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Prospective Comparison of Arm Veins and Greater Saphenous Veins as Infrageniculate Bypass Grafts

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Objectives: *to compare arm and saphenous veins for infrageniculate bypass grafting.*
Design: *prospective non-randomised study.*
Materials: *two hundred patients, of which 197 had ischaemic tissue loss or rest pain.*
Methods: *two hundred and eleven infrageniculate vein bypass procedures using 176 greater saphenous veins and 35 arm veins.*
Results: *the cumulative primary graft patency rate at 1-month and 2 years was 80% and 61% for saphenous vein and 89% and 42% for arm vein. The corresponding rates for secondary patency were 84.5% and 68%, and 91% and 57%, respectively. These results corresponded to a relative risk of secondary failure of 1.53 (95% CI 0.71, 3.31) for arm vein grafts. In subgroup analyses, this estimate was 0.93 and 2.1 for primary vs secondary bypasses and 0.38 and 2.06 for single-vein vs spliced-vein bypasses. Among arm veins, cephalic vein grafts performed better than basilic vein grafts. Early mortality was 14% for arm vein and 10% for saphenous vein.*
Conclusion: *in the setting of infrageniculate bypass grafting, arm vein grafts are not equivalent to greater saphenous vein grafts, but contribute importantly to a policy of using autologous veins. The possibility of equivalence remains for the arm vein graft that uses a cephalic vein or is a primary procedure.*

Key Words: Arterial occlusive diseases; Arm vein; Bypass grafts.

Introduction

The use of an arm vein (AV) for infrainguinal arterial reconstruction was first reported by Kakkar in 1969,[1] but interest in this technique[2,3] did not increase until the limitations of prosthetic graft material became established.[4,5] When the ipsilateral greater saphenous vein (GSV) is unsuitable, some surgeons harvest the contralateral GSV,[6,7] whereas others resort to AV.[8] Despite the disagreement on the preferred strategy, the renewed interest in AV grafts as part of a policy for the maximal utilisation of autologous tissue has led to improvements in reconstructive techniques[8–11] and to better results in large surgical series.[2,12,13]

Although there are no biological grounds for assuming the supremacy of any *ex situ* autologous vein as a conduit, the superiority of GSVs in terms of graft patency has rarely been challenged.[14] In a recent retrospective study, however, Gentile *et al.*[7] found a lower incidence of graft failure for alternative veins (mostly AVs) compared with contralateral GSVs. This was so in spite of these authors' preference for the contralateral GSV alternative. In the present prospective study, AVs and GSVs were compared to determine their relative merits as bypass grafts to the infrageniculate arteries.

Material and Methods

Patients

The compared series were well balanced at baseline for most demographic variables, risk factors for peripheral arterial disease, and important clinical variables, but there was a severe imbalance for previous bypass (Table 1).

Study design

In a prospective series of autologous vein bypass grafts to an infrageniculate artery, AV grafts were compared

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Table 1. Differences at baseline between the study groups.

	AV grafts ($n=35$)	GSV grafts ($n=176$)
Female sex (%)	14 (40)	70 (40)
Median age	66	69
Diabetes (%)	26 (74)	109 (62)
Smoking (%)	16 (46)	75 (43)
Heart disease (%)	15 (43)	74 (42)
Surgical indication		
Claudication (%)	0 (0)	2 (1)
Rest pain (%)	7 (20)	17 (10)
Skin lesion (%)	27 (77)	157 (89)
Failing graft (%)	1 (3)	0 (0)
ABI <0.5 (%)	26 (75)	123 (70)
Infrapopliteal bypass (%)	24 (69)	123 (70)
Previous infrainguinal bypass (%)	16 (46)	5 (3)

ABI is the ankle–brachial systolic blood pressure index and was measured before 24 AV grafts and 142 GSV grafts.

to GSV grafts. A graft was included in the AV cohort if most of it consisted of an AV, whereas a graft in the GSV cohort consisted of a GSV alone or in combination with a smaller segment of another autologous vessel of the lower limb. Primary and secondary graft failures as strictly defined elsewhere were the end-points of prime interest,[15] but major amputation, death, and the need for non-autologous grafts were also assessed.

The rationale for subgroup analyses was that (1) a former arterial reconstruction in the affected limb negatively influences graft patency of a subsequent bypass,[6] (2) the construction of spliced-vein grafts is potentially more aggressive to vein integrity, and (3) cephalic and basilic veins differ in length, uniformity of diameter, and rates of use in bypass surgery.[2,3,8]

Subgroups determined by the ordering of operation, number of venous segments used, and source of vein were also analysed. Considering the target limb, a primary graft ($n=177$) was the first bypass performed, while a secondary graft ($n=34$) was a bypass performed subsequent to any previous infrainguinal reconstruction. A single-vein graft ($n=188$) used only one vein segment while a spliced composite vein graft ($n=23$) included at least two spliced venous segments or a venous segment spliced to a segment of endarterectomised femoral artery. Either combined or not to a vessel of the lower limb, the cephalic AV grafts ($n=20$) used cephalic but not basilic veins while the basilic AV grafts ($n=15$) used a basilic vein combined or not to a cephalic vein.

The date of grafting was adopted as zero time for the follow-up and the unit of analysis was the first infrageniculate vein bypass performed in the index limb during the study.

Assembling the cohorts

Ethical principles guided patient allocation to one of the two study groups.[16] This meant that an AV bypass graft was done only when a GSV was absent, had obvious pre-existing disease, or would be better spared. Prosthetic and allograft bypasses were not considered for inclusion and the following entry criteria were adopted: (1) the presence of ischaemic rest pain, non-healing ulceration, gangrene, disabling claudication or a failing graft, (2) palpable femoral but absent pedal pulses or the diagnosis of a failing graft, and (3) the use of either a GSV or an AV in a bypass inserted in the below-knee popliteal artery or more distally.

Absent pedal pulses suggested, but was insufficient to determine, the presence and extent of arterial occlusion. An ankle–brachial systolic blood pressure index (ABI) of less than 0.5 indicated arterial occlusion in 117 extremities. Preoperative arteriography confirmed this diagnosis and showed the extent of occlusion in 113 instances, but was not obtained for four extremities, all of which with an ABI of less than 0.3. Preoperative arteriography was also done in 48 extremities with an ABI equal to or greater than 0.5, and 45 extremities in which the ABI was not measured. In the remaining extremity, a popliteal-to-plantar bypass was performed without the assistance of ABI or arteriography.

The Institutional Review Board approved the allocation procedure and the study protocol. From January 1991 to the end of December 1995, 35 AV grafts and 176 GSV grafts were done consecutively in 200 patients at two tertiary referral centres and one private hospital. Other six prosthetic bypasses and 24 allograft vein bypasses were not considered for inclusion. Indication for surgery is given in Table 1. The reasons for not using a GSV included previous arterial reconstruction (21 in the same and seven in the other leg), previous vein stripping (four in the same and three in the other leg), vein inadequacies (10 in the same and six in the other leg), and contralateral major amputations in six patients. The absence of peripheral pulses or the presence of severe ischaemia made harvesting of the GSV in the contralateral leg inadvisable in 13 instances.

Surgical techniques

When the use of an AV graft was foreseen, one of the upper limbs was chosen and bandaged as a safeguard against possible venipunctures. The skin over the selected vein was marked with black ink on the day

Table 2. Level of arterial anastomoses. Grafts using spliced veins or segments of autologous artery are shown between parentheses and secondary grafts are shown between brackets.

Proximal anastomosis	Distal anastomosis			
	Previous bypass	Popliteal	Tibial/ peroneal	Pedal
AV grafts				
Previous bypass	1	2 (2)[2]	2 (1)[2]	1 [1]
External iliac		1 [1]	2 (1)[2]	
Common femoral		6 (1)[1]	3 (2)[2]	1 (1)
Superficial femoral		1 [1]	5 (1)[5]	2 (2)[1]
Popliteal				3 (1)[2]
GSV grafts				
Previous bypass		3 [3]	2 [2]	
External iliac		1	2 (1)[1]	
Common femoral		26 [1]	31 (1)[2]	2 (1)
Superficial femoral		21 (3)[1]	44 (3)[2]	11 (1)
Profunda femoris		2 [2]		
Popliteal			14 (1)	15
Tibial				2

before surgery, but on rare occasions the decision about which vein to harvest was deterred until surgical exploration. Since two surgical teams worked simultaneously, one on the upper limb and the other on the lower limb, general anaesthesia was mostly preferred. A long skin incision enhanced vein harvesting in the upper limb, but GSVs were harvested through three or more interrupted skin incisions. Since AVs are thin-walled, their small tributaries must be handled with great care as avulsions are not rare and stumps must be kept longer than 2 mm to allow proper ligation and the introduction of valvulotomes. The blood flow into the selected vein was maintained for as long as possible and desiccation was avoided by using surgical pads moistened in saline. These technical aspects have all been appropriately stressed by others.[2,17]

The proximal anastomosis was usually constructed first to take advantage of vein dilation under arterial pressure[2,18,19] and most grafts ended in an infrapopliteal artery (Table 2). AV grafts included 23 single-vein conduits, but 12 composite conduits were needed. The former were done with three reversed cephalic veins and 20 (12 cephalic, five basilic, and three combined cephalic-basilic) veins used as non-reversed grafts. Spliced composite AV grafts were constructed with a cephalic vein in five instances, a basilic vein in two, and with both sources of vein in five. There were 98 non-reversed, 67 reversed, and 11 composite grafts in the GSV cohort. Additional graft material in the GSV composite conduits consisted of six endarterectomised arteries,[20] three accessory saphenous veins, and two lesser saphenous veins.

Follow-up

Patients were reassessed every 4 months according to an active plan that included home visits when necessary. A time period of over 12 months with no assessment of graft patency was defined as loss to follow-up. By this criterion, 22 grafts were lost. Of these, 15 grafts did not complete a one-year follow-up. In addition to palpating pulses over the graft and in the foot, Doppler ultrasound pressures were measured routinely to assess graft patency. Duplex-scanning and arteriography were used only when arterial pulses became weak or a fall of 0.15 or more was found in the ABI.

Statistics

Long-term results were described by the Kaplan–Meier product-limit method,[21] but the relative risk of graft failure was estimated using the Mantel–Haenszel procedure to provide a uniform approach for all the comparisons.[22] A 95% confidence interval was calculated using the Miettinen formula for the observed relative risk. Since patency curves for AV grafts and GSV grafts crossed, the assumption of proportional hazards was not verified. Therefore, the log-rank test would not apply to the entire follow-up and the Cox model was not warranted.

A two-factor sensitivity analysis was done under two assumptions. First, the difference in the one-month graft patency rate between the preferred, non-reversed GSV grafts and the reversed GSV grafts should not

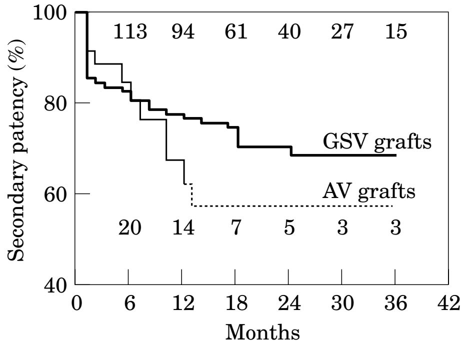

Fig. 1. Kaplan–Meier estimates for secondary graft patency. Dotted lines indicated 1 SD >10%. The numbers indicate the number of patients under observation (—) AV grafts; (▬) GSV grafts.

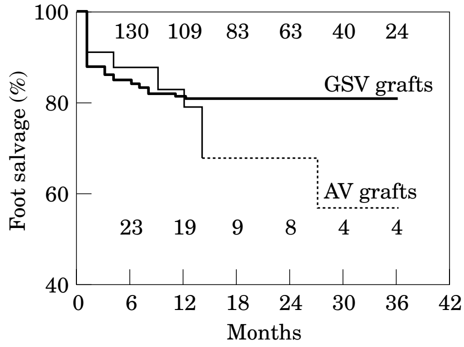

Fig. 2. Kaplan–Meier estimates for foot salvage. Dotted lines indicated 1 SD >10% (—) AV group; (▬) GSV group.

exceed 5%. This assumption implied decreasing the number of early failed grafts of the latter type from 17 to eight. Second, up to 60% of the grafts lost to follow-up within 12-months were assumed to have failed.[23] Degrees of correction of 50% and 100% were applied simultaneously to both factors.

Results

Graft patency

The primary graft patency rate at 36 months was 42% and 61% respectively, for AV grafts and GSV grafts (n.s.). The secondary graft patency rates at 12 and 36 months were 62% and 57% for AV grafts and 76% and 68% for GSV grafts (n.s.), respectively (Fig. 1). Secondary analyses for some surgical covariates are shown in Table 3.

Foot salvage

Loss of the foot was the result of graft occlusion (seven AV and 22 GSV) or extensive tissue damage despite a patent graft (two AV, and 10 GSV) and included 20 (three AV and 17 GSV) below-knee as well as 21 (six AV, and 15 GSV) above-knee amputations. The cumulative foot salvage rate at 1 month, 1 year, and 4 years was 94%, 79%, and 57% for AV grafts and 88%, 81%, and 81% for GSV grafts, respectively (Fig. 2).

Patient survival

Eleven AV patients and 63 GSV patients died during the study. Their deaths were attributed to cardiovascular events (four AV and 34 GSV), septic complications (four AV and 17 GSV), renal failure (four GSV), cancer (two AV and one GSV), pulmonary embolism (one AV and three GSV), bleeding disorders

Table 3. Relative risks of graft failure.

	Group size	Failed grafts	Graft-months	RR	95% CI	χ^2	*p*-value
All grafts							
GSV	176	45	2546	1.00			
AV	35	11	406	1.53	0.71, 3.31	2.17	0.14
Cephalic AV	20	5	289	0.98	0.78, 1.22	0.03	0.85
Basilic AV	15	6	117	2.90	1.14, 7.41	8.47	0.004
Primary grafts							
GSV	171	43	2450	1.00			
AV	19	4	246	0.93	0.23, 3.75	0.01	0.91
Secondary grafts							
GSV	5	2	96	1.00			
AV	16	7	160	2.1	0.68, 6.48	1.67	0.20
Single-vein grafts							
GSV	165	41	2458	1.00			
AV	23	8	233	2.06	1.07, 3.96	4.68	0.03
Spliced-vein grafts							
GSV	11	4	88	1.00			
AV	12	3	173	0.38	0.05, 3.03	0.83	0.36

RR is the relative risk, and 95% CI is the 95% confidence interval.

(one GSV), and unknown causes (five GSV). The cumulative patient survival rate at 1 month, 1 year, and 4 years was 86%, 73%, and 62% for AV grafts and 90%, 79%, and 47% for GSV grafts, respectively.

Sensitivity analyses

In the comparison of primary AV grafts and primary GSV grafts, the relative risk of AV graft failure increased from 0.93 to 0.98 (50% correction) and 1.11 (100% correction). When comparing cephalic AV grafts and GSV grafts, the corresponding estimate of 0.98 increased to 0.99 and 1.01 with corrections of 50% and 100%, respectively.

Discussion

The policy of using AV grafts in this series increased the use of totally autologous bypasses from 73% to 89%. The overall comparison between AV grafts and GSV grafts was biased by design because the stringent inclusion criteria made the AV group a more disadvantageous one in which the prevalence of previous bypass at baseline was much higher. A second source of bias was the preferential use of cephalic veins over basilic veins and the higher proportion of both spliced veins and non-reversed veins in the AV group. Our preference for non-reversed conduits, which relies on better size match at the anastomoses, allowance for reverse flow within the graft, and vein dilation with normothermic blood under arterial blood pressure, has been reported.[20,24–26] Subgroup analyses completed by a sensitivity analysis were useful for dealing with such overt biases.

The 4-year patency rate for cephalic AV grafts was identical to the estimate reported by Harris *et al.*[2] In the GSV cohort, the corresponding estimate was superior to the rates reported for other consecutive series,[27–29] but did not reach the higher figures obtained in some modern series.[7,30,31] Despite low precision, the point estimate for the relative risk suggested clinical equivalence between cephalic AV grafts and GSV grafts and was resistant upon sensitivity analysis.

Hölzenbein *et al*. achieved good results with the basilic-cephalic vein loop graft,[32] but no other report has dealt with AV grafts using basilic vein conduits in the straight configuration. The reasons for the poor performance of straight basilic AV grafts in this study were not restricted to the vein source. Indeed, preference was given mostly to the harvesting of cephalic veins and fewer basilic AV grafts were primary bypass procedures. In addition, AV grafts using basilic and cephalic vein segments spliced together, clearly a subset of grafts at higher risk, were arbitrarily included in the basilic AV subgroup.

The subset of primary AV grafts performed as well as the much larger subgroup of primary GSV grafts and the observed relative risk was barely responsive to extreme variation at sensitivity analysis. AV grafts definitely performed worse than GSV grafts in reoperations, thus contributing to the increased overall risk of AV graft failure (Table 3).

As a non-randomised concurrent cohort comparison, this study was level three evidence[33] and the results of the subgroup analyses were useful information.[34] Level two evidence incorporates randomisation and is thus theoretically superior, but the random allocation of patients who have a usable GSV to receive an AV bypass would hardly be ethical. Furthermore, the enrolment of 888 patients is required when using probabilities of 0.10 and 0.30 for statistical errors (one-tailed comparison in an equivalence trial of low power), a cumulative event rate of 32% in the control group, and a relative risk of 1.1.[35] In the absence of such a trial, a meta-analysis of individual patients becomes attractive, but the difficulties in obtaining full adherence to this idea should not be underestimated.[36]

In a broad perspective, this study may be perceived as a contribution to a global effort, rather than a one-step route to an answer.[34] The present results confirmed the prevailing opinion that AV grafts contribute importantly to a policy of bypass grafting using autologous veins. As a whole such grafts are not equivalent to GSV grafts as infrageniculate bypasses, but the possibility of equivalence remains for the AV graft that uses a cephalic vein or is a primary procedure.

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