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Title: TOLTERODINE IS EQUALLY EFFECTIVE IN PATIENTS WITH MIXED INCONTINENCE

Aims of Study:

Patients with mixed incontinence (stress and urge) pose a particular therapeutic challenge as there are no scientifically based guidelines for treatment. Currently, the primary therapy for these patients includes behavior modification, pelvic floor exercises and drugs. However, there has never been a report of a controlled trial examining the utility of drug therapy in this population.

Methods:

Data from a single blind randomized controlled multi-center trial of patients with overactive bladder was used for this analysis. Urodynamics were not performed as the diagnosis was clinically based. All 994 incontinent patients (24% with mixed incontinence) were started on tolterodine 1mg bid for 4 weeks and then depending on response were dose escalated to 2 mg bid for a further 12 weeks. Patients were allowed to reduce their dose if they so wished. 723 patients (73%) finished the 16 week study and these 171 (24%) had mixed incontinence. Efficacy was assessed by changes in diary variables from baseline to study end. Cure was arbitrarily defined at 16 weeks as being dry, or micturition frequency of less than 8 per 24 hours, or no pad use or less than 2 nighttime micturitions for nocturia. Tolerability was assessed based on adverse events reported.

The data is presented as mean values where the distribution is consistent with normality or as median values where the data is skewed.

Results:

The baseline characteristics are shown in Table 1. The two groups were well matched except that there were only 6 males in the mixed incontinence group. Half of the patients in both groups had had prior therapy for overactive bladder.

The study dropout rate for the two groups was the same. Table 2 shows the efficacy data as a change form baseline with statistical analysis for difference between groups. All diary variables showed a significant change from baseline ($p<0.001$ for all) but no significant difference between those in the mixed incontinence group compared to those in the urge incontinence group. Surprisingly nocturnal voiding was more impacted in the mixed group but this did not quite reach statistical significance ($p=0.06$). The drug was well tolerated with dry mouth being the most common side effect (mixed 23%, urge 27%).

Table 1: Baseline Data

Variable	Mixed Incontinence (n=171)	Urge Incontinence (n=552)	Probability
No. of Women	165 (96%)	464 (84%)	0.001

Mean (range) Age, Yrs	62 (21-88)	65 (20-88)	0.13
Duration of symptoms (>5 yrs)	91 (53%)	259 (46%)	0.15
Previous drug therapy for Overactive bladder	85 (50%)	275 (50%)	0.98
Previous surgery affecting lower urinary tract	65 (38%)	233 (42%)	0.33
Mean number of incontinence episodes/24h	3.8	3.6	0.27
Mean number of micturations 24/h	11.2	11.5	0.11
Mean number of nighttime voids/24h	1.8	1.9	0.22
Mean volume voided mls/24h	184	177	0.31
Mean number of pads/24h	2.0	1.9	0.07

Table 2: Changes in diary variables from baseline

Variable	**Mixed Incontinence**	**Urge Incontinence**	**Statistical Significance Between Groups**
Median incontinence/24h	-66.7%	-75%	P=0.386
Mean micturitions/24h	-15.5%	-15.2%	P=0.879
Median nighttime voids/24h	-50%	-33%	P=0.064
Mean volume voided/24h	18.8%	22.4%	P=0.528
Median number of pads/24h	-40%	-50%	P=0.089

Table 3: Percentage cure rates

Variable	**Mixed Incontinence**	**Urge Incontinence**	**Statistical Significance Between Groups**
Incontinence	39%	44%	NS
Nighttime voiding	83%	76%	NS
Urinary frequency	24%	24%	NS
Pad Usage	21%	27%	NS

Conclusions:

These data show that tolterodine is equally effective in patients with urge incontinence as in patients with symptomatic mixed incontinence. It is not clear why this should be the case and it is possible that many of the patients with mixed incontinence may have had detrusor overactivity as the underlying cause. Nonetheless these data are interesting as this the first report of its kind and has significant implications for clinicians having to treat such patients.

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