# A Clinical Study of the Effect of *Nishalauha choorna* in the Management of Hepatitis (*Kamala*)

**Jayawardhana N.D.N[1*], Tiwari S.K.[2]**

## Abstract

Hepatitis is an inflammatory condition of the liver which correlated with the *Kamala* in Ayurveda. *Kamala* is a *Rasa* and *Rakta dhatugata*, *Pittaja nanatmaja* and *Raktavaha srotodushtijanya vyadhi*. Although, there is a high prevalence of *Kamala*, minimum number of sufficient clinical studies constructed to find the effectiveness of the formulae on *Kamala*. Therefore, this clinical study was conducted to evaluate the therapeutic efficacy of *Nishalauha choorna* on *Kamala* patients. Randomly selected twenty-two patients who were attended to the Sir Sunderlal Hospital, India and suggestive of Kamala/Hepatitis in history, clinical signs and symptoms and laboratory investigations especially by doing hepatitis profile were included in this study. The prepared *Nishalauha choorna* 5gm given to those patients orally twice a day after meals with 5 ml bee honey and 2.5 ml Ghee for a period of three months and signs and symptoms and laboratory investigations were determined before and after the treatments. The efficacy of the *Nishalauha choorna* was evaluated by the improvement of signs and symptoms along with the laboratory findings. Statistical analysis was calculated by using mean and standard deviation, Kruskal Wallis H test, Friedman and Chi square test. The results showed markedly significant improvement of the symptoms such as status of *Agni* and *Ama* ($P<0.01$), abdominal pain, abdominal tenderness, burning sensation, easy fatigability, anorexia, clay colour stools, nausea, vomiting, fever and pruritus ($P<0.001$). And also, there was a significant influence ($p<0.001$) on SGOT, direct bilirubine, indirect bilirubine and serum alkaline phosphatase at the end of the three months of treatment period. Hence, it can be concluded that the *Nishalauha choorna* is effective in the treatment of Hepatitis/ *Kamala*.

**Keywords**: Hepatitis, *Kamala*, *Nishalauha choorna*

## Introduction

Hepatitis is an inflammation of the liver that may be due to various causes including a number of viruses called Hepatitis A, B, C, D, and E. The symptoms of hepatitis include yellowish discoloration in the eyes and the skin, nausea, vomiting, stomach pain, fever, extreme fatigue, muscle and joint pain and unexpected weight loss[1]. The Hepatitis A and E are most commonly transmitted by consuming food or water contaminated by feces from a person infected with hepatitis A and E. Hepatitis B, C, and D are transmitted through direct contact with infected body fluids, by contaminated blood in needles shared by drug users, by sexual activity with infected partners and infected mothers who pass it to their babies[2].

Hepatitis can be correlated with the Ayurvedic disease *Kamala*[3]. Clinically Jaundice can correlate with *Kamala* in Ayurveda. But the term *Kamala* denotes the clinical as well as pathological process rather than a sign or a symptom as in case of Jaundice. The characteristic features of *Kamala* include *Peeta* or *Haridra* (yellowish discolouration) are visualized on the *Netra* (eyes), *Tvaca* (skin) and

[1]*Department of Ayurveda, Institute of Indigenous Medicine, University of Colombo, Sri Lanka.*
[2]*Banaras Hindu University, [BHU], Varanasi-221005, U.P., India.*

*Correspondence: Dr. N.D.N. Jayawardhana, Unit of study in Kayachikithsa, Department of Ayurveda, Institute of Indigenous Medicine, University of Colombo, Sri Lanka. Email: namalayur@iim.cmb.ac.lk*

*Mutra* (urine) etc. These exceptionalities are recognized caused by *Rakta dushti* due to *Pitta vriddhi* in the disease of *Kamala*. Among the five types of *Pitta*, *Ranjaka pitta* is mainly contributed for the above said symptoms. The authentic Ayurvedic texts mentioned *Yakrt* (liver) is a seat of *Ranjaka pitta*.[4,5,6,7] And also mentioned that, due to vitiated *Ranjaka pitta* the whole body can be vitiated. This can be caused by excessive indulgence of *Pitta vriddhikara ahara* and *Viharana* by *Pittolbana* person, and this leads to vitiates *Agni* of the person. This vitiated *Agni* leading to vitiate *Pitta* and the person gets *Saama pitta*. This *Saama pitta* vitiates the *Rasa*, *Rakta* and *Maamsa dhatu* of the body and manifests *Kamala*[8]. *Kamala* is mentioned as *Rasa* and *Rakta dhatugata*, *Pitta nanatmaja* and *Raktavaha sroto dushtijanya vyadhi*. Two classification of *Kamala* stated in the texts, namely *Koshtashrita* and *Shakhashritha kamala* and *Shakhashrita kamala* is strikingly similar to medical and obstructive Jaundice in Western Medicine. Acute Viral Hepatitis is described the recent infection of the liver in a person who was healthy earlier that can be well correlated with *Kamala*.

Chronic active Hepatitis correlates with untreated complicated types of *Kamala* such as *Kumbha kamala*, *Halimaka*, *Lagharaka*/*Alasaka* and *Paanaki;* all of which refer to various stages of Decompensated Liver Disease.

Most of the causes of Hepatitis cannot be distinguished on the basis of the pathology but some do have particular features that are suggestive of a particular diagnosis. And although most of those carrying Hepatitis do not know they have it, they can unknowingly transmit it to others

and at any time in their lives, it can develop to kill or disable them[9,10].

Although, many Ayurvedic drugs have been indicated for management of *Kamala* in authentic texts of Ayurveda, very few numbers of drugs have been undergone extensive clinical and experimental research trials with special reference to Hepatitis. Therefore, further studies are needed to evaluate their role in the management of Hepatitis/ *Kamala*. Hence, this study has been designed to determine the effect of Ayurveda formula namely, *Nishalauha choorna* in the Management of Hepatitis (*Kamala*)[11].

## Material and Methods

### Study Site:

The patients attend to the O.P.D and I.P.D. of the Department of Kayacikitsa, Sir Sunderlal Hospital, Banaras Hindu University, UP, Varanasi during the period of August 2010 to November 2011.

### Inclusion criteria:

- Age between 11 – 70 years, both sex
- History, clinical signs and symptoms and laboratory investigations especially by doing Hepatitis profile suggestive of *Kamala*/Hepatitis.
- Patients willing to participate in the above trail and giving informed consent

### Exclusion criteria:

- Patients having history of chronic illness such as Diabetes Mellitus, Hypertention, Asthma, Chronic heart failure, Tuberculosis and AIDS etc.
- Patients who have developed gross swelling of the limbs, Portal Hypertension, Esophageal Varices, Bleeding disorders and Hepato-Renal Syndrome, Cirrhosis, Malignancy, Hepatic Encephalopathy and other systemic complications.
- Patients in whom, there is need of surgery (Obstructive Jaundice, liver transplant)
- Pregnant and lactating women.

### Sample size:

Randomly selected 22 patients having *Kamala* were selected to this study.

### Test Drug:

*Nishalauha choorna*

The test drug is prepared in the well reputed Ayurvedic drug manufacturing pharmaceutical company, Varanasi, Uttara pradesh, as per the classical reference of Caraka Samhitha, *Pandu roga adhikara*[11].

**Ingredients of the *Nishalauha choorna***

Table 1 mentioned the ingredients of *Nishalauha choorna.*

**Table 1: ingredients of the *Nishalauha choorna***

| | Ingredient | Scientific name | Part used | Amount |
|---|---|---|---|---|
| 1. | *Haritaki* | *Terminalia Chebula* | Fruit | 1kg |
| 2. | *Bibheetaki* | *Terminalia belerica* | Fruit | 1kg |
| 3. | *Àmalaki* | *Embelica Officinalis* | Fruit | 1kg |
| 4. | *HaridrÁ* | *Curcuma Longa* | Rhizome | 1kg |
| 5. | *Daruharidra* | *Berberis Aristata* | Stem | 1kg |
| 6. | *Kutaki* | *Picrorhiza Kurroa* | Rhizome | 1kg |
| 7. | *Lauha Bhashma* | Ferrous Oxide | | 1kg |

**Method of preparation of the *Nishalauha choorna***

All herbal ingredients were cleaned with the tap water and dried under the shade for 2 days. The mineral ingredient, *Lauha*, was purified according to the purifying methods mentioned in Ayurveda[12]. All ingredients were powdered by pounding in with mortar and pestle separately and sieved through 80 mesh sieve. Then weighted the required quantities of the ingredients and then mixed altogether well. Compound form of powder once again filtered with sieve and preserved in glass container.

**Management plan**

Prepared *Nishalauha choorna* advised to take 5gm twice daily after meals for a period of three months along with one tea spoon full (5 ml) bee honey and half tea spoon full (2.5 ml) Ghee[13].

**Assessment criteria**

Each and every patient was examined and assessed using standard proforma (before and after treatment). The first treatment period was recorded on 3rd day after the initial treatment and then after every 15 days up to 3 months was recorded.

**Subjective criteria**

Subjective criteria included the findings from chief complaints, history of present illness, history of past illness, drug history, family history and personal history.

**Objective criteria**

1. Physical examination: general examination, systematic examination according to Modern and Ayurveda
2. Laboratory Investigations- routing investigations: Hb %, WBC, Erythrocyte Sedimentation Rate (ESR), Renal Function Test (RFT), Liver Function Test **(**LFT), Fasting Blood Sugar (FBS) and USG Abdomen

**Parameters for the assessment of the overall effect of the trial drug**

Parameters for the assessment of the overall effect of the trial drug were used as mentioned in the table 2.

**Table 2: Parameters for the assessment of the overall effect of the trial drug**

| Overall effect | Hepatitis profile | Renal Function Test (RNF), Liver Function Test (LFT), Urine analysis | Signs and symptoms |
|---|---|---|---|
| Completely cured – 100% | Negative | Within Normal Limit | Completely Reduced |
| Marked improvement - 75 - 99% | Positive | Within Normal Limit | Completely Reduced |
| Moderate improvement- 51 - 74% | Positive | Above Normal Limit (Mild Difference) | moderately reduced |
| Mild improvement- 25 - 50% | Positive | Above Normal Limit (Moderate Difference) | mildly reduced |
| Unchanged – < 25% | Positive | Above Normal Limit (Large Difference) | not reduced |

**Statistical analysis**

Mean and Standard Deviation (SD) were used as parameters of before treatment (BT) and after treatment (AT) scores. Variables which are not followed normal distribution then non parametric test was used according to the suitability of data. In that Kruskal Wallis H test was used to test the

significant changes in the quantitative variables from base line to completion of the treatment and Friedman & Chi square Test for different follow ups for within group comparison. SPSS 16.0 for windows software was used for statistical analysis in this study.

## Results

### Demographic profile

Out of 22 Hepatitis patients, trial was conducted on 21 patients and one case dropped down from the treatment study in 4th report on due to incomplete follow up.

As per the Ayurvedic diagnosis, maximum number of patients of 15 were diagnosed as *Koshthashritha kamala* (68.2%) while 5 (22.7%) for *Shakhashritha kamala* and 2 for (9.1%) *Kumbha kamala*.

In accordance to the modern diagnosis, the incidence of viral hepatitis B recorded from 20 of patients (90.9%) appears to be more common in population as compared to other types of hepatitis. Among 22 cases, 2 patients (9.1%) had hepatitis A.

### Incidence of symptomatology in the therapeutic trial

Effect of trial drug on mean changes in status of *Ama, Agni, Koshtha* and Bowel habits mentioned in Table 3.

Effect of trial drug on mean changes in status of *Aruchi, Thila pishtha nibha mala, Udgara, Chardi, Deha kandu* and *Daha* mentioned in Table 4.

Table 5 indicates the effect of trial drug on clinical features of *Kamala.*

### Effect of trail drug on hematological and biochemical laboratory parameters

Effect of trail drug on hematological and biochemical laboratory parameters mentioned in the table 6 to 12.

**Table 3: Effect of trial drug on mean changes in status of *Ama, Agni, Koshtha* and Bowel habbits**

| Symptom and Signs | Grade | BT | % | AT | % | Within the group comparison Wilcoxon Signed Ranked Test BT vs. AT |
|---|---|---|---|---|---|---|
| *Ama* | *Nirama*/No | 0 | 0.0 | 13 | 61.9 | Z= 4.16 HS |
| | Mild | 4 | 18.2 | 6 | 28.6 | |
| | Moderate | 12 | 54.5 | 2 | 9.5 | |
| | Severe | 6 | 27.3 | 0 | 0.0 | |
| *Agni* | *Samagni* | 3 | 13.6 | 14 | 66.7 | Z= 3.02 P< 0.01 S |
| | *Mandagni* | 11 | 50.0 | 4 | 19.0 | |
| | *Vishamagni* | 8 | 36.4 | 3 | 14.3 | |
| | *Tikshanagni* | 0 | 0.0 | 0 | 0.0 | |
| *Koshtha* | *Samanya* | 6 | 27.3 | 18 | 85.7 | Z= 3.18 P<0.001 HS |
| | *Mrudu* | 6 | 27.3 | 2 | 9.5 | |
| | *Krura* | 10 | 45.5 | 1 | 4.8 | |
| Bowel | Normal | 4 | 18.2 | 16 | 76.2 | Z= 2.50 P<0.01 S |
| | Loose | 6 | 27.3 | 2 | 9.5 | |
| | Constipation | 9 | 40.9 | 1 | 4.8 | |
| | Loose/ Constipation | 3 | 13.6 | 2 | 9.5 | |

*BT: Before Treatment AT: After Treatment*

**Table 4**: **Effect of trial drug on mean changes in status of *Aruchi, Thila pishtha nibha mala, Udgara, Chardi, Deha kandu* and *Daha***

| Symptom | Grade | BT | Treatment period | | | | | AT | Group comparison Friedman & Chi-Square |
|---|---|---|---|---|---|---|---|---|---|
| | | | 1st visit | 2nd visit | 3rd visit | 4th visit | 5th visit | | |
| Aruchi (Anorexia) | Absent / Normal Appetite | 4 | 7 | 20 | 21 | 21 | 21 | 21 | 87.58 P<.001 HS |
| | Mild / 1 main meal + BF | 13 | 13 | 1 | 1 | 0 | 0 | 0 | |
| | Moderate / only Breakfast | 4 | 2 | 1 | 0 | 0 | 0 | 0 | |
| | Severe / only light Breakfast | 1 | 0 | 0 | 0 | 0 | 0 | 0 | |
| *Tilapishtha Sannibha Mala* (Clay colour Stools) | Normal Colour | 15 | 20 | 21 | 22 | 21 | 21 | 21 | 28.86 P<0.001 HS |
| | Light / Clay Colour | 7 | 2 | 1 | 0 | 0 | 0 | 0 | |
| *Udgara* (Nausea) | Absent | 11 | 19 | 21 | 21 | 21 | 21 | 21 | 49.81 P<0.001 HS |
| | Mild / Occasional | 8 | 2 | 0 | 1 | 0 | 0 | 0 | |
| | Moderate / Daily on/off | 2 | 0 | 1 | 0 | 0 | 0 | 0 | |
| | Severe / Continuously | 1 | 1 | 0 | 0 | 0 | 0 | 0 | |
| *Cardi* (Vomiting) | Absent | 17 | 19 | 22 | 22 | 22 | 22 | 22 | 20.84 P<0.002 HS |
| | Mild - Occasional | 2 | 3 | 0 | 0 | 0 | 0 | 0 | |
| | Moderate - 1-2 times /day | 1 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | Severe – > 2times / day | 2 | 0 | 0 | 0 | 0 | 0 | 0 | |
| *Jvara* (Fever) | Absent | 13 | 18 | 21 | 22 | 22 | 22 | 22 | 39.87 P<0.001 HS |
| | Mild 99-100$^0$F | 4 | 4 | 1 | 0 | 0 | 0 | 0 | |
| | Moderate 100.1-103$^0$F | 5 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | Severe > 103$^0$F | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| *Deha Kandu* | Absent | 13 | 15 | 21 | 21 | 21 | 21 | 21 | 41.21 P<0.001 HS |
| | Mild | 2 | 5 | 0 | 1 | 0 | 0 | 0 | |
| | Moderate | 4 | 1 | 1 | 0 | 0 | 0 | 0 | |
| | Severe | 3 | 1 | 0 | 0 | 0 | 0 | 0 | |

*BT: Before Treatment AT: After Treatment*

**Table 5: Effect of trial drug on clinical features of *Kamala***

| Symptom | Grade | BT | Treatment period | | | | | AT | Group comparison Friedman & Chi-Square |
|---|---|---|---|---|---|---|---|---|---|
| | | | 1st visit | 2nd visit | 3rd visit | 4th visit | 5th visit | | |
| *Haridra netra* (Yellowish discolouration of the eyes) | Absent/Normal | 0 | 3 | 6 | 9 | 13 | 14 | 17 | 479.43 P<0.001 HS |
| | Mild – Light yellow col. Sclera | 10 | 9 | 9 | 10 | 7 | 6 | 4 | |
| | Moderate – Mild < Severe | 8 | 5 | 5 | 1 | 0 | 1 | 0 | |
| | Severe – Dark yellow col. Sclera | 4 | 5 | 2 | 2 | 1 | 0 | 0 | |
| *Rakta pita mutrata* | Absent/Normal | 1 | 7 | 10 | 12 | 17 | 19 | 20 | 83.85 P<.001 HS |
| | Mild – light yellow colour and transparent | 11 | 7 | 7 | 7 | 3 | 2 | 1 | |
| | Moderate – cloudy / semitransparent | 5 | 3 | 1 | 1 | 0 | 0 | 0 | |
| | Severe – Dark yellow | 5 | 5 | 4 | 2 | 1 | 0 | 0 | |
| *Udara vedana* (Abdominal pain) | Absent | 10 | 15 | 20 | 22 | 21 | 21 | 21 | 54.13 P<0.001 HS |
| | Mild | 8 | 5 | 2 | 0 | 0 | 0 | 0 | |
| | Moderate | 3 | 2 | 0 | 0 | 0 | 0 | 0 | |
| | Severe | 1 | 0 | 0 | 0 | 0 | 0 | 0 | |
| *Udara shula* (Abdominal Tenderness) | Absent | 7 | 10 | 19 | 19 | 20 | 21 | 21 | 69.74 P<0.001 HS |
| | Mild | 12 | 9 | 2 | 3 | 1 | 0 | 0 | |
| | Moderate | 2 | 3 | 1 | 0 | 0 | 0 | 0 | |
| | Severe | 1 | 0 | 0 | 0 | 0 | 0 | 0 | |
| *Daha* (Burning Sensation) | Absent | 6 | 9 | 16 | 20 | 20 | 20 | 20 | 70.30 P<0.001 HS |
| | Mild / Occasional | 13 | 9 | 5 | 1 | 0 | 1 | 1 | |
| | Moderate / Daily on/off | 1 | 3 | 0 | 1 | 1 | 0 | 0 | |
| | Severe / Continuously | 2 | 1 | 1 | 0 | 0 | 0 | 0 | |
| *Daurbalya* (Fatigability) | Absent | 6 | 15 | 20 | 21 | 20 | 20 | 20 | 71.01 P<0.001 HS |
| | Mild | 7 | 5 | 1 | 0 | 0 | 0 | 1 | |
| | Moderate | 7 | 1 | 0 | 0 | 0 | 1 | 0 | |
| | Severe | 2 | 1 | 1 | 1 | 1 | 0 | 0 | |

*BT: Before Treatment AT: After Treatment*

**Table 6: Effect of trial drug on hepatitis profile**

| Hepatitis profile | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ***Koshtasrita kamala*** | | | ***Shakasrita kamala*** | | | ***Kumba kamala*** | | |
| **BT** | **AT** | **Improve %** | **BT** | **AT** | **Improve %** | **BT** | **AT** | **Improve %** |
| 15 | 14 | 6.7 | 5 | 5 | 0.0 | 2 | 2 | 0.0 |

*BT: Before Treatment AT: After Treatment*

**Table 7: Effect of trial drug on hepatomegaly**

| **Clinical feature** | **Grade** | ***Koshtasrita kamala*** | | ***Shakasrita kamala*** | | ***Kumbha kamala*** | | **Total BT** | **Total AT** | **Within the group comparison Friedman &Chi-Square Test** |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **BT** | **AT** | **BT** | **AT** | **BT** | **AT** | | | |
| Hepatomegaly | Not palpable | 6 | 15 | 2 | 5 | 0 | 0 | 8 | 20 | Z= 3.50 P<0.01 HS |
| | Mild / < 2 cm | 8 | 2 | 3 | 0 | 0 | 1 | 11 | 3 | |
| | Mod - >2 cm – <5 cm | 1 | 0 | 0 | 0 | 2 | 0 | 3 | 0 | |
| | Severe >5 cm | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Spleenomegaly | Not palpable | 13 | 15 | 2 | 5 | 0 | 0 | 15 | 20 | Z= 2.45 P<0.05 S |
| | Mild | 2 | 0 | 3 | 0 | 1 | 1 | 6 | 0 | |
| | Moderate | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | |
| | Severe | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

**Table 8: Effect of trial drug on haemoglobin percentage (Hb%)**

| **Clinical parameter** | **BT** | **AT** | **Within the group comparison Paired 't' test BT - AT** |
|---|---|---|---|
| Hemoglobin (gm/dl) Mean ±SD | 8.88 ± 1.75 | 9.87 ± 1.23 | 0.95± 0.89 t = 4.86 p<0.001 |
| Total Leucocytes Count / TLC Mean ±SD (per $mm^3$) | 8415.45 ± 1682.74 | 8239.81 ± 1074.46 | + 160.00 ± 1377.60 t = 0.53p>0.05 |

*BT: Before Treatment AT: After Treatment*

**Table 9: Effect of trial drug on Liver enzyme (SGPT, SGOT), Total bilirubin level, Direct bilirubin level, Indirect bilirubin level**

| Clinical Parameter | BT | Treatment period | | | | | AT | Within the group comparison Paired 't' test BT vs. AT |
|---|---|---|---|---|---|---|---|---|
| | | 1st visit | 2nd visit | 3rd visit | 4th visit | 5th visit | | |
| SGPT/ALT (IU) | 254.8 ± 222.34 | 226.18 ± 237.15 | 185.45 ± 218.57 | 128.95 ± 151.73 | 76.38 ± 73.94 | 61.33± 57.58 | 50.62 ± 39.87 | 194.62 ± 188.20 t = 4.74 p<0.001 |
| SGOT/AST (IU) | 178.36 ± 142.26 | 141.14± 130.97 | 106.36 ± 99.57 | 70.45 ± 50.82 | 51.38± 36.70 | 41.95 ± 28.40 | 37.76± 22.70 | 142.81 ± 127.45 t = 5.14 p<0.001 |
| Total Bilirubin Level (mg/dl) | 4.16 ± 3.09 | 3.69±3.17 | 2.80 ± 2.92 | 2.16± 2.07 | 1.53 ± 1.28 | 1.31± 0.64 | 1.17± 0.51 | 2.74± 2.46 t = 5.10 p<0.001 |
| Direct Bilirubin Level (mg/dl) | 2.83 ± 2.24 | 2.37± 2.16 | 2.18 ± 2.40 | 1.63± 1.66 | 1.17 ± 0.96 | 1.00± 0.35 | 0.92 ± 0.38 | 1.73 ± 1.86 t = 4.28 p<0.001 |
| Indirect Bilirubin Level (mg/dl) | 1.33 ± 1.11 | 1.32 ± 1.13 | 0.61± 0.66 | 0.53 ± 0.50 | 0.36± 0.44 | 0.31 ± 0.33 | 0.25± 0.22 | 1.00± 0.97 t = 4.73 p<0.001 |

*BT: Before Treatment AT: After Treatment*

**Table 10: Effect of trial drug on liver enzyme in Ayurveda diagnosis of *Kamala***

| Clinical parameter | Investigation period | *Koshtasrita kamala* | *Shakasrita kamala* | *Kumba kamala* |
|---|---|---|---|---|
| (SGPT/ALT) | **BT** | 241.60 ± 191.02 | 130.40 ± 76.61 | 665.00 ± 295.57 |
| | **AT** | 48.87 ± 37.08 | 34.80 ± 5.89 | 156.00 ± 0 |
| SGOT/AST | **BT** | 176.53 ± 116.68 | 104.80 ± 63.40 | 376.00 ± 345.07 |
| | **AT** | 34.40 ± 13.24 | 30.80 ± 6.57 | 123.00 ± 0 |
| Total Bilirubin | **BT** | 3.47 ± 2.03 | 3.16 ± 0.81 | 3.00 ± 0 |
| | **AT** | 1.09 ± 0.29 | 1.04 ± 0.37 | 1.19 ± 3.18 |
| Alkaline Phosphatase (mg/dl) | **BT** | 196.87 ± 50.61 | 170.60 ± 52.69 | 399.00 ± 77.78 |
| | **AT** | 181.00 ± 30.41 | 161.00 ± 41.45 | 280.21 ± 34.67 |

*BT: Before Treatment AT: After Treatment*

**Table 11: Effect of trial drug on Serum alkaline phosphatase, Total protein, Serum albumin, Serum globulin, Serum urea, Serum creatinine, Fasting blood sugar in the patients with *Kamala***

| Clinical parameter | Mean ±SD | | Within the group comparison Paired 't' test BT - AT |
|---|---|---|---|
| | BT | AT | |
| Serum Alkaline Phosphates (mg/dl) | 209.27 ± 80.11 | 180.95 ± 39.76 | 21.90 ± 46.22 t = 2.17p>0.05 |
| Total Protein (g/dl) | 6.76 ± 0.98 | 7.02 ± 0.49 | 2.33 ± 0.94 t = 1.14p>0.05 |
| Serum Albumin | 3.98 ± 0.95 | 4.27 ± 0.61 | 2.05 ± 0.84 t = 1.11p>0.05 |
| Serum Globulin | 2.78 ± 0.69 | 2.76 ± 0.39 | 2.86 ± 0.70 t = 0.19 p>0.05 |
| Serum Urea | 37.60 ± 12.99 | 33.67± 5.10 | 2.57 ± 10.38 t = 1.14p>0.05 |
| Serum Creatinine(mg/dl) Mean ±SD | 1.34 ± 0.22 | 0.90 ± 0.14 | 1.26 ± 0.30 t = 0.19 p>0.05 |
| Fasting Blood Sugar (FBS) | 93.36 ± 22.26 | 92.19 ± 9.06 | 0.67 ± 20.86 t = 0.15p>0.05 |

*BT: Before Treatment AT: After Treatment*

**Table 12: Comparison of overall effect**

| Total | | Unchanged | | Mild Improvement | | Moderate Improvement | | Marked Improvement | | Completely cured | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No | % | No | % | No | % | No | % | No | % | No | % |
| ***Koshthashritha kamala*** | | | | | | | | | | | |
| 15 | 23.0 | 0 | 0 | 0 | 0 | 6 | 9.4 | 8 | 12.5 | 1 | 1.6 |
| ***Shakhashritha kamala*** | | | | | | | | | | | |
| 5 | 7.8 | 0 | 0 | 0 | 0 | 2 | 3.1 | 3 | 4.7 | 0 | 0 |
| ***Kumbha kamala*** | | | | | | | | | | | |
| 2 | 3.1 | 0 | 0 | 0 | 0 | 1 | 1.6 | 0 | 0 | 0 | 0 |

Completely cured result was found in only 1 case (4.56%). Out of 22 patients 11 cases (50%) patients were showed marked improvement. Moderate improvement of the trial drug was observed in 40.9% of cases.

**Discussion**

The entire range of digestive and metabolic activity of the body takes place with the help of biological fire of the body called *Agni*. *Ama* is a condition due to undigested or unmetabolised food formed as a result of abnormality in *Agni*. In this clinical study

with *Nishalauha choorna*, there was highly significant ($p<0.001$) improvement can be seen in status of *Agni* and *Ama* before and after the treatment within the treated group. In addition to that, the study was observed a highly significant and rapid symptomatic improvement in the scores for symptoms such as *Udara vedana* (abdominal pain), *Udara shula* (abdominal Tenderness), *Daha* (burning sensation), *Daurbalya* (easy fatigability), *Aruci* (anorexia), *Tilapishtha sannibha* (clay colour Stools), *Udgara* (nausea), *Chardi* (vomiting), *Jvara* (fever) and *Deha kandu* (pruritus).

Although the exact mechanism of this herbal formulation on liver function and body metabolism is not yet clearly know. But in this study, significant reduction of SGPT/ALT, SGOT/AST, total bilirubin level, direct bilirubin level, and indirect bilirubin level can be seen. Therefore, these results can be suggested that this treatment might reduce hepatic inflammation, perhaps by masking viral antigens and thereby reducing host mediated cell damage.

There were no clinically significant alterations in hematological and other biochemical safety parameters such as WBC, Serum urea, Serum creatinine and FBS levels, as compared to pretreatment values and also there were no clinically significant abnormal laboratory investigative findings, either observed or reported, during the entire study period.

Due to dominant *Tikta rasa* of the *Nishalauha choorna,* few patients were complaint the unpleasant palatability induced nausea and vomiting in mild in nature. And there were no any adverse effects were occurred during the trial period of the test drug.

## Conclusion

According to the critical Ayurvedic and modern review; *Kamala* can be identified as an example for metabolic disorders which is comparable to the most pertinent infectious disease Hepatitis and several types of Hepatitis can be correlated with *Kamala roga*. In the light of the results obtained this study proved the fact that *Nishalauha choorna* has been immensely effective and safe Ayurvedic drug for *Kamala roga*. More clinical implementations with large scale of population with time compliancy are important to find the more accurate conclusion.

## Reference

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