Results: IgE against to rPhl p 1 were found in 99% (205/207) of patients, to rPhl p 5 in 67% (139/207), to rPhl p 12 in 32% (66/207) and to rPhl p 7 only in 5% (10/207). Sensitization only to major allergenic molecules of Phleum pratense was detected in 65% (135/207) of children, while the remaining patients were sensitized to major and minor allergens. Good correlations with statistical significance were observed between timothy grass pollen IgE and IgE against rPhl p 1, rPhl p 5, rPhl p 7, rPhl p 12 and their sum (total Phleum IgE). rPhl p 1 sensitization is detectable at any level of grass pollen IgE, while monosensitization to rPhl p 1 is very important in patients with lower grass pollen IgE levels and it disappears with the increase of grass pollen IgE level. Although rPhl p 5 IgE positivity rises with the increase of grass pollen IgE and becomes the same of rPhl p 1 in patients with higher grass pollen IgE. Sensitization to rPhl 1 seems to appear early (even before the age of 5 years), while rPhl p 5 positivity increases with the rise of the age.

Conclusion: Our data shows the predominant role of rPhl p 1 as the most relevant sensitizing allergen detectable at all ages and at all levels of grass pollen IgE, while the importance of rPhl p 5 rises with the increase of patients' age and of grass pollen IgE level. Therefore this study confirms the importance of sensitization for rPhl p 1 in grass pollen allergic patients in paediatric age, in our country, while don't support the use of rPhl p 5 alone, especially in the smaller children, as the only allergenic molecule of Phleum pratense on which to base diagnosis of grass pollen allergy and specific immunotherapy.

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Health-related quality of life in children with grass pollen allergy

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Background: It is well known that the allergic responses have systemic components which gives concomitant systemic disease manifestations and affects the functioning on a daily basis. The aim of this study was to investigate the HRQoL in children with grass pollen allergy during and out of grass pollen season. We used PADQLQ, a disease specific questionnaire including both asthma and rhinitis symptoms. We also used the DISABKIDS, a generic questionnaire covering non-organ specific burden of disease.

Methods: Children with grass pollen allergy completed the questionnaires in parallel to ordinary Visual analogue scales (VAS) during and out of grass pollen season. The Mann-Whitney U test was performed to test differences between groups. To assess the relationship between DISABKIDS and symptoms, age, gender, asthma and hay fever, linear regression was used.

Results: A total of 98 children 7–18-years-old were included. 91% completed the study. A total of 90 % of the children had rhinitis and 61% had asthma. The HRQoL was significantly worsened during pollen season assessed both with DISABKIDS and PADQLQ. The correlation between the questionnaires was 0.71. The physical domain score assessed with the DISABKIDS was significantly lowered and so was the emotional domain score. The children felt unhappier during pollen season than out of season. The PADQLQ was highly correlated to symptom score (0.91). Children with asthma and rhinitis had lower HRQoL than children with rhinitis only ($P = 0.01$). Multiple regression analysis showed a highly significant impact on HRQoL for symptoms from nose, eyes and lungs.

Conclusion: We have shown that the quality of life in children with grass pollen allergy is greatly affected during pollen season. The disease specific questionnaire was highly correlated to symptom score and had a high sensitivity to change making it useful as a follow up instrument in clinical practice. The generic questionnaire showed in addition to physical worsening during pollen season also influence on mental wellbeing. The children experienced that they could not do the things they wanted to and felt more unhappy during pollen season. This highlights the importance of taking a careful history when deciding about treatment for the children and assess not only symptoms but also the mental and social consequences to get a picture of the real burden of disease.

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Rupatadine improves nasal symptoms control at 4 and 6 weeks in children with persistent allergic rhinitis

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Background: Clinical trials with the newer non-sedating antihistamines in children under the age of 12 years have been performed in the previous years but further studies are needed in order to show efficacy and safety in the most unfavourable clinical conditions such as persistent allergic rhinitis (PER). Rupatadine is a promising treatment for children with allergic rhinitis in view of its rapid onset of action and its lack of relevant side effects at higher than therapeutic doses. The aim of this study was to assess the efficacy and safety of rupatadine (RUP) oral solution in children between 6 and 11 years with PER.

Methods: A randomized, double-blind, multicenter, international and placebo-controlled study was carried out in 34 centres in Argentina, South Africa, Hungary and Spain. Main selection criteria included patients between 6–11 years diagnosed as PER according to ARIA criteria, with a positive prick test, weight ≥16 kg and a basal nasal symptoms score (including rhinorrhea, nasal blockage, sneezing and nasal itching assessment) ≥24 obtained in 4 days throughout the 2-week screening period. Patients were allocated to treatment with either RUP oral solution (1 mg/ml) or placebo during 6 weeks. The dose was adjusted by body weight: 2.5 ml for children < 25 kg and 5 ml for children ≥25 kg. The main efficacy endpoint was the change from baseline of the nasal and global symptoms score at 4 and 6 weeks of treatment.

Results: A total of 445 patients were screened, of which 360 were finally included and randomized to rupatadine ($n = 180$) or placebo ($n = 180$). Table 1 summarizes the efficacy results:

Adverse events were scarce in both treatment groups throughout the study. Only headache was reported with higher incidence in the rupatadine group compared to placebo. ECGs (QTc) and lab tests did not show any relevant finding.

Table 1 For abstract 23.

Parameter	Placebo ($n = 180$)	Rupatadine ($n = 180$)	*P*-value
4TSS baseline	7.2 (1.1)	7.2 (1.1)	NS
Change 4TSS *versus* baseline at 4 weeks	–2.5 (1.9)	–3.1 (2.1)	0.018
% of reduction at 4 weeks	34.7%	43.1%	
Change 4TSS *versus* baseline at 6 weeks	–2.7 (1.9)	–3.3 (2.1)	0.048
% of reduction at 6 weeks	37.5%	45.8%	

Conclusion: Rupatadine oral solution (1 mg/ml) was significantly more effective than placebo in reducing nasal symptoms (4TSS) at 4 and 6 weeks. Rupatadine was well tolerated, without differences in somnolence between both groups. This is the first clinical evidence of a H1-receptor antagonist efficacy in children with PER.

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Influence of concurrent use of intranasal and inhaled fluticasone on hypothalamic-pituitary-adrenal axis in children with allergic rhinitis and asthma

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Background: Allergic rhinitis occurs in 80% of individuals with asthma. As inhaled and intranasal steroids are the first-line therapy for both conditions, their concurrent use is often required in patients with inhalative allergy. Although both inhaled and intranasal steroids are considered to have minimal bioavailability, further studies are needed to evaluate the systemic effect of their concurrent use, especially in children. The aim of the study was to compare the function of hypothalamic-pituitary-adrenal axis (HPA axis) in children with allergic rhinitis (AR) receiving intranasal fluticasone alone and children with comorbid AR and bronchial asthma (BA) receiving intranasal and inhaled fluticasone concurrently.

Methods: A total of 60 patients aged 4–18 years were enrolled in the study: 35 with AR (group 1) and 25 with AR and BA (group 2). Over pollening season group 1 received intranasal fluticasone alone while group 2 received both intranasal fluticasone and moderate dose of inhaled fluticasone. The function of HPA axis was evaluated by the low dose adrenocorticotropin stimulation test (1 mcg/1.7m^2) performed before and right after fluticasone treatment. Cortisol serum concentration was assesed using radioimmunoassay.

Results: We did not detect the signifficant difference in cortisol response to stimulation between groups after treatment period (mean post-stimulation cortisol of 22.78 mcg/dL in group 1 and 20.59 mcg/dL in group 2, $P > 0.05$). The abnormal cortisol response after treatment was observed in 2 patients from group 1 and 2 patients from group 2.

Conclusion: Concurrent treatment with intranasal and inhaled fluticasone does not influence the HPA axis function comparing to treatment with intranasal fluticasone alone. However there are individuals in whom noticeable suppression of HPA axis function in the course of treatment is detected. This entails the potential risk of developing clinical symptoms of adrenal insufficiency in stressful situations, such as serious infection or surgical procedure. Therefore, performing HPA axis functional test in all children undergoing inhaled or intranasal steroid therapy should be considered.