

Clinical Evaluation of Efficacy and safety of Himcocid in Non-ulcer Dyspepsia: An Open Comparative Clinical Trial

Dwivedi, K.N., M.D. (Ay.), Ph.D.,

Senior Lecturer, Department of Dravyaguna, Faculty of Ayurveda, Institute of Medical Sciences,
Banaras Hindu University, Varanasi, Uttar Pradesh, India.

and

Kala Suhas Kulkarni*, M.D.,

Medical Advisor, R&D Center, The Himalaya Drug Company, Makali, Bangalore, India.

[* Corresponding author]

ABSTRACT

One hundred patients with symptoms of non-ulcer dyspepsia were selected from the clinical unit of Department of Dravyaguna, S.S. Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi and randomly divided into two groups, with 50 patients in each. One group was treated with Himcocid tablet and the other group with Digene tablet. The dosage of both drugs was 1 tablet, thrice daily. After 6 weeks, a 100% relief of symptoms in Himcocid-treated patients was observed. In Digene-treated group most of the symptoms relapsed and remained incompletely relieved in few patients even after six weeks of continuous treatment. No untoward side effects were found in both groups. The study shows promising effect of Himcocid in non-ulcer dyspepsia.

INTRODUCTION

Non-ulcer dyspepsia is a major health problem among general population. In earlier studies it has been found that 20-25% persons with dyspepsia seek medical care¹. It leads to major health care expenditure, both in direct costs of visits to physicians, expensive investigations and medication, absenteeism from work and diminished productivity at the work place². All these contribute to substantial decline in quality of life.

Dyspepsia is often used to refer to upper abdominal pain or discomfort, but may also encompass symptoms, post-prandial abdominal bloating or distension, nausea and vomiting³.

Due to lack of objective criteria, non-ulcer dyspepsia can be understood only by its symptomatology, whether in modern or Ayurvedic terminology. In the present study, the symptom profiles used for assessment are epigastric discomfort, heartburn, nausea, vomiting, belching, flatulence, fullness of stomach and abdominal distension.

Relief in symptoms and prevention of relapses are the primary aims of treatment along with lifestyle and dietary recommendations. Antacids have long been the mainstay of treatment, based on physiological studies showing reduced acid exposure with symptomatic relief⁴.

In the present study, an Ayurvedic formulation namely Himcocid tablet has been used to evaluate the efficacy and safety in symptomatic relief of non-ulcer dyspepsia. The

formulation contains powders of Cowrie shell, Soft stone, Oyster shell and extract of *Glycyrrhiza glabra*.

In previous clinical studies, evaluating the efficacy of Himcocid therapy for 45 days, results showed that all the symptoms of non-ulcer dyspepsia were relieved⁵. In another study, there was reduction in all the symptoms for 2nd week onwards. It was observed that there was excellent to good response in 87% of the patients after treatment. At the end of the study, the investigators rated efficacy and tolerance of treatment as excellent to good in 90% of the patients⁶. The objective of the present study has been to evaluate the safety and efficacy of Himcocid tablets.

MATERIALS AND METHODS

The study was conducted in 100 patients with symptoms of non-ulcer dyspepsia who satisfied the inclusion and exclusion criteria. Patients with symptoms of epigastric discomfort, heart burn, nausea, vomiting, belching, flatulence, fullness in stomach and abdominal distension were included in the study. Pain attributed to angina or gall bladder stones were ruled out in history and physical and systemic examinations. Patients who suffered from hypertension and peptic ulcer were also excluded. Patients receiving other anti-ulcer agents like H₂-blockers, proton pump inhibitors etc., were not included in the trial. Those below 18 years of age, pregnant and lactating women were also excluded from the study. The patients were randomized into 2 groups to receive either Digene (Group I) or Himcocid (Group II). Among 100 patients there were 66 males and 34 females in the age group of 18-65 years of age (Table 1). Ninety-five patients had epigastric discomfort, 99 heart burn, 56 nausea, 15 vomiting, 69 belching, 93 flatulence, 94 fullness of stomach, 71 abdominal distension (Table 2). The patients were administered either Digene or Himcocid tablets at a dose of 1 tablet, thrice daily (1 tablet to be chewed between two meals and 1 tablet at bed time) for a period of 6 weeks. They were evaluated every 2 weeks for improvement in dyspeptic symptoms and observed for any adverse events or relapse of symptoms. The assessment was carried out on a four-point-scale symptoms as 3: Severe; 2: Moderate; 1: Mild and 0: No symptoms.

Group	No. of patients	Male	Female
I	50	31	19
II	50	35	15
Total	100	66	34

Symptoms	Group I	Group II
	No. of patients	No. of patients
Epigastric discomfort	49	46
Heart burn	49	50
Nausea	29	27
Vomiting	5	10
Belching	33	36
Flatulence	46	47
Fullness in stomach	45	49
Abdominal distension	29	42

RESULTS

All the 100 patients completed the 6 weeks treatment. Relief of symptoms was seen from the 2nd week onwards in Group II whereas in Group I relief was observed from the 4th week, except for nausea and vomiting.

Epigastric discomfort was fully relieved in 2 patients, after 2 weeks of therapy. Forty-two patients were fully relieved after 4 weeks and all the patients were completely relieved at the end of therapy in Himcocid-treated group (Group II), whereas in Group I, none of the patients showed complete relief after 2 weeks. Six patients were completely relieved after 4 weeks and 40 patients had complete relief at the end of the therapy. In 1 patient the symptoms relapsed and 9 patients remained with persistent symptoms at the end of 6 weeks. In Group II, 2 patients were completely relieved of heart burn after 2 weeks, 49 patients after 4 weeks and all the patients completely relieved at the end of therapy, while in Group I no patient had complete relief at 2 weeks, 18 had relief at 4 weeks and 45 patients were relieved at 6 weeks, out of which 1 patient showed relapse and 4 remained with persistent symptoms.

Nausea and vomiting was relieved in all patients in both the groups. There was no relapse in any group. In Group I, 7 patients were relieved of nausea and 2 patients were relieved of vomiting at 2 weeks. Twenty-five and 5 patients each were relieved at 4 weeks, and, 29 and 5 patients each at 6th week. In Group II, 9 patients were relieved from nausea at 2 weeks and all patients were completely relieved at 4 weeks duration.

Vomiting was relieved in 7 patients after 2 weeks, 8 patients after 4 weeks and all were relieved after 6 weeks. Belching and flatulence was relieved in 3, and 1 patient respectively after 2 weeks, 24 and 18 respectively after 4 weeks and complete relief was seen after 6 weeks in Group II. In Group I no relief was found in 2 weeks, 15 and 18 respectively were relieved in 4 weeks, 29 and 40 patients respectively after 6 weeks of therapy. There was relapse of belching in 2 patients and flatulence in 3 patients.

Fullness in stomach and abdominal distension was relieved in 2 patients at 2 weeks, 20 and 16 patients at 4 weeks, 47 and 40 patients at 6 weeks, in Group II. There was relapse of fullness in stomach and abdominal distension in 2 patients each. In Group I, fullness of stomach and abdominal distension was not relieved at 2 weeks, 19 and 12 patients were relieved at 4 weeks and 40 and 26 patients were relieved at 6 weeks. Fullness in stomach and abdominal distension was relapsed in 4 and 3 patients respectively in Group I. Five patients had persistent fullness in stomach and 3 had persistent abdominal distension after 6 weeks of therapy. No adverse effects were observed in both the groups (Tables 3 and 4).

Table 3: Patients showing clinical response of Digene in NUD

Symptoms	No. of patients	Cured at week 2	Cured at week 4	Cured at week 6	Not completely cured at week 6	Baseline score	Score at week 6	Relapse
Epigastric discomfort	49 (98%)	0	6 (12.24%)	40 (81.63%)	9 (18.37%)	134	11	1 (2.04%)
Heart burn	49 (98%)	0	18 (36.73%)	45 (91.84%)	4 (8.16%)	143	5	1 (2.04%)
Nausea	21 (58%)	7 (24.14%)	25 (86.21%)	29 (100%)	0	48	0	0
Vomiting	5 (10%)	2 (40%)	5 (100%)	5 (100%)	0	6	0	0
Belching	33 (66%)	0	15 (45.45%)	29 (87.88%)	4 (12.12%)	81	6	2 (6.06%)
Flatulence	46 (92%)	0	18 (39.13%)	40 (86.96%)	6 (13.04%)	110	9	3 (6.52%)
Fullness in stomach	45 (90%)	0	19 (42.22%)	40 (88.89%)	5 (11.11%)	109	9	4 (8.89%)
Abdominal distension	29 (58%)	0	12 (41.38%)	26 (89.66%)	3 (10.34%)	68	6	3 (10.34%)

Table 4: Patients showing clinical response of Himcocid in NUD

Symptoms	No. of patients	Cured at week 2	Cured at week 4	Cured at week 6	Not completely cured at week 6	Baseline score	Score at week 6	Relapse
Epigastric discomfort	46 (92%)	2 (4.35%)	42 (91.30%)	46 (100%)	0	134	0	0
Heart burn	50 (100%)	3 (6%)	49 (98%)	50 (100%)	0	148	0	0
Nausea	27 (54%)	9 (33.33%)	27 (100%)	27 (100%)	0	54	0	0
Vomiting	10 (20%)	7 (70%)	8 (80%)	10 (100%)	0	15	0	0
Belching	36 (72%)	3 (8.33%)	24 (66.67%)	36 (100%)	0	89	0	0
Flatulence	47 (94%)	1 (2.13%)	18 (38.30%)	47 (100%)	0	124	0	0
Fullness in stomach	49 (98%)	2 (4.08%)	20 (40.82%)	47 (95.92%)	2 (4.08%)	111	2	2
Abdominal distension	42 (84%)	2 (4.76%)	16 (38.10%)	40 (95.24%)	2 (4.76%)	115	2	2

DISCUSSION

Pathophysiology of non-ulcer dyspepsia is poorly understood. Several hypotheses have been proposed and a number of non-motility and motility disorders have been identified as potential causative factors⁷. Few cases may present with *Helicobacter pylori* (*H. pylori*)

infection and subsequently progress to peptic ulcer disease. Another opinion is that reflex of bile into stomach may be an etiological factor though objective studies did not support the theory⁷ sometimes an underlying psychiatric condition is also suspected. As compared with healthy subjects, patients with non-ulcer dyspepsia have higher scores of anxiety neuroticism and depression on personality assessment⁸. Most patients have increased visceral sensitivity and delayed emptying of solids i.e., post-prandial antral hypomotility. However, etiopathological role of these abnormalities is not demonstrated in practice⁷.

Treatment approaches include use of antacid, H₂-receptor antagonists and antibiotics (for the eradication of *H. pylori*). Clinical studies have shown that higher doses of acid – compressing agents had a positive effect on symptoms⁹.

Cowrie shell is used in ancient era for symptomatic treatment of hyperacidity, indigestion, heart burn, loss of appetite and abdominal pain due to indigestion or hyperacidity^{10,11}. Dugdhasana magnesium silicate is sweet in taste, has cooling, antifatulent and ulcer healing properties^{12,13}. Mouktika Sukti has demulcent, acid neutralizing, antispasmodic and appetite improving properties^{14,15} and is used in digestive disorders for the management of hyperacidity. Yashtimadhu (*Glycyrrhiza glabra*) has demulcent, cooling and acid neutralizing properties¹⁶. It has anti-inflammatory, ulcer healing and immunomodulatory effect. *Emblica officinale* has cooling, antifatulent, carminative, styptic and immunomodulator effects¹⁶. *Tinospora cordifolia* has acid neutralizing, cooling effects¹⁷ and anti-inflammatory properties. *Emblica officinale* and *Boerhaavia diffusa* has potent antioxidant action and *Tinospora cordifolia* is a well known immunomodulator. All the drugs have been used in the treatment of gastric ulcers and hyperacidity. They have a long history, safety and efficacy, which was confirmed in the earlier clinical trials of Himcocid in non-ulcer dyspepsia¹⁸.

Findings of the present study are in agreement with prior studies, with respect to safety and efficacy. There is complete cure of symptoms of epigastric discomfort, heartburn, nausea, vomiting, belching and flatulence with Himcocid, whereas Digene did not show complete relief in epigastric discomfort, heartburn, belching, flatulence fullness in stomach and abdominal distension. Both the drugs were safe and no adverse effects were reported in any of the patients.

CONCLUSION

Thus, Himcocid was found to be effective in relieving symptoms of non-ulcer dyspepsia. Although the efficacy was comparable with Digene, relapse of symptoms were observed in more number of patients with Digene. Persistent epigastric discomfort, heartburn, belching and flatulence were seen with Digene in some patients even after 6 weeks of therapy. No side effects were reported during the trial.

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