Angioplasty of Superficial Femoral and Popliteal Artery in Patients with Lower Limb Chronic Ischemia

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Abstract

Background: Occlusion of the femoropopliteal artery can lead to claudication and can contribute to chronic critical ischemia. The Ankle brachial index (ABI) is established as a first-line screening tool for lower limb ischemia.

Objectives: Assessment of different techniques and outcomes of superficial femoral and popliteal artery Angioplasty in patients with lower limb chronic ischemia.

Patients and methods: This was a randomized controlled clinical trial. Our inclusion criteria included patients with chronic ischemia of lower limb and with femoropopliteal artery lesions. Exclusion criteria were patients with accompanying aorto-iliac occlusions or infra-popliteal occlusions. Medical history and complete examination were done. Laboratory and radiological investigations were obtained. We used combined endovascular and surgical treatment modalities, tailored to lesion complexity with follow up at 3,6 and 12 months.

Results: ABI postoperatively in the immediate period, the 3-month period, 6-month period, and the 12-month period was higher than preoperative ABI. (12%) of patients needed reintervention, and (19%) had an amputation during the 1 year postoperatively, 13 were minor amputations and only 6 had major amputations. (18%) of patients had flush occlusion of SFA, (33%) were with long segment stenosis or occlusion, (44%) had short segment stenosis or occlusion, and finally (5%) had subacute ischemia with sudden cut.

Conclusion: Endovascular interventions combined with surgical modalities such as thrombectomy, thromboendarterectomy and open surgical vascular access as treatment for femoropopliteal occlusive disease give better limb salvage rates in complex lesions. Planning for treatment of femoropopliteal occlusive disease should be individualized according to type and lesion complexity to ensure best possible outcomes.

Keywords: Angioplasty; Chronic lower limb ischemia; Superficial femoral artery; Popliteal artery.

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Introduction

Peripheral vascular disease commonly affects the arteries supplying the leg and is mostly caused by atherosclerosis (**Beard, 2000**). Restriction of blood flow due to arterial stenosis or occlusion often leads patients to complain of intermittent claudication pain, any further reduction in blood flow causes ischemic pain at rest. Ulceration and gangrene may then supervene and can result in loss of the limb if not treated. The Fontaine score is useful when classifying the severity of ischemia (**Beard, 2000**).

Occlusion of the superficial femoral artery (SFA) can lead to claudication and can contribute to chronic critical ischemia (**Suroweic et al., 2005**). For critical ischemia, revascularization, if possible, is standard of care (**Suroweic et al., 2005**). The Ankle brachial index (ABI) is established as a first-line screening tool for lower limb ischemia (**Gerhard-Herman et al., 2017**)

The Society for Vascular Surgery has proposed the wound, ischemia, and foot infection (WIfI) classification system as a prognostic tool for the one-year amputation risk and the added value of revascularization in patients with chronic limb threatening ischemic (**van Reijen et al., 2019**). About 80% of all major amputations may be preventable with the use of new interventional and vascular surgical procedures (**Dohmen et al., 2012**)

Current literature favors the use angioplasty for short SFA stenoses or occlusions. However, primary stenting using Nitinol stents may be a superior initial treatment for intermediate and long length lesions (**Tadros et al., 2015**). Stents are used (at the discretion of the operator) for flow-limiting dissections, intimal flaps, or poor technical results; in general, for TASC C and D lesions (**Suroweic et al., 2005**).

Simultaneous hybrid endovascular and open lower extremity arterial reconstructive procedures have the advantages of obviating the need for major surgery and avoiding separate staged interventions and their associated morbidity (**Reed and Amy, 2008**). In most complex situations, retrograde recanalization can be applied (**Fanelli and Cannavale, 2014**). The main indication to this technique is when conventional antegrade recanalization fails or cannot be applied (**Fanelli and Cannavale, 2014**). The most common retrograde access is through the popliteal artery (**Fanelli and Cannavale, 2014**).

Patients and methods

This was a randomized controlled clinical trial that was conducted on a total of 100 patients randomly selected from those attending the outpatient clinic of Vascular Surgery Department of Qena University Hospital between 2022 and 2023. Our inclusion criteria included patients with chronic ischemia of the lower limb and with SFA and/or popliteal artery lesions. Exclusion criteria were patients with accompanying aorto-iliac occlusions or infra-popliteal occlusions.

The study gained consent from the ethical committee from Qena Faculty of Medicine, South Valley University, under the ethical code SVU-MED-SUR011-1-22-4-385. Informed consent was obtained from every patient, followed by complete history taking (personal history, current complaint, past medical and surgical history, and family history) as well as complete physical examination including vital signs recording (blood pressure, temperature, heart rate, and respiratory rate).

Vascular clinical examination was done by inspection for signs of chronic limb ischemia and palpation of the lower limb to detect the level of ischemia. ABI was measured using continuous wave handheld Doppler.

The following laboratory investigations were obtained, complete blood count, coagulation profile, renal chemistry, lipid profile and HbA1C.

We used imaging techniques such as lower limb arterial duplex and lower limb CT angiography. Patients were categorized into four groups according to Femoropopliteal lesion: SFA flush occlusion, short segment stenosis or occlusions, long segment stenosis or occlusions, and subacute ischemia with sudden cut.

Procedure: In PTA, patients lied in a supine position. Sterilization of the access point whether ipsilateral, contralateral, retrograde or antegrade, followed by subcutaneous injection of a local anesthetic agent. An introducer sheath was inserted into the artery via the Seldinger technique All patients were given 5000 units of intravenous heparin before maneuvering. Then a conventional diagnostic angiography was done. Under fluoroscopic guidance, a guide wire was passed through the stenosis in the artery and a balloon on a catheter is passed over the wire and into the desired position. Balloon inflation was performed for 30 to 90 seconds. Inflation was repeated twice and followed by angiographic assessment of the result. If a residual stenosis > 30% was present, angioplasty was repeated with a larger balloon. After dilatation, angiography was repeated and in case of failure of balloon inflation, low-friction stent was used. After the intervention, 15-20 m compression was applied on the puncture site for hemostasis.

In hybrid techniques, patients were given spinal or general anesthesia, Proper sterilization of the surgical field was done and surgical exposure of the access point (mostly the femoral artery) followed by insertion of sheath through an adequate arteriotomy and the previously mentioned steps were followed. When a filling defect or a thrombotic material was encountered, thrombectomy was done using a Fogharty catheter (**Fig.1**). If the performed arteriotomy revealed a large plaque, thromboendarterectomy was done and at the end of the procedure, closure of the arteriotomy with a vein patch was performed (**Fig.1**). After ensuring a proper hemostasis, surgical closure of the wound in 2 layers was done.

Fig.1. Thrombi from Superficial Femoral Artery A. Old thrombus removed from Superficial Femoral Artery. B. Plaque removed from Superficial Femoral Artery. C. Thrombectomy using a fogharty catheter.

Follow up: All patients were followed up at 3, 6 and 12 months. Assessment of angioplasty outcomes was done using post-operative ABI, the need for

re-intervention, and need for amputation at each follow up.

Statistical analysis

Data was checked, entered and analyzed using the Statistical Package for Social Sciences (SPSS) version 23 for data processing. Data was expressed as number and percentage for qualitative variables and mean + standard deviation (SD) for quantitative one.

Level of significance: For all above-mentioned statistical tests done, the threshold of significance was fixed at 5% level (P-value). P value of > 0.05 indicates non-significant results. P value of < 0.05 indicates significant results. The smaller the P value obtained the more significant are the results.

Results

Demographic data

Our study included 100 patients, the mean age of the patients was 64.28 years (SD = 9.03, median = 65, range = 37:86). 34 patients (34%) were females and 66 patients (66%) were males. Of them, there was 84 (84%) diabetic patients, 72 (72%) were hypertensive patients, 35 (35%) were cardiac patients, 14 (14%) were renal patients. Only 4 (4%) patients had COPD and 55 (55%) patients were smokers (**Fig.2**).

The entire 100 (100%) patients had an ischemia level of SFAO. 31 (31%) patients had Fontaine Classification grade III (with no lesions) and 69 (69%) patients had grade IV. Regarding the lesion severity, 15 (15%) patients had a major lesion and 54 (54%) patients had a minor lesion. The mean preoperative ABI was 0.57 (SD = 0.33, median = 0.5, range = 0.3:>1.3). 30 patients had an ABI of 0.5, 24 had an ABI of 0.4, and 16 patients had an ABI of over 1.3 (**Table.1**).

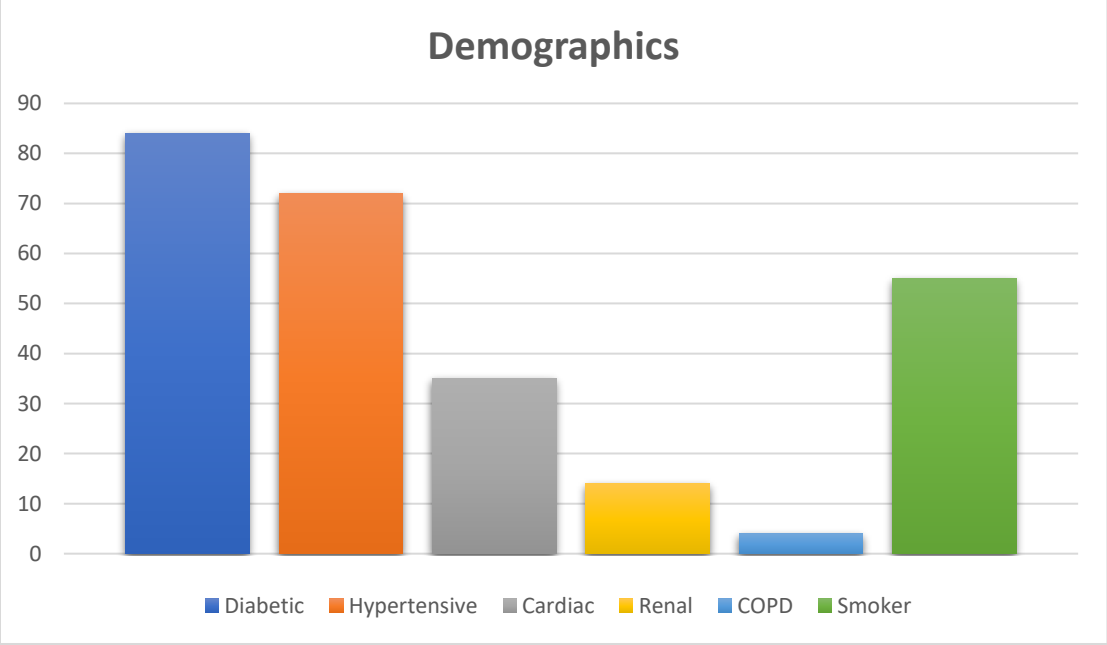

Fig.2. Comorbidities and risk factors

Table 1. Grouping of patients according to preoperative ABI, regarding treatment modalities

Preoperative ABI group	Number of Patients
Falsely high ABI (>1.3)	16 (16%)
Normal ABI (1:1.3)	0 (0%)
Mild PAD (0.8:0.9)	0 (0%)
Moderate PAD (0.5:0.7)	40 (40%)
Severe PAD (<0.5)	44 (44%)

75 (75%) patients had PTA while 25 (25%) patients had hybrid. The access was femoral in 97 (97%) patients, popliteal in 2 (2%) patients, and ATA in 1 (1%) patient (**Fig.3**). Only 16 (16%) patients required stenting. Only 10 (10%) patients underwent thrombectomy. And only 6 patients underwent SFA endarterectomy (**Figs. 4-8**).

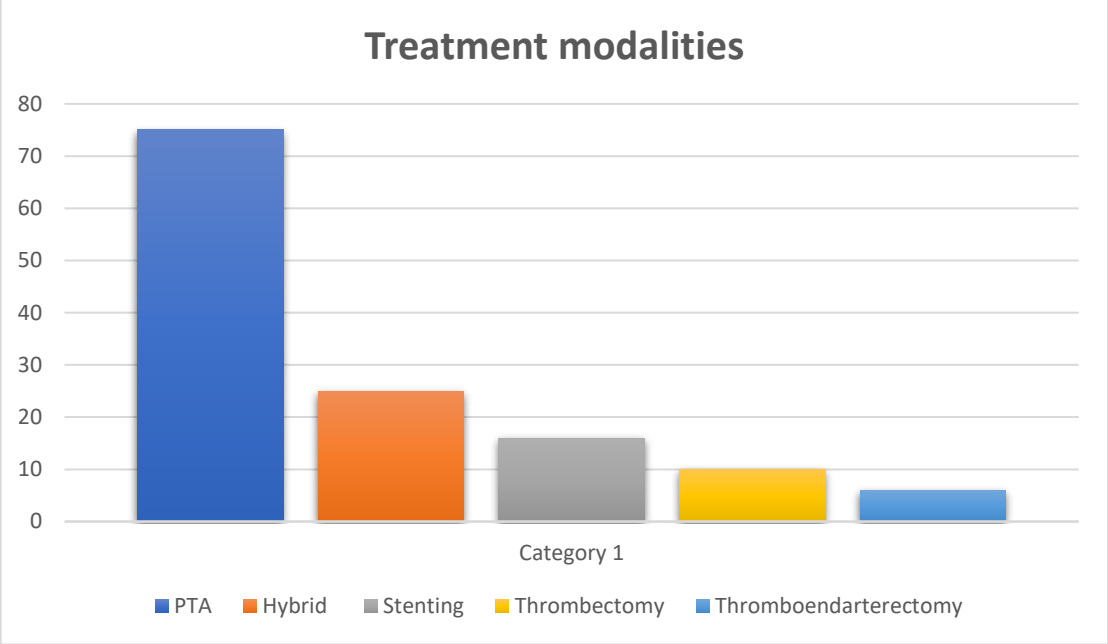

Fig.3. Treatment modalities used in the study

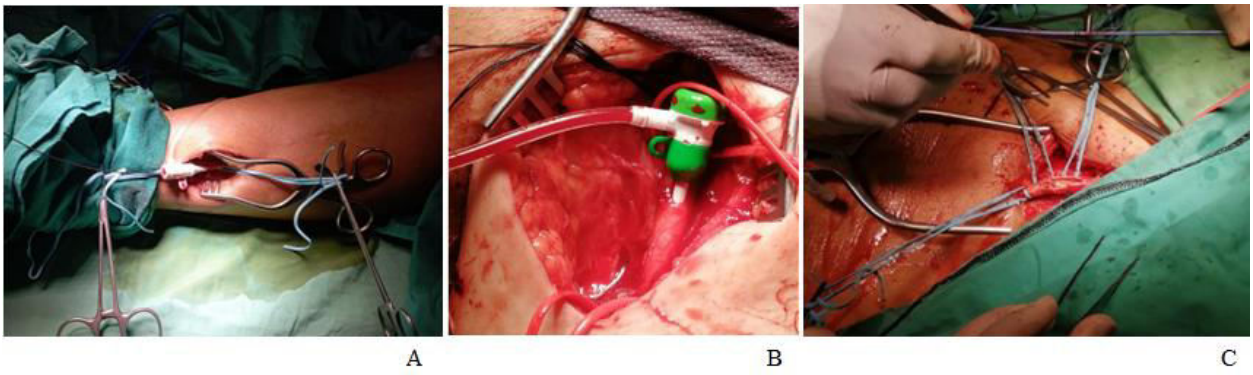

Fig. 4. Hybrid Access. A. Hybrid Anterior Tibial Artery Access. B. Hybrid Femoral Access. C. SFA Thromboendarterectomy.

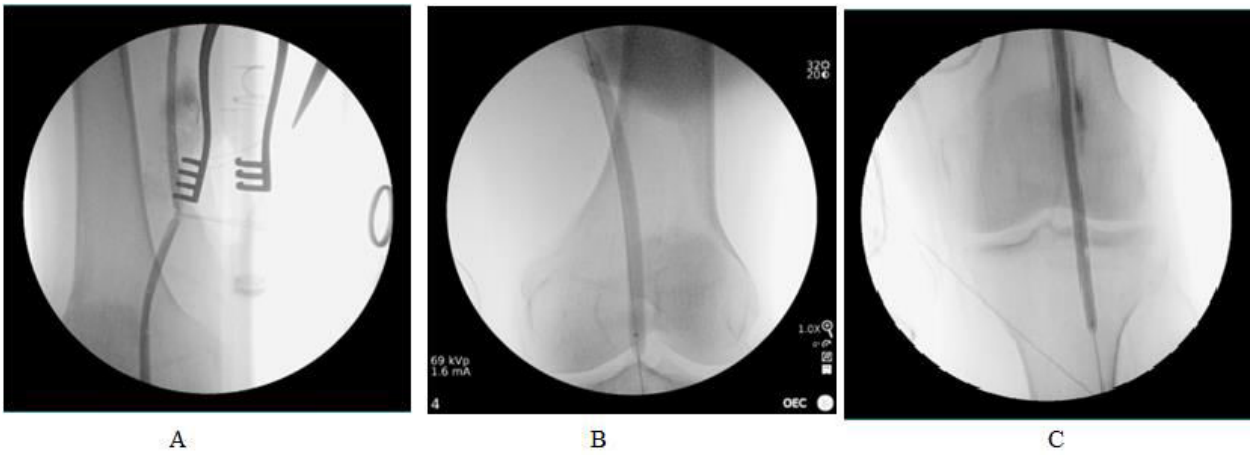

Fig.5. Artery Access. A. Hybrid Popliteal Access. B. & C. Popliteal Balloon Dilation.

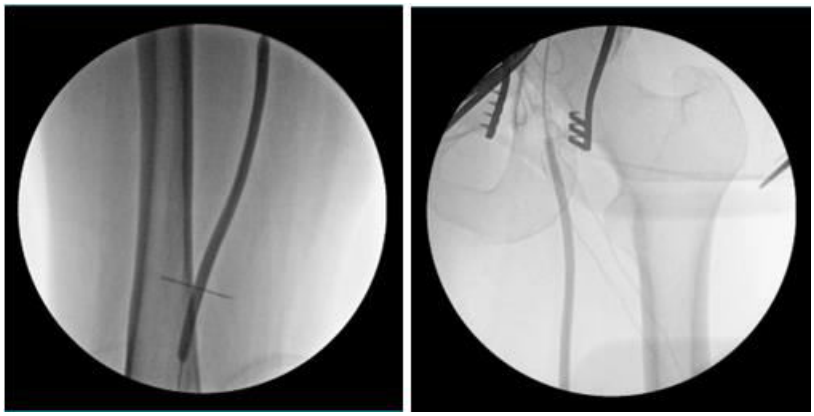

Fig. 6. SFA Balloon Dilation

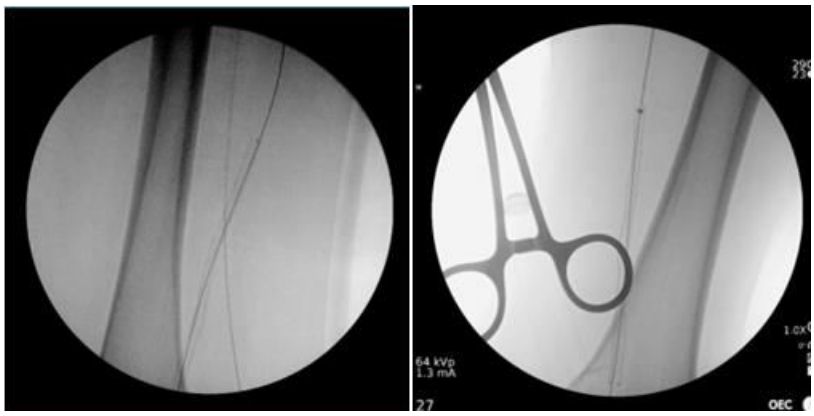

Fig.7. SFA Stent

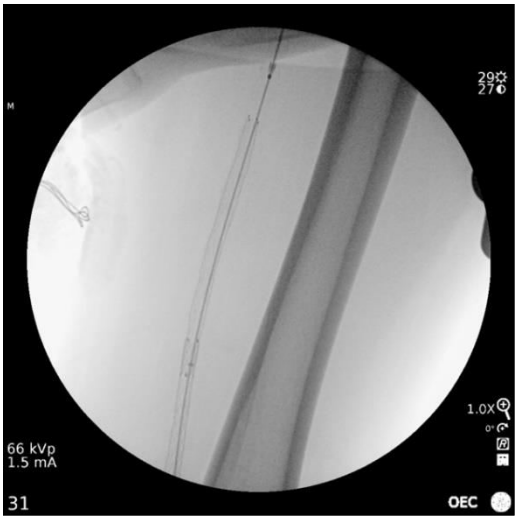

Fig.8. Double SFA

In the immediate postoperative period, the mean ABI was 0.94 (SD = 0.2, median = 0.9, range = 0.5:>1.3), three months postoperative, the mean ABI was 0.9 (SD = 0.22, median = 0.9, range = 0:>1.3), After 6 months of the operation, the mean ABI was 0.82 (SD = 0.27, median = 0.8, range = 0:>1.3), Finally, 12 months postoperative, the mean ABI was 0.79 (SD = 0.3, median = 0.8, range = 0:>1.3) (**Table .2**).

Table 2. Grouping of patients according to postoperative ABI

Variables	ABI group	Number of Patients
Immediately	Falsely high ABI (>1.3)	14 (14%)
	Normal ABI (1:1.3)	26 (26%)
	Mild PAD (0.8:0.9)	45 (45%)
	Moderate PAD (0.5:0.7)	15 (15%)
	Severe PAD (<0.5)	0
3 Months	Falsely high ABI (>1.3)	11 (11%)
	Normal ABI (1:1.3)	25 (25%)
	Mild PAD (0.8:0.9)	49 (49%)
	Moderate PAD (0.5:0.7)	13 (13%)
	Severe PAD (<0.5)	2(2%)
6 months	Falsely high ABI (>1.3)	8 (8%)
	Normal ABI (1:1.3)	18(18%)
	Mild PAD (0.8:0.9)	45 (45%)
	Moderate PAD (0.5:0.7)	20 (20%)
	Severe PAD (<0.5)	9 (9%)
12 months	Falsely high ABI (>1.3)	7 (7%)
	Normal ABI (1:1.3)	22 (22%)
	Mild PAD (0.8:0.9)	32 (32%)
	Moderate PAD (0.5:0.7)	26 (26%)
	Severe PAD (<0.5)	13 (13%)

Postoperatively 12 (12%) patients needed reintervention, and 19 (19%) patients had an amputation during the 1 year postoperatively. 13 minor amputations as 7 (36.8%) amputations were TMA, while 3 (15.8%) underwent big toe amputation. Only 6 had major amputations as 5 (26.3%) amputations were BKA and 1 (5.3%) was AKA. 7 (36.8%) amputations were within 3 months, 7 (36.8%) were within 6 months, and 5 (26.3%) were within 12 months (**Tables. 3, 4**).

Table 3. Grouping of patients according to time to Amputation

Time to Amputation	Number of Patients
Short term (<3 months)	7 (36.8%)
Intermediate (3:6 months)	7 (36.8%)
Long term (>6 months)	5 (26.3%)

Table 4. Grouping of patients according to type of Amputation

Type of Amputation		Number of Patients
Minor	Local Amputation (Toes)	5 (26.3%)
	TMA (Transmetatarsal amputation)	8 (42.1%)
Major	BKA (Below Knee Amputation)	5 (26.3%)
	AKA (Above Knee Amputation)	1 (5.3%)

Our cohort was divided into 4 groups; flush occlusion of SFA included 18 (18%) patients, long segment stenosis or occlusion included 33 (33%) patients, short segment stenosis or occlusion included 44 (44%) patients, and finally subacute ischemia with sudden cut included 5 (5%) patients (**Fig.9**).

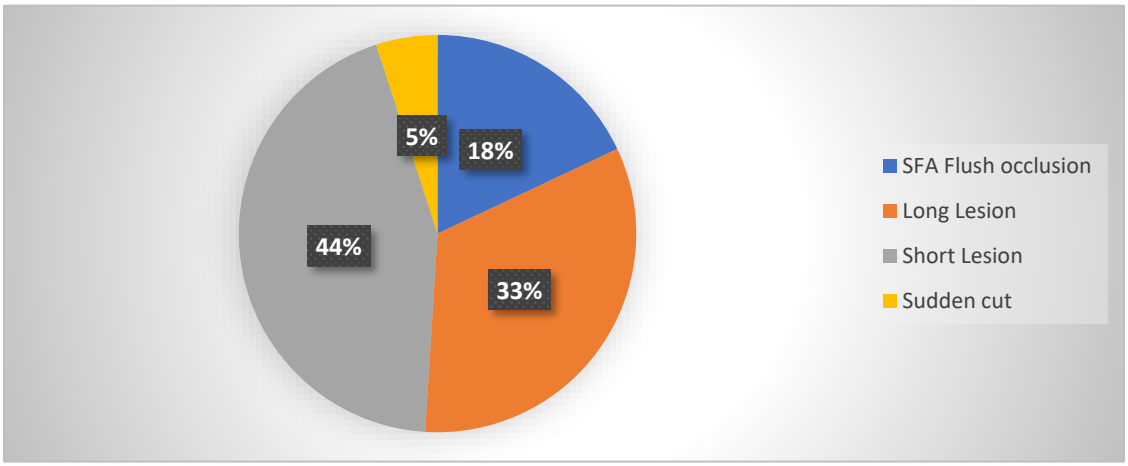

Fig. 9. Groups according to type of lesion in femoropopliteal segment

Discussion

Peripheral arterial disease (PAD) or peripheral vascular disease (PVD) is defined as narrowing and obstruction of antegrade flow of major systemic arteries other than those of the cerebral and coronary circulations (**Conte and Vale, 2018**). In this study, we used a combination of endovascular minimally invasive techniques and open surgical procedures to establish revascularization. Treatment plans were adjusted to every patient's needs and to the complexity of the femoropopliteal lesions.

Regarding age, our study included 100 patients, the mean age of the patients was 64.28 years (SD = 9.03, median = 65,

range = 37:86), while in the study of **Fujihara et al. (2017),** in total, 621 patients were included in the final analysis. The mean age was 72.8±9.5, whereas in a study by **Rocha-Singh et al., 2021,** the mean age was 69.6 ± 9.7.

Regarding gender, our patient population ware predominantly males (66%) and the females represented (34%), With similar results in a study by **Klumb et al., 2019** where the males treated by DCB presented (64.9%), also similar to a study by **Caradu et al., 2019,** as the males treated by POPA represented (67.4%). **_Ortmann et al., 2011** also had a majority of male patients, unlike a study by **Nehler et al., 2014,** who had a cohort of patients who were predominantly females (56.3%).

Regarding risk factors, in our cohort, the most common comorbidity was diabetes with a percentage of (84%) and (72%) were hypertensive patients, whereas in a study by **Gray et al.(2019),** where (43%) of the cohort were diabetic and the most common comorbidity was hypertension with a percentage of (89.7%), and in a study by **Giannopouloset al.(2021),** (67.9%) were diabetic and (93.7%) were hypertensive which supports our findings.

In our study (35%) were cardiac patients and (14%) were renal patients. and (55%) patients were smokers and only 4 (4%) patients had COPD, with similar results shown in a study by **Shammas et al.(2019)**, as (66.7%) were cardiac, (6.7%) were renal and (73%) were smokers, whereas in a study by **Stavroulakis et al.(2023)**, (55%) of the cohort had CHD, (66%) had CKD and 15% were smokers.

Regarding classification grade, (31%) of our patients had Fontaine grade III and (69%) had Fontaine grade IV, similar to the work of **Stabile et al., 2021** who had a total of 453 patients with Fontaine grade III being diagnosed in 39% of their patients and 60.9% of patients having Fontaine grade IV, whereas in a study by **Schoenweger, Petra, et al., 2020** who found that (4.0%) of the patients had Fontaine Classification grade I, (42.2%) patients had grade II, (20.9%) patients were with grade III and (32.9%) patients had grade IV.

Regarding preoperative ABI, in our cohort the mean preoperative ABI was 0.57 (SD = 0.33, median = 0.5, range = 0.3:>1.3). 30 patients had an ABI of 0.5, 24 had an ABI of 0.4, and 16 patients had an ABI of over 1.3, similar to the works of **Giannopoulos et al.(2021),** where the mean preprocedural ABI was 0.63±0.30, While in a study by **Tacke et al.(2019)**, 97 patients underwent PTA + stent. 20.6% of these patents had a baseline ABI of lower than 0.5, 69.1% had an ABI of (0.5–0.8), 1.0% had an ABI of (0.9–1.0), 2.1% had an ABI of (1.0–1.2), and 2.1% had an ABI over 1.2.

Regarding our treatment modalities used and vascular access, in this study (75%) patients had PTA while (25%) patients had hybrid angioplasty, unlike a study by **Holyachenko et al.(2022)** where (45.8%) of the study had PTA and (54.8%) had hybrid surgery.

The access was femoral in 97 (97%) patients, popliteal in 2 (2%) patients, and ATA in (1%) patient, whereas in a study by **Krishnappa et al. (2020)**, In isolated SFA lesions, (54%) were ipsilateral femoral access and (29%) had popliteal approach.

In our study, (16%) patients required stenting, while in **Barilla et al., 2020,** in (41%) SFA occlusions, PTA was completed with covered stents.

In our cohort, (10%) patients underwent thrombectomy. And only (6%) underwent SFA endarterectomy, while in a study by **Serna et al.(2021)**, (5%) had Thromboembolectomy and (79%) had femoral endarterectomy.

Regarding post operative ABI follow up, In the immediate postoperative period, The mean ABI in our study was 0.94 (SD =

0.2, median = 0.9, range = 0.5:>1.3), which is supported by a study by **Wei et al.(2022),** where the mean postoperative ABI was 0.88±0.07.

In the 3 months follow up, the mean ABI was 0.9 (SD = 0.22, median = 0.9, range = 0:>1.3). similar to a study by **Micari et al.(2011)**, where the mean ankle-brachial index (ABI) was 0.82 ± 0.25.

In the 6 months follow up, the mean ABI was 0.82 (SD = 0.27, median = 0.8, range = 0:>1.3), resembling a study by **Scheeret al.(2014),** as in the follow up after 6 months, the ABI increased to 0.91 ± 0.25.

In the 1 year follow up, the mean ABI was 0.79 (SD = 0.3, median = 0.8, range = 0:>1.3), with similar results in a study by **Giannopoulos et al.(2021),** as the mean ABI after 1 year was 0.65±0.41.

Regarding need for re-intervention, in our study, (12%) patients needed reintervention, similar to a study by **Mazari et al.(2012)**, where (15%) of the PTA group needed reintervention, whereas in a study by **Giles et al.(2008)**, where (26%) needed reintervention, and in a study by **Kawaji et al.(2022)** the need for reintervention was at (41.2%).

Regarding incidence of amputation, (19%) of the patients had an amputation during the 1 year postoperatively. 13 minor amputations as 7 (36.8%) amputations were TMA, while 3 (15.8%) underwent big toe amputation. Only 6 had major amputations as 5 (26.3%) amputations were BKA and 1 (5.3%) was AKA, Similar to a study by **Mao et al.(2014),** where 12.6% underwent below knee amputation and 2.2% underwent above knee amputation, and also similar to another study by **Long et al.(2020),** who found that the rate of major amputation was 8.4% and the rate of minor amputation was 5.1%, Unlike a study by **Nienaber et al.(2022)**, where 220 patients had major amputations representing (28.4%), and 25 of the cohort had minor amputations representing (6.7%).

Regarding Time of amputations, in our study, (36.8%) of the amputations were within 3 months, (36.8%) were within 6 months and 5 (26.3%) were within 12 months, while in a study by **Dua et al.(2019)**, (15%) of patients needed amputations within 1st month postoperative, (30%) had amputations within 3 months and (37%) needed amputations within 6 months.

Regarding lesion type, in our cohort, flush occlusion of SFA included (18%) of patients, long segment stenosis or occlusion included (33%) of the cohort, Resembling the findings in a study by **Bernardini et al.(2022)**, where SFA flush occlusions represented (17%) and long lesions represented (32%) of the technical success group, whereas in a study by **Giusca, et al.(2020)**, the SFA flush occlusions represented (42%) and the rest were long lesions in TASC C and D categories.

In our cohort short segment stenosis or occlusion included (44%) of the patients, which is supported by a study by **Takahara et al.(2020)**, where short lesions described in TASC A category represented (40.1%).

Finally, in our study, subacute ischemia with sudden cut included (5%) patients, with similar results in a study by **Wholey et al.(1998)**, where (5%) of the cohort were with subacute occlusions, whereas in a study by **Shammas et al.(2012)**, (60%) patients were with subacute ischemia, while in a study by **Kasirajan et al.(2001)**, 21 patients with a percentage of (24%) had subacute occlusions.

This study has some important limitations. In particular, the small size of our sample and the heterogenous nature of the patients' population. There is also, the fact that this is a single center study. These limitations can be addressed by further investigating the femoropopliteal occlusive disease in a multicentric study with a bigger and homogenous sample size.

Conclusion

Endovascular interventions combined with surgical modalities such as thrombectomy, Thromboendarterectomy and open surgical vascular access as treatment for femoropopliteal occlusive disease give better limb salvage rates in complex lesions. Planning for treatment of femoropopliteal occlusive disease should be individualized according to type and lesion complexity to ensure best possible outcomes.

Declarations

Ethical approval: The research was granted an exemption from the research ethics committee of the Faculty of Medicine, South Valley University, code SVU-MED-SUR011-1-22-4-385.

Consent to participate Patients signed consent to participate in this research.

Conflict of interest: The authors declare no competing interests.

Data availability: Data are available from the first author upon request.

Funding: No funding was received.

Authors'cContribution: All authors participated in study conception and design. Patient collection was done by Eslam A. Abd El-Rahman. Data analysis was done by Eslam A. Abd El-Rahman. Eslam A. Abd El-Rahman wrote the first draft of the manuscript. Walid M. Abd El-Motaal, Mohamed A. Mohamed, and Abd El-Rahim F. Mohammed revised and edited the manuscript. All authors read and approved the final manuscript.

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