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A clinical study to evaluate the effect of *Shreekhandasava* in *Madatyaya* w.s.r. to Alcohol use disorder

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ABSTRACT

Objective: To study *Madatyaya* / Alcohol use disorder conceptually and to evaluate the therapeutic effect of *Shreekhandasava* in *Madatyaya*/Alcohol use disorder. **Design of the study:** An open labelled clinical study with pre and post-test design. **Source of data:** 20 patients diagnosed as *Madatyaya* fulfilling the diagnostic and inclusion criteria were selected from IPD and OPD of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kutpadi, Udupi. **Intervention:** *Shreekhandasava* in a dose of 24ml, twice a day after food for 14 days. **Main outcome measures:** Percentage changes in symptoms including CIWA-Ar score. **Results:** the statistical analysis was done by paired 't' test and results obtained were highly significant ($p < 0.001$). Overall improvement of patients, 10% got complete remission, 85% got marked improvement and 5% got moderate improvement from the symptoms. **Conclusion:** Test drug (*Shreekhandasava*) shows significant results in remission of signs and symptoms of *Madatyaya*.

Key words: *Madatyaya*, *Mada*, *Shreekhandasava*, *Alcohol use disorder*, *Intoxication*.

INTRODUCTION

Since the antiquity man is using *Madya* (Alcohol) and it is a part of social and cultural life. The *Madya* has nectar like properties when used judiciously following all norms, otherwise it acts as a poison.^[1] Alcohol use disorder is defined by a cluster of behavioural and physical symptoms, which can include withdrawal, tolerance and craving. Alcohol withdrawal is characterized by withdrawal symptoms that develop approximately 4-12 hours after the reduction of intake following prolonged, heavy alcohol ingestion

because withdrawal from alcohol can be unpleasant and intense, individual may continue to consume alcohol despite adverse consequences, often to avoid or to relieve withdrawal symptoms. Some symptoms (e.g. sleep problems) can persist at lower intensities for months can contribute to relapse.^[2] In Ayurveda alcohol related disorders can be correlated to *Madatyaya*. Here we observe the vitiation of *Shareerika* and *Manasika Doshas*, which ruins the physical, psychological, social, economical and occupational wellbeing.

Madatyaya is caused due to improper use of *Madya*, which is considered as *Tridoshaja Vyadhi*. As per our classics treatment of *Madatyaya* mainly consists of *Doshavsechana*, *Rasayana* and *Satvavajaya Chikitsa*. *Shreekhandasava*^[3] is one such *Yoga* told for *Chikitsa* of *Madatyaya*, which has *Tridoshahara* properties and indicated in *Panatyaya*, *Paramada*, *Panajeerna* and *Panavibhrama*.

So with intension of providing a better and safer treatment a study was carried out with internal administration of *Shreekandasava*, 24ml, twice a day after food.

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OBJECTIVES

1. To study *Madatyaya* and Alcohol use disorder conceptually.
2. To evaluate the therapeutic effect of *Shrikhandasava* in *Madatyaya* / Alcohol use disorder.

MATERIALS AND METHODS

The study was initiated after obtaining the institute human ethic committee's permission (IEC: Ref. No. SDMCAU/ACA-49/EC46/14-15, Date - 23/04/2015). *Shreekhandasva* (Batch No. 160752, Mfg. Date January 2017) was obtained from SDM Ayurvedic Pharmacy, Udupi.

Source of data

A minimum of 20 patients diagnosed as *Madatyaya* were selected from IPD and OPD of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kutpadi, Udupi.

Statistical analysis done based on Sigma stat Statistics software version 3.5 with the mean (\pm SE), standard deviation and the results were analysed statistically using paired 't' test.

Method of collection of data

A special proforma was prepared with details of history taking, physical and psychological signs and symptoms as mentioned in Ayurvedic classics and allied sciences. The parameters of signs and symptoms were scored based on standard methods and will be analyzed statistically.

Study design

It was an open labelled clinical study with pre and post test design.

Diagnostic Criteria

1. Based on *Madatayaya Samanaya Lakshana* told in our classics patients were diagnosed.
2. Based upon AUDIT Questionnaire^[4] diagnosis is made as Alcohol used disorder.

Inclusion Criteria

1. Patient presenting fulfilling the above mentioned diagnostic criteria.
2. Patients between 16 to 70 years of age.

Exclusion Criteria

1. Patients suffering from complications of *Madatyaya* and alcohol use disorder
2. Patients suffering from other type of addiction and systemic disorders
3. Pregnant women.

Assessment Criteria

CIWA-Ar score^[5]

Intervention

Diagnosed 20 patients were given *Shreekhandasava* - 24ml, twice a day after food.

Duration of clinical study - 14 Days

Follow up - 14 days after treatment with weekly interval.

Total duration - 28 days

OBSERVATION AND RESULTS

Observations

Among the 20 patients taken for the study, maximum i.e. 40 % of the patients belong to the age group of 41-50, 95% of the patients belonged to Hindu Religion, 90% of patients were married, coolie worker and businessman were 30%, 35% patients started drinking alcohol in between 16-20 years of age, 40% at 26-30yrs and 5% patient at 31-35 yrs of age. 35% patients had the habit of drinking alcohol from 21-30 years, 30% patients from 31- 40 yrs, 25% patients had from 11-20 yrs and 10% patients from 1-10 yrs, 50% patients started drinking alcohol due to peer group pressure and 20% due to curiosity, 45% patients were taking alcohol daily since 11-20 years, majority of patients (70%) were drinking spirit type of alcohol, 60% patients used to take 181-360 ml of alcohol per day. 65% patients shows self-motivated attitude towards alcohol. 80% patients not having any other

substance use, 55% patients having family history of drinking, 65% had harmonious family atmosphere, 25% had committed and 10% had conflicted family atmosphere, 85% patients had cordial relationship with their spouse, 55% of the patients had reduced and disturbed sleep, 75% patients belong to *Anupa Desha*. Majority of patients belonged to *Vatapitta Prakruti* i.e. 45%, 40% patients exhibited *Vataja Madatyaya*, 95% patients exhibited *Madhyama Sara*, 95% recorded *Madhyama Samhanana*, 80% patients had *Madhyama Pramana*, 55% patients having *Madhyama Satva*, 80% had *Madhyama Satmya*, 90% of patients had *Madhyama Abhyavaharana Shakti*, 75% of patients had *Madhyama Jarana Shakti*, 75% of the patients had *Madhyama Vyayama Shakti*. 55% patients belong to the group of increasing risk, 20% patients belong to the higher risk and 25% patients belong to possible dependence. 100% patients had *Shrama* (tiredness) and *Prajagara* (sleeplessness), 85% had *Shirashoola* (headache), 80% had *Hrullasa* (nausea) and *Shareera Kampa* (tremors), 65% *Atisweda* (sweating), 60% had *Aruchi* (tastelessness), 55% *Panduta* (paleness), 25% had *Brhama* (giddiness), 20% had *Rupanamasatmadarshnam* (Hallucinations), 15% had *Mandajwara* (fever) and *Pratatatrishna* (thirst), 10% had *Vistambha* (constipation) and *Atisara* (loose stools), 5% patients had *Alasya* (fatigue) and *Moha*. 90% patients had *Sheelavibrhrama* (improper habits and temperament), 80% had *Bhakti Vibrahama* (improper desires), 45% had *Mano Vibhram* (improper perception) 40% had *Chesta Vibhrama* (improper conducts), 25% had *Sanjnavibrahama* (altered consciousness) and *Achara Vibrahama* (improper conducts), 20% had both *Buddhi* and *Smriti Vibhrama* (altered state of memory).

RESULT

Among 20 patients, major improvement is seen on the symptom orientation which shows 100% improvement, Nausea / vomiting 98.38% relief, agitation 90.62% relief, headache 88% relief, sweating 85% relief, tremors 82.27% relief, visual disturbance 61.53% relief, anxiety 45% relief. Overall effect of treatment in *Madatyaya*, out of 20 patients in this study 1 (5%) got moderate improvement, 17 (85%)

patients got marked improvement and 2 (10%) patients got complete remission from the symptoms.

DISCUSSION

Madya is considered as one of the *Ahara Dravya* and it acts like nectar if taken properly following the rules and regulations, otherwise it acts like a poison. As in the literature it is corroborated as *Madatyaya* is a *Tridoshaja Vyadhi* where in the symptoms are also categorised among *Vataja*, *Pittaja*, *Kaphaja*, *Dwandwaja* and *Tridoshaja*. Alcohol is a potent drug that causes both acute and chronic changes in almost all neurochemical systems. Thus alcohol abuse can produce serious temporary psychological symptoms including depression, anxiety and psychosis. In long term consumption can produce tolerance as well as such intense adaption of the body that cessation of use can precipitate with drawal syndromes marked by insomnia, hyperactivity and feeling of anxiety. Different factors for development of alcohol used disorders in a person certain observations were made in the study. According to the W.H.O up to 16% people are at risk of AUD,^[6] many religions around the world forbid the consumption of alcohol and some like Christianity have specific place for it (specially wine),^[7] early onset of drinking can affect the person with AUD early as the age proceeds.^[8] Spirit are considered to have high percentage of alcohol content and people who involve in drinking such kind of beverage in more quantity (i.e. more than 2 standard drink per day) can be suspected to suffer from AUD.^[9] Person having low self control and aggression before initiation of drinking would be associated with early onset of drinking and are at higher risk of developing AUD.^[10] *Madatyaya* is a *Tridoshajavyadhi*, initially *Vata* and *Pitta* gets vitiated then later these two together vitiated *Kapha* to cause *Agnimandya*, *Aruchi* etc. To treat any disease *Agni* should be in normal condition hence *Kapha Chikitsa* is considered to be the first line of treatment. The following *Yoga* is *Kaphahara*. *Shrikandasava* a *Shamana Yoga* in *Madatyaya* with main ingredient as *Shrikanda* which is popularly known as *Chandana*. According to classical reference, it is said that

Shrikhanda is *Kaphapitta Shamaka*, which is indicated in *Daha, Ati Svedajanya Dourgandhya, Manasikavyagrata, Dourbalya, Trisna, Amlapitta, Kamala, Hridorbalya, Visha* which are found in *Madatyaya* also and *Shrikhanda* due to its *Katu Vipaka* pacifies *Vata* and *Kapha*, its *Sheeta Guna* acts against *Ushna* and *Teekshna Guna* of *Pitta*. *Maricha* is *Kaphavatahara, Medohara*, stimulant and tonic for nerves, remedy in liver dysfunction. *Jatamamsi* is *Tridosahara*, mainly indicated in *Nidranasha, Agnimandya, Kampavata* and has anti-anxiety action. *Haridra* has properties such as *Raktaprasadana, Tridoshashamaka*, anti hepatotoxic and CNS depressant. *Tagara* is *Kapha-Vatahara, Rasayana*, tranquilizer and nervine, *Pippali* is *Kaphavatahara*, anti giardial immune stimulatory, hepatoprotective. All the drugs collectively act as *Tridosahara* and based on their chemical composition they act on CNS and other systems to provide relief from the *Madatyaya* condition.

Overall effect of treatment in *Madatyaya*, out of 20 patients in this study 1 (5%) got moderate improvement, 17 (85%) patients got marked improvement and 2 (10%) patients got complete remission from the symptoms, some symptoms like visual and auditory disturbance were found to be statistically insignificant though patient had relief from these symptoms as number of patients presented with these symptoms were less. It shows that *Shreekhandasava* is effective in both physiological and psychological symptoms of alcohol use disorder.

CONCLUSION

Madatyaya is considered as a serious illness which is mainly caused due to excess intake of alcohol and variants of psychosocial aspects. *Madatyaya* can be correlated with the Alcohol use disorder in the contemporary science where as the clinical presentation matches equally. As per *Ayurvedic* literature, *Shreekandasava* is explained as one of *Shamana* medication in *Madatyayaadhikara*. Based on the clinical presentation of *Madatyaya* has been treated accordingly considering complications and

psychological changes especially alcohol withdrawal symptoms. As per statistical analysis done for symptoms namely nausea and vomiting, tremors, agitation, sweating and headache shows statistically significant with 'p' value <0.001, some symptoms like visual and auditory disturbance were found to be statistically insignificant though patient had relief from these symptoms as number of patients presented with these symptoms were less. Overall effect of *Shreekhandasava* is 84.55%. Thus *Shreekandasava* can be practiced wisely in the patients of *Madatyaya*.

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