

## COMPARISON OF TWO DIFFERENT ANTIMUSCARINICS, IMIDAFENACINE AND SOLIFENACIN, FOR TREATMENT OF OVERACTIVE BLADDER: A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

### Hypothesis / aims of study

We assess the efficacy and safety of two different antimuscarinics, imidafenacin and solifenacin in patients with overactive bladder (OAB).

### Study design, materials and methods

Twenty years or older male or female patients who had urgency (more than 1 episode per 24 hours), with or without urgency urinary incontinence and residual post-void residual urine volume (PVR)  $\leq$ 100 ml were randomized into 2 groups, group I- imidafenacin (0.1mg twice a daily), group S-solifenacin (5mg once daily) for a 12-month treatment regimen. Male OAB patients complained of urgency symptoms even after alpha1 blocker administration. Subjective symptoms were assessed using the International Prostate Symptom Score (IPSS), QOL index, Overactive Bladder Symptom Score (OABSS), urinary urgency assessed in three grades by referring to the Urgency Perception Scale (UPS), the degree of dry mouth, constipation using visual analogue scale (VAS), and the post-void residual urine volume (PVR) detected by ultrasonography before, 1, 3, 6, and 12 months after treatment. The duration time of dry mouth was also assessed at each time points.

### Results

A total of 109 patients, including 55 (mean 72.0 years old, 32 females and 23 males) in group I and 54 (mean 70.4 years old, 36 females and 18 males) in group S were treated. The persistent rates were 94.5% and 96.3% at 1 month, 61.8% and 81.5% at 3 months, 38.2% and 46.3% at 6 months, and 29.1% and 35.2% at 12 months after treatment, respectively. IPSS, QOL index, OABSS, and UPS were significantly improved in group I and S after treatment. There were no significantly different between 2 groups. PVR did not significantly increase in both groups. As to adverse event, VAS of dry mouth and constipation significantly increase in group S. On the other hand, only VAS of dry mouth significantly increased in group I after treatment. However, the duration time of dry mouth of group I was significantly shorter than that of group S. No acute urinary retention was found in this study.

### Interpretation of results

Although the persistent rates of group I was slightly worse than that of group S, the subjective efficacy was similar in both groups. As to the adverse effects, group I showed better than group S.

### Concluding message

Imidafenacin and solifenacin were efficacious, safe, and well-tolerated treatment that improved OAB. Profiles of each drug differ and should be considered in making treatment choices.

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| <b>Specify source of funding or grant</b>                             | <b>not declared</b>            |
| <b>Is this a clinical trial?</b>                                      | <b>Yes</b>                     |
| <b>Is this study registered in a public clinical trials registry?</b> | <b>No</b>                      |
| <b>Is this a Randomised Controlled Trial (RCT)?</b>                   | <b>Yes</b>                     |
| <b>What were the subjects in the study?</b>                           | <b>HUMAN</b>                   |
| <b>Was this study approved by an ethics committee?</b>                | <b>Yes</b>                     |
| <b>Specify Name of Ethics Committee</b>                               | <b>Kawasaki Medical School</b> |
| <b>Was the Declaration of Helsinki followed?</b>                      | <b>Yes</b>                     |
| <b>Was informed consent obtained from the patients?</b>               | <b>Yes</b>                     |