Off-label use of Angio-Seal vascular closure device for the repair of femoral pseudoaneurysm after transfemoral coronary intervention

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ABSTRACT

Pseudoaneurysm was caused at the puncture site of the left groin after percutaneous coronary intervention. Balloon tamponade was attempted for hemostasis at the aneurysmal site. However, hemostasis was not achieved. Next, direct puncture of the pseudoaneurysm was tried. A 0.014-inch guidewire was crossed from the neck of the pseudoaneurysm to the left common femoral artery. The wire was replaced with a 0.035-inch guidewire. An 8F Angio-Seal (Terumo Interventional Systems, Somerset, NJ) was inserted, and a collagen plug was deployed at the neck of the pseudoaneurysm. Final angiography revealed completion of hemostasis. Three-dimensional computed tomography angiography after 8 months revealed no evidence of recurrence. (J Vasc Surg Cases and Innovative Techniques 2019;5:38-40.)

Keywords: Pseudoaneurysm; Endovascular therapy; Angio-Seal

Femoral artery access is a well-established approach to enable percutaneous interventional procedures, such as percutaneous coronary intervention (PCI) and percutaneous peripheral intervention. However, puncture site complications, such as bleeding, hematoma formation, thrombophlebitis, and ecchymosis, can occur.[1] Of these complications, iatrogenic pseudoaneurysm is common. Previous papers reported that the incidence of iatrogenic pseudoaneurysm of the femoral artery ranges from 1.1% to 2.9%.[2,3] Hence, interventional cardiologists should be familiar with management. The most common nonsurgical treatment options are duplex ultrasound-guided compression and duplex ultrasound-guided thrombin injection, which are widely used and fairly successful. However, a novel approach with suture-based closure devices to treat pseudoaneurysms was recently reported.[4] In this case report, we describe the off-label use and the long-term outcome of the Angio-Seal vascular closure device (Terumo Interventional Systems, Somerset, NJ) to repair a femoral pseudoaneurysm.

We obtained informed consent of the patient for publication of this case report.

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Author conflict of interest: none.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2468-4287

https://doi.org/10.1016/j.jvscit.2018.10.001

CASE REPORT

An 84-year-old man was referred to the emergency department of our hospital for chest pain. He was receiving antiplatelet agents and anticoagulation (aspirin 100 mg/d, prasugrel 3.75 mg/d, and warfarin 2.5 mg/d) because he had a history of having a coronary artery stent and paroxysmal atrial fibrillation. In the laboratory data, prothrombin time-international normalized ratio was 1.31. He was diagnosed with acute coronary syndrome and underwent urgent PCI by an intra-aortic balloon pump with a 7F sheath through the left common femoral artery (CFA) because of cardiogenic shock. After PCI, the intra-aortic balloon pump was removed. Hemostasis was obtained through manual compression. The next day, a vascular murmur was heard at the puncture site. Three-dimensional computed tomography angiography (3D-CTA) revealed a femoral pseudoaneurysm at the puncture site in the left groin (Fig 1, *A*). The diameter of the pseudoaneurysm was 6 mm; the neck width was 2 mm. There was not an associated large hematoma. Hemostasis was reattempted by ultrasound-guided manual compression. However, hemostasis was not achieved even by ultrasound-guided manual compression for 30 minutes; it was difficult to compress effectively because the neck of the pseudoaneurysm was short and wide. We decided to perform hemostasis with balloon tamponade. Initial angiography showed the pseudoaneurysm at the puncture site (Fig 1, *B*). Balloon tamponade was initially attempted for hemostasis (Fig 1, *C*). However, hemostasis was not achieved even by balloon tamponade for 15 minutes (Fig 1, *D*). Next, direct puncture of the pseudoaneurysm was tried percutaneously under both ultrasound and angiographic guidance (Fig 1, *E*). A 0.014-inch guidewire was crossed from the neck of the pseudoaneurysm to the left CFA (Fig 1, *F*). The 0.014-inch guidewire was replaced with a 0.035-inch guidewire using a 4F sheath. An 8F Angio-Seal was inserted, and a collagen plug was deployed at the neck of the pseudoaneurysm. Final angiography revealed completion of hemostasis

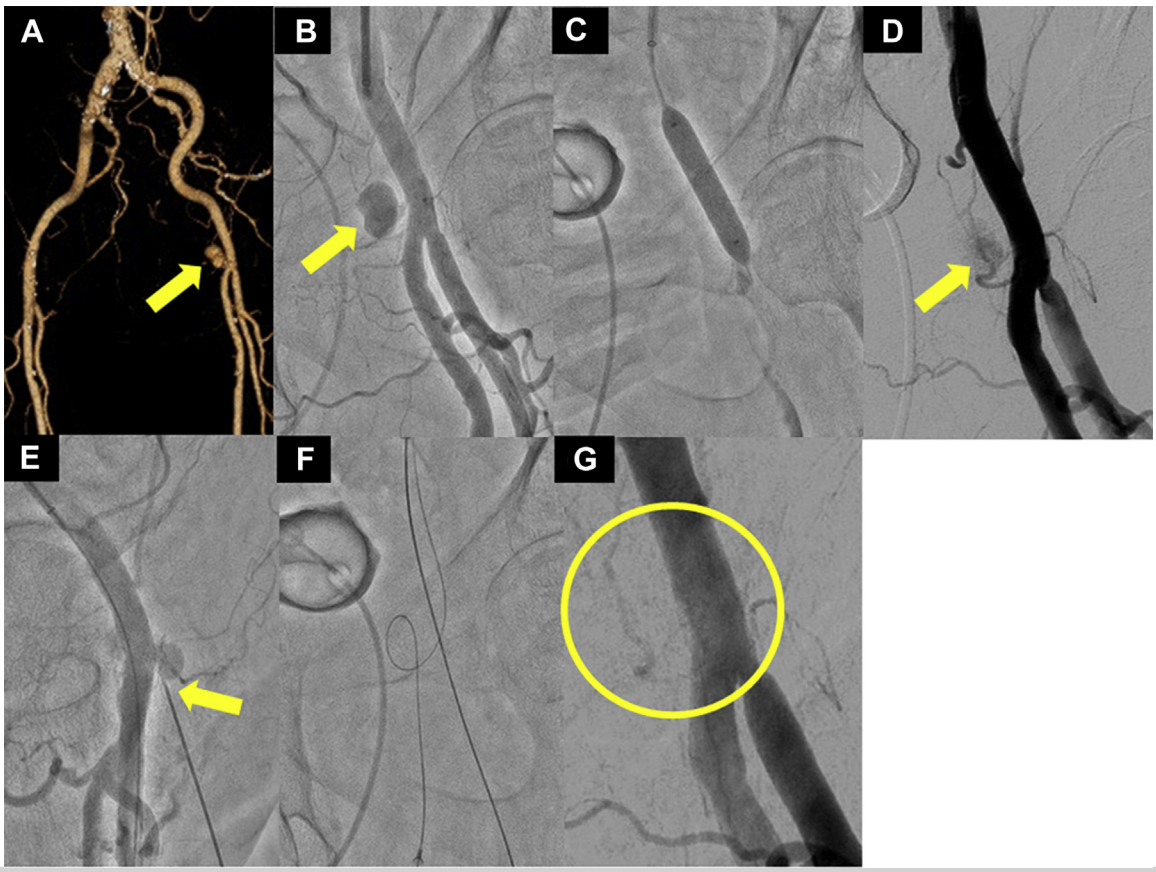

Fig 1. A, Three-dimensional computed tomography angiography (3D-CTA). The *arrow* indicates the pseudoaneurysm. **B,** Initial angiography. The *arrow* indicates the pseudoaneurysm. **C,** Balloon tamponade was attempted for hemostasis. **D,** Angiography after balloon tamponade. Hemostasis was not achieved. **E,** Direct puncture to the pseudoaneurysm. The *arrow* indicates the puncture needle. **F,** The 0.014-inch guidewire was crossed from the neck of the pseudoaneurysm to the left common femoral artery (CFA). **G,** Angiography after deployment of the Angio-Seal collagen plug. The *circle* indicates complete hemostasis.

(Fig 1, *G*). The next day, vascular ultrasound revealed complete hemostasis and an Angio-Seal collagen plug at the wall of the left CFA (Fig 2, *A*). No complications occurred after endovascular repair. Furthermore, 3D-CTA after 8 months revealed no evidence of recurrence (Fig 2, *B*).

DISCUSSION

This is a report of the off-label use of the Angio-Seal vascular closure device to repair femoral pseudoaneurysm. Hemostasis was instantaneously achieved, and no major complications were observed at any time. Only minor complications, including mild pain and a small subcutaneous hematoma, were noted. This method has several advantages. First, patients who are currently undergoing treatment with oral anticoagulants and antiplatelet agents can be successfully treated because the vascular closure device is effective independent of concomitant medications. Second, this method can be used to treat patients in whom hemostasis is difficult to achieve through manual compression, such as severely obese patients and those who have pseudoaneurysms with short necks. Third, it cannot be concluded whether this technique may be superior to other percutaneous devices from the result of only this single successful case. However, we believe that this technique may be superior to thrombin injection because potential complications that might occur with thrombin injection, such as peripheral embolism of thrombin or anaphylactic reactions, are avoided, and it is less invasive than open repair. However, this technique also has some potential risks. First, the collagen sponge might not be compressed against the outer vessel wall because the pseudoaneurysm also contains liquid components of blood.[5] Furthermore, pseudoaneurysms with wide necks (>8F) cannot be treated. Although we describe the off-label use of the Angio-Seal vascular closure device to repair femoral pseudoaneurysm, our report is not enough to

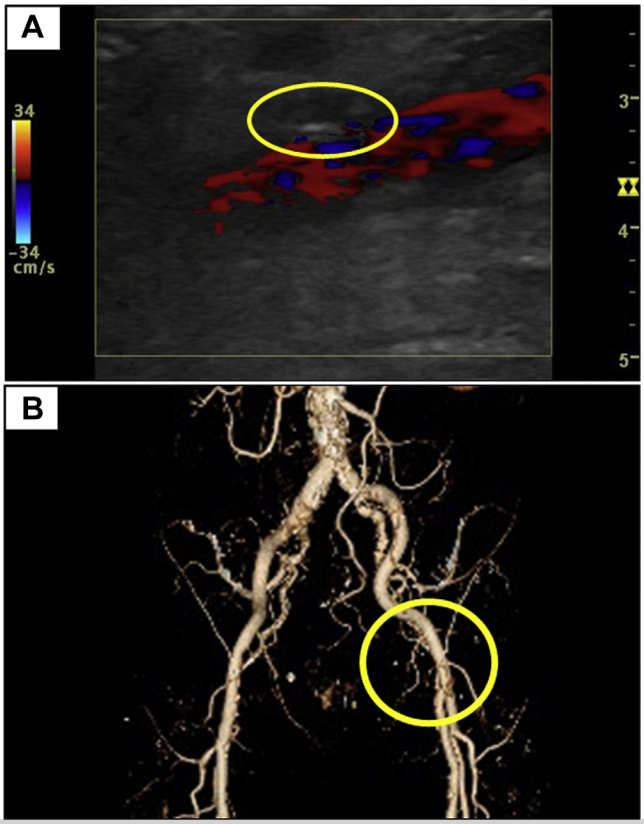

Fig 2. A, Vascular ultrasound findings the day after hemostasis. The *circle* indicates the collagen plug of Angio-Seal at the wall of the left common femoral artery (CFA). **B,** Three-dimensional computed tomography angiography (3D-CTA) after 8 months. The *circle* indicates no evidence of recurrence.

demonstrate the safety and efficacy of this method. Previous papers had described the same method.[6,7] However, we additionally reported the long-term outcome by 3D-CTA. Further trials are warranted with a prospective design and a larger cohort of patients.

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Submitted May 26, 2018; accepted Oct 3, 2018.