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Thomas A. Boyle, Bruce L. Wilkoff, Joseph Pace, Moeen Saleem, Samuel Jones, Roger Carrillo

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Title: Balloon-Assisted Rescue of Four Consecutive Patients with Vascular Lacerations Inflicted During Lead Extraction

Short Title: Balloon-Assisted Rescues

Thomas A. Boyle\textsuperscript{a}; Bruce L. Wilkoff, MD, FHRS\textsuperscript{b}; Joseph Pace, MD\textsuperscript{c}; Moeen Saleem, MD\textsuperscript{d}; Samuel Jones, MD\textsuperscript{e}; Roger Carrillo\textsuperscript{a}, MD, FHRS, MBA

From \textsuperscript{a}University of Miami Miller School of Medicine, Department of Cardiothoracic Surgery; \textsuperscript{b}Cleveland Clinic Lerner College of Medicine of Case Western Reserve University; \textsuperscript{c}Heart and Vascular Center of Bradenton, FL; \textsuperscript{d}Edward Heart Hospital, Naperville, IL; \textsuperscript{e}San Antonio Military Medical Center.

Contact: Thomas A. Boyle, 55 SE 6\textsuperscript{th} St. #2706, Miami, FL 33131
+1 (973)634-8233 | tab127@miami.edu

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Boyle: None

Wilkoff:

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- Medtronic Inc. – Physician Advisory Board
- St. Jude Medical Corp. – Physician Advisory Board
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- Convatec - Speaker
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- Boston Scientific – Consultant/trainer
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Saleem
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Jones: None

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Introduction:

An undeniable consequence of the increased frequency of cardiac implantable electronic device (CIED) implantation has been the proliferation of procedures to remove those devices when they malfunction or become infected. Over the years, the practice of lead extraction has benefited from the introduction of technological and procedural innovations such as laser sheaths, training simulators, and interdisciplinary heart teams. Today, reviews of lead extraction describe an overall safe procedure when performed by experienced operators. Major complication rates have been reported between 0.7% and 1.9%. Although infrequent, vascular laceration is considered to be the most catastrophic of those complications, carrying a mortality rate as high as 50%. Faced with major vascular injury, operators face the grim prospect of a hasty thoracotomy and repair on a patient, often with comorbidities, whose condition is deteriorating rapidly.

A new tool designed specifically for lead extraction (Bridge™, Spectranetics, Colorado Springs, CO) aims to reduce the lethality of these events by providing rapid temporary endovascular occlusion of the superior vena cava (SVC). The device received FDA approval in February of 2016 and, since that time, a small number of publications have described its performance in animal models and hemodynamically stable patients. The device has been unproven in patients acutely compromised from vascular injuries secondary to transvenous lead extraction. The following series describes the first four consecutive cases in which the Bridge occlusion balloon was used in response to vascular tears.
Case One:

A 50-year-old Hispanic female with a non-ischemic cardiomyopathy and left ventricular ejection fraction of 30% required the extraction and replacement of a 5-year-old dual coil defibrillation lead due to non-capture with maintenance of the normally functioning atrial lead. There was no history of open heart surgery, diabetes, renal failure, or malignancy.

The extraction was performed in a hybrid operating room with cardiothoracic surgeons on standby. Prior to opening the device pocket, the electrophysiologist advanced a guidewire through a 12F sheath from the right femoral vein to the right internal jugular vein under fluoroscopic guidance. After opening the pocket and preparing the lead for extraction, a 16F laser sheath was advanced over the defibrillating lead through the left subclavian and left innominate veins. The operator detected few adhesions and described the sheath as passing with relative ease. Immediately after freeing the lead, the patient’s blood pressure began to deteriorate, with the systolic dropping below 60mmHg, and at times was undetectable. A transesophageal echocardiogram demonstrated progressive cardiac tamponade. Within roughly 30 seconds, the team successfully deployed the occlusion balloon over the prepositioned wire and filled it with 60cc of diluted contrast from a pre-prepared syringe. After opening the chest, surgical findings included a 3mm tear at the cavoatrial junction with the balloon providing effective tamponade. The balloon was left in place while the surgeons performed a direct repair without cardiopulmonary bypass. The patient was later discharged.

Case 2:

A 52-year-old white female presented with infective endocarditis, a history of intravenous drug use and a 12-year-old dual-chamber ICD system implanted for long-QT
syndrome. The patient presented with bacteremia and a large tricuspid vegetation detectable by transthoracic echocardiography. Her hospital course was further complicated by severe diarrhea and hypokalemia related to drug withdrawal. The patient was started on IV antibiotics and taken to a hybrid operating suit with cardiothoracic surgery on standby for ICD system removal. A stiff guidewire for potential deployment of the Bridge occlusion balloon was advanced from the right femoral vein to the right internal jugular vein. The team began by extracting the atrial lead, but were unable to retract the active fixation screw and were not able to advance the locking stylet to the tip of the lead. The 12F laser sheath was advanced over the atrial lead from the left subclavian vein to the left innominate and the lead was withdrawn through the sheath. At this time, the blood pressure dropped, but returned to baseline following fluid infusion and small bolus of phenylephrine. With the right atrial lead removed and the patient stable, the ventricular lead was prepped with a locking stylet, although the active fixation screw was not retracted. The 14F laser sheath was advanced to the SVC and the lead released while counter pressure was applied. The lead was observed to have a substantial amount of tissue attached at the distal electrode. The patient’s blood pressure immediately fell into the 50s.  

The team administered phenylephrine and blood products. In the following minutes, the patient had multiple episodes of asystole and ventricular arrhythmias treated effectively with chest compressions and external defibrillation. The occlusion balloon – after some minor adjustments to the wire position – was advanced to the SVC, where it was inflated with 40cc of fluid. The blood pressure rebounded to achieve systolic pressures in the 80s. The cardiothoracic surgeons accessed the chest via median sternotomy and identified a 2cm
laceration of the cavoatrial junction with minimal bleeding from around the balloon. The injury was directly repaired without the use of cardiopulmonary bypass, and the occlusion balloon was subsequently deflated. In all, the balloon was deployed for approximately 30 minutes. It was not clear to the team whether the atrial or ventricular lead caused the tear, but they believed that it was the ventricular lead. In the following days, the patient was implanted with a subcutaneous ICD. On the third day after the extraction, she was discharged home.

Case 3:

A 45-year-old white female with ischemic cardiomyopathy after an anterior wall myocardial infarction had a 7-year-old ICD system. The lead requiring replacement was a passive fixation single coil ICD lead with a conductor fracture. Preparation of the patient included advancement of a stiff guidewire from the right femoral vein to the right internal jugular vein. There was calcification of the capsule noted during preparation of the leads. After prepping the lead with a locking stylet, a 14F laser sheath and an outer sheath were advanced into the left subclavian vein but could not advance into the left innominate. After several attempts and adjustments, a 16F laser sheath was advanced over the lead to the cavoatrial junction. After 2-3 seconds of laser application in this position, the patient’s systolic blood pressure dropped to 50-60mmHg systolic. The Bridge balloon was advanced over the guidewire and positioned in the SVC. After filling the balloon with 30cc of contrast, the balloon position was observed superior to the extraction sheath tip and was repositioned more inferiorly. The balloon was re-inflated with approximately 40% of its body in the right atrium within 2 minutes of initial insertion. During this time, the laser sheath remained in the SVC. The blood pressure
held in the 50-60mmHg range and within 9 minutes of recognizing the injury, cardiothoracic surgeons opened the chest via sternotomy and placed the patient on cardiopulmonary bypass. A 5mm tear was visualized at the cavoatrial junction with minimal bleeding and the laser sheath visibly compressed against the vascular wall. The tear was closed with a direct repair without repositioning the laser sheath, then the balloon was deflated and the laser sheath was removed. The patient was extubated later that day, implanted with a subcutaneous ICD, and discharged without further complications.

Case 4:

An 83-year-old white female with a 9-year-old pacing system required transvenous lead extraction of LV and RV leads due to persistent bacteremia and a right atrial vegetation. The extraction took place in a hybrid operating room with cardiothoracic surgeons present. Preparation included advancement of a guidewire to the right internal jugular via the right femoral vein access. The coronary sinus lead was removed using a 12F laser sheath without an outer sheath and the patient’s blood pressure remained steady at 120/70. Extraction of the ventricular lead was labored, with the laser sheath meeting numerous stopping points in the left innominate vein. When the lead was freed, the patient’s blood pressure dropped to 60/40 and the surgical team immediately intervened. The chest was opened before any attempt was made to deploy the balloon, revealing massive bleeding from the SVC. The surgeons provided manual compression of the tear while cannulating the patient for cardiopulmonary bypass. Shortly before the patient was placed on bypass, the balloon was inflated with 50cc of fluid without the aid of fluoroscopy. Deployment provided hemostasis and allowed the surgeons to
visualize an 8cm tear in the SVC (Figure 1a), which they repaired. 20 minutes later, the repair was complete and the balloon was removed (Figure 1b). During that time the team transfused 12 units of blood. The patient was extubated the following day. The patient was discharged 5 days later and continued to improve during follow up.

Discussion:

Safe and effective lead extraction requires experienced teams that are properly trained and equipped. Physicians involved in all four of these cases demonstrated best practices with respect to facilities and cross-disciplinary cooperation. They also displayed effective utilization of an emerging technology. With any one of those elements missing, it would seem less likely for all four of the patients to be discharged in good condition following events that are often fatal.

Over 2/3 of vascular emergencies during lead extraction occur in the superior vena cava. As illustrated in Figure 2, there are intra- and extra-pericardial portions of the SVC. Cadaver and MRI studies tell us that the average SVC measures roughly 6cm, with 50% of that length inside and 50% outside the confines of the pericardium. As a result, the clinical presentation of an SVC tear is either exsanguination into the thorax, pericardial tamponade or a combination. At 8cm, the Bridge balloon is designed to cover both the intra- and extra-pericardial portions of the SVC, which would not be possible with a smaller balloon.

Other features of the device that make it particularly suited for addressing these complications include its cylindrical shape, radiopaque markers, and compliance. The balloon is expanded using 30-60cc of saline mixed with contrast. The compliance allows the device to fill
the SVC regardless of leads or other obstacles in the vascular space (Figure 3). A non-compliant balloon may worsen vascular tears, especially with leads and sheaths still crossing the site of the tear. The Bridge allows the team to stem further blood loss and provides time to supplement the patient’s blood volume and to open the chest for repair of the injured vessel. The balloon also clears up the field to allow for a careful and controlled surgical repair. For tears that occur in the right atrium, right ventricle, or coronary sinus this balloon is unlikely to provide tamponade.

For the patients described in this series, the indications for extraction and the apparent risks varied considerably. On one end of the spectrum, patient 2 was in overall poor health, possessed 12-year-old leads, and presented with a large vegetation on her tricuspid valve. On the other end of the spectrum, patient 3’s extraction was considerably less urgent, and her leads had the relatively modest dwell time of 7 years. Neither of these patients suffered from diabetes, renal failure or cancer. Previous attempts to predict risk of procedural complications or mortality have been unsuccessful despite repeated attempts. This array of risk factors raises questions about the ability to predict the catastrophic lacerations that require balloon occlusion.

The interval from injury to repair must be kept as short as possible. Physicians involved in this series reported deployment times between 30 seconds and 2 minutes. In each scenario, debriefing revealed steps that could be taken to speed delivery even further. Recurrent themes included (1) being careful to avoid moving the guidewire during chest compressions or other emergency maneuvers, (2) having the proper size introducer ready in the femoral vein, and (3) having a pre-filled syringe available for inflation. The fourth case stands alone in that
Deployment was attempted only after the chest was open. The approach was effective in this case, but proper positioning without the aid of fluoroscopy may add difficulty.

In the absence of large clinical trials, field experience is a critical for informing protocols.

It is believed that these four cases represent the first four emergency deployments of the occlusion balloon following vascular tears in lead extraction. To our knowledge, and according to the manufacturer’s database, there have not been any cases in which the balloon was utilized and the patient outcome was not positive.

**Conclusion:**

These four cases demonstrate that endovascular occlusion balloons made specifically for lead extraction can dramatically strengthen a team’s response to vascular injuries.

**References:**


Legend:

**Figure 1:** Images from case 4 showing (a) inflated Bridge balloon visible through a large tear in the anterior of the SVC (b) Repaired SVC.

**Figure 2:** There are intrapericardial (IP-SVC) and extrapericardial (EP-SVC) segments of the superior vena cava. Recalling this anatomy is important for recognizing different presentations of SVC injury.

**Figure 3:** Bridge deployed in the SVC of a stable patient prior to lead extraction.