332

Karram M[1], Chancellor M[2], Andoh M[3]
1. Tri-State Urogyenecology, Cincinnati, OH, 2. University of Pittsburgh, Pittsburgh, PA, 3. Astellas Pharma, Inc., Deerfield, IL

SOLIFENACIN REDUCES OVERACTIVE BLADDER SYMPTOMS AND IMPROVES HEALTH-RELATED QUALITY OF LIFE IN PATIENTS PREVIOUSLY TREATED WITH TOLTERODINE

Hypothesis / aims of study

Physicians often try a number of overactive bladder (OAB) treatment options in an attempt to find an acceptable balance between efficacy and tolerability. One pharmacoeconomic study reported that only 30 to 40% of patients who were prescribed an antimuscarinic in a Medicaid managed care population were persistent with therapy (based on prescription refill) after 30 days. Among persistent patients, 15 to 18% switched to a different OAB drug during the period of observation [1]. The present study was conducted to measure efficacy, tolerability, and health-related quality of life (HRQL) in subjects who reported residual urgency symptoms while receiving tolterodine tartrate and were switched to solifenacin treatment for 12 weeks.

Study design, materials and methods

VERSUS (VESIcare® Efficacy and Research Study US) was an open-label, flexible-dosing, multicenter study designed to assess the efficacy and safety of daily oral solifenacin in patients dissatisfied with tolterodine treatment. Patients (n = 441) were enrolled who were currently receiving tolterodine extended release (ER) for 4 weeks or longer (median length of previous therapy = 190 days) but were not satisfied with treatment and had residual urgency symptoms (defined as ≥ 3 urgency episodes per 24 hours reported in the screening 3-day diary). Following a washout period of approximately 14 days, all patients were started on 5 mg solifenacin per day. Patients could maintain or increase their dose to 10 mg per day at Week 4, and maintain or decrease to 5 mg at Week 8. Improvements in urgency, urge incontinence, frequency, nocturia, and nocturnal voids, as recorded in micturition diaries at multiple study visits, were evaluated at pre-washout (during tolterodine treatment) and post-washout visits. The primary endpoint of this study was the mean change from pre-washout to Week 12 in number of urgency episodes per 24 hours. HRQL was assessed via the OAB-q questionnaire which was administered to subjects at pre-washout, post-washout, and Week 12. The OAB-q is a validated, self-administered questionnaire comprising 33 items that evaluate the impact of OAB symptoms on subjects' HRQL [2,3].

Results

The mean change in the number of urgency episodes per 24 hours was reduced by 3.41 from pre-washout (on tolterodine treatment) to Week 12 on solifenacin treatment (P<.0001). Micturitions, incontinence episodes, nocturia episodes, and nocturnal voids were reduced by 1.57, 1.86, 0.72, and 0.79, respectively (P<.0001 for all four parameters). At Week 12, subjects reported significant improvements in mean changes from pre-washout to study end for all subscales of the OAB-q (P<.0001). Mean changes from pre-washout scores improved by 27.4 points for the bother subscale, by more than 21 points for the coping, concern, sleep, and HRQL subscales, and by 11.1 in the social interaction subscale with solifenacin treatment. Similar significant improvements were seen when Week 12 data were compared to post-washout data.

Interpretation of results

The results suggest that switching patients from tolterodine to solifenacin may offer additional improvements in multiple OAB symptoms including urgency, frequency, incontinence, and nocturia, as well as positive changes in HRQL.

Concluding message

Treatment with solifenacin was effective in improving OAB symptoms and HRQL in OAB subjects with residual urgency who switched from tolterodine ER because of dissatisfaction with efficacy.

1. Am J Manag Care. 2005 Jul;11(4 Suppl):S121-9.
2. Qual Life Res 2002;11(6):563-574.
3. Qual Life Res. 2005 Apr;14(3):849-55.

FUNDING: NONE
DISCLOSURES: NONE
CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the The study protocol and amendments were reviewed and approved by either the Institutional Review Board of each center or the Copernicus Group Institutional Review Board. and followed the Declaration of Helsinki Informed consent was obtained from the patients.