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Research

Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules

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KEY WORDS

Clinical prediction rule
Lower extremity
Amputation
Leg prosthesis
Rehabilitation outcome

ABSTRACT

Questions: Can rules be developed to predict the risk of non-use of prostheses by people with lower limb amputation following discharge from rehabilitation? Are these clinical prediction rules valid? **Design**: Retrospective and prospective cohort study designs. **Participants**: Consecutive tertiary rehabilitation patients: 135 retrospective (103 males, mean age = 56 years, SD 15) and 66 prospective (58 males, mean age = 54 years, SD 16). **Method**: Medical records were audited for potential predictor variables. Retrospective participants were interviewed at a median of 1.9 years after discharge (IQR 1.4 to 2.5) and prospective participants at a median of 1.3 years (IQR 1.1 to 1.4). **Results**: Clinical prediction rules were identified at 4, 8 and 12 months after discharge, and validated. Amputation levels above transtibial and mobility-aid use were common predictors for all three time frames. At 4 months, if four out of five predictor variables were present (LR+ = 43.9, 95% CI 2.73 to 999+), the probability of non-use increased from 12 to 86% ($p < 0.001$). At 8 months, if all three predictor variables were present (LR+ = 33.9, 95% CI 2.1 to 999+), the probability of non-use increased from 15 to 86% ($p < 0.001$). At 12 months, if two out of three predictor variables were present (LR+ = 2.8, 95% CI 0.9 to 6.6), the probability of non-use increased from 17 to 36% ($p < 0.031$). **Conclusions**: These validated clinical prediction rules have implications for rehabilitation and service model development. **[Roffman CE, Buchanan J, Allison GT (2014) Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *Journal of Physiotherapy* 60: 224–231]**

Introduction

Multidisciplinary rehabilitation following lower limb amputation plays an important role in restoring function for activities of daily living, work and recreation. Amputee rehabilitation service models and clinical practice guidelines for prosthetic prescription vary widely throughout the world and have been developed largely from expert consensus.[1,2] In Western Australia, patients achieve independent transfers and wheelchair mobility during inpatient rehabilitation while prosthetic gait retraining is performed as an outpatient service.[3]

Limited research exists on long-term outcomes in relation to prostheses following discharge from rehabilitation. In particular, there is a lack of quality evidence to inform clinical decisions that may impact on the continued use of prostheses following lower limb amputation.[4–9] In their literature review, Sansam et al[5] called for further investigation of predictive factors to more accurately estimate walking potential because the studies they reviewed reported different predictors; this was probably due to differences in methodology, outcome measures and definitions of prosthetic rehabilitation success.

Some studies have quantified prosthetic rehabilitation success relative to surgery-related outcomes, the duration that the prosthesis is worn as opposed to functional use, or short-term outcomes while individuals were still participating in rehabilitation; other studies have limited their analyses to cohorts with limited rehabilitation potential.[8–11] None of these quantify long-term functional prosthetic use following discharge, which is important in understanding the quality of life of these people. In general, for those with atraumatic causes of amputation there is a decline in health status following discharge and 5-year mortality as high as 77%.[9,12–14] In some cases, prosthetic gait may impair health and wellbeing through associated morbidity (eg, falls, myocardial infarction) and many individuals stop using their prosthesis within 12 months of discharge.[12,15]

Factors associated with prosthetic outcome have been considered in univariate analyses. Pre-operative factors such as comorbidities, age, pre-morbid mobility, medications, skin integrity, ethnicity, socioeconomic status, cognition and social support have been reported as being associated with outcome.[5,6,11,15–18] Weak evidence supports an association between psychological factors, self-efficacy, motivation and outcome.[5] Prosthetic outcome has also

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been associated with postoperative factors including high-level or multiple limb amputation, postoperative complications, wound healing, oedema, contractures, pain, delay to prosthesis, falls, energy cost of gait, and functional factors.[5,6,9,19–26]

Prosthetic outcome is therefore multifactorial and complex. To date, no studies have examined the factors that in combination are able to identify individuals at risk of prosthetic non-use following discharge from rehabilitation. A methodological approach of developing clinical prediction rules has been used in similar prognostic studies (eg, ankle fractures, neck pain)[27,28] and is yet to be established in the area of lower limb amputation. Clinical prediction rules are tools that assist clinicians to make evidence-based decisions and assign patients to interventions and targeted models of care using a parsimonious subset of predictor variables.[27–30] If clinical prediction rules could be generated to accurately identify individuals at risk of early prosthetic non-use, then rehabilitation teams could intervene with targeted models of care and prosthetic innovations to optimise functional outcome and allocation of healthcare resources. Therefore the research questions for this study were:

1. Can rules be developed to predict the risk of non-use of prostheses by people with lower limb amputation following discharge from rehabilitation?
2. Are these clinical prediction rules valid?

Methods

Participants

Inclusion criteria were: at least one recent major lower limb amputation (ie, transtibial level or above); community dwelling and ambulant prior to amputation; Medicare Functional Classification K-level 1 to 4 (from Gailey et al[24]); and had participated in and been discharged from prosthetic rehabilitation at Royal Perth Hospital, which is the state centre for amputee rehabilitation. Royal Perth Hospital rehabilitates 85% of all individuals with lower limb amputation in Western Australia.[3] Individuals with multiple limb amputations were included, as this was important for validity of the clinical prediction rules.

Participants were excluded if they were unable to communicate, did not consent, or were not prosthetic candidates (ie, K-level 0) as assessed collaboratively by the rehabilitation physician and senior physiotherapist. Reasons for K-level 0 categorisation included comorbidities, cognitive impairment, high-level amputation, multiple limb amputation, remaining limb pathology, increased body weight, mental health issues, poor motivation, no social support, poor premorbid mobility or falls history. These participants were monitored through amputee outpatient clinic but remained at K-level 0.

K-level 0 to 4 participants underwent inpatient rehabilitation to achieve independent transfers, wheelchair mobility and discharge home. K-level 1 to 4 participants received the standardised outpatient prosthetic rehabilitation service, as detailed in Appendix 1 (see eAddenda).

An independent research assistant contacted potential participants from the Amputee Physiotherapy Service database to obtain informed verbal consent for the interview. The interview process involved coordinating telephone interviews with country physiotherapists on remote community visits, Aboriginal Health workers, nurses, and the use of telehealth.

Procedure

Clinical prediction rules development

Medical records were audited for potential predictor variables and this was undertaken blind to the interviews. Box 1 outlines the predictor variable domains investigated. All potential variables were dichotomised (eg, amputation cause: atraumatic or traumatic). Receiver Operator Characteristic (ROC) curves were used to generate a threshold for dichotomous classification of continuous variables (eg, age). This was performed with an equal weighting for sensitivity and specificity. Table 1 in the eAddenda details the dichotomous variable classifications.

Medical comorbidities (including mental health issues and musculoskeletal pathology) were recorded and counted for each participant. Charlson Comorbidity Index and Combined Age Charlson Comorbidity Index were calculated from medical comorbidities data.[31]

In the present study, amputation level was classified as transtibial or above transtibial. Bilateral lower limb amputation was defined as having undergone two major lower limb amputations. Participants were classified as able to independently perform the locomotor skill or being dependent (ie, required assistance or unable to perform). Mobility aids were either used or not used, and the aid type was not statistically weighted for its level of support.

The operational definition of a successful prosthetic user was use of the prosthesis for locomotor activities (eg, transfers, standing, walking) on one or more week days. Participants were asked on which days they used their prosthesis and for one day of normal activity how long they wore the prosthesis, how many sit to stands they performed, and the duration they performed prosthetic walking and standing activities.

Prosthetic non-users did not use their prosthesis for locomotor activities on any days. Individuals who only wore their prosthesis for cosmesis were classified as non-users. Non-users were asked

Box 1. Predictor variable domains for prosthetic users and non-users investigated by this study.

Intrinsic predictor variables
- gender
- age
- indigenous status
- metropolitan versus country
- accommodation at discharge: home versus residential care
- medical comorbidities: diabetes type I or II, peripheral arterial disease, cardiac condition, renal failure, stroke, transient ischaemic attack, lower limb pathology
- number of medical comorbidities, including mental health issues and musculoskeletal pathology

Amputation predictor variables
- amputation cause
- amputation level
- bilateral lower limb amputation
- time to second lower limb amputation
- time from amputation to prosthetic milestones: casting, fitting and definitive prosthesis

Functional predictor variables
- mobility level achieved without a prosthesis: wheelchair mobility, transfers, hopping
- independence with donning and doffing prosthesis, and monitoring prosthetic fit at discharge
- mobility aid use at discharge
- mobility level achieved using a prosthesis at discharge: walking indoors, outdoors, stairs, slopes, grass, gravel, uneven terrain, high-level balance activities and running