

Reliability and Validity of the Korean Version of QOLIE-10 in Epilepsy

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Background and Purpose: It is necessary in clinical practice to screen patients with epilepsy for quality-of-life factors. The purpose of this study was to develop a Korean version of the Quality of Life in Epilepsy (QOLIE)-10 survey and to determine its reliability and validity.

Methods: Data were collected from 397 adult epilepsy patients. The ten items of QOLIE-10 were derived from the Korean version of QOLIE-31. We assessed factor analysis, internal consistency, test-retest reliabilities, construct validity, and discriminant validity. Test-retest was performed in 97 patients.

Results: The ten items of QOLIE-10 were grouped into two factors: epilepsy effects/role function (driving, social, work, physical effect, mental effect, and memory) and mental health (overall quality of life, depression, and energy). The internal consistency reliability coefficient (Cronbach's α) was 0.843 for epilepsy effects/role function and 0.606 for the mental-health scale. Test - retest data revealed statistically significant correlations for individual items (range, $r=0.66-0.38$) and scales (range, $r=0.63-0.48$), except for one item, driving ($r=0.21$, $p=0.133$). QOLIE-10 was significantly correlated with the source scales in the Korean version of QOLIE-31 and with several external measures. The QOLIE-10 scores discriminated between patient groups according to their seizure severity and level of education.

Conclusions: QOLIE-10 was derived from the Korean version of QOLIE-31. The results of this study show that QOLIE-10 can be applied as a screening measure of quality of life in Korean epilepsy patients.

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Key Words : Epilepsy, Quality of life, QOLIE-31, QOLIE-10

INTRODUCTION

Epilepsy produces recurrent and unpredictable seizures with substantial serious consequences on quality of life (QOL).¹ Patients with epilepsy are exposed to a host of social difficulties such as stigma and discrimination.² The World Health Organization (WHO)

has defined health as the state of complete physical, mental, and social well-being, not merely as the absence of disease or infirmity.³ Therefore, determining the health status of a patient should include the domains listed for the WHO's definition of QOL.

In the outpatient clinic, physicians generally pay more attention to how well patients are doing," depending exclusively on laboratory values and other medical

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symptoms, with much less attention being paid to “how patients feel and function in everyday life.” Consequently, patients and physicians often view the impact of seizures and side effects differently. Using a questionnaire as part of clinical care for patients allows them to depict their concerns about a variety of issues influenced by the diagnosis, including seizure frequency, fear of seizures, medication effects, and impact on daily life. Various instruments are available for the assessment of aspects of health-related QOL (HRQOL) in adults.^{4,9} HRQOL can be assessed by disease-specific inventories, as well as by more general or generic QOL inventories.^{4,9} Unlike diagnostic or laboratory tests that report whether a patient’s results are within the normal range, QOL instruments indicate how an individual functions in the real world (e.g., work and social opportunities, driving, independent living, fear of having a seizure).¹⁰

To improve the specificity of information, generic questionnaires need to be modified for special populations, such as people with epilepsy, with supplementary items relevant to problems typically experienced by that population.^{5,11,12} These are designed to reflect the patient’s own perception of how they feel about their disease. The Quality of Life in Epilepsy 31 (QOLIE-31) survey,¹³ which was designed to assess epilepsy-specific QOL issues, has been translated into several languages including Korean,¹⁴ which allows its use in multinational clinical trials and other studies of HRQOL.

There is a need for screening questions that aim to improve communication and raise particular issues between patients and physicians. QOLIE-10,¹⁵ which is a brief, ten-item questionnaire, was therefore developed to screen QOL issues for patients with epilepsy in clinical practice. QOLIE-10 provides individual patients with an opportunity to announce epilepsy-related problems and express their concerns to healthcare providers. The purpose of this study was to develop the Korean version of QOLIE-10 as a disease-specific screening measure of the QOL of Korean epilepsy patients. Thus, the reliability and validity of QOLIE-10 derived from the Korean version of QOLIE-31 were evaluated in this study.

MATERIALS AND METHODS

1. Subjects

Data were collected from 397 adult epilepsy patients (60.4% male; mean age 31.2 years, range 17-65 years). Patients were recruited from five epilepsy centers in Korea. Criteria for inclusion were as follows: (1) being aged 17-65 years, (2) minimum of 1 year since diagnosis of epilepsy, (3) seizure-free for the previous 24 hours at the time of recruitment, and (4) a full-scale intelligence quotient (IQ) score higher than 80. The full-scale IQ measure derived from the revised and standardized version of the Korean Wechsler Intelligence Scale¹⁶ was used. All types of epilepsy were included. Patients were excluded if (1) they had an active psychiatric, neurological, or medical disorder that would impair judgment or impact QOL beyond the effects caused by epilepsy, (2) they had a change in their regimen of antiepileptic drugs in the past 2 months, (3) they had brain surgery in the past year, or (4) they used a concomitant medication that has central nervous system effects. The detailed demographic and clinical characteristics of the sample are given in Table 1.

2. HRQOL assessment

HRQOL was assessed by administering the Korean version of QOLIE-31.¹⁴ For examination of the test-retest reliability, an interval of 2 or 3 between each assessment was chosen so as to minimize the subject’s recall of previous answers.¹⁷ Test-retest was performed in 97 patients. The Korean components of QOLIE-10 were derived from the Korean version of QOLIE-31.

3. QOLIE-31 questionnaire

QOLIE-31¹³ is a 31-item self-administered questionnaire designed for completion by patients alone, and was derived from QOLIE-89.⁷ QOLIE-31 contains seven multi-item scales that cover the following health concepts: seizure worry (five items), overall QOL (two items), emotional well-being (five items), energy/fatigue

Table 1. Demographic and clinical characteristics of the sample

Variable	
Age, years, mean (SD)	32.2 (9.8)
Sex	
Male	239 (60.4%)
Female	158 (39.6%)
Duration of education, years, mean (SD)	12.6 (2.7)
Elementary	21 (5.3%)
Middle	35 (8.8%)
High	191 (48.1%)
University	150 (37.8%)
Marital status	
Currently married	142 (36.8%)
Not married	232 (60.1%)
Divorced, widowed, or separated	12 (3.1%)
Employment	
Employed	223 (61.8%)
Unemployed	138 (38.2%)
Economic status	
High	34 (9.3%)
Middle	213 (58.4%)
Low	118 (32.3%)
Mean age at onset, years, mean (SD)	18.5 (9.9)
Type of epilepsy	
Idiopathic generalized	64 (16.2%)
Symptomatic (probably symptomatic) focal	267 (67.2%)
Undetermined	29 (7.3%)
Others	37 (9.3%)
Seizure frequency	
Remission for ≥ 2 years	19 (4.8%)
Rare: < 1 year	122 (32.3%)
Moderate: 1-11 times/year	156 (41.2%)
Frequent: ≥ 1 /month	100 (26.4%)
Full-scale intelligence quotient, mean (SD)	103.0 (12.7)
Antiepileptic drug treatment	
Monotherapy	166 (41.8%)
Polytherapy	215 (54.2%)
No therapy	16 (4.0%)

(four items), cognitive functioning (six items), medication effects (three items), and social functioning (five items). QOLIE-31 also includes a single item that assesses overall health. Responses can be scored to provide subscale scores and a total score. Higher scores in QOLIE-31 reflect a better QOL.

We completed the adaptation process of QOLIE-31

into a Korean version. During development, the Korean version of QOLIE-31 was found to have good psychometric properties.¹⁴ Internal consistency reliability coefficients (Cronbach's α) ranged from 0.69 (overall QOL) to 0.86 (seizure worry). The test-retest reliability was acceptable (range $r=0.50-0.71$). Item-to-scale correlations were calculated for 30 items comprising seven scales, and were uniformly very high for all scales: seizure worry ($r=0.61-0.76$), overall QOL ($r=0.72-0.74$), emotional well-being ($r=0.38-0.49$), energy/fatigue ($r=0.37-0.42$), cognitive functioning ($r=0.45-0.72$), medication effect ($r=0.51-0.73$), and social function ($r=0.41-0.67$). The Korean version of QOLIE-31 was sensitive to differences in seizure frequency and severity categories.¹⁴

4. QOLIE-10 questionnaire

QOLIE-10 was derived from QOLIE-31.¹³ QOLIE-10 comprises seven components: five of them correspond to a single item from each of five subscales (seizure worry, overall QOL, emotional well-being, energy/fatigue, and cognitive functioning), one component includes two items on medication effects (physical effects and mental effects), and the last component includes three items on social function (work, driving, and social limits).¹⁵ Thus, QOLIE-10 had ten items drawn from seven QOLIE-31 scales.¹⁴

5. Tests administered for constructive validity

(1) Functional Assessment of Chronic Illness Therapy (FACIT)

The term "FACIT" aims to portray an expansion of the more familiar "FACT" series of questionnaires describing other chronic illnesses and conditions (e.g., multiple sclerosis, human immunodeficiency virus infection, and Parkinson's disease).¹⁸ The measurement system, which has been under development since 1987, began with the creation of a generic core questionnaire, the Functional Assessment of Cancer Therapy-General (FACT-G).¹⁹ The FACT-G is a 27-item compilation of general questions divided into 4 primary QOL domains (physical well-being, social/family well-being, emotional

Table 2. Correlation of each QOLIE-10 item with the source summary scale in QOLIE-31

Item in QOLIE-10	Source scale in QOLIE-31	Correlation of QOLIE-10 item with source scale*
Seizure worry	Seizure worry (five items)	0.846
Overall QOL	Overall QOL (two items)	0.882
Depression	Emotional well-being (five items)	0.669
Energy	Energy/fatigue (four items)	0.718
Memory	Cognitive functioning (six items)	0.760
Physical effect	Medication effect (three items)	0.908
Mental effect	Medication effect (three items)	0.884
Driving	Social function (five items)	0.646
Social	Social function (five items)	0.844
Work	Social function (five items)	0.809

*: All $p < 0.001$

well-being, and functional well-being). Equivalent foreign-language versions of the FACIT questionnaires are now available in 24 languages, permitting cross-cultural comparisons of people from diverse backgrounds.¹⁹ A higher score in the FACT-G also reflects a better QOL.

(2) State-Trait Anxiety Inventory (STAI)

The most widely used measure of anxiety in its two distinct forms assesses state anxiety and trait anxiety. Only the scale of state anxiety was analyzed in this study. A higher score reflects a greater anxiety.²⁰

(3) Center for Epidemiological Studies-Depression scale (CES-D)

The CES-D is used for measuring depression in the general and nonpsychiatric population.²¹ Scores on this scale range from 0 to 60, with higher scores reflecting a greater level of depression. A cut-off of 16 was used, with patients having a score of 16 or more being classified as having significant depressive symptoms.²²

6. Data analyses

Varimax rotation was selected for the factor analysis. Variables with a loading of ≥ 0.4 were included in subscales. Factor analysis was performed on ten items in the Korean version of QOLIE-10. We assessed the test-retest reliability of QOLIE-10 using Pearson correlation coefficients. Cronbach's α coefficients were calculated for each scale. Construct validity was assessed

by examining the relationship between individual items compared with the source subscales and other external measures such as FACT-G, STAI, and CES-D. Discriminant validity was assessed by association with clinical and demographic features of samples including seizure frequency, type of antiepileptic drug treatment, and level of education.

Probability values of $p < 0.05$ were considered statistically significant. Statistical analysis was conducted with standard SPSS Statistical Analysis System (V. 12.0) software (Chicago, IL, USA) on a personal computer.

RESULTS

1. Correlation of QOLIE-10 items with the source scale in QOLIE-31

Table 2 lists the item correlations between QOLIE-10 items and QOLIE-31 parent scales (range, 0.908-0.646). All correlations were statistically significant ($p < 0.001$).

2. Factor analysis of QOLIE-10

Factor analyses of ten items yielded two factors with eigenvalues of > 1.0 . The first factor comprised three items (driving, social, and work) of social function, two items (physical and mental effect) of medication effect, one item (memory) of cognitive functioning, and one item (seizure worry) of seizure worry (Table 3). The second factor comprised one item each (overall QOL,

Table 3. Factor analysis and reliability of QOLIE-10

	Cronbach's α	Percentage variance	Test-retest Pearson correlation*
Epilepsy effects/role-function scale	0.843	36.5	0.629
Physical effect			0.484
Mental effect			0.537
Memory			0.631
Seizure worry			0.660
Driving			0.211
Social			0.449
Work			0.490
Mental-health scale	0.606	20.1	0.484
Overall QOL			0.461
Depression			0.380
Energy			0.387

*Test-retest was performed in 97 patients. All items except driving had less than six missing values. However, there were responses for the driving item from only 52 of the 97 patients. All $p < 0.001$, except driving ($p = 0.133$)

Table 4. Correlation of each item and scale of QOLIE-10 with FACT-G, STAI and CES-D

	FACT-G					STAI*	CES-D*
	Overall*	Physical*	Social [†]	Emotional*	Functional*		
QOLIE-10	-0.602	-0.526	-0.283	-0.541	-0.496	-0.630	-0.559
Epilepsy effects/role function scale	-0.516	-0.478	-0.230	-0.495	-0.394	-0.547	-0.481
Physical effect	-0.338	-0.334	-0.133	-0.360	-0.232	-0.356	-0.283
Mental effect	-0.340	-0.282	-0.159	-0.332	-0.274	-0.392	-0.309
Memory	-0.403	-0.364	-0.217	-0.342	-0.309	-0.439	-0.396
Seizure worry	-0.461	-0.474	-0.145	-0.512	-0.324	-0.479	-0.409
Driving	-0.326	-0.290	-0.220	-0.285	-0.217	-0.240	-0.295
Social	-0.429	-0.375	-0.193	-0.380	-0.369	-0.474	-0.434
Work	-0.393	-0.367	-0.160	-0.359	-0.326	-0.437	-0.366
Mental-health scale	-0.595	-0.430	-0.320	-0.449	-0.583	-0.608	-0.554
Overall QOL	-0.506	-0.393	-0.273	-0.397	-0.471	-0.545	-0.450
Depression	-0.480	-0.364	-0.229	-0.427	-0.443	-0.492	-0.488
Energy	-0.385	-0.255	-0.233	-0.221	-0.417	-0.377	-0.326

*; All p value < 0.001 , [†]; All p value < 0.001 except seizure worry, driving, work, physical effect and mental effect $p < 0.01$

depression, and energy) from overall QOL, emotional well-being, and energy/fatigue scales. Based on the content of items loading on each factor, the first factor was labeled as epilepsy effects/role function and the second factor was labeled as mental health. Scales were derived for each of these factors by summing the raw scores for each item that loaded at > 0.40 on each factor.

3. Reliability of QOLIE-10

Internal consistency reliability coefficients (Cronbach's α) were 0.843 for epilepsy effects/role function and 0.606 for the mental-health scale (Table 3).

Test-retest data revealed statistically significant correlations for individual items (range, $r = 0.66$ - 0.38) and scales (range, $r = 0.63$ - 0.48), except for one item, driving ($r = 0.21$, $p = 0.133$).

4. Constructive validity

Correlation coefficients between QOLIE-10 and FACT-G, STAI, and CES-D questionnaires are presented in Table 4. The summary score of QOLIE-10 was strongly correlated with FACT-G, STAI, and CES-D (range, $r = -0.63$ to -0.56). STAI and CES-D were most strongly correlated with the mental-health

Table 5. Differences in QOLIE-10 according to the degree of seizure frequency and education

	Seizure frequency			<i>p</i>
	<1/year	1-11/year	≥1/year	
QOLIE-10	68.5 (19.7)	57.9 (18.8)	56.8 (19.1)	<0.001
Epilepsy effects/ role-function scale	72.8 (21.7)	58.5 (27.4)	58.3 (24.5)	<0.001
Mental-health scale	58.8 (19.7)	55.8 (18.8)	53.9 (15.5)	0.131
	Antiepileptic drug therapy			
	Monotherapy	Polytherapy		
QOLIE-10	66.3 (21.1)	57.0 (19.4)		<0.001
Epilepsy effects/ role-function scale	69.5 (25.0)	58.1 (25.0)		<0.001
Mental-health scale	58.7 (19.7)	54.3 (17.3)		0.02
	Education			
	Elementary/ middle school	High school	University	
QOLIE-10	56.2 (21.0)	59.9 (22.4)	64.7 (17.5)	0.015
Epilepsy effects/ role-function scale	58.0 (24.7)	61.2 (28.0)	68.2 (21.8)	0.011
Mental-health scale	52.2 (21.1)	56.8 (18.6)	56.7 (17.2)	0.174

Data are mean (SD) values

QOLIE-10 subscale ($r=-0.61$ and $r=-0.55$, respectively), where a negative correlation represents higher levels of anxiety or depression and worse QOL status, whereas they were poorly correlated with driving and physical-effect items (range, $r=-0.22$ to -0.36). These findings indicate convergent and divergent validities of QOLIE-10.

5. Discriminant validity

Several variables were significantly associated with a summary or with the subscale scores of QOLIE-10, including seizure frequency, antiepileptic drug therapy, and level of education (Table 5). Patients who suffered less than one seizure per year had significantly higher scores on QOLIE-10 than did patients who suffered at least one seizure per year. Moreover, patients receiving monotherapy for their epileptic condition or with a higher level of education were associated with higher scores on QOLIE-10. However, the mental-health subscale of QOLIE-10 was not related to seizure frequency or level of education. Other variables were not

significant, including gender, age, age at onset, duration of epilepsy, or type of epilepsy.

DISCUSSION

Our data revealed a good correlation between the items of QOLIE-10 and their source scales in the Korean version of QOLIE-31. They also showed similar internal consistency and test-retest reliability as those reported by Cramer et al.¹⁵ The Korean version of QOLIE-10 was strongly correlated with external measures such as FACT-F, STAI, and CES-D. These findings indicated the constructive validity of our QOLIE-10 questionnaire. In addition, QOLIE-10 could discriminate among patients according to their seizure severity and level of education. These data suggest the usefulness of the Korean version of QOLIE-10 as a screening tool in clinical practice.

The ten items of the original QOLIE-10 fall into three categories based on the content of items loading on each

factor: (1) epilepsy effects (three items), (2) role function (four items), and (3) mental health (three items).¹³ Compared to the original version, the factor analyses of the Korean version of QOLIE-10 in this study yielded two factors: (1) epilepsy effects/role function (seven items), and (2) mental health (three items). The items that constituted the mental-health factor in the original QOLIE-10 (overall QOL, depression, and energy) were identical to those of this factor in the Korean version of QOLIE-10. The items that constituted the epilepsy-effects and role-function factors in the original QOLIE-10 were not divided as two separate factors, instead being loaded onto one factor in this study.

Test-retest data demonstrated statistically significant reliability for individual items and scales of the Korean version of QOLIE-10, except for one item, driving. In this study, test-retesting was performed on 97 patients. All items except driving had less than six missing values. However, there were responses for the driving item from only 52 of the 97 patients. Such a large number of missing values for this item was probably the reason why the test-retest reliability for driving was not statistically significant.

McHorney et al.²³ compared the validity and relative precision in assessing constructs between six general-health-status instruments. They found that relative precision estimates favored long-form over short-form (SF) multi-item scales, and favored multi-item scales over single-item global measures and poster charts. Although the multi-item scales are expected to have higher reliability and validity, SF measures can be correlated well with longer instruments.²⁴ Our data demonstrated a good correlation between QOLIE-10 items and their source scales in the Korean version of QOLIE-31. SF-12 has been recently released based on major items from the SF-36.²⁵ SF-12 has some similarities to QOLIE-10 in that it includes one or two items from each of the original subscales. Hurny et al.²⁶ also supported the use of single-item scales in a comparison of a single-item and multi-item scales. They found correlations averaging 0.60 between single-item linear-analogue-scale questions for mood and a 28-item mood adjective scale.

The brevity of QOLIE-10 has the potential to save physician time without sacrificing the quality of information collected or interfering with the physician-patient relationship. Moreover, SF measures allow healthcare providers to assess a variety of issues without spending the extra time and resources required for the administration and scoring of longer instruments, and without requiring an extended interview to review all topics at every visit.¹⁵

This study was subject to a limitation that was already pointed out by Cramer et al.¹⁵ Patients included in this study were exposed to multiple questions for each subscale that gave a particular shape to the topic. This could have improved in the understanding of the single item in QOLIE-10 that represented the subscale. Separation of the ten items from QOLIE-31 may have resulted in patients having a worse appreciation of the issues, as with the multiple items. A separate study is needed in which QOLIE-10 items are presented before the remaining 21 items in QOLIE-31 to confirm these findings.

In summary, QOLIE-10 was derived from the Korean version of QOLIE-31 as a disease-specific screening measure of the QOL of Korean epilepsy patients, and its reliability and validity were confirmed. This study showed that it can be reliably applied as a screening measure of QOL in Korean epilepsy patients.

Appendix A

The Korean QoL in Epilepsy Study Group comprised the following people: Sang-Ahm Lee, M.D. (P.I.), Hee-Jung Yoo, Ph.D, and Joong-Koo Kang, M.D. (University of Ulsan College of Medicine, Seoul); Byung-In Lee, M.D., Kyoung Heo, M.D., and Ryeo Won Ko, Ph.D. (Yonsei University College of Medicine, Seoul); Sang-Do Yi, M.D. and Ju-Hwa Lee, Ph.D. (School of Medicine, Keimyung University, Daegu); Seung-Bong Hong, M.D. (School of Medicine, Sungkyunkwan University); and Jae-Moon Kim, M.D. (College of Medicine, Chungnam National University, Daejeon).

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