

The following gastroesophageal reflux disease (GERD)-related studies were presented at the Digestive Disease Week 2010 meeting, held in New Orleans, Louisiana, May 1–5, 2010.

Examination of Acid or Symptom Rebound Following Dexlansoprazole MR or Lansoprazole Discontinuation

To determine whether patients experience acid or symptom rebound following therapy withdrawal, data were evaluated from dexlansoprazole MR (DEX) trials of *Helicobacter pylori*-negative erosive esophagitis (EE) patients healed following 4 or 8 weeks of DEX 60 mg, DEX 90 mg, or lansoprazole (LAN) 30 mg QD who then underwent randomization to placebo for maintenance trials. Mean gastrin values did not change much from baseline to months 1 and 3 post–placebo randomization, suggesting that gastrin normalized within 1 month of proton pump inhibitor withdrawal. Mean heartburn (HB) severity was significantly lower at maintenance month 1 than at baseline, even with the lack of maintenance therapy. In patients healed at week 4 or 8 with DEX or LAN, HB severity was similar, suggesting that longer exposure or more effective therapy was not related to rebound. In patients with month 2 data, mean HB severity during the first 2 months was significantly lower than baseline (median decrease of 0.54 and 0.58 points; both $P < .001$), showing an ongoing symptom response up to 2 months after discontinuation of therapy.

Safety Profiles of Long-term GERD Treatment With Laparoscopic Antireflux Surgery or Esomeprazole

In the LOTUS study, a multicenter clinical study conducted in 11 European countries over 5 years, patients underwent randomization to laparoscopic antireflux surgery (LARS; $n=288$, of which 248 actually underwent the procedure) or 20 mg (or 40 mg if necessary) daily esomeprazole (ESO; $n=266$). There was no clinically relevant difference in the extent of serious adverse events reported in the treatment arms. Both arms reported a low number of fatal events as well as cardiac events (5 cases of death/MI in the ESO arm and 4 in the LARS arm), and there were no more of these events reported between the third and fifth years of the study. Laboratory tests (routine blood and liver variables, electrolytes, vitamin B12, folate, and homocysteine) did not demonstrate any clinically relevant changes over time. The pattern of bone metabolism biomarkers (alkaline phosphatase, calcium, vitamin D) was stable over the duration of the study and did not differ between the arms. The ESO arm experienced elevated gastrin and chromogranin A levels

(as expected after acid suppression), which appeared to level off at 5 years.

Quality of Life and Symptom Severity With DEX Therapy in GERD Patients

A study evaluated quality of life and symptom severity in adult symptomatic nonerosive GERD patients who underwent a 4-week trial of placebo, DEX 60 mg, or DEX 90 mg QD and were then enrolled in a multicenter, open-label, 12-month safety study and randomized to DEX 60 mg or 90 mg QD. A total of 313 patients (mean age, 49.4 years; women, 69.3%) comprised the study. At the end of the 4-week study, and sustained at each visit during the 12-month study, patients previously on DEX demonstrated statistically significant improvements from baseline in their Patient Assessment of Upper Gastrointestinal Disorders–Quality-of-Life scores as well as statistically significant reductions from baseline in symptom severity. Patients who had previously been on placebo achieved a comparable improvement in quality of life and reduction in symptom severity by the end of month 1 of the 12-month study. There were similar trends for the subscales as well.

Intraesophageal pH During Nighttime GERD

A study was conducted to assess nighttime esophageal acid exposure in patients with EE versus patients with nonerosive reflux disease (NERD) using a computer program that analyzed the topographic distribution of intraesophageal pH. Twenty-two patients were found to have NERD (mean age, 45 ± 2.5 years; M/F 16/6), and 38 were found to have EE (mean age, 41.8 ± 3.6 years; M/F 26/12). Time in bed did not differ between the 2 arms. The number of acid reflux events, the reflux time that pH was less than 4, and the percent of the total time that pH was less than 4 during the night was significantly lower in the NERD arm compared to the EE arm (19.95 ± 5.9 ; 24.7 ± 7.7 min; 3.96 ± 1.12 vs 25.9 ± 4.5 ; 30.1 ± 7.7 min; 5.4 ± 1.5 , respectively, all $P < .05$). There were very few reports of symptoms during the night (SI for EE, 15.8% vs NERD, 9.1%; $P < .05$). Overall, the topographic intraesophageal pH distribution did not differ much between the NERD and EE arms for all pH brackets except pH 1–0 (pH 4–3, 55% vs 54%; pH 3–2, 32.9% vs 27%; pH 2–1, 11% vs 13.2%, respectively; $P > .05$). The difference in nighttime acid exposure between EE and NERD was attributed to duration rather than intensity.