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TITLE- : UTILITY OF DIGITAL PULSE OXIMETRY AND ANKLE-BRACHIAL INDEX IN THE DETECTION OF ASYMPTOMATIC PERIPHERAL VASCULAR DISEASE IN TYPE 2 DIABETES MELLITUS

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Abstract

Poor glycemic control in undiagnosed or undertreated diabetes patients, leads to the development of complications like peripheral vascular disease. A routine annual screeningfor lower extremity arterial disease in patients with type 2 diabetes and those aged over 40 years old was recommended by American Diabetes Association as well as American Heart Association. The primary objective of the present study is to assess the diagnostic accuracy of ABI and pulse oximetry as a screening tool to detect asymptomatic PVD in Indian diabetic patients against duplex ultrasonography as the reference standard. This cross-sectional observational study was conducted on 162 diabetic individuals aged above 40 years.After initial screening for diabetes, we have performed Ankle Brachial Index (ABI), pulse oximetry and Doppler ultrasonography on each subject. A diagnosis of PVD was done based on duplex ultrasonography. In addition the ABI <0.9 and toe saturation being less than finger saturation by >2% in an elevated position were considered as PVD. Among 162 patients included in the study, prevalence of PVD was 21%. The sensitivity and specificity of left sidepulse oximetry were 73.5% (95% CI: 55.6-87.1) and 100% (95% CI: 97.2-100) respectively, while those of right side pulse oximetry as well as ABI on right and left sides were 64.7% (95% CI: 46.5-80.3) and 100% (95% CI: 97.2-100) respectively. The PPV was 100% for all diagnostic methods. In conclusion, pulse oximetry showed sufficient sensitivity as screening method for PVD in Indian diabetes mellitus patients.

Keywords: Diabetes, Peripheral Vascular Diseases, Pulse Oximetry, Ankle-Brachial Index,Sensitivity and Specificity.

Introduction

Diabetes mellitus is a metabolic diseases characterized by chronicity of hyperglycemia that associated with long-term damage and organ failures especially eyes, kidneys, nerves and blood vessels (1). Diabetes is the seventh leading cause of death globally (2). The results of the first phase of a national study revealed the prevalence of diabetes and prediabetes in India states and projected that the prevalence of diabetes as 62.4 million in the whole of India (3).In India, there are about 69.2 million people with diabetes and are expected to cross 123.5 million by 2040 (4). Poor glycemic control in undiagnosed or undertreated diabetes patients, leads to the development of complications like peripheral vascular disease (PVD). Peripheral vascular disease is stenosis or occlusion in the arteries of limbs and is also associated with thrombosis of other vascular beds, including the cardiovascular and cerebrovascular systems (5). Prevalence of PVD among overt diabetic patients was estimated to be about 6 to 8% in Indians (6, 7). Stenosis in PVD usually develops gradually and is accompanied by formation of extensive collaterals so most of the patients are asymptomatic. Compared to non-diabetic PVD, diabetes PVD is predominately seen in bilateral distal vessels and multi- segmental in nature that leads to poor prognosis and is difficult to treat (8).

Early detection and treatment of PVD in patients with diabetes mellitus can surely limit its debilitating effects. Further, annual screening for lower extremity arterial disease in patients with type 2 diabetes and those aged over 40 years old was recommended by American Diabetes Association as well as American Heart Association (9). Hence, establishing an efficient clinical non-invasive diagnostic tool to determine vascular competence inasymptomatic PVD patients is essential (10). Since 17th centaury a variety of both invasive and non-invasive diagnostic devices have been developed to facilitate accurate diagnosis of PVD (11). Among the available

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methods, duplex ultrasonography, computerized Tomography (CT) angiography and Magnetic Resonance Angiography (MRA) are the gold standard methods for diagnosing the PVD (12). However, all these imaging modalities are expensive in clinical practice. Consequently, several simple and most inexpensive tests have been designed for the detection of PVD in clinical practice. Ankle-Brachial Index (ABI) and pulse oximetry are common methods used for screening PVD (13, 14). The accuracy of ABI and pulse oximetry in detecting the PVD has been tested in number of studies, but the findings are liable to spectrum bias. However there is not much studies conducted for assessing the accuracy of ABI and pulse oximetry in detecting asymptomatic PVD in Indian patients (15). Thus, the primary objective of the present study is to assess the diagnostic accuracy of ABI and pulse oximetry as a screening tool to detect asymptomatic PVD in Indian diabetic patients against duplex ultrasonography as the reference standard.

Material and method

Subjects

This cross-sectional observational study was conducted in the Department of Medicine, Dr.B.R.A.M. Hospital, Raipur (C.G.), during 2019 to 2020. Institutional ethics committee of Pt.JNM Medical College, Raipur has approved this study. Written informed consent was obtained from all study participants. About 162 diabetic individuals defined according to International Diabetes Federation criteria were consecutively included in this study. All subjects were aged above 40 years and not previously investigated for or diagnosed as PVD. Socio-demographic characteristics, clinical history, diabetic complications and smoking history were collected using a semi-structured questionnaire.

Methods

After initial screening for diabetes, we have performed Ankle Brachial Index (ABI), pulse measuring systolic BP at the elbows (brachial artery) and ankles (posterior tibial artery) after the patient has been at rest in the supine position for 10 minutes. The ratio of the ankle to brachial systolic blood pressure was used to define the peripheral vascular diseases according to a consensus conference report (16). Arterial oxyhemoglobin saturation (SpO2) was measured by applying Pulse oximeter to both index fingers and great toes. Toe saturation wasmeasured in two positions, one in supine and other at 12-inch elevation from the horizontal plane. Further, as direct confirmatory evidence for PVD, lower extremity vasculatures were imaged in each lower extremity using standardized imaging protocols (Presence of monophasic waveforms) with Duplex ultra sound scanning system. Spectral wave forms recorded at standard locations such as common and deep femoral, tibial arteries at their originor at the level of foot.

Criteria for PVD diagnosis

The pulse oximetry reading in the toes was defined as > 95% O2 Saturation and ±2 of finger pulse oximetry reading was considered as normal. If toe saturation is less than finger saturation by >2% or if the foot saturation decreased by >2% in the elevated position was considered as PVD (17). With regard to ABI, a value of < 0.9 for any leg was considered positive for PVD

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(18). If any one leg of the patient has abnormal results, it was considered as positive for PVD.

Statistical analysis

Demographic data was expressed as percentage and mean ± S.D. The number of true-positive (TP), false-positive (FP), true-negative (TN), and false-negative (FN) test results was calculated for each test conducted and was compared to the gold standard. Further, sensitivity (SN), specificity (SP), positive predictive value (PPV) and negative predictive value (NPV) were calculated for each test. Finally, a receiver-operating characteristic (ROC)curve analysis was used to examine the overall discriminatory power and to calculate the area under the curve (AUC) for each test (19). All the statistical analysis was performed using statistical package SPSS version 20.0.

Results

Baseline comparison of characteristics of study subjects is shown in Table 1.

Table 1: Demographic and baseline characteristics of study participants

Characteristic	Overall N (%) or Mean±SD	Normal N (%) or Mean±SD	PVD N (%) or Mean±SD	P value (Chi square/t-test)
Male	75 (46.3)	64 (50.0)	11 (32.4)	
Female	87 (53.7)	64 (50.0)	24 (70.6)	0.082
Hypertensive	108 (66.7)	75 (58.6)	33 (98.1)	<0.001
CAD present	15 (9.3)	7 (5.5)	8 (23.5)	0.004
Smoking	42 (25.9)	25 (19.5)	17 (50.0)	0.001
Tobacco chewing	79 (48.3)	60 (46.9)	19 (55.9)	0.441
Alcohol drinking	54 (33.3)	37 (28.9)	17 (50.0)	0.025
Age (Yrs.)	58.5±11.2	56.6±10.8	65.5±9.5	<0.001
BMI	26.9±2.04	26.4±1.9	28.6±1.6	<0.001
DM duration (Yrs.)	16 (9.9)	11.8±6.3	22.6±7.2	<0.001
FBS (mg/dl)	143.1±22.9	135.5±17.9	171.8±15.6	<0.001
PPBS (mg/dl)	170.0±31.3	158.8±22.3	212.0±23.5	<0.001
HBA1c (%)	8.6±1.1	8.1±0.7	10.2±0.8	<0.001
Cholesterol (mg/dl)	256.2±55.1	244.5±53.9	300.3±33.2	<0.001
TG (mg/dl)	249.7±53.1	236.7±47.6	298.6±43.8	<0.001
LDL (mg/dl)	197.3±120.2	192.9±134.0	213.7±33.0	0.371
HDL (mg/dl)	44.4±10.6	45.4±11.5	40.5±3.8	0.017

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Of the 162 patients recruited 46.3% (75/162) are male patients. Hypertension was found in 66.7% (108/162) patents. Coronary artery disease (CAD) was found in 9.3% (15/162) of patients. The distribution of various risk factors between normal (n=128) and PVD (n=34) subjects was also documented in table 1. Fasting blood sugar, PPBS, HbA1c and duration of diabetes are significant more in PVD subjects compared to normal. Elevated levels of cholesterol and triglycerides were observed in PVD subjects.

Distribution of normal and PVD subjects based on color Doppler, ABI and pulse oximetry diagnostic criteria were shown in table 2.

Table 2: Distribution of normal and PVD subjects based on diagnostic test

Diagnostic test	Normal	PVD	Chi-square test
Colour Doppler	128	34	Chi-square: 5.11 p-value: 0.276
ABI Right side	140	22	
ABI Left side	140	22	
Pulse oxymetry right side	140	22	
Pulse oxymetry left side	137	25	

The proportion of PVD is almost similar in all methods compared to the standard color Doppler method (p=0.276).

Sensitivity, specificity, NPV and PPV were shown in table 3.

Table 3: Sensitivity, specificity and predictive values of diagnostic classification test.

Index test		PVD (by Color Doppler) Present (N)	PVD (by Color Doppler) Absent (N)	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)
ABI Right	Positive	22	0	64.7 (46.5-80.3)	100 (97.2-100)	100	91.4 (87.1-94.4)
	Negative	12	128				
ABI Left	Positive	22	0	64.7 (46.5-80.3)	100 (97.2-100)	100	91.4 (87.1-94.4)
	Negative	12	128				
	Positive	22	0		100 (97.2-		91.4

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Pulse oximetry Right	Negative	12	128	64.7 (46.5-80.3)	100)	100	(87.1-94.4)
Pulse oximetry Left	Positive	25	0	73.5 (55.6-87.1)	100 (97.2-100)	100	93.4 (89.0-96.1)
	Negative	9	128				

The sensitivity and specificity of left side pulse oximetry were 73.5% (95% CI: 55.6-87.1) and 100% (95% CI: 97.2-100) respectively, while those of right side pulse oximetry as well as ABI on right and left sides were 64.7% (95% CI: 46.5-80.3) and 100% (95% CI: 97.2-100) respectively. The PPV was 100% for all diagnostic methods. The NPV for left side pulse oximetry was 93.4% (95% CI: 89.0- 96.1) and those of right side pulse oximetry as well as ABI on right and left sides were 91.4% (95% CI: 87.1-94.4).
The area under the ROC curve (AUC) indicated that the left side pulse oximetry test was, on average 86.8% accurate (Figure 1) with the 95% confidence interval from 77.7% to 95.8% (Table 4).

Figure 1: ROC plots of sensitivity versus specificity for the discrimination between PVD and normal status

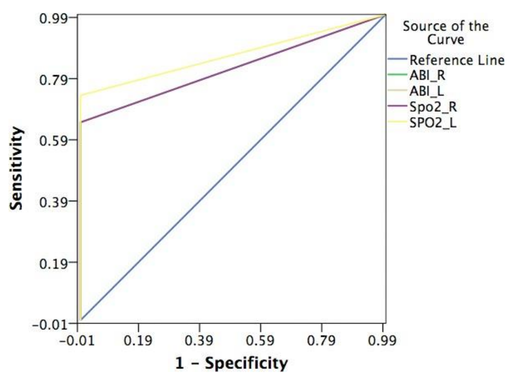

Table 4: Area under receiver operating characteristic curve of ABI and pulse oxymetry for diagnosis of asymptotic PVD.

Diagnostic test	Area % (95% CI)	Standard error	P level fornull hypothesis AUC = 0.50
ABI Right side	82.4 (72.3-92.4)	0.051	<0.001
ABI Left side	82.4 (72.3-92.4)	0.051	<0.001
Pulse oxymetry right side	82.4 (72.3-92.4)	0.051	<0.001
Pulse oxymetry left side	86.8 (77.7-95.8)	0.046	<0.001

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Discussion

Doppler ultrasound scan performed on 162 type 2 diabetic patients asymptotic for PVD, confirmed the presence of PVD in 34 patients (21%). The prevalence identified in the present study is consistent with prevalence reported in a south Indian study (15). However, few population-based studies from India have reported lesser prevalence (~8.3%) of PVD (20, 21). This discrepancy could be due to the variation in the methodology used for assessing the PVD or the study sample included in the study. PVD defined by ABI and pulse oximetry on showed lesser prevalence (~13.6%) on both right and left sides. However, prevalence is comparable among all methods used in the study. The sensitivity of left side pulse oximetry was higher than those of right side pulse oximetry as well as right and left ABI. Nevertheless, all screening methods showed 100% specificity. Further, the AUC indicated that the left side pulse oximetry test was 86.8% accurate compared to other methods.

The utility of ABI and pulse oximetry as tools for screening PVD has been the primary focus of a number of studies, but the results of these studies have been mixed and inconclusive. The sensitivity of ABI test in screening the PVD varied widely in type 2 diabetes and the elderly populations. ABI seems to be less accurate (sensitivity 28.4%) as a screening test in patients without symptoms or signs of PVD (22). Multiple studies have demonstrated that the diabetes status and aging contributed to the lower sensitivity (ranging from 15–70%) for detecting PVD using ABI test (23, 24). While an ABI ≤ 0.90 has been recommended by the American Heart Association (AHA) (25), different methods of ABI calculation and different cutoff values of ABI have been used several investigators. With regards to pulse oximetry, in patients having moderate PVD the sensitivity was found to be 16% only (17). In another study done in primary care setting, the pulse oximetry of the toes seems as accurate (sensitivity 77% and Specificity 97%) as ABI to screen for PVD in patients with type 2 diabetes (26). Another study showed statistically significant correlation between Pre- SpO_2 and pre-ABI in all-symptomatic PVD patients (13), whereas in the present study it was found that the left side pulse oxymetry could able to screen asymptomatic patients better than ABI. Simultaneous measurement of arterial blood gas and pulse oximeter readings showed that carboxyhemoglobin concentration of blood could affect the pulse oximeter readings (27). Moreover, pocket pulse oximeters showed insufficient sensitivity (42.6%) and specificity (79.1%) as screening method for detecting peripheral arterial disease in spanish diabetes mellitus patients (28).

Conclusion -:

It has been observed in some studies, that the patients' age, ethnicity, and health status, as well as other methodological factors contribute to the sensitivity of ABI and pulse oxymetry. In our study; left side pulse oxymetry is more accurate in detecting the PVD. In our study ABI and pulse oxymetry were compared side-by-side with results from color doppler has facilitated the accurate evaluation of the data. Hence the pulse oxymetry can be used for a preliminary diagnosis of PVD due to its high degree of accuracy, sensitivity and simplicity in clinical practice. In conclusion, pulse oximeters showed sufficient sensitivity as screening method for PVD in Indian diabetes mellitus patients.

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Conflicts of interest –: There are no conflicts of interest.

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