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Han J¹, Yoo D¹, Lee H S², Lee K², Park C H³, Lee J G⁴, Kim D Y⁵, Lee Z Z⁶, Park W H⁷, Kwon D D⁸, Na Y G⁹, Choo M¹

1. Asan Medical Center, University of Ulsan College of Medicine, 2. Samsung Medical Center, Sungkyunkwan University School of Medicine, 3. Keimyung University School of Medicine, Daegu, Korea, 4. College of Medicine, Korea University, Seoul, Korea, 5. College of Medicine, Daegu Catholic University, Daegu, Korea, 6. Pusan National University School of Medicine, Busan, Korea, 7. Inha University College of Medicine, Incheon, Korea, 8. Chonnam National University Medical School, Gwangju, Korea, 9. Chungnam National University College of Medicine, Daejeon, Korea

EFFICACY OF SOLIFENACIN SUCCINATE FOR FREQUENT MICTURITION PATIENTS WITH OR WITHOUT URGENCY: A MULTICENTER PROSPECTIVE RANDOMIZED COMPARATIVE STUDY

Hypothesis / aims of study
The overactive bladder (OAB) is defined as urgency with or without urgency incontinence, usually with frequency and nocturia. Urgency is the key symptom of OAB and the cause of frequency (1). But patients reported that the most troublesome OAB symptom was daytime frequency (2). Since some of patients might not complain their urgency because of difficulty in expressing it or urinate frequently before they feel urgency. So we assumed that antimuscarinic drug could be effective for frequency without urgency as well as frequency with urgency. We compared the efficacy of solifenacin between patients complaining frequent micturition without urgency and with urgency.

Study design, materials and methods
This is a multi-center, open label, comparative study and non-inferiority study based on the hypothesis, “The efficacy of solifenacin for frequency is non-inferior to that of solifenacin for frequency with urgency”. We enrolled the patients with frequency of micturition >8 voids/day without urgency in group 1 and the patients with frequency of micturition >8 voids/day with urgency (urgency grade ≥3 (5 scales) & ≥2/day) in group 2. The primary efficacy variable was the mean change of daily micturition frequency from baseline and secondary efficacy variables included the changes in PPBC (Patients' Perception of Bladder Condition), OABSS (OAB Symptom Score) and BSW (Benefit, Satisfaction, Willingness to continue) questionnaires at the end of treatment. Safety was evaluated by adverse events, maximal urinary flow rate (MFR) and post-void residual (PVR).

Results
Of 286 patients enrolled, 240 (83.9%) completed the study (group 1: 115, group 2: 125). The mean change of daily micturition frequency were -1.9 ± 3.0 in group 1 and -2.4 ± 3.2 in group 2 (p=0.176). There was no significant difference between two groups in terms of frequency reduction. But, the lower limit of confidence interval set were -1.33 and -1.80, respectively and didn’t met the predetermined non-inferiority limit (-0.8). There was no significant difference between the portions of patients who improved in PPBC (group 1:85.7%, group 2:74.6%, p=0.23). The portion of patients who improved to mild grade from moderate or severe grade in OABSS was higher in group 1 than group 2 (group 1:88%, group 2: 62.8%, p=0.016). There was no significant difference in BSW questionnaire at the end of treatment. MFR decreased (group 1: -1.4±11.3, group 2: -0.11±10.3, p=0.216) and PVR increased (group 1:5.5±32.1, group 2:9.3±44.1, p=0.341) in both groups. Solifenacin was well tolerated in both Groups.

Interpretation of results
After 12 weeks of solifenacin treatment, there was no significant difference in change of daily micturition frequency between patients complaining frequent micturition without urgency and with urgency. However, we couldn’t verify that the efficacy of solifenacin for frequency without urgency is non-inferior to that of solifenacin for OAB because didn’t met the predetermined non-inferiority limit.

Concluding message
Solifenacin was effective for frequency without urgency as well as frequency with urgency. However, we couldn’t verify that the efficacy of solifenacin for frequency without urgency is non-inferior to that of solifenacin for frequency with urgency, i.e. OAB.

References