ORIGINAL RESEARCH PAPER

Unani Medicine

MANAGEMENT OF HUMUZAT-E-MEDA (HYPERACIDITY) WITH JAWARISH AMLA & HABB-E-PAPITA- A MULTI CENTRIC STUDY

KEY WORDS: Hyperacidity, Jawarish Amla and Habb-e-Papita, Humuzat-e-Meda

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ABSTRACT

Background – Hyperacidity is one of the most common diseases seen in all ages. Hyperacidity simply means an increased level of acid in the stomach. Unani system of medicine has a treasure of formulations for the treatment of hyperacidity.

Methods- Present open labeled, multi-centric, single arm validation was conducted to evaluate the safety and efficacy of Unani pharmacopeial drug *Jawarish Amla* and *Habb-e-Papita* in *Humuzat-e-Meda* (Hyperacidity). Patients with symptoms of hyperacidity like retro-sternal burning, epigastric pain with retro-sternal heaviness, acidic brash, anorexia, nausea and vomiting were included. Patients with known duodenal ulcers, peptic ulcer, gastric surgery gastric carcinoma, Crohn's Diseases, Zollinger Ellison Syndrome, cardiac disorders, respiratory ailments, Diabetes Mellitus, pregnant and lactating females were excluded. Unani formulations, *Jawarish Amla* 10 g and *Habb e Papita* 2 tablets were given twice daily after meals for 6 weeks. Clinical & haematological parameters were assessed before and after the treatment to evaluate the safety and efficacy of the drug.

Results– No significant changes are observed after 28 days and 84 days during the therapy in the safety profiles of laboratory investigations such as complete haemogram, LFT, KFT. There is significant improvement in the sign and symptoms associated with *Humuzat-e-Meda* (Hyperacidity).

Conclusion- Unani compound formulations *Jawarish Amla* and *Habb-e-Papita* are safe and effective in the management of *Humuzat-e-Meda* (Hyperacidity).

INTRODUCTION

Humuzat-e-Meda (hyperacidity) is a condition wherein acid secretion in stomach is much more than normal. Unani physicians have mentioned it by different names such as *Sozish-e-Meda, Tezabiyat* or *Besh Tezabiyat* and *Hurqat-e-Meda.* In modern terminology, *Humuzat-e-Meda* may be translated as Acid Dyspepsia, Hyperacidity or Hyperchlor Hydria which simply means acidity in the stomach or excessive amount of HCl in the stomach[1-2].

According to Unani system of medicine, cause of *Humuzat-e-Meda* is the weakness of *Quwwat-e-Hazm* of stomach which results in fermentation of food and produces various kinds of organic acids. These organic acids give rise to acidity and other symptoms of *Humuzat-e-Meda.* It is common in those people who live in sedentary style. In Unani literature, it is defined as a syndrome rather than a disease which is characterized by various symptoms like epigastric and retrosternal burning either at full or empty stomach, nausea, sour or bitter belching, regurgitation of food or vomiting of sour substances, improper digestion, abdominal discomfort or pain, suppression of thirst, anorexia, and acid reflux[3-4].

Unani physicians have described the signs and symptoms of *Humuzat-e-Meda* according the cause of the disease, which include epigastric burning or irritation after taking food. Some patients complain of epigastric heaviness or pain which exist until the food passes the stomach. *Razi* has mentioned some other signs and symptoms of *Insibab-e-Sauda* like *Su-e-Hazm, Nafakh-e-Shikam*, sour or bitter belching and vomiting of *Sauda*. In case of excess of *Insibab-e-Safra*, patients complains of burning or irritation at the site of stomach, epigastric pain, bitter taste, vomiting of *Safra*, desire for cold water, loss of appetite, restlessness and palpitation.[5-6,7-8]

Treatment of hyperacidity in conventional medicine is satisfactory, but medicine has to be continued for long duration. Life style changes and reassurance are primary treatment for those who suffer from mild symptoms while for severe symptoms or nonresponsive to the latter treatment, proton pumps inhibitors (PPIs) and prokinetics are good choices.

Therefore, the limited effectiveness of chemical drugs and the side effects of synthetic drugs make assessments of herbal preparations an appealing prospect. Approaches based on alternative medicine in the treatment of hyperacidity have a long history, and several modalities have been investigated with some promising results. A considerable amount of literature in Unani Medicine is available to support different drugs for the treatment of dyspeptic symptoms.

Jawarish Amla and *Habb-e-Papita* is a poly herbal preparation in the treatment of *Humuzat-e-Meda* since long by eminent Unani physicians but the scientific data on its efficacy is lacking. Therefore, this study had been undertaken to validate the efficacy and safety of *Jawarish Amla* and *Habb-e-Papita* in the management of *Humuzat-e-Meda.*

MATERIAL AND METHODS

Study was conducted over a period of around two years. The protocol was approved by the Institutional Ethics Committee of Central Council for Research in Unani Medicine, New Delhi and was implemented in accordance with provisions of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines.

The study was designed as open labelled, multi-centric, single arm validation study and was conducted in the three

peripheral institutes of CCRUM viz. Central Research Institute of Unani Medicine CRIUM, Lucknow; Regional Research Institute of Unani Medicine (RRIUM) Patna and RRIUM, Srinagar. The objectives of the study are to evaluate the safety and efficacy of Unani pharmacopeial drug *Jawarish Amla* and *Habb e Papita* in *Kasrat- e- Ratoobat-e-Hamoozi* (Hyperacidity).

Test drugs were procured from CRIUM, Hyderabad. Standardization for the quality control of the test was conducted on various parameters in the laboratories of the CRIUM, Hyderabad. Patients of both genders within age group between 18 to 60 years who had symptoms of hyperacidity like retrosternal burning, epigastric pain with retrosternal heaviness, acidic brash, anorexia, nausea and vomiting were included in the study. Patients with known duodenal ulcers, peptic ulcer, gastric surgery gastric carcinoma, Crohn's Diseases, Zollinger Ellison Syndrome, cardiac disorders, respiratory ailments, Diabetes Mellitus, pregnant and lactating females were excluded from the study.

Out of total 400 patients screened, 350 patients who fulfilled the study inclusion criteria were explained regarding the dosage, duration and purpose and duration of the trial and after obtaining the written informed consent, were enrolled in the study. Baseline investigation namely Hb %, TLC, DLC, ESR, LFT, KFT were done in all patients.

Jawarish Amla, a compound Unani formulation in semisolid form were given in the dose of 10 gm twice daily in the morning and evening with water and two tablets of *Habb e Papita* twice daily after meals were given for 6 weeks. Of the 350 enrolled patients, only 251 patients completed the study and rests were dropped out due to failure of follow-up. After completion of the trial, data was entered and statistical tools were used to analyse. Baseline and follow up values of biochemical and pathological tests are statistically analyzed using Student's paired 't' test and the significance level of $P < 0.05$ are used in this study. Assessment of the safety of the drug was done on clinical parameters and investigations which include Hb %, TLC, DLC, ESR, LFT, KFT and efficacy of the drug was assessed on various questionnaire used for the purpose, which include visual analogue scale (VAS) for assessment of pain, frequency scale for the symptoms of GERD, scale for Functional Well-being for assessment of Nausea and Appetite and Geriatric Depression Scale. Patients were followed up at week 1 (day 7), week 3 (day 21) and week 6 (day 42) of the protocol therapy.[9-11]

RESULT AND DISCUSSION

Demographic Details

In the present study, out of total 251 patients, 157 (62.50%) were females and 94 (37.50%) were males. Mean age of the participants was 37.21 ± 11.12, as far as socio-economic status of the patients is concerned, highest number of patients 154(61.40%) belong to low income group followed by middle income group 94 (37.50%) and high-income group 3 (1.20%). Assessment of *Mizaj* (temperament) of the patients was done at baseline and it was revealed that maximum number of patients 127(50.60%) belonged to *Safravi* (bilious), followed by *balghami* (phlegmatic) 89(35.50%), *Damvi* (sanguine) 29(11.60%) and *Saudawi* (melancholic) 6(2.40%). (Table 1)

Table 1: Demographic Details

Variable	N=251
Gender n(%)	
Female	157(62.50%)
Male	94(37.50%)
Age (in years) mean ±SD	37.21 ± 11.12
Income n(%)	
Low income	154(61.40%)
Middle income	94(37.50%)
High Income	3(1.20%)
Mizaj n(%)	
Damvi	29(11.60%)
Phelgematic	89(35.50%)
Bilious	127(50.60%)
Melancholic	6(2.40%)

Safety Evaluation

As far as safety of *Jawarish Amla* and *Habb-e-Papita* are concerned, it is evaluated on clinical symptoms and bio-chemical parameters as well. After 6 weeks of treatment no adverse event had been reported by the patients or observed by the clinician. Similarly, no significant derangement was observed in the laboratory investigations after the completion of treatment. (Table 2)

Table 2: Change In The Laboratory Parameters

Laboratory Investigations	Before treatment (Mean ± SD)	After treatment (Mean ± SD)	p-value
Haemoglobin	12.1 ± 1.3	12.0 ± 1.5	0.015
TLC	3737.2 ± 3211.7	3803.7 ± 3342.9	0.385
Neutrophil	62.3 ± 6.5	62.8 ± 7.0	0.367
Lymphocyte	33.2 ± 5.4	33.0 ± 6.7	0.611
Monocyte	1.5 ± 0.8	1.3 ± 1.0	0.005
Eosinophils	3.0 ± 1.9	3.5 ± 3.1	0.014
ESR	16.5 ± 13.3	18.7 ± 14.3	0.001
Blood Urea	22.3 ± 6.8	21.9 ±6.7	0.33
Serum Creatinine	0.8 ± 0.2	0.8 ± 0.2	0.189
Serum Uric acid	4.6 ± 1.1	4.8 ± 2.7	0.313
Serum Bilirubin	0.7 ± 0.3	0.7 ± 0.6	0.076
SGOT	23.3 ± 9.7	24.8 ± 10.9	0.019
SGPT	27.6 ± 12.2	29.6 ± 15.3	0.009

Efficacy Evaluation

Effect On Pain Using VAS-

For the assessment of efficacy of Unani formulations, *Jawarish Amla* and *Habb e Papita* in hyperacidity Visual Analogue Scale (VAS) was used to assess the intensity of pain. Mean reduction of 3.76 ± 3.9 with p value 0.001 in VAS after one week of intervention therapy was noted in first week of follow-up. The reduction in VAS became 1.89 ± 3.04 and 0.31 ± 2.4 after 3 weeks and 6 weeks respectively. This reduction in VAS is again found statistically significant with p value 0.001 at both follow ups period. (Table 3, figure 1)

Table 3: Mean reduction in VAS score for pain in hyperacidity

Visual Analog scale for assessment of pain	Mean ± SD	p-value
1 week	3.76 ± 3.9	0.001
3 weeks	1.89 ± 3.04	0.001
6 weeks	0.31 ± 2.4	0.001

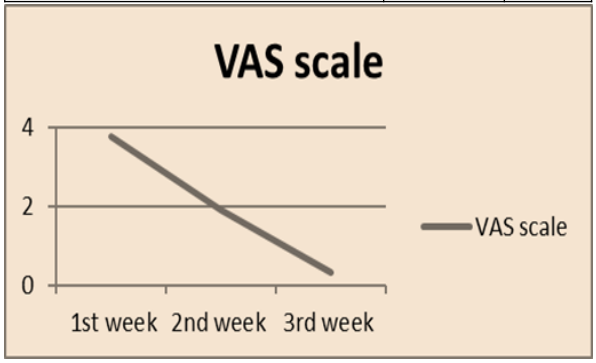

Figure 1: Trend In The VAS Score Assessed For Reduction In Pain

Effect On Symptoms Of GERD Using Frequency Scale For Symptoms Of GerD –

It was assessed at 1st week (day 7), 3rd week (day 21) and 6th

week (day 42) of protocol therapy. When assessed on 1st week, mean change of 13.82 ± 5.61 was noticed with p value 0.001 which is statistically significant. Values of FSSGD, when assessed at 3rd and 6th week became 8.00± 5.99 and 3.86 ± 5.79 respectively. (Table 4, Figure 2)

Table 4: Mean Reduction In FSSGD Scores

Frequency Scale for the symptoms of GERD	Mean ± SD	p-value
1 week	13.82 ± 5.61	0.001
3 weeks	8.00± 5.99	0.001
6 weeks	3.86 ± 5.79	0.001

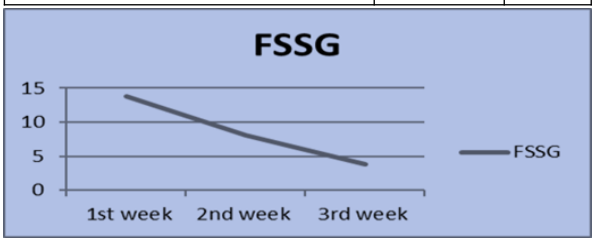

Figure 2: Trend In The Mean Reduction In FSSGD Scores

Effect On Nausea And Appetite Using Scale For Functional Well -being –

Scale for Functional Well -Being for assessment of nausea and appetite was evaluated at every follow-up visit which was conducted on 1st week (day 7), 3rd week (day 21) and 6th week (day 42). Mean change of 12.25±3.81 was noted on first follow at 1st week, which is statistically significant with p value 0.001. This change became 14.92 ± 5.72 at 3rd week and further changes to 17.17 ± 8.80 after 6 week of protocol therapy. This improvement in the nausea and appetite symptoms of hyperacidity attributed to *Qat-e-safra* and *Muqavvi-Meda* activity of the compound Unani drug *Jawarish Amla*. (Table 5, Figure 3)

Table 5: Mean reduction in Scale for Functional Well-Being

Scale for Functional Well-Being for assessment of Nausea and appetite	Mean ± SD	p-value
1 week	12.25±3.81	0.001
3 weeks	14.92 ± 5.72	0.001
6 weeks	17.17 ± 8.80	0.001

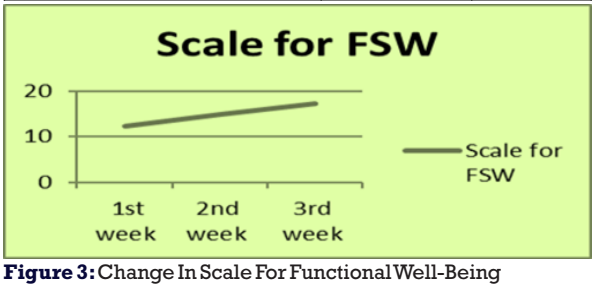

Figure 3: Change In Scale For Functional Well-Being

CONCLUSION-

It could be inferred that the Unani compound formulations *Jawarish Amla* and *Habb e Papita* are safe and effective in managing hyperacidity. As far as efficacy of drugs is concerned, it is revealed that there is significant improvement in the sign and symptoms of hyperacidity. This improvement is more considerable, when therapy continues for longer duration. Further studies can be done to explore the mechanism of action of Unani compound formulation.

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