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Research Article

CLINICAL EFFICACY OF UNANI DRUG IN THE MANAGEMENT OF TABKHEER-I-MEDA (GASTROESOPHAGEAL REFLUX DISEASE)

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ABSTRACT

Tabkheer-i-meda has been described as reflux of acid from stomach in the Unani classical literatures. This disease is characterized by various symptoms like indigestion, pain in abdomen, suppression of thrust, burning sensation in the epigastrium, anorexia, nausea and acid reflux etc. In modern medicine, Gastro-esophageal Reflux Disease (GERD) is defined as symptoms or mucosal damage produced by the abnormal reflux of gastric contents into the esophagus or beyond, into the oral cavity (including larynx) or lungs. The objective of the present study was to evaluate the efficacy of *Safoof-i-Tabkheer* on the patients suffering with associated symptoms of *Tabkheer-i-Meda* (Gastro-esophageal Reflux Disease). Patients were advised orally 5grams of *Safoof-i-Tabkheer* with water twice daily after the meal. It was observed that after the treatment, all associated symptoms of *Tabkheer-i-Meda*/ GRED including retrosternal burning, epigastric pain acidic brash and anorexia were significantly ($p<0.05$) reduced. The percentage reduction in retrosternal burning, acidicbrash, epigastric pain and anorexia were 53.89%, 51.56%, 48.53% and 40.65% respectively as compared to base line. No adverse effect of drug was found. Highly significant improvements ($p<0.001$, paired t test) in all associated symptom of the disease suggest that the results are really due to the therapy. On the ground of above observation, it can be concluded that the Unani pharamacopieal formulation Safoof-i-Tabkheer is very effective and safe in the treatment of Tabkheer-i-Meda.

INTRODUCTION

Nafkh al-Mi'da, Tabkheer-*i*-Meda, Tukhma, Su'al-Hadm, Du'f al-Hadm, Fasad al-Hadm, Hurqa al-Mi'daand Waja'al-Fu'adterms are used for acidic reflux from stomach in the ancient Unani classic literatures.[1,2]

Pain of the cardiac end of stomach is felt on the anterior chest or upper abdomen. The acid reflux is called Gastro-esophageal reflex or GER.[3]

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The disease is characterized by various symptoms like indigestion, pain in abdomen, suppression of thrust, burning sensation in the epigastrium, anorexia, nausea and acid reflux etc. In modern medicine, Gastro-esophageal reflux disease (GERD) is defined as symptoms or mucosal damage produced by the abnormal reflux of gastric contents into the esophagus or beyond into the oral cavity (including larynx) or lungs.[4] It occurs when the upper portion of the digestive tract does not function properly, causing stomach contents to flow back into the esophagus. According to Unani scholars, it is caused by *Ghadha-i-Ghalizkham*, (foods that is partially cooked and hard to digest), disturbance in *Quwwat-i-Hadm*,[1] stomach weakness, *Fudlat* (waste product), intake of spicy foods, rotten fruits, hard fibrous diets, alcoholism, indigestion gastric secretions, prolonged stress and strain.[5,6,2,7] Many agents that reduced gastric acidity often have a tendency to induce secondary rise in acidity within a

short time of administration. These include H2-recepter blockers, proton pump inhibitors and much antacid preparation.[8] Rebound acid hyper secretion may contribute to high ulcer relapse rate after discontinuation of H2 receptor antagonists and secondary hyper gastrinemia may also lead to tolerance to prolonged course of H2 antagonists associated with decreased acid inhibition.[8,9,10]

The prevalence of GERD varies widely in the word and according to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), 20% (approx.) of population of United States are suffering from GERD. Recent studies indicate that its prevalence in India ranges between 8-20%, which is comparable to prevalence of the GERD in west countries.[11]

OBJECTIVE

The objective of the present observational study was as follows:

1. To evaluate the efficacy of '*Safoof-i-Tabkheer*', an Unani pharmacopoeial formulation in the treatment of *Tabkheer-i-meda* (GERD) because the drug is very effective, safe, non-invasive, cost effective, having long lasting effect.
2. To assess the safety of the trial drug which has no adverse effect on the human body.

MATERIAL AND METHOD

Study Drug: The study drug was Safoof-i-Tabkheer, which composition is given in Table-1.[12]

The present observational study was carried out from April 2018 to August 2018 on 30 patients of both genders suffering from Tabkheer-i-Meda (GERD), whom came for treatment in the General OPD of Central Research Institute of Unani Medicine, Lucknow.

Patients Selection

The patients presenting signs and symptoms of Tabkheer-i-Meda (GERD) i.e. retrosternal burning, epigastria pain, acidic brash and anorexia etc. were subjected to inclusion and exclusion criteria before to their final selection for the study.

Inclusion Criteria

- Patients of Tabkheer-i-Meda of age not less than 18 years.
- Patients having signs and symptoms of Tabkheer-i-Meda such as, persistent and recurrent retrosternal burning, epigastric pain, acidic brash and anorexia.
- Patients suffering from Tabkheer-i-Meda for period of at least one month.

Exclusion Criteria

- Those suffering with duodenal ulcer, peptic ulcer.
- Those suffering from concomitant disease.
- History of previous gastric surgery.
- Pregnant and lactating women.
- Cases of diabetes mellitus cardiac and lungs diseases. Zollinger-Ellison Syndrome, Crohn diseases.
- Any other condition that in the investigator's opinion makes the patient participation in the study difficult.

Diagnostic Criteria

Diagnosis of each case was made with the help of history in respect of selected patient's i.e. previous similar episode, physical and systemic examinations.

Treatment of Patients

All patients of Tabkheer-i-Meda selected as per the inclusion/exclusion criteria were diagnosed and were given 5gm of Safoof-i-Tabkheer with water after meal, twice daily for one week.

Safety Assessment

The safety was assessed by monitoring adverse events volunteered by the patients or observed during the course of the study. No adverse effect of the Safoof-i-Tabkheer was either reported by the patients or observed during the course of the study.

Clinical Evaluation

The efficacy of the drug was assessed on clinical parameters of Tabkheer-i-Meda (GERD) i.e. retrosternal burning, acidic brash, epigastric pain andanorexia. Severity of the symptoms of disease were measured on 4 points scale i.e. absent=0, mild=Grade 1, moderate=Grade 2, sever=Grade 3 for appropriate assessment and statistical evaluation of the test drug.

Statistical Analysis

All the data at the baseline and after the treatment were statistically analyzed by applying paired 't' test, wherein $p<0.05$ has been considered as statistically significant and $p<0.001$ has been considered as statistically highly significant.

OBSERVATIONS

During the course of study, the patients were divided into four age groups 18-30 years, 31-40 years, 41-50 years and 51-60 years. Out of 30 cases, 15 (50%), 7 (23.33%), 5 (16.67%) and 3 (10%) cases were of age groups 18-30, 31-40, 41-50 and 51-60 years respectively (Table-2). It was observed that the prevalence of the disease was decreased with

increasing of age and was relatively lower in people of age group >51-60 years (Table-2).

Table no 3 shows distribution of patients according to gender. Out of 30 selected patients, 21 (70%) patients were female and 9 (30%) patients were male.

The patients were divided into three groups according to their socio-economic status. It was observed that out of 30 selected patients, 4 (13.33%), 17 (56.67%) and 9 (30%) patients were of higher, middle and lower socio-economic status respectively (Table-4). It was observed that incident of disease was relatively lower in high income group.

Patients were divided into three groups i.e. sedentary, moderate and active in accordance with their life styles. It was observed that numbers of patients of sedentary, moderate and active life styles were 14 (46.67%), 9 (30%) and 7 (23.33%) respectively. High incidences of the disease were observed in people, who adopted sedentary life style (Table-5).

Among the 30 patients, 10 patients (33.33%) were vegetarian and 20 patients (66.67%) were non vegetarian (Table-6). It was observed that the high incidences of disease i.e., 66.66% were, in the people having non-vegetarian habits.

The classification of patient according to bowels habits is done to determine the bowels habits relation with the disease. It was found that out of thirty patients, five (16.67%) patients had regular bowel habit, fifteen (50%) patients had irregular bowel habit and 10 (33.33%) had constipated bowel habit (Table-7).

Table No 1: Formulation of Safoof-i-Tabkheer (Anonymous 2006)[12]

S.no.	Ingredients	Scientific Name	Quantity
1.	*Badiyan*	*Foeniculum vulgare.*	50 gm.
2	*Kishneez Khushk*	*Coriandrum sativum*	50 gm.
3	*Dana-e- Heel Khurd*	*Elettaria cardamomum*	50 gm.
4	*Tabasheer*	*Bambusa arundinacea*	50 gm.

Table 2: Age wise distribution of the patients

S. No.	Age-groups	Patients	
		Nos.	Percentage
1.	18-30	15	50.00
2.	31-40	07	23.33
3.	41-50	05	16.00
4.	51-60	03	10.00
Total		30	100

Table 3: Gender wise distribution of the patients

S.No.	Genders	Patients	
		Numbers	Percentage
1.	Male	09	30.00
2.	Female	21	70.00
	Total	30	100

Table 4: Distribution according to socio economic status

S.No.	Socio Economic Status	Patients	
		Nos.	Percentage
1.	Higher income group	04	13.33
2.	Middle income group	17	56.67
3.	Lower income group	09	30.00

Table 5: Distribution of patient according to their life styles

S.No.	Lifestyles	Patients	
		Nos.	Percentage
1.	Sedentary	14	46.67
2.	Moderate	09	30.00
3.	Active	07	23.33

Table 6: Distribution of patient according to their dietary Habits

S.No.	Dietary habits	Patients	
		Nos.	Percentage
1.	Non Vegetarian	20	66.66
2.	Vegetarian	10	33.33
	Total	30	100

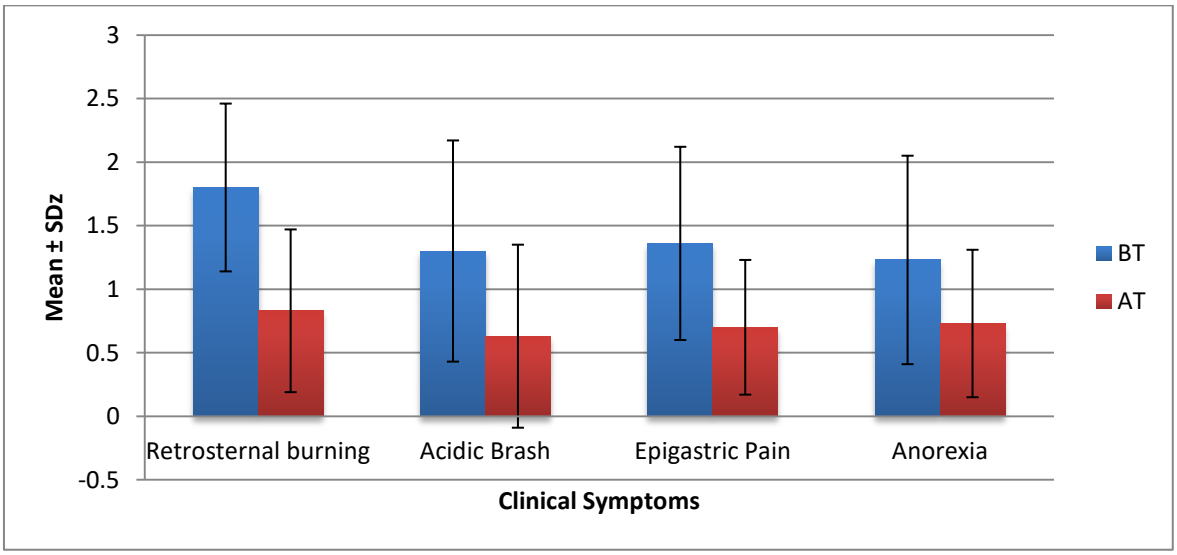
Table 7: Distribution according to bowel habits

S.No.	Bowel habits	No. of patients	Percentage (%)
1.	Regular	05	16
2.	Irregular	15	50
3.	Constipated	10	33.33
	Total	30	100

Table 8: Efficacy of Safoof-i-Tabkheer on clinical parameters of Tabkheer-i-Meda (Gastro-esophageal Reflux Disease)

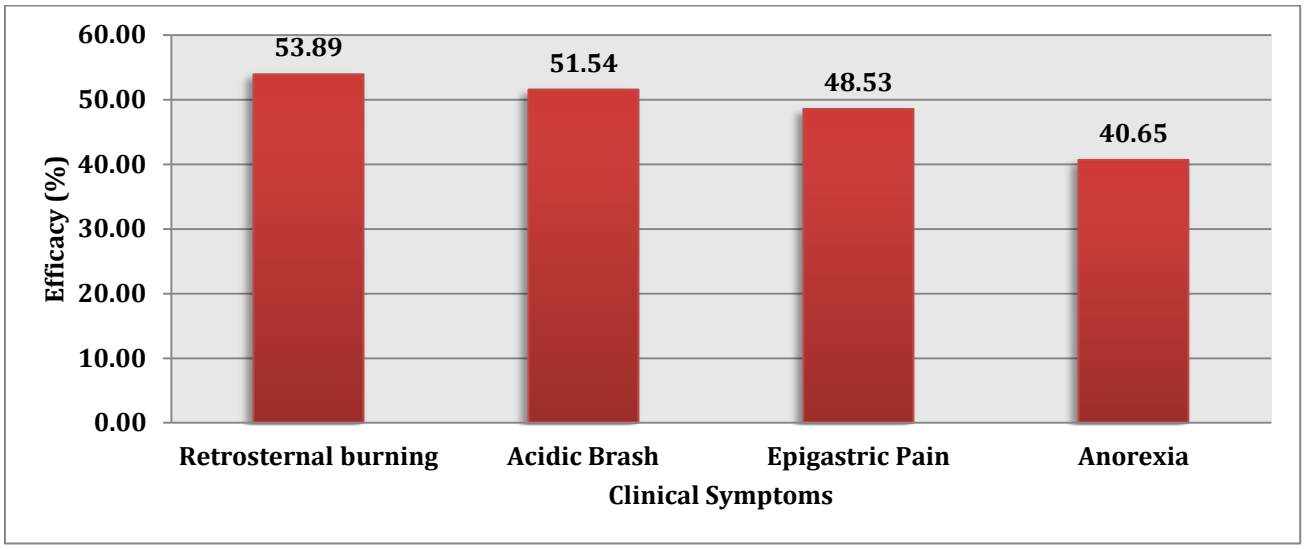
S.No.	Clinical parameters	Mean ± S.D at Before Treatment	Mean ± S.D at After Treatment	Efficacy (%)	p-value
1.	Retrosternal burning	1.8 ± 0.66	0.83 ± 0.64	53.89	<0.001
2.	Acidic Brash	1.3 ± 0.87	0.63 ± 0.72	51.54	<0.001
3.	Epigastric Pain	1.36 ± 0.76	0.7 ± 0.53	48.53	<0.001
4.	Anorexia	1.23 ± 0.82	0.73 ± 0.58	40.65	<0.001

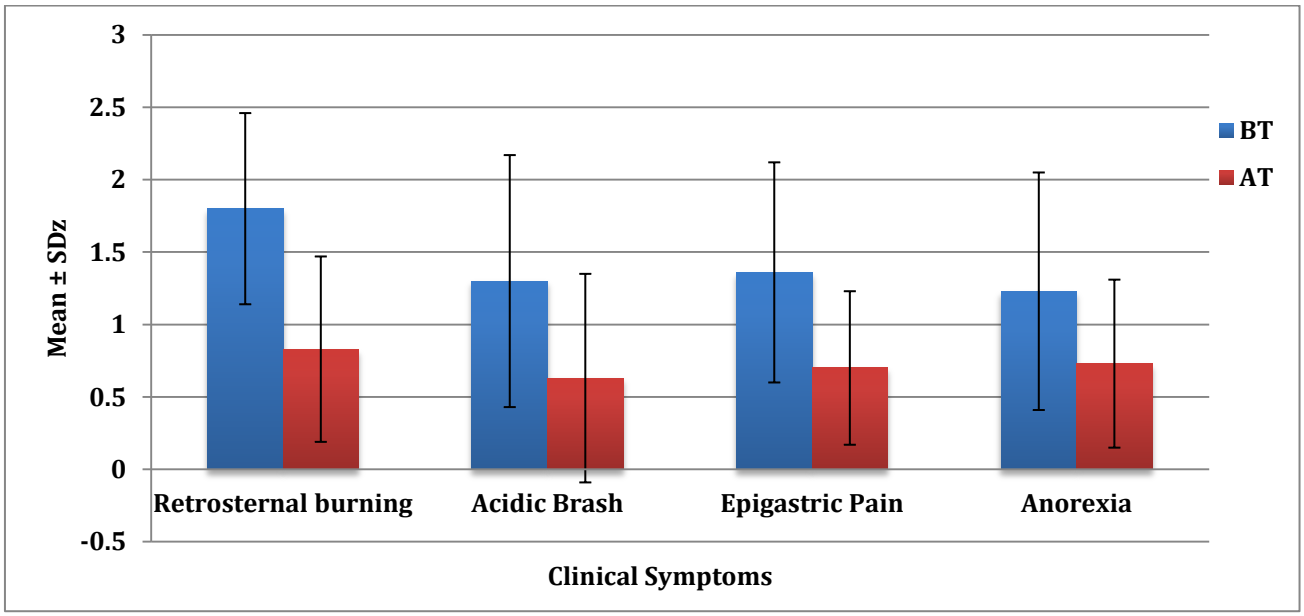
Graph-1 Improvement in clinical parameters of Tabkheer –i-Medabefore and after treatment (Gastro-esophageal Reflux Disease)



BT=Before Treatment/ AT=After Treatment

Graph-2: Efficacy (improvement in %) of Safoof-i-Tabkheer on clinical parameters of Tabkheer –i-Meda (Gastro-esophageal Reflux Disease)





RESULTS AND DISCUSSION

Our study demonstrated that people of all age-group share at the risk of Tabkheer-i-Meda (GERD). In our study, the prevalence of Tabkheer-i-Meda was found higher in the people of age group 18-30 years and lower in age group 51-60 years. The prevalence of disease was found decreasing with increasing of age and was relatively lower in the people of old age group. The finding of our study agrees with the finding of Fujiwara et al., who also reported similar findings that the prevalence of GERD symptoms was relatively lower in the people of old age group.[13]

The Prevalence of Tabkheer-i-Meda (GERD) was higher among the people having non-vegetarian habits. The intake of fatty non-vegetarian diets in large quantities led to the development of heartburn and regurgitation because fat delays gastric emptying and is a well-known risk factor of Tabkheer-i-Meda (GERD). Low fat vegetarian diets reduce the gastric fluid secretion in the stomach.[14]

In our study, the prevalence of Tabkheer-i-Meda (GERD) was found relatively higher in women. There are limited studies, which investigated sex-gender differences between women and men, who were suffering with Tabkheer-i-Meda. Recently, Asanuma et al., have nicely reviewed the sex difference of GERD incidences and the important role of female estrogen.[15]

Our result demonstrated that the prevalence of Tabkheer-i-Meda (GERD) also depends on socio-economic status of the people and is relatively lower in the people of higher socio-economic status. Prevalence of this disease is associated with the low education level and low income of the people. The

subjects with low education level and low income might have fatty diets which are believed to delay gastric emptying. The delayed gastric emptying is a significant factor related to the disease. Our finding agrees with the finding of Moshkowitz and others, who found that this disease was associated with low income and low education level of the people.[16] The incidence of the disease i.e. 46.66% was found in the people, who live a sedentary life style. It reflects that the disease is also closely related to life styles of the people.

Our study has suggested that people with irregular bowel habit are relatively at higher risk of the disease. The irregular bowel syndrome causes belly pain along with changes in bowel habits in the form of either diarrhoea or constipation and is often accompanied by the chronic form of acid reflux. Large population-based studies have used validated questionnaires to investigate a possible association between GERD and Irritable Bowel Syndrome (IBS).The studies suggested that GERD can affect a considerable proportion of patients with IBS.[17,18]

At the end of the study, the severity scale of the associated symptoms of the disease i.e., retrosternal burning, acidic brash, epigastria pain and anorexia were found significantly reduced by 53.89%, 51.54%, 48.53% and 40.65% respectively as compared to baseline. After treatment, decrease in Mean+/- SD scores of the associated symptoms of disease including retrosternal burning, acidic brash, epigastria pain and anorexia were found highly significant ($p<0.001$) as compared to baseline. Reduction in severity and intensity of the associated symptoms of Tabkheer-i-Meda was due to the treatment by drugs. The ingredients of the drugs are Badiyan, Khishneez-khushk, Dana-e-Heel-*i*-khurd and Tabasheer, in which Badiyan has the carminative effect to remove pain of intestine. Kishneez-khushk has analgesic and anti-inflammatory effects; Danaheel-e-khurd also has carminative effect and is used for relief in heart burns. Coriandrum has musakkin (analgesic) effect.[19] Recent study carried Jahan et.al. Revealed that Tukhm-*i*- Kishneez is very effective in peptic and gastric ulcers.[20] Tabasheer (Bambusaarundinacea) has anti-inflammatory and antiulcer activity.[21] Reduction in severity and intensity of the associated symptoms of Tabkheer-i-Meda (GERD) was really due to treatment of the disease with formulated drug, which ingredients have carminative, analgesic and anti-inflammatory effects.

CONCLUSION

It can be concluded that the Unani pharmacopoeial formulation Safoof-*i*-Tabkheer is very effective and safe in the treatment of Tabkheer-i-Meda. However, as the current observational study was limited to only 30 patients at CRIUM in Lucknow, therefore study with larger numbers of patients needs to be carried out.

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