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A Comparison of Clinical Outcomes Following Femoropopliteal Bypass or Plain Balloon Angioplasty with Selective Bare Metal Stenting in the Bypass Versus Angioplasty in Severe Ischaemia of the Limb (BASIL) Trial

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WHAT THIS PAPER ADDS

This by-treatment-received analysis of data from the publicly funded Bypass Versus Angioplasty in Severe Ischaemia of the Limb (BASIL-1) randomised controlled trial (RCT) confirms the superiority of bypass over plain balloon angioplasty, with or without bare metal stenting, in patients with chronic limb threatening ischaemia who require femoropopliteal 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 ongoing, publicly funded, pragmatic RCTs, such as BASIL-2, BASIL-3, and BEST-CLI.

Objective: To compare outcomes in patients with chronic limb threatening ischaemia (CLTI) due to femoropopliteal (FP), with or without infrapopliteal (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.

Methods: 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 ($n = 183$; six 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 (runoff) Bollinger angiogram scores between groups. Immediate technical success was significantly higher for OSB (98% vs. 81%; $p < .001$). OSB was associated with a longer mean index hospital admission ($p = .001$), but there was no difference in hospital days at 12 months. FF-MALE (hazard ratio [HR] 1.51; $p = .04$) and FF-R (HR 1.68; $p = .02$) but not AFS (HR 1.18; $p = .4$), OS (HR 1.14; $p = .5$), and LS (HR 1.09; $p = .8$) were significantly better after 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.

Keywords: Chronic limb threatening ischaemia, Femoropopliteal bypass, Peripheral arterial disease, Plain balloon angioplasty
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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 (PBA), 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 femoropopliteal (FP) disease and intervention, while in about 25% the disease and intervention were predominantly infrapopliteal (IP). A recently

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

	Surgical bypass (n = 128)	PBA ± BMS (n = 183)	p value
Conduit			
Vein	89 (70)	–	
Synthetic	39 (30)	–	
PBA ± BMS	–	183 (100)	
Men	78 (61)	94 (51)	.09
Right limbs	57 (45)	75 (41)	.50
Mean age ± SD, years	71.7 ± 8.0	73.1 ± 8.6	.20
Mean follow-up ± SD, months	46.2 ± 27.2	43.6 ± 24.7	.40
Indication			
Rest pain	52 (41)	69 (38)	.40
Tissue loss	14 (11)	14 (8)	
Both	62 (48)	100 (55)	
Mean creatinin ± SD, μmol/L	111.7 ± 79.4	107.7 ± 60.2	.60
Smoker			
Never	17 (13)	36 (20)	.04
Ex-smoker	65 (51)	67 (37)	
Current	46 (36)	80 (44)	
Diabetes mellitus	47 (37)	74 (40)	.50
Congestive heart failure	5 (4)	8 (4)	.80
Hypertension	77 (60)	108 (59)	.80
Coronary artery disease	35 (27)	50 (27)	1.00
Chronic obstructive airway disease	19 (15)	15 (8)	.06

Data are n (%) unless otherwise indicated. PBA = plain balloon angioplasty; BMS = bare metal stent; SD = standard deviation.

published BASIL-1 IP subgroup analysis showed that, when compared with 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 subgroup 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 between OSB and PBA ± BMS. Patients were followed up by six dedicated research nurses at one, three, six and 12 months post-randomisation and then annually until death or 1 July 2007. The primary end point was AFS and secondary end points included OS, limb salvage (LS), and requirement for re-intervention. BASIL-1 was a multicentre, 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 subgroup 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 subgroup analysis, 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 are reported. Major amputation was classified as amputation of the trial limb above the ankle. Minor amputation as a re-intervention is not included as this is regarded as being mainly determined by the condition of the foot at presentation and not by the type of primary revascularisation. 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 that comprises death, myocardial infarction, or cerebrovascular event. Unplanned interventions for post-operative complications, revascularisation (OSB or PBA ± BMS), or

Table 2. A comparison of Bollinger scores between open surgical bypass and plain balloon angioplasty ± bare metal stent groups

Arterial section	Surgical bypass (n = 128)	PBA ± BMS (n = 183)	p value
Profunda femoris	1.6 ± 2.6	2.1 ± 3.4	.20
Proximal superficial femoral	7.0 ± 5.9	7.0 ± 5.5	.90
Distal superficial femoral	10.3 ± 4.9	10.2 ± 5.0	.80
Proximal popliteal	6.9 ± 5.8	7.1 ± 5.7	.70
Distal popliteal	1.5 ± 2.5	2.7 ± 4.4	.007
Tibioperoneal trunk	2.5 ± 3.6	2.8 ± 4.3	.60
Proximal posterior tibial	6.8 ± 5.9	8.2 ± 6.6	.05
Distal posterior tibial	8.3 ± 6.6	9.3 ± 6.5	.10
Proximal peroneal	4.4 ± 4.8	4.6 ± 5.2	.70
Distal peroneal	5.8 ± 6.2	4.5 ± 5.6	.10
Proximal anterior tibial	6.0 ± 6.1	5.8 ± 5.7	.80
Distal anterior tibial	7.2 ± 6.8	6.7 ± 6.6	.60
Plantar	6.7 ± 4.0	6.5 ± 4.4	.80
Total	*70.7 ± 24.5*	*75.1 ± 27.3*	*.20*
Total infrapopliteal	*44.4 ± 22.4*	*46.6 ± 24.1*	*.40*

Data are mean Bollinger scores ± standard deviation. PBA = plain balloon angioplasty; BMS = bare metal stent.

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 end point or the other secondary end points reported here. Patients who partially withdrew had their clinical outcome data collected via UK centralised databases, now known as the Office of National Statistics (ONS) and hospital episode statistics data.

Statistics

Time to event analyses comparing all OSB (VB and SynB) with PBA ± BMS are presented over a seven year period using Kaplan—Meier plots and the log rank test for significance. Hazard ratios were used to detect statistically important differences in outcomes using 95% confidence intervals (CIs). Differences between the groups were compared using Student t, chi-square, and Wilcoxon rank sum tests according to distribution of data using SAS version 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Demographics

There were 311 patients; 128 underwent primary OSB (89 VB, 39 SynB) and 183 had primary PBA ± BMS (six stents). Mean lengths of follow up were 46.2 months (range 0—91 months) and 43.6 months (range 0—93 months), respectively. Ipsilateral great saphenous vein was used for 83 (93%) VB; arm vein was used for 1 (1%) and composite vein (arm and leg vein spliced) for five (6%). Most VB were reversed (n = 63; 71%), with 23 (26%) being *in situ* and three (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 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 = .2) (Table 2). IP disease severity was also statistically similar in the two groups (Bollinger score 44.4 vs. 46.6; p = .4) with the peroneal artery being the least diseased runoff vessel.

Short-term outcomes

Immediate technical success was highly significantly better for OSB (98% vs. 81%; p < .001). Although patients undergoing OSB had a longer median (interquartile range [IQR]) index hospital admission (16 days [IQR 10—27] vs. 8 days [IQR 2—19]; p = .001), by 12 months patients in both

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

	Surgical bypass (n = 128)	PBA ± BMS (n = 183)	p value
Mortality (30 d)	7 (5)	6 (3)	.30
Morbidity and mortality (30 d)	58 (45)	59 (32)	.02
Myocardial infarction	5 (4)	5 (3)	.60
Transient ischaemic attack	0	2 (1)	.20
Cerebrovascular accident	1 (1)	3 (2)	.50
Haematoma (not operated)	7 (5)	8 (4)	.70
Haematoma (operated)	2 (2)	1 (1)	.40
Wound infection[a]	37 (29)	29 (16)	.006
Lower respiratory tract infection	4 (3)	5 (3)	.80
Urinary tract infection	2 (2)	3 (2)	1.0
False aneurysm (not operated)	1 (1)	0	.2
False aneurysm (operated)	0	0	–
Major amputation	3 (2)	9 (5)	.3
Surgical intervention (30 d)	3 (2)	13 (7)	.06
Major adverse cardiovascular event	10 (8)	10 (5)	.4

Data are n (%).
[a] Includes foot infection, as well as infection at the intervention site. PBA = plain balloon angioplasty; BMS = bare metal stent; d = days.

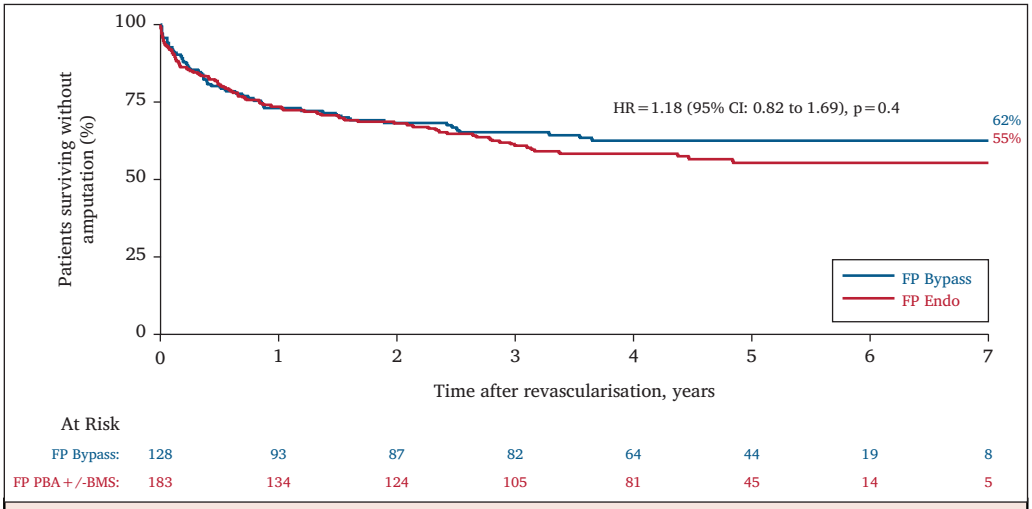

Figure 1. Cumulative Kaplan Meier estimate of amputation free survival in patients undergoing femoropopliteal (FP) bypass and plain balloon angioplasty (PBA) ± bare metal stent (BMS) in the Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL)-1 trial. Endo = endovascular; HR = hazard ratio; CI = confidence interval.

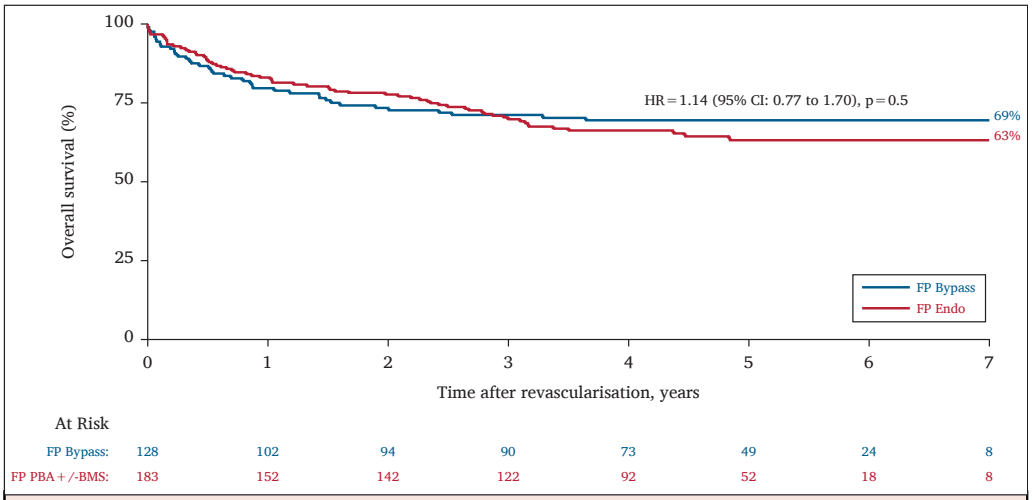

Figure 2. Cumulative Kaplan Meier estimate of overall survival in patients undergoing femoropopliteal (FP) bypass and plain balloon angioplasty (PBA) ± bare metal stent (BMS) in the Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL)-1 trial. Endo = endovascular; HR = hazard ratio; CI = confidence interval.

groups had spent an equivalent median number of days (17 [range 11–28] vs. 17 [range 6–41]; $p = .7$) in hospital. Statin use was low in both groups (OSB 30% vs. PBA ± BMS 37%; $p = .2$). Antiplatelet use was significantly higher in OSB patients (66% vs. 55%; $p = .05$). 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%; $p = .06$).

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; $p = .4$]) (Fig. 1), OS (69% vs. 63% [HR 1.14, 95% CI 0.77–1.70; $p = .5$]) (Fig. 2), or LS (85% vs. 85% [HR 1.09, 95% CI 0.59–2.01; $p = .8$]) between OSB and PBA±BMS. However, FF-MALE (67% vs. 56% [HR 1.51, 95% CI 1.01–2.25; $p = .04$]) (Fig. 3) and FF-R (72% vs. 63% [HR 1.68, 95% CI 1.09–2.60; $p = .02$]) (Fig. 4) were significantly lower following OSB. Resolution of rest pain (85% vs. 76% [HR 0.84, 95% CI 0.63–1.11; $p = .2$]) and wound healing at three years (90% vs. 84% [HR 0.78, 95% CI 0.55–1.10; $p = .2$]) (Fig. 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%; $p = .2$), OS (72% vs. 64% vs. 63%; $p = .4$), and LS (90% vs. 72% vs. 85%; $p = .3$) between VB, SynB, and PBA ± BMS, although the number of SynB was small. FF-

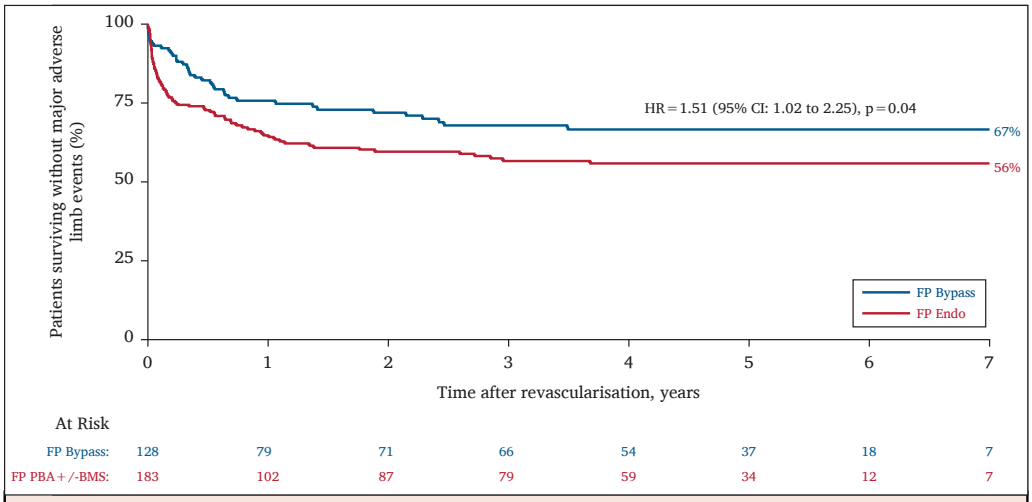

Figure 3. Cumulative Kaplan Meier estimate of freedom from major adverse limb events in patients undergoing femoropopliteal (FP) bypass and plain balloon angioplasty (PBA) ± bare metal stent (BMS) in the Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL)-1 trial. Endo = endovascular; HR = hazard ratio; CI = confidence interval.

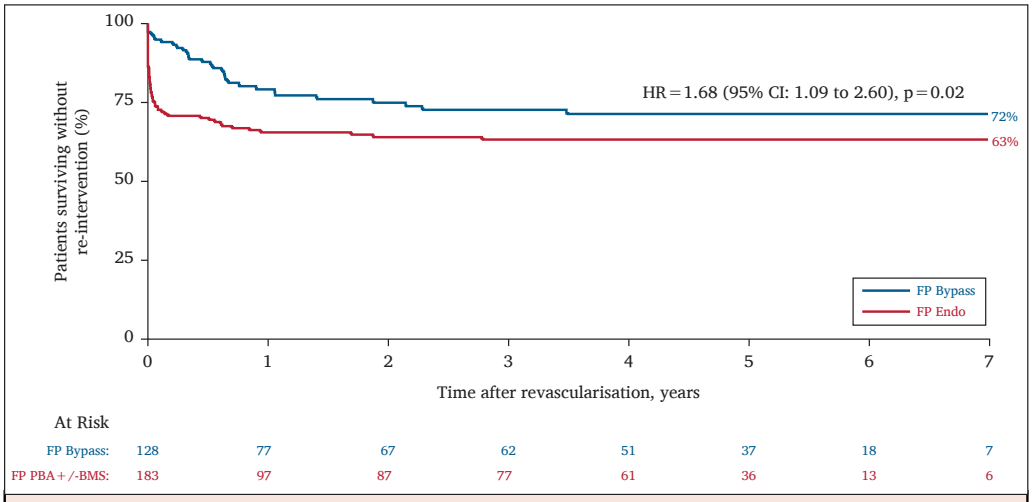

Figure 4. Cumulative Kaplan Meier estimate of freedom from re-intervention in patients undergoing femoropopliteal (FP) bypass and plain balloon angioplasty (PBA) ± bare metal stent (BMS) in the Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL)-1 trial. Endo = endovascular; HR = hazard ratio; CI = confidence interval.

MALE (71% vs. 58% vs. 56%; $p = .02$) 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; $p = .2$). Patients in the PBA ± BMS group underwent more secondary bypass procedures ($n = 47$ [55%] vs. $n = 3$ [8%]; $p < .001$) and more repeat angioplasties ($n = 21$ [25%] vs. $n = 5$ [13%]; $p = .1$). OSB patients underwent more angioplasties for in-graft stenosis ($n = 13$ [35%] vs. $n = 1$ [1%]; $p < .001$).

DISCUSSION

The main finding of this BASIL-1 FP subgroup 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 the longer term, this seems unlikely to be the case. Present data add further weight to

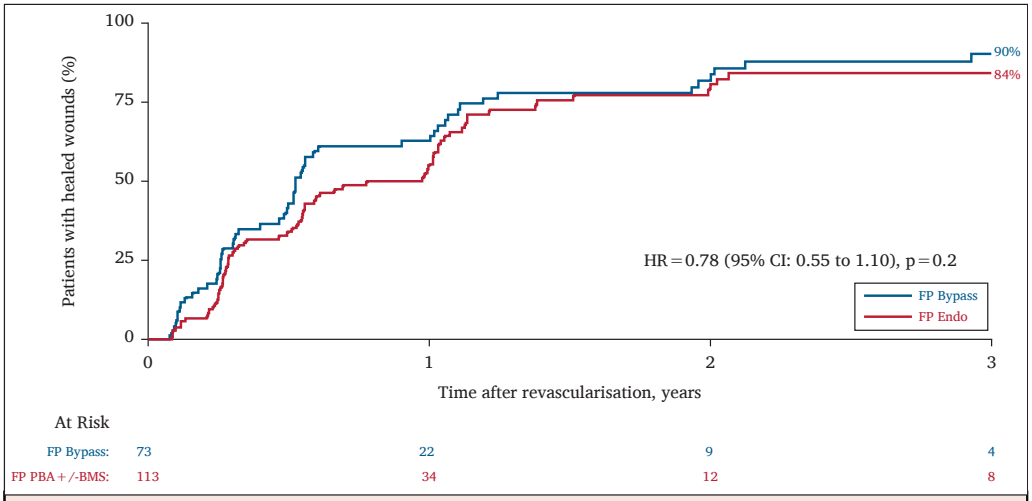

Figure 5. Cumulative Kaplan Meier estimate of wound healing in patients undergoing femoropopliteal (FP) bypass and plain balloon angioplasty (PBA) ± bare metal stent (BMS) in the Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL)-1 trial. Endo = endovascular; HR = hazard ratio; CI = confidence interval.

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 subgroup 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 three years. These three 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

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

Re-intervention	Surgical bypass (*n* = 128)	PBA ± BMS (*n* = 183)
Number of patients	24 (19)	63 (34)
Total re-interventions (n)	38	85
Inflow		
Iliofemoral bypass	2 (5)	1 (1)
Iliac PBA ± BMS	2 (5)	4 (5)
Axillofemoral bypass	1 (3)	0 (0)
Aortobifemoral bypass	0 (0)	1 (1)
Common femoral endarterectomy	1 (3)	2 (2)
Femorofemoral crossover	1 (3)	0 (0)
Femoropopliteal 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)
Profundaplasty	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)

Data are *n* (%) unless otherwise indicated. PBA = plain balloon angioplasty; BMS = bare metal stent; OSB = open surgical bypass.

endovascular techniques and technologies, the trial would show a clear advantage in favour of an endovascular first strategy for most, perhaps even all patients. While that is possible, there is no evidence to suggest that such an outcome is likely. Indeed, the evidence 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 with PBA ± BMS.[12–22] While DCB and DES may be associated with better anatomical 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 ups 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 owing 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 with 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) has recommended against the use of DCB and DES and is awaiting the outcome of ongoing RCTs, specifically BASIL-2[25] and BASIL-3[26] in the UK, and the 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 subgroup confirms the superiority of VB as the preferred primary FP re-vascularisation procedure for most patients with CLTI. 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 patients with CLTI.

CONFLICTS OF INTEREST

None.

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