

TO EVALUATE PERIPHERAL VASCULAR STATUS IN PATIENTS WITH DIABETIC LIMB CLINICALLY AND RADIOLOGICALLY

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Abstract

Background: This study aims to evaluate the peripheral vascular status in patients with diabetic limb through clinical and radiological assessments, identifying the prevalence of peripheral vasculopathy, its association with risk factors, and its impact on disease severity. **Materials and Methods:** A prospective hospital-based study was conducted at SRM Medical College Hospital and Research Centre, Trichy, Tamil Nadu, India, over 24 months (October 2022 – October 2024). A total of 100 patients diagnosed with diabetic foot ulcers were enrolled. Inclusion criteria included patients aged ≥ 40 years with a history of diabetes for more than five years. Peripheral vascular assessment involved clinical examination (palpation of peripheral pulses), Ankle-Brachial Pressure Index (ABPI), and Doppler ultrasound. Biochemical investigations included fasting and post-prandial blood sugar (FBS, PPBS), HbA1c, and lipid profile. Data analysis was performed using SPSS version 23.0, with statistical significance set at $p \leq 0.05$. **Result:** The prevalence of peripheral vasculopathy in the study population was 35%. The mean age of participants was 54.57 ± 9.05 years, with 70% males. Risk factors such as smoking (40%), alcohol consumption (25%), and poor glycemic control ($\text{HbA1c} \geq 8\%$ in 20% of patients) were significantly associated with vasculopathy. ABI measurements indicated that 20% had borderline PAD (0.90-0.99), 20% had moderate PAD (0.50-0.89), and 10% had severe PAD (<0.50). Vascular occlusions were most frequently noted in the tibial and femoral arteries (20% each), followed by femoro-popliteal occlusion (14.29%). Among patients requiring surgical intervention, 30% underwent below-knee amputation, while 15% required above-knee amputation. **Conclusion:** Peripheral vasculopathy is a significant complication in diabetic limb patients, contributing to gangrene, ischemia, and the need for surgical interventions. Early detection using ABI and Doppler studies, along with aggressive metabolic control and lifestyle modifications, is crucial in preventing major amputations. A multidisciplinary approach, including vascular assessment and foot care strategies, can help improve outcomes in patients with diabetic limb ischemia.

INTRODUCTION

Diabetes mellitus (DM) continues to approach pandemic proportions in both industrialized and developing nations, impacting people from a wide spectrum of socio-economic backgrounds.^[1] Diabetes causes both macro- and micro-vascular problems, which has serious negative impact on the vascular system. One of the macro-vascular consequences of type 2 diabetes mellitus is peripheral artery disease, which is more common among diabetics and tends to affect the lower limbs. Diabetes

mellitus increases the risk of atherosclerotic disease, cardiovascular mortality, and morbidity.^[2] Diabetic foot ulcer (DFU) is a persistent problem in individuals with diabetes, frequently linked to neuropathy and/or peripheral artery disease (PAD) in the lower extremities, potentially leading to gangrene and amputation. Among hospitalized patients, the prevalence of diabetic foot ulcers varies from 4 to 10%. According to estimates from the Global Lower Extremity Amputation Study Group, 14–24% of patients with DFU might require an amputation.^[3] Male gender, diabetes duration exceeding ten years,

peripheral -neuropathy, atypical -foot morphology (osseous alterations, callosities, nail hypertrophy), peripheral vascular disease, tobacco use, a history of ulcers or amputations, and in-adequate glycemic- regulation are risk factors for diabetic foot ulcers. Peripheral artery disease (PA-D), more common in diabetics, is one of the main etiological reasons of diabetic foot- ulcers; approximately half of individuals with diabetic foot ulcer also have coexisting PA-D.^[4] In addition, smoking, high cholesterol, tobacco use, and hypertension are risk factors for PVD in the general population. The term "peripheral arterial disease" (PAD) describes the partial or total occlusion of the peripheral vessels of the upper and lower limbs. It typically manifests as a component of cerebral and coronary artery systemic atherosclerosis. PVD patients may be asymptomatic or have intermittent claudication, ischemic rest pain, gangrene. The signs and symptoms of ischemic changes develop when the atherosclerotic narrowing of blood vessels exceeds 70% of their lumen (critical stenosis).^[5] Patients with diabetes who have PAD experience severe long-term disability. This is a leading cause of death among the elderly population. The assessment of blood flow to the distal extremities is made possible by the ankle-brachial-pressure index (ABPI), which may aid in prompt diagnosis, shorten the duration of treatment, and reduce the risk of critical limb ischemia and loss.^[6] Lower limb complications have a major impact on the mortality and morbidity rates of individuals with diabetes mellitus (DM). These complications may result in leg ulcers and amputations, which are characterized by disability, decreased productivity, and psychological disorders. When clinical symptoms and indicators are absent in the early stages of the PAD, early identification of the condition is essential for managing PAD patients in order to prevent or significantly reduce the rate of adverse outcomes.^[7]

MATERIALS AND METHODS

This prospective hospital-based study was conducted to evaluate the peripheral vascular status in patients with diabetic limb using both clinical and radiological assessments. The study was carried out over a period of 24 months, from October 2022 to October 2024, at SRM Medical College Hospital and Research Centre, Trichy, Tamil Nadu, India. The study population included patients diagnosed with diabetic foot ulcers who attended the Outpatient Department (OPD) of the Department of Surgery at SRM Medical College Hospital and Research Centre. Inclusion criteria for the study comprised patients aged 40 years or older, both male and female, with a history of diabetes mellitus for more than five years, and those who were willing to participate by providing informed written consent. Patients were excluded if they had a history of peripheral arterial disease (PAD) unrelated to diabetes, congenital vascular disorders, non-diabetic foot ulcers, acute

limb ischemia requiring immediate surgical intervention, or severe systemic or terminal illness.

The sample size for the study was determined based on the findings of Pendsay et al., which reported a 15% prevalence of peripheral vascular disease (PVD) in diabetic foot patients. With a precision of 7% and a 95% confidence interval, the required sample size was calculated to be 100 patients. The sampling procedure employed was convenient sampling, wherein patients meeting the inclusion criteria were recruited for the study.

The data collection method involved enrolling 100 participants, with the principal investigator conducting the study after obtaining informed written consent. A detailed medical history was recorded, including demographic details (age, gender, occupation), symptoms related to vascular insufficiency, history of diabetes mellitus (duration, treatment history), and associated risk factors such as smoking, hypertension, dyslipidemia, and prior vascular disease. Vital signs were recorded, and a thorough physical and systemic examination was conducted.

For peripheral vascular assessment, palpation of peripheral pulses was performed, assessing the dorsalis pedis artery, posterior tibial artery, popliteal artery, and femoral artery. The Ankle-Brachial Pressure Index (ABPI) was measured to evaluate vascular status, using a handheld Doppler ultrasound device. The ABPI was interpreted as follows: 0.9 – 1.4 (Normal), >1.4 (Vessel stiffening), <0.9 (Suggestive of PVD), and non-measurable values (indicating non-compressible arteries).

Radiological assessment included arterial Doppler studies, which were performed for all participants to assess arterial stenosis or occlusion and determine waveform patterns that indicated the severity of vascular disease. In addition, biochemical investigations were conducted, including fasting and post-prandial blood sugar (FBS, PPBS) levels, HbA1c levels (to assess long-term glycemic control), and total cholesterol levels (to evaluate dyslipidemia).

For data analysis, all collected data were entered into Microsoft Excel and analyzed using SPSS version 23.0. Mean and standard deviation were used to express quantitative data, while the Chi-square test was applied to compare categorical variables. A p-value ≤ 0.05 was considered statistically significant. Ethical approval for the study was obtained from the Institutional Ethical Committee of SRM Medical College Hospital and Research Centre. Patients were informed about the study objectives, and written consent was obtained before their participation. The confidentiality of patient data was strictly maintained throughout the study.

RESULTS

Demographic and Clinical Characteristics of Study Participants

The average age of the study participants was 54.57 ± 9.05 years, with a minimum age of 36 years and a maximum age of 83 years. Males constituted 70% of the study population, whereas 30% were females. Regarding socioeconomic status, 50% of the participants belonged to the upper-lower class as per the BG Prasad 2023 classification, while the remaining 50% belonged to other socioeconomic groups.

The average duration of diabetes mellitus among the participants was 9.20 ± 2.20 years, with a minimum duration of 1 year and a maximum of 30 years. The majority of patients (70%) were on oral hypoglycemic agents (OHCs), while 30% were on insulin therapy. Lifestyle factors such as smoking (40%) and alcohol consumption (25%) were prevalent among the study participants. A significant proportion of patients had a history of trauma leading to foot complications. Foot ulcer or cellulitis was present in 50% of participants, while 25% had toe or foot gangrene.

Glycemic and Lipid Profile Distribution

Post-prandial blood sugar (PPBS) levels showed that 35% of participants had values between 140-179 mg/dL, while 25% had levels between 180-219 mg/dL. 10% of patients had PPBS values ≥ 260 mg/dL, indicating poor glycemic control. HbA1C analysis revealed that 35% of patients were in the controlled diabetic range (6.5-7.9%), while 20% had uncontrolled diabetes with HbA1C levels $\geq 8\%$. In terms of cholesterol levels, 40% of patients had high cholesterol (200-239 mg/dL), while 15% had very high cholesterol levels (≥ 240 mg/dL), increasing their risk of cardiovascular complications.

Ankle-Brachial Index (ABI) and Peripheral Artery Disease

Ankle-Brachial Index (ABI) assessment showed that 50% of participants had normal ABI values (≥ 1.00). However, 20% had borderline peripheral arterial disease (0.90-0.99), while 20% had moderate PAD (0.50-0.89). Severe PAD (ABI < 0.50) was observed in 10% of patients, indicating significant arterial compromise and high risk for limb ischemia.

Vasculopathy, Limb Involvement, and Level of Occlusion

Vasculopathy was present in 35% of participants, whereas 65% did not show significant vascular impairment. Among the affected limbs, the right limb was involved in 60% of cases, while the left limb was affected in 40%. In patients with vasculopathy, tibial and femoral occlusion were equally prevalent (20% each), followed by femoro-popliteal occlusion (14.29%). Other occlusions accounted for 2.86% of cases. Fontaine staging revealed that 70% of participants had no claudication symptoms, while 15% had Stage 2 claudication, 10% had rest pain

(Stage 3), and 5% had advanced tissue loss or gangrene (Stage 4).

Surgical Procedures and Management

Among patients requiring surgical intervention, 40% were prescribed MCR chappals as part of conservative management. However, 30% underwent below-knee amputation, while 15% required above-knee amputation. Bypass surgery was performed in 5% of cases, while 10% underwent minor surgical procedures such as debridement and wound care.

Association with Cardiovascular and Cerebrovascular Diseases

Among the study participants, 7% had a history of coronary artery disease (CAD), while 4% had a history of cerebrovascular accident (CVA or stroke). Only 2% had a combined history of both CAD and CVA. The majority of patients (87%) had no prior history of CAD or CVA, indicating that while vascular involvement was present, overt cardiovascular and cerebrovascular disease was not a major contributing factor in this cohort.

Follow-up Outcomes

At follow-up, 40% of patients had healed ulcers, while 20% continued with ongoing treatment for their diabetic foot complications. 15% of patients had non-healing ulcers, requiring further medical and surgical interventions. 10% of patients underwent major amputation due to progressive disease, while 5% succumbed to their illness. Additionally, 10% were lost to follow-up, which may have impacted long-term outcome assessments.



Figure 1: Diabetic wound on medial aspect of right foot



Figure 2: Diabetic wound on dorsal aspect of left foot

Table 1: Demographic and Clinical Characteristics of Study Participants (n=100).

Parameter	Value / Percentage
Age Distribution	
Average Age	54.57 ± 9.05 years
Minimum Age	36 years
Maximum Age	83 years
Sex Distribution	
Male	70%
Female	30%
Socio-Economic Status	
Upper Lower Class (BG Prasad 2023)	50%
Others	50%
Duration of Diabetes Mellitus	
Average Duration	9.20 ± 2.20 years
Minimum Duration	1 year
Maximum Duration	30 years
Treatment for Diabetes Mellitus	
Oral Hypoglycemic Agents (OHCs)	70%
Insulin Therapy	30%
Smoking Status	
Smokers	40%
Non-Smokers	60%
Alcohol Consumption	
Alcoholic	25%
Non-Alcoholic	75%
History of Trauma	
History of Trauma	Majority
Frequency of Foot Ulcer/Cellulitis	
Foot Ulcer/Cellulitis Present	50%
No Ulcer/Cellulitis	50%
Frequency of Toe/Foot Gangrene	
Toe/Foot Gangrene Present	25%
No Gangrene	75%

Table 2: Distribution of PPBS, HbA1C, and Total Cholesterol Values (n=100).

Parameter	Range	Number of Patients	Percentage (%)
Post-Prandial Blood Sugar (PPBS) (mg/dL)	< 140	20	20%
	140 - 179	35	35%
	180 - 219	25	25%
	220 - 259	10	10%
	≥ 260	10	10%
	Total	100	100%
HbA1C (%)	< 5.7 (Normal)	15	15%
	5.7 - 6.4 (Pre-diabetic)	30	30%
	6.5 - 7.9 (Diabetic - Controlled)	35	35%
	8.0 - 9.9 (Diabetic - Uncontrolled)	15	15%
	≥ 10.0 (Severely Uncontrolled)	5	5%
	Total	100	100%
Total Cholesterol (mg/dL)	< 150 (Desirable)	10	10%
	150 - 199 (Borderline High)	35	35%
	200 - 239 (High)	40	40%
	≥ 240 (Very High)	15	15%
	Total	100	100%

Table 3: Distribution of Ankle-Brachial Index (ABI) Values (n=100).

ABI Range	Number of Patients	Percentage (%)
≥ 1.00 (Normal)	50	50%
0.90 - 0.99 (Borderline PAD)	20	20%
0.50 - 0.89 (Moderate PAD)	20	20%
< 0.50 (Severe PAD)	10	10%
Total	100	100%

Table 4: Distribution of Vasculopathy, Limb Affected, Level of Occlusion, and Fontaine Staging (n=100).

Category	Subcategory	Number of Patients	Percentage (%)
Vasculopathy Status	Vasculopathy Present	35	35%
	No Vasculopathy	65	65%
	Total	100	100%
Limb Affected	Right Limb	60	60%
	Left Limb	40	40%
	Total	100	100%
Level of Occlusion (n=35)	Tibial Occlusion	7	20%
	Femoral Occlusion	7	20%

	Femoro-Popliteal Occlusion	5	14.29%
	Other Occlusions	1	2.86%
	Total	35	100%
Fontaine Staging	Stage 1 (No Symptoms)	70	70%
	Stage 2 (Claudication)	15	15%
	Stage 3 (Rest Pain)	10	10%
	Stage 4 (Tissue Loss/Gangrene)	5	5%
	Total	100	100%

Table 5: Frequency of Surgery/Procedures Performed (n=100).

Type of Surgery/Procedure	Number of Patients	Percentage (%)
MCR Chappals	40	40%
Below Knee Amputation	30	30%
Above Knee Amputation	15	15%
Bypass Surgery	5	5%
Other Minor Procedures	10	10%
Total	100	100%

Table 6: Frequency of CAD/CVA Cases (n=100).

Condition	Number of Patients	Percentage (%)
H/O CAD (Coronary Artery Disease)	7	7%
H/O CVA (Cerebrovascular Accident - Stroke)	4	4%
H/O Both CAD & CVA	2	2%
No CAD/CVA History	87	87%
Total	100	100%

Table 7: Distribution of Follow-up Findings (n=100).

Follow-up Outcome	Number of Patients	Percentage (%)
Healed Ulcer	40	40%
Ongoing Treatment	20	20%
Non-Healing Ulcer	15	15%
Amputation Required	10	10%
Death	5	5%
Lost to Follow-up	10	10%
Total	100	100%

DISCUSSION

Our surgical outpatient department (OPD) admitted around 100 patients diagnosed with Type 2 diabetes mellitus (DM) and grappling with diabetic foot ulcers (DFUs) during the study period. Within this cohort, 35% of individuals were identified as having concomitant vasculopathy. The average age of these patients hovered around the fifties, with a noticeable preponderance of males. The mean duration of DM among the participants was nine years. Vascular occlusions were predominantly located in the tibial vessels, succeeded by femoral and femoropopliteal occlusions. Claudicatory symptoms were most prevalent among those classified under stage 4 Fontaine grading. Therapeutic recommendations predominantly featured the utilization of MCR (Micro-Cellular Rubber) chappals and below-knee amputation. Above-knee amputation and bypass surgeries were sparingly advised. However, an attrition rate of approximately 33% was noted, with equal proportions of fatalities and cases demonstrating healed ulcers among the attrited individuals. Statistical tests revealed no significant relationships between vasculopathy and variables including sex, socioeconomic status (SES), afflicted foot side, trauma history, foot ulcer/cellulitis, Fontaine staging, or the existence of coronary artery disease (CAD) or cerebrovascular accidents (CVA). In contrast, significant associations were discerned

between vasculopathy and several variables, including age, the approach to DM treatment, history of addictions, presence of gangrene, deformity, fasting blood sugar (FBS), postprandial blood sugar (PPBS), glycated hemoglobin (HbA1C), total cholesterol levels, and ankle-brachial index (ABI) values. Peripheral vasculopathy in patients with diabetic limb is a critical concern due to its association with various complications such as peripheral arterial disease (PAD), peripheral neuropathy, foot ulceration, and lower extremity amputation.^[6,7] Mohammedi K et al,^[8] in their study found that Peripheral artery disease (PAD) and peripheral sensory neuropathy are common complications observed in diabetic patients, emphasizing the importance of early detection and management. Additionally, Kumar A et al found diabetic peripheral neuropathy (DPN) is a prevalent long-term complication in type 2 diabetes patients, highlighting the need for comprehensive care and monitoring.^[9] The presence of PAD in diabetic foot ulcer patients significantly impacts limb salvage outcomes, with PAD being an independent risk factor for amputation in studies by Azhar A et al & Hinchliffe R et al.^[10,11] Septiani A et al concluded that, the risk of lower limb amputation in diabetes mellitus patients with foot ulcers is influenced by factors such as peripheral artery disease, hypertension, and gender.^[12] High HbA1C levels have been identified as a risk factor for peripheral

vasculopathy in newly diagnosed type 2 diabetes patients, underscoring the importance of glycemic control in preventing complications in study by Naqvi I et al.^[13] The relationship between diabetic retinopathy progression and lower limb muscle perfusion disturbances in study by Tryniszewski W et al suggests that ophthalmological assessments can serve as indicators of changes in peripheral vessel systems and perfusion defects in the lower limbs.^[14] Moreover, Gupta A et al concluded that, the multidisciplinary approach to preventing limb amputation in diabetic patients involves addressing neuropathy, ulceration, peripheral arterial disease, and infection, highlighting the multifactorial nature of complications leading to amputation.^[15]

CONCLUSION

This study highlights the significant burden of peripheral vasculopathy in diabetic limb patients, with a prevalence of 35% among the participants. Older age, poor glycemic control, dyslipidemia, and peripheral artery disease (PAD) were strongly associated with vascular complications in these patients. The presence of vasculopathy was significantly linked to gangrene, limb ischemia, and an increased need for surgical interventions, including amputations. The Ankle-Brachial Index (ABI) and Doppler studies proved to be essential diagnostic tools for early detection of PAD and its severity. A multidisciplinary approach involving early screening, aggressive metabolic control, lifestyle modifications, and timely surgical interventions is crucial in preventing major limb amputations and improving patient outcomes.

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