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Evaluation of Safety and Efficacy of Gastrone A Multi herbal Formulation in Various Gastro-Intestinal Disorders

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ABSTRACT

Digestive disorders affect people from all parts of the world. This cause significant impact on health cost and absenteeism at work place. There are various treatments available in modern medicine but they are either associated with side effects or recurrence. Gastrone a purely herbal remedy has been found to be effective in the treatment of GI disorders. In this study Gastrone was found to be highly effective in the alleviating symptoms of FGDs. There was no adverse effect reported and more than 88% patients responded to treatment.

Keywords: Dyspepsia, Gastrone, Hyperacidity, Belching.

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INTRODUCTION

Digestive disorders and diseases significantly affect millions of persons worldwide inducing a highly significant economical impact comprising health care costs and work absenteeism, in addition to patient's decreased quality of life. Gastrointestinal (GI) diseases affect an estimated 60 to 70 million US citizens annually. In 2004, there were an estimated 4.6 million hospitalizations, 72 million ambulatory care visits, and 236,000 deaths attributable to GI disease. Spending on GI diseases in the United States has been estimated at $142 billion per year in direct and indirect costs[1]. Functional gastrointestinal disorders (FGDs) is a term used to define several variable combinations of chronic or recurrent gastrointestinal (GI) symptoms with no identified underlying etiopathology. Dyspepsia is derived from the Greek words dys and pepse and literally means "difficult digestion." Dyspepsia can occur due to organic causes, but the majority of patients suffer from functional dyspepsia (FD). It is broadly defined as pain or discomfort centered in the upper abdomen with symptoms such as epigastric pain, postprandial fullness, early satiety, anorexia, belching, nausea and vomiting, upper abdominal bloating, and even heartburn and regurgitation[2]. People with functional dyspepsia have a significantly reduced quality of life when compared to the general population. The prevalence of dyspepsia varies considerably between different populations and this difference might be related to, (1) true difference in frequency of the condition, (2) criteria used to diagnose it and (3) degree of meticulousness to exclude organic causes. The annual incidence of dyspepsia is approximately 9–10%, and 15% of patients have chronic (> 3 months in a year), frequent (> 3 episodes per week) and often severe symptoms[3.4]. Due to the diversity of dietary habits within individual populations the role of diet in dyspepsia has not been established. Some western studies havereported that excessive coffee or tea intake has not been shown to be related to the presence of dyspepsia/UD[5.6]. However one Canadian survey showed that heavy intake of cola was associated with markedly increased prevalence of dyspepsia[7]. Study from Mumbai India have shown that vegetarians or non vegetarian diet have no effect on dyspeptic symptoms, and spicy, fried or food prepared outside the home contributed insignificantly to worsening of symptoms[8]. While a population-based study from Malaysia showed that high chilly intake was an independent risk factor for dyspepsia[9]. Rice-based diet, popular among many Asian population may be better tolerated than Western wheat-based diet by many patients with functional bowel disorders[10]. Association of regular smoking and dyspepsia has not been consistent. In the few population-based studies that have examined FD, smoking has not been shown to be a risk factor[11.12.13]. Two studies from India and New Zealand have showed definite associations between alcohol and UD. Two population based studies have revealed a relationship of dyspepsia and NSAIDs[14]. Many

modern drugs have been tried in the treatment of FD that includes H_2 receptor blockers, Proton pump inhibitors, Antacids, Antidepressants but none of them have been found to effective in the treatment of this disorder. Herbal medicines have been found to be highly effective in the treatment of various digestive disorders. These drugs can be taken regularly without any side effect and tolerance. Gastrone is a well researched herbal remedy that has been found to be effective in the treatment of various digestive disorders. It contains herbs like Ginger, Pepper, Cumin seeds, Plumbago that helps in the treatment of dyspepsia. Ginger root is a medicinal herb used primarily for the treatment of Dyspepsia (discomfort after eating), this includes the symptoms of bloating, heartburn, flatulence, and nausea[15]. It is also considered helpful as a preventative for motion sickness and as a digestive[16]. Cumin is extremely beneficial for digestive disorders and other related problems, such as biliousness, morning sickness, indigestion, atonic dyspepsia, diarrhea, mal absorption syndrome and flatulent colic. Cumin contains an aromatic organic compound called Cuminaldehyde, which activates the salivary glands, thereby helping in the digestion process[18]. Fine powder of Piper nigrum fruits works well, when given with water in treating chronic colitis. Piper nigrum is an excellent panacea for anorexia, dyspepsia, the enlargement of the liver and spleen and is beneficial[19]. Looking at the beneficial effects of Gastrone ingredients, a study was planned to evaluate the efficacy of this product in the treatment of dyspepsia.

MATERIALS AND METHOD

Inclusion Criteria: Thirty seven patients between 35-67 years of age who were suffering from chronic dyspepsia were selected for this trial. These patients had no other systemic illness and were not taking any drugs including health supplements. Exclusion Criteria: Patients who had history of peptic ulcer, cancer or severe vomiting or any other terminal illness were excluded from this trial. It was an open, non-randomized clinical trial conducted at the M.A Hospital, Varanasi as per ethical guidelines of the declaration of Helsinki. The patients who attended the OPD of the medicine department were informed about the study drug, its effects, duration of the trial, and overall plan of the study. Patients were included in the clinical study only after a written informed consent was obtained from them, and a witness, independent of the clinical trial, signed the informed consent form. After they signed the consent form a thorough clinical and symptomatic evaluation was carried out by the investigator. After proper blood investigation these patients were given tablet Gastrone at the dose of 1tablet twice daily for 4 weeks before meals. Patients reported to the out-patient department every week for 6 weeks. They were asked to report to the investigator any side effects reported during and 2 weeks after the trial.

RESULTS AND DISCUSSION

Total 37 patients were included in the trial and all of them successfully completed the 4 weeks treatment period. There were 27 men and 10 women included in the trial and the mean age of the group was 38.67 years. The analysis showed that all 37 patients had upper abdominal discomfort and in addition 27 patients had heartburn and hyperacidity, 32 patients had indigestion, 35 patients had belching. After 4 weeks all the patients were found to have excellent response to Gastrone treatment (Figures 1 to 5). None of the patients had any side effect or adverse reaction.

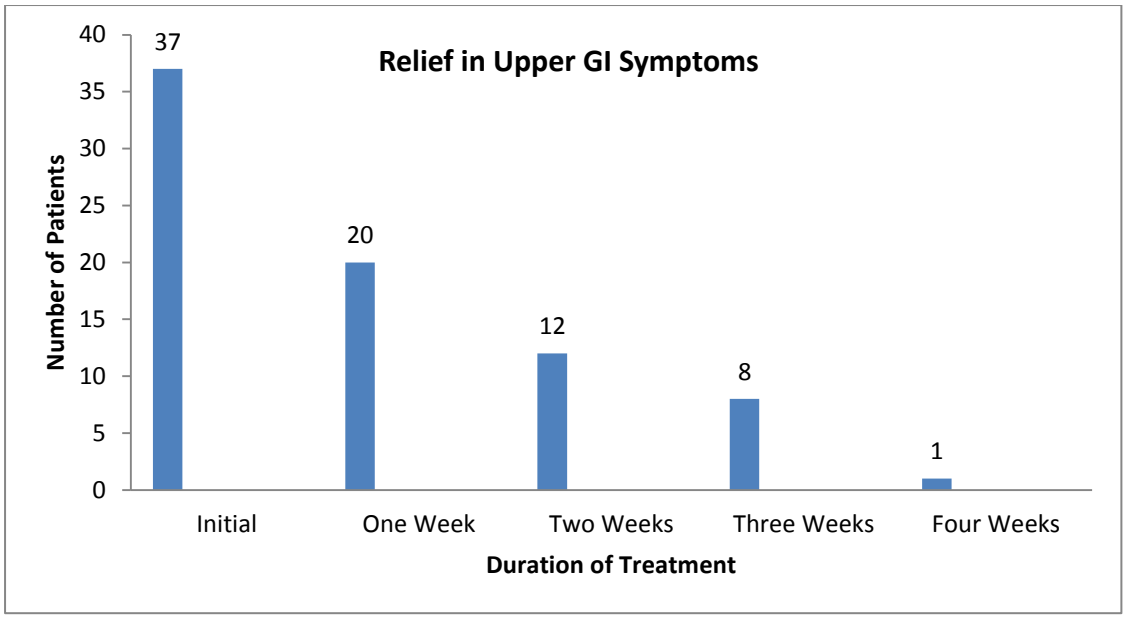

Figure 1: Showing Response of Gastrone on Upper Gastrointestinal Symptoms

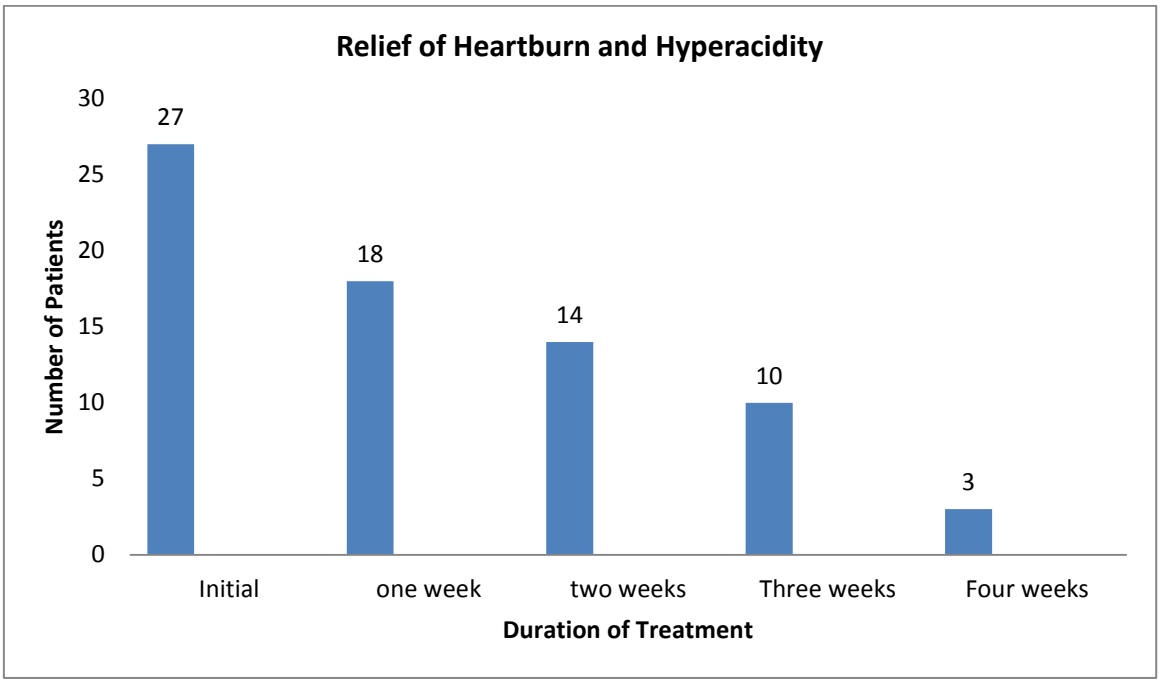

Figure 2: Showing response of Gastrone on Heartburn and Hyperacidity in patients

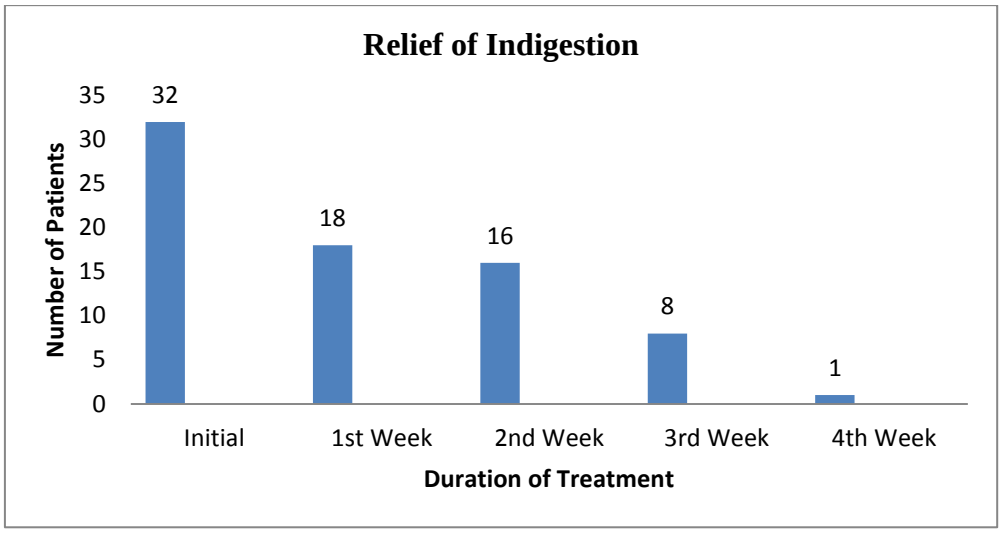

Figure 3: Showing response of Gastrone on indigestion in patients

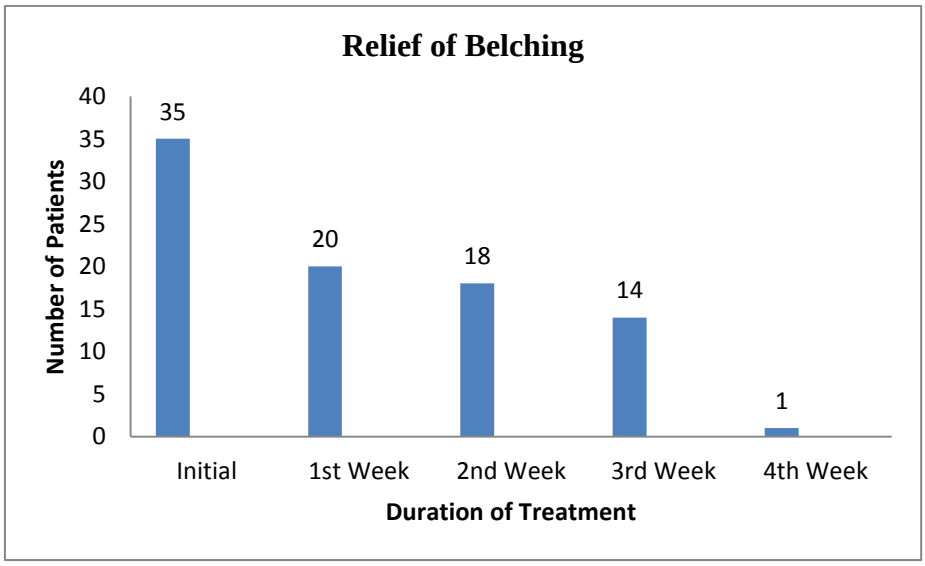

Figure 5: Showing Response of Gastrone in Belching in Patients

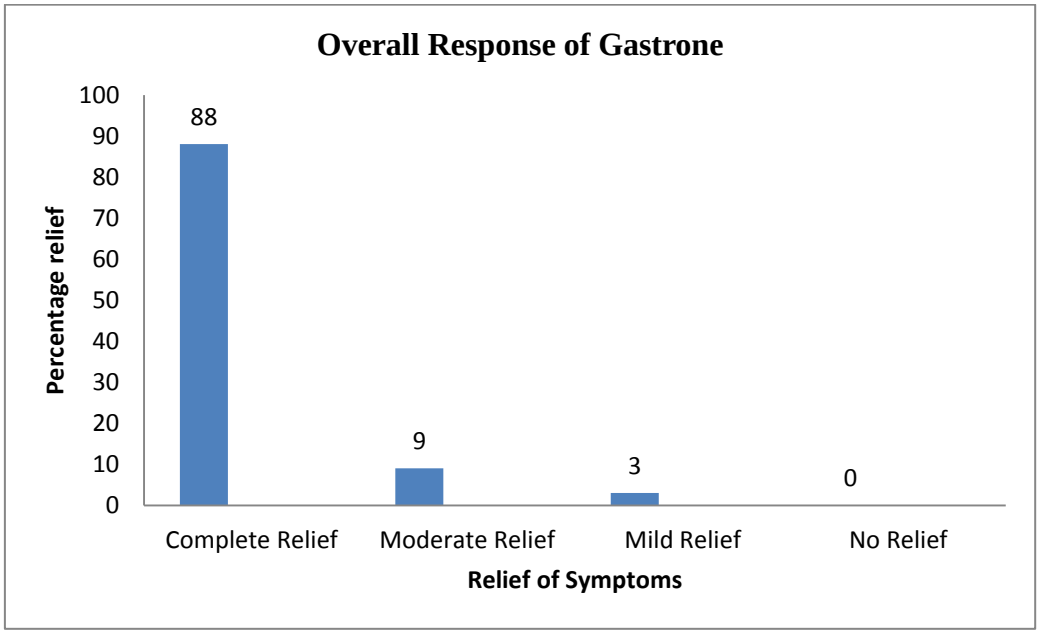

Figure 6: Showing Over all Response of Gastrone in various GI symptoms

Functional gastrointestinal disorders (FGIDs) are a broad spectrum of different disorders that are grouped together. At the moment functional gastrointestinal disorders no cause is known and thus the ability to diagnose them correctly is sometimes challenging. One of the most important societal perspectives resulting from functional bowel disorders is the degree of absenteeism that is recorded among patients with these conditions[20]. For example, it has been estimated that patients with IBS recorded work or school absences of up to 13 days per year compared with a control population, who reported 5 days of absence per year[21]. This level of absenteeism is equivalent to that associated with the common cold and flu and presents a significant burden to any nation's economy.More recently, however, the annual costs incurred by 8 major industrialized countries were estimated at approximately $41 billion, including $25 billion in the United States and over $4 billion each in Japan and Germany[22]. In this study, Gastrone was found to be effective in the treatment of functional gastrointestinal disorders. It now grows in most hot countries, especially India, North Africa, China and the Americas. The spice is especially associated with Morocco, where it is often smelt in the abundant street cookery of the medinas[15]. Cumin is extremely good for digestion and related problems. The very smell (aroma) of it, which comes from an aromatic organic compound called Cuminaldehyde, the main component of its essential oil, activates our salivary glands in our mouth (the mouth watering flavor), facilitating the primary digestion of the food[18]. Next is Thymol, a compound present in cumin, which does same to the glands which secrete acids, bile and enzymes responsible for complete digestion of the food in the stomach and the intestines, due to its Stimulating properties. Ginger root is known for its efficacy in nausea and vomiting. Ginger is also an excellent remedy for indigestion, wind, colic, irritatable bowel and loss of appetite. It is also an good for dyspepsia like bloating, heartburn and hyperacidity[16]. Gastron an Ayurvedic remedy contains these herbs in therapeutic proportions and helps in complete relief of GI symptoms. In this trial Gastrone was found to be effective in relieving symptoms of GI disorders. None of the patients complained of any side effects during and 2 weeks after the discontinuation of treatment.

CONCLUSION

Gastrone was found to be effective in the treatment of various GI disorders. None of the patients complained of any side effects.

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