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Short Communication

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# Increased Risk of Erosive Gastritis Using Oral Sulfate Tablet Bowel Preparation: A Retrospective Single-Center Cohort Study

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## Abstract

**Background:** In 2020, the Food and Drug Administration approved an oral sulfate tablet (OST) containing sodium sulfate, magnesium sulfate, and potassium chloride as a colonoscopy preparation that is more palatable and convenient than polyethylene glycol (PEG) with comparable efficacy. There is a precautionary warning regarding potential risk of mucosal ulcerations in patients with inflammatory bowel disease (IBD), but post-marketing reports describing gastritis and gastric ulceration have been sporadically reported, and the occurrence of gastric erosive disease in non-IBD patients has not been extensively documented. This study aimed to assess the occurrence of erosive gastritis in adult patients who received OST bowel preparation compared to patients who received PEG prior to same-day esophagogastroduodenoscopy (EGD) and colonoscopy.

**Methods:** A single-center, blinded, retrospective study was conducted of adults who underwent same-day EGD and colonoscopy. A total of 177 patients who received OST were matched with 219 patients who received PEG. Data collection involved a detailed review of the patients' demographics, procedural, and pathology reports.

**Results:** The OST group demonstrated a significantly higher incidence of both gastric ulcers (13.6% vs. 2.3%, P-value < 0.001) and erosions (16.9% vs. 5.0%, P-value < 0.001) compared to the PEG group. There was no statistically significant difference between the locations of erosions and ulcers between groups.

**Conclusion:** The use of OST bowel preparation prior to colonoscopy is associated with increased incidence of erosive gastritis compared to PEG in patients undergoing EGD and colonoscopy on the same day at our center. Prospective, randomized studies are needed to definitively establish the risks associated with OST and to evaluate the mechanism by which it may increase the occurrence of mucosal injury.

**Keywords:** Oral sulfate tablet; Gastric ulcers; Gastric erosions; Bowel preparation

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## Introduction

Colonoscopy remains the gold standard for screening colon cancer as it allows for direct visualization and intervention upon pre-malignant and cancerous lesions [1]. Historically, the procedure required a high-volume bowel preparation involving 2 - 4 L of polyethylene glycol (PEG) to cleanse fecal matter for adequate assessment of the colonic mucosa. The PEG preparation process has often been cited by patients as the least tolerable aspect of a colonoscopy [2]. Various alternatives have been developed, and in 2020, the Food and Drug Administration approved an oral, poorly absorbed sulfate salt tablet (OST) composed of sodium sulfate, magnesium sulfate, and potassium chloride as an alternative to high-volume bowel preparations. A single-blind multicenter study enrolled 1,500 adult patients and demonstrated that the OST was comparable to PEG in terms of bowel cleansing efficacy, with no major reported adverse effects [3]. The poorly absorbed sodium salt retains luminal water while potassium chloride replenishes potassium lost due to diarrhea. Another multicenter study of 500 patients favored OST over PEG for its ease of use, and 78% reported they would choose the OST for future colonoscopy procedures [4].

However, post-market case series/report and two retrospective cohort studies have reported safety concerns related to OST association with gastric erosions and peptic injury [5-8]. While the manufacturer's warning and precaution label for OST mentions potential mucosal ulcerations in patients with inflammatory bowel disease (IBD), there is no mention of this risk in non-IBD patients. The aim of this retrospective cohort study was to compare the occurrence of gastric injury in adult

**Table 1.** Baseline Demographics and *H. pylori* Status

| Characteristics | OST (n = 177) | PEG (n = 219) |
|---|---|---|
| Age (years) | 57.6 ± 13.0 | 57.5 ± 13.7 |
| Sex | | |
| Female | 124 (70.1%) | 156 (71.2%) |
| Male | 53 (29.9%) | 63 (28.8%) |
| Race | | |
| African American | 4 (2.3%) | 6 (2.7%) |
| Asian | 38 (21.5%) | 37 (16.9%) |
| White | 116 (65.5%) | 147 (67.1%) |
| Other | 19 (10.8%) | 29 (13.2%) |
| Ethnicity | | |
| Hispanic | 17 (9.6%) | 22 (10.0%) |
| Non-Hispanic | 160 (90.4%) | 197 (90.0%) |
| *H. pylori* positive | 13 (7.3%) | 12 (5.5%) |

*H. pylori*: *Helicobacter pylori*; OST: oral sulfate tablet; PEG: polyethylene glycol.

patients at our center who received OST versus a liquid-based bowel preparation regimen on the day prior to bidirectional scopes.

## Materials and Methods

We used the electronic medical record (EMR) to conduct a retrospective, cohort study including all patients ≥ 18 years of age seen for non-urgent, outpatient colonoscopy with same-day EGD between January 2021 and August 2022 at Scripps Clinic in San Diego, California. We excluded patients with documented history of peptic ulcer disease (PUD), gastric cancer, or prior Roux-en-Y gastric bypass or sleeve gastrectomy. The comparator group was assigned by the colonoscopy preparation prescribed in the 3 months preceding the endoscopy and confirmed by the nursing flowsheets. Propensity score matching with a 1:1 was used to match the OST group to the PEG group based on age, sex, race, and ethnicity. As this matching was done on EMR data, it was initially unknown which group a patient would be in as some were prescribed multiple types of bowel preparation.

A blinded reviewer to the preparation assignment assessed EGD and pathology reports for erosions, defined as any break in the mucosa of any size, or ulcers, defined as a submucosal break of at least 5 mm [9]. To be counted as a mucosal injury, procedure reports had to be associated with similarly classified histopathologic results. Secondary outcomes included diagnosis of *Helicobacter pylori* (*H. pylori*) collected from pathology reports and location of the gastric erosions and ulcers.

Baseline demographic and clinical characteristics were compared between groups. For outcome comparisons, Chi-square tests were used for categorical variables, and Fisher's exact tests were used for continuous variables. *T*-tests were performed to assess for statistically significant differences, set as P-value ≤ 0.05, and all analyses were conducted in R version 4.3.3.

Ethical approval was granted by the Scripps IRB (approval No. IRB-22-8096).

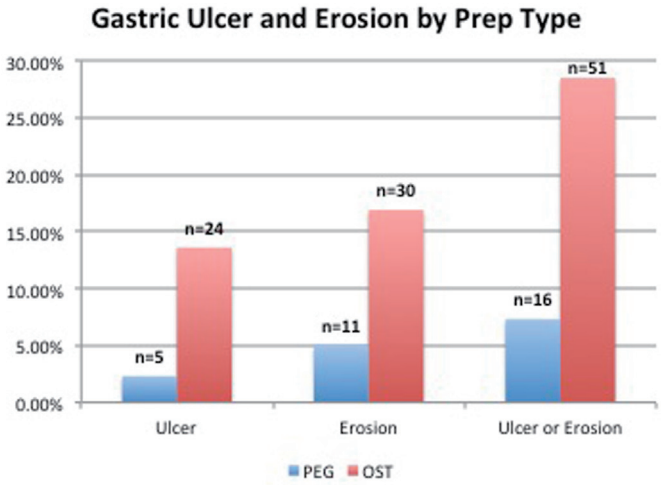


**Figure 1.** Gastric ulcers and erosion by preparation type.

## Results

Matching produced a study population of 402; six were excluded based on the exclusion criteria. There were 177 patients who used OST and 219 patients who used PEG, with a mean age of 57.6, approximately 70% female, 65% White, and 90% non-Hispanic (Table 1). The OST group demonstrated significantly more gastric ulcers than the PEG group (13.6% (n = 24) vs. 2.3% (n = 5), P-value < 0.001) (Fig. 1). Similarly, the incidence of gastric erosions was higher in the OST group compared to the PEG group (16.9% (n = 30) vs. 5.0% (n = 11), P-value < 0.001). In both groups, most erosions and ulcers occurred in the antrum and body of the stomach with no significant differences in injury location between groups. Eighty percent of the biopsies from the antrum indicated ulcers in the PEG group as compared to 50% in the OST group (P-value = 0.342). For erosions, 83.3% occurred in the antrum in the OST group as compared to 72.7% in the PEG group (P-value = 0.658).

In the OST group, 13 patients were *H. pylori* positive. Comparing *H. pylori* positive and negative patients, there was no significant difference in the occurrence of ulcers (P-value = 0.685) or erosions (P-value = 0.338) among patients using the OST bowel preparation (Fig. 2).

## Discussion

Our study revealed an increase in gastric ulcers and erosions following OST bowel preparation, adding to growing post-market reports of gastric mucosal injury after use of OST for colonoscopy preparation [5-8]. Although we noted that most gastric ulcers and erosions occurred in the antrum, there was

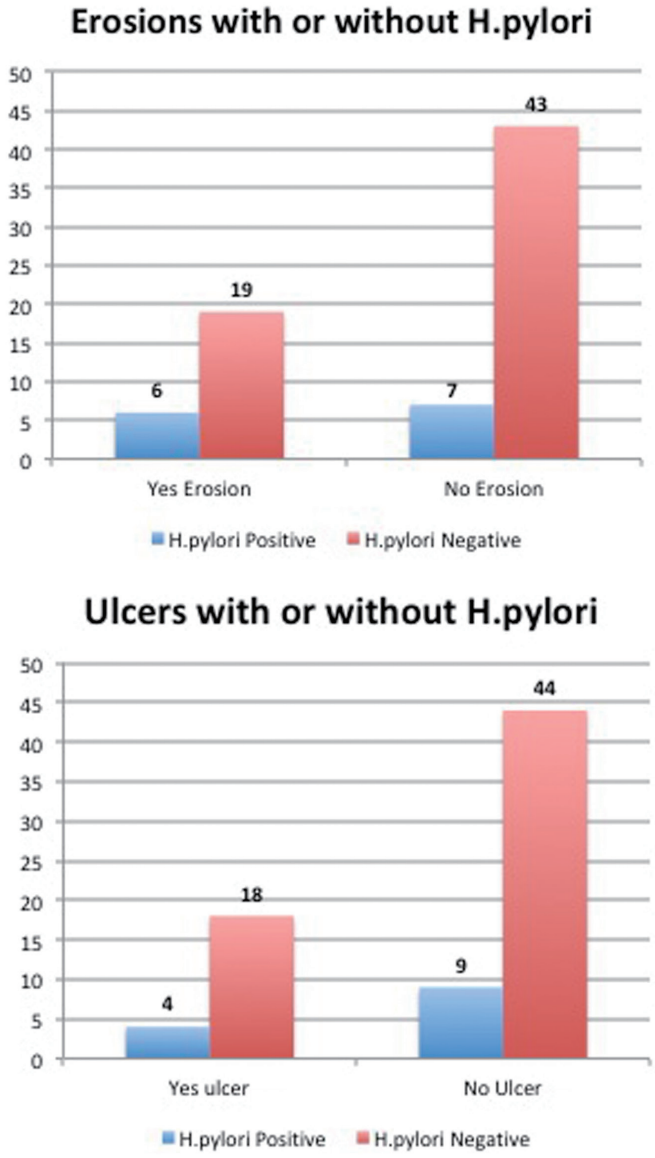


**Figure 2.** Erosions and ulcers in patients with or without *H. pylori* in the OST group. *H. pylori*: *Helicobacter pylori*; OST: oral sulfate tablet.

no statistically significant difference noted between both groups in terms of location of gastric injury, suggesting that regional susceptibility is independent of preparation type. There was also no difference in the incidence of gastric injury with a diagnosis of *H. pylori*, suggesting that it may not increase susceptibility to OST-related damage; however, the small number of *H. pylori*-positive patients limits conclusions and warrants further study. Our study combined with others suggest a safety concern beyond just IBD patients and a need to find ways to mitigate injury risk [5-8].

A retrospective review by Villa et al (2022) found that increasing the time interval between the tablets reduced the incidence of gastric erosions, likely by decreasing mucosal contact time [10]. Additionally, prior small, randomized trials found that potassium chloride does have erosive effects on the gastrointestinal mucosa, which could explain our findings of higher rates of gastric injury [11, 12]. Notably, a separate retrospective review by Khouri et al (2024) demonstrated an increased incidence of gastroduodenal lesions associated with oral sulfate solution as a bowel preparation compared to PEG [13]. These findings raise the possibility of a sulfate-related mechanism underlying gastric mucosal injury; however, further studies are needed to clarify this potential link [13].

Our findings parallel prior studies showing an association between the OST use and risk for peptic injury. Strengths of our study are inclusion of all OST-receiving patients without a history of gastric ulceration, avoiding inclusion bias, propensity matching, and blinding of the outcome assessor to the bowel preparation. Limitations include its retrospective analysis of data, which cannot measure patient compliance with bowel preparation instructions. Finally, our chart review was not able to determine and match for some additional pertinent confounders such as indications for EGD and concurrent nonsteroidal anti-inflammatory, bisphosphonates, and anti-acid medications.

In summary, our retrospective cohort study demonstrated an increased incidence of erosive gastritis with the OST as a bowel preparation regimen adding to a growing body of evidence for mucosal safety concerns in patients. If additional studies corroborate a link between OST and gastric injury, this suggests the potential for costly subsequent testing and treatment and increased patient morbidity.

## Acknowledgments

None to declare.

## Funding Disclosure

None to declare.

## Conflict of Interest

None to declare.

## Informed Consent

Informed consent was not obtained as it was not applicable because the data was retrospective and approved by IRB.

## Author Contributions

Tara Alleyasin, MD: data analysis/interpretation, manuscript drafting; Jeffrey Nguyen, MD: data interpretation, manuscript editing; Nabil El Hage Chehade, MD: manuscript revision; Natalie A. Savini, MD: study planning, data collection and analysis; Emily Singh, MD: study planning, data interpretation, manuscript editing; Leah Puglisi, MS: data collection and

statistical analysis; Quan Nhu, MD, PhD: manuscript revision; Stuti Jaiswal, MD, PhD: data analysis, manuscript revision; Laura Nicholson, MD, PhD: manuscript revision.

## Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

## Abbreviations

CRC: colorectal cancer; EGD: esophagogastroduodenoscopy; EMR: electronic medical record; *H. pylori*: *Helicobacter pylori*; IBD: inflammatory bowel disease; OST: oral sulfate tablet; PEG: polyethylene glycol; PUD: peptic ulcer disease

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