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Garely A [1], Kaufman J[2], Andoh M[3]
1. Winthrop University Hospital, Mineola, NY, 2. Urology Research Options, Aurora, CO, 3. Astellas Pharma, Inc., Deerfield, IL

PATIENTS BOTHERED BY INCONTINENCE REPORT IMPROVEMENTS FOLLOWING TREATMENT WITH SOLIFENACIN IN THE VOLT TRIAL

Hypothesis / aims of study
Overactive bladder (OAB) is a common chronic disease defined by symptoms of urinary urgency with or without urge incontinence, often with frequency and nocturia. Numerous patient-reported outcomes (PRO) have been developed in an attempt to quantify patient perceptions of symptom improvement and satisfaction with OAB treatments. The VOLT study used three of these tools to evaluate patients' perceptions of improvements in symptom bother and quality of life following solifenacin treatment. Analyses performed using all patients in the full analysis population (FAS) were compared to a subset of patients who reported incontinence as their most bothersome symptom at baseline to assess symptom improvement and impact on daily living in patients with OAB-related incontinence.

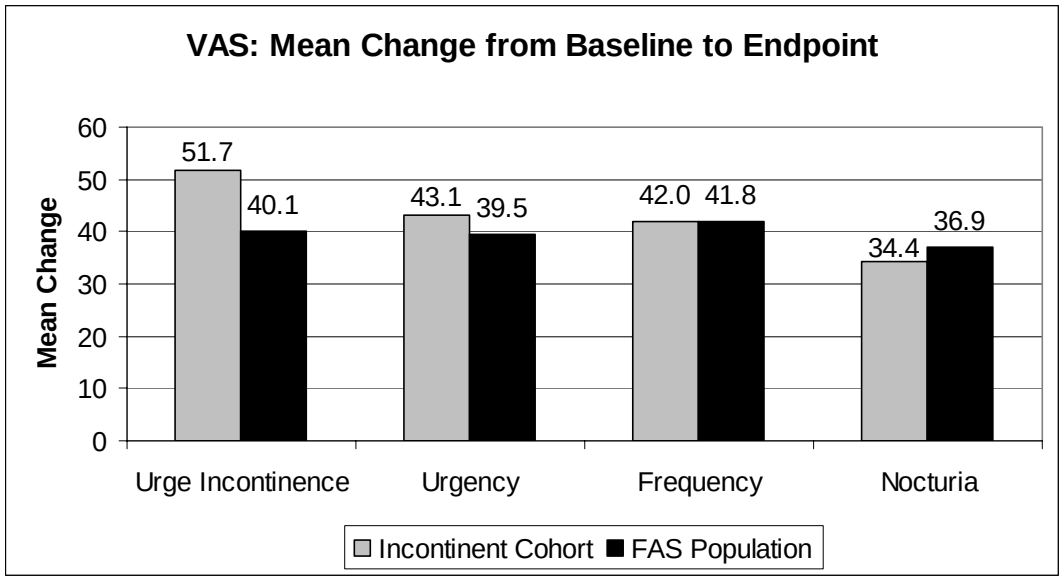
Study design, materials and methods
VOLT was a large prospective, open-label trial in men and women (n = 2225) with urgency, urge urinary incontinence (UUI), frequency or nocturia for at least 3 months who received once-daily solifenacin for 12 weeks. All patients were started on 5 mg solifenacin per day and, at subsequent study visits (Weeks 4 and 8), could maintain their original dose, increase the dose to 10 mg/day, or decrease back to 5 mg/day. Subjective symptom improvement was assessed using 3 separate and independent PRO measurement tools: the Patient Perception of Bladder Condition (PPBC; 1-6 points) survey, the Overactive Bladder Questionnaire (OAB-q), and four visual analog scales (VAS; 0-100 mm) which allowed patients to rate individual symptom bother for urgency, urge incontinence, frequency, and nocturia. A post-hoc analysis was performed that included subjects enrolled in the VOLT trial who had a history of UUI and who listed incontinence as their most bothersome symptom at baseline (incontinent subset).

Results
Of 2225 patients enrolled, 2205 received at least 1 dose of study drug and provided at least 1 on-treatment assessment. A total of 1586 patients (71.3%) had urge incontinence on physician's assessment of OAB at baseline. Of these 1586 patients, 582 (36.7%) reported urge incontinence as their most bothersome symptom; these patients comprised the incontinent subset. Significant improvements in PPBC scores were seen as early as 1 week after treatment initiation, with mean changes at that time of -0.8 and -1.1 points in the FAS population and the incontinent cohort, respectively. Patients in both the FAS population and the incontinent cohort reported similar PPBC baseline (4.4 and 4.6, respectively) and endpoint (2.9 for both groups) measurements, with mean changes from baseline of -1.4 and -1.7, respectively. Eighty-seven percent and 93% of patients reported a PPBC score of 4-6 (moderate to severe problems) at baseline and 65% and 66% reported a PPBC score of 1-3 (no problems or mild problems) at endpoint in the FAS and incontinent cohort, respectively. Thus, a majority of patients perceived their bladder problems to be "moderate" to "severe" at baseline and "minor" to "no problem at all" at study end. Overall, 73.3% of patients in the FAS population and 80.4% in the incontinent cohort experienced improvements in the PPBC scale. Significant changes from baseline in all of the OAB-q scoring domains (symptom severity, coping, concern, sleep, social interaction, and overall health-related quality of life) were observed in both groups ($P<0.001$ for all subscales). Based on the VAS, statistically significant reductions in symptom bother were achieved for urgency, urge incontinence, frequency, and nocturia in both groups ($P<0.001$ for all values). Mean changes from baseline to endpoint on the VAS ratings were comparable between the two cohorts (Figure), with the largest difference occurring in the VAS rating for urge incontinence. Patients in the incontinent cohort reported more bother for urge incontinence at baseline (VAS scores of 64.1 and 78.5 for the FAS population and incontinent cohort, respectively). Mean changes of 40.1 (FAS population) and 51.7 (incontinent cohort) units were reported at endpoint.

Interpretation of results
Results in the incontinent subset mirrored those of the FAS population, with the exception of the VAS, where patients in the incontinent subset reported more bother for urge incontinence at baseline and greater improvements in their assessment of symptom bother related to urge incontinence at endpoint. These findings offer evidence that the VAS captures both increased bother and treatment-related improvement in a symptom (e.g. urge incontinence) reported as highly bothersome by this subset of patients.

Concluding message
Patients treated with solifenacin in an open-label, flexible-dosing regimen, reported significant reductions in symptom bother and improvements in health-related quality of life using 3 independent patient-reported outcome measurement tools. Among patients reporting incontinence as their most bothersome symptom, PRO scores were similar to those seen in the full study population; in particular the VAS ratings revealed both the increased bother and degree of symptom improvement reported by the incontinent subset.

Figure. Mean Changes in VAS from Baseline to Endpoint



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HUMAN SUBJECTS: This study was approved by the The study protocol, protocol amendments, subject information and informed consent forms were reviewed and approved by the Investigational Review Boards (IRBs) responsible for the participating centers. and followed the Declaration of Helsinki Informed consent was obtained from the patients.