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EVALUATION OF OAB TREATMENT AND PATIENT SATISFACTION REFLECTING 'REAL LIFE CONDITIONS' IN UROLOGICAL OFFICES IN AUSTRIA

Aims of Study

There is a broad basis of large randomised trials on the usage of antimuscarinics, such as tolterodine, for the treatment of patients with OAB symptoms. The day-to-day setting in a normal office can usually not reflect the stringent inclusion criteria of such studies. In this investigation we aimed to assess the outcome of treatment of a broad range of patients with OAB symptoms typical for an office-based setting in order to find evidence that the results from controlled clinical trials are 'reproduceable' in the normal life situation.

Methods

406 patients with OAB were documented in an open-label evaluation by 45 urologists (36 office based, 9 outpatient clinics) at baseline and in median 4 and 9 weeks after initiation of treatment with Detrusitol IR (2 x 2 mg). To avoid a possible bladder-training effect voiding diaries were not compulsary. The outcome measurement was based on the change of the perception of bladder condition and the assessment of effect of the treatment on restriction of daily life, nocturnal disturbances and treatment satisfaction.

Included were patients with OAB symptoms eligible for antimuscarinic treatment. 30 % of the patients were recruited prospectively, 70 % included retrospectively, 39 % had experienced other drug treatments for OAB previously, 61 % were treatment-naïve. There were no statistically significant differences of baseline characteristics between these groups. The evaluated outcome variables were change of patient perception of bladder condition assessed with a validated 6-point bladder condition scale[1)], patient assessment of change of restriction of daily life, nocturnal disturbance and treatment satisfaction, complemented by an assessment of the physicians on treatment success. Tolerance was evaluated by assessing the severity of dry mouth.

Results

Of 406 patients included 390 completed the 1st assessment after 4 weeks, 335 the 2nd after 9 weeks and 299 the final assessment after 11 weeks (values: median). The majority of patients were female (66 %) and the median age was 67 years. All outcome variables showed highly significant improvements.

The bladder condition (rated from 'many severe problems' to 'no bladder problems') was perceived improved by 85 % / 90 % of the patients at the 1st /2nd assessment. The subgroup of pretreated patients showed a slightly but statistically not significant lower improvement of their bladder condition with 81 % and 87 % respectively.

Regarding restriction of daily life 86 % of patient judged their life at baseline as very restricted or restricted by their bladder problems. At the 2nd assessment 82 % reported an improvement resulting in a drastic shift of 77 % of the patients judging no or minor restrictions of their daily life.

At baseline, an unexpected high share of 68 % of the patients reported that they have nocturia 2 or more times per night. This share improved to just 19 % after the 2nd assessment.

The treatment was well tolerated: 55 % reported no and 37% just minimal dry mouth, 6 % severe and only 1,5 % experienced very severe dry mouth problems and just one patient terminated treatment because of side effects. The rate of dry mouth compared favourable to the rate experienced at prior drug treatment with 62 % showing very severe or severe dry mouth.

Regarding overall patient satisfaction 79 % / 88 % at 1st/2nd assessment of the patients were very satisfied or satisfied with their OAB treatment.

At final evaluation of the treatment outcome 86 % of patients assessed the therapy success as very good or good and 89 % reported an amelioration of their quality of living.

Not surprisingly also the final physician assessment of the treatment effectiveness was evaluated with 44 % as very good and 43 % as good.
The comparison of the results of the prospective and the retrospective group showed an inconsistent picture. In the variables change of bladder condition, restriction of every day life and final patient assessment of treatment success the results for the prospective group were slightly better, whereas for nocturnal disturbance and the rate of dry mouth the outcome was marginally better for the retrospective group, all other variables showed no significant difference. Overall, these differences did not change the total picture of the results.

Conclusions

The results on clinical effectiveness in a true reflection of the real-world situation in Austria showed a very favourable assessment of patients and physicians of the treatment of OAB symptoms with tolterodine in a representative number of patients. All outcome variables improved statistically highly significant compared to baseline. From this assessment we conclude that the results from international randomised trials can be extrapolated to the every-day practice. With tolterodine the clinical effectiveness in the treatment of OAB intended is achieved in a high majority of the patients according to assessments by patients and physicians.

References

1) Coyne KS, Matza LS. Validation of the perception of bladder condition measure in overactive bladder. Poster at ISPOR (Int. Soc. for Pharmacoeconomics and Outcome research) 7th Annual Meeting May 19-22, 2002, Arlington.