Department of Veterans Affairs

Journal of Rehabilitation Research and Development
Vol. 38 No. 4, July/August 2001
Pages 379–384

Predictive factors for successful early prosthetic ambulation among lower-limb amputees

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Abstract—Objective: To predict successful prosthetic ambulation for patients immediately transferred to an inpatient rehabilitation facility after amputation surgery. **Methods**: Seventy-five individuals with lower-limb amputation were studied at a tertiary acute care and rehabilitation facility. Successful prosthetic ambulation, defined as the ability to ambulate with a prosthesis at least 45 m, was measured in addition to other key demographic and medical factors. **Results**: Sixty-eight percent were successful prosthetic ambulators at rehabilitation discharge. The absence of residual-limb contracture and a longer length of stay during rehabilitation showed a significant relationship to successful prosthetic ambulation with regression analysis. Younger age was modestly correlated to outcome. There were no significant differences when comparing success of the early rehabilitation program with surgical level or etiology of amputation. For successful prosthetic users, mean wear time at rehabilitation discharge was 5.7 hours with a mean distance walked of 67 m. Of those who failed this approach, 70% were related to a failure of wound healing. **Conclusions**: In this cohort, 68% of patients who were selected for a trial of early prosthetic rehabilitation ambulated using a prosthesis at rehabilitation discharge. This approach appears to be more effective for younger patients without contractures who are medically stable to participate in the rehabilitation process.

Key words: *amputation, outcomes, prosthesis, rehabilitation.*

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INTRODUCTION

Lower-limb amputation can cause permanent disability if mobility issues are not addressed through rehabilitation. The goals of rehabilitation are to improve an individual's functional mobility and to successfully reintegrate the patient into the community. Rehabilitation that begins soon after surgery has been felt to have a number of advantages such as minimizing phantom and residual-limb pain and mastering prosthetic ambulation (1). One study also proposes that immediate post-amputation rehabilitation can be cost-effective by decreasing days spent in acute care (2). Another multicenter study suggests that dysvascular transtibial patients have a decreased life expectancy after amputation (3). Therefore, patients should not wait to begin rehabilitation until the residual limb matures, since this period of healing may represent a major portion of their remaining lifetime (3). However, prosthetic rehabilitation begun too early could potentially cause irritation along the incision, and this could result in residual-limb infection with prolonged length of stays in rehabilitation.

The definition of successful prosthetic ambulation varies from daily use of a prosthesis with or without external support (4) to independence in activities of daily living with or without a prosthesis (5). Previous literature has suggested that age, level of amputation, comorbidities, and cause of amputation can affect the ability to successfully ambulate with a prosthesis (4–11). Given the pressure to make discharge decisions quickly after amputation surgery, it is critical to determine who is appropriate for receiving a trial of early prosthetic rehabilitation. Moreover, patients who can be predicted to do poorly with early prosthetic fitting may be better served by going home, or to a convalescence facility if home discharge is unsafe. Current literature has not determined which factors may predict early, successful prosthetic ambulation after amputation surgery.

The purpose of this study was to determine if specific factors could be identified to predict who would succeed with early prosthetic ambulation. We defined early rehabilitation as direct admission from acute care to inpatient rehabilitation. Successful prosthetic ambulation was defined as the ability to ambulate with a prosthesis at least 45 m as measured at discharge from rehabilitation. To fully assess this approach, we studied patients from the date of surgery through discharge from rehabilitation.

METHODS

Subjects

We reviewed the records of 139 transtibial and transfemoral amputees who had inpatient rehabilitation at our university rehabilitation unit from January 1991 to March 1998. Seventy-five subjects met the inclusion criteria, which stipulated that all patients were admitted to the inpatient rehabilitation unit directly from acute care. Both surgery and rehabilitation had to be performed at our center so that we would have full access to data for the complete episode of care. Patients who had delayed rehabilitation or revision surgery and then rehabilitation were excluded. In addition, all patients must have been admitted to rehabilitation with the goal of becoming independent prosthetic ambulators. Patients admitted for preprosthetic or transfer training only were excluded since prosthetic ambulation was not a goal for these individuals. Subjects with bilateral amputation were included, provided that there was at least a two-year interval between amputations and that they were ambulating with a prosthesis after their first amputation.

Medical records were reviewed after obtaining approval from the university IRB. Both acute care and rehabilitation admissions were reviewed. Multiple independent variables were analyzed for each patient and were chosen based upon review of prior literature (4–6,12,13). The factors included demographics, amputation-specific data, blood chemistry, and type of rehabilitation care. Unless otherwise specified, data could be obtained from either the acute care or inpatient rehabilitation admissions. While the rehabilitation protocol was not formally studied, the approach was consistent at our institution. Surgical levels were decided by the operating surgeon with an attempt to maximize residual limb length. Physiatric evaluations were completed postoperatively on all patients. Residual-limb edema was managed with ace wraps or residual-limb shrinkers in most patients. The prosthetic socket was casted from an impression of the limb and fabricated with carbon-reinforced laminate with the use of endoskeletal construction. Strengthening, range of motion, weight acceptance, and gait mechanics were then addressed, and patients received three to four total therapy sessions per day on weekdays and one to two sessions per day on weekends while on the rehabilitation unit.

Each patient was classified as either a successful or failed prosthetic user, based on whether the patient ambulated at least 45 m with a prosthesis by the time of discharge from the rehabilitation unit as measured by the physical therapist. Use of assistive devices such as walkers or canes was permitted. Subjects were considered to be prosthetic failures if they only used the prosthesis for transfers, walked less than 45 m, or did not use a prosthesis at the time of rehabilitation discharge. Patients who were transferred out of rehabilitation because of medical instability were considered failures.

Data Analysis

Statistical analysis was performed with SAS-PC software (SAS Institute, Cary, North Carolina). We compared patients based on whether they were successful prosthetic users or failures using either the t-test for continuous data, Mann-Whitney U test for ranked data, and Chi square for categorical data. Continuous data were expressed as mean ± standard deviation. In order to determine possible trends given the retrospective study design, an exploratory analysis was initially performed.

Two different regression models were then developed. The outcome factor was the success or failure of ambulating 45 m with the prosthesis. As the outcome was dichotomous, we used stepwise logistic regression. A statistical model was developed by including factors that had been highly (<0.001) significant at a univariate level. The decision to use highly significant factors in the model was based on limiting the number of factors that can reasonably be entered into a regression model with the number of subjects enrolled in the study. Factors that were found to have high correlations with other factors in the model were eliminated to allow for convergence of the model. As age has been shown to be a confounding factor for success in previous research, we controlled it in the model. The second model was a clinically relevant model that included factors that have been shown to have a significant relationship to success of outcome in previous research (4–6,13). Factors included in this model were age, phantom pain, wound drainage upon admission to rehabilitation, amputation level, diabetes, and residual limb contracture. As in the previous model, age was also controlled.

RESULTS

Seventy-five patients were included in the study, with 87 percent white (n=65), 12 percent African American (n=9), and 1 percent Hispanic (n;e11). The majority were male (59 percent), and individuals with amputation at the transtibial level made up 71 percent of the total population. The most common reason for amputation was peripheral vascular disease with or without diabetes (81 percent), followed by trauma (16 percent), then tumor (3 percent).

Of the total cohort, 68 percent (51 of 75 subjects) attained successful prosthetic ambulation by discharge from the rehabilitation unit. No significant differences were observed when comparing success of the early prosthetic rehabilitation program to level of amputation or etiology of the amputation (**Table 1**). Successful ambulators had a significantly higher rehabilitation length of stay (20.9 days±8.4) compared to the nonusers (13 days±6.5). There were no significant differences in the acute care LOS, although large variations were noted in the successful group because of a few outliers. The onset time to begin rehabilitation was comparable between groups. All other measured variables are listed in **Table 1**. Of those who were successful prosthetic users, mean wear time at rehabilitation discharge was 5.7 h with a mean walking distance of 67 m.

The statistical regression model showed that successful outcome was predicted by being of a younger age, staying longer in the rehabilitation unit and having a home nurse upon discharge from rehabilitation (**Table 2**). All other factors dropped out and were not significant. The results of the clinically relevant regression model showed that only absence of residual-limb contracture predicted success of the early rehabilitation program (**Table 3**). All other factors dropped out of the model and were not significant, including age. It should be noted that in both the statistical and clinically relevant models, the confidence intervals and odds ratios for age were close to being significant and not being significant, respectively.

Of the 24 subjects who failed the prosthetic ambulation trial, 70 percent of the failures involved wound issues of the residual limb and included either local infection, dehiscence, or excessive drainage (n=17). Two patients fell on their residual limb, causing hematoma and/or skin breakdown, and five patients were transferred to acute care because of medical reasons unrelated to the residual limb.

DISCUSSION

Our study examined the relationship between a number of critical factors and inpatient prosthetic ambulation training begun shortly after amputation surgery. In a recent study by Pezzin et al., inpatient rehabilitation for persons with trauma-related amputations has been related to improved health and vocational prospects (14). In our cohort, 68 percent of patients were successful prosthetic ambulators with early inpatient rehabilitation. Of those who failed early prosthetic rehabilitation, 70 percent were related to wound healing or wound complications. While this approach has benefits in terms of rapid acceptance and use of a prosthesis, not all patients may be candidates. Delayed fitting may be a better alternative for some individuals and a randomized study comparing early to delayed prosthetic rehabilitation would be useful to determine the most effective approach.

Among all factors examined, the absence of residual limb contracture, increased rehabilitation LOS, visiting nurse upon discharge, and younger age of subject showed a relationship to successful prosthetic outcome. Our data suggest that contractures should be aggressively

Table 1.
Independent variables comparing successful prosthetic users to failures.

	SUCCESS N=51	FAILURE N=24	P VALUE
Etiology			
peripheral vascular #, (%)	40 (67)	20 (33)	0.762^
trauma/other # (%)	11 (73)	4 (27)	
Level			
transtibial # (%)	33 (62)	20 (38)	0.113#
transfemoral # (%)	18 (82)	4 (18)	
Age (years)	58.4 ± 15.7	63.8 ± 12.2	0.138
Sex (male %)	57	62	0.802
BMI	26.2 ± 7.6	26.9 ± 4.6	0.67
Smoker (%)	29	21	0.578
Lives alone (%)	31	46	0.303
Acute care LOS (days)	19 ± 19.5	14.5 ± 9.2	0.179
Rehab LOS (days)	20.9 ± 8.4	13.3 ± 6.5	<0.001*
Albumin (g/dl)	3.2 ± 0.43	3.2 ± 0.48	0.982
Without contracture (%)	94	70	0.008*
Abs lymph. count	1.7 ± 0.70	1.8 ± 0.72	0.639
Calcium (mg/dl)	9.0 ± 0.68	8.5 ± 0.68	0.017*
Drainage at rehab admission (%)	20	29	0.386
Phantom pain (%)	37	32	0.791
Phantom sensation (%)	56	38	0.197
BUN (mg/dl)	17.3 ± 11.3	17.1 ± 11.3	0.947
Creatinine (mg/dl)	1.3 ± 1.3	1.4 ± 1.3	0.783
Assistive device (% not requiring)	8	0	<0.001*
Visiting nurse (%)	62	16	0.001*
Hypertension (%)	43	75	0.01*
Other neurologic (%)	4	17	0.06
Hours of prosthetic use	5.7 ± 2.5	0	0.001*

* Statistically significant
^ Comparing prosthetic outcome to etiology of amputation
# Comparing prosthetic outcome to level of amputation

Table 2.
Results of the statistical regression model.

Factor	Beta	P value	Odds ratio	CI
Age	0.06	0.02	1.07	1.0, 1.1
Length of rehab stay	–0.31	>0.001	0.74	0.6, 0.9
Visiting nurse	2.68	0.002	14.7	2.6, 77.9

Table 3.
Results of the clinically relevant regression model.

Factor	Beta	P value	Odds ratio	CI
Age	0.02	0.21 NS	1.02	0.98, 1.07
Contracture	–1.84	0.009	0.16	0.03, 0.69

NS = not significant

addressed before attempting a prosthetic ambulation trial and preventative strategies such as prone and side lying, the use of soft and rigid splints, and aggressive pain control can be implemented to decrease contracture. It is likely that the rehabilitation LOS was longer with successful prosthetic users because of early identification of failures with appropriate discontinuation of the prosthetic trial. The relationship of a visiting nurse is unclear other than that it may reflect that nursing was deemed important to monitor successful patients at home.

Our study did show modest outcome differences with respect to age in the statistical regression model, and this is consistent with prior literature, which suggested that increasing age negatively affects prosthetic ambulation (4,6,8). However, the data from the clinically relevant model are consistent with Harris et al. (15) and Stewart and

Jain (16) who showed that age did not preclude elderly (over 80 years) active patients from mastering prosthetic rehabilitation. In addition, our data also showed that there were no significant differences between transtibial *versus* transfemoral amputees with respect to the percentage who were successful prosthetic ambulators with the early rehabilitation program. We did not measure parameters such as gait velocity or energy expenditure that most likely would show differences between the surgical amputation levels. However, our data suggest that regardless of surgical level, patients who are appropriately prescreened for receiving an early prosthetic trial have similar chances of success.

Several practical issues were identified from this analysis. The presence of wound drainage at the beginning of inpatient rehabilitation was not predictive of outcome. It is, however, judicious to monitor the amount of wound drainage and to hold prosthetic wear temporarily for 1 to 2 days if drainage or erythema increases. Weiss et al. (5) have suggested that serum albumin and total lymphocyte concentration, which are factors that can identify malnutrition and immunosuppression, respectively, should be monitored and aggressively corrected. Our data did not find a significant relationship to prosthetic outcome, although each patient had nutritional screening, and this was incorporated into the rehabilitation management plan for all patients.

Some consideration should be given to the limitations of the study. While we were able to capture data from the acute and inpatient rehabilitation admissions, the design was retrospective. Our goal was to gain an understanding of variables that contribute to the failure or success in an early prosthetic ambulation protocol. The fact that many independent variables were not significant may reflect the preselection process of enrolling patients thought to have a high probability of success. We would have to study all individuals with amputation, regardless of perceived rehabilitation potential, to measure the overall effects of each variable. Yet, as these data show, not all patients are successful with early rehabilitation, and we have attempted to add to the current literature by controlling confounding variables with our statistical methods.

Use of prosthesis for transfers only is important for certain individuals, but this was not examined because our focus was on prosthetic ambulation. We also did not measure transcutaneous oxygen levels that have been helpful in determining prosthetic success in one report (17). However, in that study, only transtibial amputees were examined, and it was not clear how early after surgery transcutaneous oxygen measurements were employed (17). Future studies should incorporate transcutaneous oxygen measurements to determine if they predict prosthetic outcome. Also, our study design was cross sectional and additional work focusing on longitudinal outcomes would be useful.

In conclusion, 68 percent of patients who were selected for a trial of early prosthetic ambulation were successful at rehabilitation discharge. This approach appears to be more effective for younger patients without contractures who are medically stable to participate in the rehabilitation process. Future clinical investigations should determine the most cost-effective rehabilitation algorithms to allow patients to regain functional independence as soon as possible after limb-loss surgery.

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Submitted for publication May 21, 2000. Accepted in revised form October 30, 2000.