

all parameters except wheezing were significantly improved in the salmeterol group vs the montelukast group. Subjects in the salmeterol group used significantly less rescue albuterol than the montelukast group. Regarding patient satisfaction with the drug, the salmeterol group had greater satisfaction other than in how long the medication worked, where there was no difference in scores. The number of asthma exacerbations and the number of adverse events was similar in both groups, with 13 in each group withdrawing from the study because of adverse events.

**Conclusion.** The addition of salmeterol in moderate to severe persistent adult asthmatics poorly controlled on ICS was superior to the addition of montelukast in improvement in PEF and overall symptom control.

**Reviewer's Comments.** The addition of inhaled salmeterol in subjects who were not adequately controlled on ICS showed significantly greater improvement in lung function and control of symptoms (other than wheezing) compared with oral montelukast. Other groups have compared salmeterol as an additive agent versus doubling the ICS dose and versus another leukotriene modifier, but not all in that study were on baseline ICS. Future studies are needed to determine if these findings will hold true over longer study periods and whether either long-acting  $\beta$ -agonists or leukotriene modifiers have a bearing on the natural history of asthma. In addition, similar studies in children are needed to see if the same patterns of response occur in all age groups.

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## STEROID THERAPY

### COMPARISON OF THE COST-EFFECTIVENESS OF BUDESONIDE AND SODIUM CROMOGLYCATO IN THE MANAGEMENT OF CHILDHOOD ASTHMA IN EVERYDAY CLINICAL PRACTICE

Andersson F, Kjellman M, Forsberg G, Moller C, Arheden L. *Ann Allergy Asthma Immunol.* 2001;86:537-544

**Purpose of the Study.** Both inhaled glucocorticosteroids and sodium cromoglycate are recommended as first-line maintenance drugs for the control of persistent asthma. The objective of this study was to compare the cost-effectiveness of these 2 treatment strategies in everyday clinical practice.

**Study Population.** Children, 5 to 11 years old, with mild to moderate persistent asthma not previously treated with inhaled steroids or cromones.

**Methods.** The children were recruited from 10 secondary care centers in Sweden. The study was performed as a randomized, parallel-group, open-label pharmacoeconomic clinical trial. After the asthma was first stabilized using 4 to 6 weeks of inhaled budesonide, the children received either budesonide 200 to 400  $\mu$ g twice daily ( $N = 69$ ) or sodium cromoglycate 20 mg 3 times a day ( $N = 69$ ) as maintenance therapy for 12 months. To better simulate normal clinical practice, investigators were instructed to maintain asthma control with normal procedures, including the ability to switch patients from one study treatment to the other, use additional therapy when required, or alter dosages as needed. Direct health care consumption costs and indirect costs attributable to loss of productivity by the family were recorded along with lung function and asthma symptoms.

**Results.** Twenty-nine children (42%) in the cromoglycate arm were switched to budesonide, with 24 (35%)

attributable to lack of effect. Despite this, budesonide treatment resulted in a 24% lower annual cost than in those treated with cromoglycate. This trend was not statistically significant. Most of the reduction reflected the direct cost of medication with cromoglycate more than double the daily cost of budesonide. No statistically significant differences were noted in peak flow rate, symptoms, albuterol use or exacerbation rates, although budesonide was superior in almost all categories. However, there was a significant 14% increase in the number of symptom-free days after the change to budesonide from cromoglycate.

**Conclusion.** The study demonstrates that budesonide resulted in lower costs and less drug switches than a maintenance treatment strategy using sodium cromoglycate.

**Reviewer's Comments.** This important long-term study suggests that an inhaled corticosteroid in asthmatic children not only results in lower costs than cromoglycate, but is more effective over a 12-month period. This is supported by the striking findings of the large number (35%) of children who had to switch from cromoglycate to budesonide because of inadequate control. The lack of statistical significance of several of the clinical and economic parameters may be a reflection of the rather small numbers compared and the fact that those remaining in the cromoglycate group were less severe.

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### EFFECTIVE ONCE-DAILY ADMINISTRATION OF BUDESONIDE INHALATION SUSPENSION BY NEBULIZER WITH FACEMASKS OR MOUTHPIECES FOR PERSISTENT ASTHMA IN INFANTS AND YOUNG CHILDREN

Georgitis JW, McWilliams B, Cruz-Rivera M, Fitzpatrick S, Smith JA. *Pediatr Asthma Allergy Immunol.* 2001;15:3-13

**Purpose of the Study.** A retrospective analysis comparing the efficacy and safety of nebulized budesonide inhalation suspension (Pulmicort Respules, AstraZeneca, Lund, Sweden) administered once daily by facemask or mouthpiece for mild persistent asthma.

**Study Population.** A total of 359 children aged 6 months to 8 years with mild, persistent asthma.

**Methods.** Children were randomized to receive 0.25, 0.5, or 1.0 mg budesonide inhalation suspension once daily or placebo for 12 weeks via facemask or mouthpiece. Efficacy variables included nighttime and daytime asthma symptom scores, use of breakthrough bronchodilator medications, and pulmonary function tests (in children capable of consistently performing spirometry or peak flows).

**Results.** Changes in nighttime and daytime asthma symptom scores were not significantly different between children using facemasks and those using mouthpieces. Use of breakthrough medications and pulmonary function test results (in the subset of children able to perform them) also were not significantly different in facemask users and mouthpiece users.

**Conclusions.** These results suggest that budesonide inhalation suspension is equally effective whether administered by facemask or mouthpiece and that young children who require the use of a facemask may be successfully treated.

**Reviewer's Comments.** The efficacy and safety of once-daily budesonide inhalation suspension in this age group was previously reported in a multicenter, randomized,

## Comparison of the Cost-Effectiveness of Budesonide and Sodium Cromoglycate in the Management of Childhood Asthma in Everyday Clinical Practice

Otto Liao and Stanley Galant

*Pediatrics* 2002;110:460

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