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Case Report

Efficacy of Unani Formulation in Patients with GERD: A Case Series

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ABSTRACT

Objective: Gastro-oesophageal reflux disease (GERD) is defined as the backward flow of gastric contents into the oesophagus. A small amount of reflux occurs in normal individuals. It is a common disease with a prevalence as high as 10% - 20% in the western world. The disease may develop typical, atypical oesophageal and extra-oesophageal symptoms, complications, and can adversely affect an individual's quality of life. Management of GERD may involve lifestyle modification, medical therapy with PPIs, and anti-reflux surgery. But this is having adverse effects. So, the present study aims to assess the safety and efficacy of unani formulation in the treatment of GERD.

Material & Methods: We conducted this study on ten clinically diagnosed cases of GERD attending the Moalejat OPD at AKTC, AMU Aligarh.

Results: All the symptoms like heartburn, regurgitation, nausea, water brash, sleeplessness were significantly improved after the 45 days treatment with this Unani formulation. The result was analyzed and shown on Likert's scale.

Conclusion: The preliminary findings indicate that this Unani drug formulation is effective in patients with GERD.

Keywords: GERD, Unani formulation, PPIs.

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INTRODUCTION

Gastroesophageal reflux disease (GERD) is defined as symptoms and/ or complications resulting from reflux of gastric contents into the oesophagus and more proximal structures.¹ It is the most common oesophageal disorder, accounting for nearly 75% of all patients with oesophageal disorder. Transient lower esophageal sphincter relaxation is one of the most important causes for GERD.²

GERD is prevalent worldwide, and the disease burden may be increasing. Prevalence estimates show considerable geographic variation, but only East Asia shows ratings consistently lower than 10%.³

Monozygotic and dizygotic twins showed that genetic factors might contribute by 31% to the etiology of typical GERD.⁴ Although genetic factors are involved, reflux is likely to be caused mainly by environmental factors.⁴ Obesity has recently been established as a risk factor of the internal environment, particularly among women^{5,6}. External environmental factors include various exposures related to

lifestyle, tobacco, smoking, alcohol drinking, coffee, and tea consumption, as well as regular use of aspirin and other non-steroidal anti-inflammatory drugs, have all been proposed to be risk factors for reflux.^{7,5,8}

Two cardinal esophageal symptoms signalize the GERD, i.e., heartburn, a burning sensation in the retrosternal and regurgitation, a perception of the flow of gastric contents into the mouth or hypopharynx. The prevalence of these two symptoms is 75% to 98% and 48% to 91% respectively. Above two symptoms can diagnose GERD without the need for endoscopy.²

Extra-esophageal symptoms such as non-cardiac chest (epigastric) pain, dental erosion, cough, laryngitis, and asthma are associated with but are not specific for GERD. It is also commonly associated with lower quality of life, poor quality of sleep, and decreased work productivity. Complications of GERD include reflux esophagitis (most often), esophageal stricture, Barrett's esophagus, and esophageal adenocarcinoma.^{9, 10}

In a significant proportion of patients, symptom control and maintained quality of life can only be attained by either continuous proton pump inhibitors (PPIs) therapy or antireflux surgery (ARS), both in the short and long term.^{11,12,13,14}

Unani Description:

GERD is a new term in this era, classical literature does not give the description of term on one hand, but the clinical features mentioned under the headings of *sue hazm* (Dyspepsia), *bad hazmi* (Indigestion), *Hazm-ki-khraabi* (Digestion disorder) in various books correspond with the signs and symptoms of GERD.^{15, 16, 17, 18}

Some scholars described the term *Zauf-e-meda*, *Zauf-e-Hazm*, *Sue-Hazm* (Dyspepsia) and *Tukhma* (Indigestion) in agglomeration,¹⁵ in which deleterious effects occur in the process of digestion of food. Food particles remain in the stomach and become the cause of nausea, abdominal pain, vomiting, belching, flatulence, water brash, heartburn, etc.^{15,17}

Its common causes include malfunctioning of the stomach, the diet has taken disproportionately, and food particles are not chewed congruously. While alcohol, tobacco, tea, coffee, ice cubes etc if taken in inadequate amount may be its rare causes. Sometimes, it occurs due to heavy physical and mental work, anxiety and depression.^{15, 16.}

Unani scholars have been treating this disease since ages. A large number of single and compound drugs have been documented for their efficacy in heartburn, regurgitation, dyspepsia, etc. This unani formulation contains various ingredients like *heel kalaan* (*Amomum subulatum*), *tabaasheer* (*Bambusa arundinacea*), *kishneez khusk* (*Coriandrum sativum*), *gul-e-surkh* (*Rosa damascene*) and *baadiyaan* (*Foeniculum vulgare*) all in equal amount. It is mainly used as *Dafa e humoozat e meda*. So present case series was carried out with the aim to explore the effect of this unani formulation on patients with GERD.

MATERIAL AND METHODS

Informed consent was taken from all the patients. The study was conducted on the patient attending Moalejat OPD-4 at Ajmal Khan Tibbiya College & Hospital, AMU, Aligarh.

Intervention

We enrolled ten patients in this case series. The Unani formulation was supplied in a powdered form and given to the patients of GERD twice daily after the meal in a dose of 6 gram for 45 days with fortnightly follow up. Patients were also advised lifestyle modifications. Diagnosis was made on the basis of clinical symptoms compatible with the classical description of the disease.

Case Presentations

Case 1: A 42-year-old female, housewife came to Moalejat OPD of AKTCH AMU with the complaints of nausea, vomiting, belching, heartburn, water brash, pain in the epigastric region. She was advised to take the formulation along with dietary and lifestyle modifications. She got alleviation in her clinical features after 45 days of treatment.

Case 2: A newly married 20 years old female visited Moalejat OPD of AKTCH AMU with the chief complaints of regurgitation, heartburn, epigastric pain, loss of appetite.

After taking proper history, it was found that she was fond of taking coffee and spicy foods. Patient was advised to stop drinking coffee and also to take easily digestible and non spicy diet during the course of the treatment with test drug formulation. Subsequently, she got relief in all the symptoms after 45 days of treatment.

Case 3: A 36-year-old male, a businessman came with complaints of restlessness, heartburn, water brash, anorexia, epigastric pain. On taking the history, it was found that he was in stress for some family problem. He was advised to take test formulation. After 45 days of treatment, he got subsequent dilution in his symptoms.

Case 4: A 26-year-old married woman came to OPD with the chief complaints of, flatulence, epigastric pain, regurgitation, nausea, water brash. We advised her to take the test formulation. After 45 days of treatment, she reported gradual relief in symptoms.

Case 5: A 58 years old female patient came to OPD with complaints of regurgitation, heartburn, sore throat along with a history of acid reflux into the mouth for two years. On the per abdomen, tenderness of mild grade was found in the epigastric region. After 45 days of treatment with Unani formulation, she got partial relief in her symptoms.

Case 6: A 22 years old female student having complaints of mild regurgitation, water brash, nausea. She was fond of eating junk food. We advised her to quit junk food and to take easily digestible diet along with test formulation. There was found gradual easement in her symptoms on 2nd follow up.

Case 7: A 53-year-old male, serviceman came to OPD with the complaints of heartburn, regurgitation, nausea, sore throat, epigastric pain. On investigation, it was found that he was on anxiolytics for seven months. He was advised to continue the same treatment and to take test formulation. After 45 days, his symptoms were found mitigated except regurgitation.

Case 8: A 33-year-old male patient visited OPD with the complaints of nausea, heaviness in the abdomen after meal, regurgitation. He was found alcoholic on the investigation. We advised him to stop drinking alcohol and treat him with the test formulation for 45 days. He got partial relief in symptoms.

Case 9: A 26-year-old male presented the OPD with complaints of acid reflux into the mouth, pain in the epigastric region, and nausea. He takes tea seven times per day. We advised him to reduce the number of cups per day and treat him with test formulation. After treatment, he reported a subsequent reduction in his symptoms.

Case 10: A 40-year-old male visited OPD with the complaints of regurgitation, heartburn, water brash. He was advised to take Unani formulation. He got relief in all the symptoms after the completion of the trial.

RESULT

Based on the clinical symptoms, ten cases were analyzed. It was found that regurgitation and heartburn were prominent symptoms in all cases. Whereas nausea, water brash, epigastric pain and sleeplessness were the associated symptoms. After 45 days of treatment, patient found alleviation in the symptoms which were analyzed and graded on Likert Scale.

Grading of Symptoms on Likert Scale

S.No.	Regurgitation		Heartburn		Nausea		Water brash		Epigastric pain	
	P1	P2	P1	P2	P1	P2	P1	P2	P1	P2
1.	0	0	2	1	2	0	1	0	1	0
2.	1	0	2	0	1	0	0	0	2	0
3.	0	0	3	1	0	0	1	0	2	0
4.	2	0	0	0	3	1	2	0	2	0
5.	3	2	2	1	0	0	0	0	1	0
6.	1	0	0	0	2	0	2	0	0	0
7.	3	1	2	0	2	0	0	0	2	0
8.	3	2	2	1	2	1	0	0	0	0
9.	0	0	0	0	2	1	3	1	2	0
10.	1	0	1	0	0	0	2	0	0	0

0=Nil, 1=Mild, 2=Moderate, 3=Severe , P1=Pre-treatment P2=Post-treatment

Composition of Test Drug Formulation

S.No.	Drug name	Botanical name	Medicinal properties ^{21,22}
1.	<i>Heel kalaan</i>	<i>Amomum subulatum</i>	Stomachic, antiemetic, antibilious, astringent, alexipharmic; used for the treatment of indigestion, biliousness, abdominal pains, vomiting, in congestion of the liver. Pericarp-in headache and stomatitis.
2.	<i>Tabaasheer</i>	<i>Bambusa arundinacea</i>	stomachic, antiemetic, desiccant, absorbs the dampness of stomach.
3.	<i>Gul-e-surkh</i>	<i>Rosa damascene</i>	Desiccant, astringent to stomach muscle, analgesic, resolvent, cardiac tonic, laxative.
4.	<i>Kishneez khushk</i>	<i>Coriandrum sativum</i>	Stomachic, carminative, anti-inflammatory, diuretic, hypoglycemic, analgesic, antispasmodic. Used in dyspepsia and gastroenteritis.
5.	<i>Baadiyan</i>	<i>Foeniculum vulgare</i>	Carminative, stomachic, antispasmodic, emmenagogue, galactagogue, anti-inflammatory, diuretic. Relieves bloating, nausea, settles the stomach, and stimulates the appetite. Also used in amenorrhoea and enuresis.

DISCUSSION

GERD symptoms have a profound impact on health-related quality of life. So this case series was designed to determine the effect of this unani formulation in the treatment of GERD. In the present study, almost all the patients showed a good response during and after the treatment of 45 days, which was analyzed and shown on Likert's scale.

Almost all the patients have chief complaints of regurgitation and heartburn along with associated symptoms of nausea, vomiting, water brash, restlessness, and sore throat. Overall symptoms were reduced to the nadir in most of the patients, whereas partial relief in regurgitation was noted in 2 patients. And incomplete relief was found in heartburn in 3 patients.

During the entire case series, not a single case reported any adverse event. Thus validating the formulation as significantly effective in long as well as short term management of GERD with maximum socioeconomic advantage.

The drug regimen also shows the anxiolytic effect as it lowers the anxiety of the patient, this may be due to the presence of khishneez and gul e surkh. *Kishneez (Coriandrum)* possesses properties like analgesic, stomachic, brain tonic, cardiac tonic, whereas *Gul e surkh (Rosa damascene)* is analgesic, resolvent, and cardiac tonic. The formulation is also found effective as an appetizer and digestive, which is due to the presence of digestive and stomach tonic drugs present in it.

CONCLUSION

Given the findings of result and discussion, it can be concluded that the test formulation provided significant improvement in the sign and symptoms of the patient of GERD. It is economically fair treatment without any non-compliance. Therefore further studies may be performed to know the effectiveness & mechanism of action of this formulation in GERD with a control group on a large scale.

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