

# Study of the Efficacy of Automated Oscillometry in Evaluating Ankle-Brachial Index for the Assessment of Peripheral Arterial Disease in Diabetes Mellitus

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## Abstract

Peripheral arterial disease (PAD) is defined as a clinical disorder in which there is stenosis or occlusion in the aorta or arteries of the limbs. Type 2 diabetes is a strong risk factor for atherosclerotic diseases including cardiovascular as well as peripheral arteries. The risk of development of peripheral arterial disease increases three to four folds in patients with diabetes. Most diabetic amputations are due to peripheral arterial disease (PAD), peripheral neuropathy and infection. Ankle-brachial index is helpful in assessing the prognosis in the symptomatic as well as asymptomatic patients in contrast to the variability of pulse assessment and the physical examination. The present study included 50 patients with diabetes mellitus for more than ten years, irrespective of their symptoms. ABI was calculated by dividing the ankle systolic blood pressure by the brachial systolic blood pressure of the respective sides. The lower of the two ABI values for the legs was used to define ankle brachial index. Of 50 patients, 20 had signs of PAD among whom 11 (55.0%) had abnormal ABI and 9 (45.0%) had normal ABI. Out of 30 patients with no signs of PAD, 8 (26.7%) had abnormal ABI and 22 (73.3%) had normal ABI. Automated oscillometry method for evaluating ankle-brachial index for the assessment of peripheral arterial disease in diabetes mellitus had a sensitivity of 68.18%, a specificity of 85.71%, positive predictive value (PPV) of 78.95% and negative predictive value (NPV) of 77.42%. The Accuracy of the test was 78.0%. Thus, our study has proved that the oscillometric method of ABI is a very useful procedure for detecting PAD. By repeating the test the sensitivity and specificity may probably increase. The oscillometric method of performing ABI is a simple procedure, automated, easy to perform, negligible cost of the instrument, does not require training and can be performed as an outpatient procedure.

## Keywords

Ankle-Brachial Index, Diabetes mellitus, Peripheral arterial disease, Blood pressure, Atherosclerosis.

## Introduction

Peripheral arterial disease (PAD) is defined as a clinical disorder in which there is stenosis or occlusion in the aorta or arteries of the limbs (1,2).

As in patients with atherosclerosis of the coronary and cerebral vasculature, there is an increased risk of developing PAD in advanced stage, cigarette smokers and in persons with diabetes mellitus, hyperlipidemia, obesity, hypertension or hyperhomocysteinemia.

The primary site of involvement are the abdominal aorta and iliac arteries (30% of symptomatic patients), the femoral and popliteal arteries (80-90% of patients), and the more distal vessels including the tibial and

peroneal arteries (40-50% of patients).

It has been reported that more than half of the patients with PAD are asymptomatic or have atypical symptoms and one third have claudications and the remainder have severe form of disease.

The term diabetes mellitus describes a metabolic and vascular syndrome of multiple etiologies, characterized by chronic hyperglycemia leading to changes in both small blood vessels (microangiopathy) and large blood vessels (macroangiopathy).

Type 2 diabetes is a strong risk factor for atherosclerotic diseases including cardiovascular as well

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as peripheral arteries. The risk of development of peripheral arterial disease increases three to four folds in patients with diabetes. Eight percent (8%) of the diabetics would have PAD at the time of diagnosis of diabetes, which increases to 45% by 20 years of the duration of diabetes (3).

Majority of diabetic patients lack classic symptoms of PAD such as claudication because of distal pattern involvement. Most of the others are asymptomatic because of almost invariable association with peripheral neuropathy with blunted pain perception.

Most diabetic amputations are due to peripheral arterial disease (PAD), peripheral neuropathy and infection. The triad is the harbinger of the final pathologic events, gangrene and amputation.

The history and physical examination are crucial in evaluating the patient with peripheral arterial disease. The absence of pulses in an extremity is probably the most common physical finding. Palpation to detect the presence of abdominal and peripheral aneurysm should be performed. Risk factors, especially smoking, hypertension and diabetes should prompt a research for peripheral arterial disease.

The ankle brachial index is the ratio of the higher systolic blood pressure between the dorsalis pedis and the posterior tibial artery to the higher of the systolic blood pressure in the two brachial arteries. Vascular claudication does not occur without a drop in the ABI.

Ankle-brachial index is helpful in assessing the prognosis in the symptomatic as well as asymptomatic patients in contrast to the variability of pulse assessment and the physical examination.

Ankle-Brachial index is usually measured by using specialized equipment (hand held doppler) and a standard mercury sphygmomanometer.

Oscillometric (automated) determination of blood pressure is approved for blood pressure measurement and is commonly available, reliable and simple to use.

Oscillometer measures the magnitude of the pressure vacillation in the limb as the cuff is deflated from supra systolic pressure. The cuff is inflated to a pressure value above the expected systolic pressure. The small pulses detected by the pressure transducer connected to pneumatic cuff are pulses occurring proximally to the site of occlusion. With a step wise decrease in cuff pressure, there is a sudden increase in pulse amplitude or oscillations when the cuff pressure equals the blood systolic pressure. The pulse amplitude continues to increase until the cuff pressure approaches the mean

blood pressure. The pulse amplitude then decreases while the cuff pressure falls from mean to diastolic values. The pulse is uniform for sub diastolic pressures (4).

This method is very often used in the automatic device for the measurement of the blood pressure because of its excellent reliability. Oscillometric method of blood pressure monitoring when applied to brachial and ankle arteries can be used to determine ankle-brachial index(5).

The ABI helps to define the severity of the disease and a successful screening of the hemodynamically significant PAD. The office based assessment of the Peripheral Vascular Disease by ABI is limited by the need of specialized equipment (handheld doppler), its cost, the time required for performing the test and the skill of the performer.

A test that is automated, easy to perform and less reliant on specialized skills, may facilitate the performing of ABI in more number of people in less time, thus increasing the diagnosis of PAD in a susceptible population. The study has utilized an automated digital BP apparatus (oscillometric method) to measure ABI in diabetics and in detecting number of PAD cases.

## Material and Methods

The present study included 50 patients attending different wings of Acharya Shri Chander Hospital, Sidhra, Jammu including both indoor and outdoor patients. Patients with diabetes mellitus for more than ten years, irrespective of their symptoms were included for study purpose from november 2010 to october 2011.

### *Exclusion criteria:*

- Patients with a history of known diabetes mellitus < 10 years.
- Those patients who had severe limb ischemia.
- Those patients who were critically ill.

A detailed history of diabetes, hypertension, smoking, dyslipidemia, ischemic heart disease and claudication or rest pain in the lower limb was taken. Detailed systemic examination along with palpation for diminution or absence of dorsalis pedis and posterior tibial pulse in both the limbs was done. All the routine investigations Hb, TLC, DLC, FBS, RFT, routine urine examination and lipid profile was done. The diabetic status of the patients was assessed by testing fasting plasma glucose level at two occasions.

Patient was kept in supine position for 5 minutes. Systolic blood pressure was recorded starting with the right brachial, right ankle, left ankle and the left brachial

by using an OMRAN DIGITAL AUTOMATIC BLOOD PRESSURE MONITOR (Model-SEM 1).

ABI was calculated by dividing the ankle systolic blood pressure by the brachial systolic blood pressure of the respective sides. The lower of the two ABI values for the legs was used to define ankle brachial index.

*ABI Grading:*

0.90 or above	Normal
0.81-0.89	Mild disease
0.51-0.80	Moderate disease
0.31-0.50	Severe disease

All patients were then subjected to colour Doppler for evaluation of both the lower limbs to confirm the results (6). Those patients who had positive ABI and confirmed by doppler were taken as true positives and those who had a positive ABI and negative doppler were taken as false positive. Similarly those who show obstructive flow in colour doppler with normal ABI were considered false negatives, and true negatives had normal ABI and normal colour doppler

**Statistical Analysis**

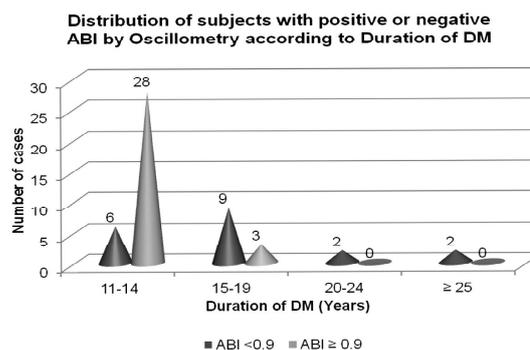
The statistical package for social sciences (SPSS) variation 17.0 was utilized to analyze the results. Parametric variables are presented as mean± standard deviation. Chi-Square test was used for analysis of non parametric data. P-values <0.05 were considered statistically significant. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy of Ankle-Brachial Index by oscillometry method against colour doppler test of lower limbs was calculated.

**Results**

In our study of 50 patients, 31 (62%) were males and 19 (38%) of patients were females. The age of patients ranged from 32-75 years with mean age of 59.32 years. Most of the patients were in age group of 50-59 years. (Table 1)

In our study, the duration of diabetes among the subjects taken ranged from 11 years to 32 years with mean duration of diabetes of 13.80. 68% of patients were having duration of diabetes between 11-14 years.

In our study of 50 patients, out of 34 patients with duration of diabetes 11-14 years; 6 had positive ABI and 28 had negative ABI. Out of 12 patients with duration of diabetes 15-19 years; 9 had positive ABI and 3 had negative ABI. All patients with duration of diabetes 20 and above in our study had positive ABI with Chi-square = 19.477 and p <0.001. Thus, it is evident that there is significant statistical difference in relation to duration of diabetes mellitus as with P value <0.001. (Figure 1)

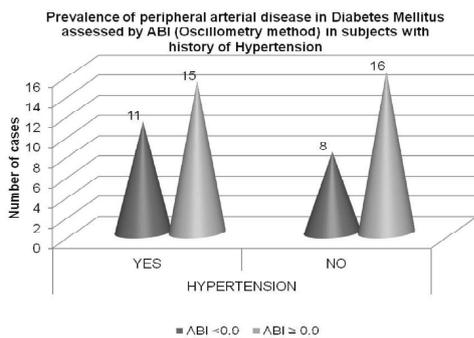


**Fig. 1: Distribution of subjects with positive or negative ABI by oscillometry in relation to duration of diabetes mellitus.**

**Table 1: Mean of various parameters in study sample.**

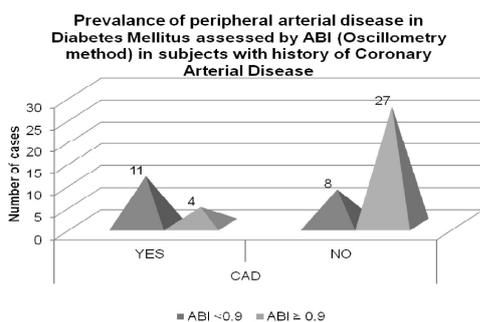
Variable	Mean	Standard deviation	Standard error mean
Age	59.32	8.615	1.218
Duration of Diabetes Mellitus	13.80	4.165	0.589
LDL	113.72	32.093	4.539
HDL	49.04	9.575	1.354
Triglycerides	146.34	48.414	6.847
Fasting Blood Sugar	148.42	56.241	7.953
Post Prandial Sugar	195.92	66.622	9.421
ABI by Oscillometry	0.970	0.128	0.018

In our study of 50 patients 26 were having hypertension among whom 11 (42.3%) had abnormal ABI and 15 (57.7%) had normal ABI. Out of 24 patients who were normotensive 8 (33.3%) had abnormal ABI and 16 (66.7%) had normal ABI. Chi- square = 19.477 and  $p < 0.001$ . 19 patients had positive ABI by oscillometry out of which only 11 (57.9%) had hypertension. Thus it is evident that there is no significant statistical difference between two groups as with P value 0.514. (Figure 2)



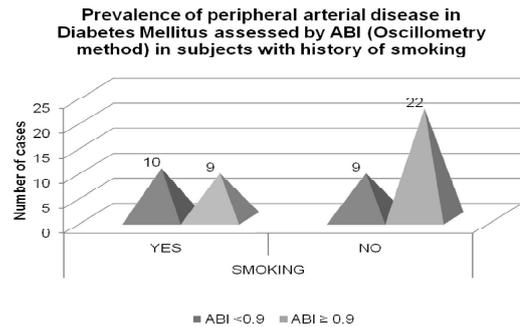
**Fig. 2:** Prevalence of peripheral arterial disease in diabetes mellitus assessed by ABI (oscillometry method) in subjects with history of hypertension.

In our study of 50 patients, 15 were having CAD among whom 11 (73.3%) had abnormal ABI and 4 (26.7%) had normal ABI. 35 patients had no history of CAD among whom 8 (22.9%) had abnormal ABI and 27 (77.1%) had normal ABI. Out of 19 patients with positive ABI by oscillometry 11 (57.9%) were having CAD with Chi-square = 19.477 and  $p < 0.001$ . Thus it is evident that there is a very significant statistical difference between the two groups as with P value 0.001. (Figure 3)



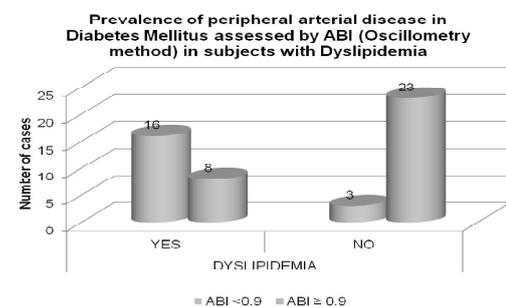
**Fig. 3:** Prevalence of peripheral arterial disease in diabetes mellitus assessed by ABI (oscillometry method) in subjects with history of coronary arterial disease.

In our study of 50 patients, 19 were smokers among whom 10 (52.6%) had abnormal ABI and 9 (47.4%) had normal ABI. Out of 31 non smokers 9 (29.0%) had abnormal ABI and 22 (71.0%) had normal ABI. Out of 19 patients with positive ABI by oscillometry 10 (52.6%) were smokers with Chi- square = 19.477;  $p < 0.001$ . Thus it is evident that there is no significant statistical difference between the two groups as with P value 0.095. (Figure 4)



**Fig. 4:** Prevalence of peripheral arterial disease in diabetes mellitus assessed by ABI (oscillometry method) in subjects with history of smoking. (Fig. 4)

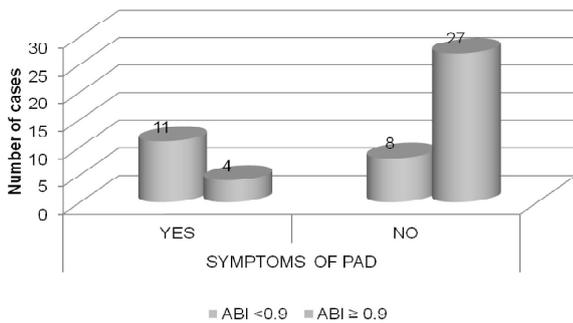
In our study of 50 patients, 24 were having dyslipidemia among whom 16 (66.7%) had abnormal ABI and 8 (33.3%) had normal ABI. Out of 26 patients with no dyslipidemia 3 (11.5%) had abnormal ABI and 23 (88.5%) had normal ABI. Out of 19 patients with positive ABI by oscillometry 16 (84.2%) were having dyslipidemia. With Chi-square = 16.099;  $p \text{ value} = < 0.001$ . Thus, it is evident that there is highly significant statistical difference between the two groups as with P value  $< 0.001$ . (Figure 5)



**Fig. 5:** Prevalence of peripheral arterial disease in diabetes mellitus assessed by ABI (oscillometry method) in subjects with dyslipidemia.

In our study of 50 patients 15 were having symptoms of PAD among whom 11 (73.3%) had abnormal ABI and 4 (26.7%) had normal ABI. Out of 35 patients with no symptoms of PAD 8 (22.9%) had abnormal ABI and 27 (77.1%) had normal ABI. Out of 19 patients with positive ABI by oscillometry 11 (57.9%) had symptoms of peripheral arterial disease. With Chi-square = 11.355; p value = 0.001. Thus it is evident that there is a very significant statistical difference between the two groups as with P value 0.001. (Figure 6)

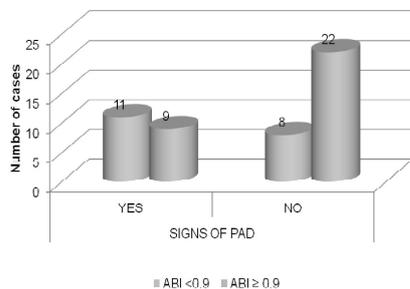
**Prevalence of peripheral arterial disease in Diabetes Mellitus assessed by ABI (Oscillometry method) in relation to Symptoms of PAD**



**Fig. 6: Prevalence of peripheral arterial disease in diabetes mellitus assessed by ABI (oscillometry method) in relation to symptoms of PAD.**

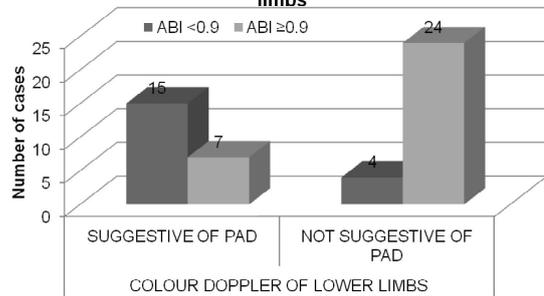
In our study of 50 patients, 20 had signs of PAD among whom 11 (55.0%) had abnormal ABI and 9 (45.0%) had normal ABI. Out of 30 patients with no signs of PAD 8 (26.7%) had abnormal ABI and 22 (73.3%) had normal ABI. Out of 19 patients with positive ABI by Oscillometry 11 (57.9%) had signs of peripheral arterial disease with Chi-square = 4.089; p value = 0.043. Thus it is evident that there is significant statistical difference between the two groups as with P value 0.043. (Figure 7)

**Prevalence of peripheral arterial disease in Diabetes Mellitus assessed by ABI (Oscillometry method) in relation to Signs of PAD**



**Fig. 7: Prevalence of peripheral arterial disease in diabetes mellitus assessed by ABI (oscillometry method) in relation to signs of PAD.**

**Confirmation of results obtained from ABI by Oscillometry method by Colour Doppler of lower limbs**



**Fig. 8: Confirmation of results obtained from ABI by oscillometry method against colour doppler of lower limbs.**

Out of 19 patients with positive ABI by oscillometry method, 15 patients had features suggestive of PAD in colour doppler examination of lower limbs and 4 patients had no features suggestive of PAD in colour doppler examination. Out of 31 patients with negative ABI by oscillometry 7 patients had features suggestive of PAD in colour doppler examination of lower limbs and 24 patients had no features suggestive of PAD in colour doppler examination. (Figure 8)

In comparison of ABI by oscillometry with gold standard colour doppler of lower limbs there were 15 True positives (that is having positive ABI by oscillometry and positive colour doppler examination of lower limbs) and 24 True negatives (that is having negative ABI by oscillometry and negative colour doppler examination of lower limbs).

There were 4 False positives (that is having positive ABI by oscillometry and negative colour doppler examination of lower limbs) and 7 False negative (that is negative ABI by oscillometry and positive colour doppler examination of lower limbs).

Automated oscillometry method for evaluating Ankle Brachial Index for the assessment of peripheral arterial disease in diabetes mellitus had a sensitivity of 68.18%, a specificity of 85.71%, positive predictive value (PPV) of 78.95% and negative predictive value (NPV) of 77.42%. The accuracy of the test was 78.0%.

### Discussion

Atherosclerosis is a systemic process with variable expression in different vascular beds. Mortality is inversely related to the severity of PAD as assessed with the ankle brachial index (ABI).

The main aim of the study was to determine whether the oscillometric method used for the evaluation of ABI was good enough to be used in general practice by clinicians, to detect a large number of PAD cases. The ancillary objectives were to look at the importance of the risk factors and to correlate the signs and symptoms with PAD after ABI.

Among the number of tests that are available to detect PAD, ankle brachial pressure index (ABI) is the method of choice that can be used in outpatient situations. ABI measured using a handheld doppler of 5-10 Mhz and the routine blood pressure cuff where both brachial systolic pressure and ankle systolic pressure are measured is considered gold standard measurement.

It has a sensitivity of 89%, specificity of 99%, and positive predictive value of 90% and negative predictive value of 99% with an overall accuracy of 98%. ABI of <0.9 showing possibility of PAD, 0.5-0.8 being highly likely and <0.5 depicting multi segment disease (7).

Richart (2009) did a study on validation of automated oscillometric device for the measurement of the ABI against manual measurement. They concluded that automated ABI measurements by an oscillometric technique requires little observer training and significantly increases the reproducibility of ABI estimates compared with the manual approach (8).

There are also different opinions regarding the accuracy of the oscillometric device in measuring ankle brachial pressure. Ramanathan et al. 2002 and Hamel et al. 2010 concluded that automated oscillometric device cannot be recommended as a reliable alternative to access the ABI (9,10). However, Lee et al. 1996, Beckma et al. 2006, Kawamura et al. 2008, Premanath et al. 2010 have shown good results with the use of oscillometric device and have recommended it for ABI estimation in PAD (11-14).

Our study proves that with increasing duration of diabetes mellitus, the risk for atherosclerotic disease increases. As far as the risk factors are concerned, diabetics and smoking are the strongest risk factors, and other well known risk factors are advanced age, hypertension and dyslipidemia (15).

The confirmation of results obtained by ABI (automated oscillometric method) was done by using colour doppler of lower limbs because of the fact that this method is a precise method for defining obstruction and stenosis, as it has a sensitivity of 95% for occlusion and 92% for stenosis and specificity of 99% and 97% for occlusion and stenosis respectively (16).

Premanath and Raghunath (2010) did a study on 200 diabetic patients to assess ABI by oscillometry and their results showed a sensitivity of 70% and specificity of 75% for ABI by oscillometry against colour doppler of lower limbs. They concluded that oscillometric method of performing ABI is a simple procedure, easy to perform and does not require training and can be performed as an outpatient procedure not only by doctors, but also by the paramedical staff to detect more PAD cases (14). Our study had a sensitivity of 68.18%, specificity of 85.71%, positive predictive value of (PPV) of 78.95% and negative predictive value of (NPV) 77.42% for automated oscillometry ABI measurements against colour doppler of lower limbs. The accuracy of the test was 78.0%. The results obtained were similar to the results shown in the study done by Premanath and Raghunath (14).

The oscillometric method for eliciting ABI has its limitations. The apparatus has to be a standard one. Individual blood pressure on DP and PT arteries cannot be performed as it is performed by the doppler; hence the systolic BP elicited in the lower limbs is an average of pressures in each artery. Obstruction in a particular vessel cannot be distinguished, as the individual ABI for that vessel cannot be performed. Similarly, ABI can be normal if the obstruction is higher.

In spite of these limitations, this method scores over the standard method by its simplicity, no bias as far as reading are concerned, as they are automatic, negligible cost of the instrument (Rs 3000 aprox.), ease of performance and the rapidity with which it can be done (6 to 8 minutes) not only by the doctors, but even the paramedical staff. Confirmation has to be completed with colour doppler in either of the methods. When that is so, the oscillometric method can be used on a daily basis as an outpatient procedure, to detect a large number of PAD cases.

The office based assessment of ABI is limited by the need of specialized equipment (handheld doppler), it's cost (15-20 thousand), the time required for performing the test (at least 20 minutes) and the skill of the performer.

## Conclusion

Our study has thus proved that the oscillometric method of ABI is a very useful procedure for detecting PAD. By repeating the test the sensitivity and specificity may probably increase. The oscillometric method of performing ABI is a simple procedure, automated, easy to perform, negligible cost of the instrument (Rs 3000), does not require training and can be performed as an outpatient procedure.

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