ABSTRACT:
The most of the population in our country resides in overcrowded, unhygienic conditions with poor dietary habits like imbalanced diet and alcoholic habits etc. which are responsible factors to promote hepatic damage which clinically reflects as Kamala Roga. Kamala can be fatal if not treated properly. In modern system of medicine, there is no effective remedy for kamala (jaundice) so everybody is in search of safe and side effect free alternative medicine. So, this clinical study has been conducted with Eladi churna and Phaltrikadi kwath in the management of Kamala. Ethical clearance from IEC was obtained. Total 30 patients of Kamala fulfilling all the inclusion and exclusion criteria were registered from O.P.D./I.P.D. of Rajiv Gandhi Govt. Ayurvedic college & Hospital, Paprola, Himachal Pradesh. Total 30 patients were registered. Out of them 27 patients completed the trial. The study was carried out in double group with 15 patients in each group for 28 days.
The effect of treatment was assessed in relation to improvement in overall clinical signs and symptoms and biochemical investigations on the basis of grading and scoring system. The statistical analysis of these scores was done before and after the treatment and improvement was assessed on percentage basis. Both drugs were very effective in reducing most of clinical symptoms as well as biochemical investigations of Kamala.

Key words: Koshthasakhashrit Kamala, Eladi churna, Phaltrikadi kwath.

INTRODUCTION: Kamala is a disease in which whole body is vitiated, because of the accumulation of mala i.e. Mala of Rakta dhatu i.e. Ranjaka Pitta. In ayurvedic literature Kamala has been mentioned as a sequel of Pandu roga. It occurs when the pandu rogi takes more paittik aahar & vihar. It is mainly a paittik disease which involves Mamsa and Rakta dhatu. But according to Madhav and Vagbhatta, Kamala can occur as an independent disease also. If we pay attention on clinical presentations of Kamala and Jaundice, it seems that both are similar. In modern medicine, Jaundice has
been mentioned only as a symptom but in Ayurveda, it has been mentioned as a full disease by the name “Kamla Roga”.

The term jaundice was derived from a French word “Jaunisse” means yellow, so it refers to the yellowish appearance of the skin, sclera and mucus membrane resulting from an increased bilirubin concentration in the body fluids. Internal tissues and body fluids are colored yellow but not the brain as bilirubin does not cross the blood brain barrier other than in the immediate neonatal period. In jaundice, serum bilirubin level increases, when its production from the haem, exceeds its metabolism and excretion. Imbalance between production and clearance may result either from excess release of bilirubin precursors into the bloodstream or from physiological processes that impair the hepatic uptake, metabolism or excretion of this metabolite. Clinically icterus or jaundice is particularly noticeable in the eyes because of the high scleral content of elastin, which has high affinity for bilirubin. Jaundice always signifies hyperbilirubinemia but it does not become clinically evident until the serum bilirubin level exceeds 2 mg/dl. Similarly early sign of hyperbilirubinemia is darkening of the urine, which results from renal excretion of bilirubin. With pronounced jaundice, skin may take a greenish hue because of oxidation of some of circulating bilirubin to biliverdin. This effect is seen more commonly in conditions with profound or long standing conjugated hyperbilirubenemia such as in cirrhosis.

AIMS AND OBJECTIVES OF THE RESEARCH WORK:

1. To evaluate the therapeutic effect of Eladi churna and Phaltrikadi kwath in Kamala as described in Yogratnakar6 and Chakradatta7 respectively.
2. To assess the laboratory profile of Kamala.
3. To review the Ayurvedic and Modern literature related to Kamala.

MATERIALS AND METHODS:

This study was unicentral, open and prospective clinical trial in double group with Sample size of 30 and 15 patients in each group. It was approved by Institutional Ethical Committee. Trial was conducted in the Deptt. of Rog Nidan at R.G.G.P.G.Ayu.College & hospital Paprola, (H.P.). Patients from 10-70 years age of either sex were selected for trial. After counselling, informed written and witnessed consent was received from the patients. Willing Patients then were registered as trial subjects.

Inclusion criteria:
Patients presenting with signs and symptoms of Kamala.
Age above 10 years and below 70 years irrespective of sex, caste and religion etc.
Patients willing for the trial.

Exclusion criteria:
Patients who have developed cirrhosis, malignancy (Hepatocellular carcinoma) and acute hepatocellular failure. Patients with surgical jaundice and with inherited haemoglobinopathies

Subject withdrawal criteria: Voluntary withdrawal by the research subject with or without information, uncooperative patient, complication of the procedure or appearance of any ailments during the trial requiring medical or surgical intervention.
Treatment protocol:

Dose of formulation

*Group A - Eladi Churna* - 3gm Empty stomach in morning

*Group B - Eladi Churna* - 3gm Empty stomach

*Phaltriadi Kwath* - 20-40ml BD After Meal.

Duration of trial: 28 days

Follow-up: 4 follow up after 7 days interval during trial. 1 follow up 15 days after completion of trial.

ASSESSMENT CRITERIA: Assessment was done on subjective criteria i.e. Anoexia, Nausea and vomiting, Fatigue, Icterus, Pain, Hepatomegaly and Splenomegaly and objective criteria which includes LFTs. Each variable of the criteria was graded according to the severity.

a. Subjective Criteria:

**Anorexia (Repugnance for food):**
- Good appetite
- Patient has little desire to take breakfast, lunch and dinner
- Take breakfast and dinner with little desire and not associated with nausea/vomiting
- No desire to take meals and associated with nausea/vomiting

**Nausea / Vomiting:**
- No nausea/vomiting
- Present occasionally
- Present frequently and to recognizable extent
- Present quite regularly and to intolerable extent

**Fatigue:**
- No feeling of fatigue on any kind of work -0
- Feeling of fatigue on doing light work -1
- Feeling of fatigue on doing heavy work -2
- Feeling of fatigue even at rest -3

**Icterus:**
- Normal coloration of all -0
- Yellow coloration of sclera -1
- Yellow coloration of sclera and mucous membrane -2
- Yellow coloration of all -3

**Hepatomegaly** (enlargement of liver):
- Normal liver -0
- Just palpable -1
- Enlarged more than 3cm below costal margin -2
- Enlarged more than 5cm below costal margin -3

**Splenomegaly:**
- Spleen is not palpable even on deep inspiration -0
- Spleen is palpable below costal margin usually On deep inspiration -1
- Spleen is palpable but not beyond a horizontal line half Way between costal margin & vertically from left nipple -2
- Spleen is palpable below umbilical level, but not below a horizontal line drawn half way between umbilicus and symphysis pubis -3
b. Objective Criteria:

<table>
<thead>
<tr>
<th>Feature</th>
<th>Grade 0</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT</td>
<td>&lt;50U/l</td>
<td>50-100U/l</td>
<td>100-500U/l</td>
<td>&gt;500U/l</td>
</tr>
<tr>
<td>AST</td>
<td>&lt;44U/l</td>
<td>44-90U/l</td>
<td>90-350U/l</td>
<td>&gt;350U/l</td>
</tr>
<tr>
<td>ALP</td>
<td>&lt;113IU/l</td>
<td>113-230IU/l</td>
<td>230-900IU/l</td>
<td>&gt;900IU/l</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>&lt;1.0mg/dl</td>
<td>1.0-1.5mg/dl</td>
<td>1.5-2.5mg/dl</td>
<td>&gt;2.5mg/dl</td>
</tr>
<tr>
<td>T.Protein</td>
<td>6-8gm/dl</td>
<td>6-5gm/dl</td>
<td>5-4gm/dl</td>
<td>&lt;4gm/dl</td>
</tr>
<tr>
<td>Albumin</td>
<td>3.5-5gm/dl</td>
<td>3.5-2.5gm/dl</td>
<td>2.5-1.5gm/dl</td>
<td>&lt;1.5gm/dl</td>
</tr>
</tbody>
</table>

In this clinical study, total 30 patients were registered. Out of them 27 patients completed the trial while 3 patients dropped out from the trial which were then analyzed statistically to obtain the result of therapy. Maximum number of patients in the present study belonged to the age group 11-30 years (46.66%), resident of Rural area (90%), students (40%) and belonged to upper middle class group (56%) and mixed diet (73.68%). The clinical features found in Patients are Anorexia (90%), Fatigue (60%), Icterus (60%) and Pain (46.66%).

RESULTS: Unpaired T test was used for the statistical analysis of the observation

1. Effect of Therapy (Eladi churna) on Clinical features in Group-I after completion of the trial:

<table>
<thead>
<tr>
<th>Sign Symptom</th>
<th>Mean Score BT</th>
<th>Mean Score AT</th>
<th>% Diff</th>
<th>SD</th>
<th>S.E±</th>
<th>‘t’</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anorexia</td>
<td>1.93</td>
<td>0.80</td>
<td>58.70</td>
<td>0.51</td>
<td>0.13</td>
<td>8.50</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nausea /Vomiting</td>
<td>0.53</td>
<td>0.20</td>
<td>62.26</td>
<td>0.61</td>
<td>0.15</td>
<td>2.0</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.60</td>
<td>0.93</td>
<td>41.25</td>
<td>0.61</td>
<td>0.15</td>
<td>4.18</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Icterus</td>
<td>1.26</td>
<td>0.53</td>
<td>57.93</td>
<td>0.59</td>
<td>0.15</td>
<td>4.78</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain</td>
<td>0.86</td>
<td>0.40</td>
<td>53.48</td>
<td>0.63</td>
<td>0.16</td>
<td>2.82</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Pruritus</td>
<td>0.20</td>
<td>0.06</td>
<td>65</td>
<td>0.35</td>
<td>0.09</td>
<td>1.46</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

II. Statistical Analysis Showing Effect of Therapy (Eladichurna and Phaltrikadi kwath) on Clinical features in Group-II

<table>
<thead>
<tr>
<th>Sign Symptom</th>
<th>Mean Score BT</th>
<th>Mean Score AT</th>
<th>% Diff</th>
<th>S.D</th>
<th>S.E±</th>
<th>‘t’</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anorexia</td>
<td>2.08</td>
<td>0.33</td>
<td>84.13</td>
<td>0.75</td>
<td>0.21</td>
<td>8.04</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nausea /Vomiting</td>
<td>0.66</td>
<td>0.08</td>
<td>87.87</td>
<td>0.79</td>
<td>0.22</td>
<td>2.54</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Fatigue</td>
<td>0.91</td>
<td>0.25</td>
<td>72.52</td>
<td>0.77</td>
<td>0.22</td>
<td>2.96</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Icterus</td>
<td>1.91</td>
<td>0.75</td>
<td>60.73</td>
<td>0.71</td>
<td>0.20</td>
<td>5.63</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain</td>
<td>1.33</td>
<td>0.25</td>
<td>81.20</td>
<td>1.08</td>
<td>0.31</td>
<td>3.46</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Pruritus</td>
<td>0.16</td>
<td>0.08</td>
<td>50</td>
<td>0.28</td>
<td>0.08</td>
<td>1.00</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>
III. Effect of therapy on LFTs in Group I

<table>
<thead>
<tr>
<th>Blood Investigations</th>
<th>Mean Score</th>
<th>% Diff.</th>
<th>S.D</th>
<th>S.E±</th>
<th>‘t’</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSB</td>
<td>1.93</td>
<td>62.17</td>
<td>0.41</td>
<td>0.10</td>
<td>11.22</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>SGOT</td>
<td>0.66</td>
<td>69.69</td>
<td>0.51</td>
<td>0.13</td>
<td>3.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>SGPT</td>
<td>0.66</td>
<td>60.60</td>
<td>0.50</td>
<td>0.13</td>
<td>3.05</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>ALP</td>
<td>0.80</td>
<td>7.5</td>
<td>0.25</td>
<td>0.06</td>
<td>1.0</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

IV. Effect of therapy on LFTs in Group-II

<table>
<thead>
<tr>
<th>Blood Investigations</th>
<th>Mean</th>
<th>% Diff.</th>
<th>S.D</th>
<th>S.E±</th>
<th>‘t’</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSB</td>
<td>2.75</td>
<td>78.54</td>
<td>0.57</td>
<td>0.16</td>
<td>13</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>SGOT</td>
<td>1.16</td>
<td>86.20</td>
<td>0.85</td>
<td>0.24</td>
<td>4.06</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>SGPT</td>
<td>1.25</td>
<td>80</td>
<td>0.85</td>
<td>0.24</td>
<td>4.06</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>ALP</td>
<td>1.00</td>
<td>41</td>
<td>0.51</td>
<td>0.14</td>
<td>2.80</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Comparison of Overall Effect of Therapy in Both Groups (27 patients)

<table>
<thead>
<tr>
<th>Results</th>
<th>Group I (n=15)</th>
<th>Group II(n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
<td>%age</td>
</tr>
<tr>
<td>Cured</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Markedly Improved</td>
<td>1</td>
<td>6.63</td>
</tr>
<tr>
<td>Moderately Improved</td>
<td>10</td>
<td>66.66</td>
</tr>
<tr>
<td>Mildly Improved</td>
<td>4</td>
<td>26.66</td>
</tr>
<tr>
<td>Unchanged</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

DISCUSSION: The Kamala Roga discussed in Ayurveda is mainly due to vitiation of pitta, which takes place mainly due to virudha Ahara and Vihara. In ancient Ayurvedic texts, it has also been described as Swatantra and Partantra Kamala. Partantra Kamala means when it is produced as a complication of pre-existing disease. Swatantra Kamala means when disease is produced alone by self etiological factors. Most of the clinical features of kamala have close resemblance with Jaundice. Both the drug formulations used in this trial were effective in treating Kamala. Most of the ingredients have tikta , katu rasa, madhur vipaka, sheeta virya which have pittashaman, dhatuposhana, deepana, srotoshodhana properties.

Probable Mode of Action of Trial Drugs: Ayurveda has a unique way of explaining the mode of action of drugs. The action of drug is executed in the body through its pharmacodynamic properties like rasa, guna, veerya and vipaka. Along with these, there is prabhava, which is the specific property inherited by the drugs which cannot be explained. The action of every drug is determined by the dominant pharmacodynamic factor in that particular drug and that may be anyone out of rasa, guna, veerya, vipaka and prabhava. According to Acharya Charaka, principle of the treatment for kamala is Samshodhana
with Mriduvirechana by the dravyas of Tikta rasa. Here virechana is in the sense of pitta-rechana.\textsuperscript{10}

**Probable mode of action of Eladi churna:**
- **Action by Rasa:** Most of the drugs have madhura, tikta and kashaya rasa which belong to Saumyavarga, provide Sheetata and cause pitta-shamana.\textsuperscript{11} Where as drugs with katu rasa dialate the pathways and have agnideepak properties.\textsuperscript{12}
- **Action by Guna:** Most of the drugs have Laghu and Rukshaguna. Due to laghuguna, drugs cause Deepana, Srotoshodhana\textsuperscript{13} and made the drugs to easily digest.
- **Action by Veerya:** Most of the drugs have sheetaveerya due to which they cause Pitta shaman and Dhatuposhana. Whereas drugs with ushna virya having Raktavardhaka, Agnivardhaka and Srotasa dilation properties.
- **Action by Vipaka:** Most of the drugs have madhuravipaka which causes pittashaman, dhatupashaman and immunomodulation and have antioxidant effect. According to modern pharmacology, this drug has antioxidant, immunomodulatory and hepatoprotective properties.

- **Eladi churna** by virtue of properties of its ingredients helps to dissociate the pathogenesis of disease process and thereby cause regression of symptoms.

**Probable mode of action of Phaltrikadi Kwath:**
The trial drug has following rasa, guna, vireya, vipaka and prabhava:
- Most of the drugs having tikta and kashaya rasa. Both these rasa pacify pitta. Tikta rasa is agnideepak, aahar pachak and pacify aruchi and daha which are among common symptoms of kamala. Whereas kashaya rasa pacifies Pitta with its sheet guna.\textsuperscript{14}
- The drug has Ruksha and Laghu properties. Laghu guna have deepana, pachana and srotoshodhana whereas rukhsa guna pacify sneha guna of pitta.
- In Phaltrikadi kwath some of drugs have sheeta virya. Sheeta virya pacify Pitta dosha. Whereas some drugs have ushana virya which have Raktavardhaka, Agnivardhaka and Srotasa dilation properties.
PHALTRIKADI KWATH

Tikata, Kashaya Rasa, Ruksha Guna,

Tikata Rasa

Agnideepana, Aahar Pachaka, Aruchi, Daha Shamaka

Laghu Guna

Deepan Pachana, Srotoshodhana

Relief In Sign And Symptoms Of Kamala

CONCLUSION: Both the trial drugs were effective in relieving the signs and symptoms of Kamala.

In Eladi churna treated Group, 58.70% relief in anorexia, 41.25% in fatigue and 57.93% was found in icterus which was highly significant. 62.26% relief was found in nausea and vomiting which was significant. 62.17% relief was found in values of TSB, 69.69% in SGOT & 60.60% in SGPT which were statistically significant.

In Eladi churna and Phaltrikadi kwath treated Group, 84.13% relief was found in anorexia and 60.73% in icterus which was highly significant. 87.87% relief was found in nausea & vomiting, 72.52% in fatigue and 81.20% in pain which was statistically significant. 78.5% relief was found in values of TSB, 86% in SGOT & 80% in SGPT & 41% in ALP which were statistically significant.

Overall effect of therapy revealed that, out of 27 patients, 1 patient cured in Group-II while none of patients cured in Group-I. 4 patients were showed highly improvement in Group-II, while it was only one patient in Group-I.

In Group-II, 7 patient showed moderately improvement, while in Group-I, 10 patients were moderately improved.

In Group-I, 4 patients were mildly improved whereas none of the patient showed mild improvement in Group-II.

In present study no one patient remained unchanged in both groups. In this study both trial drugs shown remarkable results in individual groups. But Eladi churna along with Phaltrikadi Kwath had shown better effect than only Eladi churna.

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