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Original Article

Usefulness of the controlled-rotation dilator sheath "Evolution RL" for extraction of old leads in two Japanese centers – An experience in use

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ABSTRACT

Background: Transvenous lead extraction (TLE) is an established procedure for the management of cardiovascular implantable electronic devices. However, some difficulties and risks of complications still exist, especially in old and adhered leads. Evolution RL (Cook Medical, Bloomington, IN, USA) is a newly introduced device for TLE; however, no clinical results have been reported in Japan, and the results with older leads are unknown. We investigated the efficacy and safety of Evolution RL and its usefulness for old leads at two TLE centers in Japan.
Methods: A total of 27 consecutive patients who underwent lead extraction using Evolution RL at Shinshu University Hospital and Tokyo Women's Medical University Hospital from September 2017 to December 2019 were retrospectively enrolled. We examined the backgrounds of the patients and leads and investigated the efficacy and safety of the procedures. We divided the leads into two groups according to the number of years of implantation (10 years) and compared the results.
Results: Among the 27 patients, 20 (74.1%) were men, and the median age was 62 (14 91) years. The total number of leads was 58, and the median implantation duration was 136 months (8 448). We achieved clinical success in all patients and complete procedural success in 24 patients (88.9%). In three patients, the broken tip of the lead remained in the heart. No major complications were noted. Of the 58 leads, there were 34 leads with more than 10 years of implantation, with significantly more Evolution RLs used (94.1% vs. 54.2%, $p = 0.001$) and significantly higher percentages of Evolution 11Fr, 13Fr, and steady sheaths used (79.4% vs. 33.3%, $p = 0.001$, 52.9% vs. 16.7%, $p = 0.006$, and 64.7% vs. 20.8%, $p = 0.001$, respectively).
Conclusions: In two TLE centers in Japan, Evolution RL was shown to be safe and effective, even in leads older than 10 years.

Introduction

Transvenous lead extraction (TLE) is an essential procedure for lead management in patients with cardiovascular implantable electronic devices (CIEDs) in cases of infection, malfunction of leads, and vascular problems [1]. Over the past 20 years, the outcome of the TLE procedure has improved owing to the introduction of devices such as laser sheaths, mechanical rotational sheaths, and snares [2 5]; however, there are still some difficulties and risks of complications, especially in the extraction of old and adhered leads [5,6].

The second generation Evolution RL (Cook Medical, Bloomington, IN, USA) was permitted for use in Japan in 2018. The first generation Evolution was capable of dissecting firm adhesions by rotating a stainless steel blade in one direction with hand force [7]. The second generation Evolution RL adopted a unique bidirectional rotational mechanism and less aggressive tip to prevent a "lead wrapping" phenomenon and insulation damage of adjacent leads, which was a central problem of the first generation Evolution [7,8]. Starck et al. reported the efficacy and safety of the second generation Evolution RL in their initial experience [8]. The effectiveness and safety of Evolution RL have been reported in high volume multi centers [9 12], but not in Japanese facilities. In addition, there are no data on the efficacy and safety of Evolution RL focusing on leads implanted for over 10 years.

Old leads implanted for over 10 years were challenging in a mechanical rotational sheath and excimer laser sheath era [5], and the efficacy

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and safety of Evolution RL for those old leads have not been reported to date.

In this study, we aimed to report the outcomes of Evolution RL in two TLE centers in Japan and to evaluate the efficacy and safety of old leads implanted for over 10 years.

Methods

Study population

We retrospectively evaluated 27 consecutive patients who underwent lead extraction using Evolution RL at Shinshu University and Tokyo Women's Medical University between September 2017 and December 2019. The indications for each TLE procedure were determined based on the 2017 Heart Rhythm Society Expert consensus statement [1].

This study retrospectively analyzed the characteristics, type of de vice, and indications for the extraction of leads from patients using Evo lution RL. We also assessed the efficacy and safety of Evolution RL in TLE for long term implanted leads by dividing the lead implantation period into more than 10 years and less than 10 years.

This study was conducted with all coauthors in compliance with the ethical standards described in the Declaration of Helsinki under in formed consent.

Extraction procedure

Before the TLE procedure, we performed enhanced cardiac tomogra phy and venous angiography to evaluate lead adhesion and venous occlusion or stenosis. In cases of CIED infection, transesophageal echo cardiography was performed to assess the evidence and size of the vegetation.

All TLE procedures were performed in the operating room or hybrid operating room under general anesthesia with a cardiac surgeon and cardiopulmonary bypass equipment backup. Electrocardiography, inva sive arterial blood pressure measurement, and transesophageal echo cardiography were continuously monitored during the procedure.

Fig. 1 shows the procedural strategy for TLE. After removing the CIED generator, a normal or locking stylet was inserted into the stylet lumen of each lead. First, an excimer laser sheath with a repetition rate of 80 Hz (GlideLight, Spectranetics, Colorado Spring, CO, USA) or a polypropyl ene mechanical sheath (Cook Medical) was used in most cases. If TLEs did not succeed with excimer laser sheaths or mechanical sheaths in cases of severe lead adhesion or severe calcification, we used the Evolu tion RL rotational sheath. Depending on the operator's discretion, we se lected Evolution RL first if the leads were implanted for a long time or if there was a risk of severe adhesion of the leads or venous occlusion be fore the TLE procedure. We used the Evolution RL lead only in areas with strong adhesions and replaced it with a laser sheath or mechanical sheath in other areas to minimize damage to the collateral tissues. The tip of the lead was removed using the countertraction technique. If the TLE procedure from the subclavian lead entry site failed due to lead break or severe adhesion, we switched to the femoral approach with snares or a hybrid tandem approach dissecting adhesions with Evolution RL from the subclavian vein while pulling with a snare from the femoral vein [13].

In infected cases, new device implantation was performed after an adequate period of antibiotic infusion and certification of negative blood cultures following Heart Rhythm Consensus (HRS) consensus [1]. On the other hand, new devices were sometimes implanted simul taneously with the TLE procedure, depending on the cases in non infected patients.

Clinical outcomes were defined according to the HRS expert consen sus statement [1]. Complete procedural success was defined as com plete lead removal, and clinical success was classified when a small piece of lead (<4 cm) remained. Major and minor complications were defined according to severity. Major complications were defined as im mediate life threatening or death, whereas minor complications re quired other medical interventions that did not significantly affect patient function.

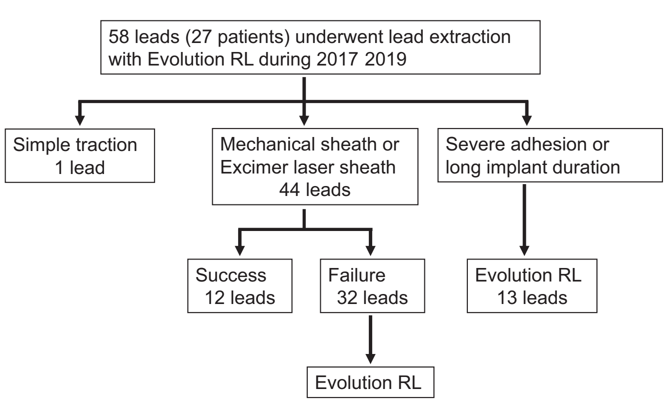

Fig. 1. Flow chart of the strategies for transvenous lead extraction.

Statistical analysis

Descriptive statistics are reported as medians with ranges. Categorical variables are presented as numbers and percentages. Differences in pro portions were compared using chi square and Fisher's exact tests. Statis tical significance was set at $p < 0.05$. All statistical analyses were performed using SPSS software version 26 (IBM Corp, Armonk, NY, USA).

Results

Baseline characteristics

The baseline clinical characteristics of patients are listed in Table 1. A total of 27 patients were enrolled in the study. The median patient age was 62 (14 91) years, and 20 patients (74%) were male. Twenty two patients (81%) had CIED infection and the rest of the 5 patients had no infected indicators for TLE. Twenty three patients (85%) had a pacemaker, two had an implantable cardioverter defibrillator (ICD) ($n = 2$), and two had cardiac resynchronization therapy (CRT) (n = 2). The median implant duration of the oldest lead per patient was 167 months (9 448).

Table 2 shows the baseline leads' characteristics. Of the leads, 58 were extracted. The median implant duration was 136 months (8 448). Most leads were implanted from the left side, 40 (69%) were passive fixation leads, and 4 (7%) were broken leads that had been cut intravascularly and the distal portion removed during heart transplantation or other

Table 1
Baseline patients' characteristics.

Patients	n = 27
Median age, years	62 (14–91)
Sex:	
Male, n (%)	20 (74.1%)
BMI, kg/m^2	25 (15–30)
Indication for lead extraction:	
Infected, n (%)	22 (81.5%)
Non-infected, n (%)	5 (18.5%)
Device type	
Pacemaker, n (%)	23 (85.2%)
ICD, n (%)	2 (7.4%)
CRT-D/CRT-P, n (%)	2 (7.4%)
Leads	2 (1–4)
Median implant duration, months	167 (9–228)

BMI, body mass index; ICD, implantable cardioverter defibrillator; CRT D, cardiac resynchronization therapy defibrillator; CRT P, cardiac resynchronization therapy pacemaker.

cardiac surgery. Seventeen (29%) were right atrial (RA) leads, 34 (58%) were right ventricular (RV) leads, and 3 (5%) were left ventricular leads. VDD leads occupied 7 (12%). Vegetations existed in three leads.

Outcome

Clinical success was achieved in all the patients ($n = 27$, 100%; Table 3). Complete success was achieved in 89% ($n = 24$); however, of the three patients where the lead tips remained in the heart; there were no clinical problems.

Table 4 presents the TLE outcomes for each lead. Among the 58 leads, 45 (78%) leads required the Evolution RL. Thirteen (22%) leads were ex tracted using simple manual traction or excimer laser sheaths and did not require Evolution RL. Fifty five leads (95%) were completely re moved. The three lead tips remained in the heart. Lead breaks occurred in five leads. The implantation duration of the leads that experienced lead breaks were 78, 88, 189, 267, and 377 months, and all used 11Fr or 13Fr Evolution RLs. A hybrid femoral approach was required for nine leads.

The distribution of the lead implantation time and the outcomes are shown in Fig. 2. Old leads with over 60 months of history comprised the majority, and very old leads implanted for more than 10 years accounted for 58%. The short tip of the three old leads over 121 months remained. The durations of these latter leads were 139, 267, and 377 months, respectively.

There were no major complications, and minor complications of pocket hematoma occurred in two patients. One patient with a 31 year old non functional passive fixation developed a massive pocket hematoma after the procedure, requiring evacuation and blood transfu sion. In this case, an 11Fr Evolution with a steady sheath and a 13Fr shortie were used. Another case with a 10 year passive fixation led to a pocket hematoma that did not require any intervention. In that case, an 11Fr Evolution shortie and steady sheath and a normal 11 Fr Evolu tion with steady sheath were used.

Table 5 shows the differences in the results between the leads im planted for more than 10 years and those implanted for fewer years. Of the leads, 24 leads were implanted for less than 10 years, and 34 leads were implanted for more than10 years. Laser and mechanical sheaths were used to the same extent in both groups. Leads implanted for more than 10 years cannot be removed by simple traction. Use of the Evolution RL was significantly more common in the above 10 years' group than in the group where the use had been for less than 10 years (94.1% vs. 54.2%, $p = 0.001$). Only leads less than 180 months old could be extracted without using Evolution RL, and Evolution RL was used in all cases for leads greater than 180 months old (Fig. 3).

Comparing the caliber of Evolution RL used, there was no difference in the use of the 9Fr sheath in the group with more than 10 years of lead compared to the group with less than 10 years of lead, but there was a significant difference in the use of the 11Fr sheath (79.4% vs. 33.3%, $p = 0.001$), 13Fr sheath (52.9% vs. 16.7%, $p = 0.006$), and 11Fr or greater sheath (88.2% vs. 33.3%, $p < 0.001$). There was no difference between the two groups in cases requiring only the shortie sheath, lead break phenomenon, or use of the femoral approach. The success rates did not differ between the two groups, but a residual lead tip re mained in the group with leads older than 10 years, which was not seen in the group with leads used for less than 10 years (91.2% vs. 100%, $p = 0.260$). The steady sheath was used significantly more frequently in leads that were older than 10 years (64.7% vs. 20.8%, $p = 0.001$).

Table 2
Baseline leads' characteristics.

Leads	$n = 58$
Median implant duration, months	136 (8–448)
Side of implantation	
Left, n (%)	49 (84.5%)
Lead fixation:	
Active, n (%)	14 (24.1%)
Passive, n (%)	40 (70.0%)
Broken[a], n (%)	4 (6.9%)
Lead position:	
Right atrium, n (%)	17 (29.3%)
Right ventricle, n (%)	34 (58.6%)
VDD, n (%)	7 (12.1%)
Coronary sinus, n (%)	3 (5.2%)
Broken[a], n (%)	4 (6.9%)
Vegetation, n (%)	3 (5.2%)

[a] Broken refers to a lead that had been cut and its distal portion removed.

Table 3
Extraction outcomes (per patient).

Patients	n = 27
Clinical success, n (%)	27 (100%)
Complete procedural success, n (%)	24 (88.9%)[a]
Procedural time, min	195 (130–328)
Bleeding, mL	105 (31–747)
Major complication, n (%)	0 (0%)
Minor complications, n (%)	2 (7.4%)[b]

[a] In three patients, less than 4 cm of the lead tip remained.
[b] Two patients experienced device pocket hematoma.

Discussion

In this study, we evaluated the efficacy and safety of Evolution RL in two TLE centers in Japan, especially in leads older than 10 years. Clinical success was achieved in all 58 leads in 27 patients who underwent TLE using Evolution RL, with high rates of success (88.9% per patient, 94.8% per lead). No major complications or deaths occurred.

In the present study, the duration of the lead implantation was very long, with a median of 136 months (range 8 448). Compared with pre vious large TLE studies, the lead implantation duration averaged 65 to 69 months in the PLEXES Trial [3], 6.4 ± 5.4 years in the ELECTRa study [5], and 84.7 ± 61 years in the PROMET study [14]. Although this study was limited to cases in which Evolution RL was used, the clin ical success and completely successful rates were as high as those in conventional large scale studies.

In the PROMET study, the median duration of lead implantation was 106 months (interquartile range 66 145 months) in the group using Evo lution RL [14]. The implantation duration in other studies regarding the re sults of Evolution RL, include an early report by Starck of 80.9 (12−300) months [8], Witte's study of 9.10 ± 5.82 years [9], Migliore's study of 95.4 ± 59.7 months [10], Sharma's study of 8.8 ± 6.0 years [11], and an other by Sharma of 6.77 ± 4.42 years [15]. The present group of patients had a longer implantation period, with a median of >10 years. In Sharma's study, residual lead tips of 4 cm or less occurred in 3.6% of cases using Evolution RL [15], and similar results were obtained in this study.

In Sharma's study, the distribution of implantation duration was highest in the group with the least number of years of implantation, with 68.9% of leads less than 10 years, 13.8% between 11 and 20 years, and 16.4% >21 years [15]. However, this study only included patients who used the Evolution RL, that is, those who failed the excimer laser

Table 4
Extraction outcomes (per lead).

Leads	n = 58
Leads extracted by Evolution RL	45 (77.6%)
Leads extracted by simple manual traction, n (%)	1 (1.7%)
Leads extracted by mechanical sheath or laser sheath, n (%)	12 (20.7%)
Lead break, n (%)	5 (8.6%)
Wrapping phenomenon, n (%)	0 (0%)
Hybrid with femoral approach, n (%)	9 (15.5%)
Lead removal with clinical success, n (%)	58 (100%)
Lead removal with complete success, n (%)	55 (94.8%)

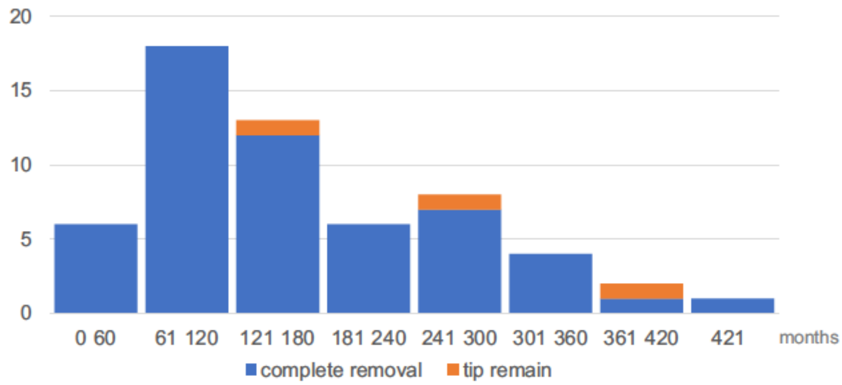

Fig. 2. Distribution of lead implantation time by extraction outcome.

sheath or mechanical sheath, or those who were expected to have strong adhesions or long implantation duration. Thus, as shown in Fig. 2, the distribution of leads peaked at 61 120 months, with few leads less than 60 months. Even for leads with >10 years of implantation, we obtained 100% clinical success and 91.2% complete success (Table 5). Since a long lead implantation duration was a predictor of unsuccessful procedures and complications [5,6], our high success rate and safety were noteworthy.

When dividing the lead implantation duration into groups of more than 10 years and less than 10 years, the use of Evolution RL, 11Fr sheath, 13Fr sheath, and steady sheath were used significantly more frequently in leads over 10 years old (Table 5). The amount of fibrous adherent tissue in old leads was large, and the adherent tissue could be clumped and wedged into the sheath due to the snow prowling phenomenon during dissection procedures. Then, we needed to size the sheath to 11Fr or 13Fr. The steady sheath was useful when the tip could not be rotated properly because the adherent tissue rotated with the Evolution RL tip (collateral rotation). The fact that steady sheath was more necessary for older leads meant that co lateral rotation occurred more frequently due to the strength of adherent tissue of old leads, and a steady sheath was essential for the removal of long duration leads.

Although lead age is a predictor of the incidence of lead breaks [16], there was no difference in the incidence of lead breaks between the two groups. The number of remaining tips was higher in leads older than 10 years, although the difference was not statistically significant. This means that even if lead break occurred, the tip could be removed in leads less than 10 years old by the femoral approach or other means, but it was more difficult in leads older than 10 years. The percentage of complete procedural success was 91.6% in Pecha et al.'s study

Table 5
Comparison of the results of the procedure in groups divided by the duration of lead implantation, more or less than 10 years.

	<10 years (n = 24)	>10 years (*n* = 34)	*p*-Value
Median implant duration, months	81(8–119)	200(122–448)	
Manual traction	1 (4.2%)	0 (0%)	0.414
Laser sheath	13 (54.2%)	19 (55.9%)	1.000
Mechanical sheath	14 (58.3%)	19 (55.9%)	1.000
Evolution RL use	13 (54.2%)	32 (94.1%)	0.001
Used Evolution RL type			
9Fr	5 (20.8%)	4 (11.8%)	0.467
11Fr	8 (33.3%)	27 (79.4%)	0.001
13Fr	4 (16.7%)	18 (52.9%)	0.006
≥11Fr	8 (33.3%)	30 (88.2%)	<0.001
Only shortie	8 (33.3%)	17 (50.0%)	0.283
Use of steady sheath	5 (20.8%)	22 (64.7%)	0.001
Lead break, n (%)	2 (8.3%)	3 (8.8%)	1.000
Hybrid with femoral approach, n (%)	6 (25.0%)	3 (8.8%)	0.142
Lead removal with clinical success, n (%)	24 (100%)	34 (100%)	0.260
Lead removal with complete success, n (%)	24 (100%)	31 (91.2%)	0.260

limited to the extraction of leads older than 10 years [17] and 93.9% in Issa's study limited to leads older than 20 years [18]. The complete success rate of 91.2% in the present study is comparable to these results.

In the patients' background of our study, age (62, 14 91 years) and sex (male: 74.1%) were similar to those in large studies such as LEXICON, ELECTRa, and PROMET [4,5,14]. However, there were more indications of infection (81.5%), more passive fixation leads (70.0%), and fewer ICDs and cardiac resynchronization therapy defibrillator/cardiac resynchronization therapy pacemaker (CRT D/CRT P) (7.4% and 7.4%, respectively). In the PROMET study, the indications due to infection, passive fixation lead, and ICD were 46.0%, 46.6%, and 24.6%, respectively [14]. The global trend in TLE indications is a balance between infected and non infected indications, with an increasing proportion of non infected indications [4,14]. In addition, passive fixation leads are more difficult to remove than active fixation leads owing to tip adhesion [19] and are one of the predictors of lead break [16]. Since the ICD lead is more likely to be an active fixation lead [12], the small number of ICD leads was another reason for the high percentage of passive fixation leads in our study. Moreover, the percentage of VDD lead was high (12.1%), but it was more difficult to remove due to the adhesion of the sensing ring in the right atrium [20]. It could be assumed that many of the cases in this study were difficult cases with a high risk of TLE, such as long implant duration leads, passive fixation leads, or VDD leads, in patients who underwent TLE due to infection. This study demonstrated the effectiveness of Evolution RL in such cases.

No major complications were observed in this study. The duration of lead implantation is a predictor of major complications [6], and it was noteworthy that no major complications occurred in this study, which included many long term implanted leads. In terms of complications, two patients (7.4%) had pocket hematomas requiring transfusion. Both patients had long term leads (>10 years) and used 11Fr or larger Evolution RL and steady sheaths, although the larger sheaths and steady sheaths may be more prone to bleeding due to the larger diameter of the sheath and the outward facing metal blade. However, in Sharma's study of patients with Evolution RL, the number of hematomas requiring evacuation decreased over time [15], so it might be possible to reduce the number of hematomas by institutional effort. When using the Evolution RL, the stiffness of the shaft and the slightly outwardly positioned metal tip of the lead make it difficult to insert veins, and there is a risk of vascular damage. In this study, no major complications, such as damage to major vessels, were observed, even though we prepared a bridge balloon for all TLE procedures.

This is the first report on the results of the use of Evolution RL in Japan. The number of TLE cases in Japan has been increasing every year, and according to the J LEX registry, nearly 100 cases were performed per month at 42 centers as of May 2020 [21]. There are still a large number of potential patients who require TLE, especially for non infected indications. Along with the advancement of TLE devices, the rate of TLE performed in cases requiring lead revision or CIED upgrade is increasing annually

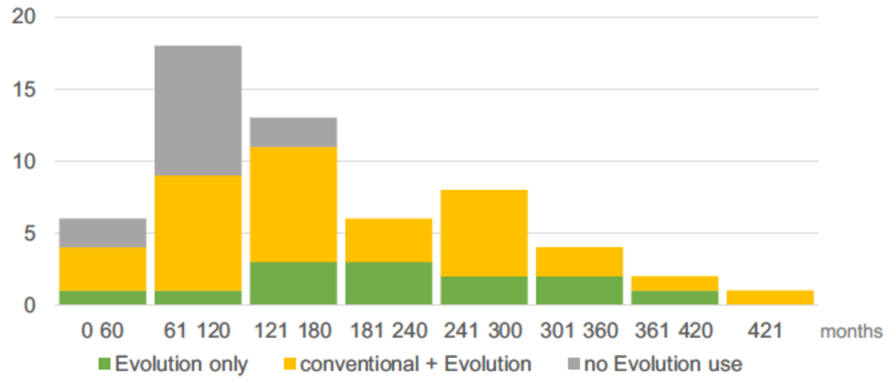

Fig. 3. Distribution of lead implantation time by Evolution RL use.

[22]. In the PROMET study, the introduction of Evolution RL led to the discarding of the laser sheath in many centers [14]. Considering the use fulness and safety of the Evolution RL shown in this study, it is possible that many facilities in Japan, which had been unable to perform TLE due to the high cost of the excimer laser, could safely perform TLE on old leads using the Evolution RL, mechanical sheath, and femoral approach without a laser sheath. As shown in Fig. 3, we could extract both long and short implanted leads using only the Evolution RL, without using the laser sheath. In Japan, TLE for non infected diseases is mainly admin istered to younger patients [23], but with the Evolution RL, it may be pos sible to expand the use of TLE in high risk elderly patients in the future.

Study limitations

The present study had several limitations. First, the number of pa tients was small. The cumulative number of complications was also small and may have been overestimated or underestimated. Second, the patient background might be unique and biased due to the small number of non infected and ICD cases and the high rate of passive fixa tion leads. Third, the strategy of using Evolution RL, sheath diameter, and steady sheath was left to the operator's discretion, and prospective randomized trials are needed to evaluate the actual usefulness and safety of Evolution RL for older leads.

Conclusion

In this study of two TLE centers in Japan, we showed that the Evolu tion RL was safe and useful even in leads over 10 years of age.

Declaration of competing interest

The authors declare no conflict of interest for this article.

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