Primary Open Bypass Is Better Than Endo-First Approach For CLTI Patients With Extensive Gangrene And Advanced WIfI Lesions

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A Comparison of Outcomes in Patients with Infrapopliteal Disease Randomized to Vein Bypass or Plain Balloon Angioplasty in the Bypass vs. Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial

Objective: To compare outcomes in a subgroup of patients with infrapopliteal (IP) disease randomized to infrapopliteal vein bypass (VB) or plain balloon angioplasty (PBA) in the original BASIL trial.

Methods: A comparison of outcomes from patients randomized to VB or PBA undergoing revascularization for severe limb ischaemia (SLI) because of IP disease with or without femoropopliteal disease. The primary outcome was amputation free survival (AFS); secondary outcomes included overall survival (OS), 30 day mortality and morbidity, freedom from arterial re-intervention, immediate technical success, repeat and crossover interventions, length of hospital stay, and quality of revascularisation.

Results: A total of 104 patients were identified in the BASIL study with IP disease, 56 randomised to IP VB, and 48 to IP PBA. Groups were similar at baseline except for more chronic kidney disease in the VB group, and more previous surgical arterial intervention in the PBA group. There were no statistically significant differences in AFS or OS; however, clinically important trends were apparent in favour of a VB first strategy. Patients allocated to VB demonstrated significantly quicker relief of rest pain when compared with PBA (p < .005), but no significant differences in improved tissue healing. Median length of index hospital admission was significantly greater in the VB than in the PBA group (18 vs. 10 days, p < .0001) but there was no difference between the two groups in median total hospital stay between randomisation and the primary endpoint (VB 43.5 vs. PBA 42 days).

Conclusions: Further randomised trials, like BASIL-2 and BEST-CLI, are required to determine whether patients with severe limb ischaemia who require IP revascularisation and who are suitable for VB should have bypass or endovascular intervention as their primary revascularisation procedure.

Disclosure
No conflict of interest related to this presentation

Determinants of mid-term functional outcomes, wound healing, and resources used in a hospital-based limb preservation program

WIfI clinical stage 3-4 were associated with major amputation

Significant difference between EVT and VB

VB is associated with significantly lower major amputation rate compared to EVT

A systematic review and meta-analysis of revascularization outcomes of infringuinal chronic limb-threatening ischemia

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Background: The optimal strategy for revascularization in infringuinal chronic limb-threatening ischemia (CLTI) remains debatable in terms of both endovascular and open surgical strategies, with only limited randomized evidence. This review evaluates patient-relevant outcomes of infrainguinal revascularization procedures in adults with CLTI. Independent pairs of reviewers selected articles and extracted data. Random-effects meta-analysis was used to pool outcomes across studies.

Methods: We searched multiple databases through May 7, 2017, for prospective studies with at least 1-year follow-up that evaluated patient-relevant outcomes of infrainguinal revascularization procedures in adults with CLTI. Independent pairs of reviewers selected articles and extracted data. Random-effects meta-analysis was used to pool outcomes across studies.

Results: We included 44 studies that enrolled 8602 patients. Periprocedural outcomes (mortality, amputation, major adverse cardiac events) were similar across treatment modalities. Overall, patients with infrapopliteal disease had higher patency rates of great saphenous vein graft at 1 and 2 years (primary: 87%, 78%; secondary: 94%, 87%, respectively) compared with all other interventions. Prosthetic bypass outcomes were notably inferior to vein bypass in terms of amputation and patency outcomes, especially for below knee targets at 2 years and beyond. Drug-eluting stents demonstrated improved patency over bare-metal stents in infrapopliteal arteries (primary patency: 73% vs 50% at 1 year), and was at least comparable to balloon angioplasty (66% primary patency). Survival, major amputation, and amputation-free survival at 2 years were broadly similar between endovascular interventions and vein bypass, with prosthetic bypass having higher rates of limb loss. Overall, the included studies were at moderate to high risk of bias, and the quality of evidence was low.

Conclusions: There are major limitations to the current state of evidence guiding treatment decisions in CLTI, particularly for severe anatomic patterns of disease treated via endovascular means. Periprocedural (30-day) mortality, amputation, and major adverse cardiac events are broadly similar across modalities. Patency rates and limb salvage are markedly inferior for prosthetic grafting to below the knee targets. Among endovascular interventions, percutaneous transluminal angioplasty and drug-eluting stents appear comparable for focal infrapopliteal disease, although no studies included long segment tibial lesions. Heterogeneity in patient risk, severity of limb threat, and anatomy treated renders direct comparison of outcomes from the current literature challenging. Future studies should incorporate both limb severity and anatomic staging to best guide clinical decision making in CLTI.

Vein Bypass First Choice

PREDICTIVE CRITERIA
- TASC II C and D lesions
- Extensive calcification in the BTK vessels
- Extensive Gangrene and WIfI CS 3 and 4

UCBM Experience

From May 2014 to September 2018
454 pts with CLTI and advanced WIfI lesions
423 (93%) VEIN BYPASS (VB)
31 (7%) ENDOVASCULAR PROCEDURES (EVT)

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<th>EVT n (%)</th>
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<tr>
<td>2</td>
<td>8 (25)</td>
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0 10 20 30 40 50 60 70 80 90
Primary patency Secondary patency Limb salvage Survival

UCBM Experience

From May 2014 to September 2018
Mean Cumulative FU (18±7.3 months)

Characteristics and clinical outcomes of repeat endovascular therapy after infrapopliteal balloon angioplasty in patients with critical limb ischemia

Less than 50% wound healing rates and need for repeated EVT in WIfI CS 4

Calcification and ESRD are associated with repeated EVT

A severe wound needs much more stable and ample blood flow


UCBM Experience

From May 2014 to September 2018
454 pts with CLTI and advanced WIfI lesions
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Primary patency Secondary patency Limb salvage Survival
UCBM Experience

From May 2014 to September 2018
Cumulative One-Year Limb Salvage Rate for Pts with Infrapopliteal Disease and Wifi CS 3 & 4: 88%


Conclusions

Patients with Wifi Clinical Stage 3 & 4 and Infrapopliteal Disease treated by EVT need multiple interventions and have poor long term results.

Calcifications, three vessel disease and poor outflow are contraindications for EVR, but not for VB.

After multiple EV interventions an open VB is the only alternative to a major amputation.

Our data show that a primary VB is the best option for Wifi CS 3 & 4, giving far better outcomes than EVT.