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Evaluation of Pulse Oximetry as a Screening Tool for Lower Extremity Arterial Disease in Diabetic Foot

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Abstract: ***Background: A major cause of morbidity in patients with diabetes is foot pathology and it is a leading cause of hospitalization in such patients. With increased duration, severity of DM there is increased incidence of PVD, and higher rates of death, microvascular complications and major amputation. Therefore early and prompt identification of PVD in asymptomatic diabetics is important to prevent functional disability or limb loss due to complications and also to identify individuals with high risk of morbid micro and macrovascular complications such as myocardial infarction, stroke, etc. Aims and objectives: 1. To assess the role of Pulse oximetry in detecting PeripheralVascular Disease in patients with diabetic foot. 2. To compare pulse oximetry with reference standard of Doppler study of the foot. Methodology: It is a hospital based cross sectional study of 70 patientsconducted in a tertiary care centre in Mangalore, Karnataka, from December 2020 to November 2022. Pulse oximetry values of both upper and lower limb digits were noted and compared to the reference standard of Duplex studies of the respective lower limbs. A diagnosis of PVD is based on monophasic and biphasic waveforms in any artery by Colour Doppler Ultrasonography, and a patient is considered positive for PVD even if any one leg has abnormal results. Results: Mean Pulse oximetry in right index finger was 98.40 ± 0.90, left index finger was 98.54 ± 0.95, right great toe was 96.80 ± 2.33 and left great toe was 97.34 ± 1.66. 65.7% patients had abnormal Doppler findings. Among the patients 58.6% had confirmed Peripheral Vascular Disease, which was significant. Therefore, in the study it was observed that patients with PVD had significantly lower pulse oximetry findings compared to patients without PVD. Conclusion: Pulse oximetry is good enough as a screening tool to detect PVD, however it has a lower accuracy when used alone. A combination of Pulse oximetry with ABI has good accuracy and can be a better screening test for asymptomatic PVD patients.***

Keywords: Diabetes mellitus, peripheral vascular disease, peripheral arterial disease, lower extremity arterial disease, pulse oximetry, diabetic foot ulcer, ankle brachial pressure, Doppler ultrasonography, atherosclerosis.

1. Introduction

Diabetes mellitus (DM) affects over 170 million people worldwide, and by 2030, it is expected to affect 366 million people.[1,2] Impaired insulin secretion or insufficient insulin responsiveness are the main causes of DM. A significant risk factor for atherosclerotic disease and cardiovascular mortality and morbidity is DM.[3,4]

Diabetic patients experience a rise in atherosclerotic disease incidence as well as an acceleration of the illness's progression, which can account for up to 44% of allcause death. All significant arterial beds, including the coronary arteries, carotid vessels, and arteries in the lower extremities, can develop difficulties as a result of DM-associated atherosclerosis.[4–6]

Peripheral artery disease (PAD) is defined as atherosclerotic occlusive disease of lower extremities. The risk of lower extremity amputation is enhanced by PAD, which is also a marker for atherothrombosis in the cardiovascular, cerebral, and
renovascular systems. Therefore, patients with PAD have a higher risk of MI, stroke, and death. Furthermore, PAD significantly impairs patients with diabetes over the long run. Due to the requirement for a multitude of diagnostic tests, therapeutic procedures, and hospitalisations, treating individuals with PAD can therefore be costly.[7,8]

An higher risk of PAD is seen in patients with pre-existing DM and is correlated with age, duration of diabetes, and peripheral neuropathy. The prevalence of PAD in individuals with DM over the age of 40 has been calculated to be 20% using ABI to detect PAD.[9,10]

Diagnosing peripheral arterial disease is of clinical importance for two reasons. The first is to identify a patient who has a high risk of subsequent myocardial infarction or stroke regardless of whether symptoms of peripheral arterial disease are present. The second is to elicit and treat symptoms of peripheral arterial disease, which may be associated with functional disability and limb loss. The goal of the current study is to evaluate whether pulse-oximetry can detect Peripheral Vascular Disease and assess the severity of Peripheral Vascular Disease and diabetic foot and throw light on the prognosis of diabetic foot.

Aims and objectives

1) To assess the role of Pulse oximetry in detecting Peripheral Vascular Disease in patients with diabetic foot.
2) To compare pulse oximetry with reference standard of

Doppler study of the foot.

2. Materials and Methods

Source of data
Inpatients and outpatients at A J Institute of Medical Sciences and Research Centre seen from December 2020 to November 2022 coming to the General Surgery department or referred from medical or from any other departments because of clinically suspected diabetic foot were asked to participate in this study.

Method of collection of data
Study design: Hospital based cross sectional study
Study period: From December 2020 to November 2022.
Study placce: A. J. Institute of medical sciences, Mangalore.

Inclusion criteria:
- Patients of age 21 and above.
- Patients pre-diagnosed with Diabetes Mellitus (as per American Diabetes Association criteria).
- Patients with asymptomatic PVD.

Those who give informed consent.

- **Exclusion criteria:**
- Patients with:
- Heart failure with consequent lower-extremity edema,
- Stroke or ischaemic attack with residual nerve dysfunction,
- Severe peripheral edema,
- Gangrene of all foot toes,
- Amputations of feet where it will not be possible to place the pulse oximetry probe and other serious chronic disease that can affect wound healing,
- Treatment with antineoplastic drugs or glucocorticoids,
- Pregnant or lactating women

Those who do not give consent.

Methodology
70 patients fitting into inclusion and exclusion criteria were selected and subjected to detailed medical history, general physical examination, systemic examination and required investigations with prior consent of the patients was done. Patients were asked to lie down comfortably in supine posture on the examination couch of the examination room in the department. Finger pulse oximeter is applied first to the right index finger and the left index finger of the patient and the readings noted. This is immediately followed by recording the percentage of oxygen saturation readings in the right great toe and left great toe. Diagnosis of PVD is considered when toe saturation is less than finger saturation by >2% with abnormal results in at least one limb. Colour Doppler Ultrasonography was done of the limb involved with Doppler Ultrasonography machines to evaluate the flow of blood in the vessels. It is considered as the reference standard. A diagnosis of PVD is based on monophasic and biphasic waveforms in any artery by Colour Doppler Ultrasonography, and a patient is considered positive for PVD even if any one leg has abnormal results.

3. Results

Mean Age in the study was 57.20 ± 11.02 years.
74.3% patients were male and 25.7% were female.

Based on ulcer location, Bilateral involvement was observed in 51.5%, Left sided involvement in 41.4% and Right sided involvement in 7.1%.

Based on Random Blood sugar, 12.9% had RBS <140mg/dl, 30% had RBS value 140-200 mg/dl, 21.4% had RBS value 200-300mg/dl, 21.4% with RBS value range from 300-400 mg/dl, 14.3% had RBS value >400.The mean RBS value in the study was 266.80 ± 125.05.

7.1% had HbA1c of <6.5, 32.9% with HbA1c of 6.6 – 9, 6% had HbA1c of >9.The mean HbA1c in the study was 10.08 ± 2.69.

34.3% had normal dopplerfindings, 65.7% had abnormal findings.

58.6% patients in the study were observed to have Peripheral vascular disease.

Table 1: Peripheral vascular disease and Pulse oximetry findings

	PVD		P value
	Yes (n=41)	No (n=29)	
Right index finger (RF)	98.19 ± 0.87	98.68 ± 0.89	0.02*
Left index finger (LF)	98.29 ± 0.92	98.89 ± 0.90	00008*
Right great Toe (RT)	96.17 ± 2.34	97.68 ± 2.03	0.0006*
Left Great Toe (LT)	96.68 ± 1.72	98.27 ± 1.03	0.0001*

Distribution based on Pulse oximetry findings and PVD, in the study it was observed that patients with PVD had significantly lower Pulse oximetry finings compared to patients without PVD. This observation was statistically significant.

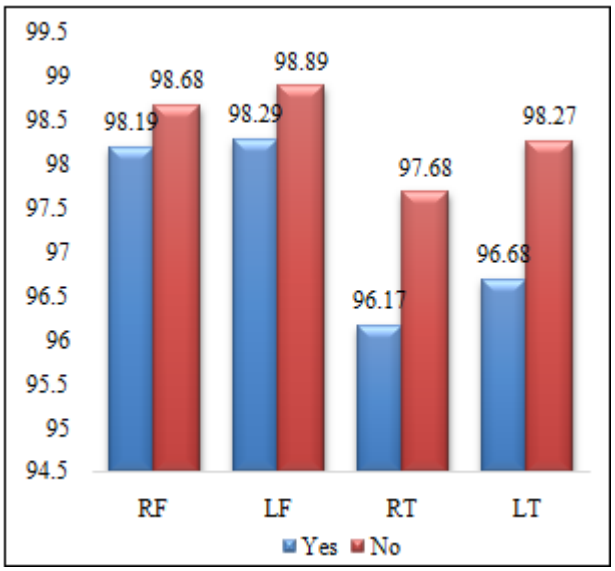
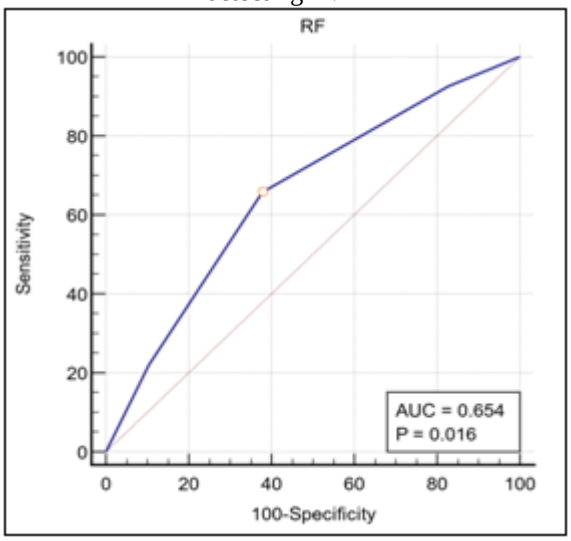


Table 2: Diagnostic utility of Pulse oximetry - RF in detecting PVD



Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.654
Standard Error [a]	0.0638
95% Confidence interval [b]	0.531 to 0.764
z statistic	2.411
Significance level P (Area=0.5)	0.0159

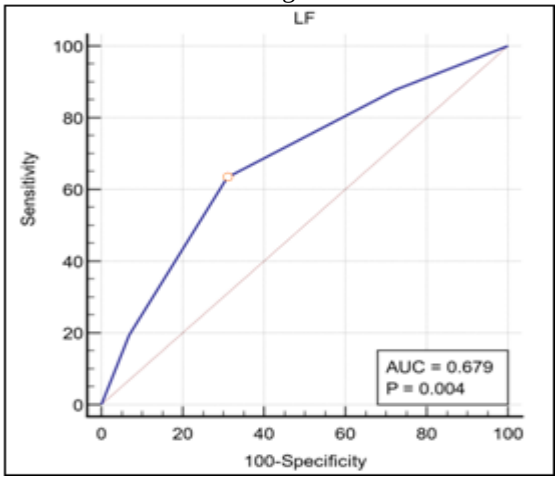
[a] DeLong et al., 1988
[b] Binomial exact

Youden index

Youden index J	0.2792
Associated criterion	≤98
Sensitivity	65.85
Specificity	62.07

Table 2 shows ROC analysis to determine the diagnostic accuracy of Pulse oximetry – Right index Finger in detecting PVD. Pulse Oximetry readings of Right Index finger at a cut of value of <98 has a sensitivity of 65.85%, and specificity of 62.07%, Positive predictive value of 71.07% and Negative predictive value of 56.21% to detect Peripheral vascular disease. This observation was statistically significant.

Table 3: Diagnostic utility of Pulse oximetry - LF in detecting PVD



Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.679
Standard Error [a]	0.0625
95% Confidence interval [b]	0.556 to 0.785
z statistic	2.86
Significance level P (Area=0.5)	0.0042

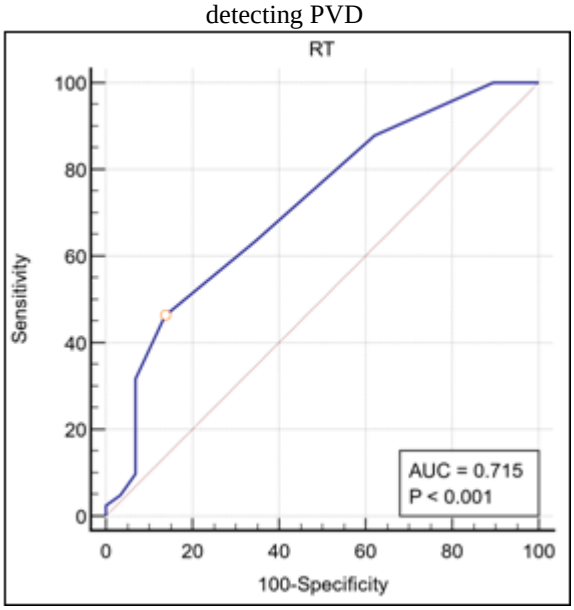
[a] DeLong et al., 1988
[b] Binomial exact

Youden index

Youden index J	0.3238
Associated criterion	≤98
Sensitivity	63.41
Specificity	68.97

Table 3 shows ROC analysis to determine the diagnostic accuracy of Pulse oximetry – Left index Finger in detecting PVD. Pulse Oximetry readings of Left Index finger at a cut of value of <98 has a sensitivity of 63.41%, and specificity of 68.97% a Positive predictive value of 74.30% and Negative predictive value of 57.11%to detect Peripheral vascular disease. This observation was statistically significant.

Table 4: Diagnostic utility of Pulse oximetry - RT in detecting PVD



Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.715
Standard Error [a]	0.0618
95% Confidence interval [b]	0.595 to 0.817
z statistic	3.485
Significance level P (Area=0.5)	0.0005

[a] DeLong et al., 1988
[b] Binomial exact

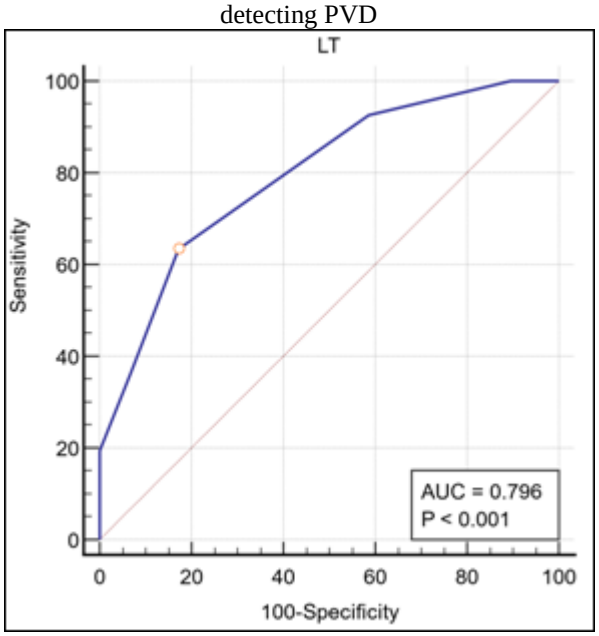
Youden index

Youden index J	0.3255
Associated criterion	≤96
Sensitivity	46.34
Specificity	86.21

Table 4 shows ROC analysis to determine the diagnostic accuracy of Pulse oximetry – Right Great Toe in detecting

PVD. Pulse Oximetry readings of Right Great Toe at a cut of value of <96 has a sensitivity of 46.34%, and specificity of 86.21%, Positive predictive value of 82.62% and Negative predictive value of 53.16% to detect Peripheral vascular disease. This observation was statistically significant

Table 5: Diagnostic utility of Pulse oximetry - LT in detecting PVD



Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.796
Standard Error [a]	0.0507
95% Confidence interval [b]	0.683 to 0.883
z statistic	5.846
Significance level P (Area=0.5)	<0.0001

[a] DeLong et al., 1988
[b] Binomial exact

Youden index

Youden index J	0.4617
Associated criterion	≤97
Sensitivity	63.41
Specificity	82.76

Table 5 shows ROC analysis to determine the diagnostic accuracy of Pulse oximetry – Left Great Toe in detecting PVD. Pulse Oximetry readings of Left Great Toe at a cut of value of <97 has a sensitivity of 63.41%, and specificity of 82.76% Positive predictive value of 83.88% and Negative predictive value of 61.50% to detect Peripheral vascular disease. This observation was statistically significant.

4. Discussion

A higher than 2% discrepancy between finger and toe oxygen saturation is considered abnormal in pulse oximetry and may be utilised to identify lower extremity peripheral vascular disease.[11,12]

However, studies on pulse oximetry and PAD had variable sensitivity results. Studies of the groups of Kwon and Parameswaran[11] included an additional pulse oximetry determination following elevation of the leg from a baseline supine position.

This manoeuver may account for increased sensitivity in their studies[13]. In our investigation, we regarded a toe SpO2 measurement done with the foot in a resting posture or on a 12-inch leg elevation as positive for PAD if the discrepancy between the great toe and index finger measurements was at least 2%.

An ideal screening test should be very sensitive, affordable, simple to use, non-invasive, comfortable, and consistent. Cost-effective and non-invasive, pulse oximetry and ABI determination are both. The researchers discovered that pulse oximetry is more comfortable and convenient than ABI in terms of speed, simplicity, and susceptibility to intra- and inter-observer variability.

Both tests have restrictions that are specific to them. Pulse oximetry cannot be used on individuals with gangrenous digits or large wounds. Ankle BP determination is also impossible in individuals with foreleg cellulitis, fractures, or open wounds.

Based on diagnostic cohort study[11]
57 adults aged 41-84 years with type 2 diabetes and no symptoms of peripheral artery disease (PAD) had ankle-brachial index measured, pulse oximetry of index fingers and big toes, and Doppler waveform analysis exam of lower extremity arteries.

Pulse oximetry considered positive for PAD if oxygen saturation ≥ 2% lower in toes than fingers, or ≥ 2% decrease with 12-inch elevation of foot.

Diagnostic performance using monophasic Doppler waveform as reference standard

- Pulse oximetry had 77% sensitivity, 97% specificity
- Ankle-brachial index ≤ 0.9 had 63% sensitivity, 97% specificity
- Combination of both tests had 86% sensitivity, 92% specificity

Parameswaran et al[14] reported that Pulse oximetry had a sensitivity of 77% (95% confidence interval [CI], 61%-88%) and a specificity of 97% (95% CI, 91%-99%); ABI had a sensitivity of 63% (95% CI, 46%-77%) and a specificity of 97% (95% CI, 91%-99%). Positive likelihood ratios were 30 (95% CI, 7.6-121) for pulse oximetry and 24.8 (95% CI, 6.2-99.8) for ABI; negative likelihood ratios were 0.23 (95% CI, 0.12-0.43) for pulse oximetry and 0.38 (95% CI, 0.25-0.59) for ABI. For the combination, sensitivity was 86% (95% CI, 71%-94%) and specificity was 92% (95% CI, 84%-96%).

According to Ria Mari Siao et al[15], using arterial duplex ultrasonography as the gold standard, pulse oximetry's sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were, respectively, 76.7%, 85.3%, 76.7%, and 85.3%. The combined sensitivity and specificity of pulse oximetry and ABI were found to be 88.1% and 74.2%, respectively, with a positive result defined as either a positive pulse oximetry result or an ABI

of ≤0.9. This resulted in a PPV of 68.4% and NPV of 90.8%.

Hardeep et al[16] reported that The sensitivity, specificity, positive predictive value and negative predicted value of pulse oximetry to diagnose asymptomatic PVD in diabetics was found to be 98.31% (95% CI: 90.91-99.96), 41.46% (95% CI: 26.32- 57.89), 70.73% (95% CI: 65.08-75.81) and 94.44% (95%CI: 70.19-99.19) respectively. The sensitivity, specificity, positive predictive value and negative predicted value of ABI to diagnose asymptomatic PVD in diabetics was found to be 77.97% (95% CI: 65.27-87.71), 97.56% (95% CI: 87.14-99.94), 97.87% (95% CI: 86.85-99.69) and 75.47% (95% CI: 65.51-83.29) respectively.

A similar study was conducted by M Satheesh Kumar et al[17], at Government Rajaji Hospital, Madurai on a total of 120 patients with type 2 diabetes mellitus aged >40 years and asymptomatic with regards to symptoms and signs of PVD. ABI had a sensitivity and specificity of 70.3% (51.5, 84.2) and 87.1 (78.8, 92.5) compared to pulse oximetry's 74.1% (95% CI: 55.3, 86.8) and 95.7% (89.4, 98.3). In terms of PPV and NPV, ABI had values of 61.3% (43.8, 76.3) and 91.0% (83.3, 95.4) while pulse oximetry had values of 83.3% (64.1, 93.3) and 92.7% (85.7, 96.4). Net sensitivity grew to 92.3% during parallel testing, while net specificity fell to 83.3%.

5. Conclusion

Screening tests are used to determine whether an asymptomatic individual has an undetected disease. The ideal screening test for PVD should be inexpensive, non-invasive, accurate, and easily administered in the physician's office.

The benefit of a screening test is evaluated by its sensitivity and specificity. As sensitivity increases, diagnosis of asymptomatic patients by a test increases.

In our study, Pulse Oximetry readings of Right Index finger at a cut of value of <98 has a sensitivity of 65.85%, and specificity of 62.07%, Positive predictive value of 71.07% and Negative predictive value of 56.21% Pulse Oximetry readings of Left Index finger at a cut of value of <98 has a sensitivity of 63.41%, and specificity of 68.97% a Positive predictive value of 74.30% and Negative predictive value of 57.11%to detect Peripheral vascular disease. Pulse Oximetry readings of Right Great Toe at a cut of value of <96 has a sensitivity of 46.34%, and specificity of 86.21%, Positive predictive value of 82.62% and Negative predictive value of 53.16% to detect Peripheral vascular disease. Pulse Oximetry readings of Left Great Toe at a cut of value of <97 has a sensitivity of 63.41%, and specificity of 82.76% Positive predictive value of 83.88% and Negative predictive value of 61.50% to detect Peripheral vascular disease.

Therefore, according to our study, pulse oximetry is good enough as a screening tool to detect PVD, however it has a lower accuracy when used alone. A combination of Pulse oximetry with ABI has good accuracy and can be a better screening test for asymptomatic PVD patients.

6. Limitations

The current study is a hospital based study; hence it may not provide the clinical presentation of diabetic foot in general population. The current study was a time bound study and hence was done on a small sample size. However, as the sample size was scientifically calculated, this limitation can be justified. The study participants weren't followed up following their discharge, and hence long term outcome couldn't be assessed. We were unable to investigate the impact of a few factors that affect the development of peripheral vascular disease, such as occupation, diabetes control, level of physical activity, and lipid profile. With a bigger sample size, future studies could examine the impact of these variables.

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