

INTERIM RESULTS FROM A PAN-EUROPEAN NON-INTERVENTIONAL STUDY ASSESSING QUALITY OF LIFE AND PERSISTENCE IN OVERACTIVE BLADDER PATIENTS PRESCRIBED MIRABEGRON

Hypothesis / aims of study

Oral pharmacotherapy options for treatment of overactive bladder (OAB) are antimuscarinics and the β 3-adrenoceptor agonist, mirabegron. The efficacy and safety profile of mirabegron, which has a different mode of action to antimuscarinics, has been established in a clinical trials programme [1]. Observational studies can provide evidence about patient outcomes in routine clinical practice. This prospective, non-interventional study in adult OAB patients was designed to evaluate the impact of mirabegron on quality of life (QoL), treatment satisfaction, persistence with treatment, patterns of healthcare resource utilization and safety in a real-world clinical practice setting across 8 European countries.

Study design, materials and methods

Patients were invited to enroll prior to starting treatment with mirabegron at a dose of 25 mg or 50 mg. Follow-up was for 12 months; 863 patients were enrolled. This abstract presents data from an interim analysis (IA), performed when the first 396 patients had completed 6 months of observation. For the IA, the focus was on changes from baseline to 2–4 months. A 1–5 month broadened window was also included to reflect the typical timing of first follow-up in clinical practice. The primary endpoint was change from baseline in QoL based on OAB-q subscales [2]. Patients who achieved a change from baseline that exceeded the 10-point minimal important difference (MID) in the total overactive bladder questionnaire (OAB-q) and its subscales (Health-Related quality of life [HRQoL] and Symptom Bother scale) [2] were assessed. Secondary endpoints included treatment patterns, persistence with treatment and adverse events (AEs).

Results

Overall, 863 patients were enrolled in the study. In total, 396 (45.9%) had completed 6 months of observation at the time of the IA; of those 351 (88.6%) were included in the Full Analysis Set (FAS; all enrolled patients who completed the OAB-q at baseline and at ≥ 1 follow-up visit), and 394 (99.5%) were included in the safety analysis set (SAF; all patients who received ≥ 1 dose of mirabegron during the study). The majority of patients in the SAF were from the UK (34.6%), Czech Republic (26.3%) and Slovakia (23.0%). Women accounted for 71.2% of the FAS, mean age was 59.7 years, 42.7% of patients were ≥ 65 years. At baseline, 52.1% of patients had moderate OAB symptoms and 39.3% had severe OAB symptoms. The majority of patients (48.1%) had switched from other OAB treatments; 35.9% were treatment naïve, 8.8% were lapsed and 7.1% were on combination treatment. The baseline OAB-q Symptom bother score was 53.5 (standard error 1.2). Mean Total HRQoL and symptom bother scores improved from baseline to 2–4 months and 1–5 months (Figure). In total, 54.8% and 58.1% of patients had a ≥ 10 point-improvement in OAB-q Symptom bother score at 2–4 months and 1–5 months, respectively. Total HRQoL score improved by ≥ 10 points for 45.5% and 48.6% of patients at 2–4 months and 1–5 months, respectively. Observed persistence was high, with 86.4% of patients remaining on mirabegron at 2–4 months and 84.0% remaining on mirabegron at 1–5 months. Overall, 143/394 (36.3%) patients in the SAF reported at least 1 AE; 19.5% of patients were assessed by the investigator to have AEs that were probably or possibly related to mirabegron. A total of 26 patients (6.6%) reported at least 1 serious AE. Two deaths occurred during the trial due to sepsis; one case involved a patient with a diverticular abscess and the second case occurred in a patient hospitalised following a fall with associated back injuries. In neither case did the investigator consider the deaths to be related to treatment with mirabegron.

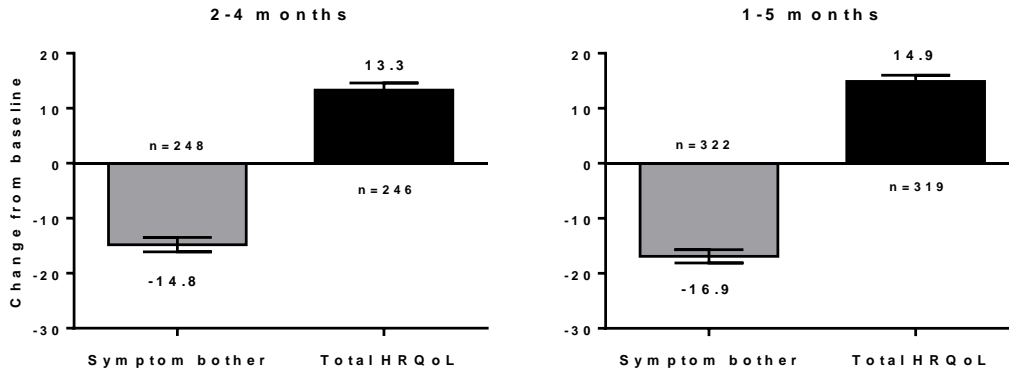
Interpretation of results

Baseline OAB-q Symptom bother score was 53.5 (standard error 1.2), indicating that patients had OAB of slightly higher severity than in previous mirabegron clinical trials [3]. In this IA at 6 months, patients receiving mirabegron reported improvements in QoL, as measured by improvements from baseline in OAB-q subscale scores. These improvements achieved the MID in more than 50% of patients, indicating that they were meaningful to patients.

Concluding message

Interim results from this prospective, non-interventional observational study showed that patients receiving mirabegron reported meaningful improvements in QoL. More than half of patients receiving mirabegron experienced a reduction in symptom bother which exceeded the MID. Persistence with mirabegron treatment was high and AEs were in line with previously reported results [1].

Improvements in OAB-q subscales



Patients exceeding the MID: 54.8% 45.5% 58.1% 48.6%

References

1. 1 Chapple C, et al. Neurourol Urodyn. 2014; 33(1):17-30.
2. 2 Coyne KS, et al. J Urol 2006; 176: 627.
3. 3 Khullar V, et al. Eur Urol. 2013; 63(2): 283-295.

Disclosures

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Ethics Committee: Several, including Etická komise, Fakultní nemocnice Královské Vinohrady for Czech Republic, Ethics Committee of University hospital of Patras for Greece, Research Ethics Committee HSE- Midland Area for Ireland, Etická komisia Trencianského samosprávneho kraja for Slovakia, CEIC Grupo Hospitalario Quirón en Barcelona for Spain, Regionala Etikprovningsnamnden I Lund for Sweden, Medway NHS Foundation Trust for UK, **Helsinki:** Yes **Informed Consent:** Yes