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Central Pseudo-Aneurysm Formation Following Arterial Closure with a StarClose SE Device: When a StarClose Doesn't Completely Close

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
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Conflict of interest: None declared

Patient: Male, 77
Final Diagnosis: Femoral artery pseudoaneurysm
Symptoms: None
Medication: —
Clinical Procedure: Cardiac catheterization and coronary stenting with Starclose vascular closure
Specialty: Interventional Cardiology

Objective: Educational Purpose (only if useful for a systematic review or synthesis)

Background: Vascular closure devices (VCDs) are frequently used for hemostasis with endovascular procedures by employing sutures or plug devices (using collagen or hydrogel) or through the use of a metal clip made of nickel and titanium, such as the StarClose SE device. In comparison to manual compression (MC), VCDs are associated with earlier time to discharge and ambulation, improved patient comfort, and better cost-effectiveness.

Case Report: A 77-year-old man with history of ischemic cardiomyopathy with non-ST segment elevation myocardial infarction (NSTEMI) underwent diagnostic cardiac catheterization with deployment of a StarClose SE vascular closure device for hemostasis. Upon repeat access 4 days later for coronary intervention, retrograde sheath angiography revealed a pseudo-aneurysm emanating from the center of the StarClose clip.

Conclusions: A review of the literature shows VCDs to be non-inferior to MC, with an overall high success rate. Major and minor complications rates are comparable to those with MC, and pseudo-aneurysm is an infrequent complication.

MeSH Keywords: Aneurysm, False • Coronary Angiography • Diagnostic Techniques, Cardiovascular • Endovascular Procedures • Vascular Access Devices

Full-text PDF: http://www.amjcaserep.com/abstract/index/idArt/896587

Background

Femoral arterial hemostasis after cardiac catheterization can be achieved through manual compression (MC), mechanical compression, or vascular closure devices (VCDs).

Although VCDs have been shown to be non-inferior to MC with respect to access site hemostasis and complications, MC is still considered the standard traditional method [1]. Use of VCDs avoids the need to interrupt anticoagulation, improves patient comfort, provides faster time to ambulation and discharge, and reduces healthcare burden by freeing staff resources [2]. The literature shows pseudo-aneurysm formation with StarClose vascular closure device to be infrequent. In deciding which method to use for arterial closure – MC versus VCD – one must take into account numerous factors, from patient characteristics to the site of arterial puncture, to minimize VCD-related complications.

Case Report

A 77-year-old man with history of ischemic cardiomyopathy with left ventricular ejection fraction 20-25% and atrial fibrillation was transferred to our hospital after cardiac arrest. He was noted to have positive troponins and was diagnosed with NSTEMI. Anticoagulation was started with a loading dose of aspirin 325 mg and Plavix 600 mg with maintenance dose of 81 mg and 75 mg, respectively, along with intravenous heparin infusion. After stabilization, cardiac catheterization was performed via a right femoral approach due to limited radial arterial access, revealing multi-vessel coronary artery disease with a syntax score of 16. Hemostasis post-procedure was achieved with a StarClose SE device with no post-deployment oozing or delayed hemostasis. He was felt to be at extreme surgical risk and was referred for high-risk percutaneous coronary intervention (PCI). Again, right femoral arterial access was obtained and a 6F sheath was introduced. PCI was performed with the placement of 4 drug-eluting stents: 1 in the proximal LAD, 1 in the ramus intermedius, and 2 in the first obtuse marginal. Prior to PCI, retrograde sheath angiography was performed to evaluate the access site for hemostasis and suitability for closure.

The femoral arterial cannulation site was noted to be approximately 2 cm cranial to the prior access site closed with the StarClose SE device (Figure 1A). Retrograde sheath angiography revealed the previously deployed StarClose clip with a 0.5-cm pseudo-aneurysm (PSA) emanating from its center (Figure 1B).

As the pseudo-aneurysm was small, the decision was made to achieve hemostasis and to treat the pseudo-aneurysm simultaneously by applying manual pressure for hemostasis.

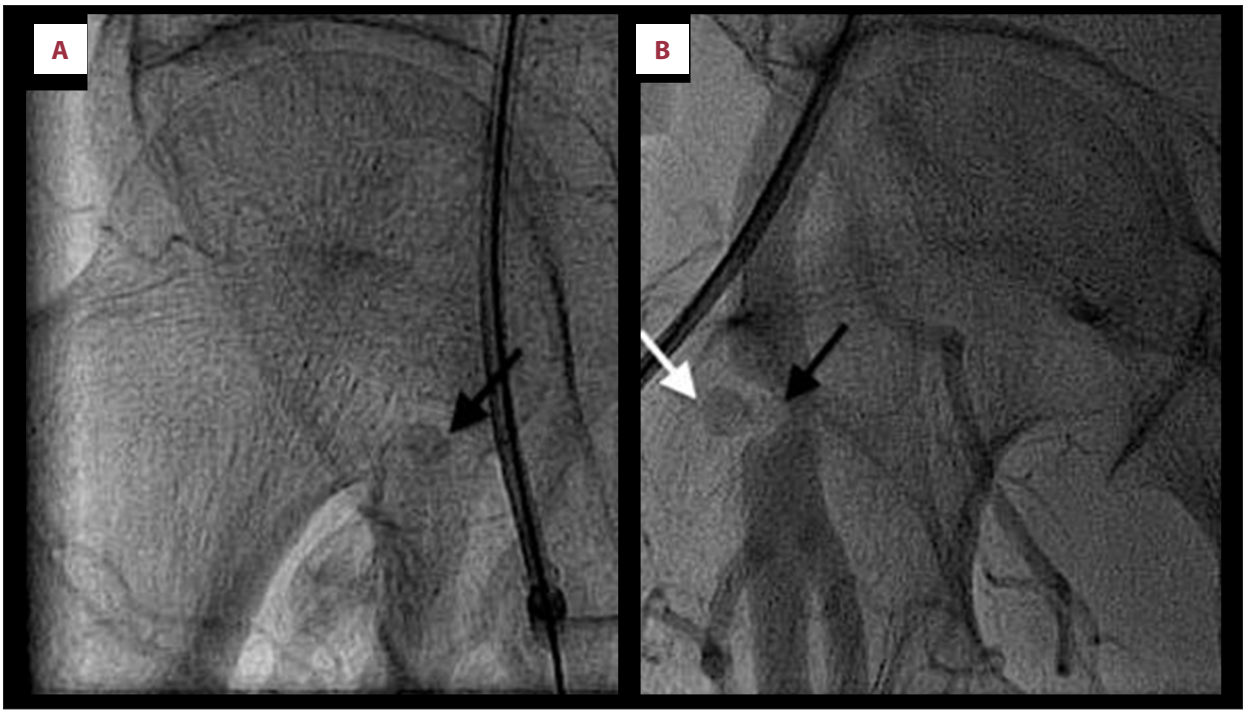

Figure 1. Right femoral X-ray (**A**) and femoral artery arteriogram (**B**) showing StarClose nitinol clip (black arrow) at the common femoral artery level approximately 2 cm distal to the initial cannulation site with a 0.5-cm pseudo-aneurysm (white arrow) emanating centrally through the StarClose clip.

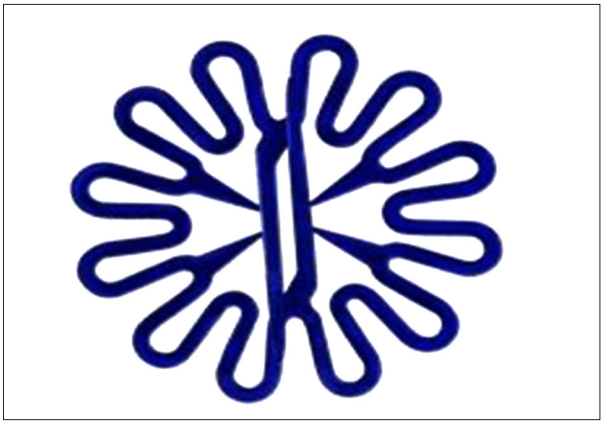

Figure 2. The 4-mm StarClose nitinol clip attached extravascularly at the femoral arterial puncture site.

There was no post-compression bleeding, oozing, or other post-procedure complication.

Discussion

The StarClose device (Abbott Vascular, Abbott Park, IL) is a 4-mm circular nitinol clip that is deployed at the arterial puncture site, drawing the edges of the arteriotomy together for closure (Figure 2). Complications associated with the device as published in trials, case reports, and database searches have revealed PSA occurrence to be infrequent. Johnson et al. reported major and minor complications with StarClose SE device in a 16-month period, using the Manufacturer and User Facility Device Experience (MAUDE) database. A total of 1118 device complications were reported, which included: failure to achieve hemostasis (409; 36.6%), inability to complete deployment sequence (268; 24%), entrapped deployment device (224, 20%), clip not being deployed (151, 13.5%), late bleeding or oozing from dermatotomy site (25, 2.2%), vessel occlusion (19, 1.7%), retroperitoneal hematoma (12, 1.1%), PSA (6, 0.4), and death (4, 0.4%) [4]. Other case reports have reported bleeding requiring transfusions, vascular injury requiring repair, ipsilateral lower extremity ischemia, vessel occlusion requiring stenting, re-access catheter entrapment requiring surgical extraction, and ipsilateral deep venous thrombosis [3–7].

The StarClose SE device has shown comparable results to MC in many trials. In the pivotal CLIP trial, StarClose was non-inferior to MC with respect to major complications and with successful access site closure of 100% and 98.9% in patients undergoing diagnostic and interventional procedures, respectively. There were fewer incidences of minor complications and reduced times to discharge, ambulation, and hemostasis in the StarClose arm [8]. In addition, no PSA or arterial-venous malformations (AVM) were reported. An ultrasound substudy of the CLIP trial assessed patency of the femoral artery and determined access site complications with use of duplex ultrasonography in a prospective fashion. No difference in access site complications was found, and both groups maintained vessel patency without PSA, AVM, hematoma, vessel stenosis, or thrombosis [9]. A systematic review of 34 randomized controlled trials including 14401 total subjects comparing complications, overall cost, and time to hemostasis, discharge, ambulation, and quality of life was reported by Cox et al. comparing MC and all VCDs. Procedural success for all VCDs was 95.7%, with a reduced time to hemostasis, ambulation, and discharge for both diagnostic and interventional procedures. Complication rates were similar between the 2 groups but varied depending upon the device used. Upon surveying patients, 94.45% of patients preferred VCD for future angioplasties, and a 13% reduction in overall costs was reported due to reduced use of staff resources and earlier time to discharge [10].

Many recent trials have shown similar results when evaluating the safety and efficacy of MC with the StarClose SE device. Tavris et al. reported StarClose to be 1 of 4 VCDs demonstrating significantly lower bleeding or vascular complications compared to MC controls [11]. An analysis of anterograde and retrograde femoral access in more than 1000 consecutive peripheral angioplasty procedures reported the overall hemostasis success rate to be 93.9%, with overall major and minor complications rates to be 0.3% and 5.3%, respectively [12]. Williams et al. reported closure of anterograde punctures with the StarClose device following infrainguinal endovascular interventions to be successful in 94.6% of 212 patients. The reasons for failure were device failure in 5, obesity was 1, groin scarring in 2, and uncertain cause in 4 patients [13]. Ratnam et el prospectively compared StarClose with MC and the collagen plug-based Angio-Seal device, with significantly more StarClose patients requiring additional MC to achieve hemostasis; however, the incidence of major complications was lowest with StarClose patients (1.9%) *vs.* Angio-Seal (2.9%) and was the greatest with MC (3.7%) [14]. The StarClose device has been associated with increased post-deployment oozing, but it is successfully deployed in most patients and has a lower incidence of major complications than MC.

Pseudoaneurysm formation after StarClose clip deployment is an extremely infrequent occurrence. The initial multicenter randomized CLIP Study evaluating major and minor complications in 208 diagnostic and 275 interventional patients at 17 centers in the U.S. reported no post-procedure PSAs [15,16]. The subsequent prospective RISE study, following 171 patients for post-procedure 30-day complications and early time to ambulation with StarClose device in cardiac and peripheral vascular procedures reported only 1 patient with PSA [17].

Risk factors that increase incidence of PSA include: use of anti-platelet agents (aspirin and Plavix), anticoagulation, large

sheath size (>8F), age over 65 years, obesity, poor post-procedural compression, simultaneous artery and vein catheterization, hypertension, peripheral arterial disease, hemodialysis, complex interventions, and low- or high-grade punctures at external iliac or superficial or deep femoral artery level [18]. PSA is a rare occurrence with StarClose, but further risk can be decreased by careful patient population selection.

The treatment of PSA after cardiac catheterization is dependent upon size and associated complications. A PSA of less than 1.8 cm may thrombose spontaneously in the absence of anticoagulation and antiplatelet agents. Rupture is the most feared complication of PSAs and is seen more commonly with size greater than 3 cm, symptoms, a large expanding hematoma, or infection, which can lead to septic emboli. The most common treatment modalities are ultrasound-guided compression (USGC) repair, ultrasound-guided thrombin injection (UGTI), and surgical repair. UGTI seems to be the most common modality but has an average time to occlusion of about 33 min, with a range of 10 to 120 min, and is associated with patient discomfort and prolonged staff resource utilization [19]. A prospective study by Paschalidis et al. reported MC to be as successful and more cost-effective in treating PSA when compared with USGC, although the success rate may be lower in the presence of anti-coagulation, 95% versus 86% [20]. Surgical intervention is reserved for PSAs at vascular anastomosis sites, of mycotic origin, causing compression of underlying structures, including claudication, neuropathy, critical limb ischemia, neuropathy, or skin necrosis [21]. Currently, there are no studies demonstrating the most effective way to treat PSA caused by VCDs, and this field requires further research.

Conclusions

The StarClose SE closure device has a success rate of achieving hemostasis approaching 97% [2]. We present a case report with an interesting radiographic image of a pseudo-aneurysm emanating from the center of the StarClose clip. The small pseudo-aneurysm was successfully treated with manual compression.

Pseudo-aneurysm is an infrequent occurrence with the StarClose clip device. However, it can still occur, even with optimal access and closure technique.

Conflict of interest

The authors declare that there is no conflict of interest.

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