84

Staskin D R[1], Nitti V W[2], Dmochowski R R[3]
1. -Cornell Medical School, New York Presbyterian Hospital, New York, NY, 2. , New York University School of Medicine, 3. Vanderbilt University School of Medicine

QUALITY OF LIFE FOLLOWING TREATMENT WITH TRANSDERMAL OXYBUTYNIN: THE EFFECTS OF PRIOR THERAPY

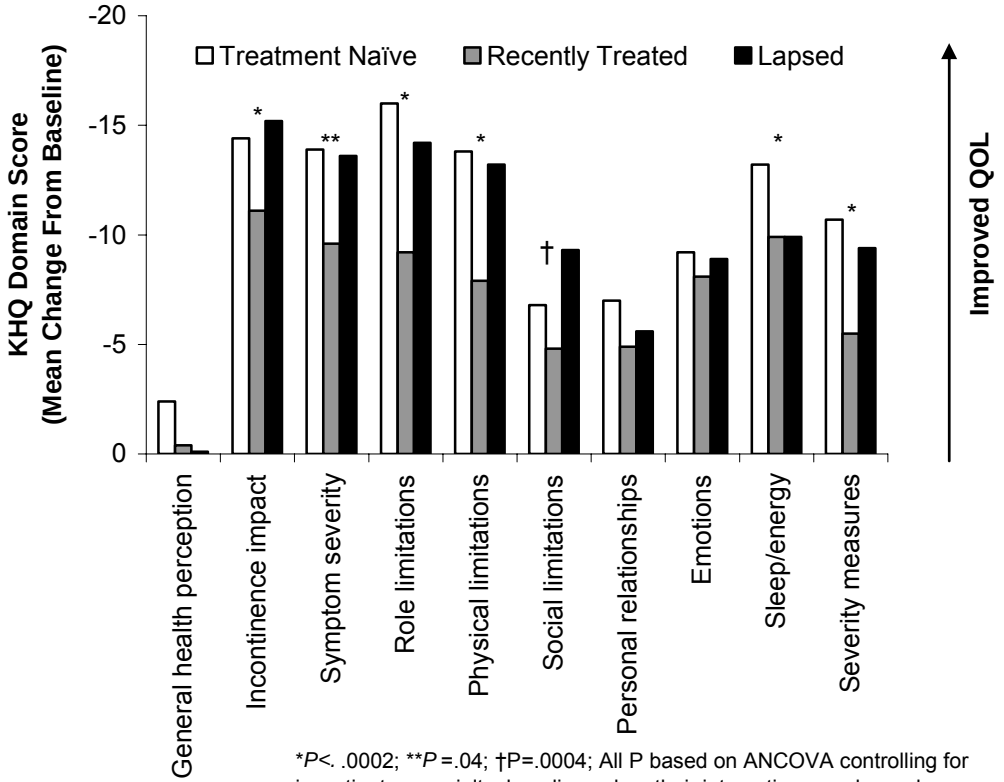
Hypothesis / aims of study

Overactive bladder (OAB) negatively impacts patient quality of life (QOL). The Multicenter Assessment of Transdermal Therapy in Overactive Bladder With Oxybutynin (MATRIX) trial was conducted to investigate the effects of OXY-TDS treatment on QOL and related assessments in a large, community-based population of patients with OAB. This analysis examines the impact of prior OAB therapy on QOL outcomes.

Study design, materials and methods

Adults ≥18 years of age with ≥1 symptoms of OAB (urinary urgency, urge incontinence, or frequency) were enrolled in this open-label, prospective study. Eligible patients had to discontinue any current OAB therapy prior to enrollment. Patients were excluded if they had contraindications for OXY-TDS therapy, had received OXY-TDS previously, or resided in a long-term care facility. Patients were classified into 3 groups at enrollment by history of OAB treatment: treatment naïve, recently treated (stopped <30 days), and lapsed (stopped ≥30 days). Patients received OXY-TDS at the FDA-approved dosage of 3.9 mg/day (2 patches per week) for up to 6 months. The patient perception of bladder condition (PPBC) questionnaire was used to assess disease impact at baseline; scores range from 1 (no problem) to 6 (many severe problems). Patient QOL data were collected at baseline and during clinic visits at 3 and 6 months, using the King's Health Questionnaire® (KHQ). KHQ composite domain scores (100=most impairment, 0=least) were calculated to assess QOL impairment. Patient satisfaction with OXY-TDS treatment was monitored with monthly telephone interviews conducted by an independent call-centre. The primary study endpoint was mean change in KHQ domain score from baseline to end of study for the intent-to-treat (ITT) population, which included patients who received ≥2 doses of OXY-TDS and had ≥1 post-baseline assessment. Last observations were carried forward for patients who discontinued early. A change in KHQ domain score of ≥5 points (≥3 points for General Health Perception or Symptom Severity) was considered clinically meaningful. *P* values for within group comparisons generated using a 1-sample, 2-tailed t-test, and those for between group comparisons using ANCOVA. Adverse events were collected during clinic visits at 1, 3, and 6 months; the safety population included all patients who received ≥1 treatment with OXY-TDS.

Change in KHQ Domain Scores, Baseline to End of Treatment, by History of Prior OAB treatment.



**P*<. .0002; ***P* =.04; †P=.0004; All P based on ANCOVA controlling for investigator specialty, baseline value, their interaction, gender and age

Results

The study population (N=2878) was mostly Caucasian (83.6%); 12.8% of study participants were male. The mean age was 62.5 ± 14.8 years (range of 18 – 100). Most participants (88.0%) had a history of OAB symptoms lasting ≥1 year;

57.1% had been treated previously for OAB. The most common prior medications were oral formulations of tolterodine or oxybutynin; the most common primary reasons for stopping these therapies were lack of efficacy (53.2%), side effects (22.3%), and compliance issues (7.7%). At baseline, 78.2% of patients rated their OAB severity as ≥4 on the PPBC. In the ITT population (n=2593), 42.5% were treatment naïve, 33.5% were recently treated, and 24.0% were lapsed. In all 3 groups, the greatest QOL impairments at baseline were seen in the incontinence impact, symptom severity, and sleep/energy domains. Significant differences (*P*<.04) between groups were seen in all domains except general health perception, personal relationships, and sleep/energy. At end of study, clinically meaningful improvement was seen in all KHQ domains except General Health Perception (see Figure). Significant differences in the magnitude of improvement between groups were seen in all domains except general health perception, personal relationships, and emotions. After 1 month of treatment, most patients reported that OXY-TDS offered more benefits than their previous OAB therapy in terms of overall satisfaction (62.9% of respondents), efficacy (57.1%), and tolerability (60.3%). In the overall study population, the majority (89.4%) of drug-related adverse events were mild or moderate in severity; the most common drug-related adverse events were application site reactions (ASR) ASR–pruritus (4.9%); ASR–erythema (4.6%); ASR–dermatitis (4.4%); ASR–irritation, (3.2%), rash (3.0%), dry mouth (2.6%), and pruritus (2.6%). The overall incidence of serious adverse events was low (3.6%), with only 1 event (urinary tract infection) in which the relationship to study drug could not be excluded.

Interpretation of results

Mean QOL assessments improved for patients in the MATRIX study, regardless of prior treatment. This suggests that patients who are dissatisfied with other therapies may still benefit from use of OXY-TDS. Most patients who had discontinued other OAB medications were relatively more satisfied with OXY-TDS and felt that it was more efficacious and tolerable.

Concluding message

Treatment with OXY-TDS resulted in clinically meaningful improvements in QOL for patients with OAB, regardless of prior treatment history.

FUNDING: **Watson Pharmaceuticals**
DISCLOSURES: **Dr Nitti: Allergan, Astellas, Novarits, Ortho McNeil, Pfizer, Schwarz Pharma, Watson; Dr Staskin: Watson, Pfizer, Astellas, Novarits, Ortho McNeil, Esprit; Dr Dmochowski: Indevus, Watson**
CLINICAL TRIAL REGISTRATION: **NCT00224146**
HUMAN SUBJECTS: **This study was approved by the Independent Review Consulting, Inc, Conte Madera, CA, USA and followed the Declaration of Helsinki Informed consent was obtained from the patients.**