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CLINICAL EFFICACY OF MIRABEGRON IN THE TREATMENT OF PATIENTS WITH NOCTURIA PREDOMINANT HYPERSENSITIVE BLADDER

Hypothesis / aims of study

Overactive bladder (OAB) is a symptom complex of urgency, with or without urgency incontinence, and is usually associated with frequency and nocturia. Nocturia is defined as waking from sleep at night to void. The β3-adrenoceptor agonist mirabegron has similar efficacy to most antimuscarinic agents with a lower incidence of dry mouth in patients with OAB. The aim of this study was to evaluate the clinical efficacy of mirabegron 25 mg per day in adults with nocturia predominant hypersensitive bladder.

Study design, materials and methods

Patients with nocturia predominant hypersensitive bladder were enrolled into this study. HSB was defined as functional capacity <350 mL and USS = 0 or 1. Mirabegron 25 mg per day was given treat the hypersensitive bladder. Clinical evaluation instruments including uroflowmetry, International Prostate Symptom Score (IPSS) with quality of life (QoL) index, Overactive Bladder Symptom Score (OABSS), the modified Indevus Urgency Severity Scale (USS), Patient Perception of Bladder Condition (PPBC) and Global Response Assessment (GRA) questionnaires were used at baseline, 1-month, 3-month and 6-month follow-up. All of them signed inform consent of this study. Continuous variables were represented as mean ± standard devation (SD). A p-value < 0.05 was considered to indicate statistical significance.

Results

A total of 260 adults were enrolled into this study, including 98 patients with treatment naïve, 162 patients who had used antimuscaric agents. In the treatment naïve group, IPSS-voiding score, IPSS-total score and QoL index showed significant improvement at 1-month mirabegron treatment follow-up. For patients who had used antimuscaric agents, significant improvements in postvoid residual, OABSS and USS score were noted. However, there were no differences in nocturia episodes per night from baseline to 1 month, 3 months and 6 months follow-up in both groups.

Interpretation of results

In patients who had used antimusacrinics and treatment naïve group, mirabegron did not show significantly improvements in mean number of nocturia episodes per night from baseline to 1 month, 3 months and 6 months follow-up. Although OAB symptom score and IPSS improved at the first month after treatment, these scores did not show improvement at 3 and 6 month after mirabegron treatment. Placebo effect is likely the cause for the initial success of treatment by mirabegron.

Concluding message

Nocturia is known to be related to many other conditions such as overactive bladder, benign prostatic enlargement, congestive heart failure and obstructive sleep apnea. In this study, no significant efficacy of mirabegron in treatment of patients with nocturia predominant hypersensitive bladder was found.

Table 1. Changes in nocturia episodes, uroflow parameters and symptom scores in treatment naïve group

	Baseline (n=88)	1 month (n=58)	3 months (n=30)	6 months (n=20)	P value B-1mo	P value 1-3mo	P value 3-6mo
Nocturia (episodes/night)	3.9±1.1	3.7±1.2	3.7±1.0	3.8±1.2	0.090	0.473	0.481
Qmax (mL/sec)	12.2±7.4	13.1±9.0	13.3±8.5	11.8±7.4	0.053	0.623	0.629
Voided volume (mL)	194.1±137.3	221.7±164.8	242.7±180.4	221.2±184.5	0.062	0.848	0.217
Postvoid residual (mL)	40.5±68.9	44.9±57.6	68.4±88.1	48.3±41.9	0.954	0.256	0.086
IPSS_voiding	5.6±5.5	4.2±4.9	5.1±5.6	4.4±5.3	0.048	0.761	0.854
IPSS_storage	5.4±2.1	4.8±2.1	4.2±1.5	4.4±2.1	0.055	0.084	0.858
IPSS_total	11.0±6.5	9.0±5.3	9.3±6.2	8.8±6.5	0.015	0.529	0.942
QoL	3.2±1.2	2.5±1.0	2.3±1.1	1.8±1.4	0.000	0.419	0.452
OABSS	3.4±0.7	3.9±1.9	3.7±1.8	3.6±1.9	0.007	0.858	0.851
USS	0±0	0.4±1.0	0.2±0.7	0.4±1.2	0.001	0.750	0.825
PPBC	3.4±1.8	2.3±1.5	1.9±1.5	2.4±1.9	0,000	0.135	0.108
GRA	-	1.1±1.2	1.6±1.5	1.6±1.2	-	0.230	0.719

Table 2. Changes in nocturia episodes, uroflow parameters and symptom scores in patients who had used antimuscarinics

	Baseline (n=123)	1 month (n=123)	3 months (n=100)	6 months (n=79)	P value B-1mo	P value 1-3mo	P value 3-6mo
Nocturia (episodes/night)	3.0±1.3	3.1±1.3	3.1±1.3	3.2±1.2	0.227	0.839	0.544
Qmax (mL/sec)	12.2±8.3	12.7±7.6	12.1±8.4	13.6±9.0	0.371	0.727	0.1.7
Voided volume (mL)	190.0±129.1	195.9±125.2	182.3±138.6	194.9±123.8	0.445	0.391	0.659
Postvoid residual (mL)	68.3±77.6	46.4±51.6	44.5±46.9	44.1±52.3	0.000	0.766	0.422
IPSS_voiding	5.1±5.0	4.4±4.6	3.2±3.9	3.3±4.2	0.055	0.060	0.734
IPSS_storage	3.6±1.8	4.0±2.4	3.8±2.2	4.2±2.2	0.075	0.642	0.370
IPSS_total	8.6±5.5	8.4±5.6	7.0±4.9	7.5±5.2	0.357	0.113	0.908
QoL	2.3±1.0	2.3±0.9	1.8±1.0	1.7±0.9	0.674	0.001	0.268
OABSS	2.7±0.9	4.1±2.7	4.0±2.5	4.4±2.8	0.000	0.814	0.118
USS	0±0	1.0±1.6	1.0±1.7	1.3±1.8	0.000	0.961	0.164
PPBC	2.0±1.4	1.8±1.3	1.5±1.2	1.4±1.1	0.198	0.067	0.676
GRA	-	0.9±1.4	1.5±1.3	1.6±1.4	-	0.001	0.785

Disclosures

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