Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: An analysis of 553 consecutive patients

Spence M. Taylor, MD, Corey A. Kalbaugh, MS, Dawn W. Blackhurst, DrPH, Steven E. Hamontree, CPO, David L. Cull, MD, Hayley S. Messich, R. Todd Robertson, Eugene M. Langan III, MD, John W. York, MD, Christopher G. Carsten III, MD, Bruce A. Snyder, MD, Mark R. Jackson, MD, and Jerry R. Youkey, MD, *Greenville and Clemson, SC*

Background: **Despite being a major determinant of functional independence, ambulation after major limb amputation has not been well studied. The purpose, therefore, of this study was to investigate the relationship between a variety of preoperative clinical characteristics and postoperative functional outcomes in order to formulate treatment recommendations for patients requiring major lower limb amputation.**

Methods: **From January 1998 through December 2003, 627 major limb amputations (37.6% below knee amputations, 4.3% through knee amputations, 34.5% above knee amputations, and 23.6% bilateral amputations) were performed on 553 patients. Their mean age was 63.7 years; 55% were men, 70.2% had diabetes mellitus, and 91.5% had peripheral vascular disease. A retrospective review was performed correlating various preoperative presenting factors such as age at presentation, race, medical comorbidities, preoperative ambulatory status, and preoperative independent living status, with postoperative functional endpoints of prosthetic usage, survival, maintenance of ambulation, and maintenance of independent living status. Kaplan-Meier survival curves were constructed and compared by using the log-rank test. Odds ratios (OR) and hazard ratios (HR) with 95% confidence intervals were constructed by using multiple logistic regressions and Cox proportional hazards models.**

Results: **Statistically significant preoperative factors independently associated with not wearing a prosthesis in order of greatest to least risk were nonambulatory before amputation (OR, 9.5), above knee amputation (OR, 4.4), age >60 years (OR, 2.7), homebound but ambulatory status (OR, 3.0), presence of dementia (OR, 2.4), end-stage renal disease (OR, 2.3), and coronary artery disease (OR, 2.0). Statistically significant preoperative factors independently associated with death in decreasing order of influence included age ≥70 years (HR, 3.1), age 60 to 69 (HR, 2.5), and the presence of coronary artery disease (HR, 1.5). Statistically significant preoperative factors independently associated with failure of ambulation in decreasing order of influence included age ≥70 years (HR, 2.3), age 60 to 69 (HR, 1.6), bilateral amputation (HR, 1.8), and end-stage renal disease (HR, 1.4). Statistically significant preoperative factors independently associated with failure to maintain independent living status in decreasing order of influence included age ≥70 years (HR, 4.0), age 60 to 69 (HR, 2.7), level of amputation (HR, 1.8), homebound ambulatory status (HR, 1.6), and the presence of dementia (HR, 1.6).**

Conclusions: **Patients with limited preoperative ambulatory ability, age ≥70, dementia, end-stage renal disease, and advanced coronary artery disease perform poorly and should probably be grouped with bedridden patients, who traditionally have been best served with a palliative above knee amputation. Conversely, younger healthy patients with below knee amputations achieved functional outcomes similar to what might be expected after successful lower extremity revascularization. Amputation in these instances should probably not be considered a failure of therapy but another treatment option capable of extending functionality and independent living. (J Vasc Surg 2005;42:227-35.)**

In 2006, the first of the 76 million "baby boomers" will turn 60 years old. Although the overall impact of aging on society will be significant, perhaps no area will be affected as much as health care. Treatment of diseases associated with aging, such as lower extremity peripheral arterial disease (PAD), will have the potential to bankrupt our current third-party payer system. Economics will play a major role in the treatment of such illnesses. "Pay for performance" oriented payers will, no doubt, insist that approved treatments be evidence-based and that the initial therapy be the best, most durable treatment with the lowest potential for failure and expensive retreatment. It can also be speculated that treatment will be geared toward maximizing functional independence to minimize the cost of long-term care institutionalization.

Treatment strategies to maximize functional performance in patients with critical limb ischemia (CLI) have not been a study priority. Published reports regarding the sur-

From the Academic Department of Surgery, Greenville Hospital System, and The Clemson University/Greenville Hospital System, Limb Health Research Project.

Competition of interest: none.

Presented at the Southern Association for Vascular Surgery Meeting, Marco Island, Fla, Jan 19-22, 2005.

Correspondence: Spence M. Taylor, MD, Academic Department of Surgery, Greenville Hospital System, 701 Grove Road, Greenville, SC 29605 (e-mail: staylor2@ghs.org).

0741-5214/$30.00

doi:10.1016/j.jvs.2005.04.015

gical treatment of lower extremity PAD have traditionally emphasized arterial reconstruction patency and limb salvage as measures of success. The realization that these measures do not always predict the best functional performance has prompted investigators to re-examine all treatments for CLI by using maintenance of independent living status and ambulation preservation as a new standard for success.

Maintenance of ambulation, either through limb salvage or through the use of a prosthetic limb, has been shown to be an important factor associated with preserving independence.[1-3] In the case of lower extremity PAD, limb salvage is best achieved by arterial intervention. Unfortunately, revascularization will fail in some patients; in others, intervention is not an option. In these patients, a major amputation that preserves as much limb length as possible can result in ambulation with a prosthetic limb. In many instances, and especially after open surgery, some series suggest that a failed vascular intervention will result in a higher level of leg amputation.[4,5] Because a higher level of amputation results in increased disability, correct decision making regarding bypass surgery or primary amputation can be pivotal for the ultimate functionality of the patient.

Other factors associated with enhanced functional performance after limb amputation have been poorly studied. The literature on outcomes after amputation tends to be vague; the findings of large cohorts have been group together, resulting in gross generalizations. Which specific subset of patients do well and which will do poorly is not well delineated. The purpose of this study, therefore, was to investigate the relationship between a variety of preoperative characteristics and the postoperative functional outcomes of patients after a major limb amputation.

METHODS

Postoperative functional status was assessed for 553 consecutive patients who underwent 627 major lower extremity amputations from January 1998 through December 2003 at a single nonuniversity teaching center. The 627 amputations, all performed by surgeons on the vascular surgery service, included 236 (37.6%) below knee amputations (BKA) in 236 patients, 27 (4.3%) through knee amputations (TKA) in 27 patients, 216 (34.5%) above knee amputations (AKA) in 216 patients, and 148 (23.6%) bilateral amputations in 74 patients that consisted of 84 bilateral AKA in 42 patients, 44 bilateral BKA in 22 patients, 14 BKA/AKA in 7 patients, 4 BKA/TKA in 2 patients, and 2 AKA/TKA in 1 patient.

A retrospective review was performed, correlating the various preoperative factors with the eventual postoperative functional status of each patient. For the purpose of the analysis, the classification of amputation level was considered to be the eventual amputation level. For example, a patient who received a guillotine foot amputation and then a revision to a BKA, which failed, requiring AKA, which healed, was counted as one amputation—an AKA.

Preoperative factors assessed included age, level of amputation, race, gender, presence of diabetes mellitus, history of cigarette smoking, presence of end-stage renal disease (ESRD), presence of severe coronary artery disease (high-risk by the Eagle criteria),[6] presence of dementia, nutritional deficiency (as defined by ICD-9 code at discharge), diagnosis necessitating amputation (peripheral vascular disease vs trauma or neuropathy), a history of prior vascular intervention of the lower extremity (angioplasty or surgery), ambulatory status before amputation, and independent living status before amputation.

Preoperative ambulatory status was characterized as ambulatory (independent ambulation out of house), ambulatory/homebound (ambulatory in the home only), nonambulatory/transfer (eg, uses legs to transfer from the bed to the chair or from the chair to the commode), and nonambulatory/bedridden. Preoperative living status was characterized as independent, defined as living in an independent dwelling without external assistance; or nonindependent, defined as living in an assisted living environment or in a private residence with external assistance for activities of daily living.

Of the 533 patients analyzed, 230 underwent limb amputation without an attempt at revascularization. Of these, 47 experienced neuropathic complications from diabetes mellitus and had normal circulation. Sixty-eight patients had evidence of PAD (ankle-brachial index <0.8) but had neuropathic infectious complications that prompted their amputation. Twenty-six patients were homebound ambulators, 39 were nonambulators/transfer only, and 50 were bedridden. In the judgment of the surgeon, amputation was considered the best first option for each of these patients. The remaining 303 underwent at least one attempt at revascularization before amputation.

Postoperative outcome measures assessed included the ability or inability to wear a prothesis, defined as donning the artificial limb for at least 1 hour a day at some point in time after the amputation healed; death; decline in ambulatory function, defined as a significant postoperative decline in ambulatory classification (eg, ambulatory to nonambulatory/transfer, ambulatory to nonambulatory/bedridden, ambulatory/homebound to nonambulatory bedridden, or nonambulatory/transfer to nonambulatory/bedridden); and decline in independent living status, defined as a permanent change to an assisted living residence or incorporation of permanent help into the postoperative domicile to enhance the functions of daily living. Short-term assisted living in the recovery period was not considered a loss in independence.

Information was gathered for this study after institutional review committee approval. Cases were identified from the vascular surgery registry and follow-up attained through review of the clinical records in the vascular outpatient office and prosthetic rehabilitation clinics.

The χ^2 test for association was used to examine preoperative patient characteristics by prosthesis wear postoperatively (bivariate analysis). All factors significantly associated with prosthesis wear in bivariate analysis were included in a multiple logistic regression model. Nonsignificant factors were then removed using backward stepwise elimina-

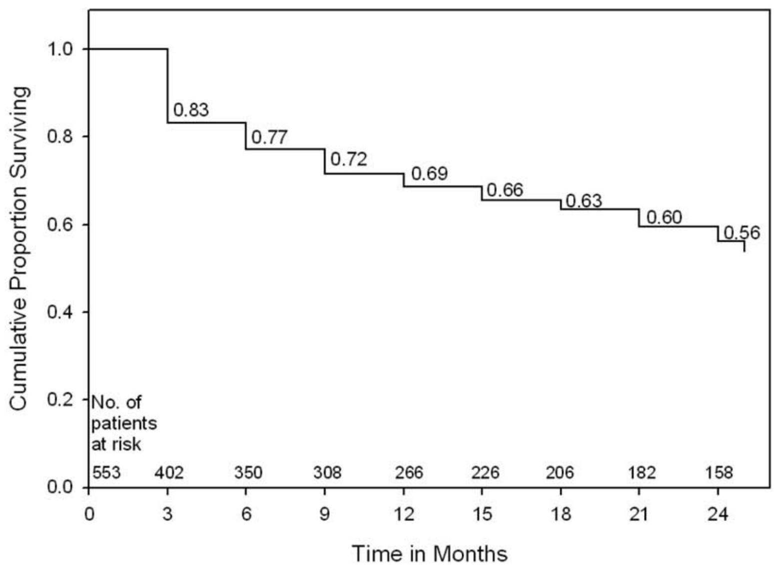

Fig 1. Kaplan-Meier life tables showing overall survival in a cohort of 533 consecutive lower limb amputees.

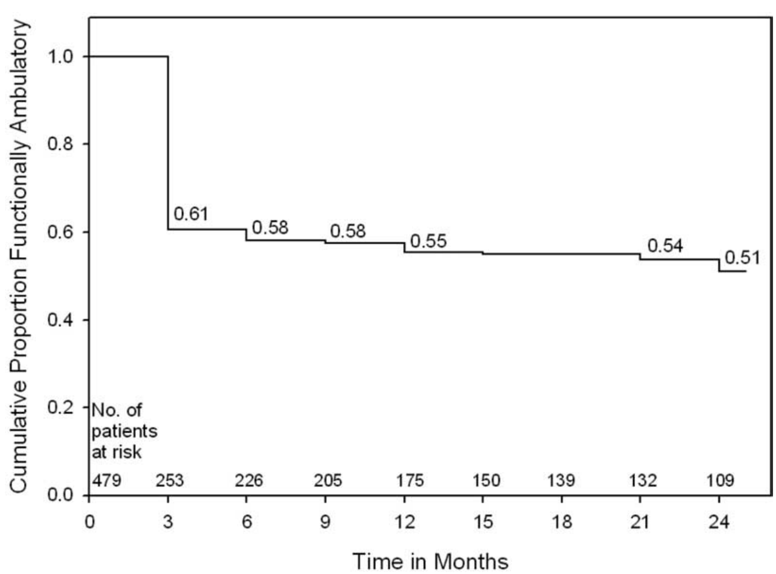

Fig 2. Kaplan-Meier life tables showing overall maintenance of ambulation in a cohort of 533 consecutive lower limb amputees.

tion (at $\alpha = 0.005$). Odds ratios (OR) and 95% confidence intervals from the final model were used to describe the risk of the event (not wearing prosthesis).

Kaplan-Meier survival curves were used to assess survival, maintenance of functional ambulatory status, and maintenance of independent living status over time. The log-rank test was used to assess differences in these curves. All factors significantly associated with time to the measured event (death, loss of ambulation, or loss of independence) in bivariate analysis were then entered into a Cox proportional hazards model. Backward stepwise elimination was used to remove nonsignificant factors from the model. Hazard ratios (HR) and 95% confidence intervals from the final model were used to describe event time risk.

RESULTS

Overall results for survival, maintenance of ambulation, and maintenance of independence using Kaplan-Meier life-table curves are shown for the entire cohort in Figs 1, 2, and 3, respectively. Mean and median follow-up were 525 days and 321 days (range, 0 to 2,192 days).

The influence of each individual preoperative characteristic on postoperative prosthesis wear was determined. Factors not influencing prosthesis wear included race ($P =$

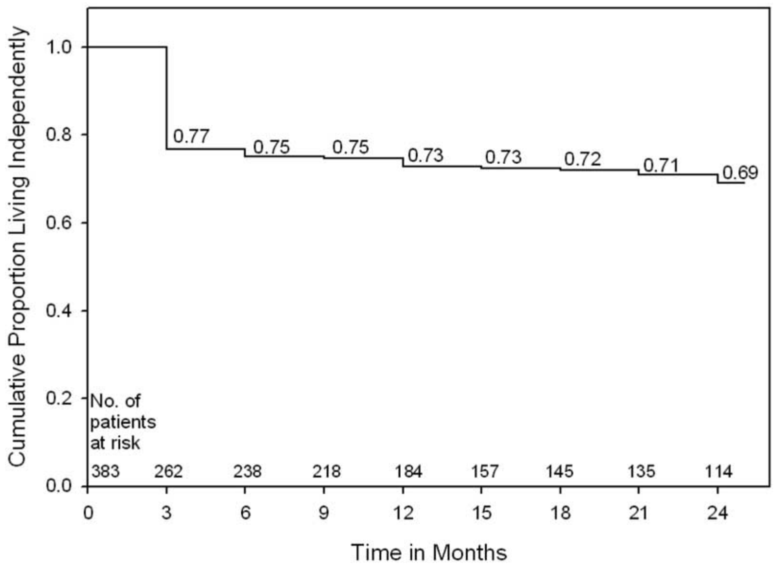

Fig 3. Kaplan-Meier life tables showing overall maintenance of independent living status in a cohort of 533 consecutive lower limb amputees.

.59), the presence of diabetes mellitus (P = .61), and the presence of lower extremity PAD defined as ankle-brachial index of <0.8 (P = .1). Characteristics that influenced prosthesis wear rates included advancing age (<50 years old, 65.3%; 50 to 59 years old, 58%; 60 to 69 years old, 36.5%; 70 to 79 years old, 23.4%; >80 years old, 21.9%; P < .001), level of amputation (BKA, 58.5%; TKA, 66.7%; AKA, 13.9%; bilateral amputee, 31.1%; P < .001), history of smoking (no, 32.8%; yes, 42.1%; P = .025), ESRD (no, 41.3%; yes, 31.5%; P = .023), presence of CAD (no, 47.8%; yes, 29.3%; P < .001), dementia (no, 45.4%; yes, 17.3%; P < .001), nutritional deficiency (no, 39%; yes, 9.1%; P = .005), prior vascular surgery (no, 32.2%; yes, 41.8%; P = .021), preoperative functional status (ambulatory, 55.1%; ambulatory homebound, 20%; transfer only, 13.7%; bedridden, 0%; P < .001), and preoperative living status (independent, 50.4%; nonindependent, 9.4%; P < .001).

Multiple logistic regressions identified independent predictors of not wearing a prosthesis, which are listed in Table I. From greatest to least, preoperative factors associated with not wearing a prosthesis were nonambulation/transfer only before amputation (OR, 9.5), AKA (OR, 4.4), homebound but ambulatory status (OR, 3.0), age >60 years old (OR, 2.7), and the presence of dementia (OR, 2.4), ESRD (OR, 2.3), and CAD (OR, 2.0).

Preoperative factors influencing survival were determined. Survival curves at 1 year were not significantly affected by the preoperative characteristics of diabetes mellitus (P = .99), smoking (P = .24), race (P = .38), or prior vascular surgery (P = .91). Survival at 1 year was significantly affected by the preoperative characteristics of advancing age (<50 years old, 87%; 50 to 59 years old, 75.5%; 60 to 69 years old, 64.3%; >70 years old, 61.4%; P < .001); amputation level (BKA, 75.5%; TKA, 80.8%; AKA, 56.5%; bilateral, 71.4%; P < .001), gender (male, 73.2%; female, 61.9%, P < .001), ESRD (yes, 60%; no, 72.8%; P = .02), CAD (yes, 59.9%; no, 77.8%; P < .001), dementia (yes, 59.2%; no, 71.4%; P = .001), nutritional deficiency (yes, 34.9%; no, 69.5%; P = .006), diagnosis of lower extremity PAD (yes, 66.7%; no, 83.6%, P = .006), preoperative functional status (ambulatory, 79.8%; ambulatory/home-

Table I. Multiple logistic regression model results for prediction of not wearing prosthesis after amputation

Patient characteristic	*OR estimates (95% CI)*	P
Prefunctional status		
Ambulatory	— Referent	—
Amb/homebound	3.0 (1.5, 6.2)	.002
Nonambulatory/transfer	9.5 (4.5, 20.2)	<.001
Age group		
<50	— Referent	—
50-59	1.3 (0.6, 2.8)	.581
60-69	2.8 (1.4, 5.8)	.005
≥70	3.0 (1.4, 6.2)	.003
Level of amputation		
BKA/TKA	— Referent	—
AKA	4.4 (2.6, 7.4)	<.001
Bilateral	1.7 (0.9, 3.2)	.11
ESRD		
No	— Referent	—
Yes	2.3 (1.5, 3.7)	<.001
CAD		
No	— Referent	—
Yes	2.0 (1.3, 3.2)	.002
Dementia		
No	— Referent	—
Yes	2.4 (1.3, 4.1)	.003

OR, Odds ratio; *CI,* confidence interval; *BKA,* below knee amputation; *TKA,* through knee amputation; *AKA,* above knee amputation; *ESRD,* end-stage renal disease; *CAD,* coronary artery disease.

Table II. Cox proportional hazards model results for analysis of time to death after amputation

Patient characteristic	*HR estimates (95% CI)*	P
Prefunctional status		
Ambulatory	— Referent	—
Amb/homebound	1.1 (0.7, 1.6)	.83
Nonambulatory	2.0 (1.4, 2.7)	<.001
Age group		
<50	— Referent	—
50-59	2.4 (1.3, 4.5)	.007
60-69	2.5 (1.4, 4.5)	.005
≥70	3.1 (1.8, 5.4)	<.001
CAD		
No	— Referent	—
Yes	1.5 (1.2, 2.0)	.003
Diagnosis		
BKA/TKA	— Referent	—
AKA	0.9 (0.6, 1.2)	.046
Bilateral	0.6 (0.4, 0.9)	.003
Prosthesis wear post-op		
No	— Referent	—
Yes	0.2 (0.2, 0.3)	<.001

HR, Hazard ratio; *CI,* confidence interval; *CAD,* coronary artery disease; *BKA,* below knee amputation; *TKA,* through knee amputation; *AKA,* above knee amputation.

Table III. Cox proportional hazards model results for analysis of ambulatory deterioration/failure after amputation

Patient characteristic	*HR estimates (95% CI)*	P
Prefunctional status		
Ambulatory	— Referent	—
Amb/homebound	1.6 (1.1, 2.2)	.008
Nonambulatory/trans	0.6 (0.4, 0.9)	.014
Age group		
<50	— Referent	—
50-59	1.6 (1.0, 3.0)	.10
60-69	1.6 (1.0, 2.8)	.07
≥70	2.3 (1.4, 3.9)	.002
Level		
BKA/TKA	— Referent	—
AKA	1.6 (1.2, 2.2)	.003
Bilateral	1.8 (1.3, 2.7)	.002
ESRD		
No	— Referent	—
Yes	1.4 (1.1, 1.8)	.020

HR, Hazard ratio; *CI,* confidence interval; *BKA,* below knee amputation; *TKA,* through knee amputation; *AKA,* above knee amputation; *ESRD,* end-stage renal disease.

bound, 69.4%; transfer only, 53.2%; bedridden, 22.2%; $P < .001$), preoperative independence status (independent, 78.7%; nonindependent, 42.6%; $P < .001$), and prosthesis wear postoperatively (yes, 96.7%; no, 48.5%; $P < .001$).

Cox proportional hazards models were used to derive preoperative factors independently associated with death (Table II). In decreasing order of influence they included age ≥70 years (HR, 3.1), age 60 to 69 (HR, 2.5), age 50 to 59 (HR, 2.4), nonambulatory/transfer (HR, 2.0), and the presence of CAD (HR, 1.5). The hazard of death for patients wearing a prosthesis after amputation, adjusting for prefunctional status, presence of CAD, age, and diagnosis, was 80% less than that for patients not wearing a prosthesis.

Preoperative factors that significantly affected the Kaplan-Meier curves for ambulatory failure were determined. Postoperative ambulation at 1 year was not significantly different when considering the preoperative factors of race ($P = .27$), diabetes mellitus ($P = .06$), history of smoking ($P = .13$), diagnosis ($P = .12$), prior vascular surgery ($P = .54$), or preoperative living status ($P = .41$).

Preoperative factors that significantly influenced the cumulative proportion of patients (excluding nonambulatory/bedridden patients) who maintained their preoperative ambulation status at 1 year included advancing age (<50 years old, 77.1%; 50 to 59 years old, 66.3%; 60 to 69 years old, 56.8%; >70 years old, 39.6%; $P < .001$), amputation level (BKA, 66.6%; TKA, 61.6%; AKA, 44.5%; bilateral, 42.6%; $P < .001$), gender (male, 61.2%; female, 45.9%; $P < .002$), ESRD (no, 56.6%; yes, 52.6%; $P = .037$), CAD (no, 62.5%; yes, 48.9%; $P = .002$), dementia (no, 58%; yes, 45.4%; $P = .009$), and preoperative functional status (ambulatory, 58.9%; ambulatory/homebound, 23.2%; transfer only, 70.3%; $P < .001$).

Cox-proportional hazards models were used to derive independent preoperative factors independently associated with failure of ambulation (Table III). In decreasing order of influence they included age >70 (HR, 2.3), age 50 to 69 (HR, 1.6), bilateral amputation (HR, 1.8), homebound ambulator (HR, 1.6), and ESRD (HR, 1.4).

Preoperative factors that significantly affected independent living after surgery were determined. Life-table curves for maintenance of independent living status were not significantly different at 1 year for the preoperative characteristics of race ($P = .5$), gender ($P = .06$), diabetes mellitus ($P = .28$), history of smoking ($P = .054$), nutritional status ($P = .10$), diagnosis ($P = .31$), or prior vascular surgery ($P = .99$).

Preoperative factors that significantly influenced the cumulative proportion of patients (excludes preoperative nonindependent patients) who maintained their preoperative independent status at 1 year included advancing age (<50 years old, 90%; 50 to 59 years old, 86.5%; 60 to 69 years old, 73.6%; >70 years old, 55.5%; $P < .001$), amputation level (BKA, 82.1%; TKA, 78%; AKA, 51.4%; bilateral, 78.7%; $P < .001$), CAD (no, 78.4%; yes, 67.4%; $P = .019$), dementia (no, 76.8%; yes, 57.1%; $P = .009$), and preoperative functional status (ambulatory, 77.9%; ambulatory/homebound, 46.4%; transfer only, 66.7%; $P < .001$).

Cox proportional hazards models were used to derive preoperative factors independently associated with failure to maintain independent living status (Table IV). In decreasing order of influence they included age >70 (HR, 4.0), age 60 to 69 (HR, 2.7), AKA level of amputation (HR, 1.8), homebound ambulatory status (HR, 1.6), and the presence of dementia (HR, 1.6).

Table IV. Cox-proportional hazards model showing preoperative factors associated with failure in independent living after amputation

Patient characteristic	*HR estimates (95% CI)*	P
Prefunctional status		
Ambulatory	— Referent	—
Amb/homebound	1.6 (1.1, 2.6)	.041
Nonambulatory	1.2 (0.3, 4.9)	.821
Age group		
<50	— Referent	—
50-59	1.5 (0.6, 4.0)	.410
60-69	2.7 (1.1, 6.5)	.027
≥70	4.0 (1.7, 9.5)	.002
Level		
BKA/TKA	— Referent	—
AKA	1.8 (1.2, 2.8)	.005
Bilateral	1.0 (0.5, 1.9)	.958
Dementia		
No	— Referent	—
Yes	1.6 (1.1, 2.4)	.022

HR, Hazard ratio; *CI,* confidence interval; *BKA,* below knee amputation; *TKA,* through knee amputation; *AKA,* above knee amputation.

DISCUSSION

Because of the aging of our population and the focus of our health-care system on immediate outcomes of acute care, economics will play an ever-greater role in total patient care rendered over the next two decades. Whether overt rationing of care in certain circumstances will occur is unclear. Certainly, therapy will be required to be evidenced-based, adhering to the principle that selected treatment should be the most durable and cost-effective. In the case of lower extremity PAD, for example, it is doubtful that our system will be able to afford a staged treatment approach where a patient who presents with severe lower extremity PAD is first treated with endovascular intervention only for the sake of performing the least invasive intervention first, followed by attempted bypass surgery when the endovascular treatment fails to remedy the ischemia. Further, this regimen will be truly cost prohibitive if the bypass fails and high limb amputation results, with consequent loss of independence and nursing home placement.

Unfortunately this "triumvirate" of treatment failure in patients with PAD is not unusual. It is therefore reasonable to speculate that reimbursement will be linked to evidence-based treatment protocols, where objective findings at presentation will determine appropriate treatment directed toward optimal functional outcomes.

When the aforementioned scenario becomes reality, much clinical research will be required. Determination of the most effective definitive treatment on the basis of objective findings at presentation for lower extremity PAD is no exception. Our group has had a long-standing interest in this, having developed the Lower Extremity Grading System (LEGS) score for the standardization of lower extremity PAD intervention.[7-9] Although this scoring tool attempts to link objective findings at presentation to the most appropriate intervention, it merely previews what we believe will be the future.

As a side observation while testing the LEGS score, we found that major limb amputation did not always portend a poor prognosis. In fact, many amputees maintained ambulation and independent living status despite their disability. We soon realized that any future treatment algorithm designed to maximize functional performance and contain cost must consider including amputation as a best treatment option in certain situations. However, difficulty arose when we tried to define what these situations were. After an unsatisfactory literature search, this investigation was developed.

The literature on lower extremity amputation is voluminous, but only recently have functional outcomes been studied. Traditional reports focused on increased late mortality and the overall disability of amputees, rationalizing aggressive limb salvage revascularization in all but the most desperate cases.[10-12] More recent outcomes studies tend to group large cohorts and provide only general observations regarding patient outcomes. A summary of findings show that older patients with higher-level amputations and senile dementia who lose their limbs because of acute ischemia do poorest after amputation.[13-21] Unfortunately, these recent reports lack the sensitivity to provide worthwhile information for therapeutic decision making. They fail to identify subsets of patients who do well and do not attempt to weight factors found to be detrimental to functional outcome.

Consequently, our study was designed to correlate objective preoperative findings with postoperative functional performance. We also weighted factors detrimental to outcome by using statistically derived odds and hazard ratios. We found that consistently poor performers included patients >70 years, patients with limited preoperative functional ability, and patients who underwent AKA. For example, when looking at Tables I, II, III, and IV, one can see that patients >70 years old experienced a 3 times greater chance of not wearing a prosthesis, a 3.1 times greater chance of death, a 2.3 times greater chance of being nonambulatory, and a 4 times greater chance of losing functional independence at 1 year compared with the referent individuals. Conversely, patients <60 years old who were ambulatory preoperatively and had well-controlled medical comorbidities could anticipate an ambulatory rate of 70%, a 1-year survival of 80%, and an independent living status rate of nearly 90%.

Further interpretation suggests palliative AKA, a treatment traditionally reserved for nonambulatory bedridden patients, should also be performed on older patients who experience nonambulatory/transfer only status (10 times less likely to wear a prosthesis, 2 times more likely to experience death at a year), dementia (2.4 times less likely to wear a prosthesis), CAD (2 times less likely to wear a prosthesis, 1.5 times more likely to die at 1 year), or ESRD (2.3 times less likely to wear a prosthesis, 1.4 times less likely to ambulate), or a combination of these. It is implausible that these patients will ever ambulate. Thus palliative AKA is preferable to BKA, a procedure at higher risk for nonhealing and more prone to pressure ulceration in nonambulators.

These data also suggest that younger functional patients with severe peripheral vascular disease and very poor distal vascular anatomy may be better served with a functional BKA and aggressive rehabilitation than with a high-risk vascular bypass that, after failure, may necessitate a less functional AKA. Unfortunately, the design of the study did not allow us to definitively identify which younger patients might do better with limb amputation than with revascularization, and we believe this area should be the focus of further prospective research. The patients between the two extremes of palliative and functional amputation represent a group that also deserves further study and may benefit from intense risk factor modification and prosthetic limb research to improve their overall functional performance.

As with many studies from our institution that have looked at chronic limb ischemia and functional outcomes, this report mandates further investigation. This study is limited by its retrospective nature, short follow-up, and large size. It, unfortunately, raises as many questions as it answers. An example is the aforementioned problem of which younger patients might function better with a primary amputation. Another might be the functional effect of multiple failed revascularizations on patients undergoing amputation. The amount of data alone—35 single-point statistical comparisons and over 100 Kaplan-Meier life tables—make generalized treatment recommendations difficult. However, the information in this report does provide reference data and identifies patient groups best suited for further retrospective and prospective study.

In summary, functional outcomes after limb amputation can be partially predicted based upon preoperative clinical characteristics. Such information has the potential to direct therapy that can maximize functional performance and contain total cost of the care of a patient with a threatened limb.

Specifically our data suggest that older, sicker patients have a limited capacity for functional rehabilitation and may be best served with a palliative AKA. Conversely, healthier amputees with a BKA achieve functional outcomes similar to those that might be expected after successful lower extremity revascularization. Although further study is needed, BKA in these instances should not be considered a failure of therapy but another treatment option capable of extending functionality and independent living—a concept particularly true if a staged treatment regimen has significant risk of resulting in the long-term disability and dependence associated with AKA.

REFERENCES

1. Pell JP, Donnan PT, Fowkes FG, Ruckley CV. Quality of life following lower limb amputation for peripheral arterial disease. Eur J Vasc Surg 1993;7:448-51.
2. Critical limb ischaemia: management and outcome. Report of a national survey. The Vascular Surgical Society of Great Britain and Ireland. Eur J Vasc Endovasc Surg 1995;10:108-13.
3. Buzato MA, Tribulatto EC, Costa SM, Zorn WG, van Bellen B. Major amputations of the lower leg. The patients two years later. Acta Chir Belg 2002;102:248-52.
4. Van Niekerk LJ, Stewart CP, Jain AS. Major lower limb amputation following failed infrainguinal vascular bypass surgery: a prospective study on amputation levels and stump complications. Prosthet Orthot Int 2001;25:29-33.
5. Ebskov LB, Hindso K, Holstein P. Level of amputation following failed arterial reconstruction compared to primary amputation–a meta-analysis. Eur J Vasc Endovasc Surg 1999;17:35-40.
6. Eagle KA, Brundage BH, Chaitman BR, Ewy GA, Fleisher LA, Hertzer NR, et al. Guidelines for perioperative cardiovascular evaluation for noncardiac surgery. Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Perioperative Cardiovascular Evaluation for Noncardiac Surgery). J Am Coll Cardiol 1996;27:910-48.
7. Taylor SM, Kalbaugh CA, Gray BH, Mackrell PJ, Langan EM 3rd, Cull DL, et al. The LEGS score: a proposed grading system to direct treatment of chronic lower extremity ischemia. Ann Surg 2003;237:812-9.
8. Kalbaugh CA, Taylor SM, Cull DL, Blackhurst DW, Gray BH, Langan EM 3rd, et al. Invasive treatment of chronic limb ischemia according to the Lower Extremity Grading System (LEGS) score: a 6-month report. J Vasc Surg 2004;39:1268-76.
9. Andros MP, Kalbaugh CA, Taylor SM, Blackhurst DW, McClary GE Jr, Gray BH, et al. Does a standardization tool to direct invasive therapy for symptomatic lower extremity peripheral arterial disease improve outcomes? J Vasc Surg 2004;40:907-15.
10. Albers M, Fratezi AC, De Luccia N. Walking ability and quality of life as outcome measures in a comparison of arterial reconstruction and leg amputation for the treatment of vascular disease. Eur J Vasc Endovasc Surg 1996;11:308-14.
11. Perler BA. Cost-efficacy issues in the treatment of peripheral vascular disease: primary amputation or revascularization for limb-threatening ischemia. J Vasc Interv Radiol 1995;6(6 Pt 2 Su):111S-5S.
12. Thompson MM, Sayers RD, Reid A, Underwood MJ, Bell PR. Quality of life following infragenicular bypass and lower limb amputation. Eur J Vasc Endovasc Surg 1995;9:310-3.
13. Nehler MR, Coll JR, Hiatt WR, Regensteiner JG, Schnickel GT, Klenke WA, et al. Functional outcome in a contemporary series of major lower extremity amputations. J Vasc Surg 2003;38:7-14.
14. Davies B, Datta D. Mobility outcome following unilateral lower limb amputation. Prosthet Orthot Int 2003;27:186-90.
15. Cruz CP, Eidt JF, Capps C, Kirtley L, Moursi MM. Major lower extremity amputations at a Veterans Affairs hospital. Am J Surg. 2003 Nov;186:449-54.
16. Larner S, van Ross E, Hale C. Do psychological measures predict the ability of lower limb amputees to learn to use a prosthesis? Clin Rehabil 2003;17:493-8.
17. Campbell WB, Marriott S, Eve R, Mapson E, Sexton S, Thompson JF. Amputation for acute ischaemia is associated with increased comorbidity and higher amputation level. Cardiovasc Surg 2003;11:121-3.
18. Toursarkissian B, Shireman PK, Harrison A, D'Ayala M, Schoolfield J, Sykes MT. Major lower-extremity amputation: contemporary experience in a single Veterans Affairs institution. Am Surg 2002;68:606-10.
19. Haboubi NH, Heelis M, Woodruff R, Al-Khawaja I. The effect of body weight and age on frequency of repairs in lower-limb prostheses. J Rehabil Res Dev 2001;38:375-7.
20. Fusetti C, Senechaud C, Merlini M. Quality of life of vascular disease patients following amputation. Ann Chir 2001;126:434-9.
21. Kazmers A, Perkins AJ, Jacobs LA. Major lower extremity amputation in Veterans Affairs medical centers. Ann Vasc Surg 2000;14:216-22.

Submitted Jan 18, 2004; accepted Apr 6, 2005.

DISCUSSION

Dr Marc A. Passman, (Nasvhille, Tenn). I would like to thank the society for the invitation to discuss this paper and Dr Taylor and colleagues for sending their well-written manuscript in a timely fashion.

The premise here is that as the economics of our health-care system evolve, reimbursement may soon be linked to evidence-based treatment protocols where clinical decision making at the time of presentation will be directed toward the best potential and most cost-effective outcome. The dilemma soon facing vascular surgeons and our patients may be whether our health-care system will be able to afford the staged approach of limb preservation, which at times involves multiple endovascular procedures followed by open bypass, re-do bypass, expensive wound care, and toe amputations, and sometimes leading to limb amputation (below knee followed by above knee) despite these efforts. Or will care just be rationed to primary amputation? From an economic and functional standpoint, will patients be better off with every necessary effort to preserve their limb, or will they be better off with a primary amputation? In other words, are they better off with a fem-pop/chop/chop scenario or just a chop?

The group from Greenville, South Carolina has in the past addressed standardization of lower extremity peripheral arterial disease intervention with tools such as the LEGS score, observing that major amputation did not always portend a poor prognosis. So based on their prior published work, the purpose of this article was to focus on the amputation side of the equation, i.e., do preoperative clinical factors predict postoperative functional outcome after major lower limb amputation?

Over a 6-year period, 627 limb amputations on 553 patients were performed (equating to approximately two amputations per week). A retrospective review of preoperative risk factors was correlated with defined functional outcome parameters through multiple logistic regression analysis. Kaplan-Meier methods were used to assess survival, maintenance of functional status, and maintenance of independent living status. In short, to summarize their findings: patients with limited preoperative ambulatory status, advanced age, dementia, end-stage renal disease, and advanced coronary artery disease did poorly, whereas younger healthy patients did well.

In this regard, the authors have confirmed what we know intuitively. The problem here is that the patients identified in this study who did well functionally after major lower limb amputation are likely the same patients who would do well functionally after a vascular operation, and the patients who did poorly after amputation are likely the same patients who would do poorly after a vascular operation. However, when it comes to clinical decision making in a "rationing of care model" based on using preoperative factors to predict functional outcomes, the key group we should rather be identifying is patients who would do poorly with efforts at limb preservation, but well—or no worse—with a primary amputation.

This leads to my specific questions. In the manuscript, there is only a passing reference to the fact that 58% of the 553 patients had a prior vascular operation, but it is unclear how many of the 627 limbs had prior vascular operation. Regardless, we need more information about this group. First, for patients (or legs) with prior vascular operations, what was the nature of the failure? How many of these patients did well functionally after both vascular operation and eventual amputation versus how many had a functional stepoff between vascular operation and amputation? Second, for the patients (or legs) who did not have a prior vascular operation, what was the reason for primary amputation? Was it based just on ischemic disease-related factors, or were there preoperative and/or functional factors that lead to this decision? In other words, did you intuitively select primary amputation based on perceived potential functional outcome, thereby biasing some of your results?

Again, an excellent manuscript and presentation. Thank you for allowing me to comment.

Dr Taylor. This study simply scratches the surface, and we realize that you can't do justice to this type of outcomes research with a single-center retrospective study. However, I think it gives some ideas of where we need to work toward. Sadly, we found that about 60% of the amputations that were done occurred with patients who had had previous vascular intervention, many of who had a functioning bypass. I think as we see the proportion of older patients become more prevalent, amputations in this group are going to be more common.

Contrary to what this study might suggest, we do indeed actually try to intervene on some people in Greenville to save legs. But I don't think there is any question that most vascular practices in this room are seeing older, more decrepit patients and the question is, "When somebody presents with a threatened limb and marginal functionality, what do you do? How much effort should you put in to it?" That was sort of the premise of the LEGS score. When a patient presents with certain objective findings, what is the right thing to do?

For example, we have a manuscript on next month at the Southeastern Surgical looking at this from the perspective of patients older than 80 years of age who undergo revascularization, looking exactly at functional outcomes based on condition at presentation. Your point is exactly right: patients that do well, do well, and the ones that do poorly, do poorly. The question is how can we figure this out before surgery in a prospective fashion? How can you decide what is the best therapy for the poor little old lady who is sick and can barely get around and who presents with a threatened limb? How can we better predict people's fate based on objective findings preoperatively? As the financial condition of our health-care system continues to deteriorate, these decisions are going to be huge. Again, we have only scratched the surface with this study.

Dr Ralph Pfeiffer (Mobile, Ala). We have always performed our own amputations over the last 25 years because we do them better and we have a better relationship with the patient. I would be interested to know how many vascular surgeons do their own amputations or do they send them to their orthopaedic colleague. Frankly, it never made sense to me that at that point in time of treatment therapy that you would send them to another individual and, gosh, they put a tourniquet on a leg that is already ischemic for an hour or so to make it totally ischemic to do an amputation. That never made sense to me, so I'd be interested to know: Do most vascular surgeons still do their own amputations?

Dr. Taylor. Raise your hand if you do.

Dr. Pfeiffer. Okay, good. Thank you.

Dr. Taylor. That's pretty good.

Dr Anil Hingorani (Brooklyn, NY). When you have this amount of data and you look at it retrospectively, sometimes it is difficult to find the patient from 1998 and see whether or not they were ambulatory at the time of their amputation or what was going on at that point in time when you looked at it retrospectively. Were these data collected prospectively and entered into a database or were the patients called back . . .

Dr. Taylor. These data were collected prospectively and put in the database. Many of these patients were in the LEGS study database. It is part of the limb health project we have at Clemson University.

Dr John Mannick, (Boston, Mass). How many amputations do you do in proportion to other procedures at your institution?

Dr. Taylor. We perform approximately 3,000 procedures annually in Greenville. One thousand are vascular access procedures for dialysis, 1,000 are endovascular procedures, and 1,000 are open operations. About one-half of the nonaccess procedures are performed to treat limb-threatening ischemia and of those, about 125 are major limb amputations.