

OPEN-LABEL NON-COMPARATIVE 24-WEEK STUDY WITH FLEXIBLE DOSING OF SOLIFENACIN TO PATIENTS WITH OVERACTIVE BLADDER IN THAILAND

Hypothesis / aims of study

Solifenacin succinate 5 and 10 mg QD doses are reported to be well tolerated and effective in treating overactive bladder. Our aim was to study the efficacy and safety of solifenacin administered over 24 weeks to 44 adult patients (6 men, 38 women) in Thailand with symptoms of overactive bladder (OAB) for ≥ 3 months.

Study design, materials and methods

The open-label non-comparative study began with a run-in period of 2 weeks, followed by Treatment Period I (4 weeks) to begin patients on the 5 mg dose and observe outcomes; the dose for Treatment Period II (20 weeks) was adjusted according to outcomes and adverse events reported

Results

At the last visit, 94.1% (16/17) of symptomatic patients achieved urinary continence, 68.0% (17/25) reported no urgency, and 39.5% (15/38) experienced normalized frequency of micturition. There was an overall improvement in patient perception of bladder condition (PPBC), and 81.3% (35/41) of patients and 79.0% (34/41) of physicians assessed treatment as a great benefit. Primary adverse events reported were mild dry mouth and dry throat, and constipation.

Interpretation of results

Our PPBC results at study end (mean change -2.06; median, -2; 95% CI, -2.59 to -1.54; $P < 0.001$, one-sample Wilcoxon test) were comparable to those reported in the VESicare Open-Label Trial (VOLT) (mean change -1.4; 95% CI, -1.49 to -1.38, $P < 0.001$, Student's t test).

Concluding message

Patient perceived benefits of flexible dosing of solifenacin to this subgroup of Asian patients were comparable to other open-label studies of solifenacin.

<i>Specify source of funding or grant</i>	This research was funded by Astellas Pharma
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</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>	Faculty of Medicine , Chiangmai University
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes