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RESEARCH ARTICLE

Validation of the Turkish version of the Quality of Life in Patients with Anal Fistula Questionnaire

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ABSTRACT

Aim: This study aimed to examine the psychometric properties of the Turkish version of the Quality of Life in Patients with Anal Fistula Questionnaire (QoLAF-Q), recently introduced to the literature, in line with the principle that every disease should have its own quality of life (QoL) scale. The 14-question QoLAF-Q has not been validated in Turkey and was validated in this study for use in practice with Turkish individuals by assessing whether it yields similar results to the Short Form-12 Health Survey (SF-12).

Method: This was an observational cross-sectional study to facilitate the development and validation of the QoLAF-Q and was conducted between 2020 and 2023.

Results: All questions passed the 0.35 threshold in confirmatory factor analysis (CFA). The Tucker-Lewis Index value was 0.979 (>0.90 acceptable, >0.95 perfect). The comparative fit index was 0.983 (>0.90 acceptable, >0.95 perfect), and the root mean square error of approximation was 0.075 (<0.08 acceptable, <0.05 perfect) based on the 14-question, two-factor CFA result. The Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the SF-12, as well as the PCS and MCS scores of the QoLAF-Q, had a significant relationship (p>0.05).

Conclusion: As demonstrated in a previous Spanish study, the QoLAF-Q is a valuable measurement tool that possesses sufficient psychometric properties for assessing general health status and health-related QoL in clinical practice and scientific research in Turkey.

Keywords: Questionnare, validation, QoLAF-Q

Introduction

The concept of being healthy is one that continually evolves. In 1947, the World Health Organization defined health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity".[1] Physicians have strived to align their treatments with this definition, with efforts to comprehend the meaning of health first initiated in the 1960s.[2] Although treatments benefit the afflicted, they can also have unintended consequences, such as antibiotic resistance in response to treating infections. This has prompted physicians to contemplate the ethical boundaries of these treatments.

In 1966, the Annals of Internal Medicine articulated the desire of every physician for their patients, young or old, as not merely the absence of death but a life imbued with the vitality associated with youthful vigor.[3]

In this context, health-related quality of life (HRQoL) tools have been developed to assess patients' well-being. With the advent of customized treatments for specific ailments, the need for tailored HRQoL tools has grown.[4] However, customized HRQoL assessment tools for patients with anal fistula (AF) are lacking.[5,6]

AF presents with common symptoms such as suppuration, hemorrhage, and pain, often following the drainage of a perianal abscess, considerably affecting patients' quality of life (QoL).[5-8] Various surgical procedures are available to treat AF, but they come with a potential recurrence risk ranging from approximately 10% to 60%. Moreover, surgical complications, including incontinence, abscesses, and the necessity for multiple interventions, can further impact patients' QoL.[5,9,10] Therefore, colorectal surgeons typically consider patient QoL when determining the

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most appropriate treatment approach and evaluating its effectiveness.[10]

A literature review revealed that the assessment instruments employed to evaluate QoL in patients diagnosed with AF were originally developed for assessing general HRQoL. These instruments include the Short Form-12 Health Survey (SF-12) and the SF-36.[11] In particular, the SF-12v2, a 12-item self-rated scale, has been validated in numerous languages and for various medical conditions.[4]

In this study, we utilized the Quality of Life in Patients with Anal Fistula Questionnaire (QoLAF-Q), recently introduced to the literature by Ferrer-Márquez et al.[5], in line with the principle that every disease should have its own QoL scale. The purpose of this research was to examine the psychometric properties of the Turkish version of the QoLAF-Q and validate it for the Turkish population by comparing its results to those of the SF-12.

Materials and Methods

Study Design

The current investigation employed an observational cross-sectional design to facilitate the development and validation of the QoLAF-Q. This study was conducted between 2020 and 2023. The inclusion criteria for participation were age ≥18 years and a diagnosis of cryptoglandular AF. The exclusion criteria for participation were as follows: 1) patients whose native language was not Turkish; 2) patients with comprehension and speech disorders due to cognitive problems; 3) patients with anovaginal fistula; 4) a history of radiotherapy; and 5) the presence of anal cancer. The study procedures were approved by the Ankara University Human Research Ethics Committee (approval number: İ01-32-23, date: 23.01.2023). Prior to participating in this research, volunteers completed an informed consent form. Demographic data, including age, sex, and prior anal surgery, were collected using the personal information form included with the questionnaire. The questionnaires were administered on postoperative days 15 and 30. Concurrently, the SF-12 was also administered to the patients.

SF-12

Ware et al.[12] developed a more practical and concise version of the SF-36 in 1995, resulting in the SF-12, which includes the same subscales as the SF-36 but with a reduced number of questions. The advantage of the SF-12 is its ability to yield the same component summary scores as the SF-36, and it takes less time to administer due to its reduced item count. The reliability of the scale, evaluated by calculating Cronbach's alpha, was 0.73 for the Physical Component Summary (PCS) and 0.72 for the Mental Component Summary (MCS). The SF-12 has been validated in multiple languages.

QoLAF-Q

The initial version of the QoLAF-Q was developed in Spanish. The answers were based on a 5-point Likert scale. Fourteen questions were validated in the Spanish version of the QoLAF-Q. The reliability of the QoLAF-Q was assessed by calculating Cronbach's alpha, which was 0.908.

The researchers involved in the creation of the QoLAF-Q, including manuel Ferrer-Márquez, were contacted, and the necessary permissions were obtained.

During the translation process, the questionnaire was initially translated into Turkish by two native English speakers. The translated version was then reviewed by two colorectal surgeons (CA, MAK), who are native Turkish speakers and proficient in English (Supplement Table 1). This process resulted in a version of the questionnaire that was in a common language and easily understood.

Statistical Analysis

Internal Construct Validity

Two-factor confirmatory factor analysis (CFA) was conducted using categorical data in MPlus to assess the dimensionality of the "Anal Fistula Scale".[13] Factor loadings that were positive and/or above 0.35 were retained in the scale. The Tucker-Lewis Index [(TLI); >0.90, considered acceptable; >0.95, considered excellent], Comparative Fit Index [(CFI); >0.90, considered acceptable; >0.95, considered excellent], and root mean square error of approximation [(RMSEA); <0.08, considered acceptable; <0.05, considered excellent] were used as measures of goodness-of-fit.[14]

Known-Group Validity

The scale's ability to discern expected differences based on patient age, sex, and anal surgery history was examined. The disparities in subdimension scores based on sex and anal surgery history were analyzed using the Mann-Whitney U test, and the correlation with age was assessed using Spearman's correlation coefficient.

External Construct Validity

In the context of external construct validity, the relationship between the scores obtained from the Anal Fistula Scale and those of the SF-12 was evaluated using Spearman's correlation coefficient.

Reliability

Following the confirmation of internal and external construct validity, reliability was assessed for both internal consistency and test–retest reliability. Internal consistency was evaluated using Cronbach's alpha coefficient and test-retest reliability was measured using the intraclass correlation coefficient along with its associated confidence interval.[15,16]

RESULTS

Patient Demographics

A total of 100 individuals participated in our study. The sample had an average age of 43.3 years, ranging from 18 to 72 years. Twenty-four percent of the participants were female, and 76% of the participants had no history of anal surgery.

Understandability

Independent native Turkish speakers reported no difficulties when reading and completing the QoLAF-Q. Furthermore, the mean completion time was less than 5 minutes, ranging from 4 to 6 minutes.

Internal Construct Validity

Following the CFA conducted on the 14 questions with a 2-factor structure, goodness-of-fit statistics slightly below acceptable limits were observed. In response, two modifications recommended by the program were applied to improve the fit. Specifically, the error values of "How often do you experience discharge (suppuration) from the fistula?" were correlated with the error values of "How much discharge (suppuration) from the fistula do you experience?", and the error values of "How often do you experience uncontrollable flatulence (farting) since having the fistula?" were correlated with the error values of "What is the amount of unintentional stool loss that you usually experience since having the fistula?." These adjustments aimed to address errors related to the questions. Following these modifications, the TLI was 0.979, the CFI was 0.983, and the RMSEA was 0.075, according to the 14-question, two-factor CFA result. The factor loadings of the questions based on the factors are presented in Table 1.

Known-Group Validity

The scale's ability to disclose the expected differences based on the age, sex, and previous anal surgery of the patients was assessed, and the results are presented in Table 2.

Statistically significant differences in the known groups, including age, sex, and previous anal surgery, were not determined.

External Construct Validity

In terms of external construct validity, the relationship between the scores obtained from the QoLAF-Q and the SF-12 was evaluated using Spearman's correlation coefficient, and the results are presented in Table 3.

Table 1. Results of the CFA

Questions	Physical	Biopsychosocial
How often do you experience discharge (suppuration) from the fistula?	0.543	
How much discharge (suppuration) from the fistula do you experience?	0.578	
How often do you experience uncontrollable flatulence (farting) since having the fistula?	0.387	
How often do you experience unintentional loss of stool since having the fistula?	0.423	
What is the amount of unintentional stool loss that you usually experience since having the fistula?	0.504	
How often do you experience pain in the anal area because of the fistula?	0.901	
What is the intensity of the pain that you experience because of the anal fistula?	0.879	
Since suffering the symptoms of the anal fistula, how would you describe your health?		0.715
How much does the anal fistula affect your physical health? (e.g., energy and activity levels, sleeping patterns, general well-being...)		0.898
How much does the anal fistula affect your psychological health? (e.g., your body image, self-esteem, state of mind, ability to focus on a particular task...)		0.856
How much does the anal fistula affect your independence level? (e.g., mobility, ability to work, daily activities...)		0.913
How much does the anal fistula affect your social relationships and interactions with others? (e.g., your relationships with friends, family, partner...)		0.762
How much does the anal fistula affect your sexual relationships?		0.673
How much does the anal fistula affect other aspects of your life? (e.g., your freedom, your economic income, your free time...)		0.792

CFA: Confirmatory factor analysis

The MCS and PCS scores of both the SF-12 and QoLAF-Q exhibited a statistically significant correlation. The QoLAF-Q and SF-12 demonstrated moderate consistency in correlation coefficients.

Reliability

Reliability was tested for both internal consistency and test-retest reliability, and the results are presented in Table 4.

Discussion

It is of crucial importance to not only treat patients with AF but also evaluate their QoL after necessary treatment methods have been applied. This is partly to understand the negative impact of AF complications (e.g., incontinence, hemorrhage, and disease recurrence) on patients' QoL and partly to assess the effectiveness of applied treatment methods. To date, general health questionnaires such as the SF-12 have been used to evaluate the QoL of patients with AF in Turkey. However, there was no previously designed, validated, and published specific tool for assessing the QoL in Turkish patients with AF.

Table 2. Results of known-group validity

		Physical	Biopsychosocial
Sex*	Female	1.2989 (1-2,29)	1.4656 (1-3,89)
	Male	1.2272 (1-2,17)	1.3953 (1-3,60)
	p	0.369	0.393
Anal surgery history*	Yes	1.3881 (1-2,29)	1.8511 (1-3,13)
	No	1.3004 (1-2,17)	1.4806 (1-3,89)
	p	0.567	0.267
Age		0.002 (0.982)	-0.109 (0.281)

*For the variables indicated with, the cell values correspond to the median (minimum-maximum) and the correlation coefficient (p-value) for age

Table 3. Correlation coefficients of the QoLAF-Q and SF-12

	Physical	Biopsychosocial
SF-12_PCS	-0.366 (<0.001)	-0.378 (<0.001)
SF-12_MCS	-0.305 (0.002)	-0.512 (<0.001)

Cell values represent the correlation coefficient (p-value). QoLAF-Q: Quality of Life in Patients with Anal Fistula Questionnaire, SF-12: Short Form-12 Health Survey, PCS: Physical Component Summary, MCS: Mental Component Summary

Table 4. Reliability results

	Cronbach's alpha coefficient	ICC (95% confidence interval)
Physical	0.721	0.664 (0.539-0.761)
Biopsychosocial	0.893	0.681 (0.560-0.773)

ICC: Intraclass correlation coefficient

The properties of the QoLAF-Q must be understood in terms of its ability to accurately evaluate psychometric qualities, what it truly measures, and its practicality for daily use. Psychometric analysis conducted on these properties demonstrated that the internal consistency and stability of the QoLAF-Q are adequate. Such qualities can be considered evidence of the reliability and repeatability of the evaluation tool. Moreover, having an average completion time of 5 minutes can be associated with understandability and practicality. The results of external construct validity showed that, even though the correlation between these questionnaires was moderate, the QoLAF-Q is still as effective as the SF-12 in measuring HRQoL (Table 3). Therefore, both the SF-12 and QoLAF-Q can be used to evaluate HRQoL in patients with AF.

The known-group analysis involved age, sex, and prior anal surgery. It was anticipated that anal sphincter tone would be influenced by these factors, subsequently impacting the QoL of patients with AF. However, the investigation revealed that a statistically significant difference between the known groups themselves was not established in the QoLAF-Q. In a study conducted in Korea by Kim et al.[17], it was observed that age is related to worsening anorectal functions due to lower anal resting and squeezing pressure, anal sphincter denervation, increased anal compliance, and decreased anal senses. A separate study conducted in Spain by Pla-Martí et al.[18] evaluated the relationship among previous anal surgery, incontinence, and QoL. In our study, we also analyzed the known groups, including previous anal surgery, sex, and age groups. However, a statistically significant difference was not determined.

When internal consistency was analyzed, the Cronbach's alpha value for the physical component was 0.721 and the biopsychosocial component value was 0.893. This indicates that the QoLAF-Q assesses the physical and biopsychosocial components collectively, concurrently, and intentionally. According to the scale, these values are considered to represent "good" consistency.[19] Similarly, in other studies (e.g., the original QoLAF-Q study, an Iranian validation study, and a Nigerian validation study), the determined values ranged between good and excellent.[20,21] Notably, a Chinese survey revealed relatively low values (0.67 for the PCS and 0.60 for the MCS).[22]

The intraclass correlation coefficient value for the physical component was 0.663, and the biopsychosocial value was 0.681. These satisfactory values were obtained from the evaluation of the consistency coefficients and the reliability coefficient re-evaluation, which was conducted 2 weeks later. These values indicate the stability of the QoLAF-Q, signifying that similar scores were and will be obtained in measurements taken at different times. This also supports the reliability of the Turkish version of the QoLAF-Q.

Study Limitations

In our study, we included only patients with cryptoglandular AF. Patients with Crohn's disease were not included, which is considered a limitation of our research. Therefore, our study does not provide information regarding the properties of the QoLAF-Q related to Crohn's disease. This subject can be further evaluated in future studies. It is also important to note that female patients accounted for only 24% of the participants. This does not align with the sex distribution of the general population and can be considered another limitation. Therefore, a future study with a more homogeneous and larger sample size can be conducted to address these limitations.

Conclusion

As demonstrated in the previous Spanish study, the QoLAF-Q is a valuable measurement tool. It possesses sufficient psychometric properties for assessing general health status and health-related QoL in clinical practice and scientific research in Turkey. The introduction of a Turkish HRQoL measurement tool for patients with AF that is both easily understandable and allows for quick QoL assessment is expected to facilitate the expansion of applications and research in the field of AF.

Ethics

Ethics Committee Approval: The study procedures were approved by the Ankara University Human Research Ethics Committee (approval number: İ01-32-23, date: 23.01.2023).

Informed Consent: Prior to participating in this research, volunteers completed an informed consent form.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: M.A.K., Ş.E., C.A., Concept: M.A.K., C.A., Design: K.Ö., C.A., Data Collection or Processing: M.A.K., K.Ö., M.S.S., Analysis or Interpretation: K.Ö., D.G., Literature Search: M.S.S., Ş.E., Writing: K.Ö., M.S.S.

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Supplement Table 1. Turkish version of QoLAF-Q

İsim-soyisim:
Tarih:
1. Ne sıklıkla fistülden akıntı (irin) yaşamaktasınız?
1. Hiçbir zaman, 2. Nadiren (haftalarca irin sızıntısı olmaz), 3. Bazen, 4. Sık sık (neredeyse her gün), 5. Her zaman ya da sürekli (her gün).
2. Fistülünüzden ne kadar akıntı (irin) gelmektedir?
1. Hiç, 2. Biraz (iç çamaşırlarında küçük lekeler), 3. Orta derecede (iç çamaşırında biraz fazla leke ve günde bir gazlı bez ihtiyacı), 4. Biraz fazla (günde bir ped ya da birden fazla gazlı bez kullanmam gerekiyor), 5. Çok fazla (günde 4 pedden ya da bir paket gazlı bezden daha fazlasını kullanmam gerekiyor).
3. Fistülünüz oluştuktan beri ne sıklıkla istemsiz gaz çıkarma (osuruk) yaşamaktasınız?
1. Hiç, 2. Çok az (iç çamaşırında hafıf kirlenme), 3. Orta derecede (daha fazla kirlenme ve günde 1 gazlı bez ihtiyacı), 4. Biraz fazla (günde bir ped ya da birden fazla gazlı bez kullanmam gerekiyor), 5. Çok fazla (günde 4 pedden ya da bir paket gazlı bezden daha fazlasını kullanmam gerekiyor).
4. Fistülünüz oluştuktan beri ne sıklıkla istemsiz gayta kaçırma yaşamaktasınız?
1. Hiçbir zaman, 2. Nadiren (haftalarca ağrı olmaz), 3. Bazen, 4. Sık sık (neredeyse her gün), 5. Her zaman ya da sürekli (her gün).
5. Fistülünüz oluştuktan beri kaçırmakta olduğunuz gayta miktarı nedir?
1. Hiç, 2. Çok az (iç çamaşırında hafıf kirlenme), 3. Orta derecede (daha fazla kirlenme ve günde 1 gazlı bez ihtiyacı), 4. Biraz fazla (günde bir ped ya da birden fazla gazlı bez kullanmam gerekiyor), 5. Çok fazla (günde 4 pedden ya da bir paket gazlı bezden daha fazlasını kullanmam gerekiyor).
6. Ne sıklıkla anal bölgenizde fistüle bağlı ağrı yaşamaktasınız?
1. Hiçbir zaman , 2. Nadiren (haftalarca ağrı olmaz), 3. Bazen, 4. Sık sık (neredeyse her gün), 5. Her zaman ya da sürekli (her gün).
7. Anal bölgenizde fistüle bağlı yaşadığınız ağrının şiddeti nedir?
1. Hiç, 2. Hafif, 3. Orta derecede, 4. Yüksek, 5. Aşırı derecede ya da hayal edilemeyecek kadar kötü.

Supplement Table 1. Continued

8. Anal fistül semptomları yaşamaya başladığınızdan beri sağlığınızı nasıl tanımlarsınız?

1. Mükemmel,
2. İyi,
3. Makul,
4. Kötü,
5. Berbat.

9. Anal fistül fiziksel sağlığınızı ne kadar etkilemektedir? (örneğin; enerji ve aktivite seviyeniz, uyku modeliniz, genel iyilik haliniz, ...)

1. Hiç,
2. Az,
3. Biraz,
4. Oldukça fazla,
5. Çok fazla.

10. Anal fistül ruh sağlığınızı ne kadar etkilemektedir? (örneğin; vücut imajınız, özgüven, ruhsal durum, bir işe odaklanma becerisi, ...)

1. Hiç,
2. Az,
3. Biraz,
4. Oldukça fazla,
5. Çok fazla.

11. Anal fistül özgürlük seviyenizi ne kadar etkilemektedir? (eg, hareket, iş yapma kabiliyeti, günlük aktiviteler, ...)

1. Hiç,
2. Az,
3. Biraz,
4. Oldukça fazla,
5. Çok fazla.

12. Anal fistül başkalarıyla sosyal ilişki ve etkileşiminizi ne kadar etkilemektedir? (örneğin; arkadaşlarınızla ilişkiniz, aile, partner, ...)

1. Hiç,
2. Az,
3. Biraz,
4. Oldukça fazla,
5. Çok fazla.

13. Anal fistül cinsel ilişkilerinizi ne kadar etkilemektedir?

1. Hiç,
2. Az,
3. Biraz,
4. Oldukça fazla,
5. Çok fazla.

14. Anal fistül hayatınızın diğer alanlarını nasıl etkilemektedir? (örneğin; bağımsızlığınız, gelir durumunuz, boş zamanlarınız, ...)

1. Hiç,
2. Az,
3. Biraz,
4. Oldukça fazla,
5. Çok fazla.