

## THE THERAPEUTIC EFFECTS OF ORALLY SOLIFENACIN COMBINED WITH PELVIC FLOOR MUSCLE EXERCISES IN TREATMENT OF FEMALE OVERACTIVE BLADDER

### Hypothesis / aims of study

In 2002, International Continence Society (ICS) defined overactive bladder (OAB) as a set of symptoms implying lower urinary tract dysfunction, which mainly included urgency of urination with or without urge incontinence, and usually, frequency of urination and nocturia. OAB can occur in both men and women although the incidence is higher in women. Based on the statistics made available by Abrams (1997), the incidence rate in female population was: 15% for 20~30 years, 16% for 40~50 years, and 20% for 60~70 years of age. This study reported the satisfactory therapeutic effects of solifenacin on OAB symptoms between December 2009 and May 2010 as follows.

### Study design, materials and methods

- 1.1 General information: From Dec. 2009 to May 2010, 242 female patients (age range: 24-72 yrs; average age: (51±6) yrs). Their disease duration were in the range of 1 to 11 years with the average duration of 3.2±1.0 years. The patients had therapeutic history of different period with antibiotics prior to this treatment, but not controlled well. Any patient with disease of nervous system, diabetes, organic diseases in urinary system, overactive bladder diagnosed clinically should be excluded.
- 1.2 Therapeutic Approach: 242 patients were randomized into 3 groups: group A: 82 patients, orally taking solifenacin, 5mg once daily; group B: 80 patients, pelvic floor muscle exercises, once daily; group C: 80 patients, orally taking solifenacin + pelvic floor muscle exercises. The duration of treatment was 4 weeks. No statistically significant differences were found among the 3 groups (P>0.05).
- 1.3 Observation parameters : Micturitions per 24 h, number of episodes of Overactive Bladder per 24h, and volume voided per micturition in 24h were recorded according to micturition diary in the 3 groups.
- 1.4 Statistical analysis t-test was used for quantification data (described with  $\pm S$  ) ; P values less than 0.05 were considered statistically significant.

### Results

- 2.1 Comparisons of the results from the 3 groups: all the parameters (Micturitions per 24 h, number of episodes of Overactive Bladder per 24h, and volume voided per micturition in 24h) in groups C were superior to that in group A and in group B (P<0.05).
- 2.2 Safety and Tolerability Evaluations: All the patients were included in the analysis of safety; the common AE of solifenacin was dry mouth, which occurred in 17 patients (20.7%) in group A, and 14 patients (17.5%) in group C.

### Interpretation of results

The study indicated that oral administration of solifenacin alone could achieve positive therapeutic effects and better outcome might be acquired in combination with pelvic floor muscle exercises. We considered that such combination therapy might either inhibit the occurrence of Overactive Bladder, and either being able to effectively reduce or avoid the incidence of AEs caused by the medication, and was deserved to be extensively adopted clinically.

### Concluding message

solifenacin; overactive bladder; pelvic floor muscle exercises

### Disclosures

**Funding:** No **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics not Req'd:** It is investigator driven study and there is not treatment before for these kinds of patients **Helsinki:** Yes **Informed Consent:** Yes