Cases of Azygous Coil Extraction



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BACKGROUND Procedural and clinical outcomes of patients undergoing extraction or removal of azygous coils are not well characterized.

OBJECTIVE Evaluate outcomes in patients who undergo device extraction with an azygous coil in situ.

METHODS Patients undergoing extraction with an azygous coil in situ between May 2015 and January 2021 were included in this retrospective single-center analysis. Outcomes included procedural success, use of laser and mechanical cutting tools during the procedure, procedural complications, and mortality.

RESULTS We identified 2 patients undergoing device extraction with an azygous coil in situ with a dwell time greater than 12 months. The patients were male, aged 73 and 83 years. Both had a history of hypertension, atrial fibrillation, heart failure (ejection fractions <15% and 20%), and cardiomyopathy (nonischemic and ischemic), and presented with an infection (case 1 with a single-chamber ICD and Staphylococcus aureus bacteremia, case 2 with a cardiac resynchronization therapy defibrillator pocket infection). The mean dwell time of all 6 leads extracted was 6.43 years (range

Introduction

Although infrequent, elevated defibrillation thresholds (DFTs) significantly complicate the management of patients with implantable cardioverter-defibrillators (ICDs). Numerous strategies are available to reduce DFTs, including repositioning the right ventricular lead, altering the shock waveform, and reversing shock polarity.¹ Other, more invasive methods involve placing epicardial patches or adding coils to the subcutaneous space, the subclavian vein, or the coronary sinus. An alternative approach, first described in 2004 by Cesario and colleagues,² is to place a defibrillation coil in the azygos vein. Given its position posterior to the left ventricle, such a coil provides an alternative shock vector for defibrillation and has proven effective in improving DFTs.³

As with any pacemaker lead or defibrillation coil, azygous coils carry a risk of infection and failure, and thus may require

1.33–12.63 years), and the 2 azygous coils had dwell times of 1.33 and 6.04 years. In case 1, the azygous coil was inferior to the cardiac silhouette, while in case 2 it was superior. A 14F laser sheath was employed to remove both azygous coils. Both extractions were a complete procedural success in which all leads were removed completely without intraoperative complications.

CONCLUSION These cases demonstrate the variable courses of azygous coils, provide proof of concept that they can be removed safely, and illustrate that azygous coils can be removed with the same techniques that are commonly used to remove other types of leads.

KEYWORDS Lead management; Lead extraction; Azygous coil; Implantable cardioverter-defibrillator; Cardiac implanted electronic devices

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extraction. Given the relative rarity of azygous coils, however, most operators do not have extensive experience in their extraction. There are no published data on the clinical outcomes of patients who have undergone extraction or removal of azygous coils. In order to better understand azygous coil extractions, we identified patients at our institution who underwent extraction of an azygous coil and described their characteristics, procedural outcomes, and clinical course.

Methods

Study cohort

We identified patients who underwent cardiac implantable electronic device (CIED) extraction at Duke University Hospital between April 2015 and January 2021 for any reason (n = 586). Of those, 2 were identified who underwent device extraction of an azygos vein coil, both in the setting of CIED infection. CIED infections were defined by the most recent Heart Rhythm Society guidelines.⁴ These include CIED pocket infections and persistent bacteremia with or without a confirmed source or echocardiographic evidence of infection.

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KEY FINDINGS

- Procedural and clinical outcomes of patients undergoing extraction or removal of azygous coils are not well characterized.
- These cases provide proof of concept that azygous coils can be extracted safely.
- Azygous coils can be extracted with the same techniques that are commonly used to remove other types of leads.

All patients were treated with guideline-directed antibiotic therapy. Patient characteristics and outcomes including extraction indication, CIED generator and lead data, procedural details, and long-term clinical outcomes were abstracted from a comprehensive manual chart review in the electronic medical record. The study was approved by the Duke University Hospital Institutional Review Board, and patient consent was waived in accordance with the retrospective nature of the study. The study was conducted in accordance with the Declaration of Helsinki.

Lead extraction

All leads were extracted via a percutaneous-transvenous approach. There were no open surgical lead removals performed in this cohort. As per Heart Rhythm Society consensus recommendations, a lead extraction was defined as a lead removal procedure in which at least 1 lead required the implementation of special tools such as laser sheaths and locking stylets to facilitate removal or in which at least 1 lead had a dwell time of greater than 1 year.⁴

Consistent with our institutional protocol, all patients received both an electrophysiological and cardiothoracic surgical consultation, along with an infectious disease consultation if warranted. Cases were done in the Duke University hybrid operating room in conjunction with cardiothoracic surgery as per institutional protocol, or, if the patient was declared to not be a surgical candidate, in the electrophysiology (EP) lab without cardiothoracic surgery. Transesophageal echocardiography was performed before, throughout, and after the procedure for cases in the operating room. Intracardiac echocardiography (ICE) was used for the case in the EP lab. During the procedures, some combination of the lead locking device (LLD) stylets, laser sheath, and/or rotational cutting tools was used.

Results

We identified 2 patients who underwent extraction of an azygous coil at our center. Table 1 details the characteristics of these patients, the indications for device extraction, and their hardware descriptions, including dwell time. The 2 patients were 73 and 83 years old, and both were male with a history of hypertension, atrial fibrillation, heart failure (ejection fractions of <15% and 20%), and cardiomyopathy

(nonischemic and ischemic). Patient 1 presented with a single-chamber ICD and methicillin-sensitive *Staphylococcus aureus* bacteremia, while the other patient presented with a cardiac resynchronization therapy defibrillator (CRT-D) pocket infection. The procedural characteristics are described in Table 2. Patient 1 had 2 leads removed, while patient 2, with a CRT-D, had 4 leads removed. Of the 6 leads, the mean dwell time was 6.43 years (range 1.33–12.63 years). A laser sheath was utilized in both cases, and a TightRail (Philips Healthcare, Andover, MA) rotational cutting tool was also used in case 2 for the removal of an abandoned right ventricle (RV) lead.

The 2 patients had azygous coil dwell times of 1.33 and 6.04 years. As illustrated by Figure 1, these coils had variable positioning. In patient 1, the azygous coil tip extended below the diaphragm, potentially into the hemiazygos vein; and in patient 2, the azygous coil was superior to the cardiac silhouette, near where the azygos vein meets the superior vena cava. Based on standardized computed tomography scans done prior to extraction procedures, the azygous coils appeared to have eccentric positioning within the vein in both cases. A 14F laser sheath was used to remove both azygous coils.

Case 1

A 73-year-old man with a history of paroxysmal atrial fibrillation, predominant nonischemic cardiomyopathy with a left ventricular ejection fraction <15%, coronary artery disease status post percutaneous intervention, and prior appropriate

Table 1Patient characteristics

Patient	1	2
Age at extraction (years)	73	83
Sex	Μ	М
BMI (kg/m²)	26.72	26.31
Diabetes mellitus	Yes	Yes
eGFR	52	39
(mL/min/1.73 m²)		
HTŇ	Yes	Yes
CAD	Yes	Yes
PAD	No	No
Atrial fibrillation	Yes	Yes
Prior sternotomy	No	Yes
HF	Yes	Yes
EF (%)	<15	20
Etiology of CM	Nonischemic	Ischemic
Type of CIED	Single-chamber	CRT-D
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Device indication	1° prevention	2° prevention
Implant side	Left	Left
Pacemaker dependent	No	No
Extraction indication	MSSA sepsis	Localized pocket infection

 1° = primary; 2° = secondary; BMI = body mass index; CAD = coronary artery disease; CIED = cardiac implantable electronic device; CM = cardiomyopathy; CRT-D = cardiac resynchronization therapy defibrillator; EF = ejection fraction; eGFR = estimated glomerular filtration rate; HF = heart failure; HTN = hypertension; ICD = implantable cardioverter-defibrillator; MSSA = methicillin-susceptible *Staphylococcus aureus*; PAD = peripheral arterial disease.

Patient	Time, generator implant to removal (years)	Lead location	Lead model	Time from lead implant to removal (years)	Removal technique by lead	Extraction outcome	Procedural complications
1	1.3	RV Azvanos	6947 6937∆	6.58 1 33	14F laser (16 s) 14F laser (6 s)	Complete procedural success	None
2	9	Azygos RV	6937A 6935	6.01 6.01	14F laser (5 s) 14F laser (8 s)	Complete procedural success	Patient death 26 days after procedure
		S	4196	6.01	14F laser (6 s)		
		RV (aband.)	0062	12.63	16F laser (1 s), 13F TightRail (Philips Healthcare, Andover, MA) (5 clicks)		
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 Table 2
 Procedural details

= abandoned; CIED = cardiac implantable electronic device; CS = coronary sinus; RA = right atrium; RV = right ventricle Aband. shocks for ventricular tachycardia with a single-chamber ICD and addition of an azygous lead was admitted with decompensated heart failure. During his admission he was found to have leukocytosis and blood cultures positive for S aureus.

Given the patient's symptoms in the presence of *S aureus* bacteremia, the decision was made to proceed with CIED extraction in the hybrid operating room with cardiothoracic surgery backup. After prophylactic testing of a superior vena cava balloon, the leads were prepped and loaded with LLD EZ locking stylets. The dual-coil right ventricular lead (Medtronic 6947) was removed with a 14F 80 Hz laser sheath. There were significant binding sites in the axillary vein and at the superior vena cava (SVC) / innominate junction. We then turned our attention to the azygous coil (Medtronic 6937A). The 14F laser was required to eliminate binding by the axillary vein, and afterwards gentle traction freed the lead. Laser application within the azygos vein itself was not required. The patient ultimately underwent reimplant with a right-sided dual-chamber ICD with successful DFT testing (without an azygous coil) and did well until 2 years after extraction, when he died owing to COVID-19 pneumonia.

Case 2

An 83-year-old man with Parkinson disease, permanent atrial fibrillation, atrioventricular block, ischemic cardiomyopathy status post coronary artery bypass grafting with a left ventricular ejection fraction of 20%, severe pulmonary hypertension, and ventricular tachycardia had an ICD that reached elective replacement indicator. At the time of generator replacement, he was found to have evidence of a chronic indolent pocket infection, despite the absence of prior symptoms and a normal physical examination of the pocket.

Given the presence of a pocket infection, he was evaluated for CIED extraction. However, cardiothoracic surgery assessed the patient and declared that he was not a candidate for surgical backup owing to his extensive comorbidities and severe pulmonary hypertension. Multiple discussions were had with the patient about his options, which included CIED removal without surgical backup vs a more palliative approach with antibiotics alone. Through a shared decisionmaking model, the patient elected to proceed with CIED removal without surgical backup. Thus, his extraction was performed in the EP lab. An ICE (ACUSON AcuNav, Biosense Webster, Inc., Irvine, CA) catheter was advanced to the right atrium and RV, revealing a trace pericardial effusion. A 6F sheath was placed in the right femoral vein, and a quadripolar catheter was passed to the RV in the event backup pacing was needed. The leads were cut and prepped with LLD EZ locking stylets, except for the coronary sinus lead, with which was loaded with an LLD E. A 14F laser sheath with a medium 33 cm sheath (VisiSheath, Philips Healthcare, Andover, MA) was used to extract the azygous coil (Medtronic 6937A), including application of the laser within the proximal portion of the azygos vein. The outer sheath was not advanced into the azygos vein at any point.



Figure 1 Azygous coils on radiography (x-ray) and computed tomography (CT) images. Pt = patient.

The RV lead (Medtronic 6935) and coronary sinus lead (Medtronic 4196) were extracted with a 14F laser sheath. A 16F laser and outer sheath were used to free the abandoned RV lead (Guidant 0062) to the proximal coil; at that point, the outer sheath was used to free the lead to the tip. After an attempt with the 13F TightRail started to fragment the lead, we switched back to the outer sheath and successfully removed the lead. At this point, all of the hardware was successfully removed. ICE demonstrated no interval change or development of a pericardial effusion. The patient ultimately underwent implant of a CRT pacemaker (rather than CRT-D, due to the patient's goals of care). He tolerated the extraction and reimplantation procedures well and was discharged to a skilled nursing facility, per physical therapy recommendations. The patient died 26 days after extraction, with an unknown cause of death.

Outcomes

Each case was a complete procedural success, with all leads removed without any intraoperative complications. Both patients tolerated the procedure well and were able to be discharged within 3–7 days after extraction. Each patient underwent device reimplantation. Both patients have died since extraction (2 years later and 26 days later, respectively, with neither death known to be related to the procedure).

Discussion

While azygous coils can lead to substantial improvements in defibrillation in individuals with high DFTs, they can present challenges in lead management. These cases provide a proof of concept that azygous coils can be extracted safely. Additionally, these cases suggest that azygous coils can be removed by the same standard techniques that are used to extract other types of leads.

The 6937A Transvene SVC-CS defibrillation lead became available in 2001 in the United States. It is the most commonly used lead in the azygos vein. The lead utilizes a unipolar coil electrode that is 8 cm in length with a surface area of 160 mm². The lead has a tip diameter of 2.3 mm, has a maximal lead body diameter of 3.2 mm, and is insulated with silicone and a polyurethane overlay (Figure 2). It was designed for long-term implantation in the SVC and venous system. At 9 years, the lead has an 11% failure rate. From an extraction perspective, the lead is prepped and approached similarly to other high-voltage leads.⁵ In our center we use a locking stylet and we secure the insulation with 0-Tycron ties. As with most leads, we attempt to remove the lead with gentle traction. If traction does not free the lead, then we use a laser sheath as our first-line extraction tool. If there is failure to progress with the laser, we typically switch to a rotational cutting tool.

The imaging from these cases demonstrated that azygous coils have variable positioning, consistent with the known variation in the venous anatomy of the azygos system and the variable slack that is difficult to predict in a lead with no active or passive fixation that is placed when the patient is supine. The azygos vein typically arises from the inferior vena cava around the level of the renal veins and travels superiorly through the diaphragm, ultimately draining into the SVC. Given this length, leads in the azygos vein can be placed in a wide range of locations within the mediastinum to provide an optimal defibrillation vector. This concept is visualized in Figure 1. In patient 1, the azygous coil was



Outer diameter 2.3 mm / 6.9 Fr

Figure 2 Construction of the 6937A defibrillator coil. The lead has a single conductor with inner silicone and outer polyurethane insulation. The outer diameter is 2.3 mm or 6.9 French.

inferior to the cardiac silhouette below the level of the diaphragm (potentially in the hemiazygos vein), while the azygous coil in patient 2 was superior to the cardiac silhouette near the junction of the azygos vein and SVC. This difference in positioning highlights the value of preprocedure imaging with both chest radiographs and computed tomography scans for azygous coil extraction procedural planning.

These cases also provide a proof of concept that azygous leads can be removed safely. The implantation of azygous coils to improve defibrillation thresholds has been characterized since 2004.^{1–3} However, in our search of the literature, we have found no published cases or outcomes of patients who undergo extraction or removal of azygous coils. On the one hand, one may expect such an extraction to proceed similarly to that of an SVC coil, given their residence in the venous system. On the other hand, given the wider range of positioning in the much longer azygos vein and the angles involved in traveling from the SVC through the azygos vein (ie, a \sim 90-degree turn posteriorly from the vertical SVC to the initially horizontal azygos vein, which then turns nearly another ~ 90 degrees inferiorly), one may also expect azygous coils to provide a more complex challenge for extraction. For this reason, we reviewed these cases and found that both were a complete procedural success, without intraoperative complications, supporting the idea that azygous coil extraction can be performed safely.

These cases also suggest that azygous coils can be removed by the same techniques that are typically used to extract other types of leads. A 14F 80 Hz laser sheath was utilized to remove both of the azygous coils. Of the 6 leads extracted in all, only an abandoned RV lead required the use of the TightRail mechanical cutting tool. Thus, our cases indicate that azygous coils do not require different tools for extraction than other leads, and that, as with other types of leads, choice of equipment can be determined on a case-bycase basis.

Limitations

This study includes only 2 patients from a single institution. These cases also carry the inherent limitations of a retrospective analysis. Additionally, our patients presented with infection (bloodstream or device-localized); therefore, these results may not be generalizable to other contexts, such as those in which patients have a fractured azygous coil.

Conclusion

These cases demonstrate the variable courses taken by azygous leads, suggest that azygous leads can be extracted safely, and indicate that similar equipment and techniques can be used with azygous leads as with other pacing and ICD leads.

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References

- Cooper JA, Smith TW. How to implant a defibrillation coil in the azygous vein. Heart Rhythm 2009;6:1677–1680.
- Cesario D, Bhargava M, Valderrabano M, Fonarow GC, Wilkoff B, Shivkumar K. Azygos vein lead implantation: a novel adjunctive technique for implantable cardioverter defibrillator placement. J Cardiovasc Electrophysiol 2004;15:780–783.
- Cooper JA, Latacha MP, Soto GE, et al. The azygos defibrillator lead for elevated defibrillation thresholds: implant technique, lead stability, and patient series. Pacing Clin Electrophysiol 2008;31:1405–1410.
- 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:e503–e551.
- Medtronic, Inc. CRHF Product Performance eSource. 6937A Transvene SVC-CS. 2021. https://wwwp.medtronic.com/productperformance/model/6937A-transve ne-svc-cs.html.