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

Short title: Safety of transvenous lead extraction

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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 transoesophageal echocardiographic monitoring (TEE), 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 an optimal organizational model of the procedure is applied (meeting all safety requirements).

ABSTRACT

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

Aims: Assessment of the impact of the organization of TLE on the safety of procedures.

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

Results: The rate of MC in EP-lab was 1.55% and the rate of procedure-related deaths (PRD) was 0.33%. 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 an organization of procedure that enables emergency cardiac surgery. TLE performed in a hybrid room with cardiac surgeon in collaboration 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 optimal organizational model of the procedure is used.

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

INTRODUCTION

The need for lead extraction has been increasing in line with the increasing rate of infection related to cardiac implantable electronic devices (CIED), lead malfunction, CIED revision and upgrade [1-4]. Transvenous lead extraction (TLE) is now being recognized as part of lead management strategy. Despite progress in extraction tools and techniques TLE still carries a substantial risk of complication, 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, and hemopericardium with acute cardiac tamponade or massive right haemothorax 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 electrophysiology laboratory (EP-LAB) or interventional cardiology laboratory (IC-LAB) with cardiac surgery and anesthesia support on call. TLE in high-risk patients is tried to be performed in the hybrid room or in the operating theatre using 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 in patients even with short implant duration [23]

Goal of the study

The aim of the study was 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 transvenous lead extraction between March, 2006 and September, 2021 in two high volume centers but with the same first operator. Organisational model of TLE procedures has evolved with time. In all patients who underwent TLE in 2005–2013 (pioneering era), procedures were performed in EP-LAB, in the period 2013–2016 (in-between era/ safety staging era) either in the operating theatre for cardiac surgery or in EP-LAB - depending on the initial risk assessment and in 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 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., USA, TightRail (Spectranetix / Phillips, 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., CA, US) or formerly Basket Catheters (Cook Medical Inc, US). The excimer laser was not used. When necessary, femoral access and Femoral Working Station was 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 for the occurrence of major complications related to TLE [20] using an online calculator available at http://alamay2.linuxpl.info/kalkulator/. Acronym explanation: 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 more precisely compare the study groups, we also used other scales: EROS score [24] — assessment of increased risk of MC and the need for cardiac surgery, MB scale [25] analyzing indicators of increased complexity of the procedure (need for advanced tools to achieve TLE success), LED index [26] — TLE difficulty assessment, defined by the time of fluoroscopy, Mazzone score [27] — assessment of the need for advanced TLE techniques) [27], as well as the IKAR scale [28] for the assessment of 1-year survival after TLE.

Procedure complexity was expressed as all lead extraction time ("sheath to sheath time") and average time of single lead extraction (sheath-to sheath / number of extracted leads) and the necessity utility of second line tools and advanced tools [21, 25–27].

Technical problems during TLE — situations which increased procedure complexity but not being complications (detailed explanation in Supplementary material).

Characteristics of organisational models of TLE procedures

Model 1: "Modern era" from 2017 to 2021. All procedures performed in the hybrid room with the cardiac surgeon as co-operator ("shoulder-to-shoulder"), in patients under general anaesthesia, with mandatory arterial line (AL), expiratory gas monitoring and TEE monitoring during the whole procedure. Pump for extracorporeal circulation with perfusion team was on

standby. Patients were prepped for sternotomy. No grading in the application of safety requirements, all TLEs performed in the same conditions.

Model 2: “In-between /safety staging era” from 2013 to 2016 — the era of a graded approach to safety requirements. The transition period in which it was possible to perform lead extraction in selected individuals (most difficult and high-risk patients) in the cardiac surgery operating theatre. Due to limited availability of the cardiac surgery operating theatre (unplanned operations), we had to sort patients into those who would undergo TLE either in EP-LAB (subgroup A) or the operating theatre (subgroup B). Patients with implant duration >12 years, young age at first implantation, female gender, multiple leads, abandoned leads, old UP pacemaker lead models were intentionally 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 gender, recent <3 leads and BP active lead models qualified for the procedure in EP-LAB (subgroup A). Intermediate-risk patients were managed depending on room availability. In spite of 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 anaesthesia, cardiac surgeon participation and monitoring).

Subgroup B — operating theatre, mobile C-arm X-ray machine (lower quality than in the hybrid room), general anaesthesia with AL but without TEE monitoring. Cardiac surgeon on duty, usually without close co-operation. 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” from 2006 to 2013. The oldest period when all TLE procedures were performed in EP-LAB, without a collaborating cardiac surgeons who was only on the premises, in patients under intravenous analgesia and sedation without TEE and AL. Cardiac surgery operating theatre and staff (anaesthesia, operating theatre attendants) were on duty and fit for urgent operation (necessary patient transfer from EP-LAB to 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 in the 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 fate of 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 number and percentage. The significance of differences between groups was determined using the χ^2 test (dichotomous data) or the Student's t-test (parametric data) or 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 occurrence. To 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 log-rank test was used to assess the difference in event-free survival between groups of patients divided by approach to safety and venue of TLE. 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 use anonymous data from their medical records, 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 with a mean age of 66.41(14.32) there were 864 (38.98%) females. Infection indications for TLE were found in 848 (38.27%) patients. Most of the patients-1587 (71. 61%) had an implanted some kind of pacing system, 493 (22.25%) had ICD and 136 (6.14%) — CRT. Mean left ventricular ejection fraction (LVEF) was 49.65(14.94)%, ischaemic heart disease (IHD) was present in 1150 (51.90%) patients, renal failure occurred in 431 (19.45%) patients, and 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 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 and had IHD and higher Charlson comorbidity index more often compared to other groups.

There was a statistically significant difference in type of indications for TLE- with the highest percentage of infectious indications in the low level of 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 proximal ending in 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 “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 approach, extraction of leads with redundant loops and extraction of abandoned lead(s) declined over time. Extraction of ICD leads increased over years

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

Analysis of the TLE procedure complexity and lead management strategy in compared patient’s 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 different TLE risk scales demonstrated some differences in the clinical profile of patients (SAFeTY-TLE and EROS), while the evaluation using scales based on only system -dependent factors (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 time periods did not show any significant differences between the study groups, however, it should be emphasized that the overall number of large complications in the study population was very small (39 MC-1.76%). Moreover, the MC analysis showed that in the group of patients undergoing TLE in the hybrid room, there was no peri-procedural death, while the percentage of deaths during TLE conducted in EP-LAB was 0.33%, and in the group with grading of safety measures — 0.29%. It should also be noted that in the "In between” — safety staging era group, three cardiac

tamponades (including one fatal tamponade) occurred during TLE procedures in EP-LAB in patients with potentially low risk of MC (SAFeTY-TLE score <2.46%: respectively: 0.48%, 0.91% and 1.50%).

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

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

Patient survival throughout the FU period

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

Regression analysis confirm significance of common risk factors of major complications; female gender, dwell time of the oldest extracted lead and number of extracted leads. Venue of TLE had no impact on the major complication occurrence. The prognostics of minor complications were female gender, dwell time of the oldest extracted lead, extraction of defibrillation lead. The earliest model of TLE (pioneering era- EP-LAB without c-surgeon and general anesthesia) predisposed do minor complications occurrence. The predictors of complete clinical success achieving were: age of extracted lead and number of extracted leads. Under multivariable analysis venue of TLE had no impact on the complete clinical success achieving. The predictors of procedural success were patients age during first CIED implantation, age of extracted lead, leads with passive fixation and number of extracted leads. Similarly to complete clinical success, the venue of TLE had no impact on the complete procedural success achieving (Table 7).

The multivariate analysis of the impact of the main organizational factors on the occurrence of complications and the effectiveness of TLE did not confirm that the logistics of TLE influenced the occurrence of major complications and thus the effectiveness of the procedure (Supplementary material, *Table S2*).

DISCUSSION

The present study analyzed a large database of patients undergoing TLE by a single operator in two centers in Poland in 2006–2021. The novel concept of assessing the impact of the organizational model of the procedure evolving over time on the effectiveness and safety of TLE allows for the analysis of the occurrence of serious complications depending on the precautions used.

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 gender) [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, haemothorax related to TLE ranges from 0.19% to 1.8% [1, 3, 10–14, 16, 19–22, 32]. In the event of a complication, surgical intervention is required in most cases to prevent fatal consequences. [1, 3, 5–11]. The time to sternotomy is crucial and it should be 5-10 min optimally [1, 3, 7]; if the above time limit is exceeded, the risk of CNS damage increases significantly [7]. Thus, the ideal setting for TLE is the one that allows immediate sternotomy. The main role of a 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 the event 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 locations such as EP-LAB or interventional cardiology laboratory are taken into account, however with 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-LAB or IC-LAB, high-risk patients are transferred to hybrid rooms, whereas intermediate-risk patients are managed according to the availability of a procedure location. 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 among theoretically low-risk patients.

There is some evidence to indicate that rates of procedure-related deaths decrease over decades [13]. Because 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 machine or large EP-LABs with a surgeon and anaesthesia team on call and off-site equipment is a worse option [10, 14–18]. But for organisational (and economic) reasons several TLE centers continue to use a graded approach to safety requirement [14–18].

The results of this study show that TLE in EP-LAB without surgical and anaesthesia staff and equipment was associated with the occurrence of major complications and procedure-related deaths in 1.55% and 0.33%, respectively. The graded approach to safety requirements (categorisation of patients on the basis of the setting of extraction procedure) was associated with the occurrence of major complications and procedure-related deaths in 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 graded approach showed that two unexpected major complications appeared in EP-LAB during the extraction of a 8.7-y-old atrial lead and 1.8-y-old coronary sinus lead. Both patients were urgently transferred to the operating room, lesions were sutured but the delayed intervention (30 minutes) had fatal consequences. Four procedure-related deaths among patients operated on in EP-LAB (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 a newly established TLE center (modern era) — 300 TLEs with one significant major complications and without procedure-related deaths with 99.00% clinical success and 97.99% procedural success in spite of even longer implant duration than other groups, on condition of 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, in spite of the longer implant duration, the rate of procedure-related death was ero [11-13, 31, 32].

Study limitations

This is a presentation of a single, very experienced first operator acting as a proctor recently. TLE procedures were performed in two with two experienced cardiac surgeons, two anaesthesia 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

1. A setting that allows emergency cardiac surgery is the most important factor to avoid major complications-related deaths. The presence of cardiac surgeons as co-operator seems less important to prevent complications-related deaths.
2. TLE procedure performed in a hybrid or operating room by an electrophysiologist and cardiac surgeon in collaboration, with constant monitoring of vital signs and with TEE monitoring appears to be the safest possible option for the patient.
3. Graded approach to safety requirements is associated with the risk of unexpected major complications and procedure-related deaths due to delayed surgical intervention in seemingly low-risk patients who can also develop major complications.
4. 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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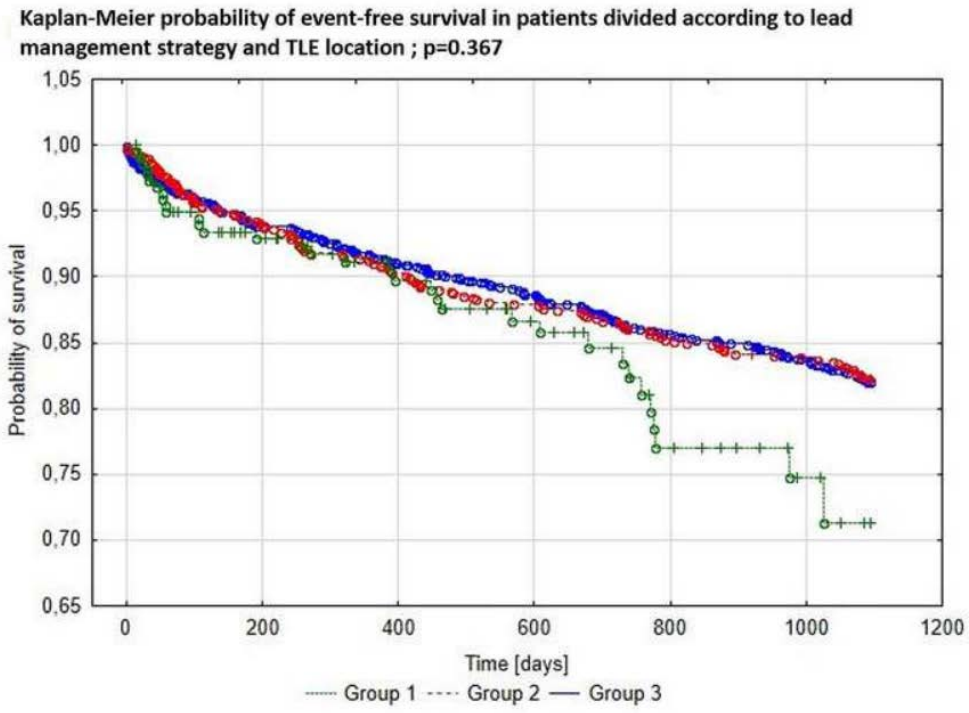

Figure 1. Probability of survival depending on organizational model of transvenous lead extraction (TLE)

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

The comparison of patient-related risk factors	**Modern era. Full safety precaution, without stagging**	**In-between era. Attempt of stagging of TLE safety**	**A pioneering era, EP-LAB without c-surgeon and g. anaesthesia**	**Statistics**		
Organisational 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 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
Carlson'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; EF, ejection fraction; EP-LAB- electrophysiology laboratory; IHD, ischaemic heart disease; MI, myocardial infarction; NYHA class, New York Heart Association class; TLE, transvenous lead extraction

Table 2. Potential CIED-related risk factors of major TLE complications in compared patient's groups

The comparison of CIED — related risk factors	**Modern era Full safety precaution, without stagging**	**In-between era. Attempt of stagging of TLE safety**	**A pioneering era, EP-LAB without c-surgeon and g. anaesthesia**	**Statistics**		
Organisational 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 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 in X-ray before TLE, n (%)	6 (1.98)	40 (5.65)	92 (7.76)	0.009	<0.001	0.16
Lead with proximal ending in 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 oldest one 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 of major TLE complications and technical problems in compared patient's groups**

The comparison of procedure-related potential risk factors	**Modern era. Full safety precaution, without stagging**	**In-between era. Attempt of stagging of TLE safety**	**A pioneering era. EP-LAB without c-surgeon**	**Statistics**

			and g. anaesthesia			
Organisational 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
Utilised approach other than lead venous entry, n (%)	0 (0.00)	3 (0.43)	82 (6.69)	0.56	<0.001	<0.001
Extraction of lead 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

Table 4. TLE procedure complexity and realised lead management strategy in compared patient's groups

Procedure complicity and TLE strategy	**Modern era Full safety precaution, without stagging**	**In-between era. Attempt of stagging of TLE safety**	**A pioneering era, EP-LAB without c-surgeon and g. anaesthesia**	**Statistics**		
Organisational 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 complicity						
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 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
Utility of 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 compared patient's groups using available scores

The comparison of procedure-related potential risk factors	**Modern era Full safety precaution, without stagging**	**In-between era. Attempt of stagging of TLE safety**	**A pioneering era, EP-LAB without c-surgeon and g. anaesthesia**	**Statistics**		
Organisational 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 scale (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 scale (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 utilised: the SAFeTY — TLE calculator (risk of MC), EROS score (risk of MC), MB score (the need for advanced tools to achieve TLE success), LED score (the difficult TLE, defined by means of the fluoroscopy time) and Mazzone score (the need for advanced TLE techniques)

Table 6. **TLE procedure efficacy and complications and mortality after TLE procedure in compared patient's groups**

Efficacy, complications, mortality and prognosis	**Modern era Full safety precaution,**	**In-between era. Attempt of stagging**	**A pioneering era, EP-**	**Statistics**

	without stagging	**of TLE safety**	**LAB without c-surgeon and g. anaesthesia**			
Organisational 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
Haemothorax, n (%)	0 (0.00)	0 (0.00)	4 (0.33)	N	0.72	0.33
Number of hemopericardium or haemothorax 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 follow-up						
Time of follow-up, days, median, (IQR)	621 (327-915)	1095 (1095–1095)	1095 (1095–1095)	<0.001	<0.001	0.81
	Log-rank *P* = 0.441					
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-y 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

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 (with-out 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 gender (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 to 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. anaesthesia (yes/no)	0.735	(0.393–1.376)	0.34			
In-between era. Attempt of stagging 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 stagging (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 gender (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 to 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. anaesthesia (yes/no)	2.312	(1.641–3.257)	<0.001	2.237	(1.539–3.253)	<0.001
In-between era. Attempt of stagging of TLE safety (yes/no)	0.507	(0.343–0.748)	<0.001			
Full safety precaution, without stagging (yes/no)	0.520	(0.302–0.896	0.02			
Predictors of complete clinical and complete procedural TLE successes						
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 gender (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 to 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. anaesthesia (yes/no)	0.704	(0.418–1.183)	0.19			
In-between era. Attempt of stagging of TLE safety (yes/no)	0.926	(0.543–1.579)	0.78			
Full safety precaution. without stagging (yes/no)	3.49	(1.088–11.21)	0.04	1.745	(0.518–5.877)	0.37
			Ful procedural success			
Patient’s age during first system	1.033	(1.022–1.044)	<0.001	1.015	(1.002–1.028)	0.03

implantation, by one year						
Female gender (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 to 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. anaesthesia (yes/no)	0.777	(0.523–1.155)	0.21			
In-between era. Attempt of stagging of TLE safety (yes/no)	0.896	(0.590–1.358)	0.60			
Full safety precaution. without stagging (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