The objectives of the study are to:

1. To estimate the proportion of PVD among type 2 diabetes mellitus patients.
2. To determine the risk factors associated with the development of PVD.
3. To determine the role of ABPI in predicting PVD.

AIM OF STUDY: The main objectives of the study are as follows:

1. To estimate the proportion of PVD among type 2 diabetes mellitus patients.
2. To determine the risk factors associated with the development of PVD.
3. To determine the role of ABPI in predicting PVD.

MATERIALS AND METHODS: After obtaining informed written consent, 75 randomly chosen established cases of type 2 diabetic mellitus attending Tirunelveli Medical College between September 2014 and September 2015 have formed the study sample and followed up every 3 months for subsequent 1 year. Lipid profile, h/o smoking and h/o hypertension were recorded. During each follow up the glycemic control of the patient, Hypertension control were analyzed. A comprehensive physical examination was done with focus to the peripheral nerve and vascular examination. ABPI was recorded during the start of the study, during each follow up and at the end of 1 year.

RESULTS AND OBSERVATION: The incidence of PVD is 9.33%. Incidence of PVD was maximum in the geriatric age group with a mean age of 63.57 years. Incidence of PVD was 10% among the males and 7% among the females. The mean duration of diabetes for the PVD in the sub group is 13.57 years. 33.33% of HT with DM had PVD compared with 3.33% of Normotensives with Diabetes. The incidence of PVD in smokers was 25% compared with that of non-smokers (0%). Those with elevated lipid profile had an increased incidence of PVD (20%) when compared with that of the normal lipid profile patients (2.22%). In this study, among 8 patients with ABPI of <0.9, 7 patients had the duplex evidence of PVD.

CONCLUSION: Incidence of PVD is about 10% in the present study. This has to be viewed seriously considering the huge diabetic population and due importance to be given for screening and prevention of PVD. Almost all of the PVD patients are totally asymptomatic and hence the need for active screening with estimation of ABPI is to be done annually for all diabetes patients. Modifiable risk factors to be controlled to prevent the development of PVD.

BACKGROUND OF STUDY: Peripheral vascular disease (PVD), diabetes mellitus, hypertension, smoking, dyslipidemia

1. To estimate the proportion of PVD among type 2 diabetes mellitus patients.
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INCLUSION AND EXCLUSION CRITERIA: After obtaining informed written consent, 75 randomly chosen established cases of type 2 diabetic mellitus attending Tirunelveli Medical College between September 2014 and September 2015 have formed the study sample and followed up every 3 months for subsequent 1 year.

Patients who have other potential causes for PVD other than diabetes related factors were excluded from the study.

The exclusion criteria used were:
1. Clinical evidence of thromboangiitis obliterans, as per Ollin’s criteria
2. Suspected arteritis subjects
3. Collagen vascular disorders
4. Known case of diabetic PVD.

Clinical criteria (Ollin’s criteria) for thromboangiitis obliterans includes:
1. Age <45 years
2. Tobacco exposure
3. Absence of other atherosclerotic risk factors
4. Absence of other atherosclerotic risk factors

KEYWORDS:
Peripheral vascular disease (PVD), diabetes mellitus, hypertension, smoking, dyslipidemia
STUDY DESIGN
Cross sectional study

PROTOCOL
Patients were interviewed with special note on elicitation of history regarding symptoms of PVD, in the form of intermittent claudication, ischemic rest pain, history of foot ulcers in the past and present. Smoking habit also was recorded and classified as smokers and non-smokers. HbA1C values and duration of diabetes since diagnosis was recorded and they were grouped accordingly. Fasting lipid profile was taken and results were compared with normal limits and patients classified as dyslipidemic patients. Also, they are documented as normotensive, hypertensive not on drugs or on anti-hypertensive medications. In hypertensive, the duration of hyper tension since diagnosis was also noted.

A comprehensive physical examination was done with focus to the peripheral nerve and vascular examination. ABPI was recorded during the start of the study, during each follow up and at the end of 1 year.

STATISTICAL TOOL
The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done and 'p' values were calculated. Chi-square test (osocscistatistics.com) was used to test the significance of difference between quantitative variables. 'p' < 0.05 denotes significant relationship.

RESULTS AND OBSERVATION
Incidence of peripheral vascular disease
The total number of cases studied - 75. The incidence of PVD - 9.33% (n = 7) (Chart 1).

Chart 1. Incidence of PVD in diabetic patients.

Age distribution of PVD
The age of patients studied ranged from 33 years to 73 years. Incidence of PVD was maximum in the geriatric age group with a mean age of 63.57 years (chart 2).

Chart 2. Age group wise distribution of cases

Sex distribution of PVD
Males constituted 64% (n = 48) and Females 36% (n = 27) of the study group (Table 3). Incidence of PVD was 10% among the Males (n = 5) and 7% among the Females (n = 2).

Duration of diabetes mellitus and PVD
The duration of diabetes ranged from 1 to 20 years. The mean duration of diabetes for the PVD in the sub group is 13.57 years. (Table 1).

Table 1. Relation of duration of diabetes with PVD

<table>
<thead>
<tr>
<th>Diabetes duration years</th>
<th>Total number of case</th>
<th>PVD</th>
<th>NO PVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; OR = 5</td>
<td>49 (65.33%)</td>
<td>2 (2.04%)</td>
<td>48 (97.96%)</td>
</tr>
<tr>
<td>6 – 10</td>
<td>8 (10.67%)</td>
<td>1 (12.5%)</td>
<td>7 (87.5%)</td>
</tr>
<tr>
<td>&gt;10</td>
<td>18 (24%)</td>
<td>5 (27%)</td>
<td>13 (73%)</td>
</tr>
<tr>
<td>Total</td>
<td>75 (100%)</td>
<td>7 (9.33%)</td>
<td>68 (90.67%)</td>
</tr>
</tbody>
</table>

Hypertension and PVD
Prevalence of hypertension was 20% (n = 15) among the study group. Among the hypertensive diabetic subjects (n=15), 33.33% had PVD and the incidence of PVD among normotensive diabetes subjects (n=60) was 3.33% which was statistically significant (p = 0.0329) (chart 3).

Chart 3. Incidence of PVD in hypertensives

Smoking and PVD
41.67% of male patients (n = 20) were smoking in the study group. There was no smoking in the female sub set. Smokers had a six fold increased risk of having PVD compared with non smokers. The incidence of PVD in smoker male was 25% when compared with that of non-smokers (0%) which was statistically significant (p = 0.05) (Table 2).

Table 2. Incidence of pvd in smokers with diabetes

<table>
<thead>
<tr>
<th>Smoking (among males)</th>
<th>Total number of case</th>
<th>PVD</th>
<th>NO PVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoker</td>
<td>20 (41.67%)</td>
<td>5 (25%)</td>
<td>15 (75%)</td>
</tr>
<tr>
<td>Non Smoker</td>
<td>28 (58.33%)</td>
<td>0</td>
<td>28 (100%)</td>
</tr>
<tr>
<td>Total</td>
<td>48 (100%)</td>
<td>5 (10.41%)</td>
<td>43 (89.59%)</td>
</tr>
</tbody>
</table>

Dyslipidemia and PVD
Two study groups were compared. Those with elevated lipid profile (20% of study population n=30) had an increased incidence of PVD, 20% (n=6) when compared with that of the normal lipid profile patients which was 2.22% (n=1) and it was statistically significant (p=0.0095).

Ankle brachial pressure index and PVD
In this study, among 8 patients with ABPI of <0.9, 7 patients had the duplex evidence of PVD.

DISCUSSION
Incidence of PVD
Incidence of PVD in this study was 9.33% which was comparable to the incidence as described in other studies. One meta-analysis has presented age and gender adjusted results of the incidence of PVD ranging from 5.5% to 14.7%. In one study, PVD was rare at the time of diagnosis but after 6 years of follow up 11% of the patients had PVD. Thus, it is to be noted that PVD is a significant complication of diabetes mellitus.

Symptomatic and asymptomatic PVD
The symptoms of intermittent claudication are not seen in any of the patients affected with PVD in this study as in Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) & Meijer WT et al, This may be due to
i. Modern age sedentary life-style.
ii. Many elderly patients not walking far enough to experience symptoms of intermittent claudication.
iii. co-existing neuropathy masking pain sensation.

Since, many of the patients with PVD are asymptomatic, it's vital for active screening with ABI in all diabetic subject.

Sex distribution of PVD
The incidence of PVD was 10.4% among males and 7.4% among females in the study group. Diabetes seems to repeal the protective effect of female gender on PVD when compared to non diabetics as seen in other epidemiological studies’. The higher incidence among males could be partially due to smoking.

Aging and PVD
As the age advances, the incidence of development of PVD increases and in this study, age adjusted incidence rates show a linearly progressive raising trend, and the highest incidence was found among the geriatric age group as shown in the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Thus it's to be noted that aging is a non-modifiable risk factor for PVD

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diabetic patients must be given special attention for PVD prevention and management.

Hyperglycaemia and PVD
As the duration of diabetes increased, the risk of PVD increased in the study group. The large multi centric study also has categorically proved that the duration of hyperglycaemia has a definite role in PVD(12). In the large multi centric study, as the HbA1C increased by every 1 %, there was an increase of 26% in PVD prevalence(2). Tight glycemic control in general reduces peripheral arterial disease and risk of amputation.

Hypertension and PVD
Hypertension raised the risk of PVD, among diabetic patients. Duration of hypertension among hypertensive diabetic subjects ranged from 2 to 15 years with a mean duration of 7.73 years. Among the hypertensive diabetic subjects, the mean duration of hypertension among the PVD subjects was found to be 11 years, which was significantly higher than the non – PVD sub group mean of 1 year (p = 0.0003). Hypertension associated with diabetes raised the risk of PVD in our study subjects in par with the Macgregor A5 et al study. Another interesting observation noted in the study group was that the duration of hypertension also significantly correlated with the risk of PVD.

Smoking and PVD
The incidence of PVD in smoker male was 25% when compared with that of non-smokers (0%) which was statistically significant (p = 0.05). Hence, smoking is one of the strongest risk factor in the pathogenesis of PVD. It is advisable for the patient not to smoke, since it will lead onto peripheral vascular disease in the future. Thereby the associated coronary vascular disease can also be prevented(6).

In the study group, smokers had more than six fold increased risk of having PVD, compared to non-smokers. Thus smoking was found to be the single most important risk factor in comparison to other risk factors.

A multivariate analysis, identified smoking as the strongest risk factor for development of PVD (13). In this study, smoking in a diabetic hypertensive exponentially increased the risk of PVD. Smoking is the single most modifiable risk factor and hence smokers must be actively counselled for cessation of smoking(14).

Dyslipidemia and PVD
In this study population, the dyslipidemia patients have ten times increase in the incidence of PVD. The cardiovascular health study and the Edinburg artery study reported higher prevalence of PVD in association with dyslipidemia patients. Hence, management of atherogenic dyslipidemia is vital, and lipid level to be maintained within optimal cut-off limits(7). Lipid lowering agents are crucial in the management of dyslipidemia and atherosclerosis thereby chronic vascular insufficiency(8).

Duration of diabetes mellitus and PVD
For patients affected with PVD, the duration of diabetes was found to be longer than others(9). The mean duration of diabetes for the PVD in our sub group is 13.57 years. While for the rest of the study group it is 5.0 years which was statistically significant (p = 0.005).

Ankle brachial pressure index and PVD
In this study among 8 patients with ABPI of <0.9, 7 patients had the duplex evidence of PVD. Hence, we can conclude that the sensitivity of ABPI is 87.5%, which make the ABPI an efficient screening tool for diagnosing PVD even in asymptomatic individuals.

CONCLUSION
1. Incidence of PVD is about 10% in the present study. This has to be viewed seriously considering the huge diabetic population and due importance to be given for screening and prevention of PVD.
2. Almost all of the PVD patients are totally asymptomatic and hence the need for active screening with estimation of ABPI is to be done annually for all diabetes patients. Low ABPI is also associated with cardiovascular complications.
3. Uncontrolled chronic hyperglycaemia, hypertension, dyslipidemia and smoking are the modifiable risk factors associated with development of PVD. Advancing age, male gender and the duration of Diabetes were found to be the non modifiable risk factors for development of PVD.

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