ORIGINAL ARTICLE

Development and Psychometric Properties of the Dialysis Module of the WHOQOL-BREF Taiwan Version

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Background: Quality of life (QOL) is now considered to be an important part of the assessment of dialysis patients. The aim of this study was to develop and assess the reliability, validity and sensitivity of the dialysis module of the World Health Organization Quality of Life – Brief (WHOQOL-BREF) Taiwan version [WHOQOL-BREF(TW)] in patients undergoing regular hemodialysis (HD).

Methods: QOL survey was administered to 283 regular HD patients in metropolitan Taipei. The instruments used included: (1) the proposed module – composed of the core part, the WHOQOL-BREF(TW), and the six specific items; (2) the symptom/problem (S/P) scale – composed of 12 items specific for dialysis patients; (3) the utility measure, which was performed with standard gamble (SG) methods; and (4) the rating scale (RS).

Results: Based on the six criteria of validity, reliability and variance of the items, four HD-specific items were selected. Reliability study showed that Cronbach's alphas, composite reliability, and test–retest reliability (intraclass correlation at an average retest interval of 4–8 weeks) of the four domains of physical, psychological, social relationship and environment, ranged from 0.74–0.82, 0.79–0.84 and 0.61–0.79, respectively. Validity study showed that all the correlations between an item and its corresponding domain were highly significant ($r > 0.4$, $p < 0.01$) and larger than the correlations between the item and other domains. SG and psychometric measures showed relatively low correlations (0.12–0.26). The module showed the same construct as the WHOQOL-BREF(TW) under confirmatory factor analysis, whereas the exploratory factor analysis showed mild variation. Convergent and discriminant validity were good. Global QOL, physical, psychological and environment domains had some sensitivity to differentiate the severity of the condition of patients receiving HD. Clinical validity was demonstrated in global QOL, physical and psychological domains to have significant correlations with S/P scores.

Conclusion: Besides broader coverage than the core WHOQOL-BREF(TW), the dialysis module of the WHOQOL-BREF(TW) is a valid, reliable and sensitive QOL instrument for the assessment of HD patients in Taiwan. [*J Formos Med Assoc* 2006;105(4):299–309]

Key Words: dialysis module, hemodialysis, quality of life, WHOQOL

Quality of life (QOL) has become an independent and important variable in the evaluation of dialysis patients in the last several decades.[1–4] The measurement of QOL can be made based on either economic utility (called utility measure),[5] or psychometrics (called profile analysis).[6] Utility measures usually obtain preference values using the standard gamble (SG) method, or the time-

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tradeoff method, or even by using one of the prescored multiattribute health status classification systems.[5] Utility measures were the basis for integrating the assessment of QOL with survival to form quality-adjusted survival (QAS) and quality-adjusted life years (QALY).[4] Profile analysis was generally performed using a questionnaire, which is either generic or disease-specific. A disease-specific questionnaire[6] could be developed with some dimensions totally different from a generic questionnaire;[1,7] or with a generic questionnaire as a core part and some specific dimensions/items augmented. This combinational approach results in a modular instrument, and has been useful especially in interventional studies for cross-cultural, population or intradisease comparisons.[1,7]

Health was universally defined by the World Health Organization (WHO) to have physical, mental and social dimensions.[8] In 1991, the WHO initiated a cross-cultural project to develop the standard WHOQOL-100 questionnaire for generic use and defined QOL as individuals' perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns.[9] This definition became more comprehensive after incorporating the environment domain.[10] It also highlighted the view that QOL refers to a subjective evaluation, and is different to the concept of health status that usually includes both subjective and objective evaluations. The WHOQOL study group then simplified the WHOQOL-100 to a short form called WHOQOL-BREF,[11,12] which was translated later in Taiwan to the WHOQOL-BREF, Taiwan version[13] [WHOQOL-BREF(TW)], with two local items added.

Patients with end-stage renal disease (ESRD) have the general manifestation of uremic syndrome and need renal replacement therapy to maintain life.[1,14] Hemodialysis (HD), which accounts for a major proportion of replacement therapy,[15] prolongs life but is accompanied by some QOL impairment. The number of HD patients increased from 27,143 in 1999 to 39,574 in 2003. Among them, 36,172 were receiving HD.[15] The high health care expenditure of HD[16] has led to attention being paid to outcome evaluations because of the concern for cost-effectiveness. Various tools of measuring QOL in HD patients have been developed,[17–19] such as the SF-36 and the Kidney Dialysis Quality of Life (KDQOL).[18,19] Although several of these methods have been adopted in Taiwan,[3,20] in general, they lack broad coverage and intercultural comparability.[18,19] For HD patients in Taiwan, the recently developed WHOQOL-BREF (TW) would be a potentially suitable instrument for cross-culture and cross-disease comparison. Using a formal standard procedure,[12,13] we developed a modular type questionnaire with WHOQOL-BREF(TW) as a core part. This study analyzed the psychometric properties of this module to substantiate its reliability and validity for use as a QOL instrument for assessing HD patients in Taiwan.

Methods

Subject recruitment and development of HD-specific items

Ten patients with different ages, genders, socioeconomic status, and dialysis durations were enrolled to form a focus group on October 25, 2001; three nephrologists were invited to form an expert committee. With participants' permission, the content of the meeting was tape-recorded and later transcribed. After considering the frequencies of concerns mentioned in the focus group and extracting concepts from literature review, the expert committee reviewed the major concerns and judged their importance. From the conclusion from these meetings, six specific items were drafted.

Survey of draft version of the dialysis module

Two hundred and eighty-three patients undergoing regular HD at the dialysis centers of 10 regional hospitals or outpatient clinics in metropolitan Taipei were enrolled between February 1 and March 31, 2002. After excluding subjects with outlying clinical values and respondents who answered < 80% (23 items) of the WHOQOL-BREF (TW), 249 subjects were included in the study. To

evaluate test–retest reliability, 20 patients agreed to and were retested after 4–8 weeks. The absolute inclusion criteria to receive HD were ESRD with creatinine clearance ≤ 5 mL/min or creatinine concentration ≥ 8.0 mg/dL. The relative inclusion criteria to receive HD were severe chronic renal failure and creatinine clearance ≤ 15 mL/min or creatinine concentration ≥ 6.0 mg/dL plus at least one of the following complications: congestive heart failure or pulmonary edema; pericarditis; bleeding tendency; neurologic symptoms; intractable hyperkalemia, nausea, vomiting, acidosis or cachexia; severe azotemia with blood urea nitrogen > 100 mg/dL. Patients with current consciousness disturbance, or who had been hospitalized during the last 3 months, or who refused to complete the survey questionnaire were excluded.

Assessments of the draft version of the dialysis module

Instruments

The draft version of the dialysis module[16] for the WHOQOL-BREF(TW) consisted of the core part, the WHOQOL-BREF(TW), and the six draft HD-specific items. The WHOQOL-BREF(TW) consisted of 28 items, including two global items – one item (G1) for general QOL and another (G2) for general health. The remaining 26 items belonged to the following four domains: physical, psychological, social relationship, and environment. The method of administration, reference time point, and the scoring of items were as described in the original WHOQOL-BREF.[12,21] A descriptor study had been performed during the development of the WHOQOL-BREF(TW).[22] The questionnaire was self-administered, although interviews were done by a trained interviewer whenever self-administration was inconvenient for patients. Participants were required to evaluate their QOL during the recent 1 month on the corresponding diverse items. Items were scored from 1 to 5 on a Likert scale. Each domain's score ranged from 4 to 20, which was calculated by multiplying the average of the scores of all items in the domain by four.[13]

The KDQOL is a questionnaire that has been used to evaluate QOL in kidney/dialysis patients; it has good psychometric properties.[23] The symptom/problem (S/P) scale of the KDQOL consists of 12 items describing various symptoms and dialysis problems. The item score ranges from 1 to 5, with a higher score indicating a more severe state of ESRD on dialysis. The S/P score is the mean of the 12 item scores, and indicates the severity of ESRD in patients receiving regular HD.[24] When the S/P score is higher, the condition of ESRD in patients receiving HD is more severe. According to utility theory,[5] utility measured by the SG method describes scenarios in which the responding patient has to make a series of decisions under conditions that represent various probabilities of his/her disease or death occurring. The SG scores ranged from 0.00 (worst imaginable state, death) to 1.00 (best imaginable state, perfect health). Rating scale (RS) scores were assessed using a line segmented from 0 (death) to 10 (the best state). Respondents were asked to place their QOL value at one point on the RS line. SG and RS are regarded as criteria to be compared in criterion validity (including prediction validity). Kt/V was calculated as dialysis dose using the Daugirdas formula,[14] and residual glomerular filtration rate (rGFR) was calculated using the Cockcroft-Gault formula.[25]

Selection of HD-specific items

After administering and analyzing the draft version of the dialysis module in enrolled patients, HD-specific items were selected and classified into the two domains by adopting the following criteria:[26] (1) Pearson's correlation between the specific item and its hypothetical domain was larger than 0.3 and those between the specific item and other domains; (2) there were significant correlations between the item and the global items G1 and G2; (3) the mean of the item was in the range 2–4; (4) the variance of the item was larger than that of other items in the same domain; (5) the specific item could be classified into the latent factor related to the domain originally assigned based on the result of exploratory factor

analysis, and the factor loading of the specific item was larger than 0.3; (6) Cronbach's α was decreased if the item of interest was deleted (Table 1). After adding the HD-specific items, the dialysis module for WHOQOL-BREF(TW) was formally constructed.

Reliability assessment

The internal consistency reliability was evaluated by Cronbach's α, the composite reliability in the four domains, and the indicator reliability for all the items.[27] The test–retest reliability was evaluated with the correlations between the two tests for the four domains.[28]

Validity assessment

Pearson's correlation was used to evaluate content validity. We hypothesized that if the dialysis module of WHOQOL-BREF(TW) accurately assessed the QOL of HD patients, and the classification of domains and their items was correct, then correlations between a domain and its items would be stronger than correlations between a domain and items of other domains.

Other assessments

The following five criteria were selected to test criterion-related validity: G1, G2, global QOL (mean of G1 and G2), SG and RS values. We hypothesized that accurate assessment of the QOL of HD patients by the four domains would be indicated by significant correlations among the four domains and all five criteria measures, and that the correlations among the four domains and psychometric global measures (global QOL, G1, G2) would be stronger than those among the four domains and utility measures (SG and RS). Regression analysis was used to test concurrent validity, with global measures as the dependent variables, and all four domains as the independent variables. In addition, the utility measures (SG and RS) were considered as the dependent variables, and the four domains plus G1 and G2 as the independent variables.

Construct validity was tested using both exploratory and confirmatory factor analyses.[28] The exploratory factor analysis (EFA) was conducted on all items of the WHOQOL-BREF(TW) except for G1 and G2 through extracting factors by principal axis factoring and promax rotation with Kaiser Normalization.[13,24] Confirmatory factor analysis (CFA) was performed taking the four domains as the latent factors with their corresponding items as the indicators, as described in the user's manual of the WHOQOL-BREF(TW).[13] Chi-square, normed chi-square (χ^2/degrees of freedom), the comparative fit index (CFI), and the non-normed fit indices (NNFI) were adopted as goodness-of-fit indices.[28,29] Under the CFA model,[29] *t* tests for factor-loading values on each of the items were performed to evaluate convergent validity. For any pair from the four domains, the following three

Table 1. Summary of item selection

Selection criteria	Items					
	Q29	Q30	Q31	Q32	Q33	Q34
Item-domain correlation greater than 0.30 and greater than correlations between item and other domains	✔	✔	✔	✔	✔	✔
Both the correlations between the item and the two global items (G1 and G2) were significant	✔	✘	✔	✔	✔	✘
The range of the item mean was between 2 and 4	✔	✔	✔	✔	✔	✔
The score variance of the item was greater than the score variances of the other items in the same domain	✘	✔	✔	✘	✘	✔
From exploratory factor analysis, the item could be significantly classified ($\lambda > 0.3$)	✔	✔	✔	✔	✔	✘
Cronbach's α was decreased if the item of interest was deleted	✔	✘	✔	✔	✔	✘

kinds of tests were performed to evaluate discriminant validity: chi-square difference test, confidence interval, and variance extracted test.[28]

Sensitivity is the ability of measurements to detect differences among different groups of HD patients.[5,6] HD patients were stratified into three groups according to Kt/V values (Kt/V ≤ 1.2; 1.2 < Kt/V ≤ 1.6; Kt/V > 1.6), and into two groups based on S/P scores (S/P ≥ 3.0; S/P < 3.0). ANOVA and independent *t* test were used separately to evaluate the sensitivity of QOL items/domains. Clinical validity was evaluated using Pearson's correlations between QOL items/domains and clinical variables (comorbidity, S/P, albumin, Kt/V, rGFR, hemoglobin [Hb], hematocrit [Hct], erythropoietin injection amount per week [EPO/w]). We hypothesized that global QOL, G1, G2, the four domains and the HD-specific items would show significant correlations with the clinical variables.

Results

Characteristics of subjects and descriptive statistics

Of the 249 enrolled patients, 51% were male; 62% and 20% were younger than 50 and 40 years old, respectively. Education was elementary or below in 56%; only 18% had been employed within 1 year; 90% were married; 51% had a comorbid condition; 15% and 8.6% had a smoking and drinking habit, respectively; 87% had a monthly income < 30,000 NT dollars (1 US dollar = 32 NT dollars). The average clinical values (and standard deviations) of Kt/V, rGFR, albumin, Hb, Hct, calcium (Ca), phosphate (P), and EPO/w were 1.68 (0.36), 17.0 (5.0) mL/min, 3.5 (1.0) g/dL, 9.8 (1.9) g/dL, 30.0% (4.6%), 9.5 (1.0) mg/dL, 5.1 (1.7) mg/dL, and 1418 (1429) units per dialysis, respectively.

Development of draft version of HD-specific items

The HD patients suffered from a variety of symptoms, signs and problems, most of which were already included in the WHOQOL-BREF(TW). Major specific issues of HD patients were summarized at the expert committee meeting, including "transport to HD center"; "time wasted in the HD process"; "to be known to receive HD therapy"; "family and social support for HD"; and "gain knowledge about ESRD and HD". Twenty-five potential items were identified. Three nephrologists reviewed each potential item and established the draft list of items. Both the frequency of items mentioned by HD patients in the focus group and the importance of items as judged by experts were considered together. Six draft HD-specific items were derived and classified into the original four domains of the WHOQOL-BREF(TW).

Item Q30 was "How frequently do you feel that the duration of dialysis influences your quality of life?" and belonged to the physical domain. Item Q34 was "How uncomfortable do you feel when others know you are receiving dialysis?" and belonged to the psychological domain. Item Q29 was "Are you satisfied with the support from your family?" and belonged to the social relationship domain. Items Q31–Q33 were "How much do you want to understand about dialysis?", "Are you satisfied with dialysis quality?", and "Are you satisfied with the care service provided by society to dialysis patients?" respectively, and belonged to the environment domain.[16]

Construction and assessment of the dialysis module

The six criteria were used to assess the six draft items in the 249 HD patients (Table 1). Each item was required to be significantly and moderately related to domains and global items, and the distribution of item scores not skewed too much. Each item was required to be significantly classified into one factor and have adequate internal consistency. An item was selected if it passed at least five of the six criteria. The following four items were selected: Q29, Q31, Q32 and Q33, as shown in Table 2. Thus, the newly constructed dialysis module has 32 items. Quantitative vali-

dation was performed using this dialysis module thereafter.

Internal consistency and test–retest reliability[30]

Cronbach's α values for the four domains of physical, psychological, social relationship and environment were 0.79, 0.77, 0.74 and 0.72, respectively. The test–retest reliability of the four domains were 0.61, 0.79, 0.75, and 0.78, respectively. All items demonstrated good indicator reliability (IR > 0.15), except for pain (IR = 0.13), medication dependency (IR = 0.02), personal belief (IR = 0.07), and social care (IR = 0.11). The composite reliability of the four domains were 0.83, 0.81, 0.79 and 0.84, respectively.

Content validity

Pearson's correlation between the physical and social relationship domains (0.47) was lower than the correlations among the other domains, but all correlations were significant and high ($r > 0.40$, $p < 0.001$). The correlation values between items and their corresponding domains were all significant ($p < 0.001$) and larger than those between the items and other domains.

Criterion-related validity

The correlation values between the four domains and SG were lower (range, 0.12–0.26) than those between the four domains and psychometric global items (range, 0.37–0.53). The correlation values between the four domains and RS (range, 0.22–0.45) were about the same compared with those between the four domains and psychometric global items (Table 3).

Regression analyses showed that around 30% of the total variances of the global items could be explained by the four domain scores. The physical domain was the best predictor of G2, and the psychological domain was the best predictor of G1. When SG or RS were set as dependent variables, regressed by G1, G2, and four domains, the results showed that 7.8% and 27.7% of the total variance of SG and RS were explained by the global items and four domains, respectively. The physical domain was the best predictor of SG, while the physical and psychological domains were the best predictors of RS. The multicollinearity problem seemed to have a relatively small effect on the results, because tolerance and variance inflation values were larger than 0.1 and smaller than 10, respectively.

Construct validity

According to the results of EFA (Table 4), four latent factors were extracted. They were renamed as the "general non-social factor", "socioeconomic factor", "physical-environmental factor", and "physicopsychological factor". Among the four goodness-of-fit indices[29,31] of CFA, CFI (0.93) and NNFI (0.92) reached the criteria of model fit, and construct validity was demonstrated. All factor loadings for the items were significant (greater than twice their standard errors), indicating good convergent validity. Each pair of factors was tested with three kinds of tests.[28] Discriminant validity was demonstrated through tests of chi-square difference and the confidence interval in all six pairs of the four factors. However, only the pairs of physical-social relationship and psychological-social relationship demonstrated discriminant validity through the variance extracted test.

Table 2. New construct of the dialysis module for WHOQOL-BREF(TW)

Domain	Items contained
Physical	F3, F4, F10, F15, F16, F17, F18
Psychological	F5, F6, F7, F11, F19, F26
Social relationship	F20, F21, F22, F27, Q29
Environment	F8, F9, F12, F13, F14, F23, F24, F25, F28, Q31, Q32, Q33

The construct is the WHOQOL-BREF(TW) core with four new items added.

Table 3. Criterion validity and clinical validity assessment: Pearson's correlations between quality of life (QOL) measures and clinically-related variables (n = 249)

	G1	G2	Global QOL	Domains			
				Physical	Psychological	Social relationship	Environment
Comorbid or not	–0.08	–0.01	–0.05	–0.10	–0.07	0.07	0.09
S/P	–0.09	–0.25†	–0.21*	–0.46‡	–0.23†	–0.08	–0.11
Albumin	0.16	0.07	0.13	–0.01	0.09	0.00	0.03
Kt/V	0.03	–0.14	–0.08	0.11	0.10	0.14	0.15
rGFR (mL/min)	–0.04	–0.10	–0.08	–0.15	0.01	0.11	0.04
Hematocrit (%)	0.07	–0.02	0.02	0.01	–0.01	–0.09	–0.01
Hemoglobin (mg/dL)	0.04	0.06	0.06	0.09	0.10	0.02	0.20*
EPO/w	0.21*	0.19*	0.23*	0.24†	0.16	0.16	0.20*
G1				0.37‡	0.51‡	0.44‡	0.44‡
G2				0.53‡	0.47‡	0.34‡	0.35‡
Global QOL				0.53‡	0.57‡	0.45‡	0.45‡
SG				0.26‡	0.21‡	0.12	0.17*
RS				0.45‡	0.44‡	0.22‡	0.30‡

**p < 0.05; †p < 0.01; ‡p < 0.005. S/P = score of symptom/problem scale; rGFR = residual glomerular filtration rate; EPO/w = injection dose per week in hemodialysis patients receiving erythropoietin (n = 129); G1 = one global item of WHOQOL-BREF about general QOL; G2 = another global item of WHOQOL-BREF about general health; Global QOL = mean of (G1+G2); SG = utility measure of standard gamble; RS = utility measure of rating scale.*

Clinical sensitivity and validity

The three groups classified according to Kt/V value had about the same QOL scores in global QOL, G1, G2, the four domains, and the four specific items, indicating the lack of sensitivity in different doses of dialysis. There were significant differences in scores of global QOL, G2, physical, psychological and environmental domains between groups with S/P score less than or higher than 3, indicating sensitivity in differentiating the severity of the condition in patients receiving HD. Table 3 also shows that S/P scores and EPO amounts were better correlated with the four domains, G1, G2 and global QOL.

Discussion

Fayers and Machin described validation as the process of determining whether there are grounds for believing that an instrument measures what it intends to measure.[6] Validation is not an all-or-none phenomenon. An instrument may reflect a high level of validity, a relatively low level, or any level in between.[28] In this study, we developed a modular questionnaire for dialysis patients in Taiwan through a formal process of item selection. The module had a broader coverage than the core WHOQOL-BREF(TW). We also evaluated the reliability of the dialysis module in terms of internal consistency (Cronbach's α and composite reliability) and test–retest reliability. Although Nunnally advocated minimum reliability coefficients of 0.90 for measures to assess group differences and 0.95 for assessing individual differences, and also advocated a reliability coefficient of 0.80 for the initial stages of developing a measurement tool,[32,33] many highly regarded QOL instruments failed to meet this standard.[34] Bonomi et al set the lowest standard of reliability at 0.70 in their evaluation of the United States' WHOQOL-100.[35,36] The α coefficients (0.74–0.82) and test–retest reliability (0.61–0.79) of the four domains in this newly developed module were comparable to other WHOQOL studies in ethnic Chinese.[29,30,37,38] The physical domain had the lowest test–retest reliability of the four domains, probably because of a longer follow-up period (4–8 weeks) that might cause some change in physical condition. Although all 20 patients tested twice in this study were in apparently stable clinical condition, we found that the average

Table 4. Exploratory factor analysis: iterative principle axis factoring and promax rotation, using 30 items of the dialysis module of the WHOQOL-BREF(TW) with depletion of global items (G1 and G2)

Item	Domain	Label	Factor 1	Factor 2	Factor 3	Factor 4
F6	D2	Life meaning	0.517*	0.303	–0.054	–0.190
F7	D2	Concentration	0.636*	0.055	0.097	–0.028
F8	D4	Life safety	0.555*	0.048	0.216	0.090
F10	D1	Vitality	0.790*	–0.108	0.075	0.152
F11	D2	Acceptance of appearance	0.638*	0.017	0.204	–0.197
F13	D4	Daily information availability	0.549*	0.126	0.131	–0.066
F14	D4	Opportunity for leisure activities	0.570*	0.083	–0.165	0.157
F15	D1	Ability to get around	0.746*	0.029	–0.102	0.176
F16	D1	Satisfaction with sleep	0.477*	–0.130	0.244	0.012
F17	D1	Satisfaction with ability to perform daily living activities	0.712*	0.034	0.067	0.225
F18	D1	Satisfaction with work capacity	0.689*	0.039	0.022	0.109
F19	D2	Self-satisfaction	0.721*	0.104	–0.055	0.047
Q31	D4	Active access to dialysis-related knowledge	0.407*	0.267	–0.128	–0.305
F5	D2	Life enjoyment	0.330	0.337*	–0.019	0.037
F12	D4	Enough money for needs	0.226	0.327*	0.119	0.106
F20	D3	Satisfaction of personal relationships	0.157	0.596*	–0.029	–0.070
F21	D3	Satisfaction with sex life	0.284	0.396*	–0.120	0.178
F22	D3	Satisfaction with friend support	0.103	0.635*	0.031	–0.213
F23	D4	Satisfaction with living place	0.077	0.423*	0.261	–0.005
F27	D3	The feeling of being respected by others	0.202	0.340*	0.235	–0.027
F28	D4	Food accessibility	0.029	0.329*	0.145	0.274
Q29	D3	Satisfaction with family support	–0.187	0.641*	0.188	0.228
F9	D4	Physical environmental health	0.189	–0.108	0.505*	–0.031
F24	D4	Satisfaction with access to health services	0.082	0.068	0.657*	–0.012
F25	D4	Satisfaction with transportation	0.012	0.159	0.489*	0.119
Q32	D4	Satisfaction with the dialysis quality	0.070	–0.015	0.571*	–0.206
Q33	D4	Satisfaction with social care	–0.153	0.131	0.514*	0.054
F3	D1	Pain	0.303	–0.039	–0.068	0.372*
F4	D1	Medical dependency	0.039	–0.050	–0.001	0.485*
F26	D2	Negative feeling	0.108	0.062	–0.022	0.453*

**Higher factor loadings (> 0.3) for extracted factors. D1 = physical domain; D2 = psychological domain; D3 = social relationship domain; D4 = environmental domain; F3–F28 = items of WHOQOL-BREF(TW); Q29, Q31, Q32, Q33 = hemodialysis-specific items.*

scores of S/P rose from 2.1 to 2.3, and 17 patients showed a change in S/P score.

Because the WHOQOL-BREF(TW) is a well-developed questionnaire with its construct of four domains, CFA for HD patients was conducted and showed a high degree of goodness of fit (CFI = 0.92).[28] The purpose of the EFA here was to explore the relationship of the four new QOL items to domains of WHOQOL-BREF(TW). The EFA extracted four latent factors. The first factor consisted of many items of physical, psychological and environment domains, but none from the social relationship domain. Thus, it could be renamed as the "general non-social factor". The second factor contained F5 (enjoy), F12 (finance), F23 (home), F28 (eating), and all of the original five items of the social domain, and it was renamed the "socioeconomic factor". All of the five items extracted for the third factor belonged to the original environment domain, and we kept this original domain name. F3, F4 and F26 were extracted as the fourth factor, and might be grouped together because "pain" and "negative feeling" depend on "medication", which

was called the "physicopsychological factor". An alternative explanation was that these items, F3, F4 and F26, were asked in a negative way and clustered to a new factor. The item "understanding dialysis" had the highest factor loading on the first factor (0.407), but it also had a negative loading on the fourth factor. This negative loading signified that HD patients with more medication dependence and sensation of pain are more eager to gain knowledge about ESRD and HD. Comparison of the original construct of the WHOQOL-BREF(TW) with the newly formed one revealed that the items of the original environment domain scattered on the first three factors, and the mixing of the items of the original physical and psychological domains seemed to fall into the same factor. This indicated that the original four domains stand well, and the physical and psychological items were closely related in HD patients.

A two-step approach to CFA was adopted for the subsequent study of discriminant validity and convergent validity.[39,40] Discriminant validity was demonstrated in all six pairs of factors through the chi-square difference test and confidence interval test, but only the pairs of physical-social relationship and psychological-social relationship showed a high degree of discrimination on the variance extraction test. This finding might indicate that both chi-square difference and confidence interval tests were looser in their criteria compared with the variance extracted test. Alternatively, it may suggest a low or moderate correlation between physical and social relationship domains (0.47), and between psychological and social relationship domains (0.60).

In regression analyses of concurrent validity, global QOL scores were explained by physical, psychological and social domains, which corroborated with previous reports.[1,18] Many items in the environmental domain were closely related to some items of physical, psychological and social domains. For example, items of "safety" and "information" in the environment domain were highly correlated with the item "vitality" of the physical domain, with $r = 0.58$ and 0.52, respectively (both $p < 0.001$); the item "information" also had a high correlation with the "appearance" item of the psychological domain, with $r = 0.53$ ($p < 0.001$). These items were mostly explained by the other three domains in the linear models. Because some environment items, such as accessibility to HD services and facilities, were very clinically important to HD patients, such items should be studied in future QOL assessment for HD patients.

The SG could not be explained significantly by psychometric items and domains in HD patients. When comparing Pearson's correlations between various measures, the correlations between SG and other psychometric QOL measures were lower than those among different psychometric QOL measures. The SG measure was framed under uncertainty and choice, and related to risk attitude.[41] Usually, when a person is risk-averse, the SG measure obtained will be larger than psychometric scores or RS measures, which are framed under certainty and scaling. Lin et al showed that SG and RS values in HD patients were 0.75 ± 0.24 and 0.57 ± 0.16, respectively.[42] In this study, the SG value (0.78) was significantly higher than all domain scores (range, 0.45–0.53) when we converted the score linearly to range from 0 to 1. This indicated that the SG measurements in this study were similar to a previous report,[42] but it probably represents its utility in QOL instead of health-related domains only.

In sensitivity assessment, all domains except social relationship had the sensitivity to detect patients with low S/P scores. However, none of the four domains were able to differentiate low versus high values of Kt/V, which is the usual indicator of dialysis dose and associated with the mortality of dialysis patients,[43,44] although some disagree.[45] As previous reports suggested that QOL may be associated with mortality in HD patients,[43,44] future studies are needed to test this hypothesis and should include the environment domain.

There were several limitations in this study. It was a cross-sectional survey and responsiveness could not be assessed. Only 20 HD patients were

recruited for the test–retest reliability study, and mixed results were found for self-administered and interviewer questionnaires, which might introduce some selection bias to our sample. However, our study results pertaining to reliability and validity were not worse than that of comparable studies which used WHOQOL-BREF(TW) in a normal population[29] and an AIDS patient population.[37] Because only subjects whose conditions were sufficiently stable to complete questionnaires or who could tolerate interview survey were recruited, the final sample might not have included many patients with severe comorbid conditions, and the QOL scores might, thus, have been overestimated. Moreover, the relative homogeneity of our sample might have precluded the demonstration of a clear clinical sensitivity to detect low Kt/V. In conclusion, the dialysis module for WHOQOL-BREF(TW) is a reliable and valid instrument to evaluate QOL and to serve as a basis for cross-disease, cross-culture comparison. Longitudinal study of this module is needed to assess its responsiveness.

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