

## Vascular Closure Device: To Close or Not To Close?

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### Abstract

Angio-Seal is a femoral arterial closure device that is commonly used following coronary angiography and angioplasty, to achieve haemostasis at the access site. It is reasonably well tolerated and is proven to improve the time to ambulation. Nonetheless they are associated with certain complications which can cause significant morbidity to the patients unless intervened in time. Here we describe details of complications that we have encountered over the last year, and discuss the evidence base with regard to the use of these devices.

**Keywords:** Angio-seal; Vascular closure device; Femoral artery; Percutaneous coronary angiography; Embolic complication

### Introduction

Over the last decade, vascular closure devices (VCD) are increasingly being used following cardiac catheterisation. They are well recognised to reduce the time to haemostasis and time to ambulation thereby reducing the length of hospital stay. Angio-Seal™ (St Jude Medical Minnetonka, USA) is a femoral arterial closure device and consists of a polymer anchor that is deployed intra-arterially, a collagen sponge that is placed on the outer wall of the femoral artery and a self tightening suture. Once the suture is tightened, the anchor and the plug compress the vascular puncture site resulting in haemostasis [1,2].

### Case 1

A 57 year old female, who presented to us with complaints of recurrent central chest pain, underwent coronary angiogram through the right femoral artery using 5 Fr Judkins catheters. The puncture site was subsequently closed using an Angio-Seal closure device. Around two weeks following the procedure the patient started experiencing paraesthesia and claudication in her right leg. Clinical examination revealed absent dorsalis pedis and posterior tibial in the affected leg. The patient then underwent a right femoral angiography which showed complete occlusion of the proximal SFA with distal reconstitution. (Figure 1, 2)

The patient was then taken for an exploratory surgery. After arteriotomy the distal CFA was found to be occluded by a thrombus which appeared to be attached to the anchor of the Angio-Seal device and the intimal layer of the vessel. She subsequently underwent CFA thrombectomy with vein patch angioplasty. Following the surgery the distal pulses returned and the patient had an uneventful recovery.

### Case 2

A 55 year old diabetic gentleman underwent an elective coronary angioplasty through his right femoral artery following complaints of exertional angina, using 5 Fr Judkins catheters. The vascular puncture site was closed using an Angio-Seal closure device. A week after his discharge the patient presented to the hospital with right groin swelling, fever, chills and rigors. Clinical examination did not reveal any evidence of distal vascular insufficiency.

An ultrasound scan of his right groin was organised which showed the presence of 2.9 cm collection in his right groin, most likely representing an abscess. (Figure 3, 4) Peripheral blood cultures confirmed *Staphylococcus aureus* bacteraemia and the patient was managed with intravenous augmentin and flucloxacillin. On the third

day after admission the abscess spontaneously burst with purulent discharge. Following this the patient started improving and he was subsequently discharged.

### Discussion

The management of the arterial access site in coronary angiography appears to have changed significantly over the recent years in favour of vascular closure devices. The evidence, with regard to their superiority over the conventional method of manual pressure however, is still debated. There are currently different types of VCDs available in the market, which can be classified based on their mechanism of action.



Figure 1: Right femoral angiography demonstrating occluded SFA

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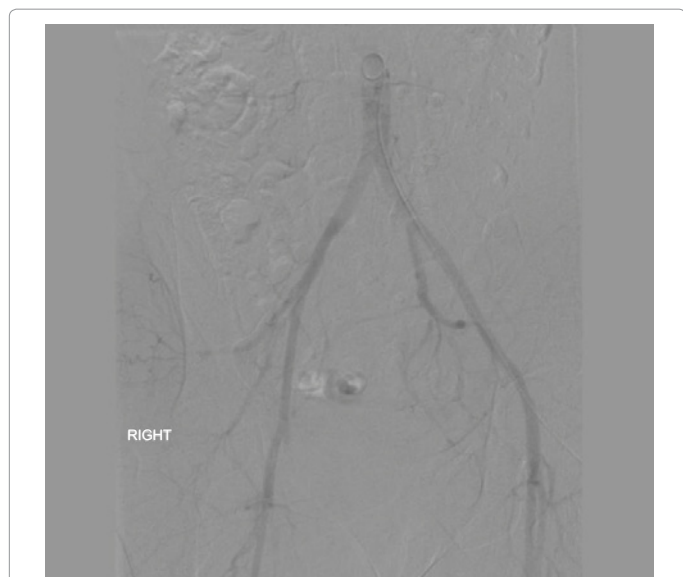


Figure 2: Right femoral angiogram with SFA occlusion and distal reconstitution.

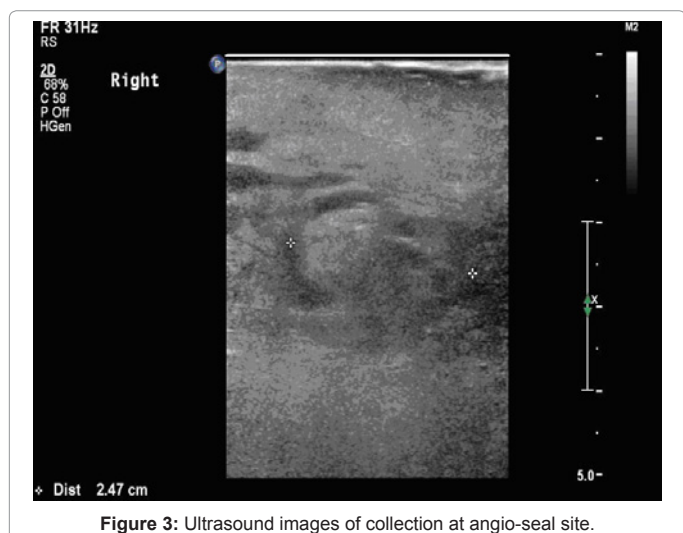


Figure 3: Ultrasound images of collection at angio-seal site.

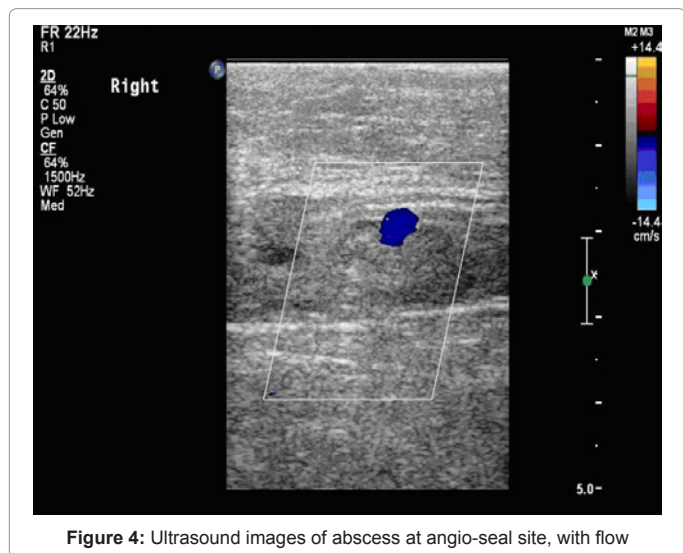


Figure 4: Ultrasound images of abscess at angio-seal site, with flow

These include the suture based devices (e.g. Perclose), sealant or collagen based (e.g. Angio-Seal) and clip or staple based (e.g. Starclose). The important complications that could be encountered with the use of VCDs include device failure, risk of infection (especially in elderly and diabetic patients), thrombotic or thrombo-embolic events, bleeding and hematoma.

Most of the studies looking at the efficacy and safety of VCDs involved devices like Angio-Seal, Vasoseal, Perclose and Starclose. One study comparing them, involved 304 patients (204 in the closure device arm and 102 in the compression arm), and showed that although the incidence of bleeding and vascular complications were higher in the device group, they did not approach statistical significance (9% vs 6%,  $p=0.397$ ). Furthermore the time to haemostasis and discharge were shorter in the VCD group ( $p<0.0001$ ) [3]. A similar finding was reported by a relatively more recent study, involving 401 patients, which noted a statistically significant reduction in the time to haemostasis and ambulation in the VCD group. The 30 days access-site related complication rates were remarkably low in both the groups in this study [4]. However, most of the pivotal studies comparing vascular closure devices and standard manual pressure comprised of small numbers and were underpowered [5]. This limitation in sample size has prompted researchers to meta-analyse the available data.

A systematic review and meta-analysis by Koreny et al., which included 30 trials with a total of 4000 patients, concluded that the effectiveness of closure devices over standard manual compression was only marginal. The researchers felt that while the methodologies for many of the trials in the analysis were poor, there was a reason for concern regarding an increased risk of hematoma and pseudoaneurysms with the VCDs [2].

In another meta-analysis Nikolsky et al. looked at 30 trials ( $n=37066$ ), and did not find any significant difference in terms of complications with the use of Angio-Seal device in patients undergoing diagnostic angiogram (OR: 1.08, CI: 0.11-10.0) and angioplasty via the femoral artery (OR: 0.86, CI: 0.65-1.12), when compared to standard manual compression. However there were significant heterogeneity in the included studies studies, and the confidence interval for these were quite wide. The meta-analysis of randomized trials on its own, showed a trend toward less complications using Angio-Seal in a PCI setting (OR 0.46, 95% CI 0.20 to 1.04;  $p=0.062$ ), however it did not approach statistical significance. On the other hand when only studies with intention to treat were included VCDs were associated with an increased risk of hematomas (RR: 1.80, 95% CI: 1.13-3.15) and pseudoaneurysm (RR: 5.40 95% CI: 1.21-24.5) [6].

A recent cost effectiveness study by Resnic et al. using a decision analytical model, showed that the routine use of Angio-Seal device post PCI in their institution was associated with 44\$ net cost savings per person [7,8]. However it is worth noting that any evaluation of the merits of vascular closure devices should also take into account a trend in the gradual reduction of vascular complications post angiography that has been noted over the last few years [9]. It's also worth noting that VCD trials do not usually include high risk patients, which in turn has resulted in a lengthy list of do's and don'ts that are associated with the use of these devices (Table 1).

Although there are no adequately powered studies available that can directly compare the different makes of VCDs, results from the meta-analysis suggest that while Angio-Seal and Perclose reduced the major complications, Vasoseal was associated with an increased risk of vascular complications. It is worth noting that there are significant

Indications, warnings and precautions with Angio-Seal insertion [5,10]	
Indication	Precaution
Diagnostic angiogram	On warfarin
Percutaneous intervention	If undergoing thrombolysis
Femoral arterial access	If punctured through vascular graft
8 French or smaller for 8F sheath	Uncontrolled hypertension (> 180 mm of Hg)
6 French or smaller for 6F sheath	Pre-existing auto-immune disorders
<b>Warning: not for use if</b>	Small femoral artery (< 4mm diameter)
Superficial femoral artery (SFA) or Profunda Femoris Artery (PFA) insertion	Pregnancy or lactation
Inserted above the inguinal ligament	Allergic to beef, collagen, polyglycolic or polylactic acid products
Posterior wall puncture	Anaemia (Hb: < 10 mg/dl) Or platelet < 100,000
Inserted at or distal to PFA, SFA bifurcation	Bleeding disorders including thrombasthenia, von WilleBrand's disease
<b>Contra-indication:</b> none mentioned	

**Table 1:**

variations in the study protocols and operator experience amongst these studies, which should be taken into account before interpreting these results.

While considering the role of VCDs it would be important to consider the benefit of radial access in coronary catheterization. Considering the superficial location of the artery, hemostasis can be achieved relatively easily, thereby reducing the risk of access site bleeding complications and avoiding the need for expensive vaso-occlusive devices. The patient can start ambulating almost immediately after the procedure and hence the hospital stay requirement is much shorter. From the patient's perspective, it is more convenient and acceptable. On the other hand radial access is technically more difficult and requires operator experience. There is also a small risk of radial arterial occlusion [11].

While, most of the recent studies have shown that vascular closure devices improve the time to hemostasis and ambulation following coronary catheterisation via a femoral approach, the evidence regarding a reduction in vascular complication post procedure is lacking. With the rising popularity of radial approach for vascular access, and the continuing fall in the incidence of vascular complications, the use of vascular closure device may have reached peak. However it is worth noting that vascular closure device remains an effective tool to achieve hemostasis in patients with low risk factors, following coronary angiogram or angioplasty.

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