Efficacy and Tolerance of Propiverine in Neurogenic Detrusor Overactivity in Comparison with Oxybutynin

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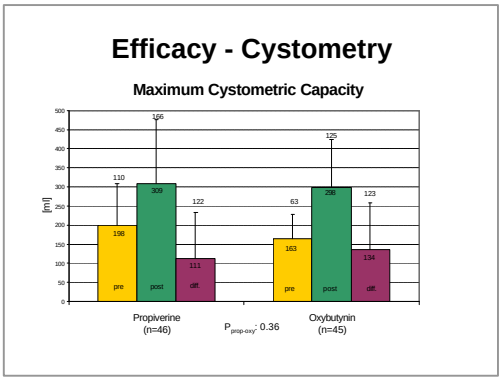
Aims of Study:
To compare the efficacy and tolerability of propiverine and oxybutynin in patients suffering from neurogenic detrusor overactivity (1).

Material and Methods:
Efficacy and tolerability of propiverine and oxybutynin were compared in a randomised, double-blind, multicenter clinical study.
Patients were eligible, if at least 18 years of age and suffering from neurogenic detrusor overactivity with a maximum cystometric capacity of less than 300 ml. After a one-week run-in period propiverine 15 mg t.i.d. or oxybutynin 5 mg t.i.d. (double-dummy technique) were allocated. Urodynamics were assessed as the primary efficacy parameters before (V 1) and after (V 2) a treatment period of at least 21 days: maximum cystometric capacity (i.e. for patients with impaired sensation defined as cystometric capacity according to the new definitions (1)), and maximum detrusor pressure during filling phase. Furthermore, bladder diaries, which had to be filled by the patients, were applied.
For evaluation of tolerance the percentage of patients with newly manifesting adverse events was determined.

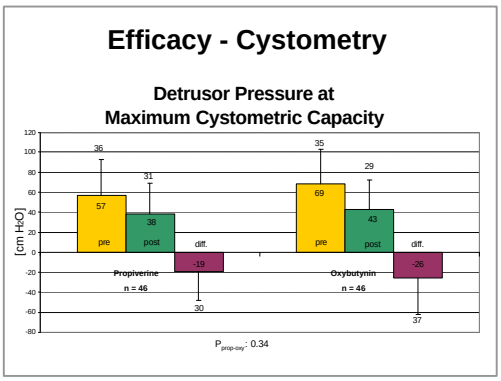
Results:
131 patients (safety population) were recruited in 20 study centers (propiverine 70, oxybutynin 61). Demographic data were comparable between both treatment groups.

1. Efficacy

1.1. Efficacy – Cystometry: In the per-protocol population the maximum cystometric capacity was increased significantly in both the propiverine (n = 46; V 1: 198 ± 110, V 2: 309 ± 166) and the oxybutynin group (n = 45; V 1: 164 ± 64, V 2: 298 ± 125).
Between the treatment groups no significant (p = 0.36) difference resulted.



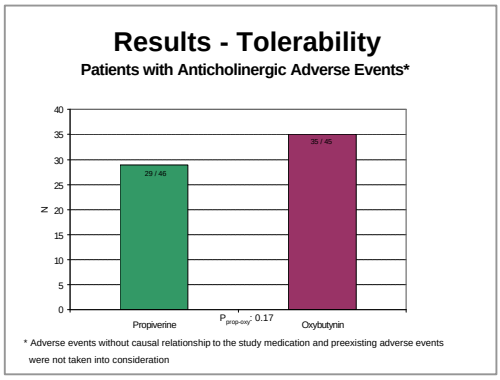
Maximum detrusor pressure during filling phase was decreased significantly in the propiverine (V 1: 57 ± 36, V 2: 38 ± 31) as well as in the oxybutynin group (V 1: 69 ± 35, V 2: 43 ± 29). There was no significant (p = 0.34) difference between the groups. The same holds for secondary efficacy parameters, e.g. urodynamic compliance (p = 0.11) and post void residual (p = 0.13).



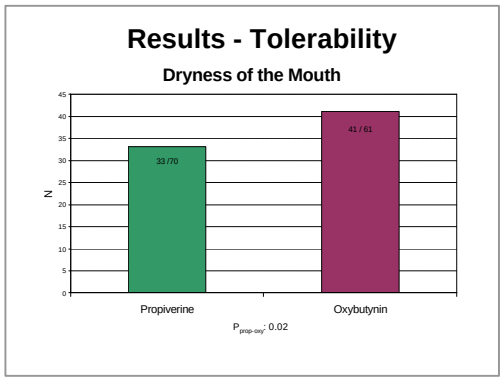
Intention-to-treat analysis is in accordance with the results of the per-protocol group.

1.2. Efficacy – Bladder Diary: Frequency (per 24 hrs) decreased in both groups: propiverine V 1: 10.9, V 2: 7.9 and oxybutynin V 1: 12.0, V 2: 9.5. Incontinence episodes were reduced: propiverine V 1: 3.9, V 2: 2.3 and oxybutynin V 1: 3.3, V 2: 2.0.

2. Tolerability: In the propiverine group 63 % of patients developed anticholinergic adverse events compared to 78 % in the oxybutynin group. Between both groups no significant difference resulted (p = 0.17).



However, dryness of the mouth was reported significantly more often (p = 0.02) in the oxybutynin compared to the propiverine group (67 % vs. 47 %).



Conclusions:
1. Propiverine and oxybutynin are effective in the treatment of neurogenic detrusor overactivity.
2. Both drugs have to be considered equieffective, as evidenced by urodynamic assessment and by bladder diaries.
3. There is a favourable trend for propiverine regarding the tolerability.
4. There is a significant lower incidence rate of dryness of the mouth for propiverine compared to oxybutynin.

References:
(1) Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, Keerebroeck P van, Victor A, Wein A (2002). The Standardisation of Lower Urinary Tract Function: Report from the Standardisation Sub-committee of the International Continence Society. Neurourology & Urodynamics, 21: 167 –178.

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