The experience with Bridge Occlusion Balloon

Samer Hakmi
University Heart Center Hamburg, Germany

HRC 8. October 2018 Birmingham, United Kingdom
Disclosures

I have presented on behalf of, or advised:

Boston Scientific
Spectranetics / Philips
St. Jude Medical
Zoll Medical
Disclosures

I am

Cardiac surgeon
Extraction tools
Extraction tools

Mechanical dilator sheath
Excimer laser sheath
Needle’s eye snare
A Transvenous Lead Extraction procedure via subclavian route
3D Reconstruction & 2D CT
19 years old ICD lead with aggressive adhesions

Laser sheath plus outer sheath
Intraoperative venography
Mechanical dilator sheath
Unfortunately, sometimes not everything goes well during a TLE.
- Major complication rates have been reported between 0.7% and 1.9%.*

- More than two-thirds of vascular emergencies during lead extraction occur in the SVC. **

* Wazni et al, Nat Rev Cardiol. 2016 Apr

** Brunner et al, Heart Rhythm. 2014 Mar
GermAn Laser Lead Extraction Registry*

* New data, not published yet
The GALLERY

Similar Studies

- PLEXES trial 1999: 153 Patients
- Total US 2002: 1,684 Patients
- EU experience 2007: 292 Patients
- LExICon Study 2010: 1,449 Patients
- ELECTRa 2017: 1,250 Patients
- The GALLERY: 2,533 Patients

2533 Patients
24 Centers
## The GALLERY Results

<table>
<thead>
<tr>
<th>Major complications</th>
<th>n = 2533</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergent sternotomy for vascular tears</td>
<td>52</td>
<td>2,05</td>
<td></td>
</tr>
<tr>
<td>SVC tears</td>
<td>46</td>
<td>1,81</td>
<td></td>
</tr>
<tr>
<td>Procedure related mortality</td>
<td>14</td>
<td>0,55</td>
<td></td>
</tr>
<tr>
<td>Infection related mortality</td>
<td>76</td>
<td>3,00</td>
<td></td>
</tr>
</tbody>
</table>
Real life story ...
Case 1 & 2 were performed!
Case 3:

- 69 years
- Male
- ICM, VTs
- ICD implant 2007
- Lead revision 2009
- Systemic infection

Lead extraction
Case 3:

- Blood pressure dropped
- TEE tamponade
- Femoral sheaths available
- Femoral Cutdown
- CPB fem-fem
- Median sternotomy
- SVC laceration identified
- Hemodynamic instability!
If BOB was available?
Do we have data?
BOB timeline
FDA approval

CE mark approval

Animal lab study

Heart Rhythm, 2016 Jun 23.
Animal lab study
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 developed in awake swine models. Animals were used to develop and test strategies to evaluate hemodynamic, behavioral, and neurological outcomes to evaluate hemodynamic, behavioral, and neurological outcomes to guide the decision to tear and repair. An occlusion balloon (Bard balloon, Bard Corporation, Colorado Springs, CO) was advanced via the innominate vein to the location of the injury and inflated to occlude the tear. Anterior subclavian artery access was gained and the perforation was surgically repaired.

Results

After SVC perforation and clamp release, the mean time from SVC tear to occlusion balloon inflation was 30 ± 10 minutes. Mean arterial pressure decreased from 76 ± 7 to 62 ± 7 beats/min. After the deployment of the balloon, total 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.
2016 Feb: FDA approval
2016 May: CE mark approval
Rescue of four consecutive patients: Heart Rhythm, 2016 DEC 15.
Rescue of four consecutive patients

University of Miami
Balloon-assisted rescue of four consecutive patients with vascular lacerations inflicted during lead extraction

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Introduction
An undeniable consequence of the increased frequency of cardiac implantable electronic device 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.

The device has been unproven in patients acutely compromised from vascular injuries secondary to transvenous lead extraction. The following series describes the first 4 consecutive cases in which the Bridge occlusion balloon was used in response to vascular tears.
Multi center data

EP lab or hybrid operating room

EP & cardiac surgeon on standby

Super stiff guidewire positioned in the SVC

Sheath in the fem. vein, prefilled syringe available

No history of open heart surgery!
<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Gender</th>
<th>Extraction Indication</th>
<th>Leads</th>
<th>Device</th>
<th>Implant duration years</th>
<th>BOB</th>
<th>CC</th>
<th>Time</th>
<th>Injury</th>
<th>CPB</th>
<th>surgical repair</th>
<th>Outcome</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>50</td>
<td>F</td>
<td>RV lead dysfunction</td>
<td>2</td>
<td>ICD dual coil</td>
<td>5</td>
<td></td>
<td></td>
<td>30 s</td>
<td>BOB dep.</td>
<td>no</td>
<td>direct repair</td>
<td>discharged</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>BOB dep.</td>
<td>3 mm cavo-atrial junction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>52</td>
<td>F</td>
<td>systemic infection</td>
<td>2</td>
<td>ICD ?</td>
<td>12</td>
<td></td>
<td></td>
<td>30 m</td>
<td>BOB in place</td>
<td>no</td>
<td>direct repair</td>
<td>discharged</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40</td>
<td>BOB in place</td>
<td>2 cm cavo-atrial junction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>45</td>
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<td>lead fracture</td>
<td>1</td>
<td>ICD single coil</td>
<td>7</td>
<td></td>
<td>9 m</td>
<td>ster.</td>
<td>yes</td>
<td>no</td>
<td>direct repair</td>
<td>discharged</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td>30</td>
<td>5 mm cavo-atrial junction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>83</td>
<td>F</td>
<td>systemic infection</td>
<td>2</td>
<td>CRT-P</td>
<td>9</td>
<td></td>
<td>20 m</td>
<td>repair</td>
<td>no</td>
<td>Patch*</td>
<td>Patch*</td>
<td>discharged</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50*</td>
<td>8 cm SVC</td>
<td></td>
<td></td>
<td>Patch*</td>
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<td></td>
</tr>
</tbody>
</table>
Conclusion
These 4 cases demonstrate that endovascular occlusion balloons made specifically for lead extraction can dramatically strengthen a team’s response to vascular injuries.
2016 Feb
FDA approval

2016 May
CE mark approval

Heart Rhythm, 2016 Jun 23.
Animal lab study

Heart Rhythm, 2016 DEC 15.
Rescue of four consecutive patients

BOB reduces the lethality
BOB reduces the lethality of SVC tears during TLE

University of Miami
Compliant endovascular balloon reduces the lethality of superior vena cava tears during transvenous lead extractions

Ryan Azarrafy, BA,* Darren C. Tsang, BS,* Thomas A. Boyle, BS,* Bruce L. Wilkoff, MD, FHRSD,† Roger G. Carrillo, MD, MBA, FHRSE

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BACKGROUND Superior vena cava (SVC) lacerations have been identified as the most lethal complication encountered during cardiac implantable electronic device lead extraction. The case fatality rate of these events approximates 50% due to rapid exsanguination. A novel, compliant balloon specifically designed for use in the SVC may provide hemostasis in the event of endovascular perforation. By temporarily occluding the compromised vessel, the endovascular balloon should delay hemodynamic collapse, provide a more controlled surgical field for repair, and thereby reduce the mortality of SVC tears complicating transvenous lead extraction.

OBJECTIVE To assess the early impact of the compliant endovascular balloon on the management of SVC tears and survival outcomes.

METHODS We searched a publicly available, United States Food and Drug Administration–maintained database for adverse events from 1 manufacturer of lead extraction tools. Reports from July 1, 2016, to December 31, 2016 were reviewed by 2 physicians to identify instances of SVC tears. Extracting physicians were contacted for further case details. Confirmed SVC tears were analyzed for patient demographics, repair strategies, and index hospitalization mortality.

RESULTS Of the complications reported, 35 cases of surgically confirmed SVC tears were identified. One hundred percent of patients (9/9) were discharged alive when the endovascular balloon was properly utilized, compared to 50% of patients (13/26) when the device was not used (P = .0131). Differences between all other variables analyzed were statistically insignificant.

CONCLUSION During the study period, we observed a reduction in mortality in patients who suffered SVC tears while undergoing lead extraction when treatment included an endovascular balloon.

KEYWORDS Lead extraction; Cardiac device; Repair; Superior vena cava; Laceration; Tear; Endovascular; Balloon

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experience

35 Confirmed SVC Events

9 Balloons Properly Used
- 9 Survivals (100%)

26 Non-Balloon
- 13 Survivals (50%)
- 13 Deaths (50%)
2016 Feb
FDA approval

2016 May
Animal lab study

Heart Rhythm, 2016 Jun 23.
Rescue of four consecutive patients

Heart Rhythm, 2016 DEC 15.

BOB reduces the lethality

BPP derived from early clinical experience
Best practice protocol derived from early clinical experience with BOB

Federated Agreement from the Eleventh Annual Lead Management Symposium
Bridge to surgery: Best practice protocol derived from early clinical experience with the Bridge Occlusion Balloon. Federated Agreement from the Eleventh Annual Lead Management Symposium

Bruce L. Wilkoff, MD, FHRS,* Charles Kennergren, MD, PhD, FHRS,† Charles J. Love, MD, FHRS,‡ Steven P. Kutalek, MD, FHRS,§ Laurence M. Epstein, MD, FHRS,‖ Roger Carrillo, MD, FHRS¶

From the *Cleveland Clinic, Cleveland, Ohio, †Sahlgrenska University Hospital, Göteborg, Sweden, ‡Johns Hopkins Hospital, Baltimore, Maryland, §Drexel University College of Medicine, Philadelphia, Pennsylvania, ‖Brigham and Women’s Hospital, Boston, Massachusetts, and ¶University of Miami Hospital, Miami, Florida.
Table 1  Best practice protocol

1. **Guidewire**: All patients should have a stiff 0.035-in guidewire deployed from the femoral vein through the SVC preferably to the right internal jugular or subclavian vein before every lead extraction procedure.*

2. **Introducer sheath**: All patients should have either a 6-F peel-away or 12-F femoral vein introducer sheath inserted for the introduction of the stiff 0.035-in guidewire before every lead extraction procedure.*

3. **Immediate deployment**: The Bridge Occlusion Balloon and prefilled inflation syringe must be ready for deployment, without delay, as soon as a tear in the SVC is **suspected**.

4. **Tamponade and hemothorax**: The Bridge Occlusion Balloon should be immediately deployed when there is evidence of either cardiac tamponade or hemothorax. Intrapericardial SVC tears may cause cardiac tamponade.

5. **Bridge familiarity**: All team members that are part of extraction cases should be familiar with the Bridge Occlusion Balloon and the deployment workflow.

6. **Bridge competence**: Extracting physicians should become competent and comfortable in deployment and inflation of the Bridge Occlusion Balloon in nonemergent settings.

7. **Bridge prophylaxis**: Prophylactic placement of the Bridge Occlusion Balloon may be considered for reasons including, but not limited to, physician preference, procedures and patients deemed high risk, new physician practicing lead extraction, low-volume operators, and an intraprocedural increase in the perceived risk.
German experience

University of Hamburg
The Bridge Occlusion Balloon as a safety net in a high-risk transvenous lead extraction procedure

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Abstract

Injuries to the superior vena cava (SVC) during transvenous lead extraction (TLE) procedures are a rare but life-threatening complication. The Bridge Occlusion Balloon (BOB) is specifically designed for temporary SVC occlusion in TLE procedures. We report the first case of a 27-year-old man using the BOB as a safety net in a high-risk TLE procedure. This patient, with a congenitally corrected transposition of the great arteries and a third-degree atrioventricular block, presented with 4 dysfunctional pacemaker leads, venous stenosis and the necessity for a new pacemaker system. The leads were implanted for 10 and 19 years. The BOB was placed with a radiopaque marker at the cavoatrial junction and was inflated with 46 ml of an 80/20 saline/contrast agent mixture. An angiography was performed to confirm SVC occlusion. With the deflated balloon in place, the TLE procedure with laser and mechanical sheaths was performed. Successful extraction of 2 dysfunctional leads, as well as venous recanalization, for the new right atrial and right ventricular lead implantation was achieved. We have shown the feasibility of using powered extraction sheaths with a deflated BOB in place. This allows for immediate balloon inflation, in case of an SVC perforation.

Keywords: Bridge Occlusion Balloon • Superior vena cava • Lead extraction
<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Gender</th>
<th>Extraction Indication</th>
<th>Leads</th>
<th>Device</th>
<th>Implant duration years</th>
<th>Tools</th>
<th>Time prep. m</th>
<th>Time dep. s</th>
<th>Adaptability</th>
<th>BOB CC</th>
<th>Major comp.</th>
<th>Outcome</th>
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<td>46</td>
<td>M</td>
<td>pocket perforation</td>
<td>1</td>
<td>ICD single coil</td>
<td>14</td>
<td>GlideLight 16 Fr. Evolution 13 Fr.</td>
<td>6</td>
<td>60</td>
<td>yes</td>
<td>50</td>
<td>no</td>
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<tr>
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<td>M</td>
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<td>4</td>
<td>DDD PM</td>
<td>10</td>
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<td>1</td>
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<td>37</td>
<td>GlideLight 14 Fr. Needle’s Eye Snare</td>
<td>3</td>
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<td>45</td>
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<tr>
<td>5</td>
<td>76</td>
<td>M</td>
<td>pocket infection</td>
<td>3</td>
<td>CRT single coil</td>
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<td>40</td>
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<td>no</td>
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<tr>
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<td>29</td>
<td>F</td>
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<td>2</td>
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<td>13</td>
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<td>30</td>
<td>yes</td>
<td>40</td>
<td>yes*</td>
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*Indicates a specific condition or note.
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<th>Tools</th>
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<th>BOB CC</th>
<th>Major comp.</th>
<th>Outcome</th>
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<td>7</td>
<td>55</td>
<td>M</td>
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<td>8</td>
<td>90</td>
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<td>86</td>
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<td>17</td>
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Access preparation
X-ray
Deployment and Venography
Adaptability and anatomical plasticity
<table>
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<tr>
<th>Event</th>
<th>Date</th>
<th>Publication</th>
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<tr>
<td>FDA approval</td>
<td>2016 Feb</td>
<td>Heart Rhythm, 2016 Dec 15.</td>
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<td>2016 May</td>
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<td>Rescue of four consecutive patients</td>
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<td>Heart Rhythm, 2017 Jul 14.</td>
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<td>BOB reduces the lethality</td>
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<td>Heart Rhythm, 2017 Aug 7.</td>
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<td>BPP derived from early clinical experience</td>
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<td>Long-term outcomes of prophylactic BOB</td>
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Long-term outcomes of prophylactic placement of the BOB in the vena cava for high-risk TLEs

University of Hamburg & University of Miami
Long-term outcomes of prophylactic placement of an endovascular balloon in the vena cava for high-risk transvenous lead extractions

Darren C. Tsang, BS,* Ryan Azarrafiy, BA,* Simon Pecha, MD,† Hermann Reichenspurner, MD, PhD,† Roger G. Carrillo, MD, MBA, FHRS,* Samer Hakmi, MD†

From the *Division of Cardiothoracic Surgery, University of Miami Miller School of Medicine, Miami, FL, and †Department of Cardiovascular Surgery, University Heart Center Hamburg, Hamburg, Germany.

BACKGROUND Many clinicians use the strategy of prophylactically placing an endovascular balloon before transvenous lead extraction, yet there are no data regarding this practice.

OBJECTIVE This study assesses long-term outcomes of prophylactic placement of an endovascular balloon in the venae cavae of patients during transvenous lead extraction.

METHODS From April 1, 2016 to March 31, 2017 data were prospectively collected at 2 international cardiovascular centers on patients who had the balloon prophylactically placed in the venae cavae. Patients were monitored for a minimum of 3 months to capture any associated adverse events.

RESULTS Twenty-one patients had the balloon prophylactically placed in the venae cavae during lead extraction. Sixteen patients were male (76%); the mean age was 57.6 ± 18.7 years; and the mean body mass index was 26.1 ± 4.4 kg/m². The mean lead dwell time was 11.2 ± 8.3 years, with an average of 2.2 ± 1.1 leads per case, and most indications for extraction were noninfectious (62%). Two minor complications (10%, pocket hematomas) and 1 major complication (5%, cardiac tamponade) occurred during the procedure. All cases (100%) were procedural successes, and all patients (100%) were discharged alive. On follow-up (6.8 ± 3.7 months), all patients were alive and reported no adverse events related to prophylactic balloon placement, such as pulmonary emboli or deep venous thrombi.

CONCLUSION During the study period, we observed no acute or long-term adverse outcomes associated with prophylactic placement of an endovascular balloon in the venae cavae of patients undergoing transvenous lead extraction.

KEYWORDS Transvenous lead extraction; Prophylactic placement; Bridge; Endovascular balloon; Long-term outcomes

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<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
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<td>3-mo survival</td>
<td>21 (100)</td>
</tr>
<tr>
<td>Pain at the site of insertion</td>
<td>0 (0)</td>
</tr>
<tr>
<td>AV fistula</td>
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<tr>
<td>Deep vein thrombosis</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pulmonary embolus</td>
<td>0 (0)</td>
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<tr>
<td>Hospitalizations</td>
<td>6 (29)</td>
</tr>
<tr>
<td>ICD reimplantation</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Lead revision</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Hematoma drainage</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Cardioversion</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>

Values are presented as n (%).

AV = atrioventricular; ICD = implantable cardioverter-defibrillator.
Conclusion
During the study period from April 1st, 2016 to March 31st, 2017, we observed no acute or long-term adverse outcomes associated with prophylactic placement of an endovascular balloon in the venae cavae of patients undergoing transvenous lead extraction.
2016 Feb
FDA approval

2016 May
CE mark approval

Animal lab study
Heart Rhythm, 2016 Jun 23.

Rescue of four consecutive patients
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BOB reduces the lethality

BPP derived from early clinical experience

Long-term outcomes of prophylactic BOB

2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction

Developed in collaboration with and endorsed by the American College of Cardiology (ACC) (endorsement pending), American Heart Association (AHA) (endorsement pending), Asia Pacific Heart Rhythm Society (APHRS), American Society of Anesthesiologists (ASA) (endorsement pending), European Heart Rhythm Association (EHRA), Infectious Diseases Society of America (IDSA) (endorsement pending), Latin American Heart Rhythm Society (LAHRS), Pediatric and Congenital Electrophysiology Society (PACES), and Society of Thoracic Surgeons (STS)

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10.3.8 Vascular Tears

Vascular tears involving the subclavian and innominate veins can result in ipsilateral hemothorax but can be difficult to identify or accurately localize. Awareness of the position of the working sheath and imaging with TEE or fluoroscopy can be helpful in identifying potential sites of injury. More importantly, about two-thirds of life-threatening vascular tears occur in the SVC, half of which are below and half of which are above the pericardial reflection. This results in pericardial effusion and tamponade when below the pericardial reflection and in hemothorax and rapid demise when above the pericardial reflection unless the bleeding is immediately controlled. Deployment of an occlusive compliant balloon can control the severity of bleeding while the chest is opened and definitive repair is pursued. Although venography, coated stent implantation, and pericardiocentesis have been successfully employed, the time lost in avoiding opening the chest often results in avoidable mortality in many patients. Positioning an introducer sheath and a stiff guide wire that extends from the femoral vein to the right internal jugular or subclavian vein at the beginning of the extraction procedure allows for rapid deployment of an occlusive balloon to minimize bleeding as the patient is rapidly prepared for definitive repair. Initial studies have suggested that the occlusive balloon is safe and associated with improved survival in the setting of vascular tears of the SVC.
Thank you for your attention …