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Kelleher C[1], van Kerrebroeck P[2], Ridder A[3]
1. Guys and St. Thomas' Hospital NHS Trust, London, UK, 2. University Hospital Maastricht, Maastricht, The Netherlands, 3. Yamanouchi Europe B.V., Leiderdorp, The Netherlands for the Solifenacin Study Group

SOLIFENACIN IMPROVED THE QUALITY OF LIFE IN PATIENTS WITH SYMPTOMS OF OVERACTIVE BLADDER

Hypothesis / aims of study

Symptoms of overactive bladder (OAB) negatively impact quality of life (QoL) for affected individuals. It has been reported [1] that most QoL domains, including physical and social functioning, role limitations, and vitality, were statistically significantly (*P*<.001) reduced in patients with OAB relative to age-matched controls. Solifenacin succinate is a once-daily (od) oral antimuscarinic agent that has been evaluated at 5 mg (suggested starting dose) and 10 mg dosage strengths for the treatment of OAB. In clinical studies, solifenacin has demonstrated a favourable balance of efficacy and tolerability by statistically significant reductions in the key symptoms of OAB: urgency, incontinence, and frequency, and a low incidence of anticholinergic side effects especially at the 5 mg once-daily dose [2, 3]. We report the effect of solifenacin treatment on QoL outcomes in two phase 3 clinical studies.

Study design, materials and methods

Quality of life was assessed using data combined from two pivotal phase 3 multinational, multicentre, randomised, double-blind, placebo-controlled, 12-week studies designed to assess the safety, efficacy and tolerability of solifenacin 5 mg od and 10 mg od (n=1640). The two studies had similar protocols and designs, which permitted pooling of data. The King's Health Questionnaire (KHQ), a reliable and valid measure of QoL in patients with OAB, was used in these studies. It contains 21 questions distributed among 9 domains (general health perception, incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy, and severity measures), plus a 10th domain containing 11 questions designed to identify symptom severity in the patient with OAB. Having been instructed on how to use the questionnaire at visit 2 (start of double-blind treatment), participants in the two studies were asked to complete the KHQ at visits 2, 3 (week 4), and 5 (week 12) or end of study.

Results

Pooled data from 1640 patients (mean age, 57 years) were included in this evaluation of QoL with the following treatment groups: solifenacin 5 mg od (n=552), solifenacin 10 mg od (n=554), and placebo (n=534). Compared with placebo, statistically significant improvements were seen with solifenacin treatment in 9 of the 10 domains of the KHQ.

	Change From Baseline to End Point (*P* Value vs Placebo)		
Domain	**Placebo**	**Solifenacin 5 mg od**	**Solifenacin 10 mg od**
General health perception	−2.3	−4.3 (<.001)	−4.0 (.031)
Incontinence impact	−18.2	−24.7 (<.001)	−27.3 (<.001)
Role limitations	−15.4	−20.6 (<.001)	−22.7 (<.001)
Physical limitations	−13.7	−17.7 (.002)	−20.3 (<.001)
Social limitations	−7.8	−11.3 (.003)	−11.7 (.015)
Personal relationships*	−9.7	−8.7 (.650)	−9.3 (.747)
Emotions	−12.3	−16.0 (<.001)	−17.7 (<.001)
Sleep/Energy	−10.0	−13.8 (.002)	−14.4 (.001)
Severity measures	−7.3	−10.5(<.001)	−13.2 (<.001)
Symptom severity	−2.6	−3.4 (<.001)	−3.6 (<.001)

od = once daily

*Response was insufficient to calculate a total score.

Interpretation of results

Results from this pooled analysis of QoL data from two clinical studies comprising patients with OAB showed that solifenacin treatment was associated with statistically significant improvements relative to placebo in 9 of the 10 domains of the KHQ.

Concluding message

Improvements in QoL reported here with solifenacin treatment, in addition to reductions in key symptoms of OAB seen in multiple trials, support solifenacin therapy as both efficacious and clinically meaningful in this patient population.

References

1. Quality-of-life aspects of the overactive bladder and the effect of treatment with tolterodine. *BJU Int.* 1999;83:583-590.
2. Randomized, double-blind placebo- and tolterodine-controlled trial of the once-daily antimuscarinic agent solifenacin in patients with symptomatic overactive bladder. *BJU Int*. 2004;93:303-310.
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