

Different Modalities of Treatment of Peripheral Arterial Disease

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Abstract

Aims & objectives: To study the different modalities of treatment of peripheral arterial disease. To study the treatment modalities in acute and chronic limb ischemia. To compare the efficacy of bypass grafting versus endovascular stenting in the treatment of critical limb ischemia in patients with aorto-iliac disease (inflow disease)

Materials and methods: The present study was carried out with 50 patients admitted with peripheral arterial disease (of which 30 patients were operated for Critical limb ischemia of the inflow region) in the General Surgery Department of a tertiary care hospital with vascular surgery facility, between August 2017 to October 2019.

Result: Among the 50 patients, 15 patients of Critical Limb Ischemia underwent bypass surgery, 15 underwent angioplasty and stenting. 6 patients with Acute Limb Ischemia were managed with thromboembolectomy, 2 underwent catheter directed thrombolysis and 2 underwent primary amputation due to unsalvageable limbs. 10 patients with intermittent claudication were subjected to medical management and supervised exercise therapy for 6 months. Primary patency rates in stenting group were 86.67% (13/15) at 1 month and 60% (9/15) at 6 months. Primary patency rates for grafts at both 1 month and 6 months were 86.67% (13/15).

Conclusion: PTA is better than bypass grafting but requires frequent reinterventions.

Bypass surgery it is the Gold Standard therapy for revascularisation of extremities. In the patients with Acute Limb Ischemia, Embolectomy is generally preferred than catheter directed thrombolysis.

Key words: Critical limb ischemia, thrombolysis, bypass surgery

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I. Introduction

Peripheral Arterial disease (PAD) refers to the obstruction or deterioration of the arteries other than those supplying the heart and within the brain¹. There are a number of pathological processes that manifest their effects on the arterial circulation. The common denominator among these processes is the impairment of circulation and resultant ischemia to the end organ involved.

PAD of the lower extremity is an important cause of morbidity and affects 10 million people in India². The prevalence of peripheral arterial disease (PAD), as defined by ankle brachial index (ABI) of <0.90, ranges from 2.5% in the age group 50-59 years to 14.5% in subjects >70 years^{3,4,5}. The risk factors for peripheral

arterial disease include race, gender, age, smoking, diabetes mellitus, hypertension, dyslipidemia, hypercoagulable state, hyperhomocysteinemia and chronic renal insufficiency^{6,7}.

Patients with PAD may present with intermittent claudication or as chronic critical limb ischemia (CLI) or acute limb ischemia (ALI) with/ without severe rest pain^{8,9}. Natural history of patients with intermittent claudication over 5 years includes worsening of claudication in 20% patients and development of critical limb ischemia in 5-10% and 5-10% of patients will die because of cardiovascular problems.

In CLI patients, however, 30% end up with amputation, 20% die and only 40% patients will be alive with both limbs intact at 1 year⁸. The determination of the best method of revascularization for treatment of symptomatic peripheral arterial disease (PAD) is based upon the balance between risk of a specific intervention and the degree and durability of the improvement that can be expected from this intervention.

The endovascular technique for the treatment of patients with lower extremity ischemia includes peripheral balloon angioplasty, stents, stents-grafts and plaque debulking procedures. Surgical options include autogenous or synthetic bypass grafting, endarterectomy or/and hybrid procedure. Change in the life style and initiation of best medical management are part of overall management of patients with peripheral arterial disease. Smoking cessation has been a corner stone of the management of PAD as is the case in CAD and thrombo angiitis obliterans (TAO)⁸.

All patients should also receive antiplatelet therapy¹⁰. Management of co-morbidities like diabetes mellitus, hypertension, IHD or any other major vascular insufficiency is equally important in patients with peripheral arterial disease. The 5-year patency following femoral popliteal bypass, in patients with intermittent claudication is 80% using vein; 75% with above knee PTFE and 65% with below knee PTFE. In critical limb ischemia, 1 yr patency is 66% using vein, 47% in above knee PTFE and 65% is seen in below-knee PTFE^{11,12}. The most striking feature of critical limb ischemia (CLI) is the dismal prognosis for both life and limb outcomes no matter what treatment are employed¹². This study aims to evaluate, outcome of interventions at 30 days and 6 months post procedure.

II. Material and Methods

The present study was carried out with 50 patients admitted with peripheral arterial disease (of which 30 patients were operated for Critical limb ischemia of the inflow region) in the General Surgery Department, VS hospital, Ahmadabad with vascular surgery facility, between August 2017 to October 2019.

To maintain confidentiality, patient identification was deleted and a new code was assigned to each patient. Informed consent was taken.

Cases were selected consequently with following inclusion and exclusion criteria.

Inclusion Criteria:

- Must be aged 18 years or older.
- Have symptoms of Intermittent Claudication or Critical Limb Ischemia or Acute Limb Ischemia.
- Has a resting ABI of less than 0.9 or an abnormal exercise ABI if the resting ABI is normal; patients with non-compressible arteries (ABI >1.3) must have a toe brachial index of less than 0.8.
- Has a TASC II B and C lesion in aortoiliac region (inflow disease) with CLI (For Revascularisation Procedure).

Exclusion Criteria:

- Asymptomatic patients of PAD.
- TASC II A and D lesions.
- Presence of associated outflow and runoff disease.
- A known allergic reaction to any of the study medications: aspirin, clopidogrel bisulfate, and ticlopidine hydrochloride.
- A bleeding disorder or refusal to receive a blood transfusion.
- Prior stenting or bypass of aortoiliac region (prior angioplasty is not an exclusion criterion).
- Unstable angina or a recent myocardial infarction (within 1 month).
- A malignant tumor or other condition limiting life expectancy to less than 2 years.
- Chronic renal insufficiency (serum creatinine >2.0mg/dl).

III. Methodology:

For operative interventions, following methodology was followed:

- A dose of prophylactic antibiotic was given 30 minutes before surgery.
- Postoperatively the patients were kept nil by mouth and advised complete bed rest till the effect of anesthesia is completely worn out, till then they are given supportive maintenance intravenous fluids.
- Patients were advised and encouraged to ambulate and start their activities of daily life as early as possible.
- Prophylactic oral antibiotics were given for duration of 5 to 7 days, of which parenteral antibiotics were given for at first 24 hours. Analgesics were given at 12 hour interval for a period of 3 to 5 days, on first POD intravenous analgesics was given then shifted on to oral tablets.
- Patients were observed for any complications like haemorrhage, hematoma, seroma or wound infection
- Patients were discharged once free of complications and once they resumed their activities of daily normal life. At discharge they were advised to come for stitch removal after 10 days, (1st follow up), and then after 1 month (2nd follow up), and then after 6 month of surgery, (3rd follow up).

Statistical test for analysis:

Descriptive statistical analysis has been carried out in the present study using SPSS 20. Results on categorical measurements are presented in Number (%). Significance is assessed at 95% level of significance. Student's t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups.

Operative methods:

Patient underwent either Open Bypass Grafting or Endovascular Percutaneous transluminal angioplasty with stenting for critical limb ischemia.

IV. Results

In the present study, 50 patients were enrolled as per the selection criteria and allocated to different treatment modalities as per their type of presentation. An observational study consisting of 50 cases of peripheral arterial disease patients (of which comparative study of 30 cases of inflow aortoiliac disease), who met the criteria of the study, was taken up for investigating the role of endovascular stenting v/s bypass grafting and their complications, patency and limb salvage.

Following are the observations and their relevant discussion of treatment modalities of peripheral arterial disease and comparison between open and endovascular technique of revascularization of aortoiliac disease:

Table 1: Type of Grafts Used in Bypass Surgeries

Graft type	No. Of patients
PTFE	8
Dacron	7

Among the 15 bypass surgeries for CLI, 12 underwent aorto-femoral bypass and 3 patients underwent aorto-iliac bypass. PTFE was used for 8 aorto-femoral bypasses and Dacron was used for 4 aorto-femoral bypasses. Dacron was used for all 3 aorto-iliac bypasses.

Table 2: Types of Stents Used In PTA

Type of stent	No. Of patients
Balloon expandable	8
Self-expanding	7

Among the 15 endovascular surgeries for CLI, balloon expandable stents were placed in 8 patients and self-expanding stents were placed in 7 patients.

Table 3: Complications of Interventions in Peripheral Arterial Disease

Complications	Bypass	PTA	Total
Infection	4	1	5
Seroma	3	0	3
Hemorrhage	1	3	4
Hematoma	0	4	4
Total no. Of complications	8	8	16

In our study there was no difference in wound complication rates overall between two study groups according to chi square test ($p>0.05$).

Table 4: Success Rates of Interventions in CLI at 6 Months

Type of intervention	Success of intervention	Failure of intervention
Bypass	13	2 (13%)
PTA	9	6 (40%)

Out of 15 patients undergoing bypass surgery, the failure of intervention occurred in 2 patients within 6 months (13%) and those undergoing endovascular stenting, the failure of intervention occurred in 6 patients within 6 months (40%).

Table 5: Amputation Rates Among Interventions In CLI

Type of intervention	No. Of patients undergoing amputation	
	Present study	E. Baubeta et.al
Bypass	2 (13.33%)	12%
PTA	2 (13.33%)	12%

Among CLI patients, the amputation rates during the first 6 months following Revascularisation is 2 out of 15 for bypass and PTA each.

Table 6: Success Rates Among Interventions In ALI

Type of intervention	Success of intervention	Failure of intervention	Total
Embolectomy	5	1	6
CDT	1	1	2
Amputation	2	0	2

Out of the 10 patients with ALI, 6 patients underwent embolectomy, 2 patients underwent CDT, and 2 patients underwent primary amputation due to unsalvageable limbs.

V. Discussion

Among the 50 patients, 15 patients of critical limb ischemia (CLI) underwent bypass surgery, 15 underwent angioplasty and stenting. 6 patients with acute limb ischemia (ALI) were managed with thromboembolectomy, 2 underwent catheter directed thrombolysis and 2 underwent primary amputation due to unsalvageable limbs. 10 patients with intermittent claudication were subjected to medical management and supervised exercise therapy for 6 months.

Among the 15 bypass surgeries for CLI, 12 underwent aorto-femoral bypass and 3 patients underwent aorto-iliac bypass. PTFE was used for 8 aorto-femoral bypasses and Dacron was used for 4 aorto-femoral bypasses. Dacron was used for all 3 aorto-iliac bypasses.

In the study conducted by Mutharaju KR, all the suprainguinal revascularizations including both anatomical and extra-anatomical bypasses were done with PTFE graft¹³.

Out of the 7 self-expanding stents, 2 patients had failure of intervention (71% primary patency rate).

Out of the 8 balloon expandable stents, 4 patients had failure of intervention (50 % primary patency rate).

In our study there was no difference in wound complication rates overall between two study groups according to chi square test ($p>0.05$). Most common complication in bypass surgeries was infection and in PTA was hematoma.

In the study conducted by Anand dayama et al., patients with bypass-first revascularization had higher wound complication rates (9.7% vs 3.7%; or, 2.75; CI, 1.71-4.42) compared with patients in the endovascular-first cohort¹⁴.

Out of 15 patients undergoing bypass surgery, the failure of intervention defined as amputation/death/graft block occurred in 2 patients within 6 months (13%).

Out of 15 patients undergoing endovascular stenting, the failure of intervention defined as amputation/death/ stent blockage occurred in 6 patients within 6 months (40%).

In the study conducted by Anand dayama et al. There was no difference in 30-day untreated loss of patency, reintervention of treated arterial segment, readmissions, and reoperations between the two cohorts¹⁴. Similar results were obtained in our study at 1 month.

Primary patency rates in stenting group were 86.67% (13/15) at 1 month and 60% (9/15) at 6 months. Primary patency rates for grafts at both 1 month and 6 months were 86.67% (13/15). In the study conducted by Mutharaju KR, the graft patency rate at 1 month was 87% (34/39), at 6 months it was 77% (30/39)¹³.

In our study, among CLI patients, the amputation rates during the first 6 months following Revascularisation is 2 out of 15 for bypass and PTA each (13.33%).

According to the study conducted by Baubeta Fridh, among CLI patients, the amputation rate during the first 6 months following Revascularisation was 12.0% (95% CI)¹⁵. 2 patients required amputation at 1 month and of them 1 patient died within 6 months in both endovascular and bypass surgery groups.

Patients required amputation at 1 month and of them 1 patient died within 6 months in both endovascular and bypass surgery groups.

In our study, out of the 10 patients with ALI, 6 patients underwent embolectomy, with primary patency rates of 83.33%; 2 patients underwent CDT, with primary patency rates of 50%; 2 patients underwent primary amputation due to unsalvageable limbs.

VI. Conclusion

In our study we conclude that, Bypass surgery is better than PTA because of higher primary patency rates, good long-term patency, and ability to treat multiple level stenoses at once. Peripheral angioplasty with stenting is generally preferred in patients with stenosis rather than occlusion, short segmented disease, non-calcified lesions, concentric stenosis, large vessel involvement, intermittent claudication in early stages, older patients with higher perioperative morbidity, and failure of medical management. Amputation should generally be considered in patients with overwhelming infection, unreconstructable vascular disease and patients who are too sick/ debilitated to realize the functional benefits of revascularization.

In the patients with acute limb ischemia, embolectomy is generally preferred than catheter directed thrombolysis due to higher primary patency rates (83.3% > 50%).

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