Protocol-based removal of intra-aortic balloon pump using bioabsorbable anchor/collagen–based vascular closure device following cardiac surgery

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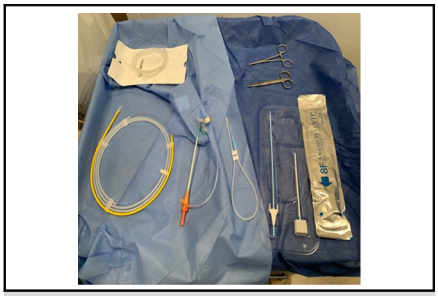

ANGIO-SEAL device layout before insertion.

CENTRAL MESSAGE

The use of ANGIO-SEAL for the removal of intra-aortic balloon pump in the ICU setting is a safe reproducible technique: herein lies a protocol for its use.

The use of the intra-aortic balloon pump (IABP) in cardiac surgery to support the heart is a well-established, standardized therapy. Most cardiac surgical units practice direct manual compression of the insertion site for post-IABP removal hemostasis. The ANGIO-SEAL device (Terumo) is a standardized technique for the closure of femoral artery puncture in a variety of settings. This is usually performed in the interventional suite with angiographic imaging. Kato and colleagues[1] have shown previous success with the ANGIO-SEAL to remove the IABP in the intensive care unit (ICU) with good outcomes. Using ANGIO-SEAL reduces the need for the patient to lie flat for 4 hours after removal of balloon pump to just 30 minutes, allowing earlier mobilization[2] and reducing the risk of respiratory complications and the risk of venous thromboembolism. Previous studies have shown the use of the ANGIO-SEAL without angiography to be a safe and effective way to remove IABPs.[3] This article describes a technique for closure device deployment following IABP removal that can be undertaken in a ward or ICU-based setting.

TECHNIQUE

Before device insertion and deployment, the following equipment is needed: 018 wire, a 7-Fr access sheath, sterile drape, dressing scissors ×3, marking pens, chlorhexidine prep, sterile gown, dressing pack, and sterile gloves.[1] The procedure involves 3 people; 2 proceduralists and a third person to operate the balloon pump. Throughout this process, sterility is meticulously maintained (Figure 1).

Following informed consent and assessment of patient's coagulation profile, the following protocol is used:

1. The insertion site is assessed using ultrasound to ensure the puncture site is at least 5 mm above the common femoral bifurcation, the vessel is at least 5 mm in diameter, and no prohibitive calcification exists in the vessel (Figure E1). The blood pressure is ensured to be less than 120 mmHg systolic. Preprocedure Doppler signals of both posterior tibial and dorsalis pedis pulses are checked.
2. The patient is kept supine, and the operator formally scrubs and puts on 3 layers of gloves. We prep and drape the field to include the balloon pump and connections; the sutures holding the balloon pump are removed using scissors, which are then discarded along with top layer of gloves. A barrier drape is then placed.
3. The remaining equipment is laid on the drape: 018 guidewire, 7-Fr dilator sheath, and the ANGIO-SEAL introducer.
4. The balloon pump is placed in standby mode and a mark is made 12.5 cm from the entrance of the balloon arterial line. All lines of balloon pump are divided at this point and the balloon pump is switched off.

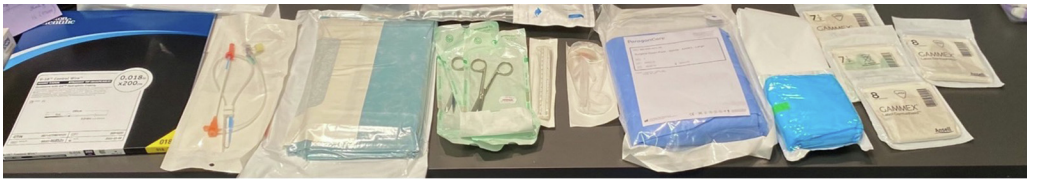

FIGURE 1. Equipment for vascular closure device insertion, from *left* to *right*: 018 wire, 7-Fr access sheath, sterile drape, 3× sterile scissors, chlorhexidine prep, sterile gown, dressing pack, 3× pairs of sterile gloves.

Removal

1. Removal begins with insertion of a 200-cm 018 guidewire to 90 cm. The balloon is then withdrawn until felt to be touching the sheath. The 018 wire is inserted another 25 cm (Figure 2 and Figures E2 and E3).
2. Balloon and sheath are removed simultaneously ensuring the wire is still inside the artery while applying pressure to the groin to maintain hemostasis.
3. The 7-Fr sheath is loaded with the dilator on an 018 wire and inserted into the femoral artery, and the 018 wire and dilator are removed. The second pair of gloves is removed at this point.
4. The ANGIO-SEAL device is opened, with care taken not to touch the footplate; an 035 wire is introduced into the 7-Fr sheath, which is removed.
5. The ANGIO-SEAL device is then inserted using the standard technique with the locator device placed in the femoral artery before inserting the device until 2 clicks are felt, denoting the release of the footplate before being withdrawn. The collagen plug is then tamped and the suture cut at the skin with a fresh pair of sterile scissors.[4] The patient then lies flat for 30 minutes before mobilizing.
6. Peripheral arterial supply is checked using Doppler, and neurovascular observations are performed for 2 hours.

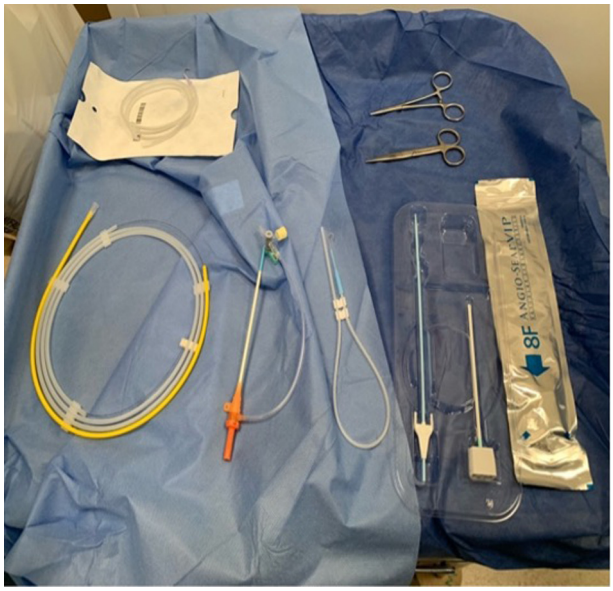

FIGURE 2. ANGIO-SEAL wire with marker indicating to where 90 cm equates.

DISCUSSION

Using this protocol, 35 patients underwent removal of IABP with the ANGIO-SEAL. Of these, 3 instances of failure to deploy the device occurred, 1 due to difficulty advancing the sheath and 2 to accidental removal of the wire, managed with manual pressure. These complications were all at the beginning of our use of the ANGIO-SEAL, and as our technique improved, no further complications occurred. There were no major bleeding or ischemic complications. The results show similarities to the previously mentioned studies[5] as well as the literature provided by the device manufacturer. Mean follow-up for this was 56 days (range, 0-186 days).

Deployment of the ANGIO-SEAL device for the closure of femoral artery puncture sites is common in vascular surgery, interventional radiology, and interventional cardiology. Through this protocol, we describe a safe and repeatable technique for performing this in the ICU or ward-based setting without the need for angiography. The challenges associated with the deployment in the ICU are the lack of angiographic imaging and maintaining sterility.

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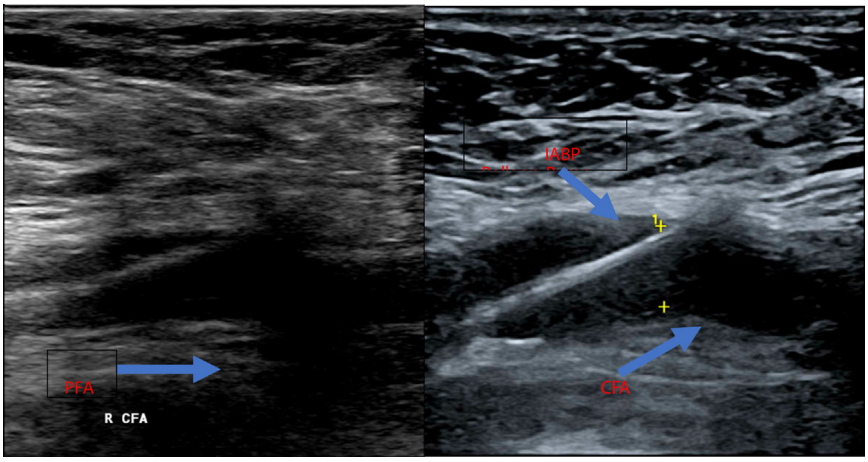

FIGURE E1. *Left*, Ultrasound scan of the common femoral artery before ANGIO-SEAL deployment showing appropriate position of IABP for ANGIO-SEAL deployment (>5 mm form femoral bifurcation). *Right*, Showing IABP in close proximity to the femoral bifurcation, making it unsuitable for ANGIO-SEAL. *CFA*, Common femoral artery; *IABP*, intra-aortic balloon pump; *PFA*, profunda femoris artery.

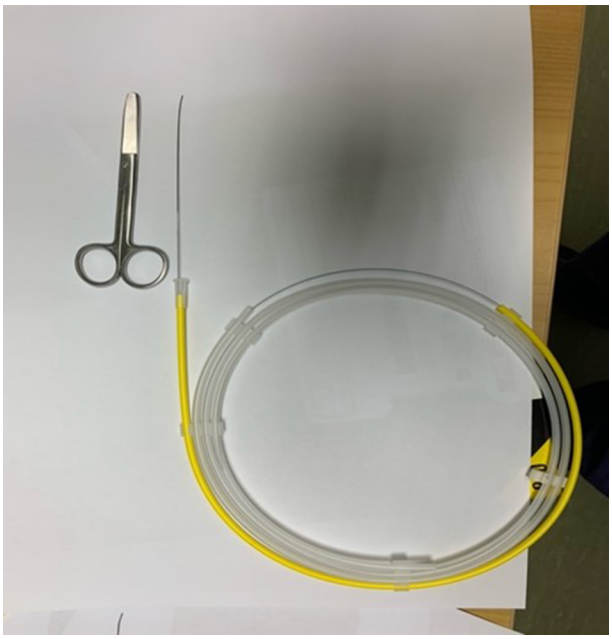

FIGURE E2. Using scissors to measure 15 cm on the wire.

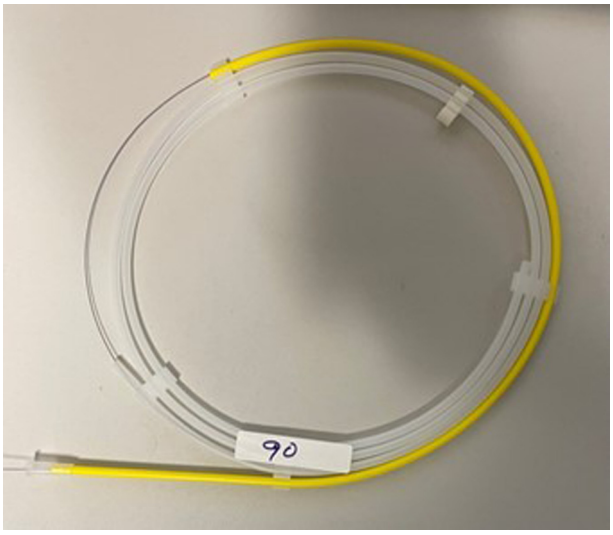

FIGURE E3. 90 cm Mark on 018 guide wire.