Critical lower limb ischemia from an embolized Angio-Seal closure device

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Vascular closure devices were introduced in the early 1990s in an effort to reduce time to hemostasis, enable early ambulation, and improve the comfort of patients undergoing femoral artery access for endovascular procedures. Many of these devices leave a foreign component in or around the artery, which can lead to complications such as hematoma, pseudoaneurysm, infection, or limb ischemia. Here we present a case where device embolization led to arterial occlusion and critical limb ischemia.

CASE REPORT

A 51-year-old woman with ventricular premature complex-induced cardiomyopathy was referred to Baylor University Medical Center at Dallas for an electrophysiology study and possible radiofrequency ablation. Her right common femoral artery was accessed for the procedure, and the electrophysiology study and radiofrequency ablation were performed without incident.

An Angio-Seal (St. Jude Medical, St. Paul, MN) was employed to close the femoral artery puncture site. The Angio-Seal device consists of three bioabsorbable components to actively seal the arteriotomy. The anchor is placed against the inside of the arterial wall. The collagen plug sits on top of the arteriotomy in the tissue tract. The suture and compaction tube cinch the anchor and collagen together to form a secure seal (*Figure 1*). In this patient, as the compaction tube was advanced, the suture snapped near the sheath. The compaction tube was removed and the suture cut near the skin surface. This resulted in partial hemostasis with some continued oozing but no pulsatile flow or hematoma. Complete hemostasis was obtained with manual compression. The patient was observed overnight and discharged the next morning without incident.

Several days later she began to experience right leg claudication after walking 100 feet. On examination, she had a cool right lower extremity with diminished peripheral pulses. Examination of the left lower extremity was normal. A computed tomography scan was performed at an outside hospital and revealed critical right tibioperoneal trunk stenosis. Intravenous heparin therapy was initiated, and she was transferred to Baylor University Medical Center at Dallas.

She underwent an aortobifemoral angiogram performed via a 5 French left common femoral micropuncture. Digital subtrac-

Figure 1. Angio-Seal vascular closure device components. Image courtesy of St. Jude Medical.

tion angiography of both limbs demonstrated a large amount of thrombus in the distal right popliteal artery extending into the tibioperoneal trunk. The anterior tibial artery was occluded at the ostium. There was a 99% stenosis at the tibioperoneal trunk (*Figure 2*). Manual and rheolytic thrombectomy were performed, and a 4 French Cragg-McNamara infusion catheter was placed in the distal right popliteal artery for alteplase thrombolysis. After 36 hours of intermittent thrombolysis, a large thrombus burden remained and operative embolectomy was performed in the distal popliteal and proximal tibial arteries. In addition, the remnants of the Angio-Seal closure device (string and collagen plug) were removed from the distal popliteal artery. She tolerated the procedure well and peripheral pulses returned to normal. She was discharged 2 days later.

DISCUSSION

For several decades, manual compression followed by hours of bedrest was the sole method of femoral artery puncture site

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Figure 2. Angiogram showing thrombus in the right popliteal artery with an occluded anterior tibial artery.

hemostasis. Compression requires a trained medical professional to maintain pressure on the access site for up to 30 minutes, depending on sheath size, anticoagulation status, and several other patient and procedural characteristics. While this method is highly effective, it can also be extremely uncomfortable for the patient and labor intensive for the medical staff.

In the early 1990s vascular closure devices (VCDs) were introduced as an alternative to manual compression, and today a variety of VCDs are available. The appeal of early ambulation and enhanced patient comfort, as well as the reduction of cost associated with manual compression and in-hospital observation, has made the use of VCDs commonplace. It is estimated that over 1 million VCDs are used yearly in the United States (1).

Despite widespread use, the superiority of VCDs over manual compression in terms of complications has not been definitively proven. There are no large randomized clinical trials comparing complication rates of manual compression to those of VCDs. Several large metaanalyses and registries have yielded conflicting data regarding superiority (2–9). Tavis et al reviewed 166,680 patients from the American College of Cardiology–National Cardiovascular Data Registry database who underwent cardiac catheterization in 2001. In this cohort, 53,655 patients received a VCD to obtain hemostasis, while 113,025 patients

received manual compression. The risk of experiencing any vascular complication was 1.1% in the VCD group and 1.7% in the manual compression group ($P < 0.001$) (9). In 2004, Nikolsky et al conducted a metaanalysis of 30 studies involving 37,066 patients undergoing cardiac catheterization. In this study vascular complication rates were higher in the patients who received a VCD (odds ratio 1.34; 95% confidence interval 1.01–1.79) (6).

Complications related to VCDs may be broadly classified into three categories: hemorrhagic, obstructive, and infective (10). The most feared complication of VCDs is limb ischemia. This can occur as a result of embolization, thrombosis, or occlusion from the intravascular component of the device (11). Several studies have reported the incidence of lower limb ischemic complications following Angio-Seal use (12–16). Thalhammer et al reported their single-center experience with Angio-Seal–related ischemic complications. They noted 14 instances of symptomatic lower limb ischemia in 7376 patients (0.2%) undergoing catheterization between 2003 and 2006 (12). Castelli et al discovered 4 cases of lower limb ischemia in 175 patients who received an Angio-Seal following cardiac catheterization (2.3%) (13). One possible explanation for the wide variation in ischemic complication rates may be operator experience. Balzer et al clearly demonstrated that VCD delivery success rates increased as the operator’s experience and familiarity with the device increased (17).

Limb ischemic symptoms can present acutely in the minutes after device deployment, but may also have a subacute presentation with claudication in the days or weeks following the procedure (18). Endovascular approaches to treat limb ischemia caused by VCDs have been described, but most authors recommend direct surgical cutdown, retrieval of the device, and definitive arterial repair, most often with venous patch plasty (10). Steinkamp et al reported on their experience using excimer laser and balloon angioplasty in 13 patients with lower limb ischemic symptoms as a result of either vessel occlusion or stenosis related to an Angio-Seal device. Four of the 13 patients had complete vessel occlusion while the remaining 9 had lower-extremity vessel stenosis. All patients were successfully treated and experienced increased walking distance and an improved ankle-brachial index immediately following the procedure and at 3- and 6-month follow-up (19).

Although endovascular or open surgical treatment of limb ischemia resulting from VCDs can be limb sparing, it can be associated with additional significant morbidity. Wille et al described several cases of limb ischemia resulting from Angio-Seal deployment (18). One patient required a four-compartment fasciotomy of the lower leg to treat reperfusion-induced compartment syndrome. In addition, the lateral skin defect needed split skin grafting 6 weeks after the procedure. A second patient experienced postoperative groin infection that required debridement, sartorius muscle transposition, and a prolonged course of intravenous antibiotics. Fortunately, our patient had no postoperative sequelae.

While VCDs may reduce the time to ambulation and discharge, enhance patient comfort, improve staff efficiency, and

reduce costly in-hospital monitoring, they can expose patients to additional risks, which can be life and limb threatening. Physicians, nurses, and ancillary staff must be aware of such risks, recognize early signs of potential problems, and act expeditiously.

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