Findings From BASIL-3, An RCT Comparing Clinical And Cost Effectiveness Of 3 Treatment Modalities For CLTI From FemPop Disease: POBA Versus DCBs Versus DESs

Andrew Bradbury on behalf of the BASIL-3 Investigators

Wednesday November 2020, 2024, 4:04 PM - 4:09 PM

I have no disclosures

VEITH SYMPOSIUM Connecting The Vascular Community 51st

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BASIL-3 BASIL-2 BCTU Birmingham Clinical Trials Unit

BASIL-3

35 UK vascular centres randomised 481 CLTI patients who had been offered an endovascular first FP+/-IP revascularisation strategy to either FP:

PBA*+/-BMS*	DCBA*+/-BMS*	DES
(n = 160)	(n = 161)	(n = 160)

Three arm trial as DCBA and DES are very different technologies

Primary outcome **amputation free survival (AFS)**

Minimum follow-up 2 years

BASIL-3 Statistical Considerations

We performed **two** time-to-event analyses (97.5% CI) comparing:

- PBA +/- BMS vs. DCBA +/- BMS
- PBA +/- BMS vs. DES

Anticipated PBA +/- BMS outcomes were based on the BASIL-1 trial

We assumed a 5% attrition rate for the primary outcome (was only 1.5%)

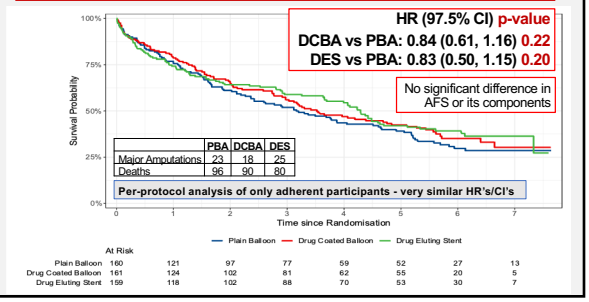
The *a priori* effect size was a 40% relative reduction in "no-AFS"

= an absolute reduction in "no-AFS" of 13% at two years (NNT = 7)

For 90% power, we required 291 primary events (296 were observed)

BASIL-3 power > 90%

BASIL-3 Amputation Free Survival (ITT)



BASIL-3 Health Economics

We performed a within trial HE analysis

Minimal incremental differences in costs and outcomes in terms of:

- QALY's (out to 2 years) in the cost utility analysis (CUA)
- AFLY's (out to 7 years) in the cost effectiveness analysis (CEA)

Overall:

- DCBA unlikely to be cost-effective compared to PBA
- DES *potentially* cost-effective compared to PBA (but only at high WTPT)

Findings generally consistent:

- over different clinical scenarios
- across different patient sub-groups

BASIL-3 Conclusions

Power > 90%, long (median 5.7 years) and complete (98.5%) follow-up

BASIL prospective cohort study (PCS) shows good generalisability with a high proportion of eligible patients being randomised

Outcomes very likely to be a realistic representation of what can be reasonably achieved with these technologies across the UK NHS

Neither DCBA nor DES, when used in the FP segment:

- conferred significant clinical benefit over PBA, and neither
- were cost-effective at NICE UK WTPT

NNTB: 24 DCBA, 32 DES at the 2-year time point

BASIL-3 does not support the use of DCBA or DES in the FP segment in CLTI patients within the UK NHS


BASIL-3
FUNDED BY
NIHR | National Institute for Health and Care Research
https://fundingawards.nihr.ac.uk/award/12/35/45
Thank you
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