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Abbreviations:
NHB = net health benefit
PTA = percutaneous transluminal angioplasty
QALY = quality-adjusted life-year

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Cost and Patency Rate Targets for the Development of Endovascular Devices to Treat Femoropopliteal Arterial Disease[1]

PURPOSE: To determine the criteria that would make use of an endovascular device cost-effective compared with bypass surgery and percutaneous transluminal angioplasty in the treatment of femoropopliteal arterial disease.

MATERIALS AND METHODS: A decision model was developed to compare treatment with the use of a hypothetical endovascular device with established therapies. Cost-effectiveness from the perspective of the health care system was considered. Outcome measures were lifetime costs and quality-adjusted life-years. With the use of net health benefit calculations and threshold analysis, combinations of costs and patency rates were determined that would make the device cost-effective compared with established therapies. In subgroup and sensitivity analyses, the effect on decision-making of sex, age, indication, lesion type, procedural risk, and society's willingness to pay for incremental gain in health were explored.

RESULTS: Use of a device that costs $3,000 would be cost-effective compared with bypass surgery for critical ischemia if the 5-year patency rate is 29%–46%. Use of the same device would be cost-effective compared with angioplasty for disabling claudication and stenosis if the 5-year patency rate is 69%–86%.

CONCLUSION: The target combinations of costs and patency rates found in this study are probably attainable, and further development of such endovascular devices seems warranted.

Although bypass surgery and percutaneous transluminal angioplasty (PTA) are commonly used revascularization procedures in the treatment of femoropopliteal arterial occlusive disease, both procedures have disadvantages (1). Percutaneous transluminal balloon angioplasty is a low-risk and low-cost procedure, but it is associated with a fairly high restenosis rate (2–5). Primary stent placement does not improve the patency rate of PTA performed for femoropopliteal arterial disease and is thus currently used only to salvage a failed balloon angioplasty procedure (6,7). Bypass surgery, on the other hand, has higher long-term patency rates but is also associated with a higher procedural risk, higher cost, and longer convalescence period (4,5). In general, PTA is performed as primary treatment of short focal lesions of the femoropopliteal artery, whereas bypass surgery is the primary treatment in diffuse disease.

Endovascular devices are currently being developed as alternative interventions to overcome the problems of established procedures. Important considerations in choosing the optimal treatment strategy are the effectiveness of the device, the risks of the procedures, and the costs. These parameters are generally unknown during the development of a new technology. In particular, the patency and cost estimates associated with endovascular devices are uncertain and may even change with time. It is difficult, if not impossible, to predict what the precise values for the parameters of a new technology will be. Given

TABLE 1
Data on Currently Used Femoropopliteal Revascularization Procedures

Parameter	Bypass Surgery	Angioplasty
Procedural mortality (%)		
Claudication	0.8	0.2
Critical ischemia	4.7	3.2
Procedural nonfatal systemic morbidity (%)	8.5	1.3
Time lost due to convalescence (d)	7	2
Procedural cost*		
Claudication	20,531	10,168
Critical ischemia	25,881	18,171
Primary patency, 1-y/5-y (%)		
Claudication and stenosis	91/80	79/68
Claudication and occlusion	91/80	53/35
Critical ischemia and stenosis	84/66	62/47
Critical ischemia and occlusion	84/66	28/12

* In 1999 U.S. dollars. Costs are from the perspective of the health care system and include materials used, personnel, equipment, administration, overhead, professional fees, and room and board. The cost of surgical revision of a bypass was assumed to be in the same order of magnitude as that of primary bypass surgery.

the outcome and cost of established procedures, however, we can calculate under what conditions a new technology can become cost-effective compared with the established procedures, thereby setting standards for the new device. The merit of such an approach is that it can potentially focus the development of new technology (8,9). This applies not only to femoropopliteal interventions but also to many other procedures such as the use of an abdominal aortic endoprosthesis and placement of a carotid stent.

The purpose of this study was to determine the criteria that would make the use of an endovascular device for the treatment of femoropopliteal arterial disease cost-effective compared with PTA and bypass surgery. A secondary objective was to illustrate how decision and cost-effectiveness analysis can be used to focus the development of new technologies.

MATERIALS AND METHODS

Overview Decision Model

Previously, a decision analytic model was developed to examine the choice between bypass surgery and PTA for femoropopliteal arterial occlusive disease (10). The model was used to consider different types of patients (age, sex, other risk factors), varying severity of disease (disabling claudication, rest pain, tissue loss), and different types of lesions (stenosis, occlusion) and to combine literature data on risks, benefits, and costs. The main outcome measures were quality-adjusted life expectancy and lifetime cost for each strategy, depending on patient characteristics, clinical indication, and lesion type.

In the current study, another treatment option was added to the model, namely, treatment with a hypothetical endovascular device. We compared three treatment strategies. Each strategy allowed at most two treatments. Initial revascularization was accomplished with balloon angioplasty, with autologous saphenous vein bypass surgery, or use of the hypothetical endovascular device. Secondary treatment for primary failure was undertaken with bypass surgery if the initial treatment was angioplasty or use of the endovascular device or with surgical revision if the initial treatment was bypass surgery.

Because the procedural risk, cost, and patency curves of the endovascular device are unknown, the following assumptions were made. The patency curve of the endovascular device was assumed to relate, through a proportional hazards model, to that of PTA, which implies that the curves of the endovascular device and of PTA were similar in shape but different in height. The 5-year patency rate was used as a measure for the height of the patency curve. The risk and complications of an endovascular device and the procedural cost, excluding the cost of the device itself, will ideally be approximately the same as those of PTA or lower.

However, since the procedural risk of a hypothetical device is unknown, we assumed that the morbidity, mortality, and convalescence period associated with an endovascular device would be 1.5 times higher than that of PTA. The procedural cost of the device (excluding that of the device itself) was assumed to be approximately the same as that of PTA.

Threshold analysis was performed to determine criteria (ie, combinations of 5-year patency rates and costs) that would make the device equivalent in terms of cost-effectiveness compared with bypass surgery and PTA. The model was developed from the perspective of the health care system. All costs were adjusted to 1999 U.S. dollars with the use of the medical care–specific consumer price index.

Data and Data Sources

Estimates of procedural mortality, morbidity, amputation rate, quality-of-life adjustments, costs, and patency rates following femoropopliteal PTA and bypass surgery were based on findings from a published meta-analysis and decision analysis (4,10). The meta-analysis involved a combination of literature data published between 1985 and 1993 and pooled patency results following bypass surgery and PTA for the treatment of femoropopliteal arterial disease, with the use of a method based on the proportional hazards model and the actuarial life-table approach (4). The decision analysis involved a combination of literature data published in 1995 and earlier and an examination of the choice between bypass surgery and PTA for femoropopliteal arterial disease (10).

Table 1 presents the data on bypass surgery and PTA incorporated in the model. The costs for angioplasty and bypass procedures, physician services, noninvasive testing during outpatient follow-up, amputation plus rehabilitation, and annual costs of treatment after an amputation or with major morbidity were based on published and unpublished data on charges from the Brigham and Women's Hospital Vascular Service (10,11). All data on charges were adjusted with the use of cost-to-charge ratios specified by the cost center and the fiscal year.

Quality-of-life adjustments were based on the experience of two vascular surgeons, two interventional radiologists (including M.G.M.H.), and an internist who estimated the various health states related to peripheral arterial disease with the use of an abbreviated form of the Health Utilities Index. This index is used to rate physical function, role function, social and emotional well-being, and general health (10).

The amputation rate following revascularization was assumed to depend on the initial symptomatic status. Each year, on average, 1.2% of patients with claudication, 2.3% of patients with rest pain, and 6.4% of patients with tissue loss underwent amputation (12,13). Of these pa-

tients, an estimated 11.5% did not survive the amputation, and another 38% experienced major morbidity (14–16). The convalescence period following amputation was approximately 82 days (16).

The total cost of amputation, including cost of rehabilitation, was estimated to be $34,384 (17,18). Follow-up of patients after revascularization cost, on average, $543 in the 1st year, $182 annually thereafter if the artery or bypass remained patent, and $543 annually if failure occurred (10). The annual cost of long-term care and treatment in patients who underwent amputation of a lower limb was estimated to be $48,877 per year (17,19–21). The cost of care and treatment of patients with major morbidity following revascularization or amputation was estimated to be $11,947 (22).

The relative risk of overall mortality of patients with peripheral arterial disease was estimated to be 3.1 compared with that of the general population matched for age and sex (12,23). In view of the recommendations of the Panel on Cost-effectiveness in Health and Medicine (24), both costs and benefits were discounted at a rate of 3%.

TABLE 2
Health Effects, Costs, and NHB of Currently Available Therapies for Femoropopliteal Arterial Disease

Indication and Lesion	Initial Treatment	QALE (QALY)	Cost ($)	NHB (QALY equivalents)
Claudication				
Stenosis	PTA	5.85	22,758	4.71
Stenosis	Bypass	5.46	33,229	3.80
Occlusion	PTA	5.59	32,131	3.99
Occlusion	Bypass	5.46	33,229	3.80
Rest pain				
Stenosis	PTA	5.26	42,372	3.14
Stenosis	Bypass	5.00	44,694	2.76
Occlusion	PTA	4.83	55,074	2.08
Occlusion	Bypass	5.00	44,694	2.76
Tissue loss				
Stenosis	PTA	5.20	48,589	2.77
Stenosis	Bypass	4.92	53,346	2.25
Occlusion	PTA	4.74	65,578	1.46
Occlusion	Bypass	4.92	53,346	2.25

Note.—QALE = quality-adjusted life expectancy. All costs are from the perspective of the health care system and include hospital and physician costs for the initial and secondary procedures, treatment of complications, follow-up, long-term care, and amputation and rehabilitation.

Determination of Criteria and Threshold Analysis

A strategy was considered cost-effective compared with another if the gain in quality-adjusted life-years (QALYs) justified the additional monetary costs. The trade-off between QALYs and additional monetary cost was considered justified if it did not exceed society's maximum willingness to pay for an incremental gain of 1 QALY.

To facilitate the calculation of the threshold values for patency and cost, the net health benefit (NHB) approach was used to compare the use of the hypothetical endovascular device with currently used interventional strategies (25). The NHB is used to combine costs, QALYs, and an estimate of society's willingness to pay, λ, for an incremental gain of 1 QALY in one expression. For each strategy, we computed the NHB with the use of the equation NHB = QALYs − costs/λ (25). Two strategies were considered equivalent in terms of cost-effectiveness if they yielded the same NHB.

The NHB makes a trade-off between QALYs gained and monetary expense. In essence, the use of the NHB is the same as the use of incremental cost-effectiveness ratios, but technically, the use of NHB is more practical. The difference between the use of the NHB approach and the incremental cost-effectiveness ratio approach is that in the use of incremental cost-effectiveness ratios, society's willingness to pay can be considered after the results are obtained, whereas in the use of the NHB approach, an estimate of society's willingness to pay must be incorporated in the calculation. For a given estimate of society's willingness to pay, however, the conclusions with the use of either method will be the same. To estimate the effect of the chosen willingness-to-pay value, one can repeat the analysis for a range of values. Published estimates (25) for willingness to pay range from $20,000 to $100,000 per QALY gained, and we therefore considered this range in our calculations.

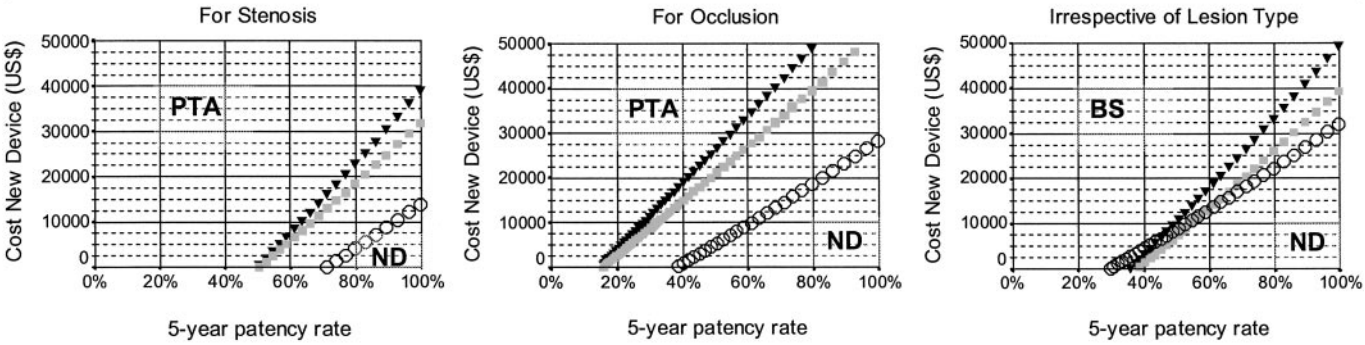
Baseline and Sensitivity Analysis

The baseline case used in the analysis was that of a 65-year-old man with femoropopliteal arterial disease without comorbidity or other risk factors. In our baseline analysis, we assumed society's willingness to pay to be $20,000 per QALY gained. In the subgroup analysis, we explored the effect of disease severity (disabling claudication, rest pain, tissue loss) and lesion type (stenosis, occlusion).

In a one-way sensitivity analysis, we explored the effect of varying age (55 and 75 years), sex, society's willingness to pay for the gain of 1 QALY ($50,000 and $100,000), and the discount rate (2% and 5%) on our results. Furthermore, we performed one-way sensitivity analyses to explore the effect of a lower and higher (one and two times that of PTA) procedural risk of the device, including morbidity, mortality, and time lost due to the intervention. We assumed that the morbidity, mortality, and time lost due to the intervention of the endovascular device would not exceed that of bypass surgery. Finally, we explored the effect of varying age, sex, society's willingness to pay, and procedural risk simultaneously in a four-way sensitivity analysis.

RESULTS

Whereas bypass surgery yielded the highest NHB (Table 2) in patients with chronic critical ischemia (rest pain or tissue loss) and a femoropopliteal occlusion, PTA yielded the highest NHB in stenotic femoropopliteal lesions irrespective of the clinical indication. The Figure presents the target values that would make the use of an endovascular device cost-effective compared with currently used procedures. For example, the Figure, part a, shows that an endovascular device that costs $2,500 and that is associated with a 5-year patency rate of 80% would be cost-effective compared with PTA for the treatment of a femoropopliteal stenosis, independent of the clinical indication. However, an endovascular device with the same long-term patency but with a cost of $7,500 would not be cost-effective compared with PTA for the treatment of a stenosis and claudication, whereas it would be cost-effective for the treatment of a stenosis and critical ischemia. The Figure, part b, shows that the lines are



Target values that would make an endovascular device cost-effective compared with **(a)** angioplasty for a stenosis, **(b)** angioplasty for occlusions, and **(c)** bypass surgery. The x axis represents hypothetical 5-year patency rates of the endovascular device; the y axis, hypothetical costs. Lines represent combinations of 5-year patency rates and costs that would make the endovascular device equivalent to the therapy to which it is being compared in terms of cost-effectiveness, depending on clinical indication: tissue loss (▼), rest pain (▨), and claudication (○). Area below the lines represents the target combinations of patency rates and costs that would make the device (*ND*) more cost-effective than the therapy to which it is being compared. Area above the lines represents combinations that would make either bypass surgery (*BS*) or angioplasty (*PTA*) more cost-effective.

TABLE 3
Primary Patency Rates Required to Make an Endovascular Device Equivalent to Currently Available Treatments in Terms of Cost-Effectiveness

	Patency with $3,000 Device		Patency with $6,000 Device	
Procedure and Indication	One Year	Five Year	One Year	Five Year
Bypass surgery				
Claudication	53 (41–57)	37 (25–41)	59 (44–64)	44 (28–49)
Critical ischemia	58 (45–61)	43 (29–46)	63 (47–68)	48 (31–54)
PTA for occlusion				
Claudication	60 (53–65)	45 (36–51)	66 (54–73)	52 (38–61)
Critical ischemia	36 (28–39)	20 (13–22)	42 (29–46)	25 (14–29)
PTA for stenosis				
Claudication	85 (79–91)	77 (69–86)	89 (80–98)	84 (70–96)
Critical ischemia	69 (61–72)	55 (46–60)	72 (62–78)	60 (47–67)

Note.—Patency rates were determined at baseline analysis. Numbers in parentheses represent the range of patency rates found after performing a four-way sensitivity analysis with simultaneously varying sex, age (55, 65, and 75 years), society's willingness to pay ($20,000, $50,000, and $100,000 per QALY), and procedural risk of the new device (1, 1.5, and 2 times that of PTA).

more to the left compared with those in part a, which implies that for the treatment of occlusions, the target 5-year patency rates are less stringent.

By considering the treatment of critical ischemia and an occlusion, the graphs show that for any given cost of the endovascular device, the patency rates needed to make use of the device cost-effective compared with bypass surgery (Fig 1, part c) were higher than those required to make the device cost-effective compared with PTA (Figure, part b). This is consistent with the findings presented in Table 2, which shows that bypass surgery yielded a higher NHB than PTA in the treatment of critical ischemia and occlusion.

A striking finding was the high acceptable cost for an endovascular device, provided that it is associated with a high long-term patency rate. For example, the Figure, part c, shows that, if an endovascular device has a 5-year patency rate of 80%, the cost of the device may increase to $20,000, and it would still be cost-effective compared with bypass surgery, irrespective of the clinical indication.

The results are shown in more detail in Table 3 for two endovascular devices, one device that costs $3,000 and a second device that costs $6,000. For clarity, rest pain and tissue loss were replaced by critical ischemia to take into account the highest patency rate required. Table 3 shows the 5-year patency rates and the associated 1-year patency rates that would make an endovascular device equivalent in terms of cost-effectiveness compared with currently used procedures. For example, the 5-year patency rate that would make a device that costs $3,000 cost-effective compared with bypass surgery for the treatment of critical ischemia was 43% in the baseline analysis.

Results of one-way sensitivity analyses demonstrated that with an increase in society's willingness to pay, female sex, and a younger age, lower patency rates would be acceptable for an endovascular device. A higher procedural risk and a higher age increased the required patency rates. The tabulated ranges (Table 3) indicate the lowest and highest required patency rates found when age, sex, procedural risk, and society's willingness to pay were simultaneously varied in a sensitivity analysis. Variation of the discount rate from 2% to 5% in one-way sensitivity analyses resulted in an absolute difference of, at most, 1% when these rates were compared with the 5-year patency rates found in the baseline analyses.

DISCUSSION

We report target values of primary patency rates and costs that a hypothetical endovascular device for the treatment of femoropopliteal arterial disease would have to attain to be cost-effective compared with currently used therapies. The results help predict under what conditions an endovascular device would be the most promising and can help focus future technologic development of endovascular devices. As previously demonstrated (10), the results illustrate that when currently used procedures are considered, PTA is more cost-effective compared with bypass surgery in the treatment of milder forms of femoropopliteal arterial disease, and bypass surgery is the

treatment of choice in more severe disease.

When an endovascular device is considered, the results suggest that the target 5-year primary patency rate that would make a device that costs $3,000 equivalent in terms of cost-effectiveness compared with bypass surgery ranges from 25% to 46%. The 5-year patency rates that would make a device that costs $3,000 equivalent in terms of cost-effectiveness compared with PTA in the treatment of claudication and femoropopliteal stenosis ranged from 69% to 86%. Furthermore, the results suggest that use of a hypothetical endovascular device, with a 5-year patency rate of 80%, would be cost-effective compared with bypass surgery, even if the device costs up to $20,000, irrespective of clinical indication.

Caution should be exercised when conclusions are made about cost-effectiveness. Cost-effectiveness is always relative. In the current study, we compared treatment with use of an endovascular device with bypass surgery and with PTA. If more than one endovascular device were to be made available on the market, they would have to be compared with each other. Thus, an expensive currently available device may have a cost-effectiveness ratio just below the willingness-to-pay threshold compared with bypass surgery or with PTA, whereas in the future, that device may no longer be cost-effective if another device yields nearly the same effectiveness at a lower cost.

Limitations of the analysis lie within the assumptions of the model. First, we did not update the data concerning the currently used procedures in the model. Although the patency rates and risks of both PTA and bypass surgery are continually improving, a major improvement in the past 5 years is unlikely (1). Therefore, we assumed that the data used in the 1995 model were still valid. Furthermore, there is evidence that the cost of femoropopliteal revascularization has not changed considerably during the past few years (5).

Second, the data on costs associated with current therapies were collected in a teaching hospital in the United States. Caution should be exercised when the results are generalized to nonteaching hospitals or hospitals in other countries.

Third, we assumed that the procedural risk (complications, mortality) of an endovascular device would be 1.5 times higher than that of PTA. We assumed this because, ideally, the procedural risk of an endovascular treatment would be the same as that of PTA or lower. However, to make the baseline results also applicable for an endovascular treatment associated with less favorable morbidity and mortality rates, we assumed that the procedural risk associated with the endovascular device was 50% higher than that of PTA. In sensitivity analyses, we explored the effect of varying the procedural risk and the convalescence period, ranging from one to two times that of PTA, and found that an increase in procedural risk and convalescence period resulted in more stringent target values for the endovascular device.

Fourth, the hypothetical patency curves of the endovascular device were based on the patency curve of PTA. By doing this, we assumed that most failures occur during the 1st year after the procedure. We assumed this because both are endovascular treatments, but the true curve is unknown.

Fifth, the choice of the threshold value of society's willingness to pay may have been a limitation. Estimates of society's willingness to pay are highly dependent on the societal and decision context (26). In the baseline analyses of the current study, we assumed society's willingness to pay to be $20,000 per QALY gained, and we explored the influence of choosing a threshold of $50,000 per QALY gained and that of $100,000 per QALY gained on our results. Because we chose a higher threshold, which implies the acceptance of higher costs for the same health effect, the results yielded less stringent criteria for the hypothetical endovascular device.

Current research on endovascular devices to treat femoropopliteal arterial disease focuses on the problem of intimal hyperplasia, which causes secondary obstruction after an angioplasty procedure or stent implantation. The idea is to prevent secondary obstruction by covering the arterial wall with prosthetic material, such as polytetrafluoroethylene, now often used as the conduit material in bypass surgery. Primary patency rates reported (27-29) thus far associated with such stent-grafts range from 73% at 12 months to 59% at 18 months to 46% at 24 months. One group of investigators (30) recently reported less favorable results (12-month patency rate, 29%). The results in the current analysis suggest that the target 12-month primary patency rate for an endovascular device that costs $3,000 is approximately 41%–61%. This finding suggests that, if the assumptions in this study hold true, the use of these devices may already be cost-effective compared with bypass surgery. The validity and generalizability of the reported patency rates in these initial studies were, however, low because the sample sizes were limited and because data on long-term results were not available.

The methods used in this study can be applied to many situations where investigators are developing therapeutic technologies. Other examples of new technologies under development are endovascular devices for the treatment of abdominal aortic aneurysms and catheter techniques with the use of coiling devices for the treatment of cerebral aneurysms. Perhaps the first step in investigations of new technologies, both therapeutic and diagnostic, should be to establish clear-cut goals for the performance of such technologies compared with existing ones. Such analyses could help focus research and the development of new technologies and thereby help to save valuable resources (8,9).

In conclusion, the results of this cost-effectiveness analysis in which target cost and patency rates were estimated demonstrate that there is a place for a new endovascular therapy in the treatment of femoropopliteal arterial disease. The target values of patency rates and costs determined in this study that would make the use of an endovascular device cost-effective compared with the currently used therapies are probably attainable, and further development of endovascular devices seems warranted.

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