DRUG THERAPY OF URGE INCONTINENCE IN CHILDREN AND ADOLESCENTS - EFFICACY AND TOLERABILITY OF PROPIVERINE

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ABSTRACT

AIMS OF STUDY

There is a necessity to achieve data for the treatment of children and adolescents aside data for adults [1]. Data of children and adolescents were achieved in an international post marketing drug surveillance (PMS) with propiverine (prop.) in the treatment of urge incontinence. It was to compare the efficacy, tolerability and dosage of prop. for children, adolescents and adults.

METHODS

The PMS comprised 4390 patients including subpopulations of children (age group up to 11 years), adolescents (age group 12-17 years) and adults (age group 18-65 years). Pre (V0), after 4 weeks (V4) and after 12 weeks of therapy (V12), demographic data as well as data from frequency/volume charts were evaluated for efficacy (episodes of incontinence, frequency and pad use). Tolerability was assessed by directly questioning of adverse events including typical anticholinergic adverse events, and by documenting of residual urine, as well.

RESULTS

Data of 547 children (mean age 7.4 y., mean body weight 28.0 kg), 92 adolescents (mean age 13.0 y., 45.8 kg), and 2349 adults (mean age 50.0 y., 70.7 kg) were analysed.

Mean day time incontinence episodes, micturition frequency and pad use decreased from V0 to V12 (compare table). The daily dosage adjusted to the body weight was within a comparable range for all age groups displaying a decrease of the daily dosage during the surveillance period.

Dryness of the mouth was reported in children in 11.0 %, in adolescents in 12.0 % and in adults in 41.0 %. In neither of the groups a clinical relevant increase of residual urine was documented.

	children	adolescents	adults
patients	547	92	2369
sex			
male [%]	50.5	44.6	10.7
female [%]	49.5	55.4	89.3
incontinence day time			
V0 [episodes]	1.3	1.4	3.5
V12 [episodes]	0.2	0.3	1.0
frequency day time			
V0 [episodes]	6.8	6.9	9.2
V12 [episodes]	5.5	5.5	5.8
wet or damp pads			
V0 [% of patients]	34.2	31.5	58.2
V12 [% of patients]	6.6	10.9	21.9
dryness of the mouth			
V0 [% of patients]	4.8	7.6	18.4
V12 [% of patients]	11.0	12.0	41.0
premature termination due to improvement [%]	20.5	15.2	16.2
premature termination due to insufficient therapy [%]	11.3	5.4	3.5
daily dosage V0			
[mg]	12.7	18.4	36.4
[mg/kg body weight]	0.4	0.4	0.5

CONCLUSIONS

Prop. is effective and well tolerated in the treatment of urge incontinence in children, adolescents and adults, as well. The rate of premature termination due to insufficient therapy in children may be minimised, if the recommended daily dosage - 0.8 mg/kg BW - would be applied as proven in clinical studies [2]. Nevertheless, the rate of complete remissions of clinical symptoms was higher than the assumed rate of spontaneous remissions of about 15 % per year. Prop. is recommended for the treatment of urge incontinence in children, adolescents and adults as well.

[1] CPMP and FDA Guidelines 462/95

[2] Siegert et al. Jahrbuch der Urologie 1994: 177-181

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