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Authors: R.U. Anderson,* R. Dmochowski, D.J. Lama, J.E. Gottesman, D. Staskin, J. Antoci, and H. Ritter on behalf of the OBJECT Study Group
Institution: *Stanford University Medical Center
Title: CENTRAL NERVOUS SYSTEM ADVERSE EVENTS WITH ANTICHOLINERGIC MEDICATION FOR OVERACTIVE BLADDER

Aims of Study:

Anticholinergic medication is the mainstay of treatment for overactive bladder. However, the potential for adverse events in the central nervous system (CNS) with anticholinergic medication has raised concern about their use, particularly in elderly patients. We evaluated the incidence of CNS adverse events in patients randomly assigned to one of two treatments for overactive bladder, once-a-day controlled-release oxybutynin and tolterodine. Results were assessed in female patients, patients over age 75, and patients naïve to drug therapy.

Methods:

Female patients (n=315; mean age: 59 yrs; range 21-87 yrs) with urge incontinence or mixed incontinence were randomized 1:1 to controlled-release oxybutynin 10 mg QD or tolterodine 2 mg BID for 12 weeks. Patients completed daily urinary diaries, and were periodically questioned about adverse events by the investigator.

Results:

Controlled-release oxybutynin was significantly more effective than tolterodine at 12 weeks with regard to urge incontinence, total incontinence, and micturition frequency (p=0.005, p=0.006, and p=0.044, respectively). The overall incidence of CNS adverse events (including dizziness, somnolence, and insomnia) was low and comparable for both medications (see Table 1). The incidence of CNS adverse events in the 53 patients over age 75 was not statistically different than in the younger patients and similar in both treatment groups. 228 patients were naïve to treatment with anticholinergics, potentially putting them at a higher risk for adverse events. In this group, CNS adverse events were not statistically different from those with prior exposure to anticholinergics and similar in both treatment groups.

Table 1. N(%) of Patients with CNS Adverse Event

	Controlled-Release Oxybutynin	Tolterodine
Female Patients	19 (12.5%)	19 (11.7%)
Patients > 75 years	2 (8.3%)	3 (10.3%)
Patients naive to anticholinergics	13 (11.9%)	16 (13.4%)

Conclusions:

In this study, controlled-release oxybutynin was significantly more effective than tolterodine. Both treatments had an excellent safety profile with a low incidence of CNS adverse events in female patients, elderly patients, and those naïve to anticholinergic treatment.

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