Kinjo M¹, Enomoto K¹, Sekiguchi Y¹, Yoshimura Y¹, Okegawa T², Nutahara K²

1. MD, 2. Prof

COMPARISON OF LONG TERM COMPLIANCE WITH MIRABEGRON AND SOLIFENACIN IN TREATMENT-NAIVE FEMALE OVERACTIVE BLADDER PATIENTS

Hypothesis / aims of study
Overactive bladder (OAB) is a condition characterized by urinary urgency, with or without urge urinary incontinence, usually associated with daytime urinary frequency and nocturia. It is a common health problem and negatively impacts patients’ quality of life (QOL). Therefore, there is a need for effective treatment.

It is well known that antimuscarinic drugs are predominant pharmacologic treatment for OAB for long time. However, low persistency rate of anticholinergics due to side effects such as dry mouth and constipation, and their poor efficacy seen in some patients had promoted the new drugs, known as β3-adrenoreceptor agonist. Recently, many studies were reported that Mirabegron, an orally active β3-adrenoreceptor agonist was equal efficacy and low side effect compared to antimuscarinics. However, most of the study period was short (within 3 months) and longer follow-up (more than 3 months) has not been shown yet, especially in comparing antimuscarinics and β3-adrenoreceptor agonist. And also, there were few reports about the reasons for discontinuation of the drugs.

Thus, in this study, we compared the persistency and the reasons for discontinuation of the Mirabegron and Solifenacin at 6 months in treatment naïve female OAB patients.

Study design, materials and methods
A total 192 post-menopausal female treatment-naive OAB patients who presented to female urology clinics were enrolled in the study. The design was retrospective chart of review, randomized two arms with active treatment study. Patients were randomized to receive Mirabegron 50mg (n=76), or Solifenacin 5mg (n=72) once a daily.

All patients were subjected to a diagnostic work-up of medical history, physical examination, 3 days voiding chart, and post voided residual (PVR) before starting medication.

And to evaluate compliance of the drugs, persistence rate (the number of patients who persist in using medication during the period) and the reason for the discontinuation the drugs were investigated 6 months after the medication.

All participants provided informed consent before entering the study.

For statistical analysis, paired t-test was used and p value <0.05 was considered statistically significant.

Results
148 out of 192 (77.1%) patients were complete the study. Before the treatment, there was no significant differences between Mirabegron group (n=76) and Solifenacin (n=72) group in age (63.4±11.0 vs 61.5±10.7) (n.s), Body Mass Index (21.8±2.7 vs 22.4±4.0) (n.s), number of parity (1.4±1.0 vs 1.0±0.3) (n.s).

There were no significant differences in persistency rate at 6 months (Mirabegron group: 29.2%, Solifenacin group: 36.5% respectively) (n.s).

The reasons for discontinuation, lack of effect was significantly higher in Mirabegron group (36.8%) than Solifenacin group (2.8%) (p<0.05). In contrast, the reasons for discontinuation by side effects were significantly higher in Solifenacin group (27.8%) than Mirabegron group (7.9%) (p<0.05) respectively. There were no statistically significant differences in the reasons for discontinuation by improvement without medication in both groups (Mirabegron group: 20.3%, Solifenacin group: 12.8%) (n.s).

Interpretation of results
This study demonstrated that overall persistency of both Mirabegron and Solifenacin were low at 6 months in post-menopausal treatment naïve female OAB patients.

But the discontinuation of their background were contrast in both drugs. It could be one of the information about prescribe the medication to the OAB patients.

Concluding message
At the best of our knowledge, this is the first clinical study which compared the antimuscarinic and β3-adrenoreceptor agonist not only in persistency rate but also the reasons for discontinuation.

Disclosures
Funding: no disclosures Clinical Trial: Yes Public Registry: No RCT: Yes Subjects: HUMAN Ethics Committee: LUNA clinic Ethics Committee,U14033 Helsinki: Yes Informed Consent: Yes