

Prevalence of peripheralvascular disease in patients of diabetes

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Prevalence of peripheral vascular disease in patients of diabetes Diabetes is a chronic disease, which occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. This leads to an increased concentration of glucose in the blood (hyperglycaemia). The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8 percent in 2000 and 4.4 percent in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. This has risen to diabetic prevalence of 50.8 million in India.

Diabetes mellitus causes between two and four times increased risk of peripheral vascular disease(PVD) by causing endothelial and smooth muscle cell dysfunction in peripheral arteries. Diabetics account for up to 70 percent of non-traumatic amputations performed, and a known diabetic who smokes runs an approximately 30percent risk of amputation within 5 years. Dyslipidemia (high low density lipoprotein [LDL] cholesterol, low high density lipoprotein [HDL] cholesterol) - elevation of total cholesterol, LDL cholesterol, and triglyceride levels each have been correlated with accelerated PVD.

Peripheral vascular disease(PVD) is a condition which includes diseases to arteries and veins outside the thoracic region. PVD in patients with diabetes can be diffuse and early in onset and is characterized by atherosclerotic occlusive disease especially of lower limbs. The predilection for atherosclerosis and microangiopathy plays a role in the vessel occlusion that occurs in diabetes and affects upto 30 percent of all people with diabetes. The World health organization (WHO) definition includes exercise-related pain and / or Ankle brachial index (ABI) <0.9. Measurement of ankle blood pressure may identify both people with and without diabetes at an early asymptomatic stage. About 20 percent of patients with mild PAD may be asymptomatic; other symptoms include

Claudication-pain, weakness, numbness, or cramping in muscles due to decreased blood flow.Sores, wounds, or ulcers that heal slowly or not at all.

Noticeable change in color (blueness or paleness) or temperature (coolness) when compared to the other limb (termed unilateral dependent rubor; when both limbs are affected this is termed bilateral dependent rubor). Diminished hair and nail growth on affected limb and digits.Peripheral arterial disease (PAD) is divided into 4 stages (Fontaine).

1. Asymptomatic (ABI <0.9)
2. Functional pain (Claudication)
3. Rest pain
4. Non-healing ulcers or gangrene.

The diabetes control and complications trial (DCCT) research group showed an association between glycaemia and the progression of microvascular complications in patients with diabetes for haemoglobin A1c over the range of 6-11 percent after a mean of six years of follow up.

The incidence of symptomatic PAD is 3-4 percent and in asymptomatic cases where the ABI is <0.9 is much higher and approximately 20 percent of all persons above 60 years of age. The incidence of PAD in diabetics depends on the usual atherosclerotic risk factors and duration of diabetes. There are few demographic studies studying the general population .Using ABI<0.9 as selection criteria, Lange et al found a prevalence of 26.3percent in people with diabetes compared to 15.3percent in people without diabetes when screening 6880 people above 65 years of age of whom 1743 had diabetes. Similar findings have been reported by others:20-30percent of those with diabetes have PAD and even claudication. In another study conducted by Hans U. Janka and others (12) found Data of 623 nonselected diabetic outpatients presented who were screened for peripheral vascular disease (PVD) and for cardiovascular risk factors. PVD was diagnosed in 15.9percent of the diabetic patients (14.4% women and 18.0percent men). Nine percent of the patients had signs of marked mediasclerosis at the ankle level. Multivariate statistical analysis revealed that PVD was closely associated with systolic hypertension and also with the duration of diabetes, a relationship that was highly significant ($P < 0.001$) for the peripheral type (below the knee) of PVD.Therefore, ABI will quantify the ischemia and can be used to monitor changes in the disease.ABI >1.3 is associated with a marked increased mortality and treatment can be instituted at an early stage. So it is important to understand patients with PAD derived as much or greater benefit from lifestyle modification and aggressive, preventive medical therapy.ABI is simple to perform, a non-invasive, quantitative measurement of the patency of the lower extremity arterial system.

Aims & objective

To establish the prevalence of lower extremity peripheral arterial disease (pad) defined as an abi<0.9 in patients with diabetes (type1 &2 both).

To establish the co-relation between prevalence of pad with the duration of diabetes.

To establish the co-relation between abi with other risk factors of PAD.

Research methodology

This research is descriptive in nature and includes the analysis of the cross-sectional observations collected from the department of Medicine of a Tertiary care hospital -Safdarjung Hospital, New Delhi. The sample

size in the research study is 50 which includes diabetic patients (both type 1 and type 2), 18-80 years of age of either sex, admitted in the ward in the department of medicine. In addition to this the other criteria of including the patients in the research study are as follows:

1. Receiving insulin and/or oral hypoglycaemic agents.

2. Having lipid profile data at least of past 6 months.

3. Willingness to participate in the study & complying with study by signing a written consent. Patients, who meet the following criteria, are excluded from the study:

1. No past history and present smoker/chain smokers.

2. Patients not having the lipid profile data collected in the last 6 months.

3. Patient who are unwilling /unconscious /unable to provide consent. The data is collected from the available information in the department, interview and questionnaire method as discussed below:

1. Interview-questionnaire method: a self designed open ended questionnaire was used.

2. Manual sphygmomanometers: Ideally operated by a trained person, mercury manometers are considered to be the gold standard and cannot be decalibrated, they are consistently accurate. Due to their accuracy, they are often required in clinical trials of pharmaceuticals and for clinical evaluations of determining blood pressure for high risk patients including pregnant women. Manual sphygmomanometers require a stethoscope for auscultation. Although it is possible to obtain a basic reading through palpation, this only yields the systolic number.

3. Doppler study-Philips HD11 XE Machine.

4. Data on GPE, height, weight, BMI, B.P(supine) and diabetic complications was recorded.

5. biochemical aspect-

- a) Fasting blood samples from the participants are collected and analysed for HbA1c and post-prandial blood sugar levels.

- b) Blood urea, serum cholesterol, serum triglycerides, serum creatinine, HDL cholesterol and LDL cholesterol were measured. The patients fulfilling the inclusion criteria are selected randomly in the study. The selected participants are divided into 2 groups:

- Recently diagnosed diabetes <5 years.

- Known diabetes >5 years duration. After explaining the entire procedure in the study and taking a written consent from the participant the information is gathered from them and analysed. The study questionnaire consists of two parts: first part is an open ended questionnaire which is filled after explaining every question to the patient in the local language. Second part, is a reporting about the general physical examination of the patient and the various biochemical investigations carried out. A structured interview is used

to record details of hypertension, diabetes, alcoholism and answers to the questionnaire used in the study. Anthropometric measurements included height, weight and BMI is determined according to the kilogram per meter squared. The blood pressure is recorded using a mercury sphygmomanometer in the right arm in the supine position. Two readings are taken 5 min apart, and the mean is taken. Alcohol intake was categorized as none and alcohol (social/regular). A general physical examination of the patient was carried out and the data was recorded followed by

Biochemical investigations

A fasting blood sample and a post prandial blood sample was collected under all aseptic conditions in sterile bottles. All of the blood samples were transported safely under all precautions to the nearest lab, ICMR building. Reports were received within 24 hours and the result was recorded.

Calculating AB

The tool required to perform ABI measurement includes a manual mercury sphygmomanometer and a stethoscope for auscultation. The systolic blood pressure (SBP) was measured in both the arms around the brachial artery after placing the patient in supine position for 5 minutes. Similarly, recordings were made of the dorsalis pedis & posterior tibial pulses in the lower limb by inflating the cuff proximal to the ankle, and mean of these readings was taken as ankle pressure. The ankle-brachial index (ABI) was calculated in every subject as: $ABI = \text{mean SBP of ankle} / \text{mean SBP of upper limb}$. Because of logistical reasons, it was decided to restrict the Doppler studies to 50 percent of the participants of the study i.e every alternate individual (i.e 25 patients). The ankle brachial index (ABI) was calculated in every subject similarly as performed using sphygmomanometer. The Doppler studies were performed by a single observer using the Philips HD11 XE Machine. The criterion for diagnosis of PVD was an $ABI < 0.9$.

Definitions & diagnostic criteria

Diabetes was diagnosed in the study participants based on the past medical history, drug treatment for diabetes (oral hypoglycaemic agents or insulin) and/ criteria outlined by WHO.

Diabetes was diagnosed if fasting blood sugar level $> 130 \text{ mg/dl}$ and post prandial $> 180 \text{ mg/dl}$ (7,8). Normal values of HbA1c: The International Diabetes Federation and American College of Endocrinology recommend HbA1c values below 48 mmol/mol (6.5%), while American Diabetes Association recommends that the HbA1c be below 53 mmol/mol (7.0%) for most patients.

Hypertension was diagnosed based on history of drug treatment for hypertension or blood pressure was $> 140/90 \text{ mm Hg}$ (10) Hypertriglyceridemia and

Hypercholesterolemia were diagnosed if serum cholesterol or triglycerides were $>2.26\text{mmol/l}$ (200mg/dl) and $>5.2\text{mmol/l}$ (200mg/dl), respectively, according to National cholesterol Education program guidelines.

Statistical Data Analysis

The data analysis is done using the software's MS Excel and SPSS- 18.

Discussion

There have been various studies conducted worldwide in the past to find out the prevalence of peripheral vascular disease and the associated risk factors. However, very few studies have been conducted in the Indian medical setup. Thus, this study was conducted among the diabetic patients visiting Safdarjung Hospital, New Delhi aiming to find out the prevalence of peripheral vascular disease and to establish a correlation between ankle brachial index and other risk factors. In the present study, we observed out of all the 50 diabetic patients 13 patients are found to have ABI less than 0.9 are considered to have a peripheral vascular disease, whereas rest of the patient (37) are having ABI greater than 0.9. Therefore, the prevalence of PVD in recently diagnosed diabetic subjects is 19.23 percent vs. 33.33 percent in known diabetic subjects. Which is considerably similar to the studies reported in the European study. The results indicate that there exist no co-relation between the age of the patient with PVD. However, there exists a significant negative co-relation (significant at the 0.05 level) between BMI and ABI. Hence

it can be concluded from the result if the BMI of the person increases the ABI value will decrease which results in PVD. In the past, it was believed that duration of diabetes was related to the increased risk of PVD but according to the present study there was no significant correlation between PVD and duration of diabetes.

Conclusion

Diabetes is a major risk factor of PVD. This article shows the prevalence of PVD is low in the population studied (19.23% in recently diagnosed and 33.33% in known diabetic patients). In contrast, high prevalence rates of PVD have been reported from the Netherlands (16), the U.K. (14 & 15), and the U.S. (13). Thus, this study confirms our earlier clinic-based data that the prevalence of PVD is low among Indians if ABI is used as the criterion for the diagnosis of PVD.

A significant strong association of PVD with BMI. Patients should aim to keep their BMI to the normal value to reduce the risk of PVD.3.

Weak association of hypertension with PVD.4.

Duration of diabetes has no significant relationship with PVD.

Correlation of the level of ABI is high with serum cholesterol in PVD patients as compared to non PVD patients.

No significant correlation between the level of ABI and blood sugar (fasting).