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Efficacy of Clidinium and Chlordiadepoxide as Add-On Therapy in Gastric Disorders

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Abstract: Background and Aim: ***The treatment of Gastric disorders is a challenge. Clidinium/chlordiazepoxide is a combination of antispasmodic and anxiolytic drugs that has been used as an adjunct treatment for GERD, Functional Dyspepsia, and Organic dyspepsia in clinical practice with limited supporting evidence of efficacy. The study aims to assess the efficacy and safety of clidinium/chlordiazepoxide as an adjunct treatment to a proton pump inhibitor (PPI) in refractory dyspepsia.***
Materials and Methods: ***This prospective, observational, and comparative study was conducted in outpatient and inpatient units of the Gastroenterology Department at a tertiary care hospital. The study was carried out over 6 months, with a sample size of 82 subjects.***
Results and Discussions: A total of 82 patients were treated with Clidinium/Chlordiazepoxide out of which 42 and 40 were found to be female and male. among 32 patients, the condition after add-on therapy in functional dyspepsia 21(65.6%) improved, and 11(34.4%) remained unchanged. Among 39 patients, the condition after add-on therapy in GERD, 28(71.8%) was improved, 9(23.1%) remained unchanged, and 2(5.1%) was worsened. among 11 patients, the condition after add-on therapy in organic dyspepsia 8(72.7%) improved, and 3(27.3%) remained unchanged.
Conclusion: The study revealed promising results for Functional Dyspepsia and Organic Dyspepsia, with a significant proportion of patients experiencing improvement. However, the outcomes for GERD were more varied, with a notable portion of patients showing no change or even worsening symptoms.
Keywords: Epigastric Pain Syndrome, Functional Dyspepsia, gamma-aminobutyric acid, Gastro oesophageal reflux disease, hydrogen-potassium adenosine triphosphatase, Lower oesophageal Sphincter, Small intestinal bacterial overgrowth, Postprandial Distress Syndrome.

I. INTRODUCTION

A. Gastric Disorders

GERD (GASTROESOPHAGEAL REFLUX DISORDERS) is a digestive disorder caused by the backflow of stomach acid into the esophagus. This can lead to heartburn and other symptoms. Factors contributing to GERD include a weak esophageal sphincter, hiatal hernia, delayed stomach emptying, poor esophageal muscle function, and lifestyle factors like obesity, smoking, and certain dietary habits.

Dyspepsia is a common digestive disorder characterized by upper abdominal pain or discomfort. It can be classified into two types:
Organic Dyspepsia: Caused by underlying medical conditions like peptic ulcers, often due to H. pylori infection or NSAID use.
Functional Dyspepsia: Not caused by any underlying medical condition, often related to factors like impaired gastric emptying or sensitivity to food.

Both GERD and dyspepsia can cause symptoms like heartburn, acid reflux, bloating, nausea, and abdominal pain. Diagnosis involves a combination of medical history, physical exam, and diagnostic tests. Treatment approaches vary depending on the specific condition and severity of symptoms.

B. Proton-Pump Inhibitors

Proton Pump Inhibitors (PPIs) are medications that reduce stomach acid production. They are effective in treating conditions like acid reflux, ulcers, and H. pylori infections. However, PPIs can have side effects such as bone fractures, kidney problems, and increased risk of infections. They can also interact with other medications, so it's important to use them under medical supervision.

C. Clidinium / Chlordiazepoxide

This drug is given as adjunctive therapy along with Proton pump inhibitors. It is started when the PPI therapy is not as effective as expected.

GENERIC NAME: CLIDINIUM/ CHLORDIAZEPOXIDE
COMMON BRAND NAME: Equirex, Librax, Spasrax, Spasril, Libratex, Gutrex, Ulcon
ROUTE: ORAL
DOSE: Chlordiazepoxide (5mg) + Clidinium (2.5mg)

Clidinium and chlordiazepoxide are combined to treat gastric conditions like peptic ulcers, GERD, and dyspepsia. Chlordiazepoxide hydrochloride is a versatile, therapeutic agent for anxiety relief. It works by slowing gut movements and relaxing stomach and intestine muscles, blocking acid secretion in the GI tract. The drug is used in therapy for peptic ulcers, GERD, and dyspepsia.

Overdose can be fatal, with symptoms including dry mouth, blurred vision, drowsiness, confusion, muscle weakness, loss of consciousness, and constipation. It can cause allergic reactions, severe drowsiness, seizures, mood changes, and withdrawal symptoms. The combination may also have liver-related adverse effects and central nervous system effects.

It is contraindicated in individuals with a history of porphyria, severe liver impairment, or alcohol or substance abuse. It interacts with tricyclic antidepressants and other drugs.

II. METHODOLOGY

A. Materials and Methods

The study is a prospective, observational and comparative study lasting for six months, with follow-ups scheduled for 4 weeks.

A total of 82 adult patients were enrolled in this study. Participants include both diabetic and non-diabetic individuals diagnosed with gastric disorders and on therapy with clidinium/chlordiazepoxide as add-on therapy. The study population comprised both male and female patients. Informed consent was obtained from all eligible participants. Patients who declined participation, pregnant and lactating women, and individuals who were not on the add-on therapy were excluded from the study.

B. Statistical Analysis

All subsequent tests utilized patient categorization based upon the standardized questionnaire. Demographic factors (gender, age) were assessed and compared for the different groups of patients utilizing Pearson Chi-square tests and descriptive measures were calculated, including frequencies, percentages, means, and standard deviations. To fulfill the study's objective, researchers applied a component bar diagram for final data analysis. All statistical tests were two-sided, and p values < 0.05 were considered significant.

III. RESULTS AND DISCUSSION

A. Results

Table-1: Frequency distribution of age

Age group	Frequency	Percentage
<30 years	17	20.7
30-40 years	18	22.0
41-50 years	16	19.5
>50 years	31	37.8
Total	82	100
Mean Age	43.52	

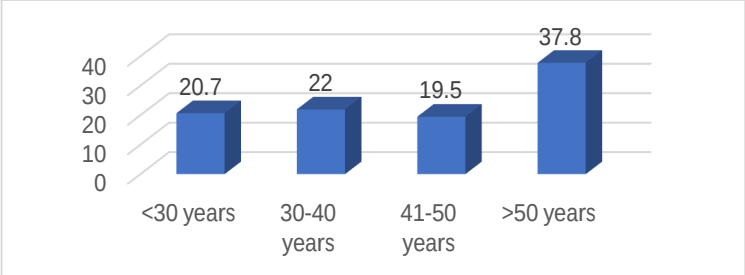
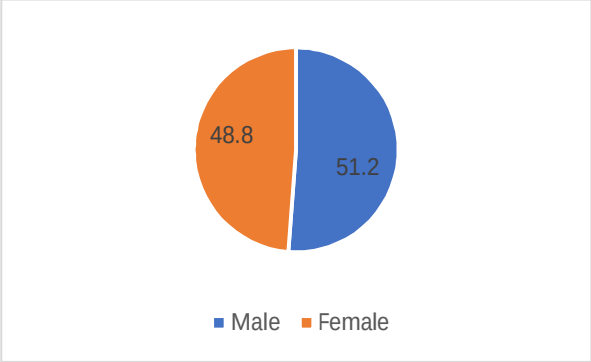


Table-2: Frequency distribution of gender

	Frequency	Percentage
Male	42	51.2
Female	40	48.8
Total	82	100



1) Patient Condition Before add-on Therapy

Patient condition was unchanged after PPI therapy. Hence Clidinium/chlordiazepoxide was given as an add-on therapy for improving the Patient condition.

Table-3: Frequency distribution of Patients' condition after add-on therapy

Patient condition after add on therapy	Frequency	Percentage
Improved	57	69.5
Unchanged	23	28.0
Worsen	2	2.4
Total	82	100

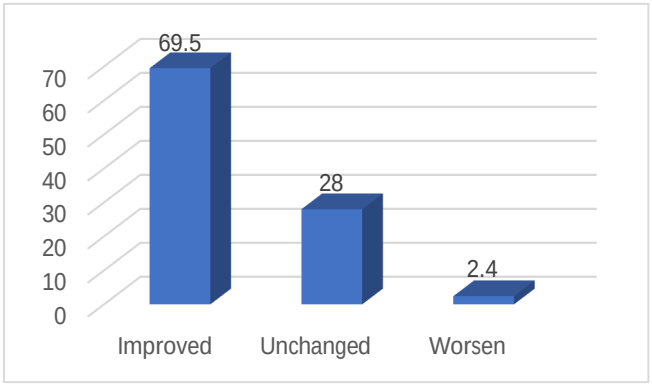


Table-4: Frequency distribution of Patients' condition after add-on therapy based on gender

Gender	Patient condition after add-on therapy			Total No. (%)	P value
	Improved No. (%)	Unchanged No. (%)	Worsen No. (%)		
Female	31 (73.8)	11 (26.20)	0 (0)	42	0.296
Male	26 (65)	12 (30)	2 (5)	40	
Total	57 (69.5)	23 (28)	2 (2.4)	82	

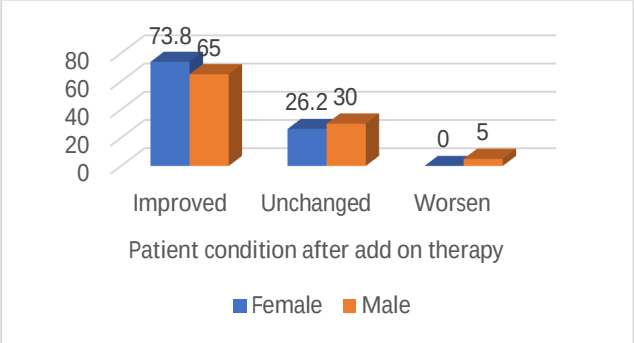


Table-5: Frequency distribution of Patients' condition after add-on therapy based on Age groups

Age group	Patient condition after add on therapy			Total No. (%)
	Improved No. (%)	Unchanged No. (%)	Worsen No. (%)	
<30 years	15 (88.2)	2 (11.8)	0 (0)	17
30-40 years	11 (61.1)	6 (33.3)	1 (5.6)	18
41-50 years	11 (68.8)	4 (25)	1 (6.3)	16
>50 years	20 (64.5)	11 (35.5)	0 (0)	31
Total	57 (69.5)	23 (28)	2 (2.4)	82

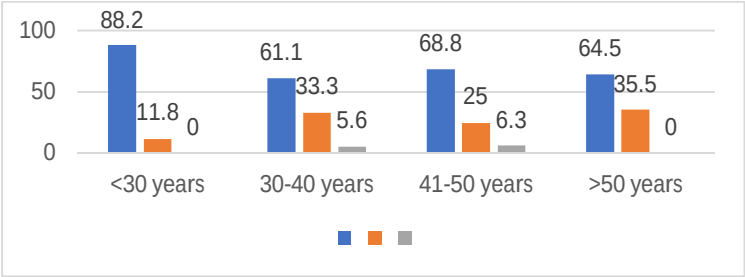


Table-6 : Frequency distribution of Patients condition after add-on therapy based on diseases:

Diagnosis	Patient condition after add on therapy			Total No. (%)	Mc Nemer test (P value)
	Improved No. (%)	Unchanged No. (%)	Worsen No. (%)		
Functional Dyspepsia	21 (65.6)	11 (34.4)	0 (0)	32	0.537
GERD	28 (71.8)	9 (23.1)	2 (5.1)	39	
Organic Dyspepsia	8 (72.7)	3 (27.3)	0 (0)	11	
Total	57 (69.5)	23 (28)	2 (2.4)	82	

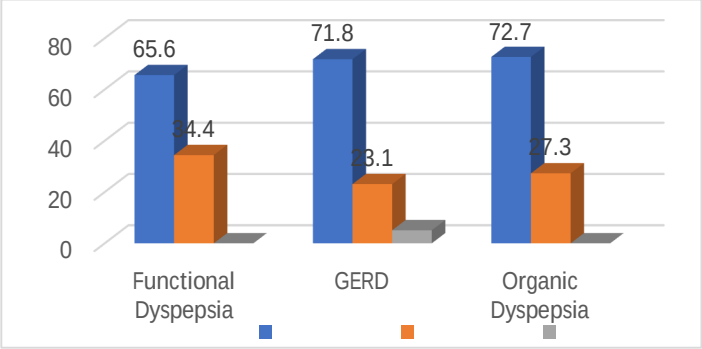
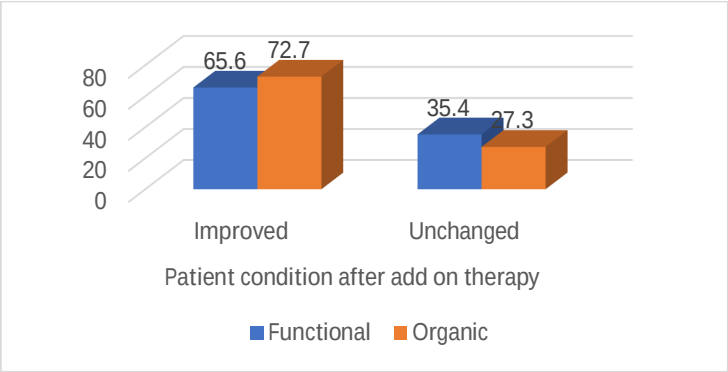


TABLE 7: Frequency distribution of Patients' condition after add-on therapy in functional and organic dyspepsia:

Type of dyspepsia	Patient condition after add on therapy		Total No. (%)	P value
	Improved No. (%)	Unchanged No. (%)		0.665
Functional	21 (65.6)	11 (34.4)	32	
Organic	8 (72.7)	3 (27.3)	11	
Total	29 (67.4)	14 (32.6)	43	



IV. DISCUSSION

The study investigated the safety and effectiveness of adding Clidinium/Chlordiazepoxide to proton pump inhibitors (PPIs) for improving symptoms in 82 patients with different gastric conditions. Results showed that 73.8% of female patients experienced improvement, while 65% of male patients experienced improvement. The addition of Clidinium/Chlordiazepoxide improved conditions in functional dyspepsia, GERD, and organic dyspepsia, while remained unchanged in organic dyspepsia. Overall, the study suggests that Clidinium/Chlordiazepoxide as safe and effective treatment option.

V. CONCLUSION

The study evaluated the efficacy and safety of clidinium/chlordiazepoxide as an adjunctive therapy for dyspepsia in 82 patients who did not respond well to PPIs. The results indicated that the drug was moderately effective, with 69.5% of patients experiencing improvement in their condition. However, 28% remained unchanged and 2.4% worsened.

The study also analyzed the outcomes for different types of dyspepsia. Functional dyspepsia and organic dyspepsia showed improvement in 65.6% and 72.7% of patients, respectively. GERD, on the other hand, had a more varied response, with 71.8% improving, 23.1% remaining unchanged, and 5.1% worsening.

While these findings suggest the potential benefit of clidinium/chlordiazepoxide as an adjunctive therapy, further research is necessary to better understand the underlying mechanisms of dyspepsia and develop more targeted treatments. This combination is used as an add-on therapy in different gastric disorders which significantly improves symptoms and quality of life.

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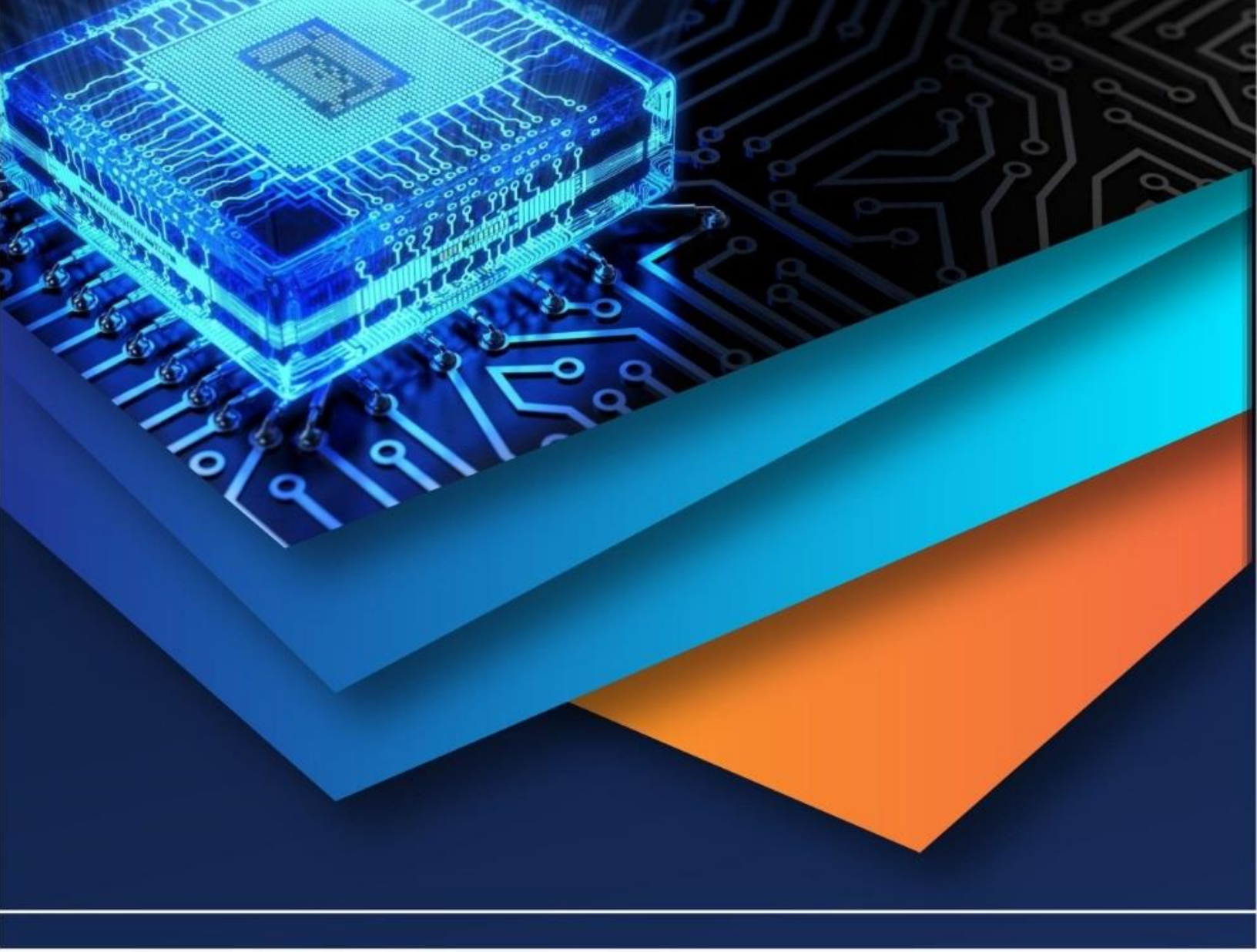

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