Safety and Effectiveness of Closure Devices Applied to a Stented Common Femoral Artery: A Retrospective Analysis

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Abstract

Bailout stenting of the common femoral artery (CFA) may become necessary with failed balloon angioplasty or atherectomy or in case of bleeding requiring a covered stent over the arteriotomy site. Reaccessing the CFA through a previously placed stent may occur during angiography. The safety and effectiveness of applying a closure device, or manual compression to achieve hemostasis through an accessed stented CFA are unknown. All patients in our practice that underwent CFA stenting were identified using billing records for 3 years (January 1, 2010–February 28, 2013). Patients were included if there has been documentation of access through the stented CFA segment on angiography. In-hospital and up to 2 weeks postdischarge major adverse events were recorded from medical records. A total of 48 patients were included in the study. The mean age was 65.9 ± 10.9 years, males 60.4%. Perclose (Abbott Vascular, Santa Clara, CA) was used in 85.7%, AngioSeal (St. Jude Medical, St. Paul, MN) in 8.3%, Mynx (Access Closure, Santa Clara, CA) in 2%, and manual compression in 4% of the patients. Major adverse events consisted of in-hospital mortality in two patients: one probably related to index access-site thrombosis complicated by subsequent acute renal failure following reintervention; the other mortality was related to major bleeding possibly related to the index access site. The remaining patients had no adverse events and there were no reported problems at 2 weeks follow-up. Accessing and applying closure device in stented CFA can be accomplished successfully in approximately 96% of the patients with low major adverse events.

Keywords

- stent
- common femoral artery
- closure device
- safety

Arterial closure devices (ACDs) are frequently used following endovascular procedures to close the common femoral artery (CFA) arteriotomy site. Randomized trials have shown that these devices are likely to achieve faster hemostasis and early ambulation.¹ Applying these ACDs, however, across stented CFA is off label and its safety is unknown. Currently visualization of the CFA in a 20 degrees ipsilateral angulation is made before deploying these devices to rule out significant CFA disease. The intensity of the complication tends to be higher

when ACD was deployed in high-risk patients such as peripheral arterial disease patients.²

To our knowledge, no reports have been published on the application of ACD in patients with stented CFA when the arteriotomy site was performed through the stent. Although stenting the CFA is generally discouraged, bail out stenting may become necessary with failed balloon angioplasty or atherectomy or in case of bleeding requiring a covered stent over the arteriotomy site. Reaccessing these stents may occur

in subsequent procedures and the best method for closure of the arteriotomy site through the stent is unknown.

We report our experience with patients who underwent endovascular procedures by obtaining access through a CFA stent.

Methods

All patients in our practice that underwent CFA stenting irrespective of etiology were identified using billing records for 3 years (January 1, 2010–February 28, 2013). Patients who underwent stenting of the CFA and then underwent a subsequent procedure using the same stented CFA site (index vessel) had their angiograms reviewed to ensure that site access was performed through the stented segment. Patients were excluded if the access site could not be verified to be through the stent. In-hospital and up to 2 weeks postdischarge major adverse events (MAE) were recorded from medical records. MAE were adjudicated by an interventional cardiologist not involved in the procedure and included major bleeding, amputation, mortality, vascular complications requiring treatment, acute renal failure, acute closure of the index vessel, and infection. Each complication was classified as definitely, probably, possibly or not related to accessing the index vessel. Descriptive analysis was done on all patients with mean $\pm$ standard deviation for continuous variables and percentages for categorical variables.

Results

A total of 48 patients were included in the study. Descriptive analysis is shown in ► **Table 1**. The mean age was 65.9 ± 10.9 years, males 60.4%, current smokers 50%, history of coronary artery disease 66.7%, and diabetics 31.3%. Sheath sizes were: 5F, 2.1%; 6F, 6.3%; 7F, 16.7%; 8F, 72.9%; and 9F, 2.1%. Accessed stents were covered graft stents in 6.4%. Perclose (Abbott Vascular) was used in 85.7%, AngioSeal (St. Jude Medical) in 8.3%, Mynx (AccessClosure) in 2%, and manual compression in 4%. Overall, 100% of patients were on aspirin and 93.7% on an adenosine diphosphate receptor antagonist. Intraprocedural anticoagulants included heparin 89.3%, bivalirudin 6.4%, and heparin with abciximab and tPA 4.3%.

Major adverse events consisted of in-hospital mortality in two patients: one probably related to index site thrombosis complicated by subsequent acute renal failure following reintervention; the other mortality was related to major bleeding possibly related to index site. In a third patient acute limb ischemia occurred and was not related to index site and was treated successfully. No other in-hospital complications were noted. There were no reported MAE at 2 weeks follow-up. Below is a review of the three cases with their respective complications.

First Case

The patient is a 73-year-old male with a history of atrial fibrillation and has been on coumadin (international normalized ratio 1.5 on day of procedure). The patient underwent right CFA access with subsequent deployment of a Viabahn graft (Gore, Newark, DE) stent into the left CFA for a major bleeding after a

Table 1 Demographic, clinical, and angiographic variables

Variables	n	Mean $\pm$ SD
Age (y)	48	65.9 $\pm$ 10.9
BMI	48	26.4 $\pm$ 4.9
Admission creatinine (mg/dL)	48	1.12 $\pm$ 0.44
Hemoglobin on admission (g/dL)	48	12.96 $\pm$ 1.52
Hemoglobin on discharge (g/dL)	44	11.66 $\pm$ 1.67
> 50% narrowing in CFA (before closure device)	17	4.47 $\pm$ 12.71
Sheath size (mm)	48	7.58 $\pm$ 1.14
		Percentage
Gender (male)	48	60.4
Coronary artery disease	48	66.7
Renal insufficiency (creatinine > 1.5)	48	6.3
Hypertension	48	91.7
Cerebrovascular disease	48	10.4
Diabetes mellitus	48	31.3
Hyperlipidemia	48	
No		12.5
Yes		87.5
Tobacco use	48	
Never		4.2
Current		50
Past		48.8
Type of stent	47	
Protégé stent		53.2
Viabahn/Wallgraft		6.4
Lifestent		4.3
Supera		2.1
Smart stent		6.4
Others		25.6

Abbreviations: BMI, body mass index; CFA, common femoral artery.

failed Perclose following an angiogram. The AngioSeal closure device was then deployed for hemostasis in the right CFA leading to the sudden closure of the right CFA and subsequent thrombosis of the right lower extremity. Treatment with AngioJet (Boston Scientific, Maple Grove, MN) embolectomy and stenting was then carried on via access through the left CFA covered stent (index vessel). Left CFA hemostasis was then achieved with the Perclose system through the CFA stent. A few hours after arrival to the floor, patient experienced sudden hypoxia, hypotension, and a drop in hemoglobin to 7.6 g/dL (baseline on admission 14.5 g/dL). This was followed by cardiac arrest and death. No autopsy was performed.

This case was adjudicated as mortality secondary to major bleeding. This could have been related to left CFA Perclose failure through the covered stent, right CFA bleed or a spontaneous

bleed. Since it is uncertain to where the source of bleed was, this was labeled as possibly related to accessing the stented CFA.

Second Case

The patient is a 79-year-old female admitted for a peripheral angiogram and intervention for severe left lower extremity claudication. She has a history of aortobifemoral bypass surgery. She had intervention on the left femoropopliteal segment and left tibial vessels using an antegrade ipsilateral approach from the mid-to-distal left CFA using an 8F sheath size. Hemostasis was then achieved with a Proglide (Abbott Vascular, Santa Clara, CA) closure device. Shortly after returning to her room, she experienced sudden hypotension and she was brought back to the cardiac catheterization laboratory where the proximal left CFA was engaged and a wall graft 8×40 mm stent was deployed in the mid-left CFA with good hemostasis. The Perclose closure device was then deployed. Shortly after the end of the procedure, patient experienced pain in her left leg and she had closure to the left limb of her aortobifemoral bypass with subsequent thrombosis of her left lower leg. The right CFA was accessed but could not achieve contralateral access to the left leg because of angulation and tortuosity of her bypass graft. The left CFA was then accessed through the previously placed stent (index vessel) and retrograde access was accomplished. The left limb of the bypass was then treated with embolectomy and a retrograde wire was then passed into the contralateral right limb and snared into the right CFA sheath. The right CFA sheath was then removed and a destination contralateral sheath was advanced to the left limb of the bypass. The left CFA retrograde sheath was then removed and the Perclose closure device was deployed with good hemostasis. Perclose was then deployed in the right CFA also with good hemostasis. Patient however developed acute renal failure and disseminated intravascular coagulation disorder following the procedure and died.

This case was adjudicated as mortality secondary to acute renal failure and disseminated intravascular coagulopathy probably secondary to closure device failure and thrombosis in the left leg requiring a prolonged procedure to treat.

Third Case

The patient is an 85-year-old female developed right cold foot and underwent emergency procedure using a left CFA access. AngioSeal was used for hemostasis in the left CFA. Acute closure of the right CFA recurred. The reaccess of the left CFA was then obtained and the patient was retreated via the contralateral approach with establishing flow. Another AngioSeal closure device was then utilized to obtain hemostasis in the left CFA. Shortly after the procedure, patient developed hypotension and an acute retroperitoneal bleed with left groin bleeding. Right CFA reaccess was then obtained and the left CFA was treated with a covered stent. Right cold leg recurred again and the left CFA stent was accessed (index vessel) to retreat the right CFA with embolectomy and angioplasty. A left CFA Perclose was then used to achieve hemostasis. The patient then developed left leg cold foot and the right CFA was reaccessed again. The access site was patent, but patient had a left external iliac flap with flow impairment. This was treated successfully. The patient did well and was discharged home.

The case was adjudicated as acute closure of the left external iliac and not the left CFA access site. This was not related to failure of the Perclose system deployed through the stent.

Discussion

Stenting of the CFA is generally highly discouraged. However, this may become a necessity in case of a flow-limited dissection or perforation during percutaneous intervention. Reaccessing the stented CFA may be later needed for additional endovascular interventions. Although this can generally be accomplished with relative ease and under fluoroscopic guidance, it remains unclear what is the optimal method to achieve hemostasis following sheath removal. Theoretically, manual compression can lead to stent deformity and thrombosis. Also, the use of closure devices may carry the risk of stent disruption or intraluminal collagen deposition when using the AngioSeal device.

In this series, we demonstrate that the application of a closure device through a stented CFA is feasible and safe. Two MAE were seen in this study, one related to acute renal failure postprocedure secondary to radiocontrast nephropathy and the other one was possibly related to bleeding although the source of the bleed have not been confirmed. We recommend that operators always image the right CFA before closure device deployment to ensure that the stented segment is patent with no restenosis. Anchor-based closure devices such as the Perclose or AngioSeal should not be advanced too far into the vessel before deployment to avoid anchor attachment to stent struts.

This study is limited by a small number of patients and it is retrospective in nature. Selection bias cannot be ruled out. This is however the first series to address closure-device deployment within stented CFA. A larger prospective database is needed to confirm these findings and compare effectiveness and safety among different closure devices within a stented CFA.

Conflict of Interest

None relevant to this study. Supported by the Nicolas and Gail Shammas Research Fund at the Midwest Cardiovascular Research Foundation. Full disclosure available at: www.mcrcfmd.com.

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