Status of the BASIL-2 and 3 RCTs: Compares Crural Vein Bypasses with Endo Treatments; 3 compares DCBs / DESs with PTA and uncoated stents: what will they tell us and when

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Veith Symposium 2018

BASIL-2 – infra-popliteal (IP) CLTI

Vein Bypass \textit{first} (n = 300)

Best Endovascular Treatment \textit{first} (n = 300)

BASIL-3 – femoro-popliteal (FP) CLTI

PBA +/- BMS (n = 282)

DCB +/- BMS (n = 282)

DES (n = 282)

Follow-up 24-60 months

Quality of revascularisation

Quality of life

Functional status

Amputation free survival

Overall Survival

Clinical end-points

Monthly Recruitment (updated 09/11/18)

Cumulative no. of patients

Month

Recruitment

Why BASIL-2?

There is no ‘level 1’ evidence to support endovascular intervention as the preferred treatment for CLTI due to IP disease in patients who can have a vein bypass

Indeed, what data we have suggests that endovascular is \textit{unlikely to be better} and should usually be reserved for those who cannot have distal vein bypass
BASIL-1 IP: overall survival

Time to Death

\[ N \text{ only 104 but } P = 0.06 \]

<table>
<thead>
<tr>
<th>Survival Time (Years)</th>
<th>Vein Bypass</th>
<th>PBA</th>
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<tr>
<td>0</td>
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HR = 0.60, 95% CI: 0.36-1.02

B-2 Delphi Consensus Study

- 15 DSA's from patients randomised in BASIL-2
- Shown to 67 vascular surgeons and interventional radiologists
- Assumptions: fit for surgery, good vein, tissue loss
- Asked to choose between 4 options
  - Best endovascular
  - Vein bypass
  - Primary amputation
  - Equipoise – would randomise
- DSA 8 + 14 same trial patient (same images shown < 15 minutes apart)
- Only 63% respondents chose same option!! (Pearson’s χ² = 0.38 = weak)
- CLTI IP revascularisation decisions appear arbitrary

BASIL-2: quo vadis?

Recruitment difficult: lack of equipoise (but note Delphi!)
However, statistical power ↑ due to
- Slower recruitment = longer follow-up
- Higher than expected event rate (need 247 “events”)
Original target of 600 no longer required – 400?
Currently 296 randomised = 74% of anticipated target
Target = 6 / month = another 18 months (Q2 2020)
Minimum 2 year follow-up (Q2 2022)
Report results Q3/4 2022
IPD Meta-analysis with BEST-CLI in the US

Why BASIL-3?

Almost all published studies are industry sponsored
Almost all (90%) patients are claudicants
Almost all CLTI (90%) have rest pain only (no tissue loss)
Highly selected (centres, patients, lesions)
Exclusions and short (incomplete) follow-up
Anatomic >> clinical end-points
No credible evidence of clinical effectiveness in real world
(Some evidence of possible harm?)
No credible evidence of cost-effectiveness (WTPT)
Conclusions

RCTs (BASIL-2 / 3) important – NICE AAA

Small studies with conflicting data

Data to inform clinical practice is weak

Lack of consensus on best therapy

Require on-going support to complete

Trial Information


BASIL-3: quo vadis?

Currently 404

47% of 861

Recruitment ↓

Follow-up ↑

Event rate ↑

Overpowered?

600?

15/month = Q2 2021

2 year FU = Q2 2023

Report Q4 2023

But if 600, not 861

Q4 2021?