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Translation and Validation of Prolapse-Quality of Life Questionnaire into Urdu Version

Amna Riaz[1], Mehwish Khalid[2], Hassan Bin Akram[3], Mahrukh Asif[4]

[1 4] Physical Therapist, Lahore College of Physical Therapy, LMDC, Lahore, Pakistan
[2] Assistant Professor, Lahore University of Biological and Applied Sciences, LMDC, Lahore, Pakistan
[3] Clinical Manager, Department of Physical Therapy, Ghurki Trust and Teaching Hospital, Lahore, Pakistan

Author`s Contribution

[1] Substantial contributions to the conception or design of the work for the acquisition, analysis or interpretation of data for the work, [2] Drafting the work or reviewing it critically for important intellectual content, [3] Final approval of the version to be published, [4] Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Address of Correspondence

Name: Mehwish Khalid
Email Id: mehwish.khalid@ubas.edu.pk
ORCID: 0000-0002-1812-7179

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A B S T R A C T

Background: Pelvic organ prolapse (POP) causes the inner and outer layers of the vagina to descend which can influence female quality of life in physical, social, mental and sexual ways. The Prolapse Quality of Life Questionnaire is a reliable tool for assessing symptom severity and impact, guiding treatment decisions, and evaluating outcomes.

Objective: To translate and validate the Prolapse-Quality of Life Questionnaire into the Urdu version.

Methodology: The P-QOL was translated and back-translated to and from Urdu, pretested and reviewed by a committee following the Guillemin criteria, and then cross-cultural linguistic validation study was conducted on 150 Urdu-speaking patients with pelvic organ prolapse. The months from June 2023 to December 2023 were the total study duration. Data entry and analysis were done using SPSS. Descriptive analysis was presented in the form of tables and graphs.

Results: The average participant was 47.9 years, with a SD of 7.67 years. All participants were between 35 and 60 years old. The Urdu form of the P-QOL questionnaire scored well for internal consistency, showing a Cronbach's alpha of 0.96. The content validity was strong at 0.87. The high reliability was clear from the value for the intra-class correlation coefficient, ranging from 0.35 to 0.9.

Conclusion: The Urdu version of the Prolapse Quality of Life Questionnaire allows us to reliably assess symptoms, Severity of the condition and the quality of life of someone with pelvic organ prolapse. The consistency over time and between different assessments, as well as its content relatedness, is all acceptable.

Keywords: Translation, Validation, Reliability, Prolapse-Quality of life, and Pelvic Organ Prolapse

Introduction

When the front, back or top posterior parts of the vagina or the uterus, descend and cause symptoms, it is called pelvic organ prolapse.[1] Most commonly, women with POP experience something descending and may report a bulge, pressure in the vagina, pain during intercourse and changes in bladder or bowel function.[2] Normally, women with POP also suffer from other pelvic floor problems, including urinary and bowel symptoms and issues during sex, which often worsen in the later hours. Even though POP is not fatal itself, it may cause important health issues.[3] Pelvic organ prolapse are the leading cause for hysterectomies in older women.[4]

Pelvic organ prolapse (POP) is thought to occur in anywhere between 3.4 and 56.4%, with averages around 19.7%.[5] The likelihood of experiencing POP rises with age and the number of childbirths, and approximately 11% of women can anticipate undergoing prolapse repair during their lifetime. POP occurs in between 20% and 50% of women

worldwide, as its risk goes up with age, the number of births, and lifting heavy items.[6, 7]

The risk factors for POP include advancing age, obesity, early childbirth, hard weight lifting, heavy housework during prenatal and postnatal periods, chronic constipation, vaginal delivery, poor delivery methods and poor nutrition.[8] Management of urogenital prolapse is based on the doctor's assessment to see if treatment is necessary and how much recovery the patient can hope for, depending on the patient's condition and the severity of her symptoms.[9]

Certain tests have been made to appraise the perceptions of quality of life and symptoms in women with pelvic floor diseases. The Pelvic Floor Impact Questionnaire (PFIQ-7) and the Pelvic Floor Distress Inventory (PFDI-20) are used to understand if someone has pelvic floor diseases and what effect those diseases have on their quality of life.[10, 11] However, they are not designed to judge the severity of individual pelvic floor disorder types but rather the total impact of the overall dysfunction (urinary, anal, bowel and sexual).[12] For this reason, there are no special methods to improve the quality of life for women with pelvic organ prolapse.

Understanding how severe prolapse is and how it affects daily life is important when managing and keeping an eye on women's health. The P-QOL has proven to provide a convenient, trustworthy, and accessible means for monitoring the effects of prolapse.[13] In 2005, the P-QOL questionnaire was designed to serve women who have pelvic organ prolapse (POP), no matter how severe their condition is.[14] It has 38 short questions that cover all significant quality of life categories relevant to the idea of urogenital prolapse.[1, 15]

The questionnaire has been adapted to many languages, such as English [16] Spanish [1, 14] Turkish [17] Brazilian [7] Dutch [18] Polish [19] The study aims to make the questionnaire content accessible and understandable to individuals who speak Urdu and come from diverse cultural backgrounds.[7]

Methodology

One-fifty women, from different hospitals and clinics in Lahore, participated in a Cross-cultural linguistic validation study. The Ethical Review Committee of Lahore College of Physical Therapy, LMDC, (Ref No: DPT/ERB/14) approved this study. The study started after the approval of the synopsis in June 2023 and ended in December 2023. All participants signed a consent form giving their approval before the study was started. Non-probability, a convenient sampling technique was used for data collection in this study.[20] The numbers of participants were calculated following guidelines for questionnaire validation studies.[21]

The intervention included standard conventional treatment given to both groups which was the application of an electrical heating pad with low-frequency TENS (transcutaneous electrical nerve stimulation) between 80 Hz and 120 Hz (according to the patient tolerance) to the affected knee for 10 minutes with passive knee range of motion exercises, knee isometrics and strengthening exercises after PRP therapy with home plan included knee isometrics exercises with 20 reps and 10 seconds hold, 3sets a day and heating therapy for 10 minutes before exercise.

Strengthening exercises application on his abductors, adductors, extensors, and flexors (10 reps, 1 set each) with Thera band. Resistance was according to patient tolerance and increased gradually according to the Thera Band colors as given below:

Condition	Sample size
4 or more loadings>0.6	Any sample size
10 or more loadings=0.4	150
Only a few loadings = 0.4	300

Inclusion criteria were multiparous obese women who have vaginal deliveries and age between 35 to 60 years old. Women having a history of high-risk pregnancy, neurological diseases, and non-responsive and non-cooperative patients were excluded from the study.

The transition and modification of P-QOL to the Urdu language were conducted following the five standard steps mentioned by previous international guidelines.[22]

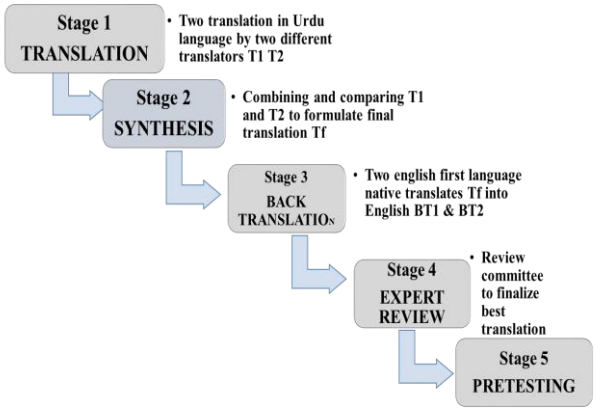

Figure1. Translation steps

Prolapse Quality of Life Questionnaire (P-QOL).

In the forward translation step, two separate and trained linguistic translators collected the data. The one who is an expert in Urdu and the other who is a medical specialist. Then, the backward translation of the first two versions of the questionnaire was completed and the final version was checked by the expert panel against the full psychometric testing of the pre-final version in a sample.

Stage 1: Forward Translation

Translation of P-QOL was carried out by two native speakers of Urdu in Pakistan. A physician who understood this study and a native translator with foreign origins were among those we recruited.

Stage 2: Synthesis

In this stage, experts did synthesis of the 2 versions of the translation material, T-12, in Urdu. All Urdu materials were completed for this health-related quality of life scale at this moment.

Stage 3: Backward Translation

At this point, an English version of the Urdu translation was made. For this reason, the work was carried out in collaboration with two bilingual translators. Both were native speakers of Urdu and English.

Stage 4: Expert Review

The committee's job was to merge all versions of the questionnaire and create what was considered the pre-final version for trials. Because the committee of 10-20 medical rehabilitation specialists was familiar with the study's purpose, they compared the two drafts. The members of the committee revised and updated the scale after reviewing the Urdu and English translations.

Pretesting

A pre-final version of P-QOL in English and Urdu went through testing, after which a sample of 150 participants had the test fully evaluated. Patients gave their agreement before being tested. A group of 10-20 medical rehabilitation experts assessed these findings.

Results

The average participant was 47.9 years, with a SD of 7.67 years. All participants were between 35 and 60 years old. The Urdu form of the P-QOL questionnaire scored well for internal consistency, showing a Cronbach's alpha of 0.96. The content validity was strong at 0.87. The high reliability was clear from the value for intra-class correlation coefficient, ranging from 0.35 to 0.9.

Table 1: Law SHE method of content validity ratio

Sections	Expert in agreement (total sections review)	Content validity index	Content validity ratio
Section 1	20	1	1
Section 2	100	0.9	0.8
Section 3	65	0.92	0.85
Section 4	180	0.94	0.89
Total	365	3.76	0.87

Content validity was assessed using Lawshe's method, yielding a Content Validity Ratio (CVR) of 0.87, which indicates that the items were rated as essential by the expert panel. The Content Validity Index (CVI) across different sections ranged from 0.90 to 0.94, further supporting the questionnaire's validity.

Table 2: Intra-class correlation coefficient

Intraclass Correlation Coefficient							
Measures	ICC	95% C. I		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig.
Single Measures	0.356	0.305	0.416	20.3	149	5066	<0.001
Average Measures	0.951	0.939	0.961	20.3	149	5066	<0.001

People effects are analyzed as random variations, while measures are modeled as fixed in these two-way mixed effects model.

a. Using a consistency definition for Type C ICCs, the between-measure variance was taken out of the denominator.

b. When no interaction exists, the effect estimation is still performed in the same way.

ICC values ranged from 0.35 (single measures) to 0.951 (average measures), indicating moderate to high reliability. Because the 2-tailed significance value was not less than 0.05, we conclude that the result observed with the paired t-test lacked statistical significance.

Paired samples t-tests evaluated score stability between test and retest, showing significant improvement in Sections 2, 3, 4, and in Total Scores. No significant improvement was observed in Section 1, i.e., ($p = 0.425$). Other sections and total scores demonstrated statistically significant differences ($p < 0.001$), which may indicate increased participant familiarity or understanding upon retest.

The relationship between test results from the same group was established by calculating the Pearson correlation coefficient. Stability over time is indicated by the Pearson correlation coefficients between test and retest results, which ranged from 0.905 to 0.986 ($p < 0.01$).

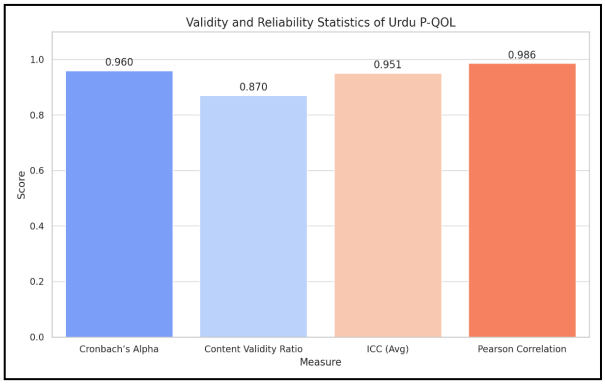

Figure 1: Graphical Representation of Validity and Reliability Measures

Table 3: Paired T-Test

Pairs	Paired Differences					T	Df	Sig. (2-tailed)
	Mean difference	SD	Std. Error Mean	95% C.I of the Difference Lower	Upper			
Section1 Reading1 - Section1 Reading2	-0.03	0.51	0.04	-0.11	0.04	-0.80	149	0.42
Section2Reading1- Section2Reading2	-1.44	2.11	0.17	-1.78	-1.10	-8.36	149	<0.001
Section3Reading1- Section3Reading2	-0.82	1.04	0.08	-0.99	-0.65	-9.72	149	<0.001
Section4Reading1- Section4Readings2	-0.76	0.83	0.06	-0.90	-0.63	-11.3	149	<0.001
Total Score1- Total Score2	-5.36	3.47	0.28	-5.91	-4.80	-18.9	149	<0.001

Table 4: Test-Retest Reliability

Correlations

	Section1Reading1- Section1Reading 2	Section2Reading1- Section2Reading2	Section3Reading1- Section3Reading2	Section4Reading1- Section4Readings2	Total Score 1 - Total Score 2
Pearson Correlation	.905	.976	.974	.967	.986
Sig. (2-tailed)	<0.001	<0.001	<0.001	<0.001	<0.001
N	150	150	150	150	150

**. Correlation is significant at the 0.01 level (2-tailed).

Discussion

The goal of this study was to create a standard Urdu version of the P-QOL, validate it, and measure its basic psychometric qualities. The analysis of 39 items demonstrates that the scale fits well, has very high reliability, and shows strong agreement with other tests. Previously, it was seen that this tool works well for understanding how much genital prolapse and its outcomes change life in Portuguese communities.[7]

It has been shown that the English form of the P-QOL can accurately and reliably determine symptoms of prolapse in women following vaginal deliveries. It contains helpful details about symptoms and the usual living conditions of women with urogenital prolapse, and the current research proved that the Urdu version of the P-QOL questionnaire is reliable for such assessments. There was an excellent correlation of 0.80 between the P-QOL's test and retest results, and our study found an even higher correlation of 0.964 using the Pearson method.[16]

The Polish version of the P-QOL underwent a standardized process involving translation and back translation. The results showed that the Cronbach's alpha coefficient of internal consistency was 0.94 for the translated P-QOL, and test-retest reliability over a 30-day interval showed high reliability, with strong intra-class correlation coefficients.[19] The current study also showed an excellent correlation, with a Pearson correlation coefficient of 0.964 and high reliability, indicated by an intra-class correlation coefficient over a 3 to 7-day interval.

Step by step, the P-QOL in Spanish was translated and then back to Spanish by experienced translators.[1] Cronbach's alpha ranged from 0.751 to 0.877, and the results for test-retest reliability ranged from 0.725 to 0.938.[1] The current study also showed an excellent correlation of 0.96 using the Pearson correlation coefficient method.

A reliable method for measuring how prolapse is affecting their daily life helps to decide on the best treatment for each woman. Measuring symptoms of the lower urinary tract through quality of life questionnaires helps clinicians and researchers evaluate these symptoms in any clinical trial. The recently introduced PFDI and PFQI measures the stress and difficulties from pelvic floor symptoms and are meant to help with medical and surgical trials in American women with disorders of the lower urinary tract, the gastrointestinal tract or pelvic organ prolapse.[23]

The results indicate that the P-QOL questionnaire should be used frequently to better discover women who should have therapy. Even so, limitations exist with the study. Translating into English allowed the research to be performed on a smaller sample size; therefore, the translation's findings may not apply everywhere. Therefore, future studies should be carried out on a larger population. To produce better, generalizable results, a random sampling method should be employed. The general population is targeted in this study, including symptomatic and asymptomatic women, so it is recommended to do a study on the grades of prolapse in symptomatic women.

Conclusion

Using the Urdu version of the Prolapse Quality of Life Questionnaire allows us to reliably assess symptoms, how severe the condition is and the quality of life of someone with pelvic organ prolapse. The consistency over time and between different assessments, as well as its content relatedness, is all acceptable.

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