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Batinic D. [1], Mürtz G. [2], Schnabel F. [2], Gramatté T. [2], Kirch W. [3]
1. University Hospital Salata, Children´s Department, 2. Apogepha, Dresden, Germany, 3. Technical University, Institute of Clinical Pharmacology

EFFICACY AND TOLERABILITY OF PROPIVERINE IN CHILDREN SUFFERING FROM OVERACTIVE BLADDER – A DOUBLE-BLIND, RANDOMIZED, CLINICAL TRIAL VERSUS OXYBUTYNIN AND PLACEBO

Aims of Study
To compare efficacy and tolerability of propiverine (prop) with that of oxybutynin (oxy) and placebo (plac) in children with overactive bladder (enuresis diurna, diurna et nocturna, nocturna with urge).

Methods
266 children (prop n=85; oxy n=91; plac n=90) were recruited. Dosages of 10 mg prop b.i.d., 5 mg oxy b.i.d. or plac were administered. The treatment period of 12 weeks was followed by 2 weeks of administering half of the initial dosage. The study was finalized with a medication-free post-therapy phase of 6 weeks. Efficacy was assessed by micturition diaries (weekly numbers of enuretic events). Additionally, bladder capacity at max. urge was evaluated in a subpopulation (prop n=35; oxy n=35; plac n=30). Tolerability was assessed by directly questioning of adverse events.

Results
Efficacy: The number of enuretic events per week demonstrated a marked decrease for prop (baseline: 11.2; weeks 15-17: 6.4) and oxy (baseline: 10.9; weeks 15-17: 6.3). Due to marked effects of plac (baseline: 11.6; weeks 15-17: 7.5) drug effects did not reach level of significance. However, the bladder capacity at max. urge increased significantly with prop (baseline: 133.9; week 12: 162.8; $p<0.05$) and oxy (baseline: 138.3; week 12: 167.4; $p<0.05$), but not with plac (baseline: 134.1; week 12: 136.4; n.s.).
Tolerability: There were 57 adverse events in the plac group. Comparable frequencies were observed under prop (64); in contrast twice that number (126) occured under oxy. The frequency of adverse events was significantly higher with oxy compared to plac and prop.

Conclusions
The study demonstrated a superior tolerability of prop compared to oxy. The number of enuretic events per week was decreased in a comparable manner for prop and oxy, and surprisingly for plac as well. Moreover, urodynamic data demonstrated prop and oxy as effective drugs in the treatment of overactive bladder in children. An unexpected lack of correlation between urodynamics and micturition diaries was also shown in the European Bladder Dysfunction Study (van Gool, 1999).