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Is Infrainguinal Bypass Grafting Successful Following Failed Angioplasty?

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Objectives. *Angioplasty is often used in the management of lower limb ischaemia and can reduce the need for infrainguinal bypass in some patients. There is an associated failure rate with this technique and bypass surgery is often used in this situation as a secondary limb salvage procedure. We aimed to evaluate the outcome of infrainguinal bypass grafting following failed attempt at angioplasty.*
Methods. *All cases of infrainguinal bypass at a single centre over a seven year period were identified and notes reviewed. Cases were divided into four groups according to their indication for surgery; acute ischaemia, chronic critical ischaemia, failed angioplasty and an 'other' group including aneurysmal disease and claudicants. The failed angioplasty group was compared with the other three groups. Survival analysis was performed using Kaplan Meier curves and groups compared in terms of long term patency and survival.*
Results. *Primary patency was 61.2% in the failed angioplasty group at 12 months compared with 60.6% in the other groups (*$P = 1.11$*). There was also no significant difference in primary patency at 60 months (50% vs 40.6%,* $P = 0.26$*). Survival at 12 months was also comparable between the groups (failed angioplasty group 74.2% compared with 77.3% in the other groups,* $P = 0.662$*) as was 60 months survival (33.3% and 35.4% respectively,* $P = 0.166$*).*
Discussion. *In this study, outcome of infrainguinal bypass following failed angioplasty was comparable to outcome of surgery performed for another indication. This paper supports the use of distal bypass surgery for limb salvage in cases where minimal access techniques have failed.*

Keywords: Infrainguinal bypass; Outcome; Angioplasty.

Introduction

Infrainguinal bypass grafting (IIB) has traditionally been the standard treatment for lower limb ischaemia. Controversies still exist over choice of graft material[1–3] and traditional outcome measures such as graft patency and mortality have been suggested to overestimate success.[4,5] In an effort to improve patencies and reduce wound complications a number of minimal access approaches have been attempted however these have seen variable results and have not yet found a place in routine clinical practice.[6,7]

Over the last 10 years, angioplasty has provided an alternative to bypass surgery in many cases. Evidence suggests that outcome following lower limb angioplasty may be comparable to surgery, producing patencies of up to 79% at six months and 64% at five years post procedure.[8] Technical success rates achieved at angioplasty are reported at around 85%.[9] Angioplasty may be unsuccessful due to a number of reasons: (1) Failure to cross the occlusion; (2) distal embolisation; (3) perforation of vessel; (4) failure to re-enter the lumen (in the case of a subintimal approach); (5) early re-occlusion.

In cases where angioplasty has failed, decisions regarding further management may be difficult. It may be that angioplasty has failed because of poor 'run-off' vessels, and therefore attempt at bypass surgery would also be likely to fail. In addition to this, the patient population are often elderly with significant co-morbidity and may have a poor outcome from a lengthy bypass procedure.

Currently, no reports describe outcome of IIB following failed attempt at angioplasty. The aim of this study was to determine the outcome of infrainguinal bypass following failed angioplasty and compare this with grafts performed for other indications in order to aid decision making when faced with this clinical scenario.

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Methods

A retrospective review of the case notes of patients undergoing infrainguinal bypass at a single centre during a seven year period from January 1995 to December 2002 was performed. Notes were reviewed by a single investigator (RMS) and details recorded regarding patient demographics, co-morbidity, anaesthesia, graft type and post operative course. Patients were then divided into 4 groups according to their indication for surgery. Group 1 underwent surgery for an acutely ischaemic limb, group 2 for a chronic critically ischaemic limb (defined by rest pain or tissue loss) without prior attempt at angioplasty, group 3 had operations following a failed attempt at elective angioplasty for peripheral vascular disease and group 4 had another indication for bypass, commonly claudication or popliteal aneurysm.

Patients with lesions considered to be suitable for angioplasty underwent primary angioplasty in the first instance, and those patients in group 2 who went straight to surgery had lesions considered unsuitable for angioplasty. Angioplasty was considered to have failed if the procedure was technically unsuccessful or re-occluded before the first post-procedure clinic visit at 6 weeks. All patients were followed up after IIB with duplex ultrasound scans 6 monthly in a Graft Surveillance Clinic.

Patencies and survival data were collected from the notes. Patients were censored from further analysis at the time of death with a functioning graft. Primary patency was defined as uninterrupted patency, not requiring any additional procedures, and secondary patency described grafts which required intervention following thrombosis.

Statistical analysis was performed using the SPSS statistical package version 12.0. Survival analysis was performed using Kaplan Meier curves. A probability value of <0.05 was taken to be significant.

Results

There were 273 grafts performed over the study period in a total of 252 patients. Notes were available for 202 of the patients who underwent 208 grafts. Where notes were unavailable, patients were excluded from the analysis but clinic letters were reviewed to ensure there was no selection bias. Demographic data are shown in Table 1. Cardiovascular risk factors were similar in all groups except for diabetes which was more common in the failed angioplasty group (33.3% diabetic vs 10.1% diabetic in other groups combined).

Table 1. Demographic data

Group	Number of patients	Median Age (range)	% Male	IHD (%)	↑BP (%)	DM (%)
1	42	67 (30–87)	83%	10 (24)	12 (29)	3 (7)
2	60	75 (45–92)	63%	16 (27)	23 (38)	11 (18)
3	66	77.5 (33–92)	45%	18 (27)	38 (58)	22 (33)
4	40	62 (24–85)	85%	6 (15)	8 (20)	2 (5)

Where IHD = ischaemic heart disease (defined as previous myocardial infarct or angina), ↑BP = hypertension (defined as currently treated with antihypertensives) and DM = diabetes.

There were 42 grafts performed for acute ischaemia, 60 for critical ischaemia, 66 for failed angioplasty and 40 in the 'other' category. The small number of grafts performed for critical ischaemia over this time period (group 2) reflects the policy of our centre to perform primary angioplasty for all lesions considered suitable. Indications for angioplasty varied, but were often for critical ischaemia (defined by rest pain or tissue loss) associated with superficial femoral artery and 'run off' vessel occlusion (see Table 2). 23 (35%) patients underwent intraluminal angioplasty for stenoses, where 43 (65%) underwent subintimal angioplasty for occlusion. Seven of the 66 (11%) grafts in group 3 (the failed angioplasty group) were performed as an emergency due to distal embolisation during angioplasty. Other reasons for failure of angioplasty included failure to cross the stenosis in 22% of cases, perforation in 13% of cases, heavy calcification in 6% and early re-occlusion in 31%. In 17% of cases, angioplasty was not possible due to the presence of fresh thrombus. Of those in group 4, there were 11 grafts performed for claudication, 16 for popliteal aneurysms and 3 following lower limb trauma.

During the study period, there were 3802 angioplasties performed. The failure rate from angioplasty at our centre has been previously reported to be 2.3% (defined as requiring immediate surgical intervention for bleeding or ischaemia).[10] The series reported here considers only those requiring infrainguinal bypass grafting and other emergency surgical procedures such as embolectomy or false aneurysm repair have not been included. Patients were considered for surgery in the event of a failed angioplasty (or early reocclusion) based on individual factors such as co-morbidity, presence suitable 'run off' vessels to graft and patient wishes.

The level of the graft was recorded as above knee femoropopliteal (AKFP), below knee femoropopliteal

Table 2. Pattern and level of disease in group 3

Clinical presentation	SFA	Popliteal	Infragenicular
Critical Ischaemia	26	7	12
Claudication	14	3	4

(BKFP) or femorodistal (FD). The graft material used was recorded as *in situ* vein graft (ISVG), reversed vein graft (RVG) or prosthetic graft invariably polytetrafluoroethylene (PTFE) (see Table 3). There were no significant differences between groups in terms of level of graft or material used. Patients undergoing subintimal angioplasty for superficial femoral artery (SFA) occlusions went on to have an infragenicular graft in14 cases. In 4 cases, subintimal angioplasty for 'run off' vessel occlusions in association with SFA occlusions resulted in successful grafting to the above knee popliteal.

There were 7 patients who underwent subintimal angioplasty for 'long' SFA occlusions and of these, 4 went on to require infragenicular bypass grafts (57%). Of the 36 patients undergoing subintimal angioplasty for 'short' SFA occlusions, only 10 required below knee grafts (28%). Although this would seem to suggest that the outcome following subintimal angioplasty for long occlusions is worse than that for short occlusions, 2 of the 4 patients with 'long' occlusions were known to have distal 'run off' vessel disease. Therefore, only 2 of the 7 patients who had subintimal angioplasty for long SFA occlusions required below knee grafts without underlying disease at or below the knee (29%). This is in keeping with the group who had 'short' SFA occlusions.

There was no significant difference between those patients who failed angioplasty and the other groups combined in terms of primary patency or survival at either time point. Twelve month patency was 61.2% in group 3 vs 60.6% in groups 1,2&4 ($P = 1.11$) and 12 month survival was 74.2% in group 3 vs 77.3% in groups 1,&4 ($P = 0.743$) Tables 4a and 4b. Sixty month patency was 50% in group 3 vs 40.6% in groups 1,2&4 ($P = 0.256$) and 60 month survival was 33.3% in group 3 vs 35.4% in groups 1,2&4 ($P = 0.881$) Tables 5a and 5b. Survival and patency curves were constructed and are given in Figs. 1 and 2. Log rank tests were performed at 12 and 60 months for both patency and survival and are given in Tables 6a and 6b.

There were 11 (26%) patients in group 1, 12 (20%) in group 2, 13 (20%) in group 3 and 2 (5%) in group 4 who went on to undergo below knee amputation at 0.5 months, 14 months, 30 months and 24 months post-operatively (median time point) respectively. In the failed angioplasty group, 3 patients underwent amputation following a more distal graft as a result of angioplasty at a median time point of 6 months after surgery.

Of the seven patients who underwent bypass as an emergency procedure following distal embolisation during attempted angioplasty, two patients had successful procedures with no post operative complications; their primary patencies were 87 months and 79 months. Three patients had fasciotomies performed during the surgery in order to prevent a compartment syndrome. Of these three patients, one died at 10 months of an unrelated cause with a functioning graft. The other two had primary patencies of 12 months and 14 months with a primary assisted patency of 19 months in the latter case (each was functioning at the end of the study follow up period). Two patients had grafts which failed, one during the first post-operative day requiring a below knee amputation 2 weeks later, and the other requiring amputation at 1 month. One patient developed a chest infection and one patient had an episode of acute left ventricular failure; both of these complications responded to medical treatment. There were no perioperative deaths in this group of patients.

Table 3. Graft material and level

Group	AKFP(%)	BKFP(%)	FD(%)	ISVG(%)	RVG(%)	PTFE(%)
1	10 (24)	16 (38)	15 (36)	16 (38)	15 (36)	9 (21)
2	24 (40)	19 (32)	15 (25)	12 (20)	23 (38)	22 (37)
3	16 (24)	23 (35)	27 (41)	19 (29)	33 (50)	13 (20)
4	10 (25)	21 (48)	8 (20)	8 (20)	23 (58)	8 (20)

Where AKFP = above knee femoropopliteal graft, BKFP = below knee femoropopliteal graft, FD = femorodistal graft, ISVG = in situ vein graft, RVG = reversed vein graft and PTFE = prosthetic graft.

Table 4a. 12 month percentage patency and survival

Group	Primary patency	Secondary patency	Survival	Censored
1 ($n = 42$)	53% (17/32)	72% (23/32)	76%	24% (10/42)
2 ($n = 60$)	50% (23/46)	83% (38/46)	73%	23% (14/60)
3 ($n = 66$)	61% (30/49)	84% (41/49)	74%	26% (17/66)
4 ($n = 40$)	79% (26/33)	94% (31/33)	83%	18% (7/40)

Discussion

We reviewed all cases of infrainguinal bypass at out centre over a seven year period in order to compare the outcome following failed angioplasty with outcome following surgery for another indication. This time period was chosen as it was felt to be representative of current practice in the management of lower

Table 4b. 60 month percentage patency and survival

Group	Primary patency	Secondary patency	Survival	Censored
1 ($n = 42$)	45% (5/11)	45% (5/11)	26%	74% (31/42)
2 ($n = 60$)	27% (7/26)	58% (15/26)	45%	57% (34/60)
3 ($n = 66$)	50% (11/22)	73% (16/22)	33%	67% (44/66)
4 ($n = 40$)	50% (6/12)	67% (8/12)	35%	70% (28/40)

Table 5a. Survival Table for Survival

Group	No. at risk 12/12	Cum. Surv. 12/12	Std. Error 12/12	No. at risk 60/12	Cum. Surv. 60/12	Std. Error 60/12
1, 2 & 4	122	0.65	0.03	62	0.16	0.02
3	62	0.57	0.05	35	0.15	0.03

Where No. at risk = number of patients at risk; Cum. Surv. = cumulative survival; and Std.Error = Standard Error.

limb ischaemia. There were some limitations to this study. Firstly, data were collected retrospectively and missing notes/information may have reduced the sensitivity of the study. In addition, data were not available regarding patients who underwent unsuccessful angioplasty but did not undergo bypass surgery, thus preventing analysis of surgical outcome with a matched control group. However, in spite of these limitations, some valid conclusions may be drawn.

The failed angioplasty group included a mixed group in terms of clinical presentation, pattern and level of disease and type of angioplasty performed. However, in this series, patency and survival following IIB amongst the failed angioplasty group were comparable with those following bypass for another indication at both 12 and 60 month follow up. The level of graft performed may have been adversely affected by subintimal angioplasty in 14 cases, and positively affected in 4 cases, but the patency and limb salvage rates were not affected by this.

The use of angioplasty in the management of lower limb ischaemia has become standard practice in our centre over the last decade. Although in general debate may exist between surgeons and radiologists over the suitability of cases,[11,12] significant success has been demonstrated particularly with short superficial femoral artery stenoses.[9] There are reports, in fact, of comparable patencies and limb salvage rates between groups treated with angioplasty and those treated with surgery.[13]

There are however, some limitations to the use of angioplasty. Firstly there is a recognised associated complication rate of up to 5% including puncture site problems such as haematoma or false aneurysm, but also distal embolisation and limb loss. Secondly, a number (in the region of 10%) of plastied segments do re-occlude over time, often necessitating further intervention.[14] Finally, a small proportion of attempts at

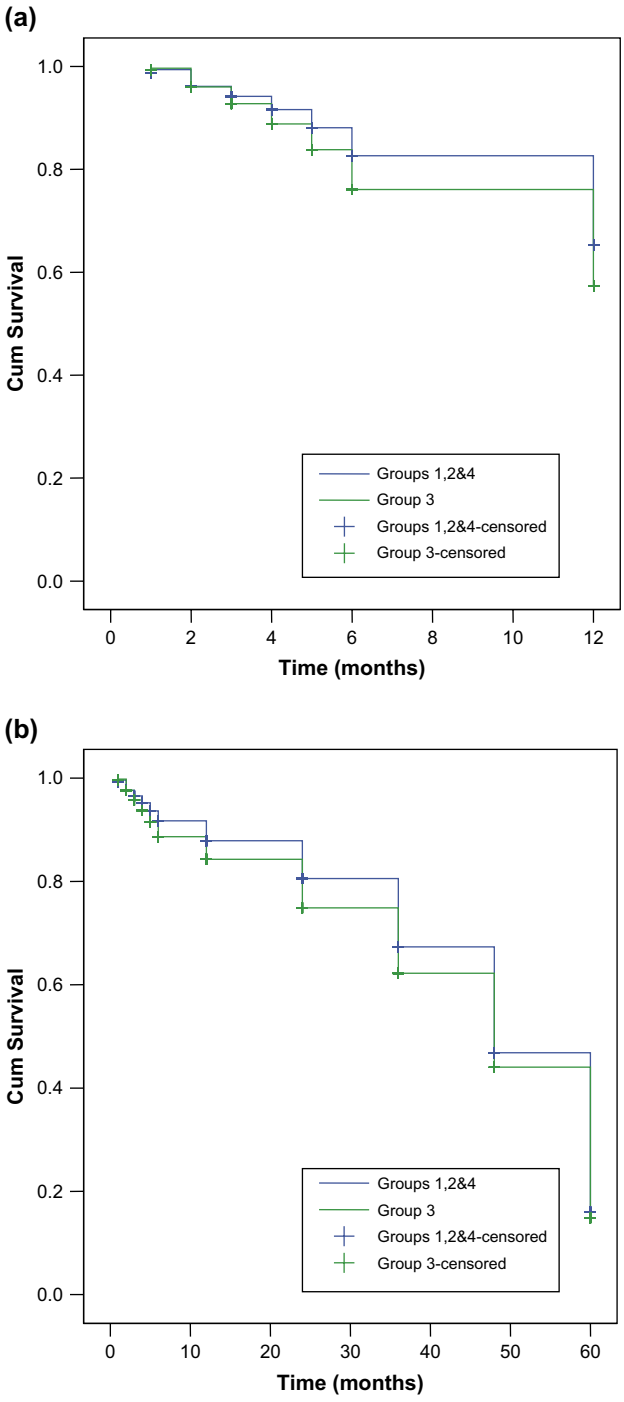

Fig. 1. (a) Survival at 12 months. (b) Survival at 60 months.

Table 5b. Survival Table for Patency

Group	No. at risk 12/12	Cum. Surv. 12/12	Std. Error 12/12	No. at risk 60/12	Cum. Surv. 60/12	Std. Error 60/12
1, 2 &4	110	0.76	0.03	47	0.39	0.05
3	49	0.69	0.05	22	0.45	0.07

Where No. at risk = number of patients at risk; Cum. Surv. = cumulative survival; and Std.Error = Standard Error.

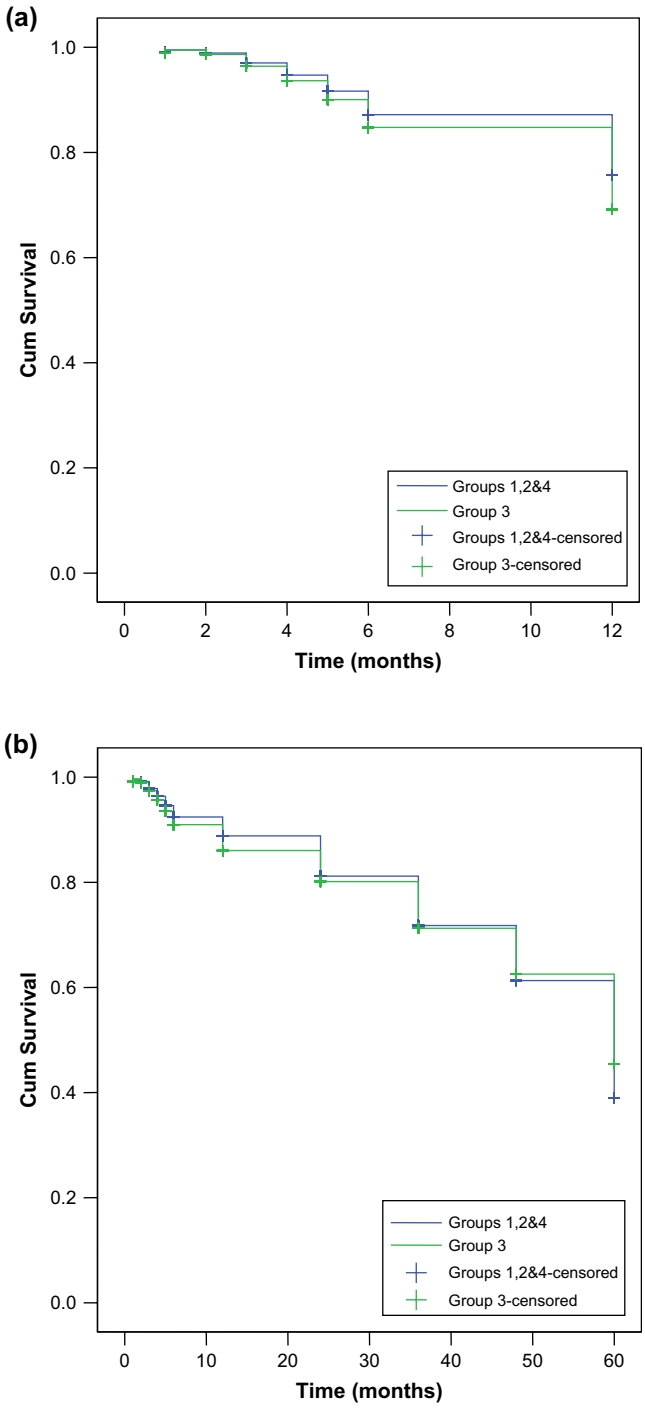

Fig. 2. (a) Patency at 12 months. (b) Patency at 60 months.

Table 6a. Log rank tests of patency and survival at 12 months

Group	Number still patent (%)	Log rank statistic	Significance	Number still alive (%)	Log rank statistic	Significance
1,2&4	110 (77)	1.21	0.27	122 (86)	3.74	0.05
3	49 (74)			62 (94)		

Table 6b. Log rank tests of patency and survival at 60 months

Group	Number still patent (%)	Log rank statistic	Significance	Number still alive (%)	Log rank statistic	Significance
1,2&4	47 (33)	0.04	0.84	62 (44)	2.76	0.10
3	22 (33)			35 (53)		

angioplasty are technically unsuccessful. Reported figures are in the region of 10–15%.[8,9]

In cases where angioplasty has failed, there are no clear guidelines for the subsequent management of the patient. Although prior attempt at angioplasty has not been shown to adversely affect any later attempt at surgical reconstruction,[8] it may be that failed angioplasty is representative of severity of underlying vascular disease and therefore a poor prognostic factor for surgery.

This study supports the use of lower limb vascular reconstruction using bypass grafting where angioplasty has failed. Although this group of patients could be considered as 'high risk', long term patency and survival is acceptable and comparable with bypass performed for other indications.

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