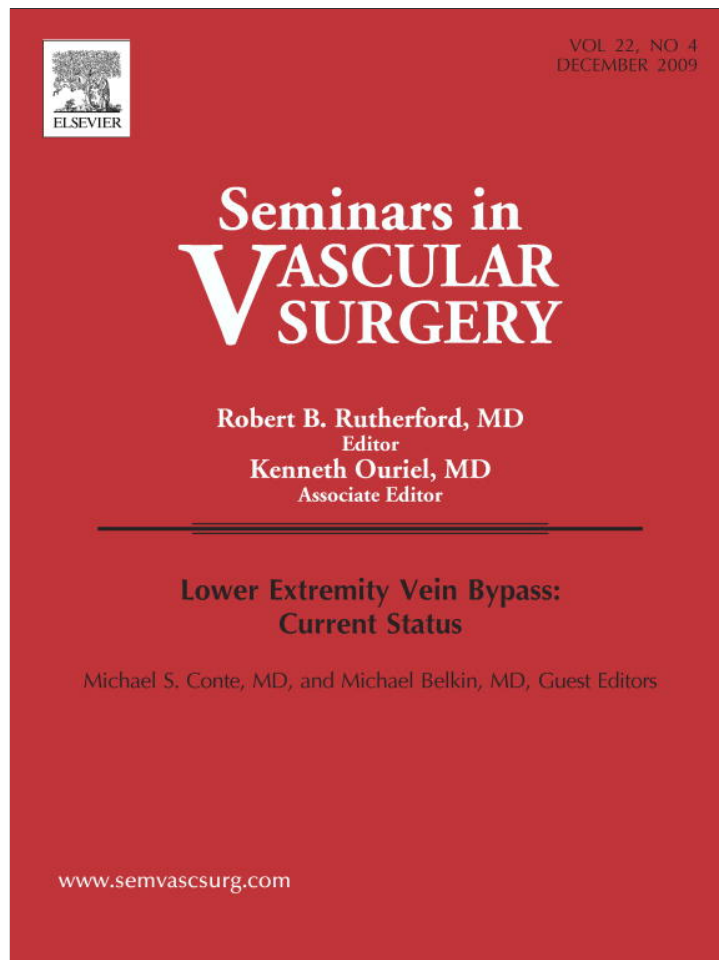


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Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial: What Are Its Implications?

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Lack of Level I evidence from randomized controlled trials (RCT) means that the relative merits of surgical and endovascular revascularization strategies for severe limb ischemia (SLI) due to infrainguinal disease remain unclear. The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial remains the only multicenter RCT to have compared the clinical and cost-effectiveness of bypass surgery (BSX)-first and balloon angioplasty (BAP)-first revascularization strategies for infrainguinal SLI. An intention to treat analysis shows that out to 2 years both strategies were associated with similar amputation-free (AFS) and overall survival (OS) rates, as well as improvements in health-related quality of life. In the short-term, BSX was significantly more morbid and expensive. However, for those patients who survived for 2 years after randomization, initial randomization to a BSX-first strategy was associated with a significant increase in subsequent OS of about 7 months and a nonsignificant increase in subsequent AFS of about 6 months. Vein BSX performed significantly better than prosthetic BSX in terms of AFS but not OS. For most patients BAP also appears preferable to prosthetic BSX. Patients who underwent BSX after a failed BAP-first strategy did not fare as well as those who received BSX as their first procedure. Patients who are expected to live less than 2 years should usually be offered BAP first, especially when the alternative is prosthetic BSX. Those expected to survive beyond this time horizon (approximately 75% of the BASIL cohort) should usually be offered BSX first, especially where vein is available. Further RCTs to confirm or refute these findings and recommendations are required.

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SEVERE LIMB ISCHEMIA (SLI), which manifests itself as rest (night) pain and tissue loss (ulceration/gangrene), imposes a major health, social, and economic burden on all developed, and an increasing number of developing, countries. Our aging populations, the increasing prevalence of diabetes and obesity and their vascular complications worldwide, together with the failure thus far to significantly reduce global tobacco consumption mean that, despite advances in medical therapies, the numbers of patients requiring lower-limb revascularization for SLI are likely to increase significantly in the foreseeable future.¹ The two available interventions, bypass surgery

(BSX) and balloon angioplasty (BAP), have generally been considered to have a number of relative advantages and disadvantages (Table 1). Previous studies have attempted to compare BSX with BAP, but all have had one or more serious methodological limitations.²⁻⁴ The resulting absence of Level I evidence has resulted in a lack of clarity as to whether BSX or BAP is associated with a better clinical outcome and a more effective use of health care resources in patients whose legs are threatened by SLI. To address this problem the UK National Institute of Health Research Health Technology Assessment program (<http://www.hta.ac.uk/>) funded the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial in 1998.⁵⁻⁷

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Dr. Bradbury is the principal investigator of the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial.

Objective

The aim of the BASIL trial was to compare, for the first time in a multicenter RCT, the clinical and cost-effectiveness of BSX- and BAP-first revascularization strategy for SLI due to infrainguinal disease.

Table 1 Potential Advantages and Disadvantages of Bypass Surgery and Balloon Angioplasty as a First-Line Treatment for Severe Limb Ischemia Due to Infringuinal Disease

	Bypass Surgery	Balloon Angioplasty
Pros	Superior long-term anatomic patency and clinical durability	Low morbidity and mortality and requirement for urgent surgical intervention Low cost Quick to perform Shorter hospital stay Can be repeated Failed angioplasty has been said not to jeopardize subsequent surgery Preserves collaterals so that even if the angioplasty site occludes symptoms may not return and tissue loss may remain healed
Cons	Significant morbidity and mortality Significant resource utilization (theater time and personnel, prolonged hospital stay) Graft surveillance, often leading to repeated prophylactic reintervention, required to optimize patency Vein as a conduit often unavailable, inadequate in length or poor quality Use of prosthetic material associated with poorer patency and risk of graft infection	Limited anatomic and hemodynamic patency and clinical durability Only a minority of patients may be suitable, especially with the transluminal technique The technique, particularly using the sub-intimal approach, is technically demanding and satisfactory results may not be widely achievable

Methods

Prior to the trial, a Delphi consensus study of vascular surgeons' and interventional radiologists' views on the most appropriate treatment of SLI due to infringuinal disease was undertaken with the aim of identifying the "grey area of clinical equipoise" for the trial.^{8,9}

Between August 1999 and June 2004, 452 patients presenting to 27 UK hospitals with SLI due to infringuinal disease, and who required immediate/early revascularization, were randomized to either a BSX-first (n = 228) or a BAP-first (n = 224) revascularization strategy¹⁰ (Fig 1). The main outcomes were amputation-free survival (AFS), overall survival (OS), Health-Related Quality of Life (HRQL), and use of hospital resources. All patients provided written informed consent and the study was approved by the Multi-Centre Research Ethics Committee for Scotland. The BASIL trial was registered with the National Research Register and the International Standard Randomised Controlled Trials Number Scheme (number 45398889). Follow-up data were obtained from dedicated research nurses; the Information and Statistics Division of the National Health Service in Scotland using record linkage to Scottish Morbidity Records (SMR01) and the General Registrar Office (Scotland); the Office of National Statistics in England; paper and electronic hospital records; and General Practitioners. Preintervention angiograms were scored using the Transatlantic Inter-Society Consensus (TASC) II on the Treatment of Peripheral Vascular Disease (PVD) classification¹ and the Bollinger scoring system.¹¹

Results

Delphi Consensus Studies

There was very substantial disagreement between and among vascular surgeons and interventional radiologists with regard

to the appropriateness of BSX or BAP for SLI due to infringuinal disease across a wide range of different clinical and angiographic scenarios.^{8,9} This disagreement was greater among surgeons. Surgeons and interventionalists viewed the risks and benefits of their own, and their counterpart's, treatment modality very differently.

BASIL Trial Audit

Approximately half of the patients presenting to the top six BASIL recruiting centers during the recruitment period with SLI due to infringuinal were judged to require, be suitable for, and give their consent to, immediate/early revascularization by either BSX or BAP. Of these, approximately 30% were considered eligible for randomization in that they were judged by the responsible surgeon and interventionalist to be equally suitable for either a BSX-first or a BAP-first strategy; approximately 70% of such patients were randomized (Fig 2).

Patient Characteristics

Trial patients were well-matched in terms of baseline clinical data and the angiographic severity and extent of disease. Over 40% patients had diabetes; more than a third were still smoking; three-quarters had tissue loss; more than half had an ankle pressure <50 mm Hg; a quarter had bilateral SLI; and most were elderly with a significant cardiovascular past medical history. Despite this, a third of patients were not receiving an antiplatelet agent and only a third of patients were receiving a statin when referred to the vascular service for consideration of intervention.

With regard the distribution and severity of infringuinal disease, >40% of the cohort were TASC II group C or D and

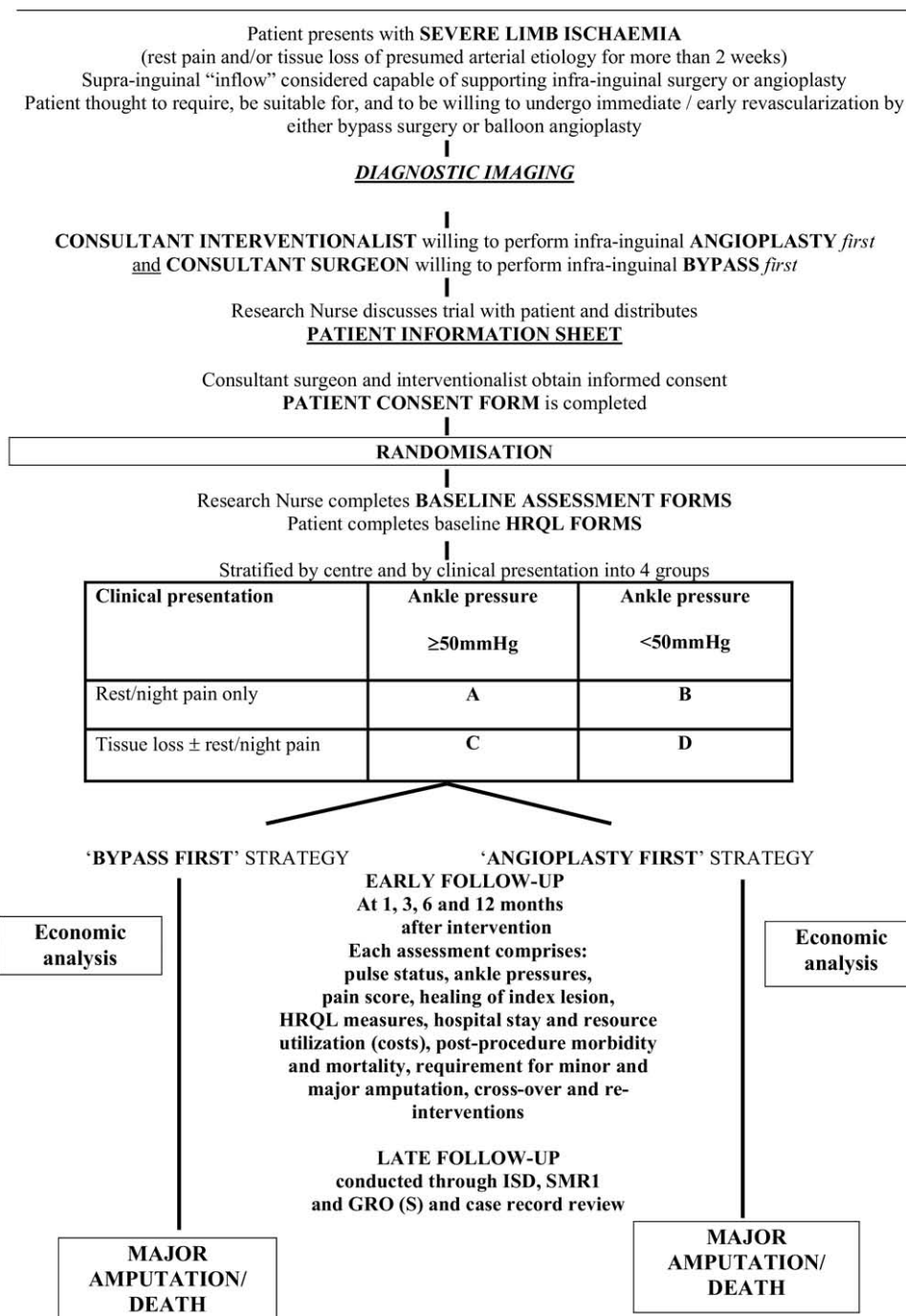


Figure 1 Flow Diagram of Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial design.

>40% were TASC II B. The profunda femoris artery was relatively spared with most disease being concentrated in the distal superficial femoral and proximal popliteal arteries where most patients had occlusion. Approximately one half of patients had occlusion in the proximal and/or distal half of the posterior tibial artery. The anterior tibial artery was less affected with distal and/or proximal occlusions in approximately one third of patients. The peroneal artery was relatively spared. Where forefoot views were available the plantar arch was considered occluded in almost 20% of cases.

Nature of the Interventions Received

One-quarter of BSX involved prosthetic material; 90% of vein grafts were constructed using great saphenous vein; and the distal anastomoses were fashioned in approximately equal numbers at the above-knee popliteal, below-knee popliteal, and crural arteries. With regard to BAP, in approximately 70% of patients, interventional radiologists attempted to treat a single length of disease; in the remainder attempts were made to treat several (up to four) separate disease lengths. The numbers of transluminal and

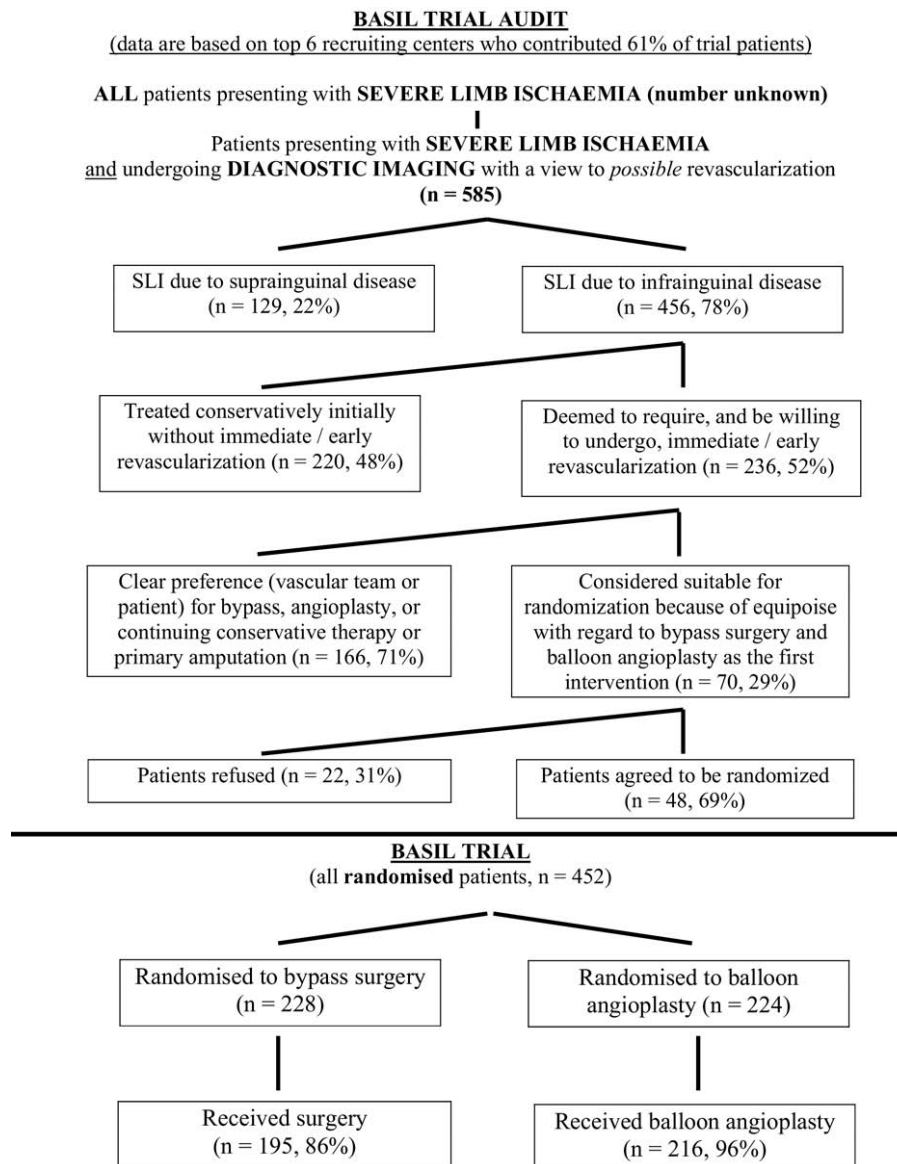


Figure 2 Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial audit: CONSORT diagram showing patients flow into trial.

subintimal BAP were approximately equal with just over 10% being reported as mixed. Approximately 80% of the BAP patients underwent treatment of the superficial femoral artery either alone (approximately 40%) or in combination with the popliteal artery (approximately 40%) and crural arteries (approximately 20%). Most of the remaining BAP patients underwent treatment of the popliteal segments either alone or more usually in combination with crural arteries; the number of isolated crural artery balloon BAP was small. Patients who had BAP-first were significantly more likely to suffer an immediate technical or early clinical failure (approximately 27%) than those who had BSX-first (approximately 7%). In more than two-thirds of patients, a failed-first attempt at BAP was followed by a further intervention and in >90% of cases that was surgery.

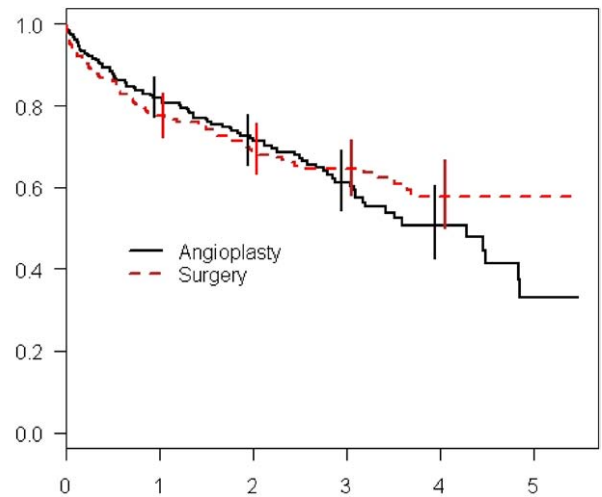
Interim Intention to Treat Analysis—2005

Following randomization, 195 of 228 (86%) patients randomized to BSX and 216 of 224 (96%) to BAP underwent an attempt at their allocated treatment at a median of 6 (interquartile range, 3-16) and 6 (interquartile range, 2-20) days, respectively. BSX was associated with significantly lower immediate failure (3% v 20%), higher 30-day morbidity (57% v 41%), and lower 12-month reintervention (18% v 26%) rates than BAP. The 30-day mortality was similar (BSX 5%, BAP 3%). By 2005, 99% of patients had been followed-up for 1 year, 48% for 3 years, 248 (55%) patients were alive with their trial leg intact, 38 (8%) were alive with their trial leg amputated, 36 (8%) had died subsequent to having their trial leg amputated, and 130 (29%) had died with their trial leg intact. AFS at 1 and 3 years was not significantly different; 68% and 57% for BSX and 71% and 52% for BAP. However,

a post-hoc analysis found a significantly reduced hazard in terms of AFS (adjusted hazard ratio [HR] = 0.37 [95% confidence interval {CI}, 0.17-0.77]; $P = .008$) and OS (adjusted HR = 0.34 [95% CI, 0.17-0.71]; $P = 0.004$) for a BSX-first strategy relative to a BAP-first strategy beyond 2 years from randomization¹⁰ (Figs 3 and 4). We therefore followed the patients for another 2½ years to gather further long-term outcomes data.

Final Intention to Treat Analysis—2008

Apart from four patients lost to follow-up, by 2008 100% of patients were followed for 3 years and 54% for more than 5 years; the longest follow-up was more than 7 years. At the end of follow-up, patients were either dead ($n = 250$; 56%), alive without amputation ($n = 168$; 38%), or alive with amputation ($n = 30$; 7%) (of trial leg). Considering the follow-up period as a whole, AFS and OS did not differ between randomized strategies. However, for those patients surviving 2 years from randomization, a BSX-first revascularization strategy was associated with a reduced HR for subsequent AFS (HR = 0.85 [95% CI, 0.5-1.07]; $P = .108$) and for subsequent OS (HR 0.61 [95% CI, 0.50-0.75]; $P = .009$) in an adjusted, time-dependent Cox proportional hazards model. For those patients who survived for 2 years after randomization, initial randomization to a BSX-first revascularization strategy was associated with an increase in subsequent restricted mean OS of 7.3 months (95% CI, 1.2-13.4 months; $P = .02$), and an increase in restricted mean AFS of 5.9 months (95% CI, 0.2-12.0 months; $P = .06$), during the subsequent mean follow-up of 3.1 (range, 1 to 5.7) years. A nonrandomized “by treatment received” analysis showed that patients receiving vein BSX-first fared better than those receiving prosthetic BSX-first ($P < .01$ for AFS, $P = .11$ for OS, log-rank tests). There were no differences in outcome be-



At risk	0	1	2	3	4	5
Angio	224	173	116	63	25	6
Surgery	228	169	120	71	26	7

Figure 4 All-cause mortality following bypass surgery (BSX) and balloon angioplasty (BAP) by intention to treat (2005 analysis).

tween transluminal and subintimal BAP. Overall, prosthetic BSX performed significantly worse than both transluminal and subintimal BAP. Patients who underwent BSX after failed BAP fared significantly worse in terms of OS and especially AFS than those who underwent BSX as their first treatment.

Factors Predicting Survival to 2 Years

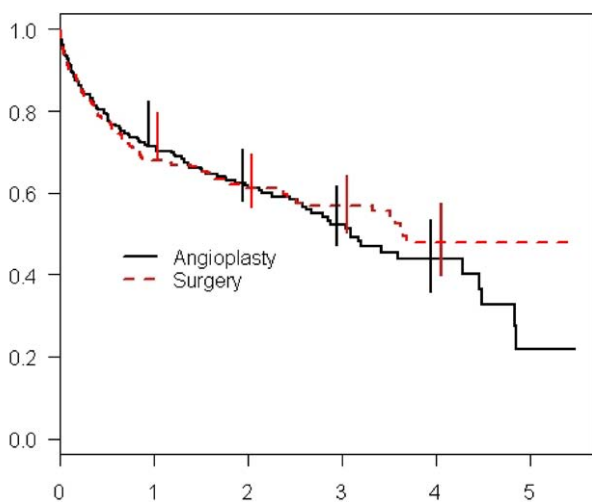
In a multivariate model, increasing age; presence of tissue loss (as opposed to ischemic pain only); diabetes; current smoking; a history of angina or myocardial infarction, stroke or transient ischemic attack; increasing severity of below-knee disease (as measured by the Bollinger angiogram score)¹¹; abnormal body mass index, low number of recordable ankle pressure measurements; and low ankle pressure were highly predictive of those patients unlikely to survive 2 years after intervention.

HRQL

HRQL response rates fell significantly over time (approximately 70% to 75% at 12 months and approximately 40% at both 24 and 36 months), but were very similar for all HRQL instruments used (SF-36, VasculQoL, and EuroQoL) and in the two arms. Amputation was associated with a significant reduction in HRQL. When compared to BAP, BSX was associated with (nonsignificantly) better HRQL before intervention and at all time intervals out to 3 years.

Use of Hospital Resources

During the first-year hospital costs in patients randomized to BSX (UK£22,002) were significantly higher than in those randomized to BAP (UK£16,582). This decreased to UK£3,533 (UK£29,006 BSX v UK£25,472 BAP; nonsignificant) by the end of year 3 and to UK£2,310 (UK£33,539 BSX



At risk	0	1	2	3	4	5
Angio	224	149	100	51	19	2
Surgery	228	148	108	64	23	7

Figure 3 Amputation free survival following bypass surgery (BSX) and balloon angioplasty (BAP) by intention to treat (2005 analysis).

v UK£31,228 BAP; nonsignificant) by the end of year 7. After 3 years, procedure costs accounted for 9% of the BAP group costs compared with 14% for the BSX group; most these were incurred in the first year following randomization. During 7 years, the average number of hospital stays for both groups was four and average total length of stay was just over 2 months (71 days). On average, BASIL patients spent 5 to 6 weeks of their first postrandomization year in hospital and then 2 to 3 weeks per year thereafter. Most of this was in the wards and not in high-dependency and intensive-therapy units. Patients randomized to BSX used around a half day more of high-dependency units and few more hours of intensive-therapy units than those randomized to BAP. A 7-year (nonquality adjusted) perspective shows that patients randomized to BSX live, on average, 41 days longer with their trial leg intact at an additional average cost of UK£2,310 when compared to BAP. The additional cost per AFS year is, therefore, UK£20,579. The 7-year (nonquality adjusted) cost-effectiveness ratio for OS (additional 29 days) is UK£29,095. A 36-month quality-adjusted perspective generates a mean quality-adjusted life time of 442 days for BAP and 452 days for BAP (mean difference 10 days [95% CI, -48-68]); nonsignificant). This extra 10 days is obtained at an estimated additional average hospital cost of UK£3,533 for BSX so giving point estimate of the cost-effectiveness of BSX compared with BAP over 3 years, the "cost per QALY [quality-adjusted life years]," of UK£125,499.

Conclusions

Clinical Outcomes

The Delphi study showed, as expected, that there was substantial disagreement between and among surgeons and radiologists with regard to the appropriateness of BSX or BAP for SLI. The broad "grey area of clinical equipoise" revealed by the study confirmed the need for the trial and helped to persuade surgeons and radiologists to participate.

Most BASIL patients had developed their SLI slowly over months and often years. Despite that, and despite clearly being at exceptionally high cardiovascular risk as a result of multisystem atherosclerosis, a third of trial patients were not receiving an antiplatelet agent and only a third of patients were receiving a statin when referred to vascular services. These data confirm those from many other groups that the diagnosis and medical treatment of patients with peripheral arterial disease (PAD) often falls below an acceptable standard. One can only speculate how many BASIL patients would not have developed SLI (or at least had the onset delayed) had their PAD been diagnosed earlier leading to prompt evidence-based medical therapy.

Patients who survived 2 years (about 75% of the BASIL cohort) and who were initially randomized to a BSX-first strategy gained a significant approximately 7 months of additional life and an additional (nonsignificant) approximately 6 months of amputation-free life when compared to those randomized to BAP. Some might argue that these gains are not clinically meaningful. However, this survival advantage for BSX has to be viewed in the context of a condition that has an overall prognosis

not dissimilar from many common malignancies. For such patients, an additional 6 to 7 months of life with leg(s) intact seems likely to be viewed as an important benefit.

By contrast, SLI patients unlikely to live at least 2 years are probably better served by a BAP-first strategy because they are unlikely to reap the longer-term benefits of BSX; may be more likely to suffer surgical morbidity and mortality; and because BAP is significantly less expensive and less morbid in the short-term.

A prognostic model developed from baseline clinical and angiographic trial data was highly predictive of individual patient survival to 2 years. Although such models must be used with great caution, they may aid decision-making regarding the relative merits of a BSX-first versus a BAP-first revascularization strategy for future "BASIL-like" patients.

The BASIL trial confirms that prosthetic BSX usually performs poorly in this patient group; usually worse than BAP. Had only those patients able to undergo vein bypass been randomized in BASIL then the longer-term advantages of BSX over BAP might have been substantially greater. However, the investigators believe that it was appropriate to include prosthetic grafts as it reflects real-world practice and because the trial was a comparison of best surgical option first versus best endovascular option first. Nevertheless, a nonrandomized by treatment received (as opposed to intention to treat) analysis of the BASIL data suggests that many patients who could not undergo a vein BSX-first would probably have been better served by a first attempt at angioplasty. The trial reaffirms once again that surgeons should make every effort to use vein and to view prosthetic material in such patients as a last resort.

An important question is whether BAP alone still represents best endovascular therapy for this patient group. Stenting and various other adjuncts, such as atherectomy, may have reduced immediate technical and early clinical failure rate in the endovascular arm—but would they have improved longer term clinical and cost-effectiveness? All we can be certain about at this stage is that such adjuncts would have significantly increased the costs. Further RCTs are clearly required as are further analyses of the BASIL and other datasets to determine if we can predict when BAP alone is likely to be a near futile exercise.

It has often been claimed that unsuccessful BAP does not jeopardize the chances of subsequent BSX. The BASIL trial data do not support this "free shot" view of BAP. Patients who underwent BSX after failed BAP fared significantly worse than those who underwent BSX as their first procedure. This may be because a failed BAP selects out patients who were going to do badly whatever intervention is offered; or because angioplasty per se reduces the chances of successful subsequent BSX by affecting the type and extent of bypass required and/or the run-off. Again, further research is required in this important area.

Generalizability

One of the main criticisms leveled against all RCTs is their lack of generalizability; and BASIL is no exception. It is important to emphasize that BASIL was not a trial of all patients presenting with SLI any more than the landmark carotid or

aortic aneurysm trial were studies of all patients presenting with those conditions. Patients were, of course, only eligible for BASIL if:

1. They required, were suitable (fit) for, and would give consent to immediate/early revascularization (about 50% of patients in the BASIL audit of top recruiting centers).
2. In the joint opinion of the responsible surgeon and interventionalist they could reasonably be treated by either a BSX-first or BAP-first strategy (about a third of that 50%, approximately 70% of whom were randomized, a high proportion by RCT standards)

So BASIL was likely to have excluded those patients with more:

1. Limited (proximal) disease who were suitable for BAP, where BSX was thought to be inappropriate; and
2. Extensive (distal) disease who were considered unsuitable for BAP and to be candidate for (often very) distal BSX.

All RCTs must driven by the “uncertainty principle” and operate in this “gray area of clinical equipoise” that characterizes patients who occupy the middle ground; not to do so would be ethically and scientifically unacceptable.

BASIL trial patients had, for the most part, severe and extensive multilevel disease, and poor outcomes in terms of loss of life and limb almost regardless of what treatment was offered. Nevertheless, for the reasons discussed above, BASIL patients are likely to represent the “better” end of the SLI disease spectrum in that they were offered a revascularization procedure at all and, also, considered potentially suitable for BAP. Outcomes for the SLI (or critically ischemic) patient group as a whole are likely to be significantly worse still. By reporting the clinical and angiographic severity of disease of the BASIL trial cohort in great detail we believe we are allowing clinicians to assess for themselves with a high degree of accuracy and confidence whether and how the BASIL trial cohort (and its findings) relates to their own SLI patient population.

Cost-Effectiveness

Although in the short-term, surgery was more expensive, overall there was little difference in costs between the two trial arms. It is clear that in this highly morbid patient group of patients there were a wide range of medical and social factors (other than the status of the trial leg and its treatment) that determined admission, readmission, length of stay in hospital, and outcomes. Furthermore, the higher procedure costs and morbidity associated with BSX have to be weighed against the significantly higher immediate failure and reintervention rates with BAP. Hospital costs were largely driven by the time spent in wards rather than in specialist high-density or intensive-therapy unit environments, or by procedure costs. In the context of the UK National Health Service, discharging patients more promptly and effectively from expensive acute hospital beds to properly resourced, “step-down” convalescence and rehabilitation facilities would seem likely to both improve functional outcomes and reduce costs. There

was no attempt in the BASIL trial to collect data on medical or social care resource utilization or costs from outside hospital. However, it is reasonable to assume that such costs will be considerable (perhaps as much as, or even more than, the direct hospital costs) and that they will be broadly similar in the two trial arms.

Although a 3-year quality adjusted perspective suggests BSX will be highly cost-ineffective when compared to BAP (UK£125,499 per quality-adjusted life years), a 7-year (non-quality-adjusted) perspective suggests the additional cost per AFS year is UK£20,579 and per year of OS is UK£29,095. However, there remains a substantial possibility that surgery may in fact remain cost-ineffective at broadly accepted willingness to pay thresholds. Whether such economic analyses should affect clinical decision making when faced with a SLI patient who could reasonably be treated by either BSX or BAP is a matter for debate.

Implications for Practice

The greatest gains in SLI lie in early diagnosis, aggressive best medical therapy and prompt referral.

As discussed here, it seems likely that measures aimed at:

- Detecting PAD at an earlier stage (before it becomes life and limb threatening);
- Ensuring that all patients with PAD are offered “best medical therapy” and help with life-style modifications (smoking cessation, diet);
- Ensuring appropriate and prompt referral to a vascular unit for specialist care.

Would significantly diminish the social and financial burden imposed by SLI on economies of developed and developing countries alike.

Thus, the humbling reality for vascular surgeons and interventionalists is that regardless of what form of revascularization we offer, most patients with SLI have an extremely poor prognosis. The answer to SLI as far as the “health of the nation” is concerned lies in better public health and primary medical care and not in the operating room or interventional suite.

Multidisciplinary Team Working

BASIL trial data show that the best outcomes for SLI are achieved when vascular surgeons and interventional radiologists work closely together with colleagues from other professions (eg, nursing, physiotherapy, occupational therapy, rehabilitation services, orthotists, and prosthetists) as part of a multi-disciplinary team. It seems likely, therefore, that SLI may be another example of where vascular care is best delivered in specialist, high-volumes centers. This requires further evaluation but appears entirely consistent with the general direction of travel regarding training in, and delivery of, vascular services in the UK (www.vascularsociety.org.uk) and in many other countries.

Delphi Consensus Studies

It would seem highly desirable to repeat these studies to determine whether there has been any convergence of views as to the relative merits of bypass surgery and balloon angioplasty in SLI patients in the light of the BASIL trial data.

Treatment Recommendations Based on BASIL Trial Data

The BASIL trial clinical outcome data suggest that, in SLI due to infrainguinal disease requiring immediate/early revascularization, patients expected to live:

- Less than 2 years should usually be offered balloon angioplasty first; especially where there is no vein for bypass; and
- More than 2 years should usually be offered bypass surgery first; especially where vein is available for bypass.

Validation of the BASIL Trial Prediction Model

Given that the main factor determining whether a BSX-first or a BAP-first strategy is preferable in patients with SLI who could be treated by either method appears to be the likelihood of them being alive at 2 years, it would seem important to validate the BASIL trial survival prediction model in a separate cohort of "BASIL-like" patients.

Role of Prosthetic Bypass in the Management of SLI

Patient outcomes following prosthetic BSX in the BASIL trial were extremely poor. It seems clear that vascular surgeons should use vein for BSX wherever possible and view prosthetic BSX as very much a last resort. Even in patients expected to live more than 2 years it appears likely that attempting BAP in the first instance is preferable to embarking upon prosthetic BSX. In some cases even primary amputation might be preferable to reconstruction with prosthetic material.

Role of Balloon Angioplasty in Management of SLI

In keeping with other studies the immediate technical and early clinical failure rate of balloon angioplasty in the BASIL trial was high (>25%). There is clearly an urgent need for further research to:

- Identify those patients and anatomies where angioplasty is unlikely to be successful;
- Understand the mechanisms of failure; and
- Develop new procedures, techniques and devices (such as stents and stent grafts) that may increase the success of peripheral vascular endovascular interventions both initially and in the longer-term.

We respectfully suggest that it would be preferable if such research were to be publicly funded rather than predominantly commercially funded.

Role of Amputation in Management of SLI

Regrettably, many SLI patients soon require major limb amputation despite the best efforts of vascular surgeons and interventionalists to revascularize the limb. Clinical and resource utilization data from BASIL, taken together with the prediction model, suggest that the interests of a significant proportion of BASIL patients might have been best served by primary amputation, followed by high-quality rehabilitation, rather than, often repeated, unsuccessful attempts at revascularization. Although controversial, the BASIL trial leaves the way open for a trial of (probably largely endovascular) revascularization versus primary amputation versus best medical and nursing care only in selected poor prognosis patients.

Need for Further Publicly Funded Trials in Peripheral Vascular Disease

Given the socioeconomic burden that SLI places upon developed and increasingly developing nations it seems quite extraordinary that, to our knowledge, BASIL remains the only RCT to compare the surgical and endovascular treatment of this condition. Further comparable trials are clearly required in order to confirm (and expand) or refute the BASIL findings and recommendations. We suggest that it is not in the public interest that responsibility for such trials should be left entirely with the private sector where research is understandably driven by commercial interests. The need for further publicly funded trials in peripheral vascular disease would seem clear.

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