

PHANTOM LIMB PAIN RATING SCALE: A SCALE DEVELOPMENT STUDY

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ABSTRACT

Purpose: The aim of this study was to develop a valid and reliable scale to evaluate and measure phantom limb pain.

Material and Methods: This study, which was designed in a methodological type, was conducted with a total of 258 patients. A demographics form and a draft scale developed by the research authors were used to collect the study data. Kuder-Richardson Formula 20 was used to provide descriptive statistics and reliability analyses for the study data. Exploratory Factor Analysis was used in the development of the phantom limb pain rating scale, and Reliability and Confirmatory Factor Analysis were used for the study's validity and reliability evaluations.

Results: The Kuder-Richardson 20 value, which shows the internal consistency of the questions of the 16-item the rating scale, was found to be 0.921. The total score of the rating scale ranged from 1 to 16, with an average of 11.19 ± 4.94 . It was determined that the fit criterias and corrected chi-square values showed acceptable fit, and that the scale was both statistically significant and valid (p=0.001; p<0.01). **Conclusion:** The self-reported scale developed in this study was found to be a reliable and valid measurement tool for evaluating phantom limb pain in affected patients.

Keywords: Amputation, Pain Measurement, Phantom limb pain, Scale, Pain.

INTRODUCTION

Problems following limb amputation can result in insufficiencies that impact the daily living activities of affected patients across different dimensions, potentially causing these individuals to become completely or partially physically, economically, and socially dependent Phantom Limb Pain (PLP) is a common chronic problem following amputation (1). PLP is defined as the experience of pain in a non-existing extremity and the sensation that an amputated extremity is still in place following amputation. The incidence of PLP following amputation is reported to be 49–83%. This subject is worth examining since post-amputation pain can result in functional limitations due to limb loss and can reduce quality of life among affected patients (2-4).

The severity of pain resulting from PLP is based on believing the severity of pain reported by the affected patient. However, patients may not be able to express their pain objectively due to various social and psychological factors. Therefore, the level of severity of the pain should be evaluated using objective pain scales whenever possible. This indicates the importance of using objective pain scales when evaluating the level of pain experienced as a result of PLP (4).

Pain perception, diagnoses, and reactions to pain vary from person to person. For this reason, the patient's pain assessment should be undertaken by taking a detailed anamnesis, continuous close observation, and the use of appropriate measurement tools. Pain is a difficult phenomenon to evaluate and manage due to its subjective nature (1). The first step in pain management, which is one of the most important components of a holistic approach to nursing care in surgical nursing, is to increase the quality of care through accurate diagnosis, the continuous evaluation of pain, and to offer a systematic approach to relieve the individual's pain through successful pain management. The management of PLP poses a challenge for nurses, patients, and the patient's relatives when evaluated together with the psychosocial adjustment problems experienced by the patient following limb amputation (1,2,5). As there is no validated and reliable scale for the diagnosis of PLP in particular, previous studies on PLP use general pain-rating scales.

MATERIAL AND METHODS.

This study was designed and conducted as a methodological study to develop a valid and reliable scale to evaluate PLP in patients who underwent limb amputation for any reason.

Study data were collected between 29 March and 10 May 2021 in a training and research hospital. Before starting the research, ethics committee approval (Decision Date: 07.01.2021, No: 2019/158) was obtained from the Social and Humanities Studies Ethics Committee of Istanbul University-Cerrahpaşa Rectorate. Patients were informed that participation in this research was voluntary, and informed consent was obtained.

Inclusion criteria for patients were as follows: aged 18 years or over; without communication problems; had undergone major limb amputation within the past 1–5 years to exclude stump pain and incision pain; experienced PLP of a severity of at least 3 out of 10 according to the Numeric Rating Scale (NRS), and voluntarily agreed to participate in this study. Patients who met these inclusion criteria participated in this research. Those without PLP, those with an NRS score below 3, and those with incision and stump pain (n=83) were excluded.

The study population consisted of 442 patients who underwent amputation between January 1, 2015 and December 31, 2020 in the Orthopedics and Traumatology Clinic of a training and research hospital in Istanbul. The study sample was determined to be at least ten times the number of items, considering the number of items in the scale and since this number of items should be determined as 5-10 times. Of the 442 patients, 23 could not be reached due to incorrect phone numbers, and 48 people could not be interviewed because they had died. 30 people who experienced phantom limb pain were not included in the sample because a pre-study was made and the questions were modified as a result of the pre-study. 83 of 341 people were excluded from the study because they did not have phantom limb pain. 258 patients, who experienced PLP and whose pain severity was 3 or above out of 10 according to NRS (scores from 3 to 4 indicate mild pain), comprised the study sample.

Research data were collected using the demographics form and the revised Phantom Limb Pain Rating Scale, which was developed by the authors of the present study based on previous studies in the literature.

Demographics Form: The Demographics Form consists of 26 questions created in line with the literature (1,3,5-10).

Phantom Limb Pain Rating Draft Scale: The statements in the draft scale were designed as a 36question form evaluating PLP by using information from the literature and the opinions of expert academics who were expert in their field. First, a question pool was created within the scope of the related literature, after which the opinions of the researchers and their colleagues were used to determine the surface validity of those question pool items. The content validity of the 36-item draft scale was determined through examination and evaluation by the faculty members of the nursing faculty and those related branches of the institution with which the researchers were involved (1-10). Subsequently, Turkish grammar experts were consulted and the Davis technique was used to correct any language and spelling errors in the prepared version. The resulting version was sent via e-mail to five experts for evaluation. A value of 0.80 was accepted as a criterion for Content Validity Index (CVI) (11). The 16th guestion, the CVI value of which was found to be 0.60, was therefore removed from the draft scale. Consequently, the final draft scale comprised as 35 items and included those corrections suggested in the expert evaluation.

Before determining the validity of the scale, a preliminary study of the scale was undertaken by the researcher who distributed the scale to 30 participants. In this preliminary study, those scale questions participants had difficulty understanding were corrected (11 items out of a total of 26–36

items), thereby improving and ensuring the clarity of all scale questions. The wording of several questions were changed; for instance, "the pain in my amputated limb lasts for hours", "the pain in my amputated limb lasts for days", "my pain in my amputated limb lasts for weeks", "the pain in my amputated limb lasts for months", and "the pain in my amputated limb lasts for years" were changed and amalgamated into a single item: "the pain in my amputated limb is constant". With this arrangement, the number of scale items was reduced from 35 to 24. After the pre-study had been repeated through test– retest, the 24-item draft scale was then applied to the study sample (11) The test-retest reliability coefficient was determined to be 0.83 and acceptable (Figure 1). The Number Cruncher Statistical System Utah, USA, 2007 (NCSS) program was used to conduct the study's statistical analysis. Descriptive statistical methods (mean, standard deviation, median, frequency, ratio, lowest value, highest value) were used to evaluate the study data. The conformity of the quantitative data to the normal distribution was tested using the Kolmogorov–Smirnov test, the Shapiro–Wilk test, and graphical evaluations. The Mann–Whitney U test was then used to compare two groups of data that did not show normal distribution, the



Figure 1. Implementation of the Research

Kruskal–Wallis test was used to compare groups of three or more groups that did not show normal distribution, and the Bonferroni–Dunn test was used for pairwise comparisons. Spearman's correlation analysis was used to evaluate the relationships between the variables that did not show normal distribution; the Wilcoxon signed-ranks test was used for in-group comparisons of parameters that did not show normal distribution. Exploratory factor analysis was used in the development of the phantom-limb pain rating scale, and Reliability Analysis and Confirmatory Factor Analysis (AMOS) were used for the validity and reliability evaluations of the study data. Statistical significance was evaluated at the p<0.05 level.

RESULTS

The sociodemographic characteristics of the patients participating in the study are presented in Table 1.

Phantom Limb Pain Rating Scale Factor Analysis Results

There are 16 items in the PLP rating scale. Data obtained from the scale were analyzed using exploratory factor analysis (EFA). The results of the PLP rating scale Kaiser–Meyer–Olkin (KMO) and Bartlett's test are presented in Table 2. This single

Socio-Demographic		n	%
Characteristics			
Gender	Female	82	31,8
	Male	176	68,2
Age (years)	18-35 years	19	7,3
	36-55 years	70	27,1
	56-75 years	143	55,4
	≥ 76 years	26	10,1
Cause of Amputation	Vascular Diseases	32	12,4
	Diabetes Mellitus	128	49,6
	Traffic accident	40	15,5
	Other	58	22,6
Amputated Limb	Under the knees	152	58,9
	Above knee	47	18,2
	Below the elbow	35	13,6
	Above elbow	12	4,6
	Multiple limbs	12	4,7
Postoperative Phantom Pain	Median (Lowest-Top)	7 (3-10)	
Intensity	Mean±SD	6,95±2,12	

Table 1. Demographic characteristics of patients (N=258)

SD: Standard Deviation

Table 2. Phantom limb pain rating scale Kaiser-Meyer-Olkin and Bartlett Sphericity Test results and factor analysis Eigen Values and announced total variance results

Kaiser-Meyer-Olkin Sample Adequacy Measurement				
Bartlett Test of Sphericity		Chi square Degrees of freedom		2238,085
	120			
		Signific	cance	0,001
	Sum of Eigen values	Variance %	Total Varia	ince %
Factor 1	7,395	46,217	46,217	

factor explains 46.217% of the variance of the PLPRS. When the factor weights related to the factor analysis of the PLP rating scale were examined it was found that the lowest value was 0.483 and the highest value was 0.815.

Phantom Limb Pain Rating Scale Validity and Reliability Analysis Results

The Kuder–Richardson 20 (KR-20) value was used to test the reliability of the scale. The "Alpha if Item Deleted" value was then calculated to determine the extent and direction of the effect questions had on this value (11,12). Alpha if Item Deleted values show the internal consistency of the remaining variables when any variable is deleted. When the KR-20 values of the table were examined, it was determined that removing any item from the factor would not increase the reliability. In this framework, the single factor structure was preserved (Table 3).

The KR-20 value, which indicates the internal consistency of the questions of the PLP rating scale, was found to be 0.921. Accordingly, the scale was determined to be highly reliable. The total score of the PLP assessment scale was 1–16, with a mean score of 11.19±4.94 (Table 4).



Figure 2. Confirmatory factor analysis of the phantom limb pain rating scale (Q: Question)

Phantom Limb Pain Rating Scale Confirmatory Factor Analysis Results

Figure 2 presents the standardized loads of questions comprising the single dimension of the PLP rating scale resulting from the confirmatory factor analysis. On examination of the model results, it was revealed that the Root Mean Square Error of Approximation (RMSEA) fit criterion was 0.089, showing an acceptable fit. Among the other fit criteria, Normed Fit Index (NFI) was found to be 0.90, Relative Fit Index (RFI) 0.85, Standardized Root Mean Square Residual (SRMR) 0.055, Goodness of Fit Index (GFI) 0.90, and Adjusted Goodness of Fit Index (AGFI) 0.85; accordingly, acceptable fit was determined for all the results. In addition, it was determined that the corrected chi-square value (3.0) showed acceptable fit, the PLP rating scale had an acceptable fit, and that the scale was statistically significant and valid (p<0.01).

DISCUSSION

PLP is known to be difficult to assess and treat. The major challenge in the management of a PLP is the difficulty in assessing PLP symptoms due to the physical absence of the affected body part (12). Therefore, good observation and anamnesis should first be taken after amputation and/or nerve injury to identify phantom pain and evaluate how it occurs and what affects this pain (13,14). Other studies in the literature show that patients who are being treated for a chronic disease do not express their pain unless explicitly asked about its severity (15,16). Scales have been developed for the assessment of pain in critically ill patients; however, these have not been validated for use in patients with phantom pain. Accordingly, the scale designed in the present study was developed with the aim of creating a pain assessment system through which patients with PLP could clearly and easily describe their pain for the improvement of pain management.

The experience of PLP is expressed differently in each individual and a patient may experience more than one type of PLP. All PLP complaints are expressed as one of the following sensations: a stabbing pain, a burning-like stabbing pain, pins and needles, tingling, cramps, itching, contraction, compression, an electric shock, a stinging, a temperature increase, or a cold throbbing and sensation. It is difficult to state which of these is the most commonly experienced (1,5,15,16). In the present study, it was found that "as if someone is

Table 3. The Effects of the Items Forming the Factors of the Phantom Limb Pain Rating Scale on Reliability

	Scale mean when the item is deleted	Scale variance when item deleted	Corrected item- total correlation	KR-20 when item deleted
My pain in my amputated limb is throbbing (Q1)	10.438	22.037	0.534	0.919
My pain in my amputated limb is a feeling of pulling (Q2)	10.558	20.808	0.761	0.912
I have pain in my amputated limb as if stabbing with a knife (Q3)	10.492	21.488	0.632	0.916
The pain in my amputated limb seems to have become stiff (blunt) (Q4)	10.574	20.736	0.771	0.912
I have pain like electric shock in my amputated limb (Q5)	10.430	22.114	0.521	0.919
The pain in my amputated limb is like burning (Q6)	10.562	21.002	0.712	0.914
I have pain like crushing in my amputated limb (Q7)	10.566	20.924	0.729	0.913
I have pain like someone is drilling my amputated limb (Q8)	10.512	21.208	0.689	0.914
My pain in my amputated limb is aching (Q9)	10.465	21.931	0.540	0.919
I'm in pain like my amputated limb is torn into pieces (Q10)	10.512	21.457	0.627	0.916
I have pain as if my amputated limb is cutting right now (Q11)	10.419	22.058	0.547	0.918
I feel sharp pain in my amputated limb (Q12)	10.426	22.152	0.515	0.919
In my amputated limb, my pain is in the form of cold/coldness/freezing (Q13)	10.457	21.782	0.584	0.917
I have pain as if my amputated limb is cramped (Q14)	10.446	21.859	0.574	0.918
I have pain like my amputated limb is stuck somewhere (Q15)	10.547	20.887	0.747	0.912
I have pain in my amputated limb as if ants are lurking (Q16)	10,446	22,427	0,429	0,922

Q: Question

Table 4. Distribution of Phantom Limb Pain Rating Scale Internal Consistency Value and Scores

Phantom limb pain assessment scale total score161-16 (14)11.19±4.940.921		Number of Items	Top-bottom (Median)	Mean±SD	KR-20	
	Phantom limb pain assessment scale total score	16	1-16 (14)	11.19±4.94	0.921	

SD: Standart Deviation KR-20: Kuder-Richardson 20

cutting right now" was most frequently reported among patients' expressions of PLP experiences, which support the results of existing studies in the literature.

It is important that both healthcare professionals and patients have knowledge about the assessment tool used to measure PLP, that they understand PLP measurement scales, and that they can easily and practically use these scales. In particular, the patient's knowledge of how to use one-dimensional scales determining the severity of their pain, and their perceptions and responses to these measurement tools, depend on the selection of the correct scale (12).

Since there is no specific scale to evaluate PLP in the literature, general pain assessment scales were used in the studies (1-4). It was designed with the thought that it would be easier to design a pain scale in the evaluation of phantom pain in clinical practice than with existing pain scales and that patients would be successful in pain management. It is stated in the literature that applying a draft scale prepared for use with a small representative sample group will be beneficial; therefore, it will be beneficial to conduct a preliminary study (17). In the present study, the preliminary application of the 35-question draft scale was carried out with 30 patients before the validity application of the scale commenced. With this preapplication, corrections were made to those questions that were difficult to understand and, as a result, the clarity of the questions was improved and ensured. Test-retest was performed on the same patients with an interval of 2 weeks, and surface validity was ensured by testing the comprehensibility of the draft scale, with 24 items evaluating PLP; this 24-item scale was also prepared by consulting the opinions of expert academics. The test-retest reliability coefficient was determined to be 0.83 and acceptable.

Two prerequisites were determined regarding the use of the draft scale: first, that the patient evaluated the PLP according to a NRS evaluation, ranging from 0 (no pain) to 10 (unbearable pain), with values of 3 or above (mild pain) indicting PLP; second, that the patient was able to clearly express their experience of PLP while differentiating it from other pain. When pain becomes chronic, after three to six months of acute pain, the pain can become centralized. A lower threshold for experiencing pain is required for centralized pain. Lowered thresholds are problematic. Pain is an adaptive response to a stimulus that is painful. A lower threshold for pain subjectively means that pain can be experienced from non-painful stimuli (allodynia), or mildly painful stimuli can be experienced as severe pain (hyperalgesia). Central pain is the maladaptive type of pain. Neuropathic pain is a disorder of the somatosensory pathway of the nervous system, not the spinothalamic pathway (18,19). Central and neuropathic pain often occur together but are not mutually exclusive. Neuropathic pain may be both peripheral and central. Centralized and neuropathic pain are both considered functional (pain) gains. Both play a role in the development of chronic pain (20,21). Incongruence between motor intention and sensory feedback and corresponding activation of parietal and frontal brain areas may be involved in painful sensations such as PLP (22). Therefore, the physiopathology of pain perception does not show major differences, and the Phantom limb pain rating scale in its current form does not focus on the type of pain (nociceptive, nociceptive, nociciplastic or neuropathic), but allows for a unidimensional assessment of pain through selfreport. It was also analyzed that it would be appropriate to answer only as "agree" or "strongly disagree" instead of a 5-point Likert-type rating, since the prerequisite for the scale was that the current pain was at least 3 according to the NRS.

It is recommended that a study sample size should be 5–10 times greater than the number of items used in the data-collection scale or tool as this will ensure validity and reliability of the study data and the analysis of those data (23,24). In the present study, the number of items in the draft scale was 24; accordingly, the study sample size should comprise 240 participants. The number of patients in the present study who experienced PLP with a severity of 3 or above was 258, thereby corroborating their reliability and validity.

The factor analysis method is mostly used to evaluate whether items in the scale will be grouped under different dimensions; it is divided into two groups: explanatory factor analysis and confirmatory factor analysis (23,24). EFA was used in the statistical analysis of the PLP rating scale. When varimax rotation was applied in the exploratory factor analysis, it was determined that the questions were gathered under a single factor and the explanatory coefficient was 46.22%.

The KMO value is normally between 0–1 and should be close to 1 for factor analysis to be performed. Although it is considered sufficient for the KMO coefficient to be above 0.60, values of 0.80 or above are more desirable (11,24). The KMO sample adequacy measurement value of the present study was determined to be 0.894, a very good value for analyzing the study's sample.

Bartlett's sphericity test is used to evaluate the universal significance of the correlation matrix found by the exploratory factor analysis. Bartlett's test revealed a p value of less than 0.05, indicating that the correlation matrix is suitable for factor analysis (11). Bartlett's sphericity test was used to determine if the correlation matrix is a similar matrix. This value was rejected at the p<0.001 level, thereby demonstrating the existence of a relationship between the items and the suitability of the data for factor analysis (12).

Eigen values and total variance were then analyzed according to the scale analysis results. This single factor explains 46.217% of the variance of the PLP rating scale. Higher variance rates obtained as a result of the analysis reflect a stronger factor structure of the scale (17,23,24). For the present study, the variance rate was found to be 46.2%. According to the eigenvalues it was determined that the factors would be collected in one dimension. In health sciences, a higher variance ratio may be more appropriate due to the potential for greater heterogeneity in patient populations and treatment outcomes. However, it is essential to note that there is no universally accepted threshold for a strong factor structure in health sciences, and the appropriate variance ratio will depend on the specific context and the nature of the data being analyzed. In summary, while a variance ratio between 40% and 60% is often considered sufficient in social sciences, a higher threshold may be more appropriate in health specific threshold should sciences. The be determined based on the nature of the data and the context of the analysis (25-27). This suggests that no generally accepted threshold for a strong factor structure exists in the health sciences, and that the appropriate proportion of variance is dependent on the specific context and nature of the data under analysis.

The KR-20 reliability coefficient is expressed as a weighted standard variation obtained by dividing the sum of the variances of all items in the scale by the general variance. A KR-20 value of 0.90 or above is considered "highly reliable" (24). One of the fit criteria, RMSEA, represents the approximate square root of the means "It takes a value between zero and 1". An

RMSEA below 0.05 indicates a good fit, an RMSEA value below 0.08 indicates a fair value, and an RMSEA value of 0.08–0.10 indicates a moderate fit. RMSEA values above 0.10 are not acceptable. "In addition, factor loads are required to be above 0.30. Factor load values of 0.60 and above are high; load values of 0.30–0.59 can be defined as of medium magnitude" (11,24). The RMSEA fit criterion in the study was 0.089, which showed acceptable fit. Acceptable fit was also determined in NFI (0.90), RFI (0.85), SRMR (0.055), GFI (0.90), and AGFI (0.85), among other fit criteria.

For a model to be acceptable, the fit criteria chisquare value should not be statistically significant. This is due to the fact that the chi-square value is sensitive to the sample size. Instead, the chi-square value were evaluated by dividing it by degrees of discretion. Values of 2 or less show that the model is good; values of 5 or less show that the model has an acceptable fit (24). In the present study, the corrected chi-square value was determined as 3 and therefore showed an acceptable fit. According to the fit criteria, the PLP rating scale was found to have an acceptable fit, and the scale was found to be statistically significant and valid (p<0.01).

Pain rating scales can help healthcare providers gain a better understanding of certain aspects of a person's pain, such as the duration, severity, and type of pain. Pain rating scales can also help healthcare providers with accurate diagnosis, treatment planning, and measurement of treatment effectiveness. By consistently using a pain scale to monitor symptoms, feelings, and sensations, people can explain the nature, severity, and duration of their pain when communicating with healthcare providers, which helps them receive the best possible treatment. Pain scales also help healthcare providers assess how each person feels on an individual, case-by-case basis (12-16,28).

CONCLUSION

This self-report-based scale, which was developed to evaluate the PLP of individuals who experienced PLP after amputation, was determined as a valid and reliable measurement tool. It is recommended that the scale is used by nurses employed in surgical units for the evaluation of the pain of patients with PLP.

Limitations

The limitations of the study include the inability to conduct face-to-face interviews with patients due to

the Covid-19 pandemic, thus the stump area of the limb could not be examined by the researcher, and the inability to compare this scale with other similar pain scales due to the lack of a pain assessment scale to evaluate phantom limb pain before.

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