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Clinical Efficacy Of *Brahmi Vati* On Insomnia W.S.R. To *Madatyaya* : A Randomized Control Trial

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Abstract-

The substance on administration produces disturbance of the intellect faculty by virtue of its *tamoguna*, or substance which causes intoxication by its excessive consumption is called as ***Madya***. Intake of Alcohol in improper manner for long time in excess quantity leads to the disease called ***Madatyaya*** **or** ***Panatyaya***. In ayurvedic setting symptom Anidra (Insomnia) is difficult to treat, because the use of drugs containing opium or its derivative or cannabis, is like giving an addiction to treat addiction. So in present study "Clinical Efficacy Of *Brahmi Vati* On Insomnia W.S.R. To *Madatyaya* : A Randomized Control Trial" we try to conclude out the efficacy of drug not containing opium or cannabis on insomnia as a symptom of madatyaya. Group A contains Brahmi Vati, Jatamansi oil nashya and syp. M liv and Group B

contains Syp. Shankhapushpi, , Jatamansi oil nashya and syp. M liv. The data collection, analysis and conclusion drawn from it is elaborated in this article.

Key Words- ***Madatyaya,*** cannabis, *Brahmi Vati*, Jatamansi oil, data analysis

Introduction:

Human body is the most previous gift of the God to mankind. To keep Human body free from various diseases and to maintain health, clinical research work is required to be undertaken from time to time. Before employing any method, any medicine or therapy, it is essential, first to conduct research on a small group of patients, to study the efficacy of particular method medicine, or therapy.

According to *Ayurvedic* classics the basic approach to the concept of health is essentially psychosomatic in nature. *Manasika* and *Shariri*ka are regarded as separate entities in *Ayurveda* but not in the sense of separatism because an organism is the complex combination of mind, soul and body. *Sharirika* and *Manasikadoshas* are found to be affecting mutually each other[i]. In *Ayurveda* classic, the effects of psychic (or mental) disorders on the body have also been mentioned. The present study entitled *"*Clinical efficacy of *Brahmi vati* on Insomnia w.s.r. to *Madatyaya* : A Randomized control trial*."* was undertaken.

1. Aims and Objectives

Present research work includes following objectives-

1. To evaluate, elaborate and discussion of *Ayurvedic* aspect of alcohol addiction, withdrawal and management.
2. To study the clinical efficacy *Brahmi vati* on insomnia as symptom of alcohol withdrawal syndrome.
3. To compare the clinical efficacy of *Brahmi vati* with S*hankhpushp*i syp on insomnia as symptom of alcohol withdrawal syndrome.

2. Material and Methods

Patients:

For the clinical study, 30 Patients were selected from the O.P.D and I.P.D of PG Deptt. of *Agad tantra evam Vyavhar ayurveda*, National Institute of *Ayurveda, Jaipur*. Voluntary written informed consent had been taken from each subject before trial starts. Patients fulfilling the criteria for selection were integrated into the study irrespective of caste, religion etc. A detailed history was filled up in dully prepared Performa on *Ayurvedic* guidelines.

Method of collection of data:

30 patient's desires to withdraw the alcohol will be selected from OPD of National Institute of Ayurveda, Jaipur and will be treated after proper physical examination in OPD and IPD levels. Selected 30 patients will be randomly divided in 2 groups

1. **Study group (Gp.-A)** – *Brahmi vati* will be given in 15 patients of alcohol addiction and withdrawal along with *jatamansi oil nasya*, syp M-liv.

2. **Control group (Gp.-B)** – syp *Shankhapushpi* will be given in 15 patients of alcohol addiction and withdrawal along with *jatamansi oil nasya*, syp M-liv.

Both the groups will be given psychological counseling and suggested normal healthy diet & meditation along with medicines.

Criteria for selection of patient:

Inclusion Criteria

1. Diagnosed patient of alcohol addiction.
2. Clinical manifestation of insomnia as a alcohol withdrawal syndrome which will be presented at that time.
3. Age between 20 – 70 years
4. Either sex.

Exclusion Criteria

1. Alcohol addicted patients suffering from liver failure, gastrointestinal bleeding, Mallory-Weiss tears, Wernicke Korsakoff's syndrome (WKS), cerebellar degeneration.
2. Alcohol addicted patients who are suffering from major psychiatric disorders.
3. Alcohol addicted patients suffering from major systemic illness like diabetes, hypertension, myocardial infarction, ischemic heart disease, pulmonary tuberculosis etc.

Criteria for diagnosis:

All the patients confirming the above said inclusion criteria were included in the study and subjected to thorough interrogation, physical examinations. Patients were selected on the basis of their clinical presentation particularly related *Insomnia w.s.r. to Madatyaya*.

Clinical Diagnosis

1. The insomnia assessment criteria.
2. Clinical Assessment of Alcohol Withdrawal Patients (as per CIWA-Ar).
3. Pathological Assessment in Alcohol Addicted Patients.

Method of research:

The method adopted in present study was open randomized clinical trial. Ethical clearance was obtained for the study from the Institutional ethics committee. Total 30 patients were registered and categorized into Group A and B.

Informed consent:

The purpose of the study, nature of the study drugs, the procedures to be carried out and the potential risks and benefits were explained to the patients in detail in non-technical terms. Thereafter their written consent was taken before starting the procedure.

Treatment protocol:

Posology:

Group	Drug	Form	Dose	Route and Time of Administration	Duration
A	***Brahmi vati***	*Vati*	500 mg	**Route: Oral** **Time:** Twice daily after meal ***Anupan*-** milk	*1 month*
	Jatamansi oil	*Oil*	2-2 drops (*pratimarsha nasya*) twice a day	**Route:** *pratimarsha nasya* **Time:** Twice daily after meal	
	Syp. M-LIV (IMPCL)	*Syp.*	15 ml twice a day	**Route: Oral** **Time:** Twice daily after meal	
B	**Syp. *Shankhapushpi***		15 ml twice a day	**Route: Oral** **Time:** Twice daily after meal	*1 month*
	Jatamansi oil	*Oil*	2-2 drops (*pratimarsha nasya*) twice a day	**Route:** *pratimarsha nasya* **Time:** Twice daily after meal	
	Syp. M-LIV (IMPCL)	*Syp.*	15 ml twice a day	**Route: Oral** **Time:** Twice daily after meal	

Criteria for assessment

1. **THE INSOMNIA ASSESSMENT CRITERIA**

Clinical features	*Study group (Gp. A)*		*Control group (Gp. B)*	
	Before Treatment	*After Treatment*	*Before Treatment*	*After Treatment*
INSOMNIA SCORE				

2. INSOMNIA SCREENING QUESTIONNAIRE[ii]

S. No.	Over the past month	Circle the best answer				
		Never	Rarely	Occasionally	Most nights/days	Always
1.	Do you have trouble falling asleep?	**1**	**2**	**3**	**4**	**5**
2.	Do you have trouble staying asleep?	**1**	**2**	**3**	**4**	**5**
3.	Do you wake up un-refreshed?	**1**	**2**	**3**	**4**	**5**
4.	Do you take anything to help you sleep?	**1**	**2**	**3**	**4**	**5**
5.	Do you use alcohol to help you sleep?	**1**	**2**	**3**	**4**	**5**
6.	Do you have any medical condition that disrupts your sleep?	**1**	**2**	**3**	**4**	**5**
7.	Have you lost interest in hobbies or activities?	**1**	**2**	**3**	**4**	**5**

3. Clinical Assessment of Alcohol Withdrawal Patients (as per CIWA-Ar)[iii]

Nausea/Vomiting - Rate on scale 0 – 7

0 – None
1 - Mild nausea with no vomiting
2
3
4 - Intermittent nausea
5
6
7 - Constant nausea and frequent dry heaves and vomiting

Tremors - have patient extend arms & spread fingers. Rate on scale 0 - 7.
0 - No tremor
1 - Not visible, but can be felt fingertip to fingertip
2
3
4 - Moderate, with patient's arms extended
5
6
7 - severe, even with patient's arms not extended

Anxiety - Rate on scale 0 – 7
0 - no anxiety, patient at ease
1 - mildly anxious
2
3
4 - moderately anxious or guarded, so anxiety is inferred
5

Agitation - Rate on scale 0 – 7
0 - normal activity
1 - somewhat normal activity
2
3
4 - moderately fidgety and restless
5
6

6
7 - equivalent to acute panic states seen in severe delirium or acute schizophrenic reactions.

7 - paces back and forth, or constantly thrashes about

Paroxysmal Sweats - Rate on Scale 0 - 7.
0 - no sweats

1- barely perceptible sweating, palms moist
2
3
4 - beads of sweat obvious on forehead
5
6
7 - drenching sweats

Orientation and clouding of sensorium - Ask, "What day is this? Where are you? Who am I?" Rate scale 0 – 4
0 – Oriented
1 – cannot do serial additions or is uncertain about date
2 - disoriented to date by no more than 2 calendar days
3 - disoriented to date by more than 2 calendar days
4 - Disoriented to place and / or person

Tactile disturbances - Ask, "Have you experienced any itching, pins & needles sensation, burning or numbness, or a feeling of bugs crawling on or under your skin?"
0 – none
1 - very mild itching, pins & needles, burning, or numbness
2 - mild itching, pins & needles, burning, or numbness
3 - moderate itching, pins & needles, burning, or numbness
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Auditory Disturbances - Ask, "Are you more aware of sounds around you? Are they harsh? Do they startle you? Do you hear anything that disturbs you or that you know isn't there?"
0 - not present
1 - Very mild harshness or ability to startle

2 - mild harshness or ability to startle

3 - moderate harshness or ability to startle

4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Visual disturbances - Ask, "Does the light appear to be too bright? Is its color different than normal? Does it hurt your eyes? Are you seeing anything that disturbs you or that you know isn't there?"
0 - not present
1 - very mild sensitivity
2 - mild sensitivity
3 - moderate sensitivity
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Headache - Ask, "Does your head feel different than usual? Does it feel like there is a band around your head?" Do not rate dizziness or lightheadedness.

0 - not present
1 - very mild
2 – mild
3 – moderate
4 - moderately severe
5 – severe
6 - very severe
7 - extremely severe

Result-

A. Intergroup comparison of Subjective Parameters

To access the efficacy of two therapies intergroup comparison was done. As the variables are nonparametric we used **Mann-Whitney Test** for statistically analysis. The results are as follows

Intergroup comparison of therapy's Effect on CIWA-Ar Score

Variable	Mean Diff.		SD±		SE±		P	Result
	Group A	Group B	Group A	Group B	Group A	Group B		
Nausea/ vomiting	4.733	2.600	0.7988	1.242	0.2063	0.3207	<0.0001	ES
Tremors	4.000	2.667	0.7559	1.447	0.1952	0.3737	0.0098	VS
Anxiety	4.000	2.600	0.5345	1.242	0.1380	0.3207	0.0006	VS
Agitation	2.200	1.800	1.656	1.265	0.4276	0.3266	0.4653	NS
Proxymal sweat	1.867	1.533	1.407	1.302	0.3634	0.3362	0.4718	NS
Tactile disturbance	2.400	1.533	0.6325	0.7432	0.1633	0.1919	0.0025	VS
Headache	2.467	2.067	1.552	1.100	0.4008	0.2840	0.2644	NS
CIWA-Ar Score	22.267	14.457	2.915	5.604	0.7526	1.4470	<0.0001	ES

Intergroup comparison of therapy's Effect on INSOMNIA SCREENING QUESTIONNAIRE Score-

Variable	Mean Diff.		SD±		SE±		P	Result
	Group A	Group B	Group A	Group B	Group A	Group B		
Q1. Do you have trouble falling asleep?	3.600	3.267	0.5071	0.5936	0.1309	0.1533	0.1256	NS
Q2. Do you have trouble staying asleep?	3.533	3.000	0.5164	0.5345	0.1333	0.1380	0.0135	S
Q3. Do you wake up un-refreshed?	3.333	2.933	0.7237	0.7037	0.1869	0.1817	0.1328	NS
Q4. Do you take anything to help	2.933	2.533	0.7037	0.6399	0.1817	0.1652	0.1170	NS

you sleep?								
Q5. Do you use alcohol to help you sleep?	3.667	3.533	0.4880	0.5164	0.1260	0.1333	0.4787	NS
Q6. Do you have any medical condition that disrupts your sleep?	0.800	0.533	0.8619	0.5164	0.2225	0.1333	0.4812	NS
Q7. Have you lost interest in hobbies or activities?	2.333	1.600	0.4880	0.6281	0.1260	0.2138	0.0852	S
Total Insomnia Screening Score	19.33	17.93	1.676	1.163	0.4328	0.3768	0.0814	S

Intergroup comparison of therapy's Effect on Laboratory Investigation Score-

Variable	Mean Diff.		SD±		SE±		T	P	Result
	Group A	Group B	Group A	Group B	Group A	Group B			
Serum Bilurubin (T)	0.7000	0.7667	0.7946	0.8130	0.2052	0.2099	0.2271	0.8220	NS
Serum Bilurubin (D)	0.3100	0.3533	0.3577	0.3021	0.0923	0.0779	0.3585	0.7227	NS
SGOT	49.533	31.067	31.959	28.179	8.252	7.276	1.679	0.1044	NS
SGPT	77.400	34.933	88.037	33.221	22.731	8.578	1.748	0.0914	NS
Hb %	0.5667	0.2600	0.311	0.2324	0.0984	0.600	2.661	0.1284	NS

Distribution of patient according to Severity in Alcohol Withdrawal Symptoms-

(The maximum score is 67; Mild alcohol withdrawal is defined with a score less than or equal to 15, moderate with scores of 16 to 20, and severe with any score greater than 20.)

Severity	Alcohol Withdrawal Group A		Alcohol Withdrawal Group B		Total	
	BT	AT	BT	AT	BT	AT

Minimal withdrawal (<15)	3	13	6	11	9	24
Mild to Moderate withdrawal (16-20)	11	2	9	4	20	6
Severe withdrawals (> 20)	1	0	0	0	1	0

Distribution of patient according to Relief in Alcohol Withdrawal Symptoms

Relief	**Alcohol Withdrawal Group A**		**Alcohol Withdrawal Group B**		**Total**	
	Patient	**%**	**Patient**	**%**	**Patient**	**%**
No relief	0	0	3	20%	3	10%
Mild	3	20%	4	26.66%	7	23.33%
Moderate	2	13.33%	2	13.33%	4	13.33%
Marked	8	53.33%	3	20%	11	36.66%
Excellent	2	13.33%	2	13.33%	4	13.33%

In both study and control group there was 13.3% of patient has showed **excellent relief**. 13.3% and 13.3% patient has showed **moderate relief** in control and study group respectively. 53.33% patient in study group showed **marked relief** while only 20% patient in control group has showed **marked relief**. 33.33% patient in study group and 20% patient in control group has showed **mild relief** in withdrawal effect and also the percentage of **no relief** patient was zero in study groups and in control group it is 20.0%.

Result of clinical trial on alcohol addicted Patient

Result	Group A		Group B		Total	
	Patient	%	Patient	%	Patient	%
De-addict	13	86.6%	10	66.6%	23	76.6%
Not De-addict	2	13.3%	5	33.3%	7	23.3%
Total	15	100%	15	100%	30	100%

In study group out of 15 patient 86.6% i.e.13 patient were de-addicted successfully and rest of the 2 patient were not de-addicted while in control group 10 patient were de-addicted and rest 5 patient were not de-addicted and finally total 76.6% patient were de-addicted during the observation of entire one month

Distribution of patient according to Severity in Insomnia due to madatyaya-

(Patients who answer 3, 4 or 5 on any question likely suffer from insomnia. If they answer 3, 4 or 5 to two or more items and have significant daytime impairment the insomnia requires further evaluation and management. If there is no evidence of a primary sleep disorder and/or no identifiable secondary cause of insomnia, this is conditioned insomnia.)

Severity	Alcohol Withdrawal Group A		Alcohol Withdrawal Group B		Total	
	BT	AT	BT	AT	BT	AT
Minimal insomnia (<15)	0	15	0	11	3	10
Mild to Moderate insomnia (16-25)	10	0	11	4	21	4

Severe insomnia (> 26)	5	0	4	0	9	0

Distribution of patient according to Relief in Insomnia due to madatyaya-

Relief	**INSOMNIA Group A**		**INSOMNIA Group B**		**Total**	
	Patient	**%**	**Patient**	**%**	**Patient**	**%**
No relief	0	0	3	20%	3	10%
Mild	2	13.3%	6	40%	8	26.33%
Moderate	2	13.33%	2	13.33%	4	13.33%
Marked	9	60%	4	26.6%	13	43.3%
Excellent	2	13.33%	0	0	2	6.66%

In group A 2 patient shows excellent relief but in group B there was no patient showing **excellent relief**. 13.3% and 13.3% patient has showed **moderate relief** in control and study group respectively. 60.0%% patient in study group showed **marked relief** while only 26.6% patient in control group has showed **marked relief**. 13.33% patient in study group and 40% patient in control group has showed **mild relief** in withdrawal effect and also the percentage of **no relief** patient was 13.3% in study groups and in control group it is zero.

Result of clinical trial on Insomnia due to madatyaya-

Result	**Group A**		**Group B**		**Total**	
	Patient	**%**	**Patient**	**%**	**Patient**	**%**

NO INSOMNIA	14	93.3%	10	66.6%	24	80%
INSOMNIA	1	6.66%	5	33.3%	6	20%
Total	15	100%	15	100%	30	100%

In study group out of 15 patient 93.3% i.e.14 patient had no insomnia successfully and rest of the 1 patient had insomnia while in control group 10 patients had no insomnia and rest 5 patients had insomnia and finally total 80% patient had no insomnia during the observation of entire one month.

Conclusion-

- Alcohol, acute alcoholism, chronic alcoholism, and alcohol withdrawal has already mentioned in *Ayurveda* under the heading of *Madya, Mada, Madatyaya* and *Panapkaram* respectively in detail.
- *Acharya Charak* has described the psychosomatic disorders in the patients of chronic alcoholisms who have not control their senses due to sudden withdrawals of alcohol but the clinical manifestation has not given in details.
- *In* Barhtri and Laghutari and other Books of Ayurveda, Anidra or nidranasha was not described as a disease separately and the clinical manifestation has not given in details as well as treatment of anidra is not in detail.
- During this entire clinical trial the patients of Insomnia w.s.r. to Madatyaya were managed without any adverse action and complications.
- There was no statistical difference in the clinical manifestation of Insomnia w.s.r. to Madatyaya in both groups, but before and after treatment most of the clinical manifestation was controlled/ cured in both groups.
- Though there was no significant difference statistically in study and control groups but clinical relief in patient belonging to study group were found better than control group.
- Though there is no significant difference statistically in view of number of Insomnia w.s.r. to Madatyaya patients after completion of 1 month therapy in both study as well as control groups. Overall of

patients were found de-addicted and having no insomnia during the entire clinical trial which is a big achievement for *Ayurveda* science.

SUGGESTION FOR FURTHER STUDY

- The duration of our study was for 30 days only, as this is the period for which the patients were admitted in the center. After this they were discharged, thus further administration and follow up was not possible. Greater period of treatment can improve the efficacy of the drug.
- The patients can be observed after discharged from the de-addiction center. This follow-up study at regular intervals can prove the action of drugs more precisely.
- The diet regimen of the patients can be altered as per the *Pathya-Apathya* of *Ayurveda* which could give better results
- Some tie-ups should made with NGOS who can help in de-addiction and improving Insomnia due to madatyaya of patients and form a bridge between addicted patient , his family and Doctors
- As patient of alcohol addiction has serious, social and family consequences thus the family should involve so that they motivate the patient to get rid of this bad habit.
- As study was conducted over small group of patients, a similar study performed over a large sample could have presented much sharper and more accurate results.

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