ORIGINAL ARTICLE

Assessment of Retrograde Recanalization by using Balloon Angioplasty for Long Segment Superficial Femoral Artery Occlusion

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Abstract

Background: ***The most common cause of peripheral arterial disease (PAD) and claudication is disease of the superficial femoral artery (SFA). The prevalence of PAD is increasing, with recent estimates putting the number of affected individuals at around 200 million. About 20% of PAD patients experience claudication, and nearly 50% show no symptoms at all.***

Aim and objectives: ***Evaluation of retrograde angioplasty for the treatment of SFA occlusive illnesses following the failure of antegrade recanalization procedure with respect to limb salvage rates in cases of chronic lower limb-threatening ischemia, secondary patency rate, comorbidities, and overall success rate.***

Patients and methods: ***Thirty patients presenting to the Vascular Departments of Al-Azhar University Hospitals (Cairo) and Military Hospitals between August 2021 and June 2023 with chronic lower limb threatening ischemia and SFA occlusive diseases (Rutherford classification category 2 to 6), comprised one arm of this prospective study clinical trial.***

Results: ***Our technical success in crossing the lesion was 90% with only 10-patients needed stenting. Our follow up Primary patency rate after 12-months was 75% and secondary patency rate was 100% after 24-months.***

Conclusion: ***In cases of SFA atherosclerotic occlusive diseases, endovascular procedures are thought to be safe and effective management options. This is especially true for retrograde access procedures, which have a high technical success rate and a high percentage of lower limb salvage in cases of chronic lower limb threatening ischemia. Our results demonstrated that recanalization of SFA complete blockage with proximal PA lesion can be accomplished safely and effectively using the US guided retrograde popliteal artery (RPA) endovascular method.***

Keywords: Retrograde recanalization; Balloon angioplasty; Femoral artery occlusion

1. Introduction

The primary cause of claudication and peripheral arterial disease (PAD) is superficial femoral artery (SFA) disease. Current estimates indicate that more than 200 million people have PAD, and the number is growing. About 20% of people with PAD experience claudication, and nearly half are asymptomatic.[1]

Because of its comparatively low risk of morbidity and mortality and its high success rate due to technological advancements, the SFA's endovascular intervention is the recommended option, especially for short-segment illness. However, the SFA's distinct biochemical, anatomical, and hemodynamic factors make endovascular intervention extremely difficult.[2]

The most common method for treating SFA illness, whether as a primary treatment or as an adjuvant to stents or other devices, is balloon angioplasty. A suitable balloon needs to be chosen after the lesion has been crossed. A variety of balloons can be employed in various situations.[3]

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The retrograde popliteal approach was initially limited and served as a backup option. However, refinements to this technique have made this an attractive option, and it has been advocated as the first-line treatment in selected patients.[4]

With regard to primary patency rate, secondary patency rate, complications, and limb salvage rates in chronic lower limb threatening ischemia, this study attempts to evaluate the use of retrograde angioplasty in the treatment of SFA occlusive diseases in the event that the antegrade recanalization technique fails.

2. Patients and methods

This is a prospective study clinical trial one arm was conducted on 30 patients suffered from chronic lower limb threatening ischemia with superficial femoral artery occlusive disease (Rutherford classification category 2 to 6) presented from August 2021 until June 2023 to the vascular departments of Al-Azhar University Hospitals (Cairo) and Military Hospitals.

Inclusions:

This study included patients 50 years of age or older with chronic lower limb-threatening ischemia with SFA occlusion presented by persistent rest pain of more than two weeks duration, minor tissue injury, and major tissue injury.

Exclusions:

The exclusion criteria included patients with: unsalvageable limb with extensive ischemic ulceration, gangrene, or acute limb ischemia, and those with severe comorbidities and life expectancy less than 1 year, or terminal patients, hypersensitivity to contrast material, impaired renal function, and those who had previous major amputation.

Methods:

Patients' personal histories (name, age, sex, occupation, residence, and particular habits), present and prior medical histories, family histories, and complaints (pain at rest and tissue loss) were all examined after they gave their written, informed consent. General examination, including the following: weight, appearance, breathing, temperature, pulse rate, rhythm, head and neck, heart, lungs, abdomen, and scars. Analyses conducted locally include the affected limb's pulse, the ankle-brachial pressure index (ABPI), and any skin lesions at the puncture site.

Investigations:

Complete blood picture(CBC), coagulation profile(e.g. bleeding time, clotting time, prothrombin time and INR), kidney function tests: Serum urea and creatinine levels. Liver function tests: Bilirubin, plasma proteins, SGOT and SGPT, hepatitis markers: B, C and HIV, blood glucose level: fasting & post prandial & HbA1c, lipid profile: cholesterol & triglycerides.

We analyzed the morphologic criteria of the patient's arterial lesions in terms of: lesion site, lesion type, lesion length, number of lesions per artery, lesion nature, number of tibial arteries involved, the status of inflow& outflow(foot) arteries.

Color duplex ultrasound of arterial system of the affected lower limb and computerized topographic arteriography(CTA), were also done.

Pre-medication:

Clopidogrel bisulfate (75 mg/day) and/or aspirin (75–150 mg/day) were started at least five days before endovascular procedures. Clopidogrel loading doses (300 mg/day) were started on the same day for patients who did not finish their course of treatment as directed.

If the patient had previously taken oral anticoagulant medication (which was stopped 6–8 hours before the procedure), subcutaneous heparin was investigated. Hydration was maintained through IV or oral fluids.

Technique of the procedure:

The procedures were done in the operating room under complete aseptic technique with radiological angiography suite or C-Arm. All cases were done under local anesthesia. Retrograde access(popliteal or tibials arteries) ultrasound guided in case of failed antegrade recanalization technique.

Equipment:

Single-wall Seldinger's needle assembly 16-18 gauge. The usually used sheath for pedal access was either a 4F-micro puncture set or a 6F-radial sheath kit, while in popliteal access, the ordinary 6F and 7F sheaths were used. The choice of the guide wire depended on the intended procedure. A short uncoated guide wire was used for preliminary arterial access and introduction of the sheath. Teflon-coated guide wire with an F-shaped flexible tip of different sizes and lengths was used in all diagnostic procedures. Hydrophilic-coated guide wires(Terumo):0.035, 0.018, and 0.014-diameter and 120-160 length. Exchange guide wires: A long wire (220-260cm) for exchanging balloons while maintaining the wire in a safe position across the stenosis in distally situated lesions. Pigtail catheter(Size of 5 or 7 French) for: flush aortography.

Low-profile balloon catheters were used: Selection of size and length of balloon used in angioplasty was based on the size of the native artery (non-diseased artery adjacent to the lesion). In infra-popliteal angioplasty, (3-4mm) diameter(20-60mm) long balloon catheters were used. In SFA and popliteal artery angioplasty, (4-5mm) diameter(40-60mm) long balloon catheters were used. Balloon catheters with a 6 mm

diameter and 40–60 mm length were utilized in EIA angioplasty. Long angioplasty balloons were not used carelessly in order to avoid damaging or dissecting nearby arteries. All of the used balloons had a maximum inflation pressure of 10–12 atmospheres.

Procedure Details:

Following vascular access, patients were given intravenous (IV) 60μg/kg (3000-5000IU) of unfractionated heparin. Breaking through the occlusion: Since the 0.014-inch wire typically lacks sufficient body to support the retrograde crossing of the tibial occlusion, its usage has been disappointing. Instead, the 0.035-inch Terumo Guidewire R (Terumo Medical, Somerset, New Jersey) is utilized, supported by a 4F-guiding catheter. The procedure's goal was to restore a straight-line flow from SFA to the foot. Over a 0.014-inch distance, tibial procedures for stenotic lesions are carried out. For occlusive lesions, a 0.018 or 0.035-inch guidewire can be necessary. Long or calcific lesions were traversed with catheter assistance.

Most stenosis and occlusions could be overcome using a 4–5Fr catheter and a 0.035 hydrophilic guidewire for proximal infra-geniculate lesions. Before PTA, the 0.035 guidewire might be swapped out for a lower caliber guidewire after the lesion has been passed. For distal lesions, a 0.018 hydrophilic guidewire and a 0.018 or 0.035 balloon catheter were utilized in tandem. As the guidewire breaks through the occlusion or is moved through the stenosis, the balloon is advanced.

Low-profile balloon catheters (4-fr) with a diameter of 2.5–3 mm for tibial arteries, 4 mm for infra-genicular popliteal arteries, and 4-5 mm for SFA and a length of 40–80 mm are used for dilatation once the lesion has been crossed. An inflator was used to inflate balloons at 6–10 atm for 30–60 seconds. After the balloon was deflated, routine angiography (completion angiography) was carried out (with the guide wire still over the lesion). Any severe stenosis that remained, affecting more than 30% of the lumen, was repeatedly dilated. The ultimate result of the surgery was then documented.

Two hours after the angioplasty, the catheter was removed, the sheath was taken off, and digital pressure was applied over the puncture site. This should be enough to stop the bleeding, but it won't completely block the artery. Until total hemostasis is achieved, compression should be maintained for at least ten to fifteen minutes. The patient was kept on bed rest for four hours after the treatment, and a pressure dressing was placed on the puncture site for twenty-four hours.

Post-procedural:

Heparin was administered intravenously (IV) to patients whose partial thromboplastin time (PTT) was 1.5 times the control value for 24 to 48 hours following the procedure. Every patient was meticulously watched both during and for an average of 24 to 48 hours following the treatment. Acetylsalicylic acid 75–150 mg (continued indefinitely unless contraindicated) and clopidogrel bisulfate 75 mg daily for 6–12 weeks as part of long-term antiplatelet therapy.

Definition of study endpoint:

The restoration of direct "in-line" flow to the foot via at least one IP artery with no appreciable residual stenosis (or PTA with less than 50% residual stenosis of the initial lesion following dilatation) was considered a technical success. Less than 30% of residual stenosis is ideal. 30–50% of residual stenosis is suboptimal. Failure: more than half of the stenosis remains

Technical Failure: PTA caused: Failure to traverse the lesion, so no dilatation is done from the start "initial failure"; this resulted in >50% residual stenosis of the original lesion after dilatation (needing subsequent endovascular or surgical revascularization, needing above or below knee amputation). Because of calcification, lesions are difficult to dilate. immediate restenosis following balloon dilatation. Complications (thrombosis, dissection, or perforation) may occur.

For patients with non-compressible arteries, hemodynamic success was defined as an improvement in PVR tracing of at least 5 mm or a rise in ABI of at least 0.10.

Any further amputations over the level of a Syme amputation or the requirement for a surgical bypass were considered clinical failures.

Presentation category to the higher one, such as a patient who develops claudication from rest discomfort. However, in order to be deemed clinically better, individuals with gangrene and ischemic tissue loss must be moved to the claudication category at the very least.

The primary patency, Freedom from restenosis (Ultrasound patency) during the follow-up, was considered clinical success, as was the patients' transition from the clinical. (Continuous patency without any re-intervention, such as amputation, surgery on or near the edges of the treated lesion, or angioplasty) .

Post-procedure Follow-up:

At every clinic appointment, clinical follow-up data was gathered and documented. The following points were the subject of follow-up at 1, 3, 6, 12, and 24 months in our vascular surgery outpatient clinic: based on Rutherford's upward categorical shift, which was accompanied by either increasing tissue healing or the absence of rest pain over the study's follow-up period. Using the Texas University Classification, wound healing was recorded as either full, better, stable, or worse.

Using duplex ultrasonography, the patency rate

was evaluated. At 1, 3, 6, 12, 24 months, or whenever new symptoms surfaced, all patients were reexamined to check for access site problems and to confirm patency. This process was continued for six months. In cases with absent or decreased pulse or recurrence of symptoms, follow-up included clinical examination and imaging studies (duplex US, angiography) if necessary.

Substantial problems included substantial bleeding or acute thrombotic occlusion, major amputations, renal failure, the necessity for emergency surgery because of artery perforation, and procedure-related mortality.

When the sheath approach was applied, two occurrences of minor problems, including groin hemorrhage, were managed with localized compression.

Statistical analysis

The results were presented as numbers (%) or means±standard deviation of the means. The unpaired t-test was used to compare the various parameters. The chi-square test was used to compare the category data. Data analysis was conducted using the Statistical Package for Social Sciences (SPSS) computer application (version 19 Windows). F-tests and ANOVA were also employed, and a P-value of less than 0.05 was deemed significant.

3. Results

The 30-patients in the study had an average age of 64.67±6.35. 60% Male patients made up 60% of the study's participants, while female patients made up 40%.

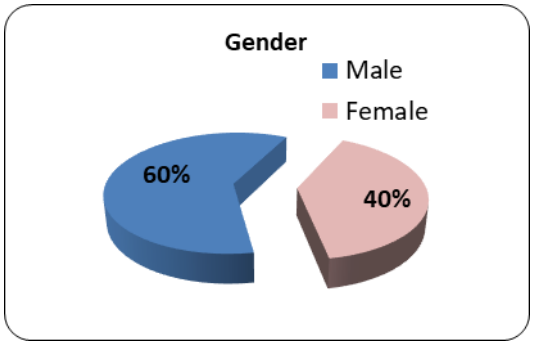


Figure 1. Sex distribution among study population.

Table 1. Presence of co-morbidities among the studied patient.

DEMOGRAPHIC DATA		TOTAL NO=30
AGE	Mean±SD	64.67±6.35
	Range	52-80
GENDER	Male	18(60.0%)
	Female	12(40.0%)
HEIGHT METER	Mean±SD	1.70±008
	Range	1.56-188
WT KG	Mean±SD	87.00±9.70
	Range	65-110
BMI	Mean±SD	30.20±3.47
	Range	23.6-36.36
SMOKING	No	11(36.7%)
	Yes	19(63.3%)
DM	No	5(16.7%)
	Yes	25(83.3%)
HTN	No	7(23.3%)
	Yes	23(76.7%)
IHDS	No	16(53.3%)
	Yes	14(46.7%)

The 30-patients that were part of the study had an average age of 64.67±6.35. Forty percent of the study's participants were female, and sixty percent of the patients were male. The patients weighed between 65 and 110 kg. The elevation ranged from 1.5 to 128 meters. The bulk of the patients had significant comorbidities, as seen in the table, and their BMI ranged from 23.6-36.36. Concomitant coronary arterial disease was present in 46.7% of people (n = 14), 63.3% of people (n = 19) smoked, 83.3% of people (n = 25) had type 2 diabetes, and 76.7% of people (n = 23) had hypertension, (table 1).

Table 2. Pre-operative data among the studied patients.

PRE OPERATION		TOTAL NO=30
RUTHERFORD CLASSIFICATION	II	2(6.7%)
	III	7(23.3%)
	IV	7(23.3%)
	V	12(40.0%)
	VI	2(6.7%)
PRE ABI	Mean±SD	0.45±0.10
	Range	0.3-0.7
CTA CLASSIFICATION PRE (ACCORDING TO GLASS)	III	11(36.7%)
	IV	19(63.3%)

The percentage of patient presented with moderate claudication pain 2-cases(6.7%) (Rutherford category II), severe claudication pain 7-cases(23.3%) (Rutherford category III) ischemic rest pain 7-cases(23.3%) (Rutherford category IV), Two instances (6.7%) had significant tissue loss (Rutherford category VI), while twelve patients (40%) had ischemic ulcers or mild tissue loss (Rutherford category V). The patients' average ABI was 0.45±0.10, (table 2).

Table 3. Procedure data among the studied patients

OPERATION		TOTAL NO=30
ACCESS	Trans-POP	24(80.0%)
	Infra-POP	6(20.0%)
POSITION	Supine	6(20.0%)
	Prone	24(80.0%)
W/WO STENT	With	10(33.3%)
	Without	20(66.7%)

Technical success rate of retrograde puncture guided with duplex ultrasound was 100%. Prone position with trans-popliteal access was 24-cases(80.0%), Supine position with infra popliteal access was 6-cases(20.0%). Stents were deployed in 10(33.3%) of cases, 20(66.7%) of cases not need stents, (table 3).

Table 4. Pulse, duplex and symptoms immediately postoperative, after 1-month, after 6-months, after 1-year and after 2-years among the studied patients

		IMMEDIATELY POSTOPERATIVE	ONE-MONTH	6-MONTH	1-YEAR	2-YEARS	TEST VALUE	P-VALUE	SIG.
PULSE REGAINED	No	3(10.0%)	2(6.9%)	5(17.2%)	6(25.0%)	2(8.3%)	5.088*	0.278	NS
	Yes	27(90.0%)	27(93.1%)	24(82.8%)	18(75.0%)	22(91.7%)			
DUPLEX PATENCY	No	3(10.0%)	2(7.1%)	5(17.2%)	6(25.0%)	2(8.3%)	5.088*	0.278	NS
	Yes	27(90.0%)	26(92.9%)	24(82.8%)	18(75.0%)	22(91.7%)			
SYMPTOMS RELIEF	No	2(6.7%)	2(6.9%)	5(17.2%)	4(16.7%)	0(0.0%)	6.447*	0.168	NS
	Yes	28(93.3%)	27(93.1%)	24(82.8%)	20(83.3%)	24(100.0%)			

P-value>0.05:Non-significant; P-value<0.05: Significant; P-value<0.01:Highly significant
*:Chi-square test

Table 5. Percentage of complications, mortality and re-intervention among the studied patients.

COMPLICATIONS		TOTAL NO=30
COMPLICATIONS	Not complicated	23(76.7%)
	Complicated	7(23.3%)
	Hematoma	2(6.7%)
	Amputation	5(16.7%)
SUCCESS IN NON COMPLICATED CASES	success	23(76.7%)
DIED	No	29(96.7%)
	Yes	1 (3.3%)
RE-INTERVENTION	No	24 (82.8%)
	Yes	5(17.2%)
	Bypass	3(60.0%)
	Angioplasty	2(40.0%)

Regarding to complications: Hematoma occurred in two-cases(6.7%) and Amputation needed in five cases(16.7%). Regarding to success: success in non-complicated cases detected in 23-cases(76.7%). Regarding to mortality: One-patient died at 6-months after procedure due to myocardial infarction,(table 5).

Case presentation:

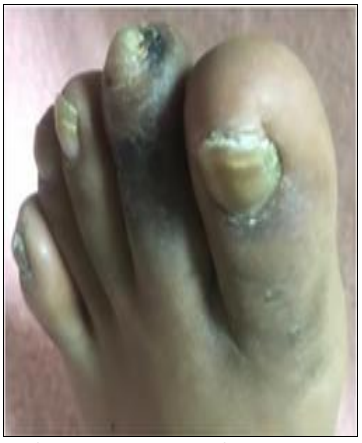
A male non-smoker, fifty-seven years old, with diabetes, hypertension, and dyslipidemia, complained of a month-long resting ache in his left lower limb and a gangrenous tip on his second toe.

Procedure:

Angiography revealed blockage of the remaining SFA and severe stenosis of the left SFA at its onset. By retrogradely puncturing the left popliteal artery, the first attempt to antegradely bridge the whole blockage using a Terumo hydrophilic guide wire was successful. Using a 5mmx250mm DEB catheter, an angioplasty was carried out. Angiography performed after angioplasty revealed that the SFA was satisfactorily patent throughout.

Follow-up:

The diagnostic angiography conducted at 24 months verified the patency of the left superficial femoral artery (SFA).



Figure(2):Left gangrene 2nd toe.

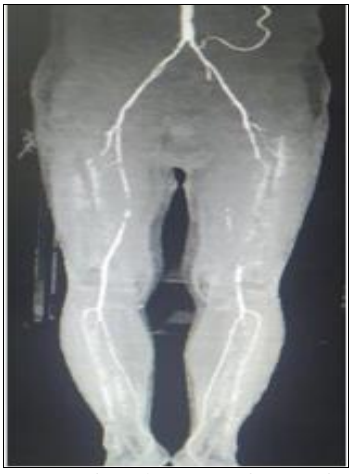


Figure 3. CTA showing total occlusion of left SFA

Access: Duplex guided retrograde access trans-popliteal artery of the left lower limb and insertion of 6F sheath while the patient in prone position.

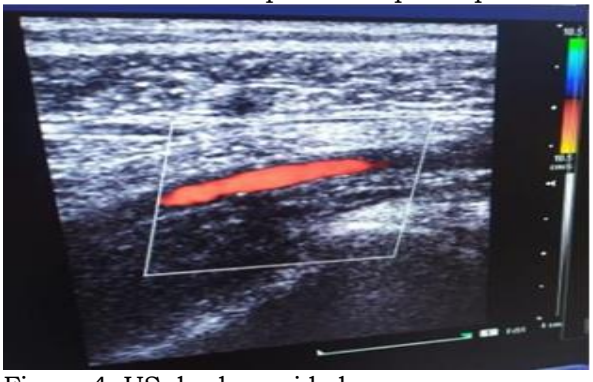


Figure 4. US duplex guided.

PROCEDURE: Introducing of 0.035 wire and BERN catheter which passed the lesion and re-entry was done easily into CFA.

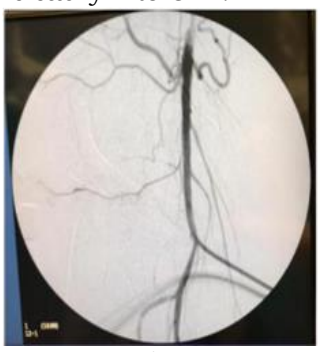


Figure 5. BERN catheter over 0.035 wire passing the occlusion

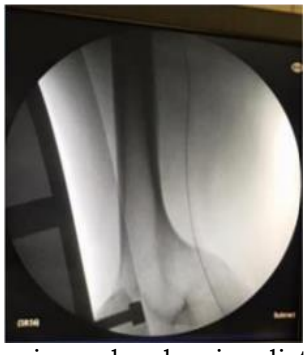


Figure 6. Angiography showing distal lesion

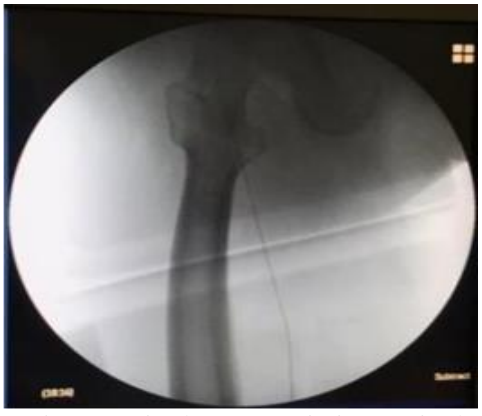


Figure 7. 0.035 wire passed the occlusion into CFA lumen.

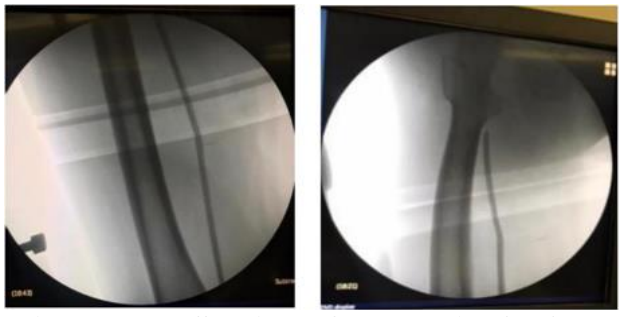


Figure 8. Ballooning of SFA using5x250mm balloon

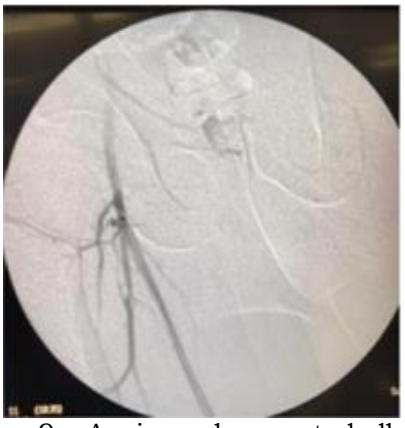


Figure 9. Angiography post ballooning of proximal SFA

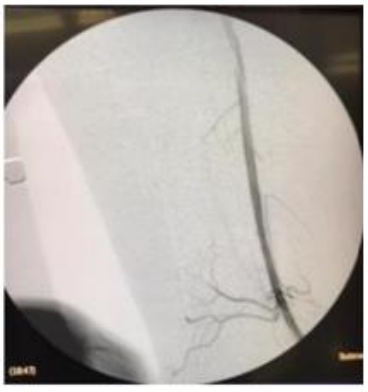


Figure 10. Angiography post ballooning of Mid, distal SFA & proximal popliteal a

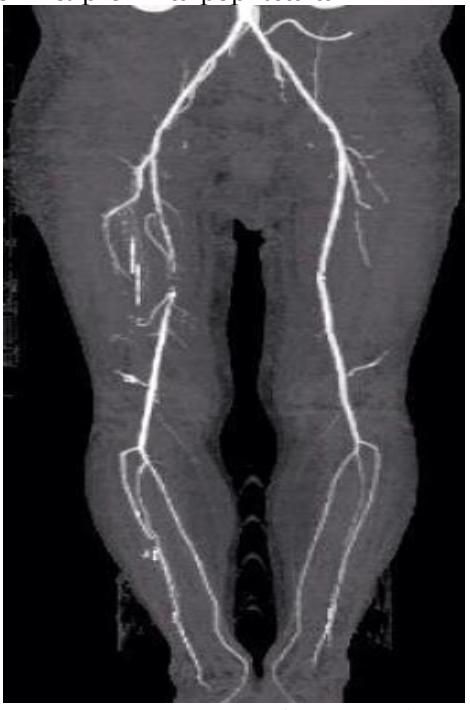


Figure 11. CTA 24-months post intervention showing patent left SFA

4. Discussion

In our study, the majority of patients were males (60%), but in the study of Khalil E.,[5] where 85% of patients were males, and the study of Kuserli & Kavala[6], where 76.3% of patients were males. With mean age 64.67±6.35 years old, but the mean age range of the study of Khalil & Ozcan[7] where the mean age was 64±9 and the study of Elhaieg et al.,[8] where the mean age was 65±3.

As regard risk factors and comorbidities, our patients had multiple risk factors such as smoking (63.3%), hypertension (76.7%), diabetes mellitus(83.3%), ischemic heart diseases(46.7%), So the main risk factors in our study was diabetes mellitus not like the study of Komshian et al.,[9] where smoking was the main risk factor(83.1%) and the study of Kuserli & Kavala [6] where smoking also was the main risk factor(76%).

In our study, the majority of the patients have tissue loss (46.7%), as in the study of Silvestro et al.,[10] where the majority of the patients have tissue loss(84.4%).

Site of lesion in our study, which was in SFA with proximal popliteal artery lesion, as in the study of Khalil & Ozcan[7] and the study of Silvestro et al.,[10]

In our study, all the patients were TASC D, as in the study of Elhaieg et al.[8]

Regarding the position of the patient during retrograde popliteal artery access, the majority in our study were in the prone position (80.0%) while the other 20% were in the supine position. While in the study of Silvestro et al.,[10] and Elhaieg et al.,[8] were in supine position.

As regard access site, in our study access was through popliteal artery as first choice as in the study of Kuserli & Kavala[6] while in the study of Khalil & Ozcan[7] was RPA as 1st choice in 20-patients and after failure of antegrade in 23-patients.

In our study, the complication rate (seven cases, five cases with major complication(amputation) two cases with minor complication (resolved haemaoma not need intervention) and restenosis in 5-cases (need re-intervention) was 23.3%, but in the study of Silvestro et al.,[10] (14.6%) and the study of Elhaieg et al.,[8] (16.7%).

As regard success rate, our study direct post-operative success rate was 93.3% which is in the study of Kuserli & Kavala[6] (92.4%).

In our study, primary patency rate after 12-months was 75% which is in the same average in the study of Komshian et al.,[9] (70.3%), Elhaieg et al.,[8] (76.7%) and Kuserli & Kavala[6] (72.1%).

4. Conclusion

Endovascular procedures are considered effective and safe management options in cases of SFA atherosclerotic occlusive diseases, especially the antegrade access procedure, which gives a high technical success rate and a high percentage of lower limb salvage in cases with chronic lower limb-threatening ischemia. Our findings prove that the US-guided retrograde popliteal artery (RPA) endovascular approach can be used as a safe and effective technique for recanalization of SFA total occlusion with proximal PA lesion.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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