Original Article

Ankle brachial index and its correlation with cardiovascular risk factors in pre-diabetes: Two-year cross-sectional study

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Abstract

Background: A state of impaired glucose tolerance is called prediabetes. The diagnosis of prediabetes is controversial, yet it still puts a person at risk for developing diabetes. The ankle-brachial index (ABI) is useful for identifying persons at risk for peripheral artery disease and for diagnosing the condition in those who have symptoms in their lower extremities and subclinical atherosclerosis. This study highlights ABI and its correlation with cardiovascular risk factors like lipid profile and anthropometric measurement including neck circumference in prediabetes so that primary care physicians may be able to diagnose early before advancing to diabetes. **Materials and Methods:** This cross-sectional study of 2 years duration from December 2020 to September 2022 was conducted in the Department of Medicine, at a tertiary care teaching hospital situated in a rural area. Patients with pre-diabetes were enrolled and Ankle Brachial Index was calculated. The correlation of ABI with anthropometric measures and lipid profile was assessed. **Results:** On calculating ABI by manual method 21% which is 42 out of 200 had low ABI (<0.9). On the other hand, on calculating ABI by probe method low range of ABI was found to be 37% which is 74 patients out of 200. There was a significant correlation between ABI and body mass index and lipid profile. The diagnostic performance of ABI < 0.9 had 56.8% sensitivity and 100.0% specificity. **Conclusion:** ABI can be used as a noninvasive and cost-effective modality for assessing subclinical atherosclerosis in patients with prediabetes and thus prevent its morbid complications even assessed at the primary care physician level.

Keywords: Ankle brachial index, BMI, lipid profile, neck circumference, pre-diabetes, subclinical atherosclerosis, waist hip ratio

Introduction

Diabetes is a chronic disease caused by either inadequate pancreatic insulin production or ineffective systemic insulin use. The insulin hormone regulates blood sugar levels.

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The pace at which people progress from prediabetes to diabetes varies depending on the demographic and the definition of prediabetes.[1,2] The diagnosis of prediabetes is controversial; yet, it still puts a person at risk for developing diabetes. The World Health Organization (WHO) uses two specific parameters to define prediabetes as a state of impaired blood sugar level. Impaired glucose tolerance (IGT) is defined as 2 hours after consuming 75 grams of glucose at 7.8–11.0 mmol/L (140–200 mg/dL), whereas impaired fasting glucose (IFG) is defined as fasting plasma glucose (FPG) of

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6.1–6.9 mmol/L (110 to 125 mg/dL) (OGTT).[3] According to American Diabetes Association (ADA), on the other hand, lower cut-off values for IFG were 100–125 mg/dL, and for IGT, it was 140-200 mg/dL. Additional hemoglobin A1c (HbA1c)-based criteria of a level of 5.7% to 6.4% for the categorization of prediabetes were also considered in ADA.[4] There is little correlation between HbA1c, IFG, and IGT, according to several research.[5-8]

It is unknown whether prediabetes itself or the onset of diabetes is to blame for the greater risk of developing macrovascular disease that has been linked to the condition.[9,10] Even while cross-sectional studies have indicated a higher frequency of coronary heart disease in those with prediabetes, this correlation may be complicated by the same risk factors for both conditions.[11,12]

The ankle-brachial index (ABI) is useful for identifying persons at risk for peripheral artery disease and for diagnosing the condition in those who have symptoms in their lower extremities and subclinical atherosclerosis. The ABI also predicts the risk of cerebrovascular events, cardiovascular events, and even morbidity from any cause. Few tests offer such high diagnostic precision and prognostic data at such little cost and risk.[13]

The first-line test for both diagnosing and screening peripheral artery disease is the ABI.[14,15] In comparison to angiography, the gold standard, it is less costly, less intrusive, and has a higher specificity (95% to 96%) and sensitivity (79% to 95%).[16,17] It is simple to measure in the office, and every healthcare professional who treats patients at risk for cardiovascular disease may receive the training necessary to measure its proficiency.[18,19]

Low ABI has been linked to morbidity and cardiovascular outcomes in prediabetic individuals but less is known about its relationship to other problems.[20] The risk of both high and low ABI values has also been explored in certain research, but nothing has been said about the relationship between problems and the severity of arterial impairment (obstruction or pathological constriction), particularly in the case of microvascular complications.[21,22] But for those with pre-diabetes or diabetes, primary prevention is crucial since a first cardiovascular event is linked to higher morbidity and death in this population than in the general population without diabetes. Additionally, prior studies in people with asymptomatic peripheral vascular disease included patients with previous cardiovascular events.[23,24] Therefore, in this study, we have evaluated the correlation of categorized ABI with cardiovascular risk factors like anthropometric measures and lipid profiles in patients with prediabetes even at the primary care physician level.

Materials and Methods

Setting

This cross-sectional study was conducted in the Department of Medicine, at a tertiary care teaching hospital situated in a rural area after approval from the institute's ethical committee [DMIMS (DU)/IEC/2022/1227]. The study duration was from December 2020 to September 2022.

The study's criteria were based on the WHO Criteria for Diagnosis of Prediabetes, which specified that the HbA1c level should be between 5.7 and 6.4% and the fasting blood glucose level should be between 110 mg/dL and 125 mg/dL (IFG) or/and the two-hour plasma glucose level after a 75-g OGTT should be between 140 and 199 mg/dL. Patients with bilateral lower limb filariasis, lower limb cellulitis, lower limb malignancy, lower limb amputation, and patients who refused to provide permission were excluded from the research.

The sample size was calculated based on a formula with an intended margin of error which is n = (Z alpha/2 square X P (1 - P))/d square, where Z alpha/2 is the level of significance at 5% =1.96 P = Prevalence of prediabetes = 14%.[25] The minimum sample size required was 184 patients. We took a sample size of 200 patients.

Detailed history and examination of the patients were undertaken. Family history and previous history of diabetes, history of smoking and alcohol intake, and medication history were taken. Assessment of pre-existing comorbidities in a patient if any will be enquired by history of hypertension, cancer, chronic kidney disease, and chronic liver disease. Measurement of the ABI was done in patients while they were lying flat, with their heads and heels properly supported, that is, not protruding over the end of the examination table, and after 5-10 minutes of rest. For at least two hours before the assessment, the patient was instructed to abstain from smoking, strenuous activity, and alcohol use. The manual blood pressure readings were taken on each patient by a single observer. Two systolic and two diastolic auscultatory readings at the right posterior tibial artery, and finally two systolic and two diastolic auscultatory readings in the right brachial artery were obtained. An 8 MHz portable Aloka Prosound Alpha -7 (20259721), Bangalore, India, was utilized by the observer for the Doppler measurements, and a conventional mercury sphygmomanometer was employed for the auscultatory measurements. The bladder sizes of the cuffs used for the brachial and posterior tibial BP measures were 12 cm by 22 cm and 15 cm by 31 cm, respectively. For the Doppler measurement, an 8 MHz Doppler probe was employed. The sensor was covered in machine Doppler gel. The probe was positioned at a 45° to 60°angle to the skin's surface in the vicinity of the pulse after the Doppler device had been turned on. Once the clear signal was picked up, the probe began to move. The cuff was then slowly deflated to identify the pressure level at which the flow signal reappeared after being gradually inflated up to 20 mmHg above the level of disappearance. The highest inflation was measured at 300 mmHg. The maximum amplitude of the waveform on the Doppler machine's panel indicates that the systolic pressure was measured in both lower limbs. The placement of the tubing-equipped cuff was avoided since it could interfere with how the probe is positioned. ABI was computed by dividing the average systolic blood pressure of the index arm by that of the index ankle artery. ABI of 0.9 or less and an ABI of 1.4 or more are potentially suggestive of peripheral arterial disease (PAD) and incompressible arteries, respectively, in accordance with current guidelines.

Since the positioning of the tubing-equipped cuff may interfere with how the probe is positioned, it was avoided. The average systolic blood pressure in the index arm was divided by that in the index ankle artery to get the ABI. In agreement with current recommendations, we saw an ABI of 0.9 or less and an ABI of 1.4 or greater, respectively, as possibly indicative of PAD and incompressible arteries.

Using a digital weighing scale, the weight was calculated. The study subject was told to remove their shoes and stand in the middle of the scale with their hands at their sides, feet slightly apart, and their heads straight ahead. A portable stadiometer with an adjustable headpiece and a fixed vertical backboard was used to measure standing height. Waist circumference was measured using a non-stretchable tape; the subject's waist was measured to the nearest 0.1 cm at the midway between the tip of the iliac crest and the final costal margin in the back and the umbilicus in the front at the conclusion of a typical expiration. The patient was standing straight and relaxed. According to NCEP ATP III, the average waist circumference for males was 0.90 while for women it was >0.85.[26] Hip circumference was measured at t the participant's highest ischial tuberosity circumference and the participant's hip circumference was measured with a measuring tape and recorded in centimeters, to the closest 0.1 cm. As per WHO, the cut-off for WHR for men and women was >0.90 in men and >0.85 in women. NC was measured to the nearest 0.1 centimeters just below the laryngeal prominence (Adam's apple) in both sexes.[15] The body mass index (BMI) or Quetelet index was calculated as body weight in kg divided by height in meter square (kg/m^2). Asia Pacific criteria-based BMI was used.[27]

Fasting blood glucose levels between 110 to 125 mg/dL and an oral glucose tolerance test showing blood glucose levels between 140 to 199 mg/dL was diagnosed as prediabetes according to WHO. Flow chart of the study has been highlighted in Figure 1.

Statistical analysis

The Chi-square test was used to determine the relationships, and the test of proportion was used to compare the different proportions and get the Standard Normal Deviate (Z). The means of the two groups were compared using the *t*-test. To determine the risk variables, the odds ratio (OR) was used. Non-parametric tests (Spearman Correlation) were used to explore the correlation between ABI and BMI, neck circumference, and waist-hip ratio as at least one of the variables was not normally distributed. Thus, non-parametric tests (Wilcoxon-Mann-Whitney U Test) were used to make group comparisons. Cohen's Kappa test was employed since there was significant agreement between the two approaches McNemar's test was used to assess the difference in ABI Category. The final analysis was performed using the Statistical Package for Social Sciences (SPSS) software, manufactured by IBM, Chicago, USA, ver 21.0. Data entry was completed in a Microsoft Excel spreadsheet.

Result

Out of 200 patients with prediabetes, 74 had ABI <0.9, 126 had 0.9–1.4 by probe method; while 42 had <0.9 and 158 had 0.9-1.4 by manual method. 52 (70.3%) male prediabetics had ABI <0.9 by probe method and 30 (71.4%) had ABI <0.9 by manual method. All other baseline characteristics are shown in Table 1.

Out of 200 patients with prediabetes, 42 (21%) patients out of 200 had low ABI by manual method and the remaining 158 (79%) had ABI in the normal range. Although (34%) patients had low ABI by probe method and remaining 126 (63%) had normal ABI as shown in Figure 2.

There was no significant difference between the groups in terms of Neck Circumference (W = 5349.000, $P = 0.081$) (W = 3490.000, $P = 0.605$) as shown in Figure 3.

There was a significant difference between the two groups in terms of BMI (Kg/m²) (W = 7054.000, $P \leq 0.001$) (W = 5507.000, $P \leq 0.001$), with the median BMI (Kg/m²) being highest in the ABI Category (Probe and Manual) <0.9 group as shown in Figure 4. There was no significant difference between the groups in terms of Waist Hip Ratio (W = 5339.500, $P = 0.086$) (W = 3189.500, $P = 0.700$) as shown in Figure 5. There was a moderate negative correlation between Total Cholesterol (mg/dL) and ABI (Probe and Manual), and this correlation was statistically significant (rho

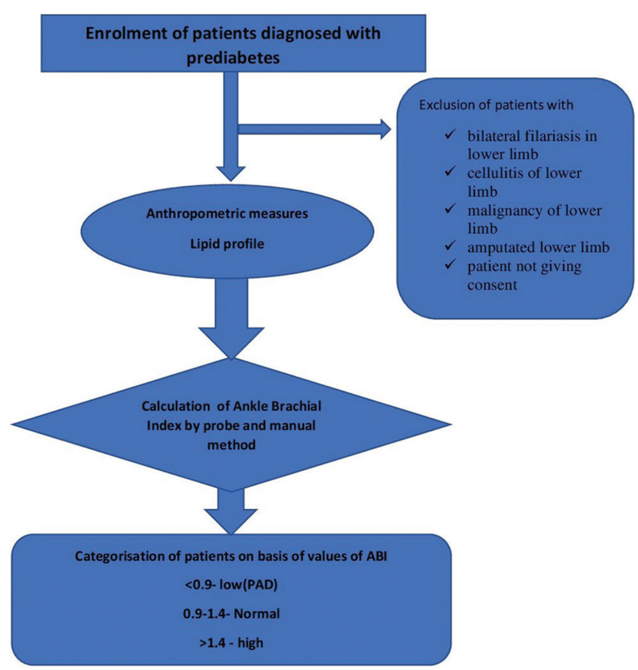

Figure 1: Flow chart of the study

Table 1: Base line characteristics of the patients

Parameters	ABI Category (Probe)		ABI Category (Manual)		*P*
	<0.9 (*n*=74)	0.9-1.4 (*n*=126)	<0.9 (*n*=42)	0.9-1.4 (*n*=158)	
Age (Years)***					<0.001[1]
18-40 Years	4 (5.4%)	18 (14.3%)	3 (7.1%)	19 (12.0%)	
40-60 Years	22 (29.7%)	76 (60.3%)	10 (23.8%)	88 (55.7%)	
>60 Years	48 (64.9%)	32 (25.4%)	29 (69.0%)	51 (32.3%)	
Gender					0.203[2]
Male	52 (70.3%)	74 (58.7%)	30 (71.4%)	96 (60.8%)	
Female	22 (29.7%)	52 (41.3%)	12 (28.6%)	62 (39.2%)	
Waist Circumference	89.36±10.24	89.63±8.55	88.86±9.40	89.71±9.15	0.371[1]
Neck Circumference	32.88±2.16	32.20±3.34	32.66±1.89	32.40±3.20	0.605[1]
BMI (Kg/m^2)***	25.28±2.48	23.53±1.57	25.65±1.81	23.79±2.03	<0.001[1]
Waist Hip Ratio	0.97±0.07	2.33±10.88	0.96±0.07	2.06±9.72	0.700[1]
ABI (Manual)	0.89±0.10	0.99±0.03	0.81±0.04	0.99±0.03	<0.001[1]
ABI (Probe)***	0.81±0.04	0.99±0.04	0.81±0.04	0.95±0.08	<0.001[1]

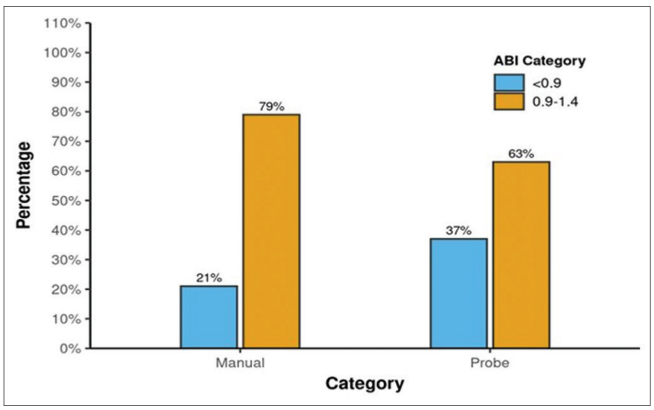

Figure 2: Bar graph of Distribution of ABI Category (Probe and Manual) in the percentage of total patients

= -0.59, $P \leq 0.001$) (rho = -0.42, $P \leq 0.001$) as shown in Figure 6. For every 1 unit increase in Total Cholesterol (mg/dL), the ABI (Probe) decreases by 0.00 units. Conversely, for every 1 unit increase in ABI (Probe), the total Cholesterol (mg/dL) decreases by 344.94 units by probe method and 285.14 units by manual method.

There was a significant difference between the 2 groups in terms of LDL (mg/dL) (W = 6098.000, $P \leq 0.001$) (t = 2.736, P = 0.008), with the median LDL (mg/dL) being the highest in the ABI Category (Probe and Manual) <0.9 group as shown in Figure 7. There was a moderate positive correlation between HDL (mg/dL) and ABI (Manual), and this correlation was statistically significant (rho = 0.43, $P \leq 0.001$) (rho = 0.66, $P \leq 0.001$). For every 1 unit increase in HDL (mg/dL), the ABI (Manual) increases by 0.00 units. Conversely, for every 1 unit increase in ABI (Manual), the HDL (mg/dL) increases by 93.33 units by Probe. There was a strong positive correlation between HDL (mg/dL) and ABI (Probe), and this correlation was statistically significant. For every 1 unit increase in HDL (mg/dL), the ABI (Probe) increases by 0.00 units. Conversely, for every 1 unit increase in ABI (Probe), the HDL (mg/dL) increases by 123.13 units as shown in Figure 8.

@@@@@@There was a strong negative correlation between Triglycerides (mg/dL) and ABI (Probe), and this correlation was statistically significant (rho = -0.67, $P \leq 0.001$). For every 1 unit increase in Triglycerides (mg/dL), the ABI (Probe) decreases by 0.00 units. Conversely, for every 1 unit increase in ABI (Probe), the Triglycerides (mg/dL) decrease by 402.33 units. There was a moderate negative correlation between Triglycerides (mg/dL) and ABI (Manual), and this correlation was statistically significant (rho = -0.44, $P \leq 0.001$). For every 1 unit increase in Triglycerides (mg/dL), the ABI (Manual) decreases by 0.00 units. Conversely, for every 1 unit increase in ABI (Manual), the Triglycerides (mg/dL) decrease by 310.39 units as shown in Figure 9.

There was substantial agreement between the two methods, and this agreement was statistically significant (Cohen's Kappa = 0.623, $P \leq 0.001$). The diagnostic performance of the ABI Category in predicting the ABI Category (Probe) <0.9 showed 56.8% Sensitivity, 100.0% Specificity, 100.0% PPV, and 79.7% NPV with a Diagnostic Accuracy of 84.0%. The disagreements observed between the two methods was that 32 (16.0%) cases classified as <0.9 by ABI Category (Probe) were classified as 0.9-1.4 by ABI Category (Manual). The overall difference in ABI Category was statistically significant (McNemar's test: $\chi 2$ = 32.000, $P \leq 0.001$) as shown in Table 2.

Discussion

In this study, there was a definite correlation of categorized ABI with cardiovascular risk factors like lipid profile and anthropometric measurement including neck circumference in patients with pre-diabetes. ABI is an inexpensive test that should be used as a diagnostic and prognostic tool in prediabetic patients so that adequate intervention can be planned at an early stage of the disease process even at the primary care physician level. When we assessed the ABI category probe and the ABI category manual we found the majority of participants with category 0.9-1.4 (normal) as our patients were pre-diabetes and not

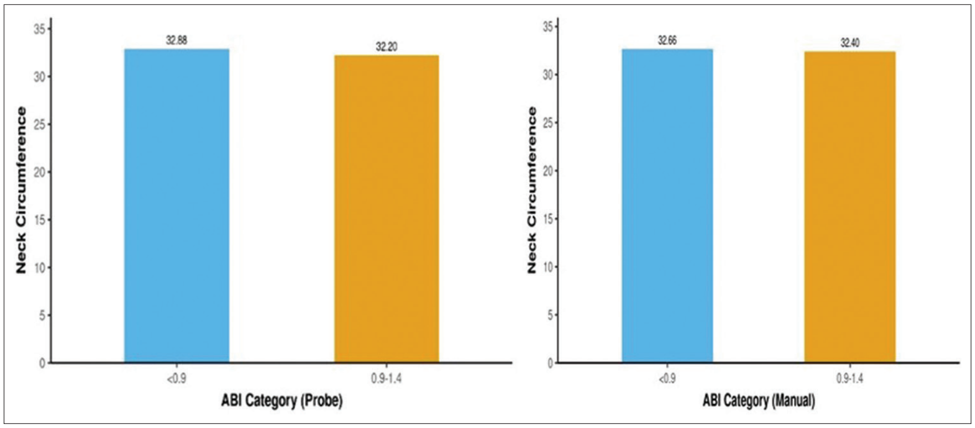

Figure 3: Bar graph of Correlation between ABI Category (Probe and manual) and Neck Circumference

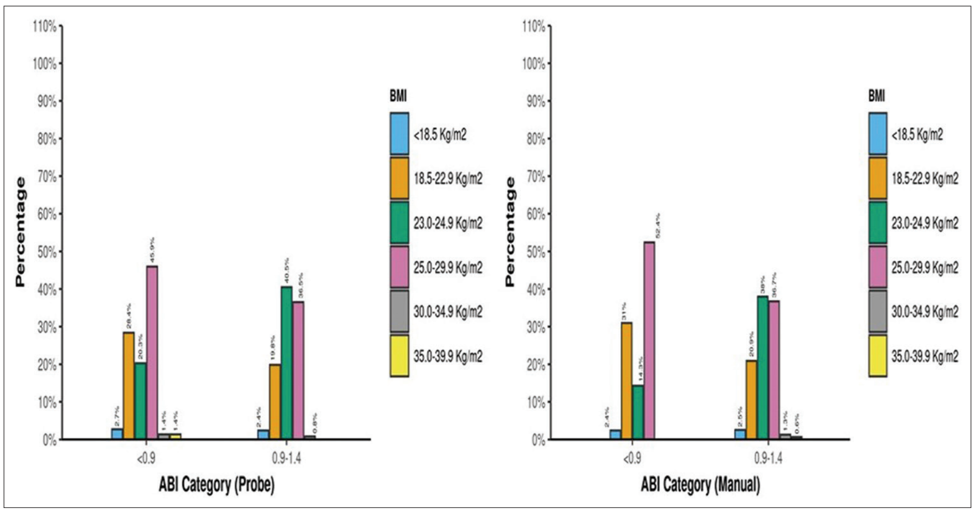

Figure 4: Bar graph of Correlation between ABI Category (Probe and manual) and BMI

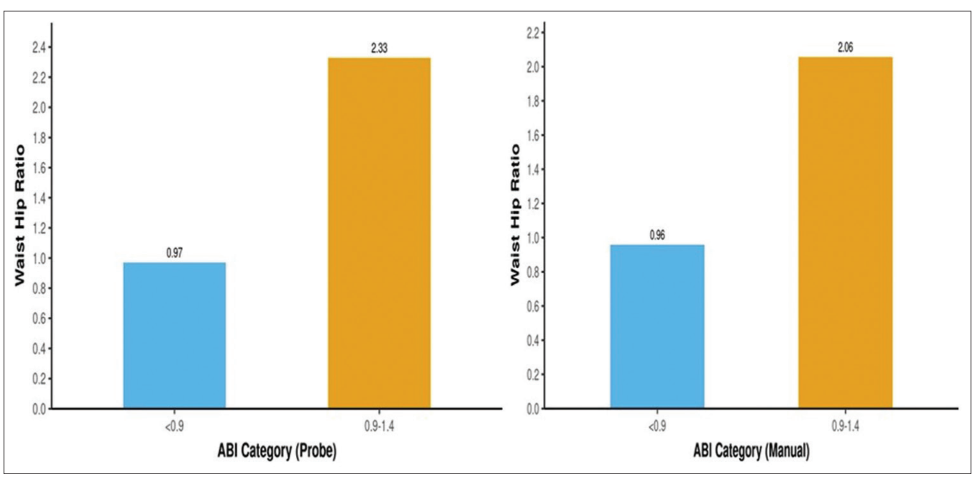

Figure 5: Bar graph of Correlation between ABI Category (Probe and manual) and Waist Hip Ratio

established as diabetes. As per the literature, a normal ABI reading is 1.0 (with a range of 0.9 to 1.4), which means that blood flow in the lower limbs and upper limbs is normal. If your lower limb blood pressure is determined to be higher, lower, or more or less than that of your upper limb, PAD or preclinical atherosclerosis is predicted. The ABI may be performed annually, if necessary, to detect illness before it worsens, and it is a straightforward test.[28] In a study by Nicolaï SP *et al*., the correlation between primary care and the vascular laboratory was determined to be 0.41 (95% confidence interval [CI] =0.22 to 0.59], showing a weak correlation beyond change.[29] Another study by Wikström J *et al*. concluded that the frequency of peripheral artery occlusive

Table 2: Diagnostic performance of ABI by manual and probe method

ABI Category		Probe			Cohen's Kappa	
		<0.9	**0.9-1.4**	**Total**	***k***	***P***
Manual	<0.9	42 (21.0%)	0 (0.0%)	42 (21.0%)	0.623	<0.001
	0.9-1.4	32 (16.0%)	126 (63.0%)	158 (79.0%)		
	Total	74 (37.0%)	126 (63.0%)	200 (100.0%)		
ABI Category		**Manual**			**McNemar's test**	
		<0.9	**0.9-1.4**	**Total**	χ^2	***P***
Probe	<0.9	42 (21.0%)	32 (16.0%)	74 (37.0%)	32.000	<0.001
	0.9-1.4	0 (0.0%)	126 (63.0%)	126 (63.0%)		
	Total	42 (21.0%)	158 (79.0%)	200 (100.0%)		

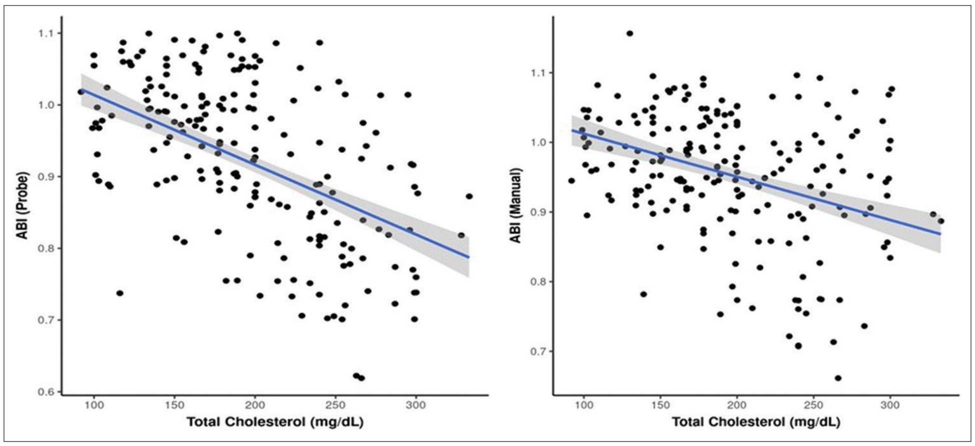

Figure 6: Scatter plot of correlation between total cholesterol (mg/dl) and ABI (Probe and Manual)

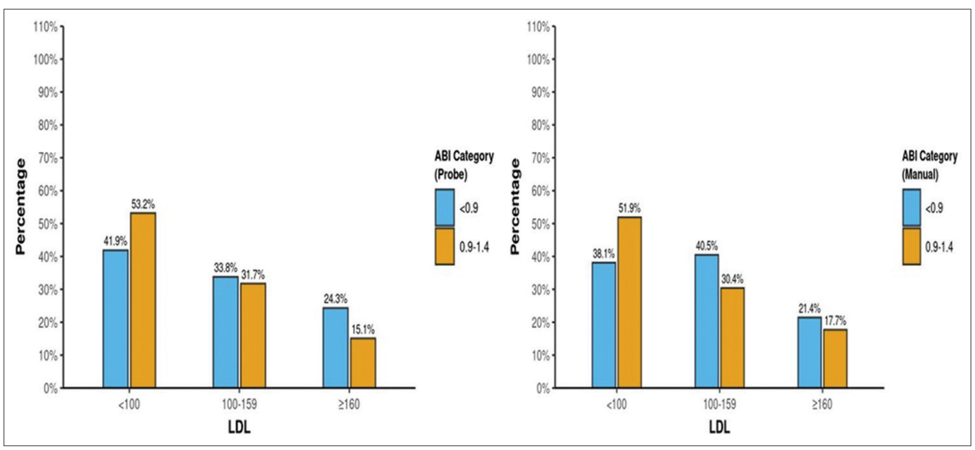

Figure 7: Bar graph of Correlation between ABI Category (Probe and manual) and LDL

disease in the overall senior population is underestimated by an ABI of 0.9.[30] Similar to our study, Li X *et al.* found that 93.1% of patients had a normal ABI (0.91-1.3), low (0.9) in 5.2% of patients, and high (>1.3) in 1.7% of patients.[31]

The present study did not show statistical significance for neck circumference. The mean Neck Circumference was 32.45 ± 2.97. There was no significant difference between the groups in terms of Neck Circumference. The mean values for scores 0.9-1.4 were higher in both categories. The correlation of ABI with neck circumference has never been studied and hence our study is the first literature to show the correlation of ABI with neck circumference.

On calculating BMI for these patients with Pre-Diabetes it was observed that out of 200, 80 (40%) patients were in the range of BMI 25.0 to 29.9 kg/m^2 which was in the majority. But there was a significant correlation between both categories for BMI. Mean BMI was higher in the score <0.9 group of both categories. Our results were similar to the study by Sridhar C *et al.*, as they found the highest mean values of BMI (26.8 ± 2.3).[32] The results of our investigation are at odds with the widely acknowledged fact

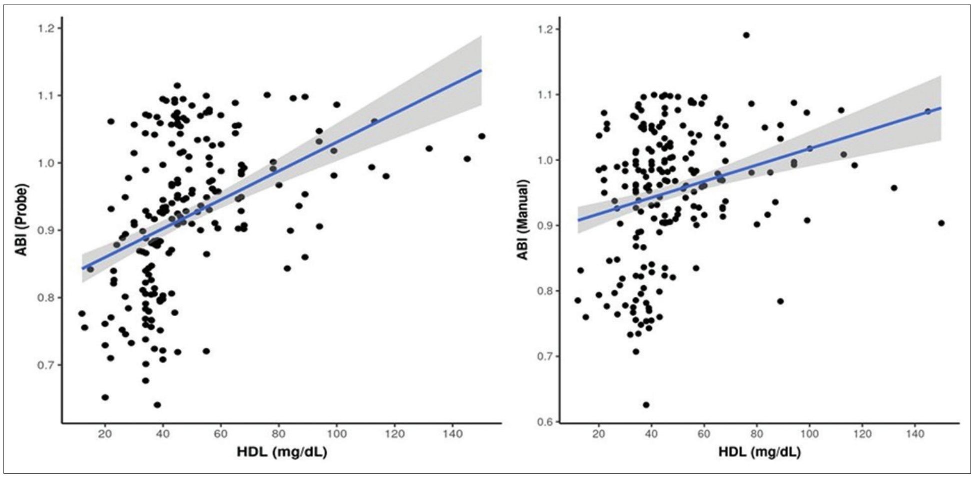

Figure 8: Scatterplot of correlation of HDL with ABI (Probe and Manual)

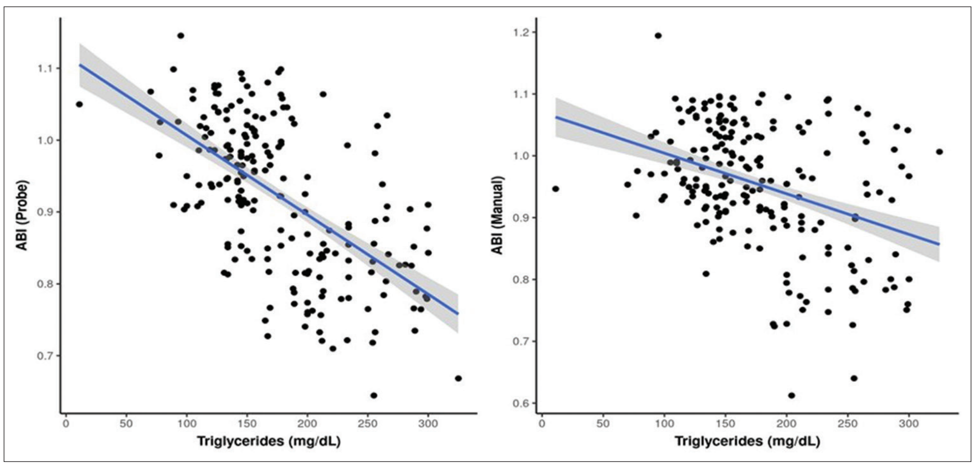

Figure 9: Scatterplot of correlation of Triglycerides with ABI (Probe and Manual)

that these risk variables are significantly associated, as shown by several studies.[33,34] The overall differences in means in several categories of ABI distribution were found to be significant for BMI for both sexes (*P* 0.001) in a study by Doza B *et al*., which is similar to our research.[35] In contrast to our study, Resnick HE *et al.* found that the mean BMI with low ABI was 0.9 (1.8 to 0.5), and for normal ABI was 0.2 (0.5 to 0.8).[36] In the present study, there was no significant difference in the hip-waist ratio. Another key element of metabolic syndrome is the waist-hip ratio, which reveals the patients' atherosclerotic load.

When we evaluated both categories for total cholesterol, we found statistical significance. Total cholesterol in the range of less than 200 mg/dl (normal) was found in 90 (45.5%) patients which was in the majority. We also observed that mean total cholesterol (mg/dL) was highest in the ABI Category (Manual): <0.9 group as well as ABI Category (probe): <0.9 group. Our results were in sync with another cross-sectional study where the TG/HDL ratios were 1.28 1.20 and 1.48 1.13 (*P* 0.0001) for those with ABI >0.9 and ABI 0.9, respectively, whereas the TC/HDL ratios were 3.96 1.09 and 4.32 1.15 (*P* 0.0001).[37] ABI 0.9 was a group that had greater total cholesterol (5.4 ± 1.3 mmol/L) according to research by Nussbaumerová *et al*. complementing our results.[38]

Similarly, 98 (49%) patients had LDL less than 100 mg/dl (normal) and the mean LDL (mg/dL) was 113.89 ± 51.72. We also found a significance of LDL and HDL similar to total cholesterol, that mean LDL (mg/dL) was highest in the ABI Category (Manual) <0.9 group as well as ABI Category (probe) <0.9 group and HDL being highest in the ABI Category (Probe) 0.9-1.4 group. Unlike our study, there was Weledji EP *et al*., a study which revealed no statistical significance, with *P* values of (0.498 for LDL and (0.899 for HDL).[39] In contrast to our study mean LDL for ABI <0.9 was 2.7 ± 1.3 and the mean HDL for ABI <0.9 was 1.1 ± 0.3 as observed in the study by Li Q *et al*.[40]

The mean Triglycerides was 177.30 ± 56.46 and 84 (42%) patients had HDL in the range of 40 to 60 and 76 (38%) patients had triglycerides more than 200 (high) and these all were the majority class. When we studied triglycerides for ABI and interestingly we found that there was a significant difference between the 2 groups in terms of triglycerides. We also observed that median triglyceride were highest in the

ABI Category (probe) with < 0.9 group and ABI category (manual) with 0.9 group. A study by Ix JH *et al.*, revealed that triglycerides were 116 (84-156) mg/dL in low ABI (< 0.9) group.[41]

Limitation

The extent of the findings may be constrained because this investigation only involved one center. Additionally, the study's conclusions were supported by data from a relatively smaller sample size. We have not considered risk factors like alcohol and smoking as these may be the confounding factor in our study, if we would have taken these factors in this study results may have been altered and better applicable. Another limitation of the current study is that the duration of risk factors was not taken into account while assessing the data.

Conclusion

Our study calculated ABI by two different methods (Probe and Manual) out of which the probe is found to be more sensitive than manual. ABI less than 0.9 has a strong correlation with cardiovascular risk factors. ABI can be considered a standard method for the prediction of subclinical atherosclerosis. The ABI is an inexpensive test that should be used as a diagnostic and prognostic tool in prediabetic patients so that adequate intervention can be planned at an early stage of the disease process even at the primary care physician level. Our study is the first study to correlate neck circumference with ABI.

Take home message

This is an inexpensive, simple, non-invasive test, thereby having greater utility in a developing country like India, and can help primary care physician prevent serious complications due to diabetes.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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