Symbicort’s Dual Effect Controls, Relieves Asthma  

BY TIMOTHY F. KIRN  
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VAIL, Colo. — The new asthma drug Symbicort can be used by patients as both their controller medication and their relief medication, Dr. Carolyn M. Kerscmar said at a meeting sponsored by the American Academy of Pediatrics.

This is because one of the two components of the drug—formoterol—is a long-acting β₂-agonist with a rapid onset, said Dr. Kerscmar, di-rector of the children’s asthma center at Rainbow Babies & Children’s Hospital, Cleveland.

The new product—a combination of the corticosteroid budesonide and formoterol (in formulations of 80/4.5 mcg and 160/4.5 mcg per inhalation)—was approved for use in the United States in July.

A growing number of trials have shown that when asthma patients have used the combination, exacerbations dropped greatly—and by as much as 79% versus fixed-dose regimens in a recent pediatric study.

That study randomized 341 children (aged 4-11 years) with asthma into three treatment groups: maintenance treatment with Symbicort, plus as-needed use; treatment with a fixed formulation of budesonide/formoterol at the same dose, plus terbutaline as rescue medicine; or treatment with a fourfold higher maintenance dose of budesonide, plus terbutaline as rescue medicine (Chest 2006;130:1733-43).

The reduction in exacerbations is thought to result from the fact that, when patients feel an asthma attack coming on and use Symbicort as a β₂-agonist reliever medication, they also get the steroid delivered as well.

Formoterol has an onset of action of fewer than 15 minutes. The other combination product available in the United States—Advair—contains the long-acting β₂-agonist salmeterol, which does not act so rapidly, she said.

Formoterol “starts working just as fast as al-buteron,” said Dr. Kerscmar, who has no finan-cial links to Symbicort or its maker, AstraZeneca Pharmaceuticals LP.

“You’re not going to reach for your albuterol; you’re going to reach for this and take a puff in stead,” she added.

The Symbicort studies have shown that even with this type of use, patients do not get exposed to excessive doses of corticosteroid. Probably, they are achieving greater asthma control over the long term, and not using reliever medication as much.

In the pediatric study, only 6 of 118 (5%) pa-tients using Symbicort for control and rescue ever used it seven or more times a day at one time, compared with 23% in the fixed-dose regi-men and 13% on the fixed-dose budesonide; the average rescue use with Symbicort was 0.58 times per day, compared with 0.76 and 0.74 in the other two groups, respectively. The study re-ported that the yearly growth of the patients on the Symbicort was better than that of patients assigned to only budesonide.

“This decreases exacerbations in a very, very safe fashion,” she said.

Dr. Kerscmar said she intends to advise pa-tients to use Symbicort as a reliever the same way she would advise them to use albuterol. They should use it when they begin to feel an asthma attack, and wait 4 hours before using it again, and should contact a health care provider if they need to use it three times within 12 hours, she said. However, the initial Food and Drug Ad-ministration-approved labeling will reflect daily scheduled use as a controlled medication product.

Automatic Airway Pressure Devices Can Treat Simple Apnea  

BY JANE SALODOF  
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SCOTTSDALE, Ariz. — Automatic devices that adjust continuous positive airway pressure (CPAP) in response to changes in airway resistance or flow, as effective as conventional machines for the treatment of uncomplicated obstructive sleep apnea, Dr. Neil S. Freedman said at a meeting on sleep medicine sponsored by the American College of Chest Physicians.

AutoCPAP (APAP) will never be superior to fixed continuous positive airway pressure (CPAP) as a treatment, but it offers two advantages: faster treatment of apnea, and the potential for lower costs, according to Dr. Freedman, who is with a group prac-tice that specializes in sleep disorders in Rancho Bernardo, Ill., and the sleep center at Lake For-est (Ill.) Hospital.

Citing long waits for sleep studies, he said that he will put a patient on APAP pending a sleep study if the person weighs 300 pounds, snores, has had observed apnea, and is drowsy during the day. In such cases, he said, the sleep study must still be done within 30 days to secure reim-bursement and to determine pressures.

Although attended APAP in a sleep labora-tory is currently accept-ed as useful for titrating fixed CPAP pressures in uncomplicated patients, Dr. Freedman said that unattended APAP has not been established as useful for that purpose. Unattended APAP also is not established as a treatment for patients who have never used CPAP, but Dr. Freedman said this may no longer be valid.

He cited a randomized con-trolled trial in which 360 pa-tients were randomized to stan-dard CPAP, APAP titrated at home, or titration at home by a predicted formula (Am. J. Respir. Crit. Care Med. 2004;170:1218-24). Successful home titration of APAP went from 83% on the first try to 96% on the second try. All groups had equivalent improve-ments in quality of life, and nearly all patients wanted to continue the treatments to which they had been assigned.

Dr. Freedman listed various monkeys for the new technolo-gy—automated, auto-titrating, auto-adjusting, and self-titrating—but settled on APAP as a common term. The devices vary considerably in efficacy, he ad-vised, and their role in treating obstructive sleep apnea is not well defined.

“All APAPs are not the same,” he said, warning against general-izing conclusions from clinical studies of any one APAP tech-nology to APAP devices as a class.

He emphasized that the de-vices use different detection methods, employ different al-go rithms, and have different re-sponse times. Notably, whereas some monitor inspiratory flow, others measure resistance.

“They all respond in different ways,” he said. “Nobody knows what the best algorithm is.” One test he cited was a benchmark testing of five APAP machines (Eur. Respir. J. 2004;24:649-58). All five sup pressed obstructive apnea, but none suppressed flow limitation. The investigators reported con-siderable variation in residual hy-popnea, control of snoring, and response to mask leaks. Four of the machines inappropriately in creased pressure in response to central apnea.

Dr. Freedman suggested APAP machines that use a forced oscil-lation technique (FOT) may be better suited than flow-based APAP for evaluation of central apnea.

“You don’t want a machine to make central apnea worse,” he said.

APAP should not be used to treat patients who hyperventi-late, have heart failure or COPD/chronic lung disease, or do not snore, according to Dr. Freedman. All these conditions have been excluded from the studies performed so far.

He said the lack of data also makes APAP’s efficacy unclear for obstructive sleep apneas that are related to rapid eye move-ment, are position dependent, in-volve high pressures, or occur in patients who are intolerant of CPAP.