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THE HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH A NEUROGENIC OVERACTIVE BLADDER TREATED WITH TOLTERODINE ER: A REAL-LIFE STUDY.

Hypothesis / aims of study

Health-related Quality of life (HRQoL) and Patient Reported Outcomes (PRO) play an important role in understanding the burden of Overactive Bladder (OAB). Validated measures are also essential to assess the efficacy/effectiveness of treatment. In this study the effectiveness of 3 months treatment with Tolterodine Extended Release (TER) was evaluated in patients with a neurogenic bladder previously treated with oxybutynin.

Study design, materials and methods

Patients with OAB of neurogenic origin who discontinued oxybutynin treatment due to lack of efficacy or unacceptable adverse events (eligible for reimbursement of tolterodine ER in Belgium), were included in this prospective non-interventional study. Data was collected using the symptom bother subscale of the OAB-q questionnaire (1), (2) at baseline and after 3, 6 and 9 months of TER treatment. The underlying condition, symptom bother and severity, treatment efficacy and tolerability as well as patient's QOL were collected at all time points. Compliance and persistence with treatment were also recorded. A sample size of 130-150 patients was sufficient to demonstrate a significant improvement of the symptom bother subscale of the OAB-q (1), (2), following treatment with TER. Here the preliminary results after 3 months of TER treatment are presented.

Results

153 of 200 patients recruited by 20 centers in Belgium were included in this analysis. Their mean (±S.D.) age was 60 (±17.1) years and the majority of patients were female (70%). The main underlying conditions of neurogenic OAB were MS (32%), paraplegia (21%), CVA (13%) and Parkinson's disease (8%). The mean total score (±SD) of the OAB-q symptom bother questionnaire decreased from 29.13 (±9.12) to 18.16 (±7.53) at month 3 ($p<0.001$). All individual OAB-q symptom bother items showed a statistically significant ($p<0.001$) improvement, with the highest impact on micturition frequency (27%) and uncomfortable/sudden urge to urinate (28%). Nocturia improved by 17% (Table 1). The severity and bother of treatment related adverse events such as memory/confusion, vertigo, constipation and dry mouth decreased statistically significantly compared to baseline oxybutynin treatment. The most pronounced improvement was seen for dry mouth: the number of patients reporting dry mouth decreased from 80% to 67%, severity decreased from 32% to 8% severe cases and the number of patients reporting discomfort associated with dry mouth decreased from 79% to 44% (all $p<0.001$). Overall mood was considered to be improved by 47% and the overall condition by 77% of patients. After 3 months of TER treatment, 92 % of patients were still taking their treatment of which 96% on a daily base.

Interpretation of results

The decrease in OAB-q symptom bother score exceeded the "Minimally Important Difference" (3), indicating clinically relevant changes in symptoms and bother related to OAB following 3 months treatment with TER in this group of neurogenic patients previously treated with oxybutynin. The more modest improvement on nocturia might be explained by the fluid retention in the lower limbs and the pelvic region during the day following the sedentary lifestyle of this type of patients, causing polyuria when laying down during the night. The decrease in adverse event related bother most likely contributes to the high persistence and compliance with TER treatment seen in this study, which in turn could contribute to improvements in efficacy.

Concluding message

Tolterodine E.R. improves symptoms and Health Related Quality of Life in patients with a neurogenic OAB previously treated with oxybutynin.

References

1: Qual Life Res 2002, 11: 563-574.
2: Adv Ther. 2005 Jul-Aug; 22(4): 381-94.
3: J of Urol. 2006, 176: 627-632.

Table 1: OAB-q symptom bother subscale: change after 3 months treatment of TER vs. baseline

	N	Mean change vs. baseline*	95% CI	p
1. Frequent urination during daytime hours	153	-1.6	(-1.91;-1.38)	<0.001
2. Uncomfortable urge to urinate	151	-1.7	(-1.94;-1.38)	<0.001
3. Sudden urge to urinate	152	-1.7	(-1.95;-1.44)	<0.001

4. Accidental loss of small amounts of urine	152	-1.1	(-1.36;-0.81)	<0.001
5. Nighttime urination	153	-1.0	(-1.30;-0.75)	<0.001
6. Waking up at night because of need to urinate	152	-1.0	(-1.25;-0.79)	<0.001
7. Uncontrollable urge to urinate	149	-1.2	(-1.46;-0.95)	<0.001
8. Urine loss associated with a strong desire to urinate	147	-1.0	(-1.23;-0.71)	<0.001

*Scale:1-6 (6 items)

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