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Research Article

Comparative study of pantoprazole and esomeprazole for erosive gastroesophageal reflux disease: a prospective study

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ABSTRACT

Background: The objective of this study was to compare the efficacy of pantoprazole and esomeprazole to heal and relief from erosive esophagitis (EE) disease related symptoms.
Methods: One hundred and ten patients (IIT-patients) with EE were randomized to receive 8 weeks of 40 mg pantoprazole (n=55) twice before food for first 7 days followed by once daily and esomeprazole 40 mg (n=55) once daily. Daily changes in heartburn and reflux were assessed.
Results: The mean heartburn score with esomeprazole is more rapidly decreased than with pantoprazole. There no mild significant differences between two groups in the rate healing of reflux esophagitis at week and 4 and 8. The LA grade severity compare with esomeprazole group is rapidly decreased compared with pantoprazole. Esomeprazole 40 mg provided significantly greater healing than pantoprazole 40 mg after 4 weeks of treatment in patients with EE (56.36% vs. 49.09 %). Esomeprazole-treated patients were healed after up to 8 weeks of treatment similar those treated with pantoprazole (94.54% vs. 70.90 %).
Conclusion: Esomeprazole is more effective than pantoprazole for rapid relief of heartburn symptoms and acid reflux symptoms in patients with reflux esophagitis.

Keywords: Erosive esophagitis, Las Angeles grade, Esomeprazole, Pantoprazole

INTRODUCTION

The reflux of gastric acid and duodenal contents into the esophagus is a normal physiological phenomenon. However, the sustained esophageal mucosal damage, e.g. erosive/reflux esophagitis induced by this kind of reflux may happen when the normal esophageal clearance and mucosal protection ability are impaired.[1] Between one-third and one-half of all patients who suffer from chronic gastroesophageal reflux disease (GERD) develop erosive esophagitis (EE).[2,3] However, patients with EE have generally been studied separately from those with ENRD despite evidence that they have symptoms, which are comparable in severity, frequency, and duration.[4] The most effective treatment for the healing of EE and for GERD symptom resolution is gastric acid suppressive therapy with a proton pump inhibitor (PPI). There is evidence that mucosal healing in patients with EE can be directly linked to the amount

of time with intragastric pH >4.[5] However, there are few head-to-head data regarding the efficacy of competing PPIs in healing and symptom relief of GERD patients with EE. Both intragastric pH studies and clinical trial data in patients with EE suggest that esomeprazole might have an efficacy advantage over other PPIs.[6] On the basis of the existing physiologic and clinical data supporting the efficacy of esomeprazole, we hypothesized that when compared with other PPIs, esomeprazole provides superior healing rates and symptom relief in patients with EE.[6] Among the PPIs, esomeprazole 40 mg has been shown to be more effective than standard doses of omeprazole,[7,8] lansoprazole[9,10] and pantoprazole.[5] Based on the study design randomized and controlled trial, the purpose of our study was to compare the efficacy and safety of esomeprazole tablet 40 mg and pantoprazole 40 mg in treating patients with endoscopically confirmed reflux esophagitis (EE) enrolled in a single center. Our primary objective was to assess the EE healing rate using both agents by an 8 weeks treatment period. While the secondary objectives were to compare the response of reflux symptoms and general well-being by both agents at week 4 and 8, respectively, to compare the time needed to relieve heartburn by both agents, and to evaluate the tolerability and safety of both agents.

METHODS

This is a prospective, randomized, single center, and observational study, which assessed the current usage pattern and comparative study of esomeprazole and pantoprazole 40 mg in EE patients. The study was conducted in BGS Global Hospital, Utharahalli and Karnataka, India and duration of study is August 2013-February 2014. Ethical committee approval was taken to conduct the study. Inclusion criteria included: patients who were EE. Patient of either sex aged 0-18 years. Patient GERD symptoms for at least 6 months immediately prior to enrolment, confirmed by endoscopy and graded using the LA grading system.[11] Exclusion criteria included: Zollinger-Ellison syndrome, gastric or duodenal ulcer, esophageal stricture, history of dysplasia in Barrett's esophagus); intake of medication liable to affect the outcome of the study (including non-steroidal anti-inflammatory drugs); pregnancy, childbearing potential (unless taking suitable precautions) or lactation; alcohol and/or drug abuse; PPI use within 4 weeks prior to the first endoscopy; pregnant women.

Study procedures

A total 110 patients endoscopically proven reflux esophagitis were included in the study. After written informed consent for enrollment in this study was obtained, two PPI (initial pantoprazole 40 mg administer morning before food twice daily for first 7 days and after once daily followed by esomeprazole 40 mg morning before food once daily, was administrated for 8 weeks (Figure 1).

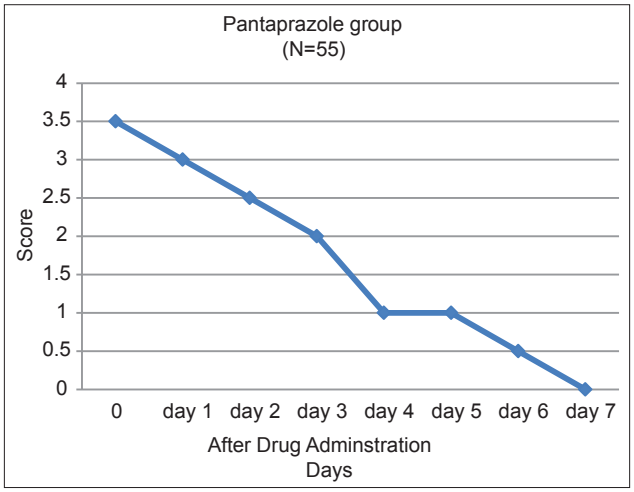

Figure 1: Daily changes in mean heartburn score for all patients with Pantaprazole group

Endoscopic diagnosis and the grading of reflux esophagitis were based on the Los Angeles (LA) classification.[11] At visit 1, physical examination was carried out and GERD symptoms were assessed. The number of days with symptoms of heartburn over the previous 7 days was also recorded.

At visit 2, physical examination and GERD symptoms were same as carried out in Visit 1. Patients underwent endoscopy and assess the severity of EE and acid regurgitation in 7 days and continued the treatment for further 4 weeks, after which EE and GERD were re-assessed. Adverse effects were recorded on each visit and we counseled the patients regarding the lifestyle modification, medication, disease condition with by providing the leaflets.

RESULTS

A total of 110 patients were randomized to treat with pantoprazole 40 mg and esomeprazole 40 mg. The baseline demographic characteristics of IIT (intent-to-treat) population are shown in Table 1. There was no clinically difference between two treatment groups. Overall treatment compliance rates were similar for the two treatment groups (esomeprazole 40 mg 92.72% and pantoprazole 40 mg 85.85%). Esomeprazole 40 mg provided significantly greater healing than pantoprazole 40 mg after 4 weeks of treatment in patients with all grades of EE severity at baseline, as shown in Table 2. Esomeprazole treated patients were healed after 8 weeks treatment similar those treated with pantoprazole. Healing rates after 8 weeks by LA grades at baseline shown in Table 3.

Time to sustained heartburn resolution (the first to 7 consecutive days with no heartburn) was equally short for patients treated with esomeprazole 40 mg and with pantoprazole 40 mg (median days were 6). The proportion of heartburn free days was mild similar in patients treated with esomeprazole 40 mg and to those with pantoprazole 40 mg.

When the patients were divided into *Helicobacter pylori* positive and negative groups, the healing rates for reflux esophagitis at a week in *H. pylori* positive patients tend to be higher than that in negative subjects (63.63% vs. 33.63%).

Table 1: Demographic details and clinical characteristics of the intent-to-population (n=110) to treat with Pantaprazole 40 mg and esomaprazole 40 mg.

Characteristics	Pantaprazole (n=55)	Esomoprazole (n=55)
Sex (male/female)	40/15	45/10
Age (Mean±SD) (year)	9.16±5.54	9.16±5.92
Symtoms N (%)		
Heartburn	28 (50.90)	31 (56.36)
Acid reflux	22 (40)	20 (36.36)
No symptoms	5 (9.09)	4 (7.27)
Habits N (%)		
Cigaratte smoking	30 (54.54)	37 (67.27)
Beedi smoking	4 (7.27)	5 (9.09)
Chewing tobacco	9 (16.36)	5 (9.09)
Both (cigarette and beedi)	10 (18.18)	5 (9.09)
All	2 (3.63)	3 (5.45)
LA Grade		
A	25 (45.45)	26 (47.27)
B	10 (18.18)	19 (34.54)
C	10 (18.18)	10 (18.18)

LA: Los Angeles

Table 2: Healing rates after 4 weeks treated with Pantaprazole 40 mg and Esomaprazole 40 mg by baseline LA grade severity score (IIT) (Chi-square test).

LA grade	Pantoprazole 40 mg N (%)	Esomeprazole 40 mg N (%)
A	15 (60)	14 (53.84)
B	4 (40)	11 (57.89)
C	8 (80)	6 (60)

p<0.18, LA: Los Angeles

Table 3: Healing rates after 8 weeks treated with Pantaprazole 40 mg and Esomaprazole 40 mg by baseline LA grade severity score (IIT) (Chi-square test).

LA grade	Pantoprazole 40 mg N (%)	Esomeprazole 40 mg N (%)
A	22 (88)	25 (96.15)
B	8 (80)	18 (94.73)
C	9 (90)	9 (90)

p<0.23, LA: Los Angeles

Figures 1 and 2 show the daily changes in the mean symptoms scores of heartburn in all patients with PPI. The heartburn score was significantly lower in subjects administered esomeprazole 40 mg after first and second than in those administered by pantoprazole 40 mg. As observed in the pantoprazole group the day 4 and 5 the stable score is 1 and where as in esomeprazole group is 1.5 and 1. Five out of 110 patients enrolled in the present study refused endoscopic examination after administration of PPI. Hence, upper gastrointestinal endoscopy was performed in 105 patient's week 4 and 8 after the commencement of PPI drugs. The endoscopic rates for EE/reflux esophagitis in subjects administered pantoprazole 85% and esomeprazole 92.72%.

DISCUSSION

GERD is caused by acid reflux, which can be treated by suppressing gastric acid secretion.[12,13] The efficacy of antisecretory drugs in healing reflux esophagitis depends on the potency of acid suppression,[14] and PPIs are considered to be the most effective drugs for reflux esophagitis.[15] The symptoms of reflux esophagitis, such as heartburn, have been demonstrated to markedly impair quality of life (QOL) in these patients[16,17] is, therefore, of critical importance in the treatment of patients with reflux disease. In a study pantoprazole (40 mg daily) and esomeprazole (40 mg daily) have an equivalent effect on intraesophageal pH after repeated intake. Both drugs were safe well-tolerated.[18] Gillessen et al.[19] and Scholten et al.[20] have reported similar effectiveness for esomeprazole 40 mg and pantoprazole 40 mg, or even greater effectiveness for latter drug in terms of speed of symptom resolution. Crossover studies in healthy subjects and patients with symptoms of GERD have shown that esomeprazole is more effective than all other PPI for providing greater time with pH >4.[21,22] The results of the present study are consistent with those of the study by Röhss et al.[22-24] and Miner et al.,[25] who reported that esomeprazole

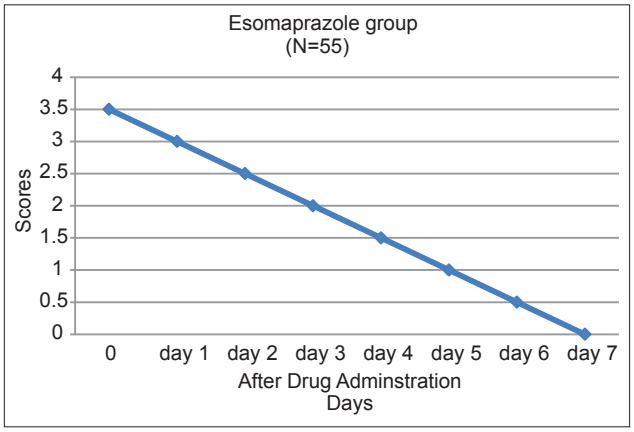

Figure 2: Daily changes in mean heartburn score for all patients with Esomaprazole group

40 mg daily was more effective than omeprazole 20 mg daily, lansoprazole 30 mg, pantoprazole 40 mg daily in the relief of heartburn symptoms during the first day and the first 5 days after the commencement of administration. Similar rates of adverse events occurred in both treatment groups. Both study drugs were well-tolerated, safe and had high patient compliance.

CONCLUSION

In this study, the esomeprazole 40 mg provides more effective healing of heartburn symptoms in patients with endoscopically proven reflux esophagitis than pantoprazole 40 mg after 4 weeks of treatment. And the difference in symptom relief in the first 7 days of administration of esomeprazole in patients with reflux esophagitis is highly remarkable, and quick symptom relief is important to enhance their QOL.

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