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Exploring factors influencing low back pain in people with non-dysvascular lower limb amputation: a national survey

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Title page

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Abstract

Background: Chronic low back pain (LBP) is a common musculoskeletal impairment in people with lower limb amputation. Given the multifactorial nature of LBP, exploring the factors influencing the presence and intensity of LBP is warranted.

Objective: To investigate which physical, personal, and amputee-specific factors predicted *presence* and *intensity* of low back pain (LBP) in persons with non-dysvascular transfemoral (TFA) and transtibial amputation (TTA).

Design: A retrospective cross-sectional survey

Setting: A national random sample of people with non-dysvascular TFA and TTA.

Participants: Participants (N = 526) with unilateral TFA and TTA due to non-dysvascular aetiology (i.e. trauma, tumours, and congenital causes) and a minimum prosthesis usage of one year since amputation were invited to participate in the survey. The data from 208 participants (43.4% response rate) were used for multivariate regression analysis.

Methods (Independent variables): Personal (i.e. age, body mass, gender, work status, and presence of comorbid conditions), amputee-specific (i.e. level of amputation, years of prosthesis use, presence of phantom limb pain, residual limb problems, and non-amputated limb pain), and physical factors (i.e. pain provoking postures including standing, bending, lifting, walking, sitting, sit-to-stand, and climbing stairs).

Main outcome measures (Dependent variables): LBP presence and intensity.

Results: A multivariate logistic regression model showed that the presence of two or more comorbid conditions (prevalence odds ratio (POR) = 4.34, $p = .01$), residual limb problems (POR = 3.76, $p<.01$), and phantom limb pain (POR = 2.46, $p = .01$) influenced the *presence* of LBP. Given the high LBP prevalence (63%) in the study, there is a tendency for overestimation of POR and the results must be interpreted with caution. In those with LBP, the presence of residual limb problems (beta = 0.21, p = .01), and experiencing LBP symptoms during sit-to-stand task (beta = 0.22, p = .03) were positively associated with LBP *intensity*, while being employed demonstrated a negative association (beta = - 0.18, p = .03) in the multivariate linear regression model.

Conclusions: Rehabilitation professionals should be cognisant of the influence that comorbid conditions, residual limb problems, and phantom pain have on the presence of LBP in people with non-dysvascular lower limb amputation. Further prospective studies could investigate the underlying causal mechanisms of LBP.

Introduction

Low back pain (LBP) is a common musculoskeletal impairment affecting between 50 to 80% of people with transfemoral (TFA) and transtibial amputation (TTA) [1-3]. While some prevalence studies report that people with TFA experience more LBP than those with TTA [1, 4], other studies show no differences [2, 5]. Regardless of the levels of amputation, LBP has been reported as 'more bothersome' than phantom-or residual-limb pain in people with TFA and TTA [1].

LBP is a multifactorial impairment with physical, personal, and amputee-specific factors contributing to symptoms and disability [6]. Physical factors such as asymmetrical postures (e.g. lifting) [7] and gait patterns (e.g. Trendelenburg gait) [8], reduced spinal muscle strength and endurance [9], and postural asymmetries (e.g. leg-length discrepancy and increased anterior pelvic tilt) [10] may contribute to the intensity of LBP in people with lower limb amputation (LLA). Personal factors identified to influence LBP in the general population include: older age [11], gender, increase in body mass [12], work status [6], and the presence of comorbid conditions (e.g. heart disease, diabetes, depression, and arthritis) [13, 14]. In terms of amputee-specific factors, the presence and intensity of LBP is thought to be worse for people with TFA compared to TTA [1], longer years of prosthetic use [15], and the presence of phantom- or residual-limb pain [2]. The interaction between the physical, personal, and amputee-specific factors is best illustrated using an example. It is common for people with TFA to lateral trunk lean toward prosthetic side during walking (i.e. Trendelenburg gait). As they age, and with greater years of prosthetic use, they may be less able to adapt to this movement strategy and the potential for LBP may increase; which, in the long-term may alter cortical pain mechanisms [16] and contribute to the intensity of LBP.

Given the complex inter-relationship of physical, personal, and amputee-specific factors influencing the presence and/or intensity of LBP in people with LLA, multivariate analyses provide scope for identifying which of these factors are the most influential in people with LLA and may help clinicians focus their treatment on the most critical factors that can modify the presence and intensity of LBP.

To date, the only previous prediction study [2] found the odds for the presence of LBP were less for men (OR = 0.7; 95% CI = 0.5 to 1.0) and older adults (OR = 0.6; 95% CI = 0.4 to 0.9), and increased with household poverty (OR = 1.4; 95% CI = 1.0 to 2.0). The odds for the presence of LBP did not vary across people with TFA or TTA ($p > .05$) and longer years of prosthetic use ($p > .05$). While the study demonstrated the impact of personal factors (i.e. gender, age, and economic status) affecting the presence of LBP, the potential influence of amputee-specific factors such as phantom- and residual-limb pain contributing to the presence and intensity of LBP were not investigated. Moreover, the study included participants with both upper- and lower-extremity amputations which limited the generalisability of study results.

As such, there is a need for further research that aims to: (1) Identify which personal (i.e. age, body mass, gender, work status, and presence of comorbid conditions), and amputee-specific factors (i.e. level of amputation, years of prosthesis use, presence of phantom limb pain, residual limb problems, and non-amputated limb pain) are associated with the *presence* of LBP in people with non-dysvascular LLA. (2) In those who report LBP, identify which physical (i.e. pain provoking postures including standing, bending, lifting, walking, sitting, sit-to-stand, getting in and out of the car, and climbing stairs), personal, and amputee-specific factors are associated with the *intensity* of LBP in people with non-dysvascular LLA.

Methods

Inclusion and exclusion criteria

Participants with unilateral TFA or TTA aged 18 to 65 years with amputation due to trauma and tumours were included. A threshold of 65 years was decided a priori as the focus of the survey was to investigate the LBP prevalence in younger and middle-aged adults with LLA. We included only people with non-dysvascular amputation (i.e. trauma or tumour) because people with non-dysvascular amputation tend to be younger, present with less comorbid conditions, and more active prosthetic users [17-19] than those with non-dysvascular amputation (i.e. peripheral vascular disease and diabetes) [20]. Thus, we sought to investigate a relative young and healthy sample as a way to control for the influence of comorbid conditions that might influence LBP. Furthermore, owing to younger age at the time of amputation, persons with non-dysvascular amputation continue to live with their prosthesis for more years [21] potentially increasing the risk of developing secondary musculoskeletal impairments such as LBP. A minimum prosthesis usage of one year since amputation was chosen similar to previous surveys conducted in this population [5, 20]. Participants with bi-lateral LLA and those with a history of lower back surgery were excluded from the survey.

Design

A cross-sectional survey was administered to a national sample of people with TFA and TTA due to trauma and tumours in XX.

Sample size calculation

This study was powered to be able to estimate the overall prevalence of LBP within a margin of error of ±5%. Based on Dillman's sample size formula [22], 295 participants were required with non-dysvascular TFA and TTA in XX assuming: 95% confidence level and 50/50 split for choosing a 'yes' or 'no' response to the LBP question. Given a recent national survey of the same population had a 56% response rate [3], and that people with TTA are twice as common as TFA [23], it was estimated that 526 surveys would need to be distributed to potential participants.

Survey implementation

A list of potential participants satisfying the inclusion criteria (N = 1268) was extracted *a priori* from the XX Artificial Limb Service (XXXXX) national electronic database (Updated in 2012)

[23]. For confidentially reasons, access to the XXXXX database is restricted only to executive officials of regional artificial limb centres in XX. A simple random sampling method was chosen using an online programme [24] to randomly select participants with non-dysvascular TFA and TTA. Each participant received a personalised cover letter, a letter of invitation from the XXXXX, an informed consent form, the survey questionnaire (Appendix), and a reply-paid envelope with a unique number code. An electronic version of the questionnaire was created in SurveyMonkey® (http://www.surveymonkey.com/) and survey respondents were given the choice of completing either the paper-based or the online survey. The electronic link for the survey was provided in the cover letter with specific instructions to respond either via mail or online, but not both. Participants responding online were requested to provide the unique number code as part of their response. After a period of 3 weeks from the initial mail-out, a reminder letter was sent to all potential respondents to maximise the response rate [25]. The survey was open for a period of 8-weeks.

Measures

The survey questionnaire (Appendix) comprised three sections: 1) Demographic information, including: amputation history and comorbid conditions, 2) LBP presence and characteristics, and 3) Functional activity questions.

Section 1 – Demographic information, amputation history, and comorbid health and pain conditions

Questions forming this section of the survey (Appendix) were adapted from the Trinity Amputation and Prosthesis Experience Scales questionnaire (TAPES) [26]. A good construct, content, and predictive validity has been demonstrated for the TAPES questionnaire [26, 27]. Questions related to age, sex, ethnicity, years since amputation, and years of prosthesis usage were included from the respondent characteristics section of the TAPES questionnaire [26]. Questions on the presence of phantom limb pain, pain in the non-amputated limb, and problems in the residual limb affecting their walking ability were adapted from the comorbid pain conditions section of the TAPES questionnaire [26]. An additional question focusing on presence of comorbid conditions (e.g. heart disease, diabetes, and depression) was included, similar to the previous national survey conducted in this population [3].

Section 2 - Low back pain presence and intensity

The LBP questions (Appendix) were adapted from standardised LBP definition questions recommended by a global panel of LBP experts for conducting prevalence studies [28]. The average LBP intensity over the last 4 weeks was measured on a 0 to 10 Numerical Pain Rating Scale (NRS). The question on 'bothersomeness' due to LBP was adapted from a similar previous survey conducted in persons with LLA [5]. This question was included as it represented the affective dimension of pain [29].

Section 3 - Functional activity questions

Only participants who answered 'yes' to the LBP question "*In the past 4 weeks, have you had pain in your low back region*?" completed Section 3: Functional Activity, of the questionnaire (Appendix). The functional activity questions were developed from the findings of focus groups conducted with people with LLA and LBP [30]. As the functional activity questions were untested in people with LLA, a series of steps were undertaken in piloting functional activity questions prior to administering the surveys.

Step 1 - Questionnaire construction

From the focus group study [30], those functional activities perceived to aggravate LBP symptoms that could be categorised as *'uneven movements and compensatory postures'* were identified. As most of the functional activities identified from the focus group study [30] were already part of the Oswestry Disability Index [31], the questions were modified as: For example, "*Do you often experience pain in your lower back while standing*?" with 'yes' or 'no' responses.

Oswestry Disability Index is a reliable and valid questionnaire specifically investigating the influence of spinal disorders including LBP on functional activities and postures in the general population [31]. The functional activities such as getting up from a chair and getting in and out of car were included as they were indicated to increase LBP symptoms in the focus group study [30].

Step 2 - Content validity

Members of the research team (PH, DR, and LH) reviewed the functional activity questions to ensure content validity [32, 33]. This team included experts in LBP research (PH and DR) and mixed methods (LH). The aim of the peer review was to identify whether the listed functional activities sufficiently captured common everyday activities and postures at work and leisure in persons with LLA. Each team member independently reviewed the functional activity questions twice to identify issues related to wording and organisation of this section of the questionnaire (PH, DR, and LH) [32]. The functional activity questions and responses were modified based on the feedback.

A 'think-aloud' cognitive interview technique with concurrent probing [34] was then conducted with two participants, one with a TFA and another with a TTA. The main advantage of using think-aloud cognitive interview technique is to provide insights on participants' perspectives in understanding the survey questions and responses [34]. Participants were requested to think aloud their thoughts as they completed the questionnaire [34]. Further, participants were asked about any difficulties they had in understanding the questions and in choosing the responses. The questions and responses were modified based on this feedback.

Step 3 - Test-retest reliability

To assess the stability of responses to functional activity questions over two weeks, this section of the questionnaire was sent to a convenience sample of participants (n = 11) with LLA and ongoing LBP. Nine participants completed and returned the repeat surveys. The percentage agreement between the responses over a two-week period was good (kappa (unweighted) = 0.63) [35]. According to Landis and Koch classification [36], this was a substantial agreement. In addition to assessing the test-retest reliability, item non-response was also assessed from the responses over a two-week period. A 100% item response was achieved for the functional activity questions in both instances.

Data coding and verification

The primary investigator (HD) verified the unique number codes of both online and paper responses to minimise overlap of participants' responding through paper and online. The primary investigator (HD) entered the paper responses in Microsoft Excel® and online responses were exported directly to Microsoft Excel®. If there were missing data for LBP 'Yes or No' question and/or missing responses for two or more functional activities in any survey, then it was excluded from analysis [37].

Data analysis

Assumption testing was conducted in accordance with the techniques described by Pallant [38] so to establish the validity of the regression model. Statistical analyses were performed using SPSS version 21 (IBM corporation, Armonk, New York). For all inferential statistics (described below) alpha was set at 0.05.

Factors influencing presence of LBP in people with LLA

A multivariate logistic regression was used to explore the factors influencing presence of LBP. The presence of LBP was considered as the dependent variable, and was measured as a dichotomous variable, i.e. 'yes' or 'no'. The following independent variables were included in the unadjusted analyses: Personal factors included: age, height, weight, body mass index (BMI), work status (Yes/No), and comorbid conditions including heart disease, diabetes, depression, arthritis, kidney disease, Parkinson's disease, and peripheral vascular disease. The number of comorbid conditions reported were categorised as: none, one or 2+ conditions. Amputee-specific factors included: level of amputation (TFA or TTA), years of prosthesis use, and pain conditions such as phantom limb pain (Yes/No), residual limb problems (Yes/No), and non-amputated limb pain (Yes/No).

Unadjusted analyses were performed to assess the individual association between each independent variable and dependent variable [39]. An a priori criterion of $p<.25$ in univariate analysis was chosen to select independent variables for final adjusted analysis [40]. According to Peduzi's recommendations [39], a minimum of 10 events per independent variable is required for logistic regression. For the current dataset, containing 208 participants (139 with LBP, 69 without LBP), a maximum of six independent variables satisfying the a priori criterion ($p<.25$) were chosen for adjusted analysis [39].

Factors influencing LBP intensity in people with LLA

In those who reported presence of LBP, a multivariate linear regression was used to investigate the factors influencing LBP intensity. Given that pain intensity measured on a 0 to 10 NRS, we tested the normal distribution of scores using visual methods (i.e. histogram and Q-Q plot) [41]. Debate exists in the literature in treating NRS as a ratio or ordinal scale [42-44]. As the data were normally distributed, we considered NRS as a ratio scale for the purpose of this study [43].

Independent variables included: Personal and amputee-specific factors as described in the multivariate logistic regression model. Physical factors included pain provoking postures such as standing, bending, lifting, walking, sitting, sit-to-stand, getting in and out of the car, and climbing stairs measured as a dichotomous variable, i.e. 'yes' or 'no'. Unadjusted analyses were undertaken to assess the individual association between each independent variable and dependent variable. Those independent variables satisfying the a priori criterion of $p<.25$ from unadjusted analyses were chosen for final adjusted analysis [40].

Results

Survey response

Of the 526 surveys sent, 36 surveys were returned as non-deliverable. Thus, a total of 490 potential respondents could have completed the survey. We received 213 responses yielding a 43.4% response rate (213/490). Five questionnaires were excluded from the final analysis due to incomplete data (n = 2), blank survey (n = 1), and response by both post and online (n = 2). Thus, 208 questionnaires were included for final analysis.

Participant characteristics

Participant characteristics are presented in Table 1. Most respondents were middle-aged (52±9), men (74%), XX - European (81%), and currently employed (64%). The number of respondents with TTA (n = 130) was greater than those with TFA (n = 78).

Factors influencing presence of LBP in persons with LLA

The results of unadjusted analyses are presented in Table 2. Eight independent variables met the a priori criterion of $p<.25$ (Table 2). As only six independent variables could be included in the adjusted analysis [40], the criterion was further revised to $p<.10$. The predictors: (1) work status, 2) phantom limb pain, 3) non-amputated limb pain, 4) residual limb problems, and 5) presence of 2+ comorbid conditions presented a $p<.01$, and were included in the final adjusted analysis (Table 2).

For the sixth predictor, the independent variable BMI had the lowest p value ($p = .07$) as compared with age ($p = .08$) and weight ($p = .09$) as shown in Table 2 and was included in the final adjusted analysis. Including BMI in the adjusted analysis reduced the sample size for final analysis to 189. As the missing value accounted for greater than 10% of sample size (N = 208), it was deemed appropriate to replace missing data using the multiple imputation approach [45].

Five iterations were performed to estimate the missing data in SPSS. The data from pooled estimates of five iterations were used for final adjusted analysis [45].

In the final adjusted analysis (Table 3), the independent variables such as presence of more than two comorbid conditions (prevalence odds ratio (POR) = 4.34, 95% CI = 1.34 to 14.04, p = .01), presence of residual limb problems (POR = 3.76, 95% CI = 1.84 to 7.68, p<.01), and presence of phantom limb pain (POR = 2.46, 95% CI = 1.24 to 4.89, p = .01) significantly predicted the presence of LBP. Prevalence odds ratios (POR) were presented for all the independent variables. Given the high LBP prevalence (63%) in the study, there is a tendency for overestimation of POR and the results must be interpreted with caution [46].

Factors influencing LBP intensity in people with LLA

In those with LBP (n = 139), thirteen independent variables satisfied the a priori criterion of p<.25 in the unadjusted analyses (Table 4), with all variables having an "n" of at least 130. Thus, it was decided not to compute multiple imputations for the missing data.

Table 5 shows the final multivariate model influencing LBP intensity in people with LLA. Of the 13 independent variables, three were statistically significant. Work status had a negative association with influencing LBP intensity (beta = -0.18, 95% CI = -1.33 to -0.06, p = .03). The presence of residual limb problems (beta = 0.21, 95% CI = 0.20 to 1.47, p = .01), and experiencing LBP symptoms during a sit-to-stand task (beta = 0.22, 95% CI = 0.09 to 1.69, p = .03) significantly predicted the intensity of LBP in people with LLA. Our model F ((13,120) = 5.03, p < .0005) explained 28.3% (adjusted R squared=0.283) of variance in LBP intensity.

Discussion

This study is the first to test which physical, personal, and amputee-specific factors influenced the *presence* and *intensity* of LBP in people with TFA and TTA. After adjusting for potential confounders, the presence of LBP was associated with presence of two or more comorbid general health conditions, residual limb problems, and phantom limb pain ($p < .05$) (Table 3). In those with LBP, the presence of residual limb problems, and experience of LBP symptoms during a sit-to-stand task had a positive association with LBP intensity, while work status had a negative association with LBP intensity in the multivariate regression model (Table 5).

Factors influencing presence of LBP in people with LLA

The presence of two or more comorbid conditions significantly predicted the presence of LBP. It must be noted that, the POR reported in the present study should not be interpreted as risk ratios due to high LBP prevalence (63%) in this population. For example, a POR of 4.3 for the independent variable (i.e. presence of 2+ comorbid conditions) translates to a risk ratio below 2.0 when the outcome is this common (63%) [47]. Thus, the risk is less than 2-fold for reporting the presence LBP in those with 2+ comorbid conditions. Therefore, misinterpreting a POR of 4.3 as 4-fold increase in the risk of reporting the presence of LBP is not recommended [46].

Similar to the present study, positive association between comorbid conditions and LBP has been previously reported in the general population [14]. Several possible mechanisms have been proposed to explain the relationship between comorbid health conditions and LBP in the general population [48]. For example, presence of comorbid conditions (e.g. heart disease and diabetes) can directly increase the risk of developing LBP via altered physiological mechanisms (i.e. viscerosomatic reflex) [14, 48]. Furthermore, psychological, behavioural, and social adjustments to chronic health conditions and associated disability may impair coping strategies of an individual thereby increasing the risk of reporting LBP [14]. It is also plausible that LBP onset could consequently increase the risk of developing comorbid conditions via dysregulated physiological mechanisms (i.e. somatovisceral reflex) [48]. Co-existent theory suggests LBP and comorbid conditions can be co-existent with no possible sequences of causality [48]. The presence of depression was also among the comorbid conditions which have been reported to be associated with bothersome LBP in persons with LLA [49]. Presence of depression could lead to dysregulated psychological, emotional, and behavioural adaptive mechanisms resulting in increased pain sensitivity [14] and may be an important factor in contributing to LBP in people with LLA.

The presence of residual limb problems had a strong association with presence of LBP as well as LBP intensity. Suboptimal socket fit and/or comfort is a common physical factor which can jeopardise the mechanics of prosthesis-residual limb interface leading to skin breakdown and pain in the residual limb [50, 51]. Pain in the residual limb can cause people to adapt their gait pattern. Given that these problems are often chronic in people with LLA, the prolonged adaptations in gait patterns (e.g. lateral trunk lean) may, in turn, lead to LBP.

The presence of phantom limb pain was a significant predictor to the presence of LBP. The presence of pain in multiple body sites has the potential to alter cortical pain mechanisms [16], a neurophysiological mechanism in which chronic pain leads to changes in stress-regulation systems [52]. Prolonged activation of stress-regulation systems can create breakdowns of muscle and neural tissue that, in turn, cause more pain resulting in a vicious pain cycle of “pain-stress-reactivity” [52]. Altered cortical mechanisms have been implicated in the causation of phantom limb pain [53]. While it is unclear which of the pain conditions develop immediately after amputation, clinical experience suggest phantom limb pain and/or residual limb pain is often experienced immediately following amputation. The development of phantom limb pain and residual limb pain early after amputation have been shown to increase the risk of depression and affect long term prosthetic outcomes [54]. Future studies could investigate whether early onset phantom limb pain and/or residual limb pain following amputation could increase the risk of developing musculoskeletal impairments, such as LBP and/or non-amputated limb pain, in people with LLA.

Factors influencing LBP intensity in people with LLA

The presence of residual limb problems was associated with increasing LBP intensity (p = .01, beta = 0.21). The presence of residual limb problems secondary to skin breakdown, profuse sweating, and pain in the residual limb is an issue of major importance in people with LLA [55]. Studies have shown that the presence of pain in the residual limb is often associated with depression and phantom limb pain [56] suggesting that this could be an important factor mediating the intensity of LBP.

Getting up from a sitting position was associated with increasing LBP intensity (p = .03; beta = 0.22,). This day-to-day activity is more demanding than walking due to increased muscle work and movement control required performing this task [57]. From the previous focus group study, participants with LLA reported that prolonged sitting often increased their LBP symptoms [30]. Similar to general population, it is possible that prolonged sitting could lead to spinal muscle fatigue in persons with TFA and TTA [58, 59]. Spinal muscle fatigue is common in people with LLA, because decreased spinal muscle endurance and strength has been reported in persons with TFA and TTA with LBP [9]. Furthermore, reduced trunk postural control has been reported in persons with TFA and TTA during sitting [60]. On getting up from a sitting position, fatigue induced deficits in trunk postural control could lead to functional instability and LBP. While evidence suggests increased lumbosacral loading during sit-to-stand task in persons with TFA as compared to general controls [61], further research is required to investigate the spinal movement and muscle characteristics during prolonged sitting and sit-to-stand tasks in persons with TFA and TTA, with and without LBP.

Work status had a negative association with LBP intensity (p = .03, beta = -0.18). The result suggests an employed person is less likely to report severe LBP and the converse is also possible where a person with severe LBP is less likely to hold a job. This result could be explained by workplace LBP taught or self-management strategies, such as pacing the activities and avoiding prolonged postures at work. Psychosocial work factors, such as high job satisfaction, peer support, and financial independence have been shown to decrease the odds of reporting severe LBP [6]. Furthermore, persons being employed could be in a different socio-economic and educated group thereby well-informed in self-managing their LBP symptoms. Firm conclusions could not be made with regards to the association between work status and intensity of LBP as the current study did not investigate the type of work (i.e. physical, desk work, or both) and work-related psychosocial factors (e.g. job satisfaction, job control, and coworker support).

Limitations

The following limitations must be acknowledged in interpreting the results of this study. First, this is a cross-sectional study, and can only detect statistical associations, without being able to assess any causal relationship to LBP.

Importantly, the study included only participants with LLA mainly due to trauma and tumours and hence the results cannot be generalisable to people with LLA due to other causes of amputation (i.e. people with dysvascular amputation). People with dysvascular amputation are often reported to be older at the time of amputation and physically inactive due to the presence of comorbid health conditions preceding the amputation [18]. We sought to investigate a relative young and healthy sample as a way to control for the influence of comorbid conditions that might influence LBP. However, people with dysvascular amputation could be equally at risk of experiencing LBP symptoms following amputation given the supporting evidence between physical inactivity and chronic LBP in the non-disabled population [62]. Future investigations could explore the prevalence and potential factors associated with LBP in people with dysvascular amputation.

Given the multifactorial nature of LBP [6], the present survey did not investigate other key factors associated with LBP such as psychosocial factors (e.g. catastrophising, depressed mood, and anxiety) [6], prosthetic factors (e.g. prosthetic mobility, perceived socket fit and comfort), physical factors (e.g. degree of gait asymmetry) as well as premorbid history of LBP and current use of pain medications and assistive devices. Although a question on depression was included, a specific tool on depression (e.g. Patient Health Questionnaire depression module - PHQ-9) was not utilised. For pragmatic reasons, the aim of the present study investigated only the main personal, amputee-specific, and physical factors associated with LBP. Future investigations could focus on the psychosocial and prosthetic factors for a more thorough understanding of their influence on the presence and intensity of LBP in this population.

Despite the best attempts to increase survey response rates by administering the surveys through both postal and online formats and sending a reminder letter after 3 weeks from the initial mail-out, the response rate was low (40.5%). This may have introduced bias in the results because individuals who have LBP may be more likely to answer the survey than those who have not had LBP. Further, the participant characteristics of non-respondents (66.6%) may differ from those who responded may increase the risk of non-respondent bias [63]. Due to confidentiality reasons, the participant characteristics of non-respondents could not be extracted from the XXXXX database. However, the mean age of the respondents represents the national mean age of people with LLA in XX [23] and therefore less likely to influence our results.

Lastly, the section of the questionnaire on functional activities used in the survey was not fully validated; for example, criterion and construct validity were not examined. These questions were mainly adapted from the Oswestry Disability Index, which is a valid and reliable questionnaire tested in the general population [31]. Therefore, we did not conduct a complete validation procedure for these questions in an amputee population. Based on that, a complete validation procedure for these questions was considered to be beyond the scope of this study. As the questions were untested in the amputee population, the steps undertaken to pre-test the questions by cognitive interviewing with a participant with TFA and TTA, and to establish excellent test-retest reliability provided preliminary evidence for reliability and validity.

Conclusions

Our results from multivariate logistic regression suggest the presence of more than two comorbid conditions, residual limb problems, and phantom limb pain influenced the presence of

LBP in people with lower limb amputation. In those with LBP, the presence of residual limb problems, and experience of LBP symptoms during a sit-to-stand task increased LBP intensity, while being employed reduced LBP intensity in the multivariate linear regression model. Further prospective studies could investigate the underlying causal mechanisms of LBP in people with non-dysvascular lower limb amputation. Importantly, the potential impact of residual limb problems on physical functioning and LBP warrants further research.

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Declaration of interest

The authors report no declarations of interest.

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Section I

1. Date of Birth (dd/mm/yyyy): __/__/____

2. Gender: Male ☐ Female ☐

3. Ethnicity: *(Please mark ■ all that applies to you)*

☐ NZ European
☐ Māori
☐ Samoan
☐ Cook Island Maori
☐ Tongan
☐ Niuean
☐ Chinese
☐ Indian
☐ Other

4. Height: ______ m (ft) _______cm (in) 4.a Weight: _______ kg (lbs)

5. Date of your amputation: _______________

6. Side of amputation: Right____________ Left____________

7. How many years have you used a prosthesis?

__________ Years _________ Months

8. Are you currently working? Yes/No

9. Do you have a troublesome stump that affects your standing/ walking abilities?

☐ No
☐ Yes

If yes, please explain ______________________

10. Do you have pain in the missing part of your limb?

☐ No
☐ Yes

If yes, please explain _____________________

11. Do you have any of the following medical conditions? *(Please mark ■ all that applies to you)*

☐ Arthritis, if yes, please specify what kind if known ____________

☐ Cardiovascular (High blood pressure and heart disease)

☐ Depression, If yes, for how long _________ years

☐ Diabetes

☐ Parkinson's disease

☐ Kidney disease

☐ Peripheral vascular disease (poor blood circulation in arms/legs). If yes, for how long _________ years

12. Do you have any problems with your non amputated leg?

☐ No

☐ Yes

If yes, please explain ______________________

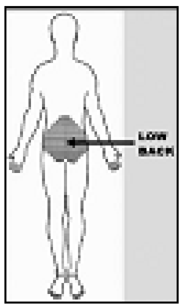
Section II. In this section, you will be asked about trouble you might have had around low back region **(IN THE AREA SHOWN ON THE DIAGRAM)**. Please do not report pain from feverish illness or menstruation. **(Please mark ■ that applies to you)**

2.1 Have you ever had a surgery to your lower back?

☐ No

☐ Yes

If yes, please explain ______________________



2.2. **<u>In the past 4 weeks</u>**, have you had pain in your low back region?

☐ No .... **If no, thanks for completing the survey**

☐ Yes................. **If yes, please continue below.**

If yes, was this pain bad enough to limit your usual activities or change your daily routine for more than one day?

- ☐ No
- ☐ Yes

2.3. If you had low back pain **in the past 4 weeks**, how often did you have the pain?

- ☐ On some days
- ☐ On most days
- ☐ Everyday

2.4. If you had low back pain **in the past 4 weeks**, how long was it since you had a whole month without any low back pain?

- ☐ Less than 3 months
- ☐ 3 months or more but less than 7 months
- ☐ 7 months or more but less than 3 years
- ☐ 3 years and more

2.5. If you had low back pain **in the past 4 weeks**, please indicate what was the usual intensity of your pain on a scale of 0 -10, where 0 is "no pain" and 10 is "the worst pain imaginable"?

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain**

2.6. If you had low back pain **in the past 4 weeks**, how bothersome has your back pain been?

- ☐ Not at all bothered
- ☐ Slightly bothered
- ☐ Extremely bothered

Section III In this section, you will be asked about common activities which may increase your lower-back pain. Please note that there are no right or wrong answers to these questions. Please mark ✓ that you feel best applies to you.

3.1 Do you often experience pain in your lower back while **sitting**? (e.g. reading, driving, watching TV or working at a desk or computer)

Yes ☐ No ☐ ***If no, please go to next question***

a. If yes, approximately how long do you have to **sit** before your back pain is aggravated?

- ☐ <15 minutes
- ☐ 15 minutes – 30 minutes
- ☐ >30 minutes
- ☐ Not sure

3.2 Do you often experience pain in your lower back while **standing**? (e.g. at home and at work etc.)

Yes ☐ No ☐ ***If no, please go to next question***

a. If yes, approximately how long do you have to **stand** before your back pain is aggravated?

- ☐ <15 minutes
- ☐ 15 minutes – 30 minutes
- ☐ >30 minutes
- ☐ Not sure

3.3 Do you often experience pain in your lower back while **lifting**? (e.g. lifting weights at work and at home, etc.)

Yes ☐ No ☐ ***If no, please go to next question***

a. If yes, approximately how long do you have to **lift** before your back pain is aggravated?

- ☐ <5 minutes

- ◻ 5-15 minutes
- ◻ >15 minutes
- ◻ Not sure

3.4 Do you often experience pain in your lower back while **bending**? (e.g. gardening, mopping etc.)

Yes ☐ No ☐ ***If no, please go to next question***

a. If yes, approximately how long do you have to **bend** before your back pain is aggravated?

- ◻ <5 minutes
- ◻ 5-15 minutes
- ◻ >15 minutes
- ◻ Not sure

3.5 Do you often experience pain in your lower back while **walking**? (e.g. at work and at home, walking for recreation, sport, and exercise)

Yes ☐ No ☐ ***If no, please go to next question***

a. If yes, approximately how long do you have to **walk** before your back pain is aggravated?

- ◻ <15 minutes
- ◻ 15 minutes – 30 minutes
- ◻ >30 minutes
- ◻ Not sure

3.6 Do you often experience pain in your lower back while **going up or down the stairs using hand rails**? (e.g. at home and at work etc.)

Yes ☐ No ☐ ***If no, please go to next question***

a. If yes, approximately how many **flights of stairs** do you have to climb before your back pain is aggravated?

- ◻ 3-5 steps

- ☐ 1-2 flights
- ☐ >2 flights
- ☐ Not sure

3.7 Do you often experience pain in your lower back while **getting up from a chair**?

Yes ☐ No ☐

3.8 Do you often experience pain in your lower back while **getting in and out of a car**?

Yes ☐ No ☐

3.9 For each of the following activities, please indicate the **effect of those activities on your lower-back pain.** Please mark ✓ that you feel best applies to you

	No effect on pain	**Minimal effect on pain**	**Moderate effect on pain**	**Severe effect on pain**
Sitting				
Standing				
Lifting				
Bending				
Walking				
Climbing Stairs				
Getting up from a chair				
Getting in and out of a car				

3.10 Are there any **other activities** which make your back pain worse?

Yes ☐ No ☐

If yes, please specify…………………………………………………………

Thank you for your time and consideration. It's only with the generous help of people like you that our research can be successful.

Table 1 Participant characteristics (n = 208)

Variables	Total (%)
Age mean (SD) year	52 (9)
Sex (% Men)	74
Ethnicity (n = 201)*	
NZ - European	169 (81)
Māori	13 (6)
Others	19 (9)
Years since amputation mean (SD) year	21 (13)
Level of amputation	
TFA	78 (37)
TTA	130 (62)
Employed (n = 207)*	
No	74 (36)
Yes	133 (64)

*** Data had missing values**
SD- Standard deviation; TFA-Transfemoral amputation; TTA-Transtibial amputation.

Table 2 Factors influencing presence of low back pain – Unadjusted analyses (n = 208)

Factors	Independent variable	p	Odds Ratio	95% CI for Odds Ratio
Personal factors	Age (years)	**.09**	1.03	1.00 to 1.05
	Height (cm)	.79	1.00	0.97 to 1.03
	Weight (kg)	**.09**	1.01	1.00 to 1.03
	BMI (kg/m^2)	**.07**	1.05	1.00 to 1.10
	Female sex	.10	1.80	0.89 to 3.65
	Work status (Yes/No)	**<.01**	0.35	0.18 to 0.70
	Comorbid conditions 1 (Yes/No)	.27	1.45	0.75 to 2.81
	Comorbid conditions ≥2 (Yes/No)	**<.01**	6.71	2.23 to 20.18
Amputee-specific factors	Level of amputation (TFA or TTA)	.24	0.69	0.38 to 1.28
	Years of prosthesis use	.73	1.00	0.98 to 1.03
	Phantom limb pain (Yes/No)	**<.01**	2.61	1.44 to 4.74
	Non-amputated limb pain (Yes/No)	**<.01**	2.58	1.43 to 4.66
	Residual-limb problems (Yes/No)	**<.01**	4.94	2.54 to 9.60

Dependent variable: Presence of low back pain (Yes/No)
BMI-Body mass index; CI- Confidence interval; LBP-Low back pain; TFA-Transfemoral amputation; TTA-Transtibial amputation.

Table 3 Factors influencing presence of low back pain – Adjusted analysis (n = 208)

Factors	p	Odds Ratio	95% CI for Odds Ratio
Work status	.26	0.65	0.30 to 1.40
BMI	.24	1.04	0.98 to 1.10
Comorbid conditions (≥2)	**.01**	4.34	1.34 to 14.04
Phantom limb pain	**.01**	2.46	1.24 to 4.89
Non-amputated limb pain	.07	1.87	0.96 to 3.62
Residual limb problems	**<.01**	3.76	1.84 to 7.68

Dependent variable: Presence of low back pain (Yes/No)
BMI-Body mass index; CI-Confidence interval; LBP-Low back pain.

Table 4 Factors influencing LBP intensity – Unadjusted analyses

Factors	Independent variable	n	p	95% CI for Beta
Personal factors	Age (years)	136	.61	-0.03 to 0.05
	Height (cm)	128	.26	-0.05 to 0.01
	Weight (kg)	129	.66	-0.01 to 0.02
	BMI (kg/m^2)	124	.46	-0.03 to 0.07
	Female sex	136	.72	-0.87 to 0.60
	Employed (Yes/No)*	136	**<.01**	-1.75 to -0.45
	Comorbid conditions ≥2 (Yes/No)	136	**.14**	-0.09 to 0.66
Amputee-specific factors	Level of amputation (TFA/TTA)	136	**.17**	-0.21 to 1.14
	Years of prosthesis use	136	.32	0.04 to 0.01
	Phantom limb pain (Yes/No)	136	.37	-1.07 to 0.40
	Non-amputated limb pain (Yes/No)	135	**.01**	0.19 to 1.54
	Residual-limb problems (Yes/No)	135	**<.01**	0.61 to 1.90
Physical factors (Pain provoking postures)	Sitting (Yes/No)	136	**<.01**	0.43 to 1.86
	Standing (Yes/No)	135	**<.01**	0.71 to 2.55
	Lifting (Yes/No)	136	**<.01**	0.66 to 1.96
	Bending (Yes/No)	135	**.18**	-0.27 to 1.44
	Walking (Yes/No)	136	**<.01**	0.51 to 2.04
	Stair climbing (Yes/No)	135	**<.01**	0.66 to 1.92
	Sit-to-stand (Yes/No)	135	**<.01**	0.76 to 2.04
	In and out of car (Yes/No)	135	**<.01**	0.59 to 1.89

Dependent variable: Low back pain intensity (0 to 10 Numerical Pain Rating Scale)
***Being employed had a negative relationship with low back pain intensity**
BMI-Body mass index; CI-Confidence interval; n-Number of eligible cases; TFA-Transfemoral amputation; TTA-Transtibial amputation.

Table 5 Factors influencing LBP intensity– Adjusted analysis (n = 132)

Factors	Independent variable	p	Beta	95% CI for Beta	Proportion of variance† %
Personal factor	Employed (Yes/No)*	**.03**	-0.18	-1.33 to -0.06	2.5
Amputee-specific factor	Residual-limb problems (Yes/No)	**.01**	0.21	0.20 to 1.47	3.6
Physical factors (Pain provoking postures)	Sit-to-stand (Yes/No)	**.03**	0.22	0.09 to 1.69	2.6

Dependent variable: Low back pain intensity (0 to 10 Numerical Pain Rating Scale)
† Proportion of variance calculated from part correlation coefficients of independent variables
***Being employed had a negative relationship with low back pain intensity**
Adjusted R^2 value for the model: 28.3%
CI-Confidence interval