

DOES LONG-TERM TREATMENT OF OVERACTIVE BLADDER RESULT IN CLINICALLY MEANINGFUL IMPROVEMENT IN HEALTH RELATED QUALITY OF LIFE IN REAL WORLD CLINICAL PRACTICE?

Hypothesis / aims of study

Overactive bladder (OAB) is a common condition, which has a recognised detrimental impact on the health related quality of life (HRQL) of sufferers. Treatment of OAB is associated with improvement in HRQL in short-term clinical trials as measured by different health related quality of life outcome measures. Whether the same occurs in clinical practice is unclear. In real world clinical practice antimuscarinic medication forms the mainstay of treatment for OAB; with the majority of patients seeking help for these symptoms being prescribed pharmacological treatment. Clinical trial data would suggest continued improvements in HRQL and OAB symptoms with long-term antimuscarinic medication use; however these findings may not be applicable in clinical practice where there may be less rigorous follow-up, poor persistence with prescribed medication and few incentives to continue long-term treatment. The HRQL impact of long-term treatment of OAB in clinical practice has not been investigated. How much improvement in HRQL scores improves the lives of patients is gauged by the Minimally Important Difference assessment (MID) defined as 'the change in questionnaire score which is associated with a clinically meaningful improvement in quality of life for the patient'. The Kings Health Questionnaire [1](KHQ/ICIQLUTS_{qol}) is a lower urinary tract symptoms (LUTS) specific quality of life questionnaire; which has been extensively used in both clinical practice and the research setting to evaluate the treatment of lower urinary tract dysfunction. MID analysis of the KHQ has revealed that a 10 point change in individual domain scores of the KHQ is associated with a significant clinically meaningful difference to the patient. [2] The aim of this study was to investigate the long-term HRQL changes in women receiving treatment for idiopathic overactive bladder in a real-world setting, using the MID concept applied to the KHQ.

Study design, materials and methods

Women with symptoms of idiopathic OAB referred from primary care to 2 tertiary referral Urogynaecology centres were recruited into a prospective study investigating the management of OAB in clinical practice. Treatment naïve patients and those women who had previously sought treatment for OAB were included in the study. Patients were recruited into the study between May 2006 and August 2007. All patients were given verbal and written information about the treatment of OAB. After a baseline and 6 week visit, patients were invited for follow-up at 3 monthly intervals for a minimum of 12 months; and asked to complete the KHQ at each study visit. Routinely patients are followed up in our clinical practice at these time intervals. The KHQ is a 33 item questionnaire which consists of 9 domains; general health perception (GHP), incontinence impact, role limitations, physical/social limitations, personal relationships, emotions, sleep/energy and coping/severity measures.

Results

251 women consented to take part in the study, of which 133 patients (53%) completed 12 months follow-up of which 68 patients (27%) completed a further 12 month follow-up at the time of reporting this study. 11 patients (4%) did not complete a baseline assessment, and 107 patients (43%) dropped out of the study within 6 months. Commonly cited reasons for non-completion of the study were withdrawal of consent for participation, resolution of symptoms, poor treatment efficacy and tolerability. Data from patients who completed a minimum of 12 months follow-up were used in this analysis. The mean age of participants was 55 years (range 20-87 years). All patients received advice about behavioural treatments for OAB and 96% of patients were prescribed antimuscarinic medication. The mean duration of medication use was 22.5 weeks. Figure 1 shows the mean KHQ domain score changes from 0-24 months follow-up when compared with baseline for patients participating in the study.

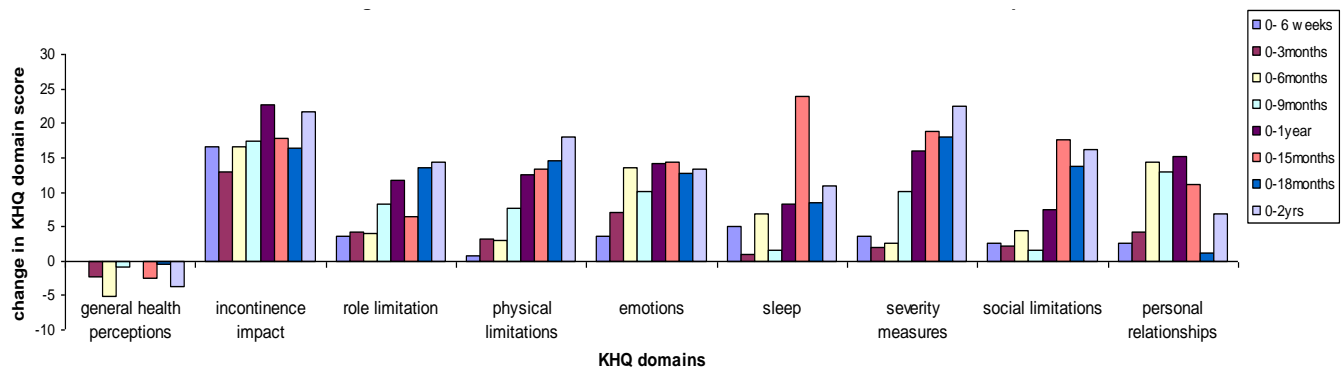


Figure 1. Mean KHQ domain score changes from baseline to 24 months

HRQL improvement was seen in all domains of the KHQ following treatment for OAB with the exception of the GHP domain. Score changes in the GHP domain did not reach the 10 point MID threshold for clinically significant change. An MID of 10 points was achieved in the remaining 8 domains of the KHQ at various time points over the follow-up period. The most rapid and largest HRQL improvement was detected in the incontinence impact domain within 6 weeks of treatment; and this clinically significant improvement was sustained for the duration of the follow-up period. Clinically meaningful improvements in the sleep and social limitations domains of the KHQ were not evident until 15 months of treatment. Improvement in the personal relationships and sleep domain scores were not sustained above the 10 point MID threshold throughout the follow-up period.

Interpretation of results

The results of this study showed that treatment of OAB is associated with improvements in HRQL that are clinically meaningful to patients in a real world clinical setting. Clinically significant improvements in the incontinence impact, emotions, and severity measures domains were detected early in the treatment period. This is similar to improvements seen in clinical trials of OAB treatment.

Concluding message

Real-world management of OAB is associated with intermittent use of behavioural and pharmacological treatments. Results from this real world study have however shown sustained, long-term clinically meaningful improvement in HRQL in patients receiving treatment for OAB. Long-term treatment of OAB is associated with improvement in additional quality of life domains.

References

1. Kelleher CJ, Cardozo LD, Khullar V et al. A new questionnaire to assess the quality of life of urinary incontinent women. BJOG 1997;104(12):1374-9
2. Kelleher CJ, Pleil AM, Reese PR, et al. How much is enough and who says so? The case of the King's Health Questionnaire and overactive bladder. BJOG 2004 Jun;111(6):605-12

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<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	St Thomas local research ethics committee
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes