

Lead extraction today: a matter of time or a matter of way?

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This editorial refers to ‘Comparison of non-laser and laser transvenous lead extraction: a systematic review and meta-analysis, by Z. Akhtar *et al.*, <https://doi.org/10.1093/europace/euad316>.

The evolution of invasive treatments follows similar paths. At first, the focus is the clinical need that emerges as an urgent request for a solution. The initial focus for implantable cardioverter defibrillator (ICD) was post-myocardial infarction (MI) sudden death, the same was the breakthrough of cardiac implantable device (CIED) infections for transvenous lead extraction (TLE) in the early 2000s.¹ When the first procedure is performed, there is wide enthusiasm and a widespread implementation of the procedure leading to a shift of the focus to the identification of the candidates, barriers to implementation, and definition of the precise technique. For ICD, we saw a shift from post-MI patients to patients with reduced left ventricular ejection fraction, discussions on cost-effective analysis, and the shift from abdominal implant to submuscular and subcutaneous approach. Similarly, it occurred to TLE. While CIED infection was the original indication of TLE, the awareness of a rapid increase in lead malfunction and recalls promoted an increase in non-infective indications to TLE. Although manual traction is an effective technique for recently implanted leads, chronically implanted leads develop strong adherences with surrounding structures requiring additional tools and techniques. This claimed for the development of powered (mechanical and laser) sheaths and different percutaneous approaches including femoral and jugular routes.¹ However, in specific situations (high-risk procedures, large vegetations, refractory heart failure, valve diseases), ‘hybrid’ or combined approaches may be preferred.²

When the procedure is well established, the focus moves to comparison of complications associated with the different approaches such as standard vs. leadless CIED and different devices for TLE.³

Safety is an essential clinical endpoint and injury to the superior vena cava (SVC) is the most dangerous and feared complication during TLE.

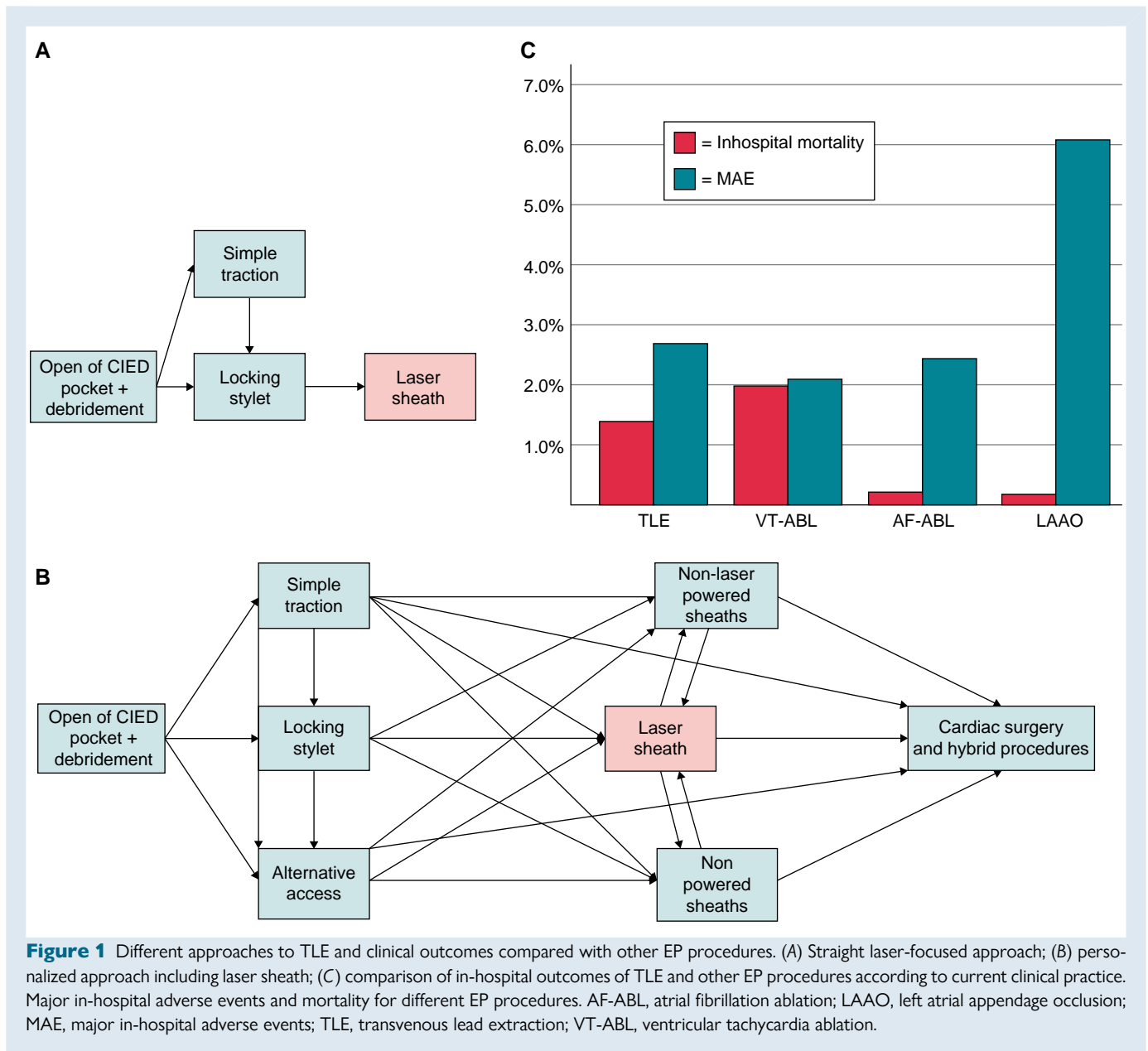
This is the focus of the paper by Akhtar *et al.*⁴ who reported an interesting meta-analysis on laser-assisted vs. non-laser-assisted approaches for TLE aimed at identifying the safer approach. The result of their huge efforts is an analysis of 68 among 6275 screened papers including 34 laser papers, 30 non-laser papers, and 4 papers including both approaches. After meta-analysing these records, they conclude that non-laser approach resulted to be superior in terms of procedural mortality (pooled rate 0 vs. 0.1%, $P < 0.01$), major complications (pooled rate 0.7 vs. 1.7%, $P < 0.01$), and superior vena cava injury (pooled rate 0 vs. 0.5%, $P < 0.001$) coupled with higher complete TLE success (pooled rate 96.5 vs. 93.8%, $P < 0.01$). In view of the recognized limitations of using data from non-randomized studies, they performed several sensitivity analyses to increase the robustness of their finding confirming their results. The authors also focused on the more recent rotational powered sheaths showing that compared with laser, their use was associated with greater complete success (pooled rate 97.4 vs. 95%, $P < 0.01$) with lower SVC injury (pooled rate 0 vs. 0.7%, $P < 0.01$), but without a significant lower mortality. This is in line with the results by Diaz *et al.*⁵ showing a lower risk of isolated extra-pericardial SVC injury with rotational TLE vs. use of laser sheaths. However, the overall rate of major complication was comparable, suggesting a different nature of major complications using laser or rotational tools with several bias.⁶ Despite the strong efforts by the authors, the results of Akhtar *et al.*⁴ have to be taken with caution: there is a high risk of bias derived from the non-randomized studies included, the possible confounding by indication (since TLE for infection is associated with more overall and procedure-related complications) and the current practice of a multi-step approach to TLE in which the identification of the role of any specific tool to generate the complication seems difficult (*Figure 1A and B*).

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In this regard, a re-assessment of the historical development of TLE approaches highlights a conceptual mistake that could have driven the findings shown by Akhtar *et al.*⁴ The two pros of laser-assisted TLE that were stressed in the PLEXES randomized trial were the superiority over standard mechanical approach (at those time) in terms of complete extraction and procedural time.⁷ The latter, in particular, should not be considered a goal for TLE procedures, especially in case of CIED infections because it is a potential driver of complications especially for less experienced operators. This is in line with the results of the ELECTRA registry in which high-volume centres had less all-cause in-hospital major complications and deaths compared with low-volume ones {2.4% [95% confidence interval (CI) 1.9–3.0%] vs. 4.1% (95% CI 2.7–6.0%), $P = 0.0146$; and 1.2% (95% CI 0.8–1.6%) vs. 2.5% (95% CI 1.5–4.1%) $P = 0.0088$ }.⁸ A difference significantly greater than that between laser and non-laser sheaths was reported by Akhtar *et al.* Another finding of this landmark registry by Bongiorno *et al.* is the general low number of complications of TLE which was in contrast with

the general consideration that TLE is a high-risk procedure. On a cohort of over 3000 consecutive unselected patients, the primary endpoint of in-hospital procedure-related major complication rate was 1.7% (95% CI 1.3–2.1%) (58/3510 pts) including a mortality of 0.5% (95% CI 0.3–0.8%) (17/3510 pts) and the all-cause in-hospital death occurred in 50 [1.4% (95% CI 1.1–1.9%)] patients.⁸ Notably, while the in-hospital mortality is in line with the findings of Akhtar *et al.*,⁴ the procedure-related mortality is closer to the pooled results of the laser arm (0.46%) rather than the estimated data by the meta-analysis already discussed, or the pooled non-laser data (0.21%). This can raise some doubts on under-reporting bias from some papers included in the meta-analysis despite the efforts of the authors. Besides this, it has to be highlighted that clinical outcomes reported by both papers are comparable to other commonly performed procedures that no physician would consider at the same level of TLE in terms of risks (see Figure 1C).^{8–11} However, many authors have recently reported late- and under-referral of patients to TLE centres also for infective

indications, including CIED-related endocarditis.¹² This has a dramatic impact on clinical outcomes of these patients both in terms of survival, overall complications, and costs for the healthcare systems.

Despite these important considerations, minimization of procedure-related risks has to be pursued as correctly underlined by Akhtar *et al.* through enhancing operators experience to face a procedure that needs careful patient personalization starting before TLE, including proper diagnosis, and following post-TLE management (monitoring, transfer, re-implantation strategy) because non-TLE death is still the leading cause of death for patients with infective indications (which is the more stringent indication to TLE) that have to be managed in a hub-and-spoke perspective.^{1,13} Ongoing research is providing support to this personalization through risk stratification, such as FDG-PET-CT scan,¹ and identification of risky area.¹⁴ New technologies have been improved to overcome disasters such as the Bridge Balloon.¹ Finally, we have not to forget the importance of working in a team. Hybrid procedures involving the collaboration of the TLE operator with the cardiac surgeon can solve tricky cases with the potential risk of a dramatic finale, moving them to a clever minimally invasive approach that can also provide an elegant happy end.²

To this regard, The 2018 EHRA Consensus Statement strongly highlights the value of a collaborative and multidisciplinary team approach to properly address the lead extraction management to optimize safety and efficacy.¹⁵

In conclusion, we thank Akhtar *et al.* in identifying possible area of improvement remembering us that we cannot strictly rely on (rather) new technology to provide effective treatments. On the contrary, during TLE, we have not to embrace a one-fits-all fast approach of doing it, but the best- personalized way of doing it while concentrating our speed to identify and refer our patients in the fastest way. Although new extraction techniques and different tools have been introduced to improve the effectiveness and maintain the safety of TLE, must be emphasized that, one of the long-held tenets of TLE has been the importance and utility of the lead extraction 'tool box' implying the having a variety of tools available increases the success and safety of the procedure. Moreover, despite the chosen approach, current outcomes of TLE clearly outweigh the risk of postponing the procedure, especially for patients with CIED infection.

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