

SOLIFENACIN ALONE AND WITH SIMPLIFIED BLADDER RE-TRAINING IN OVERACTIVE BLADDER SYNDROME: THE PROSPECTIVE, RANDOMISED SOLAR STUDY

Hypothesis / aims of study

Bladder training is often recommended for patients with an overactive bladder (OAB). Bladder training aims to resist the sensation of urinary urgency and postpone voiding, thereby modifying abnormal voiding patterns. Data evaluating the efficacy of antimuscarinic therapy combined with this form of behavioural intervention are limited.[1] The SOLAR study compared the efficacy of solifenacin 5/10mg with and without simplified bladder training in patients with OAB.

Study design, materials and methods

SOLAR was a prospective, randomised, parallel-group, open label study conducted in 92 European centres in patients aged ≥ 18 years (mean age 58 years) who had symptoms of urinary frequency and urgency, with or without urge incontinence, for at least 3 months prior to screening. Patients who had received cognitive bladder training in the last 6 months were excluded. Following a 2-week, single-blind, placebo run-in, 643 patients (86% women) were randomised to treatment with either solifenacin 5mg od alone (n=323) or with bladder training (n=320) for 8 weeks. At week 8, patients could request a dosage increase to solifenacin 10mg od for the remaining 8 weeks of the study. A standardised, simplified bladder training program was implemented across all study centres for patients randomised to receive bladder training, which outlined the principles and techniques of bladder training, bladder control, and pelvic floor muscle squeezes.

The primary efficacy endpoint was the change from baseline in the mean number of micturitions/24h after 8 weeks. Secondary efficacy measures were the change in micturition frequency at week 16, and changes in other voiding diary parameters at weeks 8 and 16. Several patient reported outcomes were also assessed at weeks 8 and 16, including patient Perception of Bladder Condition (PBC), Incontinence Quality of Life (I-QoL), and Treatment Satisfaction using a visual analogue scale score. Tolerability was also assessed.

Results

Results are summarised in Table 1 for the Full Analysis Set. The effect of solifenacin in reducing micturition frequency was significantly enhanced at week 8 when used with simplified bladder training (the primary endpoint), and this difference was maintained through to week 16. There was also a significant difference between the groups at week 16 for improvement in treatment satisfaction, and a tendency towards a greater reduction in urge incontinence episodes. There was no significant difference between the groups at weeks 8 and 16 for other secondary variables measured.

Table 1: Adjusted mean changes from baseline to endpoint for the Full Analysis Set for solifenacin alone (n=305) and with bladder training (n=297). The primary variable was the mean change in micturition frequency from baseline at week 8. Results at 8 weeks are for the 5mg dose of solifenacin, whilst data at week 16 are for combined 5mg and 10mg doses.

Solifenacin was well tolerated. The most common adverse events reported were mild dry mouth and mild constipation in both treatment groups.

Parameter	week 8			week 16		
	solifenacin 5mg od	solifenacin 5mg od + bladder training	p value	solifenacin 5/10mg od	solifenacin 5/10mg od + bladder training	p value
Micturition frequency*	-2.18	-2.87	<0.0001	-2.42	-3.11	0.0005
Urgency episodes	-1.99	-1.98	0.99	-2.20	-2.50	0.78
Incontinence episodes	-1.21	-1.30	0.54	-1.45	-1.48	0.78
Urge incontinence episodes	-1.01	-1.16	0.27	-1.13	-1.38	0.066
No. of pads used	-1.19	-1.07	0.37	-1.29	-1.11	0.28
Patient PBC	-1.24	-1.23	0.84	-1.58	-1.63	0.61
Treatment satisfaction	+3.32	+3.50	0.40	+3.72	+4.18	0.025
I-QoL total	+20.65	19.68	0.48	+24.51	25.34	0.57
* The primary efficacy endpoint was micturition frequency at week 8 Patient PBC = Patient Perception of Bladder Condition I-QoL = Incontinence Quality of Life total score p-values are for parametric analysis of estimated differences between groups						

Interpretation of results

An important part of conservative management of OAB is patient education about the lower urinary tract and the OAB syndrome, encouraging interventions such as pelvic floor muscle training and supervised bladder training to help restore normal bladder

function. The SOLAR study has demonstrated that a simplified bladder training programme can enhance results achieved with a modern antimuscarinic agent, at least with regard to reducing micturition frequency and improving treatment satisfaction. The availability and nature of bladder training programmes tend to vary between countries. Although in routine practice not all centres will have sufficient resources for sophisticated bladder training programmes, the results from SOLAR may encourage adoption of a simplified bladder training scheme in conjunction with antimuscarinic treatment to help optimise OAB treatment.

Concluding message

The SOLAR study demonstrated that solifenacin is an effective and well tolerated treatment for OAB, these results being consistent with those from other solifenacin clinical studies. The effectiveness of solifenacin in reducing micturition frequency and improving treatment satisfaction was significantly enhanced when used with simplified bladder training.

References

1. Cochrane Database of Systematic Reviews 2006, Issue 4. Art. No: CD003193. DOI: 10.1002/14651858.CD003193.pub3

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<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>	Local Independent Ethics Committees (IECs) responsible for the participating centres and, where applicable, Institutional Review Boards.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes