

# A Study of Transcutaneous Oxygen Saturation by Pulse Oximetry in Symptomatic Ischaemic Lower Limb – A Cross Sectional Analytical Study in a Tertiary Care Hospital in Tirupathi

Sadhu Nagamuneiah<sup>1</sup>, Gandikota Venkata Prakash<sup>2</sup>, P. Sabitha<sup>3</sup>, Jandla Bhulaxmi<sup>4</sup>,  
Dintyala Venkata S.S. Mythri<sup>5</sup>, Pallaki Veera Reddy<sup>6</sup>

<sup>1, 2, 3, 4, 5, 6</sup> Department of General Surgery, Sri Venkateswara Medical College, Sri Venkateswara Ram Narayana Ruia Hospital, Tirupati, Andhra Pradesh, India.

## ABSTRACT

### BACKGROUND

Chronic arterial insufficiency (CAI) results in stenotic-occlusive disease of vascularized arterial disorders of tissues and organs. CAI of the lower extremities represents a significant medical and socio-economic problem due to a high incidence of morbidity, invalidity and mortality.

### METHODS

A cross sectional analytical study was conducted in a group of 100 patients, admitted at the Vascular Department of the Sri Venkateshwara Ramnaraian Ruia Government General Hospital, Tirupati during the period from September 2018 to August 2019, with evident symptoms and signs of different stages of lower extremities CAI verified by ultrasonography. In patients with lower extremity disorder of tissue arterial capillaries, SpO<sub>2</sub> was determined by pulse oximetry. CAI of the lower extremity was determined on the basis of clinical findings and colour Doppler duplex scan echo sonography results. Using the conventional method (single-gate) and colour Doppler duplex scan (multi-gate), the presence and localization of stenosis, the segmental predominance (with multisegmental forms) and the degree of progression of stenotic-occlusive lesions were verified.

### RESULTS

Results Using pulse oximetry, depending on the of stage of lower extremities CAI, we revealed a considerable difference in the stages of functional ischemia Mean SpO<sub>2</sub>: Fontaine I – 95.50 %, Fontaine II – 92.90; in stage critical ischemia SpO<sub>2</sub>: Fontaine III – 65.00 % and Fontaine IV – 49.87 %. In 29 patients with gangrenous foot and fingers SpO<sub>2</sub> was immeasurable and progressive decrease in SpO<sub>2</sub> of arterial capillaries (p<0.01 between stages).

### CONCLUSIONS

Due to the reliability and simplicity of pulse oximetry it can be a routinely used diagnostic device for patients with early determined stage of lower extremities CAI.

### KEYWORDS

Chronic Arterial Insufficiency, SPO<sub>2</sub>, Pulse Oximetry, Ischemia

*Corresponding Author:*

*Dr. Jandla Bhulaxmi,*

*D/o. Jandla Tirupalu, 1-54,*

*Sambavaram, Gosapadu,*

*Kurnool - 518501,*

*Andhra Pradesh, India.*

*E-mail: bulakshmijandla@gmail.com*

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## BACKGROUND

In Arterial degeneration diseases, mainly atherosclerosis is continuously increasing due to a worldwide aging human population. Atherosclerosis was a disease characterized by arterial luminal stenotic occlusion, along with gradual thickening of arterial wall with loss of elasticity.<sup>1</sup>

After the 20th century, it does not give valid results in lower limb circulation because of the loss of their sensitivity and specificity. The necessary improvement in the research of instruments and techniques resulted in discovering numerous and different objective methods applied in the diagnostics of peripheral vascular diseases.<sup>2</sup>

Among the invasive procedures, besides electronic oscillometer with oscillography, plethysmography, capillaroscopy, thermometry with thermography, Doppler echo sonography and its modality (Doppler, duplex scanning and triplex scanning color Doppler), in numerous worldwide studies, pulse oximetry has not shown valuable results in the determination of the stage of peripheral ischemia.<sup>3,4</sup> Pulse oximetry non-invasively measures arterial blood oxygen saturation and frequency of pulse with the confidence interval of  $\pm 2-3$  for SpO<sub>2</sub> values from 70-100 %, and  $\pm 3$  for SpO<sub>2</sub> values from 50-70 %, indicating the desaturation of oxyhaemoglobin before the colour of the patient's skin becomes evident.<sup>5</sup>

The rapidity in progression of symptoms was due to defective aerobic metabolism which in turn signify the complex hemodynamic changes of the limb.<sup>6</sup> The measurement of transcutaneous oxygen saturation levels of the lower limb was less commonly preferred due to the easy availability of Doppler ultrasound and also due to its cost-effectivity. This study was done to overcome the cost-effectiveness of Doppler ultrasound and show the diagnostic precision of pulse oximetry in comparison with color Doppler duplex scan ultrasonography in patients with Chronic Arterial Insufficiency (CAI) of lower extremities. The present study analyses the symptomatic ischaemic lower limbs, using non-invasive SpO<sub>2</sub> measurement by applying pulse oximetry for adult patients undertaken at the Sri Venkateswara Ramnaraian Ruia Government General Hospital, Tirupati. This study assessed the efficacy of pulse oximetry as a screening tool to detect significant ischemic lower limb because of its ready availability, cost-effectivity and non-invasiveness when compared to other investigations like Doppler, angiogram, etc.

### Aim

To study the efficacy of pulse oximetry in investigating ischemic lower limb disease in patients.

### Objectives

- To record cutaneous oxygen saturation levels in early detection and determination of the symptomatic ischemic limb patients by using pulse oximetry.
- To grade the levels of ischaemic changes based on saturation levels.

- To assess the age & gender of the patients with different stages of limb ischemia viz; functional limb ischemia, critical limb ischemia and gangrene pertaining to lowerlimb which correlates with (Fontaine stage I, IIa and IIb); (Fontaine stage III and IV); & (stage V) respectively.
- To stage the diagnostics of pulse oximetry in relation to colour Doppler duplex scan echo sonography in patients with symptomatic lower extremities.

## METHODS

This is a cross sectional study conducted among 100 patients presenting with symptomatic ischemic lower limbs in the Department of General Surgery, Sri Venkateswara Ramnaraian Ruia Government General Hospital, Tirupati over a period of one Year From the approval by the ethical and scientific committee between September 2018 to August 2019, among patients who manifested signs and symptoms of the different stages of Chronic Arterial Insufficiency (CAI) of lower extremities verified by ultrasonography. CAI of the lower extremity was determined on the basis of clinical findings and colour Doppler duplex scan echo sonography results. In our study, a total of 100 limbs were taken and in cases of bilateral involvement, high severity limb was considered into this study. Informed written consent would be taken from patients included in the study. Data was collected in standardized proforma from all the Patients presenting to department of General Surgery, S.V.R.R.G.G.H. Tirupati. Patients fulfilling the inclusion and exclusion criteria are selected.

Patients were clinically graded according to Fontaine classification and then SpO<sub>2</sub> was determined. The determination of SpO<sub>2</sub> was performed in all patients using pulse oximetry as a part of monitoring, applied after the patients were acclimatized to temperature from 22-23°C. For these patients, SpO<sub>2</sub> of 95%  $\pm$  2 & higher was considered normal while lower values indirectly depict different stages of ischemia. After clinical examination, patients with different stages of limb ischemia were subjected to Colour Doppler duplex scan ultrasonography to determine various factors like extent and localization of stenosis, if present; segmental involvement etc.

### Study Methods

- Detailed history taking,
- Lower limb examination,
- Estimating great toe transcutaneous o<sub>2</sub> by using pulse oximetry.

### Inclusion Criteria

1. Patient informed and written consent
2. Patients with ischemic arterial disease of lower limbs.

### Exclusion Criteria

Patient not willing to participate in study.

**Statistical Analysis**

Data was entered into excel sheet and analyzed by using software SPSS version 21.0. Continuous variables were expressed as mean with Standard Deviation (SD) after checking for the normality. Chi-square test was performed with to find association between the Outcome of disease and various variables. Yates correction was applied wherever needed. P value <0.05 was considered as statistically significant. One-way ANOVA was performed to estimate the variance of mean oxygen saturation within different variables.

**RESULTS**

Risk Factor	<40 Years (n = 17)	41 – 60 Years (n = 63)	>60 Years (n = 20)	Total (n = 100)
Diabetes mellitus	1 (5.9 %)	46 (73 %)	14 (70 %)	61 (61 %)
Hypertension	0	26 (41.3 %)	9 (55 %)	37 (37 %)
Smoking	15 (88.2 %)	6 (9.5 %)	0	21 (21 %)
Alcohol	5 (29.4 %)	3 (4.8 %)	0	8 (8 %)
Known cardiac disease	0	2 (3.2 %)	0	2 (2 %)
Hyperlipidaemia	0	2 (3.2 %)	0	2 (2 %)

**Table 1. Distribution of Study Participants by Age and Risk Factor**

Outcome of the Disease	<40 years	41 – 60 Years	>60 years	Total
Conservative	16 (94.1 %)	20 (31.7 %)	0	36 (100 %)
Open and Endovascular Surgery	0	34 (54.0 %)	1 (5 %)	34 (100 %)
Amputation	1 (5.9 %)	9 (14.3 %)	19 (95 %)	29 (100 %)
<b>Total</b>	<b>17 (100 %)</b>	<b>63 (100 %)</b>	<b>20 (100 %)</b>	<b>100 (100 %)</b>

**Table 2. Distribution of Study Participants by Age and Outcome of the Disease**

Outcome of the Disease	Male	Female	Total
Conservative	31 (40.3 %)	5 (21.7 %)	36 (100 %)
Open and Endovascular Surgery	23 (29.9 %)	12 (52.2 %)	35 (100 %)
Amputation	23 (29.9 %)	6 (26.1 %)	29 (100 %)
<b>Total</b>	<b>77 (100 %)</b>	<b>23 (100 %)</b>	<b>100 (100 %)</b>

**Table 3. Distribution of Study Participants by Gender and Outcome of the Disease**

Grade of the Disease	SpO <sub>2</sub> (%)	
	Mean	Standard Deviation
Grade I	95.50	.516
Grade II	92.90	.718
Grade III	65.00	1.892
Grade IV	49.87	2.588
Grade V	0	0

**Table 4. Distribution of Study Participants by Grade of the Disease and Oxygen Saturation by Pulsoximetry**

Level of Obstruction in Doppler	SpO <sub>2</sub> (%)	
	Mean	Standard Deviation
Diffuse narrowing of vessels with no obstruction	94.47	.516
Aorto-iliac	66.55	16.52
Femoropopliteal	44.95	6.081
Multiple segmental	0	0
Tibio-dorsal	0	0
Tibio-peroneal	94.0	0

**Table 5. Distribution of study participants by level of Obstruction in Doppler and Oxygen Saturation by Pulsoximetry**

Severity of Occlusion	SpO <sub>2</sub> (%)	
	Mean	Standard Deviation
Skin changes with no severity	95.47	.516
Mild	93.0	.970
Moderate	59.81	15.794
Severe	3.834	14.758

**Table 6. Distribution of Study Participants by Severity of Occlusion and Oxygen Saturation by Pulsoximetry**

Outcome of the Disease	SpO <sub>2</sub> (%)	
	Mean	Standard Deviation
Conservative	94.06	.1453
Open and endovascular surgery	58.51	7.905
Amputation	0	0

**Table 7. Distribution of Study Participants by Outcome of the Disease and Oxygen Saturation by Pulsoximetry**

**DISCUSSION**

The study was conducted between September 2018 and august 2019, a total 100 patients who presented with symptoms and signs of peripheral arterial disease (PAD) were taken into study. The purpose of this study was to analyse the usefulness of transcutaneous SpO<sub>2</sub> screening tests for PAD. Peripheral Arterial Disease can present clinically with varied symptoms and thorough examination can grade the disease while clinical presentation depends on presence or absence of steno-occlusive lesion, if present, site and extent of involvement with compensatory development of collaterals. CAI can be discovered in symptomatic individuals when presented with intermittent claudication or with distal trophic lesions while in asymptomatic individuals CAI was suspected during routine physical examination.<sup>7</sup> PAD was a risk factor for increased total mortality and cardiovascular events.<sup>8</sup> This risk seems to persist even when PAD is subclinical. As reviewed by Moore diabetes was the most common risk factor followed by hypertension with fewer other common causes. However, awareness of PAD, its significance and screening for PAD was low among physicians.<sup>9</sup>

Currently recommended screening tests include pulse palpation and the ABI. The negative predictive value of a posterior tibial pulse is 96 %, but the positive predictive value is only 49 %. The dorsalispedis is congenitally absent in 4 % to 12 % of the population.<sup>10</sup> Severinghaus has been reported ABI as very sensitive and specific test in patients suspected of having arterial disease,<sup>7</sup> while others report that the ABI is not a sensitive test in patients. Hooi JD mentioned that previous reports of sensitivity and specificity in excess of 90 % for the ABI have involved patients with symptoms and signs of PAD and have not used ABI strictly as a screening test.<sup>8</sup> Study was done by Ahrens to overcome the drawback of ABI and doppler ultrasound which is cost effective and operator dependent by using simple non-invasive screening techniques such as pulse oximetry. The pulse oximetry was fast, easy to perform, inexpensive and can be used in a primary health care population in which saturation values were compared with standard arterial doppler report and shows that screening of PAD by pulse oximetry is equivalent to arterial doppler. When screening a population of PAD, a high-sensitivity is important. In their study accuracy of pulse oximetry is correlated with arterial doppler. In 1945 the French surgeon René Fontaine made a classification of stages of PAD of lower extremities according to the severity of lower extremity PAD.<sup>11</sup> The original classification according to the progression or regression of the disease was based on illness history data and it was still in use up-to-date. First stage was marked by uncharacteristic initial problems involving the lower limbs

(coldness, numbness, fatigue), second stage was characterized by intermittent claudication symptoms (intensive spasm in sporadic muscle groups of legs) with the passed claudication distance of over 100 meters in stage IIa and shorter than 100 meters in stage IIb. Third stage was presented by pains during night and at rest. Fourth stage presents with loss of sensation to the lower part of the extremity. Fifth stage presents with ulcerations and gangrene of feet and lower extremities below knees. As per epidemiological study conducted by Joyce et al., 5% of men & 2.5% of women with age above 65 years from the general population have early symptoms Lower extremity PAD. The prevalence of intermittent claudication and functional ischemia symptoms in men younger than 60 years is about 1-2 %, while it is higher in men older than 60 years (5 %).<sup>12</sup> In our study on 100 patients, 77 % are males and 23 % are females. The mean age was 50.42 years with standard deviation of 12.672 years. In this study groups (in stages of functional ischemia, with male to female ratio of 6.2:1, and in stages of patients were >60years, shows higher risk factor of Diabetes & Hypertension, which also confirms the study of Criqui et al. on the incidence of risk factor and clinical manifestation of CAI of lower extremities.<sup>13</sup> Among them 17 patients were < 40 years & shows higher risk factor of smoking & alcoholism, 63 patients were in the age group of 41-60 years and 20. Unlike an acutely ischaemic foot that is often cold, white, paralyzed, and insensate, a critical ischaemic lower limb tends to equilibrate with the temperature of the surroundings. It may feel quite warm under the bedclothes. Chronic ischemia does not produce paralysis.<sup>14</sup>

In our study, according to FONTAINE classification, 29 % of patient presents with Grade 5 (gangrene) which is more common & are seen in patients of >60 years of age & are mostly males, 20 % of patients presents with Grade 2,3 & are seen in age group of 41-60 years, 16 % of patients presents with Grade 1 are seen in patients of < 40 years of age, 15 % of patients presents with Grade 4 are seen in mostly females of age group of 41-60 years.

The results of Arterial Doppler study of our patients are as follows, in age group of <40 years, 88.2 % of patients shows diffuse vessel wall thickening with no obstruction, in age group of 41-60 years, 55 % of patients show moderate obstruction & 27 % shows mild obstruction, in age group of > 60 years, 90 % of patients show severe obstruction & 10 % of patients shows moderate obstruction, which clinically correlates as

Grade 1-diffuse vessel wall thickening with no obstruction,  
Grade 2-Mild obstruction,  
Grade 3, 4-Moderate obstruction,  
Grade 5-Severe obstruction.

The results of correlation of Transcutaneous O<sub>2</sub> saturation with Arterial Doppler are,

- Diffuse vessel wall thickening with no obstruction (Grade 1)- Mean SpO<sub>2</sub> of 95.47 %,
- Mild obstruction (Grade 2)-Mean SpO<sub>2</sub> of 93 %,
- Moderate obstruction (Grade 3, 4)-Mean SpO<sub>2</sub> of 59.81 %.
- Severe obstruction (Grade 5)-Mean SpO<sub>2</sub> of 3.83 %.

In this study, 31.2 % of male patients shows Moderate & Severe obstruction, 19.5 % Of male patients shows diffuse vessel wall thickening with no obstruction, 56.5 % of female patients shows Moderate obstruction, 26.1 % of female patients shows severe obstruction. Management of patients based on severity of occlusion in Arterial Doppler study shows

- Diffuse vessel wall thickening with no obstruction/
- Mild obstruction- 100 % were treated with Conservative management,
- Moderate obstruction-89,2 % were treated with Open Endovascular surgery,-8.1 % were treated Conservatively,
- Severe obstruction- 93.3 % were amputated &-6.7 % were undergone Open Endovascular surgery.

The above results show that, pulse oximetry is Equivalent or more to Arterial Doppler for being used as screening test for PAD.

Pulse oximetry measures peripheral blood haemoglobin 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>10</sup> Steno-occlusive abnormality can be clinically suspected when decrease in SpO<sub>2</sub> of more than 2% present with elevation of lower limb by twelve inches or decrease in SpO<sub>2</sub> of more than 2% in comparison with upper limb. In a study by Joyce, pulse oximetry investigation of SpO<sub>2</sub> of the foot dorsum and posterior tibial area in patients with peripheral arterial-occlusive disease, intermittent claudication and critical ischemia, indicates that there is a significant correlation between the decreased SpO<sub>2</sub> and the stage and the level of lower extremity arterial occlusion.<sup>15</sup>

The severity of the stenosis in PAD cases depicted by Doppler Ultrasonography and Doppler duplex scan were in accordance with SpO<sub>2</sub> values determined through pulse oximetry. In a study by Couse et al. similar results were obtained when diagnosis was made in patients with peripheral vascular insufficiency by experimental provocation of a specific stage of occlusion, through application of tourniquet pressure at a specific level of the lower extremity; indirect data on the transient major artery of the lower extremity obtained by ultrasonography colour Doppler duplex scan were compared with the findings of pulse oximetry.<sup>11</sup>

In this study, we divided patients by symptomatic criteria, not by treatment modality, open and endovascular surgery and amputation because recent publications reported no difference between endovascular treatment and open surgery in multi-level studies. All of the tests were performed on each extremity for comparison. The technique is non-invasive.

The usage of Pulse oximetry was widely noted in vivid places like Emergency departments, Out Patient Departments to assess cardiac and respiratory functionality. On average, it took 5 minutes to complete the test. Later technical development of pulse oximetry involves the solution of the problem with respect to modifications of the skin sensor of pulse oximetry which will extend the spectrum of its application and the precision of measurements by reducing sensitivity of the signal to movements and improvement of

the sensitivity in patients with darker pigmentation and disaemoglobinemia.<sup>12</sup>

The diagnostic value of pulse oximetry in CAI cases was predicted by Parameswaran et al through their study due to its high level of precision and ease of usage. SpO<sub>2</sub> values of lower extremity distal tissues can be applied for estimating the outcomes of planned surgical reconstructive procedures and determining the safe level of the amputation of extremities in patients with critical ischemia and developed tissue necrosis and gangrene.<sup>16</sup>

### Limitations

1. Sample size was a limiting factor as the duration of the study was limited to 12 months and controlled parameters are similar. If the parameters were more diverse the sample size would be much even smaller and this would have led to poor results.
2. Multicentric studies cover wide range of population with better results when compared to our single center study.
3. Subjective variability in the assessment of disease can be nullified with accountance of interobserver variability.
4. Observer Bias due to sequential clinical followed by radiological assessment of the patient might influence the results.

### CONCLUSIONS

These results suggest pulse oximetry may be a useful tool to screen for PAD in symptomatic patients. The assessment of stage and severity of CAI, done through pulse oximetry was in correlation with that of Colour Doppler Duplex Ultrasonography which depicts the diagnostic precision of pulse oximetry.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

Financial or other competing interests: None.

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