Supplementary material

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LEAD EXTRACTION PROCEDURE

Definitions

Transvenous lead extraction (TLE) indications, procedure effectiveness and complications were estimated according to recent TLE recommendations (2017 HRS consensus and 2018 EHRA guidelines) [1–3].

Lead extraction was defined as a procedure where at least one lead removal required the assistance of equipment not typically employed during lead implantation or at least one lead was implanted for greater than 1 year.

Indications for lead extractions

Main indications for TLE were: 1. infectious complications: local pocket infection, bacteraemia with or without endocarditis, or any combination of these presentations together 2. non-infectious indications including: mechanical lead damage (electric failure), lead dysfunction (exit/entry block, dislodgement, extracardiac pacing, perforation), upgrading, downgrading and another reasons of prevention of lead abandonment-prophylactic indications e.g. atrial fibrillation, overmuch of leads, threatener / potentially threatener lead (free ending, left heart, lead-dependent tricuspid valve dysfunction, and other (MRI indication, cancer, pain of pocket, the original indication of CIED has disappeared) and recapture venous access (symptomatic occlusion, superior vena cava syndrome, lead replacement / upgrading).

Efficacy and complications of TLE

Effectiveness of TLE was defined as complete procedural success if all targeted leads and all lead material from the vascular space was removed, with the absence of any permanently disabling complication or procedure-related death. Clinical success was defined as lead extraction procedures with removal of all targeted leads and lead material from the vascular

space or retention of a small portion of the lead (0.4 cm) that does not negatively impact the outcome goals of the procedure.

Major complication was define as any of the outcomes related to the procedure, which is life-threatening or results in death (cardiac or non-cardiac).

The risk of major complications related to TLE (points, percentage) was assessed using the SAFeTY TLE score [20].

Minor complication was define as 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.

Techniques of transvenous lead extraction.

Whenever possible, the implant vein was the primary access site. In cases where the proximal lead ended inside the cardiovascular system (CVS) or the lead was broken during the extraction procedure, the femoral, jugular, or subclavian regained approach was used [20, 21]. Standard stiff stylets were used to stabilise the recent models of leads with shorter dwell times, whereas locking stylets (Locking, Cook®) were used only for extraction of the oldest leads, with a high risk of break. Laser and electrosurgical dissection sheaths were not used. Polypropylene telescoping (Byrd) dilatators (Cook®) were always the first choice [22]. Powered mechanical sheath systems (Evolution, Cook; TightRail Spectranetics) were only used if the polypropylene telescoping sheaths appeared ineffective. A femoral approach, using the femoral workstation with a basket, the Amplatz GooseNeck® Snare Kit (Amplatz, US), and sometimes Byrd dilators were used to extract free floating leads with proximal portions within the CVS. We developed a method to remove leads with ingrowing scar tissue using less standard tools, including coronary sinus dedicated sheaths, pig-tail catheters, various angiographic guidewires, and lasso catheters [20, 21]. A combined approach, using two or more different approaches (jugular, subclavian, femoral) had to be used for one lead extraction in this study. These techniques were used when conventional methods appeared insufficient. Finally, a technique of simple extortion and gentle traction was used for active fixation (screw-in), straight, isodiametric leads if the vein was not intended for future vascular access (i.e., usually in the case of infection).

All extraction procedures were performed following different organizational models spanning 16 years of experience from procedures performed in the electrophysiology laboratory using intravenous analgesia/sedation [22] to procedures in the hybrid room under general anaesthesia. Over the past 6 years, the core extraction team has consisted of the same highly experienced TLE operator, experienced echocardiographer and dedicated cardiac surgeon [23–25].

Procedure complexity was expressed lead extraction time ("sheath to sheath time") and average time of single lead extraction (sheath-to sheath / number of extracted leads).

Unexpected procedure difficulty so-called "technical problems" during TLE — situations which increased procedure complexity but not being complications. They were exactly described in our previous reports [18].

RESULTS

The decision to discontinue CIED therapy was made in 169 (4.6%) patients of the entire analyzed population and it was made significantly more often in patients with PM 136 (5.3%) than in patients with ICD 28 (3.5%) or CRT-D carriers – 5 (1.9%) (Table S1).

Table S1. Frequency of non-reimplantation decisions in groups of patients with different types of CIED

Compared groups	Number of pts	Not reimplanted	Pearson's χ^2
Pacemaker (1–2)	2584 100.0%	136 5.3%	*P* = 0.03
ICD (2)	806 100.0%	28 3.5%	
CRT-D (3)	256 100.0%	5 2.1%	
All patients (4)	3646 100.0%	169 4.6%	

Abbreviations: CIED, cardiac implantable electronic device; CRT-D, cardioverter defibrillator with cardiac resynchronisation therapy; ICD, implantable cardioverter defibrillator

Multivariable regression analysis shown that independent positive prognostic factors of discontinuation of indications to CIED reimplantation in pacemakers group were: higher LVEF (OR = 1.03; *P* <0.001) and presence of AF (OR = 3.8; *P* <0.001). The negative prognostic factors were older age during first CIED implantation (OR=0.97; *P* <0.001) and higher NYHA class (OR=0.61; *P* <0.01). The only predictive parameter of discontinuation of indications for ICD/CRT-D reimplantation was the increase in LVEF (OR=1.06; *P* <0.001) (Table S2).

Table S2. Multivariable regression analysis of prognostic factors of discontinuation of indications to CIED reimplantation

	Univariable regression			Multivariable regression		
	OR	95%CI	*P*	OR	95%CI	*P*
Pacemakers (SSI, DDD, VDD)						
Patient's age during first system implantation (by 1 year)	0.97	0.96-0.98	<0.001	0.97	0.96-0.98	<0.001
NYHA FC (by 1 class)	0.41	0.3-0.56	<0.001	0.61	0.43-0.86	<0.01
LVEF (by 1%p)	1.04	1.02-1.06	<0.001	1.03	1.01-1.05	<0.001
Atrial fibrillation (y/n)	1.62	1.12-2.32	<0.001	3.8	2.41-5.7	<0.001
Defibrillators (ICD-VR, ICD-DR, CRT-D)						
LVEF (by 1%p)	1.06	1.04-1.09	<0.001			

Abbreviations: CI, confidence interval; DDD, dual chamber pacemaker; ICD-DR, dual chamber implantable cardioverter defibrillator; ICD-VR, single (ventricular) chamber implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; NYHA FC, New York Heart Association Functional Class; OR, odds ratio; SSI, single chamber pacemaker; VDD, single atrial sensing, ventricular sensing/pacing lead pacemaker; other — see Table S1

Mortality rate during long-term follow-up (FU) (1584 [718.0–2823] [1–5519] days) was significantly lower among non-reimplanted patients (11.2% vs. 33.4%). Analysis of clinical characteristic subgroup of patients which died after hospital discharge during FU indicates, that in all group predominant infections (together 73.7% in groups 1–3), older patients age (on comparison to age of whole groups before TLE) and for all patients more frequent IHD, lower EF and more frequent congestive heart failure. Characteristic of died patient were incomparable to respective whole cohort of patients (Table S3).

Table S3. The analysis of subgroups of patients who died after hospital discharge during FU

Subgroups of patients who died after hospital discharge during FU	Unnecessary pacemaker, NSR	Unnecessary pacemaker, AF, NHR	Unnecessary ICD/CRT, improvement in EF, NHR	All non-reimplanted patients	Control group Removal of necessary CIED with immediate or delayed

					reimplantation
Group	1	2	3	4	5
	χ^2 test/ Mann-Whitney U test 1 vs. 5	χ^2 test/ Mann-Whitney U test 2 vs. 5	χ^2 test/ Mann-Whitney U test 3 vs. 5	χ^2 test/ Mann-Whitney U test 4 vs. 5	
Number of deaths in the whole group, %	n =5/86 (5.8) *P* <0.001	n = 11/50 (22.0) *P* = 0.11	n = 3/33 (9.1) *P* <0.01	n =19/169 (11.2) *P* <0.001	n = 1173/3477 (33.7)
Patient age during TLE	70.0 (64.0-74.0) P=0.62	72.0 (68.0-78.0) *P* = 0.83	80.0 (15.0-82.0) *P* = 0.04	70.0 (65.0-78.0) *P* = 0.37	73.0 (65.0-80.0)
LVEF, %	56.0 (46.0–59.0) *P* = 0.07	50.0 (35.0–56.0) *P* = 0.33	50.0 (50.0–55.0) *P* = 0.25	51.0 (38.0–56.0) *P* = 0.03	45.0 (30.0–56.0)
LVEF <40%	1 (20.0) *P* = 0.47	4 (36.4) *P* = 0.73	0 (0.00) *P* = 0.31	5 (23.3) *P* = 0.14	536 (46.1)
Ischemic heart disease	2 (40.0) *P* = 0.58	6 (54.5) *P* = 0.85	2 (66.7) *P* = 0.67	10 (52.6) *P* = 0.55	721 (62.1)
Charlson's comorbidity index, points	5 (4–10) *P* = 0.61	5 (3–6) *P* = 0.6	12 (0.0–13) *P* = 0.26	5 (3–10) *P* = 0.84	5 (4–9)
Systemic infection	4 (80.0) *P* = 0.06	4 (36.4) *P* = 0.95	2 (66.7) *P* = 0.48	10 (52.6) *P* = 0.08	395 (34.0)
Pocket infection	1 (20.0) *P* = 0.85	2 (18.2) *P* = 0.93	1 (33.3) *P* = 0.99	4 (21.0) *P* = 0.47	148 (12.7)
Non-infectious indications	0 (0.0) *P* = 0.05	5 (45.5) *P* = 0.83	0 (0.0) *P* = 0.21	5 (26.3) *P* = 0.04	619 (53.3)

Continuous variables are presented as the median and first and third quartiles (Q1–Q3). Categorical variables are presented as number and percentage

Abbreviations: AF, atrial fibrillation; CRT, cardiac resynchronisation therapy; FU, follow-up; NHR, normal heart rhythm; NSR, normal sinus rate; TLE, transvenous lead extraction; other — see Tables S1 and S2

Multivariable Cox regression analysis showed that the risk of dying during follow-up increased with patient age (by 4.5% for each year), infectious TLE indications (by 49.4%), higher NYHA class (by 31.8% per one class), diabetes (by 32.6%), renal dysfunction (by 85.2%), CRT device before TLE (by 9.4%). The factors that decreased the risk of death were higher LVEF (reduction in risk by 2.1% per each 1%p) and no longer meeting implantation criteria (reduction in risk by 34.7%) (Table S4).

Table S4. Multivariable Cox regression analysis of the risk of dying during follow-up

	HR	95% CI	*P*
Female (y/n)	0.94	0.83–1.07	0.35
Patient age during TLE (by one year)	1.05	1.04–1.05	<0.001
Infectious indications (y/n)	1.49	1.34–1.67	<0.001
NYHA class (by one)	1.32	1.20–1.45	<0.001
LVEF (by one %p)	0.98	0.97–0.98	<0.001
Diabetes (y/n)	1.33	1.17–1.5	<0.001
Renal dysfunction (any) (y/n)	1.85	1.64–2.09	<0.001
ICD before TLE (y/n)	1.08	0.998–1.16	0.06
CRT-P or -D before TLE (y/n)	1.09	1.03–1.16	<0.01
Abandoned lead before TLE (y/n)	1.17	0.99–1.37	0.05
No longer meeting criteria for CIED (y/n)	0.65	0.44–0.98	0.04

Abbreviations: CRT-P, cardiac resynchronisation therapy-pacing; HR, hazard ratio; LVEF, left ventricular ejection fraction; TLE, transvenous lead extraction; other — see Tables S1–S3

Long-term telephone-based FU was performed for the purposes of this analysis. In 86.4% of them a new system was not implanted, 4.7% received a new device and we lost contact with 8.9% (all survived) (Table S5).

Table S5. The new CIED implantation during long-term FU (telephone obtained information) among patient not planned for reimplantation

Subgroups of patients discharged without CIED	Unnecessary pacemaker, NSR	Unnecessary pacemaker, AF, NHR	Unnecessary ICD/CRT, improvement in LVEF, NHR	All non-reimplanted patients
Group	1	2	3	4
Number of patients	n = 86	n = 50	n = 33	n = 169
	n (%)	n (%)	n (%)	n (%)
New CIED implantation during LT-FU (telephone-based information)				
Non-implanted	74 (86.0)	45 (90.0)	27 (81.8)	146 (86.4)
Implanted	3 (3.5)	4 (8.0)	1 (3.0)	8 (4.7)
Lack of information (loss of contact with the patient)	9 (10.5)	1 (2.0)	5 (15.2)	15 (8.9)

Abbreviations: see Tables S1–S4