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PATIENT-REPORTED OUTCOMES IN 3 COHORTS OF PATIENTS DEFINED BY LENGTH OF TIME AS ACUTE OR CHRONIC OVERACTIVE BLADDER: AN ANALYSIS OF MORE THAN 2200 PATIENTS IN THE VESICARE OPEN-LABEL TRIAL (VOLT)

Hypothesis / aims of study

Overactive bladder disease (OAB) is characterized by a syndrome of related symptoms, with the central and defining symptom being urgency. Manifestation of these OAB symptoms varies among individuals. Patient-reported outcomes (PROs) provide a means of assessing symptom bother and health-related quality of life (HRQL) in patients with OAB, both before and during treatment. Using data from the VESIcare Open-Label Trial (VOLT),[1] we report patient characteristics and results from 3 PRO assessments in each of 3 patient cohorts grouped according to duration of OAB and categorized as acute, early chronic, or late chronic OAB.

Study design, materials and methods

VOLT was an open-label, prospective study designed to assess efficacy and safety of solifenacin 5 mg and 10 mg to treat patients (n=2225) who had OAB for 3 months or longer. Study endpoints included 3 validated PRO measures: the Patient Perception of Bladder Condition (PPBC), a Visual Analog Scale (VAS), and the Overactive Bladder Questionnaire (OAB-q). The presence of OAB symptoms was noted as part of patient assessment at baseline. For this post hoc analysis, 3 cohorts of patients were categorized according to duration of OAB: 3 months to 1 year (acute), 1 year to 5 years (early chronic), and longer than 5 years (late chronic).

Results

This analysis included 2205 patients, whose characteristics are shown in Table 1.

	Duration of OAB		
	3 months to 1 year	**1 to 5 years**	**Longer than 5 years**
n at baseline	349	1124	732
Mean age (years)	56.8	59.8	60.9
Age <65	229 (65.6%)	680 (60.5%)	416 (56.8%)
Age ≥ 65	120 (34.8%)	444 (39.5%)	316 (43.2%)
Male	74 (21.2%)	216 (19.2%)	102 (13.9%)
Female	275 (78.8%)	908 (80.8%)	630 (86.1%)
White race	244 (69.9%)	878 (78.1%)	639 (87.3%)
Black race	66 (18.9%)	159 (14.2%)	49 (6.7%)
Asian race	21 (6.0%)	31 (2.8%)	7 (1.0%)
Other race	18 (5.2%)	56 (5.0%)	37 (5.1%)

A greater percentage of patients with chronic OAB (longer than 1 year) reported urge urinary incontinence at baseline: 76% for patients with OAB for longer than 5 years and 73% for 1 to 5 years, compared with 61% of patients with acute OAB (3 months to 1 year). Changes from baseline in PPBC score were similar for all 3 cohorts: –1.5 (95% CI –1.62 to –1.34) for 3 months to 1 year, –1.4 (95% CI –1.46 to –1.31) for 1 to 5 years, and –1.5 (95% CI –1.59 to –1.39) for longer than 5 years. In all 3 cohorts, VAS scores improved for each urinary symptom from baseline (Table 2). OAB-q data are also shown in Table 2.

Interpretation of results

PRO improvements from baseline after solifenacin treatment were comparable among the 3 OAB-duration cohorts in the VOLT study population, despite differences seen among the groups (including increased age with duration of OAB). This consistent improvement across groups was true for all 3 PRO measures used, indicating that solifenacin improved symptom bother in patients with recent-onset as well as long-term OAB. We suggest that early treatment for OAB may be an important therapeutic objective, as the best OAB-q improvements from baseline were seen in the shortest-duration cohort (3 months to 1 year).

Table 2. Mean OAB-q and VAS scores at end of study and mean change in OAB-q and VAS score from baseline.

	Duration of OAB								
	3 months to 1 year (Acute OAB)			**1 to 5 years (Early chronic OAB)**			**Longer than 5 years (Late chronic OAB)**		
	Base-line	End of study (n)	Δ from baseline (95% CI)	Base-line	End of study (n)	Δ from baseline (95% CI)	Base-line	End of study (n)	Δ from baseline (95% CI)
VAS: Urgency	65.3	23.1 (n=266)	–42.1 (–45.7 to –38.6)	68.0	29.5 (n=914)	–38.5 (–40.5 to –36.5)	71.2	31.3 (n=601)	–39.9 (–42.4 to –37.3)
VAS: UUI	60.2	19.6 (n=205)	–40.6 (–45.0 to –36.2)	63.0	23.9 (n=789)	–39.0 (–41.3 to –36.7)	67.4	25.9 (n=510)	–41.5 (–44.5 to –38.5)

VAS: Frequency	69.8	24.5 (n=264)	–45.3 (–49.0 to –41.6)	69.8	28.7 (n=908)	–41.1 (–43.2 to –39.0)	72.2	30.9 (n=579)	–41.4 (–44.0 to –38.7)
VAS: Nocturia	66.0	25.7 (n=251)	–40.3 (–44.1 to –36.5)	63.7	27.6 (n=857)	–36.1 (–38.3 to –34.0)	67.0	30.4 (n=551)	–36.6 (–39.3 to –33.8)
OAB-q: Symptom bother	53.2	21.9 (n=307)	–31.2 (–33.9 to –28.6)	56.4	27.8 (n=1027)	–28.6 (–30.1 to –27.2)	59.5	29.1 (n=671)	–30.4 (–32.3 to –28.5)
OAB-q: Coping	56.6	84.2 (n=304)	27.6 (24.6 to 30.5)	54.3	80.5 (n=1017)	26.2 (24.6 to 27.7)	49.6	78.7 (n=661)	29.1 (27.1 to 31.1)
OAB-q: Concern	54.2	84.7 (n=304)	30.4 (27.5 to 33.4)	51.5	80.1 (n=1018)	28.6 (27.0 to 30.2)	48.2	79.0 (n=661)	30.8 (28.7 to 33.0)
OAB-q: Sleep	50.7	79.9 (n=304)	29.2 (26.0 to 32.3)	49.9	76.4 (n=1018)	26.6 (24.9 to 28.2)	47.5	75.0 (n=661)	27.5 (25.4 to 29.6)
OAB-q: Social	78.1	92.8 (n=304)	14.8 (12.2 to 17.3)	75.9	90.3 (n=1017)	14.4 (13.1 to 15.8)	75.3	90.3 (n=660)	15.0 (13.4 to 16.7)
OAB-q: HRQL	59.0	85.2 (n=304)	26.1 (23.6 to 28.7)	56.9	81.5 (n=1015)	24.6 (23.2 to 26.0)	53.9	80.4 (n=660)	26.5 (24.7 to 28.2)

Note: n = number of patients with sufficient scores for statistical evaluation at end point per study protocol. For VAS and severity domain of OAB-q, negative values indicate improvement, ie decreased symptom severity.

Concluding message

At both 5-mg and 10-mg doses, solifenacin improves symptom bother and health-related quality of life in patients with acute or chronic OAB and irrespective of OAB duration. Furthermore, early treatment of OAB may be an important therapeutic objective in OAB disease.

References

1. Clin Ther (2006) 28; 1935-1946.

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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 All study procedures complied with the International Conference of Harmonization--the guideline for Good Clinical Practice and the Declaration of Helsinki. Investigational review boards at all participating sites reviewed and approved the protocol. and followed the Declaration of Helsinki Informed consent was obtained from the patients.