyglucose (FDG) positron emission tomography (PET)/computed tomography (CT) or radiolabelled leucocytes single-photon-emission computed tomography/CT.

### Pocket infection with bacteraemia

Local signs of pocket infection and positive blood cultures, without lead or valvular vegetation(s).

### Cardiac implantable electronic device-related endocarditis without pocket infection

Bacteraemia with or without lead or valvular vegetation(s), and without local signs of pocket infection.

### Occult bacteraemia with a presumable cardiac implantable electronic device infection

Bacteraemia without an obvious source other than the CIED. After extraction, disappearance of bacteraemia is expected.

## Lead dysfunction

In case of lead dysfunction, there is the option of abandoning the lead or extracting it (e.g. to reduce intravascular lead burden or regain access in the presence of venous occlusion). Lead dysfunction was the second most frequent reason for lead extraction in the ELECTRA registry, amounting to 38.1% of cases.<sup>4</sup> Causes for lead dysfunction may be lead fracture or insulation failure resulting in issues with lead impedance, sensing or capture. In some cases, the electrical parameters may still be normal, but the integrity of the lead is clearly compromised (e.g. inside out cable externalization of Riata leads, radiological evidence of subclavian crush etc.).

## Abandoned functional leads

There are a variety of situations where a functional lead may no longer be required, with the option of either abandoning or extracting the lead. Examples are upgrades from a pacemaker to an implantable cardioverter-defibrillator (ICD), downgrading from dual- to single-chamber systems, lead recall with prophylactic revision, system relocation for radiotherapy, lack of device indication etc. These abandoned leads may be extracted to reduce the intravascular lead burden in order to avoid future issues (see *Table 2*).

## Lead-related complications

Leads may be functional but cause complications for which extraction may be indicated (e.g. thromboembolic events, superior vena cava syndrome, arrhythmias, perforation, lead-lead interaction etc.). If stenting is planned for treating stenosis in a vein with a transvenous lead, extraction is usually performed to avoid entrapment of the lead.

## Venous access issues

Up to 25% of patients with transvenous leads develop some degree of stenosis,<sup>11</sup> which may later hinder additional lead implantation (e.g. in case of upgrades). There are a number of different management strategies,<sup>12</sup> which include tunnelling a contra-lateral lead across the

**Table 2** Definitions of terms for non-infected leads

Non infected leads	Definitions
Lead function	Any lead function, including pacing, sensing, and/or defibrillation
Lead failure	Loss of any lead function
Non-functional lead	Lead not usable for pacing and/or defibrillation due to loss of functional integrity
Abandoned lead	Lead left in place in the heart and not connected to a CIED. It may be functional or non-functional. 'Redundant' lead is sometimes used to describe an abandoned lead
Recall	Firm's removal or correction of a marketed product that the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA) consider to be in violation of the laws it administers and against, which the agency would initiate legal action. Recall does not include a market withdrawal or a stock recovery
Class 1	Dangerous or defective products with reasonable probability of causing serious health problems or death (e.g. short circuit without warning)
Class 2	Products that might cause a temporary health problem, or pose a slight threat of a serious nature (e.g. premature battery depletion)
Class 3	Products that are unlikely to cause any adverse health reaction, but that violate FDA or EMA labelling or manufacturing regulations

CIED, cardiac implantable electronic device.

chest, venoplasty, or lead extraction to provide a channel through which new leads can be implanted.

## Access to magnetic resonance imaging

There is evidence that magnetic resonance imaging (MRI) can be safely performed in patients implanted with non-conditional CIEDs, but abandoned or dysfunctional leads are considered to be contraindications (even if an MRI-conditional device is implanted).<sup>13</sup> Therefore, extraction of these leads may be performed in selected cases, with appropriate assessment of the risk and benefits of the lead extraction procedure, in order to allow access to MRI, when no other diagnostic alternatives to MRI are available.

## Chronic pain

Some patients may have severe chronic pain attributed to lead insertion (e.g. due to a periosteal reaction), for which lead extraction may be performed. It is important to recognize that chronic pain may be a sign of an infection.

## Other indications

A number of other rare indications for lead extraction exist, such as prophylactic extraction of leads that due to their design or their

failure pose a potential future threat to the patient if left in place e.g. Accufix leads (Telectronics).

## Approaches, tools and techniques

Lead removal often includes a wide spectrum of tools and techniques, ranging from simple manual traction to multiple procedures and combined approaches (see Table 3).

### Approaches

Most lead extractions are performed using a percutaneous approach as it is less invasive. In specific situations (e.g. high-risk procedures or in case of very large vegetations), an open extraction with sternotomy and cardiopulmonary bypass may be preferred. Some centres perform hybrid approaches that combine percutaneous extraction with minimally invasive surgery or thoracoscopy. The various approaches for percutaneous TLE are detailed below.

#### Superior approach

Most lead extraction procedures begin via the identical route of lead implantation, also known as venous entry or implant vein approaches. If the venous entry approach fails, or in the presence of free-floating leads, an internal jugular venous approach can be used, combining superior and femoral accesses.<sup>14</sup>

#### Inferior/femoral approach

Extraction may be performed with femoral venous access as a primary strategy or as a bailout procedure, using specialized tools.<sup>15</sup>

### Tools and techniques

When reporting data for lead extraction procedures, it is important to be specific regarding the tools and techniques used, as these will have a direct impact on outcome and also on costs. Often, a 'stepwise' approach is used whereby the operator transitions from simple to more complex strategies. Therefore, different tools and techniques may be used during a procedure, even for the same lead. In case of a stepwise approach, it is useful to report the sequence of techniques, which were employed for a given lead.

#### Simple traction

Applying mild pulling force without the use of specialized tools (other than a standard stylet) was used in 27% of patients in the ELECTRa registry,<sup>4</sup> and may be effective for leads with a short dwell time (i.e. time since implant <1–2 years).

#### Locking stylets

These are designed to improve tensile strength to facilitate traction and to stabilize leads. They may be used alone or in combination with other tools such as sheaths.

#### Mechanical non-powered telescoping sheaths

These sheaths are designed for blunt dissection of fibrotic binding sites, using simple manual pushing/rotational force. They are most often composed of polypropylene, but metallic or Teflon (PTFE) sheaths are also available. They may be used alone or with handles that facilitate rotation, and most often with a locking stylet.

**Table 3** Definition of LE approaches, techniques and tools

Type	Definitions
Approach	Defined according to vein used to remove the lead
Transvenous	Percutaneous (closed) lead removal performed through a central vein (subclavian, jugular, and femoral)
Superior approach	Lead removed above the diaphragm
Venous entry site	Lead removed using the implantation venous entry site (right or left subclavian, axillary, cephalic, and jugular vein)
Transjugular	Lead removed using the right internal jugular vein
Inferior approach	Lead removed below the diaphragm (right or left femoral vein)
Surgical	Surgical (open) lead removal. Includes standard sternotomy, minithoracotomy, or hybrid approach
Tools and techniques	Defined according to the tool used
Sheath	
Non-powered	No additional energy (i.e. simple mechanical sheath)
Powered	Additional energy (laser, assisted rotational mechanical, and RFA sheath)
Stylet	Standard, locking
Snares	
Basket	
Deflectable wires	
Lead extenders	
Compression coils	
Occlusion balloons	

LE, lead extraction; RFA, radiofrequency ablation.

#### Powered sheaths

When reporting use of powered sheaths, it is important to specify which type of tool was used, as their mechanism, efficacy and risk profiles may differ. They are used in conjunction with a locking stylet inserted into the lead, which builds a rail upon which the device is advanced. *Rotational mechanical sheaths* are currently hand powered and have a threaded tip which dissects adherent tissue.<sup>16</sup> *Electrosurgical sheaths* use radiofrequency energy to dissect fibrous tissue but are now seldom used. *Laser sheaths* use laser energy delivered circumferentially along the tip of the sheath.<sup>17</sup> As additional tools become available this list should be expanded accordingly.

#### Snares

These are most often deployed via a femoral approach, and may consist of a single or double<sup>15</sup> loop, which can be used for grasping free-floating lead extremities or the lead body (double loop design).

### Baskets

These devices are usually introduced via a femoral approach to grasp free-floating lead extremities, but are seldom used today.

### Lead extenders

These wires are used for grasping conductor cables or lumenless leads in order to be able to use an extraction sheath.

### Compression coils

These tools allow secure binding of locking stylets and the proximal components of the lead to facilitate extraction.<sup>18</sup>

### Occlusion balloons

In case of a vascular tear, these highly compliant balloons are filled with diluted contrast agents to stem bleeding while awaiting surgical bailout.<sup>19</sup>

### Other tools

Tools that are dedicated to other procedures may sometimes be used for lead extraction (e.g. for grasping leads), such as pigtail catheters, deflectable wires, deflectable catheters, biotomes, deflectable sheaths etc.

It is recommended to report the size of the tools used, as these may impact complications (e.g. bleeding at the venous entry site, collateral damage, etc.). However, it is important to realize that tool size may be labelled differently (e.g. mechanical sheath size usually refers to internal diameters, whereas laser sheath size refers to external diameter), and that use of outer sheaths will also impact tool size.

## Procedures and outcomes

To interpret studies, whether prospective randomized trials or retrospective studies, there must be clear and consistent definitions. Since many complications may occur after the patient leaves the procedural venue, appropriate follow-up should be performed. In addition, true informed consent requires each operator to know their own volumes and outcomes. This requires tracking outcomes and being able to report them in a comparable way. Definitions of what constitutes a lead extraction, procedural outcomes and complications have been well delineated in the 2009 and 2017 HRS expert consensus documents on TLE,<sup>5,6</sup> and used in the recently-reported ELECTRA Registry.<sup>4</sup> It will be the goal of this section to keep with existing definitions, to reinforce the importance of consistency.

### Definitions of procedures

A review of the literature demonstrates that the definition of lead extraction has varied widely, which makes subsequent reporting of the utility, safety and efficacy of lead extraction procedures difficult to compare. The removal of a 3-month old lead is clearly different from removing a 20-year old lead. To address this, the 2009 HRS Consensus document<sup>5</sup> created clear definitions for what is, and is not a lead extraction procedure, which have been adopted in the 2017 HRS consensus<sup>6</sup> and also in this document. When classifying a procedure the following definitions should be employed.

### Lead removal

Removal of a pacing lead or defibrillator lead using any technique. This entity includes removal of subcutaneous ICD leads.

### Lead explant

A lead removal using simple traction techniques (no locking stylets, telescoping sheaths, or femoral extraction tools) and all removed leads were implanted within 1 year.

### Lead extraction

Intervention with removal of at least one lead that has been implanted for more than 1 year, or a lead regardless of duration of implant requiring the assistance of specialized equipment that is not included as part of the typical implant package, and/or removal of a lead from a route other than the implant vein. Percutaneous removal of leadless pacemakers may be considered as extraction procedures.

### Definition of success

For scientific purposes, it is important to distinguish success of the procedure as a whole, as well as to gather data on success of extraction of individual leads (e.g. in order to compare results for atrial, ventricular, coronary sinus leads, and for defibrillator vs. pacing leads). The definition of success will depend very much upon follow-up, and can only be assumed in case the follow-up is limited. In case of infected leads, a complete CIED removal is warranted, even if a <4 cm remnant may be accepted according to consensus of opinion. In case of non-infected leads, clinical success may be obtained despite persistence of residual lead tip on imaging. A list of definitions regarding lead- and procedure-related outcome is reported in *Table 4*.

### Complete procedural success

Removal of *all* targeted leads and material, with the absence of any permanently disabling complication or procedure-related death.

### Complete procedural success rate

Procedures where there is complete success, divided by the total number of procedures.

### Clinical procedural success

Retention of a small portion of a lead that does not negatively impact the outcome goals of the procedure. This may be the tip or a small part (<4 cm) of the lead (conductor coil, insulation, or the two combined) when the residual part does not increase the risk of perforation, embolic events, perpetuation of infection, or cause any undesired outcome. Absence of any permanently disabling complication or procedure-related death.

### Procedural clinical success rate

Procedures where there is clinical success divided by the total number of extractions.

### Procedural failure

Inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedural-related death.

**Table 4** Definitions for extraction procedures and outcomes

Terms	Definitions
Lead removal procedure	Removal of a pacing or ICD lead using any technique
Lead explant	Lead removal using simple traction techniques (no locking stylets, telescoping sheaths, or femoral extraction tools) and all removed leads were implanted since <1 year
Lead extraction	Intervention with removal of at least one lead that has been implanted for more than 1 year or a lead regardless of duration of implant requiring the assistance of specialized equipment that is not included as part of the of the typical implant package and/or removal of a lead from a route other than the implant vein
Definition of success	
Lead-related	
Complete lead removal	Lead explant or extraction with removal of <i>all</i> targeted lead material
Incomplete lead removal	Lead explant or extraction where part of the lead remains in the patient's body (vascular or extra-vascular)
Procedure (patient)-related	
Complete procedural success	Removal of <i>all</i> targeted leads and material, with the absence of any permanently disabling complication or procedure-related death
Complete procedural success rate	Procedures where there is complete success, divided by the total number of procedures
Clinical procedural success	Retention of a small portion of a lead that does not negatively impact the outcome goals of the procedure. This may be the tip or a small part (<4 cm) of the lead (conductor coil, insulation, or the two combined) when the residual part does not increase the risk of perforation, embolic events, perpetuation of infection, or cause any undesired outcome. Absence of any permanently disabling complication or procedure-related death
Clinical procedural success rate	Procedures where there is clinical success divided by the total number of extractions
Procedural failure	Inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedural-related death
Procedural failure rate	Extraction procedures that failed divided by the total number of procedures

ICD, implantable cardioverter-defibrillator.

### Procedural failure rate

Extraction procedures that failed divided by the total number of procedures.

### Complete lead removal

Lead explant or extraction with removal of *all* targeted lead material.

### Incomplete lead removal

Lead explant or extraction where part of the lead remains in the patient's body (vascular or extra-vascular).

## Definition of complications

Attribution of complications is more complex as patients may also be undergoing additional procedures at the time of extraction, such as reimplantation (e.g. was the pocket haematoma post-procedure due to the extraction or the reimplantation?). In addition, pre-existing conditions can greatly impact outcomes (e.g. did the patient die 3 days post-procedure as a complication of the extraction or due to the overwhelming sepsis that was the indication for the extraction?). It is important that outcomes be reported as objectively as possible to avoid bias. The attribution of the complication is less important to the patient than the fact the complication occurred. All complications must be documented and traced (a list of possible complications is

shown in *Table 5*). Again, clear definitions help to remove subjective analysis and allow for a clearer understanding of the risks of the procedure. As per the 2009 and 2017 Consensus documents,<sup>5,6</sup> complications are defined by their time in relation to the procedure and their severity.

## Timing

### Intra-procedural complications

Any event related to the performance of a procedure that occurs or becomes evident from the time patient enters the operating room until the patient leaves the operating room. This includes complications related to the preparation of the patient, the delivery of anaesthesia, and opening and closing the incision.

### Early post-procedure complications

Any event related to the procedure that occurs or becomes evident within 30 days following the intra-procedural period.

### Late post-procedure complications

Any event related to the procedure that occurs or becomes evident after 30 days following the intra-procedural period and during the first year.

**Table 5** Complications (table from reference<sup>6</sup>)

	Incidence%
Major	0.19–1.80
Death	0.19–1.20
Cardiac avulsion	0.19–0.96
Vascular laceration	0.16–0.41
Respiratory arrest	0.20
Cerebrovascular accident	0.07–0.08
Pericardial effusion requiring intervention	0.23–0.59
Haemothorax requiring intervention	0.07–0.20
Cardiac arrest	0.07
Thromboembolism requiring intervention	0.07
Flail tricuspid valve leaflet requiring intervention	0.03
Massive pulmonary embolism	0.08
Minor	0.06–6.20
Pericardial effusion without intervention	0.07–0.16
Haematoma requiring evacuation	0.90–1.60
Venous thrombosis requiring medical intervention	0.10–0.21
Vascular repair at venous entry site	0.07–0.13
Migrated lead fragment without sequelae	0.20
Bleeding requiring blood transfusion	0.08–1.00
AV fistula requiring intervention	0.16
Pneumothorax requiring chest tube	1.10
Worsening tricuspid valve function	0.02–0.59
Pulmonary embolism	0.24–0.59

AV, arteriovenous.

## Severity

Complications are divided into major or minor groupings with observations on severity and reversibility. All unexpected occurrences must be documented and tracked. This allows accurate reporting and the ability to monitor quality and subsequent outcomes. An increased incidence in a specific complication must be investigated and a 'root cause' analysis performed. Previously unrecognized complications can be identified, only if all untoward events are tracked.

### Major complications/serious adverse events

Any of the outcomes related to the procedure, which is life-threatening or results in death (cardiac or non-cardiac). In addition, any unexpected event that causes persistent or significant disability, requires inpatient hospitalization or prolongation of existing hospitalization, or any event that requires significant surgical intervention to prevent any of the outcomes listed above.

### Minor complications

Any undesired event related to the procedure that requires medical intervention or minor procedural intervention to remedy, and does not limit persistently or significantly the patient's function, nor does it threaten life or cause death.

## Duration of follow-up

Procedural outcomes are as standard reported for a 30-day period. This helps track acute complications and outcomes directly related

to the procedure, and should be the minimum follow-up duration. Ideally outcomes should be tracked for a much longer period (e.g. 1 year). This would allow for a better understanding of the outcomes related to the underlying indication for extraction (e.g. recurrence of infection) and if an extraction approach has long term sequelae. For example, patients undergoing extraction for a systemic-related device infection have close to a 25% 1 year mortality, despite successful extraction. In addition, preliminary data suggests early extraction for infection improves 1 year survival.

## Database parameters

The quality of any scientific study or registry is principally determined by the quality of the data. As with any project, there is a trade-off between volume/detail of information to be captured, and practicality for the investigators having to enter the data (which will determine compliance). Every effort should be made to standardized items with tick boxes and scroll menus and avoid any free text.

Different database platforms are available. One such platform is Research Electronic Data Capture (<https://projectredcap.org/>), initiated at Vanderbilt University and developed by a multi-institutional consortium. This is a free, secure web-based application that can be used to create centre-specific databases. An advantage of this application is that it allows multisite access, and data can be shared between several institutions.

A list of parameters are detailed below (the necessity of capturing individual parameters will depend upon the purpose of the study/registry), and an example of a case report form is available on the [Supplementary material online](#), Appendix.

## Pre-procedure

- (1) Patient
  - Demographics (age, height, weight, medication etc.).
  - Cardiac and non-cardiac conditions (e.g. prior open heart surgery, left ventricular ejection fraction, New York Heart Association (NYHA) class, presence of ischemic heart disease, atrial fibrillation, renal insufficiency, diabetes, cerebrovascular accident etc.) as these may affect procedural outcome.<sup>20</sup>
  - Indication for the CIED.
  - Pacemaker dependence.
  - Indication for extraction.
  - Antibiotic information should be recorded (type, duration, timing).
- (2) Device and leads
  - Number of leads.
  - Type of device and all leads. The lead consists of the body, conductors, electrodes, insulation, fixation mechanisms, and each of these components can influence the extractability of the lead.<sup>21</sup> It is therefore important that these data are available for analysis. The precise characteristics of an extracted lead may be retrieved if the model is entered in the database (ideally using pull-down lists to avoid errors in data entry, for facilitating analysis, and automatically linking each lead model to the specific characteristics). As an alternative, the main characteristics (e.g. active- vs. passive-fixation, single- vs. dual-coil ICD leads, subcutaneous leads, epicardial leads, or patches etc.) may be captured manually for each lead. The

manufacturer and model for the device and leads should be noted.

- Duration of implant of all leads—as procedural success and complications are related to this factor.
  - Position of leads (right atrial appendage/lateral wall/septum; right ventricular apex/septum/outflow tract; coronary sinus tributary etc.).
  - Presence of problem of leads including externalized conductors, fractured leads, lead fragments etc.
  - Previous attempts at extraction (and the methods used).
- (3) Investigations
- Imaging findings: chest X-ray (analysis of leads, presence of calcifications), echocardiography (cardiac function, tricuspid regurgitation, intra-cardiac shunt, vegetations, pre-existing pericardial fluid etc.), contrast venography/CT (vein stenosis/occlusion, extravascular lead segments etc.), PET/CT etc.
  - Blood tests: renal function, coagulation tests, haemoglobin, platelet count etc. (as these parameters may affect outcome, and in order to compare with post-procedure values), results of blood cultures (if infection is suspected) and pathogens identified.

### Intra-procedure

- (1) Date of procedure.
- (2) Emergent or scheduled procedure.
- (3) Location: operating room, cath/electrophysiology (EP) lab or hybrid lab.
- (4) Anaesthesia (local or general).
- (5) Personnel (in particular whether a cardiac surgeon is scrubbed in or standing by, operator experience, centre annual volume).
- (6) Intra-operative imaging (type of fluoroscopy, transoesophageal and intra-cardiac echocardiography, venography etc.) and their findings (presence of 'ghosts', tricuspid regurgitation, pericardial effusion, intra-cardiac shunt etc.).
- (7) Approaches.
- (8) Specialized tools used (optionally, in which order for each lead).
- (9) Use of accessory tools (temporary pacing wire, guidewire in the superior vena cava etc.).
- (10) Additional interventions performed during the procedure (e.g. pocket debridement, venoplasty, lead abandonment with or without transection of the lead etc.).
- (11) Success of extraction for each lead: complete, partial (<4 cm remains *in situ*), failure (>4 cm remains *in situ*).
- (12) Reimplantation (if applicable): access site, type of device (as this may affect total procedure and fluoroscopy durations).
- (13) Intra-operative complications (tachyarrhythmias, atrioventricular block, pericardial bleeding etc.) and their management. If known, the location of vascular tears or cardiac perforation should be mentioned, as they have an impact on outcome.
- (14) Duration: skin-to-skin, fluoroscopy (including dose).

### Post-procedure

- (1) Monitoring performed.
- (2) Blood tests.
- (3) Post-extraction rhythm management requirements (e.g. wearable cardioverter defibrillator, temporary pacing etc.).
- (4) Reimplantation (date, type of device, access site).
- (5) Date of discharge.
- (6) Post-operative complications (including date and management).
- (7) Reinfection (type and management).
- (8) Duration of follow-up.

## Gaps in evidence

There are numerous gaps in evidence in the topic of lead extraction. Some of the gaps are listed below.

### Management of infected leads

Although in case of infected devices a complete removal is recommended, the following points have to be addressed:

- (1) Defining the role of additional diagnostic tools (PET, intra-cardiac echocardiography) in patients with occult infections.
- (2) Clinical effectiveness of different antibiotic strategies (type of antibiotic and duration of treatment) and their cost-effectiveness.
- (3) Develop a scoring system to assess the risk of serious complications associated with percutaneous removal that will identify a subset of patients for whom an open surgical approach for CIED extraction is recommended).<sup>20</sup>
- (4) Determine the safety of 1-stage contralateral device replacement compared with 1-stage epicardial or delayed device replacement as management schemes in local and systemic infection.
- (5) Timing of reimplantation, duration of antibiotics.
- (6) Evaluate whether open heart surgery is needed in patients with a prosthetic valve and lead/valvular endocarditis, but without an hemodynamic or other valve-related indication for open heart surgery (e.g. valve dysfunction). Also what is a safe vegetation size to be extracted by TLE, versus open surgical removal.

### Management of abandoned and recalled leads

Abandoned or recalled pacemaker and ICD leads create a challenging decision-making process when considering extraction. The main issues are around clearly defining: (i) the risk associated with lead abandonment and (ii) whether the potential benefit of lead extraction outweighs the risk of the procedure. In an analysis of the National Cardiovascular Data Registry (NCDR) ICD Registry, patients undergoing removal of an unused or malfunctioning ICD lead had slightly higher in-hospital complications and deaths than those with a lead abandonment strategy.<sup>22</sup> There are few data on the lead burden that results in venous access issues and superior vena cava syndrome, and consensus documents<sup>5,6</sup> are based on expert opinion as to the numbers of abandoned leads that justify extraction (a total of more than four leads on one side or five leads through the SVC). Other issues with abandoned leads, such as lead-lead interaction, are also not well studied. Collection of information on how leads are abandoned (e.g. trans-section vs. preservation of the lead terminal connector) is important since this has a bearing on future follow-up and extraction attempts. For leads under advisory or recall, surveillance and data collection is essential to aid with clinical decision making.<sup>23</sup> According to the U.S. Food and Drug Administration (FDA), a recall is an action taken to address a problem with a medical device that violates FDA law.<sup>24</sup> Recalls are classified by the FDA to indicate the relative degree of health hazard presented by the product being recalled (Table 2).<sup>25</sup> The EU provides guidance but directives are interpreted by national Competent Authorities and private Notified Bodies.<sup>26</sup> EU member states use a different recall system to the U.S. FDA system, namely the 'Field Safety Corrective Action'.<sup>27</sup> This is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a



medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a Field Safety Notice.<sup>27,28</sup> We recommend the establishment of clinical registries for monitoring device and lead performance in partnership with professional medical organizations, healthcare, academic, and governmental organizations, such as the FDA Manufacturer and User Facility Device Experience (MAUDE) database. This will foster wider surveillance of lead performance and patient outcomes in general. Standardization of terminology and data elements is important for this process. Comprehensive surveillance systems require key elements, such as the Unique Device Identification (UDI) system proposed by the FDA. Creating automated tools for prospective surveillance of CIED performance may improve the ability within a registry to detect previously unrecognized safety problems. This will require coordination and integration of information from multiple sources as proposed by the FDA and other organizations within the Medical Device Epidemiology Network (MDEpiNet) or similar frameworks. Finally, remote monitoring provides a platform from which lead (and patient) survival data can be tracked.

## Data on extraction tools

It is well accepted that the presence of a wide variety of extraction tools is of utmost importance to guarantee maximum patient safety as well as high procedural success rate. Comparison of safety and efficacy of the different tools is problematic, as some devices (e.g. snares) may be used as backup solutions for difficult cases. Nevertheless, multicentre studies are necessary for acquiring data, especially with the introduction of new tools for which sparse data exist (e.g. occlusion balloons<sup>29</sup>).

## Risk stratification

There are a number of risk factors associated with lead extraction procedures. Further research may validate scores for risk-stratification which may help with management strategies.<sup>20</sup>

## Qualifications and training of operators

There continues to be a significant lack of consensus regarding how much training should be required to become proficient in lead extraction. There are guidance documents that recommend extracting a minimum of 40 leads in at least 30 procedures as a minimal requirement for training, with minimum of 15 procedures (extracting at least 20 leads) each year to maintain competency.<sup>5,7</sup> However, it is difficult to acquire competency for the multiple available tools in performing a limited number of cases. It has been shown in a pilot study with eight trainees, that computer-based virtual reality training (with simulation of locking stylets and laser sheaths) can provide an enhanced learning experience, and may improve results.<sup>30</sup> Other types of simulated training are also available using anatomical models and phantoms, which allow measurement of parameters such as traction force at different levels.<sup>31</sup> Simulators may also provide a means to maintain competency for physicians who have a low caseload. More research is however needed to explore training pathways that can improve learning curves and positively impact procedural outcome. Furthermore, performing any number of cases cannot guarantee that an operator is competent to provide safe and effective lead extraction, and currently, there are no true 'hands on' examinations to

evaluate competency. Virtual-reality simulators may provide metrics that can evaluate handling of extraction tools and simulate complications,<sup>30</sup> but their utility will be determined by the fidelity with which they reflect the real-life setting.

## Procedural volume

There is some evidence that the incidence of major complications and death are related to the volume of a TLE centre and the individual experience of the operator.<sup>4,32–35</sup> This volume-outcome relationship is supported by data of the ELECTRa-registry,<sup>4</sup> where the cut-off for defining low- and high-volume centres was 30 procedures per year. The complication rate was significantly different between low- and high-volume centres (4.7% vs. 2.1%, respectively;  $P < 0.01$ ), with lower all-cause mortality in high-volume centres (2.8% vs. 1.2%;  $P < 0.03$ ). However, there was no significant difference in procedure-related mortality. The LExIcon-study<sup>35</sup> differentiated between low-, mid- and high-volume centres based on case numbers over a 4-year period (<60, 60–130, and >130 cases). More data are required to determine cut-off values that are associated with better patient outcome, which may have future regulatory implications.

## Procedural environment

The influence of different procedure rooms (catheterization or EP laboratory, operating room, hybrid operating room) on procedural outcomes is a topic of potential scientific interest. In a large retrospective single-centre study comprising 3258 TLE procedures on the outcomes of emergent surgical or interventional management of major procedural complications, it was shown that mortality was significantly higher, if emergent surgical or endovascular intervention was performed in the EP laboratory than in an operating room (63.6% vs. 14.3%;  $P = 0.01$ ).<sup>35,36</sup> A European Heart Rhythm Association (EHRA) EP network survey published in 2012 revealed that most (60%) TLE procedures at that time were performed in a catheterization laboratory (operating room 26%, hybrid room 14%).<sup>37</sup> In the ELECTRa registry<sup>4</sup> 52% of the procedures were performed in an operating room (catheterization laboratory 38.5%, hybrid room 9.5%). This might reflect a shift in the safety culture of TLE centres or might merely be related to the different participating centres in the two data sets. Further studies addressing the issue of complication management in TLE procedure should certainly investigate the optimal environment for such procedures focusing on safety endpoints.

## Anaesthesia

A further question with lack of solid evidence is the impact of anaesthesia type (general anaesthesia vs. local anaesthesia with or without sedation) on safety outcomes during TLE. Data from the ELECTRa registry revealed an almost even distribution between three anaesthesia types among the participating centres with a slight trend towards preferred use of general anaesthesia (general anaesthesia 38.7%, local anaesthesia 30.6%, sedation 30.7%).<sup>1</sup> Recommendations on TLE procedures do not clearly favour one specific anaesthesia type, but require immediate anaesthesia support in case the procedure is not performed under general anaesthesia.<sup>6,7,38</sup> Further data needs to be gathered and evaluated to clarify this aspect.

## Special patient populations

There exists a strong need to generate a scientific basis for future, evidence-based lead extraction recommendations in special patient populations. Such special patient populations consist of, but are not restricted to paediatric, very elderly, grown-up congenital heart disease patients, and patients potentially requiring open extraction procedures (e.g. lead vegetations greater than 20 mm or leads placed into arterial or extravascular structures). Common to all these special patient populations is the fact that the numbers of such patients in single institutional series, even in high volume centres, are too small to create statistically solid data.

It is of utmost importance to perform future studies based on a data pooling of multiple centres, either in the form of multicentre studies or registries. Ideally, a global lead extraction registry would pool pan-national data, but this is unlikely to happen in the foreseeable future. In this context, a standardization of data collection should be established to allow for complete data acquisition between multiple participating centres. As any interventional procedure requiring individual skill, lead extraction is a difficult setting for planning a randomized clinical trial, but questions about the gaps listed above should minimize bias and provide appropriate answers.

## Conclusions

Scientific societies have published clinical guidelines on TLE and initiated large registries, which are critical to improve our understanding in this domain. However, many questions still remain unanswered regarding TLE, reflecting not only the limited number of randomized trials but also the lack of standards in reporting procedures and complications. These unresolved issues have given a strong incentive for this consensus document. The recommendations are directed to all scientists and healthcare professionals and are pertinent to clinical trials, registries, scientific reports, guidelines, quality assurance, and educational programs. The document also lists numerous gaps in evidence related lead extraction, with the purpose to trigger joint collaboration in scientific trials and registries.

## Supplementary material

Supplementary material is available at *Europace* online.

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