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## TOLTERODINE IS RAPIDLY EFFECTIVE IN WOMEN WITH MIXED INCONTINENCE

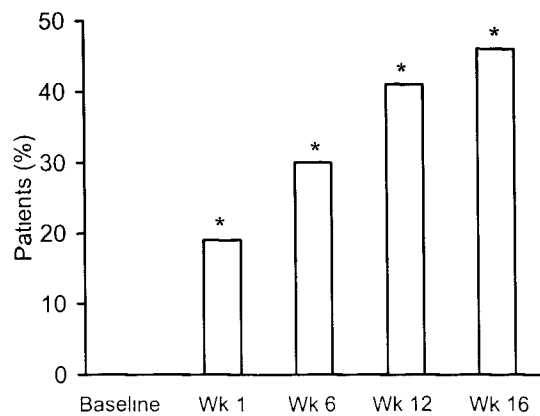
**Aims of Study:** While tolterodine has been shown to be effective in the treatment of overactive bladder characterised by urge symptomatology, data on its effect in mixed incontinence is lacking. This prospective, open-label study investigated the efficacy and tolerability of tolterodine in women with mixed incontinence, urge predominating.

**Methods:** 135 post-menopausal women aged 50–92 (mean 66) years, recruited on the basis of urinary urgency, mixed incontinence and urogenital atrophy, were treated primarily with tolterodine 2 mg twice daily for 16 weeks. Efficacy was assessed from micturition diaries, collected for 72 hours at 0, 1, 6, 12 and 16 weeks' treatment, and quality-of-life questionnaires. Tolerability was evaluated from adverse event reports.

**Results:** Changes in endpoint medians from baseline to Weeks 1 and 16, for patients who completed the study, are shown in the Table below. Statistically significant changes were seen within 1 week for the symptoms of incontinence, frequency, volume voided per micturition and pad usage. Figure 1 shows the increase in dry rate during the study (for patients with incontinence at baseline). This change is mirrored (Figure 2) by the improvement in the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ).

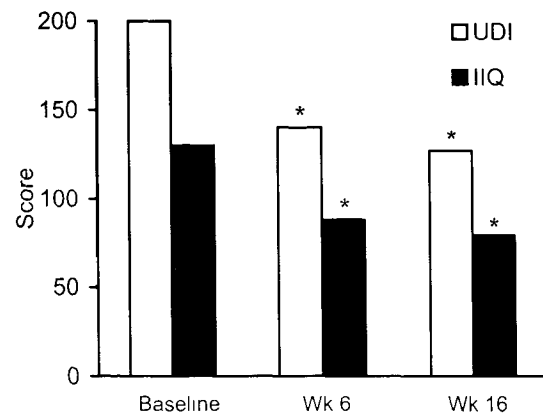
	Incontinence/24h	Micturitions/24h	Vol. voided/micturition (ml)	Pads/24h
N		103	103	103
67				
Baseline	2.7	10.3	164	2
Change at Week 1	-1.3*		-1.3*	+18*
0.7*				
Change at Week 16	-2.0*		-2.0*	+38*
1.0*				

\* p < 0.0001 vs baseline.



**Figure 1.** Dry rate during the study.

\* $p < 0.0001$  vs baseline.



**Figure 2.** Quality-of-life improvement.

\* $p < 0.0001$  vs baseline.

In patients who were using pads at study start, there was an overall 50% reduction in pad usage after 16 weeks' treatment, with 11% ( $p < 0.05$ ) and 30% ( $p < 0.0001$ ) having stopped usage at Weeks 1 and 12, respectively. Of those who had significant nocturia ( $\geq 2$  episodes) at baseline, there was a significant reduction in episodes by study end ( $p < 0.001$ ) with 30% being cured by Week 1 and 35% by Week 16 (both  $p < 0.0001$ ) [cure was defined as  $< 2$  episodes of nocturia]. Quality-of-life measures improved by 40% for IIQ and by 44% for the UDI (both  $p < 0.0001$ ). Tolterodine was well tolerated. The most frequent adverse events were dry mouth (33%), headache (9%) and constipation (7%).

**Conclusions:** These findings indicate that tolterodine is rapidly effective in patients with urinary symptoms of mixed incontinence; all clinical endpoints had significantly improved by Week 1 and continued to do so to Week 16. The frequency of antimuscarinic adverse events was low and similar to that reported in other trials.

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