An Open Label Single Arm Clinical Study To Evaluate The Combined Effect Of *Virechana* And *Trayantyadi Kashaya* In Alcoholic Liver Disease
*SEEJPH Volume XXVI, S4, 2024, ISSN: 2197-5248; Posted:01-01-2024*Article Received: 02/11/2024
Article Revised: 29/11/2024 Article Accepted: 15/12/2024

An Open Label Single Arm Clinical Study To Evaluate The Combined Effect Of Virechana And Trayantyadi Kashaya In Alcoholic Liver Disease

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KEYWORDS
Alcoholic Liver Disease, Virechana, Trayantyadi Kashaya, Yakrit Vikaras.

ABSTRACT
Alcoholic Liver Disease (ALD) comprise a spectrum of diseases associated with chronic Alcohol consumption ranging from Alcohol associated Fatty Liver Disease and Steatohepatitis (Alcoholic Hepatitis) to move advanced liver diseases including from fibrosis to cirrhosis. World Health Organisation (WHO) estimates that about 2 billion people worldwide consume alcohol beverages and 76.3 million have diagnosable alcohol disorder. According to National Family Health Survey (NFH-5) 2019-2021 has found 55% of Indians consume alcohol. According to latest WHO data published in May 2018, Liver disease deaths in India reached 216,865 or 2.44% of total death. Death rate is 21.96 per 100,000 of population. There is a high prevalence of Alcoholic Liver Disease in India and about 50% cases of Cirrhosis in India may be due to alcohol abuse. Quantity and duration of Alcohol intake are the most important risk factor for development of ALD. Alcoholic Fatty Liver is the earliest change and is almost universally present in heavy alcoholics. Among the Alcoholic Fatty Liver, 34.3% may end up with Cirrhosis. It is generally a benign condition with abstinence. Alcoholic Hepatitis occurs in 10% to 35% of heavy drinkers who develop necro inflammation with or without fat infiltration. Virechana is the first line of management for Pitta, Pittakapha, and Pittashayagata vikara. Trayantyadi Kashaya include Trayanti, as one of the main ingredients which is directly indicated in Yakrit Vikaras as mentioned in Priyanighantu. The study comprises of 30 subjects. These subjects were selected on the basis of inclusion and exclusion criteria with detailed clinical history, physical examination and other desired investigations. So, in the present study an effort has been put forth to evaluate combined effect of Virechana and Trayantyadi Kashaya in Alcoholic liver disease.

INTRODUCTION

Alcoholic Liver Disease (ALD) is the condition which describes the spectrum of liver injury caused by acute and chronic alcoholism.[1] 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.[2] India has also unfortunately, witnessed a steadily increasing consumption of alcohol in the last two decades. Alcohol consumption in India amounted to about 6.21 billion litters by 2024.[3] Alcohol consumption in India is high among men, and the prevalence varies by region and gender. The national average for men is 29.2% and women is 1.2%.[4] According to the latest WHO data published in May 2022, 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 #103rd in the world.[5]

Alcohol is a more common environmental hepatotoxin whose metabolism creates profound liver cell derangements. Daily consumption of 30 to 50 grams (1 mL ethanol = 0.79 g i.e. 23.7ml to 47.4 ml) of alcohol for over five years can cause alcoholic liver disease. Thus, Alcohol consumption becomes one of the key indicators for ill health of the liver.[6,7,8] Acharyas explained a separate chapter for Alcohol, its properties, and its complications by the name Madatyaya chikitsa which includes various Avasthas of Mada and their treatment. Madatyaya includes various clinical spectrums resulting due to excessive intake of Alcohol which is characterized by vitiation of all the doshas and impairment of Ojas. Madya has exactly opposite qualities of Ojas and at the same time exactly similar qualities of Visha.[9] Due to excessive consumption of Amla, Lavana, Madya and Teekshna dravyas cause Raktadushti and there will be Pandubhava of Twacha. The properties of

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Madya are going to damage Raktavahasrotas and Yakrut (Raktavahasrotomoola) by its Amla, Ushna, Teekshna,Vikasi guna. Madya is known to vitiate Rakta which is one among the root cause of Kamala & Yakrutodara. Yakrut and Pleeha are considered as Moola of Raktavaha srotas by Acharya Chraraka[10], from this description, it follows that Yakrut and Rakta have Samavaya relation. Therefore, for the vitiation of Rakta, there will also be derangement of functions of Yakrut and vice versa.

Alcoholic liver diseases are broadly classified into three stages.[1]

1. Alcoholic Fatty Liver (AF)
2. Alcoholic Hepatitis (AH)
3. Alcoholic cirrhosis of liver (AC)

Alcoholic Fatty liver is an earliest pathological change. In this liver cells (hepatocytes) large quantity of fat (triglycerides) gets accumulated. Alcoholic Hepatitis is an inflammatory condition where in specific histopathological conditions are seen. Alcoholic cirrhosis is an irreversible process, and resulting in disorganization of the liver architecture impairs blood flow leading to portal hypertension.[11] In this study Alcoholic Fatty Liver (AF), Mild to Moderate Alcoholic Hepatitis,[12] is included in Alcoholic Liver Disease and excluded Severe Alcoholic Hepatitis and Alcoholic Liver Cirrhosis. There are a lot of research studies have been undertaken to establish effective management of ALD yet encouraging results are lacking. So, the present study is undertaken to check the effectiveness in managing Alcoholic Liver Disease.

OBJECTIVES OF THE STUDY

To evaluate the combined effect of Virechana and Trayantyadi Kashaya in Alcoholic Liver Disease.

MATERIALS AND METHODS

MATERIALS:

1. Sootashekararasa[13]
2. Tilataila[14]
3. Trivrit lehya[15]
4. Tiktaka Ghrita[16]
5. Trayantyadi Kashaya[17]

SOURCE OF DATA:

Subjects of either sex diagnosed with Alcoholic Liver Disease, fulfilling the diagnostic criteria were selected incidentally from the OPD and IPD of JSS Ayurveda Hospital, Mysuru, medical camps and other referrals. The total number of cases selected for the study was 30.

Inclusion criteria:

- Subjects having history of Alcohol dependence for 1 year or more.
- Subjects fulfilling the diagnostic criteria.
- Subjects with or without raised bilirubin level (0.1 -10mg/dl).[18]
- Subjects not suffering from Alcoholic withdrawal symptoms.
- Subjects between the age group of 20-60 years, irrespective of gender.
- Subjects with elevated LFT values.

Exclusion criteria:

- Subjects diagnosed with HIV, HBV, Tuberculosis, Myocardial infarction, other systemic diseases which interfere with the course of treatment.
- Subjects diagnosed with Cirrhosis of liver, Ascites, Viral hepatitis, Severe Alcoholic Hepatitis, and other Psychiatric diseases which interfere with the course of treatment.
- Subjects diagnosed with other Psychoactive drug dependence.
- Subjects under active administration of hepato-toxic drugs. [19]
- Pregnant Women and Lactating Mothers.
- Subjects not fit for Virechana.

Diagnostic criteria:

- Diagnosis is done based on both subjective and objective parameters

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Subjective parameters

Subjects having signs and symptoms of Alcoholic Liver Disease (Alcoholic fatty liver, Mild or Moderate Alcoholic hepatitis)[20]

- Anorexia
- Malaise
- Nausea
- Right hypochondrial pain / discomfort

Objective Parameters

- LFT.
- Ultrasonography of Abdomen.

CLINICAL STYDY DESIGN

Study design: An Open label, single arm clinical study. A case proforma specially designed for the study was prepared with all the points of history taking, physical signs and symptoms and laboratory investigations.

Sample size: In this present study 30 patients of Alcoholic Liver Disease were selected. Subjects are advised to do abstinence from alcohol consumption (Flush out period of 7 days).

Plan of treatment

Procedure: Virechana Karma for 6 days.

Purva Karma

Deepana Pachana with Sootashekara Rasa (125mg) [13] (1-1-1) for 3 days. Snehapana with Tiktaka Ghrita for 3 days. For Vishramakala Sarvanga Abhyanga with Murchita Tila[14] Taila followed by Ushna Jala Snana for 3days.

Pradhana Karma

Sarvanga Abhyanga with Murchita Tila Taila[14] followed by Virechana with Trivrith Lehya[15] along with Ushnajala as Anupana.

Paschat Karma

Based on type of Shuddhi subjects will be administered with Samsarjana Krama (3 to 7 days).

Shamanaushadhi: Trayantyadi kashaya[17] was administered for next 30 days.

(Dose 15ml Kashaya three times a day after food with 15ml Sukoshna Jala as Anupana. Duration 30 days)

Intervention period: 42 to 46 days.

Assessment Schedule:

Pre-test: 0th day.

Post-test- After treatment: (Shamanaushadhi) i.e. (42nd to 46th days)

Assessment Criteria:

The assessment was made on the basis of the following signs and symptoms by adopting standard scoring methods and (LFT values & Ultrasonography of Abdomen findings) [20]

Table No - 1

Right upper quadrant abdominal discomfort/pain Scale by NCBI	**GRADE**
Low disability, low intensity	1
Low disability, high intensity	2
High disability, moderately limiting	3
High disability, severely limiting	4

Table No - 2

Malaise/ Fatigue Scale by Chadler EtAl	**GRADE**
No tiredness or minimal tiredness	1
More than usual tiredness after work	2
More than usual tiredness before and after work	3

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Always feeling week and drowsy	4

Table No - 3

Anorexia Scale by NCBI	**GRADE**
Loss of appetite without alteration in eating habits	1
Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated	2
Associated with significant weight loss or malnutrition; tube feedings indicated	3
Life threatening consequences, urgent interventions required	4

Table No - 4

Nausea Scale by NCI	**GRADE**
Loss of appetite without alteration in eating habits	1
Oral intake decreased without significant weight loss, dehydration or malnutrition	2
Inadequate oral caloric or fluid intake; tube feedings or hospitalization indicated	3
Life threatening	4

Objective Parameters
- LFT.
- Ultrasonography of Abdomen.

STATISTICAL ANALYSIS
The collected data was entered into Microsoft Excel Sheet (Windows 11 and then it was entered in SPSS Version 21.0.0 for statistical analysis. For the assessment of results during the treatment period Subjective parameters like Right Upper Quadrant Pain, Anorexia, Nausea and Malaise were considered. And Objective parameters like LFT and USG of Abdomen were considered.

The data was analysed as follows:
Comparisons within a group:
1. The Wilcoxon signed rank test was applied to compare any two sessions within the same group for a nonparametric continuous variable. It assessed whether there was a significant difference between these sessions.
2. Paired t-test was used to compare parametric variable within the group.

Representation and Significance:
- Observational data was visually represented using Bar Charts.
- The trend of each variable over time was illustrated using Line Diagrams.
- The Level of Significance was established as $p<0.001$ and $p<0.01$ to indicate statistically highly significant (H.S) results, $p<0.05$ to indicate significant results and $p>0.05$ to indicate non-significant (N.S) results.

OBSERVATIONS:
The present single-arm, open-labelled interventional clinical study encompassed 30 subjects, primarily male (96.7%), with the largest representation in the 31–40 years age bracket (46.7%), followed by 41–50 years (23.3%), 51–60 years (16.7%), and 20–30 years (13.3%). All subjects identified as Hindu, with a majority (80%) being married. Educational attainment varied; 56.7% held a degree, 16.7% had completed PUC or SSLC, and 10% were illiterate. Occupational profiles were diverse, dominated by farmers (33.3%) and businessmen (23.3%), with additional professions including teachers, journalists, engineers, and various others. Socio-economic status distribution indicated that over half resided within the upper middle class (53.3%), with substantial representation from the lower middle class (36.7%) and a minor segment classified as poor (10%). Urban domicile prevailed (70%).

Clinically, 30% of subjects reported right upper quadrant pain, mostly of short duration (up to three months). Nausea was highly prevalent (80%), typically lasting less than one month, accompanied by anorexia in 46.7%,

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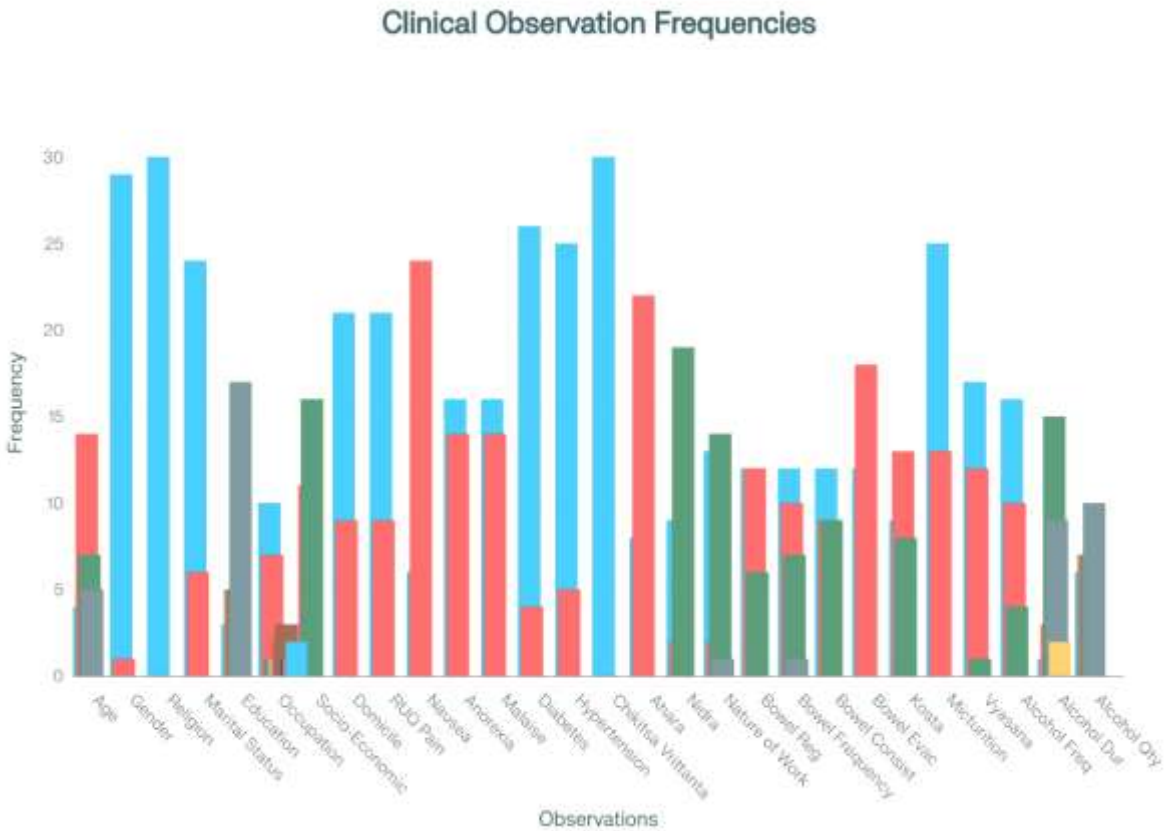
and malaise in 46.7% of subjects, predominantly acute or subacute. Sleep disturbances were common (63.3%), with only 30% reporting sound sleep and 6.7% daytime sleepiness. Dietary habits showed a predominance of mixed diet consumption (73.3%), with 26.7% adhering to vegetarianism. The nature of work was nearly equally divided between laborious (46.7%) and sedentary tasks (43.3%), with smaller proportions engaged in continuous standing or traveling.

Gastrointestinal assessments revealed a heterogeneous profile: bowel regularity was evenly split between regular (40%) and irregular (40%), with 20% constipated; bowel frequency varied from once daily (40%) and 2–3 times daily (33.3%) to every two days (23.3%), with a minority experiencing more than three times daily (3.3%). Stool consistency was evenly distributed into normal (40%), loose (30%), and hard (30%) types. Notably, more than half (60%) experienced incomplete bowel evacuation. Constitutionally, subjects were predominantly characterized as Madhyama Koshta (43.3%), followed by Mridu (30%) and Krura (26.7%). Urinary habits showed 83.3% of the subjects voiding 4–5 times per day without nocturia, while 43.3% had nocturnal voiding once.

Behavioural analyses indicated that 56.7% consumed alcohol exclusively, 40% both alcohol and smoking, and 3.3% combined alcohol with tobacco. Alcohol intake frequency was predominantly daily (53.3%) or every alternate day (33.3%), and total intake ranged widely, with 33.3% consuming over 151 ml/day, and others between 60–150 ml. Duration of alcohol consumption clustered between 4–6 years (50%) and 7–10 years (30%), with a smaller percentage reporting histories less than one year or beyond 10 years.

Comorbidities included diabetes mellitus in 13.3% of subjects—mostly recent onset (up to one year)—and hypertension in 16.7%, with similar durations. All subjects were classified as "fresh" cases from an Ayurvedic diagnostic perspective (Chikitsa Vritanta). The detailed profiling across demographic, clinical, lifestyle, and constitutional parameters establishes a comprehensive baseline. This data set affords a robust foundation to evaluate therapeutic efficacy and contributes high-value evidence for integrative management strategies in Ayurveda, paving the way for further advancement in clinical research and patient care paradigms.



Picture No -1: Depicting Graphical Representation of Observations.

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RESULTS:

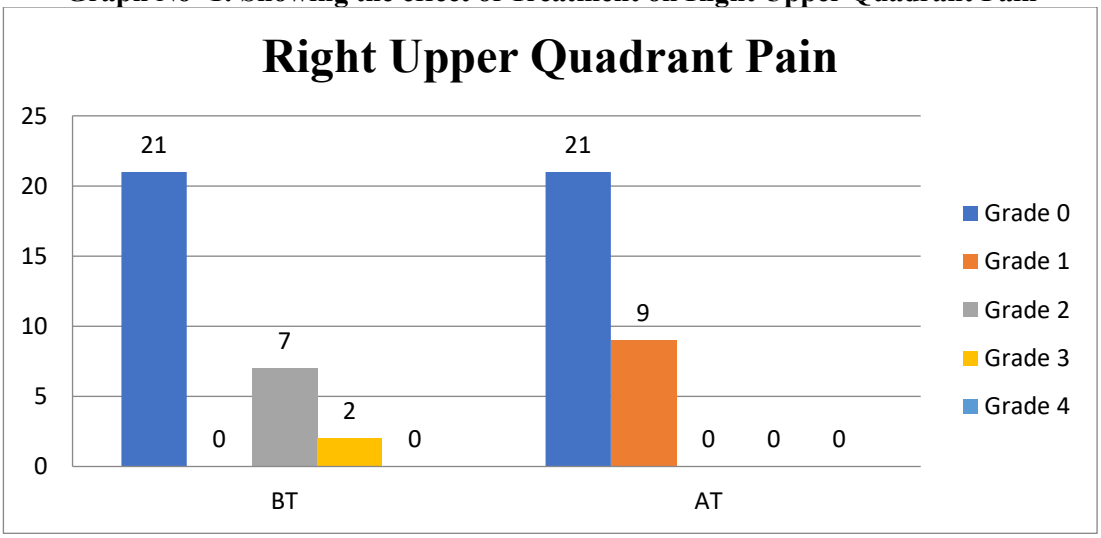
STASTICAL REPRESENTATION OF NON-PARAMETERS ASSESSED AT DIFFERENT INTERVALS AS PER THE DATA TAKEN

1. Right Upper Quadrant Pain:

TABLE NO – 5: DESCRIPTIVE ANALYSIS					
Lakshana	**Grade**	**Before Treatment**		**After Treatment**	
		No.	**%**	**No**	**%**
Right Upper Quadrant Pain	**0**	**21**	**70.0%**	**21**	**70.0%**
	1	**0**	**0.0%**	**9**	**30.0%**
	2	**7**	**23.3%**	**0**	**0**
	3	**2**	**6.7%**	**0**	**0**
	4	**0**	**0**	**0**	**0**

TABLE NO – 6: INFERENTIAL ANALYSIS- Wilcoxon Sign Rank Test							
Median Values				**Right Upper Quadrant Pain**	**Z Value**	**P value**	**Result**
BT	**IQR**	**AT**	**IQR**				
0.0	**3.0**	**0.0**	**1.0**	**BT-AT**	**-2.810**	**0.005**	**S**

Graph No -1: Showing the effect of Treatment on Right Upper Quadrant Pain



2. Anorexia

TABLE NO – 7: DESCRIPTIVE ANALYSIS					
Lakshana	**Grade**	**Before Treatment**		**After Treatment**	
		No.	**%**	**No**	**%**
Anorexia	**0**	**8**	**26.7%**	**8**	**26.7**
	1	**0**	**0.0%**	**22**	**73.3%**
	2	**22**	**73.3%**	**0**	**0**
	3	**0**	**0**	**0**	**0**
	4	**0**	**0**	**0**	**0**

TABLE NO – 8: INFERENTIAL ANALYSIS- Wilcoxon Sign Rank Test							
Median Values				**Anorexia**	**Z Value**	**P value**	**Result**
BT	**IQR**	**AT**	**IQR**				
2.0	**2.0**	**1.0**	**1.0**	**BT-AT**	**-4.390**	**0.000**	**HS**

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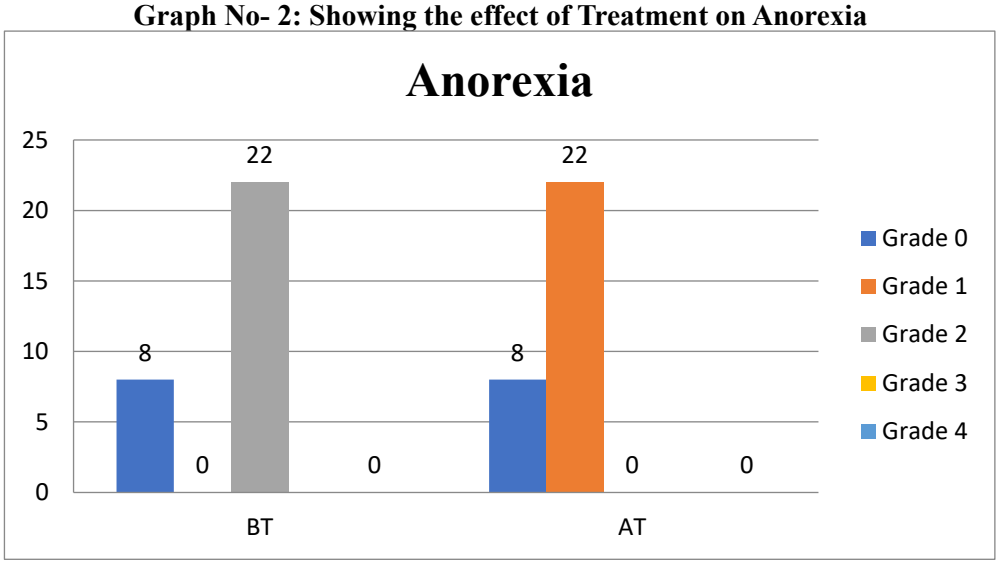
Graph No- 2: Showing the effect of Treatment on Anorexia

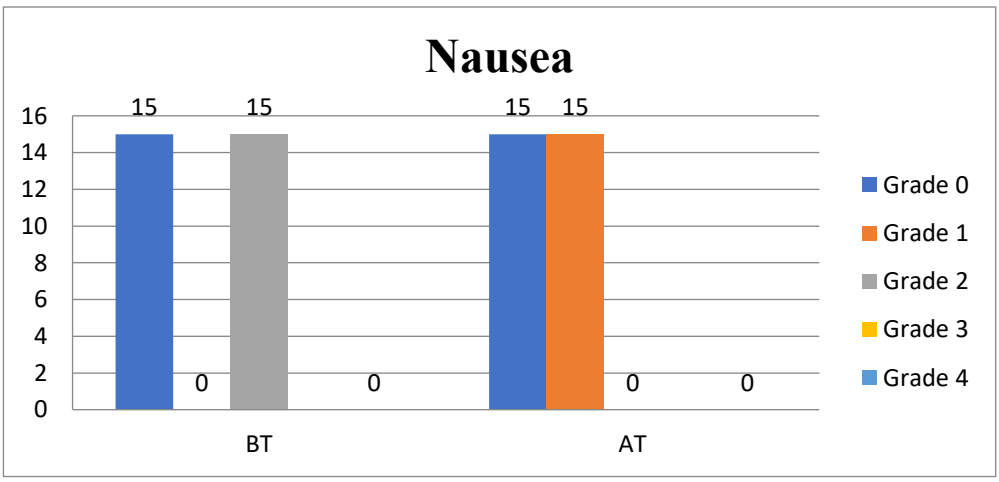


3. Nausea

TABLE NO – 9: DESCRIPTIVE ANALYSIS					
Lakshana	**Grade**	**Before Treatment**		**After Treatment**	
		No.	**%**	**No**	**%**
Nausea	**0**	**15**	**50.0%**	**15**	**50.0%**
	1	**0**	**0.0%**	**15**	**50.0%**
	2	**15**	**50.0%**	**0**	**0**
	3	**0**	**0**	**0**	**0**
	4	**0**	**0**	**0**	**0**

TABLE NO – 10: INFERENTIAL ANALYSIS- Wilcoxon Sign Rank Test							
Median Values				**Nausea**	**Z Value**	**P value**	**Result**
BT	**IQR**	**AT**	**IQR**				
1.0	**2.0**	**0.5**	**1.0**	**BT-AT**	**-3.873**	**0.000**	**HS**

Graph No -3: Showing the effect of Treatment on Nausea:



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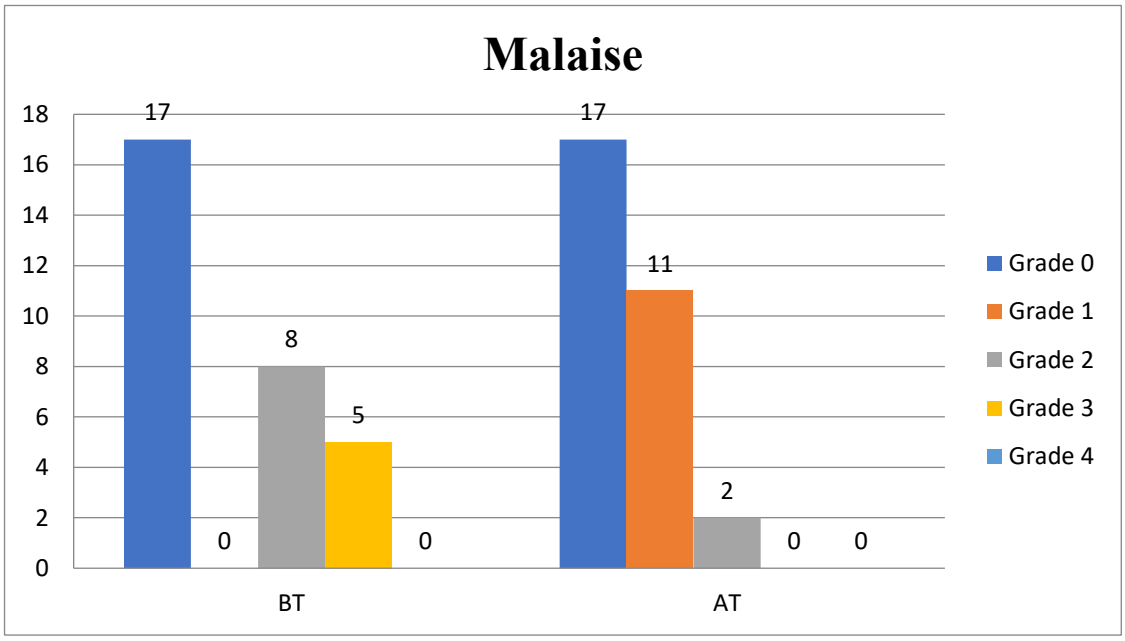
4. Malaise

TABLE NO – 11: DESCRIPTIVE ANALYSIS					
Lakshana	**Grade**	**Before Treatment**		**After Treatment**	
		No.	**%**	**No**	**%**
Malaise	**0**	**17**	**56.7%**	**17**	**56.7%**
	1	**0**	**0.0%**	**11**	**36.7%**
	2	**8**	**26.7%**	**2**	**6.7%**
	3	**5**	**16.7%**	**0**	**0**
	4	**0**	**0**	**0**	**0**

TABLE NO – 12: INFERENTIAL ANALYSIS- Wilcoxon Sign Rank Test							
Median Values				**Malaise**	**Z Value**	**P value**	**Result**
BT	**IQR**	**AT**	**IQR**				
0.0	**3.0**	**0.0**	**2.0**	**BT-AT**	**-3.358**	**0.001**	**HS**

Graph No - 4: Showing the effect of Treatment on Malaise:



5. USG Abdomen Changes

TABLE NO – 13: DESCRIPTIVE ANALYSIS					
Lakshana	**Grade**	**Before Treatment**		**After Treatment**	
		No.	**%**	**No**	**%**
USG Abdomen Changes	**1**	**0**	**0.0%**	**14**	**46.7%**
	2	**8**	**26.7%**	**14**	**46.7%**
	3	**5**	**16.7%**	**2**	**6.7%**
	4	**2**	**6.7%**	**0**	**0**
	5	**14**	**46.7%**	**0**	**0**
	6	**1**	**3.3%**	**0**	**0**

TABLE NO – 14: INFERENTIAL ANALYSIS- Wilcoxon Sign Rank Test							
Median Values				**Malaise**	**Z Value**	**P value**	**Result**
BT	**IQR**	**AT**	**IQR**				
4.50	**4.0**	**2.0**	**2.0**	**BT-AT**	**-4.842**	**0.000**	**HS**

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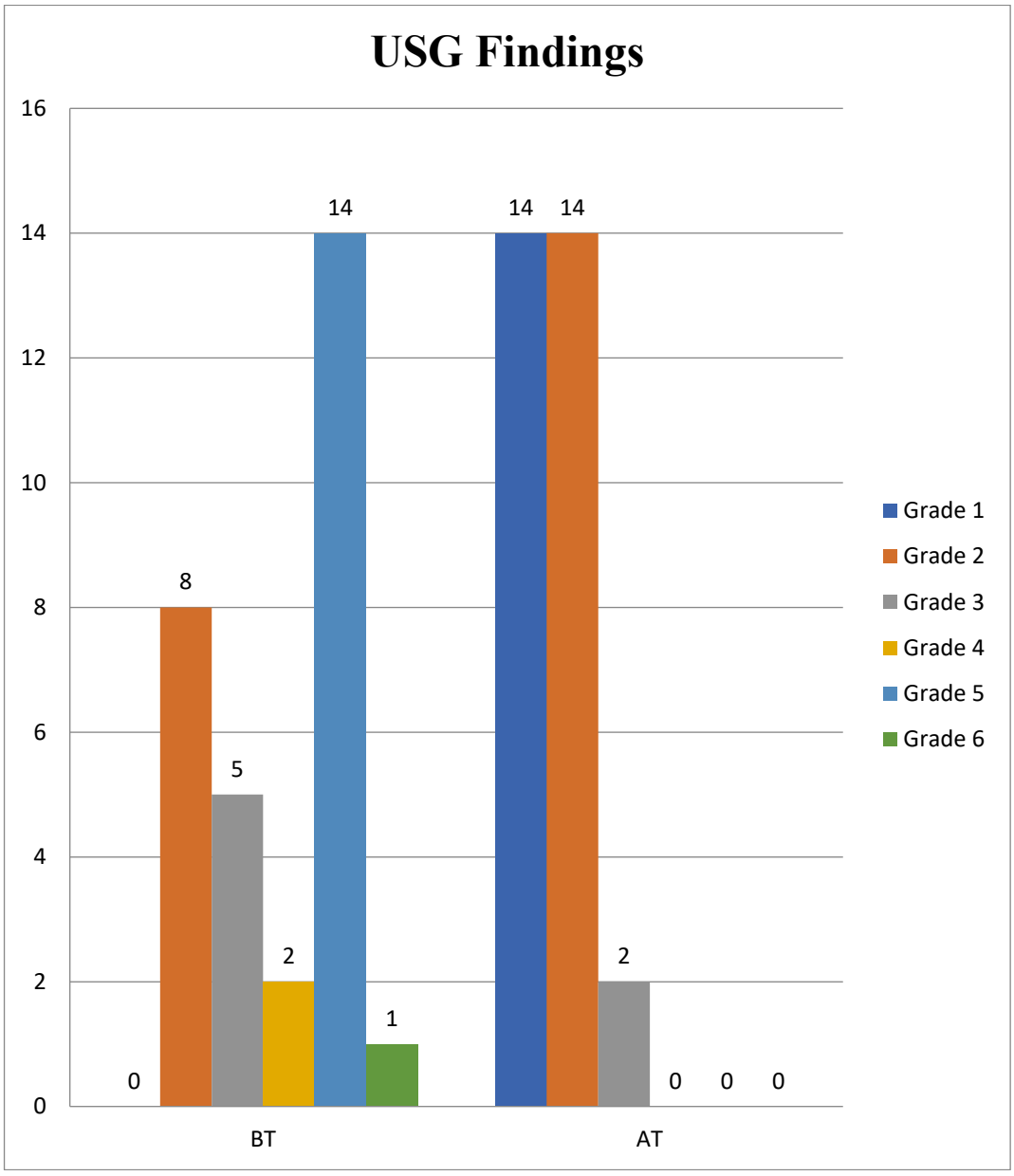
Graph No - 5: Showing the effect of Treatment on USG Findings:



STASTICAL REPRESENTATION OF PARAMETERS ASSESSED AT DIFFERENT INTERVALS AS PER THE DATA TAKEN:

Liver Function Test

1. SGOT

TABLE NO - 15: Descriptive Statistics for SGOT		
Interval	**Mean**	**SD**
BT	**135.80**	**± 41.06**
AT	**56.33**	**± 6.97**

Table No - 16: Inferential Statistics Of SGOT							
Features	**Time Frame**	**Mean**	**SD**	**t Value**	**P value**	**Alpha**	**Result**
SGOT	**BT-AT**	**79.46**	**± 38.07**	**11.431**	**0.000**	**0.05**	**HS**

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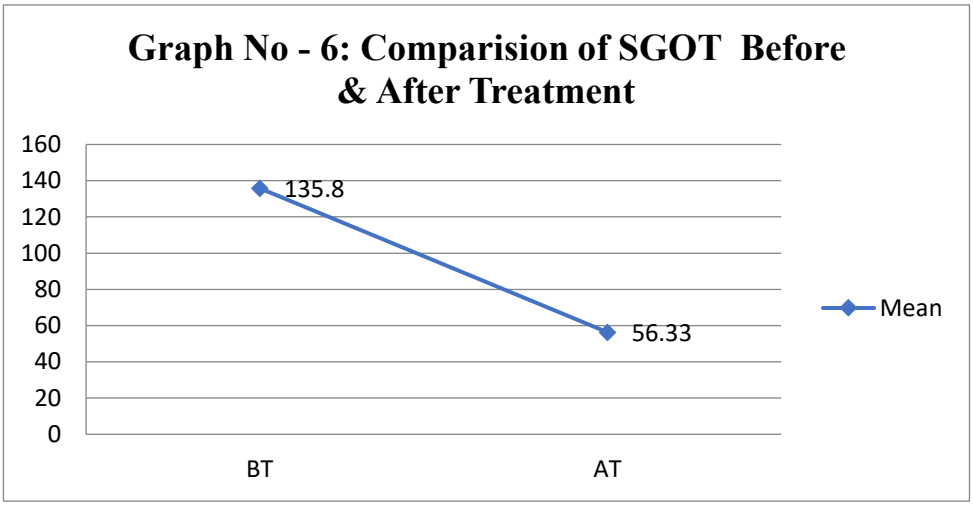
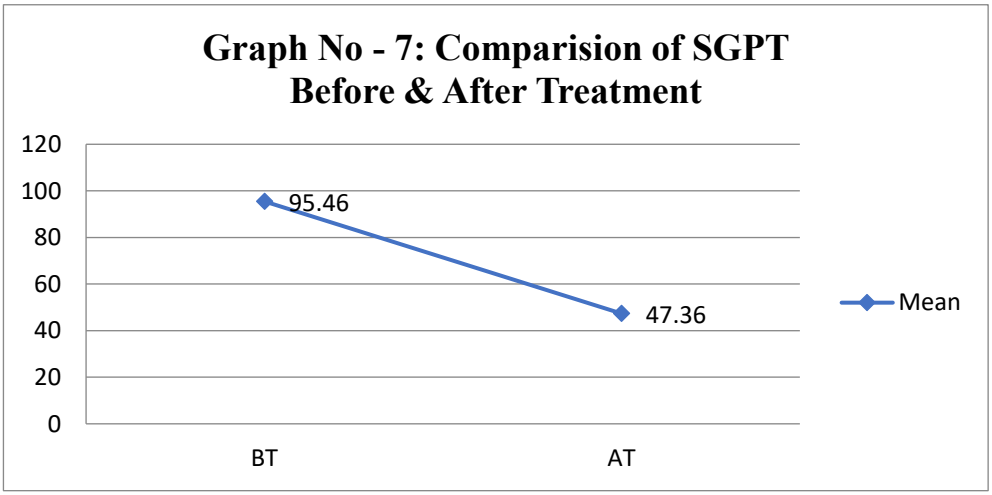


2. SGPT

Table No - 17: Descriptive Statistics for SGPT		
Interval	**Mean**	**SD**
BT	**95.46**	**± 29.64**
AT	**47.36**	**± 7.78**

Table No-18: Inferential Statistics Of SGPT							
Features	**Time Frame**	**Mean**	**SD**	**t Value**	**P value**	**Alpha**	**Result**
SGPT	**BT-AT**	**48.10**	**± 25.63**	**10.276**	**0.000**	**0.05**	**HS**



3. Direct Bilirubin

Table No-19: Descriptive Statistics for Direct Bilirubin		
Interval	**Mean**	**SD**
BT	**0.93**	**± 0.50**
AT	**0.58**	**± 0.32**

Table No - 20: Inferential Statistics Of Direct Bilirubin							
Features	**Time Frame**	**Mean**	**SD**	**t Value**	**P value**	**Alpha**	**Result**
Direct Bilirubin	**BT-AT**	**0.35**	**± 0.30**	**6.242**	**0.000**	**0.05**	**HS**

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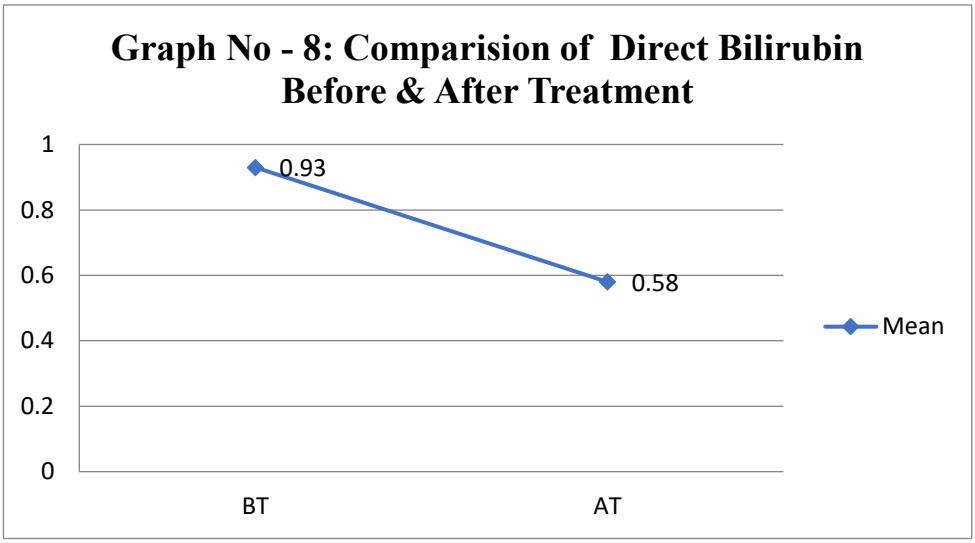
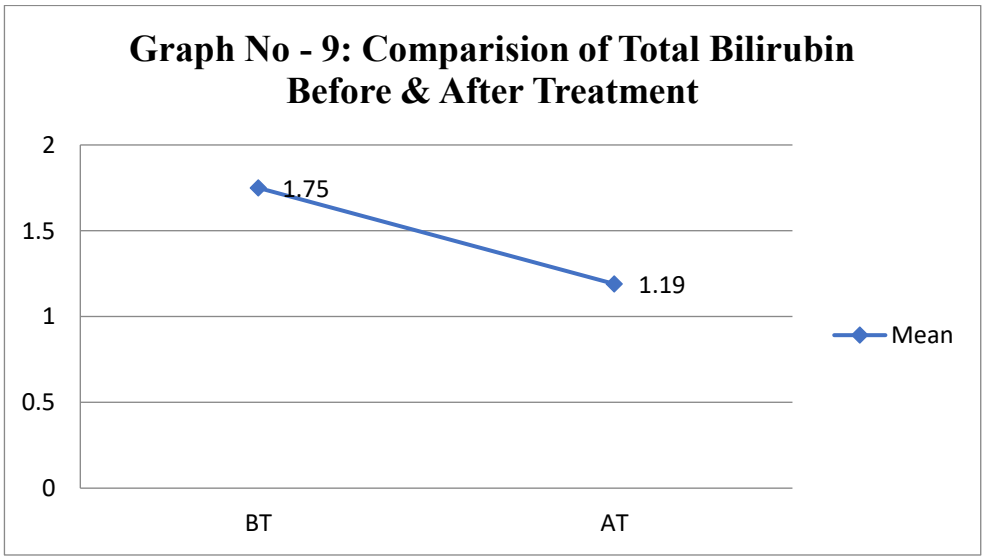


4. Total Bilirubin

Table No - 21: Descriptive Statistics for Total Bilirubin		
Interval	**Mean**	**SD**
BT	**1.75**	**± 1.02**
AT	**1.19**	**± 0.61**

Table No - 22: Inferential Statistics Of Total Bilirubin							
Features	**Time Frame**	**Mean**	**SD**	**t Value**	**P value**	**Alpha**	**Result**
Total Bilirubin	**BT-AT**	**0.56**	**± 0.54**	**5.590**	**0.000**	**0.05**	**HS**



5. Indirect Bilirubin

Table No - 23: Descriptive Statistics for Indirect Bilirubin		
Interval	**Mean**	**SD**
BT	**0.83**	**± 0.57**
AT	**0.59**	**± 0.37**

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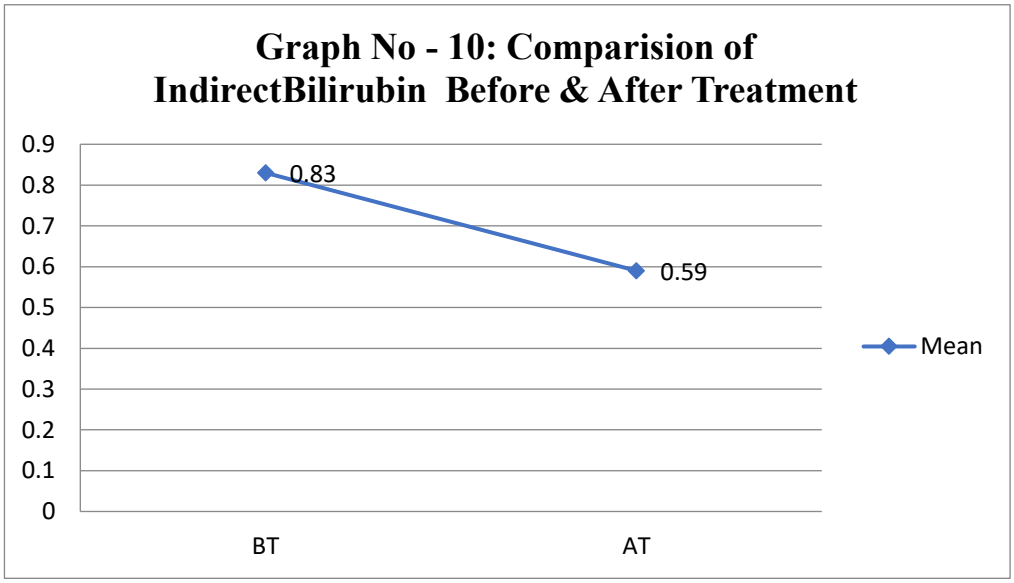
Table No-24: Inferential Statistics Of Indirect Bilirubin							
Features	**Time Frame**	**Mean**	**SD**	**t Value**	**P value**	**Alpha**	**Result**
Indirect Bilirubin	**BT-AT**	**0.23**	**± 0.33**	**3.814**	**0.001**	**0.05**	**HS**



DISCUSSION

In the present study clinical trials were conducted on 30 subjects of Alcoholic Liver Disease. Subjects were subjected to Virechana with Trivruth lehya followed by Trayantyadi Kashaya. Subjects with signs and symptoms of Alcoholic Liver Disease were treated and assessed statistically. Results were interpreted.

Amapachana with Sootashekararasa

In the present study Sootashekararasa was given 125mg thrice a day for 3 days. The drugs used in this are digestives and carminatives, stimulates enzymatic secretions, HCL secretions, pancreatic and bile secretions, thereby help in proper digestion.

Snehapana

As Snehapana is the purvakarma of Virechana karma "Tatra Kamala Pandu roginamnathi snigdena virechayet," Acharya Vagbhata restricted the usage of snehapana to little quantities mentioning that Virechana should be performed in alpa snigdha vastha only.[21]So we have administered Sneha(Tiktaka Ghrita) in the form of Sadhyo Sneha in this study.

Virechana

Yakrit is the place of Raktawaha Srotas. So the Alcoholic Liver Disease is considered under the Raktawaha Srotas Vyadhi. Yakrit is also the site of Pitta Dosha. In this view the Shodhana Chikitsa i.e., Virechana Karma will be useful Alcoholic Liver Disease state along with the Shamana Chikitsa. Trivrit Lehya used in the Virechana Karma gets hydrolysed in small intestine by lipase to give Turpethenic acid, which irritates and requires bile for hydrolysis. Bile serves as a means for excretion of several important waste products from the body. These include bilirubin, an end product of haemoglobin destruction and excesses of cholesterol synthesized by the liver cells. virechana produces local stimulant effect on motility, following mechanisms may be responsible. Inhibition of Na+, K+ cycle in crypt cell, hence increase the secretion of water and electrolyte. PAF a phospholipid pro inflammatory mediator and it produces significant stimulation of colonic secretion and gastrointestinal motility. Nitric oxide also involved in stimulation of intestinal secretion via prostaglandin and cyclic- gMP dependent mechanisms. Stimulant purgatives increase the activity of nitric oxide synthesis and further increase the biosynthesis of PAF phospholipid pro inflammatory in the gut. [22]

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Trivrit Lehya

Trivrit lehya being a sukha virechaka yoga with properties like laghu, rooksha, teekshna guna and ushna virya. Trivrit is specifically mentioned in the context of Kamala and Udara. [22] Trivrit lehya contain Trivrit as one of the main ingredients which contain A& B Turpethum as the main phytochemical in the trivrit which is responsible for Purgative action and also acts as anti-inflammatory and it is hepatoprotective in nature.[23]

Trayantyadi Kashaya [24-35]

Trayantyadi Kashaya is a formulation which is explained in Astanga Hridaya Vidradi chikitsa Adhyaya. These drugs contain Tikta, Katu Rasa Pradhanya Dravyas which are useful in symptoms of Anorexia as they pacify the vitiated Doshas and promote the Dhatu Poshana and thus reducing the Dourbalya. Amapachana effect of Patola and Haritaki present in the Kashaya might have helped in the reduction of the nausea. As Tikta Rasa is Rakta Shodhaka and Pitta Shamaka, it attributes to the reduction in Haridra of Netra, Nakha, Twak, Mutra, etc. Ruchya karma of Vibhitaki, Amalaki, Nimba,Yashtimadhu and Katuki might have reduced Anorexia.

Deepana Karma of Haritaki, Katuki, Patola and Pachana Karma present in Patola might have corrected dooshita pachaka pitta and bodhaka kapha and might have reduced Anorexia. Agni vriddhi caused by Deepaniya drugs like Haritaki, Katuki, Patola present in Kashaya leading to proper digestion and assimilation of the consumed food further facilitates the proper dhatuposhana leading to increase in the bala of the patient. Shoolahara property of Trayanti present in Kashaya might have helped in the reduction of Right Hypochondrium abdominal pain. Masoora is having Madhura rasa, madhura vipaka, sheeta veerya, kapha pittagna properties.It is good source of vitamin B1 & B2. Nutritive values of Masoora per 100 gms are as follows, Proteins-25.1g, Fat-0.7g, carbohydrates-59.7 gm, Iron-2 mg, Energy- 346 k.cal. In ALD the patients are under nourished & suffers from protein deficiency, hence a high calorie and high protein diet should be administered, as purana masura is a good source of protein and carbohydrates. [24-35]

Table No - 25: Describing the Phytoconstituents and Pharmacological actions present in the Trayantyadi Kashaya.

SL NO	DRUG	PHYTO CONSTITUENTS	PHARMACOLOGICAL ACTIONS
1.	Trayanti[36]	Tannins Alkaloids Saponins Glycosides Gentiopicrin Gentianine Terpenes Flavonoids Phenolics Carbohydrates Genianic Acid Pectin	Anti-Bacterial Anti-Oxidant Anti Arthritic Anti Inflammatory Analgesic
2.	Haritaki[37]	Casuarinin Gallic Acid Chebulinic Acid Rutin Ellagic Acid Ferugic Acid Caffeic Acid Vanillic Acid Corelating Ethyl Gallate Methyl Gallate	Immunomodulatory Anti-Oxidant Hepato-Protective Cytoprotective activity

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3.	Vibhitaki[38]	Tainternilignan Thannilignan Anolignan B Gallic Acid Beta Sitosterol Beleric Acid Galactose Chebulagic Acid	Immunomodulatory Anti-Oxidant Analgesic Antidiarrheal Anti-Inflammatory
4.	Amalaki[39]	Phyllaemblin Gallic Acid Emblicol Quercetin Ellagic Acid Pectin Putranjivan A Emblicanin A & B Punigluconin Pendunculagin	Hepato-Protective Immunomodulator Cytoprotective Antioxidant Anti-Inflammatory
5.	Nimba[40]	Nimbin Nimbinin Nimbidine Nimbasterol Quercetin	Hepato-Protective Immunomodulator
6.	Katuki[41]	D-Mannitol Kutkiol Kutkisterol Apocyanin Androsim Kutkoside Picrorhizin Arvenin Kutkin	Hepato-Protective Immunomodulator Anti-Oxidant
7	Yashti Madu[42]	Glycyrrhizin Glycyrrhetinic Acid Glabridin Quercetin Liquiritigenin Licochalcone Glycyglabrone Glabrin	Hepato-Protective Anti-Inflammatory
8	Trivrith[43]	Turpethin Turpethinic Acid B-Sitosterol Scopoletin Betulin	Anti-Oxidant Analgesic Hepato-Protective Anti-Inflammatory Antidiarrheal
9	Patola[44]	Elaeosteric Acid Linoleic acid OleicAcid Colocynthin Hentriacontane	Anti-Oxidant Hepato-Protective Anti-Inflammatory
10	Masura[45]		Anti-Oxidant Anti-Inflammatory

The above mentioned Phyto constituents present in Trayantyadi Kashaya helped in arresting the production of inflammatory cytokine and regenerating Hepatocytes and might have helped in reduction in SGPT, SGOT, Total Bilirubin, Direct Bilirubin, Indirect Bilirubin values.

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DISCUSSION ON RESULTS

30 patients who have enrolled and completed the clinical trial were considered for assessing the results. The subjective parameters were assessed on 0th day and on 43rd day. The objective Parameters, LFT values and USG Abdomen findings were statistically assessed by comparing the Pre and Post test values.

SUBJECTIVE PARAMETERS

1.Anorexia

The drug effect was statistically highly significant with p value 0.000 in reducing Anorexia. Ruchya karma of Vibhitaki, Amalaki, Nimba and Katuki might have reduced Anorexia. Deepana Karma of Haritaki, Katuki, Patola and Pachana Karma present in Patola present in Patola might have corrected dooshita pachaka pitta and bodhaka kapha and might have reduced Anorexia.

2.Malaise/Fatigue

The drug effect was statistically highly significant with p value 0.001 in reducing the Malaise/Fatigue. The anti-oxidant Property present in the Trayanti, Haritaki, Vibhitaki, Amalaki, Katuki, Trivruth, Patola and Masura of Kashaya reduces the oxidative stress and might reduce Fatigue. The effect was probably due to Agni vriddhi caused by Deepaniya drugs like Haritaki, Katuki, Patola present in Kashaya leading to proper digestion and assimilation of the consumed food further facilitates the proper dhatuposhana leading to increase in the bala of the patient.

3.Nausea

The drug effect on Nausea was statistically highly significant with p value 0.001 in reducing the Nausea. This is probably due to Amapachana effect of Patola and Haritaki present in the Trayantyadi Kashaya.

4. Right upper quadrant abdominal pain

The drug effect on abdominal pain showed statistically significant with p value 0.005 result. This effect may be due to Shoolahara property of Trayanti present in kashaya. Gentiopicrin, Gentianine of Trayanti, Turpethin, Turpethinic acid of Trivrit has Analgesic property might have reduced the Right upper quadrant abdominal discomfort/pain.

OBJECTIVE PARAMETERS

The drug effect on SGPT, SGOT, Total Bilirubin, Direct Bilirubin, Indirect Bilirubin showed statistically highly significant result with p value 0.000 respectively.

Anti-Inflammatory Property of Gentiopicrine of trayanti, Chebulinic acid of Haritaki, Bellaric Acid of Vibhitaki, Ellagic Acid of Amalaki, Glycyrrhyzin of Yashtimadu, Turpethin of trivrit, Colocynthin of Patola ; Cytoprotective activity of Chebulinic acid of Haritaki & Ellagic Acid of Amalaki ; Immunomodulatory property of Kutkin of katuki and ; Hepatoprotective action of Gentiopicrine of trayanti, Chebulinic acid of Haritaki , Bellaric Acid of Vibhitaki, Ellagic Acid of Amalaki, Glycyrrhyzin of Yashtimadu, Turpethin of trivrit, Colocynthin of Patola , Kutkin of katuki and Nimbin of Nimba , might have helped in arresting the production of inflammatory cytokine and regenerating Hepatocytes and might have helped in reduction in SGPT, SGOT, Total Bilirubin, Direct Bilirubin, In-direct Bilirubin values.

The initial assessment of GGT, ALP, Total Proteins, Serum Globulin, and AG Ratio were within the normal limits. Acute condition was taken, in the present study, in acute condition the values of GGT, ALP, Total Proteins, Serum Globulin, and AG Ratio will be within normal Values.

In USG Abdomen, Combined effect of Virechana &Trayantyadi Kashaya effect was statistically Highly significant with p value 0.000. This may be due to Anti- Inflammatory of Gentiopicrine of trayanti, Chebulinic acid of Haritaki , Bellaric Acid of Vibhitaki, Ellagic Acid of Amalaki, Glycyrrhizin of Yashtimadu, Turpethin of trivrit, Colocynthin of Patola and Cytoprotective activity of Chebulinic acid of Haritaki & Ellagic Acid of Amalaki present in the drug. During the study period and follow up, abstinence was maintained by the patient 22 Patients completed follow up of 90 days. During the follow up there was no reoccurrence of all the symptoms. So, the study reveal that treatment is having sustained effect.

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CONCLUSION

The study demonstrated that the combined Ayurvedic intervention significantly improved clinical symptoms such as right upper quadrant pain, anorexia, nausea, and malaise. Additionally, ultrasonographic findings indicated positive changes in liver condition. Biochemical assessments revealed significant reductions in liver enzymes (SGOT, SGPT) and bilirubin levels (direct and indirect), highlighting the intervention's efficacy in enhancing liver function. However, no significant changes were observed in GGT, ALP, serum proteins, and albumin-globulin ratio. Overall, the study supports the therapeutic potential of Virechana followed by Trayantyadi Kashaya as an effective integrative treatment for Alcoholic Liver Disease.

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