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The efficacy and safety of a Unani pharmacopoeal formulations-raughan kahu in *Sahar* (Insomnia): A preliminary study

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Abstract
In demographical studied, Out of 100 patients of *Sahar (*Insomnia), 35 (35.00%) were male and 65 (65.00%) female and female have higher incidence than male. The greater incidence of duration of the disease observed in 73 (73.00%) is 7-days-3 month than 34 (34.00%) 6-months to 2 years. Higher incidence of average social status patients had been observed 73 (73.00%) than poor 20 (20.00%) followed by good social status 07 (7.00%). Greater incidence of non-vegetarian 91 (91.00%) patients had been observed than vegetarian 09 (9.00%) (Table-1). Middle income group had more incidence of *Sahar* (Insomnia) 65 (65.00%) than lower income group 31 (31.00%) followed by higher income group 04 (4.00%) (Table-1). Non-smoker patients had more incidences 97 (97.00%) than smokers 03 (3.00%). Non-chewing habit Patient had more incidence 97 (97.00%) than chewing 03 (3.00%). According to present history patients who had difficulty in sleep had more incidences 69 (69.00%) than staying sleep 11 (11.00%) patients. Past history of patients of no history had more incidence 92 (92.00%) than constipation and indigestion and hypertension 02 (2.00%) followed by Insomnia, difficulty in sleep and khafkhan 01 (1.00%) patients. The higher incidence of temperament was found more in Balghami (Phlegmatic) temperament patients 94 (94.00%) than *Damavi* (Sanguine) 05 (5.00%) followed by safravi *(bilious)* 01 (1.00%) (Table-1). In Clinical assessment Insomnia Severity Index (ISI), when Unani pharmacopeial formulation *Raughan Kahu* (liquid oil) was locally applied (1.0 ml/day) to the patients for a period of 7-days. A significant reduction 27.11% (p<0.0001) in Insomnia Severity Index (ISI) had been observed, when compared with baseline to post-treatment (7-days) (Table-2). In biochemical study, No significant alterations in liver function tests and kidney function tests had been observed. Therefore, it can be inferred that it did not induce any negative or unfavorable response. The safety of the drug is therefore conformed (Table-3). In haematological study, no significant alterations in the level of haemoglobin, Red blood corpuscles (RBC), Total Leucocytes counts (TLC), Erythrocyte Sedimentation Rate (ESR) and Differential Leucocytes Counts (DLC) had been observed. When compared with the values of baseline and Post-treatment (7-days) (Table-4).

Keywords: Balghami (phlegmatic), safravi (bilious) damvi (sangvine), insomnia, sahar, insomnia severity index (ISI)

Introduction
Insomnia is defined as the subjective perception of difficulty with sleep initiation, duration, consolidation, or quality, which occurs despite adequate opportunity for sleep, and results in some form of daytime impairment (AASM, 2005) [1]. The causes of insomnia include use of excessive alcohol at night and other depressant, poor sleep habits, dietary habit, medical condition like arthritis, asthma, sleep apnea etc. (Hellstrom, 2013; CUMC, 2015; Help guide, 2015; NSF, 2015) [2, 3, 4, 5]. The most important risk factors associated with insomnia are anxiety and depression in addition to health-related variables (LeBlanc *et al*., 2009) [6]. Insomnia is recognized as the most prevalent sleep disorder and considered a major public health problem (Leger and Bayon, 2010; Morin and Benca, 2012) [7, 8]. According to the Third International Classification of Sleep Disorders (AASM, 2014) [9] criteria for an Insomnia disorder include a difficulty initiating sleep, difficulty maintaining sleep or waking up earlier than desired with daytime impairment despite adequate opportunity and circumstances to sleep. Insomnia is a prevalent sleep disorder affecting 20%-25% of adults on a situational basis and 10%-12% on a chronic basis (Ohayon, 2002) [10]. The reported prevalence of Obstructive sleep apnoea (OSA) in India was 9.3% and OSA syndromes 2.8% (Redy *et. al.*, 2009) [11].

It is common in older adults, females, and people with medical and mental ill health (Taylor *et. al.*, 2007; Buysee *et. al.*, 2008; Schutte-Rodin *et. al.*, 2008) [12, 13, 14]. The consequences of insomnia are significant, such as depression, impaired work performance, work-related/motor vehicle accidents, and overall poor quality of life.

According to Unani Doctrine sleep and awakening (Naum wa yequza,) is one of the six essential factor of life (*Asbaab sitta zarooria*) which are dormitorily working throughout the life (Ismail and Shahi, YNM) [15]. According to Avicenna, sleep directs the *Hararate Gharizia* (Innate heat) inwards and strengthens the physical faculty. It takes up the digestion and maturation of food and converts it into blood. Whilst wakefulness has the opposite effect to that of sleep. If wakefulness predominates resultant in causing disturbance in brain by producing dryness and weakness, leading to insomnia and confusion (Arzani, YNM) [16]. In Unani system of medicine sehar (insomnia) can be defined as „sleeplessness" or „awakening' which occurs mainly as a result of imbalance in the temperament of brain due to excess of yaboosat wa hararat and secondarily due to some other causes such as medical or mental disorders (Ibn Sina, 2001) [17]. Excess of awakening is known as sehar as quoted by Ibn Sina (Ibn Sina, 2001) [17]. As per the concept of Akbar Arzani sehar is bedarie mufrat (prolonged awakening) (Arzani, 2002) [18]. According to Unani system of medicine three types of possible causes which can be broadly classified as: (a) Ikhtiyari asbaab (voluntary causes) which are voluntarily and under our control; (b) Aarzi asbaab (temporary causes) which are temporary in origin and when removed or decreased sleep is restored e.g. stress; (c) Marzi asbaab (diseases) which are causes because of diseases e.g. mania (Arzani, 2002) [18].

The available treatment of insomnia (Sahar) in modern medicine includes, various antidepressants, including tricyclic antidepressants (doxepin and Doxepin) and serotonergic antidepressant benzodiazepines (triazolam, temazepam, flurazepam, alprazolam, clonazepam, and lorazepam), have sedating properties and are used for the treatment of insomnia. All these drugs have serious side effects (Richelson and Nelson, 1984; Ziegler et. al., 1978; Minkel and Krystal, 2013) [19, 20, 21].

Now attention is diverted to herbal and Unani formulations due to their versatile role in the treatment of *Sahar* (Insomnia) with no or negligible side effects and cost effective. Thus the efficacy and safety of a Unani Pharmacopoeial formulations *Raughan Kahu* were evaluated in the management of *Sahar* (Insomnia) at Regional Research Institute of Unani Medicine; Aligarh during the period from 2017-2019.

Materials and Methods

Study design

Multicentric, open level clinical study. Unani pharmacopoeial formulation *Raughan kahu* was allotted for investigation by Central Council for Research in Unani Medicine, New Delhi and the study was carried out at Regional Research Institute of Unani Medicine (RRIUM), Aligarh from 2017-2019. One hundred (100) patients, aged 19-72 years of either sex were selected from the lot o patients attending the Out Patient Department (OPD) of the institute following the predesigned inclusive/exclusive criteria. A total 139 patients visiting OPD of the institute were screened and 115 were registered for the present study. Of these 100 completes the preliminary clinical trial and 15 were dropped out. The efficacy and safety of Unani pharmacopoeial drug *Raughan kahu* was evaluated on the basis of demographical, Insomnia Severity Index (ISI), biochemical and haematological parameters. The patients were being assessed clinically for one week i.e. 0 and 7th day. All patients were included in the study after obtaining written informed consent from Institutional Ethics Committee (IEC). This research paper is the outcome of the study conducted under the project and approved by institutional ethics committee (IEC) (F. No. 5-11/2011-12/RRI-ALG/Tech/150) dated 27.12.2017.

Subject Selection criteria

Patients were enrolled on the basis of following inclusion and exclusion criteria:

Inclusion criteria

All subjects will meet the following criteria:

1. Patients of either sex in the age group 19-70 years.
2. Patients with an insomnia severity index score between 8-21.

Exclusion criteria

Patients were excluded if they meet one of the following.

Patients having severe and chronic pain due to any underlying disease.

Drug, dose and mode of administration

Unani compound drug *Raughan Kahu* (oil form) 1-2 ml was applied locally once at bed time.

Criteria for assessment of efficacy

To assess the response of treatment in patients of insomnia, Insomnia severity Index was used. The total score of the index has also been categorized as under:

0-7= No clinically significant insomnia
8-14=Sub threshold insomnia
15-21=Clinical insomnia (Moderate severity)
22-28= Clinical insomnia (Severe)

Assessment of safety

Biochemical analysis

Serum Glutamate Pyruvate Transaminase (SGPT, E.C. 2.6.1.2) and Serum Glutamate Oxaloacetate Transaminase (SGOT, E.C. 2.6.1.1.) were done by the method described by International Federation of Clinical Chemistry (IFCC) (Bradley et. al., 1972) [22], Serum Alkaline Phosphatase enzyme (S-ALP, EC. 3.1.3.1) by the method of Wilkinson *et. al*. Blood Urea by the method of (Tiffany *et. al.*, 1972.) [23], Serum Creatinine by Bowers method (Bowers, 1980) [24], Uric Acid by Trivedi and kabasakalian with modified Trinder peroxidase method (Kabasakalian *et. al*., 1973) [26], Serum Total Bilirubin by Pearlman and Lee (Pearlman and Lee, 1974) [25].

Haematological analysis

Haematological parameters were done according to the method described by Mukherjee. It included Haemoglobin (Hb) [27], Erythrocyte Sedimentation Rate (ESR), Total Leucocytes Counts (TLC), Red Blood Corpuscles (RBC), Platelets Count and Differential Leucocytes Counts (DLC): Polymorphs, Lymphocyte and Eosinophil Counts.

Collection of blood serum

Blood samples were collected by puncturing the vein at each investigation. 1.0 ml of blood with ethylene diamine tetra acetic acid (EDTA) was used for various haematological parameters and another 2.0-2.5 ml of blood sample was allowed to clot and serum was separated by centrifugation, which was used for various biochemical parameters. Biochemical and haematological investigations were carried out.

Statistical analysis

Data were analyzed statistically by one-way analysis of variance (ANOVA) followed by Dennett's' test. The values were considered significant when the P- value was found less than 0.05.

Demographic *S*tudies

Out of 100 patients of *Sahar* (Insomnia) 65(65.00%) were Female and 35 (35.00%) male. Female have higher incidence of *Sahar* (Insomnia). 85 (85.00%) patients were married and 15 (15.00%) unmarried. The duration of the disease observed in 73 (73.00%) is 7-days-3 month and 34 (34.00%) 6-months to 2 years. Average social status patients had more incidence73 (73.00%) than poor 20 (20.00%) followed by good social status 07 (7.00%). Non-vegetarian 91 (91.00%) patients had more incidences than vegetarian 09 (9.00%) (Table-1). Similar intervention had been reported by Akhtar *et. al*, 2017 [28]. Middle income group had more incidence of insomnia (Sahar) 65 (65.00%) than lower income group 31 (31.00%) followed by higher income group 04 (4.00%) (Table-1). Non-smoker patients had more incidences 97 (97.00%) than smokers 03 (3.00%). Non-chewing habit Patient had more incidence 97 (97.00%) than chewing 03 (3.00%). According to present history patients who had difficulty in sleep had more incidences 69 (69.00%) than staying sleep 11 (11.00%) patients. Past history of patients of no history had more incidence 92 (92.00%) than constipation and indigestion and hypertension 02 (2.00%) followed by Insomnia, difficulty in sleep and khafkhan 01 (1.00%) patients. The incidence of temperament was found more in Balghami (Phlegmatic) temperament patients 94 (94.00%) than *Damavi* (Sanguine) 05 (5.00%) followed by safravi *(bilious)* 01 (1.00%) t (Table-1).

Clinical assessesment of Insomnia Severity Index (ISI)

When Unani pharmacopeial formulation *Raughan Kahu* (liquid oil) was locally applied (1-2 ml/day) to the patients for a period of 7-days. A significant reduction 27.88% (p<0.0001) in Insomnia Severity Index (ISI) had been observed, when compared with baseline to 1st follow-up and no significant changes had been observed in post-treatment (7-days) (Table-2). Khan, MR, 2019 and Fatheena *et al.*, 2021 [30, 31] had also reported that *Roghan-e-Kaddu* (oil of *Cucurbeta maxima*), *Roghan-e-kahu* (oil of *Lactusa saliva*), *Roghan-e-Badam* (oil of *Prunus amygdalus*) is beneficial in insomnia patients.

Results and Discussion

Biochemical Studies

Liver Function Tests and Kidney Function Tests

When Unani pharmacopeial formulation *Raughan Kahu* (liquid oil) was locally applied (1-2 ml/day) to the patients for a period of 7-days. No significant alterations in liver function tests and kidney function tests had been observed. Therefore, it can be inferred that it did not induce any negative or unfavorable response. The safety of the drug is therefore conformed (Table-3). Similar facts had been reported by Akhtar *et al*, 2017 [28].

Haematological Studies

When Unani pharmacopeial formulation *Raughan Kahu* (liquid oil) was locally applied (1.0-2.0 ml/day) to the insomnia patients for a period &-days. No significant alterations in the level of haemoglobin, Red blood corpuscles (RBC), Total Leucocytes counts (TLC), Erythrocyte Sedimentation Rate (ESR) and Differential Leucocytes Counts (DLC) had been observed. When compared with the values of baseline and Post-treatment (7-days) (Table-4).

Conclusion

A growing number of people are affected by various kinds of psychiatric disorders, especially depression, anxiety and insomnia. These mental illnesses not only affect people's daily life, but also cause a great economic burden for society. The Unani Pharmacopoeial formulation *Raughan Kahu* (liquid oil) did not induce any negative or unfavorable response. The safety of the drug is therefore conformed (Table-3 &4). *Raughan Kahu* (liquid oil) significantly improves Insomnia Severity Index (ISI) (Table-2).

Composition of *Raughan Kahu* [28]

S. No.	Ingredients	Quantity
1.	Sheera Tukhm-e-Kahu	100 ml
2.	Raughan Kunjad/Raughan Badam	50 ml

Table 1: Demographic data of Insomnia

Name of variable ↓		Total number of patients, n=100, % age
1. Sex	**Female**	**65 (65.00%)**
	Male	**35 (35.00%)**
2. Marital Status i. Married		85 (85.00%)
ii. Un-Married		15 (15.00%)
Social Status: i. Good		07 (7.00%)
ii. Average		73 (73.00%)
iii. Poor		20 (20.00%)
3. Smoking: i. Yes		03 (3.00%)
ii. No		97 (97.00%)
Chewing Habit: i. Yes		03 (3.00%)
ii. ii. No		97 (97.00%)
4. Alcohol consumption: i.Yes		03 (3.00%)
ii. No		97 (97.00%)
5. Duration of Disease: i. 7-days to 3-months		66 (66.00%)
ii. 6-months to 2-years		34 (34.00%)
6. Present History: i. Difficulty in sleep		69 (69.00%)
ii. Staying sleep		11 (11.00%)
iii. Sleep		02 (2.00%)
iv. Falling Sleep		04 (4.00%)
v. Walking up to early		05 (5.00%)
vi. Insomnia		05 (5.00%)
vii. Palpitation		02 (2.00%)
viii. Hypertension		02 (2.00%)
7. Past History: i. No History		92 (92.00%)
ii. Insomnia		01 (1.00%)
iii. Difficulty in sleep		01 (1.00%)
iv. Sleep		01 (1.00%)
v. Consumption and Indigestion		02 (2.00%)
vi. Hypertension		02 (2.00%)
vii. Khafkhan		01 (1.00%)
8. Dietary Habit: i. Non-Vegetarian		91 (91.00%)
ii. Vegetarian		09 (9.00%)
9. Socio-economic status: i. Higher Income Group		04 (4.00%)
ii. Middle Income Group		65 65.00(%)
iii. Lower Income Group		31 (31.00%)
10. Assessment of Mizaj (Temperament): i. Balghmi (Phlegmatic)		94 (94.00%)
ii. Damvi		05 (5.00%)
iii. Safravi		01 (1.00%)

Table 2: Clinical assessesment of Insomnia Severity Index (ISI)

Name of variable - Group → ↓	Base-line n=100	Post-Treatment (7-days)	Percent Reduction in ISI Score
Insomnia severity Score	16.14±1.21	11.64±2.12***	27.88%

Table 3: Effect of Unani pharmacopeial formulation Raughan Kahu on the levels of SGPT, SGOT, Alkaline Phosphatase, Bilirubin, Blood Urea and Serum Creatinine and Uric acid in *Sahar* (Insomnia) patients.

Group → Parameter ↓	Base-Line (day-o)	Post-Treatment (7-days)
SGOT IU/L	23.99±10.30	22.94±10.25▪
SGPT IU/L	26.54±17.02	24.31±13.04▪
Alkaline Phosphatase, IU/L	77.15±28.42	76.96±26.28▪
Bilirubin, mg %	0.76±0.22	0.74±0.20▪
Blood Urea, mg %	22.30±7.24	22.63±8.24▪
Creatinine, mg %	0.94±0.16	1.25±3.20▪
Uric Acid, mg %	4.27±1.24	4.35±1.13▪

▪P is not being significant

Table 4: Effect of Unani pharmacopeial formulation Raughan Kahu in the levels of Haemoglobin, R.B.C. Count, Total Leucocyte Count (T.L.C.), Polymorph, Lymphocyte and Eosinophil count Erythrocyte Sedimentation Rate (E.S.R.), prothrombin time and clotting time in *Sahar* (Insomnia) patients.

Group → / Parameter ↓	Base-Line (day-o)	Post-Treatment (7-days)
Haemoglobin (gm %)	12.24±1.70	12.30±1.75▪
R.B.C. × (10^6 /mm^3)	4.19±0.56	4.17±0.52▪
T.L.C. × (10^3/mm^3)	6.23±1.89	5.91±1.70▪
Differential Leucocytes Counts i. Polymorphs (%)	72.0±6.78	71.0±7.53▪
ii. Lymphocyte (%)	23.0±7.03	24.0±7.37▪
iii. Eosinophis, (%)	05±1.49	05±1.31▪
E.S.R., (mm/hr): i. 1 Hour	37.0±15.02	38.0±13.43▪
ii. 2 Hour	46.0±12.38	48.0±10.82▪
Prothrombin Time (PT) (Sec.)	12.33±2.26	12.07±2.01▪
Clotting Time (CT) (Min)	8.52±3.14	9.34±7.40▪

▪P is not being significant

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Conflict of Interest
Not available

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