To Evaluate Clinical Efficacy of *Ashtang Lavan Churn* in Alcohol Addiction.

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Article Info

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ABSTRACT:

Background-Alcoholism is a growing public health and socioeconomic problem around the world. Around 20% of the alcohol drank is absorbed by the stomach. The remaining 80% is mostly absorbed by the small intestine. The circulatory system also delivers alcohol to the liver, which uses a process known as "metabolizing" to remove it from the bloodstream by converting it to a harmless molecule. Because the liver can only digest a certain amount at a time, the rest circulates throughout the body.

Aim- To assess the clinical efficacy of *Ashtang Lavan* in Alcohol addiction and withdrawal symptoms.

Materials and Methods- The clinical efficacy of *Ashtang Lavan* in the treatment of alcohol addiction and withdrawal symptoms was evaluated using a randomized single blind technique. *Ashtang Lavan* was administered to one group to help with hepatotoxicity and withdrawal symptoms such as sleeplessness, anxiety, and agitation. Before and after therapy, the Clinical Institute Withdrawal Assessment- Alcohol revised (CIWA-Ar) scale was used to examine the clinical symptoms of alcohol withdrawal. Clinical manifestations of alcohol withdrawals recorded between 5 and 10 hours after ceasing to drink were used as a baseline for before therapy, while clinical manifestations of withdrawals after 1 month were used as a baseline for after treatment.

Result- There were 26.66 percent of patients in one group who reported excellent alleviation.

Conclusion- Throughout the clinical trial, 36.00 percent of patients in one group were found to be de-addicted.

Keywords- Alcohol, *Madatya (*Alcoholism),*Ashtang lavan*.

INTRODUCTION

Alcoholism is one of the most important social problems that is escalating year after year. The developing countries of Asia, particularly India, are experiencing the quickest growth. Alcohol consumption makes a man's life more difficult. Alcohol not only harms a person's health, but it also harms his family and society. Alcoholism is one of the

three most fatal killer diseases of the twentieth century, according to the World Health Organization (WHO).[1] Each year, 2.5 million people die as a result of alcohol consumption. 32,000 young people aged 15 to 29 dies as a result of alcohol-related causes, accounting for 9% of all deaths in that age group. At least 20% of patients in mental health settings, of both genders and socioeconomic backgrounds, have alcohol dependent or associated illnesses.[2] The *Ashtang lavan churna* was found significant in Alcoholism in previous clinical hence it is included in clinical [3].

MATERIAL AND METHOD

Control drug: - *Ashtang lavan churan* has prepared by crushing it's all ingredients into powdered form.

D. **Research Performa**- Research Performa was prepared in detail along with all clinical information necessary for clinical trial.

E. **Selection of patients**: 15 patient's desires to withdraw the alcohol have selected from National Institute of Ayurveda (OPD), Jaipur and have admitted after proper physical examination. Selected 15 patients will be randomly divided in 1 group.

 Group – *Ashtang lavan,* was given to 15 patients of alcohol addiction and withdrawal.

F. **Inclusion Criteria** –

1. Alcohol addiction diagnosed patient.

2. Alcohol withdrawal patient including vomiting, nausea, tremors, anxiety, agitation etc which had presented at that time.

3. Ageing between 20 – 60 years.

G. **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 suffering from major systemic illness like diabetes, hypertension, myocardial infarction, ischemic heart disease, pulmonary tuberculosis etc.

H. **Drugs and its administration**:

2.**Control drug -***Ashtang lavan churan*- 5 gm twice a day with lukewarm water after meals for 1 month

I. **Counseling-** All patients received simple but regular counselling on an individual, marital, and family level. The dangers of alcoholism were explained to the patients. The nature of disorder was described, and comfort was offered. The patient was given assistance in dealing with emotional issues.

J. **Diet-** Normal light diet has been suggested to all the patients.

K. **Withdrawal Criteria**-Patients had been withdrawal from trial who has developed seizure, severe agitation, severe anxiety, delirium tremens (DTs) after admission.

OBSERVATION

The clinical trial registration number is - CTRI/2018/01/011858, and 15 patients were included in this. The data acquired during the clinical in the signs and symptoms of the enrolled patients were statistically examined before and after therapy. The following are observations made during the course of the research Table No.1: Distribution of Patients. Table No.2: Duration of drinking wise distribution. Table No.3: Variety of Alcohol wise distribution. Table No.4: Frequency of Alcohol wise distribution. Table No.5: Distribution of Quantity of Alcohol Consumed in one day. Table No.6: Other Habits wise distribution. Table No.7: *Asthavidh Pariksha* wise distribution

RESULT

The results of therapy were evaluated within the group before and after treatment in one group.

1. INTRAGROUP

A. Effect on Subjective Parameters within Group

For the evaluating the effect of therapy within group before treatment and after treatment for the subjective parameters **Wilcoxon matched-pairs signed-ranks test** is used. Table no.8: Effect of therapy on CIWA-Ar Score Group

Nausea/Vomiting- In group the percentage of relief was 28.56% and the effect of the therapy was significant at P=0.0313.

Tremor- The percentage of relief was 28.20% and the effect of the therapy was   significant at P =0.0156

Anxiety-The percentage of relief was 57.14% and the effect of the therapy was statistically very significant at P =0.0078

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Agitation-The percentage of relief was 55.55% and the effect of the therapy was statistically not significant at P = 0.0625

Paroxysmal sweat -The percentage of relief was only 8.25% and the effect of the therapy was not significant at P =0.08125

Orientation- One of the SD value is zero, so no result will be calculated in term of P value.

Tactile disturbances -The percentage of relief was 39.27% and the effect of the therapy was very significant at p=0.0039

Auditory disturbances -The percentage of relief was 33.3% and the effect of the therapy was not significant at p>0.9999
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Visual disturbances -The percentage of relief was 60% and the effect of the therapy was not significant at p=0.2500.

Headache - The percentage of relief was 39.27% and the effect of the therapy was very significant at p=0.0020
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Finally in **Total CIWA-Ar score** the percentage of relief was 34.83% and the effect of the therapy was significant at p=0.0156.

Table no.9: Effect of therapy on Other Subjective Parameters Group

In group B the percentage of relief in **Anorexia** was 88% and the effect of the therapy was extremely significant at p<0.0001. In **Insomnia** the relief was 68.72% and statistically very significant at P= 0.0039. In symptom **Constipation** percentage relief was 91.66% and the effect of the therapy was very significant at P=0.0020. In **Icterus** percentage relief was 70.6% and effect of therapy very significant at P= 0.0020. There is significant relief in

DISCUSSION

Alcoholism is a disease characterized by excessive and long-term alcohol usage. Alcohol abuse that is indiscriminate and repeated results in a progressive physical and moral degeneration of the individual, as well as crime or perversions.[4] Alcohol, particularly ethyl alcohol, is an inebriant cerebral poison because it primarily affects the brain in acute poisoning.[5] When a person consumes ethyl alcohol in excess, regardless of the type of ethyl alcohol consumed, such as beer, wine, brandy, jin, rum, vodka, or whiskey, it causes acute toxicity, also known as acute alcoholism.[6] People have discovered all of their solutions through numerous addictions, one of which is alcohol. There are numerous varieties of alcohol described in Ayurveda, each of which differs from one Acharya to the next. *Ruksh* (dry), *Laghu* (light), *Suksham*

Hepatomegaly with P=0.156 and percentage of relief was 46.67%. In pain in abdomen therapy was very significant with P =0.0020 and percentage relief is 73.66%

Effect on Objective Parameters

For evaluating the effect of therapy within group before treatment and after treatment for the objective parameters **Paired t test** is used in one group.

Table no.10: Effect of therapy on Hematological Investigations in Group In group the percentage of improvement in **Serum Total Bilirubin** was 30.27% and the effect of the therapy was statistically very significant at P=0.0062. The percentage of improvement in **Serum Direct Bilirubin** was 31.64% and the effect of the therapy was statistically significant at P=0.0158 .The percentage of improvement in **SGOT** was 32.18% and the effect of the therapy was statistically significant at P=0.0231

The percentage of improvement in **SGPT** was 22.67% and the effect of the therapy was statistically significant at P=0.0263

In **Serum Total Protein** the percentage of improvement was 4.89% and the effect of the therapy was statistically significant at P=0.0142

The percentage of improvement in **Hemoglobin** was 1.81% and the effect of the therapy was not statistically significant at P=0.1026

Table no.11: Distribution of patient according to Relief in Alcohol Withdrawal Symptoms In group there was 13.3% of patient has showed excellent relief.

Table no.12: Result of clinical trial on alcohol addicted Patient

(subtleness), *Vishad* (non-sliminess), *Ashuga* (swiftness), *Amala* (sourness) are some of the 10 qualities of alcohol enumerated by Acharyas.[7] While Sushruta only mentions eight attributes of alcohol, he does not include brightness or sourness. The majority of Alcohol's qualities are poisonous, yet they are the polar opposite of *ojus* (strength)[8]. As a result, if alcohol is not consumed in the prescribed dose and method, it causes toxicity and *ojus vikriti* (abnormal strength) in the human body, even if it is nectar when consumed in the prescribed dose and form.[9] In modern science Alcohol, Acute alcoholism, chronic alcoholism, Alcohol addiction and withdrawals has been described in details along with its clinical management. The clinical trial for *Ashtang lavan Churna's* clinical efficacy was conducted using a randomized single blind approach. The majority of the alcohol-addicted individuals we enrolled in the clinical experiment are from the NIA

hospital's de-addiction unit in Jaipur. In addition, the Agad tantra PG department held many de-addiction and awareness camps in Jaipur's rural districts. 15 patients with withdrawal symptoms from alcohol were administered *Ashtang lavan churna*. Before and after treatment, patients with diagnosed alcohol addiction as well as clinical manifestations of alcohol withdrawals were assessed using various methods. For example, addiction was assessed using the Alcohol Use Disorders Identification Test, also known as the AUDIT test, and alcohol withdrawals were assessed using the Clinical Assessment of Alcohol Withdrawal Patients (as per CIWA-Ar) scale. Some subjective clinical signs that were not included in CIWA-Ar but were consistently present in the majority of patients, such as sleeplessness, icterus, hepatomegaly, abdominal pain, and constipation, were also evaluated clinically before and after treatment. Pathological evaluations of hemoglobin and LFT, including serum bilirubin (T), serum bilirubin (D), SGOT, SGPT, and serum protein, were performed before and after treatment.

CONCLUSION

There was no significant difference in the clinical manifestations of alcohol withdrawal and addiction in the study group, but the majority of the clinical manifestations were controlled/cured before and after therapy. Statistically, there is no significant difference in the number of de-addicted patients after one month of treatment. Throughout the clinical experiment, 36 percent of patients were determined to be de-addicted, which is a significant milestone for Ayurveda science. As a result, Ayurveda has the potential to control alcohol addiction and withdrawal, and it may play a significant role in the treatment of alcoholism.

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Table No.1: Distribution of Patients

S.no	Group	No. of Patients		
		Complete	Discontinue	Total Registered
1	B	15	6	21

Table No.2: Duration of drinking wise distribution

Duration	Group		Total	
	No.	%	No.	%
5 years	0	0	1	3.33
6-10 years	5	33.33	9	30
11-15 years	4	26.66	9	30
16-20 years	6	40	10	33.33
21& Above	0	0	1	3.33
Total	15	100	30	100

Table No.3: Variety of Alcohol wise distribution

Type of Alcohol	Group		Total	
	No.	%	No.	%
Country liq.	2	13.33	7	23.33
Whisky	6	40	10	33.33
Rum	0	0	1	3.3
Beer	1	6.66	1	3.3
Mixed	6	40	11	36.66
Total	15	100	30	100

Table No.4: Frequency of Alcohol wise distribution

Frequency of Alcohol	Group		Total	
	No.	%	No.	%
DAILY	11	73.33	22	73.33
ALTERNATE DAYS	0	0	3	10
2 TIMES A WEEK	2	13.33	3	10
4TIMES A WEEK	2	13.33	2	6.66
Total	15	100	30	100

Table No.5: Distribution of Quantity of Alcohol Consumed in one day

Quantity (unit)	Group		Total	
	No.	%	No.	%
3-5	5	33.33	12	40
6-8	7	46.66	12	40
8-10	2	13.33	4	13.33
11& above	1	6.6	2	6.66
Total	15	100	30	100

Table No.6: Other Habits wise distribution

Habits	Group		Total	
	No.	%	No.	%
Smoking	4	26.26	7	23.33
Tobacco	4	26.26	9	30
Smoking+ Tobacco	1	6.6	3	10
None	6	40	11	36.66
Total	15	100	30	100

Table No.7: *Asthavidh Pariksha* **wise distribution**

Asthavidh Pariksha	Group		Total	
	Samanya	*Asamanye*	*Samanya*	*Asamanye*
Nadi	11	4	18	12
Mutra	4	11	9	21
Mala	4	11	11	19
Jivha	2	13	6	24
Shabad	9	6	19	11
Sparsh	10	5	20	10
Drik	4	11	7	23
Akriti	10	5	19	11

Table no.8: Effect of therapy on CIWA-Ar Score Group

Variable	Mean		Mean Diff.	% Relief	SD±	SE±	P	Results
	BT	AT						
Nausea/Vomiting	1.867	1.333	0.5333	28.56	0.7432	0.1919	0.0313	S
Tremors	2.600	1.867	0.7333	28.20	0.9612	0.2482	0.0156	S
Anxiety	0.9333	0.4000	0.5333	57.14	0.5164	0.1333	0.0078	VS
Agitation	0.6000	0.2667	0.3333	55.55	0.4880	0.1260	0.0625	NS
Paroxysmal sweat	0.8000	0.7333	0.0666	8.25	0.8837	0.2282	0.8125	NS
Orientation	0	0	0	-	-	-	-	-
Tactile disturbances	1.867	1.133	0.7333	39.27	0.7037	0.1817	0.0039	VS
Auditory disturbances	0.2000	0.1333	0.0666	33.3	0.2582	0.06667	>0.9999	NS
Visual disturbances	0.3333	0.1333	0.2000	60	0.4140	0.1069	0.2500	NS
Headache	1.867	1.133	0.7333	39.27	0.5936	0.1533	0.0020	VS
CIWA-Ar SCORE	1.053	0.6866	0.3668	34.83	0.3256	0.1030	0.0156	S
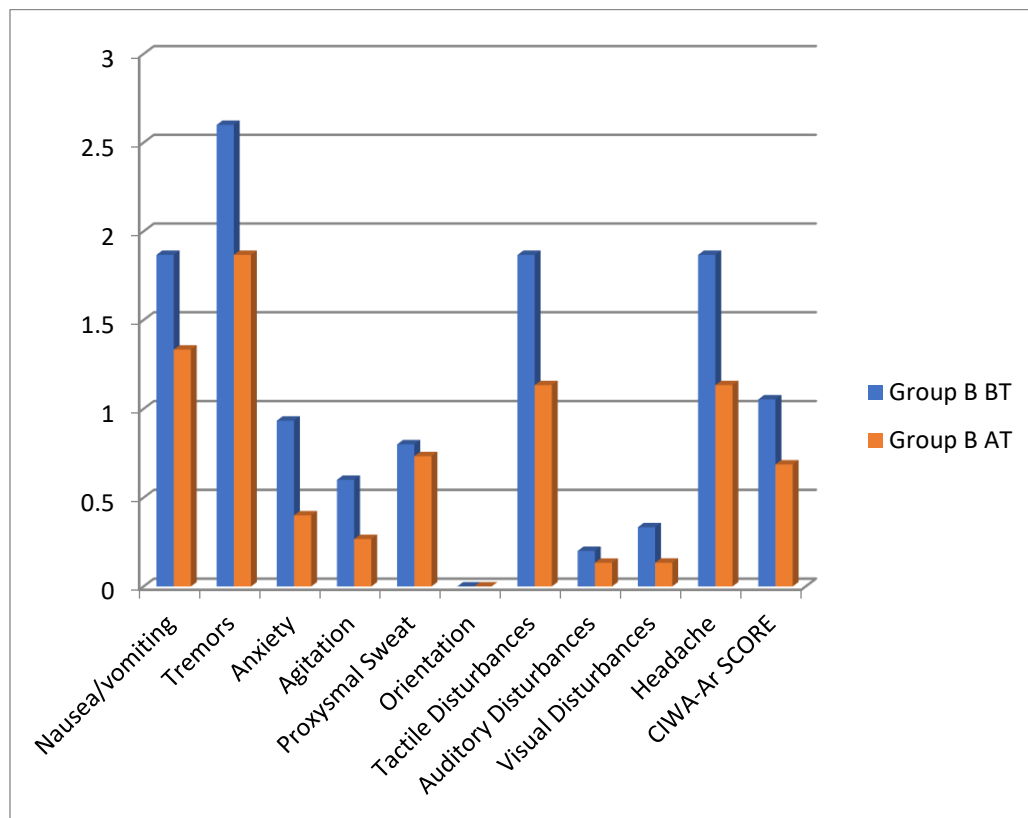
Table no.9: Effect of therapy on Other Subjective Parameters Group

Variable	Mean		Mean Diff.	% Relief	SD±	SE±	P	Results
	BT	AT						
Anorexia	1.667	0.2000	1.467	88	0.5164	0.1333	<0.0001	ES
Insomnia	1.067	0.3333	0.7333	68.72	0.7037	0.1817	0.0039	VS
Constipation	0.8000	0.0666	0.7333	91.66	0.5936	0.1533	0.0020	VS
Icterus	1.133	0.3333	0.8000	70.6	0.6761	0.1746	0.0020	VS
Hepatomegaly	1.000	0.5333	0.4667	46.67	0.5164	0.1333	0.0156	S
Pain in abdomen	1.267	0.3333	0.9333	73.66	0.7988	0.2063	0.0020	VS

Table no.10: Effect of therapy on Hematological Investigations in Group

Variables	Mean score			% Change	S.D. +/-	S.E. +/-	t	P	Results
	BT	AT	DIFF.						
Sr. BT	1.167	0.8133	0.3533	30.27	0.4257	0.1099	3.214	0.0062	VS
Sr. BD	0.5267	0.3600	0.1667	31.64	0.2350	0.06068	2.746	0.0158	S
SGOT	48.267	32.733	15.533	32.18	23.588	6.090	2.550	0.0231	S
SGPT	37.933	29.333	8.6000	22.67	13.415	3.464	2.483	0.0263	S
Sr.P	6.533	6.213	0.3200	4.89	0.4427	0.1143	2.799	0.0142	S
Hb%	13.987	14.240	0.2533	1.81	0.5617	0.1450	1.747	0.1026	NS

Table no.11: Distribution of patient according to Relief in Alcohol Withdrawal Symptoms

Relief	Alcohol Withdrawal Group	
	Patient	%
No relief	4	26.66
Mild	3	20
Moderate	4	26.66
Marked	2	13.33
Excellent	2	13.33

Table no.12: Result of clinical trial on alcohol addicted Patient

Result	Group B	
	Patient	%
De-addict	6	40
Not De-addict	9	60
Total	15	100