

A pilot study to see the suitable Unani Kit medicines in the patients of drug-induced insomnia

Abstract

Insomnia is a common disorder nowadays in the population with high rates of hypertension, diabetes mellitus, obesity, heart attack and stroke that turned the patients to take medications such as Alpha-blockers, Antidepressants, Corticosteroids, hypolipidemic, Anti-inflammatory, weight-reducing agents, and many more medicines prescribes them by the experts.

The study aims to fix a suitable kit of medicines from *Mujarrabat or Mamulat Matab* (Trended Unani prescriptions) as mentioned in *Qrabadeen/Biyadh* of the Unani classics. In a view of new disease treatment, an observational study has been conducted to see the efficacy of the selected kit of medicines in the drug induced-insomnia patients. A total of 70 participants were registered in general OPD at the Co-location Research Centre J.J. Hospital Byculla Mumbai, they were categorized into three groups with conduction of question-answer session interpreted according to the 'insomnia severity index'. All included patients have assigned scores as per the answers. Data were analyzed on the version of patients to see a relationship between the medicated and non-medicated patients and found statistically significant at $P < 0.05$. Analysis of per cent distribution of the patients' consequences and improvement observed in a lay term (Indian-currency unit) as about 20 paise, 40 paise, 60 paise, 75 paise and 80 paise of a rupee. This paise has considered the percentage of calculation. 71.43% of patients reported the remarkable effects of the given kit medicines.

The study concluded that insomnia is significantly high in medicated patients, and a result of Unani kit medicine is also satisfactory it required a clinical trial with full scientific criteria for clear and significant results.

Keywords: drug-induced insomnia, Unani kit medicines, pilot study

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Introduction

Insomnia is a common disorder and interferential health problem in the worldwide population now, in which a person has trouble sleeping or staying asleep. When a patient with comorbidity, keeps on medication for longer and has experiences of deprived sleep is called Drug induced insomnia. It is one of the great problems have faced in the Clinical practices. The cumulative effects of sleep loss and sleep disorders have been associated with a wide range of deleterious health consequences including an increased risk of hypertension, diabetes, obesity, depression, heart attack, and stroke.¹ Medication with Alpha-blockers to treat high blood pressure and prostate problems, Antidepressants, Corticosteroids, hypolipidemic, Anti-inflammatory, weight-reducing agents, caffeine and Glucosamine are contributing problem of insomnia etc.² Unspecified with psychoactive substances also induces sleep disorder.³ Any drug with activity in the central nervous system has the potential to affect the sleep-wake cycle.⁴ Prolonged light tends to be impactful, even short periods of artificial light can affect circadian rhythm. View Source but light exposure slows or halts that production.⁵

In the Unani system of medicine, it is called 'sahar' and its main cause is *Su-i-Mizaj Har yabis (hot and dehydrated)* brain; wherein dryness directly induces it, while, heat symptomatically or secondarily imposes it,⁶ instead of it much other reason as purging, diarrhoea, vomiting, diuresis, menstrual regulation and hot spices are also playing the same role.⁷⁻¹⁰

Uses of compound medicines are more trended than single in OPDs known as Mamulat Matab/ Mujarrabat (trended Unani

prescription) indeed, it is a group of medicines, preceded testaments proved in effectiveness by the Unani eminent and great practitioners. It is the biggest and most valuable part of the Unani practices. The Most popular physician is *Razi* (Rhazes 850-932 AD) who trended the pattern of *Matab* (OPD/clinic) and his clinical testaments available in the form of books "*Al-Havi Fil Tib*" in 23 volumes now.¹¹ Later, most of the great Unani physicians have written their testaments and experiences, some of them given a particular name as '*Biyadh*, or '*Qrabadeen*'. Many *Biyadh* and *Qrabadeen* are magnificent footprints for the fore-practitioners. Every *Biyadh/ Qrabadeen* has written many compounds claimed to be useful in insomnia, but the purpose of the study was to treat drug-induced insomnia, a single compound medicine is not sufficient enough, owing to co-morbidity it required a group of medicines, it motivated to do a pilot study for a pre-requisite print in the further research.

Definitions: Awakening and sleep cycle is a normal state of mind controlled by the power of psych (*Rooh-e Nafsaniya*). Indeed, deprived sleep or Excessive awakening is called Insomnia (*Sahar*).^{7-10,12} Insomnia is a result of overcasting Hotness and dryness in the brain, it further induces more psychological disorders.¹³ Bodily movements stimulate the nutrition to grow, while rest (sleep) motivates refurbishing the cells and removing wastage from them.^{6,7,12}

Aim of the study

1. Aim of the study is to evaluate the most suitable trended prescription pattern (*Mujarrabat/Mamulat Matab*) in drug-induced insomnia

2. To generate a hypothesis and data for further clinical trial studies in the patient of Drug-induced insomnia.

Research methodology

This is a purposive, non-probable and General Out patients department’s based cases study. Related literature drawn from the Unani classical books that translated by most reputed scholars and ministry of AYUSH. The supporting knowledge has been taken from newly researched studies from pub-med, research gate and other sites that available on internet. Patients who attended the General OPD in ages of 18-70 years in either gender included. Those who had Complaints of insomnia with any co-morbidity of diabetes mellitus, hypertension, obesity, ischemic heart diseases, stroke, Benign Prostatic Hypertrophy, chronic Allergies and pains or already went through all necessary investigations and had a positive history of treatments were asked to participate in the study. After Interrogation most of them found with affliction of several diseases and used to take medication since long. Ideas came to documentation of these kinds of patients and effects of medicine resolves over all problems as they served in the OPDs. To note suitability of kit medicines’ effect a set of questionnaires “Insomnia severity Index” used to know the answers of 07 questions. All Patients have interrogated in detail for their illness, treatment history, name of the drugs, present complaints with duration, severity, its impact on the body and daily activities. Every patient has assigned scores and noted down in a format, all data have been categorized into three categories as sub-threshold insomnia, clinical insomnia moderate and Clinical insomnia severe. At every 07 days interval patients assessed clinically to note the effect

of given kit medicines. The data was observed, analyzed to note the relationship between the medicated and non-medicated patients and statistical analysis was done by using of chi-square test with the significant of P<0.05. Analysis of percent distribution of the patients for consequences and effects of Unani kit medicines also was done. Observation was made by the version of the patients in their lay term (Indian-currency unit) as improved insomnia is about 20 paise of a rupee, 40 paise of a rupee, 60 paise, 75 paise and 80 paise of a rupee. These paise has considered the percentage of calculation.

WHO Unani standard terminology criteria have been followed for the authentication of Unani terminology.¹⁵⁻¹⁸

Interpretation of scores: The seven answers are added up to get a total score.

Guidelines for scoring/Interpretation: Add the scores for all seven items

$$(Questions 1 + 2 + 3 + 4 + 5 + 6 + 7) = \text{_____ total score:}$$

Total score categories

0–7 = No clinically significant insomnia; 8–14 = Sub threshold insomnia

15–20 = Clinical insomnia (moderate severity); 21–28 = Clinical insomnia (severe).¹⁹

Observation

Tables 1–3.

Table 1 Kit medicine given to the patients in OPDs

1	Mild insomnia	H Banafsha 2BD.(in case of Diabetes); Khameerah Banafsha 6 gm. BD (In non-Diabetics) ^{12,14,16}
2	Moderate Insomnia	H Banafsha 2 BD: Q Z Mohra 1BD; Roghan kahu for LA Sh. Unnab 20 ml BD(Optional) ^{12,14,16}
3	Severe insomnia	I.H Banafsha 2 BD: Roghan kahu for LA 2. Infusion of jujube, Rose petals and Sweet viola ^{12,14,16}

Table 2 Showing relationship between Non-medicated and medicated patients

Division of the pts.	Male	Female	Marginal row totals
Non Medicated	11 (6.64) [2.86]	4 (8.36) [2.27]	15
Medicated	20 (24.36) [0.78]	35 (30.64) [0.62]	55
Marginal column totals	31	39	70 (Grand Total)

Table 3 Distribution of the patients according to the uses medicine in co-morbidities

Medication/non medication	Number of patients	Count of palpitation	Count of constipation	Count of irritation	Count of General body fatigue	Count of headache
Alpha blocker	4		2	1	2	1
Angiotensin II RB	4	1	2	2	2	2
Anticholinergics	1				1	
Anticoagulants	5	2	3	1	3	1
Antihistamine	1			1		
Antihistamine with anticholinergic	2		1		1	
Beta-blocker	15	4	2		11	1
Calcium channel blocker	6	3	5	1	4	4
Deriphyline	1		1	1	1	1
Glucophage	1				1	1
Glucophage	5	2	2	2	4	2
Glucophage, Angiotensin II RB	1	1			1	
Glucophage, Beta-blocker	7	2		3	2	2
levothyroxine	1		1			
no medication	15	4	5	3	6	7
NSAID	1					1
Grand Total	70	19	24	15	39	23
percentage		27.14285	34.28571	21.4285	55.7142	32.8571

Discussion

Table 1 is showing that the given kit medicines are divided into three groups according to the categories of Insomnia, for category 1 mild insomnia-patients recommended only H Banfsha 2 BD if they are diabetics and Khameerah Banafsha 6 gm BD in case of non-diabetics. In category 2 moderate insomnia- has been given H Banafsha 2 BD, Q Z Mohra 1 BD oral and roghan Kahu for local application on the temporal bone before going to bed, some patients have been given additional Sharbat (Syp) Unnab 20 ml BD. In category 3 Severe insomnia- H Banafsha 2 BD oral, roghan Kahu for local application and Infusion of Jujube 5 numbers, rose petals 3 gm and Sweet viola 3gm BD for 1 month.

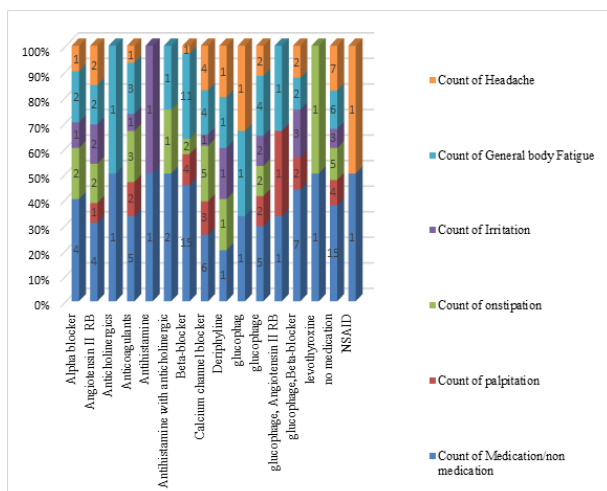
Table 2 showing that the number of patients who used to take medicines for their comorbidities and consequences with palpitation was 19(27.14%) in which 4 were on non medication whereas, 4 were on Beta blockers, while 3 patients were taking alpha-blockers. And 2 were on Glucophage, 2 on beta blockers and 2 were on anticoagulant medications. Hence, 24(34.28%) second highest number of the patients had constipation; out of this, 5 were on calcium channel blockers and

5 had no medication, while 3 patients were on anticoagulants, and 2 each were on Alpha-blockers, Angiotensin II RB, Beta-blocker and Glucophage. Further, 1 patient was in each group of Antihistamines with anticholinergic, Deriphyline and levothyroxine. Total 15 patients have Irritation out of this; 3 used to take Glucophage, Beta-blocker and 3 were have no medication. There were 39(56%) highest number of patients who had general body fatigue, out of this; 11 were on beta-blockers and 6 had no medication. 4 were on calcium channel blockers and 4 were on Glucophage. And 23(33%) third highest number of patients had headaches, out of this 7 were have no medication, 4 were on Calcium channel blockers. The above study reveals that Unani kit (*Mamulat matab*) prescription is efficient to resolve insomnia, Table 3 and Graph 1 show that the causes of insomnia in the relation of Medication and non-medication are Significant at $p < .05$. As the chi-square statistic is 6.5286. The P -value is .010616.¹⁹⁻²²

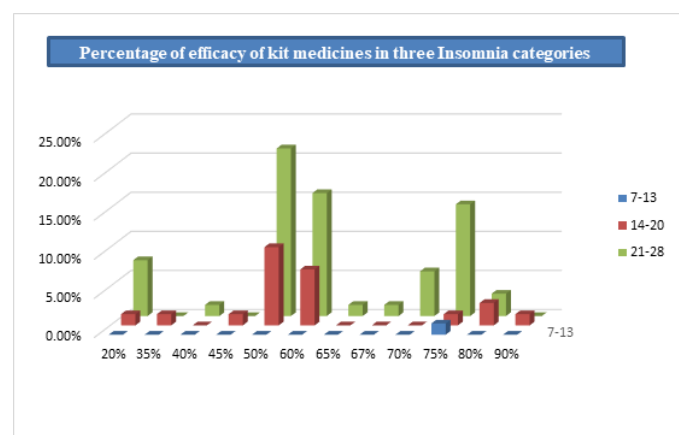
Table 4 shows the highest efficacy found in the clinical Insomnia severe, on an aggregation of 71.43% of patients reported the significant effects. After that moderate clinical insomnia patients shown second best effect while, the subthreshold group shown less effects as there were the least number of patients in this category (Graph 2).

Table 4 Showing the distribution of the patients according to the insomnia categories and efficacy of kit medicines

Percentage of efficacy of kit medicines	Sub-threshold insomnia	Clinical insomnia (moderate severity)	Clinical insomnia (severe)	Grand Total
20%	0.00%	1.43%	7.14%	8.57%
35%	0.00%	1.43%	0.00%	1.43%
40%	0.00%	0.00%	1.43%	1.43%
45%	0.00%	1.43%	0.00%	1.43%
50%	0.00%	10.00%	21.43%	31.43%
60%	0.00%	7.14%	15.71%	22.86%
65%	0.00%	0.00%	1.43%	1.43%
67%	0.00%	0.00%	1.43%	1.43%
70%	0.00%	0.00%	5.71%	5.71%
75%	1.43%	1.43%	14.29%	17.14%
80%	0.00%	2.86%	2.86%	5.71%
90%	0.00%	1.43%	0.00%	1.43%
Grand total	1.43%	27.14%	71.43%	100.00%



Graph 1 Showing the patients according to the uses of medicine in comorbidities.



Graph 2 Showing the patients according to the insomnia categories and efficacy of kit medicines.

Conclusion

Above observation and discussion reveals that patients who had visited to OPD mostly were affected with severe insomnia, and their responses are significantly high with Unani kit medicines. After evaluation of relationship between Medication and non-medication, patients also found significantly high especially in those who were taking medication for chronic illness. In the conclusion it can be say that Unani kit medicine is effective and safe in drug induced insomnia it can be bring on a large sample trial to validate on a new scientific scale.

Acknowledgments

None.

Conflicts of interest

None.

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