CLINICAL RESEARCH STUDIES

From the Western Vascular Society

An economic appraisal of lower extremity bypass graft maintenance

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Objective: Infrainguinal graft surveillance leads to intervention on the basis of duplex-identified stenoses. We have become increasingly concerned about the high frequency with which such revisions are required to maximize graft patency and limb salvage rates. The economic implications of these procedures have not been carefully analyzed or justified.

Methods: We retrospectively reviewed 155 consecutive autogenous infrainguinal bypass grafts performed for chronic leg ischemia in 141 patients. All patients were enrolled in a prospective surveillance program using color flow duplex imaging. Full economic appraisal (cost analysis, cost-effect analysis, and cost-benefit analysis) was performed for all graft surveillance and limb salvage–related interventions through use of standard accounting and valuation techniques.

Results: Mean follow-up was 27 months. Five-year assisted primary patency (72%) and limb salvage rates (91%) were calculated by means of life table analysis. A total of 61 grafts required 86 revisions. Within 1 year of implantation, 36% of the grafts required revision. During this first year, the mean cost per graft enrolled was $9417. Time intervals after the initial year demonstrated a reduced annual revision rate (6%) and cost ($1725 per graft). The mean 5-year cost of graft maintenance ($16,318) approached that of the initial bypass graft ($19,331). The sum of the initial cost of bypass graft and 5-year graft maintenance cost ($35,649) was similar to the cost of amputation ($36,273). Grafts revised for duplex-detected stenoses (n = 46), in comparison with those revised after thrombosis (n = 15), had an improved 1-year patency (93% vs 57%; $P < .01$), required fewer amputations (2% vs 33%; $P < .01$), less frequently required multiple graft revisions ($P = .06$), and generated fewer expenses (at 12 months after revision, $17,688 vs $45,252, $P < .01$).

Conclusion: The cost associated with graft maintenance is significant, particularly within the first year, and demands consideration. Revision of a duplex-identified stenosis was significantly less costly than revision after graft thrombosis. Compared with the cost of limb amputation, limb salvage–related expenses appear to be justified. (J Vasc Surg 2000;32:1-12.)

Previous reports in the literature suggest that lower extremity revascularization is cost-effective for the treatment of chronic lower extremity ischemia in comparison with primary amputation.[1,2] These studies indicate that although the initial cost of bypass grafting may be higher than that of amputation, the additional expense of postamputation rehabilitation, prosthesis construction, and support services negates the initial cost benefit of primary amputation.

Most previous studies, however, fail to account for the resources used in bypass graft maintenance, even though optimal graft patency and limb salvage depend on an active surveillance program.[3,4] Originally popularized by Bandyk et al,[5] lower extremity surveillance programs rely on interval duplex examination of the graft and eventuate in repair of identified stenoses in up to one third of all lower extremity autogenous bypass grafts.[6] Despite this relatively high rate of surgical revision, however, graft patency and limb salvage rates have improved by only 10% to 15%.[4] We have become increasingly concerned about the high frequency with which such revisions are required, the cost of which has been neither analyzed nor justified.

Competition of interest: nil.

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Table I. Patient demographics and operative indications

Mean age (y)	69.1 ± 9.8
Female gender (%)	43
Tobacco use (%)	43
Diabetes (%)	39
Hypertension (%)	65
End-stage renal disease (%)	4.5
Tissue loss (%)	45
Rest pain (%)	34
Claudication (%)	19
Popliteal aneurysm (%)	1.3

Table II. Distribution of inflow and outflow vessels

	Percent
Graft origin	
Common femoral artery	56
Superficial femoral artery	24
Profunda femoris artery	8
Popliteal artery	11
Graft insertion	
Above knee popliteal	7
Below knee popliteal	36
Tibial / pedal	56

We therefore set out to perform a detailed economic evaluation of the 141 cases most recently enrolled in our prospective infrainguinal graft surveillance program. (1) We began by performing a detailed cost analysis for the primary bypass procedure, the graft surveillance program, and alternative therapies (major amputation). (2) Through use of the derived cost data, a cost-effect analysis was carried out for the surveillance interval on the basis of the cost / limb salvage ratio. (3) Finally, a cost-benefit analysis was performed by comparison of cost / limb salvage ratios of the contemporary cohort with those of a historical group in which revision was performed only for symptoms of recurrent leg ischemia.

METHODS

Patient cohort. We retrospectively reviewed the surveillance data of the 155 most recent autogenous infrainguinal bypass procedures performed for chronic leg ischemia. All patients were considered for arterial reconstruction if maintenance of a viable limb would confer a mobility advantage (ability to transfer or independently ambulate). Indications for operation and patient demographics are listed in Table I.

Our preferred conduit was autogenous greater saphenous vein constructed through use of the reversed (70%) or in situ technique (19%). When the greater saphenous vein was unavailable, our choice was the lesser saphenous, cephalic, or basilic vein, either alone or as a spliced composite autogenous graft (10.5%). Patients in whom prosthetic material was used were excluded because previous reports had failed to demonstrate a significant benefit for surveillance of prosthetic grafts.[4] More than 90% of distal anastomoses were constructed to infrageniculate vessels (Table II).

Postoperative evaluations were scheduled at 6 weeks, 3 months, 6 months, 9 months, and 12 months and then at 6-month intervals. Follow-up consisted of a focused history and physical examination, Doppler-derived ankle / brachial index determination, and color-flow duplex scanning of the entire bypass conduit, inflow, and outflow arteries. Specific criteria for graft revision were based on an extensive review of the literature and previous experience (Table III). These criteria were previously validated through prospective application.[7]

Surgical results. Mean follow-up after revascularization was 27.3 ± 22.7 months (range, 4-110 months). The prospective application of our intensive surveillance protocol yielded a 5-year assisted primary patency of 72.3%, a secondary patency of 79.4%, and a limb salvage rate of 91.4% (Fig 1). A mean of 5.2 ± 3.3 graft surveillance evaluations per patient was performed. Because most graft stenoses develop within the first year of implantation, this interval was surveyed with the highest intensity.

A total of 86 revisions were performed on 61 of the 155 bypass grafts. Ninety-four grafts (61%) underwent no revision; 42 grafts (27%) underwent 1 revision; and 19 grafts (12%) underwent multiple revisions. Forty-six grafts were revised for duplex-identified stenoses, and 15 grafts were revised after thrombosis.

Of the 46 grafts revised electively for duplex-identified stenoses, 84% underwent preoperative angiography to confirm the location and severity of the stenosis and exclude a synchronous lesion. Procedures performed included percutaneous angioplasty (8% of revisions), patch angioplasty (18% of revisions), and graft interposition / translocation (73% of revisions). Secondary revisions were required in 12 (26%) of the 46 grafts because of the development of metachronous stenoses. Subsequent failure occurred in five (11%) of the grafts (mean time from revision to thrombosis, 4.9 months), and one limb (2%) required major amputation.

Fifteen grafts required revision after thrombosis. Six patients developed early postoperative graft thrombosis and were returned directly to the operating room for catheter thrombectomy and revision. The remain-

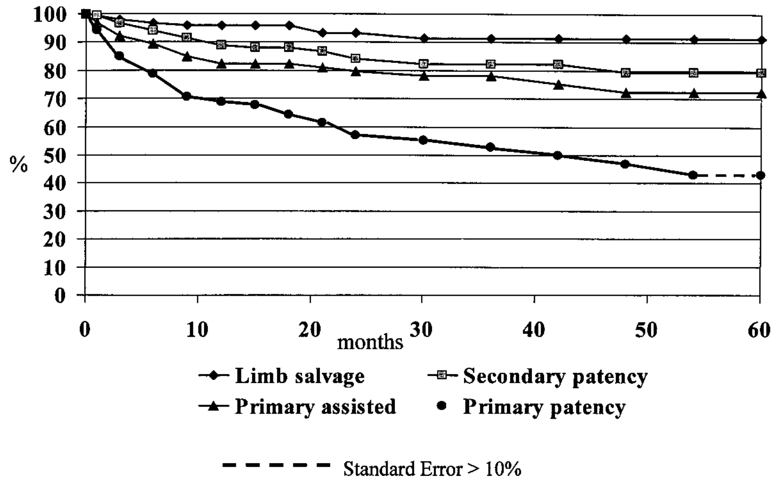

Fig 1. Cumulative limb salvage and graft patency rates of 155 consecutive bypass grafts performed for chronic lower extremity ischemia.

Table III. Stratification of risk of graft thrombosis by surveillance data

*Category**	*High velocity criteria*		*Low velocity criteria*		*Δ ABI*
I (highest risk)	PSV > 300 cm/s or Vr > 3.5	and	GFV < 45 cm/s	or	> 0.15
II (high risk)	PSV > 300 cm/s or Vr > 3.5	and	GFV > 45 cm/s	and	< 0.15
III (intermediate risk)	180 < PSV > 300 cm/s or Vr > 2.0	and	GFV > 45 cm/s	and	< 0.15
IV (low risk)	PSV < 180 cm/s and Vr < 2.0	and	GFV > 45 cm/s	and	< 0.15

PSV, Duplex-derived peak systolic velocity at site of flow disturbance; *GFV,* graft flow velocity (global or distal); *Vr,* velocity ratio of stenosis to more proximal graft segment of same caliber; *ABI,* Doppler-derived ankle-brachial index.
*Category I: patients are hospitalized and anticoagulated; lesions are repaired promptly. Category II: lesions are repaired electively (within 2 weeks). Category III: lesions are closely observed with serial duplex examination and are repaired only if they progress. Category IV: lesions are at low risk (we have observed few failures in this group).

der presented with late graft thrombosis and underwent catheter-directed thrombolysis before surgical revision. Patients in whom hemodynamically significant lesions could not be identified were treated with chronic anticoagulation (these expenses were not included in the cost analysis). Multiple revisions were required in seven (47%) of the 15 grafts. Subsequent thrombosis occurred in eight (53%) of the grafts (mean time from revision to thrombosis, 2.5 months). Five limbs (33%) required major amputation.

Statistics. Calculation of primary, primary assisted, and secondary graft patency and limb salvage rates was carried out by means of life table analysis according to the revised recommended standards of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery.[8] All cost data are presented as means ± SDs, and statistical significance was determined by application of an unpaired Student *t* test. Comparability of major risk factors among patient cohorts was performed by means of χ^2 analysis. All data are reported with regard to a level of significance of a *P* value less than .05.

Cost analysis. The simplest form of economic evaluation considers only the costs associated with a program and is therefore an incomplete form of economic appraisal. In consideration of costs, it should be remembered that the objective in valuing costs is to obtain an estimate of the worth of the resources depleted by the program. For this evaluation, hospital cost was calculated from the standpoint of the health care provider through use of a standard unit-cost system for each procedure charge unit. This system is fully loaded (ie, the system includes both direct and indirect costs) and is updated annually by the Finance Department of the University Medical Center of the Arizona Health Science Center. Hospital costs were adjusted according to the annual Consumer Price Index (CPI)* and are reported in terms of the value of the 1998 dollar. Physician expense data were derived from Medicare procedural reimbursement figures according to the Resource-

*As reported for the Western Region by the US Department of Labor, Bureau of Labor Statistics. The annual values used in the study were as follows: 1990, 78.4; 1991, 83.4; 1992, 85.2; 1993, 87.9; 1994, 90.8; 1995, 93.2; 1996, 95.3; 1997, 97.9.

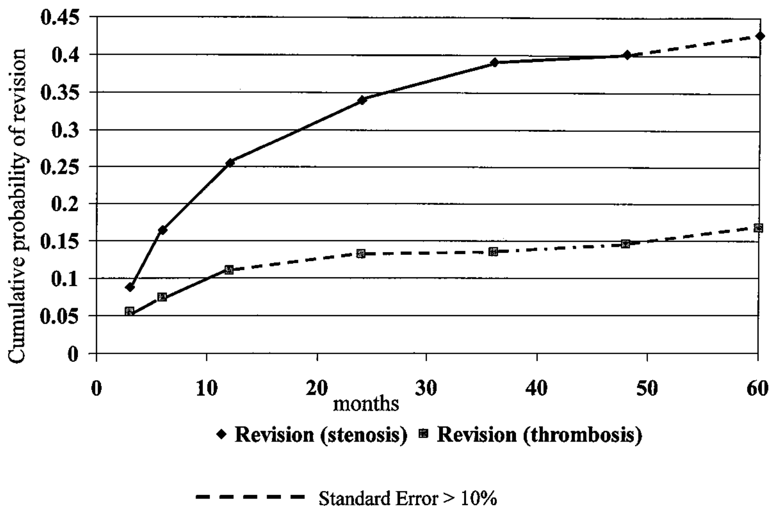

Fig 2. Cumulative probability for graft revision of duplex-identified graft stenoses (n = 46) and for graft revision after thrombosis (n = 15).

Table IV. Estimated cumulative cost of each graft enrolled in an intensive surveillance program

Interval (mo)	*Mean no. of follow-up evaluations*	*Cumulative probability of revision for stenosis*	*Mean no. of revisions per graft revised (stenosis)*	*Cumulative probability of revision for thrombosis*	*Mean no. of revisions per graft revised (thrombosis)*	*Cumulative probability of amputation*	*Mean cost per patient ($)*
3	1.4	.088	1.17	.055	1.2	.02	3,764
6	2.7	.164	1.19	.074	1.41	.034	4,896
12	3.7	.255	1.29	.11	1.40	.048	9,417
24	5.2	.340	1.35	.132	1.43	.068	12,861
36	6.5	.391	1.37	.135	1.43	.086	14,693
48	7.5	.402	1.43	.146	1.41	.086	15,259
60	8.3	.428	1.40	.168	1.41	.086	16,318

Table V. Cost effect of patient subgroups

	No. of patients	*Patency (%) 1 year after revision (± SE)*	*Limb salvage (%) 1 year after revision (± SE)*	*Mean cost per patient 1 year after implantation ($)*
Grafts without stenosis or thrombosis	94	92.8 (patency after implantation)	96.9	1,202
Grafts requiring revision for stenosis	46	93.1	97.8	17,688
Grafts requiring revision for thrombosis	15	56.8	66.0	45,252

Based Relative Value Scale for the 1997-1998 fiscal year. Allowance for differential timing of costs was performed through use of an annualized future discount rate of 5% per year.

The mean cost of each surveillance visit was based on fixed and overhead vascular laboratory operating expenses for the 1997-1998 fiscal year and yielded an estimated cost of $112 per examination (see Appendix 1). This is in close agreement with previous vascular laboratory cost analysis data[9] and the 1998 Medicare reimbursement (CPT [Current Procedural Terminology] code 93926, charge $172, reimbursement $120.25).

A comprehensive review of all limb-salvage related procedures performed at our institution generated the following cost data:

For each patient, all graft-related surveillance studies, angiographic studies, interventions, and postdischarge rehabilitation costs were recorded for the following intervals after the bypass graft proce-

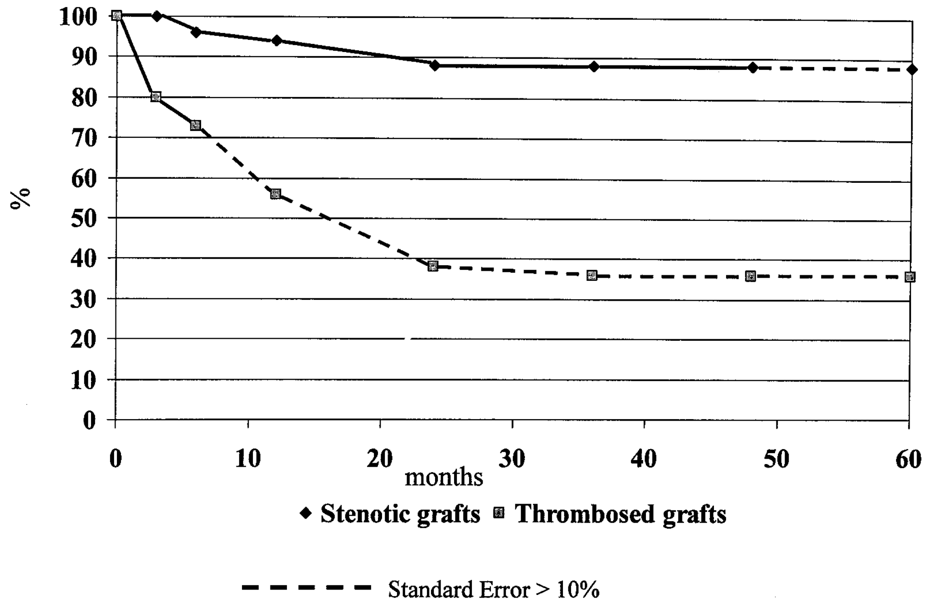

Fig 3. Cumulative patency for grafts revised after duplex identified stenoses (n = 46) and for grafts revised after thrombosis (n = 15).

Mean cost of primary bypass procedure (including preoperative angiogram):		$19,331 ± 5,300 (range, $11,321-$32,169)
Mean cost of a surveillance follow-up visit (including a duplex scan):		$112 (see Appendix 1)
Mean cost for elective revision of a duplex-identified stenosis (including preoperative angiography, when performed):		
	Surgical revision:	$13,003 ± 5,935 (range, $8,625-$39,835)
	Percutaneous transluminal angioplasty:	$3,623 ± 445 (range, $2,955-$4,685)
	Weighted average cost:	**$11,779**
Mean cost for revision after thrombosis:		
	Thrombectomy / revision:	$18,519 ± 8,267 (range, $9,215-$36,090)
	Thrombolysis / revision:	$22,532 ± 4,750 (range, $14,032-$28,275)
	Weighted average cost:	**$21,997**
Mean cost for major amputation, prosthesis, and rehabilitation:		
	Inpatient:	$15,801
	Prosthesis (temporary and / or permanent):	$6,840
	Inpatient / outpatient rehabilitation:	$13,632
		$36,273 ± 9,336 (range: $25,318-$49,879)

dure: 0 to 3 months, 4 to 6 months, 7 to 12 months, 13 to 24 months, 25 to 36 months, 37 to 48 months, and 49 to 60 months. Thirty-six percent of the grafts required revision within 1 year of implantation (11% after thrombosis, 25% for duplex-identified stenosis). Later intervals were characterized by a significantly lower (6%) annual rate of revision (Fig 2). Analysis of these procedural cost data and the cumulative revision rate curves for stenosis and thrombosis allow one to predict the average cost of lower extremity graft surveillance and maintenance on an individual basis. Because the number of scans performed and the probability of revision vary as a function of time from bypass grafting, it is necessary to express cost as a function of time from bypass grafting. Table IV presents the predicted postimplantation cost for a patient enrolled in an intensive surveillance program over specific time intervals. These data consider all limb salvage–related costs and include noninvasive examination, all diagnostic procedures, all graft interventions, amputation (when required), and postdischarge rehabilitation (when necessary). Obviously, individual grafts that developed early flow abnormalities or required multiple attempts to reestablish flow after thrombosis were more costly than grafts without such abnormalities.

With these previously unanalyzed costs documented, an equitable cost analysis of primary ampu-

Table VI. Cost-benefit analysis of an intensive surveillance program versus revision for clinical indication

	*Intensive surveillance (n = 150)**	*Clinically indicated revision (n = 222)†‡*
No. of grafts revised (%)	58 (37)	34 (13)
Revision before thrombosis	46 (29)	9 (4)
Revision after thrombosis	12 (8)	25 (9)
Cumulative graft patency (%)		
1 y	91	84
5 y	82	67
Limb salvage (%)		
1 y	96	83
5 y	92	73
Estimated cost per graft ($)		
1 y	7,742	10,842
5 y	12,194	16,352

*Excluding early failures (< 30 days) from current series.
†Clinical patient data derived from Bergamini TM, et al. Ann Surg 1995;221:507-15.
‡It is assumed that 75% of all revisions are performed within 1 year of implantation and reminders are performed in following 4 years.
Cost estimation is based on 1998 cost data at the University of Arizona Health Science Center.
Estimated cost / patient = (% amputees)(cost amputation) + (% revision for stenosis)(cost revision for stenosis) + (% revision for thrombosis)(cost of revision for thrombosis) + cost of duplex examination (3 scans in first year, 9 scans in 5 years) [surveillance group only].

tation and limb salvage is now possible. The costs of the primary limb salvage procedure ($19,331) and 5 years of graft maintenance ($16,318) yield a combined 5-year limb salvage cost of $35,649. This figure is more similar to the cost of amputation ($36,273) than previously predicted, and a pure cost analysis of primary amputation versus limb salvage demonstrates equivalency.

Cost-effect analysis. Next, we must address whether the surveillance program positively impacted limb salvage to a sufficient degree to justify the additional expenses as an efficient utilization of our medical resources. This prompts the need for a cost-effect analysis. In this form of economic evaluation, the consequences of the program cost are measured in appropriate units. In the case of a duplex surveillance program, the direct benefits of the program are defined as a quantitative measure of limb salvage. Although surgical results vary somewhat, most would agree that graft surveillance has improved the 5-year limb salvage rate by approximately 15%. That is, a surveillance program applied to 100 limbs would save approximately 15 limbs over 5 years and generate a cost of $1,631,800. Thus, the cost per limb saved by the surveillance program is calculated to be $108,786. Although at first glance this expense appears to be prohibitive, one must also recognize the potential indirect benefits of such a program. Specifically, with the identification and treatment of grafts at risk for thrombosis, costly thrombolysis procedures and amputations may be avoided and significant cost savings may thus be realized.

The need to consider these costs can more clearly be demonstrated if we examine the cost effect within subgroups of our patient cohort. Independent cumulative patency rates were calculated from the time of revision to predict the utility of graft revision for a duplex-identified stenosis versus the utility of revision after thrombosis (Fig 3). The grafts revised for duplex-identified stenoses fared far better than the grafts revised after thrombosis (for graft patency at 12 months after revision, 93.1% vs 56.8%). Moreover, 33% of limbs revised after thrombosis eventually required amputation. In contrast, only 2% of limbs revised after duplex-identified stenoses required amputation. Graft revision for a duplex-identified stenosis appears to confer a clear improvement in the limb salvage and graft patency rates. In fact, the long-term patency of grafts revised for stenosis does not differ from the patency of grafts never requiring revision. This stands in stark contrast to the results for revision of occluded grafts. Further analysis (Table V) demonstrates that the mean cost of caring for patients in whom graft thrombosis has occurred is significantly higher than the cost of caring for patients undergoing elective graft revision (for 1 year, $45,252 vs $17,688; $P < .01$). Obviously, the additional costs generated in caring for patients with thrombosed grafts resulted from a higher incidence of multiple revisions and amputation and reflected the increased cost associated with thrombolytic procedures.

Cost-benefit analysis. Although the preceding analysis demonstrates superior patency and reduced expense for grafts revised for duplex-identified stenoses versus those revised after graft thrombosis, it remains less clear whether the surveillance program prevents graft failure to a sufficient degree to justify the expense incurred with multiple elective revisions. This is a much broader question that can be answered only through a cost-benefit analysis. In this form of economic evaluation, attempts are made to value the consequences of a given program in monetary terms in such a way that one can compare its benefit with that of another program.

Ideally, a prospective randomized trial could be constructed to compare the cost benefit for patients undergoing intensive surveillance versus patients undergoing revision solely for clinical indicators of graft failure (recurrent claudication, fall in ABI, loss of a previously palpable pulse). The literature reports two such series, only one of which was randomized.[3,4] Both of these studies demonstrate a clear benefit in terms of graft patency and limb salvage, but neither addresses the potentially increased cost associated with the surveillance program.

Recognizing the distinct benefits provided by a surveillance program with respect to both graft patency and limb salvage, we believe that it would be unethical to deny surveillance to a subset of patients solely for the purpose of determining the cost-benefit ratio. Therefore, for the performance of cost-benefit analysis of our graft surveillance program, it is necessary to compare our results with those for a historical group that had not undergone intensive lower extremity duplex surveillance. For the purposes of this analysis, we chose to use the patient cohort reported by Bergamini et al[3] in 1995. The patients in this cohort, which is a contemporary series, had preoperative demographics remarkably similar to ours and were cared for in a similar university hospital environment (see Appendix 2). Significant differences between the two groups include a lower incidence of claudication, a preferred in situ bypass technique, and a higher incidence of smoking and diabetes mellitus in Bergamini's group. Early failures (< 30 days) were excluded from this analysis. Surgical revisions were performed only when clinically indicated (recurrent symptoms, fall in ABI, reduction in graft velocity, thrombosis).

Table VI compares the results from our series with those of Bergamini et al.[3] Theoretically, over 5 years an intensive surveillance program would have required revision of duplex-identified stenoses in 29% of grafts, whereas the group undergoing revision for clinical indication required elective revision in only 4% of grafts. The additional cost of these procedures was offset by the improved limb salvage rate (for 5 years, 92% vs 73%) and the avoidance of costly amputation. The reduced cost and favorable outcome in the intensive surveillance group support its continued application.

DISCUSSION

Two features are inherent to any economic evaluation. First, such analysis involves consideration of the costs and consequences of the intervention. From the standpoint of the consumer, few people would pay for a package—no matter how inexpensive it might appear—without knowing its contents. Likewise, few of us would accept a package—no matter how desirable the contents—without knowing the specific price. It is the association between cost and consequences that allows us to reach our decision. Second, an economic analysis concerns itself with choices. As the available medical resources become fixed, our inability to provide all desired outputs necessitates that choices be made on the basis of program effectiveness. Economic analysis establishes one basis on which the program may be evaluated. As such, economic analysis is founded on a comparative analysis of alternative courses of action in terms of both the costs and the consequences.

Significant effort has been expended to better characterize the incidence and time course of vein graft stenoses. It is now clear that graft stenoses develop soon after graft implantation, and the significance of this has been well described.[6] Depending on the criteria, thrombosis subsequently occurs in 23% to 65% of grafts in which stenoses are detected but not repaired.[10-15] Moreover, there is convincing evidence that vein grafts that have thrombosed before a surgical revision have significantly reduced cumulative patency and are associated with an increased amputation rate.[16-22] The reasons for this are multifactorial, but they almost certainly relate to endothelial damage resulting from graft thrombosis.

Because of the relatively high frequency with which infrainguinal vein grafts develop stenoses, the high probability of graft failure in these stenotic grafts, and the generally poor patency of graft revision when it is preceded by graft occlusion, it is not surprising that surgeons have adopted protocols of graft surveillance and elective graft revision. Since Bandyk et al[5] documented the potential applicability of such programs, duplex surveillance has been widely adopted and graft patency and limb salvage rates have improved by approximately 10% to 15%.[11,14]

However, the growing population of elderly individuals and the fact that health care resources are limited place a growing economic burden on the health care industry and may force health care systems to base future decisions on economics as well as on efficacy. Analyses that demonstrate clinical efficacy without consideration of associated costs can no longer be accepted.

As the current study indicates, the expenses associated with graft surveillance are not negligible, and claims that surgical revascularization is more cost effective than primary amputation must be revisited. This study suggests that the mean cost of maintenance for 5 years approaches the cost of the primary operation. Although the long-term cost of amputation remains less clear, our study suggests that from the standpoint of a pure cost analysis, primary amputation and limb salvage approach equivalency. Although it is beyond the scope of this report, the efficacy of each of the two procedures can be measured only through use of a cost-utility analysis, the first requirement of which is a careful assessment of the preprocedural and postprocedural quality of life. Our program has begun to gather such data, and we look forward to presenting them when they become available.

In the current study, 84% of patients undergoing elective revision underwent preoperative contrast angiography to confirm the significance of their duplex-identified lesions and exclude more distal graft lesions. Certainly, this contributes significantly to the cost of the maintenance program. In an effort to minimize these costs, we no longer perform routine preoperative angiography. We are satisfied that duplex scanning is of sufficient specificity to characterize a hemodynamically significant lesion warranting repair. We presently rule out a more distal graft lesion at the time of surgical repair using either intraoperative completion angiography or duplex scanning.

Despite one's best intentions to prevent graft thrombosis, a small percentage of patients will present with grafts that have failed. As this study indicates, considerable resources are used in this patient subgroup with suboptimal long-term outcome. In this group, the merits of thrombolysis / revision can be attributed only to technical ease. These procedures are costly and result in high rates of failure (40%-60% at 1 year) and subsequent amputation. Indeed, the repeated application of graft thrombolysis or thrombectomy and revision remains dubious. Redo bypass is likewise a costly endeavor and has the added difficulty of being very labor intensive for the surgeon, who must frequently splice together alternative conduits. The benefits of these procedures, however, are an improved patency (80% at 1 year) and durable limb salvage. Finally, the surgeon must consider the consequences of continued observation (low cost and low morbidity, but increased risk of limb loss and impaired quality of life) or a definitive major amputation (significant cost, impaired quality of life). Accordingly, this group of patients deserves careful consideration, and decisions must be individualized with regard to both the surgeon's experience and patient preference.

The real question of whether an intensive surveillance program is more cost-effective than a program in which revisions are performed for clinical indications is a difficult one. To the best of our ability, we have attempted to perform an unbiased economic appraisal of the maintenance of infrainguinal bypass grafts. This analysis not only demonstrated benefit in terms of patient outcome, measured as graft patency and limb salvage; the patients undergoing intensive surveillance also generated fewer expenses.

CONCLUSION

Novel technologies that provide incremental patient benefit must be viewed with regard to their financial consequences. Failure of health care providers to do so is irresponsible in today's era of limited resources. In a world of fixed resources, the real cost of a procedure relates not only to the resources consumed but also to the inability to provide services for other, more cost-effective programs.

In assessing the quality of this study, one should ask: How does this evaluation compare with our usual basis for decision making? Like other authors, we have demonstrated superior graft patency and limb salvage through the application of an aggressive graft surveillance program. However, it was necessary to offer labor-intensive surveillance screening to all patients and perform elective surgical revision in nearly 30% of all grafts to obtain these satisfactory rates of success. These activities generated significant postimplantation expenses that were previously unrecognized, and claims that limb salvage procedures are cost-effective in comparison with amputation cannot be supported based solely on the present cost analysis.

In comparison with a program in which revisions are performed for clinical indications alone, an intensive surveillance program appears to be effective in both reducing cost and improving graft patency / limb salvage. Despite our best efforts, however, a small percentage of patients will present with graft failure. This group represents a significant challenge to the vascular surgeon. On the basis of these data, we are reluctant to recommend thrombolysis and surgical revision. Rather, we have increased our willingness to observe these patients for recurrent signs of ischemia. After graft thrombosis, we reserve redo bypasses for otherwise functional patients in whom limb-threatening ischemia recurs.

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APPENDIX 1. ESTIMATED COST OF DUPLEX SURVEILLANCE EXAMINATION

This estimate is based on an 8-month analysis (January-August 1998) of actual surveillance studies performed at University Medical Center, Tucson, Ariz.

The following table presents information on the numbers of studies:

Month/year	*No. of graft surveillance studies/mo*	*Total no. of noninvasive studies/mo*
1/98	20	232
2/98	19	247
3/98	14	222
4/98	14	215
5/98	14	213
6/98	13	200
7/98	11	166
8/98	10	171
Totals	115	1666

Estimated number of surveillance studies per year (based on 115 studies/8 mo): 175.

Estimated percent of laboratory time dedicated to surveillance: 7.

The following table presents information on estimated annual laboratory operating expenses (all figures are in US dollars):

Equipment		
	2 Advanced Technology Laboratories (Bothell, Wash)	80,000
	Maintenance	20,000
Personnel		
	Registered vascular technologist/registered nurse/clerical	102,000
	Benefits	28,000
Facility/administrative fees		50,000
Total annual laboratory expenses		280,000

Estimated annual expense of graft surveillance program: $19,600.
Estimated cost per study (based on projected 1998 data): $112.
Medicare reimbursement / study (CPT code 93926) $120.25.

APPENDIX 2. COMPARISON OF PATIENTS UNDERGOING INTENSIVE SURVEILLANCE AND PATIENTS UNDERGOING REVISION FOR CLINICALLY INDICATED PROCEDURES ONLY

The Table at right presents information on the two patient groups.

	Intensive surveillance (n = 150)*	*Clinically indicated intervention† (n = 222)*
Patient demographics		
Age (y)	69.1 ± 9.8	65 ± 17
Female gender (%)	43	37
Tobacco (%)	43	59 ($P < .05$)
Diabetes (%)	39	53 ($P < .05$)
Hypertension (%)	65	60
Indication		
Critical ischemia (%)	79	92 ($P < .05$)
Graft origin		
Femoral artery (%)	56	77 ($P < .05$)
Superficial femoral artery (%)	24	6
Profunda femoris artery (%)	8	1
Popliteal artery (%)	11	13
Graft insertion		
Popliteal artery (%)	43	17 ($P < .05$)
Tibial / pedal artery (%)	56	83
Conduit		
In situ (%)	19	76 ($P < .05$)
Reversed (%)	70	23
Other (%)	10.5	—

*Present data set, excluding early (<30 days) failures.
†Historical control group (Bergamini TM, et al. Ann Surg 1995, 221:507-15).

DISCUSSION

Dr P. Michael McCart (Santa Ana, Calif). Dr Wixon and his colleagues analyzed the economic implications of duplex ultrasound in the surveillance of infrainguinal vein grafts. In their retrospective study, the mean 5-year cost of graft maintenance approached that of the initial bypass. Taken together, the limb salvage cost was equal to the cost of primary amputation. Failed or thrombosed grafts demonstrated very poor results with multiple revisions and an amputation rate of 33%.

I agree with the cost-effect analysis but was impressed with the $108,786 cost per limb saved. The data clearly highlight the significant costs of thrombolysis and amputation. Because of this analysis, the authors did not recommend routine thrombolysis and surgical revision in the failed graft.

I have some misgivings with the authors' cost-benefit analysis in that this study group was compared with a 1995 study at another institution. While the more aggressive approach of the authors appeared favorable, there are probably too many variables to clearly validate their conclusion. A more appropriate randomized trial was not done for ethical reasons.

Despite the significant costs and retrospective nature of the study, the data clearly show beneficial results. I have three questions for the authors: (1) As most graft revisions occurred in the first year, were completion angiography and duplex scanning done at the original operation to identify and allow repair of existing graft defects? (2) Have you been able to identify a subset of patients with whom you feel comfortable in reducing the number of postoperative duplex examinations, both in the first year and long term? (3) Have you considered anticoagulation with small diameter grafts, low-flow states, or poor distal runoff?

In summary, I enjoyed this paper and feel the authors' conclusions are appropriate. I also agree with the need to proceed with functional outcome analysis to better define when alternative approaches to bypass should be considered. I look forward to the Arizona group's further work in this area.

Dr Christopher Wixon. Thank you, Dr McCart. With regard to the first question regarding completion angiography and intraoperative duplex scanning, completion angiography is routinely performed at the conclusion of all of our bypass procedures. In addition, if there is either clinical suspicion or suspicion on the completion angiogram that there is a hemodynamically significant lesion or whether the vein was of questionable quality, then we selectively use intraoperative duplex scanning.

The second question regards a subset of patients in whom less frequent surveillance perhaps is warranted, and I think that is probably true. Patients in whom no significant flow abnormalities have been identified within the first year were very unlikely to develop a hemodynamically significant stenosis in the future. Nonetheless, because the majority of cost of a graft maintenance program is not necessarily associated with the duplex examination but more with the surgical revisions and the revisions of the thrombosed grafts, we continue to survey these grafts at 6-month intervals.

In terms of chronic anticoagulation for perhaps poor conduits, yes, that is a consideration, and it is left to the surgeon's discretion. Obviously if a graft had thrombosed and it was lysed and a hemodynamically significant stenosis could not be uncovered, all of those patients were treated with chronic anticoagulation. The cost of chronic anticoagulation was not included in this study. I guess the answer to your question is yes, it is done on a selective basis.

Dr Wesley Moore (Los Angeles, Calif). I enjoyed this paper very much, and I think the cost analysis has been extremely well carried out.

With regard to your showing the equivalence of cost between limb salvage and amputation, given that information, I doubt that there would be very many patients that would opt for amputation as opposed to salvage; rather, they would use the fact that since it cost no more for salvage, I would rather keep my leg, thank you.

My main reason for standing, however, is to just make one comment with regard to that segment of your population in which you have done femoral popliteal, not the infrapopliteal reconstructions, and to put in a plug for prosthetic reconstruction as an alternative to vein grafting.

One of the several advantages of PTFE is that you do not need to carry out surveillance, and therefore, there would be a cost savings. It is not that prosthetic grafts do not thrombose. They certainly do, but you cannot predict a prosthetic graft thrombosis on the basis of surveillance.

When they do thrombose, however, the option of carrying out lytic therapy and returning them to a prethrombotic functional status is a lot better than it is for vein grafts. I believe that you should reconsider the option of prosthetic reconstruction when you have the popliteal artery as a potential outflow site. Thank you.

Dr Wixon. Thank you, Dr Moore. I guess philosophically, our groups differ a little bit. I do agree that the surveillance of femoropopliteal prosthetic grafts is probably not warranted and there is no benefit in doing so. However, the small cost savings in avoiding several surveillance examinations is really small compared with the additional costs of multiple thrombolytic procedures.

Thrombolysis in this series was really quite an expensive endeavor. It required a lot of time in the intensive care unit, expensive drugs, and one-on-one nursing care. I have recently reviewed the complications associated with catheter-based thrombolysis, and that procedure probably carries a mortality of 1% to 2% and a major bleeding complication of up to 20%.

So I do agree that if a prosthetic graft does thrombose and the limb is threatened, then it is probably worthwhile trying to resurrect it. However, I respectfully disagree with the primary operation for patients with above-the-knee popliteal segments.

Dr Ronald Dalman (Palo Alto, Calif). I very much enjoyed your presentation. Economic cost analysis is an important addition to our growing database regarding the appropriate use of graft surveillance procedures.

Getting back to the similar point that Dr Moore brought up, if I understood that correctly, you are comparing up-front costs of amputation with the 5-year cost of limb salvage and subsequent maintenance procedures. In our experience, up-front costs of amputation are just a fraction of the total cost incurred in the first 5 years after the procedure. Many patients (especially over the age of 70) require extensive rehabilitation, revised living arrangements, prosthesis refittings and revisions. If they are ultimately unable to use a prosthesis with any regularity, additional modifications to their home and transportation infrastructure may be necessary.

This comparison is especially problematic today, because underestimating the complete costs associated with amputation may encourage third-party payers, HMO units, etc, to devalue the relative benefit / cost ratio associated with graft surveillance and improved assisted primary patency after limb salvage procedures.

A more accurate comparison would include a cohort of amputees and calculate the total costs associated with their care over a 5-year period. That distinction should be addressed in both the presentation and the manuscript to avoid confusion regarding the real "value" of graft surveillance. Thank you.

Dr Mark Nehler (Denver, Colo). Did you make a mixture? How did you come about the decision on what was going to be the cost for amputation, and how many were AKA or BKA?

Dr Wixon. The only patients who were included in the amputation category were patients who were felt to be satisfactory candidates to continue to ambulate. So if the patient was going to be bed bound, the patient was excluded.

I did include both above-knee and below-knee amputations, but do not have the data as to what percentage each one represented. The cost data for amputation did reflect the cost of a temporary prosthesis, a permanent prosthesis, and up to 30 days of rehabilitation. The additional costs of future amputation revisions and social requirements are difficult costs to obtain and, therefore, not included.

Dr Robert Rutherford (Silverthorne, Colo). I notice that 19% of your cases had claudication, and there were additional cases with aneurysms. In calculating your limb salvage rate, did you include the cases that had claudication and project that into your cost analysis?

In other words, in terms of limb salvage, you were not including the claudicants, were you?

Dr Wixon. That is correct.

Dr Ralph DePalma (Reno, Nev). Well, I enjoyed the paper; it brings to mind something that we did almost 20 years ago. I took all the index operations, aorta, fem-pop, and carotid from the Cleveland Vascular Registry to Dr Herbert Mosteller, who was then head of the AAAS and a mathematician at Harvard concerned with health care matters. We looked at cost-benefit ratios for our work because I was sure that doing vascular surgery in general was cost-effective and a very good thing to do. After 6 months Dr Mosteller, a very honest man, came back and he was very upset, very sad. He said to me, "Ralph, the better you guys get, the more it costs."

My question derives around whether cost-benefit ratios, and I have looked into them quite a bit, are something at all applicable to human beings but rather government estimates for bridges and highways. There is a discount rate in the cost ratio. More important, an age factor occurs in the denominator so that the shorter the durability of the procedure or the life of the patient, the more costly or ineffective it appears. I wonder where we are going to go with this. The better we get, the more it costs. It clearly is cheaper not to treat at all—from a "cost-benefit" point of view for a vascular disease population.

I would like to ask you to take a look at the cost-benefit ratio and look at the classic way in which it is applied to government projects such as bridges and highways. See if you can factor in, perhaps a human factor into the denominator or amplify the numerator appropriately.

Dr Wixon. I think you are right. Cost benefit, by looking only at the limb salvage or graft patency rate, is grossly inadequate. What we need to be doing is cost utility analysis, which accounts for the patient's quality of life. I think there are patients in whom bypasses are performed who do not benefit from them. They keep their leg, but their quality of life is not improved.

We have recently begun to measure quality of life on all patients with lower extremity ischemia: patients undergoing primary amputations, patients treated conservatively for claudication, and patients in whom bypasses have been constructed. We look forward to presenting those data in the future.

Dr DePalma. Well, I beg you not to put a price on it.

Dr Peter Lawrence (Irvine, Calif). This morning we have heard several different approaches to graft surveillance, with respect to frequency and criteria for repair. I wonder if you have done a closer analysis of your data to provide cost / benefit data.

Have you looked at breaking it down into the standard approaches that different institutions use to determine whether there's an optimal method of graft surveillance?

Dr Wixon. I think that is a good point. I think the frequency or interval with which we perform surveillance is less important. During the first year, I believe most institutions perform some variant of every 3-month surveillance and then go to every 6 months after that. I think that is correct as the highest incidence of graft stenosis occurs within the first year of bypass.

I think the real difference that we need to examine is the criteria by which institutions determine a graft to be a risk. We have tried to increase the specificity of our criteria by using higher velocity ratios (3.5) and peak systolic velocities (300 cm / s). I think the Oregon group reported that peak systolic velocities of 200 cm / s were used to identify grafts at risk.

For these intermediate lesions (200 cm / s < PSV < 300 cm / s), we continue to survey them with increased intensity (every 3 months). We do not subject those patients to costly arteriograms or surgical revision. We have not observed failure in any grafts with intermediate criteria.