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ROLE OF *GOMUTRA HARITAKI* WITH AND WITHOUT *LANGHANA* AND *PACHANA* IN THE MANAGEMENT OF DYSLIPIDEMIA: AN OPEN LABELLED RANDOMIZED CLINICAL TRIAL

Shivam Joshi ^{*1}, Mandip Goyal ²

¹Ph.D. Scholar, Department of Kayachikitsa, IPGT&RA, Jamnagar, India

²Assistant professor, Department of Kayachikitsa, IPGT&RA, Jamnagar, India

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*Corresponding author

E-mail: ayuholistichealth@gmail.com

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ABSTRACT

Dyslipidemia is primarily Santarpanajanya Vyadhi. So, Chikitsa aims towards Apatarpana Upakrama. Present clinical trial aimed to compare the clinical effect of Gomutra Haritaki with and without Langhana and Pachana in the management of Dyslipidemia. 153 patients with abnormal lipid profile were selected and randomly divided in two Groups. In Group A, 76 patients were registered and 70 patients completed the treatment. In Group B, 77 patients were registered and 68 patients could complete the treatment. In Group A, Langhana in the form of one-time regular diet and Green gram soup was given for 4 days followed by 200 ml Dhanyaka Shunthi Siddha Jala twice daily for 10 days while in Group B, placebo capsules were given for initial 14 days. After 14 days of Langhana and Pachana or placebo treatment, Gomutra Haritaki, 2 tablets (500 mg each) thrice daily before meal for 8 weeks was administered in both Groups. Lipid profile was significantly reduced after Langhana and Pachana treatment in Group A while no change was found with placebo treatment in Group B. After completion of the treatment; in Group A, S. Cholesterol (8.59%), S. Triglyceride (8.72%), S.LDL (11.45%), S.VLDL (10.76%) reduced while in Group B, S. Cholesterol (9.51%), S. Triglyceride (7.91%), S.LDL (13.14%), S.VLDL (7.63%) decreased which was statistically significant. Langhana and Pachana with Dhanyaka Shunthi Siddha Jala is more effective to reduce fluctuate lipids like S. Triglyceride and S. VLDL. As Gomutra Haritaki is itself Dipana and Pachana drug, so it can reduce serum lipids significantly. However, Langhana and Pachana followed by Gomutra Haritaki is more effective in patients with poor liver and renal function.

Key words: Dhanyaka Shunthi Siddha Jala, Dyslipidemia, Gomutra Haritaki, Langhana, Pachana

INTRODUCTION

Dyslipidemia is a disorder of lipoprotein metabolism which can include over production or deficiency of lipoproteins or both. The disorder can manifest as an elevation of plasma cholesterol, triglycerides (TGs) or both or a low high density lipoproteins level or all three together that contributes to the development of atherosclerosis. Dyslipidemia can be understood on the basis of studying four of the closest conditions in Ayurveda in context with etiology and disease progress viz. Kapha Medo Margavarana, Sthaulya or Medoroga or Medodosha or Prameha. Dyslipidemia is primarily Santarpanajanya Vyadhi. Chikitsa towards these conditions is mainly Apatarpana which includes Langhana, Pachana and Shodhana. Langhana is main Upakrama of Santarpana Vyadhi, Kaphaja and Rasa Pradosha conditions. Pachana indicated in Madhyambala Dosha Chikitsa¹ where in Dhanyaka (*coriandrum sativum* Linn.) and Shunthi (*Zingiber officinale* Rosc.) Siddha Jala has been indicated for Agni Dipana and Pachana purpose.² It is also referred in Anuvāsana Sneha Basti Paschhata Karma.³ Gomutra Haritaki is broad spectrum formulation consisting of Gomutra⁴ and Haritaki⁵ (*Terminalia chebula* Retz.) which is well known for hypolipidemic activity. Considering all these facts, present clinical trial was planned with objectives to compare the clinical effect of Gomutra Haritaki with Langhana and Pachana and without Langhana and Pachana in the management of Dyslipidemia.

MATERIALS AND METHODS

The present clinical trial was randomized parallel open labelled study. For this study, 153 patients with abnormal lipid profile were selected after taking written consent from O.P.D. of

Kayachikitsa department, I.P.G.T. & R.A. hospital, Jamnagar during the period February 20, 2014 to December 12, 2014 and divided in two Groups by simple random method. Out of 153 registered patients, 138 patients could complete the treatment. The 15 patients dropped out due to irregular visits. In Group A, out of 76 patients registered, 70 patients completed the treatment and 06 dropped out while in Group B, 77 patients were registered; among them 68 patients could complete the treatment. Rest 09 patients dropped out from the study. Patients who were already on known anti-hyperlipidemic drugs like statins, fibrates were advised to stop intake of these drugs during the clinical trial and registered after 15 days of washout period.

Ethical Clearance: The study had received approval from the Institutional Ethics Committee (No.PGT/7-A/Ethics/2013-14/2753) dated 09.12.2013. The study is also registered under Clinical Trial Registry India (C.T.R.I) vide CTRI/2014/06/004702 dated 24.06.2014.

Inclusion Criteria

1. Patients with age 25 to 60 years
2. Elevated levels of serum cholesterol (201 mg/dl or more) and/or elevated serum triglycerides (S. TGs) (151 mg/dl or more) and/or, elevated serum low density lipoprotein (S. LDL) (131 mg/dl or more) and/or elevated serum very low density lipoprotein (S. VLDL) (41 mg/dl or more).⁶

Exclusion Criteria

1. Age below 25 and above 60 years
2. Drug induced Dyslipidemia

3. Systemic illness like tuberculosis (TB), Carcinoma, Advanced stage of diabetes and hypertension and endocrine disorders.

Investigations

Investigations were done at base line, after 14 days of *Langhana-Pachana* or placebo treatment and eight week of the treatment with *Gomutra Haritaki*. Biochemical investigations viz., fasting blood sugar, lipid profile, SGPT, SGOT, total protein, alkaline phosphate, uric acid, serum creatinine and blood urea; Hematological investigations viz., hemoglobin, total and differential WBC count, total RBC count, ESR, platelet count and routine and microscopic urine examination were done during this period.

Grouping and Posology

Group A: Langhana and Pachana followed by Gomutra Haritaki

Patients of this Group were first put on *Langhana* for 4 days. During these 4 days, patients were asked to take one time regular diet at lunch (Eka Kala Bhojana) and *Mudga Yusha* (green gram soup) at dinner this was followed by 10 days of *Pachana* with 200 ml of *Dhanyaka Shunthi Siddha Jala* which was given twice at morning and 6 pm. *Dhanyaka – Shunthi Siddha Jala* was prepared as per method of preparation of *Shadanga Paniya*.⁷ Total 6 gm of drug which contained 4.5 gm of *Dhanyaka* (*Yavakut*) and 1.5 gm of *Shunthi* (*Yavakut*) was boiled in 400 ml of water until 200 ml of water evaporated. Following *Langhana* and *Pachana* for 14 days, *Gomutra Haritaki* was administered in the dose of 2 tablets (500 mg each) thrice a day before food with luke warm water for 8 weeks.

Method of Gomutra Haritaki preparation: Whole *Haritaki* fruit in the 1 part was boiled in the 2.5 part of *Gomutra* until *Gomutra* evaporated. From these, granules were prepared which was punched into tablets of 500 mg each.

Group B: Placebo capsules followed by Gomutra Haritaki

Patients of this Group were given placebo capsules filled with starch powder in the dose of 2 capsule, (500 mg each) twice daily at morning and 6 pm for 14 days without any diet restriction. Following placebo capsules for 14 days i.e., without approach of *Langhana* and *Pachana*, *Gomutra Haritaki* was administered in the dose of 2 tablets (500 mg each) thrice a day before food with luke warm water for 8 weeks.

Follow up: Follow up was done for one month after the completion of treatment to see the long-standing effect of the drug. 45 patients in Group A and 47 patients reported for follow up investigations.

Criteria for Assessment: Assessment was made mainly based on the improvement observed in the subjective and objective parameters at base line and after 14 days of *Langhana* and *Pachana* treatment and after completion of 8 weeks of treatment with *Gomutra Haritaki*.

Subjective criteria

In Group A, *Samyaka Langhana* was observed based on *Vata-Mutra-Purisha Visarga* (proper elimination of flatus, urine and faeces), *Gatra Laghava* (feeling of lightness of the body), *Udgara-Kantha- Asya Shuddhi* (lightness of the chest, throat, mouth), *Tandra Gate - Klama Gate* (disappearance of drowsiness and exertion), *Sweda Pravritti* (appearance of sweat), *Ruchi* (taste for food), *Kshut-Pipasa Sahodaye* (appearance of hunger and thirst).⁸ (Table 1) *Samata Lakshanas* were assessed based on *Ama Lakshana*⁹ viz., *Balabhransha* (loss of strength), *Gaurava* (feeling of heaviness of the body), *Anila Mudhata* (inactivity of *Vata*), *Alasya* (laziness), *Apakti* (loss of digestive power), *Nishthiva* (more of expectoration), *Malasanga* (constipation), *Aruchi* (anorexia), and *Klama* (exhaustion). (Table 2) All these were recorded at base line and after *Langhana* and *Pachana* treatment for 14 days. *Dyslipidemia* does not present with any specific symptoms, so the clinical presentation of *Sthaulya/Medoroga* was considered for subjective criteria.

Objective criteria

Lipid profile, body weight, BMI and body circumference were included as objective parameters in present study. Generated data was analyzed with following objectives,

1. To assess effect of *Langhana* and *Pachana* on *Dyslipidemia*, effect of therapy was calculated after 14 days of treatment.
2. To assess effect of *Gomutra Haritaki*, effect of therapy was calculated after 14 days of treatment means before administration of *Gomutra Haritaki* and after 8 weeks of the treatment.
3. Overall effect of therapy was calculated by considering base line score i.e., before administration of *Langhana* and *Pachana* or placebo and after completion of *Gomutra Haritaki*.

Results were categorized as excellent response, if patients were improved with 65% to 100% of relief. Patients with 36% to 65% of relief was considered as markedly improved, 11% to 35% of relief was considered as moderate improvement, 1% to 10% of relief was considered as mild improvement and 0% or less than 10% was considered as unchanged.

Statistical analysis

After preparing the master chart of all the generated data in Microsoft excel work sheet, statistical calculations were made with the help of *Sigmastat 3.5* software and *Instat 3* software. Descriptive statistics was used for demographic data, Paired t test was used for quantitative parametric paired data; Un-paired t-test was used for quantitative unpaired data, Wilcoxon Signed Rank test was used for non-parametric paired data and Chi-square test for non-parametric unpaired data. The results were interpreted as; if p value was less than 0.05, 0.01 or 0.001; it was considered as significant while if p value is greater than 0.05, it was considered as insignificant.

Table 1: Samyaka Langhana Lakshana reported in 70 study subjects of Group A

Samyaka Langhana Lakshana	Not Achieved	% of patients Day 1	% of patients Day 2	% of patients Day 3	% of patients Day 4
Vata Mutra Purisha Sarga	2.86%	00	1.43%	27.14%	68.57%
Gatra Laghava	00	00	17.14%	75.71%	7.14%
Udara Kantha Asya Shuddhi	00	00	5.71%	84.29%	10.00%
Tandra Gate	00	00	41.43%	52.86%	5.71%
Klama Gate	00	00	41.43%	55.71%	2.86%
Sweda Privritti	00	00	7.14%	77.14%	15.71%
Ruchi	00	00	32.86%	62.86%	4.29%
Kshuta Pipasa Sahodaye	00	00	10.53%	73.68%	7.89%

Table 2: Samata Lakshana reported in 70 study subjects of Group A

Samata Lakshana	Number of Patients	% of Patients
Balabhransha	08	11.43%
Gaurava	70	100%
Anila Mudhata	12	17.14%
Alasya	67	95.71%
Apakti	03	4.29%
Nishthiva	06	8.57%
Malasanga	16	22.86%
Aruchi	11	15.71%
Klama	22	31.43%

Table 3: Effect on lipid profile considering before treatment and 14th day interval change
(Effect of Langhana-Pachana or placebo on lipid profile)

Parameters	Gr.	Mean score		Diff.	%	SD	SEM	t	p	Significance
		BT	14 th day							
TC	A	206.2	190.4	15.8	7.66↓	29.83	3.566	4.431	<0.001	S
	B	212.85	213.94	-1.08	0.51↑	18.52	2.246	-0.485	0.630	NS
TG	A	188.1	166.6	25.	13.56↓	50.57	6.045	4.218	<0.001	S
	B	180.52	184.5	-3.98	2.20↑	42.78	5.188	-0.768	0.445	NS
S.LDL	A	118.64	109.29	9.36	7.89 ↓	27.41	3.277	2.855	0.006	S
	B	125.88	125.87	0.01	0.01 ↓	17.05	2.068	0.007	0.994	NS
S.VLDL	A	38.46	32.54	5.92	15.39↓	12.24	1.464	4.04	<0.001	S
	B	36.06	37.23	-1.17	3.24↑	8.48	1.029	-1.134	0.261	NS
S.HDL	A	50.26	48.57	1.69	3.36 ↓	7.47	0.893	1.887	0.063	NS
	B	51.25	50.66	0.59	1.15 ↓	5.77	0.700	0.840	0.404	NS

TC- Serum Cholesterol; TG- Serum Triglyceride; S.LDL- serum low density lipoprotein; S.VLDL-serum very low density lipoprotein; SD –standard deviation; SEM – standard error of mean; p < 0.05, 0.01 or 0.001: S – significant; p value > 0.05: NS non-significant, BT: Before Treatment, AT: After Treatment

Table 4: Effect on lipid profile considering 14th day and after treatment phase change (Gomutra Haritaki phase)

Parameters	Gr.	Mean score		Diff.	%	SD	SEM	t	p	Significance
		14 th day	AT							
TC	A	190.40	188.49	1.91	1 ↓	27.03	3.231	0.592	0.555	NS
	B	213.94	192.62	21.3	9.97 ↓	31.28	3.794	5.620	<0.001	S
TG	A	162.6	171.7	-9.1	5.59 ↑	59.85	7.153	-1.27	0.208	NS
	B	184.5	166.23	18.26	9.90 ↓	54.77	6.642	2.75	0.008	S
S.LDL	A	109.29	105.06	4.23	3.87 ↓	21.92	2.620	1.614	0.111	NS
	B	125.87	109.34	16.53	13.13↓	28.08	3.406	4.853	<0.001	S
S.VLDL	A	32.54	34.31	-1.77	4.44↑	11.97	1.432	-1.237	0.220	NS
	B	37.23	33.31	3.92	10.43↓	10.93	1.327	2.953	0.004	S
S.HDL	A	48.57	49.20	0.63	1.30↑	6.92	0.827	-0.76	0.450	NS
	B	50.66	49.97	0.69	1.36↓	6.43	0.780	0.886	0.379	NS

TC- Serum Cholesterol; TG- Serum Triglyceride; S.LDL- serum low density lipoprotein; S.VLDL-serum very low density lipoprotein; SD –standard deviation; SEM – standard error of mean; p < 0.05, 0.01 or 0.001: S – significant; p value > 0.05: NS non-significant, BT: Before Treatment, AT: After Treatment

Table 5: Effect on lipid profile considering base line score and after treatment change (overall effect of therapies on lipid profile)

Parameters	Gr.	Mean score		Diff.	%	SD	SEM	t	p	Significance
		BT	AT							
TC	A	206.20	188.49	17.71	8.59 ↓	34.84	4.165	4.253	<0.001	S
	B	212.85	192.62	20.23	9.51 ↓	26.15	3.172	6.380	<0.001	S
TG	A	188.1	171.7	16.4	8.72 ↓	53.97	6.452	2.542	0.013	S
	B	180.51	166.23	14.28	7.91 ↓	45.38	5.503	2.595	0.012	S
S.LDL	A	118.64	105.06	13.59	11.45 ↓	32.98	3.943	3.446	<0.001	S
	B	125.88	109.34	16.54	13.14 ↓	22.90	2.778	5.955	<0.001	S
S.VLDL	A	38.46	34.31	4.14	10.76 ↓	12.8	1.53	2.708	0.009	S
	B	36.06	33.31	2.75	7.63 ↓	9.10	1.104	2.490	0.015	S
S.HDL	A	50.26	49.20	1.06	2.11 ↑	8.21	0.982	1.077	0.285	NS
	B	51.25	49.97	1.28	2.50 ↑	6.12	0.743	1.722	0.090	NS

TC- Serum Cholesterol; TG- Serum Triglyceride; S.LDL- serum low density lipoprotein; S.VLDL-serum very low density lipoprotein; SD –standard deviation; SEM – standard error of mean; p < 0.05, 0.01 or 0.001: S – significant; p value > 0.05: NS non-significant, BT: Before Treatment, AT: After Treatment

Table 6: Comparison of effect of therapies on lipid profile considering before treatment and after treatment change

Parameters (mg/dl)	Gr.	n	Diff. in means	Unpaired 't' test				
				S.D.	S.E.M	't'	'p'	Significance
TC	A	70	17.714	34.849	4.165	-0.480	0.632	NS
	B	68	20.235	26.155	3.172			
TG	A	70	16.400	53.978	6.452	0.249	0.803	NS
	B	68	14.279	45.380	5.503			
S.LDL	A	70	13.586	32.989	3.943	-0.610	0.543	NS
	B	68	16.544	22.909	2.778			
S.VLDL	A	70	4.143	12.800	1.530	0.735	0.464	NS
	B	68	2.75	9.107	1.104			

p < 0.05, 0.01 or 0.001: S – significant; p value > 0.05: NS non-significant

Table 7: Overall effect of therapies on body weight

Group	Body weight Mean Value (kgs)		Difference	% ↓	Paired 't' test				Significance
	BT	AT			S.D.	S.E.M	't'	'p'	
A	75.84	73.49	2.35	3.10	1.570	0.188	12.562	<0.001	S
B	73.85	72.10	1.75	2.37	1.274	0.154	11.327	<0.001	S

p < 0.05, 0.01 or 0.001: S – significant; p value > 0.05: NS non-significant, BT: Before Treatment, AT: After Treatment

Table 8: Overall effect of therapies on body circumference

Circumference (in cms)	Gr.	Mean Value		Diff.	% ↓	Paired 't' test				Significance
		BT	AT			S.D.	S.E.M	't'	'p'	
Chest	A	37.79	37.74	0.05	0.13	0.137	0.016	3.054	0.003	S
	B	37.60	37.60	0.00	0.00	0.034	0.00	1.425	0.159	NS
Abdomen	A	39.32	39.12	0.20	0.34	0.221	0.026	7.583	<0.001	S
	B	38.64	38.51	0.13	0.34	0.187	0.022	5.950	<0.001	S
Hip	A	40.89	40.67	0.22	0.54	0.221	0.026	8.540	<0.001	S
	B	40.25	40.12	0.13	0.32	0.172	0.020	6.498	<0.001	S
Pelvis	A	38.31	38.15	0.16	0.42	0.226	0.027	5.920	<0.001	S
	B	37.95	37.87	0.08	0.21	0.147	0.017	4.450	<0.001	S
Mid thigh	A	21.18	21.13	0.05	0.24	0.151	0.018	2.454	0.017	S
	B	20.59	20.59	0.00	0.00	0.024	0.002	1.0	0.321	NS
Calf	A	14.48	14.46	0.02	0.14	0.067	0.008	1.953	0.055	NS
	B	14.66	14.66	0.00	0.00	0	0	0	1	NS

p < 0.05, 0.01 or 0.001: S – significant; p value > 0.05: NS non-significant, BT: Before Treatment, AT: After Treatment

Figure 1: Effect of therapies of lipid profile after Langhana and Pachana or placebo treatment

Figure 2: Effect of therapies of lipid profile (14th day till completion of treatment (Gomutra Haritaki phase))

Figure 3: Overall effects of therapies on lipid profile

Figure 4: Overall effect of therapies on subjective criteria

RESULT AND DISCUSSION

Effect of Langhana and Pachana or Placebo treatment on Lipid profile

In Group A, for the beginning base 04 days of Eka Kala Bhojana (lunch) and Mudga Yusha (dinner) followed by Pachana with Dhanyaka-Shunthi Siddha Jala for 10 days provided statistically significant decrement in the serum lipid profile of patients. After 14 days of Langhana and Pachana in Group A, S. Cholesterol was decreased by 7.66% which was statistically significant. ($p < 0.001$) S. Cholesterol in patients of Group B increased by 0.51% which was statistically insignificant ($p > 0.05$). S. Triglyceride in patients of Group A decreased by 13.56% which was statistically significant ($p < 0.001$) and S. Triglyceride in patients of Group B increased by 2.20% which was statistically insignificant ($p > 0.05$). Similarly, S. LDL was decreased by 7.89% in Group A which was statistically significant ($p < 0.001$) It was decreased by 0.01% in Group B but it was statistically insignificant ($p = 0.994$). S. VLDL in patients of Group A was decreased by 15.39% which was statistically significant ($p < 0.001$) and S. VLDL in patients of Group B increased by 3.24% which was statistically insignificant ($p = 0.261$). S. HDL was decreased by 3.16% and 1.15% in Group A and B respectively which was statistically insignificant ($p > 0.05$). (Table 3, Figure 1)

Lipids are very essential for the integrity of cell wall of all tissues as well as for the maintaining of emulsion in the body. Whenever lipids are in normal physiological limits, they are responsible for construction, repair and maintenance of tissues. Serum lipids can be considered as Prakrita Sleshma Dhatu. Physiological function of Kapha viz., Sneha, Sthiratva, Bala, Dharana etc are similar to cellular function of cholesterol in body.¹⁰ Prakrita Sleshma and cholesterol play central role in innate immunity in healthy condition as well as inflammatory in unhealthy condition. If there is increment and vitiation of Rasa-Raktagata Ama and Kleda and Sleshma Dhatu beyond physiological threshold, it leads to various symptoms of Dyslipidemia like Anga Gaurava, Bharavridhi etc. Therefore, it is clear that for the control of Rasa-Raktagata Ama-Kleda and Sama Sleshma one should follow strict diet and life style. Langhana is main treatment of Santarpanajanya Vyadhi which includes important treatment of metabolic conditions like Dyslipidemia. Upavasa and Pachana are among ten type of Langhana. Kaphaja and Pittaja Madhyamabala Roga, Hridroga, Vibandha, Gaurava etc are indicated as Pachaniya Langhana¹⁰ As mentioned in classics, Ahara Parinamkara Bhava viz. Ushma, Vayu, Kleda, Sneha, Kala and Samyoga.¹¹ are responsible for the digestion of consumed food. Proper proportion of six factors is essential for good digestion. Eka Kala Bhojana is considered as Sukha Parinamakara.¹² Proper and easy digestion of food leads to proper nutrition of all Dhatu and ultimately production of Prakrita Dhatu. Recent research on experimental models as well as pilot clinical study on fasting showed that, prolonged fasting (PF) promotes stress resistance, but its effects on longevity are poorly understood. It also concluded that alternating PF and nutrient-rich medium extended yeast lifespan independently of established pro-longevity genes. In mice, 4 days of a diet that mimics fasting (FMD) developed to minimize the burden of PF, decreased the size of multiple organs/systems, an effect followed upon re-feeding by an elevated number of progenitor and stem cells and regeneration. Bi-monthly fasting mimics diet(FMD) cycles started at middle age extended longevity, lowered visceral fat, reduced cancer incidence and skin lesions, rejuvenated the immune system, and retarded bone mineral density loss. In a

pilot clinical trial, three FMD cycles decreased risk factors/biomarkers for aging, diabetes, cardiovascular disease, and cancer without major adverse effects, providing support for the use of FMDs to promote healthspan.¹³ It directly suggests effect of Langhana on Dosha Samyata or Dhatu Samyata as Swasthya. Mudga Yusha is Kaphaghna, Dipana, Hridya and Pathya Ahara for Vrani (wound healing).¹⁴ Research also suggest that Mudga is anti atherosclerotic and improved the plasma lipid profile by normalizing insulin sensitivity and significantly reduced triglyceride levels.¹⁵

Dipaniya and Pachaniya drugs like Dhanyaka (*coriandrum sativum* Linn.) and Shunthi (*zingiber officinale* Rosc.) increase as well as regulate Agni, digest Ama and helps in removal of Kleda and Ama from Rasa, Rakta and Meda through Mutra and Sweda. Thus, decreases cholesterol level. Shunthi is Kapha-Vata Vibandhahara, Vrishya, Ama-Vatahara, Ruchikara and Hridaya Amayahara. Shunthi is Agni Gunabhuyisthama and absorbs excess Jala as Ama or Kleda in body.¹⁶ Dhanyaka is Snigdha, Vrishya and Tridoshaghna.¹⁷ Both Shunthi and Dhanyaka is having hypolipidemic, anti oxidant and anti inflammatory action. From these findings it was revealed that Shunthi and Dhanyaka are potent herbal as preventive and curative against Dyslipidemia. With the organized function of Eka Kala Bhojana, Mudga Yusha and Dhanyaka-Shunthi Siddha Jala significant decrease in serum lipids was found in Group A. On the other hand, after administration of placebo capsules in Group B with no diet restriction; there was increment in serum lipid S. Cholesterol (0.51%), S. Triglyceride (2.20%), VLDL (3.24%). Therefore, administration of Langhana in form of Laghu Anna and Pachana with Dhanyaka Shunthi Siddha Jala is useful in treatment of Dyslipidemia.

Effect of Gomutra Haritaki on Lipid profile

Overall effect of Langhana and Pachana and administration of Gomutra Haritaki provided decrease by 1% in S. cholesterol which was statistically insignificant ($p = 0.555$), S. Triglyceride increased by 5.59% which was statistically insignificant ($p = 0.208$), S. LDL decreased by 3.87% which was statistically insignificant ($p = 0.111$), S. VLDL increase by 4.44% which was statistically insignificant ($p = 0.220$), S. HDL increased by 1.30% which was statistically insignificant ($p = 0.450$) in Group A. Overall treatment of Group B i.e., placebo treatment and administration of Gomutra Haritaki provided S.cholesterol reduction of 9.97% which was statistically significant ($p < 0.001$), S. Triglyceride decreased by 9.90% which was statistically significant ($p < 0.001$), S.LDL decreased by 13.13% which was statistically significant ($p < 0.001$), S VLDL decreased by 10.43% which was statistically significant ($p = 0.004$) and HDL decreased by 1.36% which was statistically insignificant ($p = 0.379$) in Group B. (Table 4, Figure 2)

Overall effect of Langhana and Pachana or placebo capsule followed by Gomutra Haritaki on Lipid profile

Overall effect of therapy which was calculated by difference at baseline and after administration of Gomutra Haritaki showed that S. Cholesterol was decreased by 8.59% and 9.51% in Group A and B respectively ($p < 0.001$). On comparison of Langhana-Pachana or placebo capsules followed by Gomutra Haritaki, both Groups provided similar effect on S. Cholesterol. ($p = 0.632$). S. Triglyceride was reduced by 8.72% and 7.91% in Group A and B respectively which was statistically significant. On comparison, both Groups provided similar effect on S. Triglyceride. ($p = 0.803$) S.LDL was reduced by 11.45% and 13.14% in Group A and B respectively which was statistically

significant. On comparison, both Groups provided similar effect on S.LDL. ($p=0.543$) S.VLDL was reduced by 10.76% and 7.63% in Group A and B respectively which was statistically significant. On comparison, both Groups provided similar effect on S.VLDL. ($p=0.464$) S. HDL decreased by 2.11 % and 2.50% in Group A and B respectively which was statistically insignificant ($p=0.285$ Gr. A, $p=0.09$ Gr. B). (Table 5, 6 and Figure 3)

Initially 14 days of Langhana and Pachana treatment parameters of lipid profile was significantly decreased in Group A. After Langhana and Pachana and after completion of treatment in Group A, less percentage relief was found in serum lipids during administration of Gomutra Haritaki. While in Group B, placebo treatment of 14 days provided increment and no effect on serum lipids but after administration of Gomutra Haritaki, serum lipids were significantly reduced in Group B. In all, in Group A, after significant decrement in serum lipids level with Langhana and Pachana, administration of Gomutra Haritaki almost maintained lipid levels. It suggests that after achieving the base line values of serum lipids, Gomutra Haritaki does not reduce or disturb the base line lipids level of individual. Placebo treatment provided increment and no effect on serum lipids. However, significant reduction in serum lipids was found after administration of Gomutra Haritaki. Finding of both Groups suggest that Gomutra Haritaki is helpful to reduce all serum lipids efficiently and significantly as well as maintain the physiological ratio of body components i.e., prevents the excessive Karshana or Dhatukshaya.

Effect on Fasting blood sugar (FBS)

After 14 days of Langhana and Pachana, FBS was decreased by 3.45% in Group A which was statistically significant ($p=0.032$) and 0.31% in Group B which was statistically insignificant ($p>0.05$). Fasting blood sugar was decreased because of diet restriction in form of Eka Kala Bhojana and Mudga Yusha. It reported that Mudga extract lowered blood glucose, plasma c-peptide, glucagone, total cholesterol and BUN levels and the same time markedly improved glucose tolerance and increased immunoreactive levels suggesting a potent anti diabetic effect.¹⁵ Shunthi¹⁸ and Dhanyaka¹⁹ both have reported anti diabetic activity. Overall effect of therapy which was calculated by considering difference at baseline and after full course of treatment showed that FBS was decreased by 1.11% and 1.54% in Group A and B respectively which was statistically insignificant. It can be concluded that, Gomutra Haritaki decreases Rasagata Ama as well as Sama Drava Sleshma which results in decrease in fasting blood sugar levels.

Effect of Treatment on Renal function

In Group A, after administration of Langhana and followed by Pachana with Dhanyaka-Shunthi Siddha Jala, blood urea was significantly decreased by 6.91%, s.creatinine was increased insignificant within normal physiological limit by 1.05% and no change was found in uric acid level while in Group B, after administration of placebo capsules, blood urea (2.37%), uric acid (1.13%) and s.creatinine (1.04%) values were increased which was statistically insignificant. It proves the role of Dhanyaka- Shunthi to stimulate the urinary system to wash out toxic products of nitrogen metabolism. Overall effect of treatment on renal function like blood urea, s.creatinine and uric acid were decreased by 4.92%, 2.11% and 1.33% respectively in Group A while in Group B, blood urea, s.creatinine and uric acid were increased by 3.14%, 3.12% and 1.51% respectively. It suggests that there is crucial role of Pachana with Dhanyaka and

Shunthi before administration of Gomutra Haritaki. As Gomutra itself is nitrogenous waste and contain the nitrous byproduct, consumption of Gomutra Haritaki containing Gomutra increases the load of nitrogen in body. So, in order to clear the nitrogen metabolism and to stimulate the renal function and enhance the effect of the treatment, it is very important to use Pachana as Dhanyaka-Shunthi especially in patients having poor renal function along with Dyslipidemia.

Effect of Treatment on Liver function

In Group A, after administration of Langhana and followed by Pachana with Dhanyaka-Shunthi Siddha Jala, SGPT (1.98%), Alkaline phosphate (4.13%), total protein (0.14%) was decreased and SGOT was increased (0.17%) which was insignificant. In Group B, SGPT (0.04%) and SGOT (1.27%) were increased while alkaline phosphate (2.26%) was decreased and no change was observed in total protein (0%) which was statistically insignificant. After Langhana and Pachana and after completion of treatment interval in Group A, SGOT was decreased by 6.90% which was statistically significant. Rest of parameters showed statistically insignificant decrement within normal limits. Overall effect of treatment, SGOT was decreased by 6.75% in Group A and increased by 3.39% in Group B which was statistically insignificant. Decrement in liver enzymes suggests hepatoprotective and anti inflammatory action of Mudga Yusha¹⁵, Shunthi²⁰ and Dhanyaka¹⁹ and Gomutra Haritaki.

Effect on ESR

In Group A, after Langhana and Pachana treatment, ESR was reduced by 15.43% due to Amapachana and Shothaghna Karma of Langhana and Dhanyaka Shunthi Siddha Jala. Both Shunthi²⁰ and Dhanyaka²¹ are reported to possess anti inflammatory activity. In Group B, ESR was increased 0.31% after 14 days of placebo treatment. Overall effect on ESR, Langhana and Pachana followed by Gomutra Haritaki was found 8.66% of decrease which was statistically insignificant and placebo capsule followed by Gomutra Haritaki, 6.32% of decrease was found which was statistically insignificant. Results of percentage decrement on ESR suggest Ama Pachana and Shothaghna Karma of Langhana-Pachana as well as Gomutra Haritaki.

Effect on Body weight

After Langhana-Pachana treatment, body weight was decreased by 0.97% which was statistically significant and decreased by 0.01% after placebo treatment which was statistically insignificant. After completion of therapies, body weight was reduced by 3.10% and 2.37% respectively in Group A and B which was statistically significant. On comparison, Group A provided significant change on body weight ($p=0.014$). Percentage wise decrement was on high side after Langhana-Pachana followed by Gomutra Haritaki treatment which suggests additional Medoghna effect of Langhana and Pachana. (Table 7)

Effect on Body circumference

After completion of treatment in both Groups, chest circumference was reduced by 0.13% in Group A which was statistically significant and no change was reported on chest circumference in Group B. Abdominal circumference was reduced by 0.34% in both Groups which was statistically significant. On comparison of effect of treatments, both the

groups provided similar effect on abdominal circumference ($p=0.066$). Hip circumference was reduced by 0.54% and 0.32% respectively in Group A and B which was statistically significant. On comparison, Group A provided better result on hip circumference ($p=0.008$). Pelvis circumference was reduced by 0.42% and 0.21% in Group A and B respectively which was statistically significant. On comparison, Group A provided better result on pelvis circumference ($p=0.015$). Considering abdominal and hip circumference, statistically significant change suggests additional Medoghna effect of Langhana Pachana followed by Gomutra Haritaki in Group A. Mid thigh circumference was reduced by 0.24% in Group A which was statistically significant and decreased by 0.21% in Group B which was statistically insignificant. Calf circumference was decreased by 0.14% in Group A which was statistically insignificant while no change was observed in Group B. (Table-8)

Effect on Anga Gaurava, Daurbalya and Alasya

On considering overall effect of therapies, Angagaurava (heaviness in body) was reduced by 93.47% and 68.52% in Group A and B respectively which was statistically significant. Daurbalya (weakness) was reduced by 89.10% and 63.15% in Group A and B respectively which was statistically significant. Alasya (laziness) was reduced by 86.07% and 71.13% respectively in Group A and B which was statistically significant. On comparison, Group A provided better effect on Anga Gaurava, Daurbalya and Alasya than Group B. ($p<0.001$) Anga Gaurava, Daurbalya and Alasya are Samata Lakshana as well as Jwara Purvarupa. All three symptoms occur mainly due to blockage of Srotasa and Apachita Amayukta Kleda and Meda Dhatu which hampers the Rasa-Rakta Samvahana and Dhatu Poshana of further Dhatu (Uttara Dhatu). Guru Guna which is mainly responsible for these symptoms is also a causative factor for increasing Ama resulting in formation of Pralepa in Rasavaha and Raktavaha Srotasa. Laghu Guna with Tikshna, Ushna and Ruksha Guna and Amapachana Karma of Langhana - Pachana and Gomutra Haritaki removed Srotorodha and helped to improve in Rasa-Rakta Samvahanam and Dhatu Poshana ultimately, giving a feel of Laghuta as well as Utsaha (enthusiasm).

Effect on Sphika-Stana-Udara Avalambana

Sphika Stana Udara Avalambana (accumulation of Meda in Sphika, Stana and Udara) was reduced by 24.4% which was statistically significant in Group A ($p<0.001$) and 13.08% in Group B which was statistically insignificant after completion of overall therapies. Sphika- Stana-Udara Avalambana is due to increased fat as well as increased Kleda in Rasa, Rakta and Meda Dhatu which produces Dhatu Shaithilya and Sphika Stana Udara Avalambana. Gomutra Haritaki is having Medoghna Karma and also decreases Kleda, Abhishyanda and Dhatu Shaithilya. Significant change was observed on Sphika-Stana-Udara Avalambana in Group A due to additional effect of Langhana and Pachana.

Effect on Atikshudha and Atipipasa

Considering overall effect of the treatments, Atikshudha (excessive hunger) was reduced by 33.33% after Langhana and Pachana followed by Gomutra Haritaki which was statistically significant ($p<0.001$) and by 40.12% without approach of Langhana and Pachana followed by Gomutra Haritaki which was statistically insignificant. Atipipasa (excessive thirst) was reduced by 69.77% and 54.36% in Group A and B respectively

which was statistically significant. ($p<0.001$) On comparison, both treatment had provided similar effect ($p=0.067$). Due to blockage of all Srotasa, Vata Dosha moves towards Koshtha and this Koshtha Gata Vata Dosha produces Agnisandhukshana i.e., increase in appetite and person feels more hunger and thirst.²² Langhana and Pachana removes the blockage in Srotasa that's why there is natural movement of Vata Dosha in Srotasa and Koshtha, ultimately normalizing Atikshudha and Atipipasa. Gomutra Haritaki increases Jatharagni by Ama-Pachana. It clears Srotorodha and Medomargavarana. Gomutra Haritaki causes Anulomana of Vata Dosha. Removal of increased Pitta Dosha from Adhomarga as well as reduction in increased Kleda in the body which ultimately results in Prakrita Gati of Vata leading to Samyaka Kshudha and Pipasa.

Effect on Swedadhikya and Daurgandhya

On considering overall effect of therapies, Swedadhikya (excessive sweating) was reduced by 66.09% and 55.73% respectively in Group A and B which was statistically significant. ($p<0.001$) On comparison, both treatment had provided similar effect ($p=0.209$). Daurgandhya (foul smell of body) was reduced by 72.88% and 45.93% in Group A and B respectively which was statistically significant. On comparison, Group A provided better effect on Daurgandhya than Group B. ($p<0.001$) Sweda is Mala of Medo Dhatu and Ashraya Bhava of Pitta Dosha. There is Ashraya-Ashrayi Bhava between Rakta Dhatu and Pitta Dosha. Therefore, whenever there is vitiation of any one of three Sharira Bhava viz. Pitta Dosha, Rakta and Medo Dhatu, it leads to qualitative and quantitative alteration in Sweda of an individual. In Dyslipidemia, there is involvement of Rakta, Meda and Pitta Dosha which leads to Swedadhikya in those individual. Sweda has action of Kleda Vidhriti.²³ Meda Dushti causes Daurgandhya which is Sweda Swabhava. Langhana and Pachana with Dhanyaka and Shunthi reduced Swedadhikya as well as Daurgandhya with Dipana, Pachana and Mutrala properties eliminates excessive Kleda through Mutra and decreases Sweda. Gomutra Haritaki further reduced increased Kleda of Rakta and Meda Dhatu and causes Srotasa Vishodhana which relieves Swedadhikya. Increased Sweda produces Dauragandhya or typical body odour in individual therefore improvement in Swedadhikya also improves Daurgandhya. Langhana and Pachana followed by Gomutra Haritaki thus provided significant effect on Swedadhikya and Daurgandhya.

Effect on Sandhishoola

Sandhishoola (joints pain) was reduced by 55.91% and 41.49% respectively in Group A and B which was statistically significant. On comparison, Group A provided better effect on Sandhishoola than Group B. ($p=0.015$) Sandhishoola is due to Bharavridhi (Rasagata Sama Shleshma) or Samata (Medogata Sama Shleshma). On one side, Ama blocks the Srotasa and leads to hamper in Rasa Rakta Samvahana and Poshana of Sharira Sandhi. On the other hand, Kleda causes Dhatu Shaithilya and therefore Sandhishoola occurs in Dyslipidemia patients. Application of Langhana and Pachana with Dhanyaka Shunthi Siddha Jala improves removal of blockage which is useful to improve Rasa Rakta Samvahana and Dhatu Poshana. Similarly, Gomutra Haritaki helps to Prakrita Kapha and normal movement of Vata therefore reduces the Sandhishoola.

Effect on Ayasena Shwasa

Ayasena Shwasa was reduced by 58.87% and 45.14% respectively in Group A and B which was statistically

significant. ($p < 0.001$) On comparison, Group A provided better effect on Ayasena Shwasa than Group B. ($p = 0.008$) Ayasena Shwasa (dyspnoea on exertion) which is usually present in patients of Dyslipidemia when the condition is associated with obesity or cardio-vascular accidents. Ayasena Shwasa is one of the symptoms of Medo Vriddhi.²⁴ Reduction in Apachita Medovridhi (Medakshaya) results in improvement on the symptoms like Ayasena Shwasa. The morbid Kapha and inactive lifestyle make a person inert in all ways. Shwasa is Amashaya Samudbhava and Vata-Kaphatmaka and treatment for same is Ushna, Vatanulomana and Vatakaphahara Dravya. Ayasena Shwasa which is due to Amashaya Samudbhava Agnimandhya can be decreased by Langhana and Pachana with Dhanyaka-Shunthi Siddha Jala as well as Gomutra Haritaki.

Follow up

Follow up was done for one month after completion of the treatment. Out of 70 patients, who completed course in Group A, 45 patients reported for investigation of lipid profile and out of 68 patients who completed course in Group B, 47 patients reported investigation of lipid profile. Considering the status of lipid profile base line and after follow up interval, S. Cholesterol was reduced by 5.04% in Group A which was statistically insignificant and by 7.15% in Group B which was statistically significant. S. Triglyceride was reduced by 11.67% in Group A which was statistically significant and by 9.55% in Group B which was statistically insignificant. S.LDL was decreased by 4.87% in Group A which was statistically insignificant and by 9.45% in Group B which was statistically significant. S.VLDL was reduced by 14.65% in Group A which was statistically significant and by 9.49% in Group B which was statistically insignificant. S.HDL was decreased by 1.74% and 2.63% in Group A and B respectively which was statistically insignificant. However, these changes reported during this period were within normal limits and hence can be stated that withdrawal of Gomutra Haritaki but following of Pathya can maintain lipid parameters within limits.

Overall effect of therapy

On assessment of overall effect of therapy, marked improvement was observed in 38 (54.29%) patients and moderate improvement in 32 (45.71%) of patients in Group A while in Group B, marked improvement was observed in 04 (5.88%) patients, moderate improvement in 60 (88.24%) of patients, mild improvement in 03 (4.41%) patients and 01 (1.47%) patient remained unchanged.

CONCLUSION

Life threatening complication due to Dyslipidemia is directly interlinked with chronic inflammation and hence Shotha, Kapha Medo Margavarana, Medodosha, Shonita Abhishyanda and Prameha are the conditions which can be usually associated with Dyslipidemia. Langhana, Pachana followed by Gomutra Haritaki is the effective treatment protocol for Dyslipidemia. Langhana and Pachana with Dhanyaka Shunthi Siddha Jala is more effective to reduce fluctuate lipids like S. Triglyceride and S. VLDL. Gomutra Haritaki is itself Dipana and Pachana drug, so it can reduce serum lipids significantly but Langhana and Pachana with Dhanyaka Shunthi Siddha Jala followed by Gomutra Haritaki is more effective with poor liver and renal function status of patient. After Langhana and Pachana, Gomutra Haritaki did not further reduced serum lipids from physiological base line of individual. It suggests that Gomutra Haritaki prevent excess Dhatu Karshana or Dhatu Kshaya. The

formulation Gomutra Haritaki does only Dosha Paka, not, the Dhatu Paka. That's why it is ideal choice of drug (Shamana) for Dyslipidemia.

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