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Starting a transvenous lead extraction program: Lessons from a developing country

Cardiac implantable electronic devices (CIED) are an important therapeutic modality for treating patients with bradyarrhythmias, tachyarrhythmias, and heart failure. CIED implantations have increased due to population growth, aging population, increased life expectancy, and better access to healthcare. For the proper function of these CIEDs and to deliver life-sustaining therapies, the integrity and reliability of leads are critical. The leads need to survive the hostile biological environment in the human host and endure repetitive mechanical stress with millions of cardiac cycles each year and yet retain electrical integrity [1]. Leads are the weakest link in any CIED, and lead management forms an integral part of patient care. The indications for transvenous lead extraction (TLE) can broadly be grouped into CIED infections, lead failures, multiple leads (>4 leads on the ipsilateral side, or five leads in the SVC), lead-related complications (arrhythmias, thrombosis), venous access issues, and chronic pain [2]. As part of the lead management strategy, TLE has been increasing worldwide because of lead failures, CIED infection, and improvements in extraction tools. TLE should preferably be performed in the setting of a lead extraction program by a trained physician [1]. Though well-established lead extraction programs exist in many developed countries, the same is not true in many developing and underdeveloped countries.

In this issue of the Indian Pacing and Electrophysiology Journal, Soontornmanokati N et al. report their experience of TLE from a tertiary care center in Thailand [3]. They performed lead removal in 105 patients and removed 157 leads from January 2008 to December 2020. The authors divided the study into group 1(2008–2015), which was unstructured, and group 2 (2018–2020), done with a structured approach. The authors did not perform any TLE procedures for two years between 2015 and 2017. The authors have analyzed and compared the data between the two periods. Since 19 patients had a lead explant and seven had incomplete data, they were excluded from the study group. The final study group included 79 patients, 70.9% male, mean age of 57.7 ± 18.7, with 122 leads (82 pacemaker leads, 35 implantable cardioverter defibrillator leads, 5 coronary sinus leads). The average number of leads per patient was 1.54 ± 0.66 leads, and the mean implant duration was 87.8 ± 68.2 months. They achieved complete procedural success in 76 cases (96.2%), with 1 (1.3%) failure and 1 (1.3%) major complication in the form of cardiac avulsion requiring immediate surgery. One in-hospital mortality was 56 hours after the procedure due to severe sepsis and multiorgan failure. Device reimplantation was done in 48.1% at 10.6 ± 14.6 days post-extraction, and the duration of the hospital stay was 13.5 ± 17.1 days. The indication for TLE was an infection in 67.1% (56% pocket infection, CIEDs 8.9%) related endocarditis. Non-infectious indications were lead malfunctions in 29.1% and 3 cases (3.8%) of thrombosis or vascular issues.

What are the lessons that we can learn from this study? The authors need to be congratulated for meticulously collecting the data and presenting it elegantly. According to the study, the center performed around 10 extractions per year, categorizing it as a low volume center. According to EHRA and Lexicon criteria, centers performing <15 procedures/year are considered low volume; those performing 15–30 procedures/year are medium-volume centers, with high volume centers performing >30 procedures/year [4]. Transvenous lead extraction is a complex invasive procedure, and the operator and team experience is a major determinant of procedural success and a lower complication rate [2,4]. One of the most critical questions is, “how did the operator/s maintain their proficiency in the procedure?” What is not clear from the study is whether there was a single operator or multiple operators. How did the operator/s maintain their skills when there was a break of two years? Did the operator/s retrain elsewhere before restarting the program? The EHRA and HRS recommend extracting a minimum of 40 leads in 30 procedures as a minimal requirement for training, with a minimum of 15 procedures (extracting at least 20 leads) each year to maintain competency [1,2]. In low volume centers, one operator should be the primary operator, and if necessary, a second operator can assist the primary operator. This arrangement will help the primary operator to maintain adequate skills.

The incidence of major complications and death are related to the center's TLE volume and the individual operator's experience [1]. In the ELECTRa-registry, the complication rate was significantly different between low- and high-volume centers (4.7% vs. 2.1%, respectively; P < 0.01), with lower all-cause mortality in high-volume centers (2.8% vs. 1.2%; P < 0.03) although procedure-related complications did not reach statistical significance [5]. A study of TLE in the real-world setting reported a major complication rate of 2.3% and a mortality rate of 0.9%. Of the patients with major complications, 16% required urgent cardiac surgery during TLE (0.38% of total procedures) and a high (34%) mortality rate. Among the deaths, one-third occurred during the extraction procedure or surgical rescue [6]. In this study, a major complication occurred in 4 patients (5.1%), and death occurred in 1/4 (25%), which is much higher than reported in the literature.

Life-threatening complications during TLE are unpredictable, and all extraction must be performed in an environment prepared for these complications. It includes the capability to provide emergent cardiopulmonary bypass and immediate surgical repair. A careful look at the study by Soontornmanokati N et al. reveals

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that all the complications occurred in the study's first phase (group 1). After the first major complication in the catheterization laboratory, despite moving to a hybrid operating room (OR), the first case in a Hybrid OR had a stormy course requiring emergent surgery. The authors attribute it to a lack of systematic protocol and unfamiliarity of team personnel with the lead extraction procedure. The lesson is that even if TLE is performed in a suitably equipped environment, the team should be well trained and prepared to address the complication. The authors report zero complications in the second part of the study after applying a systematic protocol [3]. The other possible reasons for lower complications in the second phase (group 2) are likely to be due to the small case numbers, lower dual coil and recalled leads, lesser multiple leads, and less complex cases. It is possible that with more difficult extractions, the complications may increase, and the implant team has to be better prepared.

One of the intriguing aspects of the study is that the team stopped performing TLEs for two years between 2015 and 2017. The reason given by the authors is that it was because of the technical limitations of the laser machine. Which brings us to another question “do we stop the TLE program if there is no laser?” The answer is an emphatic “NO.” Many centers worldwide continue performing successful TLEs using the mechanical rotational powered sheaths. We continued performing TLEs using mechanical rotational sheaths at our center when our laser console was nonfunctional. Stopping TLEs for prolonged period results in deskilling the physician and not delivering a valuable therapy to the patient. Laser extraction tools that include the laser console impose a high cost during procurement and maintenance to the organization. The additional cost of the equipment adds to the overall cost of the procedure. A study comparing laser to mechanical powered sheaths shows that both are comparable regarding complete procedural success. However, clinical success and cost-effectiveness analysis favor mechanically powered sheaths [7]. The cost of laser TLE procedure can be prohibitively expensive in cost-sensitive developing and underdeveloped countries. It can act as an impediment to the delivery of patient care. It is especially so in countries where patients pay out of their pocket.

How do we prevent complications during a TLE? To answer this question, one has to look at why complications occur. It can be due to performing the procedure 1) with less experience; 2) without correct tools; 3) unfamiliar with the tools; 4)without an appropriate team; 5) not recognizing that the complication has occurred; 6) not responding immediately to a possible complication [8]. TLE is a complex but relatively safe procedure and is highly successful when performed by an experienced physician. The procedure should be performed in an appropriate setting, with a well-trained team and proper tools. Thoughtful planning, and careful consideration of every patient's situation and needs, can reduce the complications.

What are the take-home messages from this study? Lead extraction is an important lead management strategy for every country. Each country should create and maintain a successful lead management program, preferably in a tertiary care center. All such centers should develop a referral base and technical skills to keep the program successful. It is unnecessary to have laser lead extraction tools in developing or underdeveloped countries. Non-availability of laser should not impede the lead extraction program. Mechanical tools are equally effective, less expensive, safer, and more versatile than lasers. The resources required for TLE can be a barrier to the effective and timely use of extraction, and hence it is necessary to keep the operative costs low so that more patients benefit. The most important aspect of the lead extraction program is to have well-trained team members to deliver the best possible results. It calls for a well-trained team leader who can stitch together the team to get the best results.

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Declaration of competing interest

None.

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