Editor's Choice - Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL) Prospective Cohort Study and the Generalisability of the BASIL-2 Randomised Controlled Trial

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DOI:
10.1016/j.ejvs.2023.09.041

Document Version
Publisher's PDF, also known as Version of record

Citation for published version (Harvard):
Popplewell, MA, Meecham, L, Davies, HOB, Kelly, L, Ellis, T, Bate, GR, Moakes, CA & Bradbury, AW 2024, 'Editor's Choice - Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL) Prospective Cohort Study and the Generalisability of the BASIL-2 Randomised Controlled Trial', *European Journal of Vascular and Endovascular Surgery*, vol. 67, no. 1, pp. 146-152. https://doi.org/10.1016/j.ejvs.2023.09.041

Eur J Vasc Endovasc Surg (2024) 67, 146–152

Editor's Choice – Bypass *versus* Angioplasty for Severe Ischaemia of the Leg (BASIL) Prospective Cohort Study and the Generalisability of the BASIL-2 Randomised Controlled Trial

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WHAT THIS PAPER ADDS

This single centre, prospective cohort study details how the Bypass versus Angioplasty in Severe Ischaemia of the Leg-2 (BASIL-2) randomised controlled trial fits within the context of the chronic limb threatening ischaemia (CLTI) patient population as a whole. Many patients in the Bypass versus Angioplasty in Severe Ischaemia of the Leg prospective cohort study were deemed unsuitable for the BASIL-2 trial due to a wide range of patient, limb, anatomical, and operational reasons. From those who were fit enough for intervention, 92/471 had infrapopliteal disease requiring revascularisation, of which only 17 were randomised into BASIL-2. The results of BASIL-2 should be interpreted in this context.

Objective: The Bypass versus Angioplasty in Severe Ischaemia of the Leg-2 (BASIL-2) randomised controlled trial has shown that, for patients with chronic limb threatening ischaemia (CLTI) who require an infrapopliteal (IP) revascularisation a vein bypass (VB) first revascularisation strategy led to a 35% increased risk of major amputation or death when compared with a best endovascular treatment (BET) first revascularisation strategy. The study aims are to place the BASIL-2 trial within the context of the CLTI patient population as a whole and to investigate the generalisability of the BASIL-2 outcome data.

Methods: This was an observational, single centre prospective cohort study. Between 24 June 2014 and 31 July 2018, the BASIL Prospective Cohort Study (PCS) was performed which used BASIL-2 trial case record forms to document the characteristics, initial and subsequent management, and outcomes of 471 consecutive CLTI patients admitted to an academic vascular centre. Ethical approval was obtained, and all patients provided fully informed written consent. Follow up data were censored on 14 December 2022.

Results: Of the 238 patients who required an infrainguinal revascularisation, 75 (32%) had either IP bypass (39 patients) or IP BET (36 patients) outside BASIL-2. Seventeen patients were initially randomised to BASIL-2. A further three patients who did not have an IP revascularisation as their initial management were later randomised in BASIL-2. Therefore, 95/471 (20%) of patients had IP revascularisation (16% outside, 4% inside BASIL-2). Differences in amputation free survival, overall survival, and limb salvage between IP bypass and IP BET performed outside BASIL-2 were not subject to hypothesis testing due to the small sample size. Reasons for non-randomisation into the trial were numerous, but often due to anatomical and technical considerations.

Conclusion: CLTI patients who required an IP revascularisation procedure and were subsequently randomised into BASIL-2 accounted for a small subset of the CLTI population as a whole. For a wide range of patient, limb, anatomical and operational reasons, most patients in this cohort were deemed unsuitable for randomisation in BASIL-2. The results of BASIL-2 should be interpreted in this context.

Keywords: Bypass surgery, Chronic limb threatening ischaemia, Endovascular treatment, Infrapopliteal
Article history: Received 19 May 2023, Accepted 24 September 2023, Available online 30 September 2023

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https://doi.org/10.1016/j.ejvs.2023.09.041

INTRODUCTION

Chronic limb threatening ischaemia (CLTI) is defined by the presence of ischaemic rest or night pain and or tissue loss (ulceration and or gangrene) due to atherosclerotic peripheral arterial disease.[1] In patients with CLTI who are deemed suitable for revascularisation there has been debate and controversy for many years as to whether this is best achieved by vein bypass (VB) or best endovascular treatment (BET).[2] CLTI patients often require repeated attempts at revascularisation to maintain limb perfusion, and usually have multiple comorbidities that require multiple hospital admissions.[3] As a result, CLTI is associated with high levels of resource utilisation and poor health related quality of life (HRQoL).[4,5]

The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL)-2 randomised controlled trial (RCT) has recently shown that in patients with CLTI who required an infrapopliteal (IP), with or without an additional more proximal infrainguinal revascularisation procedure to restore limb perfusion, a VB first revascularisation strategy led to a 35% (HR 1.35, 95% CI 1.02 − 1.80; $p = .037$) increased relative risk of major amputation or death from any cause, whichever occurred first (no amputation free survival, AFS) when compared with a BET first revascularisation strategy.[6] The difference in AFS was mainly driven by fewer deaths in the BET first group as time to major amputation was similar in the two groups.

Although the difference in AFS observed in BASIL-2 was statistically robust, it is important that clinicians are provided with further information that enables them to make a judgement as to the generalisability of the trial and so the relevance of the trial outcomes to their own patients and practice. The BASIL Prospective Cohort Study (PCS) used BASIL-2 trial case report forms (CRF) to prospectively document the characteristics, initial management, and clinical outcomes of all patients presenting to the present authors' vascular centre with CLTI during the BASIL-2 trial recruitment period. The aim of the PCS was to place the BASIL-2 trial within the context of the UK CLTI patient population at the present authors' institution, and to investigate the generalisability of the BASIL-2 outcome data to similar patients undergoing IP revascularisation who were not randomised in the trial.

METHODS

Using BASIL-2 CRFs, the characteristics, initial and subsequent management, and clinical outcomes were prospectively documented of 471 consecutive CLTI patients who were admitted to the vascular unit between 24 June 2014 and 31 July 2018. Ethical approval was obtained from the National Research Ethics Service, West Midlands, UK (Coventry and Warwick) on 3 March 2014 (reference 14/WM/0057) as part of the BASIL-2 trial. All enrolled patients provided fully informed, written consent as part of a screening process for BASIL-2.[7] Only one additional patient admitted with CLTI declined to enter the PCS. The PCS was purely observational, and enrolment had no influence on any aspect of patient management, or on BASIL-2 trial recruitment.

Members of the research team approached patients for entry into the PCS and BASIL-2 screening at the first available opportunity within working hours and then prospectively collected data relating to the patients' first (index) admission. Following index discharge, hospital electronic patient records were regularly reviewed for information relating to all subsequent vascular and non-vascular admissions, vascular interventions, and death, whether that occurred in hospital or elsewhere. Follow up data were censored on 14 December 2022. The index limb was defined as the symptomatic limb at presentation. If patients presented with bilateral CLTI, the more symptomatic leg, or the leg that underwent the first vascular procedure, was used for analysis of limb based outcomes. Patients were allocated into a subgroup based on their management following first admission during the BASIL-PCS data collection period. Data pertaining to previous interventions were also collected.

An IP bypass was any bypass where the inflow vessel was below the inguinal ligament and the distal anastomosis was at the level of the tibioperoneal trunk or below. An IP endovascular intervention involved treatment of the tibioperoneal trunk or a more distal artery, with or without concurrent treatment of the superficial femoral or popliteal arteries. At the present authors' institution, patients undergoing IP bypass were enrolled into a vein graft surveillance programme for two years. Patients undergoing IP endovascular treatment were followed clinically and only investigated with further imaging if CLTI symptoms recurred. Re-intervention was defined as a repeat of the same type of procedure and further intervention was defined as an alternative revascularisation procedure to the first initial PCS procedure.

Here the initial management of the entire cohort is described, along with reasons why patients who required an IP revascularisation were not randomised into BASIL-2, and clinical outcomes in patients undergoing an IP revascularisation outside the BASIL-2 trial; specifically, 30 day morbidity (defined as any surgical or medical morbidity within 30 days of interventions) and mortality, AFS, overall survival (OS), limb salvage (LS) (defined as freedom from major, above the ankle amputation of the index PCS leg), and MALE death (defined as major amputation, or any further major revascularisation of the index leg [endovascular or open], or death from any cause, whichever occurred first).

Simple statistics were performed to describe the data. Categorical data were summarised by frequencies and percentages. Continuous data were summarised by the mean and standard deviation (SD) if deemed to be normally distributed or median and interquartile range (IQR) if data were non-normal, and ranges if appropriate. Additionally, for time to event outcomes, a log rank test was performed to obtain an unadjusted hazard ratio (and corresponding 95% confidence interval [CI]). Kaplan—Meier survival curves were constructed for visual presentation of time to event comparisons. Due to sample sizes no formal hypothesis testing was computed. As a result, imputation methods were not used to account for any missing data, which is clearly displayed in the results section at the bottom of each table. Analyses were performed using STATA 18 and graphical representations were prepared using STS graph.

Table 1. Baseline characteristics of all 471 patients in the Bypass versus Angioplasty in Severe Ischaemia of the Leg – Prospective Cohort Study

Characteristic	*n* = 471
Age – y	73.4 ± 11
Men	311 (66)
DM	241 (51)
DM on insulin	127/241 (53)
CKD ≥ 3	147 (31)
Previous stroke	84 (18)
Previous MI	108 (23)
Previous angina	88 (19)
Previous CABG	56 (12)
Previous PCI	50 (11)
Previous dialysis	27 (6)
Clinical status of the index leg	
Rest or night pain only	97 (21)
Tissue loss only	127 (27)
Both	247 (52)
Previous intervention to the index leg	
Surgery	56 (12)
Endovascular	77 (16)
Minor amputation	39 (8)
Mobility	
Ambulant – no walking aid	162 (34)
Ambulant – walking aid	245 (52)
Wheelchair bound	54 (11)
Bed bound	8 (2)
Missing	2 (0.4)
Smoking status	
Never	111 (24)
Ex	215 (45)
Current	145 (31)

Data are presented as mean ± standard deviation or *n* (%). Percentages refer to the proportion of the patients with named risk factor/demographic within the whole cohort. DM = diabetes mellitus; CKD = chronic kidney disease; MI = myocardial infarction; CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention.

RESULTS

The baseline characteristics of the PCS cohort as a whole were typical of CLTI patients (Table 1). Overall survival (OS) for the whole cohort was estimated at 70%, 51%, and 35% at one, three, and five years, respectively, and the median survival was 38 months. All patients had a minimum of 4.4 years of electronic follow up. Half ($n = 238$) of the cohort had an infrainguinal revascularisation (86, 36%, bypass and 152, 64% BET), and 49 (10%) underwent major amputation (26 below, one through, and 22 above knee), as their initial management (Fig. 1). Of the remaining 184 (39%) patients, 61 (13%) were treated conservatively (without surgical debridement); 31 (7%) underwent minor amputation (19 single toe, five multiple toes, and seven forefoot up to and including transmetatarsal amputation) without subsequent revascularisation; 78 (17%) had a supra-inguinal surgical or endovascular revascularisation only; 10 (2%) had surgical debridement only; and four (1%) had a thromboembolectomy (delayed, acute on chronic presentations). Seventy five patients had IP bypass ($n = 39$) or BET ($n = 36$) outside the BASIL-2 trial as their initial management. Patients selected for IP BET as opposed to IP bypass tended to be older, were more likely to be female, have diabetes, be on insulin, have chronic kidney disease and tissue loss, and reported as being never smokers (Supplementary Table S1). In terms of limb threat as measured by Wound, Ischaemia, Foot infection (WIfI)[8] grade, there were no differences between the two groups. A proportion of patients in each group could not have their limb threat adequately scored due to a lack of haemodynamic data (IP bypass 26% missing, IP BET 25% missing, Supplementary Table S2). Patients in the IP bypass group were more likely to have notable femoropopliteal disease (Grade 3, 87% *vs.* 42% in the IP endovascular treatment group) and a higher proportion of Stage III disease overall (high complexity, IP surgical bypass 92% *vs.* 61% IP BET) as measured by the Global Anatomic Staging System (GLASS)[1] (Supplementary Table S2). The procedural details of IP bypass and BET performed outside of the BASIL-2 trial are reported in Supplementary Tables S3 and S4.

In patients selected for IP bypass outside of the BASIL-2 trial, AFS (HR 0.65, 95% CI 0.39 – 1.08, Fig. 2A), OS (HR 0.74, 95% CI 0.43 – 1.30, Fig. 2B), and LS (HR 0.91, 95% CI 0.39 – 2.11, Fig. 2C) were different between the two groups. Thirty day morbidity and mortality, MALE death, technical failure, and length of stay in hospital are reported (Table 2). Median survival was better in the IP bypass group in terms of OS (IP bypass, 46 months *vs.* IP BET, 32 months) and AFS (IP bypass, 29 months *vs.* IP BET, 12 months). Further intervention was higher in the IP bypass group (23% *vs.* 1% IP endovascular intervention). This was due to patients undergoing graft angioplasty following surveillance duplex (9/9 who had further intervention).

Causes of death are presented in Supplementary Table S5.

Seventeen patients had an IP revascularisation within the BASIL-2 trial as their initial management. A further three patients did not undergo an IP revascularisation as their initial management but were later randomised into BASIL-2. Therefore 20/471 (4%) of the whole cohort, and 20/95 (21%) of patients undergoing an IP revascularisation, were randomised. There were multiple reasons why the multidisciplinary team (MDT), comprising vascular and endovascular surgeons, and interventional radiologists, could not reach clinical equipoise and more than one reason often coexisted in the same patient (Table 3).

The median AFS in the PCS was poorer than patients randomised into BASIL-2, particularly in those selected for IP endovascular treatment (median AFS BASIL-2 for patients randomised to IP BET 4.4 years *vs.* 1.0 years in those undergoing IP BET in the PCS). A much less pronounced difference was seen in those undergoing IP bypass (median AFS BASIL-2 in patients randomised to IP bypass 3.3 years *vs.* 2.3 years in those selected for IP bypass in the PCS).

Median survival for both IP BET and IP bypass was better in patients selected for revascularisation in the PCS when compared with those randomised to BASIL-2 at the present authors' unit (BASIL-2 IP bypass at the unit 2.5 years *vs.* 3.9 years in patients selected for IP bypass in the PCS; BASIL-2 IP BET at the unit 2.3 years *vs.* 2.7 years in patients selected for IP bypass in the PCS).

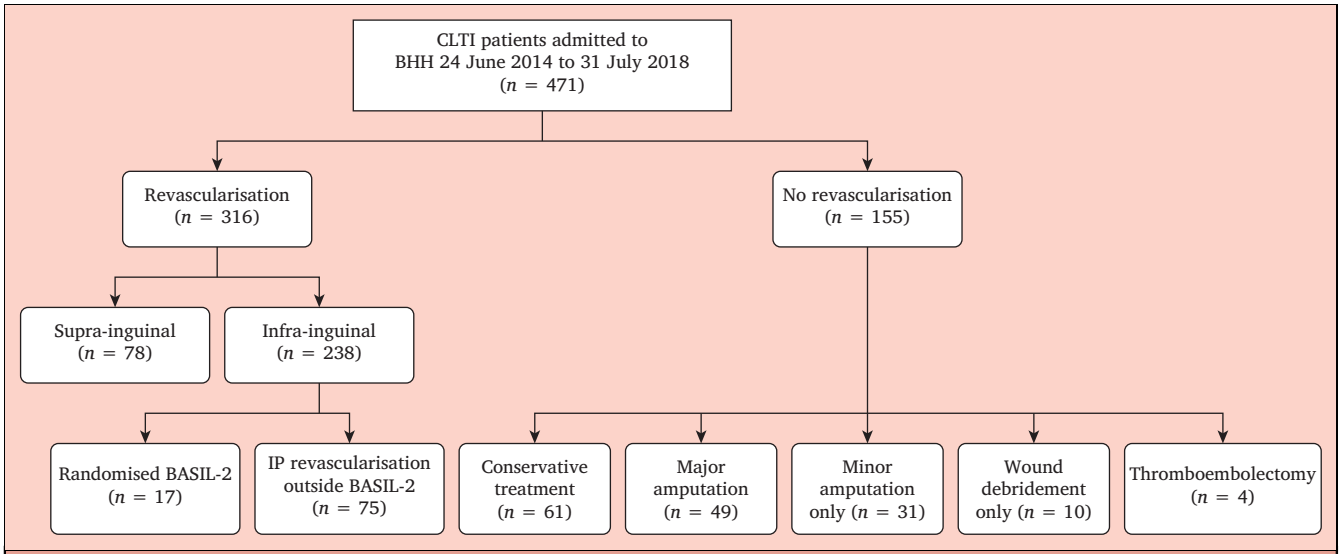

Figure 1. Flow chart to represent the initial management of patients enrolled in the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Prospective Cohort Study. 471 patients presented to the unit between 24 June 2014 and 31 July 2018. From this, 17 patients were randomised into BASIL-2. BHH = Birmingham Heartlands Hospital; CLTI = chronic limb threatening ischaemia; IP = infrapopliteal.

DISCUSSION

The PCS provides a real world description of the characteristics, management, and outcomes of 471 consecutive CLTI patients admitted to a major UK vascular unit over a four year period. The PCS demonstrates that CLTI is an extremely heterogeneous condition in terms of patient characteristics, degree of limb threat, and anatomical severity and extent of disease. To produce clinically meaningful results, RCTs can only ever study CLTI subgroups that have been defined by reasonably strict inclusion and exclusion criteria. BASIL-2 is only concerned with and can only answer questions regarding the optimal first revascularisation strategy for CLTI patients who require an IP, with or without an additional more proximal infrainguinal revascularisation, and, very importantly, who are deemed suitable for both a VB first and a BET first revascularisation strategy.[6] This was always likely to be a relatively small subset of the CLTI population as a whole and the PCS confirms this to be the case.

In the total cohort of the PCS, 67% (316/471) of patients were offered any form of revascularisation; (50% infrainguinal; 19% infrapopliteal). Of those having an IP revascularisation, only 18% (around 4% of the whole cohort) were randomised into BASIL-2. To randomise a patient into BASIL-2 several conditions had to be fulfilled. Firstly, the MDT had to find clinical equipoise regarding an IP VB *vs.* an IP BET first revascularisation strategy. Numerous clinical reasons for a lack of clinical equipoise were documented by the MDT and several often co-existed in the same patient. The anatomical severity and extent of disease was one important factor. Patients with long segment occlusive disease, often involving the SFA, tended to be offered IP VB. While those with stenotic disease and or short occlusions tended to be offered IP BET, outside of the BASIL-2 trial. Those selected for IP BET outside trial tended to be older, were more likely to be female, have diabetes, be on insulin, have chronic kidney disease, and have tissue loss. This may explain the differing outcomes of patients undergoing BET in the non-trial population. While this is in keeping with other published, non-randomised series,[3,9] it is the opposite of what was found in BASIL-2 where patients randomised to BET had to be fit for VB. This serves to show the importance of patient selection outside of a trial setting, in that many selected for IP endovascular treatment may have been better served with conservative treatment or primary amputation. From a statistical standpoint, comparisons between patients selected for IP revascularisation in the PCS were not subject to hypothesis testing. This was due to the relatively small sample sizes and inherent differences in patient profiles in selected cohorts. All analyses were unadjusted for any cofounders with high levels of uncertainty.

Secondly, the clinical team have to be confident that they can deliver both an IP VB and an IP BET revascularisation strategy in an equally timely and high quality manner. In addition to the lack of clinical equipoise, colleagues from BASIL-2 centres explained that they also faced logistical and operational obstacles to randomisation. For example, BET was often preferred over VB because it was easier to obtain imaging that confirmed suitability for BET; access to an operating theatre in which to undertake a VB that might take several hours was limited; and pressure on beds tended to favour BET as it is generally believed, rightly or wrongly, to be associated with quicker recovery and earlier discharge. And, thirdly, patients understandably prefer to have a minimally invasive intervention under local anaesthetic than what they perceive to be major surgery. The clinical, logistical, and patient preference factors described here may have varied between BASIL-2 centres. For funding and logistical reasons, it was not possible to undertake a PCS in any other BASIL-2 trial centre and so the generalisability of the present PCS to other centres cannot be determined. These important challenges to RCT recruitment may vary even more between different countries and healthcare

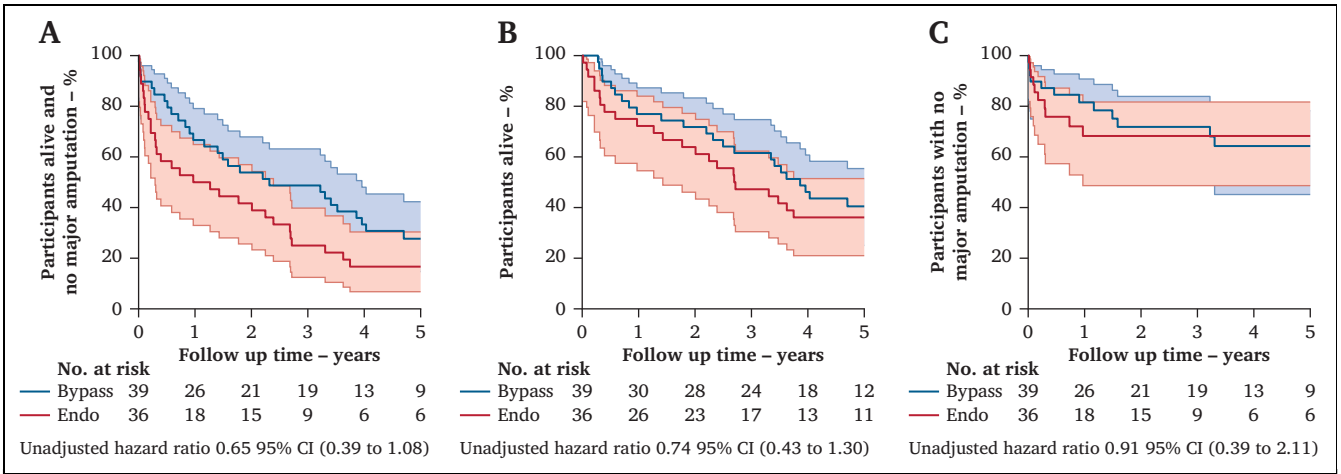

Figure 2. Cumulative Kaplan–Meier estimates for patients receiving infrapopliteal surgical bypass or endovascular intervention as their initial management outside of the Bypass versus Angioplasty in Severe Ischaemia of the Leg-2 trial. There were differences in (A) amputation free survival (AFS), (B), overall survival (OS), and (C) limb salvage but these were not subject to hypothesis testing. Shaded areas represent 95% confidence intervals.

systems. All of these factors help to explain why recruiting to BASIL-2 was much more difficult than had been anticipated. The BEST-CLI trial also faced similar difficulties despite much greater funding and a larger potential patient population.[10]

In the PCS, reported cause of death was often difficult to ascertain. In hospital deaths were recorded on electronic records at the present authors' institution. If a patient died outside of the institution or in the community, there was no access to this information. In the BASIL-2 trial, access was sought to government based mortality data for this information (Office for National Statistics[11]). The present authors did not access these data for patients in the PCS due to the substantial costs associated with access requests. This may mean that the number of cardiorespiratory deaths is under reported in this cohort (both leading causes of death in BASIL-2 patients). In similar fashion, given that the present authors had access only to the electronic systems of their own institution, if a patient moved geographical area or received treatment elsewhere following PCS admission then some outcomes may be under represented in this dataset. Unfortunately, the present authors did not have ethical cover or the resources to follow up patients on a face to face basis.

Members of the research team (M.P., H.O.B.D., L.M., G.B., L.K.) were present most working days at the institution to screen patients for entry into the PCS. Some patients were admitted and treated out of hours or on a weekend before entry into the PCS, which may explain why some haemodynamic data (and WIfI scores) were not available. The collection of haemodynamic data in BASIL-2 was generally poor across all sites with only around a half of the expected data returned.

These data represent real world outcomes of patients with CLTI outside of a RCT setting. Although the PCS was performed at a single centre, the present authors feel that many, particularly in the UK will have similar experiences and challenges in managing this population. It is difficult to say whether such data and therefore their conclusions are translatable to other healthcare systems throughout the world; however, there are likely to be some commonalities.

Other studies have reported outcomes in registry settings. The large GermanVasc study reported outcomes on 5 042 patients with peripheral artery occlusive disease.[12] The main findings reported reduced amputation free survival in those undergoing endovascular intervention compared with bypass surgery (HR 2.59, 95% CI 1.75 — 3.85); however, the majority of the patients in the study were claudicants, with very low risk of amputation or death (5.3%) at 12 months. On secondary analysis, of those patients with CLTI only, there were no differences in amputation or death between those receiving infrainguinal bypass or endovascular treatment. It is unclear how many of these patients had infrapopliteal disease or what their limb threat risk was.

Table 2. Outcomes in patients undergoing infrapopliteal surgical bypass or endovascular intervention as their initial management outside of the Bypass versus Angioplasty in Severe Ischaemia of the Leg-2 trial

Initial management	Bypass *n* = 39	Endovascular *n* = 36
No AFS	29 (74)	31 (86)
AFS time — mo	29	12
Death from any cause	24 (61)	26 (72)
Survival time — mo	46	32
Major amputation	12 (31)	10 (28)
30 day morbidity	9 (23)	9 (25)
30 day mortality	0 (0)	2 (6)
MALE death	37 (95)	32 (89)
Technical failure of index intervention	5 (13)	6 (17)
Further intervention	9 (23)	1 (3)
Re-intervention	8 (20)	6 (17)
Length of stay during revascularisation admission — d	12 (8, 21)	12 (9, 23)

Data are presented as *n* (%), median, or median and interquartile range. Percentages refer to the proportion of the patients with named variable in each subgroup. AFS = amputation free survival; MALE = major adverse limb event.

Table 3. Main reasons for the lack of multidisciplinary team clinical equipoise in patients undergoing infrapopliteal revascularisation outside of the Bypass versus Angioplasty in Severe Ischaemia of the Leg-2 trial

Infrapopliteal bypass	Patients $n = 39$	Infrapopliteal best endovascular treatment	Patients $n = 36$
Long segment occlusive disease often involving the SFA	24 (61)	Short stenotic or occlusive disease	14 (39)
Redo bypass < 6 mo	5 (13)	No distal target or poor run off	7 (19)
Acute on chronic	4 (10)	Considered unfit for surgery	4 (11)
Aneurysmal or occlusive disease	3 (8)	Tissue loss over potential target IP vessel	2 (5)
Composite sequential	1 (2)	Inadequate venous conduit	1 (3)
Significant CFA disease	1 (2)	Planned DSA only − treated	1 (3)
Patient choice	1 (2)	Randomised to BASIL-3 for concurrent FP disease	1 (3)
		Lack of capacity − least restrictive option	1 (3)
		Previous bypass − treatment of native vessels	1 (3)

Data are presented as *n* (%). Percentages refer to the proportion of the patients with named variable in each subgroup. SFA = superficial femoral artery; IP = infrapopliteal; CFA = common femoral artery; DSA = digital subtraction angiography; BASIL-3 = Balloon versus Stenting in Severe Ischaemia of the Leg-3 trial; FP = femoropopliteal.

The American College of Surgeons National Surgical Quality Improvement Program reported outcomes in patient with CLTI due to isolated infrageniculate disease undergoing either bypass or endovascular intervention.[13] The group reported superior short term (30 day) outcomes in terms of limb salvage, favouring bypass (4.3% *vs.* 7.4%; OR 0.60; CI 0.36 − 0.98) but with higher mortality (3.23% *vs.* 1.8%; adjusted OR 2.77; CI 1.26 − 6.11) and major adverse cardiovascular events (6.9% *vs.* 2.6%; adjusted OR 3.88; CI 2.18 − 6.88).

The challenges to BASIL-2 recruitment identified by the PCS are likely to affect future CLTI RCTs. As part of an initiative to improve recruitment into the trial and help clinicians find equipoise, the present authors instigated a Quintet Recruitment Intervention (QRI)[14] process at a large national investigator meeting in 2016. The QRI did see an upturn in recruitment rates; however, this was still below the expected levels from original calculations. Others have reported different methods for improving recruitment which may be helpful to others performing RCTs in the future such as the Screened, Eligible, Approached, Randomised (SEAR) framework[15] and the quantiqualitative appointment timing (Q-QAT) technique.[16] It is hoped that reporting the difficulties and challenges faced using the vehicle of the BASIL-PCS will help other researchers design better trials that integrate such tools as mentioned above.

The PCS places the BASIL-2 trial within the context of the UK CLTI patient population and provides further information that it is hoped will allow colleagues to make judgements regarding the generalisability and applicability of the BASIL-2 outcome data to their patients, practice, and healthcare system.

CONFLICT OF INTEREST

None.

FUNDING

The BASIL-2 trial was funded by the UK National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme.

ACKNOWLEDGEMENTS

The BASIL-PCS investigators would like to thank the patients, clinical and non-clinical staff at the Heart of England Foundation Trust, University Hospitals Birmingham for their support during the study period.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2023.09.041.

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COUP D'OEIL

Giant Brachial Artery Aneurysm

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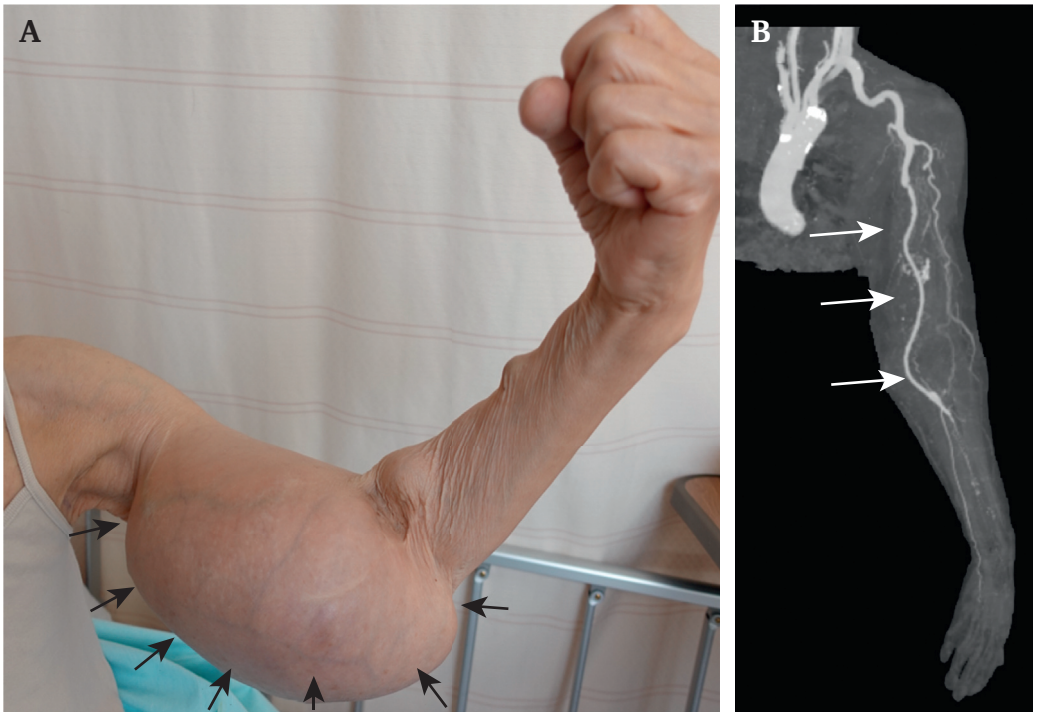

A 70 year old female was referred for swelling in the left upper arm and numbness of the left hand. She had a 25 year history of haemodialysis using an arteriovenous fistula (AVF) in the left forearm before receiving a kidney transplant 13 years ago following which the AVF was surgically closed. At presentation, an extensive pulsatile mass was found (A, arrows). Contrast enhanced computed tomography revealed a 110 mm brachial artery aneurysm. Aneurysmectomy and saphenous vein graft replacement were performed (B, arrows) to confirm a true aneurysm histologically. Although arteriovenous access aneurysms are common, brachial artery aneurysms deemed to be induced by a high flow AVF are infrequent.

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https://doi.org/10.1016/j.ejvs.2023.10.002