Effect of Ayurveda Management on Liver Cirrhosis with Ascites-A Retrospective Cohort Study

B.R. Tubaki*, Saish C. Gawas, Himani Negi

Department of Kayachikitsa, Shri BMK Ayurveda Mahavidyalaya, A Constituent Unit of KLE Academy of Higher Education & Research, Belagavi, Karnataka, India

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ABSTRACT

Liver cirrhosis with ascites is a challenging medical condition. Ayurveda Clinical experiences suggest of favourable role but lacks evidence. In a Retrospective cohort study, hospital records of patients with liver cirrhosis and ascites diagnosed through medical ultrasonography, treated at in patient division, department of Kayachikitsa, Medical Research Facility of KLE Ayurveda Hospital Belagavi were screened. Records with Nitaya virechana procedure, minimum of 7 days of admission, proper documentation and meeting the other inclusion and exclusion criteria were selected for the study. Assessment were abdominal girth measurements at umbilicus, Xiphisternum to umbilicus measurement, Umbilicus to pubic symphysis measurement, weight, clinical global impression (CGI) scales (Severity, improvement and efficacy index), hemoglobin, liver function tests, Prothrombin time, INR and renal function tests. Fifty five case records met the methodological criteria of the study. Patients were suffering from stage 3, decompensated cirrhosis and Child-Turcotte-Pugh Score was in class C. Analysis of 15 days of interventions was carried out. Assessments were carried out at base line, 7th, 9th, 11th and 15th day of treatment. Interventions included nitaya virechana, oral medications, diet, salt and fluid restrictions. Ayurveda interventions resulted in significant improvement (p<0.001) at all time points in various parameters of abdominal measurements, weight, CGI scales, hemoglobin, liver function tests, prothrombin time, INR and renal function tests. Study showed complex Ayurveda interventions through nitya virechana, oral medications, diet, fluid and salt restrictions improve the clinical profile, liver function, renal function, prothrombin time, INR parameters in patients of ascites with decompensated cirrhosis and warrants further studies.

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1. Introduction

Liver cirrhosis is the end stage of many chronic liver diseases. It has compensatory and decompensatory phases. Compensated phase lasts for several years [1]. Decompensated cirrhosis leads to major complications including jaundice, variceal hemorrhage, ascites, or encephalopathy [2]. Ascites is the most common presentation. 50% of compensated cirrhosis develops ascites in 10 years of time [3] Ascites treatment requires hospitalization, can lead to life threatening complications and need liver transplantation. The development of ascites marks the onset of worsened prognosis and increased mortality. Cirrhosis within first year of diagnosis causes death in 15% and 40% will die in first 60 months [4], 10 yrs mortality is 34–66% [5]. Alcohol consumption, viral hepatitis B & C, metabolic syndrome related to obesity are the most common causes of cirrhosis. Liver cirrhosis is responsible for 1,70,000 deaths yearly in Europe [6]. Liver diseases frequency is increasing and huge increase in the liver disease burden is expected [3]. Health care costs of liver cirrhosis in United states is between 12 and 23 billion dollars annually [7]. Hepatic cirrhosis incidence in India could be high due to high prevalence of Hepatitis B & C, fatty liver disease and even increasing trends of alcohol intake. Cost of hepatic cirrhosis on quality of life, loss of productivity, medical expenses are high [8]. Treatments to stop progression from compensated to decompensated stage are being tried [9]. Liver transplantation is the only treatment in the end stage liver disease. Liver transplantation has high costs, high mortality and has paucity of organ donors.

In Ayurveda Ascites can be correlated to Jalodara. All Udara diseases (morbid abdominal disorder) ends up into Jalodara stage.
Ayurveda management protocol mainly aims in improving the Jatharagni (metabolism) and stimulating the hepatic function. Jalodara management includes nitya virechana (C.Chi.13.61), teekshna (strong, penetrating) drugs, kshara (alkali), gomutra (Cow’s urine), fluid restriction, milk, buttermilk, diet, oral medications and rasayana (rejuvenative) drugs etc (C.Chi.13). Nitya virechana is a variant of virechana procedure in which preoperative procedures like snehapan (Internal oleation therapy), swedana (sudation therapy) are not carried out. Virechana is done in lesser intensity and more frequency. However there is scarcity in evidences of Ayurveda management of liver cirrhosis with ascites. A retrospective study in which case records of a tertiary care Ayurveda teaching hospital known for successful management liver cirrhosis with ascites were reviewed. Attempt was made to analyze the hospital data, treatment algorithms, details of virechana procedure, prescription patterns, dietary considerations, clinical outcomes and biological assessments.

2. Materials & methods

2.1. Settings

Setting of the current study was a 300 bed tertiary care KLE Ayurveda hospital, Belagavi situated in North Karnataka, India. Hospital caters to 7.38 lakhs of urban population directly and also to patients of 10 districts of Karnataka and Maharashtra.

2.2. Patient cohort

All patients receiving care for liver cirrhosis with ascites were included. Cases were identified retrospectively by evaluating manually and/or computer searches of hospital and laboratory databases from 2014 to 31 October 2020. Searches were carried out on specific terms like Kamala, Udana, Jalodara, Alcoholic liver disease, Cirrhosis and Ascites. Sonologically confirmed case of liver cirrhosis with ascites and records of patients treated in patient section, department of Kayachikitsa for a minimum of 7 days were included.

Initial screening revealed 255 case records. Cases with adequate recording of abdominal measurements, interventions (with virechana), vitals monitoring, observations etc. were included. Patients with concomitant illness like diabetes mellitus, hypertension, cardiovascular disorders were excluded (n = 65). Institutional ethics committee approval was obtained for the study. (Reference no BMK/20/BRT/01 dated 25.11.2020).

2.3. Clinical and demographic data

Details of Socio demographic information along with the detailed case history, treatment history, habits, systemic and abdominal examinations, investigations, treatments administered, day to day observations, vitals examination, fluid input and output charts and adequate clinical notes were noted. Assessments noted were.

1. Abdominal measurements at umbilicus, 1 inch above and below the umbilicus, Xiphi sternum to umbilicus and umbilicus to pubic symphysis.
2. Body Weight.
3. Blood parameters including haemoglobin, total bilirubin, indirect bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), total protein, albumin, globulin, Albu-min globulin (AG) ratio, alkaline phosphatase, prothrombin time & INR (International normalized ratio), serum creatinine and blood urea.
4. Clinical global impression scale (CGI) (Severity, improvement, efficacy index) [11].

2.4. Ayurveda management details

In all patients Nitya virechan (Daily therapeutic purgation) was planned as it is the prime Ayurvedic intervention in ascites. Other oral medications used were mild purgative, diuretic, blood purifier and hepatoprotective. These includes herbo-mineral formulations, decoctions, water extracts of herbs, diet and lifestyle style management. Virechana dosage was planned to obtain avara shuddhi of (3–6 vega) and for Sroto and purisha shodhana (cleansing). On starting days (1–3 days) only purisha shuddhi and later (>4 days) samyak virechan laxanas were observed. Shodhan of purisha, Pitta and kapha was noticed and vata antiki was seen. After virechan, assessment was done on the basis of symptoms like hridaya shuddhi (feeling of clearness in chest), clarity in mind, senses and intellect, laghutva (body lightness), increase in thirst and appetite. Pattern of increment was decided by number of vega produced due to virechana. Dose producing 3–6 vega (purgation) with no signs of vata vruddh, debility, dehydrative symptoms was retained for the next day.

During the course, virechan dose was increased whenever there was decrease in virechan vega less than 3. Virechan dosage was decreased if patients develops more than 6 vega, weakness, vata vruddh. As the virechan days increased, virechan effect was decreased and to retain shodhan effect dose escalations were done.

Data showed, 8 patients had abdominal pain after continuous hirtaki chuma intervention for 3-4 days, hence one day rest was advised and again virechan was initiated by assessing the roga bala etc. factors. Average number of nitya virechan was 10.47 in patients with 15 days of hospital stay. Oral medications were administered post lunch and dinner (Table 4).

In Ascites diet plays an important role and diet restrictions were advised. Fluid restriction was up to 1.5 L per day. It included 500 ml milk per day, boiled rice water ad linitum, green gram soup measures 100 ml twice a day and medicinal decoctions and juices which was approximately 20–100 ml twice a day. Complete salt restricted diet was administered. Post Nitya virechana (purgation) diet was Peya (boiled rice water) during day time and at night Khichadi (Dish of rice and legumes) was prescribed in all patients. In 23.63% of patients white part of one whole egg twice a day was prescribed as per serum albumin results. Slow walking was advised not producing exertion or vata vrudh. Patients were advised to maintain psychologically relaxed state by do deep breathing exercise, music etc.

Conventional medication (diuretics- Spironolactone and furosemide) was continued in the initial days. Tapering and discontinuation was advised based on reduction of pedal edema, abdominal girth and increased urine out put. Tapering was observed in 96.3% of patients and it was discontinued in 80% of patients.

2.5. Statistical methods

Statistical analysis was carried using IBM SPSS version 25 (IBM Corporation, Chicago, Illinois, United States). Descriptive data is expressed in mean, standard deviation and percentages. Pre and post assessment was done with paired sample t test. Values are reported as mean ± standard deviation. All tests were considered statistically significant at p < 0.05.

3. Results

Total records extracted during the period of 7 years 10 months were 255. Two hundred records had incomplete documentation, lack of/vague/incomplete documentation of laboratory and sonological reports at the time of admission and discharge, lack of abdominal girth measurements, inadequate documentation of intervention, inadequate documentation of observations on day to
day basis etc. 55 patient’s data met the inclusion criteria. Virechana was the first preferred panchakarma procedure in patients fit for shodhan procedures. Treatments were planned according to roga, rogi bala (strength of disease and patient) and special precautions were taken to prevent increase of vata and decrease of patient’s strength. Hence patients did not suffer from any dehydration symptoms and had no disturbance to their daily functioning. Most of the patients had laboratory and sonological data at baseline but data at the end of treatment were limited. This could be due to satisfactory clinical improvements, leading to treatment discontinuation to avoid financial burden to patients by physicians, reluctance by patients to repeat the investigations, and even due to poorer economic conditions of the patients. In many records clinical improvements could not be substantiated with sonological and blood parameter levels, leading to treatment discontinuation to avoid financial burden to patients by physicians, reluctance by patients to repeat the investigations, and even due to poorer economic conditions of the patients. In many records clinical improvements could not be substantiated with sonological and blood parameter levels.

3.1. Patient characteristics

Patients characteristics: mean age (47 years), mean duration of the illness (3.5 months), male (94.5 %), and females (5.4 %), mean weight (64 kilograms). Alcohol history was found in all male patients. Mean abdominal girth at 1 inch above umbilicus was 91.9 cms, at umbilicus was 91.9 cms, and mean abdominal girth below 1 inch of umbilicus was 89.9 cms. Mean measurement from Xipi sternum to umbilicus was 22.6 cms and mean umbilicus to pubic symphysis measurement was 14.8 centimeters. Mean clinical global impression scale - severity was 5.5. Mean duration of hospital stay was 13.2 days. Number of case records with 7 days admission were 5, with 9 days stay were 9, 11 days admission was 1 and 15 days admission were 40.

All patients were sonologically diagnosed with ascites due to liver cirrhosis. Ascites fluid was mild to moderate. Alcoholic liver disease (ALD) was in 94% and Non ALD was in 5.4%. Mean alcohol history in patients were 8 years. Hospital records did not show patients with any serious complications such as hepatic encephalopathy, gastro intestinal bleeding, hepato renal syndrome etc. at the time of admission and even during the course of intervention. Other baseline characteristics were mean systolic blood pressure (129 mm of Hg), mean diastolic blood pressure (78 mm of Hg), and mean pulse rate (76 beats per minute) were in normative limits.

In blood variables at baseline (n = 55) mean hemoglobin was 9.77 gm %. Mean erythrocyte sedimentation rate (ESR) was 59.41 mm in 1st hour, mean total bilirubin was 5.29 mg/dl, mean direct bilirubin 2.28 mg/dl and mean indirect bilirubin was 3.0 mg/dl mean AST was 89.76 and mean ALT was 45.61 mg/dl. Mean total protein was 6.19 mg/dl, mean serum albumin was 2.57 mg/dl, mean globulin was 3.49 mg/dl and mean A/G ratio was 0.75. Mean alkaline phosphatase was 139.08 IU/L, mean serum sodium levels were 142.2 mEq/L, mean serum potassium was 3.52 mmol/L. Mean serum creatinine levels were 1.48 mg/dl, mean blood urea was 20.43 mg/dl. On evaluation of PT INR at baseline average prothrombine time was 14.80 s while its control was 13.72 s. Mean albumin was 3.0 mg/dl and mean albumin was 129 mm of Hg, mean diastolic blood pressure (78 mm of Hg), and mean pulse rate (76 beats per minute) were in normative limits.

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### Table 1

| S.No | Clinical Profile | Number and percentage (%) |
|------|------------------|---------------------------|
| 1    | Age (yrs)        | 47.03 ± 10.47             |
| 2    | Sex              | 52 (94.54%)               |
|      | Male             | 94.54%                    |
|      | Female           | 5.46%                     |
| 3    | Alcohol History in Years | 7.76 ± 5.72            |
| 4    | Duration of illness (In Months) | 3.57 ± 4.52  |
| 5    | Weight (Kgs)     | 63.99 ± 10.78             |
| 6    | Virechana drug-  |                           |
|      | Haritaki         | 46                        |
|      | Trivrit leha     | 6                         |
|      | Goarka           | 1                         |
|      | Milk             | 2                         |
| 7    | Virechan First dose |                          |
|      | Haritaki churna  | 14.23 ± 5.26              |
|      | Milk (In ml)     | 15.83 ± 2.04              |
|      | Goarka (In ml)   | 1500 ± 0                  |
| 8    | Virechana Mean dose |                        |
|      | Haritaki churna  | 16.75 ± 4.73              |
|      | Milk (In ml)     | 19.69 ± 2.83              |
|      | Goarka (In ml)   | 37.69 ± 9.49              |
| 9    | Anupana first dose (In ml) |                  |
|      | Milk             | 58.33 ± 19.46             |
|      | Goarka           | 30.71 ± 12.22             |
|      | Hot water        | 48 ± 7.74                 |
| 10   | Anupana mean dose (in mL) |                |
|      | Milk             | 55.83 ± 22.34             |
|      | Goarka           | 34.19 ± 10.75             |
|      | Hot water        | 49.85 ± 10.92             |
| 11   | Mean number of Virechana in patients |          |
|      |                 | 10.47 ± 3.23              |
| 12   | Mean number of virechana vega in patients |               |
|      |                 | 4.94 ± 1.32               |
| 13   | Mean Duration of patient stay (days) |                |
|      |                 | 13.21 ± 2.99              |
6.5 cms from the baseline. **Abdominal girth at umbilicus** showed reductions as follows: 7th day 2.56 cms, 9th day 3.37 cms, 11th day 4.74 cms and on 15th day it was reduced by 6.06 cms from baseline. **Abdominal girth below 1 inch of umbilicus** decrease at 7th day by 2.17 cms, 9th day 3.02 cms, 11th day 3.98 cms and by 15th day it was dropped by 5.46 cms. **Abdominal Girth from Xiphi sternum to umbilicus** decreased on 7th day by 2.07 cms, 9th day 2.43 cms, 11th day 3.06 cms and on 15th day it was 4.00 cms. **From Umbilicus to Pubic Symphysis** decline of 0.99 cms on 7th day, 1.15 cms on 9th day, 1.34 cms on 11th day and 1.69 cms decline is seen on 15th day from baseline (Table 2, Section A) (Fig. 2, Fig. 3).

3.2.2. Blood pressure and pulse

Interventions produced significant changes in Systolic blood pressure but not on diastolic blood pressure and pulse. Systolic blood pressure showed significant change at 7th, 9th and 15th day. There was a significant decrease compare to base line but were in the normative ranges (Table 2, Section A).

3.2.3. Body weight

There was gradual decrease observed in body weight. From baseline it reduced by 1.7 kg on 7th day, 2.1 kg on 9th day, 2.7 kg on 11th day and by 15th day it was reduced by 4.9 kg (Table 2, Section A) (Fig. 3).

3.2.4. Blood parameters

Ayurveda intervention produced significant increase in haemoglobin levels. Significant reduction in elevated liver function tests including total bilirubin, indirect bilirubin, AST, ALT, total protein, albumin, globulin, alkaline phosphatase, prothrombin time and INR values were observed. Interventions produced normalcy in few parameters like total protein, globulin and alkaline phosphatase. Renal functions including serum creatinine ($p = 0.04$) and...
blood urea (p = 0.03) levels showed significant decrease as a result of interventions. However they were still in the pathological range (Table 3, Section A).

3.2.5. Clinical Global impression scale

At baseline mean CGI severity of illness scale was 5.56 which was reduced on 7th day by 1.56, 9th day by 2.08, 11th day by 2.53 and by 15th day it decreased by 2.56 compared to baseline. CGI-Global improvement scale showed that mean improvement was 3 on 7th day, on 9th day it was improved by 0.29, on 11th day 0.70 and on 15th day mean improvement was by 0.94. CGI-Efficacy Index scale showed, mean score was 5.51 on 7th day which improved by 1.06 on 9th day, 3.34 on 11th day and improvement by 2.82 was seen on 15th day (Table 2, Section A) (Fig. 4).

3.2.6. Effect of Nitya virechan, Guduchyadi yoga, diet and life style on parameters

Intervention (n = 32) showed improvement similar to cumulative assessments (n = 55). Significant reductions in abdominal measurements such as at umbilicus, and 1 inch above and below the umbilicus, Xiphisternum to umbilicus and umbilicus to pubic symphysis measurements, body weight, systolic and diastolic blood pressures, pulse and Clinical global impression scale (CGI) (Severity, improvement, efficacy index) (Table 2, Section B). Blood variables (n = 10) assessment indicated that intervention produced significant increase in hemoglobin levels, Significant decrease in elevated liver function tests like total bilirubin, indirect bilirubin, AST, ALT, total protein, albumin, globulin, Alkaline phosphatase, prothrombin time and INR values were observed. Interventions produced
normalcy in few parameters like Globulin and Alkaline phosphatase. Renal functions like serum creatinine and blood urea levels showed trends of decrease but were non-significant and were in the pathological range. Improvements in most of the parameters were similar to the cumulative sample (Table 2, Section B and Table 3, Section B).

4. Discussion

The present study has shown that complex intervention with Nitya Virechana, oral medicaments, diet, fluid and salt restriction proved to be efficacious in the management of decompensated cirrhosis with ascites. It has shown reduction in abdominal girth measurements, body weight, clinical global impression scales of cirrhosis with ascites. It has shown reduction in abdominal girth proved to be efficacious in the management of decompensated cirrhosis with ascites. It has shown reduction in abdominal girth measurements, body weight, clinical global impression scales of cirrhosis with ascites. It has shown reduction in abdominal girth measurements, body weight, clinical global impression scales of cirrhosis with ascites. It has shown reduction in abdominal girth measurements, body weight, clinical global impression scales of cirrhosis with ascites. It has shown reduction in abdominal girth measurements, body weight, clinical global impression scales of cirrhosis with ascites.

All the patients were sonologically diagnosed case of liver cirrhosis with mild to moderate ascites. Patients had stage 3, decompensated cirrhosis [13] and Child-Turcotte-Pugh Score (CTP) [14] score (calculated through serum bilirubin, serum albumin, prothrombin time, severity of ascites, and grade of encephalopathy) was 10 and was in class C. In Class C, 1 year survival is observed in 45% and 2 year survival is observed in 38% cases [17]. Majority (94%) were due to chronic alcoholic liver disease. Patients were suffering from these symptoms since 3.5 months. More number of patients were between 45 and 50 years of age. All male patients (94.54%) had chronic alcoholic liver disease. Mean alcohol consumption history was 7.76 years.

Administration of Nitya Virechan (daily mild purgatives) with either haritaki churna (fine powder of terminalia chebula retz.), Trivruta leha (compound formulation of operculina turpethum Linn), Goarka (distilled product of cow’s urine) or milk can lead to fluid loss. These drugs works as osmotic and stool wetting agents. It

### Table 3

Effect on Haemoglobin, Liver and Renal function tests by Section A- Ayurveda interventions. Section B- Nitya virechan, Guduchyadi yoga, diet, lifestyle.

| S.No | Parameter (n = 15) | Base line | 15th day | P value |
|------|-------------------|-----------|----------|---------|
| 1.   | Hemoglobin (g/dL) | 9.54 ± 2.03 | 10.16 ± 2.04 | <0.001 |
| 2.   | Bilirubin- Total (mg/dL) | 4.78 ± 4.31 | 3.04 ± 2.3 | 0.006 |
| 3.   | Bilirubin- Direct (mg/dL) | 1.59 ± 0.94 | 1.43 ± 1.38 | 0.64 |
| 4.   | Bilirubin-Indirect (mg/dL) | 2.58 ± 1.89 | 1.58 ± 1.27 | <0.001 |
| 5.   | AST (IU/L) | 99.53 ± 68.52 | 61.92 ± 37.67 | 0.002 |
| 6.   | ALT (IU/L) | 45.61 ± 32.36 | 35.04 ± 16.47 | 0.01 |
| 7.   | Total Protein (g/dL) | 6.09 ± 1.34 | 6.51 ± 0.89 | 0.02 |
| 8.   | Albumin (g/dL) | 2.66 ± 0.59 | 3.16 ± 0.45 | <0.001 |
| 9.   | Globulin (g/dL) | 3.41 ± 0.89 | 3.53 ± 0.83 | 0.03 |
| 10.  | albumin/globulin ratio | 0.6 ± 0.14 | 0.71 ± 0.19 | 0.06 |
| 11.  | Alkaline phosphatase (IU/L) | 130.08 ± 61.65 | 104.33 ± 35.68 | 0.008 |
| 12.  | Prothrombine time (Seconds) | 15.10 ± 2.81 | 13.91 ± 2.31 | 0.01 |
| 13.  | INR (International normalized ratio) | 1.25 ± 0.26 | 1.16 ± 0.18 | 0.01 |
| 14.  | Serum creatinine (mg/dL) | 1.48 ± 0.80 | 1.33 ± 0.56 | 0.04 |
| 15.  | Blood Urea (mg/dL) | 37.07 ± 17.98 | 31.54 ± 13.41 | 0.04 |

### Table 3

Effect on Haemoglobin, Liver and Renal function tests by Section A- Ayurveda interventions. Section B- Nitya virechan, Guduchyadi yoga, diet, lifestyle.

| S.No | Parameter (n = 10) | Base line | 15th day | P value |
|------|-------------------|-----------|----------|---------|
| 1.   | Hemoglobin (g/dL) | 9.62 ± 1.79 | 10.21 ± 1.77 | <0.001 |
| 2.   | Bilirubin- Total (mg/dL) | 4.97 ± 4.62 | 3.13 ± 2.64 | 0.012 |
| 3.   | Bilirubin- Direct (mg/dL) | 1.64 ± 1.01 | 1.51 ± 1.47 | 0.75 |
| 4.   | Bilirubin-Indirect (mg/dL) | 2.63 ± 2.02 | 1.58 ± 1.36 | <0.001 |
| 5.   | AST (IU/L) | 100.33 ± 71.50 | 62.33 ± 39.32 | 0.003 |
| 6.   | ALT (IU/L) | 46.37 ± 35.46 | 34.87 ± 17.86 | 0.03 |
| 7.   | Total Protein (g/dL) | 6.5 ± 1.01 | 6.68 ± 0.85 | 0.10 |
| 8.   | Albumin (g/dL) | 2.7 ± 0.57 | 3.21 ± 0.41 | <0.001 |
| 9.   | Globulin (g/dL) | 3.46 ± 0.99 | 3.58 ± 0.92 | 0.03 |
| 10.  | albumin/globulin ratio | 0.58 ± 0.14 | 0.68 ± 0.19 | 0.15 |
| 11.  | Alkaline phosphatase (IU/L) | 132.75 ± 70.14 | 106.62 ± 39.35 | 0.04 |
| 12.  | Prothrombine time (Seconds) | 14.25 ± 2.05 | 13.25 ± 1.75 | 0.03 |
| 13.  | INR (International normalized ratio) | 1.22 ± 0.26 | 1.15 ± 0.18 | 0.04 |
| 14.  | Serum creatinine (mg/dL) | 1.58 ± 0.88 | 1.42 ± 0.58 | 0.13 |
| 15.  | Blood Urea (mg/dL) | 35.33 ± 21.31 | 31.50 ± 17.61 | 0.29 |
increases water content in gut by changing the fluid dynamics of mucosal cells. These drugs may change the fluid dynamics leading to impairment in water and electrolyte absorption of villous cells inhibiting Na+, K + - ATPase [15], resulting into draining of peritoneal fluid into gut through process of osmosis [16]. Virechan drugs are ushna (hot), tikshna (piercing quality), sukshma (reach up to minute part), vyavayi (spreads all over body), vikashi (flowing capacity) sara (flowing), anu (reaching to cellular level) & vicchha (scrapping and excising) and doshā sannghatahara (dismentaling compactness of dōsha) in nature (C.S.K.1.5). By this qualities, virechan drugs may have moved the peritoneal fluid to the intestines and then evacuation through rectal route. Haritaki (Terminalia chebula Retz.) contains anthraquinones [17] which is mild and gentle laxative in nature. Anthraquinones metabolize the active aglycones which by impairing epithelial cells, deploys its lenteive action leading to the modification in intestinal absorption, secretion and motility [18]. Trivruta (operculina turpethum Linn) contains Resin glycosides [19] which has aperient property of the purified resin glycoside fraction. It attributes to NF-κB activation in the colon resulting in increment of COX-2-mediated secretion of prostaglandins and leukotrienes.

### Table 4
Oral medications used in the study.

| S.No | Oral medications (Tinospora cordifolia Miers) 50 ml with Palatalakaturhinyadi, kashay (15 ml twice a day) | Frequency of use | Action |
|------|--------------------------------------------------------------------------------------------------|------------------|--------|
| 1.   | Guduchi swarasu (Tinospora cordifolia Miers) 50 ml with Patolakaturohinyadi kashay (15 ml twice a day) | 58%              | Rasayan effect on liver |
| 2.   | Decoction of Guduchi, trishala (compound formulation of Terminalia chebula Retz., Terminalia belleric Roxb., Emblica officinalis Gaertn.), nimba (Azadirachta indica A. Juss.), haridra, (Curcuma longa L.), vasa (Adhatoda vasica NEESS) kswath.50 ml twice a day | 58%              | Rasayan effect on liver, rakta pittahara |
| 3.   | Tab Amlycure DS. 1 tab twice a day.                                                              | 25.45%           | Rasayan effect on liver |
| 4.   | Kalamegha strong syrup (15 ml twice a day)                                                       | 25.45%           | Rasayan effect on liver |
| 5.   | Punarnava mandoor. 1 tab twice a day.                                                             | 21.81%           | Rasayan effect on kidney |
| 6.   | Patolakaturohinyadi kashay (15 ml twice a day)                                                    | 20%              | Rasayan effect on liver, rakta pittahara |
| 7.   | Mutrala kash (A Preparation of KLE Ayurveda Pharmacy Belagavi, Karnataka) (50 ml twice a day)      | 20%              | Rasayan effect on kidney |
| 8.   | Arogyavardhini Rasa. 1 tab twice a day.                                                           | 18.18%           | Rasayan effect on liver |
| 9.   | Decoction of Guduchi (Tinospora cordifolia Miers). Nimba patra (Azadirachta indica A. Juss.), Bhringraj (Eclipta alba Hassik.), Bhumyamalaki (Phyllanthus niruri Linn.) 50 ml twice a day | 14.54%           | Rasayan effect on liver, rakta pittahara |
| 10.  | Kalamegha strong and Kumaryasava (15 ml twice a day)                                              | 12.72%           | Rasayan effect on liver |
| 11.  | Yakrutaplihantaka Rasa. 1 tab twice a day.                                                         | 10.9%            | Rasayan effect on liver |
| 12.  | Kalamegro strong along with Patolakaturohinyadi kashay (15 ml twice a day)                        | 9.09%            | Rasayan effect on liver |
| 13.  | Bhrayatadi Kashaya (15 ml twice a day)                                                            | 7.27%            | Rasayan effect on kidney |
| 14.  | Decoction of Guduchi (Tinospora cordifolia Miers), Brahmi (Bacopa Monnieri Linn.), Bhringraj (Eclipta alba Hassik.), Bhumyamalaki (Phyllanthus. niruri Linn.), 50 ml twice a day | 3.63%            | Rasayan effect on liver, rakta pittahara, nootropick effect |
| 15.  | Punarnavasava (15 ml twice a day)                                                                  | 3.63%            | Rasayan effect on kidney, rakta pittahara |
| 16.  | Purnaraavasavat kashay (15 ml twice a day)                                                         | 3.63%            | Rasayan effect on kidney, rakta pittahara |
| 17.  | Koklaksham kashay (15 ml twice a day)                                                              | 3.63%            | Rasayan effect on kidney, rakta pittahara |
| 18.  | Kalamegha strong, Kumaryosava and Rohitakarishta (15 ml twice a day)                               | 3.63%            | Rasayan effect on liver, rakta pittahara |
| 19.  | Decoction of Guduchi (Tinospora cordifolia Miers), Purnaravva(Borhavia diffusa Linn.), Bhringraj (Eclipta alba Hassik.), Bhumyamalaki (Phyllanthus. niruri Linn.), 50 ml twice a day | 1.81%            | Rasayan effect on liver and kidney, rakta pittahara |
| 20.  | Katakakshadradi kashay (15 ml twice a day)                                                         | 1.18%            | Rasayan effect on kidney |
| 21.  | Soothekhar rasa. 1 tab twice a day.                                                                | 1%               | Rasayan effect on liver |
| 22.  | Tabat Redema. 1 tab twice a day.                                                                   | 1%               | Rasayan effect on liver, rakta pittahara |
| 23.  | Tapayadi loha. 1 tab twice a day.                                                                  | 1%               | Rasayan effect on liver |

![Fig. 4](image_url) Change in Clinical Global impression scales-Severity, Global improvement, Efficacy index.
PGE2 which further decreases AQP3 expression leading to purgative action by absorbing water from intestine to the blood stream [20]. Cow’s Milk has various qualities including guru (heavy), sara (spreading and flowing), pithivi, jala mahabhuta dominance, mild laxative, rasayana (regenerative), jeevana (nutritive), balya (strength promoting). Goarkha has purgative action because of its ushna (hot), tikshna (penetrating), sara (spreading and flowing) and bhedana (piercing) properties. Frequently used oral formulation was G. yoga and Guduchyadi kwatha. These formulations were derived from the clinical experiences of the departmental faculty. Other oral formulations were also used. These formulations and their ingredients can potentiate the rasayana effect on liver, kidney and nootropic, hepatotrophic action, rakta pitthara (bleeding and clotting indices), anti anaemic, correcting hypoproteinaemia and diuretic effects. These drugs are nirtikta (bitter) in rasa, laghu (light), dravashoshaka (dring up fluid content), kapha hara, rasayana (rejuvenation quality) in nature. Various studies have reported Punarnava (Boerhavia diffusa Linn.) to be effective in improving the urine formation, hepatoprotective and anti-inflammatory in both in vivo and in vitro studies [21,22]. Nimba (Azadirachta indica A. Juss.) leaf extract has hepatoprotective [23] effect as it contains phytochemicals such as Azadirachtin, Nimbidin, Nimbin, Nimbinin. Guduchi (Ficus cordifolia Miers.) has anti-inflammatory, immunomodulatory, hepatoprotective, antioxidant and antidiabetic effects. Bhringaraj (Eclipta alba Hassk.) has shown hepatoprotective effect. Bhumiyalaki (P. niruri Linn) [26] in animal model has shown to decrease hepatomegaly, visceral fat weight, serum total cholesterol, low-density lipoprotein, free fatty acids (FFAs), Alanine aminotransferases, aspartate aminotransferases, insulin concentration, homeostatic model assessment of insulin resistance (HOMA-IR), hepatic content of cholesterol, triglyceride, malondialdehyde, prevented fibrosis, and has anti NAFLD effect. Fluid and salt restriction is recommended in Ascites as it is a condition of increase of Apa mahabhuta, kleda and mala. Dietary items such as milk has balya, jeevaniya, rasayana, and is indicated in kshina (debilitated individuals). Green gram soup and egg white also have balya and jeevaniya effect. Through these actions improvement in hemoglobin, total proteins and globulins could have been produced.

Comprehensive clinical assessment was through clinical global impression Scale. This intervention shown significant (p < 0.001) improvements in severity of illness, global improvement and efficacy index. This may happened due to clinical improvement in the manifestations of liver cirrhosis with ascites, decrease in the abdominal fluid, effect of drugs like immunomodulatory, anti-inflammatory, hepatoprotective, anti-anemic, diuretic, rasayana effects. Improvement in clinical manifestations can help in improving the quality of life and decrease the risk of complications like spontaneous bacterial peritonitis (SBP).

Similarly a prospective study [27] with a complex polyherbal regimen inclusive of purgation with P. kurroo, piper longum Linn administration, punaranvadi kwath, compound powder, diet and life style modifications for 24 weeks showed improvement in liver child-pugh grade scores and clinical manifestations of liver cirrhosis with ascites. A case report [28] of sonologically diagnosed ascites with nitya virechana (therapeutic purgation daily) intervention with Abhayadi modaka, cow’s urine Sharapunkha Swaras, Punarnava Kwatha, Arogya vardhini and restricted diet for 3 months showed improvement in ascites, decrease in abdominal girth and clinical improvements. Another case report [29] of liver cirrhosis with ascites with intervention in the form of nitya virechana (hingu triguna taila with milk for 10 days), punaranvadi Kashaya, pan-chakola churna, gomutra haritaki, diet, vardhamaana pipalli regimen for 60 days showed decrease in ascites and no recurrence of ascites after 1 year of observation. The present study shows the evidences for use of different virechana, anupana, oral medications and diet in decompensated cirrhosis.

Study has many merits. Treatment regimen being practiced in the clinical scenario were analyzed and hence has a strong external validity. Thorough evaluation of Ayurveda physicians’ thought process, Ayurvedic assessment of the patient, critically analyzing the treatment algorithm, whole system approach, integrating Ayurveda treatment modalities (virechana, oral medication and diet). Assessments with abdominal measurements, weight, clinical global impression scales, liver function tests, renal function tests, prothrombin time and INR values are the notable components of the study. Study has several limitations including retrospective cohort study. Lack of histopathological assessments through liver biopsy is a lacuna and these would have given better biological action of interventions. Limited study duration (15 days) is relatively shorter period for this disease condition.

5. Conclusion

Complex Ayurvedic treatment regimen consisting of Nitya virechana, Ayurveda medications, diet, salt and fluid restrictions have shown beneficial effect in the management of decompensated stage of liver cirrhosis with ascites. Study gives leads in the Ayurvedic patient assessments, treatment principles, treatment algorithms, customization, medications and diets in liver cirrhosis with ascites. Proper documentation of all the observations, correlating the clinical changes with the appropriate biological investigations, maintaining the long term follow up records, recording the ayurveda interpretations etc needs to be strongly advocated to the Ayurvedic clinicians.

Conflict of interest

None.

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Author Contributions

B R Tubaki: Conceptualization, Methodology, Writing - Original draft preparation, Writing - Reviewing and Editing, Statistical analysis. Saish Gawas: Supervision, Data curation, Writing - Reviewing and Editing. Himani Negi: Supervision, Visualization, Data collection, Writing - Reviewing and Editing.

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