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Original Research Paper

Gastroenterology

A COMPARATIVE PROSPECTIVE STUDY TO ASSESS THE CLINICAL EFFICACY OF ITOPRIDE HYDROCHLORIDE (50MG) VS RABEPRAZOLE (40MG) IN PATIENTS WITH GERD.

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ABSTRACT

Background: The chronic condition known as gastroesophageal reflux disease (GERD) causes symptoms and complications when stomach acid and contents increase into the oesophagus. Acid reflux, breathing difficulties, bad breath, tooth deterioration, chest pain and regurgitation are some of the symptoms. Barrett's oesophagus, esophageal stricture and esophagitis are all complications. Usually, cases that are refractory or when complications from reflux disease are discovered necessitate surgery (fundoplication). For the treatment of GERD, a stepwise process is used. Controlling symptoms, treating esophagitis, and avoiding complications like recurrent esophagitis are the objectives. **Methods:** This was a prospective observational study in department of gastroenterology carried out for a period of six months. Patient data were extracted from their medical records. The present prospective comparative study was carried out at Department of Gastroenterology in tertiary care hospital in Hyderabad for a period of six months. The patients enrolled in this study 100, having 50 patients in each group. **Results:** Our study reveals that most of the patients affected with GERD presented with complaints of heartburn, abdominal pain, chest pain, dysphagia, nausea. The recovery rate with rabeprazole in patients with GERD was found to be 68.57%. The recovery rate with itopride hydrochloride (ganaton) was found to be 74.28%.

Conclusion:

- The present study that is carried out showed that Itopride provided more effectiveness in treatment in patients with GERD.
- In terms of efficacy, the Itopride is more effective in altering the symptoms of GERD therby reducing the score of FSSG scale than PPI (pantoprazole) alone.
- In terms of side effects, the Itopride shows lesser side effects when compared to PPI in patients with GERD

KEYWORDS : Comparative, Itopride, Rabeprazole, GERD

BACKGROUND

The chronic condition known as gastroesophageal reflux disease (GERD) causes symptoms and complications when stomach acid and contents rise into the oesophagus. Acid reflux, breathing difficulties, bad breath, tooth deterioration, chest pain and regurgitation are some of the symptoms. Barrett's oesophagus, esophageal stricture and esophagitis are all complications.

Pregnancy, obesity, smoking, using specific medicines and having a hiatal hernia are risk factors. NSAIDs, calcium channel blockers, benzodiazepines, tricyclic antidepressants and specific asthma medications are some of the drugs that may contribute to the disease or make it worse. Esophageal pH monitoring, gastroscopy, upper GI series, or esophageal manometry may be used to make a diagnosis in patients who do not respond to less aggressive treatments.

Usually, cases that are refractory or when complications from reflux disease are discovered necessitate surgery (fundoplication). The prognosis for surgery is regarded as excellent. In addition to gastroesophageal reflux disease, patients with complex medical conditions have higher rates of surgical morbidity and mortality.

For the treatment of GERD, a stepwise process is used. Controlling symptoms, treating esophagitis, and avoiding complications like recurrent esophagitis are the objectives. Patients with mild to moderate symptoms and grades I-II esophagitis should use H2 receptor antagonists as their first line of treatment. Cimetidine, famotidine, and nizatidine are available options. Only patients with mild symptoms can benefit somewhat from prokinetic agents; patients with more severe symptoms typically need additional acid-suppressing drugs, such as PPIs.

METHODS

The present prospective comparative study was carried out at the Department of Gastroenterology in tertiary care hospital in Hyderabad for a period of six months. The patients enrolled in this study 100, having 50 patients in each group. Group I (Rabeprazole)- and Group II (Itopride Hydrochloride).

- Patients with the following criteria were included:

1) Patient age 15-75 years
2) Patients who are willing to give verbal informed consent for the study.
3) Out-patients
4) Visit follow ups
5) On call follow ups
6) RUT –ve patients
7) H. Pylori –ve patients
8) Normal USG Abdomen patients

- Patients with the following criteria were excluded:

1) Patients with previous GI surgery.
2) Pregnant and lactating females.
3) APD positive patients.
4) Patients with known endocrine diseases or any other metabolic diseases.
5) Alcoholic liver disease.

6) Patients with known hepatic or renal dysfunction.

Study Outcomes

Our study outcomes were Evaluate the symptomatic relief by either therapy to patient and to assess their effectiveness in patients with GERD, Reduce the complications of GERD such as Adult-onset esophagitis, permanent damage of esophagus etc, Improvement in clinical complaints, Avoid hospitalization, Observation of ADRs and Reducing the duration of therapy in GERD patients..

Statistical Analysis

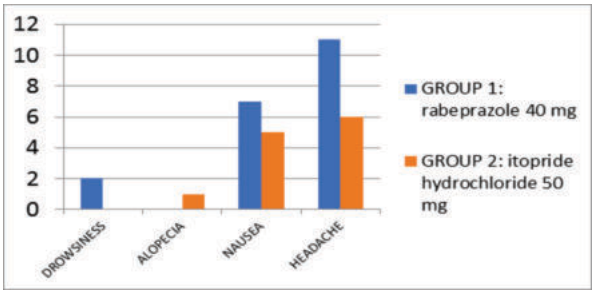
The data was analyzed using Statistical Package for Social Service (SPSS) Version 26. Means and standard deviations (SD) were calculated for continuous variables, while frequencies and percentages were calculated for categorical variables.

RESULTS

Our study reveals that most of the patients affected with GERD presented with complaints of heartburn, abdominal pain, chest pain, dysphagia, nausea. The recovery rate with rabeprazole in patients with GERD was found to be 68.57%. The recovery rate with itopride hydrochloride (ganaton) was found to be 74.28%.The main cause of GERD symptoms includes life style modifications, spicy and junk food, stress and disturbed sleep cycle. ADRs were reported by patients.

Comparison based on adverse drug reactions

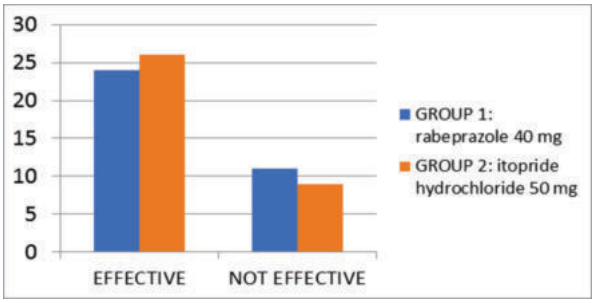
Variables	n (%)	Drowsiness	Alopecia	Nausea	Headache	P value
	32					
Group 1	20 (62.5%)	2	0	7	11	-
Group 2	12 (37.5%)	0	1	5	6	-
OR(95 % CI)		1.00 (Ref)	0.26 (0.11–0.23)	2.69 (0.68–4.28)	3.85 (2.68–9.26)	0.02*



"p value less than 0.05 or 0.05 is statistically significant"

Comparison based on effectiveness of drugs

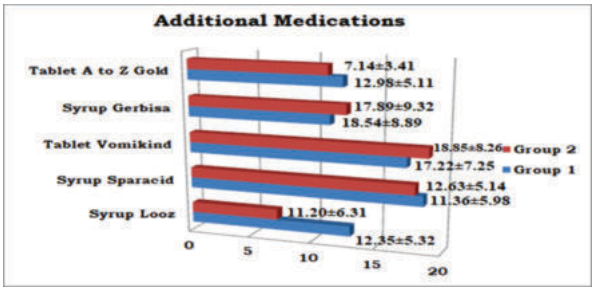
Variables	Group 1	Group 2
Effectiveness		
Effective	24	26
Not Effective	11	9



"p value less than 0.05 or 0.05 is statistically significant"

Additional Medications

Variables	Group 1	Group 2	p value
Medications			
Syrup Looz	12.98±5.11	7.14±3.41	0.03*
Syrup Sparacid	18.54±8.89	17.89±9.32	0.04
Tablet Vomikind	17.22±7.25	18.85±8.26	0.23
Syrup Gerbisa	11.36±5.98	12.63±5.14	0.21
Tablet A to Z Gold	12.35±5.32	11.20±6.31	0.12

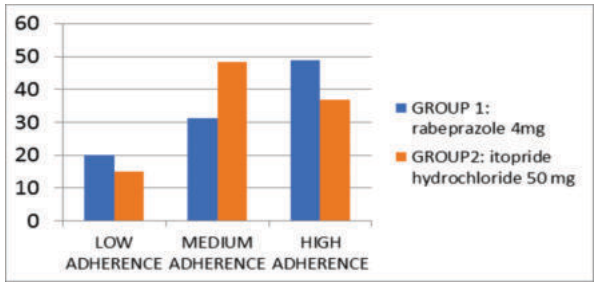


"p value less than 0.05 or 0.05 is statistically significant"

- Group 1: rabeprazole 40 mg
- Group 2: Itopride hydrochloride 50 mg

Comparison based on MMAS

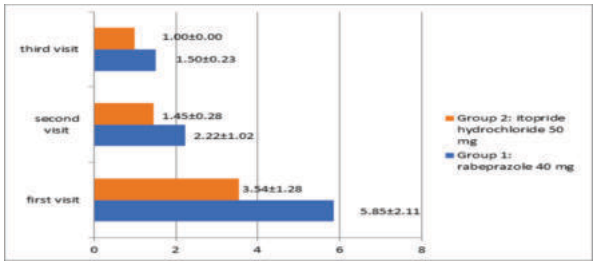
Variables	n (%)	Low adherence	Moderate adherence	High adherence	P value
	100				
Group 1	100 (100 %)	20	31.25	48.75	-
Group 2	100 (100 %)	14.90	48.28	36.82	-
OR(95% CI)		1.00 (Ref)	0.26 (0.11–0.23)	2.69 (0.68–4.28)	0.03*



"p value less than 0.05 or 0.05 is statistically significant"

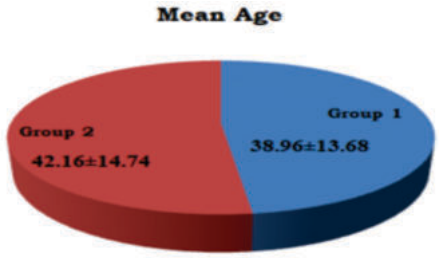
Comparison based on duration of outcome

Visits	Group 1	Group 2	p value
First visit	5.85±2.11	3.54±1.28	0.02*
Second visit	2.22±1.02	1.45±0.28	0.21
Third visit	1.50±0.23	1.00±0.00	0.35



Age

Variables	Group 1	Group 2
Mean age		
Age	38.96±13.68	42.16±14.74



FSSG score

DISCUSSION

Itopride hydrochloride, a prokinetic benzamide derivative sold under the brand name Ganaton. These medications have a gastrokinetic effect and inhibit the enzymes that produce dopamine and acetylcholine esterase. Itopride HCl used for the treatment of functional dyspepsia and other gastrointestinal conditions. It functions as both an acetyl cholinesterase inhibitor and a D2 receptor antagonist.

The goals of treatment for GERD include symptom relief and lesion healing if endoscopic or pathologic examinations reveal esophageal mucosal damage. GERD is currently thought to be a chronic, relapsing disease like high blood pressure and diabetes mellitus, necessitating long-term treatment. The goals of treatment for GERD include symptom relief and lesion healing if endoscopic or pathologic examinations reveal esophageal mucosal damage.

The pathogenic mechanisms of GERD, such as gastrointestinal motility disorder, ineffective LES relaxation, impaired esophageal acid clearance and protracted gastric emptying, have been treated and improved with the use of prokinetic agents, among other therapeutic drugs.

Till now, no such study has been conducted which shows the combination of safety and effectiveness of itopride hydrochloride (Ganaton 50mg) vs rabeprazole (40mg) in the treatment of GERD. Clinical experiences with Itopride hydrochloride (Ganaton) 50mg is limited and additional studies are required to validate the safety and clinical effectiveness of itopride. This study will help us to know the potential effectiveness of itopride hydrochloride (Ganaton 50mg) in comparison with rabeprazole 40mg in patients with GERD. The purpose of the current study is to fill a gap in the literature regarding the function of the prokinetic drug itopride hydrochloride in GERD. The duration of therapy for GERD patients was also studied.

CONCLUSION

- The present study that is carried out showed that Itopride provided more effectiveness in treatment in patients with GERD.
- In terms of efficacy, the Itopride is more effective in altering the symptoms of GERD therby reducing the score of FSSG scale than PPI (pantoprazole) alone.
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