A Multi-Center, Prospective, Post-Market Registry to Evaluate Procedural Outcomes Using the Cardiva Medical VASCADE Vascular Closure System (VCS) for the Management of the Femoral Arteriotomy After Percutaneous Endovascular Procedures Via Antegrade Access

Craig Walker, MD[1]; Stefan Kiesz, MD[2]; Barry Bertolet, MD[3]; David Weatherford, MD[4]; Pradeep K. Nair, MD[1]; Mehdi H. Shishehbor, DO, MPH, PhD[5]

From the [1]Cardiovascular Institute of the South, Houma, Louisiana; [2]San Antonio Endovascular and Heart Institute, San Antonio, Texas; [3]Cardiology Associates of North Mississippi, Tupelo, Mississippi; [4]Coastal Surgery Specialists, Coastal Surgery Specialists, Wilmington, North Carolina; and [5]University Hospitals Harrington Heart & Vascular Institute, Cleveland, Ohio.

Abstract: Objectives. The objective of the ANTEGRADE-PVD registry was to evaluate short-term outcomes when sealing antegrade femoral puncture sites with an extravascular site-closure system after peripheral endovascular procedures. **Background.** Peripheral vascular intervention via antegrade access is growing rapidly. Antegrade access has multiple advantages in treating critical peripheral arterial obstructions and is crucial in patients in whom retrograde contralateral access is contraindicated; however, this access is often shunned because of the risk of access-site complications. **Methods.** This registry was a multi-center, single-arm, post-market registry assessing the extravascular use of the VASCADE Vascular Closure System after antegrade femoral access for treatment of peripheral arterial disease. The primary efficacy outcome measure was time to hemostasis (TTH). Secondary efficacy outcome measures included time to ambulation (TTA) and time to discharge (TTD). Procedural outcomes and complications were assessed through hospital discharge and 30 ± 7 days. **Results.** A total of 52 patients were enrolled. Mean age was 66.7 ± 9.86 years, 33% of subjects were female, and mean body mass index was 28.3 ± 4.46 kg/m^2. Procedural success rate was 98%. Mean TTH was 5.87 ± 2.44 minutes. Hemostasis after a mandatory 5-minute hold was achieved in <10 minutes in 92% of subjects without reversal of anticoagulants. Mean TTA was 4.94 ± 4.97 hours and 83% of subjects achieved ambulation in ≤5 hours. Mean TTD was 5.97 ± 5.85 hours with 88% of patients achieving discharge in ≤8 hours. The major complication rate was 1.9% and minor complication rate was 1.9%. **Conclusion.** This study confirms safe and effective performance of the VASCADE VCS device when used in antegrade femoral access.

VASCULAR DISEASE MANAGEMENT 2018;15(9):E102-E107.
Key words: PAD, antegrade, access, closure

Peripheral artery disease (PAD) is a condition that affects up to 20 million in the United States with an increasing incidence attributed to our aging population and an increasing incidence of diabetes.[1] Most patients with PAD are either asymptomatic or ascribe their symptoms to other conditions or causes.[2] Some patients present with typical claudication characterized by painful muscle cramping and discomfort with walking. Others will progress to critical limb ischemia (CLI) characterized by true ischemic rest pain, ischemic ulcers and non-healing wounds, and in extreme cases, gangrene. The goal of PAD treatment is to restore blood flow to the affected limb to alleviate pain and to promote healing. This is accomplished by either surgical bypass or percutaneous interventions. Percutaneous endovascular treatment of PAD has many advantages compared to surgical bypass as it is less invasive, does not require a bypass conduit and can treat outflow disease.[3] This approach is well-established and is rapidly becoming the predominant treatment approach.

Infrainguinal endovascular treatment of PAD is most commonly performed via access utilizing either contralateral retrograde femoral approach or antegrade femoral approach. Some patients are not candidates for contralateral femoral access including those who have had prior endovascular repair of abdominal aortic aneurysm, aorto-femoral bypass surgery or placement of high iliac bifurcation stents. For these patients, an antegrade femoral access approach provides an endovascular treatment option. Antegrade femoral access has many distinct advantages compared to contralateral retrograde access including dramatic improvement in wire manipulation, better wire torque and reach, and superior push of devices (contralateral femoral access may result in prolapse into the aorta).[4,5] This better maneuverability is attributed to an improvement in vector physics

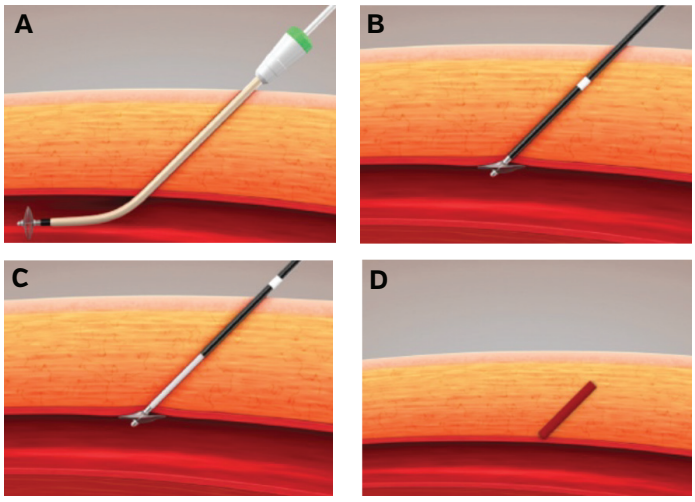

Figure 1. The VASCADE VCS device consists of a bioresorbable thrombogenic collagen patch. (A) At the completion of the interventional procedure, the VASCADE device is inserted through the existing introducer sheath, the disk is deployed in the lumen of the artery or vein. (B) The sheath is removed over the device, and the disc is brought against the vessel wall to achieve temporary hemostasis. (C) The protective sleeve is unlocked and retracted, exposing the collagen patch in the tissue tract at the arteriotomy or veinotomy site. (D) The disk is collapsed, and the device is removed, leaving only the collagen patch behind in the tissue tract.

due to the more direct course which ultimately leads to a better ability to accurately direct the wire and administer treatment. While significant advantages exist, antegrade puncture is more difficult and has been reported to have higher complication rates related namely due to access site complications.[6] The primary access site concern with antegrade access is that hemostasis may be more difficult to achieve with manual compression and there is possibility of a higher complication rate than with retrograde puncture.[5] This risk coupled with the concern that significant PAD itself may be associated with an increased risk of complications[7] drives the effort to minimize complications wherever possible.

Manual compression remains the most commonly used method for vascular access closure. Manual compression is effective; however, it is limited by the need to interrupt anticoagulation, and it requires prolonged bed rest.[8,9] In antegrade puncture, manual compression is much more difficult, particularly in obese patients, and leads to prolonged bleeding time periods. It is well described that prolonged bleeding is associated with increased morbidity and may affect mortality.[5] Additionally, theoretically, manual compression may compromise newly established blood flow to the extremity resulting in complications such as thrombosis. In addition, frequently with antegrade approach, the physician is puncturing a severely diseased artery with diminished elasticity. This is because antegrade approach is only used to treat peripheral artery disease.

Although manual compression remains the most commonly utilized technique for access management, vascular closure devices may provide benefits to patients.[8] Over the last 20 years, various vascular closure devices have become available for use to allow for early hemostasis and ambulation of patients after percutaneous femoral diagnostic or interventional coronary or peripheral procedures.[7,10,11] While many designs of vascular closure devices are available, plug-mediated devices have a reported high success rate of up to 97.9%.[12] One such device is the VASCADE VCS. The VASCADE VCS is indicated for femoral arterial access site closure while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular catheterization procedures.

The VASCADE VCS (Cardiva Medical) is a next-generation extravascular technology that consists of a bioresorbable thrombogenic collagen patch. The device is compatible with 5, 6, or 7 Fr introducer sheaths and consists of an expandable nitinol disk that locates the vessel wall and provides temporary hemostasis and a retractable/lockable sleeve that houses a bovine-derived collagen patch. At the completion of the interventional procedure, the VASCADE device is inserted through the existing introducer sheath, the disk is deployed in the lumen of the artery or vein, the sheath is removed over the device, and the disc is brought against the vessel wall to achieve temporary hemostasis. The protective sleeve is unlocked and retracted, exposing the collagen patch in the tissue tract at the arteriotomy or veinotomy site. The disk is collapsed, and the device is removed, leaving only the collagen patch behind in the tissue tract. There are no intravascular components. The patch expands upon exposure of collagen to blood and surrounding tissue fluid, filling the tissue tract and promoting coagulation and hemostasis (**Figure 1**).

VASCADE VCS is considered an active closure device that has been shown to have a significantly shorter compression time (<5 minutes) in retrograde femoral access at lower pressures than manual compression. The benefit of an extravascular device is that it does not compromise the arterial lumen and leaves nothing behind within the artery.[13] The VASCADE VCS was assessed previously in clinical trial for retrograde access in coronary procedures. In the RESPECT study,[14] a 420 patient, prospective, multicenter, randomized clinical trial comparing VASCADE VCS with manual compression (MC), VASCADE VCS proved statistically superior minor complication rates and time to hemostasis (TTH) for both interventional and diagnostic cases. Additionally, VASCADE VCS demonstrated no major complications. There are limited published data available for the closure of antegrade peripheral vascular access during endovascular procedures.[12] This type of closure is associated with perioperative access site complications.[6,15] In an effort to potentially improve antegrade access closure, a study was conducted to assess the VASCADE VCS in closure of access sites after antegrade femoral puncture performed as an element of treating patients with PAD. This post-market registry was designed to capture data specific to this procedural technique and was conducted under an FDA-approved indication.

METHODS

The ANTEGRADE-PVD registry was a United States multicenter, single-arm post-market registry to evaluate procedural

Table 1. Index limb assessment.

Rutherford Score	Number	Percentage
Stage 2 - Moderate claudication	6	12%
Stage 3 - Severe claudication	21	40%
Stage 4 - Ischemic rest pain	10	19%
Stage 5 - Minor tissue loss	14	27%
Data missing*	1	2%
Previous Amputation on Index Limb		
No	47	90%
Yes	5	10%

outcomes in subjects when the Cardiva Medical VASCADE (VCS) was used to seal antegrade femoral arterial access sites with an extravascular device following ipsilateral peripheral interventional procedures performed through 5-7 Fr introducer sheaths. Investigators experienced in antegrade access closure enrolled subjects at five United States sites. The trial was performed in accordance with the relevant parts of Title 21 CFR Parts 50 and 803.

Subjects that were scheduled for ipsilateral peripheral interventional endovascular procedure via antegrade access of the femoral artery using a 5, 6, or 7 Fr sheath and met the pre-operative inclusion/exclusion criteria were invited to participate in the study. All subjects were required to provide written informed consent before undergoing any registry-related activity. At the completion of the endovascular procedure, subjects that met all the intraoperative eligibility criteria were enrolled in the registry.

The VASCADE VCS device was deployed following peripheral endovascular intervention according to the instructions for use. Upon successful deployment of the VASCADE VCS, adjunctive compression at the site was to be used for at least 5 minutes (mandatory 5 minutes hold) or longer if arterial hemostasis (i.e., no pulsatile bleeding or a forming hematoma) was not achieved within initial hold period. After hemostasis was achieved, the access site was monitored every 15 minutes for the first hour, and then according to standard of care to confirm hemostasis.

The primary procedural outcome measure was *TTH*, which was defined as the elapsed time between device removal and first observed and confirmed arterial hemostasis. TTH was not recorded until adjunctive compression was no longer applied and arterial hemostasis was achieved. Secondary procedural performance outcome measures were *time to ambulation (TTA)* which was defined as the elapsed time between device removal and when subject first stands and walks 20 feet without evidence of arterial re-bleeding from the access site; *time to hospital discharge (TTD)*, defined as elapsed time between device removal and when subject is discharged from the facility. Also assessed were device success and procedural success. *Device success* was defined as the ability to deploy the delivery system, deliver the collagen, and achieve hemostasis with the VASCADE VCS alone or with adjunctive compression. *Procedural success* was defined as attainment of device success and freedom from major access site closure-related complications through 30 days. The primary safety outcomes were the patient incidence rate of combined major access site closure related complications through 30 days.

Procedural outcomes related to performance and complications were assessed through hospital discharge and 30 ± 7 days post-procedure. There was an office visit between 1-15 days; and a subsequent telephone follow-up done between 23-37 days as the final contact.

An Independent Physician Adjudicator (IPA) reviewed and adjudicated all serious device-related adverse event reports, deaths, and all minor and major access site closure-related complications for a determination of both seriousness and closure-relatedness. While registry withdrawal was discouraged, subjects could withdraw from the registry at any time, with or without reason and without prejudice to further treatment.

RESULTS

Patient demographics

Between January 19, 2017 and August 24, 2017, 52 subjects were prospectively enrolled for treatment with VASCADE VCS in the registry. A total of 46 (88%) of the subjects were treated at outpatient facilities, and 6 (12%) were treated at inpatient facilities. No subjects were withdrawn from the registry. Ninety-four percent (94%) of enrolled subjects completed all follow-up requirements. All subjects (100%) were contacted between 0 and 37 days post-procedure for safety follow-up. The mean age was 66.7 ± 9.86 years, 33% of the subjects were female, and the mean BMI was 28.3 ± 4.46. A total of 46% of the subjects had critical limb ischemia (CLI). See **Table 1** for additional detail regarding index limb assessment.

Procedural variables

Peri-procedure anticoagulant (administered from 24 hours pre-procedure through hospital discharge) was reported in 96% of subjects. Intra-procedural heparin was used in 29 cases (55.8%) with 6 of those cases being reversed with protamine. Bivalirudin was used in 18 cases (34.6%), and no procedural anticoagulation was used in 5 (9.6%) cases (of which 2 received no anticoagulation at all).

The antegrade access site location was via the femoral artery in the groin for endovascular treatment in through either the common femoral artery (37%) or the superficial femoral artery (62%). The endovascular treatment for peripheral arterial disease was delivered to superficial femoral, popliteal, tibioperoneal, tibial or peroneal arteries. Additional procedural data and lesion characteristics are presented in **Table 2.**

Procedural outcomes – Performance

The primary performance outcome variable was TTH. Most patients were on anticoagulation therapy and, in most cases, it was not reversed. The mean TTH was 5.87 ± 2.44 minutes (**Table 3**) which included a mandated 5-minute hold time. Hemostasis was achieved in <10 minutes in 92% of subjects.

Table 2. Procedural data and limb characteristics.

	N=52	
Access Site Location	Number	Percentage
Right Groin	24	46%
Left Groin	28	54%
Femoral Artery Branch – Access Site	N	Percent
Common femoral artery (CFA)	19	37%
Superficial femoral artery (SFA)	32	62%
Data Missing*	1	2%
Techniques Used to Gain Antegrade Access	N	Percent
Ultrasound guided	7	13%
Fluoroscopy guided	30	58%
Micropuncture	40	77%
Final Sheath Diameter[1]	N	Percent
5 Fr	11	21.15%
6 Fr	31	59.60%
7 Fr	10	19.23%
Procedure Target(s) for Ipsilateral Interventions	N	Percent
SFA	28	53.85%
Popliteal	15	28.85%
TPT	7	13.46%
AT/PT	23	44.23%
Peroneal	5	9.62%
Other	7	13.46%
Activated Clotting Time (seconds)	N	Percent
N	23	44.23%
Mean		245.3
Standard deviation		24.9
Median		248
Min		192
Max		286

*Braided sheaths were included.

The secondary performance outcome variables were TTA and TTD. The mean TTA was 4.94 ± 4.97 hours, and 83% of subjects achieved ambulation in < 5 hours. The mean TTD was 5.97 ± 5.85 hours, with 88% of subjects achieving hospital discharge in <8 hours.

Table 3. Time to hemostasis details.

Time to Hemostasis	
Number of patients	52
Mean	5.87 minutes
Standard deviation	2.44 minutes
Median	5.07 minutes
Minimum	4.58 minutes
Maximum	19.83 minutes

Table 4. Major access-site complications.

Type of Major Complication (N=52)	Number	Percentage
Any major access site closure-related complication	1	1.9%
Vascular injury requiring repair and access site re-bleeding requiring transfusion	1*	1.9%
New ipsilateral lower extremity ischemia causing a threat to the viability of the limb, requiring surgical or percutaneous intervention	0	0.0%
Access site-related infection requiring intravenous antibiotics and/or extended hospitalization	0	0.0%
New-onset neuropathy in the ipsilateral lower extremity requiring surgical repair	0	0.0%

*Both events occurred in 1 subject.

Procedural success was defined as attainment of device success and freedom from major vascular complications through 30 days. One subject did not receive the collagen, and another subject experienced two major access-site related events. All subjects were contacted at least once between 0-37 days post procedure. Procedural success was achieved in 98% of cases.

Device success, defined as the ability to deploy the delivery system, deliver the collagen, and achieve hemostasis with the Cardiva Medical VASCADE VCS alone or with adjunctive compression, was achieved in 51 of 52 cases (98%). In the subject who did not receive the device, the investigator reported that the disc did not anchor against the arterial wall, so that temporary hemostasis could not be achieved. The device was removed prior to deployment and hemostasis was achieved with manual compression.

Procedural outcomes – Safety

The primary procedural complication composite evaluated was the 30-day patient incidence rate of combined major access site closure-related complications.

There was one (1) subject reporting two (2) major access-site related events (1.9%). The event required vascular injury requiring repair and a blood transfusion. **Table 4** shows major access-site related complications by type. The event was determined to not

be serious and not related to the VASCADE VCS device. There were no ipsilateral extremity vascular or neurological complications, new-onset neuropathy, or access-site related infections.

The secondary procedural complication composite evaluated was the 30-day patient incidence rate of combined minor access-site closure related complications. There was one minor access-site closure related event reported (1.9%). **Table 5** includes minor access-site related complications by type.

DISCUSSION

Vascular closure devices have been available in the United States since 1996 for the use in percutaneous coronary procedures. The devices incorporate various design features such as mechanical, pharmacologic and biomaterial features with the goal of accelerating hemostasis by sealing or opposing an arteriotomy required to perform coronary angiography and interventional procedures.[16] These devices are quickly being adopted into peripheral endovascular procedures and are demonstrating clinical benefit. As a result, the current study was initiated to establish a baseline for clinical safety and efficacy in these procedures specifically for antegrade access.

The results of this registry are encouraging, demonstrating that good outcomes, low complication rates and fast times to hemostasis using an antegrade approach are reproducible using existing FDA approved products. This post-market prospective, multicenter United States registry successfully demonstrated the performance of the Cardiva Medical VASCADE VCS extravascular device when used in antegrade access. In most cases in this registry, vascular closure was achieved without reversal of anticoagulant and with short compression times. In this registry, the major complication rate was 1.9% and the minor complication rate was 1.9%. The mean time to hemostasis was 5.87 minutes, the mean time to ambulation was 4.94 hours, and the mean time to hospital discharge was 5.97 hours. The device success rate was 98% (51/52) and the procedure success rate was 98% (50/51) achieving hemostasis without reversing of anticoagulation.

Previously, results from a pivotal study of femoral access for coronary interventions using the VASCADE VCS were published (RESPECT trial). The RESPECT trial evaluated the safety and efficacy of the VASCADE VCS in interventional procedures performed through 6 Fr or 7 Fr retrograde femoral sheaths. The RESPECT trial was a multicenter, randomized trial comparing the use of the vascular closure device to manual compression. Since subjects were not randomized in the current registry, comparisons between the two groups are necessarily informal; however, the clinical performance results were comparable between the RESPECT study and the current registry. Both studies reported a device and procedure success rate of 98%. In the RESPECT trial, there were no major complications reported. The minor complication rate was 1.1%

Table 5. Minor access-site related complications.

Type of Minor Complication (N=52)	Number	Percentage
Any Minor Access-Site Closure Related Minor Complication	1	1.9%
Access-site related bleeding requiring >30 minutes to achieve initial arterial hemostasis	0	0.0%
Access-site related hematoma >6 cm	1	1.9%
Late access site-related arterial bleeding requiring intervention (following hospital discharge)	0	0.0%
Ipsilateral lower extremity arterial emboli documented by ultrasound	0	0.0%
Ipsilateral deep vein thrombosis documented by ultrasound	0	0.0%
Access-site related vessel laceration	0	0.0%
Access site wound dehiscence	0	0.0%
Localized access site infection treated with intramuscular or oral antibiotics	0	0.0%
Arteriovenous fistula not requiring treatment, documented by ultrasound	0	0.0%
Pseudoaneurysm requiring thrombin injection or fibrin adhesive injection	0	0.0%
New onset access-site related neuropathy in the ipsilateral lower extremity not requiring surgical repair	0	0.0%

Table 6. Comparative analysis.

	VASCADE VCS	AngioSeal	ExoSeal	Mynx
Literature	ANTEGRADE – PVD Study	Cicuto, et al[4] (2013)	Schmelter, et al[10] (2013)	Pruski, et al[5] (2017)
Study type	**Prospective Multi-Center (U.S.)**	Retrospective Single Center (U.S.)	Prospective Single Center (OUS)	Prospective Single Center (OUS)
Number of patients	**52**	50	93	66
Procedure success	**98%**		96%	
Device success	**98%**	98%	96%	94%
Minor complications	**1.9% (1)**	8% (4)	7.5% (7)	7.6% (5)
Major complications	**1.9% (1)**	2% (1)	3.2% (3)	0% (0)
Complication-free patients	**96.2%**	90%	89%	92%

for VASCADE VCS compared to 7% for manual compression. The reported VASCADE VCS minor complication rate for this registry was 1.9% which closely aligns with the results from the RESPECT trial. Due to the same access location, it would be anticipated that if a direct comparison of antegrade access closure with the VASCADE VCS device with manual compression was conducted similar results would be achieved. Improvements in clinical safety and performance relative to a reduction of access site complications would provide a distinct benefit to patients and may lead to reduced morbidity and mortality in this patient population.

The literature was queried to find other comparative studies of antegrade access closure using vascular closure devices. Three were selected for a direct comparison due to similarities in design (plug-design vascular closure devices utilized in antegrade femoral access-site closure). The results of this comparative analysis are presented in **Table 6.** In reviewing the data of these comparative studies that utilized plug-design vascular closure devices in closing femoral antegrade access sites, there is consistency among the device success rates (94%-98%) for the various closure devices. The major complication rates were also similar among the studies. There was an increased variability in the minor complication rates (1.9% for VASCADE VCS vs 7.5%-8.0%) compared to other vascular closure devices when used for antegrade access.

The results of this registry were achieved in patients with primarily Rutherford class 3-5 peripheral vascular disease with significant comorbidities such as diabetes and renal dysfunction. Increases in TTH were not associated with a higher Rutherford Score; however, time to ambulation and discharge were impacted to some degree. In all instances, patients achieved hemostasis regardless of Rutherford score. Kara et al[7] assessed the complication rates associated with severity of PAD with manual compression. They determined that complications did increase with the severity of disease (ranging from 5% for Fontaine IIb to 14% for Fontaine IV). There was a trend toward higher prevalence of complications associated with the stage of PAD. The minimal impact of Rutherford score and low complication relative to procedural outcomes in the ANTEGRADE-PVD registry demonstrate the potential efficacy in a very sick patient population.

The study is limited in that it is a small cohort; however, the study size is bolstered through the use of a prospective design and the use of multiple sites and operators. The current registry is the only study of antegrade closure that was prospectively performed at multiple United States sites with multiple investigators. Due to the increased robustness of the prospective registry design, the results were determined to be representative of the clinical use of vascular closure devices for antegrade access and present quality data that can be utilized to establish performance baselines for future studies.

CONCLUSION

This study confirms the safe and effective performance of the VASCADE VCS device when used in closure of antegrade femoral access sites during peripheral endovascular interventions in the treatment of PAD. The study provides comparable results for femoral puncture access site closure performed via antegrade access as those previously presented in a pivotal study of femoral access for coronary interventions performed via retrograde access. ■

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr. Walker is a consultant to and a shareholder of Cardiva Medical. The remaining authors report no conflicts of interest regarding the content herein.

Manuscript submitted May 7, 2018, final version accepted June 7, 2018.

Address for correspondence: Craig Walker, MD, Cardiovascular Institute of the South 225 Dunn St, Houma, LA 70360. Email: drcrwalker@gmail.com

REFERENCES

1. Yost ML. *Critical limb ischemia, Volume I. United States Epidemiology 2016 Supplement*. The Sage Group. Available at http://thesagegroup.us/pages/reports/cli-us-supplement-2016.php/. Published 2016.
2. Hirsch AT, Hiatt WR, PARTNERS Steering Committee. PAD Awareness, Risk, and Treatment: New Resources for Survival—the USA PARTNERS. *Vasc Med*. 2001;6(Suppl 1):9-12.
3. Goodney PP, Beck AW, Nagle J, Welch HG, Zwolak RM. National Trends in Lower Extremity Bypass Surgery, Endovascular Interventions, and Major Amputations. *J Vasc Surg.* 2009;50:54-60.
4. Cicuto K, Mittleider D, Kim P. Safety and efficacy of the Angioseal Closure Device with antegrade superficial femoral artery access. *J Vasc Intervent Radiol*. 2013;24(4): S118.
5. Pruski MJ, Blachut AM, Konkolewska M, et al. MynxGrip for closure of antegrade puncture after peripheral interventions with same-day discharge. *Vasc Endovasc Surg.* 2017;51:67-71.
6. Wheatley BJ, Mansour A, Grossman M, et al. Complication rates for percutaneous lower extremity arterial antegrade access. *Arch Surg.* 2011;146(4):432-435.
7. Kara K, Mahabadi AA, Berg MH, et al. Utilization of collagen-based vascular closure devices in patients with severe peripheral artery disease. *J Invasive Cardiol*. 2013;25(1):19-22.
8. Schwartz BG, Burstein S, Economides C, et al. Review of vascular closure devices. *J Invasive Cardiol*. 2010;22(12):599-607.
9. Alshehri AM, Elsharawy M. Comparison of Angioseal and manual compression in patients undergoing transfemoral coronary and peripheral vascular interventional procedures. *Int J Angiol*. 2015;24(2):133-136.
10. Schmelter C, Liebl A, Poullos N, Ruppert V, Vorwerk D. Suitability of Exoseal vascular closure device for antegrade femoral artery puncture site closure. *Cardiovasc Intervent Radiol*. 2013;36:659-668.
11. Katz SG, Abando A. The use of closure devices. *Surg Clin N Am*. 2004;84:1267-1280.
12. Barbetta I, van den Berg JC. Access and hemostasis: femoral and popliteal approaches and closure devices — why, what, when, and how? *Semin Intervent Radiol*. 2014;31(4):353-360.
13. Khanna N, Gass A. A novel vascular closure device for heart transplant patients. *Cath Lab Digest*. 2015;23(12).
14. Hermiller JB, Leimbach W, Gammon R, et al. A prospective, randomized pivotal trial of a novel extravascular collagen-based closure device compared to manual compression in diagnostic and interventional patients. *J Invasive Cardiol*. 2015;27(3):129-136.
15. Hackl G, Gary T, Belaj K, Hafner F, Eller P, Brodmann M. Risk factors for puncture site complications after endovascular procedures in patients with peripheral arterial disease. *Vasc Endovascular Surg.* 2015;49:160-165.
16. 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.