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A comparison of clinical outcomes following femoro-popliteal bypass or plain balloon angioplasty with selective bare metal stenting in the Bypass versus Angioplasty in Severe Ischaemia of the Limb (BASIL) trial

L. Meecham[1], G. Bate[1], S. Patel[2], A.W. Bradbury[1]

[1] Department of Vascular Surgery, [2] Birmingham Clinical Trials Unit, University of Birmingham

Corresponding Author: Mr Lewis Meecham

University Department of Vascular Surgery

Netherwood House

Solihull Hospital

Lode Lane

Solihull

Birmingham

B91 2JL

WHAT THIS PAPER ADDS

This by treatment received analysis of data from the publicly-funded, BASIL-1 randomised controlled trial confirms the superiority of bypass over plain balloon angioplasty, with or without bare metal stenting, in patients with chronic limb threatening ischaemia (CLTI) who require femoro-popliteal intervention. Although the interventions were carried between 1999 and 2003, there are no more recently acquired randomised data that contradict the findings presented here. BASIL-1 trial data therefore remain an important and relevant standard with which to compare outcomes in current vascular and endovascular practice and the results of on-going, publicly funded, pragmatic randomised controlled trials such as BASIL-2, BASIL-3 and BEST-CLI.

ABSTRACT

Objective: To compare outcomes in patients with chronic limb threatening ischaemia (CLTI) due to femoro-popliteal (FP), with or without infra-popliteal (IP), disease who underwent FP (vein or synthetic) open surgical bypass (OSB) or plain balloon angioplasty (PBA), with or without bare metal stenting (BMS), in the Bypass versus Angioplasty in Severe Ischaemia of the Limb (BASIL-1) trial.

Method: Data were extracted from BASIL-1 case record forms. Outcomes reported include immediate technical success, freedom from major adverse limb events (FF-MALE) and further re-intervention (FF-R), amputation free survival (AFS), overall survival (OS), and limb salvage (LS).

Results: Patients underwent primary OSB (n = 128; 89 vein, 39 synthetic) or primary PBA (n = 183; 6 had BMS). Mean follow-up was 46.2 and 43.6 months respectively. Patients were well matched at baseline except that PBA +/- BMS patients were significantly more likely to be current smokers. There was no difference in overall or IP (run-off) Bollinger angiogram scores between groups. Immediate technical success was significantly higher for OSB (98% vs. 81%, $p<0.0001$). OSB was associated with a longer mean index hospital admission ($p=0.001$) but there was no difference in hospital days at 12 months. FF-MALE (HR 1.51, $p=0.04$) and FF-R (HR=1.68, $p=0.02$), but not AFS (HR 1.18, $p=0.4$), OS (HR 1.14, $p=0.5$) and LS (HR 1.09, $p=0.8$) were significantly better following OSB.

Conclusion: Although AFS, OS and LS were similar in the two groups, OSB was associated with significantly fewer MALE and re-interventions. So, while PBA +/- BMS may be a less resource intensive (expensive) and morbid option in the short term, this appears unlikely to be the case in the longer term. Present data add further weight to the argument that, where possible, patients presenting with CLTI due to FP disease should be offered OSB as their primary revascularisation procedure.

INTRODUCTION

The Bypass versus Angioplasty for Severe Ischaemia of the Leg trial, now known as the BASIL-1 trial, remains the only published randomised controlled trial (RCT) to have compared an open surgical bypass (OSB) first, with a plain balloon angioplasty, with or without bare metal stenting, (PBA +/- BMS) first revascularisation strategy for chronic limb threatening ischaemia (CLTI) due to infra-inguinal disease[1,2]. In BASIL-1, approximately 75% of patients had predominantly femoro-popliteal (FP) disease and intervention while in about 25% the disease and intervention were predominantly infra-popliteal (IP). A recently published BASIL-1 IP sub-group analysis showed that, when compared to PBA (no IP BMS were used), a vein bypass (VB) first strategy resulted in better overall survival (OS), amputation-free survival (AFS), and quality of revascularisation (time to wound healing and relief of ischaemic rest pain)[3]. Despite BASIL-1, the only currently available 'level 1' evidence, showing better long-term clinical outcomes following OSB, there has nevertheless been a non-evidence-based trend towards offering primary endovascular intervention to patients with CLTI due to FP disease. The aim of this BASIL-1 sub-group analysis, therefore, is to compare outcomes in patients who underwent FP OSB (VB and synthetic, SynB) or PBA +/- BMS as their primary revascularisation procedure.

METHOD

BASIL-1 trial

BASIL-1 methods and ethical approvals have been published previously[4]. In brief, between August 1999 and June 2004, 452 patients with CLTI due to infra-inguinal disease were randomised to an OSB first or a PBA +/- BMS first revascularisation strategy. Patients were eligible for trial inclusion if the responsible clinicians felt that they required early revascularisation and were in clinical equipoise OSB and PBA +/- BMS. Patients were followed up by six dedicated research nurses at 1, 3, 6, and 12 months post randomisation and then annually until death or 1 July 2007. The primary endpoint was amputation free survival (AFS) and secondary end-points included overall survival (OS), limb salvage (LS) and requirement for re-intervention. BASIL-1 was a multi-centre, pragmatic, clinical effectiveness RCT that allowed participating units to continue to use their preferred post-intervention surveillance programmes. However, the majority of the re-interventions were due to persisting or recurrent symptoms and signs of CLTI.

Inclusion criteria for FP subgroup analysis

In order to be included in the current sub-group analysis, BASIL-1 patients had to fulfil two criteria. Firstly, they had to have atherosclerotic FP disease causing CLTI and, secondly, they only underwent intervention to the FP segment (with no IP intervention). Baseline and clinical outcome data were extracted from the original prospectively gathered BASIL-1 case record forms.

Outcomes

In this BASIL-1 FP sub-group analysis, we report immediate technical success (as defined by the operating surgeon or interventionalist), mean length of index hospital admission, days spent in hospital out to 12 months from randomisation, freedom from major adverse limb events (FF-MALE) and re-intervention (FF-R), AFS, OS, and LS. Major amputation was classified as amputation of the trial limb above the ankle. We have chosen not to include minor amputation as a re-intervention as we regard this as being mainly determined by the condition of the foot at presentation and not the type of primary revascularisation. Major adverse limb event (MALE) comprised any revascularisation attempt or major amputation of the trial limb during

follow up. Post-procedural complications are reported as 30-day mortality, morbidity (complications and re-interventions) and major adverse cardiovascular event (MACE) which comprises death, myocardial infarction or cerebrovascular event. Unplanned interventions for post-operative complications, revascularisation (OSB or PBA +/- BMS), or major amputation were collated and reported under the term surgical re-interventions if they occurred within 30-days. No patients were lost to follow up for the primary endpoint or the other secondary endpoints reported here. Patients who partially withdrew had their clinical outcome data collected via UK centralised data-bases, now known as ONS (office of national statistics) and HES (hospital episode statistics) data.

Statistics

Time to event analyses comparing all OSB (VB and SynB) with PBA +/- BMS are presented over a 7-year period using Kaplan-Meier plots and Log-Rank test for significance. Hazard ratios were used to detect statistically important differences in outcomes using 95% confidence intervals. Differences between the groups were compared using t-test, χ^2-squared and Wilcoxon Rank Sum tests according to distribution of data using SAS v9.4.

RESULTS

Demographics

There were 311 patients; 128 underwent primary OSB (89 VB, 39 SynB) and 183 had primary PBA +/- BMS (6 stents). The mean follow-up was 46.2 (range 0-91) and 43.6 (range 0-93) months respectively. Ipsilateral great saphenous vein (GSV) was used for 83 (93%) VB; arm vein was used for 1 (1%) and composite vein (arm and leg vein spliced) for 5 (6%). Most VB were reversed (63, 71%) with (23, 26%) being in-situ and (3, 4%) non-reversed. The two groups were very similar in terms of baseline characteristics although PBA +/- BMS patients were more likely to be current smokers, and there was a trend to more chronic obstructive pulmonary disease (COPD) in OSB patients (**Table 1**).

Distribution of Disease

There was no significant difference in the overall burden of disease between the two groups in terms of Bollinger angiographic scores (p = 0.2) (**Table 2**). IP disease severity was also statistically similar in the two groups (Bollinger Score = 44.4 vs 46.6, p=0.4) with the peroneal artery being the least diseased run-off vessel.

Short-term outcomes

Immediate technical success was highly significantly better for OSB (98% vs. 81%, p<0.0001). Although patients undergoing OSB had a longer median (inter-quartile range, IQR) index hospital admission (16 [10-27] vs. 8 [2-19] days, p=0.0001) by 12 months patients in both groups had spent an equivalent median (range) number of days (17 [11-28] vs 17 [6-41], p=0.7) in hospital. Statin use was low in both groups (OSB 30% vs. PBA +/- BMS 37%, p=0.2). Antiplatelet use was significantly higher in OSB patients (66% vs. 55% p=0.05). Although all-cause 30-day mortality was not statistically different between the two groups, OSB patients suffered more morbidity; in particular, wound infection (**Table 3**). PBA +/- BMS patients required more surgical interventions within the first 30-days (2% vs. 7%, p=0.06).

Long term clinical outcomes OSB vs PBA+/-BMS

There was no difference in AFS (62% vs. 55%, HR 1.18, 95% CI 0.82-1.69, p=0.4) (**Figure 1**), OS (69% vs. 63%, HR 1.14, 95% CI 0.77-1.70, p=0.5) (**Figure 2**) or LS

(85% vs. 85%, HR 1.09, 95% CI 0.59-2.01, p=0.8) between OSB and PBA+/-BMS. However, FF-MALE (67% vs. 56%, HR 1.51, 95% CI 1.01–2.25, p=0.04) (**Figure 3**) and FF-R (72% vs. 63%, HR=1.68, 95% CI: 1.09–2.60, p=0.02) (**Figure 4**) were significantly lower following OSB. Resolution of rest pain (85% vs 76%, HR=0.84, 95%CI 0.63–1.11 p=0.2) and wound healing at 3 years (90% vs 84%, HR=0.78, 95%CI 0.55-1.10 p= 0.2) (**Figure 5**) were similar in the two groups.

Long term clinical outcomes VB vs SynB vs PBA+/-BS

There was no significant difference in AFS (67% vs. 51% vs 55%, p = 0.2), OS (72% vs. 64% vs. 63%, p=0.4) (**Figure 7**) and LS (90% vs. 72% vs 85%, p=0.3) between VB, SynB and PBA+/- BMS, although the number of SynB was small. FF-MALE (71% vs 58% vs 56%, p=0.02) was significantly better following VB.

Re-interventions

Overall, 24 (19%) OSB, and 63 (34%) PBA +/- BMS, patients underwent re-intervention, with 38 and 85 re-interventions respectively (**Table 4)**. There was no difference in the number of inflow procedures performed in each group (7 vs. 8, p=0.2). Patients in the PBA +/- BMS group underwent more secondary bypass procedures (47, 55% vs. 3, 8% p=<0.001) and more repeat angioplasties (21 ,25%, vs 5, 13%, p=0.1). OSB patients underwent more angioplasties for in-graft stenosis (13, 35% vs. 1, 1%, p=<0.001).

DISCUSSION

The main finding of this BASIL-1 FP sub-group analysis is that although major amputation rates and all-cause mortality are similar, primary OSB, especially VB, results in significantly fewer MALE and re-interventions than primary PBA+/-BMS. So, although an endovascular first revascularisation strategy may be a less resource intensive (expensive) and morbid option in the short term, in longer term, this seems unlikely to be the case. Present data add further weight to the argument that, where possible, VB should be offered as the preferred primary revascularisation procedure to most patients presenting with CLTI due to FP disease. This is especially so in standard risk patients (anticipated life expectancy >2 years) who are more likely to enjoy the long-term benefit of VB and less likely to suffer short-term peri-operative morbidity[1,5-8]. Present data support the previously published BASIL-1 IP sub-group outcomes indicating that the durability and quality of revascularisation are better after VB than after PBA[2]. In this BASIL-1 FP cohort, unlike in the IP cohort, healing of tissue loss and speed of resolution of rest pain were not significantly different between the two groups. This may be because almost a quarter (23%) of the patients who underwent primary FP PBA +/- BMS required subsequent OSB for persistent or recurrent symptoms of CLTI. Indeed, CLTI patients presenting with the most severe disease in terms of wound, ischaemia and infection[9], seem to be those most likely to enjoy better outcomes following primary VB than primary endovascular intervention. This is especially so given that outcomes following secondary VB after failed primary endovascular intervention are significantly worse than those observed when VB is used as the primary revascularisation procedure[10,11]. The low rates of best medical therapy (antiplatelet and statin use coupled with smoking cessation) often observed in CLTI studies are worthy of discussion. In the present study, only two-thirds of patients undergoing OSB were on antiplatelet therapy at randomisation (the rate was 10% lower in PBA +/- BMS group) and only about one-third of patients in both groups were on a statin. While better medical therapy is likely to improve CLTI outcomes overall, there is no evidence this would have altered the conclusions of BASIL-1 in terms of the recommendation to offer VB first wherever possible. Thus, in a recent large case series[8], although best medical therapy rates had improved to approximately 80%, the re-intervention rate was 62% for OSB and 52% for PBA at 3 years. These 3 year re-intervention data are worse than those observed in BASIL-1

at 7 years. This is an important observation as endovascular enthusiasts often point to the fact that BASIL-1 is now a relatively old trial (patents randomised between 1999 and 2004) and argue that, if BASIL-1 were to be repeated using modern endovascular techniques and technologies, the trial would show a clear advantage in favour of an endovascular first strategy for most, even perhaps all, patients. While that is possible, there is no evidence to suggest that such an outcome is likely. Indeed, the evidence we have suggests that such an outcome would be unlikely. In particular, with regard to drug coated balloons (DCB) and drug eluting stents (DES), there are no data to show that they improve clinical outcomes in patients with CLTI when compared to PBA +/-BMS [12-22]. While DES and DES may be associated with better anatomic outcomes, the great majority of the patients entered into the plethora of industry-funded trials had intermittent claudication, underwent treatment of short segment disease, and had short follow up with little or no reporting of clinical outcomes. Even the small minority of patents in these trials who had CLTI were very largely entered on the basis of rest pain and did not have tissue loss. Other techniques such as laser atherectomy[23] and covered stents[24] have not been widely adopted due to a lack of evidence demonstrating clinical and cost-effectiveness. At the time of writing, there are no published, publicly-funded trials comparing DCB / DES to either PBA or OSB in patients with CLTI. As a result, and given their very considerable additional cost, the UK National Institute for Health and Care Excellence (NICE) have recommended against the use of DCB and DES and are awaiting the outcome of on-going RCTs, specifically BASIL-2[25] and BASIL-3[26] in the UK and BEST-CLI trial[27] in the US before reconsidering the matter. The European Society of Vascular Surgery (ESVS) and European Society of Cardiology (ESC) guidelines on the diagnosis and treatment of patients with peripheral arterial disease [28] specifically state no clinical benefit has been proven for DCB over PBA. Data reported here support the ESC/ESVS guidelines stance that vein bypass surgery for long lesions in patients with CLTI is the first choice method of revascularisation. In conclusion, this BASIL-1 FP sub-group confirms the superiority of VB as the preferred primary FP re-vascularisation procedure for most CLTI patients. However, the results of further publicly funded, pragmatic RCTs, such as BASIL-2, BASIL-3 and BEST-CLI, are required to help answer the many remaining questions regarding the clinical and cost-effectiveness of alternative revascularisation strategies in different subgroups of CLTI patients.

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TABLES

Table 1. Baseline characteristics in patients undergoing open surgical bypass and plain balloon angioplasty +/- bare metal stent

		OSB (n = 128)	PBA +/- BMS (n = 183)	P Value
Conduit	Vein	89 (70%)	-	
	Synthetic	39 (30%)	-	
	PBA+/-BMS	-	183 (100%)	
Gender	Male	78 (61%)	94 (51%)	0.09
Limb	Right	57 (45%)	75 (41%)	0.5
Age	Mean (SD)	71.7 (8.0)	73.1 (8.6)	0.2
Follow up (months)	Mean (SD)	46.2 (27.2)	43.6 (24.7)	0.4
Indication	Rest pain	52 (41%)	69 (38%)	0.4
	Tissue Loss	14 (11%)	14 (8%)	
	Both	62 (48%)	100 (54%)	
Creatinine	Mean (SD)	111.7 (79.4)	107.7 (60.2)	0.6
Smoker	Never	17 (13%)	36 (20%)	0.04
	Ex-Smoker	65 (51%)	67 (36%)	
	Current	46 (36%)	80 (44%)	
Diabetes Mellitus		47 (37%)	74 (40%)	0.5
Congestive Heart Failure		5 (4%)	8 (4%)	0.8
Hypertension		77 (60%)	108 (59%)	0.8
Coronary Artery Disease		35 (27%)	50 (27%)	1.0
Chronic Obstructive Airway Disease		19 (15%)	15 (8%)	0.06

OSB open surgical bypass; PBA, plain balloon angioplasty; BMS, bare metal stent

Table 2. A comparison of mean (SD) Bollinger scores between open surgical bypass and plain balloon angioplasty +/- bare metal stent groups

Arterial Section	OSB (n = 128)	PBA+/-BMS (n = 183)	P Value
Profunda Femoris	1.6 (2.6)	2.1 (3.4)	0.2
Proximal Superficial Femoral	7.0 (5.9)	7.0 (5.5)	0.9
Distal Superficial Femoral	10.3 (4.9)	10.2 (5.0)	0.8
Proximal Popliteal	6.9 (5.8)	7.1 (5.7)	0.7
Distal Popliteal	1.5 (2.5)	2.7 (4.4)	0.007
Tibio-peroneal Trunk	2.5 (3.6)	2.8 (4.3)	0.6
Proximal Posterior Tibial	6.8 (5.9)	8.2 (6.6)	0.05
Distal Posterior Tibial	8.3 (6.6)	9.3 (6.5)	0.1
Proximal Peroneal	4.4 (4.8)	4.6 (5.2)	0.7
Distal Peroneal	5.8 (6.2)	4.5 (5.6)	0.1
Proximal Anterior Tibial	6.0 (6.1)	5.8 (5.7)	0.8
Distal Anterior Tibial	7.2 (6.8)	6.7 (6.6)	0.6
Plantar	6.7 (4.0)	6.5 (4.4)	0.8
Total	70.7 (24.5)	75.1 (27.3)	0.2
Total Infra-popliteal Score	44.4 (22.4)	46.6 (24.1)	0.4

OSB open surgical bypass; PBA, plain balloon angioplasty; BMS, bare metal stent

Table 3. Morbidity and mortality (30 day) in patients undergoing open surgical bypass and plain balloon angioplasty +/- bare metal stent

	SB (n = 128)	PBA+/-BMS (n = 183)	P Value
Mortality (30 days)	7 (5%)	6 (3%)	0.3
Morbidity and mortality (30 days)	58 (45%)	59 (32%)	0.02
Myocardial infarction	5 (4%)	5 (3%)	0.6
Transient ischaemic attack	0 (-)	2 (1%)	0.2
Cerebrovascular accident	1 (1%)	3 (2%)	0.5
Haematoma (not operated)	7 (5%)	8 (4%)	0.7
Haematoma (operated)	2 (2%)	1 (1%)	0.4
Wound Infection	37 (29%)	29 (16%)	0.006
Lower respiratory tract infection	4 (3%)	5 (3%)	0.8
Urinary tract infection	2 (2%)	3 (2%)	1.0
False Aneurysm (not operated)	1 (1%)	0 (-)	0.2
False Aneurysm (operated)	0 (-)	0 (-)	-
Major Amputation	3 (2%)	9 (5%)	0.3
Surgical Intervention (30 days)	3 (2%)	13 (7%)	0.06
Major adverse cardiovascular event	10 (8%)	10 (5%)	0.4

OSB open surgical bypass; PBA, plain balloon angioplasty; BMS, bare metal stent

*Wound Infection includes foot infection as well as infection at the intervention site

Table 4. Re-interventions following open surgical bypass and plain balloon angioplasty +/- bare metal stent

	Re-intervention	OSB (n = 128)	PBA+/-BMS (n = 183)
Number of patients		24 (19%)	63 (34%)
Total re-interventions		38	85
Inflow	Ileo-femoral bypass	2 (5%)	1 (1%)
	Iliac PBA+/- BMS	2 (5%)	4 (5%)
	Axillo-femoral bypass	1 (3%)	0 (0%)
	Aorto-bifemoral bypass	0 (0%)	1 (1%)
	Common femoral endarterectomy	1 (3%)	2 (2%)
	Femoro-femoral crossover	1 (3%)	0 (0%)
FP Revascularisations	OSB	3 (8%)	47 (55%)
	PBA+/-BMS	5 (13%)	21 (25%)
	Graft PBA	13 (34%)	1 (1%)
	Thrombolysis	1 (3%)	1 (1%)
	Embolectomy	3 (8%)	2 (2%)
	Profundoplasty	0 (0%)	2 (2%)
	Graft patch angioplasty	1 (3%)	0 (0%)
Other	Graft explanted for infection	2 (5%)	1 (1%)
	Haemostasis	2 (5%)	0 (0%)
	Chemical Sympathectomy	1 (3%)	2 (2%)

OSB open surgical bypass; PBA, plain balloon angioplasty; BMS, bare metal stent

FIGURES

Figure 1. Amputation free survival in patients undergoing femoro-popliteal bypass and plain balloon angioplasty +/- bare metal stent in the BASIL-1 trial

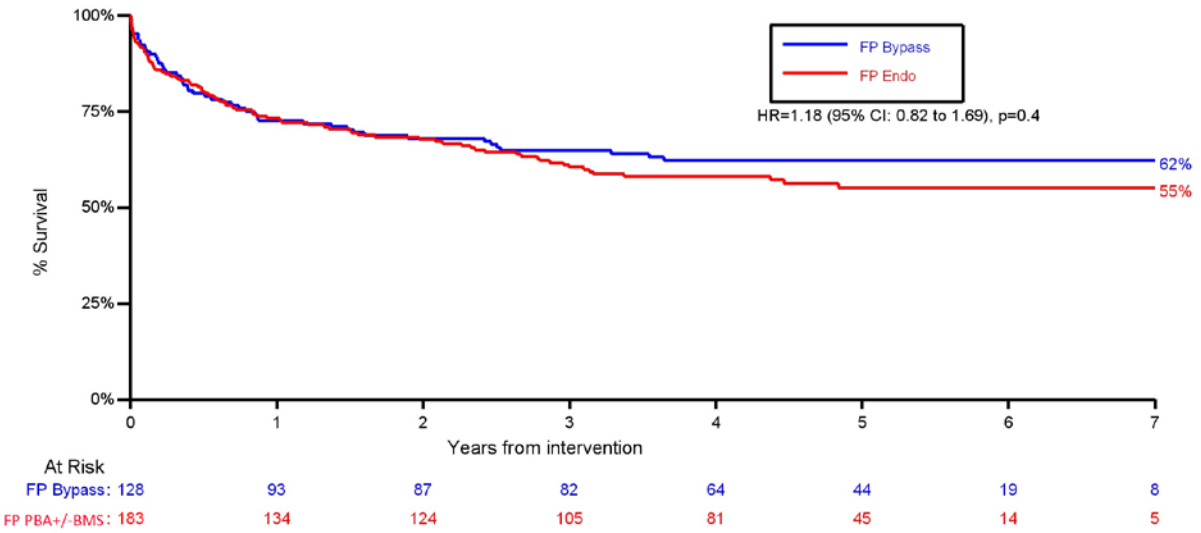

Figure 2. Overall survival in patients undergoing femoro-popliteal bypass and plain balloon angioplasty +/- bare metal stent in the BASIL-1 trial

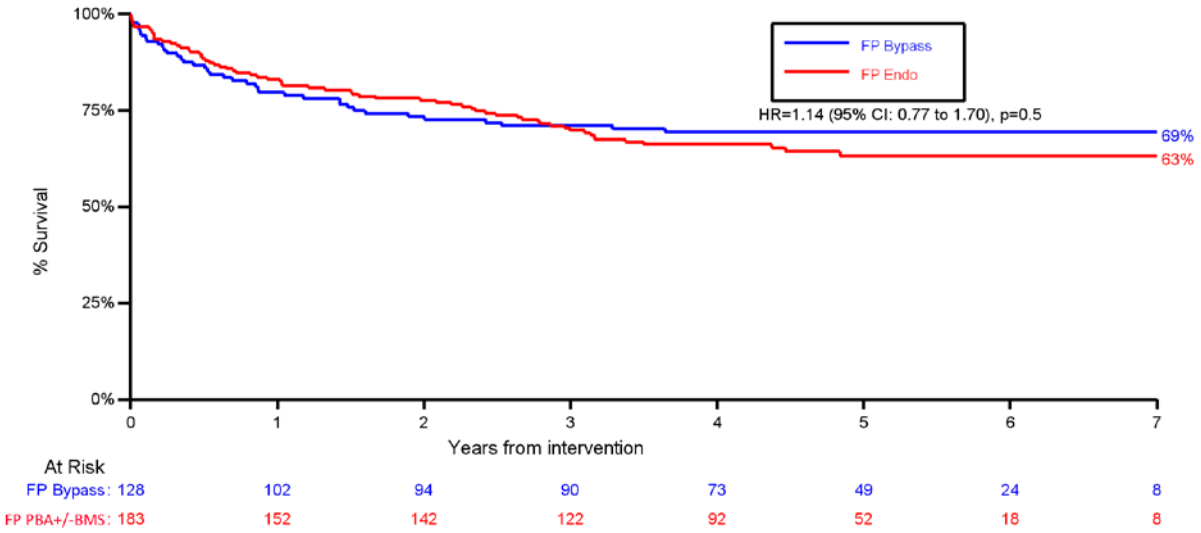

Figure 3. Freedom from major adverse limb events in patients undergoing femoro-popliteal bypass and plain balloon angioplasty +/- bare metal stent in the BASIL-1 trial

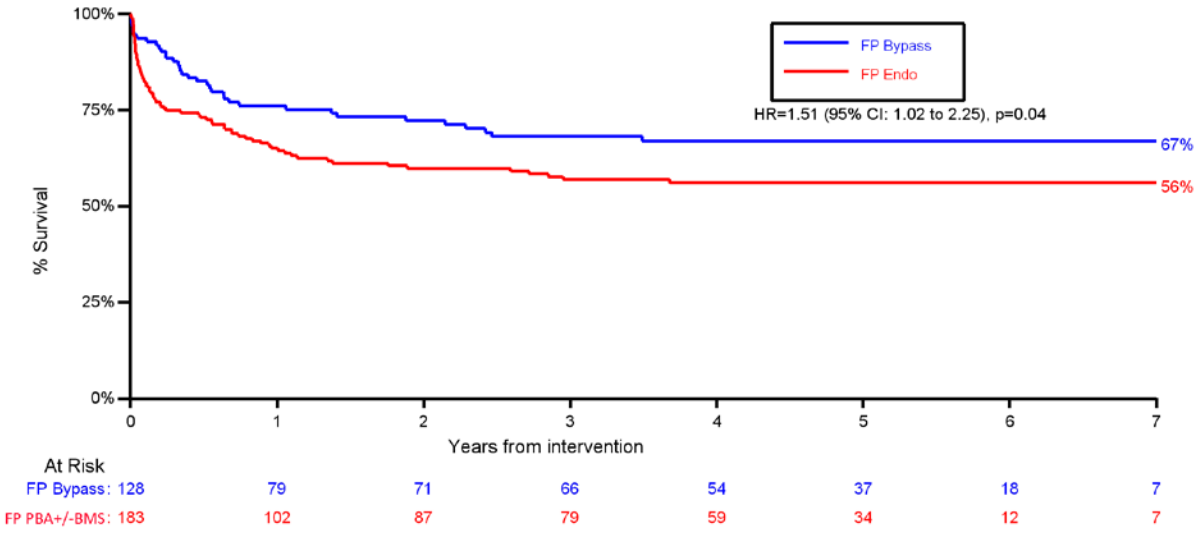

Figure 4. Freedom from re-intervention in patients undergoing femoro-popliteal bypass and plain balloon angioplasty +/- bare metal stent in the BASIL-1 trial

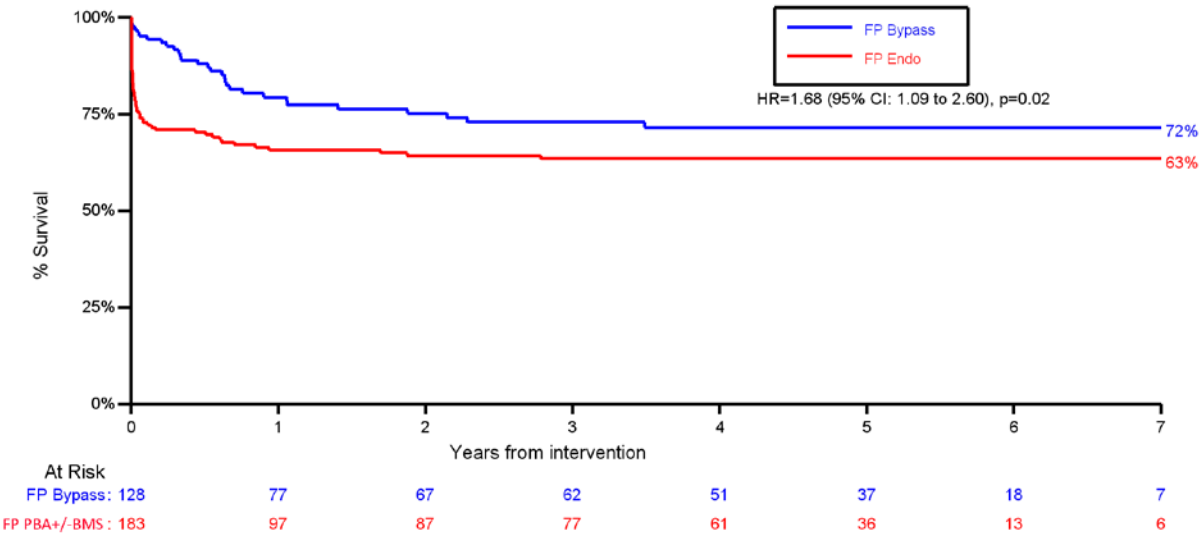

Figure 5. Wound Healing in patients undergoing femoro-popliteal bypass SB and plain balloon angioplasty +/- bare metal stent in the BASIL-1 trial