

Efficacy of a Pocket Pulse Oximeter and a Digital Pulse Oximeter as Screening Tools for Type 2 Diabetes Patients with Asymptomatic Lower Extremity Arterial Disease

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ABSTRACT

Introduction: The risk of developing lower extremity arterial diseases (LEAD) increases by 2-4 folds in patients with diabetes mellitus. Diabetic individuals with LEAD are more likely than non-diabetic individuals to have limb amputations, and they have a higher risk of cardiovascular and cerebrovascular problems. The present study sought to assess the efficacy of two pulse oximeters, a high-quality standard digital pulse oximeter and an inexpensive pocket pulse oximeter, to detect LEAD in patients with diabetes mellitus.

Material and methods: Qualifying patients were examined with a pocket pulse oximeter and digital pulse oximeter for measuring SpO₂ of their index fingers, big toes in the supine position, and at 12-inch elevation. All patients underwent Doppler waveform analysis examination of their lower extremity arteries by an investigator, who was unaware of the pulse oximetry results. Doppler waveform analysis is used as the standard. Sensitivity, specificity, the positive and negative predictive values were compared.

Results: Twenty nine of 100 legs examined had a significant LEAD, i.e., monophasic waveform by Doppler waveform analysis. Pocket pulse oximetry showed a sensitivity of 72%, a specificity of 98% and a positive predictive value of 95%, and a negative predictive value of 90%. Digital pulse oximetry showed a sensitivity of 83%, 98%, a positive predictive value of 96%, and a negative predictive value of 93%.

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Conclusion: Pulse oximetry may be a useful additional tool to screen for LEAD in patients with diabetes mellitus. It has good sensitivity and specificity in detecting LEAD even in the asymptomatic phase, especially in type 2 diabetes mellitus patients. In comparison between two oximeters, digital pulse oximetry showed a sensitivity, and the higher sensitivity is desirable in a screening test.

Keywords: pocket pulse oximeter, SpO₂, Doppler waveform analysis, digital pulse oximeter, type 2 DM, LEAD.

INTRODUCTION

Acute limb ischemias are either thrombotic or embolic (1). Chronic ischemia is primarily due to atherosclerotic changes in the lower extremity arteries, resulting from asymptomatic disease to limb-threatening gangrene (2). Lower extremity arterial disease (LEAD)/peripheral artery disease (PAD) is often one of the first signs of generalized atherosclerotic disease. Patients with intermittent claudication (IC) or critical limb ischemia (CLI) often have other atherosclerotic manifestations as well. Risk factors for LEAD are diabetes mellitus (DM), smoking, hypertension, hyperlipidemia, impaired fibrinolysis, inflammation, age, and genetic predisposition as similar to those for other manifestations of atherosclerosis, i.e., coronary artery disease and stroke (3).

The risk of developing PAD/LEAD increases by 2-4 folds in patients with diabetes mellitus (DM). Diabetic patients with LEAD had a higher risk of limb amputation and cardiovascular and cerebrovascular problems than non-diabetic patients (4).

The duration and severity of diabetes correlate with the incidence and extent of PAD. The data showed a higher prevalence of PAD in those with a longer duration of diabetes. The degree of diabetic control is an independent risk factor for PAD; with every 1% increase in HbA1c, the risk of PAD has been shown to increase by 28% (5).

The relation between asymptomatic and symptomatic LEAD is approximately 4:1. Interestingly, patients with asymptomatic LEAD have a similar increase in cardiovascular risk as those with intermittent claudication (6).

Peripheral vascular disease affects approximately 12 million people in the US (7). However, an accurate assessment of PAD prevalence in the diabetic population is confounded by various factors. Peripheral neuropathy in DM may alter pain perception; the condition often remained asymptomatic in studies using the ankle-brachial

index (ABI), which has been the preferred screening technique, the prevalence of PAD (defined as ABI<0.90) in diabetic individuals ranging from 20% to 30% (7). In the Indian subcontinent, diabetes forms the largest group of patients with atherosclerotic PAD. Eighty million people (8-10%) of the Indian population over the age of 55 years suffer from PAD (8).

It is preferable to diagnose LEAD before symptoms appear in diabetic people. It can better control risk factors, reduce morbidity, mortality, and implement an effective treatment for arterial disease associated with LEAD and cardiovascular patients.

Waveform analysis and duplex colour mapping are accurate Doppler ultrasound procedures. However, they are too expensive and ineffective for screening. On the other hand, although angiography studies are the gold standard, they are invasive and expensive; therefore, compliance among asymptomatic patients is poor, which makes it inappropriate for screening purposes (9).

Pulse oximeters are widely available and easy to use. As a result, pulse oximetry has been developed as a non-invasive screening method. The rationale for using fingertip pulse oximetry as screening for PAD is based on the hypothesis that there would be a gradient of oxygen saturation between upper and lower limbs in patients with significant arterial perfusion defects (10).

Therefore, the present study sought to assess the efficacy of two pulse oximeters, a high-quality standard digital pulse oximeter (DPO) and an inexpensive pocket pulse oximeter (PPO), to detect LEAD in patients with DM. □

METHODOLOGY

Study design: analytical, cross-sectional hospital-based study

Ethics approval: The study was authorised by the Institutional Ethics Committee, which fol-

lowed the Declaration of Helsinki, a code of research ethics (HKES/MRMC/IEC/181045).

Study location: Basaweshwara teaching and General Hospital Kalaburagi, Karnataka, India

Study duration: two years

Source of the data: type 2 diabetes mellitus (T2DM) patients attending the out-patient clinic and admitted as inpatients

Sample size: Fifty patients

Inclusion criteria: patients of both sexes aged ≥ 40 years with established T2DM and without any symptoms of lower extremity arterial disease

Exclusion criteria: painful inflammatory processes or extreme edema, revascularization procedures, or amputation over any fingers or toes.

Method: The study objectives were met by using a proforma to collect data: a complete history, general physical and systemic examination and any necessary investigations. Patients who satisfied the criteria had their SpO₂ measured using a PPO and a DPO in the supine position and at a 12-inch elevation (11). All patients underwent a Doppler waveform analysis examination of their lower limb arteries (femoral, popliteal, tibial, posterior tibial, and dorsalis pedis arteries) by an investigator who was uninformed of the pulse oximetry data at a later time in the radiology department. Abnormal pulse oximetry of the toes was characterised as SaO₂ value of more than 2% lower than the finger value or a reduction of more than 2% on an elevation of the leg (reduction from the value at the supine position) (decrease from the value at the supine position). Significant LEAD was defined as monophasic waveforms at any one of the lower extremity arteries during Doppler waveform analysis.

The benchmark for comparison is Doppler waveform analysis. When compared to arteriography, this test has a 97% specificity in the diagnosis of LEAD and has been utilised as the gold standard in prior research. □

RESULTS

Sex and age distribution

The majority of patients were males 36 (72%) when compared to females 14 (28%). The male:female ratio was 2.6:1 (Figure 1). Most patients were in the age group of 50-59 years (34%)

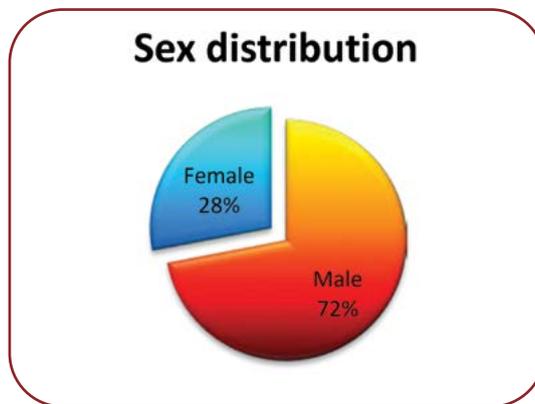


FIGURE 1. Sex distribution

Age	No. of cases	Percent
40-49	12	24.0
50-59	17	34.0
60-69	15	30.0
70-79	6	12.0
Total	50	100.0
Age		
Mean±SD	56.2±10.1	
Range	37.00	
Minimum	41.00	
Maximum	78.00	

TABLE 1. Age distribution

and 60-69 years (30%). The mean age was found to be 56.24 +/- 10.14 years with a range from 41-78 years (Table 1).

Duration of diabetes mellitus

The known duration of diabetes ranged from one year to 21 years. The mean duration of DM was 9.45 years (Figure 2).

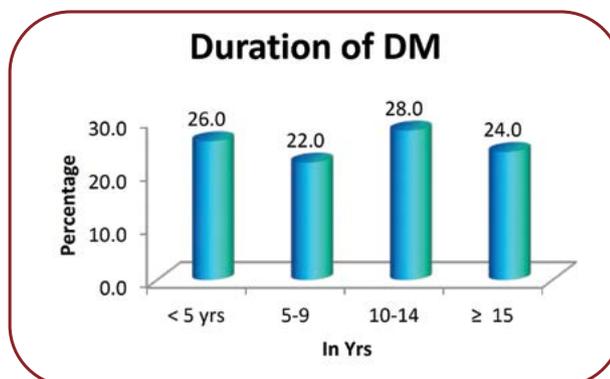


FIGURE 2. Duration of diabetes mellitus in patients screened for LEAD

TABLE 2. Relation between duration of diabetes and Doppler positivity for LEAD

Duration of DM* in years	No. of cases	Doppler positive lead	Percentage
<5	13	1	7.7%
5-9	11	2	18.2%
10-14	14	7	50%
15 and above	12	9	75%

*DM=diabetes mellitus

TABLE 3. Relation between duration of diabetes and Doppler positivity for LEAD

Comorbidities	Males	Females	Total	Percentage
Hypertension	11	08	19	38%
CAD*	08	06	14	28%
CVA**	03	00	03	06%
Smoking history	25	00	25	50%

*CAD=coronary artery disease

**CVA=cerebrovascular accident

TABLE 4. Test results for LEAD by Doppler analysis, pocket pulse oximetry and digital pulse oximetry

Test results	No of tested limbs	Positives		Negatives	
		True	False	True	False
Doppler	100	29	00	71	00
Pocket pulse oximetry	100	21	01	70	08
Digital pulse oximetry	100	24	01	70	05

TABLE 5. Efficacy of pocket pulse oximetry and digital pulse oximetry in detecting LEAD in asymptomatic T2DM patients

Oximetry	Pocket pulse oximetry	Digital pulse oximetry
Sensitivity	72%	83%
Specificity	98%	98%
PPV*	95%	96%
NPV**	90%	93%
Accuracy	91%	94%

*PPV=positive predictive value

**NPV=negative predictive value

Relation between duration of diabetes and Doppler positivity for LEAD

The occurrence of LEAD increased as the duration of diabetes increased from 7.7% in patients

with a duration of diabetes under <five years to 75% in those with a duration of diabetes >15 years (Table 2).

Selected comorbidities in type 2 diabetes mellitus patients screened for LEAD

Out of 50 patients in the study, 19 (38%) subjects had hypertension, 14 (28%) coronary artery disease (CAD) and 3 (6%) cerebrovascular accident (CVA), and 25 (50%) patients (males only) had a smoking history (Table 3).

In our study, LEAD was detected by Doppler waveform analysis in 29 (29%) of 100 studied limbs. Pocket pulse oximetry was truly positive in 21 (21%) of tested limbs, falsely positive in one (1%), truly negative in 70 (70%) and falsely negative in eight (8%). Digital pulse oximetry was truly positive in 24 (24%) of tested limbs, falsely positive in one (1%), truly negative in 70 (70%) and falsely negative in five (5%) (Table 4).

The results of pocket pulse oximetry and digital pulse oximetry were compared with the standard Doppler waveform analysis to assess their efficacy. In our study, pocket pulse oximetry showed a sensitivity of 72%, a specificity of 98%, a positive predictive value (PPV) of 95%, and a negative predictive value (NPV) of 90%, and it was found to have an accuracy of 91%. Digital pulse oximetry had a sensitivity of 83%, a specificity of 98%, a PPV of 96% and a NPV of 93%, and it showed an accuracy of 94% (Table 5). □

DISCUSSION

In our study, patients were aged between 41–78 years, with a mean age of 56.24 years. Out of 50 patients, 36 (72%) were males and 14 (28%) females, with a male to female ratio of 2.6:1. In a study conducted by G. I. Parameswaran *et al*, there were 57 patients aged between 41–84 years with a mean age of 63 years, out of

which 27 (47%) were males and 30 (53%) females (12).

In our study, the duration of DM varied between one year to 21 years, with a mean duration of 9.45 years, while in the above-quoted study (12) it varied from one year to 39 years, with a mean duration of nine years.

In their study on asymptomatic LEAD patients with T2DM, G. I. Parameswaran *et al* (12) compared the accuracy of pulse oximetry and ankle-brachial index (ABI) with Doppler waveform analysis for detecting LEAD. They discovered that the pulse oximeter had a sensitivity of 77%, a specificity of 97%, a positive likelihood ratio of 30 (95% CI) and a negative likelihood ratio of 0.23 (95% CI), while ABI had a sensitivity of 63%, a specificity of 97%, a positive likelihood ratio of 24.8 (95% CI) and a negative likelihood ratio of 0.38 (95% CI). The quoted authors concluded that toe pulse oximetry had a similar accuracy to that of ABI in screening for LEAD in T2DM patients.

In a study on 49 patients (98 limbs) regarding the utility of digital pulse oximetry in the screening of peripheral vascular disease (PVD), Jung-Nan Kwon, Whan-Bong Lee (13) found that DPO had a sensitivity of 87.06%, a specificity of 87.8%, a PPV of 84.3% and a NPV of 90%, while ABI had a sensitivity of 55.09%, a specificity of 94%, a PPV of 96.7% and a NPV of 32.02%; they concluded that digital pulse oximetry could be useful for non-invasive screening devices and ABI for PVD.

In our study, pocket pulse oximetry has shown a sensitivity of 72%, a specificity of 98%, a PPV of 95% and a NPV of 90%, while digital pulse oximetry had a sensitivity of 83%, a specificity of 98%, a PPV of 96% and a NPV of 93%. The results of pocket pulse oximetry and those of digital pulse oximetry are closely comparable to findings reported by in G. I. Parameswaran *et al* and Jung-Nam Kwon *et al*, respectively (12, 13).

Ankle-brachial index is considered a standard method for screening of LEAD in practice, but measuring the same is cumbersome since it is time-consuming, needs a dedicated device, and requires technical skills to record it – therefore, not commonly practicable in simple outpatient clinical settings. Furthermore, as reported by previous research, arteries of diabetic patients become rigid and non-compressible due to tunica medium calcification (Monckeberg sclerosis), which results in an erroneously high ABI. Hence, doubts have been cast about the accuracy of the ABI in screening for LEAD among people with diabetes (9).

Many of the previous studies evaluated the accuracy of ABI along with pulse oximetry in screening of LEAD in diabetic individuals. In contrast to other studies, ours compares the effectiveness of pocket pulse oximetry and digital pulse oximetry findings with a reference Doppler waveform analysis in individuals with no symptoms of LEAD. In our study, ABI is not tested simultaneously with pulse oximetry in the same set of patients. However, a comparative analysis

Test results	Pulse oximetry		Digital pulse oximetry	
	Present study	Parameswaran <i>et al</i> (12)	Present study	Jung-Nan Kwon <i>et al</i> (13)
Sensitivity	72%	77%	83%	87.06%
Specificity	98%	97%	98%	87.80%

TABLE 6. Comparative analysis between the present study and Parameswaran *et al*'s one (12)

TABLE 7. Comparative analysis of pulse oximetry in the present study and ankle-brachial index results of Parameswaran *et al* (12) and Jung-nan Kwon *et al* (13)

Test results	Pocket pulse oximetry results of the present study	Digital pulse oximetry results of the present study	ABI* in Parameswaran <i>et al</i> (12)	ABI in Jung-Nan Kwon <i>et al</i> (13)
Sensitivity	72%	83%	63%	55.09%
Specificity	98%	98%	97%	94.00%

*ABI=ankle-brachial index

between ABI results in the above studies and in our research shows the following findings. □

CONCLUSION

Pulse oximetry may be an additional technique for patients with DM to be screened for LEAD. The procedure has a good sensitivity and specificity in detecting LEAD even in the asymptomatic phase, especially in T2DM patients. When comparing the two types of oximeters, digital

pulse oximetry showed a sensitivity of 83%, a specificity of 98%, a PPV of 96% and a NPV of 93%. In a screening test, the higher the sensitivity, the better.

As a clinical suggestion, all patients with asymptomatic T2DM should undergo the screening tests routinely every six months to detect LEAD. □

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