PERSISTENCE IN THE TREATMENT OF OAB WITH MIRABEGRON IN A MULTICENTER CLINICAL STUDY

[1]Martan A.
[1]Mašata J., [1]Švabik K., Hanuš T., [3]Krhut J., [4]Zachoval R., [1]Dept. of Obstet. Gynecol., 1st Faculty of Med., Charles Univ. and Gen. Faculty Hosp., Prague, Czech Republic, [2]Dept. of Urology, 1st Faculty of Med., Charles Univ. and Gen. Faculty Hosp., Prague, Czech Republic, [3]Dept. of Urology, Univ. Hosp., Ostrava, Czech Republic, [4]Dept. of Urology, Thomayer Hosp., Prague, Czech Republic

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HYPOTHESIS / AIMS OF STUDY

The objective of this project was to evaluate treatment persistence in patients being treated for overactive bladder symptoms with mirabegron, employing clinical follow-up in a prospective, multicenter study. The hypothesis was that treatment persistence with mirabegron would be relatively high due to the reduced side effects and good cure effect of this medication.

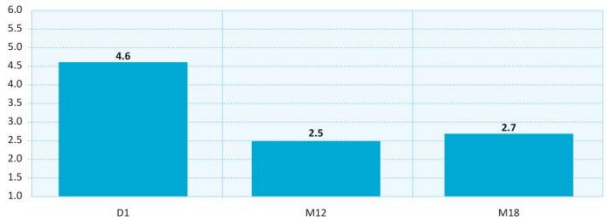
STUDY DESIGN, MATERIALS AND METHODS

This is an analysis of multicenter (6 gynecological and 4 urological centers) monitoring of patients who began treatment in May 2014 and were evaluated 18 months after the first visit. The patients were all over 18 years of age and had had symptoms of OAB for a minimum of 3 months. The dosage of mirabegron was 50 mg per day for 162 patients, while for another 44 patients at some point between the beginning of treatment (D1) and the 18-month (M18) follow-up either the dosage of mirabegron was increased to 100 mg per day (13 patients) or antimuscarinics (trospium or solifenacin) were added (30 patients). One patient ended the 18 months of treatment within the study on a dosage of mirabegron 100 mg per day combined with antimuscarinics. During the check-up it was ascertained how many patients had discontinued the treatment, and their reasons were established. Discontinuation of the treatment was first evaluated in the whole group. Then the patients involved in the monitoring were split into two groups: the first group comprised 75 patients ≤ 60 years of age (36%), and the second group was of 131 patients over 60 (64%). Discontinuation of therapy was evaluated in relation to gender, treatment type (dosage of mirabegron) and previous anticholinergic medication. For efficacy assessment we used patient perception of bladder condition scale (PPBC) and treatment satisfaction visual analogue scale TS-VAS. The statistics were calculated using the software STATISTICA 12 (Statsoft, USA) and SPSS (IBM, v.20.0).

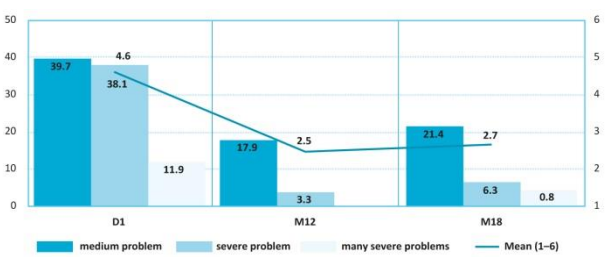
RESULTS

The mean PPBC score at baseline was 4.6 (SD 0.92) vs. 2.7 (SD 1.26) at the last follow-up, with score difference – 1.9 (p<0.001), TS-VAS was 73.4 (SD 21.93) at the last follow-up.

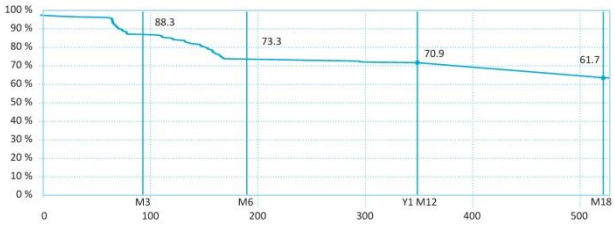
Mean PPBC score (n=127)
baseline = 4.6 (SD 0.92) M18 = 2.7 (SD 1.26)
Diff. M18-D1 - 1.8 (p<0.001)



PPBC (patients with more serious problems)



Persistence with mirabegron in patients with OAB



RESULTS

Monitoring was performed on 206 patients with OAB. 178 (86%) of patients had been given anticholinergic treatment previously, for an average of 714 days (~ 2 years). Their mean age when we started our study was 62.8 years (range 23–89), 62.7 years for females (range 23–89) years and 63.4 years in the group of males (range 30–78). Mean body mass index (BMI) for the whole group of patients was 27.3 (SD 4.96): the male group was 27.6 (SD 3.85) and the females 27.3 (SD 5.14). We did not find any statistical significant differences between these groups. At the check-up 18 months (±2 weeks) post-initiation of treatment it emerged that 79 (38.3%) patients had discontinued the treatment. The reasons for discontinuation in the whole group were: 28 (35.4%) insufficient treatment efficacy, 39 (49.4%) other reasons (the main reasons here were hospitalization, surgery, gravidity, indisposition for collaboration) and 12 (15.2%) discontinued therapy because of side effects. The side effects were tachycardia, headache, vertigo, nausea, eye irritation, lower abdominal pain.

STUDY WAS DISCONTINUED BY 79/206 (38.3% PATIENTS)

BY AGE				
Age ≤ 60 years (n = 75/206; 36%)		Age > 60 years (n = 131/206; 64%)		n.s.
27/75 (36%)		52/131 (40%)		
inefficacy	6/27 (22%)	inefficacy	22/52 (42%)	n.s.
side efects	5/27 (19%)	side efects	7/52 (13%)	
BY PREVIOUS ANTICHOLINERGIC TREATMENT				
Without		With		n.s.
11/28 (39%)		68/178 (38%)		
BY GENDER				
Female		Male		p=0.078
63/176 (36%)		16/30 (53%)		
BY MIR 50 MG / MIR 100 MG / MIR 50 MG+AM / MIR 100 MG+AM				
MIRA 50 (at the last visit)		Change to MIRA50+AM**, MIRA100, MIRA 100+AM**		p <0.001
76/162 (47%)		3/44 (7%)		

* p-value is significance level of chi-sq. test (n.s.--> not significant (p>>0.05);
**AM=trospium 15mg / solifenacin 5 mg

INTERPRETATION OF RESULTS

The hypothesis that the treatment persistence with mirabegron would be relatively high due to the reduced side effects and good cure effect of this medication was confirmed.

At the check-up 18 months post-initiation of treatment it emerged that only 79 (38.3%) patients had discontinued the treatment. The reasons for discontinuation in the whole group were: 28 (35.4%) insufficient treatment efficacy and 12 (15.2%) discontinued therapy because of side effects, 39 (49.4%) of patients had other reasons.

The mean PPBC score at baseline was 4.6 (SD 0.92) vs. 2.7 (SD 1.26) at the last follow-up, and TS-VAS was 73.4 at the last follow-up.

CONCLUDING MESSAGE

In our clinical prospective multicenter study, persistence in treatment with mirabegron reached a figure of 61.7%. The reasons were good efficacy and reduced side effects of mirabegron.

Mirabegron provides an alternative treatment option for OAB with the potential to increase treatment persistence.