

## PULSE OXIMETRY AS A POTENTIAL SCREENING TOOL FOR LOWER EXTREMITY ARTERIAL DISEASE IN ASYMPTOMATIC PATIENTS WITH DIABETES MELLITUS

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### ABSTRACT

#### BACKGROUND

India, with a population greater than 1.1 billion, has the dubious distinction of having a larger number of people with diabetes than any other country in the world. It was estimated in the year 2000 that there are 32 million diabetes patients. Diabetic foot ulcers will complicate the disease in more than 15% of these people during their life time. Foot ulcers precede more than 80% of non-traumatic lower limb amputation. Individuals with diabetes had a tenfold higher overall amputation prevalence than did people without diabetes, 2.8% versus 0.29%.

#### MATERIALS AND METHODS

A Cross sectional study was done in the department of general surgery, Government Medical College Kottayam and Diabetic Clinic, Kottayam Medical College, from April 1, 2013 to October 1, 2013.

#### RESULTS

Out of 150 patients studied 83 were males and 67 were females and 95 patients (63.3%) had POVD. Statically significant association was found between POVD and age, history of hypertension, hyperlipidaemia, smoking, alcoholism, duration of diabetes mellitus and family history of hypertension/diabetes and hyperlipidaemia. Sensitivity and specificity of Pulse Oximetry in diagnosing POVD is 80% and 92.7% respectively. Sensitivity and specificity of ABPI in diagnosing POVD is 77.9% and 89.1% respectively.

#### CONCLUSION

Pulse Oximetry is an accurate and efficient screening tool for POVD in patients with diabetes mellitus. It can be incorporated to regular outpatient visits of Diabetes patients for early detection of POVD.

#### KEYWORDS

Pulse Oximetry, Peripheral Occlusive Vascular Disease, Ankle Brachial Pressure Index Measurement.

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#### BACKGROUND

India, with a population greater than 1.1 billion, has the dubious distinction of having a larger number of people with diabetes than any other country in the world. It was estimated in 2000 that there were 32 million people with diabetes within India, a number that is predicted to increase to nearly 80 million by 2030. The global prevalence of diabetes was estimated to be 2.8% in 2000 and is predicted to increase to 4.4% by 2030, meaning that there will be more than 366 million individuals with diabetes worldwide by that year.<sup>1</sup> Diabetic foot ulcers will complicate the disease in more than 15% of these people during their life time. Foot ulcers precede more than 80% of non-traumatic lower limb

amputation.<sup>2</sup> Individuals with diabetes had a tenfold higher overall amputation prevalence than did people without diabetes, 2.8% versus 0.29%.<sup>3</sup>

The risk of peripheral vascular disease (PVD) is increased in diabetic patients. PVD occurs earlier and is often more severe and diffuse in patients with Diabetes.

Doppler ultrasound methods such as waveform analysis and duplex colour mapping are accurate but expensive and are not appropriate for screening purposes. The ankle brachial index, currently recommended screening test for POVD was shown to be a sensitive marker for POVD. It has been reported to have a sensitivity and specificity in excess of 90% in patients with POVD. Yao et al reported that in patients with angiographically proven stenosis of the lower limb arteries the Ankle Brachial was less than 1 in 93% of patients.<sup>4</sup>

Stoffers et al reported a sensitivity of 87% at an ankle brachial index cut off value of less than 0.92.<sup>5</sup>

Joyce et al reported that patients with POVD had a significantly lower SPO<sub>2</sub> in the ischemic limbs. The SPO<sub>2</sub> improved after revascularisation.<sup>6</sup>

Early detection of lower extremity arterial disease (LEAD), before the onset of symptoms in patients with

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diabetes mellitus, is desirable and can lead to tighter, better control of risk factors for arterial disease. The ideal screening test would be inexpensive, noninvasive, accurate, and easily administered in the physician's office.

**Aims and Objectives**

**Primary Objective-** To assess the efficacy of Pulse Oximetry as a screening tool to detect significant Lower extremity arterial disease in patients with diabetes mellitus and to compare it with the Ankle brachial pressure index for the same purpose.

**Secondary Objective-** To assess if the combination of Pulse Oximetry and Ankle brachial pressure index would yield better results than either one by itself.

**MATERIALS AND METHODS**

A Cross sectional study was done in the department of general surgery, Government Medical College Kottayam and Diabetic clinic, Kottayam Medical College, for a period of 6 months from April 1, 2013 to October 1, 2013 consisting of 150 patients.

**Inclusion Criteria**

All patients with an established diagnosis of type 2 diabetes mellitus with an age more than 40 years random blood glucose concentration 200 mg/dl or fasting plasma 126 mg/dl or two-hour plasma glucose 200 mg/dl during an oral glucose tolerance test.

**Exclusion Criteria**

- Age younger than 40 years
- Known case of POVD-ulceration, gangrene
- Known symptoms of POVD- intermittent claudication and rest pain
- Patients with upper limb ischemia
- COPD
- Inability to lie supine for the period of testing
- Haemoglobin less than 10.

**Procedure-** Clearance from scientific review committee and ethical committee obtained first.

1. Obtaining details regarding Patient demographics and comorbidities.

Source- Clinical examination, History & Medical record analysis Variables assessed.

- Age
- Sex
- Duration of Diabetes Mellitus
- Carotid or coronary artery disease.
- History of hyperlipidaemia/hypertension with duration.
- History of Tobacco use with duration.

2. SPO2 Measurement with Pulse Oximeter

- SPO2 of both index fingers
- SPO2 of both big toes/2nd toes of lower limb in supine position and at 30 degree elevation from Horizontal. Measured at room temperature.

3. Ankle Brachial Pressure Index Measurement

- Systolic blood pressure measured using a sphygmomanometer cuff and a handheld Doppler of both arms at the elbow and both legs at the ankles in the supine position, at tibial artery or Dorsalis pedis artery.
- The Ankle brachial pressure index measurements are to be performed after the Pulse Oximetry measurements. The Ankle brachial pressure indexes are derived for each leg by dividing the ankle pressure by the higher of the elbow pressures.

**Definitions-** Abnormal Pulse Oximetry of the toes defined as a SpO<sub>2</sub> value of more than 2% lower than the finger value or a decrease of more than 2% on elevation of the leg (decrease from the value at the supine position).

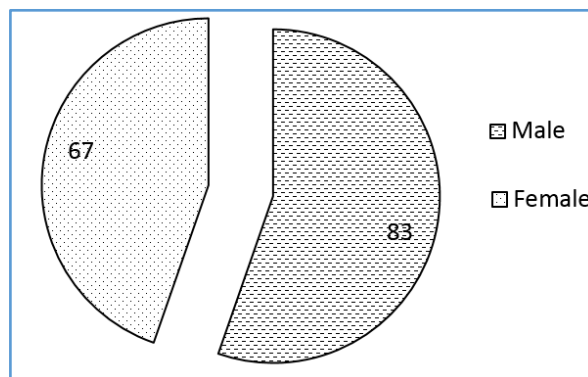
**Abnormal Ankle Brachial Pressure Index-** Defined as an Ankle brachial pressure index less than 0.9.

**Significant Lower Extremity Arterial Disease-** The presence of monophasic wave, biphasic flow in any one of the lower extremity arteries during Doppler waveform analysis.



**Figure 1. Pulse Oximetry in Patient with Diabetics**

**Analysis of Data-** The study was conducted at department of General Surgery and Diabetic Clinic Medical College, Kottayam during the period April 1, 2013 to October 1, 2013. 150 diabetic patients according to the inclusion criteria were studied. Out of the total 150 cases studied 95 (63.3%) had POVD.

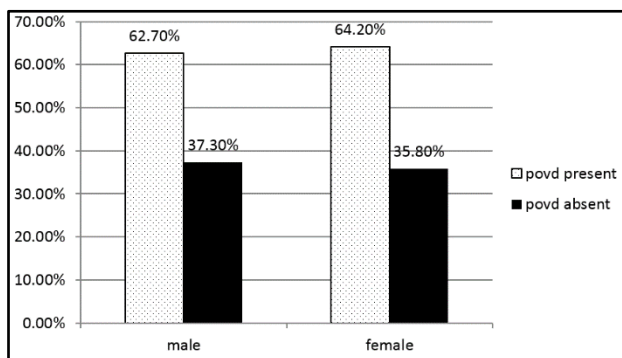


**Figure 2. Sex Distribution**

Age Group	POVD Present	POVD Absent	Total
40-60	24	44	68
60-80	31	10	41
>80	40	1	41
<b>Total</b>	<b>95</b>	<b>55</b>	<b>150</b>

**Table 2. Age Wise Distribution of POVD**

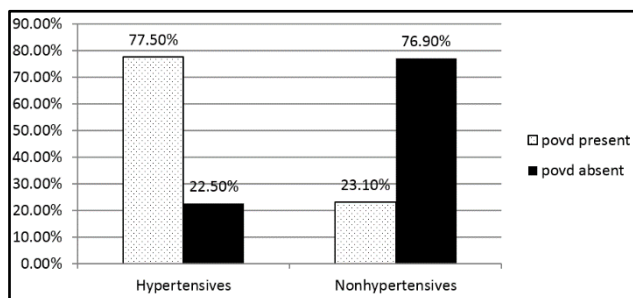
(Chi-square value: 46.367, degree of Freedom: 2, p value: 0.001).



**Figure 3. Sex Distribution of Patients with POVD**

(Chi-square Value: 0.037. degree of freedom: 1, p value: 0.847).

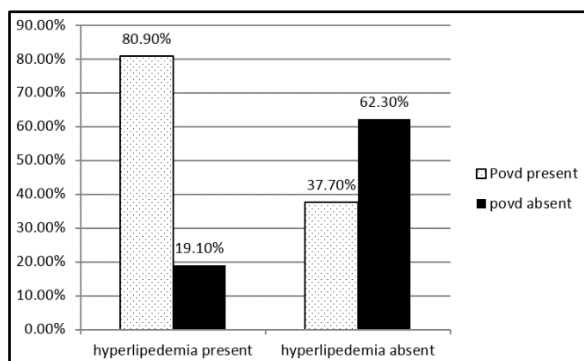
62.7% of male patients and 64.2% of female patients were suffering from POVD.



**Figure 4. Hypertension and POVD**

(Chi square value: 36.779. Degree of freedom: 1, p value: 0.001).

**Hyperlipidaemia and POVD-** Total of 89 patients with hyperlipidaemia among which 80.9% were having POVD. Only 37.7% of patients without hyperlipidaemia were having POVD.



**Figure 5. Hyperlipidaemia and POVD**

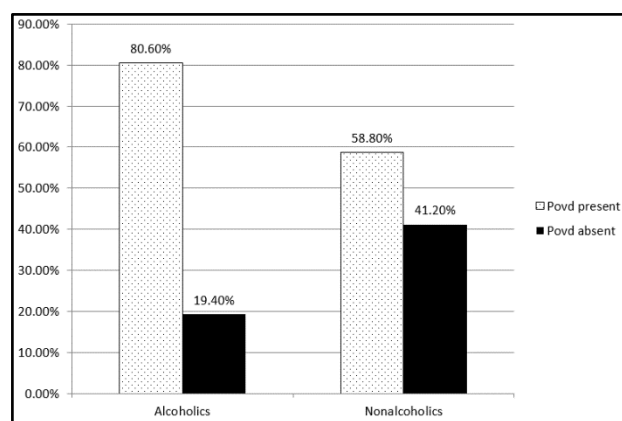
(Chi-square value: 29.078, Degree of freedom: 1, p value: 0.001).

**Smoking and POVD-** There were 51 smokers in the group 80.4% of them were having POVD. Among the nonsmokers 54.5% were having POVD.

	POVD Present	POVD Absent	Total
Smoker	41	10	51
Non-smoker	54	45	99
<b>Total</b>	<b>95</b>	<b>55</b>	<b>150</b>

**Table 3. Smoking and POVD**

**Alcoholism and POVD-** Among the total 31 of those with history of alcoholism, 80.6% were having POVD. And in those who didn't have that history 58.8% were found to have POVD.



**Figure 6. Alcoholism and POVD**

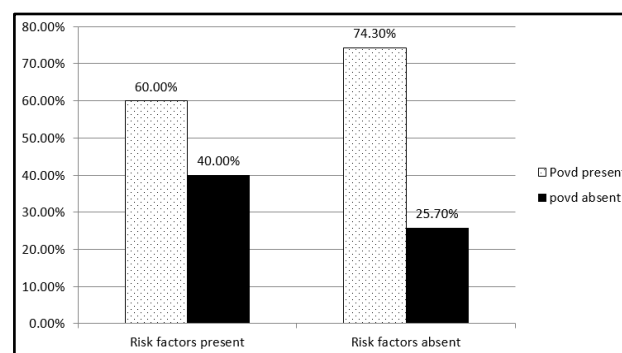
(Chi square value: 5.043, degree of freedom: 1, p value: 0.025).

**Familial risk factors of Diabetes/Hyperlipidaemia and POVD**

115 of the patients were having familial history of risk factors. Among them 60% were having POVD. But 74.3% of patients without family history were found to have POVD.

	POVD Present	POVD Absent	Total
Risk factors present	69	46	115
Risk factors absent	26	9	35
<b>Total</b>	<b>95</b>	<b>55</b>	<b>150</b>

**Table 4. Familial risk factors of Diabetes/Hyperlipidaemia and POVD**



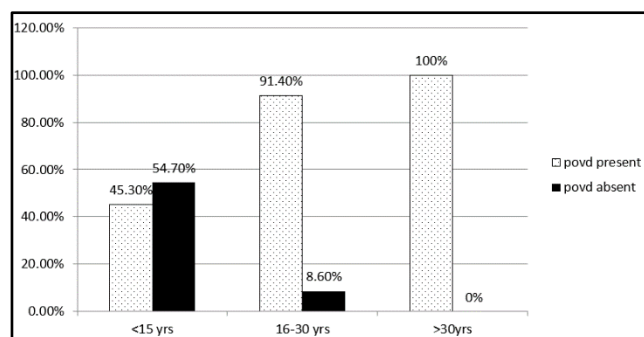
**Figure 7. Familial Risk Factors of Diabetes/Hyperlipidaemia and POVD**

(Chi Square value: 2.358, Degree of freedom: 1, p value: 0.125).

**Duration of Diabetes Mellitus and POVD-** 95 patients had a duration of less than 15 years. 45.3% of them had POVD. 35 patients had a duration between 16 and 30 years. 91.4% of them had POVD. 20 patients had a diabetes for more than 30 years. All of them had POVD.

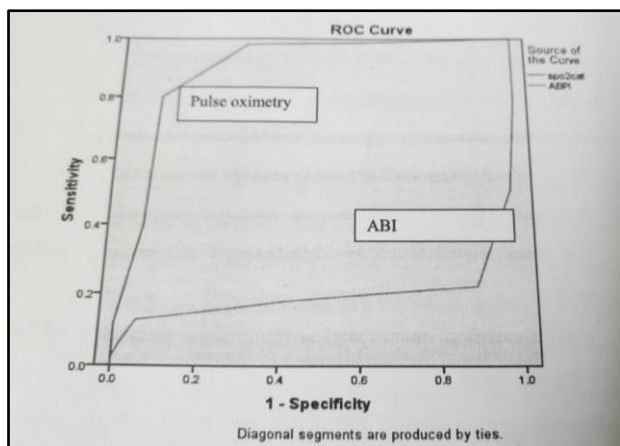
Duration (Years)	POVD Present	POVD Absent	Total
<15	43	52	95
15-30	32	3	35
>30	20	0	20
<b>Total</b>	<b>95</b>	<b>55</b>	<b>150</b>

**Table 5. Duration of Diabetes Mellitus and POVD**



**Figure 8. Duration of Diabetes Mellitus and POVD**

(Chi square value: 36.834, degree of freedom: 2, p value: 0.001).



**Graph 1. Receiver Operated Characteristic Curve**

P value 0.001.

**Sensitivity and Specificity of Pulse Oximetry and ABPI.**

**Pulse Oximetry**

Test Result	POVD Present	POVD Absent	Sensitivity	Specificity
Positive	76	4	80.0%	
Negative	19	51		92.7%

**Table 7. Pulse Oximetry**

**ABPI**

Test Result	POVD Present	POVD Absent	Sensitivity	Specificity
Positive	74	6	77.9%	
Negative	21	49		89.1%

**Table 8. ABPI**

**Pulse Oximetry and ABPI Combined**

Test Result	POVD Present	POVD Absent	Sensitivity	Specificity
Positive	76	0	80.0%	
Negative	19	55		100%

**Table 9. Pulse Oximetry and ABPI Combined**

**RESULTS**

- Out of 150 patients 83 were males and 67 were females.
- Out of the total 150 cases studied 95 (63.3%) had POVD.
- Statistically significant association was found between POVD and age, history of hypertension, hyperlipidaemia, smoking, alcoholism, duration of diabetes mellitus and family history of hypertension/diabetes and hyperlipidaemia.
- Sensitivity and specificity of Pulse Oximetry in diagnosing POVD is 80% and 92.7% respectively.
- Sensitivity and specificity of ABPI in diagnosing POVD is 77.9% and 89.1% respectively.

**DISCUSSION**

POVD is a risk factor for increased total mortality and cardiovascular events. This risk seems to persist even when POVD is subclinical. POVD if detected early helps to initiate strict control of risk factors for cardiovascular events and thus better outcomes. The prevalence of POVD in patients with diabetes mellitus is higher than in the general population, and both the American Heart Association and American Diabetes Association recommend annual screening for POVD in patients with type 2 diabetes and those older than 40 years. To be most effective, this screening should be performed in primary care settings. However, awareness of POVD, its significance, and screening for POVD is low among physicians.<sup>6</sup>

Currently recommended screening tests include pulse palpation and the ABPI.

Pulse palpation is easy to perform but has inter observer variability. The negative predictive value of a posterior tibial pulse is 96%, but the positive predictive value is only 49%.<sup>7</sup>

The reproducibility of ABI varies in literature.<sup>8</sup>

The dorsalis pedis is congenitally absent in 4% to 12% of the population.<sup>9</sup> The ABI has been reported to be very sensitive and specific in patients suspected of having arterial disease, but others report that the ABPI is not a sensitive test in patients with diabetes mellitus.<sup>10</sup>

Previous reports of sensitivity and specificity in excess of 90% for the ABPI have involved patients with symptoms and signs of POVD and have not used ABPI strictly as a screening test. When used in patients with no symptoms of

POVD, the ABPI has been reported to have a sensitivity of less than 30%.<sup>10</sup>

The ABPI is more sensitive in more severe POVD. Carter.<sup>10</sup> reported that in patients with severe arterial stenosis on arteriography, the ABPI was abnormal in 80%. However, when only mild arterial stenosis was present, the ABPI was low in only 50%. This finding suggests that for early detection of POVD before the onset of symptoms, the ABPI may not be as sensitive as reported.

Pulse oximeter was developed in 1972 by Takuo Aoyagi and Michigo Kishi.

Susumu Nakajima used it first in 1975.<sup>11</sup> Pulse Oximeters are widely available in patient-care areas and are easy to use. The technique of measuring SPO<sub>2</sub> in the blood of a finger using a Pulse Oximeter is well described and well known.<sup>12</sup>

In this study the sensitivity of Pulse Oximetry and ABI were found to be 80% and 77.9% respectively for diagnosing POVD in asymptomatic diabetic patients. We plotted receiver operating characteristic (ROC) curve to compare the Pulse Oximetry and ABI results at different cut off points (P value <0.05). It showed that Pulse Oximetry is more sensitive in detecting asymptomatic POVD when used alone. When used in combination the sensitivity was found to be 90.5% i.e. even more than sensitivities when used alone, indicating the combination can detect more cases. A significant correlation was found between increasing age, duration of diabetics. Habit of smoking, alcohol abuse, hypertension hyperlipidaemia (P value<0.05).

## CONCLUSION

1. Results suggest that Pulse Oximetry may be a useful additional tool to screen for POVD in patients with Diabetes mellitus.
2. Sensitivity and Specificity of Pulse Oximetry is better than ABI in detecting Asymptomatic POVD in patients with Diabetes mellitus.
3. Pulse Oximetry helps in early diagnosis of POVD.
4. When combined with the ABI. The results of the combination of the two tests were superior to those in which they are used alone.
5. Presence of Habits like smoking alcohol abuse, the risk factors like hypertension, hyperlipidaemia etc., are significant factors which promote POVD in Diabetic patients.
6. No statistically relevant association was found between POVD and Sex distribution and familial risk factors.
7. Pulse Oximetry is an accurate and efficient screening tool for POVD in patients with Diabetes Mellitus. It can

be incorporated to regular outpatient visits of Diabetes patients for early detection of POVD.

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