

EVALUATION OF EFFICACY OF UNANI COMPOUND DRUG ON SYMPTOMATIC RELIEF IN HELICOBACTER PYLORI INFECTIVE PATIENTS

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ABSTRACT: Aim: We undertook this study to find out the effect of Unani compound drugs on symptoms in *H. pylori* Positive Antral gastritis and/or duodenitis confirmed by upper G.I Endoscopy and Rapid Urease Test (RUT). Methods: Study was conducted on 40 patients having gastritis and/or duodenitis, confirmed by Endoscopy. Patients were given Unani compound drugs for 3 months, After 3 month upper G.I endoscopy and RUT were repeated to assess the status of gastritis and/or duodenitis and, *H. Pylori*. Results: In our study we found that 61.3% and 50% improvement in gastritis and duodenitis respectively as well as good result in symptoms relief. But, *H. Pylori* eradication rate only 22.5% Post-treatment endoscopy RUT showed that patient got relief from gastritis and /or duodenitis or *H.Pylori* infection.

Keywords: Antral, Gastritis, Upper G.I Endoscopy, *Helicobacter Pylori* infection, Rapid urease test, Unani compound Drugs.

INTRODUCTION

Dyspepsia is a poorly characterized syndrome thought to originate from anatomic or functional disorders of the upper GI tract. (1, 2, 3). Dyspepsia encompasses a variety of symptoms including epigastric discomfort, bloating, anorexia, early satiety, belching or regurgitation, nausea, and heartburn. Rome III criteria define dyspepsia as 1 or more of the following 3 symptoms for 3 months within the initial 6 months of symptom onset (4): (1) postprandial fullness, (2) early satiety, and (3) epigastric pain or burning. Chronic gastritis and peptic ulcer disease are most common disorders and antral gastritis is common finding during upper GI endoscopy. A close relationship between chronic gastritis and *Helicobacter pylori* (*H.pylori*) infection has been reported and about 75% patients with chronic gastritis have been found to have *H.pylori* infection compared to 10% in those without gastritis [5]. The pathogenesis of functional dyspepsia is unknown. Many pathogenic mechanisms have been proposed, like disturbance in gastric acid secretion, disordered gastric motility, abnormalities of electrical control activity, abnormalities of perception, psychological disturbances, environmental factors and *Helicobacter pylori* (*H. pylori*). (6). *Helicobacter* gastritis is the commonest type of gastritis present in patients presenting with dyspeptic symptoms (7). There are abundant epidemiological data to support the association of gastritis with *H. pylori* infection. Most commonly, type B gastritis affects the antrum, and it is these patients who are prone to peptic ulcer disease. *Helicobacter*-associated pan gastritis is also a very common manifestation of infection but gastritis affecting the corpus alone does not seem to be associated. *Helicobacter* may be involved in the initiation of the process. Patients with pan gastritis seem to be most prone to develop of gastric cancer (8). The treatment regimens for *H.pylori* positive antral gastritis are available in modern medicine which include a minimum of 2 antibiotics like amoxicillin, tinidazole or clarithromycin in combination with gastric acid inhibitors [9],[10], but these regimen are not satisfactory due to some other associated problems, like the patient's compliance, side effects, bacterial resistance, higher cost and recurrence [11]-[12]. Worldwide hundreds of herbal drugs are being used in traditional medicine for eradication of *H.pylori* and to treat gastritis [13]-[14]. Unani physicians in search of new, safe and effective drugs have always experimented new combinations. The combination under study is a non pharmacopoeal drug which contains four single drugs namely *Plantago ovata* (Asapghol musallam) (17) *Pistacia lentiscus* (Mastagi) (16), *Acacia arabica* (Samghe arabi) (17), *Glycyrrhiza glabra* (Asl-us-soos) (15) (Ingredients of this combination qualify the criteria of being selected as an anti gastritis as well as against *H pylori* drug owing to their attributed temperament, medicinal effect, mechanism of action and their supposed role in the combination). In Unani literature these drugs have been described widely for their role in ulcerative gastric diseases and have age-old history of their use in the management of such diseases. Further, in certain scientific studies they have been found to possess such an effect useful in the management of gastritis (18,19). Except that various drugs are used for the treatment of gastritis without any side effect e.g. some of the commonly used single drugs (Adviya mufrida), *Aloe barbadensis* Mill (Elva), *Alpinia galanga* Willd (Khulanjan), *Anchusa strigosa* Labill (Gaozaban), *Withania somnifera* Linn (Asgandh), *Andrographis paniculata* Wall (Bhuineem), *Zingiber officinale* Rosc (Adrak), *Emblica officinalis* (Amla), *Curcuma longa* Linn (Haldi), *Asparagus racemosus* Willd (Satawar), *Aegle marmelos* Correa (Bael), *Myristica fragrans* Houtt (Jaiphal) etc and in the form of compound drugs (Adviya murakkaba) are Jawarish Mastagi, Jawarish Anarain, Majoon Dabidul Ward, Sharbat Anar, Majoon Zanjbil, Qurs Satawari, Itrifal Aftimoon, Sharbat Unnab and Khammeera Sandal have been indicated by Unani physicians for the treatment of chronic gastritis and their efficacy against gastritis has also been tested by studies [20], [21], [22], [23], [24], [25].

MATERIAL AND METHOD:

This study was conducted within the duration of 2 years (from March 2015 to February 2017) in the department of Surgery (Jarahat), Ajmal Khan Tibbya College, AMU, Aligarh. This was a randomized single blind, controlled clinical trial.

Inclusion Criteria We included the patients who met the following criteria. (i) Patients having following symptoms at least for 7 days. a. Heart Burn b. Nausea c. Vomiting d. Indigestion e. Abdominal pain f. Heaviness after meal g. Belching h. Epigastric tenderness (ii) Patients with antral gastritis, diagnosed by UGI endoscopy. (iii) *H. Pylori* positive patients, confirmed by rapid urease test (RUT). (iv) Age between 15 yrs. to 70 yrs.

2. Exclusion Criteria we excluded the patients who met with any of the following criteria. (1) Patients who had NSAIDs or any antibiotics with in the last 4 weeks. (2) Any systemic disease (Hepato-renal and pulmonary malfunction). (3) Patients with prior history of pyloric stenosis gastric resection (4) Patients with prior history of peptic ulcer or gastric carcinoma. (5) Patients with active G.I. hemorrhage, Obstruction a perforation (6) Pregnancy and lactation (7) Anxiety disorders (8) Bleeding disorders (9) HBs Ag +ve and HIV +ve.

Methodology:

Permission from the institutional ethical committee was taken before conducting the study. A written and well informed consent was taken from the patients before participation into the study. The patients who were having the features of chronic gastritis like heart burn, nausea/vomiting, indigestion, abdominal pain and loss of appetite, heaviness after meal, belching, epigastric tenderness were screened and were called for endoscopy, nil orally (fasted overnight). During the examination of upper GI endoscopy the area of anomaly was documented and at the same time punch biopsy was taken from antrum of the stomach and a rapid urease test (RUT) was done from the mucosa to confirm the presence or absence of H. Pylori bacteria. Only the patients having antral gastritis and/or generalized gastritis with H. Pylori positive test (RUT) were enrolled in the study and were given the Unani drug compound. Unani drug compound was given in the dose of 2 capsules twice daily before meals with water for 3 months. In follow up all the patients were called after every 15 days and after 3 months of treatment the symptomatic relief was again noted down and repeated and RUT done endoscopy by the same endoscopist.

RESULTS AND OBSERVATIONS:

The present study entitled "Role of Unani compound drugs in the cases of H. pylori positive patient Antral Gastritis and Duodenitis patients" was conducted on 40 H. Pylori Positive in the department of Jarahat (surgery) AKTCH, AMU, Aligarh. The patient were interrogated about the symptoms of Heart burn, Nausea, vomiting, indigestion, abdominal pain, loss of appetite, Regurgitation, flatulence, Belching and also examined for epigastric tenderness. These patients underwent Upper Gastro Intestinal Endoscopy for the confirmation of the clinical diagnosis.

Table: 1 Distribution of patient according to age in years

Age group (in years)	H. pylori Positive	
	No	%
10-20	09	22.5
20-30	13	32.5
30-40	08	20
40-50	07	17.5
50 -60	03	7.5
60-70	00	00
Total	40	100

- Mean age 30.5 ± 12.2

Table: 2... Distribution of the patients according to gender

Gender	H. Pylori positive	
	No	%
Male	18	45.0
Female	22	55.0
Total	40	100

Table—3... Distribution of patients according to occupation

Occupation	H. Pylori Positive	
	No	%
Housewife	16	40
Service class	06	15
Labour class	11	27.5
Students	07	17.5
Total	40	100

Table-4.... Distribution of patients according to socioeconomic status

Socioeconomic status	H. Pylori Positive	
	No	%
High income	03	7.5
Middle income	18	45
Low income	19	47.5
Total	40	100

Table 5.. Distribution of patients according to dietary habits

	H. Pylori positive	
	No	%
Mixed (Veg + None –Veg)	36	90.0
Vegetarian	04	10.0
Total	40	100.0

Table-6..... Distribution of patients according to signs and symptoms

Clinical signs and Symptoms	Before treatment		Improvement after treatment	
	No	%	No	%
	Heart burn	25	62.5	17
Nausea	24	60	18	75
Vomiting	15	37.5	10	66.6
Indigestion	10	25	06	60
Loss of appetite	08	20	06	75.0
Regurgitation	18	45	12	66.7
Abdominal pain	21	52.5	13	61.9
Belching	09	22.5	06	66.7
Heaviness	10	25	06	60.0
Flatulence	03	7.5	02	50.0
Epigastric tenderness	23	57.5	15	65.2

Table..7-- Effect of drug on Endoscopic finding

Endoscopic finding	H. Pylori Positive		
	No. of patient	Improved	%
Antral Gastritis	31	19	61.3
Generalised Gastritis	04	02	50.0
Antral Gastris with Duodenitis	02	01	50.0

Table-8..... Effect of drug on H. Pylori +ve

H. Pylori +ve		
	No	%
Improved	09	22.5
Not improved	31	77.5
Total	40	100

Discussion:

Health of stomach (meda) has been given a prime importance in Unani Medicine. Almost all Unani physicians have contributed towards the health and disease of stomach. Unani physicians have mentioned a wide spectrum of treatment for Gastritis (warm-e-meda). According to the cause, clinical presentations, regions, climate, age, acuteness or chronicity and dietary habits with prime concern on the correction of Mizaj (temperaments) and Akhlat (humours) of the patients. A number of medicine and corrective approaches covering all these aspects have been described in Unani medicine resource books.⁽²⁶⁾ Since 1983, the association between H. pylori and inflammatory upper gastrointestinal disease has been a matter of apprehension for researchers and clinicians. However, mostly the investigators have evaluated tissues obtained from symptomatic patients. Non ulcer dyspepsia is usually caused by H. pylori associated gastritis and it is also predisposing factor for peptic ulcer disease⁽²⁷⁾. The aim of this study was to demonstrate the effect of Unani drug compound containing “Glycyrrhiza glabra (Asl–us-soos), Plantago ovata (Asapghol musallam), Acacia arabica (Samghe arabi) and Pistacia lenticus (Mastagi)” in the treatment of antral gastritis and eradicating H. pylori bacteria from the stomach, which is a major cause. Glycyrrhiza glabra (Asl–ussoos)/Licorice reduces stomach secretion, produces thick protective mucus for stomach lining which protect it from inflammation, gastritis and peptic ulceration [28]. Plantago ovata (Asapghol musallam) is a water soluble seed husk mucopolysaccharides derived from the husk of Plantago ovata showed wound cleansing and wound healing properties as well as anti-bacterial activity [29]. Acacia arabica (Samghe arabi) is shown to be protective against stress-induced gastric ulcer in vitro [30]. Pistacia lenticus (Mastagi)/Mastic gum is cytoprotective and has mild anti secretory effect, it is effective for healing gastric and duodenal ulcer [31]. We observed that the Unani drug compound relieved the symptoms effectively in. Antral gastritis was the most common (75.0%) finding through upper GI endoscopy in this study which is similar to (76.6%) that of other researchers.

Improvement in the symptoms and sign are heart burn...68.0%, nausea...75.0%, vomiting.... 66.6%, indigestion....60.0%, abdominal pain...61.9%, loss of appetite...75.0%, regurgitation66.6%, heaviness after meal.... 60.0%, flatulence....50.0%, belching...66.6%,

epigastric tenderness...65.2%, out of 40 H. pylori positive patients only...22.5% patients became negative after complete treatment. Improvement in endoscopic finding Antral gastritis...61.3%, generalized gastritis...50%, Antral gastritis with duodenitis...50%.

Conclusion:

It is era of evidence based medicine and in this study we have tried to demonstrate that Unani compound drugs not only declines the symptoms of gastritis and duodenitis but it also corrects them which was proved by repeated upper GI endoscopy after treatment. It has a good result in reliving symptoms and upper GI endoscopic finding but poor result on H. pylori eradication.

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