A Comparative Evaluation of the Effectiveness of Acotiamide ER 300mg OD Versus Acotiamide 100mg TID in the Treatment of Gerd

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***Abstract*—Background: Gastroesophageal reflux disease (GERD) is the most prevalent gastrointestinal disorder, and leads to substantial morbidity, though associated mortality is rare. It is present with heartburn and effortless regurgitation. Coexistent dysphagia is considered an alarm symptom, prompting evaluation. There is considerable overlap between symptoms of GERD and those of eosinophilic esophagitis, functional dyspepsia, and gastroparesis, posing a challenge for patient management. GERD is exceedingly common, ranking as the most frequent gastrointestinal diagnosis associated with outpatient clinic visits.**

Methods: This prospective, single- center, comparative, clinical trial was conducted in the department of Gastroenterology at Multispecialty Hospital in Hyderabad, India for the period of six months. Subjects' data was drawn out from medical records. Treatment was given for 4weeks /1month. Therapeutic responses of treatment were assessed using FSSG and GERD HRQL scale. Subject compliance was analyzed using MMAS.

Results: In our study, a total of 60 patients were included who met the inclusion criteria and they were randomly allocated into two groups namely Group 1 and Group 2. Each group consists of 30 patients. Group – 1 patients are treated with acotiamide 300mg OD and Group 2 patients are treated with acotiamide 100mg TID. They were 40 % males and 60 % female participants. They were 65 % subjects from age group 36-55 followed by 20% subjects in age group 18-35 and 15% in subject in age group 56-65. Subjects BMI (Kg/m^2) were also taken into consideration 1.67% subjects were underweight,50% subjects were normal weight, 40% subjects were overweight and 8.33patients were obese according WHO classification of BMI. Our data showed that majority of patients had heartburn (Group 1: n=18, 60% and group 2: n=20, 66.67%), regurgitation (Group 1: n=18, 60% and group 2: n=16, 53.33%) and abdominal discomfort (Group 1: n=16, 53.33% and group 2: n=18, 60%). Our data also showed that majority of patients had hypertension (Group 1: n=14, 46.67% and group 2: n=13, 43.33%), and diabetes mellitus (Group 1: n=10, 33.33% and group 2: n=6, 20%). The personal habits data revealed that patients diet history showed use of fried food (Group 1: n=16, 53.33% and group 2: n=15, 50%), spicy food (Group 1: n=12, 40% and group 2: n=13, 43.33%), and caffeine intake (Group 1: n=13, 43.33% and group 2: n=17, 56.67%).Minor ADRs such as GI upset, headache and dizziness were reported in our study which doesn't required treatment withdrawal. The study outcome parameters showed significant improvement in FSSG and GERD HRQL scores from baseline to end of treatment.

Conclusions: In our study, it illustrates that acotiamide in both the doses and frequencies that is 300mg once daily and 100mg thrice daily are effective in treatment of GERD. Still further research is required with large sample size to authenticate the results.

***Index Terms*—Gastroesophageal Reflux Disease (GERD), Acotiamide, FSSG, GERD HRQL, MMAS**

I. INTRODUCTION

Gastroesophageal reflux disease (GERD) is a most common digestive disorder that develops when there is a retrograde flow of stomach contents back into the esophagus. It can be present in two main forms: non-erosive reflux disease or erosive esophagitis. Clinically, GERD typically manifests with symptoms of heartburn and regurgitation. It can also present in an atypical fashion with extra-oesophagal symptoms such as chest pain, dental erosions, chronic cough,

laryngitis, or asthma. If left untreated, GERD can lead to complications such as stricture, ulceration, inflammation, and even Barrett's esophagus1. Barrett's oesophagus is a condition where the lining of the esophagus is replaced by abnormal cells, and it increases the risk of esophageal cancer.

The study conducted by Sharma et al. in northern India published in Indian Journal of Gastroenterology while GERD can be prevalent in certain regions, recent studies have shown a high prevalence of GERD even in Asian countries. It seems that GERD is not limited to certain regions or ethnic backgrounds. The shows a relatively high prevalence of GERD in the urban adult population, with a prevalence rate of 16.2%.

Proton pump inhibitors (PPIs) are the most popular medical anti-reflux therapy now used to treat GERD. PPIs are now the most effective class of medications for reducing GERD-related symptoms, as well as for curing and keeping erosive esophagitis in remission and enhancing health-related QOL. Use of a PPI alone is still insufficient for many GERD patients, despite the fact that PPIs are effective for treating GERD and its related complications in about 30% of GERD patients, 10-15% of erosive esophagitis patients, and 40-50% of non-erosive reflux disease (NERD) patients.

Prokinetic medications are thought to help GERD by boosting esophageal peristalsis, expediting esophageal acid clearance, and aiding gastric emptying as well as raising the baseline pressure of the lower esophageal sphincter (LES). These include dopamine receptor antagonists, GABA-B receptor agonists, and 5-hydroxytryptamine (5-HT) receptor agonists. Although many studies have demonstrated that adding a prokinetic to PPI medication helps reduce the symptoms of GERD, there is still considerable debate in the literature regarding the effects of prokinetics on esophageal function.

Acotiamide is a novel prokinetic drug that has a unique mechanism of action compared to other gastroprokinetic agents. Unlike other drugs in its class, acotiamide has little affinity for serotonin 5-HT2, 5-HT3, and 5-HT4 receptors, and weak affinity for dopamine D2 receptors. Instead, it exerts its gastroprokinetic activity through two primary actions. First, acotiamide inhibits presynaptic M1 and M2 muscarinic receptors. This inhibition enhances the release of acetylcholine (Ach), a neurotransmitter involved in regulating gastrointestinal motility. By increasing the availability of Ach released in a synaptic manner, acotiamide enhances reflex-controlled motility, which can help improve gastrointestinal symptoms.

Secondly, acotiamide inhibits the activity of acetylcholinesterase (AchE) in the stomach. AchE is an enzyme that breaks down acetylcholine, limiting its effects. By inhibiting AchE, acotiamide prolongs the action of acetylcholine in the stomach, further enhancing its prokinetic effects.

Acotiamide received initial approval in Japan as the first therapeutic agent for FD diagnosed by Rome III criteria. It is currently under evaluation in a phase 3 program in Europe for the treatment of FD. While most clinical studies have focused on the improvement of PDS symptoms, a study conducted in Europe demonstrated that the severity of heartburn in FD patients was significantly reduced with the administration of 100 mg of acotiamide compared to a placebo.

II. MATERIALS AND METHODS

2.1 Study Design

This Phase III, randomised, prospective, single-center, comparative, clinical trial was conducted in the Department of Gastroenterology at Multispecialty Hospital in Hyderabad, India for the period of six months.Before the study began, the participating hospital's institutional ethics committee examined and authorized it. This study was conducted in compliance with the Declaration of Helsinki and Indian regulatory laws governing biomedical research in human patients. Prior to the start of the trial, informed consent was obtained from all of the subjects who had been screened and enrolled in the study. Of the 80 patients diagnosed with GERD who visited the hospital, only 60 patients were taken into study because 5 patients decline to participate in study, 3 patients were not meeting the age criteria of this study,3patients were pregnant and 7 patients were not taken because of other resons. The study will employ a comparative design, recruiting patients diagnosed with GERD and randomly assigning them to either acotiamide 300mg OD or acotiamide 100mg TID groups for 1 month.

2.2 Study Criteria

A. Inclusion Criteria

- Out patients of either gender from age 18 – 65 years diagnosed with GERD & who does not respond to PPI alone.
- Patients competent & willing to participate in study.
- Subjects with H.Pylori negative.
- Patients with no abnormality in ultrasound of abdomen.

B. Exclusion Criteria

- Subjects with any significant lesions in endoscopic findings, any major abdominal surgery, psychiatric disorder.
- Subjects with symptoms of irritable bowel syndrome (IBS).
- Pregnant & lactating womens.

2.3 Statistical Analysis

Categorical variables were analyzed by chi-square testing and continuous variables by t-tests. P-values of <0.05 were considered statistically significant. Statistical analysis was performed using SPSS, version 28.0.

2.4 Results

Enrollment and Baseline Characteristics of the Patients

A flow diagram showing the process of subject enrollment is shown in Fig. 1. Out of 80 patient's 20 patients withdrew from the study before randomization and a total of 60 patients were randomized (30 each in the acotiamide 300mg OD and acotiamide 100mg TID groups) before analysis. There were no significant differences in the baseline characteristics between groups (Table 1).

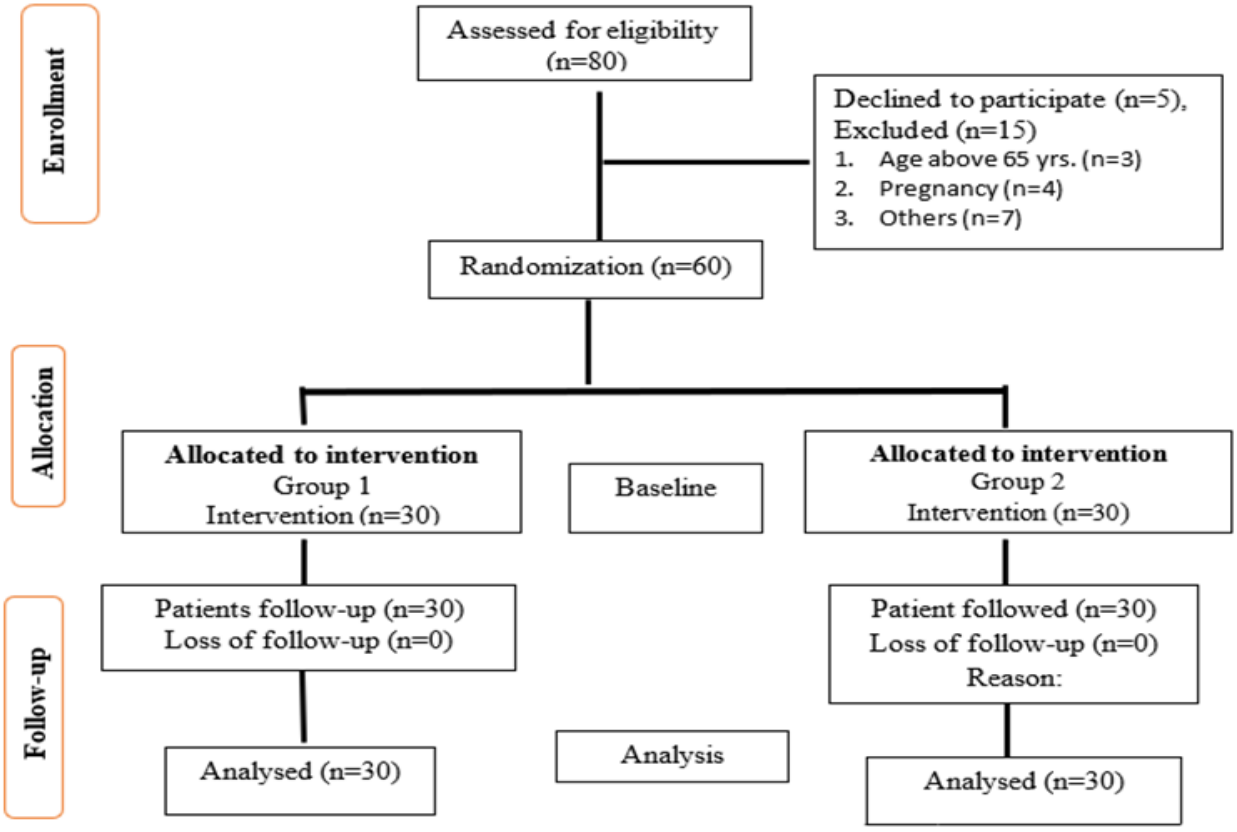

Fig.1 Flow Chart of Participants through the Study According to Consort Statement

III. DEMOGRAPHIC DISTRIBUTION

A. Age Distribution

- Age distribution analysis of both groups (according to the treatment given) revealed comparable pattern.
- The minimum age was 19 years and the maximum age was 64 years in the total sample.
- The mean±SD of group 1 and 2 was 43.36±12.01and 43.6±9.89 years respectively.
- No statistically significant difference was found in the age between the groups (p=0.93).

Table 1. Age Distribution of Patients in both Groups

Age (years)	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Mean±SD	43.36±12.01	43.6±9.89	43.6±10.91	0.93[a]
18-35	6 (20)	6 (20)	12(20)	0.933 [b]
36-55	19(63.33)	20(66.67)	39(65)	
56-65	5(16.67)	4(13.33)	9 (15)	

Data presented: Mean±SD or No (%); p>0.05, considered not significant

Tests used: [a]Unpaired t-test; [b]Chi-square test

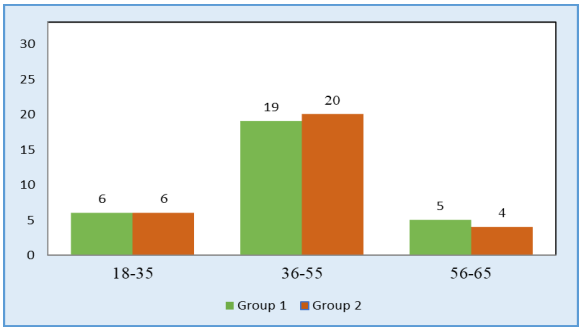

Fig. Age Distribution of Patients in both Groups

B. Gender Distribution

- The data collected on gender distribution revealed that there were more female (n=36, 60%) patients compared to male patients (n=24, 40%).
- Comparison between two groups shows no significant statistical difference (p=0.792)

Table 2. Gender Distribution of Patients in both Groups

Gender	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Male	11 (36.67)	13(43.33)	24(40)	0.792
Female	19(63.33)	17(56.67)	36(60)	

Data presented: No (%); p>0.05, considered not significant

Tests used: Chi-square test

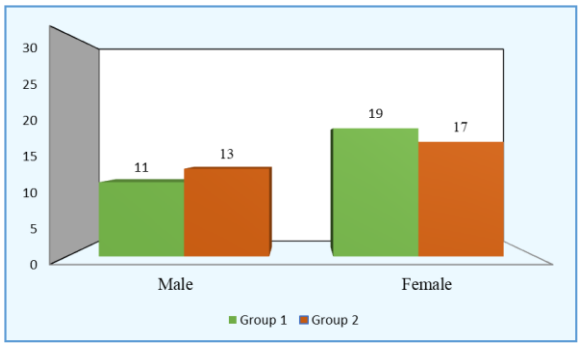

Fig 2. Gender Distribution of Patients in both Groups

C. Ethnicity

- The data collected on ethnicity revealed that all patients were not-Hispanic/Latino.
- Comparison between two groups shows no significant statistical difference (p=1.00)

Table 3. Ethnicity of Patients in both Groups

Ethnicity	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Hispanic/ Latino	0	0	0	1.00
Not Hispanic/ Latino	30(100)	30(100)	60(100)	

Data presented: No (%); p>0.05, considered not significant

Tests used: Chi-square test

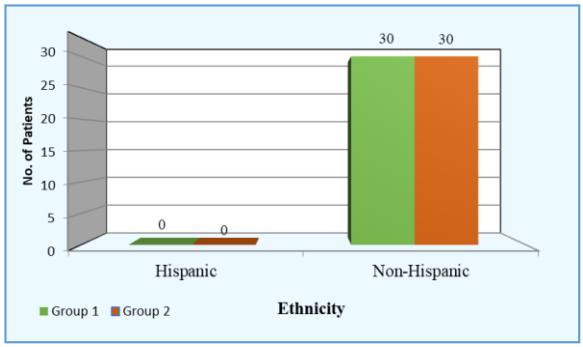

Fig 3. Ethnicity of Patients in both Groups

D. Race

- The data collected on ethnicity revealed that all patients were Asian.
- Comparison between two groups shows no significant statistical difference (p=1.00)

Table 3. Race of Patients in both Groups

Race	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Asian	30(100)	30(100)	60(100)	1.00

Data presented: No (%); p>0.05, considered not significant

Tests used: Chi-square test

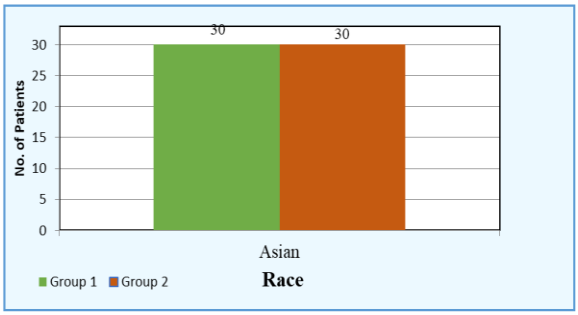

Fig 3. Race of Patients in both Groups

E. Body Mass Index (BMI)

- BMI distribution analysis of both groups (according to the treatment given) revealed comparable pattern.
- The BMI below 18 kg/ m^2 was noted in 3.33% (n=1) in group 2 and 16.67% (n=5) patients had BMI 30 kg/ m^2 and above 19 in group 1.
- The BMI mean±SD value of group 1 and 2 was 25.83±4.188 and 23.84±2.82 kg/ m^2 respectively.
- No statistically significant difference was found in the BMI between the groups (p=0.09).

Table. Body Mass Index (BMI) of Patients in both Groups

BMI Kg/m^2	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Mean±SD	25.83±4.188	23.84±2.82	24.83±3.68	
Below 18	0	1(3.33)	1(1.67)	0.09
18.5-24.9	14 (46.67)	16 (53.33)	30(50)	
25.0-29.9	11(36.67)	13(43.33)	24(40)	
30.0 and above	5(16.67)	0	5(8.33)	

Data presented: Mean±SD or No (%); p>0.05, considered not significant

Tests used: Chi-square test

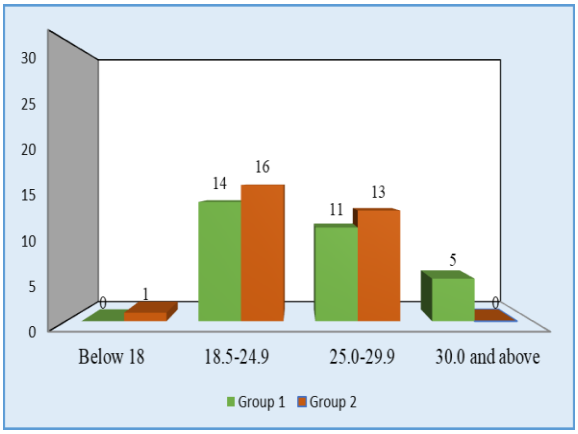

Fig. Body Mass Index (BMI) of Patients in both Groups

F. Clinical Presentation

- The data showed that majority of patients had heartburn (Group 1: n=18, 60% and group 2: n=20, 66.67%), regurgitation (Group 1: n=18, 60% and group 2: n=16, 53.33%) and abdominal discomfort (Group 1: n=16, 53.33% and group 2: n=18, 60%).
- Comparison between two groups shows no significant statistical difference (p>0.05)

Table. Clinical Signs & Symptoms of Patients in both Groups

Clinical signs & symptoms		Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Heartburn	Absent (1)	12 (40)	10(33.33)	23(38.33)	0.59
	Present (2)	18(60)	20(66.67)	37(61.67)	
Regurgitation	Absent (1)	12 (40)	14(46.67)	22(36.67)	0.60
	Present (2)	18(60)	16(53.33)	38(63.33)	
Belching	Absent (1)	23 (76.67)	24 (80)	47(78.33)	0.75
	Present (2)	7(23.33)	6(20)	13(21.67)	
Abdominal discomfort	Absent (1)	14(46.67)	12 (40)	26(43.33)	0.60
	Present (2)	16(53.33)	18(60)	34(56.67)	
Nausea	Absent (1)	23(76.67)	20 (66.67)	43(71.67)	0.30
	Present (2)	7(23.33)	10(33.33)	17(28.33)	
Chest pain	Absent (1)	25(83.33)	24(80)	49(81.67)	0.73
	Present (2)	5(16.67)	6(20)	11(18.33)	

Dysphagia	Absent (1)	27(90)	28(93.33)	55(96.67)	0.64
	Present (2)	3(10)	2(6.67)	5(8.33)	
Dry cough	Absent (1)	26(86.67)	27(90)	53(88.33)	0.68
	Present (2)	4(13.33)	3(10)	5(8.33)	

Data presented: No (%); p>0.05, considered not significant;
Tests used: Chi square test

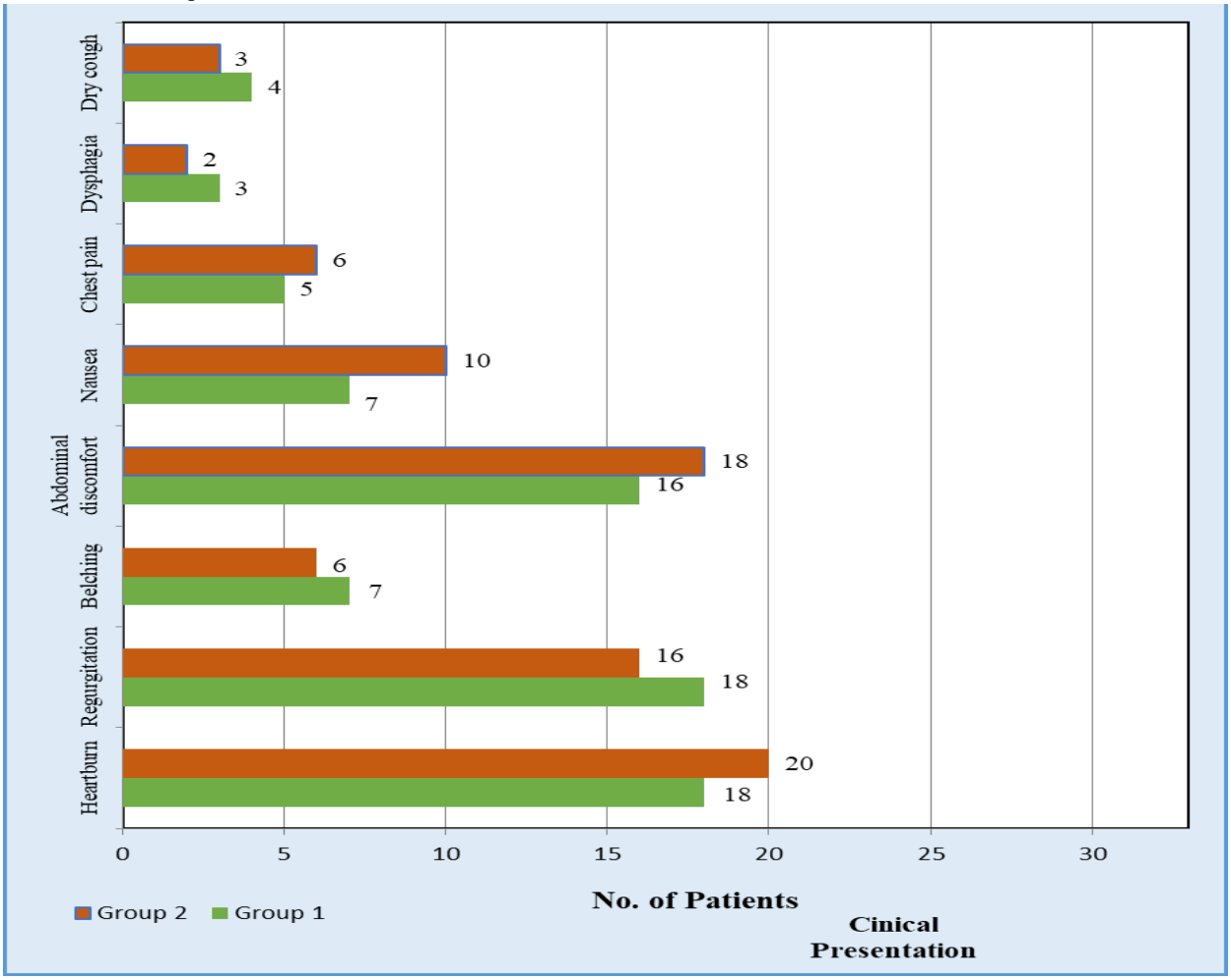

Fig. Clinical Presentation of Patients in both Groups

G. Co-morbidities

- The data showed that the majority of patients had hypertension (Group 1: n=14, 46.67% and group 2: n=13, 43.33%), and diabetes mellitus (Group 1: n=10, 33.33% and Group 2: n=6, 20%)
- Comparison between two groups shows no significant statistical difference (p>0.05)

Table. Co-morbidities of Patients in both Groups

Co-morbidities	Present/Absent	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Hypertension	Absent (1)	16 (53.33)	17(56.67)	33(55)	0.79
	Present (2)	14(46.67)	13(43.33)	27(45)	
Diabetes mellitus	Absent (1)	20 (66.67)	24(80)	44(73.33)	0.24
	Present (2)	10(33.33)	6(20)	16(26.,67)	
Hypothyroidism	Absent (1)	27 (90)	26 (86.67)	53(88.33)	0.68
	Present (2)	3(10)	4(13.33)	7(11.67)	
Asthma	Absent (1)	29(96.67)	30(100)	59(98.33)	0.31
	Present (2)	1(3.33)	0	1(1.67)	

Data presented: No (%); p>0.05, considered not significant; Tests used: Chi square test

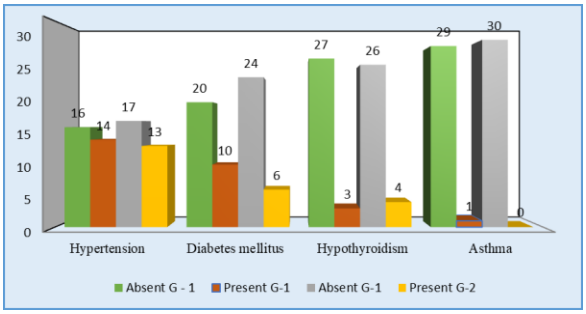

Fig. Co-morbidities of Patients in both Groups

H. Personal Habits

- The personal habits data revealed that patients diet history showed use of fried food (Group 1: n=16, 53.33% and group 2: n=15, 50%), spicy food (Group 1: n=12, 40% and group 2: n=13, 43.33%), and caffeine intake (Group 1: n=13, 43.33% and group 2: n=17, 56.67%).
- Comparison between two groups shows no significant statistical difference (p>0.05)

Table. Personal Habits of Patients in both Groups

Personal Habits	Present/Absent	Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
Fried Food	Absent (1)	14(48.27)	15 (50)	29(49.14)	0.79
	Present (2)	16(53.33)	15 (50)	31(51.67)	
Spicy Food	Absent (1)	18(60)	17(56.67)	35(58.33)	0.79
	Present (2)	12(40)	13(43.33)	25(41.67)	
Caffeine in take	Absent (1)	17(56.67)	13(43.33)	30(50)	0.30
	Present (2)	13(43.33)	17(56.67)	30(50)	
Tobacco	Absent (1)	22(73.33)	23(76.67)	45(75)	0.76
	Present (2)	8(26.67)	7(23.33)	15(25)	
Smoking	Absent (1)	25(83.33)	26(86.67)	51(85)	0.71
	Present (2)	5(16.67)	4(13.33)	9(15)	
Alcohol	Absent (1)	27(90)	28(93.33)	55(88.33)	0.64
	Present (2)	3(10)	2(6.67)	5(8.33)	

Data presented: No (%); p>0.05, considered not significant; Tests used: Chi square test

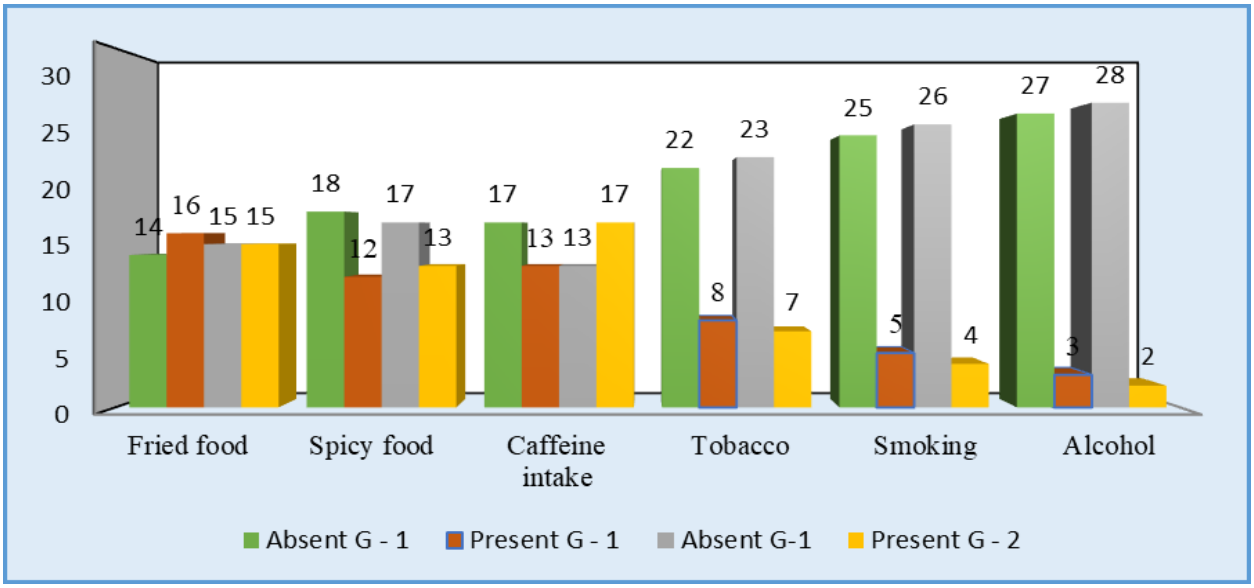

Fig. Personal Habits of Patients in both Groups

I. Adverse events

- The data showed that very few patients had adverse events.
- Comparison between two groups shows no significant statistical difference (p>0.05)

Table. Adverse Events in Patients of both Groups

Adverse Events		Group 1 (n=30)	Group 2 (n=30)	Total (n=60)	p-value
GI upset	Absent (1)	28 (93.33)	28 (93.33)	56(93.33)	1.00
	Present (2)	2(6.67)	2(6.67)	4(6.67)	
Headache	Absent (1)	30 (100)	28(93.33)	58(96.67)	0.15
	Present (2)	0	2(6.67)	2(3.37)	
Dizziness	Absent (1)	30 (100)	29 (96.67)	59(98.33)	0.31
	Present (2)	0	1(1.33)	1(1.67)	

Data presented: No (%); p>0.05, considered not significant;
Test used: Chi square test

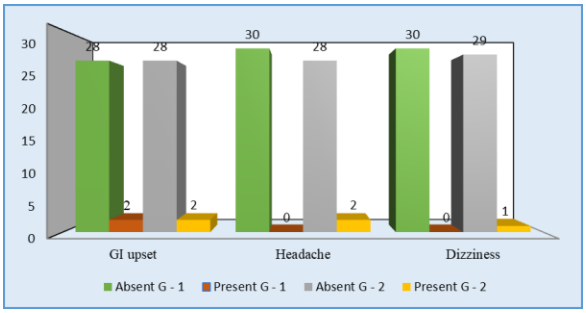

Fig. Adverse Events in Patients of both Groups

IV. STUDY OUTCOMES

A. Primary Outcome

Scoring of Frequency Scale for Symptoms of GERD (FSSG)

- FSSG scoring analysis of both groups (according to the treatment given) revealed comparable pattern.
- The FSSG mean±SD score of groups 1 and 2 was 14.36±1.71 and 14.4±1.71 respectively at baseline whereas after treatment FSSG score was 4.23±2.07 and 4.7±2.24 respectively.
- No statistically significant difference was found in the FSSG score between the groups at baseline (p=0.92) and after treatment (p=0.40) whereas intragroup comparison showed statistically extremely significant difference (p<0.0001).

Table. Scoring of GERD (FSSG) Score in Patients of both Groups

FSSG	Group 1 (n=30)	Group 2 (n=30)	p-value
Baseline	14.36±1.71	14.4±1.71	0.92
After treatment	4.23±2.07	4.7±2.24	0.40
p-value	<0.0001	<0.0001	

Data presented: Mean±SD; p>0.05, considered not significant
Tests used: Unpaired and Paired t test

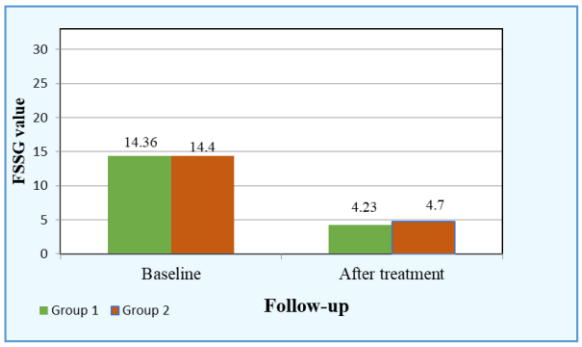

Fig. Scoring of GERD (FSSG) in Patients of both Groups

B. Secondary Outcome

Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD HRQOL) Scoring

- The table summarizes the mean±SD GERD HRQOL score of each question of groups 1 and 2.
- No statistically significant difference was found in the GERD HRQOL score between the groups at baseline (p>0.05) and after treatment (p>0.05).

Table. GERD-HRQOL Score in Patients of both Groups

GERD HRQOL Questions	Period	Group 1 (n=30)	Group 2 (n=30)	p-value
Q1	Baseline	3.23±2.19	2.83±2.93	0.55
	Follow-up	1.27±1.26	1.20±1.35	0.83
Q2	Baseline	2.50±1.81	2.03±2.01	0.34
	Follow-up	0.00±0.00	0.20±0.61	0
Q3	Baseline	2.03±1.59	2.10±2.16	0.88
	Follow-up	0.00±0.00*	0.07±0.25	0

Q4	Baseline	3.33±2.25	2.63±2.51	0.26
	Follow-up	1.00±1.17	1.23±1.41	0.49
Q5	Baseline	3.33±2.26	2.60±2.49	0.23
	Follow-up	1.63±1.61	1.27±1.42	0.36
Q6	Baseline	1.50±1.36	2.13±2.19	0.18
	Follow-up	0.23±0.82*	0.10±0.40	0.43
Q7	Baseline	0.70±1.44	0.17±0.91	0.09
	Follow-up	0.00±0.00*	0.13±0.48	0
Q8	Baseline	0.67±1.40	0.23±0.97	0.16
	Follow-up	0.00±0.00*	0.00±0.00	0
Q9	Baseline	0.57±1.28	0.83±1.90	0.53
	Follow-up	0.00±0.00*	0.13±3.52	0
Q10	Baseline	0.00±0.00	0.00±0.00	0
	Follow-up	0.00±0.00	0.00±0.00	0

Data presented: Mean±SD; p>0.05, considered not significant

Tests used: Unpaired t test

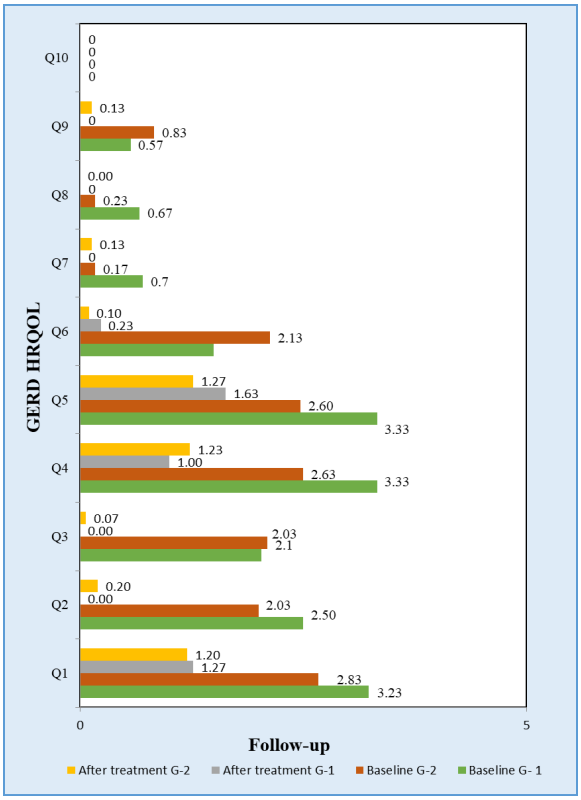

Fig. GERD-HRQOL Questions in Patients of both Groups

GERD HRQOL Scoring

GERD HRQOL scoring analysis of both groups (according to the treatment given) revealed comparable pattern.

- The GERD HRQOL mean ± SD score of groups 1 and 2 was 17.87±11.35 and 15.57±13.59 respectively at baseline whereas after treatment GERD HRQOL score was 4.13±4.36and 4.33±5.02 respectively.
- No statistically significant difference was found in the GERD HRQOL score between the groups at baseline (p=0.47) and after treatment (p=0.86). whereas intragroup comparison showed statistically extremely significant difference (p<0.0001).

Table. GERD-HRQOL Score of Patients in both Groups

GERD HRQOL	Group 1 (n=30)	Group 2 (n=30)	p-value
Baseline	17.87±11.35	15.57±13.59	0.47
After treatment	4.13±4.36	4.33±5.02	0.86
p-value	<0.0001	<0.0001	

Data presented: Mean±SD; p>0.05, considered not significant

Tests used: Unpaired t test

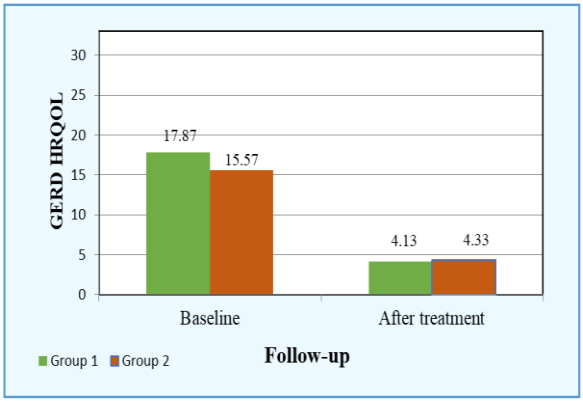

Fig. GERD-HRQOL Score of Patients in both Groups

Morisky Medication Adherence Scale (MMAS) score

- MMAS scoring analysis of both groups (according to the treatment given) revealed comparable pattern.
- The MMAS mean±SD score of groups 1 and 2 was 7.77±0.64 and 7.47±0.73 respectively after treatment.
- No statistically significant difference was found in the MMAS score between the groups after treatment (p=0.199).

Table. MMAS Score in Patients in both Groups

MMAS Score	Group 1 (n=30)	Group 2 (n=30)	p-value
After treatment	7.77±0.64	7.47±0.73	0.199

Data presented: Mean±SD; p>0.05, considered not significant

Tests used: Unpaired t test

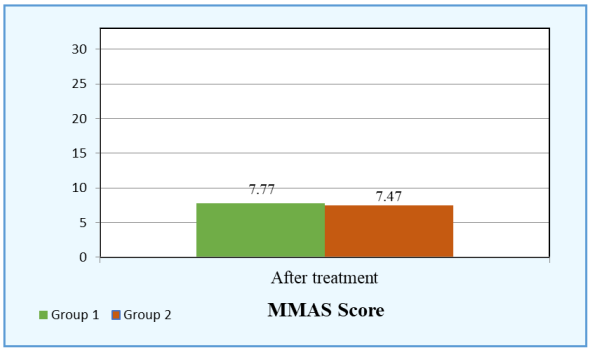

Fig. MMAS Score of Patients in both Groups

V. DISCUSSION

The present study reports the effectiveness of acotiamide 300mg OD and acotiamide 100mg in the treatment of GERD.

A total of 80 patients were assessed eligibility, out of which only 60 patients were eligible and the others 20 patients were excluded as they do not meet the specific eligibility criteria. Hence, 60 patients who met specific eligibility requirements were enrolled in the study according to inclusion criteria and were randomly allocated into two groups.

Prokinetic medications are thought to help GERD by boosting esophageal peristalsis, expediting esophageal acid clearance, and aiding gastric emptying as well as raising the baseline pressure of the lower esophageal sphincter (LES). These include dopamine receptor antagonists, GABA-B receptor agonists, and 5-hydroxytryptamine (5-HT) receptor agonists. Although many studies have demonstrated that adding a prokinetic to PPI medication helps reduce the symptoms of GERD, there is still considerable debate in the literature regarding the effects of prokinetics on esophageal function.

In the systematic review conducted by Jorabar Singh Nirwan et al. 2020 has demonstrated the significant global burden of GERD with approximately 1.03 billion individuals suffering from the condition globally. In their systematic review, authors have identified that obese individuals are significantly more at risk of suffering from GERD and females are also more at risk than males. They also highlight the prevalence of GERD was also higher in those who had a high intake of food and drinks associated with obesity, such as fatty food and carbonated drinks, and was significantly higher in those with a moderate to high intake of coffee/tea. Authors also mentioned in their study that the prevalence of GERD was higher in those aged 35–59 years than those aged 18–34 years but was slightly lower in those aged ≥60 years compared with those aged 35–59 years.

They were 40 % males and 60 % female participants in our study which supports the existing literatures. In our study it shows GERD is dominant in females than males.

They were 65 % subjects from age group 36-55 follwed by 20% subjects in age group 18-35 and 15% in subject in age group 56-65.

Subjects BMI (Kg/m^2) were also taken into consideration 1.67% subjects were underweight,50% subjects were normal weight, 40% subjects were overweight and 8.33patients were obese according WHO classification of BMI.

Our data showed that majority of patients had heartburn (Group 1: n=18, 60% and group 2: n=20, 66.67%), regurgitation (Group 1: n=18, 60% and group 2: n=16, 53.33%) and abdominal discomfort (Group 1: n=16, 53.33% and group 2: n=18, 60%).

Our data also showed that majority of patients had hypertension (Group 1: n=14, 46.67% and group 2: n=13, 43.33%), and diabetes mellitus (Group 1: n=10, 33.33% and group 2: n=6, 20%). The personal habits data revealed that patients diet history showed use of fried food (Group 1: n=16, 53.33% and group 2: n=15, 50%), spicy food (Group 1: n=12, 40% and group 2: n=13, 43.33%), and caffeine intake (Group 1: n=13,

43.33% and group 2: n=17, 56.67%). Minor ADRs such as GI upset, headache and dizziness were reported in our study which doesn't require treatment withdrawal. The study outcome parameters showed significant improvement in FSSG and GERD HRQL scores from baseline to end of treatment.

VI. CONCLUSION

In our study, we concluded that both the formulations of acetoamide have shown effective in alleviating the symptoms of GERD and in improving the Quality of Life (QoL) of patients over a 4-week treatment period. Both the formulations depict similar effectiveness in the current study. Still further research is required with large sample size to authenticate the results.

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