Eur J Vasc Endovasc Surg 15, 380–386 (1998)

A Scoring System to Predict the Outcome of Long Femorodistal Arterial Bypass Grafts to Single Calf or Pedal Vessels

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Objectives: *The aim of this study was to develop a scoring system to predict the outcome of long femorocrural and femoropedal bypass grafts performed for critical limb ischaemia.*
Setting: *Teaching hospital.*
Methods: *An analysis of 109 consecutive femorodistal bypass grafts performed for critical lower limb ischaemia between June 1991 to December 1994. Factors shown to affect the outcome were: inflow, number of patent calf vessels, graft material, straight flow to the foot and patent pedal vessels. These variables were weighted according to their relative significance (multivariate Cox regression) and a scoring system (ranging from 0 to 10) was developed.*
Results: *Patients with a preoperative score of 0–4 (n = 35) showed a secondary patency of 36% at 1 month, 12% at 3 months and 0% at 10 months (Cum SE = 6.90/0.0). Secondary patency rates for the 46 patients with score 5–7 were 88.7% at 3 months, 56.3% at 12, and 45.1% at 2 and 3 years (Cum SE = 9.82), while the respective values for the 28 patients with score 8–10 were 92.7%, 88.5% and 81.7% (Cum SE = 8.08). The difference was highly significant (p = 0.000) in all tests of equality. In addition, the median total hospital cost was £12 600 for the group 0–4 compared with £8100 (group 5–7) and £4400 (group 8–10) (p = 0.0085).*
Conclusions: *This preoperative scoring system appears to correlate well with the outcome of distal revascularisation to single calf or pedal vessels. If applied to patient selection, it could significantly reduce the total hospital cost per leg saved. A prospective testing of its predictive ability is needed and is in progress.*

Introduction

The technical feasibility of arterial bypass grafts to the crural or pedal vessels is now well established as a means to treat CLI.[5–11] However, many questions remain unanswered, particularly concerning the appropriate indications for these procedures and their long-term patency rates. Such operations often require multiple interventions to attempt to preserve patency which may be accompanied by higher morbidity and mortality rates, prolonged hospital stay and increased hospital cost.[12,13] There may be a group of patients who would benefit more from primary amputation rather than femorodistal grafting. Johnson *et al.*[14] reported that 22% of their revascularised patients would have had a more expeditious rehabilitation and minimal impairment of their lifestyle if they had been treated by primary amputation rather than revascularisation.

There is a general consensus that primary amputation should be performed only if the possibility of revascularisation has been excluded,[15] and the National Confidential Enquiry into Perioperative Deaths and complications (CEPOD) report suggested that all patients at risk of amputation should be referred for a vascular surgical opnion.[16] However, in a recent survey, 40% of surgeons participating in a congress session would recommend primary amputation in patients with just a single crural vessel shown in preoperative IADSA, while another 40% of these (15% of the whole group) would recommend amputation even if pedal vessels were shown to be patent.[17] There seems to be a great variation even among vascular surgeons as to which patients should have attempted revascularisation.

In order to make this decision, the vascular surgeon relies upon preoperative investigations, the most common of which is angiography. Some authors suggest that it may underestimate the patency of distal vessels[10,18,19] particularly in cases of CLI. The possible reasons could theoretically be the presence of severe multisegmental disease, the failure of retrograde flow via collaterals to fully outline patent distal arteries and concurrent cardiac failure which results in a low flow state.[18,19] The use of intra-arterial digital subtraction

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1078–5884/98/050380+07 $12.00/0

angiography (IADSA) seems to mostly overcome this problem, and foot vessels are shown in >93% of CLI cases and >98% of revascularised limbs.[20,21] As grafts anastomosed to distal vessels which are in continuity with the pedal arch have been shown to have better short and long-term patency rates,[11,20] it is widely believed that run-off resistance is the most important factor in determining graft patency.[22–26] Apart from angiography, many other types of investigations to assess runoff have been described, including pulse generated runoff (PGR),[18,19] intraoperative measurement of peripheral resistance,[21,24,25] ankle and toe pressure measurement,[10,22] and continuous Doppler wave insonation.[25] However, these are not widely used and may overestimate the patency of distal vessels. Some require the use of specialised equipment and experienced vascular technicians.

An ideal scoring system would provide a logical method of assessing the extent of occlusive disease, establish a basis for standardised reporting and help in patient selection for revascularisation.[25–29] We have analysed a consecutive series of 109 long femorocrural or pedal arterial bypass grafts and have identified the factors that adversely affect outcome.[30] These factors have been used in a mathematical model to predict outcome. This series is unique in that the analysis was performed only on long infrapopliteal bypass grafts to a single calf or pedal vessel undertaken for foot salvage.

Patients and Methods

A consecutive series of 109 femoro-crural/pedal bypasses were performed on 101 patients presenting with severe critical lower limb ischaemia between June 1991 and December 1994. All patients had rest pain, ulceration or gangrene, fulfilling the current European definition of CLI.[15] An aggressive surgical policy was adopted, attempting revascularisation in all patients with an occluded or an isolated diseased popliteal artery and a patent arterial segment in the calf, ankle or foot, irrespective of the presence of adverse factors.

Follow-up

The median follow-up was 14.1 months and the mean 16.4. A Quick Scan (QS) was performed before discharge and thereafter at 3, 6 and 12 months; the grafts were then scanned every 6 months. If QS detected a stenosis of 1:4 frequency ratio or greater, the patients were referred for IADSA and angioplasty.

Table 1. Categories used in cost calculation.

Duration of inpatient stay
Hotel costs
Medical/nursing staff
Duration of operation
Surgical staff
Theatre staff
Anaesthetic staff
Running costs per h
Prosthetic material
Intraoperative investigations
Medical treatment
Medications (i.e. antibiotics, heparin, etc.)
Fluids
Blood and blood products
Physiotherapy
Radiological procedures
Hotel costs
Radiological staff
Disposable material (catheters, contrast, etc.)
Films
Follow-up
Non-invasive investigations
Outpatient vists
Artificial prosthesis

Statistical analysis

The life-tables were constructed using the traditional and the Kaplan-Meier methods.[31,32] (SPSS for Windows, Chertsey, U.K.). Comparison of the actuarial curves was done by the Log-rank test.[29]

Cost assessment

Complete data were collected prospectively on a computerised audit system for all patients (admission days, radiological procedures, duration of operation, intensive care unit (ICU) stay, complications, serial re-admission, re-operations etc). The major categories used in cost calculation are given in Table 1. This consisted of radiological procedures, operating time, anaesthetic costs, synthetic grafts, ICU costs and in-hospital stay, based on NHS costing. The preoperative investigations and outpatients visits were not calculated as they were the same for all patients, reconstructable or not, and they represent a small amount of the total hospital cost.

The unit cost of the resources were estimated from a number of sources.[33,34] The ICU cost was calculated by the TISS formula. In addition, the assessment in amputees included physiotherapy and initial rehabilitation costs, together with the cost of the prosthesis. These were provided by the departments of physiotherapy and rehabilitation at Guy's Hospital. The community and disablement unit cost to improve

Table 2. Regression coefficients and probabilities in multivariate linear regression.

Factor	Regression coefficient	Significance
Calf vessels	0.0077	0.5811
Diabetes	0.0116	0.3538
Tissue loss	0.0349	0.1274
Conduit	0.0732	0.0643
Ankle vessels	0.0845	0.0484
Pedal vessels	0.1455	0.0058
Inflow	0.2184	0.0001

and maintain mobility were not included in cost calculation.

Results

Outcome

The factors shown to be statistically important as an independent variable by univariate analysis in terms of patency rates were: inflow ($p=0.0001$), conduit ($p=0.0038$), pedal vessels ($p=0.0000$), number of patent ankle vessels ($p=0.0000$) and number of patent calf vessels in at least two thirds of the calf ($p=0.0388$). Tissue loss nearly achieved significance ($p=0.0508$). Multivariate Cox regression analysis[35] was used to assess the relative significance of each factor and assign a weighted value to each parameter (Table 2). The three factors which were shown to be of the greatest significance were assigned 2 points. These were (a) inflow, (b) pedal vessels, and (c) straight flow to the foot.

Design of a scoring system

1\. *Assessment of arteriography* The angiograms of all patients were reviewed by a surgeon and a radiologist and were graded accordingly:

(a) Inflow. Aorta, iliacs and common femoral. The inflow was considered as impaired and graded 0 if there were single or multiple stenosis of less than 50% (diameter reduction), or if the vessels were ectatic or aneurysmal. Good inflow was graded as 2. If the vessels were occluded or if there was a haemodynamically significant stenosis, both of which would require treatment, the inflow was then scored according to the result of the intervention as 0 or 2.

(b) Calf vessels. The number of patent calf vessels was also noted. The vessels had to be present in both the middle and lower third of the calf. Any vessels which were seen in only the middle or the lower third scored 0. If no vessels were seen the score was 0, a single vessel also scored 0. If two or three vessels were present the score was 1.

Table 3. Criteria for scoring.

Factor	Weighted score
Diabetes	
Yes	0
No	1
Tissue loss	
Yes	0
No	1
Conduit	
PTFE and cuffs or composite grafts	0
Vein (reversed or in situ)	1
Calf vessels	
Single or none present in 2/3rds of calf	0
Two present in 2/3rds of calf	1
Straight flow to the foot	
No ankle vessel crossing the ankle	0
Single vessel crossing the ankle	1
Two vessels crossing the ankle	2
Pedal vessels	
One or two diseased vessels	0
Presence of two disease free vessels or three (arch, anterior and posterior branch)	2
Inflow	
Occluded or impaired [Stenosis <50%, multiplestenoses (<30%) diffuse disease, ectatic vessels]	0
Good	2
Total	0–10

(c) Straight flow to the foot. The number of vessels in the lower third of the calf which crossed the ankle was also noted. This therefore excluded the peroneal artery. The score was thus 0, 1 or 2.

(d) Pedal vessels. The pedal vessels constituted the dorsalis pedis, the posterior tibial artery and the pedal arch. If two of these were present and intact the grade was 2. If they were stenosed or if only one or two were present the grade was 0.

2\. *Other factors.* A variety of other factors were assessed and graded, including conduit (if vein was used 1 point was scored; synthetic material with vein cuff scored 0) and tissue loss (if there was no tissue loss, one point was scored but ulceration and/or gangrene scored 0). Diabetes was also added (1 for non diabetic and 0 for diabetic patients), forming a total score of 0–10. The criteria for the scoring system are shown in Table 3.

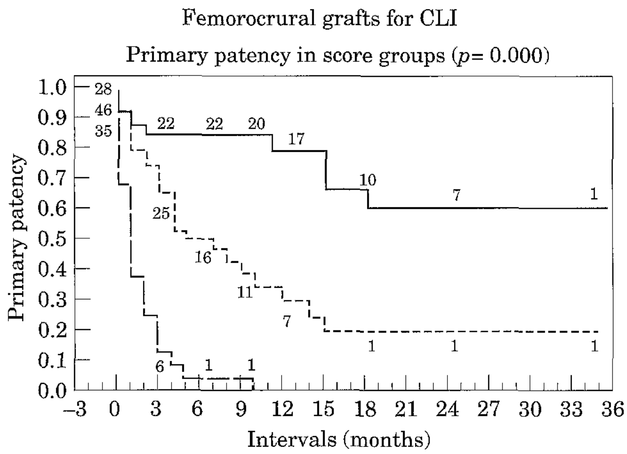

Fig. 1. Primary patency in the three score groups. The labels show the primary patency at 36 months, the percentage of censored grafts and the cumulative standard error figures which correspond to the last interval. It was shown to be extremely significant $p=0.000$. Score groups: (—) 8–10, pp = 61.5%, cens. 71.5%, CSE = 11.43; (- - -) 5–7, pp = 20.1%, cens. 43.5%, CSE = 8.26; (— — —) 0–4, pp = 0%, cens. 17%, CSE = 0.0 (4.07).

Grouping

The patency curve using each score group showed a group (0–4) with dismal outcome, a group with excellent patency rates above 70% (8–10) and an intermediate group (5–7). The patency rates for these three groups are shown in Figs 1 (primary patency) and 2 (secondary patency). Primary and secondary patency fall to 0% at 10 months in group 0–4, while they are 20% and 41% at 3 years for the intermediate group (5–7) and 61% and 82% for the upper group (8–10), respectively. The differences are extremely significant ($p=0.0000$). Limb salvage in the three score groups

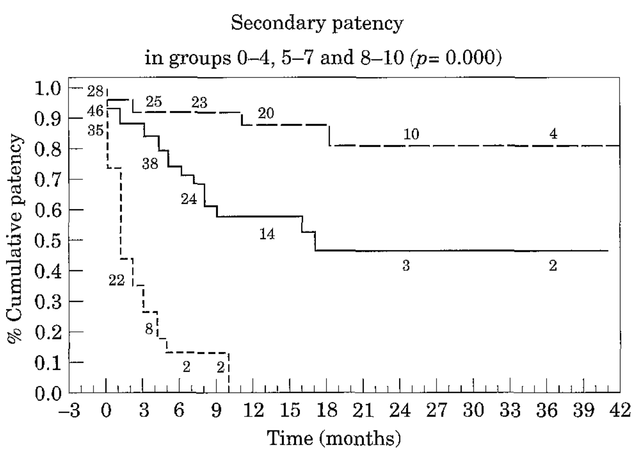

Fig. 2. Actuarial secondary patency curves for the score groups 0–4, 5–7 and 8–10. The labels show the secondary patency at 36 months and the cumulative standard error figures which correspond to the last interval. It was shown to be extremely significant ($p=0.000$). Score groups: (– –) 8–10, 81.5%, SE = 8.08; (——) 5–7, 46.7%, SE = 9.82; (- - -) 0–4, 0%, SE = 0.0.

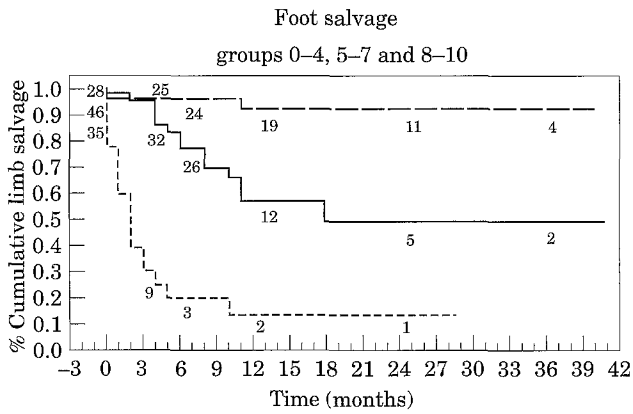

Fig. 3. Foot [limb] salvage in the score groups 0–4, 5–7 and 8–10. The labels show the salvage at 36 months, the percentage of censored grafts and the cumulative standard error figures which correspond to the last interval. It was shown to be extremely significant ($p=0.000$). Score groups: (– –) 8–10, 91.5%, SE = 5.76; (—) 5–7, 48.4%, SE = 10.04; (- - -) 0–4, 13.5%, SE = 7.76.

was shown to be equally significant (Fig. 3), with 13.5% limb salvage at 24 months for the group 0–4, compared to 48.4% and 91.5% at 3 years for the groups 5–7 and 8–10, respectively ($p=0.000$). Cumulative standard error was always less than 10, with the exception of primary patency in the upper group (8–10) where it was less than 10 at 33 months but 11.43 at 3 years.

Cost analysis

The median revascularisation cost was £4615 and the median cost of amputation following a failed bypass was £9600, while the cost of a primary amputation was £12 730. The cost of successful revascularisation was £4400, while the cost of a failed graft leading to a major amputation was £17 500. The main parameter affecting cost was the length of hospital stay, which was related to the number of secondary interventions.

The median values for total hospital cost (including secondary procedures and amputations) for the group 8–10 was £4400, £8100 for the group 5–7 and £12 600 for the group 0–4 (Fig. 4) ($p=0.0085$, Mann–Whitney).

Discussion

The high failure rate of long femorodistal arterial bypass grafts to a single foot or calf vessel, used to treat critical limb ischaemia,[5,8,11,36–41] continues to be a problem, particularly in the early post-operative period.[6,10,23,38,42]

Many authorities consider the distal run-off to be the most important factor in determining the outcome of distal grafts, and several methods have been used

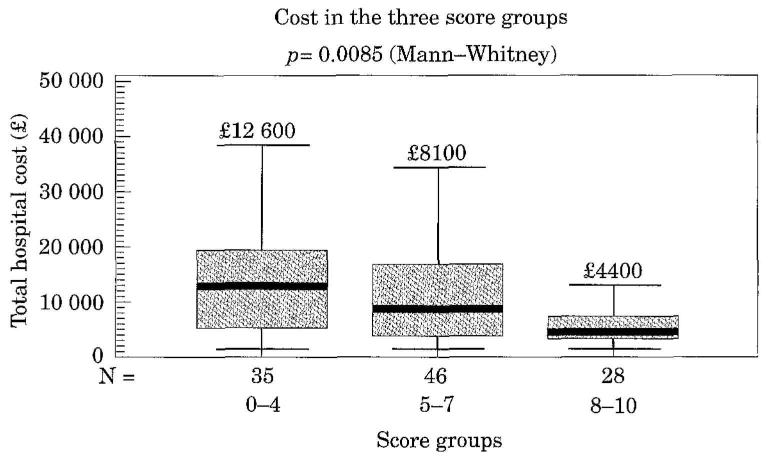

Fig. 4. Total hospital cost for the three score groups. The cost figures represent median prices. There is a significant difference between the three groups ($p = 0.000$).

to evaluate it,[18,19,24–26] although the predictive value of outflow resistance may have been overemphasised in the past.[18,22,23,30] Investigations to assess the distal run-off are complementary to angiography, which may not identify all the distal vessls which can be shown to be patent by other methods.[18,19]

In an attempt to improve the predictive value of preoperative angiography, several authors have developed scoring systems to grade the vessels distal to the proposed bypass outflow site, and to thereby calculate an overall run-off score. The traditional method based on the number of calf vessels (0–3) did not correlate well with resistance measured intra-operatively, and was unable to predict outcome.[18,26,27] A new method based on multiple linear regression to weight the various components of outflow, involving only the anterior tibial (AT), posterior tibial (PT) and pedal arch, showed improved sensitivity and specificity when compared to peripheral resistance.[27] In 1986 the ad hoc Committee of the SVS/ISCVS proposed a scheme for grading run-off[29] which graded both the degree of occlusion and the relative contribution of each outflow vessel to the outflow resistance. However, the significance assigned to each vessel was arbitrary and empirical. When modifications were introduced to improve it (MLR score[30]), there was a good correlation with peripheral resistance, but a poor relationship to outcome.

The SVS/ISCVS score failed to assess the length of the graft and the contribution of the more distal run-off beds to the peripheral resistance. A bypass to the popliteal artery with an intact PT, a 99% stenosed AT and an occluded peroneal, would receive a score of 6 (high resistance), according to the SVS/ISCVS score, while a graft to the PT under the same conditions would receive a score of 1 (optimum resistance). This does not agree with the common experience that the longer and more distal the graft, the higher the chances of failure.[11,15,41]

All the patent vascular beds distal to the outflow site can contribute to the run-off, but their importance probably differs according to their distance from the outflow site. The pedal arch should be more important for bypass grafts to the crural arteries and less important for grafts to the below knee (BK) and above knee (AK) popliteal artery. The more proximal the outflow site the less the significance of the more distal outflow components. This theory explains why the SVS/ISCVS score for grafts to the AK popliteal correlates well with outflow resistance. The pedal arch contribution is not significant, and therefore its omission from the assessment does not adversely affect the correlation. However, for grafts to the BK popliteal the score shows no correlation at all, which may well be related to the failure to assess the pedal vessels.[28] Based on the same argument, the contribution of the peroneal artery, which does not communicate directly with the foot vessels, should be less significant, and this was confirmed in this study by the significance attained by the number of vessels crossing the ankle. The MLR score modification suggested by Peterkin *et al.*[28] also omits the peroneal artery from the scoring system, while it includes the pedal arch.

There is evidence that despite a significant correlation with outflow resistance,[18,27,28,36] scoring systems based on angiography alone do not correlate well with outcome.[18,38] One reason suggested for this discrepancy is that angiography fails to depict patent distal vessels in a substantial number of patients presenting with CLI.[10,18,19,22] This may have been true of conventional angiography, but is much less common with high quality IADSA performed by ipsilateral puncture of the femoral vessel of the affected leg.[20,21] Intraoperative angiography may show patent distal vessels not seen on IADSA, but nevertheless, even when intraoperative angiography is included in run-off assessment, scores based exclusively on angiography do not seem able to predict outcome.[38] Direct surgical exploration of the distal vessels may also help in clarifying the fallacies of angiography.

We have shown previously that although outflow resistance and continuity of the pedal arch are important factors in determining patency, there are other factors which should not be ignored.[30] The inflow state, the conduit material, the degree and extent of ischaemia and the rate of progression of atherosclerosis contribute to graft patency. A scoring system which can accurately predict outcome should take all these factors into account, and each variable should be weighted according to its relative significance.

In this study the inflow state was the most significant factor in predicting outcome. Even lesions considered to be haemodynamically insignificant were important. Inflow disease progression may therefore be an important factor at every stage of graft patency.

The type of conduit was also important, as prosthetic grafts consistently yield lower patency rates compared to venous conduits.[8,11,15,42,43] Tissue loss is an important indicator of the severity of ischaemia and it is well established that this group of patients perform less well when compared with patients presenting with rest pain only.[6,15]

The incorporation of diabetes in the scoring system is arguable, as it was not shown to be significant in univariate analysis. However, arterial bypass grafts in diabetic patients seem to perform less well than in people without diabetes, and if we consider the number of patients presenting with CLI because of distal occlusive disease the number of diabetics is extremely high, and in about half of them distal arterial reconstruction is not feasible,[15] based on either angiography, PGR and direct surgical exploration. Furthermore, atherosclerosis in diabetics is more aggressive, presents at a younger age and its natural history is worse compared to non-diabetics,[15,37] especially when accompanied by renal failure.[44] Based on these observations plus the fact that firstly, the score is aiming to identify patients with an unfavourable outcome, and secondly, because a score up to 10 is easier to comprehend, we included diabetes in our scoring system. Exclusion of diabetes reduces the correlation slightly, but the score remains extremely significant ($p=0.000$).

Other factors that may be related to an adverse outcome have also been reported.[7,44] These include tobacco abuse, hyperlipidaemia, coagulopathies and renal failure. Regarding smoking, almost all patients presenting with severe CLI are smokers and incorporation of smoking in the scoring system would not have any impact in patient selection. The other conditions are associated with a more aggressive form of atherosclerosis, which would be evident and partially incorporated in the inflow and run-off assessment. However, they are present only in a small minority of the patients in this series (4% in renal failure, 12% hyperlipidaemia and 2% in hypercoaguable state). Based on these observations we did not include them in our scoring system.

This study could be criticised for the low patency and salvage rates reported. However, some issues should be addressed. Firstly, our patients are different from most of the reported series: they are older, they show reduced survival, they all have critical ischemia, most of the procedures were secondary or tertiary and most of them had poor run-off. Secondly, only long grafts from the groin to single crural/pedal vessels were analysed. Thirdly, our criteria for primary, primary assisted and secondary patency were strictly those recommended from the ad hoc Committee.[29] Fourthly, we attempted revascularisation in patients in whom many surgeons would perform primary amputation.[17] These differences in patient selection and policy may explain the low patency rates.

In conclusion, the major goal of a scoring system is to be able to predict outcome. This was a retrospective analysis and the application of the scoring system to the original data from which it is derived necessarily makes this a circular argument. These findings should therefore be verified by a prospective study. Nevertheless, it seems to suggest that there is a group of patients in whom the results of long femorodistal grafts to single vessels in the calf or foot are so poor that amputation may be both more successful and economically justified. The total hospital cost for patients with a score of 0–4 was more than twice that of the other groups. If this scoring system is applied to the selection of patients for revascularisation then it should reduce the hospital cost per leg saved.

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Accepted 20 August 1997