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CASE REPORT

ADVANCED

TECHNICAL CORNER

Novel Use of a Rotating Mechanical Dilator Sheath for S-ICD Lead Extraction

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ABSTRACT

A 53-year-old man with a subcutaneous implantable cardioverter-defibrillator (S-ICD) presented with inappropriate shocks. He underwent device extraction, and the lead was freed using a rotating mechanical dilator sheath. As patients with S-ICDs get older, extractions will become more complicated and more common. We have described a novel method of S-ICD lead extraction. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2021;3:1415–1418) © 2021 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

HISTORY OF PRESENTATION

A 53-year-old male with a subcutaneous implantable cardioverter-defibrillator (S-ICD) (Boston Scientific) presented with multiple device shocks. He was admitted in no acute distress and in sinus rhythm.

LEARNING OBJECTIVES

- To understand the indications for S-ICD extraction that include infection, sensing issues, need for pacing or cardiac resynchronization therapy functions, and recently the FDA advisory for certain S-ICD generators and leads.
- To recognize that simple traction is sufficient to extract most S-ICD leads, but adhesions along the sternum may necessitate the need for additional tools.
- To illustrate the safety and efficacy of the less well described method of using a rotating mechanical dilator sheath for S-ICD lead extraction.

MEDICAL HISTORY

He has idiopathic cardiomyopathy (left ventricular ejection fraction [LVEF] ~10%) status post transvenous ICD for primary prevention, which was complicated by lead fracture requiring system extraction and reimplantation of an S-ICD in 2017.

INVESTIGATIONS

Device interrogation revealed inappropriate therapies due to P- and T-wave oversensing (**Figure 1A**). A chest radiograph showed suboptimal lead position with the coil on the right lateral side of the sternum (**Figure 1B**).

MANAGEMENT

It was decided to extract the lead and reimplant a new lead in a more satisfactory position. The procedure was performed in the electrophysiology laboratory under monitored anesthesia care. The original implantation was performed with the 2-incision technique.

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ABBREVIATIONS AND ACRONYMS

EP = electrophysiology

ICD = implantable cardioverter-defibrillator

LVEF = left ventricular ejection fraction

MAC = monitored anesthesia care

S-ICD = subcutaneous implantable cardioverter-defibrillator

The subxiphoid pocket was opened to expose the lead, and the anchoring sutures were removed. Traction to the distal portion of the lead was then applied. However, the lead along the sternum was immobile due to the adhesions on the defibrillation coil. Multiple attempts to free the lead with blunt dissection failed. The axillary generator pocket was subsequently opened, and the generator was removed from the pocket and detached from the lead. The proximal portion of the lead with the connector pin was pulled into the subxiphoid pocket with gentle traction, and a Bulldog lead extender (Cook Medical) was attached to the lead and passed through a 13-F TightRail Sub-C (Spectranetics) rotating mechanical dilator sheath (**Figure 2A**). The blade mechanism was activated 3 times with concomitant countertraction on the lead, which was then pulled through the sheath and removed (Video 1). A new subxiphoid pocket was made, and the new lead was tunneled from the axillary pocket to the new subxiphoid pocket and secured in place. The distal end of the lead was then tunneled to the previously marked location on the manubrium. The lead was attached to the subcutaneous generator, and the pockets were closed in the standard fashion. Appropriate lead position was confirmed with fluoroscopy and later by chest radiography (**Figure 2B**), and defibrillation impedance was tested and was satisfactory.

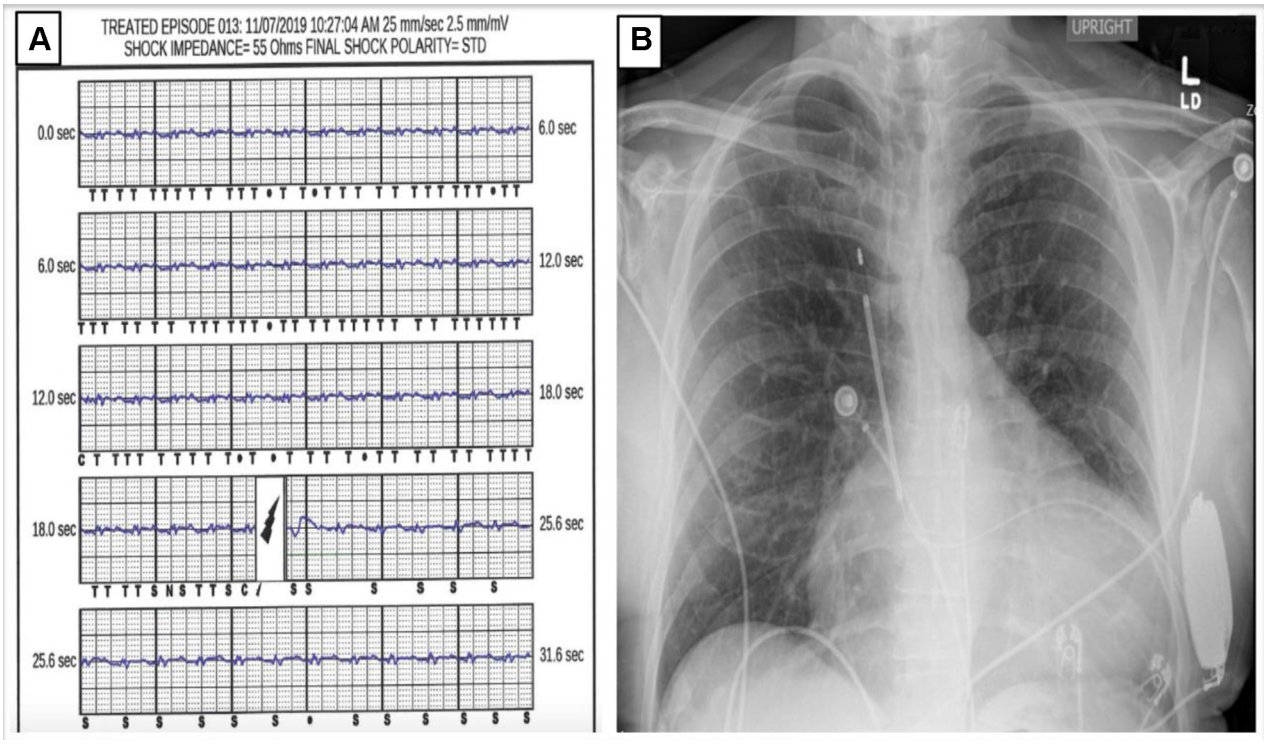
FOLLOW-UP

There were no complications, and the patient was discharged the next day. He was seen in clinic, and device interrogation demonstrated normal function and appropriate sensing.

DISCUSSION

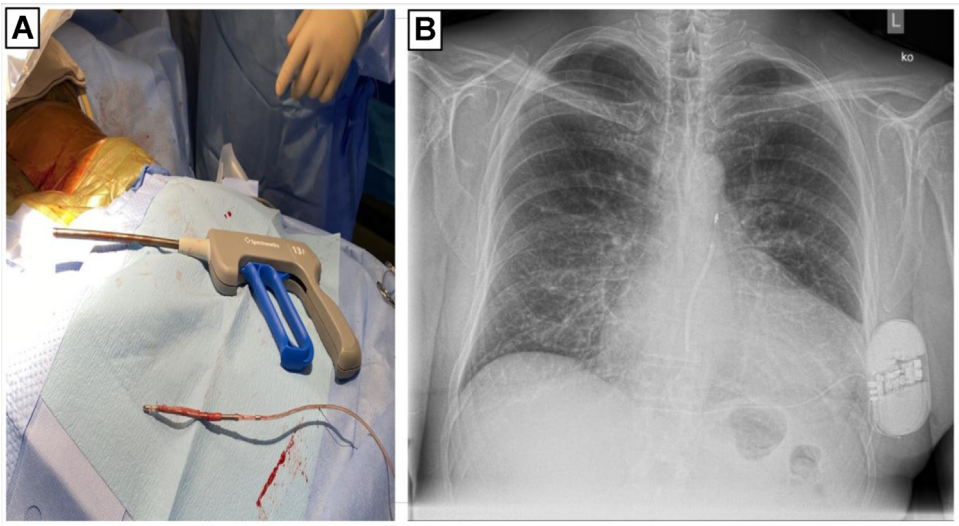
To the best of the authors' knowledge, this is the first reported use of the Sub-C rotating mechanical dilator sheath to extract an S-ICD lead. The Sub-C sheath is the newest iteration of the rotating mechanical sheath systems. The sheath length is 15.5 cm, compared to the 47.5 cm of the standard sheath, and

FIGURE 1 The Interrogation Electrogram



(A) The T-wave has an amplitude similar to that of QRS complexes and is oversensed, resulting in inappropriate device therapy. **(B)** The radiograph shows suboptimal lead position, possibly the cause of oversensing.

FIGURE 2 The Sub-C Sheath



(A) The sub-C sheath. The shaft is 15.5 cm, and the **blue trigger** on the handle exposes and activates the blade. **(B)** The radiograph shows satisfactory lead position.

is designed specifically to address fibrosis and calcification at the entry point into the vessel. The shorter sheath is more rigid and provides additional support and pushability, which allows for easier steering to keep the sheath coaxial to the lead. Some favorable features of the standard-length sheath have been replicated in the Sub-C sheath. These include a shielded rotational blade that protects adjacent tissue and is exposed only during activation of the device, as well as a low-profile that facilitates easier dilation. This system was designed for transvenous lead extraction. As such, when used for S-ICD lead extractions, the 47.5-cm sheath can be unwieldy due to awkward patient/operator/lead orientation and leverage can be compromised. The 15.5-cm Sub-C sheath surmounts this shortcoming.

Boston Scientific received U.S. Food and Drug Administration (FDA) approval for the S-ICD system in 2012 following the success of the safety and efficacy trial (1). Initially, the enthusiasm for this technology was high, as it addressed one of the major pitfalls of the standard transvenous ICD: risk of bloodstream infection and need for subsequent high-risk extraction. There is a 1.5% to 2.5% rate of infection per device per year (2). Although there are no reported cases of endocarditis associated with S-ICDs, up to 4% of S-ICDs implants can be complicated by infection, which remains the most common indication for extraction (3,4). Other indications for S-ICD extraction include lead sensing issues and the need for atrioventricular pacing, antitachycardia pacing, or cardiac resynchronization.

It must also be mentioned the recent FDA advisory notifications on some S-ICD products (5). In December 2020, the FDA issued a Class 1 recall of certain Emblem (Boston Scientific) S-ICD generators due to the risk of moisture build-up and ineffective or absent shocks, as well as a Class 1 recall of a specific model of S-ICD electrodes due to potential for mechanical lead fracture and subsequent oversensing or undersensing. Also included was a Class II recall of a subset of S-ICDs that are vulnerable to early battery depletion as a result of increased levels of hydrogen around the low-voltage capacitor. Such a recall will likely result in an increase in system extractions as providers decide that the S-ICD is no longer appropriate for some individuals that are high risk for sudden cardiac death.

The medical literature describing S-ICD extraction methods is sparse, but it is expected that, as the frequency and indications for extraction expand, so will the call for a standard technique. In the largest case series of S-ICD extractions including 32 patients, simple traction was sufficient to remove the lead in 60% of cases (6). A total of 10% of patients required an additional incision, and in the remaining 30% of cases, a nonpowered polypropylene mechanical sheath was used. Polypropylene sheath-assisted S-ICD lead extraction has been well described when traction fails to free the lead, but very little has been

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published regarding the use of a rotating mechanical dilator sheath (7,8). There are no reported cases of the excimer laser system being applied for S-ICD lead extraction, but it has been successfully used to extract a subcutaneous shocking coil attached to a pre-pectoral pulse generator (9).

CONCLUSIONS

Although most S-ICD leads can be removed with simple traction, extractions are likely to become simultaneously more common but more complicated. As such, it is important for operators to have as many instruments at their disposable as possible to ensure a successful procedure. It is reasonable to adopt a stepwise approach to S-ICD lead extraction using traction, nonpowered sheaths, and powered sheaths, as is commonly applied to transvenous lead extractions (10). When simple traction fails and additional tools are necessary to disrupt the adhesions surrounding the subcutaneous electrode, the Sub-C rotating mechanical dilator sheath is a safe and effective method for S-ICD lead extraction. It is less unwieldy and more user friendly than the standard 47.5-cm sheath and is more readily available and cost effective than the laser extraction system.

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KEY WORDS lead extraction, S-ICD, subcutaneous ICD

APPENDIX For supplemental videos, please see the online version of this paper.