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PERSISTENCE OF SOLIFENACIN TREATMENT IN OVERACTIVE BLADDER PATIENTS IN REAL LIFE PRACTICE: A 12-MONTH, PROSPECTIVE, MULTICENTER, OPEN-LABEL, OBSERVATIONAL STUDY

Hypothesis / aims of study

Antimuscarinic agents are the primary pharmacologic therapy for overactive bladder (OAB). However, high discontinuation rates have been observed for these agents in part due to lack of efficacy and adverse effect [1]. Little is known about the persistence of antimuscarinics from prospective studies in the setting of real clinical practice. Primary aim of the study was to evaluate the level of persistence and the reason for non-persistence in patients receiving solifenacin for OAB during a 12-month period based on real clinical practice.

Study design, materials and methods

From June 2009 and September 2011, prospective, open-label, multicenter, observational study was conducted with men and women who were over 18 years old and had OAB symptoms over 3 months. OAB was defined as a total OAB symptom score (OAB-SS) [2] of 3 or more with an urgency score of 2 or more, and the score of urgency perception scale (UPS) [3] of 1 or 2. Enrolled patients were prescribed a dose of 5 or 10mg solifenacin and the dose might be increased, decreased or remained according to the efficacy and tolerability for 12 months. Rates of persistence, discontinuation, switch and surgery were assessed. Reasons for non-persistence and relating factors for the persistence were evaluated.

Persistence was defined as the proportion of patients continuing solifenacin therapy without discontinuing the drug or switching to other antimuscarinic drugs. Patients were considered to be non-persistent if they failed to refill their prescription within 30 days from the expected end of supply of the previous prescription ("discontinuation"), or if a patient filled prescription with another antimuscarinic drugs other than solifenacin within the 30 days ("switch"), or if a patient had surgery for lower urinary tract symptoms including OAB. Planned sample size was 900 patients assuming the persistence rate of 20% at 12 months and the precision of +/-3% for 95% confidence interval.

Results

A thousand and eighteen (men 329, women 689) patients were enrolled and prescribed solifenacin. The mean age was 58.6±12.9 years and the mean total OAB-SS was 8.0±2.7 with the mean urgency score of 3.4±1.0. After 12 months, the persistence rate was 22.1% (men 29.5%, women 18.6%), the discontinuation rate was 69.1% (61.7%, 72.6%), the switch rate was 8.4% (8.2%, 8.6%) and the surgery rate was 0.4% (0.6%, 2 TUR-P, 0.3%, 2 midurethral slings). By periods, persistence rates were 72.4% at 3 months, 45.8% at 6 months and 31.1% at 9 months. 25.4% of patients did not have a refill after the initial prescription. Reasons for non-persistence were improvement in symptoms in 34.3% (men 34.0%, women 34.4%), unknown due to follow-up failure in 32.1% (24.1%, 35.4%), patients' perception of lack of efficacy in 15.1% (20.2%, 13.0%), adverse effects in 6.8% (8.9%, 6.0%), drug cost in 2.0% (2.0%, 2.0%) and others in 9.7% (10.8%, 9.2%). Adverse effects which resulted in non-persistence were dry mouth in 34.7% (men 27.8%, women 38.7%), aggravation of voiding symptoms in 20.4% (38.9%, 9.7%), acute urinary retention in 6.1% (5.6%, 6.4%), indigestion in 6.1% (5.6%, 6.4%), constipation in 4.1% (11.1%, 0%), urinary tract infection in 4.1% (0%, 6.4%), visual disturbance in 4.1% (0%, 6.4%), dry eyes in 2.0% (0%, 3.2%), dizziness in 2.0% (5.6%, 0%) and other diseases in 16.3% (5.6%, 22.6%). In results of univariate analysis, old age (OR 1.023, CI 1.009, 1.036, p=0.0008) and male gender (OR 1.891, CI 1.362, 2.627, p=0.0001) were related to the high rate of persistence. In results of multivariate analysis, old age (OR 1.023, CI 1.008, 1.038, p=0.0022), male gender (OR 1.942, CI 1.373, 2.747, p=0.0002) and low frequency of nocturia (OR 0.826, CI 0.707, 0.965, p=0.0159) were related to the high rate of persistence. Cut-off value for age was 60 years (p=0.0100) and the value for nocturia was 3 times/24hrs (p=0.3144).

Interpretation of results

During 12-month period, 78% patients were not persistent with solifenacin mainly due to improvement in symptoms, lack of efficacy and adverse effects. However, significant proportion of patients was lost to follow-up. Most common adverse effect which resulted in non-persistence was dry mouth in women and aggravation of voiding symptoms in men. Three patients (1 man and 2 women) were discontinued solifenacin due to acute urinary retention. Two male patients were discontinued solifenacin due to constipation. Old age, male gender and low frequency of nocturia were related to the high rate of persistence. Patients aged 60 years or over have a higher probability of persistence with solifenacin for 12 months.

Concluding message

Twelve months after the initial prescription, persistence rate of solifenacin was low. 1) Patient education and motivation to decrease the rate of loss to clinical follow-up, 2) identifying and managing unmet treatment expectation of patients to enhance patient perception of treatment efficacy, and 3) active monitoring and proper management of the adverse effects could enhance the persistence of solifenacin therapy in patients with OAB symptoms.

References

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