

## ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH OVERACTIVE BLADDER TAKING TOLTERODINE EXTENDED RELEASE VERSUS PLACEBO

### Hypothesis / aims of study

Urinary incontinence (UI) and overactive bladder (OAB) have a negative impact on the well-being and health-related quality of life (HRQL) of patients. There are multiple HRQL scales available for assessing the disease impact of UI and OAB. The King's Health Questionnaire (KHQ) was developed primarily for UI in women [1] and has been used in many OAB studies. The OAB Questionnaire (OAB-q) is a validated tool that has been specifically developed to assess HRQL outcomes in OAB [2]. This is the first time the treatment responsiveness of the OAB-q and the KHQ have been compared in the same study.

### Study design, materials and methods

This was a 12-week, randomized, placebo-controlled study of tolterodine extended release (TER; 4 mg QD) in patients with OAB. Eligible patients (aged  $\geq 18$  y) had frequency ( $\geq 8$  micturitions/24 h) and urgency with or without urgency incontinence for  $\geq 6$  months. In addition to micturition diaries, patients completed the 33-item OAB-q, which contains a Symptom Bother (8 items) and an HRQL scale (25 items). For Symptom Bother, responses to the question, "How bothered are you by. . . ?" were answered on a 6-point scale from 1 (not at all) to 6 (a very great deal). For HRQL items, responses to the question, "How often have your bladder symptoms made you. . . ?" were answered on a scale from 1 (none of the time) to 6 (all of the time). The KHQ consists of 7 multi-item domains: role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy, and severity measures that are scored from 0 (best) to 100 (worst). Two 1-item questions addressing UI impact and general health perception are scored similarly. There is a multi-item symptom severity scale that is scored from 0 (best) to 30 (worst).

### Results

Mean patient age was 59 years, 76% were women, and 87% were white. After 12 weeks of treatment, OAB-q scores on all but the Sleep subscale were significantly improved among patients who received TER (n=264) compared with scores for patients who received placebo (n=256; **Table 1**). By comparison, none of the KHQ domains showed improved scores with TER compared with placebo (**Table 2**).

**Table 1. Change in OAB-q Scores From Baseline to Week 12**

OABq Subscale*	Placebo	TER	P Value
	Mean $\pm$ SD	Mean $\pm$ SD	
Symptom Bother	-18.7 $\pm$ 21.6	-22.0 $\pm$ 19.2	0.036
Coping	18.8 $\pm$ 24.0	22.5 $\pm$ 22.1	0.026
Concern	18.5 $\pm$ 23.4	22.7 $\pm$ 21.9	0.020
Sleep	13.6 $\pm$ 24.9	16.6 $\pm$ 22.7	0.100
Social Interaction	8.6 $\pm$ 18.0	11.2 $\pm$ 16.3	0.039
Total HRQL	15.7 $\pm$ 19.8	19.0 $\pm$ 18.0	0.020

**Table 2. Change in KHQ Scores From Baseline to Week 12**

<b>KHQ Domain*</b>	<b>Placebo Mean ± SD</b>	<b>TER Mean ± SD</b>	<b>P Value</b>
General health perception	-1.3±16.8	0.3±15.9	0.2919
Incontinence impact	-21.0±27.8	-23.3±29.9	0.1775
Role Limitations	-16.2±28.1	-20.9±29.4	0.1027
Physical limitations	-16.3±29.4	-18.8±28.4	0.5051
Social limitations	-9.6±21.9	-11.0±22.4	0.7244
Personal relationship	-9.6±21.4	-7.0±22.7	0.3903
Emotions	-12.9±24.1	-12.4±24.0	0.9736
Sleep/energy	-12.9±25.9	-13.1±24.0	0.7802
Severity measures	-11.2±19.7	-14.8±22.0	0.0798
Urinary symptom severity	-3.1±4.9	-3.3±4.7	0.8745

**Interpretation of results**

These results demonstrated that the OAB-q was better able to detect treatment-related changes in HRQL than was the KHQ in a clinical trial involving patients with OAB symptoms of frequency and urgency with or without urgency incontinence.

**Concluding message**

The disease-specific OAB-q should be used to assess treatment-related changes in HRQL in clinical trials of patients with OAB.

**References**

1. Psychometric validation of an overactive bladder symptom and health-related quality of life questionnaire: The OAB-q. Qual Life Res. 2002;11:563-574.
2. A new questionnaire to assess the quality of life of incontinent women. Br J Obstet Gynecol. 1997;104:1374-1379

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