Outcome of Multilevel Angioplasty at Critical Limb Ischemia of the Lower Limb

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Abstract

Introduction: **Peripheral artery disease (PAD) affects aging population, with critical limb ischemia (CLI) being a severe form. Patients with CLI face increased risk of morbidity, mortality, and amputation. Revascularization is standard, but intravascular strategies offer benefits. Infrapopliteal PAD can occur in isolation or with proximal level disease, with endovascular approaches being best for high-risk patients. We sought to compare the results of primary patency, limb salvage, and major amputation rates at the multilevel disease at the peripheral arterial disease.** ***Methods:*** **We performed a single-centre, prospective cohort study that 21 patients with critical lower limb ischemia who underwent multilevel disease (Tibial disease and proximal popliteal and or femoral arterial disease) from in Suez Canal university hospital, Suez Canal authority hospital and Abokhalifa emergency hospital in the period from April 2022 to December 2024.** ***Results:*** **our patients reported high efficiency with better primary patency and healing processes, and limb salvage.** ***Conclusions:*** **Endovascular intervention is a recommended treatment for peripheral arterial disease, with low mortality rates and good results in wound healing and limb salvage. It is associated with low mortality rates and should be the first modality for patients unfit for surgery. Factors such as diabetes, hypertension, smoking, and hyperlipidemia may affect the disease. Endovascular has good primary patency and healing processes, and limb salvage at Multi-level arterial disease**

Keywords: Peripheral artery disease (PAD), Multilevel Angioplasty, Critical Limb Ischemia, Lower Limb

Introduction

Peripheral artery disease (PAD) is a prevalent condition affecting aging populations worldwide. Epidemiological studies estimate its prevalence to range between 3% and 10% in the general population, increasing to 15–20% among individuals over 70 years of age[(1)].Critical limb ischemia (CLI) represents the most severe manifestation of PAD. It is clinically defined as persistent ischemic rest pain requiring analgesia for at least two weeks, or ulceration/gangrene of the foot or toes, accompanied by an ankle systolic pressure below 50 mmHg or a toe systolic pressure below 30 mmHg. Patients with CLI are at substantially higher risk of morbidity, mortality, and limb amputation due to infectious complications and gangrene. Reportedly, amputation rates can reach up to 95% within one year of diagnosis, while mortality rates approach 20% [(2)].

Revascularization remains the cornerstone of CLI management, aiming to alleviate rest pain, facilitate wound healing, and enhance limb salvage. While both open surgical and endovascular techniques are available, endovascular approaches offer notable advantages, including reduced perioperative morbidity and the ability to

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address multiple distal outflow vessels simultaneously. This is particularly relevant in CLI, where multilevel disease often involving infrapopliteal and proximal lesions is common. Multivessel endovascular interventions have shown promise in restoring perfusion across extensive arterial networks[3].

Infrapopliteal PAD can present as an isolated condition or in conjunction with proximal disease. Patients with multilevel arterial involvement are generally older, exhibit greater comorbidity burdens, and have more severe vascular compromise, often leading to less favorable outcomes following intervention compared to those with isolated aortoiliac or femoropopliteal disease[4].

The Transatlantic Inter-Society Consensus II (TASC II) classifies femoropopliteal lesions from A to D, with type D representing the most severe category—characterized by chronic total occlusion exceeding 20 cm involving the common femoral artery (CFA) or superficial femoral artery (SFA), often extending into the popliteal artery and proximal trifurcation vessels[5].

Open surgical bypass remains the recommended treatment for TASC II D lesions, particularly in patients with a life expectancy exceeding two years, availability of suitable autologous conduits, and favorable general health status. Nevertheless, in high-risk surgical candidates, endovascular techniques have emerged as viable alternatives, supported by recent technological advancements that have enabled successful treatment of increasingly complex lesions[6, 7].

The aim of this study is to evaluate the outcomes of endovascular interventions for multilevel peripheral arterial disease in patients with CLI, focusing on primary patency, limb salvage, and major amputation rates.

Patients and Methods:

This prospective interventional study included 21 patients with critical lower limb ischemia (CLI) who underwent endovascular treatment for multilevel arterial disease at Suez Canal University Hospital, Suez Canal Authority Hospital, and Abokhalifa Emergency Hospital between April 2022 and December 2024. The study population included both male and female patients with documented tibial vessel lesions and concomitant superficial femoral artery (SFA) lesions. Patients were enrolled if they demonstrated salvageable limbs, major or minor tissue loss, or ischemic rest pain and were deemed suitable for endovascular intervention. Exclusion criteria included proximal iliac lesions, non-salvageable limbs with extensive tissue loss requiring primary amputation, and patients unwilling or unable to adhere to scheduled follow-up visits.

Radiological Assessment:

Each patient underwent a comprehensive preoperative imaging workup. The choice of imaging modality was based on clinical presentation and institutional protocols:

Duplex ultrasonography (DUS) was performed in all 21 patients as an initial screening tool to assess arterial flow and identify significant lesions.

Computed Tomography Angiography (CTA) was used in 18 patients (85.7%) as it described detailed vascular mapping, particularly those with extensive calcifications or complex multilevel disease.

Digital Subtraction Angiography (DSA) was utilized as the definitive diagnostic and therapeutic imaging modality in all 21 patients immediately prior to intervention. Magnetic Resonance Angiography (MRA) was not routinely used due to limited availability and used at 3 patients (14%) who were CKD.

Clinical and Procedural Protocol:

All patients underwent detailed history-taking and physical examination, including

inspection, palpation, auscultation, and measurement of the ankle-brachial index (ABI). Post-angioplasty follow-up was scheduled at five intervals: immediate postoperative, one month, three months, six months, and one year. Outcomes assessed included primary patency, assisted primary and secondary patency rates, wound healing, relief of rest pain, and incidence of major or minor amputation.

Operative technique:

We employed both local anasethia (1% lidocaine) at the ipsilateral access and spinal anasethia at the retrograde access. According to the duplex, we picked the access site (ipsilateral ante grade femoral access, contralateral femoral access, retrograde access from tibial or popliteal access). About 16 patients had ipsilateral antegrade femoral access, whereas 5 patients underwent contralateral femoral access. Sheath insertion included a regular 6f sheath for 15 patients, a radial sheath for 3 patients requiring PTA access, and an 8f sheath for 3 patients. The sheath was a medical sheath (6f, 8f).

The second step was the Angiography of the whole tree of the arterial system; the wire was V18 (Boston Scientific V-18Control Wire) and if failed, we used another wire that was the command wire with 4g tip load (Abbot Hi-Torque Command™ hybrid peripheral workhorse guide wire) at tibial lesion and 0.035 wire at femoral and popliteal disease that was terumo radio focus guide wire with angled tip and roadrunner wire (cook- Roadrunner® PC Hydrophilic Wire Guide), 4f berenstein-merit selective angiographic catheter. Then, 3m balloon at tibial vasculature, 2.5m at arch disease (pacific-medtronic balloon) and (oceanus 18 ivascular balloon), 4m balloon at popliteal disease, and 6m balloon at femoral disease (Admiral™ Xtreme PTA Catheter-medtronic) (oceanus 35 ivascular balloon). The stent was a self-expanding stent (Supera™ Peripheral Stent-Abbott). Following angioplasty, we performed angiography to determine the success of the procedure.

Example: Multi-level Arterial Disease

A 67-year-old female with a history of diabetes mellitus (DM) and hypertension (HTN) presented with a right lower limb dry ischemic ulcer over the lateral aspect of the foot and rest pain persisting for two months. On examination, only the right femoral pulse was palpable. CT angiography demonstrated occlusion of the distal superficial femoral artery (SFA), popliteal artery, and extensive tibial arterial disease.

Pre-operative Imaging: Figures 1 and 2 illustrate the angiographic findings before intervention. Figure 1shows occlusion of the popliteal artery, while Figure 2 highlights significant disease of the tibial arteries.

Post-operative Imaging: Post-procedural angiograms (Figures 3 and 4) demonstrate successful revascularization. Figure 3 reveals restored patency of the popliteal artery with stenting using a Supera stent. Figure 4 shows a patent posterior tibial artery (PTA) following angioplasty.

Follow-up: The patient reported resolution of rest pain and healing of the ischemic ulcer over the subsequent weeks, indicating favorable clinical outcomes.

Figure (1)

Figure (2)

Figure (3)

Figure (4)

Results

The data reveals that the majority of patients are aged 60–69 years (38%), with females (66.66%) outnumbering males (33.33%). Diabetes is the most prevalent risk factor, affecting 95% of patients, followed by hyperlipidemia and hypertension, each present in 71% of

cases. Smoking is noted in 38% of patients, while ischemic heart disease (IHD) is found in 33%, and renal disease in 14% as found in Table 1.

Table 1: Socio-demographic Characteristic in the studied group:		
		Patients
Age	40y-50	3 (14%)
	50y-59	6 (28%)
	60y-69	8 (38%)
	More than 70	4 (19%)
Sex	Males	7 (33.33%)
	Females	14 (66.66%)
Risk factor	diabetes	20 (95%)
	smoker	8 (38%)
	hyperlipidemia	15 (71%)
	hypertension	15 (71%)
	IHD	7 (33%)
	Renal disease	3 (14%)

The data indicates that the majority of patients (85.8%) present with tissue loss, while only 14.2% experience rest pain without tissue loss. Among those with tissue loss, the most commonly affected area is the toes (50%), followed by the forefoot (33%) and the heel (17%) as presented in Table 2.

Table 2: Patients presentations in the studied group:		
		Patients
Rest pain		3 (14.2%)
Tissue loss		18(85.8%)
Tissue loss location	Heel	3 (17%)
	Toes	9(50%)
	Forefoot	6(33%)

We used GLASS classification to classify degree of ischaemia and it was as fellow, At tibial level, there was 0 (0%) patients were with GLASS 0, 2(9%) patients with GLASS 1, 6(28%) patients with GLASS 2, 10 (47,6) patients with GLASS 3and 3 (14,2%) patients with GLASS 4 and At femoro-popliteal level, there were2 (9%) patients GLASS 0, 10 (47.6%) patients with GLASS 1, 6 (28%) patients with GLASS 2, 2 (9%) patients with GLASS 3and 1 (4.7%) patients with GLASS as at chart (1)

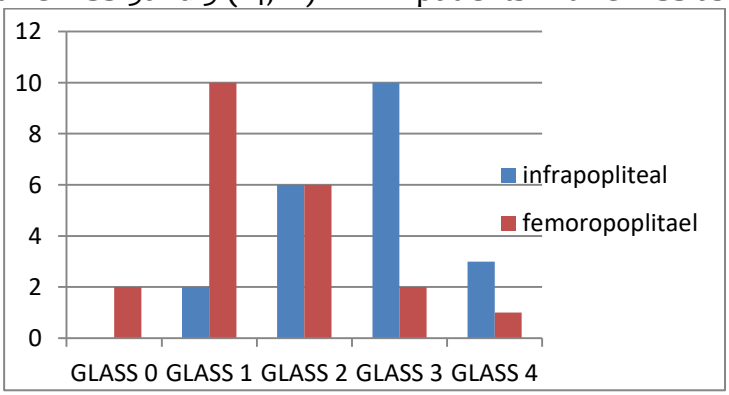

Chart 1: GLASS classification

At this study, 13 patients underwent ballooning for SFA, popliteal artery, and tibial level. Two patients experienced ballooning of popliteal artery and tibial artery, 6 patients underwent ballooning of SFA and tibial vessels and two underwent stenting with a self-expandable stent. As at table (3)

Table 3: Vessels that underwent angioplasty in the studied group	
Name of the artery	Number
SFA, popliteal and tibial vessels	13 (62%)
Popliteal and tibial vessels	2(9%)
SFA and tibial vessels	6 (29%)

In the present study, the distal runoff after angioplasty was found that ATA was at 6 patients, PTA was at 2 patients, peroneal was at 1 patient and more than one artery were at 12 patients that had significant difference as at table (4)

Table 4: Distal runoff in the studied group		
Distal run off		P value
PTA only	2 (9.5%)	0.052
ATA only	6 (28.5%)	0.065
Peroneal artery only	1 (4.7%)	0.07
More than one artery	12 (57%)	0.023

We considered successful angioplasty if there was good angiographic angiogram, palpable pulsation, increase the ABI by 0.2, resolve of rest pain and wound healing, there is one case only underwent redo angioplasty after one day of first intervention. The data on patency rates shows that assisted primary patency remains relatively high in the early follow-up period, with 90% at 3 months, 80% at 6 months, but declining to 61% at 9 months and one year. For assisted primary patency, only 2 patients (9%) maintained patency at 6 months and one year, Similarly, secondary patency was observed in 9% of patients at 9 months and one year as shown at table (5).

Table 5: Primary patency rate in the studied group		
1ry patency	3rd month	19 (90%)
	6th month	17 (80%)
	9th month	13 (61%)
	at one year	13 (61%)
Assisted 1ry patency	6th month	2 (9%)
	at one year	2 (9%)
Secondary patency	9th month	2 (9%)
	at one year	2(9%)

The data indicates favourable overall outcomes, with high healing (88.8%) and limb salvage rates (90.4%), While major amputation occurred in only 9.5% of patients, minor amputations were more frequent (38%) as shown at table (6).

Table 6: End point data in the studied group	
End point	
Major amputation	2 (9.5%)
Minor amputation	8 38%
Healing	16 (88.8%)
Limb salvage	19 (90.4%)

At this study there were some complications had been occurred, Pseudoaneurysm was not observed in any patients (0%), while hematoma was the most common complication, occurring in 14.2% of cases. Both bleeding and thrombosis were reported in 4.7% of patients each.

Table 7: Complications in the studied group	
complications	percentage
Pseudo aneurism	0 (0%)
Hematoma	3 (14.2%)
Bleeding	1 (4.7%)
Thrombosis	1 (4.7%)

Discussion

Endovascular treatment of CLTI has become as a first line at most of centers[8]. However, the results have not been conclusive with clear definition of which patients who candidate for endovascular treatment according to the anatomical and physiological candidate[9]. A meta-analysis that had been done by Romiti et al of infrapopliteal angioplasty for the treatment of CLTI showed that the overall primary patency and secondary patency rates of 58% and 68%, respectively, through 1 year, in which the limb salvage rate was 86% and patient survival was 98%.10 in spite of, this study did not look at the wound healing as the endpoint[10].

In the present study, it was found that the majority of patients are aged 60–69 years (38%), with females (66.66%) outnumbering males (33.33%). This was similar to the study of Fernandez et al., Kudo et al., and Romiti et al. found that the age of patients ranged from 64-81 yrs with mean 70yrs, about 60 % of them were male and 40% were female[10-12]. Also, Casella et al. compared the results of percutaneous transluminal angioplasty (PTA) and bypass graft surgery (BGS) for the treatment of infrapopliteal lesions at patients with critical limb ischemia (CLI), revealing that the angioplasty group mean age was 71.45 + 8.63 and 31 (64.6%) were male and 35.4% of patients were female[13]. Moreover, Guo et al. analysed 6-month follow-up data from the prospective PRIME-WIFI study with 203 consecutive patients with diabetic foot who underwent DCB angioplasty for infrapopliteal arterial occlusive disease. The mean age of these patients was 69.78 ± 9.50 years, and 61 patients (30.05%) were female[14]. Youssuf et al. included 20 diabetic patients with CLI in 28 limbs with isolated infrapopliteal arterial occlusive disease were about (60%) were male and eight (40%) were female with a mean age of 65 years that is ranged from 54 yrs to 76 years[15].

In the present study, it was found that Diabetes is the most prevalent risk factor, affecting 95% of patients, followed by hyperlipidemia and hypertension, each present in 71% of cases. Smoking is noted in 38% of patients, while ischemic heart disease (IHD) is found in 33%, and renal disease in 14%.

In line with our results, Guo et al. showed that about 152 patients (74.88%) had hypertension, and 43 patients (21.18%) had chronic renal insufficiency[14]. Similarly, Fernandez, Casella, Kudo, and Romiti found that the diabetics was the most predominant risk factor among study group[10-13]. Additionally, O'Brien-Irr et al. stated that diabetics was significant factor among patients (P value 0.002)[16]. Diehm et al. concluded that diabetes is a risk factor in the knee atherosclerotic lesions as diabetes is microvascular disease in addition to hypertension and cigarette smoking where they increase disease proximal arteries more than below knee arteries[17]. Casella et al. showed that in angioplasty group smoking were 36.2%, the diabetic patients were (85%) and the hypertensive patients were (87%), patients with cerebrovascular disease, heart disease, renal disease and hyperlipidaemia were not mentioned and there was no significant difference at these variable between groups[13]. Youssuf et al. stated that smoking were 75%, the hypertensive patients were (80%), patients with cerebrovascular disease were 20%, patients with heart disease were 55%, patients with hyperlipidemia were (20%), the patients with renal disease were not mentioned[15].

In the present study, it was found that the majority of patients (85.8%) present with tissue loss, while only 14.2% experience rest pain without tissue loss. Among those with tissue loss, the most commonly affected area is the toes (50%), followed by the forefoot (33%) and the heel (17%). In line with other results, Fernandez et al. found that rest pain was common in (21%) of patients with multi-level groups and tissue loss was at (79%) of patients with multi-level group[11] and also was similar to the study of O'Brien-Irr et al.[16]. However, Sadek et al. found that about (23%) of patients with claudication, (23%) of patients with rest pain and (54%) of patients with tissue loss. This difference can be justified by the fact that they used chronic limb ischemia and we excluded them from the current study[1]. Ryu et al. showed that 70 (75%) were diabetic patients showing that diabetic patients had a higher frequency of poor primary patency (P = 0.012) during 2- year follow-up[18].

At the current study, the TASC classification was divided into tibial level, popliteal and femoral level that were, at tibial level, there were (38%) of patients were with type A lesion, (47.6%) of patients with type B lesion, (9%) of patients with type C lesion and (4.7%) of patients with type D lesion, at popliteal level, there were (33.3%) of patients were with type A lesion, (42.8%) of patients with type B lesion, (19%) of patients with type C lesion and (4.7%) of patients with type D lesion and lastly at femoral level, there were (47.6%) of patients were with type A lesion, (38%) of patients with type B lesion, (14.2%) of patients with type C lesion and (0%) of patients with type D lesion. In line with our results, Casella et al. and Sadek et al. revealed that the most percentage of patients at the current study were at TASC A and B against the previous mentioned studies in which the large percentage of patients were at TASC C and D[1, 13].

At current study, (0%) of patients were with GLASS 0, (9%) of patients with

GLASS 1, (28%) of patients with GLASS 2, (47,6) of patients with GLASS 3and 3 (14,2%) of patients with GLASS 4, at femoro- popliteal level, there were (9%) of patients GLASS 0, (47.6%) of patients with GLASS 1, (28%) of patients with GLASS 2, (9%) of patients with GLASS 3 and (4.7%) of patients with GLASS 3 and this was different from the study of Casella et al, Sadek et al[1, 13]. Casella et al. showed that (10.4%) of patients were with type A lesion, (33.3%) of patients with type B lesion, (27.1%) of patients with type C lesion and (29.2%) of patients with type D lesion and (43.8%) of patients were with poor distal run off[13]. The study of O'Brien-Irr et al. stated that about (74%) of patients with tissue loss that is not described and (26 %) of patients with rest pain. Ninety-four percent of vessels treated were for TASC class C (53.6%) or D (37.4%) disease and (9%) with TASC B[16]. Kudo et al. revealed that (0%) of patients were with type A lesion, (9%) of patients with type B lesion, (54%) of patients with type C lesion and (37%) of patients with type D lesion and this was different from the present study at more patients presented with rest pain and more patients were at TASC C and D[12].

At the current study, we used ankle brachial index as measurement of hemodynamics, we classified it into two categories (from 0.3 to 0.49) and from (0.5 to 0.7), the patients (from 0.3 to 0.49) were (71.4%) and the patients from (0.5 to 0.7) were (28%) and this was similar to the study of Fernandez et al[11]

The study found there were 18 tissue loss (38%) of patients were having ulcer that all of them healed and (47.6%) of patients had toes gangrene (38%) of them underwent minor amputation and healed the stump and (9.5%) underwent major amputation and were healed at this was similar to the study of Fernandez et al.[11] in which healing occurred at 87%, amputation occurred at 5.3%. This results disagree with Sadek et al.[1]

At the current study, there were 18 tissue loss (38 percent) of patients were having ulcers that all of then healed and (47.6 percent) of patients had toes gangrene. The limb salvage at this study was (90%) and was different from the study of Sadek et al. in which the limb slavage 68% at multi-level group [1].

In the present study, 1ry patency rate was (90%) at first 3 months and (80%) at 6th month and (61%) at 9th, 12th month but without rest pain nor tissue loss and this was similar to the study of (Hussein et al, sadek et al and caseela et al,) but was different from the study of (Fernandez et al, Kudo etal and Rometti etal,) as the primary patency rate at these studies were decreased and was (38%), (49%), (58%) at the end of the 1st year respectively.

There was no pseudoaneurysm, hematoma occurred at (14.2%) of patients and not need intervention, bleeding and thrombosis had been occurred at (4.7%) of patients and this was similar to the study of Fernandez et al. and Sadek et al.[1, 11].

Our study included several limitations such as small sample size and single centre study. Hence, further research is needed to understand the impact of arch disease on limb salvage and wound healing.

Conclusion

Peripheral arterial disease (PAD) is a prevalent condition affecting the aging population. Chronic limb threatening ischemia is a severe form of PAD, causing high morbidity and mortality. Peripheral angioplasty is a good treatment option due to its low morbidity and mortality, and its ability to treat multi-level arterial disease simultaneously. The study found an association between PAD and

hyperlipidemia, hyperglycemia, and smoking. Multi-level arterial disease has better primary patency and healing processes, with a lower major amputation rate. Endovascular intervention has low complications, making it an attractive option for PAD treatment.

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