patients, but no LA grade was provided. In 14,401 (29.1%) patients, neither esophagitis nor Barrett’s esophagus were described.

Conclusion: The LA grade was reported in only 26.8% of patients in whom esophagitis was noted at EGD. A histologic diagnosis of active esophagitis was made in less than a third of patients in whom the LA grade was reported; it was only slightly more common than in patients for whom it was not reported (28.2% vs. 25.8%), but significantly more frequent than in patients whose endoscopic report did not mention esophagitis of Barrett’s (28.2% vs. 18.6%; p<0.001). The diagnosis of both erosive esophagitis and Barrett’s mucosa were progressively more common as the LA grade increased. However, the overall endoscopic-histologic correlation remained poor, with less than one-fifth of patients with LA grade D having a histologic diagnosis of erosive esophagitis. Eosinophilic esophagitis was similarly distributed amongst all the groups, with the exception of patients with LA grade D. Targeted prospective studies are needed to determine whether histopathologic and endoscopic interobserver variability, inadequate biopsy sampling, or inherent limitations of the grading system are at the root of the lack of correlation.

Disclosure: Drs Alden Kielhorn and Robert Genta are employees of Caris Diagnostics, Irving, Texas.

Results: To date, 58 subjects have been recruited of which 46 have completed the study [31 (67%) male, mean age 58 (SD 12.5, range 22 to 81), LA grades C=28, D=18]. Twenty-two subjects were allocated to the morning dose and 29 to the bedtime dose (with 1 and 4 dropping out of each arm, respectively). Of 21 subjects (C=10, D=11) randomized to morning IR-OME, 15 (71%) had healed at 8 weeks. The 6 with persistent esophagitis all demonstrated improvement in severity by one or two grades. Of 25 subjects (C=18, D=7) randomized to bedtime IR-OME, 19 (76%) healed (p=0.74). Four of 6 improved, one had the same grade, and one worsened in severity. Ten of 46 (22%) subjects accepted the offer to undergo pH testing while on study medication. Four discontinued the study medication prior to placement of the pH probe and were excluded from this subgroup analysis. Of the 6 subjects who underwent pH testing while on IR-OME, 5 were on the morning dose; 4 (80%) with normalization of pH parameters. One subject on morning IR-OME demonstrated acid reflux (5.5% overall, 1.9% upright, 9.9% supine). Only one subject on IR-OME at bedtime consented to pH testing; their time with acid in the esophagus was normal (6.8% overall, 1.6% upright, 0% supine).

Conclusion: These preliminary results suggest that both morning and bedtime dosing of IR-OME are effective in resolving severe LA grades C and D erosive reflux esophagitis at 8 weeks. Too few pH observations have been collected to comment on differences in nocturnal supine reflux between morning and bedtime dosing schedules.

Disclosure: Dr Alexander Consulting Meritigae Pharmaica and Wyeth; Research Funding - Merck, Novartis, and Glaxo Smith Kline. Dr Romero - Grant/Research Support and Consultant, Santarus, makers of omeprazole/sodium bicarbonate (Zegerid). No disclosures for: Drs Dawn Francis, Tushar Dabade; Adil Abdalla, Rayna Grothe, Vikneswaran Namassivayam, Kee Wook Jung, Michael Crowell, Felicity Enders, Amanda Arora, Jose Murray, Steven Adamson, Ramona Dejesus, Andrew Majka, John Patt, Matthew Lohse, Judith McElhinney, Virender Sharma, Kaiser Lim, Ganapathy Prasad, or Angela O’Neil, or Mrs Debra Geno, Mary Fredericksen, or Nancy Diehl.

Santarus provided study medication and financial support to conduct the study.

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Randomized Open-Label Trial to Assess the Impact of Dosage Timing of Omeprazole/Sodium Bicarbonate (Zegerid 40 mg) on Healing of Severe Reflux Esophagitis: Preliminary Results

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Purpose: Nighttime gastroesophageal reflux is important in the development of reflux esophagitis. For optimal efficacy, patients requiring proton pump inhibitor (PPI) therapy are advised to take their medication on an empty stomach 20 to 60 minutes before a meal which can be cumbersome. We hypothesized that immediate-release omeprazole/sodium bicarbonate (IR-OME), taken at bedtime, offers an alternative option for treatment of esophagitis. To test our hypothesis, we aimed to compare the percentage of subjects with severe esophagitis who achieve complete endoscopic resolution after 8 weeks of treatment with different dosage times: morning vs. bedtime.

Methods: This is a prospective randomized open-label cohort study of outpatients with esophagitis. Subjects were educated about reflux disease and the proper technique and timing of the medication. Esophagogastroduodenoscopy (EGD) was performed at baseline and after 8 weeks of study medication. A 24-hour pH study was offered at the time of the follow-up EGD, regardless of endoscopic findings. The goal is to treat 100 subjects (morning N=50, bedtime N=50).

Results: Twenty-two subjects were allocated to the morning dose and 29 to the bedtime dose (with 1 and 4 dropping out of each arm, respectively). Of 21 subjects (C=10, D=11) randomized to morning IR-OME, 15 (71%) had healed at 8 weeks. The 6 with persistent esophagitis all demonstrated improvement in severity by one or two grades. Of 25 subjects (C=18, D=7) randomized to bedtime IR-OME, 19 (76%) healed (p=0.74). Four of 6 improved, one had the same grade, and one worsened in severity. Ten of 46 (22%) subjects accepted the offer to undergo pH testing while on study medication. Four discontinued the study medication prior to placement of the pH probe and were excluded from this subgroup analysis. Of the 6 subjects who underwent pH testing while on IR-OME, 5 were on the morning dose; 4 (80%) with normalization of pH parameters. One subject on morning IR-OME demonstrated acid reflux (5.5% overall, 1.9% upright, 9.9% supine). Only one subject on IR-OME at bedtime consented to pH testing; their time with acid in the esophagus was normal (6.8% overall, 1.6% upright, 0% supine).

Conclusion: These preliminary results suggest that both morning and bedtime dosing of IR-OME are effective in resolving severe LA grades C and D erosive reflux esophagitis at 8 weeks. Too few pH observations have been collected to comment on differences in nocturnal supine reflux between morning and bedtime dosing schedules.

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Santarus provided study medication and financial support to conduct the study.

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Characteristics of Post-Fundoplication Syndrome

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Purpose: To assess dysphagia in patients who underwent Nissen Fundoplication as an element of post fundoplication syndrome.

Methods: Retrospective study used information from 13 patients who underwent esophagogastroduodenoscopies and esophageal manometries done pre and post-surgery.

Results: Pre-operative results showed 10 patients with normal esophageal manometry (EM), 1 with ineffective esophageal motility (IEM) and 2 patients did not have pre-operative EM. Of the 10 patients who had normal pre-operative EM, 8 remained normal post-operatively; 2 changed from normal to IEM. The patient with IEM before surgery had a normal EM after surgery. All patients had hiatal hernias prior to surgery, 7 of the 13 patients (54%) had recurrent hiatal hernias, and 10 of the 13 (77%) had endoscopic evidence of slippage or failure of the surgical wrap.