Development and Validation of an Instrument for the Measurement of Health-Related Quality of Life Based on View of Traditional Chinese Medicine Perspective

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Abstract

Objectives: The objectives of this study were to develop and validate an instrument for the measurement of health-related quality of life (HRQoL) based on view of Traditional Chinese Medicine (TCM). Design: Six domains of questions, five questions for each domain were developed about general health, and health of five major viscera according to TCM theory to measure the HRQoL. Settings: 149 patients participated in this study and all of them were interviewed in the TCM clinic of a medical center. Interventions: When interviewing, these patients’ health conditions of the five viscera were rated by a TCM physician without knowledge of the patient’s answers. A telephone interview was conducted one week later as a retest. Main outcome measures: Test-retest reliability (intraclass correlation coefficient, ICC), internal consistency (Cronbach’s alpha coefficient), and the ability to differentiate the health conditions in each domain of the patients were assessed. Results: The test-retest reliability coefficients of the six domains ranged from 0.46 for spleen to 0.69 for liver-male and kidney. The internal consistency coefficients of the six domains varied from 0.38 for spleen to 0.72 for heart. All scales except that of liver for females could significantly classify different health conditions (evidence of abnormality) assessed by TCM physicians. Ten factors were identified through factor analysis. Some items were found to be correlated with more than one domain. Most domains in the questionnaire had fair test-retest reliability and fair to good internal consistency, and could differentiate patients’ health conditions. The low internal consistency of the spleen scale and the inter-related scale structures needs further evaluation.

Keywords: Quality of life, Traditional Chinese Medicine, Validation

Introduction

Traditional Chinese medicine (TCM) has always been the major branch of complementary and alternative medicine (CAM) in East Asia, there is the need to develop a reliable tool for the evaluation of its clinical

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The current focus in medicine is expanded from the presence of disease solely to the state of general well-being perceived subjectively by the individual. From the view of Patrick and Erickson, absence of disease is not enough to define the health-related quality of life. Daily functioning and psychosocial factors should also be considered (Patrick and Erickson, 1993). Generic quality of life questionnaires that are widely used today (i.e. WHOQoL (The WHO Group, 1995), SF36 (Ware, 1993), etc) contain many questions related to what Chinese Medicine refers to as aspects of mind and spirit. TCM considers health as, not merely a disease-free state of the physical being, but as an optimal balance of both physiological and emotional well-being (Beijing University of Traditional Chinese Medicine, 1998). Nevertheless, these questionnaires do not attempt to evaluate people’s health utilizing the TCM diagnostic tools such as evaluating appetite, elimination, facial diagnosis, and adaptability to climatic changes. This is perhaps why many TCM clinical trials fail to provide statistically significant evidence for their treatment outcomes when using these questionnaires in their research studies.

In clinical practice, many TCM practitioners utilize bowel and visceral pattern identification to diagnose and treat their patients and evaluate treatment outcomes (Beijing University of Traditional Chinese Medicine, 1998). Many signs and symptoms we see clinically cannot be explained as solely physiological or psychological phenomena, but can often be grouped in terms of particular visceral organ pathologies. The visceral manifestation theory best represents the TCM view of the body as an integrated whole. Therefore we have selected bowel and visceral pattern identification as the basic guideline of this questionnaire.

The primary objective of this study is to take the first step to the development and validation of a questionnaire tailored for clinical and research purposes in TCM.

**Development of questionnaire**

The HRQoL questionnaire based on TCM perspective should be short, clear and representative for TCM concepts, while different from that based on western concept of health. After literature review and professional consultation, we decided to focus on five domains for major viscera (heart, liver, spleen, lung, and kidney) plus one domain for general health according to TCM theory. Five questions for each scale were further generated after several sessions of professional meetings and discussion. Four-point Likert’s scale (1 to 4) was used for each question to assess the patient’s self-reported condition. Positive and negative questions were mixed. Before scoring, answers were reversed in negative items. The score in each domain was then transformed into a 0-100 score by the following equation: \[ \frac{\sum \text{(answer - 1)} / 3 \times \text{items answered}}{\text{items answered}} \times 100. \]

Only those scales with more than half of whose items were answered were counted. The questionnaire was pre-tested on 20 patients and revised according to their comments. Professionals were also consulted before finalization.

**Patients and Methods**

One hundred and forty nine consecutive patients visiting the TCM clinic of Chang Gung Memorial Hospital, a medical center in northern Taiwan were interviewed. Patients completed the questionnaires primarily by themselves. Two trained research nurses helped those who had difficulties in reading and answering the questions by reading questions and answers and let the patients choose their own answers by themselves. Health conditions of the five viscera for each patient were rated by a TCM physician without knowledge of the patient’s answers. A telephone interview was conducted one week later as a retest. Patients who refused to complete the questionnaire were excluded. The response rate was about 95%. The study was approved by the Ethics Committee of the Chang Gung Memorial Hospital.

**Sample size estimation**

The sample size was firstly based on Tabachnik and Fidell’s recommendation (Tabachnik and Fidell, 1993) that for multivariate analysis the sample size should be 5 to 10 times of the variables (items). We have 30 questions, therefore estimated a need to recruit 150 patients. Secondly, for known group comparison, assuming that the standard deviation of the questionnaire-derived QOL score is 20, the sample size required for each group is 50 subjects in order to achieve 80% power for detecting a difference of ten points between two groups at the 5% significant level for a one-sided Z-test.

**Statistical analysis**

Test-retest reliability was examined with intra-
class correlation coefficient, ICC. Internal consistency was examined with Cronbach’s alpha coefficient. The ability to differentiate the health conditions (evidence of abnormality or not) of the patients for each scale were assessed by Student’s t-test. Exploratory factor analysis with varimax method was used to test the factor structure of the questionnaire. A p-value of < 0.05 was considered as statistically significant.

**Results**

A total of 150 patients were interviewed. We excluded one patient under the age of 15 years. The age was 49 ± 15 years. Most of the patients were female (65.1%), married (80.5%), and fulltime workers (58.5%). The educational levels were higher than general population in Taiwan (27.5% were college or above). Most of the major diagnoses related to the musculoskeletal system (28.9%), followed by the digestive system (14.1%) (Table 1).

The test-retest reliability coefficients of the six domains ranged from 0.46 for spleen to 0.69 for liver-male and kidney. The internal consistency coefficients of the six domains ranged from 0.38 for spleen to 0.72 for heart. The scale of spleen had a fair test / retest reliability coefficient (0.46) but low coefficient for internal consistency (0.38). Both the test-retest reliability and internal consistency coefficients for the liver scale for male were higher than the counterpart for female (0.69 vs. 0.51 and 0.67 vs. 0.44, respectively). The Cronbach’s alpha coefficient increased to 0.48 after

| Domain     | Test-retest reliability | Internal consistency |
|------------|-------------------------|----------------------|
| General    | 0.65                    | 0.51                 |
| Heart      | 0.61                    | 0.72                 |
| Liver for male | 0.69                  | 0.67                 |
| Liver for female | 0.51                 | 0.44                 |
| Spleen     | 0.46                    | 0.38                 |
| Lung       | 0.59                    | 0.49                 |
| Kidney     | 0.69                    | 0.65                 |

* * Intraclass correlation coefficients, Cronbach’s α

| Item          | Item to scale | Content                        |
|---------------|---------------|--------------------------------|
| General       |               |                                |
| RV3           | 0.09          | Heat sensation                 |
| RV4           | 0.29          | Intolerance of cold            |
| Liver for female |            |                                |
| V13           | 0.21          | Musculoskeletal wellbeing       |
| V14           | -0.10         | Smooth menstruation            |
| RV15          | 0.20          | Slow reaction                  |
| Spleen        |               |                                |
| RV17          | -0.04         | Rapid hungering                |
| V20           | 0.14          | Smooth stool passage           |
| Lung          |               |                                |
| V21           | 0.29          | Smooth breathing               |
| RV23          | 0.25          | Tendency to catch cold         |
| V24           | 0.20          | Ability to speak load          |
| RV25          | 0.24          | Nasal allergy                  |
| Kidney        |               |                                |
| RV26          | 0.21          | Sexual dysfunction             |
| V27           | 0.24          | Smooth voiding                 |

Table 3. Known Groups Comparison of Five TCM QOL Scales Based on TCM Physicians’ Assessment

| Variable / Evidence of abnormality | N (%) | Mean ± S.D. | p-value |
|-----------------------------------|-------|-------------|---------|
| Heart *                           |       |             |         |
| Positive                          | 36 (24.3) | 71.9 ± 14.8 | 0.0311 |
| Negative                          | 112 (75.7) | 78.6 ± 16.5 |
| Liver-male                        |       |             |         |
| Positive                          | 38 (73.1) | 56.6 ± 20.1 | 0.0095 |
| Negative                          | 14 (26.9) | 69.0 ± 11.0 |       |
| Liver-female                      |       |             |         |
| Positive                          | 92 (94.8) | 51.6 ± 14.9 | 0.3790 |
| Negative                          | 5 (5.2) | 45.7 ± 10.8 |         |
| Spleen                            |       |             |         |
| Positive                          | 83 (55.7) | 68.4 ± 14.5 | 0.0050 |
| Negative                          | 66 (44.3) | 75.4 ± 15.1 |       |
| Lung                              |       |             |         |
| Positive                          | 89 (59.7) | 62.3 ± 17.7 | 0.0002 |
| Negative                          | 60 (40.3) | 73.1 ± 15.8 |       |
| Kidney                            |       |             |         |
| Positive                          | 63 (42.3) | 59.4 ± 16.9 | <0.0001 |
| Negative                          | 86 (57.7) | 71.6 ± 17.6 |       |

* One data missing
Positive: positive finding in assessment by TCM physician
Negative: without positive finding
excluding question 14 for smooth menstruation (absence of dysmenorrhea) (Table 2). Items with low item-to-scale correlation in each domain are shown in Table 3. Items with extremely low item-to-scale correlation include: item 3 (heat sensation, general scale, 0.09), item 14 for female (smooth menstruation, liver scale, -0.10), item 17 (rapid hungering, spleen scale, -0.04), and item 20 (smooth stool passage, 0.14).

All scales except that of liver for females could significantly classify different health conditions (evidence of abnormality) assessed by TCM physicians (Table 4).

Ten factors were identified through factor analysis. Some items were found to be correlated with more than one domain. The scales with higher internal consistency, such as kidney and heart, remained relatively integrated. In contrast, the items in the spleen scale were separated in different factors (Table 5).

### Discussion

This study is conducted in a TCM clinic. Disease categories most often encountered in this clinic (eg. RA, SLE, Sjögren’s Syndrome) are characterized by female preponderance and with musculoskeletal symptoms. Validation of this questionnaire in a healthy population in the future may be needed for comparison. Table 2 showed spleen scale had the lowest test/retest reliability and internal consistency. Most anti-inflammatory medication prescribed for patients of rheumatic illness, such as steroid or NSAID or some Chinese herbal medicine, are notorious for their role in gastrointestinal disturbances. These gastrointestinal tract disturbances are often corrected effectively after treatment with TCM methods for one week which may be the reason for the lower test-retest reliability score for spleen, comparing with other 4 viscera scale. The item to scale correlation of questions 17 and 20 are fairly low. This is perhaps due to the opposing direction of question 16 and 17, and question 18 and 19. Question 16 and 17 are related to spleen and stomach heat, which is considered a hyperfunctional or excess condition. Question 18 and 19 are related to accumulation and stagnation from poor transformation and transportation of food which is viewed in Chinese Medicine as a dysfunction of the spleen. Because the average age of our subject population is 49, it is not surprising that very few subjects have hyperfunctional digestion.

The part of questionnaire related to spleen may be also need to be revised in the future to adjustments.

Table 3 demonstrates the low (<0.3) item to scale correlation of musculoskeletal symptoms in the “liver for female” section (0.49 in “liver for male”) and very low (-0.1) item to scale correlation of smooth menstruation in the “liver for female” section. But in TCM theory, musculoskeletal symptoms is often linked with liver viscera, and a healthy liver viscus is essential for smooth menstruation. Why there’s differences in different sex about musculoskeletal symptoms need further study. The true relationship between liver viscera and menstruation need more study.

### Table 5. Rotated Factor Pattern of TCM questions by Varimax Method After Excluding Question 14 (Menstruation)

| Factor / questions | Factor | Original domain | Focus of item |
|--------------------|--------|-----------------|---------------|
| Item-factor         | Item-factor correlation |                   |
| **Factor 1**        |        |                 |               |
| Rv29*               | 0.82231| Kidney          | Poor memory   |
| Rv30                | 0.75707| Kidney          | Poor endurance for activity |
| Rv15                | 0.75068| Liver           | Slow reaction |
| Rv28                | 0.63507| Kidney          | Back pain, knee weakness |
| Rv1                 | 0.53595| General         | Fatigue, poor concentration |
| **Factor 2**        |        |                 |               |
| Rv8                 | 0.83757| Heart           | Oppression in the chest |
| Rv7                 | 0.78473| Heart           | Palpitations   |
| Rv9                 | 0.69799| Heart           | Chest pain    |
| Rv6                 | 0.58426| Heart           | Dizziness     |
| **Factor 3**        |        |                 |               |
| V27                 | 0.74953| Kidney          | Smooth voiding |
| V20                 | 0.68290| Spleen          | Smooth defecation |
| V24                 | 0.54554| Lung            | Able to speak loud |
| V21                 | 0.50402| Lung            | Smooth breathing |
| **Factor 4**        |        |                 |               |
| V11                 | 0.77556| Liver           | Mood stability |
| V13                 | 0.69633| Liver           | Musculoskeletal wellbeing |
| Rv10                | 0.45967| Heart           | Restlessness, irritability |
| **Factor 5**        |        |                 |               |
| Rv19                | 0.71920| Spleen          | Abdominal fullness |
| Rv18                | 0.49678| Spleen          | Poor appetite  |
| V2                  | 0.39224| General         | Cheerful      |
| **Factor 6**        |        |                 |               |
| Rv25                | 0.77778| Lung            | Nasal allergy |
| Rv23                | 0.67955| Lung            | Tendency to catch cold |
| V12                 | 0.53208| Liver           | Ability to sleep well |
| **Factor 7**        |        |                 |               |
| Rv5                 | 0.82095| General         | Dry eyes and mouth |
| Rv4                 | 0.55367| General         | Sensitive to cold |
| Rv16                | 0.45481| Spleen          | Bitter taste in the mouth, halitosis, mouth sores |
| **Factor 8**        |        |                 |               |
| Rv26                | 0.83320| Kidney          | Sexual dysfunction |
| Rv22                | 0.42863| Lung            | Dyspnea       |
| **Factor 9**        |        |                 |               |
| Rv3                 | 0.62701| General         | Feel hot      |
| **Factor 10**       |        |                 |               |
| Rv17                | 0.83070| Spleen          | Easy hungering |

* R: reverse coding
Table 4 showed the scoring of liver visceral manifestation and quality of life to be opposite from evaluations by Chinese Medicine practitioners in female subjects. (Female subjects with problematic liver visceral manifestations diagnosed by Chinese Medicine practitioners tend to turn out to have a higher quality of life scoring related to their liver pathology. However, the discrepancy is not statistically significant.) The following are some possible explanations: 1. Even when there are minor signs of liver visceral pathology, scores by the Chinese Medicine practitioners tend to be recorded as “positive”. The patients may not feel any physical symptoms; therefore their overall quality of life scores related to liver visceral manifestation remain high. This also showed that the five questions in the liver section have low item to scale correlation. 2. Patients do not fully understand the wording of the questions. Take question number 15 as an example. “Do you feel your reaction is slow?” This question was intended for patients who are easily fatigued, and often complain of muzzy headedness and lethargy. However many of these patients may not think of themselves as being slow in their reaction. Another example is the question: “Do you feel you have good range of motion, and do your joints move smoothly?” However, many patients that complain of constant tightness in the neck or backache may not think that these discomforts limit their movements. We believe that the item to scale correlation may be improved in this case if we change the wording to make these questions more clear. 3. Too few female subjects received a “negative” score in this survey. However these speculations cannot clearly explain why these problems do not exist in male subjects. Perhaps the score of question 14 interfered with the analysis.

Table 5 shows the 10 factors from the factor analysis. Factors 8, 9 and 10 should be eliminated before further analysis because they only contain 1 or 2 questions. Factor analysis is not a valid base for groupings of the questions. This is because visceral manifestation is the basis of this questionnaire, and in Chinese Medicine, visceral manifestations of the organs are not independent from each other. Each viscera has engendering and restraining relationships to all the other viscera. Factor analysis is dependent on whether we can relate each grouping of questions from a Chinese Medicine perspective and create a new and reasonable correlation between the questions.

Take factor 1 as an example. The 5 questions included in factor 1 actually belong to 3 different scales – the kidneys, liver, and overall scales that include evaluating criteria such as memory, endurance, and responsiveness. They also include symptoms such as soreness and weakness of the lumbus and knees, fatigue, and inability to concentrate. Abnormalities in these areas can also be merely a result of kidney visceral pathology. This is a reasonable explanation especially considering our subject population. This questionnaire showed a fair amount of credibility and efficacy after this pioneer testing. Therefore, we can say that there is no major structural problem in the way it is designed. Nevertheless, to increase the practicality of this questionnaire we should gather a subject base with a more diversified age group and a wider range of health conditions, and continue to modify and improve the factor analysis.

This questionnaire is a generic health related quality of life questionnaire (HRQoL), using “the visceral pattern identification theory” as framework, although one study mentioned that the philosophy of balance between Yin-yang is the theoretical bases of health in TCM. The “visceral pattern identification theory” should be viewed as clinical reasoning tool for classifying syndromes and for diagnosis illness, which means it’s concept of disease not concept of health. So this theory should not be the framework of a HRQoL (Leung et al., 2005). We think as long as we can use “the visceral pattern identification theory” to evaluate the health condition of each major viscera, we are able to evaluate one’s health condition. Because TCM is a holistic kind of philosophy, all the viscera connect to each other, interfere with each other, only when establish balance, one person can be relatively healthy. This is why we choose “the visceral pattern identification theory” as framework. Besides, this theory is widely used in TCM physicians’ daily practice, which may increase this utility of the HRQoL. Therefore, we think that a questionnaire like this is appropriate and useful.

TCM is different from modern medicine in that many “patterns” are identified under the same “disease” category. Each pattern is descriptive of specific imbalances in different energy systems, which may be manifested as disturbances in the integral body function. More studies in different disease and pattern categories may shed light to future development of TCM questionnaires, enhancing the understanding of the clinical efficacy of TCM.

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