e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2026; 17(2); 325-335

Original Research Article

To Study the Prevalence of Peripheral Artery Disease in Diabetic Foot A Hospital Based Study

Sneha Patil[1], Shivani C. Rampure[2]

[1]Assistant Professor, Dept. of Pediatrics

[2]Assistant Professor, Dept. of General Surgery, Mahadevappa Rampure Medical College, Kalaburgi

Received: 24-12-2025 / Revised: 11-01-2026 / Accepted: 05-02-2026

Corresponding Author: Dr. Shivani C. Rampure

Conflict of interest: Nil

Abstract:

Background and Objective: It is necessary to do a comprehensive examination of PVD in each and every diabetic patient. In order to reduce morbidity, the information can be used to assist in the preparation of protocols for the efficient care of diabetic patients. In India, the purpose of this study is to identify the prevalence of peripheral vascular disease and to evaluate the connection between that illness and the ankle-brachial index in diabetic patients who have foot ulcers and those who do not have ones.

Methods: A prospective analytical study done on 40 patients with type II diabetes mellitus with suspected PAD admitted in Basaveshwara Hospital from August 2022 to January 2023. Necessary data was recorded including patient age, sex, clinical finding CRP, WBC, ABPI and statistical analysis was done.

Results and Interpretation: In the present study, 0.88 +/- 0.28 was the mean ABPI. Amongst those who underwent Doppler, 19 had triphasic flow, 15 had biphasic and the remaining had monophasic flow. Monophasic flow patients have significantly lower ABPI (p-value < 0.001). The ABPI did not affect the outcome of the patient in the present study**.**

Conclusion: ABPI was significantly reduced with patients with monophasic flow, but there was no correlation of the same with outcomes.

Keywords: Diabetic Foot Ulcers, Peripheral Artery Diseases, Above Knee Amputation.

DOI: 10.25258/ijpqa.17.2.50

Introduction

Diabetes Mellitus (DM) is a metabolic condition that is characterized by elevated levels of blood glucose. This elevated blood glucose is a consequence of either an absolute or relative insulin shortage, which occurs in situations where there is β-cell malfunction, insulin resistance, or both that are present [1]. Worldwide, it is one of the illnesses that is most prevalent and is expanding at a rapid rate. In India, where there are 77 million people living with diabetes [2], the great majority of them have not yet been identified, diabetes is rapidly becoming a potential epidemic.

Foot ulcers are a symptom of diabetic foot, which is a disorder that affects people who have diabetes [3]. This terrifying condition requires prolonged hospitalization, which may be quite expensive, and there is a possibility that an extremity will need to be amputated [4]. On the other hand, surgical amputation can be avoided by the use of educational and care initiatives [5]. The basic trio of neuropathy, ischemia, and infection is what distinguishes diabetic foot from other foot conditions [4]. It has been stated that the likelihood of a diabetic infected with a DFU is as high as twenty-five percent. When it comes to people with diabetes, diabetic foot is the most common reason for hospitalization (about thirty percent) [2]. One to twenty-five percent of people who have such DFU require an amputation. It is estimated that DFU is the cause of about 85 percent of all amputations. It has been suggested that there are a number of factors that contribute to the development of DFU, the most important of which is peripheral sensory neuropathy, followed by peripheral vascular disease (PVD).

In patients with peripheral vascular disease (PVD), persistent limb ischemia is invariably caused by atherosclerosis of the peripheral arteries. PVD is one of the most prevalent macrovascular problems that can arise from type II diabetes [6]. In adults under the age of sixty, the prevalence is around three percent, but it jumps to more than twenty percent in those over the age of seventy-five. PVD is a condition that only affects one fourth of persons who have it. Smoking, diabetes mellitus, hypertension, obesity, and a lack of physical exercise are some of the additional risk factors that are associated with

high blood pressure. An illness known as peripheral vascular disease (PVD) affects the arteries that supply the kidneys, intestines, legs, and feet. In patients with diabetes, peripheral vascular disease (PVD) is not only associated with a poorer prognosis, but it is also frequently more severe than in those who do not have diabetes who are equivalent. Patients who suffer from PVD are at an increased risk of myocardial infarction, stroke, and death [9,10]. Diabetes mellitus and its consequences can be effectively managed with the aid of early diagnosis of vascular alterations.

There is an additional influence that the diagnosing method has on the severity of PVD [7]. A diagnostic method that is both proven and reproducible is required in order to get a more accurate evaluation of PVD in diabetic patients. The ankle-brachial index (ABI) is a test that falls within this category. The ratio of the systolic brachial pressure to the ankle pressure is referred to as the ABPI. It has been claimed that it can be computed by dividing the higher systolic pressures observed in the brachial artery by the higher systolic pressures reported in the dorsalis pedis and tibialis posterior arteries at the ankle [11]. Simply said, ABPI is a straight forward and non-invasive method. It was discovered that the ABPI was more accurate and verified against angiographically proven illness. Additionally, it was discovered to have a sensitivity of 95% and a specificity of approximately 100% [12].

It is necessary to do a comprehensive examination of PVD in each and every diabetic patient. In order to reduce morbidity, the information can be used to assist in the preparation of protocols for the efficient care of diabetic patients. In India, the purpose of this study is to identify the prevalence of peripheral vascular disease and to evaluate the connection between that illness and the ankle-brachial index in diabetic patients who have foot ulcers and those who do not have ones.

Materials and Methods

Source of Data: The present study will be conducted in the Department of General Surgery, Basaveshwar**.** Teaching & General Hospital attached to Mahadevappa Rampure Medical College, Kalaburagi.

Methods of collection of data

Study Design: The present study is prospective descriptive study

Place of study: Department of General Surgery, Basaveshwar Teaching and General Hospital, Kalaburagi, attached to Mahadevappa Rampure Medical College, Kalaburagi.

Sample Size: 40.

Sampling Procedure: Study subjects were selected after applying inclusion-exclusion criteria. Information was collected through prepared proforma from each patient. Simple randomized sampling was done. The clinical history, physical examination, blood sugar profile, color Doppler and relevant investigation done in a patient clinically diagnosed with peripheral vascular disease in diabetic foot ulcer would be recorded, the treatment modality will also be recorded. These data will be entered in a pretested proforma.

Duration of Study:1st August 2022-31st January 2024 (18 months)

Inclusion Criteria

1. All diabetic patients with foot ulceration.
2. All diabetic patients with gangrene toes, intermittent claudication, or rest pain in feet.
3. Patients with peripheral vascular disease diagnosed on Doppler study.

Exclusion Criteria

1. Non diabetic ulcers.
2. Malignant ulcer.
3. Diabetes with previous amputations for malignancy or acute trauma.
4. Diabetes with lymphedema or osteomyelitis of foot.
5. Marjolin's ulcer/ Skin malignancies.

Results

Table 1: Treatment History

Treatment History	Frequency	%
OHA	24	60%
Irregular	7	17.5%
Insulin	5	12.5%
Insulin + OHA	4	10%
Total	40	100%
Invalid	0	0%
Total	40	100%

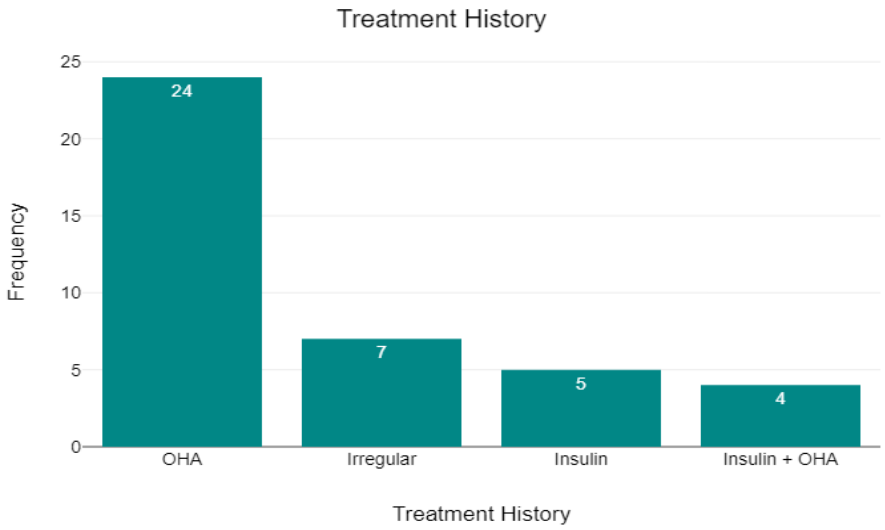

Figure 1: Treatment History

Table 2: Mean HbA1c

	HbA1c
Mean	8.12
Std. Deviation	1.97
Minimum	6.6
Maximum	12.6
95% Confidence interval for mean	7.49 - 8.75

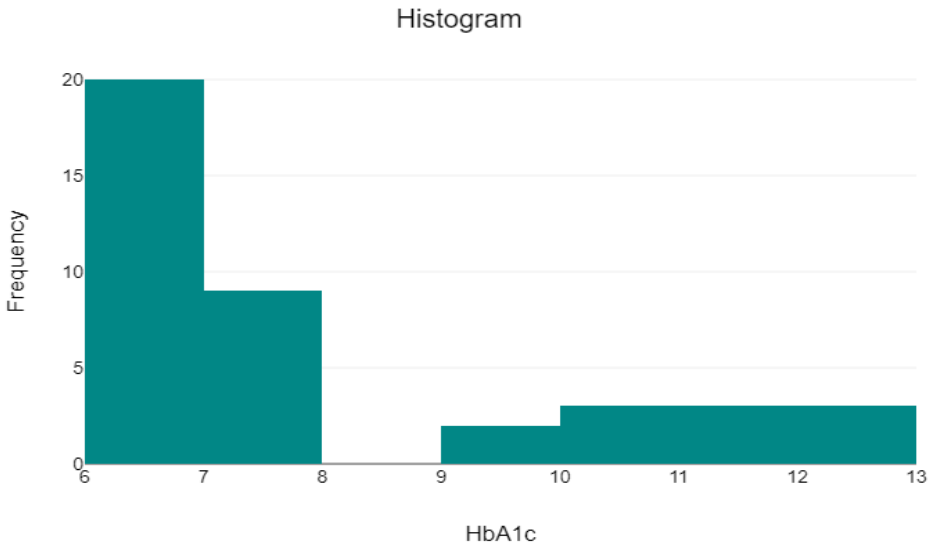

Figure 2: Distribution of HbA1c

Table 3: History of Intermittent Claudication

History of Intermittent Claudication	**Frequency**	**%**
No	22	55%
Yes	18	45%
Total	40	100%
Invalid	0	0%
Total	40	100%

45% of the patients had a history of intermittent claudication, suggestive of PVD.

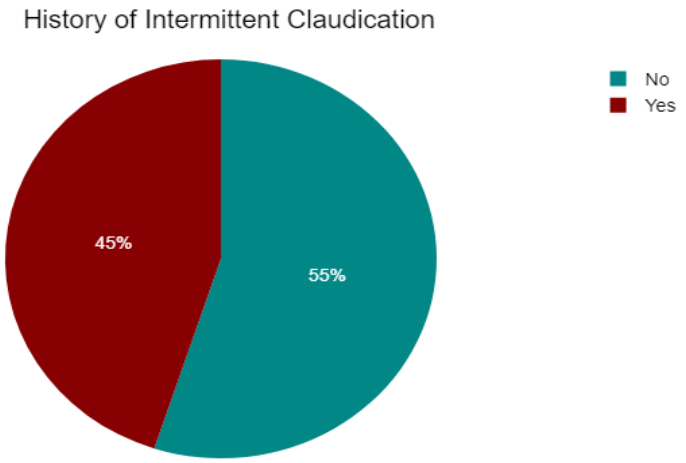

Figure 3: Distribution of Intermittent Claudication

Table 4: History of Smoking

History of Smoking	Frequency	%
No	32	80%
Yes	8	20%
Total	40	100%
Invalid	0	0%
Total	40	100%

20% of the study participants had a smoking history.

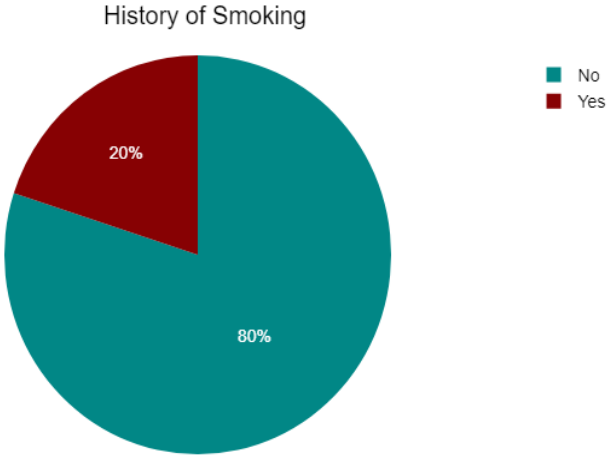

Figure 4: History of Smoking

Table 5: History of Amputation

History of Amputation	Frequency	%
No	34	85%
Ray's amputation of right great toe	4	10%
Ray's amputation of left great toe	1	2.5%
Ray's amputation of right 5th toe	1	2.5%
Total	40	100%
Invalid	0	0%
Total	40	100%

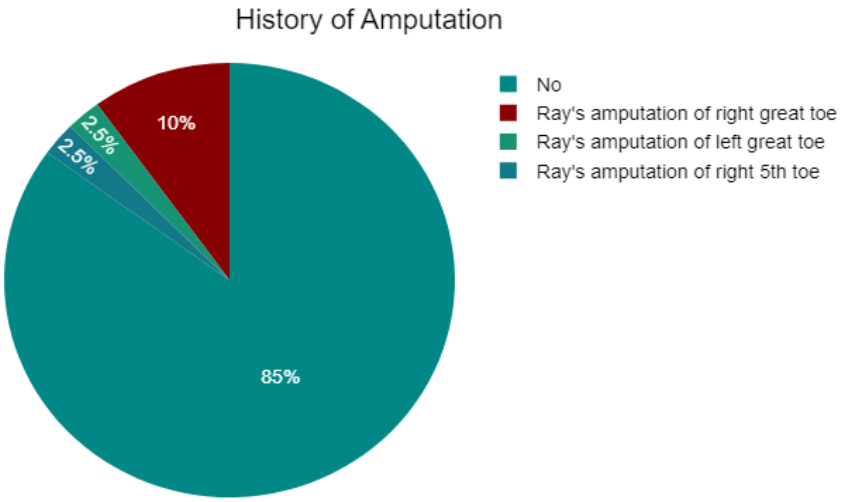

Figure 5: History of Amputation

Table 6: Mean ABPI Values

	ABPI
Mean	0.88
Std. Deviation	0.28
Minimum	0.4
Maximum	1.4
95% Confidence interval for mean	0.79 - 0.96

		Frequency	Mean	Std. Deviation
ABPI	No	22	1.07	0.18
	Yes	18	0.63	0.16

There was a significantly lower ABPI in those with prior history of intermittent claudication

Table 7: Co-Morbidities in the Study Population

Other Comorbidities	Frequency	%
None	29	72.5%
Hypertension	9	22.5%
Bronchial Asthma	2	5%
Total	40	100%
Invalid	0	0%
Total	40	100%

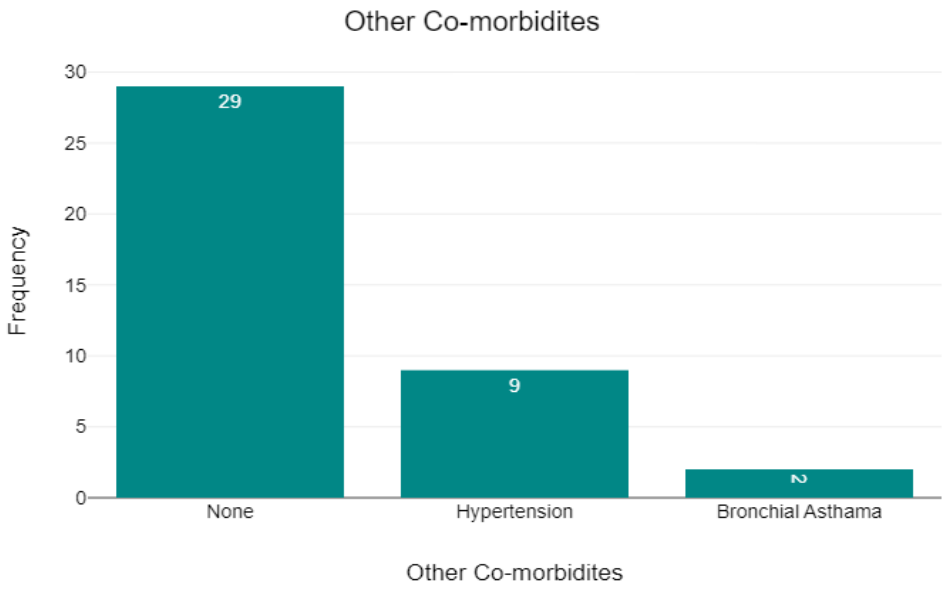

Figure 6: Distribution of co-morbidities

Table 8: Family History of DM

Family History of DM	Frequency	%
Absent	29	72.5%
Present	11	27.5%
Total	40	100%
Invalid	0	0%
Total	40	100%

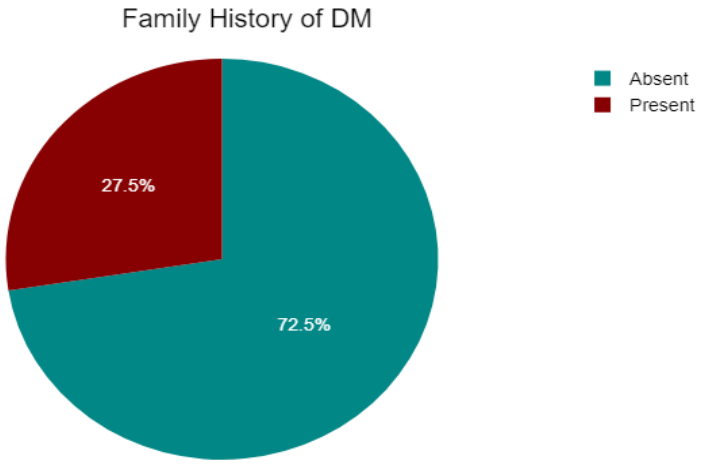

Figure 7: Family History of DM

Table 9: Wagner Classification

Wagner Classification	Frequency	%
II	24	60%
I	16	40%
Total	40	100%
Invalid	0	0%
Total	40	100%

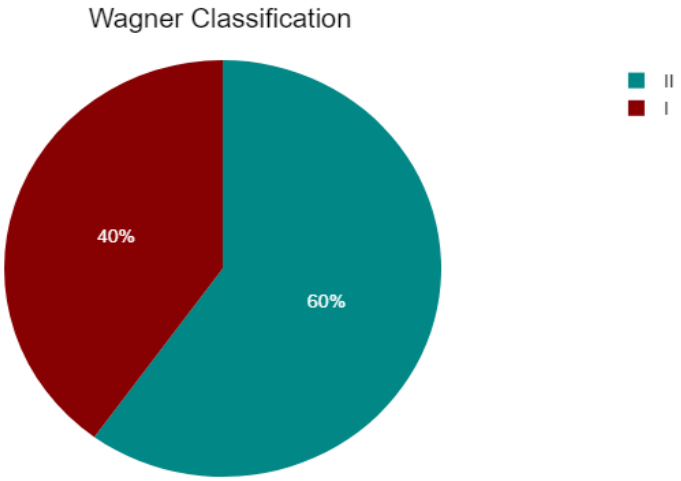

Figure 8: Distribution of DFU by Wagner Classification

Table 10: Types of flow on Doppler

Type of flow on Doppler	Frequency	%
TRIPHASIC	19	47.5%
MONOPHASIC	15	37.5%
BIPHASIC	6	15%
Total	40	100%
Invalid	0	0%
Total	40	100%

		Frequency	Mean	Std. Deviation
ABPI	TRIPHASIC	19	1.08	0.18
	MONOPHASIC	15	0.6	0.15
	BIPHASIC	6	0.93	0.19

Monophasic flow patients have significantly lower ABPI. (p value < 0.001)

Table 11: ABPI Correlation with Outcomes

		Frequency	Mean	Std. Deviation
ABPI	Debridement	18	1.03	0.26
	Debridement and skin grafting	8	0.98	0.08
	BKA	7	0.61	0.16
	Angioplasty followed by BKA	3	0.57	0.21
	Angioplasty followed by BKA	2	0.57	0.11
	AKA	2	0.7	0

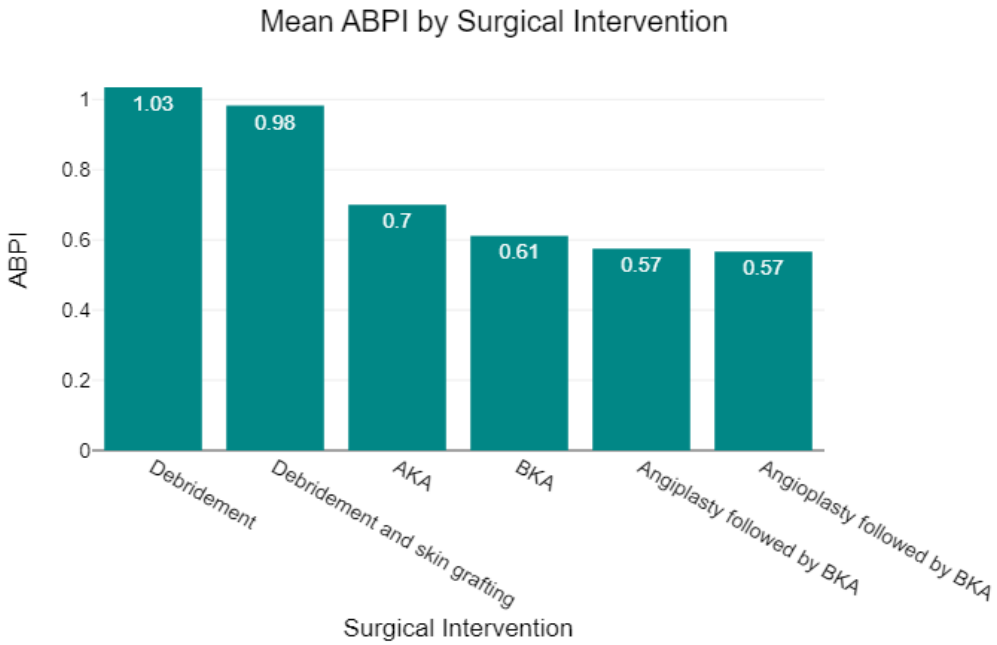

Figure 9: ABPI Correlation with Outcomes

Those with ABPI less than 0.6 underwent BKA and AKA.

Table 12: ABPI Underwent

		n	Mean	Std. Deviation	Std. Error Mean
ABPI	Improved	30	0.83	0.28	0.05
	Unchanged	10	1.02	0.22	0.07

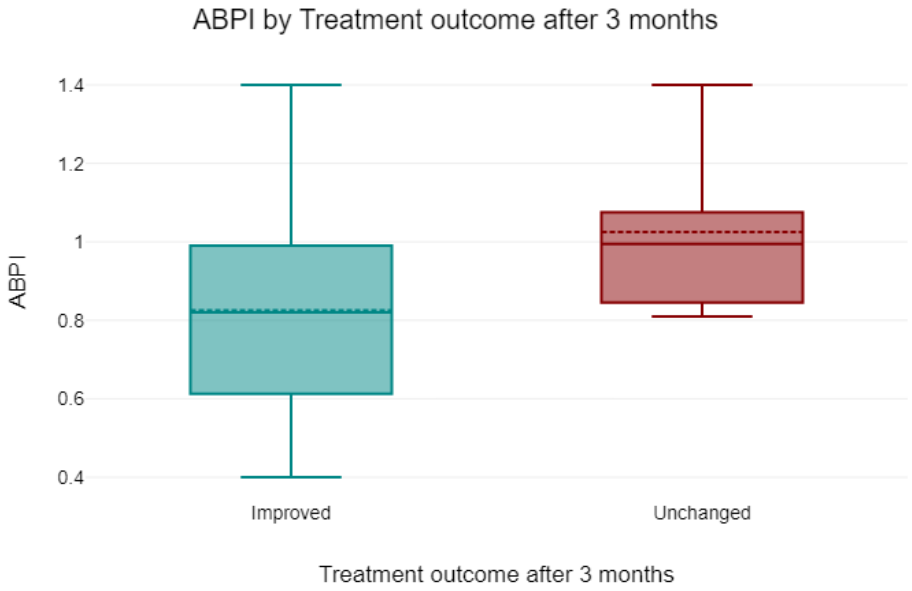

Figure 10: ABPI Underwent

		t	df	p	Cohen's d
ABPI	Equal variances	-2.03	38	.049	0.74
	Unequal variances	-2.31	19.95	.031	0.84

The ABPI did not affect the outcome of the patient in the present study.

Table 13: Logistic Regression

Model	Unstandardized Coefficients	Standardized Coefficients	Standard error	t	p	95% confidence interval for B	
	B	Beta				lower bound	upper bound
(Constant)	0.73		0.16	4.7	<.001	0.42	1.05
Age	0	0.03	0	0.33	0.743	0	0.01
Sex F	0.12	0.21	0.07	1.58	0.125	-0.03	0.27
History of Intermittent Claudication No	0.53	0.95	0.12	4.59	<0.001	0.29	0.77
History of Smoking No	-0.24	-0.35	0.12	-2.05	0.05	-0.49	0
Surgical Intervention Debridement	0.03	0.06	0.16	0.21	0.832	-0.28	0.35
Surgical Intervention Angioplasty followed by BKA	-0.04	-0.04	0.17	-0.26	0.794	-0.38	0.3
Surgical Intervention BKA	-0.12	-0.17	0.14	-0.9	0.376	-0.41	0.16
Surgical Intervention Debridement and skin grafting	-0.15	-0.21	0.17	-0.84	0.406	-0.5	0.21
Surgical Intervention Angiplasty followed by BKA	-0.13	-0.1	0.17	-0.77	.446	-0.48	0.21

Discussion

In the etiopathogenesis of diabetic vasculopathy, recent investigations have suggested that endothelial damage, platelets, monocytes, prostaglandins, lipoproteins, and hyperglycemia all play a role. It is possible for any type of injury, whether it be mechanical or immunological, to result in the disruption of the endothelium barrier.

Age: In the present study, the mean age was 44.88 +/- 11.42 years.

Tyagi et al noted similar findings in their study, Age distribution was shown in the table and here we found the youngest patient was 42 years old, male, and the oldest was a man aged 72 years. 21% of patients fell in 40-50 years of age.

In a study by Rathnaganapathi et al 13, diabetic foot ulcer is more common in the age group of 51-60 years, which was much higher than that of our study.

In a study by Das et al, those without PVD belonged to the ages of 40-49 years, while those with PVD belonged to 50-59 years.

Gender: In the present study, 55% of the study participants were males, with a ratio of 1.1:1.

In a study that was conducted by Jennifer A. Mayfield, the ratio of male to female was found to be practically equal. 17 It's possible that the higher prevalence in males is attributable to associated behaviors like smoking, drunkenness, the type of work they do, and so on.

In Tyagi et al, 69% were males, while the remaining were females. This was different from the findings of our study, with a higher male preponderance.

In Das et al, 71.3% with PVD were males, while 60% without PVD were females.

Unlike the present study, T Rathnaganpathi noted that females were in higher proportion, at 54%.

Duration of DFU and Diabetes: The mean duration of ulcer was 63.95 +/- 69.49 days, with a minimum of 10 days and a maximum of 365 days. The duration of diabetes in the present study was 5.63 +/- 3.05 years. In the current study, patients who had been diagnosed with diabetes for more than five years were more likely to experience problems. The age of the diabetic is the factor that determines the severity of the disease, not the age of the patient experiencing it. The majority of the patients had more than one lesion when they were examined. Above, only significant lesions are taken into consideration.

In a study by Tyagi et al, of 72 patients, 76% of patients were diagnosed, with the disease present for less than 5 years were found to be 76% and 24% of the patients had the disease for greater than 5 years.In the study by Rathnaganapathi et al 13 , most of the patients had duration of up to 6-10 years.

Prevalence of PVD: 45% of the patients had history of intermittent claudication, suggestive of PVD.

32% of the patients in the study by Tyagi et al showed presence of peripheral vascular disease (PVD) and majority of the patients (68%) did not

have PVD. This was similar to the findings of the present study.

In the study by Das et al, 72 persons with diabetes were enrolled over the study period; 52 patients presented with DFUs, and 20 patients were without DFUs. In this study, the prevalence of PVD in DM subjects was found to be 72.22%, with 52 out of 72 patients showing the presence of PVD.

As reported earlier by Pradeepa R et al. [10], the prevalence of PVD is higher in DM subjects than in non-DM subjects in population-based and clinic-based studies.

Smoking: 20% of the study participants had smoking history

In a study by Tyagi et al, there was no association between smoking and the incidence of PVD

In a study by Rathnaganpathi et al 13, 31 percent of the diabetic foot ulcer has associated with smoking.

Doppler and ABPI: In the present study, 0.88 +/- 0.28 was the mean ABPI. Amongst those who underwent Doppler, 19 had triphasic flow, 15 had biphasic and the remaining had monophasic flow. Monophasic flow patients have significantly lower ABPI (p-value < 0.001). The ABPI did not affect the outcome of the patient in the present study.

In a study by Das et al, the ABPI was estimated by Duplex scan. In their study, 62.5% patients with PVD shows IMT value more than 1.0 mm, 36.5% patients show IMT value in between 0.7- 1.0 mm and 1.9% patients show IMT value below 0.7 mm. In this study, 5% of patients without PVD showed an IMT value of more than 1.0 mm, 60% of patients showed an IMT value between 0.7- 1.0 mm, and 35% of patients showed an IMT value below 0.7 mm. That means IMT is strongly associated with PVD.

The absence of dorsalis pedis was discovered in a study carried out by Edmunds et al., which was 31.4%, as well as in a study carried out by Ali SM et al., which was 56%, and in the current study, it was discovered to be 40% (14,15). In the experiments that were discussed before, the absence of dorsalis pedis pulses was not consistent. Vasculopathy, cellulitis with edema, and anatomical abnormalities of the dorsalis pedis artery may be the causes of this condition.

In Tyagi et al, the presence of PVD was found in 6 of the 22 female patients with a prevalence rate of 27%.

Rathnaganpathi et al noted that ankle brachial pressure index measured in the diabetic foot ulcer patient 29 % of the patients had ischemic changes in which 12 % of the cases severe ischemia and mild to moderate ischemic changes around 17%.

Outcome Correlation with ABPI: In the present study, those with ABPI less than 0.6 underwent BKA and AKA. Patients with an ABI<0.5 had a 2-fold higher risk of requiring revascularization surgery or major amputation as compared with patients whose ABI was>0.5. In this study, we found one person <0.5, had ABI, he underwent BKA.

Conclusion

The importance of this study lies mainly in the fact that both DFU and PVD affect the quality of life, generating disability in the diabetic patients. Risk factors such as growing age, longer duration of diabetes, smoking increases the risk of amputation of diabetic foot ulcers. When it comes to investigating the arteries in the lower limbs, duplex Doppler imaging is a non-invasive treatment that is safe, cost-effective, repeatable, and non-invasive. As a result, it is the main examination of choice in all cases of lower extremity arterial disease and assists in determining whether or not additional evaluation by angiography is required.

References

1. Jia, G.; Hill, M.A.; Sowers, J.R. Diabetic Cardiomyopathy: An Update of Mechanisms Contributing to This Clinical Entity. Circ. Res. 2018, 122, 624–638.
2. Joseph, J.J.; Deedwania, P.; Acharya, T.; Aguilar, D.; Bhatt, D.L.; Chyun, D.A.; Di Palo, K.E.; Golden, S.H.; Sperling, L.S.; American Heart Association Diabetes Committee of the Council on Lifestyle and Cardiometabolic Health; et al. Comprehensive Management of Cardiovascular Risk Factors for Adults With Type 2 Diabetes: A Scientific Statement From the American Heart Association. Circulation 2022, 145, e722–e759.
3. Saeedi, P.; Petersohn, I.; Salpea, P.; Malanda, B.; Karuranga, S.; Unwin, N.; Colagiuri, S.; Guariguata, L.; Motala, A.A.; Ogurtsova, K.; et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9(th) edition. Diabetes Res. Clin. Pract. 2019, 157, 107843.
4. Juutilainen, A.; Lehto, S.; Ronnemaa, T.; Pyorala, K.; Laakso, M. Similarity of the impact of type 1 and type 2 diabetes on cardiovascular mortality in middle-aged subjects. Diabetes Care 2008, 31, 714–719.
5. Standl, E.; Balletshofer, B.; Dahl, B.; Weichenhain, B.; Stiegler, H.; Hormann, A.; Holle, R. Predictors of 10-year macrovascular and overall mortality in patients with NIDDM: The Munich General Practitioner Project. Diabetologia 1996, 39, 1540–1545.

6. Keech, A.; Simes, R.J.; Barter, P.; Best, J.; Scott, R.; Taskinen, M.R.; Forder, P.; Pillai, A.; Davis, T.; Glasziou, P.; et al. Effects of long-term fenofibrate therapy on cardiovascular events in 9795 people with type 2 diabetes mellitus (the FIELD study): Randomised controlled trial. Lancet 2005, 366, 1849–1861.
7. Salomaa, V.; Riley, W.; Kark, J.D.; Nardo, C.; Folsom, A.R. Non-insulin-dependent diabetes mellitus and fasting glucose and insulin concentrations are associated with arterial stiffness indexes. The ARIC Study. Atherosclerosis Risk in Communities Study. Circulation 1995, 91, 1432–1443.
8. Dahl-Jorgensen, K.; Larsen, J.R.; Hanssen, K.F. Atherosclerosis in childhood and adolescent type 1 diabetes: Early disease, early treatment? Diabetologia 2005, 48, 1445–1453.
9. Raghavan, S.; Vassy, J.L.; Ho, Y.L.; Song, R.J.; Gagnon, D.R.; Cho, K.; Wilson, P.W.F.; Phillips, L.S. Diabetes Mellitus-Related All-Cause and Cardiovascular Mortality in a National Cohort of Adults. J. Am. Heart Assoc. 2019, 8, e011295.
10. Valensi, P.; Prevost, G.; Schnell, O.; Standl, E.; Ceriello, A. Targets for blood glucose: What have the trials told us. Eur. J. Prev. Cardiol. 2019, 26, 64–72.
11. Howard, G.; O'Leary, D.H.; Zaccaro, D.; Haffner, S.; Rewers, M.; Hamman, R.; Selby, J.V.; Saad, M.F.; Savage, P.; Bergman, R. Insulin sensitivity and atherosclerosis. The Insulin Resistance Atherosclerosis Study (IRAS) Investigators. Circulation 1996, 93, 1809–1817.
12. Isomaa, B.; Almgren, P.; Tuomi, T.; Forsen, B.; Lahti, K.; Nissen, M.; Taskinen, M.R.; Groop, L. Cardiovascular morbidity and mortality associated with the metabolic syndrome. Diabetes Care. 2001, 24, 683–689.
13. Tyagi A, Lavanya S, Prasad GH.A clinical study of peripheral vascular disease due to atherosclerosis in diabetic foot infections. Int Surg J. 2018;5:931-6.
14. Mautner, S.L.; Lin, F.; Roberts, W.C. Composition of atherosclerotic plaques in the epicardial coronary arteries in juvenile (type I) diabetes mellitus. Am. J. Cardiol. 1992, 70, 1264–1268.
15. Djaberi, R.; Schuijf, J.D.; Boersma, E.; Kroft, L.J.; Pereira, A.M.; Romijn, J.A.; Scholte, A.J.; Jukema, J.W.; Bax, J.J. Differences in atherosclerotic plaque burden and morphology between type 1 and 2 diabetes as assessed by multislice computed tomography. Diabetes Care. 2009, 32, 1507–1512.