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INTERVENTIONAL RADIOLOGY

CASE REPORT

Acute leg ischemia secondary to embolization of an Angio-Seal device

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ABSTRACT

Angio-Seal is a vascular closure device designed for repairing arterial puncture sites used for various endovascular procedures. It has a better safety and efficacy profile compared to manual compression in the previous studies. However, there are significant complications that may arise from the use of Angio-Seal like infections, aneurysm formation, and vessel occlusion. Our case is a demonstration of one such complication. We conclude with a dicussion of the present literature available with regards to the Angio-Seal device.

Key words: • *embolization* • *ischemia* • *claudication* • *Angio-Seal™* • *closure device*

Angio-Seal™ is a vascular closure device designed for closing arterial puncture sites. It is used as an alternate means of gaining hemostasis, hence reducing the need for direct manual compression and prolonged bed rest. The use of these closure devices has gained increased acceptance, with their safety and efficacy compared to manual compression assessed by numerous studies. However, there are significant complications that may arise from the use of Angio-Seal and which a clinician must be aware of. These include infection, aneurysm formation, and vessel occlusion. Herein, we present a case with one such complication.

Case report

A 32-year-old man presented with a 6-hour history of left-sided chest pain on a background of diabetes and smoking. Blood tests and an electrocardiogram confirmed his diagnosis of an ST elevation myocardial infarction. After receiving an urgent dose of 300 mg of aspirin and 150 mg of clopidogrel, the patient was taken to the cardiac catheter laboratory. His right common femoral artery (CFA) was catheterized and an angioplasty of his left anterior descending artery was performed. An Angio-Seal (St. Jude Medical, Minnetonka, Minnesota, USA) device was used to close the femoral artery puncture site in the manner described by the manufacturers. The process of closure was uncomplicated. He was discharged on day 5 on a daily regime of clopidogrel 75 mg and aspirin 100 mg.

Two days later, the patient presented again, this time with right leg claudication at 50 m. On examination, he had a cool right foot with absent pedal pulses. He had normal left foot pulses. Working with a provisional diagnosis of acute arterial embolism, the patient was commenced on a heparin infusion (bolus of 5,000 U, aPTT maintained at 60–90 s). Given the availability of the angiography suite, an urgent aortobifemoral angiogram was performed. This was performed via a puncture of the left CFA using a 4 F sheath. A pigtail catheter was passed up into the distal aorta, and digital subtraction angiography obtained of both lower limbs (Fig. 1).

The patient consequently underwent a right popliteal embolectomy. A remnant of the Angio-Seal was removed (Fig. 2). The patient's pedal pulses returned post-procedure. The heparin infusion was ceased 24 h later, and the patient discharged on aspirin and clopidogrel.

Discussion

Angio-Seal is one of a variety of vascular closure devices. It consists of a small non-thrombogenic intra-arterial anchor and extravascular collagen sponge. The puncture site is sandwiched between the anchor and an extra-arterial plug. The device has been suggested for use in vessels

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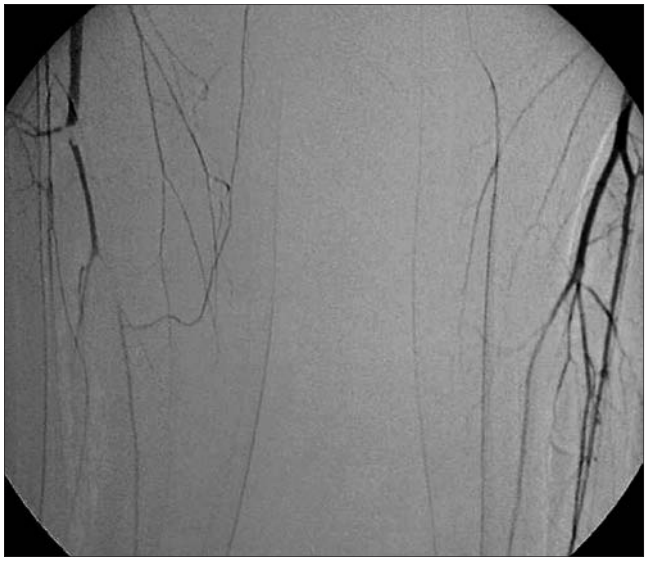

Figure 1. Angiogram showing a filling defect in the tibioperoneal trunk and also at the origin of the anterior tibial artery. Note the collateral circulation recanalizing the posterior tibial artery distally.

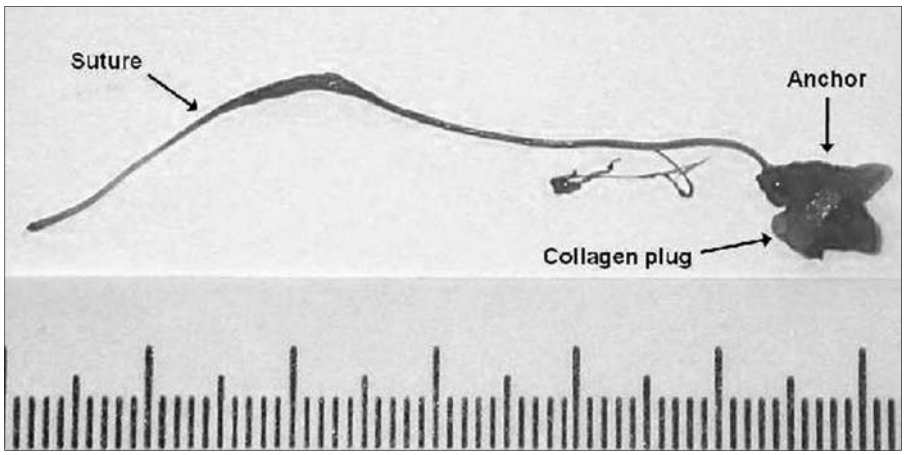

Figure 2. Remnant of Angio-Seal extracted from the right anterior tibial artery.

with minimal disease and those greater than 4 mm in diameter. Complete absorption of the device occurs between 60 and 90 days.

A number of reviews have been performed to assess the Angio-Seal device, all of which have had varying results. One of the first reviews published was that by Abando et al. (1). The study retrospectively analyzed 188 patients in whom Angio-Seal devices were deployed. The majority of the patients had a 5 F sheath inserted, and were allowed to mobilize between 58 and 219 min. The only complications were a false aneurysm and a vessel occlusion (due to the anchor lifting up an intimal plaque). The authors concluded that the Angio-Seal device was successful in almost all patients and that adverse complications could be avoided by following the manufacturer's guidelines. Goyen et al. presented a number of complications following Angio-Seal use (2). The authors claim that a total of 6400 vascular access sites were closed using Angio-Seal at their institution with a complication rate of only 0.32%. The complications they describe include thrombosis at the site of closure, embolization of part of the device and stenosis at the puncture site. Their assessment of the device revealed a small complication rate with a probable "decrease in hospital costs" due to early discharge. A study by Applegate et al. published in 2006 not only compared the use of Angio-Seal versus manual compression, but also the differences between each generation of Angio-Seal devices (3). This study assessed two groups each with 3,898 patients. The trial concluded that Angio-Seal devices were greater than 98% effective in achieving vascular closure, and also that the rates of complications were similar to that of manual compression alone. Limitations of this study include it being a non-randomized retrospective analysis. The follow-up was also only during the admission period. A prospective assessment of Angio-Seal devices was finally published by Aksoy et al. in 2006 (4). The study had a limited sample of 77 patients, but found that only 2 patients had significant complications (including a hematoma and a pseudoanuerysm). The majority of the patients had a 6 F sheath employed. The study was restricted by its size and its lack of comparative data to manual compression. In 2007, a randomized control trial was published by Upponi et al. on 100 patients (5). This trial found that there was "no significant difference in complications between manual compression and Angio-Seal", but as expected, a decreased hemostatic time. A total of 6 complications were noted in the Angio-Seal group and 7 in the compression group. It should be noted that this trial only assessed for complications up to one week post procedure. It should be stressed that for a significant difference between the two groups a much higher power (i. e., a greater number of participants) would have been required. One of the largest reviews published was in 2007 by Geyik et al. (6). This group retrospectively reviewed the placement of 1,443 Angio-Seal devices in 1,099 patients. The authors found that a small number of major complications occurred primarily in the group who had an interventional procedure performed. This group also found that the complication rate was higher in patients receiving anticoagulation (especially heparin and an antiplatelet agent). The authors concluded that the rate of complications were low and thus deemed the use of Angio-Seal as safe and effective.

A number of studies have also been performed to assess whether anticoagulation during percutaneous closure increases the risk of complications. One particular study by Exaire et al. concluded that vascular closure devices could be used safely despite "aggressive polypharmacy anticoagulation" (7). However, the type of anticoagulation is also important. Another study by the same principal investigator found that the use of glycoprotein IIb/IIIa anticoagulants were involved with a two-fold increase in complications (8). Our pa-

tient was not on this medication. The conclusions of this group are a contradiction to what was later described by Geyik et al. (6).

A thorough paper was published by Kalapatapu et al. in 2006 which provided advice on techniques for the management of complications of arterial closure devices (9). In the instance of arterial occlusion, their advice depended upon the site of occlusion. Blockage of the femoral artery at the site of puncture has been described. Their advice is that this will require operative exploration. The authors also described methods of managing embolization of a closure device. They advised that following appropriate investigations to ascertain the level of occlusion, an embolectomy should be performed. This was performed in our case.

It is interesting to hypothesize what may have lead to embolization of the device in our patient. He had healthy vessels despite being a smoker and having diabetes. The use of Angio-Seal in diseased vessels is not advised by the manufacturers, thus making smoking and diabetes a relative contraindication. Given that it was foreign material that had embolized into the patient's distal arteries, it appears almost certain only an embolectomy would have been therapeutic in this patient. One must have an index of suspicion when a patient such as this presents again following a radiological procedure.

It is apparent from our research of the literature that Angio-Seal devices have had limited assessment with well-structured randomized trials that compare it to manual compression. The consensus appears to be that they provide rapid hemostasis with a similar complication rate to manual compression. What we wish to emphasize is that major complications of their use can occur, and must be borne in mind when a patient presents again following an endoluminal procedure.

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