Femoro-distal bypass surgery at Groote Schuur Hospital — 4-year retrospective study

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Summary

An analysis of the demographics and outcome of femoro-distal bypass in patients presenting with defined critical limb ischaemia at Groote Schuur Hospital, Cape Town, is presented.

Materials and methods. A retrospective review was conducted between January 1998 and December 2001. During this period, 65 patients underwent femoro-distal bypass. Of these, 57 patients were analysed and 8 patients were excluded from the study because of incomplete medical records.

Results. The median age of the patients in this study was 62 years, with a male-to-female ratio of 34:23. Twenty-eight patients (49%) were diabetic. An overall 2-year mortality of 19.2% was recorded. Reversed saphenous vein graft (RSVG) was used in 29 legs (50.9%) and *in situ* vein graft (ISVG) in 19 legs (33.3%). There was no statistically significant difference in the graft patency between the two methods ($p = 0.39$); the 2-year cumulative patency was 40% for the RSVG and 39% for the ISVG. In our unit only 2 factors influenced the outcome of femoro-distal bypass — local sepsis in the foot and an increased early postoperative ankle-brachial index ($p < 0.05$). Diabetes mellitus, gender, age and race had no influence on the outcome. This study showed that the site of the distal anastomosis had no effect on graft patency or limb salvage. At 2 years, the cumulative patency and limb salvage rates were 40% and 56% respectively. Of the 11 grafts with stenotic lesions requiring intervention, 6 were detected between 18 and 24 months.

Conclusion. Management of critical limb ischaemia is a major part of the workload in our unit, with most patients undergoing primary amputation. The surgical outcome of femoro-distal bypass was largely influenced by local sepsis and early postoperative ABI. We found that more than half the stenotic lesions detected during graft surveillance occurred beyond 18 months postoperatively. This suggests that a graft surveillance programme should continue beyond 18 months.

Critical limb ischaemia (CLI) has been recognised by surgeons since the dawn of reconstructive vascular surgery 50 years ago. Patients usually present with increasingly severe and intolerable ischaemic rest pain involving a single toe or the entire forefoot. There is usually a preceding history of progressively worsening claudication. On presentation, these patients frequently exhibit tissue loss, gangrene, ischaemic ulceration and forefoot infection. CLI represents the end stage of lower limb atherosclerotic disease, and on the angiogram multi-segmented arterial occlusion is the rule.

Refinement in techniques of femoro-distal bypass together with complementary endovascular techniques to obtain optimal inflow, viz. balloon angioplasty, subintimal angioplasty and stenting,[1] have led many to argue that attempts at revascularisation should be offered to all patients presenting with CLI.[2,3]

The stimulus for this study arose from the strong impression that constraints on bed and theatre availability had resulted in a shift in therapeutic policy since the mid-1990s in our institution. In the case of patients presenting with CLI, ever-stricter selection criteria were applied, resulting in only patients expected to have the best outcome being offered revascularisation for limb salvage Despite the stringent selection criteria, patients undergoing femoro-distal bypass, in particular, seemed to fare badly, even in the short term, when compared with results from First World countries (Table I).

In the light of the above, a retrospective study was planned to analyse the demographics and outcome of femoro-distal bypass in patients presenting with defined CLI during the period 1998 - 2001 inclusive.

Methods

This is a retrospective study of all patients who underwent femoro-distal (crural) bypass for CLI in the Groote Schuur Vascular Unit between January 1998 and December 2001. Femoro-distal bypass is defined as any bypass where the inflow vessel is either the common femoral, superficial femoral or profunda femoral artery and the outflow vessel is any artery distal to the popliteal artery. To eliminate statistical errors from multiple observations, only patients with complete medical records who underwent femoro-distal bypass as defined above, were included in the study.

TABLE I. RESULTS OF FEMORO-DISTAL BYPASS

Authors	Patients (*N*)	Patency (%)	Limb salvage (%)	Follow-up (months)
Biancari *et al.*[4]	**66**	**67**	**88**	**24**
Panayiotopoulos *et al.*[5]	**109**	**45**	**54**	**36**
Gloviczki *et al.*[6]	**100**	**69**	**79**	**36**
Shah *et al.*[7]	**265**	**79**	**89**	**60**
Hickey *et al.*[8]	**329**	**82**	**82**	**60**
Londrey *et al.*[9]	**253**	**59**	**82**	**60**

A chart review was performed. Patients were identified from the vascular laboratory computer database, copies of operation notes and the operating theatre register. Information was extracted from patients' hospital records as well as by telephonic interviews with the patients or relatives. A single radiologist who was not aware of the surgical procedure performed or the clinical outcome, blindly reviewed the angiograms of all patients who underwent femoro-distal bypass in the study period. The system of scoring the angiograms was that described by Scott *et al.*:[10] 2 points were given for a widely patent vessel to the ankle, 1 point for a diseased but patent vessel to the ankle, and 0 points for an occluded vessel. Assessment of anterior tibial, posterior tibial and peroneal arteries produced a total score of between 0 and 6 per leg.

Statistics

Patient survival, limb salvage and graft patency were assessed by life-table analysis, using a commercial software package, 'Statistica' (version 5). Univariate data of risk factors for graft failure were analysed, comparing discrete variables were using the chi-square test and continuous variables with the Mann-Whitney test. Data expressed in the tables reflect absolute patient numbers or median values for non-parametric data with interquartile ranges (25th - 75th percentile) expressed in parentheses, unless stated otherwise. The one-sided p-value of 0.05 was used as the level of significance.

Results

During the 4 years, 65 patients underwent femoro-distal bypass. We analysed 57 patients, and 8 patients were excluded from the study because of incomplete medical records. During the same period, 488 amputations were performed for various reasons; of these, 79 primary amputations were done for CLI (non-reconstructable vessels).

Demographics

The demographics and other relevant data pertaining to the 57 patients are shown in Table II. The median age of the patients in this study was 62 years (mean 61.1 years), with a male-to-female ratio of 34:23. Twenty-eight patients (49%) were diabetic. The mean hospital stay was 20.9 days, with a minimum of 7 days and a maximum of 68 days. Five patients (8.8%) died within 30 days of the initial operation. Three died from myocardial infarction and 2 from cerebrovascular accidents. Another 5 patients died within 2 years of the initial operation, giving an overall 2-year mortality rate of 19.2%.

Indications for surgery

Forty-six patients (81%) presented with rest pain (with or without tissue loss) as shown in Fig. 1. There was a subgroup of 10 patients (18%) with tissue loss who had a peripheral neuropathy and did not have rest pain. They were all diabetic. These patients had a high incidence of local foot sepsis. One patient (2%) had less than 20 m incapacitating claudication.

Graft conduit and distal anastomosis

The choice of *in situ* vein graft (ISVG) or reversed saphenous vein graft (RSVG) was left to the individual surgeon. RSVG was used in 29 legs (50.9%) and ISVG in 19 legs (33.3%). There was no statistically significant difference in the graft patency between these two methods (p = 0.39): the 2-year cumulative patency was 40% for the RSVG and 39% for the ISVG. Six patients had a 6 mm polytetrafluoroethylene (PTFE) graft with a Miller cuff. In 1 patient cephalic vein was used, and in another 2 composite grafts of saphenous vein and 6 mm PTFE. The peroneal and anterior tibial arteries were most commonly used for the distal anastomosis (in

TABLE II. DEMOGRAPHIC CHARACTERISTICS

Parameter	Result
Number	**57**
Sex ratio (M/F)	**34/23**
Mean age and range (years)	**61.1 (27 - 88)**
Risk factor	
Smoking	**36**
Diabetes	**28**
Hypertension	**21**
Hyperlipidaemia	**6**
Coronary artery disease	**7**
Serum creatinine (µmol/l)	**96.42 (58 - 164)**

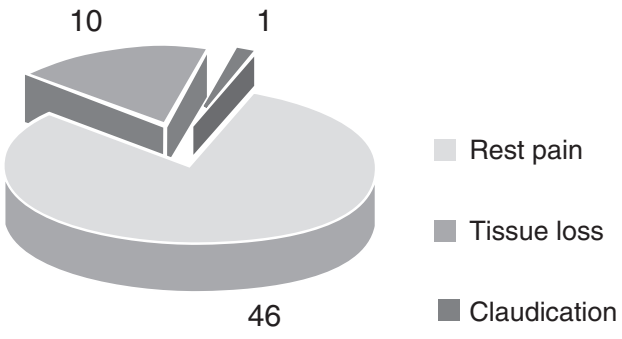

Fig. 1. Indications for femoro-distal bypass surgery.

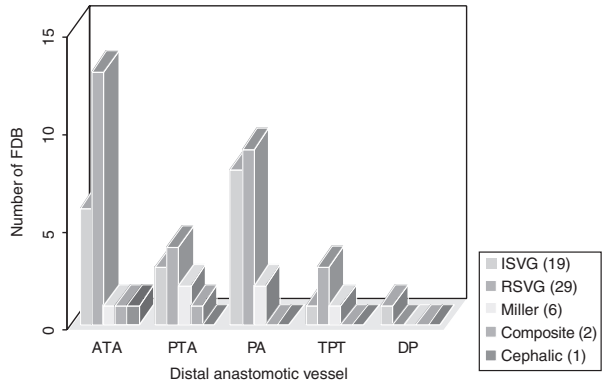

Fig. 2. Type of graft conduit and distal anastomotic crural vessel (ATA = anterior tibial artery; PTA = posterior tibial artery; PA = peroneal artery; TPT = tibioperoneal trunk; DP = dorsalis pedis artery; ISVG = *in situ* saphenous vein graft; RSVG = reverse saphenous vein graft).

19 legs (34.5%) and 22 legs (38.5%), respectively) as represented graphically in Fig. 2.

Factors associated with graft failure

In this study only 2 factors influenced the outcome of femoro-distal bypass (Table III) — local sepsis in the foot and early postoperative ABI (> 0.85), with a significance level of $p < 0.05$. Sex, age and race had no influence on the outcome. Diabetes mellitus did not influence graft patency but this may be related to the small number of patients in our study, which may constitute a type 2 error. Serum creatinine as a parameter of assessing renal function was not a factor influencing graft patency (Kruskal-Wallis test, $p = 0.16$). The site of distal anastomosis had no effect on graft patency or limb salvage. Mean hospital stay was statistically different between the two groups (26.9 and 14.9 days, respectively). There was no correlation between the run-off score determined from pre-operative angiography and early graft patency. The angiographic run-off score failed to predict which grafts would fail. Of those patients with early graft failure, 5 had a score of 0, 8 had a score of 1 - 2 and 1 had a score of 3. Of those with a patent graft after 1 month, 9 patients had a score of 0, 18 had a score of 1 - 2, 9 had a score of 3 and 7 had a score of 4 - 6.

Graft patency

At 30 days, the primary patency was 75% with a limb salvage of 75%. At 2 years, the cumulative patency and limb salvage rates were 40% and 56% respectively (Table IV).

In the surveillance programme grafts were scanned at the following intervals: 6 weeks, 3 months, 6 months, 1 year and 2 years postoperatively. Eighty-five per cent of patients booked for graft surveillance regularly attended the surveillance programme.

Fourteen grafts failed within 30 days of initial surgery. This resulted in amputation of the limb in all cases. Forty-three grafts were functional 1 month after initial surgery. These patients were followed up in the surveillance programme; 11 grafts required a secondary procedure to maintain patency. Two of the 11 (autogenous) grafts occluded and required thrombectomy. Nine grafts had areas of high-grade stenosis with a significant decrease in downstream velocity. All were asymptomatic. Six of the 11 graft stenoses were detected at 18 - 24 months. The remaining graft stenoses were picked up within 6 months of the revascularisation procedure. Six were treated with balloon angioplasty and were situated in the body of the vein graft. Three grafts were managed surgically because the stenotic lesions were either at the proximal or distal anastomosis and were not considered amenable for endovascular treatment.

Discussion

There has generally been an aggressive attitude toward the management of patients with critical limb ischaemia. In many cases this may result in inappropriate selection of patients for bypass, with patients who would have been better served by a primary amputation undergoing an ill-judged vascular reconstruction. The results achieved in our series for both graft patency and limb salvage are not comparable

TABLE III. UNIVARIATE ANALYSIS OF RISK FACTORS IN RELATION TO GRAFT FAILURE/PATENCY

	Early graft failure (< 1 month)	Patent graft (> 1 month)	*p*-value
Patients (*N*)	**14**	**43**	**-**
Average age (years)	**60**	**62**	**-**
Sex (M/F)	**9/5**	**25/18**	**0.89**
Smoking (*N*)	**8**	**32**	**0.85**
Diabetes (*N*)	**9**	**19**	**0.49**
Serum creatinine (µmol/l)	**102.5**	**90.4**	**0.12**
Hospital stay (days)	**26.9**	**14.9**	**0.02**
Angiogram score	**1.16**	**1.47**	**0.40**
Local sepsis*	**4**	**13**	**0.01**
Graft conduit			
ISVG	**3**	**13**	
RSVG	**5**	**22**	
Miller cuff	**4**	**2**	
Composite	**1**	**1**	
Cephalic	**1**	**0**	
Postoperative ABI	**0.65**	**0.9**	**0.01**

*Patient with tissue loss and infection at the foot.

ISVG = *in situ* vein graft; RSVG = reverse saphenous vein graft; ABI = ankle-brachial index.

TABLE IV. PATENCY AND LIMB SALVAGE FOR FEMORO-DISTAL BYPASS

	Time in months				
	1 month	6 months	12 months	18 months	24 months
Cumulative patency (%)	**75**	**66**	**56**	**44**	**40**
Limb salvage rate (%)	**75**	**70**	**67**	**62**	**56**

with most other series in the literature and it is important that we try to define the factors that might have been responsible for this.

Factors that influenced the outcome of femoro-distal bypass were local foot sepsis and postoperative ABI ($p < 0.05$). It has been suggested that a resting ABI after revascularisation of less than 0.85 predicts that the vein graft is at risk of failure. In 1992 Prime *et al.*[11] reported that the primary patency rate at 2 years was 88% for a resting post-operative ABI equal or more than 0.85 and 36% for a resting postoperative ABI less than 0.85. In our study, a resting post-operative ABI had a statistically significant influence on the outcome of graft patency ($p < 0.05$). We found that a post- operative ABI of more than 0.85 was associated with a graft patency of more than 2 years. The success of femoro-distal bypass depends on the integrity of the distal runoff and, particularly, the presence of an intact pedal arch. To assess this the following modalities are used: dependant Doppler, pulse-generated runoff (PGR)/Roedersheimer test, conventional/ digital subtraction angiography, magnetic resonance angiography (MRA) and intraoperative angiography. In our study, PGR has been used most for assessing the pedal arch with a high sensitivity, as shown by Immelman and Louwrens.[12]

In this study, other factors such as diabetes mellitus, age, sex, race and angiographic scoring had no significant influence or predictive value regarding the graft patency rate. It is important to emphasise that autogenous graft remains the first choice.

It is known that intervening in a failing but still functioning graft before its occlusion greatly improves the patency rate, and most importantly, preserves the limb. Reports provide evidence that strictures impose a three- to six-fold risk of graft occlusion if left untreated.[13] According to a publication in the early 1990s by Taylor *et al.*,[14] limb loss has to be prevented in only 2% of patients for a duplex scanning surveillance programme including 6 examinations in a year to be cost-effective. In 2001 Mills *et al.*[15] found a substantial body of evidence that duplex vein graft surveillance is clinically useful, cost-effective and associated with an improvement of limb salvage by 10 - 15%. Therefore, identification of failing grafts, before their occlusion seems logical, and periodic surveillance of infra-inguinal grafts has become a common policy. The initial duplex scanning is done when the patient is discharged, then again at 6 weeks and 3, 6, 9, 12, 18 and 24 months postoperatively, as well as clinical assessment of the patient with ABI measurements. We found that most of the lesions detected during graft surveillance occurred after 18 months. Most stenoses occur in the graft not at the anastomoses.[11] We therefore suggest that the graft surveillance programme should probably continue beyond 18 months.

The issue of functional outcome after a successful infra-inguinal reconstruction could not be established from this study. The hospital stay after failed bypass was prolonged, however, with a mean of 27 days.

The 2-year cumulative patency rate was 40%, with a limb salvage rate of 56%. All patients with early graft failure (less than a month) underwent amputation in our study. Aggressive management for late graft failure (more than a month) is worth while.

Fourteen patients had an amputation within 30 days of the bypass surgery, and only 4 patients were eventually fitted with a prosthetic leg. To date, only 2 use their prosthetic leg. These findings confirm that most amputees will remain wheelchair-bound or use a walking frame and crutches. The level of amputation was not influenced by a previous bypass procedure and the conversion rate from below-knee to above-knee was similar between the group of primary and secondary amputee patients.

Patients with CLI who are not suitable for surgery may be considered for an endovascular procedure such as conventional or subintimal angioplasty. Recent studies have shown a trend towards more utilisation of percutaneous transluminal angioplasty with overall cumulative patient survival and limb salvage rates respectively of 82% and 89% at 1 year, and 45% and 87% at 5 years.[16]

Conclusion

Management of critical limb ischaemia is a major part of the workload in our unit, with a majority of patients undergoing primary amputation. The surgical outcome of femoro-distal bypass was largely influenced by local sepsis and early post-operative ABI. We found that more than half the stenotic lesions detected during graft surveillance occurred 18 months postoperatively. This supports the continuance of a graft surveillance programme beyond 18 months.

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