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Comparison Study of Prevalence and Clinical Profile of Peripheral Arterial Disease in Type II Diabetes between Young and Elderly

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Abstract

Introduction: peripheral arterial disease, manifested as intermittent claudication or critical ischemia, or identified by an ankle/brachial index < 0.9, is present in at least one in every four patients with type 2 diabetes mellitus. despite continuing advances in diabetes pharmacotherapy, fewer than half of adults with type 2 diabetes mellitus (T2D) attain therapeutic goals designed to reduce long-term risks of complications, especially for glycemic control, and lifestyle interventions are disappointing in the long term. In facing these challenges, it is imperative that interventions that may interdict the disease process and complement existing therapies be expeditiously advanced into clinical practice while also balancing the costs attributed to each intervention. Peripheral arterial disease (PAD) is one of the macrovascular complications of type 2 diabetes mellitus. Unlike other complications, it has received little attention, especially in the India. With growing elderly population it is also important to address the gap between the diagnosis, treatment and prognosis amongst the young and elderly population. Hence, with this aim we carried out the present study to assess the prevalence and clinical profile of PAD in type 2 diabetes and comparing it with the young and the elderly population by measuring ankle brachial index using duplex Doppler ultrasound of the lower limbs and to correlate it with various risk factors.

Materials and Methods: Cross sectional study of patients with newly diagnosed Diabetes Mellitus presenting to MGM Institute of Health Sciences, Navi Mumbai from 2015 to 2016. They presented to physician either for routine checkup or have been admitted for some other illness and diabetes was detected. On presentation detailed history with chief complaints was taken from the patients followed by examination for detection of peripheral arterial diseases and investigations were advised to diagnose the same. Patients were included in the study after taking an informed consent.

Results: 67% patients were in the age group of >60 years followed by 23% patients from the age group of 51-60 years. Majority of the patients were male (63%) whereas female patients constituted 37% of the study group. 35% patients had ABI<0.9 while 65% patients had ABI≥0.9. 20% patients had ABI <0.5, 31.4% patients had ABI 0.5-0.79 and 48.6% patients had ABI 0.8-0.89. 59% patients were asymptomatic while 41% patients were symptomatic. 30% patients were smokers while 70% patients were non-smokers. 28% patients had HbA1c levels <7 while 72% had HbA1c levels ≥7. Ankle Brachial Index (ABI) showed Peripheral Arterial Disease (PAD) in 35 (35%) patients and absence of PAD in 65 (65%) patients whereas Colour Doppler showed PAD in 38 (38%) patients. The prevalence of PAD in Type 2 Diabetes patients showed an increasing trend with increasing age. There was higher occurrence of peripheral arterial disease in males as compared to females, however the association was insignificant. 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. Age, smoking, HbA1C, duration of diabetes, systolic BP and diastolic BP were found to be significantly different between the two groups.

Conclusion: Peripheral arterial disease is one of the macrovascular complications of type 2 diabetes mellitus and presents late, having already developed ischaemia because of the unique involvement of distal pattern of vessels and invariable association with neuropathy. The prevalence was seen more in the elderly population (67%).The prevalence of peripheral vascular disease in type 2 diabetes mellitus as measured by ankle-brachial pressure index was 35%. The high prevalence of PAD in our studied diabetic population points out to the need for routine screening and structured managements. These tasks require active measures that include patient education, risk assessment, and timely intervention.

Keywords: Type II diabetes, Peripheral arterial disease, Ankle Brachial Index, doppler ultrasound

Introduction

Peripheral arterial disease, manifested as intermittent claudication or critical ischemia, or identified by an ankle/brachial index < 0.9, is present in at least one in every four patients with type 2 diabetes mellitus. Several reasons exist for peripheral arterial disease in diabetes. In addition to hyperglycemia, smoking and hypertension, the dyslipidemia that accompanies type 2 diabetes and is characterized by increased triglyceride levels and reduced high-density lipoprotein cholesterol concentrations also seems to contribute to this association. The accelerating pandemic of diabetes is recognized as one of the greatest global public health threats of our time 1. When one reviews the latest estimates for diabetes prevalence and projections worldwide, it is easy to appreciate the magnitude of the problem facing us not only today but also for generations to come. Given the microvascular and macrovascular complications associated with this disease, as well as the resulting morbidity and mortality, the personal, medical, and societal costs are enormous 2,3. In addition, despite continuing advances in diabetes pharmacotherapy, fewer than half of adults with type 2 diabetes mellitus (T2D) attain therapeutic goals designed to reduce long-term risks of complications, especially for glycemic control 4-6, and lifestyle interventions are disappointing in the long term. In facing these challenges, it is imperative that interventions that may interdict the disease process and complement existing therapies be expeditiously advanced into clinical practice while also balancing the costs attributed to each intervention5. Type 2 diabetes mellitus (T2DM) is the commonest form of diabetes constituting 90% of the diabetic population. The global prevalence of diabetes is estimated to increase from 4% in 1995 to 5.4% by the year 2025 7. The World Health Organization has predicted that the major burden will occur in the developing countries and there will be a 42% increase (from 51 to 72 million) in the developed countries and 170% increase (from 84 to 228 million) in the developing countries. The countries with the largest number of diabetes patients are, and will be in the year 2025, India, China and United States7,8,9. The number of diabetes patients in India currently around 40.9 million is expected to rise to 80 million by 203010. In developing countries, the majority of diabetes patients are in the age range of 45-64 years whereas in the developed countries are aged >"65 years9. With growing elderly population it is also important to address the gap between the diagnosis, treatment and prognosis amongst the young and elderly population. The so-called "Asian Indian Phenotype" refers to certain unique clinical and biochemical abnormalities in Indians which include increased insulin resistance, higher waist circumference despite lower body mass index, lower adiponectin and higher high sensitive C-reactive protein levels. This phenotype makes Asians more prone to diabetes and premature coronary artery disease10. The acute and chronic complications of diabetes mellitus are major causes of hospital admissions. Asian patients had more evidence of macro and micro vascular disease at diagnosis of diabetes[11]. Several studies showed that the prevalence of microvascular and macrovascular complications were more in Asians when compared to Europeans[11]. Lifestyle modifications such as weight control, increased physical exercise, and smoking cessation are also potentially beneficial in preventing diabetes mellitus and coronary artery disease12. Peripheral arterial disease (PAD) is one of

Volume 4, Issue 6; November-December 2021; Page No 820-830

the macrovascular complications of type 2 diabetes mellitus. Unlike other complications, it has received little attention, especially in the India. Hence, with this aim we carried out the present study to assess the prevalence and clinical profile of PAD in type 2 diabetes by measuring ankle brachial index using duplex Doppler ultrasound of the lower limbs and to correlate it with various risk factors.

Aims And Objectives

1. To detect peripheral arterial disease in type 2 diabetes mellitus patients by using ankle brachial index.
2. To confirm presence of peripheral arterial disease by color doppler studies in both lower limbs in Type 2 Diabetes patients.
3. To study the prevalence of peripheral arterial disease in Type 2 Diabetes patients amongst young and elderly.
4. To study the clinical profile & various risk factors contributing to development of peripheral arterial disease.

Materials And Methodology:

Source Of Data: A Cross sectional study of 100 patients with newly diagnosed Diabetes Mellitus presenting to MGM Institute of Health Sciences, Navi Mumbai from 2015 to 2016. They presented to physician either for routine checkup or have been admitted for some other illness and diabetes was detected. On presentation detailed history with chief complaints was taken from the patients followed by examination for detection of peripheral arterial diseases and investigations were advised to diagnose the same. Patients were included in the study after taking an informed consent.

Inclusion Criteria

1. Patients with Type 2 Diabetes Mellitus presenting to MGM Institute of Health Sciences, Navi-Mumbai.
2. Age group 30-80yrs. Criteria for establishing Diabetes Mellitus according to ADA guidelines :
3. Fasting plasma glucose > 126 mg/dl (7.0mmol/dl). [Fasting is defines as no calorie intake for at least 8hours].
4. Postprandial plasma glucose >200mg/dl [2 hours after 75gm of oral glucose intake]
5. HbA1c >6.5%.The test performed in laboratory using a method that is NGSP certified and standardized to the DCCT assay.

Exclusion Criteria

1. Age group < 30yrs.
2. Type 1 Diabetes Mellitus or other types of DM except type 2 DM
3. Patients with following conditions which would interfere with the measurement of ankle brachial index:
4. Trauma, surgery or amputation involving the limbs.
5. Leg ulcers
6. Deep vein thrombosis
7. Filariasis or lower limb swelling due to other causes.
8. GDM
9. Patients on vasodilators
10. Patient unwilling to consent or co-operate.

Method Of Collection Of Data Clinical History

1. A detailed history was obtained from each patient which included age, sex, smoking, alcohol intake, history of diabetes mellitus – like polyuria, polydypsia, polyphagia and weight loss, duration, treatment. Family history of diabetes was also taken.
2. Smoking status was defined as :Smoker: smoking ≥ 1 cigarette/ bidi per day at the time of the study or quit smoking < 10 years back and non-smoker: never smoked/left smoking for ≥10 years.
3. History of peripheral arterial disease was taken in detail which included history of tingling and numbness of the legs, burning sensation in the legs and so on.

Clinical Examination And Investigations

1. All the Type 2 diabetic patients were screened by Vascular Doppler instrument, for peripheral arterial disease using ankle brachial index.
2. 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 arms. Similarly, ankle blood pressure was measured by palpatory method with the cuff placed just above the ankle and then by measuring Doppler blood

Volume 4, Issue 6; November-December 2021; Page No 820-830

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. An ABI of < 0.9 was defined as a low ABI indicative of peripheral arterial disease.

3. Patients with ankle brachial index <0.9 were subjected to color Doppler of both lower limbs to confirm presence of peripheral arterial disease.
4. Colour Doppler was done on Philips HD 15 & Philips HD 11 ultrasonography machine with High Frequency Linear Transducer (L12-3) probe producing a frequency of upto 12Hz

Sample Size Calculation:

Considering a confidence level of 95% and confidence interval of 10 the number of patients in our study to achieve statistical significance is 96. This was calculated by Survey System (http://www.surveysystem.com/sscalc.htm#one). The Survey System ignores the population size when it is "large" or unknown. Population size is only likely to be a factor when you work with a relatively small and known group of people (e.g., the members of an association). Hence a sample size of 100 was considered adequate for our study.

Statistical Analysis

Quantitative data is presented with the help of Mean and Standard deviation. Comparison among the study groups is done with the help of unpaired t test as per results of normality test. Qualitative data is presented with the help of frequency and percentage table. Association among the study groups is assessed with the help of Fisher test, Chi-Square test and logistic regression test. 'p' value less than 0.05 is taken as significant. Results were graphically represented in MS Excel 2010 where deemed necessary. Appropriate statistical software, including but not restricted to MS Excel, SPSS ver. 20 will be used for statistical analysis.

Observations And Results

A hospital based cross-sectional study among 100 patients was conducted to study Peripheral arterial disease (PAD) in Type 2 Diabetics. 67% patients were in the age group of >60 years followed by 23% patients from the age group of 51-60 years, 7% patients from the age group of 41-50 years and 3% from the age group of 31-40 years. Majority of the patients were male (63%) whereas female patients constituted 37% of the study group. An ABI <0.9 in either leg was considered abnormal, suggesting peripheral arterial disease. 35% patients had ABI<0.9 while 65% patients had ABI≥0.9. Among the patients with abnormal ABI, 20% patients had ABI <0.5, 31.4% patients had ABI 0.5-0.79 and 48.6% patients had ABI 0.8-0.89. 59% patients were asymptomatic while 41% patients were symptomatic. 30% patients were smokers while 70% patients were non-smokers. 28% patients had HbA1c levels <7 while 72% had HbA1c levels ≥7. 39% patients had diabetes for more than 10 years while 23% patients each had diabetes for ≤1 year and 6-10 years respectively. 15% patients had diabetes for >1-5 years. Colour Doppler findings showed that there was involvement of arteries in 38% patients while 62% patients showed normal findings. In the present study, Ankle Brachial Index (ABI) showed Peripheral Arterial Disease (PAD) in 35 (35%) patients and absence of PAD in 65 (65%) patients whereas Colour Doppler showed PAD in 32 (32%) patients. ABI was unable to detect PAD in 6 patients. Also 3 of the 35 patients diagnosed as having PAD by ABI were classified as normal by the Colour Doppler. Hence sensitivity and specificity of ABI is 84.2% & 95.1% respectively in comparison with Colour Doppler. The positive predictive value and negative predictive value of ABI is 91.4% and 90.75 respectively. There was a significant association of PAD with age in T2DM. It was observed that with increasing age, the occurrence of PAD in T2DM showed an increasing trend ($p<0.05$). There was higher occurrence of peripheral arterial disease in males as compared to females, however the association was insignificant. It was observed in this study that patients with peripheral arterial disease had higher occurrence of symptoms and this association was significant ($p<0.05$). There was significant association of PAD with smoking habits in T2DM and smoking is an important predictor for abnormal ABI. All patients with peripheral arterial disease had significantly higher levels of HbA1C as compared to patients without peripheral arterial disease. There was significant association of duration of diabetes with PAD in T2DM. The differences between the PAD and the non-PAD groups in terms of risk factors were

Volume 4, Issue 6; November-December 2021; Page No 820-830

assessed using Student's t-test for continuous variables and chi-square test for discrete variables. Age, smoking, HbA1C, duration of diabetes, systolic BP and diastolic BP were found to be significantly different between the two groups.

Table 1: Distribution of patients according to Age

Age	No of patients	%
31-40	3	3%
41-50	7	7%
51-60	23	23%
>60	67	67%
Total	100	100%

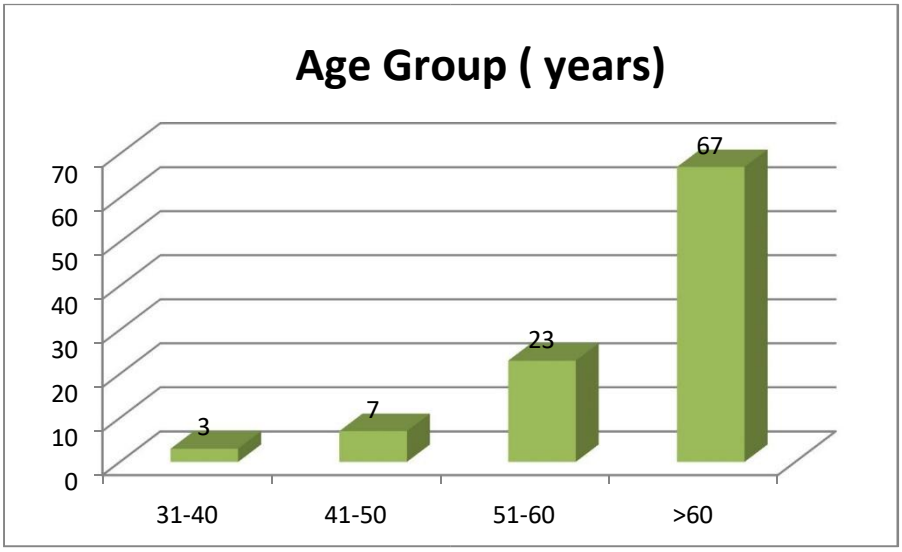
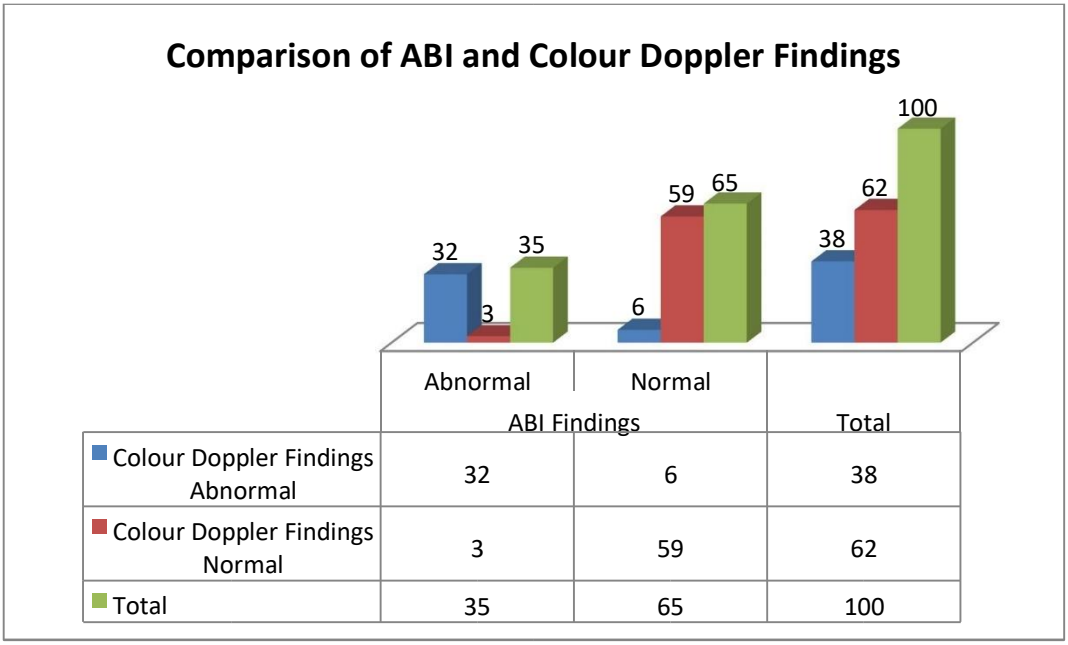


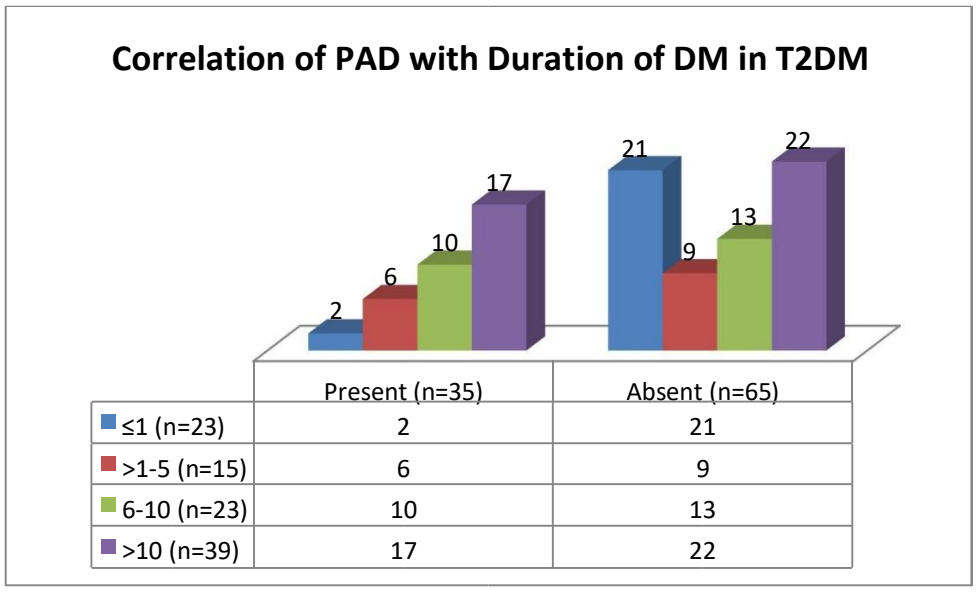
Figure 1: Distribution of patients according to Age. 67% patients were in the age group of >60 years followed by 23% patients from the age group of 51-60 years, 7% patients from the age group of 41-50 years and 3% from the age group of 31-40 years

Volume 4, Issue 6; November-December 2021; Page No 820-830



	Abnormal	Normal	Total
Colour Doppler Findings Abnormal	32	6	38
Colour Doppler Findings Normal	3	59	62
Total	35	65	100

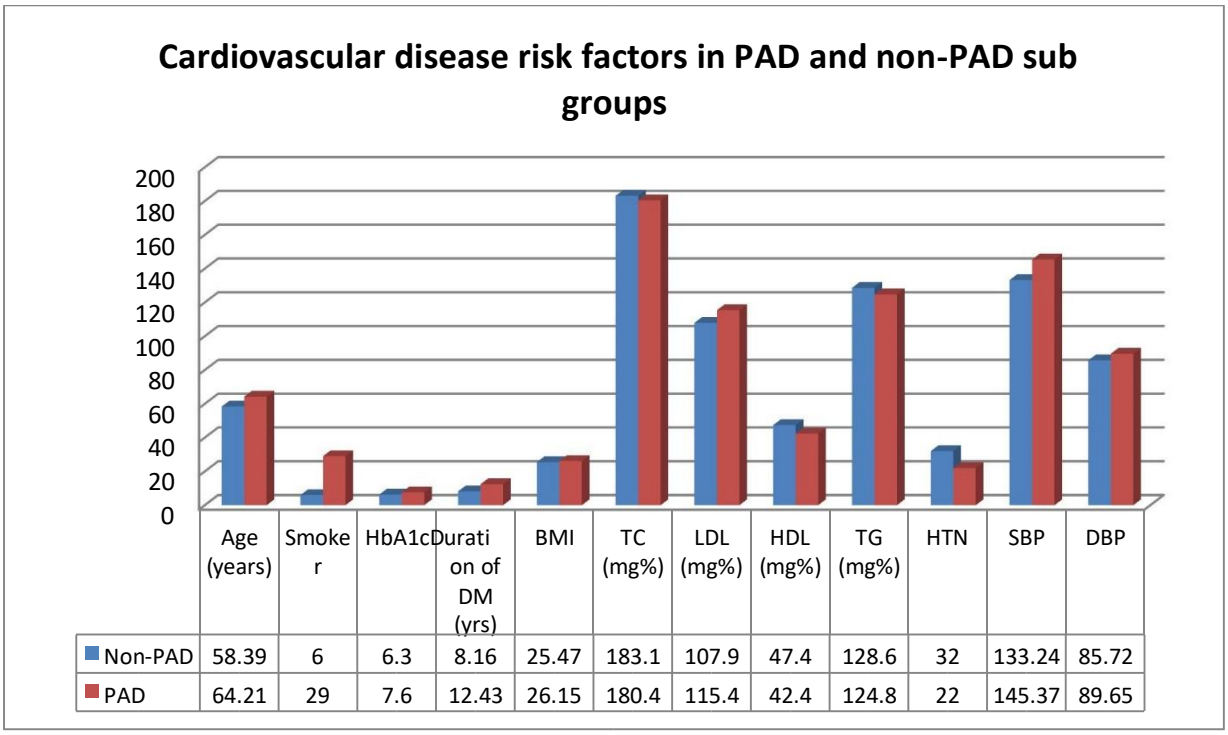
Figure 2: Comparison of Ankle Brachial Index (ABI) and Colour Doppler Findings Correlation of Peripheral Arterial Disease (PAD) with Age in T2DM



	Present (n=35)	Absent (n=65)
≤1 (n=23)	2	21
>1-5 (n=15)	6	9
6-10 (n=23)	10	13
>10 (n=39)	17	22

Figure 3: Correlation of Peripheral Arterial Disease (PAD) with Duration of DM in T2DM

Volume 4, Issue 6; November-December 2021; Page No 820-830



	Age (years)	Smoker	HbA1c	Duration of DM (yrs)	BMI	TC (mg%)	LDL (mg%)	HDL (mg%)	TG (mg%)	HTN	SBP	DBP
Non-PAD	58.39	6	6.3	8.16	25.47	183.1	107.9	47.4	128.6	32	133.24	85.72
PAD	64.21	29	7.6	12.43	26.15	180.4	115.4	42.4	124.8	22	145.37	89.65

Figure 4: Cardiovascular disease risk factors in PAD and non-PAD sub groups

Discussion

Diabetes, once considered as a disease of developed countries, is one of the endocrine disorders that has reached epidemic proportions worldwide[13]. The metabolic deregulation associated with diabetes mellitus (DM) causes secondary path physiologic changes in multiple organ systems that impose a tremendous burden on the individual with diabetes and on the health care system[14]. Peripheral arterial disease (PAD) is a condition characterized by atherosclerotic occlusive disease of lower extremities and is a marker for atherothrombotic disease in other vascular beds. Peripheral arterial disease is one of the macrovascular complications of type 2 diabetes mellitus[15]. PAD in diabetic patients presents late, having already developed ischaemia because of the unique involvement of distal pattern of vessels and invariable association with neuropathy[16].

Ankle-brachial pressure index is a non-invasive testing method which greatly increases the accuracy of clinical diagnosis for the presence of arterial disease and serves as an objective index to follow the natural history of the disease[17]. Ankle-brachial pressure index is the most efficient, objective, and practical means of documenting presence and severity of peripheral arterial disease[18]. In the present study, 100 patients were enrolled to study Peripheral arterial disease (PAD) in Type 2 Diabetics.

67% patients were in the age group of >60 years followed by 23% patients from the age group of 51-60 years. Majority of the patients were male (63%) whereas female patients constituted 37% of the study group. It was also observed that 39% patients had diabetes for more than 10 years. This is similar to the study of Al-Kaabi JM et al[19]. Al-Kaabi JM et al[19] did a prospective, cross-sectional study that assessed PAD in 394 patients with type 2 diabetes mellitus. Each patient was investigated by history, physical examination and measurements of the ankle-brachial index (ABI) by bidirectional doppler. Patient's mean (±SD) age was 54 (±12) years and duration of diabetes 10 (±8) years.

An ABI <0.9 in either leg was considered abnormal, suggesting peripheral arterial disease. 35% patients had ABI<0.9 while 65% patients had ABI≥0.9. Among the patients with abnormal ABI, 20% patients had ABI <0.5, 31.4% patients had ABI 0.5-0.79 and 48.6% patients had ABI 0.80.89. 59% patients were asymptomatic while 41% patients were symptomatic. 30% patients were smokers while 70% patients were non-smokers. This is in agreement to the findings of El Toony LF et al[20] and Mourad JJ et al[21].

Volume 4, Issue 6; November-December 2021; Page No 820-830

In the study of Toony LF et al[20], 200 type 2 diabetes mellitus patients attending the diabetic outpatient Clinic at Assiut University Hospital were subdivided according to their Ankle Brachial Index measurement (ABI) into 71 (35.5%) patients with abnormal ABI (Group I) and 129 (64.5%) patients with normal ABI (Group II). Also 29% patients were smokers. Mourad JJ et al[21] in a prospective, observational, real-life, epidemiologic study calculated the prevalence of peripheral arterial disease to be 41.1%.

28% patients had HbA1c levels <7 while 72% had HbA1c levels ≥7. In the present study, Ankle Brachial Index (ABI) showed Peripheral Arterial Disease (PAD) in 35 (35%) patients and absence of PAD in 65 (65%) patients whereas Colour Doppler showed PAD in 32 (32%) patients. ABI was unable to detect PAD in 6 patients. Also 3 of the 35 patients diagnosed as having PAD by ABI were classified as normal by the Colour Doppler. Hence sensitivity and specificity of ABI is 84.2% & 95.1% respectively in comparison with Colour Doppler. The positive predictive value and negative predictive value of ABI is 91.4% and 90.75 respectively. This is in agreement to the study of Khurana A et al[22].

Khurana A et al[22] used a 12MHz Doppler probe in the arms and legs to assess the ankle brachial index (ABI) in 200 type 2 diabetes mellitus patients aged more than 40 years. The objective was to determine the prevalence of peripheral arterial disease in type 2 diabetes mellitus using the anklebrachial pressure index. 63.6% (42) patients had HbA1C levels >7, while 36.4% (24) had HbA1C levels <7.

The prevalence of PAD as detected by Doppler ultrasound (ABI) was 32%. Previous studies by Marinelli MR et al[23], Janka HU et al[24], Walter DP et al[25], Migdolis LN et al[26] and the Fremantle diabetes study by Norman PE et al[27] found the prevalence of PAD to be 33%, 15.9%, 23.5%, 44% and 13.6%, respectively.

Few Indian studies have assessed PAD in diabetics. Two large studies from South India, namely, by Mohan V et al[27] (n=4941) and CUPS[28] (n=1262) found a prevalence of PAD in diabetics to be 3.9% and 6.3%, respectively. CUPS, a community based study, found a lower prevalence of PAD than our study which was hospital based. Two recent studies from North India, one by Agrawal RP et al[29] (n=4400) and the other by Madhu SV et al[30] (n=364) found the prevalence of PAD in diabetics to be 18.1% and 13.73%, respectively.

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. Age, smoking, HbA1C, duration of diabetes, systolic BP and diastolic BP were found to be significantly different between the two groups.

There was a significant association of PAD with age in T2DM. It was observed that with increasing age, the prevalence of PAD in t2DM showed an increasing trend ($p<0.05$). This is in similar to the study of Lekshmi NRM et al[31]. Lekshmi NRM et al[31] did a cross-sectional study among 521 diabetics and observed that prevalence of PAD was positively associated with increasing age.

There was higher occurrence of peripheral arterial disease in males as compared to females, however the association was insignificant. A population-based study of 3,280 Malay persons aged 40-80 years in Singapore was conducted by Tavintharan S, et al[32] to assess prevalence and risk factors for peripheral arterial disease with diabetes mellitus. The authors concluded that prevalence of PAD was more in the female gender.

It was observed in this study that patients with peripheral arterial disease had higher occurrence of symptoms and this association was significant. This is in agreement to the study done by BuitrónGranados LV et al[33], which showed that the presence of symptoms was more frequent in subjects with peripheral arterial disease.

There was significant association of PAD with smoking habits in T2DM and smoking is an important predictor for abnormal ABI. Smoking is thought to promote atherosclerosis by increasing LDL oxidation and augmenting endothelial dysfunction (by reducing in nitric oxide dependent vasodilatation)[34]. In the study of Dormandy JA et al[35], the authors concluded that smokers with PAD were twice as likely to undergo lower limb amputation compared to nonsmokers with PAD.

All patients with peripheral arterial disease had significantly higher levels of HbA1C as compared to patients without peripheral arterial disease. This is similar to the study of Adler AI et al[36] who studied

Volume 4, Issue 6; November-December 2021; Page No 820-830

potential risk factors for the development of peripheral arterial disease and reported that hyperglycaemia was associated with an increased risk for peripheral arterial disease, independent of other risk factors.

In the present study, there was significant association of duration of diabetes with PAD in T2DM. This is in agreement to the study of Papanas N et al[37]. Papanas N et al[37] did a study among 302 patients with Coronary Artery Disease (CAD) to evaluate the impact of Diabetes Mellitus (DM) on severity of concomitant Peripheral Arterial Occlusive Disease (PAOD). The authors concluded from their study that peripheral arterial occlusive disease in patients was associated with duration of diabetes mellitus.

The study limitations included lack of confirmatory tests, such as magnetic resonance angiography, computerized tomography scan and invasive arteriography. The study is based on a single center and thus the prevalence of PAD cannot be generalized for the entire population. Multicenter study is needed. Follow up studies are needed to assess the progression of PAD with various risk factors and outcome of using different classes of medications.

Summary

In the present study, 100 patients were enrolled to study Peripheral arterial disease (PAD) in Type 2 Diabetics. Based on the observations, the following conclusions were drawn:

1. 67% patients were in the age group of >60 years followed by 23% patients from the age group of 51-60 years.
2. Majority of the patients were male (63%) whereas female patients constituted 37% of the study group.
3. 35% patients had ABI<0.9 while 65% patients had ABI≥0.9. Among the patients with abnormal ABI, 20% patients had ABI <0.5, 31.4% patients had ABI 0.5-0.79 and 48.6% patients had ABI 0.8-0.89.
4. 59% patients were asymptomatic while 41% patients were symptomatic.
5. 30% patients were smokers while 70% patients were non-smokers.
6. 28% patients had HbA1c levels <7 while 72% had HbA1c levels ≥7.
7. Ankle Brachial Index (ABI) showed Peripheral Arterial Disease (PAD) in 35 (35%) patients and absence of PAD in 65 (65%) patients whereas Colour Doppler showed PAD in 38 (38%) patients.
8. The prevalence of PAD in Type 2 Diabetes patients showed an increasing trend with increasing age.
9. There was higher occurrence of peripheral arterial disease in males as compared to females, however the association was insignificant.
10. 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. Age, smoking, HbA1C, duration of diabetes, systolic BP and diastolic BP were found to be significantly different between the two groups.

Conclusion

Diabetes, once considered as a disease of developed countries, is one of the endocrine disorders that has reached epidemic proportions worldwide. Peripheral arterial disease is one of the macrovascular complications of type 2 diabetes mellitus and presents late, having already developed ischaemia because of the unique involvement of distal pattern of vessels and invariable association with neuropathy.

The age group which had a higher prevalence of PAD was above 60 years with 67% of the study population. The prevalence of peripheral vascular disease in type 2 diabetes mellitus as measured by ankle brachial pressure index was 35%. The high prevalence of PAD in our studied diabetic population points out to the need for routine screening and structured managements. These tasks require active measures that include patient education, risk assessment, and timely intervention.

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Volume 4, Issue 6; November-December 2021; Page No 820-830

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Volume 4, Issue 6; November-December 2021; Page No 820-830

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Volume 4, Issue 6; November-December 2021; Page No 820-830