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Risk Factors for Falls in Individuals With Lower Extremity Amputations During the Pre-Prosthetic Phase: A Retrospective Cohort Study

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ABSTRACT

Background: Falls in individuals with lower limb amputations pose significant health concerns. There is little in the literature regarding falls during the pre-prosthetic phase of rehabilitation for persons with lower extremity amputations (LLA).

Objective: To determine the incidence of falls and identify factors associated with falls during the pre-prosthetic recovery phase.

Design: Retrospective chart audit.

Setting: Inpatient rehabilitation program.

Participants: Four hundred and forty individuals with LLA (age = 61.93 ±14.53 years, 73.18% males) who attended inpatient rehabilitation from July 26, 2011 to August 21, 2017.

Interventions: Not applicable.

Main Outcome Measurements: The number of self-reported falls was recorded from the time of surgery to admission for inpatient rehabilitation. Outcomes of interest were any fall (1+ fall) and recurrent falls (2+ falls). A retrospective chart audit was performed on consecutive admissions to an inpatient rehabilitation program.

Results: The incidence of falls was 8.37 per 1000 patient-days. Falls were sustained by 60.9% of the sample. Unilateral trans-tibial amputation was independently associated with an increased risk for recurrent falls, relative risk (RR) 1.59, 95%CI (1.13, 2.23), p=.008. Diabetes mellitus was independently associated with an increased risk for any fall, RR 1.18, 95%CI (1.01, 1.38),

p=.03. Lastly, bilateral trans-tibial amputation was independently associated with a reduced risk of any fall, RR 0.59, 95%CI (0.39, 0.90), p=.014.

Conclusions: Consistent with current literature, diabetes mellitus and a unilateral trans-tibial amputation were risk factors for falling, while a bilateral trans-tibial amputation and increasing age presented new findings as factors associated with decreased falling.

Level of Evidence: Level III

INTRODUCTION

Adults with lower limb amputations (LLAs) have a high occurrence of falls and are faced with unique predisposing and post-surgical factors making them a patient population of interest for falls prevention.[1] The challenges for individuals with LLAs which may result in an increased risk of falls include relearning gait-associated skills, adjusting to changes in weight distribution, dealing with the loss of feedback from the amputated limb, and coordination of the prosthesis and other limbs.[1]

While falls are common in individuals with LLAs, it is important to note that the occurrence of falls varies across the care continuum (e.g., acute surgical ward after amputation, inpatient rehabilitation and community living after rehabilitation).[2] Prospective studies have demonstrated the percentage of people falling varies from 20.5% for acute hospital[3], 35% in inpatient rehabilitation programs[4] to a high of 42.5% in the first 6 months after discharge from inpatient rehabilitation[5]. Even years after successful completion of inpatient rehabilitation programs, more than half of community-dwelling adults with an LLA fall at least once a year, with 33% experiencing 2 or more falls.[6] Consequences of falls also differ across the phases of

care. Falls during inpatient rehabilitation can result in death, injury, a longer length of hospital stay, and greater health care costs.[3] In addition, consequences of falls for community-dwellers include limb fracture, fear of falling, lack of prosthesis use, and social withdrawal compared to individuals with LLA who do not fall.[6,7] The variation in incidence and consequences of falls between these phases highlight a need to understand the unique contributing factors for falls across the continuum of care and life span of these patients.

One area with limited research is the time frame from the amputation surgery to admission to an inpatient rehabilitation program.[2] While Yu et al.[3] evaluated falls within the acute care hospital setting after the amputation, it is important to appreciate that individuals with a new LLA may not transfer directly from the acute care hospital setting to an inpatient prosthesis rehabilitation program. Importantly, individuals with an amputation may be home up to 16 weeks between the time of amputation and admission to an in- or outpatient prosthetic rehabilitation program.[8] The purpose of this study was (1) to determine the incidence of falls and (2) to identify factors associated with falls (i.e., any fall and recurrent falls) in individuals with LLAs during the time from amputation to admittance to an inpatient prosthetic rehabilitation program.

METHODS

Sample

This was a retrospective chart audit of data collected on all admissions from July 26, 2011 to August 21, 2017 at Parkwood Institute Regional Amputee Rehabilitation Program. Admission criteria for the inpatient amputee rehabilitation program were as follows: age 18 years or older with a major LLA (which include unilateral or bilateral amputations at the Symes, trans-tibial, knee disarticulation or trans-femoral amputation levels), had identifiable rehabilitation

goals, was medically stable (i.e., person did not have a medical condition where the investigations or treatments prevented regular participation in the high intensity rehabilitation program), and was mentally and physically ready to enter the comprehensive rehabilitation program. Mental readiness was judged through a step-wise clinical assessment to determine the patient's level of motivation, access to social supports (as required), and state of acceptance of the amputation so they are able to attend to the needs of the limb and willing to learn how to function with and without a prosthesis. People also needed to demonstrate the ability to follow multi-step instructions and form memory, thereby demonstrating learning from session to session in order to meet rehabilitation goals.

Individuals admitted to the inpatient amputee rehabilitation program are not transferred immediately post-operatively, rather they are admitted from home after the incision has healed. This study was approved by the University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects.

Data Collection

Information extracted from patient charts included age, sex, level of amputation, primary etiology, date of amputation, date of admission to the inpatient rehabilitation program and number of days between surgery and admission to rehabilitation was calculated.

Outcome Measures

Self-report of the number of falls over the time frame from surgery to admission to inpatient rehabilitation was obtained by medical staff at admission to the rehabilitation program. A fall was defined as, “an unexpected event in which the participant comes to rest on the ground, floor, or lower level”.[9]

Data Analysis

Demographic and clinical information of the sample was summarized as means and standard deviations, or frequencies and percentages as appropriate. Information was presented as a full sample and then stratified by number of falls into no falls, 1 fall, and 2 or more falls. Comparison between groups (no falls, 1 fall and 2 or more falls) on sample characteristics was performed using one way ANOVA analysis.

The incidence of falls was calculated per 1000 patient-days. There were two outcomes of interest, a person sustaining any fall (1 or more falls) and recurrent falls (2 or more falls). Regression modeling was used to evaluate the association of a priori identified variables as risk factors on the outcomes of sustaining any fall (≥1) and recurrent falls (≥2). Variables of interest as risk factors were age, sex, primary etiology, amputation level, and time from surgery to admission to the inpatient rehabilitation program. Initial analysis involved univariate modified Poisson regression model[10], variables that were statistically significant in this analysis were then included in the multivariable regression. A multivariable logistic regression using backward step-wise modelling (p-value to enter was .05 and p-value for exclusion was .10) was used to determine the factors related to the each of the two fall outcomes. As "any fall" and "recurrent falls" were common outcomes, the adjusted odds ratios will overestimate the relative risk (RR); thus, a modified Poisson regression model was applied to the final logistic models to directly obtain adjusted relative risk values.

In our data analysis, amputation level was modelled as three indicator variables - unilateral trans-tibial amputation, unilateral trans-femoral amputation, and bilateral trans-tibial amputation referenced to the category of other amputation. Etiology was modelled as four indicator variables of diabetes mellitus, peripheral vascular disease, trauma, and infection

referenced to the category of other etiology. All data analysis was performed with SAS (version 9.4, Cary, North Carolina)

RESULTS

Data were obtained from 440 individuals during the time frame of interest. The average age was 61.93 ±14.53 years, 73.2% were males and 55% had diabetes mellitus. Demographic and clinical characteristics of the sample are displayed in Table 1. Unilateral trans-tibial amputation was the most common amputation type (69.8%). The average time from amputation surgery to admission to the inpatient rehabilitation program was 164.06 ±925.91 days, this was not statistically significant among groups stratified by fall status (p=.27).

At least one fall was reported by 60.9% of the sample and within this group, 54.9% reported being recurrent fallers. The number of falls per individual ranged from 0 to 20 with a median of 1 fall per person, for a total of 604 falls within the time frame of interest. The average age of the people who reported falling at least once was 61.73 ±15.75 years and those who reported recurrent falling was 58.79 ±13.67 years, yet non-fallers were the oldest group at 64.75 ±13.85 years. Age was statistically significant (p=.001) among the three groups by fall status. The incidence of falls was calculated as 8.37 per 1000 patient-days.

Results of the univariate modified Poisson regression are presented in Table 2. The variables of age, primary etiology, level of amputation and time from surgery to rehabilitation were used in the multivariable logistic regression. The results for the multivariable regression modelling are summarized in Table 3. From the multivariable regression analysis of the outcome “any fall”, bilateral trans-tibial amputation (relative risk (RR) = 0.59, 95% CI (0.39,0.90), p=.014), p=.018) was protective, while diabetes mellitus (RR = 1.18, 95% CI (1.01, 1.38), p=.033) increased falls risk and age (RR = 0.99, 95% CI (0.986-0.996), p<.001) was just below a

value of 1 which is indicative of no association. In the multivariable regression analysis for the outcome “recurrent falls”, unilateral trans-tibial amputation (RR = 1.59, 95% CI (1.13-2.23), p=.008) increased falls risk and age had the same magnitude and direction of effect as for “any fall” (RR = 0.986, 95% CI (0.978-0.994), p<.001).

DISCUSSION

This study has identified a bilateral trans-tibial amputation as protective against sustaining any fall, while having diabetes mellitus was a risk factor. In contrast, having a unilateral trans-tibial amputation was a risk factor for recurrent falls. This study provides novel findings on falls for adults with LLAs in the continuum of care from surgery to admission into an intensive inpatient prosthetic rehabilitation program.

There is falls risk information for individuals with LLAs during other phases of care. During the post-operative period, defined as the time frame immediately after amputation surgery to surgical discharge from hospital, risk factors for any fall include having a dysvacular etiology, trans-tibial level amputation, and right side amputation.[3] Consistent with our study, Yu et al.[3] also used a retrospective cohort study of consecutive admissions and had a sample size that was comparable, but it was restricted to the acute hospital stay after lower limb amputation. Our results are therefore not directly comparable with Yu et al. as they include the time frame of discharge home after the acute hospital stay prior to admission to inpatient prosthetic rehabilitation. Interestingly, time from surgery to admission to the rehabilitation program was not a significant risk factor for either fall outcome supporting the importance of intrinsic factors and not just exposure to the opportunity to fall.

In the systematic review by Hunter et al.[2], risk and protective factors varied depending on the phase of recovery, so it is not surprising that protective and risk factors were equally variable

in the pre-prosthetic phase of this study. Advancing age was statistically significant for a minimally reduced association with "any fall" and "recurrent falls" in our study, while the existing literature on falls in individuals with LLAs has demonstrated age over 71 years was associated with an increased risk[1,2]. The clinical significance of age in the relationship to falls for individuals with LLAs in the pre-prosthetic stage is limited by the value being so close to unity and the magnitude of association being very small. The lack of an increased association with age as seen in the existing literature may be the result of the physical demands for mobilization in this stage may lead all adults regardless of age not being capable of placing themselves into situations that put them at risk. Nonetheless, further research exploring age as a risk factor is needed.

Bilateral trans-tibial amputation was also found to be protective for "any fall", which has not been identified in the previous falls literature for individuals with LLA. This finding may be related to the fact that individuals with bilateral trans-tibial amputations are more likely to use a wheelchair as their primary mobility aid during this time frame as they are non-ambulatory. In contrast, and consistent with the literature[6,11], individuals with unilateral transtibial amputation are at an increased risk for falling. This may be related to their greater likelihood of using crutches or walkers for short distance ambulation and transfers. The ability to be ambulatory may increase exposure to situations that can result in falls. This finding highlights the underlying mechanisms for the variation in risk factors across the continuum of care.

Consistent with the current literature[3], having diabetes mellitus was identified as a risk factor for falls. Diabetes mellitus is associated with sensory-motor neuromuscular dysfunction, fatigue, and/or pain, affecting gait and creating instability.[12] These deficits can also apply to the

non-surgical limb and therefore highlights that individuals with LLAs with a dysvascular etiology may have compromised function bilaterally.

The risk factors identified in this study have some overlap with risk factors identified in studies of the post-operative phase, suggesting that some factors remain consistent between post-operative and pre-prosthetic recovery. That is, unilateral trans-tibial amputation and diabetes mellitus appear to be risk factors for falls throughout the post-operative and pre-prosthetic phases. From a public health standpoint, it may be more effective to address risk factors that appear across consecutive phases providing a longer period of time to effectively implement prevention strategies. Safe and independent function with crutches or walkers should be a prominent area to focus upon for rehabilitation treatment to ensure competence with the inclusion of fall prevention education for patients upon discharge home.

The unique contributions from this study are that unilateral versus bilateral trans-tibial amputations are related to increased and decreased the risk of falls respectively. Also, the data on recurrent falls is unique in our study as the existing literature has reported findings only in the areas of any falls and injurious falls.[2] Recurrent falls are distinct from any fall as they are likely due to fixed deficits, rather than a random event, that predisposes the individual to falls through continued exposure across many activities. Determination of factors associated with falls and intervention strategies through all stages of recovery will need to consider phase of recovery, setting, and clinical variables.

A strength of the study was the inclusion of all people admitted to the inpatient rehabilitation program over the 6-year time frame. Another strength is that we were able to generate relative risk estimates for the risk factors related to falls evaluated in this study. While all the existing risk factor literature in falls in individuals with LLAs has used logistic regression,

in the occurrence of common outcomes (more than 10% of the sample sustaining the outcome of interest) the odds ratio will over-estimate relative risk. Relative risk is conceptually easier to use clinically to discuss percentage increase in risk rather than speaking about the increased likelihood or odds of an event occurring. Also, we had a large sample size that provided the power to evaluate multiple fall outcomes, in particular the outcome of recurrent falls.

LIMITATIONS

Limitations of this study include that the data were collected retrospectively through chart audit, therefore we were constrained by the type of information that was routinely collected during patient care for our analyses. The use of self-report for falls occurrences has the potential to be subject to recall bias and carries a risk that falls were under reported, this would tend to bias the results to the null. As we did find associations with falls, we assume these risk estimates therefore represent conservative estimates due to the potential effects of recall bias on the reported number of falls. Though the data covered all admissions during the 6 years to our institution, the sample is not representative of all people who have a lower extremity amputation who attend inpatient rehabilitation for prosthetic training and treatment. Future research should consider providing patients with a “falls diary” so that falls and near falls can be recorded in real time. In addition, the incidence of falls was recorded during the time frame from amputation surgery to admission to inpatient prosthetic rehabilitation, which includes both a post-operative inpatient phase and a community-dwelling phase between acute hospital discharge and admission to inpatient rehabilitation. This means that the number of falls that occurred during the pre-prosthetic phase was recorded over a longer period and that our findings are assumed to be conservative estimates since it includes more days.

CONCLUSION

Falls are common among individuals with LLAs during different phases of care and recovery. Consistent with current literature, diabetes mellitus and a unilateral trans-tibial amputation were each risk factors for falling, while older age and a bilateral trans-tibial amputation presented new findings as variables associated with decreased falling. More research in the area of falls in LLAs during the pre-prosthetic phase is needed to identify mental, social, environmental, and other physical variables associated with falls.

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Table 1. Demographic and clinical characteristics of individuals with lower limb amputations on an inpatient amputee rehabilitation program (N=440).

	Mean ± SD or Frequency (%)				
Variable	**Whole Sample (N=440)**	**No Falls (n=172)**	**1 Fall (n=121)**	**2+ Falls (n=147)**	**p-value***
Age (years)	61.93 ±14.53	64.75 ±13.85	61.73±15.75	58.79 ±13.67	.001
Sex (n, % male)	322 (73.2%)	128 (74.4%)	92 (76.0%)	102 (69.4%)	.946

Primary etiology (n, %)					
DM	242 (55%)	87 (50.6%)	68 (56.2%)	87 (59.2%)	.50
PVD	109	49 (28.5%)	30 (24.8%)	30 (20.4%)	
Other	(24.8%)	36 (20.9%)	23 (19.0%)	30 (20.4%)	
	89 (20.2%)				
Amputation level (n, %)					
Unilateral trans-tibial	307	107	84 (69.4%)	116	.01
Unilateral trans-femoral	(69.8%)	(62.2%)	21 (17.4%)	(78.9%)	
Bilateral trans-tibial	67 (15.2%)	30 (17.4%)	5 (4.1%)	16 (10.9%)	
Other	35 (8.0%)	22 (12.8%)	11 (9.1%)	8 (5.4%)	
	21 (4.8%)	13 (7.6%)		7 (4.8%)	
Time from surgery to	164.06	104.90	125.59	264.95	.27
admission (days)	±925.91	±82.14	±126.28	±1594.11	

DM = diabetes mellitus; PVD = peripheral vascular disease; *, statistical analysis from ANOVA for continuous data and chi square for categorical data.

Table 2. Results of univariate modified Poisson regression for relative risk estimates of associations of risk factors to any fall (≥1 fall) and recurrent falls (≥2 falls) in a sample of individuals with lower extremity amputations. (n=440)

Risk Factor	Any Fall (RR, 95%CI)	p-value	Recurrent Falls (RR, 95% CI)	p-value
Age (years)	0.992 (0.987, 0/996)	<.001	0.986 (0.978, 0.994)	<.001
Sex (male)	1.04 (0.88, 1.23)	0.634	1.20 (0.91, 1.59)	0.194
Time from surgery to rehabilitation (days)	1.002 (1.00, 1.004)	<.001	1.0001 (1.00, 1.0001)	<.001
Level of amputation				
Unilateral trans-tibial amputation	1.27 (1.06, 1.53)	.01	1.62 (1.15, 2.28)	.005
Unilateral trans-femoral amputation	0.89 (0.71, 1.12)	.328	0.68 (0.43, 1.07)	.092
Bilateral trans-tibial amputation	0.59 (0.38, 0.91)	.018	0.67 (0.36, 1.24)	.201
Other	Reference		Reference	
Primary etiology of amputation				
Diabetes mellitus	1.12 (0.96, 1.31)	.140	1.12 (0.96, 1.31)	.140
Peripheral vascular disease	0.88 (0.73, 1.06)	.169	0.78 (0.56, 1.09)	.146
Trauma	0.98 (0.76, 1.28)	.903	1.05 (0.67, 1.64)	.821
Infection	0.89 (0.52, 1.54)	.684	1.37 (0.71, 2.66)	.347
Other	Reference		Reference	

RR, relative risk; CI, confidence interval; the relative risk for the reference group for the variables “level of amputation” and “primary etiology of amputation” is 1 and the risk estimates for the other groups within these two categories are relative to the group “other”.

Table 3. Adjusted relative risk estimates for risk factors associated with the outcomes any fall (≥ 1 fall) and recurrent falls (≥2 falls) among individuals with lower limb amputations between surgery and admission to an inpatient amputee rehabilitation program. (n=440)

Outcome	**Variable**	**RR (95% CI)**	**p-value**
Any fall	Age (years)	0.99 (0.986. 0.996)	<.001
	Time from surgery to admission (days)	1.0001 (1.000, 1.0001)	.056
	Bilateral trans-tibial amputation	0.59 (0.39, 0.90)	.014
	Diabetes mellitus	1.18 (1.01, 1.38)	.033
Recurrent falls	Age (years)	0.986 (0.978, 0.994)	.003
	Time from surgery to admission (days)	1.0001 (1.000, 1.003)	.16
	Unilateral trans-tibial amputation	1.59 (1.13, 2.23)	.008

RR = relative risk; CI = confidence interval; bilateral trans-tibial and unilateral trans-tibial amputation variables were dichotomous variables with risk estimate being made relative to the category of "other" levels of amputation.