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ORIGINAL ARTICLE

Validity of the Traditional Chinese Version of the King's Health Questionnaire for Taiwanese Patients With an Overactive Bladder

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Objective: In this study, we tested the validity of the 2009 Chinese version of the King's Health Questionnaire (KHQ) in patients with an overactive bladder (OAB).
Materials and Methods: In 2009, the Taiwan Continence Society commenced linguistic validation and other elements of production required for a Chinese version of the KHQ. Data for the psychometric assessment came from a multicenter clinical trial. Patients who visited urology clinics with OAB and symptoms of urgency frequency with or without urge incontinence were asked to fill out the KHQ at the initial visit and again 1 week later. The internal consistency was measured by Cronbach's alpha statistics. The test–retest method was used to compare the reliability of responses of the two completed questionnaires using Spearman's rank correlation coefficient. An alpha value >0.70 was considered acceptable.
Results: In total, 55 patients were enrolled, including 37 women and 18 men. Forty-seven (85.5%) patients correctly completed both questionnaires. The alpha values exceeded the minimum requirement for reliability in all domains of the questionnaire, except for the severity measure item (0.60). The internal consistency was also consistently high between tests 1 and 2 in all domains. Test–retest reliability also showed significant correlations between the two tests in all domains.
Conclusion: This study demonstrates that the 2009 Chinese version of the KHQ is a reliable instrument for assessing health-related quality of life in patients with OAB.

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1. Introduction

An overactive bladder (OAB) is defined by the International Continence Society as a complex of symptoms characterized by urinary urgency, with or without urge incontinence, usually with frequency and nocturia.[1] OAB greatly affects physical and social functioning, including work, sleep, and sexual and interpersonal relationships.[2,3] These symptoms can cause great discomfort, embarrassment, loss of confidence, and withdrawal from social life.[4,5] Patients often develop a variety of coping behaviors and strategies; for example, because of symptom frequency, OAB patients usually reduce water (fluid) intake and limit daily activities to avoid discomfort.[6] To minimize the potential for embarrassment from incontinence episodes, OAB patients may wear protective garments,

use pads, and carry a change of clothing.[4] Daily activities, including hobbies, household chores, and physical recreation, are often scheduled around the location of toilets to avoid potentially embarrassing situations.[7] OAB, especially in patients with urge incontinence, eventually has a negative impact on health-related quality of life (HRQoL).

Even though OAB is diagnosed by symptoms only, its assessment is very important for patients and physicians, especially for evaluating treatment effectiveness. Multi-item questionnaires were introduced to evaluate the impact of OAB and treatment outcomes.[8–10] On the other hand, there is no disease-specific HRQoL instrument that serves as a gold standard for OAB patients.[7] Kelleher et al.[11] published the King's Health Questionnaire (KHQ), which covers dimensions of importance to OAB patients, particularly urgency and frequency. The KHQ was developed with patient input and has been validated in a large cohort of incontinent women.[11] Reese et al.[7] evaluated the psychometric properties of the KHQ. Their study supported the reliability, validity, and responsiveness to change of the KHQ to treatment-induced changes in HRQoL in a clinical trial. The authors suggested that it is reasonable to employ the KHQ in other studies assessing disease-specific HRQoL in patients with OAB.[7]

1.1. KHQ in traditional Chinese (2009 Chinese version of the KHQ, Taiwan)

The KHQ is now widely accepted as a useful instrument for evaluating HRQoL of OAB patients. There was a need to translate and validate the questionnaire in Chinese so that it would be available for use in Taiwanese patients. Linguistic validation is the first step and a very important part of the cultural adaptation of a questionnaire. In 2006, Acquadro et al.[12] translated the OAB-q into 14 languages. The process included six steps: (1) two forward translations; (2) comparison and reconciliation of the translations; (3) back-translation; (4) comparison of the source and back-translation; (5) review by a urologist or gynecologist; and (6) a comprehension test, using patients.

In 2009, the Taiwan Continence Society commenced linguistic validation and other elements of production required for a Chinese version of the KHQ (Appendix).

2. Materials and Methods

2.1. Translations and back-translations

Two forward translations were prepared: one version was translated by a urologist (H.C. Kuo), and another version was translated by experts of a translation company. Comparison and reconciliation of the translations were performed by urologists in expert meetings via an Internet Skype conference (hosted by H.C. Kuo) in Taiwan. The back-translated KHQ was emailed to C.J. Kelleher (the first author of the KHQ) for comparison of the source and back-translation. The final KHQ in traditional Chinese was reviewed by a urologist (H.C. Kuo).

2.2. Patients

Data for the psychometric assessment came from a multicenter clinical trial. All patients visited urology clinics with OAB and symptoms of urgency frequency with or without urge incontinence. Patients had not been treated with any type of antimuscarinics before the test. If they were taking antimuscarinics, the medicine had to be discontinued for more than 2 weeks. Urinalysis was performed on patients, and they were proven to be free of active urinary tract infection. Each patient or his/her legally acceptable representative agreed to participate in the KHQ study. Patients with urinary retention and urodynamically-proven detrusor underactivity, those with a postvoid residual >150 mL, those with a neurogenic bladder that limited ambulation, and patients who could not record the KHQ were excluded.

All patients were asked to fill out the KHQ. We requested that patients fill out the questionnaire by themselves. One study nurse provided instructions to the patients before they began to fill out the questionnaire. No medication that might affect lower urinary tract function, such as antimuscarinics, alpha-blockers, tricyclic antidepressants, tranquilizers, sedatives, 5-alpha-reductase inhibitors, or baclofen was prescribed. An appointment was made 1 week after the initial visit, and a repeat KHQ was completed by all enrolled patients. Before the repeat questionnaire was completed, patients were questioned about changes in their symptoms. If there were significant changes, they were excluded from the study.

2.3. Validation of the Chinese version of the KHQ

The Chinese version of the KHQ includes three parts: (1) part 1—general health perceptions and incontinence impacts; (2) part 2—impacts associated with urinary symptoms, including role limitations, physical limitations, social limitations, personal relationships, emotional problems, and sleep/energy disturbances; and (3) part 3—severity measurements. This questionnaire has been widely used to assess HRQoL with urinary incontinence.

Validation of the questionnaire was assessed by its internal consistency, and by measuring its test–retest reliability. The internal consistency was measured by Cronbach's alpha statistics. Internal consistency refers to the degree of correlation among items forming a scale. It is expected that items forming a domain of the questionnaire should be moderately correlated with each other but should independently contribute to the overall score in that domain. It was suggested that an alpha value ≥ 0.7 is acceptable.[13] The test–retest reliability compared the responses to the two completed questionnaires using Spearman's rank correlation coefficient. The interval between the two visits should not be too short

in case a patient remembers what he/she had answered in the first questionnaire. We chose 1 week as an appropriate interval to ensure that the urinary symptoms were unchanged.

3. Results

In total, 55 patients were enrolled, including 37 women and 18 men. Their mean age was 56±17 years (range, 37–80 years). Forty-seven (85.5%) patients correctly completed both questionnaires. The other eight patients did not return for the repeat questionnaire. All patients felt that the questionnaire was easy to understand and complete.

3.1. Internal consistency

Values of internal consistency using Cronbach's alpha are listed in Table 1. Alpha values exceeded the minimum requirement for reliability in all domains of the questionnaire, except for the severity measure item (0.60). Good internal consistency was also shown between tests 1 and 2 in all domains.

3.2. Test–retest reliability

Test–retest reliability also showed significant correlations between the two tests in all domains. The mean and standard deviation of the individual domain scores and the correlation of the two test results are shown in Table 2.

4. Discussion

This study is the first multicenter validation study of a questionnaire concerning lower urinary tract dysfunction under sponsorship of the Taiwan Continence Society. This study demonstrated that the 2009 Chinese version of the KHQ is a reliable instrument for assessing the HRQoL of patients with OAB. The high rate of repeat questionnaire completion suggests that this questionnaire is easy to understand and answer.

Urinary incontinence is a complex problem resulting from many different causes. It is also complex because of the different ways and varying severities with which it affects the lives of sufferers. Urinary symptoms affect the physical, psychological, social, domestic, and interpersonal aspects of patients with OAB.[14] Assessing the impact of

Table 1 Internal consistency of the Chinese version of the King's Health Questionnaire (KHQ) for overactive bladder in 47 patients*

KHQ domain	Items (*n*)	Test 1	Test 2	Internal consistency
General health perceptions	1	52.66±18.96	48.40±18.36	–
Incontinence impacts	1	68.09±34.72	57.45±30.06	–
Role limitations	2	28.26±34.76	25.69±30.06	0.92
Physical limitations	2	32.25±31.51	27.31±29.57	0.92
Social limitations	3	24.88±31.88	22.95±29.01	0.86
Personal relationships	2	20.71±31.74	16.67±24.27	0.92
Emotions	3	40.19±32.89	35.22±30.94	0.92
Sleep/energy	2	41.49±29.26	32.62±23.56	0.70
Severity measure	5	18.72±14.35	17.59±18.25	0.60
Symptom severity	11	18.47±12.69	16.01±13.98	0.70

*Data presented as mean±standard deviation.

Table 2 Test–retest reliability analysis of the Chinese version of the King's Health Questionnaire (KHQ) in 47 patients*

KHQ domain	Test 1	Test 2	Rho	Correlation coefficient
General health perceptions	52.66±18.96	48.40±18.36	0.676†	0.81
Incontinence impacts	68.09±34.72	57.45±30.06	0.777†	0.87
Role limitations	28.26±34.76	25.69±30.06	0.745†	0.85
Physical limitations	32.25±31.51	27.31±29.57	0.669†	0.80
Social limitations	24.88±31.88	22.95±29.01	0.692†	0.82
Personal relationships	20.71±31.74	16.67±24.27	0.641†	0.77
Emotions	40.19±32.89	35.22±30.94	0.715†	0.83
Sleep/energy	41.49±29.26	32.62±23.56	0.604†	0.74
Severity measure	18.72±14.35	17.59±18.25	0.755†	0.85
Symptom severity	18.47±12.69	16.01±13.98	0.624†	0.74

*Data presented as mean±standard deviation; †$p<0.01$.

urinary symptoms on HRQoL should focus on different lifestyle aspects.

Evaluating the severity of urinary symptoms usually involves a record of symptom scores or a voiding diary, or is based on urodynamic study. Although these measures may provide valuable information regarding the type and severity of bladder dysfunction, they might not reflect the impact of urinary incontinence on patients' lives. Therefore, an evaluation and assessment of the impact of urinary symptoms on the QoL of different voiding dysfunctions should be standardized, such as in OAB syndrome.[15]

There are a number of different validated QoL questionnaires that have received widespread acceptance and endorsement for assessing men and women with urinary incontinence, and they have been used in clinical trials of continence care.[8–11] Among these questionnaires, the KHQ is considered to be good at addressing patients' concepts of the disease burden and may reflect real-life inconvenience due to urinary symptoms.[11] Therefore, we tried to validate this questionnaire in the Chinese language for future clinical studies in Taiwan.

The results of this study demonstrated that the Chinese version of the KHQ was excellent in terms of its internal consistency and test–retest reliability. Scores on the repeat questionnaire tended to be lower than those on the first one, but the difference was not statistically significant. The cause of the lower scores on the second questionnaire might have been due to a placebo effect after consultation with a urologist for OAB symptoms. Nevertheless, the first and second tests both showed high internal consistency, and the correlation between the two tests was excellent, suggesting that the Chinese version of the KHQ can be accepted for assessing the impact of urinary symptoms on the QoL of Taiwanese patients.

The main limitation of this study was the small number of patients tested. However, since this study attempted to prove the validity of the traditional Chinese version of the KHQ, a small cohort such as 40 with an alpha value ≥ 0.7 should be adequate. Furthermore, we did not perform a validation test because several linguistic translations of the original KHQ have been validated and adapted. It is thus not necessary to repeat the validation test. The validity of this KHQ Chinese version was proven by the good internal consistency and test–retest reliability in this study.

5. Conclusion

This study demonstrates that the 2009 Chinese version of the KHQ is a reliable instrument for assessing the HRQoL of patients with OAB. A high internal consistency in all domains of the questionnaire and good test–retest reliability were noted for this Chinese version of the KHQ.

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Appendix

金氏健康問卷

1. 您會如何描述您目前的健康狀況？(請勾選一個答案)
   □非常好　□好　□尚可　□不好　□非常不好

2. 您覺得膀胱問題對生活的影響多少？(請勾選一個答案)
   □完全不會　□很少　□中等　□非常多

下列日常活動可能受到膀胱問題影響。膀胱問題對您有多大影響？請您逐一回答下列問題。只要在您適用的空格打勾。

	1 完全不會	2 輕微	3 中等	4 非常多
3. 角色受限				
A. 您的膀胱問題是否會影響您的家務工作？(打掃、購物等).....	□	□	□	□
B. 您的膀胱問題是否會影響工作或是在家以外的正常活動？.....	□	□	□	□
4. 身體/社交受限	1 完全不會	2 輕微	3 中等	4 非常多
A. 您的膀胱問題是否會影響您的身體活動(例如：散步、跑步、運動、健身等)？.....	□	□	□	□
B. 您的膀胱問題是否會影響您的旅行能力？.....	□	□	□	□
C. 您的膀胱問題是否會限制您的社交生活？.....	□	□	□	□
D. 您的膀胱問題是否會限制您拜訪朋友？.....	□	□	□	□

	0 不適用	1 完全不會	2 輕微	3 中等	4 非常多
5. 人際關係					
A. 您的膀胱問題是否會影響您和伴侶的關係？.....	□	□	□	□	□
B. 您的膀胱問題是否會影響您的性生活？.....	□	□	□	□	□
C. 您的膀胱問題是否會影響您的家庭生活？.....	□	□	□	□	□

	1 完全不會	2 輕微	3 中等	4 非常
6. 情緒				
A. 您的膀胱問題是否會讓您感到沮喪？.....	□	□	□	□
B. 您的膀胱問題是否會讓您感到焦慮或緊張？.....	□	□	□	□
C. 您的膀胱問題是否會讓您感到自己很糟糕？.....	□	□	□	□

	1 從來不會	2 偶爾	3 經常	4 一直都是
7. 睡眠/活力				
A. 您的膀胱問題是否會影響您的睡眠？.....	□	□	□	□
B. 您的膀胱問題是否會讓您感到精疲力竭而且疲倦？.....	□	□	□	□

	1 從來沒有	2 偶爾	3 經常	4 一直都是
8. 您會做以下行為嗎？如果有，頻率如何？				
A. 穿著護墊以保持乾爽？.....	□	□	□	□
B. 留意喝多少水？.....	□	□	□	□
C. 因為尿濕而更換內褲？.....	□	□	□	□
D. 擔心自己可能發出異味？.....	□	□	□	□

我們想要了解您的膀胱問題，以及對您的影響有多大。從下列各項選出您目前所遭遇的問題。請略過不適用的問題。

下列問題對您有多大影響？	1 有一點	2 中等	3 非常多
頻尿：經常如廁.....	□	□	□
夜尿：夜晚起床去排尿.....	□	□	□
急尿：強烈而難以憋住的排尿念頭.....	□	□	□
急尿性失禁：伴隨著強烈排尿感而漏尿.....	□	□	□
應力性尿失禁：身體活動時漏尿（例如咳嗽、跑步）.....	□	□	□
夜間尿床：夜晚睡覺時尿床.....	□	□	□
性交尿失禁：性交時漏尿.....	□	□	□
泌尿系統感染.....	□	□	□
膀胱疼痛.....	□	□	□