Effectiveness of Secondary Interventions to Rescue Threatened Distal Bypasses for Limb Salvage

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Objective: This study is evaluating the effectiveness of salvage interventions to rescue threatened infra-popliteal (IP) bypasses in critical limb ischemia (CLI) patients.

Materials and methods: Data of all CLI patients who underwent distal IP bypasses at a single institution between 2016 and 2021 are analysed retrospectively. Patency rates, amputation-free survival, patient survival, and wound healing rates after a 1-year follow-up period are calculated. Comparative analyses of amputation free survival and patient survival rates between non-threatened, threatened and acutely occluded grafts are also done.

Results: A total of 121 IP bypasses were performed in 115 patients (84 male; mean age, 74.4±8; hypertension, 84%; diabetes mellitus, 69%). 24% originated from the common femoral artery, 40% from the superficial femoral artery and 36% from the popliteal artery. The most common outflow arteries are the anterior tibial artery (36%) and the posterior tibial artery (33%). Secondary interventions in the form of endovascular and surgical revisions are necessitated in 53 (44%) grafts.

At one-year follow-up, primary, assisted-primary, and secondary patency rates are 50%, 78% and 88%, respectively. Amputation-free survival and patient survival rates are 93% and 86%, respectively. Complete wound healing rate is 83%. Amputation-free survival among acutely occluded grafts is significantly worse when compared with threatened and non-threatened grafts (P-value<0.001).

Conclusion: Secondary interventions to rescue threatened distal bypasses are successful at maintaining graft patency with amputation-free survival rate comparable to non-threatened grafts. Salvage angioplasty is a viable alternative to surgical revision to rescue limbs with threatened grafts in CLI patients.

Key words: Critical limb ischemia, endovascular therapy, threatened graft, distal bypasses.

Introduction

Critical limb ischemia (CLI) is advanced peripheral arterial occlusive disease that affects one per cent of population aged ≥60 years and it is progressively increasing with ageing.[1] It is defined according to Rutherford classification as presence of ischemic rest pain, ulceration, or gangrene. Despite advances in endovascular therapy (EVT), distal bypasses are now firmly established as effective durable techniques for treatment of CLI cases with infra-popliteal (IP) occlusive disease particularly those with life expectancy more than two years, long arterial segment occlusion, or after unsuccessful EVT.[2] Amputation free survival and overall patency rates associated with IP bypasses approach 87% and 83% respectively.[3]

Graft surveillance is necessitated to detect significant stenosis or thrombosis that threatens bypass patency.[4] Threatened bypasses requiring secondary interventions ranged from 36% to 48%.[3,5] Secondary interventions can be in the form of salvage balloon angioplasty of inflow, in-graft or outflow stenosis, thrombolysis, and/or surgical revision with an overall procedural success ranging from 91% to 96%.[6,7] However, data regarding the frequency, timing, and optimal choice of such interventions remain limited.

The purpose of the current study is to report clinical outcomes of salvage interventions to maintain or restore IP bypass graft patency and compare these with non-threatened grafts at one-year follow-up.

Materials and methods

Study design

We retrospectively screened a prospectively collected bypass database, based on the clinical, operative and outpatient reports to identify all patients who underwent distal bypasses for CLI in Vascular Surgery Department - Zagazig University Hospitals – Egypt from December 2016 to March 2021. A distal bypass is defined as any bypass with a distal anastomosis onto the tibioperoneal trunk (TPT), anterior tibial artery (ATA), posterior tibial artery (PTA) or peroneal artery (PerA). All patients had preoperative duplex assessment together with CT angiography (CTA). MRA replaces CTA in renal impairment cases. Patients' demographics, operative details, one-year follow-up data, secondary intervention details along with 1-year outcomes are evaluated.

Inclusion criteria

All patients with CLI (Rutherford 4-6) with IP arterial occlusive disease particularly those with life expectancy ≥2 years, long femoro-popliteal (FP) segment occlusion, or after failed EVT are included.

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Exclusion criteria

Patients with no IP vessels disease, revascularization procedures other than distal bypasses and patients with unsalvageable limbs are excluded.

Operative details

All procedures are performed under spinal anaesthesia after patient assessment of medical co-morbidities using the American Society of Anaesthesiologists (ASA) physical status classification system.

The greater saphenous vein (GSV) is the preferred conduit used. It is harvested, reversed and prepared on a back table. However, if not suitable, polytetrafluoroethylene (PTFE) grafts are then used. The conduit is tunnelled anatomically. Proximal anastomosis is performed on the common femoral artery (CFA), superficial femoral artery (SFA) or popliteal artery (PA) (supragenicular or infragenicular) depending on the presence of triphasic inflow and absence of angiographic lesions. Distal anastomosis is done onto an outflow vessel chosen according to the angiosomal distribution in cases with tissue loss or onto a vessel that provides straight line flow to the foot.

Systemic heparinization is administered intra-operatively before vascular clamping. Intraoperative Doppler assessment is done at the end of the bypass to ensure graft patency. Minor amputations and ulcer debridement are carried out during the same session after finishing the revascularisation. Subcutaneous low molecular weight heparin (Clexane, Sanofi Winthrop Industrie, France) is given to all patients as postoperative anticoagulation at a dose of 1mg/kg twice daily till hospital discharge. Dual anti-platelet agents are then continued for the first three months then a single anti-platelet thereafter for life.

Follow-up

All patients are enrolled into a one-year surveillance program. The program consists of duplex scans that are performed predischarge and every 3 months for the first 12 months in addition to regular clinical follow-up visits.

A threatened graft is diagnosed when finding a focal peak systolic velocity (PSV) >200 cm/s, global PSV <40 cm/s, or PSV ratio >2.0 (>50% stenosis). Acutely occluded graft is the one that occludes suddenly causing symptomatic lower limb ischemia. Non-threatened graft is a patent or occluded graft without duplex evidence of significant stenosis. This group also includes occluded grafts found on surveillance duplex and remained asymptomatic.

Threatened grafts undergo urgent angiography, and if significant stenosis is confirmed, immediate salvage balloon angioplasty is arranged. Ipsilateral or contralateral femoral access is chosen aiming at optimizing access according to the site of the lesion. Revision surgery is undertaken if EVT failed, deemed unsuitable or if the stenosis recurred. After secondary interventions, patients are discharged home on their preoperative antiplatelet medications and the duplex surveillance protocol is continued till one-year follow-up is completed without reintervention.

Study endpoints and outcome measures

Technical success is defined as <30% residual stenosis on duplex scan. Primary end points are graft primary, assisted-primary and secondary patency. Secondary endpoints include wound healing, freedom from major amputation and patient survival. Major amputation is defined as limb loss above the ankle level. Current study follow-up period is 12 months after IP bypasses.

Statistical analysis

Statistical analysis is performed using the IBM SPSS Statistical Analysis platform, version 28. Pearson Chi-2 test is used to analyse categorical data while numerical variables are analysed using independent t-test. P-value <0.05 is considered statistically significant. Kaplan-Meier life-table method is used to analyse study endpoints.

Results

Patient population

A total of 121 distal bypasses were performed in 115 patients (84 males, 31 females). The mean age is 74.4 years (range from 50 to 88 years). Cardiovascular risk factors include history of hypertension (84%), cigarette smoking (73%), hypercholesterolemia (74%) and diabetes mellitus (69%). Modifiable risk factors are modified. Patient demographics and cardiovascular risk factors are listed in **(Table 1).**

Indications for revascularisation include Rutherford clinical category 4 (27%), 5 (46%) or 6 (27%). Femoro-popliteal lesions are found in 102 (84%) cases which are classified according to the Trans-Atlantic Inter-Society Consensus II (TASC II) classification into TASC II-A in 6 (5%), TASC II-B in 61 (50%), TASC II-C in 8 (7%), and TASC II-D in 27 (22%). Proximal anastomosis originated from CFA in 29 (24%), SFA in 48 (40%), or PA in 44 (36%). Distal anastomosis is performed onto the TPT (12%), ATA (36%), PTA (33%) or PerA (19%). Bypasses characteristics are summarised in **(Table 2)**.

Re-interventions

Grafts are classified as non-threatened in 68 (56%), threatened grafts in 45 (37%) and acutely occluded in 8 (7%). Regarding threatened grafts, 61 EVT attempts are performed to rescue 41 (91%) bypasses

with an overall technical success rate of 93%. Three EVT technical failures occurred necessitating surgical revision of proximal anastomosis by femoral endarterectomy and patch plasty in one and unsuccessful surgical trial to control anastomotic leak from distal anastomosis secondary to EVT in another. The third failure case occluded after 23 days of EVT but no further intervention needed due to resolving of rest pain symptoms. The remaining four threatened grafts (9%) were unsuitable for EVT thus underwent surgical revision in the form of jump graft to a distal tibial vessel in 3 cases and CFA pseudoaneurysm repair in one **(Table 3).** 84% of threatened grafts required re-intervention in the early postoperative period (<6 months after bypass).

Regarding the acutely occluded grafts (N=8), all patients underwent attempted thrombectomy at a median of 4 days (Range, 0-60 days) after bypass. Thrombectomy was successful in 6 (75%) patients, who required additional procedures to deal with underlying lesions in the form of revision of distal anastomosis using Taylor patch in 2, jump graft from a more proximal inflow to the graft in 3 and redo whole bypass in one . The two failed thrombectomies had redo bypasses which deemed unsuccessful and above knee amputation followed 6 days later in both. Of the 6 acutely occluded grafts that underwent successful rescue, two went on to have further EVT procedures to maintain patency. Table 3 summarizes secondary intervention details on threatened and acutely occluded grafts.

Outcome

Overall outcome

By Kaplan-Meier analysis; overall primary patency, assisted-primary patency and secondary patency rates are 50%, 78%, and 88%, respectively at 1-year follow-up **(Figure 1).** Overall amputation free survival exceeded 93% at 12 months **(Figure 2).** Eight major limb amputations (6 above knee and 2 below knee) were performed for Rutherford 4 (N=4) and Rutherford 5 (N=3) and 6 (N=1) stages at a median of 87 days (range, 5-176 days) after bypass surgery. 89 patients presented with tissue loss, of which complete wound healing is achieved in 74 (83%) in addition to 12 (13%) patients who died with healing wounds.

By the end of the follow-up period, patient survival at 30-days and 1-year follow up reached 98% and 86%, respectively **(Figure 3).**

Re-interventions outcome:

87% of secondary interventions occurred early (<6months after the bypass). Out of the 45 threatened grafts, 27 (60%) had a single re-intervention while 18 (40%) underwent multiple revisions. By the end of the study period, 3 (7%) threatened grafts got occluded; all belong to the single revision group. Out of the 8 acutely occluded bypasses, 4 (50%) become occluded by the end of the study. Out of 68 non-threatened (Non-revised) grafts, 61 (90%) were functioning and 7 (10%) occluded at the end of the study period. Figure 4 illustrates the fate of the 121 bypasses at the end of the study period.

The median interval from bypass to first EVT revision was 16 days (Range, 0-361 days) with a mean duration of 74±94 days while operative revisions occurred later at a median of 26 days (Range, 0-248 days) after bypass when compared with endovascular interventions but this is not statistically significant.

Eight major limb amputations were performed during the study period distributed as four, one and three amputations among acutely occluded, threatened, and non-threatened grafts, respectively. Amputation free survival is significantly worse in acutely occluded grafts when compared with threatened and non-threatened grafts by log-rank test (P-value <0.001; **Figure 5)**. All five major amputations that complicated secondary intervention cases occurred in grafts having early intervention (<6months). Graft proximal anastomosis origin has no statistically significant effect on amputation free survival (P-value =0.25).

Overall 30-day mortality rate of 2% (3 cases) is recorded, all belong to non-threatened grafts. Causes of death are myocardial infarction in one, congestive cardiac failure in another and unknown in the third. Among threatened and acutely occluded grafts, no 30-day mortality is recorded after secondary interventions. At the end of the study period, overall mortality is 17 cases (14%), of which 14 (12%) with non-threatened grafts, 3 (2%) with threatened grafts and no mortalities observed in acutely occluded grafts. Thus, among secondary intervention cases, a mortality rate of 6% (3 cases) is scored during the follow up period and causes of death remained unknown.

Diabetes mellitus (P-value= 0.022) and PA originating grafts (P-value= 0.043) are statistically significant independent factors leading to graft events necessitating secondary interventions.

EVT revised grafts have comparable amputation free survival and patient survival rates to non-threatened (Non-revised) grafts **(Figures 5,6).**

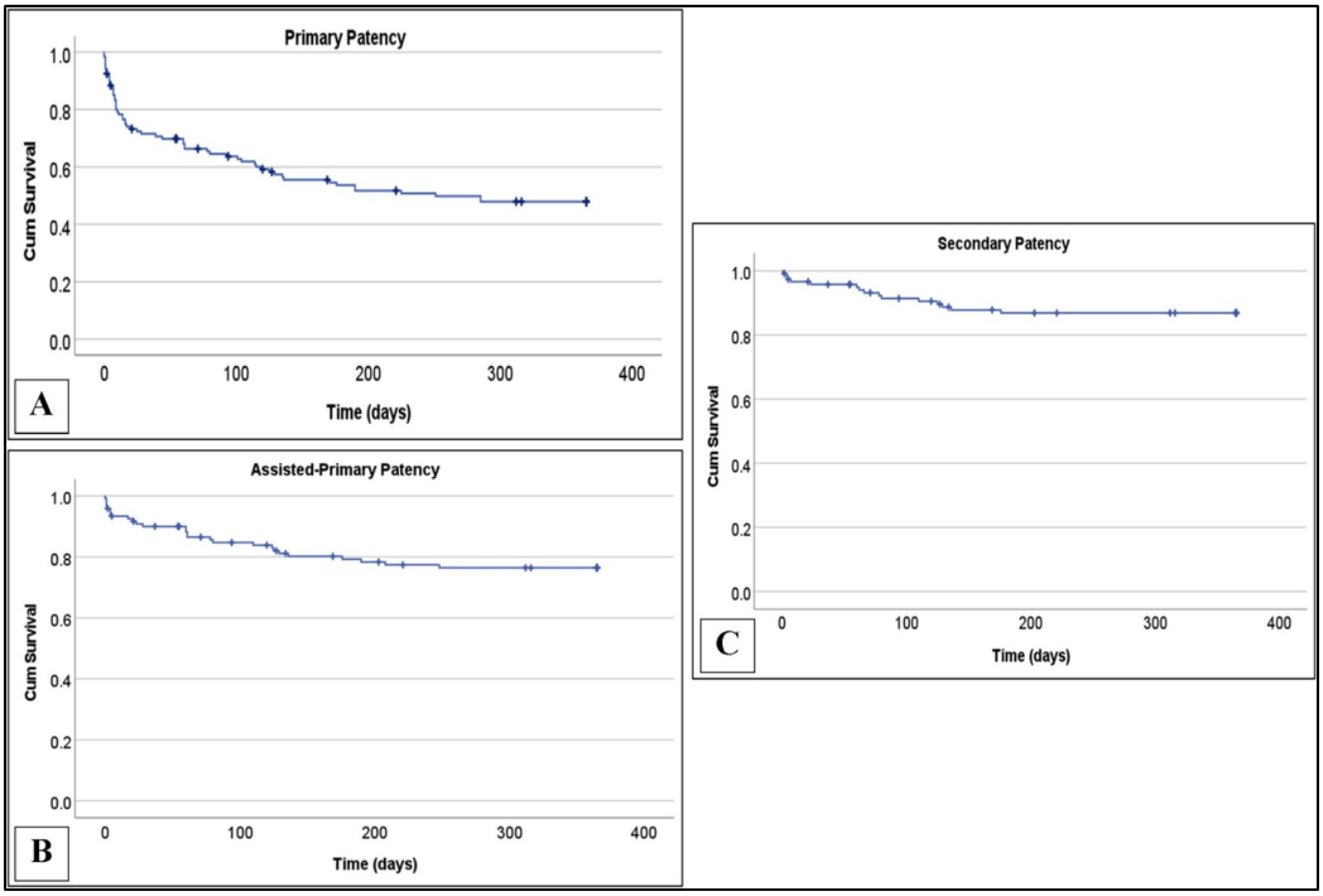

Fig 1: A: Primary patency. B: Assisted-primary patency. C: Secondary patency by Kaplan-Meier analysis.

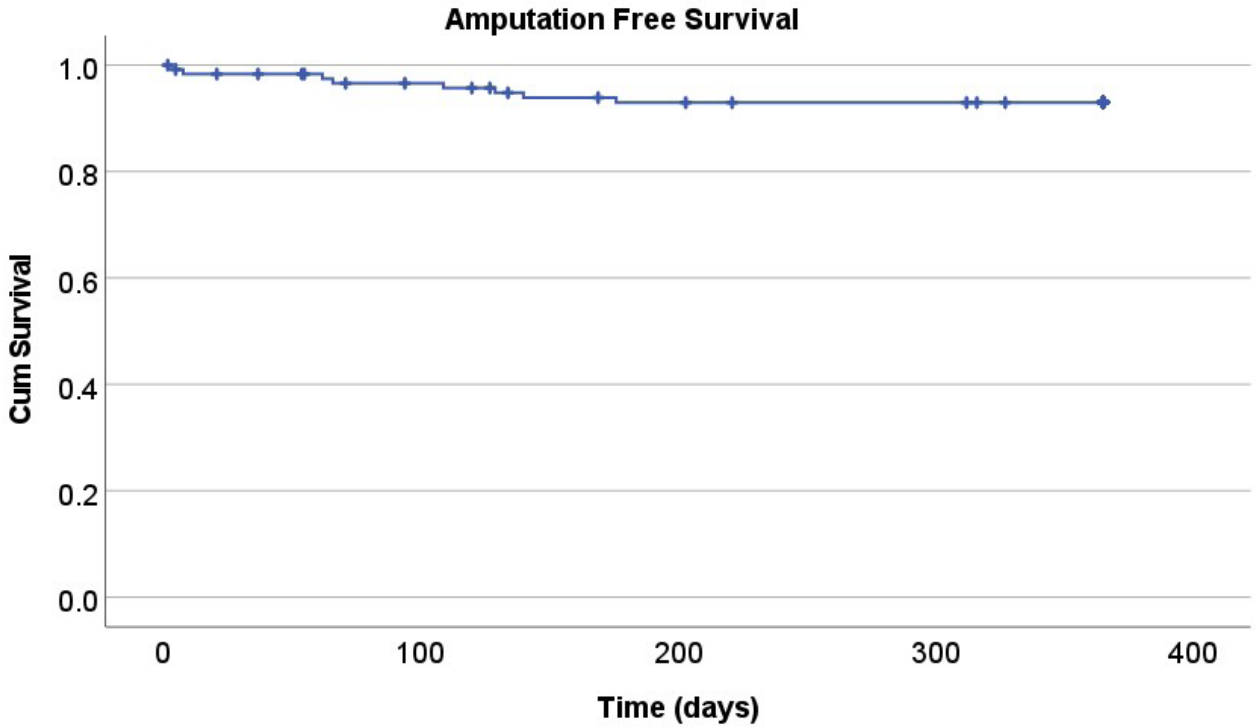

Fig 2: Amputation free survival by Kaplan-Meier analysis.

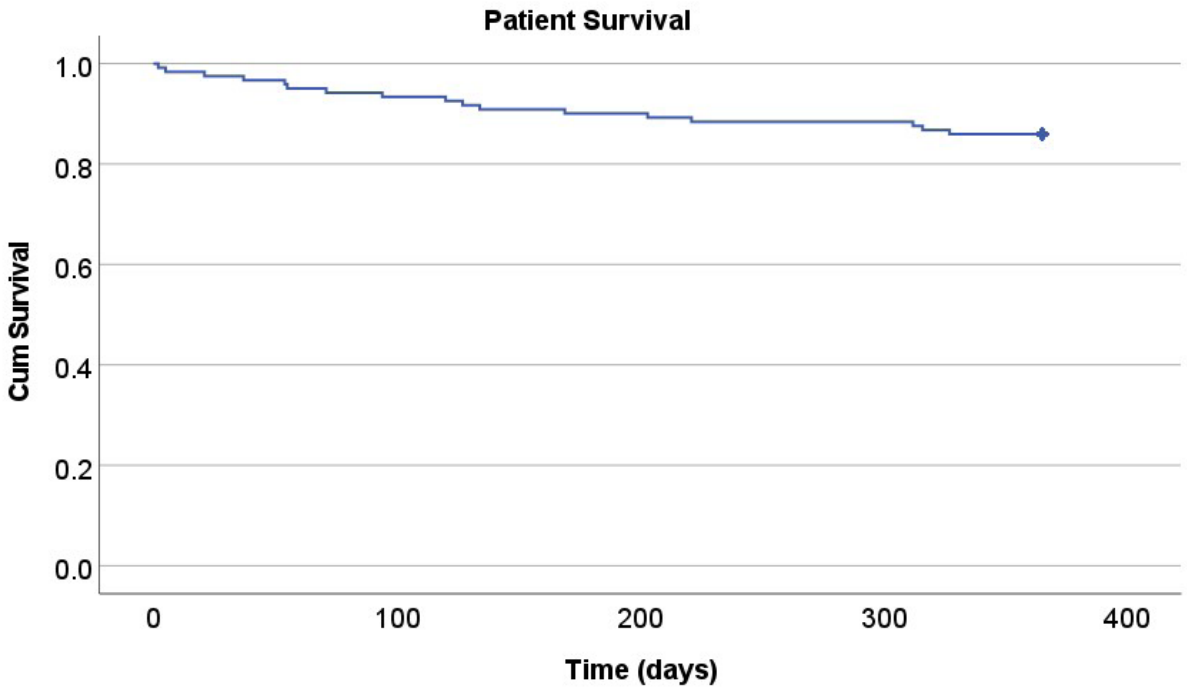

Fig 3: Patient survival by Kaplan-Meier analysis.

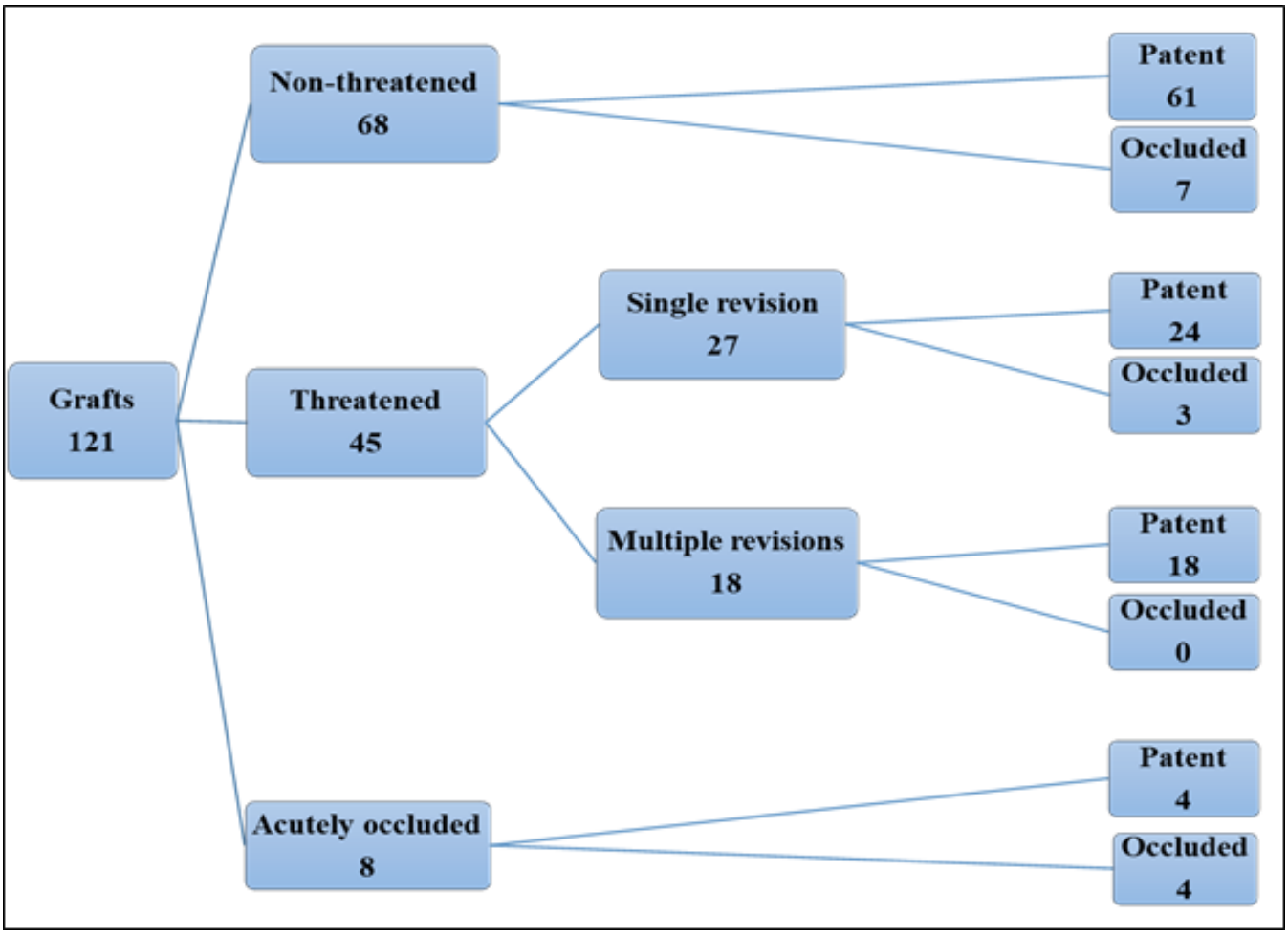

Fig 4: Outcome of 121 grafts by the end of the study period (12 months).

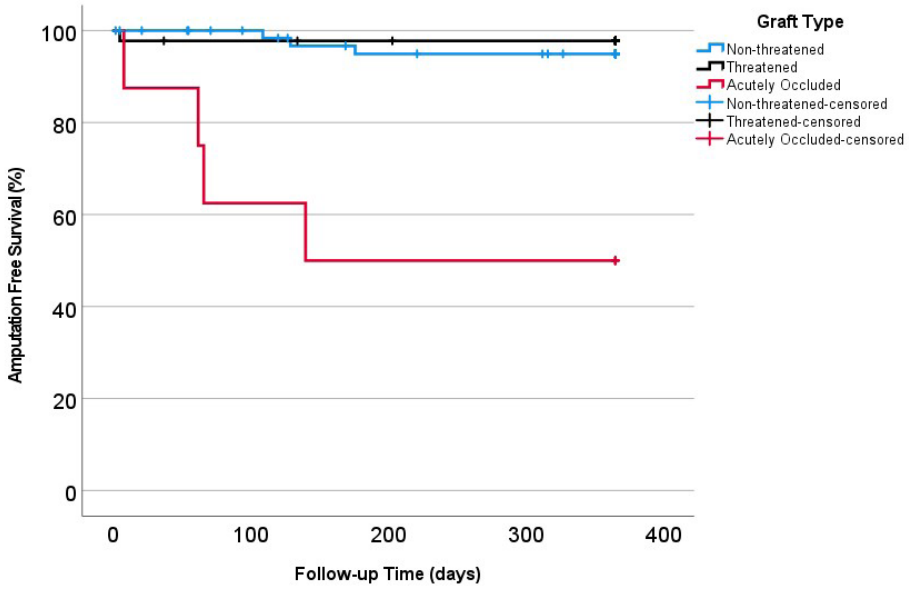

Fig 5: Amputation Free Survival between different graft types.

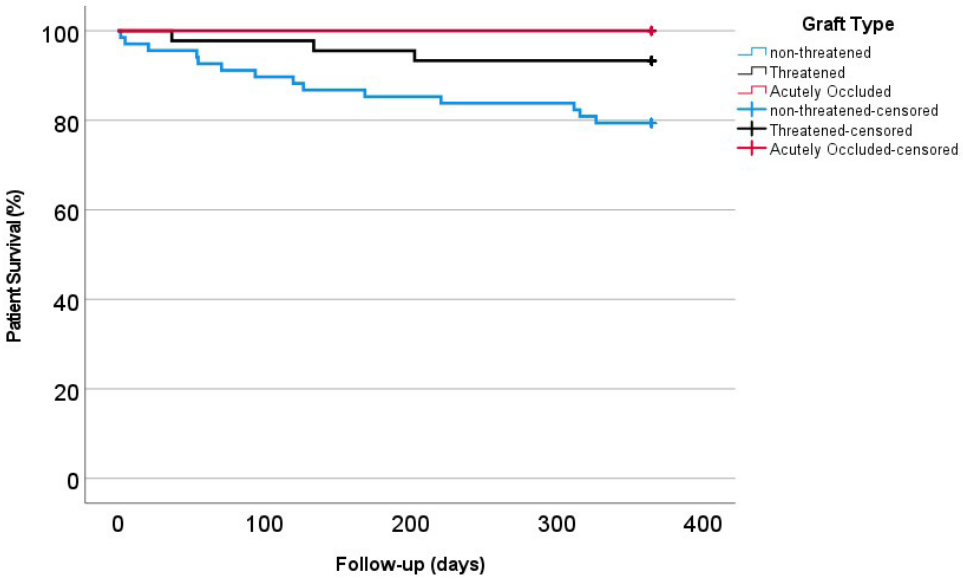

Fig 6: Patient Survival between different graft types.

Table 1: Patients demographics and cardiovascular risk factors

Number of patients	115
Mean age ± SD	74.4±8
Gender	
- Male	84 (73%)
- Female	31 (27%)
Hypertension	97 (84%)
Diabetes Mellitus	79 (69%)
Dyslipidaemia	85 (74%)
Smoking/ex-smoking	84 (73%)
Coronary artery disease	55 (48%)
Renal impairment	31 (27%)

SD: Standard deviation.

Table 2: Procedure characteristics

Characteristic	Number (%)
Number of bypasses	121
Limb affected	
Right	61 (50%)
Left	60 (50%)
Rutherford classification	
4	32 (27%)
5	56 (46%)
6	33 (27%)
TASC classification of FP lesions:	
TASC A	6 (5%)
TASC B	61 (50%)
TASC C	8 (7%)
TASC D	27 (22%)
Origin of bypasses:	
CFA	29 (24%)
SFA	48 (40%)
PA	44 (36%)
Target outflow vessels:	
TPT	15 (12%)
ATA	43 (36%)
PTA	40 (33%)
PerA	23 (19%)
Conduit used:	
GSV	109 (90%)
PTFE	12 (10%)

TASC: Trans-Atlantic Inter-Society Consensus, FP: femoro-popliteal, CFA: common femoral artery, SFA: superficial femoral artery, PA: popliteal artery, TPT: tibio-peroneal trunk, ATA: anterior tibial artery, PTA: posterior tibial artery, PerA: peroneal artery, GSV: great saphenous vein, PTFE: polytetrafloroethylene.

Table 3: Secondary interventions details

Secondary intervention	No (%).
EVT attempts	61
Lesion location:	
Inflow	19 (32%)
Proximal anastomosis	15 (25%)
In-graft	10 (16%)
Distal anastomosis	10 (16%)
Outflow	7 (11%)
Treatment modality:	
POBA	58 (95%)
Stenting	3 (5%)
Surgical revisions	22
Thrombectomy	8 (36%)
Jump graft	6 (27%)
Redo whole bypass	3 (14%)
Revision of distal anastomosis	2 (9%)
Revision of proximal anastomosis	1 (5%)
CFA pseudoaneurysm repair	1 (5%)
Surgical control of anastomotic leak	1 (5%)

EVT: Endovascular Therapy, POBA: plain-only balloon angioplasty, CFA: common femoral artery.

Discussion

In the era of EVT, distal bypass surgery remains an effective and durable treatment method of CLI patients with IP arterial occlusive lesions especially long-segment occlusions or after failed EVT.[2] Although autologous vein graft is still the conduit of choice, maintaining graft patency remains a challenging task for vascular surgeons. This is owed to hemodynamic significant anastomotic or in-graft stenoses that develop from atherosclerotic disease progression and intimal hyperplasia.[8] Improvements in duplex scanning and surveillance programs allowed detection of grafts at risk for occlusion.[9] Once a threatened graft is picked up, the surgeon must choose the best course of action to maintain its patency.

In 2004, Carlson et al reported their experience with 36 threatened infrainguinal vein bypasses. 45 EVT attempts were performed and classified as 36 balloon angioplasties of the vein bypass grafts and 9 balloon angioplasties of the inflow/outflow arterial lesions. Sites of vein graft stenotic lesions were 3 (8%) at the proximal anastomosis, 6 (17%) in-graft, and 27 (75%) at the distal anastomosis. Technical success of vein graft EVT was achieved in 33 cases (>91%). Overall primary patency rates were 74.2% and 62.7%, at 6 and 12 months, respectively. Repeat interventions included surgical thrombectomy (With vein patch plasty or bypass graft revision) or repeat EVT (With or without thrombolysis). Cumulative assisted-patency rates (Freedom from occlusion or threatening stenosis) were 87% and 83% at 6 and 12 months, respectively. No deaths in the perioperative period.[6]

In 2006, Eagleton et al reviewed 593 consecutive infrainguinal bypasses for arterial occlusive or aneurysmal disease. 39 anastomotic strictures affecting 36 patients were analysed. At time of presentation, 20 (51%) presented with thrombosed grafts and the anastomotic stricture was identified only after thrombolytic therapy. 15 (38%) and 24 (62%) strictures affected the proximal and distal anastomoses, respectively.[10]

In Eagleton's study, re-interventions included EVT in 26 (67%) and open revisions in 13 (33%). Among the 20 thrombosed grafts, 16 (80%) required EVT revision and 4 (20%) necessitated operative interventions. Out of the 19 non-thrombosed bypasses, 10 (52%) had EVT rescue and 9 (48%) underwent open surgical revision. Endovascular

revisions included balloon angioplasty alone with concomitant iliac stenting necessitated in 3 patients. Open surgical revisions included vein patch plasty, short interposition grafts at stricture site, or redo bypass. After a mean follow-up period of 28±3 months, overall primary, assisted-primary, and secondary patency rates were 36%, 42%, and 53%, respectively. Overall limb salvage rate was 76%. No intervention-related deaths were recorded.[10]

Over the past decade, treatment of grafts at risk has changed significantly, with a variety of EVT and surgical revision techniques available to treat stenosis and acutely occluded grafts. Thus, maintaining graft patency and promoting limb salvage.[11]

In 2014, Oostenbrugge et al analysed a total of 48 EVT procedures performed for anastomotic stenoses in 43 infrainguinal bypasses. Technical success was 96%. The 2 failed EVT procedures were surgically revised at the proximal and distal anastomosis of the original bypass. At 1-year follow-up, the primary, assisted-primary, and secondary patency rates were 80%, 88%, and 88%, respectively.[7]

In 2016, Patel et al reported 114 IP bypasses performed in 102 CLI patients. Target outflow vessel was ATA (27%), PTA (24%), PerA (21%), TPT (20%), and dorsalis pedis artery (8%). Grafts were classified as non-threatened in 58 (51%), threatened in 42 (36%), and acutely occluded in 14 (12%). Different EVT salvage intervention options included balloon angioplasty, drug-coated balloons, drug-eluting stents, nitinol stents, and thrombolysis with an overall technical success rate of 92%. Surgical salvage revisions included jump grafts (N=7), revision of anastomotic stenosis (N=3), and thrombectomy (N=2).[11]

In Patel et al study, out of the 42 threatened grafts, 6 (14%) got occluded. Of the 14 acutely occluded grafts, 6 grafts (43%) become occluded. Out of 58 non-threatened grafts, 48 (83%) were fully patent and 10 (17%) occluded by the end of the study period. At 1-year follow-up, primary patency, assisted-primary patency, and secondary patency rates were 57%, 76%, and 82%, respectively. Amputation free survival was 80% at 12 months. 30-days and 1-year mortality rates were 0.8% (1 patient) and 10%, respectively.[11]

1n 2021, Kobayashi et al retrospectively reviewed 316 distal bypasses performed in 241 patients with CLI. Of these, 113 failing grafts (94 patients) that underwent EVT (Balloon angioplasty) as primary intervention were analysed. Of the 113 grafts, 54 (48%) were asymptomatic, 41 (36%) with recurrent tissue loss, and 18 (16%) with rest pain. Procedural success was 98%. A single EVT attempt was required in 63 grafts (56%) and multiple attempts in 50 grafts (44%). Primary and assisted-primary patency rates of EVT-revised grafts were 41% and 80% at one year, respectively. Among patients with recurrent tissue loss, complete wound healing rate reached 71% and 84% at 3 months and 12 months, respectively. Major amputation was necessitated in 8 cases, and amputation free survival rate was 96% at 1-year follow-up. Patient survival rate in EVT-revised grafts was 86% at one-year follow-up.[12]

In our study, at one-year follow-up, primary patency, assisted-primary and secondary patency rates are 50%, 78% and 88%, respectively. Amputation free survival is >93%. Wound healing rate reached 83% and patient survival rate is 88%. These are comparable to Patel's and Kobayashi's studies.[11,12] Our relatively low primary patency rate in comparison to Carlson and Oostenbrugge studies,[6,7] can be justified by our intensive duplex surveillance program that identifies early graft failure (50% stenosis) requiring EVT or surgical intervention. Thus, a clearly defined clinical follow-up system and a duplex surveillance program are needed to improve graft patency.[9]

Patel and his colleagues found that amputation free survival in salvaged threatened and acutely occluded grafts was comparable to non-threatened (Non-revised) grafts. Also, freedom from major amputation was better in late re-intervention grafts (>6 months from bypass) compared to early re-intervention ones (<6months from bypass). So, they concluded that once a threatened graft is detected, intervention can improve amputation free survival to become comparable to grafts without revisions.[10]

In the current study, amputation free survival is comparable in salvaged threatened and non-threatened bypasses but significantly worse in salvaged acutely occluded grafts **(Figure 5).** No statistically significant difference in freedom from major amputation rate among early and late re-intervention grafts (P-value =0.22)

Diabetes mellitus (P-value= 0.022) and PA originating grafts (P-value= 0.043) were statistically significant independent factors leading to threatened and acute graft occlusion necessitating secondary interventions, thus meticulous follow-up is needed.

Conclusion

Secondary interventions to rescue threatened distal bypasses are successful at maintaining graft patency with amputation free survival comparable to non-threatened grafts. Salvage angioplasty is a viable alternative to surgical revision to rescue limbs with threatened grafts in CLI patients. Thus, endovascular first rescue strategy is advised.

Limitation

This study is limited by the long duration of patient

recruitment, which makes long-term follow up quite difficult.

Recommendation

Further multiple centre studies with long term follow up is needed.

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