



ISSN (E): 2320-3862
ISSN (P): 2394-0530
NAAS Rating 2017: 3.53
JMPS 2017; 5(5): 01-03
© 2017 JMPS
Received: 01-07-2017
Accepted: 02-08-2017

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Clinical study on *Ibtedai Sehar* (Primary Insomnia) with therapeutic evaluation of *Roghan Kaddu* and *Safoofe Kahu*

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Abstract

Sleep is one of the basic necessities of life such as air food and water etc for every animal species from insects to mammals. *Sehar* (Insomnia) is described as sleeplessness and its causes considered as yaboosate sada or yaboosate maddi saudavi, hararat wa yaboosat sada or maddi safravi, accumulation of rutubate shor in brain, plethora of body with waste humours, mal digestion, acute fevers and their toxic irritable vapours, acute sadness, apprehensions, and phobias etc. *Sehar* has been classified into *Sehar Yabis*, *Sehar Rutubi*, and others.

This study was a single blind to evaluate the efficacy and safety of Unani formulation (*Roghan Kaddu*, *Safoof Kahu*) in *Ibtedai Sehar* (Primary Insomnia). The test drug *Roghan Kaddu*: 5 ml for local application over the scalp and *Safoof Kahu*: 5 grams oral administration at night for 15 days. The data was analyzed statistically used repeated measure Anova test and using the student t-test (paired). The test drug was found significantly effective in both subjective and objective parameters. Hence, it can be concluded that the test drugs are safe and effective.

Keywords: *Ibtedai Sehar* (Primary Insomnia), *Roghan Kaddu*, *Safoof Kahu*

1. Introduction

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^[1]. 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^[2].

Sehar (Insomnia) is described as sleeplessness and its causes considered as yaboosate sada or yaboosate maddi saudavi, hararat wa yaboosat sada or maddi safravi, accumulation of rutubate shor in brain, plethora of body with waste humours, mal digestion, acute fevers and their toxic irritable vapours, acute sadness, apprehensions, and phobias etc. *Sehar* has been classified into *Sehar Yabis*, *Sehar Rutubi*, and others^[4, 5]. An insomnia complaint lasting one to several nights (within a single episode) is termed as transient insomnia. It is typically the result of situational stress or a change in sleep schedule or environment. Insomnia lasts from few days to 3 weeks is termed as short-term insomnia. It is usually associated with more protracted stress such as recovery from surgery or short-term illness. Chronic insomnia lasts from months to years. Various causes of insomnia are described in modern medicine such as stress, severe pain, change in the sleep environment, vigorous exercise or hot showers before sleep, caffeine, aging, use of glucocorticoids, asthma etc^[3]. The clinical features are sleeplessness, dryness, irritability of moods, burning sensation in eyes, thirst, fatigue, and drowsiness etc^[2].

Based on the etiology of the disease it has been treated accordingly by using *Murattib Tila*, *Nutool*, *Roghan*, *Majoon*, *Safoof*, and *Sheerajat* etc^[5]. Promoting sleep in natural way reduces the used for medication with sedation^[6]. Avicenna suggests that an applying *Roghan Kaddu* (*Lagenaria siceraria*) on forehead and temporal regions will helps in promoting sleep.^[2] Jalinoos prescribed and used *Kahu* (*Lactuca sativa* Linn.) to induce sleep^[5].

Methodology

The clinical study was conducted in Hospital of National Institute of Unani Medicine, Bangalore. Before embarking upon the patients, a comprehensive protocol was chalked out with the ethical clearance for bio-medical research from institutional ethical committee of National Institute of Unani Medicine. After the ethical clearance, clinical study was started by enrolling eligible patients from the OPD and IPD of National Institute of Unani Medicine into test group. This was a single blind study, with 30 patients.

The Inclusion Criteria: 1. Age between 18 to 60 years. 2. Both gender (male and female), 3. Primary Insomnia, 4. Agreed to sign the informed consent and follow the protocol.

The Exclusion Criteria: 1. Asthmatic patients, 2. Migraine or cluster headache, 3. Drug users of glucocorticoids, 4. Known cases of Parkinson, chorea, Epilepsy, Dementia, 5. Patients of skin diseases like eczema, scabies and psoriasis, 6. Known case of Chronic Obstructive Pulmonary disease, 7. Mental diseases, 8. Cardiac disease, 9. Other's any specific disease

The Subjective parameters: 1. an inability to fall sleep, 2. An inability to continue/maintain sleep, 3. Restless wakening after night sleep, 4. Sleepiness or tiredness during the day.

The objective parameters: the study outcome measures were recorded by using Pittsburgh Sleep Quality Index. Safety was assessed by clinically examinations. Adverse events were recorded at every visit after the base line visit.

The duration of protocol: Duration of treatment period was 15 days.

The sample size: The sample size was 30 patients.

Method of preparation, dosage and mode of administration of test drug: Crude fresh bottle guards were collected from the local market and crushed to obtain juice (Aabe Kaddu) later it was mixed with roghan kunjad and boiled till the watery content from the oil to be evaporated. Tukhm kahu was grounded well and sieved to make fine powder.

Roghan Kaddu: 5 ml for local application over the scalp
Sofoof Kahu: 5 grams oral administration at night

Follow up: Assessment of subjective and objective parameters were carried out on base line (0th day) 8th and 15th days.

Assessment of Mizaj: In each selected patient mizaj was assessed based on the Ajnase Ashra mentioned in Unani literature. Separate temperament assessment Performa has been enclosed with each case report form.

Investigation: Haemogram, ESR, RBS, LFT, KFT, Urine routine and Microscopy, ECG, X ray chest / Skull AP lateral.

Result and Discussion

The clinical trial was conducted to evaluate the efficacy of a test formulation in the management of *Ibtadai Saher*. Total 30 patients between 18-60 years of ages, both sex diagnosed as cases of primary insomnia as per DSM-IV diagnostic criteria were enrolled. The discussion on the data showing efficacy of the treatment in various subjective and objective parameters

along with demographic profile is being presented below in order to draw inference and to arrive at a conclusion.

In this study out of 30 patients, the highest number of patients 13 (26.67%) were found in the age group of 51-60 years, followed by 8 (23.33%) between 18-30 years, 7 (33.33%) between the 31-40 years and only 2 (6.67%) patients between 41-50 years. This data suggested that the disease is more prevalent in the age group of 51-60 and this is in accordance with the finding described by Sivertsen B²⁰ and European Medicine Agency London^[14].

This study evidences 19 (63.33%) male and 11 (36.67%) female patients, indicating the disease more common in male, but a study by Sivertsen B and Zisapel N reports that female are more prone to develops the disease^[11, 16]

Out of 30 patients 28 (93.33%) patients were non-vegetarian or mixed dietary habits and only 2 (6.67%) patients were purely vegetarian. Association of types of diets with *Ibtadai Saher* has not been studied comprehensively and thus any type of diet does not seem to have a casual relationship with *Ibtadai Saher*. Whilst in Unani system of medicine, dietary factors are believed to play an important role in the causation and prognosis of *Saher*. Hot and dryness producing diets such as tea, coffee, red chili, salty items and flatulence diets are all held responsible for *Saher*^[5, 8, 12, 10]

A maximum of 23 (76.67%) patients were found having a safravi mizaj, followed by 7 (23.33%) saudavi, and no patient found either from damvi and balghami mizaj. This finding supported Akber Arzami, Hkm Azam Khan and M Kabiruddin's opinions that this disease is common among *saudavi* and *safravi mizaj* individuals^[3, 7]

Effect on an inability to fall sleep in this study all 30 (100%) patients had an inability to fall sleep before starting treatment. After treatment 10 (33.33%) patients were responded in the first follow up on 8th days and 16 (53.33%) were responded on 15th days, 04 (13.33%) were not responded even after completion of the treatment.

Effect on an inability to continue sleep in this test all 30 (100%) patients had an inability to continue sleep before treatment. After treatment, 20 (67.67%) patients were responded on 8th days and 22 (73.33%) patients on 15th days, no response was reported in rest of the patients.

Effect on restless wakening after night sleep in this study 29 (96.67%) patients had restless wakening after night sleep before treatment. After treatment, 22 (73.33%) patients were cured on 8th days and 24 (80%) patients on 15th days.

Effect on sleepiness or tiredness during the day in this test all 30 (100%) patients had sleepiness or tiredness during the day before the treatment. After treatment 21 (70%) patients were cured on 8th days as well as on 15th days.

Effects on PSQI (Pittsburgh Sleep Quality Index) score in this study were significant ($P < 0.001$).

The effect of test drug may be because of *murattib*, *musakkin*, *mubarrid* and *munawwin* property of all of the its ingredients kaddu, *tukhm kahu*. There results are in accordance with the properties of the drugs suggested by Ibn Sina, Jalinoos, Ibn Baitar, Abdul Hakim, Najmul Ghani, Azam Khan, Ajmal Khan and M Kabeeruddin^[9, 13, 15, 17, 18, 19, 20, 21, 22].

In order to determine adverse effect of test drug, safety parameters like haemogram, LFT and RFT were carried out at baseline and at the end of treatment. After the completion of the treatment, all safety markers were found within the normal limits.

Conclusion

In this study, the effect of the Roghan Kaddu and Safoof

Kahu in the treatment of *Ibtedai Saher* (Primary Insomnia) was effective in both subjective and objective parameters due to *murattib*, *musakkin*, *mubarrid* and *munawwin* property of its ingredients. Clinically no any side effects were observed in the study. The evaluation of subjective and objective parameters were statistically significant ($p < 0.01$) by using repeated measure Anova test and using the student t-test (paired) for safety parameters. Hence it's concluded that these drugs are safe and effective in the management of *Ibtedai Saher* (Primary insomnia).

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