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ORIGINAL ARTICLE

Clinical Trial on Entocid Chewable Tablet for Hyperacidity and Gastroesophageal Reflux Disease

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ABSTRACT

Objective: To investigate the therapeutic effects of the herbal medication Entocid chewable Tablet a product of Herbion pharmaceutical on the indications and gastric motility of patients with hyperacidity and gastroesophageal reflux disease (GERD).

Methods: Total 50 patients were selected for this study. The patients were selected using a modified Reflux Disease Questionnaire, which is a validated, self-administered scale that is widely used for the assessment of anti-reflux treatment effects. Patients were advised to take study medicine 2 tablets twice daily after meal for 1 week. We take follow up after 1 week. We select the subjects from Sharafi Goth Govt. Hospital Naik Muhammad Dispensary.

Results: Entocid Chewable tablets were innocuous and well endured and compact the occurrences of all the evaluated GERD symptoms, with no adverse events requiring withdrawal.

Conclusion: Entocid chewable tablets may provide a harmless and active management for decreasing the symptoms of GERD.

INTRODUCTION

GERD is a long-lasting periodic and reformist illness which associated with esophageal and non-esophageal complications. Damage of mucosal membrane in gastroesophageal reflux disease shows the similar symptoms to functional dyspepsia or irritable bowel syndrome [1]. GERD symptoms experience by US people one time a month and one time a week is 44 % and 20% correspondingly [2,3]. GERD is most common gastrointestinal disease in the world wide. 10% to 20 % occurrence in western world [4]. The decisive finding and clinical diversity of GERD from other disease is tough although it has high prevalence. GERD symptoms alter the daily activities and quality of life of the patients [5,6]. The treatment options for GERD is proton pump inhibitor and H2 receptor blockers, the Corresponding treatment required continuous and long-term therapy because GERD is recurrent in nature. However, these drugs have potent effects on GERD but also have antagonistic occasions for example hypochlorhydria, cardiac events and augmented risk of hip fractures have led to concerns over the protection of these drugs [7,8]. It is subsequent in an intensification of attention to identify natural therapies that can successfully regulate GERD symptoms and avert difficulties. GERD is concomitant with reduced health-related grade of life [9], diminish work fecundity [10] and accrued risk of esophageal adenocarcinoma [11]. The annual frequency of esophageal cancer is aggregate worldwide, from 3.5% in Scotland to 8.1% in Hawaii, which is

matching to the increasing prevalence of GERD [12]. In addition, diagnostic tests and treatments for GERD carry high costs for society [13]. The pathophysiology of GERD is dominated by anatomical and functional defects in the gastroesophageal junction, including reduced pressure and augmented reflux periods accompanying with temporary relaxations of the lower esophageal sphincter and the formation of a hiatal hernia, which promotes and facilitates reflux [14-16]. Esophageal motility and salivary bicarbonate contributes to esophageal clearance acid and buffer, respectively, and reduce the contact time with the acid in the esophagus [17,18]. Visceral obesity increases the pressure on the gastro-esophageal junction, thus facilitating the reflux [19] and consumption snuff reduces secretion of esophageal sphincter pressure and salivary bicarbonate, facilitating reflux and decreases buffering acid, respectively [20,21]. The main recognized danger factors of GERD are heredity, obesity, smoking and snuff [22-24]. High intake of dietary fiber and moderate exercise appear to reduce this risk [25], while sex and age did not strongly influence the risk of GERD [26,27], obesity is of specific attention because it is growing in prevalence in corresponding with GERD, and numerous studies have shown a greater than before risk of gastroesophageal reflux, especially abdominal obesity [28,29]. GERD is frequently identified by the fundamental symptoms of heartburn or acid regurgitation [30] and determination of indications after inhibition of acid with a proton-pump inhibitor (PPI) [31]. If symptoms are not resolved, usually it performed an endoscopy and mucosal erosions (esophagitis) or peptic strictures are diagnostic of GERD [32]. Endoscopy can also demonstration Barrett's esophagus a premalignant columnar metaplasia and esophageal adenocarcinoma. If endoscopy is normal esophageal pH measurement can still indicate pathological acid reflux (pH <4) [33]. The pH measurement can be combined with measurement of impedance to distinguish reflux liquid and gas weakly acid or non-acid, which can cause symptoms of reflux refractory acid inhibition [34]. Treatment of GERD is mainly medication with antacids, H2 receptor antagonists and PPIs, while surgery (usually with fundoplication) is used in selected patients. Recent confirmation has uncovered that long-term PPI medication is hindered by adverse effects. This includes secondary hypergastrin and rebound acid hyper-secretion, inducing symptoms of reflux in the withdrawal of the PPI [35] medication; increased risk of enteric infections and community-acquired pneumonia, probably due to increased gastric pH causing reduced host defense [36,37] and increased risk of vertebral and hip fractures, probably because calcium malabsorption [38]. This research article is to focus on the herbal treatment of gastroesophageal reflux disease.

METHODOLOGY

Composition*:* Each Tablet contains extract from:

- Ammomum Subulatum (Illaichi Kalan)
- Berberis Aristata (Zarishk)
- Cinnamomum Tamala (Tezpaat)
- Coriandrum Sativum (Dhaniya Khushk)
- Cuminum Cyminum (Zeera Safaid)
- Foeniculum Vulgare (Badyaan/Saunf)
- Vitis Vinifera (Munaqqa)
- Mesua Ferrea (Nagkesar)
- Glycyrrhiza glabra (Mulethi)
- Mentha Piperita (Podina)

Patients with gastroesophageal disease were recruited from the government hospital of sharafi goth Naik Muhammad Dispensary. A total of 50 subjects meeting the diagnostic criteria defined below were selected for the study. The mean age range is 13 to 65 years.

The study procedure was appropriate by the Ethics Committee of the first from affiliated Hospital and then clinical trial and patients' safety committee. Informed consent forms were shared and dully signed by all participant on the start of study.

Inclusion criteria

Those who had minimum 2 of the following 5 indications, minimum for one month, deprived of any improvement with routine treatments: Vomiting instantly afterward eating, restlessness between one to three hours afterward meal, apnea and respiratory distress subsequently meal, poor weight gain. Patients whose endoscopic result showed that they have GERD were also suitable for this study.

Exclusion criteria

Patients were omitted from the study if there was a history or incidence of clinically notable medical or surgical illnesses, important laboratory irregularities, recommended or proven mental or neurological complaints. Patients who underwent from other types of gastroesophageal diseases, peptic ulcer or erosive gasteroduodenitis were also omitted.

Efficacy measures

Assessment of treatment effectivity was indication based. Enhancements in collective GERD symptoms were measured rendering to an adapted Reflux Disease Questionnaire, which is a authenticated, self-administered scale that is usually used for the evolution of anti-reflux treatment effects. The frequencies of 8 chief symptoms of GERD, namely heartburn, food regurgitation, flatulence, belching, dysphagia, nausea, vomiting and acid regurgitation, were measured at treatment start date and after 1 week of the trial.

RESULTS

In this study we collected the 50 patients from government hospital of Sharafi Goth Naik Muhammad Dispensary. The mean age of patients is 35.38 years with (13.169 STD). 14% (n=7) were male and 86% (n=43) were females. 34% (n=17) have hyperacidity, 42% (n=21) have heart burn and reflex esophagitis and 24% (n=12) have GERD. Out of 100% (n=50), 84% (n=42) were reported marked improvement, 12% (n=6) were reported moderate improvement and 4% (n=2) were stated mild improvement in their symptoms. All subjects were stated that there is no adverse effect distinguished during and after the treatment with Entocid chewable tablet. As a result of twice daily administration of Entocid chewable tablet the study subject indicated expressively decrease in their major symptoms (Table **1-4**).

Table 1. Statistics (Mean, Median and Std. Deviation).

		Age in Years	2nd Week Outcome	Diagnosis	Gender
N	Valid	50	50	50	50
	Missing	0	0	0	0
Mean		35.38	2.8000	1.90	1.86
Median		30.00	3.0000	2.00	2.00
Std. Deviation		13.169	0.49487	0.763	0.351

Table 2. Outcomes.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Mild improvement	2	4.0	4.0	4.0
	Moderate improvement	6	12.0	12.0	16.0
	Marked improvement	42	84.0	84.0	100.0
	Total	50	100.0	100.0	

Table 3. Diagnosis.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Hyperacidity	17	34.0	34.0	34.0
	Heart burn and reflex esophagitis	21	42.0	42.0	76.0
	GERD	12	24.0	24.0	100.0
	Total	50	100.0	100.0	

Table 4. Gender.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	7	14.0	14.0	14.0
	Female	43	86.0	86.0	100.0
	Total	50	100.0	100.0	

Safety measurements

Safety assessments were grounded on information of adverse events (AEs) and results of monotonous physical examinations, laboratory determinations, vital and physical sign measurements. All of the AEs were detected during the study and measured to see if there was a direct connotation between this intervention and that particular complication that they had stated. Patients with clinically applicable AEs and/or nonstandard laboratory test results at the final visit were interrogated about whether the complaint occurred before the start of the study or it had increased in severity or frequency during the study. Entocid chewable tablet was well accepted by most of the patients, and no adverse effects, neither indigenous nor systemic, were stated by them. Additionally, no abnormal physical examination was noted on the follow-up contacts.

CONCLUSION

In this study we tried to evaluate a drug which based on traditional herbs to treat gastroesophageal diseases. The result of the current study shows that Entocid chewable tablet is well tolerated and effective therapy for gastroesophageal disease. Since of the various side effects of allopathic drugs, and comparable or enhanced effects of Entocid chewable tablets in GERD indications, it is suggested that larger studies are directed with esophageal manometry and pH monitoring with a larger sample size in directive to assess both short-range and long-range results of Entocid chewable tablets.

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