

Early results of surgical and Endovascular intervention procedures in Lower extremity arterial disease.

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Abstract

Objective : To assess the early results of surgical and endovascular intervention in peripheral arterial disease

Materials and methods : Retrospectively, we analysed the early results of treatment of lower extremity arterial diseases, managed at our institute. Depending up on the lesion characters and the distal run-off as evident from imaging, patients underwent either surgical or endovascular intervention for their disease. Over a period of one-year from July 2018 to July 2019, twenty-two patients were managed in total. Nine of them underwent surgical bypass for either aortoiliac or femoro-popliteal lesions. Another thirteen patients underwent endovascular intervention for lesions at aorto-iliac, femoro-popliteal and "Below the Knee" lesions. Procedure related morbidity, procedural success rate, postoperative pain score, hospital stay, flow patency and symptomatic improvement at follow-up at three and six months were analysed.

Results:

The results were optimistic with ischemic ulcers showing signs of healing, patients symptomatically better with improved walking distance and relieved of rest pain. Due to a smaller study population, limited study time and the study itself being a non-randomised one, no intragroup comparisons were made. The procedural success was 100% for each group, no periprocedural morbidity. The hospital stay was 9 days for surgical aorto bifemoral bypass patients, 5.8 days for femoropopliteal patients. For those who underwent endovascular intervention, average hospital stay was 3.4, 2.5 and 3 days respectively for the aorto-iliac, femoropopliteal and "Below the Knee" level groups. The average pain score was 6.3 and 5.8 for surgical aortobifemoral bypass and femoropopliteal bypass. Pain scores for the endovascular intervention group was 4.4, 3.2 and 4.7 respectively for the aortoiliac, femoropopliteal and "Below the Knee" level groups. The improvement in the Rutherford gradings at six months were Aorto bifemoral Bypass (4.6 to 3.6), Femoro-popliteal (4.1 to 2.6) in the surgical group and Aortiliac (4.4 to 3.4), Femoropopliteal (4.2 to 2) and no change in the score for the "Below the Knee" group. At six-month follow-up, Doppler interrogation revealed a triphasic flow pattern in surgical and

endovascular bypasses involving the aortoiliac and femoropopliteal segments. The doppler interrogation for the "Below the Knee" lesions at six-month follow-up was biphasic (n=3) to monophasic (n=1).

Conclusion: Surgical bypass and endovascular intervention either as an independent treatment modality or in combination as a Hybrid procedure looks promising in the management of LEAD. Surgical bypass is no doubt morbid, but early results are satisfactory in terms of patency rates and clinical improvement. The early six months results of endovascular intervention, are particularly encouraging in the femoropopliteal segment with poor distal run off. The results are inconsistent for the "Below the Knee" segment disease. TASC II- A and B lesions are addressed by endovascular interventions, whereas TASC II- C and D lesions are addressed by surgical bypass. Multi-disciplinary individualised treatment approach should be adopted in deciding which treatment to be provided for a particular patient based on clinical, imaging findings and institutional protocols.

Introduction

Lower extremity arterial disease (LEAD), is a common problem. Life-style limitation, ischemic ulcers, rest pain and amputations, cripple the patient socially, economically and psychologically. Etiologically related association with coronary and cerebrovascular disease further worsens the owes not only to the patient, but also to the entire family. Surgery and / or Endovascular procedures provide symptomatic improvement, postpones amputations, and in some cases, provides a cure. We analysed the early results of treatment of LEAD performed at our institute

Materials and methods

This is a retrospective non-randomised study. Between July 2018 and July 2019, all patients who underwent revascularisation procedures at our institute were studied. Of twenty-two such patients, nine patients underwent surgical bypass for disease at aorto-iliac (n= 3) or femoro-popliteal (n= 6) segments. The rest thirteen patients underwent endovascular interventions for their diseases. Of them, patients with disease at aorto-iliac (n= 5), or femoro-popliteal segments (n= 4) underwent balloon angioplasty and stenting. Patients

with isolated or predominantly “Below the Knee” disease (n=4), underwent balloon angioplasty alone. Patients with multi-level occlusive disease were excluded from our study. The stage of the disease based on TASC II class, our institute protocol, depending up on distal run off, and patient’s choice of intervention decided which therapy the patients received. Those with poor distal run off, underwent endovascular procedures. Those with good distal run off, were selected for surgical bypass. Good distal run off was determined by angiographic evidence of patency of all three or at least two of the crural vessels. If the vessels were not in continuity with popliteal artery or if only one of the three vessels are opacified, it is deemed poor run-off. Procedural success was defined as on table return of pulses, or a triphasic or at least a biphasic flow on duplex scan. All patients received antiplatelet and statin in the postoperative period to continue indefinitely.

During three and six months post-operative follow-up, patients were enquired about improvement in symptoms i.e. clinical improvement by at-least one category in Rutherford classification, improvement of claudication distance at least by 50%, resolution of rest pain and healing of ulcers. Flow patency and hemodynamic assessment done by duplex ultrasound in each visit.

Results

Aortoiliac disease

Total number of patients in this category were eight. Three of them, with TASC II type D disease with infra-renal aortic disease, were subjected to surgical bypass. They underwent aorto-bifemoral bypass by trans-peritoneal approach. Procedural success was 100%, as judged by on table return of pulsations in the dorsalis pedis and the posterior tibial artery. Three-months after surgery, one patient developed thrombosis in the right limb of the graft, which required endovascular intervention. The average hospital stay was 9 (± 2.1) days (8, 7 and 12 days). Pain score on a scale of 1 to 10, the average pain score on the first Postoperative day was 6.3 (± 1.2) (6, 8 and 5). On average postoperative ileus lasted for 18 (± 4.3) hours (14, 16 and 24 hours). The average time for early ambulation was 3.6 (± 0.9) days (3, 3 and 5 days). Two patients presented with minor tissue loss (Rutherford category 5) and one presented with rest pain (Rutherford category 4). During follow up, ischemic ulcers were healing and the rest pain improved to mild claudication. At six-month follow-up, Doppler interrogation was triphasic pattern.

The remaining five patients in this group underwent endovascular intervention for their TASC-II, type B (n= 2) and C (n= 3) lesions. These lesions were treated with angioplasty and stenting. Procedural success was 100%. The average hospital stay was 3.4 (± 0.8) days (3, 3, 5, 3 and 3 days). Pain score on a scale of 1 to 10, the average pain score on the first Postoperative day was 4.4 (± 1.4) (5, 4, 3, 7 and 3). The average

time for early ambulation was 2 (± 0.6) days (2, 2, 2, 1 and 3 days). Of the five patients, three had minor tissue loss (Rutherford category 5), one presented with ischemic rest pain (Rutherford category 4) and one with life-style limiting claudication (Rutherford category 3). During follow up, ulcers were healing, symptomatically improved to mild claudication. Triphasic flow pattern was noticed at six-month follow-up in all the patients.

Femoro-popliteal disease

There were ten patients in this group. Six of them with good distal run off underwent surgical bypass using ipsilateral reversed saphenous venous graft. One patient with TASC II, type D lesion, required endarterectomy of distal popliteal artery. Another patient with a similar lesion, required endarterectomy of common femoral artery. In all six of them, the procedural success was 100%. There was no periprocedural morbidity. The average hospital stay was 5.6 (± 1.1) days (5, 5, 8, 5, 5 and 6 days). The average pain score on a scale of 1 to 10 was 5 (± 1.3) (6, 5, 4, 7, 5 and 3). The average time for ambulation was 3 (± 0.5) days (3, 3, 2, 3, 3 and 4 days). At six-months follow up, there was satisfactory symptomatic improvement in all patients. Two patients presented with minor tissue loss (Rutherford category 5), three presented with ischemic rest pain (Rutherford category 4) and one presented with life-style limiting claudication (Rutherford category 3). During follow up, two patients with rest pain were left with moderate claudication, one had mild to no symptoms and the ulcers showed definitive signs of healing. The doppler interrogation revealed triphasic flow pattern in all the patients.

The remaining four patients underwent endovascular intervention with balloon angioplasty and stenting. They had TASC II, type C lesions. Angiographically, they had poor distal run off in the infra crural vessels. Procedural success was 100% and there was no periprocedural morbidity. The average hospital stay was 2.5 (± 0.5) days (3, 2, 2 and 3 days). The average pain score on a scale of 1 to 10 was 3.2 (± 0.4) (3, 3, 4 and 3). The average time for ambulation was 2.2 (± 0.4) days (2, 2, 2 and 3 days). At six-months follow up, there was satisfactory symptomatic improvement in all patients. Three patients presented with ischemic rest pain (Rutherford category 4), one with minor tissue loss (Rutherford category 5). Their rest pain was relieved and had only mild to no claudication. The doppler interrogation in all patients revealed triphasic flow pattern.

“Below the Knee” arterial occlusion

There were four patients in this group. All of them had diffuse atherosclerotic changes, not deemed suitable for surgical bypass and as per our institutional protocol, all of them underwent endovascular intervention. The procedural success was 33%, as three patients did not have any palpable pulse in the immediate postoperative period. There was no periprocedural morbidity. One patient had repeat intervention

with balloon angioplasty for re-occlusion. Phasic flow hemodynamics were biphasic (n=3) to monophasic (n=1) at six-months. The average hospital stay for these patients was three days (3, 3, 3 and 3 days). Pain score was 4.7(\pm 2.1) (4, 2, 5 and 8). The average time to ambulation was 2.7(\pm 0.8) days (2,

2, 3 and 4 days). Three patients presented with minor tissue loss (Rutherford category 5) and one had major tissue loss (Rutherford category 6). During follow up, ischemic ulcers did show healing tendency, but symptomatically, there was only a marginal improvement.

Table 1

Patient characteristics
No of patients (N=22)
Male-22, Female-0
Diabetes(n=6)
Coronary artery disease (n=4)
Aortoiliac disease (n=8)
Femoropopliteal disease(n=10)
Below knee arterial occlusion(n=4)

Table 2

Aorto-iliac disease (n=8)	Aorto-bifemoral bypass (n=3)	Endovascular intervention (n=5)
Procedural success	100%	100%
Periprocedural morbidity	Nil	Nil
Hospital stay (days)	9.0	3.4
Early ambulation (days)	3.6	2
Average pain score (on a scale of 1-10)	6.3	4.4
Follow up (improvement in average Rutherford grade)	From 4.6 to 3.6	From 4.4 to 3.4
Follow up Doppler at six months	Triphasic flow	Triphasic flow

Table 3

Femoro-popliteal disease (n=10)	Femoro-popliteal bypass bypass (n=6)	Endovascular intervention (n=4)
Procedural success	100%	100%
Periprocedural morbidity	Nil	Nil
Hospital stay (days)	5.8	2.5
Early ambulation (days)	3	2.2
Average pain score (on a scale of 1-10)	5	3.2
Follow up (improvement in average Rutherford grade)	From 4.1 to 2.6	From 4.2 to 2
Follow up Doppler at six months	Triphasic flow	Triphasic flow

“Below the Knee” arterial occlusion- Results (n=4)	Endovascular intervention (n=4)
Procedural success	100%
Periprocedural morbidity	Nil
Hospital stay (days)	3
Early ambulation (days)	2.7
Average pain score (on a scale of 1-10)	4.7
Follow up (improvement in average Rutherford grade)	5.2 (no change in grade)
Follow up Doppler at six months	Biphasic to Monophasic flow

Discussion:

Endovascular procedure is a percutaneous procedure, less invasive and non-injurious to the deeper tissue. This defines the low rate of pain and in such category of patients.^{1,2}

In our study the maximum pain score observed in surgical aorto-bi-femoral bypass (6.3 /10) as it is more invasive with a longer incisional line, but the observed pain score in patients who underwent intervention by endovascular approach was less in their respective category. Amongst these “The “Below the Knee”” disease patients had average pain score 4.7/10, which may be defined by the pain and sensory neuropathy associated with patients of peripheral artery disease, so far it is unknown to what extent the pain and sensory parameters can be ameliorated by endovascular intervention used to resolve the arterial obstruction.³ Percutaneous procedures performed successfully is highly effective in reducing the exercise induced pain in patients with intermittent claudication. In one randomised study on 44 patients, Gilles Soulez et al.⁴ observed that there was not much of difference in pain level in early postoperative period between patients who underwent Endovascular and surgical procedure for abdominal aneurysm repair, but the consumption of opioid analgesic drug significantly greater in the patients, who underwent intervention by open surgical method. They also observed that the postoperative stay was longer in patients who underwent intervention by surgical procedure in comparison to Endovascular group (11.5 +/- 8.1 days Vs 4.5 days +/- 2.4 days) which is quite similar to our study where patients who underwent surgical intervention for Aortobifemoral bypass showed longer duration of hospital stay than patients subjected to endovascular intervention in this category(Average 9 days Vs 3.4 days). Similar results also observed in the Femoropopliteal disease category (5.8 days Vs 2.5 days). To our experience we observed that the longer duration of hospital stay is not only due to higher pain score in the postoperative period, but also due to the complexity and procedural morbidity. Endovascular procedures though

less invasive, but it is associated with complications like arterial dissection, pseudo aneurysm formation, atheroembolism, contrast induced renal failure, arteriovenous fistula and hematoma. In literature, such complications are attributed to improper technique and ionised dyes. In our study no periprocedural morbidity seen in all patients except one patient in Aorto iliac disease category, who had endovascular procedure related external iliac artery injury which was managed by placing a covered stent. The same patient had developed access site thrombosis, which needed a surgical embolectomy few hours later. This patient was discharged without any residual complication.

Endovascular techniques introduced as balloon angioplasty (BAP) (in 1970s) there after the other revascularisation strategies adopted by intervention radiologist are Sub intimal angioplasty (in 1980s), usage of stents and recently, the Stent grafts with drug eluting modifications in LEAD.

The U K Based multicentric randomised trial (Bypass versus Angioplasty In severe Ischemia, BASIL) among other trials has been the landmark study discussed about the utility of balloon angioplasty in severe lower limb ischemia. Though its enrolment started in 1998 and for a period of five years included 452 patients over 27 countries, in 2005 the trialist in their intention to treat analysis reported no difference in short term amputation free and overall survival in the two groups. Surgical bypass was reported to have more morbidity in first 12 months. Beyond 2 years, the surgical by pass group was seen to have more amputation rate, but fewer deaths. In a short-term duration of 1-2 years, bypass was not significantly hazardous than angioplasty group, but was more expensive. (1-year amputation free survival 68% for by pass first and 71 % for angioplasty first). The reason sought was perhaps the fit patients would tolerate surgical outcomes.⁵

The trialists of BASIL suggested that in patients with SLI, who are candidates for revascularization and likely to live

more than 2 years, the vein bypass surgery is a better modality of treatment as their initial procedure. Prosthetic bypass grafts are inferior to vein bypass surgery in SLI/ CLI, and hence should not be used as primary treatment. Failure after angioplasty may increase the risk for subsequent bypass surgery; therefore, endovascular treatment should not be regarded as a risk-free choice for the patient. BASIL confirms that, regardless of initial treatment, patients with advanced limb ischemia undergo complex journeys with many reinterventions. They also require longitudinal care from dedicated specialists. It also confirms that high-quality open bypass surgery remains a critical element of the therapeutic armamentarium for limb preservation⁶

A short-term study of 6-months in our patient population revealed no amputation at mid tibial level and above (the Criteria included in BASIL trial as amputation free survival) and death in each category. The Basil trial had included patients with both above and below knee disease. The durability of above knee endovascular interventions is clearly better than tibial interventions as revealed in our study i.e. “the below knee” endovascular intervention had higher restenosis rate than above knee interventions. The phasic flow was seen monophasic and biphasic in six-months follow up.

The suitability of endovascular intervention procedure and open surgical procedure according to the anatomical extent and complexity of lesion well discussed in documents (update 2007) of Trans-Atlantic intersociety consensus (TASC II). There is evidence that shorter lesions (TASC II- A and B) do well with endovascular intervention while longer lesions (TASC II-C and D) have significantly lower patency rates.⁷⁻⁹ The latest TASC II recommendations include an endovascular approach for shorter lesions and a bypass for longer lesions.¹⁰ In our study the primary patency rate by endovascular intervention in Femoropopliteal category after 6 months is 100% where as it is 66% and 55% after 24 months reported by Surowiec et al⁷ and Dearing et al⁸ respectively. We are with the opinion that the early results are better as the disease progression is less. Contrary to the BASIL trial, Malas et al. demonstrated a higher rate of reintervention for femoropopliteal bypass compared with angioplasty and stenting. Probably the patients who underwent bypass graft surgery had much more advanced disease in this study and secondly, the endovascular procedure enjoyed better patency due to placement of stents¹¹. In another study by Mihriban Yalcin et al, the bypass group had a patency rate of 94.6%, whereas the rate was 86.7% and 82.5% in the angioplasty and stent group respectively at the end of 24 months for superficial femoral artery disease. They concluded that there was no significant difference between groups in terms of reintervention and patency rates.¹² Rodrigo Bruno Biagioni et al also observed more reintervention rate in patients who underwent endovascular interventions than surgical approach in patients with popliteal artery disease with trifurcation disease¹³

In one study¹⁴, the endovascular intervention in aortoiliac disease has initial technical success was 99% and the initial hemodynamic success and clinical improvement was also 99% with balloon angioplasty with or without stenting also claimed to have very low total rate (0.7%) of local, general, and vascular complications, which is similar to our study where the patients subjected to endovascular treatment had 100% technical success rate and without any local and general complications. Aortobifemoral bypass reported to have primary patency rate 97% at one year and 89% at 5 year reported in a study by H Lau et al.¹⁵ where they concluded it as a preferred treatment option for good risk patients with complete occlusion or extensive stenosis of aortoiliac arteries. In our study one patient had graft occlusion with a primary patency rate of 66% at 3 month follow up. We attribute this occlusion to poor distal run off in the ipsilateral limb. We are also in opinion that the Aorto femoral bypass is a preferred treatment of choice for extensive TASC II C and D aortoiliac diseases.

Conclusion

Surgical bypass and endovascular intervention either as an independent treatment modality or in combination as a Hybrid procedure looks promising in the management of LEAD. Surgical bypass is no doubt morbid, but early results are satisfactory in terms of patency rates and clinical improvement. The early six months results of endovascular intervention, are particularly encouraging in the femoropopliteal segment with poor distal run off. The results are inconsistent for the “Below the Knee” segment disease. TASC II- A and B lesions are addressed by endovascular interventions, whereas TASC II- C and D lesions are addressed by surgical bypass. Multi-disciplinary individualised treatment approach should be adopted in deciding which treatment to be provided for a particular patient based on clinical, imaging findings and institutional protocols.

Limitations of the study

Because this is a non-randomised study, no intragroup comparison is made. Long-term patency should be studied in a well-designed and randomised manner, in order to comment the superiority of one procedure over the other. Our study is limited by its very short duration of follow-up, whereas others have published at 24 months.

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How to cite this article : Khuswant Popli, Sistla VPL Chandrakumar, Padhy A, Sartaj Ahmed Guroo, Khuswant Popli, Madhur Kumar, P Garg P, Gupta A. Early results of surgical and Endovascular intervention procedures in Lower extremity arterial disease. Perspectives in Medical Research 2020; 8(1):75-80

Sources of Support: Nil, Conflict of interest: None declared.