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CLINICAL RESEARCH

A head-to-head comparison of laser vs. powered mechanical sheaths as first choice and second line extraction tools

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Aims During transvenous lead extraction (TLE) longer dwelling time often requires the use of powered sheaths. This study aimed to compare outcomes with the laser and powered mechanical tools.

Methods and results Single-centre data from consecutive patients undergoing TLE between 2012 and 2021 were retrospectively analysed. Efficacy and safety of the primary extraction tool were compared. Procedures requiring crossover between powered sheaths were also analysed. Moreover, we examined the efficacy of each level of the stepwise approach. Out of 166 patients, 142 (age 65.4 ± 13.7 years) underwent TLE requiring advanced techniques with 245 leads (dwelling time 9.4 ± 6.3 years). Laser sheaths were used in 64.9%, powered mechanical sheaths in 35.1% of the procedures as primary extraction tools. Procedural success rate was 85.5% with laser and 82.5% with mechanical sheaths ($P = 0.552$). Minor and major complications were observed in similar rate. Procedural mortality occurred only in the laser group in the case of three patients. Crossover was needed in 19.5% after laser and in 12.8% after mechanical extractions ($P = 0.187$). Among crossover procedures, only clinical success favoured the secondary mechanical arm (87.1 vs. 54.5%, aOR: 0.09, 95% CI: 0.01–0.79, $P = 0.030$). After step-by-step efficacy analysis, procedural success was 64.9% with the first-line extraction tool, 75.1% after crossover, 84.5% with bailout femoral snare, and 91.8% by non-emergency surgery.

Conclusion The efficacy and safety of laser and mechanical sheaths were similar, however in the subgroup of crossover procedures mechanical tools had better performance regarding clinical success. Device diversity seems to help improving outcomes, especially in the most complicated cases.

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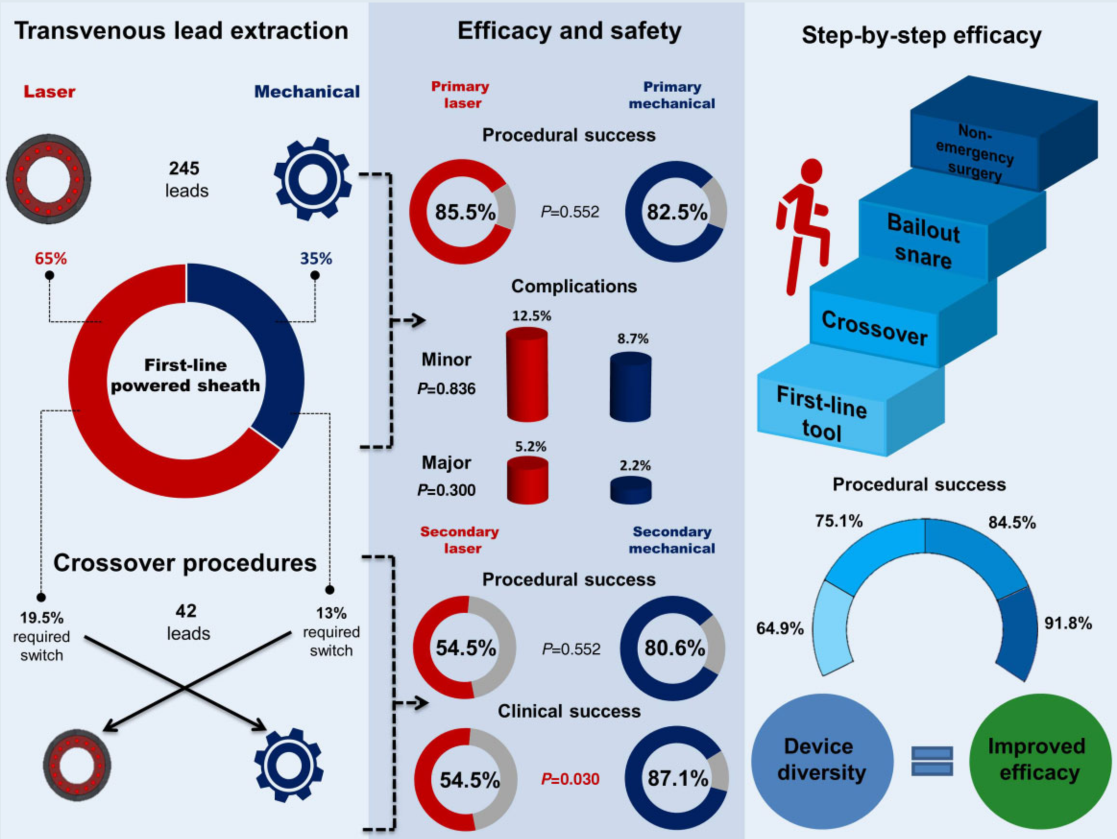
Graphical Abstract



Keywords Transvenous lead extraction • CIED • Laser sheath • Mechanical sheath • Primary extraction tool

What's new?

- Our study compares directly the safety and efficacy of primary laser and powered mechanical lead extraction procedures in a high-risk cohort with predominantly infectious indications.
- Previous publications reported data regarding laser-to-mechanical extractions, but this is the first study that gives also a straight comparison between these and mechanical-to-laser crossovers.
- We also provide data about the efficacy of each level of the stepwise approach, outlining the impact of different extraction techniques and tools.

Introduction

Transvenous lead extraction (TLE) is the gold standard therapy of cardiac implantable electronic device (CIED) related infections. The improvement of tools and techniques has made the procedure safer and more successful, resulting in widened indications.[1] Long lead dwelling time is associated with the formation of an encapsulating scar tissue around the intravascular leads,[2] therefore is considered the most important risk factor of TLE. The arrival of specialized tools, such as femoral snares, telescoping sheaths, and locking stylets made the procedure more effective and the mortality rate more favourable. The biggest improvement came with the advent of powered sheaths, which have been proved to be effective even in chronic cases with severe fibrosis.[3–7] Laser sheaths and mechanical rotating dilators are the most commonly used powered sheaths in the daily clinical practice.

Follow-up data suggest that long-term mortality after TLE is favourable,[8] however, it is important to emphasize, that procedural failure or mortality rates are low, but still not negligible. Although powered sheaths are effective, one should not forget about the hazard of vascular and cardiac lacerations which can easily lead to the patient's death even in well-prepared cases. TLE procedures often require an interdisciplinary approach,[9] especially in the case of leads with long implant times, requiring gradual implementation of various techniques and sometimes a crossover between powered sheaths. Up to these days, there has been no clear consensus regarding first-line extraction sheath selection. These complex devices impose a significant financial burden; therefore, both from safety and economical perspective it would be reasonable to choose the most effective one as first-line tool, avoiding unnecessary crossover procedures whenever is possible, saving resources and time. Since there are only few studies in the literature directly comparing different powered sheaths, we aimed to analyse the efficacy and safety of these extraction tools as first-line and as crossover devices.

Methods

Patient population

We retrospectively analysed data from consecutive patients undergoing TLE at the University of Szeged between January 2012 and February 2021. Patients' demographics, comorbidities, echocardiographic data, device and lead characteristics, indication, and details of the extraction procedures were collected at baseline.

TLE indications, procedural outcomes, and complications were defined concordant to current guidelines.[10] Indications were classified as pocket infection (local signs of inflammation, without involvement of the transvenous part of the device), systemic infection (positive blood cultures, lead or valvular vegetations or clinical signs of systemic infection), and non-infectious (broken, dysfunctional lead, other complication, upgrade, etc.).

Cases not requiring a powered sheath in order to free targeted leads were excluded. A crossover between laser and mechanical powered sheaths was implemented if success was not achievable after multiple attempts with the first-line tool.

The study was approved by the institutional review board of the University of Szeged and complies with the ethical guidelines of the Declaration of Helsinki (No: 4871).

Extraction procedure

TLE procedures were performed in our EP labs, either in deep sedation or in general anaesthesia in the vast majority of cases. Complete anaesthesiology and cardiothoracic surgical team with heart-lung machine and surgical set for emergency sternotomy were on standby. All the extractions were performed under fluoroscopic and intracardiac echocardiography guidance.

In accordance with current guidelines,[11] a stepwise approach was used during the procedures. After opening the pocket and removing the fibrotic tissue from the leads, the active fixation screw, if available, was retrieved and manual traction was performed with a conventional stylet. If this failed, a locking stylet (lead locking device, Spectranetics/Philips; Liberator, Cook Medical) was inserted and the traction was repeated. When this manoeuver was unsuccessful, a powered sheath was used. A laser (Glide Light laser sheath, Spectranetics/Philips) or a mechanical (TightRail, Spectranetics/Philips; Evolution, Cook Medical) powered extraction sheath was used at the decision of the operator. Laser sheaths were used from the beginning of the study period, mechanical sheaths were first introduced in clinical practice later, Evolution sheaths in 2013, TightRail dilators in 2015, and the Evolution RL in 2019. If necessary, a transition from laser to powered mechanical tool and vice versa was executed. These cases were considered as crossover procedures, the type of the first- and second-line powered sheath was recorded. Snare technique was also used, predominantly via femoral approach. According to the purpose of its deployment, we classified femoral snare into two categories: support approach (i.e. caudal traction) or bailout technique (i.e. attempting lead removal via the femoral vein). In a few cases, non-powered mechanical dilators (SightRail, Spectranetics/Philips; Byrd, Cook Medical) were also used at the discretion of the operator, but not in a systematic fashion.

Study endpoints

First, we analysed the efficacy of the primary powered extraction sheath. All targeted leads were divided into two groups according to the first used powered sheath (laser or mechanical). Complete procedural success (i.e. the removal of all targeted leads without any remnant or any lasting or irreversible complication), clinical success (i.e. retention of a small portion of a lead that does not negatively impact procedural goals, does not increase the risk of perforation, embolic events, perpetuation of infection, or cause any undesired outcome),[10] as well as the percentage of crossover procedures were compared between groups.

Secondly, a comparison was made including only cases where a crossover was carried out between powered sheaths, comparing the outcomes of secondary laser or secondary mechanical interventions. In this analysis, we examined if the second-line device could lead to success in situations where the first-line tool failed. To further clarify the impact of the second-line tool, the percentage of bailout femoral snare technique in the two groups was also analysed.

The safety of the two extraction tools was compared, analysing the occurrence of procedural mortality, major and minor complications.

Finally, we examined the amount of completely extracted leads at each step during the stepwise approach, after the implementation of different tools and techniques. The successful extraction process was divided into four stages: first-line powered sheath, crossover to different device, bailout femoral snare, and non-emergency surgery.

Statistical analysis

Statistical analyses were performed using SPSS version 23.0.0 (Statistical Package for Social Sciences Inc.). Continuous variables were expressed as mean ± standard deviation. Categorical data were expressed as frequencies and percentages. Two-sided *P*-values <0.05 were considered statistically significant. Risk factors for extraction outcomes were assessed by univariate and multivariate logistic regression models. Parameters with a $P < 0.10$ on univariate analysis were included into the multivariate models. The Kolmogorov–Smirnov test was used to evaluate the normal distribution of continuous data. Pearson's chi-squared test was used for categorical variables and the two-sample *t*-test or the Mann–Whitney U test for continuous variables to assess differences among patients groups. All statistical analyses were adjusted to clinical parameters that may influence outcomes (comorbidities, lead characteristics, indications of TLE, laboratory markers, additional use of non-powered mechanical dilators).

Results

Study population

One hundred and sixty-six patients underwent TLE procedure between May 2012 and February 2021 at the University of Szeged. A total of 337 leads were extracted. Patients, whose extraction procedure required at least one powered extraction tool, were included in the current study. One hundred and forty-two patients met this inclusion criterion with a total of 289 leads. The average number of leads per patient was 2.1 ± 0.9. The mean age of the patients was 65.4 ± 13.7 years, 78% ($n = 111$) being male. Fifty-Four per cent ($n = 77$) of the patients had pacemakers, 26% ($n = 37$) implantable cardioverter defibrillators, and 20% ($n = 28$) cardiac resynchronization therapy systems. Patients' demographics and comorbidities are shown in *Table 1*.

Of the above-mentioned 289 leads, 245 (mean dwelling time 9.4 ± 6.3 years) required the help of at least one powered sheath in order to be extracted, forming the cohort of our study. Of these, 38% ($n = 93$) were right atrial, 37% ($n = 89$) right ventricular pacing, 20% ($n = 50$) right ventricular defibrillator, and 5% ($n = 13$) coronary sinus leads. Seventy-one per cent ($n = 175$) of the leads had passive fixation. Among defibrillator leads, 30 were dual and 20 single-coil electrodes.

Extraction procedure

The indication of the procedure was predominantly infectious, pocket infection in 74% ($n = 105$) and systemic infection in 20% ($n = 29$). Non-infectious indications were present only in 6% ($n = 8$) of the cases. Twenty-five per cent ($n = 35$) of the patients had a previous extraction attempt in other institutions.

In the case of the 245 leads whose extraction required the use of powered sheaths, a laser device was used in 64.9% ($n = 159$), a powered mechanical dilator in 35.1% ($n = 86$) at first step. Among powered mechanical tools, a TightRail sheath was used in 90%, an Evolution device in 10% of the cases. A crossover between laser and mechanical powered sheaths was needed in 17.1% ($n = 42$) of the leads. The deployment of femoral snare technique was necessary in 27.3% ($n = 67$) of the cases. The technique was used as a support approach in the case of 26 leads and for bailout lead removal in the case of 41 leads. Of the 41 bailout femoral lead removal attempts, 23 were successful. Non-powered mechanical sheaths were used in a very low percentage, in 6% ($n = 15$) of the cases, all in the primary laser group, two of these cases being a crossover procedure. Complete procedural success was

Table 1 Patient baseline characteristics

***n* = 142**	
Sex (male)	111 (78%)
Age(years)	65.4 ± 13.7
Device type	
PM	77 (54%)
ICD	37 (26%)
CRT	28 (20%)
Comorbidities	
Hypertension	115 (81%)
Heart failure	69 (48.6%)
Cardiomyopathies (CM)	57 (40.1%)
Dilated CM	29
Ischaemic CM	24
Hypertrophic CM	4
Ischaemic heart disease	56 (39.4%)
Atrial fibrillation	52 (36.6%)
Diabetes mellitus	38 (26.8%)
Obesity	33 (23.2%)
Hyperlipidaemia	30 (21.1%)
COPD	15 (10.6%)
Chronic kidney disease	14 (9.9%)
Stroke/TIA	11 (7.7%)
DVT	10 (7%)
PAD	9 (6.3%)
Laboratory parameters	
EF (%)	53.1 ± 17
Se creatinine (umol/l)[a]	99.3 ± 43
CRP (mg/l)[b]	<2 2–50 50<
	29 93 9
PCT (ng/ml)[c]	<0.06 >0.06
	49 35

[a]Available for 139 pts.
[b]Available for 131 pts.
[c]Available for 84 pts.
COPD, chronic obstructive pulmonary disease; TIA, transient ischaemic attack; DVT, deep vein thrombosis; PAD, peripheral artery disease; EF, ejection fraction; CRP, c-reactive protein; PCT, procalcitonin.

achieved in 85% ($n = 207$), clinical success in 90% ($n = 220$) of the leads. Eighteen leads were extracted during non-emergency sternotomy, leading to a 92% ($n = 225$) complete procedural and 97% ($n = 237$) clinical success.

Efficacy of primary extraction tool

In 93 patients with 159 leads, a laser sheath and in 49 patients with 86 leads a powered mechanical sheath was used as first-line extraction tool. The two groups' demographics, comorbidities, and lead characteristics were comparable, including the average lead dwelling time (9.4 ± 5.8 years for laser and 9.5 ± 7.1 for mechanical extractions). Detailed comparison of the groups is showed in *Table 2*.

The efficacy of the primary extraction tool was not different in terms of complete procedural (85.5% for laser vs. 82.5% for mechanical extractions, adjusted OR: 1.49, 95% CI: 0.63–3.53, $P = 0.363$) or clinical success (91.2% for laser vs. 86% for mechanical extractions, adjusted OR: 1.75, 95% CI: 0.7–4.39, $P = 0.229$). Regarding complete procedural success, univariate analyses identified cardiomyopathies and longer lead dwelling time as prognostic factors for extraction failure. After multivariate analysis only longer lead dwelling time remained statistically significant (adjusted OR: 0.84, 95% CI: 0.79–0.9, $P < 0.001$) (see Supplementary material online, *Table S1*).

Although crossover was needed in a numerically higher percentage after using laser sheaths (19.5 vs. 12.8%), in multivariate analysis longer lead dwelling time (adjusted OR: 1.12, 95% CI: 1.07–1.2, $P < 0.001$) and defibrillator or coronary sinus lead type (adjusted OR: 2.25 95% CI: 1.25–4.04, $P = 0.007$) but not the primarily used sheath type (adjusted OR: 1.77, 95% CI: 0.80–3.90, $P = 0.157$) proved to be significant risk factors for crossover.

Comparison of crossover procedures

In order to assess the outcomes of complex scenarios, extraction data of leads requiring a switch between powered tools were analysed (42 out of 245 leads). A laser sheath was used in the case of 31 leads, a powered mechanical sheath in the case of 11 leads as first-line extraction tool before the implementation of crossover. The comparison of these two groups is presented in *Table 3*. Notably, dwelling time and defibrillator lead ratio were higher in the secondary laser arm, indicating more complicated cases in this subgroup. Regarding complete procedural success, a powered mechanical sheath was successful in 80.6% (25 out of 31 leads), a laser device in 54.5% (6 out of 11 leads) of the cases as second-line tool, without statistically significant difference after adjustment to dwelling time and lead type (adjusted OR: 0.16, 95% CI: 0.02–1.22, $P = 0.077$). Although, for clinical success, the difference crossed the significance threshold even after adjustment, powered mechanical sheaths having a success rate of 87.1%, while this being 54.5% in the case of laser sheaths (adjusted OR: 0.09, 95% CI: 0.01–0.79, $P = 0.030$) (see Supplementary material online, *Table S2*). The level at which the first-line device failed is shown in *Figure 1*, suggesting higher incidence of crossover at extracardiac level in the primary laser arm.

Femoral snare technique was predominantly used after crossover, except six cases (two in secondary mechanical and four in secondary laser group), when this tool was already used for caudal traction before crossover. The percentage of successful bailout femoral snare was numerically higher in the case of second-line laser procedures than in the case of second-line mechanical extractions, without statistically significant difference (16 vs. 9%, OR: 1.93, 95% CI: 0.19–18.57, $P = 0.572$).

Device safety and complications

Major complications occurred in 4.2% ($n = 6$) of the overall cohort, minor complications in 11.4% ($n = 16$) without significant difference between primary laser and mechanical groups (*Table 4*). Major complications occurred in form of hemothorax in one case which resulted in death despite urgent sternotomy and hemopericardium in five cases of which two were manageable with pericardiocentesis and one with cardiac surgery. Multivariate analysis identified longer implant duration predictive for major complications (adjusted OR: 1.12, 95% CI: 1.02–1.32, $P = 0.018$) and heart failure for minor complications (adjusted OR: 3.68, 95% CI: 1.08–12.51, $P = 0.037$).

Three procedural deaths were recorded, all in the primary laser arm, one being a crossover procedure. All three patients had a previous extraction attempt at other institutions. A superior vena cava (SVC) injury was observed in all three cases, death occurred despite pericardiocentesis and urgent sternotomy. One patient died after completely successful TLE at the referral center's intensive care unit in generalized sepsis.

Table 2 Distribution of baseline characteristics between primary laser and mechanical groups

Variable[a]	Total $n = 142$	Laser $n = 93$	Powered mechanical $n = 49$	*P*-value
Sex (male)	111 (78%)	70 (75.3%)	41 (83.7%)	0.249
Age (years)	65.4 ± 13.7	67 ± 13.6	62.6 ± 13.8	0.069
Indication				
Pocket infection	105 (73.9%)	69 (74.2%)	36 (73.5%)	0.926
Systemic infection	29 (20.4%)	20 (21.5%)	9 (18.4%)	0.659
Non-infectious	8 (5.6%)	4 (4.3%)	4 (8.2%)	0.447
Hypertension	115 (81%)	71 (76.3%)	44 (89.8%)	0.052
Cardiomyopathies	57 (40.1%)	33 (35.5%)	24 (49%)	0.119
Ischaemic heart disease	56 (39.4%)	36 (38.7%)	20 (40.8%)	0.807
Atrial fibrillation	52 (36.6%)	35 (37.6%)	17 (34.7%)	0.730
Diabetes mellitus	38 (26.8%)	23 (24.7%)	15 (30.6%)	0.452
Obesity	33 (23.2%)	26 (28%)	7 (14.3%)	0.067
Heart failure	69 (48.6%)	48 (51.6%)	21 (42.9%)	0.321
Hyperlipidaemia	30 (21.1%)	20 (21.5%)	10 (20.4%)	0.879
COPD	15 (10.6%)	8 (8.6%)	7 (14.3%)	0.295
Chronic kidney disease	14 (9.9%)	7 (7.5%)	7 (14.3%)	0.240
Stroke/TIA	11 (7.7%)	8 (8.6%)	3 (6.1%)	0.748
DVT	10 (7%)	9 (9.7%)	1 (2%)	0.165
EF (%)	53.1 ± 17	55.3 ± 16	49.2 ± 18.3	0.079
Se creatinine (umol/l)	99.3 ± 43	98.2 ± 38.4	101.5 ± 52.1	0.870
Lead characteristics	**Total N = 245**	**Laser N = 159**	**Powered mechanical N = 86**	
Lead dwelling time (years)	9.4 ± 6.3	9.4 ± 5.8	9.5 ± 7.1	0.339
Pacing lead	182 (74.3%)	118 (74.2%)	64 (74.4%)	0.972
Defibrillator lead	50 (20.4%)	33 (20.8%)	17 (19.8%)	0.855
Single/dual coil ratio	30/20	18/15	12/5	0.273
Coronary sinus lead	13 (5.3%)	8 (5%)	5 (5.8%)	0.773
Crossover procedure	42 (17.1%)	31 (19.5%)	11 (12.8%)	0.184
Successful bailout snare	23 (9.4%)	19 (11.9%)	4 (4.7%)	0.062

[a]Values are the number of patients (%) or mean (SD).

Step-by-step efficacy

Procedural success was 64.9% with first-line extraction tool, 75.1% after crossover to a different powered sheath, reached 84.5% with the utilization of bailout femoral snare technique and finally was 91.8% after extracting 18 leads during non-emergency surgery (*Figure 2*).

Discussion

Main findings

With the constant increase of CIED implantations,[12] the number of TLE procedures is also growing. Previous studies identified numerous factors that can influence the outcomes of TLE.[13,14] The most important ones are implant duration, lead characteristics, patient comorbidities, the indication of the extraction, and the experience of the operator. However, even taking in consideration these factors, it is hard to formulate a one fits all extraction algorithm. Nowadays, thanks to technical advancements, even leads with longer dwelling time are candidates of a potentially successful TLE. The two important powered tools, dominating the arena of lead extraction, are laser and powered mechanical sheaths; however, only a few studies compared directly the strengths and weaknesses of these devices. The question of first-line tool selection is still seeking an answer. Our study showed similar efficacy and safety between laser and powered mechanical extraction sheaths with moderate superiority favouring powered mechanical tools in the subgroup of crossover procedures. Based on our results, the availability of different extraction tools, including both mechanical and laser sheaths, femoral snare technique and back-up heart surgery, may help to improve outcomes in the case of the most complicated procedures.

Device efficacy

Our analysis did not reveal significant difference between the efficacy of laser and mechanical tools as first-line powered sheaths. These findings are in line with previously published studies comparing the two

Table 3 Comparison of crossover groups

	Secondary powered mechanical ($n = 31$)	Secondary laser ($n = 11$)	*P*-value	
Lead dwelling time (years)	11 ± 6.87	14.7 ± 7.6	0.181	
Pacing lead	71% (22)	54.5% (6)	0.459	
Defibrillator lead	16.1% (5)	45.4% (5)	0.094	
Single/dual coil ratio	4/1	2/3	0.524	
Coronary sinus lead	12.9% (4)	0% (0)	0.558	
Pocket infection	74.2% (23)	90.9% (10)	0.403	
Systemic infection	12.9% (4)	9.1% (1)	1	
Non-infectious	12.9% (4)	0% (0)	0.558	
Successful bailout snare	16.1% (5)	9.1% (1)	1	
Complete procedural success	80.6% (25)	54.5% (6)	0.077	adjusted
Clinical success	87.1% (27)	54.5% (6)	0.030	adjusted

approaches,[15–18] success rates ranging from 76.7 to 97.3% for laser and from 88.9 to 93.3% for powered mechanical sheaths. Our complete procedural success rate was 85.5% for laser and 82.5% for mechanical extractions, the results of the mechanical arm being poorer than those published in the literature. However, it is important to mention that the average lead dwelling time in our cohort was the highest of the above-cited studies (9.4 years vs. 6.45–8.9 years). In our multivariate logistic regression analysis, only longer implant duration was identified as an independent predictor for procedural failure. Lead dwelling time is a well-known risk factor[1,2,13] that may explain the observed discrepancy. The fact, that a quarter of our patients already underwent an unsuccessful extraction procedure, may also have contributed to the lower success rate.

Only two studies reported data regarding crossover procedures.[17,18] In our series, the overall complete procedural success rate of crossover extractions was 73.8%, which is in line with the results published by Quin *et al*. and Misra *et al*. (75.8 and 61.5%, respectively).

In the case of laser-to-mechanical procedures, we found that leads which could not be extracted with a primary laser approach were freed in 80.6% after switching to powered mechanical sheath. Quin *et al*. also published a 75.8% success rate in the case of laser-to-mechanical procedures, concluding that powered mechanical tools can be used efficiently as a second-line extraction tool. Misra *et al*. also stated that in their study, there was a trend towards benefit in the use of powered mechanical tools after laser devices.

To the best of our knowledge, no previous study has reported thorough results of opposite crossover situations and compared directly laser and powered mechanical tools as second-line devices. In our series, mechanical-to-laser procedures had a 54.5% complete procedural success rate. After adjustment to lead dwelling time clinical success rates differed significantly between the two groups in favour of powered mechanical tools (87.1 vs. 54.5%). Although procedural success rate also favoured powered mechanical tools, it was not significantly different between the two groups in multivariate analysis; therefore, it would be misleading to conclude, that powered mechanical sheaths are superior to laser devices. On the contrary, the fact that half of the crossover procedures in the primary mechanical arm would have failed without switching to a laser tool emphasizes the necessity of device diversity, which is essential in a tertiary extraction centre. Further investigation in larger cohort or a proper meta-analysis is warranted to clarify if there is a clinically significant difference between the two extraction methods.

Device safety and complications

Regarding procedural safety, we did not find significant difference between powered sheaths. Despite the fact that procedural mortality occurred only in primary laser group, we consider that it would be inappropriate to attribute these deaths only to device choice. All three procedures were complex, targeting leads with long dwelling times (oldest leads 19, 19 and 8 years old) that already underwent a previous extraction attempt.

The major complication and all-cause in-hospital mortality rate of our study are slightly higher, than in the case of similar procedure volume centres in the ELECTRa registry.[13] Notably, in the current study, only patients whose extraction required at least one powered sheath were enrolled, indicating more complicated procedures. This is well reflected by the difference in the average dwelling-times between the two studies (9.4 ± 6.3 in our vs. 6.4 ± 5.4 in the ELECTRa registry). The infectious indication rate was also substantially higher in our cohort (94 vs. 53%), which may also have contributed to the higher complication rate.

Data regarding device safety are scarce in literature. In a recent study, Diaz *et al.*[19] find that in the case of laser sheaths, procedural mortality risk was almost seven times higher compared with powered mechanical sheaths based on the MAUDE database. However, as mentioned in their study and in a letter by Defaye *et al.*,[20] considerable limitations were present, patient and lead related data (comorbidities, dwelling times) being gappy. In an abstract, SunYong Lee *et al.* compared the results of 13 powered mechanical and 33 laser TLE studies, and found a 6.5-fold higher mortality risk in the case of laser tools. A serious limitation of their analysis was, that none of the examined studies compared directly procedural safety between powered sheaths, thus their results should be interpreted carefully.

Step-by-step efficacy

Our results emphasize the necessity of a stepwise approach, every tool and technique playing an essential role in the TLE orchestra. In a recent study, Issa *et al.*[21] raised the idea of omitting surgical backup in the case of low-risk patients. This would mean a more resource friendly approach, however, some questions still arise, well summarized by Picini *et al.*[22] in their editorial commentary. As stated by them, the possibility of SVC tears and cardiac perforation is not fully eliminated by avoiding the use of laser in the SVC. Beside emergency sternotomy, the presence of a surgical back-up team also entails the possibility of non-emergency surgical lead extraction, without the interruption of the procedure and abandoning targeted leads.

To further emphasize the impact of device diversity, it is important to mention that there are other extraction tools that were not analysed thoroughly in the current study. For instance, several publications support the use of the non-powered mechanical dilators. Bongiorni *et al.* reported a 98.4% procedural success with a 0.7% major complication rate (0.3% procedural death rate) using polypropylene sheaths and multiple venous approaches in a large cohort.[23] Segreti *et al.* reported no SVC tear during the extraction of 2343 leads using polypropylene sheaths, major complications occurred only in 0.7% ($n = 9$) of the cases in form of cardiac tamponade, of which seven patients survived the procedure.[24] In a report from the ELECTRa registry, Zucchelli *et al.* found that mechanical dilatation was an independent predictor of a lower incidence of vascular avulsion or tear as compared with the use of powered sheaths.[25] Stefańczyk *et al.* observed no in-hospital death after the extraction of 1000 patients, using mainly non-powered mechanical dilators.[26]

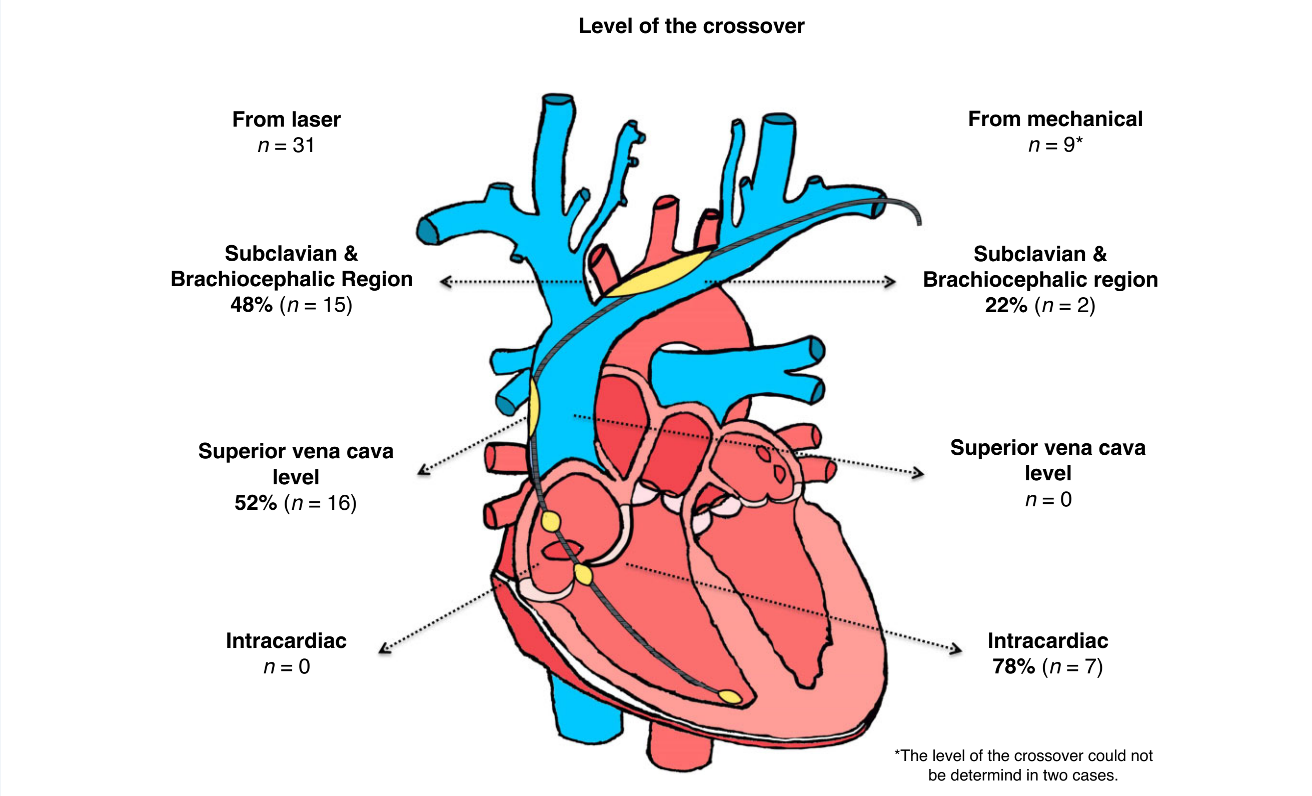


Figure 1 Level of the crossover procedures.

Table 4 Procedural complications with the primary extraction tool

	Laser (*n* = 96)	Powered mechanical (*n* = 46)	adjusted OR	95% CI	*P*-value
Minor complications	12 (12.5%)	4 (8.7%)	1.15	0.32–4.05	0.836
Haematoma	8	4			
Hypotension	2	0			
Arrhythmia	2	0			
Major complications	5 (5.2%)	1 (2.2%)	3.36	0.34–33.35	0.300
Pericardial effusion	2	1			
Death	3	0			

Different extraction techniques also proved to be valuable in order to achieve better outcomes. In our study, the jugular approach was used only in a minority of the cases, but there are studies which confirm, that this method can increase TLE success rate.[23,27,28]

As showed in *Figure 2*, 64.9% of the leads were removed with a single tool alone, while another about 30% required the application of further approaches. Thus, in a tertiary extraction centre optimally the whole TLE arsenal, including heart surgery, should be available and the operators should be experienced in the application of different techniques.

Limitations

Our study has all the limitations of retrospective analyses. At our institution, powered mechanical extraction sheaths were first introduced in clinical practice in 2013, thus in the case of previous procedures a crossover from laser to a mechanical device was not possible. Primary laser procedures were almost twice as common as mechanical extractions; therefore, the mechanical arm was underrepresented in our cohort. Two types of powered mechanical extraction sheaths were used in this study that may inhomogenize our results. Only 42 leads (17% of the 245 leads) formed the crossover subgroup; therefore, the crossover subgroup analysis is definitely underpowered. The high infectious indication rate and the number of previous extractions attempts in our study make it hard to generalize the results to the ordinary TLE population, in which the number of non-infectious indications is increasing. There were devices and techniques (for instance, polypropilen sheaths, jugular approach, etc.), which were used only in a few cases, therefore our study could not analyse their impact on TLE outcomes.

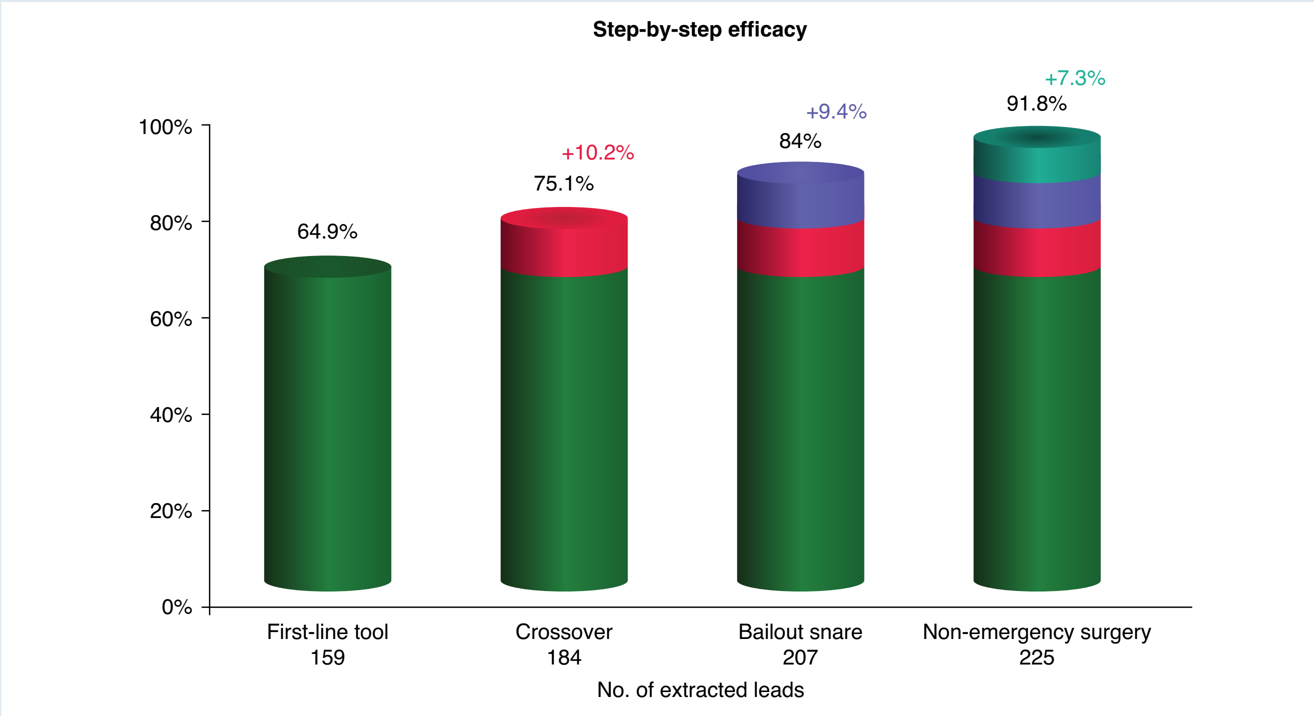


Figure 2 Step-by-step complete procedural success rate.

Conclusion

In our study, there was no significant difference between laser and mechanical devices as primary extraction sheaths. In the subgroup of crossover procedures, the complete procedural success rates did not differ significantly, although, clinical success favoured the secondary mechanical arm. Based on the step-by-step analysis device diversity can help to improve TLE outcomes, especially in complicated cases.

Supplementary material

Supplementary material is available at *Europace* online.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

References

1. Diemberger I, Mazzotti A, Giulia MB, Cristian M, Matteo M, Letizia ZM *et al.* From lead management to implanted patient management: systematic review and meta-analysis of the last 15 years of experience in lead extraction. *Expert Rev Med Devices* 2013;**10**: 551–73. Erratum in: Expert Rev Med Devices. 2013 Nov; 10(6):855. PMID: 23895081.
2. Esposito M, Kennergren C, Holmström N, Nilsson S, Eckerdal J, Thomsen P *et al.* Morphologic and immunohistochemical observations of tissues surrounding retrieved transvenous pacemaker leads. *J Biomed Mater Res* 2002;**63**:548–58. PMID: 12209900.
3. Wilkoff BL, Byrd CL, Love CJ, Hayes DL, Sellers TD, Schaerf R *et al.* Pacemaker lead extraction with the laser sheath: results of the pacing lead extraction with the excimer sheath (PLEXES) trial. *J Am Coll Cardiol* 1999;**33**:1671–6. PMID: 10334441.
4. Wazni O, Epstein LM, Carrillo RG, Love C, Adler SW, Riggio DW *et al.* Lead extraction in the contemporary setting: the LExICon study: an observational retrospective study of consecutive laser lead extractions. *J Am Coll Cardiol* 2010;**55**:579–86. Erratum in: J Am Coll Cardiol. 2010 Mar 9; 55(10):1055. PMID: 20152562.
5. Starck CT, Gonzalez E, Al-Razzo O, Mazzone P, Delnoy PP, Breitenstein A *et al.* Results of the patient-related outcomes of mechanical lead extraction techniques (PROMET) study: a multicentre retrospective study on advanced mechanical lead extraction techniques. *Europace* 2020;**22**:1103–10. Erratum in: Europace. 2020 Nov 1; 22(11):1702. PMID: 32447388; PMCID: PMC7336182.
6. Sharma S, Lee BK, Garg A, Peyton R, Schuler BT, Mason P *et al.* Performance and outcomes of transvenous rotational lead extraction: results from a prospective, monitored, international clinical study. *Heart Rhythm O2* 2021;**2**:113–21. PMID: 34113913; PMCID: PMC8183877.
7. Monsefi N, Waraich HS, Vamos M, Erath J, Sirat S, Moritz A *et al.* Efficacy and safety of transvenous lead extraction in 108 consecutive patients: a single-centre experience. *Interact Cardiovasc Thorac Surg* 2019;**28**:704–8. PMID: 30597017.
8. Zsigmond EJ, Miklos M, Vida A, Benak A, Makai A, Schvartz N *et al.* Reimplantation and long-term mortality after transvenous lead extraction in a high-risk, single-center cohort. *J Interv Card Electrophysiol* 2021. https://doi.org/10.1007/s10840-021-00974-4. PMID: 33723694.
9. Benak A, Kohari M, Besenyi Z, Makai A, Saghy L, Vamos M *et al.* Management of cardiac implantable electronic device infection using a complete interdisciplinary approach. *Herzschrittmacherther Elektrophysiol* 2021;**32**:124–7. English. Epub 2020 Oct 23. PMID: 33095291.
10. Bongiorni MG, Burri H, Deharo JC, Starck C, Kennergren C, Saghy L *et al.* 2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS. *Europace* 2018;**20**:1217. Erratum in: Europace. 2018 Jul 1; 20(7):1167. PMID: 29566158.
11. Blomström-Lundqvist C, Traykov V, Erba PA, Burri H, Nielsen JC, Bongiorni MG *et al.* European heart rhythm association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections-endorsed by the heart rhythm society (HRS), the Asia pacific heart rhythm

society (APHRS), the latin American heart rhythm society (LAHRS), international society for cardiovascular infectious diseases (ISCVID) and the European society of clinical microbiology and infectious diseases (ESCMID) in collaboration with the European association for cardio-thoracic surgery (EACTS). *Europace* 2020;**22**:515–49. PMID: 31702000; PMCID: PMC7132545.
12. Bradshaw PJ, Stobie P, Knuiman MW, Briffa TG, Hobbs MS. Trends in the incidence and prevalence of cardiac pacemaker insertions in an ageing population. *Open Heart* 2014;**1**: e000177. PMID: 25512875; PMCID: PMC4265147.
13. Bongiorni MG, Kennergren C, Butter C, Deharo JC, Kutarski A, Rinaldi CA *et al.* The European lead extraction ConTRolled (ELECTRa) study: a European heart rhythm association (EHRA) registry of transvenous lead extraction outcomes. *Eur Heart J* 2017; **38**:2995–3005. PMID: 28369414.
14. Milman A, Zahavi G, Meitus A, Kariv S, Shafir Y, Glikson M *et al.* Predictors of short-term mortality in patients undergoing a successful uncomplicated extraction procedure. *J Cardiovasc Electrophysiol* 2020;**31**:1155–62. Epub 2020 Mar 13. PMID: 32141635.
15. Starck CT, Rodriguez H, Hürlimann D, Grünenfelder J, Steffel J, Salzberg SP *et al.* Transvenous lead extractions: comparison of laser vs. Mechanical approach. *Europace* 2013;**15**:1636–41. Epub 2013 Apr 12. PMID: 23585255.
16. Mazzone P, Tsiachris D, Marzi A, Ciconte G, Paglino G, Sora N *et al.* Advanced techniques for chronic lead extraction: heading from the laser towards the evolution system. *Europace* 2013;**15**:1771–6. Epub 2013 May 3. PMID: 23645529.
17. Qin D, Chokshi M, Sabeh MK, Maan A, Bapat A, Bode WD *et al.* Comparison between TightRail rotating dilator sheath and GlideLight laser sheath for transvenous lead extraction. *Pacing Clin Electrophysiol* 2021;**44**:895–902. Epub 2021 Mar 27. PMID: 33675073.
18. Misra S, Swayampakala K, Coons P, Cerbie C, Guifarro A, Lesiczka M *et al.* Outcomes of transvenous lead extraction using the TightRail™ mechanical rotating dilator sheath and excimer laser sheath. *J Cardiovasc Electrophysiol* 2021;**32**:1969–78. Epub 2021 Jun 1. PMID: 34028112.
19. Diaz CL, Guo X, Whitman IR, Marcus GM, Pellegrini CN, Beygui RE *et al.* Reported mortality with rotating sheaths vs. laser sheaths for transvenous lead extraction. *Europace* 2019;**21**:1703–9. PMID: 31545350.
20. Defaye P, Diemberger I, Rinaldi CA, Hakmi S, Nof E. Mortality during transvenous lead extraction: is there a difference between laser sheaths and rotating sheaths? *Europace* 2020;**22**:989. PMID: 32087009.
21. Issa ZF. Transvenous lead extraction in 1000 patients guided by intraprocedural risk stratification without surgical backup. *Heart Rhythm* 2021;**18**:1272–8. Epub 2021 Mar 27. PMID: 33781982.
22. Piccini JP Sr, Carrillo RG. Attempted lead extraction in low-risk patients without surgical backup: progress or peril? *Heart Rhythm* 2021;**18**:1279–80. Epub 2021 May 20. PMID: 34023502.
23. Bongiorni MG, Soldati E, Zucchelli G, Di Cori A, Segreti L, De Lucia R *et al.* Transvenous removal of pacing and implantable cardiac defibrillating leads using single sheath mechanical dilatation and multiple venous approaches: high success rate and safety in more than 2000 leads. *Eur Heart J* 2008;**29**:2886–93. Epub 2008 Oct 23. PMID: 18948356.
24. Segreti L, Giannotti Santoro M, Di Cori A, Fiorentini F, Zucchelli G, Bernini G *et al.* Safety and efficacy of transvenous mechanical lead extraction in patients with abandoned leads. *Europace* 2020;**22**:1401–8. PMID: 32681177.
25. Zucchelli G, Di Cori A, Segreti L, Laroche C, Blomstrom-Lundqvist C, Kutarski A *et al.* Major cardiac and vascular complications after transvenous lead extraction: acute outcome and predictive factors from the ESC-EHRA ELECTRa (European lead extraction ConTRolled) registry. *Europace* 2019;**21**:771–80. PMID: 30590520.
26. Stefańczyk P, Nowosielecka D, Tułecki Ł, Tomków K, Polewczyk A, Jacheć W *et al.* Transvenous lead extraction without procedure-related deaths in 1000 consecutive patients: A single-center experience. *Vasc Health Risk Manag* 2021;**17**:445–59. PMID: 34385818.
27. Bongiorni MG, Segreti L, Di Cori A, Zucchelli G, Viani S, Paperini L *et al.* Safety and efficacy of internal transjugular approach for transvenous extraction of implantable cardioverter defibrillator leads. *Europace* 2014;**16**:1356–62. Epub 2014 Apr 2. PMID: 24696221.
28. Bongiorni MG, Di Cori A, Segreti L, Zucchelli G, Viani S, Paperini L *et al.* Transvenous extraction profile of riata leads: procedural outcomes and technical complexity of mechanical removal. *Heart Rhythm* 2015;**12**:580–7. Epub 2014 Dec 10. PMID: 25499627.