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EVOLUTION MECHANICAL DILATOR SHEATH AS A FIRST CHOICE FOR TRANSVENOUS LEAD EXTRACTION

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Refaat MM, Costa R, Wang JI, Skouri H, Lahoud P, Khoury M, Abchée AB, Lee BK, Abi-Saleh B. La gaine de dilatation mécanique Evolution comme premier choix pour l'extraction des sondes intravasculaires. J Med Liban 2019; 67 (1): 23-27.

ABSTRACT • Objectives: The Evolution mechanical dilator sheath (Cook Medical) uses a rotational mechanism and a bladed tip to overcome fibrosis around cardiovascular implantable electronic devices (CIED) leads. There are only a few reported case series where the Evolution system was used as the first-line choice for CIED lead extraction. The purpose of this study was to report the success of the Evolution system as a first line tool in two centers: the University of California San Francisco Medical Center (San Francisco, CA, USA) and the American University of Beirut Medical Center (Beirut, Lebanon). **Method:** Between July 2011 and May 2015, the Evolution sheath was used for extraction of pacemaker or implantable cardioverter-defibrillator (ICD) leads in 43 patients (88 leads). Success and complications were defined according to the Heart Rhythm Society expert consensus document on lead extraction. **Results:** Indications for extraction were infection with or without bacteremia, lead malfunction and subclavian vein stenosis. Evolution was used as first choice in all patients, with 100% clinical success. Complete procedural success was achieved in 38 patients (88.3%); in five patients, the distal electrode with the distal end of the right atrial (RA) or right ventricular (RV) coil was retained. Adverse events were limited to one patient having a consequent pneumothorax and another having a pericardial effusion that did not cause any hemodynamic compromise. **Conclusion:** Our data suggest that the Evolution mechanical dilator sheath is a useful and safe tool to be used as first line management in transvenous lead extraction.

Keywords: defibrillation-ICD; pacing; extraction; Evolution system

RÉSUMÉ • Objectifs: La gaine de dilatation mécanique Evolution (Cook Medical) utilise un mécanisme de rotation et une pointe à lame pour surmonter la fibrose autour des dérivations d'appareils électroniques implantables cardiovasculaires (CIED). Il n'y a que quelques séries de cas rapportés pour lesquels le système Evolution a été utilisé comme premier choix pour l'extraction de CIED. L'objectif de cette étude est de rapporter le succès du système Evolution en tant qu'outil de première ligne dans deux centres: le centre médical de l'Université de Californie à San Francisco (San Francisco, Californie, États-Unis) et le centre médical de l'Université américaine de Beyrouth (Liban). **Méthodes:** Entre juillet 2011 et mai 2015, la gaine Evolution a été utilisée pour l'extraction des sondes de stimulateur cardiaque ou de défibrillateur automatique implantable (ICD) chez 43 patients (88 sondes). Le succès et les complications ont été définis selon le document de consensus des experts de la Heart Rhythm Society sur l'extraction. **Résultats:** Les indications pour les extractions étaient des infections avec ou sans bactériémie, dysfonctionnement de la sonde et sténose de la veine sous-clavière. La gaine Evolution a été utilisée comme 1^{er} choix chez tous les patients, avec un succès clinique de 100%. Le succès complet de la procédure a été atteint chez 38 patients (88,3%). Les événements indésirables ont été limités à un patient ayant un pneumothorax et un autre ayant un épanchement péricardique ne causant aucun trouble hémodynamique. **Conclusion:** Nos données suggèrent que la gaine de dilatation mécanique Evolution est un outil utile et sûr à utiliser comme traitement de première intention dans l'extraction transveineuse du CIED.

Mots-clés: défibrillateur; stimulateur cardiaque; extraction; système Evolution

INTRODUCTION

Since the implantation of the first pacemaker in 1958, it is estimated that more than 400,000 CIEDs, including implantable cardioverter defibrillators and permanent pacemakers, are currently implanted yearly in the United States [1,2]. As experience with CIEDs grew, more and

more clinical issues started to arise. Additionally, the increasing use of CIEDs, due to broader indications and improved cardiovascular outcomes, and the longer life expectancy of patients brought complicated procedures to the frontline [3]. During this time, everything from the insulation material placed on leads to the technique of insertion was questioned and studied in order to improve

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the process of CIED implantation and to decrease the complications thereafter.

One of the largest hurdles tackled at that point was the safe removal of problematic CIEDs. In general, it was noticed that removal of the pulse generator system was relatively straight forward, as well as the removal of recently implanted leads. However, removal of chronically inserted leads rose as a challenge [3]. Chronic contact with venous and endocardial structures induces fibrosis and eventual calcification, making extraction a delicate and complicated procedure. Thus, the area of safe lead extraction developed quickly, mainly after 1988, to the point where it has become a specialized procedure with specific techniques and recommendations as well as improving results [3,4].

Many methods for lead extraction have been developed including manual traction, locking stylets, snares, mechanical sheaths, laser sheaths, electro-surgical sheaths and telescoping sheaths [1]. The Evolution mechanical dilator sheath system (Cook Medical, Bloomington, IN, USA) was introduced as a new hand-powered method for overcoming adhesions and fibrosis that surround chronically implanted leads.

The Evolution sheath is composed of a relatively flexible substance (Teflon) and metal (steel) with threaded metal distal tip which allows the system to pass through adhesions. The external polymer sheath protects the vessel wall by covering the internal metal tip in a telescoping fashion, simultaneously allowing the metal tip to be rotated by the operator for release of adhesions [5]. Few centers have reported cases or case series of their use of Evolution, with only one center reporting it as a first-line choice for extraction [6-8].

In this case series, we report our experience with the Evolution mechanical dilator sheath as first line choice for transvenous lead extraction.

METHODS

Patient population

Our case series included 43 patients who underwent CIED lead extraction between the months of July 2011 and May 2015 in two medical centers: the University of California San Francisco Medical Center (UCSF, San Francisco, CA, USA) and the American University of Beirut Medical Center (AUBMC, Beirut, Lebanon). A total of 88 leads were removed, all using the Evolution system as a first-line choice for extraction. The decision for lead removal was based on the indications stated in the consensus document of the Heart Rhythm Society (HRS) published in 2009 [1]. Blood cultures were drawn from all patients with suspected infection of the CIED pocket or leads and transesophageal echocardiography

was done in case of positive blood cultures to determine the presence of endocarditis and dictate further medical management.

Definitions of success and complications

As per the consensus document of the HRS published in 2009 [1], *complete procedural success* was defined as the “removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure related death”. On the other hand, it was determined that *clinical success* was achieved if all targeted leads and lead material were removed from the venous structure or if the retained portion was too small to cause any negative impact on the outcome of the procedure or the life of the patient. *Failure* was defined as the inability to achieve either of the above or the occurrence of a permanent disability or procedure related death.

Complications were divided into intra-procedural or post-procedural complications. Major complications were outcomes not amenable to intervention and caused a permanent disability, life-threatening consequences or death. Minor complications, on the other hand, were outcomes simple to treat and did not affect the patient’s function or threaten life [1].

Procedure

All patients underwent lead extraction in the electrophysiology laboratory under general anesthesia. Invasive arterial pressure and noninvasive oxygen saturation were monitored in all patients while they were in the electrophysiology laboratory. In patients dependent on bradycardia support, a temporary pacemaker was inserted from the femoral vein.

After opening the pocket, capsulectomy was performed and all at risk tissue was removed. The leads were dissected down to the tie down sleeves. Simple traction or traction on a locking stylet with insulation-bound suture was attempted initially. If this approach was not sufficient, then the Evolution sheath was used for extraction (Figure 1). Binding of the conductor and insulating elements were used to exert control over the lead body and tip.

Three major principles were followed during the procedure: dissection of fibrotic adherences when needed, control of the entire lead body, and countertraction at the tip of the lead. Locking stylets were used to control the conductor coil down to the tip of the lead being extracted. The lead’s outer insulation and conductor usually were bound together by a suture tied at the insulation. All patients were monitored for complications related to the procedure at the time of extraction and during their hospital stay.

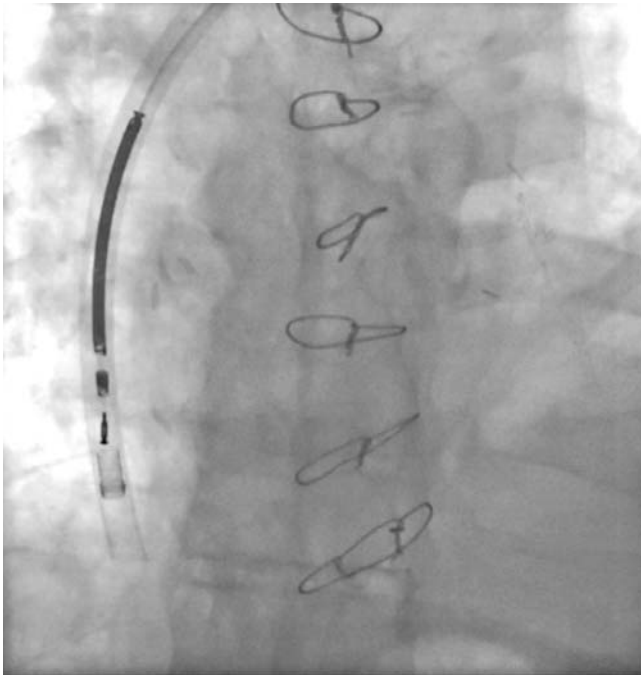


Figure 1

A right ventricular defibrillator lead completely extracted into an Evolution dilator sheath

Statistical analysis

Statistical analyses were performed with STATA 13 software (College Station, TX: Stata Corp LP). All continuous variables are reported as mean \pm standard deviation (SD). All categorical variables are reported as number (percentage).

RESULTS

The Evolution mechanical dilator sheath was first used at AUBMC in July 2011. Between July 2011 and May 2015, the Evolution was used for extraction of 88 leads in 43 patients at UCSF and AUBMC.

Baseline characteristics of the patients are summarized in Table I. Thirty-five patients were male (83.3%). The mean age was 59 ± 11 years.

TABLE I BASELINE CHARACTERISTICS

CHARACTERISTICS	Number	%
Male	35	83.3
Age	$59 (\pm 10.7)$	
Coronary artery disease	17	40.5
Coronary artery bypass graft	7	16.7
Congestive heart failure	15	35.7
Diabetes mellitus II	8	19.1
Hypertension	11	26.2
Lead age (months)	$84 (\pm 10.7)$	

TABLE II OVERVIEW OF EXTRACTED LEADS

EXTRACTED LEADS		
(Total = 88; Total patients = 43)	Number	%
By Type		
Defibrillator lead	32	74.4
Pacemaker lead	11	25.6
By Location		
Atrial	35	39.8
Ventricular	53	60.2
By Approach		
Left-sided	34	79.1
Right-sided	9	20.9
By Indication		
Pocket infection/erosion	17	39.5
Persistent bacteremia	7	16.3
Lead fracture	18	41.9
Subclavian vein stenosis	1	2.3
By Brand		
St. Jude	26	38.2
Biotronik	5	7.4
Medtronic	13	19.1
Ela	2	2.9
Boston Scientific	3	4.4
Unspecified	19	27.9

Similar to what is stated in the literature [3,9] the most frequent indication for lead extraction was an infectious process in 24 patients (55.8%), followed by lead malfunction in 18 patients (41.9%) and subclavian vein stenosis in one patient (2.3%) as shown in Table II. Mean implantation time was 84 months (range 1-270 months). Thirty-two (74.4%) ICD leads and 11 (25.6%) pacemaker leads were extracted. Of the leads extracted, 35 (40%) were atrial and 53 (60%) were ventricular. A right-sided approach was used in nine (20.9%) out of the 43 patients.

The Evolution system was used as first choice in all patients, with 100% clinical success. Complete procedural success was achieved in 38 patients (88.3%), with retention of the distal electrode with the distal end of the RA or RV coil in five patients. These patients on follow-up were cured from their bacteremia and were able to undergo reimplantation of a new CRT-D system.

The presence of multiple leads posed some technical difficulties to the procedure caused by wrapping adjacent leads around each other.

This was occasionally approached by the use of a large diameter Evolution sheath (13 French) that can take two leads at a time allowing extraction of two

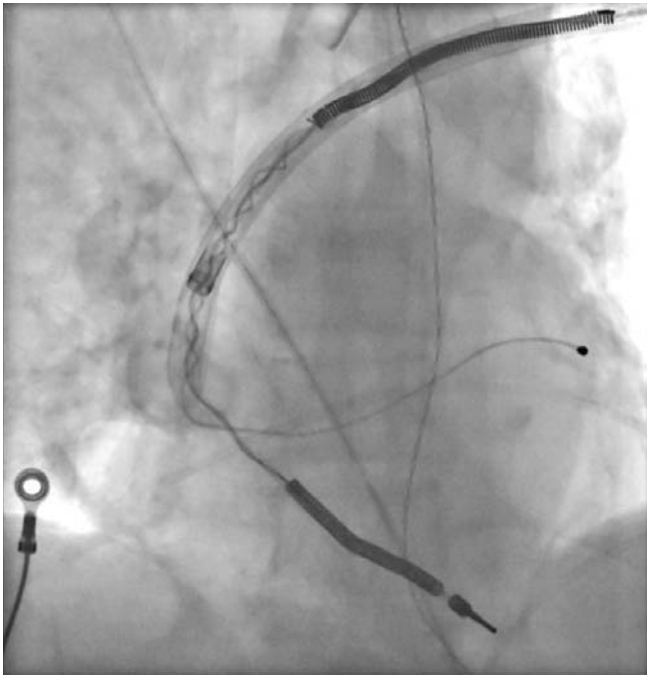


Figure 2

A 13 French Evolution dilator sheath extracting a left ventricular lead and a right ventricular lead simultaneously

leads together (Figure 2). Factors that were associated with partial success were extraction of an ICD lead and the prolonged age of the lead.

No major complications occurred in our cohort. One patient developed hypotension during the procedure. However, an emergent transthoracic echocardiogram revealed no pericardial effusion or cardiac tamponade. The patient's symptoms were transient and responded immediately to intravenous fluids. Another patient developed a pneumothorax and a third patient had a small pericardial effusion, neither of which caused any hemodynamic compromise. There were no deaths.

DISCUSSION

Our data supports the use of the Evolution sheath as a first-line tool given its high rate of clinical and procedural success. As with some of the older extraction methods, the Evolution system proved to be efficient in the release of fibrous material surrounding the targeted leads, allowing for easy removal of problematic leads. In our centers, it was used in the setting of old leads (mean lead age 84 months) and in patients with multiple leads, suggesting its ease of handling and safe maneuverability.

Due to experience and comfort-level among electrophysiologists with other techniques, the Evolution system has been mostly used as an adjuvant, rather than first-line, choice after trying laser/radiofrequency sheaths [7,9].

However, a study similar to ours by Oto *et al.* – including 23 patients (with a total of 41 leads) – resulted in a comparable 91% procedural success rate and 100% clinical success rate [8]. It is also worth noting that approaching such a difficult procedure with one sufficiently successful technique such as the Evolution system will most likely allow for faster extraction, shorter fluoroscopy time and less radiation exposure [7,10]. Complications like those that occurred within our cohort are also infrequent. In a cohort of 212 patients undergoing CIED lead extraction, only three (1.4%) were reported to have pneumothorax or pericardial tamponade [11].

Compared to laser-assisted systems which are costly and limited to institutions that have the required facilities for their use, the Evolution system is a simpler and more cost-effective device that allows the electrophysiologist easier access to extraction tools. Problems were faced with wrapping of leads around the Evolution system but this was overcome with the proper use of the outer sheath that acts as a barrier between the system and the adjacent leads. In addition, the utilization of a large diameter sheath can reduce friction between the tip of the Evolution and the lead, allowing the operator to extract two leads at a time.

The issue of severance of the lead is a major concern and this risk might be less with the laser powered sheath [5,7-8]. This can be a considerable barrier especially when it comes to extraction of leads with inside-out abrasion and externalized conductors [12]. The Evolution system may, therefore, be used as first-line system in transvenous lead extraction in high-volume medical centers with experienced personnel.

Study limitations

There were a few limitations to our study. First, the small number of patients limits the significance of the results, despite a high success rate and a negligible rate of complications. Second, the results were a single operator's experience and, thus, cannot be generalized since the outcomes may differ from center to center as well as from operator to operator, due to differences in level of training. Furthermore, there is the lack of randomization. As previously mentioned, this study is a retrospective cohort in which our experience with the Evolution system was reviewed. However, no comparison of safety and efficacy was made between the Evolution system and other devices available for lead extraction in a randomized controlled trial.

CONCLUSION

To our knowledge, our data is among the first and few reported case series where the Evolution system was

used as the first-line choice for CIED lead extraction [8], as opposed to a rescue or second-line approach. Our data, though with a limited number of patients, suggest that it is a safe, efficient and likely cost-effective strategy to manage problematic CIED leads.

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