Research Article

Feasibility, Reliability, and Validity of the Iranian Version of the Quality of Life Questionnaire for Pregnancy

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Abstract

Background: Clinical studies are giving increased importance to quality of life assessments as measures of the relative effectiveness of prevention and treatment programs used during pregnancy and antenatally.
Objectives: The aim of this study was to validate the Quality of life gravidarum (QOL-GRAV) questionnaire for Iranian women during the pregnant period
Patients and Methods: In this cross-sectional methodological study, content validity following back and forward translation was assessed by a panel of experts. Using the two-stage cluster sampling method, 565 pregnant women referred to health care centers from April to June 2015 in Tabriz, Iran were enrolled in the study. Construct validity by assessing the factor structure, and convergent and discriminant validity were evaluated using scale-item correlations and known group analyses. Internal consistency and test–retest reliability were assessed in a sample of 30 pregnant women by the Cronbach's α coefficient and intra-class correlation coefficient (ICC).
Results: The QOL-GRAV showed good content validity (CVI value = 0.95 and CVR value = 1), internal consistency ($\alpha = 0.79$), and test–retest reliability (ICC = 0.86). The results of the CFA for two-factor models indicate an acceptable fit of the proposed model (RMSEA; 90% CI = 0.083; 0.068–0.099, CFI = 0.95, GFI = 0.96, and AGFI = 0.92).
Conclusions: The findings support the validity and reliability of the Iranian version of the QOL-GRAV questionnaire. Therefore, it is recommended to be used for both clinical and research purposes.

Keywords: Feasibility, Validity, Reliability, Quality of Life, Pregnancy, Iran

1. Background

Many changes occur in the physical, mental, and social aspects of health and overall quality of life for pregnant women during the different pregnancy trimesters (1, 2). The world health organization defines the quality of life as "beliefs of individual from their position in life within the context of cultural and valuable systems in which they live and the relationship of these beliefs to the goals, expectations, standards and their concerns" (3).

Although the purpose of care during pregnancy is for a desirable maternal and neonatal outcome, particular attention should also be given to the effects these changes have on the woman during pregnancy (4). Less attention is given to the woman's quality of life during pregnancy compared to normal process of pregnancy (5).

The aim of care for women during pregnancy and antenatally in developed countries is highlighted by more comprehensive goals such as encouraging psychological adaptation to pregnancy, and in the prevention, diagnosis, and management of complications of pregnancy. This means that special attention is provided to the quality of life and the psychological state of pregnant women (6).

Although the importance of the antenatal period has been recognized in recent years, research into areas that affect the quality of life for women during pregnancy could help adopt appropriate strategies for the promotion of maternal health. There is very little information about the physical, mental, and social changes that pregnant women experience indicating that the quality of life of pregnant women need more attention (7, 8). Improving the quality

of life during pregnancy is one of the main goals and is effective compared with post-delivery outcomes (9).

Assessing the quality of life in clinical studies has growing importance in investigating the relative effectiveness of prevention and treatment programs during pregnancy and antenatally (10).

A case study stating that 57% of the studies that evaluated the quality of life in pregnant women used general tools like the long and short form of SF-36; world health organization's quality of life scale- BREF (WHO QoL- BREF) and only 20% used specific tools such as mother-generated index (MGI) (11). Symon analyzed 32 studies that examined the quality of life during pregnancy and concluded that the present specific questionnaires (PUQE, NVP, and QOL) focused more on specific problems in pregnancy rather than on women's overall well-being and their quality of life (12). Hence, the QOL-GRAV developed in 2013 to address this (5).

Because of the high dependency of measurement tools to cultural differences, it is necessary that these tools be evaluated and benchmarked for other environments (13). Based on searches conducted, the validity and reliability of the QOL-GRAV has not been evaluated in another country. Despite its importance, no study has determined the validity and reliability of QOL-GRAV for Iranian women to date. Therefore, this study was conducted to determine the psychometric characteristics of the newly designed QOL-GRAV questionnaire.

2. Objectives

The aim of this study was to translate and validate the QOL-GRAV questionnaire for Iranian women in the antenatal period.

The following questions were addressed?

Would the content validity of QOL-GRAV be confirmed?

Is the QOL-GRAV questionnaire consistent and stable over time ?

Does a factor model for the QOL-GRAV confirm the construct validity, based on the results of exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) ?

Does the measurement have reasonable convergent and discriminant validity ?

3. Patients and Methods

3.1. Study Design, Participants, and Setting

This cross-sectional methodological study is part of a larger study entitled "The relationship of depression and sleep quality with quality of life in pregnant women." The sample size in was calculated based on the two variables of

depression and sleep quality. According to Jahdi and colleagues, the sample size was estimated at 250 with regard to d = 0.05 around the average score of sleep quality (m = 7.78, sd = 3.14, α = 0.05) (14). Baghi and colleagues estimated the sample size as 377 with regard to d = 0.05 around the average score of sleep quality (m = 10.5, sd = 5.2, α = 0.05) (15). As the sampling was a cluster type, the final sample size was calculated as 565 with regards to design effect equal to 1.5. A sample size that was 5 times the number of items in the questionnaire was used for factor analysis ($5 \times 9 = 45$). Others suggest that a sample size of 200 is adequate in most cases of factor analysis; however, we still recruited 565 pregnant women.

The target population was pregnant women with a gestational age of 28 - 38 weeks, referred from health care centers in Tabriz in 2014. The health care centers were public, government, and first-level referral centers and treated the highest number of pregnant women in Tabriz. The inclusion criteria was as follows: Iranian, Muslim, resident of Tabriz, pre-planned and wanted pregnancies, married, singleton pregnancy, non-shift worker, and a willingness to participate in the study with the possibility of a phone call. Patients who did not complete the consent form and those unwilling to participate were excluded.

3.2. Sampling

A two-stage cluster sampling method was used. One third of the 60 health centers and 25 bases were selected randomly through the www.random.org website. Then, according to the sample size of the study and number of pregnant women covered by the health centers, the sample was stratified for each selected center. Eligible women were listed and numbered and the final participants were randomly selected based on the quotas set for each center. The selected pregnant women were called and invited for the study. The participants were initially assessed in terms of basic information and the inclusion and exclusion criteria. If they were eligible, they were provided with comprehensive information on the research aims, advantages, results, confidentiality, and the way the research was to be conducted. If they were willing to participate they were requested to fill out the informed consent forms. Data was collected using research tools. The questionnaires were completed during a 15-minute interview. All data was collected during a 3-month period.

3.3. Data Collection Tools

3.3.1. QOL-GRAV Questionnaire

This questionnaire was developed by Vachkova et al. in 2013 using the WHO's quality of life short form questionnaire. It contains 9 questions addressing an individual's

experiences of their quality of life during pregnancy. Internal consistency of the questionnaire was reported at more than 0.7. The method to score each item is a scale of never (score 0) to absolutely (score 4). The final 3 questions of the questionnaire (questions 7, 8, and 9) are scored in a reversed manner. The total score ranges from 15 to 35. In case of a low scale mean, an individual's quality of life will be better without any pregnancy problems (9). The investigator via interview will complete this questionnaire during pregnancy from 28 - 38 weeks.

The Persian translation of the questionnaire was carried out in a forward-backward translation procedure. The questionnaire was translated into Persian by 2 experts in both the English and Persian languages. The final version of the translated questionnaire was obtained by comparing and incorporating the initial translations by the 2 experts in both English and Persian languages. Later, the questionnaire was again translated into English by a third-party translator and was compared to the original questionnaire for validation.

Participants also completed a socio-demographic characteristics questionnaire, which includes year of birth, gestational age, height and weight before pregnancy, level of education, occupation, husband's level of education, income adequacy for living expenses, housing status, satisfaction with husband's job, relationship with husband, history of abortion and preterm birth, the way of receiving care during pregnancy and satisfaction rating of it, wanted pregnancy, and mother's and father's satisfaction with fetus's gender.

3.4. Ethical Considerations

Informed consent was obtained from all eligible participants. All patient information remained confidential. This survey was approved by ethics committee of the Tabriz University of Medical Sciences dated 2015/2/2, No 5/4/10676.

3.5. Statistical Analysis

Ceiling and floor effects were evaluated based on percentage of scores at the extremes of the scoring range. Internal consistency was assessed by calculating Cronbach's α coefficient and convergent validity was assessed by the item-total correlations. An α coefficient $\geq$ 0.70 and correlation values > 0.5 were considered satisfactory. Test-retest reliability of the questionnaire was evaluated by repeating it for 30 pregnant women after a period of 2 weeks. Intraclass correlation coefficient (ICC) was computed to evaluate the stability over time. Content validity index (CVI) was calculated relative to 3 indices; simplicity, relevance, and transparency, while content validity ratio (CVR) was calculated on the basis of item relevancy. To assess how well

the EFA extracted model fitted to observed data, we conducted CFA. The method of estimation was a robust maximum likelihood.

Statistical analysis was performed using SPSS 16.0 (SPSS Inc., Chicago, IL, USA) and AMOS. P < 0.05 was considered statistically significant.

4. Results

4.1. Sample Characteristics

Mean (SD = standard deviation) age and BMI was 28.7 (5.5) years and 25.2 (2.3) kg/m^2 respectively. One third of the participants (33.5%) had a diploma and most of them were housekeepers (98.0%). The majority (63.8%) reported that their monthly income was lower than adequate. In total, 95% received pregnancy care from health centers and bases and 64% were satisfied with their husbands' jobs. In total, 76% reported that they had wanted the pregnancy. Moreover, 78% of the women and 76% of the husbands were satisfied with the fetus's gender. Mean (SD) of the total score of quality of life was 2.9 (0.3) within the accessible score range of 1-5 (Table 1).

4.2. Content Validity

The QOL-GRAV questionnaire was reviewed for content validity by a panel of professional experts (this panel consisted of 10 faculty members of Tabriz University of Medical Sciences including 3 reproductive health specialists, 2 experts with a PhD degree in nursing, 1 person with a PhD degree in health promotion, and 4 with MSc degree in midwifery) for both qualitative and quantitative manners associated with Iranian culture. The overall quality of the content of QOL-GRAV was confirmed using this panel. In addition, some items were corrected and improved by applying the qualitative opinions of the expert panel. Scores of relevancy, clarity, simplicity, CVI, and CVR of QOL-GRAV are listed in Table 2. The CVI and CVR as the indicators for content validity were calculated as 0.95 and 1 respectively.

4.3. Reliability

Cronbach's α coefficient, which assesses internal correlation was 0796. In addition, ICC was 0.86.

4.4. Factorial (Construct) Validity

Exploratory factor analysis with Varimax rotation extracted 2 factors from the QOL-GRAV accounting for 59.49% of total variance. A kaser-meier-olkin (KMO) value of 0.830 and P < 0.001 of Bartelet test of sphericity (approximate x^2 = 1870.93, df = 36 and P < 0.001) confirmed the adequacy of factor model.

Table 1. Socio-Demographic Characteristics of the Participants (n = 565)

Characteristic	Number (%)[a]	Characteristic	Number (%)
Age (years)		**Body mass index (kg/m^2)**	
< 18	6 (1.1)	< 19.8	11 (2.0)
18 - 25	152 (27.4)	19.8 - 25.9	388 (70.8)
25 - 30	194 (35.0)	26 - 29	125 (22.8)
> 30	202 (36.5)	> 29	24 (4.4)
Mean (SD)	28.7 (5.5)	Mean (SD)[b]	25.2 (2.3)
Education level		**Husband's education level**	
Illiterate	19 (3.4)	Illiterate	10 (1.8)
Elementary	151 (26.7)	Elementary	165 (29.2)
Secondary	116 (20.5)	Guidance	145 (25.7)
High school	49 (8.7)	High school	38 (6.7)
Diploma	189 (33.5)	Diploma	152 (26.9)
University	41 (7.3)	University	55 (9.7)
Job		**Sufficiency of income for expenses**[c]	
Housewife	549 (98.0)	Fairly sufficient	197 (36.2)
Employed	11 (2.0)	Insufficient	347 (63.8)
Residence		**History of abortion**	154 (27.3)
Personal	207 (36.6)	**Place of receiving prenatal care**	
Rental	358 (63.4)	Health center	538 (95.9)
History of preterm labor	7 (1.2)	Private clinic	5 (0.9)
Marital relationship		Health center and Private clinic	18 (3.2)
Very good	92 (16.3)	**Satisfaction of husband job**	
Good	368 (65.4)	Fairly satisfied	202 (35.8)
Fairly good	103 (18.3)	Completely satisfied	362 (64.2)
Wanted Pregnancy	432 (76.5)	**History of depression**	2 (0.4)
Woman interest in fetal sex	443 (78.8)	**Husband interest in fetal sex**	427 (76.3)

[a]Valid percent has been reported in all the variables because of missed data.
[b]All data indicate number (percent), unless has been specified.
[c]2 Cases reported that the income was completely sufficient.

A factor structure consisting of 2 factors (Table 3) resulted as follows: 1) The first domain factor included items 1 to 6 and 2) The second domain factor including items 7 to 9.

All items with minimum and maximum factor loading of 0.4 and 0.87 respectively, were placed at the right factor. Factor loading of items QOL1, 2, 3, 4, 5, and 6 (first domain) were respectively 0.802, 0.830, 0.814, 0.814, 0.807, 0.620. QOL 7, 8, and 9 (second domain) were 0.409, 0.874, and 0.795 respectively (Table 3).

The results of the CFA for two-factor models indicated an acceptable fit of the proposed model [RMSEA (90% CI) = 0.083 (0.068; 0.099), CFI = 0.95, GFI = 0.96, and AGFI = 0.92].

In addition, all parameters relating to factors and all correlations among 2 factors (Figure 1) were statistically significant (all P < 0.001).

The normality of the variables was assessed and was normal. Thus, we have reported the mean (SD). The following results were obtained by calculating the mean (SD) of scores for each subscale: first domain 3.5 (0.4) and second domain 1.7 (0.3) (Table 4).

4.5. Feasibility

No ceiling and floor effects were observed for each subscale (Table 4).

Table 2. The Scores of Relevancy, Clarity, Simplicity, CVI and CVR for QOL-GRAV

Item Content	CVI			(CVI)	(CVR)
	Relativity	Clarity	Simplicity		
To what extent do you feel that your physical changes associated with this pregnancy do not allow you to do what you need?	1	1	1	1	1
To what extent do you feel that your psychological changes associated with this pregnancy do not allow you to do what you need?	1	1	1	1	1
How worried are you about not being able to handle household chores?	1	1	1	1	1
How worried are you about carrying out the pregnancy successfully?	1	1	1	1	1
How worried are you about not being able to handle labor and delivery?	1	1	1	1	1
Have you been forced to cut down on your physical activity during this pregnancy?	1	1	1	1	1
How satisfied are you with your partner now?	0.87	1	0.87	0.91	1
How satisfied are you with your social life now?	1	1	1	1	1
Hw satisfied are you with how you manage to adapt to this pregnancy?	0.75	0.625	0.625	0.67	1
Total	0.96	0.96	0.94	0.95	1

Table 3. Exploratory Factor Loadings for Subscales of QOL-GRAV[a]

Items	First Domain	Second Domain
QOL1	0.802	0.146
QOL2	0.830	0.054
QOL3	0.814	0.107
QOL4	0.814	0.043
QOL5	0.807	0.023
QOL6	0.620	-0.140
QOL7	0.022	0.409
QOL8	-0.111	0.874
QOL9	0.173	0.795

[a]Extraction method, principal component analysis; rotation method, varimax with kaiser normalization; values higher than 0.3 are considerable loading and highlighted.

5. Discussion

This study is the first to assess the validity, reliability, and feasibility of the QOL-GRAV in Iranian pregnant women. The findings of this study showed that the Persian version of QOL-GRAV could measure the quality of life in Iranian pregnant women. The high number of samples is a strong point of the present study.

Vachkova and colleagues compared the general tools of the WHO QoL- BREF with the specific tools of QOL-GRAV for 225 women with uncomplicated pregnancy referred to a private clinic for women in Hradec Kralove, Czech Republic. According to the results of this study, the specific tools of QOL-GRAV are more sensitive to pregnancy changes that
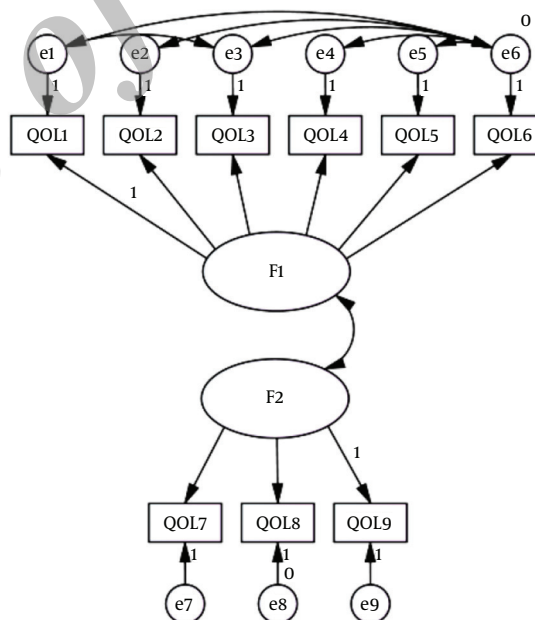

Figure 1. Path diagram revealing the standardized parameters relating items to relevant factor. All parameters were statistically significant and all two factors were correlated significantly (all P < 0.001).

affect the quality of life significantly compared to the general tools. The QOL-GRAV questionnaire was made on the basis of the short form of the WHO quality of life in 2013, and the Cronbach's α coefficient was higher than 0.7 for all

Table 4. Means, Standard Deviations, Percent Floor And Ceiling Effects, and Cronbach's Alpha for the Iranian Version of QOL-GRAV scales (N = 565)

Item	Mean (SD)	Skewness	Kurtosis	Floor. N (%)	Ceiling. N (%)	Cronbach's Alpha
First domain	3.5 (0.4)	-0.7	0.6	0 (0.0)	0 (0.0)	0.875
Second domain	1.7 (0.3)	-0.6	-0.9	0 (0.0)	0 (0.0)	0.677
Total	2.9 (0.3)	-0.6	0.2	0 (0.0)	0 (0.0)	0.796

items of this tool (5).

Content validity is one of the most important factors for validating a questionnaire (16). Content validity of the QOL-GRAV questionnaire was examined qualitatively and quantitatively by evaluating expert opinions and by calculating the CVR and CVI. The original version of the questionnaire did not report on CVR and CVI.

Reliability of the tools refers to the issue that the results of a questionnaire or test should be repeated at different times (17). In the present study, the reliability was reported using ICC and Cronbach's α coefficient. The Cronbach's α coefficient for the questionnaire was 0.796, and as the value is more than 0.7, the internal correlation of QOL-GRAV questionnaire was confirmed. The Cronbach's α coefficient obtained in this study is consistent with the study of Vachkova and colleagues, in which the coefficient was reported as 0.72 , 0.74, and 0.75 α for the first, second, and third trimester, respectively (5). In the study, ICC was 0.86, which shows the repetition capabilities of the test. Construct validity determines whether a structure can meet study objectives (17).

Factor analysis shows whether the 9 items were sorted correctly or not. To validate the construct the correlation of items should be examined prior to factor analysis using the Bartlett test and KMO index. KMO index should not be less than 0.5 (16). The KMO was 0.83 and shows good factor analysis. For each subscale of the QOL-GRAV, the null hypothesis of data sphericity was rejected (P < 0.05) and the KMO statistics were confirmed. Thus, EFA fitted the data and confirmed the validity of the instrument. There are no other similar studies and therefore no credible source is available to compare the results of the present study.

The selection of pregnant women only in the city of Tabriz was one of the limitations of our study. Given that other cities differ from Tabriz in terms of culture, this study should be repeated in other cities. Because this is the first study it was necessary to evaluate these tools in a clinical setting. The sensitivity, specificity, and its predictive value should be compared and assessed in comparison to other proprietary tools.

5.1. Conclusion

Results of the present study showed that the translated QOL-GRAV questionnaire or Iranian pregnant women validates and it enjoys a good reliability and validity. Therefore, this tool can be used to measure the quality of life for pregnant women in research and clinical positions.

Acknowledgments

Footnotes

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