International Journal of Advanced Research and Development
ISSN: 2455-4030, Impact Factor: (RJIF 5.24)
www.newresearchjournal.com/advanced
Volume 1; Issue 4; April 2016; Page No. 07-10

A study on clinical profile of peripheral arterial disease among people attending surgical OPD at tertiary care centre in South Kerala

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Abstract
Background: Peripheral Arterial Disease (PAD) is one of the common health problems in India and also globally. PAD is also associated with other Coronary Artery Disease, Cerebro Vacular Accident and erectile dysfunction. Approximately 50% of the patient having peripheral artery disease is asymptomatic; this makes it difficult to know the true prevalence of the disease in the population [1]. The optimal management of patients with PAD requires a comprehensive treatment strategy incorporating both lifestyle changes, including smoking cessation and exercise [3].
Objectives: To find out the correlation between cholesterol and PAD. To find out the correlation between PAD and selected socio-demographic variables.
Materials and Methods: A hospital-based observational study involving 55 patients was conducted in the Department of General surgery, Dr. S.M.C.S.I Medical College Karakonam, Trivandrum a tertiary care centre in south Kerala during a period of 2 years. Patient details like age, sex, clinical symptoms, Co morbidities, addictions are collected using pre-tested Questionnaire. Patients are started on Statins, Cholesterol level in the initial and after 6 months are compared.
Data Analysis: Data will be analyzed using SPSS software version 18.0V. The significant differences were tested using paired "t" test for various assessment schedule on cholesterol levels.
Results: A total of 55 adult male and female participants ≥31 years of age (mean age: 62.76 ± 10.79) years; 67.3% male and 32.7% female) were evaluated. Among the study subjects 78.2% and 74.5% were diabetic and hypertensive respectively. 41.8% and 25.5% were found to be smokers and alcoholics. 38.2% of the participants were having coronary artery disease. Mean difference between Cholesterol of first and sixth month is 78 with SD =48 (P value <0.001).
Conclusion: Peripheral vascular disease is associated with hyperlipidemia and cardiac diseases. So the effect of therapy with Atorvastatin has a major role in treating PAD patients. It also reduces the incidence of cardiac problems like angina, myocardial infarction.

Keywords: Peripheral Vascular Disease, Smoking, Coronary Artery Disease, Cholesterol.

Introduction
Peripheral Arterial Disease (PAD) is one of the common health problems in India, but also globally. PAD is associated with other Coronary Artery Disease, CVA and erectile dysfunction. Approximately 50% of the patients having peripheral artery disease are asymptomatic; this makes it difficult to know the true prevalence of the disease in the population. A progressive increase in prevalence is noted among patients over 40 years of age [1]. Statins reduce the incidence of intermittent claudication and improve exercise duration until the onset of intermittent claudication in patients with PAD and hypercholesterolemia [2]. The optimal management of patients with PAD requires a comprehensive treatment strategy incorporating both lifestyle changes, including smoking cessation and exercise, as well as optimal medical therapy for hypertension, diabetes mellitus, stress and hyperlipidemia [3].
Peripheral Arterial Disease (PAD) is a circulatory problem in which chronic arterial occlusion of lower limb reduces the blood flow to the limbs. PAD causes chronic arterial insufficiency leading to dry gangrene [4]. The prognosis of patients with PAD is favorable in view of the claudication pain. With proper medical management and avoidance of risk factor the claudication pain remains stable in 70% to 80% patients over a period of 10 years [5].
Most of the time peripheral artery disease is neglected by both patient and the doctors. The prevalence of PAD was almost the same all over the world. In a study conducted by Agarwal AK *et al* the prevalence of PAD was 14.4% [6]. As the age increases there is a chance of increased prevalence of PAD. Almost 20% of the population above the age of 70 years are affected with PAD [5]. The control of PAD is achieved by regular exercise, medications for revascularization and atherosclerotic plaque stabilizing drugs. Discontinuation of tobacco and good control of diabetes, hypertension and cholesterol is needed for better prognosis. Therefore the present study was undertaken to evaluate the usefulness of statins in PAD. Hence, this Hospital – based study was conducted to find out the correlation between cholesterol and PAD and its association with selected socio-demographic factors in the tertiary care centre at south Kerala.

Objectives
1. To find out the correlation between cholesterol and PAD.

2. To find out the correlation between PAD and selected socio-demographic variables.

Methodology

Study design- Hospital-based-Observational-study (Prospective)

Study Area- Department of General surgery, Dr SMCSI medical college, Karakonam.

Study Period- 2 YEARS (December 2013 to October 2015)

Study Subjects- The consecutive patients with PAD attending in the General Surgery OPD was enrolled in the study after getting written informed consent and Institutional Ethical Clearance (IEC) was also obtained.

Study Tool-Pre tested proforma, Clinical examination and laboratory test.

Data collection was done using a pre-tested structured interview schedule. Proforma was prepared in English and local language, was used during interview to make it convenient for the population. Details regarding socio-demographic variables were collected. Further information was collected regarding duration of Diabetes mellitus, smoking habit, alcohol consumption. Clinical examinations were done. Cholesterol levels were obtained from the institutional laboratory. The patients were advised to consume Statin 10 mg at night daily till the end of study period and ABPI was monitored every month, and at the end of 6 month cholesterol was also estimated.

- **Inclusion Criteria**
  All the patients with clinically proven peripheral vascular disease.

- **Exclusion Criteria**

➢ Arterial occlusion due to trauma
➢ Bilateral Amputee.
➢ Patients with bleeding due to Aspirin.
➢ Patients receiving anticoagulation therapy (e.g., warfarin).
➢ Patients allergic to Aspirin or Statin.
➢ Patients who were already taking Statin.

Variables used in the study are,

A. Outcome variables:

1) Clinical assessment of peripheral pulses Peripheral pulse quality (palpable or not palpable).
2) Cholesterol level

B**.** Independent variables: Age, clinical data, sex. Occupation, co morbidities (Diabetes, hypertension) alcohol, smoking.

Sample size

From previous studies and from a preliminary available data in our department the prevalence is about 12%. We calculated required sample size for the study using the formula,

$$n = \frac{t^2 \times p(1-p)}{m^2}$$

p- Estimated prevalence, m is the marginal error and t is the confidence limit.

We calculated sample size for prevalence12 %, 95% confidence interval and effect. We reached to a sample size 50.08, approximately 55.So we decided to recruit 55 participants for our study.

Data collection method: One to one interview method.

Data entry: Data was entered in Microsoft Excel.

Data Analysis: Data was be analyzed using SPSS software version 18.0V. The significant difference was tested using paired "t" test for various assessment schedule on cholesterol levels.

Results

The current study is an Observational study done among the patients attending the surgery Out Patient Department of Dr. SMCSI Medical College Karakonam. In this study 55 patients with peripheral vascular disease are included out of which 38(67.3%) were male and 17(32.7%) were female. Participants age was 31 to 88 with a mean of 62.76 (SD = 10.79).The total number of males is more when compared to the number of female participants. Among the study subject 78.2% and 74.5% were diabetic and hypertensive respectively. 41.8% were smokers and 25.5% were alcoholics. In the present 38.2% of the participants were found to be having coronary artery disease. 20% of the study subjects were affected with COPD and 1.8% were having Cerebrovascular accident. As the age increases the proportion of Peripheral Arterial Disease is higher. Mean difference between Cholesterol of first and sixth month is 78 with SD =48 (P value <0.001).

Table 1: Frequency distribution of Clinical and selected-demographic variable

Variable	N	%
Diabetes		
Yes	43	78.2
No	12	21.8
Hypertension		
Yes	41	74.5
No	14	25.5
Smoking		
Yes	23	41.8
No	32	58.2
Alcohol		
Yes	14	25.5
No	41	74.5
Anemia		
Yes	14	25.5
No	41	74.5
CAD		
Yes	21	38.2
No	34	61.8
COPD		
Yes	11	20.0
No	44	80.0

Table 2: Age Wise Distribution of Study Subjects with Pad

Age	N	%
31-40	1	1.8
41-50	5	9.1
51-60	17	30.9
> 61	32	58.2
Total	55	100.0

As shown in the table, 58.2% of the study subjects were above 60 years of age. As the age increases the severity of the disease increases.

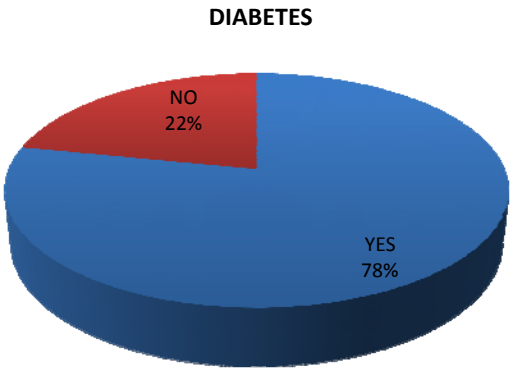

Fig 1: Study subjects with Diabetes

Out of the 55 patients included in the study 78% of the patients are diabetic.

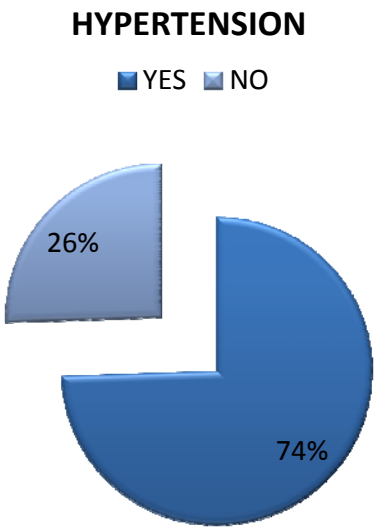

Fig 2: Study subjects with Hypertension

Among the participants 74% are hypertensive and were on regular medication.

Table 3: Comparison of cholesterol values according to first and sixth month (n=55)

	Mean	Standard Deviation	t – value	P value
First month	239.78	62.9	13.184	<0.001
Sixth month	161.78	26.45		

Mean cholesterol level variation between first and sixth month using paired t-test. Cholesterol level at sixth month was significantly lower (P<0.001) in comparison with first month.

Discussion

This study was conducted in Department of General surgery, Dr. S.M.C.S.I medical college, Karakonam among 55 patients having Peripheral arterial disease for a period of 2 years. A study done in china showed comparisons of sex distribution among study groups with PAD revealed that it has the highest percentage of men population [7, 8], which was similar to that of present study this may be due to the higher incidence of atherosclerosis due to Smoking habits and the hormonal protection in females.

In a cross-sectional study of community-dwelling Korean men by Young-Hoon Lee *et al*, they assessed the association of cumulative smoking exposure and duration of smoking cessation with peripheral arterial disease (PAD) and found the odds ratio (OR, 95% confidence interval) of PAD was 2.31 (1.20-4.42) for former smokers and 4.30 (2.13-8.66) for current smokers, after adjusting for other cardiovascular risk factors. There was a significant dose-response relationship between pack-years of smoking and PAD. Compared with those who had never smoked, the multivariate-adjusted ORs of PAD for smokers of 0.1-20.0, 20.1-40.0, and >40.0 pack-years were 2.15 (1.06-4.38), 2.24 (1.08-4.65), and 2.93 (1.41-6.09) respectively. There was a significant decrease in PAD risk as the years since quitting smoking increased. The multivariate-adjusted ORs of PAD for 11-20 and ≥21 years smoking cessation were 0.41 (0.19-0.86) and 0.49 (0.24-0.98), compared with current smokers [9]. Only 23(42 %) participant in our study are smokers which is a less percentage than other studies. It may be due to the social habit of females of this population not having the habit of smoking.

Olin JW *et al*, [5]. Done a study among PAD subjects in the year 2010 and found out that as the age increases as the prevalence of PAD is more which is similar to current study. The association of risk factors of PAD like diabetes and hypertension are high in the current study which is similar to other studies done by Mehler P S *et al* [10]. And Tseng CH *et al* [11] conducted in the population group. Hence treatment with statin not only prevents PAD it also prevents the incidence, progression and helps in the treatment of CAD and CVA.

Mean cholesterol level variation between first and sixth month using paired t-test was significantly lower in this study denoting that the medication not only reduces the chance of plaque formation and stabilizes the plaque in PAD but also helps in controlling the lipid profile. Ref (Table No. 3) p value < 0.001. Control of cholesterol level after a period of six month of treatment with Statin. Which is similar to the study conducted by Kumeo Ono *et al* in Japan concluding that there is no correlation between the levels of ABPI and the cholesterol level [12].

Conclusion

Peripheral Artery Disease is quite common in the old age group patients in our population. It is caused by multiple factors like uncontrolled diabetes, hypertension, hyperlipidemia, smoking and sedentary lifestyle. It is usually associated with coronary artery disease and cerebrovascular accidents. So the effect of therapy with Atorvastatin has a major role in treating PAD patients. It also reduces the

incidence of cardiac problems like angina and myocardial infarction.

Acknowledgement
The Authors like to thank the Professors of General surgery Department Dr. Easwara Pillai, Dr. Punitha Thetaravu Oli for the enormous support, significant pieces of advice and directions. The Authors also like to thank Dr. Sandeep Kumar David, Dr. Naranthran, Dr. John Suresh, Dr. Benny P.B, Dr. Bipin for the constant support and encouragement throughout the study. The Authors thank the study subject for the cooperation throughout the study.

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