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## Evidence of desloratadine syrup efficacy and tolerability in children with pollen-induced allergic rhinitis

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**Key words:** children; rhinitis; asthma; desloratadine syrup; efficacy.

The new antihistamine desloratadine (DL) was shown to be effective and safe (1), but data in children are still few. The syrup formulation of DL has become recently avail-

**Desloratadine syrup is effective in children with allergic rhinitis and asthma.**

able, and positive data have been reported (2). We assessed, in an open trial, the efficacy and safety of DL syrup in paediatric patients.

Children aged 6–12 years were enrolled. They all suffered from seasonal allergic rhinitis for 2 years at least, with or without concomitant intermittent asthma. The allergic sensitization was documented by the positivity of skin-prick tests to pollens including grasses, *Parietaria*, olive and birch. All the patients were treated for 4 weeks with DL syrup 2.5 mg daily during the 2003 pollen season. Nasal, non-nasal (rhinorrhea, itching, sneezing, congestion, ocular itching and redness) and asthma symptoms (wheezing, difficult breathing, cough, chest tightness) were graded from 0 (none) to 3 (severe). Patients had to have a total symptom score  $\geq 8$  with a nasal congestion score  $\geq 2$ , and a non-nasal symptoms score  $\geq 2$  at baseline. The protocol was approved by the ethical committee.

Fifty-four children (age  $9.0 \pm 1.7$  years, 63% male, height  $136.7 \pm 10.5$  cm, weight  $35.2 \pm 10$  kg) were enrolled; 75% of patients were polysensitized, 67% suffered from eye symptoms, and asthma was present in 76% of patients. Forty-nine children concluded the study, five were withdrawn (four because of unrelated adverse events and one because of protocol ineligibility).

The upper panels of Fig. 1 reports patient distribution over the symptom severity scale during the study, and the lower panels report lower airway symptoms. Rhinorrhoea, sneezing, stuffiness and itching were reduced in a considerable proportion of children. Almost all children were free of cough at the end of treatment and lower airway symptoms similarly subsided. In addition, the need for short-acting beta-2-agonist was reduced in patients with concomitant asthma symptoms. A positive correlation was observed between the reduction of the cough score and the sneezing score ( $r = 0.70$ ;  $P = 0.011$ ), thus supporting the strict link between upper and lower airways. Eye symptoms disappeared in almost all children after DL treatment.

A total of 22 adverse events were reported in 13 children. One case of insomnia and one of diarrhoea were considered possibly related to treatment. Vital signs (blood pressure, pulse, tem-

perature, breath rate) were monitored during the study and no relevant change in any of these parameters was observed. This confirms the excellent safety profile of DL syrup in young children also.

This study provides preliminary original data about upper and lower airway symptom improvement in children with respiratory allergy after a 4-week treatment with DL syrup at the dose of 2.5 mg once a day during the pollen season.

**Desloratadine syrup was effective in reducing nasal symptoms, including nasal obstruction.** This observation is in agreement to what was reported in adults by Horak et al. (3). In children with coexisting asthma and/or conjunctivitis, DL also induced a significant improvement of asthma and eye symptoms and a reduction of the need for rescue bronchodilators, as reported in adults by Berger et al. (4). This is in line with the proposed strategy of combining the treatment of lower and upper airway disease reported in the ARIA document (5). DL was well tolerated and most of the adverse events were mild in severity and experienced by a small proportion of patients. Thus, DL met the requirements for antihistamines proposed by EAACI/ARIA (1) also in children.

This study is not randomized and not controlled, therefore our findings need to be confirmed with a rigorous design. Nevertheless, given the number of patients, the results worth of interest, as they provide, for the first time, evidence of the efficacy and safety of DL syrup in children.

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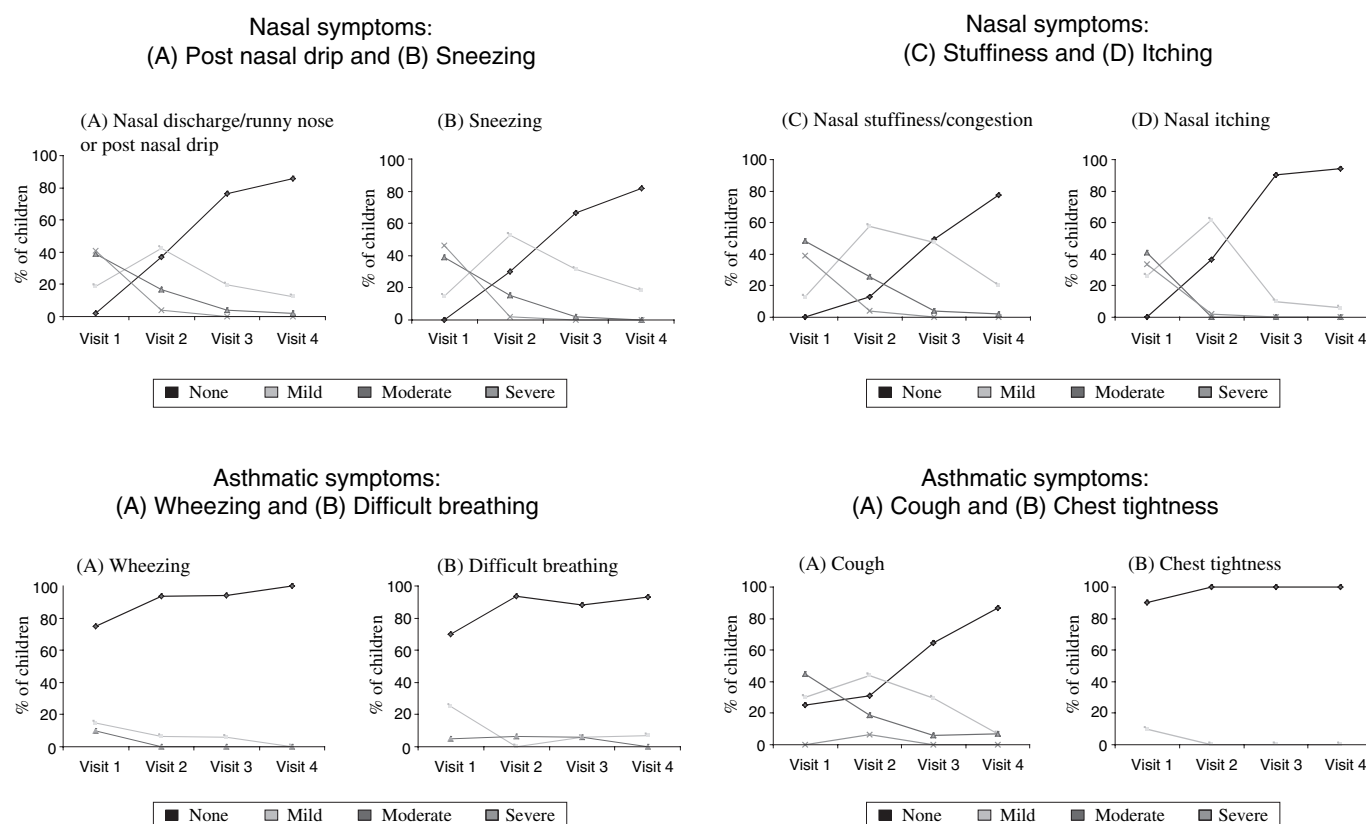


Figure 1. Distribution of children (%) with respect to severity of symptoms.

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