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Original Research Article

An Observational Study to Assess the Prevalence of PVD in Type 2 Diabetes Measuring Ankle Brachial Index using Duplex Doppler Ultrasound of the Lower Limbs

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Abstract

Aim: The aim of the present study was to assess the prevalence of PVD in type 2 diabetes measuring ankle brachial index using duplex Doppler ultrasound of the lower limbs and to correlate its occurrence with various risk factors.

Material & Methods: A cross-sectional, prospective and observational study, conducted in Department of Medicine, Study period was of 2 years. 200 patients were included in the study.

Results: The age of the patients ranged from 40 to 80 years with a mean age of 61.08±7.13 years. The duration of diabetes ranged from 1 to 25 years with a mean of 9.21±3.96 years. More than half of the patients (53%) had history of hypertension and 18.66% were smokers. Family history of diabetes was present in 59%. In the present study, hypertension, diabetes, BMI>25kg/m^2, HbA1c>7% etc. were the risk factors. The differences between the PAD and the non-PAD groups in terms of risk factors were assessed using Student's t test for continuous variables and chi square test for discrete variables. CAD was found in 10 PVD patients as compared to 25 non-PVD patients ($p=0.046$). Binary logistic regression was used to assess significant independent predictors of CAD. Old age, high HbA1c level, and dyslipidemia (total cholesterol and HDL) ($p<0.05$) were found to be significant predictors of CAD.

Conclusion: Risk factors associated with PVD were age, duration of diabetes, systolic and diastolic blood pressure, smoking, HbA1C, high total cholesterol low HDL and CAD and correlation was significant. This study also showed a higher prevalence of CAD in patients with PVD.

Keywords: Ankle-brachial index, Coronary artery disease, Diabetes mellitus, Peripheral artery disease

Introduction

The disease burden related to diabetes is high and rising in every developing and developed country, it is fuelled by the global rise in the prevalence of obesity and unhealthy lifestyles. [1] The aetiological classification of diabetes has now been widely accepted. Type 1 and type 2 diabetes are the two main types, with type 2 diabetes accounting for the majority (>85%) of total diabetes prevalence. Both forms of diabetes can lead to multisystem complications of microvascular endpoints, including retinopathy, nephropathy and neuropathy, and macrovascular endpoints including ischaemic heart disease, stroke and peripheral vascular disease. The premature morbidity, mortality, reduced life expectancy and financial and other costs of diabetes make it an important public health condition. [2]

Type-2 diabetes accounts for over 95% of all diabetics in India. Due to its insidious onset and lack of alarming symptoms, the disease often remains undiagnosed for many years. Type-2 diabetes mellitus has significant relationship with obesity and almost 90% type-2 diabetics are obese although only a minority of obese people are diabetic. [3] Decreased physical activity and changes in dietary habits favour the occurrence of diabetes in Indians, who already have a racial and genetic susceptibility for the disease. [4]

The reasons for the higher incidence of diabetes in Indians include increased insulin resistance, genetic predisposition and environmental factors, particularly those associated with urbanisation. Insulin resistance is thought to promote

atherosclerosis, in part through its associated metabolic abnormalities. Patients with diabetes mellitus suffer from an excess of premature and severe atherosclerosis. [5] Peripheral arterial disease (PAD) is a manifestation of atherosclerosis characterized by atherosclerotic occlusive disease of the lower extremities and is a marker for atherothrombotic disease in other vascular beds. [6] In newly detected diabetics, the prevalence of PVD is 3.5% vs. 7.8% in known diabetic subjects. It is a chronic complication of diabetes mellitus (DM) and a risk factor for foot ulceration and amputation- more than two-thirds of patients with diabetic foot ulceration have associated PAD. [7] This arthero – occlusive disease of the extremities does increase the risk of coronary artery disease as well. [8,9] Although PAD occurs in non- diabetic patients, it is up to four times more common in patients with DM. [10] Symptoms such as intermittent claudication and calf pain at rest suggest PAD but in DM, these symptoms may be obscured by the concomitant presence of peripheral neuropathy. [11] In studies using the ankle-brachial index (ABI), which is the preferred screening technique, the prevalence of PAD (defined as an ABI <0.90) in diabetic individuals ranges from 20% to 30%. [11-13]

A reliable diagnosis of PAD can be made using the ankle brachial index (ABI). This simple, painless and highly reproducible test can be performed in a physician's office and requires only a blood pressure apparatus and a handheld, continuous-wave doppler probe. Hence, present study was undertaken to study the prevalence of PVD in type 2 diabetes measuring ankle brachial index using duplex Doppler ultrasound of the lower limbs and to correlate its occurrence with various risk factors.

Material & Methods

A cross-sectional, prospective and observational study, conducted in Department of Medicine, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar. Study period was of 2 years. 200 patients were included in the study.

Inclusion Criteria:

Patients, > 30 years age, either gender, diagnosed as diabetics (WHO criteria) being treated by dietary restrictions and / or oral hypoglycaemic agents and / or insulin for at least 6 months, Diabetes mellitus: Fasting venous plasma glucose concentration more than or equal to 126 mg% or postprandial plasma glucose more than or equal to 200 mg% on 2 or more occasions in accordance with WHO criteria or known case of diabetes mellitus on diet control/insulin/oral hypoglycaemic agents.[14]

Exclusion Criteria:

Patients with history of Leg trauma, fracture, Leg surgery, amputation, Leg ulcers. Patients with history Deep vein thrombosis, Filariasis. Patients with lower limb swelling (impairs quality image)

Methodology

Each patient gave written, informed consent to participate in the study A detailed history included Age, Sex, Smoking Alcohol intake, Diabetes mellitus/ Hypertension (duration, treatment), Symptoms of coronary artery disease, a history of CABG or PTCA. Family history of diabetes, coronary artery disease, hypertension, CVA was recorded in CRF. Standing height (meter), Weight (in kg), Waist circumference (in cms), Hip circumference (in cms), Pulse, Blood pressure were measured. A resting 12- lead electrocardiogram (ECG) was taken. After eight hours of fasting, venous samples were collected for estimation of Blood glucose, Blood urea, Serum creatinine, Uric acid, Serum cholesterol, HDL cholesterol, Serum triglycerides, VLDL and LDL, Glycated haemoglobin (HbA1C). Urinary albumin estimation was done. Colour Doppler scan - of the arteries of the lower limbs was performed using a general purpose linear probe with Image frequency of 5.7-10.0 Mhz. Arteries were have been evaluated both longitudinally and transversely by EVB 700 HV ultrasound machine of Hitachi. Ankle Brachial Index - With patients in the supine position, brachial artery systolic pressure was first measured by palpatory method and then by Doppler blood flow method in both the arms. The resumption of blood flow by Colour Doppler technique was seen as the sphygmomanometer cuff pressure was gradually released. The first wave seen during deflation of cuff was taken as systolic blood pressure. The higher reading was taken as brachial arterial systolic pressure. Similarly, ankle blood pressure was taken first by palpatory method with the cuff placed just above the ankle and then by measuring Doppler blood flow in the dorsalis pedis artery or the posterior tibial artery of both feet. Individual ABI was obtained for each leg by dividing corresponding ankle pressure by the brachial pressure. The lower of the values obtained for the two legs was taken as the true ABI for that patient. 8 A cut-off point of 0.9 was defined as a low ABI.

Statistical Analysis

The data was collected, entered in Microsoft excel and analysed with SPSS version 23. Statistical significance of the difference was determined using the MANN-WHITNEY U TEST. Statistical significance was defined as a P value of less than 0.5.

Results

Table 1: Demographic and clinical profile of patients in the study group

	Men (n=150)	Women (n=50)	Total (n=200)
Age (in years) Mean±SD	61.06±8.52	62.17±6.44	61.08±7.13
Duration of diabetes (in years) Mean±SD	9.45±4.36	8.72±3.44	9.21±3.96
History of hypertension	80 (53.33%)	26 (52%)	106 (53%)
Family history of diabetes	84 (56%)	34 (68%)	118 (59%)
Smoking	28 (18.66%)	0 (0%)	28 (14%)

The age of the patients ranged from 40 to 80 years with a mean age of 61.08±7.13 years. The duration of diabetes ranged from 1 to 25 years with a mean of 9.21±3.96 years. More than half of the patients (53%) had history of hypertension and 18.66% were smokers. Family history of diabetes was present in 59%.

Table 2: Prevalence of cardiovascular risk factors in the study group

Risk Factor	N	%
Hypertension	106	53
Smoking	32	16
F/H of DM	118	59
BMI>25kg/m^2	130	65
HbA1c>7%	104	52
Serum total cholesterol ≥200 mg/dl	84	42
Serum LDL cholesterol≥100mg/dl	86	43
Serum HDL cholesterol≤40 mg/dl	128	64
Serum triglycerides ≥150 mg/dl	50	25
Albuminuria >30mg/24 hours	64	32

In the present study, hypertension, diabetes, BMI>25kg/m^2, HbA1c>7% etc. were the risk factors.

Table 3: Cardiovascular disease risk factors in PAD and Non-PAD groups

	Non-PAD N=160	PAD N=40	p value
Age (in years) Mean±SD	59.61±6.34	65.05±6.54	0.000
Duration of diabetes (in years) Mean±SD	8.42±3.47	12.8±4.36	0.000
History of hypertension	80	26	0.182
Smoking	22	12	0.036
CAD	25	10	0.046
SBP (mmHg)	134.96±9.62	141.37±7.13	0.001
DBP (mmHg)	83.67±6.52	88.32±3.27	0.007
BMI (kg/m^2)	25.52±3.57	26.24±3.57	0.455
Fasting blood glucose (mg%)	142.78±44.06	144.96±35.45	0.852
Post-prandial blood glucose (mg%)	201.12±61.56	203.28±44.76	0.860
Total cholesterol (mg%)	184.36±41.29	198.02±32.28	0.150
Serum LDL (mg%)	103.47±38.22	104.56±44.66	0.924
Serum HDL (mg%)	45.05±11.22	40.2±9.63	0.205
Serum triglycerides (mg%)	131.17±56.14	132.72±44.46	0.930
HbA_{1c} (%)	6.94±0.96	7.73±1.16	0.005
Albuminuria (mg/24 hours)	58.62±244.10	76.02±192.54	0.794

The differences between the PAD and the non-PAD groups in terms of risk factors were assessed using Student's t test for continuous variables and chi square test for discrete variables. CAD was found in 10 PVD patients as compared to 25 non-PVD patients (p=0.046). Binary logistic regression was used to assess significant independent predictors of CAD. Old age, high HbA1c level, and dyslipidemia (total cholesterol and HDL) (p<0.05) were found to be significant predictors of CAD.

Discussion

In newly detected diabetics, the prevalence of PVD is 3.5% vs. 7.8% in known diabetic subjects. PVD is uncommon till middle age and then the prevalence rate rises dramatically. Age more than 50 years and hypertension are closely associated with PVD.5,6 Using more sophisticated screening techniques like duplex colour Doppler or high-resolution ultrasound about 30% of those with a normal ankle brachial

index have demonstrable plaques/ stenosis in the peripheral arteries. [15,16]

The age of the patients ranged from 40 to 80 years with a mean age of 61.08±7.13 years. The duration of diabetes ranged from 1 to 25 years with a mean of 9.21±3.96 years. More than half of the patients (53%) had history of hypertension and 18.66% were smokers. Family history of diabetes was present in 59%. The Fremantle diabetes study, a community-based study, included subject with a mean age of 63.4±10.9 years and a mean duration of diabetes as 4 years in subjects without PVD. Subjects with PAD had a mean age of 70.7±13.2 years with a mean duration of diabetes of 5 years. Both variables, age and duration of diabetes, attained statistical significance (<0.05) as predictors of PAD. [17] In a study identifying coronary risk factors in 167 type 2 diabetic patients Walia et al [18] found 53.12 and 8.86 years as the mean age of their patients and the mean duration of diabetes, respectively. 28.6% of diabetic men had a history of smoking and (or) consuming alcohol and 20.4% had a family history of CAD. Two large studies namely by Mohan et al [19] (n=4941) and CUPS5 (n=1262) found a prevalence of PVD in diabetics of 3.9% and 6.3% respectively. Agrawal et al [20] (n=4400) and Madhu et al [21] (n=364) found prevalence of PVD in diabetics to be 18.1% and 13.73% respectively.

In the present study, hypertension, diabetes, BMI>25kg/m^2, HbA1c>7% etc. were the risk factors. The differences between the PAD and the non-PAD groups in terms of risk factors were assessed using Student's t test for continuous variables and chi square test for discrete variables. CAD was found in 10 PVD patients as compared to 25 non-PVD patients (p=0.046). Binary logistic regression was used to assess significant independent predictors of CAD. Old age, high HbA1c level, and dyslipidemia (total cholesterol and HDL) (p<0.05) were found to be significant predictors of CAD. Walters et al, and Janka et al, concluded in their studies that blood sugar values were found to be significant predictors of PAD. [16,22] These studies suggest a relationship between poor glycemic control and PAD. In present study, no significant differences were found between serum triglyceride levels, serum HDL levels and serum LDL levels between the PAD and the non-PAD subgroups.

The Cardiovascular Health Study [23], a prospective study to evaluate the association of PVD and CAD, enrolled 5,888 participants above 65 years of age. ABI was measured at the baseline. The crude mortality rate at 6 years was highest (32.3%) in those with prevalent CVD and a low ABI, and lowest in those with neither of these findings (8.7%). The risk for incident congestive heart failure (relative risk [RR]=1.61) and for total mortality (RR=1.62) in those without CVD at baseline but with a low ABI remained significantly elevated even after adjustment for cardiovascular risk factors. For each 0.1 decrement in the ABI below 1.0, event rates increased. Even within this group a low ABI was associated with increased age- and gender- adjusted risk of total and CVD mortality and remained independently associated with CVD mortality. A low ABI was associated with increased age and gender adjusted risk of total and CVD mortality and remained independently associated with CVD mortality. The risk for incident congestive heart failure in those without CVD at baseline but with a low ABI remained significantly elevated after adjustment for cardiovascular risk factors. [24] Because ABI is one of the first obvious indicators of atherosclerosis, some authors have proposed using it to screen for atherosclerotic disease to direct more aggressive treatment in patients at the highest risk for cardiovascular events.[25]

Conclusion

Risk factors associated with PVD were age, duration of diabetes, systolic and diastolic blood pressure, smoking, HbA1C, high total cholesterol low HDL and CAD and correlation was significant. This study also showed a higher prevalence of CAD in patients with PVD. However, further studies, with a larger sample size, are needed to investigate the possible mechanisms linking PVD and CAD and to determine whether PVD predicts the development and progression of CAD.

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