Assessment of Ankle Brachial Index in Diabetic patients in Urban area of West India.


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Abstract: Background & Objectives:-Peripheral Artery Disease (PAD) is a manifestation of Diabetes Mellitus that is asymptomatic to begin with. There is always a need of cost effective non-invasive technique to quantify this problem. The aim of the study was to determine its prevalence in diabetics of this region by a cross sectional study using Ankle Brachial Index (ABI) as a non-invasive tool. Method:-110 diabetic patients of either sex presenting to medicine OPD were evaluated subjectively by questionnaires. Vascular Doppler was used to derive ratio of ankle pressure to brachial pressure (ABI) using standard protocol. ABI<0.9 was defined as PAD. Results: - Result revealed 46% prevalence of symptoms for PAD in study group. Low ABI prevailed in 35% of subjects more so in females (39 %) than males (31 %), more in symptomatic (55 %) subjects than asymptomatic (17 %) and further lowering of ABI with increasing duration of disease. Interpretation & Conclusion:-This study showed high prevalence of PAD in our region in diabetics with female disadvantage, positive correlation with presence of PAD symptom and cumulative effect of disease. It proved ABI as a non-invasive and reliable screening tool for PAD in our region requiring further larger study for its consolidation.

Key Words:-Ankle brachial index, diabetes mellitus, non-invasive, peripheral artery disease.

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Introduction: Type 2 Diabetes Mellitus is prevailing with increasing trend around the world and more so in developing countries like India owing to rapid urbanisation. PAD (Peripheral Artery Disease) is one of the rapidly progressing and diffuse complication of this disease imposing risk of foot ulcer, foot infection, fatal myocardial infarction that can lead to limb amputation and increase mortality due to Cardiovascular diseases. It is however difficult to diagnose PAD amongst diabetic patients without proper screening due to sensory neuropathy delaying clinical manifestation of symptoms of disease. Ankle Brachial Index (ABI) is a ratio of Systolic blood pressure at ankle and in the arm. ABI measurement provides a simple, repeatable, non-invasive, effective tool to access vascular status in diabetics with high sensitivity and specificity. Many studies have been commenced for establishing ABI as a reliable investigation at primary care level in western countries and in other Asian countries with few such studies reported in India and perhaps none in Bhavnagar, Gujarat. Present research work aimed to quantify the burden of PAD in outdoor diabetic patients of this region.

Material and Method: Study Design: This observational horizontal study was carried out from 15 September to 5 November 2012 on previously diagnosed Diabetic patient over 18 years of age of both sexes. After taking approval from Institutional Review Board, sample size was calculated by sample size calculator software Raosoft keeping confidence level 99% and margin of error 5% for population of Bhavnagar city. Subjects were recruited from Diabetic camp and OPD of private clinics, Medicine OPD of Sir T Hospital and Diabetic Clinic of Urban Health Training Centre (UHTC) so as to have a blend of patients coming from various socio economic statuses that formed a fairly representative sample of this region. Subjects taking irregular treatment, newly diagnosed, having amputated limb were excluded from study.

Base line data collection: All invited subjects were interviewed face to face by pre designed pre validated questionnaires that included demographic characteristics, medical history, risk factor assessment, symptomatic evaluation for PAD, investigations related to blood sugar whatever been available which was entered on ABI worksheet.

ABI measurement: ABI was measured in supine position using principle of Doppler effect by portable instrument VERSADOP (table top vascular Doppler with 8 MHz of Diabetik Foot Care India Limited, Chennai, India) having 12 cm occluding cuff. ABPI was derived by dividing the
higher reading of the ankle pressure at dorsalis pedis artery by brachial pressure of same side.\textsuperscript{14} ABI > 0.9 was considered as normal and ABI < 0.9 was defined as PAD.\textsuperscript{15} ABPI > 1.3 is indicative of incompressible arteries due to atherosclerosis.\textsuperscript{16}

Statistical Analysis: The data was transferred on Excel spreadsheet and descriptive analysis was expressed as mean ± standard deviation. All calculations were accomplished by using GraphPad InStat3 software. The comparison of mean differences was done by student’s t test. Difference was considered statistically significant with P value <0.05.

Results: Present study tested Ankle Brachial Index of patients of either sex already diagnosed to have Diabetes Mellitus attending Medicine OPDs of and urban area. It was further evaluated by dividing them into groups based on gender, duration of disease and presence of PAD symptom.

Table 1 Baseline data of study group (mean ±SD)

<table>
<thead>
<tr>
<th>Age(years)</th>
<th>54.72 ±10.68</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex distribution</td>
<td>Male = 48 Females=62 (Total 110)</td>
</tr>
<tr>
<td>Height(cm)</td>
<td>158.44 ±8.54</td>
</tr>
<tr>
<td>Weight(kg)</td>
<td>65.50± 11.47</td>
</tr>
<tr>
<td>BMI(kg/m\textsuperscript{2})</td>
<td>26.41± 4.78</td>
</tr>
<tr>
<td>Presence of PVD symptom</td>
<td>51 out of 110(46%)</td>
</tr>
<tr>
<td>Mean FBS (mg %)</td>
<td>167.85 ±11.33</td>
</tr>
<tr>
<td>Mean PP2BS (mg%)</td>
<td>224.26± 91.20</td>
</tr>
<tr>
<td>Mean Hb1Ac (gm %)</td>
<td>6.87±2.22</td>
</tr>
<tr>
<td>Duration of Diabetes(years)</td>
<td>6.28± 1.8</td>
</tr>
</tbody>
</table>

Table 1 shows baseline information about study group with noticeable fact being more females than males and high mean values of BMI, FBS, PP2BS, Hb1Ac and strikingly high prevalence of symptom of PAD.

Table 2 shows High percentage of low ABI profile in females than males.

Table 3 Effect of gender on ABI (mean ±SD)

<table>
<thead>
<tr>
<th>Group</th>
<th>ABI &lt; 0.9</th>
<th>ABI &gt; 0.9</th>
<th>P value Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (n=48)</td>
<td>15 (31%)</td>
<td>33 (69%)</td>
<td>1.01± 0.22</td>
</tr>
<tr>
<td>Female (n=62)</td>
<td>24 (39%)</td>
<td>38 (61%)</td>
<td>0.94± 0.16</td>
</tr>
<tr>
<td>Total (n=110)</td>
<td>39 (35%)</td>
<td>71 (65%)</td>
<td>0.99± 0.19</td>
</tr>
</tbody>
</table>

Table 2 shows High percentage of low ABI profile in females than males.

Table 3 shows that ABI become low more as the duration of disease increases.

Table 4 Effect of Presence of PAD symptom on ABI (mean ±SD)

<table>
<thead>
<tr>
<th>Group</th>
<th>ABI &lt; 0.9</th>
<th>ABI &gt; 0.9</th>
<th>P value Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic (n=51)</td>
<td>28 (55%)</td>
<td>23 (45%)</td>
<td>0.87± 0.147</td>
</tr>
<tr>
<td>Asymptomatic (n=59)</td>
<td>11 (17%)</td>
<td>48 (83%)</td>
<td>1.06± 0.191</td>
</tr>
<tr>
<td>Total (n=110)</td>
<td>39 (35%)</td>
<td>71 (65%)</td>
<td>0.99± 0.192</td>
</tr>
</tbody>
</table>

Table 4 shows that in symptomatic subjects low ABI was extremely significantly prevalent.

Discussion: Results disclosed a high prevalence of low ABI in this study conducted in an urban area of West India. In various studies done in western world the prevalence found was 17.3% in Caucasian population(Hoorn study)\textsuperscript{17}, 23.5% in UK\textsuperscript{18}, 12.8% in Poland\textsuperscript{19}, 4.9% in Strong Heart Study USA.\textsuperscript{20} When we look at the scenario of Asian countries it was found 5% in Japan\textsuperscript{21}, 12% in China\textsuperscript{22}, 2.2% in males and 1.8% in females in Korea\textsuperscript{23}, 16% in Malaysia\textsuperscript{24}, 10-15% in Taiwan.\textsuperscript{25} American Indians have high prevalence of
Diabetes Mellitus, PAD and Low ABI. 26, 27 Amongst various Asian countries Indians have highest percentage of abnormal ABI profile as reported by a study done on Asian population. In few studies like The Strong Heart Study done outside India prevalence of low ABI was strikingly higher in Indians than other ethnic groups. 28 In a study done in Malaysia the prevalence of PAD was 5.8% in Malays, 19.4% in Chinese and 19.8% in Indians. 29 These are pointing towards some genetic link as a causative of high susceptibility to develop vasculopathy associated with Diabetes Mellitus. Few Indian studies revealed the prevalence to be 34.4 % in East India 30, 11.8% in South India 30, 4.67% in females and 4.47% in males in North India 31. 

Our sample study showed it higher than other regions of India. It can be attributed to high mean BMI32, increased mean age33, 34, 35 and increased blood mean sugar level36, 37, 38 in this study population. Further they are not given any prophylactic medication like aspirin or ACE inhibitors in absence of cardiac indication. Low ABI is a good predictor of cardiovascular diseases and even death. 13,39,40,41,42 It is indicative not only of limb ischemia but also of increased risk by cardiac death. 40 Low ABI makes cardiovascular event 5 times more probable than in case of ABI within normal range. 43

High ABI in females can be due to abnormal lipid profile in post menopausal period of life leading to withdrawal of hormonal support that was preventive against vasculopathy otherwise. 44 Few studies shows no gender difference25, 30, 45, 46 and few opposite result21, 23 but as there was more than half share of female subjects this gender difference which is statistically significant cannot be neglected. Diabetes Mellitus with chronic progression increases the low ABI profile as in line with previous observations. 30, 47

India will ranks top in Diabetes now and continue to do so by 2025.Only few studies have been conducted in India to quantify PAD burden and perhaps none in this region. Recently Gujarat has shown to rank first in the prevalence of Diabetes one can think of difficulties to be faced by healthcare providers and policy makers. Fortunately simple therapies have been shown to prevent adverse cardiovascular events in peripheral artery disease, including antiplatelet drugs, statins, and angiotensin-converting enzyme inhibitors48, 49, 50 and we have a simple sensitive tool like ABI to detect those at risk.

By present study we try to correlate ABI results neither in age group which is a proven fact nor with glycaemia control that is often disproved by few studies.24,25, 36, 46 Also measurement of Hb1Ac, Lipid profile in all patients is not cost effective and results may show some different picture. However it was seen that ABI profile become worse after 5 years of duration of disease and more so in the patients who are symptomatic for PAD regardless the age and gender. This technique is highly specific and fairly specific and cost effective when compared with Colour Doppler. 25 It is affordable, reproducible, not requiring much space or technical support or training and can be practiced even at primary care level to screen those who are at risk and who are showing sign of PAD.

Limitations of Study: We did not try to correlate various risk factors with ABI values and as it was not feasible to get costly investigations like Hb1Ac and Lipid profile done in all patients. Study being cross sectional cannot prove cause and effect relationship and further prospective study is required for reinforcement of observation. However it provides an insight into current magnitude of this serious health issue.

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Conclusion: The present study revealed high prevalence of low ABI in Diabetics that is an individual risk factor for CVD. This cost effective method can be used as a primary preventive measure to screen PAD patients having Diabetes and proper intervention can be insinuated to stop its progression. This simple non-invasive method is a boon for developing countries like India when looked in context of high prevalence of Diabetes and its complications.

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