

# Influence of propiverine ER 30 mg once daily on cognitive function in elderly female and male patients with overactive bladder: a non-interventional study to assess real life data

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## Hypothesis / Aim of Study

The prevalence of OAB as well as cognitive impairment and dementia increases with aging. Therefore, the number of elderly people with OAB and cognitive impairment/dementia is growing due to the increasing life expectancy. The aim of this study was to evaluate the influence of propiverine ER 30 mg QD on cognitive function in elderly patients with OAB under real-life conditions.

## Study Design, Material & Methods

Female and male OAB-patients were enrolled in this non-interventional study if they fulfilled the following inclusion criteria: age  $\geq 70$  years and no treatment of OAB with anticholinergics within 4 weeks prior to study inclusion. Mini Mental State Examination (MMSE) test and Patient Perception of Bladder Condition (PPBC) questionnaire were completed at baseline and after 12 weeks of treatment with propiverine ER 30 mg QD. Post-void residual urine (PVR) and number of pads/24 h were recorded before and after 4 and 12 weeks of treatment with propiverine ER 30 mg QD. PVR and patient-reported adverse drug reaction (ADR) were monitored as safety parameters.

## Results

Of 225 patients who participated in this study (safety population) 201 patients (124 women, 74 men, 3 not reported, mean age: 75.8 years, range 70-93 years) fulfilled the inclusion criteria and were included in the analysis. 136 patients (68%; 100 women, 34 men, 2 not reported) had urinary incontinence at baseline.

The mean MMSE at baseline showed a score in the lower normal range (mean: 27.0). No significant change of the MMSE score was observed after 12 weeks of treatment with propiverine ER 30 mg QD (mean: 27.1; Figure 1a). At study begin, 66 patients (33%, 32 women, 34 men) had mild cognitive impairment with a mean MMSE score of 23.7. In this patient group, no significant change of the MMSE score was detected as well (mean: 24.1; Figure 1b).

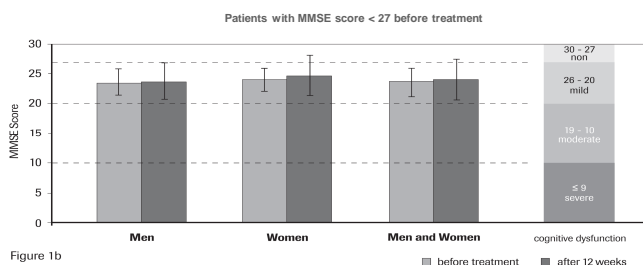
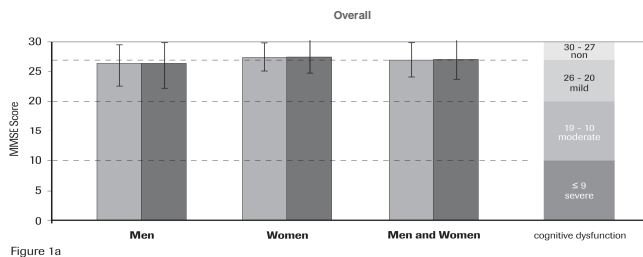


Figure 1: MMSE score at baseline and end of treatment in all patients (1a) and patients with MMSE score < 27 before treatment (1b)

The mean PPBC improved significantly from 4.4 to 2.9,  $p < 0.001$  (Figure 2). Incontinent patients at baseline experienced a higher burden as documented by a higher score before treatment (4.5 vs. 4.2); after 12 weeks of treatment, no difference was found between patients with or without incontinence (2.9 vs. 2.8).

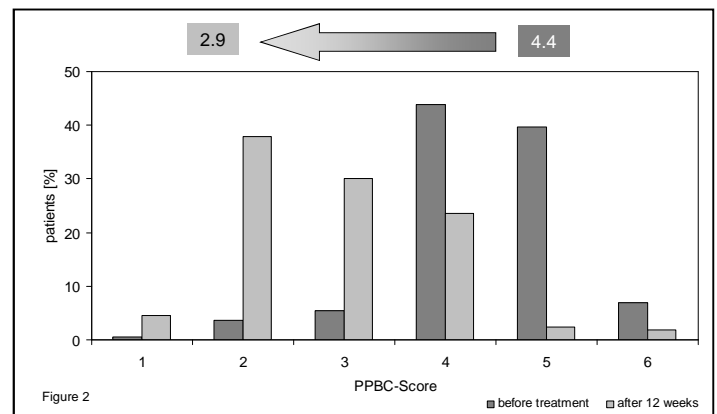


Figure 2: PPBC score at baseline and end of treatment in all patients

Patients used 2.7 pads/24 h on average before treatment. The number of pads/24 h decreased significantly by 52 %. After 12 weeks, 62 patients (31 %) and 62 patients (31 %) used no or only 1 pad/24 h, respectively.

Average PVR did not change during the 12-week treatment period (20.7 ml before vs. 21.7 ml after 12 weeks). Treatment with propiverine ER 30 mg was well tolerated. 38 patients (17%) reported ADRs and dry mouth was the most frequent ADR (9.8%).

## Interpretation of Results

This is the first study evaluating the influence of propiverine ER 30 mg on cognitive function (MMSE) and perception of bladder condition (PPBC) in elderly patients under real-life condition. The results of this study confirm earlier findings that propiverine does not influence cognitive function [1]. The improvement of the subjective perception of bladder condition and the decrease of the number of pads/24 h reflect the efficacy of the treatment in the geriatric population.

## Conclusions

Results from this non-interventional study show no signs of cognitive alteration under real-life condition in patients aged 70 years or older during treatment with propiverine ER 30 mg QD. Furthermore, elderly patients reported a significant improvement of the subjective perception of their bladder condition and a decrease of the number of pads/24 h.

## Reference:

[1] Sakakibara et al. How to manage overactive bladder in elderly individuals with dementia? A combined use of donepezil, a central acetylcholinesterase inhibitor, and propiverine, a peripheral muscarine receptor antagonist. *J Am Geriatr Soc* 2009; 57(8): 1515 – 17.

## Abbreviations:

ER – Extended release; QD – Quaque Die