

## **RISK OF LOWER EXTREMITY PERIPHERAL ARTERY DISEASE AND PRESENCE OF SYMPTOMS OF INTERMITTENT CLAUDICATION AMONG DIABETIC PATIENTS: CROSS SECTIONAL STUDY**

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### **ABSTRACT**

**Background:** Diabetes mellitus, a chronic metabolic non-communicable disease (NCD), has attained epidemic proportions worldwide <sup>1</sup>. Peripheral arterial disease (PAD) is one of the diabetic macro vascular complications <sup>2</sup>. It is a marker of generalized systemic atherosclerosis and is closely associated with symptomatic coronary and cerebrovascular disease. Among diabetic populations, screening and diagnosis of PAD are frequently suboptimal<sup>2</sup>. Epidemiologic data have shown a strong association between PAD and DM. ABI was unanimously recommended as the primary diagnostic tool for PAD <sup>3</sup>. International studies indicate that screening is rarely performed in the primary care setting <sup>4, 5</sup>. To document the presence or absence of the symptoms of intermittent claudication i.e. leg-muscle discomfort on exertion that is relieved with rest <sup>6</sup>, the Edinburgh intermittent claudication questionnaire was used. It clearly indicates if the patient had an asymptomatic disease or not <sup>6</sup>.

**Objective:** This study aimed to evaluate the risk of Lower Extremity Peripheral Artery Disease among diabetic patients and to identify the presence of intermittent claudication among diabetic patients.

**Design:** Cross-sectional study design.

**Setting:** Diabetic Outpatient Department of K.G. Hospital, Coimbatore.

**Methods:** A total of 60 subjects were selected by the purposive sampling technique. Lower extremity peripheral arterial disease was assessed in all patients using Ankle Brachial Pressure Index, the Edinburgh Claudication Questionnaire was used to determine if patients had the symptomatic disease or not.

**Results:** Peripheral Arterial Disease was prevalent in 14[23 %] study participants of these 11[79 %] had symptoms of definite intermittent claudication.

**Conclusion:** This present study helped to give insight, into the training programme that should be organized for patients with Diabetes Mellitus to create awareness about the risk of Peripheral Artery Diseases.

**KEYWORDS:** Ankle Brachial Pressure Index, Diabetes Mellitus, Edinburgh Claudication Questionnaire, Intermittent Claudication, Peripheral Arterial Disease

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## INTRODUCTION

Worldwide, there come several diseases such as Hypertension, Coronary Artery Disease, Cerebrovascular Disease, Muscular Deformities, Obesity, and mainly Diabetes Mellitus which are pandemics on all continents. An estimated 463 million adults aged 20-79 years are currently living with Diabetes Mellitus and this number is estimated to increase to 700 million by 2045<sup>7</sup>. The most frequent diabetes forms are Type I Diabetes and Type II Diabetes<sup>4, 5</sup>. 90 % to 95 % of those have type II Diabetes Mellitus<sup>4</sup>. It is reported that globally more than 70 % of diabetics develop foot ulcers in their lifetime, which precede almost 85 % of amputations; Diabetic patients are vulnerable to foot ulcers because of the complication of Diabetic Neuropathy (DPN), Peripheral Artery Disease (PAD) and Limited Joint Movement (LJM) with a high risk of infection. Most commonly Peripheral Artery Disease affects the legs in the lower extremities<sup>6</sup>.

Peripheral Artery Disease is a narrowing of the arteries other than those supply heart and brain. There is an inadequate supply of oxygenated blood to the peripheral tissues. People with diabetes are prone to Peripheral Artery Disease that damage the blood vessel and nerves. This in turn may result decreased ability to sense trauma or pressure foot<sup>9</sup>. Poor economic ignorance, inadequate medical facilities, and inadequate knowledge are some of the other contributing factors. Usually where the patients are not prepared for self-care.

International Diabetic Federation (IDF) reported that every 30 seconds a person loses a limb somewhere in the world due to a diabetic foot problem. It is estimated that one out of three people with Diabetes Mellitus over the age of 50 have a Peripheral Arterial Disease.

International Diabetes Federation (IDA) lists of top 10 countries with diabetes as follows China 116.4 million, India 77.0 million, United States of America 31.0 million, Pakistan 19.4 million, Brazil 16.8 million, Mexico 12.8 million, Indonesia 10.7 million, Germany 9.5 million, Egypt 8.9 millions and Bangladesh 8.4 million<sup>8</sup>.

The National Urban survey conducted in 2014 across the metropolitan cities of India reported 13.5 % in Chennai and about 5708 people in Coimbatore. The patient with Diabetes Mellitus has various associated complications which include, nerve damage (neuropathy) 90 %, nephropathy, 44 %, retinopathy 90 %, foot damage 60 %, Alzheimer's disease 8 %, stroke 1, 5 %, cardiovascular disease 50 %<sup>8</sup>.

Even though people with Diabetes Mellitus have several other co-morbid conditions, Peripheral Artery Disease is one of the severe complications where the signs and symptoms remain silent while compared to other complications<sup>8</sup>. Peripheral Artery Disease finally ends up with the lower extremity amputation<sup>8</sup>.

ANKLE BRACHIAL PRESSURE INDEX (ABPI) is defined as the systolic blood pressure measured at the ankle divided by the systolic blood pressure in the arm during supine rest. Is the most widely used quantitative measure to determine the presence and severity of Peripheral Artery Disease.<sup>8</sup>

CLAUDICATION is defined as the pain that is caused by reduced blood flow to the legs or arms because of atherosclerosis which is usually the symptom of Peripheral Arterial Disease.

INTERMITTENT CLAUDICATION is an aching, cramp and sometimes burning pain in the legs that comes and goes. It typically occurs with walking and goes away with rest due to poor circulation of blood in the arteries of the legs.<sup>10</sup>

DEFINITE CLAUDICATION is stated only when a person indicates pain in the calf, regardless of whether pain also occurs in the other site showing the presence of Peripheral Artery disease among patients with Diabetes Mellitus<sup>1</sup>.

ATYPICAL CLAUDICATION is stated only if person indicates pain in the thigh or buttock, in the absence of any pain in the calf muscle showing the presence of Peripheral Artery Disease among patients with Diabetes Mellitus<sup>7</sup>.

## **INCLUSION CRITERIA**

Type-II Diabetic patients above 40 years, both male and female patients, Patients with a history of Diabetes Mellitus for more than 5 years, Patients with a history of comorbid conditions including hypertension, Coronary Artery Disease, Cerebrovascular Disease, Patients who can understand Tamil and English, and Patients who are willing to participate were included.

## **Exclusion Criteria**

Patients with a known case of Peripheral Artery Disease, Patients with Type-I Diabetes Mellitus, Patients who have skin ulcers or bluish skin in the lower extremities, and Patients who are deaf and dumb.

## **METHODS**

In this research study, the researchers had adopted a quantitative approach and descriptive cross sectional study design. The study was conducted by purposive sampling technique which was conducted on 60 Diabetes Mellitus patients of diabetic Outpatient Department of K.G. Hospital Coimbatore. Data collection was done for two weeks. The subjects who met the inclusion and exclusion criteria were selected. Before the data collection, the researchers introduced themselves, explained the purpose of the study, and assured the confidentiality of the patient and written consent was obtained from them individually.

Pre tested and pre coded questionnaires were used to collect the study information which included socio demographic characteristics.

Ankle-brachial index (ABI) is widely accepted as a simple, non-invasive, inexpensive, yet reliable measurement for PAD and cardiovascular risk assessment. ABI measurement can easily be obtained with a blood pressure cuff and a Doppler ultrasonic sensor in 10–15 minutes. To ensure accurate measurement, the following instructions are recommended: 1) Ask patients to recline and rest for 5–10 minutes in a supine position. 2) Measure systolic blood pressure in both arms and in both ankles from the dorsalispedis and posterior tibial arteries. 3) Choose appropriate cuff size with cuff width approximately 20 % larger than the limb diameter. 4) Place the blood pressure cuff approximately 2–3 cm above the medial malleolus. 5) Locate and listen to the pulse signal. Normal pulse generates three arterial components or triphasic signals. Stenosis is associated with monophasic sounds. 6) Inflate the cuff to at least 20 mmHg beyond the calibration where the pulse signal disappears. 7) Slowly deflate the cuff until the signal returns, concordant with the measurement of systolic pressure for that vessel<sup>11</sup>.

The Doppler signal from the brachial artery was used to obtain the arm pressure while that from the dorsalispedis and posterior tibial arteries was used to obtain the ankle pressure. ABI was calculated by this formula:

$$\text{ABI} = (\text{maximum systolic pressure of dorsalispedis artery or tibialis posterior}) / (\text{maximum Systolic pressure of brachial artery})^{12}$$

Risk for Peripheral Arterial Diseases was identified from each sample using the Ankle Brachial Pressure Index (ABPI) method<sup>10, 11</sup>. PAD was defined as an ABI 0.9 Mild, moderate and severe obstruction were defined as ABIs of 0.7–0.9, 0.4–0.69 and <0.4 respectively. A value of 0.91–1.3 was defined as a normal ABI while an ABI >1.3 signified poorly compressible arteries or arterial calcification<sup>13</sup>.

To document the presence or absence of the symptoms of intermittent claudication, the Edinburgh intermittent claudication questionnaire was used<sup>12, 15, 16</sup>. 7-8 patients were selected per day.

### ETHICAL APPROVAL

Ethical approval to conduct this study was obtained from K.G. College of Health Sciences and the research and ethics committee K. G. Hospital, Coimbatore.

All the study participants provided written informed consent to participate in this study.

### STATISTICAL ANALYSIS

The collected data were analyzed using descriptive and inferential statistics.

**Table 1: Distribution of Demographic Variables among Diabetic Patients**

n=60			
S. No	Demographic Variables	Number	Percentage (%)
<b>1.</b>	<b>Age in Years</b>		
	41-50	13	22
	51-60	23	38
	61-70	17	28
	71	7	12
<b>2.</b>	<b>Gender</b>		
	Male	30	50
	Female	30	50
<b>3.</b>	<b>Family History of Diabetes Mellitus</b>		
	yes	33	55
	No	27	45
<b>4.</b>	<b>Duration of Diabetes Mellitus in Years</b>		
	5-10	28	47
	10-15	24	40
	>15	8	13
<b>5.</b>	<b>Diabetic Treatment</b>		
	Metformin only	10	17
	Glibenclamide only	7	12
	Glibenclamide and Metformin	19	31
	Insulin only	9	15
	Insulin and Metformin	15	25
<b>6.</b>	<b>Fasting Blood Sugar</b>		
	< 110 mg/dl	1	2
	110-125 mg/dl	5	8
	>126 mg/dl	54	90
<b>7.</b>	<b>Body Mass Index</b>		
	18.5-24.9, 33	20	33
	25.6-29.9	33	55
	30.0-34.9	7	12
<b>8.</b>	<b>The Current Habit of Smoking</b>		
	Yes	6	10
	No	54	90
<b>9.</b>	<b>The Former Habit of Smoking</b>		
	Yes	7	12
	No	53	88

**Table 2: Distribution of Ankle Brachial Pressure Index among Patients with Diabetic Mellitus**

n=60			
S. No	Ankle Brachial Pressure Index	Number	Percentage (%)
1.	Normal Ankle Brachial Pressure Index	46	77
2.	mild Peripheral Artery Disease	8	13
3.	moderate Peripheral Artery Disease	6	10

**Table 3: Distribution of Presence of Symptoms of Intermittent Claudication among Patients with Diabetic Mellitus Who Are At Risk of Lower Extremity Peripheral Artery Disease**

n=60			
S. No	Variable of Intermittent Claudication	Number	Percentage (%)
1.	Atypical Claudication	3	21
2.	Definite Claudication	11	79

**Table 4: Association of Risk of Peripheral Artery Disease among Patients with Diabetes Mellitus with Selected Demographic Variables**

n=60					
S. No	Demographic Variables	Mean		Calculated Value	Tabulated Value at X <sup>2</sup> at 5% level of Significance
		Above Mean	Below Mean		
<b>1.</b>	<b>Age</b>				3.84
	41-60 Years	25	10	15.4	
	>61 Years	5	20	(S)	
<b>2.</b>	<b>Gender</b>				
	Male	17	13	3.29	
	Female	10	20		
<b>3.</b>	<b>Family History</b>				
	Yes	20	8	14.8	
	No	7	25	(S)	
<b>4.</b>	<b>Duration of Diabetes Mellitus in Years</b>				
	5-10 years	28	15	14.8	
	> 10 years	1	16	(S)	
<b>5.</b>	<b>Fasting Blood Sugar</b>				
	<126 mg/dl	6	3	0.69	
	> 126 mg/dl	23	28	(NS)	
<b>6.</b>	<b>Body Mass Index</b>				
	18.5-29.9	24	29	0.189	
	30.0-34.9	2	5	(NS)	
<b>7.</b>	<b>Current Habit of Smoking</b>				
	Yes	2	28	0.20	
	No	1	3	(NS)	
<b>8.</b>	<b>Former Habit of Smoking</b>				
	Yes	27	27	1.25	
	No	1	5	(NS)	

(S-Significant) ((NS – Not Significant)

## RESULTS AND DISCUSSIONS

Table 1 shows the distribution of demographic variables among diabetic patients.

Regarding the age of diabetic patients, 13(22 %) of them were between 41-50 years, 23(38%) of them were between 51-60 years, 17(28 %) were between 61-70 and 7(12 %) of them were above 71 years. Of the 60 patients recruited in the study, concerning gender 30(50 %) of them were males and 30(50 %) of them were females, giving a male: female ratio of 1:1.

Considering the family history of diabetes, 33(55 %) of them do not have any family history of Diabetes Mellitus.

Regarding the duration of Diabetes Mellitus, 28 (47 %) of them had diabetes for 5-10 years, 24 (40 %) had diabetes for 10-15 years and 8(13 %) of them had diabetes for more than 15 years.

Along with conservative management using diet and exercise, participants received pharmacological therapy for glucose lowering. 10 (17 %) were taking metformin only, 7 (12 %) were taking Glibenclamide only, 19(31 %) were taking Glibenclamide and Metformin, 9(15 %) were taking Insulin only and 15 (25 %) were taking Insulin and Metformin.

Regarding fasting blood sugar levels 1(2 %) had blood sugar value between 110-125 mg/dl, and 54 (90 %) had blood sugar value above 126mg/dl.

Regarding the Body Mass Index of patients with Diabetic Mellitus Normal BMI, overweight and obesity were documented in 20 (33 %),33 (55 %) and 7(12 %) respectively.

While considering the habit of smoking 6(10 %) of them have the habit of smoking and majority of the study participants were non-smokers 54 (90 %).

About the former habit of smoking 7(12 %) of them were ex-smokers and 53(88 %) of them did not have the former habit of smoking.

Table 2 shows the distribution of ABPI among Diabetes patients which revealed that, using the ABI measurement, a low ABI of 0.9 to define the presence of PAD was noted in 14(23 %) participants, among these 6(10 %) participant who had moderate obstruction, the rest of the participants had mild obstruction 8(13 %). No study participant had severe PAD and poorly or non-compressible vessels. 46 (77 %) had normal Ankle-brachial Pressure Index.

Table 3 shows the presence of intermittent claudication in lower extremity peripheral artery disease among Diabetes Mellitus patients. Using the Edinburgh intermittent claudication questionnaire in the 14 study participants with a low ABI of 0.9, 11(79 %) had definite claudication whereas 3(21 %) had atypical claudication.

Table 4 shows the level of association of risk factors of Peripheral artery Disease among diabetic patients with the selected demographic variables. An association was found by using the chi-square test. From table 4, we observed that the calculated value of  $X^2$  greater than the tabulated value of  $X^2$  at a 5 % level of significance ( $p > 0.05$ ) to the demographic variables including age, family history of Diabetes Mellitus, and duration of Diabetes Mellitus. The results showed that there was an association between age, family history, duration of Diabetes Mellitus, and the risk of Peripheral Artery Disease among patients with Type II Diabetes Mellitus.

## Discussion

To our knowledge, this is the study to examine the prevalence of PAD in diabetic patients using ABI measurement. We report a prevalence of PAD among 14(23 %) participants in this study population. Majority of the study participants had mild obstruction 8(13 %), 6(10 %) participants who had moderate obstruction according to the ABI measurement. In this study risk of Peripheral Artery Disease was associated with age, family history, duration of Diabetes Mellitus.

Peripheral arterial disease is often referred to as an under-diagnosed and under-treated public health problem. Patients with PAD have a significantly increased risk for serious CVD events, and risk factor management in PAD patients would likely reduce this risk. Therefore, routine screening for PAD using ABI has been advocated for all people's 50 years old with history of smoking or diabetes, and among all adults with lower extremity circulation problems indicative of claudication symptoms.<sup>17</sup>

The study results are similar to a cross-sectional observational study conducted by Jane H Davies et al., Ankle Brachial Index (ABI) was used to screen the participants and they completed Edinburgh Claudication Questionnaires. A total of 368 people participated in the study (participation rate: 33 %). Prevalence of PAD was 3 % (n=12). Among them, 33 % reported severe lifestyle-limiting symptoms of intermittent claudication that warranted subsequent endovascular intervention.<sup>18</sup>

Another study results are similar to a cross sectional study carried out on 200 Type 2 diabetes mellitus patients attending the medicine OPD and indoor departments of a tertiary care Hospital to assess the prevalence of Peripheral Arterial Disease conducted by Vaibhav Shukla et al., Ankle brachial pressure index was used to assess PAD. Prevalence of PAD was 36 % in T2DM patients. There was a significant association between PAD and duration of diabetes, waist circumference, hypertension and micro vascular complications.<sup>19</sup>

Among different studies carried out in Indian subcontinent the prevalence of PAD in diabetes ranged from 4.47 % to 39.28 %<sup>12-14, 20</sup> depending upon patient characteristic, geographical differences and other study specific correlates.<sup>20, 21, 22</sup>

## **CONCLUSIONS**

The study showed that Lower Extremity Peripheral Artery disease occurs most commonly in Diabetes Mellitus patients. It also reveals that a section of patients with PAD can be asymptomatic. The training programme should be organized for patients with Diabetes Mellitus to create awareness about the risk of Peripheral Artery Diseases. Regular national or regional awareness and training seminars for health workers and patients should be introduced with an aspiration of improving diabetes care i.e. ensuring optimal glycemic, blood pressure and lipid control, screening for macro and micro vascular complications and appropriate primary and secondary prophylaxis against PAD.

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## **CONFLICT OF INTEREST**

The authors declared no conflict of interest.

## **AUTHOR'S CONTRIBUTIONS**

Santhipriya A and Dr. V. Selvanayaki conceptualized the study and were involved in data acquisition; performed data analysis and drafted the manuscript and critically revised the manuscript. Both the authors read and approved the final version of the manuscript.

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