Validity and reliability of the Persian epilepsy quality of life questionnaire

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ABSTRACT

الأهداف: تأثير واختبار مدى صدق وثبات الاستبيان الذي يقيم تأثير مرض الصرع على الحياة والمكون من 31 سؤالاً وذلك بين المرضى الإيرانيين المصابين بالصرع.

الطريقة: لقد قمنا بعمل الترجمة الرجعية والتقدمية للنسخة الإنجليزية من هذا الاستبيان وتحويلها إلى اللغة الفارسية وذلك بواسطة الترجمة الإدراكية وبواسطة تكييف بعض الأفكار بما يتناسب مع الحضارة الفارسية. شمل هذا الاستبيان المرضى المصابين بالصرع والذين تتخطى أعمارهم 18 عاماً، وقد تم تحويلهم إلى عيادة مطهري في مدينة شيراز، إيران وذلك خلال الفترة من مارس 2007م إلى مارس 2008م. تم تقدير ثبات الاستبيان والاتساق الداخلي بواسطة طريقة ألفا كرونباخ، فيما تم تقدير مدى صدق الاستبيان من ناحية معدل الصدق التقاربي ومعدل الصدق التباعدي من خلال معادلة سبيرمان.

النتائج: شملت هذه الدراسة 211 مريضاً مصاباً بالصرع حيث بلغ عدد الإناث 88 مريضة (41.7%)، والذكور 123 مريضاً (58.3%)، وكان معدل أعمارهم ± ومعدل الانحراف المعياري يساوي 28.7±11.6 عاماً. لقد كانت نتائج تحليل مدى ثبات الاستبيان مرضية (Cronbch's α=0.890)، كما أن نتائج تحليل الاتساق الداخلي كانت مرضية وذلك بما يتعلق بصفات المرضى الديموغرافية والسريرية (α≥0.70). ولقد وصل معدل النجاح إلى 100% وذلك فيما يتعلق بمعدل الصدق التقاربي بين فقرات الاستبيان، وكانت نتائج معدل الصدق التباعدي بين فقرات الاستبيان السبعة جيدة.

خاتمة: تشير الدراسة بأن خصائص النسخة الفارسية من استبيان تقييم تأثير الصرع على الحياة والمكون من 31 سؤالاً كانت جيدة، كما أنه يعد أداة قياس صادقة وثابتة وبالإمكان استخدامها لتقدير مدى تأثير مرض الصرع على حياة المصابين به.

Objectives: To translate and test the reliability and validity of the 31-item epilepsy quality of life questionnaire (QOLIE-31) in Iranian epileptic patients.

Methods: In order to standardize the questionnaire, using a standard "forward-backward" translation, cognitive debriefing, and cultural adaptation procedure, the English version of the QOLIE-31 was translated to Persian (the Iranian official language). The subjects were Epileptic patients, over 18 years old, referred to the Motaharri Clinic, Shiraz, Southern Iran from March 2007 to March 2008. The reliability and internal consistency of the questionnaire were assessed by Cronbach's alpha coefficient. Validity was assessed using convergent and disconvergent validity through Spearman's correlation.

Results: Two hundred and eleven epileptic patients (88 females [41.7%], 123 males [58.3%]), with a mean ± SD age of 28.7±11.6 years were enrolled in the study. Reliability analysis showed a satisfactory result (Cronbach's α=0.890). Internal consistency was satisfactory for both demographic and patients' clinical characteristics (α≥0.70). The scaling success rates were 100% for convergent validity of each scale. Disconvergent validity for all 7 scales was good.

Conclusion: The Persian version of the QOLIE-31 questionnaire has good structural characteristics, is a reliable and valid instrument, and can be used for measuring the effect of epilepsy on the quality of life.

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Epilepsy is one of the most common chronic neurologic disorders. With the recent advancement in antiepileptic drug (AED) treatment and surgical techniques, epileptic seizures are nowadays well

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managed. However, epilepsy can still adversely affect patients, overall health status and decrease the patients, quality of life (QOL).[1] Epilepsy is unique among chronic neurologic diseases in its potential influence on QOL. Epilepsy often begins at a young age and may hinder social and cognitive development.[2] The efficacy of interventions in epilepsy has been evaluated mainly on the basis of clinical endpoints, although patients and their families face a range of psychosocial problems. As a consequence, a variety of epilepsy-specific questionnaires have been developed for the assessment of health-related QOL (HRQOL), an important concept to better understand the distress of people with epilepsy, even when seizures are controlled.[3,4] Some of these instruments have been internationally accepted, although multinational epilepsy studies that include assessments of QOL require rigorous translation and adaptation to the culture of each country in which they will be used. After translation, validation is necessary to check whether the psychometric properties of these inventories are fulfilled and comparable to those of the original version.[5] One of the most widely used instruments, the Quality of Life in Epilepsy-89 Inventory (QOLIE-89), the generic core of which was the 36-item Medical Outcomes Health Survey (SF-36), was developed in the United States.[6-8] Its derivative, the Quality of Life in Epilepsy-31 Inventory (QOLIE-31), comprises 31 of the 89 items, excluding the 36 of the SF-36 and other nonspecific topics (for example, pain), and includes those subscales that appeared to be most important from reports by patients with epilepsy.[9] It has been the most frequently used instrument worldwide because of its concise and easy evaluation.[9] The QOLIE-31 is a survey of HRQOL for adults (18 years or older) with epilepsy. Consequently, in a short interval, it has been validated and adapted for use in Spain,[3] Germany,[10] France,[5] Italy,[4] Hungary,[11] Georgia,[12] in Portuguese (Brazil),[13] and in Thailand,[14] and the French version has been used in Benin.[15] There are around 70 million people in Iran, with more than 60% 18 years and older, who speak Farsi except for the Afghani and Tajikian people. The objective of this study was to develop the Persian version of the QOLIE-31 to evaluate QOL in epileptic patients speaking the Farsi language in Iran.

Methods.

Instruments. Quality of Life in Epilepsy-31 Inventory. The QOLIE-31 is an epilepsy-specific measure of QOL.[9] It includes 30 items organized into 7 subscales - seizure worry (5 items), emotional well-being (5 items), energy/fatigue (4 items), social functioning (5 items), cognitive functioning (6 items), medication effects (3 items), overall QOL (2 items), and an additional item assessing overall health status. The raw scores are re scaled from 0 to 100, with higher values reflecting better QOL.

Fatigue severity scale (FSS). This is a questionnaire for assessing fatigue. It can distinguish fatigue from clinical depression as a great masquerader.[16]

Translation and adaptation. Translation and cultural adaptation of the QOLIE-31 into Farsi was conducted the by forward-backward procedure as our previous study.[17] The final version was examined in a pilot study with 20 subjects. The comprehensibility of each and every question was verified. This stage was considered as the pilot study.

Patients. The subjects were regular patients (both newly diagnosed and follow-up cases) referred to the epilepsy clinic at Nemazee Hospital in Shiraz, Iran, from March 2007 to March 2008. Inclusion criteria were clinically definite, or laboratory supported epilepsy. Age, gender, marital, socio-economic, educational status, epilepsy type, duration of the disease, and number of seizures per month were recorded. All the patients gave their informed consent, and the institutional ethics committee approved the study. The questionnaire was completed by literate patients in a convenient and comfortable situation. For illiterate patients, the questions were asked through face-to-face interview in Persian. The intervention of the interviewer was restricted just to elaborate the meaning of questions for illiterate patients. The relevance and clarity of the questions were also assessed.

Statistical analysis. The Statistical Package for Social Sciences 11.5 (SPSS Inc, Chicago, IL, USA) was used. The QOLIE-31 scale scores were calculated using the Likert method for summed ratings, and the raw scores were linearly transformed into 0-100 scales: the higher the transformed score, the better the patient's HRQOL. Internal consistency reliability and convergent validity were measured by Cronbach's alpha and Spearman correlation coefficient. Factor Analysis was used to assess construct validity.

Results.

Cultural adaptation. Generally, patients had no problems with understanding and answering most of the questions of the Persian version of the QOLIE-31. In the translation process, certain concepts in English are not available in Persian, therefore, we used phrases that bring the same concepts. For example "pep" has the concept of "happiness because drunk" in Persian, whereas the meaning of this word in the questionnaire is "lots of happiness" therefore, we used a word that brings the concept of "lots of happiness". Also, "a good of the bit" and "most of the time" have the same meaning in Farsi, therefore, we used 2 words that provide the main meaning of the 2 original phrases.

Descriptive analysis. Two hundred and eleven epilepsy patients aged 18-37 years completed the questionnaire. **Tables 1 & 2** summarize the patient's

Table 1 - Patients characteristics (n=211).

Variables	n	(%)
Gender		
Male	88	(41.7)
Female	123	(58.3)
Marital status		
Single (never married)	136	(64.5)
Married	72	(34.1)
Widow(er)	3	(1.4)
Residential		
Rural	181	(85.8)
Urban	30	(14.2)
Income (Iranian Rials per month)		
Low (<2,000,000)	4	(19.9)
Middle (2,000,000-5,000,000)	154	(74.8)
High (>5,000,000)	11	(5.4)
Epilepsy type		
Uncontrollable	22	(13.5)
Poorly controlled	36	(22.1)
Controllable	105	(64.4)
Seizure kind		
Focal, motor, sensory	6	(4.2)
Generalized tonic-clonic	92	(64.8)
Complex partial	27	(19.0)
Juvenile myoclonic	13	(9.2)
Other	4	(2.8)
Years of education		
≤6 (Primary school)	31	(15.2)
7-12 (High school)	70	(34.3)
≥13 (University education)	103	(50.5)

Table 2 - Descriptive clinical data (n=211).

Variables	Mean ± standard deviation	Range	Median
Age	28.7 ± 11.6	18-73	25
Seizure frequency per month	7.7 ± 21.2	0-101	
Duration of disease, years	10.5 ± 8.9	0.6-48	
Seizure worry	48.1 ± 28.9	0-100	49.32
Overall quality of life	60.7 ± 17.3	10-100	60.0
Emotional well-being	56.2 ± 17.5	8-100	56.0
Energy/fatigue	54.3 ± 17.7	10-100	55.0
Cognitive	61.5 ± 21.6	0-100	63.3
Medication effects	48.5 ± 30.1	0-100	50.0
Social function	71.6 ± 20.5	5-100	72.0

demographic characteristics, and descriptive clinical data. Eleven (5.9%) patients were illiterate and a researcher asked them the questions, and the remaining patients completed the questionnaire by themselves. Completion of the questionnaire took an average of 17 minutes (illiterate patients 14 minutes versus literate patients 20 minutes).

Reliability and validity. The reliability of the 31 questions of the questionnaire was obtained by Cronbach's alpha coefficient (α=0.89), and was acceptable according

Table 3 - Internal consistency of quality of life questionnaire-31 by demographic and clinical data.

Demographic	n	Cronbach's alpha
Gender		
Male	71	0.89
Female	73	0.81
Marital status		
Single	94	0.89
Married	48	0.86
Residence		
Rural	124	0.88
Urban	28	0.91
Education		
≤5	11	0.88
6-11	49	0.89
≥12	82	0.88
Clinical variable		
Fatigue		
No	106	0.86
Yes	29	0.90
Seizure frequency per month		
0	17	0.73
1-3	36	0.87
≥4	15	0.94
Disease type		0.93
Uncontrollable	16	
Poorly controlled	25	0.90
Controllable	79	0.86
Seizure type		
Focal, motor, sensory	5	0.76
Generalized	65	0.89
Complex partial	22	0.89
Juvenile myoclonic	8	0.71
Duration of disease, (years)		
≤2	18	0.88
3-5	33	0.88
≥6	75	0.89

to demographic and clinical data (α≥0.70), as shown in **Table 3**. Spearman's correlation was used for assessing convergent validity between items within scales and between-scales correlations and was acceptable for all scales, as shown in **Table 4**. As can be seen, there is an acceptable correlation between each scale and its items (recommended r≥0.40). Internal consistency for all scales, except for overall QOL, was acceptable (α≥0.70). However, each scale shows <0.60 correlation with other items. Therefore, the disconvergent validity for all scales is satisfactory. The scaling success rates were 100% for the convergent validity of each scale (**Table 4**). The results of internal consistency of each subscale of QOLIE-31 according to gender and marital status are shown in **Table 5**. As can be observed, the Cronbach's alpha of overall QOL scale in both single and married patients, and Cronbach's alpha of cognitive scale in female patients is a little less than 0.70, but the internal consistency for all other scales according to gender and marital status is acceptable (α≥0.70). **Table 6** shows the results of internal consistency of each subscale of QOLIE-31 regarding disease type and duration of

Table 4 - Item scaling tests: convergent and disconvergent validity for quality of life questionnaire-31 scales.

Scale	No. of items per scale	Convergent validity (range of correlation)	Scaling success[1]	Scaling success[2]	Internal consistency (Cronbach's alpha)	Disconvergent validity (range of correlation)
Seizure worry	5	0.699-0.848	5/5	100	0.79	0.072-0.359
Overall quality of life	2	0.846-0.858	2/2	100	0.64	0.075-0.533
Emotional well-being	5	0.629-0.701	5/5	100	0.79	0.063-0.476
Energy/fatigue	4	0.601-0.741	4/4	100	0.74	0.059-0.564
Cognitive	6	0.609-0.758	6/6	100	0.78	0.066-0.345
Medication effects	3	0.707-0.851	3/3	100	0.71	0.070-0.512
Social function	5	0.427-0.778	5/5	100	0.75	0.059-0.499

[1]Number of correlations between items and hypothesized scale corrected for overlap >0.4 / total number of convergent validity tests,
[2]Scaling success rate of previous column as percentage

Table 5 - Internal consistency (Cronbach's α) of each subscales of quality of life questionnaire-31 by gender and marital status.

Scale	Male	Female	Single	Married
	Cronbach's alpha			
Seizure worry	0.80	0.77	0.79	0.78
Overall quality of life	0.79	0.74	0.65	0.69
Emotional well-being	0.71	0.75	0.75	0.72
Energy/fatigue	0.79	0.81	0.76	0.73
Cognitive	0.78	0.69	0.76	0.81
Medication effects	0.72	0.76	0.71	0.73
Social function	0.72	0.81	0.75	0.78

Table 6 - Internal consistency of each subscale of quality of life questionnaire-31 regarding disease type and duration of disease (years).

Scale	Uncontrollable	Poorly controllable	Controllable	≤2	Disease 3-5	Direction ≥6
			Cronbach's alpha			
Seizure worry	0.86	0.76	0.77	0.71	0.83	0.80
Overall quality of life	0.79	0.76	0.70	0.66	0.76	0.69
Emotional well-being	0.65	0.72	0.79	0.76	0.78	0.78
Energy/fatigue	0.60	0.68	0.76	0.71	0.70	0.70
Cognitive	0.91	0.85	0.72	0.73	0.75	0.82
Medication effects	0.78	0.80	0.79	0.70	0.75	0.71
Social function	0.77	0.68	0.63	0.79	0.75	0.72

disease. As shown, the internal consistency for overall QOL scale in patients with ≤2 and ≥6 years of disease duration, emotional well-being scale in patients with uncontrollable epilepsy, and energy/fatigue scale in patients with uncontrollable and poorly uncontrollable epilepsy is less than 0.70. Social function has shown internal consistency for patients with poorly controllable and controllable epilepsy. The other scales regarding disease type and duration of disease show acceptable internal consistency (α≥0.70).

Discussion. The current study was carried out to translate the QOLIE-31 into Farsi and to assess its reliability and validity among Iranian epileptic patients. Psychometric properties of the Persian adaptation of the QOLIE-31 questionnaire are good, and similar to those of the Spanish,[7] German,[10] French,[5,15] Italian,[4] Hungarian,[11] Georgian,[12] Portuguese,[13] and Thai[14] versions. The timing of completion of the questionnaire and the percentage of missing answers to the item of «driving» was similar to Italian study.[4]

Reliability was assessed by Cronbach's alpha coefficient and it was acceptable for all subscales except for overall QOL, similar to the findings of the Italian[4] and Portuguese version.[13] This may be due to the small number of items (2) in the scale. The internal consistency of the 31-items of the QOLIE-31 was satisfactory for patients with ≤6 and >6 years education.

The internal consistency of each scale according to gender, marital status, epilepsy type, and duration of disease was acceptable, except for overall QOL due to the small number of items as mentioned before, and also, for energy/fatigue, emotional well-being, and social function for subgroups of epilepsy type. They could be explained by the small number of patients in each subgroup. We could not compare our results with others as there is a lack of studies assessing the internal consistency in subgroups of demographic and clinical patients' characteristics.

This study shows a high convergent validity for all subscales of the QOLIE-31. The scaling success rate for all scales was 100, similar to the Italian study.[4] The disconvergent validity for all subscales was acceptable and good, but this finding has not been reported by other studies. As a shortcoming, we could not assess reliability through test-retest procedure. In order to get precise result, we suggest examining test re-test reliability in further studies.

In conclusion, the study findings indicate that the Persian version of QOLIE-31 has a good structured characteristic and convergent validity, between items within scales and between scale correlations. Moreover, it is a reliable instrument that can be used for measuring the effects of epilepsy on the quality of life. We completed the translation, cultural adaptation, validation, and reliability studies of QOLIE-31 for Iranian patients. The Persian version of QOLIE-31 can be considered a valuable and specific instrument to assess different aspects of health related quality of life in epileptic patients, and is applicable in clinical research and practice.

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