Clinical Evaluation of Himcocid Suspension and Tablets in Non-Ulcer Dyspepsia

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ABSTRACT
Sixty patients suffering from non-ulcer dyspepsia with chronic epigastric pain and no evidence of any organic disease were included in the study. The patients were admitted to the cardiac and urology emergency wards, divided into 2 groups and were randomly assigned an herbal antacid tablet or suspension known as Himcocid. The dosage of Himcocid tablets was 2 tablets, twice daily in between meals and at bedtime. The dosage of Himcocid suspension was 2 teaspoonfuls in between meals and at bedtime. The patients were regularly followed up for 2 weeks. After 2 weeks they were thoroughly evaluated for elevation of dyspeptic symptoms. The results showed that epigastric pain was relieved in 65.62%, heartburn in 73.68%, fullness in 60%, flatulence in 72.72%, nausea in 64.86%, abdominal distension in 58.62% and vomiting in all the patients. Thus, Himcocid therapy was found useful in all the patients with dyspeptic symptoms. No untoward incidents were seen in any of the patients.

INTRODUCTION
Large groups of patients seen by gastroenterologists in clinical practice with chronic or recurrent gastrointestinal symptoms continue to defy explanation, despite structural and biochemical studies. These patients are generally labelled as having a functional gastrointestinal disorder. Functional gastrointestinal disorders are common conditions in otherwise healthy persons. Upto two-thirds of such persons have one or more symptoms1.

Dyspeptic symptoms are prevalent in one-fourth of the adult population2. The majority of people, however, never seek medical attention for their symptoms. In medical practice, it is among the most common complaints evaluated by both general practitioners and gastroenterologists. The direct and indirect costs of dyspepsia that include diagnostic evaluation, drug therapy and days lost from work are staggering3.
Dyspepsia is a vague, imprecise term that encompasses variety of upper abdominal or epigastric symptoms. According to the Rome II Multinational Consensus, the minimum criteria of diagnosis are as follows:

- Episodic or persistent pain or discomfort centered in the upper abdomen or epigastrium (centered implies that the pain or discomfort is mainly in or around the midline).

- Commonly associated with other symptoms of bloating, early satiety, distension or nausea.

- Many possible causes; clinical history of limited value.

- Physical examination usually normal. Signs of organic disease warrant further investigation.

- Upper endoscopy is the study of first choice.

Dyspepsia may arise from a variety of reasons. These include peptic ulcer disease, gastroesophageal reflux, gastric neoplasms, malabsorption syndromes, NSAIDs, biliary tract disease, pancreatic disease, systemic diseases and others. Certain kinds of food such as tomatoes, spices, fatty foods and coffee can cause symptoms of dyspepsia. Mechanisms underlying include abdominal distension, delayed gastric emptying (cholecystokinin-induced), direct mucosal irritation and the provocation of the gastroesophageal reflux.

A number of organic and functional disorders of the upper gastrointestinal tract may cause dyspepsia. Approximately 20% of the patients with dyspepsia have peptic (gastric or duodenal) ulcer disease and others can be diagnosed with non-ulcer dyspepsia. Gastroesophageal reflux disease is seen in patients who represent with symptoms of substernal burning and regurgitation. A great number of medications may cause dyspepsia and should not be overlooked. Withdrawal of a potentially offending drug trial may often result in symptomatic relief. Pancreatic (pancreatic carcinoma, chronic pancreatitis) and biliary tract disease (cholelithiasis, choledocholithiasis, sphincter of Oddi dysfunction) can also be confused with other causes of dyspepsia. Systemic conditions including pregnancy, diabetes mellitus (gastroparesis diabeticorum or diabetic radiculopathy of the thoracic nerve root), intra-abdominal malignancy, coronary ischemia and thyroid dysfunction. In these patients symptoms may arise from a complex interaction of psychological factors, abnormal visceral pain perception and motility disorders. Dyspepsia may also be associated with other functional gastrointestinal disorders, such as irritable bowel syndrome.

A clinical history is of limited value in distinguishing the causes of dyspepsia. The complete drug and dietary history (including lactose) should be taken. The primary goal should be in identifying patients who are at a high risk for organic disease. Patients should be asked about the character and location of pain, its pattern of radiation, whether it is constant or intermittent and factors that alleviate it. Predominant substernal burning (heartburn) and
regurgitation is highly specific for gastroesophageal reflux disease. The epigastrium is the most common site of pain in dyspepsia of all causes, including biliary tract disease. Peptic ulcer disease is more likely when episodic bouts of rhythmic, gnawing epigastric pain occur between meals or at night\(^\text{12}\).

Non-ulcer dyspepsia patients are more likely to experience an exacerbation of symptoms after meals and seldom have nocturnal pain. Non-ulcer dyspepsia is more likely in younger patients with chronic, vague epigastric pain associated with a variety of other complaints such as bloating and distension. Although these clinical features of dyspepsia may provide clues to the cause, they are nonspecific and cannot be relied upon to make anything other than a speculative diagnosis.

There is no convincing evidence that functional dyspepsia is related to psychological abnormalities or chronic stress. Personality profiles happen to be similar to those patients with other functional gastrointestinal disorders (such as irritable bowel syndrome) or peptic ulcer disease. Patients in all these groups have higher degrees of neurosis, depression, anxiety and hypochondriasis on standard testing. However, these differences are small and unlikely to be of clinical importance, in most cases. Similarly, dyspeptic patients often report onset of symptoms after an acute or chronic stress, but not to a greater extent than other patients do\(^\text{13}\). However, the perceived magnitude of this stress may be greater. In other words, stress, objectively defined, may not be greater but may subjectively be perceived as being more deleterious to persons with functional dyspepsia. Therefore, psychological factors are likely to be important in at least some patients with dyspepsia. To understand a patient’s illness, the clinician must recognize the interplay of personality traits, life events and social structure that may be important in the way a patient perceives and reports symptoms.

A clinical trial was planned to evaluate the efficacy of an herbal antacid known as Himcocid in patients with non-ulcer dyspepsia. The patients had to fulfil at least 3 of the following inclusion criteria: 1) at least 12 consecutive weeks of dyspeptic symptoms without obvious organic cause, 2) No abnormalities on physical examination or laboratory tests, and 3) No focal or structural abnormalities in upper GI endoscopy.

Himcocid suspension or tablet has 4 important ingredients, which offer complete protection from development of non-ulcer dyspepsia. Himcocid is a herbomineral formulation comprising Varatika (Cowrie shell), Dugdhapashana (Soft stone), Mouktika sukti (Oyster shell) and Yashtimadhu (\textit{Glycyrrhiza glabra}).

**MATERIAL AND METHODS**
Patients admitted with cardiac emergency at the Heritage Hospital, Varanasi with no prior history of acid peptic disease and who developed dyspeptic symptoms were included in this trial. A complete physical examination was mandatory in patients, which included a stool test for occult blood testing. Every symptom of dyspepsia had a score on a scale of 1 to 4 depending on whether it was mild, moderate, moderately severe or severe. Sixty patients
presenting with different symptoms of dyspepsia were included in the study and divided into
two groups of thirty each (Table 1). They were randomly dispensed either Himcocid tablets
or suspension. The dosage of the suspension was 10 ml (2 teaspoonsful) twice daily in between
meals and at bedtime. The dosage of Himcocid tablets was 2 tablets in between meals and at
bedtime. Himcocid was given for a period of 2 weeks and the same dyspeptic symptoms again
scored on a scale of 0 to 3; complete disappearance of symptoms=0; moderate relief=1;
mild relief=2 and no relief=3. Any new symptoms were also recorded during the course of drug trial.
Not much of a difference was seen in the results between Himcocid suspension and tablet.

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<th>Table 1: ble showing different symptoms in all the patients (n=60)</th>
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<td>Symptoms</td>
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<td>Epigastric discomfort</td>
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<td>Fullness in the stomach</td>
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<td>Flatulence</td>
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<td>Nausea</td>
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<td>Vomiting</td>
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<td>Abdominal distension</td>
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RESULTS
All the 60 patients completed the study period. Results showed that 21 out of 38 had
complete relief of epigastric discomfort. Heartburn reduced in 14 out of 19 patients and there
was absence of fullness in the stomach in 6 out of 14 patients. Flatulence reduced in 8 out of
18 patients and there was control of nausea in 24 out of 37 patients. The abdominal distension
reduced in 10 out of 17 patients. Vomiting was controlled in all the patients (16 out of 16).
The earliest response was seen in 3-4 days. After 1 week, a majority of the patients reported
relief in symptoms. At the completion of the trial, most of the patients were relieved from
symptoms (Table 2).

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<th>Table 2: Symptomwise score (Pre- and Post-Himcocid therapy)</th>
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DISCUSSION
In general, the most important aspect of therapy is the development of a solid therapeutic
relationship between the physician and patient. The physician should foster the trust and
confidence of the patient by taking a careful history and performing a through physical
examination. Life stress should also be explored, related to the patient’s family, workplace,
personal relationships or living situation. Changes in diet or medications should be
considered. The physician should be aware of the patient’s psychological state, as
gastrointestinal symptoms may be a somatic manifestation of serious psychiatric disease,
such as depression, anxiety or even psychosis. After initial evaluation, a reasonable, cost-
effective diagnostic workup should be proposed to the patient. Although in most cases endoscopy is required, an empiric therapeutic trial may be appropriate in younger patients. The physician should try to reduce the fear that the symptoms will progress into other illness. Follow-up visits should be scheduled initially to determine the patient’s course and response to treatment. Over the course of time, life events that trigger symptoms may become more apparent. In a few cases, referral to a trained psychologist or social worker may be indicated.

Although the role of food in functional dyspepsia is unclear, many patients report improvement with dietary alterations. In some cases a food diary may be helpful. This should suggest foods or life stressors that may be precipitating symptoms. Life stressors are present in virtually everyone’s life, but patients should be counselled on stress reducing measures, such as exercise and good eating and sleeping habits.

Antacids are the most frequently used drugs in the treatment of functional dyspepsia. Controlled studies have shown their superiority to other agents, and their safety and ease of use makes them popular among both patients and doctors. Over the counter sale (OTC) was used in one study as a measurement of dyspepsia prevalence in the general population.

The Himcocid formulation used in this study contains naturally available minerals such as Varatika (Cowrie shell), which is a potent antacid used in the symptomatic treatment of hyperacidity, acid indigestion and heartburn. Dugdhapashana (Soft stone) has cooling, ulcer healing and styptic properties. It is used to treat ulcers and hyperacidity. Mouktika sukti (Oyster shell) has demulcent, acid neutralizing properties that treats pain in the abdomen and dyspepsia\textsuperscript{14}. Yashtimadhu (\textit{Glycyrrhiza glabra}) has ulcer healing and immunomodulatory activity that helps to treat gastric ulcers and hyperacidity\textsuperscript{15}.

In this clinical trial, patients with cardiac and urology history were observed if non-ulcer dyspepsia complications appear during the course of medical and surgical emergencies. Therefore, they require special attention when a physician is managing critically ill patients, to prevent or treat through antacids and H\textsubscript{2} blockers. Himcocid suspension is quite effective in a majority of patients and in almost all symptoms of dyspepsia. There was an overall 60-70\% reduction of symptoms. It was most effective against vomiting, which is the most serious symptom of non-ulcer dyspepsia. Some of the patients with mild dyspeptic symptoms had complete relief from symptoms and a significant reduction in symptom score was found in severe dyspepsia.

**CONCLUSION**

Himcocid (suspension and tablet) is an effective drug to treat non-ulcer dyspepsia. It is effective against almost all symptoms of non-ulcer dyspepsia, especially in vomiting, epigastric discomfort, nausea, heartburn and abdominal distension.
ACKNOWLEDGEMENT
We are thankful to The Himalaya Drug Company, Bangalore, for providing the drug Himcocid (suspension and tablet) to carry out this trial at Heritage Hospital. We are extremely thankful to Dr. (Brig.) R.K. Rakshit, Director, Heritage Hospital for granting his permission to conduct the above study at this institute.

REFERENCES

