

SINGLE ARMED CLINICAL STUDY ON ALCOHOLIC LIVER DISEASE WITH SHODHANA AND SHAMANA – A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Excessive alcohol intake is associated with various diseases, such as alcoholic liver disease (ALD), cardiovascular disease, cancer etc. Alcoholic liver disease is commonly diagnosed when the complications such as jaundice, ascites, edema, and encephalopathy's start to appear. Improper indulgence in *Madya* is the cause of *Raktavaha sroto dusti* due to its properties such as *Amla, Ushna, Teekshna, Vikasi gunas*. When the srotas gets vitiated, the sroto moola i.e. yakrit also gets affected. Unfortunately, the liver is often the most abused organ in the body, as it is exposed to alcohol, drugs, and a multitude of environmental toxins which place a burden on this vital organ. In the present study an effort has been made to formulate an effective, economic and simple remedy to help in the total cure of Alcoholic Liver Disease and effective in preventing the complications. Present clinical study comprises of randomly selected 30 registered cases of Alcoholic liver disease from OPD and IPD of department of PG studies in Kayachikitsa Ayurveda Mahavidyalaya, Hubballi have been treated with *Amapachana, Ruksha Virechana* therapy followed by *Shamanaoushadhis Vasaguduchyadi Kashaya* and *Rohitakadi vati* for 30 days to assess the clinical efficacy of *Ruksha virechan* and these *Ayurvedic* remedies. Significant changes in Subjective and objective criteria were observed.

Keywords: *Avipatti churna, Madatyayajanya Yakrit Vikara, Rohitakadi Vati, Alcoholic Liver Disease,*

INTRODUCTION

Sura is explained as '*shramaharanam shreshta*¹' by Acharya Charaka, but if consumed inappropriately hampers the wellbeing of an individual in all the above said ways. We were among the first civilizations to discover the science of distillation and put it to good use. Ayurveda has always strongly advocated

alcohol usage for medical purposes. Primarily used as an narcotic to operate upon the patients, In present era, the consumption of Alcohol has become a fashion, which is again due to the never ending fascination towards the western culture. The harmful effects of Alcohol are a worldwide problem resulting in millions

of Deaths, including thousands of young lives lost. Hence alcohol is not only a causative factor in many diseases, but also a precursor to injury and violence. Furthermore, its negative impacts can spread throughout a community or beyond. Alcoholic Liver Disease (ALD) is a term that encompasses the Hepatic manifestations of Alcohol over consumption. Unfortunately, the liver is often the most abused organ in the body, as it is exposed to alcohol, drugs, and a multitude of environmental toxins which place a burden on this vital organ. Excessive consumption of alcohol leads to two major problems, both of which can be present in the same patient. 1. Alcohol Dependence Syndrome 2. Physical damage to various tissues². India has also unfortunately, witnessed a steadily increasing consumption of alcohol in the last two decades. According to the latest WHO data published in May 2014, Liver Disease Deaths in India reached 216,865 or 2.44% of total Deaths. The age adjusted Death Rate is 21.96 per 100,000 of population and about 50% cases of Cirrhosis in India may be due to Alcohol abuse. India ranks #61 in the world³. Due to excessive consumption of *Amla*, *Lavana*, *Madya* and *Teekshna dravyas* cause *Raktadushti* and there will be *Pandubhava* of *Twacha*. The properties of *Madya* (Alcohol) are going to damage *Raktavahasrotas* and *Yakrut* (*Raktavahasrotomoola*) by its *Amla*, *Ushna*, *Teekshna*, *Vikasiguna*. Ayurveda makes clear that alcohol quickly and easily reaches the *Hrudaya* and has a direct effect on the ten qualities of the *Ojas*⁴. Because its qualities are opposite those of *Ojas* – which has a direct effect on the *Sattva*, or purity of the mind – By this the patient also suffers with *Kama*, *Krodha*, *Mada*, *Matsarya* etc. *manasika vikaras* and due to that agitation or intoxication can be observed. The etiopathogenesis of *Yakrutodara* includes the clinical manifestation of Alcoholic liver disease. The symptoms such as *Yakrutvridhi*, *Dourbalya*, *Arochaka*, *Avipaka*, *Pipaasa*, *Karshya*, *Angasada*, *Pandu*, *Daha* etc. present in *Yakrutodara*⁵, are also found in Alcoholic Liver Disease. Considering these similarities in *Pandu*, *Kamala*, *Yakrutodara* & *Madatyaya* etc. combined with Alcoholic Liver Disease, the present work was undertaken to study the scope and limitations of *Ayurvedic* treatment. In spite of having extra-ordinary

capacity of regeneration in the Liver, a slight ignorance may lead to fatal complications with grave prognosis. Hence the present study was undertaken to formulate an effective treatment measure in Alcoholic Liver Disease.

Aim and Objectives

1. To study the efficacy of *Ruksha Virechana* with *Avipatti Choorna*⁶ in selected cases of Alcoholic Liver Disease.
2. To study the efficacy of *Rohitakadi Vati*⁷ in Alcoholic liver disease.
3. To study the efficacy of *Vasaguduchyadi Kashaya*⁸ as an *Anupana*.
4. To study Alcoholic liver disease as per modern literature and to understand the condition in the light of *Ayurvedic* literatures by comparing with different clinical conditions.

MATERIALS AND METHODS

The patients were selected and registered after their fulfillment of diagnostic criteria of Alcoholic Liver Disease (ALD). The patients were thoroughly questioned and examined on the basis of Proforma which include both subjective and objective criteria's. Ethical clearance and informed consent were obtained before conducting the clinical trial.

Inclusion Criteria

- Subjects presenting with symptoms of Alcoholic Liver Disease.
- History of Alcohol abuse for at least 6 months.
- Subjects aged between 20-60years.
- Subjects of either sex will be taken for the study.
- Alcoholic fatty liver, alcoholic hepatitis will be included.

Exclusion Criteria

- Subjects who do not fulfill the inclusion criteria will be excluded from the study.
- Subjects who are unfit for *Rooksha Virechana* will be excluded from the study.
- Subjects having Uncontrolled DM/HTN.
- Subjects with Tuberculosis, HIV, HBsAg, Epilepsy and other systemic disorders.
- Moderate to severe Ascites, Cirrhosis of Liver.
- Obstructive Jaundice, Viral hepatitis, Drug induced hepatitis.

- Pregnant & Lactating woman.
- Subjects with Changes in mental state, confusion & encephalopathy will be excluded.

PARAMETERS OF THE STUDY

Subjective Parameters:

Loss of Appetite; Weight Loss; Nausea & Vomiting; Abdominal Pain / Right hypochondrial dull aching pain; Yellowish discoloration of Skin, Urine & Sclera; Fever.

Objective Parameters:

Hepatomegaly; Serum Bilirubin – Total, Serum Bilirubin – Direct, SGOT; SGPT; ALP; Hb%; Urine for Bile Salts and Bile Pigments,

Study Design: A comprehensive clinical study.

Sample size: A minimum of 30 subjects diagnosed with ALD fulfilling the diagnostic and inclusion criteria will be selected for the clinical study.

Table 1: Interventions

<i>Ama Pachana</i>	Hareetakyadi Churna Dose: 5gms of Churna with warm water before food.(Till Nirama Laxana) (3 to 5 days)
<i>Ruksha Virechana</i>	Avipatti Churna Dose –15-20 grams Anupana : Ushna jala
<i>Shamanoushadhi</i>	1. Rohitakadi Vati Dose: 500mg BID Duration: For 30 days 2. Vasaguduchyadi Kashaya. Dose: 30 ml twice daily as anupana. Duration : For 30 days
Total duration of study	48 days

Table 2: Overall assessment of Results based on Grades

OVERALL ASSESSMENT OF RESULTS	GRADE OF IMPROVEMENT
Marked Relief	Above 75% Improvement
Moderate Relief	50 to 74 % Improvement
Mild Relief	26 to 49 % Improvement
Unchanged	<25 % or No Improvement

Table 3: Effect of therapy on Subjective Parameters and objective parameters

Parameter	Mean		Mean diff	% of improvement	S.D.	S.E.	“t”	P value	Remark
	BT	AT							
Loss of appetite	2.1	0.3	1.8	85.71%	1.76	0.32	10.87	0.0001	S.H.S
Nausea	1.73	0.23	1.5	86.70%	0.718	0.31	11.53	0.0001	S.H.S
Vomiting	0.933	0.06	0.87	93.56%	0.845	0.15	5.77	0.0001	S.H.S
Abdominal Pain	1.66	0.366	1.3	77.99%	0.818	0.149	8.66	0.0001	S.H.S
Fever	0.766	0.1	0.66	86.95%	0.787	0.14	4.61	0.001	S.H.S
Yellowish discoloration	1.167	0.43	0.73	62.96%	0.72	0.14	5.61	0.0001	S.S
Hepatomegaly	0.966	0.366	0.6	62.11%	0.61	0.11	5.45	0.0001	S S
Hb%	0.8	0.6	0.2	25%	0.87	0.15	1.25	0.400	S.S
Bilirubin total	1.267	0.566	0.7	55.2%	0.73	0.136	5.147	0.0001	H.S
Bilirubin Direct	0.57	0.27	0.3	52.63%	0.64	0.12	2.5	0.25	S.S
Bilirubin Indirect	0.67	0.43	0.23	35.32%	0.78	0.14	1.61	0.200	S.S
SGOT	0.57	0.16	0.4	70.17%	0.71	0.129	3.10	0.005	S.H.S

SGPT	0.366	0.16	0.03	54.56%	0.65	0.118	0.282	<0.500	S.N.S
Alkaline Phosphatase	0.66	0.033	0.49	50.29%	0.31	0.05	8.71	0.0001	H.S
Bile salts	0.46	0.26	0.2	43.47%	0.53	0.009	2.04	0.05	S.H.S
Bile Pigment	0.56	0.26	0.3	53.57%	0.58	0.10	3.0	0.01	S.H.S

Table 4: Showing effect of therapy on both subjective and objective parameters of the study.

Parameter	Mean		Percentage of relief
	BT	AT	
Loss of apatite	2.1	0.3	85.71%
Nausea	1.73	0.23	86.70%
Vomiting	0.933	0.06	93.56%
Rt Hypochondrium dull aching Pain	1.66	0.366	77.99%
Yellowish discoloration of skin, eyes, urine and stool	1.167	0.43	62.96%
Fever	0.766	0.1	86.95%
Hepatomegaly	0.966	0.366	62.11%
Hemoglobin %	0.8	0.6	25%
Bilirubin Total	1.267	0.566	55.2%
Bilirubin Direct	0.57	0.27	52.63%
Bilirubin Indirect	0.67	0.43	35.32%
SGOT	0.57	0.16	70.17%
SGPT	0.366	0.16	54.56%
Alkaline Phosphatase	0.66	0.033	50.29%
Bile salts	0.46	0.26	43.47%
Bile pigment	0.56	0.26	53.57%

Table 5: Distribution of Subjects according to overall assessment of the result

Relief	No. of subjects	Percentage	Remarks
Above 75%	18	60%	Marked relief
51% to 75%	8	26.66%	Moderate relief
26% to 50%	2	6.66%	Mild relief
Less than 25%	2	6.66%	No relief

Chart 1: Showing Overall assessment of the result on Subjective parameters

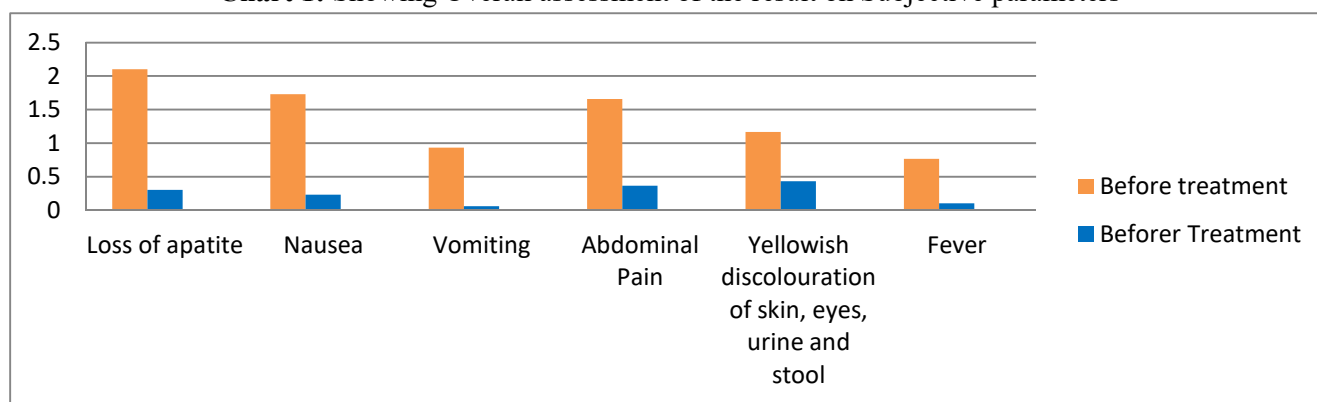
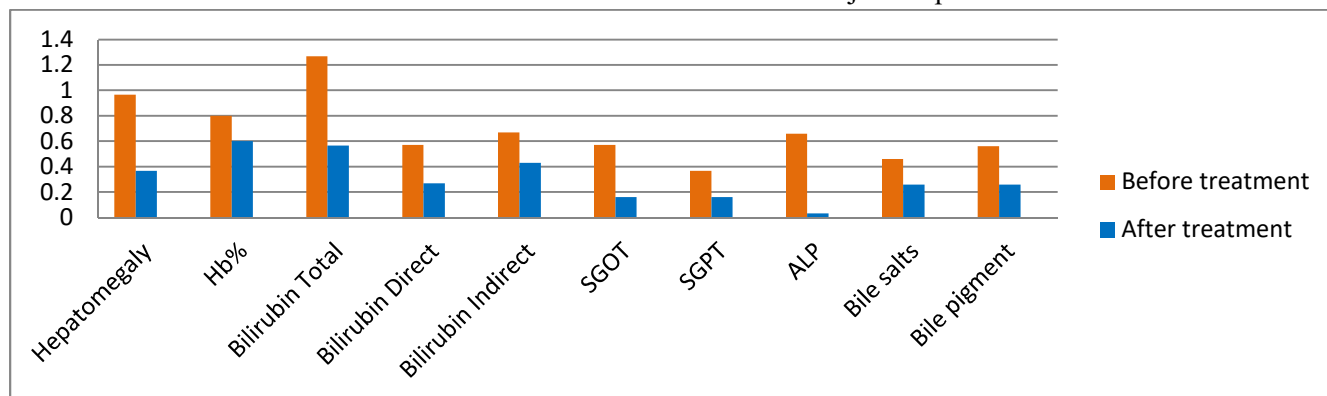


Chart 2: Overall assessment of the result on Objective parameters**Role of Ruksha Virechana:**

According to Acharya Charaka, the body with excessive *sneha* should be treated with *ruksha virechana* only.⁹ In certain diseases like *visarpa* (acute bacterial infections of the dermis), *shotha* (edema), *kamala* (jaundice) etc where *snehana* is contraindicated; *ruksha virechana* is preferred instead of *snigdha virechana*. Especially in *Udararoga* there is *Malasanchaya* or *Malavruddhi* due to *Agnidosha* and improper intake of food and other beverages. Therefore the treatment should comprise of *Mala Nirharana* by doing *Virechana*¹⁰ followed by *Shamanoushadhis*. So, in the present study considering the above context and its validity, *Avipatti Choorna* is chosen for *Rooksha virechana*.

DISCUSSION

Raktha vaha sroto moola dushti is a part of *madatyayajanya Yakrit vikara*. Alcohol is the mother of all sins. Alcohol abuse for a long term makes a person suffer from physical, mental and social consequences. *Rohitakadi Vati* is also called as *Yakrut shoola vinashini gutika* in *Bhaishajya Ratnavali*. The ingredients of the formulation such as *Navasadara*, *Saindhava Lavana*, *Chitraka*, *Ajamoda* are *ushna*, *teekshna*, *Amadosha hara*, and *srotoshodhana*. *Rohitaka* is well known for its hepatoprotective activity. It is *Kapha pitta shamaka* and *Pleehaghna*. According to the latest study conducted in Dept. of *Rasashastra* & B.K., NIA, Jaipur, Rajasthan, The Hepatoprotective effect of the *Rohitakadi vati (Yakrut shoola vinashini gutika)* was evaluated by the assessment of biochemical parameters such as SGOT, SGPT ALP, To-

tal Bilirubin, Total Protein & histopathological studies of Liver, which showed significant results.¹¹ *Vasaguduchyadi Kashaya*; the ingredients; *vasa*, *guduchi*, *triphal*, *katuki*, *bhunimba* and *nimba* are *Tikta* (Bitter), *Katu rasatmak* (Pungent), *Deepan* (stimulators of appetite), *Pachan* (digestive), *Raktaprasadak* and *Shodhana* (blood purifier) and indicated in the treatment of *Pandu*, *Raktapitta* and *Kamala*. It is a *Shodhan* (mild purification) *Kalpa* and has an affinity to act on *Yakrit* (liver). The *Raktashodhan* and *Prasadan* properties on the other hand attribute to the reduction in *Nakh-Netra-TwakMala Pitatva*. The *Yakritottejak* (hepato-stimulant) and *Yakritprasadan* (hepato-protective) properties of the formulation are responsible for the better results in alleviation of elevated SGOT, SGPT, Total, Direct & Indirect Bilirubin and Alkaline phosphatase.¹² **Discussion on Results:** In a nutshell, in present clinical trial 30 subjects who completed the clinical study were assessed twice, before and after the treatment of 48 days. Along with the subjective parameters, laboratory findings viz, LFT values were also statistically assessed by comparing pre and post-test values. Systematic approach with *Amapachana*, *Ruksha virechana* and *Shamana chikitsa* provides remarkable changes and assured results in relieving toxic, inflammatory changes in ALD. *Vasaguduchyadi kashaya* and *Rohitakadi vati* act as anti-inflammatory, anti-fibrotic, carminative, catalytic agent, hepatoprotective and Immunomodulator etc.

CONCLUSION

Alcoholic Liver Disease can be considered as *Madatyayajanya Yakrit Vikara* in Ayurveda. Alcoholic fatty liver can be considered as *Kaphaja Yakrit Vikara*, Alcoholic Hepatitis as *Pittaja Yakrit vikara* and Alcoholic Cirrhosis can be considered as *Vataja Yakrit Vikara*. Broadly Alcoholic Liver Disease can be said as *Raktavaha sroto mula dushti*. All types of *madya* can cause *Rakta dushti* there by causes *Yakrit vikara*, if consumed inappropriately. Alcohol not only effects on health of the individual but also causes social, economic and personal hazards.

Study shows that the black box design including *Amapachana*, *Ruksha virechana* and *Shamanoushadhi* proved effective in reducing the symptomatology including improving altered LFT Parameters and also remarkable results in reducing hepatomegaly. These therapies along with strict abstinence of Alcohol significantly reduced the Fatty changes in the subjects of Alcoholic Fatty liver and Hepatitis. Overall study shows well appreciable results with marked improvement in 60% of cases and Moderate improvement in 26.66% with $p < 0.0001$ which is statistically significant.

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