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Assessment of the impact of organisational model of transvenous lead extraction on the effectiveness and safety of procedure: an observational study

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ABSTRACT

Objectives To estimate the impact of the organisational model of transvenous lead extraction (TLE) on effectiveness and safety of procedures.

Design Post hoc analysis of patient data entered prospectively into a computer database.

Setting Data of all patients undergoing TLE in three centres in Poland between 2006 and 2021 were analysed.

Participants 3462 patients including: 985 patients undergoing TLE in a hybrid room (HR), with cardiac surgeon (CS) as co-operator, under general anaesthesia (GA), with arterial line (AL) and with transoesophageal echocardiography (TEE) monitoring (group 1), 68 patients—TLE in HR with CS, under GA, without TEE (group 2), 406 patients-TLE in operating theatre (OT) using 'arm-C' X-ray machine with CS under GA and with TEE (group 3), 154 patients-TLE in OT with CS under GA, without TEE (group 4), 113 patients-TLE in OT with anaesthesia team, using the 'arm-C' X-ray machine, without CS (group 5), 122 patients-TLE in electrophysiology lab (EPL), with CS under intravenous analgesia without TEE and AL (group 6), 1614 patients-TLE in EPL, without CS, under intravenous analgesia without TEE and AL (group 7).

Key outcome measure Effectiveness and safety of TLE depending on organisational model.

Results The rate of major complications (MC) was higher in OT/HR than in EPL (2.66% vs 1.38%), but all MCs were treated successfully and there was no MC-related death. The use of TEE during TLE increased probability of complete procedural succemss achieving about 1.5 times (OR=1.482; p<0.034) and were connected with reduction of minor complications occurrence (OR=0.751; p=0.046).

Conclusions The most important condition to avoid death due to MC is close co-operation with cardiac surgery team, which permits for urgent rescue cardiac surgery. Continuous TEE monitoring plays predominant role in immediate decision on rescue sternotomy and improves the effectiveness of procedure.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study used data from the world's largest database of patients undergoing transvenous lead extraction to assess the effectiveness and safety of the procedures.
⇒ The methodology is noteworthy due to the analysis of as many as seven organisational models of the procedure.
⇒ The generalisation of this study is limited due to the presentation of single, very experienced first operator and very high volume centres.

INTRODUCTION

Background

Transvenous lead extraction (TLE) is currently considered as a pivotal element of strategy of lead-related problems.[1–5] TLE is a complex procedure that sometimes leads to fatal complications that require urgent surgical repair.[6–11] All TLE guidelines recommend cardiac surgeon and anaesthesia team back-up readiness and various forms of monitoring (arterial line (AL) and echocardiography) to promptly diagnose and accurately assess internal bleeding.[1–5] Organisational difficulties and economic aspects still force many TLE centres to step up security requirements. Simpler extraction procedures (for low-risk patients) are performed in the electrophysiology lab (EP-LAB) with on-call cardiac surgery and anaesthesia support. TLE in high-risk patients is attempted in a hybrid room (HR) or in an operating theatre (OT) with the use of a mobile X-ray machine with the C-arm.[12–16] The main problem is the error-free assessment of the difficulty of the procedure, the complexity and the risk of serious complications. The effects of these strategies in clinical practice have so far been rarely discussed and, to the best of our knowledge, to date no comparison of the efficacy of TLE has been carried out according to the procedural organisational model.

Objective

The aim of this study was to identify the most important factors in the organisation of TLE affecting the safety of the procedure.

METHODS

Study design

This post hoc analysis used clinical data of 3462 patients who underwent TLE by one operator in three high volume centres in Poland (Medical University of Lublin, The Pope John Paul II Province Hospital of Zamość, Masovian Specialistic Hospital of Radom) between March 2006 and February 2021. All information concerning patients and procedures were up to date inserted to computer database.

Patient and public involvement

No patient involved—post hoc data analysis after giving informed consent of the patient to data processing.

STUDY SETTING

Organisational models of TLE procedures carried out in 2006–2021

The comparative analysis of seven organisational models of TLE procedure (1–7) was performed. The difference between the individual types of organisation concerned: venue of procedure: EPL, cardiac surgery OT and HR, type of participation of the cardiac surgeon (on duty in the hospital or a direct co-operator), type of anaesthesia (intravenous sedation or general anaesthesia (GA) with mandatory AL) and monitoring of the procedure using transoesophageal echocardiography (TEE). These seven models represent the evolution of the organisation of the TLE procedure over the past 15 years.

Group 1 (985 patients/procedures) presents the modern times of TLE since June 2015, when the most difficult TLE procedures were performed in a HR, with cardiac surgeon as co-operator, under GA, with mandatory AL and with TEE monitoring. Cardiac surgeon was scrubbed and extracorporeal circulation pump with perfusion team was in stand-by—ready for action as soon as the chest is opened.

Group 2 (68 patients/procedures) presents the similar group of procedures performed in the HR, with scrubbed cardiac surgeon as co-operator, under GA, with obligatory AL but without TEE monitoring due to medical contraindications for oesophageal tube or failure of oesophageal tube or urgent echocardiographer call for another operating room. Extracorporeal circulation pump with perfusion team was in stand-by—ready for action as soon as the chest is opened.

Group 3 (406 patients/procedures) represents slight earlier era when HR was unavailable and TLE was performed in cardiac surgery OT using ‘arm-C’ X-ray machine (lower quality of fluoroscopy) but with scrubbed cardiac surgeon as a co-operator, under GA, with mandatory AL and with TEE monitoring. Pump for extracorporeal circulation with perfusion team was also in stand-by. If possible, less difficult procedures were selected for this group (elements of staging safety precautions).

Group 4 (154 patients/procedures) represents middle era of TLE (from January 2013). During this period, limited access to the cardiosurgical operating room was obtained, and the most difficult procedures were selected by grading precautionary measures in OT. Cardiac surgeon was present as scrubbed co-operator, procedures were performed under GA and with AL but without TEE monitoring (anaesthesia preferred pharyngeal tube for

Table 1 Diagram of the seven organisational models of transvenous lead extraction

	Surgeon as co-operator in HR with TEE, GA and AL	Surgeon as co-operator in HR without TEE with but with GA and AL	Surgeon as co-operator in OT with TEE, GA and AL	Surgeon as co-operator, with GA and AL in OT without TEE	Surgeon on stand-by only but TLE in OT but with GA and AL without TEE	Surgeon as co-operator in EPL without TEE, GA and AL	Surgeon on stand by only and TLE in EPL without TEE, GA and AL
Organisational model of TEE	1	2	3	4	5	6	7
Venue: EPL/ OT/HR	HR	HR	OT	OT	OT	EPL	EPL
Surgeon as co-operator	Yes	Yes	Yes	Yes	No	Yes	No
Anaesthesia, AL	Yes	Yes	Yes	Yes	Yes	No	No
TEE monitoring	Yes	No	Yes	No	No	No	No
Organisational safety level	Very high	High	Very high	High	Moderate	Moderate	Low
No of patients	985	68	406	154	113	122	1614

AL, aterial line; EPL, electrophysiological lab; GA, general anaesthesia; HR, hybrid room; OT, operating theatre; TEE, transoesophageal echocardiography; TLE, transvenous lead extraction.

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Table 2 Clinical data of study group

Study group-3462 patients undergoing TLE	Count/average	%/SD
Patient's age during TLE (years)	65.85	15.69
Patient's age during first system implantation (years)	57.59	17,15
Sex (% of female patients)	1346	38.88
Aetiology of implantation: IHD, MI	1921	55.49
Aetiology of implantation: cardiomyopathy, valvular heart disease	519	14.99
Aetiology of implantation: congenital, channelopathies, neurocardiogenic, postcardiac surgery	1020	24.46
LVEF average(%)	49,16	15.15
Renal failure (any)	717	20.71
Previous sternotomy	526	15.19
Carlson's index (points)	4.64	3.64
Systemic infection (with pocket infection or not)	774	22.36
Local (pocket) infection	346	9.99
Lead failure (replacement)	1710	49.39
Change of pacing mode/upgrading, downgrading	200	5.78
Other* indications	430	12.42
Type of implanted system: pacemaker (any)	2446	70.65
System: ICD (VVI, DDD)	768	22.18
System: CRT	246	7.11
Mean dwell time of oldest one lead in the patient before TLE (months)	99.90	74.48
Cumulative dwell time of leads before TLE (years)	15.03	12.76
Major complications all	70	2.02
Major complications (with rescue cardiac surgery)	41	1.18
Major complications (without rescue cardiac surgery)	29	0.847
Procedure-related death	6	0.17

Other (abandoned lead/prevention of abandonment (AF, overmuch of leads), threatening/potentially threatening lead (loops, free ending, left heart, LDTVD) Other (MRI indication, cancer, pain of pocket, loss of indication for pacing/ICD) recapture venous access.
AF, atrial fibrillation; CRT-D, cardiac resynchronisation therapy defibrillator; ICD, implantable cardioverter defibrillator; IHD, ischaemic heart disease; LDTVD, lead dependent tricuspid valve dysfunction; LVEF, lef ventricular ejection fraction; MI, myocardial infarction; TLE, transvenous lead extraction.

ventilation). Unfortunately perfusion team was on call (20 min until arrival).

Group 5 (113 patients/procedures) presents situations of performing procedures in the operating room with anaesthesia team (and AL), using the 'arm-C' X-ray machine (with lower quality of fluoroscopy), but without the close cooperation of the cardiac surgeon (presence of a cardiac on duty, but without direct participation in TLE).

Group 6 (122 patients/procedures) represents oldest TLE era, when all procedures were performed only in the EPL, with scrubbed cardiac surgeon as co-operator but under intravenous analgesia and sedation without TEE and AL. Cardiac surgery OT and other staff (anaesthesia, OT attendant) were on duty and fit for urgent operation (translocation of patient was necessary).

Group 7 (1614 patients/procedures) represents the oldest period of TLE (from March 2006 to December 2012) when all TLE procedures were performed in EPL, without cardiac surgeon as co-operator, only on duty in hospital. Procedures were performed under intravenous analgesia and sedation without TEE and AL. Cardiac surgery OT and staff (anaesthesia, OT attendant) were on duty and fit for urgent operation (translocation from EPL to OT of patient was necessary) (table 1).

Variables/definitions

Lead extraction procedure was defined according to guidelines on cardiovascular implantable electronic device lead management and extraction (HRS 2009 i 2017 and EHRA 2018).[2–5] All lead extraction procedures in this study were performed using mechanical systems such as polypropylene Byrd dilator sheaths (Cook Medical, Leechburg, Pennsylvania, USA), mainly via extracted lead venous entry approach. If technical difficulties arose, a different vascular access and/or additional tools such as Evolution (Cook Medical, USA), TightRail (Spectranetix, USA), lassos, basket catheters were used. Laser cutting sheaths were not used. Indications for TLE and type of periprocedural complications were defined according to the 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction.[4]

All lead extractions were performed by the same, an experienced TLE operator. Second operator having experience with pacing therapy; cardiac surgeon, anaesthesiologist and echocardiographer were present frequently but not always. The role of cardiac surgeon participation, availability of OT or HR, kind of anaesthesia, echocardiography monitoring availability evolved during the time.

Indications for TLE, procedure effectiveness and complications were assessed according to the 2009 and 2017 HRS consensus and 2017 EHRA guidelines.[2–5] The efficacy of TLE was determined based on the percentage of procedural success and clinical success including complete and partial radiographic success. Radiographic and procedural success was defined as the removal of all targeted leads and lead material from the vascular space with the absence of any permanently disabling complication or procedure-related death. Clinical success was defined as the removal of all targeted leads or retention of a small portion (<4 cm) of the lead that did not negatively impact the outcome goals of the procedure (ie, residual lead did not increase the risk of perforation, embolic events, perpetuation of infection or cause any undesired

Table 3 Comparison of the seven organisational models of TLE

Comparison of organisational modelsof TLE	Group 1 Surgeon as co-operator in HR with TEE, GA and AL	Group 2 Surgeon as co-operator in HR without TEE but with GA and AL	Group 3 Surgeon as co-operator in OT with TEE, GA and AL	Group 4 Surgeon as co-operator, with GA and AL in OT without TEE	Group 5 Surgeon on stand-by only but TLE in OT but with GA and AL without TEE	Group 6 Surgeon as co-operator in EPL without TEE, GA and AL	Group 7 Surgeon on standby only and TLE in EPL without TEE, GA and AL	1 vs 2	1 vs 3	1 vs 4	1 vs 5	2 vs 3	2 vs 4	2 vs 5	3 vs 4	3 vs 5
Patient characteristic																
Patient's age during TLE (mean SD)	66.29 ±17.93	61.18 ±22.98	69.06 ±12.11	56.41 ±25.73	62.45 ±16.20	64.08 ±14.43	66.38 ±14.00	0.172	0.102	<0001	0.004	0.048	0.128	0.531	<0001	<0001
Patient's age during first system implantation (SD)	55.79 ±19.61	52.90 ±24.22	62.17 ±12.13	46.05 ±25.96	48.75 ±17.67	56.29 ±16.59	59.68 ±15.21	0.870	<0001	<0001	<0001	0.012	0.023	0.005	<0001	<0001
Female (n, %)	378 (38.38)	26 (28.24	153 (37.68)	61 (39.61)	54 (47.79)	44 (36.07)	629 (39.00)	0.915	0.867	0.831	0.065	0.961	0.965	0.272	0.748	0.067
Presence of abandoned lead before TLE	83 (8.43)	6 (8.82)	25 (6.16)	18 (11.69)	21 (18.58)	22 (18.03)	221 (13.70)	0.913	0.186	0.240	<0001	0.577	0.690	0.117	0.404	<0001
4 and >4 in the heat before TLE	20 (2.03)	2 (2.94)	6 (1.48)	5 (3.25)	8 (7.08)	6 (4.92)	68 (4.22)	0.944	0.637	0.507	0.004	0.720	0.767	0.399	0.315	0.003
Large lead loop presence in X-ray before TLE	31 (3.21)	2 (2.94)	9 (2.22)	11 (7.14)	14 (12.39)	12 (9.84)	89 (5.52)	0.789	0.444	0.026	<0001	0.946	0.358	0.058	0.012	<0001
Dwell time of oldest one lead in the patient before TLE	126.49 ±84.90	99.99 ±70.18	83.63 ±49.06	125.2 ±92.91	164.9 ±80.85	94.61 ±81.40	81.16 ±60.98	0.007	<0001	0.403	<0001	0.170	0.090	<0001	<0001	<0001
Global implant duration before TLE in years	18.77 ±15.16	14.17 ±10.78	12.78 ±8.95	18.15 ±15.13	23.99 ±15.16	14.72 ±13.71	12.30 ±10.38	0.027	<0001	0.369	<0001	0.284	0.202	<0001	0.002	<0001
Potential risk factors of major TLE complications and technical problems																
Three or more leads were extracted	103 (10.45)	6 (8.82)	33 (8.13)	14 (9.09)	17 (15.04)	19 (15.57)	179 (11.10)	0.827	0.221	0.709	0.185	0.964	0.849	0.324	0.844	0.043
Utilised approach other than lead venous entry	8 (0.81)	0 (0.00)	1 (0.26)	8 (5.19)	2 (1.79)	9 (7.38)	78 (4.86)	0.981	0.408	<0001	0.622	0.309	0.128	0.712	<0001	0.235
Extraction of lead with to long loop Large	25 (2.54)	2 (2.94)	9 (2.22)	11 (7.14)	15 (13.24)	12 (9.84)	93 (5.77)	0.848	0.874	0.005	<0001	0.946	0.358	0.041	0.012	<0001
Extraction of abandoned lead(s) (any)	76 (7.72)	5 (7.35)	24 (5.91)	17 (11.04)	20 (17.70)	19 (15.57)	206 (12.77)	0.897	0.287	0.213	<0001	0.853	0.546	0.083	0.058	<0001
Oldest extracted lead dwelling time	125.4 ±84.54	99.99 ±70.18	82.93 ±48.38	122.7 ±92.43	161.1 ±82.97	91.23 ±76.34	78.99 ±58.69	0.012	<0001	0.327	<0001	0.126	0.138	<0001	<0001	<0001

Continued

Table 3 Continued

Comparison of organisational modelsof TLE	Group 1 Surgeon as co-operator in HR with TEE, GA and AL	Group 2 Surgeon as co-operator in HR without TEE but with GA and AL	Group 3 Surgeon as co-operator in OT with TEE, GA and AL	Group 4 Surgeon as co-operator, with GA and AL in OT without TEE	Group 5 Surgeon on stand-by only but TLE in OT but with GA and AL without TEE	Group 6 Surgeon as co-operator in EPL without TEE, GA and AL	Group 7 Surgeon on standby only and TLE in EPL without TEE, GA and AL	1 vs 2	1 vs 3	1 vs 4	1 vs 5	2 vs 3	2 vs 4	2 vs 5	3 vs 4	3 vs 5
Cumulative dwell time of extracted lead (in years)	17.55 ±15.20	12.57 ±11.07	10.81 ±8.76	16.84 ±15.38	21.78 ±15.01	13.09 ±12.29	10.60 ±9.60	0.006	<0001	0.333	<0001	0.368	0.105	<0001	<0001	<0001
No of points in SAFETY TLE score	6.61 ±4.59	5.92 ±3.87	5.05 ±3.81	7.35 ±4.44	8.52 ±4.49	5.89 ±4.31	5.20 ±3.90	0.146	<0001	0.181	<0001	0.051	0.024	<0001	<0001	<0001
Intermediate risk of MC according to SAFeETY TLE score	2.28 ±3.51	1.54 ±2.37	1.26 ±2.22	2.43 ±3.17	3.17 ±3.96	1.77 ±3.04	1.41 ±2.91	0.146	<0001	0.181	<0001	0.051	0.024	<0001	<0001	<0001
TLE complexity and outcomes TLE procedure																
Average time of single lead extraction (sheath-to sheath/no of extracted leads)	10.00 ±15.81	7.29 ±8.54	6.49 ±7.04	10.15 ±11.85	9.91 ±10.54	9.36 ±12.88	8.67 ±11.35	0.183	<0001	0.529	0.072	0.073	0.068	0.009	<0001	<0001
Technical problem during TLE (any)	239 (24.26)	14 (20.59)	87 (21.43)	40 (25.97)	24 (21.24)	26 (21.31)	266 (16.49)	0.593	0.291	0.715	0.554	0.997	0.489	0.933	0.301	0.931
Necessity to change venous approach	18 (1.83)	0 (0.00)	2 (0.49)	10 (6.49)	4 (3.54)	9 (7.38)	94 (5.83)	0.522	0.099	<0001	0.380	0.667	0.072	0.295	<0001	0.029
Two or more technical problems	77 (7.81)	2 (2.94)	12 (2.96)	6 (3.90)	6 (5.31)	2 (2.50)	32 (1.98)	0.216	<0001	0.116	0.445	0.704	0.969	0.706	0.768	0.358
TLE efficacy and complications																
Major complications (any)	24 (2.44)	1 (1.47)	6 (1.50)	9 (6.90)	5 (5.40)	2 (1.64)	23 (1.43)	0.926	0.361	0.037	0.347	0.590	0.273	0.518	0.010	0.120
Haemopericardium	15 (1.52)	0 (0.00)	2 (0.43)	6 (3.90)	4 (3.54)	1 (0.82)	14 (0.87)	0.621	0.182	0.086	0.239	0.667	0.230	0.295	0.008	0.029
Tricuspid valve damage during TLE (severe)	9 (0.91)	0 (0.00)	3 (0.74)	2 (1.30)	2 (1.79)	0 (0.00)	3 (0.19)	0.913	0.999	0.990	0.713	0.908	0.862	0.712	0.900	0.358
Rescue cardiac surgery	18 (1.93)	1 (1.47)	3 (0.74)	5 (3.25)	2 (1.79)	2 (1.64)	10 (0.62)	0.796	0.204	0.391	0.742	0.916	0.762	0.654	0.067	0.654
Death procedure related (intraprocedural, postprocedural)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.82)	5 (0.34)	N	N	N	N	N	N	N	N	N

Continued

Table 3 Continued

Comparison of organisational modelsof TLE	Group 1 Surgeon as co-operator in HR with TEE, GA and AL	Group 2 Surgeon as co-operator in HR without TEE but with GA and AL	Group 3 Surgeon as co-operator in OT with TEE, GA and AL	Group 4 Surgeon as co-operator, with GA and AL in OT without TEE	Group 5 Surgeon on stand-by only but TLE in OT but with GA and AL without TEE	Group 6 Surgeon as co-operator in EPL without TEE, GA and AL	Group 7 Surgeon on standby only and TLE in EPL without TEE, GA and AL	1 vs 2	1 vs 3	1 vs 4	1 vs 5	2 vs 3	2 vs 4	2 vs 5	3 vs 4	3 vs 5
Death indication-related (intraprocedural, postprocedural	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.82)	3 (0.19)	N	N	N	N	N	N	N	N	N
Partial radiological success (remained tip or <4 cm lead fragment)	37 (3.75)	3 (4.41)	7 (1.72)	15 (9.74)	6 (5.31)	3 (2.64)	63 (3.09)	0.958	0.072	0.002	0.581	0.331	0.283	0.933	<0001	0.067
Full clinical success	973 (98.78)	67 (98.50)	402 (99.02)	149 (96.75)	107 (94.69)	117 (95.90)	1570 (97.30)	0.659	0.806	0.155	0.007	0.781	0.762	0.369	0.128	0.010
Full procedural success	939 (95.33)	64 (94.10)	396 (97.54)	137 (88.96)	104 (93.02)	115 (94.26)	1536 (95.23	0.903	0.068	0.003	0.216	0.248	0.336	0.820	<0001	0.014
Mortality after TLE procedure																
< First 2 days (first 48 hours)	2 (0.20)	0 (0.00)	0 (0.00)	0.00%	0 (0.00)	2 (1.64)	7 (0.43)	0.285	0.897	0.634	0.493	N	N	N	N	N
1-month mortality after TLE 2–30 days	18 (1.83)	2 (2.94)	3 (0.74)	1.30%	0 (0.00)	0 (0.00)	20 (1.24)	0.847	0.204	0.894	0.291	0.316	0.764	0.272	<0001	N
1-year mortality after TLE (31–365 days)	67 (6.80)	6 (8.82)	25 (6.16)	5.84%	7 (6.19)	14 (11.48)	109 (6.76)	0.693	0.752	0.790	0.966	0.577	0.599	0.714	0.953	0.836

AL, arterial line; EPL, electrophysiological lab; GA, general anaesthesia; HR, hybrid room; OT, operating theatre; TLE, transvenous lead extraction.

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Table 4 Comparison of the organisation of the TLE procedure depending on the level of safety

Comparison of organisational models of TLE	Venue: operation theatre or hybrid room	EPL	A versus B	With cardiac surgeon as co-operator	Without cardiac surgeon as co-operator	B versus C	With TEE monitoring	Without TEE monitoring	E versus F
No of patients	A N=1726	B N=1736		C N=1735	D N=1727		E N=1393	F N=2069	
Patient characteristic	Average±SD no (%)	Average±SD no (%)		Average±SD no (%)	Average±SD no (%)		Average±SD no (%)	Average±SD no (%)	
Patient's age during TLE (years)	65.55 ±18.18	66.16 ±14.19	0.266	65.65 ±18.05	66.12 ±14.18	0.202	67.03 ±16.67	65.11 ±15.90	<0001
Patient's age during first system implantation (years)	55.79 ±19.57	59.39 ±15.49	<0001	55.29 ±19.40	58.97 ±15.61	<0001	57.58 ±18.15	57.65 ±17.33	0.950
Sex (% of female patients)	673 (38.97)	673 (38.79)	0.958	663 (38.19)	683 (39.57)	0.425	532 (38.22)	814 (39.32)	0.536
TLE procedure potential risk factors of major TLE complications and technical problems									
Three or more leads were extracted	174 (10.08)	198 (11.21)	0.224	176 (10.14)	196 (11.36)	0.271	135 (9.70)	237 (11.45)	0.115
Utilised approach other than lead venous entry	19 (1.10)	87 (5.01)	<0001	26 (1.50)	80 (4.65)	<0001	9 (0.65)	97 (4.47)	**<0001**
Extraction of broken lead with to-long loop	13 (0.75)	28 (1.61)	0.025	11 (0.63)	30 (1.74)	0.004	3 (0.22)	38 (1.84)	**<0001**
Extraction shifted of lead with to-long loop	49 (2.84)	76 (4.38)	0.019	48 (2.77)	77 (4.46)	0.009	31 (2.23)	94 (4.54)	**<0001**
Extraction of abandoned lead(s) (any)	142 (8.22)	225 (12.96)	<0001	141 (8.12)	226 (13.09)	<0001	100 (7.18)	267 (12.90)	**<0001**
Oldest extracted lead body dwelling time (months)	116.4 ±80.52	79.88 ±60.17	<0001	111.7 ±79.40	84.36 ±63.86	<0001	112.9 ±78.24	88.13 ±68.10	<0001
Cumulative dwell time of extracted lead (years)	15.98 (14.16)	10.77 (9.83)	<0001	15.40 ±13.91	11.33 ±10.42	<0001	15.58 ±13.97	11.88 ±11.09	<0001
Ste TLE SAFETY Risk Score (points)	6.52 ±4.46	5.25 (3.93)	<0001	6.34 ±4.42	5.41 ±4.02	<0001	6.29 ±4.44	5.60 ±4.10	<0001
TLE complexity and outcomes									
Average time of single lead extraction (sheath-to sheath/ no of extracted leads) (minutes)	9.08 ±13.37	8.73 ±11.46	0.021	9.04 ±13.50	8.75 ±11.30	0.009	8.98 ±13.92	8.85 ±11.26	<0001
Technical problem during TLE (any)	405 (23.45)	292 (16.83)	<0001	407 (23.45)	290 (16.80)	<0001	327 (23.49)	370 (17.87)	**<0001**

Continued

Table 4 Continued

Comparison of organisational models of TLE	Venue: operation theatre or hybrid room	EPL	A versus B	With cardiac surgeon as co-operator	Without cardiac surgeon as co-operator	B versus C	With TEE monitoring	Without TEE monitoring	E versus F
Necessity to change venous approach	34 (**1.97**)	103 (5.94)	<0001	39 (2.25)	98 (5.68)	<0001	20 (1.44)	117 (5.65)	<0001
Two or more Technical Problems	106 (6.14)	35 (2.02)	<0001	103 (5.93)	38 (2.20)	<0001	92 (6.60)	49 (2.40)	<0001
TLE efficacy and complications									
Major Complications (any)	46 (2.66)	24 (1.38)	0.011	43 (2.48)	27 (1.56)	0.379	30 (2.16)	40 (1.93	0.540
Haemopericardium	30 (1.74)	15 (0.86)	0.034	27 (1.56)	18 (1.04)	0.238	17 (1.22)	28 (1.35)	0.749
Tricuspid valve damage during TLE (severe)	16 (0.93)	3 (0.17)	0.006	14 (0.81)	5 (0.29)	0.068	12 (0.86)	7 (0.34)	0.070
Rescue cardiac surgery	29 (1.69)	12 (0.69)	0.012	29 (1.67)	12 (0.65)	0.074	21 (1.44)	20 (0.97)	0.198
Death procedure related (intraprocedural, postprocedural)	0 (0.00)	6 (0.35)	0.042	1 (0.06)	5 (0.29)	0.216	0 (0.00)	6 (0.29)	0.050
Death indication related (intraprocedural, postprocedural	0 (0.00)	4 (0.23)	0.135	1 (0.06)	3 (0.70)	0.613	0 (0.00)	4 (0.19)	0.258
Partial radiological success (remained tip or <4 cm lead fragment)	68 (3.94)	66 (3.80)	0.908	65 (3.47)	69 (4.00)	0.765	44 (3.16)	90 (4.35)	0.092
Full clinical success	1699 (98.37)	1687 (97.23)	0.029	1709 (98.45)	1677 (97.16)	0.014	1376 (98.85)	2010 (97.10)	<0001
Full procedural success	1641 (95.02)	1651 (95.16)	0.913	1652 (96.14)	1640 (95.02)	0.907	1366 (95.98)	1956 (94.49)	0.042

EPL, electrophysiological lab; TEE, transoesophageal echocardiography; TLE, transvenous lead extraction.

Table 5 Predictors of major and minor complications of TLE

	Univariable regression			Multivariable regression (without components of TLE models)			Multivariable regression (including components of TLE models)		
	OR	95% CI	P value	OR	95% CI	P value	OR	95% CI	P value
Major complications									
Patient's age during first system implantation (by 1 year)	0.970	0.959 to 0.981	<0.001	0.988	0.974 to 1.002	0.089			
Female gender (yes/no)	3.291	1.989 to 5.446	<0.001	2.587	1.530 to 4.372	<0.001			
Oldest extracted lead dwelling time (by 1 year)	1.152	1.121 to 1.185	<0.001	1.118	1.078 to 1.161	<0.001			
Extraction of pacing leads (yes/no)	4.304	1.964 to 9.432	<0.001	12.68	0.349 to 459.7	0.166			
Extraction of lead(s) with passive fixation (yes/no)	3.005	1.638 to 5.512	<0.001	0.964	0.482 to 1.929	0.918			
No of leads planned to extraction (by one)	1.785	1.380 to 2.307	<0.001	1.498	1.059 to 2.120	<0.001			
Extraction of abandoned lead(s) (yes/no)	2.790	1.557 to 4.998	0.001	0.802	0.378 to 1.698	0.563			
Extraction of defibrillating lead(s) (yes/no)	0.288	0.131 to 0.631	0.002	8.449	0.233 to 306.8	0.244			
Surgeon as co-operator (yes/no)	1.530	0.858 to 2.729	0.150						
Surgeon on stand-by (yes/no)	0.654	0.366 to 1.166	0.150						
Hybrid operating room (yes/no)	1.980	0.609 to 6.437	0.256						
Cardio surgery operating room (yes/no)	0.921	0.407 to 2.085	0.844						
Electrophysiology laboratory (yes/no)	0.895	0.435 to 1.839	0.762						
TLE monitored by TEE (yes/no)	1.119	0.700 to 1.787	0.639						
General anaesthesia (yes/no)	1.118	0.574 to 2.179	0.743						
Arterial line presence (yes/no)	1.100	0.538 to 2.251	0.793						
Minor complications									
Patient's age during first system implantation (by 1 year)	0.986	0.980 to 0.993	<0.001	0.994	0.986 to 1.002	0.132	0.995	0.987 to 1.003	0.193
Female gender (yes/no)	1.257	0.979 to 1.613	0.073	1.118	0.862 to 1.448	0.400	1.115	0.860 to 1.445	0.421
Oldest extracted lead dwelling time (by 1 year)	1.072	1.054 to 1.091	<0.001	1.037	1.014 to 1.060	<0.001	1.045	1.021 to 1.069	<0.001
Extraction of pacing leads (yes/no)	1.709	1.274 to 2.293	<0.001	0.773	0.433 to 1.380	0.384	0.766	0.429 to 1.367	0.366
Extraction of lead(s) with passive fixation (yes/no)	2.630	1.955 to 3.537	<0.001	1.750	1.265 to 2.422	<0.001	1.622	1.162 to 2.265	0.004
Number of leads planned to extraction (by one)	1.483	1.278 to 1.720	<0.001	1.224	1.030 to 1.455	0.022	1.228	1.033 to 1.459	0.020
Extraction of abandoned lead(s) (yes/no)	2.359	1.690 to 3.292	<0.001	1.289	0.873 to 1.904	0.202	1.219	0.823 to 1.807	0.323
Extraction of defibrillating lead(s) (yes/no)	0.520	0.376 to 0.718	<0.001	0.560	0.299 to 1.050	0.071	0.574	0.306 to 1.078	0.084
Surgeon as co-operator (yes/no)	0.914	0.675 to 1.237	0.560						

Continued

Table 5 Continued

	Univariable regression			Multivariable regression (without components of TLE models)			Multivariable regression (including components of TLE models)		
	OR	95% CI	P value	OR	95% CI	P value	OR	95% CI	P value
Surgeon on stand-by (yes/no)	1.145	0.517 to 2.538	0.738						
Hybrid operating room (yes/no)	1.102	0.749 to 1.237	0.623						
Cardio surgery operating room (yes/no)	0.897	0.624 to 1.289	0.557						
Electrophysiology laboratory (yes/no)	0.758	0.585 to 0.981	0.035						
TLE monitored by TEE (yes/no)	1.115	0.782 to 1.590	0.548				0.751	0.567 to 0.995	0.046
General anaesthesia (yes/no)	1.092	0.758 to 1.574	0.635						
Arterial line presence (yes/no)	0.914	0.675 to 1.237	0.560						

Results of univariable and multivariable regression analysis.
TEE, transoesophageal echocardiography; TLE, transvenous lead extraction.

outcome), absence of any permanently disabling complication or procedure-related death. The complications of TLE were also defined as major complications (MC) being those that were life-threatening, resulted in significant or permanent disability or death, or required surgical intervention and minor complications being those that required medical or minor procedural interventions.[3–5]

Estimating of the exact risk of MC was performed using SAFeTY TLE score.[17] The SAFeTY TLE score assesses the risk for the occurrence of MC related to TLE. The SAFeTY TLE score calculator, is an online tool available at http://alamay2.linuxpl.info/kalkulator/.

Statistical analysis

The distribution of numerous data was evaluated with Shapiro-Wilk test. Most of continuous variables were normally distributed. For uniformity, all continuous variables are presented as the mean±SD. The categorical variables are presented as number and percentage. The significance of differences between groups was determined using the nonparametric tests: χ^2 test with Yates correction Pearson's χ^2 test or the unpaired Mann-Whitney U test, as appropriate. Univariable and multivariable logistic regression was used to assess the predictors of minor and MC, clinical success and complete procedural success occurrence. For each dependent variable (minor and MC, clinical success and complete procedural success), two models of multivariate analysis were constructed; the first one covering clinical data, the second one supplemented with particular components of models of TLE (surgeon as co-operator, surgeon on stand-by, hybrid operating room, cardiosurgery operating room, electrophysiology laboratory, TEE monitoring, GA and AL presence). To the multivariable regression analysis, the variables which in the univariate analysis reached the value of $p<0.1$ were included. Statistical analysis was performed with Statistica V.13.3 (TIBCO Software).

RESULTS

In the period from 2006 to 2021, TLE was carried out in 3654 patients with an mean age of 65 years (38,88% females). 70.65% of patients had pacemakers (PM), 22.18% implantable cardioverter defibrillator, 7.11%—cardiac resynchronisation therapy (CRT). The most often indications for TLE included: failure of the lead (49.39%) and systemic infections (22.36%). Dwell time of the oldest lead in the patient was 74.48 months, cumulative dwell time of leads before TLE was 12.,76 years. The rate of MC of TLE in the study population was 2.02%, periprocedural deaths occurred in 0.17% of cases (table 2).

Comparison of patients groups

Implant duration was longer in all groups, in which TLE was performed in the OT or in the HR (1–5) than in groups when TLE was performed in the EPL (6 and 7). Similarly, the rate of MC was higher (46/1726=2.66%) in OT/HR than in EPL (24/1736=1.38%), but all MCs

Table 6 Predictors of complete clinical and complete procedural success of TLE

	Univariable regression			Multivariable regression (without components of TLE models)			Multivariable regression (including components of TLE models)		
	OR	95% CI	P value	OR	95% CI	P value	OR	95% CI	P value
Complete clinical success									
Patient's age during first system implantation (by 1 year)	1.027	1.016 to 1.038	<0.001	1.016	1.002 to 1.029	0.021	1.014	1.000 to 1.027	0.049
Female gender (yes/no)	0.737	0.469 to 1.159	0.187						
Oldest extracted lead dwell time (by 1 year)	0.899	0.876 to 0.924	<0.001	0.943	0.910 to 0.977	<0.001	0.920	0.886 to 0.956	<0.001
Extraction of pacing leads (yes/no)	0.381	0.205 to 0.709	0.002	1.400	0.489 to 4.008	0.531	1.420	0.494 to 4.086	0.515
Extraction of lead(s) with passive fixation (yes/no)	0.264	0.142 to 0.490	<0.001	0.571	0.291 to 1.118	0.102	0.761	0.381 to 1.517	0.437
No of leads planned to extraction (by one)	0.545	0.428 to 0.694	<0.001	0.664	0.490 to 0.899	0.008	0.655	0.486 to 0.884	0.006
Extraction of abandoned lead(s) (yes/no)	0.323	0.188 to 0.555	<0.001	0.900	0.465 to 1.744	0.755	1.070	0.551 to 2.079	0.841
Extraction of defibrillating lead(s) (yes/no)	3.382	1.621 to 7.056	0.001	2.974	0.871 to 10.16	0.082	2.725	0.792 to 9.378	0.112
Surgeon as co-operator (yes / no)	0.751	0.424 to 1.328	0.324						
Surgeon on stand-by (yes/no)	1.332	0.750 to 2.367	0.328						
Hybrid operating room (yes/no)	0.873	0.218 to 3.499	0.848						
Cardio surgery operating room (yes/no)	0.922	0.452 to 1.880	0.822						
Electrophysiology laboratory (yes/no)	1.101	0.585 to 2.073	0.766						
TLE monitored by TEE (yes/no)	2.454	1.427 to 4.221	0.001				3.035	1.695 to 5.433	<0.001
General anaesthesia (yes/no)	0.908	0.464 to 1.779	0.779						
Arterial line presence (yes/no)	1.031	0.493 to 2.156	0.935						
Complete procedural success									
Patient's age during first system implantation (by 1 year)	1.036	1.029 to 1.044	<0.001	1.028	1.019 to 1.037	<0.001	1.027	1.018 to 1.036	<0.001
Female gender (yes/no)	0.928	0.685 to 1.257	0.630						
Oldest extracted lead dwelling time (by 1 year)	0.895	0.877 to 0.912	<0.001	0.951	0.927 to 0.975	<0.001	0.942	0.917 to 0.968	<0.001
Extraction of pacing leads (yes/no)	0.371	0.242 to 0.576	<0.001	1.387	0.648 to 2.965	0.399	1.404	0.655 to 3.007	0.383
Extraction of lead(s) with passive fixation (yes/no)	0.155	0.093 to 0.257	<0.001	0.285	0.167 to 0.487	<0.001	0.319	0.185 to 0.550	<0.001
No of leads planned to extraction (by one)	0.645	0.539 to 0.773	<0.001	0.753	0.603 to 0.940	0.012	0.748	0.600 to 0.934	0.010
Extraction of abandoned lead(s) (yes/no)	0.466	0.307 to 0.708	<0.001	1.245	0.754 to 2.055	0.392	1.347	0.812 to 2.234	0.249
Extraction of defibrillating lead(s) (yes/no)	3.341	2.038 to 5.479	<0.001	2.665	1.118 to 6.352	0.027	2.547	1.077 to 6.152	0.033
Surgeon as co-operator (yes/no)	0.909	0.597 to 1.382	0.654						
Surgeon on stand-by (yes/no)	1.101	0.748 to 1.620	0.626						
Hybrid operating room (yes/no)	0.749	0.298 to 1.880	0.537						

Continued

Table 6 Continued

	Univariable regression			Multivariable regression (without components of TLE models)			Multivariable regression (including components of TLE models)		
	OR	95% CI	P value	OR	95% CI	P value	OR	95% CI	P value
Cardio surgery operating room (yes/no)	1.018	0.108 to 9.633	0.988						
Electrophysiology laboratory (yes/no)	1.049	0.472 to 2.334	0.906						
TLE monitored by TEE (yes/no)	1.389	1.001 to 1.929	0.049				1.482	1.030 to 2.132	0.034
General anaesthesia (yes/no)	0.953	0.601 to 1.511	0.837						
Arterial line presence (yes/no)	1.072	0.660 to 1.739	0.780						

Results of univariable and multivariable regression analysis.
TEE, transoesophageal echocardiography; TLE, transvenous lead extraction.

were treated successfully and nobody died: haemopericardium with acute cardiac tamponade appeared two times more frequently in groups 1–5 (27/1726=1.56%) than in groups 6–7 (15/1736=0.86%) but there were no deaths related to the procedure in groups 1–5. Similarly, the necessity of rescue cardiac surgery was noted nearly 3 times more frequently in groups 1–5 (29/1726=1.68 %) than in groups 6–7 (12/1736=0.69%). It confirms, that patients from groups 1–5 had higher risk of MC.

All 6 procedure-related deaths happened (in groups 6 and 7) when TLE was performed in EPL 6/1736 (0.35%) vs 0/1726 (0.00%) when TLE was performed in OT or HR (Pearson's χ^2 $p<0.001$).

Analysis of the role of quality of fluoroscopy showed no significant differences in the effectiveness of TLE between groups: partial radiological success (lead remnants) in groups 1–2: 40/1053–3.80% vs groups 3–7: 94/2409=3.92%, similarly, procedural success in groups 1–2 and 3–7 1003/1053=95.25% vs 2288/2409=94.98% was comparable.

It should be pointed, that his 7 groups of patients represents different periods and organisational possibilities of TLE (availability of OT or HR) and only partial staging of TLE safety precautions were possible. Operator always tried to make TLE in risky patients in operating or HR, 'arm-to-arm' with experienced in TLE cardiac surgeon and under GA. But it was not always possible in the past (table 3).

Seven organisational models functioning in the period 2006–2021 made it possible to classify the level of safety as very high (columns 1 and 3), high (columns 2 and 4), moderate (column 5) and low (column 6). In the years 2006–2015, attempts were made to ensure appropriate precautions and either the participation of a cardiac surgeon in the procedures at the EPL or the procedures in the OT was organised. Table 4 presents the direct comparison especially selected new subgroups of patients: TLE in OT or HR vs EPL, TLE performed with cardiac surgeon as co-operator versus TLE without cardiac surgeon as co-operator and TLE performed with TEE monitoring versus TEE without TEE monitoring. General anaesthesia with AL for blood pressure monitoring take place when TLE was in OT or in HR but never in EPL and they are inseparable complex. Cardiac surgeon presence and TEE monitoring were strongly awaited but not always possible. The only one difference between TLE in HR and OT was the kind of X-ray machine and quality of fluoroscopy.

Comparison depending on the venue of the procedure

The oldest extracted lead dwell time, cumulative dwell time of extracted lead and number of points in Safety TLE score were much higher in OT/HR group. Percentage of MC: haemopericardium, severe tricuspid valve damage during TLE and necessity of rescue cardiac surgery was two times more frequent in these patients. In parallel, the rates of radiological success, complete clinical success and procedural success were the same. Mortality rate in patients undergoing TLE in OT and HR was zero.

Table 7 Analysis of the influence of patient parameters and organisational parameters on death related to major complications

Analysis of patients with major complications of TLE comparing patients with and without complication-related death	6 patients with major complications and complication-related death	64 patients with major complications and without complication-related death	Statistic
Patient-related and CIED-related risk factors of major TLE complications	Average±SD no (%)	Average±SD no (%)	
Female gender	4 (66.67)	44 (68.75)	0.651
Patient's age during TLE (years)	68.50±10.21	62.72±17.72	0.508
Patient's age during first system implantation (years)	52.83±13.27	45.98±19.97	0.549
NYHA functional class	1.67±0.82	1.51±0.62	0.702
Permanent AF	1 (16.67)	7 (10.94)	0.803
Hypertension	4 (66.67)	27 (42.19)	0.469
Renal failure (any)	0 (0.00)	8 (12.50)	0.803
Renal failure (advanced) (create. >2.2 mg/dL or haemodialysis)	0 (0.00)	4 (6.25)	0.773
Highest creatinine level in the patient's records (mg/dL)	1.07±0.18	1.10±0.51	0.450
Charlson's index (points)	4.50±2.88	3.15±2.92	0.193
Left ventricular EF (%)	41.17±13.45	56.03±11.44	0.008
Passive fixation lead was extracted	5 (83.33)	53 (82.81)	0.593
ICD lead was extracted	2 (33.33)	5 (7.81)	0.200
Unipolar lead was extracted	0 (0.00)	24 (37.50)	0.161
Dwell time of oldest extracted lead (years)	12.33±6.19	16.77±8.25	0.264

AF, atrial fibrillation; CIED, cardiac implantable electronic device; EF, ejection fraction; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association class of heart failure; TLE, transvenous lead extraction.

TLE with cardiac surgeon versus without cardiac surgeon as co-operator

The oldest extracted lead dwell time, cumulative dwell time of extracted lead and number of Safety TLE score were much higher in group with cardiac surgeon as co-operator. Similarly to previous analysis, procedure complexity and percentage of MC: haemopericardium, severe tricuspid valve damage during TLE and necessity of rescue cardiac surgery was two times more frequent. The rates of radiological success, complete clinical success and procedural success were the same. The percentage of deaths related to the procedure (during and after procedure) and deaths related to indications (during and after procedure) was significantly lower when the cardiac surgeon was a co-operator

TLE with and without monitoring by TEE

Patients in the TEE-monitored group were at high risk for TLE: dwell time of the oldest extracted lead, cumulative dwell time of extracted leads and the number of TLE safety points were significantly higher in these patients. The rate of radiological, full clinical and procedural success was similar or even shows tendency to be better in group with TEE monitoring. The percentage of MC: haemopericardium and necessity of rescue cardiac surgery were slightly more frequent. The rate of procedure-related death and rate of indication-related death were different (zero intraprocedural and postprocedural deaths when TLE was monitored with TEE) (table 4).

Regression analysis confirm significance of common risk factors of MC; female gender (OR=2.629; p<0.001), dwell time of the oldest extracted lead (OR=1.119, p<0.001) and number of extracted leads (OR=1.512; p=0.021). None of the components of the analysed TLE models had a direct impact on the occurrence of serious complications. The prognostics of minor complications were dwell time of the oldest extracted lead (OR=1.045; p<0.001), extraction of lead(s) with passive fixation (OR=1.622; p=0.004) and number of leads planned to extraction (OR=1.228; p=0.020). The use of TEE during TLE was connected with significantly reduction of minor complications occurrence (OR=0.751; p=0.046) (table 5).

Predictors of the achievement of clinical success were: older patients age during first cardiac implantable electronic device (CIED) implantation, younger age of extracted lead and lower number of extracted leads. The use of TEE during TLE increased probability of complete clinical success achieving about three times (OR=3.035; p<0.001). Predictors of procedural success were older patients age during first CIED implantation, younger age of extracted lead, leads with passive fixation, number of extracted leads and TLE od defibrillating leads. The use of TEE during TLE increased probability of complete procedural success achieving about 1.5 times (OR=1.482; p<0.034) (table 6).

Analysis of clinical data and parameters related to the organisation of the procedure in the population of patients with MC, showed no significant differences

Table 8 Review of the literature assessing the effectiveness of TLE

Year, journal author References 18–42	Kind of the study/ leads	No of pts	Methods of TLE (predominant, first line tool)	Mean lead dwell time (months)	% of infective indications	Procedural success (%)	Major complications (%)	Procedure-related death (%)
Studies 1999–2014								
1999 Byrd CL Pacing Clin Electrophysiol	U.S. Extraction Database analysis	**2338**	Cook's extraction kit	**47**	27.00	CPS 93	**1.40**	**0.4**
2007 Kennergren C Europace	Multicentre study LExICON Study	**292**	Laser sheath	**74**	45.00	CPS 90.9	**3.40**	**0.0**
2008 Bongiorni M Eur Heart J	Single-centre study	**1193**	Cook's extraction kit	**69**	82.00	CPS 98.4	**0.70**	**0.3**
2009 Agarwal SK JCE Pittrsburgh	Single-centre study	**212**	Laser 75%	**68**	78.00	98	**4.20**	**0.5**
2009 Kennergren C Europace	Single-centre study	**647**	Laser 60%	**91**	58.00	CLS 97.6	**0.90**	**0.00**
2010 JACC Wazani O JACC LEXICon Sudy	Multicentre register	**1449**	Laser sheath	**82**	57.00	CPS 96.5	**1.40**	**0.30**
2014 Gomes S Europace	Single-centre study	**510**	Cook's extraction kit	**47**	65.00	CPS 96	**0.30**	**0.20**
2014 E Deck S uropace (Leuven)	Single-centre study	**176**	Laser 62% Evol 9%	**56**	53.00	CLS 95.5 CPS 91.5	**3.40**	**0.60**
2014 Maytin M CAE (Boston)	Single-centre study	**985**	Laser 58%	**72**	50.00	CPS 99. CLS 95	**0.60**	**0.00**
2014 Brunner MP HR	Single-centre study	**2999**	Laser 70%	**61**	43.00	CPS 95.1	**1.80**	**0.20**
All studies 1999–2014		10 801		**64**	**49.20**		**1.42**	**0.24**
Studies 2015–2017								
2015 Hai-Xia Hu Pacing Clin Electrophysiol (Mayo Clin)	Single-centre study	**652**	Laser 51%	**57**	59	CPS 96.6	**2.01**	**0.30**
2015 El-Chami MF Heart Rhythm	Single-centre study	**462**	Laser 45%	**55**	15	PS 98 CS 98	**1.30**	**0.65**
2015 Merchant FM (Atlanta) PACE	Single-centre study	**508**	Laser 57%, mech 8%	**61**	33	CPS 96.5	**1.60**	**1.10**
2016 Gomes S Pacing Clin Electrophysiol (Sydney)	Single-centre study	**510**	Cook's extraction kit	**47**	74	PS 92 CS 98.2	**0.20**	**0.20**
2016 Bashir J Circ Arrhythm Electrophysiol	The British Columbia Cardiac Registry	**1082**	Laser	**129**	45	???	**3.00**	**0.37**

Continued

Table 8 Continued

Year, journal author References 18–42	Kind of the study/ leads	No of pts	Methods of TLE (predominant, first line tool)	Mean lead dwell time (months)	% of infective indications	Procedural success (%)	Major complications (%)	Procedure-related death (%)
2017 Barakat AF Heart Rhythm	Single-centre study	**503**	Laser 62% Evol 9%	**57**	0	PS 96.6 CS 97.2	**1.00**	**0.40**
2017 Hussein AA JACC Clin Electrophysiol	Single-centre study	**1836**	Laser, Evolution as second	**108**	100	PS 94.2 CS 95.1	**1.93**	**0.29**
2017 Kutarski A Europace	Single-centre study	**2049**	97% Cook's extraction kit	**89**	40	PS 95.0 CS 97.9	**1.80**	**0.36**
All studies 2017–2018		**7602**		**88**	**54.45**		**1.82**	**0.40**
Registers 2017–2017								
2017 Bongiorni M Eur Heart Journal	The European Lead Extraction ConTRolled Registry (ELECTRa)	**3555**	Laser 19,3%	**77**	52	CS 96.7	**1.70**	**0.50**
2018 Sood N Circ Arrhythm Electrophysiol	Multicentre register	11 304	Laser 63%	**65**	14	About 97	**2.30**	**0.16**
All registers 2018–2021		14 859		**68**	**23.09**		**2.16**	**0.24**
Studies 2018–2021								
2018 Yoshitake T Circ J.	Single-centre study	**215**	Laser 100%	**92**	71	PS 97.4	**2.30**	**0.00**
2018 Sharma S JACC Clin Electrophysiol	Single-centre study	**400**	Evolution	**81**	54	PS 97.0 CS 99.7	**1.50**	**0.00**
2019 Kancharla K JACC Clin Electrophysiol	Single-centre study	**187**	Laser, rotational mechanical	**67**	48	CS 97.9 PS 92.5	**2.70**	**0.15**
2019Monaco F J Cardiothorac Vasc Anesth.	Single-centre study	**389**	stepwise approach	**74**	54	P5 95.0 CS 98.4	**1.30**	**1.00**
2019 Gould J Pacing Clin Electrophysiol	Single-centre study	**925**	Laser 56%	**85**	55	CS 98.5	**1.60**	**0.30**
2019 Jacheć W Pacing Clin Electrophysiol.	Two-centres study	**3810**	98% Cook's extraction kit	**86**	46	PS 94.6 CS 97.6	**1.44**	**0.17**
2020 Pecha S. Interact Cardiovasc Thorac Surg	Two-centres study	**154**	Laser as first line	**168**	64	PS 91.6 CS 96.8	**3.30**	**0.00**
2020 Segreti L Europace	Single-centre study	**1210**	Cook's extraction kit	**72**	67	CS 96	**0.70**	**0.16**
2020 Yap S.C. J Interv Card Electrophysiol	Single-centre study	**264**	Femoral snare and rotational powered sheath	***91***	27	PS 90 CS 98	**1.10%**	**0.00**

Continued

Table 8 Continued

Year, journal author References 18–42	Kind of the study/leads	No of pts	Methods of TLE (predominant, first line tool)	Mean lead dwell time (months)	% of infective indications	Procedural success (%)	Major complications (%)	Procedure-related death (%)
2020 Starck CT Europace	Multicentre study ((PROMET)	**2205**	rotational TLE tools	**74**	46	PS 97 CS 96	**1.00**	**0.18**
2020 Giannotti Santoro M, Pacing Clin Electrophysiol	Single-centre study	**1316**	Cook's extraction kit	**72**	66	CS 97	**0.70**	**0.00**
2020 Zhou X Heart Vessels	Single-centre study	**492**	Needle's Eye Snare	**113**	91	PS,CS 98	**1.90**	**0.20**
2021 Stefańczyk P	Single-centre study	**1000**	Cook's extraction kit	**112**	22	CS 99.1, PS 95.9	**2.20**	**0.00**
All studies 2018–2021		12 567		**85**	**51.38**		**1.35**	**0.16**
ALL studies		45 829		**75**	**42**		**1.71**	**0.25**

Cook's extraction kit: looking stylets, dilator sheaths and/or transfemorally using snares, retrieval baskets, and sheaths and if necessary another tools.
CPS, complete procedural cuccess; CS, clinical success; PS, complete procedural success; TLE, transvenous lead extraction.

(apart from the EF value) between the group of patients who died as a result of MC and those who survived despite MC. This seems to support the fact that the cause of MC-related deaths was a marked delay in cardiac surgery (table 7).

We would like to emphasise that in the entire study we analysed the appearance of MC-related deaths, which could occur both during the operation and during the entire hospitalisation period. We did not analyse deaths resulting from the disease itself (so-called indication-related deaths).

DISCUSSION

TLE is a relatively safe procedure. The rate of MC ranges from 0.7% to 4.2% and procedural mortality from 0% to 0.65%.[18–41] An analysis of the literature showed that the mortality rate associated with serious complications of TLE has been declining over the past 30 years (especially in the last 4 years) despite the slight increase in mean lead dwell time of extracted leads. As there has been no significant change in lead extraction technology (only new mechanical rotational sheaths with threaded ending)—the improvement in TLE safety may be related mainly to the better organisation of the TLE procedure (surgical back-up on site) (table 8).

Damage to cardiac and venous structures during lead extraction is the most serious complication, which probably depends from kinds of preferred specialised tools that disrupt encapsulating fibrous tissue.[6 11 34 42 43] The participation of the cardiac surgery team in TLE procedures is unquestionable, because the time from the diagnosis of the catastrophe to sternotomy plays a key role, optimally it should be 5–10 min,[2 4 6–8 12–16] after exceeding this, the risk of central nervous system damage increases significantly. The need for direct cardiac surgery during TLE was discussed in several reports from single centres,[7 8 10 12–16] in three analyses of large databases[6 9 18] and finally included in lead management guidelines.[1–5] This study showed that participation of cardiac surgeon as co-operator during TLE had no influence on rate of radiological, clinical and procedural success but was connected with lower rate of procedure-related death. Several reports have been designed to assess the safety of procedures depending on the venue of the TLE.[11 13–15 43–49] There is only one conclusion: emergency cardiac surgery must be performed at the site of the complication. The present analysis showed that all six procedure-related deaths happened when TLE was performed in EPL, without GA. Until now, some procedures are performed at the EPL or the Interventional Cardiology Lab with varying availability of urgent on-site sternotomy.[11 13–15 43–49] In recent years, several scales for calculating the risk of TLE have been developed.[17 49–53] Low-risk patients are selected for TLE at the EPL or Interventional Cardiology Lab, high-risk patients—for TLE at HR or OT, and intermediate-risk patients—according to current possibilities. The current observation, based on the results of 3462 procedures performed for 15 years in various conditions, confirmed very good effects of grading the safety precautions. The qualification of high-risk patients (especially those with long lead dwell time) for OT or HR, despite a twice higher percentage of MC, showed high rates of radiological, clinical and procedural success and no death related to the procedure. However, it should be emphasised, that catastrophic complications can occur even in low-risk patients. Our 15 years of experience seem to confirm this opinion. Therefore, we should strive to perform all procedures in HR/OT with a complete cardiac–anaesthetic staff and monitoring with TEE.

According to the multivariate analysis, the very important factor influencing the effectiveness and safety of the procedure is continuous monitoring of the procedure using TEE. Previous reports have not documented such a significant role of echocardiography in TLE procedures. Of course, it should be emphasised that continuous monitoring is possible only under full anaesthesia, and the presence of a scrubbed cardiac surgeon is essential for a quick response to the echocardiographers' warnings.

In conclusion, good organisation of the procedure is of paramount importance for the survival of a patient with MC. The idea (concept) of a surgical facility has evolved over the decades. Our 15 years of experience show that the best place for TLE is an HR, close cooperation with the cardiosurgical and anaesthetic team is necessary, and all possible monitoring (AL, TEE, exhaled CO2 measures) are very useful for the safety of the procedure.

CONCLUSIONS

1. High level of safety precautions (operating or HR, GA, TEE monitoring and close co-operation with cardiac surgery team) make possible TLE without MC-related deaths.
2. Accurate monitoring of the structures and functions of the heart (continuous monitoring of TEE) plays a dominant role in the immediate decision to perform emergency sternotomy, and also improves the effectiveness of the procedure.
3. The analysis of the literature shows a slow but steady decline in deaths related to complications of TLE and it seems that this is a result of the better organisation of procedures.

Study limitations

There are some limitations of this study. It is three centres but the same first operator experience. The database was prospectively integrated, but analysis was performed retrospectively. The organisational model of TLE procedures has evolved over time—from safety precautions staging during 2006–2015, up to full safety precautions since 2015. This is presentation of single, very experienced first operator. It would not give the overview on general TLE safety and efficacy in low volume centre and with less experienced operator and his team.

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