Case Report

Surgical Treatment of Complications Associated with the Angio-Seal Vascular Closure Device: Report of Three Cases

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The Angio-Seal arterial closure device consists of several bioabsorbable components and is used for hemostasis of arterial puncture sites. We report 3 cases of hemorrhagic and ischemic complications related to Angio-Seal use. Two cases were treated successfully by surgical removal of the device. In the third case surgical removal of the device failed and additional intervention was necessary. The unique structure of the Angio-Seal and the most likely cause of failure should be considered when treating device-related complications.

Key Words: hemostatic device, complication, vascular access

INTRODUCTION

The Angio-Seal arterial closure device (St Jude Medical, St Paul, Minnesota) is widely used for sealing arterial puncture sites. This device is composed of a collagen sponge, an absorbable anchor and a connecting suture. Such arteriotomy closure devices are thought to reduce hemostasis time and facilitate early ambulation, potentially decreasing hospital length of stay and improving patient satisfaction. However, in terms of vascular complications, it remains controversial as to whether vascular closure devices are better than mechanical compression.

We report 3 cases of complications associated with the Angio-Seal that required surgical treatment. We also consider the mechanism of failure in each case.

CASE PRESENTATION

Case 1

A 61-year-old man underwent percutaneous coronary intervention (PCI). We sealed the puncture in the right common femoral artery (CFA) with an Angio-Seal but did not achieve hemostasis. Manual compression also failed to stop the bleeding so we performed emergency surgery. We exposed his right CFA and found the device suture tail was found at the puncture site anterior to the artery. We made a small horizontal incision in the artery at the puncture site and found calcification of the inner arterial wall. We located the anchor just under our incision and removed it easily by traction on the suture tail.

Case 2

An 80-year-old woman with critical left lower limb ischemia underwent percutaneous transluminal angioplasty (PTA). She had already undergone endovascular therapy for her lower limb ischemia several times but her rest pain was gradually worsening. She also had chronic renal failure requiring hemodialysis. The Angio-Seal did not adequately control bleeding from the PTA puncture site in her left groin and additional mechanical compression was required. An angiography performed the following day showed a lucent spot near the bifurcation of the superficial femoral artery (SFA) and the deep femoral artery (DFA, Fig. 1). Something at that location appeared to be obstructing blood flow. Under local anesthesia, we made an arteriotomy in the CFA just proximal to the apparent location of the trapped matter. The Angio-Seal anchor, collagen sponge, and suture tail were found in the artery. We were...
Four weeks later, we successfully treated the occlusion in his left SFA with balloon angioplasty and stenting.

**Discussion**

The Angio-Seal consists of 3 bioabsorbable components: a small rectangular anchor, a collagen plug, and a connecting polyglycolic suture. The anchor is inserted into the artery and positioned on the intraluminal wall by pulling the connecting suture and the collagen plug is compressed against the outer arterial wall. Although this device has become popular in clinical practice various device-related complications have been reported, including bleeding, which also occurs with manual compression, and vascular stenosis and occlusion. Nikolsky et al. have described in their meta-analysis study that the incidence of the Angio-Seal-related complications is up to 2.5% and the risk of those complications was similar with manual compression.

When treating Angio-Seal related complications, the unique structure of the device and the most likely cause of failure should be considered. In Case 1, arteriosclerotic change at the puncture site may have prevented the anchor from fitting snugly to the inner arterial wall and unable to remove the material by grasping it directly with forceps, but extracted it successfully from the arterial lumen by traction on the suture tail.
sandwiching the arterial puncture site (Fig. 3A). In such a case, additional manual compression may be useless because of the interspace between the arterial calcification and the anchor. In Case 2, intra-arterial deposition of the collagen plug occurred (Fig. 3B). Stein et al. suggest that vigorous tamping with inadequate tension on the suture or deployment of the anchor too deep within the vessel can cause inappropriate placement of the collagen plug in the arterial lumen.\(^5\) In Case 3, the anchor disk may have caught in some distal intravascular atherosclerotic calcifications and the puncture hole was not closed, causing bleeding and occlusion of the SFA (Fig. 3C). It seems that arterial atherosclerosis along the site of Angio-Seal usage cause various complications in our cases. Therefore careful ascertainment of arterial wall character before using the Angio-Seal would be important to avoid those complications.

Before surgical treatment of these complications, it is also important to locate the foreign bodies by angiography or duplex ultrasound because the anchor is sometimes found at a distance from the puncture site, as in Case 2 and Case 3. The arteriotomy should be made near the anchor location to allow easy removal. However, atherosclerotic change frequently hardens the arterial wall such that the incision must be made away from the anchor, as in Case 2 and Case 3. In such situations, it is sometimes difficult to withdraw the anchor directly with forceps. In Case 2, we were able to retrieve the anchor by pulling on the connecting suture through a separate arteriotomy. Stein et al. have also reported successful percutaneous removal by pulling on the suture.\(^5\)

In Case 3, however, pulling the suture did not help and the anchor remained in the artery causing ischemia of the lower limb. Additional interventional dilation and stent deployment resolved the stenosis. Some authors have reported many device-specific complications can be treated with interventional therapy, including balloon angioplasty, stent grafting, extraction with a snare catheter and arterectomy with a cutting device.\(^4,6,7\) Although such interventional procedures may not remove the whole intravascular foreign body and introduce the possibility of further complications, they may be useful when surgical
treatment fails due to severe atherosclerosis.

Although our cases are acute complications, Dregelid et al. have reported a case of ischemic symptoms occurring several weeks after using an Angio-Seal device. They describe ischemia caused by microembolization of device-associated thrombi or embolization of the device itself or its components. As device-associated ischemic complications may appear some time after deployment, it is important to record Angio-Seal use in the procedural report.

REFERENCES


