Purpose of the Study. To compare the efficacy of inhaled corticosteroids with that of orally or intravenously administered corticosteroids in the treatment of acute moderate/severe asthma.

Study Population. The 135 subjects were 6 to 17 years of age, with at least 1 previous episode of wheezing, and were recruited from 1 of 2 emergency centers (ECs) after presentation with acute asthma symptoms.

Methods. Patients were randomized, after receiving an initial dose of albuterol, to 1 of 3 corticosteroid treatment groups if their Wood asthma scores were 4 or 5. All patients received their corticosteroid dose within 15 minutes after the initial albuterol dose. Group A received triamcinolone (600 μg, 100 μg/puff) via inhaler with a spacer, group B received orally administered prednisone (2 mg/kg), and group C received intravenously administered methylprednisolone (2 mg/kg). The decision to hospitalize was made by the EC attending physician, without input from investigators. After EC discharge, group A patients continued to receive triamcinolone (6 puffs 3 times daily for 1 day and then 4 puffs 3 times daily for 3 days); group B and C patients continued to receive orally administered prednisone (1 mg/kg twice daily for 4 days). Outcomes measured were the number of patients hospitalized from each treatment group and the number of unscheduled return visits 1 week after discharge from the EC.

Results. Seven percent of group A patients were hospitalized, compared with 22% and 29% of patients in groups B and C, respectively (P = .020). There were significantly more unscheduled return visits in groups B and C (41.5% combined), compared with group A (12%; P = .007). Hospitalizations or unscheduled return visits were considered treatment failures; rates were 19%, 62%, and 70% in groups A, B, and C, respectively (P = .001).

Conclusions. Patients who received inhaled triamcinolone were less likely to be hospitalized for treatment of acute asthma, compared with those who received orally or intravenously administered corticosteroids. Patients who received inhaled triamcinolone had significantly fewer unscheduled return visits 1 week after EC discharge, compared with patients in the oral or intravenous corticosteroid treatment groups.

Reviewers’ Comments. This was a small, prospective, clinical trial, suggesting that children with asthma could be effectively treated with inhaled corticosteroids in an acute care setting and might experience fewer treatment failures, compared with those who received orally or intravenously administered corticosteroids. One major limitation of the study was the lack of blinding. The attending EC physician might have been biased and more likely to discharge patients from the EC if they were in the inhaled corticosteroid group. Other limitations included the small number of patients and a poorly defined asthma diagnosis. A larger, prospective, double-blind study in a well-defined asthma population would strengthen these findings and might change acute asthma treatment.

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EFFECTS OF BUDESONIDE INHALATION SUSPENSION, COMPARED WITH CROMOLYN SODIUM NEBULIZER SOLUTION, ON HEALTH STATUS AND CAREGIVER QUALITY OF LIFE IN CHILDHOOD ASTHMA


Purpose of the Study. To compare the effects of 2 nebulized anti-inflammatory asthma medications on asthma control and caregiver quality of life.

Study Population. Children 2 to 6 years of age, with mild/moderate persistent asthma, were studied.

Methods. This was a 52-week randomized trial in which the children received either budesonide inhalation suspension (0.5 mg once or twice daily) (N = 168) or cromolyn sodium nebulizer solution (20 mg 4 times daily) (N = 167) initially for 8 weeks, after which the dosage was adjusted at the discretion of the investigator. The Pediatric Asthma Caregiver’s Quality of Life Questionnaire, Compliance/Caregiver Satisfaction Questionnaire, and Modified Child Health Questionnaire-Parent Form 50 and Functional Status-II(R) questionnaires were administered at baseline and at weeks 8, 28, and 52. At the conclusion of the
EARLY INTERVENTION WITH BUDESONIDE IN MILD PERSISTENT ASTHMA: A RANDOMIZED, DOUBLE-BLIND TRIAL


Purpose of the Study. To determine whether treatment with low-dose inhaled budesonide would prevent severe asthma-related events and accelerated lung function decline among patients with recent-onset, mild, persistent asthma.

Study Population. A group of 7241 patients, 5 to 66 years of age, with mild asthma symptoms for 3 months to 2 years, were recruited from 499 sites in 32 countries.

Methods. Patients were randomly allocated to receive 400 μg of budesonide (200 μg for patients <11 years of age) or placebo once daily. The primary outcome measure was time to the first severe asthma-related event (admission, emergency treatment, or death), analyzed with an intent-to-treat approach. Follow-up visits, with spirometry and adverse event monitoring, occurred at 6 and 12 weeks after randomization and then every 3 months for 3 years. Patients recorded asthma-related events between visits. Changes in medication regimens, including the addition of inhaled corticosteroids, were allowed if considered clinically necessary.

Results. Budesonide reduced the risk of severe asthma-related events by 44% (hazard ratio: 0.56; 95% confidence interval: 0.45–0.71; \( P < .0001 \)) and prolonged the time to the first asthma-related event. Budesonide-treated patients experienced significantly fewer severe asthma-related events, life-threatening exacerbations, days with symptoms, and courses of inhaled or systemic corticosteroids. The improvements in postbronchodilator forced expiratory volume in 1 second (FEV1) after 3 years were more marked among adults than among children (\( P = .004 \)), although the improvements in postbronchodilator FEV1 after 1 year and in prebronchodilator FEV1 were similar. Surprisingly, budesonide did not improve postbronchodilator FEV1 among adolescent patients. Children in the budesonide group exhibited slowed growth (mean height difference: –0.43 cm/year; 95% confidence interval: –0.54 to –0.32 cm/year; \( P < .0001 \)) to a lesser degree with each successive year.

Conclusions. Long-term, once-daily treatment with low-dose budesonide decreased the risk of severe exacerbations and improved asthma control among patients with mild persistent asthma of recent onset.

Reviewer’s Comments. Data on asthma-related events, symptoms, and medication use were not reported separately for the 2 pediatric age groups included in the study (5–10 years and 11–17 years). However, the morbidity associated with mild persistent asthma and the improvements in prebronchodilator FEV1 with budesonide treatment observed in this study suggest that children with mild persistent asthma may benefit from budesonide treatment early in the course of their disease. As always, the benefits of inhaled corticosteroids among children must be weighed against the potential side effect of mild growth delay.

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FLUTICASONE PROPIONATE IN ASTHMA: A LONG-TERM, DOSE-COMPARISON STUDY


Purpose of the Study. To compare the efficacy and tolerability of 2 doses of fluticasone propionate (FP), 100 μg and 200 μg, administered twice daily, among children with moderate/severe asthma. This was in effect a dose-response study of FP among children.

Study Population. A total of 528 children, 4 to 11 years of age, who had at least a 6-month history of asthma and required high doses of inhaled corticosteroids (ICSs) were eligible for the study. These children had received budesonide, beclomethasone dipropionate, triamcinolone acetonide, or flunisolide (800–1600 μg/day), FP (400–600 μg/day), or orally administered corticosteroids (≤5 mg/day)
EFFECTS OF BUDERONIDE INHALATION SUSPENSION, COMPARED WITH CROMOLYN SODIUM NEBULIZER SOLUTION, ON HEALTH STATUS AND CAREGIVER QUALITY OF LIFE IN CHILDHOOD ASTHMA

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