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Validity and Reliability of The Persian Version of Uterine Fibroid Symptom and Health-Related Quality of Life Questionnaire: A Psychometric Study

Hanieh Najafiarab, M.D.[1], Amirreza Keyvanfar, M.D.[1], Farima Rahimi Mansour, M.Sc.[1, 2], Hamidreza Didar, M.D.[1], Shaghayegh Hooshmand Chayijan, B.Sc.[1], Shahrzad Rajaei Firouzabadi, M.D.[3], Maryam Sadat Hosseini, M.D.[1], Zahra Bakhtiyari, M.Sc.[1], Farah Farzaneh, M.D.[1*]

1. Preventative Gynecology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
2. Department of Cell and Molecular Biology, Faculty of Biological Sciences, Kharazmi University, Tehran, Iran
3. School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Abstract

Background: Women with uterine fibroids (UFs) experience many clinical manifestations that affect their quality of life (QOL). The Uterine Fibroid Symptom and Health-related Quality of Life (UFS-QOL) questionnaire is an English instrument specifically designed to assess fibroid-related symptoms and their impact on QOL. This study aims to investigate the reliability and validity of the Persian version of the UFS-QOL questionnaire in Iranian women with UF.

Materials and Methods: In this psychometric study, women with UFs who presented to Imam Hossein Hospital (Tehran, Iran) between August 2022 and January 2023 were enrolled in this study. A forward-backward approach was applied to translate the UFS-QOL questionnaire into Persian. The reliability of the UFS-QOL questionnaire was assessed by internal consistency and test-retest correlation. Confirmatory factor analysis (CFA) was used to assess convergent validity between items and subscales of the UFS-QOL questionnaire. Pearson's correlation coefficient was used to assess convergence validity between subscales of the UFS-QOL and the World Health Organization Quality of Life Brief Version 26 questionnaire (WHOQOL-BREF-26).

Results: Overall, we assessed 226 women with UFs. All subscales of the UFS-QOL questionnaire had acceptable internal consistency (Cronbach's alpha>0.7). Test-retest analysis indicated significant positive correlations between two measurements of all subscales of the UFS-QOL questionnaire: symptom severity (P<0.001), concern (P<0.001), activities (P<0.001), energy/mood (P<0.001), control (P<0.001), self-consciousness (P=0.002), and sexual function (P<0.001). The Kaiser-Meyer-Olkin (KMO) measure value was 0.920, and the result of Bartlett's test of sphericity was significant (P<0.001). CFA identified six factors for the health-related QOL (HRQL) questionnaire, which explained 73.827% of the total variation. Most subscales of the UFS-QOL questionnaire correlated with domains of the WHOQOL-BREF-26 questionnaire (P<0.05).

Conclusion: The Persian version of the UFS-QOL questionnaire is a valid and reliable instrument to evaluate UF-related symptoms and QOL among Iranian women.

Keywords: Leiomyoma, Quality of life, Psychometrics, Surveys and Questionnaires

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Introduction

Uterine fibroids (UFs), also called leiomyomas, are the most common benign uterine tumours that arise from the myometrium in reproductive-age women. They are the most common diagnosis associated with hysterectomy in the United States (1, 2). According to a systematic review, the prevalence of UFs varies from 4.5 to 68.6% (3). Many women with UFs suffer from heavy menstrual bleeding (a leading cause of anaemia in reproductive-age women), abdominopelvic pain, urinary frequency, and urinary incontinency. Clinical manifestations of UFs restrict the physical and social activities of patients and impact their quality of life (QOL) (4). Furthermore, UFs may cause gynaecological dysfunctions such as infertility, recurrent miscarriage, and preterm labour (5).

Treatment of UFs is based on size, location, and

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*Corresponding Address: P.O.Box: 1617763141, Preventative Gynecology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
Email: pgrc@sbmu.ac.ir

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symptoms. This imposes direct (hospitalisation, outpatient visits, medication, and other medical services) and indirect (work loss and costs associated with incapacity for household work) expenses. In the United States, it is estimated that approximately 34.4 billion USD per year is spent on UFs treatment, which is more than the costs spent on breast, colon, and ovarian cancer treatments (6, 7). Around a third of hysterectomies performed in the USA are due to fibroids, with costs for their management estimated to be over two billion USD per year. Non-surgical treatments may be more beneficial for women with UFs, especially for those who want to preserve fertility (8). Clinicians need an instrument to compare the efficacy of different therapeutic options for women with UFs by assessing the impact of patients' symptoms on their QOL before and after treatment.

The Uterine Fibroid Symptom and Health-related Quality of Life (UFS-QOL) is an English instrument specially designed to assess the broad spectrum of fibroid-related symptoms and their impact on QOL. It has been translated into Brazilian, Portuguese, Spanish, and Chinese. Measurement of UF-related symptoms and QOL can provide an efficient practice and comprehensive management for patients from different cultures (9). Thus, this study aims to investigate the reliability and validity of the Persian version of the UFS-QOL questionnaire in Iranian women with UFs and proffer an instrument with acceptable psychometric properties to assess the impact of UF symptoms on QOL.

Materials and Methods

Study design and participants

This was a psychometric study conducted at Imam Hossein Hospital (Tehran, Iran) between August 2022 and January 2023. The inclusion criteria consisted of: women with UF diagnosed with ultrasound by an expert radiologist; largest diameter of UF between 2 and 10 cm; age between 18 and 45 years; and the ability to read and write. Patients with the following characteristics were excluded: use of oral contraceptive pills in the last three months; history of surgery due to gynaecological diseases; underlying diseases such as malignancy, chronic kidney disease, liver failure, metabolic diseases (diabetes mellitus, hyperthyroidism, hypothyroidism, adrenal disorders), hypertension; mental disorders; the presence of other pathologies visualised by ultrasound (e.g., adenomyosis or gynaecological malignancies); and pregnancy or breastfeeding.

Sample size

The sample size was calculated based on factor analysis (five patients per item) (10). The UFS-QOL questionnaire contains 37 items and we took into consideration a 20% drop out rate to derive a sample size of 222. We used consecutive sampling in this study.

Data collection

Initially, eligible patients signed an informed consent form for study participation. A research team member interviewed the participants about their demographics and clinical characteristics. Ultrasound findings of the patients were obtained after reviewing patients' medical records. All patients completed the study questionnaires.

Study instruments

The World Health Organization Quality of Life Brief Version 26 questionnaire (WHOQOL-BREF-26) is an abbreviated English version of the WHOQOL-100 developed by the World Health Organization. It is a 26-item questionnaire that assesses QOL of a person during the previous two weeks. Each item is scored on a Likert scale that ranges from 1 (very dissatisfied) to 5 (very satisfied) with the exception of three questions (3, 4, and 26) that are scored inversely. This questionnaire consists of four domains (physical health, psychological, social relationships, and environment) and an overall QOL and general health score. In this questionnaire, higher scores indicate better QOL. Jahanlou and Karami (11) assessed the psychometric properties of the Persian version of the WHOQOL-BREF-26.

The UFS-QOL is a 37-item questionnaire that assesses symptoms and health-related QOL (HRQL) in women with UF over the previous three months. Each item is scored on a Likert scale that ranges from 1 (none of the time/not at all) to 5 (a very great deal/all of the time). This questionnaire consists of seven subscales: symptom severity, concern, activities, energy/mood, control, self-consciousness, and sexual function. In this questionnaire, higher scores indicate better QOL. The original English version of the UFS-QOL questionnaire was developed by Spies et al. (12), which had acceptable validity and reliability.

Translation

A forward-backward approach was applied to translate the UFS-QOL questionnaire into Persian. The English version of the UFS-QOL questionnaire was independently translated into Persian by two translators. These translated drafts were assessed by a committee of two gynaecologists, a methodologist, and a general practitioner. The questionnaire was translated back into English by another translator who was proficient in Persian and English to ensure that the back-translated version of the questionnaire was similar to the original version. After solving any problems, the Persian version of the UFS-QOL questionnaire was approved, and the study entered the subsequent steps.

Reliability

The reliability of the UFS-QOL questionnaire was assessed by internal consistency and test-retest correlation. Internal consistency investigates the association between different items within a subscale. We considered a Cronbach's alpha of >0.7 to have acceptable internal consistency. A total of 20 patients completed

the Persian version of the UFS-QOL questionnaire for the second time, with an interval of four weeks from the first completion. Test-retest reliability was assessed using Pearson's correlation test. We interpreted the correlation coefficient as follows: low <0.20, 0.21<fair<0.40, 0.41<moderate<0.60, 0.61<substantial<0.80, and 0.80<almost perfect<1.00 (13).

Validity

Confirmatory factor analysis (CFA) was conducted to assess convergent validity between items and subscales of the HRQL (items 9 to 37). First, sampling adequacy and data appropriateness for CFA were examined using the Kaiser-Meyer-Olkin (KMO) measure and Bartlett's test of sphericity, respectively. A KMO value of >0.6 with significant Bartlett's test of sphericity (P<0.05) was considered suitable for CFA. Then, we determined CFA by using the principal components method with varimax rotation (Eigenvalue>1.00). Items with weak loading (value<0.40) were excluded from the analysis (1). Pearson's correlation coefficient was used to assess convergence validity between subscales of the UFS-QOL and WHOQOL-BREF-26 questionnaires. In order to interpret the correlation coefficient, we undertook the same procedure as for test-retest reliability.

Statistical analysis

Data were processed using the IBM® Statistical Package for Social Sciences (SPSS) ® software version 23.0 (IBM®, USA). Variables were described as frequency, percentage, mean and standard deviation. Pearson's correlation test was used to assess test-retest reliability and convergence validity between instruments. In this study, a P<0.05 was considered statistically significant.

Ethical considerations

The Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran approved this study (IR.SBMU.RETECH.REC.1401.219). All steps of the study were performed in accordance with the Declaration of Helsinki 2000.

Results

Patients' baseline characteristics

Initially, 232 patients were included in the study and six patients were excluded after application of the exclusion criteria (adenomyosis [4], gynaecologic cancer [1], and pregnancy [1]). The mean age of the 226 included patients was 42.10 ± 6.02 years (range: 18 to 45). Most had a normal body mass index (42.9%), while others were overweight (37.6%) and obese (19.5%). Patients mainly complained of abnormal uterine bleeding (49.1%), while others came because of routine check-ups (43.4%) and abdominopelvic pain (7.5%). Table 1 shows the baseline characteristics of the patients. On ultrasound examination, 57.5% had one UF, 20.8% had two UFs, and the remaining (21.7%) had three or more UFs. According to the International Federation of Gynaecology and Obstetrics (FIGO) classification system, the most common location of the UFs was 4 or intramural (49.1%), followed by 6 (19.5%), 5 (15.9%), 7 (5.3%), 2 (3.5%), 0 (2.7%), 1 (2.7%), and 8 (1.3%).

Table 1: Baseline characteristics of the patients (n=226)

Variables	Values
Demographic characteristics	
Age (Y)	42.10 ± 6.02
Body mass index (kg/m^2)	
Normal (<25)	97 (42.9)
Overweight (25-30)	85 (37.6)
Obese (≥30)	44 (19.5)
Marital status	
Married	194 (85.8)
Single	32 (14.2)
Employment status	
Unemployed	133 (58.8)
Employed	93 (41.2)
Educational status	
Elementary	42 (18.6)
Diploma	88 (39.0)
Bachelor or higher degree	96 (42.4)
Clinical characteristics	
Chief complaint*	
Abnormal uterine bleeding	111 (49.1)
Abdominopelvic pain	17 (7.5)
Menstrual volume	
Decreased	17 (7.5)
Normal	114 (50.5)
Increased	95 (42.0)
Menstrual duration	
Decreased	17 (7.5)
Normal	169 (74.8)
Increased	40 (17.7)
Menstrual regularity	
Regular	175 (77.4)
Irregular	51 (22.6)
Family history of UFs	79 (35.0)
Ultrasound findings	
Number of UFs	
One	130 (57.5)
Two	47 (20.8)
Three or more	49 (21.7)
Size of the largest UF (mm)	44.15 ± 34.64
Endometrial thickness (mm)	7.26 ± 3.03

Data are reported as frequency (%) or mean ± SD. *; Others (43.4%) came for a routine check-up and UFs; Uterine fibroid.

Reliability

Table 2 presents the internal consistency of the UFS-QOL questionnaire. All the subscales had acceptable internal consistency: symptom severity (α=0.812), concern (α=0.856), activities (α=0.902), energy/mood (α=0.919), control (α=0.861), self-consciousness (α=0.839), and sexual function (α=0.949). Additionally, total HRQL (all subscales, except for symptom severity) had acceptable internal consistency (α=0.956).

Table 2: Internal consistency of the UFS-QOL questionnaire

Subscales	Number of items	Cronbach's alpha*
Symptom severity	8 (Q1-Q8)	0.812
Concern	5 (Q9, Q15, Q22, Q28, Q35)	0.856
Activities	7 (Q10, Q11, Q13, Q19, Q20, Q27, Q29)	0.902
Energy/mood	7 (Q12, Q17, Q23, Q24, Q25, Q31, Q34)	0.919
Control	5 (Q14, Q16, Q26, Q30, Q33)	0.861
Self-consciousness	3 (Q18, Q21, Q32)	0.839
Sexual function	2 (Q36, Q37)	0.949
HRQL total	29 (sum of subscales except symptom severity)	0.956

HRQL; Health-related quality of life, UFS-QOL; Uterine Fibroid Symptom and Health-related Quality of Life, and *; α>0.70 is considered acceptable internal consistency.

Table 3 depicts test-retest reliability of the UFS-QOL subscales. Test-retest analysis indicated significant positive correlations between two measurements of all subscales: symptom severity (r=0.757, P<0.001), concern (r=0.822, P<0.001), activities (r=0.806, P<0.001), energy/mood (r=0.709, P<0.001), control (r=0.827, P<0.001), self-consciousness (r=0.652, P=0.002), and sexual function (r=0.723, P<0.001).

Validity

In our study, the KMO measure value was 0.920, which indicated sampling adequacy. Bartlett's test of sphericity was significant (chi-square value=5653.929, df =406, P<0.001), which indicated that the CFA was suitable for data. Figure 1 depicts a scree plot of Eigenvalues for each item before applying the rotation. After application of the varimax rotation, the test variables explained 73.827% of the total variance. The Eigenvalues and percentages of variance were as follows: factor one: 4.692 (16.178%), factor two: 4.628 (15.959%), factor three: 3.771 (13.003%), factor four: 3.180 (10.966%), factor five: 2.984 (10.291%), and factor six: 2.155 (7.429%). Table 4 illustrates the rotated component matrix to assess convergent validity between the items and subscales of HRQL. By comparing the factors obtained from CFA and subscales of the HRQL, we noted that all items belonged to the same subscales, with the exception of items 9, 14, 19, 27, and 29. Table 5 shows the convergent validity of subscales of the UFS-QOL questionnaire. The symptom severity subscale of the UFS-QOL questionnaire had a negative correlation with all domains of the WHOQOL-BREF-26 questionnaire. The concern (r=0.098, P=0.141), self-conscious (r=0.111, P=0.095), and sexual function (r=0.057, P=0.396) subscales of the UFS-QOL questionnaire did not significantly correlate with the environment domain of the WHOQOL questionnaire. Other subscales of UFS-QOL had a positive correlation with domains of the WHOQOL questionnaire.

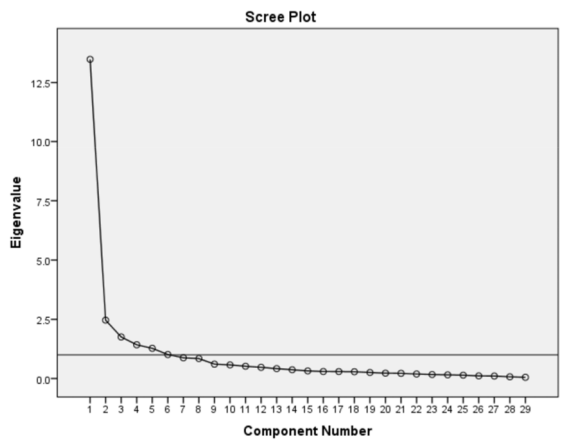

Fig.1: Scree plot of Eigenvalues for each item before applying rotation.

Table 3: Test-retest reliability of UFS-QOL subscales

Subscales	Symptom severity	Concern	Activities	Energy/ mood	Control	Self-con-sciousness	Sexual function
Correlation coefficient (r)	0.757	0.822	0.806	0.709	0.827	0.652	0.723
P value	<0.001	<0.001	<0.001	<0.001	<0.001	0.002	<0.001

UFS-QOL; Uterine Fibroid Symptom and Health-related Quality of Life.

Table 4: Rotated component matrix to assess convergent validity between items and subscales of the HRQL

Items	Factor 1 (Energy/ mood)	Factor 2 (Activity)	Factor 3 (Concern)	Factor 4 (Self-consciousness)	Factor 5 (Control)	Factor 6 (Sexual dysfunction)
Q23	**0.787**					
Q24	**0.784**					
Q25	**0.750**					
Q17	**0.644**	0.473				
Q12	**0.611**	0.611				
Q34	**0.579**					
Q31	**0.573**					
Q11		**0.800**				
Q13		**0.760**				
Q10		**0.624**			0.403	
Q16		**0.584**				
Q20		**0.533**		0.454		
Q14	0.411	0.513				
Q35			**0.854**			
Q22			**0.839**			
Q15			**0.826**			
Q28			**0.482**			
Q29			0.464			
Q18				**0.854**		
Q21				**0.825**		
Q32				**0.781**		
Q19		0.524		0.547		
Q27					0.681	
Q26					**0.658**	
Q30	0.447				**0.647**	
Q33	0.443				**0.580**	
Q9		0.436			0.488	
Q36						**0.909**
Q37						**0.894**

Extraction method; Principal component analysis, Rotation method; Varimax with Kaiser normalization, HRQL; Health-related quality of life. Values in bold indicate that they belong to the factors named in the column. Rotation converged in ten iterations.

Table 5: Convergent validity: pearson's correlation between subscales of UFS-QOL and WHOQOL-BREF-26

Subscales		Overall QOL	Physical health	Psychological	Social relationships	Environment
Symptom severity	r	-0.262	-0.307	-0.283	-0.269	-0.146
	P value	<0.001	<0.001	<0.001	<0.001	0.029
Concern	r	0.200	0.228	0.296	0.222	0.098
	P value	0.003	0.001	<0.001	0.001	0.141
Activities	r	0.215	0.274	0.289	0.262	0.144
	P value	0.001	<0.001	<0.001	<0.001	0.03
Energy/mood	r	0.372	0.405	0.473	0.377	0.296
	P value	<0.001	<0.001	<0.001	<0.001	<0.001
Control	r	0.357	0.327	0.446	0.306	0.307
	P value	<0.001	<0.001	<0.001	<0.001	<0.001
Self-consciousness	r	0.117	0.324	0.238	0.206	0.111
	P value	0.079	<0.001	<0.001	0.002	0.095
Sexual function	r	0.180	0.178	0.267	0.242	0.057
	P value	0.007	0.007	<0.001	<0.001	0.396

UFS-QOL; Uterine Fibroid Symptom and Health-related Quality of Life, WHOQOL-BREF-26; World Health Organization Quality of Life Brief Version 26 questionnaire.

Discussion

This study investigated the reliability and validity of the Persian version of the UFS-QOL questionnaire in Iranian women with UFs. Our assessed Persian version of the UFS-QOL questionnaire has acceptable psychometric properties and it can help researchers and clinicians to evaluate UF-related symptoms and HRQL in Iranian women.

The USF-QOL questionnaire is an efficient instrument to investigate the impact of UFs on patients' perspectives of their QOL. The original questionnaire was developed by Spies et al. (12) in English in 2002, and further validation was conducted by them and Coyne et al. (14). The USF-QOL questionnaire is an international instrument that has been translated and validated in Chinese (2), Spanish (15), Dutch (10), Brazilian Portuguese (16), Bengali (1), and Sinhala (17).

In our study, all subscales of the UFS-QOL questionnaire had acceptable internal consistency. In other words, three subscales (activities, energy/mood, and sexual function) had excellent internal consistency (Cronbach's alpha >0.9), while others (symptom severity, concern, control, and self-consciousness) had high internal consistency (Cronbach's alpha 0.70-0.90) (18). The Chinese version of the UFS-QOL indicated almost perfect Cronbach's alpha scores in the activities, energy/mood, and sexual function subscales (2). A study by Keizer et al. (10) illustrated that the sexual function and control subscales had the same Cronbach's alpha score and the concern subscale had more internal consistency than the sexual function subscale in the Dutch version of UFS-QOL.

Test-retest was performed to ensure that the measurements remained constant. Three subscales of the UFS-QOL questionnaire (concern, activities, and control) had almost perfect reliability (Pearson's correlation coefficient 0.81-1.00), while others (symptom severity, energy/mood, self-consciousness, and sexual function) had substantial reliability (Pearson's correlation coefficient 0.61-0.80) (13). In the Dutch version, concern (0.93), activities (0.9), and energy/mood (0.9) had the highest intraclass correlation coefficient in test-retest results (10), which is in line with our findings.

Based on the CFA, most items of the Persian version of the UFS-QOL questionnaire belonged to the same subscales of the English questionnaire. Inconsistencies in other items may be attributed to cultural context and language differences (9).

Convergent validity is frequently used in psychological and behavioural sciences and indicates the relationship between the new scale and other scales with the same construct (19). The symptom severity subscale of the UFS-QOL questionnaire had a negative correlation with all domains of the WHOQOL-BREF-26 questionnaire, which was due to the scoring method of this subscale. The higher scores indicate more severe symptoms. Symptom severity is associated with decreased QOL. Furthermore, most subscales of the UFS-QOL questionnaire did not correlate with the environment domain of the WHOQOL-BREF-26 questionnaire. This shows that our questionnaire does not probably cover the "environment" domain. A study by Oliveira Brito et al. (20) demonstrated that scores obtained from the Brazilian Portuguese version of UFS-QOL and the subscales of the Short Form-36 questionnaire were negatively correlated, which was consistent with our findings.

Our study had some limitations. We did not evaluate responsiveness as the psychometric properties of the UFS-QOL questionnaire. Based on factor analysis, 5 to 15 individuals should be considered for each item to calculate the sample size. However, due to the limited number of patients, we considered five patients per item.

Conclusion

The Persian version of the UFS-QOL questionnaire is a reliable and valid instrument to evaluate UF symptoms and HRQL in Iranian women with UFs. It could be helpful for clinicians and researchers to assess the severity of symptoms from the patient's perspective.

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Authors' Contributions

H.N.; Conceptualisation, Study design, Data collection, Data analysis, and Wrote the primary draft. A.K.; Study design, Data analysis, Critical thinking, and Edited the manuscript. F.R.M.; Data collection and Wrote the primary draft. H.D.; Conceptualisation and Wrote the primary draft. Sh.H.Ch.; Participated in statistical analysis and drafting. Sh.R.F.; Participated in study design, Resources, and Data curation. Z.B.; Data collection, Resources, and Data curation. M.S.H.; Study design, Critical thinking, and Edited the manuscript. F.F.; Conceptualisation, Supervision, Critical thinking, and Edited the manuscript. All authors read and approved the final manuscript.

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