Distal versus Ultradistal Bypass Grafts: Amputation-free Survival and Patency Rates in Patients with Critical Leg Ischaemia

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Abstract
Objectives: Compare the outcome of distal (bypass to the crural arteries) versus ultradistal (bypass to the pedal arteries) bypasses in patients with critical leg ischaemia (CLI).

Design: Retrospective analysis of prospectively collected data of patients with CLI undergoing infra-popliteal bypass surgery is performed.

Materials and Methods: Patients undergoing infra-popliteal bypass at a single institution between 2004 and 2010 are included. Patency rates at 1-year and amputation-free survival at 12 and 48 months are analysed.

Results: Two hundred and thirty bypasses were performed in 209 consecutive patients (156 men, median age; 76 years, range; 19–96 years). One hundred and seventy nine (78%) bypass were classified as distal and 51 (22%) as ultradistal. The incidence of diabetes mellitus was significantly higher in the ultradistal group (p = 0.0025). At 1-year, the distal group primary, assisted-primary and secondary patency rates were 61.7%, 83.1% and 87.4% compared to 61.9%, 87.4% and 87.4% in the ultradistal group respectively. Amputation-free survival at 12 and 48 months was 82.9% and 61.5% in the distal group compared to 83.0% and 64.9% in the ultradistal group.

Conclusions: This study show that both distal and ultradistal bypass have comparable outcome regardless of the co-morbidities. The authors believe that elderly patients should be offered ultradistal bypass if indicated to avoid major amputation.

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Introduction
The incidence of critical leg ischaemia (CLI) is progressively increasing with the ageing population.1–3 Crural and pedal arteries bypass are now firmly established as an effective technique for the treatment of such patients. Although there is a wide consensus that revascularisation should be
attempted in these patients, there are still doubts regarding the level of the bypass, with many surgeons reluctant to perform bypasses below the ankle level.

Many studies have shown good results following either distal bypass (bypass to the crural arteries) or ultradistal bypass (bypass to the pedal arteries). However, to our knowledge, only one study has compared the outcome of crural bypass versus pedal bypass at the same institution, though, this was undertaken in a relatively young population. The aim of this study is to look at the outcome of distal versus ultradistal bypass including an elderly population with CLI at a single institution.

Methods

All patients undergoing infrapopliteal bypass between January 2004 and December 2010 were evaluated. This included 230 infrapopliteal bypasses performed by two vascular surgeons.

All patients with CLI (Rutherford classification, category 4, 5 or 6) due to long occlusive femoro-popliteal disease and/or trifurcation disease (The Inter-Society Consensus for Management of PAD (TASC) type C and D classification for femoro-popliteal disease) requiring infrapopliteal bypass surgery were included. Patients’ demographics, details of the operation and follow-up information were recorded and entered prospectively into a database (Microsoft Excel, Redmond, WA, USA) and were analysed retrospectively.

Bypass grafts were divided into two groups, namely distal (bypass to the crural arteries) or ultradistal (bypass to the pedal arteries). All patients underwent preoperatively a detailed arterial duplex scan in combination with conventional digital subtraction angiography (DSA) to delineate the anatomy of the arterial system. Arterial pedal arch images were taken in two planes to fully demonstrate the state of the pedal arteries. Computed tomography and magnetic resonance angiography were occasionally used in selected cases. Planned angioplasty of the inflow was performed prior to surgical intervention, should there be a stenotic lesion of >50% proximal to the site of the proposed proximal anastomosis. Any other inflow lesions (TASC A and B) were offered preoperative angioplasty.

As a large proportion of these patients was diabetic and had renal failure, the ankle–brachial pressure index was not used in the assessment, due to the artificially high readings associated with these co-morbidities. However, duplex waveform analysis at the ankle level was carefully studied in all patients.

The authors’ policy was to operate on patients on clinical presentation and the presence of damped duplex waveforms in the pedal arteries at the ankle level. The decision to perform either a distal or ultradistal bypass was based on anatomical and radiological factors to restore straight-line flow to the foot.

The greater saphenous vein (GSV) was used as the preferred conduit of choice. However, if unavailable, other vein conduit or polytetrafluoroethylene (PTFE) grafts were used. Preoperative duplex of the superficial vein for mapping of both GSVs was performed in all patients, according to a standard protocol. The lesser saphenous veins (LSVs) and arm veins (bilateral cephalic and basilic) were mapped using a similar technique, if needed. The smallest vein conduit used was 2 mm in internal diameter. This has been shown to have good patency rate in infraguinal and infrapopliteal bypasses.

The tunnelling of the bypass graft was performed anatomically. Bypasses to the anterior tibial and dorsalis pedis arteries were tunnelled laterally through the interosseous membrane, whereas bypasses to the peroneal artery were performed via a medial approach. Intra-operative continuous-wave Doppler was used to assess the graft patency at the end of the procedure for quality control. Postoperative anticoagulation was maintained using subcutaneous therapeutic dose of low-molecular-weight heparin (Clexane, Sanofi Winthrop Industrie, France) adjusted according to patients’ body weight (1.5 mg kg\(^{-1}\) once daily) in all bypasses and maintained throughout the in-hospital period. Anti-platelet and statin therapy was initiated before surgery, and maintained postoperatively.

All patients were recruited into a 1-year duplex graft surveillance programme. Graft follow-up scans were performed prior to hospital discharge and then every 3 months for the first year. A threatened graft was diagnosed upon the finding of focal peak systolic flow velocity >200 cm s\(^{-1}\), velocity ratio exceeding 2.0 (50% stenosis) or global graft flow velocity uniformly <45 cm s\(^{-1}\). Patients with threatened grafts were offered urgent angiography, and if a significant stenosis was confirmed, immediate angioplasty was performed. If this was unsuccessful or if the stenosis recurred, then corrective surgery was undertaken. Patients were discharged from the surveillance programme, only if they completed a full intervention-free year of surveillance.

The distal bypass group was analysed separately from the ultradistal group. The primary end points were amputation-free survival and primary, assisted primary and secondary patency rates of the bypass leg. Only data from the first year of follow-up was analysed. Kaplan–Meier life-table analysis, log-rank and chi-square tests were used where appropriate. Values <0.05 were considered significant. Statistical analysis was performed using the Prism software 5.0 (GraphPad Software, La Jolla, CA, USA).

Results

A total of 209 patients with CLI underwent 230 infrapopliteal bypasses. Out of the 230 bypasses, 179 (78%) were classified as distal and 51 (22%) as ultradistal. The demographic characteristics and risk factors (defined and graded according to the Society of Vascular Surgeons/International Society for Cardiovascular Surgery (SVS/ISCVS) recommended criteria\(^{2}\) for both groups are summarised in Table 1. Diabetes mellitus was significantly higher in the ultradistal group (\(p = 0.0025\)). In the distal bypass group, 46 (28.0%) patients had renal insufficiency, out of which 19 had impaired renal function (creatinine range: 123–416 \(\mu\)mol, median: 171 \(\mu\)mol), seven on haemodialysis, one on peritoneal dialysis and one with kidney transplant. In the ultradistal bypass group, 15 (33.3%) patients had renal insufficiency, out of which, nine had impaired renal function (creatinine range: 150–263 \(\mu\)mol, median 177 \(\mu\)mol) and six on haemodialysis.
All patients had CLI (Rutherford grade 4, 5 and 6). The presenting symptom was ischaemic ulcers in 114 (49.6%) cases, gangrene in 62 (27.0%) and rest pain in 54 (23.5%). Autologous GSV was used in 201/230 (87.4%) cases, arm veins in six (2.6%) and PTFE with venous cuff in 23 (10.0%).

Twenty-five out of the 230 cases had previous open vascular procedures. Eleven were on the ipsilateral leg (one iliofemoral bypass, eight femoro-popliteal bypasses, seven femoro-distal bypasses and seven endarterectomies) and 14 on the contralateral leg (six femoro-popliteal bypasses, five femoro-distal bypasses and three endarterectomies).

Seventy out of the 230 legs were found to have inflow disease >50% stenosis and underwent successful preoperative inflow angioplasty. Target arteries were six common iliac, three external iliac, two common femoral, 27 superficial femoral (SFA), 19 popliteal artery (PA) and 13 combined SFA and PA.

Details of the inflow artery in both groups are summarised in Table 2. The site of the distal anastomosis in the distal bypass group was tibioperoneal trunk 24 (13.4%), anterior tibial in 67 (37.4%), peroneal in 40 (22.3%) and posterior tibial artery in 48 (26.8%) cases. The site of the distal anastomosis in the ultradistal group was inframalleolar posterior tibial artery in 12 (23.5%), dorsalis pedis in 30 (58.8%) and the medial plantar in nine (17.6%) cases.

The overall 30-day mortality rate was 1.7% (4/230). In the distal group, the 30-day mortality rate was 2.2% (4/179), compared with none in the ultradistal group. The overall 1-year mortality rate was 12.2% (28/230). In the distal group, the 1-year mortality rate was 12.3% (22/179), compared with 11.8% (6/51) in the ultradistal group (p = 0.578).

The percentage of threatened grafts that required salvage angioplasty was similar in the distal and ultradistal groups (64/179 (36%) and 17/51 (33%) respectively, p = 0.8683). The number of repeated salvage angioplasties was 81/179 (45%) in the distal group compared with 21/51 (41%) in the ultradistal group. This was not statistically different (p = 0.6349). Details of the salvage angioplasty sites are summarised in Table 3. Eighty of the 81 and three of 21 salvage angioplasties in the distal and ultradistal groups, respectively, were for the previously treated inflow artery.

A total of 182 bypasses had at least 1-year follow-up. Out of these bypasses; 143 grafts were in the distal group and 39 grafts in the ultra-distal group. At 1 year, the distal group’s primary, assisted primary and secondary patency rates were 61.7%, 83.1% and 84.7%, respectively. This compares with patency rates of 61.9%, 84.7% and 84.7% in the ultradistal group (Figs. 1–3). The amputation-free survival at 12 and 48 months was similar in both groups (82.9% and 61.5% in the distal group compared with 83.0% and 64.9% in the ultradistal group) (Fig. 4). There was no statistically significant difference between the groups.

During the total follow-up period, 15 legs required major amputations in the distal group and two in the ultradistal group. The limb salvage rate during this period was 92% and 96% in the distal and ultradistal groups, respectively. Sixty legs required minor amputation and 107 required ulcer debridement. All ulcers and minor amputations healed fully; however, in 14 cases with extensive foot debridement (area measuring >7 cm) split-thickness skin graft was required.

At 1 year, in the distal group, 20 grafts occluded and seven legs required major amputations. Out of the 20 occluded grafts, 10 occluded between 65 and 232 days following the procedure. However, by the time of graft occlusion, the tissue loss had healed and this did not result in major amputation. In the ultradistal group, six grafts occluded and one patient required major amputation. Out of the six grafts, four occluded between 92 and 204 days following the bypass with healed ulcers.
Discussion

With an increasingly aged population, life-limiting CLI is becoming a more frequent presentation of peripheral arterial disease (PAD). CLI prevalence is estimated at 1% of the population aged 60 years or older, with the percentage increasing with age.2,3 These elderly patients often suffer from severe co-morbidities, such as ischaemic heart disease and renal dysfunction.11,12 However, recent guidelines from the Second European Consensus Document on chronic limb ischaemia,2 the Transatlantic Intersociety Consensus Document on Revascularisation (TASC)3 and the international consensus on the management of the diabetic foot5 suggested that revascularisation is the optimal management in these patients before considering major amputation.

Treatment options for patients with CLI vary based on the type and level of the occlusive lesion, patient factors and the availability of expertise. Long-term results of minimally invasive endovascular treatments for distal arterial revascularisation need to be considered with caution.13 Even 1-year patency rates for subintimal angioplasty are still not comparable to surgery (50% vs. >80%).14 Results from the multicentre BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg) trial have suggested no difference in outcomes with the use of either subintimal or transluminal angioplasty.15 It also showed that >90% of the failed angioplasties required a further surgical intervention resulting in worse amputation-free and overall survival compared with those who had surgery performed in the first instance.15 Due to these limitations in the available treatment options and a relatively elderly patient group, infrapopliteal arterial reconstruction has remained a challenging yet hopeful treatment option for CLI.

Autogenous vein bypass to crural and pedal arteries is now firmly established as an effective technique for the treatment of CLI. Recent series of crural artery revascularisation showed at 5-year a secondary patency rate of 68—83%, limb salvage rate of 81—93% and patient survival rate of 45—47%.16—18 Other series for pedal artery revascularisation showed at 5 years a secondary patency rate of 63—77%, limb salvage rate of 74—87% and patient survival rate of 49—50%.19—21 However, there are little data comparing the outcome between both distal and ultradistal bypass at the same institution. Schneider et al.8 demonstrated a 3-year primary graft patency of 58% for pedal versus 61% for tibial bypass, secondary patency of 82% for pedal versus 79% for tibial bypasses, limb salvage of 92% for...
In this series, the ultradistal group had fewer grafts requiring salvage angioplasty of the runoff artery compared with the distal group. However, due to the small sample size, this did not achieve statistical significance. The authors believe that positioning the graft in the ultradistal region avoids the progression of disease occurring in the crural vessels that is more frequently seen in distal bypass.

The authors acknowledge that a propensity score would have been ideal to have a conclusive analysis between the two groups; however, the sample size could not allow this analysis.

**Conclusion**

This study shows that both distal and ultradistal bypass have comparable outcome, regardless of the co-morbidities. The authors believe that elderly patients should be offered ultradistal bypass, if indicated to avoid major amputation.

**Conflict of Interest/Funding**

None.

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