Impact of fixation mechanism and helix retraction status on right ventricular lead extraction

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BACKGROUND The impact of lead fixation mechanism on extractability is poorly characterized.

OBJECTIVE We aimed to compare the technical difficulty of transvenous lead extraction (TLE) of active vs passive fixation right ventricular (RV) leads.

METHODS A total of 408 patients who underwent RV TLE by a single expert electrophysiologist at Oregon Health & Science University between October 2011 and June 2022 were identified and retrospectively analyzed; 331 (81%) had active fixation RV leads and 77 (19%) had passive fixation RV leads. The active fixation cohort was further stratified into those with successfully retracted helices (n = 181) and failed helix retraction (n = 109). A numerical system (0–9) devised using 6 procedural criteria quantified a technical extraction score (TES) for each RV TLE. The TES was compared between groups.

RESULTS Helix retraction was successful in ≥55% of active fixation TLEs. The mean TES for active-helix retracted, active-helix non-retracted, and passive fixation groups was 1.8, 3.5, and 3.7, respectively. The TES of the active-helix retracted group was significantly lower than those of the active-helix non-retracted group (adjusted $P < .01$) and the passive fixation group (adjusted $P < .01$). There was no significant difference in TES between the passive fixation and active-helix non-retracted groups in multivariate analysis ($P = .18$). The TLE success rate of the entire cohort was >97%, with a major complication rate of 0.5%.

CONCLUSION TLE of active fixation leads where helical retraction is achieved presents fewer technical challenges than does passive fixation RV lead extraction; however, if the helix cannot be retracted, active and passive TLE procedures present similar technical challenges.

KEYWORDS Transvenous lead extraction; Technical difficulty; Fixation mechanism; Passive fixation lead; Active fixation lead; Helix retraction

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Introduction

Transvenous lead extraction (TLE) has evolved dramatically over the years and remains a dynamic area of innovation. New technologies coupled with improvements in the familiarity and availability of advanced extraction techniques have enhanced the safety and success rates of TLE procedures, contemporaneously expanding their clinical indications.[1–4] Amidst a rapidly evolving clinical climate, more evidence is needed to guide TLE management practices safely and systematically into the future. The impact of lead fixation mechanism on TLE is one area warranting further investigation.

A perception of easier extractability of active fixation leads in comparison to their passive fixation counterparts is a frequently quoted benefit in the TLE community.[5–9] However, there is little conclusive literature to verify that claim.[4,5] This study aims to help fill that data gap by comparing the technical difficulty of TLE of active vs passive fixation right ventricular (RV) leads via the development of a standardized scoring system.

Methods

Four hundred eight patients who underwent RV TLE by a single expert electrophysiologist at Oregon Health & Science University between October 2011 and June 2022 were identified from an institutional database and retrospectively analyzed. Single- and dual-chamber devices, with either pacing or implantable cardioverter-defibrillator (ICD) RV lead types, were included in the study. Patients with multiple RV leads were excluded. Of the 408 patients who met

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KEY FINDINGS

- We established a standardized scoring system to help retrospectively quantify the difficulty of transvenous lead extraction procedures.
- Lead fixation mechanism and helical retraction status are both significant contributing factors to transvenous lead extraction (TLE) difficulty. Passive fixation right ventricular (RV) leads and active fixation RV leads with unretracted helices present greater technical challenges during TLE than do active fixation leads in which helical retraction is achieved.
- Active fixation leads with retracted helices have a significantly higher TLE success rate overall.

inclusion criteria, 331 (81%) had active fixation RV leads and 77 (19%) had passive fixation RV leads. The active fixation lead cohort was further stratified into those with successfully retracted helices and those with failed helix retraction.

The extraction procedure generally followed the Heart Rhythm Society guidelines.[10] Briefly, the procedure was performed in the hybrid operating room for patients with leads >3 years old and in the electrophysiology laboratory for patients with leads <3 years old. In the operating room, patients were under general anesthesia with a transesophageal echocardiogram probe in place and a radial arterial line. The chest was prepped for sternotomy. Groin access was obtained for temporary pacing, placement of a rescue balloon, and snaring of the leads in addition to access for large-volume resuscitation. A cardiac surgeon with full support was immediately available for complications. After the pocket was opened and leads mobilized, the RV lead was typically targeted for extraction first, and the laser was typically the first advanced tool used, with a mechanical tool as a second choice, and groin was used if the superior approach failed. For cases done in the electrophysiology laboratory, these were typically under monitored anesthesia care and often done without transesophageal echocardiography or arterial line monitoring.

A summative numerical system (0–9) was devised using 6 procedural criteria to quantify a technical extraction score (TES) for each RV lead extraction (Figure 1). Zero points were assigned if the lead was removed by manual traction only. The use of a locking stylet and the use of any singular tool type (laser or mechanical sheath) were assigned point values of 1. The use of multiple size tools of the same type and the combinational use of both a laser and a mechanical tool during the procedure were assigned point values of 2. Finally, the use of any groin tool was assigned a point value of 3. Points were summed accordingly on the basis of the procedural requirements of each TLE to obtain a total TES.

Statistical analysis and definitions

Data are presented as frequency and percentage for categorical variables and mean and standard deviation or median and interquartile range for continuous variables. The Fisher exact test and the Kruskal-Wallis test were used for overall group comparison of categorical and continuous variables, respectively. The Dunn test with Bonferroni correction was used to test pairwise differences in TES among subgroups. Multivariate analysis of the effect of fixation mechanism on TES

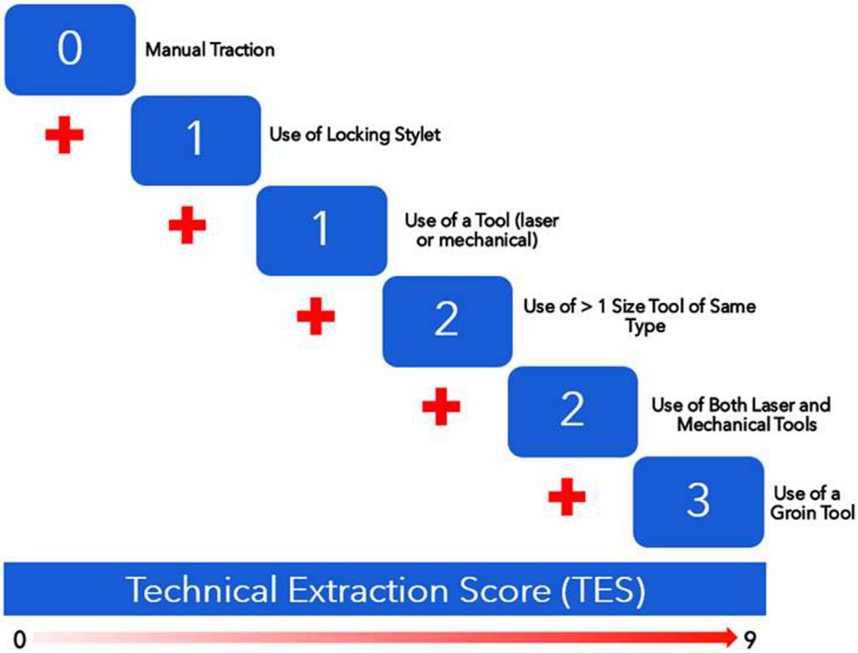

Figure 1 Diagrammatic representation of additive technical extraction score components.

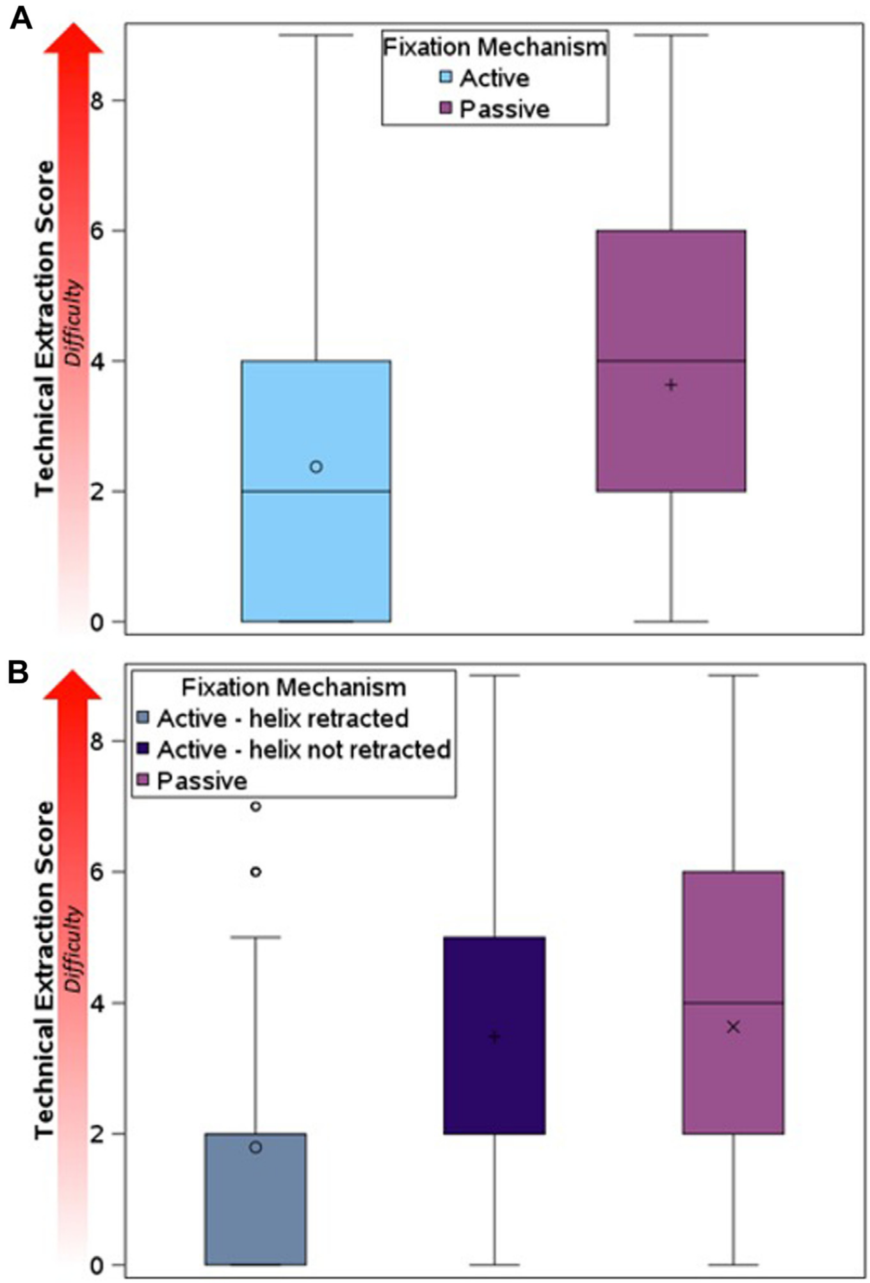

Figure 2 Technical extraction score by fixation group for (**A**) overall active vs passive leads and (**B**) active leads stratified by helix retraction status vs passive leads.

was performed using a generalized additive model with a Poisson distributional assumption. Univariate and multivariate logistic regression models were used to predict the risk of higher extraction difficulty (TES > 4). All significance tests were 2-sided, with $P < .05$ considered statistically significant. These statistical analyses were performed using SAS Studio 3.6 (SAS Institute Inc, Cary, NC) and RStudio (Posit Software, PBC, Boston, MA).

TLE success in this study included complete procedural success or clinical success as defined in the 2017 Heart Rhythm Society consensus statement. Major complications were also defined accordingly.[10]

Results

TESs were initially calculated for all 408 patients who underwent RV lead extraction and compared between the active (n = 331 [81%]) and passive (n = 77 [19%]) fixation lead groups (Figure 2). The mean TES for active and passive TLE procedures was 2.4 and 3.6, respectively ($P < .01$). The active fixation group was then further stratified into those with successfully retracted helices (n = 181 [62%]) and those with failed helix retraction (n = 109 [38%]). Helix retraction was successful in at least 55% of active fixation lead extractions. Forty-one patients with active fixation leads had a helical retraction status that could not be characterized and were

Table 1 Patient and RV lead characteristics

Characteristic	Active-helix retracted (n = 181 [49%])	Active-helix non-retracted (n = 109 [30%])	Passive (n = 77 [21%])	Overall *P*
Age (y)	65 (51–75)	59 (46.5–68.0)	60.5 (48.5–70.0)	.007
Male sex	112 (62)	71 (65)	44 (57)	.49
Infectious extraction indication	85 (47)	35 (32)	19 (25)	.001
Noninfectious extraction indication				
End of life/upgrade	2 (1)	0 (0)	0 (0)	.7062
Venous occlusion	11 (6)	3 (3)	6 (8)	.25
Lead failure	28 (15)	47 (43)	33 (43)	<.0001
Abandoned lead	4 (2)	2 (2)	2 (3)	1
Pericardial effusion	1 (1)	0 (0)	0 (0)	1
Pain	5 (3)	1 (1)	0 (0)	.3503
Other/not recorded	45 (25)	21 (19)	17 (22)	.5470
Dwell time (y)	3.95 (1.77–6.52)	7.12 (4.68–9.63)	5.48 (2.28–14.64)	<.0001
Lead type				.0183
Defibrillator	83 (46)	69 (63)	37 (48)	
Pacing	97 (54)	39 (36)	40 (52)	
Unknown	1 (1)	1 (1)	0 (0)	

Values are presented as median (interquartile range) or n (%).
RV = right ventricular.

excluded from subsequent analyses. Pairwise comparisons between the 3 groups showed that the TES of the active-helix retracted group was significantly lower than those of both the active-helix non-retracted group (adjusted $P < .01$) and the passive fixation group (adjusted $P < .01$). There was no significant difference in TES between the active-helix non-retracted and passive fixation groups (adjusted $P > .99$).

On the basis of the pairwise findings, all proceeding analyses were completed using these 3 distinct patient subgroups to better characterize the relationship between helical status and fixation mechanism. The median age at the time of TLE in the overall cohort (n = 367) was 62 (51–75) years, with 62% of patients being male. The median age, median dwell time, lead type, and extraction indication were all significantly different between the groups in univariate analysis. The median dwell time for active-helix retracted, passive, and active-helix non-retracted groups was 4.0, 5.5, and 7.1 years, respectively. Upon pairwise comparison, the median dwell time was significantly less in the helix retracted group than in the helix non-retracted group ($P < .01$). In the active-helix non-retracted group, defibrillator leads were the dominant RV lead type (63%), whereas RV pacer leads

Table 2 TES breakdown and procedural outcomes

Variable	Active-helix retracted (n = 181 [49%])	Active-helix non-retracted (n = 109 [30%])	Passive (n = 77 [21%])	Overall *P*
TES				
Removal by manual traction	71 (39)	5 (5)	8 (10)	<.0001
Locking stylet used	110 (61)	104 (95)	69 (90)	<.0001
Use of a tool	105 (58)	99 (91)	67 (87)	<.0001
Use of >1 size tool of the same type	23 (13)	33 (30)	23 (30)	.0002
Use of both laser and mechanical tools	19 (11)	28 (26)	27 (35)	<.0001
Use of a groin tool	9 (5)	20 (18)	15 (19)	.0001
TES	1.80 ± 1.89	3.53 ± 2.17	3.65 ± 2.48	<.0001
Dichotomized TES				<.0001
>4	17 (9)	31 (28)	26 (34)	
≤4	164 (91)	78 (72)	51 (66)	
Outcomes				
Extraction success rate				
Complete procedural success	180 (99)	104 (95)	73 (95)	.0185
Clinical success*	180 (99)	104 (95)	73 (95)	.0185
Major complication rate	1 (0.6)	0 (0)	1 (1.3)	.4637

Values are presented as mean ± SD or n (%).
TES = technical extraction score.
*Clinical successes were the same as complete procedural successes in this study, as there were no small (<4 cm) retained lead portions.

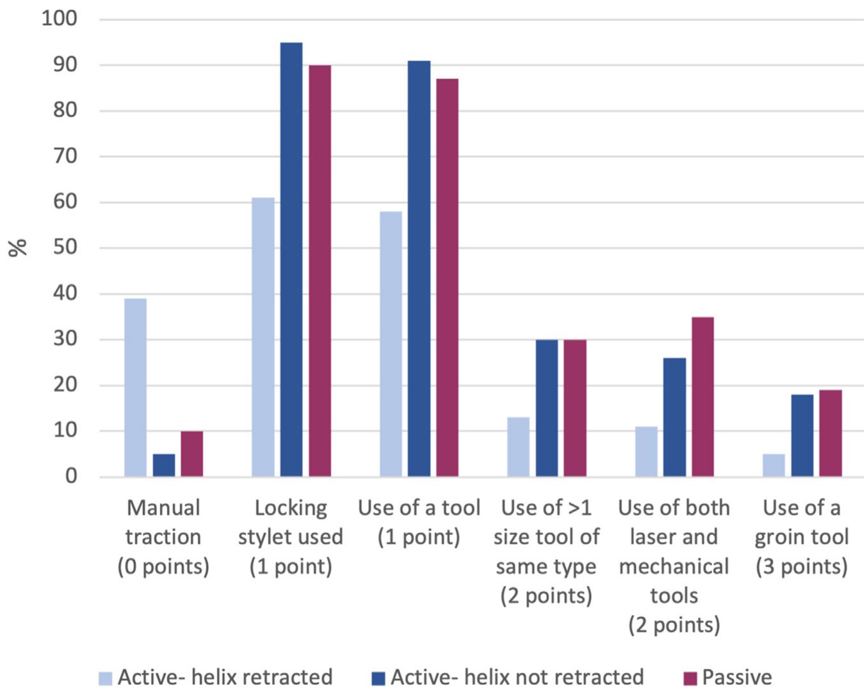

Figure 3 Proportion of discrete technical extraction score components by fixation group.

compromised the small majority in both the active-helix retracted (54%) and passive fixation lead (52%) groups. Patients with active fixation leads in which helix retraction was successful had the largest proportion of infectious extraction indications among all the groups at 47%, while only 25% of passive fixation lead extractions had an infectious indication. A detailed summary of patient and lead characteristic data is provided in Table 1.

As shown in Figure 2, the TES was significantly lower in the active-helix retracted group than in the passive fixation group. The mean TES for active-helix retracted, active-helix non-retracted, and passive fixation groups was 1.8, 3.5, and 3.7, respectively. Notably, although age, dwell time, lead type, and extraction indication were significantly different between the 3 groups in univariate analysis, the pairwise differences in TES observed univariately persisted after controlling for the effects of these variables. In nonparametric multivariate regression, the TES remained statistically different between the active-helix retracted and passive fixation groups ($P < .01$) while no significant difference was found between the active-helix non-retracted and passive fixation groups ($P = .12$).

The summative TES was broken down and each discrete criterion analyzed. TLE using manual traction only was most prevalent in the active-helix retracted group (39%). Extraction tools were used more frequently in the active-helix non-retracted and passive fixation groups, as evidenced by higher percentages in all nonzero TES categories in Table 2 and Figure 3.

Given the practical challenges of using nonparametric regression estimators, the TES variable was dichotomized to facilitate clinical interpretability and application. The overall cohort upper quartile TES value of 4 was chosen as the cutoff. As such, TLE procedures with a TES of >4, corresponding to the highest 25% of patient TESs, were categorized as having a high degree of technical difficulty, and those with a TES of ≤4 were categorized as less technically challenging. The results of the logistic regression of dichotomized TES are comprehensively presented in Table 3 and Figure 4.

Table 3 Univariate and multivariate logistic modeling for the risk of TES > 4

Variable	Univariate analysis OR (95% CI)	*P*	Multivariate analysis OR (95% CI)	*P*
Active-helix non-retracted vs passive	0.78 (0.42–1.46)	.05	0.95 (0.47–1.92)	.18
Active-helix retracted vs passive	0.20 (0.10–0.40)	<.0001	0.41 (0.19–0.87)	.008
Age	0.99 (0.98–1.01)	.44	1.00 (0.99–1.02)	.72
Dwell time	1.15 (1.10–1.21)	<.0001	1.13 (1.07–1.19)	<.0001
Infectious removal indication	0.35 (0.19–0.64)	.0007	0.37 (0.19–0.74)	.005
Defibrillator lead type	1.34 (0.80–2.24)	.27	1.30 (0.73–2.32)	.37

CI = confidence interval; OR = odds ratio; TES = technical extraction score.

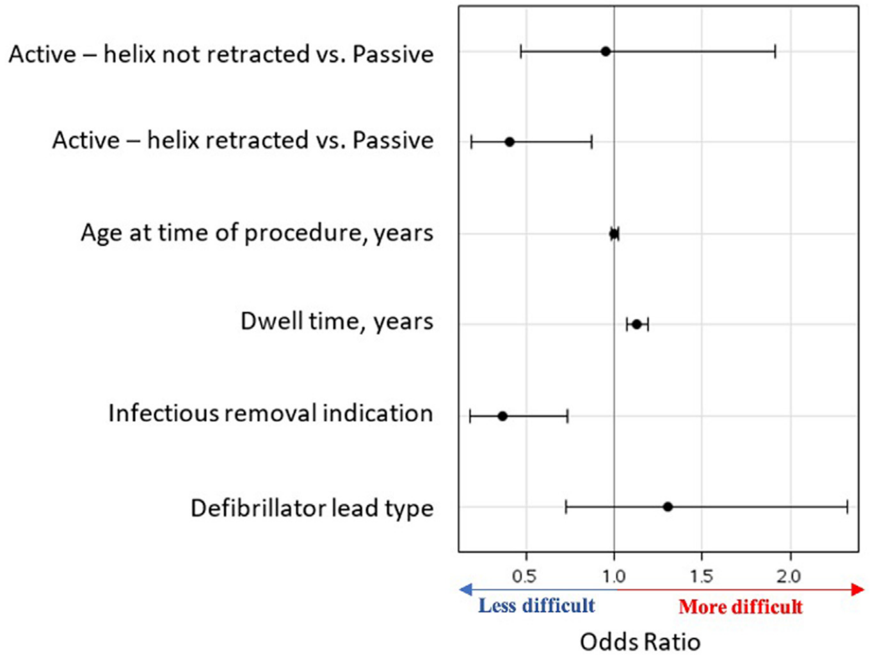

Figure 4 Adjusted odds ratios for the risk of high difficulty transvenous lead extraction with technical extraction score > 4.

Notably, in univariate analysis, the active-helix retracted group was found to have a lower risk of TES > 4 when compared with the passive fixation group (odds ratio 0.20; $P < .01$). This relationship persisted in multivariate analysis after adjusting for age, dwell time, extraction indication, and lead type, with the active-helix retracted group having 60% lower odds of TES > 4 than does the passive fixation group (odds ratio 0.41; $P < .01$). A statistically significant difference in risk between the active-helix non-retracted and passive fixation groups was not found in either univariate or multivariate analysis. Infectious extraction indication was associated with a lower risk of TES > 4, while dwell time was associated with an increased risk of TES > 4 in both univariate and multivariate regression. Patient age and lead type were not significantly associated with high TES risk. However, in additional post hoc subgroup analysis, ICD leads were further broken down into single-coil and dual-coil lead types. In this case, dual-coil ICD leads were found to be significantly more difficult to extract ($P = .013$) with a mean TES of 3.54 as compared with single-coil ICD leads, which had a mean TES of 2.77.

Overall, the lead extraction success rate of the entire cohort was >97%, with a major complication rate of 0.5%. A statistically significant difference in TLE success rates ($P = .02$) was driven by the pairwise difference between the active-helix retracted and active-helix non-retracted groups ($P = .03$) as well as between the active-helix retracted and passive groups ($P = .03$). There was no statistically significant difference in TLE success between the active-helix non-retracted and passive lead groups ($P = 1$). The complete procedural success rate was 99%, 95%, and 95% for active-helix retracted, active-helix non-retracted, and passive lead groups, respectively (Table 2). Clinical success rates were synonymous with the complete procedural success rates for all groups, as there were no retained lead portions in any of these cases. There was no statistically significant difference in the rate of major complication between groups. Major complications included 1 occurrence of complete heart block in the passive fixation group (1.3%) and 1 occurrence of hemothorax from a left brachiocephalic vein tear in the active-helix retracted group (0.6%), which required urgent sternotomy and venous repair by the cardiothoracic surgery team. There were a total of 9 failed lead extractions, the majority of which occurred in the passive (44%) and active-helix non-retracted (44%) lead groups. All 4 of the failed passive lead extractions were due to fractured or separated leads. In the active-helix non-retracted group, lead fracture was the cause of 1 of the 4 total TLE failures; TLE was aborted in the other 3 cases because of a variety of reasons including dense adhesions, unsuccessful sheath advancement, and lead-lead interaction. There was 1 failed TLE case in the active-helix retracted group (11%), which was due to unsuccessful sheath advancement.

Discussion

The decision to pursue TLE is often multifactorial and can require a nuanced clinical assessment.[1,2,11] Within the cardiac electrophysiology community, there is a widespread perception among professionals that passive fixation leads are more difficult to extract. In an era where expanding technological competencies have liberalized noninfectious indications for performing TLE, surveyed experts have cited passive fixation mechanism to be a determining factor when opting to pursue lead abandonment rather than extraction in various observational studies.[4,5,12,13] Despite an abundance of experiential acumen, outside of the recent analysis conducted by Levi et al from the European Lead Extraction ConTRolled Registry,[5] there is a paucity of data to corroborate clinical perceptions on the impact of passive lead fixation on TLE risk. The results of the present study substantiate and expand on these clinical notions to include helical retraction status as an equally important consideration when differentiating between active and passive fixation lead extraction difficulty.

According to the TES comparisons in this study, passive fixation RV leads and active fixation RV leads with unretracted helices are technically analogous and present greater challenges during TLE than do active fixation leads in which helical retraction was achieved. The deleterious effect of passive fixation and unsuccessful helix retraction on TLE difficulty was independently demonstrated in multivariate analysis of both continuous and dichotomized TESs. There was an observable 20% decrease in the magnitude of difficulty difference between the passive and active-helix retracted fixation groups in multivariate analysis of the dichotomized TES in comparison to univariate results, as demonstrated by an estimated odds ratio of 0.4 vs 0.2, respectively. It seems plausible that the higher degree of TES risk found in the univariate model is attributable to differences in dwell time and rates of noninfectious TLE indications between the groups, both of which were lowest in patients with the active-helix retracted lead type in our study.

Longer dwell time and noninfectious extraction indications are associated with increased TLE difficulty, a correlation that has been serially demonstrated in the existing literature.[5,14–18] The passive fixation group and its active-helix non-retracted counterpart had higher and more compatible values for dwell time and rates of noninfectious extraction indications in this study, which may have contributed to their similarities in TES. Notably, the median dwell time in the active-helix non-retracted group (7.12 years) was significantly higher than that in the active-helix retracted group (3.95 years), which raises a question of the effect dwell time may have on helical retraction status. Presumably, as dwell time increases and fibrous encapsulation accumulates at the lead tip, the ability to retract the helix could be impeded. Passive fixation leads have been shown to develop more intracardiac fibrous adherence over time,[19] which likely is a primary driver of their higher TES. However, the results of this study suggest that if the helix of an active fixation lead is unretractable, functionally their extraction requirements are on par with passive leads. Interestingly, in a single small study ($n = 40$) evaluating whether helical retraction mechanisms remained intact after lead removal, longer dwell times did not correlate with a higher probability of helical retraction failure.[6]

As alluded to during the earlier discussion, various scoring systems have already been created to predict the difficulty and risk associated with TLE procedures.[14–17] Of these, the lead extraction difficulty index by Bontempi et al[14] was the only model to consider lead fixation mechanism in its development. Interestingly, active fixation leads were associated with an increased risk of TLE difficulty in multivariate analysis, though the reliability of that particular finding was called into question by authors given an array of cohort characteristics that may have led to confounded results.[5,14] Ultimately, fixation type was excluded from the final lead extraction difficulty index. It is important to distinguish these former predictive scores from the TES devised in this study, in terms of both functionality and applicability. In contrast to prior studies, the purpose of this research was not to develop a predictive model for TLE, but rather to systematically quantify intraprocedural complexity to analyze, compare, and interpret the effect of fixation mechanism more feasibly in the postprocedural setting. With that in mind, while we acknowledge the challenges that a novel operator-dependent scoring system may pose to generalizability, as a nonpredictive, retroactive tool, the immediate utility of the TES in this context should not be stringently discounted. Furthermore, to overcome the inherent limitations of a single-center retrospective analysis, we anticipate the need for future study iterations to further validate the TES. Although not the primary aim of this study, multivariate analysis of TES corroborated the significant influence of dwell time and infectious extraction indication on TLE difficulty, as demonstrated in several of the prior scoring systems. Additional variables such as female sex, younger patient age, defibrillator lead type, and the presence of multiple leads, which were included in some of the other predictive models, either were not tested or did not consistently demonstrate significance in this study.[5,14–17]

The differences in technical extraction difficulty between the lead groups contributed to similar differences in overall TLE success rates. The active-helix retracted lead group had a significantly higher TLE success rate (99%) than did both the active-helix non-retracted (95%) and passive groups (95%), whereas no difference was observed in TLE success between the active-helix non-retracted and passive groups. Despite statistically significant differences in TLE success rates, TLE difficulty did not impact the rate of major complications between groups. Clinically, high procedural success rates with low rates of major complications were maintained in all groups, irrespective of lead fixation type or helical retraction status. Unsurprisingly, TLE of active-helix non-retracted and passive fixation leads consistently required more advanced extraction techniques and tools. These findings emphasize the importance of appropriate facilities, personnel, experience, and equipment in ensuring the safety and success of TLE.[10,14] Patients with passive fixation leads or active leads with the possibility of failed helix retraction may warrant additional preprocedural planning to accommodate higher technical requirements. Finally, we anticipate that the results of this study will serve to empirically consolidate long-held clinical perceptions and enhance the clinical decision-making process inherent in complex extraction procedures.

Conclusion

TLE of active fixation leads in which helical retraction is achieved presents fewer technical challenges than does extraction of passive fixation RV leads; however, if the helix cannot be retracted, the active and passive leads present similar technical challenges. Furthermore, differences in technical extraction difficulty translates to higher rates of procedural success for active fixation leads with retracted helices. Low complication rates are maintained regardless of lead fixation mechanism or helical retraction status.

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Ethics Statement: The research data reported in this study are derived from an institutional review board–approved research database and retrospectively analyzed.

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