An Outcome Analysis of Interventions in Peripheral Vascular Disease

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ABSTRACT

Introduction: Peripheral arterial disease of the lower extremity is an important cause of morbidity in India. It is a common condition with variable morbidity affecting men and women over the age of 45 years. Study aimed to analyze the 30 day and 6 month outcomes after vascular interventions (both open and endovascular) for peripheral arterial disease, to evaluate the role of peri-operative and subsequent anticoagulation after vascular interventions and to assess the quality of life at admissions and at 1 month and 6 month after interventions.

Material and methods: All patients with limb ischemia presenting to a general surgery unit of a tertiary hospital with vascular surgery facility were included in the study. It was a combined retrospective and prospective group study.

Result: Limb salvage rate was 80% at 1 month and 76% at 6 month after revascularization. Perioperative anticoagulation and antiplatelet therapy plays a very important role in ensuring graft patency and limb salvage. In our study, we found significant improvement in all eight parameters of quality of life including physical functioning, physical health, emotional problems, energy/fatigue, emotional well being, social functioning, pain and general health at 1month and 6 month of follow up.

Conclusion: Revascularization is the optimal treatment for patients with critical limb ischemia and this can be achieved by surgical or by endovascular interventions. From the patients point of view functional outcomes in the form of quality of life benefits are more important than just the graft patency and limb salvage. Antiplatelet and anticoagulation treatment have distinct roles in the management of these patients with PAD.

Keyword: Peripheral Vascular Disease

INTRODUCTION

Peripheral arterial disease involving the limbs is a common health care problem not only of elderly group but also of people in the young productive age. It more commonly affects the lower limbs than the upper limbs. Atherosclerosis is the commonest cause, however other causes include Buerger's disease and vaculitic syndromes especially in the Indian subcontinent.

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.[1-3] The risk factors for peripheral arterial disease include race, gender, age, smoking, diabetes mellitus, hypertension, dyslipidemia, hypercoagulable state, hyperhomocysteinemia and chronic renal insufficiency.[4,5]

Patients with PAD may present as claudicants or as chronic critical limb ischemia (CLI) or acute limb ischemia (ALI).[6,7] Natural history of claudicants over 5 years includes worsening of claudication in 20% patients and development of critical limb ischemia in 5-10%; 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 year.[6] 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 balloon angioplasty, stents, stents-grafts and plaque debulking procedures. Surgical options include autogenous or synthetic bypass, endartectomy 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.[7] All patients should also receive antiplatelet therapy.[8] Management of co-morbidities like diabetes mellitus, hypertension, IHD is equally important in patients with peripheral arterial disease.

The 5 year patency following femoral popliteal bypass, in claudicants 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.[9,10]

The most striking feature of critical limb ischemia (CLI) is the dismissal prognosis for both life and limb outcomes no matter what treatment are employed. A successful revascularization may reduce pain and improve quality of life for a limited period of time. Therefore assessment of quality of life after interventions at 30 days and 6 months is relevant. This study aims to evaluate, outcome of interventions at 30 days and 6 months post procedure.

Aim and objectives of the study were to analyze the 30 day and 6 month outcomes after vascular interventions (both open and endovascular) for peripheral arterial disease, to evaluate the role of peri-operative and subsequent anticoagulation after vascular interventions, to assess the quality of life at admissions and at 1 month and 6 month after interventions.

MATERIAL AND METHODS

All patients with limb ischemia presenting to a general surgery unit of a tertiary hospital with vascular surgery facility were included in the study. It was a combined retrospective and prospective group study.

From August 2010 to December 2012, all patients presenting

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with peripheral arterial disease who required vascular interventions, either open or endovascular were included in prospective study group.

Record of all patients who had undergone interventions for peripheral arterial disease from August 2005 to July 2010 and who were on follow up were reviewed and proforma filled up during their follow up visits to assess the final out comes.

In the period from August 2010 to December 2012, 176 peripheral arterial disease patients, treated at a tertiary centre with vascular surgery facilities, were included in the study. Out of these, 58 patients formed the prospective study group and 118 formed the retrospective group. Prospective study group (n-58) included patients who presented with symptoms, were evaluated and underwent intervention during the study period. Retrospective group (n-118), included patients who were on follow up in vascular OPD, after having undergone intervention at this centre, for peripheral vascular disease from August 2005 to July 2010. The details recorded for all the patients included their age, sex, tobacco consumption habits, other risk factors for atherosclerosis, co-morbidities and previous history of vascular surgery on the same limb or major amputation of opposite limb. All patients underwent detailed history and physical examination, noninvasive vascular lab evaluation and arteriography when indicated. Screening for immunological and hyper-coagulable disorder was done when indicated.

A proforma was filled up at preoperative, 1 month and at 6 months interval which included general information, risk factors for peripheral arterial disease, clinical presentation, pre-operative quality of life, pre-operative imaging findings, type of intervention, post-operative clinical status, details of medications including anticoagulation, post operative imaging findings and post-operative quality of life at the end of 1 month and 6 months interval.

The outcome of interventions in PAD and quality of life of patients after treatment at the end of 1 month and at 6 months were analyzed. The parameter analyzed were; a) Graft patency, b) Limb salvage, c) Anticoagulation therapy, d) Mortality

The quality of life assessment was done for PAD patients in the prospective group. The quality of life of every patient was assessed using the RAND 36- Item Health Survey 1.0 form. This form evaluates eight health concepts namely physical functioning, bodily pain, role limitations due to physical health problems, and role limitations due to personal or emotional problems, emotional well being, social functioning, energy/fatigue and general health perceptions. It also includes a single item that provides an indication of perceived change in health.

STATISTICAL ANALYSIS

Microsoft office 2007 was used for the statistical analysis. Mean, percentages and Wilcoxon Signed Ranks Test (Z) were used to interpret the data.

RESULTS

Prospective group

Among the prospective study group (n-58), there were 50 males (86%) and 8 female (13%). The average age of the patients was 52 years with a range of 20-80 years. Sixteen patients including 14 male and 2 female (27%) were ≤ 45 yeas age, 24 patients including 21 male and 3 female patients (41%) belonged

to the 46-59 years age group and 18 patients including 15 male and 3 female patients (31%) were ≥ 60 years age.

Risk factor analysis of patients showed that 43 (74%) out of the total of 58 patients in this group, consumed tobacco in one form or the other. Among them 23 smoked cigarettes, 12 smoked beedis and 8 chewed tobacco. The average duration of consumption of tobacco was 28 years. During the study period all patients were advised to quit tobacco consumption in all forms and during follow-up 40% patients professed to have quit while 60% patients continued to consume tobacco.

Dyslipidaemia was the next most common risk factor, which was present in 32 patients (55%). Hypertension was present in 28 patients (48%) and diabetes mellitus in 16 patients (27%). The other risk factors/co-morbidities present were coronary artery disease in 14 patients (24%), carotid artery disease in 9 patients (15%) and renal insufficiency in 3 patient (5%). Among the 8 patients in prospective group 45 presented with critical limb ischemia and 13 with acute limb ischemia. Clinical presentation of peripheral arterial disease with CLI can be with rest pain, or tissue loss in the form of ulcer or gangrene. Ten patients presented with rest pain (22%), 20 patients presented with ulcers (44%) and the remaining 15 patients presented with gangrene (33%) of toes/forefoot.

Based on the imaging findings, 8 (13%) patients had proximal disease and 32 patients had infrainguinal disease, 11 patients (24.44%) had both aortoiliac and infrainguinal disease and 7 patients had brachial artery disease.

Among prospective group, thirteen patients had presented with ALI, 9 male and 4 female patients. Among the male patients 2 cases presented with upper limb ALI and 7 cases with lower limb ischemia. Among female, 2 presented with upper limb ALI and 2 with lower limb

Treatment Modalities

Among the 58 patients, 39 patients of CLI underwent bypass surgery, 6 underwent angioplasty and stenting. Thirteen patients with ALI were managed with thromboembolectomy.

Revascularization modalities

Among the 39 bypass surgeries, 35 were anatomical bypass and 4 were extra-anatomical bypass. Among the anatomical bypass surgeries, 22 were infrainguinal revascularizations and 13 were suprainguinal revascularizations. Among the infrainguinal revascularizations, there were 12 femoropopliteal bypasses with reversed GSV graft, 5 femoropopliteal bypasses with PTFE graft, 2 femoroperoneal bypasses, and 2 fem – PTA bypasses with reversed saphenous vein graft and 1 femoro-PTA bypass with PTFE graft using a vein cuff. Among the anatomical suprainguinal revascularizations, there were 5 aorto-profunda bypasses, 3 aorto-iliac bypasses, 5 aorto bifemoral bypasses. Among the extra-anatomical revascularizations, there were 2 femorofemoral crossover bypasses and 2 axilloprofunda bypass. All the suprainguinal revascularizations including both anatomical and extra-anatomical bypasses were done with PTFE graft.

Four patients required fasciotomy after revascularisation, 3 patients underwent 4 compartment fasciotomy in leg and one patient underwent flexor and extensor fasciotomy of forearm. These required split skin graft for wound closure.

Patients were reviewed at 1 month and at 6 months after the

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initial surgery to assess the outcome of treatment in terms of graft patency, limb salvage, change in ambulatory status and mortality. The change in quality of life was also assessed. Statistical analysis was done using the Wilcoxon Signed Ranks Test (Z).

The graft patency rate at 1 month was 87%(34/39), at 6 months it was 77%(30/39). The cause of graft failure at 6 month was attributed to continued smoking by the patient and stoppage of antiplatelet drugs on their own initiative.

Limb salvage rate at one month among all 58 patients was 78% (45/58) and at 6 month was 76% (44/58).

As regards antiplatelet and anticoagulation therapy, 10 patients with peripheral arterial disease without other co morbidities were put on with aspirin alone in the post operative period. Thirty patients who had more than one vascular bed involved were treated both with aspirin and Clopid. Nine patients who had primary thrombotic disease were put on oral anticoagulation for 6 months. Nine patients were given preoperative heparin infusion and discharged on antiplatelet therapy alone.

Retrospective study

The retrospective study included patients, who had undergone interventions for CLI and ALI, from August 2005 to July 2010. Records of the patient were assessed when they came up for follow up visits to vascular OPD. There were 118 cases of peripheral arterial disease, in this group.

Among the retrospective study group (n-118), there were 110 males (93%) and 8 female (7%). The average age of the patients was 49.67 years with a range of 14-79 years. Forty two patients including 39 male and 3 female (35.5%) were <45 years age, 38 patients including 37 male and 3 female (31.3%) belonged to the 46-59 years age group and 34 including 32 male and 2 female (28.8%) were >60 years age. Among 118 patients, 90 (76%) had a past history of smoking as the most common risk factor, followed by dyslipidaemia 42(35%), hypertension in 39(33%). Thirty (25%) had diabetes mellitus, 28(23%) had associated heart disease, 11 (9%) patients had associated renal disease, 10(8%) had carotid disease, 9(7%) patients had previous history of cerbrovascular accidents and 27 (22%) used to consume alcohol.

Among 118 cases of retrospective study, infrainguinal disease was the most common with 41 cases (34%), Aortoiliac occlusion were 33 (27%) cases, both aortoiliac and infrainguinal disease 38 (32%). Six cases had presented with occlusion of brachial artery.

Among the 118 patient, 88 patients presented with CLI and 30 presented with ALI. Thirty patients had presented with ALI,

19 male and 11 female cases. Among the male patients 6 cases presented with upper limb ALI and 13 cases with lower limb ischemia. Among female, 4 presented with upper limb ALI and 7 with lower limb ALI (Table 1-7). Among CLI patients 20 presented with rest pain (22%), 40 patients presented with ulcers (45%) and the remaining 28 patients presented with gangrene (32%) of toes/forefoot.

Treatment Modalities

Among the 118 patients, 18 patients underwent Aorto- iliac bypass, 15 patients underwent Aorto – profunda bypass, 5 underwent Axillo –profunda bypass, 41 underwent Fem –pop/ distal bypass, 8 Aorto – bi-fem bypass, 5 fem – fem crossover bypass, 9 popliteal thrombectomy,11 patients angioplasty and 6 brachial artery thrombectomy.

Among the 92 bypass surgeries, 82 were anatomical bypass and 10 were extra-anatomical bypass. Among the anatomical bypass surgeries, 55 were infrainguinal revascularizations and 27 were suprainguinal revascularizations.

In retrospective study, group out of 118 patients, 20 patients underwent amputation in the follow up period. There were 2 below knee amputation, 9 through knee and 9 above knee amputation. Amputations were performed due to spreading gangrene /no healing ulcer of the foot involving the heel.

There where total 15 mortalities in retrospective study. Ten cases died due to ischemic heart disease and 5 due to unrelated causes like malignancy. Over all limb salvage rate was 70% (83/118).

Quality of life assessment

Quality of life assessment was done for patients in prospective study group (n=58) alone. Each participant completed version 1 of the SF-36 questionnaire, which contained validated questions regarding physical functioning, physical health, emotional problems, energy/fatigue, emotional well being, social functioning, pain and general health.

The QOL or physical functioning improved gradually after surgery. Improvement was much more at 6 months compared to 1 month after intervention (Table 1)

Improvement in QOL for physical health was similar to physical functioning (Table 2).

Statistically [Wilcoxon Signed Ranks Test (Z)] significant improvement was seen in QOL for emotional health as well as for role limitation due to emotional health (Table 3).

There was significant improvement in energy levels of the study group immediately after surgery, i.e. at 1 month and also at 6 month of follow up (Table 4).

There was significant improvement in emotional well being at 1

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	28.79	9.566	4.227	<0.001
Month - 1	58	36.84	7.560		
Comparison between pre and month – 6					
Pre	58	28.79	9.566	6.343	<0.001
Month - 6	58	52.88	9.795		
Comparison between month - 1 and month – 6					
Month - 1	58	36.84	7.560	6.20	<0.001
Month - 6	58	52.88	9.795		
Table-1: Comparison of Physical functioning					

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month follow up and at 6 month follow up (Table 5).

Social functioning also improved both at 1 month and 6 month of follow up (Table 6).

Significant improvement in pain was felt immediately following surgery than after 6 month of follow up (Table 7).

General health also improved significantly at 1 month and at 6

month of follow up after intervention (Table 8).

DISCUSSION

Aim of the study was to evaluate the outcomes of revascularization in peripheral arterial disease patients. Traditional measures of outcome assessment include graft patency rate, limb salvage

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	18.14	8.313	6.454	<0.001
Month – 1	58	43.41	9.310		
Comparison between pre and month – 6					
Pre	58	18.14	8.313	6.645	<0.001
Month – 6	58	59.03	10.543		
Comparison between month - 1 and month – 6					
Month – 1	58	43.41	9.310	5.701	<0.001
Month – 6	58	59.03	10.543		
Table-2: Comparison of Physical health					

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	32.29	9.296	5.225	<0.001
Month - 1	58	44.41	9.739		
Comparison between pre and month – 6					
Pre	58	32.29	9.296	6.404	<0.001
Month - 6	58	59.45	8.984		
Comparison between month - 1 and month – 6					
Month - 1	58	44.41	9.739	5.912	<0.001
Month - 6	58	59.45	8.984		
Table-3: Comparison of emotional problems					

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	18.97	7.029	6.407	<0.001
Month - 1	58	37.45	7.231		
Comparison between pre and month – 6					
Pre	58	18.97	7.029	6.630	<0.001
Month - 6	58	52.02	10.020		
Comparison between month - 1 and month – 6					
Month - 1	58	37.45	7.231	5.860	<0.001
Month - 6	58	52.02	10.020		
Table-4: Comparison of energy / fatigue					

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	29.90	9.039	5.407	<0.001
Month - 1	58	39.74	8.433		
Comparison between pre and month – 6					
Pre	58	29.90	9.039	6.553	<0.001
Month - 6	58	59.60	9.894		
Comparison between month - 1 and month – 6					
Month - 1	58	39.74	8.433	6.217	<0.001
Month - 6	58	59.60	9.894		
Table-5: Comparison of emotional well being					

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	19.19	10.851	5.720	<0.001
Month - 1	58	33.41	7.730		
Comparison between pre and month – 6					
Pre	58	19.19	10.851	6.567	<0.001
Month - 6	58	58.74	8.670		
Comparison between month - 1 and month – 6					
Month - 1	58	33.41	7.730	6.640	<0.001
Month - 6	58	58.74	8.670		

Table-6: Comparison of social functioning

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	46.33	7.158	6.641	<0.001
Month - 1	58	46.33	7.158		
Comparison between pre and month – 6					
Pre	58	51.76	7.994	6.636	<0.001
Month - 6	58	51.76	7.994		
Comparison between month - 1 and month – 6					
Month - 1	58	51.76	7.994	3.983	<0.001
Month - 6	58	51.76	7.994		

Table-7: Comparison of pain

	N	Mean	Std. Deviation	Wilcoxon Signed Ranks Test Z	P
Comparison between pre and month – 1					
Pre	58	32.07	7.782	2.96	<0.003
Month - 1	58	36.86	7.895		
Comparison between pre and month – 6					
Pre	58	32.07	7.782	6.638	<0.001
Month - 6	58	66.47	9.552		
Comparison between month - 1 and month – 6					
Month - 1	58	36.86	7.895		<0.001
Month - 6	58	66.47	9.552		

Table-8: Comparison of general health

rate, and survival rates. These outcomes measures are surgeon centric. From the patients point of view, outcomes end points need to relate to functional status, ambulatory status and their quality of life.

In the present study we assessed both the traditional measures of outcome and quality of life measures for functional outcomes.

Male preponderance of peripheral arterial disease was seen both in prospective (86%) and retrospective study group (93%). This male preponderance is observed on review of world literature.[1-3] TASC group reported male to female ratio of 3:1 in chronic CLI.[6]

Increasing age is associated with increasing prevalence of PAD. In both prospective and retrospective group, maximum number of patients were in age group 45-59 yrs. Review of world literature shows that maximum incidence in age group 70-75 yrs.[6] Compared to western population, Indians seem to be more prone to vascular disease at an early age group. This fact has been reported for coronary artery disease and cerebrovascular disease in Indian population.[11]

Tobacco consumption in any form, cigarette, beedis, smoking and tobacco chewing is known to increase risk of developing PAD, as well increase risk of post- graft thrombosis. In both prospective and retrospective group, >75% of patients consumed tobacco in one form or other. One of the causes of graft occlusions in the prospective study group was attributed to persistent consumption of tobacco in these patients after discharge. All patients were counselled to quit smoking. However only 40% of patients of these professed to have done so. Others said to have reduced consumption from 20 cigarettes/beedis to 4-5 but that is of no use as it is an "all or none" phenomenon. Cessation of smoking is essential to improve the graft patency and limb salvage rate in these patients.[6,7]

Independent risk factors for PAD include Dyslipidaemia with elevated levels of total cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, and lipoprotein (a). In the Framingham study, a fasting cholesterol level greater than 7 mmol/L (270mg/dL) was associated with a doubling of the incidence of intermittent claudication but the ratio of total to high-density lipoprotein (HDL) cholesterol was the best predictor of occurrence of PAD.[6] In our study 55% in prospective and 35% in retrospective patients had dyslipidaemia. All these patients were put on statins.

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In our study, 25% of patients in prospective and 33% in retrospective study had associated heart disease. The prevalence of CAD in patients with PAD is reported to be around 10% to 30%.[6] Coronary artery disease is also the major cause of mortality in these patients. In our study 4 patients had MI in postop period, inspite of being best medical management for IHD.

Many studies have shown an association between diabetes mellitus and the development of PAD. In patients with diabetes, for every 1% increase in haemoglobin A1c there is a corresponding 26% increased risk of PAD.[12] In our study 25 to 27% of patients of PAD had associated diabetes mellitus, which was diagnosed based on blood sugar level alone. Haemoglobin A1c was not done on a regular basis for all our patients. All patients however had strict glucose control monitoring with perioperative insulin on sliding scale.

By duplex examination, carotid artery disease occurs in 26% to 50% of patients with IC, but only about 5% of patients with PAD will have a history of any cerebrovascular event.[6] In our study 15% in prospective group and 8% in retrospective group of patients with PAD had associated carotid artery disease and 3% in prospective group and 7% in retrospective group of patients had history of cerebrovascular accidents. No patient developed cerebrovascular accident in post op period. We did not stop antiplatelet agents before surgery. If the patients were on aspirin and Clopidogrel, Clopidogrel alone was stopped 4 days before surgery.

There is an association of renal insufficiency with PAD, with some recent evidence suggesting it may be causal. In the HERS study (Heart and Estrogen/Progestin Replacement Study); renal insufficiency was independently associated with future PAD events in postmenopausal women.[13] We also found 5 to 8% of patients with PAD had documented renal insufficiency, which correlates with world literature.

In our study, infrainguinal disease was the most common ranging 32% (prospective group) to 41%(retrospective group), aorto-iliac disease was 13 to 27% and both aortoiliac and infrainguinal disease constitute 24% to 32%, Taylor et al reported in his study with 20% patients had aortoiliac occlusive disease alone, 72% patients presented with infrainguinal disease only and 8% presented with both.[14]

Optimal treatment of CLI is revascularization. This revascularization can either done by open surgical bypass or endovascular procedure. In our prospective study 39(67.2%) patients were found suitable for bypass surgery. Anatomical bypass have better patency rate and limb salvage rate.[6] In our study 35 patients were found suitable for anatomical bypass. These included 22 infrainguinal revascularization and 13 suprainguinal revascularization. Aorta bifemoral and aorta bi-iliac bypasses have better patency and limb salvage rate than aorta-profunda bypasses. We however had to 5 aortoprofunda bypasses due to severe occlusive disease in external iliac arteries and common femoral arteries which was not amendable to endarterectomy. One of these patients occluded postoperatively within a month.

In the infrainguinal revascularization, reverse saphenous vein is ideal conduit. Limb patency rate for fem Poplitieal bypass with reverse saphenous graft are reported to be 74-76% at 5 years, but when using polytetrafluoroethylene(PTFE) graft as conduit, the patency rate is up to 39-52% at 5 years.[16,17] In our study, out of 17 fempopliteal bypass, 5 had to be done with PTFE due to none availability of suitable saphenous vein. Graft patency rate in our study at 1 month is 87% and 77% at 6 month. Kalbaugh et al study showed graft patency at 6 month was 82.4%.

All infragenicular bypasses should be done using venous conduit. However when none is available PTFE graft can be used with the vein cuff. Out of 5 infragenicular bypass in prospective study group, one patient was done with PTFE using vein cuff.

Limb salvage rate was 80% at 1 month and 76% at 6 month after revascularization. Feinglass et al had reported with limb salvage rate at 1 month was 97% and 82% at 5 years.[18] Slightly lower limb salvage rates are probably due to poor socioeconomical status of our patients and discontinuation of antiplatelet medications.

Perioperative anticoagulation and antiplatelet therapy plays a very important role in ensuring graft patency and limb salvage. Aspirin or other antiplatelet alone recommended in patients who have any PAD without any coronary artery disease or cerebrovascular disease.[6] In our prospective group 17 patients and in retrospective group 52 patients remain on long time aspirin (75-150mg OD). Aspirin and Clopidogrel (75mg OD) is recommended in patients who have more than one vascular bed.[6,19,20] Sixty five % patients in prospective group and 18% in retrospective group remained on both these antithrombotic drugs. Oral anticoagulation in the form of warfarin/acitrom is not recommended in patients as treatment in patients with CLI.[6] However in patients with primary thrombotic disease, with objectively proven deficiency of Protein C, Protein S/ Antithrombin or Factor V Leiden mutation or any other hereditary prothrombotic disease required anticoagulation treatment. So 16% in prospective group and 21% in retrospective group were put on oral anticoagulation for 6 months and re evaluated by haematologist for continuation of anticoagulation.

Heparin infusion at the rate of 1000U/hr to maintain APTT 1.5 times was used in preoperative period of 1 to 5 days in some high risk ALI cases. These patients were subsequently discharged on antiplatelet therapy alone after negative results of thrombophilia screen.

In our study, overall mortality rate after interventions in PAD is 6.8%. Nowygrod R reported mortality rate of 3-4%.[6]

Eskers describes PAD as having physiological, psychological and sociological effects. The latter relate to the wider aspects of the person's life, such as the impact on family and careers. Social interactions are a feature of quality of life.[21] Seabrook et al expanded this by stating that it is the individual's own perception of social interaction that must be considered when assessing life with PVD.[22] Bennett adds that physical illness not only affects family life and relationships with friends but can also pose economic difficulties.[23] Therefore it seems important to assess the effect of intervention in PAD on quality of life.

The quality of life was measured at 1 month after intervention and at 6 month of intervention using RAND 36-Item Health Survey 1.0 form for our patients. In our study, we found significant improvement in all eight parameters of quality of life including physical functioning, physical health, emotional problems, energy/fatigue, emotional well being, social functioning, pain and general health at 1month and 6 month of follow up. Langan et

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al study showed statistically significant improvement in essential areas of the examination seen at 6 months after intervention.[24] Nguyen e al used Vascular Quality of life Questionnaire, the overall and domain specific scores improved at 3 months and at 12 months after revasculrization.[25] We observed that patients who quit smoking after revascularization had a better quality of life. It confirms up to the fact that revascularization is the ideal treatment for PAD and smoking cessation associated with better prognosis.

In our study, relief of pain significantly improved after revascularization in PAD at 1 month and 6 month follow up. Our patients had better life style changes and physical functioning after intervention. There were significant improvement in emotional health level compare to pre intervention period.

All the eight parameters of quality of life showed significant improvement both at 1 month and at 6 months after treatment.

CONCLUSION

Revascularization is the optimal treatment for patients with critical limb ischemia and this can be achieved by surgical or by endovascular interventions. Traditional outcome measures of interventions are graft patency rate, limb salvage rates and survival rates. In our study graft patency was 87% at 1 month and 77% at 6 months, limb salvage rate was 80% at 1 month and 76% at 6 months. From the patients point of view functional outcomes in the form of quality of life benefits are more important than just the graft patency and limb salvage. In our study all eight parameters of quality of life as analyzed by SF-36 form improved at 1month and 6 months after interventions. Improvement was more at 6 months than at 1month. Infact the improvement at 6 months was more than at 1 month. Antiplatelet and anticoagulation treatment have distinct roles in the management of these patients with PAD. All patients received long term antiplatelet therapy in the form of aspirin or Clopidogrel. Anticoagulation was reserved for only for those with a proven hypercoagulable state.

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