



S T A R S
St Thomas' Advanced Revascularisation Symposium



BASIL 2 Trial: Up-date

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Friday 3 June 2016, 15.30-15.40

NHS
*National Institute for
Health Research*

Heart of England
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Research programmes

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HTA - 12/35/45: 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 infrageniculate arterial disease (Bypass v Angioplasty in Severe Ischaemia of the Leg, BASIL-2)

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

£2.02m



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

Vein Bypass *first*
(n = 300)

**Best Endovascular
Treatment *first* (n = 300)**

BASIL Centres

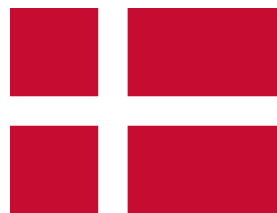


UK = 49

The outer Islands



Denmark = 1





Why B-2?

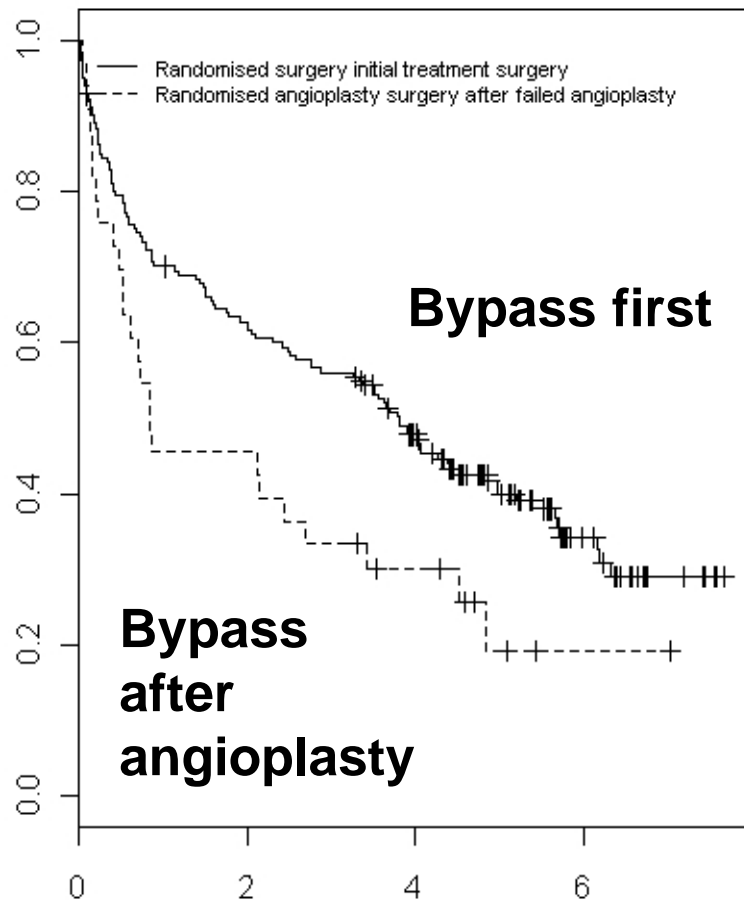


“Why do we need BASIL-2 when it is *obvious* that endovascular revascularisation is the best strategy for almost all patients requiring infra-popliteal intervention for SLI?”

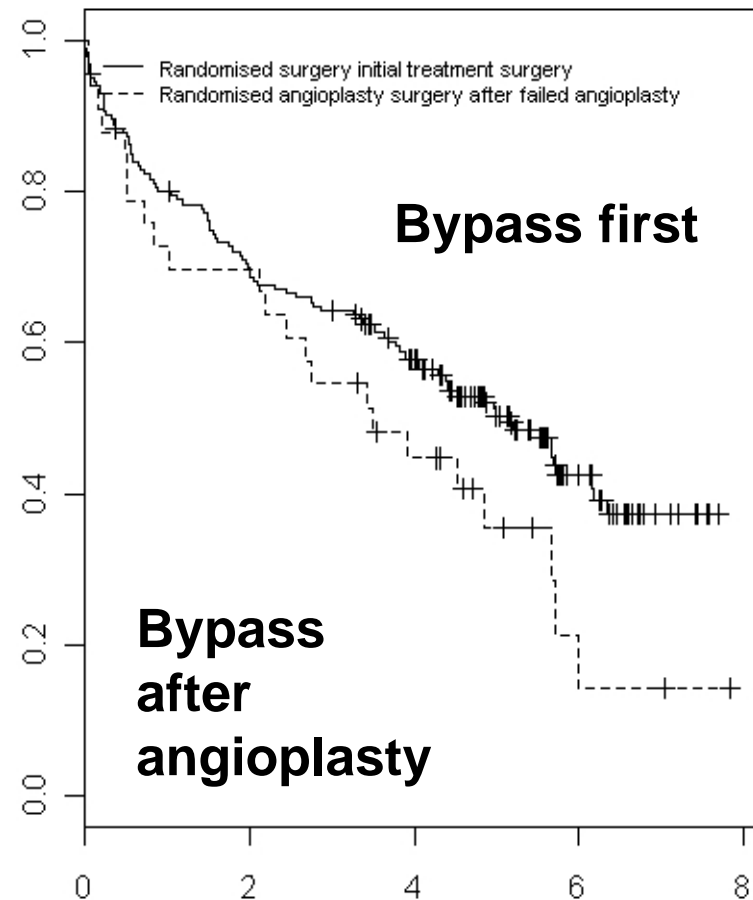
(i.e. reserve surgery for “endo-impossibles” and “endo-failures”)

Reason 1: in BASIL-1 bypass after “endo-failure” was much less successful than primary bypass
So, endovascular is not a “free shot”

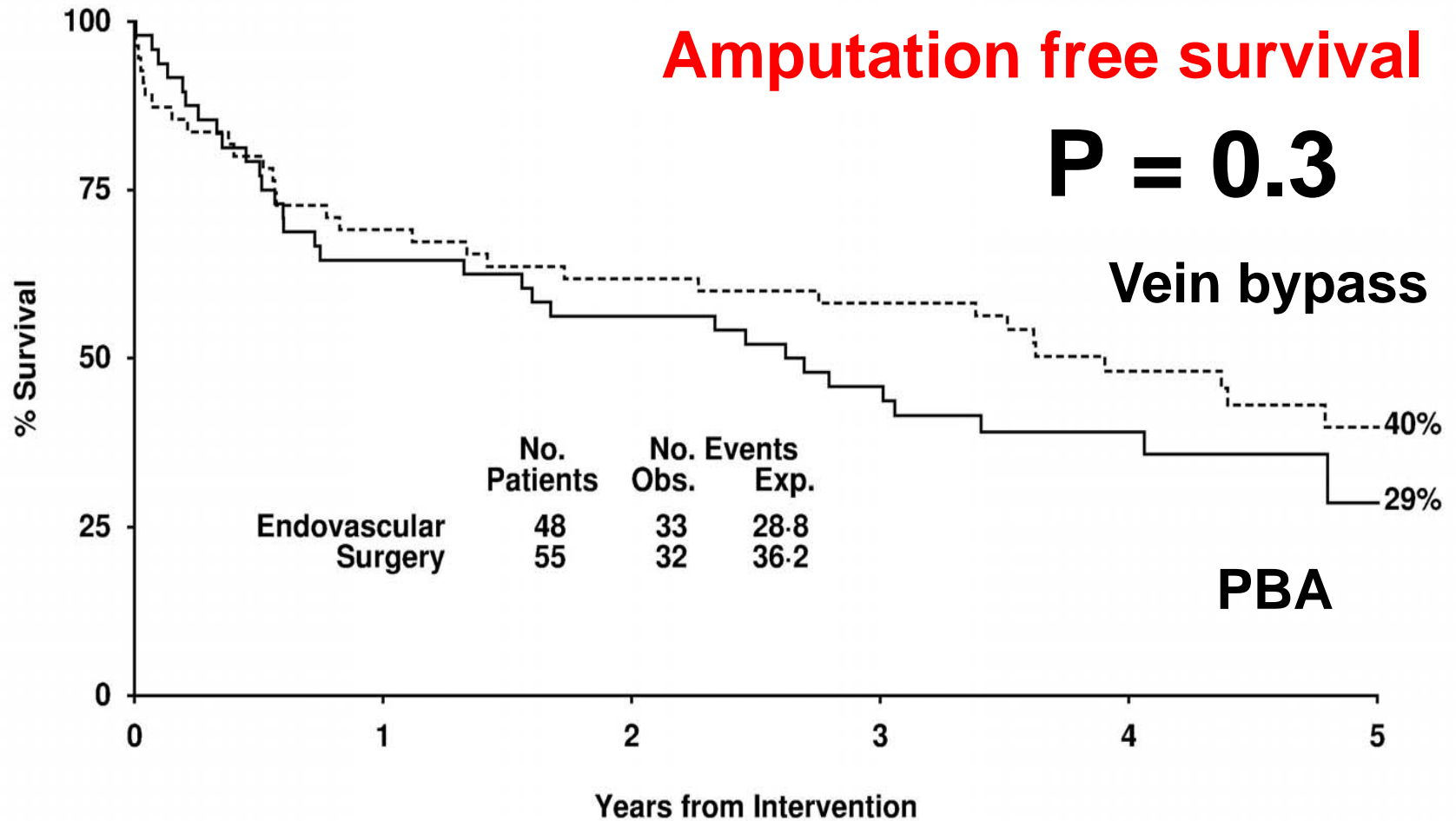
Amputation free survival



Overall survival



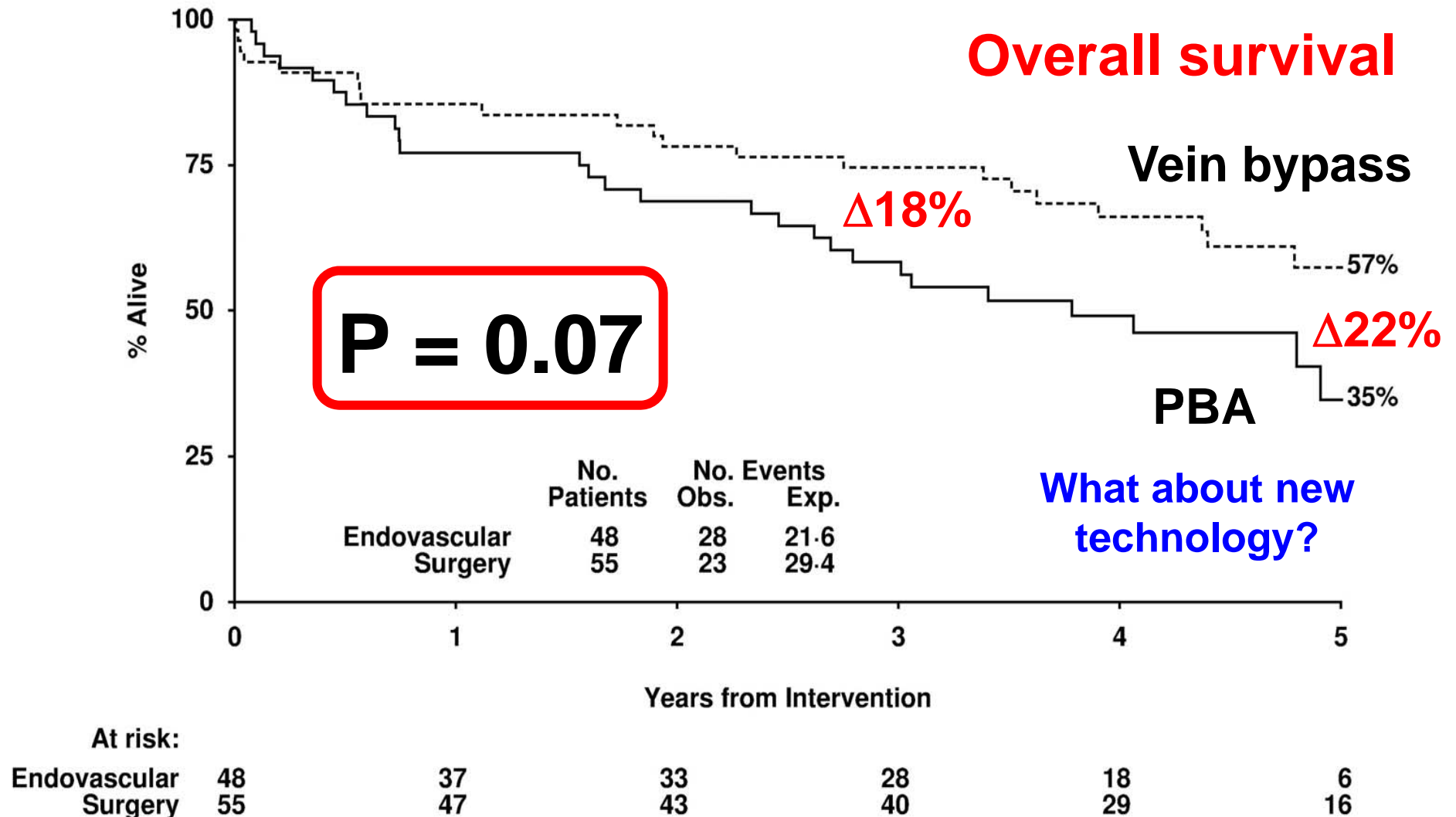
Reason 2: In BASIL-1, IP vein bypass (VB) and IP plain balloon angioplasty (PBA) were similar in terms of amputation free survival (AFS)



At risk:

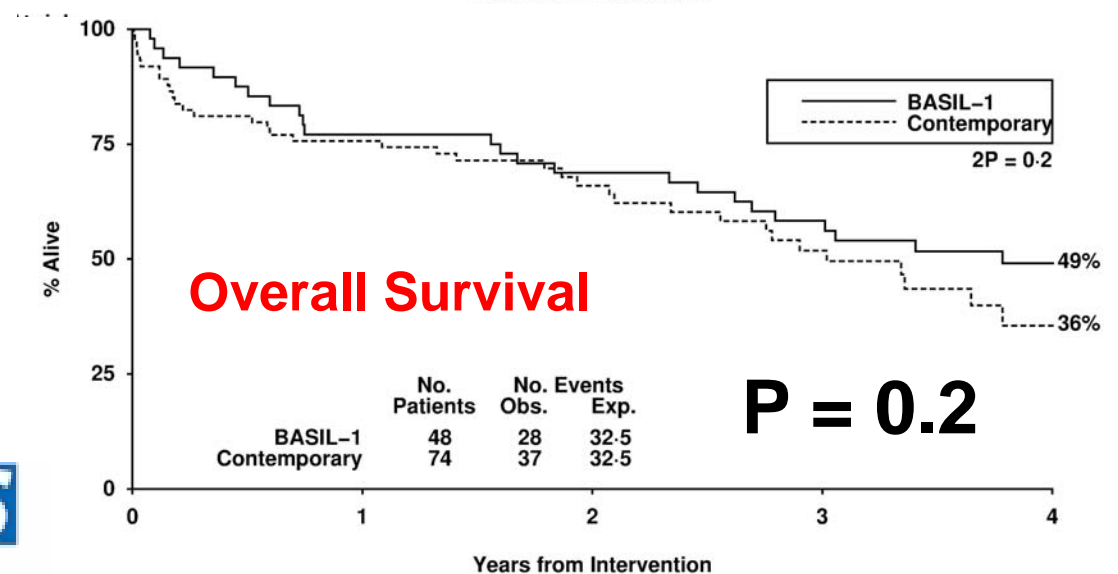
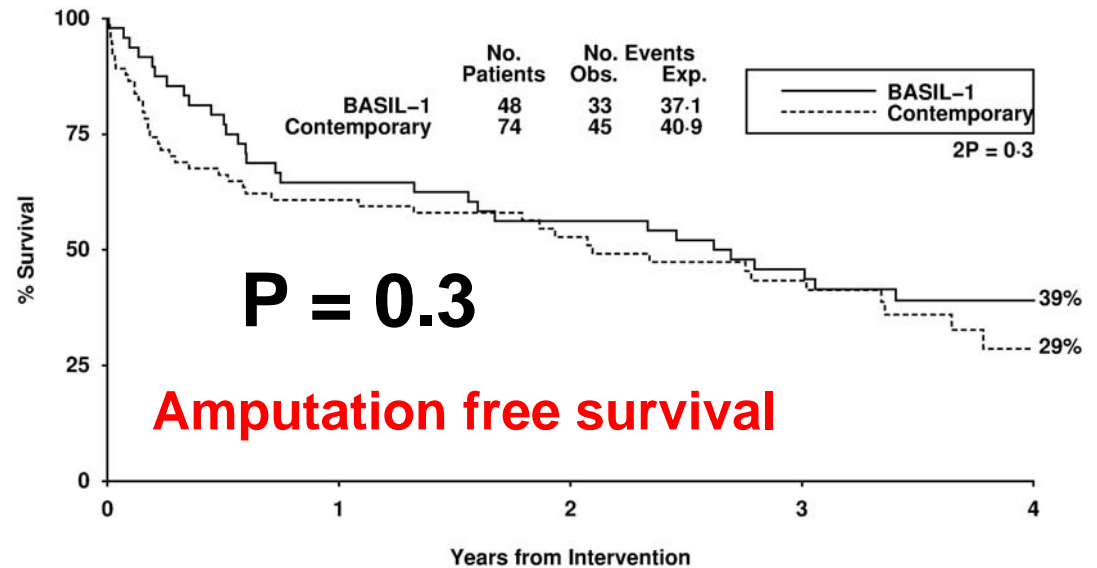
Endovascular	48	31	27	22	13	4
Surgery	55	38	34	32	22	12

But, in BASIL-1, IP VB was much better than IP PBA in terms of overall survival



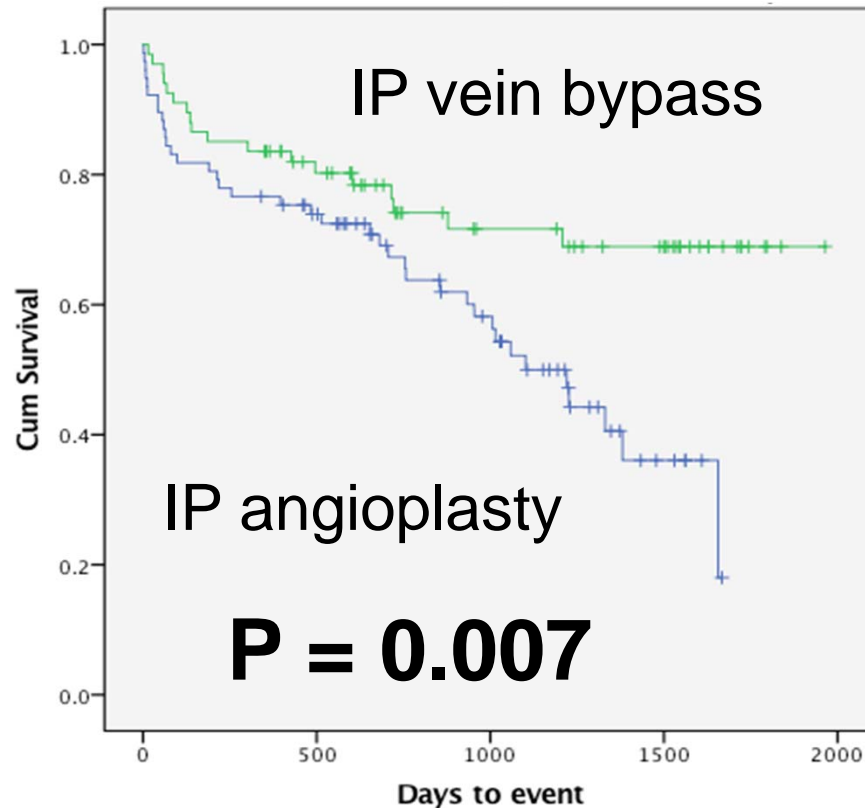
Reason 3: outcomes following IP endovascular intervention have not improved since B1?

Despite fewer technical failures, AFS and OS after IP endovascular intervention in our unit (HEFT) are currently (2009-2014) no better than those observed in BASIL-1 (1999-2004)

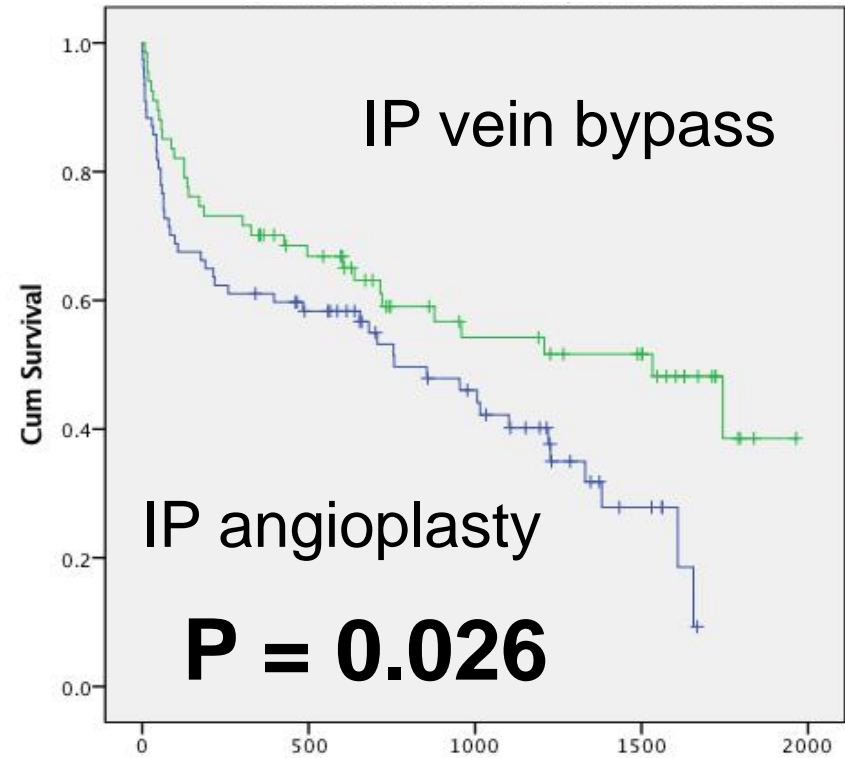


Reason 4: Outside BASIL-2, at HEFT, contemporary (2009-2014) IP vein bypass is highly significantly better than IP endovascular intervention

Overall survival



AF Survival



Heart of England



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Conclusions

- In B-1, bypass after failed PBA was much less successful than primary bypass (AFS / OS)
- In BASIL-1, IP PBA and vein bypass resulted in similar AFS but there was a strong trend (**p = 0.07**) towards better OS with IP vein bypass
- Contemporary IP 'best endovascular treatment' (BET) at HEFT is not more clinically successful than IP PBA in BASIL-1 (AFS / OS)
- Outside trial, at HEFT, contemporary IP VB is highly superior to BET (AFS **p = 0.026**, OS **p = 0.007**)