Utility of a multi-purpose catheter for transvenous extraction of old broken leads: A novel technique for fragile leads

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Utility of a multi-purpose catheter for transvenous extraction of old broken leads: A novel technique for fragile leads

Short title: Multi-purpose catheters for broken lead extraction

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Conflicts of interest: None

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Abstract

Background

Transvenous lead extraction has been possible since the 1980s. However, complications during lead extraction, such as the distal end fragment of the lead remaining in the myocardium or venous system and injury to the veins or heart, have been reported.

Objective

Extraction of long-term implanted devices is difficult using standard methods and may require additional procedures. Therefore,. the removal of leads with inner conductor coil and lead tip separated from outer insulation, conductor coil and proximal ring electrode using a multi-purpose catheter is reported.

Methods

In total, 345 consecutive patients who underwent transvenous lead extraction (TLE) from April 2014 to March 2021 were retrospectively analyzed. Lead characteristics, device type, and indications for extraction were further analyzed in 20 patients who developed separation of the proximal ring electrode and outer conductor coil from the inner conductor and distal tip at the time of extraction.

Results

Extractions were performed using an excimer laser sheath laser and a Byrd polypropylene telescoping sheath (n=15), a laser, a Byrd polypropylene telescoping sheath, and an Evolution RL (n=2), a laser and an Evolution RL (n=3), a Byrd polypropylene telescoping sheath and an Evolution RL (n=1), a Byrd polypropylene telescoping sheath only (n=4), and an Evolution RL only (n=2). Twenty-seven leads had been implanted >10 years ago, which resulted in lead separation. A multi-purpose catheter was used to protect the fragile leads from further damage. All leads were completely extracted.

Conclusion

All distal tip-to-proximal ring electrode separated leads were successfully removed using laser and other sheaths with the assistance of a multi-purpose catheter, without any part of the leads remaining in the heart.

Key words: Multi-purpose catheter, device extraction, complication, non-functional lead, success rate

Introduction

Cardiac implantable electrical devices (CIEDs) require the removal of the entire system if an infection develops. Between 1996 and 2003, the number of hospitalizations associated with CIED infections increased 3.1-fold. Infection rates for CIEDs have recently increased to 1%-2% in Japan.[1] In addition, the risk of hospital-acquired death due to CIED infection has more than doubled.[2] Even non-infected leads often need to be extracted due to lead damage or upgrades. The length of lead implantation is recognized as one of the risk factors for failed extractions and complications, and older leads are often associated with severe adhesions. In particular, the presence of leads implanted for more than 10 years was found to be correlated with intraoperative mortality.[3]

Extraction of long-term implanted CIED leads is generally difficult by standard methods due to the high incidence of adhesions and lead damage and may require additional procedures. For example, leads with tightly adhered tips may separate between the distal tip and proximal ring electrode during extraction. Some older leads break easily, and if the locking stylet is pulled hard while bringing in the sheath, only the outer coil lumen and stylet may be extracted, leaving the lead tip and inner coil. Failure to achieve complete removal and leaving fragments in the cardiovascular system may not be desirable because of the risk of not curing infection in infected cases and the risk of cardiovascular injury in non-infected cases. However, with fragile leads, there is a possibility that the tip electrode of the lead may separate from the proximal ring electrode. In the event of separation, the tip electrode and wire may remain in the cardiac cavity, and methods to prevent this were investigated. This study aimed to examine our method for complete removal of a separated lead.

Methods

A total of 345 consecutive patients who underwent transvenous lead extraction (TLE) at Shinshu University Hospital (99 patients) or Tokyo Women's Medical University (246 patients) from April 2014 to March 2021 were retrospectively analyzed. The total number of leads extracted was 576 (218 vs. 358) (Figure 1). A total of 27 leads (20 patients) in which the proximal ring electrode component, outer conductor, and outer insulation became separated from the tip electrode component and inner conductor during extraction were identified. The characteristics, devices, indications, procedures, and clinical outcomes of TLE for the extracted leads were investigated.

All TLE procedures were performed with the patient under general anesthesia with the backup of a cardiovascular surgeon. Indications for TLE were based on the Heart Rhythm Society recommendations.

All data were collected from the patients' medical records. The definition of the outcome of the extraction procedure was based on the Heart Rhythm Society's expert consensus statement.[4, 5]

This study was conducted in accordance with the ethical standards outlined in the Declaration of Helsinki. Written, informed consent was obtained from all subjects. The need for review board approval was waived due to the retrospective nature of the study.

Method for using a multi-purpose catheter

Once the proximal ring electrode and insulation separate from the distal electrode, the insulation and proximal ring electrode are fully removed from the body. The remaining insulation and conductor coil are long enough that a multi-purpose catheter is able to be advanced over them to provide protection and stability for the extraction sheath use. The multi-purpose catheter is trimmed to the length of the inner wire that remains in the body.

A bulldog or extension wire, etc. is not needed. The inner wire is covered with a multi-purpose catheter trimmed from the subclavian puncture site.

The catheter is inserted up to the distal ring. After that, an extraction sheath is placed over the catheter to control the traction force, and the catheter is advanced to the tip electrode and removed by countertraction (Figure 2A-D).

Statistical analysis

Unless otherwise stated, data are presented as means ± standard deviation if normally distributed and as medians and interquartile range (25^{th}-75^{th} percentiles) if not normally distributed. The unpaired two-tailed Student's *t*-test was used for inter-group comparisons of normally distributed data. Unpaired data that were non-normally distributed were evaluated using the Mann–Whitney test, whereas non-normally distributed paired data were analyzed by the Wilcoxon signed-rank test. Categorical variables were compared using the chi-squared test and Fisher's exact test, as appropriate. A p-value of < 0.05 was considered significant. Statistical analyses were performed using SPSS ver. 27 software (SPSS Inc., Chicago, IL).

Results

Table 1 summarizes the characteristics of the 20 lead-separated patients with 27 leads (mean age: 72.4 years, age range: 43–91 years; 16 males). Indications for device removal were infection (n=18) and lead dysfunction (n=2).

A total of 27 leads (active fixation lead: n=3, passive fixation lead: n=24) were inserted, with a median duration of 13.6 years. Patients had three types of devices implanted: pacemakers (n=18 [90%]); cardiac resynchronization therapy defibrillators (n=1 [5%]); and implantable cardioverter defibrillators (ICDs) (n=1 [5%]) (Table 1). In our previous study, the overall indication for removal was infection in 89.9%, and 10.1% were non-infected. The number of active fixation leads was clearly lower in the present study.

Removal was performed using an excimer laser (Philips, Andover, MA) and a Byrd polypropylene dilator sheath (n=15) (Cook Medical Inc., Bloomington, IN), a laser sheath, and an Evolution RL (n=3) (Cook Medical Inc.), a laser sheath, a Byrd polypropylene dilator sheath, and an Evolution RL (n=2), a Byrd polypropylene dilator sheath only (n=4), a Byrd polypropylene dilator sheath and an Evolution RL (n=1), and an Evolution RL only (n=2).

Twenty-seven broken leads that were more than 10 years old after implantation broke at the time of removal. Table 2 presents data on lead type, duration, and lead number; there were 3 active fixation leads and 24 passive fixation leads.

The most frequently encountered fragile lead was the Isoflex optim (Abbott, Sylmar, CA). The average implantation period was 9.1 years, with a maximum of 26 years (Capsure SP lead, Medtronic, Minneapolis, MN). A multi-purpose catheter was used for removal of these leads to protect the inner wire as described in method for using a multi-purpose catheter. (Figure 3).

Regarding the results of TLE, all leads were completely extracted, with no lead tips remaining in the heart. The average procedure time was 4.1 hours. No serious adverse events or cardiac tamponade requiring cardiac surgery were recorded. Mean blood loss was 193 mL. No intraoperative blood transfusions were required. In-hospital, 30-day, and 1-year mortality rates were all 0% (Table 3).

Discussion

In this study, 20 CIED TLE procedures were successfully performed without any part of the lead remaining in the heart. As for the choice of TLE technique, patient background characteristics, lead type, implant duration, and whether it was a passive fixation or an active fixation lead were factors correlated with the success rate and safety of the extraction procedure. The present results showed that the use of a multi-purpose catheter to remove a lead with conductor separation was very effective.

The main reported risk factors for adverse events during TLE procedures are infection, low body mass index, female, and long implantation duration.[6,7] However, all lead removals were successful, and the in-hospital, 30-day, and 1-year death rates due to CIED infection were all 0%, all of which were superior to previous reports of a 96.5% success rate for lead removals and a 0.3% in-hospital death rate.

No major complications were observed in the present study. The incidence of major adverse events directly related to the TLE procedure in the LExICon study was 1.4%,[2] including death in 0.28% of cases. The clinical success rate in that trial was 97.7%. The incidence of death and fatal injury was 1%, and the incidence of major complications, including superior vena cava laceration and massive pulmonary embolism, was reported to be about 1%.[3,8, 9] On the other hand, complete removal was achieved in 96.7%, and perioperative complications were observed in 4.1% of cases in Japan.[10]

Older leads with strong adhesions may separate between the tip and the proximal ring electrode during extraction. In the case of severe infection, the adhesion is often mild, but in young patients with calcification, removal is difficult and requires open thoracotomy at worst.[11] However, in the present study, all leads could be removed by a transvenous approach.

The Evolution RL, the Byrd polypropylene telescoping sheath, and the excimer laser can be used for countertraction, and they sometimes do not require rotation of the sheath at the time of extraction. However, it was sometimes not possible to dissect calcified or tightly adhered areas with the laser sheath. In such cases, the mechanical sheath or Evolution RL was used instead. Starck reported that the Evolution RL was very effective in removing old leads, with few complications. In that article, the success rate was 100% for TLE with the Evolution RL, and no complications were observed.[12] Although Starck et al reported that the Evolution RL was very effective in removing old leads with few complications, management of lead breakage was not clearly described.[13]

The present study suggested that examining the possibility of conductor separation at coaxial bipolar leads beforehand and immediately shifting to an extraction method using a multi-purpose catheter when conductor separation occurs strongly contribute to the high success rate and low complication rate. In addition, TLE for infected cases was generally associated with high mortality and complications.[7] The present lead extraction strategy was described in previous reports, but we sometimes changed methods depending on the case.[14-16] We predominantly used a laser sheath, but promptly switched to a mechanical sheath when the laser sheath could not be advanced due to dense fibrous adhesion or calcification. We selected a mechanical sheath as the first device in cases with non-infected leads or those with tight entry site adhesions.[17] For extraction of non-infected leads, the remaining lead wire was removed using a laser or other sheath. By using the multi-purpose catheter, we have eliminated the disparity between the outer diameter of the inner conductor coil and the inner diameter of the extraction sheath.

Collateral damage did not occur when the sheath was used for extraction.

If calcification precluded proceeding with a Byrd polypropylene telescoping sheath, we sometimes switched to an Evolution RL. In cases with strong lead adhesions or long indwelling periods, the Evolution RL was used as the first device.

The inner wire of the separated lead is like a thread and has no strength. However, the ring is attached to the myocardium and needs to be detached with a sheath. If the sheath is forcefully advanced as it is, the inner wire will be severed, and only the ring will remain in the heart. By placing a multi-purpose catheter over the sheath, the strength of the inner wire is increased, and the sheath can be advanced to the tip.

The purposes of using a multi-purpose catheter are below.

1) To prevent leads with only the inner wire from being damaged by a mechanical or laser sheath with a large inner diameter.

2) The difference between the inner diameter of the inner lumen and the outer diameter of the sheath is reduced, making it easier to advance the sheath.

3) To advance with the minimum power necessary to avoid damage to the inner wire.

The risks involved in TLE must always be weighed against the success rate. The possibility of major complications during the procedure indicates that leads should only be extracted using the appropriate equipment and personnel available to address all potential situations, including the need for thoracotomy, sternotomy, or cardiopulmonary bypass.[18] A recent presentation [19] of the experience in the U.S. indicated that extractions are being conducted appropriately and in a timely manner in less than 20% of U.S. patients. In Japan, the number of extirpation procedures has been increasing because insurance reimbursement has recently been extended to include this procedure. However, there is often hesitation because of the complications associated with the extraction procedure and the difficulty of the technique. We must remove the device and communicate the effectiveness and safety of this approach to Japan and other countries.[20]

Leaving fragments without complete removal can lead to recurrent or severe infections that can be life-threatening. In the present study, no device fragments remained, and no recurrence of infection was observed, even in septic cases.[21]

Based on the results of the present study, it appears that clinicians can confidently remove broken leads using our method.

Study limitations

This retrospective study included few cases. Further investigation is required with more patients, particularly those without infection.

Conclusions

Twenty leads that underwent conductor separation intraoperatively required complete removal to prevent residual materials in the cardiac cavity. Therefore, a multi-purpose catheter was used to protect the bare internal coil and distal tip. All conductor-separated leads were protected with a trimmed multi-purpose catheter and were completely removed successfully.

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References

1. Nakajima H, Taki M. Incidence of cardiac implantable electronic device infections and migrations in Japan: Results from a 129 institute survey. J Arrhythm 2016;32:303-307.

2. 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.

3. Fu HX, Huang XM, Zhong LI, et al. Outcomes and complications of lead removal: can we establish a risk stratification schema for a collaborative and effective approach? Pacing Clin Electrophysiol 2015;38:1439-1447.

4. 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.

5. 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.

6. Tarakji KG, Wazni OM, Harb S, Hsu A, Saliba W, Wilkoff BL. Risk factors for 1-year mortality among patients with cardiac implantable electronic device infection undergoing transvenous lead extraction: the impact of the infection type and the presence of vegetation on survival. Europace 2014;16:1490-1495.

7. 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.

8. Deckx S, Marynissen T, Rega F, et al. Predictors of 30-day and 1-year mortality after transvenous lead extraction: a single-centre experience. Europace 2014;16:1218-1225.

9. Gomes S, Cranney G, Bennett M, Giles R. Long-term outcomes following transvenous lead extraction. Pacing Clin Electrophysiol 2016;39:345-351.

10. Shoda M, Kusano K, Goya M, et al. Japanese Lead EXtraction (J-LEX) registry: Annual report 2019. J Arrhythm 2022;38:187-191.

11. Zabek A, Boczar K, Debski M, et al. Analysis of electrical lead failures in patients referred for transvenous lead extraction procedures. Pacing Clin Electrophysiol 2018;41:1217-1223.

12. Starck CT, Steffel J, Caliskan E, et al. Clinical performance of a new bidirectional rotational mechanical lead extraction sheath. Europace 2016;18:253-256.

13. Starck CT, Gonzalez E, Al-Razzo O, et al. Results of the Patient-Related Outcomes of Mechanical lead Extraction Techniques (PROMET) study: a multicentre retrospective study on advanced mechanical lead extraction techniques. Europace 2020;22:1103-1110.

14. Okada A, Shoda M, Tabata H, et al. Single-center experience with percutaneous lead extraction of cardiac implantable electric devices. J Cardiol 2018;71:192-196.

15. Higuchi S, Shoda M, Saito S, et al. Safety and efficacy of transvenous lead extractions for noninfectious superfluous leads in a Japanese population: A single-center experience. Pacing Clin Electrophysiol 2019;42:1517-1523.

16. Okada A, Tabata H, Shoda M, et al. Safe and effective transvenous lead extraction for elderly patients utilizing non-laser and laser tools: a single-center experience in Japan. Heart Vessels 2021;36:882-889.

17. Bongiorni MG, Soldati E, Zucchelli G, et al. Transvenous removal of pacing and implantable cardiac defibrillating leads using single sheath mechanical dilatation and multiple venous approaches: high success rate and safety in more than 2000 leads. Eur Heart J 2008;29:2886-2893.

18. Bashir J, Fedoruk LM, Ofiesh J, Karim SS, Tyers GF. Classification and surgical repair of injuries sustained during transvenous lead extraction. Circ Arrhythm Electrophysiol 2016;9.(9):e003741. doi:10.1161/CIRCEP.115.003741.

19. ACC Late Breaking Clinical Trials, Pokorney SD, Zepel L, Greiner MA, et al on April 3, 2022

20. Nishii N, Morimoto Y, Miyoshi A, et al. Prognosis after lead extraction in patients with cardiac implantable electronic devices infection: Comparison of lead-related infective endocarditis with pocket inection in a Japanese single-center experience. J Arrhythm 2019;35:654-663.

21. Pecha S, Ziegelhoeffer T, Yildirim Y, et al. Safety and efficacy of transvenous lead extraction of very old leads. Interact Cardiovasc Thorac Surg 2021 Apr 8;32(3):402-407.doi:10.1093/icvts/ivaa278.

Table 1. Patients' baseline characteristics

	n=20
Age (y)	72.4 (59.5-83.8)
Sex (male)	16 (80.0%)
BMI (kg/m^2)	23.3 (20.3-24.8)
Indication for lead extraction	
Infection	18 (90.0%)
Non-functional or recalled lead	2 (10.0%)
Device type	
Pacemaker	18 (90.0%)
ICD	1 (5.0%)
CRTD	1 (5.0%)
Implant duration (y)	13.6 (8.0-20.0)
Extracted leads using multi-purpose catheter	27
Active fixation leads	3
Passive fixation leads	24

Age, BMI, and implant duration are presented as quartiles.

BMI, body mass index; CRTD, cardiac resynchronization therapy pacemaker (defibrillator); ICD, implantable cardiac defibrillator

Table 2. Leads requiring the use of a multi-purpose catheter

Lead	Tined/screw	Duration (y)	n
Isoflex optim	Tined	9.1 (6.7, 13.0)	11
Selute picotip	Tined	13, 8	2
AV plus	Tined	12, 20	2
Endotak endurance	Screw	8	1
Membrance EX	Tined	20	1
Pacesetter	Tined	20	1
Capsure SP	Tined	26	1
FINELINE II steroxZ	Screw	8	1
Durata ICD	Screw	8	1
VDD lead	Tined	12	1
Synox	Tined	12	1
Capsure Z novus	Tined	14	1
Capsure VDD	Tined	22	1
Tendrill	Tined	13	1
Capsure sense MRI	Tined	7	1

Table 3. Extraction procedures and outcomes

Use of multi-purpose catheter	n=20 (27 leads)
Anesthesia duration (h)	4.5 (4.0-5.2)
Procedure duration (h)	4.1 (3.2-4.8)
Duration of ICU stay (d)	1
Blood loss (mL)	193.0 (60.0-150.0)
Blood transfusion	1
Complications	
Major/minor	0/0
Death	0
	Leads extracted (n)
Laser sheath + Byrd polypropylene telescoping sheath	15
Laser sheath + Evolution RL	3
Laser sheath + Byrd polypropylene telescoping sheath + Evolution RL	2
Byrd polypropylene telescoping sheath	4
Evolution RL	2
Byrd polypropylene telescoping sheath with Evolution RL	1
Success rate	Complete success: 27 (100%)

Anesthesia duration, procedure duration, and blood loss are presented as quartiles.

Figure legends

Figure 1. Flow chart of the lead extraction strategy in this study.

Figure 2. Method for using a multi-purpose catheter.

A: Normal outer view of lead.

B: If the ring electrode, outer wire, and outer insulator are separated and removed from the body in one piece, and only the tip electrode and inner wire remain in the body, it becomes very difficult to remove the remnants completely.

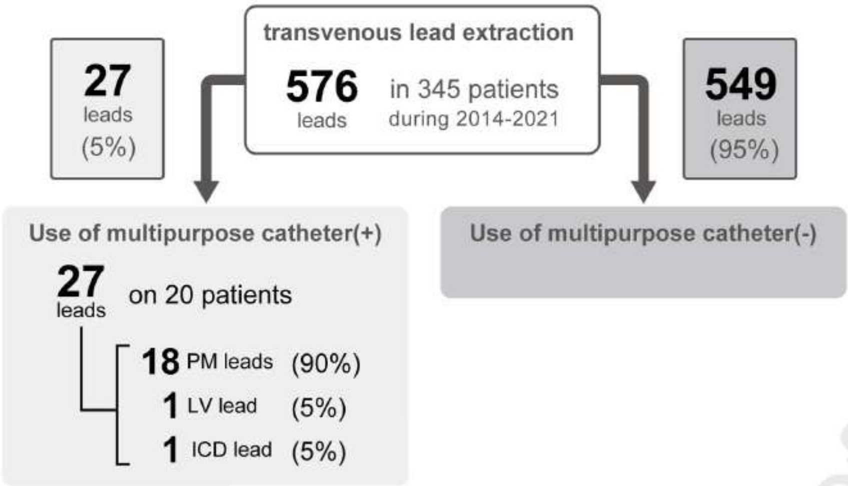
C: To strengthen the lead, a multi-purpose catheter is placed over the broken lead.

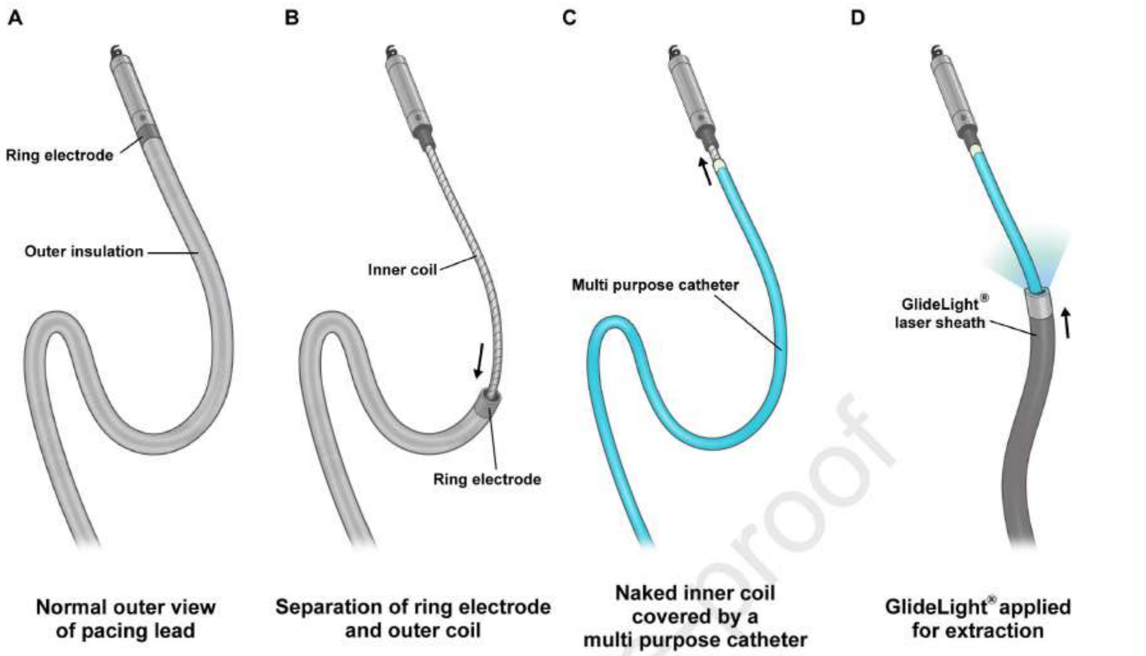
D: A laser sheath is inserted over the broken lead that has been covered by a multi-purpose catheter, and complete extraction is attempted.

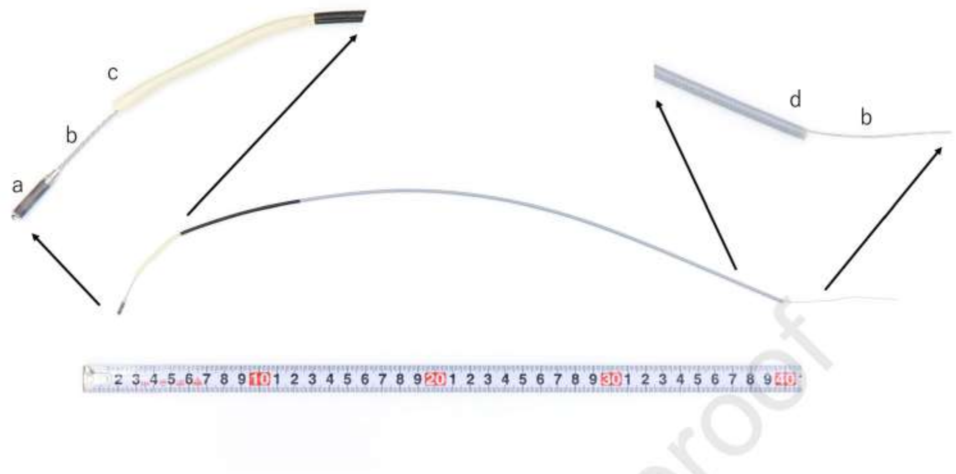
Figure 3.

Diagram of a ring-separated lead covered by a multipurpose catheter.

a; tip electrode. b: inner wire. c; soft-tip at distal end of multipurpose catheter. d; cut-off end of multipurpose catheter. The multipurpose catheter is trimmed to fit the length of the ring-separated lead.


transvenous lead extraction
576
leads
in 345 patients
during 2014-2021
27
leads
(5%)
549
leads
(95%)
Use of multipurpose catheter(+)
27
leads
on 20 patients
18 PM leads (90%)
1 LV lead (5%)
1 ICD lead (5%)
Use of multipurpose catheter(-)


A
B
C
D
Ring electrode
Outer insulation
Inner coil
Ring electrode
Multi purpose catheter
GlideLight®
laser sheath
Normal outer view
of pacing lead
Separation of ring electrode
and outer coil
Naked inner coil
covered by a
multi purpose catheter
GlideLight® applied
for extraction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