## In Bronchiolitis, Take the Evidence-Based Route

BY NANCY WALSH New York Bureau

NEW YORK — Optimal management of bronchiolitis involves rational use of adrenergic drugs and avoidance of unnecessary tests and treatments, Dr. Howard M. Corneli said at a meeting sponsored by the American College of Emergency Physicians.

We are spending over \$700 million annually in hospital charges for this condition, and there is a paucity of evidence as to what works for it. And what little evidence we do have, we don't put into practice,"Dr. Corneli said.

An example of this is the use of x-rays. There is no evidence supporting the routine practice of obtaining x-rays in bronchiolitis, and no experts have ever recommended it, he said. They add considerable cost and are associated with a significant delay in care. And because multiple infiltrates often are seen, patients can be misdiagnosed as having pneumonia, which leads to inappropriate, ineffective antibiotic use.

In a systematic review that evaluated chest film data from 17 trials, abnormalities were seen on 20%-96% of films, yet there was no evidence that the x-rays helped differentiate bacterial from viral disease (Arch. Pediatr. Adolesc. Med. 2004:158:119-26).

Emergency department treatment of bronchiolitis is not systematic. In a study of 601 inpatients from 10 U.S. children's centers, 92% were given bronchodilators (Pediatrics 2001;108:851-5). Nebulized albuterol eases symptoms for some patients, but the response must be evaluated objectively and treatment continued only if benefits are seen—which is often not the case.

"In a study [at my institution] of 68 patients who received albuterol in the ED, 52% had no documented effect, yet 94% had written orders on admission to continue the drug," said Dr. Corneli, professor of pediatrics, University of Utah, and ED medical director for transport at Primary Children's Medical Center, both in Salt Lake City.

It's also important to keep in mind that the effects of albuterol are only temporary, and there is no evidence that treatment changes the course of disease. Moreover, it can actually worsen symptoms in 20%-30% of patients, he said.

Racemic epinephrine has more potent effects on airway edema than does albuterol, and studies have found that just one treatment is needed and fewer patients worsen when treated with it. But it is potentially toxic, and there are case reports of babies having myocardial infarctions after repeated epinephrine inhalations, he said.

The rational use of epinephrine, therefore, involves a one-time trial in patients with moderate to severe bronchiolitis, an avoidance of repeated doses, and observation for at least 60 minutes. It can be used as rescue therapy for patients who worsen with albuterol, he noted.

Systemic corticosteroids also have been widely used, and it makes sense that their anti-inflammatory properties would be beneficial, he said. Many of the small early studies were negative, but firm conclusions could not be drawn because inconsistent disease definitions and outcomes were used.

However, in a small but well-conducted trial, 70 patients with moderate to severe disease were randomized to 1 mg/kg oral dexamethasone or placebo, Dr. Corneli said. At 4 hours, respiratory assessment change scores improved more in the steroid group, and admission rates were much lower, at 19%, compared with 44% in placebo patients (J. Pediatr. 2002;140:27-32).

Experts thought that this single-center trial's data could not yet be considered conclusive, so in a trial under the auspices of the Pediatric Emergency Care Applied Research Network, some 600 patients were enrolled over 3 years in 20 centers, and the effects of corticosteroids were analyzed. "The data remain under publication embargo, but in general we found insignificant differences in respiratory assessment change scores, later outcomes, or risk for admission with the use of steroids," Dr. Corneli said.

Emerging evidence suggests that corticosteroids may not help in alleviating the airway inflammation associated with bronchiolitis because corticosteroid therapy may actually increase replication of the respiratory syncytial virus. There also is evidence that inflammation may be beneficial in slowing the spread of the virus out of the nasopharynx down into the bronchi and bronchioles, Dr. Corneli said.

Simple measures, such as suction, stimulation, and positioning of the child, along with the use of mist and fluids, can also help in the ED management of bronchiolitis.



## **Important Safety Information**

- AMITIZA is indicated for the treatment of chronic idiopathic constipation in the adult population.
- . AMITIZA should not be used in patients with a known hypersensitivity to any components of the formulation and in patients with a history of mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be evaluated prior to initiating AMITIZA treatment.
- The safety of AMITIZA in pregnancy has not been evaluated in humans. In guinea pigs, lubiprostone has been shown to have the potential to cause fetal loss. AMITIZA should be used during pregnancy only if the benefit justifies the potential risk to the fetus. Women who could become pregnant should have a negative pregnancy test prior to beginning therapy with AMITIZA and should be capable of complying with effective contraceptive measures.
- AMITIZA should not be administered to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment. If the diarrhea becomes severe, patients should consult their health professional.

Printed in U.S.A.

• In clinical trials, the most common adverse event was nausea (31%). Other adverse events (≥5% of patients) included diarrhea (13%), headache (13%), abdominal distention (7%), abdominal pain (7%), flatulence (6%), sinusitis (5%) and vomiting (5%).

Relief is defined as ≥3 spontaneous bowel movements (SBMs) per week.

Please see Brief Summary of Prescribing Information on adjacent page.

\*57%-63% of patients had a first SBM within 24 hours.

†In 4-week clinical trials. ‡Demonstrated in 6-month and 12-month safety studies.

Reference: 1. AMITIZA [package insert]. Bethesda, Md: Sucampo Pharmaceuticals, Inc.; 2006. AMITIZA is a registered trademark of Sucampo Pharmaceuticals, Inc.

© 2007 Takeda Pharmaceuticals North America, Inc. LUB-00789



www.amitiza.com