Effective and safe mechanical transvenous lead extraction in a low-volume center

Lin Li, MD,* Anna Busija, MD, PhD,† Han Feng, PhD,‡ Amitabh C. Pandey, MD,*§ Thierry Le Jemtel, MD,* Bassam G. Wanna, MD*

*From the *Department of Cardiology, Tulane University School of Medicine, New Orleans, Louisiana, †Department of Medicine, Tulane University School of Medicine, New Orleans, Louisiana, ‡Tulane Research Innovation for Arrhythmia Discovery, Tulane University School of Medicine, New Orleans, Louisiana, and §Department of Cardiology, Southeast Louisiana Veteran Health Care System, New Orleans, Louisiana.*

BACKGROUND Transvenous lead extraction (TLE) of cardiac implantable electronic devices was once deemed highly risky by high-volume centers. However, advancements in technology have significantly reduced the risk, making TLE a safer procedure in electrophysiology.

OBJECTIVE The purpose of this study was to examine the efficacy and safety of mechanical TLEs in a low-volume center with a single operator.

METHODS This study retrospectively accessed electronic medical records from the Tulane University School of Medicine system in New Orleans, Louisiana, and included patients who received mechanical TLE from 2016 to 2023. We analyzed the indications for TLE, patient characteristics, lead characteristics, success rate, and complications.

RESULTS We included 149 consecutive mechanical TLEs with an average implant duration of 105 months. A total of 53.7% (80) of TLEs were indicated for infectious reasons, and 37.6% (56) were high-voltage leads. Clinical success and complete procedural success rates were both 94.6% with no procedure-related mortality or major complications. The periprocedural mortality rate was 1.25% (1). Minor complications included a left chest pocket hematoma, a left groin hematoma, and urinary retention.

CONCLUSION The efficacy and safety of mechanical TLEs performed in a low-volume center are comparable with those in high-volume centers.

KEYWORDS Mechanical transvenous lead extraction; Success rate; Complications; Low-volume center

(Heart Rhythm O^2 2024;5:639–643)

Introduction

With the growing need for cardiac implantable electronic devices (CIEDs), the demand for transvenous lead extraction (TLE) has also increased. With the ongoing technological advancements, TLE of CIEDs is no longer considered one of the riskiest procedures in electrophysiology, with a major complication rate of 0.3%–5.2% and a mortality rate of 0%–1.5%.[1–10] The national TLE registry in 762 US centers reported no correlation between operator volume and major complications or mortality.[1] An average of 21 TLEs/y are performed by a single operator (B.G.W.) in the Tulane University School of Medicine system. Our study aimed to retrospectively review the clinical outcomes of 80 consecutive patients who underwent TLE from 2016 to 2023. As with any procedure, the safety and success rate of TLE in low-volume centers must be reviewed in the context of the global experience.

Address reprint requests and correspondence: Dr Bassam G. Wanna, Department of Cardiology, Tulane University School of Medicine, 8th Floor, 131 S Robertson St, New Orleans, LA 70112. E-mail address: bwanna@tulane.edu.

Methods

Data collection

We performed a retrospective study using the electronic medical records of the Tulane University School of Medicine system (Tulane Medical Center, University Medical Center, and Lakeview Hospital). The study was reviewed and approved by the Tulane University Institutional Review Board. Informed consent was waived for this retrospective study.

Patients' medical records were systematically reviewed. We excluded patients who underwent lead removal within 1 year of lead implantation. We extracted data including clinical information (age, sex, race, and indication for lead extraction), lead characteristics (implant duration, lead placement, high-voltage coils, fixation pattern, insulation material, and lead diameter), extraction methods, and clinical outcomes (clinical success, procedural success, mortality, and complications).

2666-5018/

https://doi.org/10.1016/j.hroo.2024.07.015

KEY FINDINGS

- Despite the presence of high-risk features, the success rate of transvenous lead extraction is high and the complication rate is low in our low-volume center study.
- Transvenous lead extraction in a low-volume center is as safe and effective as in the high-volume centers.
- Centers' volume is not the independent factor in the outcomes of transvenous lead extraction.

Mechanical lead extraction procedure

After device interrogation, TLE was performed in a hybrid laboratory under general anesthesia with cardiothoracic surgery backup. A temporary pacing wire was inserted if needed. After sterile skin preparation and draping, the device pocket was opened and the leads were separated from adhesions. If removal by simple traction was unsuccessful, a Cook Medical Liberator Beacon tip locking stylet was inserted and then deployed in the lead with the combination use of Cook Medical One-Tie compression coil as a lead control (Cook Medical, Bloomington, IN). We used Bulldog lead extenders in leads without a patent lumen. In most cases, we performed mechanical dissection from subclavian vein access by using a Cook Medical Evolution RL controlled-rotation dilator sheath. Occasionally, we used a Cook Medical Needle's Eye Snare via femoral vein access to extract the leads from below or to create the rail to aid mechanical dissection from above. We did not use laser sheaths, nor did we use trans-internal jugular vein approaches.

Definitions

The definition of lead extraction, procedural success, clinical success, and major complications in this study are based on the 2017 Heart Rhythm Society (HRS) expert consensus statement on CIED lead management and extraction.[11] *Lead extraction* is defined as any lead removal procedure in which at least 1 lead was implanted for >1 year. Complete procedural success is removal of all targeted leads, without any permanently disabling complication or procedure-related death. Clinical success is removal of all targeted leads or retention of a small portion of the lead (<4 cm) that does not negatively affect the clinical goals of the procedure. Failure occurs when clinical success cannot be achieved, permanent disabling complications develop, or procedure-related death occurs. Major complications include death, cardiac avulsion, vascular laceration, respiratory arrest, cerebrovascular accident, pericardial effusion requiring intervention, hemothorax requiring intervention, cardiac arrest, thromboembolism requiring intervention, flail tricuspid valve leaflet requiring intervention, or massive pulmonary embolism.

The research reported in this article adhered to Helsinki Declaration.

Results

One hundred fifty-six leads were removed from 85 patients between February 2016 and December 2023. TLEs amount to ~5% of the total electrophysiological procedures in the same period. After excluding 5 patients with 7 leads who were younger than 1 year, we included 149 leads from 80 patients in the data analysis. The number of TLEs performed per year is shown in Figure 1.

Patient characteristics

The mean patient age was 62.4 ± 14.0 years, and 28.8% (23) were female. Of the total study population, 42.5% (34) patients were African American, 46.3% (37) patients were white, and 5% (4) patients were Asian or Hispanic. Eighty TLEs (53.7%) were indicated for infectious reasons (eg, pocket infection, infective endocarditis, lead vegetation, and persistent bacteremia), while 69 TLEs (46.3%) were indicated for noninfectious reasons including lead malfunction, chronic pain, need for device upgrade, or patient preference (Table 1).

Lead characteristics

There were 88 right ventricular leads, 50 right atrial leads, and 11 left ventricular (LV) leads extracted. Among the right ventricular leads, there were 56 high-voltage leads with 26 dual-coil leads. The average implant duration was 105 ± 79 months. The duration of the oldest lead was 345.8 months. Nineteen patients (23.8%) had ≥3 leads extracted in the same procedure. The maximum number of leads we extracted from a single patient at one time was 7, including 4 abandoned leads from previously failed extractions. Of the 138 non-LV leads, active fixation was present in 114 leads (83.3%). Ten LV leads were passively wedged, while 1 LV lead had active fixation (Table 2).

Procedure outcome

Of the 115 active fixation leads, 44 lead tips could not be retracted. We extracted 32 leads by simple traction, 80 leads with Cook Medical Evolution RL controlled-rotation dilator sheaths via the subclavian vein, 3 leads with a femoral snare, and 32 leads with a combined subclavian RL rotation sheath and femoral snare approach.

We extracted 140 leads successfully without any visible retention by fluoroscopy. The tip of 1 lead was retained in the right femoral vein while being snared out and required surgical removal. The remaining 8 leads were partially removed with retention >4 cm. One of these 8 leads was extracted for an infectious indication. Therefore, the complete procedural success rate and clinical success rate were both 94.6%.

We had no procedure-related deaths. One patient with acquired immunodeficiency syndrome died 3 days after the procedure due to septic shock. Thus, periprocedural mortality was 1.25%. No procedure-related major complications occurred. One patient developed a left chest pocket hematoma that was treated with compression. One patient

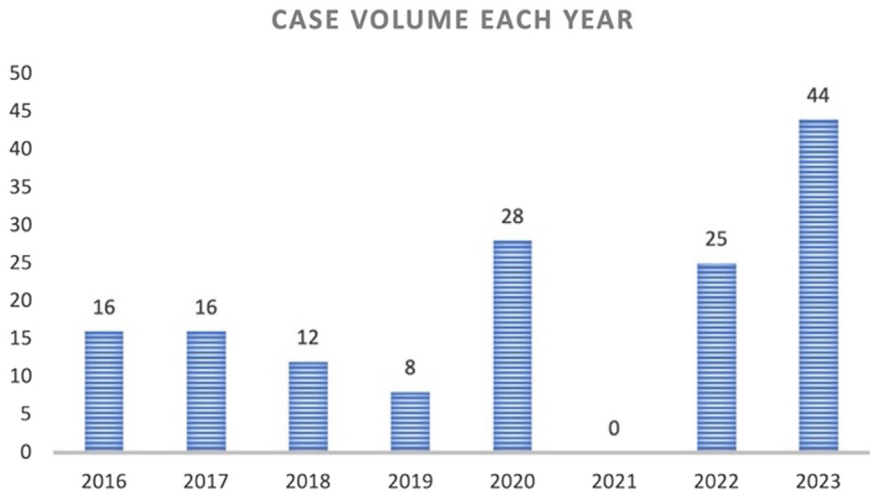

Figure 1 Number of transvenous lead extractions performed per year.

developed a left groin hematoma and required vascular surgery intervention. One patient developed urinary retention and required a foley catheter and overnight stay (Table 3).

Discussion

The overall clinical success rate for TLE in the literature ranges from 94% to 99%, and the complete procedural success rate ranges from 92.3% to 96.7%.[2–10,12–15] The operators' experience, skills, equipment, and the availability of multidisciplinary team support can affect success rates; however, there are additional factors behind these statistics, including the definition of success and lead implant duration.

The clinical success rate was 96.7% and the radiology success rate was 95.7% in the European Lead Extraction ConTRolled study, which used an European Heart Rhythm Association registry of 3510 CIED lead removals from 2012 to 2014 in 73 European centers from 19 countries.[5] Importantly, the definition of clinical success did not include the allowed length of the residual lead, and leads with <1 year implant duration were not excluded. The Lead Extraction in Contemporary Settings study reviewed laser sheath–assisted 2405 lead removals between 2004 and 2007, with a clinical success rate of 97.7% and a complete procedural success rate of 96.5%.[12] As this study was completed before the HRS statement was published, their definition of clinical success was not as strict. The 2018–2019 Japan's registry reported 1253 lead removals, a clinical success rate of 98.9%, and a complete procedural success rate of 96.7%, but they did not include a definition of success.[6] In an Australian study in New South Wales, 1006 leads were removed from 1993 to 2012 with a 96% complete procedural success rate; however, leads had a short average implant duration of 47 months.[4] In these studies, a combination of a less strict definition of success and shorter implant duration may have contributed to the reported higher success rate.

Average lead implant durations are longer in recent studies. In 226 TLEs from 2019 to 2021 in the Poland EVO registry, the clinical success rate was 99.1% and the complete procedural success rate was 94.7%.[9] Investigators

Table 1 Patient characteristics

Characteristic	Value
Age (y)	62.4 ± 14.0 (27 to 92)
Female	28.8% (23)
Race	
White	46.3% (37)
African American	42.5% (34)
Asian or Hispanic	5% (4)
Indication	
Infectious indication	53.7% (80)
Noninfectious indication	46.3% (69)

Values are presented as mean ± SD (minimum to maximum) or percentage.

Table 2 Lead characteristics

Characteristic	Value
Average implant duration (mo)	105 ± 79 (14.4 to 345.8)
Average lead diameter (F)	6.83
Lead insulation	
Silicone alone	57/149 (38.3)
Others	92/149 (61.7)
Lead placement	
Right ventricle	88/149 (59.1)
Right atrium	50/149 (33.5)
Left ventricle	11/149 (7.4)
High-voltage leads	
Single coil	30/149 (20.1)
Dual coil	26/149 (17.4)
Number of leads extracted per patient	
1	38/80 (47.5)
2	23/80 (28.7)
≥3	19/80 (23.8)
Active fixation	115/149 (77.2)

Values are presented as mean ± SD (minimum to maximum) or n/total n (%).

Table 3 Procedure outcomes

Outcome	Value
Extraction approaches	
Simple traction	32/149 (21.5)
Mechanical sheath	80/149 (53.7)
Femoral snare	3/149 (2.0)
Combined mechanical sheath and femoral snare	32/149 (21.5)
Data not available	2/149 (1.3)
Clinical success	141/149 (94.6)
Complete procedural success	141/149 (94.6)
Procedure-related death	0 (0)
Periprocedural death	1/149 (0.67)
Major complications	0 (0)

Values are presented as mean ± SD (minimum to maximum) or n/total n (%).

adhered to the HRS 2017 consensus, and leads were older, with an average implant duration of 133.3 months. The Poland EVO registry reported a noninfectious indication in 66.9% of lead removals. However, intraprocedural mortality was 1.5% and major complications occurred in 5.2% of TLEs. In the 350 TLEs performed from 2013 to 2021 in Zurich, the clinical success rate was 94%, the complete procedural success rate was 92.3%, and the procedure related mortality was 1.45% for patients with a mean lead implant duration of 112.5 months.[10] In 441 TLEs from an Italian multicenter series in 2014–2022 with an implant duration of >10 years, the clinical success rate was 98.2% and the complete procedural success rate was 94.8%. In this study, the definition of clinical success was again not clear.[7] Lastly, the United States National Data Registry study from 2010 to 2012 reviewed 11,304 TLEs' complications but did not report success rates.[1]

Both clinical success and complete procedural success rates were 94.6% at Tulane University School of Medicine, with no procedure-related mortality or major complication. Our average implant duration was longer than that in many large-volume studies. We also had a broad patient age range and more complex cases, with >3 TLEs per patient.[1,16] Overall, our safety and efficacy were comparable with those in large-volume centers.

Unfortunately, data from individual low-volume centers are scarce. The European Lead Extraction ConTRolled study/European Heart Rhythm Association registry defines high volume as >30 TLEs/y. In that study, low-volume centers reported a clinical success rate of 94.2% and a radiological success rate of 93.4%, which were significantly lower than high-volume centers' success rates of 97.3% and 96.2%, respectively. However, the rates of procedure-related death and major complications were similar. Low-volume centers had a higher in-hospital mortality rate, which may be attributable to insufficient multidisciplinary support.[5] The Lead Extraction in Contemporary Settings study defines high volume as >15 TLEs/y. The low-volume centers had a lower clinical success rate and similar rates of mortality and major complications.[3] In the United States, the National Data Registry encompassed 11,304 TLEs between 2010 and 2012 and separated TLE operators into 4 different groups on the basis of their TLE volumes (<20, 21–50, 51–75, >75 TLEs/y). Extraction-related major complications and inpatient mortality were similar among the 4 groups.[1] Di Monaco et al[12] performed a meta-analysis in 2014 including 66 studies comparing high- and low-volume centers. Centers were separated into 3 groups on the basis of annual TLE volumes (<15, 15–30, and >30 TLEs/y). Intraprocedural mortality and major complications were again similar among the 3 groups. Mortality at 30 days and minor complications were higher in low- than in high-volume centers. However, this meta-analysis suffers from a lack of a priori, publication bias, and duplicate data.[12]

Last but not least, we need to address the fact that the individual operator's skills and case volume could be important confounding factors when analyzing center volumes and outcomes. The 2009 HRS expert consensus recommends extraction of a minimum of 20 leads annually per operator to maintain competency.[17] However, low-volume centers with multiple operators will not be able to meet this standard, which may affect their outcomes. On the contrary, in a high-volume center with multiple operators, the individual operator's annual extraction volume may be close to the volume of a single operator in a low-volume center such as ours. According to the United States National Data Registry report a decade ago, the percentages of operators whose annual extraction volumes are <20, 21–50, 51–75, and >75 are 75.7%, 18.3%, 1.0%, and 5.0% respectively.[1] Our operator's average extraction volume is 21 per year, which is a reasonable amount. This may positively contribute to the outcomes in our low-volume center.

Overall, low-volume centers have the same mortality rate and major complications rate as high-volume centers but may have lower success rates. Lower success rates may reflect a less aggressive approach than in high-volume centers, as there is always a fine balance between safety and efficacy in high-risk procedures. In TLEs indicated for infectious reasons, we always aim for complete procedural success to achieve the clinical goal. However, in the literature, the higher mortality rate of TLEs for infectious indications compared with noninfectious indications was usually due to other comorbidities and not related to the procedure.[18–20] For noninfectious indications, if the retention of the lead is >4 cm, it is defined as clinical and procedural failure. Seven of our 8 clinical failures were due to retention of slightly more than 4 cm. These 7 TLEs were all indicated for noninfectious reasons. The 4-cm cutoff is based on expert consensus. However, most of these noninfectious residuals may not have a negative effect clinically.

Limitations

This study was subject to the limitations of any retrospective study, including unknown confounders and bias in patient selection for TLE extraction. There was a relatively small sample size, limiting the ability to draw deeper conclusions on the basis of patient demographics and leading to the possibility of

sampling errors. Only mechanical sheaths were used in this study, but in other centers, laser and other types of sheaths are commonly used. In addition, as this is a low-volume center, we were unable to directly compare results with large-volume centers, and the operator's volume may be a confounder that could not be addressed in this study. Further research involving more patients and more centers is needed.

Conclusion

This study revealed that despite an increased number of leads per patient, wide patient age range, and long implant duration, success rates were high and complication rates were low in this low-volume, single-operator hospital system. The safety and effectiveness of TLEs are comparable in low- and high-volume centers. Low-volume centers are not as aggressive as high-volume centers when the indication for extraction is noninfectious.

Funding Sources: The authors have no funding resources to report.

Disclosures: There is no conflict of interest for all authors.

Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: Informed consent was waived for this retrospective study.

Ethics Statement: The study was reviewed and approved by the Tulane University Institutional Review Board. The research reported in this article adhered to Helsinki Declaration guidelines.

References

1. Sood N, Martin DT, Lampert R, Curtis JP, Parzynski C, Clancy J. Incidence and predictors of perioperative complications with transvenous lead extractions: real-world experience with National Cardiovascular Data Registry. Circ Arrhythm Electrophysiol 2018;11:e004768.
2. Kennergren C, Bjurman C, Wiklund R, Gabel J. A single-centre experience of over one thousand lead extractions. Europace 2009;11:612–617.
3. Wazni O, Epstein LM, Carrillo RG, 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;55:579–586.
4. Gomes S, Cranney G, Bennett M, Li A, Giles R. Twenty-year experience of transvenous lead extraction at a single centre. Europace 2014;16:1350–1355.
5. Bongiorni MG, Kennergren C, Butter C, 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.
6. Shoda M, Kusano K, Goya M, et al. Japanese Lead EXtraction (J-LEX) registry: annual report 2019. J Arrhythm 2022;38:187–191.
7. Migliore F, Pittorru R, Dall'Aglio PB, et al. Outcomes of transvenous lead extraction of very old leads using bidirectional rotational mechanical sheaths: results of a multicentre study. J Cardiovasc Electrophysiol 2023;34:728–737.
8. Gladysz-Wańha S, Joniec M, Wańha W, et al. Transvenous lead extraction safety and efficacy in infected and noninfected patients using mechanical-only tools: prospective registry from a high-volume center. Heart Rhythm 2024;21:427–435.
9. Przybylski A, Jagielski D, Hrymniak B, et al. Employment of the Evolution RL sheath as a first-choice device shortens transvenous lead extraction time without affecting procedural safety and efficacy compared to its auxiliary use: insights from the prospective multicenter EVO registry. Adv Clin Exp Med 2023;32:1249–1256.
10. Hofer D, Kuster N, Bebie MC, Sasse T, Steffel J, Breitenstein A. Success and complication rates of transvenous lead extraction in a developing high-volume extraction center: the Zurich experience. J Clin Med 2023;12:2260.
11. Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14:e503–e551.
12. Di Monaco A, Pelargonio G, Narducci ML, et al. Safety of transvenous lead extraction according to centre volume: a systematic review and meta-analysis. Europace 2014;16:1496–1507.
13. Zabek A, Boczar K, Ulman M, et al. Mechanical extraction of implantable cardioverter-defibrillator leads with a dwell time of more than 10 years: insights from a single high-volume centre. Europace 2023;25:1100–1109.
14. Knutsen TM, Skretteberg PT, Vanberg P, et al. Transvenous lead extractions in a single high-volume center over a 24-year period: high success rate and low complication rate. Heart Rhythm O2 2023;4:232–240.
15. Sharma S, Ekeruo IA, Nand NP, et al. Safety and efficacy of transvenous lead extraction utilizing the evolution mechanical lead extraction system: a single-center experience. JACC Clin Electrophysiol 2018;4:212–220.
16. Tan MC, Ang QX, Yeo YH, et al. Effect of age on in-hospital outcomes of transvenous lead extraction for infected cardiac implantable electronic device. Pacing Clin Electrophysiol 2024;47:577–582.
17. Wilkoff BL, Love CJ, Byrd CL, et al. Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management: this document was endorsed by the American Heart Association (AHA). Heart Rhythm 2009;6:1085–1104.
18. Aleong RG, Zipse MM, Tompkins C, et al. Analysis of outcomes in 8304 patients undergoing lead extraction for infection. J Am Heart Assoc 2020;9:e011473.
19. Gould J, Klis M, Porter B, et al. Predictors of mortality and outcomes in transvenous lead extraction for systemic and local infection cohorts. Pacing Clin Electrophysiol 2019;42:73–84.
20. Chung DU, Burger H, Kaiser L, et al. Transvenous lead extraction in patients with systemic cardiac device-related infection—procedural outcome and risk prediction: a GALLERY subgroup analysis. Heart Rhythm 2023;20:181–189.