Predictors of the need for supportive femoral approach during transvenous extraction of pacemaker and defibrillator leads in Japanese patients

Tsuyoshi Isawa MD1 | Taku Honda MD1 | Kazuhiro Yamaya MD2 | Masataka Taguri PhD3

Abstract

**Background:** Studies on femoral approach during transvenous lead extraction (TLE) are limited.

**Methods:** We retrospectively evaluated 75 patients undergoing TLE from September 2014 through November 2019 via supportive femoral approach (Femoral/Superior group; n = 22) and superior approach alone (Superior group; n = 53).

**Results:** No significant between-group differences were observed regarding patients’ baseline characteristics except for a higher incidence of access vein occlusion in the Femoral/Superior group (59.1% vs. 31.4%; *P* = .037). The Femoral/Superior group exhibited significantly longer dwell times of the oldest extracted lead (median: 13.4 years; interquartile range [IQR]: 8.8-21.2 years vs. median, 7.2 years; IQR: 3.7-10.8 years; *P* < .001) and a higher incidence of passive fixation ventricular pacemaker lead (81.8% vs. 39.6%; *P* = .001). Multivariate logistic analysis showed that access vein occlusion (odds ratio [OR]: 4.07, 95% confidence interval [CI]: 1.08-15.3; *P* < .001) and dwell time of the oldest extracted lead (per year) (OR: 1.22, 95% CI: 1.09-1.37; *P* = .038) were predictors of the need for supportive femoral approach. Receiver operating characteristic curve analysis revealed that 11.8 years from implant was the cutoff for the need for supportive femoral approach (sensitivity 68.2%, specificity of 81.1%, area under the curve 0.81).

**Conclusions:** Access vein occlusion and long dwell time of the oldest extracted lead predict a high probability of the need for supportive femoral approach. Supportive femoral approach may be necessary in patients with leads that are implanted for >11.8 years and whose access veins are occluded.

**Keywords**
access vein occlusion, lead dwell time, lead extraction, supportive transfemoral approach
Transvenous lead extraction (TLE) procedures are being increasingly performed as cardiovascular implantable electronic device (CIED) implantations continue to rise globally.1,2 Due to the operator preference and availability of powered sheaths (laser or mechanical), the most popular approach for performing TLE is via the subclavian vein, called the superior approach (implant vein approach)3, whereas lead extraction via the femoral vein is occasionally required when superior approach causes a complete failure, referred to as bailout femoral approach.4,5 To date, studies have focused on the outcomes and the predictors for bailout femoral approach.4,5 However, lead extractors sometimes encounter difficult cases where superior approach with the help of snare catheter inserted from the femoral vein is indispensable (simultaneous traction approach).6 Using femoral approach during lead extraction may be useful not only as a bailout strategy but also as a supportive strategy for superior approach, and therefore, predicting the need for femoral approach in advance either as a bailout or as a support for superior approach is essential for procedural planning, including the preparation of lead extraction devices and the location choice for the procedure. Here, we broadly defined femoral approach called "supportive femoral approach" as either (a) an approach for removal of the targeted lead through the femoral vein as a bailout procedure after complete failure of the superior approach or (b) an approach supporting the superior approach during lead extraction, by the removal of the targeted lead through the subclavian vein with the aid of a snare catheter from the femoral vein. Thus, we conducted this retrospective study to investigate the predictors of the need for supportive femoral approach during lead extraction in Japanese patients.

2 | METHODS

2.1 | Patient selection

We screened 83 consecutive patients undergoing TLE for CIED-associated infection, lead malfunction, or device upgrade at the Sendai Kousei Hospital from September 2014 through November 2019. Of these patients, one was excluded from the analysis due to the indication for "primary femoral approach" because the lead's cut point was too deep in the pacemaker pocket (intravascular lead), making it impossible to grasp its free end via the subclavian route; furthermore, seven patients were excluded due to the extraction of leads implanted for ≤1 year because removal of any lead implanted ≤1 year did not meet the definition of lead extraction.7 Of the patients whose leads were implanted for >1 year, no one underwent lead explant (ie, lead removal requiring no specialized extraction tools) during the study period. Consequently, we retrospectively evaluated 75 patients undergoing TLE via supportive femoral approach (n = 22) or superior approach alone (n = 53) (Figure 1). The indications for TLE were based on the 2009 and 2017 Heart Rhythm Society (HRS) consensus documents.7,8 Patients’ baseline characteristics, lead and device characteristics, and predictors that indicate the need for supportive femoral approach were investigated.

2.2 | Lead extraction procedure

Preprocedural evaluation included routine laboratory studies, electrocardiography, chest X-ray, spirometry, transthoracic echocardiography, and bilateral subclavian venography. Blood and wound cultures were also collected from all infection cases. Meanwhile, the bilateral subclavian venography was performed 2 or 3 days before TLE to confirm the diagnosis of access (implant) vein occlusion and the patency of contralateral subclavian vein to prepare for future CIED reimplantation. All procedures were performed in a hybrid operating room under general anesthesia with transvenous temporary pacing, invasive arterial blood pressure monitoring, transesophageal echocardiography, and immediate onsite cardiovascular surgical coverage. Each patient’s chest was cleaned and prepared for emergent thoracotomy, with a set of tools needed for thoracotomy at hand. TLE was performed by the same two trained cardiologists and primarily done by superior approach; the procedure was followed by debridement of the affected pocket and dissection of lead adhesion close to the clavicle by an experienced cardiac surgeon to secure traction in line with the subclavian vein. Using a locking stylet (LLD lead locking device; Spectranetics, Colorado Springs, CO, USA), the superior approach using a laser sheath (Spectranetics) was used as the primary approach...
(first-line laser-assisted strategy); when this did not work well, use of a telescopic or “hand-powered” mechanical sheath—the bidirectional rotational Evolution® RL (Cook Medical Inc, Bloomington, IN, USA)—was attempted. In some cases, upsizing the powered sheaths in a stepwise manner was also attempted. If all these approaches failed, supportive femoral approach was attempted to provide good support by pulling the lead caudally to advance a powered sheath over the lead through the subclavian vein, using a Needle’s Eye Snare (Cook Medical Inc) for a lead that did not have a free end or the EnSnare kit (ev3 Inc; Paris, France) for a lead that had a free end. When using the former, we usually employed a “spaghetti-twisting” technique, where the snare was twisted around the targeted lead by clockwise or counterclockwise rotation of the snare to easily catch and secure the pacemaker and defibrillator leads.9 In this study, internal transjugular approach was not included because it is not part of our routine practice. All patients underwent a chest X-ray to evaluate the presence of hemothorax after the procedure. The choice to pursue blood transfusion was left to the anesthesiologists’ or the operators’ discretion. A representative case wherein supportive femoral approach was required is shown in Figure 2 and Videos S1-S4.

2.3 | Definition of outcomes and complications

On the basis of the 2009 HRS consensus statement7, complete procedural success was defined as the complete removal of all targeted leads and lead material without any serious adverse events or death. Separately, clinical success was defined as the complete removal of all targeted leads and lead material or the retention of a small portion of the leads that would not negatively impact procedure outcome. Procedure time was defined as the interval from open incision with the debridement of the affected tissue to wound closure. Intraprocedural major complications included procedure-related death and hemothorax, pericardiocentesis, or requirement of urgent surgery occurring during the TLE procedure. Postprocedural cardiovascular events included all-cause death, pulmonary embolism, ischemic stroke, life-threatening arrhythmia, symptomatic exacerbation of heart failure by at least one New York Heart Association functional class, and any access site-related complications occurring from the time the patient left the hybrid operating room to 1 year of follow-up.

2.4 | Statistical analysis

Data pertaining to continuous variables were presented as medians (interquartile ranges [IQRs]) and pertaining to categorical variables as frequencies (percentages). Continuous variables were compared using Wilcoxon’s rank-sum test, whereas categorical variables were compared using Fisher’s two-tailed exact test. Predictors of the need for supportive femoral approach were investigated first using univariate logistic regression analysis. A multivariate logistic regression
model with all significant variables (<0.05) was established to estimate odds ratios (ORs) and inclusive 95% confidence intervals (CIs). ORs for continuous variables represent the relative increased risk of endpoint per unit increase. A two-sided $P$-value of $<.05$ was considered significant. All statistical analyses were performed using the JMP software (version 14; SAS Institute Inc, Cary, NC, USA).

3 | RESULTS

Of the 75 included patients, a total of 22 patients required supportive femoral approach (Femoral/Superior group), whereas 53 underwent TLE via superior approach alone (Superior group). Infection (77.3% overall) was the most frequent indication for lead extraction. No significant between-group differences were observed regarding baseline patient characteristics except for access vein occlusion, defined as occlusion of venous vessels (axillary, subclavian, innominate veins, or superior vena cava [SVC]) with indwelling transvenous leads (Table 1). The patients in the Femoral/Superior group exhibited significantly longer dwell times of the oldest extracted lead and a higher incidence of passive fixation ventricular lead placement than those in the Superior group (Table 2). The recorded procedural outcomes and complications are presented in Table 3. The rates of achieving complete procedural success or clinical success were not significantly different between the two groups (Femoral/Superior group, 90.9% vs. Superior group, 100%; $P = .083$). Procedure failure occurred in two patients in the Femoral/Superior group due to distal lead retention of 5-6 cm in both cases. The Femoral/Superior group required a significantly longer procedure time (median: 211.5 minutes; IQR: 169.3-280.0 minutes vs. median: 108.0 minutes; IQR: 96.5-135.0 minutes; $P < .001$) and exhibited a significantly higher incidence rate of peri-procedural transfusion (54.6% vs. 11.3%; $P < .001$) than the Superior group. None of the patients developed intra-procedural major complications associated with lead extraction. No post-procedural major hematomas were observed, except for two patients in the Superior group in whom major wound hematomas associated with superior approach occurred and required blood transfusion. Univariate and multivariate analyses of clinical and lead-related factors were performed to determine the predictors of the need for supportive femoral approach. In univariate analysis, access vein occlusion, dwell time of the oldest extracted lead, and the presence of a passive fixation ventricular pacemaker lead were found to be significant factors. A multivariate logistic regression model including access vein occlusion, dwell time of the oldest extracted lead, and the presence of a passive fixation ventricular pacemaker lead was established to estimate ORs and inclusive 95% CIs (Table 4). Multivariate logistic regression analysis showed that access vein occlusion (OR: 4.07, 95% CI: 1.08-15.3; $P < .001$) and dwell time of the oldest extracted lead (per year) (OR: 1.22, 95% CI: 1.09-1.37; $P = .038$) were the independent predictors of the need for supportive

| TABLE 1 | Baseline characteristics of the patients |
|---------|----------------------------------|
| Variables | Overall N = 75 | Femoral/Superior n = 22 | Superior n = 53 | $P$ |
| Age (years) | 76.0 (67.0-83.0) | 79.0 (72.3-85.3) | 75.0 (67.0-82.5) | .11 |
| Sex (male), n (%) | 49 (65.3) | 11 (50.0) | 38 (71.7) | .11 |
| Body mass index, kg/m$^2$ | 22.6 (20.5-25.0) | 22.2 (20.5-24.8) | 22.8 (20.8-25.2) | .63 |
| Diabetes mellitus, n (%) | 20 (26.7) | 6 (27.3) | 14 (26.4) | 1.0 |
| Coronary artery disease, n (%) | 15 (20.0) | 6 (27.3) | 9 (17.5) | .66 |
| Previous cardiac surgery, n (%) | 6 (8.0) | 2 (9.1) | 4 (7.5) | .71 |
| Stroke, n (%) | 10 (13.3) | 2 (9.1) | 8 (15.1) | .41 |
| NYHA class II or greater, n (%) | 9 (12.0) | 1 (4.6) | 8 (15.1) | .41 |
| Indication for extraction | | | | |
| Infection, n (%) | 58 (77.3) | 18 (81.8) | 40 (75.5) | .76 |
| Noninfectious, n (%) | 17 (22.7) | 4 (18.2) | 13 (24.5) | .37 |
| Access vein occlusion, n (%) | 29 (39.7) | 13 (59.1) | 16 (31.4) | .037$^b$ |
| Laboratory data on presentation | | | | |
| White blood cells ($\times 10^3$/μL), per μL | 5.2 (4.3-6.8) | 5.6 (3.9-7.3) | 5.2 (4.4-6.4) | .67 |
| Hemoglobin, g/dL | 12.5 (10.8-13.6) | 12.1 (10.5-13.5) | 12.5 (10.8-13.8) | .37 |
| C-reactive protein, mg/dL | 0.13 (0.06-0.40) | 0.17 (0.06-0.37) | 0.13 (0.06-0.48) | .99 |
| Serum creatinine, mg/dL | 0.96 (0.78-1.19) | 0.91 (0.79-1.22) | 0.99 (0.77-1.19) | .76 |

Note: Data are presented as medians (interquartile ranges) or n (%). “Femoral/Superior” and “Superior” denote the supportive femoral and superior approach alone, respectively. NYHA, New York Heart Association.

$^a$P values are based on Wilcoxon’s rank-sum test or Fisher’s two-tailed exact test, as appropriate, for comparisons between the groups.

$^b$Significant difference between patients in the Femoral/Superior (supportive femoral approach) and Superior (superior approach alone) groups.
femoral approach. Receiver operating characteristic (ROC) curve analysis revealed that 11.8 years from implant placement was the cutoff period for the need for supportive femoral approach, with a sensitivity of 68.2% and a specificity of 81.1% (area under the curve: 0.81). Regarding postprocedural cardiovascular events occurring within 1 year of TLE, one patient in the Femoral/Superior group experienced pulmonary embolism, whereas one patient developed access site-related venous insufficiency; one suffered from stroke; and three died of life-threatening arrhythmia, chronic heart failure exacerbation, and pneumonia in the Superior group. However, there were no significant between-group differences regarding postprocedural cardiovascular event-free survival rates at 1 year (Femoral/Superior group, 93.8% vs. Superior group, 86.3%; P = .45) (Figure 3).

**DISCUSSION**

To the best of our knowledge, this study is one of the first to determine predictors of the need for supportive femoral approach during transvenous extraction of pacemaker and defibrillator leads in Japanese patients. The main findings of the study were as follows: (a) a long lead dwell time of the oldest lead and access vein occlusion

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**TABLE 2** Extracted device and lead characteristics

| Variables | Overall N = 75 | Femoral/Superior n = 22 | Superior n = 53 | P<sup>a</sup> |
|-----------|----------------|-------------------------|----------------|------------|
| Dwell time of the oldest extracted lead, years | 8.7 (4.8-12.7) | 13.4 (8.8-21.2) | 7.2 (3.7-10.8) | <.001<sup>b</sup> |
| No. of leads extracted per procedure | 2 (n/a) | 2 (n/a) | 2 (2-3) | .30 |
| Failure of the locking stylet to advance to the lead tip in ≥1 pacemaker or ICD lead, n (%) | 26 (34.7) | 11 (50.0) | 15 (28.3) | .11 |
| Lead fixation of atrial or ventricular leads | | | | |
| Active fixation atrial pacemaker lead, n (%) | 17 (22.7) | 2 (9.1) | 15 (28.3) | .13 |
| Passive fixation atrial pacemaker lead, n (%) | 36 (48.0) | 12 (54.6) | 24 (45.3) | .61 |
| Active fixation ventricular pacemaker lead, n (%) | 21 (28.0) | 4 (18.2) | 17 (32.1) | .27 |
| Passive fixation ventricular pacemaker lead, n (%) | 39 (52.0) | 18 (81.8) | 21 (39.6) | .001<sup>b</sup> |
| Active fixation ICD lead, n (%) | 15 (20.0) | 1 (4.6) | 14 (26.4) | .054 |
| Passive fixation ICD lead, n (%) | 9 (12.0) | 0 (0) | 9 (17.0) | .051 |

Note: Data are presented as medians (interquartile ranges) or n (%). “Femoral/Superior” and “Superior” denote the supportive femoral approach and superior approach alone, respectively. ICD, implantable cardioverter-defibrillator; n/a, not applicable.

<sup>a</sup>P values are based on Wilcoxon’s rank-sum test or Fisher’s two-tailed exact test, as appropriate, for comparisons between the groups.

<sup>b</sup>Significant difference between patients in the Femoral/Superior (supportive femoral approach) and Superior (superior approach alone) groups.

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**TABLE 3** Procedural outcomes and complications

| Variables | Femoral/Superior n = 22 | Superior n = 53 | P<sup>a</sup> |
|-----------|-------------------------|----------------|------------|
| Complete procedural success or clinical success, n (%) | 20 (90.9) | 53 (100) | .083 |
| Procedure time, min | 211.5 (169.3-280.0) | 108.0 (96.5-135.0) | <.001<sup>b</sup> |
| Periprocedural transfusion requirements, n (%) | 12 (54.6) | 6 (11.3) | <.001<sup>b</sup> |
| Intraprocedural major complications, n (%) | 0 (0) | 0 (0) | n/a |
| Postprocedural major hematoma requiring blood transfusion | | | |
| Associated with superior approach, n (%) | 0 (0) | 2 (3.8) | 1.00 |
| Associated with femoral approach, n (%) | 0 (0) | n/a | n/a |

Note: Data are presented as medians (interquartile ranges) or n (%). “Femoral/Superior” and “Superior” denote the supportive femoral approach and superior approach alone, respectively. n/a, not applicable.

<sup>a</sup>P values are based on Wilcoxon’s rank-sum test or Fisher’s two-tailed exact test, as appropriate, for comparisons between the groups.

<sup>b</sup>Significant difference between patients in the Femoral/Superior (supportive femoral approach) and Superior (superior approach alone) groups.
were independent predictors of the need for supportive femoral approach in Japanese patients undergoing TLE; (b) ROC curve analysis revealed that 11.8 years from implant placement was the cutoff period for the need for supportive femoral approach; and (c) reducing the threshold for introducing the femoral approach within the lead extraction strategy contributed to avoiding vascular tear, particularly an SVC tear.

Our study showed that a long lead dwell time was the predictor of the need for supportive femoral approach during TLE, which was common to that of bailout femoral approach4,5; to date, a few studies have focused on comparing patients undergoing TLE via superior approach alone with those undergoing TLE via bailout femoral approach to identify predictors of the latter4,5 and reported that a longer lead dwell time, higher number of leads extracted per procedure, and the presence of infection are associated with the need for bailout femoral approach. In this study, in addition to a long lead dwell time, access vein occlusion was found as an additional predictor of the need for supportive femoral approach. Hence, subclavian venography can help extractors prepare for a potentially complex lead extraction procedure. A previous study of a large cohort of patients showed that total occlusion of the subclavian or innominate vein occurred in 26% of transvenous lead placement cases; furthermore, a significant association existed between venous stenosis/occlusion and the number of implanted leads and also the sum of the lead diameters, and no significant association existed between venous stenosis/occlusion and implant duration.10 Therefore, our study advocates for routine subclavian venography using 10-15 mL of contrast prior to TLE, particularly in patients implanted with multiple leads because if access vein occlusion were present, the need for supportive femoral approach would be suggested, irrespective of implant duration. Similar to our study results, one previous study found that patients with venous occlusion require more advanced tools for lead extraction such as dilator sheaths, Evolution sheaths, and Needle's Eye Snares (Cook Medical).11 Of note, venography did make a difference to our TLE strategy; in case of access vein occlusion, we were always able to prepare in advance many tools that are required for various transfemoral snaring techniques. Thus, when performing TLE in patients with occluded access veins, obtaining femoral venous access beforehand may be routine for the potential use of transfemoral lead extraction tools and snaring techniques. In contrast, implantable cardioverter-defibrillator (ICD) lead and passive fixation ventricular pacemaker lead placements were not significant predictors; ICD lead placement was not significant in univariate analysis, whereas passive fixation ventricular pacemaker lead placement was significant in univariate

### TABLE 4 Multivariate logistic regression analysis to determine predictors of the need for supportive transfemoral lead extraction

| Variables                              | Adjusted OR (95% CI) | P     |
|----------------------------------------|----------------------|-------|
| Access vein occlusion                  | 4.07 (1.08-15.3)     | <.001 |
| Dwell time of the oldest extracted lead (per year) | 1.22 (1.09-1.37)     | .038  |
| Passive fixation ventricular pacemaker lead | 4.11 (0.98-17.2)     | .053  |

Abbreviations: CI, confidence interval; OR, odds ratio.

![Femoral/Superior Superior](image)

**FIGURE 3** Kaplan-Meier cardiovascular event-free survival rate for patients undergoing TLE via supportive femoral approach (Femoral/Superior group) vs those undergoing TLE via superior approach alone (Superior group). TLE, transvenous lead extraction
analysis, but became nonsignificant in multivariate analysis. These findings may be attributable to a lack of power, given the lower number of patients enrolled in this study.

To the best of our knowledge, this study is one of the first analyses to show the cutoff period of lead dwell time for the association with the need for supportive femoral approach, although the value of 55 months (around 4.6 years) has been reported to best predict crossover to the internal transjugular approach during the TLE of ICD leads. The difference between the cutoff value determined in this study and that reported for bailout internal transjugular approach may be due to (a) our calculation from data mainly concerning pacemaker lead extraction and (b) low threshold of femoral approach in our lead extraction strategy. Knowing the cutoff of lead dwell time for the need for femoral approach can help operators plan the location for the procedure. Indeed, the best location for performing TLE is a hybrid operating room so as to remain prepared for potential complex procedures, including the need for femoral approach, but a cardiac catheter laboratory can also be an option when a hybrid operating room is not available if a patient’s oldest pacemaker lead was implanted <11.8 years ago, if a patient has a patent access vein, and if a patient presents very few comorbidities.

Results of this study suggest that reducing the threshold to introduce the femoral approach within the lead extraction strategy would prevent vascular tear, particularly an SVC tear, despite supportive femoral approach having a longer procedure time and increased transfusion rates. In performing TLE, avoiding vascular injury is the highest priority, particularly an SVC injury. In this regard, we believe that the low threshold of support for the femoral approach is important in avoiding vascular injury, because sticking to the superior approach alone in challenging and difficult cases may cause vascular avulsion or tear, presumably due to a failure to maintain the coaxial alignment of a powered sheath with an access vein. In our study, due caution was exercised with coaxial alignment with the subclavian/innominate vein or SVC while advancing a powered sheath (laser or mechanical). When a powered sheath could not be advanced forward because of the failure to maintain coaxial alignment with the subclavian/innominate vein or SVC during our first or second attempt to advance, a prompt introduction of the Needle’s Eye Snare (Cook Medical) or EnSnare kit (ev3 Inc) was completed via the femoral vein to enable simultaneous traction from the subclavian and femoral veins to targeted leads. Combining the femoral approach with the superior approach—that is, applying simultaneous traction from the subclavian and femoral veins to leads—would create a greater leftward fluoroscopic shift than that with traction from above and a greater separation between the lead and the SVC wall, resulting in maintaining the coaxial alignment of the lead with the SVC wall, which would contribute to reducing the risk of SVC injury as previously reported.

In this study, supportive femoral approach accounted for approximately 30% of all TLE procedures; this rate is much higher than that reported previously from the United States and United Kingdom (approximately 5% and 10%, respectively). This might have been due to the different definition between “bailout” and “supportive,” and due to the low threshold of support of femoral approach in our strategy for preventing vascular avulsion or tear. In the previous reports regarding bailout femoral approach, lead extraction was initially attempted via the superior approach, with transfemoral extraction reserved in case the superior approach was completely unsuccessful. Therefore, target leads were extracted through the femoral veins. Conversely, the supportive femoral approach, as defined in our study, included the removal of the targeted lead through the femoral vein as a bailout procedure after a complete failure of the superior approach as well as the support for the superior approach during lead extraction, by the removal of the targeted lead through the subclavian vein with the aid of a snare catheter from the femoral vein.

Indeed, our study showed that the Femoral/Superior group presented significantly longer procedural time and increased transfusion rates. However, these results have to be interpreted cautiously. When comparing the cases in which the supportive femoral approach was required with those in which the leads were extracted via the superior approach alone, we were able to show that the dwell time of the oldest extracted lead was significantly longer in the Femoral/Superior group. This factor is known to be a determinant of extraction failure or incomplete extraction. Thus, the Femoral/ Superior group contained the cases that were more challenging for lead extraction, reflecting the use of femoral approach as a supportive procedure. This negative selection needs to be considered when interpreting the significantly longer procedural time and increased transfusion rates in the Femoral/Superior group. When comparing our procedural success rate of the supportive femoral approach with that of the superior approach alone, they were not significantly different between the two. Therefore, these findings are not indicative that the supportive femoral approach is inferior to the superior approach alone. There is increased blood loss in the supportive femoral approach. However, this is not due to femoral approach itself, but due to prolonged time of a powered sheath (laser or mechanical) placement via superior approach because we must place the powered sheath via the implant vein during the supportive transfemoral procedure; consequently, the blood continues to leak around the powered sheath or leak through its opening, resulting in more blood loss. In general, the intraoperative salvage of red blood cells using a cell saver is beneficial for blood conservation. However, it was not performed in our study. Retrospectively, a cell saver should have been actively used during TLE to minimize blood transfusion requirement. Moreover, femoral hematoma is one of the most common complications during transfemoral lead extraction. Particularly, the risk of femoral hematoma might be high after femoral venous access using a large caliber sheath. Therefore, in our hospital, the subcutaneous “Z”-stitch was generally applied to achieve hemostasis, resulting in faster hemostasis and no major femoral hematoma.

4.1 | Clinical implications and future direction

The oldest extracted lead dwell time and the access vein occlusion predict the need for supportive femoral approach in lead
extraction. This should be considered when planning the lead extraction procedure. Although our data suggest that long dwell time and access vein occlusion are predictors of the need for supportive femoral approach, evidence at this time is still limited to endorse them as predictors of the need for supportive femoral approach. In the near future, large multicenter registries will be needed to further validate these findings and provide additional valuable insights into the safety and effectiveness of supportive femoral approach.

4.2 | Study limitations

This was a retrospective, observational, and nonrandomized study that included a limited number of patients seen at a single center. Moreover, our study did not include bailout transjugular lead extraction.

5 | CONCLUSIONS

Access vein occlusion and long dwell time of the oldest extracted lead predicted high probability of the need for supportive femoral approach. A cutoff of 11.8 years from implant placement was identified as indicating the need for supportive femoral approach. Therefore, supportive femoral approach may be necessary in patients with leads that are implanted for >11.8 years and whose access veins are occluded. We believe that gaining much experience with the femoral approach and lowering the threshold for introducing the femoral approach within the lead extraction strategy would become the cornerstone for successful lead extraction.

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DISCLOSURES

The authors declare that there is no conflict of interest for this article. All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the Institutional Research Committee of Sendai Kousei Hospital (approval number: 1-96; approval date: March 24, 2020). Written informed consent was obtained from the patients.

DATA AVAILABILITY STATEMENT

The data used to support the findings of this study are available from the corresponding author upon request.

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ORCID
Tsuyoshi Isawa https://orcid.org/0000-0003-1271-0344
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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section.

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