

FROM AN OAB PATIENT PERSPECTIVE: HEALTH-RELATED QUALITY OF LIFE IMPROVES WHEN FREQUENCY AND URGENCY IMPROVE

Hypothesis / aims of study

Overactive bladder (OAB) is defined as urinary urgency with or without urgency incontinence, usually with frequency and nocturia [1]. While the reduction of either frequency or urgency as stand-alone symptoms has often been an OAB treatment outcome, a measure that inherently captures both frequency and urgency may provide a better assessment of treatment impact. This study examined the validity of a combined outcome of urgency rating and urinary frequency by comparisons with standard micturition diary variables, symptom bother, and health-related quality of life (HRQL).

Study design, materials and methods

This was a post hoc analysis of patients with OAB and nocturia enrolled in a 12-week, double-blind, placebo-controlled trial of tolterodine extended release (ER; 4 mg QD). The Overactive Bladder Questionnaire (OAB-q), a validated symptom bother and HRQL questionnaire, and 7-day micturition diaries were completed at baseline and week 12. For each micturition, patients rated their level of urgency on a 5-point rating scale: 1 = no urgency ("I felt no need to empty my bladder but did so for other reasons"); 2 = mild urgency ("I could postpone voiding as long as necessary without fear of wetting myself"); 3 = moderate urgency ("I could postpone voiding for a short time without fear of wetting myself"); 4 = severe urgency ("I could not postpone voiding but had to rush to the toilet in order not to wet myself"); and 5 = urgency incontinence ("I leaked before arriving at the toilet") [2]. To account for both frequency and urgency ratings, a Sum Urgency variable was calculated by summing the individual urgency ratings. Such a variable implicitly reflects each patient's urinary frequency and provides a frequency-urgency rating. Sum Urgency was analyzed both continuously and as grouped data with the groups based on clinical judgment and data distribution. Change scores were calculated for the OAB-q and diary variables by subtracting the baseline values from the 12-week values. *T*-tests and analysis of variance using general linear models (SAS[®] GLM) were performed, controlling for treatment group, age, sex, and baseline OAB-q values.

Results

Five hundred ninety-six patients completed the OAB-q and diaries at baseline and week 12 (285 placebo; 311 tolterodine ER). Mean $\pm$ SD age was 58 $\pm$ 13 y, 51% were women, 86% were white. At 12 weeks, there were significant differences in the mean reduction of Sum Urgency between the tolterodine ER and placebo groups (–54.0 vs –35.9, respectively; *P*<0.01). In the tolterodine ER group, greater improvements in Sum Urgency were associated with greater improvements in symptom bother and HRQL subscales (**Table 1**) and micturition diary variables (**Table 2**).

Interpretation of results

Among patients with OAB, HRQL improved when urgency and frequency improved. Tolterodine ER was more effective than placebo for clinically meaningful reductions in urgency rating and frequency in patients with OAB and nocturia. Reductions in Sum Urgency were associated with significant improvements in symptom bother, HRQL, and micturition diary variables.

Concluding message

The Sum Urgency variable was designed to capture changes in both urinary frequency and urgency rating, 2 key outcome symptoms when assessing OAB treatments. This initial analysis supports the validity of this measure; further validation is needed on combining symptoms as outcome measures.

Table 1. OAB-q Change Scores in Relation to Sum Urgency

OAB-q Subscale	Sum Urgency		
	No Worse (≥0) (n=154)	Change/ Some Improvement (-60 to (n=201)	Great Improvement <0) (<-60) [†] (n=193)
Symptom bother [‡]	-7.1±1.3	-13.6±1.1	-24.1±1.2***
Coping	4.2±1.4	11.1±1.3	18.9±1.3**
Concern	2.8±1.4	11.6±1.2	17.7±1.3**
Sleep	7.1±1.8	17.1±1.6	30.1±1.6***
Social interaction	-0.5±1.0	5.2±0.9	8.4±0.9*
HRQL total scale	3.5±1.3	11.2±1.1	18.8±1.1***

[†]Scheffe's pairwise comparisons were performed.

[‡]Symptom Bother scores are inverse to HRQL scores. Improvements in symptom bother are negative values; improvements in HRQL subscales are positive values.

P values: *<0.05, **<0.01, ***<0.001.

Table 2. Micturition Diary Change Values[†] in Relation to Sum Urgency

Micturition Diary Variables	Sum Urgency		
	No Worse (≥0) (n=165)	Change/ Some Improvement (-60 to (n=218)	Great Improvement <0) (<-60) [‡] (n=213)
Micturations/24 h	0.2±0.2	-1.8±0.1	-4.1±0.1***
Urgency rating	0.3±0.0	0.0±0.0	-0.3±0.0***
Urgency Incontinence/24 h	0.2±0.1	-0.2±0.1	-0.5±0.1*
Nocturia episodes/night	-0.2±0.1	-0.7±0.1	-1.3±0.1***

[†]Least squares means ± standard error.

[‡]Scheffe's pairwise comparisons were performed.

P values: *<0.05, **<0.01, ***<0.001.

References

- 1) The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. *Urology*. 2003;61(1):37-49.
- 2) European Agency for the Evaluation of Medicinal Products. Committee for Proprietary Medicinal Products. Note for Guidance on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence in Women. Nov 2001.

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