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Duplex-Guided Ipsilateral Antegrade Approach for Flush Superficial Femoral Artery Occlusion

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Abstract

Objective: Recanalization of flush ostial superficial femoral artery (SFA) occlusion is a very challenging procedure. Using the ipsilateral antegrade approach in such lesions has some difficulties. This study aimed to assess the feasibility, efficacy, and outcomes of duplex-guided ipsilateral antegrade access for endovascular treatment of atherosclerotic flush occlusion of the SFA. **Methods:** This is a prospective two-center study that included chronic lower extremity ischemia patients with flush occlusion of SFA who underwent duplex-guided ipsilateral antegrade endovascular revascularization due to unfeasible contralateral femoral approach. Flush occlusions were preoperatively documented by duplex ultrasound and computed tomography angiography in all patients. The outcome measures were technical success, patency rates, perioperative morbidity and mortality, limb salvage, and amputation free survival rates. **Results:** Between April 2019 and March 2021, 49 patients were enrolled in the current study with a mean age of 63.7 ± 5.7 years. Diabetes was the most common risk factor and was found in 40 (81.6%) patients. Associated popliteal lesions were found in seven (14.3%) patients, while 10 (20.4%) patients had combined tibial disease. Selective stenting was done in nine (18.4%) patients. Technical success was achieved in 43 (87.8%) patients. All failures were due to inability to cross the lesion rather than failure to access the common femoral artery. All complications were minor and occurred in seven (14.3%) patients. Primary, assisted primary, and secondary patency rates were 63.9% ± 7.1%, 82.8% ± 5.6%, and 93.5% ± 3.7% at 12 months, respectively. The overall 12-month limb salvage and amputation free survival rates were 91.8% and 83.3% ± 5.4%, respectively. **Conclusion:** Duplex-guided ipsilateral antegrade femoral access is a feasible, safe, and effective endovascular treatment option for flush SFA occlusion when contralateral femoral access is not possible.

Keywords

duplex ultrasound, chronic limb ischemia, flush occlusion, ipsilateral femoral access, superficial femoral artery, endovascular treatment

Introduction

Flush occlusion involving the ostium of the superficial femoral artery (SFA) presents a unique challenge for endovascular revascularization.[1] Currently, contralateral common femoral artery (CFA) cross-over access is the standard approach for endovascular intervention for chronic occlusions at the proximal SFA. However, this access is not possible in patients with contralateral iliac artery disease, previous kissing iliac stenting, or excessive iliac tortuosity which preclude up and over passage of the guidewire.[2] A brachial approach is another option but it is associated with higher risk of complications while requiring long wires, sheaths, and balloons to treat concomitant infra-genicular arterial lesions.[3]

Although ipsilateral antegrade CFA access can be an alternative, it is not ideal for flush SFA occlusions because of the lack of sheath stability. When there is no patent stump of the SFA, antegrade ipsilateral common femoral access with dedicated catheters and wires often yields low success rates and may jeopardize the adjacent profunda femoris artery (PFA).[4] In addition, the ostium of SFA cannot be detected under angiography guidance in those cases. Adding duplex ultrasound (DUS) examination facilitates the visualization of the ostium of the flush occluded SFA and subsequent wire crossing.[5]

The aim of this study was to assess the technical feasibility, efficacy, and safety of using the ipsilateral CFA approach

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guided by DUS in the endovascular therapy of flush SFA occlusion.

Materials and Methods

All consecutive chronic limb ischemia patients with flush SFA occlusion were prospectively studied for percutaneous transluminal angioplasty (PTA) using ipsilateral antegrade femoral approach during the period between April 2019 and March 2021 in the Vascular Surgery Departments of two centers: Assiut University and Qena University Hospitals. The study was conducted in accordance with the declaration of Helsinki and was approved by the institutional review board of Assiut Faculty of Medicine (approval number 17300831). All patients gave their informed written consent before participation in the study.

Inclusion/Exclusion Criteria

All study patients presented with chronic lower extremity ischemia (Rutherford categories 3-6)[6] with atherosclerotic flush SFA occlusion, with or without arterial lesions at the popliteal and/or tibial arteries. All patients had at least one distal runoff vessel along with a contraindication to using the contralateral femoral approach including contralateral iliac occlusion, difficult iliac anatomy, kissing iliac stent, or contralateral hostile groin.

Patients with acute lower limb ischemia, autoimmune disease, or associated ipsilateral iliac or CFA disease were excluded from the study. Patients with high CFA bifurcation (above the upper margin of the head of femur) and those with occluded PFA were also excluded.

Preprocedural Evaluation

All patients were evaluated by detailed history taking and clinical examination. Both DUS and computed tomography angiography (CTA) were performed to confirm presence of flush SFA occlusion, and to assess the run-off vessels and patency of the PFA. Iliac arteries tortuosity or previous iliac stent were also noted. Assessment of the patency of the CFA and the level of its bifurcation in relation to the upper margin of the head of femur are key points in this technique. Calcification of SFA was quantified according to the peripheral artery calcium scoring system (PACSS).[7] All patients were given dual antiplatelet therapy of aspirin 100 mg and clopidogrel 300 mg six hours before the procedure.

Procedural Technique

All procedures were performed under local infiltration anesthesia with lidocaine 2% in a hybrid operating room equipped with a mobile digital angiographic system (Philips BV Pulsera; Philips Medical Systems, Eindhoven, the Netherlands).

Under fluoroscopic guidance, a “high” ipsilateral CFA puncture site is chosen and a slight bent (10°-15°) of the needle was made manually to facilitate puncture of the artery (Figure 1). Skin puncture was made about 2-3 cm above the expected arterial puncture site. We typically enter the CFA in an oblique direction at the upper margin of the femoral head leaving at least 2-3 cm between the artery puncture site and CFA bifurcation. This will allow for placing the distal 2-3 cm of the sheath into CFA and another 2-3 cm in a subcutaneous tunnel at the lowermost abdominal wall. This “high” puncture is needed to maximize the working length in the CFA and to support the sheath inside the subcutaneous tissue.

After successful needle entry, a 7-Fr 11-cm vascular sheath (Prelude; Merit Medical, South Jordan, UT, USA) was inserted into the PFA due to the flush SFA occlusion. Therefore, presence of severe stenosis or occlusion at the PFA ostium rules out the use of this technique. Afterwards, a 5000 IU bolus of heparin was given then a .018-inch guidewire (V18; Boston Scientific, Marlborough, MA, USA) was passed into the PFA. The sheath tip was then retrieved into the CFA to perform angiography at 30° ipsilateral oblique projection with the “road-map” function to confirm the origins of both SFA and PFA and the location of distal artery reconstitution.

Negotiation of the occluded ostium of the SFA was then done under DUS guidance (Philips HD5, Philips Medical Systems, Eindhoven, the Netherlands) equipped with a linear probe (7.5-12 MHz). For color-mode, we used the lowest levels of pulse repetition frequency (PRF) and color-gain to avoid aliasing artifacts. The “default” setting was 2000-2500 Hz for the PRF and 70-80% for the color-gain with a low wall filter between 150 and 350 Hz. The color box was kept as small as possible to maintain a high frame rate.[8]

While the .018-inch guidewire is secured into the PFA, DUS was used to locate the often-invisible occluded SFA origin and to guide an angled stiff .035-inch guidewire supported by a 5-Fr Bern catheter (Boston Scientific) into the ostium of SFA rather than the patent PFA (Figure 2). Both the catheter and wire were forced to engage the ostial cap of the occlusion. On successful entry into the SFA, the catheter was exchanged with a .035-inch support catheter (TrailBlazer; Medtronic, Santa Rosa, CA, USA). Both the catheter and the guidewire were pushed through the subintimal plane until the guidewire was successfully reentered into the true lumen distal to the lesion. Angiography was performed to confirm the reentry. If antegrade SFA recanalization was unsuccessful due to failure of lesion crossing or failure to return to the true lumen after subintimal wire passage, retrograde intervention from popliteal or tibial arteries access was performed.

The occluded SFA was then dilated using a plain balloon catheter (Admiral Xtreme; Medtronic) with appropriate diameter (5-6 mm) and length (Figure 3). Concomitant lesions of the popliteal or tibial arteries were treated by balloon dilation using 4 mm (Admiral Xtreme, Medtronic) or 3 mm balloon (Pacific Plus, Medtronic), respectively.

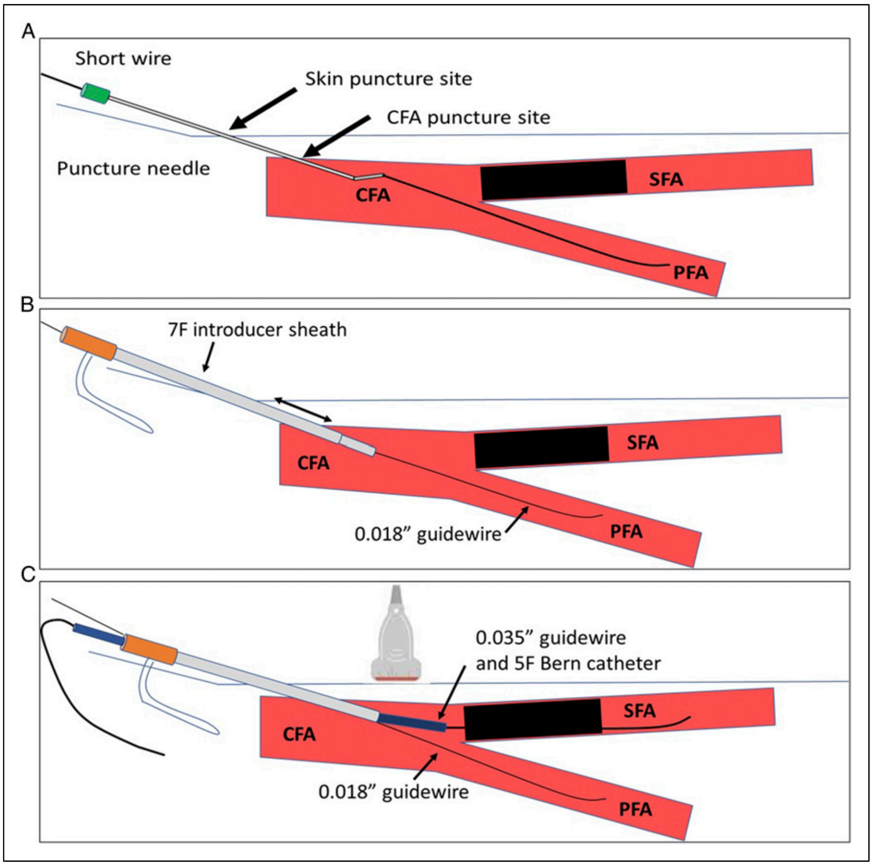

Figure 1. Schematic diagram of the used sheath tunneling technique showing: (A) A high ipsilateral skin puncture site (arrow) made about 2-3 cm above the expected arterial puncture site (arrow 2) leaving at least 2-3 cm between the artery puncture site and CFA bifurcation. The needle is tracked downwards in an oblique direction with a slight (10°-15°) bent of the tip to allow easy needle tip engagement into CFA. (B) A 7-F introducer sheath is entered into CFA (arrow) then a .018" wire (arrow) is advanced into the PFA. The distance marked by the double-headed arrow is the subcutaneously tunneled segment of the introducer sheath (C) Ultrasound-guided direct engagement of the occluded SFA ostium by using a .035" guidewire and 5F Bern catheter (arrow). The .018" wire is maintained inside the PFA throughout the procedure for sheath stabilization (arrow). CFA, common femoral artery; SFA, superficial femoral artery; PFA, profunda femoris artery.

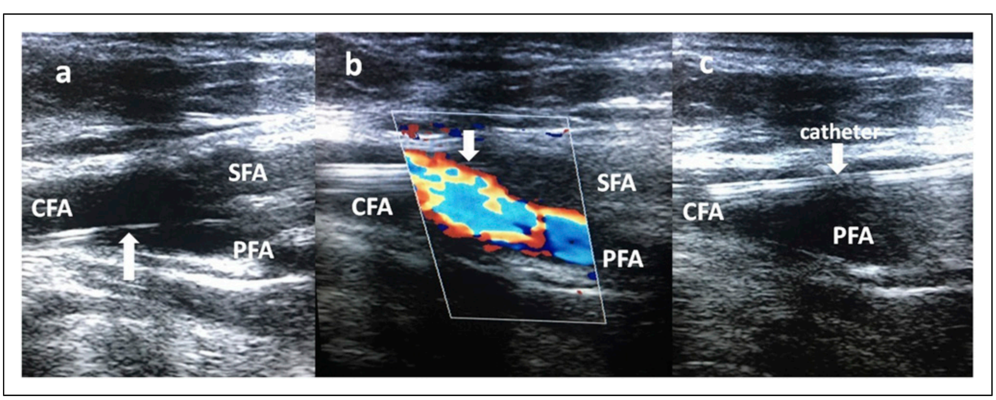

Figure 2. (A) Duplex ultrasound image showing severely calcified lesion occluding the ostium of SFA and passage of guidewire (arrow) inside the PFA. (B) The catheter (arrow) is directed towards the origin of SFA under ultrasound guidance. (C) The catheter and guidewire are advanced through the SFA. CFA, common femoral artery; PFA, profunda femoris artery; SFA, superficial femoral artery.

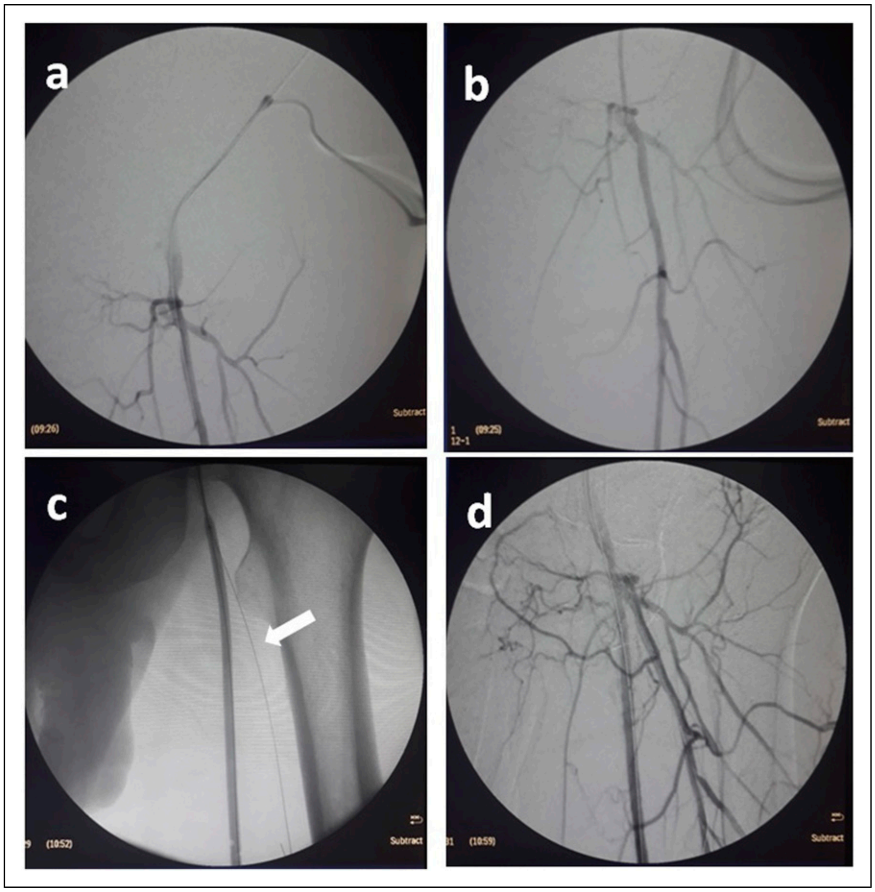

Figure 3. Diagnostic angiogram through ipsilateral antegrade approach showing occlusion of the SFA ostium and no patent stump in the posteroanterior view (A) and left anterior oblique 30° view (B). (C) Angioplasty of flush SFA occlusion by a 6 × 150 mm balloon with safety guidewire (arrow) in the PFA. (D) Completion angiogram shows the patency of the SFA with good flow. SFA, superficial femoral artery; PFA, profunda femoris artery.

Stenting of the SFA was reserved for residual stenosis ≥30% or flow-limiting dissection. A 6-mm self-expandable bare metal stent of variable lengths (E-Luminexx, Bard Peripheral Vascular Inc, Tempe, AZ, USA) was used when needed.

A completion angiography was done at the end of the procedure to check for any residual significant stenosis. When the procedure was completed, the access sheath was removed, and hemostasis was achieved by manual compression.

Follow Up

All patients underwent clinical evaluation, ankle brachial index (ABI) measurement, and DUS examination on the first postoperative day and every three months during the one year follow up for detection of any restenosis or occlusion of the vessels. Aspirin 100 mg/day for life and clopidogrel 75 mg/day for at least one month was prescribed.

Study Outcomes and Definitions

The primary outcome measure was technical success. Primary, assisted primary, secondary patency rates, perioperative morbidity and mortality, limb salvage, and amputation free survival rates were endorsed as secondary outcome measures.

Flush occlusion was defined as chronic occlusion starting at the SFA origin by visual estimation. Technical success was defined as achieving vessel patency with direct in-line flow to the foot with a residual stenosis <30% as demonstrated on completion angiography using the described technique. Primary patency was defined as absence of occlusion or binary restenosis (a >50% diameter stenosis by angiography or a peak systolic velocity ratio >2.4 by DUS) within the treated segment. Assisted primary patency was defined as patency maintained with the use of additional surgical or endovascular procedures as long as occlusion of the primary treated site did not occur. Secondary patency was defined as patency obtained with the use of additional surgical or endovascular procedures after occlusion had occurred. Perioperative morbidity and mortality were defined as complications or death occurring within 30 days following the procedure. Limb salvage was defined as no amputation proximal to the metatarsal bones.

Statistical Analysis

Statistical analysis was performed using SPSS version 24.0 (IBM, Armonk, NY, USA), and MedCalc version 16.8 (MedCalc Software, Ostend, Belgium). Continuous variables were expressed as mean ± standard deviation (SD) and/or median and interquartile range (IQR), and categorical variables as frequency and percentage. Comparisons of continuous variables were computed via t-test (for pre- and post-ABI). Patency rates were analyzed using Kaplan-Meier survival curves and were reported as proportion ±standard error. A P value <.05 was considered statistically significant.

Results

Forty nine chronic lower extremity ischemia patients with flush SFA occlusion underwent endovascular revascularization using duplex-guided ipsilateral antegrade femoral access during the study period. The mean age was 63.7 ± 5.7 years. Thirty five patients (71.4%) were males. Diabetes was the most common risk factor and found in 40 patients (81.6%). The indication of intervention was predominantly ischemic tissue loss or gangrene (69.4%). All baseline characteristics are illustrated in Table 1.

The ipsilateral antegrade approach alone was performed in 45 patients (91.8%) while a combined ipsilateral and retrograde approach was attempted in the remaining four patients. Contralateral femoral access was contraindicated due to difficult iliac anatomy (28.6%), kissing iliac stent (10.2%), contralateral iliac artery disease (55.1%), and contralateral hostile groin (6.1%). Selective SFA stenting using 6 mm self-expandable nitinol bare metal stents was performed in nine (18.4%) patients. Other lesion and procedural details are presented in Table 2.

Technical success was achieved in 43 (87.8%) patients. Technical failures occurred in six patients due to failure to engage the guidewire into the ostium of the SFA. Of the six failures, two patients underwent successful endovascular revascularization using retrograde tibiopedal access and another two received successful bypass surgery. The remaining two patients were poor candidates for surgical revascularization and underwent a deferred below-knee amputation after failed retrograde recanalization attempts. Post-operatively, the mean ABI significantly increased from .48 ± .11 to .98 ± .10 (P < .0001).

No postprocedural (≤30 days) major adverse events (including retroperitoneal hematoma, acute myocardial infarction, stroke, or death) or major amputations occurred in the

Table 1. Demographics and Clinical Presentation of the Study Cohort.

	Number	Percentage
Age, y		
Mean ± SD	63.7 ± 5.7	
Median (IQR)	64 (59-68)	
Male gender	35	71.4
Current smoking	31	63.3
Diabetes	40	81.6
Hypertension	27	55.1
CAD	23	46.9
CVD	8	16.3
CKD (eGFR <60 mL/min/1.73 m^2)	11	22.4
COPD	7	14.3
Dyslipidemia	19	38.8
Obesity (BMI >30 kg/m^2)	10	20.4
Rutherford stage		
Stage 3	5	10.2
Stage 4	10	20.4
Stage 5	25	51.0
Stage 6	9	18.4
ABI		
Mean ± SD	.48 ± .11	
Median (IQR)	.50 (.39-.55)	

Continuous data are presented as the means ± standard deviation (SD) and/or median and interquartile range (IQR); categorical data are given as the counts (percentage).

Abbreviations: ABI, ankle brachial index; BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; eGFR, estimated glomerular filtration rate.

Table 2. Lesion Characteristics and Procedural Details.

	Number	Percentage
Indications		
Difficult iliac anatomy	14	28.6
Kissing iliac stent	5	10.2
Contralateral iliac disease	27	55.1
Contralateral hostile groin	3	6.1
Side		
Right	19	38.8
Left	30	61.2
Length of SFA lesion, mm		
Mean ± SD	161.6 ± 25.4	
Median (IQR)	169 (140-180)	
Concomitant arterial lesions		
Popliteal artery	7	14.3
Tibial vessels	10	20.4
Calcification (PACSS)		
Grade 0	11	22.4
Grade 1/2	16	32.7
Grade 3/4	22	44.9
Runoff vessels		
1	17	34.7
2	23	46.9
3	9	18.4
Provisional stenting		
1 stent	7	14.3
2 stents	2	4.1

Continuous data are presented as the means ± standard deviation (SD) and/or median and interquartile range (IQR); categorical data are given as the counts (percentage).
Abbreviations: PACSS, Peripheral Artery Calcium Scoring System; SFA, superficial femoral artery.

present study. Minor complications were observed in seven (14.3%) patients including small puncture site hematoma in five (10.2%) patients that were all treated conservatively and two (4.1%) pseudoaneurysms, one at the CFA and another at mid SFA because of a minute vessel perforation that was not detected during the procedure. Both pseudoaneurysms were surgically treated by simple repair.

During the follow up period, three (6.1%) patients lost follow-up and four (8.1%) patients died for unrelated causes to the endovascular revascularization. Restenosis of the target lesion was observed in three patients, while occlusion recurred in eight patients. Endovascular balloon dilatation succeeded to maintain/restore patency in eight patients. For the remaining three patients, two had major amputation after failure of both endovascular and surgical bypass and one patient was treated conservatively. The overall primary, assisted primary, and secondary patency rates were 63.9% ± 7.1%, 82.8% ± 5.6%, and 93.5% ± 3.7% at 12 months, respectively (Figure 4). The overall 12-month limb salvage and amputation free survival rates were 91.8% and 83.3% ± 5.4%, respectively.

Discussion

Although contralateral cross over femoral access is the preferred approach for proximal SFA occlusion, it can be extremely difficult or even unfeasible in certain occasions like difficult iliac anatomy (eg, extremely tortuous iliac arteries or acuity of the aortic bifurcation).[9] The major limitations of ipsilateral antegrade puncture of CFA in the presence of flush SFA occlusion are the partially inserted sheath that can be easily slipped from the artery and the close proximity to the lesion which does not give enough space for the guide wire manipulation during lesion recanalization.[10]

To overcome these limitations, we adopted the strategy of tunneled ipsilateral sheath that is modified from the one described by El-Maadawy et al.[11] In their technique, two skin punctures are made, one is located directly over the CFA (standard puncture) where the guidewire is passed through the needle into the PFA, while the second skin puncture is made few centimeters proximal to the first one. The second puncture needle is advanced subcutaneously towards to the first puncture site so the guidewire of the first puncture site can be flossed into the tip of the second needle to exit from the second puncture site. Then, the sheath can be advanced over the wire from the second puncture site, through the subcutaneous plane, to the CFA. We modified that technique by utilizing a single "high" skin puncture site located about 2-3 cm above the expected arteriotomy site. With a slightly bent puncture needle at an angle of 10°-15°, the needle runs from the skin puncture to be tracked subcutaneously for 2-3 cm in an oblique downwards course until it enters the CFA in a sloping direction.

To further support the tunneled sheath, we also placed a .018-inch guidewire into the PFA throughout the procedure to stabilize the sheath within CFA and to facilitate treatment of possible dissection of PFA during manipulation of the lesion.[10] Eleissawy et al used a similar technique to ours but they only pass the basic short wire into the PFA after failed attempt of subintimal crossing of the flush occluded SFA.[12]

The present study was performed to evaluate the feasibility and outcomes of endovascular recanalization of flush SFA occlusions using ipsilateral antegrade femoral approach in patients with contraindications to using the contralateral femoral access. The technical success rate in our study was 87.8%. All failures in the current study were due to inability to engage the guidewire inside the flush SFA occlusion rather than failure to access the ipsilateral CFA. Most of these failures were observed in obese patients. It seems that presence of a hanging abdomen may have caused some angulation of the sheath which may deviate the force applied to the wire away from the intended direction. Our technical success rate is consistent with those reported in most relevant studies with a technical success rate of subintimal angioplasty of long SFA lesions ranging from 80% to 90%.[13,14] Eleissawy et al randomized 53 critical limb ischemia patients with flush SFA occlusion to either ipsilateral antegrade angioplasty or surgical

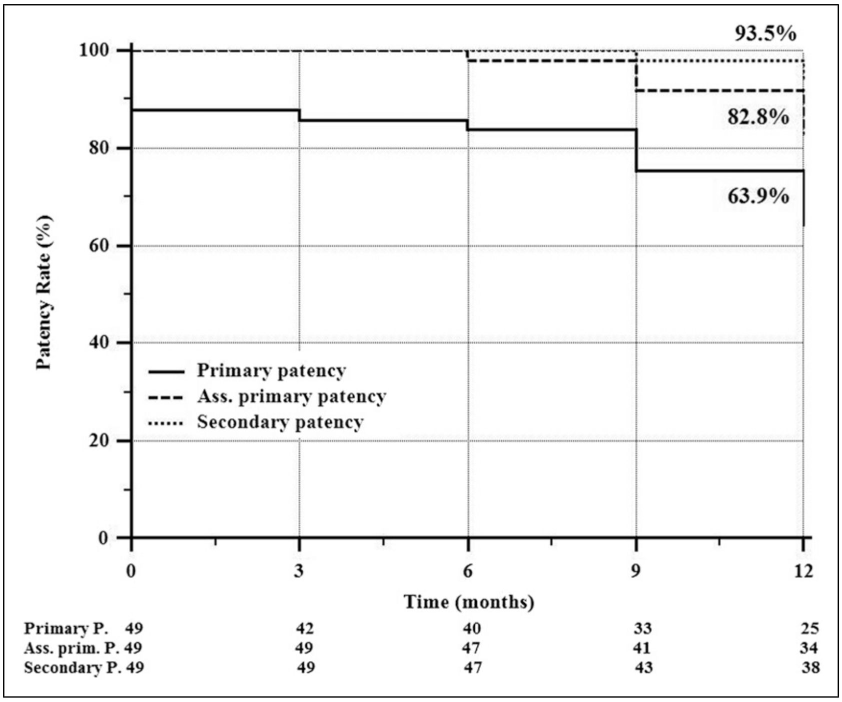

Figure 4. Kaplan-Meier curve of the 12 months patency rates of study patients.

bypass.[12] Technical success was achieved in 89.3% of their endovascular patients and all the three failures in their study were due to inability to engage the guidewire into the ostium of the SFA.

The main disadvantage of the sheath tunneling techniques is the need for a "high" CFA puncture. The CFA access site, although located under DUS guidance, could be above the level of inguinal ligament which can be complicated with a retroperitoneal hematoma due to inefficient manual compression. We routinely used DUS in addition to CTA to confirm the location of the CFA bifurcation in relation to the superior margin of the femoral head prior to needle access. In the current study, no retroperitoneal hematoma or any major complications were encountered. DUS examination was also useful in the diagnosis of the two iatrogenic pseudoaneurysms encountered in the present study owing to its reported high sensitivity and specificity rates in the diagnosis of peripheral arterial pseudoaneurysms.[8] Postoperative complications occurred in 14.3% of our patients, which is quite similar to the corresponding rates reported in other studies.[12,15]

Our primary, assisted primary, and secondary patency rates at 12 months were 63.9% ± 7.1%, 82.8% ± 5.6%, and 93.5% ± 3.7%, respectively. Limb salvage rate was 91.8% at one year. Our patency rates are higher than the primary (57.5%) and secondary (64%) patency rates reported in Ghoneim et al study, which included 43 patients presenting with critical limb ischemia and flush SFA occlusion.[16] Their lower patency and limb salvage rates (76.7%) may be attributed to the higher prevalence of patients with tissue loss (84%) compared to 69.4% in our study. In their analysis to determine factors affecting patency and limb salvage, their limb salvage rates were clearly better in patients presenting with rest pain compared to those with tissue loss (100% vs 76%, respectively).

In contrast, Faglia et al, reported better rates for primary (78.6%) and secondary patency (97.1%) as compared to ours although all of their patients were diabetic with critical limb ischemia and 66.6% of their lesions were combined femoropopliteal and infrapopliteal lesions.[17] This could be explained by the difference in the morphology of the arterial lesion since about half of their femoropopliteal lesions were Transatlantic Inter-society Consensus (TASC) A and B with a shorter mean lesion length than ours (134 mm vs 162 mm, respectively). Moreover, in contrast to Faglia et al study, the present investigation enrolled only patients with flush SFA occlusions. Indeed, TASC[18] and TASC II,[19] the most known angiographic anatomical classification of lower extremity arterial lesions, did not consider SFA stump morphology in their recommendations for treatment of chronic limb ischemia. Flush SFA occlusion, however, was recently found to be a significant predictor of presence of long-standing arterial occlusions, which are known to have harder plaques with more calcification, making them more difficult for endovascular recanalization.[20] This may raise a concern that endovascular revascularization of ostial arterial occlusions may behave differently in terms of both immediate and late outcomes as compared to treating non-ostial lesions.

There are limitations in the present study due to the small number of patients and lack of long term follow up. There was no control group with absent comparison to other endovascular techniques. A future goal will be conducting a randomized controlled trial to compare the results of ipsilateral vs contralateral access for flush SFA occlusion, as well as outcomes of endovascular treatment of SFA lesions without ostial occlusions vs those with flush occlusion or with a very short patent stump.

Conclusions

This study demonstrates that endovascular therapy via the ipsilateral antegrade femoral approach is technically feasible, safe, and effective approach for patients with flush SFA chronic total occlusion, particularly when the use of contralateral access is not feasible. In this approach, duplex ultrasound guidance is mandatory to visualize the SFA ostium that is usually undetected under fluoroscopy. Basic prerequisites to this technique include certain anatomic criteria like a non-diseased CFA, normal or low CFA bifurcation, and patent PFA.

Declaration of Conflicting Interests

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