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Case Report

The effect of Chamomile Oil Nasal Drop on Insomnia Severity Index in Managing Short-Term Insomnia in Young Adults: A Series of Case Reports

Abstract

Background

Insomnia significantly affects quality of life and often leads to treatment relapse, highlighting the need to explore safe and alternative clinical interventions. Chamomile oil (roghan-e-baboona) nasal drop has extensive clinical uses in traditional-Unani medicine for its therapeutic properties. However, there is currently no clinical evidence supporting their use in treating insomnia. This study aimed to evaluate the effects of chamomile oil on the management of insomnia.

Case Presentation

Seven participants (4 female and 3 male) ages 18-34 were diagnosed with short-term insomnia based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria. They underwent a 14-day treatment with chamomile oil nasal drops before bedtime. Concurrently, two Unani interventions, namely Jawarish Shahi and Habb-e-Muqil, were administered for the management of constipation. Therapeutic response was evaluated using the primary measures (Insomnia Severity Index [ISI] and Pittsburgh Sleep Quality Index [PSQI]) and secondary measures (Quality of Life [QoL] and routine blood test). Results showed statistically significant improvements in ISI and PSQI ($p < 0.001$ for both scores), whereas QoLS, exhibited marked enhancement ($p < 0.007$). No participant reported adverse events during or after the study.

Conclusion

This case series suggests that, fourteen days chamomile oil nasal drop before bedtime, could be effective for insomnia. Further studies with larger sample sizes and control groups are needed to determine the efficacy and safety of this treatment for insomnia management.

Keywords: Chamomile oil, Insomnia, Nasal drops, Roghan-e-Baboona, Sa'ūṭ, Unani Regimenal Therapy

1. Introduction

Sleep is an essential process for maintaining good health and overall well-being (Grandner and Fernandez, 2021). However, sleep problems and lack of sleep are becoming more common and affect many people around the world (Hombali et al., 2019; McArdle et al., 2020). Those with sleep disorders often face difficulties in their daily lives and responsibilities (Sateia, 2014; Morin et al., 2015). The incidence of drug-induced insomnia is notably high, particularly in individuals over 60 years of age, with reports indicating about 50% in this age group. Overall, it is estimated to affect approximately 30% of the general population. Among patients with insomnia, 66.5% reported experiencing it, with sleep-maintenance insomnia being the most common problem, followed by early morning awakening and difficulty falling asleep. Research shows that insomnia is linked to mental health issues, substance abuse, medical problems, and neurological conditions.

Long-term sleep issues can also increase the risk of serious health problems, even death (Parthasarathy et al., 2015; Riemann et al., 2017). Various treatment options are available for sleep disorders, including psychotherapy and medications (Abad and Guilleminault, 2003; Kansagra, 2020; Bukhari et al., 2021) However, these approaches have challenges like limited availability, high costs, insufficient evidence, and the risk of dependency (Qaseem et al., 2016). Notably, more than two-thirds of people with insomnia do not seek medical help and instead use over-the-counter medications or self-treatment (Ozminkowski, Wang and Walsh, 2007). This has led to growing interest in complementary and alternative medicine (CAM) approaches, such as herbal remedies, to improve sleep quality and duration (Afrasiabian et al., 2019; Lowe et al., 2019; Baglioni et al., 2020; Luo and Jiang, 2022; Meraj et al., 2024).

Meraj Meraj,[1] Noushiba Khan,[2] Abdul Rehman M.I.,[1] Sadique Husain,[3] Syed Mohd Abbas Zaidi,[4] Almas Furquan[1]

1. Meraj Meraj : Department of Ilāj bi'l Tadbīr (Regimenal Therapy), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital, Bhopal, Madhya Pradesh, India
Email: meraj786786.mk@gmail.com
2. Noushiba Khan : Department of Tahaffuzi Wa Samaji Tibb (Preventive & Social Medicine), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital, Bhopal, Madhya Pradesh, India.
Email: khannoushiba123@gmail.com
3. Abdul Rehman M.I.: Department of Ilāj bi'l Tadbīr (Regimenal Therapy), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital, Bhopal, Madhya Pradesh, India.
Email: drarehman80@gmail.com
4 . Sadique Husain: Department of Ilmul Advia (Unani Pharmacology), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital, Bhopal, Madhya Pradesh, India.
Email: dr.shkhan84@gmail.com
5. Syed Mohd Abbas Zaidi : Department of Moalajat (Internal Medicine), Hakim Syed Ziaul Hasan (HSZH) Government Unani Medical College and Hospital, Bhopal 462003, Madhya Pradesh, India.
Email: drsymab@gmail.com.
6. Almas Furquan
Department of Ilāj bi'l Tadbīr (Regimenal Therapy), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital, Bhopal, Madhya Pradesh, India.
Email: almasfurqan269@gmail.com
Corresponding Author:
Name: Meraj Meraj
Address: Department of Ilāj bi'l Tadbīr (Regimenal Therapy), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital AYUSH Campus, Nehru Nagar Kolar Bypass Road, Behind MANIT, Bhopal, Madhya Pradesh, India- 462003.
Email: meraj786786.mk@gmail.com
ORCID ID: https://orcid.org/0009-0001-7594-8272
Mobile and WhatsApp No. 7408601426

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In the Unani System of Medicine, insomnia is called Sahar (Meraj, 2024; Meraj et al., 2024). It is considered a psychological condition caused by an increase in heat and dryness in the brain. This can happen due to excessive evacuation from the body, consuming hot medicines or foods, stimulation from waste products in the digestive system, the accumulation of salty fluids in the brain, or certain illnesses and severe health conditions (Jurjani, 2010; Majoosi, 2010; Sena, 2010). Chamomile oil (roghan-e-baboona) is recommended for managing insomnia in the Unani system of medicine (Kabeeruddin, 2003). However, there is no scientific evidence to confirm its effectiveness. Therefore, it is pressing need to conduct scientific studies to evaluate its safety and effectiveness in treating insomnia. The information collected from the study participants followed the ethical principles of the Helsinki Declaration. Additionally, the compilation of this case reports followed the CARE case report guidelines (Riley et al., 2017).

2. Patient's information

This study includes seven participants, four female and three male, aged 18 to 34, who visited the outpatient department (OPD) at our Hospital. All of them had trouble falling asleep, staying asleep, waking up in the morning, generalized weakness and felt impaired during the day. Their symptoms had lasted for 1.5 to 2.5 months, and they had not used any insomnia medication for a month before clinical consultation [Table 1].

3. Clinical findings

During the general examination, all participants had normal vital signs, and no abnormalities were found in their systemic examination. One female participant had a family history of insomnia. All participants also had a history of constipation. Mizāj (temperament) was assessed during the disease condition [Table 1]. The average disease duration among all participants was 2.29 ± 0.76 years, with a range spanning from 1.5 to 2.5 months. On mental status examination all participants were found restless, well dressed, cooperative, appropriately behaved and could build a good rapport. It is noteworthy that each patient had previously undergone unsuccessful treatments, having received one to two different medications from both self medicated and homeopathic modalities prior to the initiation of Unani intervention [Table 1].

4. Timeline

The first patient started treatment on May 7, 2024, and the last patient completed their 14-day treatment on June 03, 2024 [Table 1].

Table 1: Clinical-demographic profile of the seven participants studied

Case No.	Age	Sex	Mizāj (Temperament)	Family history	Disease duration (Months)	Past interventions	Outcome of past interventions	Other clinical findings	Timeline of trial therapy (dd/mm/yy)
1.	*18*	*F*	*Ṣafrāwī (bilious)*	*Not present*	*2*	*Self treatment*	*Got temporary relief in the symptoms*	*Not significant*	*07/05/2024 to 20/05/2024*
2.	*34*	*F*	*Sawdāwī (melancholic)*	*Not present*	*2*	*Homeopathic*	*Do not experience satisfactory relief*	*Not significant*	*09/05/2024 to 22/05/2024*
3.	*25*	*F*	*Ṣafrāwī (bilious)*	*Mother with history of insomnia*	*2.5*	*Self treatment and homeopathic*	*Experienced temporary relief from the symptoms*	*Not significant*	*09/05/2024 to 22/05/2024*
4.	*30*	*F*	*Ṣafrāwī (bilious)*	*Not present*	*2.5*	*Self treatment*	*Experienced temporary relief from the symptoms*	*Not significant*	*11/05/2024 to 24/05/2024*
5.	*28*	*M*	*Damawī (sanguineous)*	*Not present*	*2*	*Homeopathic*	*Do not experience satisfactory relief*	*Not significant*	*15/05/2024 to 28/05/224*
6.	*34*	*M*	*Ṣafrāwī (bilious)*	*Not present*	*1.5*	*Homeopathic*	*Experienced relief in sleep initiation*	*Not significant*	*17/05/2024 to 30/05/2024*
7.	*29*	*M*	*Balghamī (phlegm)*	*Not present*	*2*	*Self treatment and homeopathic*	*Do not experience satisfactory relief*	*Not significant*	*21/05/2024 to 03/06/2024*

5. Diagnostic assessments

All participants underwent routine blood tests, including HbA1c and electrolytes, and the results were within normal limits. They were all diagnosed with short term insomnia based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V). The main outcomes measured were reductions in insomnia severity, assessed through Insomnia Severity Index (ISI) (Bastien, Vallières and Morin, 2001) and Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989). Quality of life was assessed using the Quality of Life Scale (QoLS) (Burckhardt and Anderson, 2003).

The response to treatment was assessed by comparing data collected at baseline, on the 5 weeks post-treatment initiation, and one week after the treatment concluded (week 6).

6. Data Analysis

Statistical analysis was done using SPSS software, version 27.0. A p-value of less than 0.05 was considered statistically significant. Descriptive statistics were calculated, including minimum, maximum, and mean values. For comparing results within the group, the paired t-test was applied to data with a normal distribution, while the Wilcoxon rank-sum test was used for data with a non-normal distribution.

7. Therapeutic Intervention

The Unani formulation, chamomile oil, 8 drops was instilled in each nostril one after the other at bedtime daily. The other nostril was covered during drug delivery in one nostril and patient was to inhale oil slowly.

The same process was repeated in other nostrils. Each 10 ml of chamomile oil contains Gul-e-Baboona [Matricaria chamomilla (Fl.)] 1.28 g and Roghan Kunjad [Sesamum indicum (Sd.) (Ol.)] 10 ml. Concurrently, potent Unani pharmacological interventions, namely Jawarish Shahi and Habb-e-Muqil, were administered for the management of constipation with 5 g and two pills respectively, twice daily after meals. Jawarish Shahi, in each 5-gram dose, included Murabba Halela [Terminalia chebula (Fr.)] 0.857 g, Murabba Amla [Emblica officinalis (Fr.)] 0.674 g, Kishneez Khushk [Coriandrum sativum (Dr. Fr.)] 0.084 g, Elaichi Khurd [Elettariacardamomum (Dr. Fr.)] 0.021 g, Arq Bed Musk [Salix caprea (Fl.)] 0.038 ml, Qand Safed (Saccharum officinarum Crystal) 3.466g. Each pill of Habb-e-Muqil composed of Muqil [Commiphora wightii (Arn.) Bhandari] 44.68mg, Post Halyla Zard (Terminalia chebula Retz.half-ripe fruit) Post Halyla Kabuli (Terminalia chebula Retz. ripe fruit), Halyla Siyah (Terminalia chebula Retz. unripe fruit), Amla Khushk (Phyllanthus emblica L.) each 31.91mg, Sakbeenaj (Ferula persica Willd.) 10.63 mg, Khardal (Brassica nigra W. D. J. Koch) 5.31 mg, Roghan-e-Badam (Prunus amygdalus Batsch oil) 10.63 ml, Aab-e-Gandana (Allium ascalonicum L. juice) 52.6 ml.

For this study the formulation manufactured by Government Unani Pharmacy, Bhopal and supplied by Government of Madhya Pradesh.

8. Follow up and outcomes

The study included fourteen days follow-up, with a mean age of 28.28 ± 5.55 years and a female predominance of 57.14 %. The average duration since Insomnia diagnosis was 2.07 ± 0.34 months. No side effects were reported during the treatment.

Evaluation tools including ISI, PSQI, and QoLS showed steady improvements in scores from baseline to 14-days, indicating significant symptom relief [Table 2]. Blood test analyses revealed no significant changes from baseline to post-treatment [Table 3].

Table 2: Change in Symptom severity of Insomnia patients that before and after 2 weeks of treatment N = 7; ISI: Insomnia Severity Scale, PSQI: Pittsburgh Sleep Quality Index, QoLS: Quality of life scale.

Variable	Baseline Mean (SD)	2 Weeks Mean (SD)	Difference Mean (SD)	T- value	P value
ISI	*19.4286 (1.13389)*	*2.4286 (0.53452)*	*17.00000 (1.41421)*	*31.804*	*< 0.001*
PSQI	*13.1429 (0.89974)*	*2.5714 (0.53452)*	*10.57143 (0.78680)*	*35.548*	*< 0.001*
QoLS	*42.6667 (0.57735)*	*49.6667 (0.57735)*	*-7.00000 (1.00000)*	*-12.124*	*0.007*

Table 3: Blood sample results comparison means before and after treatment in MDD patients N=3. Glycated hemoglobin (HbA1c), Hemoglobin (Hb), Red Blood Cell (RBC), WBC (White blood cells), ESR (erythrocyte sedimentation rate), AST (Aspartate aminotransferase), ALT (Aspartate aminotransferase), BUN (Blood urea nitrogen).

Variable	Baseline Mean (SD)	2 Weeks Mean (SD)	Difference Mean (SD)	T- value	P value
HbA1c %	*4.3857 (0.21157)*	*4.3429 (0.21492)*	*0.04286 (0.05345)*	*2.121*	*0.078*
Hb g/dL	*13.7857 (0.90449)*	*13.6857 (0.80711)*	*0.10000 (0.18257)*	*1.449*	*0.197*
RBC Count 10^12/L	*4.0857 (0.08997)*	*4.0286 (0.04880)*	*0.05714 (0.07868)*	*1.922*	*0.103*
Platelet Count (PLT) 10^12/L	*325.0000 (47.87136)*	*324.4286 (47.96477)*	*0.57143 (0.78680)*	*1.922*	*0.103*
WBC 10^12/L	*6.0571 (1.18301)*	*6.0286 (1.17291)*	*0.02857 (0.04880)*	*1.549*	*0.172*
ESR mm/hr	*6.9286 (1.17006)*	*6.9571 (1.13704)*	*-0.02857 (0.04880)*	*-1.549*	*0.172*
Bilirubin (Total) mg/dL	*0.5429 (0.09759)*	*0.5786 (0.12199)*	*-0.03571 (0.04756)*	*-1.987*	*0.094*
AST U/L	*28.1429 (0.62678)*	*28.1143 (0.60945)*	*0.02857 (0.04880)*	*1.549*	*0.172*
ALT U/L	*27.2857 (2.64350)*	*27.2571 (2.62225)*	*0.02857 (0.04880)*	*1.549*	*0.172*
Creatinine –Serum mg/dL	*0.7714 (0.11127)*	*0.7429 (0.11339)*	*0.02857 (0.04880)*	*1.549*	*0.145*
BUN mg/dL	*14.6371 (2.77879)*	*14.6143 (2.77274)*	*0.02286 (0.04071)*	*1.486*	*0.188*
Sodium mmol/L	*140.6429 (2.24934)*	*140.5571 (2.19989)*	*0.08571 (0.18645)*	*1.216*	*0.270*
Potassium mmol/L	*4.2714 (0.24300)*	*4.2429 (0.26992)*	*0.02857 (0.04880)*	*1.549*	*0.172*
Chloride mmol/L	*101.5714 (2.37045)*	*101.4286 (2.29907)*	*0.14286 (0.37796)*	*1.000*	*0.356*

9. Discussion

This study investigates the efficacy of chamomile oil in managing short term insomnia. The reduction in disease activity can be attributed to its multifaceted properties, including evacuation of morbid material (Imala Mawad), resolvent (Muhallil), brain tonic (Muqawwī-i-Dimāgh), nervine tonic (Muqawwī-i-Aʿṣāb), analgesia (Taskīn-i-Alam), and relaxant (Murkhi), as described in classical Unani literature (Nabi, 2007; Ghani, 2010, YNM). Nasal drop is a nasal drug delivery method, involves the administration of oily or watery preparations into the nasal cavity (Meraj et al., 2024). This delivery system offers numerous advantages, including rapid and high bioavailability, avoidance of first-pass metabolism, non-invasiveness, and ease of administration (Keller, Merkel and Popp, 2022). Matricaria chamomilla L. has a long history of traditional use for its calming and sedative properties (Chaves et al., 2020; Dai et al., 2022). The primary ingredient of chamomile oil, is chamomile flower which contains bioactive compounds such as flavonoids (e.g., apigenin, luteolin, quercetin) [35, 38] and terpenoids (e.g., chamazulene, bisabolol, bisabolol oxide) (Ghasemi et al., 2016; Hosseinipour et al., 2024). These compounds are believed to contribute to its sleep-enhancing effects. Previous research has demonstrated that chamomile improves the quality of sleep in various populations, including postmenopausal women,(Abbasinia et al., 2016; Rasool, Ishtiaq and Rehman, 2019) individuals with poor sleep, (Zick et al., 2011) the elderly, (Abdullahzadeh, Matourypour and Naji, 2017; Adib-Hajbaghery and Mousavi, 2017) postnatal women with sleep disruptions, (Chang and Chen, 2016) patients with dysmenorrheal (Murtiningsih et al., 2022) and heart failure. The effects of chamomile on sleep are believed to be due to its interaction with benzodiazepine and gamma-aminobutyric acid (GABA) receptors, which have hypnotic effects on sleep-wake cycles. Additionally, chamomile infusion contains high melatonin content, which is essential for promoting sleep. Its antidepressant and anxiolytic properties may also contribute to its beneficial effects on sleep quality. The antioxidant properties of chamomile may support its sleep-promoting effects since chronic oxidative stress is reported to disrupt key mechanisms in the regulation of circadian rhythms and sleep homeostasis (Morris et al., 2018).

Our study has some limitations first; the small sample size which restrict the applicability of its findings to broader population. Second limitation is the absence of a control group that limits the ability to discern the specific effects of chamomile oil nasal drops from other potential influences or placebo effects. Third limitation is the simultaneous administration of other Unani treatments, such as Jawarish Shahi and Habb-e-Muqil, which may have contributed to the therapeutic outcomes and complicates attributing the effects solely to chamomile oil. Fourth limitation is the homogeneity of the demographic profile, with all participants being young adults aged 18–34, limits the findings' generalizability to other age groups or individuals with chronic or complex insomnia conditions. These limitations underscore the importance of conducting well-structured randomized controlled trials with larger, diverse populations and extended follow-up periods to validate the effectiveness and safety of chamomile oil nasal drops for managing insomnia.

10. Conclusion

In conclusion, fourteen days instillation of chamomile oil before bedtime was found to be statistically and clinically significant in alleviating insomnia symptoms. There were no side effects reported during the treatment in all participants. However, further research is needed to evaluate the effectiveness of chamomile oil in insomnia through well-structured retrospective controlled studies or prospective studies with larger sample sizes and longer durations before progressing to randomized controlled trials.

Patients perspective

From the patient's perspective, they fully recovered from their symptoms, including difficulty falling asleep, waking up early in the morning, and daytime problems.

Informed consent

Patients were apprised of the study procedure and the potential publication of their de-identified data in a language they could understand, after which written informed consent was obtained from all participants.

Ethical statement

This study involving human subjects followed all relevant national regulations and the principles of the Helsinki Declaration (2013 revision).

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