

The Validity of A New Practical Quality of Life Measure in Patients on Renal Replacement Therapy

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Objective: A new quality of life measure, a part of the National Health and Welfare 2003 survey, is a promising tool for outcome evaluation of clinical practice due to its brevity, validity, reliability, and providing easy interpretation against general population norm-based scores. The measure consisting of 9-items, and so called 9-item Thai Health status Assessment Instrument (9-THAI) was used to assess its validity and reliability in patients on renal replacement therapy (RRT).

Material and Method: Three hundred and two patients on RRT who visited Srinagarind Hospital from March to May 2005 were studied. Convergent and divergent validity were assessed using SF-36 as the concurrent measure. Concurrent validity was also assessed using hematocrit level and hospitalization history in the last year as concurrent clinical measures. Test-retest reliability was studied by repeated measure within one month. Responsiveness of 9-THAI was studied in patients who reported health improvement.

Results: Results of correlations between 9-THAI and SF-36 domains were as hypothesized. 9-THAI scores were significantly correlated with hematocrit level and hospitalization history. The results confirmed the validity of 9-THAI for use as a quality of life measure. Intraclass correlation coefficients of 9-THAI scores in stable patients were satisfactory. Among patients on RRT who reported overall health improvement, 9-THAI scores significantly increased, thus adding further evidence of the responsiveness of 9-THAI.

Conclusion: The 9-THAI is a valid and reliable generic health status measure that can be used as an ideal core in a battery of quality of life measures in clinical practice for patients on RRT.

Keywords: Health-related quality of life, Quality of life, Generic health status measure, Renal replacement therapy, SF-36, Validity, Reliability, Responsiveness

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Patients with end stage renal disease (ESRD) struggle for survival from the deterioration of their health as consequences of the disease. At present, dialysis and kidney transplantation (KT) modalities are the effective renal replacement therapy (RRT) for prolonging ESRD patients' lives. The patients usually experience

uncomfortable and unpleasant conditions as consequences of the therapy especially dialysis modalities. Patient-centered outcomes such as physical activities, psychological and social well-being should be a primary concern by health care providers. Moreover, the outcomes should be longitudinally monitored as a part of quality of care in these patients⁽¹⁾.

Several terms have been used as patient-centered outcomes and 'Quality of life' (QoL). QoL is the most well-known and widely used term. Because the

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term 'QoI' was considered to be too comprehensive and included environmental aspects that were not considered a medical point of view, the authors suggest using the term 'health status' instead⁽²⁾. Unlike clinical or laboratory information, patient-centered outcome measures are more subjective and should be directly reported by patients. Instruments for assessing health status are usually designed as self-reported multi-item questionnaires due to their subjective nature and wide range of dimensions. The need of patient-centered outcome evaluation is recognized, however the burden of tool administration should be of concern. Thus, a practical measure for use in clinical practice should be simple, quick to complete, easy to score, and providing useful clinical data⁽³⁾.

In 2003, the National Statistical Office (NSO) of Thailand revolutionized the health survey, a part of its National Health and Welfare Survey. The joint committee of the NSO and the International Health Policy Program (IHPP), an office under the Ministry of Public Health of Thailand, was established to revise the survey content, and one of its tasks was the development of a new Thai generic health status measure. The measure was developed by comprehensive review of available health status measures. It was designed to be short, understandable to lay persons with limited education, and consistent with Thai cultural values. The final version included 9 items, and the so called 9-item Thai Health status Assessment Instrument (9-THAI). It has been found that 9-THAI is able to distinguish different health status in a Thai population⁽⁴⁾. The major advantage of 9-THAI over other instruments is that the National Health and Welfare 2003 survey data provided mean and standard deviation of general population for deriving norm-based scores. The norm-based scores are useful as they provide interpretation of derived scores against the average general population.

Though there was evidence of the validity of 9-THAI in general population, however its validity in specific disease groups should be examined before future applications. The main objective of the present study was to verify the validity, reliability and responsiveness of 9-THAI in patients on RRT.

Material and Method

Convergent and divergent validity was assessed by comparing it with the Short Form 36 Health Survey (SF-36)⁽⁵⁾, one of the most widely used generic health measures⁽⁶⁾. For convergent validity, it was hypothesized that a positive correlation would be found between domains or components of the two instru-

ments that measure similar constructs, for example a positive correlation between the mobility domain of 9-THAI and the physical functioning domain of SF-36. For divergent validity, it was hypothesized that a low correlation would be found between domains or components of the two instruments that measure different constructs such as the mobility domain of 9-THAI and the mental health domain of SF-36.

Two concurrent clinical measures of health status, hematocrit level and hospital admission in the last year were used for assessing concurrent validity. Since the evidence of an association between anemia and cognition decrement was reported⁽⁷⁾, it was hypothesized that hematocrit level would be positively associated with 9-THAI mental scores that consist of cognition domain. The evidence of an association between SF-36 physical component scores and hospitalization was reported⁽⁸⁾, thus this hypothesis was also proposed.

Two measures were taken approximately one month apart for assessing test-retest reliability of 9-THAI. At the second assessment, patients were asked whether their health was stable, worse or better. Patients with stable health were used to assess test-retest reliability of the measure, while data from patients with health improvement were used to assess responsiveness.

Participants

The present study was conducted at Srirangarind Hospital where the target population for applying the measure in future studies was located. The protocol of the present study was approved by the ethics committee of Khon Kaen University.

Participants were ESRD patients who received KT or were maintained on hemodialysis (HD) or continuous ambulatory peritoneal dialysis (CAPD) for more than 3 months, and visited the hospital out-patient unit during the period from March to May 2005. Only patients on regular follow up were studied. Patients who visited by irregular schedule with problems such as peritonitis, graft losing were considered unstable conditions and were excluded. Patients with hearing impairments or speaking problems were excluded. Patients were informed of the study details and were asked to give written informed consent, those who refused to participate were not included.

Measures

The study questionnaire consisted of 9-THAI, and SF-36 Thai version⁽⁹⁾. Patient demographic data,

self-reported chronic diseases, and hospital admission in the last year were also recorded. Creatinine and hematocrit levels of patients who were on CAPD or received KT were obtained from their medical records of that visit. Post dialysis creatinine and hematocrit levels of patients who were on HD and KT waiting list were obtained from their follow up forms. The forms were reported by dialysis staffs at their regular dialysis units.

The 9-THAI is composed of seven domains and two global health ratings. The 7 domains enable subjects to rate their experiences with health problems during the last month including 'mobility', 'self care', 'usual activities', 'illness/discomfort', 'anxiety/depressed', 'cognition', and 'social functions'. Response choices for the 7 domains are rated according to perceived severity of the problems on a 5-point scale: 1 = very severe, 2 = severe, 3 = moderate, 4 = mild, and 5 = not at all. The first global question was to compare subject's health at present with that of the last year. The second was to compare his/her health with that of others who have similar age, gender, social & economic status, type of employment, and living style. Response choices for the 2 global questions are 1 = much worse, 2 = a little bit worse, 3 = the same as, 4 = a little bit better, and 5 = much better. The scores of all items were coded such that higher scores reflect better health. Appendix 1 shows the questions in detail. The preliminary analysis of the National Health and Welfare Survey 2003 data using confirmatory factor analysis indicated that the 4 domains ('mobility', 'self care', 'usual activities', 'illness/discomfort') measure physical constructs, and the 3 domains ('anxiety/depressed', 'cognition', 'social functions') measure mental constructs⁽¹⁰⁾. The results suggested that the standardized T scores⁽¹¹⁾ of summated physical and mental scores could be used to represent the two higher-order constructs for easy interpretation of scores against general population norms. Means and standard deviations of specific gender and age groups were used to calculate the scores, an example of transformation formula is as follows.

Standardized T score of summated physical score for group of female age 15-19 year:

$$\text{Standardized T score of summated physical score} = \frac{50 + [10 \times (\text{mobility} + \text{self care} + \text{usual activities} + \text{illness} - 19.87330)]}{0.7174588}$$

The transformed standardized T summated physical and mental scores were called PHY and MEN, respectively in the present study.

The SF-36 is composed of 35 items assessing 8 domains of health and one health transition item (RHT). Eight domains are physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH). Four domains including PF, RP, BP, and GH form a higher-order physical component summary score (PCS), while VT, SF, RE, and MH form a higher-order mental component summary score (MCS)^(5,12).

Participants were interviewed by well-trained interviewers that were prior field-tested with normal volunteers. The sequence of 9-THAI and SF-36 administration was randomized. To assess test-retest reliability and responsiveness of 9-THAI, participants were re-interviewed by phone using only 9-THAI within approximately one month after the first interview. To classify patients into subsets providing data for the test-retest or the responsiveness analysis, patients were asked that 'compared to the last month, their health today was worse, same or better'.

Data analysis

Descriptive statistics and univariate analysis were appropriately applied according to measurement levels and data distribution. P-value of less than 0.05 was considered significant. Spearman rank correlation coefficients between domains and higher-order construct scores of 9-THAI and SF-36 were used to examine convergent and divergent validity of the measures. Multiple linear regression was used to address the association of PHY, MEN, and hematocrit level adjusting for major contributing factors including gender, age, education, diabetes, creatinine level, dialysis modalities and hospital admission. Logistic regression was used to address the association of PHY, MEN, and hospital admission adjusting for the same set of major contributing factors and hematocrit level. For assessing test-retest reliability of the measure, data of stable patients were used to analyze the intraclass correlation coefficients of PHY, MEN from the two assessments. For assessing responsiveness, PHY, MEN data from patients who reported improvement on the health transition were used to calculate effect size, standardized response mean, and Guyatt's responsiveness index^(11,13). Analyses were performed using SPSS for Windows.

Results

Three hundred and two patients participated, 133 patients received KT, 62 patients were on CAPD, and 107 patients were on HD. Health status demographic

characteristics of patients on CAPD were significantly lower than other groups. Patients on CAPD were older, had lower education, having diabetes comorbidity and more report of hospitalization history in the last year (Table 1). The average creatinine level of patients on KT was significantly lower than that of dialysis patients, and the average hematocrit level of patients on KT was significantly higher than that of dialysis patients. These results were expected as KT usually results in more favorable clinical outcomes.

Percentage of patients on CAPD who reported no problem were significantly lowest in 4 domains of 9-THAI ('mobility', 'self care', 'usual activities', and 'illness/discomfort'), and the average PHY score of these patients was also lowest. Percentage of patients on KT who reported no problem in 'social functions' (9-THAI) domain was the highest by a significant margin. Percentage of patients on CAPD who reported no problem in 'anxiety/ depressed' (9-THAI) domain was slightly higher than that of two groups but no statistical significance was found. Percentages of patients who reported no problem in 'cognition' domain were similar. The average MEN score of HD group was lowest, and this resulted from low percentages of patients who reported no problem in 'anxiety/ depressed' & 'social functions' (9-THAI) domains. The low physical health status of patients on CAPD was consistently measured by SF-36 with low average scores in 4 physical domains (PF, RP, BP, GH) and a low average PCS. Results of mental aspect as measured by the two measures differed in 2 domains, SF & MH. While 'social functions' (9-THAI) of KT group was better than others, however average SF (SF-36) scores of 3 groups were equal. For MH (SF-36) domain that consists of an anxiety question, the average MH score of KT group was highest among 3 groups, and these results differed from 'anxiety/depressed' (9-THAI) domain previously explained. The average MCS (SF-36) of HD was lowest, the result was consistent with the MEN (9-THAI). Since PHY, MEN, PCS, MCS scores of 50 mean equal to general population health status, scores of lower or higher than 50 mean lower or higher health status than general population. Thus, health status of patients on RRT was lower than the general population, and this supported the construct validity of both measures.

Convergent and divergent validity: associations with SF-36

Convergent and divergent validity was assessed through Spearman rank correlations. Convergent validity was revealed by correlation values of

more than 0.4 indicating meaningful association⁽¹⁴⁾ for almost prior hypothesized pairs of domains and constructs from both measures (Table 2). The values ranged from 0.43 ['illness/ discomfort' (9-THAI) & BP (SF-36)] to 0.77 ['compared with last year' (9-THAI) & RHT (SF-36)]. However, a slightly low value of correlation (0.37) was found between 'self care' (9-THAI) & PF (SF-36) domains. Additionally, some reasonable correlations were found between non prior hypothesized pairs including 'social functions' (9-THAI) & RP, RE (SF-36), 'mobility' (9-THAI) & BP (SF-36), 'usual activities' (9-THAI) & VT (SF-36). Low correlations of domains that measured different aspects are shown in Table 2, for example a low correlation (0.24) of 'anxiety/ depressed' (9-THAI) & PF (SF-36), and these confirmed the divergent validity. For higher-order constructs, convergent validity was notified by the correlation of PHY & PCS (0.49) and correlation of MEN & MCS (0.56). Divergent validity was notified by lower correlation values of 0.41 (PHY & MCS) and 0.25 (MEN & PCS), however value of 0.41 indicated somewhat correlation to be of concern.

Concurrent validity: association with hematocrit level

Hematocrit level was positively associated with PHY and MEN (Table 3). Only MEN were significantly associated with the hematocrit level. An increment of 1% in hematocrit level associated with an increment of 0.05 unit in MEN score. The results supported the hypothesis, and added the evidence for concurrent validity.

Concurrent validity: association with hospital admission

Patients who reported one or more hospitalization during the last year had average lower PHY and MEN scores (PHY: 25.5 versus 36.5, $p < 0.001$; MEN: 29.9 versus 32.8, $p = 0.240$). An increment of PHY scores significantly associated with a decreased likelihood of being hospitalized (Table 4). The association of hospitalization and MEN was not significant. The results further supported the concurrent validity of the measure.

Test-retest reliability

Two hundred and thirty nine patients of the 302 RRT patients (79.1%) were interviewed via telephone within approximately one month (31.9 + 2.1 days) after the first interview. Characteristics of patients who responded to the telephone interview were similar to those who did not, except for age. Those who did not

Table 1. Characteristics of participants

Characteristics	Total (n = 302)	KT (n = 133)	CAPD (n = 62)	HD (n = 107)
Male	185 (61.3)	87 (65.4)	34 (54.8)	64 (59.8)
Age (year) ^(a)	47.5 (11.4)	45.1 (9.6)	56.5 (12.3)	45.3 (10.2)
Under bachelor ^(a)	193 (63.9)	77 (57.9)	48 (77.4)	68 (63.6)
Family income (Baht/month)				
< 10,000	58 (20.1)	27 (20.9)	16 (28.6)	15 (14.6)
10,000 – 20,000	92 (31.9)	42 (32.6)	12 (21.4)	38 (36.9)
20,000 – 30,000	52 (18.1)	24 (18.6)	9 (16.1)	19 (18.4)
> 30,000	86 (29.9)	36 (27.9)	19 (33.9)	31 (30.1)
Diabetes comorbidity ^(a)	79 (26.2)	31 (23.3)	29 (46.8)	19 (17.8)
Creatinine (mg%) ^(a)	7.3 (11.2)	1.4 (0.8)	9.9 (4.6)	13.3 (5.7)
Hematoctrit (%) ^(a)	33.8 (6.9)	37.1 (6.7)	31.9 (5.8)	30.4 (5.8)
Self-reported hospitalization ^(a)	150 (49.7)	52 (39.1)	50 (80.6)	48 (44.9)
9-THAI				
Mobility ^(a)	146 (48.3)	71 (53.4)	19 (30.6)	56 (52.3)
Selfcare ^(a)	212 (70.2)	108 (81.2)	34 (54.8)	70 (65.4)
Usual activities ^(a)	155 (52.7)	82 (62.6)	19 (33.3)	54 (50.9)
Illness/Discomfort ^(a)	99 (32.8)	42 (31.6)	16 (25.8)	41 (38.3)
Anxiety/ Depressed	123 (40.7)	54 (40.6)	28 (45.2)	41 (38.3)
Cognition	117 (38.7)	52 (39.1)	24 (38.7)	41 (38.3)
Social functions ^(a)	159 (53.2)	84 (64.1)	27 (44.3)	48 (44.9)
9-THAI physical scores (PHY)	36.4 (28.6)	38.3 (20.7)	30.4 (27.9)	39.3 (35.7)
9-THAI mental scores (MEN)	34.0 (30.7)	35.4 (32.7)	35.4 (29.4)	32.4 (32.7)
SF-36				
Physical functioning (PF) ^(a)	75.0 (30.0)	85.0 (25.0)	55.0 (37.5)	75.0 (25.0)
Role-physical (RP) ^(a)	50.0 (100.0)	75.0 (50.0)	25.0 (50.0)	25.0 (75.0)
Bodily pain (BP) ^(a)	62.0 (28.0)	72.0 (23.0)	61.5 (28.0)	62.0 (29.0)
General health (GH) ^{(a)3}	42.0 (30.0)	52.0 (28.0)	35.0 (20.0)	35.0 (25.5)
Vitality (VT) ^(a)	60.0 (25.0)	65.0 (20.0)	45.0 (25.0)	55.0 (25.0)
Social functioning (SF)	75.0 (37.5)	75.0 (37.5)	75.0 (31.3)	75.0 (37.5)
Role-emotional (RE) ^(a)	66.7 (100.0)	66.7 (66.7)	33.3 (100.0)	33.3 (100.0)
Mental health (MH) ^(a)	68.0 (28.0)	68.0 (26.0)	64.0 (24.0)	64.0 (28.0)
Physical component scores (PCS) ^(a)	42.7 (8.1)	46.5 (6.8)	37.0 (7.3)	41.0 (7.7)
Mental component scores (MCS) ^(a)	44.9 (9.7)	47.2 (8.8)	43.5 (9.1)	42.8 (10.6)

Notes: Abbreviations; KT: kidney transplantation, CAPD: continuous ambulatory peritoneal dialysis, HD: hemodialysis, SD: standard deviation, IQR: interquartile range

(a) p-value < 0.05, thus significant difference between groups.

(b) Number (Percentage) of subjects reported no problem at all.

Table 2. Spearman rank correlation of 9-THAI and SF-36 domains and components (n = 255-302)

9-THAI domains & higher order constructs	SF-36 domains & components										
	PF	RP	BP	GH	VT	SF	RE	MH	RHT	PCS	MCS
Mobility	0.45	0.44	0.48	0.25	0.38	0.22	0.30	0.26	0.16	0.50	0.24
Self care	0.37	0.40	0.35	0.24	0.29	0.32	0.35	0.36	0.15	0.37	0.35
Usual activities	0.46	0.48	0.40	0.32	0.43	0.30	0.46	0.36	0.17	0.46	0.41
Illness/ Discomfort	0.33	0.34	0.43	0.33	0.25	0.27	0.30	0.32	0.18	0.38	0.29
Anxiety/ Depressed	0.24	0.31	0.34	0.33	0.35	0.38	0.49	0.58	0.19	0.17	0.61
Cognition	0.18	0.17	0.28	0.20	0.23	0.25	0.28	0.31	0.03	0.15	0.36
Social functions	0.35	0.46	0.33	0.36	0.33	0.51	0.41	0.40	0.12	0.40	0.44
Compare with the last year	0.21	0.24	0.16	0.38	0.32	0.23	0.17	0.25	0.77	0.28	0.25
Compare with others	0.36	0.33	0.28	0.54	0.41	0.18	0.26	0.35	0.29	0.38	0.36
9-THAI physical (PHY)	0.45	0.48	0.52	0.37	0.38	0.41	0.43	0.40	0.19	0.49	0.41
9-THAI mental (MEN)	0.26	0.35	0.35	0.34	0.32	0.49	0.46	0.50	0.11	0.25	0.56

Notes: Abbreviations; PF: physical function, RP: role physical, BP: bodily pain, GH: general health, VT: vitality, SF: social function, RE: role emotional, MH: mental health, RHT: reported health transition, PCS: physical component scores, MCS: mental component scores

Bold number indicated hypothesized correlations for convergent validity

Table 3. Unstandardized regression coefficients of multiple linear regression using the hematocrit level as the dependent variable (N = 274)

Independent variables	β	95%CI of β		p-value
		Lower	Upper	
Male	0.36	-1.19	1.92	0.644
Age (year)	-0.01	-0.09	0.07	0.868
Under bachelor	-1.41	-2.93	0.10	0.068
Diabetes comorbidity	-0.81	-2.64	1.01	0.382
Creatinine (mg%)	-0.22	-0.39	-0.04	0.014
CAPD (Ref: KT)	-2.72	-5.53	0.08	0.057
HD (Ref: KT)	-3.93	-6.55	-1.32	0.003
Self-reported hospitalization	-0.76	-2.30	0.78	0.334
9-THAI physical scores	0.01	-0.03	0.05	0.650
9-THAI mental scores	0.05	0.01	0.09	0.028

Notes: Abbreviations; β : unstandardized regression coefficient, CAPD: continuous ambulatory peritoneal dialysis, KT: kidney transplantation, HD: hemodialysis

respond to the telephone interview were significantly older than those who did (51.0 ± 11.9 versus 46.6 ± 11.1 years).

Of the 239 patients, 99 patients reported better health, 105 patients reported stable health, and 35 patients reported worse health. Data from the 105 patients with stable health were used for assessing test-retest reliability. The intraclass correlation coefficients (ICC) of PHY and MEN scores were 0.79 and 0.78, respectively. The ICC values of the two domains

were satisfactory, though the values are not high.

Responsiveness

Data from the 99 patients who reported better health were used to assess the responsiveness of 9-THAI. Both PHY and MEN scores of these patients significantly increased at the second interview ($p = 0.038$ and 0.012 , respectively). The responsiveness indices ranged from 0.18-0.34 (Table 5). Guyatt's responsiveness index gave the highest values. These

Table 4. Adjusted odds ratio (95% CI) of the logistic regression using self-reported hospitalization in the last year as the dependent variable (N = 274)

Independent variables	Adjusted odds ratio (OR)	95% CI of OR		p-value
		Lower	Upper	
Male	0.76	0.43	1.33	0.338
Age (year)	1.01	0.98	1.04	0.557
Under bachelor	1.48	0.85	2.56	0.167
Diabetes comorbidity	1.08	0.56	2.12	0.812
Creatinine (mg%)	1.03	0.96	1.10	0.418
Hematocrit (%)	0.98	0.94	1.02	0.339
CAPD	3.00	1.02	8.83	0.046
HD	0.78	0.29	2.12	0.629
9-THAI physical scores	0.98	0.96	0.99	0.001
9-THAI mental scores	1.00	0.99	1.02	0.591

Table 5. Mean and standard deviation of two assessments and responsiveness statistics of the better health transition patients (n = 97)

Responsiveness statistics		9-THAI			
		Physical scores		Mental scores	
1 st assessment (1 st)	[Mean (SD)]	29.56	(24.21)	31.53	(20.50)
2 nd assessment (2 nd)	[Mean (SD)]	33.94	(20.52)	36.91	(17.39)
Observed change (OC)	[Mean (SD) of (2 nd - 1 st)]	4.38	(20.51)	5.38	(20.77)
Effect size (ES)	[OC/SD of 1 st]	0.18		0.26	
Standardized response mean (SRM)	[OC/SD of OC]	0.21		0.26	
Guyatt's responsiveness index (GRI)	[OC/SD of OC change among stable patients]	0.28		0.34	

results supported the responsiveness of 9-THAI.

Discussion

The new generic health status, 9-THAI, has been confirmed of its validity, reliability, and responsiveness in the sample of patients on RRT in the present study. Results of concurrent validity with two clinical measures in the present study supported the clinical applicability of 9-THAI for future studies. Considering its brevity and satisfactory psychometric properties, 9-THAI is thus a practical tool to use as a self-reported health status measure in clinical practice.

For almost three decades of health status or QoL measure research, not only have numerous measures been developed, but they have also increasingly been administered in routine clinical practice. Therefore brief but comprehensive property of measures is a prime concern. The SF-36 measure is an example of a successful short version of measure, and the shorter

versions of SF-36 such as SF-12, SF-8 are also available. EQ-5D⁽¹⁵⁾, the EuroQol measure consisting of 5 items and one global health rating (visual analog scale) is another example of a successful very brief generic health measure that has been widely used. Hence the development of 9-THAI follows the lessons learnt from brief and comprehensive properties of previous measures.

Results of the associations of 9-THAI and two clinical variables supported the clinical applicability of the measure. Increasing hematocrit levels were significantly associated with higher mental construct scores of 9-THAI. Thus decreasing mental construct scores might indicate mental problems especially the cognition problem due to anemia. Awareness of patients with anemia should be achieved to prevent its complications. Additionally, in the case of physical construct scores and hospitalization association, a thorough examination for physical health problems should be

investigated to reduce hospitalization rate in patients on RRT. Therefore, 9-THAI might be an additional tool for assessing patient circumstances from their point of view.

Another consideration issue was the positive association of hematocrit level and PHY scores. This phenomenon was not unexpected, as there were evidences of such association⁽⁷⁾. When patients were classified into 2 groups according to guideline of anemia work up initiation (hematocrit level; female: < 33% versus \geq 33%, male: < 37% versus \geq 37%)⁽⁷⁾. Average PHY scores of anemia tendency group were significantly lower (35.0 ± 33.5 versus 42.5 ± 22.2 , p-value = 0.019). However, the strong relation of anemia and cognition domain diminished the association of PHY scores and hematocrit level in multiple linear regression analysis.

It should be noted that descriptive health status scores of patients on CAPD in the present study were lower than that of patients on HD or KT, however this resulted from the characteristics of CAPD group. The analysis adjusting for gender, age, diabetes comorbidity, hospitalization history, creatinine and hematocrit level (not presented here) found no statistically significant differences between health status scores of CAPD and HD group, and this result was consistent with previous studies⁽¹⁶⁻¹⁷⁾. All patients on HD in the present study were on the KT waiting list, thus their health status was considered higher than ordinary patients on HD. As stringent criteria of KT waiting list result in younger and healthier patients with minor anemia condition. For these reasons, known group validity based on different modalities was considered not appropriate to propose in the present study.

There were some consideration issues from correlations of 9-THAI and SF-36. A correlation of PHY (9-THAI) & MCS (SF-36) was higher than expectation for divergent validity. This might have arisen from a high correlation of 'usual activities' (9-THAI) & RE (SF-36). In the previous SF-36 Thai version study, the authors suggested the cautious interpretation in RE domain among the Thai general population due to differences in culture context⁽⁹⁾. Consequently, the high correlation between PHY (9-THAI) & MCS (SF-36) might be due to the problem of RE domain that should be further studied. However, the validity of 9-THAI in patients on RRT was confirmed by overall results.

Conclusion

Although SF-36 is widely used in outcome research for evaluation of RRT, results from the present

study showed that 9-THAI can be used as an alternative outcome measure with the advantage of its simplicity. The universal coverage health policy of the Thai Ministry of Public Health does not currently cover RRT due to its high cost. The revision policy will move towards more coverage to all RRT modalities in the very near future. The brevity of 9-THAI and availability of national norms, make it an ideal core in a battery of measures. Thus, 9-THAI will be a promising tool to be used in evaluation of the extended policy.

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ความตรงและความเที่ยงของแบบวัดคุณภาพชีวิตชนิดใหม่ที่เหมาะสมในทางปฏิบัติกับผู้ป่วยที่ได้รับการรักษาทดแทนไต

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วัตถุประสงค์: แบบวัดคุณภาพชีวิตชนิดใหม่เป็นส่วนหนึ่งของแบบสัมภาษณ์ที่ใช้ในการสำรวจอนามัยและสวัสดิการ พ.ศ. 2546 ซึ่งมีแนวโน้มเหมาะนำมาใช้ในทางคลินิก เนื่องจากเป็นแบบวัดที่กระชับ มีความตรงและความเที่ยงในกลุ่มประชากรปกติ ตลอดจนมีค่าคะแนนที่แปลความหมายได้ง่าย โดยการเปรียบเทียบกับคะแนนเฉลี่ยของประชากรปกติ แบบวัดชนิดใหม่มีคำถาม 9 ข้อ จึงให้ชื่อว่า 9-THAI (9-item Thai Health status Assessment Instrument) การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาความตรงและความเที่ยงของ 9-THAI ในผู้ป่วยที่ได้รับการรักษาทดแทนไต

วัสดุและวิธีการ: การศึกษานี้ทำในผู้ป่วยนอกที่ได้รับการรักษาทดแทนไต ณ โรงพยาบาลศรีนครินทร์ระหว่างเดือนมีนาคม ถึงพฤษภาคม พ.ศ. 2548 จำนวน 302 ราย โดยใช้แบบวัด SF-36 เป็นแบบวัดคู่ขนานในการประเมินความตรงแบบ convergent และ divergent, และใช้ตัวแปรทางคลินิก ได้แก่ ความเข้มข้นของเลือดและประวัติการเข้าพักรักษาตัวในโรงพยาบาลในรอบปีที่ผ่านมา ในการประเมินความตรงแบบ concurrent และทำการประเมินความเที่ยงแบบ test-retest โดยการประเมินซ้ำหลังจากประเมินครั้งแรกเป็นเวลาหนึ่งเดือน นอกจากนี้ ได้ศึกษา responsiveness ของ 9-THAI เฉพาะในผู้ป่วยที่ประเมินตนเองว่ามีการเปลี่ยนแปลงไปในทางที่ดีขึ้น

ผลการศึกษา: พบว่าค่าสหสัมพันธ์ที่แสดงถึงความสอดคล้องระหว่างมิติต่างๆ ของ 9-THAI และ SF-36 เป็นไปตามสมมติฐานที่ตั้งไว้ คะแนน 9-THAI ยังสัมพันธ์กับความเข้มข้นของเลือดและประวัติการเข้าพักรักษาตัวในโรงพยาบาล ผลดังกล่าวข้างต้นแสดงว่า 9-THAI มีความตรงในการประเมินคุณภาพชีวิตของผู้ป่วย และในผู้ป่วยที่ประเมินว่าตนเองมีสุขภาพไม่เปลี่ยนแปลงพบว่า ค่าสถิติที่แสดงถึงความเที่ยง (intra-class correlation coefficient) ของคะแนน 9-THAI อยู่ในระดับที่น่าพอใจ นอกจากนี้ ผลการศึกษาในผู้ป่วยที่ประเมินตนเองว่ามีการเปลี่ยนแปลงของสุขภาพไปในทางที่ดีขึ้น พบว่า คะแนน 9-THAI มีค่าสูงขึ้นอย่างมีนัยสำคัญ ซึ่งสอดคล้องกับการประเมินตนเองของผู้ป่วย ดังนั้นจึงแสดงว่า 9-THAI มีคุณสมบัติ responsiveness ด้วย

สรุป: 9-THAI เป็นแบบวัดที่มีความเที่ยงตรง และเหมาะสมในการนำมาใช้เป็นแกนของเครื่องมือวัดคุณภาพชีวิตในทางคลินิกสำหรับผู้ป่วยที่ได้รับการรักษาทดแทนไต

Appendix 1. Details of questions in 9-THAI (Thai version and English translation version)

Domain	Thai	English Translation
Mobility	<ol style="list-style-type: none"> 1. ระหว่างหนึ่งเดือนก่อนหน้านี้อ่านมีความยากลำบากในการเคลื่อนไหว มีอ. แขน, ขา, ลำตัว หรือ ทั้งร่างกาย หรือไม่ อยุ่ในระดับใด 	<ol style="list-style-type: none"> 1. During the past 1 month, have you had difficulty with the mobility of your hand, limb, torso or the whole body or not? If so, to what level?
Self Care	<ol style="list-style-type: none"> 2. ระหว่างหนึ่งเดือนก่อนหน้านี้อ่านมีความยากลำบากในการดูแลตัวเองหรือไม่ อยุ่ในระดับใด (การดูแลตัวเอง เช่น การแต่งตัว, การทำความสะอาดร่างกาย, การขับถ่าย เป็นต้น) 	<ol style="list-style-type: none"> 2. During the past 1 month, have you had difficulty in self care or not? If so, to what level? (The example of self care are dressing, cleaning the body, getting rid of waste from the body, etc.)
Usual Activities	<ol style="list-style-type: none"> 3. ระหว่างหนึ่งเดือนก่อนหน้านี้อ่านมีความยากลำบากในการทำงานนอกบ้าน หรือการทำงานหรือไม่ อยุ่ในระดับใด 	<ol style="list-style-type: none"> 3. During the past 1 month, have you had difficulty in doing work, both outside the home or housework, or not? If so, to what level?
Illness/ Discomfort	<ol style="list-style-type: none"> 4. ระหว่างหนึ่งเดือนก่อนหน้านี้อ่านเจ็บป่วย หรือรู้สึกไม่สบายหรือไม่ อยุ่ในระดับใด 	<ol style="list-style-type: none"> 4. During the past 1 month, have you had any sickness or not felt very well, or not? If so, to what level?
Anxiety/ Depressed	<ol style="list-style-type: none"> 5. ระหว่างหนึ่งเดือนก่อนหน้านี้อ่านมีความรู้สึกหงุดหงิด เศร้า เสียใจ หรือวิตกกังวล หรือไม่ อยุ่ในระดับใด 	<ol style="list-style-type: none"> 5. During the past 1 month, have you felt depressed, blue, or anxious, or not? If so, to what level?
Cognition	<ol style="list-style-type: none"> 6. ระหว่างหนึ่งเดือนก่อนหน้านี้อ่านมีความยากลำบากในการที่จะสมาธิ หรือจดจำสิ่งต่างๆ หรือไม่ อยุ่ในระดับใด 	<ol style="list-style-type: none"> 6. During the past 1 month, have you had difficulty in concentrating or remembering, or not? If so, to what level?
Social Functions	<ol style="list-style-type: none"> 7. ระหว่างหนึ่งเดือนก่อนหน้านี้อ่านมีความยากลำบากในการรวมกิจกรรมกับบุคคลอื่น หรือ การเข้าร่วมในสังคม/ชุมชนหรือไม่ อยุ่ในระดับใด 	<ol style="list-style-type: none"> 7. During the past 1 month, have you had difficulty in participating with others in activities or in social/ community activities, or not? If so, to what level?
Global Question 1: Compare with Last Year	<ol style="list-style-type: none"> 8. เมื่อเปรียบเทียบกับสุขภาพของท่านในวันนี้ กับสุขภาพของท่านเมื่อปีที่แล้ว วันนี้เป็นอย่างไร 	<ol style="list-style-type: none"> 8. When you compare your health today with your health in the last year, how would you rate your health?
Global Question 1: Compare with Others	<ol style="list-style-type: none"> 9. เมื่อเปรียบเทียบกับสุขภาพของท่านกับผู้อื่นที่มีอายุเพศ ฐานะ หน้าที่การงาน และความเป็นอยู่ ที่คล้ายคลึงกับท่าน แต่ไม่มีโรคประจำตัว ท่านเห็นว่าสุขภาพของท่านเป็นอย่างไร 	<ol style="list-style-type: none"> 9. When you compare your health with others' health who are similar to you in age, gender, social and economic status, type of employment, and living style, how would you rate your health?

Note. Response choices for item 1-7 are 'very severe', 'severe', 'moderate', 'mild', and 'not at all'.

Response choices for item 8-9 are 'much worse', 'a little bit worse', 'the same as', 'a little bit better', and 'much better'.