## 1063 Redefining the Late Phase Reponse in Allergic Rhinitis

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**RATIONALE:** The incidence of a late phase response (LPR) in individuals with allergic rhinitis (AR) varies depending on the criteria used to define it. The aim of this study was to characterise the LPR based on symptom scores, peak nasal inspiratory flow (PNIF) and mediator release.

**METHODS:** 48 males with AR were intranasally challenged with Der p 1, rye grass or cat dander. The severity of nasal symptoms including sneezing, nasal blockage and rhinorrhea were measured for 10.5 h post-challenge using the Lebel, visual analogue scale, categorical scoring systems as well as PNIF. Albumin, tryptase, MPO, ECP, ENA-78, IL-5 and CXCL8 levels in nasal secretions were compared in subjects that did and did not exhibit a LPR up to 24 h after allergen challenge.

**RESULTS:** Between 44-75% of subjects exhibited a LPR. The severity of all nasal symptoms significantly increased within 10 min of allergen challenge. Rhinorrhea and nasal blockage persisted for up to 10.5 h post-allergen challenge with blockage being the most severe symptom. No single symptom scoring system was significantly more sensitive or specific than any other. Significant differences in release of albumin, tryptase, ECP, IL-5, CXCL8 and MPO were observed in subjects that exhibited a LPR compared to those that did not. Subjects with a LPR exhibited a more severe EPR.

**CONCLUSIONS:** Based on symptoms alone, nasal responses to inhaled allergens are best described as a persistent response rather than a dual-phase response. However, the early and late phase reactions are characterised by the release of specific mediators.

**Funding:** GlaxoSmithKline

## 1064 Growth Velocity and HPA Axis Function During 1-Year Treatment With Triamcinolone Acetonide Aqueous (TAA) Nasal Spray in Children With Allergic Rhinitis (AR)

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**RATIONALE:** AR is most effectively treated with intranasal corticosteroids but there is some concern that this therapy may suppress HPA axis function and decrease growth velocity.

**METHODS:** This study reports 1-year follow-up data on 24 children (12 female, 9 African American), aged 6-14 years (mean 10.4 years) at entry, enrolled in a long-term growth trial of intranasal TAA for treatment of AR. Primary measures included height velocity and salivary cortisol levels.

**RESULTS:** All subjects followed their expected age-appropriate growth velocities. Average growth velocities were 5.6 and 5.8 cm/year for girls and boys aged <12 years, respectively, and 5.5 and 7.7 cm/year for girls and boys aged >12 years, respectively. Mean salivary cortisol levels were 16.7$\pm$8.0 and 11.5$\pm$6.5 nM/L at entry and 1-year follow-up, respectively.

**CONCLUSION:** These results demonstrate no significant effect of one year of intranasal treatment with TAA on growth velocity or HPA function in children with AR.

**Funding:** Aventis

## 1065 Efficacy of Montelukast for Treating Perennial Allergic Rhinitis

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**RATIONALE:** Up to 40% of allergic rhinitis (AR) patients report symptoms of perennial allergic rhinitis (PAR), a persistent allergic inflammation of the upper respiratory tract due to perennial (year-round) allergens like dust mites, animal dander, molds and cockroaches. The antileukotriene montelukast has previously demonstrated clinical benefit in seasonal AR, and this study evaluated montelukast for treatment of PAR.

**METHODS:** This was a 2-arm, multicenter study performed during the winter. Following a placebo run-in period, adult patients with perennial allergen sensitivity and active symptoms of PAR were randomized to montelukast 10 mg (n=1002) or placebo (n=990) once daily during a 6-week, double-blind, active-treatment period. The primary endpoint was the Daytime Nasal Symptoms (DNS) score (scale 0=none to 3=severe), average of daily scores for Congestion, Rhinorrhea, and Sneezing.

**RESULTS:** Significant improvements in PAR symptoms were seen in patients treated with montelukast. The DNS score was significantly reduced over the treatment period, versus placebo: difference between treatments in mean change from baseline was -0.08 (95% CI -0.12, -0.04), $p \leq 0.001$. Montelukast significantly improved the endpoints of Global Evaluation of AR by patients and Rhinoconjunctivitis Quality-of-Life: differences (vs placebo) were -0.15 (-0.27, -0.04) and -0.15 (-0.24, -0.06). Other endpoints showing significant improvement with montelukast were Nighttime Symptoms, Daily Rhinitis Symptoms (measuring efficacy over 24h), and each of the four nasal symptoms of Congestion, Rhinorrhea, Sneezing, and Itching. The treatment effects of montelukast were stable and persistent over the entire 6 weeks.

**CONCLUSION:** Montelukast provided significant benefit for relief of symptoms of perennial allergic rhinitis over a 6-week treatment period.

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## 1066 A Sinusitis Questionnaire to Assess Longitudinal Changes During Acute Sinusitis

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**RATIONALE:** There are few instruments to assess sinusitis severity or changes over time.

**METHODS:** A Sinusitis Score questionnaire was developed by adding a Sinus Pain and Fullness domain to the modified Rhinitis Score of Wasserfallen et al. (J Allergy Clin Immunol 100:16-22, 1997). Symptom severity was scored on a 5 point ordinal scale, and the sum determined for each domain. Acute sinusitis subjects were treated with amoxicillin/clavulanate, pseudoephedrine, oxymetazoline and nasal steroids, and randomized to either fluticasone (F; n=12) or its vehicle (V; n=12). Questionnaires were completed on enrollment (Day 1) and Days 7 and 42.

**RESULTS:** The Sinus Pain and Fullness domain score was significantly reduced by F from 28.3±2.8 (SEM) on D1 to 7.7±1.6 on D7 ($p=0.001$, paired Student's t-test) compared to 25.1±2.2 to 15.9±3.4 with V. Nose, Pharynx, Chest and Bother domains improved in parallel for F and V. Total Symptom Score dropped from 60.9±7.5 to 24.3±4.8 on D7 with F ($p=0.003$) compared to 60.3±6.3 to 37.7±6.9 with V ($p=0.02$).

**CONCLUSIONS:** The Sinusitis Questionnaire was responsive to usual treatment of acute sinusitis, and may be a valuable tool for future clinical and research studies. The addition of a nasal steroid spray significantly improved Sinus Pain and Fullness in the 1st week of acute sinusitis.

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