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Seminars in VASCULAR SURGERY

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]

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.

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Table 1 Potential Advantages and Disadvantages of Bypass Surgery and Balloon Angioplasty as a First-Line Treatment for Severe Limb Ischemia Due to Infrainguinal 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 infrainguinal 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 infrainguinal disease, and who required immediate/early revascularization, were randomized to either a BSX-first (n = 228) or a BAP-first (n = 224) revascularization strategy[10] (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) classification[1] 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 infrainguinal 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 infrainguinal 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 infrainguinal disease, >40% of the cohort were TASC II group C or D and