Percutaneous occlusion balloon as a bridge to surgery in a swine model of superior vena cava perforation

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BACKGROUND Superior vena cava (SVC) perforation is a rare but potentially fatal complication of transvenous lead removal.

OBJECTIVE The aim of this study was to evaluate the feasibility of hemodynamic stabilization using an occlusion balloon during SVC tear in a porcine model.

METHODS A surgically induced SVC perforation was created in Q3 Yorkshire cross swine ($n = 7$). Three animals were used to develop and test surgical repair methods. Four animals were used to evaluate hemodynamic, behavioral, and neurological effects up to 5 days after SVC tear and repair. An occlusion balloon (Bridge Occlusion Balloon, Spectranetics Corporation, Colorado Springs, CO) was percutaneously delivered through the femoral vein to the location of the injury and inflated. Once hemodynamic control was achieved, the perforation was surgically repaired.

RESULTS After SVC perforation and clamp release, the rate of blood loss was 7.0 ± 0.8 mL/s. Mean time from SVC tear to occlusion balloon deployment was 55 ± 12 seconds, during which mean arterial pressure decreased from 56 ± 2 to 25 ± 3 mm Hg and heart rate decreased from 76 ± 7 to 62 ± 7 beats/min. After the deployment of the occlusion balloon, the rate of blood loss decreased by 90%, to 0.7 ± 0.2 mL/s. The mean time of balloon occlusion of the SVC was 16 ± 4 minutes and hemodynamic measures returned to baseline levels during this time. Study animals experienced no major complications, demonstrated stable recovery, and exhibited normal neurological function at each postoperative assessment.

CONCLUSION Endovascular temporary balloon occlusion may be a feasible option to reduce blood loss, maintain hemodynamic control, and provide a bridge to surgery after SVC injury.

KEYWORDS Bridge; Endovascular repair; Occlusion balloon; Superior vena cava; Swine model

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Introduction

As the number of individuals with pacemakers and implantable cardioverter-defibrillator (ICD) devices continues to grow,[1] there is a parallel need for ongoing management of chronically implanted devices. Approximately 10,000–15,000 patients worldwide require transvenous lead removal each year due to infection, lead malfunction, lead recalls, excess scar tissue formation around leads, or upgrade from a ventricular pacing lead to an ICD lead.[2–6] While removal of recently introduced leads can usually be performed without the use of specialized equipment, removal of a chronic lead is a more technically challenging procedure that involves separation of the lead from encapsulating fibrous tissue and vein wall. Such procedures may endanger nearby thin-walled heart and venous structures.[7,8] Although major complications from lead removal procedures such as myocardial perforation and venous laceration occur in only 0.8%–2.0% of cases, mortality from these complications can be significant.[9–14]

The most common injury during lead removal is superior vena cava (SVC) perforation, which typically results in sudden hemodynamic compromise and requires emergency open or endovascular repair.[9,15] Immediate control of bleeding after SVC perforation is crucial since time to surgical repair is the main predictor of mortality and delays of only

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5–10 minutes to hemostasis can significantly affect survival.[5] A recent report depicts successful attenuation of hemorrhage due to SVC perforation during lead removal[16] using a percutaneously delivered occlusion balloon. The Bridge Occlusion Balloon (Spectranetics Corporation, Colorado Springs, CO) device was developed specifically for the anatomy of the SVC and was recently cleared by the Food and Drug Administration 510(k) process on February 5, 2016 (K153530). It is the only device indicated for temporary vessel occlusion of the SVC in applications including intraoperative occlusion and emergency control of hemorrhage. The aim of this study was to determine the feasibility of the Bridge Occlusion Balloon as a tool for maintaining hemodynamics in a porcine model of SVC perforation.

Methods

Study population

Seven domestic Yorkshire cross swine (weight 56.7 ± 0.4 kg) were prepped for SVC injury and repair experiments. The study protocol was approved by the Institutional Animal Care and Use Committee at Yale University and American Preclinical Services. All procedures and animal care conformed to the *Guide for the Care and Use of Laboratory Animals*.

Study device

The Bridge Occlusion Balloon Catheter is made of a compliant polyurethane material mounted on a multi-lumen catheter shaft. The study device used was a modified version of the commercially available Bridge Occlusion Balloon. A shorter balloon (65 mm vs 80 mm) was used in this study to accommodate porcine SVC anatomy.

Animal prep

Vascular access was achieved using a 14-F introducer (Performer Introducer and Sets, Cook Medical, XXXX, XX) in the right femoral vein, 6-F introducers (Prelude PRO Sheath Introducers, Merit Medical Systems, XXXX, XX) in the left femoral vein and right femoral artery, and a 7-F introducer (Prelude PRO) in the external jugular veins. Full sternotomy and partial pericardiectomy were performed to provide direct access to the SVC. Two permanent pacing leads (Refino 58 R, Oscor Inc, XXXX, XX) were placed from the right jugular access into the right ventricle and were anchored into the heart wall to prevent migration during the procedure. To block collateral flow and to simulate the body of an ICD lead, a 7-F Swan-Ganz catheter (Edwards Life Sciences, XXXX, XX) was placed from the right internal jugular access into the azygous vein and inflated. Positioning and blockage was confirmed on the venogram using a 50/50 mixture of saline and contrast (Isovue-300, Bracco Diagnostics Inc, XXXX, XX) from the right jugular access. Blood obtained from donor animals (2000 mL, heparinized) was connected to the left femoral artery access via a pressure bag for rapid transfusion. Finally, a 60-mL syringe of an 80/20 mixture of saline and contrast was prepared for occlusion balloon inflation.

Tear initiation and occlusion balloon deployment

With direct visualization of the SVC from the innominate/SVC to cavoatrial junctions, a 4-cm Satinsky clamp was used to isolate a portion of the SVC (Figure 1). A scalpel was used to cut a 2-cm incision through the lateral SVC wall along the length of the clamped section. The Satinsky clamp was left in place to maintain hemostasis. A 0.035-in guidewire (Amplatz Extra Stiff Guidewire, Cook Medical, XXXX, XX) was placed from the right femoral vein access, across the SVC area, to the right internal jugular vein. The Bridge Occlusion Balloon was then placed on the guidewire up to the 14-F introducer hemostatic valve. The chest cavity was evacuated using suction as necessary. Under fluoroscopy, the Satinsky clamp was removed to initiate bleeding from the SVC area, simulating exsanguination with SVC perforation during lead removal. The mean arterial pressure (MAP) was allowed to decrease to 30 mm Hg (47.5 ± 6.3 seconds) to simulate the identification and clinical consequences of SVC perforation. Transfusion of donor blood was initiated, and the occlusion balloon was advanced to the SVC area. The proximal radiopaque marker was placed at the cavoatrial junction and the occlusion balloon was inflated to approximately 30 mL with an 80/20 saline/contrast mixture until occlusion was achieved. Vessel occlusion was confirmed with venograms from the right external jugular and the inferior vena cava using a diagnostic catheter. The fluoroscope was removed from the field, allowing for direct visualization of SVC tear (Figure 2).

Surgical tear repair

There were 2 surgical repair techniques used: pericardial patch repair (n = 2) and direct clamping and suturing (n = 5).

Pericardial patch repair

With the occlusion balloon still inflated, a 2 × 3 cm pericardial patch (PeriSeal Tissue Patch, Avalon Medical, XXXX, XX) was sutured to the SVC using continuous 4-0 Prolene suture (Ethicon Inc, XXXX, XX). Surgical forceps facilitated the exposure of the vein edges. A plastic spoon

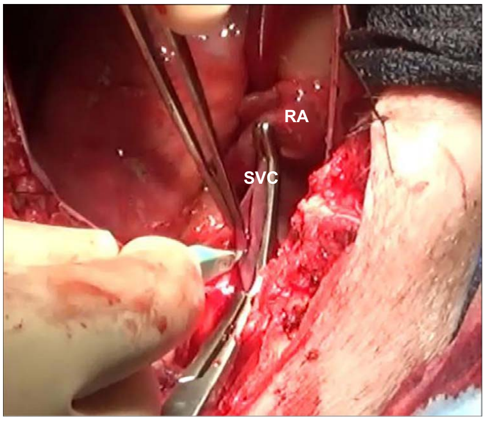

Figure 1 Initiation of SVC tear in a porcine model. Representative image demonstrates side clamping of SVC and creation of a tear using a scalpel blade. RA = right atrium; SVC = superior vena cava.