Profile of patients with Atherosclerotic Aortoiliac Occlusive Disease presenting to CMCH, Vellore – A Descriptive study.

Thesis presentation in partial fulfillment of the requirement for examination to be held in January 2007 by Dr.MGR Medical University for MS General Surgery.

INDEX

AIM

TO EVALUATE THE EPIDEMIOLOGY, PATIENT PROFILE, VESSEL INVOLVEMENT PATTERN, AND TO ASSESS THE TYPE OF TREATMENT GIVEN AND OUTCOME FOR ATHEROSCLEROTIC AORTOILIAC OCCLUSIVE (AOD) DISEASE IN A TERTIARY CARE HOSPITAL.

OBJECTIVES

1. To evaluate the general characteristics of the patients presenting with Atherosclerotic aortoiliac occlusive disease (AOD)

2. To evaluate the anatomical pattern of vessel involvement based on Angiogram or the arterial Doppler study, including multiple level occlusions.

3. To determine the type of treatment given, whether conservative (including Antiplatelet therapy and chemical sympathectomy), endovascular radiological intervention or open (surgical) reconstruction.

4. To evaluate the outcomes of these treatment modalities i.e., symptomatic relief as well as complication rates, in the view of underlying risk factors.

REVIEW OF LITERATURE

Development of vascular surgery dates back to the landmark repair of vessel by Dr. Alexis Carrel [1]. The surgeon caring for the patient with peripheral vascular disease needs to evaluate and manage the associated disorders and he has to understand and assess the risk management more effectively in view of long term results, whether it be management of the risk factors or deciding on an intervention, nonoperative or operative revascularization.

Atherosclerosis

Atherosclerosis is a complex chronic inflammatory process that affects the elastic and muscular arteries. The disease is both systemic and segmental, with clear predilections for certain locations within the arterial tree while sparing the others. The earliest lesions (i.e., fatty streaks) may be detected as early as in the childhood in susceptible individuals [2].

Lesions progress through a series of well-characterized pathologic stages before clinical manifestations develop. Hemodynamics plays an important role in the development of atherosclerosis. Low flow, flow recirculation, low mean wall shear stress, and oscillations in shear stress are hypothesized to play a role in the localization of atherosclerotic lesions in the carotid bifurcation, coronary arteries, and abdominal aorta [33]. These low shear stress areas are hypothesized to be

more susceptible to cholesterol accumulation because of low local diffusional efflux from the arterial wall to the flowing blood and enhanced monocyte adhesion[32]. In contrast to the effects of low shear stress, increases in blood flow have been shown to stimulate the expression of nitric oxide synthase and superoxide dismutase, resulting in the reduction of cellular superoxide anion concentration and expression of monocyte chemotactic protein-1 and vascular cell adhesion molecule-1[34].

These effects reduce the adhesiveness of monocytes on the endothelium and are hypothesized to protect arteries from atherosclerotic plaques. Furthermore, elevated mean wall shear stress stimulates cellular structural changes, including cell elongation in the direction of maximum stress, inhibiting cholesterol accumulation from less permeable endothelial cell junctions [35].

Population based studies have demonstrated a number of important risk factors that have become targets for preventive therapy as well as potential clues into the pathogenesis of the disease. The influence of each of these risk factors on lower extremity arterial disease is discussed below.

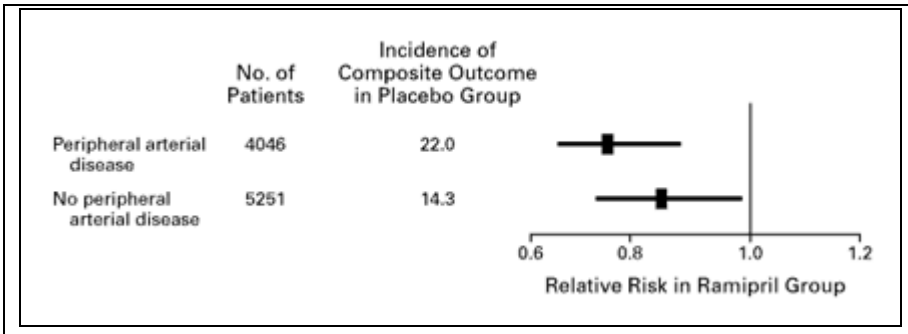
Risk factors for atherosclerosis:

Firmly established:	Hypertension	**Relative factors:**	Advanced age
	Diabetes mellitus		Male gender
	Hypercholesterolemia		Triglyceridaemia
	Tobacco-consumption		Homocysteinimia

Hypertension:

Hypertension has been repeatedly reconfirmed as the most potent force for developing the atherosclerotic diseases [(3)]. Better blood pressure control has been demonstrated to reduce adverse end-organ effects on the vasculature. For example, in a Meta analysis of 14 randomized trials of blood pressure control, the overall incidence of stroke was reduced 42% by a 5 – 6 mm Hg reduction in the diastolic blood pressure (4). Equally important is the reduction of the blood pressure in high-risk population such as group of patients with peripheral vascular disease.

In a study evaluating the results of Ramipril therapy in patients with and patients without peripheral arterial disease (Heart Outcomes Prevention Evaluation, HOPE, Study), the rate of the composite outcome of death from vascular causes, nonfatal myocardial infarction, and stroke was reduced in patients treated with ramipril; the outcomes did not differ significantly between patients with and patients without peripheral arterial disease.



Horizontal bars denote 95 percent confidence intervals. In the graph, values below unity favor ramipril treatment.

The atherogenic affect of hypertension is due to the high levels of Angiotensin II in these patients. Angiotensin II stimulates the vascular smooth muscles to constrict as well as proliferate. On the other hand, it stimulates the Lipo-oxygenase pathway releasing the inflammatory mediators locally which trigger off the cycle of chronic inflammation and propagate the process of plaque

formation [5]. However, it is not definitely known which antihypertensive drug can alter the clinical course, hypertension, likely to be present in vascular patients, should be identified and treated aggressively.

Diabetes Mellitus:

Atherosclerotic occlusive disease is a common complication of diabetes, accounting for 80% of the mortality rate [6]. An older study highlighted the

problem by observing extremity gangrene to have occurred 53 times more frequently in diabetic men and 71 times more frequently in diabetic women than in their non-diabetic counterparts [7]. Most of the evidence points to a non-occlusive thickening of the basement membrane of the vessel, which in turn impairs the exchange of nutrients and leucocytes between the capillary and interstitium. Furthermore, persons with diabetes have a sevenfold higher rate of lower extremity amputation than persons without diabetes. However, the increased risk of amputation is likely multifactorial in origin and may be related to more distal and diffuse atherosclerosis among persons with diabetes, as well as concomitant peripheral sensory neuropathy that can lead to traumatic ulceration

The disease is further complicated by the diabetic neuropathy predisposing to the development of foot ulcerations and infections in an already ischemic limb and hence the importance of maintaining euglycaemia in these patients. Vascular complications affect the patients with both insulin dependent (type I) and non-insulin dependent diabetes mellitus (type II) at an accelerated rate, as well as those with lesser glucose intolerance [8].

Hence, strict medical control of the diabetes, with prompt wound-care management is essential in management of these patients.

Tobacco:

Tobacco smoking is the leading preventable cause of death, with its impact on three areas of concern: atherosclerotic vascular change, chronic obstructive

pulmonary disease, and cancer. The association between smoking and lower extremity arterial disease may be, in fact even stronger than between smoking and coronary heart disease. All epidemiological studies of lower extremity arterial disease have confirmed cigarette smoking as a strong risk factor for development of lower extremity arterial disease, with relative risk ratios ranging from 1.7 to 7.5. The two main compounds identified to be responsible for the deleterious effects of tobacco consumption are Nicotine and Carbon monoxide.

Presence of nicotine has shown increased number of vascular desquamation and endothelial cell death in addition to increased arterial injury-induced myointimal thickening. Nicotine interferes with the Prostacyclin activity causing vasoconstriction and platelet aggregation, promoting the atherosclerotic plaque. The catecholamine surge increases intracellular lipid deposition, further complicating the pathogenesis of the disease.

Carbon monoxide, on the other hand binds preferentially to the hemoglobin. It increases the hypoxic insult as well as permeability of the vessels and thus involved in the pathogenesis of atherosclerosis.

Nearly all patients with peripheral vascular disease have atherosclerosis and about three of four affected patients are smokers. The Framingham study clearly relates smoking to the development of intermittent claudication [(9)]. Follow up reports disclosed smoking as the major risk factor measured for atherosclerosis; results showed pronounced effects on claudication [(10)]. Furthermore, a diagnosis of lower extremity arterial disease is made up to a decade earlier in smokers than

in nonsmokers. It is strongly suggested that a decrease in smoking can prevent progression of the disease process [11].

Hyperlipidaemia:

The principle importance of the dyslipidemias in clinical medicine derives primarily from their role in atherogenesis. Abundant evidence is available establishing the strong association between various lipid disorders and atherosclerotic vascular disease [12, 13]. The processes that lead to the growth of atheromata in the coronary vessels are similar to those leading to atherosclerosis in the peripheral vasculature. Almost 50% of patients with lower extremity arterial disease have hyperlipidemia. In the Framingham Study a fasting cholesterol level >270 mg/dL (7 mmol/L) was associated with a doubling of the incidence of intermittent claudication. Although other studies have failed to confirm an association between lower extremity arterial disease and elevated cholesterol levels, there is evidence that treatment of hyperlipidemia reduces both progression of atherosclerosis in the peripheral arteries and incidence of intermittent claudication.

Majority of case control studies have shown that and prospective studies have shown a positive correlation between serum triglyceride, LDL levels and coronary heart disease.

Although not an independent factor, the presence of established atherosclerotic disease in non-coronary vessels must also be considered a risk factor for coronary heart disease (14).

Age

The incidence of lower extremity arterial disease increases with age. For a man younger than 50, the prevalence of intermittent claudication is about 1% to 2%, whereas for those older than 50, prevalence increases to about 5%. A similar trend is seen in women. Given these findings, it is likely that lower extremity arterial disease will become more common as life expectancy increases

Male gender:

There has been significant difference between the two genders in the occurance of both atherosclerosis as well as its ill effects with respect to ischaemic damage in various systems. It has been observed that large-vessel peripheral artery disease is 50% more prevalent in men as compared with women before the age of 75 years[29], and abdominal aortic aneurysms occur in six times as many men as women for all ages.

Clinical Manifestations of lower limb ischaemia:

Approximately one third of patients with peripheral arterial disease have typical claudication, defined as pain in one or both legs on walking, primarily affecting the calves, that does not go away with continued walking and is relieved by rest. In patients with claudication, the severity of the condition increases slowly; 25 percent have worsening claudication, and 5 percent undergo an amputation within five years. Less than 5 to 10 percent of patients have critical leg ischemia (ischemic pain in the distal foot, ischemic ulceration, or gangrene), but their risk of limb loss is substantial. More than 50 percent of patients identified as having peripheral arterial disease on the basis of an abnormal ankle–brachial index value do not have typical claudication or limb ischemia at rest but, instead, have other types of leg pain on exertion, with reduced ambulatory activity and quality of life. Thus, most patients with peripheral arterial disease have a reduced functional capacity that limits their ability to perform daily activities.

The goals of treatment for patients with claudication are to relieve their exertional symptoms, improve their walking capacity, and improve their quality of life. These goals are similar for patients with critical leg ischemia, with the additional goals of relieving ischemic pain at rest, healing ischemic ulceration, and preventing limb loss. The overall approach to the diagnosis and treatment of peripheral arterial disease was extensively reviewed in a recent consensus publication that provides a comprehensive discussion of the medical and surgical therapies for the disease [36].

Natural history of Aortoiliac occlusive disease:

As mentioned above, knowledge of the natural history of lower extremity arterial disease is necessary when planning management strategies. When patients with intermittent claudication are followed for 5 years, about 50% either have no change in symptoms or may show improvement in functional status presumably due to development of collateral flow. Symptoms progress in about 16% of these patients, and a full 25% will require. surgery or experience tissue loss. Less than 4% of patients require a major amputation (15). In the Framingham Study only about 30% of patients with intermittent claudication had persistent symptoms for a minimum of 4 years.

The long-term amputation rate for patients with intermittent claudication is consistently less than 4%. For example, in two large population studies only 1.8% to 2.5% of patients diagnosed with intermittent claudication ever required a major amputation. More recently, the estimated major amputation rate has been tabulated based on the results of two independent studies. The major amputation rate in persons without diabetes ranged from 200 to 280 per million per year, whereas in persons with diabetes the rate was markedly higher at 3000 to 3900 per million per year.

In one population-based study of patients with lower extremity arterial disease undergoing initial revascularization surgery, about 20% of patients eventually required an ipsilateral amputation, and 26% required at least one repeat ipsilateral revascularization procedure [17]. Patients undergoing aortoiliac or aortofemoral surgery were less likely to require amputation than patients with a more distal revascularization procedure were (26% versus 16%; *P*=.03).

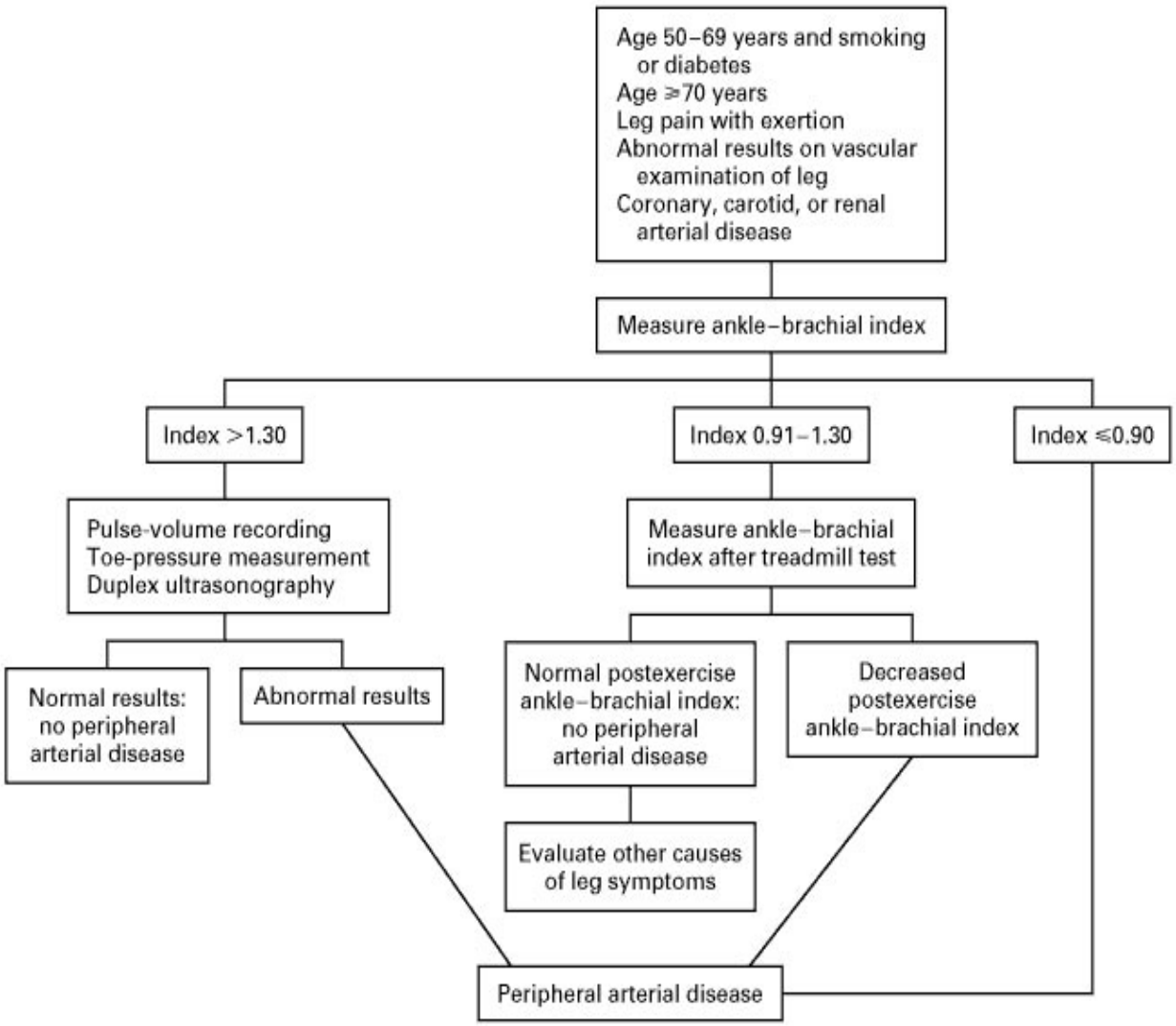
Risk of Systemic cardiovascular Ischemia.

Because patients with either asymptomatic or symptomatic lower extremity arterial disease have widespread arterial disease, they have a significantly increased risk of stroke, myocardial infarction, and cardiovascular death. At least 10% of patients with lower extremity arterial disease have cerebrovascular disease, and 28% have coronary heart disease [16].

Evaluation of the patient with chronic limb ischaemia:

The principle goals of evaluation of these patients are to determine the level of occlusion and the severity of the disease.

Evaluation of Patients in Whom Peripheral Arterial Disease Is Suspected.



Objectives for Diagnostic Evaluation of Patients With Critical Limb Ischemia[38]

The diagnostic evaluation of patients with critical limb ischemia should be directed toward the following objectives:

- Objective confirmation of the diagnosis
- Localization of the responsible lesion(s) and a gauge of relative severity
- Assessment of the hemodynamic requirements for successful revascularization (vis-à-vis proximal versus combined revascularization of multilevel disease)
- Assessment of individual patient endovascular or operative risk

A well-performed physical examination can often determine the proximal site or sites of involvement by obvious pulse deficits and the presence of a bruit at sites of narrowing. For example, absent foot and popliteal pulses indicate an occlusion proximal to the popliteal artery but tell the examiner nothing about the extent of disease below the knee. Before the availability of noninvasive testing, nothing more was usually done unless there was some indication for intervention to increase peripheral blood flow and relieve symptoms. However, with time and experience, it is now known that noninvasive testing can provide the physician

with valuable information that can be used for both diagnostic and follow-up purposes.

Diagnostic Tests:

Pressure Measurements: Ankle-Brachial Index

With increasing degrees of arterial narrowing, there is a progressive fall in systolic blood pressure distal to the sites of involvement. This can be assessed using methods of indirectly measuring this pressure drop. To accomplish this, a pneumatic cuff is applied to measure the pressure, and the sensing unit is placed distal to the cuff. The cuff is then rapidly inflated above systolic pressures, thereby obliterating flow to the part under study. As the pressure in the cuff is gradually deflated, the point at which flow is resumed is taken as the opening or systolic pressure at that level.

Normally, there is amplification of systolic pressure farther down the limb, ie, systolic pressure at the ankle level should be higher than that recorded from the upper arm. This means that the systolic pressures recorded from both tibial arteries at the ankle should be at least equal to or higher than that recorded from the arm. Thus, the normal ABI should be $\geq$1.0. To account for variability in the measurement, it is generally agreed that a value of $\geq$0.95 is normal (18). For

follow-up purposes, changes in the ABI within the range of ±0.15 are considered within the experimental error of the test, whereas changes outside this range are considered indicative of the disease process [19]. Assessment of the ABI helps to establish the diagnosis and also serves as a baseline measure for follow-up purposes.

Patients should be evaluated for peripheral arterial disease if they are at increased risk because of their age or the presence of atherosclerotic risk factors, have leg pain on exertion, or have distal limb ulceration for which the history and examination do not provide an obvious explanation. Additional vascular studies can be performed in patients with an ankle–brachial index value above 1.30, including pulse-volume recording, measurement of pressure in the first toe, or duplex ultrasonographic imaging of the peripheral vessels, to determine whether peripheral arterial disease is present. Patients with leg pain on exertion who have ankle–brachial index values of 0.91 to 1.30 should be considered for an exercise test. An ankle–brachial index value that is over 0.90 at rest but decreases by 20 percent after exercise is diagnostic of peripheral arterial disease. If the initial ankle–brachial index value is 0.90 or less at rest, the patient probably has peripheral arterial disease, and no additional tests are necessary.

ABI determinations may be of limited value in persons with diabetes, however, because calcification of the tibial and peroneal arteries may render them noncompressible. This is an important distinction because there is no

relation between calcification and the extent of atherosclerotic disease within these arteries.

Another advantage of measuring ABI in elderly patients is that it is a surrogate measure of atherosclerosis throughout the body. Thus, an abnormal ABI is one of the best predictors of subsequent cardiovascular events. Because it is so simple to perform, it could well become a standard

part of the physical examination of elderly patients and those who appear at risk for development of atherosclerosis

Ultrasonic Duplex Scanning

The first study of the peripheral arterial circulation by duplex scanning was published in 1985 [20]. This study clearly showed that the method was as accurate in defining the location and severity of arterial lesions as were two radiologists reading arteriograms done in the same patients. Similar results have been obtained when the technique has been applied prospectively [21].

Color doppler alone can be used to estimate the degree of narrowing, and although not as precise, it does provide a rough index of disease severity. Normally there is a triphasic color response. Poststenotic turbulence and the presence of a bruit at the site of narrowing are indicative of >50% stenosis,

whereas the complete absence of color and evidence of collateral arteries proximal to the site of obstruction suggest total occlusion [22].

Peripheral Angiogram:

Contrast Angiogram, with digital subtraction (DSA), is an excellent study that helps in direct visual assessment of the level and extent of the disease and is considered gold standard in preoperative evaluation of arterial stenosis world wide [32].

The disadvantage of an angiogram is that it is an invasive procedure with attendant risks of contrast nephropathy, anaphylaxis, incidence of haematoma formation at the puncture site and dissection of the vessel being catheterized. Catheter related complications like inability to retrieve the delivery device necessitating open arterotomy to remove these have been frequently reported.

Magnetic resonance angiography (MRA) has recently become instrumental in the diagnosis of arterial disease in various body districts and is gaining an increasingly important role in the study of peripheral vascular lesions[37].

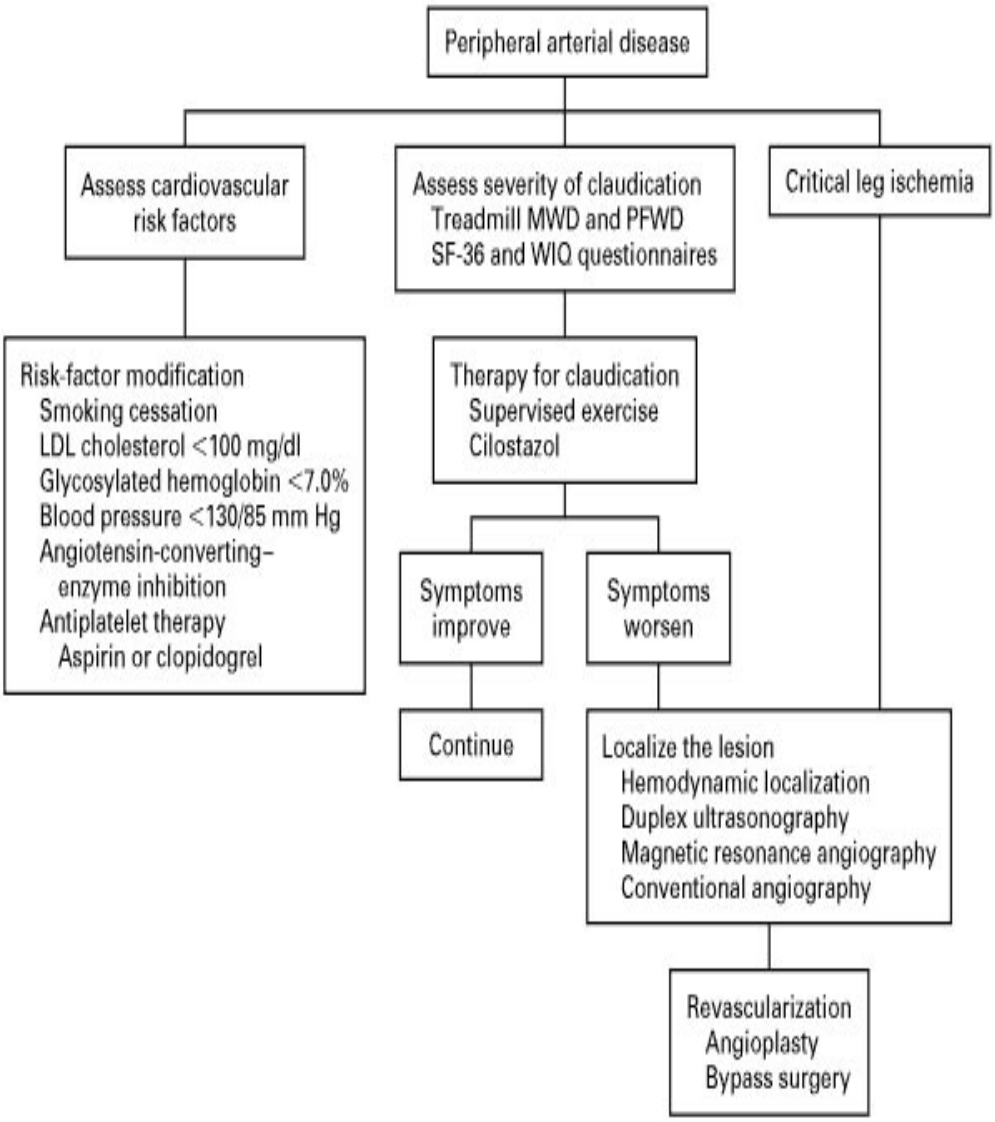
PERIPHERAL ANGIOGRAM

MAGNETIC RESONANCE ANGIOGRAM

DIGITAL SUBTRACTION ANGIOGRAM

Strategies in management of Atherosclerotic lower limb ischemia

Successful management of a patient with clinical and radiological features of atherosclerotic occlusive disease involves an overall perspective of the disease process and the patient factors.



Non-operative management

The medical management of atherosclerosis is targeted to reduce the progression, induce regression, and prevent morbid end points of lesion formation. Risk factor management is the primary approach

AHA Guidelines for Risk Factor Modification: (23)

1. Smoking: Complete cessation of all forms of tobacco consumption, including chewing and sniffing. Approach: behavior modification, counseling, nicotine analogues
2. Weight reduction to less than 120% of the ideal body weight
3. Blood pressure to be maintained below 140/90 mm of mercury.
4. Lipid management: primary – LDL < 100 mg/dl

   Secondary – HDL > 35 AND TG < 200 mg/dl

   Low fat diet, Specific drug therapy to target lipid profile
5. Physical activity: At last 30 minutes of moderate exercise 3-4 times a week.

Antiplatelet therapy constitutes the other major medical treatment option. The goal is to prevent thrombosis, embolisation, and perhaps even the progression of atherosclerotic disease. Aspirin remains the cornerstone of antiplatelet therapy here and large Meta analyses from the Antiplatelet Trialists, 31 randomized trials involving more than 29 000 patients with vascular disease were analyzed and have clearly demonstrated the beneficial effects of Aspirin in patients with prior myocardial infarcts, carotid atheroembolism, and peripheral arterial surgery (24).

The newer Antiplatelet agents have been developed with an increased potency and specific antiaggregative effects like Ticlopidine and Clopidogrel which hane shown efficacy in reducing some cardiovascular endpoints.

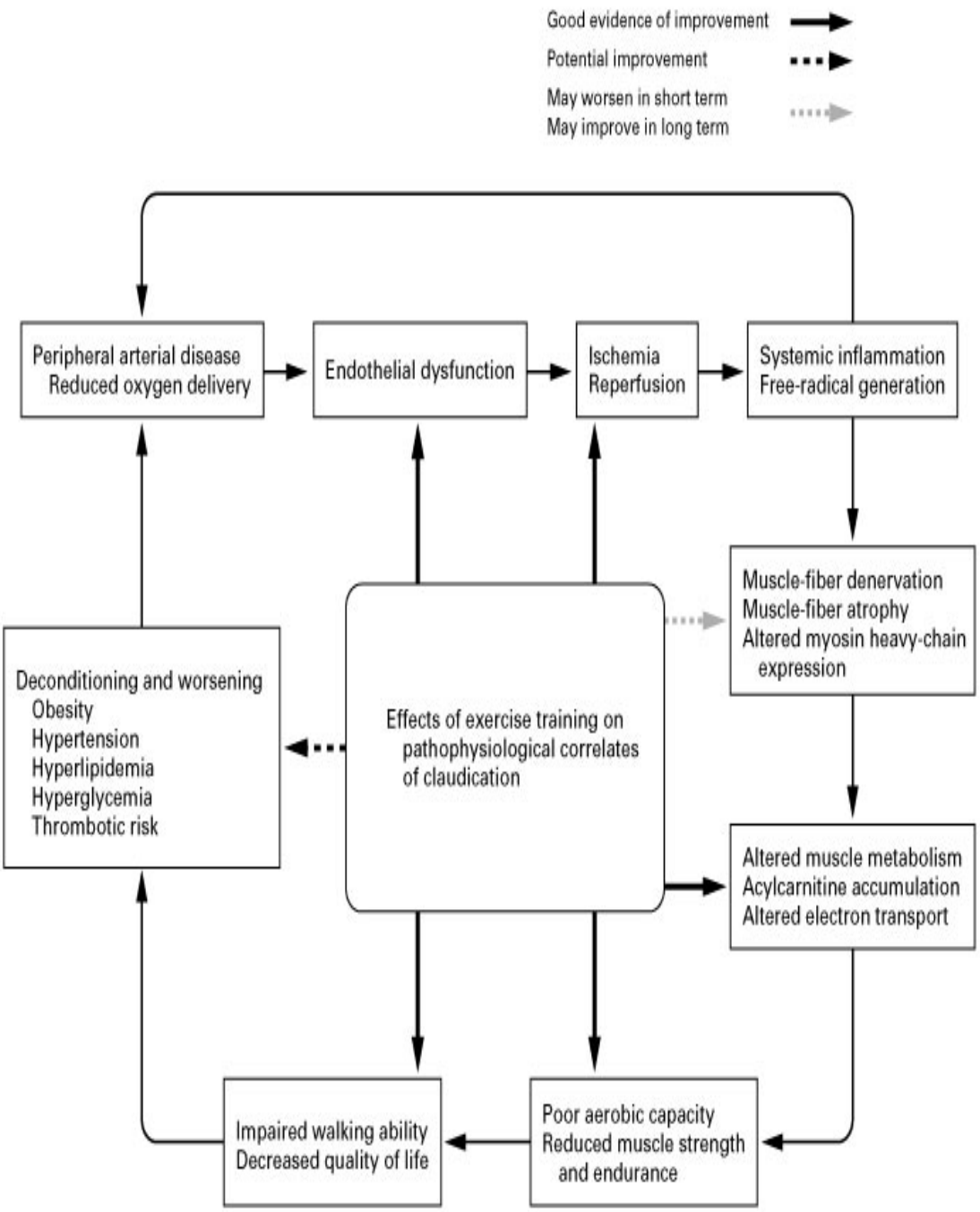
Rheological agents like pentoxifylline has been reported to improve abnormal erythrocyte deformability, reduce blood viscosity, and decrease platelet reactivity and plasma hypercoagulability in experimental setup but may not be clinically important compared with the effects of placebo, and does not justify the added expense for most patients.

Cilostazol, which inhibits phosphodiesterase type 3, thereby increasing intracellular concentrations of cyclic AMP, prevents platelet aggregation, the formation of arterial thrombi, and vascular smooth-muscle proliferation and causes vasodilatation

Exercise therapy is based on the concept of breaking the disability cycle which most of these patients enter further worsening the clinical scenario. Prospective studies have demonstrated a benefit of exercise training in patients with claudication. Because most patients studied have had mild-to-moderate claudication, little is known about the clinical benefits of exercise in patients with asymptomatic peripheral arterial disease or in patients with critical leg ischemia. Although exercise-induced improvement in walking ability is well established, the magnitude of the responses to training across studies has varied. Such variability may be explained by study-specific differences in the intensity, duration, and frequency of the exercise prescription and the methods of measuring exercise capacity.

One meta-analysis that examined both nonrandomized and randomized trials showed that exercise training improved pain-free walking time in patients with claudication by an average of 180 percent and improved maximal walking time by an average of 120 percent. The greatest improvements in walking ability occurred when each exercise session lasted more than 30 minutes, when sessions took place at least three times per week, when the patient walked until near-maximal pain was reached, and when the program lasted six months or longer

The cycle of disability resulting from claudication, the mechanisms involved, and the role of exercise training are shown in the following figure:



Revascularisation

Indications for Revascularization in Intermittent Claudication as per recommendations of Trans Atlantic Inter-Society Consensus (TASC) Working Group :

1. A predicted or observed lack of adequate response to exercise therapy and claudication pharmacotherapies

2. Presence of a severe disability, either being unable to perform normal work or having very serious impairment of other activities important to the patient

3. Absence of other disease that would limit exercise even if the claudication was improved (e.g., angina or chronic respiratory disease)

4. The individual's anticipated natural history and prognosis

5. The morphology of the lesion must be such that the appropriate intervention would have low risk and a high probability of initial and long-term success.

Accepted Treatments for Symptomatic Lower Extremity Atherosclerotic Occlusive Disease

Surgical	Endovascular	Nonoperative
Endarterectomy	Transluminal angioplasty	Risk factor modification
Bypass grafting	Endovascular stents	Exercise
AutogenousProsthetic	Intra-arterial thrombolytic therapy	Drugs (including thrombolytic agents)
Amputation		

To date, indications for surgical treatment of lower extremity ischemia have been defined in terms of severity of symptoms, with hemodynamic data serving to confirm the diagnosis but not as the primary indication for surgery. There is general agreement that surgical treatment is indicated to relieve symptoms of limb-threatening ischemia, including ischemic pain at rest, ischemic ulcers, and gangrene. There also is general agreement that surgery is indicated to remove or bypass and exclude sources of atheroemboli. On the other hand, currently, the primary indications for an interventional procedure in patients with lower extremity arterial disease include (1) incapacitating claudication interfering with work or lifestyle; (2) limb salvage in patients with limb-threatening ischemia as manifested by pain at rest, nonhealing ulcers, and/or infection or gangrene; and (3) vasculogenic impotence.

Interventional radiology

In recent years there has been a dramatic increase in the use of interventional radiological procedures for the treatment of acute and chronic lower extremity arterial disease. This reflects advances in vascular imaging that have made percutaneous transluminal angioplasty (PTA) more feasible, the development of intravascular stents, and the more widespread use of intra-arterial thrombolysis for the treatment of peripheral arterial thrombosis.

Percutaneous Transluminal Angioplasty / Stent placement.

Although the majority of patients with symptomatic aortoiliac disease do not require an invasive intervention, for those with incapacitating claudication or limb-threatening ischemia, angioplasty and lower extremity bypass surgery are the two major therapeutic options. Currently, the primary indications for an interventional procedure in patients with lower extremity arterial disease include (1) incapacitating claudication interfering with work or lifestyle; (2) limb salvage in patients with limb-threatening ischemia as manifested by pain at rest, nonhealing ulcers, and/or infection or gangrene; and (3) vasculogenic impotence.

PTA is an appropriate choice only when two important criteria are met. These include arterial disease localized to a vessel segment <10 cm in length and the

availability of a skilled vascular interventionalist[25]. Although data comparing surgery with PTA in patients with lower extremity arterial disease are limited, in a randomized trial (level II) that included 252 patients, there was no difference in clinical outcomes during a mean follow-up of 4 years[26].

There is level V evidence suggesting that PTA of the iliac arteries is associated with better long-term success rates than more distal angioplasty[27]. Iliac PTA is useful not only for dilatation of primary lesions but also as an adjunct to definitive femoropopliteal surgery where success rates are high when the procedure is carefully performed. For example, in a level V case-series study of 667 consecutive iliac PTA procedures done at the University of Toronto, initial success rates were as high as 90%. However, at 5 years the overall patency rate fell to 53%. The extent of disease at presentation influenced the long-term patency rate. Thus, in patients with isolated lesions in the common iliac arteries and good distal arteriographic run-off, the 5-year patency rate was 63%, whereas in those with poor run-off, it was only 51%. The complication rate was relatively low at 4%[28].

It has been suggested that vascular stenting provides more durable vascular dilatation than simple PTA, particularly when the patient is at high risk for restenosis. Currently available intravascular stents are either balloon expandable (eg, the Palmaz and Strecker stents) or self-expandable (eg, the Wallsten and Gianturco stents). In 1990 the first large trial (level V) evaluating the Palmaz stent showed only a 2% stent thrombosis rate at 6 months, with almost 90% of patients

experiencing some clinical benefit. At present the role of stents in treatment of lower extremity arterial disease is unclear. Although stent placement is a reasonable adjunct to PTA when a dissection occurs or when the lesion is particularly complex, the role of stents in primary PTA has yet to be established.

Operative revascularization:

There is general agreement that surgical treatment is indicated to relieve symptoms of limb-threatening ischemia, including ischemic pain at rest, ischemic ulcers, and gangrene. There also is general agreement that surgery is indicated to remove or bypass and exclude sources of atheroemboli. In contrast, intermittent claudication is considered only a relative indication for surgical treatment and then only after an adequate trial of nonsurgical therapy. Presently there is no consensus regarding disease severity, whether assessed by symptoms or hemodynamic parameters, for which operative treatment of claudication is appropriate [29].

Various surgical procedures have been described to improve the inflow to the lowerlimbs in aortoiliac disease:

-Aortobifemoral bypass

-Aortoiliac or aortofemoral bypass

-Aorto / Iliac endarterectomy

-Femorofemoral bypass

- Axillofemoral bypass

- Axillofemoral-femoral bypass

For aortoiliac disease the results of aortofemoral bypass and aortoiliac endarterectomy are equivalent with respect to patency. Most surgeons prefer bypass because endarterectomy operations are longer, more technically demanding, and associated with greater blood loss. For elderly patients and those with increased operative risk, satisfactory results have been reported with extra-anatomic bypass grafting procedures (axillofemoral, femorofemoral) that avoid the physiological stress of aortic clamping and abdominal cavity surgery. Patency rates of extra-anatomic bypass grafting have historically been lower than those of aortofemoral grafting.

Choice of the operative procedure depends on the pattern of the vessel involved. Most commonly, patients demonstrate diffuse disease of the infrarenal aorta and iliac vessels, with the lesions of greatest hemodynamic consequence located in the iliac arteries. The most effective surgical procedure for the treatment for this pattern of atherosclerotic occlusive disease is aortobifemoral bypass. Aortobifemoral grafting is associated with an operative mortality of 3.3% and a morbidity of 8.3% [39]. The expected patency of aortobifemoral bypass as the sole procedure for the treatment of critical limb ischaemia is excellent [39.]

If the aortoiliac lesions are confined to the area of the aortic bifurcation, localized aortoiliac endarterectomy may be considered. This procedure is effective but is

uncommonly performed because few patients have such a limited manifestation of atherosclerosis. Nonetheless, when the operation is indicated, the results demonstrate good patency, in the range of 48% to 77% at 10 years.

For patients with adequate aortic flow but stenoses or occlusions of both iliac vessels who are not considered acceptable candidates for aortobifemoral bypass, a somewhat less invasive approach may be appropriate. If 1 iliac artery can be made widely patent by angioplasty and stent placement, endarterectomy, or a unilateral iliofemoral bypass, a femoral-femoral bypass can be constructed. In the absence of an inflow stenosis within the donor iliac arterial segment, this procedure can effectively improve flow to both lower extremities.

Unilateral iliac stenoses or occlusions that cannot be treated effectively by angioplasty and stent placement can be treated by iliac artery endarterectomy, aorto-iliac bypass, aortofemoral bypass, or iliofemoral bypass if the origin of the iliac artery is free of disease.

The surgical treatment of unilateral iliac disease by aortoiliac, iliofemoral, or femoral-femoral bypass graft placement provides excellent results for the restoration of inflow into the lower extremity. Ipsilateral bypasses that originate from the aorta or proximal iliac artery have a 3-year patency rate in the range of 90% [40]. Femoral-femoral bypass grafting yields a 3-year patency rate that ranges from 60% to 80% and a 5-year patency rate of 60% to 90%

Patients with severe infrarenal aortic atherosclerosis who are at high cardiovascular or surgical risk for open aorto-bifemoral bypass may be treated with axillofemoral-femoral bypass. Because this graft is based on the axillary artery, preoperative assessment of bilateral arm blood pressures, duplex ultrasound flow assessments, and/or imaging of the aortic arch and great vessels to the origin of the donor vessel should be obtained.

Axillofemoral and axillobifemoral grafts are significantly inferior to aortobifemoral bypass grafts or aortoiliac endarterectomy for the treatment of severe diffuse aortoiliac disease. The 5-year patency rate for axillofemoral grafts ranges from 19% to 50%. The results of axillobifemoral bypass are somewhat better, with 5-year patency rates that range from 50% to 76% .

A comparison of surgical reconstruction with PTA for treatment of lower extremity ischemia in a level 2 study showed that the surgical group maintained slightly higher success rates, with the differences being explained almost entirely by the lower initial success rate of angioplasty. Successful angioplasty in this study was as durable as successful surgery[30].

The numerous options available for the treatment of aortoiliac occlusive disease have led to controversy over which is best. Not only are the technical aspects of direct aortoiliac reconstruction debated but the role of lower risk but less durable options such as extraanatomic bypass and balloon angioplasty and/or stenting is still unsettled.

Rather than yield to the tendency to apply one method preferentially over the others, it is important to realize that each approach has a selective role to play in the overall management of aortoiliac occlusive disease, if applied in appropriate settings [31].

An observational study was done, to evaluate the patients with atherosclerotic aortoiliac disease, in view of this background knowledge of the available literature, in an attempt to understand the disease process as well management strategies.

Methodology

1. 20 patients with aortoiliac disease diagnosed clinically and proven with arterial doppler and or an angiogram were studied prospectively for an year. Also, 360 patients with peripheral vascular disease visiting our hospital for past nine years were evaluated, and data collected for 91 patients with aortoiliac disease (total no.= 111).
2. Epidemiological evaluation, risk factors, disease severity, treatment options and outcome was studied and analyzed using the SSPS software for windows.
3. Frequency tables were drawn for each of the parameters using the statistical analysis and incidence of the variables in each category was calculated.
4. Using this basic data sheet, all the variables were cross tabulated and evaluated based on their strength of association.
5. Finally inferences were drawn and conclusion made based on the analysed data.

The patient factors studied were drawn up into a Vascular Proforma.

PROFORMA

1. Demography: Age , Gender
2. Clinical presentation: Claudication, Rest pain, Gangrene, Acute ischemia, Ischemic ulcer
3. Risk factors and co-morbidities: History of tobacco intake, Diabetes mellitus, Hypertension, Dyslipidaemia.
4. Past treatment obtained: Conservative, Sympathectomy, Revascularization, Amputation/debridement.
5. Clinical examination including general physical examination and examination of the affected limb(s)
6. Ankle Brachial Pressure Index
7. Angiogram and/ or Arterial color doppler findings: Level of obstruction.
8. Management of the patient: Conservative, Operative revascularization, Radiological intervention, Amputation/debridement
9. Morbidity specific to the management strategy
10. Outcome – Pain relief, Palpable pulse, Improvement in ABPI, Healing of the ulcer

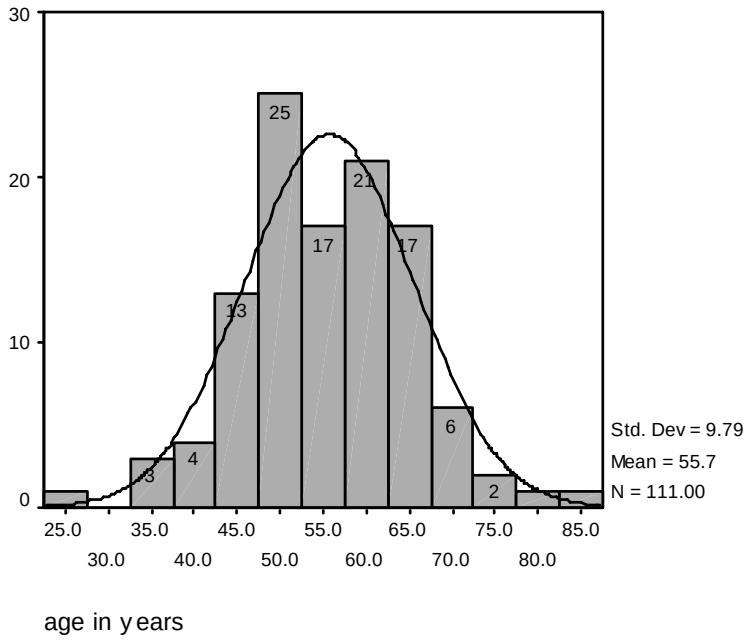
RESULTS

The results of this study are based on, as mentioned in the methodology,

20 patients evaluated prospectively for one year and 91 patients evaluated retrospectively for the past 9 years, with a total of 111 patients, diagnosed to have atherosclerotic aortoiliac occlusive disease.

Epidemiology

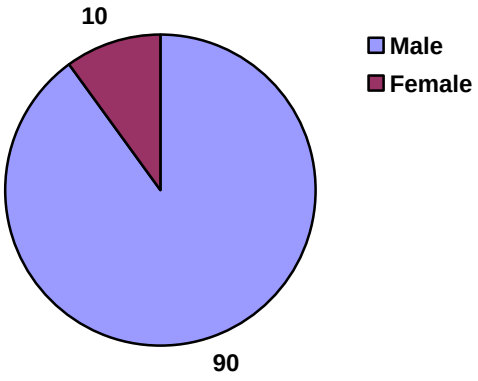
1. Age:



Increasing age was clearly shown to be associated with higher incidence of aortoiliac occlusive disease. The mean age of presentation with symptomatic disease is 56 years

In an age distribution analysis, 83% of the patients were in the 45 – 65 age group.

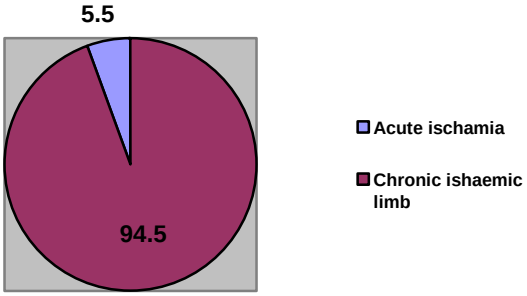
2. Gender:



Gender (%)

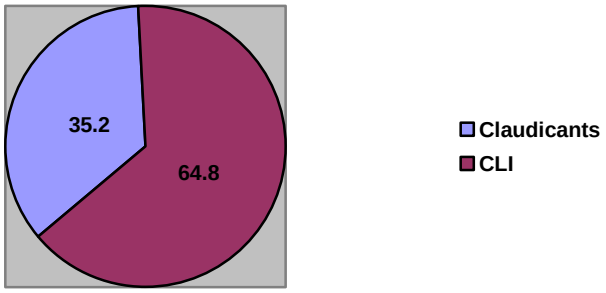
Males had a significantly higher preponderance to the disease with 90% of the patients being men.

3. Presentation



5.5 percent of the patients presented as acute ischemia while the rest 94.5 presented with chronic illness.

4. Symptoms in aortoiliac dasease:



Patients were regrouped into claudicants and those with critical limb ischemia based on their symptoms at present. 64.8% had critical limb ischemia while the rest 35.3% were in the claudication stage only.

Claudication was the principle symptom reported by the patients, occurring as either the only symptom or having experienced it before entering the critical ischemic state. A non-healing ulcer was the next common symptom and almost same number of patients had rest pain, 39% and 37% respectively. About 29 % of the patients also had distal gangrene because of ischemia.

5.Associated ischemic symptoms in other systems:

System involved	No	Percentage
Cardiac	17	15.3%
Impotence	12	10.8%
Cerebral	10	9%
Mesenteric	1	<1%

15.3% of patients gave history of cardiac ischemia requiring treatment in the past. 10.8 % of the patients had impotence while another 9% had past episodes of a cerebral vascular event. One patient reported symptoms suggestive of chronic mesenteric ischemia.

6. Risk factors for Atherosclerotic arterial disease:

Risk factor	No.	Pecentage
Smoking	96	86.5%
Diabetes mellitus	64	57.7%
Hypertension	49	44%
Dyslipidaemia	14	12.6%

86.5% of the patient consumed tobacco in one form or the other making it the major risk factor for the atherosclerotic disease.

57% of the patients with lower limb ischaemia had Diabetes mellitus currently on treatment. Hypertension was the next important risk factor found in 44%. Dyslipidaemia was seen in 12.6% of the subjects.

7. Past treatment history

81% of the patients had received medical treatment prior to admission. These include analgesics, antiplatelet therapy. 8% of the patients had lumbar sympathectomy for pain relief and equal number already had some form of r revascularization done, either open surgical or radiological intervention.

8.Clinical assessment

Clinical Feature	**No.**	**Percentage**
Undernourished	70	63%
High blood pressure	60	54%
Femoral pulse not palpable	83	75%
Bruit	13	12%
Trophic changes	106	95.5%
Affected limb cold	98	88%

Clinical examination of the patient showed about 63% of the patients to be undernourished. Blood pressure readings were high (>140/90 mm Hg) in 45.5%, which is marginally higher than the number of patients actually presented with hypertension (44%).

In 75% of patients, the pulse was not palpable from femoral downward. In rest of the patients, popliteal downward was not palpable with a weak femoral pulse. 12% 0f them had an audible bruit. Trophic changes in the affected limb, namely muscular atrophy, loss of hair, shiny skin etc, were seen in 95.5% and the limb was cold compared to the non-affected limb in 88% of the patients.

9. Ankle Brachial Pressure Index

ABPI	**No.**	**Percent**
0 – 0.3	51	45.9%
0.4 – 0.6	44	39.6%
> 0.7	9	8%

91% of the patients had an ABPI of less than 0.6 with half of the total patients reaching index less than 0.3.

Ischaemic heart disease:

Though only 17% of patients gave history of a previous cardiac event, evaluation of the patient in the ward with an ECG or echocardiogram revealed evidence of ischemia in about 30% of the patients.

Pattern of vessel involvement:

Segment involved	**NO.**	**Percentage**
Aortoiliac segment	60	54.1%
Iliofemoral segment	35	31.5%
Multiple levels	18	16.2%

Using either color Doppler study or contrast digital subtraction angiogram, the level of block (complete or partial) was at the aortoiliac segment in 54% of the patients, while 35.5% had the disease in the iliofemoral segment. 18% of the

patients had multiple level obstructions starting from aortoiliac segment downwards.

Level of block	% patients	Details
Clinical examination	87 %	Femoral pulse absent in 75% and weakly palpable in 12% of patients
Radiological diagnosis	86.1 %	Aortoiliac segment involved in 51.4% and Iliofemoral segment involved in 31.5%

Radiological evidence of level of the inflow obstruction was compared with the clinically assessment of blood flow (absent or weak pulse). No significant difference was found between the two.

Management of the patients with Aortoiliac occlusive disease:

- **Conservative management**: 26.1%
- **Intervention rate :** 87.3%

Operative revascularization - 42 (38.5%)

Radiological intervention - 25 (22.5%)

Primary amputation/ Debridement - 30 (27%)

38.5% of the patients underwent operative revascularization, either a aorto-femoral bypass or a ilio-femoral bypass graft. 22.5% of the patients received radiological revascularization including PTA and stenting of the occluded segment under guidance of digital subtraction angiography. Another 27% underwent some degree of primary amputation / debridement resulting in tissue loss. Two patients underwent combined radiological and operative revascularization.

Treatment outcome:

Pain relief	**No.**	**Percentage**
Operative revascularization	35 (42)	83.3%
Radiological intervention	19 (25)	76%

Palpable pulse	**No.**	**Percentage**
Operative revascularization	36 (42)	85.7%
Radiological intervention	21 (25)	84 %

Improved ABPI	No.	Percentage
Operative revascularization	39 (42)	93%
Radiological intervention	22 (25)	88%

The improvement in the ABPI and post procedure palpable pulses were calculated specific to the intervention provided. In the operative revascularization group, pulse was palpable post op in about 86%, and there was improvement in the ABPI in 93% of patients. 84% had satisfactory pain relief among these patients. In the group which received radiological intervention, the pulse returned in 84% and ABPI improved in 88% of patients. 86% had relief from pain. Healing of the ulcers could not be completely evaluated during the stay in hospital, nevertheless, signs of healing was seen in 63% of patients. Healing was worse in those consuming tobacco (33%) and those with diabetes (37%).

Complications:

Complications were tabulated again specific to the intervention. Of the 25 patients who underwent radiological intervention, 7 developed procedure related

complications i.e. dissection of the vessel or post procedure thrombosis of the vessel (24%).

In the operative revascularization group, 5 of the 42 patients developed graft thrombosis requiring either revision or subsequent amputation (11.9%). 3% of total patients finally developed gangrene regardless of the treatment modality. An overall 15% underwent amputation or debridement after any of the above treatment, including conservatively managed patients.

CONCLUSIONS

This observational study has revealed following important conclusions

1. The previously known risk factors play vital role in pathogenesis and progression of the atherosclerotic vascular disease. The major factors found in this study were:
2.

Modifiable:	**Non-modifiable:**
Tobacco consumption	Advancing age
Diabetes mellitus	Male gender
Hypertension	
Dyslipidaemia	

In order to stop the disease process and prevent further progression, these modifiable factors need to be aggressively identified and treated. Tobacco use, in any form, should be strongly discouraged.

3. Majority of the patients (64%) with Aortoiliac disease presented with critical ischemia and the rest (36%) complained only of claudication.

4. Ischemic heart disease was major comorbidity when other systems were affected by atherosclerosis. This was followed by impotence

and almost equal number of patients had a cerebral vascular ischemic event. This observation further emphasizes the importance of strict risk factor control on a preventive basis.

5. The undernourishment was probably due to reduced food intake secondary to chronic pain and morbidity. Typical features of limb ischemia, namely trophic changes and coldness of the affected limb were seen in almost all the patients.

6. Ischemia was at critical level, as indicated by ABPI of < 0.3, in about half the patients. Majority of patients (91%) had ABPI of < 0.6.

7. Radiological evaluation correlated well with the clinical examination in determining the pattern of the vessel involvement.

   Most patients had block in the aortoiliac segment. A small proportion of the patients also had blocks at multiple levels.

8. Most of the patients had some form of intervention – operative or radiological revascularization.

9. About one third of the patients required only conservative treatment including antiplatelet therapy, which is very important in the management of any occlusive disease of the arteries.

10. About one third of the patient had tissue loss in form of amputation or debridement.

This was at a higher rate in the patients with diabetes and who consume tobacco. These two factors also delayed the signs of ulcer healing.

11. Both surgical and radiological interventions, in the appropriately chosen patients, had comparable results with respect to post procedure palpable pulse, improvement in ABPI and in giving patients relief from the ischemic pain.

Bibliography

1. Morris D Kerstein, Non operative management of lower extremity arterial disease, *The surgical clinics of North America* , June 1998, 78:3.
2. Ross R, Atherosclerosis – a problem of the biology of the arterial wall cells and their interactions with the blood components. Atherosclerosis, 1981, 1:293-311.
3. Kannel W B, Blood pressure as cardiovascular risk factor: Prevention and treatment, *JAMA* , 1996 275:1571.
4. Collins R, Peto R et al Blood pressure, heart and coronary heart disease, overview of the randomized trials in their epidemiological context. *Lancet*, 1990, 335:827.
5. Itoh H, Mukoyama m, Pratt RE et al Vascular smooth muscle growth response to Angiotensin II. *J Clin Invest*, 1993, 91:2268.
6. Gracia MJ, McNamara PM, Gordon T et al Morbidity and mortality in the population in Framington population: 16 year follow-up study. *Diabetes*, 1974, 23:105.
7. Bell ET Atherosclerotic gangrene of the lower extremities in diabetic and non diabetic persons. *Am J Clin Pathol*, 1957, 28:27.
8. West KM, Ahuja MS, Bennet PH The role of glucose and triglyceride concentrations and their interactions with other risk factors as determinats of arterial disease from WHO multinational study. *Diabetes care*, 1983, 19:361.

9. Wolf PA, D'Agostino RB, Kannel WB Cigarette smoking as a risk factor for stroke: The Framingham study, 1998*, JAMA* 259:1025.
10. Kannel WB, McGee d, Gordon T: A general cardiovascular rik profile: The Framingham study. *Am J Cardiol*, 1976, 38:4.
11. Calphos SC, Huribal, Marsan Nicotine and its metabolites are mitogenic for smooth muscle cells. *J Vasc Surg*, 1977, 25:682.
12. Stamler J, Wentworth, Neaton, Multiple risk factor intervention trial (MRFIT) *JAMA*, 1986, 256:2823.
13. Assman G, Schulte H, Triglerides and atherosclerosis, *Atherosclerosis reviews*, 1991, 22:51.
14. Criqui MH, Langer RD et al : Mortality over a period of 10 years in patients with peripheral vascular disease.
15. McDaniel MD, Cronenwett JL. Basic data related to the natural history of intermittent claudication. *Ann Vasc Surg..* 1989; 3:273-277
16. Farkouh ME, Rihal CS, Gersh BJ, Rooke TW, Hallett JW Jr, O'Fallon WM, Ballard DJ. Influence of coronary heart disease on morbidity and mortality after lower extremity revascularization surgery: a population-based study in Olmsted County, Minnesota (1970-1987). *J Am Coll Cardio.* 1994; 24:1290-1296
17. Widmer LK, Biland L, DaSilva A. Risk profile and occlusive periphery artery disease (OPAD). In: *Proceedings of the 13th International Congress of Angiology*; June 1985; Athens, Greece; 28

18. Sumner DS, Strandness DE Jr. The relationship between calf blood flow and ankle blood pressure in patients with intermittent claudication. *Surgery* 1969; 65:763-771.
19. Strandness DE Jr, Bell JW. Ankle pressure responses after reconstructive arterial surgery. *Surgery..* 1966; 59:514-516
20. Jager KA, Phillips DJ, Martin RL, Hanson C, Roederer GO, Langlois YE, Ricketts HJ, Strandness DE Jr. Noninvasive mapping of lower limb arterial lesions. *Ultrasound Med Biol..* 1985; 11:515-521.
21. Kohler TR, Nance DR, Cramer MM, Vandenburghe N, Strandness DE Jr. Duplex scanning for diagnosis of aortoiliac and femoropopliteal disease: a prospective study. *Circulation..* 1987; 76:1074-1080.
22. Hatsukami TS, Primozich JF, Zierler RE, Harley JD, Strandness DE Jr. Color Doppler imaging of infrainguinal arterial occlusive disease. *J Vasc Surg..* 1992;16:527-533.
23. Data from American Heart Association Council newsletter, Fall 1995.
24. Antiplatelet Trialists' Collaboration: Maintenance of vascular graft or arterial patency by Antiplatelet therapy. *BMJ,* 1994,308:159-168.
25. Wolf GL, Wilson SE, Cross AP, Deupree RH, Stason WB, for the principal investigators and their associates of Veterans Administration Cooperative Study Number 199. Surgery or balloon angioplasty for peripheral vascular disease: a randomized clinical trial. *J Vasc Interv Radiol..* 1993;4:639-648
26. Casarella WJ. Noncoronary angioplasty. *Curr Probl Cardiol..* 1986;11:141-174

27. Johnston KW, Rae M, Hogg-Johnston SA, Colapinto RF, Walker PM, Baird RJ, Sniderman KW, Kalman P. Five-year results of a prospective study of percutaneous transluminal angioplasty. *Ann Surg..* 1987;206:403-413
28. Tegtmeyer CJ, Hartwell GD, Selby JB, Robertson R Jr, Kron IL, Tribble CG. Results and complications of angioplasty in aortoiliac disease. *Circulation.* 1991; 83(suppl I): I-53-I-60.
29. Labarthe D. Other major conditions. In: Colilla J, ed. *Epidemiology and prevention of cardiovascular diseases: a global challenge.*. Gaithersburg [MD]: Aspen Publishers, Inc 1998:91-117.
30. Wilson SE, Wolf GL, Cross AP. Percutaneous transluminal angioplasty versus operation for peripheral arteriosclerosis: report of a prospective randomized trial in a select group of patients. *J Vasc Surg..* 1989; 9:1-9.
31. R B Rutherford, Options in the surgical management of aortoiliac occlusive disease: a changing perspective. *Cardiovascular surgery*. 1999; 7:1:5-12.
32. Nelemans P, Leiner T, de Vet H, van Engelshoven J. Peripheral arterial disease: meta-analysis of the diagnostic performance of MR angiography. *Radiology*. 2000;217:105-114
33. Caro CG, Fitz-Gerald JM, Schroter RC. Atheroma and arterial wall shear: observation, correlation and proposal of a shear dependent mass transfer

mechanism for atherogenesis. *Proc R Soc London B Biol Sci*. 1971;177:109-159.

34. Cybulsky MI, Gimbrone Jr. MA. Endothelial expression of a mononuclear leukocyte adhesion molecule during atherogenesis. *Science*. 1991;251:788-791.
35. Zarins CK, Bomberger RA, Glagov S. Local effects of stenoses: increased flow velocity inhibits atherogenesis. *Circulation,* . 1981;64(2 Pt 2):II-221-II-227.
36. Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). *J Vasc Surg* 2000;31:S1-S296.
37. Gozzi M, Amorico MG et al : Peripheral arterial occlusive disease: role of MR angiography. *Radiol Med (Torino).* 2006 Mar;111(2):225-37
38. Dormandy JA, Rutherford RB, for the TransAtlantic Inter-Society Consensus (TASC) Working Group, Management of peripheral arterial disease (PAD), *J Vasc Surg*, 31, S1–S296
39. de Vries SO, Hunink MG. Results of aortic bifurcation grafts for aortoiliac occlusive diseasea meta-analysis*. J Vasc Surg* 1997;26:558-569.
40. Brothers TE, Greenfield LJ. Long-term results of aortoiliac reconstruction J Vasc *Interv Radiol* 1990;1:49-55.