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A preliminary study on the safety and efficacy of the compound Unani medicine *Jawarish-e-Shahi* in the treatment of palpitation

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Heart palpitations are the sensations or feelings that accompany an excessively rapid, skip-beat, or fluttering heartbeat. Heart palpitations can be brought on by a variety of factors, such as anxiety, tension, fear, caffeine, nicotine, some medications, dietpills, physical activity, and fever. Herbal remedies have long been utilized widely in the therapeutic management of palpitations because available synthetic medications have substantial negative effects. The purpose of this study is to assess the safety and effectiveness of the Unani medication *Jawarish-e-Shahi* in patients experiencing palpitations. The information provided here is an open-level, multicentric clinical study that was carried out at the "Regional Research Institute of Unani Medicine in Aligarh", Uttar Pradesh, from 2016 to 2019 on 74 cases of palpitation streated with *Jawarish-e-Shahi*. A p-value of<0.05 was proved to be significant in the statistical analysis of the presented data, which was conducted using one-way analysis of variance (ANOVA) and Dunnett's test. The study's findings, which were compared to baseline data from various follow-ups of palpitation cases treated with *Jawarish-e-Shahi*, demonstrated a notable improvement in a number of palpitation symptoms, including anxiety, perspiration, nausea, vomiting, and chest heaviness. A significant decline in diastolic pressure and pulse rate had also been observed. Reduction in number of pallor (pale appearance of patients) in baseline, 1st follow-up and post-treatment had been noted. Based on the investigation, the Unani medicine is safe and non-toxic. More research on a large size of population with palpitations is suggested for further study.

Keywords: *Jawarish-e-Shahi,* Nausea, Palpitation, Sweating, Vomiting

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Palpitation is the term for anir regular, uncomfortable, or heightened awareness of one's own heartbeat[1-5]. The majority of palpitations have cardiac origins, which are followed by psychological and other causes[6,7]. Heart palpitations can have a normal or irregular heart rhythm; if the rhythm is regular, healthy behaviours including quitting smoking, losing weight, exercising, and eating better meals may help erduce the symptoms. Palpitations may sometimes be benign[8], but in other situations, they may indicate dangerous cardiac arrhythmias[9]. Heart arrhythmias, or irregular heartbeats, are caused by malfunctioning electrical impulses that coordinate heart beats, making the heart beat too quickly, too slowly, or irregularly[10,11]. Benignpal pitations are heart beats that aren't brought on by a serious cardiac disorder. People with the illness experience some disease and discomfort, even though the prognosis is generally favorable[12]. Demand for Unani remedies has increased due to the higher adverse effects of allopathic medications[13-18]. Therefore, the purpose of this study is to evaluate the safety and efficacy of the Unani drug *Jawarish-e-Shahi* in the therapeutic treatment of palpitation cases. It appears that no prior study was conducted to confirm the medication's ability to control palpitations.

Many plants and herbs, including Lemon balm (*Melissa officinalis* L.), Myrtle (*Myrtus communis* L.), Emblic myrobalan (*Phyllanthus emblica* L.), Clover dodder (*Cuscuta epithymum* Linn.), Lavender (*Lavandula spica* L.), Mediterranean mandarin (*Citrus deliciosa* L.), and (*Prunus* sps.) are used for the therapeutic control of palpitation, including the Unani medications, Khamira Abresham, Khamira Sandal Sada, Khamira Marwareed, Khamira Khas, Dawa-ul-Misk, Safoof Lului, Sharbat Sandal Tursh,

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Qurs Kafoor, Mufarreh Baarid, and Yaqooti[19-21] etc. Scientific confirmation is required for all such medications. This modest initiative aims to validate the use of the Unani compound medication *Jawarish-e-Shahi* to treat palpitations.

Methodology

Ethical consideration

Written informed consent has been granted by each patient involved in the study for this investigation. The study carried out under the CCRUM project produced this research article, which was accepted by the institutional ethics committee (IEC) on May 17, 2016, vide no. "F. No. 8-22/2014/RRI-ALG/Misc/20".

Study design

Open-level, multicentric clinical investigation. The "Central Council for Research in Unani Medicine, New Delhi", is the source of the Unani medication *Jawarish-e-Shahi*. "Regional Research Institute of Unani Medicine (RRIUM), Aligarh", was the site of the study. 129 individuals, of any gender, between the ages of 19 and 60, were chosen from the outpatient department (OPD) based on predetermined inclusive and exclusive criteria. There were 129 cases in all that were registered, 74 cases that were completed and 55 cases that were dropped. *Jawarish-e-Shahi*, a Unani compound medication, was assessed for safety and efficacy based on haematological, biochemical parameters, and the reduction of symptoms in three vital signs: blood pressure, pulse rate, and electrocardiogram (ECG).

Selection standards for participants

Based on the following inclusion and exclusion criteria, patients were enrolled:

Conditions of inclusion

Every subject will fulfill the subsequent requirements:

1. Patients of either gender between the ages of 19 and 60 years.
2. Individuals experiencing palpitations who exhibit any of the following symptoms and manifestation: chest heaviness, anxiety, perspiration, nausea, vomiting, and missing heartbeat.

Criteria for exclusion

Patients who satisfied any of the following criteria were not allowed to continue in the study: they had to have a history of heart disease other than palpitations; they also had to have a history of hepatic or renal disorders; diabetes mellitus; hypertension; anaemia; chronic obstructive pulmonary disease (COPD); a history of thyroid dysfunction; a history of hypersensitivity to any ingredients in the study drug; patients who had previously used other drugs for an extended period of time, such as anti-epileptic, anti-arrhythmic, and anti-psychotic drugs; and pregnant or nursing women were not allowed to participate in the study.

Medication, dosage, and route of administration

The patients received 5.0 g of the Unani medication *Jawarish-e-Shahi* orally twice a day for two weeks, 30 min before their meals[22] (Table 1).

Evaluation of temperament (mizaj)

At baseline, temperament (mizāj) was assessed. The patients' temperaments were evaluated using the 10 predetermined factors found in the *Ajnas-e-Ashra*, a major work of Unani literature.

Evaluation of the follow-up

The patients underwent a clinical assessment one week post-medication, and every two weeks, the subjective and objective observations were documented.

Clinical evaluation

S. No.	Parameter	Grading
1.	Anxiety	0= No 1= with > ordinary physical activity 2= with ordinary physical activity 3= with < ordinary physical activity 4= at rest
2.	Sweating	0= No 1= with > ordinary physical activity 2= with ordinary physical activity 3= with < ordinary physical activity 4= at rest
3.	Nausea	0= No 1= with > ordinary physical activity 2= with ordinary physical activity 3= with < ordinary physical activity 4= at rest
4.	Vomiting	0= No 1= with > ordinary physical activity 2= with ordinary physical activity 3= with < ordinary physical activity 4= at rest
5.	Heaviness of chest	0= No 1= with > ordinary physical activity 2= with ordinary physical activity 3= with < ordinary physical activity 4= at rest

Physical parameters

S. No.	Parameter	Grading
1.	Pulse Rate (bpm)	0=Normal 1= Improved but not normal 2=Abnormal (<60 or>100)
2.	Electro Cardiogram (ECG)	0=Normal 1=Abnormal

Biochemical analysis

The following well-established laboratory assays were used in biochemical investigations: "Serum glutamate pyruvate transaminase (SGPT, E.C.2.6.1.2) and serum glutamate oxaloacetate transaminase (SGOT, E.C. 2.6.1.1.)[23], serum alkaline phosphatase enzyme (S-ALP, EC. 3.1.3.1)[24], blood urea[25], serum creatinine[26], serum total bilirubin[27], uric acid[28], cholesterol[29], triglycerides[30], HDL[31], calcium[32], sodium and potassium[33]".

Haematological analysis

Haematological parameters were done[34]. Blood tests for haemoglobin (Hb), erythrocyte sedimentation rate (ESR), total leucocyte counts (TLC), red blood corpuscle counts (RBC), platelet counts, and differential leucocyte counts (DLC) that comprise polymorphs, lymphocytes, and eosinophil counts were listed.

Collection of serum

Haematology and biochemistry investigations were conducted. A vein was punctured to obtain blood samples. For different haematological parameters, "1.0 mL of blood was treated with ethylene diamin etetra acetic acid (EDTA). For different biochemical parameters, 2.0-2.5 mL of blood was left to coagulate and the serum was separated by centrifugation".

Statistical evaluation

Dunnett's test was performed after one-way analysis of variance (ANOVA) for statistical data analysis. When the p-value was less than 0.05, the values were observed significant.

Table1 — Constituents of *Jawarish-e-Shahi* (*NFUM Part-I*)[22]

Name of ingredient Scientific name	Quantity
Murabba-e-Halela (*Terminalia chebula* Retz.)	100 g
Murabba-e-Aamla (*Phyllanthus emblica* L.)	100 g
Arq-e-Badmushk (*Salix caprea* L.)/*Arq-e-Goazaban* (*Onosmabracteatum Wallich*)	Q.S.
Kishneez (*Coriander sativum* L.)	20 g
Heel Khurd (*Elettaria cardamomum* L.)	5.0 g
Nabat Safaid (Crystalline Sugar)/Qand Safaid (*Saccharum officinarum* L.)	250 g

Results and Discussion

Demographic evaluation

Out of the 74 palpitation patients, 05 (6.76%) were male and 69 (93.24%) were female. This indicates that the incidence is higher in women than in men. Patients between the ages of 16 and 29 (mean age of 22.43 years) and 30-45 (mean age of 37.32 years) were the most prone to palpitation (Table 2). In the socioeconomic status research, there was more prevalence in the lower income group 71 (95.95%) than in the middle income group 03 (4.05%) (Table 2). In a dietary habit research, non-vegetarians 71 (95.95%) had more prevalence as compared vegetarians 03 (4.05 %) (Table 2). Phlegmatic patients (balghami) accounted for 60 (81.08%) of the incidence, whereas sanguine patients (damavi) accounted for 11 (14.87%) and bilious patients (safravi) accounted for 03 (4.05%) (Table 2). In Unani literature all four temperaments might produce palpitations, with derangement in damavi being the most common, followed by safravi, balghami, and saudavi[35]. Female patients in 30-45 age group were the most likely to have a BMI of more than 25, followed by those in the 16-29 and 46-60 age groups (Table 2) respectively. The highest percentage of female patients in the 30-45 age group had BMIs under 25, which was followed by patients in the 16-29 and 46-60 age groups, respectively (Table 3 and Fig. 1).

A) Clinical assessment

The assessment of therapy efficacy was conducted using the subsequent objective and subjective parameters:

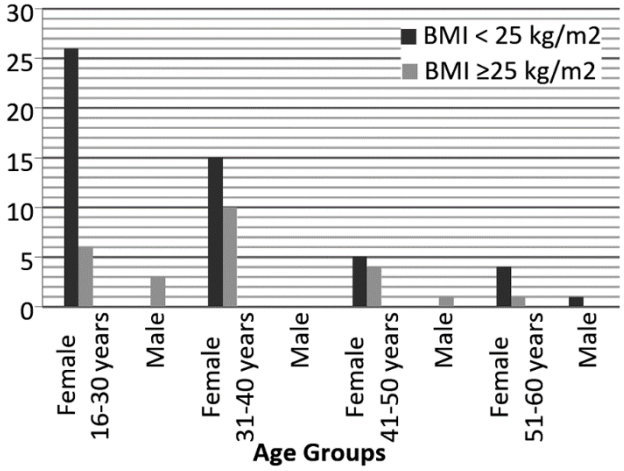

Fig. 1 —Impact of Unani medication *Jawarish-e-shahi* on body mass index on palpitation patients

1. Subjective parameters:

i. Effect on anxiety

A significant decline in score of 22.61% ($p<0.0001$) in the first week and 51.59% ($p<0.0001$) in the second week was noted, and they were contrasted with the baseline and various treatment follow-up values for a two-week period (Table 4 and Fig. 2).

ii. Effect on sweating

A significant decline in score of 25.51% ($p<0.0001$) in the first week and 52.31% ($p<0.0001$) in the second week was noted, and they were contrasted with the baseline and various treatment follow-up values for a two-week period (Table 4 and Fig. 2).

iii. Effect on nausea

Scores decreased significantly in the first and second weeks, by 37.21% and 66.98%, respectively ($p<0.0001$), and these were compared to the baseline and various follow-up treatment values for a two-week period (Table 4 and Fig. 2).

iv. Effect on vomiting

A significant decrease in score of 62.39% ($p<0.0001$) during the first week and 76.30%

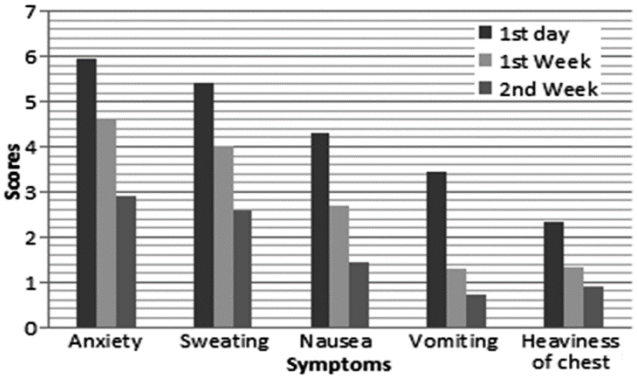

Fig. 2 —Impact of Unani medication *Jawarish-e-shahi* in reducing different symptoms of palpitation patients

Table 2 —Demographic information illustrating the distribution of various characteristics in patients with palpitation

Variables / Group	Sex	No. of patients, % age, n=41	Mean age± S.D (yrs)
1. Sex wise	Female	69 (93.24%)	34.28±1.33
	Male	05 (6.76%)	33.80±8.00
2. Age-wise (yrs)	Female	23 (31.08%)	
i. 16-29	Male	03 (4.05%)	
ii. 30-45	Female	38 (51.35%)	
	Male	01 (1.35%)	
iii. 46-60	Female	07 (9.46%)	
	Male	01 (1.35%)	
	i.7-days to 6.0 months	68 (91.89%)	
3. Duration of disease	ii. 7.0 months to 1.0 year	04 (5.41%)	
	iii. 1.1year to 2.0 year	02 (2.70%)	
4. Occupation	i. House wife	62 (83.78%)	
	ii. Labour	09 (12.16%)	
	iii. Stuydent	02 (2.70%)	
	iv. Retired	01 (1.35%)	
5. Socio-economic status (SES)	i. Lower income group (LEG)	71 (95.95%)	
	ii. Middle income group (MEG)	03 (4.05%)	
	iii. Higher income group (HEG)	Nil	
6. Dietary habits	i. Non-vegetarian	71 (95.95%)	
	ii. Vegetarian	03 (4.05%)	
7. Type of Temperament	i. Phlegmatic (Balghami)	60 (81.08%)	
	ii. Sanguine (Damvi)	11 (14.87%)	
	iii. Bilious (Safrawi)	03 (4.05%)	
	iv. Melancholic (Saudawi)	Nil	

Table 3 —Data illustrating the body mass index (BMI) distribution in cases of palpitation

Age-wise	Sex	No. of patients,%, BMI<25(kg/m^2)	No. of patients, %, BMI≥25 (kg/m^2)
16-29 years	Female	18 (24.32%) 20.77±0.48	05 (6.76%) 26.51±0.57
	Male	03 (4.05%) 16.20±1.16	Nil
30-45 years	Female	25 (33.78%) 21.53±0.43	14 (18.92%) 27.65±0.70
	Male	Nil	01 (1.35%) 28.34
46-60 years	Female	05 (6.76%) 22.17±0.35	02 (2.70%) 27.90±3.15
	Male	01 (1.35%) 15.79	Nil

($p<0.0001$) during the second week was noted, and they were contrasted with the baseline and various treatment follow-up values for at two-week period (Table 4 and Fig. 2).

v. Effect on heaviness of chest

A significant decrease in score of 42.92% ($p<0.05$) during the first week and 61.80% ($p<0.0001$) during the second week was noted, and they were contrasted with the baseline and various treatment follow-up values for a two-week period (Table 4 and Fig. 2).

vi. Effect on physical examination

a. Effect on blood pressure and pulse rate

Palpitation patients experienced a significant reduction in diastolic pressure of 2.67% ($p<0.05$) and 1.33% on the first and second weeks, respectively, and in pulse rate of 3.53% ($p<0.05$) and 5.88% ($p<0.001$) on the first and second weeks, respectively. These findings were compared with the values of the baseline and various follow-up treatments for two weeks (Table 5).

b. Effect on pallor condition (pale appearance)

There was a decrease in the number of cases of pallor condition (pale look) in palpitation patients at baseline 38 (51.35%), first follow-up 33 (44.64%), and in percentage terms when these were compared to baseline and post-treatment (2^{nd}-week) values (Table 6).

The present study on efficacy of Unani drug *Jawarish-e-Shahi* on palpitation with symptomatic relief is a pioneer attempt and there seems no earlier reference available in literature.

B) Safety assessment

Based on biochemical analysis, the following findings about the test drug's safety have been made:

i. Liver function tests and kidney function tests

There had been no discernible changes to the results of the liver function tests or kidney function tests. It follows that there was no adverse or negative reaction to the test medication. As a result, the drug's safety is confirmed (Table 7). Previous writers had reported similar observations[36].

ii. Effect on electrolyte profile

When the levels of sodium, potassium, and sodium were compared to the values at baseline and various treatment follow-ups, no discernible changes were found (Table 7). Previous researchers had made similar observations[36,37].

iii. Lipid profile

There had been no discernible change in the levels of HDL cholesterol, triglycerides, or cholesterol. Previous researchers have noted similar findings[36].

Haematological evaluation

There have been no discernible changes in the levels of Hb, RBC, TLC, ESR, or DLC. These were compared with the baseline values and several treatment follow-ups (Table 8). Previous workers had reported a similar interpretation[37]. Our findings, therefore, collaborate with earlier reports on similar

Table 4 — The impact of the Unani medication *Jawarish-e-shahi* on symptoms in palpitation patients. [*p<0.05 &**p<0.01 are significant,***p<0.001 is highly significant]

Group / Symptom	Baseline (1^{st}-day)	1^{st} F-up (1^{st}-wk)	Post-treatment (2^{nd}-wk)
Anxiety (n=74)	5.97±0.07	4.62±0.12***	2.89±0.13***
Sweating (n=74)	5.41±0.15	4.03±0.16***	2.58±0.15***
Nausea (n=74)	4.30±0.20	2.70±0.18***	1.42±0.14***
Vomiting (n=14)	3.43±0.25	1.29±0.34***	0.71±0.34***
Heaviness of chest (n=09)	2.33±0.24	1.33±0.47*	0.89±0.35***

Table 5 — Impact of the Unani medication *Jawarish-e-shahi* on blood pressure and pulse rate on patients experiencing palpitation. [*p<0.05 & **p<0.01 are significant, ***p<0.001 is highly significant]

Group / Blood pressure	Base line	1^{st}-week	Post-treatment (2^{nd}-week)
Systolic (mmHg)	119.00±0.77	119.00±0.41	119.00±0.39
Diastolic (mmHg)	75.00±0.64	73.00±0.58*	74.00±0.56
Pulse rate (bpm)	85.00±1.29	82.00±1.08*	80.00±0.78***

Table 6 — Impact of the Unani medication *Jawarish-e-shahi* on pallor condition (pale appearance) in patients experiencing palpitation

Group / Pallor	Base line (1^{st}-day)	1^{st}-week	Post-treatment (2^{nd}-week)
Present	38 (51.35%)	33 (44.64%)	24 (32.43%)
Absent	36 (48.65%)	41 (55.41%)	50 (67.57%)

Table 7 — Impact of the Unani medication *Jawarish-e-shahi* in the concentration of uric acid, serum creatinine, bilirubin, SGPT, SGOT, alkaline phosphatase, and blood urea in patients experiencing palpitation

Parameter / Group	SGOT (IU/L)	SGPT (IU/L)	Alkaline Phosphatase (IU/L)	Bilirubin (mg %)	Blood Urea (mg %)	Creatinine (mg %)	Uric Acid (mg %)	Sodium m Mol/L	Potassium m Mol/L	Calcium mg/L
Baseline (1^{st} -day)	25.10±0.90	23.42±1.20	82.79±3.53	0.73±0.02	22.23±0.91	0.86±0.14	3.94±0.12	130.03±1.53	4.46±0.04	9.09±0.29
Post-treatment (2^{nd} -week)	24.50 ±0.91	22.70±1.12	80.06±2.85	0.72±0.03	21.63±0.99	0.87±0.17	4.05±0.14	131.19±1.61	4.49±0.06	8.92±0.30

Table 8 — The impact of the Unani medication *Jawarish-e-shahi* in the level of haemoglobin, R.B.C. count, total leucocyte counts (TLC), erythrocyte sedimentation rate (ESR), polymorphs, lymphocytes and eosinophils count in patients experiencing palpitation.

Parameter / Group	Haemoglobin (g %)	RBC (10^6/mm^3)	TLC (10^3/mm^3)	E.S.R. (mm /h)		Differential leucocyte counts (DLC)		
						Polymorphs (%)	Lymphocytes (%)	Eosinophils (%)
				1 H	2 H			
Baseline (1st -day)	11.53±0.17	3.91±0.06	6.66±0.22	39.00±1.29	48.00±1.01	68.00±0.94	26.00±0.92	6.0±0.22
Post-reatment (2nd-week)	12.66±1.42	3.90±0.05	6.57±0.20	40.00±1.39	49.00±1.14	69.00±0.94	25.00±0.97	6.0±0.21

studies, particularly safety evaluation of Unani medicines *viz.,* liver and kidney function tests[36], electrolyte profile[36], lipid profile[36] and haematological evaluation[37].

Conclusion

The findings demonstrate the potential of the medication *Jawarish-e-Shahi*, which significantly reduced the symptoms of palpitation patients, including anxiety, perspiration, nausea, vomiting, and a heavy feeling in the chest. The heart's diastolic pressure and pulse rate were found to be rather consistent and normal. The medicine is safe and non-toxic for human use, according to the study. Therefore, it is advised that more clinical trials be carried out on a large size population in order to obtain additional data/ information and develop this potential herbal medication as a safe and efficient treatment for palpitations that may be used by people all over the world. Before this Unani medication is finally approved for use in humans, post-market surveillance data are also required for safety evaluation.

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Conflict of Interest

Authors declare that there is no conflict of interest.

Author Contributions

All authors have equally contributed in the study and for preparation of manuscript.

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