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Research Article

# A CONTROLLED CLINICAL STUDY ON ROLE OF "*DHATRI LOHA YOGA*" IN *KAMALA* WITH SPECIAL REFERENCE TO HYPERBILIRUBINAEMIA

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**ABSTRACT**

Ayurved system mainly deals with digestion and associated metabolic methods. Liver i.e. *Yakrita* is the *Moolasthana* of *Pachak Pittas*, *Raktavaha strotasa*. Which we can correlate with Hepatobiliary system. Disturbance or diseases of hepatic system leads to mortality all the way through failure of remaining systems of our body. *Kamala* is one of the most important and specified disease of *Yakrita* which can be correlated with Hyperbilirubinemia or Jaundice.

Hyperbilirubinemia is a primary sign of disturbed Liver function. Liver disease is 8th leading cause of death worldwide. 50% of patients with Liver cirrhosis and 70% with cirrhosis plus alcoholic hepatitis die within 48 months. Overall, cirrhosis is the 4th leading cause of death. The overall mortality of acute viral hepatitis is 0.5% under the age of 40 yrs. and 3% in patients over 60 yrs. In which mortality rate of HAV and HEV is 0.5%, HBV is less than 2% and that of HCV is 0.5 -1%. Most of the patients develop chronic infection after acute hepatitis which continues for lifetime. Taken as a whole Hepatitis not only disturbs mental, physical health of patient but also social, economical, cultural and family life of a person.

In present study *Dhatri Loha Yoga* from Ayurvedic granthas tested along with proven efficient drug *Kutki* over *Kamala* (Hyperbilirubinemia). *Dhatri Loha Yoga* is a combination of drugs which directly deals with bilirubin metabolism. *Dhatri LohaYoga* significantly reduces symptoms of *Kamala* upto 94.2 % which is very favorable. It shows reduction in Sign, Symptoms, and Specific biochemical markers like SGPT, SGOT, and Serum Bilirubin. From the statistical analysis through Chi-square Test the two-sided P value is < 0.0001, Thus *Dhatri loha yoga* is extremely significant in the management of *Kamala* and regulating bilirubin metabolism.

**KEYWORDS:** *Dhatri Loha Yoga,* Hyperbilirubinemia, *Kamala*, Liver function Test.

## INTRODUCTION

Ayurveda (science of life) is one of the branch of Vedas. The system has been descended through various gods & *Rishis* who in turn had given it to various scholars in the form of *Samhita Granthas*. In *Samhitas* it has been said that *Tridosha* - *Vata*, *Pitta* & *Kapha* are the main constituent of the body and when they get vitiated they causes the disease in our body. According to that one of the diseases is described in Samhitas i.e. *Kamala* which is caused by vitiated *Pitta dosha*.

*Kamala*[1] is one of the prominent conditions which attract attention of modern day student of medicine as it is seen frequently in various forms today. Though the description of disease is not elaborate, basic principles of aetiopathology, symptomatology & management are described fully in *Samhitas*. There are two types of *Kamala* described in Charaka samhita *Shakhashrita Kamala* i.e. *Aalpapitta Kamala* or *Rudhaapatha Kamala* and *Koshthashakhashrita Kamala* i.e. *Bahupitta Kamala.*

According to that Both types of *Kamala* can be correlated with Hyperbilirubinaemia[6] or Jaundice. There are many mechanisms which causes Jaundice as follows - 1. Increased production 2. Impaired excretion 3. Hepatocellular Jaundice 4. Cholestasis. As described above hepatocellular Jaundice is one of the serious conditions of liver diseases. There are so many causes of hepatocellular Jaundice, like viral infections, alcohol, drug toxicity, obesity, pregnancy. But viral hepatitis & alcoholic hepatitis are two major problems in India. The people India are living in congested places in bad sanitation, eating roadside fast-food, junk foods, drinking polluted water that's why prevalence of viral hepatitis in India is so high.

The overall mortality of acute viral hepatitis is 0.5% under the age of 40 yrs. and 3% in patients over 60 yrs. In which mortality rate of HAV and HEV is 0.5%, HBV is less than 2% and that of HCV is 0.5 -1%. Most of the patients develop chronic infection after acute hepatitis which continues for lifetime. Many patients develop cirrhosis & progress to hepatocellular carcinoma. Along with viral hepatitis alcoholism and alcoholic liver disorder is one of most leading disease in India.

In modern medical sciences, there is no conventional line of treatment regarding hepatitis and many modern medicines can damage the liver. At this stage Ayurveda can provide suitable treatment for jaundice or "*Kamala*" and with the help of Ayurveda we can reduce the duration of illness and prevention of the

complications also. Ayurveda has described various drugs & preparations for the treatment of "*Kamala*".

" *Dhatri Loha Yoga*[2]", which having common and unique notation part as *Phalashruti* in different Ayurved literatures. Properties of *Dhatri Loha Yoga* are *Pitta*, *Rakta*, *Mansa shodhana*, *Yakritagamitva*. This is helpful to alleviate factors responsible for *Samprapti*. As drug is having property *Yakritgamitva* it is helpful to alleviate *Dushti* of *Moolasthana* i.e. *Yakrita*.

**MATERIALS AND METHODS**

**AIMS:** 1. To study efficacy of *Dhatri Loha Yoga.*

**OBJECTIVES**

1. To study the clinical features and details of '*Kamala*' along with hyperbilirubinemia.
2. To evaluate effect of *Dhatri Loha Yoga* in *Kamala.*
3. To compare the efficacy of *Dhatri Loha Yoga* in *Kamala* with established drug *Kutaki Choorna.*

The methodology adopted considering to main objectives. 40 patients were studied, categorized in two groups randomly, with total follow up of 21Days. After diagnosis patient were advised to take drug for 21 days.

**Study type-** Prospective open randomized study.

**Selection of cases**

Randomly cases of *Kamala*, specifically Hyperbilirubinemia were selected. Follow-up assessment of every patient was done by specially prepared case record forms, to meet all baseline requirements. At each follow up signs and symptoms were recorded.

**Inclusion criteria –**

Case selection was done as follows-

Age – 17 to 60 yrs Sex – Both sexes

Patients – Having raised serum bilirubin (> 3 mg/dl)

Patients – Having signs and symptoms of *Kamala* uncomplicated patient

**Exclusion criteria –**

- Age below 17 yrs and above 60 yrs
- Known cases of HIV infection/ AIDS
- Cases of liver abscess, liver cirrhosis, HBsAg positive and known case HIV Positive.
- Patients having malignancy
- Patients in acute alcohol withdrawal state, intoxication, hepatic encephalopathy
- Serum bilirubin more than 20 mg/dl
- Hyperbilirubinaemia due to congenital causes, Drug toxicity, AKT.
- Obstructive pathology

**Drug preparations**

The drug '*Dhatri Loha Yoga*' was prepared as per reference of *Yogaratnakarsamhita*[2], *Bhaishajya-ratnavali*[3].

Standardization was done in standard pharmacy.

***Dhatri Loha Yoga*[4]**

Duration-21 days

Dose - 5gm twice a day

***Anupana–****Madhu, Sharkara* and *Ghrita* in unequal quantity.

**Time of administration –** During meals in the morning & evening (*Samana Kala*)

**Diet –** Specific diet like *Khichadi, Mug-dal*

**No. of patients –** 20 patients

***Kutaki Choorna* –** Control group

**Duration-**21 days

**Dose -** 5gm twice a day

***Anupana* –** Lukewarm water.

**Time of administration –** During meals in the morning & evening (*Samana Kala*).

**Follow up -** For symptomatic improvement every 7 days follow up was done.

Laboratory follow up was performed weekly in the same manner for 3 weeks.

**Case record forms & trial procedure**

Case record forms (CRF) has been described after criteria of diagnosis confirmed, according to our requirements containing age, sex, address, economical status, place of birth, case registration number etc.

- Investigations & systemic examination done along with that

- Symptomatic assessment done on grade scale, severity & present/absent.

- *Ashthavidha, Dashavidha & Strotasaparikshana* was done according to Ayurveda

**Investigations**

1. Liver Function Test [5, 7] – SGPT (ALT) – weekly, SGOT (AST) – weekly, Serum bilirubin level –weekly

2. Urine for – Bile salt and Bile pigment – weekly

3. Serum protein, Albumin, Alkaline Phosphate – at the start and end of study.

4. USG Abdomen – at the start of the study

5. Other investigations – Haemogram, ESR, RFT's, Lipid profile, BSL - at the start and end of the study

- HIV, VDRL, HBsAg - at the start of the study.

6. Stool examination – Routine and microscopic was done as per requirement

**Parameters of assessment**

1. Overall relief was checked on objective & subjective measures.

   Subjective measures were graded in the form of mild/moderate/severe.
2. All signs & symptoms were assessed.

**Subjective assessment**

| | | |
|---|---|---|
| **1.** | ***Netra Pitata*** | |
| | Absent | 0 |
| | Mild | 1 |
| | Can be seen in Sunlight | 2 |
| | Can be seen without Sunlight also | 3 |
| **2.** | ***Peet Mutrata*** | |
| | Normal urine colour | 0 |
| | Yellowish coloured urine | 1 |
| | Dark yellow coloured urine | 2 |
| | High coloured urine | 3 |

| | | |
|---|---|---|
| **3.** | ***Yakrita Vrudhhi*** | |
| | Absent | 0 |
| | 1 finger | 1 |
| | 2 finger | 2 |
| | 3 finger ++ | 3 |
| **4.** | ***Jwara*** | |
| | Absent | 0 |
| | Temp.99-100 degree F | 1 |
| | Temp.100-102 degree F | 2 |
| | Temp. above 102 degree F | 3 |
| **5.** | **Chhardi (Vomiting)** | |
| | No vomiting | 0 |
| | Less than 3 episodes | 1 |
| | 3-6 episodes per day | 2 |
| | More than 6 episodes per day | 3 |
| **6.** | ***Sadana* (*Anganam anutsaha*)** | |
| | No weakness | 0 |
| | Weakness not disturbing daily routine work | 1 |
| | Weakness disturbing daily routine work | 2 |
| | Weakness required complete bed rest | 3 |
| **7.** | ***Daha*** | |
| | Absent | 0 |
| | *Daha* tends *Trishna* (Thirst) | 1 |
| | *Daha* tends *Murcha* (Unconsciousness) | 2 |
| | *Daha* tends *Pralapa* (Irrelevant talk) | 3 |
| **8.** | ***Twaka Pitata*** | |
| | Absent | 0 |
| | mild | 1 |
| | Can be seen in Sunlight | 2 |
| | Can be seen without Sunlight also | 3 |
| **9.** | ***Avipaka*** | |
| | Normal stool (motions) | 0 |
| | Heaviness in the Abdomen | 1 |
| | Heaviness with sticky/ hard stool | 2 |
| | Heaviness with constipation more than 2 days | 3 |
| **10.** | ***Udarashoola*** | |
| | Absent | 0 |
| | Mild | 1 |
| | Moderate | 2 |
| | Severe | 3 |
| **11.** | ***Aruchi* (Anorexia)** | |
| | Normal | 0 |
| | Less desire to eat | 1 |
| | Less desire to eat with nausea | 2 |
| | Less desire to eat with severe nausea | 3 |

**Stool colour**

To evaluate effect on Yellowish Discoloration of stool, system adopt as present or absent as visual colour assessment faint yellow to too dark brownish yellow colour (0-3). Whitish stool colour also considered as grade 3.

**Objective Assessment**

As stated earlier, the patients of *Kamala* were assessed objectively by laboratory methods on the basis of values of liver function tests like SGOT, SGPT, Serum Bilirubin (total) and urine examination for the presence/ absence of bile salts, bile pigments, on every 7th day of the trial. Serum proteins, serum albumin, alkaline phosphatase were performed before the start and end of the study. USG abdomen was done before the start of the study.

Urine bile salt & bile pigment can be evaluate as gradation 3+, 2+, 1, 0.

**Dropouts**

The patient who did not continue the drug for 3 weeks were dropped out

**Assessment of drug response**

Overall assessment of drug response was done on following basis-

1. Duration of the disease
2. Severity of the disease
3. Effect of overall health during trial of the drug
4. Clinical response & changes in abnormal laboratory findings

**Total effect of Therapy**

Percentage of relief in symptoms and signs with respect to each of the patient will be as follows and will be classified as per definition of cured, markedly improved, Improved and Unchanged.

The criteria described by Thatere A.A. (2003 -04) in his P.G.Thesis submitted to Nagpur University is considered.

**Cured**

Complete relief in signs and symptoms along with certain laboratory parameters will be considered as cured.

**Markedly Improved**

50% or more than 50% relief in the signs and symptoms of thepatients along with certain definite changes in physical and biochemical parameters will be considered as markedly improved.

**Improved**

25% to 50% relief in the signs and symptoms as mentioned in the criteria of the assessment will considered to be improved.

**Unchanged**

The patient who doesn't have any relief in sign, symptom and laboratory investigations will be considered as unchanged. Along with this the patient exhibiting improvement less than 25% will also kept in this category.

**L.A.M.A.**

Those patients who lefts the treatment before advised duration or who didn't followed instruction about the study will be considered as left against medical advice (L.A.M.A.).

**OBSERVATION & RESULTS**

After completion of duration 21 days, all the patients of this series were explored for investigations, which were carried out before the start of treatment. The status of all the symptoms & signs were also noted down after completion of treatment. Thus the change in the status of symptoms, sign & investigations were recorded. The history recorded in this study on case record form, revealed the facts & findings which are presented herewith in the tabular form.

**Table 1- Age wise distribution of patients of *Kamala***

| Sr. No. | Age Group (Yrs) | No. of Pt.Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | 16 - 35 | 7 | 35 % | 9 | 45 % |
| 2 | 36 – 45 | 8 | 40 % | 6 | 30 % |
| 3 | 46- above | 5 | 25 % | 5 | 25 % |

**Table 2: Showing Sex wise distribution of patients**

| Sr. No. | Sex group | No. of Pt. Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | Male | 12 | 60 % | 15 | 75 % |
| 2 | Female | 8 | 40 % | 5 | 25 % |

**Table 3: Showing Type of food ingested by patients of *Kamala***

| Sr. No. | Type of Diet | No. of Pt. Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | Pure Vegetarian | 8 | 40 % | 7 | 35 % |
| 2 | Mixed diet | 12 | 60 % | 13 | 65 % |

**Table 4: Showing Type of *Vyasana* (Addiction) in 40 patients of *Kamala***

| Sr. No. | Type of Addiction | No. of Pt. Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | Alcohol+ Smoking/ Tobacco | 11 | 55 % | 12 | 60 % |
| 2 | Tobacco/ Smoking | 5 | 25 % | 4 | 20 % |
| 3 | Tea / coffee | 3 | 15 % | 2 | 10% |
| 4 | Non addicted | 1 | 5 % | 2 | 10% |

**Table 5: Showing Habits related to *Vihara* of patients of *Kamala***

| Sr. No. | Type of *Vihara* | No. of Pt. Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | *Prakritanidra* | 6 | 30 % | 5 | 25 % |
| 2 | *Divaswap* | 3 | 15 % | 4 | 20 % |
| 3 | *Ratrojagarana* | 3 | 15 % | 2 | 10% |
| 4 | *Atapasevana* | 1 | 5 % | 4 | 20% |
| 5 | *Manasikhetu* like *Chinta, Krodha* | 7 | 35% | 5 | 25 % |

**Table 6: Showing *Doshajaprakriti* of patients of *Kamala***

| Sr. No. | *Doshajaprakriti* | No. of Pt. Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | *Vatapittaja* | 6 | 30 % | 8 | 40 % |
| 2 | *Pitta kaphaja* | 8 | 40 % | 9 | 45 % |
| 3 | *Kaphavataja* | 6 | 30 % | 3 | 15 % |

**Table 7: Showing *Dosha* dominance in disease wise distribution of 40 patients of *Kamala***

| Sr. No. | *Dosha* dominance | No. of Pt. Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | *Pitta* | 9 | 45% | 10 | 50 % |
| 2 | *Vaata* | 8 | 40 % | 5 | 25 % |
| 3 | *Kapha* | 3 | 15% | 5 | 25 % |

**Table 8: Showing *Agni-Parikshana* of 40 patients of *Kamala***

| Sr. No. | *Agni* | No. of Pt. Trial group | Trial group pt. % | No. of Pt. Control group | Control Group pt. % |
|---|---|---|---|---|---|
| 1 | *Tikshana* | 7 | 35% | 7 | 35 % |
| 2 | *Vishama* | 8 | 40 % | 9 | 45 % |
| 3 | *Mandagni* | 5 | 25% | 4 | 20 % |

**Subjective assessment**

The patients suffering from *Kamala* which was included in the trial had to undergo clinical examination at every follow up for clinical assessment of the improvement in signs & symptoms.

**Table 9: Showing effect of therapy on symptoms: Trial group**

| Symptoms | BT (Before Treatment) | AT (After Treatment) | Difference | Percentage of relief |
|---|---|---|---|---|
| *NetraPeetata* | 56 | 1 | 55 | 98% |
| *Peetamutrata* | 49 | 1 | 48 | 97% |
| *Yakritavruddhi* | 30 | 3 | 27 | 88% |
| *Jvara* | 11 | 3 | 8 | 85% |
| *Chhardi* | 17 | 1 | 16 | 95% |
| *Sadana* | 37 | 2 | 35 | 94% |
| *Daha* | 20 | 1 | 19 | 95% |
| *TwakaPeetata* | 56 | 1 | 55 | 97% |
| *Avipaka* | 17 | 1 | 16 | 95% |
| *Udarshoola* | 40 | 2 | 38 | 95% |
| *Aruchi* | 56 | 1 | 55 | 97% |
| Avarage | 35.36 | 1.54 | 33.81 | 94.2% |

**Table 10 : Showing effect of therapy on symptoms: Control group**

| Symptoms | BT | AT | Difference | Percentage of relief |
|---|---|---|---|---|
| *NetraPeetata* | 44 | 6 | 38 | 80% |
| *Peetamutrata* | 47 | 2 | 45 | 93% |
| *Yakritavruddhi* | 18 | 2 | 16 | 60% |
| *Jvara* | 16 | 2 | 14 | 63% |
| *Chhardi* | 33 | 8 | 25 | 63% |
| *Sadana* | 43 | 10 | 33 | 76% |
| *Daha* | 33 | 4 | 29 | 75% |
| *TwakaPeetata* | 44 | 4 | 36 | 77% |
| *Avipaka* | 32 | 4 | 28 | 81% |
| *Udarshoola* | 47 | 4 | 43 | 91% |
| *Aruchi* | 46 | 6 | 40 | 90% |
| Avarage | 36.63636 | 4.727273 | 31.54545 | 75.20% |

**Table 11: Wilcoxon match paired sign rank test : Trial group**

| No. | Symptoms | Mean | SD | SEd | W | N | Z | p |
|---|---|---|---|---|---|---|---|---|
| 1 | *NetraPeetata* BT & AT Diff. | 2.75 | 0.53 | 0.119 | 210 | 20 | 3.92 | <0.001 |
| 2 | *Peetamutrata* BT & AT Diff | 2.4 | 0.66 | 0.032 | 210 | 20 | 3.92 | <0.001 |
| 3 | *Yakritavruddhi* BT & AT Diff | 1.35 | 0.72 | 0.162 | 171 | 18 | 3.72 | <0.001 |
| 4 | *Jwara* BT & AT Diff | 0.4 | 0.73 | 0.164 | 29 | 8 | 2.03 | <0.05 |
| 5 | *Chhardi* BT & AT Diff | 0.81 | 0.87 | 0.19 | 66 | 11 | 2.93 | <0.05 |
| 6 | *Sadana* BT & AT Diff | 1.75 | 0.82 | 0.185 | 190 | 19 | 3.82 | <0.001 |
| 7 | *Daha* BT & AT Diff. | 0.95 | 0.58 | 0.131 | 136 | 16 | 3.51 | <0.001 |
| 8 | *TwakaPeetata* BT & AT Diff | 2.75 | 0.43 | 0.096 | 210 | 20 | 3.92 | <0.001 |
| 9 | *Avipaka* BT & AT Diff | 0.8 | 0.87 | 0.194 | 66 | 11 | 2.93 | <0.05 |
| 10 | *Udarashoola* BT & AT Diff | 1.9 | 0.83 | 0.185 | 190 | 19 | 3.82 | <0.001 |
| 11 | *Aruchi* BT & AT Diff | 2.75 | 0.43 | 0.09 | 210 | 20 | 3.92 | <0.001 |

**Table 12: Wilcoxon match paired sign rank test : Control group**

| No. | Symptoms | Mean | SD | SEd | W | N | Z | p |
|---|---|---|---|---|---|---|---|---|
| 1 | *NetraPeetata* BT & AT Diff | 1.9 | 0.99 | 0.222 | 171 | 18 | 3.72 | <0.001 |
| 2 | *Peetamutrata* BT & AT Diff | 2.25 | 0.88 | 0.198 | 190 | 19 | 3.82 | <0.001 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3 | *Yakritavruddhi* BT & AT Diff. | 0.8 | 0.74 | 0.167 | 78 | 12 | 3.06 | <0.05 |
| 4 | *Jwara* BT & AT Diff | 0.7 | 0.71 | 0.159 | 92 | 14 | 2.88 | <0.001 |
| 5 | *Chhardi* BT & AT Diff | 1.25 | 0.94 | 0.21 | 144 | 17 | 3.40 | <0.001 |
| 6 | *Sadana* BT & AT Diff | 1.65 | 0.79 | 0.177 | 171 | 18 | 3.72 | <0.001 |
| 7 | *Daha* BT & AT Diff | 1.45 | 1.02 | 0.228 | 136 | 16 | 3.51 | <0.001 |
| 8 | *TwakaPeetata* BT & AT Diff | 1.8 | 0.92 | 0.20 | 171 | 18 | 3.72 | <0.001 |
| 9 | *Avipaka* BT & AT Diff | 1.4 | 1.15 | 0.258 | 91 | 13 | 3.18 | <0.05 |
| 10 | *Udarashoola* BT & AT Diff | 2.15 | 0.79 | 0.177 | 210 | 20 | 3.92 | <0.001 |
| 11 | *Aruchi* BT & AT Diff | 2.0 | 0.77 | 0.173 | 210 | 20 | 3.92 | <0.001 |

To study the significance between symptomatic relief in trial and control group evaluated as-

**Table 13: Mann-whitnys test**

| | R | U | Mean U | SD (U) | Z | p | |
|---|---|---|---|---|---|---|---|
| *NetraPeetata* | 401 | 169 | 180 | 34.2 | 0.3 | 0.0075 | Very significant |
| *Peetamutrata* | 324 | 161 | 190 | 35.59 | 0.8 | 0.7736 | Not significant |
| *Yakritavruddhi* | 239 | 148 | 108 | 23.62 | 1.67 | 0.0449 | Significant |
| *Jwara* | 65 | 83 | 56 | 14.65 | 1.8 | 0.1676 | Not significant |
| *Chhardi* | 106 | 180 | 93.5 | 21.25 | 4.04 | 0.1024 | Not significant |
| *Sadana* | 294 | 238 | 171 | 32.9 | 2.02 | 0.8268 | Not significant |
| *Daha* | 157 | 235 | 128 | 26.53 | 4.01 | 0.1447 | Not significant |
| *Twakapeetata* | 430 | 140 | 180 | 34.2 | 1.15 | 0.0014 | Very significant |
| *Avipaka* | 141 | 73.5 | 84.5 | 19.5 | 0.5 | 0.9891 | Not significant |
| *Udarshool* | 295 | 275 | 190 | 35.59 | 2.37 | 0.4052 | Not significant |
| *Aruchi* | 450 | 160 | 200 | 36.96 | 1.06 | 0.0044 | Very significant |

**OBJECTIVE ASSESSMENT**

**Table 14: Showing effect of therapy on Hb% in 20 patients of *Kamala* of Trial group by *Dhatri loha yoga* And 20 patients of control group with *Kutaki Choorna***

| Objective criteria | Mean ± SD | | Mean of difference ± SD | SED | t value | p value |
|---|---|---|---|---|---|---|
| | BT | AT | | | | |
| Trial group HB % | 11.62 ± 2.05 | 13.03 ± 1.48 | 1.405± 1.28 | 0.288 | 4.87 | < 0.001 |
| Control group HB % | 11.42 ± 1.78 | 11.47 ± 1.65 | 0.045± 0.2924 | 0.065 | 0.688 | > 0.05 |

**Table 15: Showing effect of therapy on RBC, WBC in 20 patients of *Kamala* of Trial group by *Dhatriloha yoga* And 20 patients with *Kutaki Choorna***

| Objective criteria | Mean ± SD | | Mean of difference ± SD | SED | t value | p value |
|---|---|---|---|---|---|---|
| | BT | AT | | | | |
| Trial group RBC | 4.415 ± 1.22 | 4.98 ± 0.871 | 0.565± 0.493 | 0.1103 | 5.12 | < 0.001 |
| Control group RBC | 4.085 ± 1.19 | 4.18 ± 1.112 | 0.095± 0.1883 | 0.0421 | 2.255 | > 0.05 |
| Trial group WBC | 6500±2408.1 | 6490± 2044.2 | 10± 824.56 | 184.38 | 0.0542 | >0.05 |
| Control group WBC | 6020± 613.9 | 6175± 1563.3 | 155± 785.16 | 175.57 | 0.88 | > 0.05 |

**Table 16: Showing effect of therapy on Cholesterol, Triglycerides, HDL, LDL, in 20 patients of *Kamala* of Trial group by *Dhatriloha yoga* And 20 patients with *Kutaki choorna***

| Objective criteria | Mean ± SD | | Mean of difference ± SD | SED | t value | p value |
|---|---|---|---|---|---|---|
| | BT | AT | | | | |
| Trial group - Total cholesterol | 199.7 ± 37.32 | 176.3 ± 28.08 | 23.4 ± 28.93 | 6.47 | 3.6166 | < 0.001 |
| Control group Total cholesterol | 238.8 ± 34.80 | 228.8 ± 30.25 | 9.95 ± 15.419 | 3.4478 | 2.8859 | <0.001 |
| Trial group Triglycerides | 182.3 ± 40.44 | 165.9 ± 38.74 | 16.4 ± 27.359 | 6.1178 | 2.6807 | < 0.05 |
| Trial group HDL | 44.65±. 9772 | 45 ± 7.1274 | 0.35 ±4.72 | 1.0566 | 0.33 | > 0.05 |
| Trial group LDL | 124.5± 7.979 | 118.35±16.05 | 6.15 ± 13.101 | 2.9294 | 2.0994 | >0.05 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Control group Triglycerides | 190.9 ± 33.323 | 183.05 ± 28.895 | 7.85 ± 16.841 | 3.7658 | 2.0845 | >0.05 |
| Control group HDL | 47.15 ± 7.95 | 45.8 ± 7.39 | 1.35 ± 4.0654 | 0.9091 | 1.4851 | >0.05 |
| Control group LDL | 135.75 ± 19.015 | 131.55 ± 19.067 | 4.2 ± 9.6778 | 2.164 | 1.9408 | >0.05 |

**Table 17: Showing effect of therapy on S. Protein, Albumin, S. Alkaline Phosphate in 20 patients of *Kamala* of Trial group by *Dhatri Loha Yoga* And 20 patients with *Kutaki Choorna***

| **Objective criteria – Trial group** | **Mean ± SD** | | **Mean of difference ± SD** | **SED** | **t value** | **p value** |
|---|---|---|---|---|---|---|
| | **BT** | **AT** | | | | |
| S. Protein | 6.395 ± 1.256 | 6.231 ± 0.9959 | 0.182 ± 0.6296 | 0.1408 | 1.2929 | >0.05 |
| S.Albumin | 4.465 ± 1.026 | 4.835 ± 1.1016 | 0.37 ±1.0664 | 0.2385 | 1.552 | >0.05 |
| S.Alkaline phosphate | 92.1 ± 24.959 | 87.4 ± 21.397 | 4.7 ± 8.82 | 1.9738 | 2.3812 | < 0.05 |
| **Objective criteria- Control group** | **Mean ± SD** | | **Mean of difference ± SD** | **SED** | **t value** | **p value** |
| | **BT** | **AT** | | | | |
| S. Protine | 6.43± 1.251 | 6.23± 1.005 | 0.2 ± 0.6249 | 0.139 | 1.431 | >0.05 |
| S. Albumin | 4.62± 0.989 | 4.805± 1.092 | 0.185 ± 1.1068 | 0.247 | 0.747 | > 0.05 |
| S.Alkaline phosphate | 76.± 20.70 | 78.7± 14.66 | 2.65 ± 16.045 | 3.587 | 0.739 | > 0.05 |

**Table 18 : Showing effect of therapy on SGPT in 20 patients of *Kamala* of Trial group by *Dhatri Loha Yoga* And 20 patients with *Kutaki Choorna* with follow up at 7th, 14th and at end 21th day**

| **SGPT** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 343.5 ±278.24 | 236.55±212 |
| | After 7 days | 272.2 ±213.93 | 182.1±152.7 |
| Mean of difference ± SD | | 71±79.057 | 54.45±77.319 |
| t value | | 4.016 | 3.1494 |
| p value | | <0.001 | <0.01 |

| **SGPT** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 343.5 ±278.24 | 236.55±212 |
| | After14days | 128.75±63.515 | 151.35 ±95.322 |
| Mean of difference ± SD | | 214.75±235.22 | 85.2±128.28 |
| t value | | 4.0828 | 2.97 |
| p value | | <0.001 | <0.01 |

| **SGPT** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 343.5 ±278.24 | 236.55±212 |
| | AT -21 days | 43.8±22.409 | 101.05±48.16 |
| Mean of difference ± SD | | 299.7±260.18 | 135.5±192.22 |
| t value | | 5.1513 | 3.1525 |
| p value | | <0.001 | <0.01 |

**Table 19 : Showing effect of therapy on SGOT in 20 patients of *Dhatri Loha Yoga* of Trial group by *Dhatri Loha Yoga* And 20 patients with *Kutaki Choorna* with follow up at 7th, 14th and at end 21th day**

| **SGOT** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 346.15 ±267.28 | 235.05±185.27 |
| | After7days | 266.35 ±231.79 | 180.9±118.25 |
| Mean of difference ± SD | | 79.8±67.763 | 54.15±74.418 |
| t value | | 5.2665 | 3.25 |
| p value | | <0.001 | <0.01 |

| **SGOT** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 346.15 ±267.28 | 235.05±185.27 |
| | After14days | 122.15±76.542 | 154.9 ±96.079 |
| Mean of difference ± SD | | 224±205.58 | 80.15±99.88 |
| t value | | 4.8728 | 3.5887 |
| p value | | <0.001 | <0.01 |

| **SGOT** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 346.15 ±267.28 | 235.05±185.27 |
| | AT21days | 61±29.452 | 119.55±49.497 |
| Mean of difference ± SD | | 285.15±248.02 | 115.5±146.14 |

| | | | |
|---|---|---|---|
| t value | | 5.1417 | 3.5345 |
| p value | | <0.001 | <0.01 |

**Table 20: Showing effect of therapy on Total Bilirubin in 20 patients of *Kamala* of Trial group by *Dhatri Loha Yoga* And 20 patients with *Kutaki Choorna* with follow up at 7th, 14th and at end 21th day**

| **Bilirubin** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 9.28±3.602 | 7.465±3.92 |
| | After 7 days | 4.365 ±2.7002 | 5.475±2.511 |
| Mean of difference ± SD | | 4.915±1.8062 | 1.99±1.734 |
| t value | | 12.17 | 5.1322 |
| p value | | <0.0001 | <0.001 |

| **Bilirubin** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 9.28±3.602 | 7.465±3.92 |
| | After 14 days | 1.785±1.10 | 3.64 ±2.2087 |
| Mean of difference ± SD | | 7.494±3.0179 | 3.825±2.2669 |
| t value | | 11.107 | 7.5459 |
| p value | | <0.0001 | <0.001 |

| **Bilirubin** | | **Trial group** | **Control group** |
|---|---|---|---|
| Mean ± SD | BT | 9.28±3.602 | 7.465±3.92 |
| | AT 21 days | 1.02±0.5537 | 1.965±1.185 |
| Mean of difference ± SD | | 8.26±3.393 | 5.5±3.2633 |
| t value | | 10.887 | 7.5374 |
| p value | | <0.0001 | <0.001 |

**Table 21: Showing effect of therapy on Urine Bile salt, Bile pigment in 20 patients of *Kamala* of Trial group by *Dhatri Loha Yoga* And 20 patients with *Kutaki Choorna***

| **Objective criteria –Trial group** | **Mean ± SD BT** | **AT** | **Mean of difference ± SD** | **SED** | **t value** | **p value** |
|---|---|---|---|---|---|---|
| Bile salt | 3 ± 0 | 0.05 ±0.217 | 2.95 ± 0.217 | 0.047 | 60.53 | > 0.0001 |
| Bile pigment | 3 ± 0 | 0.05 ±0.217 | 2.95 ± 0.217 | 0.047 | 60.53 | > 0.0001 |
| Control group | | | | | | |
| Bile salt | 3 ± 0 | 0.25± 0.433 | 2.75 ± 0.433 | 0.0968 | 28.402 | >0.001 |
| Bile pigment | 3 ± 0 | 0.25± 0.433 | 2.75 ± 0.433 | 0.0968 | 28.402 | >0.001 |

**Table 22: Showing effect of therapy on stool colourin patients of *Kamala* of Trial group by *Dhatri Loha Yoga* and patients with *Kutaki Choorna***

| **Objective criteria–Trial group** | **Mean ± SD BT** | **AT** | **Mean of difference ± SD** | **SED** | **t value** | **p value** |
|---|---|---|---|---|---|---|
| Stool colour | 3 ± 0 | 0.05 ± 0.2179 | 2.95 ± 0.2179 | 0.048 | 59 | < 0.001 |
| Control group. Stool colour | 3 ± 0 | 0.25 ± 0.433 | 2.75 ± 0.433 | 0.096 | 27.68 | <0.001 |

**Table 23: Group I Trial group -Total effect of therapy on patients, having 21days follows up according to subjective & objective assessment**

| **No. patient** | **% of relief in symptoms** | **% of relief in signs** | **Average %** | **Remark** |
|---|---|---|---|---|
| 1 | 100% | 13.19497 | 56 | Markedly improved |
| 2 | 100% | 19.25751 | 59.629 | Markedly improved |
| 3 | 94% | 18.83454 | 56.4175 | Markedly improved |
| 4 | 77% | 28.02904 | 52.5 | Markedly improved |
| 5 | 91% | 23.48296 | 57.24 | Markedly improved |
| 6 | 94% | 21.58152 | 57.791 | Markedly improved |
| 7 | 100% | 24.60557 | 62.303 | Markedly improved |
| 8 | 82% | 18.08887 | 49.0445 | Improved |
| 9 | 85% | 19.39101 | 52.1955 | Markedly improved |
| 10 | 100% | 26.49482 | 63.18 | Markedly improved |
| 11 | 94% | 26.36656 | 60.18 | Markedly improved |
| 12 | 100% | 27.0354 | 63.515 | Markedly improved |
| 13 | 91% | 20.26309 | 55.6315 | Markedly improved |
| 14 | 100% | 25.60537 | 62.8025 | Markedly improved |
| 15 | 95% | 22.14254 | 58.57 | Markedly improved |
| 16 | 95% | 21.36425 | 58.18 | Markedly improved |

| | | | | |
|---|---|---|---|---|
| 17 | 100% | 21.7997 | 60.9 | Markedly improved |
| 18 | 100% | 25.20772 | 62.604 | Markedly improved |
| 19 | 91% | 26.98678 | 58.9935 | Markedly improved |
| 20 | 100% | 27.81322 | 63.9065 | Markedly improved |

**Table 24: Group 2 Control group -Total effect of therapy on patients, having 21days follows up according to subjective & objective assessment**

| No. patient | % of relief in symptoms | % of relief in signs | Average % | Remark |
|---|---|---|---|---|
| 1 | 78.78788 | 8.73627 | 43.76207 | Improved |
| 2 | 84.84848 | 12.6297 | 48.73909 | Improved |
| 3 | 87.87879 | 15.19955 | 51.53917 | Markedly improved |
| 4 | 78.78788 | 10.00844 | 44.39816 | Improved |
| 5 | 77.27273 | 13.85844 | 45.56558 | Improved |
| 6 | 100 | 13.30869 | 56.65435 | Markedly improved |
| 7 | 74.24242 | 17.8103 | 46.02636 | Improved |
| 8 | 72.72727 | 17.06195 | 44.89461 | Improved |
| 9 | 81.81818 | 18.79199 | 50.30509 | Markedly improved |
| 10 | 81.81818 | 17.52801 | 49.6731 | Improved |
| 11 | 90.90909 | 19.48255 | 55.19582 | Markedly improved |
| 12 | 51.51515 | 26.30229 | 38.90872 | Improved |
| 13 | 81.81818 | 16.4569 | 49.13754 | Improved |
| 14 | 86.36364 | 18.85166 | 52.60765 | Markedly improved |
| 15 | 63.63636 | 15.30176 | 39.46906 | Improved |
| 16 | 68.18182 | 22.61787 | 45.39984 | Improved |
| 17 | 74.24242 | 17.59552 | 45.91897 | Improved |
| 18 | 63.63636 | 11.84175 | 37.73905 | Improved |
| 19 | 45.45455 | 13.18858 | 29.32156 | Improved |
| 20 | 60.60606 | 14.16061 | 37.38334 | Improved |

**Table 25: Chi square Test**

| | Cured | Markedly improved | Improved | Uncured | Total |
|---|---|---|---|---|---|
| Trial group | 0 | 1 (48%) | 1 (3%) | 0 | 20 |
| Control group | 0 | 5 (13%) | 15 (38%) | 0 | 20 |
| Total | 0 | 24 (60%) | 16 (40%) | 0 | 40 |

**Chi-square Test**

For the above data value of $x^2 = 19.2$

The two-sided P value is < 0.0001, considered extremely significant.

The row/column association is statistically significant.

Thus Trial group is extremely significant than control group.

**Total effect of therapy**

With the consideration of gradation as cured, improved, markedly improved, uncured we found due to effect of *Dhatri Loha Yoga* 19 patients having marked improvement which is about 95 % and rest 5% have improved results. As compared to above *Kutaki Choorna* gives marked improvement in 25 % patients and 75 % had results as improved.

There difference of significance calculated with Chi square test, and results found as highly significant.

It means Role of *Dhatri Loha Yoga* is very highly significant than *Kutaki choorna* for reduction of Sign, Symptoms, and Specific biochemical markers like SGPT, SGOT, and Serum Bilirubin.

It shows that, *Dhatri Loha Yoga* is one of the effective remedy for treatment of *Kamala* (Hyper-bilirubinaemia).

*Kamala* is one gravies problem in the world, because of which patient is always in trouble. This initial study is toddler step forward for further study to find satisfactory solution.

**CONCLUSION**

Clinical evaluation of *Dhatri Loha Yoga* in *Kamala* was completed in 40 patients. In Trial group of 20 treated with *Dhatri Loha Yoga* and 20 patients in control group treated with *Kutaki Choorna*. Conclusion drawn according to observation and results are given here:

1. Most of the patients were from Middle class income group and were educated.
2. Maximum patients having the habit of diet of *Katu Rasa*. Then *Amla, Lavana rasa* dominance was also observed.
3. Majority of patients having history of mixed diet.
4. Most of patients having *Vyasana* such as Alcohol, smoking, Tobacco etc. tea coffee addiction was next to them.
5. Maximum patients having history of *Ratrijagarana, Diwaswap*.
6. *Manasikahetu* –From total sample in 30% of patient's *Mansikahetu* like stress, anxiety was observed.

So we conclude that, Middle economic class, indulgence of *Katu, Lavana, Amla rasa*; history of addiction, Non-veg consumption, habit of *Ratrijagarana, Diwaswapa*,

psychological factors like stress, anxiety were observed as main causative factors for *Kamala*.

1. Percentage of *Kamala* was observed more in *Vata-Pittaja prakriti*.
2. Percentage of *Kamala* was observed more in *Pittajadosha* dominant.
3. Evidence of *Kamala* was very much seen in patients having *Tikshna* & *Mandagni*.
4. Conclusion of symptoms as per scoring system in patients of *Kamala- Dhatri Loha Yoga* significantly reduces symptoms upto 94.2 % which is very beneficial As compared *Kutaki Choorna* which reduces symptoms to 75.2 %. Wilcoxon test applied to effect of therapy on symptoms of both groups was found highly significant. Mann Whitney test applied for testing significance of difference between trial and control group which found significant.
5. Conclusion of Biochemical markers as per scoring system in patients of *Kamala*. After applying paired t test for biochemical markers we found *Dhatri Loha Yoga* reduces Cholesterol, LDL, Triglycerides, S.Alkalinephosphate; which was not reduced by *Kutaki Choorna* in control group patients. Due to presence of *Lohabhasma* is *Dhatri Loha Yoga* it increases Hb %, RBC level. Rest of all markers had no significant changes.
6. Conclusion of SGOT, SGPT, S. Bilirubin as per scoring system in patients of *Kamala.* After examining patients each after 7 days for total 21 days we found both *Kutaki Choorna* and *Dhatri loha yoga* reduces SGPT, SGOT & S. Bilirubin level significantly. This was evaluated by paired t test. After calculating significance of difference between trial and control group with the help of unpaired t test we found *Dhatri Loha Yoga* is highly significant in decreasing bilirubin, SGPT and SGOT levels.

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