



A PROSPECTIVE OBSERVATIONAL COMPARATIVE STUDY ON THE EFFECTIVENESS OF PANTOPRAZOLE VERSUS ESOMEPRAZOLE FOR EROSIVE GASTRO-ESOPHAGEAL REFLUX DISEASE AND ASSESSMENT OF MEDICATION ADHERENCE

¹Hridya Unnikrishnan, Amritha G R, Aswin I J, Sree Lekshmi S Nair, ²E.Sam Jeeva Kumar, ³Dr. Unnikrishnan L.S, ⁴Dr. Sivalekshmi S P, ⁵Dr. Prasobh G R

¹Pharm.D Internship Students, ²Department of Pharmacy Practice,, ³Senior Consultant, Department of Gastroenterology, ⁴Assistant Professor, Department of Pharmacy Practice, ⁵Principal

¹Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram,

²Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram,

³Cosmopolitan Hospitals Post Graduate Institute of Health Science and Research, Thiruvananthapuram,

⁴Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram,

⁵Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram

ABSTRACT

Aim: To compare the Effectiveness of Pantoprazole versus Esomeprazole and to assess the Medication Adherence in Erosive Gastro-Esophageal Reflux Disease patients. **Methods:** The Prospective Observational Comparative Study was carried out in 56 patients with GERD. The study was conducted by categorising them into two groups, 28 patients taking Pantoprazole and 28 patients taking Esomeprazole. Initially, Pantoprazole or Esomeprazole were given twice daily for both the groups respectively for two weeks followed by once daily for six weeks. The grading of Reflux Esophagitis was based on the LA grade classification. Symptom severity was assessed by using FSSG Scale. Patient's medication adherence was assessed by using ARMS Scale. Patient's Quality of Life was measured using GERD-HRQL questionnaire. **Result:** This study shows a mild difference in the healing rate of EE between the two groups. By using LA grade and FSSG scale it shows that the severity of healing and resolution of heartburn symptoms is rapidly decreased in Esomeprazole than in Pantoprazole. Esomeprazole 40mg provided significantly greater healing than Pantoprazole 40mg after 8 weeks of treatment in patients with EE. **Conclusion:** Esomeprazole is more effective than Pantoprazole for rapid relief of heartburn symptoms and acid reflux symptoms in patients with Reflux Esophagitis.

KEYWORDS: Gastro Esophageal Reflux Disease (GERD), Erosive Esophagitis (EE), Los Angeles (LA) grade, Frequency Scale for the Symptom of GERD (FSSG), Adherence to Refill and Medication Scale (ARMS), GERD-Health Related Quality of Life Scale (GERD-HRQL).

INTRODUCTION

Gastro Esophageal Reflux Disease (GERD) is a common medical disorder. Definition of GERD states it is "a condition that occurs when the refluxed stomach contents lead to troublesome symptoms and/or complications." Episodic heartburn that is not frequent enough or painful enough to be considered bothersome by the patient is not included in this definition of GERD^[1]. The main cause of gastro-esophageal reflux is incompetence of the anti-reflux barriers at the esophago-gastric junction. The anti-reflux barriers include two "sphincter" mechanisms: the lower esophageal sphincter (LES), and the crural diaphragm that functions as an external sphincter^[1]. Acid reflux happens because a valve at the end of esophagus, the lower esophageal sphincter, doesn't close properly when food arrives at stomach. Erosive esophagitis is a type of esophagitis in which there is damage to the tissue lining. This causes heartburn and trouble swallowing.

ETIOLOGY

Currently, there is no known cause to explain the development of GERD. Motor abnormalities such as esophageal dysmotility causing impaired esophageal acid clearance, impairment in the tone of the Lower Esophageal Sphincter (LES), transient LES relaxation, and delayed gastric emptying are included in the causation of GERD. Anatomical factors like the presence of hiatal hernia or an increase in intra-abdominal pressure, as seen in obesity are associated with an increased risk of developing GERD^[1].

PATHOPHYSIOLOGY

The key factor in the development of GERD is the abnormal reflux of gastric contents from the stomach into the esophagus. In some cases, it is associated with defective lower esophageal sphincter (LES) pressure or function. Patients may have decreased gastro-esophageal sphincter pressures related to

(a) Spontaneous transient LES relaxations

(b) Transient increases in intra-abdominal pressure

(c) An atonic LES, all of which may lead to the development of gastro-esophageal reflux. Problems with other normal mucosal defence mechanisms, such as abnormal esophageal anatomy, improper esophageal clearance of gastric fluids, reduced mucosal resistance to acid, delayed or ineffective gastric emptying, inadequate production of epidermal growth factor, and reduced salivary buffering of acid, may also contribute to the development of GERD.

SIGNS AND SYMPTOMS

Typical symptoms (May be aggravated by activities that worsen gastro-esophageal reflux such as recumbent position, bending over, or eating a meal high in fat.) Heartburn (hallmark symptom described as a sub sternal sensation of warmth or burning rising up from the abdomen that may radiate to the neck. Water brash (hyper salivation), Belching

MATERIALS AND METHODS

Ethics approval

The study was approved by the Institutional Ethical Committee of Cosmopolitan Hospital, Pvt.Ltd., Trivandrum, on 14th January 2023.

AIM OF THE STUDY

To compare the effectiveness of Pantoprazole versus Esomeprazole and to assess the medication adherence in erosive Gastro-Esophageal Reflux Disease patients.

METHODOLOGY

This Prospective Comparative Study was intended to carryout in EE patients in Gastroenterology Department. Study was conducted after getting clearance from the Institutional Ethical Committee. Patients satisfying the inclusion and exclusion criteria and who were willing to participate in the study were included after obtaining their informed consent. Endoscopy was done in patients as soon as possible at the time of admission and the grading of Reflux Esophagitis was based on the Los Angeles (LA) classification. The follow up was conducted at the end of 8th week. The study population were divided into two groups, one group taking Pantoprazole and the other group taking Esomeprazole. Data was collected using a suitably designed proforma. Initially, Pantoprazole or Esomeprazole were given twice daily for both the groups respectively for two weeks followed by once daily for 6 weeks. The severity of symptoms was assessed by using FSSG Scale at 1st and 8th week of the study. Medication Adherence was assessed by using Adherence to Refill and Medication Scale (ARMS) at 4th and 8th week of the study, for better adherence, patients were provided counselling. Quality of Life was measured before and after treatment using GERD-HRQL questionnaire.

Study period and study setting

The study period was 6 months after getting clearance from Institutional Ethical Committee in the Department of Gastroenterology, Cosmopolitan Hospitals Post Graduate Institute of Health Science and Research, Thiruvananthapuram, Kerala.

Study design

A Prospective Observational Comparative Study was conducted in Gastro-Esophageal Reflux Disease patients from the Department of Gastroenterology in Cosmopolitan Hospital, Thiruvananthapuram a tertiary care centre after obtaining permission for collecting data from the Institutional Ethical Committee.

Inclusion Criteria

- Patients who were having EE.
- Patients aged between 30-60 years.
- Patients with GERD symptoms for at least 6 months confirmed by endoscopy & graded using LA grading system.

Exclusion criteria

- Pregnant & nursing mothers.
- Zollinger - Ellison syndrome.
- History of dysplasia in Barrett's esophagus.
- Esophageal stricture.
- Gastric or duodenal ulcer.
- Intake of medication liable to affect the outcome of study.

Study procedure

This Prospective Comparative Study was intended to carryout in EE patients in Gastroenterology Department. Study was conducted after getting clearance from the Institutional Ethical Committee. Patients satisfying the inclusion and exclusion criteria and who were willing to participate in the study were included after obtaining their informed consent. Endoscopy was done in patients as soon as possible at the time of admission and the grading of Reflux Esophagitis was based on the Los Angeles (LA) classification. The follow up was conducted at the end of 8th week. Initially, Pantoprazole or Esomeprazole were given twice daily for both the groups respectively for two weeks followed by once daily for 6 weeks. The severity of symptoms was assessed by using FSSG Scale at 1st and 8th week of the study. Medication Adherence was assessed by using Adherence to Refill and Medication Scale (ARMS) at 4th and 8th week of the study. Quality of Life was measured before and after treatment using GERD-HRQL questionnaire.

Statistical analysis

Paired-T Test was used to analyze the statistical difference between two groups. It was done by using SPSS Software. Datas were entered in Microsoft Excel. The healing effect and Quality of Life was expressed as Mean±SD. A p value <0.05 with a confidence interval of 95% was considered as statistically significant.

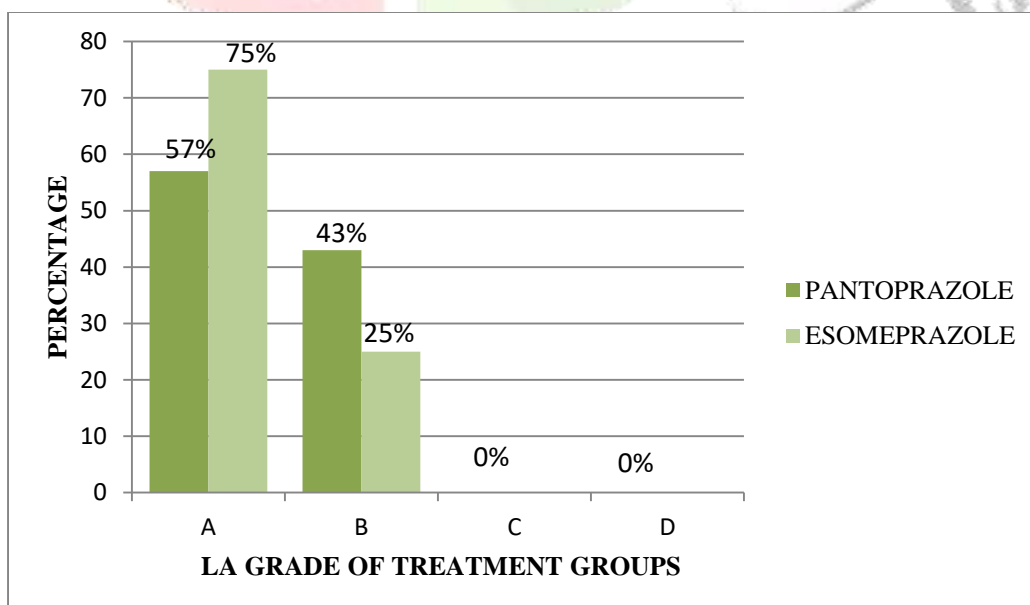
RESULT

As per the study criteria 56 patients were enrolled into the study from the Gastroenterology Department. Patients were divided into two groups. The first group was treated with Pantoprazole and the second group with Esomeprazole. During the study period 56 patients had completed the follow-up. GERD patients were found to be more in the age group of 50- 60 years with 50%, followed by 28.5% of patients belonging to 40-50 years and 21.4% of patients were in the age group of 30-40 years respectively. Gender wise distribution of the overall study population indicates that male population over-rides female population with 75% dominance over 25%.

ASSESSMENT OF EFFECTIVENESS IN PANTOPRAZOLE AND ESOMEPRAZOLE USING LA GRADE

The assessment of healing rate was evaluated by using LA classification. The study was conducted in two groups, one group taking Pantoprazole and another group taking Esomeprazole. The initial data collection was done as soon as possible at the time of admission. The follow up was conducted at the end of eighth week.

As per LA grade scale interpretation, patients were categorized based on the degree of mucosal break. There are four grades Grade A, Grade B, Grade C and Grade D. In the initial data collected, since the severity of mucosal break is high most of the patients are graded as C and D.



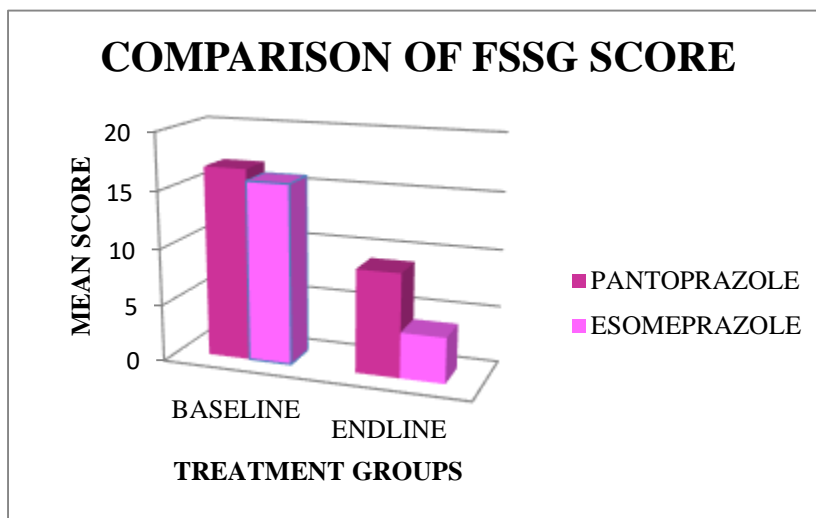
The endline grading was done upon the completion of eight weeks of the treatment. In group A, 57.1% of patients were graded as A and 42.8% of patients were graded as B.

In group B, 71.4% of patients graded as A and 25% of patients were graded as B.

ASSESSMENT OF EFFECTIVENESS OF PANTOPRAZOLE AND ESOMEPRAZOLE USING FSSG SCORE

Comparison of FSSG Score of Pantoprazole and Esomeprazole

REVIEWS	BASELINE	ENDLINE
PANTOPRAZOLE	16.8±1.97	9.07±2.81
ESOMEPRAZOLE	15.8±4.01	4±1.67

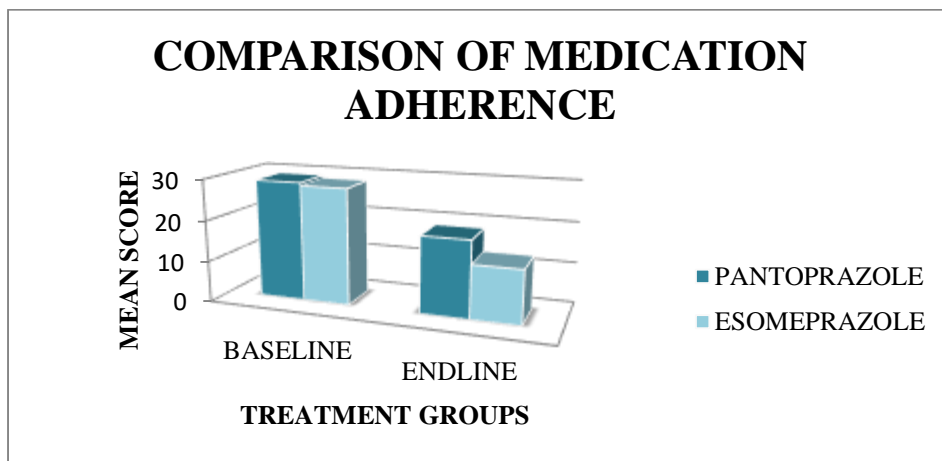


The FSSG baseline mean score of 16.8±1.97 was reduced to a score of 9.07±2.81 at the endline assessment in group A patients. This demonstrates that on treating with Pantoprazole for a period of two months gives an improvement of patient's condition by 7.8%. In group B patients, the baseline mean score of 15.8±4.01 was reduced to 4±1.67 at the endline. This exhibits that on treatment with Esomeprazole for a period of two months improves the condition of the patient by 11.8%.

ASSESSMENT OF MEDICATION ADHERENCE USING ARMS SCALE

Comparison of Medication Adherence of Pantoprazole and Esomeprazole

REVIEWS	BASELINE	ENDLINE
PANTOPRAZOLE	29±2.5	18.6±2.73
ESOMEPRAZOLE	28±4.34	13±1.15

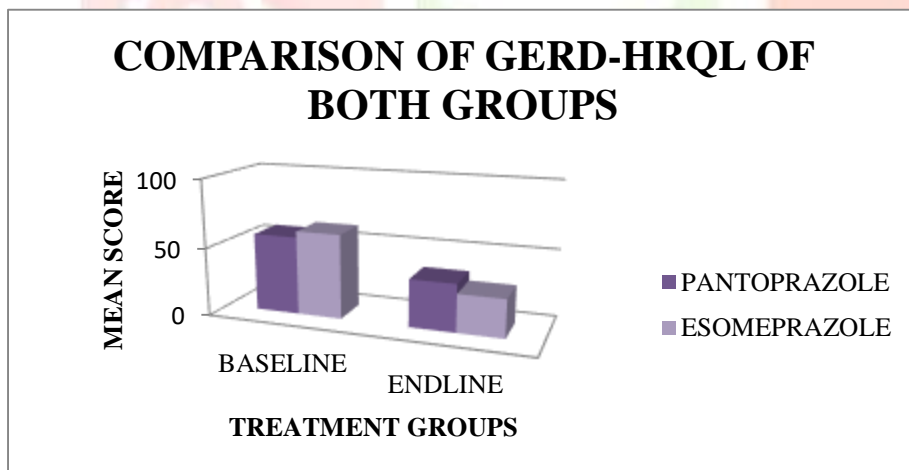


In group A, the baseline score was 29 ± 2.5 and at the endline, score became 18.6 ± 2.73 . This shows that on treating with Pantoprazole for a period of two months gives an improvement of patient’s condition by 10.4%. In group B, the baseline score was 28.3 ± 4.34 and after the endline assessment the score became 13 ± 1.15 . This exhibits that on treatment with Esomeprazole for a period of two months improves the condition of the patient by 15.3 %.

ASSESSMENT OF QUALITY OF LIFE USING GERD-HRQL QUESTIONNAIRE

Comparison of Gerd-Hrql of Pantoprazole and Esomeprazole

REVIEWS	BASELINE	ENDLINE
PANTOPRAZOLE	57.2 ± 4.13	34.8 ± 5.97
ESOMEPRAZOLE	61.8 ± 3.42	27.9 ± 5.52



In group A, the baseline QOL score of 57.2 ± 4.13 was reduced to 34.8 ± 5.97 during the endline scoring. This demonstrates that on treating with Pantoprazole for a period of two months gives an improvement of patient’s condition by 22.4%. In group B, the baseline score of 61.8 ± 3.42 reduced to 27.9 ± 5.52 at the endline. This exhibits that on treatment with Esomeprazole for a period of two month improves the condition of the patient by 33.9 %.

DISCUSSION

This study aims to compare the effectiveness of Pantoprazole and Esomeprazole in patients with endoscopically confirmed reflux esophagitis, to assess medication adherence using ARMS scale and to assess health related quality of life using the GERD-HRQL questionnaire. The two drugs concerned in the study are Pantoprazole and Esomeprazole. Esomeprazole is used in the study than other PPI like Lansoprazole, Omeprazole etc., since Esomeprazole provides superior healing rates and symptom relief in patients with Erosive Esophagitis.

In this study 56 patients with GERD were taken. Among which 28 patients taking Pantoprazole and 28 patients taking Esomeprazole. Statistical analysis was performed using paired-t test and a detailed analysis was performed. The main aim of our study is to compare the effectiveness of Pantoprazole and Esomeprazole. This study demonstrated that there is increase in effectiveness in patients with GERD taking Pantoprazole and Esomperazole, and it is done by assessing the LA classification which shows the severity of mucosal break and also by assessing the symptoms of GERD. Better result was achieved in patients treated with Esomperazole. The observation of our study was similar to the result of the study conducted by **G.Srikanth et.al.** In their study “**Comparative study of Pantoprazole and Esomeprazole for Erosive Gastroesophageal Reflux Disease**”. This prospective study describes that esomeprazole provides significantly greater healing than pantoprazole after upto 8 weeks of treatment. In our study after the 8 weeks of treatment, the endline reading of LA grade and FSSG score shows an increase in improvement of healing and effectiveness in patients taking Esomeprazole than Pantoprazole.

The observation of our study was similar to the result of the study conducted by **J. Labenz et.al.** In their study “**A randomized comparative study of esomeprazole 40mg versus pantoprazole 40mg for healing erosive oesophagitis: the EXPO study**”. This study shows that Esomeprazole provides greater healing than Pantoprazole after two months of treatment.

The FSSG scale is used to evaluate the symptom severity of GERD patients. The result of our study showed that the FSSG baseline mean score in patients taking Pantoprazole was 16.8 ± 1.97 and in patients taking Esomeprazole the score was 15.8 ± 4.01 . The endline mean score in patients taking Pantoprazole was 9.07 ± 2.81 and in patients taking Esomeprazole was 4 ± 1.67 . This shows that as the score decreases, the symptom of the patient improves. Therefore, Esomeprazole shows better symptom reduction than Pantoprazole at the end of 8 weeks of treatment.

The quality of life is the degree to which an individual is healthy and able to participate in or enjoy life events which is highly specific. At the beginning of the study, the quality of life of patients was significantly low. The QOL evaluated using GERD-HRQL questionnaire shows that the mean score for patients taking Pantoprazole before the treatment was 57.2 ± 4.13 and after the treatment, the score was 34.8 ± 5.97 . In patients taking Esomeprazole the score before the starting of treatment was 61.8 ± 3.42 and after the treatment, the score was 27.9 ± 5.52 . As the score reduces, QOL increases. This shows that in

patients taking Esomeprazole, the QOL increases than that of Pantoprazole at the end of 8 weeks of treatment.

The medication adherence score is evaluated using the ARMS scale and showed that the baseline mean score in patients taking Pantoprazole was 29 ± 2.5 and those who taking Esomeprazole was 28.3 ± 4.34 . The endline mean score in patients taking Pantoprazole was 18.6 ± 2.73 and in those patients taking Esomeprazole was 13 ± 1.15 . This shows the patients were more adherent to therapy as the decreasing score indicates better adherence. In this study, patients taking Esomeprazole were more adherent to therapy than those taking Pantoprazole. To conclude Esomeprazole is more effective than Pantoprazole for rapid relief of heartburn symptoms and acid reflux symptoms in patients with GERD.

CONCLUSION

From this study, it was concluded that Pantoprazole and Esomeprazole have almost similar effect in the healing of heartburn symptoms. However, patients taking Esomeprazole 40mg provides more effective healing of heartburn symptoms in patients with endoscopically proven reflux esophagitis than Pantoprazole 40mg after 8 weeks of treatment. For the study a total of 62 patients were selected, out of which six patients were eliminated at different stages of the study so the rate of dropout was 10%. The study was conducted on two groups, one group taking Pantoprazole and the other group taking Esomeprazole. Group A and group B involve 28 patients each. By comparing Pantoprazole and Esomeprazole, it demonstrates that both the treatment shows almost similar effect and improves the rate of outcome. The FSSG scale is used to evaluate the symptom severity of GERD patients. The result of our study showed that the FSSG final score in patients taking Pantoprazole was 7.8% and in patients taking Esomeprazole the score was 11.8%. This shows that Esomeprazole shows better symptom reduction than Pantoprazole at the end of 8 weeks of treatment. The medication adherence score is evaluated using the ARMS scale and showed that in patients taking Pantoprazole were 10.4% and those who taking Esomeprazole was 15.3%. This shows the patient was more adherent to therapy by the end of 8 weeks of treatment. The quality of life of the patients assessed by the GERD-HRQL showed steep improvement in the quality of life, which was assessed before and after the treatment and was compared to determine the difference. On the comparison done, the QOL demonstrated by the Pantoprazole was 22.4% while that of Esomeprazole was 33.9%. The results assessed from the study clearly indicates that the treatment with Esomeprazole showed better outcome in both aspects of effectiveness, improvement in rate of adherence and the quality of life of the patients. Even though the Pantoprazole produces more outcome, the treatment with Esomeprazole is far beneath in case of outcome.

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