

COMMENTARY

Aerosol Beclomethasone Dipropionate Compared With Theophylline as Primary Treatment of Chronic, Mild to Moderately Severe Asthma in Children, by David G. Tinkelman, MD, et al, Pediatrics, 1993;92:64–77

Comments by Clifton T. Furukawa, MD

ABSTRACT OF ORIGINAL ARTICLE. *Objective.* To compare the benefits and adverse reactions of theophylline and beclomethasone (BDP) in the long-term control of mild to moderate chronic asthma in children.

Design. Multicentered, double-blind, double-placebo, randomized, controlled trial.

Patients. One hundred ninety-five children between the ages of 6 and 16 years with mild to moderate asthma.

Intervention. Treatment with either BDP, 84 μg four times a day, or sustained-release theophylline administered twice daily I doses adjusted for optimum control of symptoms.

Main Outcome Measures. Daily diary record of symptoms, peak flow rates, supplemental bronchodilator and glucocorticoid treatment, doctor and hospital visits, absence from work and school, and side effects.

Results. Aerosol BDP and sustained-release theophylline were effective primary treatments for mild to moderate chronic asthma. BDP resulted in comparable symptom control with less bronchodilator use and fewer courses of systemic steroids than did theophylline. Side effects were observed significantly more frequently with theophylline than with BDP. Growth velocity suppression was noted with BDP and was more pronounced in boys. Suppression was not associated with alterations in cortisol measurements either at baseline or following stimulation.

Conclusions. Both theophylline and BDP are effective therapy for mild to moderate asthma. Caution must be used with the administration of BDP in children because of possible growth velocity suppression.

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This study contributes two important points for clinicians.¹ Theophylline dosage designed to achieve a blood level of 8 to 15 $\mu\text{g}/\text{mL}$ 12 hours after ingestion and inhaled beclomethasone (BDP) at a dose of two puffs (42 μg per puff) four times per day were both effective therapies, but BDP was more effective because it required less use of a supplemental bronchodilator and less use of systemic corticosteroids, yet provided earlier symptom improvement.² Side effects such as headache, tremor, nausea, and vomiting were noted significantly more often among children taking theophylline. However, although BDP did not alter the cortisol peak response to cosyntropin, it did decrease growth velocity. Thus, both medications were associated with potentially undesirable side effects.

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Address correspondence to: Clifton T. Furukawa, MD, Northwest Asthma and Allergy Center, 4540 Sand Point Way NE, #200, Seattle, WA 98105. PEDIATRICS (ISSN 0031 4005). Copyright © 1998 by the American Academy of Pediatrics.

This report is pivotal because it represents the formal change in tactics for the pharmacologic therapy of children with asthma. Side effects from theophylline again are reconfirmed, and with therapy focused more on inflammation and less on bronchodilation, concerns are raised about the risks and benefits of inhaled steroid use. These concerns about side effects and long-term harmful effects are very different for children than for adults. This article emphasizes the importance of evaluating effects on growth and being aware of potential long-term sequelae. Because the study is relatively long term (1 year), with a large number of subjects (195), and is conducted by an objective allergy specialty society, the information has impact on present and future standards of care. Also, the rationale for a "step-care" or "step-up" then "step-down" approach¹ to pharmacologic therapy is provided by the data showing potential side effects with both forms of therapy.

With "steroid phobia" so common with the American public, and with potential and subtle side effects of pharmacologic therapy, this study addresses concerns about children and the use of inhaled steroids directly. Clearly, treatment protocols must take risk/benefit ratios into consideration, and more so in children. In addition to obvious steroidal side effects, growth must be monitored.

Although not stated in the paper, it is implied that there really is no absolutely safe pharmacologic approach. This article, without saying so, infers the importance of prevention, environmental control measures,² etc, because drug side effects are not a concern with these ways of treating children with asthma. It is fitting that a recent publication evaluating risk of hospitalization and emergency room visits found that written asthma-management plans and washing bed sheets in hot water at least twice a month were of significant benefit.³ These measures should not be ignored, because they may allow use of lower and potentially safer doses of pharmacologic agents.

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