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Complications with the use of Angio-Seal vascular closure device and their management

Mohd Shariq[1], Krishna Prasad Bellam Premnath[1], Ahmed Tarek Saleh[1], Julian Coker[2]

Departments of [1]Clinical and Interventional Radiology, [2]Vascular Surgery, Queens Hospital, Romford, United Kingdom.

***Corresponding author:**
Mohd Shariq,
Department of Clinical and Interventional Radiology, Queens Hospital, Romford, United Kingdom.

m.shariq01@gmail.com

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ABSTRACT

Vascular closure devices (VCDs) are being increasingly used for achieving hemostasis after diagnostic and therapeutic endovascular procedures. Although uncommon, complications may be encountered which are associated with the use of these VCDs. We report four cases where the use of Angio-Seal (Terumo, Somerset, New Jersey, USA) was followed by complications. Three cases presented with acute limb ischemia, among them, two patients had arterial occlusion at the vascular access site and one patient had embolization of the footplate anchor of the closure device. One case presented with pseudoaneurysm at the common femoral artery access site along with occlusion at origin of the superficial femoral artery. We have described the mechanism in which these complications occur and the successful management of these cases preventing potential amputation and limb loss. The risk factors which increase the risk of complications with the use of Angio-Seal VCD were reviewed and the strategy to avoid these complications with particular emphasis on the utility of ultrasound when using Angio-Seal VCD is discussed. A strategy to manage these complications has been discussed while deciding on endovascular management or surgical management, especially in patients with challenging presentation and those with multiple comorbidities making them at very high risk for surgery.

Keywords: Vascular closure devices, Angio-Seal, Endovascular, Acute limb ischemia

INTRODUCTION

Various methods available for achieving hemostasis at the arterial access site for endovascular procedures include manual compression, surgical closure, and the use of vascular closure devices (VCDs). Manual compression followed by 6–8 h of bedrest was the method of achieving hemostasis before the routine use of VCDs. The access site complications with manual compression includes bleeding, hematoma, and pseudoaneurysm formation. With the use of VCDs, there is a small risk of infection and acute leg ischemia due to mechanisms specific to the closure device.

The various closure devices in use include Angio-Seal (Terumo, Somerset, New Jersey, USA), Perclose Prostyle and Starclose (Abbott Vascular, Chicago, USA), Mynx control and Exoseal (Cordis medical, Florida, USA). Angio-Seal is one of the most commonly used closure devices. It consists of a copolymer absorbable anchor, collagen plug, and suture. The design of the Angio-Seal makes it easier to use with a short learning curve and provides predictable and effective hemostasis at the access site; however, the intra-arterial anchor/footplate sometimes can result in inadvertent complications.

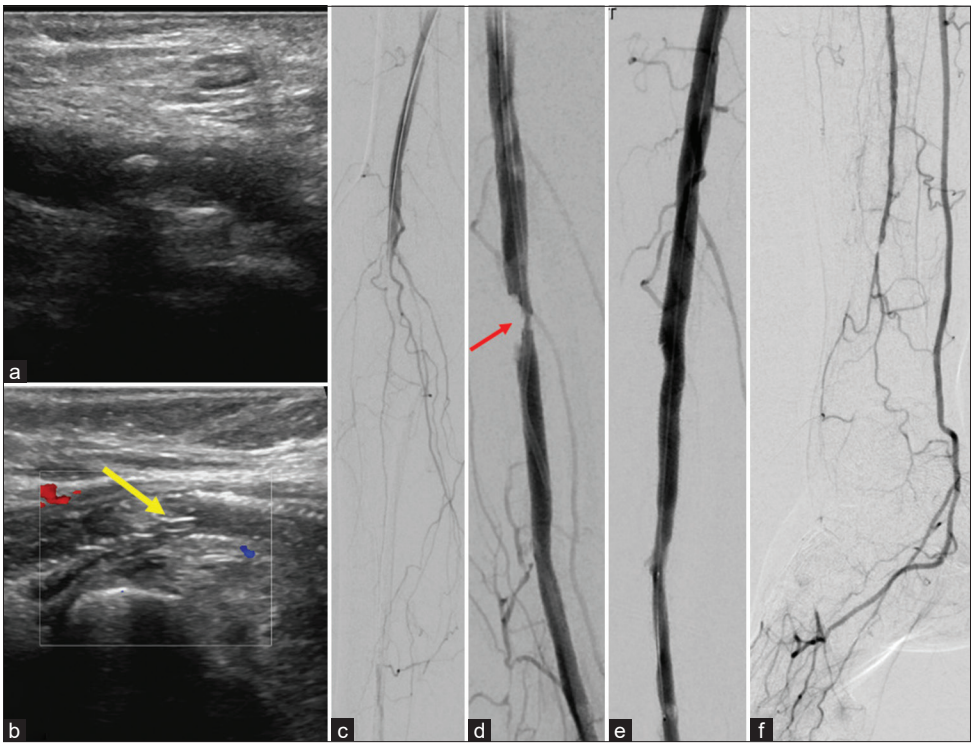

Figure 1: A 72-year-old lady who underwent right leg thrombolysis (a) Common femoral artery access site with calcified atherosclerotic plaques on anterior and posterior walls. (b) Embolized footplate seen as echogenic structure (Yellow arrow) within the popliteal artery stent with acute thrombosis. (c) Right leg angiogram showing complete thrombosis of popliteal artery stent. (d) Post 24-h thrombolysis resolution of thrombus with filling defect (red arrow). (e) Post-stenting angiogram showing good flow across the popliteal artery with no stenosis. (f) Distal right leg angiogram showing good flow to foot through posterior tibial and peroneal arteries. The anterior tibial artery is chronically occluded.

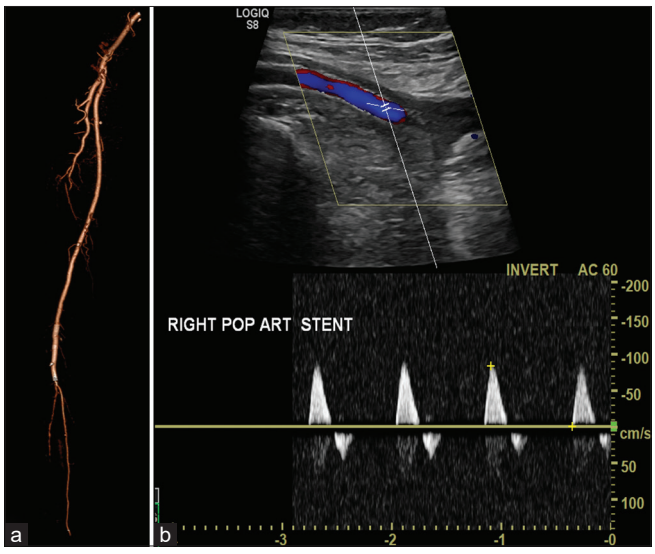

Figure 2: A 72-year-old woman who underwent right leg thrombolysis developed rethrombosis due to embolized footplate which was managed with endovascular intervention. Follow-up imaging (a) Computed tomography angiogram showing patent right popliteal artery stents. (b) Ultrasound Doppler showing good flow across the right popliteal artery stent with no in-stent stenosis.

CASE 1

A 72-year-old lady, chronic smoker with Type 2 diabetes, ischemic heart disease, and interstitial lung disease, with previous right popliteal artery/tibioperoneal trunk stenting done presented with acute limb ischemia and stent thrombosis. She underwent successful catheter directed thrombolysis. A 6 Fr Angio-Seal was used for access site closure [Figure 1a shows right CFA access site with calcified plaques] and she was discharged. She presented with acute limb ischemia after 7 days, the limb was cold with increased capillary refill time. A computed tomography (CT) angiogram suggested rethrombosis of the right popliteal artery stent. An ultrasound Doppler revealed embolized footplate of Angio-Seal trapped in the popliteal artery stent with thrombosis [Figure 1b]. The possibility of embolectomy was discussed among the interventional team and vascular surgery; however, the presentation was after 7 days and the footplate anchor was within the stent so it was decided to do a repeat thrombolysis and consider a distal infrapopliteal bypass in future. A 6 Fr antegrade access of the right proximal superficial femoral artery (SFA) was taken; in post 24-h thrombolysis, there was persistent severe narrowing

at proximal end of the popliteal artery stent which did not respond to angioplasty; hence, another short Supera (Abbott Vascular, Chicago, USA) stent 5.5 mm × 40 mm was placed [Figure 1c-f]. She was restarted on aspirin and apixaban, clopidogrel was also added for 3 months. Follow-up at 6 weeks and 6 months has been done; she is asymptomatic with patent right popliteal artery stents [Figure 2].

CASE 2

A 61-year-old man, chronic smoker, hypertensive, treated prostate cancer and bladder cancer, and pelvic irradiation underwent bilateral common iliac artery stenting; on the left SFA, retrograde 6 Fr access was taken, which was closed with Angio-Seal; however, ultrasound revealed severe narrowing at the closure site with slow flow distal to it. An urgent vascular surgical opinion was obtained, as the access site was SFA, it was decided to attempt endovascular recanalization. A 6 Fr antegrade access of the left common femoral artery (CFA) was taken and the narrowing could be crossed with a guidewire, angioplasty with 6 mm balloon was not successful; hence, a Viabahn (GORE, Newark, USA) 6 mm × 50 mm stent graft was placed across the narrowing with good result [Figure 3]. A follow-up ultrasound Doppler after 3 months revealed patent iliac and left SFA stents with resolution of clinical symptoms.

CASE 3

A 63-year-old lady underwent a cerebral angiogram with 6 Fr right CFA access. A 6 Fr Angio-seal device was used for hemostasis, in post-procedure, her right leg was cold and distal pulses were not palpable. CT angiogram revealed occlusion in the right CFA at the access site [Figure 4a and b]. She was taken for an urgent surgical endarterectomy and the footplate was retrieved from the CFA [Figure 4c and d]. Follow up color Doppler ultrasound revealed good flow across the common femoral artery [Figure 4e].

CASE 4

A 66-year-old lady with multiple comorbidities – dementia, diabetes, hypertension, and chronic kidney disease –

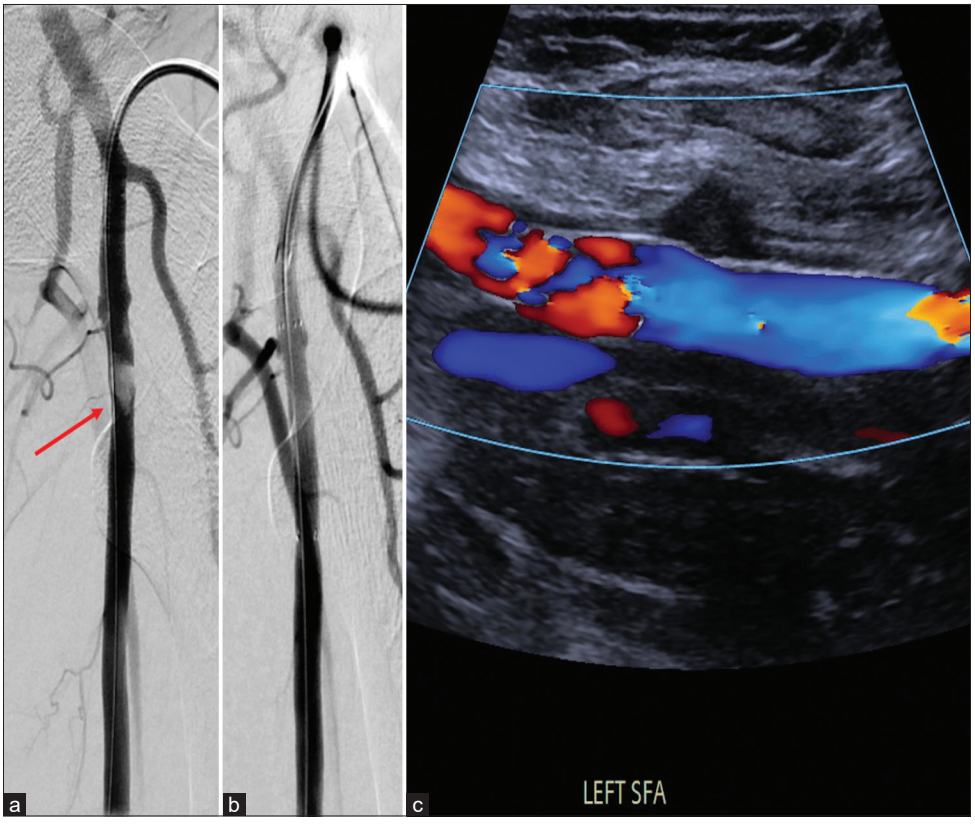

Figure 3: A 62-year-old man underwent bilateral iliac stenting and had left access site arterial occlusion following Angio-Seal deployment (a). Left leg angiogram showing filling defect in the proximal superficial femoral artery (Red arrow). (b). Post-stenting (6 mm × 50 mm) angiogram showing good flow across the proximal superficial femoral artery. (c). Follow-up ultrasound Doppler at 3 months showing patent stent with good flow, the hypoechoic area possibly represents fibrotic reaction to the Angio-Seal device components.

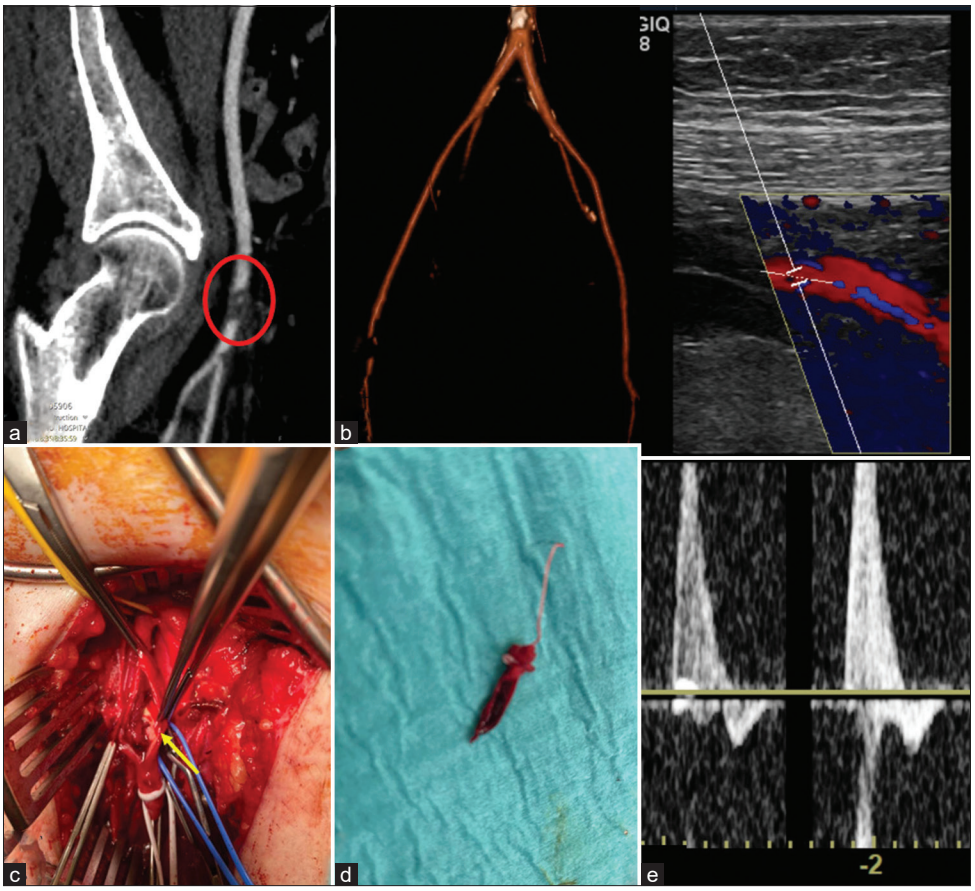

Figure 4: A 63-year-old woman developed right common femoral arterial occlusion following Angio-Seal deployment (a and b) Right leg computed tomography angiogram showing focal occlusion (Red circle) in common femoral artery (CFA). (c and d) Surgical endarterectomy (Yellow arrow) and retrieval of the Angio-Seal device. (e) Follow-up ultrasound Doppler showing patent right CFA with good flow.

underwent successful angioplasty of the right leg [Figure 5a] for an infected foot ulcer. She had unsuccessful closure of the right CFA access with Angio-Seal and manual compression had to be given. On follow-up, there was severe narrowing in the previously patent proximal SFA and pseudoaneurysm at the CFA access site. The pseudoaneurysm was treated with ultrasound-guided percutaneous thrombin injection [Figure 5b and c] and an angioplasty was planned for the proximal SFA stenosis [Figure 5d] considering her multiple comorbidities; however, she succumbed to severe lower gastrointestinal hemorrhage before the repeat angioplasty.

DISCUSSION

Closure devices are being increasingly used to achieve hemostasis at the access site for various endovascular procedures. The main advantages of using a closure device include achieving quick hemostasis, operator convenience, patient comfort, early mobility, same day discharge facilitating faster patient turnover, and thus reducing hospitalization costs.[1] However, the rate of complications and patient safety is reportedly similar for VCDs compared with manual compression.[2] The various closure devices available are classified as active approximators (involve physical closure of arteriotomy site, e.g.: Starclose, Perclose Proglide), passive approximators (deploy plug/sealant/gel at arteriotomy site, e.g.: Angio-Seal, Exoseal, Mynx), and external hemostatic devices (involve application of external pressure). None of the devices is proved to be clearly superior to others and there is learning involved before clinical use of these devices; however, some studies have reported better rates of successful hemostasis with the use of Angio-Seal. Perclose Prostyle has the main advantage of being approved for closure of large arteriotomies up to 21 French (maximum 26 Fr outer diameter) using preclose technique which is particularly useful for percutaneous endovascular aneurysm repair and transcatheter aortic valve repair. Due to the unique design and mechanism, sometimes, complications specific to the closure device can be encountered. There is a small risk of infection with the use of closure devices with this being reported from 0.2% to 0.6%.[1,3] The other complication sometimes encountered is acute limb ischemia

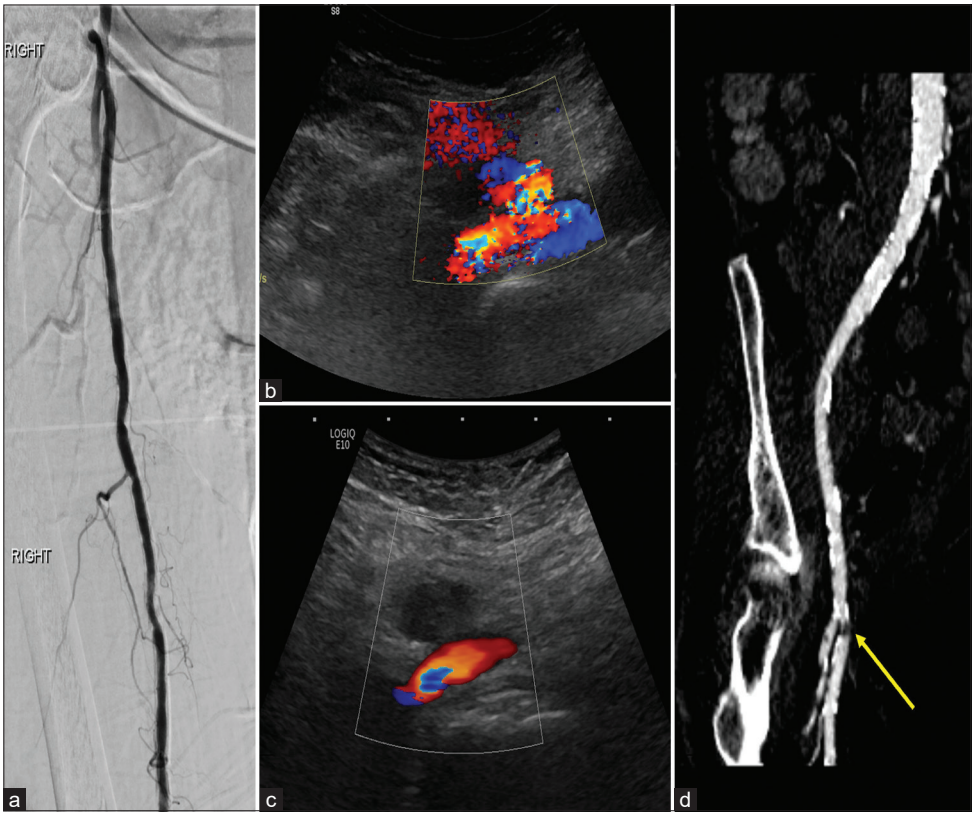

Figure 5: A 66-year-old woman underwent right leg angioplasty and developed common femoral artery (CFA) pseudoaneurysm. (a) Right leg angiogram showing patent superficial femoral artery origin. (b) Post-angioplasty ultrasound (US) Doppler revealed pseudoaneurysm arising from the CFA. (c) Thrombosed pseudoaneurysm following US-guided thrombin injection. (d) Computed tomography angiogram showing resolution of pseudoaneurysm with occlusion at previously patent superficial femoral artery origin (Yellow arrow).

which can be due to severe narrowing at the arterial closure site, vessel thrombosis at the access site due to intravascular deployment of the device, focal arterial dissection, and distal embolization of the device.[4,5]

The Angio-Seal device consists of three bioabsorbable components: Copolymer anchor which stays against the inner wall of the artery at access site, collagen plug at the outer surface of artery, and a suture that approximates these to form a seal. As proven in previous studies, Angio-Seal is a safe and effective closure device with low complication rates,[6] however, there can be complications encountered in arteries with calcific plaques especially when these plaques are on the posterior wall of the artery adjacent to the vascular access site and resulting in luminal narrowing. A study evaluating 188 femoral artery closures with Angio-Seal suggested that Angio-Seal should not be used if the vessel diameter is <5 mm or if there is stenosis of 40% or more near the puncture site.[7] The study by Siani *et al.* identified obesity, diabetes, severe atherosclerotic disease near access site, bigger access sheath size, and increase in procedure time as risk factors for ischemic VCD-associated complications.[8]

In our cases, the mechanism of complications was reviewed and it was considered that the obstruction to withdrawal of the anchor by posterior plaques prevented the optimal deployment of the device. In Case 1, the footplate embolized distally which could have been due to additional anterior wall calcification and lack of compaction of the collagen plug. In Cases 2 and 3, the intravascular deployment resulted in occlusion of the artery at the access site while in Case 4, the footplate was caught in the SFA due to calcified stenosis near its origin.

The calcified plaques can hold onto the footplate of the device and result in intravascular deployment of the device resulting in acute occlusion. Sometimes, attempts to forcibly retract the device against such plaques can also result in lifting up of the plaque resulting in a focal dissection flap. These instances can be avoided using the Angio-Seal under continuous ultrasound guidance. In our experience, Angio-

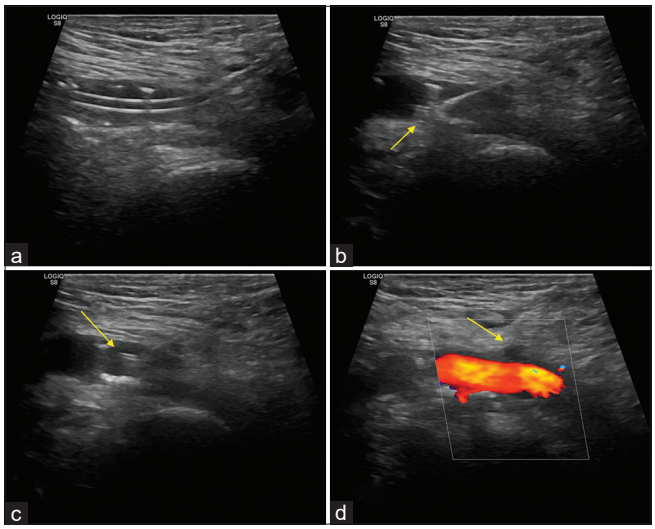

Figure 6: A 76-year-old man who underwent left leg angioplasty – Maneuver to avoid complications using ultrasound during Angio-Seal deployment. (a) Common femoral artery (CFA) with vascular sheath showing multiple calcified plaques. (b) Angio-Seal device footplate obstructed due to calcified plaque on posterior wall of artery. (c) Rotating the device 180° and withdrawing it followed by rotating back to neutral position thus avoiding intravascular deployment. (d) Ultrasound Doppler showing successful hemostasis with patent CFA access site.

Seal should not be used when there is a significant calcified posterior plaque adjacent to the vascular access site and other closure devices or manual compression should be used. Furthermore, if Angio-Seal is being used and simultaneous ultrasound while pulling back on the device shows that the anchor/footplate is obstructed by a plaque then rotating the device by 180°, withdrawal of device till the footplate crosses the distal margin of the plaque and turning the device back to neutral position helps avert the complications [Figures 6a-d].

However, if still there is a complication, then further management depends on clinical presentation, timing of presentation, site of occlusion, and patient comorbidities. Acute occlusion due to intravascular deployment at the CFA site should be treated by endarterectomy.[4,8] If the patient is at very high risk for endarterectomy, then this can be managed with endovascular approach, angioplasty is usually not successful at treating acute occlusions and stenting is required. Although it was thought that stenting across the hip joint may result in stent fracture and occlusion recent studies have concluded that CFA stenting can be safely performed without any significant increase in risk of stent fracture.[9,10] If the patient presents late with CFA occlusion or stenosis, that is the stage when the device is resorbed and there is fibrosis then treatment can be surgical (endarterectomy requiring patch angioplasty) or endovascular (angioplasty) after discussion in a multidisciplinary meeting.[11] Distal embolization is unique to Angio-Seal device and is a rare complication. There is a report where endovascular retrieval has been attempted successfully;[12] however, embolectomy is more predictable and likely to have higher chances of successful retrieval of the device.[13,14] The site where the footplate usually lodges after embolization is the popliteal artery or tibioperoneal trunk, these are more likely to be symptomatic and have an early clinical presentation. If detected early, these should be treated with surgical embolectomy, while for a delayed presentation angioplasty can be done. Case 1 presented a unique clinical scenario where the footplate had embolized into the stent in distal popliteal artery/tibioperoneal trunk and the patient presented after 1 week. Hence, anticipating the technical difficulty of retrieving the footplate from within a stent and some inflammation with early fibrosis around the anchor, this was treated with an endovascular approach with a satisfactory outcome.

CONCLUSION

VCDs are widely used as they provide high operator convenience, and patient satisfaction with better utilization of hospital resources. Use of ultrasound while using Angio-Seal can help avoid ischemic complications and also recognize these early. Ischemic complications can be managed with surgical or endovascular approach depending on clinical presentation, timing of presentation, site of occlusion, and patient comorbidities.

Declaration of patient consent

Patient's consent not required as patient's identity is not disclosed or compromised.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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