



Transvenous Lead Extraction (TLE) Procedure: Experience from a Tertiary Care Center in Thailand



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ABSTRACT

Background: Transvenous Lead Extraction (TLE) is a standard treatment for some late Cardiac Implantable Electronics Device (CIED) complications. The outcome of transvenous lead extraction procedure in Thailand is not robust.

Methods: A Single-center retrospective cohort of TLE procedures performed at Ramathibodi hospital between January 2008 and December 2020 was studied.

Results: There were 157 leads from 105 patients who underwent lead removal procedure during the specified period. Data analysis was performed from 79 TLE patients due to incomplete data and lead explant procedure of the excluded subjects. Mean patients' age was 57.7 ± 18.7 years, with 70.9% male. There were 82 pacemaker leads, 35 ICD leads, and 5 CS leads (mean number of leads were 1.54 ± 0.66 per patient), with mean implanted duration of 87.8 ± 68.2 months. Main indication for TLE was infection-related, which accounted for 67.1% of the cases.

Overall clinical success rate was 97.5%. Mean operative time was 163.8 ± 69.5 min. Major complications occurred in 4 patients (5.1%) with one in-hospital mortality from severe sepsis.

Conclusion: TLE using laser sheath and rotating mechanical sheath for transvenous lead extraction is effective and safe, even outside high-volume center.

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1. Introduction

Cardiac Implantable Electronics Devices (CIEDs) are mandatory for some cardiac arrhythmia patients. In line with globally increased CIED implantations, Ramathibodi hospital has been performing approximately 300 CIED implantations per year [1]. As previously reported, long term CIED complications such as CIED infections occur around 1.9 per 1000 device-years [2], while lead failure or malfunction occur in 13.2% at 15 years [3]. These

complications necessitate transvenous lead removal procedures. Early lead removals can be manually done within the first year after implantation. After one year, fibrosis and calcification around pacing and defibrillating leads result in difficult transvenous lead removal procedure. In those cases, more specialized equipment such as locking stylets, laser sheaths, or rotational mechanical sheath play important roles [4,5]. Data from a large US registry that included 12,257 TLE patients between 2003 and 2015 showed all-cause in-hospital mortality rate of 4.11%, with major adverse events in 10.42% of cases [6]. Latest RELEASE study included 230 TLE patients who underwent TLE by rotational mechanical sheath between 2018 and 2020. The study showed high clinical success rate (98.7%) with low clinical events committee (CEC)-adjudicated device-related complication (2.6%). Only one cardiac injury at the inferior vena cava-right atrium (IVC-RA) junction occurred, with no patient death [7].

Due to the scarcity of centers that can perform this high-risk procedure, data on outcomes of lead extraction procedures in Thailand is not robust. Ramathibodi hospital started transvenous

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lead extraction (TLE) in 2008 and has become one of the largest TLE referral centers in Thailand. This study aims to present the safety, efficacy, and outcomes of transvenous lead extraction (TLE) procedure performed at our center, with detailed analysis comparing between procedures performed before and after introduction of formal extraction protocol and the availability of rotational mechanical sheath.

2. Methods

2.1. Patient selection

Patients who underwent TLE at Ramathibodi Hospital between 2008 and 2020 were screened, using electronic medical record search with ICD-10 and ICD-9 of T82.7 (Cardiac implantable electronic device infection), T82.1 (Cardiac implantable electronic device malfunction), 37.77, 37.89 (Cardiac implantable electronic device removal). Of note, we refrained from the operation during 2015–2017 due to technical limitations of our laser machine.

Data collection included patients' demographics, underlying diseases, CIEDs information, indication for lead removal, intraprocedural features, microbiological data, length of stay in hospital, and reimplantation rate. Follow-up assessments were recorded at 4 weeks after extraction procedure. Patients were divided into 2 groups: group 1 included patients who underwent TLE before 2015 ($n = 60$) and group 2 included those who underwent TLE after 2018 ($n = 19$) because we refrained from the operation during 2015–2017 due to laser machine malfunction. In group 2, TLEs were performed with new laser machine, new formal extraction protocol, and rotational mechanical sheath.

This study protocol was approved by Ramathibodi hospital institutional review board.

2.2. Lead extraction procedure

In the first period of the study (2008–2012), a lead extraction procedure was performed without a formal protocol. Unfortunately, there was an IVC-RA junction tear occurred in 2012. Since then, a standard protocol (details in Supplementary 1) was developed and implemented.

Our transvenous lead extraction procedures are performed under general anesthesia (Fig. 1) with cardiovascular thoracic surgery team backup. Transesophageal echocardiogram (TEE) is used for intraprocedural monitoring since 2018. Femoral veins are accessed with three sheaths for right ventricular (RV) pacing catheter, snaring tools or rescue balloon, and Extracorporeal Membrane Oxygenation (ECMO) cannulation if needed. One femoral arterial sheath is inserted for arterial blood pressure monitoring and possible ECMO cannulation.

A superior approach via the implant-related vein was the first-line method. The skin incision was chosen to achieve appropriate coaxial alignment of extraction sheath with targeted lead. Leads were dissected and freed from adhesions under the generator pocket. The tips of leads were unscrewed from myocardium followed by gentle traction and manual removal if possible. Then the leads were cut, and insulators were peeled to expose inner cables. The lead locking device LLD® EZ or LLD® E (Philips) was introduced into the inner lumen of the lead and deployed. Fibrous adhesions surrounding leads were dissected using 12–14 Fr. SLS™II Laser sheath (Philips). In case of extensive scarring or calcification, 9–13Fr. TightRail™ Sub-C 9–13 Fr. (Philips) Rotating mechanical sheath was used.

When superior approach did not result in complete removal, a transfemoral approach were used to remove fragmented lead by snaring. Operation duration, fluoroscopic time, acute procedural

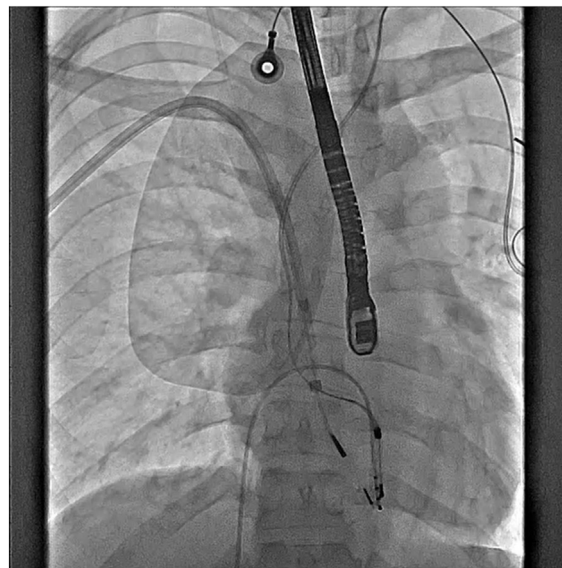


Fig. 1. The patient was under general anesthesia. Transesophageal echocardiogram (TEE) was used for intraprocedural monitoring. A laser sheath was inserted via right axillary vein for right sided pacemaker lead.

outcomes were recorded. Hospital stays and clinical outcome were also recorded.

2.3. Procedural outcome

According to 2017 Heart Rhythm Society association definition, complete procedural success was defined as the removal of the targeted lead and all lead material from the vascular space, with the absence of permanently disabling complications or procedure-related death. Clinical successes were defined as the removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead (fragment ≤ 4 cm) that did not impact the outcome goals of the procedure. Procedural failure is defined as an inability to achieve either complete procedural or clinical success or the development of any permanently disabling complications or procedure-related death [8].

Major complications were defined as any outcomes related to the procedure that were life threatening or resulted in death (cardiac or noncardiac). Major complications also included unexpected events that caused persistent or significant disability, events that required inpatient hospitalization or prolongation of existing hospitalization, or any event that required surgical intervention to prevent any of the outcomes including death, cardiac avulsion, vascular laceration, respiratory arrest, cerebrovascular accident, pericardial effusion requiring intervention, hemothorax requiring intervention, cardiac arrest, thromboembolism requiring intervention, flail tricuspid valve leaflet requiring intervention and massive pulmonary embolism.

Minor complications included any undesired event related to the procedure that required medical intervention or minor procedural intervention that did not persistently or significantly alter the patient's function or threaten the life of the patient.

Primary endpoints of study were defined as procedural outcome, including incidence of intra-procedural complication in our center. Secondary endpoints included operative time, fluoroscopic time, length of stay, reimplantation rate.

2.4. Data analysis

Continuous variables were summarized with mean \pm standard

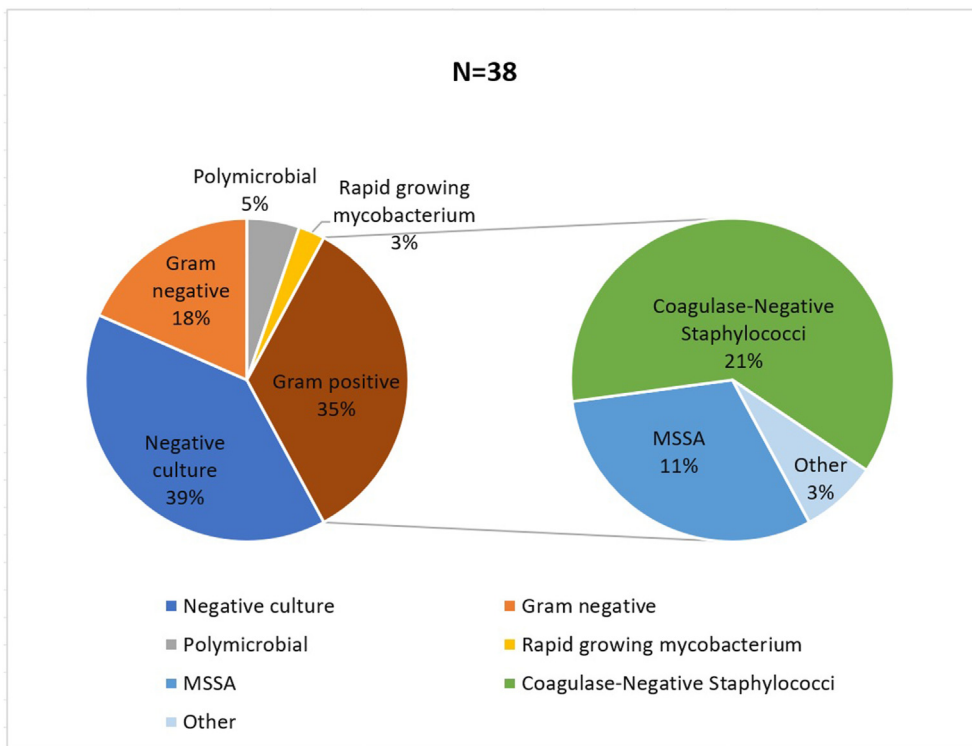


Fig. 2. Microbiology of transvenous lead extraction from 37 patients in 2008-2020.

deviation (SD) or median with interquartile range (IQR). Categorical variables were reported as count and percentages. Significant differences were defined by 2-tailed $p < 0.05$ from T-test for continuous data and Chi-square test for categorical variables. All analyses were performed using IBM SPSS version 23.

3. Results

There were 105 patients (total of 157 leads) who underwent lead removal at Ramathibodi hospital between January 1, 2008, and December 31, 2020. 19 patients underwent lead explant procedure within 12 months of implant and the leads were removed without specialized tool, so they were excluded. 7 patients were excluded from analysis due to incomplete data.

Between 2008 and 2020, a total of 79 patients (70.9% male, mean age 57.7 ± 18.7) with 122 leads (82 pacemaker leads, 35 implantable cardioverter defibrillator leads, 5 coronary sinus leads) met inclusion criteria. Cardiac implantable electronic devices were dominated by 43 cases (54.4%) of pacemakers and 31 cases (39.2%) of automatics implantable cardioverter defibrillator (AICD). Indications of pacemaker implantation were sinus node diseases (18 cases, 58.1%) and atrioventricular nodal diseases (13 cases, 41.9%). Main implantable cardioverter defibrillator devices were single chamber AICD (28, 90.3%), and predominant indication was primary prevention (21, 68.2%). There were only 5 patients (6.4%) with Cardiac resynchronization therapy (CRT) in this study.

Overall mean implanted duration of extracted lead was 87.8 ± 68.2 months. Average number of leads in each procedure were 1.54 ± 0.66 leads. Main indication for transvenous leads extractions were cardiac implantable electronic devices related infection 67.1% dominated by around 56% of pocket infection, followed by CIEDs related endocarditis 8.9%. Non-infectious indications were mainly lead malfunctions 29.1%, with 3 cases (3.8%) of thrombosis or vascular issues.

In infection-related group, pathologic organisms were identified in 61% of 38 recorded cases. Only 3 cases had positive blood cultures, and the remainder had positive cultures from hardware. Positive microbiologic culture results showed Gram-positive in 35%, Gram-negative bacteria in 18%, multiple organisms in 5%, and rapid growing mycobacteria in 3% of total cultures. *Staphylococcus* is the main species of pathogen in Gram-positive bacteria group, mainly Coagulase-negative Staphylococci 18% followed by methicillin-susceptible *Staphylococcus aureus* 11% (Fig. 2).

Overall mean procedural time was around 160 min (163.8 ± 69.5), with fluoroscopic time of 13 min (12.7 ± 17.1). As shown in Table 3, reimplantation rate at our center was 48.1% and timing of reimplantation was 10.6 ± 14.6 days post extraction. In pacemaker dependent patients (10.1%), externalized permanent pacemakers were used for bridging. One of the patients was reimplanted with CRT-P and one with leadless pacemaker. 41 patients (51.9%) did not undergo reimplantation at our center. Out of the 41 patients, 25 (31.6%) were referred back to primary centers and the information about reimplantation is not retrievable. Two patients (2.5%) had complications that precluded reimplantation. And interestingly, 14 (17.7%) patients had had minimal utilization of their extracted devices, and preferred not to undergo reimplantation. Length of stay in hospital was 13.5 ± 17.1 days.

Among 79 TLE cases, complete procedural success was achieved in 76 cases (96.2%). There was only 1 case (1.3%) of procedural failure with major complication due to cardiac avulsion during procedure, which led to termination of the procedure and emergent surgical intervention. One in-hospital mortality was from severe sepsis with multiorgan failure that occurred 56 h after complete procedural success. Other minor complications were one case of pericardial effusion requiring pericardial window, and one effusion requiring pericardiocentesis, as shown in Table 2.

There was no significant difference among baseline characteristics of both groups (Table 1). Overall mean age was 58 years-old,

Table 1
Patients characteristics.

Characteristic	Total (n = 79)	2008–2014 (n = 60)	2018–2020 (n = 19)	p value
Age	57.7 ± 18.7	57 ± 19.8	58.7 ± 15	0.786
Male sex	56(70.9)	42(70)	14(73.7)	0.758
Body surface area	1.71 ± 0.22	1.67 ± 0.21	1.76 ± 0.23	0.143
Body mass index	23 ± 3.62	22.2 ± 2.95	24 ± 4.22	0.112
Body mass index >25	18(22.8)	5(13.2)	7(36.8)	0.051*
Diabetes mellitus	10(12.3)	6(10.5)	3(15.8)	0.568
Hypertension	32(40.3)	19(31.6)	11(57.9)	0.056
Dyslipidemia	15(19.3)	11(18.4)	4(21.1)	0.812
Chronic obstructive pulmonary disease	3(3.5)	2(2.6)	1(5.3)	0.611
End-stage renal disease	3(3.5)	0	2(10.5)	0.042*
Number of leads extracted per procedure	1.54 ± 0.66	1.53 ± 0.68	1.58 ± 0.6	0.794
Implant duration of extracted lead (months)	87.8 ± 68.2	63 ± 44.9	130.2 ± 82.8	<0.010*
Pacemaker	43(54.4)	31(51.7)	12(63.2)	0.381
Single chamber pacemaker	16(37.2)	13(41.9)	3(25)	
Dual chamber pacemaker	27(62.8)	18(58.1)	9(75)	
Sinus node disease	18(58.1)	18(58.1)	7(58.3)	
Atrioventricular node disease	13(41.9)	13(41.9)	5(41.7)	
AICD	31(39.2)	25(41.7)	6(31.6)	0.433
Secondary prevention	10(31.8)	9(36)	1(16.7)	
Primary prevention				
ICM	8(27.3)	6(24)	2(33.3)	
NICM	3(9.1)	2(8)	1(16.7)	
BrS	10(31.8)	8(32)	2(33.3)	
CRT-P	1(1.3)	1(1.3)	0	0.827
CRT-D	4(5.1)	3(5.1)	1(5.3)	
Indication for TLE				
Infection related indication	53(67.1)	38(63.3)	15(78.9)	0.207
Pocket infection	44(55.7)	32(53.3)	12(63.2)	0.603
Left side endocarditis in a CIED carrier	2(2.5)	1(1.7)	1(5.3)	
CIED-related endocarditis	7(8.9)	5(8.3)	2(10.5)	
Occult bacteremia with probable CIED infection	0	0	0	
Noninfectious indication	26(32.9)	22(36.7)	5(21.1)	
Thrombosis/Vascular issue	3(3.8)	2(3.3)	1(5.3)	
Lead malfunction	23(29.1)	20(33.3)	3(15.8)	
CIED implantation require more than 4 leads in one side, more than 5 leads through SVC	0	0	0	

Note: Values are mean ± SD or number of patients (%).

Abbreviations: AICD, automatics implantable cardioverter defibrillator; ICM, ischemic cardiomyopathy; NICM, non-ischemic cardiomyopathy; BrS, Brugada syndrome; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; CIED, cardiac implantable electronics device; SVC, superior vena cava.

with 70.9% male. Common underlying diseases were hypertension (40.3%), dyslipidemia (19.6%), diabetes (12.3%), chronic obstructive pulmonary disease (COPD) (3.5%) and end-stage renal disease (ESRD) (3.5%). There was no significant difference in CIEDs type and number of leads in both groups. Patients in group 2 have longer implanted duration (130.2 vs 65.3 months, p = 0.01).

Our operative protocol started from superior approach (100%) with locking stylets application (100%). In group 1, laser sheath was the only main equipment for lead extractions. But in group 2, rotating mechanical sheaths were used for extensively scarred and calcified leads, which accounted for 36% of the cases.

Patients in group 2 had shorter procedural time (129.7 vs 176.1,

Table 2
Procedural outcome.

Variable	Total (n = 79)	2008–2015 (n = 60)	2018–2020 (n = 19)	p value
Procedural data				
Superior approach alone	70(84.2)	52(86.7)	18(94.7)	
Lead locking device	79(100)	60(100)	19(100)	
Laser sheath only	71(87.7)	60(100)	12(63.2)	
Rotating mechanical sheath	5(8.8)	0	5(26.3)	
Both	3(3.5)	0	2(10.5)	
Combined femoral approach	9(11.4)	8(13.3)	1(5.3)	
Outcome				
Complete procedural success	76(96.2)	58(96.6)	19(100)	0.719
Clinical success	1(1.3)	1(1.7)	0	
Procedural failure	1(1.3)	1(1.7)	0	
Duration of operation (minutes)	163.8 ± 69.5	176.1 ± 71.6	129.7 ± 50.7	0.014*
Fluoroscopic time (minutes)	12.7 ± 17.1	14.3 ± 14.2	7.8 ± 4.8	0.139
Length of stay (days)	13.5 ± 17.1	10.2 ± 13.0	20.4 ± 22.4	0.003*
Complication				
Major complication	4(5.1)	3(5)	0(0)	0.732
Death	1(1.3)	1(1.7)	0	
IVC-RA junction tear	1(1.3)	1(1.7)	0	
Pericardial Effusion	2(2.5)	2(3.3)	0	

Note: Values are mean ± SD or number of patients (%).

Clinical successes were defined as retention of a small portion of the lead (fragment ≤4 cm) that does not negatively impact the outcome goals of the procedure.

Table 3
Reimplantation and reason for no-reimplantation.

Variable	Total (n = 79)	2008–2015 (n = 60)	2018–2020 (n = 19)	p value
Reimplantation	38(48.1)	30(50.0)	8(42.1)	0.548
Bridging with externalized pacemaker	8(10.1)	6(10.0)	2(10.5)	
Timing of reimplantation(days)	10.6 ± 14.6	6.59 ± 12.2	25.9 ± 13.9	0.001*
Type of CIED reimplantation				0.384
Dual chamber pacemaker	11(13.9)	8(13.3)	3(15.8)	
Leadless pacemaker	1(1.3)	0	1(5.3)	
AICD	21(26.6)	18(30.0)	3(15.8)	
CRT-P	2(2.5)	2(3.3)	0	
CRT-D	3(3.8)	2(3.3)	1(5.3)	
Reason no-reimplantation				
Refer back to referral center	25(31.6)	18(30.0)	7(36.8)	
Patient preference	14(17.7)	10(16.7)	4(21.1)	
Major complication	2(2.5)	2(3.3)	0	

Note: Values are mean ± SD or number of patients (%).

Abbreviations: AICD, automatic implantable cardioverter defibrillator CRT-P, cardiac resynchronization therapy pacemaker; CRT-D, cardiac resynchronization therapy defibrillator; CIED, cardiac implantable electronics device.

Table 4
Successful and adverse event.

Study (Year)	Population No./Leads (n)	Implanted duration (minutes)	Successful rate (%)	Major complication (%)	Lowercase Hospital mortality (%)
Transvenous lead extraction					
LElCon (2010) [9]	1,449/2405	82.1	97.7	1.4	1.86
A.Di Monaco	18,433/NA	N/A	N/A	1.6	N/A
Meta-analysis(2014) [12]	LoV < 15/yr			1.8	
ELECTRa (2017) [10]	3, 510/4917	76.8	96.7	1.7	1.4
	LoV < 30/yr		94.3	2.4	2.5
Hosseini (2019) [6]	12,257/NA	N/A	N/A	10.42	4.11(In-hosp mortality)
				1.88 (Open heart surgery)	
Rotational mechanical sheath					
PROMET (2020) [11]	2,205/3,849	84.7	97	1	1.7
Sharma (2021) [7]	230/460	88.8	98.7	2.6	0
Ramathibodi Hospital(2021)	79/122	83.2 ± 65.9	97.5	5.1	1.3

Note: Values are mean ± SD.

Abbreviations: N/A, not available; LoV, low volume center.

p = 0.014) with a trend towards less fluoroscopic time (7.8 vs 14.3, p = 0.139). Moreover, cases of TLE after 2018 had 100% complete procedural success with no major complication.

4. Discussion

This study showed result from a low-volume, single center in Thailand where less than 10 TLE procedures are performed each year. Patients are quite younger in this study comparing to other large studies such as LEXlCon [9], ELECTRa [10] and PROMET [11] (Mean age 58 vs 63–65 years). Proportion of male was comparable to the aforementioned studies (70.9%). Proportions of types of implanted devices were similar to other previous studies, with majority of cases being pacemaker (54.4%), followed by ICDs (39.2%). Mean implanted duration of this study was 87.8 months, comparable to PROMET (84.7 month) and ELECTRa (76.8 months) as Table 4.

Infection-related indications in our study were higher than other large studies (73.2% vs 46–57%) [9–11]. This may be because of higher threshold for performing TLE in non-infected CIEDs due to the high-risk nature of TLE procedures, and financial reasons.

By using superior approach, locking stylet, laser sheath, and rotating mechanical sheath followed by transfemoral venous snaring, complete procedural success was achieved in 96.2%. This is comparable to all previous transvenous lead extraction studies (94.3–98.7%) [6,7,9–11]. Our procedural failure from cardiac avulsion occurred in 1 patient (1.8%). The incidence was in line with previously reported studies.

After the first case that required cardiac repair from apical

perforation, we moved the procedure area from cardiac catheterization laboratory to Hybrid Operating Room (Hybrid OR) for the subsequent cases. Despite moving to Hybrid OR, the first case that required open chest in the Hybrid OR did not go smoothly due to lack of systematic protocol and unfamiliarity of OR personnel to the lead extraction procedure. The systematic protocol for TLE has been developed and implemented since then.

When focused on group 2 that were performed after year 2018, the results were excellent (100% complete procedural success, 0% major complication). Moreover, although the leads in this group had longer implanted time (130.2 vs 65.3 months, p = 0.01), procedural time and fluoroscopic time were lower than group one, 129.7 vs 175.1 min (p = 0.014) and 7.8 vs 14.4 min respectively. The systematic protocol could have caused increased success rate and decreased complication. This finding correlates with clinical outcomes of TLE around the world that trended towards improved results due to more experience of operators and better operative techniques and equipment. Moreover, from our center's experience, having a systematic protocol for TLE significantly improved outcomes of the procedure despite having more complicated cases.

5. Study limitations

This retrospective study was a small observational single center study. Main limitation was the small number of patients which limits data analysis. Second limitation which is native to all retrospective studies is the inability to obtain all desired data and 8.1% of the cases had to be excluded due to this reason.

6. Conclusions

This retrospective study demonstrates that TLE using superior approach with laser sheath and rotating mechanical sheath for transvenous lead extraction is effective and safe, even outside high-volume center. Moreover, a systematic protocol for TLE help improve outcomes of the procedures.

CRedit authorship contribution statement

Natcha Soontornmanokati: Conceptualization, Methodology, Data curation, Writing – original draft. **Chulaporn Sirikhakorn:** Data curation. **Nilubon Methachittiphan:** Writing – review & editing. **Kumpol Chintanavilas:** Writing – original draft, Formal analysis. **Sanatcha Apakuppakul:** Formal analysis. **Tachapong Ngarmukos:** Supervision, Validation. **Sirin Apiyasawat:** Supervision, Validation. **Wachara Lohawijarn:** Supervision. **Pakorn Chandanammattha:** Supervision.

Declaration of competing interest

Authors declare no conflict of interest for this article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ipej.2022.02.021>.

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