**ANAPHYLAXIS**

**RISK OF ANAPHYLAXIS AFTER VACCINATION OF CHILDREN AND ADOLESCENTS**


**Purpose of the Study.** Anaphylaxis is a risk of vaccination. This study retrospectively quantified the risk in a population of pediatric patients.

**Study Population.** Children and adolescents enrolled in 4 West Coast health maintenance organizations that participated in the Vaccine Safety Data Link Project between 1991 and 1997 were studied.

**Methods.** A total of 7,644,049 vaccine doses were administered to 2,226,907 children between the ages of 0 and 17 years at 3 sites and between 0 and 6 years at a fourth site. Potential cases of anaphylaxis were identified by using International Classification of Diseases, 9th revision, codes suggesting anaphylaxis. A total of 657 cases were reviewed, of 664 cases of interest. Missing chart information excluded 7 cases. Criteria including organ systems involved in reactions, timing of reactions after vaccination, and treatments were reviewed, to identify possible or probable cases of anaphylaxis. Two analyses were performed. One included all sites, and 1 included a single site for which more detailed data on outpatient diagnoses were available.

**Results.** Six possible cases of anaphylaxis were identified. After a more detailed chart review, 2 cases were considered unlikely to be anaphylaxis, 1 case was unlikely to be secondary to vaccination, and 1 case of anaphylaxis predated and was not attributable to vaccination. The final risk of anaphylaxis was calculated as 0.26 case per 1,000,000 doses (2 cases per 7,644,049 doses). At the single site with more complete data on outpatient diagnoses, a risk of 1.53 cases per 1,000,000 cases was calculated. Rates for individual vaccines ranged from 0 to 14.4 cases per 1,000,000 doses. Most reactions were seen with diphtheria-and tetanus-containing vaccines, hepatitis B vaccine, measles-mumps-rubella vaccine, and oral polio vaccine. These vaccines were also more commonly administered. No reactions were seen with diphtheria-tetanus-acellular pertussis vaccine, influenza vaccine, inactivated polio vaccine, adult diphtheria-tetanus vaccine, hepatitis A vaccine, or varicella vaccine. However, these vaccines were less commonly administered. No deaths resulted from the anaphylactic episodes. No association was made with atopic status.

**Conclusions.** The frequency of vaccine-associated anaphylaxis is very low. Nonetheless, providers should be prepared to provide immediate treatment should it occur.

**Reviewer’s Comments.** Vaccination remains one of the most effective preventative treatments provided for children. Some advocates for better access to vaccination lobby for administration of vaccines at locations where acute health care is absent (eg, pharmacies). Although the risk of anaphylaxis is extremely low, it is not negligible. Providers of vaccines must be prepared to provide immediate treatment if anaphylaxis should occur, and society must determine when the need for vaccine access outweighs this risk.

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**ANAPHYLAXIS: RISK FACTORS FOR RECURRENCE**

Mullins RJ. *Clin Exp Allergy.* 2003;33:1033–1040

**Purpose of the Study.** To determine the incidence of anaphylaxis and risk factors for recurrence.

**Study Population.** Four hundred thirty-two patients with anaphylaxis who were referred to a community-based specialist practice in the Australian Capital Territory were studied. Twenty-seven percent were of school age (5–18 years of age).

**Methods.** Patients referred to an allergist for evaluation of anaphylaxis were enrolled during a 5.5-year period and evaluated prospectively. Medical record review, patient questionnaires, allergy skin testing, and challenge testing (for a small subset of patients) were used.

**Results.** Of 432 patients (48% male, 73% atopic; mean age: 27.4 years; SD: 19.5 years; median: 26 years) with anaphylaxis, 260 patients were examined after the first episode; 172 experienced 584 previous reactions. Fifty-four percent of index episodes were treated in a hospital. Causes were identified for 91.6% patients, ie, food (61%), stinging insects (20.4%), or medication (8.3%). The minimal occurrence and incidence of new cases of anaphylaxis were estimated as 12.6 and 9.9 episodes/100,000 patient-years, respectively. Follow-up data were obtained for 304 patients (674 patient-years). One hundred thirty experienced additional symptoms (45 serious), 35 required hospitalization, and 19 were administered epinephrine. Accidental ingestion of peanuts or tree nuts caused the largest number of relapses, but the highest risk of recurrence was associated with sensitivity to wheat and/or exercise. Rates of overall and serious recurrence were 57 and 10 episodes/100 patient-years, respectively. Among patients prescribed epinephrine, three-fourths of the patients carried it, two-thirds of the doses were in date, and only one-half of the patients faced with serious symptoms administered epinephrine. Five patients developed new triggers for anaphylaxis.

**Conclusions.** In any 1 year, 1 of 12 patients who have suffered anaphylaxis will experience recurrence and 1 of 50 will require hospital treatment or will use epinephrine. Compliance with carrying and using epinephrine is poor. Patients occasionally develop new triggers.

**Reviewer’s Comments.** There are few studies on the incidence or recurrence of anaphylaxis, but the limited data suggest that the incidences of anaphylaxis and food allergy...
are increasing. In this study, allergic reactions to peanuts and tree nuts were the most common cause of anaphylaxis and the most common reason for recurrence, but other foods, such as eggs, fruits, vegetables, wheat, fish, and shellfish, were also common triggers. Compliance with the use of self-injectable epinephrine was only 50%. Because of the high risk of recurrence, each anaphylactic event should be reviewed and patients should be reeducated regarding trigger avoidance, recognition of symptoms, and use of epinephrine.

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LACK OF EFFECT OF FLUTICASONE PROPIONATE AQUEOUS NASAL SPRAY ON THE HYPOTHALAMIC-PITUITARY-ADRENAL AXIS IN 2- AND 3-YEAR-OLD PATIENTS


Purpose of the Study. To determine the effects of fluticasone propionate (FP) (200 μg daily) on the hypothalamic-pituitary-adrenal (HPA) axis among patients 2 to 3 years of age.

Study Population. Children 2 to 3 years of age who demonstrated positive skin test responses to ≥1 seasonal allergen and the presence of nasal symptoms for ≥1 hour daily on most days or the use of rhinitis medication on most days during the relevant allergen exposure season were studied.

Methods. Children were administered FP (200 μg daily) (N = 33) or vehicle placebo (N = 32) for 6 weeks. Twelve-hour urine samples were collected, for determination of urinary cortisol levels, at the end of the 6-week treatment and at baseline. Routine chemical analyses, hematologic assessments, and electrolyte measurements were also performed at screening and at the last treatment visit. The secondary safety measures included the incidence of clinically significant alterations in laboratory test results, in the case of adverse effects.

Results. There were no differences in urinary cortisol levels between the children who received FP and those who received placebo. The most common adverse events reported for either group were cough and fever. Vomiting was observed more frequently for the FP group (18% vs 3%), as was abdominal pain (12% vs 6%) and epistaxis (6% vs 0%). However, there were no statistically significant differences in any of these findings.

Conclusions. FP (200 μg/day) was equivalent to placebo with respect to its effects on HPA axis function, as determined by 12-hour urinary free cortisol levels, among 2- to 3-year-old children. FP was otherwise well tolerated by these 2- to 3-year-old children with allergic rhinitis.

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EFFICACY OF THE TOPICAL NASAL STEROID Budesonide ON IMPROVING SLEEPE AND DAYTIME SOMNOLENCE IN PATIENTS WITH PERENNIAL ALLERGIC RHINITIS


Purpose of the Study. To determine the efficacy of topical nasal corticosteroids in the improvement of sleep and daytime somnolence among patients with perennial allergic rhinitis (PAR).

Study Population. Twenty-two subjects (18–65 years of age) with positive skin test responses to perennial allergens but not seasonal allergens were enrolled in the study.

Methods. The study was a double-blind, placebo-controlled, crossover study that incorporated Balaam’s design. Patients were randomized to 1 of 4 treatment groups, ie, active-placebo, placebo-active, active-active, or placebo-placebo. Patients received 2 sprays of the active medication (budesonide, 128 μg/day) or placebo once daily for 4 weeks. After a 1-week washout period, patients crossed over to the second arm of the study, according to the randomization sequence. Patients completed daily diaries, commenting on nasal symptoms, sleep, daytime somnolence, quality of sleep, and medication response. At weeks 1, 4, 5, and 8, patients completed subjective questionnaires during clinic visits, to assess quality of life, somnolence, and fatigue.

Results. Analyses of data obtained from the daily diaries showed that patients receiving active medication demonstrated significant improvements in daytime fatigue, somnolence, sleep problems, and quality of life, compared with those receiving placebo. There was no significant difference in nasal congestion or other symptoms of rhinitis between the treatment groups. Patients receiving active medication were significantly less likely to fall asleep during normal daily activities, but there was no difference in the numbers of hours of sleep or nighttime arousals. Those in the active group also had significantly more restorative sleep and reported feeling more refreshed, compared with those receiving placebo.

Conclusions. Patients with PAR who were receiving the topical nasal corticosteroid budesonide demonstrated significant improvements in daytime somnolence, fatigue, and sleep problems.

Reviewers’ Comments. Patients with allergic rhinitis frequently complain of nocturnal symptoms, such as nasal congestion and rhinorhea, that interfere with sleep, and previous studies showed that patients with allergic rhinitis have significantly more difficulty with daytime somnolence and sleep problems. This study offers encouraging data on the usefulness of topical applied nasal corticosteroids in improving sleep-related problems among patients with PAR and provides more evidence supporting the recommendation of topical applied nasal corticosteroids as the primary treatment for allergic rhinitis.

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THE EFFECTS OF INTRANASAL TRIAMCINOLONE ACETONIDE AND INTRANASAL FLUTICASONE PROPIONATE ON SHORT-TERM BONE GROWTH AND HYPOTHALAMIC-PITUITARY-ADRENAL AXIS IN CHILDREN WITH ALLERGIC RHINITIS


SUPPLEMENT 525
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Pediatrics 2004;114;524

The online version of this article, along with updated information and services, is located on the World Wide Web at:
/content/114/Supplement_1/524.2.full.html