

## Original Research Article

# Prevalence of peripheral arterial disease in type 2 diabetes mellitus and its correlation with carotid intima-media thickness

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## ABSTRACT

**Background:** Peripheral arterial disease (PAD) is one of the major macrovascular complications of diabetes mellitus (DM) which is largely neglected by clinicians. DM-associated atherosclerosis can lead to complications in all major of vascular beds, including the coronary arteries, carotid vessels, and lower extremity arteries. Aims and objective were to study the prevalence of PAD in patients with type 2 DM and to study the correlation with carotid artery intima-media thickness

**Methods:** Hospital based cross-sectional study was conducted among the 124 patients admitted with type 2 diabetes (age >25 year) from Dec 2019 to Oct 2021 in the various units of department of medicine or surgery, KPS institute, GSVM medical college Kanpur. Color doppler of limbs and carotid artery was done in study population.

**Results:** In our study based on doppler ultrasound, the prevalence of PAD was found in 31 patients (25%) out of 124 with men having a higher prevalence (24 out of 74; 77.4%), as compared to women (7 out of 50; 22.6%) ( $p=0.020$ ). The mean Carotid IMT (mm) (Average) was  $0.82\pm 0.16$  in all diabetics. Patients with PAD have more increase in CIMT ( $0.95\pm 0.12$ ) as compare to non-PAD ( $0.77\pm 0.15$ )  $p<0.001$ .

**Conclusions:** By using doppler, we found evidence of PAD in 25% of type 2 diabetics (M>>F). Patients with PAD have more increase in CIMT as compare to non-PAD.

**Keywords:** PAD, Type 2 DM, Carotid intima media thickness

## INTRODUCTION

Diabetes mellitus (DM) is an important health problem that is widely prevalent all over the world and the prevalence has increased dramatically over the last two decades.<sup>1,2</sup> Over 170 million people worldwide have DM and the worldwide burden is projected to increase to 366 million people by 2030 with a maximum increase in India. The prevalence of diabetes in Indian population is 8.9% according to IDF (17% of global burden).<sup>3</sup> DM-associated atherosclerosis can lead to complications in all major of vascular beds, including the coronary arteries, carotid vessels, and lower extremity arteries. The signs and symptoms of ischemia develop when the atherosclerotic narrowing of the blood vessels exceeds 70% of the lumen (critical stenosis). In the absence of clinical symptoms and

signs in the early stages of the disease, the emphasis of management in patient of PVD lies in the early detection of the disease so as to prevent or at least reduce the rate of complication.

Carotid intima-media thickness (IMT) is related to cardiovascular risk factors and diseases, and its measurement by means of ultrasound makes it possible to detect thickening in the initial phases of atherosclerosis.<sup>4,5</sup> For every 0.1-mm increase in carotid IMT, the relative risk of ischemic heart disease increases by 15% and that of cerebrovascular disease by 18%.<sup>6</sup> These wall changes, particularly in the elastic carotid arteries, may be an adaptive mechanism to cardiovascular stress in diseases like DM and hypertension as a result of atherosclerosis.<sup>7</sup>

For assessment of macrovascular complications, carotid intima media thickness (CIMT), is a well-standardized surrogate marker for assessing cardiovascular risk, and it is well accepted as a parameter of subclinical atherosclerosis. These wall changes, particularly in the elastic carotid arteries, may be an adaptive mechanism to cardiovascular stress in diseases like DM and hypertension as a result of atherosclerosis.<sup>8</sup> Studies have shown that in Asian Indians there is an association between increased CIMT and type 2 diabetes.

Microvascular complications of diabetes have been well established and studied while among the macrovascular complication, studies are very few and subclinical involvement of macrovascular diseases have not been studied very well. PAD is very common and largely neglected complication of diabetes which can be prevented if it is diagnosed early. Hence, we carried out the present study to assess the prevalence of PAD in type 2 diabetes by using duplex Doppler ultrasound of the all four limbs and to correlate it with various complications. We also sought to evaluate the relationship among PAD and carotid IMT in those with type 2 DM.

### ***Aim and objects***

The aim and objectives of the study were to study the prevalence of PAD in patients with type 2 DM and to study the correlation of PAD with carotid artery intima-media thickness.

### **METHOD**

Hospital based cross-sectional observational study was done in 124 patients with type 2 DM from OPD and IPD of the medicine and surgery dept. of GSVM medical college, Kanpur from Dec 2019 to Oct 2021.

Each patient gave written, informed consent to participate in the study and the study protocol was approved by the ethical committee of GSVM Medical College.

### ***Inclusion criteria***

All patients suffering from type 2 DM, diagnosed on the basis of past medical history, drug treatment for diabetes (insulin or oral hypo-glycemic agents at least 6 month), investigations and/or criteria outlined by the world health organization, irrespective of severity, duration of diabetes, presence or absence of chronic complications were taken up for the study.

### ***Exclusion criteria***

Patients with type 1 DM, age <25 years, trauma, surgery or amputation involving the lower limb, leg ulcers, deep vein thrombosis, filariasis or lower limb swelling due to other causes which would impair Doppler image quality and patients of chronic smokers, Buerger's disease, alcoholics, Takayasu disease, vasculitis disease, known

autoimmune disease (like SLE, RA etc) were excluded from the study.

### ***Criteria for the diagnosis of DM<sup>6</sup>***

**Symptoms:** Symptoms of diabetes plus random blood glucose concentration 11.1 mmol per L (200 mg/dl) Or fasting plasma glucose >7.0 mmol per L (126 mg/dl), Two hours plasma glucose 11.1 mmol per L (200 mg/dl) during an oral glucose tolerance test. In the absence of unequivocal hyperglycemia and acute metabolic decompensation, these criteria should be confirmed by repeat testing on a different day. Random is defined as without regard to time since the last meal. Fasting is defined as no caloric intake for at least 8 hours.

**HbA1c >6.5%:** A detailed history was obtained from each patient. This included age, sex, smoking, alcohol intake, DM-duration, treatment; hypertension-duration, treatment; symptoms of peripheral artery disease; symptoms of stroke, family history of diabetes/coronary artery disease/smoking/hypertension or cerebrovascular accident.

**Investigations performed included:** A resting 12-lead electrocardiogram recorded, complete blood count, S. TSH, Fasting and post-prandial blood glucose, blood urea, serum creatinine, uric acid, Total and HDL cholesterol, triglycerides and LDL, VLDL, glycated haemoglobin (HbA1c), urine analysis Color doppler of all 4 limbs and B/L carotid artery color doppler, CT head and MRI brain.

**Colour Doppler scan:** The arteries of the upper and lower limbs were assessed using a general-purpose linear probe with image frequency of 5-15 Mhz. Arteries were evaluated both longitudinally and transversely by ultrasound machine (SAMSUNG RS 80). With patients in the supine position and then by Doppler blood flow in both arms. Similarly, ankle blood flow by measuring Doppler blood flow in the dorsalis pedis artery or the posterior tibial artery of both feet.

**Carotid Doppler:** Ultrasonographic examination was done using ultrasound machine with 5-15 MHz transducer under real time imaging. After explanation of the procedure and consent obtained, the subjects were positioned supine with the desired neck extension achieved by pillow support under the neck. The neck was rotated 45° away from the side being examined to give appropriate neck exposure to visualize the common carotid artery and the internal carotid artery. The air interface between the probe and the skin was minimized by the application of acoustic gel. The scan of the common carotid artery began just above the clavicle and the transducer was rotated cephalad through the bifurcation and parallel to the internal carotid artery. The presence of atherosclerotic plaque was scanned for in the near and far walls of the common carotid artery, the carotid bulb and the internal carotid artery to avoid measurement of the thickness at the site of plaque which gives erroneously increased values. The intima-media

thickness of far wall of the carotid vessels was measured as the distance between the leading edge of the lumen-intima interface and leading edge of media adventitia interface as described by Touboul et al.<sup>4</sup>

The following segments were measured: 1) The common carotid artery at 1.5 cm proximal to the carotid bulb, 2) The carotid bulb and 3) the proximal internal carotid artery at 1 cm from the bulb.

Each segment was scanned in longitudinal plane with the sound wave beamed perpendicular to the arterial surface of the near and far walls of the vessel giving the two parallel echogenic lines-the lumen-intima and media-adventitia interfaces. The inner echogenic line and the adjacent hypoechoic line were taken as combined thickness of the intima-media complex. The mean of the average of 3 measurements taken at each aforementioned site on both sides was calculated in millimetre (mm). Typically, normal common carotid CIMT at age 10 is approximately 0.4 to 0.5 mm, while from the fifth decade of life onward this progresses to 0.7 to 0.8 mm or more.<sup>5</sup>

The data generated was entered into SPSS spread sheet, analyzed and presented using frequency tables, percentages, graphs and means ± standard deviation as appropriate. Associations between categorical and continuous variables were explored using the chi square and independent t test while correlations between continuous variables were explored.

**RESULTS**

The present study was conducted among the patients admitted with type 2 diabetes from OPD and IPD of the medicine and surgery dept. of GSVM medical college, Kanpur. A total of 124 patients with diabetes were evaluated in the present study for the presence of PAD.

**Table 1: Summary of all parameters.**

All parameters	Mean ± SD, median (IQR), min-max, frequency (%)
<b>Age (years)</b>	55.23±11.5, 55.00 (47.00-64.25), 30.00-85.00
<b>Gender</b>	
Male	74 (59.7)
Female	50 (40.3)
<b>Diabetes control (yes)</b>	21 (16.9)
<b>Duration of DM (years)</b>	10.49±5.70, 9.00 (6.00-14.00), 2.00-30.00
<b>Duration of DM (years)</b>	
≤5	27 (21.8)
6-10	47 (37.9)
11-15	30 (24.2)
>15	20 (16.1)
<b>HbA1c (%)</b>	10.05±3.22, 9.50 (7.38-12.43), 4.10-18.70
<b>PAD (Present)</b>	31 (25.0)

The mean age of participant (Years) was 55.23±11.54. 74 (59.7%) of the participant are male while 50 (40.3%) of the participants are female. 31 (25.0%) of the participants had PAD as compare to non-PAD group (75.0%). The 17 (54.8%) of the participants had severity of PAD: mild. 9 (29.0%) of the participants had Severity of PAD: Moderate. Five (16.1%) of the participants had severity of PAD: severe.

**Table 2: Association between PAD and parameters.**

Parameters	PAD		P value
	Present, (n=31) (%)	Absent, (n=93) (%)	
<b>Age (years)</b>	60.19±12.74	53.57±10.69	0.012
<b>Gender</b>			
Male	24 (77.4)	50 (53.8)	0.020
Female	7 (22.6)	43 (46.2)	
<b>Socioeconomic status</b>			
Upper	3 (9.7)	12 (12.9)	<0.001
Upper middle	5 (16.1)	39 (41.9)	
Lower middle	6 (19.4)	28 (30.1)	
Upper lower	13 (41.9)	8 (8.6)	
Lower	4 (12.9)	6 (6.5)	
<b>Diabetes control (Yes)</b>	2 (6.5)	19 (20.4)	0.072
<b>Duration of DM (years)</b>	14.19±6.03	9.26±5.05	<0.001
<b>Duration of DM (years)</b>			
≤5	0 (0.0)	27 (29.0)	<0.001
6-10	10 (32.3)	37 (39.8)	
11-15	9 (29.0)	21 (22.6)	
>15	12 (38.7)	8 (8.6)	
<b>Avg. CIMT (mm)</b>	0.95±0.12	0.77±0.15	<0.001
<b>HbA1c (%)</b>	12.44±3.14	9.26±2.84	<0.001
<b>Severity of PAD</b>			
Mild	17 (54.8%)		
Moderate	9 (29.0%)		
Severe	5 (16.1%)		

The mean (SD) of HbA1c (%) in the PAD: Present group was 12.44 (3.14). The mean (SD) of HbA1c (%) in the PAD: Absent group was 9.26 (2.84). The median (IQR) of HbA1c (%) in the PAD: Present group was 12.7 (10-14.7). The median (IQR) of HbA1c (%) in the PAD: Absent group was 8.8 (7-10.6). The HbA1c (%) in the PAD: Present ranged from 6.4-18.5. The HbA1c (%) in the PAD: Absent ranged from 4.1-18.7.

There was a significant difference between the 2 groups in terms of HbA1c (%) (W=2244.500, p<0.001), with the median HbA1c (%) being highest in PAD: Present group.

**Table 3: Comparison of the four subgroups of variable duration of DM in terms of CIMT (mm) (average), (n=124).**

CIMT (mm) (Average)	Duration of DM (Years)				Kruskal Wallis test	
	≤5	6-10	11-15	>15	$\chi^2$	P value
Mean (SD)	0.68 (0.13)	0.78 (0.11)	0.87 (0.12)	1.00 (0.15)	48.526	<0.001
Median (IQR)	0.61 (0.58-0.77)	0.79 (0.69-0.86)	0.9 (0.79-0.95)	1.03 (0.94-1.1)		
Range	0.54-1.07	0.55-1.01	0.6-1.05	0.63-1.18		

**Table 4: Comparison of the two subgroups of the variable PAD in terms of CIMT (mm) (average), (n=124).**

CIMT (mm) (Average)	PAD		Wilcoxon-Mann-Whitney U test	
	Present	Absent	W	P value
Mean (SD)	0.95 (0.12)	0.77 (0.15)	2367.000	<0.001
Median (IQR)	0.94 (0.87-1.03)	0.77 (0.66-0.88)		
Range	0.72-1.18	0.54-1.17		

There was a significant difference between the 2 groups in terms of CIMT (mm) (Average) ( $W=768.000$ ,  $p=0.037$ ), with the median CIMT (mm) (Average) being highest in the diabetes control: No group.

There was a strong positive correlation between duration of DM (Years) and CIMT (mm) (Average), and this correlation was statistically significant ( $RHO=0.66$ ,  $p\leq 0.001$ ).

For every 1 unit increase in duration of DM (years), the CIMT (mm) (Average) increases by 0.02 units.

Conversely, for every 1 unit increase in CIMT (mm) (Average), duration of DM (years) increases by 23.77 units.

There was a significant difference between the 4 groups in terms of CIMT (mm) (Average) ( $\chi^2=48.526$ ,  $p<0.001$ ), with the median CIMT (mm) (Average) being highest in the duration of DM: >15 years group.

There was a positive correlation between HbA1c (%) and CIMT (mm) (Average), and this correlation was statistically significant ( $RHO=0.2$ ,  $p=0.029$ ).

For every 1 unit increase in HbA1c (%), the CIMT (mm) (Average) increases by 0.01 units.

Conversely, for every 1 unit increase in CIMT (mm) (Average), the HbA1c (%) increases by 3.35 units.

There was a significant difference between the 2 groups in terms of CIMT (mm) (Average) ( $W=2367.000$ ,  $p\leq 0.001$ ), with the median CIMT (mm) (Average) being highest in the PAD: Present group.

There was a significant difference between the 3 groups in terms of CIMT (mm) (Average) ( $\chi^2=21.175$ ,  $p\leq 0.001$ ), with the median CIMT (mm) (Average) being highest in the severity of PAD: severe group.

## DISCUSSION

In the present study based on doppler ultrasound, the prevalence of PAD was found in 31 patients (25%) out of 124 with men having a higher prevalence (24 out of 74; 77.4%), as compared to women (7 out of 50; 22.6%) ( $p=0.020$ ) (Table 1 and 2). Previous studies by Marinelli et al, study by Paul et al found the prevalence of PAD to be 33%, and 15.9%, respectively.<sup>9,10</sup> Our study also shows the prevalence of PAD as conducted previously.

In our study population, most of the patients have no symptoms of PAD. In PAD group, proportion of mild, moderate and severe PAD was 55%, 29%, 16% respectively (Table 1). Two recent studies from North India, one by Agrawal et al ( $n=4400$ ) and the other by Madhu et al ( $n=364$ ) found the prevalence of PAD in diabetics to be 18.1% and 13.73%, respectively.<sup>11,12</sup> The former study was performed on outpatients with a study design similar to ours.

The prevalence of PAD in diabetic patients was found to be 3.2% in a study from South India and as high as 15.9% in a western population.<sup>13</sup> This reportedly low prevalence of PAD in India is in marked contrast to the high prevalence rate of coronary artery disease (CAD).<sup>13</sup>

In our cross-sectional study on 124 type 2 diabetes patients, the mean age of study population was  $55.23\pm 11.54$  year. The mean age in the PAD patient group was  $60.19\pm 12.74$  as compare to the non-PAD group ( $53.57\pm 10.69$ ). There was a significant difference between the 2 groups in terms of age (years) ( $t=2.606$ ,  $p=0.012$ ), with the mean Age being highest in the PAD group (Table 2). However, there was no significant difference between the various groups in terms of distribution of age ( $p=0.168$ ) (Table 2). PAD prevalence and incidence are both sharply age related, rising among patients in their 60s and 70s. With aging of the global population, it seems likely that PAD will be increasingly common in future. Our study has same results as Mohan et al, Agrawal et al ( $n=4400$ ) and

Madhu et al (n=364) in which higher age was significantly associated with higher prevalence of PAD.<sup>11,14,15</sup>

In our study, the mean HbA1c was  $10.05 \pm 3.22$  mg%. On comparing the two groups, mean HbA1c was  $9.26 \pm 2.64$ % in the non-PAD group as compared to  $12.44 \pm 3.14$ % in the PAD group ( $p < 0.05$ ). Using a cut off level of  $>7$  mg% for poor control, 79.6% had poor glycaemic control in the non-PAD group compared to 93.50% in the PAD group. Our study is not similar to most of the studies in which mean HbA1c level was  $>14$  mg%. Studies by Walters et al and Janka et al also found inferior glycaemic control to be a predictor of PAD.<sup>15,16</sup> In our opinion, current poor glycaemic control adjudged as a risk factor for PAD that has occurred retrospectively is not a justified option unless the current glycaemic control is proven to be a reflection of long-term glycaemic status of patient.

In this study, the results revealed that there was a significant association between the socio-economic status and PAD. Particularly the lower SES were found have the high prevalence. Most of the patients in upper-lower and lower group have higher prevalence as well as severity of PAD (41.9% and 12.9% respectively) as compare to other groups. There was no significant difference between the various groups in terms of distribution of severity of PAD ( $\chi^2=7.650$ ,  $p=0.551$ ).

However, there was no significant difference between the groups in terms of average CIMT ( $\chi^2=6.916$ ,  $p=0.140$ ). Although patients of higher socio-economic status have low mean HbA1c level than lower SES but there was no significant difference between the various socioeconomic groups in terms of distribution of diabetes control ( $\chi^2=3.229$ ,  $p=0.072$ ). Probable reason behind this may be higher education level and awareness related to disease.

In our study, the mean carotid IMT (mm) (Average) was  $0.82 \pm 0.16$ . There was a significant difference between the 2 groups in terms of CIMT (mm) (Average)  $p < 0.001$ . Patients with PAD have more increase in CIMT ( $0.95 \pm 0.12$ ) as compare to non-PAD ( $0.77 \pm 0.15$ ). As carotid IMT (a cut-off value of 0.75 mm reported by Holaj et al is considered to be a marker of generalized atherosclerosis. Our study also gave significant result as reported in previous studies. Mohan et al reported a higher IMT value ( $0.95 \pm 0.31$  mm) in diabetic patients than found in the present study. Mostaza et al (n=1070) also found prevalence of PAD based on low ABI in patients with increased CIMT ( $>50$ % stenosis) was 14.3%.<sup>17</sup> In our study we can say that even in the absence of the blood pressure component in T2DM patients is associated with greater carotid IMT values. Further prospective studies are recommended to demonstrate the regression of carotid IMT with management of metabolic syndrome in T2DM patients. PAD group was associated with an 0.18 mm increase in CIMT compared with non-PAD group. In patients with PAD, the average increase in CIMT was higher in severe PAD (1.12 mm) as compare to moderate (1.0 mm) and mild group of PADD (0.87 mm). Study conducted by Allen PL et al also revealed that the presence

of symptomatic (intermittent claudication) or asymptomatic PAD was significantly associated with increased IMT.<sup>18</sup> Brohall et al made systematic reviews in order to identify cross-sectional studies using the ultrasound method on 24111 patients.<sup>19</sup> Our study also has same results as carotid IMT was higher in PAD patient.

atherothrombosis is a generalized and diffuse progressive process manifesting in multiple vascular beds leading to ischemic stroke and PAD. Pathological mechanism in macrovascular disease is the process of atherosclerosis, which leads to narrowing of arterial walls throughout the body. Atherosclerosis occurs due to chronic inflammation and injury to the arterial wall in the peripheral or coronary vascular system.

The findings in the present study thus provided an overview of prevalence of PAD among diabetics and complications associated with it. Atherosclerosis, in diabetic patient, can lead to complications in all major of vascular beds, including the coronary arteries, carotid vessels, and peripheral arteries. The results were interesting and useful for preparation of a prevention and management strategy for diabetes macrovascular complications.

## CONCLUSION

By using doppler, we found prevalence of PAD is 25% (31 out of 125) of type 2 diabetics. Risk factors significantly associated with PAD were higher age ( $60.19 \pm 12.74$ ), longer duration of diabetes ( $14.19 \pm 6.03$ ), higher HbA1c level ( $12.44 \pm 3.14$ ). Prevalence of PAD seems to be higher among men than women (3:1). Patients with PAD have significantly more increase in CIMT ( $0.95 \pm 0.12$ ) as compare to non-PAD ( $0.77 \pm 0.15$ ) with  $p < 0.001$ . A high CIMT is a surrogate and reliable marker of higher risk of ischemic stroke amongst type 2 diabetic patients. Our study demonstrates the utility of carotid IMT as a simple non-invasive screening test for the assessment of atherosclerosis risk/prognosis in type 2 DM and PAD. PAD is associated with an increased risk of morbidity and mortality. It is important to diagnose PAD in patient with diabetes to elicit symptoms, complications to prevent disability and limb loss. Clinician should identify a PAD patient at high risk of stroke and death. On the basis of our study, recommendation can be done for the screening of the PAD and CIMT (by color doppler) in the patients with type 2 diabetes who are  $>50$  years of age.

## Limitations

The sample size in our study was relatively small. As a single centre hospitalized study, the enrolled patients may be different from the actual demographic profile of Kanpur or Uttar Pradesh.

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