

Eur J Vasc Endovasc Surg 32, 504–505 (2006)

doi:10.1016/j.ejvs.2006.04.023, available online at <http://www.sciencedirect.com> on 

## SHORT REPORT

**Lower Limb Ischemic Complications after the Use of Arterial Puncture Closure Devices**

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*We report three cases of lower limb ischemia occurring after the use of arterial puncture closure devices (APCDs). In two patients, who have undergone percutaneous angioplasty of lower limb arteries, the Angio-Seal APCD led to thrombosis of the common femoral artery. In another patient who has undergone coronary angiography, this device has led to dissection of the common femoral artery. Since these observations seem to not be merely sporadic, radiologists and cardiologists as well as vascular surgeons should be aware of their possible occurrence in order to avoid these complications and to provide promptly an adequate treatment.*

*Keywords: Angio-seal; Arterial puncture closure device; Lower limb ischemia; Complication.*

**Introduction**

Transfemoral catheterization is often complicated by hemorrhage and pseudoaneurysm formation at the puncture site. In order to reduce the risk of severe bleeding at puncture site, arterial puncture closure devices (APCDs) have been developed and nowadays are largely used in clinical practice. The use of these devices, however, can result in lower limb ischemic complications as occurred in three cases herein described.

*Case 1.* A 63-year old man underwent percutaneous angioplasty of an 80% stenosis of the left popliteal artery through a 5 F sheath. Angio-Seal APCD (St. Jude Medical, St. Paul, MN, USA) was inserted into the puncture site. A groin hematoma developed and was treated by manual compression. After the procedure, enoxaparin 40 mg once a day was administered subcutaneously. The day after the procedure, claudication symptoms worsened and ankle-brachial index decreased from a preoperative value of 0.86 to 0.64.

At duplex examination, the popliteal artery was patent, but the flow in the superficial femoral artery was markedly reduced. Prompt surgical exploration of the common femoral artery disclosed the polymer bar of the APCD covered by a thrombus of 1 cm in size occluding the orifices of the profunda femoris and superficial femoral artery. A Fogarty catheter with some difficulties passed through a stenotic proximal segment of the superficial femoral artery. The arteriotomy was prolonged toward the superficial femoral artery and a femoral endarterectomy was performed. The Fogarty catheter passed easily through the popliteal artery and crural arteries. Arteriotomy was closed with a dacron patch. Postoperatively, the patient underwent twice reoperation because of bleeding. He was discharged on 10th postoperative day. One and half month after surgery claudication symptoms disappeared and ankle-brachial index was 1.04.

*Case 2.* An 85-year old woman underwent percutaneous transluminal angioplasty for a restenosis of the right superficial femoral artery. At the end of the procedure an Angio-Seal APCD was inserted into the puncture site. Three days later she was readmitted because of acute ischemia of the right leg. The ankle-brachial index was 0.34. The patient underwent a surgical exploration of the right common femoral

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artery which revealed a thrombus around the polymer bar of the APCD totally occluding the vessel. The device was removed and, after endarterectomy, the arteriotomy was closed with a dacron patch. The postoperative course was uneventful and the patient was discharged four days later. At discharge, the leg was warm and the ankle-brachial index was 0.67. However, she was readmitted because of deep groin wound infection which was debrided twice. Three months after surgery, the wound was healed and the ankle-brachial index was 0.67.

*Case 3.* A 56-year old woman underwent coronary angiography and an Angio-Seal APCD was inserted into the puncture site at the end of the procedure. Three-days after the procedure the patient was readmitted because of severe lower limb claudication. The leg was cold and ankle-brachial index was 0.56. At ultrasound an occlusion of the common femoral artery was detected. On the same day, the common femoral artery was explored and a wide dissection the vessel with thrombosis of the false lumen was observed as well as the presence of atherosclerotic plaques. The APCD was found to fix the flap and it was removed. After endarterectomy, the arteriotomy was closed with a Dacron patch. The postoperative course was uneventful, symptoms were completely relieved and the patient was discharged on the second postoperative day.

### Discussion

The real benefits of using APCD are still controversial as recent meta-analyses failed to demonstrate their superiority over mechanical compression.<sup>1,2</sup> However, these devices are increasingly used worldwide. Indeed also their related complications are increasingly observed (Table 1). In two of our patients it is likely that severe atherosclerosis of the femoral bifurcation contributed to the vessel occlusion as the plug was entrapped in a stenotic area. These observations claim for caution about the use of this device in patients with severe atherosclerotic changes of the common femoral artery and of its bifurcation. In such cases, preprocedural duplex can identify those patients at risk for ischemic complications after insertion of APCD. In the third case, the mechanism leading to dissection of the common femoral artery is more uncertain and possibly related to iatrogenic injury of the vessel during puncture and/or insertion of the APCD. It is anyway clear that this device contributed

**Table 1. Reported incidence of lower limb ischemic complications after the use of Angio-seal arterial puncture closure device**

Castelli <i>et al.</i> <sup>3</sup>	2.3% (4/175 procedures)
Thalhammer <i>et al.</i> <sup>4</sup>	0.2% (14/7376 procedures)
Mukhopadhyaya <i>et al.</i> <sup>5</sup>	4.2% (1/21 procedures)
Abando <i>et al.</i> <sup>6</sup>	0.5% (1/220 procedures)
Kirchhof <i>et al.</i> <sup>7</sup>	2.9% (10/350 procedures)
Eidt <i>et al.</i> <sup>8</sup>	1.2% (5/425 procedures)
Cremonesi <i>et al.</i> <sup>9</sup>	0.2% (1/411 procedures)
Park <i>et al.</i> <sup>10</sup>	0.1% (1/961 procedures)

to artery dissection by fixing the flap to the anterior wall of the common femoral artery.

Since these observations seem to not be merely sporadic, radiologists and cardiologists as well as vascular surgeons should be aware of their possible occurrence in order to avoid these complications and to provide promptly an adequate treatment.

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Accepted 24 April 2006

Available online 14 June 2006