Screening for Peripheral Vascular Disease among Type 2 Diabetes Patients of Lower Socio Economic Status using Ankle Brachial Index - A Descriptive Cross Sectional Study

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ABSTRACT

Introduction: Diabetes mellitus is one of the key important non-communicable diseases of this century in terms of mortality and prevalence. Peripheral Vascular Disease (PVD) is one of the most common macrovascular complications of Type II DM. PVD in risky cases exhibits as claudication or gangrene, but in maximum cases, manifests hidden symptoms. Early detection of vascular changes helps in effective handling of Diabetes and its complications. Study objectives were to assess Ankle Brachial Index in all asymptomatic vasculopathy in type2 diabetic patients of low socio-economic status using a hand-held doppler and to correlate the findings of Ankle Brachial Index with PVD.

Material and methods: A descriptive cross sectional study done among the patients with asymptomatic vasculopathy in Type 2 diabetes mellitus patients coming to outpatient department as well as admitted as inpatients in Shri Sathya Sai Medical College and Research Centre, Ammapettai, Tamilnadu, India. The study duration was 18 months. Sample size was calculated to be 130.

Results: In the study population of 130, using the ankle brachial index, 110 (84.6%) were normal (1 and above). 11 (8.5%) and 9 (6.9%) were having asymptomatic claudication (0.9-0.99) and claudication (<0.9) respectively. The prevalence of PVD is 15.4% in the study population.

Conclusion: Ankle Brachial Index is a simple, easy to perform, rapid, reliable and accurate test which can be performed especially among the high risk groups.

Keywords: Peripheral Vascular Disease, Type 2 Diabetes, Ankle Brachial Index

INTRODUCTION

Diabetes is the most common metabolic disorder all over the world with the incidence of diabetes increasing in the developing countries, especially in India. Type 2 diabetes is the most prevalent form in India with 95% of the case belonging to Type 2 Diabetes. India with more than 62 million diagnosed diabetic patients is quickly getting the title of "Diabetic Capital of the World".[1] Type II Diabetes Mellitus is prevalent with growing drift around the world and more number of patients are present in developing nations like India due to rapid industrialisation and urbanisation.[2–4]

Diabetes when uncontrolled has adverse complications on the vascular system, with macrovascular and microvascular complications. Peripheral Vascular Disease (PVD) is one of the most common macrovascular complications of Type II DM. PVD in risky cases exhibits as claudication or gangrene,

but in maximum cases, manifests hidden symptoms.[5] Nearly half of the patients with PVD are asymptomatic, whereas another half of patients outlines a range of leg symptoms diverse from being asymptomatic to classical intermittent claudication.[6]

Peripheral vascular disease is one of the long-term macrovascular complications of Diabetes mellitus.[7] Diabetes explains for about 50% of all non-traumatic amputations in India especially due to Diabetic foot. There is strong correlation between occurrence of peripheral vascular disease (PVD), coronary artery disease (CAD) and cerebrovascular accidents (CVA). Diabetics are five times more prone to develop peripheral arterial disease when compared to that of non-diabetics. PVD (Peripheral Vascular Disease) is one of the quickly developing and diffuse complication of this disease, with striking risk of foot ulcer, foot infection, fatal myocardial infarction which can further lead to amputation of the limbs and raised mortality especially due to cardiovascular diseases.[8–14]

The progress of intermittent claudication can considerably decrease walking speed and distance. This will result in a progressive damage of function and finally long-term disability. In more dangerous cases, Critical Limb Ischaemia (CLI) may progress and lead to ulceration of the foot.[14,15]

Early detection of vascular changes helps in effective handling of Diabetes and its complications. Early diagnosis of PVD in patients can help them efficiently treat the condition and hence it would prevent its long-term sequelae. Ankle brachial index can be used to find how peripheral vascular disease affects type 2 diabetes patients. Ankle Brachial Index (ABI) is an index calculated by ratio of systolic blood pressure measured at ankle to the systolic blood pressure measured

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in the arm. ABI measurement delivers a simple, reliable, acceptable, valid, non-invasive, operative instrument to access vascular position in diabetics with greater sensitivity and specificity.[16–18]

ABI is considered as the screening test of choice for the diagnosis of patients with PVD due its simplicity, reproducibility and cost effectiveness. Ankle Brachial index has been developed as a non-invasive and inexpensive technique for the diagnosis of PVD. The patient is diagnosed with PVD when ABI values are less than 0.9.[19,20] The studies accomplish that a large percentage of diabetics have a reduced ABI below 0.9.[21,22]

Recent studies suggest the use of low ankle pressure ABI as the method for calculating the ABI due to its better sensitivity. Use of ABI is recommended as part of management of patients who have undergone lower extremity revascularization procedures. The outcome of the study is measuring and associating the Peripheral Vascular Disease with Ankle Brachial Index. The implication of the study will be taking timely steps through identifying the patients with low ABI which is indicative of peripheral vascular disease and hence early to avoid cerebrovascular and coronary events.

Study objectives were to assess Ankle Brachial Index in all asymptomatic vasculopathy in type2 diabetic patients of low socio-economic status using a Doppler and to correlate the findings of Ankle Brachial Index with PVD.

MATERIAL AND METHODS

This is a descriptive cross sectional study done among the patients with asymptomatic vasculopathy in Type 2 diabetes mellitus patients coming to outpatient department as well as admitted as inpatients in Shri Sathya Sai Medical College and Research Centre, Ammapettai. The study was approved by the Institutional Ethics Committee. The study duration was 18 months. Patients of chronic type 2 diabetes mellitus (as per WHO criteria) on dietary restrictions and / or treatment with oral hypoglycemic agents (OHA) and / or insulin for at least last 6 months were included in the study. Patients with associated comorbid conditions such as trauma, surgery or amputation involving the lower limbs, presence of leg ulcers, deep vein thrombosis (DVT), systemic hypertension, filariasis or conditions associated with the swelling of lower limb that may weaken doppler image quality and conditions which impede with the measurement of Ankle Brachial Index were excluded from the study. Sample size was calculated to be 130. Based on previous study, the sample size for this particular study is, Sample size $n0 = 4pq/L^2$

where p = Prevalence is 12,

q = 100 – p = 100 – 12 = 88,

L = Absolute Precision error = 6%.

n = 4 x 12 x 88 / 62,

= 4224/36,

= 117.33

(10% non response error of the total sample)

= 117.33 + 11.73 = 129

Sample size (n) = 130 (rounded off)

Procedure

Institutional Ethical Committee approval was taken prior to the study. Consecutive sampling was followed. After establishing rapport with the study subject, the purpose, procedure, benefits, risks and confidentiality of the study were explained. Informed written consent from the study subject was taken before the interview schedule was administered. Patients were rested in supine position in a warm room for at least 10 min before testing. Then the blood pressure cuffs were placed on both arms and ankles as illustrated, and then ultrasound gel was applied over brachial, dorsalis pedis, and posterior tibial arteries. Systolic pressures were measured in the arms using a hand-held doppler to locate brachial pulse by inflating the cuff above 20 mm Hg from the last audible pulse. By deflating the cuff slowly, pressure was recorded at which the pulse becomes audible. Two measurements were taken in each arm and the average of the brachial pressure in that arm was recorded. Systolic pressures in ankles were measured using the doppler to trace dorsalis pedis pulse and inflating the cuff 20 mm Hg above last audible pulse. By deflating the cuff slowly, pressure was recorded at which the pulse becomes audible. Two measurements were taken in each ankle and the average of the ankle pressure in that arm was recorded. The procedure was repeated with the above steps for posterior tibial arteries.

ABI was calculated using the following formula:

Right ABI = highest right average ankle pressure (DP or PT)/ highest average arm pressure (right or left)

Left ABI = highest left average ankle pressure (DP or PT)/ highest average arm pressure (right or left)

STATISTICAL ANALYSIS

The data was coded and entered in Microsoft Excel and analysed using SPSS version 20. Frequencies and percentages with visualisation was used for categorical variables such as gender, ABI Category. Measures of central tendency and dispersion were used for numerical variables from the serum blood levels such as age, ABI and BMI parameters. Correlation tests and ANOVA test were used as appropriate. P-value of less than 0.05 was considered as statistically significant.

RESULTS

The study population comprised of 130 type II diabetes patients of lower socio economic status with asymptomatic vasculopathy. The mean and median age of the study population is 50.77 and 49 respectively. Out of the total 130 study population 60(46.2%) were females and the rest 70(53.8%) were males. Out of the study population, 61(46.9%) were illiterates, 63(48.5%) were studied up to primary education, 5(3.8%) and 1(0.8%) were having secondary education and college level education. Out of the study population, 48(36.9%) were homemakers by occupation. 29(22.3%) were coolie, 23(17.7%) were farmer by occupation, 10(7.7%) were unemployed. The mean per capita income of the study population is 913.88 with the Std. Deviation of 114.64. 33 and 28 were having family history

Sl. No.	Variable	Category	Frequency	Percent
1	Gender	Female	60	46.2%
		Male	70	53.8%
2	Education	Illiterate	61	46.92%
		Primary	63	48.46%
		Secondary	5	3.8%
		College	1	0.8%
3	Family History	Diabetes	33	25.4%
		CVD/CAD	28	21.5%
		Total	130	100.0

Table-1: Socio-demographic details of the study subjects:

Sl. No.	Variable	Category	Frequency	Percent
1	Treatment for Diabetes	Both Insulin and OHA	12	9.2%
		Insulin	22	16.9%
		OHA	96	73.8%
2	BMI	Underweight	2	1.5%
		Normal	68	52.3%
		Overweight	57	43.8%
		Obese	3	2.3%
		Total	31	100.0

Table-2: Clinical details of the study subjects:

	Correlations	Ankle brachial index
Age	Pearson Correlation	.145
	Sig. (2-tailed)	.100
Per capita income	Pearson Correlation	.089
	Sig. (2-tailed)	.313
Duration of diabetes	Pearson Correlation	.046
	Sig. (2-tailed)	.605
BMI	Pearson Correlation	-.014
	Sig. (2-tailed)	.874
	N	130

**. Correlation is significant at the 0.01 level (p-value). *. Correlation is significant at the 0.05 level (p-value).

Table-3: Correlation of Ankle Brachial Index with continuous variables

		N	Mean	Std. Deviation	p-value (ANOVA)
Age	Normal	110	51.0455	10.17858	0.454
	Asymptomatic Claudication	11	51.4545	14.57644	
	Claudication	9	46.5556	7.51850	
Per capita income	Normal	110	916.4091	111.32260	0.33
	Asymptomatic Claudication	11	931.8182	105.52897	
	Claudication	9	861.1111	159.64370	
Duration of diabetes	Normal	110	4.7845	3.44389	0.081
	Asymptomatic Claudication	11	7.0000	7.30753	
	Claudication	9	3.2222	2.10819	
BMI	Normal	110	22.3555	2.12696	0.745
	Asymptomatic Claudication	11	22.7273	2.10195	
	Claudication	9	22.7778	1.98606	
	Total	130	22.4162	2.10480	

Table-4: ABI Category vs Continuous variables using ANOVA

of diabetes and CVD/CAD respectively. The basic socio-demographic details of the study subjects are represented in table 1.

The mean duration of diabetes of the study population is 4.86 with the Std. Deviation of 3.87. The minimum and maximum duration of Diabetes of the study population are 1 and 25 years respectively. 96 (73.9%) were taking OHA - oral hypoglycaemic agents, 22 (16.9%) were taking insulin and

12 (9.2%) were taking both oral hypoglycaemic drugs and insulin. The mean body mass index of the study population is 22.41 with the Std. Deviation of 2.10. 68(52.3%) were belonging to normal BMI category. This if followed by overweight category, 57(43.8%). Table 2 represents the clinical details of the study subjects.

The mean ankle brachial index of the study population is 1.01. The minimum and maximum ankle brachial index of the study population is 0.78 and 1.09 respectively. In the study population, 110(84.6%) were normal. 11(8.5%) and 9(6.9%) were having mild claudication (0.9-0.99) and claudication (<0.9) respectively. This is represented in the bar-chart-1.

Correlation tests were done between Ankle Brachial Index with age, per capita income, duration of diabetes and BMI using pearson correlation test. There is no significant p-value. The correlation results were represented in the following table 3. Correlation of Ankle Brachial Index with continuous variables

The difference between normal, asymptomatic claudication and claudication groups of ABI were associated with the continuous variables for significant difference in means using ANOVA. The association were not statistically significant with p-value with the duration of the diabetes close to p value of 0.05. This is represented in the following table 4.

DISCUSSION

This study was conducted in a tertiary health-care center in Chennai, TamilNadu, India. The objective of the study is to assess subclinical/asymptomatic vasculopathy in Type-2 Diabetes Mellitus patients of low socio-economic status using Ankle Brachial Index. Out of the total 130 study population 60(46.2%) were females and the rest 70(53.8%) were males. The mean age of the study population is 50.77 with the Std. Deviation of 10.43. The minimum and maximum age of the study population is 24.00 and 93.00 respectively. In other studies conducted by Premalatha G et al, Ramachandran A et al and Orchard et al, the mean age of the study population range between 46 and 59. [4,21,23]

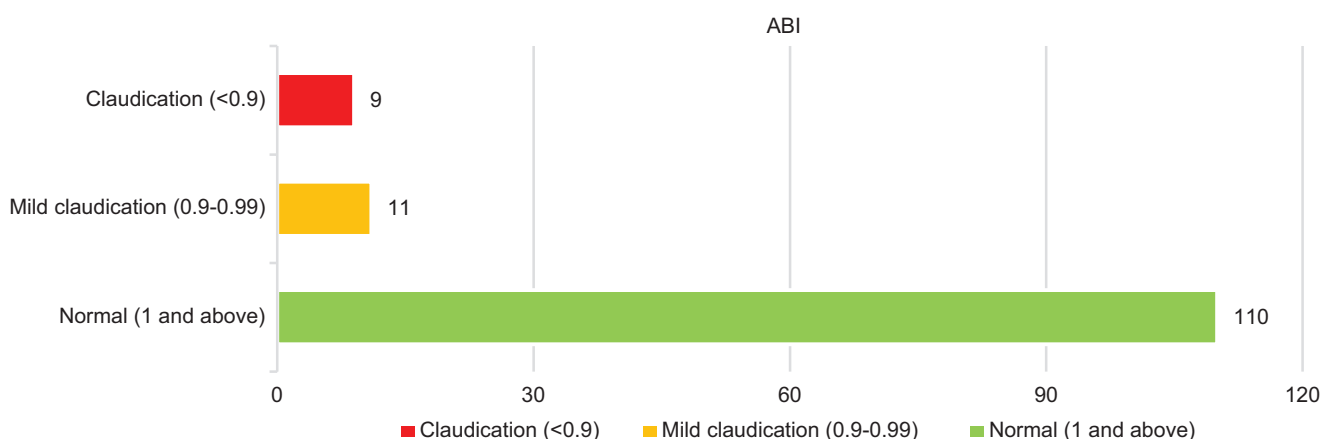The mean Ankle Brachial Index of the study population is 1.01 with the Std. Deviation of 0.074. The median and mode ankle brachial index of the study population is 1. The minimum and maximum ankle brachial index of the study population is 0.78 and 1.09 respectively. 110(84.6%) were normal (1 and above). 11(8.5%) and 9(6.9%) were having asymptomatic claudication (0.9-0.99) and claudication (<0.9) respectively.

Fares Alahdab et al, did a systematic review for the screening for peripheral arterial disease in patients who are asymptomatic and concluded that positive ABI rises the ten-year cardiovascular risk estimations in these persons. No high-quality indication, nevertheless, supports patient-important benefits from screening of low-risk asymptomatic persons or from aggressively handling those with an abnormal ABI.[24]

Ankle Brachial Index was not significantly associated with the socio economic status of the study population. The difference between normal, asymptomatic claudication and claudication groups of ABI were associated with the age, per capita income, duration of diabetes, and BMI for significant difference in means using ANOVA. The significance level was close to 0.05 (0.08) only between duration of diabetes and ABI levels. The prevalence of PVD in this South Indian population is substantially lesser than that is reported in similar Western and Indian studies.

In the study by Agarwal AK et al, risk factors significantly associated with PVD were higher age, systolic and diastolic blood pressure, longer duration of diabetes, smoking, HbA1C and coronary artery disease.[25] In the Fremantle diabetes study, high age, increased duration of diabetes, elevated systolic blood pressure and greater body mass index were found to be significant predictors of PVD.[26] Garcia LA et al, in their study showed risk factors for peripheral arterial disease include age, gender, diabetes, tobacco abuse, hypertension, and hyperlipidaemia.[16] A number of factors related with diabetes such as low High-Density Lipoprotein (HDL), elevated triglyceride, elevated Low-Density Lipoprotein (LDL), metabolic syndrome, and others, are associated with high incidence of low ABI and PVD.[27]

Faglia E et al, did a Screening for peripheral arterial disease through the ankle-brachial index in newly diagnosed patients with Type II diabetes mellitus. They concluded that ABI<0.9

Bar Chart-1: Ankle Brachial Index Category

in 21.1% of their study population.[28] J D Solanki et al, did a study for the assessment of Ankle Brachial Index in 110 patients with type II Diabetes mellitus in urban area of Bhavnagar, Gujarat. They revealed 46% prevalence of symptoms for PVD in the study group.[29] P Sahana et al, identified the high prevalence 34% of the 141 patients of neuropathy and peripheral arterial disease in patients with Type II Diabetes in SSKM Hospital, Kolkata. Increasing age and longer duration of diabetes mellitus, poor glycaemic control by HbA1C and smoking were strongly associated with PVD.[22] Premalatha G et al., conducted a study in Chennai in 2010 among the subjects of two different residential colonies. They showed a low prevalence in this study (6.3%) as matched to the present study (6.9%).[21]

Ankle Brachial Index is a worthy primary screening tool. However, some patients with substantial stenosis in lower extremities would be unidentified, if Ankle Brachial Index is single-handedly used for diagnosis of PVD.[23] ABI<0.9 has 90% sensitivity and specificity.[30,31] The main limitations of the study were firstly the smaller sample size of the study in tertiary care centre and hence the generalisability of the study results is limited. Secondly, the study design was cross sectional one and hence the study cannot demonstrate cause and effect connection and future prospective studies are necessary for reinforcement of observation. Thirdly, the lack of confirmatory tests like invasive arteriography in the study setting (considered the gold standard of diagnosis) disabled us from confirming the diagnosis.

Recommendations

Ankle Brachial Index is a simple, easy to perform, rapid, reliable and accurate test which can be performed especially among the high risk groups.

Future studies can be done with higher sample size so that inferences will be with higher precision, multi-centred so that generalisability to the whole population can be better. Follow up and date on survival can be done so that it will reveal the prognostic factors and factors related to survival can be studied.

CONCLUSION

In the study population of 130, using the ankle brachial index, 110 (84.6%) were normal (1 and above). 11 (8.5%) and 9 (6.9%) were having asymptomatic claudication (0.9-0.99) and claudication (<0.9) respectively. The prevalence of PVD is 15.4% in the study population. This is comparable with the prevalence obtained from other studies from India and the world. Ankle Brachial Index was not significantly associated with the socio economic status of the study population. The significance level was close to 0.05 (0.08) only between duration of diabetes and ABI levels.

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