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A comparison of clinical outcomes between primary bypass versus secondary bypass after failed plain balloon angioplasty in the Bypass versus Angioplasty for Severe Ischaemia of the Limb (BASIL) trial

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ABSTRACT

Introduction: Chronic limb threatening ischaemia (CLTI) is a growing global health problem. The UK NIHR HTA-funded BASIL trial is still the only randomised controlled trial to have compared a bypass surgery first with a plain balloon angioplasty (PBA) first strategy for the management of CLTI. In patients who were likely to survive for 2 years and had a suitable vein, primary bypass (PB) was associated with better clinical outcomes. Furthermore, PBA was associated with a high technical and clinical failure rate and many went on to have secondary bypass (SB).

Aim: To compare clinical outcomes following PB and SB in the BASIL trial.

Methods: Demographic, procedural and outcome data were obtained from the BASIL case report forms. Outcomes were amputation free survival (AFS), limb salvage (LS), overall survival (OS), and freedom from revascularisation (FFR). The SB cohort comprises patients whose first trial intervention was PBA and subsequently underwent bypass during follow-up. The PB cohort comprises those patients whose first trial intervention was bypass.

Results: The 190 PB and 49 SB patients were well matched except that the SB patients were more likely to be current smokers. At a median of 7 years, PB was associated with better AFS (PB 60% vs SB 40%; HR=1.58, p=0.04), LS (PB 85% vs SB 73%, p=0.06), and OS (PB 68% vs 51%, p=0.06). FFR was equivalent (PB 53% vs 53%, p=0.3).

Conclusion: In the BASIL trial, clinical outcomes following PB were significantly better than in patients undergoing SB after failed PBA. Prior to treating patients with CLTI with primary PBA, clinicians should consider that if this should fail, the outcome of attempted subsequent bypass is likely to be significantly worse than if PB were attempted.

INTRODUCTION

Although chronic limb threatening ischaemia (CLTI) is a growing global health problem [1,2], the evidence underpinning the choice of revascularisation strategy remains poor. The UK NIHR HTA-funded Bypass versus Angioplasty for Severe Ischaemia of the Limb (BASIL) trial remains the only randomised controlled trial (RCT) to have compared a 'bypass surgery first' with a 'plain balloon angioplasty (PBA) first' strategy for CLTI due to infra-inguinal disease [3]. An intention to treat analysis (ITT) of BASIL outcome data showed that, in patients who were likely to survive for at least 2 years and who had a suitable vein; primary bypass (PB) was led to better clinical outcomes than primary PBA. Furthermore, primary PBA was associated with a high technical and clinical failure rate such that many of the patients went on to have secondary bypass (SB). Despite this 'level 1' evidence in support of surgical bypass as the preferred revascularisation strategy for patients with a suitable vein, enthusiasm for an endovascular-first approach to most, perhaps even all, patients with CLTI continues to grow [4]. As a result, vein bypass is increasingly being viewed as a secondary, salvage procedure to be performed when all endovascular revascularisation options have been exhausted [5,6]. There are surprisingly few published reports of outcomes following SB for failed endovascular revascularisation. Furthermore, in the few studies that are available, patient numbers are often small, patients were not randomised, and patients with intermittent claudication and CLTI are often conflate [7,8,9]. This topic was briefly reported in the analysis by treatment received, only SB within 8 weeks of primary PTA were included and only AFS was reported but no further in depth analyses were performed[10]. The aim of this study, therefore, was to compare clinical outcomes following PB and all SB after failed primary PBA in the BASIL trial.

METHOD

The BASIL trial methodology has been published previously[3]. Ethical approval was obtained from the Multi-Centre Research Ethics Committee for Scotland. Briefly, patients with CLTI due to infra-inguinal disease were randomised to either a PB or primary PBA revascularisation strategy between 1999 and 2004. Patients were followed up until death or the censor date of 1 July 2007. This provided all surviving patients with a minimum of 3 years follow-up (median 51, range 0-92, months).

BASIL trial case report forms (CRF) were interrogated to obtain demographic, procedural and outcome data including amputation free survival (AFS), limb salvage (LS), overall survival (OS), and freedom from re-intervention (FFR) defined as any further revascularisation of the index limb. The SB cohort comprises patients whose first trial intervention was PBA and who subsequently underwent SB (with any conduit) at any point during trial follow-up. The PB cohort comprises those patients whose first trial intervention was PB with any conduit. Time to event analyses are presented over a 7-year period using Kaplan-Meier plots. Hazard ratios were used to detect statistically important differences in outcomes using 95% confidence intervals. Differences between the cohorts were compared using t-test, chi-squared and Wilcoxon Rank Sum tests according to distribution of data. Statistical analysis was performed using SAS v 9.4.

RESULTS

There were 238 attempted primary PBA in the BASIL trial; of these, 69 patients went on to have a secondary intervention, 17 had a tertiary intervention and 7 had a fourth intervention. 25 (36.2%) of the secondary interventions were PBA; of these, 3 (12%) subsequently underwent SB. The remaining 46 SB's were performed after failed primary PBA. In BASIL, 190 patients underwent PB.

The 190 PB and the 49 SB patients were well matched at the time of randomisation in terms of baseline demographics except that the SB patients were more likely to be current smokers (**Table 1**). Medical management was also similar (**Table 2**). 49% (24/49) of those who went on to have SB had a technically successful primary PBA. Tissue loss was present in most patients in both groups (ulcer 62% vs 69% p=0.3, gangrene 34% vs 29% p=0.5). The median time interval between primary PBA and SB was 0 months (range 0-20 months). Of those who underwent PB, 9.5% (18/190) underwent secondary PTA, 94.4% (17/18) of these were for vein graft stenosis and 100% survived with their limb at the end of trial follow up.

At a median of 7 years, PB was associated with significantly better AFS (PB 60% vs SB 40%; HR=1.58, 95% CI: 1.03-2.44, p=0.04). Although LS and OS did not reach statistical significance there was a trend to better outcomes in the PB group (LS; PB 85% vs SB 73%; HR=1.86, 95% CI: 0.97-3.58, p=0.06, and OS; PB 68% vs 51%; HR=1.57, 95% CI:0.97-2.54, p=0.06). FFR was the same in both groups (PB 53% vs 53%; HR=1.43, CI:0.74-2.74, p=0.3) except that, of course, by definition, those patients undergoing SB were all undergoing a re-intervention (**Figures 2-5**).

Procedural data were available for all patients who underwent SB (**Table 3**). All SB were deemed technically successful at the end of the procedure. Four (8%) SB were prosthetic compared with 22% (41/190) PB (p=0.03). Absolute amputation rate to end of follow up was 15.3% vs 26.5% (p=0.06). The distal anastomosis was not statistically different between PB and SB with 68% (130/190) vs 64% (31/49) being to the popliteal artery (p=0.4). There was no significant difference between PB and SB in terms of 30-day morbidity and mortality (**Table 4**).

DISCUSSION

In the BASIL trial, 190 patients underwent PB and, of the 238 patients who underwent an attempt at primary PBA, 49 (21%) went on to require a SB at some point during the trial follow-up. The key finding of the present study is that PB was associated with statistically significant better AFS and a strong trend ($p = 0.06$) towards better LS and OS. We accept the SB group are a group of failures which suggests they are different to the PB group, the challenge for this analysis is to identify why? We also accept the BASIL trial was not powered to investigate this relationship, nevertheless it is an important relationship that is poorly understood. The two cohorts were well matched in terms of baseline demographics and medical therapy at randomization, PB patients were more likely to be current smokers and have a history of TIA, however we note this group was observed to have better clinical outcomes. This suggests the observed differences are not related to the patient's medical characteristics. Anatomical burden of disease is certainly influential in type of revascularization required and outcome of said intervention. Bollinger analysis of these groups suggests there is no difference in burden or distribution of disease between these groups.

The appropriateness of the observed trend in recent years towards an endovascular first strategy for most, perhaps even all, CLTI is now being challenged [11-13]. However, although several groups have reported outcomes following PB and primary endovascular revascularisation, few have analysed the effect of failed endovascular intervention on the success of SB. But, these reports, taken with the data from the BASIL trial presented here, indicate that primary endovascular intervention is not the "free shot" that it has so often been claimed to be.

Although BASIL trial data are often said to be outdated and so no longer relevant to current practice, in reality, there is no evidence that that is the case[14]. For example, Darling and colleagues recently studied 2869 patients undergoing lower limb revascularisation for CLTI and concluded that PB resulted in better outcomes in wound healing, FFR and OS; and that patients undergoing SB had higher rates of further intervention[15]. In another study, Jones and co-workers analysed 1154 CLTI patients undergoing SB and concluded these patients had worse MALE, FFR, OS and AFS[16].

Interestingly, although more BASIL patients in the PB group underwent synthetic bypass (PB 22% SB 8%), overall, the clinical results of PB were far superior to those observed after SB. In the UK, synthetic grafts are almost always reserved for those patients with no usable leg or arm vein [17-19]. As such, it could be argued patients undergoing prosthetic bypass should have been removed from this analysis. However, we decided to include them as a proportion CLTI patients requiring bypass will

not have useable vein. Approximately a third of the patients in each group underwent infra-popliteal bypass and so we can discount this as a cause of the differences observed between PB and SB.

Going forward, it will be important to determine if drug coated balloons and drug eluting stents will increase the clinical success of primary endovascular intervention for CLTI. The on-going UK NIHR HTA funded BASIL 2 and 3 trials [20,21], and US NIH funded BEST CLI trial[22], will together recruit more than 3,500 CLTI patients undergoing PB and primary endovascular intervention and will address this and many other important question so informing evidence-based revascularisation (EBR).

Conclusion

In the BASIL trial, clinical outcomes following PB were significantly better than in patients undergoing SB after failed PBA. Prior to treating patients with CLTI with primary PBA, clinicians should consider that if this should fail, the outcome of attempted subsequent bypass is likely to be significantly worse than if PB were attempted.

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TABLES

Table 1. Comparison of primary and secondary bypass patients in the BASIL trial

		Primary Bypass	Secondary Bypass	p-value
Number of Patients		190	49	
Age (years)	Mean (SD)	72 (9.3)	73 (7.3)	0.4
	Range	39 – 98	58 – 87	
Gender	Male	127 (66%)	28 (57%)	0.2
Limb	Left	105 (55%)	27 (55%)	1.0
	Right	85 (45%)	22 (45%)	
ABPI	Mean (SD)	0.5 (0.18)	0.48 (0.11)	0.5
Smoker	Never	30 (16%)	12 (24%)	**0.05**
	Ex	86 (45%)	13 (27%)	
	Current	74 (39%)	24 (49%)	
Diabetes	No	113 (60%)	23 (47%)	0.2
	IDDM	31 (16%)	12 (24%)	
	NIDDM	46 (24%)	14 (29%)	
Hypercholesterolemia	No	45 (24%)	11 (22%)	0.6
	Yes, untreated	22 (11%)	3 (6%)	
	Yes, treated	66 (35%)	17 (35%)	
	No record of assessment	57 (30%)	18 (37%)	
Hypertension	No	77 (41%)	19 (39%)	0.8
	Yes, untreated	12 (6%)	2 (4%)	
	Yes, treated	101 (53%)	28 (57%)	
Mobility	Independent	91 (48%)	22 (45%)	0.8
	Cane	79 (41%)	22 (45%)	
	Prosthesis	2 (1%)	1 (2%)	
	Wheelchair	13 (7%)	4 (8%)	
	Bed bound	5 (3%)	0 (-)	
Myocardial Infarction	Yes	26 (14%)	8 (16%)	0.6
Angina	No	153 (81%)	44 (90%)	0.2
	Yes, on exercise	31 (16%)	3 (6%)	
	Yes, at rest	6 (3%)	2 (4%)	
TIA	Yes	19 (10%)	1 (2%)	**0.07**
Stroke	Yes	25 (13%)	6 (12%)	0.9
Rest Pain	Yes	170 (89%)	45 (92%)	0.6
Ulcer	Yes	117 (62%)	34 (69%)	0.3
Gangrene	Yes	64 (34%)	14 (29%)	0.5
Creatinine	N	186	45	
	Mean (SD)	116 (79.4)	111 (62.0)	0.7
	Range	50 – 702	40 – 452	

Abbreviations

IDDM - Insulin Dependent Diabetes Mellitus

NIDDM - Non-Insulin Dependent Diabetes Mellitus

TIA - Transient Ischaemic Attack
ABPI - Ankle Brachial Pressure Index

Table 2. Medical management in patients undergoing primary and secondary bypass in BASIL

		Primary Bypass	Secondary Bypass	p-value
Number of Patients		190	49	
Antiplatelet	None	52 (27%)	17 (35%)	0.2
	Single	111 (59%)	24 (49%)	
	Double	2 (1%)	1 (2%)	
	Antiplatelet + Other	15 (8%)	1 (2%)	
	Other	10 (5%)	6 (12%)	
Antihypertensive	None	81 (43%)	18 (37%)	0.3
	One	53 (28%)	19 (39%)	
	Two	40 (21%)	6 (12%)	
	Two or more	16 (8%)	6 (12%)	
Statin	None	123 (65%)	31 (63%)	0.8
	Yes	67 (35%)	18 (37%)	
Diabetes Treatment	None	131 (69%)	25 (51%)	0.1

Table 3. Frequencies of proximal and distal anastomosis location for primary and secondary bypass.

		Primary Bypass	**Secondary Bypass**	**p-value**
Number of Patients		190	49	
Distal Anastomosis	Not Known	2 (1%)	0 (-)	0.4
	AKPA	63 (33%)	10 (20%)	
	BKPA	67 (35%)	21 (44%)	
	PTA	17 (9%)	2 (4%)	
	ATA	20 (11%)	9 (18%)	
	PA	17 (9%)	6 (12%)	
	DP	2 (1%)	0 (-)	
	TPS	1 (0.5%)	1 (2%)	
	DPP	1 (0.5%)	0 (-)	
Conduit	Vein	149 (78%)	45 (92%)	0.03
	Synthetic	41 (22%)	4 (8%)	

Abbreviations
AKPA - Above Knee Popliteal Artery
BKPA - Below Knee Popliteal Artery
PTA - Posterior Tibial Artery
ATA - Anterior Tibial Artery
PA - Peroneal Artery
DP - Dorsalis Pedis
TPS - Tibial Peroneal Stem
DPP - Dual Popliteal and Pedal

Table 4: Mortality and morbidity (30 days) in patients undergoing primary and secondary bypass in BASIL

	Primary Bypass	**Secondary Bypass**	**p-value**
Number of Patients	190	49	
Angina	2 (1%)	0 (-)	0.5
MI	8 (4)	2 (4)	1.0
TIA	0 (-)	0 (-)	-
CVA	1 (0.5%)	1 (2%)	0.3
Haematoma (no surgery)	8 (4%)	1 (2%)	0.5
Haematoma (surgery)	3 (2%)	0 (-)	0.4
LRTI	6 (3%)	1 (2%)	0.7
UTI	9 (5%)	1 (2%)	0.4
False Aneurysm (no surgery)	1 (0.5%)	0 (-)	0.6
False Aneurysm (surgery)	0 (-)	0 (-)	-
30 Day Mortality	11 (6%)	4 (8%)	0.5
30 Morbidity & Mortality	83 (44%)	19 (39%)	0.5
MACE	17 (9%)	6 (12%)	0.5

Abbreviations

MI – Myocardial Infarction
TIA - Transient Ischaemic Attack
CVA - Cerebro-Vascular Accident
LRTI - Lower Respiratory Tract Infection
UTI - Urinary Tract Infection
MACE - Major Adverse Cardiac Event

Table 5. A comparison of Bollinger scores between primary and secondary bypass.

SEGMENT	STATS	PB	SB	P-VALUE
Profunda	MEAN (SD)	2.4 (3.4)	2.5 (3.6)	0.828
Proximal SFA	MEAN (SD)	6.7 (5.6)	5.8 (5.3)	0.3
Distal SFA	MEAN (SD)	9.2 (5.4)	10.4 (5.0)	0.2
Proximal POP	MEAN (SD)	6.6 (5.7)	7.3 (6.3)	0.5
Distal POP	MEAN (SD)	3.7 (5.1)	3.7 (5.1)	1.0
TPT	MEAN (SD)	4.1 (5.8)	2.8 (5.0)	0.2
Proximal PT	MEAN (SD)	8.5 (7.0)	8.7 (7.0)	0.9
Distal PT	MEAN (SD)	9.7 (6.5)	9.2 (6.9)	0.7
Proximal AT	MEAN (SD)	6.9 (6.5)	8.5 (7.0)	0.2
Distal AT	MEAN (SD)	7.3 (6.9)	8.7 (7.0)	0.3
Proximal PERO	MEAN (SD)	4.8 (5.8)	4.2 (5.9)	0.6
Distal PERO	MEAN (SD)	5.5 (6.5)	2.2 (5.0)	**0.005**
Total FP score	MEAN (SD)	25.7 (9.9)	26.3 (9.0)	0.7
Total IP score	MEAN (SD)	45.3 (24.8)	46.3 (26.6)	0.8
Total score	MEAN (SD)	71.1 (26.4)	72.7 (26.6)	0.8

Abbreviations

SFA – Superficial Femoral Artery
POP - Popliteal Artery
TPT - Tibio-Peroneal Trunk

PT	–	Posterior Tibial Artery
AT	-	Anterior Tibial Artery
PERO	-	Peroneal Artery
SD	-	Standard Deviation

FIGURES

Figure 1. Comparison of amputation free survival in patients undergoing primary and secondary bypass in the BASIL trial

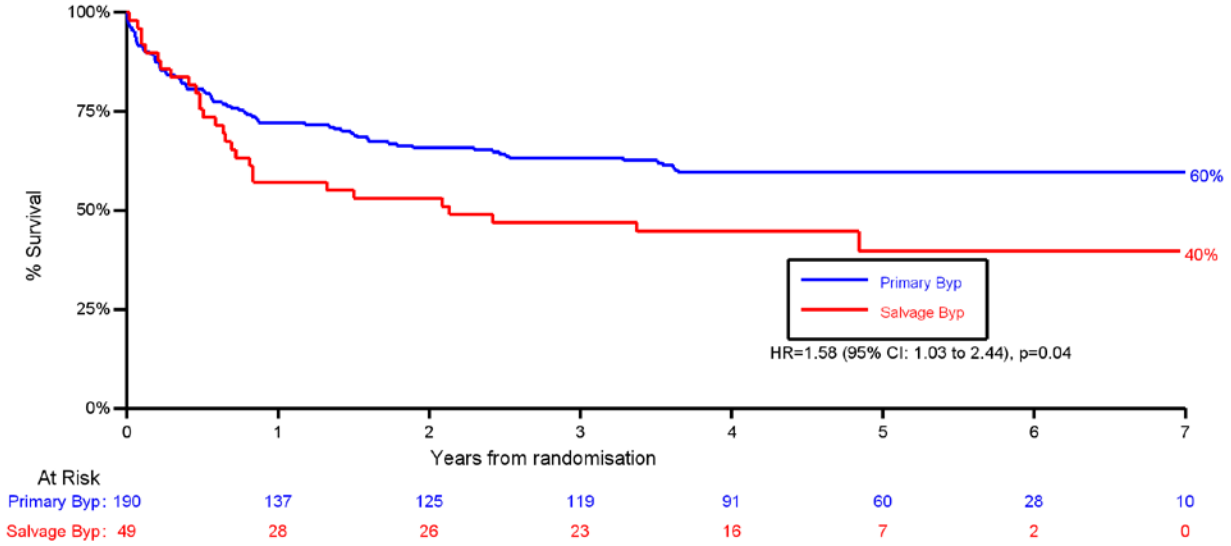

Figure 2: Comparison of limb salvage in patients undergoing primary and secondary bypass in the BASIL trial

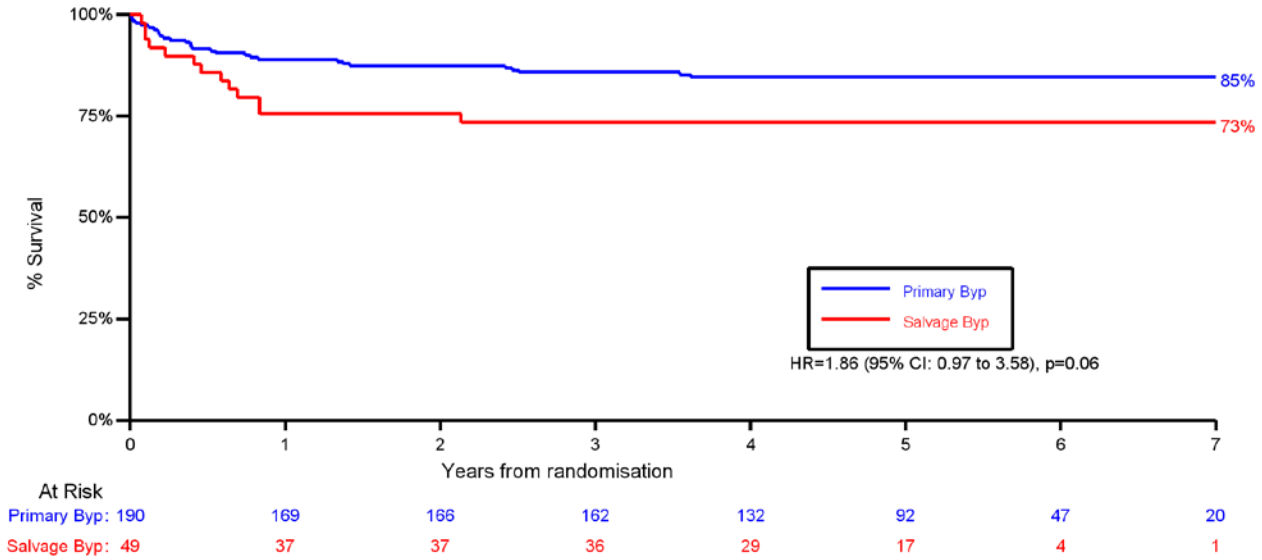

Figure 3: Comparison of overall survival in patients undergoing primary and secondary bypass in the BASIL trial

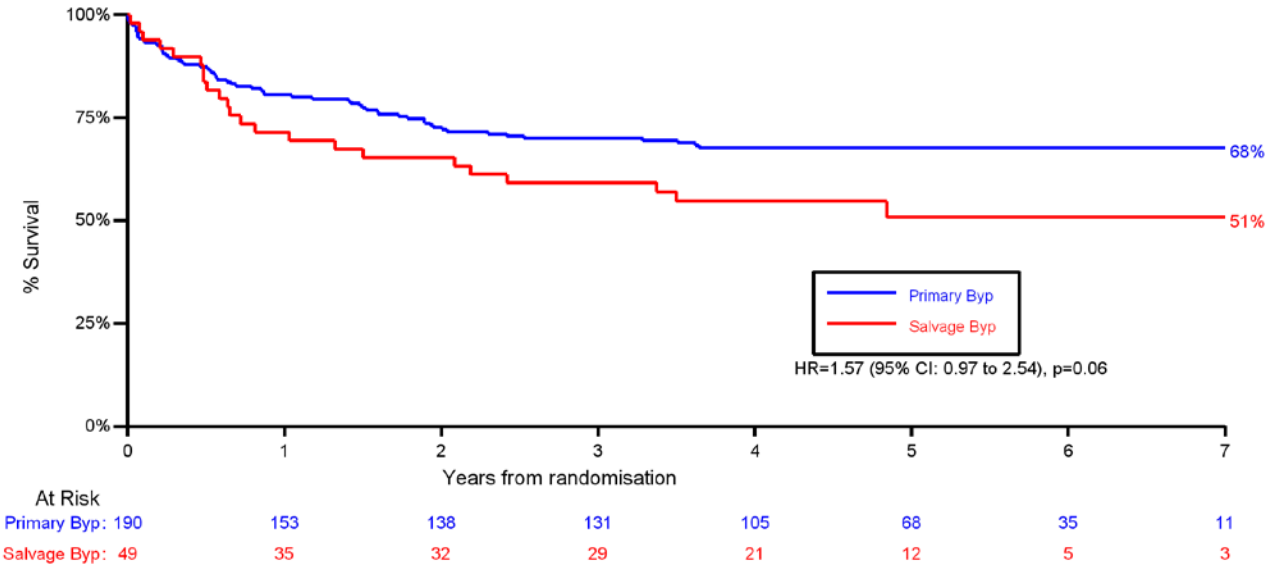

Figure 4: Comparison of freedom from re-intervention in patients undergoing primary and secondary bypass in the BASIL trial