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CLINICAL VALIDATION OF UNANI PHARMACOPEIAL FORMULATION *JAWARISH PUDINA WILAYATI* IN THE MANAGEMENT OF *SŪ' AL-HAZM (DYSPEPSIA*)

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Abstract

Background: Dyspepsia is a sensation of discomfort in the upper part of abdomen usually starts immediately after having a meal. Patients usually reports stomach-ache, over-fullness, bloating and sometime acid reflux, heartburn, and excessive burping.

Aim: This study aims to validate the efficacy of 5g of *Jawarish Pudina Wilayati* in the Management of *Sū' al-Hazm (Dyspepsia*) for a period of six weeks.

Method: Multicentric open label clinical study was strategized; 100 patients completed the 6 weeks protocol therapy from 18/08/2020 to 03/03/2022. 5 g of Jawarish *Pudina Wilayati* was given twice daily.

Result: 37% patients were completely relieved while 49% patients were partially relieved. *Safrāvī* patients aged between 29-39 years showed maximum response. No side effects were observed.

Conclusion: *Jawarish Pudina Wilayati* is safe and effective in the management of *Sū' al-Hazm (*Dyspepsia)

Keyword*: Sū' al-Hazm,* Dyspepsia, *Jawarish*, Unani, *Quwat Jaziba*, *Fasad al-Hazm*

Introduction

Gastrointestinal (GI) symptoms such as indigestion/dyspepsia, heartburn, bloating, constipation is common in every population. However, these symptoms may be misinterpreted and their impact and consequence are misunderstood both by medicos and patients. Dyspepsia/ Indigestion or upset stomach is a discomfort in upper abdomen. It is either a symptom of digestive disorder or caused by lifestyle factors. Approximately 80% of individuals with dyspepsia have no structural explanation for their symptoms. It includes belching (burping), bloating (swelling in the abdomen), feeling of fullness after eating, pain or burning in the stomach (heartburn), nausea or early satiety. [1,2,3] Unani Medical practitioners in antiquity identified the digestive system as one of the major principal systems of the body and thought it responsible for the metabolic functions chiefly the digestion (*Quwat Hazima*), absorption (*Quwat Jaziba*) and production and storage of humors (*Akhlat*) for nourishment, growth and development of the human body. [4,5,6] *Su' al-Hazm or Fasad al-Hazm* simply means incomplete digestion resulting into putrefaction of food due to dietary factors or weakness of any one of the four faculties of stomach, namely *Quwat Jaziba* (absorptive power), *Quwat e Masika* (retentive power), *Quwat e Hazima* (digestive power) and *Quwat e Dafia* (excretive power).[5,7] There are various single as well compound formulations are mentioned in Unani literature which are used for the management of *Sū' al-Hazm* and Unani scholars have been treating digestive disorders effectively. This study was conducted to validate one such compound formulation- *Jawarish Pudina Wilayati* in the management of Dyspepsia.

Methodology

Study Design: The study was prospective, an open-labelled, multi-centric, single arm clinical study. Although the study was multi-centric, this study represents the result of one of the centre i.e. Clinical Research Unit, Meerut.

Ethical consideration: The protocol was approved by Ethics Committee of the study centre on 12/06/2019. The study is registered with Clinical Trial Registry of India

(CTRI/2020/02/023637) and was implemented in accordance with provisions of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines.

Study participants: Informed consent was obtained and each patient was screened for eligibility to participate in study. Total 100 patients completed the study.

Inclusion criteria: The patients aged between 18-60 years were screened and patients meeting the Rome III diagnostic criteria for post prandial distress syndrome were included.

Exclusion criteria: Patient with alarming symptoms like weight loss, severe anaemia, haematemesis, melena or any abdominal mass or uncontrolled systemic disease were not included. Pregnant and lactating mothers were also excluded.

Intervention: Study medicine- *Jawarish Pudina Wilayati* is a classical poly-herbal formulation and was procured from NRIUMSD, Hyderabad. 5g of *Jawarish Pudina Wilayati* twice daily was given orally for 6 weeks, the patients were clinically examined on baseline, 14th day, 28th day 42nd day.

Study Procedure: The study was conducted for a period of 3 years approximately from 18/08/2020 to 03/03/2022 at Clinical Research Unit, Cantonment General Hospital, Meerut, Uttar Pradesh. 108 patients were screened and those fulfilling the inclusion criteria were enrolled; 08 cases were dropped out and rest 100 patients completed the research study.

Outcomes: For evaluating efficacy, Rome III criteria for dyspepsia and Postprandial Distress Syndrome was evaluated at baseline and after every two weeks for 6 weeks. For assessing safety, all patients were questioned for adverse effects. Systemic examination and laboratory parameters such as CBC with ESR, Liver and Kidney function test, and Urine routine microscopic were done before and after the treatment.

Statistical Analysis: The data analysis was done by statistician using IBM SPSS Statistics 2.0 (1989-2011). Student t-test, Mann-Whitney test and Chi-square/ Fisher Exact were used to find the significance of study parameters on continuous scale and categorical scale respectively.

Observation & Results:

Table 1. Demographic details

Gender	**Male**	**Female**
	49 (45.37%)	59 (54.6%)
Age in Years	34.81 yrs.	37.27 yrs.
Marital Status	**Married**	**Unmarried**
	85 (78.7%)	23 (21.29%)
Dietary Habits	**Vegetarian**	**Mixed**
	14 (12.96%)	94 (87.04%)
Socioeconomic Group	**LIG**	**MIG**
	84 (77.78%)	24 (22.22%)
Mizaj of the Patient	***Balghamī***	***Safrāvī***
	42 (38.89%)	66 (61.1%)

Table 2. Safety assessment of *Jawarish Pudina Wilayati in Sū' al-Hazm (*Dyspepsia)

	Before Treatment	**After Treatment**
Hemogram	11.17 ± 0.12	11.51 ± 0.12
TLC	8664 ± 112	8278 ± 94
Neutrophils	55.42 ± 0.48	55.98 ± 0.43
Lymphocytes	35.73 ± 0.46	35.96 ± 0.45
Eosinophil	5.6 ± 0.15	4.68 ± 0.09
Monocytes	3.22 ± 0.11	3.38 ± 0.09
ESR	13.7 ± 0.39	9.53 ± 1.14

Serum Bilirubin	0.86 ± 0.01	0.79 ± 0.02
SGOT	28.41 ± 0.66	26.91 ± 0.75
SGPT	31 ± 0.95	29.7 ± 1.13
ALP	96.96 ± 0.81	91.87 ± 0.91
Serum Creatinine	0.89 ± 0.01	0.81 ± 0.01
Serum Urea	23.46 ± 0.21	21.96 ± 0.20

Table 3. Response of *Jawarish Pudina Wilayati in Sū' al-Hazm (*Dyspepsia)

Response	No. of Patients
Relieved	37 (37%)
Partially Relieved	49 (49%)
Not Relieved	14 (14%)

Figure 1. Response of *Jawarish Pudina Wilayati in Sū' al-Hazm (*Dyspepsia)

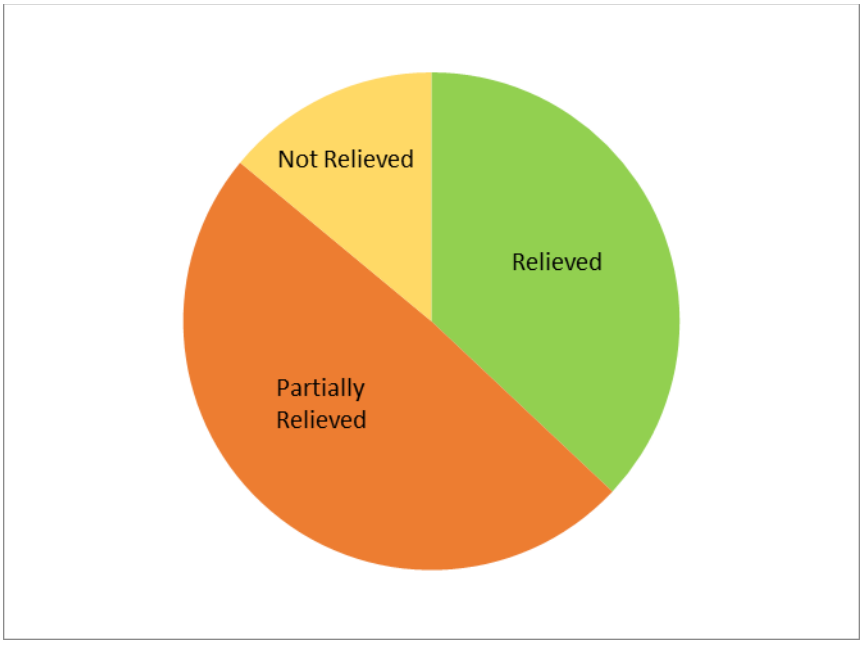


Table 4. Response on Symptoms *of Sū' al-Hazm (*Dyspepsia)

Postprandial Fullness		
Severity	**Before Treatment**	**After Treatment**
Absent	0	0
Mild	1% (1)	22% (22)
Moderate	4% (4)	74% (74)
Severe	95% (95)	4% (4)
Early Satiety		
Absent	0	0
Mild	0	0
Moderate	21% (21)	50% (50)
Severe	79% (79)	50% (50)
Abdominal Discomfort		
Absent	0	21% (21)
Mild	2% (2)	66% (66)
Moderate	49% (49)	13% (13)
Severe	49% (49)	0
Heartburn		
Absent	0	33% (33)
Mild	1% (1)	56% (56)
Moderate	66% (66)	11% (11)
Severe	33% (33)	0

Figure 2. Response on Symptoms *of Sū' al-Hazm (*Dyspepsia)

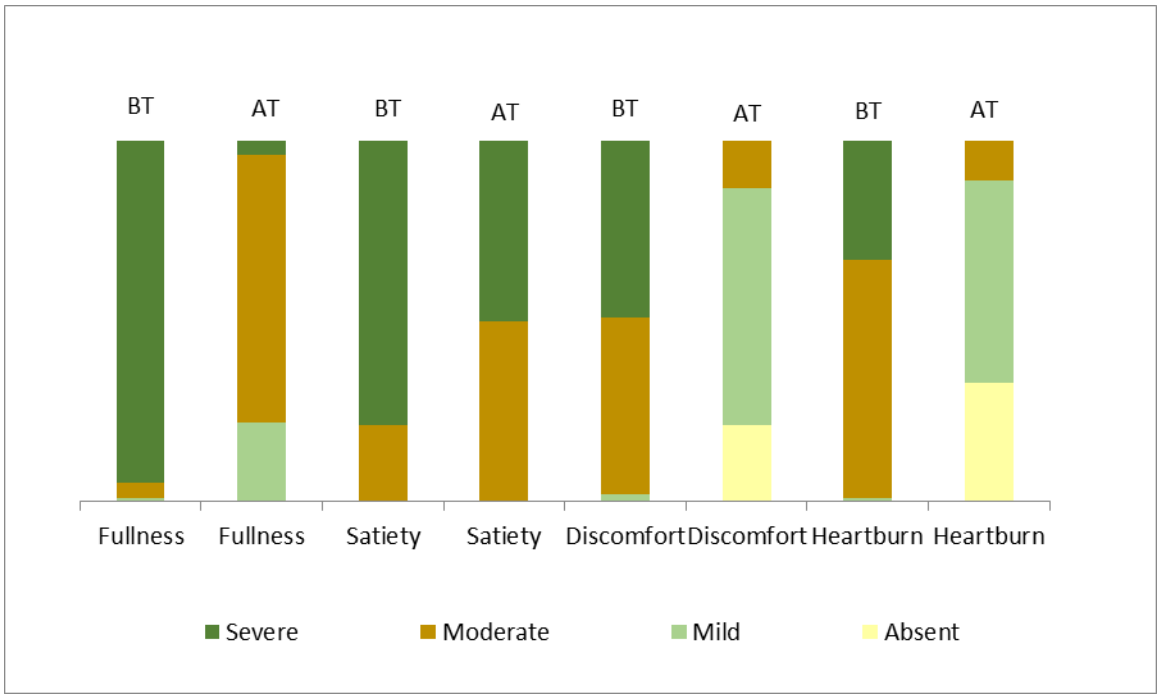
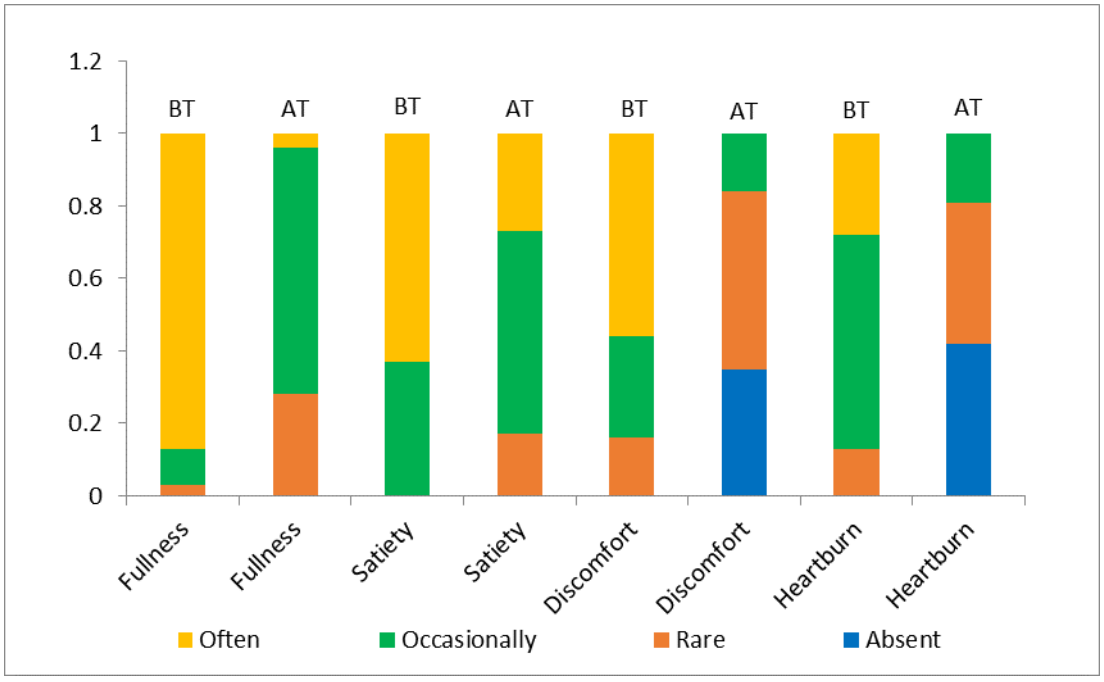


Table 5. Response on Frequency of Symptoms *of Sū' al-Hazm (*Dyspepsia)

Postprandial Fullness		
Severity	**Before Treatment**	**After Treatment**
Absent	0	0
Rare (once or twice a month)	3% (3)	28% (28)
Occasionally (once a week)	10% (10)	68% (68)
Often (multiple times a week)	87% (87)	4% (4)
Early Satiety		
Absent	0	0
Rare (once or twice a month)	0	17% (17)
Occasionally (once a week)	37% (37)	56% (56)
Often (multiple times a week)	63% (63)	27% (27)

Abdominal Discomfort		
Absent	0	35% (35)
Rare (once or twice a month)	16% (16)	49% (49)
Occasionally (once a week)	28% (28)	16% (160
Often (multiple times a week)	56% (56)	0
Heartburn		
Absent	0	42% (42)
Rare (once or twice a month)	13% (13)	39% (39)
Occasionally (once a week)	59% (59)	19% (19)
Often (multiple times a week)	28% (28)	0

Figure 3. Response on Frequency of Symptoms *of Sū' al-Hazm (*Dyspepsia)



Discussion

Demographic distribution

Highest incidence of *Sū'al-Hazm (*Dyspepsia) i.e. 43.52% (n-44) was observed in the age group 29-39 years wherein 78.7% (n-85) patients were married. As per the Kuppuswamy scale, maximum number of patients in the study belongs to Lower Income Group i.e. 77.78% and this could be due to the catchment areas of the hospital. 87.04% (n-94) had mixed type of diet. *Mizaj* of the patient was determined as per the *Ajnās 'Ashra* and 61.1% (n-66) were bilious (*Safrāvī*) and 38.89% (n-42) were phlegmatic (*Balghamī*) (Table 1).

Safety assessment

All Haematological & Biochemical parameters remained normal throughout the treatment and it was concluded that the *Jawarish Pudina Wilayati* is safe and didn't cause any alteration in the safety parameters. While evaluating statistically, p value was not significant in the parameters evaluated under Hemogram, Liver Function Test, Kidney function test, (Table 2).

Efficacy Assessment

Out of 100 Patients, 37% (n- 37) were completely relieved and 49% (n-49) were partially relieved (Table 3 Figure 3). 99% (n-99) patients complained about severe postprandial fullness at baseline and after the treatment only 4% (n-4) had severe symptoms while 74% and 22% had moderate and mild symptoms respectively. Patient with multiple frequency of postprandial fullness per week was 87% (n-87) at baseline, while after the treatment the frequency was decreased to once a month (28%) and once a week (68%). About 79% (n-79) had severe early satiety while after the treatment 50% (n-50) each had severe and moderate symptoms. The frequency of severe early satiety was 63% (n-63) before the treatment while only 27% had severe, 56% had moderates and 17% had rare early satiety after the medication. Before the treatment, 49% (n-49) patients each had severe and moderate abdominal discomfort while after the treatment 21% (n-21) had no abdominal discomfort and 66% had mild discomfort. Severe frequency of abdominal discomfort was observed in 56% patients that reduced to moderate in 16% and 35% had no abdominal discomfort. Out of 100 patients, 99% (n-99) patients complained about severe to moderate heartburn and after the treatment 33% (n-33) and 66% (n-66) had no heartburn and mild heartburn respectively. Frequency of heartburn once in a week was observed by 28% patients and once

or twice a month by 59% patients and after the treatment there were 42% patients with no heartburn and 39% patients with rare heartburn symptom (Table 4 & Figure 4).

Conclusion

The objective of obtaining scientific validation of *Jawarish Pudina Wilayati's* efficacy in managing *Sū' al-Hazm* (dyspepsia) was successfully accomplished. According to the findings of the study carried out at the Clinical Research Unit Meerut, *Jawarish Pudina Wilayati* can be utilized to treat dyspepsia/ *Sū' al-Hazm*. More research is needed to determine the mode of action of *Jawarish Pudina Wilayati*.

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