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Research Article

Effectiveness of Pulse Oximetry and Ankle Brachial Index in Detecting Peripheral Arterial Disease in Diabetic Foot Ulcer Patients

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Abstract: ***Background***: Peripheral arterial disease (PAD) leads to significant morbidity and mortality in Diabetic population due to the development of "Diabetic Foot Syndrome". Peripheral Arterial Disease (PAD) is underdiagnosed, undertreated, poorly understood and much more common than thought. Despite its high morbidity and mortality, PAD remains underdiagnosed and undertreated. The ideal screening test for PAD should be inexpensive, non-invasive, accurate, easily administered and universally acceptable. ***Aims and Objective***: To evaluate the effectiveness of Pulse Oximetry and Ankle Brachial Pressure Index (ABPI) in detecting Peripheral Arterial Disease (PAD) among patients with Diabetic Foot Ulcers. ***Materials and method***: A hospital-based cross-sectional study was conducted in the Department of Surgery, Regional Institute of Medical Sciences (RIMS), Imphal, over a period of two years (December 2020 – November 2022). Patients with diabetic foot ulcers were assessed using both Pulse Oximetry and ABPI. Data were analysed using SPSS version 26.0 (IBM Inc.), with a p-value < 0.05 considered statistically significant. ***Results***: Pulse Oximetry demonstrated an accuracy of 92.87%, with sensitivity of 88.88%, specificity of 96.87%, positive predictive value (PPV) of 94.11%, and negative predictive value (NPV) of 93.93%. ABPI showed an accuracy of 91.31%, sensitivity of 88.88%, specificity of 93.75%, PPV of 88.88%, and NPV of 93.75%. ***Conclusion***: Both Pulse Oximetry and ABPI are effective, non-invasive screening tools for diagnosing PAD in diabetic foot ulcer patients. Pulse Oximetry, with its high specificity and ease of use, may serve as a valuable point-of-care diagnostic method, particularly in primary and resource-limited settings. Early identification and intervention can significantly reduce the risk of limb-threatening complications.

Keywords: Peripheral Arterial Disease (PAD), Diabetic Foot Ulcer, Pulse Oximetry, Ankle Brachial Pressure Index (ABPI).

INTRODUCTION

Type 2 Diabetes Mellitus is one of the important risk factors for atherosclerotic Peripheral Arterial Disease (PAD).[1] Peripheral arterial disease leads to significant morbidity and mortality in Diabetic population due to the development of "Diabetic Foot Syndrome" and it is one of the important contributors for foot ulcers and amputations in Diabetics. [2-5]

Peripheral Arterial Disease is an expression of atherosclerosis which compromises with the blood circulation of the lower limbs. The prevalence of Peripheral Vascular Disease (PVD) has been difficult to estimate and is around 13-45 % in various studies.[6] Based on long-term surveillance from the Framingham Study, impaired glucose tolerance and diabetes are well-established, independent risk factors for symptomatic PAD, increasing the risk approximately two- to threefold. Although Framingham did not report the exact proportion of diabetics among symptomatic PAD patients, these findings emphasize that diabetes significantly contributes to PAD risk—particularly in individuals who may still be asymptomatic and undiagnosed. [7]

Peripheral Arterial Disease is poorly understood, underdiagnosed, undertreated and much more common than thought. Approximately 12% of adult population has Peripheral Arterial Disease (PAD) and the prevalence is equal in men and women. [8]

The diagnosis of PAD should not be ignored for 2 important reasons. Firstly, patients with PAD may experience many problems, such as claudication, ischemic rest pain, ischemic ulcerations, repeated hospitalizations, revascularizations and limb loss. These lead to a poor quality of life and high, smaller calf muscle area and greater calf muscle fat than age-matched groups of patients without PAD. Secondly, patients with Peripheral Arterial Disease have a greater probability of experiencing a myocardial infarction (MI), stroke and cardiovascular death and have a higher rate of all-cause deaths compared with patients without PAD. Diagnosing Peripheral Arterial Disease (PAD) early is very crucial because it not only reduces the functional disability and limb loss of patient but also places a substantial economic burden on the health care system of the country.

Currently recommended are several non-invasive tests including pulse palpation, ankle brachial pressure index (ABPI), pulse oximetry, color-doppler ultrasonography, arteriography, computed tomographic angiography (CTA) and magnetic resonance angiography (MRA).[9] Till date, many studies have already been conducted to assess the usefulness of various tools to diagnose PAD before the patient presents with the disease complication. The ideal screening test for Peripheral Vascular Disease should be inexpensive, non-invasive, accurate, easily administered and universally acceptable. The Ankle-Brachial Pressure Index (ABPI) is measured using standard size sphygmomanometer cuffs. The detailed methodology is discussed later. A cheaper and more commonly available tool that has been studied for its usefulness in detecting Peripheral Vascular Disease is the finger pulse oximeter probe. The finger pulse oximeter uses spectrophotometry with optical plethysmography and has sensitivity of more than 80% and specificity of 90% in detecting Peripheral Arterial Disease.[10] It is cheap and simple tool which can be used at the grass root level such as Primary Health Centres and Sub-Centres without any special training by medical as well as paramedical personnel alike.

There are not many studies which have tested the usefulness of pulse oximeter as an individual tool in detecting peripheral arterial disease in diabetic individuals. This justifies the need for my study which aims to compare pulse oximeter with Ankle Brachial Pressure Index and tests its power as an independent tool in detecting peripheral arterial disease.

AIMS AND OBJECTIVE:

To determine sensitivity, specificity, positive predictive value and negative predictive of Pulse oximetry and Ankle-Brachial Index in detecting Peripheral Arterial Disease in Diabetic Foot Ulcer patients.

MATERIALS AND METHODS

This Cross-sectional study was conducted in the Department of General Surgery, Regional Institute of Medical Sciences, Imphal, Manipur for a period of 2 years from January 2021 to November 2022. The study was carried out after obtaining approval from the Research Ethics Board, Regional Institute of Medical Sciences, Imphal. Strict confidentiality and privacy were maintained. All patients, older than 18 years diagnosed with diabetic foot ulcer according to the World Health Organization definition attending department of Surgery, both admitted and treated on OPD basis were included in the study. Patients with history of any co-morbidity like hyper-coagulable states, congestive heart failure, suspected arteritis or collagen vascular diseases, extremely sick requiring care in intensive care unit (ICU), Pre-diagnosed with Peripheral Artery Disease and unwilling to participate and follow study protocol were excluded from the study.

SAMPLE SIZE:

Using the formula (As used in a study conducted by Kumar MS et al) [9]

$$n = \frac{4\,[Sensitivity\,(100 - Sensitivity)]}{Precision2}$$

$n = 26.5$

Where

n = PAD patients required

Sensitivity = 98.31 % (Sensitivity of Pulse oximeter as concluded in study conducted by Deep HS et al) 6

Precision = 5 %

Now, that the prevalence of PAD in patients of type 2 Diabetes mellitus with foot infection is 72 % as concluded in study by Agarwal S et al. 7 So, 27 is 72% of "X"

Therefore, the sample size "X" is calculated as

X = 27/72 x 100 => X= 38

Applying a non-response rate of 10%, the final number of Diabetic patients required for the study is calculated as 38 + 4 = 42.

Therefore, 50 patients were included in the study.

The outcome variable included independent variables like demographic profile, duration of diabetes, complications, symptoms, co-morbidities, pulse characteristics and dependent variables like Spo2 measures, ABPI and Duplex Ultrasonography. A thorough medical history and the clinical examination was done as per the proforma for each patient.

The finger pulse oximeter readings were noted from the right and left index finger of the patients in supine position. This was immediately followed by recording the percentage of oxygen saturation readings in the right great toe and the left great toe. The pulse oximeter readings were recorded again in both the great toes after elevating one by one in turn to a height of twelve inches off the examination table with patient supine (12 inches from heel to horizontal plane of examination table). After recording the six pulse oximeter readings, measurement of the ankle-brachial index was done in all the four limbs. Brachial and ankle pressure were measured by USG doppler. The pressures for both dorsalis pedis artery and posterior tibial artery were noted. The higher pressure of the two arteries at the ankle was taken as the Ankle pressure for a given leg. The Ankle Brachial Index value was calculated for each leg by taking the higher pressure of the two arteries at the ankle and was divided by the brachial artery systolic pressure. The value was recorded to two decimal places.

Example:

$$Right\ ABPI = \frac{Systolic\ pressure\ of\ Right\ Foot}{\text{Highest systolic pressure among arms}}$$

ABPI Value	Interpretation
>1.4	Calcification/Vessel hardening
1.0 – 1.4	Normal

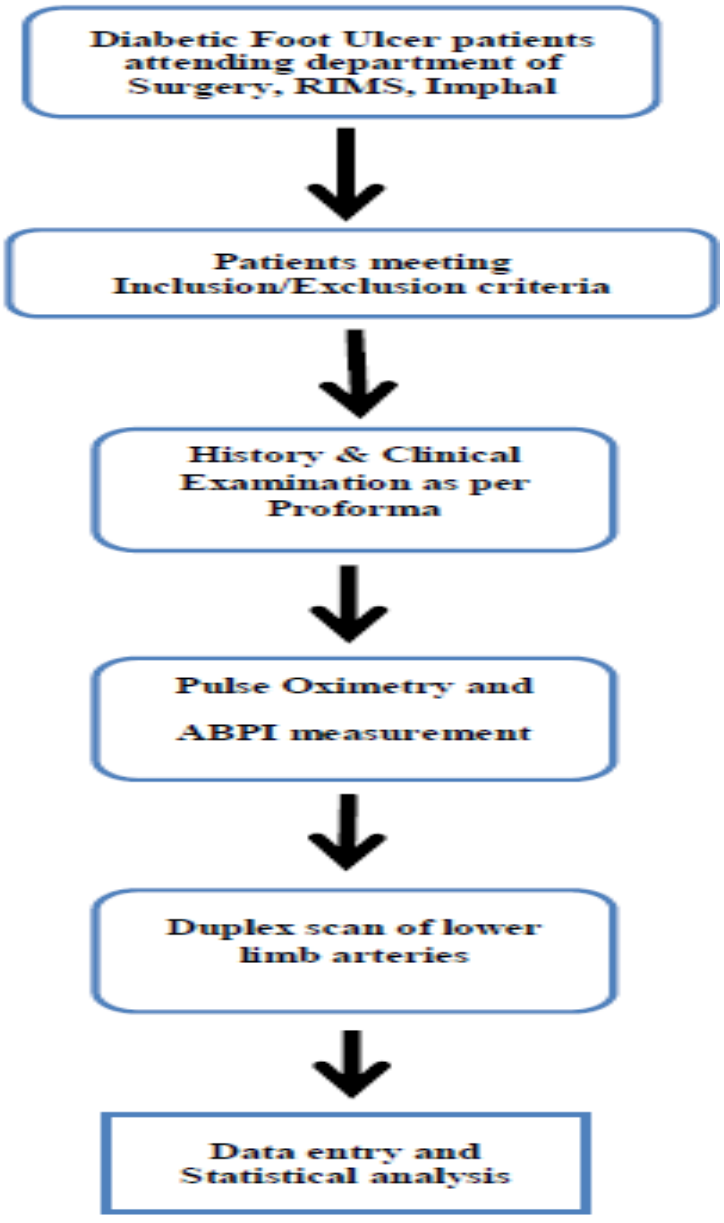
0.9 – 1.0	Acceptable
0.8 – 0.9	Some arterial disease
0.5 – 0.8	Moderate arterial disease
<0.5	Severe arterial disease

Duplex ultrasonography of both lower limb arteries was recorded within one week of the initial ankle pressure measurement as per their convenience. Peak systolic velocities of eight arteries in each leg were recorded in the duplex ultrasonography. The arteries included were common femoral artery, profunda femoris artery, superficial femoral artery, popliteal artery, peroneal artery, anterior tibial artery, posterior tibial artery and dorsalis pedis artery .

The result of Duplex ultrasonography was considered as the final diagnosis and results of individual modality viz. pulse oximetry and ABPI were recorded in the table and data analysed for Sensitivity, Specificity, Positive predictive value, Negative Predictive value.

Statistical Analysis: Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance.

To find the accuracy, sensitivity, specificity, positive predictive value and negative predictive value, the appropriate formulae was used with Received Operating Curve (ROC). The Statistical software namely SPSS 26.0 was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.



RESULTS

A total of 50 patients, as compared to the calculated sample size of 42 were included in the study. Patients with Diabetic foot ulcers of grade 3 & above as per "Wagner's classification" were admitted for treatment and evaluated. Rest was treated on OPD basis and evaluated.

The mean (SD) age of the study population was 58.2 (± 8.8) years. Highest proportion of age range consisted of 6th decade followed by 7th. (Table 1)

Table 1. Age group of study population (N=50).

Age group (in years)	Number of patients (N)	Percentage (%)
40 – 50	13	26 %
51 – 60	17	34 %
61 – 70	16	32 %
Above 70	4	8 %
Total	**50**	**100 %**

There was a preponderance of male gender (72%) and the ratio of M:F was 2.6:1.

The prevalence of peripheral arterial disease in the study population i.e. patients already having diabetic foot ulcers was found to be 36%.

It was found on comparing the demographic baseline parameters that the Peripheral arterial disease had a higher percentage of elderly population. (Figure 1)

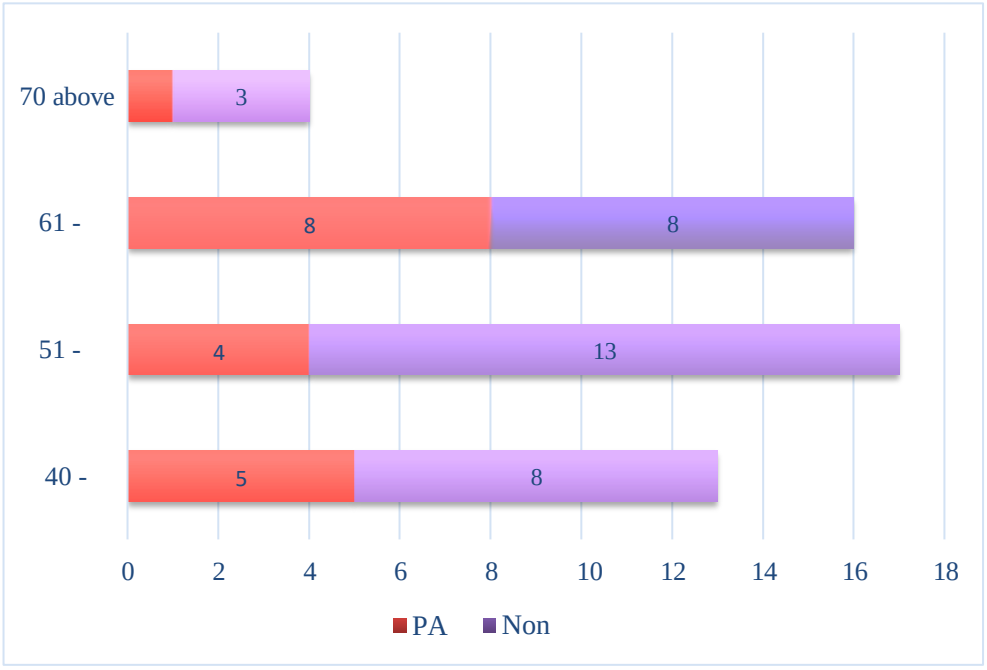


Figure 1. Age wise prevalence of PAD.

It was observed in our study population that greater proportions of PAD group were chronic smokers (50 %) as compared with the non-PAD group (18.75 %). The duration of the diabetes mellitus and its relation to the prevalence of Peripheral Arterial Disease (PAD) was also studied by perusing the baseline demographic parameters. It was observed in the study population (N) that proportion of PAD uniformly increased with increased duration of Diabetes mellitus. [Table 2]

Table 2: Smoking Habits and duration of Diabetes

		No PAD		PAD	
		Frequency	Percentage %	Frequency	Percentage %
Smoking Habits	Yes	6	18.7	9	50
	No	26	81.2	9	50
Duration of Diabetes	< 5 years	9	28.1	2	11.1
	5years-10years	12	37.5	6	33.3

	> 5 years	11	34.3	10	55.5

Out of 50 patients 18 were diagnosed as PAD by Pulse oximetry, of which 16 showed positive confirmation by USG Doppler. Only 1 out of 50 patients showed negative Pulse oximetry but positive USG doppler. Similarly, 18 were diagnosed as PAD by ABPI, of which 16 showed positive confirmation by USG Doppler. Only 2 out of 50 patients showed negative ABPI but positive USG doppler.(Table 3)

Table 3: Comparison of Pulse oximetry and ABPI with USG Doppler

	Pulse Oximetry			ABPI			Combined Parallel Testing		
	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
USG Doppler Positive	16	1	17	16	2	18	17	3	20
USG Doppler Negative	2	31	33	2	30	32	1	29	30
Total	18	32	50	18	32	50	18	32	50

Both Pulse oximetry and ABPI showed high specificity 96.87% and 93.75% respectively. The sensitivity of the test increases when used in combination (94.4%) compared to individual test done separately. The positive predictive value of Pulse oximetry was higher compared to ABPI. The diagnostic accuracy of the tests done independently as well as in combination also showed high accuracy (>90%). (Table 4)

Table 4: Diagnostic Performance of Pulse Oximetry, ABPI, and Combined Parallel Testing

Test	**Sensitivity (%)**	**Specificity (%)**	**PPV (%)**	**NPV (%)**	**Diagnostic Accuracy (%)**
Pulse Oximetry	88.88	96.87	94.11	93.93	92.87
ABPI	88.88	93.75	88.88	93.75	91.31
Combined (Parallel)	94.44	90.62	85	96.66	92.53

DISCUSSION:

The prevalence of Peripheral Arterial Disease (PAD) in our population was fairly high (36%). More recent studies done on prevalence of Peripheral Arterial Disease (PAD)/ Peripheral Vascular Disease (PVD) in Diabetic population, even in India, have agreed upon increasing trend. Bajaj S et al [11] and Muthiah A et al [12] in their study reported a prevalence of 30 % and 38 % respectively which were similar to our study. Hypertensive male patients who were smokers and having longer duration of diabetes were more prone to develop Peripheral Arterial Disease (PAD).

Majority of the patient in our study belonged to the 6th and 7th decade. Reason for lower proportion of age category above 70 years could be their physiological condition favoring less ambulation, thus leading to less OPD attendance. Prevalence of PAD amongst the age groups were directly proportional to increasing age. It was observed in our study population that greater proportions of PAD group were chronic smokers (50%) as compared with the non -PAD group (18.75%). Tyagi A et al [13] in their study also found significant correlation with age, tobacco usage and other risk factors. There is a proportionate relation between duration of diabetes to development of PAD. Other studies have also shown steady and a significant rise in prevalence of PAD with duration of diabetes.[14]

In our study the result of the Sensitivity, Specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of Pulse Oximeter, Ankle Brachial Pressure Index (ABPI) and combine parallel testing to diagnose Peripheral Arterial Disease in Diabetic Foot Ulcer patients were found to be highly predictive in screening as well as diagnosing Peripheral Arterial Disease in Diabetic Foot Ulcer patients. Pulse oximetry showed a high specificity and PPV with an accuracy of 92.87%. making it a strong rule-in test for PAD. Both tests offer high NPV (>93%), indicating strong utility in ruling out PAD, thus avoiding unnecessary angiographic studies in negative cases. This study reinforces the role of Pulse Oximetry and ABPI as effective bedside screening tools for PAD in diabetic foot patients.

Similar study done by Kumar MS et al [9] reported a high specificity in but the sensitivity was less than our study in both the Pulse oximeter and ABPI tests. Parallel testing though showed an increase in net sensitivity to 92.3% and net specificity decreased to 83.3%. Parameswaran GI et al [10] conducted a cross-sectional study of patients with type 2 diabetes mellitus and compared the accuracy of pulse oximetry, ankle-brachial index (ABI), and a combination of the also found a similar result. Other similar 14studies showed a high sensitivity with pulse oximeter and better results with the combination.[15-18]

CONCLUSION:

Pulse Oximetry was equally as good as Ankle Brachial Pressure Index in screening for Peripheral Arterial Disease (PAD) in Diabetic Foot Ulcer population.

The combination of the two index tests viz. Pulse Oximetry

and Ankle Brachial Pressure Index had marginally higher sensitivity and diagnostic accuracy than either of the two index tests done alone. They both meet the criteria of being ideal screening test i.e. inexpensive, non-invasive, accurate, easily administered and universally acceptable.

Pulse Oximeter had a superior edge over Ankle Brachial Pressure Index in terms of cheaper in price, more readily available, lesser time consuming, no special training and convenience of usage, storage and single piece instrument. Both the index tests are definitely recommended for regular use for screening of Peripheral Arterial Disease (PAD), especially for places which are not so privileged to have sophisticated diagnostic modalities.

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