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Original Research Article

Significant correlation of ischemic stroke with peripheral artery disease in type 2 diabetes mellitus patients

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ABSTRACT

Background: Atherosclerotic disease is not only increased in incidence in type 2 diabetic patients, but its course is also accelerated. Stroke is one of the major causes of morbidity and mortality among the elderly population. The relationship between ischemic stroke and PAD (peripheral artery disease) has been poorly investigated in India. So, we studied the risk of stroke in PAD patients with type 2 diabetes. The aims and objectives of the study were to study the prevalence of PAD in patients with type 2 diabetes mellitus and to study the correlation of stroke in PAD patients with type 2 diabetes.
Methods: Hospital based cross-sectional study was conducted among the 124 patients admitted with type 2 diabetes (age >25 years) from December 2019 to October 2021 in the various units of department of medicine/surgery, KPS institute, GSVM medical college, Kanpur. Color Doppler of limbs and carotid artery was done in study population. Clinical sign and symptoms, history of stroke or diagnostic investigation were used for evaluate cerebrovascular events.
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 prevalence of stroke was 32.3% in PAD patients and 11.8% in non-PAD patients (p=0.009).
Conclusions: By using Doppler, we found evidence of PAD in 25% of type 2 diabetics (M>F). The prevalence of stroke was 32.3% in PAD patients and 11.8% in non-PAD patients (p=0.009). PAD is associated with an increased risk of cerebrovascular disease morbidity and mortality. Clinician should identify a PAD patient with diabetes to elicit symptoms, complications like stroke to decrease mortality or morbidity.

Keywords: PID, Ischemic stroke, Diabetes mellitus

INTRODUCTION

Diabetes mellitus is an important health problem that is widely prevalent all over the world and the prevalence has increased dramatically over the last two decades.[1] Over 170 million people worldwide have diabetes mellitus (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).[2] PAD is one of the major macrovascular complications of DM. Atherosclerotic disease is not only increased in incidence in diabetic patients, but its course is also accelerated, therefore it causes 44% of all-cause mortality.[3] DM-associated atherosclerosis can lead to complications in all major vessels 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).[4] In the absence of clinical symptoms and signs in the early stages of the disease, the emphasis of management in patient of peripheral vascular disease lies in the early detection of the disease so as to prevent or at least reduce the rate of complication. The gold standard for

diagnosis of PVD is angiography. Ankle brachial index is less sensitive test in diabetes in the presence of detectable peripheral neuropathy. Color waveform Doppler combine sonography and Doppler analysis is used to localize and determine the significance of a stenosis or occlusion. It detects and localizes haemodynamically significant lesions in the vessel segment as effectively as angiography.[5]

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 stroke in those with type 2 DM.

METHODS

Hospital based cross-sectional observational study was done in 124 patients with type 2 DM from OPD and IPD of the medicine and surgery department of GSVM medical college, Kanpur from December 2019 to October 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 hypoglycemic agents at least 6 month), investigations and/or criteria outlined by the WHO, 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, aged <25 years; patients with 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; patients of chronic smokers, Buerger's disease, alcoholics, Takayasu disease, vasculitis disease, known autoimmune disease (like SLE, RA) were excluded in the study.

Criteria for the diagnosis of DM

Symptoms of diabetes plus random blood glucose concentration 11.1 mmol/l (200 mg/dl) or fasting plasma glucose >7.0 mmol/l (126 mg/dl), two hours plasma glucose 11.1 mmol/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 was defined as without regard to time since the last meal. Fasting was 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, diabetes mellitus-duration, treatment; hypertension-duration, treatment; symptoms of PAD; 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, serum 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.

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 department of GSVM medical college, Kanpur. A total of 124 patients with diabetes were evaluated in the present study for the presence of PAD.

The mean age of participant (years) was 55.23±11.54. 74 (59.7%) of the participant were male while 50 (40.3%) of the participants were female. 31 (25.0%) of the participants had PAD as compared to non-PAD group (75.0%). 17 (54.8%) of the participants had severity of PAD: mild. 9 (29.0%) of the participants had severity of PAD: moderate. 5 (16.1%) of the participants had severity of PAD: severe.

Table 1: Summary of all parameters.

Parameters	N (%)
Age (years)	Mean±SD=55.23±11.5; IQR=55.00 (47.00-64.25); min-max=30.00-85.00
Age (in years)	
30-39	8 (6.5)
40-49	28 (22.6)
50-59	39 (31.5)
60-69	31 (25.0)
70-79	16 (12.9)
80-89	2 (1.6)
Gender	
Male	74 (59.7)
Female	50 (40.3)
Diabetes control (yes)	21 (16.9)
Duration of DM (years)	Mean±SD=10.49±5.70; IQR=9.00 (6.00-14.00); min-max=2.00-30.00
Duration of DM (years)	
≤5	27 (21.8)
6-10	47 (37.9)
11-15	30 (24.2)
>15	20 (16.1)
Stroke (yes)	21 (16.9)
HbA1c (%)	Mean±SD=10.05±3.22; IQR=9.50 (7.38-12.43); min-max=4.10-18.70
PAD (present)	31 (25.0)

Table 2: Association between PAD and parameters.

Parameters	PAD		P value
	Present (n=31)	**Absent (n=93)**	
Age (years)	60.19±12.74	53.57±10.69	0.0121
Age (years)			0.1682
30-39	1 (3.2)	7 (7.5)	
40-49	5 (16.1)	23 (24.7)	
50-59	8 (25.8)	31 (33.3)	
60-69	8 (25.8)	23 (24.7)	
70-79	8 (25.8)	8 (8.6)	
80-89	1 (3.2)	1 (1.1)	
Gender			0.0203
Male	24 (77.4)	50 (53.8)	
Female	7 (22.6)	43 (46.2)	
Socioeconomic status			<0.0013
Upper	3 (9.7)	12 (12.9)	
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)	
Diabetes control (yes)	2 (6.5)	19 (20.4)	0.0723
Duration of DM (years)	14.19±6.03	9.26±5.05	<0.0014
Duration of DM (years)			<0.0013
≤5	0 (0.0%)	27 (29.0)	
6-10	10 (32.3)	37 (39.8)	
11-15	9 (29.0)	21 (22.6)	
>15	12 (38.7)	8 (8.6)	
Stroke (yes)	10 (32.3)	11 (11.8)	0.0093
HbA1c (%)	12.44±3.14	9.26±2.84	<0.0014

Continued.

Parameters	PAD		P value
	Present (n=31)	Absent (n=93)	
Severity of PAD			
Mild	17 (54.8)		
Moderate	9 (29.0)		
Severe	5 (16.1)		

Table 3: comparison of the 2 subgroups of the variables PAD in terms of age (years) (n=124).

Age (years)	PAD		t test	
	Present	Absent	t	P value
Mean (SD)	60.19 (12.74)	53.57 (10.69)		
Median (IQR)	63 (50-70.5)	55 (45-60)	2.606	0.012
Range	35-85	30-80		

Table 4: Association between PAD and gender (n=124).

Gender	PAD			Chi-squared test	
	Present	Absent	Total	χ^2	P value
Male	24 (77.4)	50 (53.8)	74 (59.7)		
Female	7 (22.6)	43 (46.2)	50 (40.3)	5.407	0.020
Total	31 (100.0)	93 (100.0)	124 (100.0)		

Table 5: Comparison of the 2 subgroups of the variables PAD in terms of HbA1c (%) (n=124).

HbA1c (%)	PAD		Wilcoxon-Mann-Whitney U test	
	Present	Absent	W	P value
Mean (SD)	12.44 (3.14)	9.26 (2.84)		
Median (IQR)	12.7 (10-14.7)	8.8 (7-10.6)	2244.500	<0.001
Range	6.4-18.5	4.1-18.7		

Table 6: Association between PAD and duration Of DM (n=124).

Duration of DM (years)	PAD			Chi-squared test	
	Present	Absent	Total	χ^2	P value
≤5	0 (0.0)	27 (29.0)	27 (21.8)		
6-10	10 (32.3)	37 (39.8)	47 (37.9)		
11-15	9 (29.0)	21 (22.6)	30 (24.2)	22.814	<0.001
>15	12 (38.7)	8 (8.6)	20 (16.1)		
Total	31 (100.0)	93 (100.0)	124 (100.0)		

Table 7: Association between PAD and diabetes control (n=124).

Diabetes control	PAD			Chi-squared test	
	Present	Absent	Total	χ^2	P value
Yes	2 (6.5)	19 (20.4)	21 (16.9)		
No	29 (93.5)	74 (79.6)	103 (83.1)	3.229	0.072
Total	31 (100.0)	93 (100.0)	124 (100.0)		

Table 8: Association between PAD and stroke (n=124).

Stroke	PAD			Chi-squared test	
	Present	Absent	Total	χ^2	P value
Yes	10 (32.3)	11 (11.8)	21 (16.9)		
No	21 (67.7)	82 (88.2)	103 (83.1)	6.898	0.009
Total	31 (100.0)	93 (100.0)	124 (100.0)		

Table 9: Association between severity of PAD and stroke (n=31).

Stroke	Severity of PAD				Fisher's exact test	
	Mild	Moderate	Severe	Total	χ^2	P value
Yes	3 (17.6)	3 (33.3)	4 (80.0)	10 (32.3)		
No	14 (82.4)	6 (66.7)	1 (20.0)	21 (67.7)	6.881	0.055
Total	17 (100.0)	9 (100.0)	5 (100.0)	31 (100.0)		

The variable age (years) was normally distributed in the 2 subgroups of the variable PAD. Thus, parametric tests (t test) were used to make group comparisons.

The mean (SD) of age (years) in the PAD: present group was 60.19 (12.74). The mean (SD) of age (years) in the PAD: absent group was 53.57 (10.69). The median (IQR) of age (years) in the PAD: present group was 63 (50-70.5). The median (IQR) of age (years) in the PAD: absent group was 55 (45-60). The age (years) in the PAD: present ranged from 35-85. The age (years) in the PAD: absent ranged from 30-80.

There was a significant difference between the 2 groups in terms of age (years) (t=2.606, p=0.012), with the mean age (years) being highest in the PAD: present group.

However, there was no significant difference between the various groups in terms of distribution of age (χ^2=7.858, p=0.168) (Table 2).

Chi-squared test was used to explore the association between PAD and gender.

There was a significant difference between the various groups in terms of distribution of gender (χ^2=5.407, p=0.020).

77.4% of the participants in the group (PAD: present) had (gender: male). 22.6% of the participants in the group (PAD: present) had (gender: female). 53.8% of the participants in the group (PAD: absent) had (gender: male). 46.2% of the participants in the group (PAD: absent) had (gender: female).

Participants in the group PAD: present had the larger proportion of gender: male. Participants in the group PAD: absent had the larger proportion of gender: female.

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 the PAD: present group.

There was no significant difference between the various groups in terms of distribution of diabetes control (χ^2=3.229, p=0.072).

Chi-squared test was used to explore the association between PAD and stroke.

There was a significant difference between the various groups in terms of distribution of stroke (χ^2=6.898, p=0.009).

32.3% of the participants in the group (PAD: present) had (stroke: yes). 67.7% of the participants in the group (PAD: present) had (stroke: no). 11.8% of the participants in the group (PAD: absent) had (stroke: yes). 88.2% of the participants in the group (PAD: absent) had (stroke: no).

Participants in the group PAD: present had the larger proportion of stroke: yes. Participants in the group PAD: absent had the larger proportion of stroke: no.

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.[6,7] Our study also showed 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.[8,9] 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 lndia and as high as 15.9% in a western population.[10,11] This reportedly low prevalence of PAD in India was in marked contrast to the high prevalence rate of coronary artery disease (CAD).[10] In our cross-sectional study on 124 type 2 diabetes patients, the mean age of study population was

55.23±11.54 year. The mean age in the PAD patient group was 60.19±12.74 as compare to the non-PAD group (53.57±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 had same results as Mohan et al in 2000, Agrawal et al in 2004 (n=4400), Madhu et al 2006 (n=364) in which higher age was significantly associated with higher prevalence of PAD.[8,12,13]

In our study, the mean HbA1c was 10.05±3.22 mg%. On comparing the two groups, mean HbA1c was 9.26±2.64% in the non-PAD group as compared to 12.44±3.14 % in the PAD group (p<0.05) (Table 5). 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 was 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 glycemic control to be a predictor of PAD.[13,14] In our opinion, current poor glycemic control adjudged as a risk factor for PAD that had occurred retrospectively was not a justified option unless the current glycemic control was proven to be a reflection of long-term glycemic status of patient.

There was a significant difference between the various groups in terms of distribution of stroke (Table 8). The prevalence of stroke was 32.3% in PAD patients and 11.8% in non-PAD patients (p=0.009). As we knew, atherothrombosis was a generalized and diffuse progressive process manifesting in multiple vascular beds leading to ischemic stroke and peripheral arterial disease. Pathological mechanism in macrovascular disease was the process of atherosclerosis, which led to narrowing of arterial walls throughout the body. Atherosclerosis occurred due to chronic inflammation and injury to the arterial wall in the peripheral or coronary vascular system. Hirsch et al also found in their study that 35% patients had PAD and cerebrovascular events.[15] Leunardo et al also showed that In PAD patients (total 100 PAD), there was a history of ischemic cerebrovascular symptoms in the carotid territory.[16] The presence of cerebrovascular symptoms was statistically significant in influencing the degree of stenosis in the carotid arteries (p=0.02 at overall assessment and p=0.05 in the subgroups of significant and non-significant stenoses). Sen et al in a 1-year period, evaluated 102 patients, from which 26% had asymptomatic PAD.[17] All patients were followed for a median period of 2.1 years from the index stroke/TIA (range, 1.0 to 2.7 years) for vascular events. Kaplan-Meier curve showed fewer patients with asymptomatic PAD remained free of composite vascular events (48% compared with 84% in the no-PAD group; log rank, p=0.0001). Asymptomatic PAD was significantly associated with composite vascular events before (hazard ratio, 4.2; 95% CI, 1.9 to 9.3; p=0.0003) and after adjustment for confounders (hazard ratio, from model 1, 2.8; 95% CI, 1.1 to 7.2; p=0.03 and model 2, 3.4; 95% CI, 1.4 to 8.2, p=0.006). A few population-based COHORT studies have confirmed that a decrease in the ABI was highly correlated with an increase in the prevalence rate of coronary artery disease and cerebrovascular disease.[17-19]

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. PAD was associated with high rates of cardiovascular and/or cerebrovascular ischemic events (MI, stroke and other thromboembolic phenomena), increased morbidity and mortality. It was one of the major causes of mortality among the elderly population. The results were interesting and useful for preparation of a prevention and management strategy for diabetes macrovascular complications.

The limitations of our study were a lower sample size which could not represent whole population.

CONCLUSION

PAD is associated with an increased risk of cerebrovascular disease 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 to prevent macrovascular complication of DM.

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