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## **TREATMENT SATISFACTION AND IMPROVEMENTS IN BLADDER CONDITION ARE CLOSELY LINKED TO A REDUCTION IN URGENCY BOTHER IN PATIENTS WITH OVERACTIVE BLADDER SYNDROME**

### Hypothesis / aims of study

Urgency is a key symptom of the overactive bladder syndrome (OAB) and is considered to be a driver for other symptoms [1]. The solifenacin SUNRISE study, which had urgency as the primary outcome measure [2,3], included patient-reported outcomes for urgency bother, perception of bladder condition and treatment satisfaction. The objective of the present post-hoc analysis was to investigate the strength of the correlation between these patient-reported outcomes and other outcome variables, to try and determine which factors were the most important in reducing the severity of problems caused by OAB.

### Study design, materials and methods

The SUNRISE study included male and female patients aged  $\geq 18$  years with symptoms of OAB for  $\geq 3$  months and  $\geq 3$  episodes of urgency with or without incontinence. The study was a prospective, double-blind, 2-arm, parallel group, 16-week Phase IIIb study involving 105 centres in 14 European countries. After a 2-week, single-blind, placebo-controlled run-in, patients were randomised to double-blind treatment with solifenacin 5mg od (n=641) or placebo (n=224) for 16 weeks, with an optional patient-requested dose increase at week 8.

Urgency severity was assessed on a validated 5-point Patient Perception of Intensity of Urgency Scale (PPIUS), in which the primary variable was the change in number of episodes of PPIUS 3+4 per 24h (Grade 3 = severe urgency: "I could not postpone voiding but had to rush to the toilet in order not to wet myself"; Grade 4 = urge incontinence: "I leaked before arriving at the toilet"). Secondary variables included total urgency episodes/24h (PPIUS 1-4), micturition frequency/24h, incontinence and urge incontinence episodes/24h, urgency bother, treatment satisfaction and patient Perception of Bladder Condition (PBC). Urgency bother was measured using a 0-10 visual analogue scale (VAS) in which patients answered the question "How much bother has urgency been for you in the past week?" (0 = no bother at all, 10 = worst possible bother). Treatment satisfaction used a 0-10 VAS with the question "Are you satisfied with your treatment?" (0 = not at all, 10 = yes, completely). PBC is a validated 6-point rating scale for patient assessment of severity of problems associated with OAB (1 = "does not cause me any problems at all", 6 = "causes me many severe problems"). A post-hoc Spearman correlation was performed for the Full Analysis Set (FAS).

### Results

Correlations between changes in treatment outcomes from baseline to endpoint are summarised in table 1. PBC and Treatment Satisfaction both correlated very strongly with a reduction in urgency bother (0.74 and -0.69, respectively). The least strong correlations were with incontinence and urge incontinence.

Table 1: Spearman rank correlations, mean baseline values, and mean changes from baseline to endpoint for patients treated with solifenacin

Outcome variable	Baseline mean	Mean change from baseline to endpoint	Correlation with PBC*	Correlation with treatment satisfaction**
Urgency bother (VAS) (%)	68	-35	0.74	-0.69
Treatment satisfaction (VAS) (%)	29	39	-0.60	
Perception of Bladder Condition (6-point scale)	4.6	-1.5		-0.60
Severe urgency/urge incontinence episodes/24h (PPIUS 3+4)	5.1	-2.6	0.41	-0.36
Urgency episodes all grades/24h (PPIUS 1-4)	10.7	-2.3	0.40	-0.30
Maximum urgency rating/24h	3.5	-0.8	0.49	-0.33
Micturitions/24h	11.1	-2.1	0.34	-0.25
Incontinence episodes/24h	2.5	-1.7	0.20	-0.16
Urge incontinence episodes/24h	2.4	-1.7	0.20	-0.16
* all p<0.0003, ** all p<0.0051. A negative correlation for Treatment Satisfaction means that satisfaction increased in relation to a reduction in the tested variable. Numbers of patients analysed in the correlations for each variable ranged from 488 to 492, except for incontinence (n=319) and urge incontinence (n=316)				

#### Interpretation of results

Treatment satisfaction was strongly correlated with improvement in PBC, which indicates that any factors that might potentially decrease satisfaction (such as adverse effects) have only a minor impact. Patients equated measures of solifenacin treatment success (bladder condition and treatment satisfaction) with reductions in the amount of bother caused by urgency, more so than with reductions in the actual incidence of urgency, frequency or incontinence. This analysis suggests that effective treatment of urgency bother may be the most important target for OAB treatments.

#### Concluding message

This post-hoc analysis of results from the solifenacin SUNRISE study in OAB patients showed that patient-reported improvements in bladder condition and treatment satisfaction were most strongly correlated with a reduction in urgency bother, more so than with reductions in the number of episodes of urgency, frequency or incontinence. The ability of an antimuscarinic agent to reduce urgency bother may, therefore, be an important indicator of its overall efficacy in treating OAB.

#### References

1. BJU Int (2005) 95; 335-340
2. 36th Annual Meeting of ICS, Christchurch, New Zealand (2006); Abstr 281
3. Int Urogynecol J (2006) 17 (Suppl 2); S88: Abstr 052

**FUNDING:** The study was undertaken with a research grant from Astellas Pharma Europe Ltd.

**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study was approved by the This study was approved by the central IECs of 14 countries and followed the Declaration of Helsinki. Informed consent was obtained from the patients. and followed the Declaration of Helsinki Informed consent was obtained from the patients.