

## HEALTH RELATED QUALITY OF LIFE OF PATIENTS WITH OVERACTIVE BLADDER RECEIVING TOLTERODINE EXTENDED RELEASE IN JAPAN

### Aims of Study

This study compared the health-related quality of life (HRQOL) as measured by the Kings Health Questionnaire-Japanese (KHQ) in overactive bladder (OAB) patients receiving treatment with tolterodine extended release (ER) 4mg once daily (q.d.) or placebo in Japan.

### Methods

A phase III, 12-week, randomised, double-blind, placebo- and active (oxybutynin) controlled study to compare the clinical efficacy and safety of tolterodine 4 mg extended release with placebo. OAB patients (n = 608) with a minimum of eight micturitions/24 hrs and  $\geq 5$  urge incontinence episodes/week received tolterodine ER 4 mg q.d. or placebo. The KHQ, self-administered at baseline and end of treatment (12 weeks), is a 33-item, disease-specific HRQoL measure designed to evaluate the impact of urinary incontinence on HRQoL, including areas of physical and emotional function shown to be important to patients [1,2]. It is a valid, reliable measure with 20 validated language translations [1,2,3]. It has also been translated and linguistically validated in Japanese [4]. The KHQ is scored from 0-100 where 0 indicates the best possible HRQoL.

Treatment comparisons were made using an analysis of covariance model with baseline response, age and gender as covariates.

### Results

The tolterodine group experienced statistically significant improvements in both Incontinence Impact and Role Limitations scores compared with the placebo group. Role Limitations includes the ability to perform household tasks, perform work, and carry out other normal daily activities. Patients in the tolterodine group also experienced a statistically significant improvement in the Severity (coping) Measures, Physical Limitations, Social Limitations, Sleep and Energy, Personal Relationships, and Symptom Severity scores versus the placebo group.

KHQ Domains	Tolterodine vs Placebo	p-value
Incontinence Impact	-9.43	0.0205
Role Limitations	-6.70	0.0382
Physical Limitations	-9.88	0.0048
Social Limitations	-7.56	0.0093
Personal Relationships	-4.57	0.0278
Emotions	-6.89	0.0697
Sleep and Energy	-7.10	0.0316
Severity (coping) Measures	-7.45	0.0053
General Health Perception	0.87	0.7737
Symptom Severity	-7.52	0.0005

### Conclusions

Compared to placebo, tolterodine ER 4mg q.d. significantly improves the quality of life of patients with overactive bladder, as evidenced by the statistically significant changes in the important dimensions of Role Limitations and Incontinence Impact. Tolterodine patients also experienced statistically significant changes in the Severity (coping) Measures, Physical Limitations, Social Limitations, Sleep and Energy, Personal Relationships, and Symptom Severity scores versus the placebo group.

### References:

1. Kelleher C., Cardozo L., Toozs-Hobson P. Quality of life and urinary incontinence. *Curr Opin Obstet.Gynecol.* 1995;7:404-408.
2. Kelleher C., Cardozo L., Khullar V., Salvatore S. A new questionnaire to assess the quality of life of urinary incontinent women. *Br J Obstet.Gynaecol.* 1997;104:1374-1379.
3. Kobelt G., Kirchberger I., Malone-Lee J. Quality-of-life aspects of the overactive bladder and the effect of treatment with tolterodine. *BJU Int* 1999;83:583-590.
4. (author omitted), Gotoh M., Ando T., Fukuhara S. Development of Japanese version of QoL questionnaires for urinary incontinence [in Japanese]. *Jpn. J. Neuro Bladder Soc* 1999; 10: 225-236.

