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Sustained extraction program: How to establish and organize

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Hradec Králové, 29.2.2024



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Motto: Při diagnóze BE, nebo vysokém podezření na tuto dg., je konzervativní postup v léčbě pacientů s implantáty inferiorní a vždy je potřeba zvážit vhodnou formu extrakce systému (endovazální, chirurgickou, hybridní ...)

Introduction

- Transvenous lead extraction (TLE), as a part of an overall lead management strategy, has been increasing, not only as a consequence of medical care, but also because of increasing rates of infection, lead failure, awareness of indications for lead management, and development of extraction tools
- 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 mandatory in order to analyze, compare, and pool data for scientific purposes



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I: Co říkají data z registrů



The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) Registry of Transvenous Lead Extraction Outcomes

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Investigators[†]

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Aims

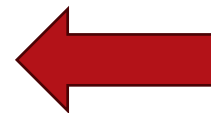
The European Lead Extraction ConTRolled Registry (ELECTRa), is a prospective registry of consecutive transvenous lead extraction (TLE) procedures conducted by the European Heart Rhythm Association (EHRA) in order to identify the safety and efficacy of the current practice of TLE.

Methods and results

European centres performing TLE, invited by the organizing committee on behalf of EHRA, prospectively recruited all consecutive patients undergoing TLE at their institution. The primary endpoint was TLE safety defined by pre-discharge major procedure-related complications including death. Secondary endpoints included clinical and radiological success and overall complication rates. Outcomes were compared between Low Volume (LoV) vs. High Volume (HiV) centres (LoV < 30 and HiV ≥ 30 procedures/year). A total of 3555 consecutive patients (pts) of whom 3510 underwent TLE at 73 centres in 19 European countries were enrolled between November 2012 and May 2014. The primary endpoint of in-hospital procedure-related major complication rate was 1.7% [95% CI 1.3–2.1%] (58/3510 pts) including a mortality of 0.5% [95% CI 0.3–0.8%] (17/3510 pts). Approximately two-thirds (37/58) of these complications occurred during the procedure and one-third (21/58) in the post-operative period. The most common procedure related complications were those requiring pericardiocentesis or chest tube and/or surgical repair (1.4% [95% CI 1.0–1.8%]). Complete clinical and radiological success rates were 96.7% [95% CI 96.1–97.3%] and 95.7% [95% CI 95.2–96.2%], respectively. The all cause in-hospital major complications and deaths were significantly lower in HiV centres vs. LoV centres (2.4% [95% CI 1.9–3.0%] vs. 4.1% [95% CI 2.7–6.0%], $P=0.0146$; and 1.2% [95% CI 0.8–1.6%] vs. 2.5% [95% CI 1.5–4.1%] $P=0.0088$), although those related to the procedure did not reach statistical significance. Radiological and clinical successes were more frequent in HiV vs. LoV centres.

Úspěšnost extrakčních procedur

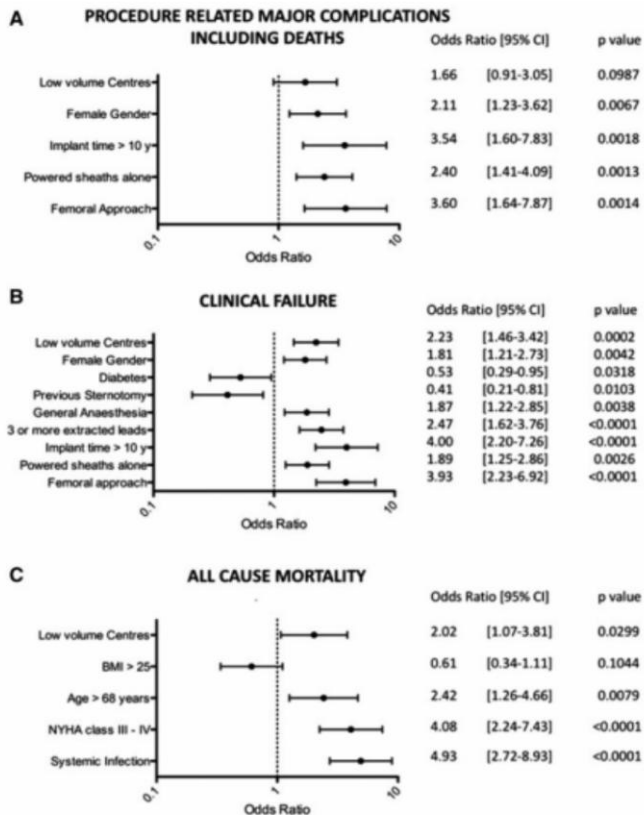
| Patients outcomes | All patients (N = 3510) |
|--|------------------------------|
| Leads extracted per patient | 1.8±0.9 (N = 3510) |
| Duration per patients | |
| Procedure time (min) | 83.0 [57.0–120.0] |
| Median [IQR] (N) | (N = 3403) |
| Extraction time (min) | 19.0 [6.0–40.0] |
| Median [IQR] (N) | (N = 3274) |
| Duration of hospital stay related to lead extraction (days) | 6.4±8.6 |
| Mean ± SD (N) | (N = 3459) |
| Leads outcomes, N/Total N (%), [95% CI] | All leads (N = 6493) |
| Radiological outcome | |
| Complete | 6212/6493 (95.7) [95.2–96.2] |
| Partial | 184/6493 (2.8) [2.4–3.3] |
| Failure | 97/6493 (1.5) [1.2–1.8] |
| TLE techniques | |
| Lead removed with traction alone | 1741/6376 (27.3) [26.2–28.4] |
| Locking stylets | 3975/5589 (71.1) [69.9–72.3] |
| Sheaths used | 4127/6492 (63.6) [62.4–64.7] |
| Mechanical not powered sheaths | 2359/6492 (36.3) [35.2–37.5] |
| Powered sheaths (any) | 1757/6492 (27.1) [26.0–28.2] |
| Laser sheaths | 1250/6492 (19.3) [18.3–20.2] |
| Evolution [®] mechanical dilator sheaths ^d | 500/6492 (7.7) [7.1–8.4] |
| Electrosurgical dissection sheaths (EDS) | 7/6492 (0.1) [0.04–0.2] |
| Other | 11/6492 (0.2) [0.08–0.3] |



Komplikace extrakcí

| Complications, N/Total N (%), [95% CI] | |
|--|---------------------------|
| Procedure related major complications including deaths | 58/3510 (1.7) [1.3–2.1] |
| Intra-procedural | 37/3510 (1.1) [0.7–1.5] |
| Post-procedural | 21/3510 (0.6) [0.4–0.9] |
| Details of procedure related major complications including deaths, N/Total N (%), [95% CI] | |
| Procedure related deaths* | 17/3510 (0.5) [0.3–0.8] |
| Intra-procedural | 9/3510 (0.3) [0.1–0.5] |
| Post-procedural | 8/3510 (0.2) [0.1–0.5] |
| Cardiac avulsion or tear | 30/3510 (0.9) [0.6–1.2] |
| Vascular avulsion or tear | 20/3510 (0.6) [0.4–0.9] |
| Cardiovascular lesions requiring pericardiocentesis, chest tube, surgical repair | 49/3510 (1.4) [1.0–1.8] |
| Heart failure | 1/3510 (0.03) [0.001–0.2] |
| Sepsis | 1/3510 (0.03) [0.001–0.2] |
| Respiratory arrest | 2/3510 (0.06) [0.01–0.2] |
| Multi organ failure | 1/3510 (0.03) [0.001–0.2] |
| Cerebrovascular accident | 2/3510 (0.06) [0.01–0.2] |
| Arrhythmias | 1/3510 (0.03) [0.001–0.2] |
| Acute superior vena cava syndrome | 1/3510 (0.03) [0.001–0.2] |
| Anesthesia related complications | 2/3510 (0.06) [0.01–0.2] |
| Acute abdominal occlusion | 1/3510 (0.03) [0.001–0.2] |
| Disseminate intravascular coagulation | 1/3510 (0.03) [0.001–0.2] |
| All cause in-hospital major complications including deaths, N/Total N (%), [95% CI] | |
| All cause major complications | 95/3510 (2.7) [2.2–3.3] |
| All cause deaths | 50/3510 (1.4) [1.1–1.9] |

Prediktory komplikací extrakcí





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II: Jak optimálně organizovat extrakční centrum

Each extraction center should have its own clearly defined standards for TLE



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DOPORUČENÝ LÉKAŘSKÝ POSTUP A STANDARD č. DLPS-L023-1IK-016

Extrakce implantabilních přístrojů (CIEDs)

1. vydání ze dne: 1. 4. 2023

Skartační znak: A

Účinnost od: 1. 4. 2023

Stupeň důvěrnosti: N1

všeobecný DLPS

klinický DLPS

vlastní DLPS

pro pracoviště: I. interní klinika - kardiologická

převzatý DLPS

zdroj převzatého DLPS včetně el. odkazu:

| | Jméno | Funkce | Datum | Podpis |
|----------------------------------|--|---|-------|--------|
| Odborný garant (autorský tým) | MUDr. Marián Fedorco, Ph.D., FESC | vedoucí lékař Oddělení 1 I. interní kliniky - kardiologické | | |
| Oponent (přezkoumavatel) | prof. Miloš Táborský, CSc., MBA, FESC, FACC | přednosta I. interní kliniky - kardiologické | | |
| Schválil | prof. Miloš Táborský, CSc., MBA, FESC, FACC | přednosta I. interní kliniky - kardiologické | | |



Informed Consent

- The final step in the preparatory phase is informed consent, which ideally, takes place with the patient in the presence of family members or other social support.
- A review of this discussion, including alternatives to extraction, and potentially life-threatening complications, should be discussed with the patient and his or her family members and clearly documented in the patient's chart

Poučení a informovaný souhlas pacienta s odstraněním stimulačních/defibrilačních elektrod a kardiostimulátoru nebo implantabilního kardioverter/defibrilátoru (zákonného zástupce pacienta)

| | |
|--|------------------------------------|
| Pacient(ka) – jméno a příjmení: | Rodné číslo (číslo pojistěnce): |
| Datum narození: (není-li rodné číslo) | Kód zdravotní pojišťovny: |
| Adresa trvalého pobytu pacienta: (případně jiná adresa) | |
| Jméno zákonného zástupce (opatrovníka): | Rodné číslo: |

Název výkonu
odstranění (extrakce) stimulačních/defibrilačních elektrod/y a kardiostimulátoru (KS) nebo implantabilního kardioverter/defibrilátoru (ICD)

Účel výkonu
Odstranění zdroje infekce (infekce kapsy, odstranění vegetací infekčních hmot nitrosrdečních oddílů a chlopní spojených s elektrodou), obnovení průchodnosti žily, odstranění známého rizika spojeného s elektrodou, snaha o zachování požadovaného stimulačního režimu, odstranění nefunkčních elektrod/y, odstranění potíží v oblasti kapsy přístroje (bolest, hrozící defekt či infekce kůže)

Povaha výkonu
Odstranění elektrod/y a přístroje se provádí v místním zneitlivění s podáním léků proti bolesti a k mírnému usnání – analgosedaci. Ke zvýšení bezpečnosti výkonu je pacientovi zavedena do tepny na zápěstí nebo v tříšle kanylka k invazivnímu měření krevního tlaku a cestou stehenní tepny v oblasti třísla zavedena do srdce ultrazuková sonda umožňující zobrazení srdečních struktur a osrdečníku. Dále se u všech pacientů zavádí žilní cestou z oblasti krku nebo třísla dočasná kardiostimulace, k předcházení zpomalování či zastavování srdce. Prvním krokem je otevření kapsy přístroje, jeho vyjmutí a následně vypreparování elektrody. Poté se pomocí speciálních (mechanické, laserové extraktory) nástrojů provede odstranění elektrody. Následně je provedené nevyhnutelné vyčištění kapsy přístroje, v případě potřeby zavedení hadičky na odsávání sekretu a nakonec zašití rány. V případě potřeby, se do doby implantace nového přístroje ponechává tzv. dočasná kardiostimulace.

Předpokládaný prospěch výkonu
Odstranění elektrod/y a přístroje by mělo odstranit potíže, pro které Vám bylo doporučeno výkon podstoupit.

Alternativa výkonu
Kompletně kardiochirurgické odstranění s nutností otevření hrudníku, výkon v celkovém usnání, na umělé plicní ventilaci.

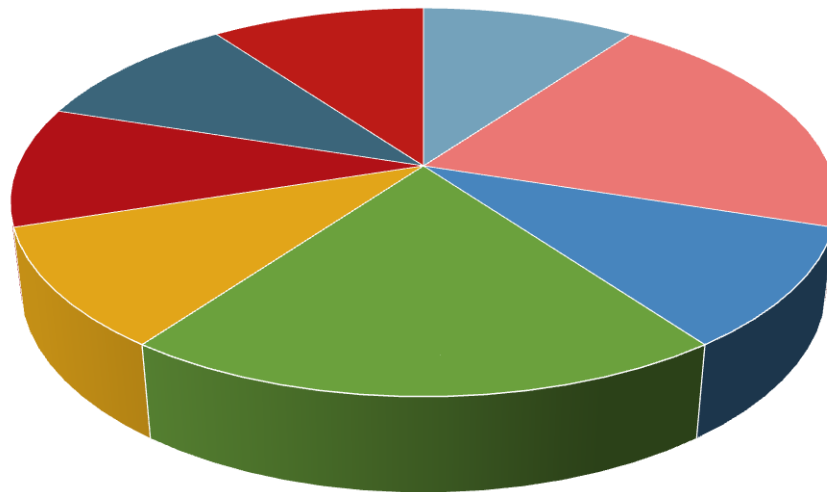
Možná rizika zvoleného výkonu
Malé komplikace – tekutina v osrdečníku nevyžadující léčeni, krvácení do hrudní dutiny bez nutnosti odsátí, hematoma v místě odstraněného přístroje vyžadující reoperaci a zavedení hadičky na odsávání, otok horní končetiny nebo trombóza žily s nutností léčeni, nutnost sešití žily v místě výkonu, hemodynamicky významné proniknutí vzduchu do cévního systému, migrující části elektrody bez následků, nutnost podání krevní transfuze z důvodu krevních ztrát při výkonu, proniknutí vzduchu do hrudní dutiny s nutností jeho odsátí, plicní embolie bez nutnosti chirurgické léčby.

Velké komplikace – infekce stimulačního systému na předtím nepostížené straně, mozková mrtvice, dechová zástava nebo komplikace eventuelně nutné umělé plicní ventilace vedoucí k prodloužení hospitalizace, plicní embolie vyžadující chirurgické řešení, natržení nebo odtržení cévy s nutností odsátí krve z osrdečníku nebo hrudní dutiny, otevření hrudníku, chirurgické léčeni, poranění srdeční stěny či její natrženi s nutností otevření hrudní dutiny, odsátí krve z osrdečníku, odsátí krve z hrudní dutiny, nebo chirurgické léčeni, smrt.

Následky výkonu
Úspěch lékařských výkonů a jejich absolutní nerizikovitost nelze nikdy zcela zajistit. Všechny eventuelní komplikace jsou vzácné a léčitelné.

Indication and TLE should be a team decision

Extraction/endocarditis team



- EP
- Cardiac Surgery
- Anesthesiology
- CIED/ LE specialist
- Microbiology
- EP technician
- Educated nurses
- Support staff

Each patient and TLE procedure should be classified for potential risks of the procedure

- The correct estimation of the risk of the extraction performance is a crucial part of choosing the correct procedure for the extraction procedure.
- We divide the risk of extraction performance into low, medium and high.
- For **low-risk patients**, the extraction can be safely performed in the EP room I. IKK FNOL with a complete cardiac surgery team.
- For patients with **moderate and high procedure risk**, extraction must be performed in a hybrid operating room with a full cardiac surgical team.

Different scoring systems can be used to determine risk: MB scoring system

| Risk factor Points | | | | | Points | |
|----------------------|-----------|----------|---------------|-----------|----------------------|--|
| Age of electrodes | ≥ 3 years | +1 point | ≥ 5 years | +2 points | ≥ 10 years +3 points | |
| Number of electrodes | ≥ 2 | +1 point | | | | |
| Electrode type | passive | +1 point | ICD electrode | +1 point | | |
| Score | | | | | | |

MB score 0 = low risk, 1-2 = medium risk, 3 = high risk, >3 = very high risk

SAFETY TLE risk calculator available online

- <http://usuwanieelektrod.pl/akalkulator/>
- SAFETY TLE score
 - S** = sum of lead dwell times,
 - A** = anemia,
 - Fe** = female,
 - T** = treatment (previous procedures),
 - Y** = young patients.
- Filling out a simple calculator is a determined extraction procedure risk score for a given patient

Risk factors for potential complications I

Among the factors predisposing to non-infectious complications are:

1. Mainly suboptimal implantation technique (especially medial puncture in the subclavian vein),
2. Less experience of the operator, (optimal is the preference for dissection technique during primary implantation of EL, with the exception of LV EL)
3. Mechanical structural resistance of electrodes and others...

Risk factors for potential complications II

- On the patient side, previous prospective and retrospective analyzes and studies clearly demonstrated that **patients older than 65, women and patients with comorbidities have a higher risk of infection.**
- Associated diseases include **diabetes, advanced stage renal failure, COPD, use of corticoids, malignancy, history of previous implant infection, heart failure, fever and use of antithrombotic medication.**

Preparation before procedure I

- A medical history is key to obtaining essential information for proper and safe management of a patient indicated for electrode extraction.
- In addition to the basic diagnosis leading to device implantation, it is important to find out comorbidities and eventual history of previous cardiosurgical or vascular procedures.
- It is advisable to find out the type and age of the implanted electrodes from the technical information.

Preparation before procedure II

Imaging examination

- All patients should have a chest X-ray to define the number and position of electrodes. Furthermore, a **transthoracic echocardiographic examination and, in indicated cases, esophageal echocardiography** should be performed. In some cases, it is necessary to complete a PET-CT examination for differential diagnostic reasons.

Laboratory examination

- All patients should have complete blood samples for basic biochemical examination (Na, K, urea, crea, GF, liver tests, CRP, NT-proBPN, glycemia), as well as blood count and coagulation parameters (aPTT, INR, platelets + blood type).

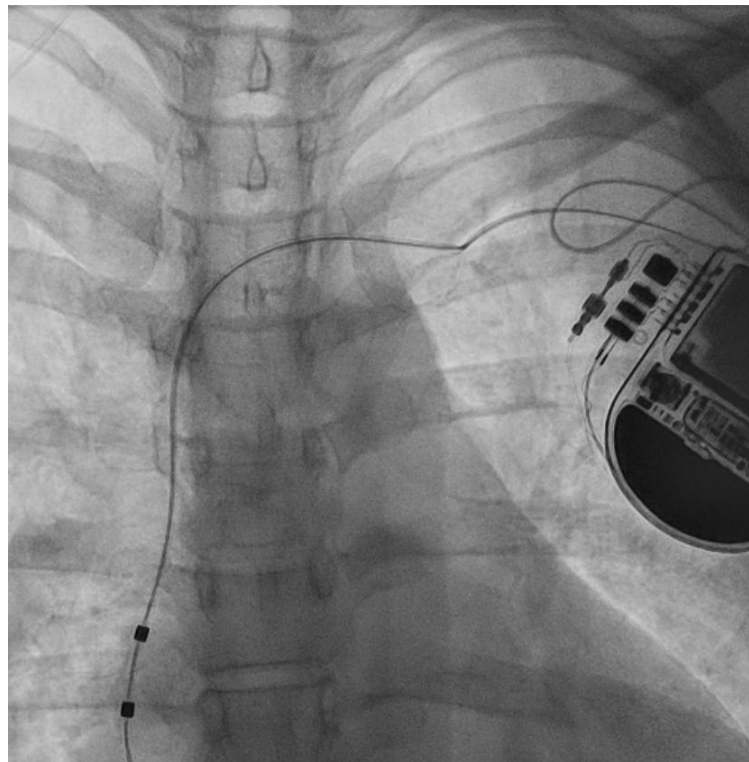
Blood substitution

- The doctor in the department who admits the patient to the extraction procedure will secure 4 transfusion units of erythrocytes to the blood bank before the procedure. In case of other coagulation disorders, ordering and preparation according to the hematologist's office.

Preparation before procedure III

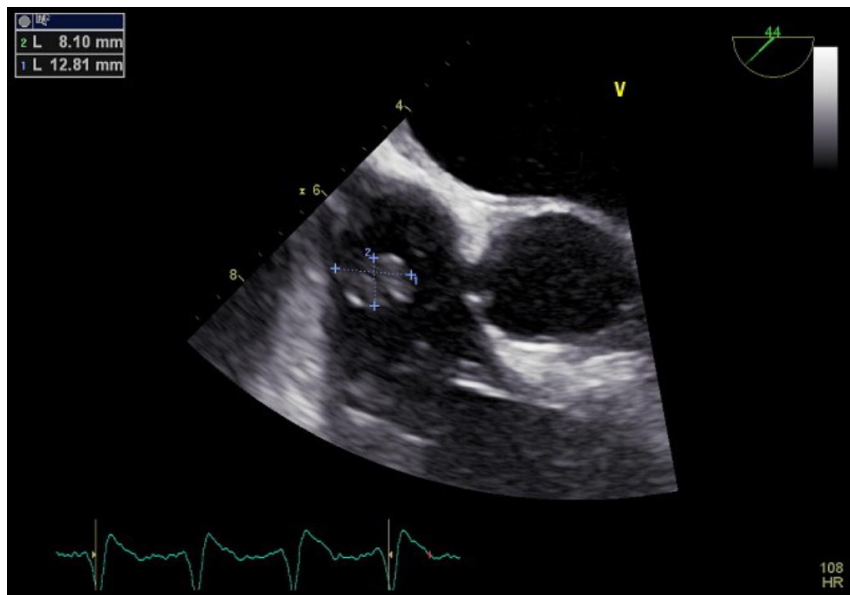
- Complex lead extraction is a potentially extremely risky procedure with potentially fatal consequences caused almost exclusively by bleeding in the mechanical complication of extraction.
- Therefore, knowledge of coagulation parameters and proper preparation of the patient before the procedure is key to minimizing the risk of complications.
- All patients should have normalized/standardized coagulation parameters (aPTT, INR [in patients on continuous warfarin therapy, INR <2.8 is recommended], platelet count, coagulation factors). If necessary, a consultation with a hematologist is recommended to recommend the correct preparation of the patient before the procedure (administration of blood derivatives)
- Any antithrombotic medication must be stopped in advance, the time must be adjusted according to the characteristics of the individual preparations, their pharmacodynamics and kidney function (creatinine clearance).
- With antiplatelet treatment, especially DAPT, the risk of withdrawal must always be considered for elective procedures, i.e. risk thrombosis risk on withdrawal x bleeding risk on continuous treatment.
- For procedures for acute/vital indications, we always deal with the patient individually and emphasize surgical management of the wound

Chest X-ray(or CT) is the basic imaging method before TLE

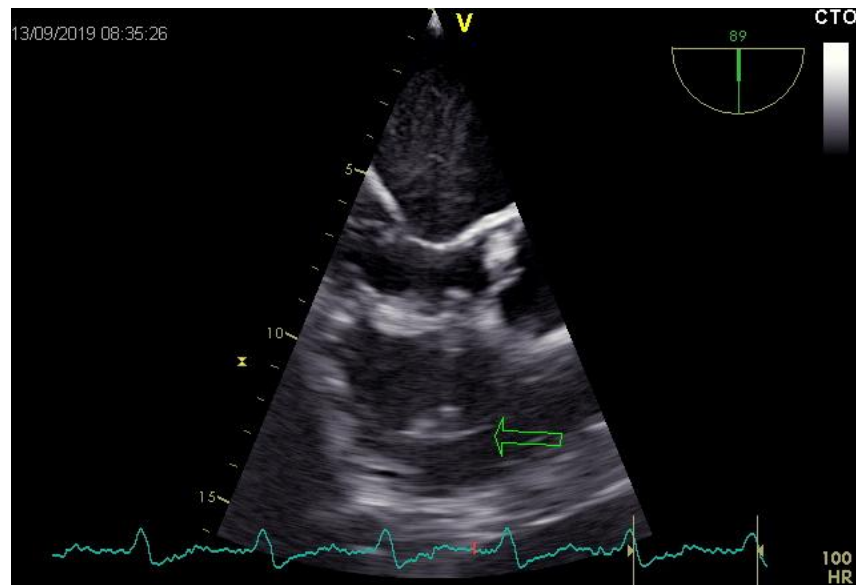


Echocardiographic finding is clear in many cases, but sometimes differentiation is difficult

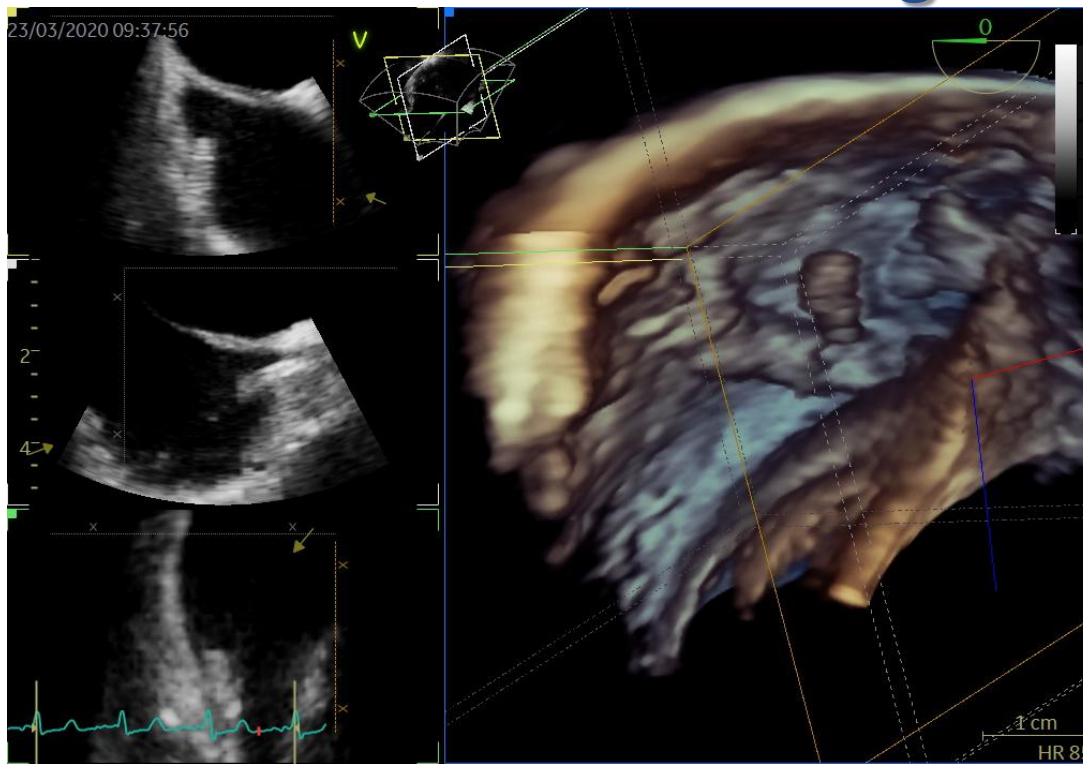
Clear vegetation of bacterial endocarditis



Patient with CIED and high temperatures of unclear origin ...



In some cases, 3D echocardiography is useful to differentiate the finding





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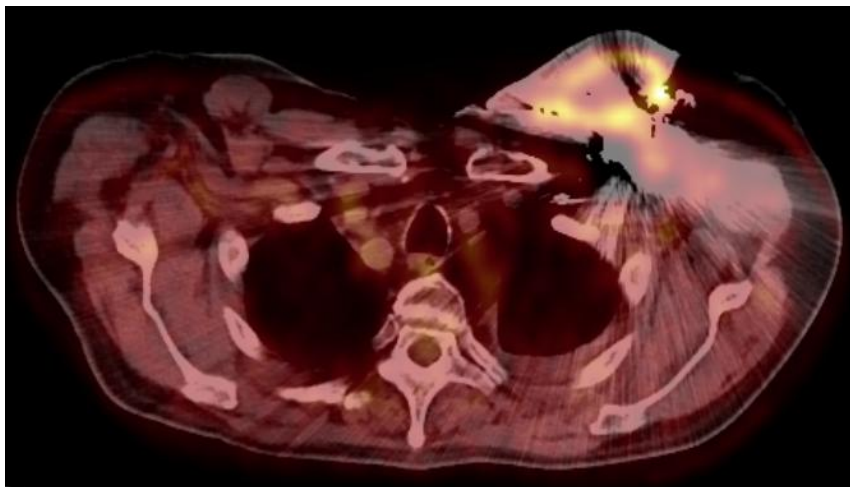


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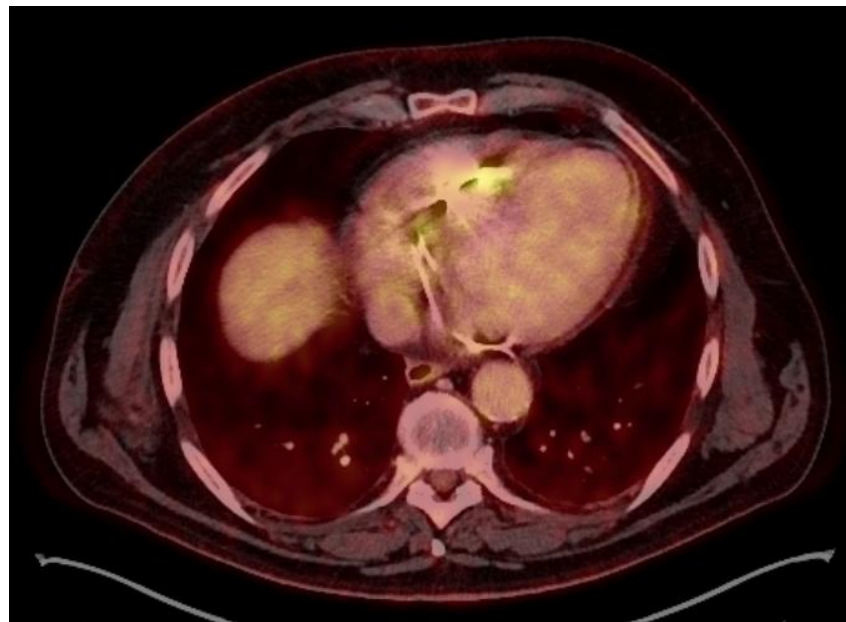
In some cases, it is necessary to perform a PET-CT examination for differential diagnostic reasons

PET-CT

Pocket only infection



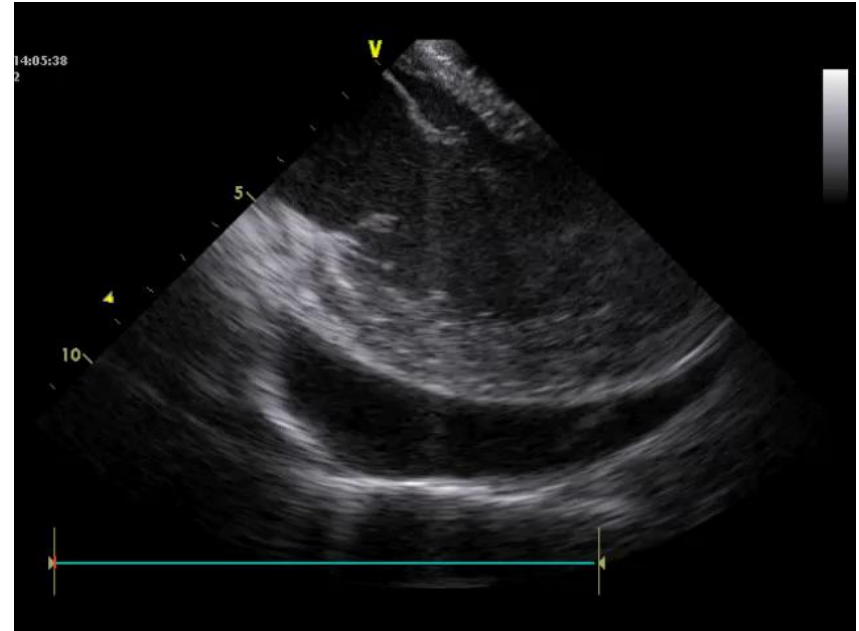
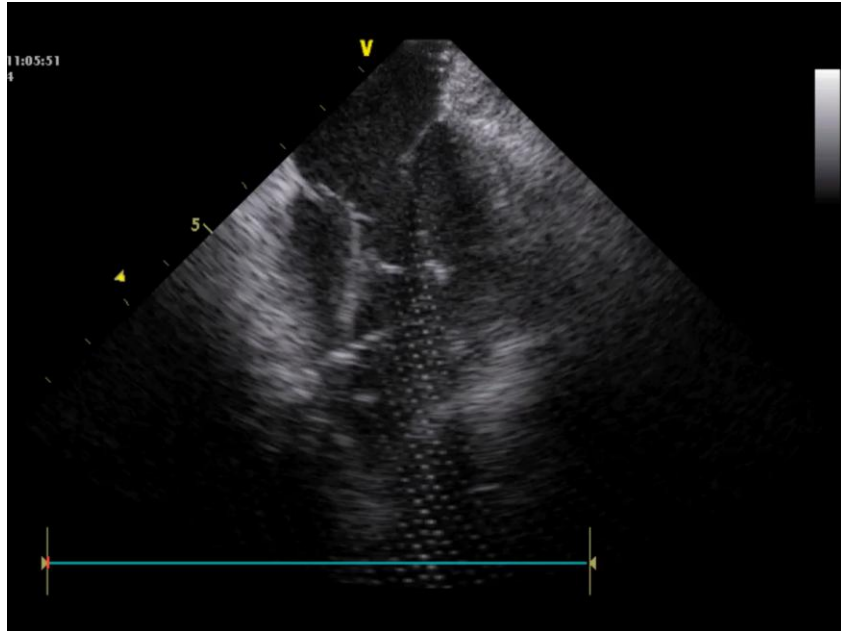
Endocarditis



The TLE procedure should be aimed at:

1. security
2. achieving as complete an extraction of the electrodes as possible
3. continuous monitoring of vital functions
4. echocardiographic monitoring – ideally ICE
5. for the interplay of the team
6. patient management after the procedure

ICE is mandatoty during the TLE procedure



Temporary pacing

- During the extraction procedure, all patients are provided with temporary transvenous cardiac stimulation.
- As a rule, it is introduced from the femoral approach and canceled after the procedure in the extraction room.
- In case of need for longer temporary cardiac stimulation, the patient has „**permanent**“ **temporary cardiac pacing** introduced with the introduction of a stimulation electrode with active fixation and connection of a standard pacemaker.
- Care for the pacing electrode is standard and identical to care for invasive venous access.

Monitoring after LE procedure

- After the procedure, the patient is transferred accompanied by a nurse from the sending department. In justified cases, transport is provided by a nurse and a doctor. If the state of consciousness or hemodynamics requires intensive care, the patient is transferred to OAC IKK FNOL by appointment, and transport is provided by a doctor and nurse from OAC IKK FNOL.
- After the procedure, the patient's heart rhythm is telemetrically monitored, blood oxygen saturation is measured, and the frequency of blood pressure measurement is determined according to the hemodynamic status.
- According to the LE protocol recommendation, bedside echocardiography is performed with a focus on mechanical complications of the extraction, no later than two hours after the procedure.
- In the case of hemodynamic instability, an chest X-ray or a CT chest examination is indicated, focusing on the exclusion of possible complications of the procedure (pneumothorax, hemothorax, hemopericardium).

Quality indicators

- **Quality indicators** include the success of complete electrode extraction or clinically successful extraction defined **as electrode extraction with electrode residue < 4 cm without affecting the clinical condition.**
- These quality indicators comparable to the data published in the European Lead Extraction Registry ELECTRA (ESC-EORP ELECTRA - European Lead Extraction ConTRolled Registry) (93.5% and 4.7% respectively) and the occurrence of mechanical complications (perforation of the venous wall or cardiac tamponade) requiring cardiosurgical revision or tamponade that can be solved by pericardiocentesis.

Qualifications and training of operators

- 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.
- Simulators may also provide a means to maintain competency for physicians who have a low caseload.
- 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.
- This volume-outcome relationship is supported by data of the ELECTRa-registry, 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%; $P < 0.03$).



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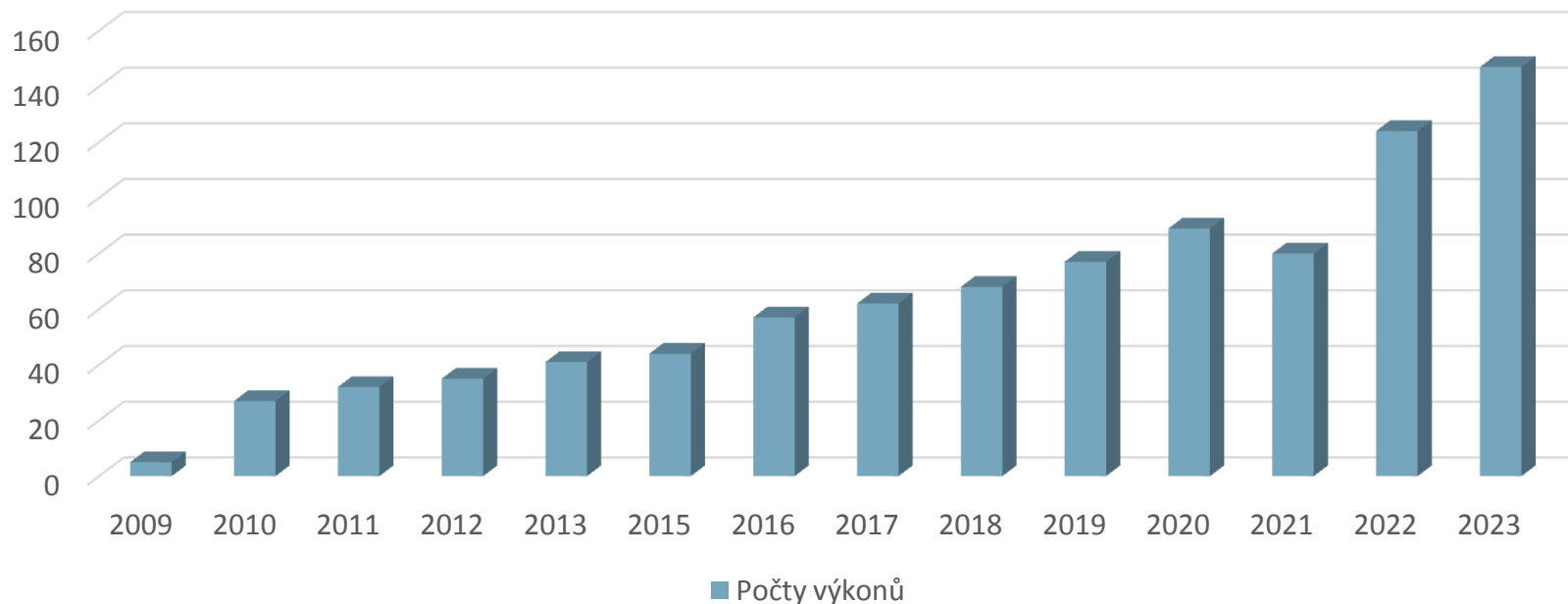
Univerzita Palackého
v Olomouci



III: Vlastní výsledky

Vývoj počtu procedur KKC FNOL

Počty výkonů



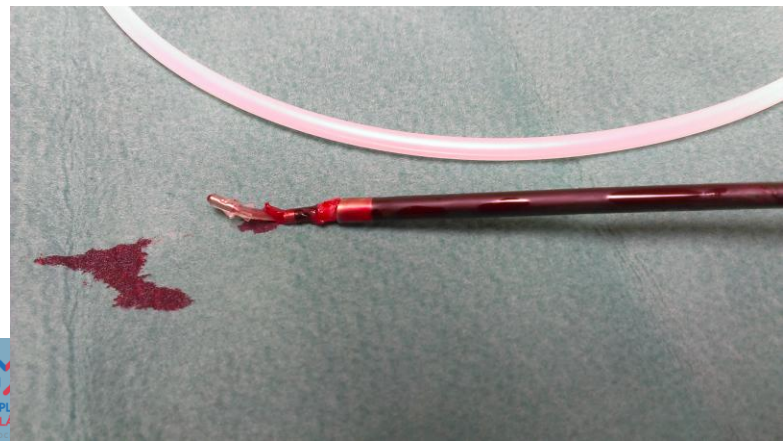
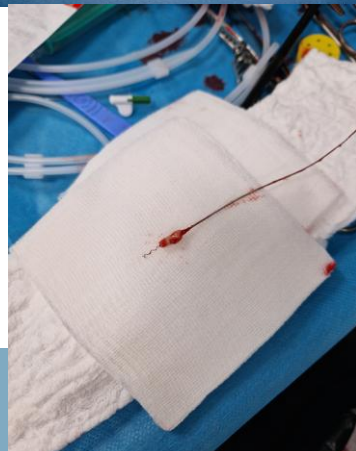
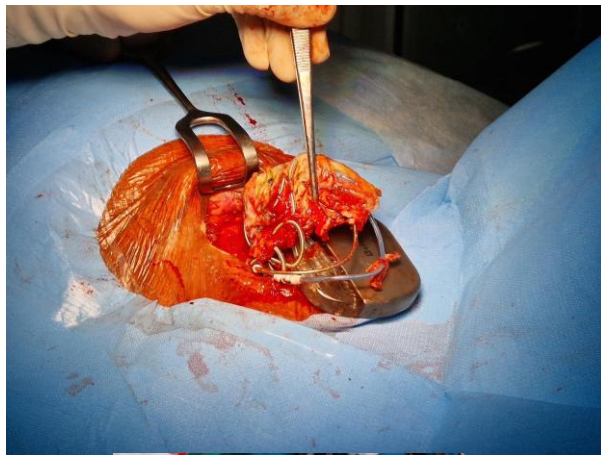
Zdroj: Registr extrakcí I. IKK FNOL

Výsledky:

| Výsledky | % |
|-----------------------------|------|
| Efektivita výkonů | 96,1 |
| Mortalita | 0,2 |
| Závažné komplikace | 1,9 |
| KCH extrakce | 3,4 |
| Laser | 63 |
| Laser/mechanické sheaty | 33 |
| Katetrizační technika (MGB) | 4 |

Zdroj: Registr extrakcí I.IKK FNOL

Nálezy, se kterými se setkáte ...



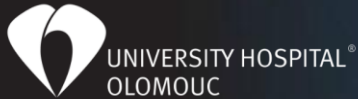
Take home message I

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).

Take home message II

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.

Thank you for your attention
Olomouc University Hospital



Faculty of Medicine
and Dentistry

Palacký University
Olomouc

