

## **PROPIVERINE VS. TOLTERODINE – EFFICACY AND TOLERABILITY IN PATIENTS WITH DETRUSOR OVERACTIVITY**

### **Aims of Study**

Comparison of the efficacy, tolerability and of the impact on quality of life of propiverine and tolterodine in the treatment of patients with idiopathic detrusor overactivity.

### **Methods**

In a randomised, double-blind, multicentre clinical trial patients with idiopathic detrusor overactivity were treated with 15 mg propiverine b.i.d. or 2 mg tolterodine b.i.d. for 28 days.

The maximum cystometric capacity was determined at baseline and after 4 weeks of therapy. The difference of both values was used as primary endpoint. Secondary endpoints were voided volume per micturition, efficacy evaluation by the investigator, tolerability, post void residual, and quality of life measured by the King's Health Questionnaire Score.

### **Results**

The per-protocol population included 155 patients (propiverine: 75, tolterodine: 80; age: 56.3 ± 14.9 years, female: 128 (82.6%)), the intention-to-treat population 201 patients (propiverine: 100, tolterodine: 101; age: 56.3 ± 14.9 years, female: 158 (78.6%)) and the safety population 202 patients.

#### **Efficacy:**

In the per-protocol population the mean maximum cystometric capacity increased significantly ( $p < 0.01$ ) in both groups. For propiverine there was an increase from 209.2 ± 64.5 to 265.1 ± 112.2 ml (+55.8 ± 116.2 ml). For tolterodine there was an increase from 202.6 ± 67.1 to 272.6 ± 116.1 ml (+70.1 ± 101.3 ml). Both groups were comparable ( $p = 0.42$ ). This was confirmed by the median values (propiverine +44.0 ml; tolterodine +47.5 ml).

The voided volume per micturition increased by 31.4 ± 60.8 ml in the propiverine group, and by 27.7 ± 56.3 ml in the tolterodine group.

In the final efficacy evaluation the investigators judged propiverine as very good or good in 60 %, moderate in 24 %, and insufficient in 15 % of the cases. Tolterodine was judged as very good or good in 58 %, moderate in 23 %, and insufficient in 19 % of the cases.

#### **Tolerability and safety:**

42/100 patients in the propiverine group and 43/102 in the tolterodine group experienced adverse events. The most common adverse event, dry mouth, occurred in 20 patients in the propiverine group and in 19 patients in the tolterodine group.

16 premature study terminations were documented. In both groups 6 of these terminations were caused by adverse events. No relevant changes in post void residual were observed. The scores for the quality of life improved comparably in both groups (propiverine: from 53.7 to 45.4; tolterodine: from 52.0 to 44.6).

### **Conclusions**

This study demonstrates for the first time comparable efficacy, tolerability, and improvement in the quality of life of 15 mg propiverine b.i.d. and 2 mg tolterodine b.i.d. in the therapy of the symptoms of detrusor overactivity.