277

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TROSPIUM CHLORIDE 60 MG ONCE DAILY IMPROVES QUALITY OF LIFE IN SUBJECTS WITH OVERACTIVE BLADDER SYNDROME

Hypothesis / aims of study
Overactive bladder syndrome (OAB) is a potentially debilitating urinary urgency condition that often exerts profoundly detrimental effects on an individual's quality of life (QoL). An extended-release formulation of the quaternary amine, trospium chloride, has recently been studied for once-daily (QD) administration in the treatment of OAB. Analyses are presented of the pooled QoL data from two double-blind, Phase III studies of trospium 60 mg QD in subjects with OAB.
Study design, materials and methods
In these multicenter, parallel-group, double-blind, placebo-controlled trials, 3-day bladder diary data were used to identify and enroll subjects aged ≥18 years with OAB of at least 6 months' duration. Subjects with urinary urgency, urinary frequency, and an average of >1 urge urinary incontinence (UUI) episode per day were randomized (1:1) to receive trospium 60 mg QD or matching placebo for 12 weeks. Health-related QoL (HRQoL) was assessed at baseline and Week 12 using the King's Health Questionnaire (KHQ) and the OAB HRQoL Questionnaire (OAB-q).
Results
Overall, 1165 subjects were randomized (trospium 60 mg QD, 578; placebo, 587). Trospium 60 mg QD demonstrated statistically significantly greater improvements (decreases) over placebo in all KHQ domains except General Health Perceptions and Personal Relationships (Table). Trospium 60 mg QD also showed significant benefits over placebo in the improvement of QoL as assessed using the OAB-q. At Week 12, OAB-q HRQoL total scores had improved from ~52 at baseline to 77.9 with trospium 60 mg QD and 72.5 with placebo ($p<0.001$). Trospium 60 mg QD also demonstrated significant benefits (decreased scores from baseline) over placebo in all domains of the Symptom Bother OAB-q subscale ($p<0.05$). Total Symptom Bother scores decreased from ~65 at baseline to 33.8 for trospium 60 mg QD and to 41.5 for placebo at Week 12 (<0.001).

Table. Changes in KHQ scores from baseline to Week 12 (ITT population, LOCF)

KHQ domain	Placebo (n=559)	Trospium QD (n=535)	p-value
General Health Perceptions	-3.4	-3.0	NS
Incontinence Impact	-18.5	-23.5	<0.05
Role Limitations	-20.8	-25.9	<0.01
Physical Limitations	-18.2	-25.4	<0.001
Social Limitations	-13.3	-17.5	<0.05
Personal Relationships	-15.4	-16.6	NS
Emotions	-16.8	-21.0	<0.05
Sleep/Energy	-15.8	-20.2	<0.05
Severity	-9.5	-12.6	<0.001

ITT, intent-to-treat; LOCF, last observation carried forward; NS, not significant.

Interpretation of results
This study demonstrates that the symptomatic improvements resulting from treatment with trospium QD translated into improvements in HRQoL, as measured using the KHQ and OAB-q. HRQoL benefits extended to statistically significant improvements in all aspects of subject-perceived symptom bother.
Concluding message
Trospium 60 mg QD significantly improved the QoL of subjects with OAB.

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the Multicenter, pooled analysis; IRB of first author: Vanderbilt University IRB and followed the Declaration of Helsinki Informed consent was obtained from the patients.