

A Thai version of a health-related quality of life instrument for epilepsy

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Abstract

Objectives: This study aimed to validate a health-related quality of life instrument for epilepsy (HQOL) in Thais with epilepsy. **Methods:** The Liverpool HQOL questionnaire, the National Hospital Seizure Severity Scale (NHS) and the Epilepsy Psycho-Social Effect Scale (EPS) were translated into Thai, back translated and then applied to 129 people with epilepsy attending neurological clinics at 4 sites located in the Central area, the South and the North of Thailand. The questionnaire was composed of 6 parts, namely: the Adverse Drug Events Scale, the Rosenberg Self-esteem Scale, the Life Fulfillment Scale, the Hospital Anxiety and Depression Scale (HADS), the NHS and the EPS. Reliability, construct and discriminant validities were analyzed. **Results:** The reliability test for each of the questionnaires was good to excellent. The construct validity of the HADS was confirmed by the other measures. Discriminant validity showed that the questionnaire could distinguish patients with good health status perception from those with poor health status, and could discriminate patients with more frequent seizure attacks from those with less frequent seizures.

Conclusions: The Thai version of the HQOL instrument is a reliable and valid measure of quality of life of Thai people with epilepsy.

INTRODUCTION

Over the past two decades, quality of life has become an issue of wide interest in clinical outcomes measurement.¹ Health-related quality of life (HQOL) has been accepted as a significant outcome measure of epilepsy management in Western countries.²⁻⁶ There is a variety of instruments available today, depending on the clinical questions asked. Quality of Life in Epilepsy (QOLIE)-89 is an epilepsy-targeted measure that includes the SF-36 as a generic core.⁷ The Liverpool HQOL developed by Baker and colleagues assesses multidimensional concepts, including physical and psychosocial aspects.⁸ The questionnaire has been validated and studied in European countries.⁹ To date, a Thai HQOL instrument, particularly for epilepsy, has not yet been developed. Most clinicians evaluate treatment outcomes by their own criteria. Although the Thai version of the WHO-QOL has been validated, it is used for studies in the general population.¹⁰ The Liverpool HQOL also incorporates the stand-alone questionnaires which were already available in Thai including the Rosenberg Self-esteem, the Hospital Anxiety and Depression Scale. Therefore, we investigated the reliability, construct and discriminant validities

of the Liverpool HQOL instrument and the Epilepsy Psychosocial Effect Scale (EPS)¹¹ in Thai epileptic patients who speak different dialects.

METHODS

Instrument

The Liverpool HQOL questionnaire consists of 6 parts, namely: a Seizure Severity Scale (SS, 20 items), an Adverse Drug Events Scale (ADES, 20 items), the Rosenberg Self-esteem Scale (RS, 10 items), a Life Fulfillment Scale (LS, 26 items) and the Hospital Anxiety and Depression Scale (HADS, 14 items, 7 items for each subscale). The SS was replaced with the National Hospital Seizure Severity Scale (NHS, 7 items) because NHS was found to be more concise and cover more seizure type than the SS.¹² We chose the Epilepsy Psychosocial Effect Scale (EPS, 42 items) to measure psychosocial impact of epilepsy. Apart from the HADS and RS, all of the questionnaires were translated into Thai and back translated into English. The back translated version was then compared with the original English version. Discrepancies were checked and cross-cultural adaptations were performed. The

Thai version of the HADS, validated by Nilchaikovich in cancer patients¹³, was used in this study. The whole set of questionnaires were piloted in 20 patients with epilepsy. The piloted subjects could not differentiate the item on nausea-vomiting from that concerning stomach upset. Therefore the ADES component of the questionnaire in this study had 19 items as the 2 items concerning nausea vomiting and stomach upset were combined.

Subjects

From November 1997 to June 1998, patients with epilepsy attending neurological clinics at 4 sites from 3 regions, namely the Prasart Institute of Neurology, the Srithanya Hospital (central region of the country), the Suansaranrom Hospital (the south), and the Saunprung Hospital (the north) were invited to complete the questionnaire by either interview or self-administration. Most questionnaires were completed by interview. Some patients completed the questionnaire by themselves and were asked to mail it back to the investigator as soon as possible. Demographic data and clinical data concerning age, sex, employment and marital status, seizure duration, seizure frequency, antiepileptic drugs (AEDs) were recorded.

Statistical analysis

Reliability testing: Internal consistencies of each subscale were determined by Cronbach's alpha coefficient with an acceptable level set at 0.7.¹⁴ Internal consistency reflects that all items of each scale measure the same attribute.

Validity testing:

Confirmatory factor analysis using a structural equation modeling program, EQS¹⁵, was used to confirm the construct validity of the HADS. There was evidence that item 7 of the HADS anxiety subscale was interchangeable with item 8 of depression subscale, so we compared the factor structure of the original version with the item7-item8 exchanged version.^{16,17} For discriminant validity, we classified patients by 2 means; global health perception (subjective criteria) and seizure frequency over a one-year duration (objective criteria). Analysis of variance (ANOVA) and *t*-tests were used to assess differences between means.

RESULTS

Demographic data

There were 129 cases in this study, including 79 males. The average age was 35.0 ± 9.4 years. The average year of education was 8.07 ± 4.32 years. 70.6% were employed and 48.8% were married.

Clinical data

The average age of onset of seizure was 17.7 ± 11.1 years. Five cases (3.9%) had a history of epilepsy in first degree relatives. Thirty cases (23.3%) had been seizure-free for two years. During the past year, 33.3% had been seizure free; 34.9% had had less than 1 seizure per month; and 31.8% had had more than 1 seizure per month. The seizure was classified according to clinical data into 6 types, i.e., generalized seizures (58.9%), absence (8.5%), complex partial seizures (21.7%), complex partial with secondary generalized seizures (5.4%), focal seizures with secondary generalized seizures (3%) and focal seizures (2.3%). On mono-therapy were 41.2%; 51.5% were on two conventional AEDs and 7.1% on more than two AEDs.

Reliability testing

The NHS, ADES, EPS, LS and HADS produced Cronbach's alpha coefficients of 0.80, 0.85, 0.95, 0.87 and 0.85 respectively. The LS contained 2 parts, i.e., Expectation (ELS) and Reality (RLS), which produced Cronbach's alphas of 0.79 and 0.85 respectively. This demonstrated that all scales had acceptable level of internal consistency coefficients.

Validity testing

The results of confirmatory factor analysis of the HADS are shown in Table 1. In model 1, the HADS was hypothesized as having 2 independent factors according to Zigmond and Snaith's postulation.¹⁸ In model 2, both factors were supposed to be related to each other and item7 was exchanged with item8. By Lagrange multiplier test¹⁹, model 2 was superior to model 1. The comparative fit index (CFI) and root-mean-square error of approximation (RMSEA) values were acceptable. This demonstrated that two subscales of the HADS measured two dependent attributes, anxiety and depression.

Table 1: Confirmatory factor analysis for Hospital Anxiety and Depression Scale

Model	Independent Model			Dependent Model		
	χ^2	CFI	RMSEA(CI)	χ^2	CFI	RMSEA(CI)
1	220.63 df 75	0.71	0.12 (0.10,0.14)	167.45	0.82	0.10 (0.08, 0.12)
2		-	-	115.25 df 74	0.92	0.07 (0.04, 0.09)

χ^2 = chi-square, CFI = comparative fit index, RMSEA = root-mean-square error of approximation
CI = 95% confident interval of RMSEA, df = degree of freedom

Table 2: Discriminant study by global health perception

Questionnaire	Score Mean (S.D.)	
	Fair-Worst (n = 62)	Good-Excellent (n =67)
ANX*	10.95 (3.86)	7.34 (4.10)
DEP*	7.19 (3.80)	3.99 (0.36)
ADES	38.71 (9.71)	36.67 (10.90)
RS*	27.11 (4.66)	29.70 (3.65)
NHS	7.89 (6.15)	6.03 (6.10)
EPS*	55.08(33.18)	32.31(30.08)
ELS	46.37(4.80)	46.97 (4.55)
RLS*	41.29(7.50)	46.03 (6.25)

S.D. = standard deviation

ANX = Anxiety, DEP = Depression, ADES = Adverse Drug Events Scale, RS = Rosenberg Self-esteem Scale, NHS = National Hospital Seizure Severity Scale, EPS = Epilepsy Psychosocial Effect Scale, RLS = Reality Life fulfillment Scale, ELS = Expectation Life fulfillment Scale

*p<0.05

Table 3: Discriminant study by seizure frequency

Questionnaire	Mean (S.D.)		
	Seizure free (n =43)	< 1 seizure/week (n = 45)	1 seizure/week (n = 41)
ANX*	7.70 (4.13)	9.16 (4.61)	10.4 (3.96)
DEP*	4.51 (3.76)	5.07 (3.81)	7.10 (3.77)
ADR	35.56 (9.24)	37.56 (9.88)	30.95 (11.65)
RS	29.60 (4.08)	28.36 (4.49)	27.37 (4.26)
SS*	2.28 (5.05)	8.13 (5.66)	10.46 (4.71)
EPS*	31.93 (31.36)	47.40 (37.31)	50.58 (28.52)
RLS	47.32 (4.24)	45.31 (5.12)	47.51 (4.31)
ELS	44.65 (7.11)	42.87 (7.57)	43.78 (7.12)

ANX = Anxiety, DEP = Depression, ADES = Adverse Drug Events Scale, RS = Rosenberg Self-esteem Scale, NHS = National Hospital Seizure Severity Scale, EPS = Epilepsy Psychosocial Effect Scale, RLS = Reality Life fulfillment Scale, ELS = Expectation Life fulfillment Scale

*p<0.05

Discriminant validity study

By subjective criteria, global health perception classified the patients into 2 groups. The first group (62 cases) rated their own health status as fair to worse; the other group (67 cases) as good to excellent. The comparisons of the means of each scale between two groups are shown in Table 2. There were differences in the means of ANX, DEP, RS, EPS and RLS while there was no difference in the means of ADES, NHS and ELS.

By objective criteria, we divided patients into three groups according to their seizure frequency. The first group had been seizure free for the past year (43 cases), the second had less than one seizure a month (45 cases) and the third had more than one seizure a month (41 cases). Table 3 showed that means of ANX, DEP, NHS, and EPS were different between groups.

DISCUSSION

Most questionnaires were completed by interview, so the effects of different dialects among the 3 regions did not have an impact. The reliability coefficient of each scale was good to excellent. Concerning the construct validity of the HADS, this study confirmed that item7 exchanged with item8 corresponded to the measure by Lippers *et al* conducted in the general population and that of Moorey in cancer patients.^{16,17} In general practice, patients with mixed anxiety/depression type are very difficult to differentiate.²⁰ Therefore, the original HADS is still recommended.

The HADS and EPS could discriminate different groups of patients distinguished by both subjective and objective criteria. The HADS captured patients' view of their psychological symptoms while the EPS their view of impact of epilepsy in their lives and both views are directly related to seizure severity. Either group of patients classified by objective or subjective criteria could not be discriminated by the ELS and the ADES. The ELS contains items on the basic needs in general, which might not be directly associated with disease status. There are many factors other than aspects of health that contribute to the way in which an individual responds to the scale.²¹ The ADES directly measures drug side effects and since most subjects were stable and have been taking AEDs for a period of time, there was no difference in the ADES scores between groups of patient classified either by objective or subject criteria. The RS and the RLS scores were not different among patients with different seizure frequency. One explanation is that both scales are

generic in nature and are not sufficiently sensitive. A generic quality of life scale was found to be less preferable to epilepsy-specific quality of life scale.²² The NHS could discriminate groups of patients with different seizure frequency. This was as expected that unwanted events associated with seizure measured by the NHS tend to occur more when seizure frequency is increased.

In conclusion, the Thai HQOL questionnaire was found to be reliable and valid for epileptic patients. This questionnaire is limited to adult patients. In clinical study, specific parts can be used depending on the clinical question raised.

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