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ORIGINAL RESEARCH

Cross-Sectional Assessment of Factors Related to Pain Intensity and Pain Interference in Lower Limb Prosthesis Users

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Abstract

Objective: To determine relationships between pain sites and pain intensity/interference in people with lower limb amputations (LLAs).

Design: Cross-sectional survey.

Setting: Community.

Participants: Lower limb prosthesis users with unilateral or bilateral amputations (N = 1296; mean time since amputation, 14.1y).

Interventions: Not applicable.

Main Outcome Measures: Patient-Reported Outcomes Measurement Information System (PROMIS) pain intensity (1 item to assess average pain), PROMIS pain interference (4-item short form to assess the consequences of pain in desired activities), and questions that asked participants to rate the extent to which each of the following were a problem: residual limb pain (RLP), phantom limb pain (PLP), knee pain on the nonamputated side, back pain, and shoulder pain.

Results: Nearly three quarters (72.1%) of participants reported problematic pain in 1 or more of the listed sites. Problematic PLP, back pain, and RLP were reported by 48.1%, 39.2%, and 35.1% of participants, respectively. Knee pain and shoulder pain were less commonly identified as problems (27.9% and 21.7%, respectively). Participants also reported significantly ($P<.0001$) higher pain interference (T-score ± SD, 54.7±9.0) than the normative sample based on the U.S. population (T-score ± SD, 50.0±10.0). Participants with LLAs rated their pain intensity on average ± SD at 3.3±2.4 on a 0-to-10 scale. Pain interference ($\rho = .564$, $P<.0001$) and intensity ($\rho = .603$, $P<.0001$) were positively and significantly correlated with number of pain sites reported.

Conclusions: Problematic pain symptoms, especially RLP, PLP, and back pain, affect most prosthetic limb users and have the potential to greatly restrict participation in life activities.

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Pain is extremely common in people with lower limb amputation (LLA). Up to 90% of people report persistent pain after amputation, including phantom limb pain (PLP) and residual limb pain (RLP).[1-3] PLP refers to pain experienced in the missing limb.[4] Approximately 58% to 79% of people with LLA experience some degree of PLP.[1-3,5] In contrast, RLP is felt in the remaining limb and is often related to issues such as prosthetic socket pressure, skin abrasions, infections, adherent scars, neuromas, or bone spurs.[4] RLP occurs in 61% to 76% of people with LLA.[1-3,5]

Back, contralateral limb, and shoulder pain are also common,[1-3,6,7] affecting up to 71%,[2] 50%,[3] and 31%[1] of people with LLA, respectively. Pain in these sites can result from compensatory strategies adopted when using a prosthesis.[8-11] While the prevalence of PLP and RLP decreases[12] or remains relatively stable over time,[2,3] a study[3] of 812 people with LLA found that intensity and bothersomeness of back pain and contralateral limb pain increase with time. In addition, back pain has been reported

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to interfere with life activities (ie, pain interference) more than amputation-related pain.[13]

Understanding pain characteristics and predictors in people with amputation is important because pain can be associated with poor rehabilitation outcomes. For example, people with PLP and RLP have reported poorer acceptance of the prosthesis and more prosthesis-related restrictions than people without pain.[14] Similarly, 54% of older veterans with LLA reported that pain-related concerns are a barrier to engagement in physical activity.[15] Another study[16] found that back pain, RLP, and PLP all contribute to pain-related disability. In addition, the risk for depression increases in those with chronic back, contralateral, phantom, and residual limb pain.[3]

Previous studies[1-3] have reported pain experiences in people with LLA, but focused primarily on pain prevalence and predictors. Less is known about the relationship between sources of problematic pain and the degree of pain interference and pain intensity experienced. In addition, prior studies[1,3,6] included prosthesis users and nonusers, so results may not characterize pain in the context of prosthesis use.

The purpose of this study was to determine the contributions of pain from 5 sites to individuals' reported pain interference and intensity. We hypothesized that pain from all sites would contribute to both pain intensity and interference. Further, we hypothesized that back pain and RLP would have the strongest relationships with pain interference and intensity because these sites have been identified as worst[1] or most interfering[13] in previous literature.

Methods

This study was an analysis of cross-sectional data collected between December 1, 2011, and August 31, 2014, for development of the Prosthetic Limb Users Survey of Mobility, a self-report measure of prosthetic mobility.[17] Recruitment for the original study was targeted to identify individuals with specific characteristics; 250 people with transtibial amputation from trauma, transtibial amputation from dysvascular causes, transfemoral amputation from trauma, transfemoral amputation from dysvascular causes, and bilateral amputation were sought.

Participants

Eligibility criteria included the following: (1) age ≥18 years; (2) unilateral or bilateral amputation below the hip and at or above the ankle; (3) regular use of a prosthesis to walk; and (4) the ability to read, write, and understand English. People with upper limb amputations were excluded. Procedures were approved by a University of Washington Institutional Review Board. All participants were provided an information statement before participation.

Procedure

Magazine advertisements, mailings, internet postings, and flyers in private and institutional clinics across the United States directed people with LLA to the study website. Interested individuals either completed an electronic survey or contacted study investigators for a paper survey. Individuals who chose the electronic survey were directed to the Assessment Center (Northwestern University, Chicago, IL).[18] Participants who requested a paper survey were mailed a survey and return envelope. Paper surveys were double-entered to minimize data entry errors.[19] All surveys were assessed for completeness and consistency; participants were contacted to resolve missing data or potentially invalid responses, or both.

List of abbreviations:

LLA	**lower limb amputation**
PLP	**phantom limb pain**
PROMIS	**Patient-Reported Outcomes Measurement Information System**
RLP	**residual limb pain**

Survey

Participants completed a survey of standardized outcome measures and health questions, including measures of pain intensity, pain interference, and pain sites. Pain intensity (1 item) and pain interference (4 items) were measured with the Patient-Reported Outcomes Measurement Information System (PROMIS) 29-item profile (PROMIS-29) v1.0 (www.nihpromis.org), a valid and reliable measure of health-related quality of life.[20,21] PROMIS instruments, with the exception of pain intensity, provide scores on the T-score metric with a mean of 50 and SD of 10. Normative scores for PROMIS-29 instruments are based on samples representative of the U.S. general population. A higher score indicates higher levels of the measured trait. Thus, a higher score of pain interference indicates more consequences of pain on participation in desired activities. Pain interference items asked how much pain interfered with day-to-day activities, work around the home, participation in social activities, and household chores over the past 7 days. Pain intensity had respondents rate their average pain over the past 7 days from 0 to 10 (ie, from no pain to the worst imaginable pain). PROMIS depression and anxiety scores were included in the regression model as potential covariates.[22,23]

Participants also rated the extent to which 5 different pain sites were a problem using a 5-option scale from "not at all" to "very much." Pain sites (ie, residual limb, phantom limb, knee, back, shoulder) were chosen by clinical investigators as most relevant to the health experience of people with LLA. Pain at these sites was characterized as "problematic" if the respondent indicated "somewhat," "quite a bit," or "very much." Sites were characterized as "nonproblematic" if the respondent indicated "not at all" or "a little bit." Participants also answered demographic and clinical questions.

Analysis

Demographic and clinical characteristics were summarized using descriptive statistics. Mean pain interference T-scores and pain intensity scores were calculated for the sample as a whole, and for subgroups based on amputation etiology and age. A 1-sample median test was performed to test whether the pain interference T-score for the whole sample was different from the PROMIS norm of 50. Spearman correlations were used to determine the relationship between the number of problematic pain sites and PROMIS pain interference T-scores/pain intensity ratings. Kruskal-Wallis tests were used to assess differences in pain interference T-scores and pain ratings grouped by number of problematic pain sites. Two multiple linear regression models were conducted to look at factors related to pain interference and pain intensity scores. Twenty-one independent variables that were hypothesized to have a relationship with pain were selected and entered into each model. Age, years since amputation, hours of prosthetic use, body mass index, and PROMIS depression and