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Devices Series

Pathways for training and accreditation for transvenous lead extraction: EHRA position paper

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Pathways for training and accreditation for transvenous lead extraction: EHRA position paper

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Definitions

Lead removal: Removal of a pacing or defibrillator lead using any technique.

Lead explant: Lead removal using simple traction techniques from venous entry site.

Lead extraction: Removal of a lead that has been implanted for 1 year, or a lead regardless of the 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 via a route other than via the implant vein.

Pathophysiology affecting lead extraction

Infection accounts for approximately two-thirds of all extractions. Lead revisions and generator changes carry a greater risk of infection than new implants. Ageing patients are more likely to be immuno-compromised, to have septicaemia and to be on anti-thrombotic agents and anticoagulants.

All leads should be extracted if the indication is infection. However, residual lead tips or conductor coils, in the absence of insulating materials, rarely prevent full recovery from infection.

Acute thrombus formation and venous occlusion are not uncommon but it is unusual for this to be evident clinically. Leads may suffer from intrinsic malfunction due to shortcomings in design and production. Such malfunction may exist at implant or develop later.
During the chronic phase of lead implant, thrombus may organize, leading to subtotal or total occlusion along the venous route, and formation of fibrous bridges or tunnels containing the pacing lead at points of adherence. The commonest binding sites are located at the venous entry, especially under the clavicle, at the brachiocephalic and/or upper caval vein, the right atrium, by adherence to the tricuspid valve or passage through the papillary muscle network, and finally at the electrode–cardiac interface.

Tools and techniques for lead extraction

Locking style: Locking style within the lumen of the lead spreads the traction forces along the lead body including the tip.

Lead traction: Refers to the pulling force applied on the lead.

Sheaths: Sheaths operate with simple mechanical action (non-powered) or additional power and may be used singly or housed within a second sheath to create a telescoping system. Using traction through a sheath enhances safety as well as success.

Counterpressure and countertraction: Counterpressure is performed by applying simultaneously a forward pressure on the sheath and traction to the lead. Countertraction is performed when the sheath has been progressed to the lead tip-myocardial surface; the traction applied on the lead is opposed and counterbalanced by pushing pressure of the overlying sheath on the endocardium thereby limiting myocardial invagination or avulsion.

Anticipated difficulty–risk of the procedure (Table 2)

Transvenous lead extraction carries risk. Major intra-procedural complications include myocardial avulsion, cardiac tamponade, vascular tear, haemothorax, pneumothorax, and pulmonary embolism. Surgical back-up is mandatory. The experience of the operator and the team is a major determinant of whether and how to go ahead. If the procedure would be best performed in a more experienced centre the patient should be referred.

Prerequisites for lead extraction (Table 3)

As for all procedural techniques there is a learning curve for extraction. To become an independent operator for transvenous extraction requires the ability to master some, if not all of the different extraction techniques in a sufficiently large number of patients of an appropriate case mix.

The recent HRS consensus document recommends extraction of a minimum of 40 leads as the primary operator to be a fully trained extractor, and 20 leads per year to maintain competency. While the Task Force accepts these figures, these numbers do not specify extraction methods, indications, patient-related risk factors, or implant duration.

Recommendations on personnel and roles (Table 4)

The team members should be trained so that they are familiar with the procedure, equipment and potential complications, and emergency response protocols. In each institution, there should be a written protocol for the personnel involved in the lead extraction programme clearly detailing their specific duties during the procedure and their response in case of emergency and for activation of the surgical, anesthesiology, and operating room staff.

Cardiac surgery support

The presence of a cardiothoracic surgical team within the facility is mandatory.

Anaesthesia support

Lead extractions should be performed in an operating room, an electrophysiology or a catheterization laboratory with general anaesthesia or a combination of local anaesthesia and intravenous sedation.

Scrub personel

Lead extraction procedures often require a range of equipment and technologies. In order to safely perform the procedure, a minimum of two 'scrubbed' personnel must be available, the primary operator and an assistant.

Non-scrub personel

Depending on the centre and location of the procedure, two or more 'non-scrubbed' personnel must be available during the procedure. If one of these is responsible for monitoring sedation a third non-scrubbed person must be immediately available to provide equipment and assist in an emergency.

Technical personel

Emergency echocardiography (transthoracic and/or transoesophageal) is required to rapidly diagnose a complication. In high-risk cases transoesophageal echocardiography is recommended.

Recommendations on facility and equipment (Table 5)

Lead extraction procedures must only be performed in hospitals with full cardiothoracic surgical, angiographic, and CIED capacity. The extraction environment will vary between centres and will be affected in part by the wide differences in the systems of health delivery across Europe. Nevertheless, the following conditions should be met.

(1) A full range of extraction tools should be available.

(2) An operating room or procedural laboratory specifically designed for device implantation procedures. The room must be equipped with a ventilation system designed to prevent surgical infections and handle anaesthetic gases, and be of adequate size to allow for emergency intervention.

(3) Equipment and instruments necessary for pericardiocentesis, chest drainage, vascular repairs, thoracotomy, sternotomy, and cardio-pulmonary bypass must be present in the room or immediately available, and in good working order.

(4) High-quality fluoroscopic equipment with image storage, either as an integral part of a lab or a modern mobile C-arm, is essential for safe performance and for visualization of small lead components, sheaths, and guidewires.

(5) External and transvenous temporary pacing equipment must be readied even if the patient is not pacing dependent.

Recommendations for patients with congenital heart disease/paediatric patients

Due to the anticipated small numbers of extractions required for this population, these procedures should be performed by a physician trained in extraction, in close collaboration with a centre accredited for the care of patients with congenital heart disease/paediatric patients. In addition to the requirements for adult patients the service should ensure:

(I) Collaboration with a physician specialized in paediatric/congenital heart diseases. This physician should be on-site during the procedure and provide adequate input and assistance by any means, including being second operator.
(I) The procedure is performed under general anaesthesia, in the operating room with a scrubbed surgeon present in the room and specialized personnel and equipment prepared for paediatric/congenital heart disease cardiac catheterization and surgery.

Patient and site preparation

Pre-procedural preparation and work-up

Pre-procedural preparation and work-up starts with a detailed patient history and complete physical examination. Co-morbidities, such as need for anticoagulation therapy, renal impairment, allergies, and resistance to antibiotics may affect peri-procedural care. To plan the means and route of extraction, the operator has to assess the vascular access used for implantation. Antibiotic use through the period of device extraction, whether infected or not, is dealt with extensively elsewhere. Perioperative anticoagulation therapy should be the same as for heart surgery.

The nature of the underlying rhythm will determine whether temporary pacing is required. Drugs causing bradycardia or atrio-ventricular delay, should if possible, be discontinued pre-operatively. Even if not pacing dependent, bradycardia may be provoked during the procedure and the device should be set so that this is detected (VVI 40). Tachycardia detection must be switched off to avoid rate response and shocks.

Site preparation

If temporary pacing is indicated, to reduce the risk of displacement during the extraction, an active fixation lead is preferable to a passive lead. Continuous pulse oximetry, electrocardiogram, and invasive arterial blood pressure monitoring are mandatory. For reliability and access, the femoral artery is preferable to the radial. Placing vascular sheaths in the femoral vein enable volume, drug, and blood administration, emergency temporary pacing and an insertion route for extraction tools. The echo equipment must be available and online during the whole length of the procedure. Adhesive external antero-posterior cutaneous defibrillating and pacing pads and diathermy pads are applied.

Re-implantation timing, route and technique

The original indications for device implantation may no longer be present and re-implantation may not be required. In patients with non-infectious indications for lead extraction, re-implantation can be performed either during the same session, or shortly afterwards, using the same or alternative venous routes. However, for those patients, in whom infection was present, the new system is usually inserted via the contralateral side.

Intra-operative protocol

Regardless of the pre-operative microbiological results, further sampling is necessary during the procedure.

Microbiology

Cooperation with a microbiology lab and regular consultation with a microbiologist is strongly recommended.

Table 1 Estimated need for transvenous lead extraction

New implants/million/year	Prevalence of infection (%)	Prevalence of extraction (%)	Extractions/million/year
500	1–4	1.5–6	7.5–30
1000	1–4	1.5–6	15–60
1500	1–4	1.5–6	22.5–90
2000	1–4	1.5–6	30–120

Table 2 Lead extraction: factors associated with higher procedural risk

Factor	Criteria	Comments and references
Body mass index	<25 kg/m^2	Related more to size than gender[33,34,43,46]
Co-morbidities	Age, poor LV function, renal failure, coagulopathy, large vegetations	Most of the risk is peri-procedural[13,34,41,47]
Venous status	Occluded or severely stenosed	Higher risk with greater lead cross-sectional area in the young.[48] Limited access for additional procedures[49 – 51]
Congenital heart disease	Complex anatomy	Size, tortuous lead routes, shunts[52,53]
Number of leads	Greater number of leads present or extracted	More lead–lead and lead–tissue interactions[43,54]
Fixation mechanism	Passive	Active fixation safer to extract even if not isodiametric[24,41]
Lead body geometry	Non-isodiametric	Catching on bridging tissues[41]
ICD lead	Coil(s)/complexity	Greater diameter. Uneven surface[11,15,54 – 56] unless coated[57]
Implantation time	Greater than 1 year, rising further thereafter	Time-dependent tissue reaction to leads[11,15,34,41,43,52,55]
Special/damaged leads	Design/provoked deficiencies	Notable examples: Starfix,[58] Accufix, Encor[43,59]

Table 3 Recommendations on minimum training and volume for lead extractor operators and centres			
Lead extraction status	Minimum number of leads	Minimum number of procedures	Additional requirements
Trainee	40 leads under supervision: 10 ICD leads, 10 leads >6 years old	30 10 with ≥2 leads	Full qualification in CIED implantation
Primary operator (trained)	20/year	15/year	
Supervisor trainer	75 total	30/year	
Non-training centre	20/year	15/year	1 primary operator
Training centre		30/year	1 supervisor trainer

Table 4 Required personnel and roles for lead extraction procedures	
Required personnel[a]	Qualification
Primary operator	A physician who is properly trained and experienced in device implantation, lead extraction, and the management of complications according to the guidelines
Cardiothoracic surgical backup	Where the primary operator is a cardiologist
Anaesthesia support backup	Specialized anaesthesia personnel
'Scrubbed' assistant	Physician/nurse/technician
'Non-scrubbed' assistant	Nurse/technician trained in respiratory support
Personnel capable of operating fluoroscopic equipment	Physician/nurse/technician/radiographer
Echocardiographer	Physician/nurse/technician

[a]Depending on the situation and the environment, one person can hold expertise in several areas and satisfy the requirements (e.g. the extractor could be the cardiothoracic surgeon), but at least four people (two scrubbed and two non-scrubbed/sedation and airway management) need to be in the room at all times with the immediate availability of additional personnel as needed.

Table 5 Required facility and equipment for lead extraction procedures	
Facility/equipment	Description
Facility	Operating theatre or room or a cardiac catheter/EP lab
High-quality fluoroscopy	'Angiographic quality' equipment with image storage, either as an integral part of a lab or a mobile C-arm
Surgical instruments	Appropriate for transvenous lead extraction, device implantation, vascular repairs, thoracotomy, sternotomy, and cardio-pulmonary bypass—must be in good functional order and in the room or immediately available
Extraction tools	Depending on the operator(s) preferences, a selection of extraction stylets, sheaths, and femoral tools
CIED implantation tools	All standard implantation equipment as well as a variety of stylets, guidewires, wrenches, lead end caps
Echocardiography	'On-line' during the procedure for immediate use
Drainage sets	For emergency pericardiocentesis and for drainage of haemothorax
Temporary pacing	Venous sheath for temporary pacing electrode placement

Table 6 Lead extraction–registry requirements and standards
Enrolling of all patients who undergo procedures in which lead removal is attempted using transvenous techniques
Compilation of patient characteristics including indications and risk factors for extraction
Recording of lead extraction data on the procedure, tools, techniques and approaches used, success, and complications
Obtaining follow-up at the end of the post-operative period (30 days)
Data analysis should be reviewed at least on an annual basis. Review of individual physician's data should be done in a confidential manner and compared to national or international data
The individual physician/centre may be identified by name or code, at the discretion of the physician and the reporting institution

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