

ADHERENCE TO FESOTERODINE TREATMENT IN ROUTINE CLINICAL PRACTICE

Hypothesis / aims of study

The primary aim of this study was to assess compliance with fesoterodine treatment among women diagnosed with overactive bladder (OAB) in routine clinical practice. The secondary aims were to identify factors associated with treatment persistence and the reasons for non-compliance/withdrawal of fesoterodine medication

Study design, materials and methods

This was an observational cross-sectional, prospective, multicenter study. Adult women diagnosed with OAB according to the International Continence Society (ICS) definition, without pelvic organ prolapse (\leq grade II Baden-Walker) and who had been on fesoterodine treatment (either 4mg or 8mg) for at least three months after diagnosis were included. Data about factors that might be related to persistence were recorded at the time of diagnosis; they included age, educational level, place of residence (urban, rural), number of concomitant drugs, impact of OAB on patients' lives [OAB questionnaire Short Form (OABqSF)] and OAB severity [International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF)]. Treatment compliance assessment and main reasons for non-compliance with the treatment were recorded three months after diagnosis. Compliance was assessed using the Morisky-Green test (compliers were those patients that did not answer affirmatively to any question non-favourable to treatment compliance). In addition, both compliers and non-compliers were asked whether they had discontinued the treatment at any time and about the reasons for discontinuation.

Results

Ninety-seven patients with a mean age of 62.0 ± 11.4 years with severe OAB [mean (standard deviation) ICIQ-SF score 13.3 (4.1)] at diagnosis were included in the study. 41 of 84 (48.8%) patients were considered compliers. No statistically significant differences were observed between complier and non-complier groups regarding any of the factors associated with treatment persistence analyzed. 51 of 84 (60.7%) patients declared that they had discontinued the fesoterodine treatment [14 of 41 (34.1%) in the complier group vs. 37 of 43 (86.0%) non-compliers, $p < 0.001$]. Reasons for treatment discontinuation were available on 39 patients; side effects were the main cause (53.8%) followed by other causes (28.3%) [patient neglect (33.3%), clinical improvement (22.2%), change of treatment (11.1%)] and lack of clinical benefits (17.9%). Principal side effects included dry mouth (38.1%) and constipation (14.3%).

Interpretation of results

In routine clinical practice, a high percentage of patients (48.8%) were considered compliers with fesoterodine treatment three months after the initial prescription. However, more than half of the study population discontinued the treatment due in some cases to intolerance or lack of efficacy. Those who at some time had discontinued treatment were more frequent in the non-complier group. Being aware of the reasons for discontinuation may help caregivers introduce interventions to increase adherence to treatment, i.e. provide information on reasons for withdrawal for those who discontinue due to clinical improvement, or for dealing with mild to moderate side effects for those who discontinue due to intolerance.

Concluding message

Despite well-established efficacy in the clinical trials of fesoterodine, treatment non-compliance is a major obstacle to its effectiveness in clinical practice. Identification of reasons for non-compliance/discontinuation of fesoterodine medication would give clinicians the opportunity to achieve more successful selection of patients who are eligible for potential adherence-focused interventions.

Disclosures

Funding: This study received funding support of a Pfizer grant **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Comitè d'Ètica i Investigació Clínica (CEIC) de l'Hospital de la Santa Creu i Sant Pau **Helsinki:** Yes **Informed Consent:** Yes