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A Novel Technique to Extract Implanted Leads Using Simple Stylets and Reused Rotational Sheaths in Patients with a Cardiac Implantable Electronic Device

Kalp İçine Yerleştirilebilir Elektronik Cihazı Olan Hastalarda Basit Stiletler ve Yeniden Kullanılmış Döner Kılıflar Kullanılarak Yerleştirilmiş Elektrotların Çıkarılması İçin Yeni Bir Yöntem

ABSTRACT

Objective: Transvenous lead extraction (TLE) is used in various clinical scenarios, such as device-related infections. Mechanically powered sheaths are one of the most commonly used tools for TLE procedures. We evaluated the procedural and clinical outcomes of a novel extraction technique for chronically implanted leads in the treatment of device-related infections.

Method: The novel extraction technique utilizing standard implantation stylets, snares, reused rotational sheaths, catheters, and wires was evaluated for procedural success and clinical outcomes.

Results: A total of 12 consecutive patients with device-related infections underwent the novel TLE procedure. Complete procedural success was achieved in all patients, with a minor complication rate of 8% (one patient). No major complications or procedure-related mortality were observed. During a median follow-up period of 435 days, one patient died due to a multidrug-resistant systemic infection, one due to end-stage heart failure, and one underwent valve surgery for concomitant valve endocarditis. No cases of reinfection were reported in the study population. Additionally, this novel technique was approximately 85% less costly than the conventional standard technique using locking stylets and unused rotational sheaths.

Conclusion: In situations where unused extraction tools are unavailable or limited by reimbursement constraints, this novel TLE technique offers an effective and safe alternative.

Keywords: Extraction, infection, reused, stylets

ÖZET

Amaç: Transvenöz elektrot ekstraksiyonu (TLE), cihazla ilişkili enfeksiyonlar gibi çeşitli klinik durumlarda kullanılmaktadır. Mekanik tahrikli kılıflar, TLE prosedürlerinde yaygın olarak kullanılan araçlardandır. Bu çalışmada, cihazla ilişkili enfeksiyonların tedavisinde kronik olarak implante edilmiş elektrotların yeni bir ekstraksiyon tekniğiyle çıkarılmasının işlem ve klinik sonuçları değerlendirildi.

Yöntem: Standart implantasyon stiletleri, kementler, yeniden kullanılmış döner kılıflar, kateterler ve teller kullanılarak uygulanan yeni ekstraksiyon tekniği; işlem başarısı ve klinik sonuçlar açısından değerlendirildi.

Bulgular: Cihazla ilişkili enfeksiyonu olan toplam 12 ardışık hasta yeni TLE prosedürü ile tedavi edildi. Tüm hastalarda tam işlem başarısı elde edildi ve minör komplikasyon oranı %8 (1 hasta) olarak kaydedildi. Hiçbir majör komplikasyon veya işlemle ilişkili ölüm gözlenmedi. Medyan 435 günlük takip süresince bir hasta çok ilaca dirençli sistemik enfeksiyon nedeniyle, bir hasta son evre kalp yetmezliği nedeniyle yaşamını yitirdi; bir hasta ise ek kapak endokarditi nedeniyle kapak cerrahisi geçirdi. Çalışma grubunda hiçbir yeniden enfeksiyon vakası görülmedi. Ayrıca bu yeni tekniğin, kilitleme stiletleri ve kullanılmamış döner kılıflar içeren geleneksel standart teknikten yaklaşık %85 daha ucuz olduğu bulundu.

Sonuç: Kullanılmamış ekstraksiyon araçlarının temin edilemediği veya geri ödeme sorunlarının bulunduğu durumlarda, bu yeni TLE tekniği etkili ve güvenli bir çözüm sunabilir.

Anahtar Kelimeler: Ekstraksiyon, enfeksiyon, yeniden kullanım, stiletler

ORIGINAL ARTICLE
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Transvenous lead extraction (TLE) is essential for preventing morbidity and mortality in patients with cardiac implantable electronic device (CIED) system infections and malfunctions.[1] Mechanical-powered tools, such as rotational dilator sheaths, are commonly used for extracting CIED leads, particularly those that are chronically implanted. Two prominent types of rotational sheaths, Evolution® and TightRail™, equipped with specially designed locking stylets, have demonstrated effectiveness and safety in TLE procedures.[2–6] However, the high costs associated with these extraction tools may pose a barrier to performing transvenous extraction procedures, especially in settings where reimbursement limitations restrict the use of mechanical rotational dilator sheaths and locking stylets.

While we advocate for the extraction via the implanted vein using rotational sheaths and locking stylets as the first-line approach, in some centers, access through the femoral vein or, in selected cases, the jugular vein may be preferred for advancing extraction tools.

In this report, we present a novel technique for performing TLE via the implanted vein in patients with CIED system infections, particularly in cases where locking stylets and unused rotational sheaths are unavailable.

ABBREVIATIONS

CIED	Cardiac implantable electronic device
ECG	Electrocardiogram
EO	Ethylene oxide
HRS	Heart Rhythm Society
IQR	Interquartile range
NYHA	New York Heart Association
SD	Standard deviation
SVC	Superior vena cava
TLE	Transvenous lead extraction

Materials and Methods

Study Design and Patient Selection

We conducted a single-center retrospective analysis of our lead extraction database to identify patients who underwent percutaneous lead extraction for CIED system infection using simple lead stylets and reused rotational mechanical dilator sheaths. A total of 12 patients were identified and analyzed for their clinical and procedural characteristics. The decision to use simple stylets and reused rotational sheaths for these patients was prompted by reimbursement issues, despite the fact that the standard approach in our division typically involves the use of locking stylets and unused mechanical rotational dilator sheaths from manufacturers such as Cook Medical and Spectranetics (Philips), particularly when electrodes cannot be manually extracted using simple stylets.

In cases where extraction from the implanted vein was unsuccessful, an alternative percutaneous venous approach, other than the implanted vein, was pursued as a bailout strategy. Notably, all extraction procedures in this cohort were performed due to CIED system infections; no procedures were conducted for other indications such as lead malfunction or system upgrades. Additionally, this technique was not applicable to leads with damaged or occluded lumens, or to lumenless leads, and therefore could not be used in such cases. Although the use of locking stylets with reused rotational sheaths could be a cost-saving strategy, it has not been implemented in our center due to reimbursement constraints. These limitations are important in real-world clinical practice, where lumenless leads—such as Medtronic's SelectSecure MRI SureScan Model 3830—are increasingly used in conduction system pacing, and occluded lumens may be encountered in older or chronically implanted leads due to fibrosis or calcification. Based on our institutional experience and published data, these limitations affect an estimated 10-20% of extraction candidates. In such patients, standard locking stylets cannot be inserted, precluding formation of the lead-stylet unit necessary for our novel technique. Although our current approach is not feasible in these scenarios, future iterations of the technique might explore external lead anchoring or snare-only stabilization strategies, potentially enhanced by three-dimensional imaging guidance to ensure safe traction without intraluminal support.

Consultations were conducted with local representatives of the manufacturers for both Evolution® and TightRail™ regarding the reuse of sterilized rotational sheaths. Although both companies do not recommend this practice, they indicated that, theoretically, it may be feasible.

Prior to extraction attempts, informed procedural consent was obtained from all patients. Furthermore, this retrospective study, based on our institutional database, received approval from Ankara Bilkent City Hospital No. 2 Clinical Research Ethics Committee (Approval Number: E2-24-6620, Date: 21.02.2024) before its commencement.

The reuse of single-use medical devices, such as rotational sheaths and stylets, naturally raises important safety, ethical, and regulatory concerns. While our study utilized ethylene oxide (EO) sterilization for these components, which is a widely accepted method to ensure sterility without compromising material integrity, the legal and regulatory landscape surrounding the reuse of single-use devices must be carefully addressed.

In Türkiye, the reuse of single-use medical devices is not formally regulated at the national level, and no established national guidelines or permissions explicitly authorize the practice. However, some healthcare institutions have adopted internal protocols that allow for the reuse of such devices following validated sterilization procedures, provided that the reuse is medically justified and informed consent is obtained from the patient. In our study, institutional approval was secured, and all patients gave informed consent after being made aware of the reuse of medical materials.

We acknowledge that, despite these precautions, medico-legal risks remain associated with the off-label reuse of single-use medical tools. These include potential liability in the event of adverse outcomes, even if unrelated to device sterility or integrity. It is imperative that institutions engaging in such practices ensure thorough documentation, obtain explicit patient consent, and secure ethical board oversight. We recommend that future regulatory frameworks address this issue to provide clearer guidance, particularly for resource-limited settings where such practices may be considered.

Sterilization Method

Ethylene oxide sterilization is a vacuum-based process in which the gas penetrates the surfaces of most medical devices, ensuring contact with all accessible areas of the rotational sheath. This method delivers the required sterility assurance level without exposing the device to excessive heat, moisture, or radiation, thereby preserving the integrity of the sheath materials and ensuring the safety of the extraction procedure.

EO is an alkylating agent that disrupts the cellular metabolism and reproductive processes of microorganisms. Sterilization occurs when EO gas molecules react with cellular components via the alkylation pathway, involving the addition of alkyl groups to DNA, RNA, and proteins, ultimately destroying these microbial structures.

Regarding sterility validation, ethylene oxide sterilization was performed by a certified central sterilization unit within our hospital. This process included the use of biological indicators to verify microbial inactivation and chemical indicators to confirm adequate exposure to EO gas. Following sterilization, all devices underwent visual inspection to assess for any potential structural damage or degradation.

Extraction Procedure

All TLE procedures were conducted by a skilled device operator specializing in lead extraction (SC). Standard procedural preparations were meticulously performed and included the following: CIED interrogation, antisepsis, administration of general anesthesia, provision of oxygen and continuous saturation monitoring, establishment of arterial and venous access, availability of an on-site echocardiography machine, and creation of femoral accesses for guidewire parking in the superior vena cava (SVC) (to enable the deployment of an SVC occlusion balloon in case of potential SVC rupture during the procedure) and for electrode retraction during extraction. Additional steps included the provision of temporary pacing via the right jugular vein if necessary, administration of local anesthesia, opening of the pocket, exploration of the pulse generator, inspection of the proximal lead segments and fixation sleeves using a soft tissue dissection device, unscrewing of active-fixation leads, and cutting of the proximal lead portions. Surgical backup was available for all procedures and could intervene within less than 10 minutes if required.

In accordance with the latest expert consensus,[1] our standard protocol always begins with an attempt at simple manual traction using either a standard or locking stylet before employing specialized extraction tools. This method is particularly effective for leads with a short dwell time or those that remain mobile within the vein, such as in cases of infection. In our series, this initial approach was applied to all leads. If unsuccessful, further extraction using the novel technique described herein was then pursued.

In the initial stage of the procedure, a stiff, simple stylet, which had been previously used for left ventricular leads and was retained from prior implantation procedures, was inserted into the distal tip of the lead, unlike the procedure performed with a locking stylet. The proximal torquer portion of the stylet was then removed using lead scissors, resulting in a lead with the stylet extending outside the lead (Figure 1A).

A sterilized, reused mechanical rotational dilator sheath, either with or without an outer sheath (Evolution® or TightRail™), obtained from prior transvenous extraction procedures, was then prepared. When necessary, more than one sheath was used for upsizing.

Next, a standard goose-neck snare with its overlying guiding catheter was advanced from the proximal end of the mechanical rotational sheath through the inner lumen, eventually emerging from the sheath's tip (Figure 1B-D). The snare was then deployed from its catheter to open the loop, allowing the lead-stylet system to be introduced through the snare loop (Figure 1E, F).

After positioning the snare at the junction of the lead-stylet system, where the stylet emerged from the proximal part of the cut lead (Figure 1G), the stylet was bent over the lead in the opposite direction. Subsequently, small spirals were created from proximal to distal and from distal to proximal along the lead using a needle holder (Figure 1H, I). These small spirals were then compressed at multiple points using the needle holder (Figure 1J). Although this connection technique proved sufficient and secure in our experience, we acknowledge that this area could be considered a potential weak point in the system. An alternative approach to enhance stability could involve securing the connection with multiple non-absorbable or strong Vicryl sutures around the lead-stylet junction, including the electrode's silicone portion. However, we preferred this mechanical compression method, as it allows for a quicker setup and creates a more compact structure during extraction. In this regard, it may offer advantages over suture-based alternatives. This method is somewhat conceptually similar to the Cook Medical One-Tie compression system, which also provides mechanical locking without internal lead support.

Finally, the loop of the snare was locked in the parked position at the lead-stylet junction, effectively simulating a locking stylet and extension cable (Figure 1K).

In the second stage of the procedure, the lead-stylet system was manipulated to disengage the lead from the lateral walls of the SVC and the right atrium.[7] The lead-stylet system, once formed, was grasped from the distal portion, where the lead approaches the inferior vena cava, and pulled downward using a modified snare technique.[8] This technique involved the use of a reused steerable sheath with a 12F inner lumen (FlexCath Advance™, Medtronic), a large-loop goose-neck snare, and a standard stiff guidewire (Figure 1L).

Initially, the steerable sheath was positioned near the lead-stylet system at the point where the lead approaches the inferior vena cava. Subsequently, the snare and guidewire were advanced through the steerable sheath and passed across opposite sides of the lead (Figure 2A). The guidewire was then directed through the open loop of the snare and grasped at its stiff segment by closing the snare loop (Figure 2B, C). This formed a locked snare-guidewire system, which was pulled back to the ostium of the steerable sheath to establish a robust traction mechanism. Additionally, this system facilitated more distal torque generation during traction and counter-traction maneuvers applied simultaneously from the rotational sheath and the snare-lead-stylet system (Figure 2D).

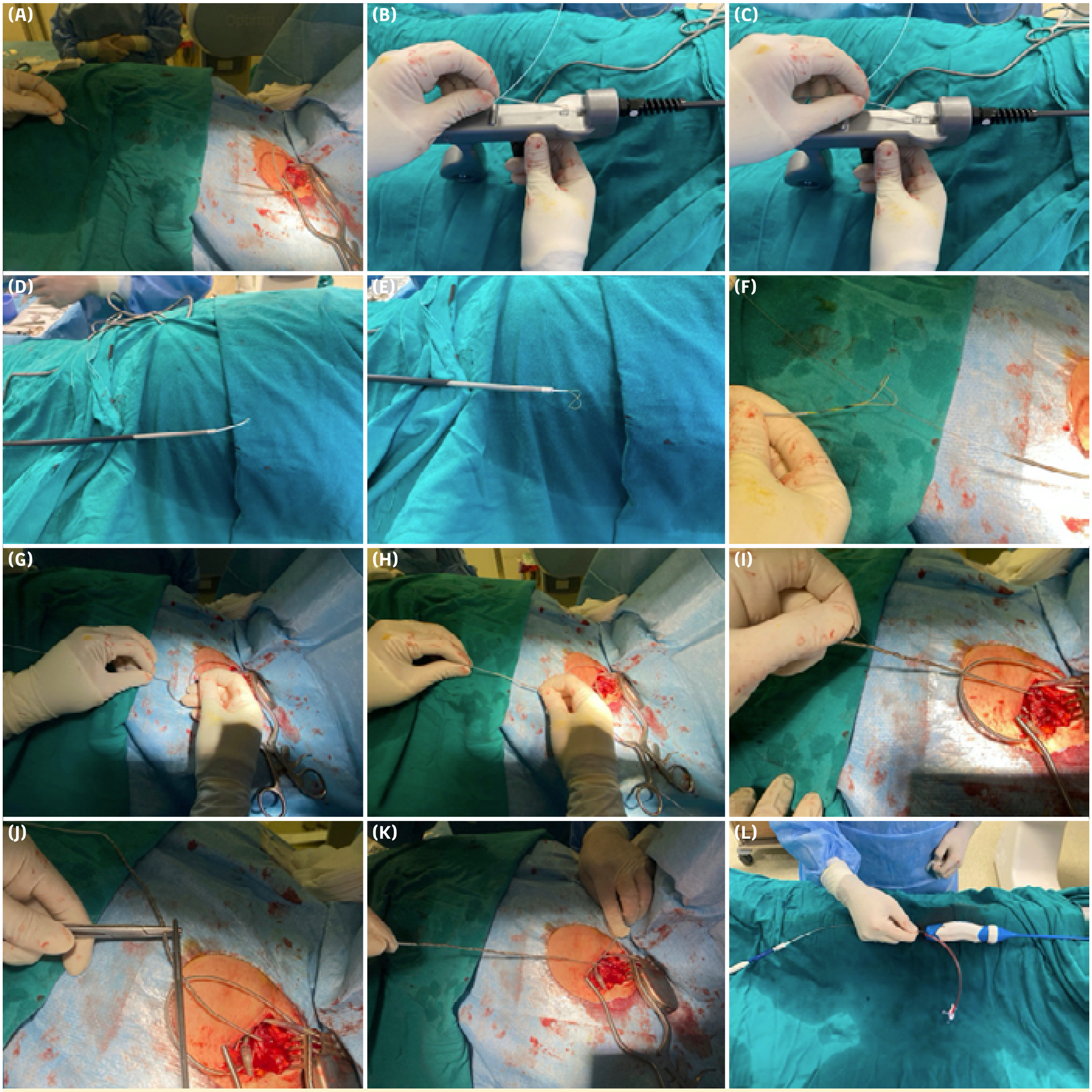

Figure 1. The lead-stylet system consists of a lead that has been cut proximally, with a long, simple implantation stylet housed inside the lead lumen (A). The snare and its guiding catheter are then advanced from the proximal hole to the distal tip of the rotational sheath (B-D). Subsequently, the snare is maneuvered from its catheter into a loop shape, and the lead-stylet system is advanced through this loop (E, F). Once advanced, the snare is positioned at the junction of the lead-stylet system, and the stylet is bent in the opposite direction (G, H). The bent stylet is then twisted over the lead in both proximal-to-distal and distal-to-proximal directions (I). After twisting, the segments are compressed using a needle holder (J). Finally, the snare is firmly closed at the lead-stylet junction using its catheter (K). Additionally, a steerable catheter with a stiff guidewire and a second snare inside it is advanced from the right femoral vein (L). These panels depict the procedure from patient 2.

In the third stage of the procedure, the rotational sheath was introduced over the snare-stylet-lead system. Traction was applied from the femoral system, and standard extraction maneuvers were performed. These included triggered rotation of the cutting blades, dissection of fibrous tissue, use of the outer sheath when necessary, and traction/countertraction movements, all continued until complete removal of the entire CIED system (Figure 2E, F).

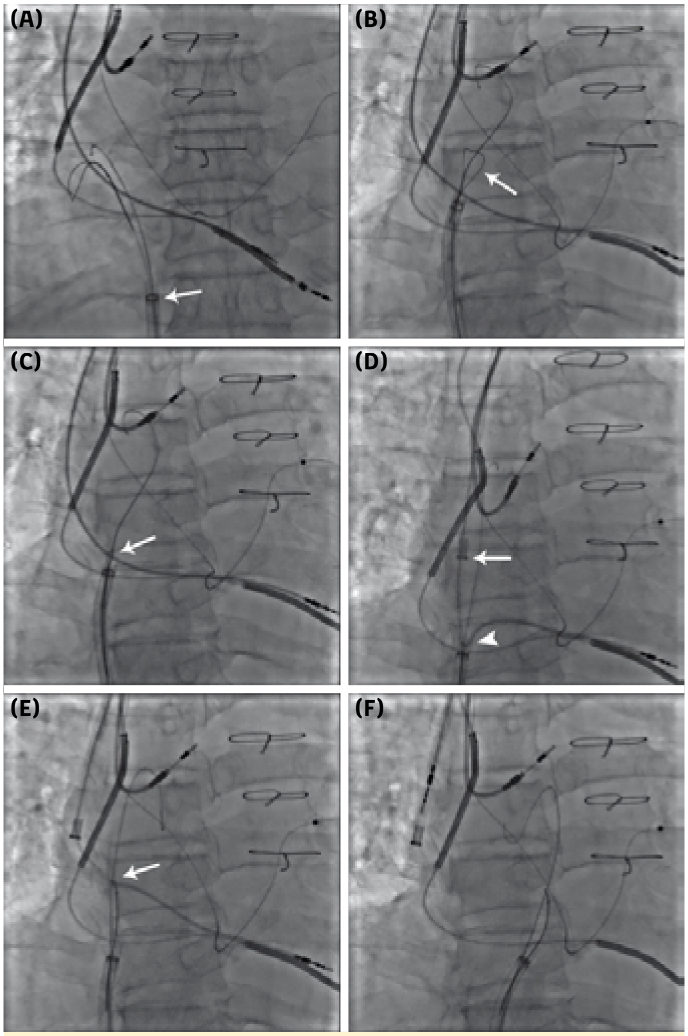

Figure 2. Through the steerable catheter (arrow), the stiff guidewire and the snare are advanced on both sides of the targeted lead (A). The guidewire is then advanced into the loop of the snare (arrow), and the snare is closed to grasp the lead-stylet system distally (arrow) (B, C). Traction is applied (arrowhead) from the catheter-snare-guidewire system to create distal locking and stability of the lead-stylet system, as well as to separate it from the vasculature during advancement of the rotational sheath (arrow) (D). The snare-guidewire system is loosened (arrow) as the rotational sheath approaches, relieving the lead-stylet system and allowing the rotational sheath to be advanced more distally, ultimately resulting in the lead removal (E, F). These panels depict the procedure from patient 2.

For a comprehensive visual demonstration of the complete extraction procedure described above, please refer to Video 1. Additionally, Video 2 provides an illustration of an additional extraction procedure.

Extraction Definitions and Follow-up

Procedural success, clinical outcomes, and complications were reported according to previously established criteria.[2] There were no instances of loss to follow-up. All patients, except one, underwent routine follow-up visits at one month and then every six months thereafter, whenever feasible. These follow-ups included clinical assessment of CIED-related symptoms, 12-lead electrocardiogram (ECG), interrogation of newly implanted CIEDs (if applicable), chest X-ray, and examination of the healed wound site.

Hospitalization outcomes and post-discharge follow-up data, including morbidity and mortality, were documented and reported.

Statistical Analysis

Baseline demographic, clinical, laboratory, and procedural characteristics of patients at the time of extraction were reported at the individual patient level. Categorical variables were presented as numbers and percentages. The Shapiro-Wilk test was used to assess the normality of distribution. Continuous variables that did not follow a normal distribution were described using the median and interquartile range (IQR), while normally distributed continuous variables were reported as mean ± standard deviation (SD). Statistical analyses were conducted using Stata®, version 16.0 (StataCorp LLC, Texas, USA).

Results

Baseline Variables

A total of 12 consecutive patients who underwent CIED extraction procedures using the novel technique for infectious indications were included in the study. The demographic, clinical, laboratory, and procedural characteristics of the patients are summarized in Appendix 1. All patients were male, with a mean age of 55 ± 20 years. The median left ventricular ejection fraction was 41% (interquartile range: 20%-60%). The indications for CIED implantation varied among patients. Half of the cases had undergone at least one prior pulse generator replacement, and one-third were found to be pacemaker-dependent. The majority of patients (58%) had a defibrillator device, and 60% of the implanted leads (n = 30) featured an active-fixation mechanism. The average lead count per patient was 2 (interquartile range: 2-3.75), including both active and abandoned leads. The mean implant duration from initial implantation was 95 ± 54 months. Pocket infection was the primary indication for extraction in 67% of cases. A 13 French rotational sheath was used in 58% of patients. Complete procedural and clinical success was achieved in all cases, with 92% of patients experiencing no complications. The mean procedure and fluoroscopy times were 130 ± 28 minutes and 23 ± 7 minutes, respectively. Positive culture results for the pocket, blood, and lead were reported in 33%, 33%, and 42% of cases, respectively.

Follow-up Data and Clinical Outcomes

The median follow-up duration was 435 days (interquartile range: 128-450 days). There were no instances of loss to follow-up, and all patients, except one, attended routine follow-up appointments at one month and then every six months thereafter. No reinfection was observed in 92% of patients during the follow-up period.

One patient with lead endocarditis and systemic infection, who had a history of drug addiction, died in the hospital due to uncontrolled systemic infection, despite achieving complete procedural success and receiving multiple broad-spectrum antimicrobials. Additionally, after successful lead extraction, the only pediatric patient in the study underwent tricuspid valve surgery due to valve endocarditis with a large vegetation detected during follow-up. Another patient died during mid-term follow-up due to advanced heart failure.

Re-implantation strategies were individualized based on the type of extracted device, infection resolution status, and current clinical indications. According to the 2017 Heart Rhythm Society (HRS) expert consensus statement,[1] device re-implantation should ideally be deferred until complete resolution of infection, guided by negative blood cultures and clinical signs of recovery. In our cohort, re-implantation was most commonly performed via contralateral implantation sites in high-risk patients. In terms of patient-reported outcomes, symptom relief and patient satisfaction with the procedure were assessed during follow-up visits through structured in-clinic interviews. Patients reported relief from infection-related symptoms and expressed satisfaction with the treatment outcomes. Additionally, no late complications, such as lead dislodgement or recurrent bacteremia, were observed during the follow-up period, which extended up to 450 days.

When comparing the novel procedure, which utilizes sterilized implanting stylets, snares, sterilized reused catheters, and sterilized reused rotational sheaths, with the standard approach, which uses locking stylets and new rotational sheaths, it was found that the total cost related to tools used in the novel extraction technique was significantly lower than that of the standard extraction technique ($640 vs. $4,550, respectively).

Discussion

The primary finding of our study highlights the effectiveness and feasibility of this novel extraction technique, even in the absence of locking stylets and unused new rotational sheaths. This approach demonstrated high efficacy and a low complication rate in a diverse patient population with device-related infections and various types of CIEDs and leads. Furthermore, mid-term clinical follow-up showed favorable outcomes with respect to CIED-related events.

As global rates of cardiac implantable electronic device implantation continue to rise, so does the likelihood of encountering complications such as infection, venous stenosis, or electrode failure. Regardless of the specific cause of these adverse events, transvenous lead extraction has emerged as the primary approach for managing CIED-related complications in most patients with implanted devices.[9] Extraction procedures can vary widely in complexity, ranging from simple manual techniques to the use of multiple tools and combined approaches.[10] Mechanical-powered tools, such as mechanical rotational dilator sheaths, are commonly used for extracting CIED leads, particularly those that have been chronically implanted.[2-6]

However, the high costs associated with these extraction tools can present a barrier to performing TLE procedures, especially in cases where reimbursement limitations restrict access to mechanical rotational dilator sheaths and locking stylets. The estimated costs and healthcare burdens of CIED infections alone have been reported as substantial in both the United States and the United Kingdom.[11] The average cost of TLE was reported to be £10,727, increasing to £22,615 when device reimplantation was also planned.[12] Research indicates that in high-volume centers with established TLE programs, where the increased costs of the procedure are effectively reimbursed, optimal results can be achieved through the proficient utilization of various complex extraction devices.[2-6,13,14] Nevertheless, in many centers where such resources may not be readily available, there is a need to implement cost-effective and easily applicable techniques to optimize outcomes and shorten the learning curve.[15]

In our study, we demonstrated the safety and efficacy of a cost-effective extraction method that can be applied in many centers, eliminating the need for locking stylets or newly purchased, unused rotational sheaths. The average cost of TLE using our novel extraction technique was calculated to be $640. This approach holds promise as an effective and accessible solution to the challenges associated with CIED lead extraction. Although economically advantageous, the tedious sterilization and reuse of mechanically complex rotational sheaths may not be permitted in all centers. In such cases, another simple and cost-effective alternative is the use of inexpensive telescopic propylene sheaths as the first-line option.[16] The use of expensive rotational sheaths can then be reserved as a second-line strategy.

While we reported that the novel technique was approximately 85% less expensive than the conventional method, this estimate primarily reflects the direct material costs. A comprehensive cost analysis would ideally include additional factors such as staff time, training requirements, sterilization labor, and the potential costs associated with complications, safety assurance, or legal liabilities related to the reuse of medical devices. Unfortunately, such data were not systematically collected in our retrospective analysis. Nonetheless, we believe our findings provide an important starting point for highlighting the economic advantages of this technique in low-resource settings. Future studies should aim to include these indirect costs, as well as long-term clinical and economic outcomes, to enable a comprehensive cost-effectiveness analysis.

In addition to our approach, several alternative low-cost methods for transvenous lead extraction have been described in the literature, including the use of telescoping polypropylene sheaths, mechanical-only extractions, and femoral or jugular snaring techniques. These methods have also demonstrated safety and efficacy in resource-constrained environments. For instance, telescopic sheaths, which are less expensive than powered tools, have shown promising outcomes when used with a lead-locking device system, particularly under local anesthesia.[16] Similarly, mechanical-only extractions using traction and countertraction principles without powered sheaths can be effective, especially in experienced hands.[9] The femoral snaring technique, used either alone or in combination with jugular access, can serve as a bailout or primary strategy, depending on anatomical constraints and operator experience.[7,17] Compared to these methods, our technique maintains cost-efficiency while incorporating rotational sheaths to manage more complex adhesions, potentially offering a middle ground between manual traction and advanced powered tools. More comparative studies are needed to determine the optimal technique based on cost-effectiveness, safety, and procedural success.

In our series, both Evolution® and TightRail™ mechanical rotational sheaths were reused following EO sterilization. We did not observe any procedural or clinical differences attributable to the specific sheath type during the novel extraction technique. Selection between sheath types was based primarily on availability rather than performance characteristics. However, due to the small sample size, no definitive conclusions can be drawn regarding comparative performance or complication rates. In the context of clinical practice in Türkiye, two studies have directly compared the Evolution® and TightRail™ systems, highlighting their relative safety and efficacy. In the first study, the authors found no significant differences in procedural success or complication rates between the two systems.[2] Another Turkish study supported these findings, reporting that both systems are effective tools for mechanical lead extraction, with favorable safety profiles when used by experienced operators.[18] These findings support the use of either system, depending on operator preference, tool availability, and economic considerations.

Factors such as long dwell time (> 10 years), extraction of three or more leads, procedures performed in low-volume centers, the use of powered sheaths, and the femoral approach have been identified as predictors of clinical failure. Additionally, older age, procedures performed in low-volume centers, New York Heart Association (NYHA) Class III/IV heart failure, and systemic infection have been associated with higher all-cause in-hospital mortality.[10]

The risks associated with TLE must always be carefully weighed against the likelihood of procedural success. In our study, the use of a stepwise technique resulted in a procedural success rate of 100%, an uncomplicated procedure rate of 92%, and a procedure-related mortality rate of 0%. These outcomes align well with previous reports, which indicate a 96.5% success rate for lead removal and a 0.3% in-hospital mortality rate.[19]

The ability to perform a cost-effective extraction method with high success and low complication rates is crucial for healthcare teams performing TLEs in institutions with developing programs and limited extraction experience.

While the use of locking stylets during device removal procedures offers benefits, such as providing internal support to intracardiac leads, reducing fluoroscopy time, and enabling the application of distal traction force, the high cost of these specially designed tools often makes them inaccessible for many clinics. Therefore, in the initial stage of our extraction procedure, we simulated the locking stylet and extension cable using a goose-neck snare and an unused stiff simple stylet for left ventricular leads remaining from previous implantation procedures. We believe this method can be safely and effectively employed in cases where locking stylets are unavailable or cost-prohibitive.

In addition to the established efficacy of this cost-effective approach, the technique introduces novel aspects that merit further emphasis. The most innovative component is the simulated locking mechanism using a reused snare and simple stylet, which provides internal support to the lead without requiring a traditional locking stylet. Despite the technique's resourcefulness, there are procedural challenges that must be acknowledged. One significant difficulty is the successful grasping and securing of the cut lead-stylet system, particularly in the presence of dense fibrotic tissue or multiple adjacent leads. These conditions can complicate the maneuvering of the snare loop and the creation of stable spirals for traction. Care must also be taken to avoid unintended disturbance or dislodgement of other functional leads during the manipulation of extraction tools, which can be particularly challenging in patients with multiple leads or abandoned systems. These limitations underscore the importance of experienced operators and careful procedural planning.

Transvenous lead extraction procedures can be performed via either a superior or inferior approach. The effectiveness of using mechanical dilator sheaths via the superior approach has been demonstrated in numerous clinical studies.[2–6,9,13,14]

The "tandem" technique combines both superior and inferior approaches to balance the applied forces during extraction. In the second stage of our extraction procedure, the lead-stylet system was grasped from the distal portion, where the lead approaches the inferior vena cava, and pulled downward using the modified snare technique. Then, in the third stage, traction was applied from the femoral system, and standard maneuvers of the extraction procedure were performed from the superior approach until complete lead removal. Regardless of the equipment or vascular access site used, effective TLE requires control over the extraction forces. Many complications related to the central venous system can arise from an inappropriate relationship between the sheath and the vein wall geometry, or from inadequate lead support when traction is applied solely to the lead. To prevent fatal complications such as intrathoracic vascular injury, particularly SVC tears, simultaneous traction from both superior and inferior directions should be employed. This technique enhances and balances the forces applied to the targeted lead, creating a stronger rail for extraction.[20,21] Additionally, balancing the forces helps draw the lead away from the lateral walls of the SVC and right atrium, improving the geometric relationship between the vessel and the dissecting sheath, and thereby reducing the risk of SVC injury. Moreover, since most of the countertraction force is absorbed by the snare-wire-catheter system from below, the risk of damage to the right ventricle and tricuspid valve is minimized.

In a retrospective series utilizing this technique, particularly beneficial for leads with long dwell times, complete lead extraction was achieved in 96.2% of cases, with a major complication rate of 3.8%, and no reported instances of death or SVC injury.[21]

In our study, the majority of the extracted CIEDs were defibrillator devices, and 27% of all implanted leads featured a dual-coil design with a proximal coil and long dwell times. Such characteristics (long implant durations and dual-coil configurations) have been identified as predictors of increased risk for adhesion to venous and cardiac tissues. Lead-to-vessel or myocardial adhesions, along with fibrosis and calcification, represent the primary challenges encountered during TLE.

Pathological evaluation of extracted materials has shown that the adhesion process depends on both time and the presence of foreign material. Additionally, studies have demonstrated that longer indwelling times of leads are associated with higher complication rates during extraction procedures.[22,23] In our novel technique, despite a long mean lead indwelling time, we achieved a high procedural success rate and a low complication rate. This suggests that our approach effectively addresses the challenges posed by lead adhesion and prolonged implantation, contributing to the favorable outcomes observed in our study.

It should be acknowledged that all procedures in this study were performed by a single, highly experienced operator, which may have significantly contributed to the 100% procedural success rate and low complication rate (8%). These outcomes may not be easily replicable in centers with less experience in lead extraction techniques. Therefore, operator experience likely played a major role in the observed results. To ensure broader and safer implementation of this novel extraction approach, structured training pathways—including hands-on workshops, supervised procedural mentoring, and simulation-based training—should be developed, particularly for mastering the complex maneuvers involving snare techniques.

Lastly, there are some scenarios we have not yet encountered using this novel method: non-tandem approaches; patients in whom the stylet cannot be advanced distally due to occluded or lumenless leads; and cases where catheters with a lumen smaller than 12F are used in the inferior approach. However, we believe that, theoretically, the novel lead-stylet system could also be adapted for use in these situations. Additionally, the smaller-lumen catheters mentioned earlier also offer a comparable economic advantage.[17] The primary benefit of using a large-lumen sheath is that it allows for the advancement of tools such as a snare and wire/catheter through a single sheath.

Although our study demonstrated promising results, an important limitation is the lack of a control group using conventional extraction tools, such as locking stylets and unused rotational sheaths. This absence precludes a direct comparison of procedural and safety outcomes with standard techniques. While a matched cohort or historical comparison is beyond the scope of this retrospective series, such an approach would provide more meaningful clinical context. Future studies incorporating these types of comparative analyses are warranted to strengthen the generalizability of our findings.

Limitations

This study has several limitations that should be acknowledged. First, the results were obtained from a single tertiary center with a lead extraction practice serving both local and referral patient populations. Therefore, the findings may not be generalizable to other settings with different patient demographics or varying levels of expertise in lead extraction procedures. Additionally, the small sample size and retrospective design limit the strength of the conclusions. With only 12 patients included, the statistical power of the study is inherently limited, which significantly restricts the generalizability of the results. As such, the findings presented here should be interpreted as hypothesis-generating rather than conclusive. Robust clinical conclusions cannot be drawn without further validation in larger, prospective, multicenter trials.

Although local representatives of the manufacturers have stated that the reuse of rotational sheaths and deflectable catheters may be theoretically possible, these devices were only manually and visually inspected in our study. For reused rotational sheaths, tool integrity and potential structural deformation were checked, and the functionality of the trigger mechanism, sheath body, and distal rotation system was manually assessed. For reused deflectable catheters, tool integrity and potential structural deformation were similarly evaluated, and deflection functionality was tested by manipulating the handle mechanism. However, no formal mechanical or performance testing (e.g., tensile strength or leak testing) was conducted. This constitutes a limitation, and we recommend that further validation including objective testing be considered in future studies utilizing reused equipment.

Further randomized, multicenter clinical studies with larger sample sizes are warranted to more accurately determine the success and complication rates of this novel extraction technique compared to other established TLE methods. Another limitation is the low event rate observed in transvenous lead extraction procedures in our study, which may affect the generalizability of the findings.

It is worth noting that the high success rate and low complication rate observed in our study may be attributed to the operator's expertise. Additionally, since device-related infection was the sole indication for extraction in our study, data on the efficacy of this technique for malfunctioning leads, device upgrades, and other indications are not available. Future research should aim to address these limitations and provide a more comprehensive understanding of the utility and effectiveness of this novel extraction technique.

Conclusion

Mechanical-powered tools and locking stylets are commonly used for the extraction of chronically implanted leads. However, we believe that our novel extraction technique presents a viable alternative, particularly in centers facing economic challenges. While we have suggested that this technique can be easily adopted once the learning curve is overcome and a sufficient number of procedures have been performed, we must acknowledge that this claim was not directly supported by quantitative data. Therefore, the current study should be interpreted as a preliminary, proof-of-concept evaluation. The technique may potentially be adopted following adequate operator experience and institutional familiarity, but further validation in larger, external populations is warranted. We also posit that this technique may be particularly beneficial in settings where specialized extraction tools are not readily available for TLE procedures. By offering a cost-effective and accessible solution, our technique has the potential to expand the reach of lead extraction procedures and improve patient outcomes across a variety of healthcare settings. However, given the small patient sample size in this retrospective study, the conclusion must emphasize the need for further research to assess the safety of this new procedure in a larger patient population. Therefore, future prospective studies involving larger sample sizes and multicenter collaboration are necessary to confirm the generalizability, safety, and effectiveness of this approach. Considering the extremely limited number of cases in this study, the proposed technique should be viewed as a bail-out option, applicable primarily when conventional tools are unavailable, particularly in infection-related CIED extractions.

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Video 1. Complete extraction procedure of patient 2.

Video 1. Complete extraction procedure of patient 4.

References

1. 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(12):e503-e551. [CrossRef]
2. Cay S, Ozeke O, Ozcan F, Topaloglu S, Aras D. Comparison of two types of rotational mechanical dilatator sheath: Evolution® and TightRail™. *Pacing Clin Electrophysiol*. 2019;42(9):1226-1235. [CrossRef]
3. 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(7):1103-1110. [CrossRef]
4. Migliore F, Pittorru R, Dall'Aglio PB, et al. Outcomes of transvenous lead extraction of very old leads using bidirectional rotational mechanical sheaths: Results of a multicentre study. *J Cardiovasc Electrophysiol*. 2023;34(3):728-737. [CrossRef]
5. Misra S, Swayampakala K, Coons P, et al. Outcomes of transvenous lead extraction using the TightRail™ mechanical rotating dilator sheath and excimer laser sheath. *J Cardiovasc Electrophysiol*. 2021;32(7):1969-1978. [CrossRef]
6. Artus A, Mansourati J, Fatemi M, et al. Efficacy and safety of the new TightRail™ mechanical sheath for transvenous lead extraction: Results of a French multicenter study. *J Cardiovasc Electrophysiol*. 2022;33(4):731-737. [CrossRef]
7. Fischer A, Love B, Hansalia R, Mehta D. Transfemoral snaring and stabilization of pacemaker and defibrillator leads to maintain vascular access during lead extraction. *Pacing Clin Electrophysiol*. 2009;32(3):336-339. [CrossRef]
8. Aras D, Ozcan F, Ozeke O, Cay S, Topaloglu S. Modified snare removal of a retained lead. *Int J Cardiol*. 2016;203:596-597. [CrossRef]
9. Gładysz-Wańha S, Joniec M, Wańha W, et al. Transvenous lead extraction safety and efficacy in infected and noninfected patients using mechanical-only tools: Prospective registry from a high-volume center. *Heart Rhythm*. 2024;21(4):427-435. [CrossRef]
10. Bongiorni MG, Burri H, Deharo JC, et al. 2018 EHRA expert consensus statement on lead extraction: Recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: Endorsed by APHRS/HRS/LAHRS. *Europace*. 2018;20(7):1217. [CrossRef]
11. Clémenty N, Carion PL, Léotoing L, et al. Infections and associated costs following cardiovascular implantable electronic device implantations: A nationwide cohort study. *Europace*. 2018;20(12):1974-1980. [CrossRef]
12. Brough CEP, Rao A, Haycox AR, Cowie MR, Wright DJ. Real-world costs of transvenous lead extraction: The challenge for reimbursement. *Europace*. 2019;21(2):290-297. [CrossRef]
13. Migliore F, Cavalli G, Bottio T, et al. Hybrid minimally invasive technique with the bidirectional rotational Evolution® mechanical sheath for transvenous lead extraction: A collaboration between electrophysiologists and cardiac surgeons. *J Arrhythm*. 2018;34(3):329-332. [CrossRef]
14. Mazzone P, Tsiachris D, Marzi A, et al. Advanced techniques for chronic lead extraction: Heading from the laser towards the evolution system. *Europace*. 2013;15(12):1771-1776. [CrossRef]
15. Sadek MM, Goldstein W, Epstein AE, Schaller RD. Cardiovascular implantable electronic device lead extraction: Evidence, techniques, results, and future directions. *Curr Opin Cardiol*. 2016;31(1):23-28. [CrossRef]
16. Manolis AS, Georgiopoulos G, Metaxa S, Koulouris S, Tsiachris D. Cardiac implantable electronic device lead extraction using the lead-locking device system: Keeping it simple, safe, and inexpensive with mechanical tools and local anesthesia. *Anatol J Cardiol*. 2017;18(4):289-295. [CrossRef]
17. Jiratham-Opas J, Prasertwitayakij N, Nantsupawat T, Wongcharoen W. Procedural outcome of lead explant and countertraction-assisted femoral lead extraction in Thai patients with cardiac implantable electronic device infection. *J Arrhythm*. 2021;37(5):1124-1130. [CrossRef]
18. Bahadır N, Canpolat U, Kaya EB, et al. Comparison of acute and long-term outcomes of Evolution® and TightRail™ mechanical dilator sheaths during transvenous lead extraction. *J Cardiovasc Electrophysiol*. 2021;32(5):1395-1404. [CrossRef]
19. 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(1):73-84. [CrossRef]
20. Akhtar Z, Kontogiannis C, Elbatran AI, et al. Transvenous lead extraction: Experience of the Tandem approach. *Europace*. 2023;25(11):euad331. [CrossRef]
21. Muhlestein JB, Dranow E, Chaney J, Navaravong L, Steinberg BA, Freedman RA. Successful avoidance of superior vena cava injury during transvenous lead extraction using a tandem femoral-superior approach. *Heart Rhythm*. 2022;19(7):1104-1108. [CrossRef]
22. Segreti L, Di Cori A, Soldati E, et al. Major predictors of fibrous adherences in transvenous implantable cardioverter-defibrillator lead extraction. *Heart Rhythm*. 2014;11(12):2196-2201. [CrossRef]
23. Witte OA, Delnoy PPH, Ghani A, et al. Lead extractions: Dissecting adhesions up to the lead-tip of the right ventricle: Safety and success-rates. *Pacing Clin Electrophysiol*. 2022;45(1):132-140. [CrossRef]

Appendix 1. Demographic, clinical, laboratory, and procedural characteristics of the patients

Patient no.	Age	Sex	Implantation indication	Previous replacement	Extraction İndication	CIED type	Lead types	Abandoned lead	Number of leads	Implant duration (months)	Max sheath diameter used (F)	Follow-up (months)	Adverse outcomes during follow-up	Follow-up reinfection	Procedural success	Complications (major/minor)	Fluoroscopy time (min)	Procedure time (min)	LVEF (%)	Pacemaker dependency	Culture results
1	15	M	HCMP	–	Lead endocarditis	DDD ICD	Dual-coil active, RA active	–	2	27	13	14	–	–	Complete	–	19	122	70	–	Pocket - Blood + Lead -
2	70	M	Heart failure with QRS widening	+	Pocket infection	CRT-D	Dual-coil active, CS passive	+ RA and RV active pace leads	4	160	13	15	Heart failure-related mortality	–	Complete	–	36	186	15	–	Pocket - Blood - Lead -
3	66	M	AV block	–	Pocket infection	DDD Pace	RA passive, RV active	–	2	62	11	15	–	–	Complete	–	16	110	56	+	Pocket - Blood - Lead -
4	48	M	VT	+	Pocket infection	VVI ICD	Dual-coil active	+ RV dual-coil active	2	170	13	15	–	–	Complete	–	23	128	32	–	Pocket + Blood - Lead -
5	76	M	AV block	–	Pocket infection	DDD Pace	RA passive, RV active	–	2	50	11	1	–	–	Complete	–	14	105	60	+	Pocket - Blood - Lead +
6	56	M	SSS	–	Pocket infection	DDD Pace	RA passive, RV passive	–	2	111	11	15	–	–	Complete	–	26	136	60	–	Pocket - Blood - Lead +
7	21	M	AV block	–	Pocket infection	DDD Pace	RA active, RV active	–	2	56	11	5	–	–	Complete	–	21	109	60	–	Pocket + Blood + Lead +
8	66	M	AV block	+	Lead endocarditis	DDD Pace	RA active, RV active	+ RV passive pace lead	3	141	11	4	–	–	Complete	–	23	145	50	+	Pocket - Blood - Lead -
9	46	M	Primary prevention	–	Lead endocarditis + Systemic infection	VVI ICD	Dual-coil active	–	1	20	13	17 days	In-hospital mortality	Mortality related to systemic infection	Complete	–	15	86	20	–	Pocket - Blood + Lead +
10	74	M	Heart failure with QRS widening	+	Pocket infection	CRT-D	Dual-coil passive, RA passive, CS passive	+ CS passive	4	156	13	14	–	–	Complete	–	32	168	20	+	Pocket + Blood - Lead -
11	54	M	Primary prevention	+	Lead endocarditis	VVI ICD	Single-coil active	+ RV dual-coil passive	2	120	13	17	–	–	Complete	–	20	115	25	–	Pocket - Blood + Lead +
12	72	M	Heart failure with QRS widening	+	Pocket infection	CRT-D	Single-coil active, RA active, CS passive	+ RV dual-coil active	4	72	13	33	–	–	Complete	Femoral hematoma	30	148	15	–	Pocket + Blood - Lead -