Distal Cuff Occlusion: A Novel, Simple Approach for Distal Embolic Protection in Peripheral Vascular Intervention

Shwan Jalal, MD[1]; Jihad A. Mustapha, MD[2]; Howard S. Rosman, MD[1]; Rajendra H. Mehta, MD, MS[3]; Thomas P. Davis, MD[1]

ABSTRACT: Aim. To evaluate the feasibility, effectiveness, and safety of the cuff-occlusion method for distal embolic protection in peripheral artery disease. **Methods and Results.** We evaluated 61 patients who underwent peripheral vascular intervention (PVI) for infrainguinal lesion at a single center where a blood pressure cuff occlusion method for distal embolic protection was utilized during the procedure. Primary endpoint included incidence of distal embolization, acute limb ischemia, or emergency limb amputation. Safety endpoints were freedom from bleeding, vessel perforation, or dissection. Lesion location was in the superficial femoral artery in 39% of cases and popliteal and infrapopliteal in 61% of patients. Procedural success was achieved in 98.4% of patients and 1 patient had distal embolization. There was no bleeding or perforation or major flow-limiting vessel dissection. **Conclusion.** Our study demonstrated that the cuff-occlusion strategy was feasible and safe for protection form distal embolization in PVI. Further study is required to evaluate the efficacy and safety of this novel method compared with existing devices for distal protection.

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Endovascular therapy is an attractive modality for the treatment of peripheral arterial disease (PAD) because it is less invasive and results in shorter hospital stays than surgery.[1,2] As with any invasive procedure, this strategy poses challenges and has inherent complication risks. One such risk, embolization into distal arteries during peripheral vascular intervention (PVI), has the potential to worsen already compromised blood flow into an ischemic limb, which in some cases can result in limb loss.[1] The prevalence of distal embolization during PVI recognized by angiographic or clinical manifestations has ranged from 2% to 10%.[1,3-8] However, the incidence of unrecognized distal embolization is probably higher. Risk factors for embolization are long lesions, chronic total occlusion (CTO) lesions, moderate to severely calcified plaque, and increased thrombus burden.[2] Additionally, while thrombolysis, balloon angioplasty, and stenting have all been shown to be associated with distal embolization, the risk is particularly high with atherectomy.[1,2]

Use of distal protection devices in infrainguinal intervention has received less attention compared to carotid and coronary arteries and bypass vein grafts, where these devices have been effective in reducing embolic complications.[9-11] Nonetheless, distal protection for PVI has been associated with lower embolic complications and, as a result, less radiation exposure for both patient and operator, lower contrast volume use, lower procedural times, and shorter hospital stays.[12,13] There are multiple protection devices currently available for infrainguinal intervention, each with different challenges that may limit their utilization. The most common problems are inability to advance the device beyond the lesion, damage to inner vessel wall that might lead to vessel dissection or spasm, and the cost of the device.[15]

We report the feasibility and safety of a novel, simple method for distal embolic protection that is less invasive and simple, and has the potential for cost savings compared with currently available devices.

Methods

Patient population. Between February and July 2016, this method was utilized in 61 patients, who are included in this report. All interventions were performed by an operator experienced in PVI. Informed consent was obtained from all patients for the procedure.

Distal cuff occlusion. If initial peripheral angiogram indicated that a patient had a significant lesion that required intervention, a blood pressure cuff was placed around the ankle distal to the index lesion prior to initiation of the intended intervention. Before crossing the lesion, the cuff was inflated 20 mm Hg above the patient's systolic pressure during the PVI procedure. Once revascularization of the target lesion was complete, the Aspire Mechanical Thrombectomy System (Control Medical Technology) was used for aspiration of any distal debris with the affiliated negative-pressure generator. The method of suction embolectomy was the same in all cases: slow pull-back with repeated regeneration of negative pressure. This method permitted optimal capture of embolized debris. The blood pressure cuff was then released before the final angiogram to evaluate the success of the intervention.

Table 1. Baseline demographic and comorbidities.

Characteristics	(n = 61)
Age (years)	72 ± 13
Male gender	33 (54.1%)
Caucasian race	35 (57.4%)
Height (cm)	169.5 ± 10.3
Weight (kg)	83.9 ± 16.1
Medical history	
Coronary artery disease	31 (50.8%)
Hyperlipidemia	60 (98.4%)
Hypertension	61 (100%)
Diabetes mellitus	38 (62.3%)
Current smoker	20 (32.8%)
Congestive heart failure	19 (31.1%)
Atrial fibrillation	12 (19.7%)
Stroke/transient ischemic attack	16 (26.2%)
Renal failure with dialysis	6 (9.8%)
Chronic obstructive airway disease	21 (34.4%)
Bleeding risk[16]	
High	20 (32.8%)
Intermediate	34 (55.7%)
Low	7 (11.5%)
Indications	
Claudication	21 (34.4%)
Rest pain	6 (9.8%)
Ulceration	37 (60.7%)
Critical limb ischemia	0 (0%)
Preprocedural creatinine (mg/dL)	1.66 ± 1.62
Postprocedural creatinine (mg/dL)	2.08 ± 2.46
Preprocedural hemoglobin (g/dL)	11.8 ± 1.8
Postprocedural hemoglobin (g/dL)	10.8 ± 1.8

Data provided as mean ± standard deviation or number (%).

Procedure details. Contralateral retrograde femoral access was obtained in all patients for PVI of infrainguinal lesions. Intravenous unfractionated heparin was used to attain an activated clotting time >250 sec. After initial angiogram was performed and before intervening on the target lesion, a strategic method was applied as mentioned above. Target-lesion PVI was performed using balloon angioplasty, directional or rotational atherectomy, or stenting. Non-ionic contrast was used in all procedures. All patients received

Table 2. Angiographic features.

Characteristics	(n = 61)
Lesion location	
Superficial femoral artery	24 (39.3%)
Popliteal artery	4 (6.6%)
Anterior tibial artery	19 (31.1%)
Posterior tibial artery	10 (16.4%)
Peroneal artery	7 (11.5%)
Lesion length (mm)	192.4 ± 60.3
Vessel diameter (mm)	3.9 ± 2.5

Data provided as mean ± standard deviation or number (%).

intravenous hydration before and after the procedure, aspirin 325 mg before the procedure, and clopidogrel after the procedure. Besides angiography, no other invasive imaging modality such as intravascular ultrasound was used before or after the intervention to guide and/or assess the results of the procedure. Access hemostasis was achieved using vascular closure devices or manual pressure. All patients were monitored overnight in a postprocedure observation unit and discharged the next day if stable.

Data collection and definitions. Data were collected retrospectively and manually entered into an Excel database. The data included patient demographics, comorbid conditions, lesion characteristics, procedure details, in-hospital complications, and outcomes. Procedure details included total contrast used and fluoroscopy time. *Procedural success* was defined as absence of distal embolization, major dissection, perforation, acute limb ischemia, or emergency limb amputation. All angiographic films were reviewed and interpreted by an independent peripheral interventionist who recorded distal flow and distal revascularization pre and post procedure. *Distal flow* was classified as normal, slow, or no flow. *Bleeding* was defined as a decrease in periprocedural hemoglobin of >3 g/dL. *Contrast-induced nephropathy* was defined as 25% increase in creatinine from baseline within 48 hours post procedure. *Mortality* was defined as all-cause death in hospital. *Bleeding risk* at baseline for all individual patients was estimated using a previously published model.[16]

Results

Baseline demographics and comorbidities are shown in Table 1. Of the 61 patients with PAD who underwent intervention, mean age was 72 years and the majority were male, white, and had a high prevalence of comorbid conditions.

Table 3. Procedural outcomes.

Outcomes	(n = 61)
Complications	
Distal embolization	1 (1.6%)
Arterial perforation	0 (0.0%)
Arterial dissection	1 (1.6%)
Bleeding	0 (0.0%)
Emergency amputation	0 (0.0%)
Death	0 (0.0%)
Transfusion	0 (0.0%)
Contrast-induced nephropathy	0 (0.0%)
Fluoroscopy time (min)	22.4 ± 10.7
Contrast used (mL)	90.3 ± 50
Treatment after crossing chronic total occlusion	
Rotational atherectomy	39
Directional atherectomy	20
Balloon	61
Stent	5
Preprocedure flow	
No flow	33
Slow flow	24
Normal flow	4
Postprocedure flow	
No flow	0
Slow flow	1
Normal flow	60

Data provided as mean ± standard deviation or number (%).

Lesion location and characteristics are summarized in Table 2. The primary lesion was in the superficial femoral artery in 39% of cases and popliteal and infrapopliteal arteries in the remaining 61%. Lesions were long, averaging 192 mm.

Procedural success was achieved in 60 patients (Table 3). Average fluoroscopy time was 22.2 min and mean contrast used was 90 mL. Atherectomy and balloon angioplasty were most commonly used for PVI. Only 5 patients (8%) were treated with stent placement.

Procedural complications of significance (Table 3) were limited to 1 patient with slow flow, which could be due to distal embolization. Another patient had dissection that was non-flow limiting, which was managed conservatively without major adverse consequences. There were no perforations.

Review of the 61 angiograms revealed improved flow in all patients (60 with normal flow and 1 with slow flow). The slow flow could have been secondary to distal embolization or poor distal outflow from baseline severe diffuse atherosclerotic disease.

Discussion

In this single-center preliminary study, a high success rate was achieved in the prevention of distal embolization and limb ischemia with the cuff-occlusion distal-protection method. There was 1 case with possible distal embolization and none with limb ischemia or emergency amputation.

The SpiderFX (ev3) and Proteus (Angioslide) are the two devices approved by the United States Food and Drug Administration for the prevention of distal embolization. The DEFINITIVE Ca^{++} (Study of the SilverHawk/TurboHawk Plaque Excision Systems Used With SpiderFX to Treat Calcified Peripheral Arterial Disease) trial,[5] which evaluated the SpiderFX device, enrolled 133 patients. The filter was deployed in its intended location in 97.2% of patients. Major adverse events occurred in 9 patients (6.9%), and included target-vessel dissection in 1 patient (0.8%), vessel perforation in 3 patients (2.3%), and distal embolization in 3 patients (2.3%), with no reported death or amputation. The MC-LEADER (Multi-Center study for Lower-Extremity Angioplasty with Debris Removal) study[14] evaluated the Proteus device in 123 patients. Device success was achieved in 97.8% of patients. In terms of complications, vessel dissection was noted in 6 patients (3.8%), distal embolization in 4 patients (3.3%), and bleeding in 3 patients (2.4%). No patient died or had an amputation.

However, the devices used in these studies are more invasive than the method described herein, and can lead to inner vessel injury, vessel dissection, and/or spasm at the landing zone.[2,15] In addition, the relatively high cost of these devices remains a concern.[15] Finally, these devices are difficult to advance beyond the lesion, specifically when the occlusion is very tight, subtotal, or total, or when the vessel is very tortuous or small. In contrast, our strategy is less expensive, simple, easy to use, and relatively non-invasive, avoiding some of the pitfalls associated with currently available devices. Although we did not have a comparative arm, this strategy appears to have a similar success rate and incidence of distal embolization or limb ischemia compared with these two devices.

Study limitations. This is a non-randomized, single-center, relatively small case series without a concurrent control arm. Efficacy and safety of this new method for prevention of distal embolism compared with other devices needs to be evaluated in future studies.

Conclusion

The present study suggested that this simple strategy was feasible and safe and had the potential for reducing distal embolization and acute limb ischemia. Further study is required to define the efficacy and safety of this novel method compared with those currently used in prevention of distal embolization during PVI of complex lesions in patients with PAD.

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From the [1]St. John Hospital and Medical Center, Detroit, Michigan; [2]Metro Health Hospital, Wyoming, Michigan; and [3]Duke Clinical Research Institute, Durham, North Carolina.

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Address for correspondence: Shwan Jalal, MD, St. John Hospital & Medical Center, 22101 Moross Road VEP, 2nd Floor, Detroit, MI 48236. Email: shwan19822000@yahoo.com