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Intraoperative Determinants of Infrainguinal Bypass Graft Patency: A Prospective Study*

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Objectives: *To evaluate a number of currently available methods for intraoperative assessment of infrainguinal bypass grafts (IBG) in terms of detecting technical errors and predicting graft failure.*
Design: *Prospective open clinical study.*
Methods: *Forty-nine patients undergoing 54 consecutive IBG were studied. Intraoperatively, the following measurements were performed: distal pulse palpation (DPP), continuous wave Doppler (CWD), pulse volume recording (PVR), and ultrasonic volume flowmetry (UVF), followed by intraoperative angiography of the entire graft and runoff vessels. The outflow resistance was graded according to the guidelines of the Society for Vascular Surgery and International Society for Cardiovascular Surgery (SVS/ISCVS runoff score). Graft patency was determined noninvasively (PVR, colour Duplex) up to 12 months following surgery. Predictive values and likelihood ratios for the intraoperative tests in detecting a technical problem during the bypass procedure and in predicting early graft failure were calculated.*
Results: *There were five immediate revisions for problems detected intraoperatively. Angiography did not identify any additional problems but assisted in the correct location of the problems detected by the other tests. DPP and CWD were highly significant indicators of the need for revision with likelihood ratios for a positive test of 14.7 ($p < 0.01$) and 12.3 ($p < 0.01$) respectively. PVR did not achieve statistical significance in this respect. None of the intraoperative tests was a statistically significant predictor of early graft failure. The SVS/ISCVS runoff score, on the other hand, predicted early failure with a PPV of 33% (likelihood ratio for a positive test of 4.9, $p < 0.05$). None of the grafts with a perfect SVS/ISCVS runoff score ($n = 39$) failed in the first postoperative month.*
Conclusions: *Simple CWD insonation of graft and anastomoses is the best intraoperative indicator for technical inadequacies after IBG. Routine intraoperative angiography is not necessary and intraoperative anatomical imaging may be reserved for situations in which noninvasive documentation of technical success is absent. Contrary to the intraoperative haemodynamic test results, the SVS/ISCVS runoff score is a good predictor of early graft failure.*

Key Words: Peripheral arterial occlusive disease; Infrainguinal bypass graft; Intraoperative haemodynamic monitoring; Bypass graft failure; Doppler ultrasound; Blood flow volume measurement; Pulse volume recording; Noninvasive tests; Angiography; Runoff score.

Introduction

Despite significant improvements in the results of infrainguinal revascularisation over the last decade, 20% to 30% of grafts will fail within 5 years after the initial operation.[1,2] Failures after 6 months following surgery generally have been associated with intrinsic graft or anastomotic problems, notably intimal hyperplasia, and occlusions after 3 years with progression of disease proximal or distal to the graft.[3] Failures in the first month are attributed mainly to technical errors, intrinsic thrombogenicity, and inadequate outflow tracts. Because the first month failure rates vary between 5% and 15%,[4–6] the intraoperative detection of these specific problems has gained substantial interest.

Screening for the presence of a hypercoagulable state in vascular surgery patients has been suggested,[7] but the yield of such a strategy in all patients scheduled for infrainguinal bypass is presently unknown. The identification of grafts at risk by measuring outflow resistance has also been investigated, but results are contradictory.[8–10]

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The technical adequacy of an infrainguinal bypass graft can be judged intraoperatively by the external appearance of the bypass and anastomoses, and by the restoration of distal pulses and perfusion. In addition, noninvasive (ultrasonic and plethysmographic) instruments and invasive procedures (arteriography and angioscopy) may also be used for a more objective evaluation.[11–13] The parameters provided by these methods include blood pressure, flow velocity and volume, pulse waveforms, and anatomical images. At present, however, a multivariable analysis of the utility of these parameters is lacking.

The purpose of this study was to establish predictive values for a number of currently available intraoperative tests for the detection of problems that would warrant revision, and to determine whether routine intraoperative angiography is necessary. We also examined the predictive values of intraoperative parameters for early graft failure.

Materials and Methods

Patient population

Forty-nine consecutive patients admitted for elective infrainguinal bypass grafting for chronic arterial occlusive disease were asked to participate in a prospective observational study. All patients agreed and signed an informed consent approved by the Subcommittee on Human Studies of the Massachusetts General Hospital.

The study included 31 men and 18 women whose ages ranged from 38 to 95 years (median, 70 years). Diabetics made up 45% ($n = 22$) of the study population. They underwent a total of 54 bypass procedures: 37 vein grafts (including 16 with *in situ* saphenous vein), 13 polytetrafluoroethylene (PTFE) and four Dacron grafts. Conventional operative techniques were followed and *in situ* saphenous vein grafts, reversed saphenous (or ectopic) vein grafts, translocated (antegrade or retrograde) vein grafts, PTFE, Dacron, or composite grafts were used as dictated by circumstances or according to the preference of the surgeon. For the *in situ* bypass we used the open technique with exposure of the entire length of the saphenous vein. The indications for revascularisation and details of the procedures are summarised in Table 1.

Table 1. Indications and types of procedures in 54 infrainguinal bypass grafts

Indication			
SVS/ISCVS Grade	*n*		
I. Life-style limiting claudication	15		
II. Ischaemic rest pain	10		
III. Minor or major tissue loss	29		
Site of proximal and distal anastomosis			
Proximal artery	*n*	Outflow artery	*n*
Common femoral (or graft)	40	Above knee popliteal	21
Superficial or deep femoral	6	Below knee popliteal	11
Above knee popliteal	3	Tibioperoneal trunk	1
Below knee popliteal	5	Anterior tibial	4
		Posterior tibial	3
		Peroneal	7
		Posterior tibial (ankle)	3
		Dorsalis pedis	4
Procedure			
Type	*n*		
In situ vein graft	16		
Reversed vein	14		
Antegrade vein	5		
PTFE	13		
Dacron	4		
Composite	2		

Graft evaluation

Preoperative routine workup included ankle-brachial index (ABI) with exercise, pulse volume recording (PVR), and contrast angiography. In some patients preoperative contrast angiography was replaced by magnetic resonance angiography using a 1.5 tesla superconductor system with a two-dimensional time-of-flight technique and 3 to 5 mm axial slices. Intraoperatively, approximately 15 min after restoration of graft blood flow, the following studies were performed: distal pulse palpation (DPP), continuous wave Doppler (CWD), pulse volume recording (PVR), and ultrasonic volume flowmetry (UVF). With DPP the surgeon palpated the recipient artery distal to the distal anastomosis and graded the pulse as absent, weak, or normal.

For blood flow velocity assessment, a gas sterilized, hand-held 8-MHz, continuous wave bi-directional Doppler velocimeter (Model: BVM348, Bach-Simpson Ltd., London, Canada), and a real-time spectrum analyser (Echospec®, Diagnostic Electronics Corp., Lexington, MA, U.S.A.) were used. An angle of 60° between the probe and the axis of the blood flow was attempted. The audible signals were interpreted as monophasic, biphasic or triphasic. Simultaneously, the spectral analyser was running and the peak systolic velocity (PSV, cm/s) was documented.

The PVR IV® (Life Sciences Instruments, Greenwich, CT, U.S.A.) was used for pulse volume recordings. Ankle PVR tracings were obtained by inflating a

Table 2. **Definitions of negative and positive test results**

Parameter	Test result negative	Test result positive
Distal pulse palpation	Normal/weak	Absent
Continuous wave Doppler	Improvement	"Thump"/no improvement
Pulse volume recording	Improvement ≥ 1 category	No improvement
Ultrasound volume flow	≥ 50 ml/min	< 50 ml/min
SVS/ISCVS-runoff score	Score = 1	Score > 1
Minimal graft diameter	≥ 3 mm	< 3 mm
Peak systolic velocity graft	≥ 40 cm/s	< 40 cm/s

suitable sized cuff with 75 ±10 cc of air. The pulse waveform was recorded at a gain of 1, meaning 1 mmHg equals 20 mm deflection on the PVR tracing. If the distal anastomosis was placed at or below the ankle level, transmetatarsal PVRs were obtained at a gain of 2.5. Deflection in mm and presence or absence of reflected wave were categorized in five groups: (1) deflection >15 mm and reflected wave present, (2) >15 mm and reflected wave absent, (3) 5–15 mm, (4) <5 mm, barely pulsatile, and (5) flat.[14]

Intraoperative blood flow volume was measured using an ultrasonic transit-time volume flowmeter (Transonic® Flowmeter, Model: HT201D, Transonic Systems Inc., Ithaca, NY, U.S.A.) with 4, 6, or 10 mm perivascular flowprobes. Flow through the graft was obtained at a convenient site. If possible CWD and UVF were also measured at the recipient artery distal to the distal anastomosis, and together with PVR with open and with temporarily occluded graft.

Subsequently, intraoperative angiography was performed by use of thorax film cassettes and a portable radiography tube. After inflow occlusion, 20–30 ml of contrast (Renographin 60%, Squibb Diagnostics) was injected via a 19–21 gauge butterfly needle placed in a vein side branch near the origin of the vein graft left intact for this purpose. Imaging of the entire graft and outflow vessels was accomplished with two anteroposterior (AP)-projections. In prosthetic grafts the same needle was introduced in the distal portion of the graft. The presence or absence of thrombus, kinking, strictures, stenosis, retained valves, arterio-venous fistulae, intimal flaps, and perianastomotic problems was recorded. From the combined information of preoperative and intraoperative angiograms the outflow resistance was graded according to the guidelines of the Society for Vascular Surgery and International Society for Cardiovascular Surgery (SVS/ISCVS).[15]

After the necessary revisions, when the result was considered technically satisfactory, DPP, CWD, PVR, and UVF were repeated and outside graft diameter was measured to the nearest 0.5 cm.

Patients were followed in the outpatient clinic at 1, 4, 8, and 12 months to record limb status and graft patency. History, physical examination, PVR, ABI (with exercise), and absolute ankle pressures were obtained, and a colour-flow Duplex scan was performed. Endpoints were (impending) graft occlusion, amputation, and death. Median duration of follow-up was 6 months (range 1–16).

Analysis

Predictive values and likelihood ratios were calculated for the intraoperative tests and variables with respect to two clinical endpoints: a technical problem during the bypass procedure that would warrant immediate revision and loss of primary patency within 30 days after the operation (early graft failure). The parameter definitions of a negative and positive test are depicted in Table 2. A likelihood ratio is considered statistically significant at the 0.05 (or 0.01) level if the 95% (or 99%) confidence intervals does not include 1.00.

Completion angiography could not be used as a gold standard of diagnosis of intraoperative problems because the angiogram was usually postponed until after revision of the problem detected with the intraoperative tests. We therefore used as the gold standard of diagnosis the presence of any technical problem detected during the initial bypass procedure or during follow-up. This is a practical approach in which the presence of the gold standard disease is defined as a clinically significant problem, in other words if revision is considered or demonstrated to be of importance for graft patency.

The agreement between the results of the intraoperative tests was analysed using the Kappa test in which a correction is made for agreement on the basis of chance. Demographic data, including risk factors and associated diseases (diabetes mellitus, tobacco abuse, hypertension, hyperlipidaemia, and cardiac, renal, pulmonary, and carotid disease), and the presentation of peripheral vascular disease were classified and graded according to the suggested standards for reports dealing with lower extremity ischaemia by the Ad Hoc Committee on Reporting Standards of the SVS/ISCVS.[15] Risk factors were graded from 0 (risk factors absent) to 3 (major risk factor) and a total risk factor score was calculated by adding the grade for each of these eight risk factors.

Graft patency was assessed by the Kaplan-Meier life-table method,[16] and univariate comparisons were performed using the log rank test. Test results together with graft and patient characteristics were subjected to a multiple regression analysis with a Cox proportional hazard model of primary patency, calculating relative risk and likelihood ratios.[17]

Results

In 51 of the 54 cases DPP, CWD, PVR, and UVF data of the final reconstruction was obtained. In three cases flow measurement was not possible. In 24 bypasses all four parameters were satisfactory, and in only four cases they agreed on the presence of a problem. In the remaining 23 cases, one or more of the four intraoperative parameters were abnormal, leading to a poor agreement between the individual pairs of tests (range agreement: 63%–80%, Kappa:0.14–0.43).

A completion angiogram was obtained in 38 procedures, including all cases without PVR or CWD improvement. In 16 cases intraoperative angiography was omitted for various reasons: in eight a good quality preoperative runoff image was available together with normal intraoperative haemodynamic test results, in seven angiography was deferred because of renal insufficiency and in one the angiogram was unsuccessful and not repeated. Twenty-five angiograms were considered normal and eight demonstrated outflow disease, in accordance with the preoperative angiograms. Five intraoperative angiograms showed outflow disease not suspected from the preoperative films, but these were all grafts with a distal anastomosis at the pedal level not amenable to more distal extension of the reconstruction.

In two cases angiography showed thrombus in the bypass or outflow tract and thrombectomy was performed. Three more revisions were performed without preceding angiography of which DPP missed an additional one (Table 3). Revision was not performed in another two cases with a less than 50% stenosis or spasm distal to the distal anastomosis and normal DPP, CWD, PVR, and UVF. All five problems necessitating revision were detected by CWD. PVR missed one and DPP missed two. Angiography did not prompt any revision by itself but assisted in the correct location of the problems detected by the other tests.

Table 3. Detection and treatment of the problems found during the initial bypass procedure

Problem	DPP[a]	CWD	PVR	UVF	Treatment
Stenosis recipient artery	+	+	+	n/a[b]	Extension graft
Thrombus in runoff	–	+	+	n/a	Thrombectomy
Thrombus in runoff	–	+	–	n/a	Thrombectomy
Thrombus in runoff	+	+	+	+	Thrombectomy
Bad distal vein graft	+	+	+	n/a	Replaced

[a] DPP, distal pulse palpation; CWD, continuous wave Doppler; PVR, pulse volume recorder; UVF, ultrasound volume flowmetry.
[b] Not available: UVF was postponed until after revision of a lesion detected by DPP, CWD, or PVR.

The sensitivity of the intraoperative tests for detecting runoff problems was very poor: 13% for DPP, 13% for CWD, 38% for PVR, and 36% for UVF.

Table 4. Predictive values of the intraoperative tests for the detection a technical problem

Test	DPP[a]	CWD	PVR	UVF
Number of positive test results	5	9	20	n/a[b]
PPV[c]	60%	56%	20%	
LR +	14.7	12.3	2.5	
p-value	$p < 0.01$	$p < 0.01$	NS	
Number of negative test results	49	45	34	n/a
NPV	96%	100%	97%	
LR–	0.4	0.0	0.3	
p-value	NS	$p < 0.05$	NS	

[a] DPP, distal pulse palpation; CWD, continuous wave Doppler; PVR, pulse volume recorder; UVF, ultrasound volume flowmetry.
[b] Not available: UVF was postponed until after the angiogram if a lesion had been detected by DPP, CWD, or PVR.
[c] PPV, positive predictive value; NPV, negative predictive value; LR +, likelihood ratio for a positive test; LR–, likelihood ratio for a negative test.

Table 4 shows predictive values and likelihood ratios for the prediction of the presence or absence of a technical problem that warranted revision. DPP and CWD were highly significant indicators of the need for revision with likelihood ratios for a positive test of 14.7 ($p < 0.01$) and 12.3 ($p < 0.01$), respectively. PVR did not achieve statistical significance in the detection of intraoperative problems.

None of the 16 bypasses without an intraoperative angiogram failed in the first postoperative month from a technical problem that could have been detected at the initial operation if an angiogram had been performed. It can thus be assumed that no extra false-negative cases were concealed in this group. The presence of a normal test result therefore had a high negative predictive value (NPV): 96% for DPP, 100% for CWD and 97% for PVR. Only the likelihood ratio of a negative CWD, however, achieved statistical significance. (Table 4).

There were five failures in the first postoperative month. Ensuing graft revision and angiography showed no technical defects and failure was related to inadequate runoff in all five cases. Further treatment consisted of two above-knee and one below-knee amputation, one urokinase treatment followed by distal balloon angioplasty, and one distal graft extension.

For the intraoperative tests neither positive (PPV) nor negative predictive values (NPV) for early failure achieved significance. The best PPV was only 13% for UVF < 50 ml/min with a likelihood ratio of 1.3 (NS). Likelihood ratios for negative tests ranged from 0.9 to 1.2 (NS). SVS/ISCVS runoff score > 1, on the other hand, was a good predictor of early failure: PPV = 33% with a likelihood ratio for a positive test of 4.9 ($p < 0.05$). None of the grafts with a perfect SVS/ISCVS runoff score ($n = 39$) failed in the first postoperative month, but the likelihood ratio for a negative test was only marginally significant (Table 5). There was a clear correlation between SVS/ISCVS runoff scores and UVF ($r = -0.42$, $p < 0.005$), demonstrating graft flow to be dependent on outflow resistance and that these two methods measure similar characteristics.

Table 5. Predictive values of the intraoperative tests for early graft failure

Test	UVF[a]	SVS	PSV	Diam < 3mm
Number of positive test results	8	15	3	10
PPV[b]	13%	33%		20%
LR +	1.3	4.9		3.3
p-value	NS	$p < 0.05$	NS	NS
Number of negative test results	42	39	34	33
NPV	91%	100%	91%	97%
LR–	0.9	0.0	0.8	0.4
p-value	NS	$p = 0.05$	NS	NS

[a] UVF, ultrasound volume flowmetry; SVS, SVS/ISCVS runoff score; PSV, maximum peak systolic velocity derived from CWD.
[b] PPV, positive predictive value; NPV, negative predictive value; LR +, likelihood ratio for a positive test; LR–, likelihood ratio for a negative test.

Doppler-derived PSV < 40 cm/s was found in only three cases of which one failed on the 11th postoperative day and another graft after 8 months. Early failure was found in two of ten grafts with graft sizes less than 3 mm. The PPV of 20% (likelihood ratio, 3.3) and NPV of 97% (likelihood ratio, 0.4) did not achieve statistical significance (Table 5).

The overall 12 month cumulative primary, assisted primary, and secondary patency rates were 63%, 76%, and 77%. Limb salvage and survival rates at 12 months were 86% and 93%. Twelve variables were entered in a stepwise Cox proportional hazard analysis of primary patency (Table 6). SVS/ISCVS runoff score and graft diameter were the only covariants with an independent, statistically significant effect on primary patency. Graft flow almost reached statistical significance and was also entered in the final model. None of the other nine variables attained statistical significance in any combination. Figures 1 and 2 depict primary patency grouped by SVS/ISCVS runoff score and minimal graft diameter.

Discussion

Although first month failures after infrainguinal revascularisation are generally attributed to technical errors, the exact relationship between residual problems and short and long-term patency is not known. As long as it is unclear to what extent problems such as incomplete valve lysis, vein wall abnormalities, anastomotic irregularities, and outflow disease increase the risk for graft failure, it is mandatory to aim at a perfect reconstruction. Preoperative angiography, good clinical decision making and planning must establish adequate bypass in- and outflow tracts. In addition, a hypercoagulable state may be detected before bypass surgery.[7] With these factors excluded, the only remaining issues that may jeopardise early graft patency are technical problems and unexpected runoff disease. Reliable means for intraoperative assessment of the reconstruction are therefore required.

Contrast angiography remains the diagnostic standard for arterial occlusive disease.[18] With the development of miniaturised fibreoptic catheters, angioscopy became available to the vascular surgeon in the mid-1980s.[19] The angioscope provides a method of controlled guidance of instrumentation and allows immediate assessment of results.[12,13,20–22] To date, however, it is a costly and demanding technique with

Table 6. Final parameter estimates using a Cox proportional hazards model of primary patency

Covariant	T-ratio	Relative risk	*p*-value
SVS/ISCVS runoff score > 1	2.39	6.13	0.02
Minimal graft diameter < 3 mm	2.11	11.23	0.03
Ultrasound volume flow < 50 ml/min	1.78	5.65	0.08

Variables not entered in the final model:

Variable	Parameters	
Age	numeric (range, 38–95)	
Total risk factor score	numeric (range, 1–12)	
Diabetes	0 = n 1 = yes	
Vein graft	0 = n 1 = yes	
Level of distal anastomosis	1 = AP[a] 2 = BP 3 = Trunk 4 = Tib	5 = Ped
Distal pulse palpation	0 = normal/weak	1 = absent
Continuous wave Doppler	0 = improvement	1 = "thump"/no improvement
Pulse volume recording	0 = improvement ≥ 1 category	1 = no improvement
Peak systolic velocity graft	0 = ≥ 40 cm/s	1 = < 40 cm/s

[a] AP, above-knee popliteal; BP, below-knee popliteal; Trunk, tibioperoneal trunk; Tib, tibial; Ped, pedal.

a potential of major complications, including intimal and vessel wall trauma, fluid overload, and thrombosis or embolisation. Furthermore, as with arteriography, no information is provided about the haemodynamic quality of the bypass.

Another new and promising method of intraoperative anatomical imaging is intravascular ultrasound (IVUS), which can be performed with the bypass in circulation.[23] In addition, luminal and anastomotic irregularities, vein wall abnormalities and inflow and outflow problems can be detected. However, it is not known whether angioscopy and IVUS are too sensitive, which could lead to unnecessary revisions. At present, IVUS is an expensive tool and there is a risk of catheter induced injury.[23]

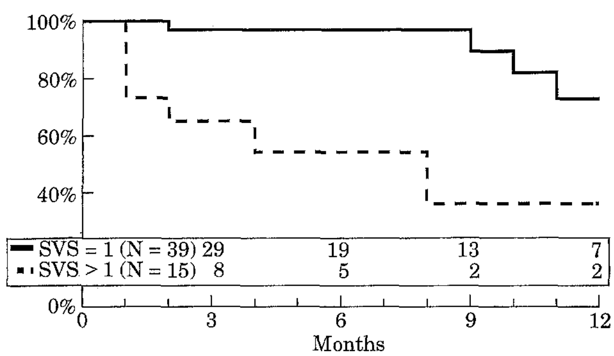

Fig. 1. Comparison of primary patency grouped by SVS/ISCVS runoff score. Thick curve, SVS-runoff score = 1; dashed curve, SVS-runoff score > 1 ($p < 0.01$, log rank).

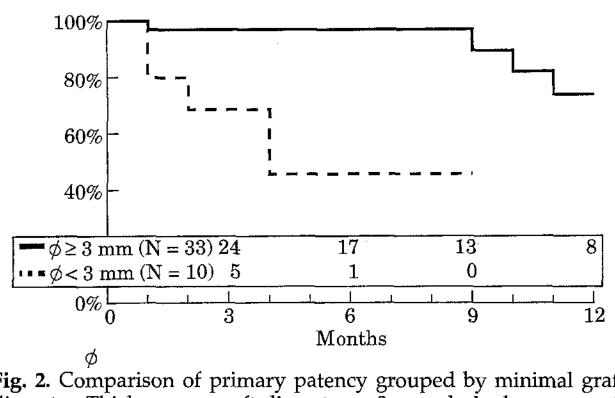

Fig. 2. Comparison of primary patency grouped by minimal graft diameter. Thick curve, graft diameter ≥ 3 mm; dashed curve, graft diameter < 3 mm ($p < 0.01$, log rank).

The past two decades have shown a remarkable increase in the number of noninvasive modalities. Because these techniques overcome the high costs, discomfort, and risks of angiography, they have become widely used for preliminary evaluation of patients with peripheral vascular disease,[24,25] for intraoperative monitoring bypass grafts,[11,26] and for follow-up.[27,28] However, the exact value of their utility in the intraoperative evaluation of infrainguinal revascularisation has not been the subject of a prospective comparative study. In this study we evaluated distal pulse palpation, qualitative and quantitative CW-Doppler data, pulse volume recording, and graft volume flow measurement as primary indicators of intraoperative problems and predictors of graft failure. We also included in the analysis intraoperative angiography and vein diameter.

The poor agreement among the four intraoperative tests confirms that DPP, CWD, PVR, and UVF assess different aspects of the haemodynamic quality of the vascular reconstruction. However, interpretation of audible signals of the CWD had the best likelihood ratios for both a positive and negative test result and thus provided the largest diagnostic gain for the detection of an intraoperative problem.

Angiography was only helpful in the correct identification of the problems already detected by

CWD and did not detect any additional technical inadequacies. On the other hand, the intraoperative tests were not sensitive for detecting outflow disease. Angiography may therefore be reserved for cases in which CWD suggests a problem or if preoperative imaging does not allow assessment of the runoff status. In addition, if the *in situ* vein graft is not exposed over its entire length, intraoperative angiography is the method of choice to detect side branches. Angioscopy, however, may be a more accurate method to establish the nature of a problem detected with CWD.[12,23]

In predicting early graft failure, the results of the intraoperative tests after the necessary corrections of problems were of no value. This corresponds with the assumption that early failure is predominantly related to runoff problems once a perfect vascular conduit has been established. Our data support this theory, as the SVS/ISCVS runoff score was the only significant predictor of early failure. With the use of the SVS/ISCVS runoff score, bypasses with high risk (33%) and low risk (0%) for early failure could be identified. An accurate SVS/ISCVS runoff score can only be obtained from high quality angiograms. Runoff scoring from inadequate preoperative films may explain why some authors could not confirm the predictive value of the SVS/ISCVS score. If first-year primary patency is considered, failures appear to be related not only to the SVS/ISCVS runoff score but also to the initial minimal vein graft diameter.

From these results we conclude that, from the intraoperative modalities tested, CWD is the best indicator of technical errors. Routine intraoperative angiography is not necessary and angiography or other means of anatomical imaging may be reserved for situations in which CWD indicates a problem, or if runoff information is inadequate. If all technical problems potentially responsible for failure can be eliminated during the initial bypass procedure, the SVS/ISCVS runoff score is a good predictor of early graft failure.

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