

## PSYCHOMETRIC PROPERTIES OF THE KOREAN VERSION OF THE OVERACTIVE BLADDER QUESTIONNAIRE (OAB-Q) IN KOREAN POPULATION

### Hypothesis / aims of study

OAB-q instrument consists of self-administered 33 items which is composed of an eight-item symptom-bother scale and 25-item HRQoL scores that constitute four subscales including coping, concern, sleep, and social interaction. Evaluation of the psychometric properties was performed, showing that U.S. English version of the OAB-q has good concurrent validity and discriminant validity, test-retest, and responsiveness [1, 2]. Proper translation and linguistic validation were conducted in 14 languages including Danish, Canadian English, French, Italian, German, and Korean [3]. To use the translated questionnaire in clinical practice as well as in the clinical research purpose, psychometric properties of the target language version should be successfully validated. To our knowledge, full validation and cross-cultural adaptation to non-English version of the OAB-q has never been demonstrated. Primary objective of this study was to investigate whether the Korean version of OAB-q is a valid and reliable questionnaire in Korean population with OAB.

### Study design, materials and methods

Prospective study involving 116 women with 58 overactive bladder (OAB) and 58 control subjects was performed. Convergent validity was assessed. Total and subscale scores of the OAB-q between control group and OAB group were compared. Internal consistency was assessed and test-retest analysis was performed. Sensitivity to score change before and after 12-week anticholinergic medication was also evaluated. Short Form 36 (SF-36), King's Health Questionnaire (KHQ), Patient Perception of Bladder Condition (PPBC), Urgency Perception Scale (UPS), ICIQ, Patient Perception of Treatment Benefit (PPTB) and bladder diary were used for comparison or correlation.

### Results

The mean age was 62.7 ( $\pm 10.2$ , *SD*) years. Assessment of face validity showed that the Korean version of OAB-q was acceptable. Significant differences were noted between scores for normal controls and the OAB patient group. All OAB-q and OAB-q Short form subscales showed sufficient discriminate validity ( $p < 0.001$ ). There were also significant differences between the two groups in all KHQ subscales. Compared with OAB-related measures, the OAB-q subscales correlated moderately with KHQ subscales ( $p < 0.05$ ). Convergent validity was acceptable with high correlation coefficients among conceptually related domains. Domains related to limitations of daily life, for example, Physical Limitations, Social Limitations, Sleep/Energy in KHQ showed high correlations with OAB-q domains. Cronbach's alpha coefficients ( $> 0.82$ ) indicated excellent internal consistency (Table 1). Test-retest analysis showed each items as well as subscale scores were reproducible. Interclass correlation coefficients for domains of OAB-q subscales and Short Form ranged from 0.55 to 0.77 (all  $p < 0.001$ ). Spearman's correlations in OAB-q HRQoL (0.69) and OAB-q short form HRQoL indicated a strong association between participant responses to each of the visit 1 and visit 2 ( $p < 0.001$ ). Analysis of each items of OAB-q indicated that the response between the two visits remained stable. A total of 35 OAB patients started anticholinergic medication and 27 patients completed followup. The OAB-q scale except Social and OAB-q Short Form demonstrated significant change ( $p < 0.001$ ) (Table 2). Effect sizes of the OAB-q subscales from baseline to week 12 ranged from 0.57 to 1.48. All subscales except subscale of Social showed large effect size. The standardized response mean also demonstrated the same pattern as the effect sizes.

Table 1. Internal consistency of OAB-q at Visit 1

		Number of items	Cronbach's $\alpha$ (N=58)
OAB-q	Symptom Severity	8	0.82
	Coping	8	0.87
	Concern	7	0.87
	Sleep	5	0.86
	Social	5	0.86
	HRQL Total	25	0.95
Short Form	Symptom Severity	6	0.77
	HRQL Total	13	0.90

Table 2. Effect size and standardized response mean for OAB-q scales: baseline to week 12

$\Delta$ OAB-q*	Effect size	Standardized response mean
Symptom Severity	-1.48	-1.55
Coping	0.91	0.95
Concern	0.86	0.64
Sleep	0.88	0.73
Social	0.57	0.36

HRQL Total	0.89	0.78
<b>Short Form</b>		
Symptom Severity	-1.24	-1.29
HRQL Total	1.04	0.88

#### Interpretation of results

In this study, full-scale psychometric properties, including content/face validity, discriminant validity, convergent validity, internal consistency, test-retest analysis, and responsiveness of the Korean version of the OAB-q was evaluated in Korean population. The OAB-q and OAB-q SF was validated in two distinct samples, controls and patients, with distinct results from both samples, thus providing evidence of discriminant validity. There were also significant differences in the KHQ subscales except for personal relationships. Significant differences were consistently found between controls and patient groups in PPBC, UPS, ICIQ. The SF-36 has been used extensively as an indicator of HRQoL, and its reliability and validity are well documented. However, convergent validity study showed that correlations between the OAB-q scores and SF-36 in OAB patients were relatively lower. This might be because SF-36 is a generic questionnaire, not a disease-specific one. Our previous study demonstrated that the generic QOL instrument is not a sensitive tool for measuring QOL than more condition-specific measure in patients with urinary incontinence. Our test-retest analysis showed each items as well as subscale scores were highly reproducible. Correlation analyses suggest a strong association between OAB-q scores at the visit 1 and the visit 2. Cronbach's alpha coefficients indicated excellent internal consistency. The usefulness of a patient-reported outcome measure depends not only on its validity and reliability, but also on its ability to detect treatment-related change over time. Effect size, standardized response mean from baseline to week 12 in this study showed OAB-q is a very sensitive tool to detect relatively small subjective symptomatic changes that occurred between two visits.

#### Concluding message

The results of this study support reasonable level of psychometric properties of the Korean version of OAB-q for use in patients with overactive bladder. This study showed the usefulness of the Korean version of OAB-q, which is essential tool for the growing need for the international clinical trials and various clinical researches on the OAB condition.

#### References

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<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Seoul National University Hospital</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>