FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

# Odborné stanovisko ČKS/EHRA ke kvalifikaci center provádějící extrakce elektrod u implantátů

Miloš Táborský

25.11.2016

# Extrakce: EHRA Position Paper

Europace (2012) **14**, 124–134
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EHRA POSITION PAPER

## Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper

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# Extrakce: Guidelines AHA/ACC/HRS

## Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management

***This document was endorsed by the American Heart Association (AHA).***

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### Preamble

On May 15, 2008, the lead extraction community convened to critically review the prior April 2000 NASPE policy statement on Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training.[1] This gathering was held as a co-sponsored satellite symposium* during the Heart Rhythm Society's 29th Annual Scientific Sessions to examine ways to revise and implement effective lead management standards.[2]

This writing committee, appointed by the Heart Rhythm Society, is a representative group of international experts in device and lead management from North America and Europe. Each of these physicians is an expert concerning the management of leads used with cardiovascular implantable electronic devices (CIEDs) including transvenous lead extraction. We were charged with the development of a consensus document for the lead extraction community regarding standards for safe and effective lead management. Central to this effort was a focus on transvenous lead extraction, including standards for training, and standards for the evaluation of new tools and techniques. Although the major intervention discussed in this document is transvenous lead extraction, it was strongly recommended that this document should focus on the management of the patient, and in particular the management of the leads.[2]

The writing group consisted of nine cardiac electrophysiologists and three cardiothoracic surgeons, who specialize in CIED implantation and extraction. This statement represents expert consensus of the writing committee based on a review of the literature, their own experience in treating patients and input from the extraction community gathered at the symposium. It is directed to all health care professionals and health care institutions that are involved in the care of patients with CIEDs.

The document represents the strong consensus of the writing committee, which was developed as a result of comments collected at the 2008 satellite symposium; as well as during a separate face-to-face all day writing group meeting, multiple international conference calls, and three web based questionnaires. In writing a "consensus" document, it is recognized that consensus does not mean that there was complete agreement among all writing group members. We identified those aspects of transvenous lead extraction for which a true "consensus" could be identified. Surveys of the entire writing group were used to identify these areas of consensus. For the purposes of this Consensus Document we defined a consensus as 83% or greater agreement by the authors of this document.

When using or considering the guidance given in this document, it is important to remember that there are no absolutes with regard to many clinical situations. The ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of all

This document was approved by the Board of Trustees of the Heart Rhythm Society on May 6, 2009. It can be found on the Heart Rhythm Society website at www.HRSonline.org/Policy/ClinicalGuidelines. **Address reprint requests and correspondence:** Donna Goldberg, MPH, Heart Rhythm Society, 1400K Street, NW, Suite 500, Washington DC 200005. E-mail address: dgoldberg@hrsonline.org.

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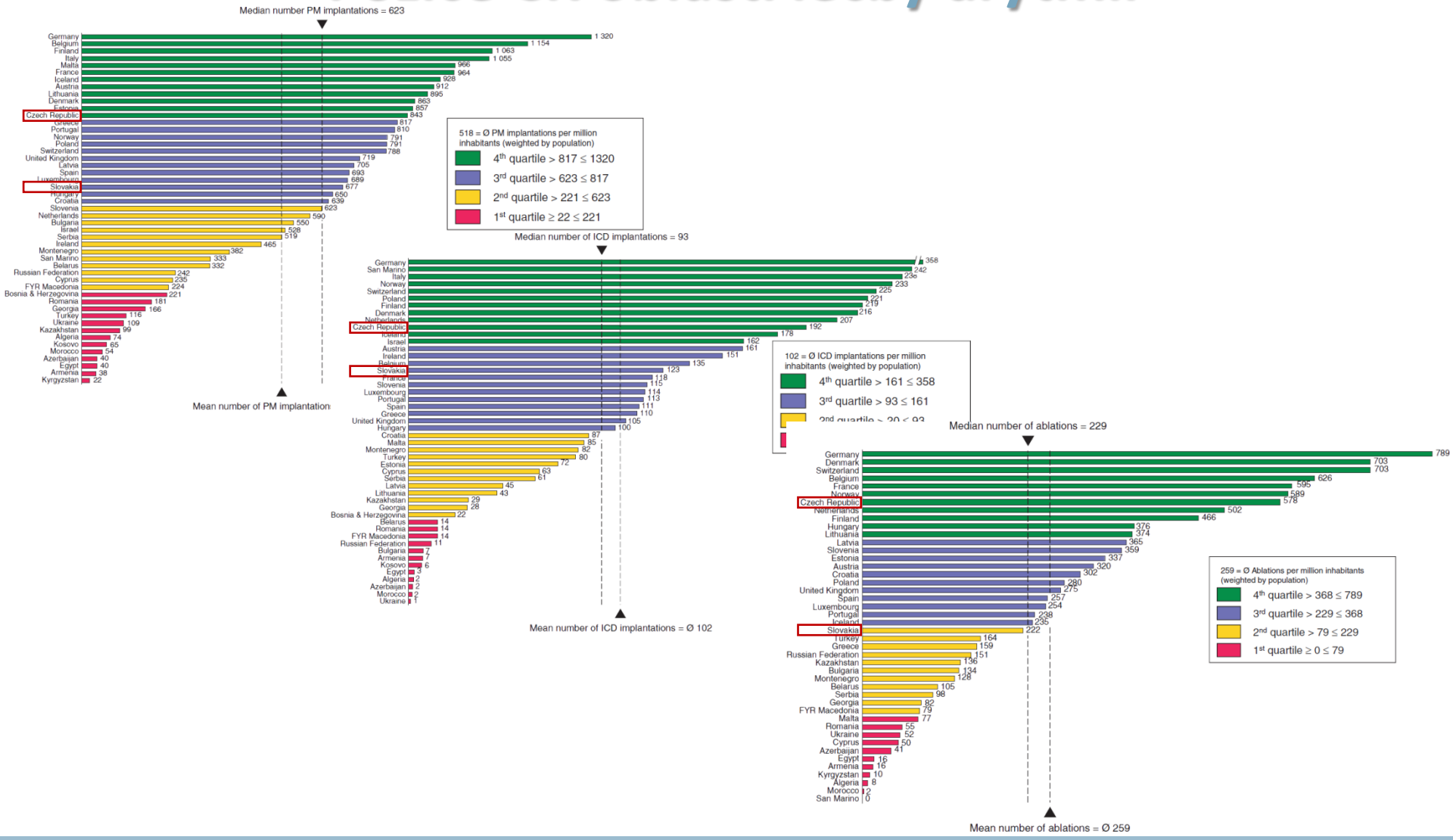
*http://www.hrsonline.org/Policy-Payment/Clinical-Guidelines Documents?SearchText=&seeall=1#sthash.IkjdaIHW.dpuf*

# Pozice ČR oblasti léčby arytmií

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I. INTERNÍ KLINIKA KARDIOLOGICKÁ
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# Předpokládaný počet transvenosních extrakcí EL

| 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 |

Reálná potřeba extrakcí v ČR: 150 – 600 ročně

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# Indikace k provedení extrakce EL I

- **Infection**
- **Class I**
- 1. Complete device and lead removal is recommended in all patients with definite CIED system infection, as evidenced by valvular endocarditis, lead endocarditis or sepsis. *(Level of evidence: B)*
- 2. Complete device and lead removal is recommended in all patients with CIED pocket infection as evidenced by pocket abscess, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system. *(Level of evidence: B)*
- 3. Complete device and lead removal is recommended in all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. (*Level of evidence: B)*
- 4. Complete device and lead removal is recommended in patients with occult gram-positive bacteremia (not contaminant). *(Level*
- *of evidence: B)*
- **Class IIa**
- 1. Complete device and lead removal is reasonable in patients with persistent occult gram-negative bacteremia. *(Level of evidence: B)*
- **Class III**
- 1. CIED removal is not indicated for a superficial or incisional infection without involvement of the device and/or leads *(Level of evidence: C)*
- 2. CIED removal is not indicated to treat chronic bacteremia due to a source other than the CIED, when long-term suppressive antibiotics are required. *(Level of evidence: C)*

- **Chronic Pain**
- **Class IIa**
- 1. Device and/or lead removal is reasonable in patients with severe chronic pain, at the device or lead insertion site, that causes significant discomfort for the patient, is not manageable by medical or surgical techniques and for which there is no acceptable alternative. *(Level of evidence: C)*

# Indikace k provedení extrakce EL II

- **Thrombosis or Venous Stenosis**
- Class I
- 1. Lead removal is recommended in patients with clinically significant thromboembolic events associated with thrombus on a lead or a lead fragment. *(Level of evidence: C)*
- 2. Lead removal is recommended in patients with bilateral subclavian vein or SVC occlusion precluding implantation of a needed transvenous lead. *(Level of evidence: C)*
- 3. Lead removal is recommended in patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead. *(Level of evidence: C)*
- 4. Lead removal is recommended in patients with superior vena cava stenosis or occlusion with limiting symptoms. *(Level of evidence: C)*
- 5. Lead removal is recommended in patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead when there is a contraindication for using the contralateral side (e.g. contralateral AV fistula, shunt or vascular access port, mastectomy). *(Level of evidence: C)*
- Class IIa
- 1. Lead removal is reasonable in patients with ipsilateral venous occlusion preventing access to the venous circulation for required
- placement of an additional lead, when there is no contraindication for using the contralateral side. *(Level of evidence C)*
- **Functional Leads**
- Class I
- 1. Lead removal is recommended in patients with life threatening arrhythmias secondary to retained leads. *(Level of evidence: B)*
- 2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat
- to the patients if left in place. (e.g. Telectronics ACCUFIX J wire fracture with protrusion). *(Level of evidence: B)*
- 3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. *(Level of evidence: B)*
- 4. Lead removal is recommended in patients with leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). *(Level of evidence: C)*
- Class IIb
- 1. Lead removal may be considered in patients with an abandoned functional lead that poses a risk of interference with the operation of the active CIED system. *(Level of evidence: C)*
- 2. Lead removal may be considered in patients with functioning leads that due to their design or their failure pose a potential
- future threat to the patient if left in place. (e.g. Telectronics ACCUFIX without protrusion) *(Level of evidence: C)*
- 3. Lead removal may be considered in patients with leads that are functional but not being used. (i.e. RV pacing lead after upgrade to ICD) *(Level of evidence: C)*
- 4. Lead removal may be considered in patients who require specific imaging techniques (e.g. MRI) that can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. *(Level of evidence: C)*
- 5. Lead removal may be considered in patients in order to permit the implantation of an MRI conditional CIED system. *(Level of evidence: C)*

# Kontraindikace k provedení extrakce EL

- **Class III**
- 1. Lead removal is not indicated in patients with functional but redundant leads if patients have a life expectancy of less than one year. *(Level of evidence: C)*

- 2. Lead removal is not indicated in patients with known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling. *(Level of evidence: C)*

# Rizikové faktory infekcí u implantátů

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

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# Doporučení min. tréninku specializovaného centra pro extrakce

| Lead extraction status | Minimum number of leads | Minimum number of procedures | Additional requirements |
|---|---|---|---|
| Trainee | 40 leads under supervision:<br>10 ICD leads,<br>10 leads > 6 years old | 30<br><br>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 |

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# Požadovaný personál a jeho úloha

| 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 |

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# Prostory a technické zázemí

| 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 → hybrid OR |
| 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 |

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# Registr extrakcí

| 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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# Požadavky na strukturu registru

| Centre ID |
|---|
| Patient ID (guarantee of privacy) |
| Gender (M/F) |
| Date of birth (D/M/Y) |
| No. of leads present (prior to procedure) |
| Date of 1st implant of current transvenous implanted leads (D/M/Y) |
| No. of leads planned to remove transvenously at the beginning of the procedure |
| Heart disease (specify) |
| NYHA class |
| LVEF (%) |
| Co-morbidities (creatinine, dialysis, diabetes, BMI, decompensated HF) |
| Procedure |
| Date (D/M/Y) |
| Anaesthesia: local, general, IV moderate sedation, IV deep sedation |
| Room: EP cath lab, operating room |
| Duration (entire procedure without reimplant or debridement) (min) |
| X-ray exposure (entire procedure without reimplant or temporary pacing) (min) |
| Reimplant during the same procedure: yes, no |
| Lead No. |
| Manufacturer |
| Model |
| (if unknown, please specify). . . |
| Pacing |
| Defibrillator |
| Poles |
| Coils |
| Fixation: active, passive |
| Insulation: silicone, polyurethane, other |
| Date of implant (D/M/Y) |
| Vein of implant (cephalic, subclavian, ext Jugular, int Jugular): R, L |
| Indication for removal |
| Previous extraction attempt: yes, no |
| Lead damage prior to removal: yes, no |
| Placement (RA, RV, LV, LA, SVC, cardiac vein, coronary sinus, other) |
| Tools (specify for each lead) |
| Standard stylet |
| Locking stylet |
| Polypropylene sheaths |
| Laser sheaths |
| RF sheaths |
| Rotational sheaths |
| Dotter Basket |
| Tip deflecting wire |
| Lasso or Gooseneck snare |
| Needle's eye snare |
| Others (describe) |
| Techniques (specify for each lead) |

| Traction without sheath advancement |
|---|
| Dilatation (counter-pressure) |
| Countertraction (endocardial surface) |
| Others (describe) |
| Venous approach (specify for each lead) |
| Cephalic |
| Subclavian |
| Femoral |
| External Jugular |
| Internal Jugular |
| X-ray results (specify for each lead) |
| Total success |
| Partial success (less than 4 cm retained) |
| Failure |
| Causes of failure (specify for each lead) |
| Extraction time (min) (specify for each lead) |
| Without sheath—from the insertion of locking stylet |
| With Sheath—sheath time |
| Clinical results (specify for each lead) |
| Success |
| Failure |
| Complications (by 30 days, specify) |
| Death: time of occurrence |
| Major: time of occurrence |
| Minor: time of occurrence |

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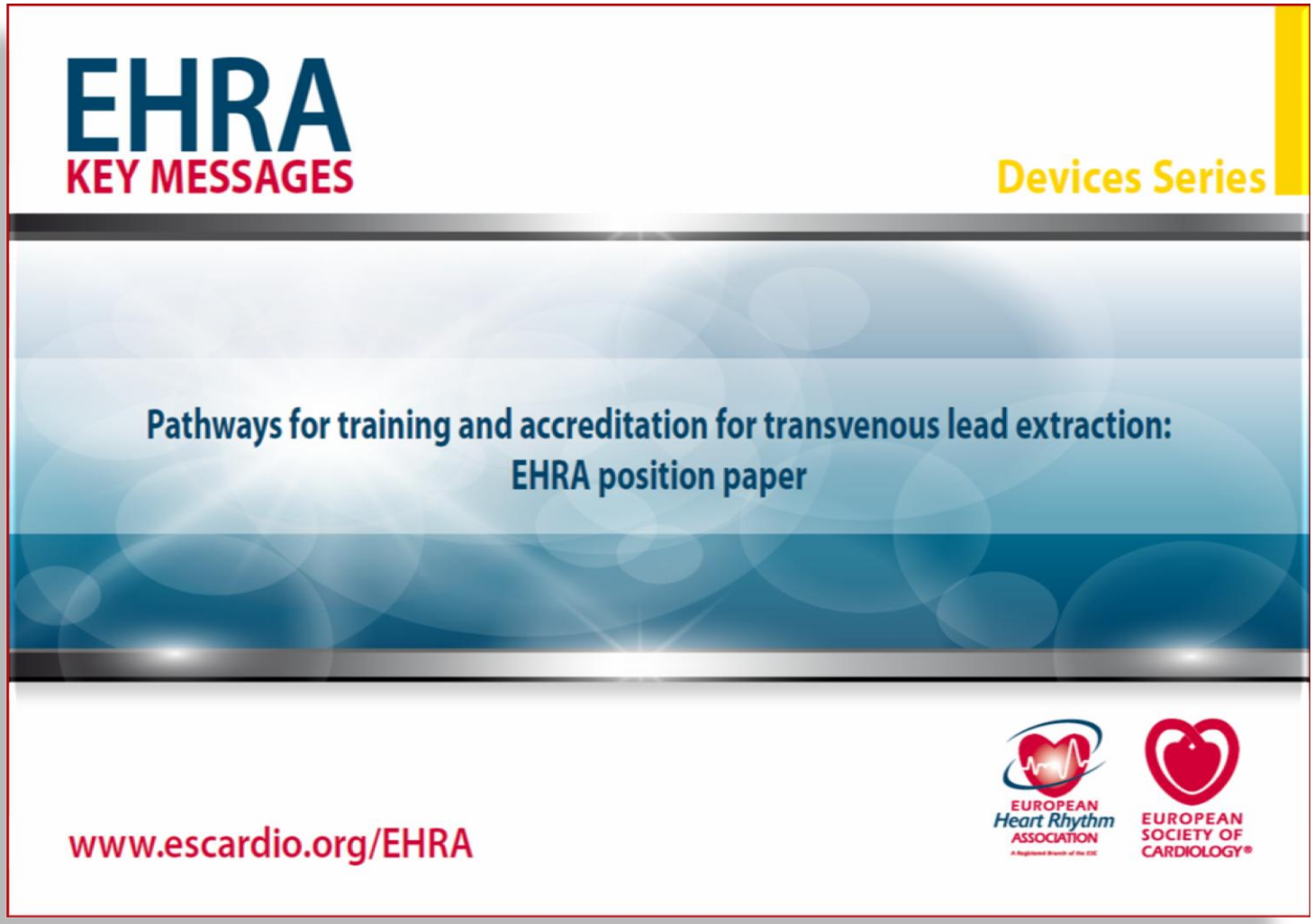
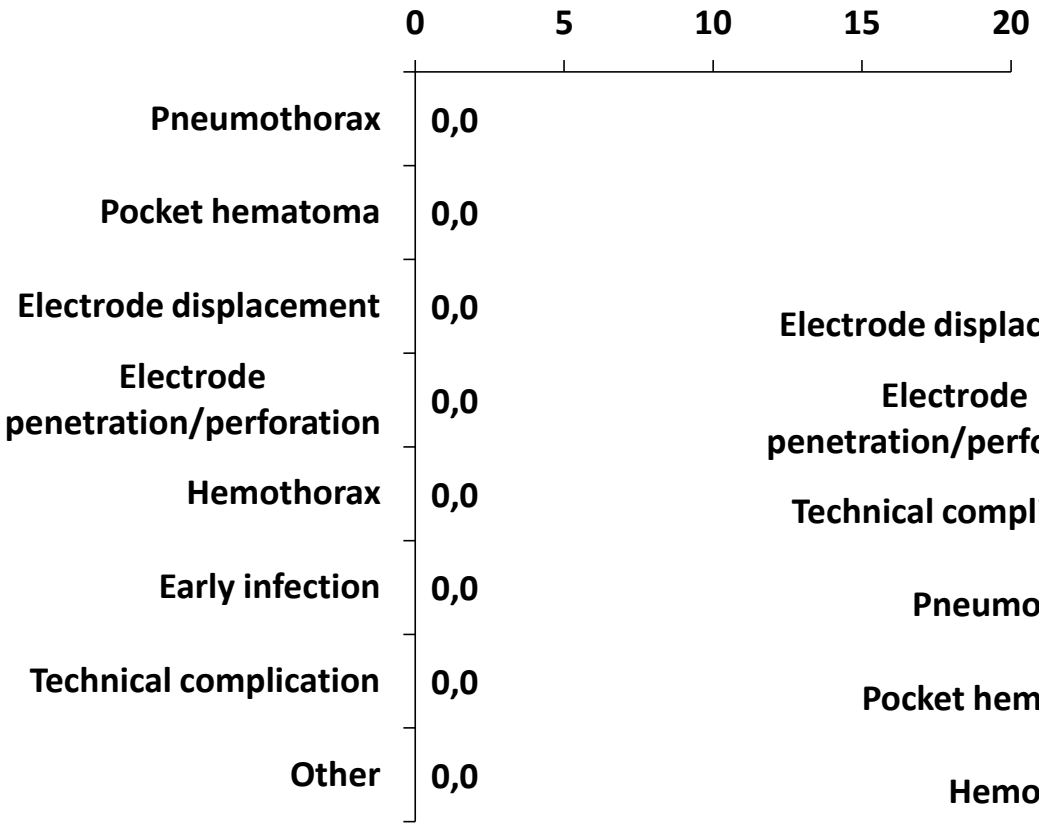
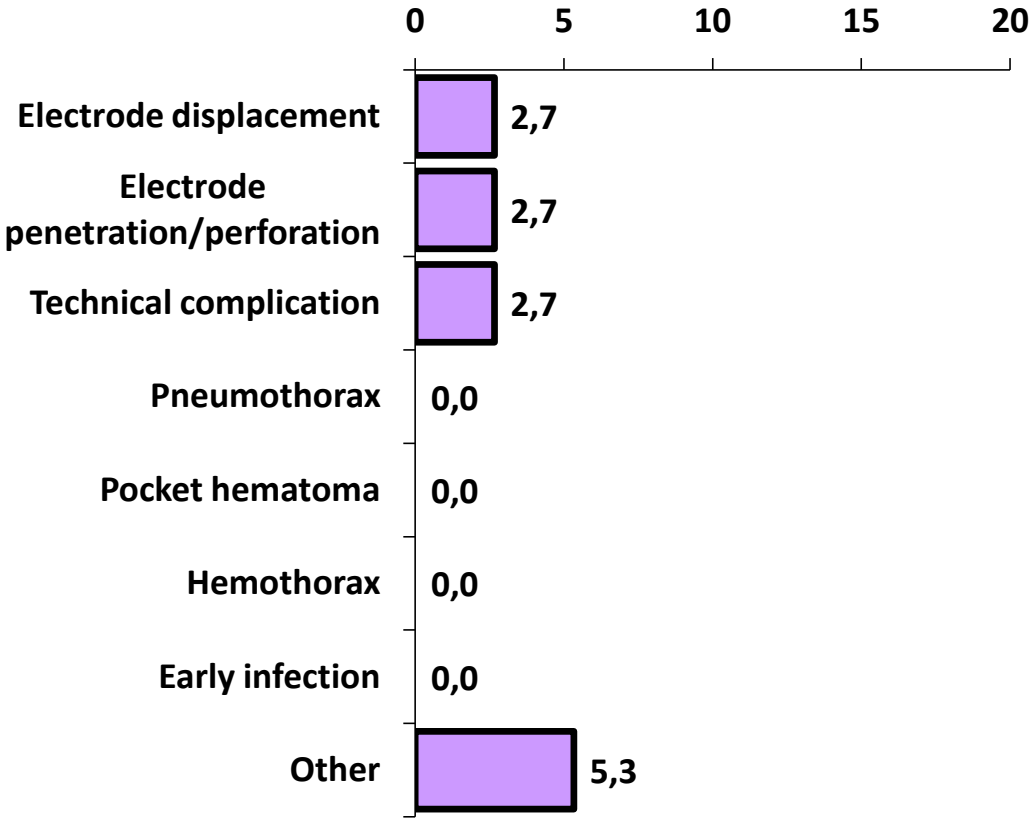
# Souhrn: EHRA Key Messages



# Underreporting: Registr REPACE




*REPACE 2015, ČASR ČKS*

# Jaká je situace v ČR ?

- Většina center nereportuje komplikace do registrů
- Řada menších center se „stydí“ za své komplikace, řeší ve vlastní režii, často v neprospěch pacienta, zejména v dlouhodobém horizontu
- Některá centra preferují KCH řešení závažných komplikací → ekonomické aspekty
- Rozumná centra včetně univerzitních referují pacienty do specializovaných center

# Kam spějeme v otázce extrakcí

- Na 10 mil obyvatel jsou postačující 3-4 centra
- Splnění personálních a technických požadavků dle doporučení EHRA
- Centra mají mít dostatečnou zkušenost s extrakčními technikami (mechanická extrakce – laser – MGB technika…) a provádět je pravidelně
- Nutný back-up KCH !!!
- Ideálně – hybridní sál
- Výkony za kontroly ICE
- Management pacientů před a po výkonu
- Zkušené ATB centrum
- Konzultační činnost

# Cíle ČKS/ČASR 2017

- Cor Vasa 2/2017: česká verze EHRA dokumentu

- 2. polovina 2017: Originální česká doporučení pro extrakce a management infekčních komplikací – publikace v IF – mezinárodní formát
  autoři: Táborský/Neužil/Kautzner

- 2017: Registr extrakcí pod vedením ČASR

# Společný projekt VZP a ČKS: Evaluace nových technologií

- **Nástin možného projektu:**
- Při požadavku na registraci nové technologie v oblasti nefarmakologické terapie:
- Definice 2-3 center, evaluace dle stanoveného protokolu
- Souhlas EK
- Možnost spolufinancování projektu
- Závěrečná zpráva : Doporučení nebo nedoporučení pro zavedení do číselníku VZP, event. zavedení nového kódu výkonu dle standardů jako koncensus odborné společnosti a VZP

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