Author’s response to reviews

Title: Esomeprazole for the treatment of erosive esophagitis in children: an international, multicenter, randomized, parallel-group, double-blind (for dose) study

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Author’s response to reviews: see over
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Dr. Rikki Graham, PhD
BioMed Central Editorial Team
*BMC Pediatrics*

Dear Dr. Graham:

Thank you for your review of our manuscript titled “Esomeprazole for the treatment of erosive esophagitis in children: an international, multicenter, randomized, parallel-group, double-blind (for dose) study.” As requested, we have provided a point-by-point response to the reviewers’ comments. In our bolded responses below, text that has been added to the manuscript is underlined. The manuscript has been revised with additions or changes highlighted and underlined.

Thank you for the opportunity to improve our manuscript. We hope that these revisions meet the reviewers’ expectations and that you now deem the manuscript suitable for publication in *BMC Pediatrics*. We look forward to hearing from you following the review of our revised manuscript. Please direct all correspondence concerning this resubmission to my attention:

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Sincerely,

Vasundhara Tolia, MD
REVIEWERS' COMMENTS:

Reviewer 1

1. The most common presenting symptom of GERD in this study is heartburn, what is the definition of heartburn in this age group, especially infants and young children less than 4 years and how diagnoses it?

Because these patients are part of the larger cohort (up to 11 years of age), the same symptoms were evaluated in all patients for uniformity of assessment. Albeit heartburn is difficult for such young patients to describe, parents/guardians described it for many patients in the entire study cohort. Parent/guardian–reported GERD symptoms, including heartburn, were derived from the NASPGHAN guidelines (Rudolph CD, et al., J Pediatr Gastroenterol Nutr 2001, 32[suppl 2]:S1-S31), which recognize that evaluation and management of specific manifestations of GERD varies among different pediatric age groups. Heartburn was defined as a burning feeling, rising from the stomach or lower part of the chest toward the neck. The definition of heartburn along with the definitions of the other GERD-related symptoms has been added to the text on pages 7-8:

“GERD-related symptoms were reported by the parents or guardians on behalf of the patients. These symptoms were derived from the NASPGHAN guidelines [4] and included heartburn (burning feeling rising from the stomach or lower part of the chest toward the neck), acid regurgitation (perception of unpleasant-tasting fluid backing up into the throat and/or mouth), epigastric pain (perception of discomfort located in the central upper portion of the abdomen), vomiting (gastric contents are forced up to and out of the mouth), difficulty swallowing (difficulty passing anything through the pharynx or esophagus), and feeding difficulties (food refusal, choking with food/drink and/or poor weight gain).”

Reviewer 2

1. Data on gross healing of EE are provided in text but there are no on-therapy data of other GERD descriptors (eg histology).

Baseline histology findings are presented in Table 4 and discussed at the end of the patient characteristics section of the manuscript (page 10). Histology was not analyzed after treatment; therefore on-therapy histology data are not available for inclusion in the manuscript.