354

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TREATMENT OF NON-URGE INCONTINENCE AND NIGHTTIME VOIDING IN PATIENTS WITH URGE-PREDOMINANT URINARY INCONTINENCE

Aims of Study

The negative impact of urge urinary incontinence on the patient's quality of life and daily activities has been well documented. Nighttime awakenings due to urine leakage can further disturb the patient's quality of life. Many patients with urge urinary incontinence also have episodes of non-urge incontinence. Although oxybutynin has been used to treat urge urinary incontinence for over 20 years, the effect of this drug on non-urge incontinence and nighttime voiding is not well documented. We examined the prevalence and impact of nighttime awakenings on sleep quality and daily life in a large cohort of community-dwelling patients before and after treatment with extended-release oxybutynin for urge incontinence and other symptoms of overactive bladder. In a separate randomized controlled trial, we evaluated the effect of extended-release oxybutynin on the frequency of non-urge incontinence episodes in patients with urge-predominant urinary incontinence.

Methods

Study I was an open-label, non-randomized study that enrolled 1,067 adults (mean age 64.2 years) with symptoms of urge or mixed incontinence. Patients completed the Sleep Impact Questionnaire and the Individual Incontinence Impact Questionnaire at baseline, at the end of dose adjustment and after 3 months of treatment with an individually titrated dose of 5-30 mg extended-release oxybutynin. The end of treatment percentages reported below are based on each patient's final measurement on the study. Study II was a randomized double-blind, placebo-controlled, multicenter study, in which 50 female patients were randomly assigned (2:1) to active drug (5, 10, and 15 mg of extended-release oxybutynin) or placebo for a 6-week, dose-escalation treatment. Inclusion criteria included the ability to distinguish stress incontinence episodes from urge incontinence episodes. Patients completed a daily urinary diary indicating type and time of each incontinence episode as well as the occurrence of urgency with each episode.

Results

Study I: At baseline 90.3% of patients reported nighttime awakenings due to urine leakage and/or bladder problems compared with 74.7% at the end of treatment. At baseline, 74.2% of patients reported that nighttime awakenings due to urine leakage and/or bladder problems interfered with daily activities some, most, or all the time compared with 48.7% of patients at the end of treatment ($p<0.001$). At baseline, 69.8% of patients reported that their urine leakage and/or bladder problems interfered with the quality and/or quantity of sleep frequently or all the time compared with 38.1% at the end of treatment ($p<0.001$).

Study II. Patients on OROS-oxy reported an 85.7% reduction in non-urge incontinence episodes per week from baseline to study end compared with a 22.2% reduction with placebo (see table). The reduction in weekly UI episodes from baseline to study end was 86.8% in patients on OROS-oxy compared with a 46.5% reduction with placebo ($p=0.005$). No patients on OROS-oxy discontinued treatment because of dry mouth or other adverse effects.

Mean Number/Week	Baseline	Endpoint	% Change
Non-urge incontinence			
OROS-oxy	1.4	0.2	85.7%
Placebo	0.9	0.7	22.2%
Urge incontinence			
OROS-oxy	16.4	1.6	86.8%
Placebo	22.3	10.9	46.5%

Conclusions

Treatment of urge urinary incontinence with extended-release oxybutynin reduced the incidence of nighttime awakenings and lessened their impact on daily life, sleep quantity and sleep quality in this cohort of community-dwelling patients. Extended-release oxybutynin was an efficacious treatment for urge urinary incontinence and also provided relief from non-urge incontinence episodes. Further studies of the effect of extended-release oxybutynin on these endpoints is warranted.