e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(11); 454-460

Original Research Article

Ankle-Brachial Index (ABI) and Toe-Brachial Index (TBI) in Type 2 Diabetes Mellitus Patients with Peripheral Artery Disease (PAD) and Their Correlation with Carotid Intima Media Thickness (CIMT)

Santosh B[1], Suhasini KA[2], Raman Boddula[3]

[1]Consultant Endocrinologist, Bangalore Baptist Hospital, Bangalore, Karnataka, India

[2]Assistant Professor, Department of Community Medicine, Sapthagiri Institute of Medical Sciences & Research Centre, Bangalore, Karnataka, India

[3]Senior Consultant and Head of Department, Department of Endocrinology, Yashoda Hospital, Secunderabad, Telangana, India

Received: 25-08-2024 / Revised: 23-09-2024 / Accepted: 26-10-2024

Corresponding Author: Dr. Suhasini KA

Conflict of interest: Nil

Abstract:

Background: Recent studies have shown that ankle brachial index (ABI) can be falsely normal even in presence of peripheral artery disease (PAD) of lower limbs in diabetes mellitus (DM) patients, especially in elderly and those with chronic kidney disease. In such patients, toe brachial index (TBI) seems to be a better screening test for detecting PAD.

Objective: To compare the sensitivity between ABI and TBI for detecting PAD in type 2 DM patients; and to study the correlation between glycaemic control and severity of PAD.

Methods: A cross-sectional study was performed in 75 type 2 DM patients with PAD of bilateral lower limbs, which was confirmed by CT angiography of lower limbs (a total 150 limbs were evaluated). They underwent Doppler for measurement of ABI and TBI. CIMT was measured using high-resolution B-mode ultrasonography.

Results: There were 57 males and 18 females, with mean age of 65.72 years and mean duration of T2DM of 15.39 years. With a cut-off of 0.9, ABI had sensitivity of 68.66% and with cut-off of 0.7, TBI had sensitivity of 97.33% for detecting PAD, respectively. Age, smoking, hypertension and HbA1c correlated positively with severity of both ABI and TBI whereas serum creatinine correlated with only ABI severity. Age, hypertension, poor glycaemic control and serum creatinine positively correlated with severity of CIMT. Severity of CIMT, in turn, had a significant correlation with severity of both ABI and TBI. In a subgroup analysis, increasing age, longer duration of DM, higher waist circumference, higher serum creatinine and high LDL-C levels were associated with ABI >0.9; whereas poor glycaemic control (higher HbA1c and FBS) and smoking were associated with ABI <0.9; and gender and hypertension were not significantly different in groups with either ABI <0.9 or >0.9. ABI >0.9 was associated with slightly increased CIMT compared with ABI <0.9.

Conclusion: In T2DM patients, TBI is more sensitive than ABI for detecting PAD, especially in elderly, those with longer duration of DM and impaired renal function.

Keywords: Ankle-Brachial Index, Toe-Brachial Index, Type 2 Diabetes Mellitus, Peripheral artery disease, Carotid Intima Media Thickness.

Introduction

Diabetes mellitus is one of the most common clinical conditions that we come across in day-to-day practice, of which type 2 diabetes mellitus accounts for 90% of the cases. The International Diabetes Federation (IDF) estimated that 1 in 11 adults aged 20–79 years (425 million adults) had diabetes mellitus globally in 2017.[1] This estimate is projected to rise to 629 million by 2045, and the largest increases will come from the regions experiencing economic transitions from low-income to middle-income levels. According to IDF, there were over 73 million cases of diabetes in India in 2017, with a prevalence of 1 per every 8.8 adults and this prevalence is estimated to rise to 134 million by 2045.[1] Peripheral arterial disease (PAD) is a chronic atherosclerotic process that causes narrowing of the peripheral arterial vasculature, predominantly of the lower limbs.[2] Patients with diabetes mellitus have 4-fold increased risk of developing PAD and it also progresses more rapidly than in people without diabetes.[2] In the improving management practices and clinical outcomes in type 2 diabetes (IMPACT) study, 31% of 20,000 Indian patients with type 2 diabetes had PAD.[3] In addition, the outcome after surgical revascularization is often worse in diabetic patients because of delay in diagnosis and this group is also at 10 to 16 times increased risk of undergoing major (above ankle) amputation.(2) Many diabetic patients with PAD often have clinically significant cerebral or coronary artery disease, which is reflected in the 6-fold increased mortality from cardiovascular disease compared with patients without PAD.[4] The prevalence of coronary artery disease was higher (52.38%) in Indian diabetic patients with PAD compared with those without PAD (24%).[5]

The ankle-brachial index (ABI) is the commonly used method to diagnose PAD. An ABI of less than or equal to 0.9 is considered abnormal. However, in diabetic patients, especially of long duration, the peripheral arteries may be stiff or calcified which can cause artificially high ankle pressure thus leading to falsely high ABI values.[6-8] The presence of diabetic neuropathy is thought to reduce the reliability of ABI by virtue of its association with medial sclerosis, which may render the vessel wall incompressible on cuff inflation.[9] Diabetes is the most common cause for high (≥1.4) ABI in patients with PAD.[9] However, this calcification of peripheral arteries in diabetes spares the digital vessels.(10) Thus, measurement of toe pressure instead of ankle pressure could be a better alternative to screen PAD in diabetic patients. In a study on diabetic patients, toe brachial index (TBI) of <0.7 showed a sensitivity of 91% to identify PAD.[10] In another study on diabetic patients with PAD, the prevalence of having normal ABI (>0.9) and low TBI (<0.7) was found to 9%.[11] There is little literature available on comparison between ABI and TBI in evaluating PAD in diabetic patients, especially in Indian population.[12] There are very few studies comparing the ABI and TBI with CIMT in diabetic patients. Hence, our study aims to compare the two pressure indices (ABI and TBI) in evaluating PAD in diabetic patients and their correlation with CIMT.

Materials and Methods

The study was a hospital-based descriptive observational research conducted in the Outpatient Departments, the Department of Endocrinology, and the Department of Vascular Surgery at Yashoda Hospital in Secunderabad, Telangana, India, from December 2016 to March 2018. The study included patients with type 2 diabetes mellitus who were over 20 years of age, encompassing both smokers and non-smokers from urban and rural areas, and diagnosed with bilateral peripheral artery disease, confirmed by CT angiography of the lower limbs. Patients with unilateral peripheral artery disease, those who had undergone medical or surgical treatment for peripheral artery disease, individuals with wounds or infections around the testing site, those who had undergone amputation (which would preclude the measurement of the toe-brachial index), patients with Raynaud's disease and connective tissue disorders, as well as those experiencing any acute illness that could alter glycaemic levels, serum creatinine, and other parameters, were excluded from the study. Furthermore, individuals who did not provide informed consent were also excluded.

A total of 75 patients attended the outpatient department and met the inclusion and exclusion criteria during the study period. According to a previous study by Kaveeshwar et al., the prevalence of type 2 diabetes mellitus in Hyderabad was found to be 16.6%. Additionally, a study by Rao et al. identified the prevalence of peripheral artery disease in type 2 diabetes mellitus to be 30%. Therefore, the estimated prevalence for the study area, which was the prevalence of peripheral artery disease in type 2 diabetes mellitus, was calculated to be 4.98%.

Data collection was performed among patients with type 2 diabetes mellitus and bilateral peripheral artery disease of the lower limbs. They underwent a complete evaluation that encompassed a detailed history-taking regarding symptoms such as pain in the lower limbs, leg numbness, paraesthesia, or weakness, as well as wounds, ulcers, changes in the colour of the lower limbs, and other symptoms. A physical examination was conducted, which included anthropometry, vital signs, and palpation of arteries such as the femoral, popliteal, anterior tibial, posterior tibial, and dorsalis pedis. Investigations included fasting blood sugar (FBS), postprandial blood sugar (PPBS), HbA1c, serum creatinine, lipid profile (LDL-C, HDL-C, VLDL-C, and triglycerides), and vascular pressures of the limbs assessed using Doppler ultrasound. Additionally, a CT angiogram of the lower limbs and carotid Doppler (for carotid intima-media thickness) was performed.

Statistical analysis: The data obtained was manually entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) v23. All the categorical variables were summarised using frequencies and percentages. Continuous variables were summarized using mean (standard deviation) and/or median (interquartile range) (based on the results of data normality, tested using Kolmogorov–Smirnov test and the Shapiro–Wilk test). To test for statistical significance, Chi square test or Fisher exact test (for categorical variables) and independent "t" test or Mann Whitney U test (for continuous variables) was used. Statistical significance was considered at p value less than 0.05.

Results

A total of 75 subjects diagnosed with type 2 diabetes mellitus and peripheral artery disease affecting the bilateral lower limbs were evaluated in this study. Consequently, 150 limbs (two limbs per subject) with peripheral artery disease were analysed. The mean age of the study population was 65.72 ± 7.67 years, and the mean duration of type 2 diabetes mellitus was 15.39 ± 5.3 years. The mean waist circumference was 94.65 ± 6.01 cm, while the mean body mass index was 29.62 ± 2.55 kg/m². The mean systolic blood pressure recorded was 131.31 ± 18.76 mmHg, the mean fasting blood glucose was 220.21 ± 62.97 mg/dL, and the mean haemoglobin A1c (HbA1c) was 10.17% ± 2.36%. The mean levels of low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol were 100.77 ± 28.2 mg/dL and 40.9 ± 2.23 mg/dL, respectively, while the mean triglycerides (TG) level was 160.55 ± 44.96 mg/dL. The mean creatinine level was 1.34 ± 0.53 mg/dL.

Among the 75 subjects studied, 57 were male (76%) and 18 were female (24%). Of the 150 limbs, the majority, 53 limbs (35.3%), exhibited mild peripheral artery disease, as confirmed by CT angiography of the lower limbs. This indicates that using an ankle-brachial index (ABI) of less than 0.9 as the diagnostic cut-off for peripheral artery disease does not identify all affected limbs. In this study, only 103 limbs (68.66%) had an ABI below 0.9, whereas the remaining 47 limbs (31.33%) had an ABI above 0.9. Thus, the sensitivity of the ABI for detecting peripheral artery disease in our study was 68.66%.

Furthermore, 68 limbs (45.3%) were categorized as having moderate peripheral artery disease based on ABI, confirmed by CT angiography. Using a toe-brachial index (TBI) of less than 0.7 as the diagnostic cut-off for peripheral artery disease, 146 limbs (97.3%) met the criteria for diagnosis, while 4 limbs (2.7%) exhibited a normal TBI despite having peripheral artery disease. Consequently, the sensitivity of the TBI for detecting peripheral artery disease in our study was 97.3%. The limbs classified as exhibiting mild peripheral artery disease according to ABI (ABI: 0.7-0.9) had a mean HbA1c of 9.121%. The data indicate a significant correlation between HbA1c levels and the severity of peripheral artery disease (as determined by ABI), suggesting that an increase in HbA1c (indicative of poor glycaemic control) corresponds to a decrease in ABI. The limbs identified as exhibiting mild peripheral artery disease based on ABI (ABI: 0.7-0.9) had a mean carotid intima-media thickness (CIMT) of 1.03 cm (SD: 0.14 cm). In contrast, limbs with moderate peripheral artery disease (ABI: 0.4-0.69) had a mean CIMT of 1.22 cm (SD: 0.10 cm), while those with severe peripheral artery disease (ABI: <0.4) exhibited a mean CIMT of 1.33 cm (SD: 0.10 cm). Limbs with normal ABI (0.91-1.3) had an average CIMT of 1.18 cm (SD: 0.11 cm), and limbs with a high ABI (>1.3, indicative of non-compressible vessels) had a mean CIMT of 1.2 cm (SD: 0.05 cm). There was a statistically significant correlation between the severity of peripheral artery disease (as measured by ABI) and CIMT, indicating that a decreasing ABI (reflecting increased severity of peripheral artery disease) is associated with an increase in CIMT.

The limbs classified as exhibiting mild peripheral artery disease according to TBI (TBI: 0.5-0.7) had a mean HbA1c of 7.93%. The data reveal a significant correlation between HbA1c levels and the severity of peripheral artery disease (as determined by TBI), indicating that an increase in HbA1c (indicative of poor glycaemic control) corresponds to a decrease in TBI. The limbs classified as exhibiting mild peripheral artery disease based on TBI (TBI: 0.5-0.7) had a mean CIMT of 0.99 cm (SD: 0.13 cm), whereas limbs with moderate peripheral artery disease (TBI: 0.3-0.49) had a mean CIMT of 1.17 cm (SD: 0.09 cm). Those limbs with severe peripheral artery disease (TBI: <0.3) showed a mean CIMT of 1.29 cm (SD: 0.07 cm), while limbs with a normal TBI (>0.7) had an average CIMT of 1.15 cm (SD: 0.05 cm). A statistically significant correlation was observed between the severity of peripheral artery disease (as measured by TBI) and CIMT, indicating that a decreasing TBI (reflecting increased severity of peripheral artery disease) is associated with an increase in CIMT.

The data presented also illustrate the correlation between the ankle-brachial index (ABI) and toe-brachial index (TBI). A moderately strong positive correlation was identified between ABI and TBI values in our study population, with a Pearson correlation coefficient of 0.469, which was statistically significant (P value: 0.001). This indicates that as ABI values increase, TBI values also tend to increase, and vice versa.

Table 1: Baseline characteristics of the study population

Characteristics	N	Mean	SD
Age (in years)	75	65.72	7.67
Duration of DM (in years)	75	15.39	5.53
WC (cm)	75	94.65	6.01
BMI (kg/m2)	75	29.62	2.55

SBP (mmHg)	75	131.31	18.76
FBS (mg/dl)	75	220.21	62.97
HbA1c (%)	75	10.17	2.36
LDL-C (mg/dl)	75	100.77	28.2
HDL-C (mg/dl)	75	40.91	2.23
TG (mg/dl)	75	160.55	44.96
Serum Creatinine (mg/dl)	75	1.34	0.53

Table 2: Prevalence of severity grades of PAD according to ABI v/s TBI

Severity of PAD	ABI n (%)	TBI n (%)
Severe	6 (4)	34 (2)
Moderate	44 (29)	68 (45)
Mild	53 (35)	44 (29)
Normal	41 (27)	4 (3)
High	6 (4)	0
Total	150 (100)	150 (100)

Table 3: Correlation between HbA1c and carotid intima media thickness (CIMT) with grades of PAD according to ABI

Variables/Severity of PAD (according to ABI)		N	Mean	SD	P value
HbA1c (%)	Severe	6	13.16	0.41	0.0001
	Moderate	44	11.68	1.82	
	Mild	53	9.12	1.87	
	Normal	41	9.38	2.38	
	High	6	10.82	2.47	
	Total	150	10.17	2.35	
CMIT	Severe	6	1.33	0.10	0.0001
	Moderate	44	1.22	0.10	
	Mild	53	1.03	0.14	
	Normal	41	1.18	0.11	
	High	6	1.20	0.05	
	Total	150	1.15	0.15	

Table 4: Correlation between HbA1c and carotid intima media thickness (CIMT) with grades of PAD according to TBI

Variables/Severity of PAD (according to TBI)		N	Mean	SD	P value
HbA1c (%)	Mild	44	7.93	0.87	0.0001
	Moderate	68	10.43	2.02	
	Severe	34	12.71	1.39	
	Normal	4	8.7	1.01	
	Total	150	10.17	2.35	
CMIT	Mild	44	0.99	0.13	0.0001
	Moderate	68	1.17	0.09	
	Severe	34	1.29	0.07	
	Normal	4	1.15	0.05	
	Total	150	1.14	0.15	

Table 5: Correlation between ABI and TBI

		TBI
ABI	Pearson Correlation	0.469**
	Sig. (2-tailed)	0.0001
	N	150

Discussion

A total of 75 patients with type 2 diabetes mellitus with peripheral artery disease of the bilateral lower limbs were evaluated in this study. Therefore, a total of 150 limbs (two limbs in each subject) with peripheral artery disease, which were confirmed by CT angiogram of lower limbs, were studied. The mean age of the study population was 65.72 ± 7.67 years and the mean duration of T2DM was 15.39 ± 5.53 years. Out of 75 subject's, majority were male

(76%). 53.3% were non-smokers. And 49 subjects (65.3%) were hypertensive.

The mean waist circumference (WC) was 94.65 ± 6.01 cm, and the mean body mass index (BMI) was 29.62 kg/m^2 ± 2.55 kg/m^2. In a study by Aboyans et al., 158 patients with T2DM of whom 88% were male and mean age of 68 years were evaluated and they had lower limb PAD, diagnosed by duplex ultrasound and 94% of them had foot ulcer. In this study, the sensitivity of ABI to detect PAD was found to be 99%.[6] Clairotte et al. studied 83 diabetic patients (71% of them being males and mean age was 63 years) with PAD of lower limbs, diagnosed with duplex ultrasound. In these, the ABI had sensitivity of 29% to detect PAD.[13]

In our study, out of 150 limbs that had peripheral artery disease, 44 limbs (29.3%) showed mild PAD according to TBI, 68 limbs (45.3%) had moderate PAD, and 34 limbs (22.7%) had severe PAD. The remaining 4 limbs (2.7%) showed normal TBI (>0.7). Thus, when we take a TBI of <0.7 as the cut-off for diagnosing PAD, 146 limbs (97.3%) met the criteria for PAD, whereas remaining 4 limbs (2.7%) had normal TBI even though they had PAD. Hence, the sensitivity of TBI for detecting PAD in our study was 97.3%.

The sensitivity of TBI for detecting PAD is reported to range from 45% to 100% in different studies. In a study done by Williams et al., where 68 diabetic patients (130 limbs) who had an average age of 63-69 years and PAD, diagnosed by duplex ultrasound, were studied, it was found that TBI had sensitivity of 100% for detecting PAD.[11] In a study by Park et al., where 15 diabetic patients (30 limbs) with PAD (diagnosed with angiography) were studied, it was found that the sensitivity of TBI was 100%.[14] In our study, the limbs which showed mild PAD according to ABI (ABI: 0.7-0.9) had a mean age of 60.77 years, limbs with moderate PAD (ABI: 0.4-0.69) had a mean age of 66.41 years, those limbs which had severe PAD (ABI: <0.4) had a mean age of 78.67 years, those limbs with normal ABI (0.91-1.3) had an average age of 68.78 years and those limbs with high ABI (>1.3). i.e. non-compressible vessels) had a mean age of 70.5 years.

This shows that there is a significant correlation between age and severity of PAD (according to ABI), which indicates that with increasing age, the ABI decreases. In a study by Li et al., where more than 3000 subjects including 969 T2DM patients were studied, it was shown that with increasing age, the ABI decreased.[15] Li et al. studied 531 T2DM patients with PAD and found that older age was associated with lower ABI.[16] Similar results were also found in other studies by Amir Ali et al.[17] And by Bak et al.[18] In T2DM patients. The result of our study was consistent with these studies. In our study, the limbs which showed mild PAD according to ABI (ABI: 0.7-0.9) had a mean HbA1c of 9.121%, limbs with moderate PAD (ABI: 0.4-0.69) had a mean HbA1c of 11.68%, those limbs which had severe PAD (ABI: <0.4) had a mean HbA1c of 13.16%, those limbs with normal ABI (0.91-1.3) had an average HbA1c of 9.38% and those limbs with high ABI (>1.3. i.e. non-compressible vessels) had a mean HbA1c of 10.817%. This shows a significant inverse correlation between HbA1c levels and ABI. Many studies have shown that the glycaemic control correlates with the initiation and progression of PAD in diabetic patients. In a study by Selvin et al.,[19] it was found that for every 1% increase in HbA1c, there is corresponding 26% increase in the risk of developing PAD. In another study by Selvin et al., which was a prospective study done on 1894 diabetic patients, it was found that higher HbA1c was associated with low ABI (mean HbA1c: 7.3%), intermittent claudication (HbA1c: 8.3%) and increased amputation or revascularization rates (HbA1c: 8.2%), compared with those with no PAD (HbA1c: 7%).[19] Another study by Muntner et al.[20] Also showed similar results, consistent with our study results.

In our study, the limbs which showed mild PAD according to TBI (TBI: 0.5-0.7) had a mean age of 61.68 years, limbs with moderate PAD (TBI: 0.3-0.49) had a mean age of 65.88 years, those limbs which had severe PAD (TBI: <0.3) had a mean age of 70.74 years, whereas those limbs with normal TBI (>0.7) had an average age of 64.75 years. This shows a significant correlation between age and severity of PAD (according to TBI), which indicates that with increasing age, the TBI decreases. In a study done by Spangeus et al.[21] On 742 T2DM patients (482 males and 260 females), it was found that increasing age was associated with lower TBI.

Another study by Fukui et al.[22] Done on 390 T2DM patients (241 males and 149 females) showed similar association. In our study, in males, 29.8% of the limbs had mild PAD according to TBI, 43.9% limbs had moderate PAD, and 22.8% limbs had severe PAD, whereas 3.5% of limbs had normal TBI. In females, 27.8% of the limbs had mild PAD according to TBI, 50% limbs had moderate PAD, and 22.2% limbs had severe PAD, whereas none of the limbs had normal TBI. This indicates that there was no significant difference in the severity grading of PAD according to TBI, in correlation to gender.

In our study, the limbs which showed mild PAD according to TBI had a mean HbA1c of 7.93%, limbs with moderate PAD had a mean HbA1c of 10.43%, those limbs which had severe PAD had a mean HbA1c of 12.71%, whereas those limbs with normal TBI (>0.7) had an average HbA1c of 8.7%.

This shows that there is a significant correlation between HbA1c and severity of PAD (according to TBI), which indicates that with increasing HbA1c (poor glycaemic control), the TBI decreases. The study by Potier et al.[23] Done on 74 T2DM patients found that increasing HbA1c levels were significantly associated with lower TBI values. In another study done by Spangeus et al.[21] On 742 T2DM patients (482 males and 260 females) also showed that increasing HbA1c was significantly associated with lower TBI and severe PAD. These studies also found that longer duration of diabetes mellitus was associated with lower TBI values. In our study, the limbs which showed mild PAD according to ABI (ABI: 0.7-0.9) had a mean CIMT of 1.03 cm, limbs with moderate PAD (ABI: 0.4-0.69) had a mean CIMT of 1.22 cm, those limbs which had severe PAD (ABI: <0.4) had a mean CIMT of 1.33 cm, those limbs with normal ABI (0.91-1.3) had an average CIMT of 1.18 cm and those limbs with high ABI (>1.3 i.e. non-compressible vessels) had a mean CIMT of 1.2 cm.

There was a statistically significant correlation between severity of PAD (when measured according to ABI) and CIMT. We found that not only lower ABI was significantly associated with higher CIMT, but even higher ABI was associated with higher CIMT, indicating that both lower and higher ABI values are associated with increased cardiovascular events. In a study by Brasileiro et al.[24] on 118 patients (48 men and 70 women), it was found that lower ABI was significantly associated with higher CIMT (r= -0.235, p value = 0.01). A study by Hayashi et al.[25] on 1311 T2DM patients also found a significant negative correlation between ABI and CIMT. In another study by Criqui et al.[4] done on 6647 subjects (which included T2DM patients also), it was found that both lower ABI (<1.0) and higher ABI (>1.4) were associated with increased CIMT and hence incident CVD events and the results of our study were consistent with this study.

In our study, the limbs which showed mild PAD according to TBI (TBI: 0.5-0.7) had a mean CIMT of 0.99 cm, limbs with moderate PAD (TBI: 0.3-0.49) had a mean CIMT of 1.17 cm, those limbs which had severe PAD (TBI: <0.3) had a mean CIMT of 1.29 cm, while those limbs with normal TBI (>0.7) had an average CIMT of 1.15 cm. This shows a statistically significant correlation between TBI and CIMT, which means that, with decreasing TBI, the CIMT increased (p=0.001). In a study done by Spangeus et al.[21] on 742 T2DM patients (482 males and 260 females), it was found that TBI was negatively associated with CIMT (r = -0.18, p = 0.03), which shows that lower TBI is associated with higher CIMT and increased cardiovascular events. Our study results also showed similar findings.

Conclusion

The present study highlights the clinical utility of the ABI and TBI in detecting PAD among patients with T2DM. Our findings demonstrate that while ABI is a useful tool, it may underestimate the prevalence of PAD, particularly in patients with borderline or normal ABI values. In contrast, TBI shows higher sensitivity, suggesting it is a more reliable diagnostic tool in this population. Both ABI and TBI were significantly correlated with Carotid Intima Media Thickness (CIMT), an established marker of atherosclerosis and cardiovascular risk, reinforcing the link between lower extremity PAD and systemic vascular disease.

The study also found a significant association between poor glycaemic control, as indicated by elevated HbA1c levels, and the severity of PAD, emphasizing the importance of optimal blood sugar management in mitigating vascular complications in diabetic patients. Additionally, the moderate positive correlation between ABI and TBI values underscores their complementary roles in diagnosing PAD, especially in cases where ABI alone may not be sufficient.

Overall, this study underscores the need for comprehensive vascular assessment, including both ABI and TBI, in diabetic patients to ensure early detection and intervention for PAD. Moreover, these findings highlight the importance of integrating glycaemic control and vascular health monitoring in the management of diabetes to reduce the burden of cardiovascular complications.

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