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Physical Function and Pre-Amputation Characteristics Explain Daily Step Count after Dysvascular Amputation

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Abstract

Background: People with dysvascular lower limb amputation (LLA) achieve one-third of the recommended steps per day and experience severe disability. Although physical function improves with rehabilitation after dysvascular LLA, physical activity remains largely unchanged, and factors contributing to limited daily step count are unknown.

Objectives: To identify factors that contribute to daily step count after dysvascular LLA.

Design: Cross-sectional, secondary data analysis.

Setting: Outpatient rehabilitation facilities.

Participants: Fifty-eight patients with dysvascular major LLA (age: 64 ± 9 years, body mass index: 30 ± 8 kg/m², male: 95%, transtibial LLA: 95%).

Methods: Data were collected by a blinded assessor after dysvascular LLA. Candidate explanatory variables included (1) demographics, (2) LLA characteristics, (3) comorbidities and health behaviors, and (4) physical function. Variables with univariate associations with log steps/day (transformed due to non-normality) were included in a multiple linear regression model

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using backward elimination to identify factors that explained significant variability in log steps/day.

Primary Outcome Measure: The primary outcome, daily step count, was measured with accelerometer-based activity monitors worn by participants for 10 days.

Results: Participants took an average (\pm SD) of 1450 ± 1309 steps/day. After backward elimination, the final model included four variables explaining 62% of the overall daily step count ($P < .0001$): 2-minute walk distance (32%), assistive device use (11%), cardiovascular disease (10%), and pre-amputation walking time (11%).

Conclusions: Average daily step count of 1450 steps/day reflects the lowest category of sedentary behavior. Physical function, cardiovascular disease, and pre-amputation walking time explain 62% of daily step count after dysvascular LLA. Although physical rehabilitation commonly focuses on improving physical function, interventions to increase daily step count after dysvascular LLA should also consider chronic disease and health behaviors that predate LLA.

Level of Evidence: III.

Introduction

People with dysvascular lower limb amputation (LLA), which is an amputation due to complications of diabetes mellitus or vascular disease, report greater disability than 95% of the general population.^{1,2} Dysvascular LLA is a chronic medical condition with complex comorbidity where only 40% of people with dysvascular LLA return to pre-amputation levels of mobility and 50% report dissatisfaction with mobility.^{3,4} In addition, people with LLA due to vascular etiologies participate in the lowest amount of physical activity when compared to people with traumatic LLA and those without LLA.⁵⁻⁷

Physical activity has known benefits for older adults, demonstrating positive relationships with psychosocial functioning, cognition, physical function, and self-reported quality of life.⁸⁻¹⁰ It is notable that physical activity is a cornerstone of chronic disease self-management in diabetes mellitus and peripheral artery disease.^{11,12} Physical activity is recommended to improve glucose control and correction of patho-physiology underlying chronic conditions (eg, inflammation, mitochondrial dysfunction) to decrease risks of morbidity and early mortality.^{11,12} In addition, increased physical activity is associated with a higher quality of life and less disability for older adults.^{13,14}

Despite the known benefits of physical activity, people with dysvascular LLA are remarkably inactive, with data showing average step counts as low as 1721 steps/day.¹⁵ Current rehabilitation practices after dysvascular LLA emphasize improvement in physical function, yet minimal change in daily step count is observed.⁷ Unchanged daily step count after rehabilitation indicates that factors beyond physical function should be intentionally targeted to improve physical activity after dysvascular LLA. Separate studies have demonstrated that greater age, shorter time since amputation, higher comorbidity burden, and dysvascular etiology are associated with lower levels of physical activity after LLA.^{16,17} Unfortunately, people with dysvascular LLA are broadly characterized by advanced age, high number of medical conditions, and poor physical function.^{18,19} These broad

characteristics lack specificity for what conditions and/or factors should be considered when targeting improved physical activity after dysvascular LLA. Therefore, the purpose of this retrospective, cross-sectional study was to identify specific factors that explain daily step count after dysvascular LLA.

Methods

Participants

Participant baseline data from two randomized controlled trials aimed at improving rehabilitation outcomes following dysvascular LLA were combined for the purposes of this cross-sectional study (NCT01929018; NCT02738086). To minimize bias, baseline data were collected after dysvascular LLA by a blinded assessor within participants' homes before group assignment and intervention. The study sample size was determined by the parent clinical trials, and a total of 58 participants were included. The following were inclusion criteria: (1) experienced an amputation above the ankle due to complications of diabetes and/or peripheral artery disease within the past 5 years, (2) 50 to 85 years of age, and (3) using a prosthesis for ambulation. Participants were excluded if they were using a wheelchair as the primary form of mobility, could not complete physical function testing, had an unstable cardiac condition (eg, uncontrolled hypertension, chest pain with physical activity), or if the LLA was performed because of cancer or trauma. Study protocols were approved by the Colorado Multiple Institutional Review Board office (COMIRB#: 13-0179; 15-1586).

Daily Step Count

Daily step count, a measure of physical activity, was monitored using a waist-mounted accelerometer (Actigraph GT3X+/GT3X + BT; Actigraph, Pensacola, FL) worn by participants for 10 days in their free-living environment. Accelerometry is a reliable and valid method of determining physical activity levels in older adults, people with transtibial amputation, and populations with asymmetric and/or slower gait speeds (eg, multiple sclerosis, Parkinson disease).^{20–24} For example, use of a waist-mounted Actigraph GT3X+ accelerometer has demonstrated good to excellent reliability for measuring steps per day for people across varying disability severity and assistive device use (intraclass correlation coefficient [ICC]: 0.77–0.91).²² The 3-axis accelerometers sample acceleration data by a 12-bit analog to digital converter at 60 Hz. Data were processed using commercially available software (Actilife 5/6; Actigraph). A device firmware algorithm filtered baseline noise level to accurately identify steps per 60-second blocks of time (epochs). Steps per day were measured based upon vertical axis accelerometer data (60-second epochs). Nonwear time was identified using an algorithm within the Actilife software that screened accelerometer data to identify time intervals greater than 60 minutes with no accelerometer signal (zero vector counts).²⁵ Days with more than 10 hours of valid wear time were used for data analysis.²⁶ Data were included if the participant had at least 4 days with valid wear time (minimum of 3 weekdays and 1 weekend day).^{27,28} The average daily step count was calculated for days with valid wear time.

Candidate Explanatory Variables

The following four groups of candidate variables for explaining daily step count were used: (1) demographics and anthropometrics, (2) LLA characteristics, (3) comorbidities and health behaviors, and (4) physical function. Measures within each group were tested to identify if they explained a significant amount of the variability in daily step count.

Demographics and Anthropometrics—Age, sex, and body mass index (BMI) are associated with physical activity in the general population and were included as candidate explanatory variables.²⁹ In addition, race/ethnicity and veteran status were considered as explanatory variables of daily step count due to associations with health outcomes.^{30–32}

LLA Characteristics—Level of major LLA and time since amputation were selected as candidate variables because evidence suggested that higher levels of amputation, bilateral involvement, and shorter time since amputation were associated with more severe disability.^{17,33,34} Level of major LLA was dichotomized as transtibial LLA or other (ie, transfemoral LLA, knee disarticulation, bilateral involvement). Residual limb quality and the presence of a wound were explored in this analysis due to the potential influence of prosthesis fit on walking activity.^{33–35} Residual limb quality and presence of a wound was determined using the Chakrabarty scale.³⁶ Construct validity of the Chakrabarty scale was determined using expert consensus of rehabilitation consultants, surgeons, and professors (n = 66) about meaningful aspects of residual limb quality after LLA and consists of 12 items assessing residual limb edema, scar, tenderness, length, shape, joint contracture, bone end, skin sensation, presence of redundant tissue, shape, and additional factors.³⁶ Although reliability of the Chakrabarty scale has not been formally assessed, our research team optimized reliability across raters by conducting regular training with physical therapists who completed the physical examination. Team consensus was used in the event there was a question about scoring of specific items. Presence of a residual limb wound (yes/no) was extracted from the Chakrabarty scale. The individual item scores were summed to obtain a final Chakrabarty score where higher scores indicate more optimal residual limb quality.

Comorbidities and Health Behaviors—Comorbidity burden may be associated with daily step counts after LLA.¹⁷ The Functional Comorbidity Index (FCI) is a self-report questionnaire of the presence of symptomatic chronic conditions known to influence physical function for older adults and people with disabilities.^{37,38} Specific conditions and groups of conditions were extracted from the FCI as potential explanatory variables, including respiratory conditions (eg, asthma, chronic obstructive pulmonary disease), cardiovascular conditions (eg, congestive heart failure, myocardial infarction, coronary artery disease), diabetes mellitus (DM), and peripheral artery disease (PAD). Finally, the combined presence of DM and PAD indicates greater risk for mortality than with only DM or PAD, and therefore was explored as a potential factor influencing daily step count.³⁹

The presence of cognitive impairment is related to more severe disability after dysvascular LLA.^{33,34,40} Cognitive status was assessed using the Folstein Mini-Mental Status Exam (MMSE; Version 1).⁴¹ The MMSE is a cognitive screening tool used with older adults, where participants are asked to respond to basic orientation, attention, and memory

questions. This scale is commonly used to screen for the presence of severe cognitive dysfunction, with lower scores indicating greater cognitive impairment.⁴¹ Only two participants in this study had scores below the cut point for possible cognitive impairment (24 points).⁴² Therefore, the potential influence of MMSE score on daily step count was analyzed as a continuous variable.⁴³

The presence of depressive symptoms was measured using the 15-item Geriatric Depression Scale.^{44,45} Participants responded to yes/no questions about their mood over the past week. A sum of depressive symptoms was used in this analysis, where higher scores indicate greater presence of depressive symptoms. Number of depressive symptoms was selected as candidate explanatory variables due to evidence that depression is related to disability outcomes after LLA of any etiology.⁴⁰

Self-reported smoking history and walking behavior was collected from participants. Prior health behaviors are known to predict future health behaviors, including physical activity.⁴⁶ Participants were asked to estimate the number of hours spent walking per day before LLA. Prior smoking history was included as a candidate explanatory variable due to the association of smoking with physical activity.⁴⁷

Physical Function—Physical function is related to physical activity in older adult populations and rehabilitation outcomes after LLA.^{33,34,48} Trained assessors completed physical function testing within participants' homes. Assessors participated in 1-hour, hands-on training sessions annually to optimize reliability of physical function testing across assessors and participants. Following training, interrater reliability assessment was used to determine competence of performance testing (ICC >0.90). Participants used assistive devices as they deemed necessary to safely complete the performance-based physical function tests.

5-Meter Walk Test (5MWT)—Gait speed (m/s) was obtained by measuring the amount of time, using a handheld stop watch, to walk the middle 5 m of a 10-m walkway. Participants were provided standardized instructions to walk at their everyday, self-selected pace.⁴⁹ After a practice trial, an average from two trials was used for analysis.

2-Minute Walk Test (2MWT)—Participants were provided standardized instructions to cover as much ground as possible during a 2-minute walking period along a walkway.^{50,51} The walkway length was obtained using a measurement wheel and ranged from 6 to 30 m, depending on participant's home environment. The total distance traveled (meters) was used as the outcome value. Use of any assistive device (yes/no) and pain ratings of any bodily location (0–10) were extracted from the 2MWT for this analysis.

Timed Up-and-Go (TUG)—Participants started from a seated position in an 18-in chair, and standardized instructions were used to rise from the chair, using upper extremity support if needed, walk 3 m, turn around, and return to sitting in the chair as quickly and safely as possible.^{52,53} The TUG, performed as quickly and safely as possible, has demonstrated high interrater reliability (ICC = 0.98) and validity for identifying community dwelling older

adults who are at increased risk for falls.⁵³ After a practice trial, an average time (seconds) from two trials was used for analysis.

Prosthesis Evaluation Questionnaire - Mobility Subscale (PEQ-MS)—

Participants completed the PEQ-MS, which was used to quantify difficulty completing mobility tasks while using a prosthesis. The PEQ-MS is a reliable (ICC = 0.77) and valid measure of self-reported mobility difficulty for people with LLA of any etiology.^{54,55} In this questionnaire, participants report the amount of difficulty they have completing mobility tasks (eg, walk, walk in confined spaces, walk upstairs), where 0 indicates inability to complete the task, and 4 indicates no problems. An average across the 12-item questionnaire was used for analysis, where lower scores indicate greater difficulty with mobility.

Analysis Plan

Candidate variables for this study were selected based on theoretic foundations of potential to explain daily step count following dysvascular LLA. Variables were inspected to determine if assumptions of linear regression were met. Candidate variables were normally distributed, where average steps/day were log transformed due to non-normal distribution. Univariate associations between log steps/day (primary outcome) and candidate variables were determined using correlations for continuous variables, *t*-tests for dichotomous variables, and analysis of variance (ANOVA) for categorical variables. Univariate screening was performed to limit candidate variables with analysis of a relatively small sample size. Variables with univariate associations ($P < .10$) were entered into a full generalized linear regression model with backward elimination to develop the most parsimonious final model. Collinearity of candidate variables in the full model was assessed, and only physical function variables (ie, 5MWT, 2MWT, and TUG) were highly correlated ($R > 0.75$). Due to noncollinearity beyond physical function measures, we continued with backward elimination. Backward elimination uses a full generalized linear regression model to eliminate candidate variables (one variable per cycle), with the smallest contribution to the outcome variable until stopping criteria have been met and the final model with significant candidate variables remain (remaining variable significance $P < .10$). Backward elimination is a recommended method of model selection due to assumptions of no bias when starting with the full generalized linear model.⁵⁶ Analyses for this study were conducted using SAS statistical software (SAS Institute Inc., Cary, NC).

Results

Participant descriptive statistics for demographics and candidate explanatory variables are presented in Table 1. Only one participant did not have adequate wear time for a weekend day and was not included in the primary analysis or the average daily step count for the sample ($n = 57$). Average daily step count for participants was 1450 ± 1309 steps/day (median: 942 steps/day; range: 284–5969 steps/day). Log steps/day had significant univariate associations with 10 variables ($P < .10$): residual limb quality, presence of cardiovascular disease, pulmonary disease, MMSE score, pre-amputation walk time, TUG time, 2MWT distance, 5MWT, assistive device use, and PEQ-MS score (Table 2). Backward elimination from the full model resulted in a final model of 2MWT, assistive device use,

presence of cardiovascular disease, and pre-amputation walking time, explaining 62% of variability in log steps/day ($P < .001$). Specifically, greater 2MWT distance, nonuse of an assistive device, absence of cardiovascular disease, and greater pre-amputation walking time were associated with greater daily step count.

Similar results were achieved when conducting a sensitivity analysis to assess the influence of missing physical activity data for the participant with inadequate weekend wear time. The participant took an average of 929 steps/day (range: 706, 1372 steps/day), wearing the accelerometer for an average of 698 minutes over 3 weekdays. Univariate associations and regression with backward elimination results did not differ when including this participant.

Discussion

In this study, we explored candidate variables that may influence physical activity after dysvascular LLA, including demographics, LLA characteristics, comorbid and health behaviors, and physical function. We found four variables that significantly explain variability in daily step count after dysvascular LLA: 2MWT distance, assistive device use, presence of cardiovascular disease, and pre-amputation walk time. The findings suggest that physical function and pre-amputation factors should be considered when targeting increased daily step count after dysvascular LLA.

An average of 1450 steps/day by participants in our sample is categorized as the most sedentary and is less than one-third of the recommended daily step count for people with disabilities or people older than the age of 65 years.^{57,58} High levels of sedentary time have twice the all-cause mortality risk when compared to people who have low sedentary time.⁵⁹ Greater physical activity for people with DM and PAD is associated with greater physical function, psychosocial functioning, and quality of life.^{13,14,60,61} Furthermore, small increases in physical activity can decrease risk of cardiovascular events and all-cause mortality, suggesting that increased physical activity should be a critical target of rehabilitation interventions for people with dysvascular LLA.^{62,63}

Use of an assistive device and 2MWT distance outcomes explained nearly 45% of daily step count after dysvascular LLA, which is consistent with previous research.^{33,34} Rehabilitation has a historic focus on remediation of physical function and activity limitations in an effort to minimize disability. Conventional interventions are effective for improving 2MWT distance, gait speed, and L-test after dysvascular LLA, yet physical function after dysvascular LLA continues to be below clinically meaningful cutoffs upon discharge.^{1,7} For example, a TUG time of 19 seconds or greater is associated with higher risk for multiple falls within 6 months of discharge from inpatient rehabilitation after unilateral transtibial amputation, yet participants in our study who are less than 5 years after LLA had an average TUG time of 20.4 seconds.⁶⁴ The findings of this study demonstrated that low daily step counts had direct univariate associations with multiple measures of physical function.

The significance of pre-amputation characteristics (ie, presence of cardiovascular disease, low walking time) in daily step count after dysvascular LLA is a novel finding. Prior research has identified that vascular etiology, greater age, and comorbidity burden are

associated with lower levels of physical activity after LLA.^{15–17,19} The broad scope of characteristics that define dysvascular LLA and clinical practice guidelines for rehabilitation after LLA provide little guidance for what pre-amputation factors should be considered when targeting improved daily step count.⁶⁵ Although cardiovascular disease and low pre-amputation walking time are not modifiable following dysvascular LLA, personal factors associated with these variables (eg, self-efficacy, motivation) may be particularly important for interventions to improve physical activity.^{66,67} For example, conventional rehabilitation interventions may improve physical function, but unless low self-efficacy and/or motivation are addressed with rehabilitation, increased physical activity following dysvascular LLA may not be achieved.^{7,68–74}

Our results support the use of interventions targeting improved chronic disease self-management to improve daily step counts for people with dysvascular LLA. Chronic disease self-management interventions largely seek to enhance self-efficacy and motivation for positive health behaviors (eg, physical activity, medication adherence) by developing psychosocial skills known to positively influence health outcomes.⁷⁵ Psychosocial skills commonly addressed by chronic disease self-management interventions include self-monitoring, education, barrier/facilitator identification, problem solving, and action planning, among others.^{75,76} Practicing these psychosocial skills with the guidance of a clinician provides an opportunity to collaboratively discuss patient-identified issues that prevent participation in positive health behaviors like walking. For example, a patient with dysvascular LLA may discuss how icy weather, poor socket fit, or fatigue negatively affect physical activity, and the clinician can guide the patient through the problem-solving process for strategies to minimize or remove such barriers.

Study Limitations

The study findings should be considered in light of potential limitations. This is a retrospective, cross-sectional study with a relatively small sample size, largely comprising men within 5 years of unilateral dysvascular transtibial LLA. Although there is sufficient power to identify four variables that explain daily step count after dysvascular LLA, the small sample size limits our ability to detect variables with smaller effect sizes. In addition, the sample size and characteristics (eg, etiology, level of amputation, time since amputation) limit the generalizability of the study findings and the ability to analyze all variables that may influence physical activity after dysvascular LLA. Due to the cross-sectional nature of this study, causality of the explanatory variables on the primary outcome cannot be assessed. Furthermore, there are inherent limitations to self-reported pre-amputation walking time. Based on the study findings and limitations, future prospective studies aimed at identifying variables that influence daily step count at post-LLA phases (eg, acute, >5 years) should have larger sample sizes with a greater proportion of women and objectively quantify daily step count prior to dysvascular LLA.

Conclusion

Daily step count for people with dysvascular LLA is in the lowest category of sedentary activity. Physical function, the presence of cardiovascular disease, and pre-amputation

walking time explain 62% of daily step count in a sample of people with dysvascular LLA who are less than 5 years post-amputation, largely transtibial, and male. Although physical rehabilitation commonly features physical function interventions, strategies to increase physical activity after dysvascular LLA should also consider the influence of chronic disease and health behaviors that predate LLA.

Disclosure

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CME Question

In this study, which of the following is associated with greater daily step count in patients with lower limb amputation?

- a. Use of assistive device
- b. Lesser pre-amputation walking time
- c. Greater 2 minute walking distance
- d. Presence of cardiovascular disease

Answer online at <http://me.aapmr.org>

Table 1

Participant characteristics

	N = 58
Physical Activity	
Steps/day	1450 (1309)
Accelerometer wear time (min)	826 (240)
Demographics and Anthropometrics	
Age (y)	64.4 (9.0)
Sex (% male)	94.8%
BMI (kg/m ²)	30.3 (7.8)
Race/ethnicity	
Caucasian	70.7%
Hispanic	12.1%
African American	10.3%
Native American	6.9%
Healthcare system (% VA)	69.0%
Lower Limb Amputation Characteristics	
Time since lower-limb amputation (months)	16.3 (19.0)
Chakrabarty score	81.3 (15.5)
Presence of residual limb wound	13.8%
Level of amputation	
Transtibial lower-limb amputation	94.8%
Comorbidities and Health Behaviors	
Mini-Mental State Exam Score	28.3 (2.0)
Geriatric Depression Scale Score	3.0 (2.9)
Functional Comorbidity Index (no. of comorbid conditions)	6.3 (2.8)
Diabetes mellitus (DM)	70.7%
Peripheral artery disease (PAD)	56.9%
DM and PAD (% with both diagnoses)	32.8%
Depression	22.4%
Anxiety	20.7%
Degenerative disk disease	34.5%
Cardiovascular disease	86.2%
Pulmonary disease	24.1%
Arthritis	48.3%
Prior smoking history	72.4%
Walking time prior to lower limb amputation (minutes)	355.1 (246.0)
Physical Function	
Use of assistive device	43.1%
Timed Up-and-Go (s)	20.4 (13.7)
2-Minute Walk Test (m)	89.2 (35.8)
5-Meter Walk Test (m/s)	0.81 (0.29)

	N = 58
Pain with gait (0–10)	0.9 (2.1)
Prosthesis Evaluation Questionnaire - Mobility Subscale Score	2.6 (0.8)

Data are mean (SD) unless otherwise specified.

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Table 2

Univariate and multiple regression with backward elimination results

	Full Model		Final Model			
	Adjusted R ² : 0.59, P < .001	Semipartial squared correlations	P value	Adjusted R ² : 0.62, P < .001		
				Semipartial squared correlations	P value	P value
Demographic and Anthropometric						
Age	0.03	.18
Sex	0.02	.31
BMI	0.00	.86
Race	0.01	.94
VA/non-VA	0.00	.91
Lower Limb Amputation Characteristics						
Time since LLA	0.01	.39
Presence of wound	0.02	.34
Chakrabarty score	0.07	.04	0.07003	...
Level of LLA	0.01	.56
Comorbidities and Health Behaviors						
FCI score	0.02	.26
DM	0.01	.53
PAD	0.04	.16
DM and PAD	0.01	.51
Depression	0.01	.61
DDD	0.00	.91
Cardiovascular Disease	0.10	.02	0.08001	0.10
Pulmonary Disease	0.06	.07	0.07004	...
Arthritis	0.00	.77
Anxiety	0.00	.72
MMSE score	0.05	.09	0.0211	...
GDS score	0.04	.12
Prior smoking history	0.02	.31
Pre-LLA walk time	0.14	.005	0.06005	0.11
						< .001

	Full Model		Final Model	
	Univariate squared correlations	P value	Semipartial squared correlations	P value
Physical Function				
TUG	0.27	< .001	0.18	<.001
2MWT	0.45	< .001	0.09	.001
5MWT	0.43	< .001	0.03	.05
Use of assistive device	0.48	< .001	0.05	.009
Pain with gait	0.01	.50
PEQ-MS	0.12	.009	0.00	.82
			Adjusted R ² : 0.59, P < .001	Adjusted R ² : 0.62, P < .001
			Semipartial squared correlations	Semipartial squared correlations
			P value	P value

BMI = body mass index; LLA = lower limb amputation; FCI = Functional Comorbidity Index; DM = diabetes mellitus; PAD = peripheral artery disease; DDD = degenerative disk disease; MMSE = Mini-Mental State Exam; GDS = Geriatric Depression Scale; TUG = Timed Up-and-Go; 2MWT = 2-Minute Walk Test; 5MWT = 5-Meter Walk Test; PEQ-MS = Prosthesis Evaluation Questionnaire – Mobility Subscale.