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

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Introduction

A league of physicians at the Eleventh Annual Lead Management Symposium convened in Miami, FL, on February 4, 2017, developed an expert opinion and federated agreement on a best practice protocol for Bridge Occlusion Balloon (Bridge; Spectranetics Corporation, Colorado Springs, CO) deployment for patients undergoing transvenous cardiac implantable electronic device lead extraction on the basis of early clinical experience with the balloon. This best practice protocol aims to increase awareness and readiness to facilitate the rapid, consistent, and safe use of Bridge to reduce mortality in patients undergoing lead extraction.

Many patients, with clear indications, are not referred for transvenous lead extraction owing to a misperception of the risk associated with the procedure. Injury to the SVC, though uncommon, is a serious and potentially fatal complication of transvenous lead extraction and occurs in approximately 0.5% of procedures.[1] While complications will always occur with invasive procedures, if mortality can be minimized, more patients will receive appropriate treatment. According to the Heart Rhythm Society guidelines,[2] prompt injury recognition and hemostasis is crucial as delays of more than 5–10 minutes from time of injury to opening the chest are associated with an increased risk of mortality. Rapid deployment and inflation of a percutaneously delivered Bridge in the SVC can control bleeding and restore hemodynamic stability until surgical intervention and repair can be performed. Under optimal conditions, in the presence of a prepositioned guidewire and with Bridge positioned on the guidewire in the inferior vena cava (IVC), deployment can occur in as little as 1 minute, and in as little as 2 minutes when ready and available in the procedure room. Deployment of the occlusion balloon decreased the rate of blood loss by 90% and allowed surgical repair with no major complications in an animal model of SVC tear.[3] A recent publication described successful deployment of Bridge after SVC tear in 4 patients undergoing lead extraction.[3] These cases demonstrated that Bridge can successfully occlude the vascular tear and provide the time needed to transition to a successful surgical repair. A comparative analysis of survival with discharge to home with and without appropriate Bridge deployment in 35 patients with SVC tears reported through the Manufacturer and User Facility Device Experience database from July through December 2016 demonstrated 100% vs 50% successful rescue.[4] Although limited, initial clinical experience with Bridge in emergent situations provides insight into the device's effectiveness in strengthening a team's response to specific vascular injuries. These experiences may also inform the lead extraction physician community about best practices for Bridge pre-case preparation and clinical workflow.

The following clinical protocol for Bridge deployment was derived from the examination of all the available clinical data, discussion of the successful and problematic scenarios,

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and consensus development among 30 representatives from high-volume extraction centers at the Eleventh Annual Lead Management Symposium (see Appendix 1). The consensus represents expert opinion and was achieved and documented by voting on 7 proposed principles that promoted best outcomes and appeared to reduce risk. While more data will strengthen the development of specific guidelines, we articulated this best practice protocol in order to promote consistent Bridge implementation and to improve the interpretation of the subsequent data set. While encouraged by the initial results, all at the meeting had a concern that some operators might view the availability of this technology as a reason to not require rapid surgical backup. The availability of Bridge in no way obviates the need for emergent cardiothoracic surgical backup. Delay in definitive treatment is potentially life-threatening and not an acceptable practice.

Best practice protocol

A summary of the best practice protocol is provided in Table 1.

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.

*Lead extraction is defined by Heart Rhythm Society consensus statement, where there is at least 1 lead to be removed over 1 y from implantation or an extraction tool other than a standard stylet is required to remove the lead.

Preprocedure preparation

In the presence of a vascular tear, delayed access to the heart of more than 5–10 minutes is associated with a higher incidence of fatal outcomes.[1,2] Therefore, the time from injury to repair must be kept short. This can be achieved with adequate pre-case training and preparation. The Bridge balloon can enable hemodynamic stability through control of hemorrhage by occluding the SVC in the minutes required for full open access to the chest. Operators should ensure that all items necessary for emergent Bridge deployment are immediately available and prepared before the lead extraction procedure. This will reduce time to balloon deployment and may also reduce potential for unnecessary errors. Before the initiation of extraction in every patient, this pre-case preparation should include the following:

- Femoral vein introducer sheath placement
- Insertion and advancement of a Bridge-compatible stiff guidewire
- Prefilled syringe for balloon inflation and visibility
- Immediate availability of Bridge in the procedure room

Principle 1: 0.035-in guidewire placement

Although the J tip and several centimeters of the distal guidewire should be relatively flexible to permit navigation and reduce the risk of vascular injury during placement, the portion of the 0.035-in guidewire that is deployed past the right atrium (RA) and through the SVC to the internal jugular or subclavian veins must be stiff enough to support the balloon and resist prolapsing of the balloon back into the RA. This guidewire should be inserted before the attempt to remove any lead requiring extraction. Placement of a stiff 0.035-in guidewire in the femoral vein during preparation for the extraction (1) ensures venous access, (2) places the wire across the region of potential venous compromise, (3) eliminates the potential of advancing the wire through the vessel tear, and (4) provides safe advancement of the 12-F sheath as required for Bridge deployment. Monitoring of the guidewire's position during the lead extraction procedure to ensure that the wire has not been dislodged is essential. It is useful to secure the guidewire to reduce the opportunity for dislodgment of the wire by clamping the wire just outside the introducer and/or to the drape cloth. When and if Bridge is deployed, the guidewire should also be maintained after Bridge positioning and balloon inflation, as removal of the guidewire may cause migration of Bridge into the RA.

The guidewire is most easily introduced from the right femoral vein to the right internal jugular vein for ease of access to the SVC anatomy, depending on the preference of access for potential femoral to femoral cardiopulmonary bypass, temporary pacing wires, or use of snaring tools from the femoral vein. Depending on other patient- and hospital-specific considerations, alternative access with the guidewire is the left femoral vein and right or left subclavian vein. The guidewire can be advanced to the right or left subclavian or internal jugular veins, depending on the patency of the vessels. In some cases, manipulation of the guidewire into the internal jugular/subclavian vein can be challenging. The use of a