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Sugino Y[1], Matsuoka T[1], Kobayashi T[1], Terada N[1], Yamasaki T[1], Matsui Y[1], Okubo K[1], Kamba T[1], Ogawa O[1], Yoshimura K[1]

1. *Department of Urology, Kyoto University*

SUBJECTIVE AND OBJECTIVE ASSESSMENT OF EFFICACY AND TOLERABILITY OF MIRABEGRON, A B(3)-ADRENOCEPTOR AGONIST, IN CLINICAL USE

Hypothesis / aims of study

The lack of an alternative to antimuscarinic drugs has led to the search for new drug targets for overactive bladder (OAB) symptoms. Mirabegron, a β(3)-adrenoceptor agonist has promising effects on reducing the number of micturition and incontinence episodes [1]. We held a preliminary study to analyze the efficacy and adverse events (AEs) of mirabegron. The AEs were compared with the control patients who prescribed antimuscarinic drugs.

Study design, materials and methods

Eighty OAB patients (man; 53, women; 27) who visited our hospital between October 2011 and November 2012 were enrolled as mirabegron group. Mean age of the patients was 72.5 (31-87). Sixty-four patients (80%) have been prescribed any antimuscarinic drugs. Twenty-four patients (45.3% of male patients) suffered from benign prostate hyperplasia (BPH). We evaluated frequency volume charts (FVCs) as well as post void residual (PVR), IPSS, OABSS, and hearing of AEs at 0, 4 and 12 weeks after medication.

Thirty-five OAB patients (man; 22, women; 13) who visited our hospital were enrolled as antimuscarinic group, which we evaluated AEs only. Mean age of the patients was 72 (53-85). The information of AEs was reviewed from patients' record. We used Wilcoxon signed-rank test to test these data. P value <0.05 was considered as significant.

Results

PVR was not significantly different between 0 week and 12 week (p=0.559, 38.6ml and 43.4ml, respectively). IPSS (p=0.001, 15→9, respectively), QOL score (p=0.001, 5→4) and OABSS (p=0.001, 8→5.5) showed significant improvement after 12 weeks (Fig.1). FVCs showed significant improvement in urinary frequency at night (p=0.021, 3→2) and whole day (p=0.027, 12→10) after 12 weeks without significant change in urine volume (p=0.556, 1810ml→1680ml).

AEs on mirabegron group occurred in 24 cases (30%), and 19 cases (23.8%) stopped using mirabegron. Six (7.5%) patients stopped using mirabegron because of insufficient effect. The main AEs to stop using mirabegron were voiding disturbance (10, 12.5%) and gastrointestinal troubles including constipation (4, 5%). On the other hand, AEs on antimuscarinic group occurred in 19 cases (54.2%), and 18 cases (51.4%) stopped using them. The main reasons to stop using antimuscarinics were gastrointestinal troubles including constipation (5, 14.3%), voiding disturbance (4, 11.4%) and dry mouth (4, 11.4%). Almost all interruption of using mirabegron occurred before 2 months after beginning of dosage (18/19, 94.7%).

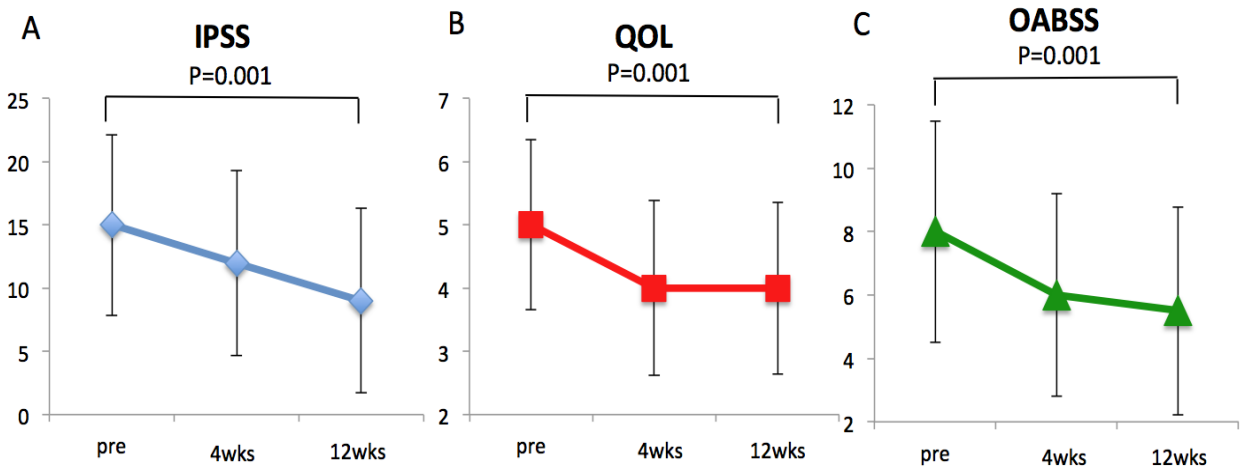
Interpretation of results

This study showed that mirabegron was effective for OAB patients and improved their QOLs. Although AEs occurred more frequent than previous clinical studies indicated [2], it was no more than the AEs on antimuscarinic group. There were few complaints about dry mouth in the mirabegron group.

Concluding message

Mirabegron is effective and tolerable in using for those who unfit for antimusucarinic drugs. Further study is needed to elucidate the proper target and the profile of AEs of mirabegron.

Fig.1 The changes of questionnaire scores in mirabegron prescribed patients



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Disclosures

Funding: N.A. **Clinical Trial:** Yes **Registration Number:** The clinical study of beta 3-agonist (Betanis) for lower urinary tract symptoms mainly for overactive bladder UMIN000008084 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Kyoto University Graduate School and Faculty of Medicine, Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes