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## **SOLIFENACIN IMPROVES ALL SYMPTOMS OF OVERACTIVE BLADDER SYNDROME**

### Hypothesis / aims of study

Urgency, the defining symptom of overactive bladder (OAB), is thought to play a central role in driving other symptoms of the condition: urinary incontinence, frequency and nocturia. However, there are few reports of studies showing improvements with current antimuscarinic therapy in all of these symptoms. Solifenacin succinate is a once-daily (od) oral antimuscarinic agent intended to treat all symptoms of OAB. The aim of the analysis presented here was to evaluate the efficacy of solifenacin succinate once daily (5 or 10 mg) against the four key symptoms of OAB listed above.

### Study design, materials and methods

Data from four multinational, double-blind, randomized Phase III studies with similar protocols were pooled. Patients (n=3032) were randomized to solifenacin 5 mg od (n=580 in two studies), solifenacin 10 mg od (n=1235) or placebo (n=1217) (or tolterodine as an active comparator in one study; data from this arm was not included in this pooled analysis). Data on urgency, incontinence, micturition frequency, nocturia and volume voided were collected from 3-day micturition diaries at baseline and prior to clinic visits at weeks 4, 8 and 12; study endpoint using last observation carried forward.

### Results

Baseline to endpoint improvements in urgency, incontinence, micturition frequency, nocturia and volume voided were statistically significantly greater for solifenacin treated patients (5 mg and 10 mg doses) compared with subjects receiving placebo (Table and Figure). Additionally, at study endpoint a significantly greater proportion of patients randomized to solifenacin achieved complete resolution of urgency (5 mg solifenacin 29%, 10 mg solifenacin 25%) and restoration of continence (5 mg solifenacin 51%, 10 mg solifenacin 52%), compared with placebo (15% and 34%, respectively;  $P<0.001$  all groups). The most common adverse events were the typical, anticipated side effects of antimuscarinic therapy: dry mouth (placebo 4.2%, 5 mg solifenacin 10.9%, solifenacin 10 mg 27.7%), constipation (placebo 2.9%, solifenacin 5 mg 5.4%, solifenacin 10 mg 13.4%) and blurred vision (placebo 1.8%, solifenacin 5 mg 3.8%, solifenacin 10 mg 4.8%). The vast majority of these adverse events were mild to moderate, and there were few discontinuations due to adverse events for either solifenacin group (2.8% and 6.8% for 5 mg and 10 mg, respectively, compared with 4.4% for placebo).

### Interpretation of results

Treatment with solifenacin 5 mg and 10 mg was effective at statistically significantly reducing all symptoms of OAB including nocturia, compared with placebo, and was well tolerated.

### Concluding message

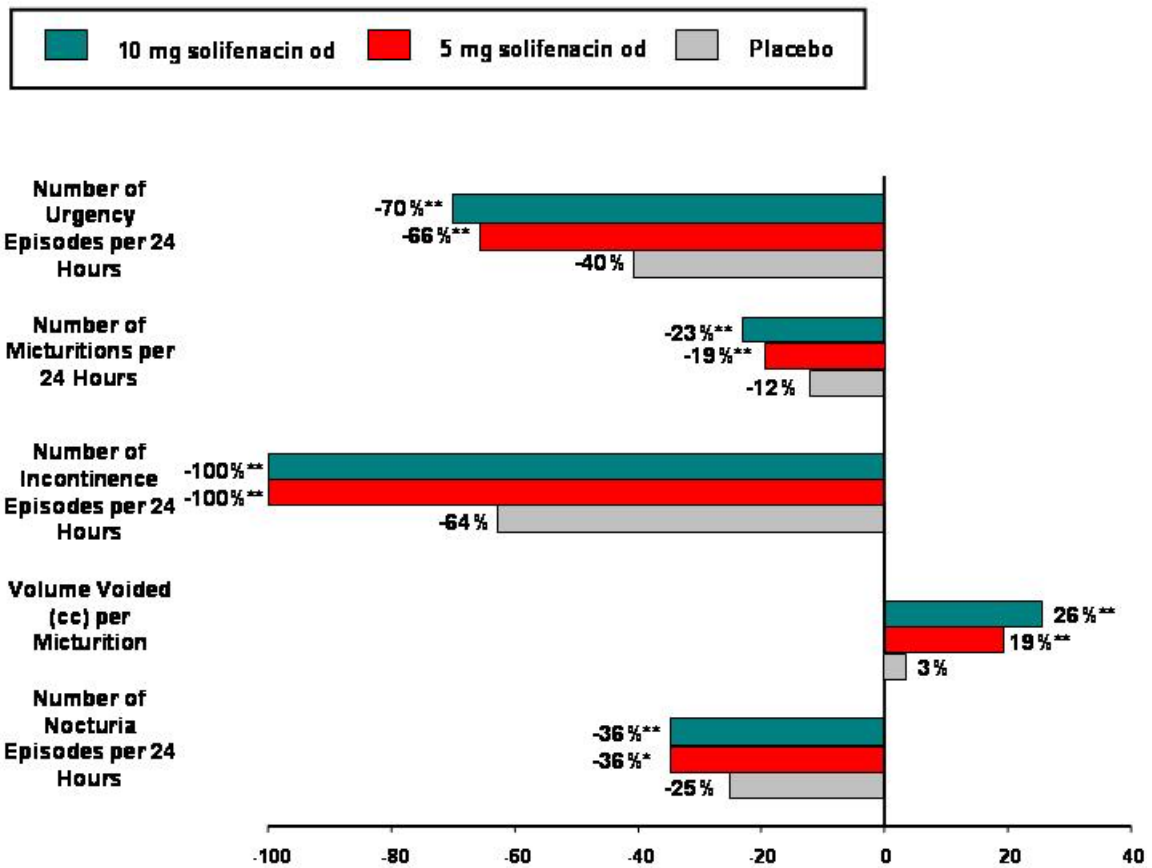
Solifenacin is a valuable treatment option for the management of OAB.

Table. Mean actual baseline to endpoint changes in OAB symptoms

	Mean baseline to endpoint change in number of urgency episodes		Mean baseline to endpoint change in number of incontinence episodes		Mean baseline to endpoint change in micturition frequency		Mean baseline to endpoint change in volume voided		Mean baseline to endpoint change in number of nocturia episodes	
	N	Change	N	Change	N	Change	N	Change	N	Change
Placebo	1124	-2.0	781	-1.1	1138	-1.4	1135	8.5	1005	-0.4
Solifenacin 5 mg	548	-2.9 <sup>†</sup>	314	-1.5 <sup>†</sup>	552	-2.3 <sup>†</sup>	552	32.3 <sup>†</sup>	494	-0.6*
Solifenacin 10 mg	1151	-3.4 <sup>†</sup>	778	-1.8 <sup>†</sup>	1158	-2.7 <sup>†</sup>	1156	42.5 <sup>†</sup>	1035	-0.6 <sup>†</sup>

<sup>†</sup>P<0.05 versus placebo; <sup>††</sup>P<0.001 versus placebo

Figure. Median percent baseline to endpoint changes in OAB symptoms. \*P <0.05 versus placebo; \*\*P <0.001 versus placebo.



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