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## Abstract Reproduction Form B-1

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Institution	University of Utah	—	—
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Title (type in CAPITAL LETTERS)	LONG-TERM EXPERIENCE WITH ONCE-A-DAY EXTENDED-RELEASE OXYBUTYNIN IN A COMMUNITY-BASED POPULATION TREATED FOR OVERACTIVE BLADDER		

**Aims of Study:** The safety and efficacy of conventional oxybutynin chloride for the treatment of urge urinary incontinence (UI) have been demonstrated in controlled and uncontrolled studies and confirmed by more than 20 years of clinical experience. However, long-term continuation of conventional oxybutynin and other anticholinergics is generally believed to be poor with reported use as low as 18 percent after six months [1]. A controlled clinical trial with once daily extended-release oxybutynin showed a reduction in urge incontinence episodes of 84% [2]. In this and other short-term (3-8 weeks) trials, the discontinuation rate for dry mouth, the most frequently cited reason for stopping conventional oxybutynin [3], was 1.2%. This current long-term study examines the first large cohort of patients using extended-release oxybutynin to be observed in a community-based practice. The aims of this study are (1) to demonstrate the continuation of extended-release oxybutynin use over 12 months, (2) assess the temporal pattern of discontinuation, and (3) to describe the reasons for discontinuation from study medication.

**Methods:** This was an open-label, non-randomized study enrolling adult patients who had symptoms of UI and were in general good health. Adverse effects were reported by telephone and at office visits every two to three months. Reasons for discontinuation of study medication were recorded. Patients were instructed to adjust their dose, beginning at 5 mg/day, to a balance of symptom reduction and tolerability, up to 30 mg/day.

**Results:** This is an interim six month report. Ninety-nine private practice urologists enrolled 1064 women (n=901) and men (n=163), ages 17-92 years, mean age of 64.2 years. At the end of six months, approximately two-thirds of the patients were still using the study medication. Discontinuation was most frequent during the first 60 days of treatment. The reasons for discontinuation were: adverse events (15%), lack of efficacy (6%), other (5%), and personal (3%). The discontinuation rate for dry mouth was seven percent.

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**Conclusions:** In a treatment setting of private practice urology, the majority of patients remained on long-term treatment with extended-release oxybutynin up to six months and longer. The new controlled release formulation may be better tolerated than conventional oxybutynin and appears to improve patient compliance with treatment.

**References:**

- (1) A medium term analysis of the subjective efficacy of treatment for women with detrusor instability and low bladder compliance. *Brit J Obstet Gynaecol* 104:988-993, 1997.
- (2) Once-a-day controlled release versus immediate release oxybutynin chloride in the treatment of urge urinary incontinence. *J Urol* in press 1999.
- (3) Comparative tolerability of drug therapies used to treat incontinence and enuresis. *Drug Safety* 19:123-139, 1998.

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