ORIGINAL ARTICLE

CLINICAL EFFICACY OF INFRA POPLITEAL ANGIOPLASTY FOR BELOW THE KNEE PERIPHERAL VASCULAR OCCLUSIVE DISEASE

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Background: Peripheral arterial disease (PAD) affects a substantial proportion of the global population, particularly older individuals, affecting around 200 million people worldwide highlighting its significant impact on human health. Critical limb ischemia (CLI) is the most severe clinical presentation of PAD characterized by ischemic rest pain tissue ulceration or gangrene. The objective of the study is to assess the efficacy of infra popliteal angioplasty (in terms of wound healing and limb salvage) in patients with below-the-knee total chronic occlusion (TCO). **Methods:** In this cross-sectional study, all consecutive patients in one year with TCO and fulfilling the inclusion criteria were included. **Results:** A total of 64 limbs underwent angioplasty. The mean age was 55.38 ± 13.12 (Range 22-88) years and there were 73% (n=47) males. Diabetes mellitus was the most prevalent risk factor in 59.4% (n=38) of patients. 48.4 % (n=31) of patients had below-knee TCO in all three arteries. Technical Success was achieved in 95.3% (n=61/64). All 3 patients who had technical failure ended up with below-the-knee amputation. Furthermore, 2 more patients who had technical success also ended up with below-the-knee amputation. The difference between these two rates was significant (100% vs 3.3%; *p*-value =0.004). In terms of wound healing, statistically significant improvement was noted within the first 6 months (*p*-value = 0.05). The limb salvage rate was 90.6% (n=59/64). The primary patency rate was 81.3% (n=52) and 76.6% (n=49) at 6 and 12 months respectively. **Conclusion:** Angioplasty results in statistically significant wound healing leading to a higher limb salvage rate, in patients with TCO of infrapopliteal arteries.

Keywords: Angioplasty; Limb ischemia; Infrapopliteal; Limb salvage

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INTRODUCTION

Peripheral arterial disease (PAD) affects a substantial proportion of the global population, particularly older individuals, affecting around 200 million people worldwide highlighting its significant impact on human health.[1] Critical limb ischemia (CLI) is the most severe clinical presentation of PAD characterized by ischemic rest pain or tissue ulceration or gangrene.[2,3] CLI often occurs in conjunction with diabetes, hypertension, chronic renal insufficiency and other comorbidities. In particular, diabetes has a significant impact on the smaller vessels (<5 mm) of the body, contributing significantly to occlusive disease distal to the popliteal artery.[4] Revascularization is urgently required due to high rates of morbidity and mortality. However, endovascular revascularization frequently faces technical challenges in below-the-knee lesions due to long lesion length, diffuse lesions, small vessel diameter, poor outflow, severe calcification, and multiple treatment paths. Infra Popliteal Angioplasty (IPA) is a minimally invasive procedure that has emerged as a promising treatment option for PAD and CLI. IPA as the sole modality is characterized by a high rate of technical success, low incidences of complications, and a relatively short hospital stay.[5,6] IPA can also be combined with stenting in certain cases where residual stenosis is not completely resolved. Infra Popliteal Angioplasty in our country is a new and emerging treatment modality. Not much is found in our national literature about IPA. This pilot study was conducted to assess the clinical efficacy of IPA as a treatment modality for PAD/CLI by evaluating outcomes such as technical success, limb salvage and wound healing.

MATERIAL AND METHODS

This multicenter cross-sectional study was carried out at Combined Military Hospital Lahore and Mid City Hospital Lahore between January 2021 and January 2022. All consecutive patients who were diagnosed as having TCO of the infrapopliteal vessels on Computerized Tomographic (CT) Angiography were included. TCO was defined as occlusion of the infrapopliteal arteries (anterior tibial, posterior tibial or peroneal) with no antegrade filling of vessel distal to the occlusion except by the collaterals. Written consent was taken from all the patients for the procedure and inclusion in the study. The study was performed according to the declaration of Helsinki and the study was approved by the Institutional Ethical Board Review Committee.

Patients with concomitant occlusion in the proximal tree needing intervention, patients with TCO in infrapopliteal arteries who had stenting done along with angioplasty and patients who underwent catheter directed thrombolysis or prior vascular intervention were excluded. Furthermore, patients with compromised renal functions not suitable for intravenous contrast and patients who did not complete the mandatory 6 months follow-up were also excluded. The endovascular interventions were performed in a fully equipped Operation Theatre by a Consultant Endovascular Surgeon. All patients had their regular dose of Aspirin 75 mg on the morning of surgery. After local anesthesia at puncture site with Lignocaine, ipsilateral common femoral artery was accessed under ultrasound guidance (GE LOGIQ Book, USA) using a 5 Fr introducer sheath. All patients were given intravenous bolus Heparin dose of 2500 IU. Angiography was performed to evaluate the entire below knee vessels, using Iohexol (OMNIPAQUE™) 350 mg/ml diluted in 1:1 part with normal saline. The occlusions were crossed with 0.014", 0.016" or 0.018" guide wire. Angioplasty was performed with a balloon of 3–4 mm diameter for upper and midcalf and 2.5–3 mm diameter for distal calf vessels. The inflation was done using a gauged inflation device (Cook Medical ™). The balloon was initially inflated for 3 minutes at a pressure of 15 ATM. A second prolonged inflation at 15 ATM for 5 to 10 minutes was performed if there was any residual stenosis on check angiogram. A final check angiogram was done to document the technical success of the procedure (Figure 1). All patients were discharged home same day with an intended follow up at 3 months, 6 months and 1 year. Primary endpoints of this study were technical success, limb salvage and primary patency. Technical success was defined as successful passage of guide wire and balloon dilatation of at least one below the knee artery without residual stenosis of less than 30% on check angiography. Limb salvage was defined as the successful resolution of rest pain and avoidance of major amputations proximal to the tarsal bones of foot. Primary patency was defined as absence of occlusion of the treated vessel on follow up CT Angiography. Procedure related postoperative complications such as hematoma at access site or access site infection were recorded.

To clinically stage the affected limb and then compare the results after angioplasty, we used two classification systems. All patient were categorized by Rutherford classification preoperatively and compared again at 3 months postoperatively.[7] Furthermore, Society of Vascular Surgery WIFI classification system for threatened lower limb was used to assess wound healing and foot infection.[8] Patients were scored preoperatively and then scores were compared at 3 months, 6 months and 12 months after the procedure. Statistical analysis was done with Statistical Package for the Social Sciences Version 24 (SPSS© Inc., IL, USA). The quantitative variables were expressed as Means±Standard Deviations (SD). The qualitative variables were expressed as Frequency and Percentage. The comparison of preoperative and postoperative groups in terms of WIFI and Rutherford classifications was done using Independent Samples T-test. A *p*-value of ≤0.05 was considered statistically significant.

RESULTS

During the study period, a total of 64 limbs fulfilling the inclusion criteria underwent below the knee angioplasty in 63 patients. Mean age was 55.38±13.12 (Range 22–88) years. There were 73% (n=47) males with male to female ratio of 2.8:1. The major atherosclerotic risk factors in these patients are described in Table 1 with Diabetes Mellitus being the most prevalent risk factor in 59.4% (n=38) patients. There were 48.4% (n=31) patients who had below knee TCO in all three (Anterior tibial, Posterior tibial and peroneal Arteries), while 40.7 % (n=26) had the disease in at least two below knee arteries and 10.9% (n=7) had single vessel below knee TCO disease.

In terms of Rutherford Category, pre operatively 26.6% (n=17) patients were in class 4 while 14.1% (n=9) and 59.4% (n=38) were in class 5 and 6 respectively. Post operatively, 3.1% (n=2), 37.5% (n=24), 37.5% (n=24), 14.1% (n=9), 3.1% (n=2) and 4.7% (n=3) were in class 1 to 5 respectively. It is worth noting that 59.4% (n=38) patients were in category 6 preoperatively but after the procedure most of the patients [75% (n=48)] were in category 2 and 3 depicting a marked improvement, with a *p*-value of 0.016 which is statistically significant.

Wound healing, improvement in ankle systolic pressure and foot infection was measured using WIFI Classification [Table 2]. Maximum improvement was noted in the first 3 months (*p*-value = 0.003). Marked wound healing was noted in first 3 months (*p*-value = 0.024) and healing continued to be significant till 6 months (*p*-value =0.05). Further improvement in wounds after 6 months was slow (*p*-value =0.16). In terms of improvement in ankle systolic pressure, maximum improvement was achieved within first 6 weeks (*p*-value = 0.005). Mean Follow up duration was 1.1±0.2 (Range 1–1.5) years. Technical Success rate was 95.3% (n=61/64). The technical failure in 3 patients was due to inability to pass guide wire across the occluded segment. All these 3 patients ended up with below the knee amputation. Furthermore, 2 more patients who had

technical success also ended up with below-the-knee amputation. The difference between these two rates was significant (100% vs 3.3%; *p*-value =0.004). The limb salvage rate was 90.6% (n=59/64). Primary patency rate was 81.3% (n=52) and 76.6% (n=49) at 6 and 12 months respectively. Access site hematoma developed in 9.3% (n=6) patients which spontaneously resolved over the period. In the first 6 weeks after the procedure, there was no procedure-related morbidity in terms of myocardial infarction or renal failure and no death was recorded.

Table-1: Demographics of patients.

Age [(Years±SD (Range)]		55.38±13.12 (22-88)
Gender [%(n)]	Male	73 (47)
	Female	26 (17)
Atherosclerotic Risk Factors [%(n)]	Diabetes mellitus	59.4 (38)
	Hypertension	35.9 (23)
	Smoking	51.6 (33)
	Hyperlipidemia	9.4 (6)
Angioplasty Side [%(n)]	Right	50 (32)
	Left	48.4 (31)
	Bilateral	1.6 (1)

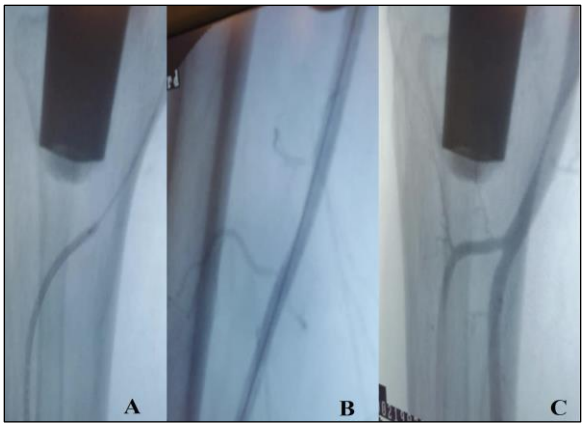

Figure-1: Balloon angioplasty of infra-popliteal vessels: The anterior tibial artery angioplasty with 4mm diameter balloon over a guide-wire (A), angioplasty of the posterior tibial artery with 4mm diameter balloon (B), and check angiogram showing successful dilation of both the anterior and posterior tibial arteries (C).

Table-2: WIFI and Rutherford Classification before and after Angioplasty.

	Classification		95% confidence interval (Lower)	95% confidence interval (Higher)	*p*-value	Cumulative *p*-value
Pre op	WIFI Class	Wound	-.147	1.314	0.113	0.163
		Ankle Pressure	-.303	.481	0.646	
		Foot infection	-.373	.601	0.638	
	Rutherford Class		-.082	.976		0.094
3 months post op	WIFI Classification	wound	.225	.075	0.024	0.003
		Ankle Pressure	.203	.203	0.005	
		Foot infection	.160	-.173	0.36	
	Rutherford Class		.132	1.214		0.016
6 months post op	WIFI Class	wound	.194	-.001	0.05	0.34
		Ankle Pressure	.154	-.021	0.068	
		Foot infection	.166	-.179	0.35	
1 Year post op	WIFI Class	wound	.060	-.035	0.16	0.22
		Ankle Pressure	.150	-.227	0.60	
		Foot infection	.105	-.063	0.16	

DISCUSSION

Peripheral arterial disease (PAD) is a common condition and critical limb ischemia accounts for approximately 2% of PAD patients. In patients with critical limb ischemia, approximately 20% will end up with major amputations.[9] Endovascular treatment options for infrapopliteal disease include angioplasty with or without stenting.[10] Various studies have assessed the impact of this procedure on the limb salvage rate and resolution of symptoms in terms of pain and wound healing.[11–13]

The major atherosclerotic risk factors leading to critical limb ischemia are diabetes mellitus, hypertension and smoking.[11–13] In our study group diabetes mellitus was the major risk factor (59.4%). The technical success rate of angioplasty in our study was 95.3%. The reasons for failure were the inability to pass the guide wire and support catheters across the stenotic segments. Park *et al* had a success rate was 93.8% with similar reasons for failure.[11] High technical success rates comparable with previous literature signify the feasibility and safety of the procedure. Low major amputation rates are recorded in literature in patients undergoing below knee angioplasty for critical limb ischemia. Mustapha *et al* had an amputation rate of 18%[12] while Gerhard-Herman *et al* had (8%)[13]. Similarly, Ferraresi *et al* also reported a major amputation rate of 7% in his patients with below the knee critical limb ischemia undergoing angioplasty.[14] In our study major amputation rate after angioplasty was 7.8% which is comparable to above mentioned studies.

In terms of wound healing, we had three post-treatment measurements at 3 months, 6 months, and 12 months. The wound healing rate at 3 months was

32.8%, at 6 months was 42.2%, and at 12 months was 3.1%, based on the WIFI staging system used. This crucial outcome measure had been evaluated in other studies having angioplasty in patients with below-knee occlusive PAD. Mustapha *et al* for example, noted that 77% of patients with critical limb ischemia who underwent angioplasty had complete wound healing at six months.[12] We also achieved maximum healing within first 6 months post angioplasty (75%). This is believed due to increase in the blood flow after the angioplasty which results in more tissue oxygenation hence promoting granulation tissue and reducing the infection.[14]

The primary patency rates have been evaluated in previous studies. Sadek *et al* reported a primary patency rate of 68% and 50% at 6 and 12 months respectively.[15] Similarly, Park *et al* reported a primary patency rate of 75% and 59% at 6 and 12 months respectively.[11] Primary patency rate in our study was 81.3% and 76.6% at 6 and 12 months respectively. The improved primary patency rate may be due to fact that only 48% patients had all three vessels showing CTO and rest of the patients either had single or double vessel disease. Furthermore, we did not use any stents in our study. Hence the incidence of stent thrombosis and stent related complications leading to reduction in patency rates was not applicable in this study which may explain a higher primary patency rates at 6 and 12 months. Moreover, the better patency rate in our study could be because only 59% of our patients were diabetic as compared to Park *et al* where all the patients in the study had diabetes.

Our study has its limitations. Firstly, the sample size was relatively small and the follow-up duration was only twelve months, which could restrict the generalizability of the findings. Secondly, the study did not compare angioplasty to other treatment modalities, making it challenging to determine if angioplasty alone is the most suitable treatment option for patients diagnosed with below-knee occlusive PAD. Furthermore, we did not analyze the data of those vessels which had partial occlusion and did not undergo angioplasty and this may have affected our outcome.

CONCLUSION

The limb salvage rate and technical success rate of angioplasty in patients with below-knee occlusive PAD are high. Angioplasty promotes wound healing and reduces the chances of major amputation. However future studies are needed to explore the long-term efficacy of angioplasty, wound healing rates and compare angioplasty alone to other treatment modalities to determine the best course of action for patients with this condition.

AUTHORS' DECLARATION

RU, MJ: Study conception. RU, MM, RF: Data collection, analysis. MJ, SM: Investigation. RU, MM, RF, MJ, SM: Critical review, revision, final approval of the manuscript, accountability for all aspects of the work.

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