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Video Demonstration

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Title (type in CAPITAL LETTERS)	TOLTERIDINE: AN EFFECTIVE, SAFE, AND WELL TOLERATED LONG TERM TREATMENT FOR OVERACTIVE BLADDER PATIENTS.

Aims of study

The major limitation of antimuscarinic treatment of overactive bladder has been that the agents were not well tolerated by patients. This led to early discontinuation of treatment, poor compliance and likely treatment with sub-optimal or sub-therapeutic doses of medication. Tolteridine is a new muscarinic receptor antagonist, indicated for treatment of overactive bladder with the associated symptoms of frequency, urgency and urge incontinence, which acts selectively on the bladder compared to the salivary glands. Tolteridine was studied in overactive bladder patients during 12 month open-label treatment. The aim of this study was to confirm the long-term tolerability, safety, and efficacy of tolteridine treatment in overactive bladder patients.

Methods

Patients enrolled in 2, 4, or 12 week double blind, placebo controlled studies (12 studies total) with tolteridine or placebo were allowed to continue on open, long-term tolteridine 2mg bid treatment for a total of 12 months.

Results

A total of 1669 out of 2220 patients (75%) of patients selected to continue on open treatment. Tolteridine was well tolerated during long-term treatment. Of the 1669 patients, 66% (1106 patients) completed 12 months of treatment. The primary reason for discontinuation was adverse events with 11.9% of patients discontinuing for this reason. Overall dry mouth was not troublesome to patients. A total of 61/1669 (4%) patients discontinued treatment with associated dry mouth. Severity of dry mouth reported during the study was low with 17% of patients reporting mild dry mouth, 9% reporting moderate dry mouth, and 3% mild severe dry mouth. Tolteridine was very safe during long-term treatment. No clinically significant changes in blood pressure, ECG, hematology, or clinical chemistry were observed during long-term treatment. Efficacy with tolteridine treatment was maintained during long-term treatment. Significant improvement in micturition frequency, incontinence episodes, volume voided per micturition noted at 1 month treatment continued throughout treatment.

	Micturition/24 hours (n=1086)	Incontinence episodes/24 hours n=(881)	Volume voided per micturition (n=1079)
Baseline	11.2	3.2	159
1 month	8.9*	1.7*	189*
3 months	8.8*	1.4*	201*
6 months	8.6*	1.4*	193*
9 months	8.9*	1.5*	199*
12 months	8.6*	1.6*	190*

*p<0.0001

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Conclusions

Tolteridine is a pure, potent, antimuscarinic with a selectivity for the bladder over the salivary glands, in vivo. This selectivity results in effective treatment for overactive bladder patients that is safe and well tolerated both during short and long-term treatment (as shown in 1669 patients).