

Reliability and validity of the Thai version of EQ-5D-5L questionnaire on patients with chronic disease

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Background : *The EuroQoL Group's 5-dimension, 5-level (EQ-5D-5L) is a frequently used questionnaire on generic health-related quality of life (HRQoL); however, studies on its psychometric properties in Thailand are rare, especially on patients with chronic diseases.*

Objective : *To evaluate the reliability and validity of the EQ-5D-5L questionnaire on patients with chronic diseases.*

Research design : *Cross-sectional study.*

Setting : *King Chulalongkorn Memorial Hospital.*

Methods : *Four hundred outpatients with chronic disease at King Chulalongkorn Memorial Hospital between July 2014 and February 2015 were surveyed. The psychometric properties of EQ-5D-5L were evaluated in terms of practicality (administration time and ceiling effect), reliability and validity (known-groups validity and convergent validity).*

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- Results** : *The average administration time was less than 2 minutes. The ceiling effect was 14%. Known-groups validity test was confirmed for the following factors: gender, number of medicines taken, disease control and experiencing ADRs. EQ-5D-5L index scores had a positive correlation with all WHOQOL-BREF domains (ρ ranged: 0.27 - 0.58) and EQ-VAS ($\rho = 0.49$, all $p < 0.01$). The intra-class correlation coefficient of EQ-5D-5L was 0.89 and weighted kappa coefficients ranged 0.44 - 0.60 in the five dimensions of EQ-5D-5L.*
- Conclusions** : *EQ-5D-5L had confirmed reliability and validity on patients with chronic disease.*
- Keywords** : *EQ-5D-5L, reliability, validity, patients with chronic disease.*

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เหตุผลของการทำการวิจัย : EQ-5D-5L เป็นแบบสอบถามในการวัดคุณภาพชีวิตด้านสุขภาพแบบทั่วไปที่ใช้กันอย่างแพร่หลาย แต่ในประเทศไทยยังมีการศึกษาคูณสมบัติการวัดเชิงจิตวิทยาของแบบสอบถามนี้ค่อนข้างจำกัด โดยเฉพาะในกลุ่มผู้ป่วยโรคเรื้อรัง

วัตถุประสงค์ : ทดสอบความเที่ยงและความตรงของแบบสอบถาม EQ-5D-5L ในผู้ป่วยโรคเรื้อรัง

รูปแบบการวิจัย : การศึกษาวิจัยเชิงพรรณนาณจุดเวลาใดเวลาหนึ่ง

สถานที่ทำการวิจัย : โรงพยาบาลจุฬาลงกรณ์

ตัวอย่างและวิธีการศึกษา : ผู้ป่วยนอกโรคเรื้อรังที่รับการรักษา ณ โรงพยาบาลจุฬาลงกรณ์ระหว่างเดือนกรกฎาคม 2557 ถึง กุมภาพันธ์ 2558 จำนวน 400 คนตอบแบบสอบถาม EQ-5D-5L และแบบสอบถามอื่น ๆ เพื่อทดสอบความสามารถในการใช้ได้จริง ความตรงเทียบกับกลุ่มที่รู้ ความตรงเชิงคู่เข้า และความเที่ยงของการทดสอบซ้ำ

ผลการศึกษา : เวลาเฉลี่ยในการตอบแบบสอบถาม EQ-5D-5L น้อยกว่า 2 นาที มี ceiling effect ร้อยละ 14 แบบสอบถามสามารถยืนยันความตรงเทียบกับกลุ่มที่รู้ในด้านเพศ จำนวนยาที่ใช้ การควบคุมโรค และการเกิดอาการไม่พึงประสงค์จากการใช้ยา ส่วนความตรงเชิงคู่เข้าพบว่า มีความสัมพันธ์เชิงบวกกับ WHOQOL-BREF และ EQ-VAS โดยค่าสหสัมพันธ์ระหว่างคะแนนของแบบสอบถาม EQ-5D-5L กับคะแนนของแบบสอบถาม WHOQOL-BREF แต่ละมีติดอยู่ระหว่าง 0.27 - 0.58 และกับคะแนน EQ-VAS เป็น 0.49 ($p < 0.01$) ส่วนความเที่ยงในการทดสอบซ้ำอยู่ในระดับดี (ICC = 0.89 และ weighted kappa coefficients = 0.44 - 0.60 ของแต่ละมิติ)

สรุป : แบบสอบถาม EQ-5D-5L มีความเที่ยงและความตรงเพียงพอที่จะนำไปใช้ในกลุ่มผู้ป่วยโรคเรื้อรัง

คำสำคัญ : แบบสอบถาม EQ-5D-5L, ความตรง, ความเที่ยง, ผู้ป่วยโรคเรื้อรัง.

Patient-reported outcomes (PROs), especially health-related quality of life (HRQoL) have been increasingly used in Medicine.⁽¹⁾ Many clinical trials have taken HRQoL as a part of their efficacy evaluation of the medicine.⁽²⁾ HRQoL is derived from the patient's perspectives which help the clinician understand more about the patients' thinking. Taking care of a patient is not only to cure a disease but also to be aware of the state of mind of the patient.

The EQ-5D is a frequently used generic HRQoL questionnaire. The scores of the questionnaire are converted into a single index value that can be used in economic studies, e.g. cost-utility or cost-effectiveness. The EQ-5D-3L was first developed in 1990 and has been translated into 158 official language versions.⁽³⁾ However, there was a high ceiling effect with the questionnaire with regard to the answer in the response category of "no health problems". Thus, in 2009 the EQ-5D-5L was developed to reduce the ceiling effect by adjusting the response choices from 3 to 5 categories.⁽⁴⁾

EQ-5D-5L shows good psychometric properties from many countries around the world;⁽⁵⁻⁸⁾ however, people from different cultures have different points of view about HRQoL. There are only a few studies of psychometric properties of EQ-5D-3L in Thailand: all focused either on disease-specific patients (diabetes and HIV/AIDS) or the general population.⁽⁹⁻¹²⁾ There have been no study on more general patient groups like those with chronic disease. As for EQ-5D-5L, to our knowledge, there was only one study of psychometric properties in Thailand. It was conducted with patients with a mild condition form diabetes which resulted in a ceiling effect of 29%.⁽¹²⁾ Also, at that time there were no Thai

preference weights of EQ-5D-5L, only cross walk value sets in Thailand. Therefore, this study was conducted to evaluate the reliability and validity of the Thai version of EQ-5D-5L in patients with chronic disease by using new Thai preference weights.⁽¹³⁾

Methods

Sample

The sample group consisted of four hundred outpatients, aged over 18 years old with chronic disease, and had been continuously taking their medicine for at least three months, and were able to understand the Thai language, and willing to participate and had no cognitive impairments. They were recruited from King Chulalongkorn Memorial Hospital by purposive sampling with 6 selected characteristics taken into account: age (< 50, \geq 50 years), gender (male, female), education (lower, higher than college), number of medicine taken (< 5, \geq 5 medicines or polypharmacy), disease control (poor, moderate, good) and experiencing adverse drug reactions (yes, no). The sample distribution with each sub-characteristic was similar in number.

The data collection of the study was a part of Master's Degree thesis of the principal investigator. This study has been approved by the Institutional Review Board (IRB) of the Faculty of Medicine, Chulalongkorn University (COA No. 329/2014, IRB No. 179/57).

Survey procedure

A cross-sectional study was conducted from June 2014 to February 2015. Patients were asked to fill in four questionnaires in the following order: Patient-Reported Outcome Measure of

Pharmaceutical Therapy: Quality of Life (PROMPT-QoL)⁽¹⁴⁾, Medical taking behavior (MTB), WHOQOL-BREF⁽¹⁵⁾ and EQ-5D-5L by self-administration. As for those who could not read well, they were interviewed face-to-face by the researcher. To evaluate the test-retest reliability of EQ-5D-5L, the patients who filled in the questionnaires by themselves were asked to bring the same questionnaires back home (PROMPT-QoL, MTB and EQ-5D-5L), filled in the questionnaires again two weeks after the initial surveys and sent them back by mail. The researcher telephoned the patients to remind them after 2 weeks of the survey. As mentioned above, this study is a part of the principal researcher's thesis so only the data of EQ-5D-5L and WHOQOL-BREF were used.

Data collection tools

EQ-5D-5L consists of five dimensions (mobility, self-care, normal activities, pain/discomfort and anxiety/depression). There are five response categories in each dimension (no problem, slight problem, moderate problem, severe problem and extreme problem). The scores were calculated using Thai preference weights into a single index value,⁽¹³⁾ a higher score indicating a better HRQoL. EQ-5D-5L also includes a visual analogue scale (EQ-VAS) for patient's self-rated health from 0 which means the worst health you can imagine, to 100 which means the best health you can imagine.

WHOQOL-BREF comprises 26 items, 24 items in four domains (physical health, psychological health, social relationships and environment) and one item each for general quality of life and HRQoL, which were combined into a general QoL domain in this study. There are five response categories in each

item (not at all, a little, moderately, very much and extremely), a higher score indicating a better HRQoL. The domain scores were calculated by multiplying the average of the scores of all items in the domain by 4. Thus, the domain scores would have the same range, from 4 to 20. It was selected to compare with EQ-5D-5L because it is a widely used questionnaire in Thailand and has been recommended by the Thai Department of Mental Health to evaluate quality of life in the Thai people. Moreover, Thailand was one of the fifteen countries where WHOQOL-BREF was developed; its reliability in Thai were also tested with Cronbach's alpha of 0.84 – 0.91.^(15, 16)

Naranjo algorithm⁽¹⁷⁾ is a 10-item questionnaire used to determine whether an adverse drug reaction (ADR) is actually due to the drug rather than other factors. The scores were classified into "definite", "probable", "possible" or "doubtful". In the case of doubtful reactions, patients were classified as not experiencing an ADR.

Socio-demographic data

Data on age, gender, disease group, education, number of medicines taken, disease controls and adverse drug reactions (ADRs) were collected before the survey started. Disease controls were rated by patients with the question "How well do you think your disease can be controlled?" and categories of "poor", "moderate" or "good". ADRs were rated by the researcher using Naranjo algorithm.

Statistical analysis

Practicality

Practicality was assessed by administration time and the ceiling effects. The ceiling effects

evaluated the percentage of patients who answered all the five dimensions of EQ-5D-5L without any problem or having the state of full health.

Validity

Known-groups validity was tested with regard to age, gender, education, number of medicines taken, disease control and experiencing ADRs by using t-test or Mann-Whitney U test for two groups and ANOVA or Kruskal-Wallis test for more than two groups, depending on its distribution. It was hypothesized that EQ-5D-5L index scores would be lower with increasing age, in females, lower education, polypharmacy, poor disease control and experiencing ADRs. We included number of medicines taken, disease control and experiencing ADRs apart from socio-demographic data in known-groups validity tests because our samples were patients with chronic disease who had been continuously taking their medicines.

Convergent validity was assessed by examining the relationship between EQ-5D-5L and WHOQOL-BREF. It was hypothesized that the EQ-5D-5L index scores would be positively correlated with all four domains and general QoL of WHOQOL-BREF but more strongly with physical health and psychological health domain due to the more similar structure of these domains between the two questionnaires. EQ-VAS was also used to assess convergent validity. Correlation coefficients were performed with Spearman's rank correlation coefficient (ρ). Considerations of correlation level were described as follows: 0 - 0.25 (little), 0.25 - 0.50 (fair), 0.50-0.75 (moderate to good), ≥ 0.75 (very good to excellent).⁽¹⁸⁾

Reliability

Patients were asked to rate their health status as "much better", "a little better", "no change", "a little worse" and "much worse" on the second survey after 2 weeks of the first one. Test-retest reliability was performed in patients who returned the questionnaires and reported "no change" in health status. It was evaluated by weighted kappa coefficient and intra-class correlation coefficient (ICC). Weighted kappa coefficient was used for ordinal data in each dimension score of EQ-5D-5L and ICC was used for continuous data in EQ-5D-5L index scores and EQ-VAS. Criteria for ICC consideration were poor (< 0.40), fair to good (0.40 to 0.75), and excellent (≥ 0.75).⁽¹⁹⁾ Criteria for weighted kappa coefficient consideration were poor (< 0.40), fair to good (0.40 to 0.75), and excellent (≥ 0.75).⁽²⁰⁾

All statistical analyses were performed using IBM SPSS statistics 22 (IBM Corp., Bangkok, Thailand).

Results

Socio-demographic

The socio-demographic distribution of the four hundred patients is presented in Table 1. The average age was 47.2 (SD 13.6); slightly more were males (51.2%) than females. The three most common diseases were namely cardiovascular disorders (11.2%), renal disorders (10.8%) and neurological disorders (9.5%). Data were collected using two methods: self-administered questionnaires (73.5%) and face-to-face interview (26.5%).

Table 1. Socio-demographic characteristics of the patients (N = 400).

Patients characteristics	N	(%)
Gender		
Male	205	(51.2)
Female	195	(48.8)
Age (years)		
Mean (SD)	47.2	(13.6)
Education level		
< College	165	(41.2)
≥ College	235	(58.8)
Disease group		
Bone and joint disorders	37	(9.2)
Cardiovascular disorders	45	(11.2)
Dermatological disorders	21	(5.2)
Endocrinological disorders	31	(7.8)
Gastrointestinal disorders	27	(6.8)
Gynecologic and urologic disorders	19	(4.8)
Hematologic disorders	21	(5.2)
Infectious diseases	27	(6.7)
Neurologic disorders	38	(9.5)
Oncologic disorders	29	(7.2)
Ophthalmic, nose and throat disorders	23	(5.8)
Psychiatric disorders	16	(4.0)
Renal disorders	43	(10.8)
Respiratory disorders	23	(5.8)
Number of medicines per day		
Mean (SD)	5.3	(3.2)
Disease control		
Poor	83	(20.8)
Moderate	94	(23.5)
Good	223	(55.7)
Adverse drug reaction		
Yes	217	(54.2)
No	183	(45.8)

SD = Standard deviation

EQ-5D-5L

The EQ-5D-5L index scores were negatively skewed, therefore nonparametric methods were applied to this study. The mean EQ-5D-5L index score was 0.87 (SD 0.13), the median 0.90 (IQR 0.13) and the mean EQ-VAS was 79.50 (SD 11.78), the median 80 (IQR 15). Patients with problems in health status who answered from slight to extreme problems registered highly in the pain/ discomfort dimension (74.5%) and least in the self-care dimension (5.8%) as presented in Table 2.

Practicality

The average administration time was 1.6 ± 0.8 minutes. The ceiling effect was 14%.

Validity

Females, polypharmacy, poor and moderate disease control and experiencing ADRs reported lower values of EQ-5D-5L index scores than male, taking <5 medicines per day, good disease control and not experiencing ADRs, respectively (all $p < 0.05$,

Table 3). However, no significant difference was found in old and young age ($p = 0.78$) and low and high education ($p = 0.33$).

The strongest correlation was found between EQ-5D-5L index scores and the physical health domain of WHOQOL-BREF ($\rho = 0.58$, Table 4). Psychological health domain, general QoL domain and environment domain showed fair correlation with the EQ-5D-5L index scores ($\rho = 0.43, 0.42$ and 0.32 , respectively). Social relationships domain of the WHOQOL-BREF had the weakest correlation with EQ-5D-5L index scores ($\rho = 0.27$). The correlation between EQ-VAS and EQ-5D-5L index scores was fair ($\rho = 0.49$).

Reliability

A total of 170 patients returned the second questionnaire and reported no change in health status. The ICC of EQ-5D-5L index scores was 0.89 and EQ-VAS was 0.84. Weighted kappa coefficients ranged 0.44 - 0.60 in the five dimensions of the EQ-5D-5L (Table 5).

Table 2. Frequencies of EQ-5D-5L dimensions.

Dimensions	No problems		With problems	
	N	%	N	%
Mobility	254	(63.5)	146	(36.5)
Self-care	377	(94.2)	23	(5.8)
Usual activities	228	(57.0)	172	(43.0)
Pain/discomfort	102	(25.5)	298	(74.5)
Anxiety/depression	216	(54.0)	184	(46.0)

Table 3. Known-groups validity of EQ-5D-5L.

Patients characteristics	N	EQ-5D-5L index scores (Median, IQR)	p valve
Gender			
Male	205	0.93 (0.11)	0.00*
Female	195	0.89 (0.16)	
Age (years)			
< 50	217	0.92 (0.13)	0.78*
≥ 50	183	0.90 (0.13)	
Education level			
<College	165	0.93 (0.14)	0.33*
≥ College	235	0.90 (0.13)	
Number of medicines taken			
< 5	186	0.93 (0.11)	0.02*
≥ 5	214	0.90 (0.16)	
Disease control			
Poor	83	0.86 (0.25)	0.00**
Moderate	94	0.88 (0.14)	
Good	223	0.93 (0.10)	
Adverse drug reactions			
Yes	217	0.89 (0.16)	0.00*
No	183	0.93 (0.10)	

IQR = Interquartile range

* Mann-Whitney U test

** *Kruskal-Wallis* test, pairwise comparisons were significances in poor-good disease control and moderate-good disease control group, p = 0.00**Table 4.** Correlations between EQ-5D-5L and WHOQOL-BREF*

Dimensions	WHOQOL-BREF				EQ-5D-5L	
	Physical	Psychological	Environment	Social**	GeneralQoL	EQ-VAS
EQ-5D-5L						
Index scores	0.58	0.43	0.32	0.27	0.42	0.49

* Spearman's rank correlation coefficient, all p < 0.01

** N = 386 in social domain, 3.5% of patients refused to answer question about sex

Table 5. Test-retest reliability of EQ-5D-5L (N = 170)

	Weighted kappa coefficient (95% CI)
Mobility	0.60 (0.50 - 0.70)
Self-care	0.59 (0.36 - 0.82)
Usual activities	0.53 (0.44 - 0.62)
Pain/discomfort	0.44 (0.35 - 0.53)
Anxiety/depression	0.49 (0.40 - 0.58)
	Intraclass correlation coefficient (95% CI)
EQ-5D-5L index scores	0.89 (0.85 - 0.92)
EQ-VAS	0.84 (0.78 - 0.88)

IC = Confidence interval

Discussion

This is the first study in Thailand reporting psychometric properties of EQ-5D-5L in patients with a variety of diseases. It was confirmed in its practicality, validity and reliability. As for practicality, EQ-5D-5L has only five items plus one EQ-VAS scale. It took less than 2 minutes to complete the questionnaire which was applicable not only to the general population but also to the patient group as well. It showed an acceptable ceiling effect of 14%⁽²¹⁾, similar to the previous studies in chronic disease and disease-specific population (5.6 - 18.8%).^(5, 7, 22, 23) However, the ceiling effect was lower compared to EQ-5D-3L (17.0 - 28.3%).^(7, 10, 23)

EQ-5D-5L index score and EQ-VAS showed excellent reproducibility in test-retest reliability. While weighted kappa coefficients showed fair test-retest reliability, similar to the previous studies.⁽⁸⁾ Known-groups validity supported the previous studies on gender^(5, 6, 22), but not in age and education level. A possible explanation for this maybe the higher proportion of patients experiencing ADRs at a young age and high education level groups

(65.4% and 56.6%, respectively) might have lower HRQoL. Known-groups validity was also confirmed in number of medicines taken, disease control and experiencing ADRs which supported the hypothesis that polypharmacy, poor disease control and experiencing ADRs groups had lower HRQoL.

The convergent validity showed the two strongest correlations between EQ-5D-5L and WHOQOL-BREF were physical domain and psychological domain, similar to Sakthong⁽¹⁰⁾ who found these two domains most strongest correlations even though EQ-5D-3L was used instead of EQ-5D-5L. However, this study found the social domain the weakest correlation with EQ-5D-5L, while Sakthong's was environment domain. There are two possible explanations. Firstly, in the Sakthong's study the sample was HIV/AIDS patients. Many HIV/AIDS patients struggled with their social lives which could affect their quality of life so the correlation between social domain of WHOQOL-BREF and EQ-5D-5L index scores was stronger than this study. Secondly, there was a number of refusal rates (3.5%, all were female) on item 25 that asked about sex in the social

domain in the study. This can be explained due to the fact that Thais have a closed attitude about sex. It is an uncomfortable subject to talk about it. In the past, it was the norm for females that they could not have sexual intercourse before they got married and many still believe in this.

There were some limitations of this study, however. It used two methods of administration-self-administered questionnaires and a face-to-face survey. There were some patients who could not respond to the self-administered questionnaires because of visual problems. They had a heavy burden of reading all questionnaires. However, this group of patients could not be ignored. Also, there were four questionnaires that might have caused a fatigue effect. Another limitation is that the responsiveness of EQ-5D-5L in this study was not evaluated. It takes time to change from one health status to another. Future studies are needed to evaluate the responsiveness of EQ-5D-5L.

Conclusion

EQ-5D-5L has confirmed reliability and validity on patients with chronic disease at King Chulalongkorn Memorial Hospital.

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