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EDITORIAL

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Use of a powered sheath for transvenous lead extraction

Over the past 40 years, the population of patients with cardiac implantable electronic devices (CIEDs) has increased. Consequently, the number of patients requiring transvenous lead extraction (TLE) procedures has been increasing. Implanted leads develop fibrotic adhesions that bind the leads to adjacent structures. To overcome this issue, several tools have been invented in clinical medicine.

In the 1990s, the Excimer laser sheath (Spectranetics, Colorado Springs, CO, USA) was introduced as the first powered sheath. A randomized trial of TLEs using the Excimer laser sheath and conventional extraction sheath (PLEXES trial) was performed. The rate of achievement of the complete lead removal was 94% in the laser group and 64% in the conventional sheath group (P = .001). This study suggested the significant clinical advantages of a laser sheath.

Successively, the LExICon study, which was a multicenter study to examine the safety and efficacy of a laser sheath-assisted TLE, was published in 2010. In this study, TLEs were performed in 1,449 patients (2,405 leads). The median implantation duration was 82.1 months. The leads were completely removed 96.5% of the time, with a 97.7% clinical success rate. The major adverse events occurred in 20 patients were directly related to the procedure (1.4%) including four deaths (0.28%). This study elucidated that TLE employing laser sheaths was highly successful with a low procedural complication rate. Moreover, the registries performed in Europe, the USA, and Canada have reported a complete procedural success rate of 90%, partial lead removal of 3%-4%, major perioperative complications rate of 2%, and in-hospital mortality of <1%.

The Excimer laser system is highly effective in TLE procedures; however, it has some disadvantages. First, the Excimer laser system is highly expensive because a double investment into the laser sheath itself and an Excimer laser system are required. Second, the ablative effects of the Excimer laser on calcified lesions are minimal.

The Evolution mechanical dilator sheath (Cook Medical) emerged in 2008 as an extraction tool. The Evolution sheath has a trigger driven handle, with a stainless steel-threaded barrel rotational tip at the end of a flexible sheath designed to cut through the fibrotic tissue around chronic implanted leads. In the original design of the Evolution power sheath, the ablation forces were directed sideways, and the tip was assumed to advance by a sort of unidirectional "screw" motion. In the R/L model, which was introduced in 2013, the tip was totally redesigned so that the ablation forces are directed forward along the lead body with a bidirectional motion and without the screw capability.

The first clinical data concerning TLEs using the Evolution were published by Hussein et al in 2010. In their study, overall, the Evolution system was successful in 25 (86%) patients (33 leads). The overall clinical success was 100%. Further, no complications occurred. In 2015, Starck et al reported the clinical performance of the Evolution R/L (40 patients, 52 leads). In their report, a clinical success of 98.1% was achieved without any major complications. These studies suggested that the Evolution could provide an equal beneficial effect in comparison to the Excimer laser sheath. Furthermore, Stark et al compared the Excimer laser and Evolution system retrospectively.[1] Regarding the complete procedural success and safety, the two systems were comparable. However, as for the clinical success and cost-effectiveness analysis, the Evolution was favorable.

The TightRail is a more recent appearing bidirectional rotational mechanical sheath. In comparison to the Evolution, the TightRail has a more flexible shaft, which facilitates the forward progression in cases with tortuous vascular structures. Therefore, this seems to provide the advantage of remaining coaxial to the extracted lead and prevents causing severance and wrapping. Another important novelty feature regarding the TightRail is the dilating metal blade at the distal tip, which is "shielded" until activated. This might lead to a greater safety of the procedure.

In the current issue of the Journal of Arrhythmia, Mazzone et al reported a series of extraction results using the TightRail.[2] As the authors mentioned, this is the first prospective multicentric study to assess the safety and efficacy of the TightRail. Mazzone et al analyzed 26 patients who underwent a TLE in two centers. According to this report, the indications for a TLE were an infection (57.7%) and lead dysfunction (42.3%). Overall, the mean implant duration of the leads extracted with the TightRail was 99.1 ± 70.2 months. The overall clinical success was 100% and complete procedural success was achieved in 98.3%. There were no cases of deaths or major complications and only two minor complications occurred. This study suggested and confirmed the usefulness of the TightRail for TLE procedures.

The Heart Rhythm Society expert consensus statement on CIED lead management[3] published in 2017 has widely spread and first Japanese guidelines concerning TLEs[4] were published in 2019. In both guidelines, there is no class III indication for a lead extraction. This suggests that normally functioning, non-recalled leads can be extracted in selected patients. Therefore, the number of TLEs is expected to increase year by year.

Now we have three kinds of powered sheaths, the Excimer laser, Evolution, and TightRail. All three devices are suggested to have almost equal safety and efficacy. At the present time, operators can select the device depending on their preferences, experience, and the cost-effectiveness. However, to further evaluate and optimize the lead extraction techniques and tools, more randomized prospective multicenter trials are required.

CONFLICT OF INTEREST

The author declares no conflict of interest for this article.

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