

**EFFICACY AND SAFETY OF POLYHERBAL FORMULATION IN ACID PEPTIC DISEASES****Dr. Porwal Ashwin<sup>1\*</sup>, Dr. Gandhi Paresh<sup>2</sup>, Gajanan Bhagwat<sup>3</sup>**

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**ABSTRACT**

**Background:** Acid peptic diseases mainly reports as increase in the gastric secretions that leads to feeling of discomfort in gastrointestinal tract. Most of the world's population (75-80%) rely on herbal medicines. This study was conducted with the objective to evaluate the efficacy and safety of polyherbal formulation in acid peptic disease. **Material and Methods:** It is open label, single center, non comparative study conducted using Polyherbal formulation in tablet form (Acideem) on patients visiting at Healing Hands Clinic OPD. Efficacy were calculate using gastrointestinal symptoms rating scale (GSRS) Scale and safety by means of adverse events reporting's. **Results:** After treatment (AT) score results [Mean= 2.16, SD 1.22] less as compare to before treatment (BT) [Mean=3.5, SD=1.88] score of GSRS scale. Improvement in overall symptoms with P value <0.001 and the Wilcoxon Signed Rank test were applied at 5% of level of significance. **Conclusion:** This polyherbal formulation (Acideem) in tablet form is found to be effective in participants with acid peptic diseases.

**INTRODUCTION**

Acid peptic diseases mainly affects the mucosal defence in gastrointestinal tract (GI). It includes multiple conditions like gastro-oesophageal reflux disease (GERD), oesophageal ulcer, Zollinger Ellison Syndrome (ZES) and Meckel's diverticular ulcer, gastritis, gastric ulcer, duodenal ulcer. In all these conditions individuals come with common problem i.e. increase in the gastric secretions that leads to feeling of discomfort in GI. With the increase in age cases of gastric ulcers reported more in number as compared to duodenal ulcers.<sup>[1]</sup> Ulcers are necrotic mucosal defects come out of muscularis mucosa and into submucosa, whereas erosions are superficial necrotic defects.<sup>[2]</sup> When there is erosion of lining of stomach or duodenum it can be called as peptic ulcer.<sup>[3]</sup> As per site of ulcers, common two types are gastric ulcer located in stomach and duodenal ulcer located in duodenal bulb, the area which is largely exposed to acid content for a time period and in concentration that produces ulcer.<sup>[4]</sup> In peptic Ulcer disease dyspepsia is a condition in which epigastric pain, discomfort, or a burning sensation majorly present as symptoms. It is been reported that worlds 10% population suffering from Peptic ulcers.<sup>[5]</sup> The most common causes are helicobacter pylori infection or use of nonsteroidal anti-inflammatory drugs (NSAIDs).<sup>[6,7]</sup>

Other causes may include disturbance of ulceration site equilibrium due to enhanced aggression or reduced mucosal resistance, alcohol abuse, smoking unhealthy food- lifestyle habits, regular stress that aggravates the chance of ulcers.<sup>[8]</sup> Most of the world's population (75-80%) rely on herbal medicine at early stage because of cultural acceptability, compatibility with human body and lesser side effects.<sup>[9]</sup> Some histological Studies reported that these herbal medicines did not show acute toxicity.<sup>[10]</sup> Even in Photochemical screening of it showed presence of flavonoids and tannins which helps in antiulcer activity. This study was conducted with the objective to evaluate the efficacy of polyherbal formulation (Tablet Acideem) in patients with acid peptic disease in reducing symptoms using patients reported outcome instrument like gastrointestinal symptoms rating scale (GSRS) and safety by means of adverse events reporting.

**MATERIAL AND METHODS**

**Material:** This polyherbal formulation contains Amala (*Embllica officinalis*) Fruit, Mulethi (*Glycyrrhiza Glabra*) Root, Guduchi (*Tinospora cordifolia*) Stem, Sunthi (*Zingiber officinale*) Rhizome, Bael Ext (*Aegle marmelos*) Fruit, Shankha Bhasma, Kapardik Bhasma,

Shuddha Svarnagairik, and Permitted Excipients & Preservative.

**Dose:1 Tablet 12 hourly**

**Subjects:** All the interested patients diagnosed with acid peptic disease were identified in OPD at Healing Hands Clinic, Pune. Total 50 Participants were screened, of which 37 were selected and out of the 37 participants, 28 were male and 09 were female. Total 30 participants have (male 22 female 8) successfully completed the study till end

**Methodology:** Voluntary informed consent were taken and screened as per inclusion and exclusion criteria. Patients with acid peptic disease were included with aged more than 18 years. Patients did followed all study directions and came for all follow-up visits as per the protocol. In addition, subjects who willingly accepted the restrictions of the study, it means not taken any antacids or any medication that may affect the gastrointestinal acid balance. Study Data were collected using Gastrointestinal Symptom Rating Scale (GSRs). Data collection started at visit 1 before treatment and followed for every week till 4th week as after treatment last day.

**Data collection:** Eligible candidates were enrolled in the study. To each participant GSRs questionnaires scale (PRO instrument) is handed over to collect the data along with demographic details. This scale is divided into total 5 domains with questionnaires on abdominal pain (3 questions), reflux syndrome (2 questions), diarrhoea syndrome (3 questions), indigestion syndrome (4 questions), and constipation syndrome (3 questions). It includes total 15 questions with total 7 options which measure the rating of inconvenience, it means score of 1 relates to minimal and score 7 to maximum. The treatment response were evaluated based on changes in the GSRs or GSRs sub-items before and after 1 week, 2 week, 3 week and after 4 weeks and during the treatment.

**Statistics:** Total 30 participant were evaluated with males 22(73.33%) and females were 8(26.67%). Average age of participants were 30.47 years (SD=7.19), average weight was 61.17 Kg (SD=8.04). All the reports reported as mean ± standard deviation. Improvement rate in each subject was calculated from the scores, and the mean values were compared between the before and after treatment using the Wilcoxon Signed Rank at 5% of Level of significance.

	Mean (SD)					P Value
	BT	AT1	AT2	AT3	AT4	
Abdominal pain	4.37 (1.19)	4.29 (1.19)	3.92 (1.33)	3.39 (1.33)	2.48 (1.14)	<0.001
Reflux syndrome	4.05 (1.43)	3.95 (1.44)	3.72 (1.37)	3.2 (1.38)	2.45 (1.2)	<0.001
Diarrhoea syndrome	1 (0)	1 (0)	1 (0)	1 (0)	1 (0)	-
Indigestion syndrome	3.92 (1.76)	4.12 (1.78)	3.38 (1.55)	3.16 (1.5)	2.38 (1.24)	<0.001
Constipation syndrome	3.92 (1.72)	4.19 (1.75)	3.63 (1.58)	3.33 (1.49)	2.51 (1.2)	<0.001
Overall Mean Score	3.5 (1.88)	3.52 (1.9)	3.11 (1.7)	2.81 (1.57)	2.16 (1.22)	<0.001

\*p values calculate by using the Wilcoxon Sign Rank test at 5% of Level of significance

**RESULTS**

There is significant difference between before treatment mean score and after treatment (after 4-week) mean score in subscale of GSRs questionnaire such as abdominal pain, reflux, indigestion and constipation except diarrhoea with p value <0.001 as mentioned in

above table and figures. After treatment (AT) score results less as compare to before treatment (BT) score, it shows improvement in symptoms. Overall GSRs mean score after treatment [Mean= 2.16, SD 1.22] is significantly lesser than before treatment [Mean=3.5, SD=1.88].

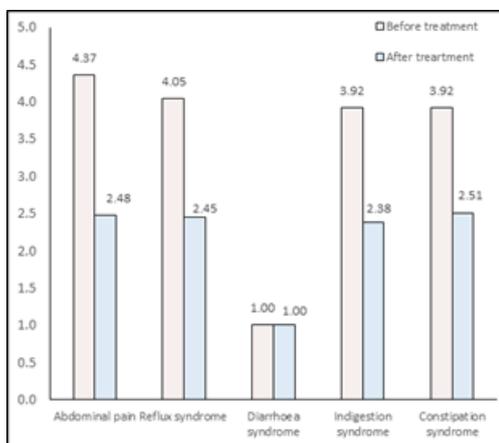


Figure 1: GSRs Subscale MeanScore.

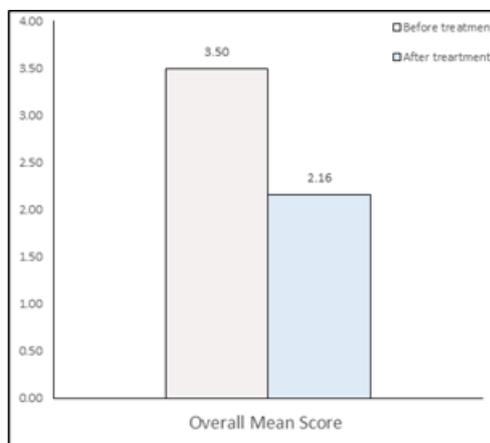


Figure 2: GSRs Mean Score.

## DISCUSSION

In 4 weeks of treatment symptoms calculated using GSRS scale shows overall score reducing from before treatment scores. This evaluated study data suggests that the formulation is effective for patients with symptoms of acid peptic diseases but not giving the enough evidence due to small sample size of 30 participants. Limitations in this study also include that the participants were not specifically divided further condition wise like gastric ulcer, duodenal ulcer, gastroesophageal reflux disease, oesophageal ulcer, Zollinger Ellison Syndrome (ZES) and Meckel's diverticular<sup>[11]</sup>. Out of 37 participants, 2 participants has reported that there is no effect after 1 week of taking tablet and discontinued the trial. However 5 participants lost to follow up. No diarrhoea symptom is been reported in the study. Acid peptic disease ideally treated by strengthening of mucosal defence as bismuth, sucralfate, and neutralizing acid with antacids, prostaglandin analogues, reduce acid secreting using histamine<sub>2</sub> (H<sub>2</sub>)-receptor antagonists or by proton pump inhibitors.<sup>[12]</sup> The ingredients in this formulation like Amla or Indian gooseberry helps in prevention of peptic ulcer, dyspepsia and improves digestion.<sup>[13]</sup> Mulethi (*Glycyrrhiza Glabra*) Root and stolon species (liquorice) reported as having anti *H. Pylori* effects.<sup>[14]</sup> Although in modern medicine its use in place of bismuth has been suggested that helps to protects against acid and pepsin secretion by covering lesion site and increase mucus secretion.<sup>[15]</sup> Guduchi (*Tinospora cordifolia*) Stem showed clear antiulcer activity in invivo study where decrease in ulcer index, acid content volume has been reported.<sup>[16]</sup> Sunthi (*Zingiber officinale*) Rhizome is a well know herb that contains ~1–4% medically active constituents as volatile oils with anti-oxidant, anti-ulcer activity<sup>[17]</sup>, anti-inflammatory, antitumor<sup>[18]</sup>, carminative, diaphoretic, digestive and gastroprotective activities.<sup>[19]</sup> Shanka Bhasma added in this formulation suggests good effects on peptic ulcer, piles, cough and supposed to have major role in treating *H. pylori* infection that has a about 70% prevalence in third world countries.<sup>[20, 21]</sup> Major component in it is calcium oxide and its preclinical tests were evaluated using aspirin-induced model and very effective antiulcer effects were noted.<sup>[22]</sup> Kapardik Bhasma mentioned in amarkosh<sup>[23]</sup> and using modern techniques its chemical constituent evaluated are Mg, Al, K, Fe and Zn.<sup>[24]</sup> Uses of kapardika bhasm includes indigestion, colic, peptic ulcer, eye diseases, dysentery, earache, ulcer<sup>[25]</sup>, dyspepsia, jaundice, enlarged spleen & liver, asthma, cough.<sup>[26]</sup> Shuddha Svarnagairikis reported as useful in abdominal conditions.<sup>[27]</sup> All the ingredients in this formulation helps to reduce harm by acid content, repair mucosal damage at site, some of them reported as effective against *H pylori* therapy.

## CONCLUSION

Acideem tablet is found to be effective in acid peptic diseases. Overall GSRS mean score after treatment

[Mean= 2.16, SD 1.22] is significantly lesser than before treatment [Mean=3.5, SD=1.88].

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