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## **IMIDAFENACIN, A NOVEL ANTICHOLINERGIC, SIGNIFICANTLY IMPROVES BOTH NOCTURIA AND SLEEP DISORDERS IN OAB PATIENTS.**

### **- EPOCH (EVALUATION OF ANTICHOLINERGICS IN PATIENTS WITH OVERACTIVE BLADDER AND NOCTURIA FOR CARED-HEALTH) STUDY IN JAPAN.**

#### Hypothesis / aims of study

Nocturia might be correlated with poor sleep and poor healthy condition. The objectives of this study are to examine the relation between nocturia and sleep disorders, and to examine the effect of imidafenacin(IM), a novel anticholinergic, on these symptoms in OAB (overactive bladder) patients.

#### Study design, materials and methods

A total 121 patients (54 males; 44.6%, and 67 females; 55.4%), with more than twice of nocturia over 50 years (mean age: 71.8 years) were enrolled in the study. The design was prospective, single-dose, one arm with 8 weeks active treatment period. All patients received IM oral tablet (0.2 mg) twice daily. Nocturia was assessed by FVC (frequency volume chart) and OABSS (overactive bladder symptom score), and sleep disorders were assessed by the Pittsburgh Sleep Quality Index (PSQI) and the Epworth Sleepiness Scale (ESS). In order to examine changes, the above parameters were evaluated. For statistical analysis, Wilcoxon signed-rank test was used and p value <0.05 was considered statistically significant.

#### Results

Before IM administration, nocturia was  $2.5 \pm 1.3$  times according to FVC, and was  $2.7 \pm 0.5$  points (full: 3 points) using OABSS. PSQI was above 5.5 (cutoff value) in 66 subjects (55.9%), and ESS was above 11 (cutoff value) in 20 subjects (16.9%). After 8 weeks of IM administration, nocturia in FVC decreased significantly from  $2.5 \pm 1.3$  to  $2.0 \pm 1.3$  times ( $p < 0.001$ ). Nocturia in OABSS decreased significantly from  $2.7 \pm 0.5$  to  $1.9 \pm 0.9$  points ( $p < 0.001$ ). Decreases were seen in PSQI global score and ESS score for sleep disorders (PSQI :  $p < 0.001$ , ESS :  $p < 0.05$ ). Examining the change in each parameter before and after IM administration, correlations were found between PSQI and ESS (correlation coefficient: 0.219), between nocturia in FVC and PSQI global score (correlation coefficient: 0.407) (Figure 1), and between nocturia in FVC and ESS score (correlation coefficient: 0.624) (Figure 2). No major adverse event was present.

#### Interpretation of results

In OAB patients, nocturia and OAB symptoms were significantly improved after 4 weeks treatment with anticholinergic agent, IM. In addition, PSQI global score and ESS score significantly decreased and the change of nocturia correlated with both PSQI global score and ESS score.

#### Concluding message

This study indicated that the improvement of nocturia by anticholinergic IM provided clinical benefit to sleep disorders.

Figure 1: Correlation between the variation of PSQI global score and number of nocturia episodes

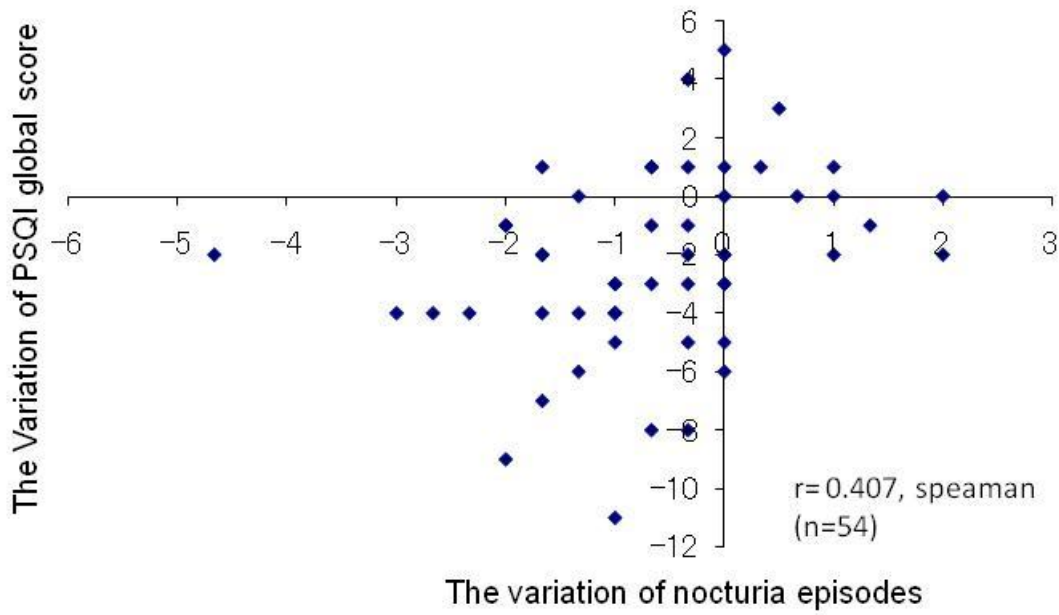
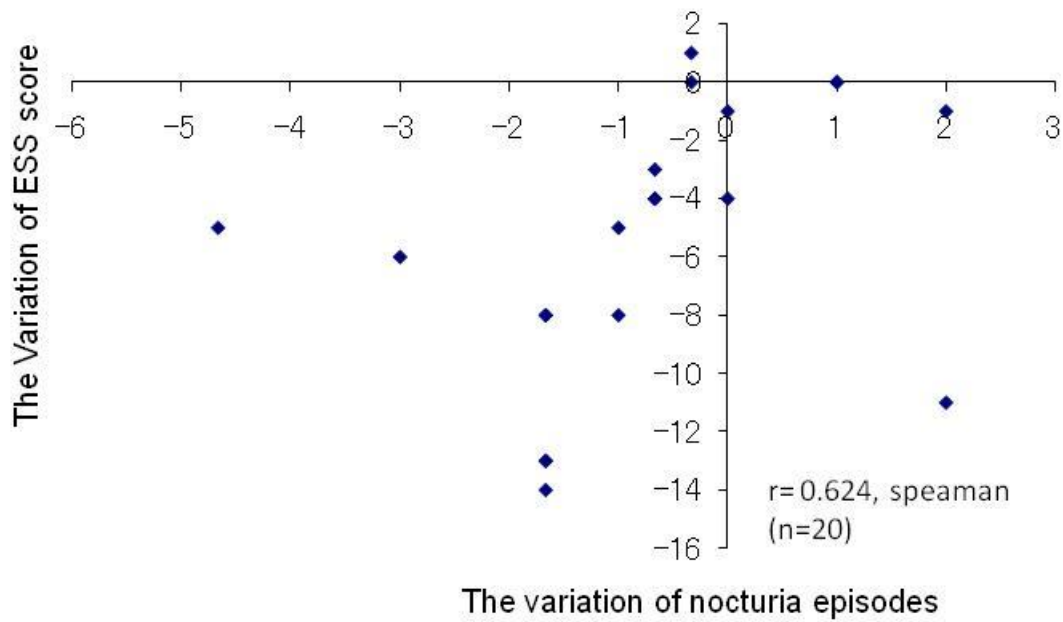


Figure 2 : Correlation between the variation of ESS score and number of nocturia episodes



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<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>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>Approved by local Ethics Committee</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>