A Comparative Clinical Trial of Rose Petal (Gul Gulaab), Rose Hydrosol Diluted (Arq Gulaab), and Rose Hydrosol (Ruh Gulaab) in Insomnia.

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Abstract

Insomnia or lack of sleep is a sleeping disorder that is taking the form of an epidemic worldwide with competitive life replacing the traditional lifestyles. Therefore a lot is in turmoil including sleep. The National Sleep Foundation estimates 47 million American adults to be at risk of injury and physical and emotional difficulty because they do not get enough sleep. Presently no specific treatment is available for this ailment. The sleeping pills and other sedatives available in the market cause psychological and physical dependence besides they are also reported to cause some memory and conginitive disturbances. As such a study was conducted to evaluate the response of gul gulaab (powdered rose petals), arq gulaab (rose distillate diluted) and ruh gulaab (rose distillate) given through oral route in 36 cases.The present article deals with the response of these patients to the three different types of rose mediated medications.

INTRODUCTION

Insomnia refers to an inability to sleep or to remain asleep for an adequate length of time. Chronic insomnia is highly prevalent and affects approximately 30% of the general population. Insomnia impairs cognitive and physical functioning. It is associated with a wide range of impaired daytime functions covering emotional, social, and physical domains. Insomniacs are more prone to accidents; insomnia adversely affects work attendance, job performance, quality of life and health in general. Elderly female, comorbid medical and psychiatric conditions are its predisposing factors. It is estimated that 40% of all insomnia patients have a coexisting psychiatric condition [1, 2] . Among the psychiatric disorders, depression is the most common, and insomnia happens to be a diagnostic symptom for depressive and anxiety disorders [3] . Recent research suggests that insomnia and depression share common pathological processes that make individuals vulnerable to both conditions—specifically, abnormal regulation of CRF. On average women are 1.4 times more prone to the disease than men.

Insomnia is of various types - transiet, acute and chronic. Transient insomnia lasts for a couple of days to weeks. It is usually due to changes in sleep environment, sleep timings or stress etc. It can lead to sleep deprivation and impaired psychomotor performance. Acute insomnia is the inability to sleep properly from three weeks to six months. Whereas; chronic insomnia may even last for years. It can be both primary and secondary to other disorders. The symptoms depend upon the primary disorder, but usually the patient present with sleepiness, muscular fatigue, hallucinations, diplopia and increased mental alertness [4-8, 9] .

The present drugs available over the counter provide short time relief with immense side effects. Alternate therapy in this regard is better accepted because of its sustained relief and no adverse effects.

Unani system of medicine is a part of alternate medicine. It was proposed by Galen 2000 years BC. According to Unani physicians Rose (Rosa damascena) has sedative and tranquilizing effect besides its other properties. Its various forms available in the market are Gul (powdered rose petals), Arq (rose hydrosol diluted) and Ruh (rose hydrosol). Rose is attributed with stimulant and immune system boasting properties. It is also known for its brain tonic, cardiotonic, stomachic, exhilarant, laxative, thirst quenching, antipyretic, contraceptive, and sensory organ stimulant properties. It is used in the treatment of palpitations, nausea,

unconsciousness, syncope, headache, diseases of heart and brain, bleeding gums, and insomnia [12-15, 16-17] .

The present study was undertaken to ascertain the efficacy of Ruh Gulaab as compared to its other forms like Arq and Gul.

HISTORY

Treatment or prevention with essential oils is known as aromatherapy. “Aromatherapy” was coined by a French chemist Rene – Maurice Gattefosse, in 1920. He devoted his life studying essential oils after an accident where he burnt his hand and accidentally applied lavender oil. There was an immediate relief in pain, and the burn healed remarkably quickly, with minimal discomfort and no scarring. Jean Valnet continued the work of Gattefossé during World War II Valnet used essential oils to treat gangrene in wounded soldiers [9] .

MODE OF ACTION

There are two theories postulated to explain the purported effect of essential oils. Firstly, it is the influence of the aroma on the brain especially the limbic system through the olfactory system. Secondly, there is the direct pharmacological effect of the essential oil [18] .

Essential oils, work in different ways, at the scent level they activate the limbic system and emotional centers of the brain. When applied to the skin they activate thermal receptors, and kill microbes and fungi. Internally, essential oil stimulates the immune system [9] .

Aromatherapy is discussed explicitly in classical Unani literature by various eminent hakims like Razi in Kitab ul Mansoori, Majoosi in Kamil us Sana and Humbal in Al Muqtaraat fit tibb. They have also described its mechanism of action as a stimulant to the olfactory nerve and subsequently the brain. They have also mentioned that excess of aroma can cause headaches and heaviness in head. To tap these properties of drugs they had advised various preparations like lakhlakha, inkebaab, shamoom etc.

PROCEDURE OF ROSE DISTILLATION

The process of rose distillation requires large stills filled with crushed rose petals and waterto start with. The still is fired for 60-105 minutes. The vaporized water and rose oil exit the still and enter a condensing apparatus which is then collected in a flask. This distillation yields very concentrated oil known as direct oil, which makes up about 20% of the final product. The water which condenses along with the oil is drained off and redistilled. This water is a bye product of steam distillation and is known is rose hydrosol or rose distillate or rose water. Classically arq gulaab is made in an apparatus which are joint together. This apparatus is known as Qarah ambeekh. The medicine is mixed with water and placed in qarah and this is covered with ambeekh. It also has two outlets. One is long enough such that it reaches the ambeekh through which the arq comes out and gets collected in a recipient. Through the second one water vapour formed during the procedure is excreted. The medicine is soaked in water overnight. The water should be three times the drug and placed in a vessel. The ambeekh is placed over it and this is made air thight and later put on stove. Cold water is placed on the ambeekh to condense the vapours [10,11]

The hydrosol is diluted in the ration of 1:3 to give rose hydrosol diluted or arq gulaab [9]

PATTERNS OF INSOMNIA.

The pattern of insomnia often is related to the etiology [19] .Onset insomnia - difficulty in falling asleep at the beginning of the night, often associated with anxiety disorders

1.Middle- of- the- night-insomnia - Insomnia that is characterized by difficulty in returning to sleep after awakening in the middle of the night or waking too early in the morning. This is also referred to as nocturnal awakenings. This encompasses middle and terminal insomnia.

2.Middle insomnia - waking during the middle of the night, difficulty maintaining sleep. It is often associated with pain disorders or medical illness.

3.Terminal (or late) insomnia - early morning waking is characteristic of clinical depression [4-8] .

CAUSES

INSOMNIA CAN BE CAUSED BY:

- Psychoactive drugs or stimulants, including certain medications, herbs, caffeine, cocaine and ephidrine, etc
- Hormone shifts such as those that precede menstruation and those during menopause.
- Life problems like fear, stress, anxiety, emotional or mental tension, work problems, financial stress, unsatisfactory sex life

- Mental disorders such as bipolar disorder, clinical depression, general anxiety disorder, post traumatic stress disorders, schizophrenia, or obsessive compulsive disorders.
- Disturbances in the circadian rhythm such as shift work and jet lag.
- Estrogen is considered to play a significant role in women's mental health (including insomnia) 20, 21 .
- Neurological disorders, brain lesions, or a history of traumatic.
- Medical conditions such as hyperthyroidism and Wilson's syndrome.
- Sedative drug abuse.
- Poor sleep hygiene.
- A rare genetic condition called fatal famalial insomnia
- Helmenthiasis 4-8 .

The causes as mentioned by unani physicians are: meningitis, mania, syphilis, pleurisy, dyspnoea, pleural effusion, cough, melancholia, jaundice, over eating, dyspepsia, flatulence, constipation, stress, severe pain, fever, dieting, gout, anemia, suffocation, noisy environment, very hard bed, fear, anxiety, excitement, euphoria, hysteria, pregnancy and labour pains [22-24, 25-27] .

PATHOPHYSIOLOGY

Insomnia is considered to be a disorder of hyper arousal experienced during the day. During the day it may exhibit itself as a state of hyper vigilance and at night as difficulty in initiating and maintaining sleep [28,29] . The cognitive theory suggests that worry and rumination about life stresses disrupt sleep, creating acute episodes of insomnia, especially in initiating sleep and returning back to sleep after an awakening [30] .

The second theory proposes that hyper arousal is due to physiologic or neurophysiologic factors. Physiological arousal is measured through body metabolic rate, heart rate variability, neuroendocrine measures, and functional neuroimaging. Insomniacs exhibited higher metabolic rates than the healthy controls. Heart rate variability is regulated by both sympathetic and parasympathetic system activities. The neuroendocrine system is measured through plasma levels of cortisol and adrenocorricotropic hormone (ACTH). Primary insomniacs have higher levels of these compounds in their plasma; with the most significant differences seen in the evening and the first half of the night [31-33] . This indicates the involvement of HPA axis in chronic insomnia.

Positron emission tomography (PET) is used to assess cerebral glucose metabolism, a procedure to measure brain metabolism [34] . Insomniacs exhibited greater cerebral glucose metabolism during waking and non-rapid eye movement (REM) sleep states. Finally, the insomniacs showed mild changes in relative metabolism from waking to non-REM sleep in wake-promoting regions of the brain. This suggests of an interaction between the neural networks involved.

Unani system of medicine defines insomnia as lack of sleep that exceeds the physiological boundaries. It can be direct, indirect as a symptom or due to voluntary reasons as in poor sleep hygiene. The principles of treatment involve medicated natool (vapour) , laklakha (aroma), saoot (snuff), sedative measures and avoidance of sedatives and lastly laxatives. [22-24, 25-27]

MATERIALS AND METHODS

The study group consisted of 36 cases of diagnosed cases of insomnia; which were divided into group A, B and C comprising of 12 cases each.

Group A was given gul Gulaab 3 gms three times a day for three weeks. The rose were collected from village Ganderbal area of Srinagar city and were dried in shade. The petals were powdered and distributed for use.

Group B was given arq gulaab purchased from the market of Hamdard brand in 3ml dosage three times a day for three weeks

The third Group C was administered ruh gulaab 3 ml, three times a day for a period of three weeks. This was again purchased from the market of Dabur brand namely gulbari.

No diet or work restriction was prescribed nor was any other drug therapy allowed. The study was single blind, randomized and comparative. The study was single blind, randomized and comparative. The study has been conducted over a period of 1 year in a private clinic in Srinagar, Kashmir.

EXCLUSION CRITERIA

Psychoactive drugs, hormones, hyperthyroidism, fatal familial insomnia, neurological disorders, and chronic pain

INCLUSION CRITERIA

History of inability to sleep well for more than 4 weeks. Defined as: difficulty falling asleep, staying asleep or nonrestorative sleep, the difficulty is present despite adequate opportunity and circumstance to sleep;the impairment in sleep is associated with daytime impairment or distress; and the sleep difficulty occurs at least 3 times a week and has been for at least 1 month.

Acute and transient insomnia, and age group (20-60) yrs

Contraindications: Pregnancy, lactation, allergies

Consent

I----------exercising my free power of choice hereby give my consent to be included as a subject in the clinical trial of a drug therapy namely---------- for the treatment of insomnia. I understand that I may be treated with this drug therapy for the disease I am suffering from and I have been informed to my satisfaction by the attending physician regarding the purpose of the clinical trial and the nature of the drug therapy and follow up including laboratory investigations to monitor and safe guard of my body functions.

I am also informed that during the therapy I may experience burning sensation, nausea, vomiting and loose motions.

I am also aware of the right to opt out of the trial at any time without assigning any reason for doing so.

Signature of the Patient----------

Name in Block Letters----------

Relation with Patient----------

Date and Time----------

Witness----------

Figure 1

Table I

	Group A		Group B		Group C	
	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)
Day time sleepiness	83	66.6	100	50	91.6	16
Irritability	66.6	50	75	50	58.11	24.9
Itching	33.3	24.9	24.9	24.9	2	2
Mental Fatigue	83	50	91.6	41.5	83	8.3
Headache	83	50	100	33.3	91.6	0
Hb (mean) gm%	10	10	10	10.5	10	10.5
SGOT (mean) IU/L	30.2	30.2	32.1	33.7	31.6	34.5
SGPT (mean) IU/L	23.4	24.2	21.5	23.2	24.7	27.4

Table showing symptomatic efficacy of the drugs

Key:

BT: Before Treatment

AT: After Treatment

Figure 2

Table II

	Complete relief	Partial relief	No relief
Gul Gulaab	2 (16.6%)	3 (25%)	7 (58.3%)
Arq Gulaab	3 (25%)	4 (33.3%)	5 (41.6%)
Ruh Gulaab	8 (66.6%)	3 (25%)	1 (8.3%)

Table showing overall efficacy of the drugs

RESULT AND DISCUSSION

The demographic data that was evident from the study was 22 females i.e.61.1% of the sample size was female where as 14 (38.89%) were male. The social status of 17 (47.22%) participants was lower income group whereas 13 (36.11%) participants belonged to middle income group and 6 (16.67 %) participants were from high income group. 10 (27.78%) of those attending the study were smoker whereas 26 (72.22%) were non smoker. The sleep environment of 22 (61.1%) individuals was normal but 14 (38.89%) slept in congested environment where they shared the room with multiple users. Regarding the sleep pattern 16 (44.44%) had mid night insomnia 5 (13.89%) onset insomnia and 15(41.67%) transient insomnia. The caffeine intake of 22 (61.1%) participants was 2 cups which contributed to a major chunk of the sample size. Followed by 3 cups in 10 (27.78%) participants, 4 cups in 2 (5.56%) participants and 1 (2.76%) individual in each category of 1 cup per day and non tea drinker. 30 (83.33%) of the participants gave signs of stress whereas 6 (16.67 %) showed no signs of stress.

In the present study insomnia was the main problem of the patient and complete improvement in the sleep disorder was after three weeks of treatment in 2 (16.6%) of patients with Gul Gulaab 3 (25%) of patients with Arq Gulaab and

8(66.6%) with Ruh Gulaab. The treatments of the three groups are significant. The paired t test assumes that the differences are sampled from a Goussian distribution. The assumption is tested using the method of Kolmogorov and Semnorov (K5) is 0.26. the p value is >0.10. the data passed the normality test with p>0.05 that the treatment group with ruh gulaab (Grp C) is most effective among the three groups. However, the Grp A and Grp B are not quite significant with p>0.057.

The patients also reported that the preparation had a positive effect on constipation. This is due to the laxative property of rose and also aids in insomnia, as constipation is also considered as a cause of insomnia. 3 patients taking ruh gulaab complained of nausea for half to one hour after taking ruh gulaab. No medication was given for this nausea. The dropouts in this group were also due to the bitter and acidic taste of the ruh.

CONCLUSION

It was observed that patients responded best to ruh Gulaab as compared to the other two preparations indicating that the essential concentration is the determining factor of the efficacy. It was observed that the improvement in the symptoms were more in the patients treated with Ruh Gulaab which happens to be three times more concentrated than arq. Arq on the other hand is far more concentrated than rose petals.

The symptoms also responded better to the therapy that had maximum concentration of essential oil. This indicates that the higher the concentration of essential oils the better the recovery in terms of symptom and the cause. The sample size was small hence the study cannot be confirmatory. Apart from this another draw back of the study was that the estimation of essential oil was not possible due to lack of infra structure.

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