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**META-ANALYSIS**

# Safety and success of transvenous lead extraction using excimer laser sheaths: a meta-analysis of over 1700 patients

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**Aims** While numerous studies have demonstrated favourable safety and efficacy of the excimer laser sheath for transvenous lead extraction (TLE) in smaller cohorts, comprehensive large-scale investigations with contemporary data remain scarce. This study aims to evaluate the safety and performance of laser-assisted TLE through a meta-analysis of contemporary data.

**Methods and results** A systematic literature search was conducted to identify articles that assessed the safety and performance of the spectranetics laser sheath (SLS) II and GlideLight Excimer laser sheaths in TLE procedures between 1 April 2016 and 31 March 2021. Safety outcomes included procedure-related death and major/minor complications. Performance outcomes included procedural and clinical success rates. A random-effects, inverse-variance-weighting meta-analysis was performed to obtain the weighted average of the evaluated outcomes. In total, 17 articles were identified and evaluated, including 1729 patients with 2887 leads. Each patient, on average, had 2.3 ± 0.3 leads with a dwell time of 7.9 ± 3.0 years. The TLE procedural successes rate was 96.8% [1440/1505; 95% CI: (94.9–98.2%)] per patient and 96.3% [1447/1501; 95% CI: (94.8–97.4%)] per lead, and the clinical success rate per patient was 98.3% [989/1010, 95% CI: (97.4–99.0%)]. The procedure-related death rate was 0.08% [7/1729, 95% CI: (0.00%, 0.34%)], with major and minor complication rates of 1.9% [41/1729; 95% CI: (1.2–2.8%)] and 1.9% [58/1729; 95% CI: (0.8–3.6%)], respectively.

**Conclusion** This meta-analysis demonstrated that excimer laser sheath-assisted TLE has high success and low procedural mortality rates. It provides clinicians with a reliable and valuable resource for extracting indwelling cardiac leads which require advanced extraction techniques.

**Keywords** Cardiac implantable electronic devices • Excimer laser sheath • SLS II • GlideLight • Transvenous lead extraction



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## What's new?

- The meta-analysis of data from 2016–2021 showed that excimer laser sheath assisted transvenous lead extraction (TLE) is a highly successful technique for the removal of cardiac leads.
- The study confirmed the safety of the procedure, demonstrating low rates of procedure-related death and both minor and major complications.
- This comprehensive meta-analysis contributes significantly to the current body of knowledge by supplementing previously small-scale studies with large-scale, contemporary data, confirming previous findings.
- Excimer laser sheath assisted TLE offers a safe and effective method for the extraction of indwelling cardiac leads requiring advanced extraction techniques.

# Introduction

Transvenous lead extraction (TLE) procedures have become increasingly prevalent, driven by the growing number of cardiac implantable electronic devices (CIED) implanted in recent decades. Indications for TLE include infection, lead malfunction, lead-related complications, access to magnetic resonance imaging, chronic pain, and system upgrade.[1] TLE can be accompanied by serious complications due to fibrous adhesions that develop between the leads and cardiovascular structures. Consequently, TLE procedures typically follow a stepwise approach, moving from simple to more complex strategies in order to achieve success while minimizing the risk of major complications.[1,2] Mechanical rotating sheaths and excimer laser sheaths are two commonly used advanced TLE tools that have improved success rates and safety profiles.[3] Both devices are designed to disrupt the tissues adhering to cardiac leads through mechanical cutting or photoablation, thereby facilitating the safe and successful extraction of the indwelling transvenous leads. To date there are no large-scale randomized studies comparing mechanical vs. laser powered sheathes-assisted TLE, and comparisons of these techniques have been reported in some non-randomized studies[4–6] with inherent bias.[7]

A recent meta-analysis of studies published between 1998 and 2017 showed higher mortality and lower success of laser-assisted TLE compared to mechanical rotating sheathes,[8] but the study evaluated historically remote studies and did not assess the current state of excimer laser sheath-assisted TLE procedures. We conducted a meta-analysis of contemporary data, concentrating on studies from the past 5 years, to assess the procedural safety and outcomes of TLE with excimer laser sheaths. Our study aims to evaluate the outcomes of laser-assisted TLE when the technique is widely implemented to provide updated evidence from extensive patient cohorts.

# Methods

## Literature search

A systematic literature search was performed to identify articles relevant to the evaluation of the safety and performance of the Spectranetics Laser Sheath (SLS) II and GlideLight laser sheath devices for TLE procedures. The literature searches were conducted in the PubMed database and using the Google Scholar online search engine.

The SLS II and GlideLight laser sheath search was performed using the search syntax covering the period from 1 April 2016 to 31 March 2021. The PubMed search syntax included: D1 ['laser' AND ('lead extraction' OR 'lead extraction' OR 'lead removal' OR 'lead placement')], D2 ('SLS II' OR 'GlideLight'). The Google Scholar search syntax was: D3 [('Philips' OR 'Spectranetics') AND ('SLS II' OR 'GlideLight')]. A total of 172 unique references were identified and reviewed with regard to their relevance using the following criteria:

(1) the article should explicitly refer to the SLS II or GlideLight devices or contain additional information indicating that these devices were used.
(2) the article should include data obtained from a sufficiently large study (≥10 patients).
(3) the article should report on data obtained from a clinical application consistent with the intended use and from the intended treatment population of the SLS II and GlideLight devices.
(4) clinical data obtained with the SLS II or GlideLight devices should be extractable for analysis.
(5) at least 75% of the procedures were performed using the SLS II or GlideLight device in combination with other devices.

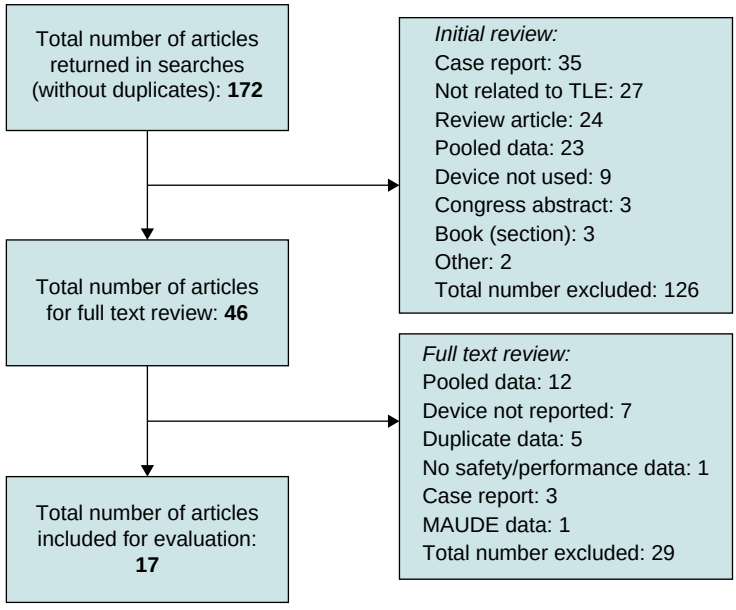


**Figure 1** SLS II and GlideLight device literature search and review flow chart.

(6) the article should be published in a peer-reviewed journal.
(7) the article should be published in the English language.

Based on these criteria, 17 clinical studies were identified and included for evaluation and data extraction. An overview of the SLS II and GlideLight literature search and assessment process is shown in *Figure 1*. Fourteen studies used the SLS II or GlideLight devices in 100% of procedures. In the remaining three studies, the laser devices were used in 75%,[9] 91%,[10] and 98%[11] of the procedures. As it was not possible to separate out the non-laser procedures in these three studies, the results from all patients were included with a small minority ($n = 56$) of patients not treated with laser devices. Notably, when using SLS II or GlideLight, many studies indicated their combined use with other lead extraction tools, like lead locking devices, mechanical dilation sheaths, and mechanical rotating sheaths. The details of the 17 included studies are provided in Supplementary material online, *Table S1*.

## Primary outcomes

Outcomes were defined according to the 2017 Heart Rhythm Society (HRS) consensus[12] on TLE and 2018 European Heart Rhythm Association (EHRA) expert consensus[1] statement on lead extraction.

Safety outcomes included procedure-related death rate and major and minor complication rates. Major complications were defined as any of the outcomes related to the procedure that are life-threatening or result in death (cardiac or non-cardiac). In addition, any unexpected event that causes persistent or significant disability requires inpatient hospitalization or prolongation of existing hospitalization, or any event that requires significant surgical intervention to prevent death or threat to life is considered a major complication. All studies either explicitly stated that complications were assessed using HRS and/or EHRA consensus statement definitions or reported major complications as serious adverse events requiring surgical interventions, hospitalization, or threat to life that were consistent with HRS/EHRA definition for major complications.

Performance outcomes included the procedural success rate and clinical success rate per patient or per lead achieved for TLE procedures. Failure was defined as inability to achieve either complete procedural or clinical success or the development of any permanently disabling complication or procedure-related death. All studies either explicitly stated that procedural and clinical successes were assessed using HRS and EHRA consensus statement definitions on lead extraction, or, reported complete removal of all leads consistent with the HRS/EHRA definition for procedural success.

## Statistical analysis

Data analyses were conducted using software R-4.0.4.

For baseline characteristics, weighted arithmetic mean ± standard deviation by patient number (age, gender, indication, and lead per patient) or by lead number (lead type and dwell time) of each study was calculated.

A random-effects, inverse-variance-weighting meta-analysis was performed by pooling the results of the included studies to estimate the weighted average of treatment effects for effectiveness and safety. The random-effects model assumes the observed estimates of treatment effect can vary across studies because of real differences in the treatment effect in each study as well as sampling variability.

The conventional meta-analysis models assume normality. However, for the estimation of proportions, when the observed values approach either 0.00 or 1.00, the induced asymmetry (skew) can cause significant violations of the Assumption of Normality. Among the selected articles, 16 out of the 19 studies had zero procedure-related death. Instead of exclusion of these studies with zero events, the arcsine-square-root transformation was employed.[13] This transformation assumes that the underlying, raw data are binomial: that is, the underlying data need to be yes/no, success/fail, or correct/incorrect. The arcsine function stretches out the upper and lower tails of the data, such that the distribution is more likely to be symmetrical, even when many values are near 0.00 or 1.00.

The arcsine transformation is calculated as:

$y_i = g(p_i) = \arcsin\sqrt{p_i}$, with variance $v_i = 1/(4n_i)$,where $p_i$ is the mortality estimate from study $i$ ($i = 1, \ldots, N$), which is calculated as $p_i = e_i/n_i$ and $e_i$ and $n_i$ are the study $i$'s deaths and sample size, respectively.

After applying an arcsine transformation to each study's mortality rate, the meta-analysis methods were subsequently performed using the transformed data, $y_i$ and $v_i$, leading to the synthesized result $y$ with a 95% CI. The synthesized result is finally back-transformed to the original proportion scale; the overall proportion is usually estimated as $p = g^{-1}(y)$, and its CI limits are also back-transformed in the same manner. The random effects model summary result provides an estimate of the average treatment effect, and the CI shows the uncertainty around the estimate. Additionally, the heterogeneity between studies is described by the $I^2$ statistics which represents the percentage of variation across studies that is due to heterogeneity rather than chance.

Compared to the log and logit transformations, the arcsine-based transformations have the important advantage of stabilizing variances.[14] As their variances depend only on the sample sizes, they can be validly treated as fixed, known values which are required by the assumption of conventional meta-analysis models and have no correlation with the transformed proportion estimates. Unlike log and logit transformations, these transformations also do not need the continuity correction for zero or one proportion. In this sense, an arcsine square root transformation would be more straightforward for these types of problems.[15]

**Table 1** Patient and lead baseline characteristics

| | | Weighted mean ± sd (total#) |
|---|---|---|
| **N Patients** | | 1729 |
| **N Leads** | | 2887 |
| **Age (year)** | | 62.4 ± 8.7 (1630) |
| **Gender (male%)** | | 69.8% ± 7.1% (1545) |
| **Indication for TLE**[a] | Infection | 38.5% ± 35.0% (1729) |
| | Non-infection | 61.5% ± 35.1% (1729) |
| **Lead type**[a] | PM | 28.9% ± 38.3% (2404) |
| | ICD | 47.9% ± 39.9% (2404) |
| | CRT-P/D | 14.5% ± 35.7% (2404) |
| **Lead per patient**[b] | | 2.3 ± 0.25 (84) |
| **Lead dwell time (year)** | | 7.9 ± 3.0 (1904) |

PM, pacemaker; ICD, implantable cardioverter-defibrillator; CRT-P/D, cardiac resynchronization therapy with pacemaker or defibrillator.
[a]The weighted mean was obtained by performing a random-effects, inverse-variance-weighting meta-analysis using arcsine-square-root transformation due to zero cell frequencies occurred.
[b]The weighted mean was obtained by performing a random-effects, inverse-variance-weighting meta-analysis using log transformation due to small sample sizes.

# Results

A total of 17 studies were identified that met the eligibility criteria and were subsequently included in the meta-analysis, among which six were prospective studies and 11 were retrospective studies. These studies evaluated the use of SLS II or GlideLight Excimer laser sheaths or pooled data from the use of both devices in 1729 patients with 2887 leads. Among these patients, a minor subset ($n = 56$) was not treated using the SLS II or GlideLight devices, due to lack of separately reported data for laser-assisted procedures in those studies. Three studies—Burger 2021,[16] Monsefi 2019,[11] and Pecha 2021[17]—indicated the use of additional mechanical rotating sheaths in 7%, 5%, and 17% of patients, respectively. The details of the included literatures are shown in Supplementary material online, *Table S1*.

## Baseline characteristics

Baseline patient characteristics are shown in *Table 1*. The clinical data obtained from the literatures covered a diverse array of indications and targeted lead types, and leads with considerable dwell time, thus offering a representative sample of the clinical applications of the SLS

**Table 2** Outcomes of transvenous lead extraction using excimer laser sheath

| Variables | SLS II & GlideLight Weighted Ave.% (#Event/# Sample) 95% CI (L-U) |
|---|---|
| **Procedure-related death rate** | 0.08% (7/1729) [0.00%–0.34%][a] |
| **Procedure success per patient** | 96.8% (1440/1505) [94.9%–98.2%][a] |
| **Clinical success per patient** | 98.3% (989/1010) [97.4%–99.0%][a] |
| **Procedure success per lead** | 96.3% (1447/1501) [94.8–97.4%][b] |
| **Clinical success per lead** | 98.3% (292/297) [96.1%–99.5%][c] |

[a]The weighted average of the rate was obtained by performing a random-effects, inverse-variance-weighting meta-analysis using arcsine-square-root transformation due to 0.00 or 1.00 proportions occurred.
[b]The weighted average of the rate was obtained by performing a random-effects, inverse-variance-weighting meta-analysis using logit transformation.
[c]No meta-analysis was performed because there was only one study.

II and GlideLight devices. The average age of patients at the time of TLE procedure was 62.4 ± 8.7 years old, with 69.8% males. Infections accounted for approximately 38.5% of extractions, while the remaining extractions were due to other non-infective causes, such as lead malfunction and system upgrade. The most frequently targeted lead type for extraction was single/dual coil implantable cardioverter-defibrillator (ICD) (47.9% ± 39.9%). On average, each patient had 2.3 ± 0.25 leads. The extracted leads had a average implant duration of 7.9 ± 3.0 years.

## Safety outcomes

We analyzed the outcomes of the TLE procedures with a meta-analysis using a random-effect, inverse-variance-weighting model. Procedure-related complications and mortality were reported in all the included studies. Major procedure-related complication rate was 1.9% (41/1729; 95% CI: 1.2–2.8%), and minor complication rate was 1.9% (58/1729; 95% CI: 0.8–3.6%) (*Table 2*). Major complications included: deaths ($n = 7$), superior vena cava tear ($n = 8$), cardiac tamponade ($n = 5$), other ($n = 5$), pericardial effusion ($n = 3$), right atrium perforation ($n = 3$), tricuspid valve damage or flail ($n = 3$), cardiac avulsion ($n = 2$), pulmonary embolism ($n = 1$), severe tricuspid regurgitation ($n = 1$), right atrial appendage laceration ($n = 1$), femoral artery haematoma ($n = 1$), and cardiogenic shock ($n = 1$) (*Table 3*).

In total, there were seven procedure-related deaths (weighted average: 0.08%, 95% CI: 0–0.34%) and 16 of 19 studies reported zero procedure-related deaths. *Figure 2* shows the forest plot of the procedure-related mortality of each study. The 95% CI of the death rate of each study provides a predicted range for the true treatment effect in an individual study. Heterogeneity analysis of the random effect model indicated a low heterogeneity among included studies ($I^2 = 18\%$, $P = 0.23$). Causes of death are shown in *Table 3*. The leading cause of death was cardiovascular injury ($n = 3$), among which two deaths were related to a superior vena cava (SVC) tear. One death occurred in a patient who had an SVC tear that was successfully repaired. However, the patient died nine days post-procedure from cerebral oedema and multi-organ failure.[11] Another cardiovascular injury-related death was due to persistent intractable hypovolemic shock following SVC laceration.[9] One death was related to pulmonary embolism of a vegetation.[18] The remaining three deaths were in-hospital deaths with no further information on the cause.[9]

**Table 3** Major complications associated with transvenous lead extraction using excimer laser sheath

| Complication | Count (N = 1729) |
|---|---|
| **Major Complications** | 41 (1.9%[a]) |
| Death | 7 |
| *Cardiovascular injury* | 3[b] |
| *Pulmonary embolism* | 1 |
| *Unknown* | 3[c] |
| Superior Vena Cava tear | 8 |
| Cardiac tamponade | 5 |
| Other | 5 |
| Pericardial effusion | 3 |
| Right atrium perforation | 3 |
| Tricuspid valve damage or flail | 3 |
| Cardiac avulsion | 2 |
| Pulmonary embolism | 1 |
| Severe tricuspid regurgitation | 1 |
| Right atrium appendage laceration | 1 |
| Femoral artery haematoma | 1 |
| Cardiogenic shock | 1 |

[a]The weighted average of the rate was obtained by performing a random-effects, inverse-variance-weighting meta-analysis using arcsine-square-root transformation due to 0.00 or 1.00 proportion occurred.
[b]One death was associated with a procedural failure. Tear of the superior vena cava occurred during extraction of a 13-year-old dual-coil defibrillator lead. Underwent emergency sternotomy and intraoperative resuscitation. Vascular tear was successfully repaired, but the patient died on postoperative day 9 of cerebral oedema and multi-organ failure.[11]
[c]Three in-hospital deaths were reported without additional details in Regoli.[9]

Details of other major complications and minor complications reported in each study are shown in Supplementary material online, *Table S1*. The most commonly reported complications (major and minor combined) were pericardial effusion/tamponade ($n = 26$) and cardiovascular injury ($n = 20$). Of the total 26 cases of pericardial effusion/tamponade reported, 23 were reported by three studies [$n = 5$ (Yagishita 2020),[19] $n = 4$ (Gaubert 2017),[18] $n = 14$ (Regoli 2018).[9]] Specifically, Regoli *et al.*[9] reported 14 cases of pericardial effusion from a study that was conducted to assess the incidence of this specific complication during TLE. All patients were thoroughly assessed by transoesophageal echocardiography for the presence of pericardial effusion.

Among the 19 reviewed studies, four studies reported in-hospital deaths. Burger *et al.*[16] noted two patients (2.8%), who died from sepsis-related multi-organ failure due to systemic infection. Pecha *et al.*[17] reported a 1.3% in-hospital mortality with one death from multi-organ failure and another from a stroke. Yagishita *et al.*[19] recorded deaths in four patients (1.7%) from causes of septic shock (2), exacerbation of heart failure (1), and pneumonia (1). Regoli *et al.* documented two deaths (0.9%)—one likely caused by embolization of a large vegetation to the lung and another due to multi-organ failure following sepsis and chronic heart failure. The details of the causes of in-hospital deaths were included in Supplementary material online, *Table S1*.

Five studies reported 30-day mortality rates. Al-Maisary *et al.*[20] recorded two deaths (1.9%) occurring after 7 and 17 days post-procedure, respectively. Monsefi *et al.*[11] reported a 30-day mortality rate of 3.7%, while Regoli *et al.*[9] documented a rate of 2.0%. The

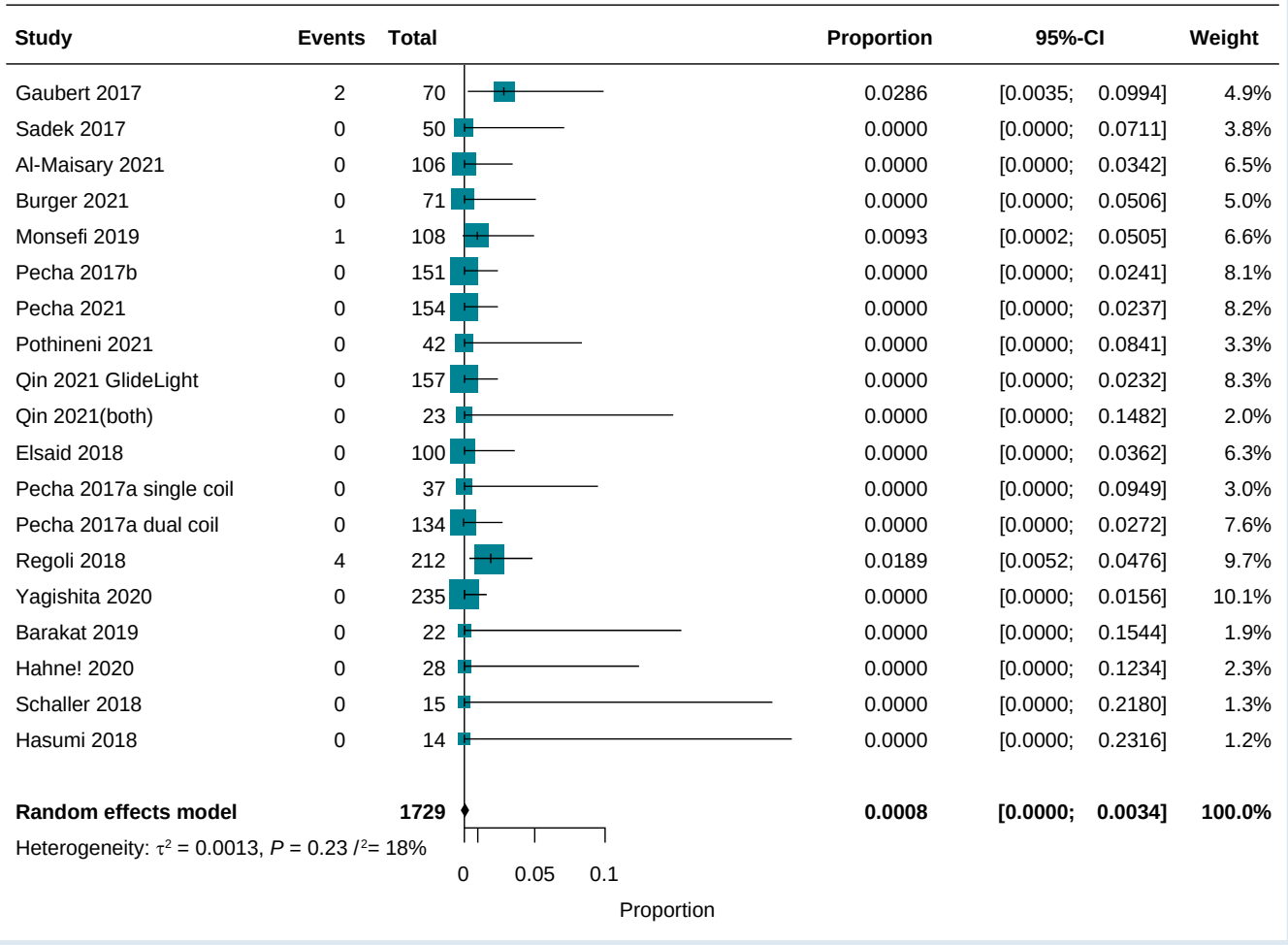


**Figure 2** Forest plot of the procedural-related death rate of the 19 studies included in the random effects meta-analysis. The prediction interval of the death rate of each study provides a predicted range for the true treatment effect in an individual study. The heterogeneity ($I^2 = 18\%$, $P = 0.23$) shows the variability in treatment effect estimates which is due to real study differences, indicating a low heterogeneity among studies.

remaining two investigations, both conducted by Pecha *et al.*,[21] one for single-coil and the other for dual-coil, reported no mortalities during the 30-day observational period.

## Performance outcomes

Fifteen studies reported procedural success rates and nine studies reported clinical success rates, variably reporting per patient and/or per targeted lead. All studies except the report by Yagishita *et al.*[19] explicitly stated that procedural and clinical successes were assessed consistent with the definitions of the HRS and EHRA consensus statements on lead extraction. Yagishita *et al.* reported complete removal of all leads, which is consistent with the HRS/EHRA definition of procedural success.

*Table 2* shows success rates reported for the SLS II and GlideLight devices. The per-patient procedure success rate was 95.3% (95% CI: 93.2–96.7%) and the per-patient clinical success rate was 97.5% (95% CI: 95.4–98.6%).

Qin *et al.*[22] reported an 82.6% clinical success rate in 23 TLE patients. These 23 patients were a subgroup of the overall cohort in which TLE was performed using the GlideLight device or the TightRail device. In these patients, TightRail was used in combination with GlideLight after initial extraction with GlideLight alone was not successful. The mean dwell time in this subgroup was 13.3 years, which was considerably longer than in the remaining patients (7.9 ± 3.0 years).

# Discussion

This current meta-analysis reports the clinical safety and performance of the SLS II and GlideLight laser sheath devices. Clinical data cover a range of clinical applications, providing full coverage of the indications for these devices as well as the lead types targeted for extraction. A random effects model was used to estimate the outcomes which considered the variations of treatment effect and sampling variability across included studies. This meta-analysis showed that the excimer laser sheath has high clinical safety [mortality: 0.08% (0–0.34%)] and performance [per patient procedure success: 95.3% (93.2%, 96.7%), clinical success: 97.5% (95.4–98.6%)] for TLE procedures. The reported success rates and procedural complication/mortality rate compare favourably with the results of the ELECTRa registry,[3] the largest cohort of contemporary lead extraction procedures, which demonstrated a procedural-related major complication rate of 1.7% and procedural-related mortality of 0.5%.

## Factors influencing TLE success and complications

The SLS II and GlideLight devices are typically used in combination with other lead extraction tools, such as lead locking devices and mechanical

dilation sheaths, and often only after less sophisticated devices failed to remove the targeted leads. Powered sheathes including laser and mechanical rotational tools are intended to be used in more complex cases which have an inherently higher risk of complications.[23] Similar to other advanced tools, the excimer laser sheath has a high procedural success rate, with higher rates of major and minor complications than simple traction, due to the intrinsically greater complexity of the TLE procedure.[24]

Various factors can influence the procedural complication rate of TLE procedures.[25] Certain lead types, particularly dual-coil ICD leads and coronary sinus (CS) leads, can be challenging to extract due to fibrous ingrowth[24,26–29] and complex coronary venous anatomy.[30] Success rates for pacemaker (PM) lead extraction are reported at 97–100%, in contrast to 88–100% success for ICD lead extractions, and 97–99% for CS leads.[24] In our analysis, the majority of extracted leads were ICD leads, potentially increasing the extraction complexity. Other factors linked to increased complication rates include longer lead dwell time,[2] abandoned leads,[31,32] large lead vegetations,[33] and femoral approach.[1] The leads included in our meta-analysis were relatively old (average indwelling time: 8 years), potentially carrying an elevated risk of procedural complications.

High-volume, established extraction centres with experienced operators demonstrate lower complication and mortality rates,[3,23,34,35] highlighting the critical role of physician expertise in managing complex TLE cases using advanced tools. With a highly skilled operator, laser-assisted lead extractions can be highly successful and life-saving, particularly in challenging scenarios, such as ICD extraction via a persistent left SVC,[36] management of patients with venous obstructions,[37] or extracting long-dwelling CS leads.[38] Given the potential for serious, life-threatening complications, identifying high-risk lead extractions and implementing safety measures could reduce the risk of adverse outcomes.[39] To reduce the risk of complications, pre-procedural planning (X-ray, echocardiography, and potentially also a CT scan) in combination with obtaining the patient's medical history and information regarding the leads implanted is required to carefully plan the procedure.[1,12] Intra-procedural echocardiography is recommended to allow for early recognition of injury and to supplement pressure monitoring of the central venous and arterial pressures. Moreover, immediate surgical backup[23,25] and bridging strategies[40,41] to surgery are crucial to a successful and safe CIED extraction practice in order to minimize damage when complications occur.

## Comparison with prior studies

The first published meta-analysis on TLE outcomes comparing different techniques for lead extractions included 62 studies published between 1998 and 2012, and showed a large inhomogeneity of patients' profile and operator approach to extraction: excimer laser-assisted TLE was associated with increased complications but achieved superior efficacy in leads with an indwelling time >1 year.[42] On the contrary, a purely mechanical approach resulted in an increase of major complications when leads with an indwelling time >1 year were considered. This highlights the concept that advanced tools such as laser and mechanical sheath-assisted TLE are more effective in the most difficult cases, where procedure risk and patients' clinical severity are also greater. A truthful comparison of TLE devices would require a common stepwise approach during the procedure for clinically similar patients, a theoretical setting far from real-life practice: This dictates a cautious approach in the evaluation of clinical reports and calls for a distinction between *procedure outcome* and *clinical outcome*, the latter being mostly unrelated to the former. Indeed, Lee et al conducted a similar analysis showing a 9.3-fold increased risk of death (0.85% mortality rate) and a lower success rate (93.4% procedural success rate per lead) for laser sheaths compared to mechanical rotating sheaths for TLE.[8] This reported mortality rate is substantially higher than that observed in the current meta-analysis and the MAUDE[6] database. This may be explained by the fact the prior meta-analysis included older studies conducted between 1998 and 2017 whereas the current analysis included more contemporary data set from 2016 to 2021. Progression in TLE protocols over time may account for some discrepancies in the results between our and these former meta-analyses. Furthermore, our study incorporated a greater number of investigations involving modern devices currently available on the market, whereas the majority of Lee *et al.*'s analysis was based on devices that are no longer commercially accessible. Another distinction is the current study assessed procedural-related mortality whereas Lee *et al*[8] incorporated studies that evaluated all-cause mortality, accounting for deaths related to patients' clinical severity rather than to the procedure itself: only two of 25 deaths at 30 days after TLE were procedure-related in a large study.[43] In-hospital mortality is much higher than TLE mortality *per se*.[44]

In keeping with the findings of the current meta-analysis, several prior studies comparing the outcomes of laser and mechanical sheaths for TLE procedures reported similar results as our meta-analysis. One investigation compared the outcomes of TLE involving laser sheaths vs. mechanical polypropylene sheaths demonstrated that the use of a laser sheath resulted in higher clinical success and a comparable complication rate compared to the mechanical sheath.[18] A prospective registry assessed the outcomes TightRail and excimer laser sheaths assisted TLE between 2013 and 2019, and found comparable outcomes across the two platforms when used as the initial tool.[45] Similarly, a retrospective study analyzing TLE outcomes from 2015–2020 found no significant differences in procedure success, clinical success, or adverse events between the TightRail and the laser sheath groups.[22] These findings reinforce that laser sheaths have similar safety and effectiveness profiles as mechanical rotating sheath for lead extraction.

Nonetheless, those device comparison analyses should be interpreted with caution due to potential biases and limitations, such as underreporting, variability in the number, type, and settings of lead extractions, use of concomitant tools, and unavailable risk factors.[7] Hence, our study purposefully focused on the outcomes of laser devices without comparing them with other extraction tools to avoid some of those risks carried by comparison analysis. TLE can be complex and often necessitates a tailored approach employing a combination of tools. Our comprehensive analysis of the recent data suggests that lead extraction using the excimer laser sheath yields high success and is associated with low complication rates.

## Limitations

This study has several limitations. First, while meta-analysis is a powerful tool for summarizing data and providing pooled estimates, it is susceptible to inherent biases. For instance, publication bias might favour the inclusion of certain studies over others. Many of the included studies are retrospective, potentially leading to selection bias and confounding factors. We only included relatively large studies to exclude case studies or studies from centres with limited experience. Additionally, our study's time frame (2016–2021) was chosen to focus on contemporary studies and update our understanding of the safety and efficacy of laser devices. However, this specific time frame may limit the scope of the study. The FDA approved SLS II and GlideLight in 2000 and 2012, respectively. Consequently, our emphasis on recent data could potentially overlook earlier clinical experiences with these devices. Nevertheless, our study aims to highlight the outcomes of TLE in a matured field, characterized by improved protocols and increased operator familiarity.

Second, our meta-analysis exclusively examined the outcomes of excimer lasers, without comparing these results with other advanced techniques such as mechanical sheaths. Although many previous studies have compared laser sheaths with other extraction tools and found comparable results (as shown in discussion), we intentionally limited our focus to laser devices. This was done to prevent potential biases and limitations posed by comparative analyses, given the potential procedural

variabilities, such as risk factors and settings of lead extraction. This may avoid the misinterpretation of favouring one technique over another only based on comparative results. It is crucial to underscore that TLE is typically a complex procedure. Often, a stepwise, tailored approach employing a combination of tools is required for successful extraction.

Third, many included studies reported the combined use of laser sheath with other extraction tools, such as lead-locking devices and mechanical dilation sheaths. The definitions of procedural and clinical successes combine technical success with safety-related outcomes and are thereby influenced by safety events that may have been caused by any of the extraction tools employed in those cases. Consequently, reported complications and successes may have resulted from the combined use of multiple devices.

# Conclusion

This meta-analysis demonstrated that TLE employing the excimer laser sheath has high success and low procedural-related mortality rates. Laser-assisted TLE equips physicians with a valuable tool for the safe and effective removal of indwelling cardiac leads, particularly in cases necessitating advanced extraction techniques.

# Supplementary material

Supplementary material is available at *Europace* online.

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## Data availability

All relevant data are within the manuscript and its Supporting Information files.

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