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Bypass or Angioplasty for Severe Limb Ischaemia? A Delphi Consensus Study

A. W. Bradbury*[1], J. Bell[1], A. J. Lee[2], R. J. Prescott[2], I. Gillespie[4], G. Stansby[5] and F. G. R. Fowkes[3]

[1]*BASIL Trial Office, Research Institute (Lincoln House), Heartlands Hospital, University of Birmingham, U.K.,* [2]*Medical Statistics Unit and* [3]*Wolfson Unit for Prevention of Peripheral Vascular Diseases, Public Health Sciences, University of Edinburgh, U.K.,* [4]*Department of Medical Imaging, Edinburgh Royal Infirmary and* [5]*Department of Vascular Surgery, Freeman Hospital, University of Newcastle, U.K.*

Objectives: *to examine the level of agreement among vascular surgeons and interventional radiologists regarding their preference for the surgical or endovascular management of severe limb ischaemia.*
Design: *Delphi consensus study using 596 different hypothetical patient scenarios.*
Participants: *Delphi consensus group for the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial.*
Methods: *twenty consultant vascular surgeons and 17 interventional radiologists completed both rounds of the study. The scenarios detailed the anatomical extent of disease, whether the patients had rest pain only or had tissue loss, and whether or not a suitable vein for bypass was available. Panellists were asked to score their treatment preference for either surgery or angioplasty on an eight-point scale. Outliers (top 10% and bottom 10% responses) were removed. If the remaining 80% of responses fell within a 3-point range, this was defined as "agreement". If they did not, this was considered "disagreement".*
Results: *there was substantial disagreement in 484 (81%) of scenarios in round 1 and 401 (67%) in round 2. This disagreement was greater among surgeon than radiologists in both round 1 (83 vs 65%) and round 2 (69 vs 42%). Surgeons also demonstrated less convergence between rounds.*
Conclusions: *there is substantial disagreement between and among surgeons and radiologists with regard to the appropriateness of surgery or angioplasty for severe limb ischaemia. This lack of consensus stems from the absence of an evidence base and means that the same patient may receive entirely different treatment depending on which hospital and consultant they attend. Not only may this unexplained variation be clinically unsatisfactory, it has major implications for the planning and use of health service resources.*

Introduction

In the U.K., over 20 000 patients are treated for severe limb ischaemia (SLI) each year at an estimated cost of £1 billion.[1] Similar data are available for many other European countires. The relative indications for bypass surgery and angioplasty remain controversial with strongly held and diametrically opposed views being expressed by surgical and radiological experts.[2–6] Two trials have suggested that surgery and angioplasty may achieve similar survival and limb salvage rates in certain patients. However, both trials were small and methodologically flawed and provide little or no evidence on which to base current treatment.[7,8] Clinicians views are, therefore, almost entirely based upon personal experience, the nature of their training and the results of uncontrolled observational studies.

Many vascular surgeons believe that surgery is the treatment of choice for virtually all patients affected by SLI. However, angioplasty is increasingly used as a first-line treatment because surgery is associated with significant mortality, not all patients have a suitable vein for bypass and there is a lack of health care resources and trained personnel to perform these demanding operations.[9] There are also a number of theoretical advantages to angioplasty; it may be safer, quicker, less expensive and may not prejudice subsequent surgical bypass if required.[10] On the other hand the surgical bypass may provide a more complete and durable revascularisation of the limb. The Bypass

* Please address all correspondence to: A. Bradbury, Professor of Vascular Surgery, BASIL Trial Office, Research Institute (Lincoln House), Heartlands Hospital, Bordesley Green East, Birmingham B9 5SS, U.K.
On behalf of the BASIL Trial Delphi Consensus Group.

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versus Angioplasty for Severe Ischaemia of the Leg (BASIL) trial is an on-going U.K.-based, Health Technology Assessment funded, multi-centre, randomised, controlled trial comparing the clinical and cost-effectiveness of a "bypass first" with an "angioplasty first" strategy in patients with SLI.[11] To examine the level of agreement among vascular surgeons and interventional radiologists with regard to the surgical and endovascular management of SLI, and to establish a "grey area of clinical equipoise" prior to the start of the BASIL trial, a Delphi consensus study was undertaken.

Participants and Methods

Modified Delphi technique

The modified Delphi consensus method is an accepted means of quantifying the level of agreement among a group of medical "experts".[12,13] The technique has been applied to a wide range of clinical areas including interventions for vascular disease.[14,15] Briefly, a panel of "experts" is asked to rate independently the appropriateness of each intervention for a range of hypothetical clinical scenarios. The median and range of these first round responses are fed back to panellists so that that each can see where their response lay in relation to those of their peers. Panellists are given the opportunity to amend their response in a second round by completing the questionnaire again. From these data the initial and final level of agreement, as well as the degree of convergence between the first and second rounds, can be quantified.

Panellists

At its inception, the BASIL trial was based in Scotland and the north-east of England. All the consultant vascular surgeons and interventional radiologists working in this geographical area had agreed to participate in the trial. The trial subsequently incorporated several other English centres. The Delphi consensus questionnaire was, therefore, sent to all 37 consultant vascular surgeons and 31 consultant interventional radiologists working in these areas/centres. Twenty (54%) surgeons and 17 (55%) radiologists (Appendix 1) provided complete and evaluable responses for both rounds.

Delphi questionnaire

Surgeons and radiologists were presented with 596 different hypothetical patient scenarios. Scenarios provided information regarding the anatomical extent of disease, whether the patients had rest pain only or had tissue loss (defined as ulceration and/or gangrene with or without rest pain) and whether or not a suitable vein for bypass was available.

Anatomical extent of disease

Panellists were presented with angiographic representations (Fig. 1) depicting three main infra-inguinal segments (superficial femoral artery, popliteal artery and crural arteries). Each segment was presented as having either "no disease", "focal (<10 cm) non-occlusive disease", "diffuse (>10 cm) non-occlusive disease", "short (<10 cm) occlusion" or "long (>10 cm) occlusion". In disease scenarios that included a long occlusion of the crural arteries, participants were also asked to consider their response in the presence of a patent (with "run-off") and occluded ("without run-off") pedal arch. Allowing for all possible disease combinations, this resulted in a total of 149 angiographic representations. We did initially intend to conduct the study with actual angiogram

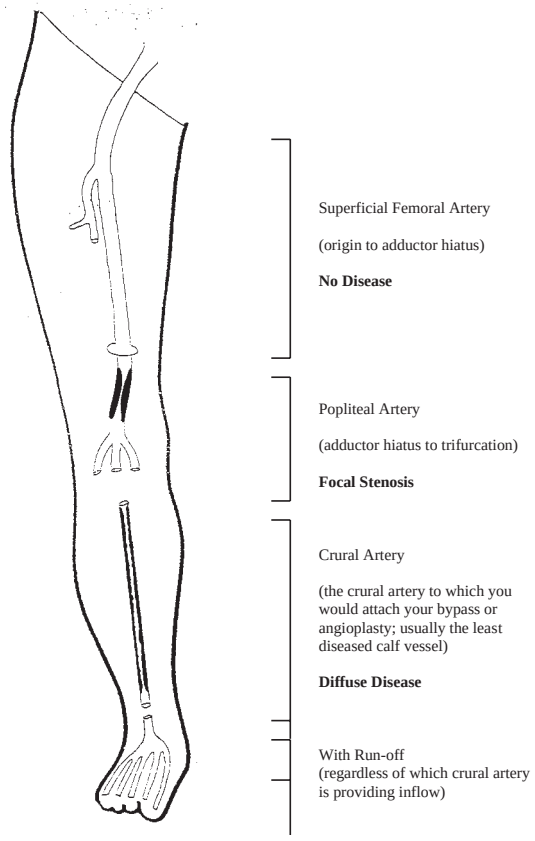

Fig. 1. Example of an angiographic representation used in questionnaire.

films. However, it became almost immediately apparent that it was going to be impossible to obtain angiograms of sufficient and, importantly, uniform quality that represented all the (very many) different combinations of disease. Furthermore, the copying and transportation of these films to all the panellists proved to been logistically and financially impossible.

Clinical severity of disease and suitable bypass
Participants were asked to consider each angiographic representation in the presence of rest pain only versus tissue loss (ulcer and/or gangrene). Panellists were asked to assume that all the patients symptom/signs were due to arterial disease. It was the view of the Consensus group that the addition of ankle pressure would not be helpful.

Presence of vein
Participants were asked to consider each angiographic representation in the presence a suitable vein for bypass vs no suitable vein. As practice varies with regard to the relative use of veins other than the ipsilateral long sapheneous vein and prosthetic grafts, the nature of the conduit to be used was not further prescribed.

Scoring
For each of the 596 scenarios, respondents were asked to score their preferred treatment option as follows:

(1) Could only be treated by PTA;
(2) Could be treated by PTA or surgery but I strongly prefer PTA;
(3) Could be treated by PTA or surgery but I prefer PTA;
(4) Could be treated by PTA or surgery and I have no preference;
(5) Could be treated by PTA or surgery but I prefer surgery;
(6) Could be treated by PTA or surgery but I strongly prefer surgery;
(7) Could only be treated by surgery;
(8) Not amenable to revascularisation – primary amputation.

Assumptions
In formulating their responses, participants were asked to make four assumptions:

(1) There was no significant supra-inguinal or profunda femoris artery disease;
(2) Medical therapy had failed such that revascularisation, either by surgery or PTA, or primary amputation were the only options;
(3) Apart from the information provided to them, there were no other contra-indications to either surgery or PTA;
(4) The crural artery depicted was the least diseased of the three and thus likely to be the target artery for surgical or endovascular treatment.

Most of the panellists found that it took 1–2 h to complete each questionnaire.

Data analysis

To allow for direct comparison between rounds only responses received from the 20 surgeons and 17 radiologists who completed both rounds were considered. By convention, the highest 10% and lowest 10% of the responses were discarded as "outliers". The remaining responses were deemed to show "agreement" if they fell within a three-point range and "disagreement" if they did not. This resulted in 6 possible agreement groups as follows:

All responses fell with the range	Agreement that
1–3	Angioplasty strongly preferred
2–4	Angioplasty preferred
3–5	No preference
4–6	Surgery preferred
5–7	Surgery strongly preferred
6–8	Surgery/Amputation preferred

The results were analysed for all respondents and for surgeons and radiologists only. Agreement was also assessed by means of the weighted Kappa (κ) statistic, which was calculated from a summary table of frequencies based upon the comparison of each possible pair of raters. As the numbers of observers and scenarios are large, these estimates are extremely precise, and confidence intervals are not presented. A κ of less than 0.40 is defined as poor agreement. Equipoise was defined as existing when there was a consensus that both angioplasty and surgery would be equally clinically effective (3-point agreement for 3–5 "no preference") or where there was disagreement about the preferred treatment.

Results

Treatment preferences in round 1

In round one, there was little difference between the distribution of surgical and radiological responses, both of which were bimodal (Fig. 2). Both surgeons and radiologists thought primary amputation was indicated in approximately 9–10% of scenarios.

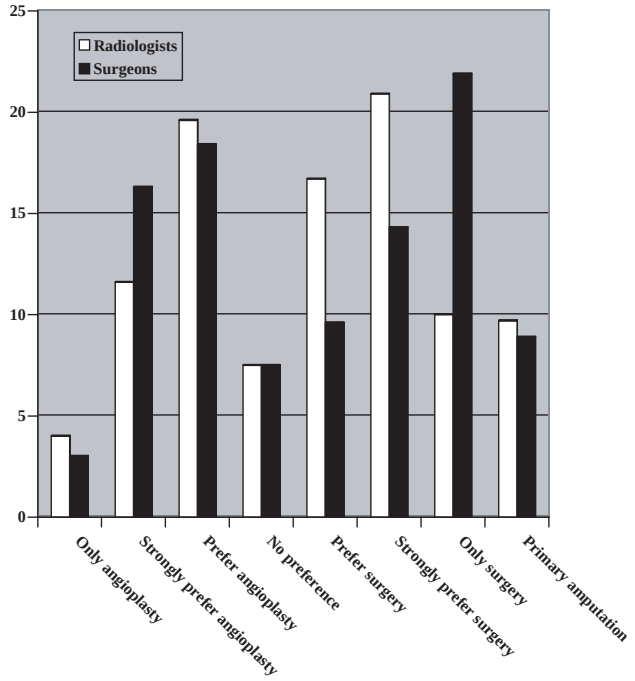

Fig. 2. Percentage of surgical and radiological responses in each category in round 1.

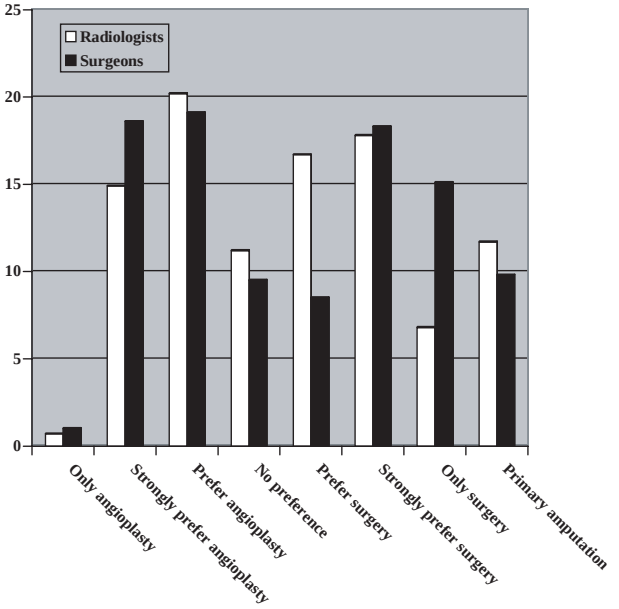

Fig. 3. Percentage of surgical and radiological responses in each category in round 2.

Although both groups felt that surgery was preferred in the majority of scenarios (surgeons 46% and radiologists 48%), the strength of the preference for surgery was greater for the surgical group. By contrast, surgeons thought angioplasty was to be preferred in 38%, compared with 35% for radiologists, with the strength of the preference being very similar between the two groups. Surgeons and radiologists expressed no preference for either treatment in 7.5%. It appears therefore that, in the great majority of scenarios, both surgeons and radiologists had moderate to strong preference for one or other treatment. However, with regard to the level of agreement as to which was the preferred treatment, when surgical and radiological responses were combined, the weighted κ statistic was 0.25. Although the weighted κ was higher for radiologists ($\kappa = 0.29$) than for surgeons ($\kappa = 0.21$), all three κ values denote poor agreement.

Treatment preferences in round 2

Although individual respondents frequently changed their responses in round 2, overall there was little change in the distribution of surgical or radiological responses (Fig. 3). Surgeons still felt that most scenarios warranted surgery but the strength of that preference diminished and there was some movement towards angioplasty by both groups. The proportion of scenarios thought to warrant primary amputation increased a little as did the proportion in which surgeons and radiologists expressed no preference for either treatment. When surgical and radiological responses were combined, the weighted κ statistic was 0.38, which was higher than in round one but still denotes poor agreement. The weighted κ for radiologists rose to 0.45, denoting moderate agreement, but agreement among surgeons remained poor ($\kappa = 0.32$).

Level of agreement and convergence between rounds

When the surgical and radiological responses were combined there was substantial disagreement in 484 (81%) of scenarios in round one and 401 (67%) in round two (Fig. 4). This disagreement was greater among surgeons than radiologists in both round 1 (83 vs 65%) and round 2 (69 vs 42%) (Table 1). Although, because of their smaller number, one would expect a greater level of agreement among radiologists, this would not account for the large differences in the level of consensus observed between surgeons and radiologists. There was a better level of agreement among surgeons ($\kappa = 0.77$) than radiologists ($\kappa = 0.61$) between the first and second rounds. This was because, in round 2, radiologists were more likely than surgeons to change their score towards the group mean on the basis of feedback from round 1.

Table 1. Number and percentage of disease scenarios falling into each three-point agreement and disagreement range for rounds 1 and 2 for surgeons only and radiologists only.

	Surgeons only				Radiologists only			
	Round 1		Round 2		Round 1		Round 2	
	n	%	*n*	%	*n*	%	*n*	%
123	25	4	62	10	45	8	93	16
234	32	5	96	16	74	12	136	23
345	0	0	1	0	22	4	72	12
456	0	0	5	1	32	5	61	10
567	46	8	68	11	77	13	86	14
678	21	4	36	6	21	3	50	8
Any agreement	103	17	187	31	210	35	343	58
Disagreement	493	83	409	67	386	65	253	42

Note that some response combinations would appear in the "any agreement" line more than once. For example, if there is a 2-point agreement of "23" this will appear in the "123" and "234" agreement categories.

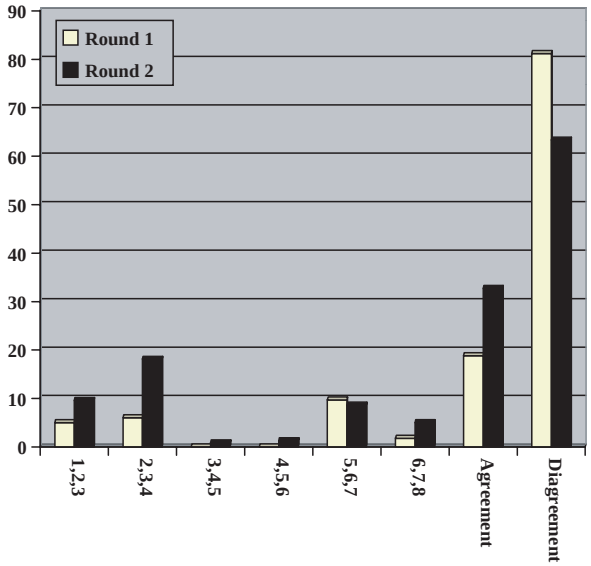

Fig. 4. Level of agreement and disagreement regarding the appropriateness of angioplasty or surgical bypass.

"Grey area of clinical equipoise" for the BASIL trial

Equipoise was defined as existing when there was a consensus that both angioplasty and surgery would be equally clinically effective (3-point agreement for 3–5 "no preference") or where there was disagreement about the preferred treatment. In round one, 81% of scenarios fell into the grey area compared with 68% of scenarios in round 2 (Table 2). In both rounds, the grey area comprised largely of scenarios in which there was disagreement rather than scenarios in which there was agreement that either treatment would be equally effective.

Table 2. "Grey area of clinical equipoise" for the BASIL trial.

	Agreement within "345" range (%)	Disagreement (%)	Total (%)
Round 1			
Surgeons	0.0	83	83
Radiologists	4	65	69
Combined	0.0	81	81
Round 2			
Surgeons	0.2	69	69
Radiologists	12	42	55
Combined	0.8	67	68

Discussion

The clinically important finding of the study is the very substantial level of disagreement between and among surgeons and radiologists with regard to the appropriateness of surgery or angioplasty for SLI over a wide range of clinical and angiographic severities of disease. Despite the fact that the information provided to the panellists was less complex than would be the case in the real clinical situation, in round 1 there was disagreement among surgeons in 83%, and among radiologists in 65%, of scenarios. Although there was some convergence of views in round 2 following feedback from peers, the level of disagreement was still 69% for surgeons and 42% for radiologists. This lack of consensus, which is reflected in the literature, stems from the absence of an evidence base and means that the same patient may receive entirely different treatment depending on which hospital and consultant they attend. Indeed, such is the lack of consensus, that surgeons and radiologists working in the same institution might disagree fundamentally about which treatment option is most desirable, possible, or even

ethical. While some would argue that a good result can be obtained in exactly the same patient using two completely different techniques, equivalence in terms of clinical and cost-effectivness is, in reality, unlikely and cannot be assumed in the absence of evidence. So it is our view that the very considerable and largely unexplained variation in practice demonstrated in this study is likely to disadvantage patients. Furthermore, it has major implications for the planning and use of health service resources, referral pathways and, of course, surgical and interventional training. Although the present study has clearly demonstrated a large collective "grey area of clinical equipoise", there is much less equipoise on the part of individual clinicians. The bimodal response distribution observed for surgeons and radiologists, and which changed relatively little between the two rounds (especially for surgeons), indicates that most clinicians have strong preferences as to how individual patients should be treated; despite a complete absence of level I evidence. Hopefully, recognition that current practice is not evidence-based, together with the results of this present study, will encourage the randomisation of patients into the BASIL trial within the U.K. However, the difficulty of changing individual clinical opinion cannot be under-estimated: "sometimes wrong, but never in doubt".

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