

Transvenous Lead Extraction without Procedure-Related Deaths in 1000 Consecutive Patients: A Single-Center Experience

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Background: Transvenous lead extraction (TLE) is now a first-line technique for the treatment of complications related to cardiac implantable electronic devices. The aim of the study was to demonstrate that it is possible to safely perform difficult TLE procedures with a maximum reduction of peri-procedural major complications.

Methods: A total of 1000 consecutive patients undergoing TLE in a single high-volume center from 2016 to 2019 were studied. All procedures were performed in a hybrid room or operating room by a specialized TLE team. TLE was performed under general anesthesia and monitored by transesophageal echocardiography, and the operating room was suitably equipped for immediate surgical intervention. The effectiveness and safety of the procedures were assessed, with particular emphasis on major complications.

Results: In all, 1952 leads with the mean implant duration of 111.7 ± 77.6 months had been extracted. Complete procedural success of patients was achieved in 95.9% and clinical success in 99.1%. Major complications, predominantly cardiac tamponade (63.3%), occurred in 22 patients (2.2%). Rapid diagnosis and immediate intervention were the key to a 100% survival in patients with this complication.

Conclusion: Performing procedures in a hybrid operating room under general anesthesia in the presence of a cardiac surgeon and with the use of transesophageal echocardiography significantly improves the safety of transvenous lead extraction.

Keywords: lead extraction, complications of lead extraction, venue of TLE, mechanical dilatation, safety precautions

Introduction

The number of patients with pacemakers and implantable cardioverter defibrillators (ICDs) has grown significantly in recent decades. Technological and pharmacological advances have significantly prolonged the lives of patients with cardiac implantable electronic devices (CIED). Unfortunately, the increase in the number of implanted devices goes in line with the increased number of complications.^{1,2} Transvenous lead extraction (TLE) is the gold standard for treating complications of CIED therapy.¹⁻⁶ Initial experience with successful extraction of the leads was described in the 1980s and '90s.^{7,8} The effectiveness of TLE is high (more than 90% in general) but rates of major complications vary between studies from 0.4 to 3.4%, whereas mortality risk is 0.00–1.86%.³⁻⁸ Generally, many factors may be associated with different outcomes of procedures, including: age of patients, New York Heart Association Class III/IV or pre-operative use of antithrombotic therapy.⁹



There are a wide variety of techniques and tools which can be used for transvenous lead extraction: conventional mechanical systems with non-powered sheaths (Byrd polypropylene sheaths, Cook) for dilating adherent fibrotic tissue and extracting the leads,⁷ and the new techniques including rotational mechanical sheaths with threaded tips such as Evolution (Cook)¹⁰ and TightRail (Spectranetics, CA),¹¹ rotating mechanical dilator sheaths as well as sheaths powered by ablative energy sources, ie, excimer laser sheaths (SLS II Laser Sheath).⁸ Mechanical dilation is associated with a lower incidence of vascular complications during transvenous lead extraction as compared to the use of powered sheaths.¹²

Major complications of TLE are quite rare, but their consequences can be very serious if proper management is delayed.^{3–6} These include hemopericardium requiring drainage or cardiac surgery, hemothorax requiring thoracic surgery or pleural drainage, pulmonary embolism requiring cardiac surgery, stroke, acute heart failure and severe tricuspid valve damage.^{3–6}

Major complications are linked to lead implant duration, number of leads and other, mainly patient-related risk factors (female gender, renal failure, patient age).^{13,14} Risk is inseparable from the removal procedure and may be reduced only if TLE is performed by an experienced operator in high volume center.¹⁵ But the main goal is to prevent deaths due to major complications. This may be achieved through detection of major complications at the earliest possible opportunity, before circulatory collapse occurs, and through proper immediate management. Success depends on patient monitoring (arterial line, transesophageal echocardiography, exhaust gases) and organization of the lead removal procedure to ensure sternotomy within 5–10 minutes after complication detection (venue, presence of cardiac surgical and anesthesia teams).^{3–6} According to the latest recommendations additional precautions should be adopted during TLE to avoid serious consequences, but there are no reports on their effectiveness in clinical practice.^{3–6}

Methods

Study Population

The first 1000 consecutive patients undergoing TLE in a single high-volume center from 2016 to 2019 were enrolled in the study. All participants provided written informed consent prior to study enrollment, and before the TLE procedure as medically indicated. All data were held anonymous. The study was approved by the Bioethics

Committee at the Regional Chamber of Physicians in Lublin no. 288/2018/KB/VII, and complied with the Declaration of Helsinki.

Organization and Course of the TLE Procedure

All procedures were performed in a hybrid operating room or operating room equipped with C-arm fluoroscopic X-ray machine and simultaneous surgical standby. The team consisted of a first operator having experience with CIED therapy and TLE, a second cardiologist, a cardiac surgeon, an anesthesiologist and an experienced echocardiographer. Patients were prepped and draped in standard fashion as for emergency sternotomy or thoracotomy. The rooms were equipped with an “open chest” cart including all necessary equipment for immediate surgical intervention, and the surgical instruments were opened and placed on the procedure table. The cardiopulmonary bypass machine was primed, and a perfusionist was immediately available. All TLE procedures were performed under general anesthesia, and blood pressure readings were obtained from invasive catheters (Arterial Line – AL) (Figure 1).

Transesophageal echocardiography was routinely used during most procedures (91%). Femoral venous access was obtained for temporary pacing, transfemoral lead extraction and as an additional site in emergency situations.

TLE procedures were performed according to our center's routine. A primary access site was the implant vein whenever possible. In patients with the proximal (usually broken) end in the cardiovascular system or with the lead fractured during the extraction procedure, the restored access site via the femoral, jugular or subclavian vein was selected. First, adherent fibrous tissue around the leads was excised in the surgical pouch, and then the sleeves were removed. In most procedures, standard stylets were used to stiffen the leads. Locking stylets (Liberator Locking Stylet, Cook Medical Inc., USA) were used only for extraction of the oldest leads when estimated risk of lead fracture was high. Simple traction or traction on a locking stylet with insulation-bound suture was very rarely applied (usually in patients with infection, when prolonged temporary pacing was not planned). Lead extraction was performed using mainly non-powered mechanical telescoping polypropylene sheaths (Byrd Dilator Sheaths, Cook Medical Inc., USA) of all diameters and lengths and using various stylets. When the polypropylene telescoping sheaths appeared ineffective, powered

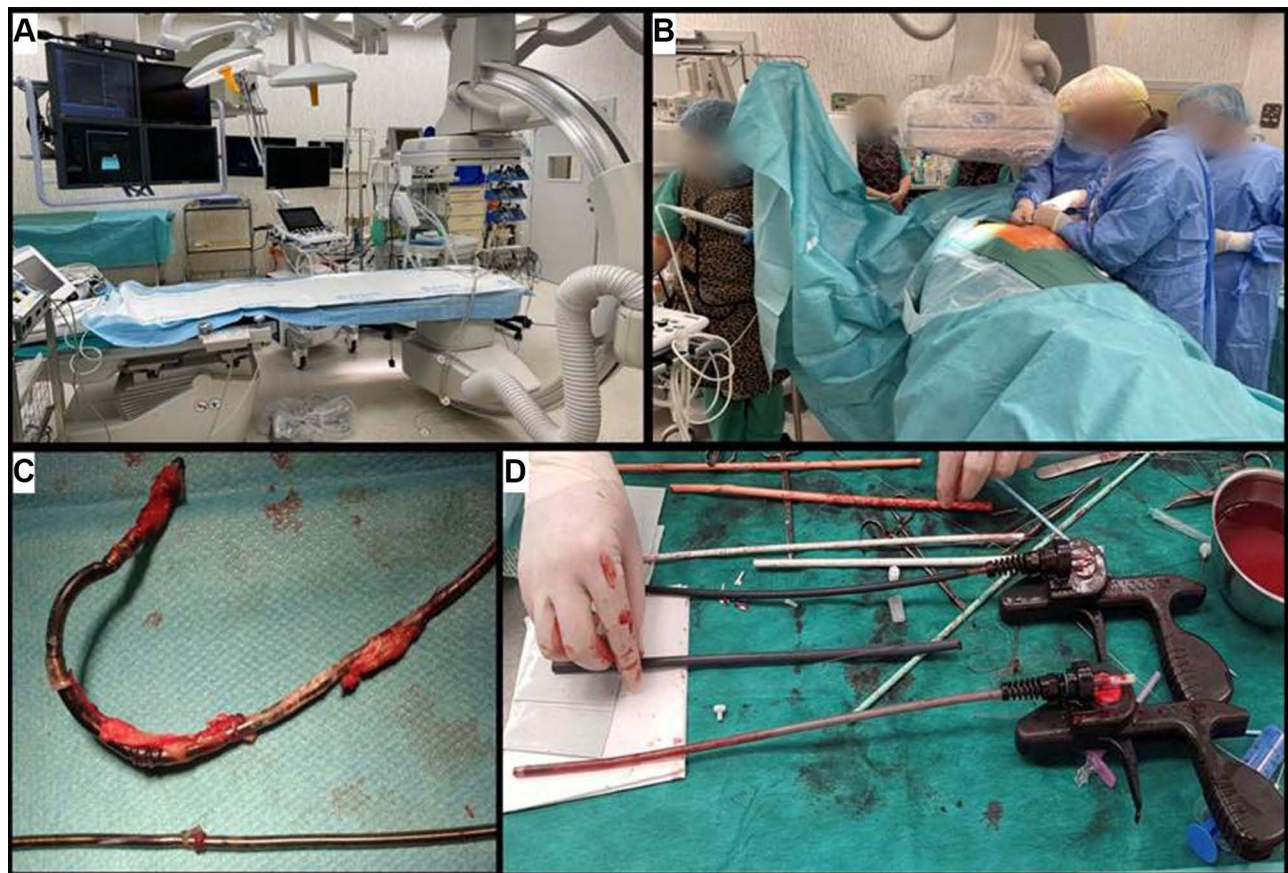


Figure 1 (A) Hybrid operating room. In the background a table with surgical instruments designed for sternotomy. (B) Cardiac surgical and anesthesia team and an echocardiographer performing TEE monitoring (C) Removed leads. Thick fibrotic tissue with calcific changes around the leads, and a variety of damage to outer silicone tube (mechanical damage during extraction and an old abrasion – dark color of the distal end of the lead). (D) “After the battle”. The tools used for lead extraction: conventional mechanical non-powered sheaths (Byrd polypropylene sheaths, Cook) in three sizes and mechanical rotational threaded sheaths - Evolution (Cook) – two sizes.

mechanical sheath systems (Evolution Mechanical Dilator Sheath, Cook Medical Inc., USA; TightRail Rotating Dilator Sheath, Spectranetics, USA) were used. A combined approach, using two or more different (jugular, subclavian, femoral) access sites, was selected when conventional methods were insufficient. An Evolution Mechanical Dilator was used in 25 patients, and TightRail Rotating Dilator Sheath in 4 patients. Laser and electro-surgical dissection sheaths were not used.

Echocardiographic Monitoring

At the stage of selection for the procedure, each patient underwent a comprehensive transthoracic echocardiogram. Transesophageal echocardiography was routinely performed during most procedures. The echocardiographic probe was inserted after the patient was intubated. TEE monitoring was performed in the following stages: 1) pre-procedural assessment 2) intra-procedural phase – procedure monitoring, and 3) post-procedural phase to evaluate the impact of TLE on tricuspid valve function, retention of lead fragments, vegetation

remnants and delayed fluid (blood) accumulation in the pericardial space^{16–19} (Figure 2).

Echocardiographic Evaluation of the Tricuspid Valve Function

Tricuspid valve function was assessed by comparing the degree of regurgitation before and after the procedure. A deterioration in the degree of regurgitation by at least 2 degrees was considered a significant dysfunction after TLE. Grade III or IV deterioration of valve function was considered a significant dysfunction of the valve, qualifying for surgery.

Anesthesia Protocol

All 1000 extractions were performed under general anesthesia given by attending cardiac anesthesiologist who monitored vital signs. Before each TLE procedure, patients were comprehensively evaluated, with particular emphasis on the respiratory system and heart function. In addition to transthoracic or transesophageal echocardiography all patients

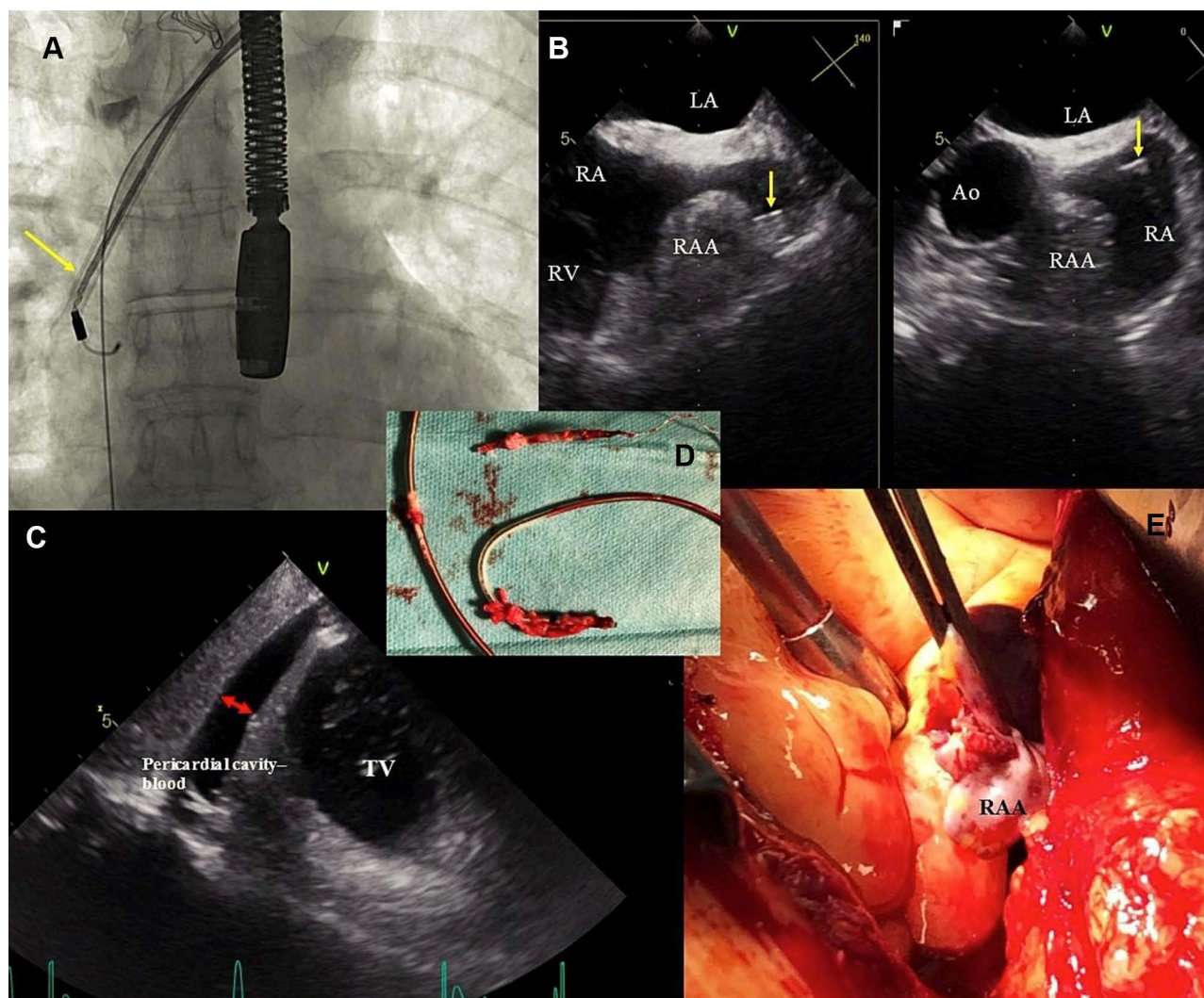


Figure 2 Transvenous extraction of an atrial lead was complicated by right atrial appendage rupture and cardiac tamponade requiring urgent cardiac repair. **(A)** Fluoroscopy. Atrial lead removal, the tip of the sheath marked with an arrow. **(B)** 2D TEE images (mid-esophageal view). The winding and pulling on the right atrial appendage (RAA) during extraction of the atrial lead. These potentially harmful effects are not visible on fluoroscopy. The sheath marked with an arrow. **(C)** 2D TEE images (transgastric view). Separation of pericardial layers – blood – immediately after removal of the lead. **(D)** Extracted leads on the table. Thick fibrotic encapsulation, partly calcified around the leads. Small abrasion of the external tube with perforation of the atrial lead – less visible. Fluid in the lead in this area. **(E)** Intraoperative view – RAA rupture/injury.

underwent chest x-ray. Routine monitoring (pulse oximetry, invasive arterial blood pressure measurements, 5-lead electrocardiogram, serial arterial blood gas analyses, urine output) was implemented in all patients during the procedure. Upon completion of the procedure, patients were moved to the recovery room, where monitoring (invasive blood pressure measurements and electrocardiography) continued for at least 2 hours.

Indications, Procedure Effectiveness and Complications

Indications for TLE, procedure effectiveness, and complications were assessed according to the 2009 and 2017 HRS consensus and 2017 EHRA guidelines.^{3–5} The

efficacy of TLE was determined based on the percentage of procedural success and clinical success. 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.^{3,4} 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, with the absence of any permanently disabling complication or procedure-related death.^{3,4}

The complications of TLE were also defined as major complications 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.⁵

Dataset and Statistical Methods

The dataset was split into the following groups: patient demographic and clinical data (Table 1), pacing system data, lead management and TLE organization (Table 2),

TLE procedure information (Table 3), effectiveness of lead extraction in terms of radiographic, clinical and complete procedural success, major and minor complications (Table 4).

Categorical variables were expressed as counts and percentages, whereas continuous variables as either the mean and standard deviation (SD) or median and the interquartile range (25–75%).

Table 1 Patient Demographic and Clinical Data, Pacing System Data, Indications for TLE

General Patient Information	No/Range	Mean±SD/%
Patient age during TLE [year]	18–99	67.32±14.34
NYHA III or IV (n)	154	15.4%
LVEF < 40% (n)	380	38.0%
Permanent AF [yes/no]	235	23.5%
Heart failure symptomatic (n)	288	28.8%
Previous sternotomy (n)	143	14.3%
Valvular implant (n)	89	8.9%
Long-term anticoagulation (n)	420	42.0%
Long-term antiplatelet treatment (n)	462	46.2%
Diabetes (any) (n)	203	20.3%
Renal failure (any) (n)	260	26.0%
Charlson's index [points]	0–16	4.87±3.69
Main TLE Indications	No	(%)
Systemic infection (n)	159	15.9%
Local (pocket) infection (n)	63	6.3%
Mechanical Lead Damage (electric failure) (n)	305	30.5%
Lead dysfunction caused by (usually dry) perforation	136	13.6%
Lead dysfunction (exit/entry block, dislodgement, extracardiac pacing) (n)	135	13.5%
Change of pacing mode/ upgrading, downgrading (n)	62	6.2%
Restored Venous Access (symptomatic occlusion, SVC syndrome, lead replacement/upgrading) (n)	45	4.5%
Threatening/potentially threatening lead (loops of the leads, free ending, left heart, LDTD) (n)	35	3.5%
Other (MRI indication, cancer, pain of pocket, loss of indication for pacing/ICD) (n)	34	3.4%
Abandoned lead/prevention of abandonment (AF, redundant leads) (n)	26	2.6%
All (n)	1000	100.0%
System before TLE procedure	No	(%), mean±SD
AAI (n)	72	7.2%
DDD	460	46.0%
VDD (n)	20	2.0%
VVI (n)	95	9.5%
CRT-P (n)	27	2.7%
ICD-V (n)	129	12.9%
ICD-D (n)	95	9.5%
CRT-D (n)	98	9.8%
PM lead, unit removed earlier (n)	1	0.1%
ICD lead, unit removed earlier (n)	3	0.3%
Lead dwell time of oldest lead in the patient before TLE [months]	1–468	112.9±77.40
Sum of lead dwell times in the patient before TLE [years]	1–104	17.31±14.13

Abbreviations: AAI, single chamber atrial pacing system; AF, atrial fibrillation; CRT-D, cardiac resynchronization therapy-defibrillator; CRT-P, cardiac resynchronization therapy-pacemaker; ICD, implantable cardioverter-defibrillator dual chamber; ICD-V, implantable cardioverter-defibrillator single chamber; LDTD, lead-dependent tricuspid dysfunction; LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging; NYHA, New York Heart Association class; PM, pacemaker; SVC, superior vena cava; TLE, transvenous lead extraction; VVI, single chamber ventricular pacing system; VDD, dual chamber pacing system without atrial pacing.

Table 2 Lead Management and Organization of TLE Procedure

General Procedure Information	No/Range	Mean±SD/%
Main goal of TLE		
Infectious indications	222	22.2%
Lead replacement	515	51.5%
Up-grading of the system	138	13.8%
Down-grading of the system	54	5.4%
Superfluous lead extraction	47	4.7%
System removal - reimplantation deferred	13	1.3%
Redundant system removal	11	1.1%
All	1000	100.0%
General options of lead management		
Extraction of all leads	770	77.0%
Functional lead was left for continuous use	227	22.7%
Non-functional, superfluous lead was extracted	91	9.1%
Non-functional lead was left	1	0.1%
Presence of abandoned lead before TLE		
Presence of abandoned lead	93	9.3%
Number of abandoned leads	0–3	0.12±0.39
Extraction of abandoned lead		
Extraction of abandoned lead (number of patients)	91	9.1%
1 abandoned lead was extracted	71	7.1%
2 abandoned leads were extracted	18	1.8%
3 abandoned leads were extracted	2	0.2%
Abandoned lead was left	1	0.1%
Organizational model of TLE procedure. The role of cardiac surgeon, TEE and general anesthesia		
Cardiac surgeon as a co-operator in hybrid room	504	50.4%
Cardiac surgeon as a co-operator in hybrid room without TEE	58	5.8%
Cardiac surgeon as a co-operator in operating (cardiac surgery) room	406	40.6%
Cardiac surgeon as a co-operator in operating (cardiac surgery) room without TEE	32	3.2%
All	1000	100.0%

Results

Baseline Characteristics

In all, 1952 leads were extracted from the first 1000 patients (61.9% males) with a mean age of 67.32 ± 14.34 years. The most common pacing system was PM DDD (46%); systems with ICD leads and left ventricular leads (LV) were less popular (32.5% and 12.5%, respectively). The mean dwell time of the oldest lead in one patient was 112.9 ± 77.40 months, the mean sum of dwell times of all leads in one patient was 17.31 ± 14.13 years. Non-infectious indications for TLE were present in 77.8% of patients; local pocket infection and endocarditis were less frequent (6.3% and 15.9%, respectively) (Table 1).

The most common indication for TLE was the need to replace the lead (51.5%); other reasons included prevention of lead abandonment (up-grading, down-grading, superfluous lead extraction, system removal with deferred reimplantation and removal of the redundant entire system; 26.3%), whereas removal of the entire system due to infection was rarest of all (22%).

Analysis of lead management options showed that all leads were removed in 77% of patients, non-functional, superfluous leads were extracted in 9.1%.

Fifty percent of procedures were performed in a hybrid room, 40% in an operating room (cardiac surgery room in cooperation with a cardiac surgeon), and over 90% of procedures were performed under TEE guidance (Table 2).

Table 3 TLE Procedure Information

Procedure Information	No/Range	Mean±SD/%
Oldest extracted lead dwell time [months]	1–468	111.7±76.99
Sum of dwell times of extracted leads (global age of extracted leads) [years]	1–104	15.6 ±14.1
Procedure duration (skin-skin time) [minute]	31–330	63.03±27.17
Procedure duration (sheath-sheath time) [minute]	1–300	15.44±24.38
Average time of single lead extraction [minutes]	1–240	9.0±14.3
Venous obstruction/occlusion n (%)	118	11.8%
Dependence on the pacemaker	234	23.4%
1 lead was extracted	480	48.0%
2 leads were extracted	405	40.5%
3 leads were extracted	99	9.9%
4 leads were extracted	15	1.5%
5 leads were extracted	1	0.1%
Selected approach		
Left subclavian approach	963	96.3%
Right subclavian approach	20	2.0%
Both	8	0.8%
Subclavian+femoral approach	4	0.4%
Other combined approach	2	0.2%
Jugular approach only	1	0.1%
Cardiac surgery. Lead remnant removal during rescue intervention	2	0.2%
All	1000	100.0%
Extraction of “challenging/ terrible leads”		
Extraction of VDD lead	23	2.3%
Extraction of lead with proximal ending in cardiovascular system	5	0.6%
Extraction of ICD lead	298	29.8%
Extraction of CS branch lead for LV pacing	73	7.3%
Extraction of CS, CSO leads for LA pacing	51	5.1%
Procedure complexity - “technical problems”		
Any technical complication	250	25.0%
Block in subclavian venous entry	118	11.8%
Byrd dilator collapse/twist	52	5.2%
Lead to lead fibrotic adherence	98	9.8%
Fracture of the extracted lead	58	5.8%
Necessity to change approach	17	1.7%
Loss of broken lead fragment	6	0.6%
Dislodgement of functional lead	10	1.0%
1 technical problem	140	14.0%
2 technical problems	50	5.0%
3 technical problems	15	1.5%
4 technical problems	6	0.6%
5 technical problems	1	0.1%
6 technical problems	1	0.1%
Unrolling ICD lead coil with dilating sheath	15	1.5%
No technical complications	788	78.8%
Necessity to use rotational mechanical sheath (Evolution or TightRail)	25	2.5%
Necessity to use metal sheath	113	11.3%
Necessity to use lasso catheter	41	4.1%
Use of lasso and guide wire loop	15	1.5%

Abbreviations: CS, coronary sinus; CSO, coronary sinus ostium; ICD, implantable cardioverter-defibrillator; LA, left atrium; LV, left ventricle; VDD, dual chamber pacing system without atrial pacing.

Table 4 Effectiveness of Lead Extraction Expressed as Radiographic, Clinical and Procedural Success, Major and Minor Complications in 1000 Procedures

TLE Effectiveness	No
Complete procedural success “with the absence of any permanently disabling complication”	
Success	945
Success but rescue cardiac surgery	13
Success explorative sternotomy	1
No, retained lead tip	10
No, retained lead fragment	24
No, significant tricuspid valve damage	7
All	1000
Clinical success „with the absence of any permanently disabling complication”	
Success	976
Success but rescue cardiac surgery	14
Success explorative sternotomy	1
No, retained lead tip, infectious indication	2
No, significant tricuspid valve damage	7
All	1000
Major complications	
Absent	978
Hemopericardium - cardiac surgery	13
Hemothorax - cardiac surgery	1
Acute heart failure	1
Tricuspid valve damage - significant	7
All	1000
Rescue (acute) cardiac surgery	
RA suture (damaged during V lead extr.)	1
Vena cava suture	1
RA suture (damaged during atrial lead extr.)	10
RV suture	1
Numerous/Complex sutures (RA, CS)	1
Acute Tricuspid Valve Repair	1
Explorative sternotomy	1
Extracorporeal circulation during rescue cardiac surgery	3
All acute surgical interventions	16
Minor complications during TLE	
Worsening tricuspid valve function	40
Bleeding requiring blood transfusion	18
Hematoma requiring evacuation	12
Pericardial effusion without surgical intervention	10
Migrated lead fragment without sequelae	0
Venous thrombosis requiring medical intervention	4
Pneumothorax requiring chest tube	3
Pulmonary embolism	0
All patients with minor complications	92
Long-term survival after TLE procedure	
Periprocedural-related death	0
7-day mortality	3
30-day mortality	13
6-month mortality	41

(Continued)

Table 4 (Continued).

TLE Effectiveness	No
All follow-up mortality	147
All	1000

Abbreviations: CS, coronary sinus; RA, right atrium.

Dwell time of the oldest extracted lead (111.7 months) and the sum of dwell times of the extracted leads (15.6 years) were slightly different than before the procedure, because functional leads had been left in place for prolonged use in 227 patients. The mean duration of the procedure (skin–skin time) was 63.03 ± 27.17 min, whereas average sheath–sheath time (measured as the time from insertion of the dilator to its removal) was 15.44 ± 24.38 min. An average duration of single-lead extraction was 9.0 min. Intraprocedural temporary pacing in pacemaker-dependent patients was used in 23.4% cases. More than one lead was extracted in 52.0% and 3 or more leads in 11.5% of patients.

Leads were most commonly accessible from their venous entry site (98.3%). A variety of technical difficulties occurred during 212 out of 1000 procedures (21.2%). Rescue tools were necessary in about 20% of cases: metal sheaths were used in 11.3% of procedures, lasso catheters in 4.1% of patients, and the lasso and guide wire loop in 1.5% of cases (Table 3).

Complete procedural success was achieved in 95.9% of procedures, clinical success was obtained in 99.1% of patients. Absent clinical success was related to abandonment of non-extractable lead remnants in infectious cases (in 0.2%) and marked tricuspid valve damage (in 0.7% of procedures) (Table 4).

Major complications were detected in 22 patients (2.2%). They were: hemopericardium requiring cardiac surgery (1.3%), hemothorax requiring cardiac surgery (0.1%), acute heart failure requiring intensive therapy (0.1%) and tricuspid valve damage requiring tricuspid valve repair urgently (one patient) or in the future (6 patients; 7.0%) (Table 4).

A careful analysis of 22 cases with serious complications showed that hemodynamically significant cardiac tamponade was predominant (63.3%). The causes of tamponade were: damage to the atrial wall in 11 cases (78.5%), perforation of the right ventricular wall in one (7.1%), damage to the coronary sinus and the superior vena cava wall in one case. Extracorporeal circulation

was necessary in 3 out of 13 interventions (18.7%) (Table 4).

Another important determinant of TLE safety is tricuspid valve function. In this study, tricuspid valve injury occurred in 33 (3.3%) patients, with significant valve dysfunction qualifying for cardiac surgery being diagnosed in 0.7% of cases (Table 4).

It is also noteworthy that 14 (1.4%) patients who were previously diagnosed with lead-dependent tricuspid dysfunction showed a significant reduction in tricuspid regurgitation after TLE.

The group of 22 patients with major complications consisted mainly of women (68%). Renal failure occurred in 14% of patients, average Charlson index was 2.8. Of the factors related to the implanted systems, only 9% of patients had an ICD, none had an LV lead. An abandoned lead was detected in 24% of patients. The mean number of leads in the heart before TLE was 2.05. Dwell time of the oldest lead before TLE was 200.3 months, the sum of lead dwell times in the heart was 33.2 years. Excessive lead loops in the heart were found in 18% of patients. The average number of CIED-related procedures before TLE was 2.89 (>1 procedure in 77% of patients). Dwell time of the extracted lead was relatively long (oldest: 468, average 111.7 months), but three major complications (acute heart failure-AHF, tricuspid valve dysfunction-TVD, hemothorax requiring surgery – HTS) occurred in patients with relatively younger leads, ie, with implant duration of less than 111.7 months (50, 97, 69, 108 months). In order to evaluate TLE-related risk in these patients, we used a previously devised SAFeTY TLE score¹⁵ and an online calculator (available at <http://alamay2.linuxpl.info/kalkulator/>), confirming that the mean score for these four patients was 12.0, reflecting a high (8–10%) risk of major complications (Table 5).

In the group of 22 patients with major complications, lead dwell time ranged from 50 to 385 months (average 200, 3 months), but the mean value may be misleading because major complications occurred in 6 patients with the implant duration of less than 10 years. What's more,

Table 5 Major Complications of TLE in Patients with Lead Implant Duration of Less Than 10 Years

Age of Oldest Extracted lead [in Months]	Safety TLE Score ¹⁵	Major Complication	Acute Surgical Intervention	Planned Delayed Surgical Intervention
385	17.9	Tricuspid valve damage		Tricuspid valve repair
363	16.6	Hemopericardium - surgery	RA suture	
348	24.8	Hemopericardium - surgery	RA suture	
324	17.9	Hemopericardium - surgery	RA suture	
300	16.6	Tricuspid valve damage		
278	14.3	Hemopericardium - surgery	RA suture	
245	15.2	Hemopericardium - surgery	RA suture	
226	15.2	Hemopericardium - surgery	RA suture	
223	10.2	Tricuspid valve damage		Tricuspid valve repair
219	11.1	Hemopericardium - surgery	RA suture	
204	13.9	Hemopericardium - surgery	RA suture	
182	11.6	Hemopericardium - surgery		
144	5.8	Tricuspid valve damage		Tricuspid valve repair
143	13.9	Hemopericardium - surgery	RA suture	
135	13.9	Tricuspid valve damage		Refused TV repair
132	7.8	Hemopericardium - surgery	RV suture	
119	3.7	Hemopericardium - surgery	RA suture	
112	7.8	Hemopericardium - surgery	RA suture	
108	8.8	Tricuspid valve damage		Borderline indications -observation
97	5.0	Tricuspid valve damage		Disqualification, cancer disease
69	6.4	Hemothorax - surgery	VCS suture	
50	6.4	Acute heart failure, suspected VCS tear	Explorative sternotomy	

even the SAFeTY TLE scores did not predict procedural complications in these patients (Table 5).

The complexity of procedures in patients with major complications was high, any technical difficulty occurred in 68% of patients. Lead-to-lead fibrotic-binding sites were found in 59% of cases, lead fracture during extraction occurred in 36% of patients, more than one technical problem occurred in 41%. The most common minor complications were: worsening tricuspid valve function in 4% of cases, bleeding requiring blood transfusion in 1.8% of patients, hematoma requiring evacuation in 1.2% and pericardial effusion without surgical intervention in 1% of cases.

None of the patients died in the periprocedural period due to major complications. Mortality at 7 days was 0.3%, at 30 days 1.3%, at 6 months 4.1% and mortality over the whole follow-up time (from January 2016 to January 2020) was 14.7% (Table 4).

Discussion

As the need for transvenous lead extraction is increasing, it becomes more and more important to ensure its efficiency and safety. It was shown previously that the occurrence of

major TLE complications was determined by risk factors related to patient characteristics (female gender, renal failure) and CIED characteristics (implant duration, number of leads, abandoned leads).¹³⁻¹⁵ Experience of the first operator and the team, as well as the use of less invasive tools, can prevent major complications but only to a limited extent.^{3-6,13} Procedure-related death remains the most serious complication of lead extraction.^{3-6,13} Safety precautions outlined in the guidelines (procedure site, TEE monitoring, general anesthesia, arterial line, gas analysis, presence of a cardiac surgeon during surgery, availability of tools and pumps for sternotomy) were designed to effectively treat serious complications as early as possible before the onset of general hypoxemia.^{3-6,13} There are many reports describing practical utility of the proposed organizational model, but our analysis has demonstrated probably for the first time the effectiveness of a comprehensive safety system in each of the 1000 procedures.

This study shows that simple, cheap and conventional tools (non-powered polypropylene mechanical sheaths) used as first-line support help us achieve excellent results

(complete radiographic success in 95.9%, clinical success in 99.1% and procedural success in 95.9%).

This report also demonstrates that such a stepwise approach can result in a safe, successful and complete lead removal in up to over 95% of patients, regardless of the specific extraction tool used. It should also be emphasized that these results were obtained in the country's TLE tertiary reference center that has the efficiency and experience to perform the most difficult procedures. Dwell time of the oldest extracted lead was 112 months (more than 10 years) which had a significant impact on the occurrence of serious complications (2.2%) despite the main operator's extensive experience (>3500 TLEs performed personally), but even so, a zero mortality rate was observed. Major complications can occur even during the extraction of leads with implant duration of less than 10 years (4/22, 18%), which clearly shows that safety strategy should be implemented during all procedures without exception. Additionally, the present study reveals that the use of minimally aggressive tools (polypropylene sheaths) as the only possible way and, if necessary, only mechanical rotating threaded tips, may reduce the risk of superior vena cava rupture (there was only one case, when using the old model of Evolution).

Out of 25 reports comprising 43,940 patients, summarized in Table 6,^{13,15,22-43} 13 studies involved more than 1000 TLE procedures.^{13,15,22,23,25,32,34-36,42}

The average implant duration in those reports was 74.5 months. In the present study, the implant duration was markedly longer (112 months), and there were two smaller studies reporting such a long lead dwell time.^{29,40} Infection was the main indication for lead extraction in 41.7% of reports. In the current study, this percentage was lower (22%), and there were only 3 studies with a higher rate of non-infectious indications.^{26,30,34} Laser sheaths were used as a first-line or predominant (50%) tool in 11 reports comprising 22,890 patients.^{13,24,25,27,28,30,32-34,36,38} Mechanical dilation with non-powered sheaths was used as a first-line or predominant (50%) option in 11 reports comprising 17,953 patients,^{15,22,23,26,29,31,35,39,40,42} whereas mechanical rotational sheaths with threaded tips were used as a first-line or predominant (50%) tool in 2 reports^{35,38} (a relatively new tool; 2,605 patients). In one report, femoral approach and Needle's Eye Snare was used as a first-line option in 492 patients.⁴³ Comparison of procedural/clinical success, percentage of major complications and percentage of procedure-related death showed no significant differences between "laser" and "non-laser"

centers. The average incidence of major complications in the studies was 1.67%, but this parameter should be evaluated in parallel with implant duration, which is the main risk factor for their occurrence. Only two studies demonstrated a higher rate of MC than in the current investigation,^{32,36} but there were only 2 studies with slightly longer implant duration^{32,43} and one of them reported a higher rate of MC.³² Procedure-related death is the most important indicator of the effectiveness of safety measures. Four studies reported a zero procedure-related mortality rate,^{24,27,37,42} but the mean implant duration in those reports was markedly shorter than in the current study (72-92 vs 112 months). The mean rate of procedure-related deaths was 0.23%, but rates of 0.5%, 0.65% and 1.10% were also reported.^{15,29,30} There were 12 studies in which mortality rate was above the average (0.23%)^{22,23,25,28-30,32-35,38} and in all but one of the studies implant duration was shorter than in the current study. The above data indirectly show that the organizational model of lead extraction plays a key role.

An important part of the TLE procedure is the venue and a standby team of cardiac surgeons. A hybrid room, a cardiac surgeon ready for immediate intervention and a perfusion pump ready for immediate use significantly improve procedure safety and reduce mortality.^{24,27,37,42} Our study is in line with these reports. Out of the 1000 patients undergoing TLE, 16 individuals required sternotomy and urgent cardiac surgery (14 with acute cardiac tamponade).

The cardiac surgeon's presence was essential for survival of all patients, mortality was 0%. The role of continuous TEE monitoring cannot be overestimated, either. The American guidelines recommend echocardiographic examinations at the following stages: before the procedure for initial assessment, during the procedure for monitoring, and after the procedure for final assessment in accordance with the precisely determined criteria.⁴ Analogically, the European statements emphasize improved efficacy and safety of the TLE procedure, if it is supported by continuous echocardiographic monitoring.⁵ In the present study, more than 90% of TLEs were performed under transesophageal echocardiographic guidance. The role of continuous TEE monitoring during TLE procedures was discussed in previous publications.¹⁶⁻²¹

Due to economic and organizational problems, many TLE centers use a graded approach in the application of safety requirements: from TLE in the cath-lab, in deep analgesia-sedation, through TLE in the operating room/

Table 6 List of Publications Describing Effectiveness and Safety of TLE Procedures

Reference Number	Author, Journal, Year	Type of Study	Number of pts	Methods of TLE (Predominant, First Line Tool)	Mean Dwell Time (Months)	% of infectious Indications	Procedural/ Clinical Success (PS)/(CS)	Major Complications (%)	Procedure Related Death (%)
1	Byrd CL Pacing Clin Electrophysiol 1999	US Extraction Database analysis	2338	Mech dilat	47	27.00%	PS 93%	1.40%	0.40%
3	Bongiorni M Eur Heart J. 2008	Single-center study	1193	Mech dilat	69	82.00%	PS 98.4%	0.70%	0.30%
5	Kennergren C Europace 2009	Single- center study	647	Laser 60%	91	58.00%	CS 97.6%	0.90%	0.00%
6	JACC Wazani O JACC 2010	LEXICon Study	1449	Laser sheath	82	57.00%	PS 96.5%	1.40%	0.30%
7	Gomes S Europace 2014	Single- center study	510	Mech dilat	47	65.00%	PS 96%	0.30%	0.20%
9	Maytin M CAE 2012	Single- center study	985	Laser 58%	72	50.00%	PS 99, CS 95%	0.60%	0.00%
10	Brunner MP Heart Rhythm 2014	Single- center study	2999	Laser 70%	61	43.00%	PS 95.1%	1.80%	0.20%
11	Fu HX Pacing Clin Electrophysiol 2015	Single- center study	652	Laser 51%	57	59.00%	PS 96.6%	2.01%	0.30%
13	El-Chami MF Heart Rhythm 2015	Single- center study	462	Laser 45%	55	15.00%	PS 98% CS 98%	1.30%	0.65%
14	2015 Merchant FM (Atlanta)	Single- center study	508	Laser 57%, Mech dilat 8%	61	32.50%	PS 96.5%	1.60%	1.10%
15	2016 Gomes S Pacing Clin Electrophysiol (Sydney)	Single- center study	510	Mech dilat	47	74.00%	PS 92%, CS 98.2	0.20%	0.20%
16	2016 Bashir J Circ Arrhythm Electrophysiol	The British Columbia Cardiac Registry	1082	Laser	129	45.00%	???	3.00%	0.37%
17	2017 Barakat AF Heart Rhythm	Single- center study	503	Laser 62% Evol 9%	57	0.00%	PS 96.6% CS 97.2%	1.00%	0.40%

18	Hussein AA JACC Clin Electrophysiol 2017	Single- center study	1836	Laser, Mech Rotat	108	100.00%	PS 94.2 CS 95.1%	1.93%	0.29%
19	Kutarski A Europace 2017	Single- center study	2049	Mech dilat 97%	89	40.00%	PS 95.0% CS 97.9	1.80%	0.36%
20	Bongiorno M Eur Heart Journal 2017	The European Lead Extraction ConTRolled Registry (ELECTRa)	3555	Laser 19.3%	77	52.00%	CS 96.7%	1.70%	0.50%
21	Sood N Circ Arrhythm Electrophysiol 2018	Multicenter register	11,304	Laser 63%	65	14.00%	PS 97%	2.30%	0.16%
23	Sharma S JACC Clin Electrophysiol 2018	Single- center study	400	Mech Rotat	81	54.00%	PS 97.0,CS 99.7%	1.50%	0.00%
26	Gould J Pacing Clin Electrophysiol 2019	Single- center study	925	Laser 56%	85	54.60%	CS 98.5%	1.60%	0.30%
27	Jacheć W Pacing Clin Electrophysiol 2019	Two-center study	3810	Mech dilat 98%	86	46.10%	PS 94.6% CS 97.6%	1.44%	0.17%
29	Segreti L Europace 2020	Single- center study	1210	Mech dilat	72	67.00%	CS 96%	0.70%	0.16%
31	Starck CT Europace 2020	Multicenter study (PROMET)	2205	Mech Rotat	74	46.00%	PS 97%, CS 96%	1.00%	0.18%
32	Giannotti Santoro M, Pacing Clin Electrophysiol 2020	Single- center study	1316	Mech dilat	72	65.70%	CS 97%	0.70%	0.00%
33	Zhou X Heart Vessels 2020	Single- center study	492	Needle's Eye Snare	113	91.00%	PS 94%,CS 98%	1.90%	0.20%
33	Stefańczyk P This paper 2021	Single-center study	1000	Mech dilat 98%	112	22.00%	CS 99.1, PS 95.9	2.20%	0.00%
	ALL studies		43,940		74,51	41.71%		1.67%	0.24%

Notes: Mech dilatation: Cook's extraction kit as locking stylets, dilator sheaths, and/or transfemorally used snares, retrieval baskets, and sheaths and if necessary other tools. Mech Rotational Evolution, TighrRail.
Abbreviations: PS, complete procedural success; CS, clinical success.

hybrid room with general anesthesia in the presence of a cardiac surgeon along with additional monitoring of the procedure (TEE, arterial line). Several predictors of major complications or even indicators have been proposed for pre-operative selection of the appropriate degree of protection.^{13,38,44} However, as shown in the present study, serious complications can occur even when leads with implant duration of less than 10 years (4/22, 18%) are being extracted. This is an argument for adopting a comprehensive safety strategy during all procedures without exception.

Conclusions

1. Performing transvenous lead extraction in a hybrid operating room, under general anesthesia, in the presence of a cardiac surgeon and under transesophageal echocardiographic guidance, contributes to the improvement of the safety of TLE. This organizational model should be recommended for all TLE procedures.
2. Serious complications may arise during the extraction of leads with implant duration of less than 10 years; therefore, all TLE procedures should be carried out with the same precautions.

Disclosure

The authors declare no conflict of interest in this work.

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