

## WHICH MEASURES OF OVERACTIVE BLADDER SYMPTOM TREATMENT CORRELATE BEST WITH PATIENT SATISFACTION?

### Hypothesis / aims of study

Historically, overactive bladder (OAB) symptoms have mainly been quantified based upon the number of episodes of cardinal symptoms such as urgency, frequency, nocturia and incontinence. However, there is growing consensus that simple episode counting may not adequately reflect patient needs. Recently, it has been reported that urgency symptom scores and rating scales may correlate better with patient perception of treatment success [1] but the specific advantages of various available scores have not been addressed. Therefore, we have correlated improvements in OAB symptoms and various symptom scores and rating scales with patient-reported treatment satisfaction in a large cohort of OAB patients.

### Study design, materials and methods

This is a pre-planned, secondary analysis of an open-label observational study into the tolerability and efficacy of solifenacin in routine urological practise [2]. 4450 OAB patients were treated for 12 weeks with 5-10 mg solifenacin according to the physician's medical judgement. Before and after treatment, the intensity of OAB symptoms was assessed by numbers of episodes for OAB symptoms, the Indevus urgency scale (IUS), the urgency perception scale (UPS), an urgency-focused visual analogue scale (VAS, based upon question "How do you rate the severity of your urgency symptoms?" converted to values of 0-100), two questions from the Kings Health Questionnaire regarding general health (KHQ general) and impact of bladder problems (KHQ bladder) as well as the quality of life question of the IPSS (QoL).

Correlation analysis was performed between the 10 items at baseline and between their treatment-associated alterations. Finally, the correlations of alterations of the 10 items were analyzed in comparison with patient-reported impression of treatment benefit. The Spearman rank correlation coefficient  $r$  was used to describe the tightness of correlations. All other data are means  $\pm$  SD.

### Results

Baseline symptoms correlated only moderately well amongst each other with most correlations exhibiting  $r$  values  $< 0.4$ . A notable exception was the correlation between urgency and frequency ( $r=0.508$ ), supporting the view that OAB can be considered as an urgency/frequency syndrome. None of the 6 symptom scores and rating scales correlated well with classical OAB symptoms (all  $r<0.4$ ). In contrast some of the symptom scales showed tighter correlations with each other, e.g. IUS vs. VAS ( $r=0.580$ ), KHQ bladder vs. VAS ( $r=0.548$ ) and KHQ bladder vs. QoL ( $r=0.509$ ).

Solifenacin treatment reduced episodes of urgency (from  $9.2\pm 6.0$  to  $3.8\pm 3.0$  per 24 h), micturitions (from  $13.3\pm 4.9$  to  $7.8\pm 2.8$  per 24 h), nocturia (from  $3.8\pm 2.0$  to  $1.7\pm 1.0$  per night) and incontinence (from  $4.6\pm 3.7$  to  $2.2\pm 2.1$  per 24 h). The IUS shifted from mostly grade 3 to mostly grade 2, the UPS shifted from grade 3 to grade 2, the VAS improved from  $71\pm 17$  to  $30\pm 19$  points), the KHQ general shifted from mostly "moderate" to mostly "good", the KHQ bladder shifted from mostly "severe impact" to mostly "mild impact" and the QoL shifted from mostly "dissatisfied" to mostly "satisfied". Treatment-associated improvements of OAB symptoms correlated only moderately (most  $r<0.4$ ) with the notable exception of a somewhat better correlation between improvements of urgency and of incontinence episodes ( $r=0.507$ ). Improvements in symptoms and scores/rating scales were also correlated only moderately in most cases, notable exceptions being improvements of urgency vs. those of IUS ( $r=0.428$ ), VAS ( $r=0.477$ ) or KHQ bladder ( $r=0.434$ ), of frequency vs. those of VAS ( $r=0.439$ ), of nocturia vs. those of VAS ( $r=0.419$ ) and those of incontinence vs. those of VAS ( $r=0.445$ ) and of KHQ bladder ( $r=0.428$ ). In the comparison of symptom scores/rating scale improvements amongst each other, the VAS consistently showed the tightest correlations (all  $r>0.5$  except for comparison with KHQ general where  $r=0.413$ ).

In the comparison of patient-reported assessment of efficacy and alteration of symptom episodes, symptom scores and rating scales, all symptom improvements correlated only moderately ( $r<0.4$ ). The best correlations were seen between patient assessment of efficacy and improvements of the VAS ( $r=0.487$ ) and of the KHQ bladder ( $r=0.452$ ).

### Interpretation of results

In line with previous observations [1], baseline assessments of OAB correlated only moderately with each other, the association between urgency and frequency being a notable exception. Similarly, treatment-associated improvements of all 10 items correlated only moderately, the association of urgency and incontinence improvements being a notable exception. Most importantly, measured improvements also correlated only moderately with patient-reported assessments of efficacy, improvements of the VAS and the KHQ bladder being notable exceptions.

### Concluding message

The overall moderate correlations indicate that the many facets of OAB are not necessarily related, and that treatment aims may differ considerably between patients. Among the tools explored in this study, the urgency-focused VAS and the KHQ bladder may be the instruments most closely related to patient needs.

### References

1. Neurourol. Urodyn. (2007) 26; 190-195
2. Drug Safety (2008) in press

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<b>Is this a clinical trial?</b>	<b>Yes</b>
<b>Is this study registered in a public clinical trials registry?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>No</b>
<b>This study did not require ethics committee approval because</b>	<b>At the time this study was performed in Germany, local regulations did not recommend ethical approval of trial</b>

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registration for purely observational studies.

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*Was the Declaration of Helsinki followed?*

Yes

*Was informed consent obtained from the patients?*

No

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