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A COMPARATIVE OBSERVATIONAL STUDY OF DUAL THERAPY ITOPRIDE AND ESOMEPRAZOLE VS MONOTHERAPY ESOMEPRAZOLE IN GASTROESOPHAGEAL REFLUX DISEASE

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ABSTRACT Gastroesophageal reflux disease (GERD) is a chronic condition characterized by reflux-related symptoms, with proton pump inhibitors (PPIs) like esomeprazole being the standard treatment. However, some patients continue to experience persistent symptoms, requiring adjunctive therapies such as prokinetics like itopride, which enhances gastric motility. This study compared the efficacy and safety of dual therapy (Itopride + Esomeprazole) versus Esomeprazole Monotherapy in GERD patients conducted over six months, the study enrolled 150 patients, with Group I (n=62) receiving dual therapy and Group II (n=88) receiving esomeprazole alone. Symptom severity was assessed using the FSSG before and after four weeks of treatment. Results showed significantly greater symptom relief in the dual therapy group (66%) compared to monotherapy (47%), with a statistically significant difference (p=0.0101). Both treatments were well tolerated, with minimal side effects, and treatment response was not influenced by age or gender. These findings suggest that dual therapy provides superior symptom relief and maybe a more effective approach for GERD patients with persistent symptoms. Further research with longer follow-ups and objective diagnostic tools is recommended to validate these results.

KEYWORDS : GERD, Lower Oesophageal Sphincter, Esomeprazole, Prokinetics, Itopride, FSSG score

INTRODUCTION

Gastroesophageal reflux disease (GERD) is a chronic gastrointestinal disorder characterized by regurgitation of gastric contents into the oesophagus. It is one of the most frequently diagnosed digestive disorders, resulting in a significant financial burden in direct and overhead expenses and adversely affecting the quality of life.[1] [2] GERD is caused by various mechanisms that can be intrinsic, structural, or both, leading to the disturbance of the esophagogastric junction barrier leading the acidic gastric contents to interact with the oesophagus lining. Clinically, GERD typically manifests with symptoms of heartburn and regurgitation and can also present atypical with extra-oesophageal symptoms such as chest pain, dental erosions, chronic cough, laryngitis, or asthma.[3] [4] Over time, the chief support in the management of GERD has been lifestyle modifications, and proton pump inhibitors (PPIs).[5]

Esomeprazole is indicated to treat conditions where there is excess acid in the stomach. It is also known to prevent stomach ulcers and stomach irritation. Esomeprazole is a proton pump inhibitor (PPI), it decreases the amount of acid produced in the stomach.[6] Esomeprazole expresses stomach acid-suppressing effects by covalently binding to sulfhydryl groups of cysteines found on the (H+, K+)-ATPase enzyme at the secretory surface of gastric parietal cells. Thus, preventing the final step in gastric acid production. This effect leads to inhibition of both basal and stimulated gastric acid secretion, irrespective of the stimulus. As the binding of esomeprazole to the (H+, K+)-ATPase enzyme is not reversible and a new enzyme must be available to resume acid secretion, esomeprazole's duration of antisecretory effect persists longer than 24 hours[7].

A novel gastroprokinetic agent, Itopride shows gastrointestinal motor activity through the dual mode of action, acting as dopamine D2 receptor antagonist and cholinesterase inhibitor. It accelerates gastric emptying, modulates gastric sensorimotor function, and has an antiemetic action. The synergistic combination of Esomeprazole and Itopride, aids in decreasing acid production plus an increase in lower oesophageal sphincter tone and oesophageal clearance, thus providing a better therapeutic response.[8]

Dual Therapy: Itopride and Esomeprazole

In recent years, the combination of prokinetic agents with PPIs has been explored to enhance therapeutic outcomes in GERD patients. Itopride, a prokinetic agent, has shown promise in improving gastric motility and accelerating gastric emptying, potentially addressing the motility-related aspects of GERD [9]. Studies comparing dual therapy with itopride and esomeprazole to monotherapy with esomeprazole have demonstrated superior symptom relief and oesophageal healing rates with the combination treatment. This suggests that addressing both acid suppression and motility enhancement may provide more comprehensive management of GERD. Further research is needed to establish the long-term efficacy and safety of dual therapy in GERD patients.

Methodology

Study Design

This study was designed as a Prospective, Comparative Observational study aimed at assessing the efficacy of dual therapy with itopride and esomeprazole versus esomeprazole monotherapy in the treatment of gastroesophageal reflux disease (GERD). The research focused on evaluating the impact of both treatment regimens on symptom relief and overall therapeutic effectiveness.

Study Duration & Population

The study was conducted, over six months from January 2024 to June 2024. A total 150 patients diagnosed with GERD through clinical symptoms and endoscopic evaluation were recruited for the study. The patients were divided into two distinct groups:

- **Group I:** Patients receiving a combination of itopride and esomeprazole.
- **Group II:** Patients receiving esomeprazole monotherapy.

Inclusion Criteria

- Age range between 18 and 80 years.
- GERD diagnosis confirmed through endoscopic evaluation.

- Patients prescribed either esomeprazole alone or in combination with itopride.

Exclusion Criteria

- Age below 18 years or above 80 years.
- Pregnant or lactating women.
- esomeprazole doses outside the standard 40 mg range.
- Presence of oesophageal complications such as esophagitis, Barrett's oesophagus, or strictures.

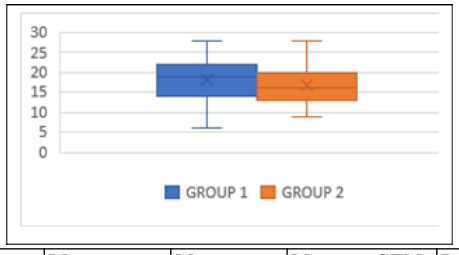
Study Procedure:

Patients were enrolled based on inclusion and exclusion criteria, provided informed consent, and underwent baseline symptom assessment using the FSSG questionnaire. They were then allocated to either Group I (itopride 50 mg + esomeprazole 40 mg) or Group II (esomeprazole 40 mg alone). Symptom progression was reassessed after four weeks using the FSSG questionnaire during follow-up evaluations.

RESULTS

The study included 150 GERD patients divided into two treatment groups: Group I (62 patients, 41%) received dual therapy with itopride and esomeprazole, while Group II (88 patients, 59%) received esomeprazole monotherapy. The allocation aimed to compare the effectiveness of both treatments in symptom relief. Age distribution was categorized into three groups: 18–35 years (Group I: 25, Group II: 41), 35–60 years (Group I: 27, Group II: 40), and above 60 years (Group I: 10, Group II: 7), with no statistically significant age difference between groups. Gender distribution showed that Group I had 37 (60%) males and 25 (40%) females, while Group II had 58 (66%) males and 30 (34%) females. No statistically significant difference in treatment groups, age and gender was found between the two treatment groups.

Baseline Symptom Severity (FSSG Score)

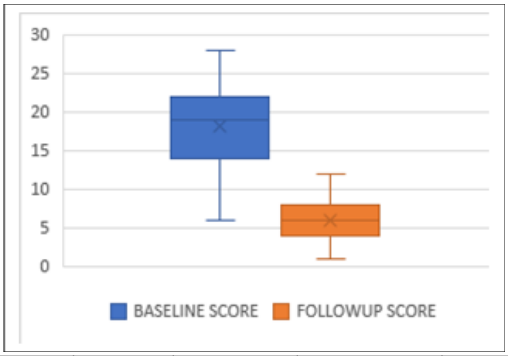


Group	Minimum	Maximum	Mean ± SEM	P value
I	6	28	18.16±5.01	0.0906
II	9	28	16.83±4.49	

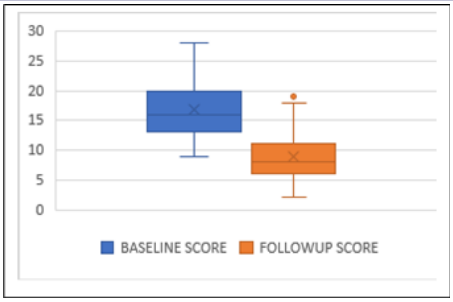
Comparison of FSSG Score at Baseline

The data obtained from Comparison of FSSG Score at Baseline. There is no significant difference was found in the Baseline FSSG Score between the two treatment groups.

Effectiveness of Treatment in Group I & Group II



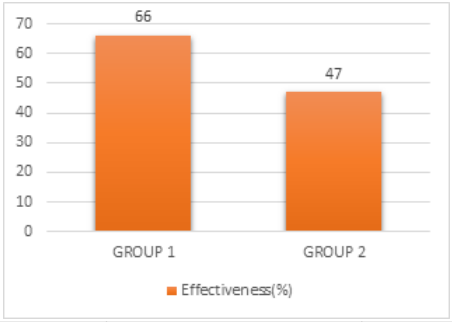
Review	Minimum	Maximum	Mean ± SEM	P value
Baseline	6	28	18.16±5.01	<0.0001*
Follow Up	1	12	6.08±2.62	



Review	Minimum	Maximum	Mean ± SEM	P value
Baseline	9	28	16.83±4.49	<0.0001*
Follow Up	2	19	8.86±3.99	

1) The data obtained by the Comparison of FSSG Score with baseline in Group I. There is significant difference was found in the FSSG Score before and after treatment in Group I.
2) The data obtained by the Comparison of FSSG Score with baseline in Group 2. There is significant difference was found in the FSSG Score before and after treatment in Group II.

Comparison Of Treatment Effectiveness



Parameter	Group		P value
	I (%)	II (%)	
FSSG SCORE	66	47	0.0101*

A Comparison of Effectiveness of treatment on FSSG Score of two groups. It is observed that, from Group I 66% and Group II 47%. Both the drugs are effective in reducing the GERD symptoms. There is statistically significant difference was found in the effectiveness between the two treatment groups.

DISCUSSION

GERD remains a challenge despite advancements in diagnosis and treatment, with many patients not fully benefiting from standard therapies. While PPIs were expected to be the solution, a significant number of patients continue to experience symptoms, and PPI-resistant cases are increasing. GERD also impacts productivity, as shown in the European Range study, which highlighted its effects on work, costs, and quality of life.

PPIs are the most effective acid suppressants, reducing gastric volume and acidity, but GERD involves more than excess acid. Adding prokinetics like Itopride enhances treatment by improving motility. Itopride, a novel prokinetic with a strong safety profile, blocks D2 receptors and boosts acetylcholine release, improving gastric emptying, motility, and reducing transient lower oesophageal relaxations (TLERs).

This study demonstrated significant symptom improvement after four weeks when Itopride was combined with Esomeprazole, addressing heartburn, reflux, bloating, and regurgitation more effectively than monotherapy. A prospective study of 150 GERD patients confirmed that dual therapy was superior to Esomeprazole alone, proving its enhanced efficacy in symptom relief.

Limitations Of The Study

Despite the promising results, this study has certain limitations including a short four-week follow-up period, which may not fully reflect long-term efficacy or symptom recurrence. Treatment effectiveness was assessed using the FSSG questionnaire, a self-reported tool that could introduce bias, while objective diagnostic methods like pH monitoring or oesophageal manometry might provide more accurate results. Additionally, patients with Barrett's oesophagus, oesophageal strictures, or severe esophagitis were excluded, leaving uncertainty about the dual therapy's effectiveness in these subgroups.

CONCLUSION

Our research compared the effectiveness of dual therapy (Itopride + Esomeprazole) with monotherapy (Esomeprazole) for managing GERD. The dual therapy showed better results, with 66% of patients experienced symptom relief, compared to 47% in the monotherapy group (p=0.0101). This is likely because Esomeprazole reduces stomach acid secretion while Itopride improves gut motility. Despite both treatments showed good toleration, and no side effects were reported, the dual therapy superior symptomatic relief and safe option for GERD treatment. Further studies are needed to confirm long-term benefits and safety.

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