

The Effect of Various Interventions on Patients Outcome In Peripheral Arterial Disease

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Abstract:-- Background: Peripheral artery disease (PAD) is defined as impairment of the blood flowing to the extremities which is a result of atherosclerotic occlusive disease. The most classic symptom is pain over limbs on walking which resolves with rest (intermittent claudication) which occurs due to poor oxygenation of muscles of lower extremities. Objectives: Mainly to classify patients of PAD as per Fountain and Rutherford's classification, Compare efficacy of various interventions based on treatment arms, Monitor response of treatment on claudication pain and claudication distance, Determine response of treatment on quality of life as assessed by SF-36 questionnaire and, Monitor short and long term effects of these interventions. Methodology: It is a prospective cohort study design studied for a duration of 2 years. Study Setting: Dept of Surgery, AVBRH, Sawangi(M), wardha. AMPLE SIZE: 75 (25 in each group). Groups: 1) PAD patients undergoing medical/ conservative management (N=25) 2) PAD patients treated or managed with intervention radiology (N=25). 3) PAD patients treated with combination of any of the two modalities like, IR and surgical (debridement/amputation) OR, Medical management followed by IR OR, Medical management followed by surgical management (debridement/amputation) (N = 25). Expected Results: All patients admitted with diagnosis of PAD will undergo comparison between medical, interventional radiological and surgical management which claims to improve the quality of living of patients with peripheral arterial disease. This study is basically inclined to prove that surgical management is the better form of management for improving quality of living of patient with PAD. Conclusion: Peripheral arterial disease is defined as a progressive disease with significant morbidity and mortality rate. The prevalence of this disease in general population is about 10–14%, affecting up to approximately 25% of those over 70 years; 65%–85% of affected individuals are asymptomatic with only a minority of population requiring revascularization or amputation. Keywords: Peripheral arterial disease, claudication pain, ankle brachial index, peripheral vascular disease, intermittent claudication, rest pain, thrombosis of arteries, gangrene.

Keywords--- PERIPHERAL ARTERIAL DISEASE, VASCULAR DISEASES, CRITICAL LIMB ISCHEMIA, CLAUDICATION PAIN

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I INTRODUCTION:

I.I. Background/rationale:

Peripheral artery disease (PAD) in leg aka peripheral vascular disease (PVD) is most commonly said to be caused by atheroma or in simpler words fatty deposition in walls of the arteries. The deposition of fatty substances in the vessel wall leads to blood flow reduction or insufficiency to the muscles and other tissues. It's a term used to determine impairment of blood that is flowing to the limbs commonly due to result of atherosclerotic occlusive disease changes. In short, it's a manifestation of systemic atherosclerosis. The experience of various symptoms depends on various demands of ischemic tissues metabolically like during workout/ exercise. Symptoms may also depend on various collateral circulation degrees and/or the location of deposits in the affected artery (1-8).

Most classical symptom in PAD is pain in limbs which is experienced during walking. This pain subsequently resolves with rest. Such pain is termed as intermittent claudication which is said to be a result of poor oxygenation of lower extremity muscles. Poor oxygenation to muscles is expressed by patients with PAD as dull aching pain, cramping type of pain or feeling of numbness in calf or buttock or hip or thigh or at the arch of foot which aggravates while walking and is comparatively relieved with rest. Various other symptoms experienced includes skin ulcers, or poor structured nail growth and hair growth, bluish discoloration of skin or cold clammy skin over the affected leg (9-17).

The most common risk factor that contributes to PAD is smoking. Other risk factors include – older age group, comorbid diseases like diabetes, heart diseases, stroke, high blood cholesterol and high blood pressure. However, many people who have been diagnosed with peripheral arterial disease (PAD) may not have any features or symptoms (18-22).

The various type of symptoms that can be seen in association with PAD are:

- Pain, numbness or heaviness in the legs which aggravates on walking or while climbing stairs (aka claudication)
- Weak or absent pulsations felt over extremities
- Decreased hair growth over the affected limb
- Pale or bluish discoloration of skin
- Wound or sores over toes or feet or legs that heals slowly or poorly or not at all
- Lower temperature over the affected limb
- Erectile dysfunction, especially among men who have diabetes

I.II. Objectives:

- Mainly to classify patients of PAD as per Fountain and Rutherford's classification,
- Compare efficacy of various interventions based on treatment arms,
- Monitor response of treatment on claudication pain and claudication distance,
- Determine response of treatment on quality of life as assessed by SF-36 questionnaire and

- Monitor short and long term effects of these interventions.

Trial design: It is a single blind and comparative study

II METHODOLOGY:

It is a prospective cohort study, done on the patients of Peripheral arterial disease requiring medical and / or surgical interventions. It will be conducted at Dept.of surgery, J.N.M.C and AVBRH hospital, Sawangi (Meghe), Wardha of DMIMS (DU).

This study will be conducted on patients of Peripheral arterial diseases requiring medical and / or surgical interventions. Informed and signed consent will be obtained from all the patients and prior approval from institutional ethical committee, DMIMS (DU) will be taken.

II.I. Eligibility_criteria:

All patients admitted with the diagnosis of peripheral arterial disease will be evaluated for participation in the study on various criteria given above. The patient population will be divided into following groups.

Group A: patients with PAD undergoing medical/ conservative treatment

Group B: patients with PAD undergoing surgical intervention

Group C: Patients with PAD treated with combination of any two modalities like medical/ conservative, surgical and/or Intervention Radiology

After enrollment, patients will be randomized into respective groups based on the treatment modality selected as per standard treatment guidelines.

II.II. Inclusion criteria:

- Patients with PAD undergoing medical/ conservative management
- Patients with PAD undergoing surgical interventions
- Patients with PAD treated with combination of any two modalities like medical/ conservative, surgical and/or Intervention Radiology.

II.III. Exclusion criteria:

- Patients already diagnosed with PAD and on treatment
- Patients who have already undergone some interventional radiology procedure
- Patients not fit for any of the above procedures.
- Patient refusal

II.IV. Variables:

The patients with the symptoms s/o PAD will be evaluated. The basic investigations like CBC, KFT, LFT, lipid profile, will be done. The arterial and venous studies will be done using color Doppler. The patients will be randomized into medical/ surgical treatment. The patients requiring surgical treatment will be evaluated further with angiography.

Based on the lesion and/ or the LEVEL OF OBSTRUCTION, the treatment option of medical/ conservative treatment, surgical intervention like debridement, amputation, PRP infiltration, or procedures using IR like stenting, intra-arterial thrombolysis, etc will be done.

The patients will be monitored for the treatment response based on following parameters:

- Claudication pain
- Claudication distance
- Level of gangrenous changes
- Rest pain
- Status of postoperative wounds
- Status of amputation flap
- Intervention radiology related parameters like flow velocity

All the patients will be assessed on the basis of SF-36 quality of life index questionnaire.

The study will be conducted on patients of Peripheral arterial diseases requiring medical and / or surgical interventions.

75 participants will be enrolled under medical, intensive radiological and surgical trial depending on the inclusion and exclusion criterias.

III FOLLOW UP:

The patients will be followed for next 6 months after the medical/ surgical intervention. At 6 months follow up, following investigations will be done:

- Repeat color Doppler
- Quality of life questionnaire
- Claudication pain
- Claudication distance

Sample size Participants: 75 (25 in each group)

Groups:

1) Patients with PAD undergoing medical/ conservative management (N=25)

- 2) Patients with PAD treated or managed with intervention radiology (N=25)
- 3) Patients with PAD treated with combination of any of the two modalities like IR and surgical (debridement/amputation)

OR

Medical management followed by IR

OR

Medical management followed by surgical management (debridement/amputation) (N = 25).

III.I. Classification:

Common staging is done by the **Fontaine staging**, introduced by René Fontaine for chronic limb ischemia

Another classification by the Society for Vascular Surgery and International Society of Cardiovascular Surgery (SVS/ISCVS), known as the **Rutherford classification**.

TABLE 3. Classification of Peripheral Artery Disease

Rutherford Classification			Fontaine Classification	
Grade	Category	Description	Stage	Description
0	0	Asymptomatic	I	Asymptomatic
I	1	Mild claudication	IIa	Mild claudication
I	2	Moderate claudication	IIb	Moderate to severe claudication
I	3	Severe claudication		
II	4	Ischemic rest pain	III	Ischemic rest pain
III	5	Minor tissue loss	IV	Ulceration or gangrene
III	6	Major tissue loss		

The TASC (and TASC II) classification is suggested for treatment of PAD based on the severity of disease as seen on angiogram findings.

Table 1 TASC II classification of SFA occlusions	
Type A	Single occlusion <5 cm in length
Type B	Single occlusion <5 cm but heavily calcified or multiple occlusions each <5 cm or single occlusion <15 cm
Type C	Multiple occlusions >15 cm
Type D	Chronic total occlusion >20 cm
TASC, TransAtlantic Inter-Society Consensus; SFA, superficial femoral artery.	

Moderate to severe degree of PAD in Fontaine's stage III to IV, or in Rutherford's category 4 to 5, is considered to present as a presence of threat to the limbs affected with a high risk of loss of limb and is found to present in the form of critical limb ischemia.

Based on the above classification the patient is graded and accordingly divided into various groups as decided by the eligibility criteria. These patients will then undergo treatment allotted under medical management that is with drugs, interventional radiological management as in thrombolysis and plasty and finally surgical management that is amputation and PRP dressings. This study is basically inclined to prove that surgical management is the better form of management for improving quality of living of patient with PAD.

IV METHODS: ASSIGNMENT OF INTERVENTIONS (FOR CONTROLLED TRIALS):

All patients admitted with the diagnosis of peripheral arterial disease will be evaluated for participation in the study on the various criteria discussed. Written informed Consent will be taken from the patient prior to the enrollment.

The patient population will be divided into following groups.

Group A: patients with PAD undergoing medical/ conservative treatment

Group B: patients with PAD undergoing surgical intervention

Group C: Patients with PAD treated with combination of any two modalities like medical/ conservative, surgical and/or Intervention Radiology

After enrollment, patients will be randomized into respective groups based on the treatment modality selected as per standard treatment guidelines.

The patients with the symptoms s/o PAD will be evaluated. The basic investigations like CBC, KFT, LFT, lipid profile, will be done. The arterial and venous studies will be done using color Doppler. The patients will be randomized into medical/ surgical treatment. The patients requiring surgical treatment will be evaluated further with angiography.

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The patients will be monitored for the treatment response based on following parameters:

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- Rest pain
- Status of postoperative wounds

- Status of amputation flap
- Intervention radiology related parameters like flow velocity

All the patients will be assessed on the basis of SF-36 quality of life index questionnaire

Implementation: the author will be in sole control of allocation of sequence.

V DATA COLLECTION, MANAGEMENT, AND ANALYSIS METHODS:

Variables: The patients with the symptoms s/o PAD will be evaluated. The basic investigations like CBC, KFT, LFT, lipid profile, will be done. The arterial and venous studies will be done using color Doppler. The patients will be randomized into medical/ surgical treatment. The patients requiring surgical treatment will be evaluated further with angiography.

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- Intervention radiology related parameters like flow velocity

All the patients will be assessed on the basis of SF-36 quality of life index questionnaire.

VI DATA SOURCES/ MEASUREMENT :

A pretested structural Performa will be made to collect information regarding detailed clinical history and examination, laboratorial and follow up of the patients. Cases will be selected consequently with the above mentioned inclusion and exclusion criteria.

VII ETHICS AND DISSEMINATION:

Institutional ethical committee clearance will be obtained before the start of the study. Confidentiality will be maintained in all stages of the study. The investigations performed in the study are otherwise necessary for the management of the underlying clinical condition. So the participants are not forced to undergo any extra investigations or procedures and hence the study will not cause any financial burden on the subjects.

VIII EXPECTED OUTCOMES/RESULTS:

VIII.I. Outcome data:

Peripheral arterial disease is defined as a progressive type of disease with significant morbidity and mortality rate. The prevalence of this disease in general population is estimated to be about 10–14%, affecting up to approximately 25% of those over 70 years; 65%–85% of affected individuals are asymptomatic with only a minority of population requiring revascularization or amputation.

The incidence of PAD patients complaining of symptoms increases with age, with an incidence of about 0.4% per year for male group aged between 40 – 60 years to about 2% per year for male group aged above 70 years. These prevalence calculated varies considerably depending on how peripheral arterial disease is described. It also depends on the various age groups of the study population.

Diagnosis of these diseases is critical because people with PAD have a higher risk fold of four to five times for heart attack and/ or stroke and it is seen to affects 1 out of 3 diabetic population above the age of 45 years.

Claudication is seen as the most common type of symptom experienced and is seen to deteriorate in about 20 - 25% of all the patients affected, with a rate of about 5%–10% in the 1st year and then subsequently seen to deteriorate to a rate of 2%–5% per year, out of these, an incidence of about 0.25–0.45/1000 people/years results in an eventual critical limb ischemia.

Besides taking relevant and appropriate history, clinical tests such as Doppler scans, MR Angiography and contrast angiography is advised in few doubtful cases. Ankle brachial index (ABI) is seen to be a highly useful investigation in patients with previously unrecognized PAD.

ABI is the ratio of ankle systolic blood pressure to brachial systolic blood pressure. A value of <0.9 is considered to be abnormal.

Many pharmacological agents that are tried include rheological agents, vasodilators, antiplatelets, anticoagulants and prostaglandins. FDA has however approved only two drugs, i.e., Pentoxifylline and Cilostazol claiming to treat intermittent claudication.

IX DISCUSSION:

All patients admitted with diagnosis of PAD will undergo comparison between medical, interventional radiological and surgical management which claims to improve the quality of living of patients with peripheral arterial disease. This study is basically inclined to prove that surgical management is the better form of management for improving quality of living of patient with PAD. Peripheral arterial disease is a progressive disease with significant morbidity and mortality rate. The prevalence of this disease in the general population is about 10–14%, affecting up to approximately 25% of those over 70 years; 65%–85% of affected individuals are asymptomatic with

only a minority of population requiring revascularization or amputation. Many articles were reviewed no different aspects of factors associated with this study (23-82).

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