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ASSOCIATED FACTORS OF DOSE ESCALATION FOR THE TREATMENT OF OVERACTIVE BLADDER WITH SOLIFENACIN

Hypothesis / aims of study

To fine out baseline clinical characteristics affecting dose escalation for the patients with overactive bladder (OAB)

Study design, materials and methods

We prospectively enrolled the OAB patients (frequency of micturition ≥8 and urgency (urgency grade ≥3/5 scales) ≥2/day) who were treated with solifenacin and followed-up for 24weeks. All the patients conducted 3-day voiding diaries, OAB Symptom Score (OABSS) and residual urine volume measurment at baseline, 4, 12 and 24 week. At 4 and 12 week patients could remain baseline dose (solifenacin 5mg) or increase dose (solifenacin 10mg) after consultation with the investigator regarding efficacy and tolerability. We divided the enrolled patients into three groups by dose escalation period; non-dose escalators, 4 week dose escalators, 12 week dose escalators. Changes of OAB symptoms from baseline to 4 week, baseline to 12 week, and baseline to week 24 among non-escalators, 4 week escalators and 12 week escalators were analyzed using a 2-sample t-test. The baseline clinical factors of dose escalation in the treatment of solifenacin were assessed using a one-way ANOVA test.

Results

A total 41 patients (male n=10, female n=31, mean age 59.5 ± 9.9 yrs) were enrolled. Demographic characteristics are BMI (23.8±2.5, 24.33±3.5, 23.5±3.0), frequency of micturition (10.9±3.0, 12.3±2.0, 10.2±2.0), urgency episodes (5.0±3.5, 9.5±4.3, 7.6±2.9), urgency incontinence episodes (0.0, 0.5±0.8, 1.3± 2.1), OABSS total score (7.1±2.7, 11.0±2.2, 10.2±1.5), voided volume (266.4±114.5ml, 155.9±141.2ml, 238.7±84.3ml), peak flow rate (22.9±8.2ml/s, 20.4±10.8ml/s, 21.3± 8.5ml/s), postvoided residual urine (23.9± 34.9ml, 11.9±31.4ml, 4.5±11.2ml) in non-escalators, 4 week escalators and 12 week escalators, respectively. The dose escalation rate during the whole treatment period was 41.5% (17/41): 17.0% (7/41) at 4week and 23.4% (10/41) at 12 week.

<Non-escalators vs 4 week escalators>

At baseline escalators reported significantly more urgency episodes per 24hr compared with non-escalators (p=0.008). At 4 week, improvement of frequency were significantly greater in non-escalators than escalators, (p=0.001) and the improvement in urgency episodes per 24 hr appeared larger in escalators versus non-escalators, but the difference was not statistically significant (p=0.372; Fig1). By 12 week after dose escalation there was no difference between escalators and non-escalators in the improvement of frequency (-25.2% vs -30.8%, p=0.542) and urgency episodes (-62.1% vs -82.7%, p=0.372). At 24 week there was no difference between escalators and non-escalators in the improvement of frequency (-31.0vs -31.1%, p=0.996) and urgency episodes (-80.7% vs-97.9%, p=0.223).

<Non-escalators vs 12 week escalators>

At baseline there were no significant differences in any variables between non- escalators and escalators (p>0.05). At 4 week the improvement in frequency (p=0.143) and urgency episodes (p=0.165) appeared larger in escalators versus non-escalators, but the difference was not statistically significant. By 24 week after dose escalation, there was no difference between escalators and non-escalators in the improvement of frequency (-28.3% -31.1% vs, p=0.671) and urgency episodes (-100% vs -97.9%, p=0.509, Fig1).

Factors related to dose escalation were type of OAB (p=0.03), OABSS total score (p= 0.012), urgency episodes (p=0.010), urgency incontinence episodes (p=0.011). At 4 week escalators was affected by OABSS total score (p=0.000) and urgency episodes (p=0.020). At 12 week dose escalator were affected by type of OAB (p=0.033), OABSS total score (p=0.000), urgency episodes (p=0.040) and urgency incontinence episodes (p=0.049).

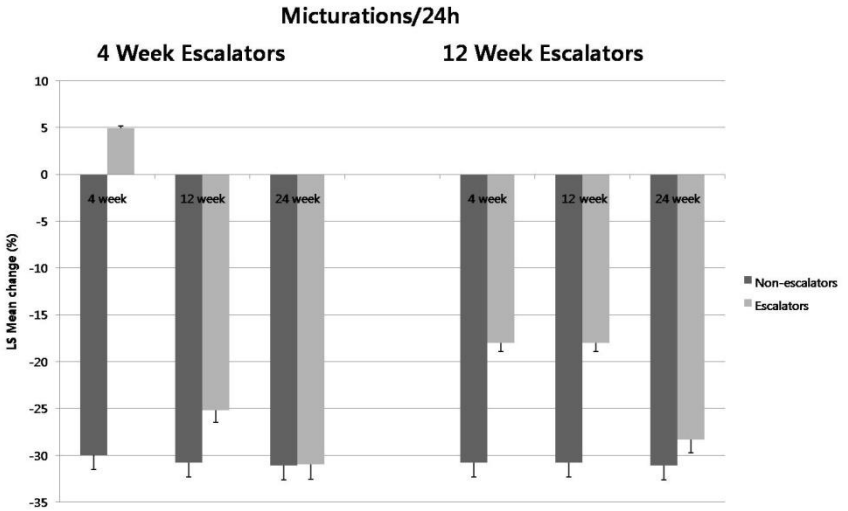
Interpretation of results

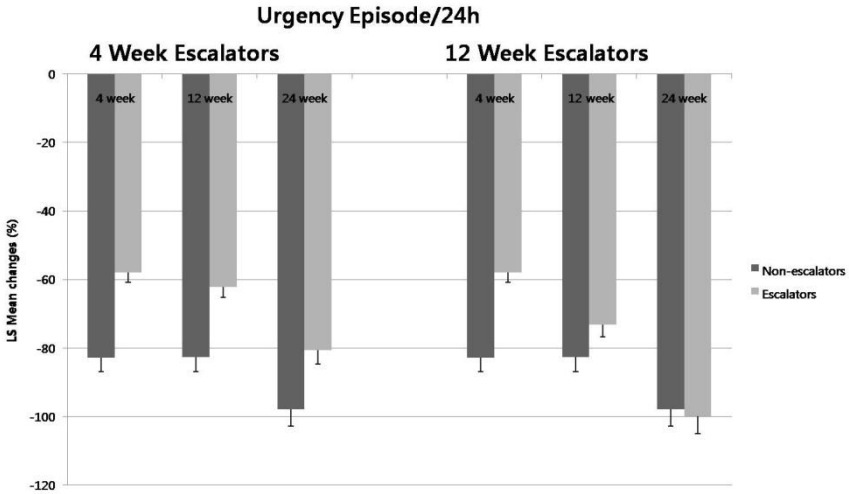
A rapid and robust response to solifenacin 5mg was demonstrated in non-escalators. Subjects who chose to escalate solifenacin at 4 week and 12 week showed significant improvement in OAB symptoms.

Concluding message

Associated factor for solifenacin dose escalation are OAB type, OABSS total score, urgency episode, urgency incontinence episodes at initial treatment.

Fig. 1. Least squares mean changes (%) from baseline in bladder diary variables. non-escalators versus escalators (within treatment groups)





Disclosures

Funding: no **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics not Req'd:** every patients take treatment as we routinely do, we just want no the factors for drug dose escalation according to their basic medical condition. This research didn't effect patients treatment plan. **Helsinki:** Yes **Informed Consent:** No