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Evaluation of efficacy of *Eladi Churna* and *Draksha Ghrita* in the Management of *Kamala* w.s.r. Impaired Liver Function

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ABSTRACT

Background: The incidence of *Kamala* is very common due to erratic lifestyle, food habits and sanitation (water pollution and contaminated food). On the basis of similarity in clinical symptomatology, *Kamala* can be co-related with jaundice as described in modern medical science. It is not an independent disease entity but a clinical condition which may arise due to diverse disease conditions. Multifactorial etiological conditions can result in impairment of liver function which clinically manifests as jaundice. Hence, apart from treating the basic disease which is responsible for this condition, every effort has to be done to improve the liver function which is primarily deranged.**Objectives:** To evaluate the effect of *Eladi Churna* and *Draksha Ghrita* in *Kamala Roga*. **Methodology:**A comparative clinical study was conducted on thirty patients of *Kamala*. Patients fulfilling the inclusion criteria were randomly selected for the trial and put into two groups of 15 patients each. Group-I was treated with *Eladi Churna* while group II was treated with *Eladi Churna* and *Draksha Ghrita*. Sign and symptoms of *Kamala* as*Netra, Twaka, Nakha, Mukha* and *Mutra Peetata, Avipaka, Aruchi, Hrullasa, Chardi, Daha, Daurbalya, Angasada, Kandu* as well as biochemical assessment was done as total serum bilirubin, serum glutamic oxaloacetic transaminases, serum glutamic pyruvic transaminases were recorded before and after treatment. Patients of obstructive jaundice, jaundice due to carcinoma of liver, gall bladder, pancreas, acute hepatocellular failure were excluded from the study. Assessment suggests improvement in patients suffering from Impaired Liver Function after 3 weeks of treatment.**Results:** Both Groups showed statistically significant result in terms of subjective as well as objective criteria. Group-II treated with *Eladi Churna* and *Draksha Ghrita*showed better result compared with Group-I treated with *Eladi Churna*.

Key Words *Kamala, Jaundice, Impaired Liver Function, Eladi Churna & Draksha Ghrita*

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INTRODUCTION

Kamala is one of the diseases described in detail in *Ayurvedic* literature. In *Charak SamhitaKamala*[1] has been considered as an advance stage of *Pandu*, whereas in *Susruta Samhita*[2] it has been considered as a complication of *PanduRoga* as well as an independent disease entity. *Kamala* is considered as a purely *Paittik Roga* caused by *Rakta Dushti* due to vitiated *Pitta* and vice-versa[3]. In fast life style of

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competitive world, people have irregular eating habits and changed lifestyle. Eating outside has become a fashion which increased risk of contaminated food and water. All these etiological factors lead to risk of related disorders. *Kamala*" is one of commonest disease[4]. It has great resemblance with the jaundice. Jaundice (*Kamala*) is a yellowish pigmentation of the skin, sclera, mucous membrane and body fluids caused by hyperbilirubinemia (increased levels of bilirubin in the blood). The incidence of Jaundice in India is 2.37-3.15 per 1000 population[5]. Hyperbilirubinemia is a primary sign of impaired liver function. Many hepato-protective drugs are available in *Ayurveda* which have potential to improve the impaired liver function. The fundamental treatment method of *Samsodhana, Samshamana* and *Nidanaparivarjana* mentioned in *Ayurvedic* classics, if administered judiciously, the desired results can be achieved. Ayurveda has described various drugs and preparations for the treatment of *Kamala*, among them ***Eladi Churna*** and ***Draksha Ghrita*** was selected for the study to evaluate its action.

METHODOLOGY

AIMS AND OBJECTIVES

- ***Primary objective***: To evaluate the efficacy of *Eladi Churna* and *Draksha Ghrita* in the management of *Kamala* w.s.r. to Impaired Liver Function.
- ***Secondary objective***: To assess the clinical safety of *Eladi Churna* and *Draksha Ghrita.*

I.E.C. APPROVAL

Vide Reg.no. Ayu/IEC/2018/1205

CTRI REGISTRATION

Vide Reg.no. CTRI No. CTRI/2020/06/026061

SELECTION OF THE PATIENTS

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

DIAGNOSTIC CRITERIA

Subjective criteria:

The patients were diagnosed on the basis of *Ayurvedic* and modern parameters. Clinical signs and symptoms as described in classical texts were considered for the diagnosis of *Kamala* as:

- *Netra, Twaka, Nakha, Mukha* and *Mutra Peetata* (Yellowish discoloration of sclera, skin, nail, mucous membrane and urine)
- *Avipaka* (indigestion)
- *Aruchi* (loss of appetite)
- *Hrullasa* (nausea)
- *Chardi* (vomiting)
- *Daha* (burning sensation)
- *Daurbalya* (weakness)
- *Angasada* (lassitude)
- *Kandu* (pruritis)

Objective criteria:

- Total Serum Bilirubin >2mg/ dl
- SGPT (ALT) >50 IU/L
- SGOT (AST) >50 IU/L

INCLUSION CRITERIA

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a) Patients who were willing to participate and able to provide signed informed consent.

b) Patient presented with classic features of *Kamala* and impaired liver functions.

- Total Serum Bilirubin- 2 to 10 mg/dl
- SGOT- 50 to 1000 IU/L
- SGPT- 50 to 1000 IU/L

EXCLUSION CRITERIA

a) Patients who were not willing for trial enrolment.

b) Patient below the age of 20 years and above 60 years.

c) Patient having malignancy and acute hepatocellular failure.

d) Patient requiring surgical intervention (obstructive jaundice)

- Total Serum Bilirubin <2mg/dl or >10 mg/dl
- SGOT >1000 IU/L
- SGPT >1000 IU/L
- Serum ALP> 3 times the normal

INVESTIGATIONS

Investigations were done to confirm the diagnosis and rule out other pathology.

A. Blood examination

i. Haematological investigations - CBC, ESR

ii. Biochemical investigations -

- FBS
- Liver Function Test- TSB, DSB, SGOT, SGPT, ALP, Total Serum proteins, Serum Albumin, Serum Globulin, A:G ratio
- Serum lipid profile
- Renal Function Test- B. Urea, S. Creatinine

B. Urine Examination - Routine and Microscopic

C. USG Whole Abdomen if required.

GROUPING OF PATIENTS

Study was conducted on 30 patients. Study subjects were randomly divided into two groups.

Group-I: In this group 15 patient of *Kamala* were managed with *Eladi Churna*.

Group-II: In this group 15 patient were managed with *Eladi Churna* and *Draksha Ghrita*.

TRIAL DRUG: *Eladi Churna*[6](Table 1)and *Draksha Ghrita*[7](Table 2)

Table 1 Components used in formulation of *Eladi Churna*

Sr. No.	Ingredients	Latin name	Family	Part used	Proportion
1.	*Ela*	*Elettaria cardamomum Maton.*	Zingiberaceae	Fruit	1 part
2.	*Jeerak*	*Cuminum cyminum Linn.*	Apiaceae	Fruit	1part
3.	*Bhoodhatri*	*Phyllanthus urinaria Linn.*	Euphorbiaceae	Whole plant	1 part
4.	*Sita*				1 part

Table 2 Components used in formulation of *Draksha Ghrita*

Sr. No	Ingredients	Botanical name	Family	Part used	Proportion
1.	*Draksha*	*Vitis vinifera Linn.*	Vitaceae	Fruit (Dry)	1 part
2.	*Murchhita Goghrita*				2 part

PREPARATION OF DRUGS

Eladi Churna- The drug was prepared as per standards of GMP in the Charaka Pharmacy of College with batch no. R/12/20 and date of manufacturing was 08/06/2020. Chemical analysis of trial formulation was done at drug

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testing laboratory Joginder Nagar Distt. Mandi (H. P).

Draksha Ghrita- The drug was prepared as per standards of GMP in the Charaka Pharmacy of College with batch no. R/13/20 and date of manufacturing was 10-6-2020. Chemical analysis of trial formulation was done at drug testing laboratory Joginder NagarDistt. Mandi (H. P).

ADMINISTRATION AND DOSE OF DRUG

Eladi Churna-3gm twice a day with water

Draksha Ghrita- 6gm twice a day

- **Route of administration**: Oral
- **Duration of Trial**: 21 days.
- **Follow up**: After every 7 days till completion of the trial.

CRITERIA OF ASSESSMENT

The effect of treatment was assessed on the basis of various subjective and objective criteria. Subjective criteria were assessed on the basis of scoring system.

1. *Netra, Twaka, Nakha, Mukha* and *Mutra Peetata* (Yellowish discoloration of sclera, skin, nail, mucous membrane and urine)

- Grade 0 - Normal coloration of all
- Grade 1 - Yellow coloration of sclera and nails
- Grade 2 - Yellow coloration of sclera, nails, mucous membrane and urine
- Grade 3 - Yellow coloration of all

2. *Aruchi*(Anorexia)

- Grade 0 - Normal desire for food
- Grade 1 - Eating timely without much desire
- Grade 2 - Desire for food only after long intervals
- Grade 3 - No desire for food at all

3. *Hrullasa*(Nausea)

- Grade 0 - No nausea
- Grade 1 - Present occasionally
- Grade 2 - Present frequently and to recognize extent
- Grade 3 - Present quite regularly as intolerable extent

4. *Chardi*(Vomiting)

- Grade 0 - No vomiting
- Grade 1 - Vomiting Present occasionally
- Grade 2 - Frequency of vomiting four to six times per week
- Grade 3 - Frequency of vomiting daily

5. *Avipaka* (Indigestion)

- Grade 0 - Normal digestion
- Grade 1 - Occasional indigestion once or twice a week
- Grade 2 - Occasional indigestion 3-5 times a week
- Grade 3 - Indigestion after every meal

6. *Angasada* (Lassitude)

- Grade 0 - No *Angasada*
- Grade 1 - Occasional *Angasada* but patient is able to do routine work
- Grade 2 - Continuous *Angasada* which hampers routine work
- Grade 3 - Continuous *Angasada* patient is unable of doing any work

7. *Daha*(Burning sensation in abdomen)

- Grade 0 - No burning sensation

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- Grade 1 - Occasional burning sensation in abdomen
- Grade 2 - Burning sensation 3-4 times a day, relieved by food and water
- Grade 3 - Continuous complaint relieved by antacids

8. *Daurbalya* (Weakness)

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

9. *Kandu*(Pruritis)

- Grade 0 - Absent
- Grade 1 - Occasional present
- Grade 2 - Present frequently without scratch mark
- Grade 3 - Present regularly with scratch mark

STASTICAL ANALYSIS

Data obtained during the trial was tabulated and statistically analysed using Students Paired 't' Test. The results were considered significant or insignificant based on the p- value.

- Highly significant $p< 0.001$
- Significant $p< 0.01$, $p< 0.05$
- Insignificant $p< 0.01$

OBSERVATIONS & RESULTS

In this study thirty patients fulfilling the diagnostic and inclusion criteria were registered. Out of which twenty five patients completed the study. They were randomly divided into two groups. Observations made during the clinical study are maximum number of patients in the present study i.e, 46.6% were in the age group of 30-40 years followed by 20% in the age group of 50- 60 years. 63.3% patients were males and remaining 36.6% were females. Marital Status wise distribution showed 93.3% patients were married while remaining 6.6% were unmarried.Majority of the patients in the present study i.e,50% were farmers, 36.6% were doing job while 6.6% patients were involved in business and 6.6% patients in the present study were engaged in other works.56.6% patients belonged to below poverty line while 43.3% belonged to above poverty line.Majority of patients i.e, 90% had mixed dietary habits while 10% were having vegetarian diet. 43.3% of the patients were addicted to alcohol. Majority of patients i.e, 53.3% patients were active while 33.3% had average lifestyle, 46.6% patients used general water supply as their source of drinking water, 46.6% patients had regular bowel habit, 43.3% had constipation while 10% had irregular bowel habit. 50% of the patients had *Pittaja-Kaphaj Prakriti* while 40%had *Vata- Pittaja Prakriti*. 60% patients had *Heena Abhyavaharana Shakti* while 30% had *MadhyamAbhyavaharana Shakti*, 70% of the patients had *Heena Jarana Shakti* while 23.3% patients had *MadhyamJarana Shakti*, 50% patients had *Mandaagni* while 20% patients had *Vishamangi.Netra, Twaka, Nakha, Mukha, Mutra*

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*Peetata*was observed in 96.6% patients followed by *Hrullasa*in 80% of patients. 73.3% patients had *Avipaka* and *Angasada*. 66.6%patients had *Daha* and *Daurbalya* while 33.3% of the patients had *Kandu*.

EFFECT OF THERAPY

Therapeutic effect of therapy was studied on the basis of various subjective (Table 3) and objective criteria (Table 4). Effect of therapy was also studied on haematological (Table 6) and biochemical investigations (Table 5).

DISCUSSION

Table 3 Effect of therapy on subjective criteria

Subjective Criteria	Group	Mean Score		% change	Mean Diff.	S.D.±	S.E.±	t-value	p-value	Inter-Group comparison
		BT	AT							
Netra, Twaka, Nakha, Mukha,Mutra Peetata	Group I	1.73	0.46	72.8	1.3	0.79	0.206	0.141	<0.001	0.014
	Group II	1.93	0.40	79.29	1.6	0.640	0.165	9.280	<0.001	
Aruchi	Group I	1.6	0.4	75	1.2	0.704	0.182	6.971	<0.001	0.054
	Group II	1.06	0.26	75	0.8	0.676	0.175	4.583	<0.001	
Avipaka	Group I	1.1	0.8	72.7	0.3	0.834	0.215	4.026	0.001	0.302
	Group II	1.26	0.33	75	0.9	0.594	0.153	6.089	<0.001	
Hrullasa	Group I	1.6	0.6	62.5	1.0	0.704	0.182	5.870	<0.001	0.005
	Group II	1.2	0.3	72.7	0.9	0.561	0.145	5.527	<0.001	
Chardi	Group I	0.6	0.2	66.6	0.4	0.507	0.131	3.055	0.009	0.059
	Group II	0.7	0.4	42.8	0.3	0.617	0.159	2.092	0.055	
Daha	Group I	1	0.4	60	0.6	0.507	0.131	4.583	<0.001	0.037
	Group II	1	0.2	80	0.8	0.775	0.2	4	0.001	
Daurbalya	Group I	0.8	0.3	62.5	0.5	0.516	0.133	4	0.001	0.024
	Group II	0.6	0.2	66.6	0.4	0.507	0.131	3.055	0.009	
Angasada	Group I	1.2	0.4	63.6	0.8	0.704	0.182	4.036	0.001	0.019
	Group II	1.4	0.4	69.2	1	0.594	0.153	6.089	<0.001	
Kandu	Group I	0.3	0.06	66.6	0.24	0.458	0.118	2.256	0.041	0.037
	Group II	0.4	0.1	75	0.3	0.458	0.118	2.256	0.041	

Table 4 Effect of therapy on Liver function test

Criteria	Group	Mean Score		% Change	Mean Diff.	S.D.±	S.E.±	t-value	p-value	Inter-Group comparison
		BT	AT							
TSB	Group I	3.9	2.1	43.5	1.8	0.79	0.204	8.429	<0.001	0.021
	Group II	2.8	1.4	50	1.4	0.77	0.19	7.407	<0.001	
DSB	Group I	1.8	0.8	50	1	0.96	0.24	3.913	0.002	0.098
	Group II	1.2	0.6	50	0.6	0.52	0.14	4.561	<0.001	
ISB	Group I	2.06	1.4	29.1	0.6	0.56	0.14	4.641	<0.001	0.032
	Group II	1.6	0.8	43.8	0.8	0.64	0.16	4.469	<0.001	
SGOT	Group I	171.8	130.2	24.2	41.6	50.42	13.02	3.190	0.007	0.110
	Group II	170.6	99.8	41.5	70.8	69.14	17.86	3.970	0.001	
SGPT	Group I	144.6	107.4	25.8	37.2	39.88	10.29	3.620	0.003	0.103
	Group II	164.1	106.4	35.2	57.7	76.56	19.76	2.921	0.011	
ALP	Group I	108.4	106.3	1.9	2.1	3.11	0.81	2.58	0.022	0.328
	Group II	100	90	0.8	10	4.38	1.14	0.765	0.457	
T. Proteins	Group I	7.24	6.68	7.7	0.6	0.66	0.16	3.360	0.104	0.454
	Group II	6.8	6.6	3.2	0.2	0.98	0.26	0.853	0.408	
Albumin	Group I	3.8	3.2	18.4	0.6	0.92	0.24	3.160	0.007	0.054

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	Group II	4.05	3.59	9.8	0.46	0.92	0.24	1.949	0.072	
Globulin	Group I	3.4	3.5	2.9	0.1	1.012	0.26	0.434	0.671	0.008
	Group II	3.06	3.18	3.92	0.12	1.118	0.28	0.416	0.684	
A/G Ratio	Group I	1.2	0.9	16.6	0.3	0.46	0.118	1.874	0.052	0.783
	Group II	1.50	1.54	2.9	0.04	0.48	0.14	0.65	0.527	

Table 5 Effect of therapy on Biochemical parameters

Criteria	Group	Mean Score		% Change	Mean Diff.	S.D.±	S.E.±	t-value	p- value	Inter-group
		BT	AT							
FBS	Group I	94.80	92.93	1.96	1.8	3.68	0.951	1.964	0.070	0.900
	Group II	98.06	97.4	0.67	0.6	6.37	1.647	0.405	0.692	
Cholesterol	Group I	172.4	166.1	3.71	6.3	26.96	6.963	0.919	0.374	0.570
	Group II	191.3	159	16.88	32.3	52.55	13.56	2.383	0.032	
Triglyceride	Group I	168.3	151.4	10	16.9	40.48	10.45	1.613	0.129	0.097
	Group II	154.3	149.8	2.91	4.5	44.44	11.48	0.395	0.699	
HDL	Group I	53.8	54.4	0.92	0.6	11.38	2.93	0.181	0.859	0.890
	Group II	50	53.7	7.4	3.7	7.26	1.88	1.993	0.066	
LDL	Group I	92.6	92	0.64	0.6	11.81	3.050	0.197	0.847	0.592
	Group II	114.3	82.6	27.7	31.7	35.66	9.21	3.44	0.004	
VLDL	Group I	33.6	39.8	18.45	6.2	13.10	3.382	1.833	0.088	0.837
	Group II	32.4	31.9	1.2	0.5	18.16	4.687	0.085	0.933	
B.Urea	Group I	32.9	32.8	0.18	0.1	1.831	0.473	0.141	0.890	0.900
	Group II	30.6	29.6	3.4	1	2.06	0.53	2.014	0.064	
S. Creatnine	Group I	0.9	0.8	12.70	0.1	0.301	0.07	1.629	0.126	0.570
	Group II	0.8	0.7	7.5	0.1	0.16	0.038	1.72	0.106	

Table 6 Effect of therapy on hematological profile

Criteria	Group	Mean Score		% change	Mean Diff.	S.D.±	S.E.±	t-value	p-value	Inter-Group
		BT	AT							
Hb%	Group I	9.6	9.7	1.25	0.1	0.668	0.172	0.696	0.498	0.673
	Group II	10.2	10.4	2.97	0.2	0.684	0.177	1.924	0.075	
TLC	Group I	8906.6	8593.3	3.5	313.3	900.68	232.55	1.347	0.199	0.888
	Group II	9546.6	9480	0.6	66.6	725.72	187.38	0.35	0.727	
Neutrophil	Group I	63.62	62.94	1.06	0.6	4.723	1.219	0.563	0.582	0.081
	Group II	60.72	60.78	0.08	0.06	6.130	1.583	0.033	0.974	
Lympho-cytes	Group I	25.94	25.16	2.7	0.78	4.655	1.202	0.649	0.527	0.680
	Group II	30.04	26.58	11.3	3.46	6.713	1.733	1.996	0.066	
Mixed	Group I	11.09	10.56	4.7	0.6	2.214	0.572	0.933	0.367	0.465
	Group II	7.53	7.14	5.17	0.39	4.136	1.068	0.368	0.718	
ESR	Group I	12.06	13.80	14.3	1.8	2.963	0.765	2.265	0.052	0.581
	Group II	16.6	16	3.6	0.6	3.291	0.850	0.706	0.492	

SUBJECTIVE CRITERIA

1. ***Netra, Twaka, Nakha, Mukha, Mutra Peetata:***The percentage of improvement of *Netra, Twaka, Nakha, Mukha,Mutra Peetata*was more in group-II i.e, 79.27% as compared to group-I which was 72.8%. Statistically the difference in the effect of two therapies was significant. Because due to the effect of trial drug (*Eladi Churna and Draksha Ghrita*) major amount of bilirubin excreted so *Peetata* of *Netra, Twaka, Nakha, Mukha, Mutra* was decreased**.**

2. ***Aruchi*:**The percentage of relief of *Aruchi* in both the groups was 75% which was statistically highly significant.But the intergroup comparison it was statistically insignificant. The trial drug act as *Deepana, Pachana, Rochana* and

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Srotoshodhaka which pacify *Aruchi* and *Daha*. It restores the *Agni Vyapara* and eliminates the vitiated *Pachak Pitta* and *Ranjak Pitta.*

3. *Avipaka:* This study revealed that 73.3% patients had complaints of*Avipaka*. Vitiation of *Vata* and *Kapha* leads to cause *Agnimandya* and favours for the manifestation of*Avipaka.* In patients of group-I, 72.7% improvement was assessed whereas 75% improvement was assessed in patients of group-II. But the intergroup comparison was statistically insignificant. Trial drug (*Eladi Churna* and *Draksha Ghrita*) acts as *Deepan*, *Pachana* and restores the *AgniVyapara* and *Ama* condition of *Kamala*.

4. *Hrullasa:* This study revealed that percentage of improvement in group-I and group-II was 62.5% and 72.7% respectively. However, the percentage of improvement was more in group-II as compared to group-I. Statistically the difference in the effect of the two therapies was significant. Due to *Shoshaka* property (*KashayaRasa*) of ingredients of trial drug, it may absorb the increased *Drava Guna* of vitiated *Pachaka Pitta*.

5. *Chardi:* In group-I, the percentage of improvement of *Chardi* was 66.6% which was statistically significant while group-II, shows 42.8% improvement. Statistically the difference in the effect of the two therapies was insignificant.

6. *Daha:* In patients of group-I, the percentage of improvement of *Daha* was 60% whereas 80% improvement was assessed in patients of group-II. Statistically, the difference in the effect of two therapies was statistically significant. The trial drug act as *Deepana, Pachana, Rochana* and *Srotoshodhaka* which pacify *Daha*. It restores the *Agni Vyapara* and eliminates the vitiated *Pachak Pitta, Ranjak Pitta, Samana* and *Vyanavata*.

7. *Daurbalya:* This study revealed that 66.6% patients had complaints of *Daurbalya*. The involvement of three *Doshas* together associated with *Rasavaha Srotas* causes *Daurbalya.*

In patients of group-I, the percentage of improvement of *Daurbalya* was 62.5% whereas 66.6% improvement was assessed in group-II, shows. Statistically the difference in the effect of the two therapies was significant. It may be due to *Madhur Rasa, Madhur Vipaka, Snigdh, Guru Guna* and *Balaya Guna* of *Draksha.*

8. *Angasada:* In group-I, the percentage of improvement of *Angasada* was 63.6% while group-II, shows 69.2% improvement. Statistically the difference in the effect of the two therapies was significant.

9. *Kandu:* This study revealed that percentage of improvement of*Kandu* in group-I and group-II was 66.6% and 75% respectively. Generally itching subsides as soon as biliary drainage is obtained. Trial drug may cause biliary drainage due to *Yakriduttejaka, Pitta-Rechana* and *Mutra Virechna Karma.*

LIVER FUNCTION TEST

Total Serum Bilirubin: This study revealed that in patients of group-I, 43.5% improvement was assessed where as 50% improvement was found

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in patients of group-II. Statistically the difference in the effect of two therapy was significant.

Direct Serum Bilirubin: This study revealed that 50% improvement was assessed in both groups. However, the difference in the effect of two therapy was statistically insignificant.

Indirect Serum Bilirubin: In patients of group-I, 29.1% improvement was assessed where as 43.8% improvement was found in patients of group-II. Statistically the difference in the effect of two therapy was significant.

It may be due to cholagogue action and purgative action of Trial drug *(Eladi Churna* and *Draksha Ghrita),* because of its cholagogue action the drug maintains the flow of bile in the gut and then due to mild purgative effect, it helps in the removal of vitiated *Pitta* from the body via stool.

SGOT: This study revealed thatin patients of group-I, 24.2% improvement was assessed where as 41.5% improvement was assessed in patients of group-II. Statistically the difference in the effect of two therapy was insignificant.

SGPT: The statistical analysis of the data revealed that in patients of group-I, 25.8% improvement was assessed where as 35.2% improvement was assessed in patients of group-II which was statistically significant in both groups. But the difference in the effect of two therapy was statistically insignificant.

ALP: In patients of group-I, 1.9% improvement was assessed where as 0.8% improvement was assessed in patients of group-II. Statistically, the difference in the effect of two therapy was insignificant.The trial drugs such as *(Eladi Churna* and *Draksha Ghrita)* have marked hepatoprotective action against tissue injury and normalize the serum parametrers like SGOT, SGPT, ALP, and bilirubin. They also showed a significant stimulatory effect on liver cell regeneration.

Total Proteins: This study revealed that in patients of group-I, 7.7% improvement was assessed where as 3.2% improvement was assessed in patients of group-II. Statistically, the difference in the effect of two therapy was insignificant.

Serum Albumin: The statistical analysis of the data revealed that in patients of group-I, 18.4% improvement was assessed where as 9.8% improvement was assessed in patients of group-II. Statistically, the difference in the effect of two therapy was significant.

Serum Globulin: In patients of group-I, 2.9% improvement was assessed where as 3.92% improvement was assessed in patients of group-II. Statistically, the difference in the effect of two therapy was significant.

Albumin: Globulin Ratio: In patients of group-I, 16.6% improvement was assessed where as 2.9% improvement was assessed in patients of group-II. Statistically, the difference in the effect of two therapy was insignificant.

BIOCHEMICAL PARAMETERS

The results obtained on the biochemical parameters like fasting blood sugar, blood urea, serum creatinine, serum lipid profile remained within normal limits beforeand after the

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completion of therapy except serum cholesterol and low-density lipid.

Serum cholesterol: In patients of group-I, 3.71% improvement was assessed whereas 16.8% improvement was assessed in patients of group-II which was statistically significant. But the difference in the effect of two therapy was statistically insignificant.

Low-density Lipid: In patients of group-I, 0.64% improvement was assessed where as 27.7% improvement was assessed in patients of group-II which was statistically significant. But the difference in the effect of two therapy was statistically insignificant.

MurchanaSamskara (processing of ghee) contributes specific properties in *Ghrita* which help to reduce total cholesterol, LDL, Triglycerides and to increase HDL. In addition to this, drugs used in the *Murchana Samskara* having *Katu*, *Tikta*, *KashayaRasa* (taste), *Laghu*, *RukshGuna*, *Kaphahara Doshagnata*, *Lekhaniya Karma*. These attribute the *Medohara* property (hypolipidemic activity) to *Murchita Ghrita*[8].

HAEMATOLOGICAL PROFILE

No untoward effect of therapy was seen on the hematological profile of the patients. The values obtained before and after the completion of therapy remained within normal limit. On intergroup comparison, it was found that there was statistically insignificant difference between both groups.

OVERALL EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS

Overall effect of therapy revealed that among twelve patients of group-I, three patients showed mild improvement,four patients showed moderate improvement while five patients showed marked improvement. In group-II, out of thirteen patients, one patient was mildly improved, five patients showed moderate improvement and seven patient showed marked improvement. (Table 7)

Table 7 Overall effect of therapy on 25 patients of *Kamala*

Group	Unimproved (<25%)	Mild Improvement (25-50%)	Moderate Improvement (51%-75%)	Marked Improvement (>75%)	Total
I	0	3	4	5	12
II	0	1	5	7	13

PROBABLE MODE OF ACTION

The fundamentals regarding treatment in *Ayurveda* are mainly based on *Doshika Chikitsa*. *Kamala Roga* is especially a *Pitta predominant disorder* and *Ranjaka Pitta* is responsible for its pathogenesis. Hence, the line of treatment adopted comprises of measures used for the pacification of *Pitta Dosha*. The action of every drug is determined by the dominant pharmaco-dynamic factor and that may be anyone out of *Rasa*, *Guna*, *Veerya*, *Vipaka* and *Prabhava*[9].

Probable Mode of Action of Drvayas Used for Chikitsa

Dravya	Mode of action
Ela	*Pittaghna*
Jeerak	*Deepan, Pachana, Agnivardhak*
Bhumyamlaki	*Pitta Sarak, Yakrit Uttejak, Rechan, Srotoshodhak,*

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	Pitta Rechana
Draksha	*Pittaghna*

Regarding mode of action we have rationally discussed above properties and action which might be responsible to bring changes in sign and symptoms of *Kamala*. However, observing the outstanding changes in the condition of patients we have opinion that drug acts certainly by *Dravya prabhava* also. Therefore, we may infer that the action of the Drug in improving the sign and symptoms of *Kamala* patients by *Dravya guna prabhava*[10]. *Kamalahara* or hepatoprotective activities of *Eladi Churna and Draksha Ghrita* are basically due to *Pittashamaka*, *Yakriduttejaka* (chloretic), *Pitta-Saraka* (cholagogue), *Anuloman* and *Rechaka* (laxative or purgative) properties.

On the modern parameters we can say that the Herbal Hepato protective preparations have Cholegouge and Cholertic action, Hepatocellular regeneration, Antiviral, Antioxident, Enzymes and Metabolic correction, Digestive, Membrane stabilizing effect, Immuno modulating action, anti inflammatory action and Antipyretic action[11].

CONCLUSION

On the basis of above observations and discussion, it is concluded that *Eladi Churna* along with *Draksha Ghrita* is more effective as compared to *Eladi Churna* given individually.No untoward effect of therapy was seen during the entire trial period.

ADVERSE EVENTS

No adverse events were reported/ observed during the course of study.

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