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IMPROVEMENTS IN HEALTH-RELATED QUALITY OF LIFE WITH FESOTERODINE IN SUBJECTS WITH OVERACTIVE BLADDER: POOLED DATA FROM TWO RANDOMIZED CONTROLLED STUDIES

Hypothesis / aims of study
Overactive bladder (OAB) is a chronic condition with a profound negative impact on subjects' health-related quality of life (HRQL) (1,2). Because standard measures of OAB, such as symptom scores, provide little or no information on the impact of OAB on subjects' daily lives and their well-being, the International Continence Society now recommends that HRQL measures be included in all trials involving subjects with urinary incontinence. Two multinational, double-blind, placebo (PBO)–controlled phase III studies evaluated the effect of fesoterodine (FESO) on HRQL in subjects with OAB using patient-reported outcomes measures. Pooled efficacy data are described elsewhere.
Study design, materials and methods
This is a pooled analysis of data from 2 multicenter, double-blind, PBO-controlled trials. Eligible subjects (≥18 y) with frequency (≥8 micturitions/24 h) and urgency (≥2 episodes/24 h) or urgency urinary incontinence (UUI; ≥1 episode/24 h) were randomized to PBO, FESO 4 mg, or FESO 8 mg for 12 weeks. A post hoc inferential analysis assessed treatment-related effects on HRQL using the King's Health Questionnaire (KHQ), International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF), and a Likert scale similar to the Patient Perception of Bladder Condition in patients treated with PBO, FESO 4 mg, and FESO 8 mg. The KHQ comprises 9 domains; scores range from 0 (best outcome) to 100 (worst outcome). A negative change from baseline indicates improved HRQL. ICIQ-SF assesses urinary frequency, urine leakage, and the effects these symptoms have on daily life; scores range from 0 (low bother) to 21 (maximum bother). Patients' bladder condition was assessed by responding on a 6-point Likert scale as follows: "My bladder causes me no (0), very minor (1), minor (2), moderate (3), severe (4), or very severe problems (5)." A decrease of ≥2 points on this scale was considered a major improvement. Subjects completed the KHQ, ICIQ-SF, and PPBC at baseline and end of study. Analysis of covariance was performed on the intent-to-treat population, with treatment and region as factors and baseline value as a covariate.
Results
By the end of the study, both FESO-treated groups showed significantly improved HRQL compared with PBO as evidenced by positive changes in most domains of the KHQ and an improvement in the ICIQ-SF score **(Table)**. Subjects receiving FESO 8 mg demonstrated statistically significant improvements over PBO in 8 of 9 KHQ domains, including personal relationships. FESO 4 mg produced statistically significant improvements in 7 of 9 domains of the KHQ. FESO 8 mg performed better than FESO 4 mg in 2 domains: emotions, and incontinence severity (P<0.05). All FESO-treated groups reported significant improvement in the ICIQ-SF score (P<0.0001), and a major improvement in bladder condition was reported by 33% of FESO 4 mg and 38% of FESO 8 mg subjects vs 21% of PBO-treated subjects (P<0.0001).
Interpretation of results
Subjects with OAB have decreased HRQL and their daily lives are adversely affected by OAB symptoms. In this pooled analysis of 2 phase III studies, FESO treatment produced statistically and clinically significant improvements in subjects' HRQL.
Concluding message
Both doses of FESO significantly improved subjects' HRQL, producing statistically significant changes in 7 (FESO 4mg) and 8 (FESO 8mg) out of 9 domains. A dose-response relationship was evident for two domains of the KHQ: emotions and incontinence severity. Both doses also significantly improved the subject's perception of their bladder condition compared with PBO.

References
1. World J Urol (2003) 20; 327–336.
2. Value Health (2004) 7; 455–463.

Table. HRQL Summary—KHQ and ICIQ-SF Mean Changes From Baseline to End of Treatment

	Mean Change from Baseline		
	PBO (n=545)	**FESO 4 mg (n=532)**	**FESO 8 mg (n=543)**
KHQ			
Severity (coping)	–7.4	–11.3*	–13.7*†
Emotions	–9.1	–12.4*	–15.3*†
Role limitations	–12.5	–18.5*	–21.4*
Physical limitations	–11.4	–17.2*	–19.6*
Social limitations	–7.9	–11.6*	–13.8*
Sleep/energy	–7.8	–10.7	–12.3*
Personal relationship	–5.9	–7.8	–9.6*
Impact on life	–14.2	–19.6*	–22.5*
General health	–2.4	–2.9	–2.6
ICIQ-SF	–2.2	–3.6*	–4.2*

*P<0.01 vs PBO; †P<0.05 vs FESO 4 mg.

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HUMAN SUBJECTS: This study was approved by the Patience B. Stevens, MD, MPH, CIP, Copernicus Group IRB, 118 Mackenan Drive, Suite 400, Cary, NC, 27511; Dr. Rodney Rivers, LREC, 1st Floor, Mint Wing, St Mary's Hospital, Praed Street, London, W2 1NY, UK and followed the Declaration of Helsinki Informed consent was obtained from the patients.