The Thai Version of the Quality-of-Life in Epilepsy Inventory (QOLIE-31-Thai Version): Translation, Validity and Reliability

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Objective: *To assess the validity and reliability of the QOLIE-31-Thai Version.*
Material and Method: *The original questionnaire of the QOLIE-31 was first translated into Thai and, then, item comprehension was assessed. Back translation into English and cross-cultural modification were conducted. Its reliability was assessed using a sample of consenting epileptics aged 18-65 years visiting community hospitals in Nakhon Ratchasima Province, Thailand.*
Results: *One hundred and sixty one epileptics completed the questionnaire. The internal consistency of each scale of the QOLIE-31 was above the accepted standard of 0.7, except for Cognitive Functioning, Medication Effect and Social Functioning.*
Conclusion: *The QOLIE-31-Thai Version is reliable for use in Thai rural epileptics even for low educated epileptics but interviews might have to be used instead.*

Keywords: *Epilepsy, Quality of life, Reliability, Validity, Thailand*

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Measurement of quality of life has become a standard endpoint in many randomized controlled trials and other clinical studies[1]. In part, this is a consequence of the realisation that many treatments for chronic diseases frequently fail to cure and that there may be limited benefit gained at the expense of taking toxic or unpleasant therapy[1]. In the field of epileptology, there have been only six internationally published scales that have assessed the quality of life of epileptic patients. These are as follows: 1) Quality of Life in Epilepsy Inventory 89 items (QOLIE-89) [2]; 2) Quality of Life in Epilepsy Inventory 31 items (QOLIE-31) [3]; 3) Quality of Life in Epilepsy Inventory 10 items (QOLIE-10) [4]; 4) Quality of Life in Epilepsy Inventory for Adolescents (QOLIE-AD-48) [5]; 5) Liverpool Health Related Quality of Life Battery (Liverpool HRQOL) [6]; 6) Epilepsy Surgery Inventory (ESI-55)[6].

ESI-55 is specific for evaluation prior to surgery[7]. The Liverpool HRQOL has eight independent scales, which were selected from different study scales to assess the quality of life of patients with epilepsy; not all scales of the Liverpool HRQOL are used repeatedly in every study[6]. In addition, six out of the eight scales of the Liverpool HRQOL are not reproducible[8].

The remaining four (QOLIE-89, QOLIE-31, QOLIE-10, QOLIE-AD-48) have sufficient internal consistency and stability. The QOLIE-89 and the QOLIE-31, which was derived from the QOLIE-89, are for intervention assessments and comparing populations (low versus high seizure frequency). The QOLIE-10 is for screening purposes[7] and the QOLIE-AD-48 is for adolescents aged 11-17 years[5].

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In Thailand, there have been several scales used for the assessment of quality of life. Some were created locally, based on the widely used Zhan's conceptual framework[9] and some were translated from other studies. However, none has assessed the quality of life of epileptics.

The authors wanted to assess the quality of life in epileptics aged between 18-65 years receiving two treatments in the authors' clinical practice. The QOLIE-31 was chosen in the present study because it has been shown to have sufficient internal consistency and stability in intervention assessment[7]. Further, the QOLIE-31, which is derived from the QOLIE-89 is easier to administer compared to its original version.

Meterial and Method

Adaptation of the QOLIE-31 into Thai

The original QOLIE-31 consists of seven multi-item scales and a single item (item 31) on overall health. The multi-item scales include: Seizure Worry (SW) (items 11, 21-23, 25); Emotional Well Being (EWB) (items 3-5, 7, 9); Energy/Fatigue (EF) (items 2, 6, 8, 10); Cognitive Functioning (CF) (items 12, 15-18, 26); Medication Effect (ME) (items 24, 29, 30); Social Functioning (SF) (items 13, 19, 20, 27, 28); Overall Quality of Life (OQOL) (items 1, 14).

The adaptation process of the QOLIE-31 into Thai included the following phases: translation into Thai; assessment of item comprehension; back translation into English; cross-cultural modification and formal assessment of its validity and reliability.

The phase of translation into Thai was performed by a local neurologist (TA). Some of the original English phrases were not familiar phrases in Thailand; for example, "pep, downhearted and blue, worn out". The phase of assessment of item comprehension after translation was refined by a clinical neurologist (KP), and a clinical epidemiologist (CS-A) for content equivalence. The back translation into English phase was done by a translator (Niramitranon U). For cross-cultural modification process, three active rural villagers received explanation of the meaning of each item of the questionnaire by the local neurologist (TA). The wording of the questions was modified to suit local context and to still maintain the same meaning. Items which refer to uncommon activities in rural Thailand were expanded by more common and, therefore, more understandable tasks. For example, "riding motorcycle" and "operating a machine" (e.g. machines used in agriculture) were selected to add to the definition of "driving".

The modified questionnaire was tested by consenting rural epileptics who visited the neurologic outpatient department of Maharat Nakhonratchasima Hospital. During the test, the epileptics were asked about their understanding of each item. Items, which were not understood were changed again through consultation involving the neurologist (TA), the epileptics and the rural villagers until the epileptics clearly understood the meaning of the whole questionnaire (language equivalence). In doing so, the layout of the questions was also modified. For example, the "horizontal" visual analogue scale to assess overall quality of life (from best to worst possible quality of life) was replaced by a "vertical" stairs format with "best possible quality of life" at the top of the ten stairs because rural villagers can relate to "higher" quality of life better if it is presented vertically. For some items, the subjects did not recognize the meaning of "not at all" used in some items (15,19,20,26,29 and 30). For these items, the "zero" responses were later added to the "not at all" responses.

QOLIE-31-Thai Version Instrument

This questionnaire, which was self-administered, contained questions on demographic and clinical characteristics as the first part and the questions for the QOLIE-31-Thai Version as the second part.

Method of analysis

The SPSS statistical package for social sciences was used to analyze the data. The Chi-Square test or Fisher Exact Test was used to compare the patient's characteristics and unpaired t-test was used to compare the mean score of each scale and of the overall score. P-value of less than 0.05 was applied to identify the statistically significant differences.

Assessment of Validity

The Thai version had content and language equivalence to the original English version; therefore the validity of the Thai version was considered to be equivalent to the original version.

Assessment of reliability

To assess the reliability in terms of internal consistency of the QOLIE-31, the authors chose a sample of epileptics who visited six participating community hospitals in Nakhonratchasima Province, Thailand. The epileptics were considered eligible if they had been registered as being epileptic at the Community Hospitals and had been taking antiepileptic medi-

Table 1. Demographic and clinical characteristics of the participants by gender

Characteristics		Male (84) N	Male (84) %	Female (77) N	Female (77) %	Total (161) N	Total (161) %	p-value Male vs female
A) Demographic								
- Age	: 18-44 years	63	75.0	59	76.6	122	75.8	0.955
	: 45-65 years	21	25.0	18	23.4	39	24.2	
- Education	: ≤ Compulsory Requirements	7	8.3	10	13.0	17	10.6	0.482
	: > Compulsory Requirements	77	91.7	67	87.0	144	89.4	
- Marital status	: Single or separated or divorced	33	39.3	37	48.1	70	43.5	0.336
	: Married	51	60.7	40	51.9	91	56.5	
- Employed	: No	7	8.3	6	7.8	13	8.1	1.000
	: Yes	77	91.7	71	92.2	148	91.9	
B) Clinical								
- Type of seizure in lifetime	: Partial type	43	51.2	35	45.4	78	48.4	0.701
	: Generalized type	37	44.0	36	46.8	73	45.3	
	: Unidentified type	4	4.8	6	7.8	10	6.3	
- Antiepileptic drug side effects in lifetime	: Yes	3	3.6	9	11.7	12	7.5	0.088
	: No	81	96.4	66	85.7	147	91.3	
	: Missing data	0	0.0	2	2.6	2	1.2	
- Seizure(s) in past 12 month	: Yes	41	48.8	45	58.4	86	53.4	0.287
	: No	43	51.2	32	41.6	75	46.6	

cations, if their age was between 18 and 65 years, if they had no mental or speech problem and if they signed a written informed consent form. This questionnaire was self-administered but for illiterate patients, their escorting relatives or rural hospital nurses read the questionnaire. Internal consistency of the QOLIE-31 scales and overall score was analyzed by using Cronbach's Alpha Coefficient.

For Overall Health, there is only one item (item 31) so we could not test for internal consistency. The Mean Overall Score (OS) and internal consistency were computed from items 1-30 according to the formula of the original paper[3].

Table 2. The number of the respondents by number of items not answered

Number of items not answered	Number of the respondents N	%
0/31	142	88.2
1/31	12	7.5
2/31	3	1.9
3/31	0	0
4/31	2	1.2
5/31	2	1.2
Total	161	100.0

Results

All of the 199 epileptics, who visited the community hospitals from 13 May to 21 June 2002, gave informed consent. Of these, 161 met all inclusion criteria and completed the demographic data; 22 were excluded from the study because their age was above or below the study criteria, 14 because they had mental or speech problems and two because they did not complete the demographic data. As shown in Table 1, there were no significant differences by gender and age or by gender and the other socio-demographic and clinical data examined.

Most of the respondents (88.2%) answered all of the items in the QOLIE-31-Thai Version Scale,

with the maximum number of items not answered being five by two respondents (Table 2). Although the non-response rates for the items and scales were generally higher among the females, these differences were not statistically significant (Table 3). Only education below or just meeting the requirements of the compulsory

Table 3. Non-Response by gender and by multi-item scales and items within scales

Multi-item Scale and Item	Number of items not answered					
	Male (84)		Female (77)		Total (161)	
	n	%	n	%	n	%
Seizure Worry (SW)	1	1.2	2	2.6	3	1.9
- Item 11	0	0	0	0	0	0
- Item 21	0	0	0	0	0	0
- Item 22	0	0	1	1.3	1	0.6
- Item 23	1	1.2	1	1.3	2	1.2
- Item 25	0	0	0	0	0	0
Overall quality of Life (OQOL)	1	1.2	3	3.9	4	2.5
- Item 1	1	1.2	2	2.6	3	1.9
- Item 14	1	1.2	3	3.9	4	2.5
Emotional Well Being (EWB)	1	1.2	1	1.3	2	1.2
- Item 3	0	0	0	0	0	0
- Item 4	1	1.2	0	0	1	0.6
- Item 5	0	0	0	0	0	0
- Item 7	0	0	1	1.3	1	0.6
- Item 9	0	0	0	0	0	0
Energy/Fatigue (EF)	1	1.2	4	5.2	5	3.1
- Item 2	1	1.2	2	2.6	3	1.9
- Item 6	0	0	1	1.3	1	0.6
- Item 8	0	0	1	1.3	1	0.6
- Item 10	0	0	0	0	0	0
Cognitive Functioning (CF)	3	3.6	3	3.9	6	3.7
- Item 12	3	3.6	0	0	3	1.9
- Item 15	0	0	0	0	0	0
- Item 16	1	1.2	0	0	1	0.6
- Item 17	1	1.2	1	1.3	2	1.2
- Item 18	1	1.2	2	2.6	3	1.9
- Item 26	0	0	0	0	0	0
Medication Effect (ME)	0	0	1	1.3	1	0.6
- Item 24	0	0	1	1.3	1	0.6
- Item 29	0	0	0	0	0	0
- Item 30	0	0	0	0	0	0
Social Functioning (SF)	2	2.4	3	3.9	5	3.1
- Item 13	2	2.4	3	3.9	5	3.1
- Item 19	0	0	0	0	0	0
- Item 20	0	0	0	0	0	0
- Item 27	0	0	1	1.3	1	0.6
- Item 28	0	0	0	0	0	0
Overall Health (OH)	0	0	3	3.9	3	1.9
- Item 31	0	0	3	3.9	3	1.9

program of Thailand for the total respondents was significantly (p-value < 0.05) related to the items not answered (Table 4).

The mean score as well as the internal consistency by gender and the multi-item scales and the overall scores are presented in Table 5. The females had lower mean scores than males in all multi-item scales but the differences were only significantly lower for Overall Quality of Life and Energy/Fatigue and for the Overall Score. The internal consistency for the multi-item scales of the QOLIE-31-Thai Version was generally similar in both genders, with the following exceptions: in the males, Cognitive Functioning was less than 0.7 (0.64) and less than that for the females (0.69); in the females, Social Functioning was considerably lower (0.55) than in males (0.64).

Discussion

The respondents in the present study had quite good education (89.4% completed their schooling above Thailand's compulsory education level) and were employed (91.9%). In addition, most of them (91.3%) had not had side effects of antiepileptic drug (AED) and 47.2% of the respondents had had no seizure in the past 12 months. These might indicate that people who can visit the community hospital and can complete the quality of life questionnaire have quite good physical and mental health status. They, therefore, can learn and work like other people. On the other hand, people who have either physical or mental disability from seizure consequences could not visit or do the questionnaire. Surprisingly, 43.5% of the total respondents were single, separated or divorced; although

Table 4. Comparison between the respondent's characteristics with item not answered by gender

Characteristics		Number of the respondents						p-value
		Male (84)			Female (77)			Male vs female
		NA (n=6)	A (n=78)	p-value*	NA (n=13)	A (n=64)	p-value#	
A) Demographic								
- Age	: 18-44 years	6	57	0.329	10	49	1.000	0.569
	: 45-65 years	0	21		3	15		
- Education	: ≤ Compulsory Requirements	1	6	0.417	4	6	0.059	0.033*
	: > Compulsory Requirements	5	72		9	58		
- Marital status	: Single or separated or divorced	4	29	0.205	6	31	1.000	0.541
	: Married	2	49		7	33		
- Employed	: No	0	7	1.000	2	4	0.266	0.653
	: Yes	6	71		11	60		
B) Clinical								
- Type of seizure in lifetime	: Partial type	4	39	0.366	4	31	0.343	0.885
	: Generalized type	1	36		8	28		
	: Unidentified type	1	3		1	5		
- Antiepileptic drug side effects in lifetime	: Yes	0	3	1.000	1	8	1.000	1.000
	: No	6	75		11	55		
	: Missing data	0	0		1	1		
- Seizure(s) in past 12 month	: Yes	2	39	0.676	10	35	0.217	0.508
	: No	4	39		3	29		

NA = Not answered; A = answered
* for male by Fisher Exact test
# for female by Fisher Exact test

Table 5. Mean scores and internal consistency of the QOLIE-31-Thai Version scales by gender

QOLIEe -31 scal	Gender						p-value Male vs
	Male		Female		Total		
	Mean Score ± SD (n)	Alpha*	Mean Score ± SD (n)	Alpha*	Mean Score ± SD (n)	Alpha*	female
SW	61.5 ± 25.96 (83)	0.85	53.7 ± 28.12 (75)	0.85	57.8 ± 27.21 (158)	0.85	0.069
OQOL	74.4 ± 19.99 (83)	0.74	65.4 ± 24.90 (74)	0.77	70.2 ± 22.82 (157)	0.75	0.013**
EWB	66.8 ± 18.17 (83)	0.69	61.8 ± 18.84 (76)	0.74	64.4 ± 18.61 (159)	0.71	0.090
EF	71.9 ± 17.03 (83)	0.69	65.3 ± 18.45 (73)	0.73	68.8 ± 17.95 (156)	0.72	0.023**
CF	71.5 ± 16.10 (81)	0.64	66.8 ± 18.24 (74)	0.69	69.3 ± 17.26 (155)	0.67	0.093
ME	70.1 ± 24.32 (84)	0.71	63.1 ± 23.35 (76)	0.64	66.8 ± 24.05 (160)	0.68	0.066
SF	77.8 ± 16.95 (82)	0.64	74.2 ± 17.23 (74)	0.55	76.1 ± 17.13 (156)	0.60	0.183
OS	71.8 ± 12.77 (78)	0.89	66.6 ± 14.76 (65)	0.92	69.4 ± 13.91 (143)	0.91	0.025**

* Cronbach's Alpha

the proportion was higher among females (48.1%) than males (39.3%), the difference was not statistically significant. Attitude and beliefs about epilepsy particularly for people in developing countries (for example: the possession of demons or superstition) stigmatizes the epileptic and this may explain why so many epileptics are single, separated or divorced. Baker mentioned that "Epilepsy has been a condition with extremely negative connotations and even now the label of epilepsy is one rejected by many people in whom seizures develop"[8].

The mean score of each scale and overall score in females was lower than in males with statistical significance in the scales of Overall Quality of Life and Energy/Fatigue and in the Overall Score. Cramer noted that " The difference between perceived status (where the authors are) compared to actual status (where the authors would like to be) creates a sense of dissonance. When the gap between actual achievements and desired status is wide, the dissonance can lead an individual to consider quality of life to be low. When the gap is small, quality of life often is perceived as high"[10]. The males in the present study might have a small gap between perceived and actual status. They, therefore, had a higher mean score for each scale and for the overall score.

Comparing to the original version[3] and the Spanish version[11], the Cronbach's alpha coefficients of the scales in both genders in the present study was below the generally accepted standard of 0.7 [11] in three scales (Cognitive Functioning, Medication Effect and Social Functioning) and was also below the alpha coefficient of both of the two versions (original and Spanish version)[3,11]. The unacceptable scales especially the Cognitive Functioning and Social Functioning might be because of the high number of respondents who did not answer items within these scales (6 in Cognitive Function and 5 in Social Function). This might explain why the internal consistency of the Cognitive Functioning and Social Functioning in the male group was also low. In addition, the high number of items not answered was significantly related to the respondent's education that might reflect inadequate reading skills and/or the lack of comprehensive skills of the respondents[10]. To improve the internal consistency of the unacceptable scales, the method of administered questionnaire might be changed to the interview technique particularly for those with low education. For Medication Effect, some items that measure this aspect might need to be added if using the interview technique does not improve the internal consistency.

Therefore, QOLIE-31-Thai Version is reliable for use in Thai epileptics. Further studies, particularly discriminant and construct validity[12], will be carried out to determine its value in the assessment of the effect of intervention.

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แบบสอบถามคุณภาพชีวิตสำหรับผู้ป่วยโรคลมชักฉบับภาษาไทย: การแปล ความถูกต้อง และความเชื่อถือได้

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วัตถุประสงค์: *เพื่อประเมินความถูกต้องและความเชื่อถือได้ของแบบสอบถามคุณภาพชีวิตสำหรับผู้ป่วยโรคลมชักฉบับภาษาไทย*

วัสดุและวิธีการ: *มีการตรวจสอบความถูกต้องของแบบสอบถามฉบับภาษาไทย โดยการแปลแบบสอบถามฉบับดั้งเดิมเป็นภาษาไทยจากนั้นมีการตรวจสอบความหมายและแปลกลับเป็นภาษาอังกฤษเพื่อให้คงความหมายดั้งเดิม จากนั้นมีการปรับเปลี่ยนภาษาไทยให้สอดคล้องกับผู้ป่วยในพื้นที่ที่จะใช้แบบสอบถาม และมีการประเมินความเชื่อถือได้ โดยผู้ป่วยโรคลมชักที่ยินดีตอบแบบสอบถามที่มีอายุระหว่าง 18-65 ปีไม่มีความผิดปกติทางด้านสติปัญญา และการใช้ภาษาที่มาตรวจที่โรงพยาบาลชุมชน 6 แห่งที่ยินดีเข้าร่วมโครงการ ในจังหวัดนครราชสีมา*

ผลการศึกษา: *ผู้ป่วยจำนวน 161 รายได้ทำแบบสอบถาม มีร้อยละ 88.2 ของผู้ป่วยที่ตอบคำถามทุกข้อ โดยที่การศึกษาของผู้ป่วยมีผลต่อการตอบหรือไม่ตอบคำถาม ความเชื่อถือได้ของแบบสอบถามในแต่ละเรื่องสูงกว่าค่ามาตรฐานที่ยอมรับได้ (0.7) ยกเว้นเรื่องความนึกคิด ผลจากยากันชัก และการเข้าสังคม*

สรุป: *แบบสอบถามคุณภาพชีวิตสำหรับผู้ป่วยโรคลมชักฉบับภาษาไทยมีความเชื่อถือได้ แต่สำหรับผู้ป่วยที่มีการศึกษาน้อยจำเป็นที่จะต้องมีผู้ช่วยในการทำแบบสอบถาม การศึกษาที่จำเป็นต่อไปคือการประเมินว่าแบบสอบถามนี้ว่าสามารถใช้เปรียบเทียบผลการศึกษาในทางคลินิกได้หรือไม่*