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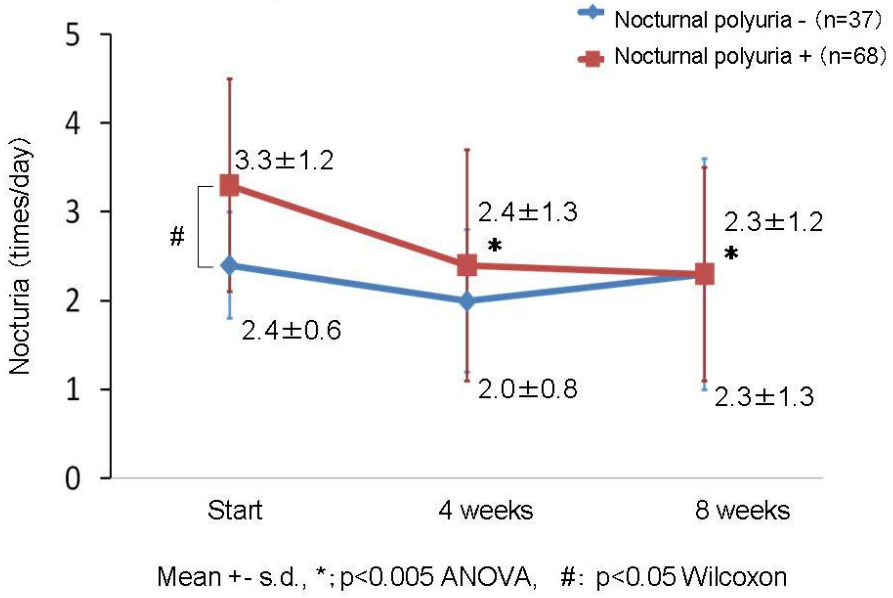
OVERACTIVE BLADDER PATIENTS WITH NOCTURNAL POLYURIA SHOWED BETTER IMPROVEMENT THAN WITHOUT NOCTERNAL POLYURIA IN BOTH NOCTURIA AND SLEEP DISORDERS BY IMIDAFENACIN, A NOVEL ANTICHOLINERGIC.
- SUBANALYSIS OF EPOCH (EVALUATION OF ANTICHOLINERGICS IN PATIENTS WITH OVERACTIVE BLADDER AND NOCTURIA FOR CARED-HEALTH) STUDY IN JAPAN -.

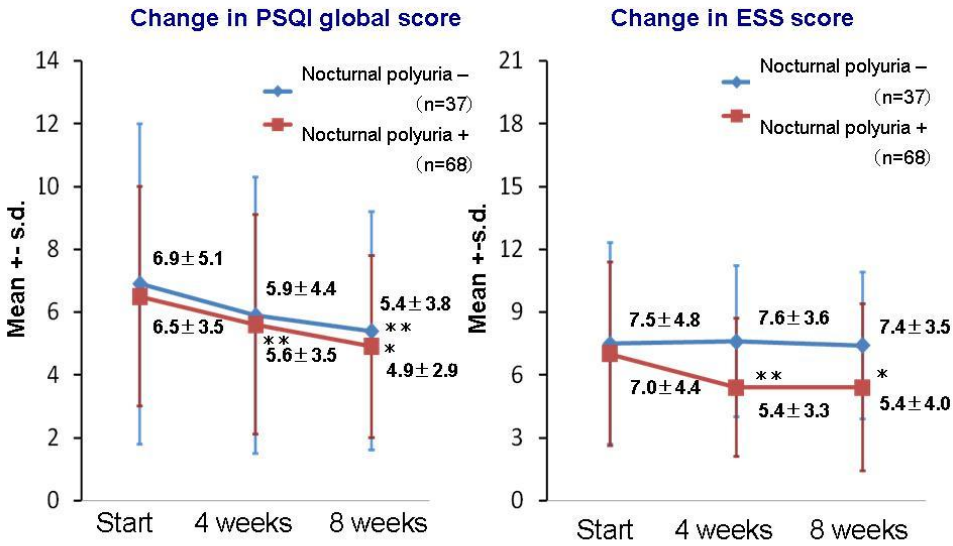
Hypothesis / aims of study
Nocturia might be correlated with poor sleep and poor healthy condition. Our previous study showed that nocturia and OAB symptoms significantly improved after 4 weeks treatment with anticholinergic agent, imidafenacin (IM), In OAB patients. In addition, sleep disorder assessed by PSQI global score and ESS score significantly improved and the change of nocturia correlated with both PSQI global score and ESS score.
The objective of this study is to examine the influence of nocturnal polyuria on the effects of IM for patients with both OAB and nocturia.
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 nocturnal polyurina was defined as nocturnal polyuria index more than 33% of 24hours' urine volume.
Sleep disorders were assessed by PSQI (Pittsburgh Sleep Quality Index) and ESS (the Epworth Sleepiness Scale). For statistical analysis, Wilcoxon signed-rank test, ANOVA, and Fisher's exact test were used, and p value <0.05 was considered statistically significant.
Results
Before IM administration, nocturia was 2.5±1.3 times according to FVC, and was 2.7±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±1.3 to 2.0±1.3 times ($p<0.001$). Nocturia in OABSS decreased significantly from 2.7±0.5 to 1.9±0.9 points ($p<0.001$). Decreases were seen in PSQI global and ESS scores for sleep disorders (PSQI : $p<0.001$, ESS :$p<0.05$).
Nocturnal polyuria index significantly correlated with the increase of age ($p=0.025$). The age of nocturnal polyuria (+) group (n=68, mean 73.5 years old) was significantly older than nocturnal polyuria (-) group (n=37, mean 69.0 years old, $p=0.016$).
In nocturnal polyuria (+) group, nocturia was significantly higher than those in nocturnal polyuria (-) group (3.3 vs 2.4, $p<0.05$, figure 1). Nocturnal polyuria (+) group showed significant improvement in nocturia after administration of IM ($p<0.005$, figure 1), however, nocturnal polyuria (-) group did not (figure 1).
PSQI global score significantly improved after administration of IM in either nocturnal polyuria (+) or nocturnal polyuria (-) group (figure 2). However, ESS significantly improved after administration of IM in nocturnal polyuria (+) group, but not in nocturnal polyuria (-) group (figure 2).
Interpretation of results
This result is very unique. IM is much more useful in OAB patients with nocturnal polyuria than without nocturnal polyuria.
Concluding message
Nocturnal polyuria may be a good indicator for responder of IM in OAB patients.

Figure 1. Change in nocturia episodes before and after administration of Imidafenacin.
- the effect of nocturnal polyuria -



Mean +- s.d., *; p<0.005 ANOVA, #: p<0.05 Wilcoxon

Figure 2. Changes in PSQI and ESS before and after administration of Imidafenacin.
- the effect of nocturnal polyuria -



*; p<0.005 ANOVA, #: p<0.05 Wilcoxon

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of University of Yamanashi**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**