International Surgery Journal
Mathew S et al. Int Surg J. 2026 Jan;13(1):59-66
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: https://dx.doi.org/10.18203/2349-2902.isj20254330

Original Research Article

Ankle brachial index and foot ulcer risk stratification among outpatients with type 2 diabetes mellitus at a public referral hospital in South India: a preventive perspective

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Received: 15 November 2025
Accepted: 16 December 2025

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ABSTRACT

Background: Peripheral artery disease is perceived to reduce blood flow to the lower extremities of patients with diabetes and lead to foot ulcers. This research investigated the possible association of ankle brachial index (ABI) with foot ulcer risk (FUR), as well as the associations of both with socio-clinical variables among a group of patients with type 2 diabetes mellitus (T2DM).
Methods: 236 patients who regularly visited the outpatient department of a public tertiary care centre in South India were enrolled. ABI was studied using a hand-held Doppler-HI. dop 2.4.5.8 MHz. Foot ulcer risk was measured using INLOW'S 60-second diabetic foot screen. Other related socio-clinical variables were also collected.
Results: The mean age of the patients was 56.06±8.09 years. The mean ABI was 1.01 (±0.15). 3.38% presented with critical limb ischemia. One fourth of the patients belonged to the high to urgent FUR category. ABI was associated with gender and alcohol consumption. FUR was associated with religion, education, history of foot ulcer or amputation, presence of foot ulcer, diabetic retinopathy, regular foot care and follow-up habits, HbA1C, serum urea, and creatinine. Median ABI scores differed significantly across FUR categories (Kruskal–Wallis H 13.09, p value 0.011).
Conclusions: ABI among patients with T2DM was related to FUR, and both these variables demonstrated different association patterns with socio-clinical variables, with no shared significant associations. Outpatient-based Doppler study is feasible and may be a useful initiative to identify the foot ulcer risk in advance.

Keywords: Foot ulcer risk stratification, Peripheral arterial disease, ABI, INLOW'S 60-second diabetic foot screen, T2DM, Prevention

INTRODUCTION

Peripheral arterial disease (PAD), foot ulcer, and foot amputations remain an unbreakable unity among patients with diabetes globally, even after joint and comprehensive efforts to break the chain. PAD affects people with diabetes in a slightly higher proportion than the general population, with prevalence ranging between 20% and 50% in those with diabetes, and 10% and 26% in those without diabetes.[1,2] Rapidly progressing atherosclerosis is one of the reasons said to be behind this.[3] PAD is perceived as a significant indicator of foot pathology and amputation, as it markedly impairs the blood flow to the lower extremities of patients with diabetes. 12-24% of diabetes patients develop foot ulcers, and 85% of foot amputations are preceded by foot ulcers.[4]

Identifying and intervening PAD on time will interfere with the development of a foot ulcer at a sufficiently early stage. This will have a positive impact on health care in terms of cost, mortality, and morbidity.[5]

Published research on using ankle brachial index (ABI) as a predictor of foot ulcer among patients with diabetes is extensive. However, there are controversies about accepting ABI as a perfect indicator of foot ulcer risk among diabetics. The argument against using ABI as the reference test is the interference of atherosclerosis. The latter often leads to false normal ABI and thus to incorrect interpretation of the results.[6]

Some authors caution that researchers may miss an actual foot risk when they use ABI, and they suggest raising the cut-off to 1 in order to make the interpretation more reliable among patients with diabetes.[7,8] Moreover, some of the socio-clinical variables of diabetes patients are undoubtedly related to ABI, and looking into those significant associations is also important while using ABI as a predictor of foot ulcer. Even with all these limitations, ABI is widely accepted as a simple and objective measure, convincingly conveying the status of blood flow to the extremities by providing the ratio of the systolic blood pressure (SBP) measured at the ankle to that measured at the brachial artery.[9]

Evidence from a prospective non-randomized observational study, conducted by a leading diabetes research foundation in South India, which compared the performances of ankle-brachial index and transcutaneous partial pressure of oxygen ($tcPO_2$) measurement in predicting wound healing in diabetic ulcers, showed that $tcPO_2$ is a better predictor for amputation, while ABI is a better predictor for ulcer healing.[10]

Another study from South India prospectively observed inpatients with diabetic foot ulcers and reported that lower ankle-brachial pressure index (ABPI) was associated with longer duration of ulcer healing (p=0.003). They also opined that ABPI can be used as a routine tool in all patients with diabetic foot ulcers for screening peripheral arterial disease.[11] A study reported from Pune, middle India recently investigated the value of pressure indexes on wound healing among patients with diabetes, emphasizing integrated routine assessment of ABPI and Toe Brachial Index into DFU management protocols.[12]

From exploring the existing evidence, spanning over eight years, in data bases, investigators could not pick any that associated ABI with FUR stratification among patients with diabetes. Since investigators wanted to concentrate on the preventive possibilities for foot ulcer by early identification and stratification, the decision to proceed with this study was arrived at. This research was an attempt to investigate the interrelation of FUR with ABI as well as to look into those possible associations of socio-clinical variables of diabetes patients with their ABI among those following up in a public tertiary care centre in South India. The study tests the null hypothesis that the medians (or mean ranks) of all the groups of FUR are equal for ABI. Hypothesis was tested at a 0.05 the level of significance.

METHODS

The one-time cross-sectional data were collected from 236 patients with T2DM visiting the medicine outpatient department (OPD) who belonged to the age group of 25 to 65 yrs. The sample size was arrived at from a recently published study with 80% power and 5% significance level, expecting 10% post-screening attrition. The study had been reviewed and approved by the Ethics Committee of the campus (G2-12/2015/CONTSR-1/2024).

Those patients without a foot ulcer or foot ulcer restricted to one leg who were self-reporting to OPD were included. Toe amputation was not a criterion for exclusion. Samples were restricted to those diagnosed with diabetes for five years or more. The patients were assumed to be able to follow instructions as they were self-reporting to OPD. This study excluded the patients who underwent bilateral lower limb amputation.

Patients with foot ulcer restricted to one of the legs were retained for inclusion in the study, considering the possibility of saving the normal limb through future intervention. Those who are otherwise susceptible to foot ulcer due to the presence of spinal cord injuries and hemiplegia were excluded. The patients classified under the non-compressible category of ABI were not included for analysis, considering the possible interference from severe atherosclerosis.

Socio-personal and clinical data of the patients were collected using a structured questionnaire. Interview responses and information from the patients' outpatient records have been utilized to fill the questionnaire. FUR screening was done using INLOW'S 60-second Diabetic Foot Screen. 10 gm microfilament was used for the assessment of foot sensations. Patients were categorized into very low risk (0), low risk (1), moderate risk (2), high risk (3), and urgent risk (4) for foot ulcer. ABPI was used to assess peripheral arterial disease with a hand-held Doppler- HI. dop 2.4.5.8 MHz, with the score categorization of 1 to 1.3 normal, 0.7 – 1.0 mild PAD, 0.4 – 0.7 moderate PAD, and less than 0.4 severe.

The lower normal limit of ABI was fixed as 1 to obtain maximum sensitivity for the measure.[13,14] The questionnaire and foot ulcer screen were content validated. Handheld Doppler was calibrated by the biomedical engineer of the medical equipment supplier agency connected to the selected tertiary care centre.

Prospective patients were selected conveniently outside the physicians' office before their scheduled visit to the doctor during the waiting time. Patients who were at least 10 token numbers behind their turn were selected to ensure that their turn would not be disrupted. Approximately 15 minutes were spent with each patient.

The consenting patient was led to a private room, which was away from the outpatient (OP) corridor and was noise-free. The researcher sat with the patient and family member, initially introduced herself, and briefly explained what was going to be done. Consent sheet was explained, and a signature or thumb impression was obtained.

The hand doppler was shown to the patient, and its working was explained in brief. The possible sensations which can be expected during the use of micro-filament and doppler examinations were explained, and also detailed on how to cooperate during the procedure. After the collection of socio-clinical data, the patient was helped to lie down supine on a cot. Ankle systolic BP was measured first, followed by brachial BP. BP was assessed in all four limbs, and the highest brachial and ankle pressures were used for subsequent ABI calculations. Doppler measurements were saved, and micro-filament examination was completed. Privacy was ensured throughout the procedure.

The ABI value and FUR category of each patient were entered in their OP file by the researchers. Cases with critical limb ischemia or those falling in the high to urgent FUR categories were highlighted. Patients were instructed to present this page to the physician during their consultation. The consultants had been informed of this arrangement beforehand, and they adhered to it consistently.

Statistical analysis

Analysis was done using statistical package for the social sciences (SPSS) version 25. Descriptive statistics were used for depicting the distribution of patients, and inferential methods to test associations. The Kruskal-Wallis test was used to identify differences in ABI across various categories of FUR. This test was used, as the data did not meet the normality assumption. Independent t-test and Fisher's Exact test were used to examine the association of socio-clinical variables with ABI and FUR, respectively.

Spearman's rank correlation coefficient was used to assess the correlation between continuous variables. Logistic regression analysis was performed to determine the predictive power of HbA1c on ABI.

RESULTS

The mean ABI was 1.01±0.15. 3.38% of patients presented with critical limb ischemia. One fourth of the patients belonged to the high to urgent FUR category (Table 1).

The mean age of the patients was 56.06±8.09 years. ABI was found to be associated with gender and alcohol consumption. FUR was associated with religion, education, history of foot ulcer/ amputation, presence of foot ulcer, diabetic retinopathy, regular foot care habit and regular follow-up among patients with diabetes (Table 2).

FUR was significantly different across various levels of serum urea and creatinine among patients with diabetes mellitus. No significant correlation of ABI with levels of serum urea and creatinine was observed (Table 3).

HbA1C was significantly different between various foot ulcer risk categories (Table 4).

Logistic regression analysis revealed that HbA1c does not meaningfully predict ABI category. There is no direct association between glycaemic control and ABI status in the sample (Table 5). There are significant differences between the medians of ABI across various categories of FUR indicating that at least one group is different from the others (Table 6).

Table 1: Distribution of patients based on ABI and FUR.

ABI	Number	Percentage (%)	Mean (SD)	FUR	Number	Percentage
Normal	119	50.64	1.01 (.15)	Very low (0)	32	13.60
Mild	72	30.38		Low (1)	91	38.60
Moderate	37	15.60		Moderate (2)	54	22.90
CLI	08	03.38		High (3)	52	22
				Urgent (4)	7	03

Table 2: Relation of socio-clinical variables with ABI and FUR among patients with diabetes mellitus.

Variables	ABI		P value (indep. t test)	Foot ulcer risk						P value (Fisher's exact test)
	Mean	SD		Very low	Low	Mode-rate	High risk	Urgent risk	Total	
Age (years)										
≤40	0.943	0.122	1.28/ 0.274	1	6	5	0	0	12	29.16/ 0.085
41-45	1.032	0.149		4	7	2	4	0	17	

Continued.

Variables	ABI		P value (indep. t test)	Foot ulcer risk						P value (Fisher's exact test)
	Mean	SD		Very low	Low	Mode -rate	High risk	Urgent risk	Total	
46-50	1.033	0.153		3	11	8	5	2	29	
51-55	1.023	0.137		7	23	5	6	0	41	
56-60	1.020	0.128		10	16	14	13	2	55	
≥61	0.987	0.153		7	28	20	24	3	82	
Gender										
Male	1.036	0.166	2.98/ 0.003	15	44	22	27	5	113	3.07/ 0.547
Female	0.981	0.115		17	47	32	25	2	123	
Religion										
Hindu	1.005	0.141	0.22/ 0.800	23	60	39	36	4	162	21.15/ 0.007
Christian	1.021	0.149		9	15	11	4	1	40	
Muslim	1.005	0.154		0	16	4	12	2	34	
Education										
Informal	0.980	0.189	0.28/ 0.926	0	3	3	2	0	8	37.58/ 0.010
Primary	0.991	0.134		3	15	10	9	3	40	
Secondary	1.006	0.152		4	18	9	16	3	50	
High school	1.018	0.149		14	47	26	20	1	108	
Higher secondary	1.001	0.045		8	4	0	2	0	14	
Degree/diploma	1.004	0.149		3	4	6	3	0	16	
Occupation										
Nil	0.990	0.137	1.13/ 0.346	6	34	21	25	4	90	37.01/ 0.044
Coolie	1.038	0.163		6	23	13	11	2	55	
Driver	1.052	0.152		2	8	0	1	0	11	
Office job	1.045	0.150		3	2	5	3	0	13	
Pensioner	0.982	0.125		2	1	0	3	0	6	
Self employed	0.987	0.140		7	14	11	8	1	41	
Government job	1.002	0.116		6	9	4	1	0	20	
Economic status										
BPL	1.015	0.149	1.31/ 0.193	25	64	34	38	6	167	3.42/ 0.490
APL	0.989	0.130		7	27	20	14	1	69	
Marital/living with										
Alone	1.088	0.058	1.18/ 0.321	2	0	1	2	0	5	11.49/ 0.386
Spouse	0.970	0.117		2	16	6	7	0	31	
Spouse and children	1.009	0.154		23	61	36	33	7	160	
Sibling or relative	0.990	0.100		2	5	2	2	0	11	
Children	1.031	0.132		3	9	9	8	0	29	
Type of family										
Nuclear	1.016	0.140	1.74/ 0.179	30	74	41	45	4	194	11.49/ 0.175
Joint	0.970	0.147		1	13	9	6	1	30	
Extended	0.970	0.189		1	4	4	1	2	12	
Smoking										
No	1.009	0.143	0.38/ 0.703	31	72	45	43	6	197	7.12/ 0.130
Yes	0.999	0.151		1	19	9	9	1	39	
Alcohol										
No	0.993	0.128	3.15/ 0.002	27	72	40	42	6	187	1.65/ 0.800
Yes	1.064	0.184		5	19	14	10	1	49	
Betel chewing										
No	1.007	0.144	0.45/ 0.655	32	87	54	51	7	231	5.74/ 0.220
Yes	1.036	0.156		0	4	0	1	0	5	
Nearby hospital										
Nil	1.058	0.076	1.87/ 0.135	0	3	0	1	0	4	18.62/ 0.098
PHC/SC	1.006	0.148		19	65	47	42	5	178	

Continued.

Variables	ABI		P value (indep. t test)	Foot ulcer risk						P value (Fisher's exact test)
	Mean	SD		Very low	Low	Mode-rate	High risk	Urgent risk	Total	
THQ	0.949	0.097		2	8	4	4	1	19	
Medical college	1.042	0.144		11	15	3	5	1	35	
Family history of DM										
No	1.002	0.144	1.26/ 0.286	13	37	29	21	4	104	11.86/ 0.754
Mother	0.986	0.142		9	26	13	18	1	67	
Father	1.053	0.145		5	12	7	3	2	29	
Both	1.027	0.149		3	11	3	6	0	23	
Don't know	1.019	0.136		2	5	2	4	0	13	
History of foot ulcer										
No	1.009	0.139	0.50/ 0.615	32	88	52	42	2	216	34.21/ 0.0001
Yes	0.992	0.191		0	3	2	10	5	20	
History of amputation										
No	1.006	0.139	1.89/ 0.059	32	90	54	52	5	233	12.77/ 0.012
Yes	1.163	0.406		0	1	0	0	2	3	
Presence of foot ulcer										
No	1.010	0.144	1.76/ 0.080	32	91	54	51	3	231	28.993/ 0.0001
Yes	0.896	0.114		0	0	0	1	4	5	
Diabetic retinopathy										
No	1.010	0.133	0.24 /0.784	28	45	24	20	1	118	50.80/ 0.0001
Yes	1.011	0.158		0	31	16	28	6	81	
Not checked	0.992	0.148		4	15	14	4	0	37	
Regular foot care										
No	1.031	0.154	1.70/ 0.090	3	26	19	23	4	75	15.29/ 0.004
Yes	0.997	0.138		29	65	35	29	3	161	
Regular blood test										
No	1.023	0.172	0.80/ 0.425	7	14	15	7	3	46	6.61/ 0.158
Yes	1.004	0.136		25	77	39	45	4	190	
Follow up										
No	1.030	0.178	1.09 /0.277	9	13	9	5	4	40	10.99/ 0.027
Yes	1.003	0.136		23	78	45	47	3	196	
Diet control										
No	1.017	0.148	0.98/ 0.329	15	44	28	24	3	114	0.48/ 0.976
Yes	0.999	0.140		17	47	26	28	4	122	
Change in dose of hpoglycemic medicines in three months										
No	1.009	0.144	0.55/ 0.584	28	81	47	47	4	207	4.61/ 0.330
Yes	0.994	0.147		4	10	7	5	3	29	

Table 3: Relation of FUR and ABI across various levels of urea and creatinine among patients with diabetes mellitus.

Variables	FUR				ABI	
	Foot ulcer risk	Mean	SD	P value (Kruskal Wallis test)	Spearman's correlation coefficient (r)	P value
Urea	Very low	23.55	09.06	0.0001	0.034	0.600
	Low	24.64	12.18			
	Moderate	22.55	04.96			
	High	43.95	23.60			
	Urgent	33.90	23.56			
Creatinine	Very low	0.89	0.27	0.0001	-0.019	0.767
	Low	0.96	0.37			
	Moderate	1.00	0.99			
	High	1.85	1.08			
	Urgent	1.87	1.07			

Table 4: Relationship of HbA1C with Foot ulcer risk.

Foot ulcer risk category	HbA1C					P value (Kruskal Wallis test)
	Mean	SD	Median	25th quartile	75th quartile	
0	7.26	1.21	7.20	6.53	7.80	14.25/0.007
1	8.54	1.89	8.50	7.30	9.70	
2	8.86	2.44	8.15	6.88	10.43	
3	8.61	2.23	8.00	6.93	9.88	
4	7.41	1.32	7.40	6.00	8.20	

Table 5: Relationship of HbA1C with ABI.

Category	B	P value	Exp (B)	95% CI	Nagelkerke R^2
CLI	-0.516	0.434	0.597	0.164–2.173	0.011
Mod. PAD	-0.201	0.281	0.818	0.568–1.178	
Mild PAD	-0.178	0.229	0.837	0.626–1.119	
Normal ABI	-0.196	0.152	0.822	0.629–1.074	

Table 6: Comparison of the medians of ABI across various categories of FUR among patients with diabetes mellitus.

Foot ulcer risk	ABI					P value (Kruskal Wallis test)
	Mean	SD	Median	25th quartile	75th quartile	
0	1.05	0.12	1.00	1.00	1.08	13.09/0.011
1	1.03	0.14	1.00	0.93	1.11	
2	0.97	0.16	0.99	0.85	1.07	
3	0.98	0.13	0.94	0.87	0.94	
4	0.96	0.19	0.93	0.92	1.00	

DISCUSSION

The current research investigated the possible relationship of foot ulcer risk with ABI among patients with type 2 diabetes mellitus. For this purpose, the FUR was stratified into very low, low, moderate, high, and urgent risk. ABI is analysed as a continuous variable. Results showed that there were significant differences between the medians of ABI across various categories of FUR (Kruskal–Wallis H 13.09, p value 0.011), suggesting that ABI can positively indicate FUR among the selected population.

The published research evidence generally investigated ABI as a predictor of FU healing, amputation, and survival among patients with diabetes. A diverse array of methodologies was adopted by various researchers to support this interrelation, ranging from RCTs, comparative studies, tool validation, cohort studies, and systematic reviews. Most of the studies were conducted among outpatients and some among the community-dwelling population. Not many have investigated the ABI-FU relationship through stratification of risk, specifically among the referred group of outpatients, and thus, this study stands distinct in its approach.

Two prominent studies were located in the repositories, out of which one investigated the usefulness of combining ABI with TcPO2 in predicting the survival of diabetes patients with DFU as a mediator. The study evidenced the usefulness of ABI combined with TcPO2 for risk stratification of DFU in predicting survival. This study conclusively accepts that this combination is a sensitive marker of macrovascular complications among T2DM patients.[15] The second study conducted in the Asian subcontinent found that low ABI was independently associated with diabetic foot ulcer in patients with type 2 DM. The adjusted odds ratio (aOR) for foot ulcers associated with low ABI was 2.712 (1.199-6.133, p=0.017).[16] This finding reveals a stronger association between the two measured variables, quite similar to the direction of association observed in our study.

Higher-level evidence from a systematic review was published from the western part of the globe which gathered evidence on the usefulness of eight non-invasive screening tests for the prediction of wound healing and the risk of amputation in diabetic foot ulcers. The authors summarized that ABI also predictive but to a lesser degree of the risk of amputations (DOR, 2.89; 95% CI, 1.65-5.05) but not of wound healing (DOR, 1.02; 95% CI, 0.40-2.64).[17]

This paradox necessitates further exploration, and the role of mediating and moderating variables needs to be explored. We also consider the recommendation from a yesteryear study on incorporating additional diagnostic methods alongwith ABI to improve the effectiveness of PAD screening in high-risk diabetes.[18]

Our study explored, as a first step, those variables that are independently associated with ABI and FUR among T2DM patients. Variables showing shared association with both ABI and FUR from the recently published studies included age, duration of diabetes, smoking/tobacco use, peripheral neuropathy, prior PAD, poor glycemic control, and chronic kidney disease.[19-21]

None except serum urea in our study showed shared interrelationship when analysed, which points to different risk-factor clusters for ABI and FUR. We did not analyse the duration of diabetes for association due to concerns about patient misreporting and the possibility of an asymptomatic period of the disease.

Neuropathy status was built in the foot screen tool and, therefore, was not evaluated separately. Further exploration using ordinal logistic regression with ABI as an independent variable to predict ulcer risk while adjusting for other socio-clinical variables as covariates may provide some helpful insights.

Strengths

The study was one of the first initiatives of its kind in which the patients attending out-patient departments where assessed for their ABI and screened for foot ulcer risk in a public health hospital. The time spent by the physicians with the patients was considerably limited due to heavy patient load, and the services of a diabetes nurse were unavailable in the OPD. In this context, the researchers' contact time with patients is observed as valuable, as they could impart some significant lifestyle advice during their interaction.

Limitations

The study had some limitations. First, one-time data was used to see the interconnection between ABI and foot ulcer risk. Secondly, samples were not representative of the general population, as most of them hailed from a lower socioeconomic stratum. Thirdly, the possible drug interactions with PAD and foot ulcer risk were not investigated in this study. Finally, the patients of incompressible ABI category were not analysed, considering their overlap with serious atherosclerosis, which may have impacted the direction and degree of association between ABI and FUR. These limitations form avenues for future research. Ordinal regression, including ABI as a predictor of ulcer risk while adjusting for other socio-clinical variables as covariates and checking for confounding or effect modification, would have been another option of data analysis. The researchers recommend further studies to consider these analyses with an enhanced sample size.

CONCLUSION

PAD among patients with T2DM is related to foot ulcer risk. A single intervention will not mitigate both types of risk, and screening strategies must be multimodal and not purely ABI-dependent. Still, outpatient based Doppler testing is feasible and may be a useful initiative to identify the foot ulcer risk in advance.

ACKNOWLEDGEMENTS

Authors would like to thank the Head of the Department and faculty members of General Medicine and staff of out-patient department of the Government Medical College, Thrissur Kerala for their guidance and co-operation in the conceptualization and implementation phases of this study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mathew S, Elavally S, Madhavan I, Prabhakaran GV, Mathew S. Ankle brachial index and foot ulcer risk stratification among outpatients with type 2 diabetes mellitus at a public referral hospital in South India: a preventive perspective. Int Surg J 2026;13:59-66.