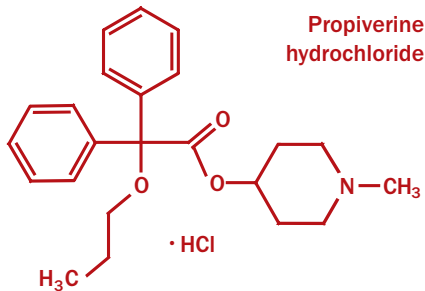


PEDIATRICS

Treating OAB in children



Propiverine is superior to placebo for treating non-neurogenic overactive bladder (OAB) and urinary incontinence in children, according to a report published in *European Urology*. This is the first published trial to confirm this finding, despite the fact that antimuscarinic agents such as propiverine hydrochloride have been in widespread use in children with this condition in Germany, the Czech Republic and Slovakia since 1985.

The lack of confirmatory trial evidence has led the International Consultation on Incontinence (ICI) to recommend antimuscarinic treatment for children with OAB with an evidence level of only 3, grade B/C, a far lower level than is usual for a therapy that has been well accepted by clinicians for almost 25 years.

The study—a randomized, double-blind, placebo-controlled phase 3 trial—was conducted in children aged between 5 and

10 years using a parallel-group design. In total, 171 children from 6 European countries were assessed by 38 investigators. One group (87 children) were treated for 8 weeks with propiverine at a dose between 10 and 15 mg per day. All doses were body-weight adjusted. A control group of 84 children were treated with placebo for the same time period. All the families of children in the study were asked to follow a 3-week lifestyle urotherapy program prior to the start of the trial. In order to encourage compliance, children were given specially designed diaries in which to record their voiding behavior.

“Urotherapy did improve symptoms in a number of patients, avoiding the necessity of medical treatment, and helped to identify the remaining patient target group,” explains Daniela Marschall-Kehrel, the study’s senior author. Superiority of propiverine over placebo was demonstrated for the primary efficacy parameter, a change in voiding frequency between baseline and the end of treatment, and for the additional parameters of voided volume and incontinence episodes. Significant improvements in all three parameters were reported.

Propiverine therapy was also well tolerated by children in the study group. Adverse effects were reported, but there was very little difference in their frequency in the study group (23%)



compared to the placebo group (20%). Dry mouth, constipation and visual disturbances—commonly induced by antimuscarinics—occurred only in those who received propiverine.

“The results support the importance of propiverine for further evaluation of treatment options in these children, resulting in recommendation by ICI,” predicts Marschall-Kehrel.

Kathryn Senior

Original article Marschall-Kehrel, D. *et al.* Treatment with propiverine in children suffering from nonneurogenic overactive bladder and urinary incontinence: results of a randomized placebo-controlled phase 3 clinical trial. *Eur. Urol.* 55, 729–738 (2009).