

Extraction of a CardioFix neurostimulator with concomitant laser-assisted lead and intracardiac cardiac defibrillator extraction due to *Staphylococcus aureus* pocket infection

Shrinivas Hebsur, MD,^{*} Travis Pollema, DO,[†] Ulrika Birgersdotter-Green, MD,^{*} Victor Pretorius, MD[†]

From the ^{*}Division of Cardiac Electrophysiology, University of California–San Diego, La Jolla, California, and [†]Division of Cardiac Surgery, University of California–San Diego, La Jolla, California.

Introduction

This is a case report of the first reported laser lead extraction of a CardioFit vagal nerve stimulator owing to automatic implantable cardioverter-defibrillator (AICD) pocket infection.

Case report

A 61-year-old man with a history of ischemic cardiomyopathy status post dual-chamber Medtronic Evera XT AICD implanted in the left infraclavicular fossa area in 2007 was subsequently enrolled in the Innervate HF trial in 2013 and had a CardioFix (BioControl Medical LTD, Yehud, Isreal) neurotransmitter implanted.

The patient developed severe *Staphylococcus aureus* infection of his AICD pocket shortly after a pulse generator change of his AICD. The decision was made to remove both implanted devices, including leads, owing to the infection. This is a description of the first reported extraction of the CardioFit neurostimulator owing to infection. [Figure 1](#) shows the chest radiograph of the patient with both devices in place and the infected AICD pocket site.

The CardioFit is a vagal nerve stimulator that is designed to modulate heart rate variability in patients with systolic heart failure. Its implantation requires dissection of the right cervical area to expose the right vagus nerve. Then a nerve stimulation lead is inserted with distal tip encircling the vagus nerve. This lead is an asymmetric bipolar multi-contact cuff that is passively fixated circumferentially on the vagus nerve. The lead is then tunneled subcutaneously down to the right infraclavicular area, where it is screwed into the pulse generator. A standard transvenous pacemaker lead with

active fixation is placed in the RV apex and attached to the pulse generator.¹ In this particular case a Medtronic CapSureFix Novus 4076-52 cm active-fixation lead was used.

The patient was taken to the hybrid operating room. As per our institution's protocol for lead extraction, general anesthesia was used with endotracheal intubation. A transesophageal echo probe was inserted to evaluate for any signs of thrombus or vegetation around the leads. There was no evidence of baseline pericardial effusion. The patient was prepped and draped to include the neck, anterior chest, and abdomen out to the anterior axillary line and the bilateral groins. Prophylactic right femoral artery and venous sheaths were inserted in case emergent bypass was required.

The location of the neurostimulator lead cuff was confirmed using fluoroscopy. An oblique 3 cm incision was made using the previous incision on the anterior border of the sternocleidomastoid muscle in the lower third of the neck. Dissection was performed with electrocautery through the platysma muscle to the level of the carotid sheath. The sternocleidomastoid muscle was retracted laterally. The vagus nerve and vagal nerve stimulator cuff were identified anterior to the internal jugular vein. The cuff was freed from the surrounding adhesions and the vagus nerve was exposed with sharp dissection. The locking mechanism on the stimulating lead cuff was undone and the lead was easily removed from the nerve ([Figure 2](#)). Careful inspection of the vagus nerve revealed no visible damage. The pulse generator of the vagal nerve stimulator was then exposed in the deltopectoral region and removed from the pocket. The stimulating lead was easily retracted into the pocket with gentle traction. A stiff stylet was inserted in the inner core of the right ventricular sensing lead and an attempt was made to unscrew the lead, which was unsuccessful. A locking stylet was inserted into the sensing lead and using gentle traction, the lead was extracted without any difficulty. The platysma muscle was reapproximated in the neck and both the right cervical and pocket wounds were closed with absorbable suture.

KEYWORDS Laser; Extraction; CardioFit; Defibrillator; Extracardiac; Surgical (Heart Rhythm Case Reports 2016;2:208–210)

Address reprints and correspondence: Dr Shrinivas Hebsur, Division of Cardiac Electrophysiology, University of California–San Diego, 9444 Medical Center Dr MC 7411, 3rd Floor, Rm 3-089D, La Jolla, CA 92037. E-mail address: shebsur@gmail.com.

KEY TEACHING POINTS

- The CardioFit vagal nerve stimulator is an emerging implantable device in heart failure patients.
- Extraction of this device is performed best with operators who have an in-depth knowledge of vital structures in the cervical area.
- As lead extractions become more complex, a multidisciplinary approach involving cardiac surgeons will be paramount.

Attention was then given to the infected AICD pocket. The infected device was removed in a similar fashion to the CardioFit device. The 2 leads of the AICD system were a Medtronic 6947-58 cm Sprint Quattro Secure active-fixation AICD lead in the right ventricular apex and a Medtronic CapSureFix Novus 4076-45 cm active-fixation lead placed in the right atrial appendage. These leads were easily extracted with the assistance of the Spectranetics Excimer CVX-300 Laser System (Colorado Springs, CO). Excisional debridement of the device capsule and infected skin edges were performed to the infected pocket and skin. A wound V.A.C. was placed on the ICD pocket wound. The patient left the operating room in stable condition and was discharged several days later following wound vac removal and delayed primary closure of his wound was performed 8 days later without incident. The patient was sent home with a LifeVest (Zoll Medical Corporation, Pittsburgh, PA) until reimplantation of a new AICD. The patient was given intravenous antibiotics appropriate for methicillin-sensitive *Staphylococcus aureus* for 10 days, then the patient was kept on oral antibiotics for an additional week. AICD reimplantation was subsequently scheduled with the patient's primary electrophysiologist.

Discussion

The incidence of intracardiac device infections has seen steady growth over the past 2 decades. This is in part because of the growing number of pacemakers, defibrillators, and resynchronization devices. Extraction of these devices has traditionally been very complex and associated with a high mortality. With the emergence of new technology such as laser and mechanical rotational sheaths, lead extraction has become much more feasible²⁻⁵. Devices such as the CardioFit, which has leads that are extracardiac, require additional skill and expertise. If careful dissection of the lead is not done, it can lead to damage of vital structures, including the carotid artery, the internal jugular vein, and the vagus nerve. As the heart failure patient population continues to grow, the use of devices for autonomic regulation and pressure sensing will also increase. These devices may have extracardiac as well as intracardiac components, making extraction a more in-depth and complex procedure.⁵ The design of new implantable intracardiac devices needs to take into consideration the possibility of device infections and that extraction will be required.

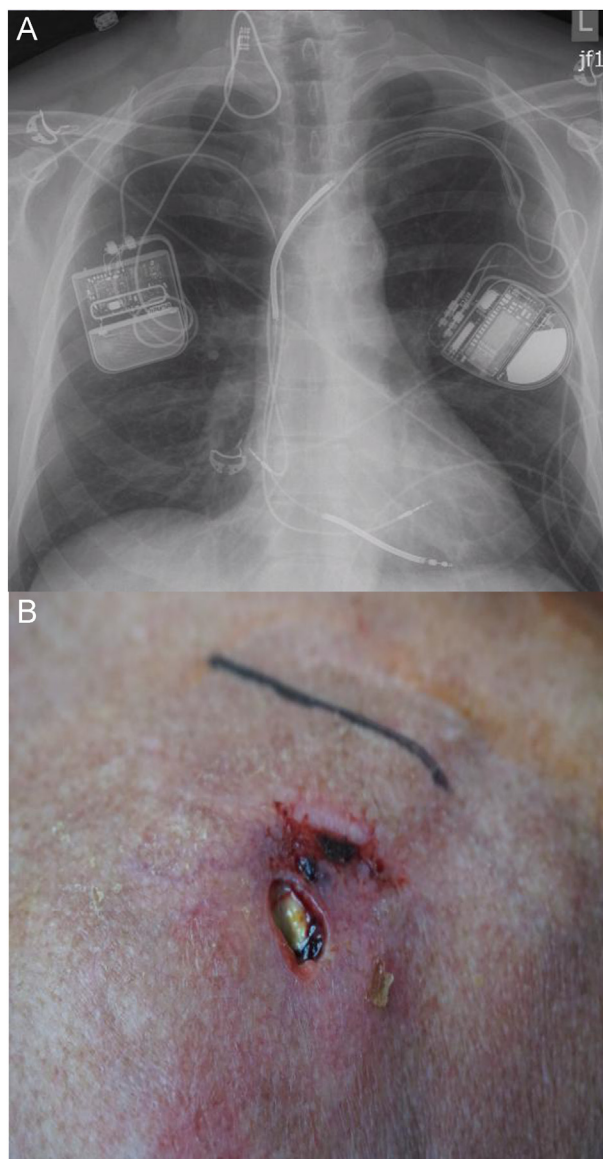


Figure 1 A: Posteroanterior chest radiograph image of dual-chamber automatic implantable cardioverter-defibrillator (AICD) (device on the left side) and vagal nerve stimulator on the right side. Note the cuff of the vagal nerve stimulator positioned on the right cervical area. B: Infection and erosion of the AICD pocket with purulent discharge.

Therefore, ease of extraction is an important factor that needs to be incorporated in future device design. Operators that are explanting devices need to expand their surgical skills or adopt multidisciplinary teams to tackle such complex extractions. We present the first ever case of the CardioFit neurotransmitter device owing to infection. By incorporating a multidisciplinary effort involving cardiothoracic surgeons and cardiac electrophysiologists, we were able to safely and effectively remove all implanted devices without any morbidity to the patient.

Conclusion

Laser lead extraction procedures will increase in technical complexity as the heart failure population grows and there is a higher utilization of implantable intracardiac devices for

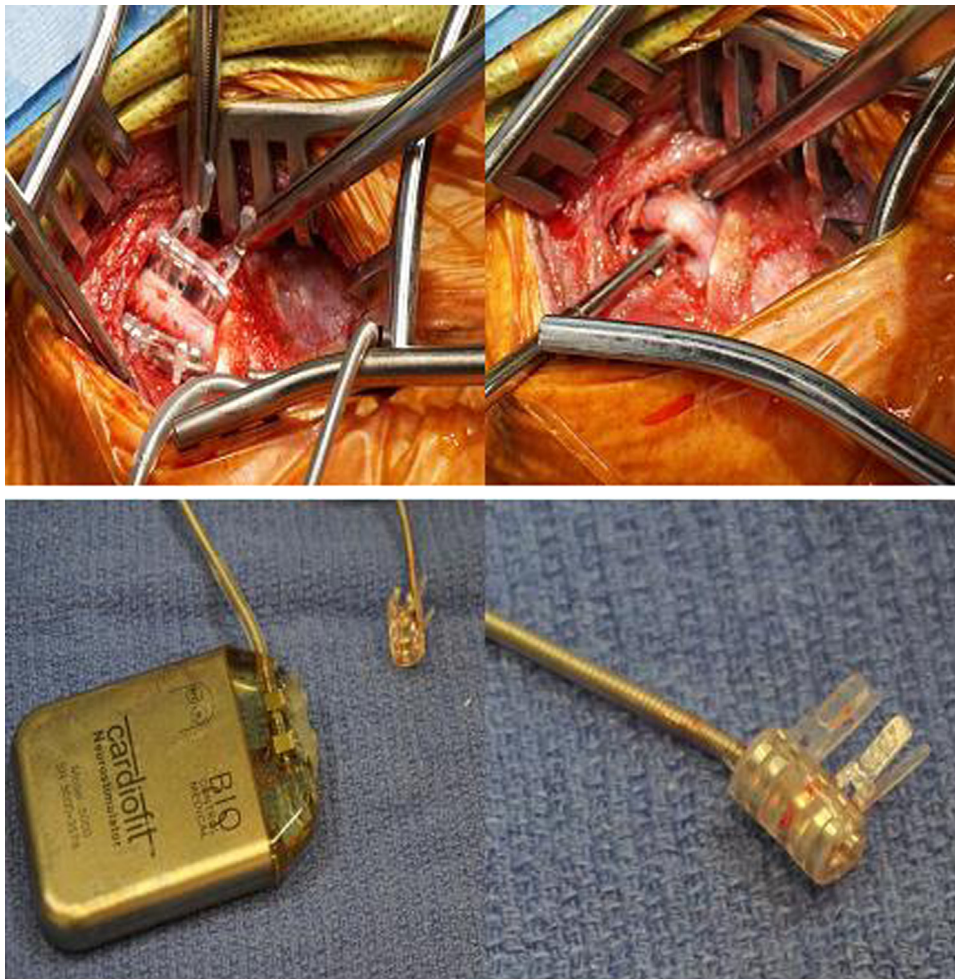


Figure 2 A: Surgical picture of vagal nerve stimulator cuff on the vagus nerve. B: Once the cuff was removed, the vagus nerve was left without any significant damage. C: Both the pulse generator and the nerve stimulator cuff. D: Inspection of the vagal nerve cuff showed no significant adhesions or damage.

pressure monitoring and autonomic regulation. Therefore, a multidisciplinary approach with electrophysiology and cardiac surgery is required for such complex cases.

References

1. De Ferrari GM, Crijns HGJM, Borggreffe M, et al. Chronic vagus nerve stimulation: a new and promising therapeutic approach for chronic heart failure. *Eur Heart J* 2011;32:847–855.
2. Epstein AE, Dimarco JP, Ellenbogen KA. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities. *J Am Coll Cardiol* 2008;51:e1–62.
3. Cabell CH, Heidenreich PA, Chu VH, Moore CM, Stryewski ME, Corey GR, Fowler VG. Increasing rates of cardiac device infections among Medicare beneficiaries: 1990–1999. *Am Heart J* 2004;147:582–586.
4. Kleemann T, Becker T, Doenges K, Vater M, SEnges J, Schneider S, Saggau W, Weisse U, Seidle K. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of > 10 years. *Circulation* 2007;115:2474–2480.
5. Pretorius V, Birgersdotter-Green U, Heywood JT, Hafelfinger W, Gutfinger DE, Eigler NL, Love CJ, Abraham WT. An implantable left atrial pressure sensor lead designed for percutaneous extraction using standard techniques. *Pacing Clin Electrophysiol* 2013;36(5):570–577.