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SHORT REPORT

Acute Arterial Occlusion after Deployment of the Angio-Seal Closure Device: Is it as Uncommon as we Think?

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Abstract Angio-Seal is a frequently used vascular closure device after arterial catheterisation. Major complications are infrequently reported. We present four cases occurring within a 2-month period in our hospital with dislodgement of an Angio-Seal causing acute arterial occlusion, resulting in loss of limb in one case.

Surgical intervention was necessary in all cases. Acute arterial occlusion after deployment of the Angio-Seal in patients with peripheral arterial disease might be less uncommon than the literature suggests.

Manual compression has been the traditional means of haemostasis after femoral artery catheterisation. Complications range from 1% to 5%, including haematoma, bleeding, arteriovenous fistulae and pseudoaneurysms.[1] This led to the development of vascular closure devices (VCDs). Advantages over manual compression include reduced haemostasis time, quicker ambulation, improved comfort, earlier discharge and fewer complications.[1–3] One of these devices, Angio-Seal, is composed of an absorbable collagen sponge and a specially designed absorbable polymer anchor connected by an absorbable self-tightening suture. The device seals and sandwiches the arterial wall between the anchor and sponge.

Notwithstanding the favourable reports, application of Angio-Seal is not without complications. In this article, we present four patients in whom the use of Angio-Seal has resulted in acute arterial occlusion and amputation in one case due to dislodgment of the device.

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Case Reports

We perform approximately 1500 angiographies per year. In half of those a VCD is deployed, mainly Angio-Seal, resulting in a total of 600 Angio-Seals. Our selection criteria for the use of a VCD are:

<5 Fr sheath: manual compression;
5,6,7 Fr sheath: Angio-Seal;
8,9 Fr sheath and/or thrombolysis: Perclose; and
≥10 Fr sheath: Prostar.

We report four cases of complications with the Angio-seal, which occurred in a 2-month period. About a hundred Angio-Seals were used during that period.

Case 1: A 50-year-old woman presented with persistent left calf pain 8 days after a subintimal angioplasty of the right superficial femoral artery (SFA) by a crossover technique with Angio-Seal closure of the left groin. Duplex scanning showed occlusion of the left SFA. After unsuccessful thrombolysis (Fig. 1), surgical exploration showed an intraluminal disrupted Angio-Seal at the femoral bifurcation. After device removal, thrombectomy was performed. Wound infection led to repeated surgery with an eventual construction of an iliacofemoral bypass.

Case 2: A 61-year-old man presented with acute left leg ischaemia 3 days after percutaneous transluminal angioplasty (PTA) of the right deep femoral artery by a crossover technique. Angiography showed occlusion of the left common femoral artery (CFA). During surgical desobstruction, the anchor of an Angio-Seal was recovered from the lumen of the CFA (Fig. 2). Despite a femorocrural bypass 5 days later, ischaemia progressed, thus requiring an above-knee amputation.

Case 3: A 65-year-old man complained of pain in the right leg 1 day after PTA of the superior mesenteric artery for ischaemic enteritis through a right groin access with Angio-Seal closure. Angiography showed an occluded CFA. Thrombolysis was unsuccessful. The Angio-Seal was extracted from the CFA lumen during endarterectomy. The patient made an uneventful recovery.

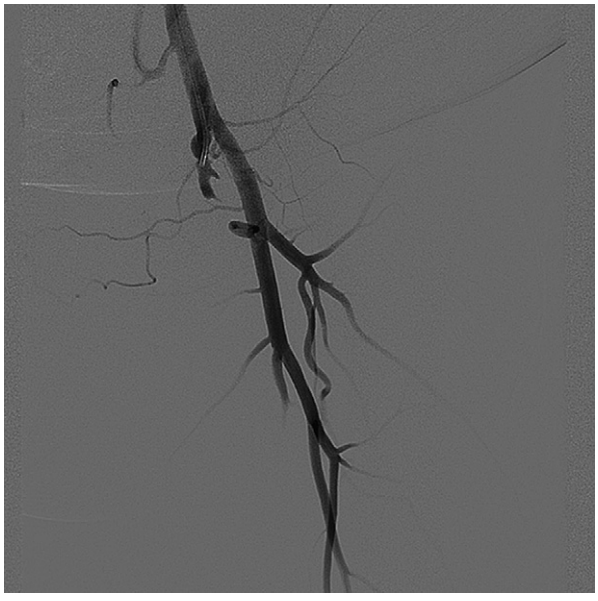

Figure 1 Angiography preceding thrombolysis showing an acute arterial occlusion of the left proximal SFA due to dislodgment of the Angio-Seal.

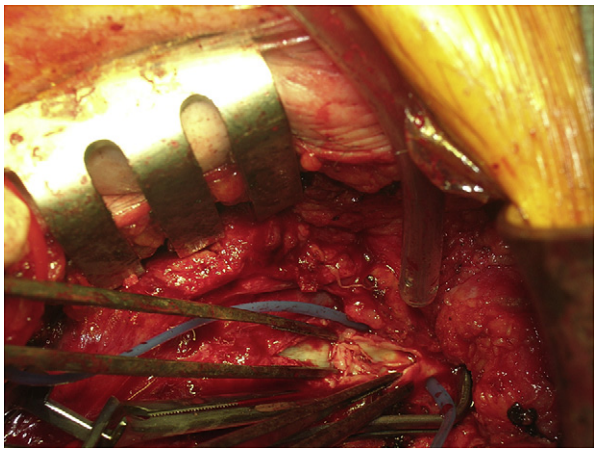

Figure 2 Peroperative picture of intimal destruction of the left CFA, with an intraluminal Angio-Seal, as the cause of arterial occlusion.

Case 4: An 80-year-old woman complained of acute ischaemia of the right foot 1 day after subintimal angioplasty of the right SFA accessed through the right groin and closed with Angio-Seal. At surgical exploration, a complete closure device was extracted from the lumen of the femoral bifurcation. After thrombectomy and additional thrombolysis, she made an uneventful recovery.

Discussion

Extensive experience with VCDs has been reported in cardiological randomised trials. Two recent meta-analyses, however, show that the overall reported advantages of VCDs over manual compression should be interpreted cautiously.[4,5] This is mainly caused by concern over the quality of the published trials.[4] In addition, studies analysing mixed diagnostic and interventional procedures show significant heterogeneity in complication rates.[5] A meta-analysis of all included studies in mixed settings and all other settings together favoured conventional compression technique over VCD.[5]

Few studies have been reported on the use of Angio-Seal in peripheral arterial disease (PAD). In a non-randomised study by Abando et al., Angio-Seal was used for femoral artery closure in 188 patients.[1] There were two complications related to device deployment (0.9%). One patient developed a false aneurysm. A second patient required operation for vessel occlusion after device deployment in a markedly diseased femoral artery. To minimise adverse events, these authors suggested several guidelines for the use of Angio-Seal in patients with PAD; for example, the device should not be used if the puncture site is above the inguinal ligament or below the femoral bifurcation or in case of small (<5 mm) or diseased arteries. The basis for these guidelines is yet unclear. These recommendations have nonetheless been included in the manufacturers'

instructions for deployment (http://www.sjm.com/_MediaAssets/documents/usifu41499.pdf).

Major complications following the use of Angio-Seal, such as infection and acute arterial occlusion, occur in 0.5—1.9% of cases.[1] Despite these low complication rates, we encountered four serious complications in 2 months. In our hospital, 1500 angiographies are performed yearly, using a total of 600 Angio-Seals. Our two interventionalists both have over 4 years of experience with Angio-Seal and have received initial training by the manufacturer. In the scope of good clinical practice, these complications have urged us to analyse them thoroughly. We could not identify a specific risk factor that could explain the technical problems encountered. We conferred with several experienced colleagues in the field, who somewhat surprisingly confirmed our negative experiences. Regarding this discrepancy between the favourable results in the literature and the less favourable experiences in clinical practice of patients with PAD, a publication bias is likely.

We would like to emphasise that using Angio-Seal for immediate haemostasis in patients undergoing interventional procedures for PAD is not without risk of serious ischaemic complications. Acute arterial occlusion might be less uncommon than the literature suggests.

Conflict of Interest/Funding

None.

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