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Research Article

Comparative Clinical Study Of *Rohitakadya Churna Ghana Vati* with *Vardhaman Pippali Rasayan* in Alcoholic Liver disease.

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ABSTRACT-

It is the major cause of liver disease in western as well as our countries. Although steatosis (fatty liver) & Alcoholic Hepatitis will develop in any individual who consumes a large quantity of alcoholic beverages over a long period of time, this process is transient and reversible. So in present study “Comparative Clinical Study Of *Rohitakadya Churna Ghana Vati* with *Vardhaman Pippali Rasayan* in Alcoholic Liver disease” we try to conclude out the efficacy of Ayurvedic treatment on Alcoholic liver disease. Group A contains *Rohitakadya Churna Ghan Vati* & *Vardhaman Pippali Rasayan* and Group B contains *Phalatrikadi Kwath Ghan Vati* & *Vardhaman Pippali*

Rasayan. The data collection, analysis and conclusion drawn from it is elaborated in this article.

Key Words- *Madatyaya*, liver disease, *Phalatrikadi Kwath Ghan Vati*, *Vardhaman Pippali Rasayan*, data analysis.

INTRODUCTION:

There is a lot of research studies being undertaken to establish effective management of ALD but still encouraging results are lacking. Some encouraging results are there with the complete abstinence of alcohol consumption. *Pippali* through various researches is established as anti fibrotic, anti inflammatory, hepatoprotective and immunomodulator. These features are aptly needed in ALD, hence a study was undertaken to evaluate the efficacy of *Pippali* in *Samprapti vighatana* of ALD. In addition balanced Diet (pathya ahara), abstinence of alcohol also plays important role in the management of ALD. *Acharyas* describes the symptoms of *Madatyaya* as *Haridra mootrata, haridra varn twak, akshi, nakha, Mookha, and whole body*.¹ *Agnimandya, aruchi, bhrama, sometimes raktanetrata, shotha all over the body, daha, avipaka, dourbalya, angasada, and karshya*²

The first part is mainly concerned with review of literature regarding *Yakrut vikara*(ALD). Various aspects of the disease

such as History *Paribasha*, *Nidana Panchaka* etc are reviewed and elaborately discussed. The second part consists of clinical trails of *Pippali Rasayana*. It comprises of materials and methods utilised for the study, results and observations of the study, discussion on them. A summary of the study is provided in the last part of the dissertation with some recommendations for future studies. The study has shown that Ayurveda has a significant role to play in the management of *Madya janya Yakrut vikara* v/s Alcoholic Liver disease.

Taking into consideration of the above description for Prolonged alcoholism causes hepatic injury and hepato-megaly, Fatty Liver hence *Vardhaman Pippali Rasayan* with *Trivruit Avleha*³ & *Rohitakadhya churna Ghana vati* will be added to regulate the hepatic functions and also it has hepato-protective property. The study drug selected for this clinical trial is *Rohitakadhya Chruna Ghana vati*⁴ stated by *Bhaisajyaratnavali Chikitsa sthan* for the

elimination of hepatic disorder like Nausea, Vomiting, Anorexia, Irregular bowel , Anaemia, Hepatitis ,and jaundice.

kwath Ghan Vati in Alcoholic Liver Disease.

AIMS AND OBJECTIVES

Present research work includes following objectives-

AIMS:

1. The aim of this the study is to find out the clinical efficacy of *Rohitakadya Churna Ghana Vati* with *Vardhaman Pippali Rasayana*⁵ in Alcoholic Liver Disease.

OBJECTIVES:

- 1 To evaluate, elaborate and discussion of *Ayurvedic* aspect of Alcoholic Liver Disease and withdrawal and management.
- 2 To study the clinical efficacy of *Rohitakadya Churna Ghana Vati* with *Vardhaman Pippali Rasayan* in Alcoholic Liver Disease.
- 3 To study the clinical efficacy *Phalatrikadi kwath Ghan Vati*⁶ with *Vardhaman Pippali Rasayan* in Alcoholic Liver Disease.
- 4 To compare the efficacy of *Rohitakadya Churna Ghana Vati* with *Phalatrikadi*

MATERIAL AND METHODS

Collection of 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 (Group-A)** – (Study Drug- *Rohitakadya Churna Ghana Vati*)

Vardhaman Pippali Rasayan had given with milk (*Anupan Kheropak bidhi*) to 15 patient as described in text (*Bardhaman cram*) for first 13 days. After that 10 grams of *Trivruttavleha* had given at early morning with Luke warm water to that above 15 patient. After passing of stool Two tablet (500 mg x 2 Tab) of *Rohikadya Churna Ghan Vati* had given for one month to the same 15 patients having Alcoholic Liver Disease (During this clinical study, alcohol withdrawal symptoms if present it will be managed symptomatically)(Total duration of treatment will be 45 days)

2. **Control group (Group-B)** – (Control Drug- *Phalatrikadi Kwath Ghan Vati*) *Vardhaman Pippali Rasayan* had given with milk (*Anupan Kheropak bidhi*) to 15 patient as described in text (*Bardhaman cram*) for first 13 days. After that 10 grams of *Trivruttavleha* had given at early morning with Luke warm water to that above 15 patient. After passing of stool Two tablet (500 mg x 2 Tab) of *Phalatrikadi Kwath Ghan Vati* (*Shaman yoga*) had given for one month to the same 15 patients having Alcoholic Liver Disease (During this clinical study, alcohol withdrawal symptoms if present

it will be managed symptomatically)(Total duration of treatment will be 45 days)

Both the groups will be given psychological counseling and suggested normal healthy diet &

meditation along with medicines.

Criteria for selection of patient:

- 1) Patients will be randomly selected based on the presence of classical symptoms of Alcoholic liver disease (Hepatitis/ Steato hepatitis). Patients will be subjected to detailed clinical history based on specially prepared Performa.
- 2) Prior consent will be taken from the patients after explaining the details regarding the treatment.

Inclusion Criteria

1. Diagnosed patients of alcohol addiction having classical symptoms of Alcoholic Hepatitis/ Hepatomegaly /Steatoepatitis such as icterus, right upper quadrant pain, fever, tachycardia, tender enlarged liver, Anorexia etc with deranged LFT (Liver Function Test)
2. Age between 20 – 60 years
3. Either sex.

Exclusion Criteria

1. Alcohol addicted patients suffering from liver Cirrhosis complicated by ascites & gastrointestinal bleeding, Mallory-Weiss tears, Wernicke Korsakoff's syndrome (WKS), cerebellar degeneration & all type of Viral Hepatitis.
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.
4. Patient having Pitta predominant *prakriti*.

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 Alcoholic Liver Diseases

Clinical Diagnosis

1. The Alcoholic liver disease assessment criteria.
2. Clinical Assessment of Alcohol Liver Disease and Withdrawal Patients (as per CIWA-Ar).
3. Pathological Assessment in Alcohol induced liver disorder of 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	<i>Vardhaman Pippali Rasayan</i>	Churna	As mentioned in table below	Route: Oral Time: Twice daily after meal <i>Anupan-Milk</i>	13 days
	<i>Trivruttavaleha</i>	Avaleha	Varying doses from 5gm to 20 gm according to the patients' individual Sensitivity to purgatives (Koshtha)	Route: oral Time: Twice daily after meal <i>Anupan-Sukoshan jal</i>	1 day
	 <i>Rohitakadya Churna Ghan Vati</i>	Vati	Two tablet (500 mg) twice a day	Route: oral Time: Twice daily after meal <i>Anupan-Sukoshan jal</i>	1 month
B	<i>Vardhaman Pippali Rasayan</i>	Churna	As mentioned in table below	Route: Oral Time: Twice daily after meal <i>Anupan-Milk</i>	13 day
	<i>Trivruttavaleha</i>	Avaleha	Varying doses from 5gm to 20 gm according to the patients' individual Sensitivity to	Route: oral Time: Twice daily after meal <i>Anupan-Sukoshan jal</i>	1 day

			purgatives (Koshtha)		
	<i>Phalatrikadi Kwath Ghan Vati</i>	<i>Vati</i>	Two tablet (500 mg) twice a day	Route: oral Time: Twice daily after meal <i>Anupan- Sukoshan jal</i>	1 month

Criteria for assessment

I. Clinical Assessment of Alcohol Withdrawal Patients (as per CIWA-Ar)ⁱ

<p><u>Nausea/Vomiting</u> - Rate on scale 0 - 7</p> <p>0 – None</p> <p>1 - Mild nausea with no vomiting</p> <p>2</p> <p>3</p> <p>4 - Intermittent nausea</p> <p>5</p> <p>6</p> <p>7 - Constant nausea and frequent dry heaves and vomiting</p>	<p><u>Tremors</u> - have patient extend arms & spread fingers. Rate on scale 0 - 7.</p> <p>0 - No tremor</p> <p>1 - Not visible, but can be felt fingertip to fingertip</p> <p>2</p> <p>3</p> <p>4 - Moderate, with patient’s arms extended</p> <p>5</p> <p>6</p> <p>7 - severe, even with patient’s arms not extended</p>
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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
 6
 7 - equivalent to acute panic states seen in severe delirium or acute schizophrenic reactions.

Agitation - Rate on scale 0 – 7

0 - normal activity
 1 - somewhat normal activity
 2
 3
 4 - moderately fidgety and restless
 5
 6
 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

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 hallucination

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

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

1.1 Total score of Before Treatment and After Treatment as per CIWA - Ar

Clinical features	Study group (Gp. A)		Control group (Gp. B)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
Nausea/Vomiting (0-7)				
Tremors (0-7)				
Anxiety (0-7)				
Agitation (0-7)				
Paroxysmal sweat (0-7)				
Orientation & clouding of sensorial (0-4)				
Tactile disturbances (0-7)				
Auditory disturbances (0-7)				
Visual disturbances (0-7)				
Headache(0-7)				

2. Pathological Assessment in Alcohol Addicted Patients

<i>Test</i>	<i>Study group (Gp. A)</i>		<i>Control group (Gp. B)</i>	
	<i>Before Treatment</i>	<i>After Treatment</i>	<i>Before Treatment</i>	<i>After Treatment</i>
<i>Serum Bilirubin (T)</i>				
<i>Serum Bilirubin (D)</i>				
<i>SGOT</i>				
<i>SGPT</i>				
<i>Serum protein</i>				
<i>Haemoglobin</i>				

3. SUBJECTIVE CRITERIA- (For Group A/B)

All the patients will be examined after fifteen days of interval during the treatment. Assessment will be done on the basis of relief in the signs and symptoms of the Alcohol liver disease (Hepatitis/ Steatohepatitis) at the end of clinical study.

S.No.	Subjective Parameters	BT	AT
1.	<u>Yakrit- vridhi (Hepatomegaly)</u> 0- Not palpable, 1- <2cm. below the right costal margin, 2- 2-5cm. below the right costal margin, 3- >5cm. below the right costal margin		
2.	<u>Jwara (Fever)</u> 0- Absent, 1- 99-100 F, 2- 100.1-10 F, 3- >103 F		
3.	<u>Mandagni (Loss of Appetite)</u> 0- Normal appetite, 1- One principal meal and one breakfast, per 24 hrs., 2- Only breakfast (two) in 24 hrs., 3- Only light one breakfast in per 24 hrs.		
4.	<u>Kshinabala (Weakness)</u> 0- Routine activity without feeling fatigue, 1- Feeling of fatigue during Routine activity, 2- Routine activity disturbed but not bed ridden, 3- bed ridden		
5.	<u>Panduta (Pallor)</u> 0- Hb- 12 - 18gm.%, 1- Hb- 10-12gm.%, 2- Hb- 7-10gm.%, 3- Hb- below 7gm.%		

RESULT-**1. INTRAGROUP STUDY****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** has used

Effect of therapy on CIWA-Ar Score Group-A

Variable	Mean		Mean diff.	% Relief	SD±	SE±	P	Result
	BT	AT						
Nausea/ vomiting	3.46 7	0.333	3.133	90.37%	0.7432	0.1919	<0.000 1	ES
Tremors	2.80 0	0.600	2.200	78.57%	1.373	0.3546	0.0001	ES
Anxiety	3.00 0	0.600	2.400	85.71%	1.502	0.3879	0.0001	ES
Agitation	2.40 0	0.333	2.067	86.12%	1.624	0.419	<0.000 1	ES
Proxymal sweat	1.86 7	0.2667	1.600	85.28%	1.121	0.2895	<0.000 1	ES
Orientation	00	00	00	00	00	00	00	-
Tactile disturbance	1.66 7	0.6000	1.067	64.27%	0.7037	0.1817	0.0002	ES
Auditory disturbances	00	00	00	00	00	00	00	00
Visual disturbances	00	00	00	00	00	00	00	00
Headache	2.33 3	0.4667	1.867	80.02%	1.302	0.3362	0.0005	ES
CIWA-Ar Score	17.6 0	2.600	15.00	85.22%	3.000	0.7746	<0.000 1	ES

Effect of therapy on CIWA-Ar Score Group-B

Variable	Mean		Mean diff.	% Relief	SD±	SE±	P	Result
	BT	AT						
Nausea/ vomiting	1.800	0.8667	0.933	51.83%	0.4577	0.1182	0.0001	ES
Tremors	2.000	0.533	1.467	73.25%	1.302	0.3362	<0.0001	ES
Anxiety	1.667	0.666	1.000	60.24%	0.9258	0.2390	0.0020	Vs
Agitation	1.733	.8000	0.9333	53.85%	0.7037	0.1817	0.0002	ES
Proxymal sweat	1.400	0.600	0.800	57.14%	0.9411	0.2430	0.0049	VS
Orientation	00	00	00	00	00	00	00	-
Tactile disturbance	1.400	0.800	0.600	42.85%	0.91.3	0.2350	0.0137	S
Auditory disturbances	00	00	00	00	00	00	00	-
Visual disturbances	00	00	00	00	00	00	00	-
Headache	1.667	0.8667	0.800	47.99%	0.7746	0.200	0.0010	VS
CIWA-Ar Score	13.067	5.200	7.867	60.23%	5.502	1.420	<0.0001	ES

Effect of therapy on Alcoholic Liver Disease Score Group-A

Variable	Mean		Mean diff.	% Relief	SD±	SE±	P	Result
	BT	AT						
Yakrit- vridhi (Hepatomegaly)	1.53 3	0.33 3	1.20 0	78.27 %	0.560 6	0.144 7	<0.000 1	ES
Jwara (Fever)	1.53 3	0.40 0	1.13 3	75.33 %	0.516 4	0.133 3	<0.000 1	ES
Mandagni (Loss of Appetite)	1.53 4	0.53 3	1.00 0	65.23 %	1.069	0.276 0	0.0043	VS
Kshinabala (Weakness)	1.40 0	0.26 67	1.13 3	80.92 %	0.351 9	0.090 8	<0.000 1	VS

Effect of therapy on Alcoholic Liver Disease Score Group-B

Variable	Mean		Mean diff.	% Relief	SD±	SE±	P	Result
	BT	AT						
Yakrit- vridhi (Hepatomegaly)	0.86 6	0.33 3	0.53 3	61.54 %	0.516 4	0.133 3	0.0039	VS
Jwara (Fever)	0.53 3	0.13 3	0.40 0	75.04 %	0.507 1	0.130 9	0.0156	S
Mandagni (Loss of Appetite)	1.26 7	0.26 6	1.00 0	78.92 %	0.378 0	0.097 5	<0.000 1	ES
Kshinabala (Weakness)	0.93 3	0.26 6	0.66 7	71.49 %	0.488 0	0.126 0	0.0035	VS

Effect of therapy on Laboratory Investigation Score Group-A

Variables	Mean score			% Change	SD±	SE±	t	P	Results
	BT	AT	DIFF						
Serum Bilurubin (T)	1.94 3	0.92 6	1.016	52.37 %	0.943 1	0.243 5	4.172	0.0005	ES
Serum Bilurubin (D)	0.78 4	0.28 0	0.504	64.12 %	0.481 6	0.124 3	4.053	0.0006	ES
SGOT	124. 2	83.6 0	40.58 0	32.67 %	50.94 8	13.15 5	3.085	0.0040	VS
SGPT	98.8 8	50.8 6	48.02	48.56 %	75.48 1	19.48 9	2.464	0.0137	S
Hb %	13.8 4	13.2 0	0.640	4.92%	4.156	1.073	0.596 4	0.2802	NS
Serum protein	7.18 7	6.00 0	1.187	16.51 %	1.860	0.480 3	2.471	0.0135	S

Effect of therapy on Laboratory Investigation Score Group-B

Variables	Mean score			% Change	SD±	SE±	t	P	Res- ults
	BT	AT	DIFF						
Serum Bilurubin (T)	1.54 0	1.333	0.206 7	13.42 %	0.208 6	0.0538	3.83 7	0.000 9	ES
Serum Bilurubin (D)	0.50 0	0.409	0.090 6	18.12 %	0.130 5	0.0336 9	2.69 2	0.018 8	S
SGOT	104. 9	96.927	7.973	7.66%	7.973	2.059	3.87 2	0.000 8	ES
SGPT	61.4 0	56.200	5.200	8.47%	8.428	2.176	2.39 0	0.015 7	S
Hb %	14.5 4	14.36	0.186 7	1.28%	0.226 4	0.0584	3.19 4	0.003 2	VS
Serum protein	7.24 0	7.027	0.213 3	1.28%	0.292 4	0.0755 1	2.82 5	0.006 7	VS

2. INTERGROUP STUDY**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	2.867	0.9333	1.060	0.4577	0.2737	0.1182	<0.0001	ES
Tremors	2.200	1.467	1.373	1.302	0.3546	0.3362	0.0308	S
Anxiety	2.467	1.133	1.350	0.915	0.3501	0.2364	0.0027	VS
Agitation	1.133	1.000	0.915	0.654	0.2364	0.1690	0.3683	NS
Proxymal sweat	1.533	0.933	1.187	0.7988	0.3065	0.2063	0.0616	NS
Tactile disturbance	1.000	0.733	0.755	0.798	0.1952	0.2063	0.1285	NS
Headache	1.867	0.800	1.302	0.774	0.3362	0.2000	0.0103	S
CIWA-Ar Score	15.267	7.733	2.987	5.700	0.7713	1.472`	<0.0001	ES

Intergroup comparison of therapy's Effect on Alcoholic liver disease-

Variable	Mean Diff.		SD±		SE±		P	Result
	Group A	Group B	Group A	Group B	Group A	Group B		
Yakrit- vridhi (Hepatomegaly)	1.200	0.533	0.5606	0.5164	0.1447	0.1333	0.0020	VS
Jwara (Fever)	1.133	0.400	0.5164	0.5071	0.1333	0.1309	0.0007	ES
Mandagni (Loss of Appetite)	1.267	1.000	0.7037	0.3780	0.1817	0.0975	0.1195	NS
Kshinabala (Weakness)	1.133	0.667	0.3519	0.4880	0.0908	0.1260	0.0042	VS

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

Variable	Mean Diff.		SD±		SE±		T	P	Result
	Group	Group	Group	Group	Group	Group			
	A	B	A	B	A	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
Serum protein	1.253	0.2267	1.871	0.2815	0.4830	0.0726	2.102	0.0223	S

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
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 Alcoholic Liver Disease due to madatyaya-

Result	Group A		Group B		Total	
	Total Registered Patient = 15		Total Registered Patient = 15		30	
	Patient	%	Patient	%	Patient	%
After treatment, No Of patients without A.L.D.	14	93.3%	10	66.6%	24	80%
After treatment, No of patients presented with A.L.D.	1	6.66%	5	33.3%	6	20%
Total	15	100%	15	100%	30	100%

In the study group total register number of patient are 15. Out of 15 patient of group A 14 patient (93.3%) successfully recovered. Rest of 1 (6.66%) patient did not cure of Group A. While in control group B total register number of patient are 15. Out of those patient 10 patient became recover but the treatment became unsuccessful to the 5 patient of Group B Madataya janya Yakrut Vikar.

DISCUSSION AND

CONCLUSION-

❖ Alcohol, acute alcoholism, chronic alcoholism, and alcohol withdrawal has already mentioned in *Ayurveda* under the

heading of *Madya, Mada, Madatyaya* and *Panapkaram*⁸ respectively in detail.

- ❖ *Acharya Charak* has described the psychosomatic disorders in the patients of chronic alcoholism 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*, there is separate chapter for liver diseases and separate chapter for madatyaya, but there is no literature having clinical sign and symptoms of alcoholic liver disease.
- ❖ During this entire clinical trial the patients of alcoholic liver disease were managed without any adverse action and complications.

- ❖ There was statistical difference in the clinical manifestation of alcoholic liver disease in both groups, before and after treatment most of the clinical manifestation was controlled/ cured in both groups.
- ❖ Though there was significant difference statistically in study and control groups so clinical relief in patient belonging to study group were found better than control group.

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 alcoholic liver disease 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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