

Comparative Study between Tibial Vessels Angioplasty with Combined Tibial Vessels and Arch Angioplasty in Diabetic Foot Salvage

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Abstract

Background: Diabetes mellitus (DM) affects around 170 million people globally, and that number is projected to rise to over 370 million in the next decade. Peripheral arterial disease (PAD) affects over 200 million people globally in 2010.

Aim and objectives: To compare the outcomes of angioplasty of tibial vessels disease with angioplasty of tibial vessels and below-the-ankle arterial diseases in diabetic patients, according to limb salvage and time of wound healing.

Subjects and methods: From August 2023 through December 2024, 50 diabetic patients were included in a prospective comparison study at the vascular surgery departments of Al-Hussein University Hospital and Elsayed Galal University Hospital.

Results: It appeared that the most common procedure done was balloon dilatation of anterior tibial artery (64%) followed by the posterior tibial artery (60%), while the least artery dilated was tibioperoneal trunk (10%). By analyzing the salvageable rate after the procedure, it was found that 17(62.96%) had minor amputation(toes) in group A, while it was 14(60.86%) in group B. However, in terms of limb salvageability, neither group differed significantly from the other. Additionally, there was an insignificant difference in the rate of debridement in group A 10(37.03%) and group B 14(60.86%).

Conclusion: Patients with diabetes who are experiencing severe lower limb ischemia can benefit from balloon angioplasty. Meanwhile, limb salvage rates were similar between tibial-only angioplasty and tibial with below-ankle angioplasty.

Keywords: Tibial Vessels Angioplasty; Arch Angioplasty; Diabetic Foot Salvage

1. Introduction

Prior research indicated that 20% of patients with PAD symptoms also had DM. But because most persons with PAD don't have any symptoms at all, this prevalence is likely substantially underreported. While a third of PAD patients experience claudication, over half show no symptoms at all or very odd signs, and the remaining patients have more severe cases of the disease.¹

About half of those who have diabetic foot ulcers also have peripheral artery disease (PAD), a serious consequence of diabetes. Diabetics often experience fast-progressing, bilateral, and primarily distal PAD. In patients with diabetes, the involvement of infrapopliteal vessels, including the anterior tibial artery, posterior

tibial artery, and peroneal artery, is increased compared to individuals without the disease.²

Peripheral vascular disease is more common than cardiovascular disease in southern India, where the bulk of diabetics live. Unfortunately, by the time most patients with diabetic foot syndrome and accompanying vasculopathy show up, tissue loss has already progressed to an advanced stage. It is not always feasible to save these limbs due to the infection and ischemia that characterize these wounds. When these patients are evaluated, infrapopliteal illness is the most common diagnosis. Research has demonstrated that tibial angioplasty, an endovascular therapy option, is just as successful as surgical bypass with reduced risk of complications.³

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Recanalization of as many infrapopliteal arteries as feasible increases the possibility of limb salvage, and it is well established that revascularization of infrapopliteal vasculature effectively avoids major amputation in patients with ischemic diabetic foot ulcers (DFUs). Nevertheless, it has been recently shown that individuals with ischemic DFUs often have involvement of the below-the-ankle (BTA) arteries, which include the plantar and pedal arteries.²

Along with being an independent predictor of non-healing in individuals with ischemic DFUs, BTA arterial disease also indicates a more aggressive form of PAD. Revascularization treatments targeting the foot arteries, as opposed to merely the infrapopliteal vessels, appear to be the most appropriate course of action in this instance. Still, there is a dearth of information about the outcomes of foot revascularization for individuals suffering from BTA artery disease and ischemic DFUs, as far as we are aware.⁴

The aim of this study was to compare the outcomes of angioplasty of tibial vessels disease with angioplasty of tibial vessels and below the ankle arterial diseases in diabetic patient according to limb salvage, time of wound healing.

2. Patients and methods

From August 2023 through December 2024, 50 diabetic patients were included in a prospective comparison study at the vascular surgery departments of Al-Hussein University Hospital and Elsayed Galal University Hospital.

Sample size:

A total of 50-diabetic patients aged above 40-years, all suffering from critical lower limb ischemia (Rutherford category IV and V) with infragenicular atherosclerotic occlusive arterial diseases were included in the study. They were divided into two groups: Group-A with 27-patients undergoing balloon angioplasty of tibial vessels, and Group-B with 23-patients undergoing combined tibial vessels and below the ankle arterial angioplasty.

Inclusion criteria:

All patients are diabetic with critical lower limb ischemia (Rutherford grades IV and V), patients aged above 40 years, patients with infrainguinal (outflow) atherosclerotic occlusive arterial diseases (tibial and pedal), and patients with renal impairment (serum creatinine levels above 2 mg/dL), for whom carbon dioxide (CO₂) angioplasty was done.

Exclusion criteria:

Patients with non-ischemic foot tissue loss, patients with unsalvageable foot at admission,

patients with non-atherosclerotic occlusive arterial lesions (e.g., Buerger's disease or vasculitis), patients with inflow ischemic arterial lesions, and patients with a reduced life expectancy.

Methods:

The following detailed procedures were performed on all patients selected for the study, ensuring a comprehensive evaluation and documentation of each case:

Management Protocol:

All patients were managed according to a pre-set limb salvage protocol, based on the Guidance of the International Working Group on the Diabetic Foot (IWGDF). This protocol includes: Surgical Debridement: Removal of necrotic tissue to promote wound healing. Antibiotic Therapy: Administered in cases of infection, based on microbial culture and sensitivity testing. Revascularization: Angioplasty will be performed to improve blood flow, respecting the patient's overall medical condition and eligibility for the procedure.

Investigations:

All patients were also subjected to routine laboratory tests, radiological assessments, lower limb ultrasound color arterial duplex, computerized tomography angiography (CTA), and magnetic resonance angiography (MRA).

Angioplasty procedure:

The primary aim of the angioplasty is to restore blood flow by addressing occluded tibial arteries. Local anesthesia was used in all patients in our study. Access: All patients of our study underwent transfemoral ipsilateral antegrade access under the guidance of duplex U/S. Equipments used: wires (0.014 & 0.018 or 0.035mm), balloon (2.5 or 3mm), and supporting and directing catheters.

Opening tibial arteries: If technically feasible, the procedure will focus on opening all occluded tibial arteries.

Target artery (Angiosomal theory): If not all arteries can be opened, the angioplasty will target the wound-related artery, following the angiosomal theory, which links specific arteries to wound healing regions.

Lesions located below the ankle (BTA): If there was stenosis or occlusion, BTA angioplasty was done. A narrowing of the lumen diameter of 50% to 99% is called stenosis. When all four major arteries- the common, medial, and lateral plantar arteries as well as the tibial and pedal arteries—are completely blocked, this condition is called occlusion.

Follow-up:

Patients were regularly followed in the vascular clinic for 6-months with assessments at 1-, 3-, and 6-months post-angioplasty. The follow-up assessments were included: pedal pulsation, wound healing progression, arterial Duplex Ultrasound, and CTA or MRA.

Ethical approval:

The study was submitted for review and approval by an ethical review board (ERB) or institutional review board (IRB) at the Al-Hussein University Hospital and Elsayed Galal University Hospital. The study was conducted in accordance with national and international ethical standards for medical research. Informed consent, designed in accordance with ethical guidelines and approved by the relevant institutional review board, was obtained from the studied patients.

Statistical Analysis:

Shapiro-Wilk normality tests and histograms were utilized to assess the distribution of quantitative variables such as blood test results (CBC, renal function, liver function, HBA1C), and follow-up parameters (e.g., wound healing and vascular improvement) in patients undergoing balloon angioplasty of tibial vessels or combined tibial and below the ankle arterial angioplasty. Parametric tests were applied if data are normally distributed.

Continuous variables such as serum creatinine levels, duration of wound healing, and distal pedal pulsation improvement will be expressed as Mean $\pm$ Standard Deviation (SD).

The Student's T-test was used to compare continuous variables between the two groups. Mann-Whitney U-test: For non-normally distributed continuous variables, such as the degree of stenosis or percentage of occlusion, the Mann-Whitney U-test was used to compare between groups. Categorical variables such as the occurrence of complications (e.g., infection or re-occlusion) and the presence of granulated or healed wounds were presented as frequency and percentage. Chi-square test: The Chi-square test was used to analyze associations between categorical variables, such as treatment group (Group-A vs. Group-B) and outcomes like wound healing success or need for additional intervention. Kaplan-Meier curve: Kaplan-Meier survival curves were used to evaluate limb salvage rates in both groups over the 6-month follow-up period, comparing the success of each angioplasty technique in maintaining foot viability. P-Value Threshold: Statistical significance will be considered at $p \leq 0.05$.

A p-value of less than 0.05 shows significant results, whereas a p-value of greater than 0.05 indicates non-significant results in all the statistical tests discussed before. The 5% level of significance was maintained throughout. The results are considered more significant when the p-value is less.

3. Results

The mean age of the studied population was 63.4 ± 7.57 years, ranging between 48-77 years; while the number of male patients in the whole

study population was 32(64%). There was no statistically significant difference in age between the two group. On the other side, the number of male participants was significantly higher in Group-A (81.5%) than Group-B (43.5%), Table 1.

Table 1. Descriptive statistics for demographic characteristics.

VARIABLE		Group-A N=27	Group-B N=23	P-value
GENDER	Male	22(81.5%)	10(43.5%)	0.005a
	Female	5(18.5%)	13(56.5%)	
AGE(MONTHS)	Mean $\pm$ SD	63.4 ± 7.57	64.3 ± 6.95	0.41b
	Range	48-77	51-76	

P-value > 0.05 is considered non-significant, P-values ≤ 0.05 is considered significant.

a: Pearson Chi-Square. b: Independent samples T-test.

Table 2. Procedure of tibial arteries (group-A)

SINGLE ARTERY BALLOON DILATATION		DOUBLE ARTERIES BALLOON DILATATION		TRIPLE ARTERIES BALLOON DILATATION
ATA	4(14.8%)	ATA+PTA	5(18.51%)	ATA+PTA+PA 3(11.11%)
PTA	2(7.40%)	ATA+PA	2(7.40%)	----
PA	7(25.92%)	PTA+PA	4(14.81%)	----

ATA: anterior tibial artery, PTA: posterior tibial artery, PA: peroneal

Table 3. Procedure of tibial arteries and pedal arch (Group-B)

SINGLE ARTERY +ARCH		DOUBLE ARTERIES +ARCH		TRIPLE ARTERY +ARCH
ATA $\rightarrow$ DPA	1(4.34%)	ATA $\rightarrow$ DPA + PTA $\rightarrow$ Planter a	4(17.39%)	ATA $\rightarrow$ DPA + PTA $\rightarrow$ Planter a + PA 3(13.04%)
PTA $\rightarrow$ PLANTER ARTERY	4(17.39%)	ATA $\rightarrow$ DPA + PA	4(17.39%)	ATA $\rightarrow$ DPA + PTA (without planter) + PA 2(8.69%)
----	----	PTA $\rightarrow$ Planter a + PA	2(8.69%)	ATA (without DPA) + PTA $\rightarrow$ planter 0(0%)
----	----	ATA $\rightarrow$ DPA + PTA (without planter)	2(8.69%)	----
----	----	ATA (without DPA) + PTA $\rightarrow$ planter a	1(4.34%)	----

ATA: anterior tibial artery, PTA: posterior tibial artery, PA: peroneal, DPA dorsalis pedis artery

There were 5(18.51%) patients had complete wound healing in group-A versus 14(60.86%) in group-B after 1-month. 9(33.33%) patients had complete wound healing in group-A versus 4(17.39%) in group-B after 3-months. 7(25.92%) patients had complete wound healing in group-A versus 1(4.34%) in group-B after 6-months, Table 4.

Table 4. Wound healing analysis in each group.

VARIABLE	1-MONTH	3-MONTHS	6-MONTHS	
GROUP-A (N=27)	5(18.51%)	9(33.33%)	7(25.92%)	Died $\rightarrow$ 2(7.40%) Major amputation $\rightarrow$ 3(11.11%) Missed $\rightarrow$ 1(3.7%)
GROUP-B (N=23)	14(60.86%)	4(17.39%)	1(4.34%)	Died $\rightarrow$ 1(4.34%) Major amputation $\rightarrow$ 2(8.69%)

			Missed→ 1(4.34%)
P-VALUE	<0.001*	0.200	.038*

There were 24 (88.89%) patients had limb salvage and 3(11.11%) patients had major amputation in group-A. There were 21(91.30%) patients had limb salvage and 2(8.70%) patients had major amputation in group-B. The limb salvage analysis showed an insignificant difference between the studied groups, [Table 5](#).

Table 5. Limb salvage analysis in each group.

			P-VALUE
GROUP-A (N=27)	Limb salvage	24(88.89%)	0.776
	Major amputation	3(11.11%)	
GROUP-B (N=23)	Limb salvage	21(91.30%)	
	Major amputation	2 (8.70%)	

Case presentation:

Group-B

Soad Nader Marsom 70-years old presented by Rt critical lower limb threatened ischemia (CLTI) with 4th toe cyanosis and sole infective gangrene.



Figure 1. Rt 4th toe cyanosis and sole infective gangrene.

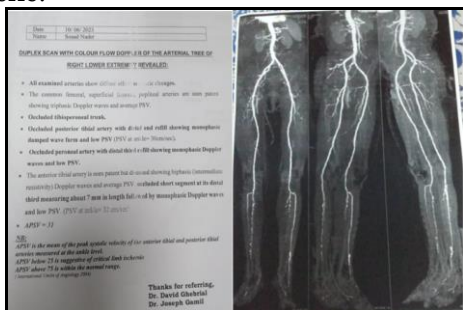


Figure 2. Arterial duplex and CT angiography was done showing: Patent origin of ATA then attenuated Occluded PTA from its origin with no distal end refillattenuated perianal artery Occluded pedal arch.

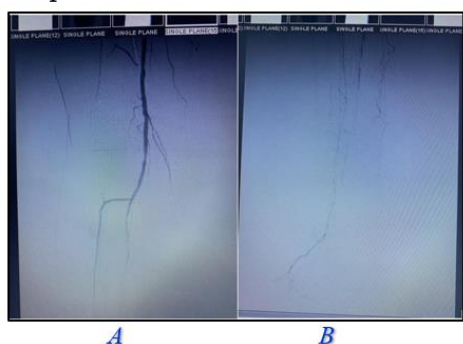


Figure 3. (A&B) diagnostic angiography showing- Patent origin of ATA then attenuated

Occluded PTA from its origin with no distal end refill attenuated perianal artery Attenuated DPA and occluded pedal and planter arteries.

Procedure:

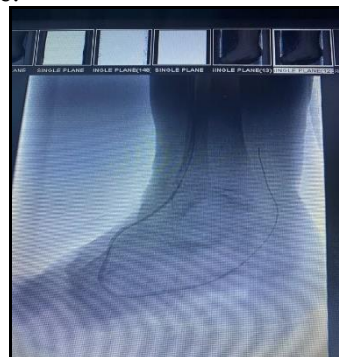


Figure 4. Balloon dilatation of ATA, DPA pedal arch and planter artery using balloon 2.5mm, length 15cm over the wire 0.018.



Figure 5. Balloon dilatation of peroneal artery using balloon 2.5mm, length 15cm over the wire 0.018.

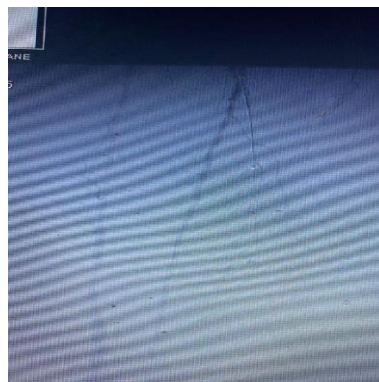


Figure 6. Trial to engage and pass occlusion of PTA but failed.

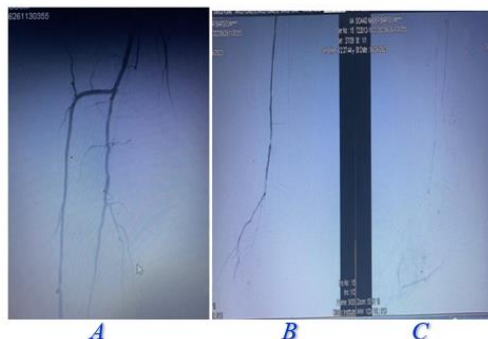


Figure 7. (A, B&C) final result: Patent ATA, DPA, pedal arch Patent peroneal artery Occluded PTA.



Figure 8. (A,B&C) patient underwent rt foot surgery immediately after intervention(4th, 5th toe amputation and sole debridement).



Figure 9. (A,B&C) clean wound and good epithelization Referred to plastic surgeon for skin grafting

4. Discussion

Diabetes mellitus is a growing global health burden that predisposes patients to numerous complications, including diabetic foot ulcers (DFUs). These ulcers often arise from a combination of neuropathy, infection, and ischemia, leading to significant morbidity and increased risk of lower limb amputation.⁵

The present study revealed that, according to demographic data in the studied groups, there was no statistically significant difference in age between the two groups. On the other side, the number of male participants was significantly higher in Group A (81.5%) than in Group B (43.5%).

This came in accordance with Ismail and Ahmed,⁶ They assessed the impact of pedal arch revascularization on wound healing, healing time, and limb salvage in diabetic patients with critical limb ischemia (CLI). In a study of 60 individuals diagnosed with CLI, no statistically significant differences were found in terms of age. There was no statistically significant difference in gender, which contradicts our results in this study.

It was shown that the gender had a significant effect on the side of ischemia with (OR=4.33). As males had 4.33 more odds to have ischemia in the left side than females.

Our results in concordance with Shaker,⁷ reported that most of the patient was males 80% indicating increased incidence of tibial disease in

males.

It appeared that the most common procedure done was balloon dilatation of anterior tibial artery (64%) followed by the posterior tibial artery (60%), while the least artery dilated was tibioperoneal trunk (10%).

Our results in concordance with Shaker,⁷ reported that the lesions were found in 40-vessels: 17(42.5%) anterior tibial, 13(32.5%) posterior tibial, 10-peroneal associated with 6-pedal and 8(20%) plantar arteries.

Furthermore, Patel et al.,⁸ stated that the most common procedure done was balloon dilatation of the anterior tibial artery (85%).

In our study we reported that by analyzing the salvageable rate after the procedure, it was found that 17(62.96%) had minor amputations (toes) in group-A while it was 14(60.86%) in group-B. However, there was no statistically significant difference between both groups regarding limb salvageable. Additionally, there was an insignificant difference rate of debridement in group-A 10(37.03%) and group-B 14(60.86%).

Our results are supported by Huizing et al.,⁹ who conducted a meta-analysis and systematic review of PAA in patients with chronic limb injury (CLI). The study looked at the effectiveness and safety of PAR and tested the hypothesis that additional PAR following tibial artery repair would enhance clinical outcomes. They found no statistically significant difference in the limb salvage rate between tibial artery revascularization alone and adding BTA angioplasty to tibial intervention. The rate of survival without amputation was 78% (95% CI, 0.69-0.87). At the 95% confidence interval (CI), 1.58, there was no statistically significant difference between the amputation-free survival rates of patients who underwent further BTA angioplasty and those who underwent BTK angioplasty alone.

As well, our results in concordance with Ismail and Ahmed,⁶ Our statistical analysis revealed no significant difference between the groups with respect to the absence of minor amputation (P=0.086). All of the patients in this study were classified as Rutherford category '5,' which raises the possibility that the ischemia wound lesion in the foot prior to revascularization is to blame for the debridement and small amputation that occurred. However, there was a statistically significant difference in the limb salvage rate (P=0.01).

The only postoperative complication that differed significantly between the two groups was postoperative infection. Compared to the tibial and arch group B, infection was more common in the tibial group A (P=0.004). Infection (n=8) and significant amputation (n=5) are the most prevalent complications that can occur after

surgery.

Our results, in concordance with Cheun et al.,¹⁰ examined the role of additional pedal interventions in patients undergoing tibial angioplasty. The study found that incorporating pedal interventions improved pedal runoff scores and was associated with better clinical outcomes.

Finally, it was shown from event summary and survival plot that time to complete heal of the wound occurred faster in group-B (median=1-month) than group-A (median=3-month). By conducting Log rank test to assess whether there was a difference between both groups; it appeared that there was a statistically significant difference between the two groups.

Our results supported by a systematic review and meta-analysis by Huizing et al.,⁹ reported that wound healing results were better when tibial plus pedal artery intervention was compared with tibial artery revascularization alone.

Also, Alexandrescu et al.,¹¹ They noted that limb preservation ($p=0.030$) and wound healing ($p=0.018$) were considerably improved in group 2 patients who underwent below-the-knee revascularization.

Also, in 2017, a study by Nakama et al.,¹² proved that the PAA group had a considerably faster rate of wound healing (59.3% vs. 38.1%; $p=0.003$) and a significantly shorter time to wound healing ($p=0.008$) than the non-PAA group.

Limitations: The trial was conducted at a single center, limiting the applicability of findings to other settings, the generalizability of the results, small sample size and need longer period follow-up.

4. Conclusion

Balloon angioplasty is an effective intervention for diabetic patients with critical lower limb ischemia. Meanwhile, limb salvage rates were similar between tibial-only angioplasty and tibial with below-ankle angioplasty.

Disclosure

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

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All authors have a substantial contribution to the article

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There are no conflicts of interest.

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