The treatment of disabling intermittent claudication in patients with superficial femoral artery occlusive disease—Decision analysis

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Objective: **To determine the preferred approach to superficial femoral artery (SFA) revascularization of Trans-Atlantic Inter-Societal Consensus (TASC) B and C lesions in claudicants requiring intervention based on a review of published data.**

Design: **Decision analysis, Markov state transition model.**

Subjects: **Hypothetical cohorts of claudicants with TASC B or TASC C superficial femoral artery lesions considered candidates for either angioplasty with selective stenting (PTA/S) or greater saphenous vein bypass (GSVB).**

Main outcome measure: **Quality adjusted life years (QALYs).**

Results: **For a 65-year-old man with disabling claudication, percutaneous transluminal angioplasty and selective stenting (PTA/S) was preferred over GSVB for a TASC B SFA lesion. In an otherwise identical patient with a TASC C lesion, bypass was the preferred therapy. Treating PTA/S failures with subsequent bypass increased the utility of PTA/S but bypass remained the preferred initial therapy for TASC C lesions. Sensitivity analysis showed that PTA/S surpasses bypass efficacy for TASC C lesions if PTA/S primary patency is >32% at 5 years, patient age is >80 years, or GSVB operative mortality is > 6%.**

Conclusion: **PTA/S is the preferred initial therapy over GSVB for TASC B SFA lesions in patients with disabling intermittent claudication who require intervention. Given contemporary published outcomes for TASC C lesions, GSVB is the preferred therapy in operative candidates. In elderly patients or patients at high risk for bypass, PTA/S should be considered over GSVB. Improved technology that results in a 5-year primary patency of 32% would also justify PTA/S for TASC C SFA lesions. (J Vasc Surg 2007;45:1179-84.)**

Intermittent claudication (IC) resulting from peripheral artery disease is present in approximately 10% of the United States population over age 50 and 20% of the population over age 70.[1] Though highly prevalent, the natural history of IC is relatively benign with deterioration to critical limb ischemia occurring in 25% to 30% over five years and amputation in only 1% to 2%.[2,3] The major risk facing patients with IC is mortality from cardiovascular causes, 30% at 5 years.[4,5] Given the relatively low risk of progression and high prevalence of cardiovascular disease, the initial management of patients IC has traditionally been conservative and includes medical therapy (Clopidogrel and statins), life style modification (smoking cessation and weight loss), and exercise. These measures have been shown in randomized clinical trials to benefit patients with IC.[6] Unfortunately, compliance is often poor and the impact on functional capacity is variable.[7] Ultimately, a significant percentage of patients fail conservative therapy.

While relief of IC symptoms is achievable with surgical revascularization, the risks of peripheral bypass are significant, so typically only severely disabled patients who fail conservative therapy are considered. The advent of endovascular therapy, which carries lower procedural risks, has led to a more aggressive approach to superficial femoral artery (SFA) revascularization in the claudicant. In certain practices, percutaneous transluminal angioplasty and selective stenting (PTA/S) has consequently not only replaced bypass as the primary mode of revascularization, but it also challenges conservative measures as the primary therapy. In 2000, the Trans-Atlantic Inter-Societal Consensus (TASC) introduced a classification system for SFA occlusive disease and proposed guidelines for its management (Fig 1). Percutaneous transluminal angioplasty was recommended for TASC A lesions (short stenosis, <3 cm) and bypass was recommended for TASC D lesions (long occlusions, >5 cm).[8] No conclusive recommendation was made for the management of TASC B (stenosis 3 to 5 cm or occlusions, <3 cm), and C lesions (occlusions 3 to 5 cm or stenosis, >5 cm). The optimal treatment for these lesions remains a matter of debate and current therapy is largely dictated by physician preference. To help resolve uncertainty surrounding the best approach to SFA revascularization in claudicants, we developed a decision-analytic model

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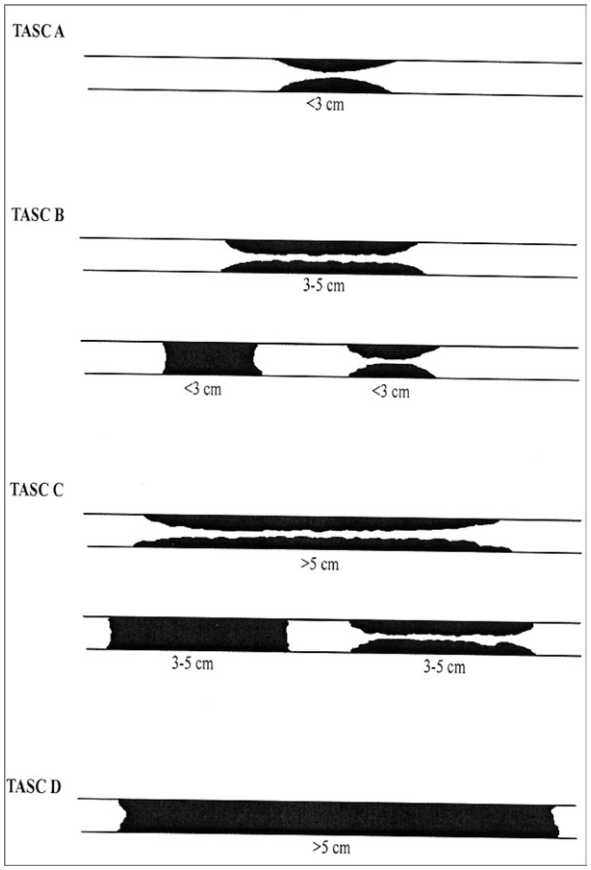

Fig 1. Trans-Atlantic Inter-Societal Classification (TASC) of femoro-popliteal occlusive disease.[8]

that integrates the best available information on long- and short-term risks and benefits of bypass vs PTA/S.

METHODS

A Markov-state transition model was developed using TreeAge Pro 2006 Suite software (TreeAge Software Inc, Williamstown, Mass) to simulate hypothetical patient cohorts (10,000 patients, Monte Carlo simulation) with intermittent claudication and SFA occlusive disease (Fig 2). Three treatment strategies were investigated: femoropopliteal bypass, PTA/S, and PTA/S with subsequent femoropopliteal bypass for PTA/S failures. Three primary sources of contemporary data (2000 to 2005) were used to estimate model input parameters including technical success, procedural risks and patency, health state specific survival, and quality of life[8-10] (Table 1). Outcomes were measured in quality-adjusted life years (QALYs). Differences were compared by *t*-test. To determine the effect of alternative assumptions, data from a fourth, older source (1994) was used in sensitivity analysis.[11]

Health states and model assumptions. The model transitioned patients between 10 possible health states based on various input probabilities. The model cycled (in 1 year intervals with half-cycle correction) until all patients

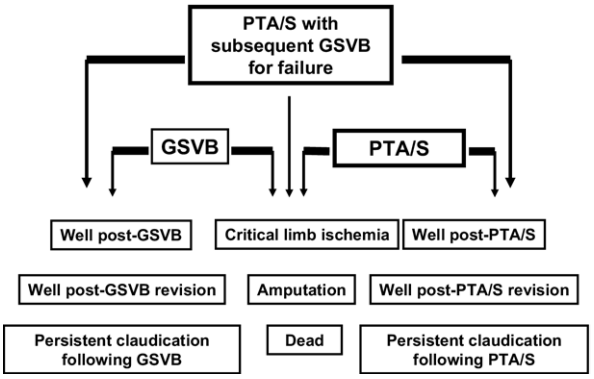

Fig 2. Multi-state transition model (Markov process) for treatment of intermittent claudication in patients with SFA occlusive disease.

in the PTA/S and bypass cohorts were dead based on expected mortality rates. The cumulative QALYs were tabulated by the software for comparison of the three groups (PTA/S, GSVB, and GSVB following failed PTA/S). The model was run for both the treatment of TASC B and C SFA lesions. To make the model tractable, simplifying assumptions were made regarding the patients and interventions. First, all patients had unilateral calf claudication with either TASC B or C SFA occlusive disease and were considered candidates for both PTA/S and bypass. Second, the specific interventions modeled were femoropopliteal bypass with greater saphenous vein (GSVB) and PTA with selective (ie, not primary) stenting. Arm vein, synthetic, composite, or other grafts were not specifically modeled. Third, the rate of primary graft failure was assumed to be constant beyond 5 years. Fourth, "assisted patencies" were based on reported primary assisted and secondary patency rates from the literature, thus, no distinction was made between the specific types of, or indications for, reintervention. Fifth, "failed PTA/S" was defined as occlusion following attempted endovascular revision, thus, patients in the "GSVB following failed PTA/S" group underwent bypass following an attempted endovascular reintervention. Sixth, all patients who failed PTA/S and subsequently developed critical limb ischemia (CLI) underwent GSVB, even in the "PTA/S only" cohort. Seventh, patients who failed GSVB and secondary salvage procedures and subsequently developed CLI, underwent amputation. Redo bypasses were not modeled. Lastly, patients who failed bypass and bypass salvage and were left with persistent claudication had no further intervention, unless they subsequently progressed to critical limb ischemia.

Mortality. A disease specific, excess mortality rate in claudicants (μ_{cl}) was determined using the declining exponential approximation of life expectancy (DEALE) equation.[12] Briefly, this is defined as the difference between the mortality of a 65-year-old male claudicant and the mortality of an age, sex, race adjusted (ASR) control.[5,13] This excess mortality was assumed to be constant over time and added to the ASR mortality rates for males (race nonspecific) aged

Table I. Procedure and patient related input variables

Variable	*Base case*	*Range*
Quality of life		
Claudication	0.44	0.20–0.75
Amputation	0.14	*
Life expectancy	14.0-yr	*
Age	65-yr	65–100
Procedural mortality		
PTA/S	0.5%	0–2%
GSVB	2%	1–10%
Amputation	17%	5–40%
Technical success		
GSVB	95%	70–99%
PTA/S TASC B	95%	90–99%
PTA/S TASC C	70%	50–90%
Convalescence (weeks)		
PTA/S and PTA/S revision	1	*
GSVB for claudication	6	*
GSVB for critical limb ischemia	7	*
Primary patency		
GSVB 1, 2, 3, 4, 5-year +	85, 80, 75, 70, 65%	5-yr: 80%
PTA/S TASC B 1, 2, 3, 4, 5-year +	82, 70, 63, 55, 55%	5-yr: 70%
PTA/S TASC C 1, 2, 3, 4, 5-year +	65, 30, 15, 15, 15%	5-yr: 40%
Assisted Patency		
PTA/S	40%	30–70%
GSVB	70%	50–90%
Progression to CLI		
PTA/S failure	50%	40–70%
GSVB failure	10%	5–25%

66 to 100 for subsequent use in the model. Similarly, an excess mortality rate in amputees was determined and added to the ASR mortality rates for the same age cohort.[14] Procedural mortality was determined as a weighted average from the studies referenced above.

Procedural risks. Procedural morbidity was accounted for in the model as a "toll" or reduction in the cumulative QALYs associated with the specific intervention. This disutility was designated as the average postprocedural recovery time (including complications) and was deducted from the reward for the first cycle of the Markov process. Recovery time estimates used in the model were 1 week for PTA/s and 6 or 7 weeks for bypass (Table I).

Procedural patency. Patency definitions were in accordance with Society for Vascular Surgery standards. Primary patency implies the maintenance of clinical and hemodynamic improvement without further intervention. Primary patency of PTA/S for TASC B and C SFA occlusive disease was determined as a weighted average of contemporary studies reporting long-term patency by Kaplan-Meier life table methodology using the TASC or American Heart Association (AHA) classification systems.[8,10,15] Data from studies that did not report patency in these formats were not included. Life table patencies were converted to annual failure rates using the DEALE equation.[12] Similarly, the primary patency of GSVB was determined as a weighted average of the long-term, life table patencies of GSVB in claudicants reported in a large meta-analysis and a large, contemporary, multicenter registry.[11,16] Although the primary patencies modeled for both PTA/S and GSVB over the first five cycles (5 years) were taken from the literature, there is little or no data on longer life-time primary patency rates, particularly with PTA/S. Given this lack of data, GSVB and PTA/S failure rates beyond 5 years were assumed to take place at a constant rate (assumption 3). The primary patency rates for PTA/S and GSVB used in the model are listed in Table I.

"Assisted patency" as defined in the model was calculated using published primary assisted and secondary patency rates. For the purpose of the model, no distinction is made between type of reintervention (PTA vs PTA/S vs interposition grafting vs patch angioplasty) or the indication for reintervention (symptomatic and asymptomatic restenosis with or without hemodynamic changes). In order to adjust for poorer patencies following multiple revisions, secondary patencies rates were decreased by 25% for both PTA/S and bypass for these scenarios. This adjustment factor is not explicitly defined in the literature but is supported based on long-term follow-up data of bypass grafts and angioplasties which require revision.[17,18]

Quality of life. Health state utilities were determined as a weighted average of quality of life studies using the Nottingham Health Profile (NHP). While quality of life in patients with chronic lower extremity ischemia has been studied using many different assessment tools, the NHP was chosen because it is the most widely used in published studies on this topic over the past 10 years. The utility of the claudication health state in the model was determined using both cohort and case control designed studies (ie, claudicants vs ASR controls, and claudicants pre- and

Table II. Results of Markov decision model Monte Carlo simulation (10,000 patients) by management strategy (PTA/S alone, PTA/S + GSVB, GSVB alone) for TASC B and C lesions. All differences statistically significant ($p < 0.001$, t-test)

Classification	*Claudication Management Strategy Results (mean QALYs and 95% C.I.)*		
TASC	*PTA/S alone*	*PTA/S + GSVB*	*GSVB alone*
B	4.7 (4.7–4.8)	5.0 (4.9–5.0)	4.4 (4.3–4.4)
C	4.0 (3.9–4.0)	4.2 (4.1–4.2)	4.4 (4.3–4.4)

Table III. Threshold values for primary PTA/S of TASC C SFA lesions

Variable	*Base case*	*Threshold*
Quality of life with claudication	44%*	27%*
Age	65	80
Operative mortality (GSVB)	2%	6%
CLI with PTA/S failure	50%	20%
CLI with GSVB failure	10%	22%
Technical success GSVB	95%	73%
5-yr primary patency, PTA/S	15%	32%

*Relative to age matched controls without claudication

postrevascularization).[2,19-21] Sensitivity analysis was performed to a lower utility limit calculated from studies in patients with critical limb ischemia. The utility of the amputation health state was determined from studies on the quality of life with major lower extremity (above and below knee) amputation.[14,22]

Base case. The base case in the model is a 65-year-old, male (race nonspecific) with unilateral, intermittent calf claudication, and either TASC B or C SFA occlusive disease. His quality of life is 44% of controls. His life expectancy is 14.0 years and his operative mortality is 2%. His recovery from GSVB is 6 weeks if performed for claudication, 7 weeks if performed for CLI. His recovery from PTA/S is 1 week. These data are listed in Table I along with the procedural patencies.

RESULTS

In the base case, PTA/S was the preferred initial therapy for a TASC B SFA lesion (4.7 QALYs for PTA/S alone and 5.0 QALYs for PTA/S followed by GSVB for failures, vs 4.4 QALYs for GSVB alone). In an otherwise identical patient with a TASC C lesion, GSVB was the preferred initial therapy (4.4 vs 4.0 QALYs for PTA/S alone and 4.2 QALYs for PTA/S followed by GSVB for failures)(Table II). A threshold analysis (tornado diagram) was used to investigate the expected QALYs over a range of values and to identify variables containing thresholds which would shift the preferred therapy for TASC C lesions. Thresholds included PTA/S primary patency, patient age, GSVB operative risk and technical success, the probability of developing critical limb ischemia following GSVB and PTA/S failure, and baseline (claudication) quality of life. By one-way sensitivity analyses, the threshold values at which PTA/S would surpass bypass for TASC C lesions were determined (Table III). For very elderly patients (age >80 years) and patients with exceedingly poor baseline quality of life (<27% of control) PTA/S was preferred over GSVB as initial therapy. Similarly, in high risk patients (>6% predicted operative mortality) and patients with a low probability of technical success with GSVB (<73%), PTA/S was preferred for TASC C lesions. The probability of a failed procedure leading to critical limb ischemia (ie, the chance of making them worse than baseline) also contained a threshold. For failed PTA/S the threshold was <20% and for failed GSVB the threshold was >22%. Two-way sensitivity analysis of PTA/S vs GSVB 5-year primary patency was performed. For the base case GSVB 5-year primary patency of 65%, the 5-year primary patency at which PTA/S would surpass bypass as the preferred strategy for a TASC C lesion was 32%. The 5-year primary patencies at which PTA/S would surpass bypass for TASC C lesions over a range of GSVB patencies are listed in Fig 3.

GSVB patency	Threshold patency for PTA/S (TASC C lesion)
50%	27%
65%	32%
70%	37%
75%	41%
80%	44%

Fig 3. Five year GSVB primary patency and corresponding PTA/S 5-year primary patency threshold for TASC C SFA lesions.

DISCUSSION

Decision analysis has previously been applied to revascularization for femoropopliteal disease by Hunink et al in 1995.[23] The analysis found that PTA was the preferred initial therapy in claudicants with SFA disease not classified by TASC. Using data stratified by TASC classification, our analysis suggests GSVB is the preferred strategy for the initial management of TASC C lesions in younger patients with a reasonable operative risk. Although the findings seem contradictory, the discrepancy is likely the result of stratification of the primary patency input parameters. Patency data (for both PTA/S and GSVB) in the Hunink model were obtained by a large meta-analysis of series reporting femoropopliteal revascularizations between 1985 and 1993.[11] At the time these series and meta-analysis were published, there were no TASC criteria for the reporting of

either SFA disease or posttreatment patency. The meta-analysis reported patencies based on whether the treated lesions were either a "stenosis" or an "occlusion". The TASC classifications stratify SFA disease into four categories. Although all TASC A lesions are stenosis and all TASC D are occlusions, considerable overlap exists between TASC B and C lesions with regards to stenosis and occlusion (TASC B up to 3 cm occlusion, 3 to 5 cm stenosis; TASC C 3 to 5 cm occlusions, >5 cm stenosis).[8] Classifying SFA lesions as simply "stenoses" or "occlusions" would, thus, mix TASC B and C lesions and possibly improve the observed results in the "occlusion" group relative to the TASC C group in the current study. Using the patency input parameters in the Hunink model, the current analysis yields the same results. PTA/S would be the preferred strategy for both TASC B and C lesions lending between-model validation to our analysis. Our model can also be validated externally using the TASC data and recommendations for the treatment of A and D lesions. Inputting the reported patencies from the TASC review in the current model, PTA/S is favored for TASC A lesions and bypass for TASC D lesions which coincides with the recommendations of the work group.

Our model predicts that the management of TASC C SFA lesions with GSVB would provide the greatest quality adjusted life year benefit in relatively young, healthy patients. Using sensitivity analysis, thresholds at which this benefit is lost were determined. Not surprisingly, the model determined that patients with high operative mortality (>6%) would benefit from PTA/S rather than GSVB. Although mortality rates in published series following infrainguinal bypass even in patients with critical limb ischemia are less than 5%, these reports are of selected patients. There is a large population of claudicants who are refused surgery because they are considered a prohibitive operative risk and who may benefit from PTA/S. Similarly, the analysis found that in patients greater than 80 years of age, PTA/S for TASC C lesions was favored. Though not previously reported, 80 years, in our analysis, is the threshold at which patients on average are not likely to live long enough to realize a clinically significant durability benefit of bypass.

The utility of the health states used in this model were derived from published data on quality of life determined using the NHP. Although the NHP is not a previously validated measure in decision analysis, precise health state utilities have not been reported in these groups of patients (claudicants, critical limb ischemia patients, and amputees). The values obtained using NHP published data are externally validated by the utility values used in the study by Hunink et al, which were obtained by polling vascular surgeons.[23] The utility of the claudication health state (a marker for severity of IC) contained a threshold at 0.27 (27% of control). Based on previous reports on quality of life, this level of disability approximates patients with critical limb ischemia.[2,21] From a modeling standpoint, the threshold occurred because utility of the claudication state approximated critical limb ischemia, at which point all patients in the PTA/S arm of the model are treated with bypass. Therefore, in patients with extremely severe claudication with borderline rest pain, a strategy of PTA/S with subsequent referral for bypass after failed PTA/S may be preferred although further studies are required for verification.

Through the use of a two-way sensitivity analysis of odds ratios for 5-year primary patency (GSVB vs PTA/S), a threshold of 32% was determined at which PTA/S would surpass GSVB benefit for primary therapy of TASC C lesions. This is a useful target for the advancement of endovascular therapy and represents an approximate two-fold improvement in currently published outcomes. Given the large and increasing number of endovascular therapies, eg, cryoplasty, LASER atherectomy, mechanical atherectomy, primary stenting, and stent grafting, all with very limited data on long term patency, we chose to restrict the endovascular arm of this analysis to the therapy with the most widely published and accepted data, namely PTA with selective stenting. In "real life", however, the use of alternative technologies is common-place and most practitioners who use them do so because of their bias that the outcomes are better than with PTA alone. While this may be the case, definitive data is lacking and according to our model, the goal for these therapies would be to provide a 5-year primary patency of 32% to justify their use vs bypass for TASC C SFA lesions.

Another threshold variable was the likelihood of developing critical limb ischemia following GSVB or PTA/S occlusion. Of note, this refers specifically to the group of patients whose bypass or PTA/S failed and could not be successfully revised. There are no precise data on progression to CLI following PTA/S failure on which to base the model. It was assumed that since PTA/S failure would mean occlusion of the native artery, where as for bypass occlusion the native artery should be unaffected, that progression to critical ischemia would be higher for failed PTA/S. Though the validity of the percentage used in the base case (50%) for progression to critical ischemia after failed PTA/S may be argued, the threshold at which PTA/S would be favored over bypass occurred at 20%. This appears to be an unlikely scenario since this is only slightly higher than the base case for GSVB failure (10%). It is possible, however, that with improvement in technology that may be achievable and, thus, increase the applicability of PTA/S.

There are limitations to any decision analysis study. Decision analysis models are hypothetical and based on probabilities from published data. The current model is based on data from large case series since no level I evidence is available. Case series are subject to selection bias, thus, these data may not truly represent all claudicants with TASC B or C SFA lesions. Furthermore, many assumptions must be made about a patient's clinical course to simplify the model so that it will function. Although, the scenarios modeled approximate "real life", there is variability which is not accounted for in the model, eg, redo bypasses, arm vein bypass, PTA/S of the native artery after failed bypass, or

any of the available endovascular technologies other than PTA/S. Nonetheless, claudicants are encountered on a daily basis in practice and decisions must be made regarding their treatment. This model represents a synthesis of contemporary data to help guide these decisions given the lack of a prospective randomized study.

The advent of minimally invasive, less morbid endovascular techniques has led to a more aggressive approach toward the treatment of claudication. As these technologies evolve, there is an increasing ability and willingness to treat complex SFA lesions despite limited data on long-term outcomes. Using a decision analytic model, we have investigated surgical and endovascular treatment strategies for TASC B and C SFA lesions in patients with disabling IC. Using data from contemporary literature, our findings suggest that in patients who are relatively young and reasonable operative candidates, percutaneous transluminal angioplasty with selective stenting is the preferred initial therapy for TASC B lesions while bypass with greater saphenous vein is preferred therapy for TASC C lesions. Bypass following PTA/S failure increases the utility of primary PTA/S, however, in the case of TASC C lesions, bypass remains the preferred initial treatment. For patients greater than 80 years of age or who are at high risk for surgery, PTA/S should be considered as primary therapy. For PTA/S to supplant bypass as primary therapy for TASC C lesions in all patients, an improvement in 5-year primary patency to 32% is necessary.

AUTHOR CONTRIBUTIONS

Conception and design: BN, SF, AT
Analysis and interpretation: BN, SF, AT, JC, RP
Data collection: BN, SF
Writing the article: BN
Critical revision of the article: BN, SF, AT, JC, RP
Final approval of the article: BN, JC
Statistical analysis: BN, SF, AT
Obtained funding: Not applicable
Overall responsibility: BN

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