

Comparison of Ankle Brachial Pressure Index (ABPI) Plus Pulse Oximetry with Duplex Ultrasound in Detecting Lower Extremity Arterial Disease (LEAD) in Diabetes Mellitus

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Abstract

Background: A large proportion of amputations of lower extremity secondary to aPAD is the major cause of significant disability and hence economic burden on individual and as well as the healthcare system in developing countries like India. LEAD is characterized by a spectrum ranging from no symptoms, intermittent claudicating, pain at rest to finally non-healing wounds & gangrene. ABPI is a not only a sensitive but cost-effective screening tool for LEAD. Pulse oximetry (PO) which is a simple, noninvasive, readily available & inexpensive tool for measurement of oxygen saturation in peripheral blood (SpO₂). This study was conducted to compare (ABPI) plus Pulse oximetry with Duplex Ultrasound in detecting LEAD in Diabetes Mellitus. **Material and Methods:** Inclusion Criteria: Adults more than 40 years with known diagnosis of Diabetes Mellitus. Exclusion Criteria: Patient having lower limb amputation, fracture, or gangrenous limb, Patient with pedal oedema or ulcer, Previous history of hypercoagulable states, congestive heart failure, suspected arteritis, or collagen vascular diseases, Patients with coarctation of aorta & Patients with pre-existing diagnosis of lower extremity arterial disease (LEAD). **Results:** This study was carried out at TMMC & RC (Moradabad, UP). It was a prospective hospital based observational study. Out of 55 participant 30 (54.5%) are smoker and 25 (45.5%) are non-smoker. Among 30 smoker 29 (96.7%) are pulse oximeter positive and 1 (3.33%) are pulse oximeter negative. In our study, Right limb analysis suggestive of 75% of sensitivity, 39.1% of specificity, 63.2% of PPV and 52.9% of NPV. Right ABPI has 60% of accuracy. Left limb analysis suggestive of 65.5% sensitivity, 42.3% specificity, 55.9% PPV and 52.4% NPV. Left limb ABPI has 54.5% of accuracy. Left limb pulse oximeter method analysis suggestive of 93.1% sensitivity, 23.1% specificity, 57.4% PPV and 75% NPV. Left limb pulse oximetry method has 60% of accuracy. Average pulse oximeter analysis: 91.8% sensitivity, 22.4% specificity, 60% PPV and 68.7% NPV. Average ABPI had an accuracy of 60.9%. **Conclusion:** A combination of ABPI & PO is most sensitive with highest negative predictive value. These methods are simple, cost effective, quick, non-invasive and easily available tools. Hence, detection of LEAD should be a part of regular work-up of DM patients.

Keywords: Ankle Brachial Pressure Index, Lower extremity arterial disease.

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Introduction

Peripheral artery disease (PAD) is defined by reduced vascular flow in limbs secondary to obstruction or narrowing of the supplying arteries.^[1] DM is an important pathological factor for developing atherosclerotic PAD (aPAD), which also accelerate its course.^[2] A large proportion of amputations of lower extremity secondary to aPAD is the major cause of significant disability and hence economic burden on individual and as well as the healthcare system in developing countries like India.^[3] LEAD is characterized by a spectrum ranging from no symptoms, intermittent claudicating, pain at rest to finally non-healing wounds & gangrene.^[4] Intermittent claudication, defined as calf pain occurring on activity that is not present at rest and that resolves following rest within a period of 10 minutes has been described as the classical symptom of PAD.^[5] Physical examination in LEAD is difficult to assess due to presence of coexisting edema, neuropathy & infection especially with ulceration.^[6]

Methods existing for evaluation & diagnosis of LEAD.^[7]

- Transcutaneous oximetry
- Stress testing
- Ankle-brachial pressure index (ABPI)
- Pulse oximetry
- Duplex ultrasonography (DU)
- Arteriography

- Computed tomographic angiography (CTA)
- Magnetic resonance angiography (MRA).

ABPI is a not only a sensitive but cost-effective screening tool for LEAD. As compared with lower extremity angiography it has high sensitivity of 85-95% and specificity of 90-100%.[8] However, presence of mural calcification noted in arteries of patients with DM may spuriously cause elevation of ABPI.[9]

Drawbacks of ABPI.[10]

- Inadequately BP monitoring
 - ❖ Wrong cuff size
 - ❖ Wrong position
 - ❖ Wrong technique
 - ❖ Anxiety
 - ❖ Intake of alcohol, caffeine, etc. before BP monitoring
 - ❖ Cold temperature
- Calcified vessels are non-compressible leading to false result
- 10% population show agenesis of dorsalis pedis artery or posterior tibial artery, making ABPI measurement impossible.
- ABPI may be in patient on certain medication e.g., antihypertensive drugs, antiplatelet drugs, and statin therapy.
- ABPI can be influence physiological variation in blood pressure eg: respiration.

Pulse oximetry

- Pulse oximetry (PO) which is a simple, noninvasive, readily available & inexpensive tool for measurement of oxygen saturation in peripheral blood (SpO₂), commonly available in the physician clinic has a sensitivity of about 80% and specificity of >90%.^[11]

AIM

- To study comparison of Ankle Brachial Pressure Index (ABPI) plus Pulse oximetry with Duplex Ultrasound in detecting Lower extremity arterial disease (LEAD) in Diabetes Mellitus.

OBJECTIVES

- To perform pulse oximetry (PO) and ankle brachial pressure index (ABPI) measurements in diabetic mellitus patients.
- To perform arterial Duplex Ultrasonography (DU) of lower limb in the same group of diabetic mellitus patients.
- To calculate accuracy of PO & ABPI separately and in combination with Duplex Ultrasonography of the lower limb arteries as reference standard.
- To correlate duration of diabetes and level of diabetic control with occurrence of lower extremity arterial disease (LEAD).

Methodology

Inclusion criteria

Adults more than 40 years with known diagnosis of Diabetes Mellitus.^[10]

Exclusion Criteria

- Patient having lower limb amputation, fracture, or gangrenous limb.
- Patient with pedal oedema or ulcer
- Previous history of hypercoagulable states, congestive heart failure, suspected arteritis, or collagen vascular diseases.
- Patients with coarctation of aorta
- Patients with pre-existing diagnosis of lower extremity arterial disease (LEAD).

RESULTS

- In this study, an analytic approach done to diagnose LEAD in diabetic patient via ABPI and pulse oximeter.
- Data obtained from 55 study participants were analyzed, compared, formulated and studied to find significance.
- Out of total 55 participant 23 (41.8%) are female and 32 (58.2%) are male.

Table 1: Distribution of study participants according to Gender

Gender	Frequency (n=55)	Percentage (%)
Female	23	41.8
Male	32	58.2

Table 2: Distribution of study participants according to Comorbidities

Comorbidities	Frequency (n=55)
CKD	9
Hypothyroidism	3
Cardiac disease	6
CVA	4

There were 9 cases with CKD, 3 cases with hypothyroidism, 6 cases with cardiac disease and 4 cases had CVA.

Table 3: Distribution of study participants according to R: ABPI S/O PAD

R: ABPI S/O PAD	Frequency (n=55)	Percentage (%)
No	17	30.9
Yes	38	69.1
Total	55	100.0

Table 4: Distribution of study participants according to Symptom

Symptom	Frequency (n=55)	Percentage (%)
Absent	48	87.3
Present	7	12.7
Total	55	100.0

There was more patient who were asymptomatic. Out of 55 subjects, 48 subjects were asymptomatic while 7 were having symptoms of disease.

Table 5: Distribution of study participants according to demographic, clinical and laboratory characteristic

Characteristic	Female		Male		Total	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	53.39	10.04	56.28	10.34	55.07	10.22
Duration of Diabetes (years)	8.63	7.00	10.47	6.44	9.70	6.68
Pulse	90.57	17.05	86.19	18.13	88.02	17.66
RR	20.48	4.28	18.53	2.68	19.35	3.54
Right Arm (S. Blood pressure)	130.00	26.20	127.06	15.02	128.29	20.28
Left Arm (S. Blood Pressure)	122.43	13.24	125.31	15.22	124.11	14.37
Right Ankle (S. Blood Pressure)	97.13	20.20	93.75	22.69	95.16	21.55
Left ankle (S. Blood Pressure)	100.78	16.35	98.13	15.83	99.24	15.95
Average SBP of Upper limb	126.22	17.53	126.19	14.64	126.20	15.76
ABPI	0.79	0.14	0.76	0.12	0.77	0.13
Right Limb (ABPI)	0.78	0.17	0.74	0.14	0.76	0.15
Left Limb (ABPI)	0.81	0.13	0.78	0.12	0.79	0.13
Right Index finger (Pulse Oximetry)	98.87	1.42	99.16	0.95	99.04	1.17
Left index finger (Pulse Oximetry)	98.83	1.44	98.94	1.13	98.89	1.26
Right Great Toe (Pulse Oximetry)	96.22	2.88	96.88	2.30	96.60	2.55
Left Great Toe (Pulse Oximetry)	96.91	2.71	96.59	2.42	96.73	2.53
Right Great Toe at 12-inch elevation (Pulse Oximetry)	95.83	2.64	95.13	2.66	95.42	2.65
Left Great Toe at 12-inch elevation (Pulse Oximetry)	95.87	2.67	95.22	2.66	95.49	2.66
HbA1c	9.03	1.66	9.19	2.88	9.12	2.42
Fasting S Glucose	253.96	85.6	283.25	134.21	271	116.36

[Table 5] shows mean values demographic, clinical and laboratory characteristic in male and female subjects.

Table 6: Distribution of study participants according to Characteristic

Characteristic	ABPI-Right	ABPI-Left	Pulse Oximetry-Right	Pulse Oximetry-Left	ABPI+ Pulse Oximetry-Rt	ABPI+ Pulse Oximetry-Lt
Sensitivity	75.0	65.5	90.6	93.1	100.0	96.6
Specificity	39.1	42.3	21.7	23.1	8.7	11.5
PPV	63.2	55.9	61.7	57.4	60.4	54.9
NPV	52.9	52.4	62.5	75.0	100.0	75.0

Accuracy	60.0	54.5	61.8	60.0	61.8	56.4
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[Table 6] shows sensitivity, specificity, positive and negative predictive value and accuracy of ABPI, pulse oximetry independently and in combination. It was observed that sensitivity increased when ABPI and pulse oximetry were used in combination. However, specificity of ABPI when used independently was greater than pulse oximetry.

DISCUSSION

This study was carried out at TMMC & RC (Moradabad, UP). It was a prospective hospital based observational study. In our study total 55 participants were taken out of which 23 (41.8%) are female and 32 (58.2%) are male. Considering other risk factors for PAD like smoking, hypertension, chronic renal disease, etc., they are compared. Out of 55 participants 30 (54.5%) are smokers and 25 (45.5%) are non-smokers. Among smokers all are males. Among 30 smoker participants 21 (70%) are ABPI positive and 9 (30%) are ABPI negative. Among 30 smoker participants 29 (96.7%) are pulse oximeter positive and 1 (3.33%) are pulse oximeter negative. Among 30 smoker participants 25 (83.3%) patients are diagnosed with LEAD via color Doppler whereas rest 5 (16.6%) have normal scan. Out of 50 participants, 27 (49.1%) are non-hypertensive and 23 (50.9%) are hypertensive. Among 27 hypertensive, 25 (92%) are ABPI positive and 2 (8%) are negative. Among 27 hypertensive, 26 (96%) are pulse oximeter positive and 1 (4%) are negative. Among 27 hypertensive, 23 (85%) are color Doppler positive and 4 (15%) are negative. Out of 55 participants, 35 (63.6%) are on regular treatment, 1 (1.8%) are on diabetic diet, 17 (30.9%) are on irregular medication and 2 (3.6%) are off treatment. Out of 55 participants, 15 (27.3%) are on insulin and 40 (72.7%) are on other treatment. There were patients with other co-morbidities namely nine had CKD, three had hypothyroidism, four had cardiac disease, four had CVA, one had pulmonary tuberculosis, one had Tubercular meningitis and one had hypothyroidism. Out of 55 patients, total 42 (76.36%) are ABPI positive, 37 (67.27%) have ABPI positive in right limb, 34 (61.81%) have ABPI positive in left limb and 29 (52.72%) participants have ABPI positive in both limbs. In our study, Right limb analysis suggestive of 75% of sensitivity, 39.1% of specificity, 63.2% of PPV and 52.9% of NPV. Right ABPI has 60% of accuracy. Left limb analysis suggestive of 65.5% sensitivity, 42.3% specificity, 55.9% PPV and 52.4% NPV. Left limb ABPI has 54.5% of accuracy. Average ABPI analysis: 70.25% sensitivity, 40.7% specificity, 59.55% PPV and 52.65% NPV. Average ABPI had an accuracy of 57.25%. Out of 55 patients, total 50 (90.5%) are pulse oximeter positive, 45 (81.8%) have pulse oximeter positive in right limb, 47 (85.5%) have pulse oximeter positive in left limb and 36 (65.4%) participants have pulse oximeter positive in both limbs. In our study, Right limb pulse oximeter analysis suggestive of 90.6% sensitivity, 21.7% specificity, 61.7% of PPV and 62.5% NPV. Right pulse oximetry method has 61.8% of accuracy. Left limb pulse oximeter method analysis suggestive of 93.1% sensitivity, 23.1% specificity, 57.4% PPV and 75% NPV. Left limb pulse oximetry method has 60% of accuracy. Average pulse oximeter analysis: 91.8% sensitivity, 22.4% specificity, 60% PPV and 68.7% NPV. Average ABPI had an accuracy of 60.9%. Polonsky et al (2021) in their study observed that an ABPI <0.9 had 57-79% sensitivity with a specificity of 83-99% for arterial stenosis of at least 50%.^[5] Summarizing both methods together concluded 98.3% sensitivity, 20.2% specificity, 57.6% PPV and 87.5% NPV with 59.1% of accuracy. Mf Abian et al (2021) in their study in 594 DM-II without LEAD patients <40 years observed LEAD in 18.4% subjects based on ABPI with significant correlation between oxygen saturation & ABPI at 30cm lower limb elevation.^[12]

Limitations of the Study

- Hospital-based study.
- Low sample size
- This study included patients with both DM-I & DM-II patients making our observations difficult to compare with pre-existing data in medical literature.
- Duplex ultrasonography was used as a reference standard in our study instead of CTA/DSA which are current gold-standard tools for diagnosing LEAD.

CONCLUSION

LEAD has been described as a predictor of CAD in many studies, hence there have been several attempts of using multiple screening tools for its early detection especially in DM which is associated with accelerated atherosclerotic process. As we have noticed in study maximum patients with LEAD are asymptomatic, these patients when left unmonitored presents with complication. With early detection we can prevent amputation decreasing burden on individual and society. Pulse oximetry of the lower limb digits, ankle-brachial pressure index and duplex ultrasonography of arteries in lower limb are various methods of detecting LEAD, each with its own set of advantages & limitations. We conclude that pulse oximetry is a very sensitive tool, useful for screening of LEAD in diabetics. Though ABPI is more specific than PO for LEAD detection, the overall accuracy of both tests is comparable. A combination of ABPI & PO, is however, most sensitive with highest negative predictive value. These methods are simple, cost effective, quick, non-invasive and easily available tools. Hence, detection of LEAD should be a part of regular work-up of DM patients.

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