

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

Sehrish Memon*, Timothy C and Ball

Department of Cardiovascular Medicine, Carilion Roanoke Memorial Hospital, Roanoke, Virginia

Abstract

Vascular closure devices are frequently used for hemostasis during endovascular procedures by employing sutures, plug devices (using collagen or hydrogel) or through the use of a metal clip made of nickel and titanium as with the StarClose device. We present a case where a StarClose SE vascular closure device (VCD) was deployed for hemostasis post diagnostic cardiac catheterization and upon repeat access, four days later for coronary intervention, retrograde sheath angiography revealed a pseudo-aneurysm emanating from the center of the StarClose clip.

Review of literature indicates StarClose to be safe and effective in achieving hemostasis in majority of endovascular procedures and the incidence of pseudo-aneurysm to be infrequent.

Keywords: Access site management; Vascular closure devices; Complications; Endovascular procedures

Introduction

Femoral arterial hemostasis post 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 [1], MC is still considered the gold standard for achieving hemostasis. The 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]. In deciding the method of arterial closure, MC versus VCD, one must take into account numerous factors including the site of arterial puncture to minimize VCD related complications.

Case Description

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 post cardiac arrest.

He was noted to have positive troponins and was diagnosed with NSTEMI. He was treated with aspirin 81mg, a loading dose of plavix of 600 mg with subsequent maintenance dose of 75 mg and 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 four drug-eluting stents: one in the proximal LAD, a second in the ramus intermedius, and two 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 canulation site was noted to be approximately 2 cm cranial to the prior access site closed with the StarClose device (Figure 1A). Retrograde sheath angiography revealed the previously

deployed StarClose clip with a 0.5 cm pseudo-aneurysm 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.

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

Discussion

The StarClose device (Abbott Vascular Abbott Park, Illinois) is

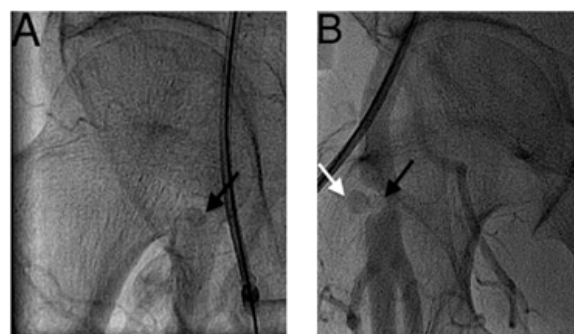


Figure 1: Right femoral X-ray (panel A) and femoral artery arteriogram (panel B) showing StarClose nitinol clip (Black arrow) at the common femoral artery level approximately 2cm distal to initial canulation with a 0.5cm Pseudo-aneurysm (white arrow) emanating centrally through the StarClose clip.

*Corresponding author: Dr. Sehrish Memon, 3113H Honeywood Lane Roanoke, Virginia 24018, Tel: 540-293-1096; E-mail: smemon24@gmail.com

Received September 09, 2015; Accepted September 21, 2015; Published September 28, 2015

Citation: Memon S, Timothy C, Ball (2015) Central Pseudo-Aneurysm Formation Following Arterial Closure with a StarClose SE Device: When a StarClose Doesn't Completely Close. Angiol 3: 158. doi:10.4172/2329-9495.1000158

Copyright: © 2015 Memon S, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.



Figure 2: 4mm Starclose nitinol clip attaches extra-vascularly at the femoral arterial puncture site.

a 4mm circular nitinol clip that is deployed at the arterial puncture site drawing edges of arteriotomy together for closure (Figure 2). Complications associated with the StarClose device as published in trials, case reports and compiled through databases such as the Manufacturer and User Facility Device Experience (MAUDE) collectively include; failure to achieve hemostasis, inability to complete deployment sequence, entrapped deployment device, clip not being deployed, late bleeding or oozing from dermatotomy site, bleeding requiring transfusions, vascular injury requiring repair, ipsilateral lower extremity ischemia, vessel occlusion requiring stenting, re-access catheter entrapment requiring surgical extraction, retroperitoneal hematoma, pseudo-aneurysm, hematoma of ≥ 6 cm and or ipsilateral DVT [3-7].

Review of literature indicates StarClose to be a safe and effective modality in achieving hemostasis when directly compared to MC and other VCDs. Tavis et al., reported StarClose to be one of four VCD's demonstrating significantly lower bleeding or vascular complications than MC control [8]. 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 [9]. Williams et al., reported closure of anterograde punctures with StarClose device following infrainguinal endovascular interventions to be successful in 94.6% of 212 patients. The reasons for failure was device failure in 5, obesity was 1, groin scarring in 2 and uncertain cause in 4 patients [10]. Ratnam et al., prospectively compared Starclose with MC and collagen plug based angio-seal device, showing significantly higher number of starclose patients requiring additional manual compression to achieve hemostasis, however the incidence of major complications was lowest with StarClose patients (1.9%) vs angioseal (2.9%) and greatest with MC (3.7%) [11]. Although StarClose may be associated with increased post-deployment oozing, it is successfully deployed in majority of the patients and has a lower incidence of major complications in comparison to MC.

Pseudo-aneurysm formation post 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 U.S reported no pseudo-aneurysms post-procedure [12,13]. 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 one patient with pseudo-aneurysm formation [14]. A more recent study utilizing the MAUDE database identified 1,118 total complications with StarClose with the

complication of pseudo-aneurysm being reported in only 6 patients [4].

The use of anti-platelet agents (aspirin and plavix), anticoagulation, large sheath size ($>8F$), age >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 have all been associated to increase the risk of pseudo-aneurysm formation [15]. Therefore, although pseudo-aneurysm is a rare occurrence with StarClose, further risk can be decreased by careful patient selection.

Conclusion

The StarClose 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 StarClose clip device and despite optimal access and closure technique it can still occur.

References

1. Schulz-Schüpke, Helde S, Gewalt S, Ibrahim T, Linhardt M, et al. (2014) Comparison of Vascular Closure Devices vs. Manual Compression After Femoral Artery Puncture The ISAR-CLOSURE Randomized Clinical Trial. *JAMA* 312: 1981-1987.
2. Schwartz BG, Burstein S, Economides C, Kloner RA, Shavelle DM, et al. (2010) Review of Vascular Closure Devices. *J Invasive Cardiol* 22: 599-607.
3. Abbott Vascular (2015) <http://www.abbottvascular.com/us/products/vessel-closure/starclose-se.html>
4. Johnson DT, Durack JC, Fidelman N, Kerlan RK, LaBerge JM (2013) Distribution of reported Star Close SE vascular closure device complications in the manufacturer and user facility device experience database. *J Vasc Interv Radiol* 24: 1051-1056.
5. McTaggart RA, Raghavan D, Haas RA, Jayaraman MV (2010) Star Close Vascular Closure Device: Safety and Efficacy of Deployment and Reaccess. in a Neurointerventional Radiology Service. *AJNR Am J Neuroradiol* 3174: 1148-1150.
6. Stefanczyk L, Elgalal MT, Szubert W, Grzelak P, Szopiński P, et al. (2013) Posterior wall capture and femoral artery stenosis following use of StarClose closing device: diagnosis and therapy. *Cardiovasc Intervent Radiol* 35: 1416-1419.
7. Varghese R, Chess D, Lasorda D (2009) Re-access complication with a Starclose device. *Catheter Cardiovascular Interv* 73: 899-901.
8. Spiliopoulos S, Katsanos K, Karnabatidis D, Diamantopoulos A, Nikolaos C, et al. (2011) Safety and efficacy of the StarClose vascular closure device in more than 1000 consecutive peripheral angioplasty procedures. *J Endovasc Ther* 18: 435-443.
9. Tavis DR, Wang Y, Jacobs S, Gallaresi B, Curtis J, et al. (2012) Bleeding and vascular complications at the femoral access site following percutaneous coronary intervention (PCI): an evaluation of hemostasis strategies. *J Invasive Cardiol* 24: 328-334
10. Williams RE, Angel CY, Bourkaib R, Brenot P, Commeau P, et al. (2007) Multicenter safety and efficacy analysis of assisted closure after antegrade arterial punctures using the StarClose device. *J Endovasc Ther* 14: 498-505.
11. Ratnam LA, Raja L, Munneke GJ, Morgan RA, Belli AM, et al. (2007) Prospective nonrandomized trial of manual compression and Angio-Seal and Starclose arterial closure devices in common femoral punctures. *Cardiovasc Intervent Radiol* 30: 182-188.
12. Dauerman HL, Applegate RJ, Cohen, DJ (2007) Vascular Closure Devices. The Second Decade. *J Am Coll Cardiol* 50: 1617-1626.

13. Hermiller JB, Simonton C, Hinohara T, Lee D, Cannon L, et al. (2006) The StarClose vascular closure system: Interventional results from the CLIP study. *Catheter Cardiovasc Interv* 68: 677-683.
14. Burke MN, Hermiller J, Jaff MR (2012) Star Close vascular closure system (VCS) is safe and effective in patients who ambulate early following successful femoral artery access closure--results from the RISE clinical trial. *Catheter Cardiovasc Interv* 80: 45-52.
15. Webber GW, Jang J, Gustavson S, Olin JW (2007) Contemporary Reviews in Cardiovascular Medicine: Contemporary Management of Postcatheterization Pseudoaneurysms. *Circulation* 115: 2666-2674.