

Validity and Reliability of the EQ-5D Self-report Questionnaire in Chinese-speaking Patients with Rheumatic Diseases in Singapore

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Abstract

Objective: We assessed the psychometric properties of a Singaporean Chinese version of the EQ-5D, a health-related quality of life (HRQoL) instrument. **Materials and Methods:** Consecutive outpatients with rheumatic diseases seen for routine follow-up consultations at the National University Hospital, Singapore were interviewed twice within 2 weeks using a standardised questionnaire containing the EQ-5D, the Short-Form 36 Health Survey (SF-36), the Learned Helplessness Subscale, a pain Visual Analogue Scale (VAS) and assessing demographic and psychosocial characteristics. To assess the validity of the EQ-5D, 13 hypotheses relating the EQ-5D self-classifier (5 dimensions) or visual analogue scale (EQ-VAS) to SF-36 scores or other variables were examined using the Mann-Whitney U test, Kruskal-Wallis or Spearman's correlation coefficient. Test-retest reliability was assessed using Cohen's kappa. **Results:** Forty-eight subjects were studied (osteoarthritis: 16; rheumatoid arthritis: 22; systemic lupus erythematosus: 8; spondyloarthropathy: 2; female: 93.8%; mean age: 56.4 years). Seven of 13 a-priori hypotheses relating EQ-5D to external variables were fulfilled, supporting the validity of the EQ-5D. For example, subjects reporting moderate or extreme problems for EQ-5D dimensions generally had lower median SF-36 scores than those without such problems. Cohen's kappa for test-retest reliability of the self-classifier ranged from 0.41 to 1.00 (n = 42; median interval: 7 days, interquartile range: 7 to 11 days). **Conclusions:** The Singaporean Chinese EQ-5D self-classifier appears to be a valid measure of HRQoL in Singaporeans with rheumatic diseases; however, the reliability of the EQ-VAS requires further investigation. These data provide a basis for further studies of the Singaporean Chinese EQ-5D.

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Introduction

Health-related quality of life (HRQoL) refers to patients' perceptions of their own functioning and well-being. HRQoL is increasingly being used as a primary or secondary endpoint in clinical research and is essential in economic evaluation of new and often expensive therapies.¹ While HRQoL is widely used in Western countries, there is a lack of validated HRQoL instruments for use in Asia because the properties of these instruments are influenced by language of administration and cultural factors. Moreover, in a multi-ethnic society such as Singapore, a HRQoL instrument should ideally be available in all the commonly used languages (English, Chinese, Malay and Tamil) in order to assess HRQoL in the majority of Singaporeans.

The EQ-5D self-report questionnaire (EQ-5D) is a generic

measure of HRQoL, which was finalised in 1994 after a period of development by a multi-national research group – the EuroQol Group.² The instrument enables respondents to conduct a self-classification and self-rating of their own health status. A subject's self-classification information can also be converted into a single index (generally ranging from 0, representing a health state of being dead, to 1, representing a health state of full health) using an EQ-5D value set, which is generated from the general population. The EQ-5D has been translated into 27 languages and has been used as an outcome measure in international clinical trials.² However, to the best of our knowledge, the subject acceptability and psychometric properties of the EQ-5D have not been assessed in Southeast Asia. Using subjects with rheumatic diseases, we

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investigated the validity and reliability of Singaporean English³ and Chinese EQ-5D versions as a prelude to future population-based valuation of health states in Singapore. In this paper, we report results pertaining to the Singaporean Chinese EQ-5D.

Materials and Methods

Subjects and Study Design

Consecutive Chinese-speaking outpatients with rheumatic diseases seen from 12 to 23 February 2001 at the National University Hospital underwent face-to-face interviews with trained nurse interviewers (lasting approximately 30 minutes) using a questionnaire containing the Singaporean Chinese EQ-5D, the Short-Form 36 Health Survey (SF-36, Hong Kong version),⁴ the Learned Helplessness Subscale of the Rheumatology Attitude Index (HS)⁵ and a 10-cm pain Visual Analogue Scale (VAS). One trained nurse examined all subjects for fibromyalgia tender points.⁶ Telephone interviews (3 attempts) using the EQ-5D were conducted within a 2-week period to assess test-retest reliability. Written consent was obtained from each subject for this IRB-approved study. The inclusion criteria were physician diagnosis of a rheumatic disease and ability to co-operate with the interview.

Instruments

The EQ-5D consists of a self-classifier and a visual analogue scale (EQ-VAS).² The self-classifier consists of a 5-item descriptive system and assesses health in the 5 dimensions of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. There are 3 responses for each dimension: no problems, some/moderate problems and extreme problems. The EQ-VAS is a vertical, graduated (0 to 100 points) 20-cm “thermometer”, with 100 representing “best imaginable health state” and 0 representing “worst imaginable health state”. Respondents classify and rate their health status on the day of the survey. The Singaporean Chinese EQ-5D was adapted from the Taiwan Chinese EQ-5D as recommended by, and in collaboration with, the EuroQol Group. In developing the Singaporean Chinese EQ-5D, a translation consultant converted traditional Chinese characters used in the Taiwan EQ-5D into equivalent simplified Chinese characters used in Singapore and revised wording which was not commonly used or was inappropriate in Singapore. The translation consultant summarised recommended revisions into an adaptation report, in which revised phrasing was back translated into English. A translation consultant appointed by the EuroQol group reviewed these revisions. The resulting test version of the Singaporean Chinese EQ-5D was administered in a pilot study to 10 Chinese-speaking native Singaporeans from diverse socio-demographic backgrounds, some of whom had chronic illnesses. These

subjects also underwent a structured interview to assess the clarity and ease of completion of the Singaporean Chinese EQ-5D. In this pilot study, subjects did not report any concerns regarding phrasing of the Singaporean Chinese EQ-5D. The average administration time was 4 minutes. However, 7 subjects did not correctly follow EQ-VAS instructions to link the box representing their state of health to the VAS. To overcome this problem, we added 2 Chinese characters meaning “black” in front of the 2 Chinese characters meaning “box” and used bold, underlined text for these characters (the box is printed in black in the questionnaire). This Singaporean Chinese version was used in the validation study.

The SF-36 is a validated⁷ 36-item instrument measuring perceived health in 8 dimensions: physical functioning (PF), role-physical (RP), bodily pain (BP), general health, vitality, social functioning (SF), role-emotional (RE) and mental health (MH). Higher scores (range: 0 to 100) reflect better perceived health. The Hong Kong Chinese SF-36 (version 1.0)⁸ has been validated in Singapore and was used in this study.⁹

The HS is a 5-item instrument measuring learned helplessness, in which subjects, as a result of adverse past experiences, believe their efforts will be ineffective.¹⁰ Higher scores (range: 0 to 100) reflect greater learned helplessness. A Chinese version of the HS has been validated in Singapore and was used in this study.¹¹

Data Analysis

Known-groups construct validity¹² of the EQ-5D self-classifier and EQ-VAS was examined by testing 13 *a-priori* hypotheses based on the literature and clinical experience. Ten hypotheses related the EQ-5D self-classifier to other variables, and were as follows: 1) subjects reporting problems for any EQ-5D dimension would have lower scores for all SF-36 scales;¹³ 2) subjects with no, some/moderate or extreme problems for any EQ-5D dimension would have higher to lower scores for all SF-36 scales, respectively;^{13,14} 3) differences in scores for SF-36 PF, RP, and BP scales between subjects reporting and not reporting problems for any EQ-5D physical dimension (i.e., mobility, self-care, usual activities and pain/discomfort) would generally be larger than the differences in scores for SF-36 MH and SF scales between the 2 groups.¹³ For example, the score difference in PF, RP and BP scales should be larger than the difference in MH and SF scores between subjects with and without problems in the EQ-5D mobility dimension (note: the SF-36 RE measures the physical domain of health in Singapore,⁹ as opposed to the mental domain of health in Western countries, and was excluded from this hypothesis). Similarly, 4) score differences in SF-36 MH and SF scales would be larger than those for PF, RP and BP scales between subjects with and without problems for the

TABLE I: RESPONSES TO AND TEST-RETEST RELIABILITY OF EQ-5D DIMENSIONS

Dimension	No problems (%)	Moderate problems (%)	Extreme problems (%)	Kappa value (95% confidence interval)
Mobility	40 (83.3)	8 (16.7)	0 (0)	0.92 (0.76 to 1.08)
Self-care	46 (95.8)	2 (4.2)	0 (0)	1.00 (1.00 to 1.00)
Usual activities	43 (89.6)	4 (8.3)	1 (2.1)	0.73 (0.38 to 1.08)
Pain/discomfort	11 (22.9)	34 (70.8)	3 (6.3)	0.41 (0.12 to 0.70)
Anxiety/depression	30 (62.5)	15 (31.2)	3 (6.3)	0.73 (0.54 to 0.92)

EQ-5D anxiety/depression dimension;¹³ subjects reporting pain/discomfort with the EQ-5D self-classifier would have 5) higher pain VAS scores¹⁵ and 6) more tender points; subjects with problems in the EQ-5D mobility dimension would have 7) higher pain VAS scores and 8) more tender points; 9) subjects reporting problems in the EQ-5D usual activities dimension would have more illnesses; and 10) subjects reporting anxiety/depression with the EQ-5D self-classifier would have higher HS scores. Hypotheses for the EQ-VAS were: 11) EQ-VAS scores would be higher in subjects reporting better global health measured using a 5-point scale (SF-36 question 1);^{16,17} and EQ-VAS scores would inversely correlate with 12) increasing age^{17,18} and 13) pain VAS scores,^{15,19} respectively. Statistical significance of differences was examined using Mann-Whitney U or Kruskal-Wallis tests. Relationships between the EQ-VAS and other variables were investigated using Spearman's correlation coefficient. Test-retest reliability of EQ-5D dimensions was investigated using Cohen's kappa.²⁰ A *P* value of less than 0.05 was considered significant. Data were analysed with SPSS for windows (version 10, SPSS Inc., IL, USA).

Results

Subject Characteristics

Forty-eight subjects completed baseline questionnaires (osteoarthritis: 16; rheumatoid arthritis: 22; systemic lupus

erythematosus: 8; and spondyloarthropathy: 2). The mean \pm SD age of the subjects was 56.4 ± 12.3 years (range: 24 to 74 years) and 45 (93.8%) were female. Eleven subjects (22.9%) received no formal education, 38 (79.2%) were living with their spouses and 13 (27.1%) were employed. Thirty-six subjects (75%) reported at least 1 acute medical condition (such as, running nose, sore throat or cough, headache and bad sleep) and 28 (58.3%) reported at least one comorbid chronic medical condition (such as hypertension and diabetes).

There were no missing data or concerns regarding EQ-5D phrasing. For each EQ-5D dimension, there were subjects reporting problems (Table I), with most subjects reporting problems with the pain/discomfort dimension. The median EQ-VAS score was 65 (interquartile range: 60 to 70). Pain VAS, tender point, SF-36 and HS scores are summarised in Table II.

Validity

Seven of the 10 hypotheses relating the EQ-5D self-classifier to other variables were fulfilled. All the hypotheses relating levels of EQ-5D dimensions to SF-36 scores were present (Table III). For example, subjects reporting moderate or extreme problems for an EQ-5D dimension had lower median SF-36 scores than those without such problems, with only a few exceptions; when subjects were dichotomised using their responses to the EQ-5D mobility dimension, the difference in median scores for the SF-36 PF scale (40 points, $P < 0.001$) was larger than that for the MH scale (4 points). Each hypothesised relationship between responses to EQ-5D dimensions and other variables was also present (Table IV). For example, subjects reporting moderate or extreme pain/discomfort with the EQ-5D self-classifier had higher median pain VAS scores. However, using the criterion of $P < 0.05$, hypotheses 6, 8 and 9 were not fulfilled, though a trend favouring each hypothesis was present.

As expected, subjects reporting better global health (SF-36 question 1) had higher median EQ-VAS scores than those reporting worse global health; subjects aged 50 or older had lower median EQ-VAS scores than younger subjects. An inverse correlation between EQ-VAS and pain VAS scores was also present (Spearman's

TABLE II: SCORES FOR CLINICAL AND HEALTH-RELATED VARIABLES

Variable	Mean \pm SD (median)
10-cm pain VAS score	4.7 \pm 2.2 (4.6)
Tender point count	2.9 \pm 3.4 (2)
SF-36 score	
Physical functioning	61.7 \pm 24.7 (60.0)
Role-physical	59.4 \pm 43.0 (75.0)
Bodily pain	57.9 \pm 21.7 (56.5)
General health	58.8 \pm 16.7 (62.0)
Vitality	48.9 \pm 17.7 (50.0)
Social functioning	70.8 \pm 22.4 (68.8)
Role-emotional	64.6 \pm 45.3 (100.0)
Mental health	64.6 \pm 16.4 (60.0)
Learned helplessness score	39.3 \pm 12.5 (37.5)

VAS: visual analogue scale

TABLE III: MEDIAN SF-36 SCORES FOR SUBJECTS WITH DIFFERING EQ-5D DIMENSION SCORES

Dimension	No.	PF	RP	BP	GH	VT	SF	RE	MH
Mobility									
No problems	40	65.0	75.0	61.5	63.5	50.0	75.0	100.0	62.0
With problems	8	25.0	0	41.0	52.5	42.5	50.0	33.3	58.0
d		40.0***	75.0	20.5*	11.0	7.5	25.0	66.7	4.0
Self-care									
No problems	46	60.0	75.0	56.0	62.5	50.0	75.0	100.0	62.0
With problems	2	30.0	0	45.5	41.0	37.5	43.8	0	40.0
d		30.0	75.0	10.5	21.5	12.5	31.2	100.0	22.0
Usual activities									
No problems	43	65.0	75.0	61.0	62.0	50.0	75.0	100.0	64.0
With problems	5	25.0	0	41.0	45.0	45.0	50.0	0	52.0
d		40.0**	75.0	20.0	17.0	5.0	25.0*	100.0*	12.0*
Pain/discomfort									
No pain/discomfort	11	85.0	50.0	70.0	70.0	50.0	87.5	100.0	60.0
With pain/discomfort	37	55.0	75.0	52.0	60.0	50.0	62.5	100.0	60.0
d		30.0	-25.0	18.0	10.0	0	25.0	0	0
Anxiety/depression									
No anxiety/depression	30	67.5	100.0	71.0	65.0	50.0	87.5	100.0	72.0
With anxiety/depression	18	55.0	25.0	41.0	52.0	45.0	50.0	83.3	54.0
d		12.5*	75.0*	30.0**	13.0**	5.0**	37.5***	16.7	18.0***
Severity of problems (all dimensions)[†]									
No problems	9	85.0	100.0	72.0	70.0	55.0	100.0	100.0	72.0
Moderate problems	36	57.5	75.0	56.5	61.0	50.0	62.5	100.0	60.0
Extreme problems	3	10.0*	75.0	21.0*	35.0*	30.0	50.0	100.0	68.0

BP: bodily pain; d: difference in median scores between subjects reporting or not reporting problems; GH: general health; MH: mental health; PF: physical functioning; RE: role limitation due to emotional problems; RP: role limitation due to physical problems; SF: social functioning; VT: vitality

* $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$

[†] Subjects were grouped according to the worst level reported for any of these dimensions.

$\rho = -0.19$, $P = 0.190$) (Table V). Although using the criterion of $P < 0.05$, none of the 3 hypotheses regarding EQ-VAS was fulfilled; the relationships between the EQ-VAS and these variables were in the hypothesised directions (Table V).

Test-retest Reliability

Forty-two subjects (87.5%) participated in the follow-up telephone interview, with a 7-day median interval (interquartile range: 7 to 11 days) between baseline and follow-up interviews. Cohen's kappa values for EQ-5D dimensions ranged from 0.41 to 1.00 ($P < 0.001$ for all dimensions, Table 1). For the self-care dimension, 2 subjects reported some problems in both baseline and follow-up interviews while the remaining reported no problems in both interviews.

Discussion

The EQ-5D is one of the select group of preference-based HRQoL instruments that are widely used in clinical research. As is the case for profile-based instruments, such as the SF-36, preference-based instruments like the EQ-5D need to

demonstrate satisfactory psychometric properties.²¹ This is particularly so for EQ-5D because of its brevity, with information for each dimension being derived from only one item. In this study, we have demonstrated the subject acceptability, reliability and validity of a Singaporean Chinese EQ-5D in subjects with rheumatic diseases. To the best of our knowledge, this is the first study to assess the usefulness of a Chinese EQ-5D version in Southeast Asia.

Validity of the Singaporean Chinese EQ-5D classifier was demonstrated using known-groups construct validity. Seven of 10 *a-priori* hypotheses relating EQ-5D dimensions to other variables were fulfilled, demonstrating that hypothesised differences in health status quantified by other measures did exist among subjects grouped according to their responses to EQ-5D dimensions. The fulfilment of those hypotheses, which were derived from the EQ-5D literature, suggests that the Singaporean Chinese EQ-5D classifier has properties similar to those of other validated EQ-5D versions.^{13,16} These results support the validity of the Singaporean Chinese EQ-5D self-classifier.

We also found strong evidence to support test-retest

TABLE IV: RELATIONSHIPS BETWEEN RESPONSES TO EQ-5D DIMENSIONS AND OTHER VARIABLES*

Dimension versus other variable	No.	Median (interquartile range) of other variable		P value
Mobility versus pain VAS scores [†]				
No problems	40	4.2	(3.2-6.2)	0.035
Some problems	8	6.3	(4.5-6.9)	
Mobility versus number of tender points [§]				
No problems	39	1.0	(0-4.0)	0.156
Some problems	8	4.0	(1.3-8.0)	
Usual activities versus number of illnesses ^{‡,‡}				
No problems	43	1.0	(0-2.0)	0.743
Some/extreme problems	5	2.0	(0.5-2.0)	
Pain/discomfort versus pain VAS scores [†]				
No pain/discomfort	11	3.7	(1.2-4.4)	0.021
Moderate pain/discomfort	34	4.8	(3.6-6.4)	
Extreme pain/discomfort	3	6.5	(6.5-10.0)	
Pain/discomfort versus number of tender points [§]				
No pain/discomfort	11	1.0	(0-3.0)	0.558
Moderate pain/discomfort	33	2.0	(0-4.5)	
Extreme pain/discomfort	3	4.0	(0-10.0)	
Anxiety/depression versus learned helplessness scores				
No anxiety/depression	30	12.0	(10.0-14.3)	0.012
Moderate anxiety/depression	15	14.0	(12.0-16.0)	
Extreme anxiety/depression	3	14.0	(14.0-22.0)	

* Scores for these variables were obtained from subject self-report or physical examination.

[†] The recall period for the pain VAS and illnesses was the preceding 4 weeks.

[‡] Illnesses were defined as cold, diarrhoea, headache, bad sleep or injury.

[§] Number of tender points was missing for 1 subject.

TABLE V: RELATIONSHIPS BETWEEN THE EQ-VAS AND OTHER VARIABLES*

Variable	No.	Median (interquartile range)	P value	Correlations between EQ-VAS and other variable (Spearman's rho)	P value
Self-rated global health					
Excellent/very good/good	27	65.0 (60.0 – 70.0)	0.092	-0.13	0.362
Fair/poor	21	60.0 (60.0 – 70.0)			
Age					
<50 years	13	70.0 (55.5 – 80.0)	0.391	-0.10	0.499
≥50 years	35	65.0 (60.0 – 70.0)			
Pain VAS					
<5.0	29	69.0 (60.0 – 70.0)	0.182	-0.19	0.190
≥5.0	19	60.0 (60.0 – 70.0)			

* Scores for these variables were obtained from subject self-report or physical examination.

reliability of the Singaporean Chinese EQ-5D classifier, with Cohen's kappa being good or very good (0.61 to 1.00) for the mobility, self-care, usual activities and anxiety/depression dimensions, and moderate (0.41 to 0.60) for the pain/discomfort dimension.¹³ One possible reason for the comparatively low kappa value for the pain/discomfort dimension is that actual changes in pain/discomfort occurred in study subjects during the test-retest period. The kappa values in our study were comparable to those in a previous study of subjects after stroke using the EQ-5D (Cohen's

kappa: 0.63 to 0.80, 3-week, n = 234).²²

Although none of the 3 hypotheses for the EQ-VAS was fulfilled using the predefined significance level of $P < 0.05$, hypothesised relationships between the EQ-VAS and other variables were in the expected direction and were similar in trend to, but weaker in magnitude than, those results reported in the literature.¹⁵⁻¹⁹ For example, the correlation between EQ-VAS and pain VAS scores in our study (Spearman's rho = -0.19) was weaker than that in 2 previous studies using larger numbers of subjects with similar medical

conditions (Spearman's rho: -0.52 (n = 1372)¹⁹ and -0.63 (n = 233),¹⁵ respectively). One possible reason for the weak correlations is the relatively small sample size. We feel that these results provide promising information on the validity of the EQ-VAS, but need to be confirmed in a larger study. To provide a more definite indication of the validity of the EQ-VAS, we are currently conducting a study of patients with a variety of illnesses seen in a tertiary hospital using both the EQ-5D and a 5-point scale for self-rated health to further investigate the relationship between the 2 scales.

Based on the small sample size (n = 48) of this 2-week study, we elected to use a significance level of 0.05 to decrease the chance of false negative results (Type II errors).²³ This contrasts with the significance level of 0.01 which was selected for a similar study of the Singaporean English EQ-5D that included 38% more subjects (n = 66)³ and was, therefore, less prone to Type II errors.

Limitations of this study include the fact that EQ-VAS test-retest reliability was not assessed because this could not be administered during the telephone-based follow-up interview. The use of face-to-face interviews at baseline and telephone interviews at follow-up may have reduced accuracy of test-retest reliability measurement of EQ-5D dimensions by introducing more variability between test and retest scores (resulting in lower kappa values). In addition, studying a relatively small sample of subjects attending a tertiary hospital limits the generalisability of our results, but the homogeneity of the subjects allowed a more accurate and precise assessment of the instrument. Besides confirming the subject acceptability and validity of the EQ-5D, our data also justify a larger, population-based study including subjects with and without medical conditions.

We conclude that the Singaporean Chinese EQ-5D self-classifier has good subject acceptability, validity and reliability in measuring health status in subjects with rheumatic diseases in Singapore. However, the validity and reliability of the EQ-VAS require further investigation. These data provide a basis for further studies of the Singaporean Chinese EQ-5D in Singapore.

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