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Clinico-Pathological Study of *Phalatrikadi Ghana Vati* and *Vasadi Ghana Vati* on Kamala w.s.r to Jaundice

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ABSTRACT:

Introduction: *Kamala*, described in Ayurveda classics resembles to the clinical features of Jaundice. 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 Jaundice. **Materials and methods:** A clinical study on 30 *Kamala* patients, (15 patients each in Group-A and Group-B) were registered from OPD and IPD of Govt. Ayurvedic College and Hospital, Balangir, Odisha. The patients presented with the Subjective Parameters of *Haridra netra, twak, nakha and mukha* (yellow discoloration of eye, skin, nail bed and oral mucosa), *Rakta pita purisha and mutra*, *Bheka varna* , *Hatendriya*, *Daha* , *Avipaka Daurbalya*, *Sadana*, *Aruci*, *Karshana* and Objective parameters as LFT, Urine Bile Salt/Bile Pigment, Stool examination and CBC were selected for clinical study. Group-A patients were treated with *Phalatrikadi Ghana Vati* (500mg) and Group-B patients with *Vasadi Ghana Vati* (500 mg) thrice daily after food with honey or luke warm water orally for 15 days respectively. The patients were assessed at 10 days interval up to 30 days in order to find the efficacy of both the trial drugs. The subjective and objective parameters were analysed statistically by Wilcoxon-W test and p-value.

Observation and result: The Statistically significant ($P<0.05$) result was revealed in both Group-A and Group-B but improvement was noticed more in Group-A.

Conclusion: -The overall study revealed that the trial on *Phalatrikadi Ghana Vati*, i.e., Group-A showed more efficacy than *Vasadi Ghanavati* i.e, Group-B. The composition of *Phalatrikadi Ghana Vati* helped more to develop the body immunity as well as maintain the LFT parameters rather than *Vasadi Ghanavati.* No adverse effects was noticed during clinical trial in both groups.

Key words: *Kamala*, Jaundice, *Phalatrikadi Ghana Vati*, *Vasadi Ghanavati*

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 Jaundice.[6] There are many mechanisms which causes Jaundice as follows -

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. 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".

" *Phalatrikadi Ghanavati*[2]", which having common and unique notation part as *Phalashruti* in different Ayurved literatures. Properties of *Phalatrikadi Ghanavati 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.*

AIMS AND OBJECTIVES

To establish co-relation between *kamala* with jaundice.

To find out the effective treatment of Jaundice in Ayurveda.

To evaluate the effect of ***Phalatrikadi Ghana Vati, Vasadi Ghanavati*.**

MATERIALS AND METHODS

CTRI Registration Number- CTRI/2021/04/033132 (Registered on: 26/04/2021)

IEC Number- 1144/GAC &H, Dated:20/05/2020

Selection of the patients:

Total 30 patients of Jaundice had been selected by a special proforma covering demography along with both Subjective and Objective parameters from OPD and IPD of Govt. Ayurvedic College and Hospital, Balangir. The Subjective parameters were *Haridra netra, twak, nakha and mukha* (yellow discoloration of eye, skin, nail bed and oral mucosa), *Rakta pita purisha and mutra, Bheka varna* (toad like color of skin), *Hatendriya* (blunting of senses), *Daha* (burning sensation of body), *Avipaka* (indigestion), *Daurbalya* (weakness), *Sadana* (malaise), *Aruci* (anorexia), *Karshana* (weight loss). and Objective parameters were LFT, HB%, CBC, BILE SALT BILE PIGMENT, STOOL EXAMINATION. The consent of patients was also taken before clinical trial.

Grouping: 30 patients were divided into two groups i.e, Group-A (15) patient's trial with *Phalatrikadi Ghanavati* and Group-B (15) trial with Vasadi Ghanavati with 500mg thrice a day with luke warm water for 15 days after meal.

***Inclusive Criteria*[6]-**

Age –05 to 50 yrs

Sex – Both sexes

Patients – Having raised serum bilirubin (> 5 mg/dl)

Patients – Having signs and symptoms of Kamala uncomplicated patient

Exclusion Criteria-

Age below 05 yrs and above 50 yrs

Known cases of HIV infection/ AIDS

Cases of liver abscess, liver cirrhosis, HBsAg positive and known case HIV Positive.

Patients having malignancy

Serum bilirubin more than 20 mg/dl

Hyperbilirubinaemia due to congenital causes, Drug toxicity, AKT.

Obstructive pathology

Patients in acute alcohol withdrawal state, intoxication, hepatic encephalopathy

Criteria for Investigation:

LFT, CBC, Bile Salt, Bile pigment, Hb were investigated

initially and in follow up periods.

SELECTION OF DRUGS:

Two medicines *Phalatrikadi Ghanavati and Vasadi Ghanavati* had been taken for clinical trial. The drugs of both medicines were identified by the experts of Dept. of Dravyaguna and Rasashastra and Bhisajya Kalpana which were approved by DRC and IEC of Govt. Ayurvedic College & Hospital and Sambalpur University. Medicines were prepared as per GMP certified method in Mini Pharmacy of College under the supervision of expert of Rasashastra and Bhisajya Kalpana. The sample of research medicines were sent to Quality control Laboratories of ALN Rao Memorial Ayurvedic Medical College and PG centre Koppa, Distt. Chikmagalur, Karnatka for Analytical study.

Table No.-01; Showing the pharmacodynamics of *Phalatrikadi Ghanavati* and *Vasadi Ghanavati*

Preparation of Trial Drug-1(*Phalatrikadi Ghanavati*):

All the above drugs were taken in 1 part each and made them into Yavakuta form. After Yavakuta, Kwatha had been prepared. The Kwatha had been converted to Ghanavati and 500 mg tablet was made for easy medication.

Preparation of Trial Drug-2 (*Vasadi Ghanavati*):

All the above drugs were taken in 1 part each and made them into Yavakuta form. After Yavakuta, Kwatha had been prepared. The Kwatha had been converted to Ghanavati and 500 mg tablet was made for easy medication.

Dose- *Phalatrikadi Ghanavati* 500mg and *Vasadi Ghanavati* 500 mg thrice daily after food with *honey*/*ushna jala* in Group A and Group B respectively.

Assessment Criteria

The Subjective parameters and Objective parameters as per Inclusion Criteria were fixed by the grading score from 0 to 3 according to the severity of disease and favorable shift to back. Both parameters were followed up 05th, 10th and 15th day of medication. The overall assessments were done considering the percentage of relief in both parameters and statistical evaluation was made.

OBSERVATION & RESULTS

The clinical study period of 30 patients were from 09-05-2021 to 16-05-2021. Within the aforesaid period the demography (Table No.-02) based on Age-Sex-Religion etc., along with incidence of *Dasvidha Pariksha* (Table No.-03) were observed and assessed. The results obtained after completion of the trial were recorded in tabular forms along with graphical presentations as follows

The Subjective and Objective Parameters of both Group-A and Group-B wereobserved during clinical study. The percentage of improvement were also observed and assessed after clinical trialwhich is placed here as Table No.-04.

The observations made before and after treatment of Objective parameters of Group-A were assessed and the statistical analysis was carried out with the help of statistical method

. (Table No.-05,06,07 and Figure No.01)

DISCUSSION

It was observed that Kamala was seen in each age group from children to old age people. Most of the patients (43.3%) were found from Middle aged (21-30 years) due to small sample study. In this study, disease is common between younger age group. The probable cause for increased prevalence in this age group might be that younger age group patients are prone to mental stress, excessive exercises, irregularity in diet and improper *viharas (Atapa sevana, Ratrijagarana* etc.) due to their professional responsibilities. Kamala was the most common and widespread infectious disorder in the world. Equal number of Sex i.e., both male and female. But in the present clinical study there has male persons are more effected than female because in India it has been estimated that 10 – 20% of all adult males drink alcohol as compared to less than 1 % of female adults. So this implies that, males are usual targets of this disease. In this study also the males outnumbered females consisting 66.67% of the total sample. However females have greater susceptibility to this disease when compared to males. Reasons might be the smaller organ size and also females have decreased alcohol dehydrogenase in their gastric mucosa, lessening metabolism. Religion wise distribution showed that maximum numbers of patients i.e., 30(100 %) were Hindus. This may reflect demographic pattern of religion. And due to small sample study couldn't conclude, that this disease was more prone towards Hindus. Regarding Occupation It was observed that Kamala was found in all occupational person i.e., serviceman (26.67%) followed by students (20.00%), farmer (16.67%), Housewives (16.67%) and labour (10.00%). In the present study the occupation incidence shows that the patients belong to heterogeneous group of different occupation i.e. physical work, field work, desk work, housewives. Physical strain, stressful life and

poverty may be the reason for more number of physical work laborers in the present study. Maximum number of patients i.e., (90%) were already taken treatment for this disease. It showed that the clinical sign and symptom persists again and again irrespective of treatment taken. This reveals that the patients were having no family history of *Kamala* .This showed that as it was not a hereditary disease. Maximum patients were educated (90.00%) and only 3(10.00%) person was Illiterate. Hence it showed that this disease can affect anyone irrespective of the literacy status. Most of the patients were found married (63.33%). But marriage does not affect the occurrence of the disease as it was found in both married and unmarried patients. It was observed that most of the patients were from middle class (60.00%) and 40% were from lower class. In the present study most of the patients were from middle class which can be attributed to consumption of normal diet not much more sufficient in high quality of food and drink. Also there can be attributed due to their stressful life. Due to small sample size, it couldn't find any patient from upper class and the result may vary in large sample. It was observed that most of the patients were taking Nonveg diet (63.33%) and 10% were vegetarians. Maximum i.e., 12(40%) patients were found to addicted to coffee, 11(36.67%) were addicted to alcohol, Smoking, and Tobacco respectively, whereas 7(23.33%) were addicted to Tea. These all are mainly of Kashaya-Rasa predominance and helps in vitiating *Vata, Pitta Doshas*, which later vitiate *Kapha dosha* and were also harmful for digestive processes. It may destroy *Dhatuposhana kriya* and leads to *Kamala*. In this study equal number of the patients i.e., 50-50% had both sound and disturbed sleep. So it attributed that there had no any specific reason related to sleep in the present clinical study. Maximum number of patients i.e., 90.00% were having abnormal bowel habit which showed that most of the patients were constipated. Maximum number of patients i.e., 63.33% were having abnormal urination habit which showed that most of the patients were less urination than the normal. This may be due less amount of water intake in the body can attributed to less urination . It was observed that all patients i.e. 100% of patients were having gradual onset. In nutshell it was revealed that, P-Values ($P<0.05$) for Subjective and Objective parameters were statistically significant in bothGroup-A and Group-B. Further it showed that, mean rank for Group A was greater than Group B and effect of *Phalatrikadi Ghanavati* (Group A) was more than *Vasadi Ghanavati* (Group B).

The overall assessment revealed that 08(53.33%) and 9(60%) patients of Group-A and Group-B respectively was noticed moderate improvement. 7(46.67%) patients from Group-A and 2(13.33%) from Group-B were marked improvement. Four patients from Group-B was under mild improvement in the study. (Table No. 08and Figure No.08)

CONCLUSION

Clinical evaluation of *Phalatrikadi Ghanavati and Vasadi Ghanavati in Kamala* was completed in 30 patients. In Trial group of A with 15 patients treated with *Phalatrikadi Ghanavati* and 15 patients in control group, which is group B treated with *Vasadi Ghanavati*. Conclusion drawn according to observation and results are given here:

Most of the patients were from Middle class income group and were educated. Maximum patients having the habit of diet of *Katu Rasa*. Then *Amla, Lavana rasa* dominance was 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.* Percentage of *Kamala* was observed more in *Vata-Pittaja prakriti.* Percentage of *Kamala* was observed more in *Pittajadosha* dominant. Evidence of *Kamala* was very much seen in patients having *Tikshna & Mandagni.* Conclusion of symptoms as per scoring system in patients of *Kamala- Phalatrikadi Ghanavati* significantly reduces symptoms upto 73.31 % which is very beneficial As compared *Vasadi Ghanavati* which reduces symptoms to 57.45 %. 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. After applying paired t test for biochemical markers we found *Phalatrikadi Ghanavati* reduces Cholesterol, LDL, Triglycerides, S. Alkaline phosphate; which was not reduced by *Vasadi Ghanavati* in control group patients. Due to presence of *Guduchi is Phalatrikadi Ghanavati* it decreases total serum bilirubin and direct serum bilirubin%, SGOT, SGPT, level. Rest of all markers had no significant changes. After examining patients each after 05 days for total 15 days we found both *Vasadi Ghanavati and Phalatrikadi Ghanavati* reduces SGPT, SGOT & S. Bilirubin level significantly. After calculating significance of difference between trial and control

group with the help of unpaired t test we found *Phalatrikadi Ghanavati* is highly significant in decreasing bilirubin, SGPT and SGOT levels.

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Table No.-01; Showing the pharmacodynamics of Phalatrikadi Ghanavati and Vasadi Ghanavati

SL.NO	*Name*	*Rasa*	*Guna*	*Virya*	*Vipaka*	*Doshaghnata*
1.	*Vasa*	*Tikta Kasaya*	*Laghu Sheeta*	*Sheeta*	*Katu*	*KaphaPitta samaka*
2.	*Guduchi*	*Katu, Tikta*	*Laghu*	*Ushna*	*Madhura*	*Tridoshasamaka*
3.	*Katuki*	*Tikta*	*Ruksha Laghu*	*Sheeta*	*Katu*	*KaphaPitta samaka*
4.	*Nimba*	*Tikta*	*Laghu Sheeta*	*Sheeta*	*Katu*	*Tridoshasamaka*
5.	*Bhunimba*	*Tikta*	*Laghu Yogavahi*	*Sheeta*	*Katu*	*KaphaPitta samaka*
6.	*Haritaki*	*Pancharasa (Alavana)*	*Ruksha Laghu*	*Ushna*	*Madhura*	*Tridoshasamaka*
7.	*Bibhitaki*	*Kasaya Pradhan*	*Sheeta Ruksha Laghu*	*Ushna*	*Madhura*	*Tridoshasamaka*
8.	*Amalaki*	*Pancharasa*	*Ruksha Laghu*	*Sheeta*	*Madhura*	*Tridoshasamaka*

Table no. 02; Demography Incidence of Registered Patients. (n=30)

Sl. No.	**Criteria**	**Maximum Percentage**	**Category**
	Age	43.33%	21-30 years
	Sex	66.67%	Male
	Religion	100%	Hindu
	Occupation	26.67% & 20.00%	Serviceman % Student
	Treatment History	83.33%	Treatment taken
	Family History	0.00%	Nofamily history
	Educational Status	90.00%	Literate
	Marrital status	63.33%	Married
	Socio-economical Status	60.00%	Middle class
	Diatary habit	63.33%	Nonveg
	Addiction	40.00%	Tea and coffee
	Sleeping habit	50.00%	Disturbed
	Urination	63.33%	Asamyak
	Bowel habit	90.00%	Abnormal
	Mode of onset	100%	Gradual

Table no. 03; Incidence of *Dashavidha- Pariksha* of Registered Patients. (n=30)

Criteria	**Maximum Percentage**	**Category**
Prakriti	53.4%	*Vatapitta*
Vikriti	100%	*Madhyama- vastha*
Sara	70%	*Madhyama-sara*
Samhanan	60%	*Madhyama*
Pramana	83.3%	*Madhyama sharira*
Satwa	86.7%	*Madhyama*
Satmya	70%	*Madhyama*
Ahara Shakti	86.6%	*Madhyama Ahara Shakti*
Vyayama Shakti	56.6%	*Madhyama Vyayama Shakti*
Vaya	76.7%	*Madhyamavastha*

Table No. 04; Showing the observation of total patients as per disease and percentage ofImprovement in Group-A and Group-B.

Subjective parameters	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value	% Effect	Result
Haridrata	Group A	15	18.00	270.00	75.000	0.027	72.22	Sig
	Group B	15	13.00	195.00			58.33	Sig
Raktapitta Mutrata	Group A	15	17.83	267.50	77.500	0.101	72.22	Sig
	Group B	15	13.17	197.50			58.33	Sig
Raktapitta Purisa	Group A	15	19.57	293.50	51.500	0.003	74.29	Sig
	Group B	15	11.43	171.50			56.67	Sig
Bheka Varna	Group A	15	13.97	209.50	89.500	0.301	75.00	Sig
	Group B	15	17.03	255.50			56.52	Sig
Hatendriya	Group A	15	18.90	283.50	61.500	0.019	71.43	Sig
	Group B	15	12.10	181.50			56.52	Sig
Daha	Group A	15	18.63	279.50	65.500	0.026	76.47	Sig
	Group B	15	12.37	185.50			59.38	Sig
Avipaka	Group A	15	19.17	287.50	57.500	0.009	73.53	Sig
	Group B	15	11.83	177.50			56.67	Sig
	Total	30						
Dourbalya	Group A	15	17.57	263.50	81.500	0.118	75.00	Sig
	Group B	15	13.43	201.50			56.67	Sig
Aruchi	Group A	15	16.50	247.50	97.500	0.476	72.00	Sig
	Group B	15	14.50	217.50			59.26	Sig
Sadana	Group A	15	17.40	261.00	84.000	0.128	75.00	Sig
	Group B	15	13.60	204.00			56.00	Sig

Table No.05: Showing the effect of Phalatrikadi Ghanavati and Vasadi Ghanavati on Objective Parameters (GroupA) (GroupB) (n=30)

Objective			Mean	N	SD	SE	t-Value	P-Value	% Change	Result
TLC	Group A	BT	1.13	15	0.35	0.09	12.475	0.000	100.00	Sig
		AT	0.00	15	0.00	0.00				
	Group B	BT	1.80	15	0.68	0.17	8.411	0.000	88.89	Sig
		AT	0.20	15	0.41	0.11				
Hb%	Group A	BT	2.33	15	0.49	0.13	18.520	0.000	100.00	Sig
		AT	0.00	15	0.00	0.00				
	Group B	BT	2.53	15	0.52	0.13	12.616	0.000	94.74	Sig
		AT	0.13	15	0.35	0.09				
AP	Group A	BT	2.87	15	0.52	0.13	15.332	0.000	88.37	Sig
		AT	0.33	15	0.49	0.13				
	Group B	BT	3.00	15	0.00	0.00	19.858	0.000	86.67	Sig
		AT	0.40	15	0.51	0.13				
SGOT	Group A	BT	2.87	15	0.52	0.13	12.616	0.000	83.72	Sig
		AT	0.47	15	0.64	0.17				
	Group B	BT	3.00	15	0.00	0.00	15.332	0.000	84.44	Sig
		AT	0.47	15	0.64	0.17				
SGPT	Group A	BT	3.00	15	0.00	0.00	19.858	0.000	86.67	Sig
		AT	0.40	15	0.51	0.13				
	Group B	BT	3.00	15	0.00	0.00	21.166	0.000	88.89	Sig
		AT	0.33	15	0.49	0.13				
Sr Total Bilirubin	Group A	BT	3.00	15	0.00	0.00	19.858	0.000	86.67	Sig
		AT	0.40	15	0.51	0.13				
	Group B	BT	2.93	15	0.26	0.07	19.000	0.000	86.36	Sig
		AT	0.40	15	0.51	0.13				
Sr Direct Bilirubin	Group A	BT	3.00	15	0.00	0.00	19.858	0.000	86.67	Sig
		AT	0.40	15	0.51	0.13				
	Group B	BT	2.93	15	0.26	0.07	19.000	0.000	86.36	Sig
		AT	0.40	15	0.51	0.13				
BS	Group A	BT	2.07	15	0.26	0.07	11.309	0.000	83.87	Sig
		AT	0.33	15	0.49	0.13				
	Group B	BT	2.13	15	0.35	0.09	12.435	0.000	84.38	Sig
		AT	0.33	15	0.49	0.13				
BP	Group A	BT	2.20	15	0.41	0.11	10.311	0.000	81.82	Sig
		AT	0.40	15	0.51	0.13				
	Group B	BT	2.00	15	0.00	0.00	13.229	0.000	83.33	Sig

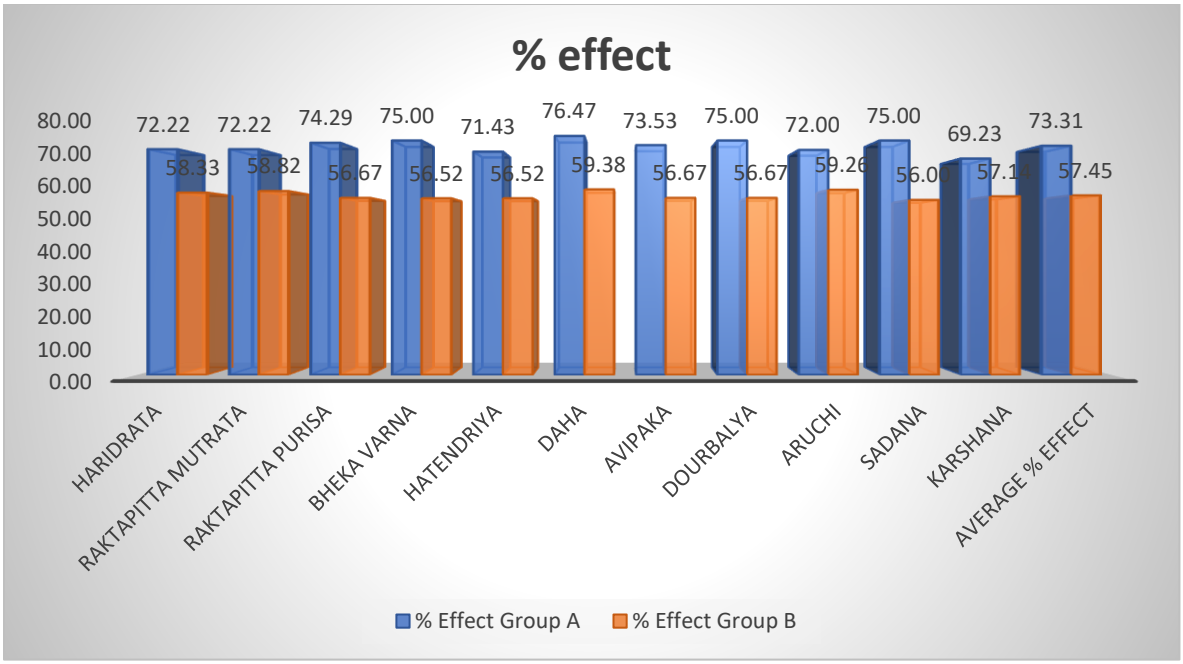

Table No.06; Showing clinical assessment of subjective parameters in GroupA andGroupB

Variable	% Effect	
	Group A	Group B
Haridrata	72.22	58.33
Raktapitta Mutrata	72.22	58.82
Raktapitta Purisa	74.29	56.67
Bheka Varna	75.00	56.52
Hatendriya	71.43	56.52
Daha	76.47	59.38
Avipaka	73.53	56.67
Dourbalya	75.00	56.67
Aruchi	72.00	59.26
Sadana	75.00	56.00
Karshana	69.23	57.14
Average % Effect	73.31	57.45

Table No.07; Showing clinical assessment of Result in Group-A and Group-B

Overall Effect	Group A		Group B	
	N	%	N	%
Complete Remission(100%)	0	0.00%	0	0.00%
Marked Improvement	7	46.67%	2	13.33%
ModerateImprovement	8	53.33%	9	60.00%
Mild Improvement	0	0.00%	4	26.67%
Unsatisfactory	0	0.00%	0	0.00%
TOTAL	15	100.00%	15	100.00%