



Table 1. Detection of Dysplasia With HDCE vs HDWLE

| | HDWLE (n = 53) | HDCE (n = 50) | P Value |
|---|-------------------|------------------|------------------|
| Patients with dysplasia, n (%) | 5 (9.4) | 11 (22) | .04 ^a |
| Total no. of dysplastic lesions detected on targeted biopsy | 6 ^b | 14 ^c | |
| No. of dysplastic lesions, mean ± SD | 0.12 ± 0.4 | 0.26 ± 0.6 | .04 ^d |
| Right-sided dysplasia | 2 of 6 | 5 of 14 | |
| Withdrawal time, min, mean ± SD | 13.6 ± 3.3 | 21.2 ± 5.8 | < .001 |

HDCE, high-definition chromoendoscopy; HDWLE, high-definition white light endoscopy.

^aIncremental yield of HDCE.

^bAll low grade.

^c1 high grade, 13 low grade.

^dDifferences in means.

The increase in time for HDCE may be a result of the study’s mandate to collect random biopsies. Since all of the dysplastic lesions detected arose from targeted biopsies rather than random biopsies, Dr Subramanian suggested that random biopsies could be omitted in practice.

HDCE significantly improves the detection of dysplastic lesions in patients with long-standing extensive UC who are undergoing surveillance endoscopy. This method could become the procedure of choice for these patients and has been recommended in recent guidelines [Shergill AK et al. *Gastrointest Endosc.* 2015]. One limitation of the study was its single-center design in a small number of patients. To confirm these results, a study enrolling about 1600 participants across the United Kingdom is being initiated.

Budesonide Shows Validated Promise in Patients With Eosinophilic Esophagitis

Written by Jaye Summers

Eosinophilic esophagitis (EoE) is a condition defined by symptoms of dysphagia or esophageal dysfunction, and an eosinophilic infiltrate that persists even after a trial of proton pump inhibitors. Evan Dellon, MD, MPH, University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA, reviewed data from a clinical trial [NCT01642212] comparing oral budesonide (OBS) with placebo in adolescents and adults with EoE.

Typical first-line medications for EoE include swallowed topical corticosteroids such as fluticasone or budesonide. Although observational data and randomized clinical trials support the use of these agents [Dellon ES, Liacouras CA. *Gastroenterology.* 2014; Liacouras CA et al. *J Allergy Clin Immunol.* 2011], neither is FDA approved

for the indication of EoE. In addition, neither of these drugs has been assessed in patients using a validated measure of patient-reported outcomes.

This randomized, double-blind, multicenter placebo-controlled trial was designed to determine whether OBS was superior to placebo in generating both a histologic and a symptomatic response. Histologic response was measured by a finding of ≤6 eosinophils/high-power field (HPF); symptom response was measured using the Dysphagia Symptom Questionnaire (DSQ) over the 16-week course of therapy. The DSQ is a daily diary that asks 3 questions relative to a patient’s symptoms and has been validated for dysphagia frequency and severity in patients with EoE [Dellon ES et al. *Aliment Pharmacol Ther.* 2013]. The histology assessment was based on biopsies obtained from the proximal, mid, and distal esophagus. All patients had a confirmed diagnosis of EoE per the 2011 updated consensus guidelines [Liacouras CA et al. *J Allergy Clin Immunol.* 2011].

Inclusion criteria included patients aged 11 to 40 years with a confirmed diagnosis of EoE, biopsy findings of ≥15 eosinophils/HPF at 2 esophageal levels, ≥4 days of dysphagia over 2 weeks during the 4-week blinded placebo run-in portion of the trial, and 70% completion of the DSQ. Key exclusion criteria included the presence of other gastrointestinal diseases, use of steroids within 4 weeks of the screening endoscopy, tight esophageal stricture, or pregnancy.

After a baseline endoscopy and biopsy, patients entered a 4-week placebo run-in period and their symptoms were assessed. Patients who met the symptom and biopsy criteria at that time were randomized to either OBS 2 mg/10 mL BID (n = 51) or placebo suspension for 12 weeks (n = 42); an open-label extension was also planned for an additional 24 weeks. Dr Dellon emphasized that this was a highly symptomatic and inflamed study group, with a mean DSQ score of 29 to 30 and a mean overall eosinophil count of 130 (placebo) and 156 (OBS).

Following the end of treatment, endoscopy and biopsy were reperformed. The coprimary outcomes were change in the DSQ from baseline and the proportion of patients with a histologic response defined as ≤6 eosinophils/HPF. Safety and adverse events were also monitored.

There were significant differences favoring OBS vs placebo in both the DSQ scores ($P = .0096$) and the histology results ($P < .0001$). Although the most common adverse event among both groups was nasopharyngitis, there were no safety signals evident in either group. In addition, although these results are encouraging, Dr Dellon noted several limitations to the study, including the short treatment course and the restricted age range of the patients.