

DallasAllergyImmunology

Advair/Serevent Questions

There have been reports in the news media of increased risks of asthma deaths in patients receiving Serevent. Because Advair contains Serevent, Advair is included in the media reports. These reports are based on information from the SMART Study, a safety study of Serevent that was active from 1996 to 2000. We participated in the SMART study and are very familiar with those results. We are also familiar with the FDA position and expert commentaries. In the SMART Study, patients receive their usual asthma medications and either Serevent or placebo (non-active inhaler). Patient monitoring in this study was limited. An interim analysis of the study data on 25,858 patients showed the following:

- Among Caucasian patients (71% of the group) there were no differences in the Serevent and placebo groups.
- Among the African American patients (17% of the group) there was a slight, but significant, increase in asthma related events in the Serevent group compared to the placebo group.
- The African American patients in this study were less likely to be using inhaled steroids than the Caucasian patients. Only about 1/3 of these patients were using inhaled steroids despite the fact that the African American patients had more severe asthma than the Caucasian patients.

Advair and Serevent have been studied and used for many years. There have been 24 million patient years experience with Serevent and more than 20 million patient years with Advair. We know a lot about these drugs.

- Advair and Serevent have been shown to be safe in many studies.
- Serevent is not a good choice as the only drug for persistent asthma. It works very well with inhaled steroids (Flovent, Beclovent, Azmacort and probably Pulmicort).
- Serevent improves outcomes for patients treated with inhaled steroids (2002 National Asthma Guideline revision) and allows the use of a lower dose of inhaled steroids. The excellent results when combining Serevent with an inhaled steroid led to the development of Advair.
- We are currently participating in a study of African-American asthma patients comparing Advair with Flovent (an inhaled steroid) alone.

Because of the outstanding benefits of Advair for patients with asthma and because the current information does not raise safety concerns about the combination of Serevent and inhaled steroid (such as in Advair), we continue to prescribe and recommend Advair for our patients.