Vascular Closure Devices for Antegrade Punctures: The Evidence is Mounting

Sahil A. Parikh, MD, FACC, FSCAl

Division of Cardiology, Department of Medicine, Columbia University Medical Center/NY Presbyterian Hospital and the Columbia University College of Physicians and Surgeons, New York, New York.

ne of the key aspects of any endovascular procedure centers upon successfully gaining percutaneous vascular access. In fact, from a safety standpoint, perhaps equally important is the ability to achieve hemostasis upon procedural completion. Common femoral arterial access has historically been the primary site for diagnostic and therapeutic peripheral vascular procedures. The incidence of access-site complications, primarily bleeding and arterial injury requiring intervention (eg, pseudoaneurysm, access-site occlusion, arteriovenous fistulae) have continued to occur with finite and reproducible probability in the range of 1%-5%.1 The introduction and refinement of vascular closure devices (VCDs) were intended to improve the safety of vascular closure; however, this has been difficult to prove in a host of large studies. 1-3 Nevertheless, VCDs are frequently utilized to enhance patient comfort by accelerating the time to hemostasis (TTH), time to ambulation (TTA), and time to discharge (TTD).1,2

Peripheral arterial disease (PAD) remains one of the primary risk factors for the development of an access-site complication, likely reflective of the presence of obstructive atherosclerosis at or near the puncture site making the achievement of hemostasis via VCD or manual compression (MC) difficult. And, despite the higher risk, the use of VCDs in peripheral arterial intervention has continued to grow as we emphasize the rapidity of turnover and same-day discharge in different venues of vascular care.² When facing particularly complex infrainguinal PAD, interventionists frequently resort to antegrade common femoral artery puncture to better improve the probability of successfully crossing and treating complex disease, especially in the setting of critical limb ischemia. Historically, hemostasis at these access sites was achieved with the use of MC alone. However, over the years, several VCDs have been evaluated in investigator-initiated studies for the purpose of closing antegrade punctures, generally with significantly higher complication rates including bleeding.⁴⁻⁸

The VASCADE Vascular Closure System has been approved by the United States Food and Drug Administration for the closure of arterial (2013) and more recently (2018) venous access sites. In the pivotal RESPECT trial, patients undergoing arterial interventions who received VASCADE as part of their hemostasis strategy experienced TTH of approximately 5.5 minutes, TTA of 5.0 hours, and TTD of 6.8 hours. In this edition of *Vascular Disease Management*, Walker et al report a prospectively collected registry of 52 patients with closure of an antegrade common femoral artery access site with the Vascade device. Five centers enrolled patients from January to August of 2017, with 94% of

patients achieving complete follow-up to study completion. The data demonstrate that nearly all patients were systemically anticoagulated for interventions, more than half with unfractionated heparin and a large percentage with bivalirudin. And, despite this complex cohort of patients, only 1.9% had a major or minor complication, which is a relatively low rate in this difficult patient population. Moreover, TTH of 5.9 minutes, TTA of 4.9 hours, and TTD of 6.0 hours was observed. These are comparable and frequently numerically better compared with those observed in the RESPECT trial when retrograde puncture was performed. As such, the use of the VASCADE closure device in carefully selected patients during peripheral vascular intervention with an antegrade common femoral artery puncture appears to be safe compared with historical studies.

In conclusion, the use of VCDs in peripheral vascular intervention has become an increasingly accepted practice. However, in the treatment of complex PAD in which antegrade access is needed, the role of VCDs remains controversial and poorly studied. In this study, Walker et al report a newer-generation VCD that is well suited to the closure of antegrade access site in patients with complex PAD. These early registry data should now be subjected to greater scrutiny and perhaps a large, prospective randomized controlled trial, which should help accurately characterize the role of VASCADE in the PAD patient.

Disclosure: Dr. Parikh is an advisory board member for Abbott Vascular, Boston Scientific, Medtronic, Cardiovascular Systems, Inc., and Philips. He consults for Terumo, Siemens, Heartflow, Meril Life Sciences, Asahi Intecc, and Abiomed. He reports research funding from Shockwave Medical, TriReme Medical, and SurModics, Inc.

Address for correspondence: Sahil A. Parikh, MD, FACC, FSCAI, Columbia University College of Physicians and Surgeons, 161 Fort Washington Avenue, 6th Floor, New York, NY 10032. Email: sap2196@cumc.columbia.edu

REFERENCES

- 1. Resnic FS, Majithia A, Marinac-Dabic D, et al. Registry-based prospective, active surveillance of medical-device safety. *N Engl J Med*. 2017;376:526–535.
- 2. Noori VJ, Eldrup-Jorgensen J. A systematic review of vascular closure devices for femoral artery puncture sites. *J Vasc Surg.* 2018;68:887–899.
- 3. Robertson L, Andras A, Colgan F, Jackson R. Vascular closure devices for femoral arterial puncture site haemostasis. *Cochrane Database Syst Rev.* 2016;3:CD009541.

EDITORIAL COMMENTARY

- Pruski MJ Jr, Blachut AM, Konkolewska M, et al. Mynx-Grip for closure of antegrade puncture after peripheral interventions with same-day discharge. Vasc Endovascular Surg. 2017;51:67-71.
- 5. Spiliopoulos S, Kitrou P, Christeas N, Karnabatidis D. Starclose SE(R) hemostasis after 6F direct antegrade superficial femoral artery access distal to the femoral head for peripheral endovascular procedures in obese patients. *Diagn Interv Radiol.* 2016;22:542–547.
- 6. Tapping CR, Dixon S, Little MW, Bratby MJ, Anthony S, Uberoi R. StarClose arterial closure after conversion from retrograde to antegrade access. *Clin Radiol*. 2012;67:889-892
- 7. Maxien D, Behrends B, Eberhardt KM, et al. Evaluation of the 6-F ExoSeal vascular closure device in antegrade femoral artery punctures. *J Endovasc Ther.* 2012;19:836-843.

- 8. Spiliopoulos S, Katsanos K, Karnabatidis D, Diamantopoulos A, Nikolaos C, Siablis D. Safety and efficacy of the StarClose vascular closure device in more than 1000 consecutive peripheral angioplasty procedures. *J Endovasc Ther.* 2011;18:435–443.
- Hermiller JB, Leimbach W, Gammon R, et al. A prospective, randomized, pivotal trial of a novel extravascular collagenbased closure device compared to manual compression in diagnostic and interventional patients. *J Invasive Cardiol*. 2015;27:129-136.
- Walker C, Keisz S, Bertolet B, Weatherford D, Nair PK, Shishehlor M. A multi-center, prospective, post-market registry to evaluate procedural outcomes using the Cardiva VASCADE Vascular Closure System (VCS) for the management of femoral arteriotom after percutaneous endovascualr procedures via antegrade access. Vasc Dis Management. 2018;15(9):E102–E107.