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Institution City Country	¹ Dept of Medicine, Royal Free & Univ. College Medical School, London, UK: ² Health Dynamics, Eschentswiller, France	
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Title (type in CAPITAL LETTERS)	TREATMENT WITH TOLTERODINE SIGNIFICANTLY IMPROVES SOCIAL FUNCTION AND ENERGY IN PATIENTS WITH OVERACTIVE BLADDER	

Alms of Study: Overactive bladder is a serious chronic condition, with symptoms of urinary frequency, urgency, with or without urge incontinence. These symptoms are associated with significant social, psychological, occupational, physical, and sexual problems, and substantially affect the lifestyles of millions of people worldwide. A generic health profile (SF-36), a generic preference-weighted health status instrument (EuroQol), and a disease-specific instrument (King's Health Questionnaire) were employed at the start of treatment and at the completion of the study to measure the impact of overactive bladder on quality of life, and to analyze the improvements in quality of life that can be achieved with a well-tolerated agent such as tolterodine.

<u>Methods</u>: Three quality of life questionnaires were available for analysis from a total of 378 patients receiving either tolterodine 2 mg BID (n = 190) or oxybutynin 5 mg BID (n = 188) for 10 weeks. This paper highlights the results with tolterodine.

The SF-36 is a generic quality of life instrument that contains 36 items assessing 8 health concepts and a 1-item measure of change in health. The 8 health domains are: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. Item scores for each domain are calculated and transformed into a scale from 0 (worst) to 100 (best). The EQ-5D estimates the utility value of 5 dimensions of quality of life-mobility, self-care, ability to perform usual activities, pain or discomfort, and anxiety or depression. As with the SF-36, normative scores have been developed for the EQ-5D. The King's Health Questionnaire (KHQ) is a specific questionnaire for the assessment of females with urinary incontinence. The questionnaire contains 8 quality of life domains, a domain assessing strategies for coping with urinary problems, and a separate scale measuring the severity of urinary symptoms. Although this questionnaire was designed for females, all patients in this study completed questionnaires. When scores were analyzed according to gender, no significant differences were observed. Quality of life scores were calculated according to the individual scoring methods for each questionnaire. Treatment efficacy was measured with micturition diaries at baseline, and 2, 4, and 10 weeks after treatment.



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<u>Results</u>: Compared with baseline, significant improvements in micturition frequency, incontinence episodes, and volume voided/micturition were noted at all timepoints for patients treated with tolterodine.

Changes in quality of life scores from baseline were not significant for either treatment group when measured using the generic measures of SF 36 or EQ-5D; however, results obtained with the disease-specific KHQ were highly significant for 6 of 8 domains, with the exception of health perceptions and personal relationships. The 4 domains that showed the most significant improvement from baseline were physical limitation, role limitation, sleep/energy, and social limitations. The mean change in KHQ scores in patients treated with tolterodine is shown in the table.

KHQ Scores in Patients Treated With Tolterodine: Mean Changes From Baseline

	Tolterodine		
Domain	п	Mean change from baseline	
Incontinence impact	167	-10.38*	
Severity measures	143	-6.16 ¹	
Personal relations	96	-2.78	
Role limitations	153	-11.44*	
Physical limitations	156	-8.23*	
Social limitations	147	-6.16 [‡]	
Emotions	162	-4.53 [†]	
Sleep/energy	159	-5.98 [‡]	
Health perceptions	167	-0.45	

^{*}p<0.0001, *p<0.05, *p<0.01

KHQ scores were higher (indicating worse quality of life in several domains) compared with baseline for patients who withdrew from the study, further underscoring the beneficial effects on quality of life in patients treated with tolterodine. SF-36 and EQ-5D scores for patients who withdrew from the study deteriorated, while they remained essentially the same for patients who completed the study.

<u>Conclusions</u>: Treatment with tolterodine significantly improves the quality of life of people suffering from overactive bladder with symptoms of frequency, urgency, and urge incontinence. In addition, patients demonstrated significant improvement in sleep and energy.

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