

Clinical study on evaluation of various parameters in chronic lower limb ischemia

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ABSTRACT

Aim: To study the modes of presentation of chronic lower limb ischaemia, co-morbid conditions like diabetes, smoking and hypertension and assess the treatment modalities with respect to outcome. **Materials and methods:** This study was conducted by random selection of 50 cases with chronic lower limb ischemia admitted to surgical wards. This was a cross sectional and observational study of 50 cases diagnosed with chronic lower limb ischemia, done for a period of 6 months. **Results:** The commonest age group affected by TAO is between 31 and 40 yrs and those affected with Atherosclerosis is above the age of 60 yrs. Almost all patients with TAO had a history of chronic smoking and 61 % of Atherosclerosis patients had a history of smoking. In the present study, all the cases of PAD presented with ischemic claudication and rest pain as common symptoms, while gangrene and ischemic ulcer were the other predominant symptoms in 80 % and 40% of cases respectively. 40 (80%) of the patients in this study presented at a late stage in the disease process, with gangrenous changes, leaving minimal options for salvaging the affected limb. The level of amputation was below knee in 42% and above knee in 58% cases. The patients who continued to smoke had aggravation of symptoms. Post operatively 24 had uneventful recovery, 21 required secondary suturing, 3 required revision amputation at a higher level. 2 cases were managed conservatively. **Conclusion:** Lumbar Sympathectomy had helped in Improvement of rest pain noted in 67% of cases, healing of ulcer in 50%. The level of amputation was below knee in 42% and above knee in 58% cases.

Keywords: Peripheral arterial disease, Lumbar Sympathectomy, Amputation.

Introduction

Peripheral arterial disease includes those entities that result in arterial occlusion in vessels other than those of coronary and intra-cranial vascular bed and the term is usually applied to disease involving the arteries of lower extremity[1]Atherosclerosis, Buerger's disease, popliteal entrapment syndrome, cystic adventitial disease etc., are various forms of presentation of lower limb ischemia. Peripheral arterial disease is an important manifestation of atherosclerosis involving arteries of the limbs. Vascular surgeons continue to encounter complications of atherosclerosis as their

most common clinical challenge. Management of atherosclerosis plays an important role in adult medical care. Although only 1-2% of people less than 50 years of age suffer from symptoms of intermittent claudication, this figure rises to 5% in those aged 50 to 70 yrs and to 10% in those older than 70 years [2].Vascular disease is a leading cause of morbidity and mortality in people with diabetes. Thrombo-angitis obliterans is an inflammatory occlusive disease primarily involving the medium sized and smaller arteries in extremities, with smoking as the strong associated causative factor. In the lower limb, the disease commences in the digital arteries and small arteries of the foot and then proceeds to involve the crural arteries. The clinical course of TAO is tremendously influenced by whether the patient quits smoking or not. If he continues to smoke there is progressive arterial insufficiency. Patients with TAO

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have a normal life span, where as those with atherosclerosis have a greatly decreased survival compared with a normal population of the same age. Major amputation is eventually required in more than a third of patients once limb threatening symptoms and signs occur[3]. Nevertheless, the cause of death in patients with Peripheral arterial disease is seldom direct result of lower limb ischemia, most patients die from complications of coronary artery or cerebrovascular disease. Popliteal artery entrapment syndrome and cystic adventitial disease of popliteal artery are rare causes of chronic arterial ischemia of young healthy individuals. Although these diseases can produce severe disability if left untreated, normal circulation can be restored surgically[4]. **Diagnostic criteria for TAO** are features of lower limb ischemia, history of tobacco use, younger age of onset, lesions of distal arterial occlusion, excluding atherosclerotic risk factors like hyperlipidemia, diabetes, hypertension, hematologic disorders or potential source of embolus. Radiological features include smooth arterial wall, generalized narrowing of the lumen, abrupt occlusion of lumen, collaterals - Cork Screw, Spider leg, tree root configuration of Vessels without any calcifications. Diagnostic criteria for Atherosclerosis are features of limb ischemia, with or without history of tobacco usage, usual age of onset is older age, proximal or Distal arterial occlusion lesions, atherosclerotic risk factors like hyperlipidemia, diabetes, hypertension, hematologic disorders or potential source of embolus may be present. Radiological features include irregular arterial walls, lumen showing localized or segmental stenosis, gradual occlusion of lumen, normal or often large collaterals and arterial calcifications.

Materials and methods

This study was conducted by random selection of 50 cases with chronic lower limb ischemia admitted to surgical wards of Government General Hospital Vijayawada, attached to Siddhartha Medical College Vijayawada. This was a cross sectional and observational study of 50 cases diagnosed with chronic lower limb ischemia, done during the period from August 2015 to February 2016 after approval from

Results

Out of total 50 cases 36 cases belong to Atherosclerosis and 14 cases are TAO. All TAO cases were males and in the atherosclerosis group there were 3 female and 33 male.

Table 1: shows 32 (89%) of the cases in atherosclerosis were above the age of 50 yrs, while in the TAO group 12 (86%) belong to the age group between 31 to 50 yrs, it also shows the pattern of clinical presentation in the present study. 29 (81%) patients of atherosclerosis and 11 (79%) patients of TAO presented with gangrenous

Institutional Ethical Committee. In all cases, a structural Proforma was used to collect the information of an individual patient.

Inclusion criteria include patients presenting with signs and symptoms of Peripheral Arterial disease of the lower extremities like intermittent claudication, rest pain, ulceration and gangrene. Patients with evidence of lower limb arterial occlusive disease on Doppler study.

Exclusion criteria include patients with Peripheral Arterial disease of regions other than the lower extremities. Patients with history of trauma to the lower extremities were excluded. Patients presenting with pain of skeletal or neurologic origin of lower limbs with or without evidence of vascular damage. Patients presenting with ulcers of traumatic or infective origin with or without evidence of ischemia. The method of the study consisted of taking a good clinical history in a chronological order as soon as the patient was admitted. A thorough clinical examination was carried out personally to find out and establish clinically first, the presence of vascular obstruction. Detailed vascular system examination was done as per the proforma provided. The degree of vascular inadequacy and extent of the spread of the disease was assessed clinically by noting the color change, extent and spread of gangrene and absence of peripheral pulses in the affected limbs. This together with history of the patient regarding the distribution and type of pain, gave in a fairly good number of cases studied, an idea of the state of patient's vascular condition. Later after clinical scrutiny, essential laboratory investigations were done as per the proforma provided to look for the presence of atherosclerotic risk factors. Patients were further evaluated objectively by Doppler scanning whenever feasible to assess the level and degree of obstruction objectively. The treatment of each patient was individualized with the aim to achieve foot salvage wherever feasible. A record of patient's progress and response to various modalities of treatment was made. Patients who returned for follow up were followed up for minimum of one month and each follow up detailed history was taken and progress of the disease was assessed.

changes. Diabetes Mellitus was the commonest associated disease among the atherosclerosis group.

Gender Distribution of patients			
Gender	Atherosclerosis	TAO	Total
Male	33	14	47(94%)
Female	3	0	3(6%)
Total	36(72%)	14(28%)	50(100%)
Age distribution of patients			
	Atherosclerosis	TAO	
21-30	0	2(14%)	
31-40	0	8(57%)	
41-50	4(11%)	4(29%)	
51-60	14(39%)	0	
>61	18(50%)	0	
Total	36	14	
Clinical presentation of patients(Symptoms)			
	Atherosclerosis	TAO	
Intermittant Claudication (IC)	0	0	
IC + rest pain	0	0	
IC + rest pain + gangrene	29(81%)	11(79%)	
IC + rest pain + ulcer	7(19%)	3(21%)	
Total	36	14	
Extent of gangrenous changes in lower limbs			
	Atherosclerosis	TAO	
Toes only	12(33%)	12(86%)	
Toes and foot	21(59%)	2(14%)	
Toes, foot and leg	3(8%)	0	
Upto thigh	0	0	
Total	36	14	
Associated comorbid conditions			
	Atherosclerosis	TAO	
Diabetes mellitus	27 (75%)	0	
Hypertension	9 (25%)	0	
Ischemic Heart Disease	6 (17%)	0	
Hypercholestermia	2 (5%)	0	

Table 2: shows that all patients with TAO had a history of smoking and 61% of atherosclerotic patients gave history of smoking. It also shows the Doppler findings in the 50 patients who were subjected to aretrial Doppler study. 23(13 atherosclerosis+ 10 TAO) patients had infra popliteal vessel involvement. TAO involves distal arteries and Atherosclerosis proximal arteries.

Associated Habits

Habits	Atherosclerosis	TAO
Beedi Smoking	14(39%)	12(86%)
Cigarette Smoking	8(22%)	2(14%)
Alcoholism	6(17%)	8(57%)
Tobacco Chewing	4(11%)	2(14%)
None	8(22%)	0
Arterial Doppler findings in the affected limbs (Site of obstruction)	Atherosclerosis	TAO
Ankle	0	4(29%)
Infra popliteal	13(36%)	10(71%)
Popliteal	18(50%)	0
Superficial Femoral	5(14%)	0
Total	36	14

Table 3: shows treatment and post operative recovery of atherosclerosis. Among 36 cases 30 patients underwent amputation (11 below knee and 19 above knee). 4 cases underwent disarticulation. 44% had uneventful recovery Among 14 cases 6 patients underwent amputation (4 below knee and 2 above knee). 4 cases underwent Lumbar Sympathectomy + Disarticulation, 57% had uneventful recovery.

Atherosclerosis						
Treatment		No. Cases	Of Post operative recovery			
			Uneventful Recovery	Revision Amputation	Secondary Suturing	Death
Amputation	Below Knee	11(30.5%)	5	2	4	0
	Above Knee	19(53%)	7	0	12	0
Disarticulation		4(11%)	4	0	0	0
Conservative Management		2(5.5%)	0	0	0	0
Total		36	16(44%)	2(6%)	16(44%)	0
TAO						
Treatment		No. Cases	Of Post operative recovery			
			Uneventful Recovery	Revision Amputation	Secondary Suturing	Death

Amputation (43%)	Below Knee	4(29%)	0	1	3	0
	Above Knee	2(14%)	0	0	2	0
Lumbar Sympathectomy(LS)		2(14%)	2	0	0	0
LS+Disarticulation		4(29%)	4	0	0	0
Disarticulation		2(14%)	2	0	0	0
Total		14	8(57%)	1(7%)	5(36%)	0

Table 4 : shows the results of Lumbar Sympathectomy in terms of improvement in symptoms. Improvement of rest pain noted in 67% of cases, healing of ulcer in 50% of cases and improvement in claudication pain in 33% of patients who underwent Lumbar Sympathectomy.

Lumbar Sympathectomy- Post operative events					
Signs and Symptoms	No. Of Patients	Relieved		Not relieved	
		Number	%	Number	%
Rest pain	6	4	67	2	33
Ulcer	2	1	50	1	50
Claudication	6	2	33	4	67

Table 5: shows the total 36 patients subjected to amputation which includes smokers and other associated habits and disorders.

Different levels of amputation in both groups			
Amputation	Atherosclerosis	TAO	Total
Below knee	11(37%)	4(67%)	15((42%)
Above Knee	19(63%)	2(33%)	21(58%)
Total	30	6	36

Table 6: shows that out of 14 beedi smokers in atherosclerosis 4 underwent below knee amputation and 7 underwent above knee amputation.

Smoking	Total no of smokers in both groups	Atherosclerosis			
		Total no of smokers in both groups	Total no of smokers in both groups	Total no of smokers in both groups	Total no of smokers in both groups
Beedi smoking	26	14	4(29%)	7(50%)	11
Cigarette smoking	10	08	2(25%)	4(50%)	6
Total	36	22	6(27%)	11(50%)	17(77%)
Smoking	Total no of smokers in both groups	TAO			
		Total no of smokers in both groups	Total no of smokers in both groups	Total no of smokers in both groups	Total no of smokers in both groups
Beedi smoking	26	12	3(25%)	1(8%)	4
Cigarette smoking	10	02	1(50%)	1(50%)	2
Total	36	14	4(29%)	2(14%)	6(43%)

Discussion

Out of the total 50 cases, 36 (72%) cases were due to Atherosclerosis and 14 (28%) were due to Thrombo Angitis Obliterans. Atherosclerosis was a more common presentation in this study. Selvin E and Erlinger TP reported from National Health and Nutrition Examination Survey (NHANES) conducted from 1999 to 2000 in the United States, that the overall prevalence of PAD (defined as an ABI <0.90) was 4.3% (95% confidence interval [CI], 3.1% to 5.5%). A recent study conducted by Sigvant B et al[5] for evaluating prevalence of PAD, found that 18% of the population suffered from PAD, with 0.5% having CLI. Kelkar *et al*[6] conducted an Indian study of 489 cases of chronic lower limb ischemia and found that 50% were due to TAO and 43% were due to Atherosclerosis, the rest being due to miscellaneous causes. The study done by Nigam R[7] had a higher incidence of TAO, accounting for 63% of the cases and atherosclerosis only 15% and the rest being miscellaneous causes. Among the 36 cases diagnosed with PAD due to Atherosclerosis in this study 33 (92%) were males and three (8%) patients were females. The

female patients in this study were of the age group 65 years or older and had other associated co morbid diseases like diabetes mellitus and hypertension. In this study all the 14 patients diagnosed with TAO were male. In a study done by Selvin E and Erlinger TP⁵ on the prevalence of and risk factors for peripheral arterial disease in the United States, it was found that although there was a slightly higher prevalence in men than in women. Ranjan B reported that in a series of 188 cases of TAO in India, 4 were found in females[8]. Atherosclerosis was commonly seen among the age group of above 60 years (50%) in this study and 89% cases were over the age of 50 yrs. 11% cases were seen in the age group of 41 -50 yrs. Although atherosclerosis may be present in younger individuals, age has a dominant influence. All forms of cardiovascular disease become more prevalent in the elderly. In several studies the risk for PAD increased 1.5 to 2.0 fold for every 10 year rise in age[7,8] Nigam R. reported in a study that 88% of the TAO cases were aged between 31-50 yrs[9] Similar to findings in the present study (86% of TAO cases belong

to 31-50 yrs). In the present study, all the cases of PAD presented with intermittent claudication and rest pain as common symptoms, while gangrene (80% of cases) and ischemic ulcer (20% of cases) were the other predominant symptoms. 81% per cent of the cases in the atherosclerosis group and 79% of the cases in the TAO group presented with gangrenous changes in the affected lower limb. Ischemic ulcer over the foot was present in 19% of the cases in the atherosclerosis group and 21% of the cases in the TAO group. A study on the clinical profile of TAO and Arteriosclerosis obliterans done by Nigam R⁷ reported that claudication was the commonest presentation in TAO and ulcer or gangrene with claudication was common mode of presentation in Atherosclerosis. In the atherosclerosis group, 8% cases presented with gangrene extending to the leg, and these patients were above the age of 60 years. Mills JL and Porter JM¹⁰ reported in their study of TAO that, 50% had isolated lower limb involvement, 40% had both upper and lower limb involvement and only 10% had isolated upper limb disease due to TAO. History of smoking was present in 61% patients in the atherosclerosis group and in 100% of the patients in the TAO group. In a study done by Nigam R, the incidence of smoking in TAO and atherosclerosis was reported to be 98% and 72% respectively.⁷ Smoking is also closely linked to PAD, a relation first identified by Erb in 1911, when the risk of intermittent claudication was reported to be three times greater in smokers. Hill et al. found that all the TAO patients in their study were cigarette smokers and patients who smoked more than 10 cigarettes per day had a much worse prognosis than those who smoked less than that[11] Many workers agreed to the fact that great majority of the patients who had Buerger's disease had been heavy smokers and smoked more than 20 cigarettes per day on the average. The best results of Lumbar Sympathectomy were reported by Persson and Co-workers who performed Sympathectomy on 22 limbs with adequate inflow but importantly with no evidence of neuropathy. Lee and colleagues reported somewhat lower healing rates for patients with superficial toe gangrene with 56% of the involved digits salvaged by Sympathectomy and a 40% toe salvages rate among those with 3 or more digits involved[11] All the patients in this study were initially started on conservative management, and eventually underwent different modalities of surgical management. Complete cessation of smoking was strongly advised as it is the mainstay of therapy. Jonason T and Bergstrom R reported in their study that smokers have poorer survival rates, a greater likelihood of progression to critical limb ischemia and amputation, and decreased artery bypass graft patency rates when compared to nonsmokers. However, patients who are able to stop smoking are less likely to develop critical limb ischemia and have improved survival[12] A study conducted by Nigam R⁷ on the clinical profile of TAO

and Arteriosclerosis obliterans had 40% cases of atherosclerosis were associated with DM and no case of TAO associated with DM. In the Framingham Heart Study, diabetes increased the risk of intermittent claudication by 3.5 and 8.6 fold in men and women, respectively. Diabetes mellitus increases the risk of lower extremity peripheral arterial disease by 2 to 4 fold and is present in 12% to 20% of persons with lower extremity peripheral arterial disease[13] Hypertension has been linked with an increased risk of peripheral arterial occlusive disease in some studies. The Framingham data documented a 25-fold increase in the risk of PAD in men with hypertension and a 39-fold increase in women with hypertension[14]. Almost every study has shown a strong association between hypertension and PAD, and as many as 50% to 92% of patients with PAD have hypertension. In the Systolic Hypertension in the Elderly Program, 5.5% of the participants had an ankle brachial index (ABI) under 0.90. In the present study 6 (17%) patients with atherosclerotic PAD gave a history of ischemic heart disease or had ECG changes suggestive of myocardial ischemia. No patients with TAO had any form of myocardial episode. These findings correlate with Nigam R study where 20% of atherosclerosis cases and only 1% of TAO cases had some evidence of cardiovascular disease[7] In NHANES (National Health and Nutrition Examination Survey), more than 60% of patients with PAD had hypercholesterolemia, whereas in the PARTNERS (PAD Awareness, Risk, and Treatment: New Resources for Survival) program, the prevalence of hyperlipidemia in patients with known PAD was 77%. Hyperlipidemia increases the adjusted likelihood of developing PAD by 10% for every 10 mg/dL rise in total cholesterol.⁴⁸ The 2001 National Cholesterol Education Program Adult Treatment Panel III considered PAD a CAD risk equivalent. A combination of DM and hypertension was seen in 6 cases among the atherosclerosis group, and all these patients were above the age of 60 yrs. None of the patients in the present study gave history of stroke or any other cerebrovascular event in the past. In the Basle longitudinal study[15] the relative risk for PAD increased from 2.3 to 3.3 to 6.3 in individuals who had one, two, or three of the risk factors, respectively: smoking, diabetes, and systolic hypertension. The commonest site of obstruction in atherosclerosis group was found to be popliteal and infra-popliteal vessels involvement. Femoral block was seen in 5 cases and all these patients had no distal collaterals. None of the atherosclerotic patients had disease limited to the ankle. In Nigam R study, ilio-femoral site of block was commonest in atherosclerosis and infra-popliteal was commonest in TAO. A study from Japan determined the distribution of arterial involvement in TAO on the basis of a nationwide survey carried out in 1993[7]. The most frequently affected arteries in the lower extremities were the anterior (41.4%) or posterior (40.4%) tibial

arteries. A recently published study states that the public is poorly informed about peripheral arterial disease, this leads to delay in presentation and diagnosis. Hence poor outcome of any intervention, the patient ultimately requiring amputation in some form[16] Limb-loss is much more frequent once symptoms of rest pain or tissue loss become evident (critical limb ischemia). In a prospective study from Italy, the risk of major amputation was 12.2% after only 3 months in patients with rest pain or ischaemic ulceration. The risk of limb-loss is increased further when patients continue to smoke, and in patients with diabetes[17].

Conclusion

TAO presented at a younger age group whereas atherosclerosis presented in the older age group. All the cases of PAD presented with ischemic claudication and rest pain as common symptoms, while gangrene (80% of cases) and ischemic ulcer (20% of cases) were the other predominant symptoms. Gangrene was limited to the distal limb in the TAO cases and extended to the proximal limb in atherosclerosis. Atherosclerosis is more frequently associated with Diabetes mellitus. Lumbar Sympathectomy had helped in Improvement of rest pain noted in 67% of cases, healing of ulcer in 50%. The level of amputation was below knee in 42% and above knee in 58% cases. 48 cases were managed with some form of surgery and 36 of them had limb loss. This is due to late presentation with gangrenous changes, thus leaving no scope for limb salvage. 2 cases managed conservatively. Post operatively 3 of the cases required revision amputation.

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Source of Support: Nil

Conflict of Interest: None