

Original Research Article

Comparative study of pulse oximetry and ankle-brachial index as a screening test for asymptomatic peripheral vascular disease in type 2 diabetes mellitus against color doppler ultrasonography as reference standard

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ABSTRACT

Background: Currently about 35 million Indians are reported to suffer from diabetes mellitus, a significant proportion of whom are either undiagnosed or diagnosed but undertreated leading to poor glycemic control. This leads to accelerated development of macrovascular complications like Peripheral Vascular Disease (PVD). As most of the patients are asymptomatic, hence, early detection and treatment of PVD in patients with diabetes mellitus carries utmost importance.

Methods: The present study was undertaken in SGRDIMSAR, Amritsar on 100 patients of type 2 Diabetes Mellitus with asymptomatic PVD. The diagnostic accuracy of Ankle-Brachial Index (ABI) and pulse oximetry as a screening tool was compared against Color Doppler ultrasonography as the reference standard.

Results: 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.

Conclusions: Pulse oximetry is better than ABI for the screening for asymptomatic PVD among diabetics. However, ABI is more accurate as compared to pulse oximetry in diagnosing asymptomatic PVD in diabetics.

Keywords: Ankle-brachial index, Color doppler ultrasonography, Peripheral vascular disease, Pulse oximetry, Type 2 diabetes mellitus

INTRODUCTION

Type 2 Diabetes Mellitus is one of the important risk factors for atherosclerotic Peripheral Vascular Disease (PVD).¹ Atherosclerotic disease is not only increased in incidence in diabetic patients but its course is also accelerated, thereby accounting for as much as 44% of all-cause mortality.^{2,3} DM-associated atherosclerosis can

lead to complications in all major vascular beds, including the coronary arteries, carotid vessels, and lower extremity arteries.^{3,4}

PVD is defined as a clinical disorder in which there is stenosis or occlusion of the arteries of the limbs, a common complication of long-standing diabetes mellitus. Individuals with diabetes tend to have a two to four fold

increase in the risk of PVD as it accelerates atherosclerosis.⁵ PVD in Diabetics is a multi-segmental, bilateral, extensive disorder involving predominately distal vessels and carries a poor prognosis as compared to PVD in non-diabetics.⁶ A large proportion of lower extremity amputations among these patients lead to significant disability and economic burden on the individual and the health system in developing countries like India.⁷

The most common symptom of PVD is intermittent claudication, defined as pain, cramping, or aching in the calves, thighs, or buttocks that appears reproducibly with walking exercise and is relieved by rest. More extreme presentations of PVD include rest pain, tissue loss, or gangrene; these limb-threatening manifestations of PVD are collectively termed critical limb ischemia (CLI).¹ PVD patients present along a spectrum of severity ranging from no symptoms, intermittent claudication, rest pain and finally to non-healing wounds and gangrene.⁸ Diabetes and smoking are the strongest risk factors for PVD. Other well-known risk factors are advanced age, hypertension, and hyperlipidemia. In people with diabetes, the risk of PVD is increased by age, duration of diabetes, and presence of peripheral neuropathy.⁵ The severity and duration of DM are important predictors of both the incidence and the extent of PVD, as observed in United Kingdom Prospective Diabetes Study, where each 1% increase in glycosylated hemoglobin was correlated with a 28% increase in incidence of PVD, and higher rates of death, microvascular complications and major amputation.^{9,10} This correlation is particularly strong in men with hypertension or active tobacco use.³ Stenosis of arteries in PVD usually develops gradually and is accompanied by formation of extensive collaterals. As most of the patients are asymptomatic, hence, early detection and treatment of PVD in patients with diabetes mellitus carries utmost importance. The ideal screening test for PVD should be inexpensive, non-invasive, accurate, and easily administered in the physician's office. Currently recommended are several non-invasive tests including pulse palpation, the ankle-brachial index (ABI), pulse oximetry, color-doppler ultrasonography, arteriography, computed tomographic angiography (CTA) and magnetic resonance angiography (MRA).¹¹

METHODS

The present study was undertaken in the Department of Medicine in Sri Guru Ram Das Institute of Medical Sciences and Research, Amritsar. 100 patients of type 2 Diabetes Mellitus with asymptomatic PVD presenting in OPD and emergency or admitted in Sri Guru Ram Das Institute of Medical Sciences and Research, Amritsar were included in this study.

Inclusion criteria

- All adult patients of type 2 diabetes mellitus, diagnosed as per latest American Diabetic

Association (ADA) criteria, irrespective of control of blood sugar, treatment and presence of other complications with duration of diabetes at least 6 years.¹²

- These selected patients were asymptomatic with regard to symptoms of PVD such as claudication, ulcers, previous amputations etc.

Exclusion criteria

- Patients of type 2 diabetes mellitus with suspected arteritis and collagen vascular disease were ruled out with proper history taking.
- All extremely sick patients who required intensive care.
- Patients of type 2 diabetes mellitus showing symptoms of PVD like claudication, ulcers and gangrene.

After taking informed consent of the patient, detailed history was taken regarding the duration of diabetes and its complications. Detailed general physical examination and systemic examination was done to rule out various complications of diabetes. ABI was calculated with the help of sphygmomanometer cuff by dividing the ankle systolic BP by the elbow systolic BP. A Doppler ultrasound blood flow detector, commonly called Doppler Wand, and a sphygmomanometer were used for measuring systolic blood pressure (SBP) of upper limb at elbow and SBP of lower limb at ankle.¹³

$$\text{ABI} = \text{PLeg} / \text{PArm}$$

Where PLeg is the systolic blood pressure of dorsalis pedis or posterior tibial arteries and PArm is the higher of the brachial systolic blood pressure in the left or the right arm. Diagnosis of PVD was considered in case Ankle-Brachial pressure index (ABI) is <0.9 in at least one limb. Oxygen Saturation (SaO₂) was determined with the help of a handheld digital pulse oximeter in both the upper limbs at index finger and in both the lower limbs at big toe. Big toe saturation was also be determined in elevated position. The maximum difference between the oxygen saturations of the upper and the lower limb was calculated. Diagnosis of PVD was considered when toe saturation is less than finger saturation by $\geq 2\%$ or when foot saturation is decreased by $>2\%$ in elevated position with abnormal results in at least one limb.

The following investigations were performed in each patient:

- Hemogram (haemoglobin, total leucocyte count, differential leucocyte count, platelet count).
- Fasting blood sugar estimation by GOD-POD method.¹⁴
- Glycosylated haemoglobin (HbA1c) estimation by Nyocard Reader (Jeppsson 2002).
- Electrocardiogram (ECG).
- Urine Complete Examination.

- Urine for albumin to creatinine ratio (UACR).
- Fasting lipid profile.
- Color Doppler Ultrasonography was done of the limb involved (i.e. showing abnormal pulse oximetry and/or ABI results) with Doppler Ultrasonography machine (Philips Logiq P6) that uses linear probe of 7.5-12 MHz to evaluate the flow of blood in the vessels. The normal ("triphasic") Doppler velocity waveform is made up of three components which correspond to the different phases of arterial flow: Rapid antegrade flow reaching a peak during systole, Transient reversal of flow during early diastole, and slow antegrade flow during late diastole. Doppler examination of an artery distal to a stenosis showed characteristic changes in the velocity profile: the rate of rise is delayed, the amplitude decreased, and the transient flow reversal in early diastole is lost. In severe disease, the Doppler waveform flattens; in critical limb ischemia it may be undetectable.¹⁵

It was considered as the reference standard. A diagnosis of PVD was based on monophasic and biphasic waveforms in any artery by Color Doppler Ultrasonography, and a patient was considered positive for PVD even if any one leg had abnormal results.¹¹ Characteristics of the study population were described in

percentages. Diagnostic accuracy of the index tests was calculated in terms of sensitivity, specificity, PPV, and NPV with 95% Confidence Intervals (CI). Data were analyzed statistically using descriptive statistics, chi square test and Student t-test. P-value <0.05 was considered as statistically significant. IBM SPSS (Statistical Package for the Social Sciences) version 20 and MS Excel were used for data analysis.

RESULTS

The age of all patients included in our study varied between 32-85 years. The most common age group studied was between 43-69 years with a mean age of 56.45 ± 12.96 years. 57 patients were male and 43 patients were female. The mean age in male patients was 56.85 ± 13.65 years and in female patients was 55.90 ± 12.12 years. The mean duration of diabetes in our study was 13.90 ± 5.51 years. The mean HbA1c in our study was $9.56 \pm 2.59\%$. Peripheral vascular disease was found in 59 cases out of 100 showing a prevalence of 59%. PVD was found most commonly in the age group 41-60 years with a mean age of 57.54 ± 13.77 years. Prevalence of PVD was 34% in males and 25% in females. The mean duration of diabetes in patients with PVD was 14.41 ± 5.55 years (Table 1).

Table 1: Demographic variables and selected comorbidities in patients with type 2 diabetes mellitus screened for peripheral vascular disease.

Variable	Category	Peripheral Vascular Disease		P-value
		Present (in %)	Absent (in %)	
Age (in years)	≤40	6	6	0.465
	41-60	30	22	
	61-80	20	13	
	≥80	3	0	
Gender	Male	34	23	0.879
	Female	25	18	
Diabetes duration (in years)	<10	19	19	0.152
	>10	40	22	
Hypertension	Present	33	16	0.096
	Absent	26	25	
Coronary Artery Disease	Present	37	14	0.005*
	Absent	22	27	
History of Smoking	Present	17	1	0.010*
	Absent	52	30	
Diabetic Neuropathy	Present	46	21	0.005*
	Absent	13	20	
Diabetic Retinopathy	Present	38	14	0.003*
	Absent	21	27	
Diabetic Nephropathy	Present	41	14	0.000*
	Absent	18	27	
HbA1c (in %)	≤6.9	10	7	0.102
	7.0-8.9	12	16	
	≥9	37	18	

*means significant statistically.

Table 2: Sensitivity, specificity and predictive values of pulse oximetry, ABI and their combination with color Doppler ultrasonography as reference standard.

Index test	PVD By Color Doppler		Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
	Positive	Negative				
Pulse Oximetry	Positive	58	98.31 (90.91, 99.96)	41.46 (26.32, 57.89)	70.73 (65.08, 75.81)	94.44 (70.79 99.19)
	Negative	1				
Ankle-Brachial Index	Positive	46	77.97 (65.27, 87.71)	97.56 (87.14, 99.94)	97.87 (86.85, 99.69)	75.47 (65.51 83.29)
	Negative	13				
Combination of pulse oximetry and ABI	Positive	58	98.31 (90.91, 99.96)	39.02 (24.20, 55.50)	69.88 (64.44, 74.81)	94.12 (68.83 99.14)
	Negative	1				

The correlation of PVD with clinical signs of atherosclerosis and coronary artery disease was found to be significant statistically with a p-value of 0.000 and 0.005 respectively. The correlation of PVD with smoking was found to be significant statistically with a p-value of 0.010. The correlation of PVD with microvascular complications of diabetes i.e. diabetic neuropathy, diabetic retinopathy and diabetic nephropathy found to be significant statistically with a p-value of 0.005, 0.003 and 0.000 respectively (Table 1).

The mean HbA1c in PVD patients was 10.08±2.79%. The correlation of PVD and HbA1c was found to be significant statistically with a p-value of 0.049. The correlation of PVD with age, gender and duration of diabetes was found to be insignificant statistically (Table 1).

The sensitivity, specificity, positive predictive value (PPV) and negative predicted value (NPV) 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 (PPV) and negative predicted value (NPV) of ankle brachial index (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. The sensitivity, specificity, positive predictive value (PPV) and negative predicted value (NPV) of the combination of ABI and pulse oximetry to diagnose asymptomatic PVD in diabetics was found to be 98.31% (95% CI: 90.91-99.96), 39.02% (95% CI: 24.2-55.50), 69.88% (95% CI: 64.44-74.81) and 94.12% (95% CI: 68.83-99.14) respectively (Table 2).

DISCUSSION

The age of all patients included in our study varied between 32-85 years. The most common age group studied was between 43-69 years with a mean age of 56.45±12.96 years. 57% patients were male and 43% patients were female. The mean age in male patients was

56.85±13.65 years and in female patients was 55.90±12.12 years. The mean duration of diabetes in our study was 13.90±5.51 years. The mean HbA1c in this study was 9.56±2.59%. In this study, peripheral vascular disease was found in 59 cases out of 100 showing a prevalence of 59%. PVD was found most commonly in the age group 43-71 years with a mean age of 57.54±13.77 years. Prevalence of PVD was 34% in males and 25% in females. The mean duration of diabetes in patients with PVD was 14.41±5.55 years.

Out of all the patients included in our study, 18% were smokers and 82% were nonsmokers. In our study 17 smokers out of 18 suffered from PVD i.e.99.4% and correlation of PVD with smoking was found to be significant statistically with a p-value of 0.010. A study was conducted by M Satheesh Kumar et al, in which 40.8% patients were smokers and 20 smokers out of 49 suffered from PVD i.e. 40.8%.¹¹ A study conducted by Kailasanadhan and Mathews consisted of 34% smokers and 41 out 51 smokers suffered from PVD i.e. 80.4%.¹⁶

In our study, 37 out of 51 patients (i.e. 72.5%) suffering from coronary artery disease (CAD) showed presence of PVD which was statistically significant with a p-value of 0.005 and 35 out of 43 patients (i.e. 81.4%) showing clinical signs of atherosclerosis suffered from PVD which was statistically significant with a p-value of 0.000. In our study, the correlation of mean total cholesterol and mean serum triglycerides with PVD were found to be significant statistically with a p-value of <0.0001 and 0.002 respectively. In a study conducted by Sarangi S et al, 24.73% patient had CAD and the occurrence of CAD in PVD positive was 46.88% while in PVD negative cases was 20% (p-value 0.001).¹⁷

The correlation of PVD with microvascular complications of diabetes i.e. diabetic neuropathy, diabetic retinopathy and diabetic nephropathy found to be significant statistically with a p-value of 0.005, 0.003 and 0.000 respectively in our study. In a study conducted by Shukla et al, on a total of 200 type 2 diabetes mellitus patients and a multivariate linear regression model was proposed which showed a significant positive correlation of retinopathy and neuropathy with ABI with a p-value of

<0.001 and 0.037 respectively. This study also showed a weak non-significant correlation between PVD and diabetic nephropathy (p-value 0.495).¹⁸ Chandy et al, found out that there was no significant association correlation between diabetic nephropathy and PVD in type 2 diabetics. In this study, 47 out of 150 patients suffering from PVD had diabetic nephropathy (p-value 0.748).¹⁹

In this study, the mean HbA1c in PVD patients was 10.08±2.79 %. The correlation of PVD and HbA1c was found to be significant statistically with a p-value of 0.049. The correlation of HbA1c with microvascular complications of diabetes i.e. diabetic neuropathy and diabetic nephropathy was found to be significant statistically with a p-value of 0.001 and 0.040 respectively in our study. However, the correlation of HbA1c with diabetic retinopathy was insignificant statistically.

The sensitivity, specificity, positive predictive value (PPV) and negative predicted value (NPV) 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 (PPV) and negative predicted value (NPV) of ankle brachial index (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. The sensitivity, specificity, positive predictive value (PPV) and negative predicted value (NPV) of the combination of ABI and pulse oximetry to diagnose asymptomatic PVD in diabetics was found to be 98.31% (95% CI: 90.91-99.96), 39.02% (95% CI: 24.2-55.50), 69.88% (95% CI: 64.44-74.81) and 94.12% (95% CI: 68.83-99.14) respectively (Table 2).

A similar study was conducted by M Satheesh Kumar et al, 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. The sensitivity and specificity of pulse oximetry were 74.1% (95% CI: 55.3, 86.8) and 95.7% (89.4, 98.3) respectively, while those of ABI were 70.3% (51.5, 84.2) and 87.1 (78.8, 92.5) respectively. The PPV and NPV for pulse oximetry were 83.3% (64.1, 93.3) and 92.7% (85.7, 96.4) respectively and those for ABI were 61.3% (43.8, 76.3) and 91.0% (83.3, 95.4) respectively. Parallel testing had net sensitivity increased to 92.3% and net specificity decreased to 83.3%.¹¹ G. Iyer Parameswarn et al, 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 two to diagnose PVD in 57 patients (114 limbs) with type 2 diabetes who had no symptoms of PVD, in a primary care setting. 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%). Thus, pulse oximetry of the toes seems as accurate as ABI to screen for PVD in patients with type 2 diabetes and a combination of the two tests increases sensitivity.²⁰

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 this study, the sensitivity of pulse oximetry and ankle-brachial index to detect asymptomatic PVD in diabetic patients was found to be 98.31% (95% CI: 90.91-99.96) and 77.97% (95% CI: 65.27-87.71) respectively. However, a combination of both has sensitivity comparable with pulse oximetry alone i.e. 98.31% (95% CI: 90.91-99.96). Therefore, according to our study, pulse oximetry or a combination of both is better than ABI alone for the screening for asymptomatic PVD among diabetics. Specificity is a measure of diagnostic accuracy of a test. In our study, specificity of pulse oximetry and ABI was found to be 41.46% (95% CI: 26.32-57.89) and 97.56% (95% CI: 87.14-99.94) respectively. Therefore, according to our study, ABI is more accurate as compared to pulse oximetry and their combination in diagnosing asymptomatic PVD in diabetics.

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