To grade or not to grade safety requirements for transvenous lead extraction: Experience with 2216 procedures

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Editorial
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ABSTRACT

Background: Transvenous lead extraction (TLE) procedures are now increasingly safe, but there is still a risk of major complications (MC).

Aims: We aimed to assess the impact of TLE organization on the safety of procedures.

Methods: We analyzed 2216 TLE procedures performed in two centers in the years 2006–2021 and compared three organizational procedural models: (1) TLE in an electrophysiology laboratory (EP-LAB) with intravenous analgesia/sedation; (2) TLE with grading of safety requirements (high-risk patients in the cardiac surgery operating theatre, others in EP-LAB); (3) TLE in the hybrid room in all patients under general anesthesia with transesophageal echocardiographic (TEE) monitoring. The safety of procedures and mortality after TLE in three-year follow-up were assessed.

Results: The rate of MC in the EP-LAB group was 1.55%, and the rate of procedure-related deaths (PRD) was 0.33%. While using the graded approach to safety requirements, the percentage of MC was 2.61% and PRD 0.29%. When performing TLE procedures in the hybrid room, the MC percentage was 1.33% and PRD 0.00%. Long-term survival after TLE was comparable in all study groups.

Conclusions: A key factor in preventing TLE-related deaths is procedure organization that enables emergency cardiac surgery. TLE performed in a hybrid room with a collaborating cardiac surgeon and vital signs monitoring appears to be the safest possible option for the patient. A graded safety approach is associated with the risk of unexpected MC and PRD. Any newly established TLE center can achieve satisfactory results if the optimal organizational model of the procedure is used.

Key words: long-term survival, organizational model, safety and effectiveness, transvenous lead extraction

INTRODUCTION

The need for lead extraction has been increasing in line with the increasing rate of infections related to cardiac implantable electronic devices (CIED), lead malfunction, CIED revision, and upgrades [1–4]. Transvenous lead extraction (TLE) is now being recognized as part of the leading management strategy. Despite progress in extraction tools and techniques, TLE still carries a substantial risk of complications, including death [5–9]. Major complications of TLE arise from damage to the major veins of the thorax or damage to the myocardium with acute bleeding into the mediastinum, right pleural cavity, or pericardium. Hemopericardium with acute cardiac tam-

WHAT'S NEW?

The results of this large study indicate greater safety of all transvenous lead extraction (TLE) procedures if performed under maximum safety conditions (hybrid room, general anesthesia, continuous transesophageal echocardiographic monitoring [TEE], and close cooperation with the Cardiac Surgery Team). Although the site of the procedure plays a key role in enabling immediate emergency sternotomy, good-quality fluoroscopy, and TEE monitoring appear to have additional benefits. Each newly established TLE center can achieve satisfactory results if it is under the supervision of a very experienced proctor and the optimal organizational model of the procedure is applied (meeting all safety requirements).

ponade or massive right hemothorax are most frequently observed [5–13]. Organizational difficulties and economic aspects still force many TLE centers to grade the application of safety requirements. Simpler extraction procedures (in low-risk patients) are performed in an electrophysiology laboratory (EP-LAB) or interventional cardiology laboratory (IC-LAB) with cardiac surgery and anesthesia support on call. Efforts are made to perform TLE in high-risk patients in the hybrid room or in the operating theatre using a mobile C-arm X-ray machine [14–18]. The main problem is error-free evaluation of procedure difficulty, complexity, and risk of major complications. Several risk calculators have been developed for patient selection [15, 19–22], but every professional knows that major complications can occur even in patients with short implant duration [23].

Aim of the study

The study aimed to assess whether the organizational model of TLE may have an impact on patient safety by reducing the risk of major complications (MC) with procedure-related deaths (PRD) and analysis of long-term survival after TLE. The second goal of the study was to estimate the practical value of a graded approach to safety requirements.

METHODS

Study population

This post hoc analysis used clinical data of 2216 patients who underwent TLE between March 2006 and September 2021 in two high-volume centers but with the same first operator. The organizational model of TLE procedures has evolved with time. In all patients who underwent TLE in: (1) 2005–2013 (pioneering era), procedures were performed in an EP-LAB; (2) in the period 2013–2016 (in-between era/safety staging era) either in the operating theatre for cardiac surgery or in an EP-LAB, depending on the initial risk assessment; and in (3) all patients undergoing TLE in 2017–2021 (modern era), the procedures were performed in a hybrid room. Information relating to patients and procedures was entered into the computer on an ongoing basis.

Lead extraction procedure

Lead extraction procedures were performed using a stepwise approach and the same protocol during the entire study period. After gaining vascular access, the lead was stabilized with a non-locking or locking stylet, and moderate traction was applied. If unsuccessful, non-powered mechanical systems, such as polypropylene telescoping dilatators (Byrd Dilator Sheath, Cook Medical Inc., Bloomington, IN, US), were used. If not effective, powered mechanical sheaths (Evolution Mechanical Dilatator Sheaths, Cook Medical Inc., Bloomington, IN, US) and TightRail (Spectranetics/Philips, Colorado Springs, CO, US) were the second-line tools. In the event of technical difficulties additional tools were used as needed, usually Multi-Snare®Device (PFM Medical Inc., Carlsbad, CA, US) or formerly Basket Catheters (Cook Medical Inc, US). The excimer laser was not used. When necessary, femoral access and Femoral Working Station were used. Our technique of lead extraction was described in more detail in previous studies [10–13].

Definition

Complete procedural success, clinical procedural success, procedural failure, and major complications were defined according to the current TLE guidelines [1, 3, 4].

SAFeTY TLE score was used to assess the risk of occurrence of major complications related to TLE [20] with an online calculator available at http://alamay2.linuxpl.info/kalkulator/. Explanation of the SAFeTY TLE acronym: S = sum of lead dwell times (>16.5 years), A = anemia (<12 g/dl before TLE), Fe = female sex, T = treatment (number of previous procedures), Y = young patients (first implantation under the age of 30), TLE = transvenous lead extraction [20].

In order to compare more precisely the study groups, we also used other scales: ELECTRa Registry Outcome Score (EROS) [24] assessing increased risk of major complications (MC) and the need for cardiac surgery, MB score [25] analyzing indicators of increased complexity of the procedure (need for advanced tools to achieve TLE success), Lead Extraction Difficulty (LED) score [26] assessing TLE difficulty, defined by the time of fluoroscopy, Mazzone score [27] assessing the need for advanced TLE techniques [27], as well as the IKAR (Infective indications; Kidney dysfunction; Age ≥56; Removal of high voltage lead) score [28] to assess 1-year survival after TLE.

Procedure complexity was expressed as total lead extraction time ("sheath-to-sheath time") and average time

of single lead extraction (sheath-to-sheath/number of extracted leads), and the necessity to use second-line and advanced tools [21, 25–27].

Technical problems during TLE were situations that increased procedure complexity but not complications (detailed explanation in Supplementary material).

Characteristics of organizational models of TLE procedures

Model 1: "Modern era" (2017-2021). All procedures were performed in the hybrid room with a cardiac surgeon as co-operator ("shoulder-to-shoulder"), in patients under general anesthesia, with mandatory arterial line (AL), expiratory gas monitoring, and TEE monitoring during the whole procedure. The pump for extracorporeal circulation with the Perfusion Team was on standby. Patients were prepped for sternotomy. There was no grading of safety requirements, and all TLEs were performed in the same conditions.

Model 2: "In-between/safety staging era" (2013–2016) — the era of a graded approach to safety requirements. During that transition period, it was possible to perform lead extraction in selected individuals (most difficult and high-risk patients) in the cardiac surgery operating theatre. Due to the limited availability of cardiac surgery operating theatres (unplanned operations), we had to divide patients into those who would undergo TLE in an EP-LAB (subgroup A) or the operating theatre (subgroup B). Patients with implant duration >12 years, young age at first implantation, female sex, multiple leads, abandoned leads, and old unipolar pacemaker (UP) were selected for the procedure in the cardiac surgery operating theatre (subgroup B). Patients with implant duration <10 years, older age at first system implantation, male sex, fewer than 3 leads recently, and bipolar (BP) active lead models qualified for the procedure in an EP-LAB (subgroup A). Intermediate-risk patients were managed depending on room availability. Despite these general rules, it was not always possible to stick to the safety plan if there was another urgent surgery to be performed at the same time. Finally, two subgroups A and B were identified for the retrospective analysis.

Subgroup A — the procedure organization was the same as in model 3 (in terms of procedure location, type of anesthesia, cardiac surgeon participation, and monitoring).

Subgroup B — operating theatre, mobile C-arm X-ray machine (lower quality than in the hybrid room), general anesthesia with AL but without TEE monitoring. A cardiac surgeon on duty, usually without close cooperation. But in the event of major complications, immediate sternotomy was possible within less than 10 minutes, though unfortunately, the Perfusion Team was on-call (20 minutes to arrive).

Model 3: "A pioneering era" (2006–2013). The most remote period was when all TLE procedures were performed in an EP-LAB, without collaborating cardiac surgeons who were only on the premises. Patients were under intravenous analgesia and sedation without TEE and AL. The cardiac surgery operating theatre and staff (Anesthesia Care Team, operating theatre attendants) were on duty and ready for urgent operation (patient transfer from an EP-LAB to the operating theatre).

Probability of survival after TLE

As this is a post hoc analysis of three consecutive TLE periods, the length of the observation period of the subsequent study groups was significantly different. Therefore, only the patients' survival in the 3-year follow-up period after TLE was analyzed. The source of data on the outcomes for patients after TLE were control visits to clinics, and in the case of loss of telephone contact, data from the National Health Fund database. The few missing data were obtained from the physicians treating the patients.

Statistical analysis

The Shapiro-Wilk test showed that most continuous variables were normally distributed. Continuous variables with a parametric distribution are presented as the mean (standard deviation [SD]) and with a non-parametric distribution as median with interquartile ranges (IQR). The categorical variables are presented as numbers and percentages. The significance of differences between groups was determined using the χ^2 test (dichotomous data) or Student's t-test (parametric data) or the Mann-Whitney U test (nonparametric data). Uni- and multi-variable logistic regression was used to assess the predictors of minor and major complications, clinical success, and complete procedural success. In the multivariable regression analysis, the variables which in the univariate analysis reached the value of P <0.1 were included. Survival analysis based on Kaplan-Meier curves and a log-rank test was used to assess the difference in event-free survival between groups of patients divided by approach to safety and TLE venue. The results were considered statistically significant if P <0.05. Statistical analysis was performed with Statistica version 13.3 (TIBCO Software Inc.).

Approval of the Bioethics Committee

All patients gave their informed written consent to undergo TLE and the use of anonymous data from their medical records, and the study was approved by the Bioethics Committee at the Regional Chamber of Physicians in Lublin no. 288/2018/KB/VII. The study was performed according to the principles expressed in the Declaration of Helsinki.

RESULTS

Among 2216 patients at a mean age of 66.41(14.32) years, there were 864 (38.98%) females. Infectious indications for TLE were found in 848 (38.27%) patients. Most of the patients, i.e. 1587 (71. 61%) had some kind of a pacing system implanted, 493 (22.25%) had ICD, and 136 (6.14%)

Table 1. Potential patient-related risk factors for major TLE complications

Comparison of patient-related risk factors	Modern era. Full safety precaution, without staging	In-between era. Attempt at staging of TLE safety	A pioneering era, EP-LAB without c-surgeon and g. anesthesia	Statistics		
Organizational safety level	Very high (2017–2021) Group 1	Moderate (2013–2016) Group 2	Low (2006–2012) Group 3	1 vs. 2	1 vs. 3	2 vs. 3
Number of patients	300	690	1226	*P*	*P*	*P*
Patient's age during TLE, years, mean (SD)	69.85 (13.05)	66.28 (13.72)	65.65 (14.69)	<0.001	<0.001	0.11
Patient's age during first system implantation, years, mean (SD)	62.19 (14.08)	58.40 (15.62)	58.38 (16.13)	<0.001	<0.001	0.40
Sex, n (% of female patients)	101 (33.67)	295 (42.75)	468 (38.17)	0.007	0.15	0.049
Etiology: IHD, MI, n (%)	200 (66.89)	377 (54.64)	573 (46.74)	<0.001	<0.001	0.001
NYHA class III & IV, n (%)	53 (17.73)	92 (13.33)	158 (12.89)	0.08	0.03	0.78
EF average, %, mean (SD)	54.75 (16.76)	48.53 (14.71)	49.03 (14.37)	<0.001	<0.001	0.59
Permanent AF, n (%)	73 (24.42)	160 (23.19)	278 (22.68)	0.70	0.54	0.80
Diabetes (any), n (%)	69 (23.08)	121 (17.54)	243 (19.82)	0.045	0.22	0.22
Renal failure (any), n (%)	60 (20.00)	120 (17.39)	251 (20.47)	0.33	0.86	0.10
Charlson's index, median, (IQR)	5.00 (3.00–7.00)	4.00 (2.00–6.00)	4.00 (2.00–6.00)	<0.001	<0.001	0.49
TLE indication: systemic infection with or without PI, n (%)	23 (7.69)	168 (24.35)	384 (31.32)	<0.001	<0.001	<0.001
TLE indication: local (pocket) infection, n (%)	32 (10.70)	61 (8.84)	179 (14.60)	0.37	0.08	<0.001
TLE indication: other non-infective, n (%)	244 (81.61)	461 (66.81)	663 (54.08)	<0.001	<0.001	<0.001

Abbreviations: AF, atrial fibrillation; c, cardiac; EF, ejection fraction; EP-LAB, electrophysiology laboratory; IHD, ischemic heart disease; g., general; MI, myocardial infarction; NYHA class, New York Heart Association class; TLE, transvenous lead extraction

had cardiac resynchronization therapy (CRT) device. Mean left ventricular ejection fraction (LVEF) was 49.65(14.94)%, ischemic heart disease (IHD) was present in 1150 (51.90%) patients, renal failure occurred in 431 (19.45%) patients, and the Charlson comorbidity index was 4.63 (3.55) points.

Analysis of potential patient-related risk factors for major TLE complications in the study groups showed that there was a significant difference in patient age during TLE and at first CIED implantation. Patients with a very high level of safety during TLE procedures were the oldest age group, had IHD and a higher Charlson comorbidity index more often compared to other groups.

There was a statistically significant difference in the type of indications for TLE, with the highest percentage of infectious indications in the low-level safety group and the highest percentage of non-infectious indications in patients from the highest safety group (Table 1).

Analysis of potential CIED-related risk factors for major complications in the study groups showed that, in the modern era, there were more ICD and CRT-D systems, fewer abandoned leads, fewer leads in the heart, redundant looping of the leads in the heart and leads with the proximal ending in the cardiovascular system (CVS) before TLE. It appears to be a delayed effect of education on optimal lead management. Lead dwell time expressed by average extracted lead age was significantly longer in patients undergoing TLE in the "modern era" (Table 2).

Procedure-related risk factors such as the number of extracted leads per patient, multiple lead extraction, necessity to use other than venous entry approaches, extraction of leads with redundant loops, and extraction of abandoned lead(s) declined over time. Extraction of ICD leads increased over the years.

Procedure duration was longer in the pioneering era and occurrence of technical difficulties during TLE differed in some aspects in the examined time intervals. A special technique for the extraction of broken leads using regained venous access eliminated the need to change the venous approach during lead extraction over the last 10 years [29, 30] (Table 3).

Analysis of TLE procedure complexity and lead management strategy in the compared patient groups showed that the need to use second-line tools was related to implant duration, but mechanical powered sheaths were available on the market at the end of the pioneering era (Table 4, Supplementary material).

The comparison of the analyzed subgroups using various TLE risk scales demonstrated some differences in the clinical profile of patients (SAFeTY TLE and EROS), while the evaluation using scales based on system-dependent factors only (MB score, LED index, Mazzone score) showed no significant differences between the study groups (Table 5, Supplementary material).

Analysis of the occurrence of major complications of TLE in particular periods did not show any significant differences between the study groups; however, it should be emphasized that the overall number of serious complications in the study population was very small (39 MC — 01.76%). Moreover, the MC analysis showed that in the group of patients undergoing TLE in the hybrid room, there were no peri-procedural deaths, while the percentage of deaths during TLE conducted in an EP-LAB was 0.33%, and in the group with safety measures grading — 0.29%. It should also be noted that in the "in-between/safety staging" group, three cardiac tamponades (including one fatal tamponade) occurred during TLE procedures in EP-LAB in patients with

Table 2. Potential CIED-related risk factors for major TLE complications in the compared patient groups

Comparison of CIED-related risk factors	Modern era Full safety precaution, without staging	In-between era. Attempt at staging of TLE safety	A pioneering era, EP-LAB without c-surgeon and g. anesthesia	Statistics		
Organizational safety level	Very high (2017–2021) Group 1	Moderate (2013–2016) Group 2	Low (2006–2012) Group 3	1 vs. 2	1 vs. 3	2 vs. 3
Number of patients	300	690	1226	*P*	*P*	*P*
Pacemakers all (with CRT-P), n (%)	190 (63.55)	490 (71.01)	907 (73.98)	0.02	<0.001	0.16
ICD, all, n (%)	85 (28.43)	141 (20.44)	267 (21.78)	0.007	0.02	0.49
ICD — CRT-D pacing system, n (%)	24 (8.03)	59 (8.55)	52 (4.24)	0.77	0.007	<0.001
Presence of abandoned lead before TLE, n (%)	6 (2.01)	65 (9.42)	212 (17.29)	<0.001	<0.001	<0.001
Number of leads in the heart before TLE, mean (SD)	1.86 (0.59)	1.95 (0.71)	2.03 (0.82)	0.05	0.002	0.05
4 and >4 in the heart before TLE, n (%)	2 (0.67)	18 (2.61)	67 (5.47)	0.05	<0.001	0.004
Large lead loop in the heart presence on X-ray before TLE, n (%)	6 (1.98)	40 (5.65)	92 (7.76)	0.009	<0.001	0.16
Lead with proximal ending on SVC before TLE, n (%)	6 (1.98)	13 (1.84)	54 (4.38)	0.90	0.06	0.004
Number of procedures before lead extraction, mean (SD)	1.54 (0.74)	1.76 (1.07)	1.97 (1.20)	<0.001	<0.001	<0.001
Dwell time of the oldest lead in the patient before TLE, years, median (IQR)	7.00 (4.42–10.00)	6.17 (3.75–10.29)	6.17 (3.00–10.33)	0.12	0.02	0.20
Average lead age in the group, years, median (IQR)	6.92 (4.33–9.92)	5.83 (3.53–9.55)	5.58 (2.83–9.17)	0.03	<0.001	0.04
Global implant duration before TLE, years, median (IQR)	11.75 (7.00–18.25)	10.67 (5.50–18.50)	10.21 (4.83–18.75)	0.10	0.02	0.31

Abbreviations: CIED, cardiac implantable electronic device; CRT-P/D, cardiac resynchronization therapy with pacemaker/defibrillator; EP-LAB, electrophysiology laboratory; ICD, implantable cardioverter-defibrillator; SVC, superior vena cava; TLE, transvenous lead extraction

Table 3. TLE procedure-related potential risk factors for major TLE complications and technical problems in the compared patient groups

Comparison of procedure-related potential risk factors	Modern era. Full safety precaution, without staging	In-between era. Attempt of staging of TLE safety	A pioneering era. EP-LAB without c-surgeon and g. anesthesia	Statistics		
Organizational safety level	Very high (2017–2021) Group 1	Moderate (2013–2016) Group 2	Low (2006–2012) Group 3	1 vs. 2	1 vs. 3	2 vs. 3
Number of patients	300	690	1226	*P*	*P*	*P*
Number of extracted leads in one patient, mean (SD)	1.47 (0.61)	1.63 (0.73)	1.71 (0.79)	<0.001	<0.001	0.03
Three or more leads were extracted, n (%)	14 (4.68)	71 (10.29)	154 (12.56)	0.004	<0.001	0.13
Approach other than lead venous entry, n (%)	0 (0.00)	3 (0.43)	82 (6.69)	0.56	<0.001	<0.001
Extraction of leads with to-long loop, n (%)	39 (13.94)	97 (14.06)	245 (19.98)	0.66	0.005	<0.001
Extraction of abandoned lead(s) (any), n (%)	4 (1.33)	61 (8.84)	198 (16.15)	<0.001	<0.001	<0.001
HV therapy (ICD) lead was extracted, n (%)	103 (34.45)	180 (26.09)	305 (24.88)	0.008	<0.001	0.56
CS (LV pacing) lead was extracted, n (%)	17 (5.69)	46 (6.67)	70 (5.71)	0.55	0.98	0.40
Oldest extracted lead body dwelling time, years, median (IQR)	7.04 (4.33–10.04)	7.66 (3.63–9.92)	5.95 (2.88–10.17)	0.07	0.01	0.27
Average extracted lead age in the group, years, median (IQR)	7.00 (4.21–10.00)	7.21 (3.50–9.25)	5.60 (2.83–9.25)	0.03	0.006	0.09
Cumulative dwell time of extracted lead, years, median (IQR)	9.21 (4.83–10.58)	12.18 (4.38–16.33)	8.79 (3.83–16.50)	0.86	0.36	0.79

Abbreviations: CS, coronary sinus; EP-LAB, electrophysiology laboratory; HV, high voltage; ICD, implantable cardioverter-defibrillator; LV, left ventricle; TLE, transvenous lead extraction

potentially low risk of MC (TLE score in these patiens was <2.46%: 0.48%, 0.9% and 1.5%).

Lower rates of complete clinical and procedural success with a higher percentage of partial radiographic success were characteristic of the pioneering era and the safety staging era (Table 6).

Detailed comparable analysis of patients' data and procedures performed in the operating theatre or EP-LAB with safety staging was presented in Supplementary material. It is worth emphasizing that there were two procedure-related deaths in EP-LABs but no deaths among those operated on in the cardiac surgery theatre (Supplementary material, *Table S1*).

Patient survival throughout the follow-up period

Analysis of the mortality rate in three-year follow-up after TLE showed that the probability of survival was comparable in the study groups, regardless of the organizational model of the procedure (Figure 1).

Regression analysis confirms the significance of common risk factors for major complications: female sex, dwell time of the oldest extracted lead, and the number of extracted leads. TLE venue had no impact on the occurrence of major complications. The prognostics of minor complications were female sex, dwell time of the oldest extracted lead, and extraction of defibrillation lead. The earliest model of TLE (pioneering era: an EP-LAB without

Table 4. TLE procedure complexity and realized lead management strategy in the compared patient groups

Procedure complexity and TLE strategy	Modern era Full safety pre-caution, without staging	In-between era. Attempt at staging of TLE safety	A pioneering era, EP-LAB without c-surgeon and g. anesthesia	Statistics		
Organizational safety level	Very high (2017–2021) Group 1	Moderate (2013–2016) Group 2	Low (2006–2012) Group 3	1 vs. 2	1 vs. 3	2 vs. 3
Number of patients	300	690	1226	*P*	*P*	*P*
TLE complexity						
Procedure duration (sheath-to-sheath), min, median (IQR)	7.00 (3.00–14.00)	8.00 (4.00–10.00)	9.00 (8.00–10.00)	0.16	<0.001	<0.001
Average time of single lead extraction (sheath-to-sheath/ /number of extracted leads), min, median (IQR)	5.00 (3.00–8.17)	4.00 (4.00–5.50)	5.00 (4.00–9.00)	0.62	<0.001	<0.001
Technical problem during TLE (any), n (%)	49 (16.39)	105 (15.22)	227 (18.52)	0.66	0.38	0.67
Necessity to change the venous approach, n (%)	2 (0.67)	18 (2.61)	96 (7.84)	0.05	<0.001	<0.001
Two or more technical problems, n (%)	13 (4.53)	18 (2.61)	26 (2.12)	0.15	0.03	0.44
Using additional tools						
Evolution (old and new-Cook) or TighRail (Spectranetics), n (%)	3 (1.00)	5 (0.73)	3 (0.25)	0.70	0.09	0.15
Metal sheath, n (%)	23 (7.69)	41 (5.94)	42 (3.43)	0.31	0.001	0.009
Lasso catheter/snare/basket catheter, n (%)	5 (1.67)	25 (3.62)	35 (2.86)	0.11	0.32	0.35
Realization of lead management strategy						
All leads were extracted, n (%)	204 (68.00)	502 (72.75)	928 (75.69)	0.13	0.006	0.16
Functional lead was left for continuous use, n (%)	96 (32.00)	183 (26.52)	280 (22.84)	0.08	0.001	0.07
Non-functional lead was left, n (%)	0 (0.00)	2 (0.29)	13 (1.06)	1.00	0.09	0.10
Non-functional, superfluous lead was extracted, n (%)	4 (1.33)	61 (8.84)	198 (16.15)	<0.001	<0.001	<0.001

Abbreviations: EP-LAB, electrophysiology laboratory; TLE, transvenous lead extraction

Table 5. Predicted risk of major complications and procedure complexity in the compared patient groups using available scores

Comparison of procedure-related potential risk factors	Modern era Full safety precaution, without staging	In-between era. Attempt at staging of TLE safety	A pioneering era, EP-LAB without c-surgeon and g. anesthesia	Statistics		
Organizational safety level	Very high (2017–2021) Group 1	Moderate (2013–2016) Group 2	Low (2006–2012) Group 3	1 vs. 2	1 vs. 3	2 vs. 3
Number of patients	300	690	1226	*P*	*P*	*P*
SAFeTY TLE calculator of major TLE complications, points, median (IQR)	4.09 (1.36–6.83)	4.10 (1.36–7.46)	4.10 (2.72–8.82)	0.007	<0.001	0.09
SAFeTY TLE calculator of major TLE complications: risk expressed as % median, median (IQR)	0.48 (0.23–1.03)	0.48 (0.22–1.23)	0.48 (0.33–1.78)	0.007	<0.001	0.09
EROS score, risk of MC, median, median (IQR)	1.00 (1.00–1.00)	1.00 (1.00–2.00)	1.00 (1.00–2.00)	<0.001	<0.001	0.80
3 EROS score, risk of MC, median (IQR)	22 (7.33)	93 (14.48)	55 (4.49)	0.008	0.06	<0.001
MB score number of points, need for advanced tools, median (IQR)	3.00 (2.00–3.00)	3.00 (2.00–3.00)	2.00 (1.00–3.00)	0.35	0.16	0.62
MB score points >4.5, need for advanced tools, median (IQR)	70 (23.33)	146 (21.16)	274 (22.33)	0.50	0.72	0.59
LED index, predicted fluoroscopy time, median (IQR)	9.00 (6.00–12.00)	8.00 (5.00–12.00)	8.00 (5.00–12.00)	0.18	0.051	0.37
LED index — values >16 points, predicted fluoroscopy time, median (IQR)	23 (7.67)	95 (13.77)	123 (10.03)	0.009	0.26	0.02
Mazzone score (1–4 points) need for advanced TLE techniques, median (IQR)	2.00 (1.00–3.00)	2.00 (2.00–3.00)	2.00 (2.00–3.00)	0.02	0.11	0.13
Mazzone score (4 points) need for advanced TLE techniques, n (%)	17 (5.67)	38 (5.51)	54 (4.41)	0.96	0.44	0.33

Abbreviations: EP-LAB, electrophysiology laboratory; MC, major complications; TLE, transvenous lead extraction

We used the SAFeTY TLE calculator (risk of MC), EROS score (risk of MC), MB score (need for advanced tools to achieve TLE success), LED index (difficult TLE, defined using the fluoroscopy time), and Mazzone score (need for advanced TLE techniques)

a c-surgeon and general anesthesia) predisposed to minor complications. The predictors of achieving complete clinical success were the age of extracted lead and number of extracted leads. Under multivariable analysis, TLE venue had no impact on achieving complete clinical success. The predictors of procedural success were patients' age during first CIED implantation, age of extracted leads, leads with passive fixation, and the number of extracted leads. Similarly to complete clinical success, TLE venue had no impact on achieving complete procedural success (Table 7).

The multivariate analysis of the impact of the main organizational factors on complications frequency and TLE

Table 6. TLE procedure efficacy and complications and mortality after TLE procedure in the compared patient groups

Efficacy, complications, mortality, and prognosis	Modern-era. Full safety precaution, without staging	In-between era. Attempt at staging of TLE safety	A pioneering era. EP-LAB without c-surgeon and g. anesthesia	Statistics		
Organizational safety level	Very high (2017–2021) Group 1	Moderate (2013–2016) Group 2	Low (2006–2012) Group 3	1 vs. 2	1 vs. 3	2 vs. 3
Number of patients	300	690	1226	*P*	*P*	*P*
TLE efficacy and complications						
Major complications (any), n (%)	4 (1.33)	16 (2.61)	19 (1.55)	0.44	0.99	0.31
Hemopericardium, n (%)	1 (0.33)	15 (2.17)	11 (0.90)	0.07	0.22	0.27
Hemothorax, n (%)	0 (0.00)	0 (0.00)	4 (0.33)	N	0.72	0.33
Number of hemopericardium or hemothorax in patients with SAFeTY TLE risk <2.46% operated in EP-LAB, n (%) of all MC)	NA	3 (18.75)	5 (26.32)	N	N	0.90
Tricuspid valve damage during TLE (severe), n (%)	3 (1.00)	4 (0.58)	3 (0.25)	0.76	0.17	0.44
Rescue cardiac surgery, n (%)	0 (0.00)	9 (1.30)	9 (0.73)	0.11	0.29	0.32
Death procedure-related (intra-, post-procedural), n (%)	0 (0.00)	2 (0.29)	4 (0.33)	0.87	0.72	0.77
Death indication-related (intra, post-procedural), n (%)	0 (0.00)	0 (0.00)	4 (0.33)	N	0.72	0.33
Death total, n (%)	0 (0.00)	2 (0.29)	8 (0.63)	0.87	0.08	0.47
Partial radiological success (remained tip or <4 cm lead fragment), n (%)	5 (1.67)	29 (4.20)	52 (4.24)	0.07	0.05	0.94
Full clinical success, n (%)	296 (99.00)	671 (97.25)	1186 (96.74)	0.26	0.11	0.51
Full procedural success, n (%)	293 (97.99)	655 (94.93)	1160 (94.62)	0.07	0.04	0.10
Survival for up to 3 years in follow-up						
Time of follow-up, days, median (IQR)	621 (327–915)	1095 (1095–1095) Log-rank *P* = 0.441	1095 (1095–1095)	<0.001	<0.001	0.81
Survivors during follow-up, n (%)	253 (84.33)	567 (82.17)	1005 (81.97)	0.44	0.24	0.68
Non-survivors during follow-up, n (%)	47 (15.67)	123 (17.83)	221 (18.03)	0.44	0.24	0.68
IKAR score (1-year survival after TLE), n (%)	2.00 (1.00–2.00)	1.00 (1.00–2.00)	2.00 (1.00–2.00)	0.45	0.19	0.006

Abbreviations: EP-LAB, electrophysiology laboratory; MC, major complications; TLE, transvenous lead extraction

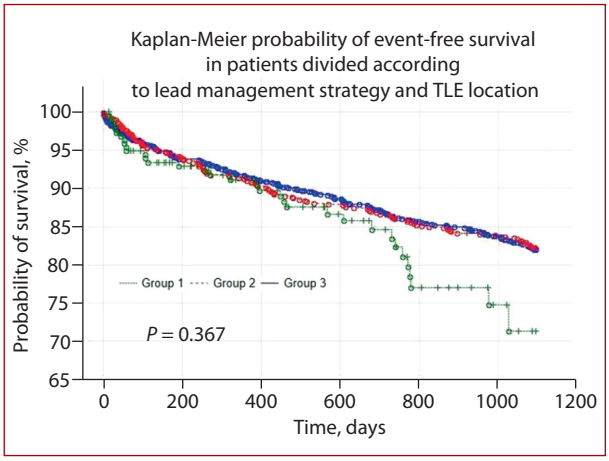

Figure 1. Probability of survival depending on the organizational model of transvenous lead extraction (TLE)

effectiveness did not confirm that TLE logistics influenced that frequency and thus procedure effectiveness (Supplementary material, *Table S2*).

DISCUSSION

The present study analyzed a large database of patients undergoing TLE performed by a single operator in two centers in Poland from 2006 to 2021. The innovative concept of the organizational model of the procedure makes it possible to reduce the occurrence of serious complications.

Several reports have shown that the occurrence of TLE-related major complications depends mainly on implant duration, operator's experience, and, to a lesser degree, on patient-dependent risk factors (such as female sex) [5, 10, 20, 31]. Additionally, the number and model of extracted leads play a role [20]. Major complications (mainly vascular laceration and myocardial injury) are an inherent part of lead extraction, and there is limited potential to prevent them (first operator experience, full set of tools, and probably quality of fluoroscopy and TEE monitoring) [30, 31]. The reported risk of major complications, such as vascular laceration, cardiac avulsion, pericardial effusion, and hemothorax related to TLE, ranges from 0.19% to 1.8% [1, 3, 10–14, 16, 19–22, 32]. In the event of a complication, in most cases, surgical intervention is required to prevent fatal consequences [1, 3, 5–11]. The time to sternotomy is crucial, and it should be 5–10 minutes optimally [1, 3, 7]; if the above time limit is exceeded, the risk of central nervous system (CNS) damage increases significantly [7]. Thus, the ideal setting for TLE should allow for immediate sternotomy. The main role of the cardiac surgeon in TLE is to prevent death due to major complications. Several reports have noted the importance of TLE location [14–18]. Overall, emergency surgery should be performed in case of complications. Due to difficulty in accessing hybrid rooms or cardiac surgical operating theatres and because there are more TLE centers than hybrid rooms, other procedure

Table 7. Predictors of major and minor TLE complications and full clinical and procedural success – results of uni- and multivariable regression analysis

	Univariable regression			Multivariable regression (without components of TLE models)		
	OR	(95% CI)	*P*	OR	(95% CI)	*P*
Major complications						
Patient's age during first system implantation, by one year	0.966	(0.954–0.977)	<0.001	1.006	(0.983–1.030)	0.62
Female sex (yes/no)	3.383	(2.048–5.589)	<0.001	3.235	(1.564–6.694)	0.002
Oldest extracted lead dwelling time, by one year	1.152	(1.120–1.184)	<0.001	1.147	(1.084–1.214)	<0.001
Extraction of pacing leads (yes/no)	4.279	(1.953–9.372)	<0.001	19.60	(0.088–4.385)	0.28
Extraction of lead(s) with passive fixation (yes/no)	3.463	(1.854–6.468)	<0.001	1.323	(0.462–3.786)	0.60
Number of leads planned for extraction, by one	1.830	(1.417–2.363)	<0.001	1.593	(1.042–2.437)	0.03
Extraction of abandoned lead(s) (yes/no)	2.806	(1.563–5.033)	<0.001	0.893	(0.347–2.298)	0.82
Extraction of defibrillating lead(s) (yes/no)	0.279	(0.121–0.611)	<0.001	16.45	(0.073–3710)	0.31
A pioneering era. EP-LAB without c-surgeon and g. anesthesia (yes/no)	0.735	(0.393–1.376)	0.34			
In-between era. Attempt at staging of TLE safety (yes/no)	1.905	(1.015–3.578)	0.045	1.680	(0.850–3.320)	0.14
Full safety precaution, without staging (yes/no)	0.467	(0.143–1.524)	0.21			
Minor complications						
Patient's age during first system implantation, by one year	0.985	(0.976–0.994)	<0.001	0.994	(0.983–1.005)	0.30
Female sex (yes/no)	1.437	(1.055–1.957)	0.02	1.408	(1.015–1.953)	0.04
Oldest extracted lead dwelling time, by one year	1.076	(1.052–1.101)	<0.001	1.048	(1.015–1.083)	0.004
Extraction of pacing leads (yes/no)	1.715	(1.178–2.495)	0.004	0.598	(0.304–1.177)	0.14
Extraction of lead(s) with passive fixation (yes/no)	2.954	(1.984–4.398)	<0.001	1.550	(0.990–2.428)	0.06
Number of leads planned for extraction, by one	1.412	(1.177–1.694)	<0.001	1.194	(0.965–1.476)	0.10
Extraction of abandoned lead(s) (yes/no)	2.124	(1.414–3.190)	<0.001	1.077	(0.668–1.736)	0.76
Extraction of defibrillating lead(s) (yes/no)	0.472	(0.310–0.720)	<0.001	0.444	(0.207–0.953)	0.04
A pioneering era. EP-LAB without c-surgeon and g. anesthesia (yes/no)	2.312	(1.641–3.257)	<0.001	2.237	(1.539–3.253)	<0.001
In-between era. Attempt at staging of TLE safety (yes/no)	0.507	(0.343–0.748)	<0.001			
Full safety precaution, without staging (yes/no)	0.520	(0.302–0.896	0.02			
Predictors of complete clinical and complete procedural TLE success. Full clinical success						
Patient's age during first system implantation, by one year	1.029	(1.015–1.043)	<0.001	1.010	(0.993–1.027)	0.27
Female sex (yes/no)	0.785	(0.474–1.302)	0.35			
Oldest extracted lead dwelling time, by one year	0.887	(0.859–0.915)	<0.001	0.917	(0.877–0.960)	<0.001
Extraction of pacing leads (yes/no)	0.476	(0.249–0.920)	0.03	1.660	(0.562–4.902)	0.36
Extraction of lead(s) with passive fixation (yes/no)	0.207	(0.094–0.457)	<0.001	0.568	(0.238–1.353)	0.20
Number of leads planned for extraction, by one	0.511	(0.396–0.661)	<0.001	0.613	(0.447–0.841)	0.002
Extraction of abandoned lead(s) (yes/no)	0.339	(0.189–0.608)	<0.001	1.094	(0.538–2.244)	0.80
Extraction of defibrillating lead(s) (yes/no)	2.967	(1.344–6.550)	0.007	2.784	(0.771–10.06)	0.12
A pioneering era. EP-LAB without c-surgeon and g. anesthesia (yes/no)	0.704	(0.418–1.183)	0.19			
In-between era. Attempt at staging of TLE safety (yes/no)	0.926	(0.543–1.579)	0.78			
Full safety precaution, without staging (yes/no)	3.49	(1.088–11.21)	0.04	1.745	(0.518–5.877)	0.37
Full procedural success						
Patient's age during first system implantation, by one year	1.033	(1.022–1.044)	<0.001	1.015	(1.002–1.028)	0.03
Female sex (yes/no)	0.813	(0.551–1.201)	0.30			
Oldest extracted lead dwelling time, by one year	0.880	(0.857–0.905)	<0.001	0.919	(0.886–0.954)	<0.001
Extraction of pacing leads (yes/no)	0.444	(0.265–0.742)	0.002	1.487	(0.607–3.646)	0.39
Extraction of lead(s) with passive fixation (yes/no)	0.128	(0.062–0.265)	<0.001	0.311	(0.143–0.676)	0.003
Number of leads planned for extraction, by one	0.557	(0.451–0.686)	<0.001	0.658	(0.509–0.852)	0.002
Extraction of abandoned lead(s) (yes/no)	0.416	(0.257–0.674)	<0.001	1.345	(0.750–2.412)	0.32
Extraction of defibrillating lead(s) (yes/no)	3.018	(1.643–5.545)	<0.001	2.357	(0.833–6.675)	0.11
A pioneering era. EP-LAB without c-surgeon and g. anesthesia (yes/no)	0.777	(0.523–1.155)	0.21			
In-between era. Attempt at staging of TLE safety (yes/no)	0.896	(0.590–1.358)	0.60			
Full safety precaution, without staging (yes/no)	2.545	(1.171–5.528)	0.02	1.356	(0.560–3.285)	0.50

Abbreviations: EP-LAB, electrophysiology laboratory; TLE, transvenous lead extraction; other — see Table 1

locations such as EP-LABs or interventional cardiology laboratories are considered; however, they have varying capabilities for urgent sternotomy [10, 11, 14–18]. The concept of a graded approach to safety requirements inspired researchers to develop risk stratification tools and algorithms to predict major complications [19–23]. Accordingly, low-risk patients undergo TLE in EP-LABs or IC-LABs, whereas high-risk patients are transferred to hybrid rooms and intermediate-risk patients are managed according to location availability. But one should bear in mind that catastrophic complications may appear even in low-risk patients [23]. This accords with our observations,

which show two unexpected procedure-related deaths in theoretically low-risk patients.

There is some evidence to indicate that rates of procedure-related deaths decrease over decades [13]. Since no new tools have been proposed, the improvement appears to be related to better organization of the procedure. The best environment for TLE is now a hybrid room, whereas cardiac surgery operating theatres with mobile "C-arm" X-ray machines or large EP-LABs with a surgeon and Anesthesia Care Team on call and off-site equipment is a worse option [10, 14–18]. But for organizational (and economic) reasons, several TLE centers continue to use a graded approach to safety requirements [14–18].

The results of this study show that performing TLE in EP-LABs without surgical and anesthesia staff and equipment was associated with the occurrence of major complications and procedure-related deaths in 1.55% and 0.33% of cases, respectively. The graded approach to safety requirements (categorization of patients based on the setting of extraction procedure) was associated with a higher frequency of major complications and procedure-related deaths of 2.61% and 0.29%, respectively. However, when all patients were operated on in the hybrid room following all safety requirements the respective rates were 1.33% and 0.00%. Detailed analysis of the graded approach showed that two unexpected major complications appeared in EP-LABs during the extraction of an 8.7-year-old atrial lead and 1.8-year-old coronary sinus lead. Both patients were urgently transferred to the operating room and lesions were sutured, but the delayed intervention (30 minutes) had fatal consequences. Four procedure-related deaths in patients operated on in EP-LABs (group 3) were caused by complications during the extraction of leads with implant duration of 16.1, 13.3, 19.3, and 19.8 years. At that time, the cardiac surgery operating theatre was not available for TLE, and there was no hybrid room in our hospital.

Additionally, this study shows that it is possible to obtain excellent results in newly established TLE centers (modern era). There were 300 TLEs with one significant major complication and without procedure-related deaths with 99.00% clinical success and 97.99% procedural success despite even longer implant duration than in other groups. These success rates depended on collaboration with a very experienced first operator and use of excellent fluoroscopy and TEE monitoring. Furthermore, rates of radiographic, clinical, and procedural success showed an upward tendency in patients with TEE monitoring. Finally, despite longer implant duration, the rate of procedure-related deaths was zero [11–13, 31, 32].

Study limitations

This study is based on the outcomes of a single very experienced first operator who has recently become a proctor. TLE procedures were performed with two experienced cardiac surgeons, two members of the Anesthesia Care Team, and three experienced echocardiographers. The study period from 2006 to 2021 does not reflect the learning curve because the proctor and his nurses started TLE many years earlier, whereas the database was launched in 2006. All procedures were performed using all types of mechanical systems but not laser-powered sheaths.

CONCLUSIONS

A setting that allows emergency cardiac surgery is the most important factor to avoid major complication-related deaths. The presence of cardiac surgeons as co-operators seems less important to prevent complications-related deaths.

TLE procedure performed in a hybrid or operating room by an electrophysiologist and a collaborating cardiac surgeon, with constant monitoring of vital signs and with TEE monitoring appears to be the safest possible option for the patient.

The graded approach to safety requirements is associated with the risk of unexpected major complications and procedure-related deaths due to delayed surgical intervention even in seemingly low-risk patients who can also develop major complications.

Any newly established TLE center can achieve satisfactory results if it applies the optimal procedure protocol (fulfilling all safety requirements).

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

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