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Efficacy and safety of Azmacort MDI and Flovent Diskhaler

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To the Editor:

Condemi et al. (J Allergy Clin Immunol 1997;100:467-74) present data that suggest that fluticasone propionate (FP) powder administered twice daily (500 µg/day) was superior in efficacy to triamcinolone acetonide (TAA) aerosol administered four times daily (800 µg/day) in patients with persistent asthma. There are several methodologic aspects of the study that suggest that this conclusion may be invalid.

This study compared Flovent Rotadisk twice daily with Azmacort MDI four times daily. Azmacort is currently labeled for twice daily dosing. Patient compliance with a four times daily dosing regimen is often not optimal, and lack of compliance would compromise the efficacy outcome of the study. Compliance data were presented only for Rotadisk placebo blisters during the screening period. Compliance data should be presented for both treatment groups for the entire study as well. It would also be of interest to ascertain whether subset analyses of compliant and noncompliant patients would yield different efficacy outcomes.

There is a statistically significant difference in morning peak expiratory flow (PEF) between the TAA and placebo treatment groups after 2 weeks of treatment, which then begins to

diminish. The dropout rate of 73% in the placebo treatment group is unusually high. If only an intent-to-treat analysis is presented, then this is an important methodologic aspect of the study not addressed by the authors. One wonders what the data would reveal if a protocol analysis or, for patients who dropped out of the study, a carry-forward analysis for the last morning PEF data point obtained were performed, with the data displayed graphically.

The authors report mean FEV₁ and morning PEF values from baseline to endpoint that were significantly greater in patients receiving FP compared with those receiving TAA. However, no statistically significant differences were noted for overall patient symptom scores, symptom-free days, or night awakenings. This raises the question of the clinical significance of the statistically significant differences in these efficacy parameters.

Treatment with FP resulted in an 8% incidence of oropharyngeal candidiasis compared with an incidence of 3% in the TAA treatment group. It is unclear from Table III whether multiple adverse events occurred in any one patient. If they did not, then for adverse events (e.g., sore throat, oropharyngeal candidiasis, and hoarseness), treatment with FP resulted in a 14% incidence compared with an incidence of 4% in the TAA treatment group. The choice of medication for the treatment of asthma depends on both efficacy and safety because there may be differences in adverse events among the various corticosteroids.

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