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Research Article

A CLINICAL STUDY TO EVALUATE THE COMPARATIVE EFFICACY OF *PHALTRIKADI KASHAYA* AND *PHALTRIKADI KASHAYA GHANA VATI* IN THE MANAGEMENT OF NON-ALCOHOLIC FATTY LIVER DISEASE

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ABSTRACT

The non-alcoholic fatty liver disease (NAFLD) has emerged as a leading type of chronic liver disease and a hepatic manifestation of "metabolic syndrome" worldwide. The emerging epidemic of childhood obesity means that increasing numbers of young people have NAFLD and early diagnoses followed by management are important. The only treatment options in early stages are weight loss, dietary fat reservation and exercise with strict control of associated diseases. A formulation mentioned in Ayurveda is *Phaltrikadi Kashaya* which is a combination of 8 widely used hepatoprotective herbs. But, since its preparation as a *Kwatha* in itself is a cumbersome task, so the present study has been planned to assess the comparative efficacy of *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* in the management of NAFLD. 50 patients, within the age of 18-70 years, having aspartate amino-transferase (AST/SGOT) and alanine transaminase (ALT/SGPT) levels twice the upper normal limit and ultrasonographical evidence of fatty infiltration of liver, were selected and divided into 2 groups consisting of 25 patients each. Group I was managed with *Phaltrikadi Kashaya* in the dose of 50ml twice a day whereas, Group II was managed with *Phaltrikadi Kashaya Ghana Vati* in the dose of 500mg tablet, twice a day for a period of 12 weeks. Both subjective and objective parameters were assessed before and after the completion of trial. Data obtained during the trial was then tabulated and statistically analysed.

INTRODUCTION

W.H.O. defines health as "a state of complete physical, mental, social and spiritual well-being and not merely the absence of disease or infirmity." Awareness about 'Health' and approach of community towards Ayurveda in the quest of 'Healthy Life' is increasing. Hypertension, diabetes mellitus, obesity etc., are very well-known lifestyle disorders and are mentioned to be the components of metabolic syndrome. NAFLD is an expanding health problem, which varies in prevalence among ethnic groups, occurring with an estimated global prevalence of 32%.[1]

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NAFLD includes spectrum of progressive liver diseases ranging from fatty infiltration alone (steatosis) to fatty infiltration with inflammation (Non-Alcoholic Steatohepatitis, NASH). A proportion of people with NAFLD will ultimately either die from liver failure or hepatocellular carcinoma (HCC), [2] or may even need a liver transplant. The prevalence of NAFLD is increasingly posing a substantial socioeconomic threat and is placing a greater burden on healthcare resources becoming the fastest growing driver of chronic liver disease, potentially accompanied by a poor prognosis. [3] The estimated global incidence of NAFLD is 47 cases per 1,000 population and is higher among males (40%) than females (26%).[1] The average age of people with NASH is 40-50 years and NASH-cirrhosis, is 50-60 years.[4] The prevalence of adult NAFLD in India has been reported between 6.7% and 55.1%.[5] There is currently no modern pharmacological treatment licensed for NAFLD as there are no satisfactory patient centred clinical

outcomes and evidences for NAFLD, although a variety of molecules have been attempted to correct wide spectrum of this disease. Most of the hepatologists recommended life style modification, weight management by restricting calorie intake and exercise.[6] The common pharmacological interventions are antioxidants, insulin sensitizing agents, lipid-lowering drugs, cytoprotective agents, anti- inflammatory and antifibrotic drugs but, all of them have serious side effects, if used for a long time. Ayurveda has immense potential in the safe and cost-effective management of non-communicable diseases and NAFLD is one of them. Clinical researches have confirmed the efficacy of several herbs described in Ayurveda in the treatment of liver diseases. One such compound herbal preparation mentioned in Ayurveda is *Phaltrikadi Kashaya. Phaltrikadi Kashaya* has been mentioned in the context of *Pandu* and *Kamala,* and has been referenced in *Chakradutta* (8/8), *Sharandhar Samhita* (2/75), *Yoga Ratnakar Pandu Roga* (5th shloka) and *Bhaishajya Ratnavali* (12/22). The reference of *Phalatrikadi Kashaya* used in this study was drawn from *Chakradutta* in *Pandurogadhikara,* Chapter 8.

AIMS AND OBJECTIVES

Primary Objective

To determine the comparative efficacy of *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* in the management of non-alcoholic fatty liver disease.

Secondary Objective

To assess the clinical safety of *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* in the patients of non-alcoholic fatty liver disease.

MATERIALS AND METHODS

Selection of Patient

- Patients were selected from the hospital OPD/IPD Department of Kayachikitsa, R.G.G.P.G. Ayu. College and Hospital, Paprola, Dist. Kangra (H.P.)
- Total 50 patients were selected for the present study irrespective of the gender, caste and religion etc.

Study Design

- Study type - Randomized Clinical trial
- Masking- Single blind
- Timing- Prospective
- Study Subjects- 50
- No. of group- 02
- Duration of trial- 12 weeks
- Follow up visit- After every 2 weeks till the completion of trial.

Diagnostic Criteria

Subjective Criteria

The patients were diagnosed on the basis of classical signs and symptoms like:

- *Udarshoola* (Pain of abdomen)
- *Utklesh* (Nausea)
- *Chhardi* (Vomiting)
- *Aruchi* (Loss of appetite)
- *Hridkanthdaha* (Burning in Epigastric region)

Objective Criteria

- Body weight
- BMI
- AST (SGOT)
- ALT (SGPT)
- Body Fat Percentage
- Body fat analysis
  - Visceral fat level
  - Skeletal muscle mass
  - Resting metabolism
  - USG of liver

Inclusion Criteria

- Patients having altered serum liver enzyme levels defined as serum AST (SGOT) and/or ALT (SGPT) > normal (35-40mg/dl) but <2 times the upper normal limit and ultrasonographical evidence of non-alcoholic fatty liver disease.
- Individuals of either gender between the ages of 18 to 70 years.
- Patients willing and able to participate for the entire duration of 12 weeks.

Exclusion Criteria

- Individuals not willing to undergo the clinical trial.
- Patients having serum liver enzyme (AST and/or ALT) levels >2 times the upper normal limit.
- Patients having hepatitis B and /or hepatitis C, malignancy of liver or having any other comorbidity.
- Patients consuming alcohol.
- Patients having ultrasonographical evidence of cirrhosis or necrosis of liver.
- History of hypersensitivity to any of the trial drug or its ingredients.
- Individuals who have completed participation in any other clinical trial during the past six months.
- Any other condition, which the principal investigator thinks might jeopardize the study.

Investigations

- **Haematological**
  CBC, ESR

- **Biochemical investigations**

  FBS, blood urea, serum creatinine, SGOT, SGPT, S. lipid profile.

  Routine and microscopic urine examination.

Grouping of Patients: Study was conducted randomly on 50 patients in two groups (25 patients in each group). Group I was managed with *Phaltrikadi Kashaya,* 50ml twice a day while Group II was managed with *Phaltrikadi Kashaya Ghana Vati,* 500mg twice a day.

Trial Drugs

Phaltrikadi Kashaya Ghana Vati

Dose– 500mg twice a day

Route of Administration- Oral

Phaltrikadi Kashaya

Dose– 50ml twice a day (50gm raw drug was soaked in 400ml water and it was reduced to 100ml, which was given in two equally divided doses)

Route of Administration- Oral

Trial Drug Composition

Table 1: Composition of *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati*

S.No.	Name	Botanical Name	Family	Part Used	Proportion
1.	*Haritaki*	*Terminalia chebula* (Retz.)	Combretaceae	Fruit pulp	1 part
2.	*Vibhitaki*	*Terminalia bellirica* (Roxb.)	Combretaceae	Fruit pulp	1 part
3.	*Amalaki*	*Emblica officinalis* (Gaertn.)	Phyllanthaceae	Fruit pulp	1 part
4.	*Guduchi*	*Tinospora cordifolia* (Thunb.)	Menispermaceae	Stem	1 part
5.	*Vasa*	*Adhatoda vasica* (Nees.)	Acanthaceae	Whole plant	1 part
6.	*Katuki*	*Picrorhiza kurroa* (Royle ex. Benth.)	Scrophulariaceae	Root tuber	1 part
7.	*Bhunimb*	*Andrographis panniculata* (Burm.F.)	Gentianaceae	Whole plant	1 part
8.	*Neem*	*Azadirachta indica* (A.juss)	Meliaceae	Stem bark	1 part

Criteria of Assessment

- Subjective and objective parameters were assessed before and after the treatment.
- The main criterion of assessment were serum liver enzymes (SGOT/AST and SGPT/ALT) levels and ultrasonography of liver, which was done before the commencement of trial and after the completion of trial.

Objective Criteria: The main criterion of assessment was serum liver enzyme levels (i.e. SGOT/PT levels < 2 times the upper normal limit i.e., 35 to 40 IU/L) and ultrasonography of liver, which was done before the commencement of trial and after the completion of trial. Body weight, BMI, body fat percentage, visceral fat level, skeletal muscle mass and resting metabolism were also noted before and after the therapy.

Statistical Analysis

Data was collected and recorded in detail in the clinical proforma. The obtained data was analysed statistically and expressed in the terms of mean score before treatment (BT), after treatment (AT), difference of mean (% change), standard deviation (SD) and standard error (SE). Overall percentage improvement of each patient was calculated.

Data was arranged in MS Excel. Student's unpaired 't' test was used to compare difference in mean values between the two groups. Paired 't'-test has been used for within group analysis. The results were considered significant or insignificant depending upon the value of p.

Highly significant $p<0.001$

Significant $p<0.05$

Insignificant $p>0.05$

OBSERVATIONS AND RESULTS

Among 50 registered patients, 52% patients were female and 48% patients were male. Maximum patients (30%) were in the age group 50-59 years, followed by 14 patients (28%), 11 patients (22%), 8 patients (16%) and 2 patients (4%) in the age group of 60-70 years, 40-49 years, 30-39 years and 20-29 years, respectively.

As far as religion is concerned, 100% patients were Hindu. 96% patients were married. 74% of the patients belonged to rural area and 26% of the patients were from urban area. Based on education, majority of the patients (38%) were matriculate, 20% were educated up to primary, 16% were graduate, 14% were post graduate while the remaining 12% were illiterate. Based on occupation, majority of the patients (46%) were homemaker whereas, 36% of the patients were in private job, 08% were farmers, 06% were from labour class and 04% patients had superannuated. 90% of the patients belonged to low socio-economic class whereas, 10% of the patients belonged to middle socio-economic class. 72% patients

had mixed dietary habit whereas, 28% patients were vegetarian. 40% patients were addicted to smoking whereas, none of the patients were addicted to alcohol, and 60% patients had no addiction. 62% people had sedentary lifestyle. 48% patients had regular bowel habit and 38% patients were constipated. 80% patients had adequate sleep whereas, 20% of the patients had disturbed sleep. 78% patients had normal appetite and 22% patients had reduced appetite. Regarding *Deha Prakriti*, 64% of the patients were *Pitta-Kaphaj Prakriti*, 22% patients had *Vata-Pittaj Prakriti* whereas, 16% had *Vata-Kaphaj Prakriti.* Majority of the patients were overweight i.e. 42%, 40% had normal BMI and the remaining 18% were Obese. Maximum patients i.e., 36% were diabetic, 26% were hypertensive, 18% were both hypertensive and diabetic and rest 20% had no co-morbidity. 78% patients had fatty liver grade I whereas, 16% and 6% patients had fatty liver grade II and III, respectively.

Aruchi (anorexia) was present in 74% of the patients, *Utklesh* (nausea) was present in 72% of the patient, *Haridkanthdaha* (epigastric burning) was present in 68% of the patients, *Chhardi* (vomiting) was present in 58% of the patients whereas, *Udarshula* (abdominal pain) was present in 60 % of the patients.

Effect of Therapy Based on Subjective Criteria

A total number of 50 patients were registered from OPD/IPD of R.G.G.P.G. Ayurvedic College & Hospital, Paprola. There were no drop outs, therefore, the effect of therapy was studied on 50 enrolled patients. These 50 patients were divided into two groups- Group I and Group II, consisting of 25 patients each. The effect of *Phaltrikadi Kashaya* was studied on Group I and the effect of *Phaltrikadi Kashaya Ghana Vati* was studied on Group II. The effect of trial drugs, on the basis of various assessment criteria was obtained after statistical analysis of the data and is presented in tabular form.

Table 2: Effect of therapy on Subjective criteria

S.No.	Category	N	Group	Mean		% Change	SD±	SE±	't' value	'p' value	Sig
				BT	AT						
1.	*Aruchi* (Anorexia)	**25**	**G-I**	0.800	0.240	70%	0.866	0.173	3.645	0.001	S
		25	**G-II**	0.880	0.520	40.9%	0.666	0.133	3.674	0.001	S
2.	*Utklesh* (Nausea)	**25**	**G-I**	0.800	0.280	65%	0.707	0.141	3.980	<0.001	HS
		25	**G-II**	0.760	0.320	57.9%	0.723	0.145	3.381	0.002	S
3.	*Hridkanthadaha* (Epigastric discomfort)	**25**	**G-I**	0.840	0.320	61.9%	0.850	0.170	3.980	<0.001	HS
		25	**G-II**	0.880	0.480	45.45%	0.833	0.167	3.098	0.005	S
4.	*Chhardi* (Vomiting)	**25**	**G-I**	0.600	0.280	53.3%	0.645	0.129	2.551	0.018	S
		25	**G-II**	0.640	0.360	43.75%	0.638	0.128	2.281	0.032	S
5.	*Udarshoola* (Abdominal pain)	**25**	**G-I**	0.840	0.400	52.4%	0.850	0.170	3.773	<0.001	HS
		25	**G-II**	0.760	0.480	36.8%	0.723	0.145	3.055	0.005	S

HS- Highly Significant, S- Significant, IS- Insignificant

Table 3: Intergroup comparison of Subjective criteria

S. No.	Symptoms	% Relief		Diff. in %	SD±	SE±	't' value	'p' value	Sig
		G-I	G-II						
1.	*Aruchi* (Anorexia)	70%	40.9%	29.1%	0.768	0.154	1.098	0.278	IS
2.	*Utklesh* (Nausea)	65%	57.9%	7.10%	0.653	0.131	0.434	0.666	IS
3.	*Hridkanthadaha* (Epigastric discomfort)	61.9%	45.45%	16.45%	0.653	0.131	0.653	0.517	IS
4.	*Chhardi* (Vomiting)	53.3%	43.75%	9.55%	0.627	0.125	0.228	0.821	IS
5.	*Udarshoola* (Abdominal pain)	52.4%	36.8%	15.6%	0.583	0.117	1.079	0.286	IS

HS- Highly Significant, S- Significant, IS- Insignificant

Effect of Therapy Based on biochemical parameters

Table 4: Effect of Therapy Based on biochemical parameters

S.No.	Category	Groups	Mean		% Change	SD±	SE±	't' value	'p' value	Sig
			BT	AT						
1.	SGOT	G-I	50.440	36.520	27.6%	5.001	1.000	5.694	<0.001	HS
		G-II	46.840	38.800	17.16%	3.555	0.711	4.170	<0.001	HS
2.	SGPT	G-I	60.840	37.920	37.67%	6.149	1.230	14.654	<0.001	HS
		G-II	54.160	41.520	23.33%	3.023	0.605	15.333	<0.001	HS
3.	TSB	G-I	0.716	0.540	24.58%	0.118	0.0236	4.433	<0.001	HS
		G-II	0.732	0.684	6.56%	0.114	0.0229	1.091	0.286	IS
4.	DSB	G-I	0.348	0.272	21.84%	0.0586	0.0117	3.919	<0.001	HS
		G-II	0.268	0.248	7.46%	0.0988	0.0198	1.000	0.327	IS
5.	FBS	G-I	112.720	104.880	6.96%	30.340	6.068	2.487	0.020	S
		G-II	114.360	106.120	7.20%	45.624	9.125	1.592	0.124	IS
6.	Cholesterol	G-I	206.72	158.32	23.41%	45.052	9.010	7.241	<0.001	HS
		G-II	180.960	160.120	11.52%	30.843	6.169	10.692	<0.001	HS
7.	Triglycerides	G-I	162.160	142.920	11.86%	9.437	1.887	14.989	<0.001	HS
		G-II	157.800	148.160	6.11%	6.652	1.330	4.775	<0.001	HS
8.	HDL	G-I	52.040	53.520	2.84%	3.208	0.642	-2.379	0.026	S
		G-II	51.320	51.600	0.54%	3.955	0.791	-0.359	0.723	IS
9.	LDL	G-I	103.600	96.920	6.45%	9.260	1.852	3.571	0.002	S
		G-II	99.400	96.440	2.98%	4.673	0.935	2.704	0.012	S
10.	VLDL	G-I	54.720	52.040	4.89%	3.169	0.634	3.744	0.001	S
		G-II	55.000	54.360	1.16%	3.082	0.616	2.426	0.023	S
11.	B. Urea	G-I	27.800	27.240	2.01%	8.832	1.766	1.011	0.322	IS
		G-II	29.520	29.200	1.08%	6.391	1.278	1.496	0.148	IS
12.	S. Creatinine	G-I	0.728	0.712	2.19%	0.376	0.075	0.288	0.776	IS
		G-II	0.760	0.752	1.05%	0.337	0.0673	0.179	0.859	IS

HS- Highly Significant, S- Significant, IS- Insignificant

Intergroup Comparison on biochemical parameters

Table 5: Inter group comparison of effect on biochemical parameters

S.No.	Symptoms	% Relief		Diff. in %age	SD±	SE±	't' value	'p' value	Sig
		G-I	G-II						
1.	SGOT	27.6%	17.16%	10.44%	12.223	2.445	1.888	0.045	S
2.	SGPT	37.67%	23.33%	14.34%	7.820	1.564	5.814	<0.001	HS
3.	TSB	24.58%	6.56%	18.02%	0.198	0.0397	2.159	0.036	S
4.	DSB	21.84%	7.46%	14.38%	0.0970	0.0194	2.010	0.050	S
5.	FBS	6.96%	7.20%	-0.24%	15.763	3.153	-0.0660	0.948	IS
6.	Cholesterol	23.41%	11.52%	11.89%	33.420	6.684	3.958	<0.001	HS
7.	Triglycerides	11.86%	6.11%	5.75%	6.418	1.284	4.013	<0.001	HS
8.	HDL	2.84%	0.54%	2.30%	3.111	0.622	-1.203	0.235	IS

9.	LDL	6.45%	2.98%	3.47%	9.353	1.871	1.716	0.093	IS
10.	VLDL	4.89%	1.16%	3.73%	3.579	0.716	2.674	0.010	S
11.	B. Urea	2.01%	1.08%	0.93%	2.770	0.554	0.404	0.688	IS
12.	S. Creatinine	2.19%	1.05%	1.14%	0.278	0.056	0.112	0.911	IS

HS- Highly Significant, S- Significant, IS- Insignificant

Effect of Therapy Based on Objective parameters

Table 6: Effect of Therapy Based on Objective parameters

S.No.	Category	Groups	Mean		% Change	SD±	SE±	't' value	'p' value	Sig
			BT	AT						
1.	USG Fatty Liver Grading	G-I	1.200	0.640	46.6%	0.500	0.1000	5.527	<0.001	HS
		G-II	1.360	1.040	23.5%	0.638	0.128	3.361	0.003	S
2.	Body Weight	G-I	67.400	65.740	2.46%	5.993	1.199	12.633	<0.001	HS
		G-II	69.040	68.300	1.07%	7.727	1.545	4.750	<0.001	HS
3.	BMI	G-I	27.240	26.568	2.47%	3.535	0.707	11.495	<0.001	HS
		G-II	27.185	26.899	1.05%	3.822	0.764	4.513	<0.001	HS
4.	Body Fat percentage	G-I	0.270	0.262	2.96%	0.0464	0.00928	3.705	0.001	S
		G-II	0.340	0.338	0.71%	0.0588	0.0118	1.809	0.083	IS
5.	Visceral fat level	G-I	304.761	279.256	8.37%	37.690	7.538	20.206	<0.001	HS
		G-II	317.506	311.857	1.78%	32.615	6.523	4.754	<0.001	HS
6.	Skeletal Muscle Mass	G-I	45.188	45.688	1.10%	3.766	0.753	-1.396	0.175	IS
		G-II	44.676	44.720	0.098%	2.835	0.567	-0.153	0.880	IS
7.	Resting metabolism	G-I	1310.12	1326.72	1.267%	126.732	25.346	-12.633	<0.001	HS
		G-II	1334.60	1342.00	0.55%	145.784	29.157	-4.750	<0.001	HS
8.	Waist circumference	G-I	92.640	90.500	2.31%	4.367	0.873	11.505	<0.001	HS
		G-II	95.640	94.040	1.67%	3.213	0.643	6.532	<0.001	HS
9.	Hip circumference	G-I	96.560	94.420	2.22%	4.369	0.874	10.988	<0.001	HS
		G-II	99.640	98.040	1.60%	3.213	0.643	6.532	<0.001	HS

HS- Highly Significant, S- Significant, IS- Insignificant

Table 7: Inter group comparison of effect on objective parameters

S. No.	Symptoms	% Relief		Diff. in %	SD±	SE±	't' value	'p' value	Sig
		G-I	G-II						
1.	USG Fatty Liver Grading	46.6%	23.5%	23.1%	0.500	0.100	2.028	0.048	S
2.	Body weight	2.46%	1.07%	1.39%	0.657	0.131	4.514	<0.001	HS
3.	BMI	2.47%	1.05%	1.42%	0.292	0.059	4.485	<0.001	HS
4.	Body fat percentage	2.96%	0.71%	2.25%	0.00539	0.00108	3.322	0.002	S
5.	Visceral Fat Level	8.37%	1.78%	6.59%	6.311	1.262	11.454	<0.001	HS
6.	Skeletal Muscle Mass	1.10%	0.098%	1.00%	1.790	0.358	-0.992	0.326	IS
7.	Resting metabolism	1.10%	0.55%	0.717%	6.570	1.314	-4.514	<0.001	HS
8.	Waist circumference	2.31%	1.67%	0.64%	0.930	0.186	1.756	0.086	IS
9.	Hip circumference	2.22%	1.60%	0.62%	0.974	0.195	1.726	0.091	IS

HS- Highly Significant, S- Significant, IS- Insignificant

Effect of Therapy on Haematological Parameters

Table 8: Effect of therapy on haematological parameters

S. No	Category	Group	Mean		% Change	SD±	SE±	't' value	'p' value	Sig
			BT	AT						
1.	Hb	G-I	12.496	12.780	2.27%	1.347	0.269	-2.246	0.034	S
		G-II	12.476	12.528	0.41%	1.572	0.314	-0.386	0.703	IS
2.	TLC	G-I	7616.00	7428.00	2.46%	1489.31	297.86	1.173	0.252	IS
		G-II	7628.00	7604.00	0.31%	1499.03	299.81	0.134	0.895	IS
3.	Neutrophils	G-I	47.932	49.604	3.48%	4.767	0.953	-1.000	0.327	IS
		G-II	54.228	51.360	5.29%	6.839	1.368	1.665	0.109	IS
4.	Lymphocytes	G-I	29.328	29.680	1.20%	1.967	0.393	-0.675	0.506	IS
		G-II	29.980	28.880	3.67%	3.630	0.726	1.942	0.064	IS
5.	Mixed Cells	G-I	9.052	8.872	1.99%	1.538	0.308	13.943	<0.001	HS
		G-II	9.172	9.092	0.87%	1.318	0.264	1.774	0.089	IS
6.	ESR	G-I	10.000	9.520	4.8%	4.203	0.841	1.423	0.168	IS
		G-II	10.920	10.600	2.93%	3.685	0.737	1.248	0.224	IS

HS- Highly Significant, S- Significant, IS- Insignificant

Table 9: Inter group comparison of Effect of therapy on Haematological parameters

S. No.	Symptoms	% Relief		Diff. in %age	SD±	SE±	't' value	'p' value	Sig
		G-I	G-II						
1.	Hb	2.27%	0.41%	1.86%	0.673	0.135	1.256	0.215	IS
2.	TLC	2.46%	0.31%	2.15%	801.21	160.24	0.681	0.499	IS
3.	Neutrophils	3.48%	5.29%	-1.81%	1.942	0.388	-3.785	<0.001	HS
4.	Lymphocytes	1.20%	3.67%	-2.47%	2.608	0.522	-1.886	0.065	IS
5.	Mixed Cells	1.99%	0.87%	1.12%	0.105	0.0211	0.161	0.873	IS
6.	ESR	4.80%	2.93%	1.87%	1.686	0.337	0.378	0.707	IS

HS- Highly Significant, S- Significant, IS- Insignificant

Effect of Therapy on Subjective Criteria

Signs and symptoms (Table no. 2, 3)

***Aruchi* (Anorexia)**

There was 70 % and 40.9% reduction in *Aruchi* in Group I and Group II, respectively, and this change was statistically significant (p value=0.001) in both the groups.

***Utklesh* (Nausea)**

There was statistically highly significant decrease (p value <0.001) in *Utklesh* by 65% in Group I. In Group II, reduction in *Utklesh* by 57.9% was observed after the therapy which was statistically significant (p value= 0.002).

***Haridkanthdaha* (Epigastric Burning)**

In Group I, *Haridkanthdaha* was reduced by 61.9% and changes were statistically highly significant (p value < 0.001). In Group II, only 45.45% decrease in *Haridkanthdaha* was observed which was statistically significant (p value = 0.005).

***Chhardi* (Vomiting)**

There was decrease in *Chhardi* by 53.3% in Group I (p value 0.018) and by 43.75% in Group II (p value = 0.032) and this change was statistically significant in both the groups.

***Udarshula* (Adominal pain):** There was 52.4% decrease in *Udarshula* in Group I and 36.8% decrease in Group II. The changes in Group I was statistically highly significant in Group I (p value < 0.001) and statistically significant in Group II (p value =0.005).

Intergroup comparison revealed that there was statistically insignificant difference between the therapy given in Group I and Group II (p value >0.05) for all subjective parameters. However, the therapy given in Group I *(Phalatrikadi Kashaya)* proved to be more effective than Group II (*Phalatrikadi Kashaya*

Ghana Vati) on the basis of percentage relief in symptoms like *Aruchi, Udarshula, Haridkanthdaha, Utklesh* and *Chhardi.*

Effect of Therapy on Objective Criteria (Table No. 4, 5)

Serum Glutamate Transaminases: SGOT level in Group I reduced by 27.6% and by 17.16% in Group II and the results were found to be highly significant (p value < 0.001) for both the groups.

Serum Glutamate Pyruvic Transaminases: After the treatment, the SGPT levels reduced by 37.67% in Group I and by 23.33% in Group II. The results were highly significant (p value <0.001) for Group I and Group II.

Total Serum Bilirubin: There was reduction in TSB level by 24.58% in Group I and by 6.56% in Group II. The changes were statistically significant for Group I (p value <0.001) whereas the changes were statistically insignificant for Group II (p value > 0.05).

Direct Serum Bilirubin: There was reduction in DSB level by 21.84% and 7.46% in Group I and Group II, respectively. The changes were statistically highly significant for Group I (p value <0.001) whereas for Group II, changes were statistically insignificant (p value > 0.05).

Fasting Blood Sugar: There was reduction in FBS level in Group I by 6.96% and the change was statistically significant (p value = 0.020). But in Group II, the levels reduced by 7.20% and this change was statistically insignificant (p value = 0.124).

Cholesterol: The cholesterol level decreased in Group I and Group II by 23.41% and 11.52%, respectively, which was highly significant (p value <0.001) for both the groups.

Triglycerides: In both Group I and Group II, the triglyceride levels were decreased by 11.86% and 6.11%, respectively and the results were statistically highly significant (p value <0.001) for both the groups.

High Density Lipoproteins: In Group I, HDL levels increased by 2.84% and the change was statistically significant (p value = 0.026). Whereas, in Group II level decreased by 0.54% and the change was statistically insignificant (p value =0.723).

Low Density Lipoproteins: LDL level reduced by 6.45% in Group I and 2.98% in Group II, respectively, with statistically significant changes i.e., p value 0.002 and 0.012 for group I and group II, respectively.

Very Low-Density Lipoproteins: In Group I, VLDL levels decreased by 4.89% whereas, in Group II, VLDL levels decreased by 1.16% and the changes were statistically significant for both the groups (p value < 0.05).

Blood Urea: There was reduction in B. Urea levels by 2.01% and 1.08% in Group I and Group II, respectively. The changes in both the groups were statistically insignificant (p value > 0.05).

Serum Creatinine: In Group I, Serum Creatinine levels decreased by 2.19% and in Group II, the levels decreased by 1.05%. However, the changes were statistically insignificant in both the groups (p value >0.05).

There was statistically significant difference between the two treatment groups of TSB, DSB, SGOT and VLDL having p value 0.036, 0.050, 0.045 and 0.010, respectively.

The difference in SGPT, S. Cholesterol and S. Triglycerides was found to be highly significant having p value <0.001 each.

The therapy given in Group I (*Phaltrikadi Kashaya*) proved to be more effective than Group II (*Phaltrikadi Kashaya Ghana Vati*) in improving SGPT, SGOT, TSB, DSB, S. Cholesterol and S. Triglycerides like parameters.

Effect of Therapy on Objective Criteria (Table No. 6, 7)

USG Fatty Liver Grading

After the treatment, the Ultrasonographical grading of fatty liver was reduced by 46.6% in Group I and by 23.5% in Group II after completion of the trial. The result was statistically highly significant (p value < 0.001) for Group I and statistically significant for Group II (p value 0.003).

Body weight

There was reduction in body weight by 2.46% in Group I and by 1.07% in Group II. The changes were statistically highly significant (p value < 0.001) in both Group I and Group II.

BMI

In Group I, BMI reduced by 2.47% after the treatment and by 1.05% in Group II. The reduction in BMI was statistically highly significant (p value <0.001) in both Group I and Group II.

Body Fat Percentage

There was reduction in body fat percentage by 2.96% in Group I and by 0.71% in Group II. The changes were statistically significant (p value = 0.001) in Group I and statistically insignificant (p value = 0.083) in Group II.

Visceral Fat Level

There was reduction in visceral fat level by 8.37% in Group I and by 1.78% in Group II. The changes were statistically highly significant (p value <0.001) both Group I and Group II.

Skeletal Muscle Mass

There was increase in skeletal muscle mass by 1.10% in Group I and by 0.098% in Group II. The changes were statistically insignificant in both the groups (p value >0.05).

Resting Metabolism

In Group-I, the mean value of resting metabolism before treatment was 1310.12 that increased to 1326.72 with a change of 1.25%. This is statistically highly significant with p-value <0.001. In Group-II, the result was highly statistically significant (p-value <0.001) as there was a change of 0.55% and mean value before and after treatment was 1334.60 and 1342.00 respectively.

Waist Circumference

In Group-I the mean value of waist circumference before treatment was 92.64 that reduced to 90.50 after treatment with a change of 2.31%. The change was statistically highly significant with p-value <0.001. While in Group-II, the mean value of 95.640 reduced to 94.040 after therapy with change of 1.67%. The change was statistically highly significant with p value <0.001.

Hip Circumference

The mean value of hip circumference in Group I before treatment was 96.560 that reduced to 94.420 with a change of 2.22% that was statistically highly significant with p-value <0.001. While in Group- II, there was 1.60% change in mean value of hip circumference from 99.640 to 98.040. The change in Group II was statistically highly significant with p-value <0.001.

However, there was statistically highly significant difference between the two treatment groups in relation to body weight, BMI, visceral fat level and resting metabolism with p value <0.001 each whereas, there was statistically significant difference between the two treatment groups in relation to USG fatty liver grading and body fat percentage with p-values 0.048 and 0.002 respectively.

There was statistically insignificant difference between the two treatment groups in relation to skeletal muscle mass, waist circumference and hip circumference having p value 0.326, 0.086 and 0.091 respectively.

The therapy given in Group I (*Phaltrikadi Kashaya*) proved to be more effective than Group II (*Phaltrikadi Kashaya Ghana Vati*) in improving body weight, BMI, body fat percentage, visceral fat level and resting metabolism like parameters.

Effect of Therapy on Haematological Parameters (Table no. 8, 9)

Haemoglobin

Haemoglobin levels in group I increased by 2.27% and 0.41% in group II. But, the results were statistically significant in Group I (p value= 0.034) and statistically insignificant in Group II (p value =0.703).

Total Leucocyte Count

There was decrease in TLC count by 2.46% in Group I and 0.31% in Group II, respectively. But, the changes were statistically insignificant i.e., p value = 0.252 for Group I and 0.895 for Group II.

Differential Leucocyte Count

In neutrophils, an increase of 3.48% was observed in Group I but the increase was statistically insignificant (p value = 0.327). In Group II, decrease of 5.29% was observed but, the decrease was insignificant (p value 0.109).

In case of lymphocytes, there was increase by 1.20% in Group I and by 3.67% in Group II. But, both the results were statistically insignificant (p value >0.05).

But in Group I, mixed cell decreased by 1.99% and the changes were statistically highly significant (p value <0.001). In Group II, mixed cell value reduced by 0.87% and this change was statistically insignificant (p value = 0.089).

Erythrocyte Sedimentation Rate

ESR value decreased by 4.8% and by 2.93% in Group I and Group II, respectively. The changes were statistically insignificant for Group I and Group II (p value >0.05).

There was no statistically significant difference between the two trial groups.

DISCUSSION

Major steps in the *Samprapti* of NAFLD are *Agnidushti*, *Ama* formation, *Kaphamedo Dushti*, *Strotorodha*, *Vataprakopa* in *Koshta* and *Sanchaya* of *Kaphamedas* in *Yakrit*. The probable mode of action *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* in *Samprapti Vighatan* of NAFLD can be explained on the following basis- *Katuki* is the best *Pitta Virechaka* as per Ayurvedic principals,[7] *Virechana* i.e., laxation tends to remove *Pitta* followed by *Kapha* which helps to control *Pitta*, *Kapha*, thus removing obstruction of *Vata Dosha*.

Guduchi plant possesses *Snigdha Guna* and *Madhura Vipaka*.[8] *Guduchi* and *Haritaki* are *Tridoshara* in nature, *Vibhitaki* is *Kapha Shamaka* predominant *Tridoshara, Amalaki* is *Pitta Shamaka* predominant *Tridoshara* whereas, *Nimb, Katuki, Vasa* and *Bhunimbh* are *Kapha Pitta Shamaka* predominant *Tridhoshara* in nature.[9] Predominant *Rasa Panchak* of *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* are *Tikta* and *Kashaya Rasa, Laghu* and *Ruksha Guna*, *Ushana Veerya*, *Katu Vipaka* and *Tridoshghana* properties which result in *Lekhana, Rechana, Deepana* and *Pachana Karma.* These properties increase the

power of *Agni* and reduces *Kapha, Meda* and *Ama* which causes reversal of the fat buildup in the liver. Thus, the drugs having *Deepana*, *Pachana*, *Kaphamedoharana*, *Srotosodhana*, *Vatanulomana* and *Yakritprasadana* would be useful in the management.

Experimental studies have also shown, *Guduchi* to be therapeutically effective in the amelioration of obesity and associated hepatic dysfunction. It is also known to stimulate the regeneration of hepatic tissue.[10,11] *Bhunimbh* has certain bioactive phytonutrients having antioxidant and anti-inflammatory activity which ameliorate rich fat diet-induced steatohepatitis and liver injury.[11,12] The combined actions of ingredients of both *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* can help improve the hepatobiliary function, protect the loss of functional integrity of the hepatic cell membrane, protect hepatic parenchyma against toxins, promotes hepatocyte regeneration. [13]

CONCLUSION

After the careful review of the results obtained from the study entitled "A clinical study to evaluate the comparative efficacy of *Phaltrkadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* in the management of Non Alcoholic Fatty Liver Disease", following conclusion can be drawn:

- In Group I i.e., *Phaltrikadi Kashaya* showed statistically highly significant results on symptoms like *Aruchi, Utklesh* and *Hridkanthadaha* but, statistically significant results on symptoms like *Chhardi* and *Udarshoola.* However, Group II i.e., *Phaltrikadi Kashaya Ghana Vati* showed statistically significant results on all the subjective parameters.
- The therapy given in Group-I *(Phaltrikadi Kashaya)* was more effective in correcting the USG grading of fatty liver, liver enzymes and dyslipidaemia profile of the study subjects having an advantage in improving TSB, DSB, SGOT, SGPT, S. Cholesterol, S. Triglycerides, S. HDL, S. LDL and S. VLDL, in comparison to the therapy administered in Group II.
- In this clinical study, statistically highly significant reduction was seen in the parameters like body weight, BMI, waist circumference, hip circumference, visceral fat levels and resting metabolism whereas, statistically significant results were observed in parameters like body fat percentage in Group-I.
- However, the therapy given in Group-II *(Phaltrikadi Kashaya Ghana Vati)* was less effective in correcting the USG grading of fatty liver, liver enzymes and dyslipidaemia profile of the study subjects in comparison to the therapy administered in Group I.
- In Group-II *(Phatrikadi Kashaya Ghana Vati)*, statistically highly significant reduction was seen in the parameters like body weight, BMI, waist circumference, hip circumference, visceral fat levels and resting metabolism whereas statistically significant results were observed in parameters like USG grading of fatty liver.
- Hence, it can be concluded that *Phaltrikadi Kashaya* proved more significant than *Phaltrikadi Kashaya Ghana Vati* in correcting the USG grading of fatty liver, liver enzymes and dyslipidaemia profile of the study subjects.
- No untoward effect of the trial drugs was noted therefore, it can be concluded that *Phaltrikadi Kashaya* and *Phaltrikadi Kashaya Ghana Vati* are safe and effective in the management of non-alcoholic fatty liver disease.

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