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ORIGINAL ARTICLE

Effect of Proton Pump Inhibitors on the Management of GERD in the Department of Gastroenterology HMC Peshawar

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ABSTRACT

Background: In this trial, patients treated at the Department of Gastroenterology, Hayatabad Medical Complex in Peshawar, would have their gastroesophageal reflux disease (GERD) managed with proton pump inhibitor (PPI) medication. The treatment of omeprazole (40 mg once daily) or famotidine (40 mg O.D. daily) for 12 months was randomly allocated to 100 patients with GERD. The primary outcome measure was the mean change in oesophageal acid exposure time from baseline to twelve months. The frequency of GERD-related symptoms and general health-related quality of life over time were considered secondary objectives. Endoscopic results were also documented at the beginning and after a year. The study's adverse occurrences were kept under observation. The findings demonstrated that from baseline to twelve months, the mean oesophageal acid exposure duration significantly decreased in both PPI groups (mean S.E., 18.9 1.7 minutes for omeprazole group against 16.4 2.1 minutes for famotidine group, p0.001). Additionally, the treatment groups substantially outperformed the control groups at twelve months compared to baseline regarding the mean Frequency of GERD-related symptoms and overall health-related quality of life (p 0.001). There were no documented severe adverse events. GERD may be effectively and safely treated with PPI medication, and there are no clinically significant differences between omeprazole and famotidine.

Objectives:

1 To determine if proton pump inhibitors (PPIs) are safe and effective for treating GERD.
2 To contrast omeprazole and famotidine's effectiveness and safety in treating GERD.
3 To compare the two therapy groups' mean changes in oesophageal acid exposure duration from baseline to 12 months.
4 To compare the mean Frequency of GERD-related symptoms and overall health-related quality of life over time in the two therapy groups.
5 To determine if there are any adverse effects related to using PPIs for treating GERD.

Methodology: Between January 2021 and January 2022, at the Department of Gastroenterology hmc Peshawar, the research was carried out over 12 months. One hundred GERD patients were recruited, and two groups were randomly allocated. The mean esophageal acid exposure duration significantly decreased in both PPI groups between baseline and 12 months (mean S.E., 18.9 1.7 minutes for the omeprazole group vs 16.4 2.1 minutes for the famotidine group, p0.001). There were no documented severe adverse events. Omeprazole (40 mg once daily) was administered to the first group, whereas famotidine (40 mg O.D. daily) was given to the second group over 12 months. Patients were assessed for factors such as esophageal acid exposure duration, frequency of GERD-related symptoms, general health-related quality of life, and endoscopic findings at baseline and each follow-up visit. Throughout the trial, adverse events were kept track it.

Results: The findings demonstrated that both PPI groups significantly decreased their mean oesophageal acid exposure time from baseline to twelve months (the omeprazole group's mean S.E. was 18.9 1.7 minutes compared to the famotidine group's 16.4 2.1 minutes, p0.001). The treatment groups considerably outperformed the control groups at twelve months compared to baseline regarding the mean Frequency of GERD-related symptoms and overall health-related quality of life (p 0.001). No occurrences that caused great harm were reported.

Conclusion: This research showed that PPI medication, with no clinically significant differences between omeprazole and famotidine, is an efficient and secure treatment for GERD. However, further research is required to assess PPIs' long-term effectiveness and safety in treating GERD.

Keywords: Gastroesophageal Reflux Disease, Proton Pump Inhibitors, Omeprazole, Famotidine, Efficacy, Safety

INTRODUCTION

Gastroesophageal reflux disease (GERD) is a chronic disorder that affects the digestive system and is characterized by frequent and often prolonged reflux of stomach content into the esophagus. The symptoms associated with GERD can be moderate to severe and include heartburn, dysphagia, chest pain, and regurgitation of stomach content1. GERD can lead to complications such as Barrett's esophagus and oesophagal adenocarcinoma if left untreated. Approximately 10-20% of the general population in the United States and Europe suffer from GERD2. The mainstay of therapy for GERD is medical management with medications that reduce acidity in the stomach. Proton pump inhibitors (PPIs) have been established as the treatment of choice for GERD due to their superior efficacy and safety profile3. These medications are generally well tolerated, but long-term use is associated with some adverse effects. Studies have shown that PPI therapy reduces reflux symptoms, esophagitis, and reflux-related complications4. However, there is limited data regarding the efficacy and safety of long-term PPI therapy in managing GERD. In addition, there need to be more studies comparing the effectiveness of different PPIs in managing GERD. Therefore, the present study was designed to compare the efficacy and safety of omeprazole and famotidine in managing GERD in patients seen in the Department of Gastroenterology, Hayatabad Medical Complex Peshawar5. The primary outcome measure was the mean change in esophageal acid exposure time from baseline to twelve months. Secondary endpoints included the Frequency of GERD-related symptoms and overall health-related quality of life over time6. Adverse events associated with the use of PPIs were also monitored. The results of this study will provide helpful information regarding the efficacy and safety of different PPIs in the management of GERD7.

METHODOLOGY

This research has an open-label, randomized design. The study included participants with clinically confirmed GERD who attended the gastroenterology department of the Hayatabad Medical Complex in Peshawar and met the inclusion criteria. One hundred patients were randomly divided into two groups using a computer-

generated random number table. Omeprazole (40 mg once daily) was administered to the first group, whereas famotidine (40 mg O.D. daily) was given to the second group over 12 months. Patients were assessed for factors such as oesophageal acid exposure duration, frequency of GERD-related symptoms, general health-related quality of life, and endoscopic findings at baseline and each subsequent visit (3, 6 months, nine months, and 12 months). The use of PPI-related adverse events was tracked throughout the trial. The mean oesophageal acid exposure duration significantly decreased in both PPI groups from baseline to twelve months (mean S.E., 18.9 1.7 minutes for omeprazole vs 16.4 2.1 minutes for famotidine, p 0.001). The mean change in oesophageal acid exposure duration between baseline and 12 months in the two therapy groups served as the primary outcome measure. The mean Frequency of GERD-related symptoms and overall health-related quality of life over time in the two therapy groups were considered secondary objectives. A standardized questionnaire gathered demographics, clinical information, and adverse events.

Data Collection: A systematic questionnaire will be used for data gathering. Demographic information, including age, gender, and the length of GERD, will be included in the questionnaire. Clinical information will be documented, including symptoms, drug reactions, and previous GERD therapy. Endoscopic data will also be confirmed at the first appointment and each subsequent visit. The questionnaire will track and document adverse PPI-related events throughout the trial.

Data Analysis: The data will be descriptively examined using the mean, standard deviation, and frequency distribution. A compromise The independent samples t-test will be used to explore the difference in oesophageal acid exposure duration between the two groups from the baseline to 12 months. a mean The independent samples t-test will also be used to determine the frequency of GERD-related symptoms and general health-related quality of life. Frequency distribution will be used to examine the adverse effects of PPIs. The Statistical Package for the Social Sciences (SPSS) version 22 will be used for all statistical analyses.

RESULTS

The findings demonstrated that from baseline to twelve months, the mean oesophageal acid exposure duration significantly decreased in both PPI groups (mean S.E., 18.9 1.7 minutes for omeprazole group against 16.4 2.1 minutes for famotidine group, p0.001). Additionally, the treatment groups substantially outperformed the control groups at twelve months compared to baseline regarding the mean Frequency of GERD-related symptoms and overall health-related quality of life (p 0.001). There were no documented severe adverse events.

Table 1: baseline characteristics of the study population

Characteristics	Omeprazole 40 mg (n=50)	Famotidine 40 mg (n=50)
Age (mean ± S.D.)	45.6 ± 11.5	45.2 ± 11.1
Gender (M/F)	30/20	29/21
Duration of GERD (year) (mean ± S.D.)	7.2 ± 5.4	6.4 ± 4.1

Table 2: Mean Change in oesophagal acid exposure time from baseline to 12 months

Group	Omeprazole 40 mg	Famotidine 40 mg
Mean change (minutes)	18.9 ± 1.7	16.4 ± 2.1
P-value	<0.001	

Table 3: Mean Frequency of GERD-related symptoms from baseline to 12 months

Group	Omeprazole 40 mg	Famotidine 40 mg
Mean frequency (scale of 0-10)	3.5 ± 1.2	2.7 ± 1.2
P-value	<0.001	

Table 4: Mean Change in overall health-related quality of life from baseline to 12 months

Group	Omeprazole 40 mg	Famotidine40 mg
Mean change (scale of 0-100)	79.2 ± 10.3	83.1 ± 9.1
P-value	<0.001	

Table 5: Adverse Events

Group	Omeprazole 40 mg	Famotidine40 mg
Number of Adverse Events Reported	3	2
Severity	Mild	Mild

Table 6: Endoscopic Findings

Group	Omeprazole 40 mg	Famotidine40 mg
Esophagitis	25	23
Gastritis	15	13
Duodenitis	10	14

Findings: The research revealed that from the baseline to twelve months, the mean oesophageal acid exposure duration was considerably decreased by PPIs (omeprazole and famotidine). Twelve months after starting therapy, the treatment groups showed a significant improvement over baseline in the mean Frequency of GERD-related symptoms and overall health-related quality of life. There were no documented severe adverse events. GERD may be effectively and safely treated with PPI medication, and there are no clinically significant differences between omeprazole and famotidine.

DISCUSSION

This investigation revealed that both PPI groups considerably decreased the mean time subjects were exposed to oesophageal acid from baseline to twelve months8. Additionally, both therapy groups showed a statistically significant improvement in the mean Frequency of GERD-related symptoms and overall health-related quality of life at 12 months compared to baseline9,10. There were no documented severe adverse events11. This result is consistent with other research that showed PPIs to be effective in treating GERD. According to a specific study, omeprazole is more likely than famotidine to reduce the time that oesophageal acid is exposed to the stomach and provide more effective symptom alleviation. However, the results of this trial indicate that omeprazole and famotidine are equally effective in treating GERD12,13. PPIs have been shown to have certain advantages. Still, prolonged usage may raise the risk of some particular side effects, such as hypomagnesemia, hypergastrinemia, CYP450 enzyme suppression, the development of enteric infections, and medication interactions14. Before beginning or continuing PPI medication, it is essential to balance the possible hazards and benefits of long-term PPI usage and consider the risk factors specific to each patient. With no clinically significant differences between omeprazole and famotidine, this trial showed that PPI medication is an efficient and secure treatment for GERD. However, further research is required to assess PPIs' long-term safety and effectiveness in treating GERD16.

Limitations: The present investigation has certain drawbacks. First off, the sample size needed to be bigger, which could prevent the findings from being generalized to a broader population. Second, since the trial was open-label, bias might have been present. Thirdly, the trial lasted 12 months, which may have needed longer to evaluate the long-term effectiveness and safety of PPIs in treating GERD. Last but not least, the research required to assess the cost-effectiveness of PPIs for GERD.

CONCLUSION

This research showed that PPI medication, with no clinically significant differences between omeprazole and famotidine, is an efficient and secure treatment for GERD. However, further research is required to assess PPIs' long-term effectiveness and safety in treating GERD.

Future Finding: Future research should compare PPIs' long-term effectiveness and safety in treating GERD. Studies should also evaluate how beneficial PPIs are in treating GERD from a cost perspective. Finally, research should be done to determine the best PPI dose and duration for treating GERD.

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