Translation into Brazilian Portuguese, cultural adaptation and validation of the Prosthesis Evaluation Questionnaire

Tradução para o português, adaptação cultural e validação do Questionário de Avaliação de Próteses

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Abstract

Background: Quality of life has been one of the main issues for patients with a chronic condition. **Objective**: To translate, adapt and validate a Brazilian Portuguese version of the Prosthesis Evaluation Questionnaire (PEQ). **Methods**: The questionnaire was translated into Portuguese, back translated into English, and cross-culturally adapted to the Brazilian Population. Sixty-five transtibial unilateral amputees were recruited. The sample comprised 45 men and 20 women with a mean age of 44 years, 47 with traumatic amputations, 14 with vascular dysfunction and 4 with other reasons for amputation, and all of them fitted with prostheses. Patients were interviewed twice, at baseline and again after 15 days. The Brazilian Portuguese version of the SF-36 (a generic Quality of Life outcome measure) and the FIM (a Functional Independence Measure) were also administered. **Results**: The internal consistency of the nine PEQ scales was tested by computing Cronbach's Alpha coefficients (0.65 - 0.89: high values). Student's *t* test coefficients were used for interobserver evaluation (0.35 to 084: reliable values with one exception- the Residual Limb Health scale), and Intraclass Correlation Coefficients (ICC), which ranged from 0.65 to 0.92: reliable values. Student's *t* test coefficients and ICCs were also used for intraobserver evaluation (0.42 to 0.83, except the Residual Limb Health scale and 0.80 to 0.94, respectively: reliable values). Correlations between PEQ, SF-36 and FIM were tested using Pearson's correlation coefficients, which were not statistically significant (p > 0, 01). **Conclusion**: The Brazilian-Portuguese version of the PEQ has high internal consistency and is a reliable quality of life measure for use in amputee patients, but is not associated with the SF-36 or FIM.

Keywords: quality of life; amputation; lower extremity.

Resumo

Contexto: Qualidade de vida tem sido a principal preocupação em pacientes com disfunção permanente. **Objetivo**: Traduzir, adaptar e validar uma versão Brasileira do Prosthesis Evaluation Questionnaire (PEQ). **Métodos**: O questionário foi traduzido para o Português, retraduzido para inglês e adaptado culturalmente para a população brasileira. Sessenta e cinco amputados transtibiais unilaterais (45 homens, 20 mulheres, média de idade: 44 anos); 47 de etiologia traumática, 14 vascular e 4 de outras causas, todos protetizados, foram entrevistados duas vezes no mesmo dia e no intervalo de 15 dias. A versão brasileira do SF 36 (Medida de Qualidade de Vida genérica) e MIF (Medida de Independência Funcional) foram aplicadas. **Resultados**: A consistência interna de 9 escalas da PEQ foi testada pelo coeficiente Alpha de Cronbach (0,65-0,89; valores altos). O teste T de Student foi usado para a avaliação interobservadores (0,35-0,84; valores de confiança, exceto para Escala de Saúde do Membro Residual) e para o Coeficiente de Correlação Intraclasses (ICC), que variou de 0,65 a 0,92, valores de confiança. O teste T de Student foi usado durante a avaliação intraobservadores (0,42-0,83; exceto para Escala de Saúde do Membro Residual) e o ICC também (0,80-0,94), ambos valores de confiança. A correlação entre PEQ, SF 36 e MIF foi testada pelo coeficiente de correlação de Pearson e foi estatisticamente insignificante (p>0,01). **Conclusão**: A versão brasileira da PEQ tem alta consistência interna e é uma medida de qualidade de vida confiável para pacientes amputados, mas não mostrou associação com SF 36 e MIF.

Palavras-chave: qualidade de vida; amputação; extremidade inferior.

INTRODUCTION

After amputations, patients are faced with a new style of life and a new challenge of how to return to their previous activities in the best possible way.[1]

Materials, equipment and training methods have been developed in attempts to improve amputees' process of re-adaptation to their new way of life.[2]

Measurements are constantly taken with the objective of evaluating the results after fitting a prosthesis, searching for new mechanisms that will provide, after due interpretation, a guide to advancing in all the procedures that may be indicated for these individuals. These measurements are basically concerned with one or both of two elements: prosthesis use and function and quality of life from the patient's point of view.

Many different measurement systems have been developed, including a range of different questionnaires, starting from the basic idea of asking simple questions ("Is your prosthesis comfortable?" –"Are you able to perform your daily activities?" –"Are you able to perform additional activities, other than your daily tasks?", for example) and with the main objective of creating instruments that are capable of identifying better prosthesis function and improved quality of life.

The underlying objective of these different measurement systems is to attempt to identify situations that could be modified and improved to make the rehabilitation process easier, thereby offering lower-limb amputees an easier process of re-adaptation to daily life.

These measurement systems are developed by different groups, in different regions, cultures and settings, and have also been formulated to assess the general conditions of a patient's life.

Adaptation of a system that is trustworthy, valid and responsive in a specific country or region to another socioeconomic and cultural surrounding and validating it in these new surroundings allows the possibility of demonstrating its reproducibility in different situations.

We have chosen the Prosthesis Evaluation Questionnaire (PEQ) because it includes recent measuring systems and is supported by reports in the literature from research groups that have administered and are administering it and because it was specifically developed to evaluate prostheses and prosthesis-related quality of life in adult unilateral lower limb amputees (which improves its specificity), is quick to complete, simple to answer, requires easy-to-collect information, and is demonstrably trustworthy when the person administering the questionnaire has been validated.

METHODS

The sample comprised 65 unilateral transtibial lower limb amputees, 45 of whom were men and 20 of whom were women, with a mean age of 42.55 years.

Inclusion criteria were as follows: patients aged 18 to 80 years, with a unilateral amputation above the ankle, who wore a prosthesis at least five times a week, were able to read Portuguese and gave informed consent.

Exclusion criteria were as follows: amputation level below the ankle; not wearing the prosthesis for at least five days per week; inability to read Portuguese; failure to provide informed consent.

Translation

The questionnaire was translated according to instructions published by Guillemin et al.[3]

First, three translators whose first language was Brazilian Portuguese each independently translated the original questionnaire from English into Brazilian Portuguese and a consensus version was generated.

Later, three others translators, blind to the original questionnaire, each performed a backtranslation. In this phase, a new consensus version was obtained and compared with the original questionnaire to determine equivalence. Comparison of this new English version to the original version demonstrated semantic and grammatical equivalence.

A meeting was then held with health care workers (two Physical Therapists, two Physiatrists and one Orthopedist) to evaluate the final PEQ version.

The example used in question 14H, which refers to the ability to walk on slippery surfaces such as snow when using ones prosthesis was removed because there is no snow in Brazil. Some other terms were changed because they were inappropriate for Brazilian patients. The main purpose of this step of the study was to test item comprehension. All questions were analyzed and those that were not understood were noted.

If 15% or more of the patients didn't understand an item, the question was modified and tested again.

Cultural equivalence

This version was then pretested on 15 people with lower limb amputations recruited at the UNIFESP outpatients clinic (Amputation and Prosthetic Group-Division of Physiatry- Department of Orthopedics and Traumatology -Federal University of São Paulo, SP, Brazil) and the Centro Marian Weiss (Clinic for treatment and rehabilitation of amputees, São Paulo,

SP, Brazil). All patients agreed to participate in the study. The statements proved comprehensible to, and could be answered by, at least 85% of the patients, thus proving they had been understood and were culturally appropriate, as found by Ciconelli et al.[4]

Reliability and validity

After cultural equivalence had been established, the questionnaire was administered three times by interviewers 1 and 2, to a new group of 65 outpatient amputees at the Centro Marian Weiss clinic. This group comprised 20 women and 45 men with a median age of 42.55 years.

The first two administrations of the PEQ were performed on the same day by two investigators (investigator 1 and investigator 2 - interobserver evaluation), with a 30-minute interval. The third administration was conducted 15 days later by investigator 1 (intraobserver evaluation).

The PEQ's validity was tested by determining its relationships to other clinical parameters and to outcome measures.

The outcomes measures employed were the Brazilian Portuguese version of the SF-36 (a generic quality of life outcome measures)[4] and the FIM (a functional independence measure).[5]

The internal consistency (a measure of how uniform an instrument is) of the nine PEQ scales was tested by computing Cronbach's alpha coefficient. Interobserver and intraobserver reliabilities were determined using Student's t test coefficients and intraclass correlation coefficients (ICC).[6]

Correlations between PEQ, SF-36 and FIM were tested using Pearson's correlation coefficients.

∎ RESULTS

The following results were observed. In the first step, translation and cultural adaptation, all of the patients answered the questions.

Table 1 shows internal consistency results for each of the nine PEQ scales, tested by computing Cronbach's alpha. Results range from 0.65 to 0.89, which are high values.

Interobserver agreement was tested by computing Student's t test coefficients. Results ranged from 0.35 to 0.84, which are considered reliable values, with the exception of one domain - the residual limb health scale). For this domain, 3 out of 4 statistical tests (Bland Altman plot, Student's t test, and the Signal test) indicated there was no agreement. Additionally, intraclass correlation coefficients

(ICC) ranged from 0.65 to 0.92, which are also reliable values (Table 2).

Intraobserver agreement was also tested by computing Student's t test coefficients. With the exception of the residual limb health scale, results ranged from 0.4 to 0.83, which are reliable values.

For this domain, 3 out of 4 statistical tests (Bland Altman plot, Student's t test, and the Signal test) indicated there was no agreement. Results for Student's t test ranged from 0.80 to 0.94, which are also reliable values (Table 3)."

Correlations between PEQ and SF-36 were tested using Pearson's product-moment correlation coefficients. Results were not statistically significant (Table 4, $p < 0.5$).

Table 1. Cronbach's alpha coefficients for the nine PEQ domains.

Domain	α	Confidence interval	
Ambulation	0.889	0.833	0.926
Appearance	0.733	0.492	0.852
Frustration	0.777	0.550	0.885
Perceived Response	0.842	0.757	0.898
Residual Limb Health	0.793	0.644	0.894
Social Burden	0.653	0.429	0.785
Sounds	0.866	0.653	0.940
Utility	0.880	0.828	0,915
Well Being	0.838	0.713	0.909

Table 2. Intraclass correlation coefficients for the nine PEQ domains.

Domain	Coefficient	Confidence interval	
Ambulation	0.915	0.865	0.947
Appearance	0.840	0.751	0.899
Frustration	0.908	0.852	0.943
Perceived Response	0.845	0.754	0.904
Residual Limb Health	0.823	0.724	0.889
Social Burden	0.857	0,773	0.911
Sounds	0.881	0.811	0,926
Utility	0.817	0.718	0.884
Well Being	0.651	0.487	0.772

Table 3. Intraclass correlation coefficients for the nine PEQ domains.

Domain	Intraclass correlation coefficient	Student's t test	
Ambulation	0.942	0.904	0.965
Appearance	0.849	0.760	0.907
Frustration	0.925	0.877	0.955
Perceived Response	0.872	0.791	0.922
Residual Limb Health	0.799	0.684	0.876
Social Burden	0.859	0.773	0.915
Sounds	0.842	0.749	0.903
Utility	0.805	0.695	0.879
Well Being	0.828	0.727	0.894

Table 4. Pearson product-moment correlation coefficients between PEQ, SF-36 domains.

PEQ	SF-36	Coefficient	Confidence interval	
Ambulation	Physical function	0.584	0.398	0.725
	General health	0.278	0.033	0.492
Appearance	Social functioning	0.084	-0.164	0.321
	Role-emotional	0.129	-0.119	0.361
	Mental health	0.083	-0.166	0.322
Frustration	Role-physical limitation	0.046	-0.204	0.291
	Vitality	0.220	-0.032	0.445
Perceived Response	Physical function	0.274	0.024	0.492
	Role-physical limitation	0.199	-0.056	0.429
Residual Limb Health	Physical function	0.163	-0.089	0.394
	Bodily pain	0.276	0.030	0.490
	General health	0.108	-0.148	0.350
Social Burden	Social functioning	0.279	0.031	0.494
	Role-emotional	0.332	0.090	0.537
Sounds	Role-physical limitation	0.123	-0.127	0.358
	Mental health	0.063	-0.188	0.305
Utility	Physical function	0.428	0.205	0.608
	Role-physical limitation	0.185	-0.062	0.410
Well Being	Vitality	0.211	-0.037	0.434
	General health	0.324	0.083	0.529

■ DISCUSSION

Self-perceived health status and quality of life in amputees is a current research topic in both clinical and epidemiological studies.

These measures do not only need to be only carefully translated, but must also have their psychometric properties tested in specific cultural contexts.[4]

The PEQ was developed by Legro et al. in 1998,[7] and is specific for lower limb amputees.

According to the authors, the objective of the project was to develop a questionnaire that was (1) specific for lower limb amputees and (2) could measure small differences in prosthesis function and in the main daily activities related to prosthesis function. The intention was to use the data thus collected to compare different methods of care.

According to Legro,[7] the PEQ is a valid and reliable questionnaire for studying the patient's care of the prosthesis, quantifying amputees' perceptions with relation to their prostheses and their quality of life with prostheses.

The method was validated against the SF-36, SIP and POMS questionnaires. It is considered valid, trustworthy and responsive to changes in patient status, and has been used in assessments of lower limb amputees by Deathe & Miller,[8] Miller et al.,[9] Harness & Pinzur,[10] O'Reilly,[11] Miller et al.,[12,13] and Legro et al.[14]

The inclusion criteria in our study were: 1- a lower limb amputation above the ankle at least one year previously; 2- wearing the prosthesis at least five days a week; 3-being able to read and write in Portuguese; 4- agreement to take part in the study.

In the first step of our study, translation and cultural adaptation, all patients answered the questionnaire.

In the second step, Cronbach's alpha coefficients were used to evaluate the internal consistency of each scale. The results show that the PEQ has good internal consistency and temporal stability. The patients understood eight domains well, with the exception being the residual limb health scale. Scores for internal consistency vary from 0 to one and the higher the value, the better the consistency. In this study, results ranged from 0.65 to 0.89, which are high values.[15]

The interobserver evaluation tests that there is agreement between evaluations made by different interviewers. In this study, values were considered reliable, with one exception, the residual limb health scale. This is important since it shows that we must conduct an in-depth study and intervene in the residual limb health scale to produce a new scale that does not produce different results with different interviewers.[16]

In the assessment of intraobserver reliability, Student's *t* test and ICC results indicated satisfactory correlations for the PEQ scales. The values ranged

from 0.42 to 0.84 with one exception: the residual limb health scale

In the third step, correlations between PEQ, SF-36 and FIM were tested using Pearson's product-moment correlation coefficients and the results were not statistically significant ($p < 0.5$). This shows that the PEQ does not have an association with the SF-36 or the FIM. The PEQ has good internal consistency, so it works alone. This questionnaire has good characteristics, but was created for a specific population. Its domains are only parts of the domains in the other questionnaires. The result is the absence of associations between the PEQ and SF-36 or FIM. The PEQ is an in-depth assessment that cannot be compared with general quality of life questionnaires.

In our opinion, if we did not use all of the PEQ domains, which are very extensive, it could be more easily compared with other quality of life questionnaires. It might then exhibit associations with them. If the number of questions in each scale had been reduced and language that was easier for our population had been employed, perhaps we wouldn't have had problems with the residual limb health scale.

■ CONCLUSION

The Brazilian Portuguese version of the PEQ has high internal consistency and is a reliable quality of life measure for use in amputees, but does not have any association with the SF-36 or FIM.

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