Vascular Access Site Management

Can vascular access site complications be reduced?

BY "LISA" HUNG YU, MD, MBA; BENJAMIN W. STARNES, MD, FACS; JEAN STARR, MD, FACS; AND FRANK R. ARKO, MD

The introduction of vascular closure devices (VCDs) in the early 1990s ushered in a new era of vascular access management. Since then, VCDs have become widely used in both diagnostic and interventional procedures as an alternative to manual compression (MC). Today, up to 50% of diagnostic and interventional procedures in the US incorporate a VCD at the end of the catheterization.[1] Despite this trend, there is still a lack of large-scale, randomized, clinical trials to prove superiority or inferiority of VCD compared with MC. The advantage of using a VCD is reduced time to hemostasis, particularly in the setting of anticoagulation, leading to earlier ambulation and shortened length of hospital stay.[2,3] VCDs have also been reported to improve patient satisfaction and provide a potential cost savings.[4,5]

Vascular access site complications are the major cause of morbidity after arteriotomy for catheterization.[6,7] The frequency of access site complications ranges from 1.5% to 9%.[2,8,9] This variability is due to inconsistent reporting standards, variations in patient risk profile, and mixed populations of diagnostic and interventional procedures. Recent studies with newer generations of VCDs have shown a decrease or lack of a significant difference in vascular complications when compared to MC, suggesting a trend toward continued improvement in safety profile.[10,11]

RISK FACTORS AND PREDICTORS

The common risk factors and predictors for complications include old age, diabetes, female gender, low body surface area or morbid obesity, uncontrolled hypertension, high level of anticoagulation, large sheath size, location of the arteriotomy, and vessel calcification.[3,6,7,10,12,13] Vascular access-site complications can be minimized with increased physician awareness of risk factors and knowledge of failure associated with specific methods of closure. Accurate access predicts effective hemostasis. Certain other measures, such as ultrasound-guided access and proper assessment of femoral angiography, have been beneficial in reducing vascular access site complications.[1,14]

We reviewed several cases with vascular complications that might have been minimized or avoided by either choosing the right method of hemostasis: MC or the most appropriate VCD based on the patient's risk profile, the type of treatment, and the physician's level of experience; or by implementing a policy of ultrasound-guided access before intervention.

CASE REPORTS

Case 1

A 66-year-old obese woman underwent coronary angiography for evaluation of chest pain. This demonstrated normal anatomy of the coronary vasculature without intervention. A 6-F sheath was utilized. After the procedure, MC was held for 30 minutes. Two hours later, the patient became hypotensive with a large right-groin hematoma. Continued compression was held. The patient continued to be hypotensive, and vascular surgery consultation was obtained. Surgical exploration of the right groin was performed to evacuate the hematoma. The hematoma measured 12 cm X 10 cm X 6 cm with extension into the retroperitoneal space. A small arteriotomy was present on the anterior surface of the right common femoral artery just under the inguinal ligament. A single 6–0 polypropylene suture was used to repair the arteriotomy. The wound was irrigated and closed over a drain. The patient was hospitalized for 4 days after the procedure for wound care. She ultimately recovered completely.

Case 2

A 54-year-old man underwent bilateral iliac stent placement via both groins for progressive bilateral calf claudication. The left femoral access site was closed with the StarClose device (Abbott Vascular, Santa Clara, CA) and the right side with the Angio-Seal device (Figure 1). Initially, his symptoms resolved. However, 10 days later, he

developed short-distance right-thigh claudication. There was an excellent right external iliac pulse above the inguinal ligament, but there was no femoral pulse more distally.

The patient was taken to the endovascular suite where an aortography and right-leg runoff was performed via the left femoral artery (Figure 2). Diffuse, irregular plaque was found throughout the common femoral artery with a small filling defect in the proximal portion, consistent with an intraluminal Angio-Seal device. An incision was made in the right groin, and a femoral endarterectomy and patch angioplasty was performed. The Angio-Seal was removed and examined. The "anchor" portion was found to be partially folded, and the collagen plug was also intraluminal. This occluded the remainder of the already stenotic lumen.

Case 3

A 67-year-old man underwent PCI with a 6-F sheath managed with the StarClose device. The device was deployed by a catheter laboratory technologist. Two hours after the procedure, the patient complained of severe right lower-extremity pain and had decreased sensation and motor function in the right foot. No palpable or Doppler signals were appreciated below the level of the groin, and there was a strongly palpable pulse in the right femoral artery.

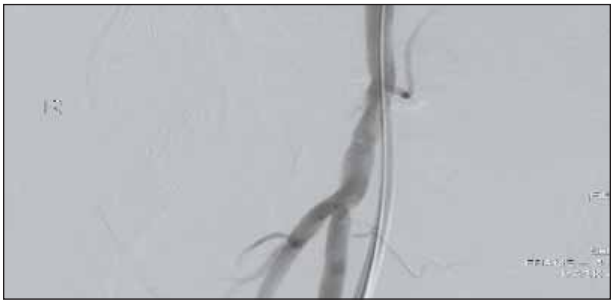

Figure 1. Angiogram before Angio-Seal (St. Jude Medical, Inc., Minneapolis, MN) deployment.

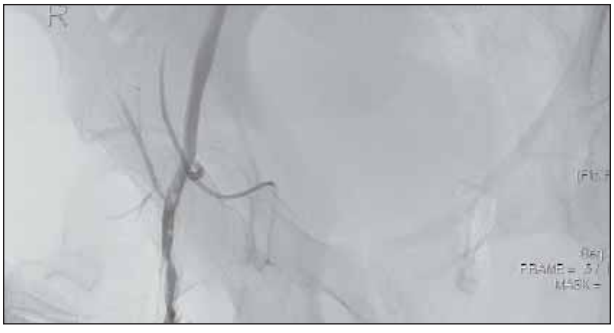

Figure 2. Angiogram 10 days after closure and immediately before surgical intervention with femoral endarterectomy.

The patient was taken to the operating room where he underwent right common femoral artery exposure (Figure 3). Upon opening the artery, the StarClose clip was noted to have closed the artery from front to back by grabbing a portion of plaque along the posterior wall (Figure 4). Endarterectomy and patch angioplasty were performed, and the patient recovered uneventfully.

Case 4

A 70-year-old man underwent uncomplicated totally percutaneous infrarenal aortic aneurysm repair. The arteriotomy was closed using 10-F single Prostar devices (Abbott Vascular) in each femoral access. The Prostar devices were deployed in a "preclose" fashion in which the device was deployed in the femoral artery before upsizing to sheath sizes as large as 24-F inner diameter. The sutures were then secured at the end of the procedure, and the arteriotomy was closed after removal of the sheath over a wire.

The patient was discharged home on postoperative day 1 and returned to the emergency department 2 days after discharge. He noted the acute onset of left scrotal pain after getting up to walk and presented with a large scrotal hematoma (Figure 5). After urgent exploration and transfusion of blood, the Prostar suture in the left groin was noted to have penetrated the inferior border of the inguinal ligament, thus anchoring the inguinal ligament to the femoral artery during closure (Figure 6). This eventually tore through the femoral artery during movement and caused this hemorrhagic complication.

DISCUSSION

Vascular complications related to VCDs may be broadly classified into three categories: hemorrhagic, occlusive, and infectious complications.[7] Hemorrhage is the most common complication, with retroperitoneal hemorrhage being infrequent albeit potentially fatal.[3,7] Occlusive complications range from claudication to acute occlusion and limb-threatening ischemia. The reported incidence for ischemia is <2.1%.[3,15] Infectious complications range from 0% to 1.9%.[15] The majority are local infections that are medically managed and do not require surgical intervention. Sohail et al reviewed retrospectively 46 cases in the medical literature and six cases referred to the Division of Infectious Diseases at Mayo Clinic. Mycotic pseudoaneurysm (22 cases) was the most common complication, and all patients underwent surgical debridement. They concluded that the infections associated with percutaneous VCD placement is uncommon but is an extremely serious complication.[16] However, we do not believe Sohail's report is typical in clinical practice in terms of the high complication and intervention rate. One explanation

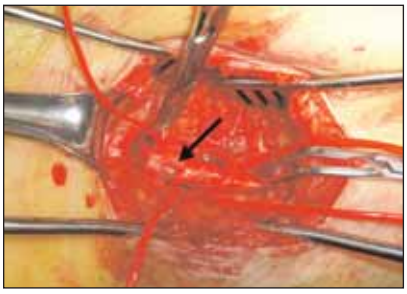

Figure 3. Right common femoral artery exposed with the patient's leg to the right demonstrating the StarClose clip on the anterior surface of the common femoral artery (arrow).

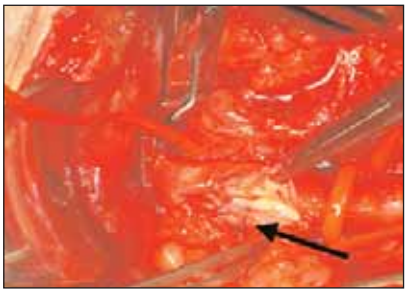

Figure 4. Operative photograph showing the StarClose clip penetrating the anterior wall of the common femoral artery and into plaque along the posterior portion of the common femoral artery (arrow).

Figure 5. Acute scrotal hematoma 3 days after totally percutaneous aneurysm repair. Notice the steri-strips overlying the access sites.

is when the patient is referred to an infectious division, the case is usually severe and more complicated. Overall, based on our reviews of currently published articles in peer-reviewed journals, in general, complications are not significantly different between MC and VCD.[12,13,17,18]

MC typically requires 15 to 30 minutes of sustained pressure over the puncture site followed by 4 to 6 hours of bed rest. This prolonged immobilization is often a source of patient discomfort and dissatisfaction. Because of that, low compliance in some patients might increase vascular complications. MC might also not be suitable for patients with a nonideal location of vascular access, as seen in case 1. The most likely cause of this complication was a high stick with inability to hold pressure on the vessel while it was cannulated under the inguinal ligament. Proper cannulation of the common femoral artery is critical to successful hemostasis management. This is especially true in patients with morbid obesity. Significant hemorrhage can occur even with the use of a small sheath. The arteriotomy was small, but due to its location, MC was inadequate in obtaining hemostasis. The use of ultrasound guidance, especially in the obese patient, may help to decrease this complication in these types of patients.

Some patients who return for a repeat catheterization are mostly concerned about the length of time required to remain flat in bed after the procedure. As the number of catheterization procedures continues to rise, the importance of safe and efficient vascular access management techniques cannot be overemphasized. VCD use has had a major impact on improving patient comfort and satisfaction. Almost every study published has shown reduced time to hemostasis and early ambulation. A deployment of a VCD versus MC allows reduction in hospitalization time, leading to significant cost savings due to decreased personnel and infrastructure demands.[4,5] There is no best VCD for all patients, nor is MC ideal for all patients.

Occlusion seems to be reported more frequently in patients with smaller vessel size or with significant luminal compromise, such as described in the Angio-Seal case. Studies reported that female gender, diabetes, and small body surface area predicted significantly small vessel size.[3,18] In case 2, the use of intravascular VCD in such patients should also raise concerns of a higher potential complication rate.[3,8,16] Choosing which closure device, if any, to employ at the completion of percutaneous femoral access should be based on the findings of a femoral angiogram. The artery should be of adequate size and free from significant disease, and the puncture site should be in the common femoral artery. In addition, undue force should not be used when deploying the Angio-Seal. The consequence could be an intraluminal collagen plug or more simply, a folded anchor, which could obstruct flow in a normal artery resulting in delayed thrombosis. In our opinion, based on experience, this type of complication can be minimized by avoiding placement of intraluminal closure devices like the Angio-Seal in arteries <5 mm in diameter or in vessels with significant luminal compromise. The instructions for use for the Angio-Seal cite a minimum lumen diameter of 4 mm. Collagen-medicated devices can also induce a late proliferative reaction that may lead to inflammatory reaction and scar formation, which might hamper future surgical access.[3]

Like most other medical devices, there is a device-specific learning curve for VCDs. It might require 20 or more patients before accomplishing a low failure rate and consistent results.[1] In case 3, we concluded that this complication occurred due to excessive application of forward pressure during deployment of the StarClose clip. The return of any patients' pulse examination to baseline must be confirmed after any endovascular procedure using a closure device. If this does not occur, aggressive investigation as to why the pulse examination

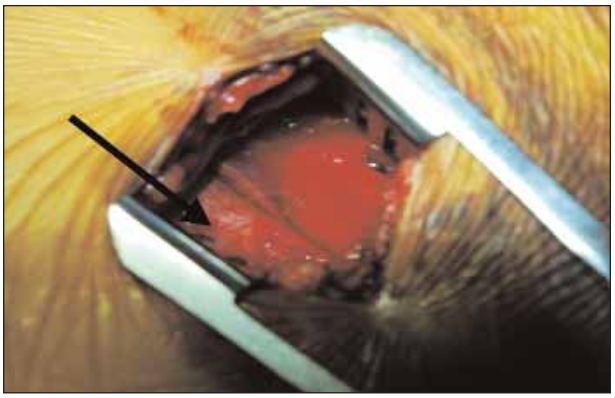

Figure 6. Operative exploration of the left groin revealing suture through the inguinal ligament (arrow) and into the femoral artery. The patient's left leg is at 2 o'clock.

has changed must be done to prevent limb loss.

The most common vascular access site for cardiac catheterization is the common femoral artery. An arteriotomy below the distal common femoral bifurcation or above the most inferior border of the inferior epigastric artery increases the risk of access-site complications as presented in case 1 and case 4. This is true whether a VCD or MC is utilized. It is imperative for access to be achieved accurately in the common femoral artery. When using a preclose technique, it is essential to be as close (or as low) to the femoral bifurcation as possible. This avoids involvement of the inguinal ligament in the closure as described in the first case. Dr. Starnes and colleagues has implemented a policy of ultrasound-guided access for each of these procedures. They were able to decrease their complication rate with ultrasound-guided access from 7% to 0% and conversion rate from 7% to 1.2%. Technical success went from 94% to 98%.[19] It is important to understand that these types of hemorrhagic complications can occur long after hospital discharge and can potentially be fatal.

CONCLUSION

Vascular access site complications can be minimized with physician awareness of risk factors and predictors of failure associated with specific methods of closure. With the number of catheter-based procedures rising and increased pressure on requirements for the ensurance of patient safety and operator efficiency, there is a need for vascular access management guidelines. ■

"Lisa" Hung Yu, MD, MBA, is from Indiana University, Kelley School of Business in Bloomington, Indiana. She has disclosed that she holds no financial interest in any product or manufacturer mentioned herein. Dr. Yu may be reached at (713) 539-5605; drlisayu@yahoo.com.

Benjamin W. Starnes, MD, FACS, is Associate Professor and Chief, Division of Vascular Surgery, University of Washington School of Medicine, and Chief of Vascular and Endovascular Surgery, Harborview Medical Center in Seattle, Washington. He has disclosed that he is a paid consultant to Abbott Vascular. Dr. Starnes may be reached at starnes@u.washington.edu.

Jean Starr, MD, FACS, is Director of Endovascular Services, The Ohio State University Medical Center, and Assistant Professor of Clinical Surgery, Division of Vascular Surgery, Ohio State University, in Columbus, Ohio. She has disclosed that she holds no financial interest in any product or manufacturer mentioned herein. Dr. Starr may be reached at (614) 293-8536; jean.starr@osumc.edu.

Frank R. Arko, MD, is Chief, Endovascular Surgery, Associate Professor, Department of Surgery Division of Vascular and Endovascular Surgery UT Southwestern Medical Center in Dallas, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Arko may be reached at (214) 645-0533; farko@mednet.swmed.edu.

1. Turi ZG. Overview of vascular closure. Endovasc Today. 2006;5:40-46.
2. Korey M, Riedmuller M, Nikfardjam M, et al. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization. Systematic review and meta-1analysis. J Amer Coll Cardiol. 2004;291:350-357.
3. Van Den Berg JC. A close look at closure devices. J Cardiovasc Surg. 2006;47:285-295.
4. Resnic FS, Arora N, Matheny M, et al. A cost-minimization analysis of the Angio-Seal vascular closure device following percutaneous coronary intervention. Am J Cardiol. 2007;99:766-770.
5. Rickli H, Unterweger M, Sutsch G, et al. Comparison of costs and safety of a suture-mediated closure device with conventional manual compression after coronary artery interventions. Cathet Cardio Interven. 2002;57:297-302.
6. Aggarwal K, Murtaza M. Commentary: vascular closure device complications: the case is not closed yet. J Invas Cardiol. 2004;16:251-251.
7. Kalapatapu VR, Ali AT, Masroor F, et al. Techniques for managing complications of arterial closure devices. Vasc Endovasc Surg. 2006;40:399-408.
8. Ratnam LA, Raja J, Munneke GJ, et al. Prospective nonrandomized trail of manual compression and Angio-Seal and StarClose arterial closure devices in common femoral puncture. Cardiovasc Invert Radiol 2007;30:182-188.
9. Arora N, Matheny ME, et al. A propensity analysis of the risk of vascular complications after cardiac catheterization procedures with the use of vascular closure devices. Am Heart J. 2006;153:606-611.
10. Kim MC. Vascular closure devices. Cardiol Clin. 2006;24:277-286.
11. Sanborn TA. Can vascular closure devices reduce complications? Future Cardiol. 2006;2:655-658.
12. Nikolsky E, Mehran R, Halkin A, et al. Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures. A meta-analysis. J Am Coll Cardiol. 2004;44:1200-1209.
13. Tavris DR, Gallauresi BA, Lin B, et al. Risk of local adverse events following cardiac catheterization by hemostasis device use and gender. J Invas Cardiol. 2004;16:459-464.
14. Sherev DA. Angiographic predictors of femoral access site complications: implication for planned percutaneous coronary intervention. Cathet Cardiovasc Interv. 2005;65:a96-202.
15. Boston US, Panneton JM, Hpfer JM, et al. Infectious and ischemic complications from percutaneous closure devices used after vascular access. Ann Vasc Surg. 2003;17:66-71.
16. Sohail MR, Khan AH, Holmes DR Jr, et al. Infectious complications of percutaneous vascular closure devices. Mayo Clin Proc. 2005;80:1011-1015.
17. Applegate RJ, Sacrinty MT, Kutcher MA, et al. Propensity score analysis of vascular complications after diagnostic cardiac catheterization and percutaneous coronary intervention 1998-2003. Cath Trend Cardiovasc Interv. 2006;67:556-562.
18. Katz SG, Abando A. The use of closure devices. Surg Clin N Am. 2004;84:1267-1280.
19. Arthurs ZM, Starnes BW, Perry J, et al. Ultrasound-guided access improves rate of access-related complications for totally percutaneous aortic aneurysm repair. Paper presented at: Annual meeting of the Peripheral Vascular Surgical Society; February 1-3, 2008; Snowmass, CO. Vascular Surgery. In press.