Infrainguinal arterial reconstruction for claudication: Is it worth the risk? An analysis of 409 procedures

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Purpose: **Infrainguinal reconstruction traditionally has been reserved for patients with limb-threatening ischemia. Surgery for debilitating claudication, however, has been discouraged as a result of the perceived fear of bypass graft failure, limb loss, and significant perioperative complications that may be worse than the natural history of the disease. In this study, the results of infrainguinal reconstructions for claudication performed during the past 10 years were evaluated for bypass graft patency, limb loss, and long-term survival rates.**

Methods: **Data were collected and reviewed from the vascular registry, the office charts, and the hospital records for patients who underwent infrainguinal bypass grafting for claudication.**

Results: **From 1987 to 1997, 409 infrainguinal reconstructions were performed for claudication (9% of all infrainguinal reconstructions in our unit). The patient population had the following demographics: 73% men, 28% with diabetes, 54% smokers, and an average age of 64 years (range, 24 to 91 years). Inflow was from the following arteries: iliac artery/graft, 10%; common femoral artery, 52%; superficial femoral artery, 19%; profunda femoris artery, 16%; and popliteal artery, 2%. The outflow vessels were the following arteries: 165 above-knee popliteal arteries (40%), 150 below-knee popliteal arteries (37%), and 94 tibial vessels (23%). The operative mortality rate was 0%, and one limb was lost in the series from distal embolization. The primary patency rates were 62%, 77%, and 86% for above-knee popliteal artery, below-knee popliteal artery, and tibial vessel reconstructions at 4 years, and the secondary patency rates were 64%, 81%, and 90%, respectively. Cumulative patient survival rates were 93% and 80% at 4 and 6 years as compared with 65% and 52%, respectively, for infrainguinal reconstructions performed for limb salvage.**

Conclusion: **Infrainguinal arterial reconstruction for disabling claudication is a safe and durable procedure in selected patients. These data indicate that concern for limb loss, death, and limited life span of the patients with this disease may not be warranted. (J Vasc Surg 1999;29:259-69.)**

Intermittent claudication is not a limb-threatening condition. Rather, it is a reflection of an underlying disease process. In most patients, the symptoms stabilize with risk factor modification alone, and many patients find that they can function adequately within their claudication distance. However, in a minority of patients with claudication, the symptoms progress and a severe disability can result, which drastically curtails normal daily activities. In these patients who are self-selecting, intervention may be regarded as worthwhile. The operations for intermittent claudication can be conveniently divided into suprainguinal procedures and infrainguinal procedures. The infrainguinal procedures have been limited in the past to above-knee bypass grafting with either autologous vein or prosthetic material. The traditional teaching has been that, because the natural history of claudication is benign compared with the life expectancy of the patient, the worst possible outcome should be the

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return to the baseline state of claudication symptoms. The use of more distal reconstructions in patients for claudication should be cautiously applied because of the consequences of graft failure and the possibility of ensuing limb loss. This is not without good reason. In some published series,[1-4] the reported primary and secondary 5-year patency rates for femorotibial bypass grafting for critical ischemia have been 63% to 69% and 72% to 85%, respectively, with limb salvage rates of 84% to 92%. However, in one reported series,[5] femorotibial bypass grafting was associated with a 26% failure rate and a 24.4% amputation rate at 30 days and an overall operative mortality rate of 3.9%. In this particular series, if the amputations after 30 days were included, 39 of the 85 reconstructed limbs (46%) underwent amputation. Such results are not just the preserve of smaller units. Indeed, one teaching hospital has reported 36-month secondary patency rates for tibial bypass grafting of 31% to 51%, but sporadic data showed improved results that justified a more liberal approach for patients with claudication.[6-10]

In Albany, there has been a long tradition of distal reconstruction for limb salvage.[7] In the past two decades, the techniques and the instrumentation for distal in situ bypass grafting gradually have evolved. Our experience with tibial bypass grafting for limb salvage now numbers some 4468 cases, with secondary patency rates of 91% and 81% at 1 and 5 years, cumulative limb salvage rates of 97% and 85% at 1 and 5 years,[8] and an operative mortality rate of 2%. In addition, we have performed distal bypass grafting on a further 884 patients with excised vein as a conduit.[9] These cases have been performed with an operative mortality rate of 2% and a limb salvage rate of 95%. With this background, we began to cautiously extend the use of distal bypass grafting to patients with claudication whose symptoms had progressed despite a trial of conservative therapy or whose symptoms severely curtailed their social or professional activities. This paper details our experience with all the patients on our vascular service who have undergone infrainguinal reconstruction for claudication.

METHODS

Patients who are seen at our office with symptoms of intermittent claudication undergo a full clinical assessment. Pulse volume recordings (PVRs) are recorded to confirm a diagnosis of chronic vascular insufficiency or to exclude other causes. The patients with vascular claudication are advised to alter their lifestyle habits, and exercise programs are prescribed. The patients then undergo reassessment every 3 to 6 months. We have the following criteria for operative intervention: continued progressive deterioration of claudication distances by history despite risk factor modification, short distance claudication that severely curtails normal social and economic activities, and otherwise healthy patients who are severely incapacitated by their claudication. Possible complications, including death, risk of limb loss in the event of graft failure, and cardiac or wound complications, are stressed.

The standards of reporting used in this paper are those suggested by the Society for Vascular Surgery/International Society for Cardiovascular Surgery committees in relation to interventional therapies for peripheral vascular disease.[10] A computerized vascular database has been prospectively maintained in our center since 1982. Details on all patients who have undergone vascular interventions have been collected. The basic patient demographic details and the pertinent risk factors for vascular disease are entered. All the operative procedures also are reported. Data on all the technical aspects of reconstructions are documented, including operative indication, inflow artery, outflow artery, vascular conduit, and vein preparation technique. Because the vein is the preferred conduit in our center, the reasons as to its nonuse also are logged.

All the patients who undergo vascular reconstructions have PVRs and duplex scan surveillance of their vein grafts performed on the first postoperative day. A PVR and duplex scan surveillance then are performed on autogenous venous reconstructions at 6 weeks, every 3 months for 12 months, and then every 6 months after surgery. PVRs with segmental pressures only were used for follow-up of prosthetic reconstructions. The improvement of claudication was determined by history and improvement in noninvasive vascular laboratory tests.

For the purposes of this study, all the patient charts also were retrieved from the hospital files. The following data were extracted: postoperative problems after hospital discharge, symptom improvement, return to desired level of activity, and recurrence of claudication symptoms or disease progression. We cross-referenced the chart data with the data from our database to confirm its accuracy. Further intervention was performed for deterioration of walking distance by history, vascular laboratory testing, and occluded or failed grafts. For purposes of comparison, we retrieved data on all the patients who underwent infrainguinal bypass grafting for limb salvage from 1987 to 1997.

RESULTS

Of the 4468 infrainguinal bypass grafting procedures that were performed in our unit from 1987 to

Table I. Demographic details by reconstruction type

	No. of AK popliteal bypass grafts	*No. of BK popliteal bypass grafts*	*No. of tibial bypass grafts*
Men	113 (68.48%)	111 (74%)	74 (78.72%)
Women	52 (31.52%)	39 (26%)	20 (21.28%)
Diabetes	50 (30.3%)	37 (24.67%)	28 (29.79%)
Smoking	94 (56.97%)	80 (53.33%)	45 (47.87%)
Average age (years)	63	63	66
Age range (years)	35 to 89	24 to 87	34 to 91

AK, Above-knee; *BK,* below-knee.

1997, 409 (9%) were for intermittent claudication. Overall, tibial bypass grafts for claudication accounted for 2.1% of all the infragenicular bypass grafting procedures that were performed in our center between 1987 and 1997. The demographics were similar in those patients who underwent above-knee popliteal artery, below-knee popliteal artery, and tibial bypass grafting (Table I). Despite attempts at risk factor modification, 219 of the 409 patients (54%) admitted to smoking at the time of surgical admission. However, when questioned more closely, 86% of the patients admitted to substantial cigarette consumption. The mean follow-up time for all the patients was 52 months (range, 1 to 166 months).

One hundred sixty-five (41%) of the 409 procedures that were performed were femoral to above-knee popliteal bypass grafts. All inflow arteries, outflow arteries, and vascular conduits are listed in Table II. Of the 165 above-knee popliteal bypass grafting procedures that were performed, most (149/165 or 90%) were carried out with expanded polytetrafluoroethylene (ePTFE) grafts. An ePTFE graft was used in the above-knee position when the ipsilateral greater saphenous vein was not available in 101 patients and when the vein was spared in 48 patients. Seven patients (4%) underwent bypass grafting with in situ vein, and nine (6%) with reversed vein. Among the 150 below-knee popliteal bypass grafts, in situ vein was preferred in 120 (80%), with excised vein used in 26 (17%) and ePTFE in four (3%). In the tibial bypass graft group, 70% of the patients underwent in situ saphenous vein reconstructions and 30% of these procedures were performed with excised vein.

Of the 409 patients who underwent infrainguinal reconstruction, 22.1% had previously undergone some form of procedure for aortoiliac occlusive disease. These procedures were performed at a mean of 29 months (standard deviation, ± 56.5 months) before the bypass grafting operation. In most of the cases (9.8% of the overall patient group), the inflow procedure was an aortobifemoral bypass grafting, and in 5.4% of all patients, this procedure was followed by a common iliac artery balloon angioplasty. Iliofemoral bypass grafting or aortoiliac endarterectomy was carried out in 6.3% of the patients, and femorofemoral crossover in 0.3%.

There were no operative deaths among the patients who underwent bypass grafting for intermittent claudication. There was one instance of limb loss, as a result of distal embolization, for an amputation rate of 0.25%. This loss occurred in a patient who underwent above-knee femoral popliteal bypass grafting with ePTFE. One patient (0.25%) required a return to the operating room for control of bleeding. Wound infections developed in 12 patients (3%) and delayed hospital discharge. Of these infections, five occurred in patients who underwent above-knee ePTFE bypass grafting, three in the below-knee bypass graft group, and four in the patients for tibial bypass grafting. There were two graft infections (0.5%), both with ePTFE reconstructions. There were eight early graft failures—one (0.6%) in the group of 165 ePTFE above-knee bypass grafts and seven (4%) in the group of 150 below-knee bypass grafts (all vein), but none in the group of 94 tibial artery bypass grafts. However, overall, early (<30 days) operative reintervention was necessitated in 14 limbs. Of these, four were simple fistula ligations performed with local anesthesia and two were prophylactic revisions of vein grafts. Of the remaining eight bypass graft interventions, those that were early failures, one was a revision of an above-knee popliteal bypass graft and seven were salvages of below-knee popliteal grafts. Intervention was necessitated between 30 days and 1 year on 24 limbs. The indication in 13 of these limbs was further claudication, with rest pain or nonhealing ulcers occurring in nine patients (one at 30 days, six at 6 months, and two at 1 year) and acute ischemia in one patient (14 days). Of the eight patients who were late symptomatic, three had progression of the disease and five had deterioration of the graft (two prosthetic, three vein). The remaining patient was asymptomatic but required fistula ligation with local anaesthesia.

Table II, A. Inflow arteries

	No. of AK popliteal bypass grafts	*No. of BK popliteal bypass grafts*	*No. of tibial bypass grafts*
Iliac artery/graft	23	10	8
Common femoral artery	119	64	31
Superficial femoral artery	14	32	32
Profunda femoris artery	9	41	16
Popliteal artery	0	3	7

AK, Above-knee; *BK,* below-knee.

Table II, B. Outflow arteries

	No. of vessels
Above-knee popliteal artery	165
Below-knee popliteal artery	150
All tibial vessels	94
Anterior tibial artery	15
Posterior tibial artery	37
Peroneal artery	43

Table II, C. Conduits

	No. of vessels
In situ vein	189
Excised vein	63
ePTFE	157

ePTFE, Expanded polytetrafluoroethylene.

The primary patency rates for all the above-knee bypass grafts at 1 year, 3 years, and 5 years were 82%, 70%, and 48%, respectively (Table III; Fig 1). For the below-knee popliteal bypass grafts, the primary patency rates were 86%, 77%, and 70%, and, for tibial artery bypass grafts, were 86%, 86%, and 79%. The secondary patency rates for the above-knee bypass grafts were 83%, 72%, and 50% at 1, 3, and 5 years after surgery. The secondary patency rates for the below-knee popliteal reconstructions were 90%, 81%, and 78%, and, for tibial artery bypass grafts, were 92%, 90%, and 83%. The primary patency rate for the comparison of a prosthetic above-knee popliteal and below-knee vein reconstructions approached statistical significance at 30 days and 1 year ($P > .01$). Otherwise, there was no statistically significant difference between these groups (Table III; Fig 2).

The cumulative patient survival rate for patients who underwent bypass grafting for claudication was 100% at 30 days (Table IV), and, at 1 year, 3 years, and 5 years, the cumulative survival rates were 98%, 93%, and 86%, respectively. When the rates were stratified by procedure, the cumulative survival rates at 5 years were similar for above-knee, below-knee, and tibial artery bypass grafting (Table IV). By comparison, the overall cumulative survival rates at 1 and 5 years for 4059 patients who underwent surgery for limb salvage were significantly worse at 86% and 59% ($P < .05$).

Of the 409 procedures that were performed primarily for intermittent claudication, 75 (18.3%) necessitated a second operative procedure. Second surgeries were carried out at a mean of 23 months (standard deviation, ± 37.5 months) after the initial operation. There were a further 5.4% of the patients in whom successful bypass grafting surgery failed to completely resolve the claudication but who did not require further intervention. Of the 75 limbs that necessitated second operations, in 50%, the indication was recurrence of claudication. In 27.9%, rest pain or nonhealing ulcer was the main symptom. Acute ischemia mandated reintervention in 7.3% of the patients. Of the 75 second procedures, 34 were bypass grafts to the below-knee popliteal artery, 21 were bypass grafts to the tibial arteries, and five were redo above-knee bypass grafts. The remaining 13 procedures were ligation of fistulae and revision of graft stenoses and two patients who underwent thrombolysis of thrombosed grafts.

The 75 second procedures were stratified according to primary operative procedure. Of those patients who underwent above-knee popliteal reconstructions, 22.5% required second procedures. Of those patients whose primary procedure was a below-knee popliteal bypass grafting, 14.5% required a further procedure, and 9.6% of those patients who underwent tibial artery bypass grafting needed a second operation. The risk of further surgery was significantly greater ($P < .005$, with χ^2 test) for patients who underwent above-knee popliteal bypass grafting as their primary operation versus below-knee popliteal or tibial bypass grafting. There were no significant differences in incidence rates of further surgery between those patients who underwent tibial versus below-knee popliteal bypass grafting.

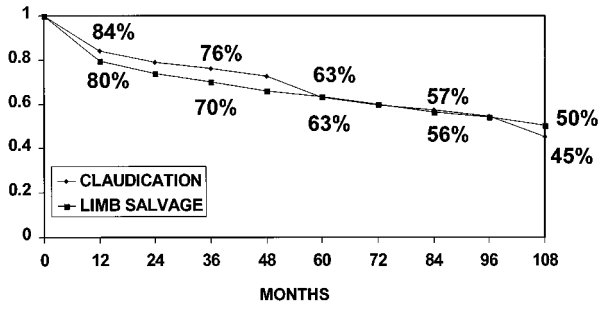

Fig 1. Comparison of primary patency rates for limb salvage and claudication.

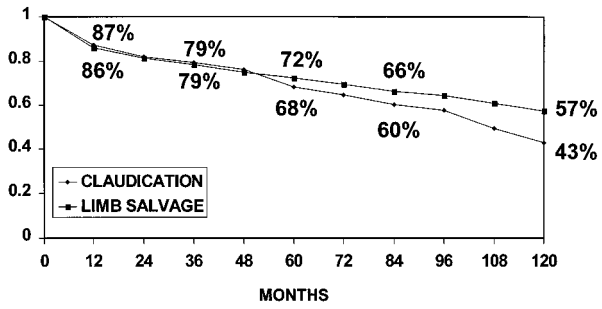

Fig 2. Comparison of secondary patency rates for limb salvage and claudication.

DISCUSSION

The data on amputation and risk of disease progression in patients with peripheral vascular occlusive disease are well known but bear reiteration. Lower extremity claudication as a result of peripheral arterial occlusive disease affects approximately 10% of the population of the United States at more than 70 years of age.[11] It affects 1% to 2% of the population aged 37 to 69 years and is five times more common in patients with diabetes.[12] Despite the large numbers of patients with some degree of peripheral vascular disease, "only" 100,000 operations are performed annually for lower extremity ischemia.[13] Obviously, most of patients undergo conservative treatment. Indeed, in 1983, the US Surgeon General estimated that only 10% of the patients with claudication required surgical intervention.[14]

In patients who do not undergo treatment for claudication, disease progression to the stage at which amputation is necessitated is a rare event. In the Framingham study, only 1.6% of the patients with claudication who were followed for 8.3 years required amputation.[15] Boyd[16] prospectively followed 1440 patients with intermittent claudication and found that, after 10 years, 12.2% required amputation. The amputation rates in other studies have been consistently low at 0.5% per annum.[17] Approximately 80% of the patients who are seen with claudication will either have a stabilized condition or, with modification of their risk factors and adherence to an exercise program, actually improve their walking distance. Indeed, the intervention rates for all the patients with claudication is only 5% per annum.[18] In those patients in whom disease progression occurs, cigarette smoking has repeatedly been identified as the most consistent adverse risk factor.[19] Progression is also more common in those

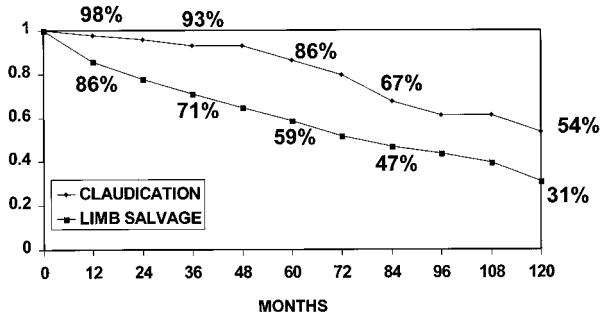

Fig 3. Comparison of cumulative patient survival rates for limb salvage and claudication.

patients with more severe disease at the time of initial presentation and in patients with diabetes.[20] In the face of these facts, compelling arguments are needed to support the use of any intervention at all when a patient is seen with symptoms of intermittent claudication. It follows that any intervention must not result in a limb loss rate of more than 0.5% per annum. However, the adoption of such a strict utilitarian approach ignores the broader aspects of the management of claudication. For a minority of such patients, living within the strict confines of a limited claudication distance represents a considerable physical disability and mental burden comparable with other chronic degenerative disease processes. In addition, cardiac rehabilitation associated with coronary artery disease may be hindered because of claudication.

Cost-utility analysis and quality of life measurements have been extensively used to assess surgical outcomes and make decisions about resource allocation. In the management of chronic diseases, the outcomes are measured in units that relate to a patient's level of well-being or "utility-based" units.[21] These

Table III. Bypass grafts for claudication

Primary patency	*Total no. of bypass grafts*	*30 days (±SE)*	*Year 1 (±SE)*	*Year 2 (±SE)*	*Year 3 (±SE)*	*Year 4 (±SE)*	*Year 5 (±SE)*	*Year 6 (±SE)*
All AK popliteal bypass grafts	165	0.981 (±0.01)	0.818 (±0.03)	0.722 (±0.05)	0.702 (±0.06)	0.619 (±0.07)	0.478 (±0.08)	0.478 (±0.10)
All BK popliteal bypass grafts	150	0.929 (±0.02)	0.863 (±0.03)	0.831 (±0.04)	0.767 (±0.06)	0.767 (±0.07)	0.698 (±0.08)	0.608 (±0.09)
All tibial bypass grafts	94	0.921 (±0.03)	0.859 (±0.04)	0.859 (±0.05)	0.859 (±0.06)	0.859 (±0.07)	0.790 (±0.10)	0.790 (±0.10)
Secondary patency	*Total no. of bypass grafts*	*30 days (±SE)*	*Year 1 (±SE)*	*Year 2 (±SE)*	*Year 3 (±SE)*	*Year 4 (±SE)*	*Year 5 (±SE)*	*Year 6 (±SE)*
All AK popliteal bypass grafts	165	0.981 (±0.01)	0.826 (±0.03)	0.743 (±0.05)	0.723 (±0.06)	0.642 (±0.07)	0.503 (±0.08)	0.503 (±0.10)
All BK popliteal bypass grafts	150	0.951 (±0.02)	0.903 (±0.03)	0.856 (±0.04)	0.814 (±0.05)	0.814 (±0.06)	0.780 (±0.07)	0.694 (±0.09)
All tibial bypass grafts	94	0.966 (±0.02)	0.920 (±0.03)	0.895 (±0.05)	0.895 (±0.05)	0.895 (±0.06)	0.826 (±0.09)	0.826 (±0.11)

SE, Standard error of the mean; *AK,* above-knee; *BK,* below-knee.

units are calculated by estimating the total life years gained from a procedure and weighing each year to reflect the quality of life in that year. Studies from several European centers[22-26] and from the Scottish Vascular Audit group[27] suggest that intermittent claudication impairs the quality of life in all aspects and that this degree of impairment seems to correlate with the degree of ischemia. In addition, it has been shown that clinicians often fail to appreciate the impact of impaired walking distance on their patients' quality of life. Furthermore, intervention in the form of balloon angioplasty or surgical revascularization can result in significant improvements in quality of life measures.[28] Data from this country[29] reinforce this impression by suggesting that the functional benefit of revascularization for claudication cannot be gauged by objective outcome measures alone, such as ankle-brachial indices, and that functional endpoints may be more important when evaluating the results of bypass graft surgery.

Other investigators have suggested that intermittent claudication may be more pernicious than previously appreciated.[30] Evidence from United Kingdom studies suggests that intermittent claudication represents repeated cycles of ischemia and reperfusion with resultant neutrophil activation and systemic vascular injury.[31,32] This suggestion has been supported by experimental animal models that showed systemic increases in leukocyte-endothelial adhesion and vascular permeability to albumin after subtotal ischemia in a single limb.[33] This has been evoked as a possible factor in the higher than expected cardiovascular mortality rate among patients with claudication. It has also been suggested that such systemic responses can be altered with surgical revascularization.[30]

Although many studies attest to the effectiveness of structured walking programs in improving claudication distances,[34-36] there have been few studies that directly compared the programs with surgical revascularization. The exception was a Swedish study[37] in 1989 that randomly allocated 75 matched patients with claudication to either supervised physical training, surgery alone, or exercise plus surgery. The surgery was the most effective therapy but was associated with more complications. The addition of training to surgery improved the results even further. The authors concluded that the improvement in their surgically-treated group was probably a result of significantly higher calf blood flow and ankle pressures after the operation. It is probably noteworthy that compliance in the supervised training group in this study was 84%. The compliance rates for unsupervised training are probably much lower.

Despite these arguments that support the surgical revascularization of the patient with claudication, we estimate that only 10% to 15% of the patients with claudication who are seen at our center undergo surgery. The vast majority continue to undergo conservative treatment. Although 409 patients with claudication undergoing infrainguinal bypass grafting may at first sight seem a large number, it still only represented 9% of all the infrainguinal reconstructions that were performed in our unit in a 10-year period. However, perhaps the most striking aspect of our experience is not that we carried out 409 infrain-

Table IV. Cumulative patient survival rates

Bypass grafts for claudification	*Total no. of bypass grafts*	*30 days (±SE)*	*Year 1 (±SE)*	*Year 2 (±SE)*	*Year 3 (±SE)*	*Year 4 (±SE)*	*Year 5 (±SE)*	*Year 6 (±SE)*
All bypass grafts	409	1.000 (±0)	0.978 (±0.01)	0.958 (±0.01)	0.931 (±0.02)	0.931 (±0.03)	0.863 (±0.04)	0.797 (±0.06)
All AK popliteal bypass grafts	165	1.000 (±0)	0.982 (±0.01)	0.982 (±0.02)	0.906 (±0.04)	0.906 (±0.05)	0.802 (±0.08)	0.802 (±0.10)
All BK popliteal bypass grafts	150	1.000 (±0)	0.970 (±0.01)	0.953 (±0.03)	0.953 (±0.03)	0.953 (±0.03)	0.953 (±0.04)	0.798 (±0.08)
All tibial bypass grafts	94	1.000 (±0)	0.984 (±0.01)	0.931 (±0.04)	0.931 (±0.04)	0.931 (±0.05)	0.793 (±0.09)	0.793 (±0.11)
Bypass grafts for limb salvage	*Total no. of bypass grafts*	*30 days (±SE)*	*Year 1 (±SE)*	*Year 2 (±SE)*	*Year 3 (±SE)*	*Year 4 (±SE)*	*Year 5 (±SE)*	*Year 6 (±SE)*
All bypass grafts	4059	0.961 (±0.003)	0.858 (±0.01)	0.778 (±0.01)	0.711 (±0.01)	0.648 (±0.01)	0.587 (±0.02)	0.515 (±0.02)
All AK popliteal bypass grafts	493	0.953 (±0.01)	0.857 (±0.02)	0.777 (±0.03)	0.729 (±0.04)	0.653 (±0.04)	0.625 (±0.05)	0.539 (±0.06)
All BK popliteal bypass grafts	840	0.979 (±0.005)	0.889 (±0.01)	0.813 (±0.02)	0.726 (±0.02)	0.667 (±0.03)	0.619 (±0.03)	0.568 (±0.03)
All tibial bypass grafts	2726	0.957 (±0.004)	0.849 (±0.01)	0.767 (±0.01)	0.705 (±0.01)	0.642 (±0.02)	0.571 (±0.02)	0.492 (±0.02)

SE, Standard error of the mean; *AK,* above-knee; *BK,* below-knee.

guinal bypass grafting procedures for claudication but that 150 of these were below-knee bypass grafts and that 94 tibial artery bypass grafting procedures were performed. Although 94 tibial artery bypass grafting procedures were performed in the last 10 years for intermittent claudication in our unit, these represent only 2.1% of all the infrainguinal revascularizations that were performed during this time. This would suggest some degree of caution in performing such bypass grafts in the patient for nonlimb salvage. It is gratifying that these 94 patients had no mortalities and no amputations and that the vast majority had an immediate relief of symptoms.

The cumulative secondary patency rates at 5 years for below-knee popliteal and tibial bypass grafts were 78% and 83%. The cumulative 5-year survival rates were 95% for below-knee popliteal bypass grafts for claudication and 79% for tibial bypass grafts. Together, these would imply a significant contribution to the quality of life of these individuals.

Overall mortality (0%) and limb loss (0.25%) rates for the infrainguinal reconstructions in this study compare with those from other studies that focus on surgical reconstruction for intermittent claudication. Our single amputation was in a patient who underwent above-knee popliteal reconstruction as a result of distal embolization. Although unfortunate, a limb-loss rate of 1/165 (0.6%) for above-knee popliteal reconstruction is comparable with reports from other centers. However, there were no early or late amputations in the below-knee popliteal or tibial artery bypass graft group. This is similar to the experience of the Brigham group[6] and would tend to reinforce their impression that the concerns about limb loss may be overstated. Our amputation rate in this series is also in keeping with the expected amputation rates from historical studies in patients with claudication.[15,16]

In this series, we reviewed our experience with vascular reconstruction for intermittent claudication. Philosophically, one might question the wisdom of performing potentially harmful procedures for what is a pathologically benign disease process, especially when 18% of those interventions necessitated second procedures. Although it is disingenuous to compare different surgical procedures, the concept of performing major surgery for chronic degenerative diseases that impair patient mobility and sense of well-being is not novel. The results from national and regional hip and knee registries[40,41] and from the Veteran Administrations Affairs studies[42] show operative mortality rates for total hip and total knee replacements of 0% to 1%, with revision rates of 9% to 15% in 5 years, morbidity rates of 1% to 3%, and cumulative 5-year survival rates of 90% to 95%—almost exactly the rates in this series of patients.

In summary, infrainguinal and infragenicular bypass grafting procedures, particularly with autogenous veins, are valid treatment options in selected

patients with claudication who warrant operative intervention. Such procedures can be performed safely with low morbidity rates and no mortalities. Tibial artery bypass grafting is a safe option in the patient with claudication, and the concerns about amputation are probably overstated. Nonetheless, such distal reconstructions for intermittent claudication may be best reserved for the patients with autogenous veins in units with a large experience of infrageniculate bypass grafts and acceptable results for limb salvage.

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DISCUSSION

Dr Lloyd M. Taylor, Jr (Portland, Ore). The Albany group has asked an important question about infrainguinal bypass graft surgery for claudication—namely, is it worth the risk? They retrospectively reviewed 409 procedures performed for this indication during 10 years. Patients were selected if nonoperative therapy failed to prevent worsening and if the symptoms severely curtailed normal social and economic activities. Although more specific indications for operation were not given, the procedures for claudication only represented 9% of the vast total of more than 4500 infrainguinal bypass graft operations performed. This fact alone indicates to me that their indications for surgery were probably appropriately conservative.

The authors clearly have described the risks of the surgery. No one died during surgery. The performance of 409 consecutive vascular reconstructions of any type without an operative death is noteworthy and indicates appropriate patient selection and skillful anesthetic and surgical care. One patient required an amputation because of complications, eight grafts failed acutely and two became infected, and 75 grafts became occluded during follow-up. By my count, this means that 86 of the 409 patients, or 21%, were harmed by the surgery, some severely. We have no information in this report about how many patients had long-term side effects, including chronic incisional pain, saphenous nerve pain, and edema. We do not know how many patients required long-term medical treatment for pain control, stockings, or other devices to control edema. It is not an exaggeration to say that the price for the improved walking ability in some patients may be a limb that is chronically uncomfortable or even painful at rest.

Unfortunately, we also have no information that allows us to determine the benefit of the surgery in this report. The patency rate of the repairs was admirably high, as we would expect from these surgeons whose experience and expertise are widely recognized. However, intermittent claudication is a functional problem. All the patients in this series underwent operation because their walking ability was impaired. This report does not tell us whether the expertly performed surgery relieved the claudication. This evaluation can only be assessed in functional terms.

To answer the question posed in the title—namely, is infrainguinal bypass grafting for claudication worth the risk?—the authors need to answer the following three questions:

1. How many patients had postoperative improvement in their walking ability, and what was the magnitude of the improvement or the lack thereof?

2. For those patients whose walking ability improved, was this improvement lessened by the inescapable side effects of the surgery?

3. Finally, for each patient, what was the answer to the simple question: If you had it to do over again, knowing what you do about the outcome of the operation, would you elect to have the surgery?

When we know the answers to these questions, then we will know whether infrainguinal bypass grafting for claudication is worth the risk. At present, on the basis of the information in this study, we do not.

Thank you.

Dr R. Clement Darling III. I would like to thank Dr Taylor for his insightful comments. Those are all excellent questions.

When we first looked at our database, I truly expected to find about a 2% mortality rate and I expected to find more limb loss. We did not go into this trying to prove a point. We went into this data evaluation essentially to see whether we could come up with a better algorithm and a better method of telling our patients what truly to expect from this operation.

Most of the questions that were posed to me by Dr Taylor can only be answered through a prospective study, especially a study that involves some kind of quality-of-life evaluation. One of our coauthors John Byrne, who worked extremely hard on this, went back and checked all the 409 charts of the patients who had undergone operation, partially to corroborate the data that we had derived from the registry and also to see whether there was any improvement in pulse volume recordings. There was improvement in the pulse volume recordings in 95% of the

patients. But whether that was translated into better walking distance or better symptomatic relief from their debilitating claudication, I really do not have that data. And I think the only way to evaluate that is by judging it prospectively.

As far as postoperative complications, there are always long-term sequelae, such as leg swelling and some incisional pain. Again, all the data we had did not show that that was a significant problem in this patient population, but, in a retrospective study, I do not think you can truly rely on that data.

Dr Anthony M. Imparato (New York, NY). The authors have reported that at worst as many as one out of three, and at best one out of 10, patients with claudication who are subjected to bypass grafting procedures will either have had failure of their bypass grafts during a 4-year follow-up period or will have required another operation. They also report that a considerable number of the patients' conditions were made worse. These results hardly indicate that the procedures were durable, especially because they were done for cosmetic reasons, claudication, which rarely indicates imminent, or early or ever limb loss. Nonoperative treatment may be effective for decades. The implication they offer is that more patients with claudication should undergo operation because the operation could be done with less than catastrophic results. Although not fully in control of the new pathologic processes set in motion by mechanical intervention on arteries of any type, I can do it, therefore, I shall do it. Will you join me?

The questions I have are as follows:

What is disabling claudication? Were the patients reassured before surgery that claudication does not equate with limb loss? We have found that when the patients are thus reassured, the claudication ceases to be disabling and operations are less attractive to them.

Did the patients stop smoking before surgery? What was the fate of those patients whose grafts failed and could not be retrieved as regards to limb-threatening ischemia? And did any amputations result from these failures?

We must guard against the attitude expressed by some that if the community of skilled vascular surgeons will not operate on patients with claudication, there are others less skilled and less knowledgeable about vascular diseases who will intervene with less-effective techniques. We also must guard against giving these interventionists the data that will permit them to say, if the vascular surgeons can do it, so can we.

I strongly suggest that the data presented by the authors do not justify their implied conclusion that a more aggressive posture towards operating on patients with claudication is indicated. Rather the reverse seems more reasonable. They may be widely quoted to the detriment of the large community of patients with claudication whose disease can be quite successfully managed nonoperatively with multiple decades of follow-up examination. And only the rare patient with claudication truly requires an operation. Thank you.

Dr Darling. Thank you, Dr Imparato. I agree with your point that everybody should be cautious when approaching distal reconstruction for patients with claudication. All of us, I think, in our group have been consistent in telling our patients that they had about a 2% chance of death from the operation and a 5% chance of a major complication. We also assured the patients of the benign nature of the natural history of the disease. We talked to them, tried to adjust their risk factors, and did not imply that an aggressive approach to revascularization was the end-all and cure-all for their walking problems.

However, still faced with these data, we gave the patients the option of either surgery or no surgery. None of these patients were brought in immediately from the office or immediately after the first evaluation for surgery. The tone of the paper is not necessarily that all patients should have distal reconstructions for claudication or that we have a reasonable mortality/morbidity and patency rate from this operation and therefore we should do it. I think that what we tried to say with this paper and with these data is that now you can go to your patients and tell them there probably will be about a 20% chance of being reoperated on in the long term. They will probably not die from the operation, and they probably will not lose their leg, but they will have to be followed up probably for their lifetime and they will have a chance of going back to the operating room, which is not insignificant.

As far as what is debilitating claudication, this is a subjective diagnosis that the patient describes to you. A wise clinician sometimes will walk their patient around and see if they do have pain in their legs when they walk. You obviously have to distinguish between neurogenic claudication and other forms of claudication as opposed to vasculogenic.

Obviously, we try to get our patients to stop smoking, but that just does not always happen. We advise them, we preach to them, and we tell them that the chance of reoperations is much higher if they continue smoking. We do not refuse to operate on them solely because of their smoking.

Dr David C. Brewster (Boston, Mass). I congratulate you and your group on your fine results, which appear to support your conclusions. I wonder if you could elaborate on decision making, because I think there is still a lot of judgment involved here. First of all, the anticipated benefit in such patients generally assumes prolonged survival rates or anticipated survival rates. Say a little bit more about risk stratification in this regard if you will.

Secondly, Dr Linton and your father always insisted that patients, particularly with claudication, stop smoking. Would you agree with that as a requirement before the surgery is undertaken?

And thirdly, because your results do appear to emphasize the importance of a vein in terms of prolonged function of these bypass grafts, do you do anything other than clinical examinations to evaluate the vein in advance of surgery?

Dr Darling. Thank you, Dr Brewster. The history of Massachusetts General Hospital in distal reconstruction has obviously been well recognized.

We try to dictate to the patients that they stop smoking. There are few ways, short of measuring their carboxyhemoglobin levels, to assure that they actually are changing or have changed their risk factors in any positive way. We have not adopted a policy, as I mentioned, of refusing to operate on these patients solely because they are smokers.

To answer your last question about venous anatomy, all the patients who underwent distal reconstructions electively will undergo venous duplex scanning to evaluate their vein. If the vein is of bad quality and if they have an above-knee popliteal segment, then we will probably use a prosthetic to above the knee. These patients did have a statistically significant increased risk of having a second operation; however, there were no limb losses that occurred as a result of the occlusion of those bypass grafts. And I do not think we have answered the question as to whether one extends the length of the patient's ability to undergo bypass grafting by performing a prosthetic bypass graft first and then a vein graft later. There is a lot of intragroup prejudice as to what operation is preferred. Some would like to do a more "definitive" operation, such as an in situ venous reconstruction to the below-knee popliteal arteries, and others are more amenable to doing an above-knee prosthetic bypass grafting procedure.

As far as patient selection, again, we tried to have our patients undergo evaluation to make sure that they were adequate cardiac risks for undergoing this type of operation. We only perform angiography or any invasive procedure if we think a patient is an adequate surgical candidate, and then we proceed if they have what we consider reasonable anatomy.

Dr Richard P. Cambria (Boston, Mass). My comments will echo those of Dr Taylor. Two years ago, before the Annual Meeting of the New England Society for Vascular Surgery, we presented our results with surgical treatment for claudication. The principal endpoint in our study was patient satisfaction. And the question posed by Dr Taylor for the patients (ie, would you do it again?) was indeed an important part of that questionnaire. In assessing those results, we found that 80% of the patients were quite satisfied with their outcome. In looking at the variables associated with the failure of patient satisfaction, there was a strong trend against infrainguinal revascularization as opposed to inflow reconstruction. On that basis, we have continued to maintain an extremely conservative posture toward recommending infrainguinal revascularization for claudication. Other variables that predicted an unsatisfactory outcome were diabetes and an age of more than 70 years. Similar to your study, we demonstrated favorable graft patency and late survival rates. However, as emphasized by Dr Taylor, that is somewhat beside the point.

Dr Anthony D. Whittemore (Boston, Mass). I have a brief question. You followed your vein grafts diligently with duplex ultrasound scan every 3 months during the first year. You did so in spite of the fact that you probably were not getting paid for all of them, and yet you did not do so with your expanded polytetrafluoroethylene grafts. The reason that you followed the vein grafts is because you cannot rely on the pulse volume recordings or the hemodynamic parameters. We know full well that at least 50% of the individuals with hemodynamically significant lesions have absolutely normal hemodynamic parameters. Do you think this represents an opportunity for improvement? Could you possibly have detected expanded polytetrafluoroethylene grafts failing at the distal anastomosis, and could you have avoided those poor results with that group?

Dr Darling. Thank you, Dr Whittemore. We have not had an extensive experience with the use of duplex scan in evaluating prosthetics. What we really want to find out when we follow up the prosthetics is whether there is an inflow and outflow lesion. We do not have to worry about the lesions intrinsic in the expanded polytetrafluoroethylene grafts. So, we found the pulse volume recording to be a relatively reliable indicator as far as diagnosing these lesions. We have not been as aggressive, as you noted, in going for secondary patency for patients who have had prosthetic reconstructions.

Dr Mark R. Nehler (Denver, Colo). There are about 10 different randomized studies that show that monitored exercise programs are effective in treating claudication and that you can double and triple walking distances. Despite those studies, there are currently no third-party payors who will pay for the studies. This is where most of our efforts should be directed. Zyban (bupropion hydrochloride; Glaxo Wellcome, Inc, Research Triangle Park, NC) is approved by the Food and Drug Administration for smoking cessation. Carnitine and Cilastazol are basically in the wings awaiting approval. I think these areas are where our efforts should be directed.

Dr Darling. Thank you. I think you make an excellent point. We actually are trying to embark on a study where we evaluate claudication by giving the patient a standardized regime in a physical therapy practice to evaluate their walking distance and to see if improvement is greater when the results are compared with patients who undergo a self-designed exercise program. As you know, you can tell your patients, go out and walk as much as you can and continue to walk through your pain. However, nobody really knows, just like the smoking, if they are really doing this constantly. Then, when the patients return 3 to 6 months later, they may say that "I tried it all I could. I have not walked any better, and I really want something done. This is debilitating."

We have tried the different methods of getting patients to quit smoking cigarettes. And I agree, much of our efforts should be in preventive medicine as much as performing distal reconstructions for this disease process.