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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ORAL PREDNISOLONE IN THE ACUTE MANAGEMENT OF CHILDREN AGE 6 TO 35 MONTHS WITH VIRAL RESPIRATORY INFECTION-INDUCED LOWER AIRWAY DISEASE: A RANDOMIZED, PLACEBO-CONTROLLED TRIAL


Purpose of the Study. Systemic corticosteroid use for the treatment of acute wheezing among preschool-aged children is controversial, with a recent meta-analysis finding only marginal positive effects with orally administered corticosteroids among children <24 months of age. The objective of this study was to investigate the efficacy of oral prednisolone treatment of virally induced lower respiratory disease among young children.

Study Population. The clinical population included 230 children, 6 to 35 months of age, who presented with virally induced lower respiratory disease. Children with previous asthma or ≥2 wheezing episodes were excluded.

Methods. The study was a randomized, double-blind, placebo-controlled trial involving treatment with orally administered prednisolone (2 mg/kg per day) or placebo for 3 days. Measured outcomes included the effects of treatment on symptoms, hospital length of stay, and duration of illness.

Results. Hospitalization rates were similar for the 2 groups. However, for admitted children (n = 123), the median length of stay was 1 day shorter in the prednisolone group (2 days vs 3 days, P = .060). The proportions of children who required ≥3 days of hospitalization were 48% in the prednisolone group and 68% in the placebo group (P = .023). There was also a reduction in the need for additional asthma medication (18.0% vs 37.1%, P = .018) in the prednisolone group. The mean duration of symptoms of respiratory distress was 1 day in the prednisolone group, compared with 2 days in the placebo group, for both the hospitalized (P < .001) and nonhospitalized (P = .006) children.

Conclusions. A 3-day course of oral prednisolone therapy effectively reduced disease severity, length of hospital stay, and duration of symptoms among children, 6 to 35 months of age, with virally induced lower respiratory disease.

Reviewer’s Comments. This study is reassuring, indicating that the common practice of using orally administered corticosteroids in the treatment of infants and toddlers with lower respiratory infections seems to be effective, even among first-time wheezers.

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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 antiinflammatory 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
study, global evaluations of the simplicity of asthma management and child health care status were obtained from caregivers and physicians.

*Results.* Improvements from baseline values in domain-specific (activities and emotional function) and total quality of life scores were greater at each time point (weeks 8, 28, and 52) for caregivers of patients treated with budesonide, compared with caregivers of patients treated with cromolyn sodium. Only the budesonide group met the criterion for a clinically important improvement (≥0.5-unit change) in all quality of life domains by week 8, which was maintained at weeks 28 and 52. Budesonide resulted in greater caregiver satisfaction, treatment convenience, ease of use, and compliance, compared with cromolyn sodium. Therefore, 90.7% of caregivers in the budesonide group were completely or very satisfied, compared with 53.4% in the cromolyn sodium group. More than one-half (54.6%) of caregivers in the budesonide group rated budesonide highly or very convenient, compared with 23% for cromolyn sodium; 77% rated budesonide extremely or very easy to use, compared with 47% for cromolyn. Adherence with daily medication regimens was reported for 76% of children in the budesonide group, compared with 57% in the cromolyn sodium group. Child health status showed improvements from baseline values for both groups at weeks 8, 28, and 52. There was a trend for these improvements to be superior in the budesonide group. In addition, budesonide was superior to cromolyn sodium in caregiver and physician global assessments.

*Conclusions.* Budesonide inhalation suspension improved the quality of life for caregivers of children with asthma. Caregivers of children treated with budesonide reported significantly fewer limitations in daily activities and emotional functioning, compared with caregivers of children treated with cromolyn sodium nebulizer solution. Children treated with budesonide inhalation suspension and cromolyn sodium experienced improvements in health status. Treatment with budesonide inhalation suspension resulted in significantly lower mean rates of asthma exacerbations, significantly longer times to first asthma exacerbation, significantly longer times to first additional use of chronic asthma therapy, and significant improvements in asthma symptom scores and breakthrough medication use, compared with cromolyn sodium therapy. Safety profiles were similar for the 2 treatment groups. Budesonide inhalation suspension was associated with significantly greater caregiver satisfaction, convenience, ease of use, and compliance, compared with cromolyn sodium nebulizer solution.

*Reviewer’s Comments.* This was a nice study but the results are certainly not surprising. How many of us would have predicted that cromolyn would prove superior to an inhaled corticosteroid?

**Christopher Randolph, MD**
Waterbury, CT

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**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.

*Reviewers’ 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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**Robert A. Wood, MD**
Baltimore, MD

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

Christopher Randolph

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Christopher Randolph
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