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RESEARCH ARTICLE

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF AYURVEDIC FORMULATIONS IN THE MANAGEMENT OF *KAMALA* W.S.R. TO IMPAIRED LIVER FUNCTION

***Dr. Uma Thakur and Prof. Mehra, B.L.**

[1]PG Scholar, PG Dept. of Kayachikitsa
[2]Professor and Head PG Dept., of Kayachikitsa Rajiv Gandhi Govt. PG Ayurvedic College and Hospital Paprola Distt. Kangra H.P.176063

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**Corresponding author:*

ABSTRACT

Introduction: *Kamala* is one of the important common clinical entity in Ayurveda whose description appears to be most comprehensive and incorporates the disorders of hepatobiliary system of modern medicine. In Ayurvedic literature *Kamala* has been mentioned as a sequel of *Pandu roga*. It occurs when *Pandu rogi* takes more *Paittikaharavihara*[1]. Jaundice, a yellowish discoloration of tissue resulting from the deposition of bilirubin is the common presentation of patients with liver and biliary diseases. The liver diseases have remained a challenge to medical profession since many of the liver disorders may ultimately lead to irreversible changes. Liver function tests along with liver enzymes constitutes group of tests used to determine the state of liver function in a patient. **Materials and methods:** Literary material from Ayurvedic and Modern texts was compiled and assessment criteria was formulated.15 patients of age 10-70yrs were registered from OPD/IPD of R.G.G.P.G.A.C Paprola fulfilling the inclusion criteria. **Drug, Dosage and Duration:** One group of minimum 15 patients were treated with both the trial drugs i.e. *Trivritchuran* with *Sharkara* 4gm orally twice a day for 7 days and *Kamalaharyoga*- Liver tone syrup 10 ml TID for 30 days and Liver tone capsule 1 BD for next 30 days . Duration of trial was 60 days with follow up after every 15 days. **Observations Effect of therapy on Subjective and Objective Parameters:** Out of those 13 patients who completed the study;38.46% patients were completely relieved, 3 patients each with the percentage of 23.07% reported mild and moderate improvement, marked improvement in patients symptoms and biochemical improvement was found in 7.70% of patient and 7.70% reported no relief in symptoms and signs of disease **Results and conclusion:** Therapy has significant role in relieving symptoms and signs of the disease. It showed better efficacy on subjective criteria than biochemical criteria. No adverse effects were observed during the course of trial.

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INTRODUCTION

Ayurveda is traditionally skillful, treating Liver diseases since centuries and drug toxicity appears to be less as compared to conventional medicine. Face is the index of mind. A person is healthy or diseased is expressed by his face. Since the origin of human being, the inquisitiveness of man and his pursuit to identify the cause of diseases compels him to think of some solution. *Kamala* is one of those clinical entities, conceived in *Ayurveda*, whose description appears to be the most comprehensive. The word *Kamala* is interpreted as, "*Kutsitam Mala Yasmin Roge Sah Kamala Rogah*"[2]. As a matter of fact the continued metabolic activities in the body lead to the formation of a series of breakdown products. All such products of systemic metabolism may be considered as *Malas*. These *Malas* when accumulated in excess or are converted into certain harmful forms, they should be considered "*KutsitaMalas*" warranting immediate excretion.

If such altered *Malas* are not removed from the body they become the basis of causation of *Kamala Roga*. *Ayurveda* is a whole medical system that is based on various theories about health and illness and on ways to prevent, manage or treat health problems. Liver is considered to be one of the vital organs which help in maintaining the health of body. Liver is said to be the seat of *Pitta*[2]. All the functions of *Pitta* especially those of *RanjakaPitta* are attributed to liver. *Kamala* is a *Raktapradoshajavikara*[3] and *Yakrit* is the *Moola* of *Raktavahasrotas*[4]. *Mriduvirechana* with *Tikta Rasa Pradhana* drugs is the preferred *Shodhana* therapy for *Kamala* as mentioned by Acharya Charaka i.e. "*Kamale tu virecanam*"[5]. Keeping this view *Trivrit Churana* was selected for this present study because of its mild purgation property. Along with this *Kamalahar yoga* containing drugs having *Pitta Rechaka* properties was also given. Acharya Vagbhata quoted "*Kamalayam tu pittaghnam Pandurogavirodi yat*" i.e. drugs

which pacify *Pitta* and drugs which do not interfere with *Panduroga* should be used[6].

AIMS AND OBJECTIVE

- To study the *Kamala Roga* according to *Ayurvedic* classics and its correlation with modern literature.
- To evaluate the effect of an *Ayurvedic* formulation (*Kamalahar Yoga*) and *Trivrita*(*Nishotha) churna* with *Sharkara* in the management of *Kamala* (Jaundice) w.s.r to Impaired Liver Function.

PATIENTS AND METHODS

To fulfill all the aims and objectives of the study, following materials and methods were used.

Selection of the patients: Patients of *Kamala* fulfilling the diagnostic criteria were registered randomly from OPD/IPD of R.G.G.P.G. Ayurvedic Hospital Paprola, Distt. Kangra, Himachal Pradesh fulfilling the criteria of diagnosis.

Inclusion criteria

- Patient willing to undergo trial and ready to give written consent.
- Between the age group of 10 years and 70 years, irrespective of sex, caste and religion.
- Patients presenting with signs and symptoms of *Kamala* along with impaired liver function tests.
- Clinical evidence of Infective hepatitis, Cirrhosis of liver, Parenchymal disease of liver, Alcoholic liver disease etc.

Exclusion criteria

- Patients not willing for trial.
- Patients who have developed malignancy and acute hepatocellular failure.
- Patient in whom there is need of surgery, in case of obstructive jaundice.
- Patients who have inherited hemoglobinopathy such as Sickle cell anemia or Thalassemia.

Investigations: For the purpose of assessing the general condition of patients to include them in clinical trial and exclusion of other pathogenesis the following investigations were performed in patients.

Hematological investigation: The routine base-line hematological investigations were done in every case before and after the completion of clinical trial such as Hbgm%, TLC, DLC, ESR.

Biochemical investigation

- Fasting Blood sugar
- RFT- Blood urea, Serum creatinine
- Liver Function test (LFT)- TSB, DSB, SGOT, SGPT, Serum protein, serum albumin, serum globulin, A:G ratio, ALP
- Lipid profile- Cholesterol, HDL, LDL, VLDL, Triglycerides

Urine examination (routine and microscopic)

Serological test- HbsAg (for HBV)

Ultra-sonography of whole abdomen to rule out the any other organic disease.

Protocol of research

- IEC Approval.
- Screening of the patients.
- Enrollment

E.C. Approval:- Approval from Institutional Ethical Committee was obtained before the initiation of research work. **(**Certificate no. Ayu/IEC/2015/1064)
The clinical trial was registered online with Clinical Trial Registry of India (https://ctri.nic.in) under CTRI No. CTRI/2018/04/013527; and Acknowledge No. REF/2018/03/018357

Screening:- Patients presenting with signs and symptoms of *Kamala* were screened from *Kayachikitsa* OPD/IPD of R.G.Govt. P.G. Ayurvedic College and Hospital, Paprola, H.P.

Enrollment

- **Consent:** Screened patients of *Kamala* who gave their consent and fulfilled diagnostic criteria and inclusion criteria were enrolled for the clinical study.
- **Patient information sheet:** Patients were detailed about the nature of disease, various aspects of clinical trial and their queries were addressed.
- **Case Record Performa:** Detailed case record Performa was prepared, which was filled up before commencement of intervention of trial drug and after completion of the trial.

Laboratory investigations like hematological and biochemical investigations were carried out in the beginning and at the completion of trial of every case. Ultra-sonography was also done to assess the cause of *Kamala* and to exclude the cases for the present clinical study falling in exclusion criteria.

Interventional products: According to the textual references of *Ayurvedic*literature, following drugs were used in the present clinical study to evaluate its efficacy in *KamalaRoga.*

- *Trivrita (Nishotha) churna* with *Sharkara*[7]
- *Ayurvedic* formulations (Liver tone syrup & capsule)

Preparation of drugs

- ***Trivrit Churana* with *Sharkara:*** The drug was prepared as per standards of GMP in the Charaka Pharmacy of College with batch no. R/6/17 and date of manufacturing was 3/5/17. Chemical analysis of trial formulation was done at DTL Joginder Nagar.
- **Ayurvedic formulations (Liver tone syrup and capsule):** Drug was prepared according to the standards of GMP by the Ayush Pharmacy, NagrotaBagwan, Distt. Kangra (H.P)

Grouping of Patient: One group of minimum 15 patients were treated with both the trial drugs i.e. *Trivrita (Nishotha)*

churna with *Sharkara* and Ayurvedic formulation (*Kamlahar Yoga*) to evaluate better efficacy in the management of the *Kamala*.

Formulation Name

Trivrit Churana* with *Sharkara

Pharmaceutical form - *Churana*
Dose - 4gm
Route of administration -Oral

Frequency of Administration-Twice a day

Anupana - water

This formulation was given for 7 days.

Formulation Name- *KamalaharYoga* (Liver tone syrup).

Pharmaceutical form-Syrup
Dose-10 ml
Route of administration -Oral
Frequency of Administration-Thrice a day
Anupana -Water

This formulation was administered for 30 days duration along with *Trivritchurana* with *Sharkara* for 7 days duration.

Formulation Name-*KamalaharYoga* (Liver tone capsule)
Pharmaceutical form-Capsule
Dose-1capsule (500gm)
Route of administration -Oral
Frequency of Administration - Twice a day
Anupana - Water
This formulation was given for next 30 days duration.

Duration of Trial

- The duration of trial was 60 days.
- Patients were asked to intimate about any adverse reaction and any adverse effect attributed to the drug, was recorded in the Case Record Performa

Follow up: First follow up after 7 days thereafter every 10 days till the completion of therapy. After starting the therapy, the patients were examined in every visit for pulse, blood pressure, temperature, signs and symptoms, appetite, bowel habits and general condition. All the cases were subjected to clinical observation throughout the course of treatment to assess the efficacy of drug from time to time and also to note any adverse effect. After 60 days, when the trial was completed, thorough examination of the patient was carried out. The patients who failed to continue the therapy for whole duration were considered dropout.

Criteria of assessment: The effect of treatment was assessed as improvement in the impaired liver function tests and overall clinical signs and symptoms on the basis of grading and scoring system.

Objective Criteria

Bilirubin
Total Serum Bilirubin
Bilirubin (Direct)
Bilirubin (Indirect)
SGPT (ALT)-Alanine Transaminase Test
SGOT (AST)-Aspartate Transminase Test
ALP
Total Protein
Albumin
Globulin
Albumin: Globulin

Subjective Criteria-The symptoms were assessed on the basis of scoring system in follow up after each 10 days. Scoring of the symptoms was done as under:

Grading of Subjective parameters

Statistical Analysis

The information gathered regarding demographic data is shown in percentage. The scores of criteria of assessment were analyzed statistically in form of mean score B.T (Before Treatment), A.T (After treatment), their mean difference (B.T.-A.T.), Standard Deviation (S.D.), Standard Error (S.E.) were calculated and "students paired t-test was carried out at $p>0.05$, $p<0.05$ and $p<0.001$. "Sigma Stat 4.0 Statistical Software" was used for the calculation. The results were categorized significant or insignificant depending upon the value of p.

- Highly Significant-p value <0.001
- Significant-p value<0.05
- Insignificant-p value>0.05

Criteria of overall assessment: The symptoms were evaluated and response of drug was recorded in terms of percentage relief of symptoms.

$$\frac{\mathbf{TotalBT-TotalAT}}{\mathbf{TotalBT}}\mathbf{x\ 100}$$

The result thus obtained from individual patient was categorized according to the following grade:

Complete relief: Patients having full clinical recovery. Normalization of the liver function tests.

Marked relief: More than 75% relief in initial chief complaints. Marked improvement in the liver function tests.

Moderate relief: More than 50% relief in initial chief complaints. Moderate improvement in the liver function tests.

Mild relief: More than 25% relief in initial chief complaints. Incomplete biochemical improvement.

No relief: No improvement in the clinical features and biochemical findings

Effect of therapy on objective parameters

Aruchi: The effect of therapy after 60 days of treatment showed highly significant result for *Aruchi* ($p= 0.0005$) with percentage relief of 82.64%. It may be due to *Tikta Rasa* of maximum ingredients, *Katu Rasa, Laghu Guna* and *Ushna Veerya* of the ingredients in this formulation having *Deepana, Pachana, Rochana, Srotoshodhaka* and *Aruchighana.*

Hrillas: The effect of therapy after 60 days of treatment showed highly significant result for *Hrillas* (p= 0.000894) with percentage relief of 84.19%. Due to *Shoshaka* property (*KshayaRasa*) of ingredients of Ayurvedic formulation, it may absorb the increased *DravaGuna* of vitiated *PachakaPitta*.

Chardi: The effect of therapy after 60 days of treatment showed statistically significant result for *Chardi* (p= 0.0348) with percentage relief of 76.9%. Due to *Shoshaka* property (*KshayaRasa*) of ingredients of Ayurvedic formulation, it may absorb the increased *DravaGuna* of Vitiated *PachakaPitta*.

Avipaka: The effect of therapy after 60 days of treatment showed statistically significant result for *Avipaka* (p= 0.0123) with percentage relief of 86.65%. *Tikta Rasa, Katu Rasa* having *Deepana, Pachana* properties; *Laghu Guna*causing *Agni Deepana, Ruksha Guna*and *Katu Vipaka*having *Kaphashamaka* property and *Amapachana* alleviates the symptom of *Avipaka.*

Angasada: The effect of therapy after 60 days of treatment showed statistically significant result for *Angasada* (p= 0.00250) with percentage relief of 69.58%. Trial drugs act as *Deepana*, *Pachana* and *Srotoshodhaka* and normalises the aggravated *Pitta Dosha*.

Haridravrana: The effect of therapy after 60 days of treatment showed statistically significant result for *Haridravrana* (p= 0.027) with percentage relief of 78.55%. Due to*Katu Rasa*and *Laghu Veeraya*having properties as *Agnideepaka, Srotoshodhaka, Kaphashamaka, Shothahara* and *Abhishyandihara* and it has *Ushna Guna*hence the channel of *Ranjaka Pitta* is cleared.

Daha: The effect of therapy after 60 days of treatment showed statistically insignificant result for *Daha* (p= 0.089) with percentage relief of 100% *Madhura* and *Tikta Rasa*of the trial drugs possess the property of *Daha Prashamana.*

Kandu: The effect of therapy after 60 days of treatment showed statistically insignificant result for *Kandu* (p= 0.337) with percentage relief of 100%. *Katu Rasa* has property of *Kandughana.* Trial drugs have *Sroto-shodhaka* properties and after removal of blockage bile is passed into the gut and excreted via stool. *Tikta Rasa* have *Raktaprasadana* property.

Effect of therapy on lft's

- **Total Serum Bilirubin:** The mean score before the initiation of therapy was 6.078 which was changed to 1.592 on completion of therapy with percentage change of 73.80% having p-value=0.049 (<0.05). The change was statistically significant. Trial drugs acts as a cholagouge action and maintains the flow of bile in the gut and then due to effect of mild purgative (e.g. *Trivrit*), it excreted via stool.
- **Direct Serum Bilirubin:** The mean score before the initiation of therapy was 2.869 which was changed to 0.662 on completion of therapy with percentage change of 76.9% having p-value=0.13 (>0.05). The change was statistically insignificant.
- **Indirect Serum Bilirubin:** The mean score before the initiation of therapy was 3.209 which was changed to 0.985 on completion of therapy with percentage change of 69.33% having p-value=0.012. (<0.05)The change was statistically significant.
- **SGOT:** The mean score before the initiation of therapy was 396.846 which was changed to 73.03 on completion of therapy with percentage change of 81.59% having p-value=0.138 (>0.05). The change was statistically insignificant.
- **SGPT:** The mean score before the initiation of therapy was 453.692 which was changed to 76.900 on completion of therapy with percentage change of 83.05% having p-value=0.108 (>0.05). The change was statistically insignificant.
- **Alkaline phosphatase:** The mean score before the initiation of therapy was 158.154 which changed to 136.538 on completion of therapy with percentage change of 13.66% having p-value=0.121 (>0.1). The change was statistically significant. The trial drugs such as *Punarnava*, *Katuki* and *Bhringraja* have marked hepato-protective action against tissue injury and normalize the serum parameters like SGOT, SGPT, ALP, and bilirubin. They also showed a significant stimulatory effect on liver cell regeneration.
- **Total protein, Albumin, Globulin, A:G Ratio :** The mean score for these parameters was 7.100, 4.285, 2.938,1.505 before the initiation of therapy which changed to 7.291, 4.384, 3.165, 1.548 respectively. The percentage change was 2.69%, 2.29%, 7.72%. 2.91% respectively and the observed change was statistically insignificant as the p-value calculated was 0.286, 0.523, 0.185, 0.527 respectively (>0.1).
- On the basis of clinical trial with *Ayurvedic* formulations, it can be concluded that the therapy has significant role in relieving symptoms and signs of the disease. It showed better efficacy on subjective criteria than biochemical criteria. No adverse effects were observed during the course of trial. The Trial drug has been proved as safe and effective therapy in *Kamala Roga*(Jaundice). **HbsAg-** All patients performed this test and result was negative.

Ultrasonography

Out of 15 patients, Ultrasonography was done in 13 patients before the commencement of trial. Ultrasonography is the most cost-efficient, sensitive, and accurate method for screening of most of the liver diseases. All patients presented with the clinical evidence of jaundice were found to have either of these findings in USG:-Infective hepatitis, Cirrhosis of liver, parenchymal disease of liver, Alcoholic liver disease, Fatty liver disease and hepatomegaly. It was important to perform Ultrasonography to exclude the cases for registration with exclusion criteria. None of the patients could repeat the Ultrasonography after completion of trial due to relief of symptoms either partially or completely.

Overall Effect of Therapy: Among 15 registered patients, 13 patients completed the therapy for full duration. Out of these 13 patients, 5 patients i.e.38.46% had reported complete absence of symptoms and normalisation of liver function tests after 60 days of trial period, 3 patients each with percentage of 23.07% reported mild and moderate improvement, marked improvement in patients symptoms and biochemical improvement was found in 7.70% and 7.70% patients reported no improvement in clinical features and biochemical findings.

Table 1. Composition of Ayurvedic formulation *Kamalahar Yoga* (Liver tone syrup and capsule)

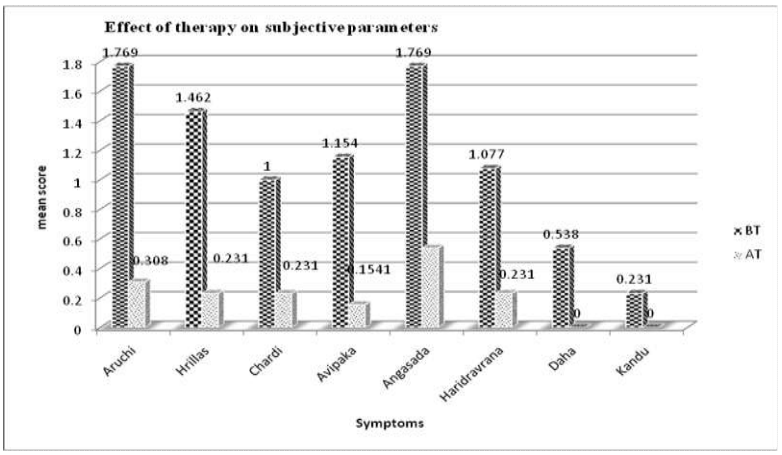
Sr. No.	Name	Latin name	Family	Part used	Qty.
1.	Milk thistle	*Silybummarianum*	Asteraceae	Whole plant	150mg
2.	*Punarnava*	*Boerhaaviadiffusa*	Nyctaginaceae	Root	50mg
3.	*Kutki*	*Picrorhizakurroa*	Plantaginaceae	Rhizome	75mg
4.	*Bhringraj*	*Eclipta alba*	Asteraceae	Whole plant	75mg
5.	*Bhumiamla*	*Phyllanthusamarus*	Euphorbiaceae	Whole plant	50mg
6.	*Sharpunkha*	*Tephrosiapurpurea*	Fabaceae	Root	25mg
7.	*Kalmegha*	*Andrographispaniculata*	Acanthaceae	Whole plant	25mg
8.	*Chirayata*	*Swertiachirata*	Gentianaceae	Whole plant	50mg
9	Sarkara	*Canesugar*			q.s

Table 2. Subjective criteria for assessment

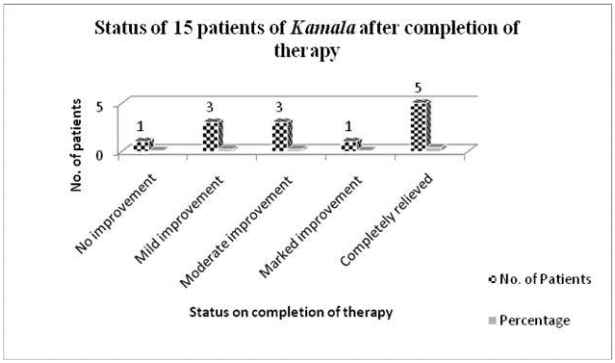
Sr. No.	Sign & Symptoms	Degree	Grade	BT	AT
1	*Aruchi*	Normal desire for food	0		
		Eating timely without much desire	1		
		Desire for food only after long interval	2		
		No desire for food at all.	3		
2.	*Hrillas*	No nausea	0		
		Present occasionally	1		
		Present frequently and to recognized extent	2		
		Present quite regularly to intolerable extent	3		
3.	*Chardi*	No vomiting	0		
		Feels sense of nausea and vomits Occasionally	1		
		Frequency of vomiting between four to six per week	2		
		Frequency of vomiting daily after every meal	3		
4.	*Avipaka*	Normal digestion	0		
		Indigestion once or twice a week	1		
		Indigestion three to five times a week	2		
		Indigestion after every meal	3		
5.	*Angasada*	No *Angasada*	0		
		Occasional *Angasada* but patient is able to do routine work	1		
		Continuous *Angasada* which hampers routine work	2		
		Continuous *Angasada*patient is unable of doing any work	3		
6.	*Haridravrana*	Normal colouration of all	0		
		Yellow colouration of sclera	1		
		Yellow colouration of sclera and mucous membrane	2		
		Yellow colouration of all	3		
7.	*Daha*	Absent	0		
		Occasional burning sensation in abdomen	1		
		Burning sensation 3–4 times a day relieved by water and food	2		
		Continuous complaint relieved by antacids	3		
8	*Kandu*	Absent	0		
		Occasional present	1		
		Present frequently without scratch mark	2		
		Present regularly with scratch mark	3		

Table 3. Overall Effect of Therapy

Status on completion of therapy	No. of Patients	Percentage
No improvement (0% improvement)	1	7.70%
Mild improvement (up to 25%)	3	23.07%
Moderate improvement (upto 50%)	3	23.07%
Marked improvement (up to 75%)	1	7.70%
Completely relieved (100% absence of symptoms & normal LFTs)	5	38.46%



Bar Diagram 1. Effect of therapy on subjective parameters



Bar Diagram 2. Status of 15 patients of *Kamala* after completion of therapy

DISCUSSION

Thus, it is clear that this *Ayurvedic* formulation (*Kamalahar Yoga* and *Trivrita churana* with *Sharkara)* is quite effective in the treatment of *Kamala Roga* as significant percentage change/relief was obtained in subjective and objective parameters pertaining to *Kamala*. There was no significant difference between the values of haematological investigation (i.e. Hb, TLC, DLC, ESR). The fundamentals regarding treatment in *Ayurveda* are mainly based on *Doshika Chikitsa*. *Kamala Roga* is especially a *Pitta* predominant disorder[8]. *Pitta Dosha* and *Rakta Dushti* are pathological factors of *Kamala*. *Yakrit* is the *Mula Sthan* of *Rakta*. *Rakta* and *Pitta* has *Ashrya-Ashryi Sambandha* and *Virechana* is the best treatment for the *Pittaj* disorders[9] . In *Charaka SamhitaMridu Virechana* is the *Chikitsa* for *Kamala.* Thus to break this *Dosha-Dushaya Samurchhana* via *Virechana Trivrita Mula Churna* was selected. As *Trivritta* is the best drug for the *Virechana*[10]; it has *Laghu, Ruksha, Tikshana Guna, Katu Tikta Rasa, Uashna Veerya* and *Pittaghana* property. By all these properties and *Virechana* action of drugs *Trivritta* removes vitiated *Pitta* from body and relief of symptoms of *Kamala Vyadhi* occurs.

Probable mode of Action

Effects on *Dosha*: *Madhura, Tikta* and *Kashaya Rasa* all are said to be *Pitta-Shamaka* and maximum ingredients by virtue of their *Rasa* pacify the aggravated *Pitta Dosha* as *Kamala* is a *Pitta-Pradhan Vyadhi.* The properties like *Laghu* and *Ruksha* (87.5%) are *Kaphaghana, Shoshana, Agnideepana, Srotoshodhana* and *Lekhana. Tikshna Guna* which is present in 25% of the drugs in this combination act as *Vatakaphahara, Lekhana* and *Mala-Pravartaka. Madhura Vipaka* acts as *Vatapittghana* and *Dhatu Vardhana. Kaphavata-Shamaka* effect was present in 50% of the drugs while 25% of the drugs were *Tridoshahara* and rest 25% were *Kaphapitta-Shamaka.*
The analysis of all the contents revealed that 37.5% of the trial drug has *Sheetaveerya* which is *Pitta-Shamaka*, while *Ushna Veerya*which is present in 62.5% of the trial drug is *Vatakapha-Shamaka.*

Effects on the Dhatu: Majority of the drugs possesses *Tikta Rasa* (87.5%), *Laghu Guna* (87.5), *Ushna Veerya, Madhura Vipaka* which induces *Agni-Deepana, Srotoshodhana, Vatakaphashamana* and *Dhatu Poshana.*

Effects on *Srotas*: The trial drug by virtue of its *Kashaya* (37.5%), *Tikta* (87.5%) and *Katu Rasa* (25%); *Laghu, Ruksha* (87.5% each) and *Tikshana Guna* (25%) and *Ushna Veerya (*62.5%) causes *Lekhana, Srotoshodhana, Kandughana, Kaphavatashamana* and *Pachana*.

Effects on Agni: The vitiated form of the *Agni* presented in this case as *Mandagni* is managed through the drug via *Tikta* (87.5%), *Katu Rasa* (25%), *Ushna Veerya* (62.5%) and *Laghu Guna* (87.5%). *Tikta* and *Katu Rasa* acts as *Deepana, Pachana, Rochana* and *Aruchighana; Laghu Guna* is *Agni-Vardhaka*[11].Thus the drugs used in this formulation have combined effect in *Sampraptivighatan* i.e. disruption of pathogenesis leading to pacification of symptoms of this disease *Kamala*.

Conclusion

Kamala is a disease in which *Pitta Dosha* affect over *Rakta a*nd *Mamsadhatu* and ultimately leads to *Kamala Roga*[12]. The *Pitta* is produced abnormally during the *Paka* of *Raktadhatu*. *Pitta* formed during the *Dhautupaka* of *Rakta* passes through the *Raktasthana* of *Yakrit* and *Pleeha* and enters into the *Kostha*. The *Bhutagnipaka* take place in the *Yakrit*, it derives additional support from some of the important post digestive functions and metabolic events which have been shown by modern advances on physiology and bio-chemistry to takes place in *Yakrit.* The trial drugs repair the *Agnivikriti* and restore the *Agnivyapara*. The drugs are considered to act as a *Deepana, Pachana* and *Pitta Prashamana* along with *Kaphahara* quality. On the basis of clinical trial with *Ayurvedic* formulations, it can be concluded that the therapy has significant role in relieving symptoms and signs of the disease. It showed better efficacy on subjective criteria than biochemical criteria. No adverse effects were observed during the course of trial. The Trial drug has been proved as safe and effective therapy in *Kamala Roga* (Jaundice)

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