PHILIPS

Bridge

Occlusion balloon

Case Study:

Staging Bridge occlusion balloon mid-case

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Case study

Background

SVC tears during lead extraction are very rare, occurring in less than 0.5% of procedures. The Philips Bridge Occlusion Balloon was designed to provide hemostasis in the rare event of a SVC tear, allowing time for surgical repair and increasing survivability. Dozens of rescues have been supported utilizing this novel device.[1]

One of several recommendations for deploying Bridge prophylactically is for high-risk cases.[2] When Bridge is staged in the IVC, it can support rapid deployment and minimize blood loss. At the onset, some cases may not appear high risk. Yet, case difficulty may increase intra-procedure, and prophylactic deployment may be considered. This case description details a lead extraction case performed by Dr. Sumit Verma. Bridge was deployed mid-case when the perception of risk increased.

Case description

- Procedure performed in a surgical OR suite with cardiovascular surgeon and perfusionist on stand by.
- Standard lead extraction protocol (central and arterial lines, femoral vein and arterial access, intraoperative TEE, blood products in the room).
- Bridge™ Prep Kit was used. An 0.035" super-stiff guidewire was advanced through a 6F peel away sheath from the left femoral vein to the right IJ. A 12F introducer sheath was on the wire outside of the body in case of emergent Bridge deployment. The bottom end of the guidewire was clamped to the drape to maintain position throughout the procedure.
- A 60 cc syringe was filled with contrast and saline mix (per the IFU, 12 cc contrast & 48 cc saline). Bridge™ Occlusion Balloon was immediately available.
- Temporary pacer was also inserted through the left femoral vein.
- The generator was then removed and access to the left subclavian vein was secured.
- To create a traction platform, LLD EZ™ locking devices were deployed in the lumen of each lead and sutures were tied to the insulation.
- In order to minimize the lead-to-sheath gap, a 12F GlideLight™ laser sheath with a VisiSheath was selected. The sheath was advanced over the RV lead.
- Significant lead-on-lead and lead-to-wall binding was encountered at the innominate/SVC junction and progression stalled.
- Before upsizing to a 14F GlideLight™ laser sheath, Bridge was advanced into the anatomy as a precaution.The 14F laser sheath was advanced from the SVC to the tricuspid valve, at which point systolic blood pressure dropped from 120 mm to 70 mm and remained low despite releasing the traction on the lead and immediate infusion of vasopressors.
- Bridge was deployed, and diagnostics were investigated. TEE showed no effusion and no tamponade. No hemothorax was seen fluoroscopically.
- Once the surgeon was in the room, the balloon was deflated and an angiogram was performed from the right arm. No extravasation was seen.
- The extraction continued and the RV and RA lead were successfully removed.

Implanted leads:	Implant date
Guidant 4087 (RA lead)	2009
Guidant 4088 (RV lead)	2009
Indication for extraction	
Pocket Infection (Class I)	

Discussion with Dr. Verma

Patient and device history

- 89-year-old male with a dual-chamber pacemaker implanted in 2009 for atrial fibrillation and complete heart block.
- Patient underwent generator change three weeks prior and developed a pacer site infection, necessitating extraction of the system.
- No prior CABG or open heart surgery. Previous atrial flutter RFA.

Prophylactic deployment mid-case

Just looking at the demographics, this patient may not have appeared high risk. Normally, I would not expect this case to give me any trouble. Yet, as heavy lead-on-lead and lead-to-wall binding was encountered and greater traction force was required, the case became higher risk in my mind. The balloon was inserted as a precaution to support a quick deployment and limit any potential blood loss.

When the blood pressure dropped and we inflated Bridge, it was impressive to see everyone in the room was composed. We were prepared and felt we had the situation under control. Bridge has changed the dynamic of the room—from panic to calm.

In the future, I plan to prophylactically inflate Bridge when I feel case difficulty has increased intra-procedure. We have surgical backup that is immediately available, yet often not in the room. Bridge provides time to stabilize the patient and transition to surgery.

> "There was no tear in this case, but had there been a tear, we would have been prepared to save the patient."
>
> Sumit Verma, MD, FACC

Patient prep

Prepping every patient undergoing extraction with a guidewire and introducer sheath has become our standard. This is part of Bridge Best Practice Protocol.[2] In this case, additional time was required to insert the guidewire because the right femoral vein was occluded. The guidewire was alternately placed through the left femoral vein to the right IJ. Also, the patient had significant binding in the vessel, and a JR4 catheter was required to guide the wire past the heart. Trying to place a wire and the balloon in an emergent situation, instead of beforehand, may have been impossible in this patient.

It is important for operators to understand that there may be unforeseen patient characteristics that add time to deployment. It is imperative to be prepared beforehand.
The more you can prepare for immediate deployment, the better off you are.

> “Bridge allows us to perform the extraction procedure with more control over potential complications.”
>
> Sumit Verma, MD, FACC

Pre-huddle timeout

We incorporate Bridge into our pre-case timeout. We know exactly where it is, and it is always immediately available. Then we decide whether the case is high-risk and if we want to stage Bridge in the IVC.

Prior to this case, I had prophylactically inflated the balloon in order to become familiar with the device and the workflow. It is important for our team to practice the workflow on a regular basis. Different extractors and support staff all need to be familiar with the balloon, patient prep and steps for deployment.

Figure 1. Practicing Bridge inflation prior to an emergent situation helps refresh the team on the workflow.

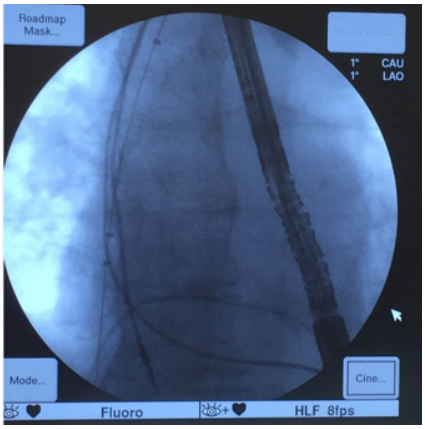

Figure 2. Determining placement in the SVC for potential inflation beforehand. Bridge can then be stationed in the IVC.

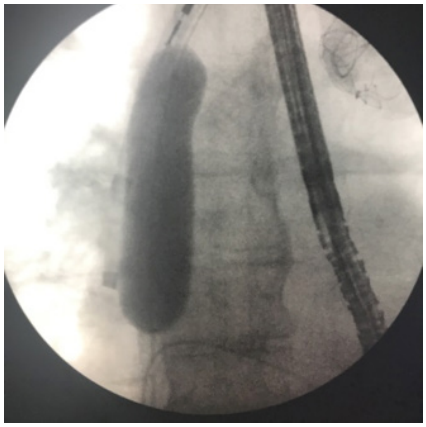

Figure 3. Bridge inflated after blood pressure dropped. Diagnostics determined no SVC tear. Bridge was deflated and the extraction completed successfully.

Important Safety Information

Indications for Use

The Bridge Occlusion Balloon Catheter is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage.

Any use for procedures other than those indicated in these instructions is not recommended

Contraindications

None Known

Warnings

Lead extraction should be performed at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. It is strongly suggested that the recommendations for lead management of the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) be followed for best results.

Prior to initiating the lead extraction procedure, a Bridge Occlusion Balloon Catheter compatible guidewire should be placed through a venous access site and across the length of the superior vena cava. Attempting to place a compatible guidewire after a venous tear occurs may:

- result in an inability to traverse the superior vena cava with the guidewire
- result in the guidewire exiting the vasculature at the tear site
- result in an inability to place the Bridge Occlusion Balloon Catheter
- delay or prevent the ability to achieve occlusion

Do not position the Bridge Occlusion Balloon Catheter in a manner that would obstruct the right atrium. Obstruction of the atrium could lead to arrhythmias and/or hemodynamic compromise. Failure to observe recommended inflation techniques may result in the formation of contrast crystals which could prevent deflation.

Do not over-inflate the Bridge Occlusion Balloon Catheter after fully occluding the vessel. Over inflation may result in damage to the vessel, rupture of the balloon, or introduction of air emboli.

Do not exceed the Maximum Inflation Volume. Over inflation may result in damage to the vessel, rupture of the balloon, or introduction of air emboli.

Occlusion of the superior vena cava beyond 30 minutes is not recommended as this may increase the risk of adverse physiologic or neurologic complications.

Do not resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.

Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties

Refer to the IFU for additional information.

Results from this case study are not predictive of future results. The opinions and clinical experiences presented herein are specific to the featured physicians and the featured patients and are for information purposes only. The results from their experiences may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes and related factors. Nothing in this material is intended to provide specific medical advice or to take the place of written law or regulations.

1. SPNC Post Market Surveillance, 2017. Data on File.

2. Wilkoff BL, Kennergren C, Love CJ, Kutalek SP, Epstein LM, Carrillo R, Bridge to Surgery: Best Practice Protocol Derived From Early Clinical Experience with the Bridge Occlusion Balloon., Heart Rhythm (2017), doi: 10.1016/j.hrthm.2017.07.008.

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