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Temporal trend of indications

# Impact of a structured institutional lead management programme at a high volume centre for transvenous lead extractions in Switzerland

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## Summary

BACKGROUND: Transvenous lead extraction (TLE) is the recommended management strategy for a variety of cardiac implantable electronic device (CIED) infections, malfunctions and other conditions. Large registries have established the safety and efficacy of TLE per se but temporal outcome data after the introduction of an institutional lead management programme remain scarce.

OBJECTIVE: To investigate the impact of a structured institutional lead management programme on TLE outcomes.

METHODS: All patients who underwent TLE at our institution between January 2013 and December 2020 were included. We assessed procedural outcomes after TLE for two separate time periods: from January 2013 to December 2018 and January 2019 to December 2020 (after introduction of a structured institutional lead management programme).

RESULTS: In 2013–2018, the median number of TLE procedures per year at our centre was 14 (range 10–19, total 84). In 2019/2020, the median number of interventions per year increased to 46 (range 41–51, total 92). Noninfectious indications for TLE became more frequent ($p < 0.001$), and the proportion of TLEs due to infections decreased. Median lead dwell time was not different (4.3 years [2013–2018] vs 4.4 years [2019–2020], $p = 0.43$). Clinical success rates improved from 90% to 98% ($p = 0.020$) and complete procedural success increased from 85% to 95% ($p = 0.027$). There was a trend towards a lower number of TLE-associated complications ($p = 0.07$).

CONCLUSION: A structured institutional lead management programme and increasing experience significantly improve TLE outcomes. TLE can be safely performed in high-volume centres, allowing for a more liberal extraction policy, including in the case of non-infectious TLE indications.

## Introduction

Implantation numbers of cardiac implantable electronic devices (CIEDs) are continuously on the rise [1]. In parallel, the incidence of CIED infections is increasing [2] and malfunction of implantable cardioverter-defibrillator and pacemaker leads is not uncommon [3, 4]. All these factors boost the growing demand for CIED system revisions that may include transvenous lead extraction (TLE).

Interventional TLE is an established therapy. Large prospective and retrospective registries such as ELECTRA [5], LEXICON [6] and PROMET [7] have shown that TLE can be performed with high clinical success rates of 97–98%. However, the invasive nature of the procedure constitutes a risk for major complications, which are, fortunately, rare (1.0–1.7%) given appropriate infrastructure, training and precautions. Accordingly, TLE is performed increasingly also for a variety of non-infectious indications [8] and not only for infectious disease complications after CIED implantation – the most widely accepted indication for TLE.

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In the present study, we investigated temporal trends of TLE indications associated with the implementation of a structured institutional lead management programme. We provide outcome data as well as a comprehensive overview on contemporary lead management strategies for daily clinical practice.

## Methods

### Study design and patient population

In this investigator-initiated cohort study, we retrospectively enrolled all patients who underwent a TLE procedure between January 2013 and December 2020 at our tertiary referral centre. TLE was defined as intervention with removal of at least one lead that had been implanted for more than one year, or regardless of implant duration if specialised extraction equipment was used (locking stylets, snares, non-powered sheaths, rotational mechanical sheaths, laser sheaths) [9]. All patients had a TLE indication according to current guidelines, no exclusion criteria applied. The study was a subgroup analysis of the SWISSEXTRACT registry, which was approved by the respective cantonal ethics committees.

### Structured institutional lead management programme

In January 2019, a dedicated lead management programme was established at our institution. This consists of a specialised lead management clinic, where patients are seen in-office by a device specialist competent in TLE. In addition to patient history and complete device interrogation, fluoroscopy of the CIED system, subclavian venography and additional diagnostic modalities (table 1) are used for a comprehensive evaluation of CIED patients. Patients with possible CIED infections are discussed by a dedicated endocarditis board (including device specialists, infectious disease consultants, cardiac surgeons and echocardiographers) [2]. If TLE is considered, preanaesthesia evaluation is requested. Definite TLE planning requires a perioperative risk assessment with participation of all involved subspecialties (cardiac anaesthetist, cardiac surgeon, perfusionist) in the choice of the extraction strategy. Before the lead management programme was introduced, no structured planning pathway for TLE, no structured risk quantification, and no interdisciplinary TLE planning was implemented. A dedicated outpatient clinic had also not yet been established.

At our centre, TLE procedures that are considered intermediate and high-risk are performed in a hybrid operation room by two lead extraction specialists. The full range of extraction tools (locking stylets, snaring tools, non-powered and rotational mechanical sheaths) is

**Table 1: Structured evaluation for optimal lead management prior to TLE. The list provides a general overview and is not exhaustive.**

| Diagnostic procedure | Main focus | When to perform |
|---|---|---|
| **Medical history** | CIED implantation indication, drugs, allergies, other comorbidities. | Always before intervention |
| **Analysis of implantation reports** | Implanted material, vascular access routes, challenges during implantation. | Always before intervention |
| **CIED interrogation** | Analysis of CIED function and PM depen-dency. In case of lead malfunction provocation maneuvers and EGM evaluation. | Always before intervention |
| **Transthoracic echocardiography** | Biventricular function, lead vegetations, presence of concomitant significant valve disease (vegetations, tricuspid regurgitation), pre-operative risk stratification. | Always before intervention |
| **Transoesophageal echocardiography** | Lead insertion points, vegetations, pericardial and pleural effusions, presence of right-to-left shunt, hemodynamics. | (Before and) during intermediate and high-risk TLE |
| **Fluoroscopy and subclavian venography** | Lead defects, patency of access routes, assessment of connective tissue bridges and lead insertion points, vessel stenosis. | Mostly before intervention |
| **Laboratory tests** | Electrolytes, creatinine, coagulation, blood count and group for potential transfusion. | Immediately before intervention |
| **FDG-PET scan** | Evidence for CIED infection. | In case of discrete signs of (pocket) infection |
| **Thoracic CT/MRI** | General anatomy, lead insertion site, vascular access/ occlusion. | In complex situations or perforated leads |
| **Coronary angiography and cardiac catheterisation** | Presence of significant concomitant coronary artery disease, grading of valve disease. | In case of planned hybrid procedure involving surgery |
| **Individualised cumulative risk assessment** | Calculation of interventional risk for interdisciplinary decision on optimal lead management strategy. | Always before definite intervention planning |

CIED: cardiac implantable electronic devices; CT: computed tomography; EGM: electrogram; FDG-PET: fluordesoxyglucose positron emission tomography; MRI: magnetic resonance imaging; PM: pacemaker; TLE: transvenous lead extraction

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**Table 2: Patient baseline characteristics.**

| Patient characteristics | 2013–2018 (n = 84) | 2019–2020 (n = 92 ) | p-value |
|---|---|---|---|
| **Clinical characteristics** | | | |
| Female sex | 27 (32%) | 29 (32%) | 1 |
| Age (years) | 69 (54–76) | 69 (54–75) | 0.58 |
| Body height (m) | 1.71 (1.65–1.76) | 1.72 (1.65–1.78) | 0.35 |
| Body weight (kg) | 75 (65–90) | 80 (69–90) | 0.12 |
| LVEF (%) | 55 (35–65) | 57 (36–61) | 0.76 |
| Arterial hypertension | 53 (64%) | 58 (63%) | 1 |
| Diabetes | 20 (24%) | 18 (20%) | 0.62 |
| Renal failure | 22 (27%) | 23 (26%) | 0.95 |
| Pacemaker dependency | 38 (45%) | 53 (58%) | 0.14 |
| Prior cardiac surgery | 27 (33%) | 22 (24%) | 0.27 |
| **Drug therapy** | | | |
| Oral anticoagulation | 42 (50%) | 47 (52%) | 1 |
| Antiplatelet therapy | 43 (51%) | 24 (26%) | <0.001 |
| Betablocker | 52 (62%) | 53 (58%) | 0.67 |
| ACE inhibitor or AT2 blocker | 42 (51%) | 58 (63%) | 0.11 |
| **CIED system** | | | |
| Single- or dual-chamber PM | 45 (54%) | 50 (54%) | 1 |
| CRT-P | 3 (4%) | 3 (3%) | 1 |
| Single- or dual-chamber ICD | 25 (30%) | 22 (24%) | 0.48 |
| CRT-D | 11 (13%) | 17 (18%) | 0.44 |
| **CIED indication** | | | |
| Sinus node disease | 13 (15%) | 16 (17%) | 0.89 |
| AV block | 29 (35%) | 31 (34%) | 1 |
| Ventricular tachycardia/fibrillation | 13 (15%) | 18 (20%) | 0.61 |
| Other | 29 (35%) | 27 (29%) | 0.57 |
| **TLE indication** | | | |
| CIED or systemic infection | 50 (60%) | 24 (26%) | **<0.001** |
| Non-infectious indication | 34 (40%) | 68 (74%) | **<0.001** |
| – Lead malfunction | 26 (31%) | 50 (54%) | **0.003** |
| – Chronic pain | 2 (2%) | 2 (2%) | 1 |
| – Thrombosis / venous occlusion | 0 (0%) | 5 (5%) | **0.06** |
| – Device upgrade | 4 (5%) | 5 (5%) | 1 |
| – Other | 2 (2%) | 6 (7%) | 0.28 |

Median values with interquartile ranges in brackets and numbers with percentages are shown. AV: atrioventricular; CIED: cardiac implantable electronic device; CRT: cardiac resynchronisation therapy; ICD: implantable cardioverter-defibrillator; LVEF: left ventricular ejection fraction; PM: pacemaker; TLE: transvenous lead extraction

available. TLE is performed under general anaesthesia. Monitoring includes invasive blood pressure measurement and transoesophageal echocardiography, among others. Femoral venous and arterial sheaths are inserted. These sheaths serve as access site for femoral extraction tools, a temporary pacing wire, an occlusion balloon in case of laceration of the superior vena cava, and for emergency extracorporeal circulation. A cardiac surgeon and perfusionist are available on site in case of urgent conversion to open cardiac surgery.

### Follow-up data acquisition

Procedural and follow-up data were collected from our institutional health records. Referring cardiolo¬gists and general practitioners were contacted to complete follow-up. The last follow-up was performed in May 2021. Success and complication rates were assessed according to widely recognised definitions [9]. Complete procedural success was defined as removal of targeted leads, without permanently disabling complications or procedure-related death [9]. Clinical success was defined as retention of a small lead portion (<4 cm) neither negatively impacting the outcome of the procedure, nor increasing the risk of complications but absence of permanently disabling complications or procedure-related death [9].

### Statistical analysis

R version 4.1.1 for Windows (R Foundation, Vienna, Austria) was used for statistical analysis. Categorical variables are expressed as numbers and percentages. Continuous variables are presented as mean ± standard deviation (SD) or median and interquartile range (IQR), as appropriate. Procedural outcomes of TLE were assessed over time. In particular, interventions performed from January 2013 to December 2018 (no structured institutional lead management programme) were compared with interventions performed from January 2019 to December 2020 (after introduction of a structured institutional lead management programme). Comparisons between categorical variables and groups were performed using a $\chi 2$ test or Fisher's test as appropriate. Continuous variable were compared using a Wilcoxon-Mann-Whitney test. A two-sided p-value ≤0.05 was considered significant.

**However, there was a significant change in TLE indications over time.**

## Results

### Baseline patient characteristics

Detailed characteristics of all patients who underwent TLE in 2013–2018 and 2019–2020 are shown in table 2. Key baseline parameters were not different for both time periods. However, there was a significant change in TLE indications over time. Noninfectious indications for TLE became more frequent (p <0.001). In particular, lead malfunction became the single most important indication for TLE at our centre, accounting for more than half of the current TLE procedures. In contrast, the relative frequency of infectious indications decreased from 60% to 26% (fig. 1).

### Procedural characteristics

The total number of TLE procedures for 2013–2020 is shown in figure 2. In 2013–2018 (low-volume era), the median number of TLE procedures per year at our centre was 14 (range 10–19), resulting in a median number of 22 extracted leads per year (IQR 19–30). In

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2019/2020 (high-volume era), the median number of interventions per year increased to 46 (range 41–51), resulting in 76 extracted leads per year (IQR 75–78).

Procedural characteristics for the two time periods are shown in table 3. In the high-volume era, more interventions were performed in the hybrid operation room (92% vs 76% in the low-volume era, p = 0.006). The use of rotational mechanical sheaths increased (p <0.001) at the cost of non-powered mechanical sheaths (p <0.001). Laser TLEs were not performed in the high-volume era, since both procedure-related deaths were associated with the use of a laser (vessel laceration). Median lead dwell time was not different (4.3 years [low volume era] vs 4.4 years [high volume era], p = 0.43).

### Procedural outcomes

Whereas overall procedural complexity seemed not to alter over time (median lead dwell time, procedure duration, number of targeted leads, CIED types and patient characteristics were not different), procedural outcomes changed (table 3). Clinical success rate improved from 90% to 98% (p = 0.020) and complete procedural success increased from 85% to 95% (p = 0.027, fig. 2). There was a trend towards a lower number of TLE-associated complications (18% vs 8%, p = 0.07, fig. 2), in particular a reduction of major complications (5% vs 0%, p = 0.05).

**The relative frequency of noninfectious TLE indications is increasing.**

## Discussion

In this large registry study of 176 TLE procedures performed in Swiss tertiary referral centre, we aimed to investigate the impact of a structured institutional lead management programme on TLE outcomes. The main findings of our study were:

1. The relative frequency of noninfectious TLE indications is increasing. This is likely attributable to a significant rate of lead failures [4], a more liberal extraction policy with increasing experience, favourable outcomes and evolution of our institution into a high-volume TLE centre.
2. Besides the temporal change of TLE indications, patients undergoing TLE seem to exhibit similar characteristics over time and compared with large multicentre registries [5]. However, TLE success rates significantly increase with the increasing use of rotational mechanical sheaths.
3. The introduction of a structured institutional lead management programme including a standardisation of TLE procedures allows individualised patient care and increased TLE success rates while maintaining very low complication rates.
4. The increase in noninfectious TLE (elective) indications may play a causative role in

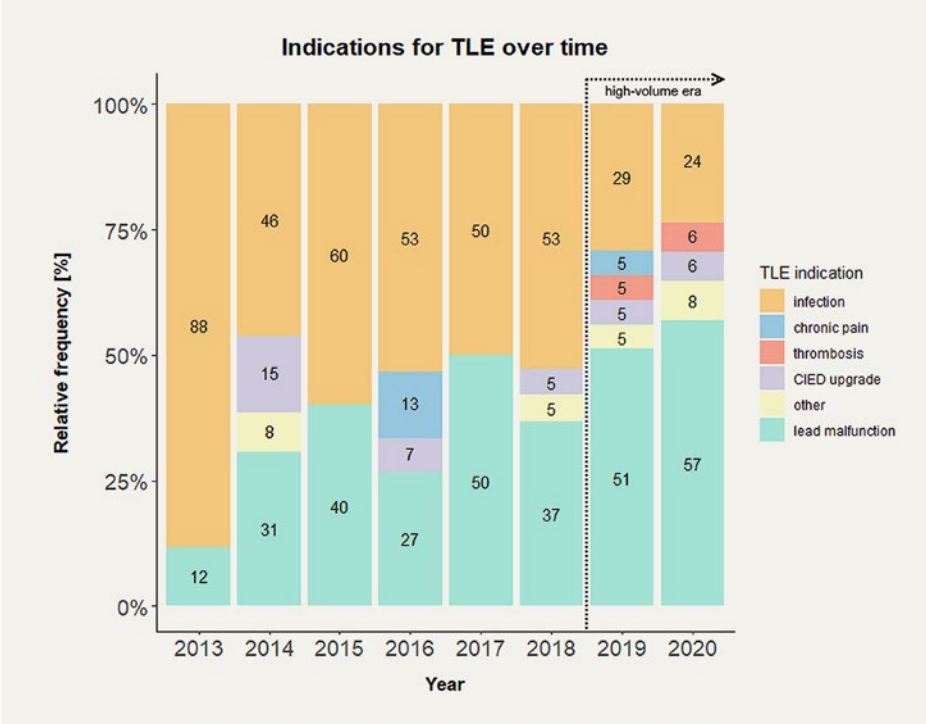


**Figure 1:** Change of TLE indications over time. Individual percentages for each bar are plotted. The category "thrombosis" also includes chronic venous occlusions. CIED: cardiac implantable electronic device; TLE: transvenous lead extraction

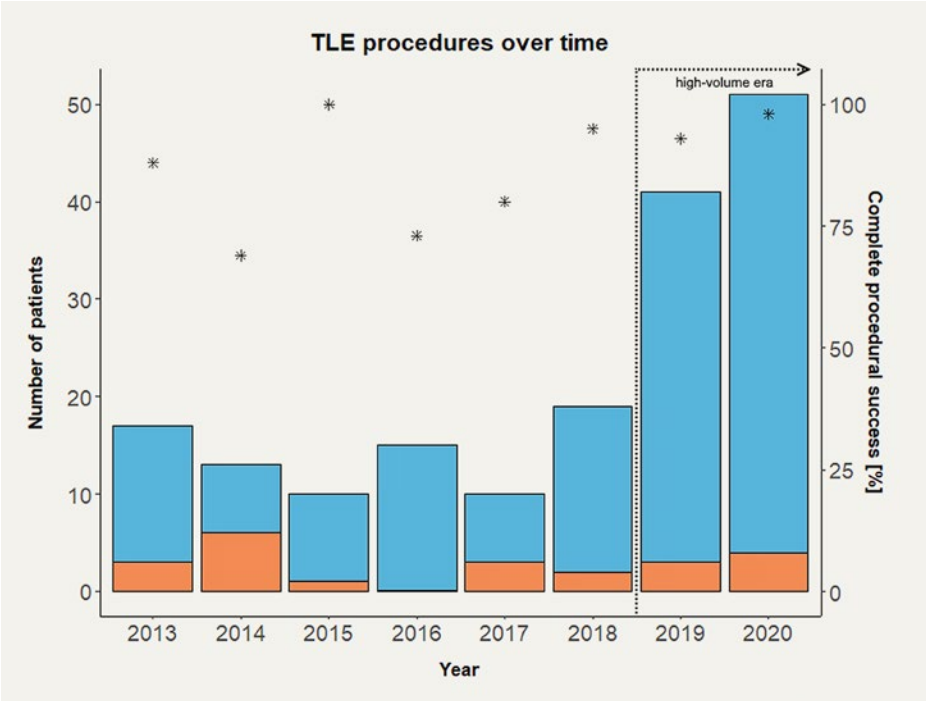


**Figure 2:** Number of transvenous lead extraction (TLE) procedures over time (low-volume era 2013–2018; high-volume era 2019–2020). The total number of treated patients is shown in blue. Absolute numbers of complications (major and minor) are shown in red. The rate of complete procedural success is highlighted by asterisks.

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the reduction of overall hospitalisation duration in TLE patients. Patients with infectious CIED complications may require intravenous antibiotics or concomitant surgery, prolonging the hospitalisation.

### Safety and efficacy of TLE

The clinical success rate of TLE in our cohort was 98%, which is similar to multicentre registries [5–7]. Major complications were rare in these studies and we did not observe any in the high-volume era. Nonetheless, TLE carries an inherent risk of severe procedural adverse events. Several strategies may minimise the risks and contribute to favourable outcomes:

- Structured preprocedure assessment in the lead management clinic allows individualised patient care. Shared decision making balancing risks and benefits of TLE vs lead abandonment is crucial to optimise the lead management strategy. A multidisciplinary approach and risk stratification involving anaesthesiologists, cardiac surgeons, perfusionists, infectious disease and imaging specialists may improve outcomes [10, 11].
- The use of rotational mechanical sheaths reduces the torque exerted on the extracted lead in comparison with unpowered sheaths, preserving lead integrity and, thus, facilitating extraction. Bidirectional rotational mechanical sheaths have been shown to be highly effective in the recently published prospective RELEASE trial [12]. They are an effective first-line tool for TLE [13] and may even outperform laser sheaths [7, 14].
- Adherence to international recommendations for TLE on-site cardiac surgery, cardiac anaesthesia availability, a full range of CIED extraction and implantation tools and high-quality fluoroscopy should be available [15]. A tertiary centre for TLE should perform at least 30 procedures per year, with each trained primary operator performing a minimum of 15 procedures and extracting at least 20 leads. At our centre, a team of two operators fulfilling the above requirements performs all TLE procedures using a dedicated setting for TLEs (fig. 3A and B). Patients who are treated in higher volume centres (mostly tertiary hospitals) have a lower probability of complications and death [16].

**Table 3: Procedural characteristics.**

| Procedural characteristics | 2013–2018 (n = 84) | 2019–2020 (n = 92) | p-value |
|---|---|---|---|
| **Procedural setting** | | | |
| Emergency procedure | 21 (25%) | 15 (16%) | 0.21 |
| Intervention site | | | **0.003** |
| – Electrophysiology laboratory | 19 (23%) | 6 (7%) | **0.005** |
| – Hybrid operation room | 64 (76%) | 85 (92%) | **0.006** |
| – Conventional operation room | 1 (1%) | 1 (1%) | 1 |
| **Procedural details** | | | |
| Procedure duration (min) | 144 (110–196) | 143 (85–240) | 0.93 |
| Passive leads | 34 (25%) | 23 (15%) | **0.06** |
| Number of targeted leads for extraction | 2 (1–2) | 2 (1–2) | 0.40 |
| Lead dwell time (years) | 4.3 (1.8–8.6) | 4.4 (2.4–8.4) | 0.43 |
| Use of conventional stylets | 18 (22%) | 21 (23%) | 0.43 |
| Use of locking stylets | 65 (78%) | 71 (77%) | 0.97 |
| Use of laser sheath | 22 (27%) | 0 (0%) | **<0.001** |
| Use of mechanical non-powered sheath | 45 (70%) | 35 (39%) | **<0.001** |
| Use of rotational mechanical sheath | 2 (3%) | 34 (38%) | **<0.001** |
| Use of femoral snares | 4 (5%) | 12 (13%) | 0.10 |
| **Procedural outcomes** | | | |
| Clinical success | 76 (90%) | 90 (98%) | **0.020** |
| Complete procedural success | 71 (85%) | 87 (95%) | **0.027** |
| Duration of hospital stay (days) | 6 (4–13) | 3 (3–6) | **<0.001** |
| Total complications | 15 (18%) | 7 (8%) | **0.07** |
| Major complications | 4 (5%) | 0 (0%) | **0.05** |
| – Procedure related deaths due to vessel laceration, haemothorax | 2 (2%) | 0 (0%) | 0.23 |
| – Cardiac tamponade requiring surgery | 1 (1%) | 0 (0%) | 0.47 |
| – Thromboembolic event requiring surgery | 1 (1%) | 0 (0%) | 0.471 |
| – Stroke | 0 (0%) | 0 (0%) | – |
| Minor complications | 11 (13%) | 7 (8%) | 0.34 |
| – Femoral bleeding | 0 (0%) | 2 (2%) | 0.50 |
| – Pocket haematoma | 5 (6%) | 0 (0%) | **0.023** |
| – Other | 6 (7%) | 5 (5%) | 0.76 |

Median values with interquartile ranges in brackets and numbers with percentages are shown.

### Practical implications for patients with infectious CIED complications

TLE is the recommended approach in patients with pocket infections or CIED endocarditis [2, 8]. CIED infections with large lead vegetations or pocket perforation are easy to diagnose, whereas discrete manifestations pose a diagnostic challenge (fig. 3C). An often forgotten TLE indication is bacteraemia without evidence of CIED infection. Bacteraemia with staphylococcal species and Propionibacteria often warrants proactive TLE [8], in particular in patients with prolonged bacteraemia (the risk of relapse increases if no TLE is performed and bacteraemia lasts >1 day [17]). TLE is critical to improve outcome in these patients even in the case of unconfirmed CIED endocarditis [18]. Conservative management of CIED infections using antibiotic suppression or salvage therapy with isolated pocket revision is rarely curative and might only be considered in very fragile elderly high-risk patients [2, 19].

### Practical implications for patients with noninfectious CIED complications

In the past, conservative management of device malfunctions with lead abandonment was often preferred [20]. Lead abandonment may

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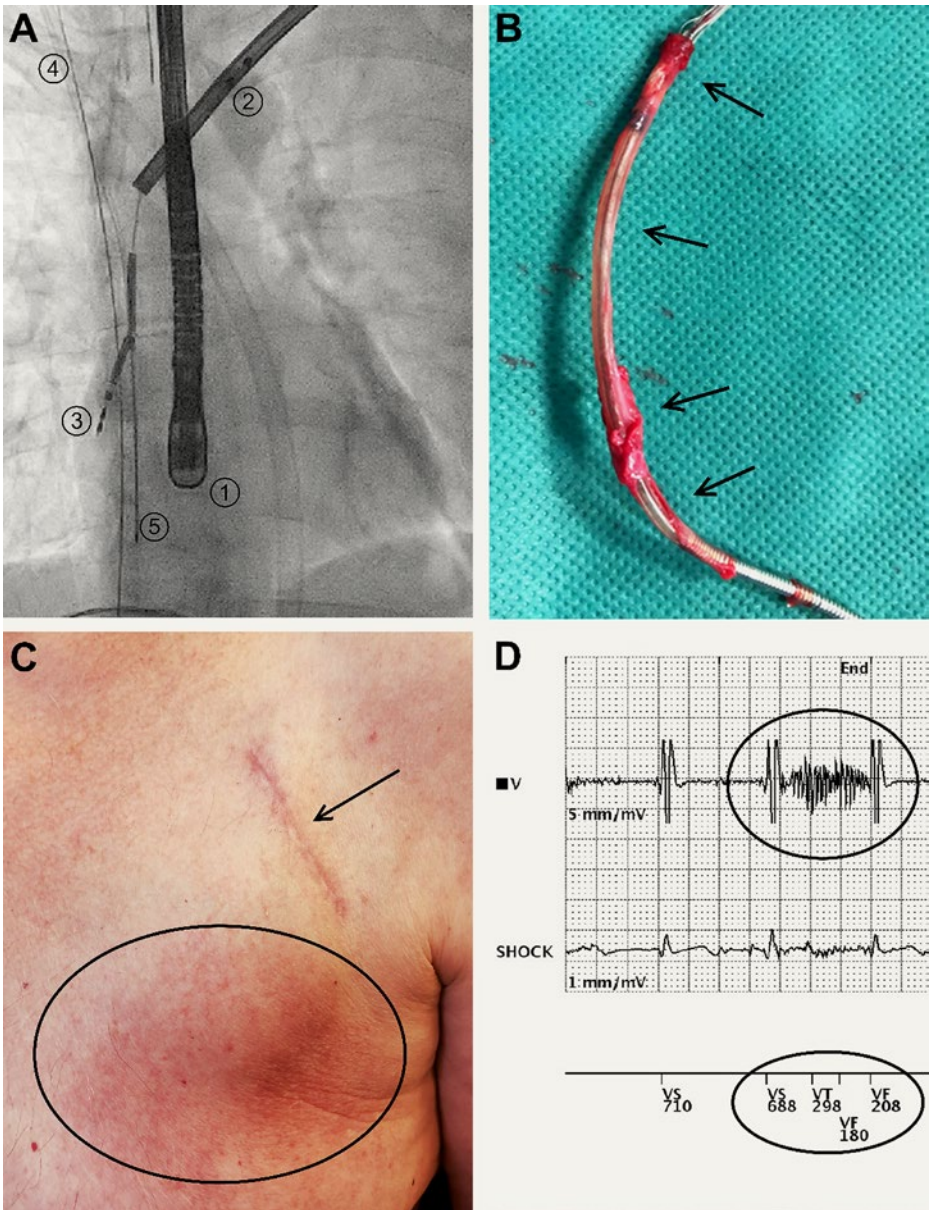


**Figure 3:** Transvenous lead extraction (TLE) technique and indications. Panel A shows a fluoroscopy image during combined superior and femoral extraction of an implantable cardioverter-defibrillator (ICD) lead (1 – echocardiography probe; 2 – rotational mechanical sheath liberating the lead; 3 – partially pulled back ICD lead; 4 – guidewire for vascular occlusion balloon in the case of superior vena cava laceration; 5 – femoral snare). Panel B shows the extracted lead from panel A with extensive adhesions (arrows). Panel C and D represent typical TLE indications. Panel C shows discrete signs of pocket infection (encircled: slightly reddish skin, palpable fluid collection, retracted and thinned skin at the lateral device border). The incision site (arrow) shows no superficial infection. Panel D shows non-physiologic oversensing in a patient with an ICD conductor defect.

be more economical, since TLEs can be associated with considerable costs (sometimes >15,000 CHF) only for the special extraction equipment and hybrid operating room use. However, abandoned leads are a source of potential complications [21], pain and disability [22]. More recent data – including our experience – show that patients with noninfectious CIED complications can safely undergo TLE. Common noninfectious indications for TLE include stenosis/occlusion of the superior vena cava, thromboembolic events (both class IC [8]), ipsilateral vessel occlusion prior to device upgrade, chronic pain and >4 unilateral leads (all class IIa [8]). TLE in the case of lead malfunction (fig. 3D) may also reduce the long-term risk of repeat lead failure compared with lead abandonment (class IIb [8]). Referral to an extraction centre with a structured institutional lead management programme should be advised in such cases.

## Limitations

This was a single-centre retrospective observational study. The generalisability of our findings to other centres may be limited, given the sample size and low number of TLE operators in this study. Since 2018, TLEs at our centre are performed by the first and last author, which may co-explain certain changes observed in the high volume era (e.g., procedural setting, preferred tools for extraction).

## Conclusion

A structured institutional lead management programme significantly improves TLE success rates while ensuring a low number of complications. TLE can be safely performed in high-volume centers, allowing for a more liberal extraction policy also in patients with non-infectious TLE indications.

### Disclosure statements

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The full list of references is included in the online version of the article at https://cardiovascmed.ch/article/doi/CVM.2022.02224.

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