

# MIRABEGRON IN OLDER PATIENTS WITH IDIOPATHIC, WET OVERACTIVE BLADDER AND MULTIPLE COMORBIDITIES

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#### Introduction

Overactive bladder (OAB) is a challenge to treat in older adults with chronic co-morbid conditions taking multiple medications. Although the conventional treatment of idiopathic (i)OAB in the older patient is represented by anticholinergics (Achs), both adherence and persistence to these agents are short mainly due to intolerable side effects. The aim of this study was to investigate the efficacy and tolerability of the  $\beta$ -3 detrusor receptor agonist Mirabegron in the treatment of iOAB in older patients affected also by concomitant chronic comorbidities, in the short- term follow- up.

# **Methods and Materials**

Forty-six wet iOAB patients refractory to standard Achs were prospectively included in the study. Baseline evaluation included the 3- day voiding diary, uroflowmetry with post- void residual (PVR) volume measurement and VAS to score the impact of urinary symptoms on Quality of Life (QoL; 0=worse; 10=best). **Patients started assuming Mirabegron 50 mg once daily.** The 3- day voiding diary, uroflowmetry with PVR and VAS were repeated again at **1**, **3 and 6 mos follow-up**. To assess the impact of age and comorbidities on the results of treatment, patients were divided into two subgroups: group 1 aged < 65 years, group 2 ≥ 65 years. In addition, number and types of comorbidities were identified. Side effects were accurately recorded.

### Results

There were 33 females and 13 males; mean ± SD age was 69.6 ± 12.2 years. Patients had been previously treated with solifenacin, propiverine and trospium chloride along different times (range: 3- 22 mos), which were stopped due to intolerable side effects. Twelve patients were in group 1; the mean ± SD age was: 53.5 ± 10.8. In these patients, concomitant chronic comorbidities were: systemic arterial hypertension (2 cases, 16.6%), BPCO (1 case, 8.3%) and depression (2 cases, 16.6%). Thirty- four patients were in group 2; mean  $\pm$  SD age was 75.2  $\pm$  6.4 yrs. Concomitant comorbidities were: systemic arterial hypertension (11 cases, 32.3%), BPCO (2 cases, 5.8%), depression (5 cases, 14.7%) and arthrosis (3 cases, 8.8%). Obviously, chronic comorbidities were more frequent in patients in group 2 as compared to those in group 1 (p=0.01).

With regards to urinary symptoms, at baseline all patients presented with urgency and urgency urinary incontinence (UUI) and with low VAS scores. Overall, urinary symptoms and VAS significantly increased in 28 cases at all the considered time- points (p< 0.00; Table), regardless of patients' age and number and types of comorbidities. Of noting, the mean ± SD value of maximum flow rate significantly reduced, but with no increase in PVR. At the 6- month follow- up, the mean  $\pm$  SD VAS score increased to 7  $\pm$  1.7 in patients in group 1 and 6.2 ± 1.1 in those in group 2 (p= n.s). Persistence rate to treatment was about 60.8% and eighteen cases were lost during follow- up because of drug's low efficacy (7 in group 1 and 12 in group 2, p= n.s.). No systemic side effects were observed; only 3 patients complained of urinary tract infections at the end of follow- up.

#### Discussion

Mirabegron, the first  $\beta$ -3 adrenoceptor agonist entered clinical practice, shows different mechanism of action from antimuscarinic medications. According to this, it may be particularly useful in iOAB older patients affected by chronic comorbidities, who frequently need for Ach medications. In the present study, 61% of patients (both adult and old cases refractory to previous Achs) showed significant improvements in urinary symptoms and consequently, in QoL. Particularly, the significant improvement in VAS score at the end of follow- up, was similar in both adult and older patients without any significant difference due to the presence of chronic comorbidities. The 61% persistence rate to treatment at the 6- mos follow- up appears to be higher than that usually reported with Achs. In patients who dropped- out to treatment, the β-3 receptor agonist appeared to be not effective, but none of these patients stopped assuming Mirabegron because of adverse effects. It is well known the anticholinergic load due to multiple pharmacological treatments with Achs in elderly people, who are generally affected by many comorbidities, also including OAB syndrome. For these patients Mirabegron may represent a first choice pharmacological agent, particularly due to the excellent tolerability profile.

Table 1

	Baseline (46 pts)	1 month (38 pts)	3 months (38 pts)	6 months (28 pts)	р
	mean ± SD	mean ± SD	mean ± SD	mean ± SD	
Urgency (episodes/ day)	9.7 ± 3.6	6.2 ± 2.9	5.9 ± 2.5	6 ± 2.7	0.00
Urgency urinary incontinence (episodes/ day)	4.2 ± 2.1	3.1 ± 1.3	2.8 ± 2.1	2.5 ± 1.8	0.00
Maximum flow rate (mL/s)	19.1 ± 3.2	9.3 ± 3.6	9 ± 3.2	9.2 ± 2.6	0.00
PVR (mL)	40 ± 24.3	36 ± 20.7	35 ± 21.5	37 ± 19.9	0.5
VAS score	3.8 ± 0.9	6.6 ± 1.7	7.1 ± 2.6	7 ± 1.8	0.00

## Conclusions

Mirabegron 50 mg once daily is effective and safe in controlling iOAB symptoms and in improving the QoL also in older patients refractory to conventional Achs. Patients more aged and affected by multiple chronic diseases can largely benefit from treatment with Mirabegron, thus avoiding an additional anticholinergic effect in their usual therapeutic regimen.

# References

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