Drug Combo Bests Monotherapy for Esophagitis

VITALS

Major Finding: Treatment with oral viscous budesonide plus a proton pump inhibitor led to a significant decrease in the mean peak esophageal eosinophil count, from 66.6 eosinophils/high-powered field pretreatment to 4.8 after 3 months of the daily therapy.

Data Source: A study published in the August issue of the journal Gastroenterology.

Disclosures: In addition to receiving funding from the maker of OVB, Dr. Dohil and two other researchers disclosed having a financial interest in the successful development and marketing of OVB. They also disclosed that the University of California, San Diego, where the investigators are employed, has a financial interest in Meritage Pharma Inc.

BY DENISE NAPOLI

FROM GASTROENTEROLOGY

Oral viscous budesonide in combination with lansoprazole was significantly more effective for pediatric eosinophilic esophagitis than was the proton pump inhibitor alone, said Dr. Ranjan Dohil and his colleagues in Gastroenterology.

Although patients with negative allergy testing appeared to respond better, "patients testing positive do also respond and should also be considered for OVB [oral viscous budesonide] therapy," the authors concluded, based on their randomized, double-blind, placebo-controlled trial (Gastroenterology 2010 [doi: 10.1053/j.gastro.2010.05.001]).

According to Dr. Dohil of the University of California, San Diego, Medical Center, the symptoms of eosinophilic esophagitis (EoE) are similar to those seen in gastroesophageal reflux disease but the condition is "often refractory to acid-suppression therapy," and therefore "the optimal therapy for EoE is unclear."

The current phase II study, sponsored by Meritage Pharma Inc., the maker of OVB, is the first placebo-controlled study to evaluate the drug, which is a viscous liquid consisting of budesonide nebulizer suspension (Pulmicort respules) mixed with sucralose (Splenda).

Eosinophilic esophagitis symptoms are similar to those in GERD but may be refractory to acid-suppression therapy, so the optimal therapy is unclear.

Dr. Dohil and colleagues studied 31 children diagnosed with EoE between February 2008 and July 2009; a total of 24 completed the study and were included in the analysis. All had esophageal eosinophil counts greater than or equal to 20 eosinophils per high-powered field (eos/hpf) except one patient, who had "panesophageal furrowing and exudates on endoscopy but a peak eosinophil count of 15"; this patient was also enrolled. In all, 20 patients were male, and the mean age was 7.8 years (range, 11-17 years).

Of the total 24 children, 15 received OVB and PPI and 9 received placebo and PPI. In the treatment group, the mean peak eosinophil count prior to OVB/PPI therapy was 66.6 eos/hpf. After 3 months of therapy, it had decreased significantly to 4.8 eos/hpf ($P = .0001$), with only one patient classified as a complete nonresponder. (The eosinophil count went from 67 to 47 eos/hpf in that patient.)

Moreover, the results were seen throughout the esophagus. Indeed, "87% of OVB post-treatment patients [had] less than or equal to 6 eos/hpf in the distal esophageal biopsies and 100% [had] less than or equal to 6 eos/hpf in proximal esophageal biopsies," wrote the authors. In contrast, among patients treated with placebo plus the PPI, the mean eosinophil count went from 83.9 to 65.6 eos/hpf, and all patients were classified as nonresponders except for one partial responder, whose counts fell from 75 to 7.

The authors said the study's duration of 3 months did not allow for long-term follow-up, but that its data "support the need for a proprietary OVB medication specifically for the treatment of EoE." ■