IMPLANTABLE DEFIBRILLATION THERAPY

COMPLEX CASE STUDY

Endovascular Occlusion of the Superior Vena Cava in a Patient with Stenosis and Chronic Intracardiac Leads

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ABSTRACT. *The aim was to increase the safety of a high-risk lead extraction with pre-emptive positioning of an endovascular occlusion balloon in the superior vena cava (SVC). A patient with lead failure was evaluated prior to lead extraction with chest computed tomography, which revealed central venous stenosis and epicardial scarring around an old device. A Bridge™ Occlusion Balloon (Spectranetics, Colorado Springs, CO) was positioned in the superior vena cava prior to extraction. The balloon occluded the SVC despite chronic indwelling leads and stenosis. The malfunctioning lead was safely removed and replaced. Endovascular occlusion is possible even with numerous intravascular obstacles. This case can help inform protocols for the use of occlusion balloons in lead extractions.*

KEYWORDS. *Implantable cardioverter-defibrillator, lead extraction, pacemaker.*

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Introduction

Injury to the superior vena cava (SVC) is a rare but devastating complication of cardiac implantable electronic device (CIED) extraction. Single and multicenter reviews of lead extractions have reported major complication rates between 0.7% and 1.9%, with vascular laceration being the event that carries the highest mortality.¹ Newly approved technology (Bridge™ Occlusion Balloon, Spectranetics, Colorado Springs, CO) aims to reduce the lethality of these events with temporary endovascular occlusion. Of course, in patients undergoing such procedures, the endovascular landscape tends to be complicated by stenosis and fibrotic or tortuous leads. Until recently, the effect of those hostile conditions on endovascular occlusion had only been simulated in

animal models.² Experience from the field will help clinicians decide which patients can or cannot benefit from proactive positioning of occlusion balloons. We present the successful deployment of an endovascular occlusion balloon in a patient's SVC, unimpeded by the presence of chronic indwelling leads and extensive stenosis.

History

A 62-year-old male with increasing fatigue was admitted to a nearby facility where his cardiac resynchronization therapy (CRT) device was interrogated. Tests revealed a lack of capture in the left ventricular (LV) lead, which was implanted in 2003. The patient was subsequently transferred to our institution.

In addition to his lead malfunction, he suffered from non-ischemic cardiomyopathy with an ejection fraction of 35%. Before placement of his CRT device in 2003, the patient underwent a left thoracotomy for placement of an epicardial mesh girdle designed to reduce wall stress and reverse cardiac remodeling (Figure 1). He was also known to have a history of type 2 diabetes, obstructive sleep apnea, kidney stones, asthma, and esophageal

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Figure 1: Three-dimensional reconstruction of preoperative chest computed tomography scan. An epicardial mesh can be seen encircling the heart.

spasms. The patient was scheduled for lead extraction and replacement of his LV lead.

Materials and methods

Following FDA approval of the occlusion balloon earlier this year, our protocol was modified to include balloon deployment in all high-risk lead extractions. At our institution, the risk stratification process considers 1) lead characteristics, 2) patient characteristics, and 3) the indication for extraction. For lead age, we have developed specific risk categories based on our own prospective data collection from over 1,000 lead extractions. Specifically, these data have informed the following classifications: leads less than 2 years old are low risk, those between 2 and 5 years old are moderate risk, those 6–20 years old are high risk, and any lead older than 20 years is severe risk. If a patient has a body mass index lower than 24, he or she is moved to the next highest risk category. Finally, if the preoperative computed tomography (CT) scan reveals extracardiac leads, the patient is automatically considered severe risk.

This patient qualified as high risk because the target for extraction had been in place for 13 years. A few unusual patient characteristics also heightened our risk assessment in this case. In particular, severe stenosis of the SVC was apparent in the preoperative chest CT and his previous thoracotomy would make emergent re-entry more difficult. The risks and benefits of this procedure were discussed with the patient, and he gave informed consent for the on-label use of the endovascular balloon. When balloon deployment is called for by our protocol, we position and inflate the device for sizing before we make any attempt at extraction. This patient was

prepped and placed under general anesthesia in the supine position. Three venous lines were placed: one in the right internal jugular vein and one in each femoral vein. A pigtail catheter was positioned in the SVC through the internal jugular vein. Through this catheter, venograms could be performed with injection of ISO-VUE-370 (iopamidol) (Bracco Diagnostics, Milan, Italy). A preliminary venogram confirmed the presence of severe stenosis in the SVC (**Figure 2**). The endovascular balloon was then introduced through a 12F sheath in the right femoral vein. Despite the stenosis, we were able to position the balloon catheter over a guidewire in the SVC. The device was then filled with 25 mL of fluid, an 80:20 mixture of saline and contrast. Once the device was fully deployed, the venogram was repeated, which demonstrated complete occlusion of the SVC (**Figure 3**). With sizing complete, the balloon was deflated and the catheter was removed, but the guidewire was left in place. In accordance with the primary goal of the procedure, laser lead extraction was then performed. The LV lead, Boston Scientific Easytrack[®] 2, model 4518 (Boston Scientific, Maple Grove, MN), was removed with the help of a 12F laser sheath. The laser sheath was advanced through the left subclavian vein then left innominate vein, at which time the lead was freed. It was replaced with a St. Jude Quartet[™], model 1458Q-86 (St. Jude Medical, St. Paul, MN). The right ventricular and atrial leads were tested; they revealed normal electrical parameters and were therefore maintained.

Results

This patient's defective lead was successfully retrieved and replaced. His recovery was uncomplicated. The endovascular occlusion was also successful. Under fluoroscopy, the device can be seen spanning the SVC and right atrium, accommodating fully to the point of greatest stenosis. The venogram taken during sizing shows complete occlusion (**Figure 3**).

Discussion

Comprehensive CIED management requires interdisciplinary teams that are trained and equipped to extract leads. For years, best practices in lead extraction have included having access to surgical support for the catastrophic complications that occur in around 0.8% of cases.¹ In order for surgical rescue to succeed in such cases, providers must be able to access the injury with great speed. For this reason, effective endovascular occlusion has been desired by many in the field. To date, human and animal tests have been unable to answer the lingering question of how effective endovascular occlusion devices would be in the setting of severe stenosis, chronic indwelling leads, and other anatomical complexities. This case represents an important early experience with the technology that can help inform its use.

The decision to deploy was based on the challenges posed by the extraction itself and obstacles that would have complicated an emergent thoracotomy. This particular

Figure 2: Still images from the initial venogram demonstrating stenosis in the superior vena cava.

Figure 3: Venogram showing complete occlusion of the superior vena cava.

balloon is compliant, so it is filled according to volume rather than pressure. It conforms to, but should not mechanically dilate, an area of stenosis. In our experience, 20–30 mL is sufficient to achieve occlusion in most patients. It is important to note that this sizing is performed visually by the operator using fluoroscopy and contrast injections. For that reason, it is preferable to size the device before any complication arises. That practice heightens the readiness of the whole team for an adverse event, and is consistent with the manufacturer's recommendations for use. The success of this case is encouraging in regards to the potential of such devices to treat hemorrhages encountered during lead extractions, even in hostile endovascular conditions.

Conclusion

Successful endovascular occlusion can take place even in the presence of severe SVC stenosis and chronic indwelling leads.

References

1. Wazni O, Wilkoff BL. Considerations for cardiac device lead extraction. *Nat Rev Cardiol*. 2016;13(4):221–229.
2. Clancy JF, Carrillo RG, Sotak R, Ram R, Ryu RK, Kennergren C. Percutaneous occlusion balloon as bridge to surgery in a swine model of superior vena cava perforation [published online ahead of print June 23, 2016]. *Heart Rhythm*. 2016;13(11):2215–2220.