

## ASSESSMENT OF PERIPHERAL VASCULAR DISEASE IN DIABETES USING PULSE OXIMETRY AS A SCREENING TEST

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### Abstract

**Introduction:** Peripheral arterial disease (PAD) is most common disease affecting arteries of lower limb. Prevalence of PAD is around 14% in Diabetic population in India. Compromise of arterial flow due to stenosis and occlusions can lead to limb ischemia which results in intermittent claudication, rest pain, local tissue loss (ulceration) or amputation. Up to two thirds of the population amongst diabetics aged >40 years is asymptomatic for (PAD) and thus under-diagnosed as usually a patient arrives when the limb ischemic symptoms have already become severe.

**Materials and methods:** The present study was carried out in individuals in Department of General Medicine, N.S.C.B. Medical College Hospital, Jabalpur (M.P). All Patients with Diabetes Mellitus as per the mentioned criteria were included and underwent detailed History taking including duration of diabetes, clinical examination and laboratory investigations. All underwent Pulse oximetry analysis. Pulse oximeter were applied to the index finger and both great toes with the patient in the sitting or supine position at room air. If the SpO<sub>2</sub> signal was not obtainable, the next toe's signal was used. All recordings of oximeter were done at room temperature and noted at the end of 30 sec. with proper precaution.

**Results:** After recording all the observations following results were obtained. Majority of patients with PAD amongst diabetics were in elderly males. Amongst the study of risk factors in the cases following was the observation, Most of them were non-smokers (116/141), Out of 141 cases most of them were non-Hypertensive (97/141), When total cholesterol was studied most of the cases had cholesterol < 200 mg/dl (119/141), In the sub group of LDL cholesterol 3 classes were studied and most of them were found to have LDL < 130 (116/141), Amongst the triglyceride level most were < 150 mg/dl (101/141). On study of association of duration of diabetes with respect to LEAD was done most of patients had duration of < 5 years (74/141) with a mean 6.34 year and standard deviation 5.84 (01-30).

**Conclusion:** Prevalence of Lower extremity arterial disease (LEAD) in diabetic patients was found to have 19.9% (28/141) in asymptomatic individuals. Smoking, Duration of diabetes more than 15 years and Nephropathy were associated with increased prevalence LEAD (40%, 65%

and 38% respectively). Sensitivity, Specificity, Positive Predictive value and Negative Predictive Value obtained are 71.4% (95% C.I limit 51.3%-86.8%), 90.3% (95% C.I limit 83.2%-95%), 64.5% (95% C.I limit 45.55-80.8%) and 92.7% (95% C.I limit 86.2%-96.8%) respectively.

**Key Words:** Peripheral arterial disease, ischemic symptoms, LDL cholesterol, pulse oximetry.

## INTRODUCTION

Peripheral arterial disease is most common disease affecting arteries of lower limb. Prevalence of PAD is around 14% in Diabetic population in India. Compromise of arterial flow due to stenosis and occlusions can lead to limb ischemia which results in intermittent claudication, rest pain, local tissue loss (ulceration) or amputation.<sup>1</sup>

Upto two thirds of the population amongst diabetics aged >40 years is asymptomatic and thus under-diagnosed as usually a patient arrives when the limb ischemic symptoms have already become severe. These patients are associated with significantly increased morbidity, mortality, myocardial infarction and stroke. It is associated with increased vascular risk in other regions increasing cardiovascular and cerebrovascular morbidity and mortality.<sup>2</sup>

India has the highest prevalence of people with diabetes in the world<sup>3,4</sup> which is predicted to increase to 120.9 million by 2030. Peripheral vascular disease is one of the macro vascular complications of diabetes mellitus. With trivial and avoidable foot lesions known to precede 85% of leg amputations in India due to diabetic foot.<sup>6</sup>

Diabetics are about five times more likely to develop peripheral vascular disease than non-diabetics and both AHA and ADA recommend annual screening for arterial disease in patients with type 2 diabetes and those older than 50 years. The ankle-brachial index (ABI) is currently the recommended screening test for arterial disease which was shown to be a sensitive marker with sensitivity of around 90% and specificity of 90-95% for Lower extremity arterial disease.<sup>8</sup>

Accuracy of the ABI is doubtful in screening for diabetes, probably due to increased incidence of arterial calcification in diabetes mellitus, which can spuriously elevate ABI.<sup>9-10</sup>

## PULSE OXIMETRY IN LOWER EXTREMITY ARTERIAL DISEASE

Pulse oximetry measures peripheral blood hemoglobin SaO<sub>2</sub>. Low blood flow in an extremity produces lower SaO<sub>2</sub> in the blood, a fact that vascular surgeons use to assess patency of arterial reconstructions.<sup>11</sup>

Abnormal pulse oximetry of the toes was defined as an SaO<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 by 12inch (decrease from the value at the supine position).<sup>12</sup>

Numerous studies have found that pulse oximetry is accurate and reliable for screening for hepato-pulmonary syndrome, congenital heart disease, diabetes, and sepsis.

Mixed results have been reported with its use in detecting arterial disease in a general group of patients. It is reported that patients with LEAD had significantly lower SaO<sub>2</sub> in the ischemic limbs.

Conformation of PAD required duplex colour doppler ultrasound or CT Angiography assessment of arteries in order to diagnose them as cases of peripheral arterial disease.

### **AIMS AND OBJECTIVES**

Identify utility of pulse oximetry as useful screening test in diagnosis of Lower Extremity arterial disease (LEAD) in asymptomatic individuals with Diabetes Mellitus.

### **MATERIALS AND METHODS**

The present study was carried out in individuals in Department of General Medicine, N.S.C.B. Medical College Hospital, Jabalpur (M.P).

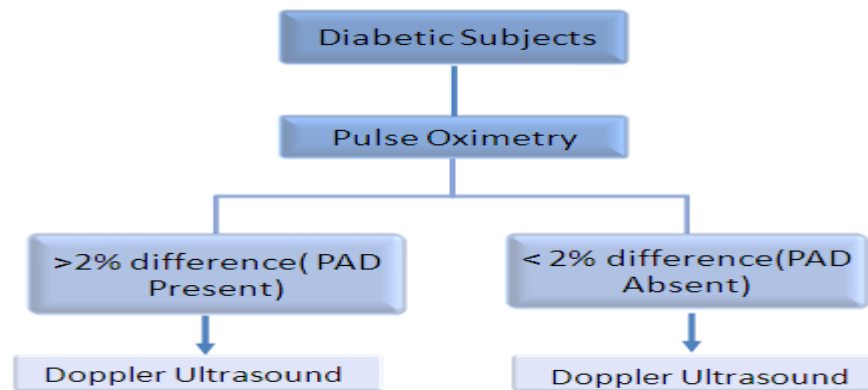
### **INCLUSION CRITERIA**

- Asymptomatic (without symptoms of PAD) patients.
- Patients willing for inclusion in the study
- Diabetic individuals will be identified as per clinical history and lab values defined according to **International Diabetes Federation criteria:**
  - FPG  $\geq$  7.0 mmol/l ( $\geq$  126 mg/dl) or,
  - 75 g OGTT with FPG  $\geq$  7.0 mmol/l (126 mg/dl) and / or 2 hour plasma glucose  $\geq$  11.1 mmol/l (200 mg/dl)
  - HbA1c  $\geq$  6.5% / 48 mmol/mol or,
  - Random Blood Glucose  $>$ 200mg/dl with symptoms of Diabetes Mellitus.

### **EXCLUSION CRITERIA**

- Patients with already diagnosed LEAD(lower Extremity Arterial Disease)
- Patients with symptoms of LEAD(intermittent claudication/rest pain)

### **METHODOLOGY**



## METHODOLOGY

All Patients with Diabetes Mellitus as per the mentioned criteria were included and had detailed History taking including duration of diabetes, clinical examination and laboratory investigations. All underwent Pulse oximetry analysis. Pulse oximeter were applied to the index finger and both great toes with the patient in the sitting or supine position at room air. If the SpO<sub>2</sub> signal was not obtainable, the next toe's signal was used. All recordings of oximeter were done at room temperature and the end of 30 sec. with proper precaution. Abnormal pulse oximetry of the toes was defined as an SaO<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 by 12 inch (decrease from the value at the supine position). Each of them underwent Doppler ultrasound for confirmation of the status of the peripheral arteries of lower limb. Identification of Abnormal results on Doppler includes, monophasic waveforms, presence of plaques and stenosis.

## RESULTS

After recording all the observations following results were obtained. Amongst the age distribution of cases in the study majority of cases were between 50-69 years with the mean of 57.71 and standard deviation of 9.64 (40-90). Sex distribution in the cases of the study revealed most of the cases were male (118/141). Amongst the study of risk factors in the cases following was the observation, Most of them were non-smokers (116/141), Out of 141 cases most of them were non- Hypertensive (97/141), When total cholesterol was studied most of the cases had cholesterol < 200 mg/dl (119/141), In the sub group of LDL cholesterol 3 classes were studied and most of them were found to have LDL < 130 (116/141), Amongst the triglyceride level most were < 150 mg/dl (101/141). On study of association of duration of diabetes with respect to LEAD was done most of patients had duration of < 5 years (74/141) with a mean 6.34 year and standard deviation 5.84 (01-30). When the complication of diabetes were compared for any association with LEAD in our study following result were obtained. Most of the patients in our study were without any evidence of ischemic heart diseases (128/141). Out of 141 cases studied

most of them did not have any evidence of Nephropathy (120/141). Out of 141 cases studies most of them did not have any evidence of retinopathy (82/141). Prevalence of Lower extremity arterial disease in cases in our study was found to have 19.9% (28/141) in asymptomatic individuals. When Pulse Oximetry difference of 2% was taken for identification of patients with LEAD on Comparison with Doppler ultrasound revealed. Prevalence of Lower extremity arterial disease in patients was found to have 19.9% (28/141) in asymptomatic individuals. Sensitivity, Specificity, Positive Predictive value and Negative Predictive Value obtained are 71.4% (95% C.I limit 51.3%-86.8%),90.3% (95% C.I limit 83.2%-95%),64.5%(95% C.I limit 45.55-80.8%) and 92.7%(95% C.I limit 86.2%-96.8%) respectively. Positive and Negative Likelihood ratios and ROC Area under curve are 7.34(3.99-13.48), 0.32(0.18-0.57) and 0.81 respectively. On study of Pulse oximetry difference of 5% among the cases for identification of LEAD with comparison to Doppler ultrasound revealed

Sensitivity, Specificity, Positive Predictive value and Negative Predictive Value obtained are 32.1% (95% C.I limit 15.9%-52.4%),99.1% (95% C.I limit 95.2%-100%),90% (95% C.I limit 55.5-99.7%) and 85.5% (95% C.I limit 78.3%-91%) respectively. Positive and Negative Likelihood ratios and ROC Area under curve are 36.32(4.80-274.90), 0.68(0.53-0.88) and 0.66 respectively.

**TABLE 1: AGE DISTRIBUTION**

S.NO	AGE IN YEARS	FREQUENCY	PERCENTAGE
1	40-49	27	19.15
2	50-59	51	36.17
3	60-69	46	32.62
4	>70	17	12.06

AGE:- Mean:57.71 Std Deviation: 9.64 (40-90)

**TABLE 2: SEX DISTRIBUTION**

S NO	GENDER	FREQUENCY	PERCENTAGE
1	MALE	118	83.69
2	FEMALE	23	16.31
	TOTAL	141	100

**TABLE 3: SMOKING**

S NO	SMOKING	FREQUENCY	PERCENTAGE
1	YES	25	17.73
2	NO	116	82.27
		141	100.00

**TABLE 4: DURATION OF DIABETES**

S NO	DURATION	FREQUENCY	PERCENTAGE%
1	LESS THAN 5 YRS	74	52.48
2	5-9	25	17.73
3	10-14	25	17.73
4	15 AND MORE	17	12.06
		141	100

Mean: 6.34 years Std Deviation: 5.84 (01-30)

**TABLE 5: HYPERTENSION**

S.NO	HTN	FREQUENCY	DURATION
1	YES	44	31.21
2	NO	97	68.79
	TOTAL	141	100

**TABLE 6: TOTAL CHOLESTROL**

TOTAL CHOLESTROL	FREQUENCY	PERCENTAGE
up to 200	119	84.40
More than 200	22	15.60
Total	141	100.00

Mean: 164.82 Std Deviation: 36.80 (102-370)

**TABLE 7: LDL CHOLESTROL**

<b>LDL CHOLESTROL</b>	<b>FREQUENCY</b>	<b>PERCENTAGE</b>
up to 100	61	43.26
101 – 130	55	39.01
More than 130	25	17.73
Total	141	100.00

Mean: 106.08 Std Deviation: 33.51 (46-247)

**TABLE 8: TRIGLYCERIDES**

<b>TRIGLYCERIDES</b>	<b>FREQUENCY</b>	<b>PERCENTAGE</b>
up to 150	101	71.63
More than 150	40	28.37
Total	141	100.00

Mean: 146 Std Deviation: 79.1 (50-538)

**TABLE 9: DIABETICS AS PER COMPLICATIONS**

<b>S NO</b>	<b>COMPLICATIONS</b>	<b>FREQUENCY</b>	<b>PERCENTAGE</b>
1	YES	77	54.61
2	NO	64	45.39
		141	100.00

**TABLE 10: IHD**

<b>S NO</b>	<b>IHD</b>	<b>FREQUENCY</b>	<b>PERCENTAGE</b>
1	YES	13	9.22
2	NO	128	90.78
		141	100%

**TABLE 11: NEPHROPATHY**

S.NO	NEPHROPATHY	FREQUENCY	PERCENTAGE
1	YES	21	14.89
2	NO	120	85.11
		141	100

**TABLE 12: RETINOPATHY**

S NO	RETINOPATHY	FREQUENCY	PERCENTAGE
1	YES	59	41.84
2	NO	82	58.16
		141	100

**TABLE 13: PULSE OXIMETRY (2%) VS DOPPLER**

PULSE OXIMETRY DIFF>2% ↓	DOPPLER S/O PAD		TOTAL
	YES(ABNORMAL)	NO(NORMAL)	
YES	20	11	31
NO	8	102	110
TOTAL	28	113	141

			95% C.I LIMITS	
Prevalence	Pr(A)	19.9%	13.6%	27.4%
Sensitivity	Pr(+ A)	71.4%	51.3%	86.8%
Specificity	Pr(- N)	90.3%	83.2%	95.0%
ROC area	(Sens. + Spec.)/2	0.81	0.72	0.90



Likelihood ratio (+)	$\text{Pr}(+ A)/\text{Pr}(+ N)$	7.34	3.99	13.48
Likelihood ratio (-)	$\text{Pr}(- A)/\text{Pr}(- N)$	0.32	0.18	0.57
Odds ratio	$\text{LR}(+)/\text{LR}(-)$	23.18	8.40	64.01
Positive predictive value	$\text{Pr}(A +)$	64.5%	45.4%	80.8%
Negative predictive value	$\text{Pr}(N -)$	92.7%	86.2%	96.8%

**TABLE 14: PULSE OXIMETRY(5%) VS DOPPLER**

PULSE OXIMETRY DIFF>5% ↓	DOPPLER S/O PAD		TOTAL
	YES(ABNORMAL)	NO(NORMAL)	
YES	9	1	10
NO	19	112	121
TOTAL	28	113	141

			95% C.I LIMITS	
Prevalence	$\text{Pr}(A)$	19.9%	13.6%	27.4%
Sensitivity	$\text{Pr}(+ A)$	32.1%	15.9%	52.4%
Specificity	$\text{Pr}(- N)$	99.1%	95.2%	100.0%
ROC area	$(\text{Sens.} + \text{Spec.})/2$	0.66	0.57	0.74
Likelihood ratio (+)	$\text{Pr}(+ A)/\text{Pr}(+ N)$	36.32	4.80	274.94
Likelihood ratio	$\text{Pr}(- A)/\text{Pr}(- N)$	0.68	0.53	0.88

(-)				
Odds ratio	LR(+)/LR(-)	53.05	8.04	.
Positive predictive value	Pr(A +)	90.0%	55.5%	99.7%
Negative predictive value	Pr(N -)	85.5%	78.3%	91.0%

**Table 15: DURATION OF DIABETES 5-9 YRS**

Doppler	Pulse oximetry Diff>2%		Total
	Pos	Neg	
Abnormal	3	0	3
Normal	1	21	22
Total	4	21	25

<b>Prevalence</b>	<b>Pr(A)</b>	<b>12.0%</b>	<b>2.5%</b>	<b>31.2%</b>
Sensitivity	Pr(+ A)	100.0%	29.2%	100.0%
Specificity	Pr(- N)	95.5%	77.2%	99.9%
ROC area	(Sens. + Spec.)/2	0.98	0.93	1.00
Likelihood ratio (+)	Pr(+ A)/Pr(+ N)	22.00	3.24	149.30
Likelihood ratio (-)	Pr(- A)/Pr(- N)	0.00	.	.

Odds ratio	LR(+)/LR(-)	.	8.31	.
Positive predictive value	Pr(A +)	75.0%	19.4%	99.4%
Negative predictive value	Pr(N -)	100.0%	83.9%	100.0%

**Table 16: LDL101-130**

Doppler	Pulse oximetry Diff>2%		Total
	Pos	Neg	
Abnormal	5	2	7
Normal	5	43	48
Total	10	45	55

<b>Prevalence</b>	<b>Pr(A)</b>	<b>12.7%</b>	<b>5.3%</b>	<b>24.5%</b>
Sensitivity	Pr(+ A)	71.4%	29.0%	96.3%
Specificity	Pr(- N)	89.6%	77.3%	96.5%
ROC area	(Sens. + Spec.)/2	0.81	0.62	0.99
Likelihood ratio (+)	Pr(+ A)/Pr(+ N)	6.86	2.64	17.78
Likelihood ratio (-)	Pr(- A)/Pr(- N)	0.32	0.10	1.03
Odds ratio	LR(+)/LR(-)	21.50	3.65	123.68
Positive predictive value	Pr(A +)	50.0%	18.7%	81.3%

Negative predictive value	Pr(N -)	95.6%	84.9%	99.5%
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**TABLE 17: LDL>131**

Doppler	Pulse oximetry Diff>2%		Total
	Pos	Neg	
Abnormal	5	2	7
Normal	1	17	18
Total	6	19	25

<b>Prevalence</b>	<b>Pr(A)</b>	<b>28%</b>	<b>12%</b>	<b>49.4%</b>
Sensitivity	Pr(+ A)	71.4%	29%	96.3%
Specificity	Pr(- N)	94.4%	72.7%	99.9%
ROC area	(Sens. + Spec.)/2	0.829	0.641	1
Likelihood ratio (+)	Pr(+ A)/Pr(+ N)	12.9	1.89	91.4
Likelihood ratio (-)	Pr(- A)/Pr(- N)	.303	.0933	.981
Odds ratio	LR(+)/LR(-)	42.5	3.84	.
Positive predictive value	Pr(A +)	83.3%	35.9%	99.6%
Negative predictive value	Pr(N -)	89.5%	66.9%	98.7%

**TABLE 18: TRIGLYCERIDES<150**

Doppler	Pulse oximetry Diff>2%		Total
	Pos	Neg	
Abnormal	12	6	18
Normal	6	77	83
Total	18	83	101

<b>Prevalence</b>	<b>Pr(A)</b>	<b>17.8%</b>	<b>10.9%</b>	<b>26.7%</b>
Sensitivity	Pr(+ A)	66.7%	41.0%	86.7%
Specificity	Pr(- N)	92.8%	84.9%	97.3%
ROC area	(Sens. + Spec.)/2	0.80	0.68	0.91
Likelihood ratio (+)	Pr(+ A)/Pr(+ N)	9.22	3.99	21.30
Likelihood ratio (-)	Pr(- A)/Pr(- N)	0.36	0.19	0.69
Odds ratio	LR(+)/LR(-)	25.67	7.30	90.64
Positive predictive value	Pr(A +)	66.7%	41.0%	86.7%
Negative predictive value	Pr(N -)	92.8%	84.9%	97.3%

**TABLE 19: TRIGLYCERIDES>150**

Doppler	Pulse oximetry Diff>2%		Total
	Pos	Neg	
Abnormal	8	2	10
Normal	5	25	30
Total	13	27	40

<b>Prevalence</b>	<b>Pr(A)</b>	<b>25.0%</b>	<b>12.7%</b>	<b>41.2%</b>
Sensitivity	Pr(+ A)	80.0%	44.4%	97.5%
Specificity	Pr(- N)	83.3%	65.3%	94.4%
ROC area	(Sens. + Spec.)/2	0.82	0.67	0.96
Likelihood ratio (+)	Pr(+ A)/Pr(+ N)	4.80	2.04	11.32
Likelihood ratio (-)	Pr(- A)/Pr(- N)	0.24	0.07	0.84
Odds ratio	LR(+)/LR(-)	20.00	3.51	109.49
Positive predictive value	Pr(A +)	61.5%	31.6%	86.1%
Negative predictive value	Pr(N -)	92.6%	75.7%	99.1%

**Table 20: RETINOPATHY**

<b>Doppler</b>	<b>Pulse oximetry Diff&gt;2%</b>		<b>Total</b>
	Pos	Neg	
Abnormal	10	6	16
Normal	5	38	43
Total	15	44	59

Prevalence	Pr(A)	27%	16%	40.3%
Sensitivity	Pr(+ A)	62.5%	35.4%	84.8%
Specificity	Pr(- N)	88.4%	74.9%	96.1%
ROC area	(Sens. + Spec.)/2	0.754	0.623	0.886
Likelihood ratio (+)	Pr(+ A)/Pr(+ N)	5.38	2.17	13.3

Likelihood ratio (-)	Pr(- A)/Pr(- N)	.424	.223	.806
Odds ratio	LR(+)/LR(-)	12.7	3.3	48.7
Positive predictive value	Pr(A +)	66.7%	38.4%	88.2%
Negative predictive value	Pr(N -)	86.4%	72.6%	94.8%

### DISCUSSION

LEAD is a risk factor for increased total mortality and cardiovascular events. This risk seems to persist even when LEAD is subclinical. Early detection of LEAD can lead to better control of risk factors for cardiovascular events and better outcomes. The prevalence of LEAD 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 LEAD in patients with type 2 diabetes and those older than 50 years. To be most effective, this screening should be performed in primary care settings. However, awareness of LEAD, its significance, and screening for LEAD is low among physicians. The purpose of this study was to analyze the usefulness of SpO<sub>2</sub> of screening tests for PAD. The non-invasive screening techniques are fast, easy to perform, inexpensive and can be used in a primary health care population.<sup>6</sup>

Currently recommended screening tests include pulse palpation and the ABI. 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%.The dorsalis pedis is congenitally absent in 4% to 12% of the population.The ABI has been reported to be very sensitive and specific in patients suspected of having arterial disease, but others report that the ABI is not a sensitive test in patients with diabetes mellitus.

Measurement of the tissue oxygen level at the toe by transcutaneous oximetry<sup>103</sup> and toe pulse pressure measurement<sup>104</sup> are more sensitive than the ABI in detecting LEAD in patients with diabetes but need special equipment and training. Pulse oximetry measures the oxygen saturation of peripheral blood (SaO<sub>2</sub>). The instrument is commonly available in physicians' offices. Mixed results have been reported with its use in detecting arterial disease in a general group of patients.Joyce et al reported that patients with LEAD had significantly lower SaO<sub>2</sub> in the ischemic limbs. The SaO<sub>2</sub> improved after revascularization.

Jawahar et al found that pulse oximetry had low sensitivity to detect LEAD when compared with the ABI used as the reference test. In our study, we compared pulse oximetry with Doppler ultrasound being considered the gold standard test for identification of lower extremity arterial

disease in which Prevalence of Lower extremity arterial disease in patients was found to have 19.9%(28/141) in asymptomatic individuals with Diabetes Mellitus. This result is similar as reported in other previous studies.

In Our study usefulness of Pulse Oximetry was tested considering Doppler ultrasound as the gold standard test. The Sensitivity, Specificity, Positive Predictive value and Negative Predictive Value obtained are 71.4% (95% C.I limit 51.3% - 86.8%), 90.3% (95% C.I limit 83.2%-95%), 64.5% (95% C.I limit 45.55 - 80.8%) and 92.7% (95% C.I limit 86.2%-96.8%) respectively, Positive and Negative Likelihood ratios and ROC Area under curve are 7.34 (3.99-13.48), 0.32 (0.18-0.57) and 0.81 respectively. This was similar to results as shown by Parmeswaran et al in their study and they also showed that this result was comparable to ABI in diabetics population.

In our study, comparison of the association of pad with various risk categories including age, sex, duration of diabetes, smoking, hypertension, total cholesterol, LDL cholesterol, VLDL cholesterol, and the association of complications of diabetes that is nephropathy, retinopathy and cardiovascular complications with respect to pulse oximetry was done. No significant association was found with risk factors which determined a deviant result of pulse oximetry which was similar as compared to study by ENA et al in which they showed poor performance of pulse oximetry in each subgroup analysis. Although Smoking, Duration of diabetes more than 15 years and Nephropathy were associated with increased prevalence (40%, 65% and 38% respectively) which is a proven fact as shown by previous studies. Previously most of studies were conducted using the difference of 2% in pulse oximetry as significant to identify patients with LEAD. Also there were some studies as conducted by Kwon and Lee et al which used a difference of 5% in pulse oximetry as significant. Thus in our study we also compared both values to identify which is a better predictor of identification of LEAD.

In our study on comparison of Pulse oximetry difference of 2% with difference of 5% we found that the results with 2% had better sensitivity as compared with 5%. The results with pulse oximetry difference of 5% were Sensitivity 32.1% (95% confidence interval [CI], 15.9%-52.4%), Specificity 99.1% (95% confidence interval [CI], 95.2%-100%), Positive Predictive Value 90% (95% confidence interval [CI], 55.5%-99.7%), NPV 85.5%(95% confidence interval [CI], 78.3%-91%), positive likelihood ratio 36.32(95% CI, 4.8-274.94) and negative likelihood ratio 0.68(95% CI, 0.53-0.88) respectively. Area under ROC curve is 0.66. On comparison with ABI pulse oximetry has been found to be as effective atleast as ABI for study of LEAD in diabetic population. ABI has been considered the choice of screening method for identification of LEAD. On the other Hand, ABI in diabetics and in asymptomatic patients has been found to have varied results probably due to increased incidence of arterial calcification in diabetes mellitus [105], which can spuriously elevate the ABI. ABI detection in diabetes and the elderly yielded lower sensitivity, 15 to 20%, 63%, 68%, 69.3%, and 70.6%, suggesting that the test may be affected by diabetes status and aging. Also ABI has been studied more in patients who are symptomatic and there has been less description of its use in asymptomatic patients. Feigelson et al.<sup>53</sup> found that



when they excluded patients with symptoms and signs of PAD, ABI values of less than 0.9 had a sensitivity of only 28.4%; and suggested that the ABI seems less accurate as a screening test in patients without symptoms or signs of PAD. Carter reported that in patients with severe arterial stenosis on arteriography, the ABI was abnormal in 80%. However, when only mild arterial stenosis was present, the ABI was low in only 50%. This finding suggests that for early detection of LEAD before the onset of symptoms, the ABI may not be as sensitive as reported

Other studies for pulse oximetry have shown varied results for usefulness of pulse oximetry. Although our study is similar to most study and found it as a useful parameter specifically in ruling out the cases of LEAD and also enabled better identification of undiagnosed patients without any symptoms. Parmeswaran et al conducted a study on 57 patients (114 extremities) which were diabetics and of those patients, 31% had Lower extremity arterial disease. 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%).

Kwon and Lee et al performed study among 49 patients (98 limbs) with lower extremity arterial occlusive disease in Korean population. They were divided in three groups with group 1 of Fontaine class 3 and 4, group 2 of Fontaine class 2 and group 3 being of asymptomatic patients. They found the sensitivity, specificity, positive and negative predictive values between active treatment groups (group I and II; endovascular and open surgery) and conservative group (group III) are all statistically significant. ABI; 55.09%, 94%, 96.7%, 39.02% (R = 12.54, P < 0.000) SpO<sub>2</sub>; 87.06%, 87.8%, 84.3%, 90% (R = 40.11, P < 0.000).

Badri et al studied pulse oximetry in 50 asymptomatic individuals in diabetics to identify lower extremity arterial disease and found Of our 50 patients (100 legs examined), 31 (31%) had LEAD. Pulse Oximetry has a Sensitivity of 74.14%, Specificity of 97.10%, and Positive predictive value of 92% and Negative predictive value of 89.3%. ABI has a Sensitivity of 60.60%, Specificity of 97.12%, and Positive predictive value of 90.9% and Negative predictive value of 87.9%. Combination has a Sensitivity of 87%, Specificity of 94.20%, and Positive predictive value of 87% and Negative predictive value of 94.20%.

Rizk et al conducted a study in 150 patients in Egypt for use of pulse oximetry in identifying lower extremity arterial disease and found taking ABI as a golden standard to diagnose significant PVD; pulse oximeter has 84.2% sensitivity and 85.4% specificity. On taking duplex-derived data as the golden standard, pulse oximeter was associated with 84.4% sensitivity and 93.5% specificity.

Joyce et al compared the ABI, pulse oximetry measurement of the toes, and transcutaneous oxygen tension measurement with the arteriographic appearance in patients suspected of having limb ischemia. They found that pulse oximetry correlated best with the arteriographic appearance.

Jawahar et al studied patients referred to a vascular laboratory with suspected LEAD and a control group not suspected of having LEAD. When an ABI less than 0.9 were considered as LEAD, pulse oximetry had a sensitivity of only 16%. Pulse oximetry results were defined as abnormal if there was a decrease of more than 2% in saturation at the toe from the finger or a decrease of more than 2% on elevation of the foot by 12 in. However, this study included patients with and without diabetes and involved patients with symptoms suggestive of LEAD. Moreover, those suspected of having LEAD had further evaluation with Duplex ultrasound scanning of leg arteries, but the control group did not.<sup>8</sup>

The limitations of our study include the fact that the study population was recruited at a single centre and accordingly, the clinical assessments, case mix and outcomes may not be generalized to other centers. The study is done in a small sample of patients and studies with larger number of sample size would be more useful in enlightening the performance of pulse oximetry. Also, as the study was performed by one observer the inter-observer variability could not be assessed.<sup>9</sup>

In totality and Brief our study found pulse oximetry as a beneficial test in identification of patients without any symptoms of LEAD. In Comparison to ABI, pulse oximetry does not have the disadvantages of varying results due to increased calcification or effect of change of results with degree of stenosis. Smoking , Duration of diabetes and Nephropathy have been associated to have increased prevalence of patients with LEAD thus pointing out to increased studies and also better identification of persons in such subset of population. Thus pulse oximetry is useful, more in specifically ruling out a patient with LEAD and with improved sensitivity when combined with other tests thus should be used more in order of better identification of Patients with LEAD.<sup>10</sup>

## **CONCLUSION**

Prevalence of Lower extremity arterial disease in patients was found to have 19.9% (28/141) in asymptomatic individuals. Smoking, Duration of diabetes more than 15 years and Nephropathy were associated with increased prevalence (40%,65% and 38% respectively). Sensitivity, Specificity, Positive Predictive value and Negative Predictive Value obtained are 71.4% (95% C.I limit 51.3%-86.8%), 90.3% (95% C.I limit 83.2%-95%), 64.5% (95% C.I limit 45.55-80.8%) and 92.7% (95% C.I limit 86.2%-96.8%) respectively. Positive and Negative Likelihood ratios and ROC Area under curve are 7.34(3.99-13.48), 0.32(0.18-0.57) and 0.81 respectively. ABI is having a sensitivity of 28.3% in patients without symptoms and sign and in contrast in our study pulse oximetry has increased sensitivity (71%) in identification in asymptomatic individuals.

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