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Original Article

Reliability, Validity, and Transcultural Adaptation of New Persian Version of Celiac Disease Quality of Life Questionnaire

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Abstract

Background: Health-related quality of life (HRQOL) assessment in patients with celiac disease (CD) leads to understanding the impact of the CD and interventions on the individual and society. The aim of this study was transcultural adaptation and evaluation of the reliability and validity of the standardized questionnaire of celiac disease quality of life (CD-QOL) in the Persian language in southwest Iran.

Methods: 150 adults with CD were randomly selected from the celiac clinic and Fars Celiac Registry to complete the New Persian version of the CD-QOL questionnaire. Transcultural adaptation of the questionnaire was conducted by a four-step procedure. The internal consistency of the CD-QOL subscales and convergent and discriminant validity were assessed using Cronbach's alpha coefficient and Spearman's correlation, respectively. Construct validity was evaluated by exploratory and confirmatory factor analysis.

Results: All domains of the CD-QOL questionnaire had acceptable internal consistency, showing excellent reliability. The scaling success rates for convergent and discriminant validity were also within an acceptable range (87-100%). In the factor analysis model, similar to the original English version, four factors were extracted characterizing the patients' answers (limitations, dysphoria, health concerns, and inadequate treatment).

Conclusion: Our Persian version of the CD-QOL questionnaire had high reliability and validity and could be used in clinical practice assessing the CD-specific HRQOL in the Iranian population.

Keywords: Celiac disease, Health-related quality of life, Persian, Questionnaire, Validation

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Introduction

Celiac disease (CD) is an autoimmune enteropathy triggered by eating foods containing gluten in genetically susceptible individuals.[1] Extensive use of serological tests for screening has led to a faster diagnosis of CD than in the past.[2] The worldwide prevalence of CD is estimated to be 1.4% (95% CI, 1.1-1.7%), and pooled prevalence of CD in the Asian continent is approximately 1.8% (95% CI, 1-2.9%).[1] In Iran, the CD prevalence is almost similar to other countries and is 1.16% in a healthy population.[3] CD is a long-term autoimmune disease associated with morbidity, and patients must have a gluten-free diet throughout their lives. So, they have impaired quality of life (QOL) in all aspects.[4]

According to the World Health Organization (WHO) definition, QOL is one's subjective perception of his/her position in life regarding the culture and value systems in which he/she lives and associated with the objectives, concerns, expectations, and standards of that individual.[5] On the other hand, health-related quality of life (HRQOL) includes only those factors related to an individual's physical, mental, and social well-being.[6] There are several questionnaires for assessing HRQOL in patients with CD.[7-9] Celiac disease quality of life (CD-QOL) is one of such scales developed by Dorn and colleagues in the English language and consists of 20 questions.[10] The CD-QOL is a questionnaire recommended by Rome IV Foundation, an organization providing educational information regarding diagnosing and treating functional gastrointestinal disorders. Transcultural adaptation and validity and reliability assessment of this standard tool for Persian-speaking patients will increase the quality of HRQOL studies by Iranian researchers and comparing the QOL indicators with other populations and countries.[11] The purpose of this study was the translation, transcultural adaptation, and evaluation of the validity and reliability of

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the standardized questionnaire of CD-QOL in the Persian language in southwest Iran.

Material and Methods

Transcultural Adaptation

The transcultural adaptation of the CD-QOL was conducted according to the structured procedure described by Beaton and colleagues.[12] In summary, the translation of the English version of the CD-QOL questionnaire into the Persian language was performed by two independent experts in linguistics (with permission from ROME Foundation as the copyright holder). Then, the translators shared their reports, and their discussion produced a common Persian questionnaire. Back translation of this questionnaire was also performed by two English first-language translators. After assessing the reports by a panel of experts and pilot testing the questionnaire on five patients to assess the document's clarity, the final version of the CD-QOL was produced.

Participants (Patients)

A total of 150 adults with CD who were referred to the celiac clinic and Fars Celiac Registry, affiliated to Shiraz University of Medical Sciences (Approval ID: IR.SUMS.REC.1397.557), participated randomly in this study from January 2020 to January 2021. Random sampling was conducted using SPSS software. All patients completed the new Persian version of the CD-QOL. One of the authors (an epidemiologist) was also available to clarify the possible questions of the patients about the instrument. The basic characteristics data, including age and sex, labor location, type of labor, type of milk consumed in infancy, family history of CD, marital status, and education were also collected. Patients signed the informed consent forms, and they were instructed in detail on how to fill out the questionnaire.

Serological and Histological Evaluation

All patients with CD (ICD10; K 90.0) who had been referred to the celiac clinic, a referral clinic in southern Iran, were assessed by a gastroenterologist for diagnosis of CD. Documentation of all patients with CD was gathered for serum levels of IgA anti-transglutaminase antibodies (anti-tTG). Patients with IgA levels below 0.006 g/dL were excluded from the study as a condition of selective serum immunoglobulin A deficiency. Anti-tTG was calculated using an Aeskulisa kit (Germany) and ELISA method for all patients and a title of 18 IU/mL or higher was considered a positive result. Small bowel biopsy samples were taken in all patients with positive anti-tTG and histological findings were classified based on Oberhuber-modified Marsh classification.[13]

Inclusion and Exclusion Criteria

The diagnosis of CD is based on duodenal biopsy as a standard diagnostic method and CD-positive serology,[14] so, in our study, CD in referred adult patients (≥18 years old) was diagnosed as an anti-tTG level of 18 IU/mL or higher in serology and Marsh type 2 or more severe in histological evaluation. Exclusion criteria were participants with incomplete records, patients who did not cooperate, IgA deficiency, Marsh type 0 and 1 in histology, and the presence of other possible causes of the villous atrophy in the pathologist's report, including neoplastic disease, infections, infiltrative disorders, and Crohn's disease.

Instrument

The CD-QOL contains four subscales including limitation (nine items), dysphoria (four items), health concerns (five items), and inadequate treatment (two items). The patients responded to the items on a 5-point Likert scale (1 = not at all, 2 = slightly, 3 = moderately, 4 = quite a bit, and 5 = a great deal). The raw subscale scores were transformed into a 0-100 scale, with higher scores representing better HRQOL.

The internal consistency of the CD-QOL subscales was evaluated by Cronbach's alpha coefficient. Internal consistency was considered satisfactory if the coefficient was greater than 0.7. Convergent and discriminant validity were assessed using Spearman's correlation. A correlation coefficient of higher than 0.40 between an item and its corresponding subscale was considered adequate evidence of convergent validity. Discriminant validity was confirmed if a correlation between an item and its hypothesized subscale was significantly greater than that of the other subscales.

Moreover, exploratory factor analysis (EFA) was performed to determine whether the Persian version of the CD-QOL measured the four dimensions including limitations, dysphoria, health concerns, and inadequate treatment subscales. To confirm the results of the EFA, categorical confirmatory factor analysis (CCFA) was also used to evaluate the construct validity of the instrument.[15] Generally, CCFA investigates the relationship between the items of the CD-QOL and four latent constructs including limitations, dysphoria, health concerns, and inadequate treatment subscales. Similar to the original English version, we investigated whether or not the hypothesized four-factor model fit the data well. Three criteria including root mean square error of approximation (RMSEA), Tucker-Lewis index (TLI) and comparative fit index (CFI) were used to evaluate the goodness of fit of the model. Values of CFI and TLI greater than 0.90,[16] and RMSEA less than 0.08[17] can support an acceptable model fit.

The lavaan package in R software was applied to fit the CCFA model and estimate the goodness of fit indices. Moreover, the semPath package in R was used to draw a path diagram and to estimate the standardized factor loadings, and correlation coefficients between subscales and residuals.

Results

According to the transcultural adaptation, the questions

were clear for all experts and participants and they found the CD-QOL easy to complete. Supplementary File 1 shows our Persian CD-QOL questionnaire.

In this study, 150 patients with confirmed CD aged 18 to 65 years (36.7% male, 63.3% female) were evaluated. Basic demographic characteristics of the participants according to the 4 domains of the CD-QOL questionnaire are demonstrated in Table 1. There was no significant difference between the distribution of demographic variables in all subscales of the questionnaire.

Psychometric Findings

CCFA supported a four-factor model similar to its original English version. Table 2 shows the Cronbach's alpha coefficients, and convergent and discriminant validity of the CD-QOL instrument. It showed that all of the domains in the CD-QOL questionnaire had acceptable internal consistency which was greater than 0.7 except for the "inadequate treatment" subscale. According to Table 2, scaling success rates for convergent validity of the CD-QOL were 100 % in all domains. Moreover, the scaling success rates for discriminant validity were 100% for "dysphoria" and "inadequate treatment", and 89% (24 out of 27) and 87% (13 out of 15) for "limitations" and "health concerns" subscales, respectively.

The result of the EFA with Varimax rotation to assess the construct validity of the CD-QOL is reported in Table 3. The proportion of variance explained by the first four factors was 63.20%. As shown in Table 3, all of the items that should have been in limitation, dysphoria, health concerns, and inadequate treatment subscales were properly loaded (greater than 0.3)[18] on these dimensions except for the items of "I feel worried about my increased risk of cancer from this disease" in the limitation and "I feel worried that I will suffer from this disease" in the health concerns subscales. Moreover, the results of the CCFA indicated that values of the CFI and TLI were greater than 0.90 (CFI = 0.993 and TLI = 0.992) and the RMSEA was less than 0.08 (RMSEA = 0.059) which supported the fit of the four-factor CCFA model in the whole sample.

Moreover, the path diagram showed that all of the items that should have been in the limitation, dysphoria, health concerns, and inadequate treatment domains were clearly loaded (higher than 0.5) on these subscales (Figure 1).

Discussion

Table 1. Demographic characteristics of patients with celiac disease in the study according to 4 domains of the questionnaire

	No. (%)	Limitations		Dysphoria		Health Concerns		Inadequate treatment	
		Mean ± SD	*P* value	Mean ± SD	*P* value	Mean ± SD	*P* value	Mean ± SD	*P* value
Gender									
Male	55 (36.7)	53.56 ± 22.30	0.81	66.81 ± 23.22	0.99	51.54 ± 24.56	0.55	49.31 ± 26.83	0.39
Female	95 (63.3)	54.47 ± 26.12		66.84 ± 25.62		48.90 ± 27.47		45.26 ± 28.95	
Age									
<35	50 (33.3)	54.83 ± 22.26		71.00 ± 23.47		54.00 ± 25.31		48.00 ± 26.53	
35-50	75 (50)	52.00 ± 26.00	0.46	62.66 ± 22.15	0.12	44.66 ± 25.89	0.051	42.50 ± 28.10	0.077
>50	25 (16.7)	59.00 ± 26.63		71.00 ± 21.03		49.86 ± 26.39		57.00 ± 29.77	
Labor location									
Home	47(31.3)	57.44 ± 24.07	0.26	67.55 ± 22.40	0.81	50.63 ± 26.59	0.81	48.67 ± 29.63	0.57
Hospital	103(68.7)	52.58 ± 24.97		66.50 ± 25.76		49.51 ± 2642		45.8 ± 27.58	
Type of delivery									
NVD	138(92)	53.54 ± 25.15	0.34	65.62 ± 25.05	0.047	49.27 ± 26.77	0.35	47.19 ± 28.09	0.52
C/S	12(8)	60.64 ± 18.64		80.73 ± 14.46		55.66 ± 21.25		41.66 ± 29.83	
Milk consumed in infancy									
Breast feeding	137 (91.3)	55.32 ± 25.05	0.05	67.29 ± 25.13	0.46	51.16 ± 26.80	0.05	47.53 ± 28.55	0.27
Formula	13 (8.7)	41.24 ± 16.58		62.02 ± 19.67		36.15 ± 16.85		38.46 ± 23.08	
Family history of CD									
Yes	26 (17.3)	59.96 ± 24.44	0.48	62.25 ± 22.25	0.30	45.00 ± 19.60	0.30	39.42 ± 27.54	0.14
No	124 (82.7)	54.77 ± 24.82		67.80 ± 25.15		50.88 ± 27.56		48.29 ± 28.16	
Marital status									
Single	63 (42)	54.67 ± 22.40	0.81	69.15 ± 24.15	0.33	53.09 ± 24.65	0.20	50.00 ± 29.20	0.23
Married	87 (58)	53.70 ± 26.40		65.15 ± 25.08		47.53 ± 27.50		44.39 ± 27.34	
Education									
≤12 years	79 (52.7)	58.50 ± 25.42	0.21	66.93 ± 25.34	0.96	53.42 ± 27.66	0.08	48.57 ± 28.30	0.40
>12 years	71 (47.3)	51.44 ± 23.81		66.72 ± 24.13		45.91 ± 24.50		44.72 ± 28.08	

NVD; Normal Vaginal Delivery, C/S; Cesarian section.

Table 2. CD-QOL Internal consistency, convergent, and discriminant validity in the Persian version

	Items	Cronbach's alpha	Convergent validity		Discriminant validity	
			Range of correlation	SSR (%)	Range of correlation	SSR (%)
Limitations	9	0.878	0.54-0.83	9/9 (100%)	0.19- 0.64	24/27 (89%)
Dysphoria	4	0.781	0.68-0.84	4/4 (100%)	0.18- 0.70	12/12 (100%)
Health concerns	5	0.821	0.70-0.84	5/5 (100%)	0.24- 0.67	13/15 (87%)
Inadequate treatment	2	0.644	0.84-0.86	2/2 (100%)	0.29- 0.51	6/6 (100%)

SSR, scaling success rate.

Table 3. Factor loadings (rotated) 1 of four-factor solutions of the CD-QOL questionnaire

	Limitation	Dysphoria	Health concern	Inadequate treatment
Q1. I feel limited by this disease	**0.623**	0.427	0.202	0.229
Q2. I feel worried that I will suffer from this disease	0.439	0.429	**0.271**	0.425
Q3. I feel concerned that this disease will cause other health problems	0.291	0.331	**0.664**	0.257
Q4. I feel worried about my increased risk of cancer from this disease	0.085	0.187	**0.777**	0.160
Q5. I feel socially stigmatized for having this disease	**0.084**	0.637	0.101	0.266
Q6. I feel like I'm limited in eating meals with coworkers	**0.751**	0.171	0.165	0.165
Q7. I feel like I am not able to have special foods like birthday cake and pizza	**0.718**	0.026	0.186	0.271
Q8. I feel that the diet is sufficient treatment for my disease	0.000	0.095	0.159	**0.787**
Q9. I feel that there are not enough choices for treatment	0.318	0.169	0.074	**0.707**
Q10. I feel depressed because of my disease	0.432	**0.525**	0.268	0.320
Q11. I feel frightened by having this disease	0.342	**0.530**	0.281	0.239
Q12. I feel like I don't know enough about the disease	-0.070	**0.625**	0.383	0.045
Q13. I feel overwhelmed about having this disease	0.137	**0.798**	0.219	0.201
Q14. I have trouble socializing because of my disease	**0.395**	0.682	0.014	0.001
Q15. I find it difficult to travel or take long trips because of my disease	**0.706**	0.436	0.117	-0.158
Q16. I feel like I cannot live a normal life because of my disease	**0.616**	0.499	0.072	0.279
Q17. I feel afraid to eat out because my food may be contaminated	**0.669**	0.017	0.265	0.117
Q18. I feel worried about the increased risk of one of my family members having celiac disease	0.349	0.111	**0.635**	-0.011
Q19. I feel like I think about food all the time	**0.308**	0.483	0.145	0.523
Q20. I feel concerned that my long-term health will be affected	0.386	0.226	**0.571**	0.425

1: Varimax rotation.
Factor loadings under 0.3 have been underlined.

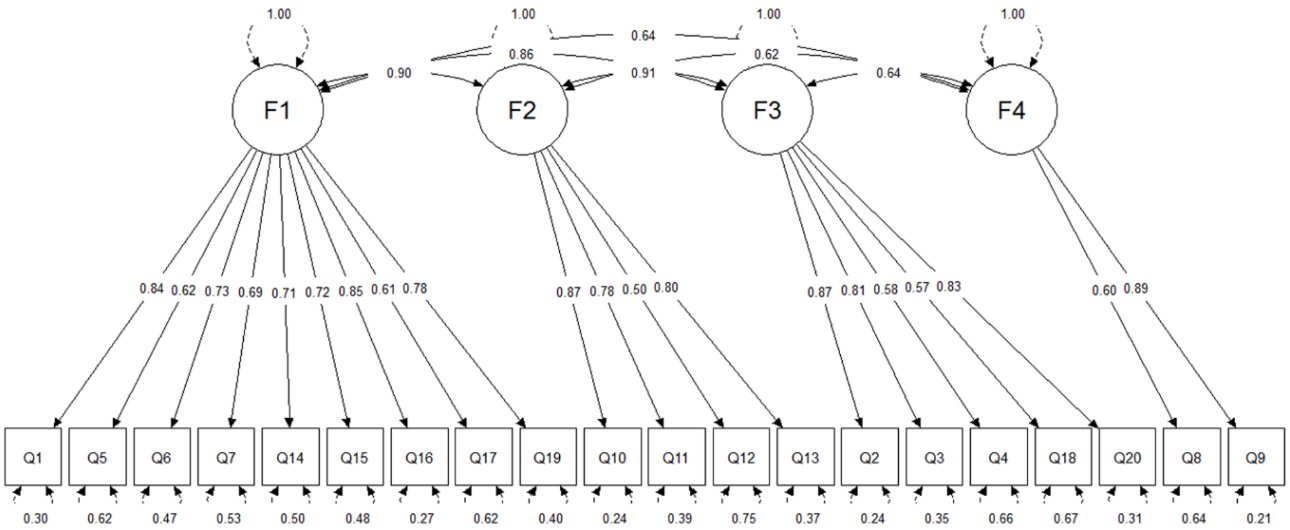

Figure 1. Path diagram for confirmatory factor analysis. F1: Limitation, F2: Dysphoria, F3: Health concerns, F4: Inadequate treatment

The use of HRQOL tools in the care of patients with CD is very important to evaluate the impact of the disease and interventions on the individual and society, as well as the implementation of strategies to improve the disease.[19,20] Non-compliance with gluten-free diet by patients as well as symptomatic disease are the most important factors affecting HRQOL in people with CD.[21] CD-QOL is a tool that focuses on the perception of the limitations and problems of the daily life of patients with CD as well as their expectancies and is preferred for clinical use.[10] This HRQOL questionnaire was developed and validated in the United States,[10] so it needs cross-cultural and language adaptation and validation to determine if this tool works similarly in different populations and also whether the identical aspects of life are similarly important for people with different backgrounds.[22] Therefore, this questionnaire has been validated in the Netherlands,[23] Spain[24] Italy[25] and the northwest of Iran,[15] and has shown acceptable psychometric properties. However, our research is the first study to evaluate the psychometric features of the Persian version of the CD-QOL instrument in patients with CD in southwest Iran.

Our findings revealed that the new Persian version of the CD-QOL questionnaire has excellent internal consistency and construct validity. The internal consistency of an instrument shows the extent to which the items of that scale correlate with each other. In our study, Cronbach's α of the four subscales ranged from 0.64 to 0.88, indicating excellent reliability. High Cronbach's α values have also been reported in the original English (>0.7),[10] Dutch (0.91),[23] Italian (0.88),[25] Spanish (0.9),[24] and northwest Iranian (0.93)[15] versions of the questionnaire. Moreover, the exploratory and confirmatory factor analysis for assessing construct validity of the Persian version of the CD-QOL instrument supported four-factor models similar to its American original version. Accordingly, all items of the dysphoria and inadequate treatment factors had a clear factor loading identical to the English version. However, the second question, i.e. "*I feel worried that I will suffer from this disease*" was closer to the dysphoria factor, instead of health concerns in the original version. In addition, question 5, i.e. "*I feel socially stigmatized for having this disease*" was more related to dysphoria instead of limitations. These differences can be attributed to different populations and cultural and socioeconomic variables between Iranian and American patients. In Iranians, the word "worried" is usually referred to fear, which may be associated with dysphoria rather than health concerns. Besides, the phrase "stigmatize" may not convey a similar meaning in Iranian and American individuals, and it caused worry in Iranian patients. Assessment of the construct validity of this scale also was performed in two previous studies. Similar to our findings, Zingone and others reported that the fifth question of the Italian version of CD-QOL was grouped among the dysphoria domain. However, the factor analysis of their translated questionnaire excluded the three questions including item 1 (*I feel limited by this disease*), item 11 (*I feel frightened by having this disease*), and item 19 (*I feel like I think about food all the time*), and consequently, they reduced the number of items in the specific factors.[25] The authors suggested that differences in demographic features, socioeconomic variables, and medical care availability can explain these discrepancies with the original version. In another study, Nikniaz and colleagues confirmed the face, content, construct, and convergent validity of the Persian-adaptation CD-QOL questionnaire in patients living in the Northwest of Iran. In this version, all items, except for two questions, were loaded in their original domains. Items 9 and 20 were loaded instead of each other in the third and fourth factors, respectively.[15] The discrepancy between our results with the findings of Nikniaz and colleagues could be due to the cultural, ethnic, and linguistic differences between the northwest (mostly with the Turkish language) and southwest of Iran (mostly with the Persian language).

In our study, variables of sex, age, labor location, type of delivery, type of milk consumed in infancy, family history of CD, marital status, and education had no effect on HRQOL and its subscale scores in patients with CD. Along the same line, age did not associate with HRQOL scores in Spanish CD adults and Swedish children and adolescents.[21,26] In contrast, Brazilian CD patients over 60 years of age who were evaluated by CD-QOL had better HRQOL compared with younger patients.[27] In another study by Pratesi and colleagues, higher HRQOL was detected in CD subjects ≥ 40 years as well as those with higher education.[20] In addition, many studies demonstrated that women with CD rated their HRQOL scores lower than men.[20,21,28]

The present study assessed the CD-QOL questionnaire in patients living in the Fars province located in the Southwest of Iran. So, its generalization to other populations is not guaranteed. However, this examination is complementary to a previous one conducted in the East Azerbaijan province of Iran, showing that CD-QOL is a culturally and psychometrically validated questionnaire that is easy for Iranian patients with CD to comprehend and is available for use in clinical practice.

Conclusion

In conclusion, our Persian version of the CD-QOL questionnaire had high reliability and validity. Therefore, this screening scale could be used in clinical practice to assess CD-specific HRQOL in the Iranian population.

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Authors' Contribution

Conceptualization: Ramin Niknam, Peyman Jafari, Ali Reza Safarpour, Sara Shojaei-Zarghani, Mohammad Reza Fattahi.
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Writing–review & editing: Ramin Niknam, Peyman Jafari, Ali Reza Safarpour, Sara Shojaei-Zarghani, Mohammad Reza Fattahi.

Competing Interests

The authors declare no conflict of interest related to this work.

Consent for publication

Not applicable.

Data Availability Statement

The datasets supporting the conclusions of this article are included within the article (and its additional file).

Ethical Approval

The study methods were approved by the Ethics Committee of Shiraz University of Medical Sciences (ethics committee approval number: IR.SUMS.REC.1399.219), and were conducted according to the principles of the declaration of Helsinki.

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Supplementary Files

Supplementary file 1. Persian Version of Celiac Disease-QOL Questionnaire

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