BASIL 2 and 3 Trials: they will provide useful information

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I have no disclosures

BASIL-1 Trial

B-1 still the only RCT  
Primary evidence base for UK NICE national CLTI guidelines

UK NICE (2012)  
Research Questions (post BASIL-1)

What about IP disease?  
What is the role of DCB and DES in CLTI?

BASIL-1 IP Subgroup Analysis 2017

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

BASIL-1 IP: overall survival

N only 104 but P = 0.06

Vein bypass  
Δ18%

PBA  
Δ22%

HR=0.60, 95% CI: 0.36-1.02
BASIL-1 IP: relief of rest pain

**HR=2.19, 95% CI: 1.27-2.78, p=0.005**

Vein bypass

PBA Δ28%

The evidence to support PBA as the preferred first line treatment for IP CLTI in patients who can have vein bypass is weak.

BASIL-1 IP data consistently favour vein (VB) bypass and the CI’s rule out the possibility of clinically important effects in favour of PBA.

BASIL-1 IP data suggest PBA should be reserved for those who cannot have distal vein bypass.

**BASIL-2 RCT comparing VB with 'best endovascular therapy' for IP CLTI is required**

BASIL-1 IP: conclusions

Evidence for DCB/DES in CLTI

Most trials are industry sponsored
Most patients are claudicants
Most CLTI patients have rest pain only (Rutherford 4)
Highly selected (centres, patients, lesions)
Exclusions and short (incomplete) follow-up
Few “head to head” comparisons
Anatomic, not clinical, end-points
No cost-effectiveness analysis

UK NICE: no credible evidence of real world clinical benefit at current ‘willingness to pay’ thresholds; await BASIL-3 before recommending DCB/DES

**BASIL-2 – infra-popliteal (IP) SLI**

<table>
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<tr>
<th>Vein Bypass first (n = 220)</th>
<th>Best Endovascular Treatment first (n = 220)</th>
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**BASIL-3 – femoro-popliteal (FP) SLI**

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<th>PBA +/- BMS (n = 282)</th>
<th>DCB +/- BMS (n = 282)</th>
<th>DES (n = 282)</th>
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Follow-up 24-72 months
Amputation free survival
Overall Survival
Clinical end-points
Quality of revascularisation
Quality of life
Functional status
Health economic

How are we doing?

B2 – tough, surgery vs. endo, 254 randomised from a revised event-driven target of 440 (58%), results Q2 2021
B3 – easier, 3 endo arms, 273 randomised from a target of 861 (32%), results Q2 2022

Conclusions

BASIL 2 and 3 are unbiased, pragmatic RCT’s that will provide ‘real world’ evidence of clinical and cost-effectiveness of IP BET vs VB and FP PBA/BMS vs DCB/BMS vs DES

Individual patient data (IPD) meta-analysis with US NIH-funded BEST-CLI (total 3,400 patients)

RCT data (level 1 evidence) that will inform evidence-based revascularisation (EBR) globally
HTA - 12/03/45: Multicentre randomised controlled trial to compare the clinical and cost-effectiveness of a vein bypass first with an endovascular first revascularisation strategy for severe limb ischaemia due to infrapopliteal arterial disease (Bypass v Angioplasty in Severe Ischaemia of the Leg, BASSIL-2) £2.02m

http://www.nets.nihr.ac.uk/projects/hta/123545

HTA - 13/81/02: RCT of clinical and cost-effectiveness of drug coated balloons, drug eluting stents and balloon angioplasty with bail-out bare metal stent revascularisation strategies for severe limb ischaemia due to femoro-popliteal disease: BASIL-3 (Balloon vs Stenting in Severe Ischaemia of the Leg) £2.54m

http://www.nets.nihr.ac.uk/projects/hta/138102