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A URODYNAMICALLY CONTROLLED MULTICENTER STUDY IN PATIENTS WITH URGE INCONTINENCE: TOLERABILITY AND EFFICACY OF PROPIVERINE HYDROCHLORIDE IN COMPARISON TO OXYBUTYNIN

AIMS OF STUDY: The tolerability (1) and efficacy (2) of propiverine (prop.) in patients with urge incontinence was studied in comparison to oxybutynin (oxy.) and placebo (plac.) in a randomized double-blind, urodynamically controlled study.

METHODS AND MATERIAL: 366 patients (prop. n=149; oxy. n=145; plac. n=72; ratio 2:2:1) suffering from urge incontinence were recruited in 32 study centers. Dosages of 15 mg prop. t.i.d., 5 mg oxy. b.i.d. or plac. were administered according to randomisation for 4 weeks. Double-dummy-technique for medication guaranteed double-blind study conditions.
(1) Tolerability was assessed by directly questioning the patients for adverse events at 4 visits (V-1; V0, V1, V4) during a 4-weeks surveillance period and by documentation of the tolerability ratings of the physicians.
(2) Efficacy was assessed (a) by urodynamics before and after 4 weeks treatment (V0-V4) evaluating cystometric bladder capacity at maximal desire to void, cystometric bladder capacity at first desire to void and detrusor pressure at first desire to void, according to ICS criteria. Additionally, (b) subjective data as the urge score of Gaudenz incontinence questionnaire, global assessment of clinical improvement and efficacy ratings by the physicians were documented.

RESULTS:
(1) **Tolerability**: A high percentage of adverse events was reported already in the wash-out period (V0: prop. 13 %; oxy. 16 %; plac. 18 %), at the final evaluation (V4) the clinically most relevant symptom, dryness of the mouth, occured in 53.4 % with prop., in 66.9 % with oxy. and in 27.8 % with plac. Prop. revealed an increasing tolerability during the course of treatment (V1-V4). The adverse events under prop., compared to oxy., were of lower severeness. 67 % of patients with prop., 59 % with oxy. and 83 % with plac. stated a „very good" or „good" tolerability.
(2) **Efficacy**: Urodynamics proved a statistically significant increase of the maximal cystometric bladder capacity for prop. (V0: 222 ± 77 ml; V4: 311 ± 125 ml; increase by 89 ± 108 ml) in comparison to plac. (Mann-Whitney U-Test, p=0.005) as well as for oxy. (V0: 226 ± 75 ml; V4 322 ± 123 ml; increase by 96 ± 106 ml) in comparison to plac. (Mann-Whitney U-Test, p=0.002). The plac. group

demonstrated only minor, non significant change (V0: 211 ± 77 ml; V4: 263 ± 93 ml; increase by 52 ± 92 ml). The cystometric bladder capacity at first desire to void increased statistically significant with prop. (V0: 93 ml, V4: 160 ml) and oxy. (V0 89 ml; V4 160 ml) whereas plac. increased non-significantly (V0 93 ml; V4 120 ml). The improvements of the objective urodynamic parameters were comparable for both vera. Detrusor pressure at first desire to void showed no significant difference between the three treatment groups. Alterations of residual urine within and between the treatment groups were only minimal and clinically not relevant.

(3) **Subjective data:** the urge score of Gaudence incontinence questionnaire (prop. V0: 14.1, V4: 5.8; oxy: 14.7, V4: 6.1; plac. V0: 14.1, V4: 6.8) global assessment of clinical symptomatology (improvement in 83.3 % with prop., in 79.3 % with oxy, in 68.3 % with plac.) and efficacy ratings by the physicians („excellent" or „good" results in 65.9 % for prop., in 67.6 % for oxy., in 52.4 % for plac., „satisfactory" results in 16.7 % for prop., in 12.4 % for oxy., in 7.9 % for plac.) supported the urodynamic results.

CONCLUSIONS: Prop. proved to be a safe and comparatively well tolerated drug in an anxious patient population documenting a high percentage of adverse events prior to the beginning of the study. The efficacy of prop. in patients with urge incontinence is comparable to oxy. The availibility of a spectrum of pharmacotherapeutic options including prop. reduces therapeutic failures and improves the success rates in this group of patients.