for at least 4 weeks before enrollment. Participants in the study were also required to have experienced at least 1 exacerbation of asthma that required oral/parenteral corticosteroid treatment or hospitalization in the previous 12 months. The children were not receiving any long-acting β-receptor agonists.

Methods. This was a multicenter, double-blind, parallel-group study that involved 39 sites, all in Europe. After a 2-week run-in period, patients were randomized to receive either 100 µg or 200 µg of FP twice daily, delivered with a Diskus inhaler (GlaxoSmithKline, Research Triangle Park, NC). Clinic visits occurred at regular intervals, and daily symptom scores were maintained. Peak flow measures were recorded twice daily. The frequency of rescue medication use was noted. The primary outcome measure was the time to the first asthma exacerbation. Exacerbations were defined as a 20% decline in peak flow for 2 consecutive days, increased use of quick reliever medications (more than twice daily for 2 consecutive days), or the use of systemic corticosteroids.

Results. Demographic characteristics were well matched between the 2 treatment groups. The median dose of ICS at baseline for both groups was 800 µg/day (range: 200–1600 µg/day). A subgroup of children experienced severe asthma (defined as ICS usage of >800 µg/day) in each arm of the study and were studied separately. The risk ratio for an asthma exacerbation with 200 µg FP versus 100 µg FP was 0.85. The risk of experiencing an exacerbation at any time was reduced by 15% for patients receiving the higher dose (200 µg) of FP. This was not statistically significant. In the subgroup analysis, there was a much larger, significant, 33% reduction in the risk of experiencing an exacerbation at any time during the study. Secondary outcomes included improved peak flow measures in the 200 µg FP group. In both groups, symptoms were controlled and few side effects were experienced.

Conclusion. The use of FP at 200 µg twice daily may offer benefits, compared with a lower dose, especially among children with more severe asthma.

Reviewer’s Comments. ICSs, alone and in combination with other agents, are the preferred treatment for all forms of persistent asthma. Increasing the dose of the ICS is frequently performed to help provide control. However, dose-response studies of ICS use among adults have yielded conflicting results, and there have been very few such studies among children. The lack of a clear dose-response relationship may lead to reluctance in optimizing the dose to increase control. This study provides insight into a dose-response relationship for the ICS FP. A difficulty with this study and many like it involves the initial mixtures of ICSs and the reporting of the doses used at baseline. It is also important to note that the modality of drug delivery was the Diskus inhaler, which is not used as frequently as metered dose inhalers. ICS usage, especially among children, has been hampered by a paucity of data providing dose-response information. One dose for all forms of persistent asthma is clearly not the way to treat children. Children with moderate asthma do not benefit from higher doses, but those with more significant disease require higher doses to achieve control.

Frederick E. Leckly, MD
Indianapolis, IN

SURVEY OF ADRENAL CRISIS ASSOCIATED WITH INHALED CORTICOSTEROIDS IN THE UNITED KINGDOM


VASCULAR COMPONENT OF AIRWAY REMODELING IN ASTHMA IS REDUCED BY HIGH DOSE OF FLUTICASONE


Purpose of the Study. To assess the effect of short-term treatment with high-dose (500 µg, twice daily) and low-dose (100 µg, twice daily) inhaled fluticasone propionate
SURVEY OF ADRENAL CRISIS ASSOCIATED WITH INHALED CORTICOSTEROIDS IN THE UNITED KINGDOM
John M. Kelso
Pediatrics 2004;114;546

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