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Innovative Devices in Vascular Access Management

A review of the Cardiva Catalyst™ II and III vascular closure devices.

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Vascular access management of the arterial puncture site remains the most important impediment to patient ambulation and/or discharge after diagnostic or interventional procedures.[1,2] The mainstay of vascular access management for patients undergoing percutaneous femoral arterial access is manual compression. Vascular closure devices (VCDs) have been used since 1995 to provide improved patient comfort and shorter ambulation time after an invasive femoral access procedure.[3] Several VCDs have been tested over the last decade to replace manual compression. These devices are mostly suture-based, collagen plug, or thrombin injection in the tissue tract and have shown marginal safety, improved patient satisfaction, and faster ambulation times as compared to manual compression; however, they have not reduced complications. The cost of most of these closure devices is prohibitory for widespread use. The annual projected sales for VCDs is between $500 million and $700 million.[4] In terms of the number of devices used, the market leaders are Angio-Seal (St. Jude Medical, Inc., St. Paul, MN) and Perclose and StarClose closure systems (Abbott Vascular, Santa Clara, CA).

MANUAL COMPRESSION

The success rate of manual compression is very high. The rule of thumb has been 3 minutes of compression for each French size of the sheath. Thus, a 5-F sheath will need 15 minutes of compression, a 6-F sheath will need 18 minutes, and so on. The time to ambulation with manual compression is approximately 1 hour for each French size; 5-F sheaths will require 5 hours of bed rest. Recently, ambulation after 4 hours for an 8-F sheath and after 3 hours for a 5-F sheath has been shown to be safe. Hematoma is the most common complication of manual pressure, followed by pseudoaneurysm, retroperitoneal bleed, vessel closure, acute limb ischemia, vasovagal reaction, arteriovenous fistula, and hemorrhage.

VASCULAR CLOSURE DEVICES

Commercially available VCDs can be categorized as:[4]

(1) Compression devices (eg, FemoStop [St. Jude Medical, Inc.] and Safeguard [Maquet Cardiovascular, Wayne, NJ])
(2)Topical hemostasis agents (eg, D-Stat [Vascular Solutions, Inc., Minneapolis, MN], Syvek [Marine Polymer Technologies, Inc., Danvers, MA], and Closure PAD [Scion Cardio-Vascular, Inc., Miami, FL]);
(3) Invasive: (A) suture-based (eg, Perclose and Prostar [Abbott Vascular]); (B) invasive, medicated collagen plug (eg, Angio-Seal, Duett [Vascular Solutions, Inc.], and VasoSeal [St. Jude Medical, Inc.]); and (C) clip-based (eg, StarClose and EVS [expanded vascular stapling] [Angiolink Corp., Taunton, MA]);
(4) Invasive without a foreign body (eg, Cardiva Catalyst [Cardiva Medical, Inc., Sunnyvale, CA]).

ADVANTAGES OF CLOSURE DEVICES

The advantages of closure devices include: (1) patients on anticoagulation can achieve complete hemostasis; (2) patients can be restarted on anticoagulation immediately after the procedure; (3) faster ambulation times; (4) increased patient satisfaction; (5) early discharge; and (6) vascular access management of large sheaths (> 10 F).

The clear contraindications for the use of closure devices are small-sized femoral arteries < 5 mm in diameter, severe atherosclerosis or heavy calcification of the common femoral artery, and high or low common femoral stick.

DEBATABLE ISSUES OF VASCULAR ACCESS CLOSURE DEVICES

The debates regarding safety, efficacy, and complications of closure devices stem from the lack of prospective, randomized, controlled trials. Data in the form of many meta-analyses do exist; however, the propensity analysis may not fully explain the variables used in the studies. A meta-analysis by Nikolsky et al[5] demonstrated that the complication rates between manual compression and closure devices were the same for diagnostic procedures, and that VasoSeal (closure device)

Figure 1. Cardiva Catalyst family of closure products.

had higher complications compared to manual compression in patients undergoing interventional procedures. Closure devices are costly compared to manual compression; however, this high cost may be offset by shorter stay and lesser complications. A recent analysis of 36,000 patients who underwent percutaneous coronary intervention with the Northern New England Cardiovascular Disease Study Group between 2002 and 2006 showed that major vascular complications have decreased from 3.4% to 2.3%.

THE INVASIVE CLOSURE DEVICE WITHOUT ANY FOREIGN BODY LEFT BEHIND

The Cardiva Catalyst II is a deployable nitinol disc sheathed in a biocompatible membrane, intended to promote hemostasis at an arteriotomy site as an adjunct to manual compression. Cardiva Catalyst II is indicated for use in patients undergoing diagnostic and/or interventional femoral artery catheterization procedures using up to 7-F sheaths. The device contains two agents (kaolin and chitosan) that, when exposed to the tissue tract, accelerate hemostasis by stimulating coagulation, platelet adhesion, and platelet aggregation. The Cardiva Catalyst II still needs assisted manual compression once the disc is collapsed and retracted out of the vessel.

The latest version of Catalyst wires is the Cardiva Catalyst III, which is used solely for heparinized patients undergoing femoral percutaneous interventions (Figure 1). The Cardiva Catalyst III wire has a protamine coating that will provide rapid hemostasis when exposed to a tissue tract in patients anticoagulated with heparin. We aim to compare the data from the recent use of Catalyst II versus Catalyst III, as well as perform a limited comparison to manual compression. Patients who underwent diagnostic and interventional procedures from June 2008 to March 2009 were evaluated across various hospitals in North America. According to the Cardiva Medical Database (June 2008 to March 2009), of the 1,798 patients evaluated, the following data were collected: 1,199 (67%) underwent a diagnostic procedure with the Cardiva Catalyst II; 403 (22%) underwent an interventional procedure with the Cardiva Catalyst II; and 196 (11%) underwent an interventional procedure with the Cardiva Catalyst III.

The baseline characteristics, listed in Table 1, did not differ among the three groups. Of the patients studied, men represented 54.4%, and the comorbidities noted were diabetics (34.85%), patients with peripheral arterial disease (34.3%), patients on hemodialysis (3.6%), and obese patients (61.2%).

The outcomes of vascular access management depend on a patient's medications, such as anticoagulants, and the site of initial arterial access. A high

TABLE 1. PATIENT CHARACTERISTICS IN CARDIVA CATALYST II AND III COMPARISON

Gender	
	Men 54.4% (n = 979)
	Women 39.7% (n = 714)
	Unknown 5.9% (n = 105)
Comorbidities	
	323 (18%) Morbidly obese (> 50 lbs)
	777 (43.2%) Obese (< 50 lbs)
	625 (34.8%) Diabetic
	618 (34.3%) Peripheral vascular disease
	64 (3.6%) Dialysis

TABLE 2. MEDICATIONS AND ACCESS SITES IN CARDIVA CATALYST II AND III COMPARISON

Medications	
	1,653 (91.9%) Aspirin
	852 (47.3%) Clopidogrel
	245 (13.6%) Bivalirudin
	362 (20.1%) Heparin
	101 (5.6%) GP IIb/IIIa
Access site	
	1,755 (97.6%) Common femoral artery
	2 (0.01%) Sidewall
	1,022 (56.8%) Previous access

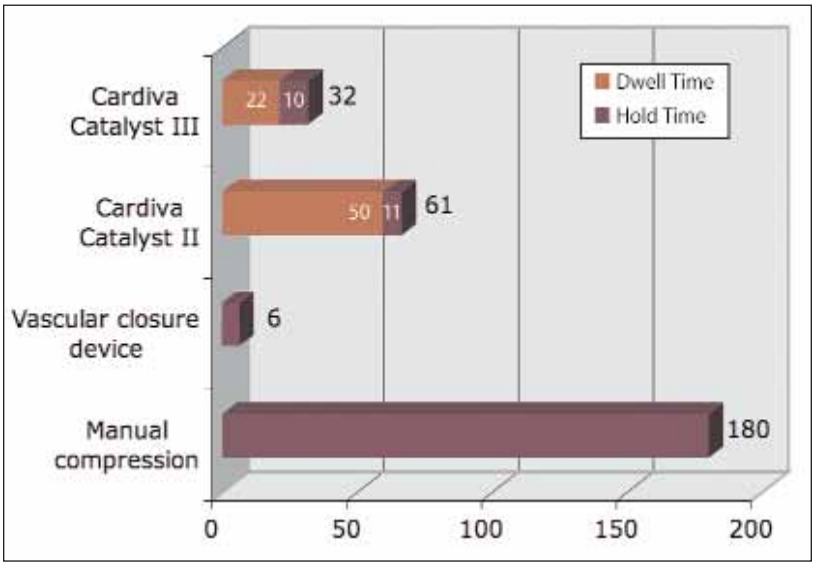

Figure 2. Time to hemostasis after angiography in interventional cases (minutes). Cardiva Catalyst II and III = dwell + hold time.

femoral access leads to retroperitoneal bleed, and a low femoral access causes the potential risk of pseudoaneurysm or arteriovenous fistula formation. The majority of patients (97%) had common femoral puncture as the initial access site. Anticoagulants and antiplatelet medications play a pivotal role in achieving hemostasis. Aspirin was the most common antiplatelet agent noted in 91.9% of the patients in the study. Anticoagulation used during the procedures included heparin in 20% of the patients and bivalirudin in 13.65% of the patients. The glycoprotein IIb/IIIa accounted only for 5.65% of the patients. The list of medications and access sites in the comparison is depicted in Table 2.

The Cardiva Catalyst II device was used in 89.1% of the patients, and 10% of the patients received the Cardiva Catalyst III device. The Catalyst II device was successfully used in 99.2% of the patients, whereas the success rate of Catalyst III was 98.5%. Successful hemostasis was achieved in 98% of the patients who received the Catalyst II and Catalyst III device. The most common sheath size used was 6 F (63.1%), followed by 5-F sheaths (26.1%). Large-caliber sheaths (eg, 7 and 8 F) accounted for 8.3% and 2.5%, respectively. The time to hemostasis in diagnostic patients noted with manual compression was 18 minutes; the time to hemostasis for other VCDs was 6 minutes. The time to hemostasis for the Catalyst II was 21 minutes, which consisted of 15 minutes of dwell for the product and 6 minutes of manual compression.

The time to hemostasis with interventional procedures was 180 minutes with manual compression and 6 minutes with a closure device, such as Perclose or Angio-Seal. The time to hemostasis with the Cardiva Catalyst II wire was 61 minutes—which included 50 minutes of dwell time and 11 minutes of manual compression—whereas the time to hemostasis using the Cardiva Catalyst III was 32 minutes, which consisted of 22 minutes of dwell time and 10 minutes of manual compression (Figure 2).

CONCLUSION

The complication rates of the VCDs are 4% in previous meta-analyses and manual compression was 1.8%.[6] In the Catalyst II trial, there was one (2%) rebleed that required 10 minutes to reestablish hemostasis, and there were no hematomas > 5 cm. Controlled ooze was seen in four diagnostic subjects, requiring an average of 5 minutes to resolve and in three interventional subjects, requiring an average of 9 minutes to resolve. One major adverse event was reported related to the access-site procedure: one delayed hematoma was diagnosed 4 days after the procedure in a patient taking warfarin. The Cardiva Catalyst II was associated with two small hematomas, each < 5 mm. The complication rates for Cardiva Catalyst II and Catalyst III are extremely low. Thus, the Cardiva Catalyst II and III devices are unique devices that leave no foreign body behind and are safe and simple to use. ■

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1. Lehmann KG, Heath-Lange SJ, Ferris ST. Randomized comparison of hemostasis techniques after invasive cardiovascular procedures. Am Heart J. 1999;138:1118-1125.
2. Allie DE, Smalling R, Hebert RT, et al. The costs of VAM complications. Endovasc Today. 2006;5:21-28.
3. Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: the second decade. J Am Coll Cardiol. 2007;50:1617-1626.
4. Turi Z. Overview of vascular closure: Endovascular Today annual review current update. Endovasc Today. 2008;7:1-7.
5. 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.
6. Koreny M, RiedmЯller E, Nikfardjam M, et al. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systemic review and meta-analysis. JAMA. 2004:291:350-357.