

SHORT FORM OF KING'S HEALTH QUESTIONNAIRE TO MEASURE QUALITY OF LIFE IN OVERACTIVE BLADDER PATIENTS

Aims of Study

The King's Health Questionnaire (KHQ) is a disease-specific health related quality of life (QOL) instrument to measure QOL of patients in urinary incontinence. In Japan, the instrument has been translated and validated for patients with overactive bladder and urinary incontinence. The KHQ has 8 domains and 16 items are grouped in these domains. An issue of concern with the KHQ is that it seems to have too many domains to be evaluated relative to other QOL instrument in this clinical area. To develop a short version of the KHQ, we applied various psychometric analyses using data from our previous validation study of the Japanese KHQ.

Methods

The study samples were participants of a 12-week, randomised, double-blind, controlled clinical trials to evaluate efficacy and safety of tolterodine and to compare placebo and oxybutinin in patients with symptoms of overactive bladder in Japan (N=290, male/female 97/193). First we applied confirmatory factor analysis (CFA) to evaluate the underlying factor structure of the KHQ. Since General Health Perception and Incontinence Impact were single item domains, they are omitted from the CFA. One item was selected from the rest of each domain. Therefore, this KHQ short version included 6 items. Selection of items was based on standardized structural coefficients estimated by CFA. Second, based on the selected 6 items, a series of psychometric analyses were conducted. Exploratory factor analysis was conducted to explore the underlying factor structure of the KHQ and to evaluate construct validity. Cronbach's alpha was calculated as a reliability index. To evaluate the responsiveness relationship between clinical change and QOL score change during treatment, multiple regressions were applied controlling for age and gender as covariates. Second order CFA was conducted based on 6 selected items. Additionally, sensitivity of the QOL score to change in patient's perception of bladder condition from the baseline to the end of treatment was evaluated by analysis of covariates. As clinical endpoints, the relative change in mean number of incontinence episodes per week from baseline to the end of treatment, the change in mean number of micturitions per 24 hours from baseline to the end of treatment, and the change in mean volume voided per micturition to the end of treatment were selected.

Results

Confirmatory Factor Analysis based on all KHQ items

Third order factor structure was confirmed by CFA. First order factors were KHQ domains; Role Limitation (RL), Physical Limitation (PL), Social Limitation (SL), Personal Relationships (PR), Emotions (EM) and Sleep and Energy (SE). Two second order factors were identified; Limitation of Daily Life (LDL) and Mental Health (MH). RL, PL and SL were categorized in LDL. PR, EM and SE were grouped in MH. The third order factor was QOL. Household(Q1) from RL, Travel(Q2) from PL, Visit Friends(Q3) from SL, Social Life(Q4) from PR, Depressed (Q5) from EM and Tired (Q6) from SE showed higher structure coefficients and were thus selected for the KHQ short version items.

Exploratory Factor Analysis: Construct Validity

Exploratory factor analysis with Promax rotation was performed for the selected six items. Two factors LDL and MH were successfully identified.

Reliability

Cronbach's alpha coefficients for the two factors identified in exploratory factor analysis and for the total 6 items were as follows; LDL = 0.83 (male), 0.86 (female); MH = 0.70 (male), 0.69 (female); Total = 0.83 (male), 0.85 (female).

Confirmatory Factor Analysis based on selected 6 KHQ items

Second order factor structure was confirmed by CFA for selected 6 KHQ items as below.

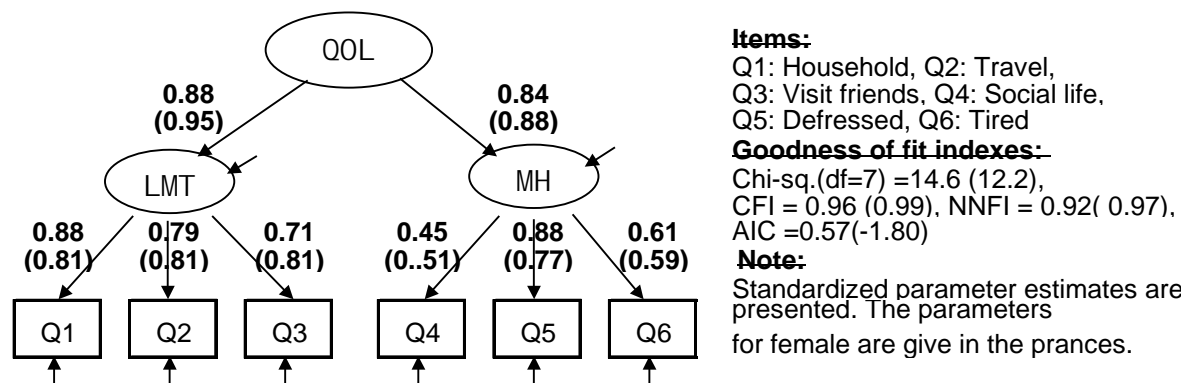


Fig.1. Second-order fator structure of selected items of King's Health Questionnaire

Clinical Validity

LDL score, MH score and the total score showed a highly significant relationship to the clinical change during treatment. Sensitivity of score change to a change in patient's perception of bladder condition from baseline to the end of treatment were excellent with all $p < 0.001$.

Conclusions

Two domains, LDL and MH, were successfully constructed for this KHQ Japanese short version. From the series of psychometric assessments, as a whole, the validity and reliability of KHQ was confirmed. It is a robust questionnaire for measuring QOL of patients with overactive bladder in clinical studies.