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.

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Is this a clinical trial?  Yes

Is this study registered in a public clinical trials registry?  No

Is this a Randomised Controlled Trial (RCT)?  No

What were the subjects in the study?  HUMAN

Was this study approved by an ethics committee?  Yes

Specify Name of Ethics Committee  Faculty of Medicine, Chiangmai University

Was the Declaration of Helsinki followed?  Yes

Was informed consent obtained from the patients?  Yes