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FESOTERODINE ESCALATION TO 8 MG AFTER SWITCH FROM FIRST OVERACTIVE BLADDER (OAB) THERAPY WITH TOLTERODINE ER IS ASSOCIATED WITH ADDITIONAL PATIENT-REPORTED TREATMENT BENEFIT IN DAILY PRACTICE: FINDINGS FROM THE IMPACTA STUDY

Hypothesis / aims of study

The aim of this study is to evaluate whether dose escalation to fesoterodine 8 mg is associated with higher patient-reported treatment (PRT) benefit compared to fesoterodine 4 mg after patient switched from tolterodine ER for the treatment of symptomatic OAB in daily practice.

Study design, materials and methods

A post-hoc analysis of cross-sectional data from a retrospective one-visit study (IMPACTA study) was carried-out. Inclusion criteria were male/female >18 years, diagnosis of OAB, currently symptomatic [OAB-V8 score ≥8], and for whom a change due to any cause to daily fesoterodine from their first tolterodine ER-based therapy had occurred at the physician's discretion within 3–4 prior months. Patients could start at 4 mg of fesoterodine, and then be titrated to 8 mg if additional efficacy was needed. Patient-reported treatment benefit of changing was assessed using the self-administered Treatment Benefit Scale (1=greatly improved, 2=improved, 3=not changed, 4=worsened during treatment). Treatment satisfaction, worry, bothersome and interference with daily living activities of urinary symptoms were assessed based on ad-hoc questions using a Likert scale (from 1=not at all to 5=very much/quite a lot). Compliance was assessed using the Morisky-Green scale.

Results

748 patients met inclusion criteria; mean [SD] age 61.4 [10.9] years; 76% women. Reasons for treatment change differed by fesoterodine dose received. Side effects was the cause of switch in 23.5% of those titrated to 4 mg and 16.1% of those escalating to 8 mg. Lack of effectiveness led to switch in 58.0% and 70.9%, respectively (p=0.018). Compliance rate was higher with 8 mg dosing; 33.5% versus 24.9%, p=0.035. Worry, bothersome and interference-related OAB symptoms improved or showed a trend to greater improvement with higher dosing; p<0.05 in most cases (see Table 1). Mean patient satisfaction with new treatment was higher with 8 mg; 3.73 [3.65-3.81] versus 3.51 [3.39-3.63], p=0.003. PRT benefit (defined as 'improved/very much improved') was also significantly higher with higher dose; 97.1% vs. 88.4%; odds ratio=4.71 [2.28-9.73], p<0.001.

Interpretation of results

The main reason for switching treatment was the lack of effectiveness in both 4 mg and 8 mg, followed by side effects which generated lower switches in 8 mg escalation. The end points related to quality of life were better with 8 mg escalation than with 4 mg titration.

Concluding message

Compared with 4 mg, fesoterodine dose escalation to 8 mg was associated with additional and higher PRT benefit in term of drug compliance, treatment satisfaction and improvement of urinary symptoms in symptomatic OAB patients who switched from tolterodine-ER-based therapy in daily practice.

Table 1. Urinary symptoms improvement after switching from tolterodine ER to fesoterodine according to fesoterodine dose at the study visit.

Urinary symptom (not at all=0 to quite a lot=5)	**Total**	**4mg**	**8 mg**	**F[§]**
Worry				
Frequency	3.2	3.4	3.1	10.4‡
Incontinence during sexual attempt	2.2	2.1	2.2	3.2
Nocturia	3.0	3.22	2.99	6.7*
Frequency of infections	2.4	2.36	2.39	0.1
Urgency	3.2	3.38	3.17	5.0*
Bladder pain	2.3	2.43	2.32	1.6
Urge incontinence	3.1	3.32	3.06	7.0*
Urinary difficulties	2.2	2.19	2.23	0.2
Stress incontinence	2.2	2.12	2.22	1.1
Bother				
Urinary frequency	3.2	3.42	3.16	10.3‡
Strong desire to urinate	3.3	3.53	3.17	16.3‡
Urine loss associated with a strong desire to urinate	3.1	3.31	3.05	7.3*
Interference with daily-living activities				
Usual activities	3.0	3.13	2.99	2.4
Leisure	3.1	3.22	3.03	4.6*
Work/domestic activities	2.5	2.48	2.44	0.1

*p significance level adjusted by sex, driven of treatment change, treatment adherence, treatment length, reason for switching; Values are mean with 95% CI. [§]Snedecor´ F from ANCOVA model. *p<0.05; ‡p≤0.001*

Disclosures
Funding: This study was funded by Pfizer, S.L.U. Isabel Lizarraga and Javier Rejas are employees of Pfizer, S.L.U. and Daniel Arumi is employee of Pfizer Inc, Europe. Francisco Sánchez-Ballester, David Castro-Díaz and Pilar Miranda have not received any financial support from Pfizer for writing or interpreting the present research, and declare that they do not have conflict of interests as a consequence of this abstract. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Consorcio Hospital General Universitario de Valencia **Helsinki:** Yes **Informed Consent:** Yes