

## **RESULTS OF THE OPERA TRIAL : A RANDOMISED, PROSPECTIVE, DOUBLE-BLIND COMPARISON OF THE EFFICACY AND TOLERABILITY OF THE EXTENDED-RELEASE FORMULATIONS OF OXYBUTYNYN VERSUS TOLTERODINE**

### **Aims of Study**

Extended-release oxybutynin chloride (Oxy-XL) was more effective in treating symptoms of overactive bladder than twice-daily tolterodine tartrate in the OBJECT trial (1). In this study, the efficacy and tolerability of Oxy-XL and extended-release tolterodine tartrate (Tol-LA) were compared.

### **Methods**

This was a prospective, randomized, double-blind, parallel group study in women with  $\geq 21$  and  $\leq 60$  urge incontinence episodes/week and an average of  $\geq 10$  voids/24 hours. After a one-week voiding diary was obtained, women received Oxy-XL 10mg qd or Tol-LA 4 mg qd for 12 weeks. Outcome measures were the weekly numbers of urge incontinence, total continence, and micturition frequency episodes at 12 weeks adjusted for baseline.

### **Results**

A total of 790 women were randomized at 71 U.S. sites, and 696 (88%) completed the study. At 12 weeks, improvements in urge incontinence and total incontinence were similar in both treatment groups. Oxy-XL was significantly more effective than Tol-LA in reducing micturition frequency episodes (66.4 vs. 71.1,  $p=0.003$ , LOCF). In addition, the percentage of women reporting no total incontinence episodes (23.0% vs. 16.8%,  $p=0.029$ , LOCF) was significantly higher in the Oxy-XL group. Tolerability was excellent in both groups, with  $<5\%$  of all participants discontinuing for adverse events. Dry mouth was the most frequently reported adverse event. While dry mouth was more common with Oxy-XL than Tol-LA ( $p<0.05$ ), rates of moderate to severe dry mouth were not significantly different between groups.

### **Conclusions**

Overall, efficacy and tolerability of Oxy-XL and Tol-LA were similar. However, Oxy-XL was significantly more effective than Tol-LA in reducing micturition frequency episodes, and there was a significantly higher percentage of patients in the Oxy-XL group who had no total incontinence episodes at LOCF.

### **References**

(1) Appell ea. Prospective randomized controlled trial of extended-release oxybutynin chloride and tolterodine tartrate in the treatment of overactive bladder : results of the OBJECT study. Mayo Clin Proc 2001;76:358-363.