

S Herschorn<sup>1</sup> and L Landy<sup>2</sup>, on behalf of the Tolterodine Study Group

<sup>1</sup> Sunnybrook and Women's Health Sciences Centre, Toronto, Canada

<sup>2</sup> Uro-Gyn Solutions, Tucson, Arizona, USA

## "CURE" RATES FOR SYMPTOMS OF OVERACTIVE BLADDER TREATED WITH TOLTERODINE

**Aims of Study:** Overactive bladder is a condition that comprises a collection of symptoms, namely urinary frequency, urgency and/or urge incontinence. On the basis of overall improvements in symptomatology, micturition diary variables and urodynamic parameters, tolterodine is considered an effective treatment for overactive bladder. At present, however, there is no consensus on the definition of cure for this condition, but it is generally believed that "cure" should not focus on "dryness" alone but on other symptoms as well. In this study, the therapeutic effect of tolterodine on arbitrarily defined, but clinically relevant, "cure" rates for the various symptoms of overactive bladder was evaluated.

**Methods:** This was a flexible-dose, 16-week study in 1380 patients (average age 61 years, 80% women) with symptoms of urinary urgency and frequency, with or without urge incontinence. The study population was heterogeneous, and comprised treatment-naive patients and those with previous experience of other antimuscarinic agents. The starting dosage of tolterodine was 1 mg twice daily (BID), which could be increased to 2 mg BID, and subsequently decreased to 1 mg BID, based on the balance of efficacy and tolerability. Dosage adjustment was at the discretion of the physician, patients were blinded to dosage adjustments throughout. Micturition diaries were collected for 72 hours at baseline and after 4, 8 and 16 weeks' treatment. Patient assessments of urinary urgency were also determined at these timepoints on a 3-point rating scale (not able to hold urine, able to hold urine until toilet visit; able to finish tasks before toilet visit).

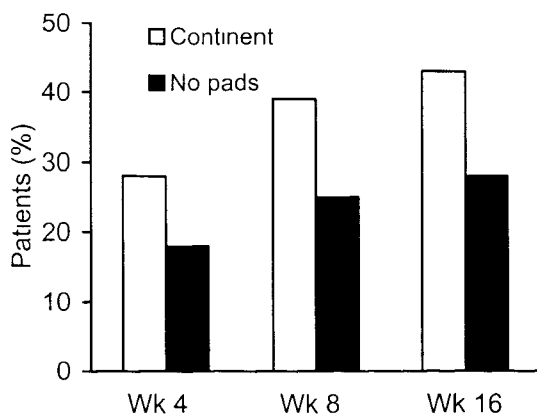
**Results:** Three dosing patterns emerged: patients who remained on 1 mg BID throughout (19%); patients who escalated to and remained on 2 mg BID (76%); and patients who oscillated between the two dosages (5%). Results are presented for all patients combined.

The definition of “cure” for the different outcomes is shown in the Table. “Cures” are those patients who were within the normal threshold at the end of the study.

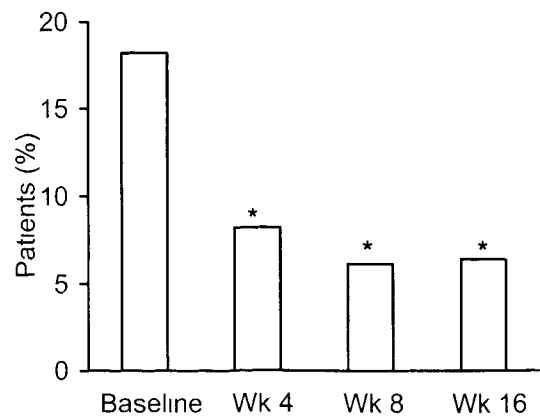
Symptom	Definition		“Cure” rate (%)
	Baseline	Week 16	
Micturitions/24h	≥8	<8	22*
Incontinence episodes/24h	>0	0	43*
Nocturia	>2	≤2	55*
Pad usage/24h	>0	0	28*

\*p<0.0001

Figure 1 shows that the cure rate for incontinence increased with treatment duration, as did the percentage of patients who no longer required pad protection. In terms of urinary urgency, Figure 2 shows that the percentage of patients not able to hold urine at all (upon experiencing the need to void) also changed with treatment duration, but appears to have reached maximum effect by 8 weeks.



**Figure 1.** Cure rates



**Figure 2.** Urgency (percentage of patients not able to hold urine at all) \*p<0.0001

**Conclusions:** Using arbitrarily defined criteria of cure, in this study of a heterogeneous population typical of that observed in routine practice, one quarter to one half of patients treated with tolterodine achieved “cure” of various overactive bladder symptoms.

This study was supported by Pharmacia & Upjohn.