Case Report

A Foot Ulcer Caused by the Use of an Angio-Seal Arterial Closure Device after Percutaneous Transluminal Angioplasty: A Case Report

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Although the Angio-Seal arterial closure device is widely used for preventing bleeding and facilitating early ambulation after arterial puncture, it is also associated with unique complications, such as stenosis, occlusion, or peripheral embolism. We report the first case of a foot ulcer that developed 70 days after an Angio-Seal application. The collagen sponge component accidently positioned itself in the arterial lumen and was not absorbed. A foreign body reaction was observed microscopically. In patients with arteriosclerosis, the Angio-Seal device should be used carefully; post procedural monitoring is necessary after implantation.

Keywords: angio-seal, complication, foot ulcer

INTRODUCTION

The need for a safe, easy-to-use, and effective hemostatic device has arisen because more percutaneous endovascular procedures are being performed. The Angio-Seal arterial closure device (St Jude Medical, St Paul, MN) is widely used for sealing arterial puncture sites. This device comprises a collagen sponge, an absorbable anchor, and a connecting suture. Such arterial puncture-closing devices are thought to reduce hemostasis time and facilitate early ambulation, which potentially reduces the length of hospital stay and improves patient satisfaction.1,2) However, these devices have not been shown to reduce access site complications.1–4) Furthermore, significant complications, such as stenosis, occlusion, or peripheral embolism, may arise from the use of an Angio-Seal device; it is necessary for clinicians to be aware of these complications.3–8)

We report the case of a patient who presented with a foot ulcer that developed because of the use of an Angio-Seal device.

CASE REPORT

A 74 year-old woman presented with a right foot ulcer 70 days after percutaneous transluminal angioplasty (PTA), which had been performed at another hospital. She had been undergoing treatment for arteriosclerosis obliterans at our hospital since 4 years earlier. During this treatment period, she showed no symptoms, although her ankle brachial index (ABI) scores were 0.68 and 0.76 for the right and left ankles, respectively. When she was admitted to the hospital for chest pain, PTA performed on the right iliac artery revealed a stenotic lesion, although no significant coronary artery stenosis was observed.

The ABI score deteriorated to 0.55 for the right ankle. Angiography also revealed a severe eccentric stenotic lesion of the right common femoral artery (CFA) at the level of the previous puncture site (Fig. 1). The superficial
femoral artery was smooth, although some stenotic lesions were observed in the calf. Duplex ultrasound scanning (DUS) clearly showed a severe stenotic lesion due to an isoechoic mass (Fig. 2). This was believed to be a nonatherosclerotic stenosis. We subsequently learned that an Angio-Seal device had been used in the original PTA.

The patient was operated under local anesthesia for treating the rest pain and foot ulcer. A pronounced fibrotic reaction surrounding the groin vessels and advanced arteriosclerosis were detected. Upon opening the CFA, we observed a collagen sponge with a thrombus attached (Fig. 3). Since arteriosclerosis was pronounced, and the condition of the foreign body was unknown, the CFA was replaced by a 7 mm thin-walled, ringed, expanded polytetrafluoroethylene stretch graft. Microscopic examination of the material removed at surgery showed evidence of an amorphous foreign material consistent with remnants of the Angio-Seal together with multinucleated giant cells, which resulted from the foreign body reaction. The patient had an uncomplicated postoperative recovery. The ABI score improved to 0.68 for the right ankle, and the foot ulcer healed promptly.

**DISCUSSION**

The Angio-Seal device is widely used for preventing bleeding and facilitating early ambulation after arterial puncture.\(^1,2\) However, in terms of vascular complications, it remains controversial as to whether vascular closure devices are better than mechanical compression.\(^1-3\) In addition, peculiar complications, such as stenosis, occlusion, and peripheral embolism, may arise from the use of an Angio-Seal device, it is necessary for clinicians to be aware of these complications.\(^3-8\) Previous studies have reported that CFA occlusion due to the use of an Angio-Seal device occurred in 0.3% to 0.4% of the devices.\(^3,5\)

Several possible mechanisms for the occlusion exist. The vessels were occluded because of the following factors: (i) the anchor of the device\(^4\); (ii) its collagen sponge, which had been unintentionally deployed in the arterial lumen\(^3,6,7\); (iii) a dissected plaque underneath the device\(^3,4\); (iv) distal embolism caused by the device\(^6,7\); (v) the intimal plaque lifted up by the anchor\(^5\);
or (vi) massive periarterial and intra-arterial fibrosis.\textsuperscript{4,8}

Abando et al. recommended against the use of the Angio-Seal device in cases in which the arterial puncture site is above the inguinal ligament or below the femoral bifurcation, or in cases involving small (<5 mm) arteries or heavily diseased arteries. In the present case, arteriosclerosis was very advanced even though the artery diameter was 6 mm.\textsuperscript{5}

While most symptoms such as claudication or severe leg ischemia can appear within a few days, there are 2 reports of cases in which a delayed major complication was treated surgically. Wille et al. described a patient with leg ischemia that developed 37 days postprocedure;\textsuperscript{4} Shaw et al. reported a case in which ischemic symptoms occurred in the patient 3 months after Angio-Seal implantation.\textsuperscript{8} Here, we report the first case of a patient who developed a foot ulcer and underwent surgery 75 days after Angio-Seal implantation.

The Angio-Seal sponge is generally completely absorbed between 60 and 90 days after implantation. However, in our case, the gross appearance and microscopic evaluation confirmed that components of the Angio-Seal had not been absorbed and had incited a vigorous foreign body reaction; these factors together caused significant stenosis to the femoral artery, as was described in the report by Shaw et al.\textsuperscript{8} Although uncommon, a patient may develop a vigorous foreign body reaction, resulting in failure of resorption.\textsuperscript{4,8}

DUS can show the location and degree of atherosclerosis prior to puncture. In addition, the collagen sponge in the CFA was easily detected using DUS in our case. We recommend that both predeployment and postprocedure DUS should be performed to reduce the incidence of complications, especially in high-risk patients with small caliber (5–7 mm) and moderately calcified femoral arteries or patients with heavily diseased arteries.

Goyen et al. interventionally treated all 5 patients with Angio-Seal-associated occlusive complications.\textsuperscript{6} However, percutaneous treatment is potentially associated with embolization and difficulty in removing large fragments of debris because they are fragile and not firmly attached to the vessel wall.\textsuperscript{5,8} Therefore, in such cases, we believe that the best therapy is open surgical removal and repair of the artery. Since the extent and time course of bioabsorbability are not predictable, conservative treatment without removing the occluding material is not appropriate.

Conclusion

In the present case, the Angio-Seal device had been deployed in the heavily diseased artery by a cardiologist at another hospital. This case highlights the fact that even if the size and position of the puncture site are good, the Angio-Seal device should be used while keeping in mind the occurrence of late occlusive complication; moreover, postprocedural monitoring after implantation is necessary, especially in the cases of severe arteriosclerosis.

References

3) Dregelid E, Jensen G, Daryapeyma A. Complications

Fig. 3  On surgical exploration, a pronounced fibrotic reaction was found surrounding the groin vessels. A collagen sponge with an attached thrombus was found in the CFA.


