13

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LONG-TERM OUTCOMES OF MIRABEGRON IN THE TREATMENT OF OVERACTIVE BLADDER IN DIFFERENT AGE GROUPS OF PATIENTS – RESULTS OF MIRACLE II STUDY

Hypothesis / aims of study

The objective of this project was to evaluate treatment results both in quality of life (subjective) and micturition diary (objective) patterns in patients being treated for overactive bladder symptoms with mirabegron, employing clinical follow-up in a prospective, multicentre study on a long-term basis.

The aim was to follow treatment results for longer period than usual and with a special aim to check possible differences by age.

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 (treatment naive or pretreated) were all over 18 years of age and had symptoms of overactive bladder for a minimum of 3 months.

For each patient sociodemographic information and history was collected, and both quality of life characteristics (TS-VAS, UB-VAS, PPBC, OAB SF) and micturition diary patterns (micturitions/day, urgencies gr.3, gr.4, gr.3+4 and nocturias) were collected at each visit (V1 (D1), V2 (M3), V3 (M6), V4 (M12), V5 (M18)).

Overall development of all observed characteristics of patients who finished the study as planned was evaluated. Breakpoint of age at 60, 65 and 70 years were set. For each breakpoint set of 2-sample t-tests for all the characteristics and all the visits was performed to check possible differences in characteristics and treatment by age.

The statistics were calculated and testing was performed using the software SPSS (IBM, v.20.0).

Results

206 overactive bladder patients entered the study, 176 females (85%) and 30 males (15%). Patients were aged 23 - 89 (mean age 62.9±12.43), males 30-78 (63.4±12.14) and females 23-89 (62.8±12.52).

178 patients (86%) switched from anticholinergics (108 due to lack of efficiency, 66 due to lack of tolerance, 4 for other reasons). Significant difference by age in the reason for therapy switch was found. Patients up to 60 years tend to switch due to lack of tolerance (52%). Patients over 60 years tend to switch for lack of efficacy of previous anticholinergic treatment (70%).

75 patients (36%) were up to 60 years, 9 males (12%) and 66 females (88%), and 131 patients (64%) were over 60 years, 21 males (16%) and 110 females (84%), at the beginning of the study.

126 patients (persistence in the study was 61.2%) finished the whole course of the study. 80 patients (39%) terminated the study prematurely - 16 males (20%) and 64 females (80%), 27 patients (34%) were up to 60 years and 53 patients (66%) were over 60 years. 6 patients up to 60 years and 22 patients over 60 years terminated the study due to lack of efficacy. 12 patients up to 60 years and 7 over 60 years terminated the study due to the lack of tolerance. The remaining 43 patients dropped the study from other reasons (lost-follow-up, gravidity, disease, hospitalization, etc.).

All the characteristics observed improved significantly within the 1.5 year's period of the study for all the patients who finished the study as planned. Slight worsening of observed quality of life patterns was observed between M12 and M18, but this was not accompanied by change in objective micturition diary patterns.

Of the three age breakpoints the 60 year break point was found the best for evaluation of differences. There were no significant differences between patients up to 70 years and over 70 years. There were still some significant differences between patients up to 65 years and over 65 years, but the difference was statistically strongest between patients up to 60 years and over 60 years. It seems that the greatest effect in perception of quality of life lies between 60 and 65 years.

Treatment development as measured by differences between D1 and M18 seems to be always slightly better for patients over 60 years either in objective characteristics from micturition diary or in quality of life characteristics TS-VAS, UB-VAS, PPBC and OAB. Differences in TS-VAS, urgencies gr.3 and urgencies gr.3+4 were found to be significant by age. TS-VAS improved by 5,4 from M3 to M18 for patients over 60 years and by 7,3 for patients up to 60 years. Number of urgencies gr. 3 decreased by 0,8 in patients up to 60 years and 2,0 in patients over 60 years. Number of urgencies gr. 3+4 decreased by 1,3 in patients up to 60 years and by 3,1 in patients over 60 years.

Interpretation of results

Mirabegron treatment leads in all patients to the significant improvement of all objective and subjective parameters in the long term follow up of 18 months.

It seems that the patients over 60 years react better to the mirabegron treatment and appreciate improvements in their quality of life more than patients up to 60 years. It seems that for patients over 60 years overactive bladder patterns are crucial for their perception of quality of life.

Concluding message

Mirabegron treatment is effective in all patients for both micturition diary and quality of life patterns in the long term follow up.

It seems that mirabegron treatment allows patients over 60 years to perceive their overactive bladder symptoms more bearable and probably to stay physically and socially more active for longer period of time.

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