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Institution: *North Texas Center for Urinary Control
Title: RANDOMIZED, DOUBLE-BLIND STUDY OF CONTROLLED-RELEASE OXYBUTYNIN AND TOLTERODINE FOR OVERACTIVE BLADDER

Aims of Study:

Controlled-release oxybutynin and tolterodine have been shown in separate studies to be effective in the treatment of overactive bladder. However, the results of these studies are difficult to compare due to differences in study design and patient populations. This is the first large-scale, randomized, double-blind study to compare these two drugs.

Methods:

Patients with urge incontinence or mixed urge and stress incontinence were randomized 1:1 to a daily dose of 10 mg controlled-release oxybutynin (QD) or 4 mg tolterodine (2 mg BID) for 12 weeks. Patients completed daily urinary diaries during the Baseline Week and Treatment Week 12. The study randomized 378 patients at 37 sites, and 332 patients (88%) completed the 12-week study. The mean age was 59.0 years (range 21-87 years), 83.2% were female, and 60% were naive to anticholinergic therapy.

Results:

At 12 weeks, controlled-release oxybutynin was statistically significantly more effective than tolterodine as measured by urge and total incontinence episodes and micturition frequency ($p=0.031$, $p=0.022$, and $p=0.022$, respectively). Controlled-release oxybutynin reduced the weekly micturition frequency from 91.8 to 67.1 whereas the reduction with tolterodine was from 91.6 to 71.5. Overall, both drugs significantly reduced the number of urge and total incontinence episodes and the micturition frequency per week ($p<0.001$ baseline vs. Week 12). Adverse events were mostly mild and included dry mouth (28.1% with controlled-release oxybutynin and 33.2% with tolterodine), constipation (7.0% with controlled-release oxybutynin and 6.2% with tolterodine), and headache (8.1% with controlled-release oxybutynin and 8.8% with tolterodine). The incidence of CNS events was low and similar between groups.

Conclusions:

In this study, a daily dose of 10 mg controlled-release oxybutynin yielded significantly fewer end-of-study urge incontinence and total incontinence episodes and a lower micturition frequency than 4 mg tolterodine (2 mg BID). The incidence of dry mouth, CNS events, and other adverse events was similar for both drugs.
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