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REVIEW

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Rotational mechanical dilator sheaths for effective transvenous lead extraction

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Abstract

Background: An exponential rise in clinical demand for cardiac implantable electronic device (CIED) therapy is observed all over the world due to the rapidly expanding lifespan. Accordingly, appropriate lead management including lead extraction is becoming increasingly essential components for the comprehensive care of patients with various CIEDs.

Main body: With a high success rate and a low complication rate, transvenous lead extraction (TLE) has now been established as first-line therapy for lead extraction. However, TLE is often challenging when there are heavily calcified fibrous adhesions between leads and cardiovascular structures. Recently, rotational mechanical dilator (RMD) sheaths were introduced to resolve this issue and facilitate TLE procedure. There are two types of commercially available RMD sheaths, Evolution® systems and TightRail™. Thorough knowledge of the proper use of the RMD devices is essential to increase success rate and to reduce complications of TLE. In the present review, mechanical features, various techniques, and clinical data of RMD sheaths will be described.

Conclusion: According to recent advancement of device technology, the clinical outcomes of TLE using the RMD sheaths are continuously improving. However, as the RMD sheath is a potentially aggressive tool, special care should be taken when used in patients with longer lead ages.

Keywords: Lead extraction, Rotational mechanical dilator, Cardiac implantable electronic device

Introduction

The number of cardiac implantable electronic device (CIED) implantations has been rapidly increasing all over the world. Along with the CIED implantations, the requirement for lead extraction is also growing fast due to the rising cases of CIED system infections, lead malfunctions, and upgrades of CIEDs, and recall issues of CIED systems [1–3]. Lead extraction is a highly challenging procedure requiring specialized tools and techniques, particularly when leads are implanted over several years because of extensive fibrotic adhesion between the leads and various cardiovascular structures [4]. Skills and tools for lead extraction have advanced significantly over several decades; therefore, transvenous lead extraction (TLE) has been established as an effective and safe approach for lead extraction or revision with a high success rate and low complications [3, 5]. However, serious complications including procedure-related mortality, cardiac tamponade, superior vena cava (SVC) tear, and tricuspid valve (TV) damage can occur during TLE procedures, even if performed by experienced operators in high-volume centers [1, 6–8].

Therefore, physicians caring for patients with CIEDs should have up-to-date knowledge of the features of various tools and techniques for TLE. The present review will focus on hand-powered rotational mechanical dilator (RMD) sheaths, which are the latest addition to the equipment for TLE procedure.

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Main text

The RMD sheath is a hand-powered device with a rotating metal blade/tip which facilitates dissection of adhesive fibrotic tissues between the leads and vessel walls or various cardiac structures [9]. Heavily calcified fibrotic lesions are often very difficult to overcome by telescoping sheaths because their tips are easily broken when used for the hard lesions. Even laser or electrosurgical sheaths are often ineffective in this situation [10]. The dissection of severely calcified adhesion can be achieved most effectively by the metal blade/tip of RMD sheaths [9, 11]. There are two types of currently available RMD sheaths (Fig. 1), TightRail™ (Spectranetics Corp., Colorado Springs, CO, USA) and Evolution® sheaths (Cook Medical, Bloomington, IN, USA).

TightRail™

TightRail is the most recent TLE tools with a metal blade, which is rotating bidirectionally by the actuation of the trigger. The dissection blade remains shielded inside the sheath until activated. However, it can advance by 0.5 mm forward, rotating 287 degrees clockwise by full pulling of the trigger, and then 287 degrees counterclockwise by the next full triggering. This alternating bidirectional dissection can prevent the 'lead wrapping phenomenon,' which was a frequently encountered complication when old version of RMD sheath with unidirectional mechanism was used [12, 13]. If dissection force is repeatedly exerted only in one direction, adjacent leads can wrap around the RMD sheath, making its advancement along the target lead very difficult or impossible. The shaft of the TightRail is designed by a unique tri-coil torque technology (inner, middle, and outer coils wound in opposite direction with each other), which makes the shaft very flexible when bent, however, relatively stiff when kept straight. The unique features of the shaft help operators keep the TightRail sheath aligned with the target leads and advance the sheath forward more effectively all the way through the target leads, even if they are tortuously placed within vessels or cardiac chambers. This flexible shaft is particularly useful, when the TLE is attempted through the right subclavian approach. In general, the leads inserted via the right subclavian vein are placed at sharper angles around the junction between the right brachiocephalic vein and SVC than the leads inserted through the opposite (left) side. Accordingly, stiffer shaft

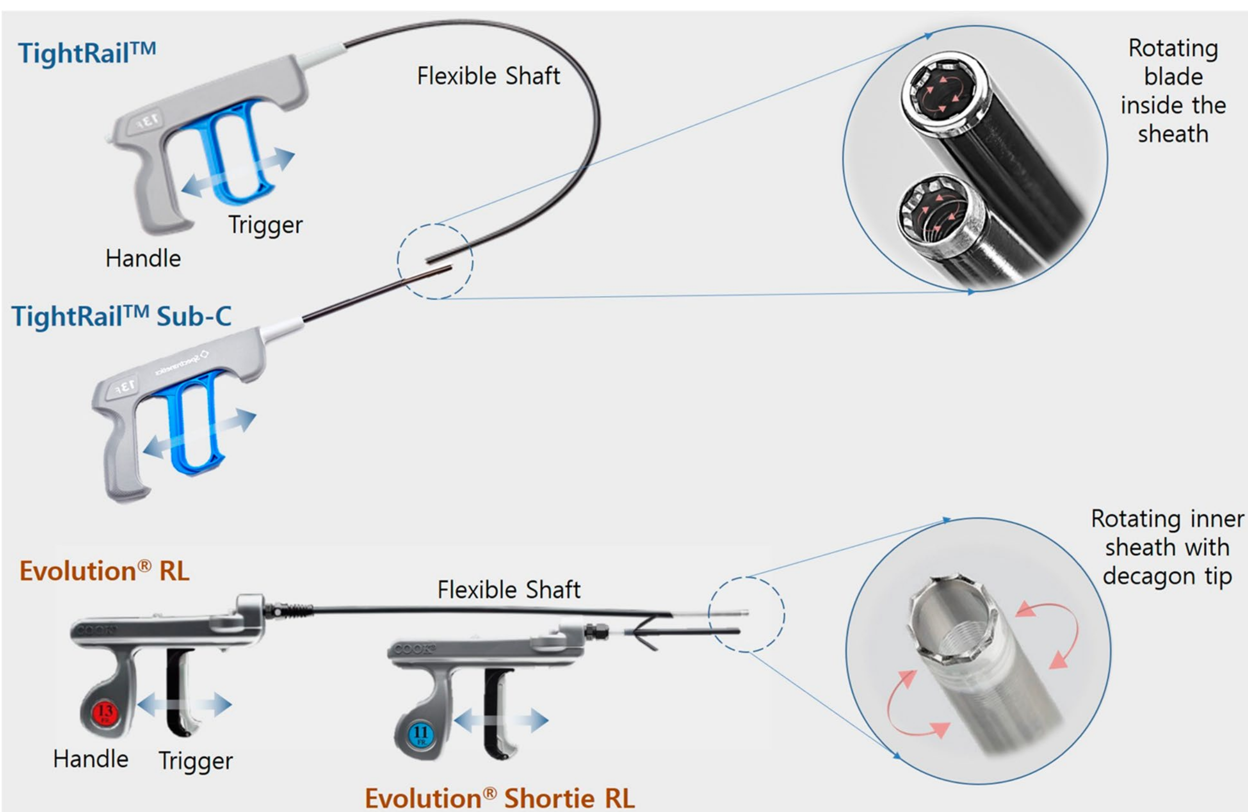

Fig. 1 Rotational mechanical dilator sheaths. TightRail and Evolution systems have standard and short versions of the sheaths. The TightRail has rotating blade inside the sheath while the Evolution RL has rotating inner sheath with decagon cutting tip

of the telescoping sheath is more prone to buckling by the acute angle. In contrast, the flexible shaft of the TightRail can adjust its shape according to the angle, allowing it to follow the sharp angle more effectively (Fig. 2).

In addition, a short version of TightRail is available (TightRail Sub-C), which has a shorter and stiffer shaft, lower profile, and improved cutting tip compared to the standard TightRail (Fig. 1 and Table 1). Thus, it can be used to facilitate vessel entry, especially under tight clavicular spots with dense fibrosis and calcification [14].

Recently, the TightRail™ Guardian, a battery-operated version, has been developed to reduce the arm fatigue and facilitate the TLE procedure [15]. Two types of action mode are available, the protective and extended modes. When in the protected mode, the rotating blade stays inside the sheath, reducing the risk of vessel injury, e.g., SVC tear or adjacent lead damage. The extended mode is useful for dissecting dense fibrotic or calcified adhesions.

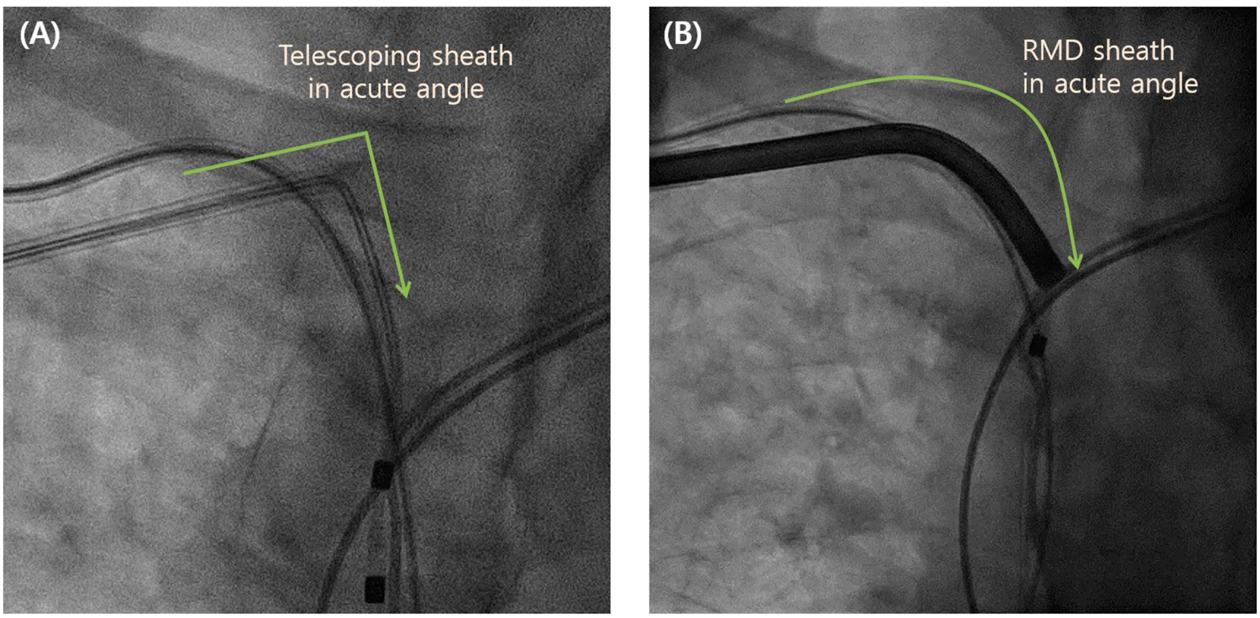

Fig. 2 Right-sided approach for lead extraction. The stiff shaft of the telescoping sheath is easy to buckle when used in the right-sided approach due to acute course of the lead (**A**). In contrast, the RMD sheath with more flexible shaft can follow the lead more effectively, staying coaxial to the targeted lead (**B**)

Table 1 Comparison of various rotational mechanical dilator sheaths

	TightRail	Evolution	Evolution RL	Comments
Inner diameter (ID)	9.2/11.2/13.2 F	9/11/13 F	9/11/13 F	Slightly bigger ID, but lower OD for TightRail
Outer diameter (OD)	15.9/18/20 F	17/19/21 F	17/19/21 F	
Outer sheath	Available, but not necessary	Necessary to avoid 'lead wrapping' phenomenon	Necessary to avoid 'lead wrapping' phenomenon	
Shaft	Very flexible	Less flexible	Less flexible	
Length (long/short)	47.5 cm/15.5 cm	36.5 cm/11.2 cm	36.5 cm/11.2 cm	
Cutting mechanism	Bidirectional (left–right), metal blade	Unidirectional (right), spiral-shaped tip	Bidirectional (left–right), decagon tip	Unidirectional sheath can wrap the leads around the device
Blades	Shielded within sheath, but exposed by 0.5 mm with each full trigger activation	Always exposed, 2 mm length	Always exposed, 6 mm length	Evolution is more aggressive
Short version for subclavian crossing	Available, TightRail mini, TightRail Sub-C	Available, Evolution Shortie	Available, Evolution Shortie	

Evolution® RL

Prior to the introduction of the TightRail, the Evolution system was available for TLE procedures. Previously, the first generation of Evolution sheath with a unidirectional rotation mechanism, which was introduced in 2008, often caused the 'lead wrapping' phenomenon [9, 14]. To address this complication, a second-generation Evolution RL with a bidirectional rotational mechanism was developed. The Evolution system has a 'hand-powered' sheath with a specialized dissection tip [12, 13]. The inner sheath with dissection (decagon) tip is rotating when the trigger is pulled. The amount of sheath rotation can be controlled by adjusting the extent of the trigger pull by the operator. If the trigger is completely released to its home position after the initial pulling, the next pull changes the direction of the sheath rotation in the opposite way. The Evolution system has also flexible shaft; however, it is less flexible than that of the TightRail. The first-generation Evolution had a spiral-shaped dissection tip, whereas the second-generation Evolution RL sheath has a ten-sided (decagon) tip, which is designed for the dissecting forces to be directed forward along the lead, instead of sideways, disrupting tissue directly in contact with the tip. The decagon tip is thought to be safer than the spiral-shaped one in terms of vessel injury or adjacent lead damage. Details of the RMD sheaths are compared in Table 1. The Evolution system has also a short version. With a shorter but stiffer sheath and a more aggressive tip, Evolution Shortie RL is designed for the same purpose as the TightRail Sub-C, i.e., to make more efficient entry into the subclavian veins through dense scar tissue and calcification (Fig. 1 and Table 1).

Lead extraction procedure

Preparation of patients

TLE using RMD sheaths is usually performed under general anesthesia preferably in the hybrid cardiothoracic operating room equipped with fluoroscopic facility [1]. However, the procedure can be performed in the electrophysiology laboratory under deep sedation using sedatives such as midazolam and propofol with continuous monitoring of arterial blood pressure and oxygen saturation. The cardiac surgeons need to be on standby during all procedures in case of emergent operations. Real-time transesophageal or intracardiac echocardiography can be used to evaluate pre-, intra-, and post-procedural status of cardiac structure and function such as the degree of TV regurgitation, the presence of pericardial effusion, and vegetations on the valves or leads. Particularly, periprocedural development of pericardial effusion or cardiac tamponade can be detected immediately using these tools. Although not fully investigated, preprocedural computed tomography scans may be useful in predicting challenging cases based on the site and burden of fibrotic adhesion or calcification [16]. If patients show pacing dependency, temporary pacing wire needs to be secured. In addition, 12-F femoral venous sheath as well as a stiff guidewire for potential insertion of a compliant occlusive balloon in the SVC should be prepared as approved by the Food and Drug Administration [7, 8].

Preparation and selection of devices

The site of incision for opening the device pocket needs to be made to optimize the alignment between the leads and RMD sheaths. After a careful dissection to release the rolled leads, an attempt to unscrew the leads is performed in case of active fixation leads. All proximal fittings are cut off using clippers. Then, the lead-locking stylet (LLS) is inserted into the lead and then tied tightly the lead and LLS using surgical suture. Lead Locking Device® (Spectranetics Corp., Colorado Springs, CO, USA) and Liberator® Beacon® Tip Locking Stylet (Cook Medical, Bloomington, IN, USA) are commercially available products for this purpose (Table 2). To increase the success rate of TLE, it is critical to insert the LLS to the end of the leads. The thinner LLS is easier to insert into the leads; however, it can slip out of the leads more easily during TLE procedures. When the leads have very tortuous courses, the thinner LLS can be more effectively inserted to the distal end of the leads. In contrast, the thicker LLS is generally more difficult to insert; however, it remains more stably inside the leads without sliding out of the lead lumen. Therefore, appropriate size of

Table 2 Comparison of lead locking stylets

	LLD EZ	LLD E	LLD #1	LLD #2	LLD #3	Cook® Liberator®
Working length	65 cm	85 cm	65 cm	65 cm	65 cm	70 cm
Locking length	Entire lead lumen	Entire lead lumen	Entire lead lumen	Entire lead lumen	Entire lead lumen	Only distal segment
Locking range (diameter)	0.38–0.58 mm	0.38–0.58 mm	0.33–0.41 mm	0.43–0.66 mm	0.69–0.81 mm	0.41–0.81 mm
Average tensile strength	19 lbs	19 lbs	12 lbs	24 lbs	45 lbs	Not published
Ability to Unlock and Reposition	Yes	Yes	Yes	Yes	Yes	No

LLD, lead locking stylet

LLS should be selected according to the lumen size or lead course. It is also very important to insert LLSs or non-locking stylets into the adjacent (companion) leads as well, which help prevent unwanted movement or rotation of the adjacent leads when rotational force is exerted around the targeted leads by triggering. A stiffer stylet is better to prevent the adjacent lead from moving along with the rotation of the RMD sheaths.

Adequate size of RMD sheath should be selected as well. In general, RMD sheaths with an inner diameter 2 to 3-F larger than lead's outer diameter are recommended. For the pacing leads, 11-F sheaths are usually used; however, 13-F sheaths are more frequently used for the defibrillator lead extraction.

Use of RMD sheaths

The RMD sheath is introduced over the targeted lead to the venous entry site, keeping the alignment with the lead direction under fluoroscopic guidance. In case of difficult subclavian entry, predilation using telescoping sheaths may be helpful. Otherwise, TightRail Sub-C or Evolution RL Shortie can be used. Gently pulling back on the targeted lead, triggering of the RMD sheath is carefully performed [9, 17]. It is essential to apply appropriate lead traction force for safe passage of the sheath over the lead. Insufficient traction may cause the sheath shaft to bend, buckle, or show an undesirable circular motion. On the contrary, excessive traction may hinder trigger from returning to its starting (home) position or can cause an excessive pulling of the cardiac chamber. Prolonged traction of cardiac chamber can decrease venous return and blood pressure. When squeezing the trigger, one squeezing per one to two seconds is an optimal speed. In addition, full compression of the trigger to the handle and complete release of the trigger to its home (starting) position is mandatory for bidirectional dissection (Fig. 3). Partial compression of the trigger results in unidirectional rotation and sometimes can prevent the trigger from returning to home position, particularly when using the TightRail. While repeating the trigger pulling, operator should watch carefully the sheath advancing little by little along the leads under fluoroscopy. If the sheath fails to advance further, slightly reduce lead traction force so the blade/cutting tip can rotate while engaging the binding site with less interference. Another useful tip is the retraction of the sheath several inches back and re-advancement of the sheath while increasing traction force gradually. During this retraction and re-advancement maneuver, alignment between the sheath and lead frequently becomes better, making the following

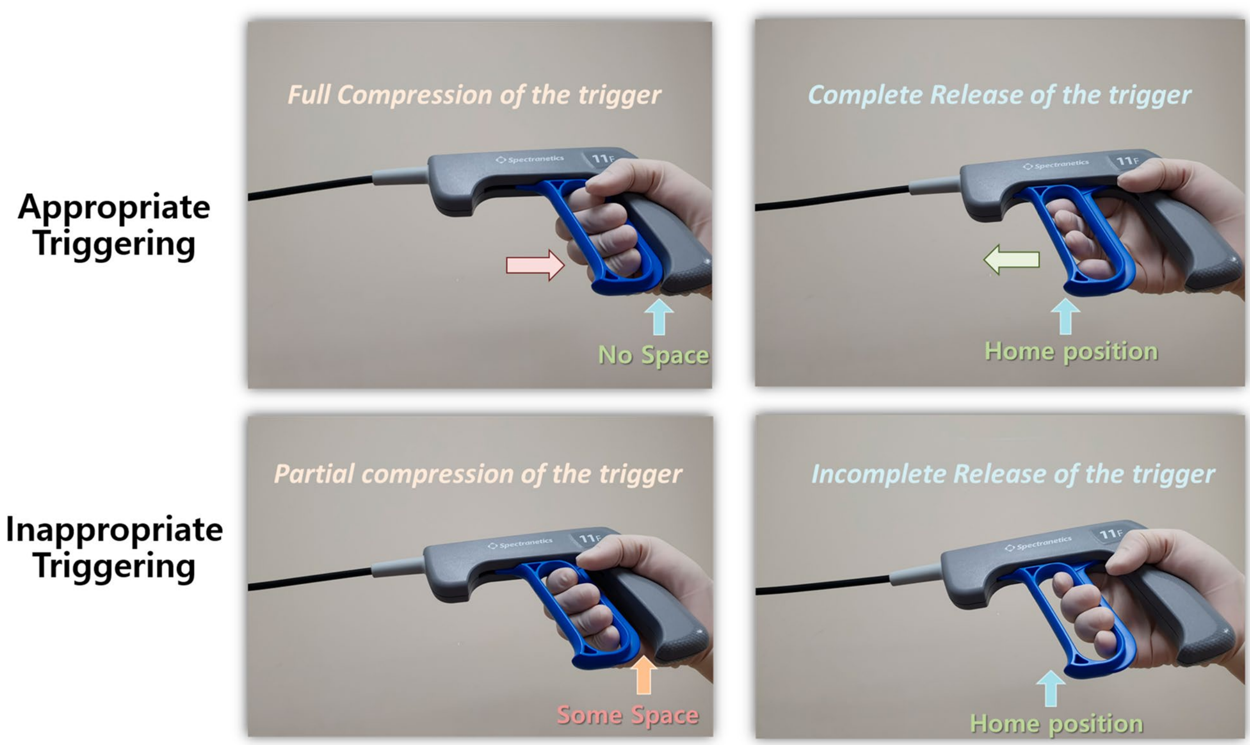

Fig. 3 Appropriate actuation of the trigger. To achieve bidirectional dissection, full compression of the trigger to the handle and complete release to its home position are required

dissection more effective. Sometimes, upsizing of sheath needs to be considered to overcome the advancement failure because some parts of the lead may be surrounded by larger amount of fibrosis which usually makes the lead thicker than its real diameter. Other extraction modalities such as laser or telescoping sheaths can also be utilized in combination with RMD sheaths to overcome challenging areas with severe fibrosis.

If the RMD sheaths arrive at the end of the lead, counter-traction maneuver is used. When providing counter-traction at the distal end of the targeted lead, actuation of the trigger should be avoided. Under fluoroscopic confirmation, place the distal tip of the RMD sheaths close to the distal end of the targeted lead. Apply steady, gentle traction on the lead until it is released from the myocardium. In the Evolution system, outer sheath should be used for counter-traction. However, in the TightRail, utilization of outer sheath is optional. In both systems, outer sheath may be used to reduce 'lead wrapping' or adjacent lead damage.

Complication with RMD sheaths

Metal blade or decagon tip of the RMD sheaths is very strong and has a relatively sharp surface, and therefore may cause serious vessel injury and adjacent lead damage particularly when the alignment between the tools and leads is not matched. When using the RMD sheaths, the rate of major cardiovascular complication rate was reported as low as approximately 1% [13, 18]; however, more attention must be paid particularly in SVC area or at the lead tip because SVC injury or tamponade can lead to catastrophic results. After the TLE procedures using the RMD sheaths, careful fluoroscopic inspection of adjacent leads should be performed, especially focusing on the areas where the targeted lead and adjacent lead were placed closely with each other.

All operators and extraction teams should have a better understanding of the potential complications to better cope with them and ultimately avoid unnecessary deaths. Extraction procedure-related complications can be divided into major and minor complication [5]. Major complications (with incidence) include death (0.19–1.20%), cardiac avulsion (0.19%–0.96%), vascular laceration (0.16–0.41%), pericardial effusion requiring intervention (0.23–0.59%), flail TV leaflet requiring intervention (0.03%), cerebrovascular accident (0.07–0.08%), massive pulmonary embolism (0.08%), and hemothorax requiring intervention (0.07–0.20%). On the other hand, minor complications include pericardial effusion without intervention (0.07%–0.16%), worsening TV function (0.32–0.59%), AV fistula requiring intervention (0.16%), vascular repair at venous entry site (0.07–0.13%), venous thrombosis requiring medical intervention (0.10–0.21%), migrated lead fragment without sequelae (0.20%), pneumothorax requiring chest tube (1.10%), and pulmonary embolism (0.24–0.59%).

Clinical data on RMD sheaths for TLE

The high efficacy and acceptable safety of the RMD sheaths for TLE have been demonstrated in previous studies and are summarized in Table 3. In 2010, Hussein et al. first described their experience with TLE using the Evolution system in 41 leads of 20 patients [9]. The first generation of Evolution was used as first choice in 12 patients (16 leads) or as 'rescue option' in 17 patients (25 leads). They showed a high rate of procedural success (86%), without complications. The 4 patients for whom the Evolution system was partially effective had very old lead ages and required laser sheaths or femoral snares for complete procedural success. This study showed encouraging initial data; however, it was limited by the small number of patients and the lack of randomization. Oto et al. reported similar results from their initial experience with the Evolution system. However, lead wrapping complication was still observed as in Hussein's data [14].

In 2017, Witte et al. compared the new and old Evolution systems in a non-randomized observational study including 103 patients [12]. The old Evolution was used for 50 patients with 56 leads while the new Evolution RL system for 53 patients with 93 leads. Complete procedural success (defined as the removal of all targeted lead materials) was higher in the bidirectional Evolution RL compared to the unidirectional Evolution groups (80 vs. 98%, $P=0.0004$). Clinical success (procedural success plus the retention of a small portion of the lead, e.g., < 4 cm) rate was 98 versus 99%. Minor complications were likely to occur less frequently in the new system: 12.0% versus 3.8%, $P=0.153$. However, there were no major complications in both systems.

In 2018, the largest retrospective data were reported by Sharma et al. in 400 patients with 683 leads for whom both old and new Evolution systems were used for TLE [13]. Complete lead removal rate was 97% with a clinical success rate of 99.8%. Major complications were noted in 6 patients (1.5%). Interestingly, no statistically significant differences were observed in overall outcomes between the old and new Evolution systems, suggesting more experience with the Evolution system has been accumulated than ever before. In the same year, Mazzone et al. reported the first prospective multicenter registry data including 124 patients with 238 leads, which were extracted only using the second-generation Evolution RL sheath [19]. Complete procedural success rate using the Evolution RL alone or combined use of a snare was 91.6% and 98.7%, respectively. There were no major complications. Unlike previous studies using the old Evolution

Table 3 Summary of studies published on rotational mechanical dilator sheaths for lead extraction

Author, reference	Extraction tools	Numbers	Lead age, patient age	Indications for TLE (*n**)	Success rates	Complications	Comments
Hussein (2010) [9]	Evolution	41 leads in 29 patients	111 ± 100 months, 64 ± 19 years	Infection (20), non-infection (9)	86% (33 leads in 25 patients)	No major complication	Snare for 2 patients, laser for 2 patients
Oto (2011) [14]	Evolution	41 leads in 23 patients	74 (25–180) months, 59 ± 14 years	Infection (7), non-infection (16)	82% (35 leads in 19 patients)	No major complication	Snare required for 6 leads
Witte (2017) [12]	Evolution RL versus Evolution	149 leads in 103 patients	6.8 versus 9.1 years, 65 versus 68 years	Infection (55), non-infection (48)	98 versus 80%	No major complication	Bidirectional Evolution superior to unidirectional device
Sharma (2018) [13]	Evolution RL, Evolution	683 leads in 400 patients	6.8 ± 4.4 year, 71 ± 13 years	Infection (29), non-infection (71)	97%	1.5%	Comparable performance of old and new Evolution
Mazzone, (2018) [17]	Evolution RL	238 leads in 124 patients	92 ± 53 months, 65 ± 14 years	Infection (63), non-infection (61)	98.7% (235 leads)	No major complication	Prospective Italian Registry, No lead wrapping
Aytemir (2016) [11]	TightRail	42 leads in 23 patients	72 (18–216) months, 59 ± 14 years	Infection (12), non-infection (11)	95.7% (TightRail alone)	No major complication	Femoral snare for one patient
Diaz (2019) [18]	TightRail, Evolution (RL), Laser	50,545 extractions	Not reported	Not reported	13 deaths in RMD sheaths versus 167 deaths with laser sheaths	7.2 times higher risk of mortality in laser than rotating sheaths	
Bahadır (2021) [16]	TightRail versus Evolution (RL)	556 leads in 302 patients	5.0 (0.6–33) years, 60 (18–90) years	Infection (130), non-infection (172)	94 versus 94%	1.2 versus 3.8%	Similar efficacy and safety in both tools
Choi (2022) [19]	TightRail	131 leads in 86 patients	11.7 ± 7.3 years, 66.3 ± 14.1 years	Infection (15), non-infection (71)	93%	8.1%	Lead age > 10 years was associated with major complication

*n**, number of patients

sheath, lead wrapping phenomenon was not observed. However, in this study, no comparison was performed between the Evolution RL sheath and other tools.

Initial experience with the TightRail reported by Aytemir et al. was also encouraging with a high procedural success rate (95.7%) and no major complications in 23 patients with 42 leads [11]. More recently, Bahadir et al. retrospectively compared the efficacy and safety of TLE performed using TightRail (333 leads in 169 patients) and Evolution sheaths (233 leads in 133 patients) [18]. The Evolution group included patients who were treated with old (unidirectional) or new (bidirectional) systems. The Evolution and TightRail sheaths exhibited a comparable performance in terms of procedural success (93.9% vs. 94%), clinical success (99.2% vs. 98%), and major complications (3.8% vs. 1.2%), respectively.

A lower risk of mortality with RMD sheath utilization was reported by a recent retrospective study by Diaz, et al., comparing RMD and laser sheaths used for 50,545 TLE cases from 2011 to 2016 [20]. Patients treated with laser sheaths had a mortality rate 7.2 times greater than those who were treated using RMD sheaths (95% confidence interval 4.1–12.7, $P < 0.0001$). However, this study was limited by its retrospective design and unadjusted analysis method that relies on event reports in the Manufacturer and User Facility Device Experience database.

Most recently in 2022, the performance of TLE using TightRail has been reported by Choi et al. in Asian patients (131 leads in 86 patients) [21]. Although the mean lead age (11.7 ± 7.3 years) was greater than those in previous studies, clinical success and major complication rates were acceptable (93.0% and 9.3%, respectively) with 6 min of median fluoroscopic time. However, in 46 patients with longest lead age ≤ 10 years, clinical success and major cardiac complication rates turned out better as 97.8% and 2.2%, respectively. Longest lead age ≥ 10 years was closely associated with TLE-related major cardiac complication ($P = 0.046$).

Overall, TLE outcomes using RMD sheaths are likely to improve over time as experience with the tool increases.

In addition to operator's experience, there are other several factors that can affect the success rate of TLE, such as lead age, the type of fixation (active vs. passive fixation), the types of defibrillator coil (single vs. dual coil; coated/backfilled vs. conventional coil), the type of indication (infectious vs. non-infectious indication), and advancement in the device technology (RMD vs. telescoping sheath; unidirectional vs. bidirectional rotating blade). Longer lead ages, passive fixation, dual and non-coated defibrillator coils, and infectious indications are usually associated with greater degree of fibrotic adhesion and/or calcification and, consequently, lower TLE success rates. Therefore, in these clinical situations, RMD sheaths can be the preferred choice over the telescoping sheaths.

Initially, the RMD sheath is considered as the more aggressive cutting tool and consequently often reserved for the more difficult TLE cases with dense fibrosis and heavy calcification. However, based on the numerous studies showing satisfactory efficacy and safety, the RMD sheath is positioning itself as a first-line as well as a second-line tool for TLE.

Conclusion

The RMD sheath is a very effective tool for TLE, particularly for dissecting heavily calcified fibrous adhesions between the leads and various cardiac and vascular structures. Unlike the unidirectional RMD sheath, bidirectional one does not cause the lead-wrapping complications, and improves TLE outcomes. Based on its satisfactory data on efficacy and safety, the RMD sheath can be utilized as a first-line as well as a second-line rescue tool. However, RMD sheath is an aggressive tool; therefore, special attention should be paid to the potential risk of cardiovascular injury or collateral lead damage.

Abbreviations

CIED: Cardiac implantable electronic device; LLS: Lead-locking stylet; RMD: Rotational mechanical dilator; SVC: Superior vena cava; TLE: Transvenous lead extraction.

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Author contributions

SP carried out the study design and wrote the manuscript. All authors read and approved the final manuscript.

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Declarations

Ethics approval and consent to participate

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Consent for publication

Yes.

Competing interests

The authors declare that they have no competing interests.

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