Introduction

To achieve hemostasis at the arterial puncture site of a percutaneous intervention, manual or mechanical compression (MC) followed by several hours of bed rest is the classic method. Since more than a decade vascular closure devices (VCD) are used increasingly to shorten the time to hemostasis and ambulation and to improve patient comfort and satisfaction (1, 2). Complications observed with MC are access site bleeding, hematoma formation and pseudoaneurysm. Since the use of VCD's also access site infection and acute limb ischemia were noticed as specific vascular closure device related complications. There are two main types of devices: collagen plugs with or without an intraluminal anchor and percutaneous suture devices. The Angio-Seal™ device (St. Jude Medical, Minnetonka, MN, USA) consists of an intra-arterially deployed polymer anchor, a collagen sponge positioned on the outer artery wall and a self-tightening suture (see illustration); the whole system is bioabsorbed within 90 days. We were faced with four cases of severe acute onset claudication following the use of the Angio-Seal device.

Case reports

In our hospital patients needing a percutaneous transluminal coronary angioplasty (PTCA) or carotid artery stenting are referred to a teaching hospital in the region. In a five month period four of those patients visited our outpatient clinic with invalidating claudication. The symptoms occurred immediately following a percutaneous procedure performed in the aforementioned centre. In all cases hemostasis at the femoral puncture site was obtained by the use of an Angio-Seal closure device. No patient had pre-existing claudication. After presentation at our centre, all patients were investigated with ankle-brachial pressure index (ABPI) measurements in combination with treadmill exercise testing and CT-angiography (CTA), duplex examination or magnetic resonance angiography (MRA). All patients underwent an endarterectomy with Dacron patch closure. In each patient, the postoperative course was uncomplicated, symptoms disappeared and ABPI normalized.

Case 1

A 62-year old woman underwent a cardiac catheterization through the right common femoral artery (CFA) in conjunction with the placement of an implantable cardioverter defibrillator. The puncture site was closed with an Angio-Seal device. Since the procedure she experienced a cold right foot with paraesthesia and a limited walking distance. CTA showed an occlusion of the CFA. At operation three weeks after the percutaneous procedure, fibrosis covering the CFA was encountered. After arteriotomy, the distal CFA is found to be occluded by scar-like tissue, while the proximal CFA is occluded by a thrombus (Fig. 1). An endarterectomy is performed and the arteriotomy was closed with a Dacron patch. Postoperatively, palpable distal arterial pulses were present.
Case 2

A 63-year old man underwent a carotid artery stenting procedure via the right groin and an Angio-Seal was deployed at the puncture site. Immediately thereafter his walking distance was importantly impaired. Non-invasive angiography showed a short occlusion at the transition zone between the external iliac artery and the CFA. At operation the collagen plug of the Angio-Seal was found intraluminally at the level of the inguinal ligament and removed. There were no stenotic atherosclerotic lesions in the CFA.

Case 3

A fit 63-year old man underwent a PTCA and stenting through the right CFA. Access site hemostasis was achieved with an Angio-Seal closure device. During his first walk shortly after the intervention he noticed an invalidating claudication. Duplex showed a near occlusion at the transition zone between the external iliac artery and the CFA. At operation the collagen plug of the Angio-Seal was found intraluminally at the level of the inguinal ligament and removed. There were no stenotic atherosclerotic lesions in the CFA.

Case 4

A 46-year old man underwent a coronaryography in our hospital. Three days later he underwent a failed PTCA attempt. An Angio-Seal was inserted in the right groin. One week later his cardiologist referred him to our outpatient clinic. CTA revealed a near occlusion just proximal to the femoral bifurcation. ABPI at rest was 0.61 and 0.30 after exercise. At exploration six days later we encountered fibrotic tissue in front of the femoral arteries. After arteriotomy the entire closure device was found intraluminally in the distal CFA (Fig. 3) which showed no other stenotic lesions. Endarterectomy and Dacron patch angioplasty were performed.

Discussion

Vascular closure devices are increasingly used worldwide in diagnostic and therapeutic cardiac and vascular percutaneous procedures to obtain access site hemostasis. Their superiority over traditional mechanical compression in terms of overall incidence of access related complications has not been proven in meta-analyses (1, 2).

The relative risks of developing distinct local vascular complications after use of any type of closure device as compared to manual compression, found by Koreny et al. (1) in their meta-analysis, are shown in Table I. The rates of seven potential vascular complications for both AngioSeal and mechanical compression were derived by Resnic et al. (3) from pooled analysis of published randomized studies and large case series and are also listed in Table I.

Since the use of VCD’s, access site infection and lower limb ischemic complications (mostly acute
Acute Claudication Caused by Angio-Seal Closure Devices

Femoral artery occlusion or stenosis (especially with collagen plugs) are increasingly reported (4-13). Ischemic symptoms can be acute limb threatening ischemia (sometimes delayed) (7, 10-13) or acute onset severe claudication (9, 12). The reported rates of lower limb ischemic complications related to the use of Angio-Seal are summarized in Table II.

The cause of this iatrogenic complication is malpositioning of the complete device intraluminally (7, 11), intimal dissection (7, 9-12), severe local atherosclerosis (14) and puncture site in the SFA (11).

Abando et al. (14) adopted some guidelines to prevent ischemic complications. They consider a CFA diameter of less than 5 mm and a stenosis of 40% or more near the puncture site, both measured on angiographic films, as an absolute contraindication to the use of an Angio-Seal. However, these measures will not prevent inadvertent intraluminal placement of the collagen sponge nor iatrogenic intimal dissection. To minimize the risk of lifting up a posterior wall plaque by the anchor of the device, Wille et al. (10) recommend not inserting the carrier system more than 0.5 cm once blood flows from the drip hole.

Almost all authors treated the vessel occlusion by surgical means, mostly endarterectomy with patch plasty. One author reported a series of laser assisted recanalisation (15).

Surgical procedures for ischemic complications are sometimes challenging (9) and often not uneventful (10, 12).

Few reports on the cost-effectiveness of arterial closure devices have been published.

In 1996 Bos et al. (16) presented a cost-effectiveness analysis comparing a collagen closure device with manual compression based on a meta-analysis of published data. They performed a decision analysis based on a mathematic model. Their results suggested that the use of collagen closure devices might reduce the complication rate but the additional cost when using the device to avert one complication was very high (exceeding $9000). Most of the studies available at that time were about Vasoseal, a collagen plug that nowadays plays a very limited role in the market.

In 2005 Legrand et al. (17) concluded that the additional cost of Angio-Seal is justified when used in selected patients undergoing percutaneous coronary intervention (PCI).

In a recent paper, using a decision analytic model, Resnic et al. (3) stated that the routine use of the Angio-Seal STS device ($190) following PCI was associated with net cost savings ($44) compared with mechanical

**Table I**

Rates and relative risks of potential vascular complications after the use of vascular closure devices. RR = relative risk; APCD = arterial puncture closing device (of any type); RPH = retroperitoneal hematoma

<table>
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<tr>
<th></th>
<th>Resnic et al. (3)</th>
<th>Koreny et al. (1)</th>
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<tbody>
<tr>
<td></td>
<td>Compression</td>
<td>Angio-Seal</td>
</tr>
<tr>
<td>Bleeding</td>
<td>3.0%</td>
<td>1.67%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>5.65%</td>
<td>4.75%</td>
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<tr>
<td>AV-fistula</td>
<td>0.83%</td>
<td>0.20%</td>
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<tr>
<td>Pseudo-aneurysm</td>
<td>1.72%</td>
<td>0.96%</td>
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<tr>
<td>RPH</td>
<td>0.14%</td>
<td>0.32%</td>
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<tr>
<td>Limb ischemia</td>
<td>0.09%</td>
<td>0.14%</td>
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<tr>
<td>Infection</td>
<td>0.05%</td>
<td>0.33%</td>
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compression (Femostop device; $110) in their institution. Incremental costs of complications were taken into account. However, the authors question the generalizability of their analysis to other centers or devices.

We would like to make a plea for monitoring and registration of Angio-Seal related complications by all centres, as inadvertent events could be more frequent than reported in published series. Although ischemic complications are uncommon, the morbidity they cause is severe and thus they could abolish the overall benefit they offer in terms of patient satisfaction over manual compression.

References


E. Mattens
Buitenerf 89
4824 HB Breda
The Netherlands
E-mail: edwinmattens@zonnet.nl