

THE EFFICACY OF SOLIFENACIN 5/10MG ON 'URGENCY' ENDPOINTS IN DIFFERENT OAB PATIENT POPULATIONS: SUBANALYSIS OF RESULTS FROM THE RANDOMISED, DOUBLE-BLIND SUNRISE STUDY

Hypothesis / aims of study

Urgency is a fundamental symptom of the overactive bladder syndrome (OAB). The SUNRISE study evaluated solifenacin in OAB using severe urgency with or without urgency incontinence as the primary efficacy variable, and showed that solifenacin 5/10mg gave a highly significant reduction in urgency severity, incidence and bother.[1] The objective of the present subanalysis was to determine if there was any difference in the effectiveness of solifenacin in improving urgency endpoints among the following subgroups of patients with OAB: male and female, 'wet' and 'dry', ≤65 years and >65 years of age.

Study design, materials and methods

The SUNRISE study included male and female patients aged ≥18 years with symptoms of OAB for ≥3 months and ≥3 episodes of urgency with or without incontinence. The prospective, double-blind, 2-arm, parallel group, 16-week Phase IIIb study involved 105 centres in 14 European countries. Following a 2-week, single-blind, placebo-controlled run-in, patients were randomised to receive double-blind treatment with solifenacin 5mg od (n=641) or placebo (n=224) for 16 weeks. Patients could request a dose increase (from 5mg to 10mg solifenacin) at week 8.

Urgency was assessed using the 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 (Table 1). Urgency bother was measured using a 0-100mm visual analogue scale (VAS) in which patients answered the question "How much bother has urgency been for you in the past week?" (ranging from 0 = 'no bother at all' to '100 = worst possible bother').

Table 1: Patient Perception of Intensity of Urgency Scale (PPIUS) for urgency assessment

Score	Intensity	Description
0	No urgency	I felt no need to empty my bladder but did so for other reasons
1	Mild urgency	I could postpone voiding as long as necessary without fear of wetting myself
2	Moderate urgency	I could postpone voiding for a short while without fear of wetting myself
3	Severe urgency	I could not postpone voiding but had to rush to the toilet in order not to wet myself
4	Urge incontinence	I leaked before arriving at the toilet

Results

Table 2 shows results for the Full Analysis Set for each of the subgroups with respect to baseline values and mean placebo-adjusted changes from baseline to endpoint.

Table 2: Mean changes in urgency variables from baseline to endpoint (week 16) for subgroups of patients treated with solifenacin, assessed using the PPIUS (primary variable) and patient-reported urgency bother (secondary variable), adjusted for placebo (Full Analysis Set).

	PPIUS 3+4 (episodes/24h)			Urgency bother (mm, 0-100 VAS)		
	n =*	mean baseline value	change from baseline, adjusted for placebo	n =*	mean baseline value	change from baseline, adjusted for placebo
Male	55	5.19	-0.96	52	67.0	-9.1
Female	448	5.10	-0.74	440	68.5	-9.2
OAB wet	329	5.83	-0.81	321	70.5	-8.0
OAB dry	174	3.74	-0.92	171	64.2	-14.5
<65 years	351	5.11	-0.83	341	67.7	-8.0
>65 years	152	5.11	-0.67	151	69.6	-13.5

*n-values in this table are for solifenacin

Interpretation of results

In another report, post-hoc analysis of results from the randomised, double-blind STAR study demonstrated that solifenacin 5/10mg improved a wide range OAB symptoms in the same subgroups of patients as studied here.[2] Their findings are supported and extended by the results of this subanalysis from SUNRISE, where the main focus was on urgency variables. In the SUNRISE study, the primary variable was the reduction in episodes of severe urgency and urgency incontinence, for which solifenacin 5/10mg was found to be effective across all the subgroups studied.

Reduction of urgency bother is an important target for OAB treatment, and the ability of an antimuscarinic agent to reduce urgency bother may be an important indicator of its overall efficacy in OAB.[3] The present subanalysis looked at patient-reported urgency

bother as a secondary variable and found that solifenacin 5/10mg reduced urgency bother in all three subgroups, with more pronounced effects in older patients and in those patients who were dry on study entry.

Concluding message

In this analysis of subgroups of patients from the SUNRISE study, solifenacin 5/10mg was effective in reducing the number of episodes of severe urgency/urge incontinence and urgency bother, irrespective of the patient subgroups evaluated, namely: men and women, OAB wet and dry patients, and patients ≤ 65 years and >65 years. There was a tendency towards greater reductions in urgency bother in OAB dry patients and in those patients over 65 years of age. These results support and extend those from a similar subgroup analysis of the STAR study, which looked at several other OAB symptoms.

References

1. Int Urogynecol J 2006;17(Suppl 2):S88, Abstr 052
2. 29th SIU, Paris, September 2007, Posters 1062, 1084, 1091
3. 37th ICS, Rotterdam, August 2007, Poster 132

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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>	The Independent Ethics Committees (IECs) responsible for the participating centres
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes