
### Study Characteristics

- **N=378**
  - n=190 tolterodine
  - n=188 oxybutynin
- **Inclusion**
  - Age ≥ 50 years
  - Overactive bladder
  - Mobile, attended outpatient clinic
  - Completed voiding diary correctly
  - Written, informed consent
- **Exclusion**
  - Significant stress incontinence
  - Urinary flow obstruction
  - Symptomatic urinary infection
  - Interstitial cystitis
  - Unexplained hematuria
  - Urinary catheterization
  - Significant hepatic or renal disease
  - Concomitant antimuscarinic medication
  - Electrostimulation therapy or bladder training
  - Treatment with tolterodine or oxybutynin in the 3 months before randomization
  - Exposure to any other investigational drug in the preceding 2 months

### Population

- **Baseline Outcome**
  - Changes in voiding diary variables and incontinence pad use after 2, 4 and 10 weeks of treatment.
  - Safety: sitting blood pressure at each visit and routine laboratory safety variables after 10 weeks of treatment.
  - Patients were considered compliant with treatment when they had ingested at least 75% of the study medication.

### Intervention

- **Treatment**
  - Initial screening visit recorded patient demographic, incontinence pad use, medical and drug history, blood samples, sitting blood pressure, electrocardiogram, and midstream urine specimen microbial culture followed by a 7-day treatment free period.
  - 7-day run-in phase that recorded voiding frequency, mean voided volume, number of urge incontinence episodes and incontinence pads used in a voiding diary.
  - After run-in period, patients randomized to receive 10 weeks of treatment with 2mg tolterodine twice daily or an initial dose of 2.5mg oxybutynin, twice daily, increasing to 5mg twice daily after 2 weeks of treatment.
  - If had intolerable adverse events, dose reduction permitted n patients receiving oxybutynin (decreased to 2.5 mg twice daily), while no dose reduction not permitted in tolterodine group.

### Results/Measures

- **Baseline**
  - No significant differences in demographic or baseline clinical characteristics between groups.
  - Overall 67% female, 91% had concomitant disease (most commonly arthritis disorders (n=108) and essential hypertension (n=106)) for which they were receiving medication.
  - 1/3 had overactive bladder symptoms for more than 5 years.
  - 1/3 A had previous therapy for overactive bladder, of whom less than a third had had a good efficacy response.

- **Outcome**
  - For both tolterodine and oxybutynin, decrease in the:
    - Mean # of voids per 24 hours
    - Mean # of urge incontinence episodes /24 hours
    - Mean # of incontinence pads used /24 hours
  - Mean volume voided per void was increased for both treatments.
  - Mean volume voided per void was increased for both treatments.
  - Significant change from baseline observed for all efficacy variables.
  - No significant between-group differences.
  - Maximal treatment effect on urge incontinence episodes and mean voided volume per void was achieved within 4 weeks in both groups.
  - Maximal effect on voiding frequency occurred within 4 to 10 weeks in each treatment group.
  - No differences between treatment groups in onset of action.
  - Similar percentage of changes in perception of bladder condition after 10 weeks.
  - Improvement (tolterodine=45%; oxybutynin=41%)
  - No change (tolterodine=42%; oxybutynin=51%)
  - Deterioration (tolterodine=12%; oxybutynin=8%)
  - Significantly higher proportion of patients reporting at least 1 adverse event in the oxybutynin than in the tolterodine group (chi-square test p=0.01).
  - Significantly more patients in the oxybutynin group had adverse events of severe intensity (oxybutynin=28% VS tolterodine=13%, chi-square test p = 0.0004).
  - Significantly higher proportion of patients had dry mouth in the oxybutynin than in the tolterodine group (oxybutynin=61% vs tolterodine=37%, chi-square test p<0.0001).
  - Severe dry mouth more common in the oxybutynin group than in tolterodine (15% vs 4%).
  - Autonomic nervous system disorders and gastrointestinal problems were the most commonly reported adverse events.
  - Dose reduction was done in 47 patients (25%) on oxybutynin and requested by 12 (6%) on tolterodine (chi-square test p <0.0001), although in this group the dose was not reduced.
  - 5 patients in each group reported serious adverse events; only 3 patients in tolterodine group were considered drug related.
  - No clinically relevant changes in blood pressure, electrocardiogram parameters or laboratory variables.

### Conclusion

Tolterodine is as effective as oxybutynin for improving the symptoms of overactive bladder but it has superior tolerability. The combination of these qualities makes tolterodine the preferred pharmacological therapy for the long-term treatment of this condition.