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ASSESSING PERSISTENCE IN PATIENTS WITH OVERACTIVE BLADDER PRESCRIBED MIRABEGRON IN ROUTINE CLINICAL PRACTICE: SUBANALYSIS OF A PAN-EUROPEAN NON-INTERVENTIONAL STUDY

Hypothesis / aims of study
Clinical trials have established the efficacy and safety profile of mirabegron [1, 2], a first-in-class β3-adrenoreceptor agonist that is an alternative therapeutic option for overactive bladder (OAB). This is the first large European, prospective, observational study on the impact of mirabegron on quality of life (QoL), patient satisfaction, healthcare resource utilization, adverse events (AEs) and treatment persistence in a non-interventional clinical setting. The primary objective was to evaluate change from Baseline (BL) in QoL based on OAB questionnaire (OAB-q) subscales. Here we focus on the evaluation of persistence with mirabegron treatment over a 12-month period.

Study design, materials and methods
Patients aged ≥18 years with OAB symptoms ≥3 months, whose physician had made the decision to prescribe mirabegron as part of routine clinical practice and who were about to start treatment were enrolled. Follow-up was done for a period of 12 months and included visit windows of 2-4 months and 10-12 months. A total of 862 patients were enrolled from 9 European countries. Overall, 848 (98.4%) were included in the Safety Analysis Set (all patients who received ≥1 dose of mirabegron during the study), 796 (92.3%) in the Full Analysis Set (all enrolled patients who completed the OAB-q at BL and at ≥1 follow-up visit, regardless of whether they remained on mirabegron therapy or not) and 452 (52.4%) in the Per Protocol Set (all enrolled patients who remained on mirabegron therapy and who completed the OAB-q at BL and at 10-12 months).

Results
In the full analysis group, at BL 42.2% of patients were 'new' or treatment naïve, 10.1% were lapsed, 41.3% had switched from other OAB treatments to mirabegron, and 6.4% were on combination treatment. Overall, there was a clinically meaningful improvement in QoL as measured by the OAB-q subscales. At all the assessment windows, the majority of patients were using mirabegron as a single agent. In the full analysis group, at 10-12 months, 53.8% of patients were receiving mirabegron either as a single agent or as a combination agent; 6.0% patients switched from mirabegron to other OAB treatment; and 13.1% patients discontinued treatment completely (Table). Additionally, treatment-naïve patients or those without treatment for OAB ≥2 years tended to stay on mirabegron as a single treatment. Similar observations were made in the per protocol group. In terms of incontinence status, 34.9% of patients from the full analysis group had an OAB dry episode at BL, which increased to 36.4% at 2-4 months and 43.7% at 10-12 months. The mean (SE) change from BL for the number of incontinence pads used in the last 7 days was -2.9 (0.47) at 2-4 months and -2.0 (0.49) at 10-12 months. Similarly, improvements in incontinence status were noted in the per protocol group. A large percentage of patients who were OAB wet at BL shifted to OAB dry after treatment. Most patients who were OAB dry at BL remained OAB dry after treatment (Table). Finally, overall incidence of adverse events (AEs) was consistent with other studies (42.8% of SAF patients reported ≥1 AE, 7.5% had ≥1 serious AE, 21.0% had ≥1 mirabegron-related AE and 1.8% of patients reported ≥1 mirabegron-related serious AE) and mirabegron was found to be well tolerated.

Interpretation of results
A notable improvement in patient reported QoL outcomes, along with incontinence status and incidence of AEs may contribute to the high persistence rate observed in this study, with 53.8% of patients remaining on mirabegron after approximately 12 months for the full analysis group.

Concluding message
In this prospective, observational study, patients receiving mirabegron reported meaningful improvements in QoL and showed high persistence with treatment over a period of 12 months.

Table: Persistence and incontinence status			
Prescription status and time on treatment at 10-12 months (FAS)			
Remained on mirabegron	428 (53.8%)		
Single	361 (45.4%)		
Combination	67 (8.4%)		
Switched	48 (6.0%)		
Discontinued	104 (13.1%)		
Missing prescription	216 (27.1%)		
Shift analysis of prescription status (FAS)			
	BL	2-4 months	10-12 months
N*		509	580
Switched treatment at BL to mirabegron	NA	184 (36.1%)	165 (28.4%)
Treatment naïve/no treatment ≥2 yrs	NA	173 (34.0%)	162 (27.9%)
Incontinence status†			
Patients in FAS, % (N=796)			
Incontinence status	793 (99.6%)	506 (63.6%)	580 (72.9%)
OAB wet	515 (64.7%)	216 (27.1%)	232 (29.1%)
OAB dry	278 (34.9%)	290 (36.4%)	348 (43.7%)
Patients in PPS, % (N=452)			
Incontinence status	452 (100%)	318 (70.4%)	422 (93.4%)
OAB wet	278 (61.5%)	122 (27.0%)	155 (34.3%)
OAB dry	174 (38.5%)	196 (43.4%)	267 (59.1%)
Incontinence pads used (change from BL)			
FAS (N=796)			
n‡	NA	490	572
Mean (SE)§	NA	-2.9 (0.47)	-2.0 (0.49)
PPS (N=452)			
n‡	NA	313	421
Mean (SE)§	NA	-2.7 (0.56)	-2.0 (0.50)

*Number of patients with available prescription status at BL and follow-up time periods. †OAB wet patients were defined as those patients having ≥1 urgency incontinence episode (Patient Perception of Intensity of Urgency Scale [PPIUS] grade 4) in the 3 days prior to the visit. Stress urinary incontinence and post-micturition dribble are not included in this assessment. OAB dry patients were defined as having 0 urgency incontinence episodes in the 3 days prior to the visit. ‡Total number of incontinence pads used in last 7 days prior to visit. §Mean change from BL for the number of incontinence pads used in last 7 days prior to visit.

BL, Baseline; FAS, Full Analysis Set; NA, not applicable; OAB, overactive bladder; PPS, Per Protocol Set; SE, standard error.

References

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