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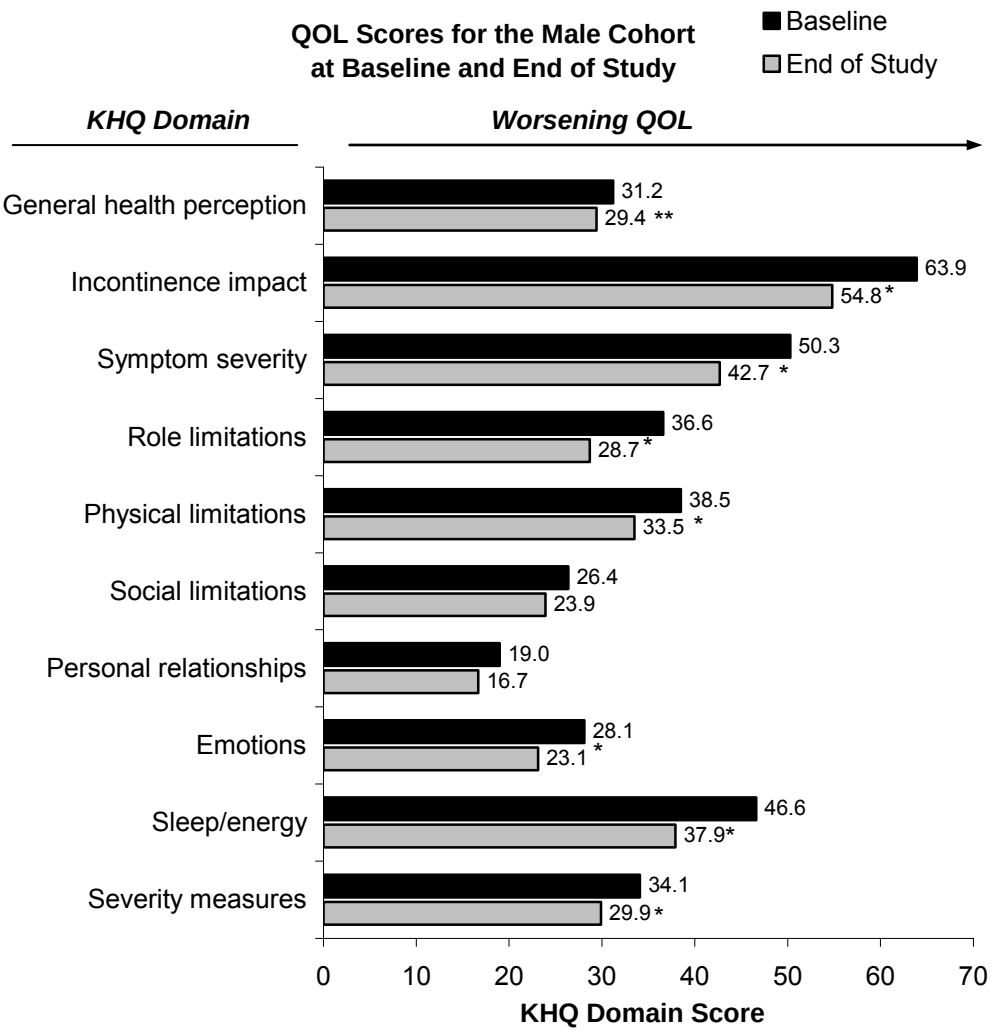
QUALITY OF LIFE IN MEN FOLLOWING TREATMENT FOR OVERACTIVE BLADDER

Hypothesis / aims of study
Although symptoms of overactive bladder (OAB) occur with comparable frequency among men (16.0%) and women (16.9%), studies of pharmaceutical interventions for OAB generally have included few male patients. The Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin (MATRIX) study was conducted to assess the effect of treatment with transdermal oxybutynin (OXY-TDS) on quality of life (QOL) in adults with OAB. This analysis focuses on the male cohort of patients in the study.

Study design, materials and methods
This multicenter, open-label, prospective study included participants ≥18 years old for whom therapy with OXY-TDS was indicated. Patients who had contraindications for OXY-TDS therapy, had received OXY-TDS previously, or were residing in a long-term care facility or nursing home, were excluded, as was concurrent use of other OAB medications. All patients were treated with 3.9 mg/d OXY-TDS (2 patches/week) for ≤6 months. Sites were randomized 1:1 to distribute either enhanced educational materials or standard product information in addition to study medication. Assessments at baseline, 3 months, and 6 months with the King's Health Questionnaire® (KHQ); KHQ domain scores range from 0 (best) to 100 (worst). The primary analysis was based on the intent-to-treat (ITT) population, comprising patients who received ≥2 treatments and had ≥1 post-baseline assessment. Clinically relevant changes in KHQ scores were defined as ≥3 points for General Health Perception (GHP) or Symptom Severity and ≥5 points for other domains. *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 summarized descriptively.

Results
Patients in the study population (N=2878) were mostly white (83.6%) and had a mean age of 62.5 +/- 14.8 y (range 18 – 100 y); 47.5% of the study population were ≥65 years old. Men (n=369) comprised 12.8% of the overall population, and 19.3% of patients ≥65. The mean age of men in the study (69.6 +/- 13.1); as a result, 71.3% of men were ≥65 years of age. These men had considerable comorbid conditions, including cardiovascular 66%; musculoskeletal 46%; gastrointestinal 37%; endocrine 31%; neurologic 31%; renal 22%; dermatologic 14%; status post prostatectomy, 6%. More than half were overweight or obese (median BMI 27.6). Most (82%) were taking multiple medications at enrollment (39% ≥7) with 18.4% taking alpha1 antagonists and/or 5-alpha-reductase inhibitors for benign prostatic hyperplasia (BPH). At baseline, the greatest QOL impairments in the male cohort were seen in the domains of incontinence impact (63.9), symptom severity (50.3), and sleep/energy (46.6). At end of study, clinically meaningful improvements were seen for the entire study population in all domains except GHP, and for the subgroup of male patients in the incontinence impact, symptom severity, role limitations, and sleep/energy domains. QOL scores for the male cohort at baseline and end of study are shown below. While the magnitude of improvement in the male cohort was less than that in the female cohort, the only significant difference between the groups was in the social limitations domain (−2.3 points vs −7.4 points; *P*=.010). In the overall study population, 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.



*P <.0006. **P =.02. All P based on one-sample t-test

Interpretation of results

At baseline, the impact of OAB on QOL was greatest in the incontinence impact, symptom severity, and sleep/energy domains. Improvements were seen across all domains at end of study. Transdermal oxybutynin was generally well-tolerated by the entire study population, with application site reactions being the most common adverse events, and no new safety concerns noted.

Concluding message

Treatment of OAB with transdermal oxybutynin improved quality of life in a population of community-dwelling men, the majority of whom were over age 65.

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