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Therapeutic evaluation of efficacy of *Nutool* therapy (Irrigation) in insomnia: A case study

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Abstract

Insomnia is described as *Sehar* in Unani system of Medicine, which can be defined as sleeplessness or awakening which occurs mainly as a result of imbalance in the temperament of brain due to excess of *Hararat* and *Yaboosat*. Insomnia is a risk factor for depression. Prevalence of Insomnia is high in women. Unani physicians have been successfully treating Insomnia (*Sehar*) through *Nutool* (Irrigation therapy) since ancient times but scientific documentation is not available. Hence it was decided to conduct single case observational open clinical study to evaluate the efficacy of *Nutool* (Irrigation therapy) in a case of Insomnia on scientific parameters

Material and Methods: Intervention was carried out on a female patient over a period of two weeks at Regional Research Institute of Unani Medicine Srinagar, Jammu and Kashmir in the month of August, 2017. Outcome measure was by Vas scale. Diagnosis was made on the basis of clinical presentation. The patient is assessed on the basis of subjective and objective parameters. Informed consent was obtained from the patient. The clinical improvement was recorded in the Case Report Form (CRF) specifically designed for the study. At the end of study pre and post treatment scores of different subjective and objective parameters were tabulated and analyzed.

Result: Efficacy of *Nutool* (Irrigation therapy) applied to the patient was found statistically significant in the treatment of Insomnia. Further, no side effect was observed during and after the study.

Conclusion: *Nutool* (Irrigation therapy) is safe and effective for Insomnia.

Keywords: *Sehar*; Insomnia; *Nutool*; Irrigation therapy; Vas scale

Introduction

Insomnia is a latin word derived from *Insomnias* which is composed of 'in' means not and *somnus* means 'sleep'. Insomnia is an acute or chronic inability to initiate or maintain sleep adequately at night^[1]. Women are at more risk for *Insomnias* than in man. It may be because of continuous change in hormones such as in menstrual cycle, during luteal phase, during pregnancy and after pregnancy period, around 40% of *Insomnia* has psychiatric condition. A study reported about 69% of cases in *Insomnia* are followed by depression, where as anxiety disorder preceded by *Insomnia* 73% of times^[2]. *Insomnia* is described as *Sehar* in Unani system of Medicine, which can be defined as sleeplessness or awakening which occurs mainly as a result of imbalance in the temperament of brain due to excess of *Harart* and *Yaboosat* and secondarily due to some other cause such as medical or mental disorder^[3]. Unani Current recommendations for managing *Insomnia* focus on relieving symptoms i.e sleeplessness, headache and awakening. No curative therapies list for *Insomnia*. Treatment options for *Insomnia* are pharmacologic treatments as sedatives like Triazolam (Halcion) or Zolpidem (Ambien) are rapidly acting drugs are more effective, such as Flurazepam (Dalmane) or Quazepam (Doral) for patients with persistent *Insomnia*, but these are not curative for *Insomnia* rather these drugs may cause side effects like debilities, loss of libido, laziness, addiction etc, which is again call for an alternative management^[4]. According to Unani system of medicine health is attributed by equilibrium of *Akhlat* (humours), besides this, there are *Asbabe Sittah Zaroorya* (Six Essential Factors) i.e. air, food and drinks, bodily movements and repose (*Harkat-wa-Sukoone Badni*), mental activity and repose (*Harkat Wa Sakoon Nafsani*), sleep and wakefulness (*Naum wa Yaqza*) and retention and excretion (*Ahtebas Wa Istefragh*). Any imbalance to any of the above factors is likely to cause disease. Normal sleep is thought to be because of *Ratoobat wa Baroodat* i.e. wetness and cold in our brain and if there is derailment of balance in sleep and wakefulness, it implies the predominance of *Yaboosat Wa Hararat* i.e. dryness and hotness widespread in the brain^[3, 5].

Unani physicians have been successfully treating Insomnia (*Sehar*) through *Nutool* (Irrigation therapy) since ancient times but scientific documentation is not available. Hence it was decided to conduct a single observational open study to evaluate the efficacy of *Nutool* (Irrigation therapy) in a case of Insomnia on scientific parameters.

Nutool is a Regimenal therapy (*Ilaj bittadbeer*). Literally *Tadbeer* is an Arabic word meaning “Regimen” (Systemic plan) while as *Ilaj* means “therapy” or “treatment”. Therefore *Ilaj bit tadbeer* (IBT) is a treatment through regimen that is decided according to the nature or pathogenesis of the disease. If patient is having *Sue Mizaj* (derangement of temperament) then it can be corrected through life style modifications; Diet, sleep, Physical Exercise, climate and intervention such as *Dalak* (Massage), *Hamam* (Turkish bath) etc. Among these methods *Nutool* is a novel method, in which decoction of certain drugs or medicated oils are poured over specific sites of body at certain height in some specific diseases^[3].

Nutool refers to pouring or dripping of drugs on specific body parts. For this purpose usually water, oil or medicated decoction is poured from a height over specific sites of body in certain diseases. This process is called as *Tanteel* (Irrigation). Depending upon the nature of liquids used for desired actions in this therapy it has been broadly divided into two types; *Nutool Har* and *Nutool Barid*. *Nutool* or irrigation is done with a pupose of acceleration of process of *Ikhraje Mawad* (Evacuation of morbid material) and *Ta'dil-i Mizaje Aza* (Defence mechanism of the body), this results in desired neurological psychological and pharmacological effects in various diseases. It also enhances the local absorption of medicines thus helps in getting the desired action of medicine locally^[6]. Keeping the historically safe and effective therapeutic use of the *Nutool* (Irrigation therapy) and to rationalize the idea scientifically, the study was designed and conducted.

Methodology

This was an open, observational, non randomised, single centred case study. Patient underwent a treatment of period of 15 days. The trial was practiced under good clinical practices guidelines. A female patient, age 20, resident of Srinagar, J and K, was screened and diagnosed as chronic Insomnia enrolled in the study in the month of August, 2017. The diagnosis was confirmed on the basis of history, physical examination and finally using the Insomnia Screening Questionnaire. The questionnaire is a screening tool used to guide the physician in the clinical evaluation of Insomnia. The Patient was subjected to comprehensive general physical and systemic examination. A thorough history clinical examination of the patient was done for its colour, pallor, cyanosis, icterus. Following investigations were carried out to exclude the patients from the study and as well as safety evaluation of the patient undergoing the study.

- I. Routine haemogram to exclude the secondary infection
- II. Random Blood Sugar to exclude diabetes mellitus
- III. RFT (Blood urea, S. creatinine) to exclude renal disease.
- IV. LFT (SGOT, SGPT, S. bilirubin) to exclude liver diseases

V. S. uric acid to exclude gout

VI. HIV to exclude AIDS

VII. VDRL to exclude syphilis

VIII. CT,BT to exclude haemophilia

After taking informed consent from patient, who attended the OPD Regional Research Institute of Unani medicine, Srinagar (J and K) she was included for the study. All the findings were recorded in the Case Report Form (CRF), designed for the study. The patient was ruled out for taking any medication and it was found that at that time of inclusion, he was not taking any medication. Wash out period was confirmed. There was no any history of diabetes, Hypertension or any other chronic debility. *Roghane Babuna* was used for Irrigation therapy. Duration of *Nutool* was 30 minutes. The patient was advised to lay on the table (specially designed for *Nutool* therapy) in supine position. The distance between the source of oil (which was to be irrigated), was four meters away but in line with patient's frontal bone area. The direction of irrigation was in 90 degree with the patient's position. Patient was kept under strict observation and advised to come in OPD for assessment till the completion of study. Fifteen days study was divided into four visits. Which were made at an interval of five days (i.e. BL, 5th day, 10th day, 15th day). At every visit, patient was asked about the progression or regression in their symptoms, and subjected to assess the clinical findings. Concomitant treatment was not allowed during the study. The Mizaj was assessed on the basis of *Ajinnase Ashra* proforma designed for assessment of Mizaj.

The assessment of efficacy in the patient was based on subjective and objective parameters. Subjective parameters are wakefulness and headache, Wakefulness was rated with Vas scores from 0-4. The assessment was carried out at 0, 5, 10 and 15 days.

Headache was rated with scores from 0-4 as Vas scale. The assessment was carried out at 0, 5, 10, and 15 days. Objective parameters were assessed on the basis of Insomnia Screening Questionnaire (ISQ Index)^[7].

After the completion of treatment, the pre and post treatment values or scores of different parameters (subjective and objective) were assessed and subjected to comparison and statistical analysis to evaluate the efficacy of *Nutool* (Irrigation). Withdrawal criteria was, a) Failure to follow the protocol, b) Any adverse reaction or adverse event. It was observed that there was no any adverse event, it is also recorded. The case report form and consent forms properly documented throughout the study was submitted to the Dept. of *Ilaj bittadbeer* (Regimenal Therapy) after completion of the study.

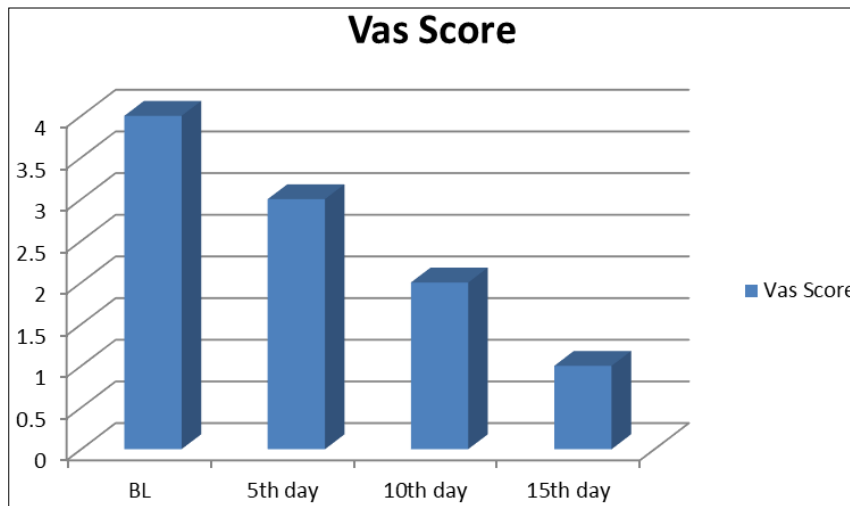
Results

It was found that Vas scores for wakefulness are reduced from 4 to 1 from baseline to 3rd follow up. (See table No.1 and graph No. 1)

It was also found that Vas scores for headache are reduced from 4 to 1 from baseline to 3rd follow up. (See table No. 2) Questionnaire {ISQ Index (Insomnia Severity Questionnaire Index)} shows the significant improvement in objective parameters i.e. 60% Improvement in the patient. (See table No. 3).

Table 1: Effect of *Nutool* (Irrigation) on wakefulness (On the basis of Vas score)

No. of patient		Assessment day			
20	Ca...	BL	5 th day	10 th day	15 th day
One		4	3	2	1



Graph 1: Effect of *Nutool* (Irrigation) on wakefulness (On the basis of Vas score)

Table 2: Effect of *Nutool* (Irrigation) on headache in Insomnia (On the basis of Vas score)

n=1	Assessment day			
	0 day	15 th day	30 th day	45 th day
	4	3	2	1

Table 3: Questionnaire {ISQ Index (Insomnia Severity Questionnaire Index)}

S. No of Question	Score obtained by th patient			
	BL	1 st Follow up	2 nd Follow up	3 rd Follow up
1.	5	4	3	2
2.	5	4	3	2
3.	5	4	3	2
4.	5	4	3	2
5.	5	4	3	2
6.	5	4	3	2
7.	5	4	3	2
8.	5	4	3	2
9.	5	4	3	2
10.	5	4	3	2
11.	5	4	3	2
12.	5	4	3	2
13.	5	4	3	2
14.	5	4	3	2
15.	5	4	3	2
16.	5	4	3	2
17.	5	4	3	2

5-2=3, i.e.60% Improvement

Discussion

Insomnia is an acute or chronic inability to initiate or maintain sleep adequately at night. Women are at more risk for Insomnias than in man. It may be because of continuous change in hormones such as in menstrual cycle, during luteal phase, during pregnancy and after pregnancy period, around 40% of Insomnia has psychiatric condition. A study reported about 69% of cases in Insomnia is followed by depression, where as anxiety disorder preceded by Insomnia 73% of times [2]. In India, prevalence of the disease is

reported to be 0.7% [6, 7, 8]. Being a chronic disease in nature, it causes both physical and mental agony to the patient. Further, chances of recurrence also add to the stigma and agony of the sufferers.

The present study was open, single case, observational and pre and post comparative, embarked to evaluate the efficacy of *Nutool* (Irrigation), prescribed to a patient, in the management of Insomnia on modern scientific parameters. The observations obtained from the trial have been depicted in tables and graphs. The discussion on the data showing

efficacy of the treatment in various subjective and objective parameters along with demographic data is being presented below in order to draw inference and to arrive at a conclusion.

The patient was with age 20 years. It resembles with findings of Michael Gelder and Dennis Gath that Insomnia is common problem affecting 10 and 30 per cent of the adult population^[8].

In the present study the patient was suffering from mild anxiety. This is in accordance to the description of Neimann AL, Porter SB, Gelfand JM^[9].

On history it is found that the patient was taking sleeping pills before this treatment which coincides the description of William T. Branch^[10]. The patient was a studious student. The patient had *Saudavi Mizaj*. This finding is supported by the description of *Ibn Sina* who have discussed the pathophysiological aspects of the disease in detail and concluded that *Sauda* is the most important cause for the genesis of Insomnia (*Sehar*)^[3].

The patient was student and she belongs to middle class group. This observation suggests that there may be relation with the occupation of the patient. No data is available to correlate this finding. The patient was suffering from this disease from two years. This indicates that the disease is chronic and tough in nature and resist to any kind of treatment. This finding is in accordance with the description given by Azam *etal* that *Sehar* (Insomnia) is one of chronic disorders and also mentioned that *Nutool* is indicated in Insomnia by Unani Physicians^[6].

Wakefulness was rated with Vas scores from 0-4. The assessment was carried out at 0, 5, 10 and 15 days. Score reduced from 4 to 1.

Headache was rated with scores from 0-4 as Vas scale. The assessment was carried out at 0, 5, 10, and 15 days. When scores were compared statistically within the pre and post scores of the patient, it was found that headache is reduced significantly i.e. from 4 to 1. Reduction in wakefulness and the improvement in the headache, itself is a good scale of recovery. Wakefulness is an important symptom of Insomnia which subsided to a great extent in our study.

Insomnia Severity Index questionnaire also shows 60% improvement in various signs and symptoms on the basis of questions asked by investigator from patient^[7].

Nutool is one of the methods, among the other techniques related with the life style modifications and regimns, which are indicated in Insomnia. These descriptions resembles with the description of Vitiello MV *et al*. Cognitive behavioural therapy for Insomnia improves sleep and decreases pain in older adults with co-morbid Insomnia and osteoarthritis^[11].

The improvement in the wakefulness in the patient may be due to the *Muhallil* (Resolvent) and *Munavvim* (Sedative) activities of *Roghane Babuna* (An oil prepared from crude drug *Babuna* (*Matricaria chamomilla*)). The flowers of this herb has ingredients Matricine and (-) - alpha-bisabolol which show anti-inflammatory and analgesic activity^[12]. These findings are in accordance with the description given by *Ibne Sina* and *CP khare*^[3, 12].

Conclusion

In the light of the above discussion, it can be concluded that the *Nutool* (Irrigation) produced significant effect in Insomnia (*Sehar*) without demonstrating any side effect. The *Nutool* (Irrigation) is effective because of it's *Muhallil*

(Resolvent) and *Munavvim* (Sedative) properties. However, detailed and large sample sized studies are required to determine relapse of the disease over a relatively long period of time.

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