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EFFICACY AND SAFETY OF INITIAL 10MG SOLIFENACIN TREATMENT IN FEMALE OAB PATIENTS

Hypothesis / aims of study
Solifenacin succinate (solifenacin) is M3 selective antimuscarinic agent for overactive bladder(OAB) having dose flexibility with 5mg and 10mg. To achieve successful OAB treatment requires good drug compliance with satisfactory effect of the drug. Disadvantage of starting with lower dose would be longer drug administration duration for better control until to reach the effective higher dose.
In this study, we aimed to investigate the efficacy and safety of starting with10mg solifenacin initially compared with conventional 5mg starting dose for treating female OAB patients.

Study design, materials and methods
This is a prospective, randomized controlled, multi-central study. Subject patients were female OAB patients aged over 20 years old. Solifenacin was administered for 12 weeks in randomly assigned two groups; group A – starting dose of solifenacin 10mg qd, group B- starting dose of solifenacin 5mg qd. In both groups, after 4weeks of each dose of solifenacin treatment, dosage of solifenacin was maintained or changed to 5mg or 10mg depend on patients' response.
Symptoms improvement, drug compliance, and adverse effects were assessed and statistically analysed after 12 weeks of solifenacin treatment.

Results
Among 75 enrolled patients, 59 patients had finished the study. Mean age of the patients in group A was 54.8 $\pm$14.1 and group B was 54.3 $\pm$13.7 years old ($p>0.05$). Daytime frequency, urgency, nocturia had decreased after 12weeks in both groups but there were no significant differences between two groups (frequency, $p=0.360$; urgency, $p=0.577$; nocturia, $p=0.707$). urge incontinence also improved after 12 weeks without any significant differences between two groups ($p=0.272$).
Patient's satisfaction in two groups were; group A 92.9%, group B 93.1% without significant differences between group A and B. Incidence of adverse effects also did not show any significant differences between two groups ($p>0.05$). There were no serious adverse effect during this clinical trials.

Interpretation of results
Solifenacin treatment in OAB with 10mg initial dose did not show any significant difference compared with initial 5mg dose. Incidence of adverse effects also did not show any significant difference between 10mg or 5mg initial dose groups.

Concluding message
In this study, 10mg and 5mg initial dose of solifenacin treatment showed no significant differences in OAB symptom improvement and development of adverse effects. Further study about lower dose of antimuscarinic treatment for OAB would be required.

Disclosures
Funding: clinical research fund from Astellas Korea, LTD. **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Ewha Womans University Clinical Trial Center IRB, Cha University Clinical Trial Center IRB, Hanllym University Clinical Trial Center IRB **Helsinki:** Yes **Informed Consent:** Yes