Publisher
Maharshi Charaka Ayurveda
www.maharshicharaka.in

E-ISSN:2456-3110

Journal of Ayurveda and Integrated Medical Sciences

2025 Volume 10 Number 1 JANUARY

Research Article

Haritaki Churna

A clinical study to determine the efficacy of Amritadya Guggulu and Haritaki Churna in the management of Medoroga w.s.r. to Dyslipidemia

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DOI:10.21760/jaims.10.1.8

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Dyslipidemia, a significant risk factor for atherosclerotic cardiovascular disease (ASCVD), necessitates effective management strategies. This study investigated the efficacy of an Ayurvedic formulation, Amritadya Guggulu combined with Haritaki Churna, in managing dyslipidemia compared to conventional treatment with Atorvastatin. Thirty patients with dyslipidemia were randomly assigned to two groups and received either the Ayurvedic formulation or Atorvastatin for 8 weeks. The results demonstrated that the Ayurvedic group showed statistically significant improvements in subjective symptoms and objective parameters, including serum cholesterol and triglyceride levels. Notably, no adverse effects were reported in this group. In contrast, the conventional treatment group exhibited improvements, but to a lesser degree. These findings suggest that Amritadya Guggulu and Haritaki Churna may serve as effective and safe alternatives for dyslipidemia management. Further investigation with larger sample sizes is warranted to provide conclusive evidence. This study contributes to the growing body of research on Ayurvedic interventions for non-communicable diseases, highlighting their potential in addressing public health concerns in developing countries.

Keywords: Amritadya Guggulu, Haritaki Churna, Medoroga, Dyslipidemia

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How to Cite this Article

Thakur N, Chaudhary V, Mishra A, Dharmani G, A clinical study to determine the efficacy of Amritadya Guggulu and Haritaki Churna in the management of Medoroga w.s.r. to Dyslipidemia. J Ayu Int Med Sci. 2025;10(1):57-68.
Available From
https://jaims.in/jaims/article/view/4174/

To Browse

Manuscript Received	Review Round 1	Review Round 2	Review Round 3	Accepted
2024-12-04	2024-12-14	2024-12-24	2025-01-04	2025-01-17

Conflict of Interest	Funding	Ethical Approval	Plagiarism X-checker	Note
None	Nill	Yes	11.41	

Introduction

Over the past few decades, developing countries like India have experienced significant shifts in population health. While infectious diseases continue to be a major concern, particularly in low-income areas, there has been a swift epidemiological transition towards non-communicable diseases. This shift is largely driven by unhealthy lifestyle changes associated with rapid urbanization and westernization, affecting people across all socio-economic levels. Dyslipidemia, especially a circulating non-optimal level of cholesterol, is one of the most important risk factors for atherosclerotic cardiovascular disease (ASCVD), which accounts for the most deaths worldwide. Maintaining a healthy level of blood cholesterol is an important prevention strategy for ASCVD, through lifestyle intervention or cholesterol-lowering therapy.

Dyslipidemia refers to either lipoprotein overproduction or deficiency, which is a consequence of abnormal lipoprotein metabolism. This leads to elevated total cholesterol, low-density lipoprotein (LDL-C) cholesterol and triglyceride (TG) concentrations, and a decrease in the high-density lipoprotein (HDL-C) cholesterol concentration in blood. It leads to the development of atherosclerosis which in turn is known to cause CVDs.

Dyslipidemia is an independent preventable risk factor for coronary heart disease and has been shown to significantly increase the risk of cardiovascular mortality. CVDs have become a growing burden across the globe and are highly prevalent, especially in the developing countries that alone account for 80% of the global CVD mortality. Dyslipidemia could be *Primary* (genetic defect in the lipid metabolism that causes abnormal lipid levels) and *Secondary* (caused due to modifiable lifestyle and environmental factors, diseases, and medications). Dyslipidemia has been strongly associated with the pathophysiology of cardiovascular diseases (CVDs) and is a major independent risk factor for coronary artery disease (CAD), further leading to the development of atherosclerosis and associated cardiovascular events. The long-term prospective epidemiological studies have revealed that individuals with healthier lifestyles and particularly with favorable lipid profile have reduced incidence of coronary heart disease.

Therefore, prevention and sensible management of dyslipidemia can hugely contribute to reducing cardiovascular morbidity and mortality. CVDs have become a growing burden across the globe and are highly prevalent, especially in the developing countries that alone account for 80% of the global CVD mortality.

The *Ayurvedic* classics have abundantly described about diet and lifestyle related health and disease conditions. In *Charaka Samhita*, it has been described that in the ancient time, wealthy people had tendency to over-eating that caused heaviness of the body. Heaviness of the body led to fatigue and lassitude resulting in various diseases and decrease in their life-span. Unhealthy eating habits, poor diet, lack of physical activity, excessive alcohol consumption and tobacco use are the prominent causes of lifestyle related diseases in the present era too. Dyslipidemia cannot be directly corelated with any disease condition described in *Ayurvedic classics*. The symptoms of Dyslipidemia described in any disease conditions modern text shows resemblance with Aam, and with many of Rasa *Dushti, Rakta Dushti*, And *Medodushti Janya* symptoms. We can correlate it to *Rasagata Sneha Vriddhi* (increased lipids in plasma), *Raktagata Sneha Vriddhi* (increased lipids in blood). Being a disorder of Meda dhatu (adipose tissue) we have correlated it with "*Medodushti*" (*Aam Dushit Meda Dhatu*).

It has been mentioned that *Kapha Dosha* and *Medo Dhatu* are interdependent, having *Ashray-Ashrayi Bhava* thus any etiological factor that vitiates *Kapha Dosha* can also vitiate *Medo* Dhatu resulting in dyslipidemia. Due to *Medodhatwagni Dushti* (disturbed fat metabolism) excessive accumulation of Aam and Meda occurs in various microchannels of circulation of body, results in obstruction. As a result of which *Vata* in the *Koshtha* causes *Jathragni Sandhukshna* which results in increased craving for food and leads to over intake of food and thus results in *Medoroga*. To open these channels *Amritadya Guggulu* and *Haritaki Churna* along with lukewarm water (*Koshna Jala*) will act by *Deepana, Aampachana*, *Lekhana* and *Srotoshodhana* properties. Number of options are available in the contemporary science for lipid management, Statins being most preferred of them. But these drugs are often accompanied with lot of side effects like myalgia, liver damage, gastric upset, rashes etc.

Hence this study of *Amritadya Guggul* has been planned for the management of *Medoroga* by boosting the metabolism of the body thus reduce the increased lipids from the body.

Aims and Objectives

Primary Objectives

1. To evaluate the effect of *Ayurvedic* formulation *Amritadya Guggulu* and *Haritaki Churna* in the management of *Medoroga* s.r. to Dyslipidemia.
2. To compare the efficacy of *Amritadya Guggulu* and *Haritaki Churna* with Tab. Atorvastatin in the management of *Medoroga* s.r. to Dyslipidemia.

Secondary Objective

1. To assess the clinical safety and untoward effects of *Amritadya Guggulu and Haritaki Churna* in patients of *Medoroga*s.r. to Dyslipedemia.

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, Distt Kangra (H.P.)
- Total 30 patients were selected for the present study irrespective of the gender, caste and religion etc.

Study Design

- Study type - Randomized Clinical trial
- Masking - No
- Timing - Prospective
- Study Subjects - 30
- of group - 2
- Duration of trial - 8 weeks
- Follow-up visit - At 4th week and after the completion of trial.

Diagnostic Criteria Subjective Criteria

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

1. Chala-Sphika-Udara-Stana
2. Kshudra Shwasa
3. Sandhi Shoola
4. Kshudha Atimatra
5. Pipasa Atiyoga
6. Nidradhikya
7. Javoprodha
8. Swedabadha
9. Daurgandhya

Objective Criteria

- Weight
- *BMI*
- Skin fold thickness:
  - Biceps
  - Triceps
  - Supra iliac
- Hip Circumference
- Waist circumference
- Waist –hip ratio
- Blood Pressure
- Serum lipid profile:

1. Serum Cholesterol >200 mg/dl
2. Serum T.G. >150 mg/dl
3. LDL >100 mg/dl
4. VLDL >30 mg/dl
5. HDL <40 mg/dl

Inclusion Criteria

- Patients willing to participate in the trial.
- Patients between the age group of 40-70 years of either gender were selected for the study
- Patients who present with sign and symptoms of *Medoroga* s.r. to *Dyslipidemia* as described in classical text were selected.
- Serum lipid profile:
  - Serum Cholesterol - 200 to 300 mg/dl
  - Serum Triglycerides - 150 to 400 mg/dl
  - Serum LDL - 100 to 200 mg/dl
  - Serum VLDL - 30 to 100 mg/dl
  - Serum HDL - 20 to 40 mg/dl

Exclusion Criteria

- Patient not willing for the trial.
- Patient having illness like Tuberculosis, Carcinoma, Renal and Liver disorders. Patient having past history of Myocardial infarction, Unstable Angina and Congestive Cardiac Failure and Cerebro Vascular Accident.

- Patients Below the age of 40yrs and above the age of 70yrs.
- Pregnant females and lactating mothers.
- Patients having Serum cholesterol >300 mg/dl, Serum Triglycerides >400 mg/dl, Serum LDL >200 mg/dl, Serum VLDL >100 mg/dl.
- Subjects who have completed participation in any other clinical trial during the past 3 months

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 30 patients in two groups (15 patients in each group). Group I was managed with *Amritadya Guggulu,* 500mg *Vati* twice a day with Luke warm water along with *Haritaki Churna* 3gm-6gm *Churna* with luke warm water as per *Koshtha* while Group II was managed with Tablet Atorvastatin 10 mg HS at bed time.

Trial Drugs

1. Amritadya Guggulu

Dose: 500mg twice a day
Route of Administration: Oral
Anupan:Luke warm water

2. Haritaki Churna

Dose: 3gm-6gm as per *Koshtha*
Route of Administration: Oral
Anupan:Luke warm water

3. Tablet Atorvastatin

Dose: 10 mg HS
Route of Administration: Oral
Anupan: water

Trial Drug Composition

Criteria of Assessment

Subjective parameters were assessed before and after the treatment.

The main criterion of assessment was:

- Serum lipid profile
- BMI
- Weight
- skin fold thickness
- Biceps
- Triceps
- Supra iliac
- Circumference
- Waist circumference
- Waist - hip ratio
- Blood Pressure

*Were done before the commencement of trial and after the completion of trial.

Table 1: Composition of *Amritadya Guggulu*

SN	Name	Botanical Name	Family	Part Used	Proportion
1.	Amrita	Tinospora cordifolia Miers ex Hook. f. & thorns	Mesispermaceae	Stem	1 part
2.	Ela	Elettaria cardamomum Maton	Zingiberaceae	Seed	2 part
3.	Vaividang	Embelia ribes Burm.f.	Primulaceae	Fruit	3 part
4.	Kutaja	Holarrhena antidysentrica Linn.	Apocynaceae	Bark	4 part
5.	Bibhitaki	Terminalia bellerica Roxb.	Combretaceae	Pericarp	5 part
6.	Amalaki	Embelia officinalis Gaertn.	Euphorbiaceae	Pericarp	6 part
7.	Haritaki	Terminalia chebula Retz.	Combretaceae	Pericarp	7 part
8.	Shudh Guggulu	Commiphora wightii Hook ex. stocks	Burseraceae	Olegum Resin	8 part

Objective Criteria:

The main criterion of assessment was Serum Lipid Profile 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 analyzed statistically and expressed in the terms of mean score before treatment (BT), after treatment (AT), difference of mean (BT-AT), 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 30 registered patients, the incidence of *Medoroga* was highest in age group 41-50 years (i.e., 36.66%), in males (i.e., 53.33 %), and in Hindus (i.e., 100%). Majority of the study subjects were household workers (i.e., 33.33 %) and maximum were Graduate (i.e., 40 %). Majority of study subjects, i.e., 70 % were above poverty line and belonged to urban areas (i.e., 53.33 %).

As far as the lifestyle is concerned, 63.33% study subjects were living with a sedentary life. Majority of study subjects have a normal appetite 83.33%. Bowel habit was normal and regular in 83.33% and bladder habit was normal (90%) in majority of study subjects. Most of the study subjects 63.33% were taking mixed diet and no addiction was found in 73.33% of study subjects and the incidence was more i.e., 40% in study subjects with *Vata Pittaj* & *Vata Kaphaj Prakriti*. Study revealed that 53.33 % patients were predominantly of *Madhyam Koshtha* and 60 % study subjects predominantly had normal BMI and 33.33% of study subjects were hypertensive majority of which dominant gender was male gender 20%.

In the present clinical trial out of a total of 30 study subject summary of frequency of signs and symptomatology observed is as follows:

- *Chalsphikudar Stana* in 16 study subjects (53.33 %)
- *Kshudra Shawasa* in 14 study subjects (46.6 %)
- *Sandhi Shoola* in 11 study subjects (36.6 %).
- *Kshudha Ati Matra* in 21 study subjects (70 %).
- *Pipasa Atiyoga* in 18 study subjects (60 %).
- *Nidradhikya* in 14 study subjects (46.6 %).
- *Javoprodha* in 16 study subjects (53.33 %).
- *Swedabadha* in 17 study subjects (56.66 %).
- *Daurgandhya* in 22 study subjects (73.33%).

Table 2: Effect of therapy on Subjective Parameter

SN	Category	N	Group	Mean		% Change	SD ±	SE ±	't' value	'p' value	Sig
				BT	AT						
1.	Chalsphikudar Stana	15	G- I	0.930	0.660	28.5↓	0.458	0.118	2.250	0.041	S
		15	G- II	0.660	0.600	10.0↓	0.258	0.060	1.000	0.334	IS
2.	Kshudra Shawasa	15	G- I	0.930	0.260	71.3↓	0.488	0.126	5.290	<0.001	HS
		15	G -II	1.130	0.930	17.9↓	0.410	0.107	1.870	0.080	IS
3.	Sandhi Shoola	15	G – I	0.267	0.200	25.0↓	0.458	0.118	0.564	0.582	IS
		15	G – II	0.667	0.533	20.0↓	0.640	0.165	0.807	0.433	IS
4.	Kshudha Ati Matra	15	G – I	0.733	0.133	81.8↓	0.507	0.131	4.583	<0.001	HS
		15	G – II	0.667	0.467	29.9↓	0.414	0.107	1.871	0..082	IS
5.	Pipasa Atiyoga	15	G – I	0.800	0.133	83.3↓	0.667	0.617	4.183	<0.001	HS
		15	G - II	0.600	0.333	44.5↓	0.594	0.153	1.740	0.104	IS
6.	Nidradhikya	15	G-I	1.067	0.333	68.7↓	0.704	0.182	4.036	<0.001	HS
		15	G-II	0.667	0.467	29.9↓	0.676	0.175	1.146	0.271	IS
7.	Javoprodha	15	G-I	0.800	0.133	83.3↓	0.617	0.159	4.183	<0.001	HS
		15	G-II	1.000	0.733	26.7↓	0.458	0.118	2.256	0.041	S
8.	Swedabhadha	15	G-I	0.667	0.267	59.9↓	0.507	0.131	3.055	0.009	S
		15	G-II	0.600	0.467	29.9↓	0.516	0.133	1.000	0.334	IS
9.	Daurgandhya	15	G-I	1.000	0.533	46.7↓	0.594	0.133	3.500	O.OO4	S
		15	G-II	0.733	0.600	18.1↓	0.352	0.090	1.468	0.164	IS

*↑ - Increase, ↓- Decrease, HS – Highly Significant, S – Significant, IS – Insignificant

Table 3: Intergroup comparison of Subjective criteria

SN	Symptoms	% Relief		Diff. in % age	SD ±	SE ±	't' value	'p' value	Sig
		G – I	G- II						
1.	Chalsphikudar Stana	28.5%	10.4%	18.1↓	0.220	0.100	1.40	0.152	IS
2.	Kshudra Shawasa	71.38	17.90	53.48↓	0.370	0.166	2.82	0.009	S
3.	Sandhi Shoola	25	20.0	5.0↓	0.664	0.251	0.00	1.000	IS
4.	Kshudha Ati Matra	81.8	29.9	51.9↓	0.485	0.184	1.448	0.025	S
5.	Pipasa Atiyoga	83.3	44.5	38.8↓	0.652	0.247	0.808	0.039	S
6.	Nidradhikya	68.7	29.9	38.8↓	0.716	0.271	1.965	0.043	S
7.	Javoprodha	83.3	26.7	56.6↓	0.506	0.191	1.042	0.069	IS
8.	Swedabhadha	59.9	29.9	30.0↓	0.452	0.171	-0.388	0.165	IS
9.	Daurgandya	46.7	18.1	28↓	0.458	0.173	2.302	0.019	S

* ↑Increase, ↓ Decrease, HS – Highly Significant, S – Significant, IS – Insignificant

Effect of Therapy Based on Subjective Criteria

All the patients were registered from OPD/IPD of R.G.G.P.G. Ayurvedic College & Hospital, Paprola, 30 patients were given the trial drugs. There were no dropouts, therefore,

The effect of therapy was studied on all enrolled patients. These 30 patients were divided into two groups - Group I and Group II, consisting of 15 patients each. The effect of *Amritadya Gugglu* and *Haritaki Churna* was studied on Group I

And the effect of *Tab. Atorvastatin* 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 4: Effect of Therapy Based on biochemical parameters

SN	Category	Groups	N	Mean		Mean diff	% Change	SD ±	SE ±	't' value	'p' value	Sig
				BT	AT							
1.	Cholesterol	G – I	15	258.40	202.80	55.60	21.5↓	33.310	8.601	6.465	<0.001	HS
		G – II	15	226.80	223.13	3.667	1.61↓	62.427	16.119	0.227	0.823	IS
2.	Triglycerides	G – I	15	262.13	206.26	55.8	21.2↓	1	12.252	4.560	<0.001	HS
		G – II	15	241.33	193.400	47.9	19.8↓	19.02	4.913	9.756	<0.001	HS
3.	HDL	G – I	15	41.133	43.667	-0.533	6.15↑	6.255	1.615	-1.569	0.139	IS
		G-II	15	46.867	54.867	-8.000	17.07↑	15.57	4.021	-1.989	0.067	IS
4.	LDL	G-I	15	157.80	124.00	33.80	21.4↓	22.304	5.759	5.869	<0.001	HS
		G-II	15	148.733	115.733	33.0	22.1↓	16.91	4.367	7.557	<0.001	HS
5.	VLDL	G- I	15	50.667	38.167	12.50	24.7↓	10.153	2.393	5.223	<0.001	HS
		G -II	15	49.750	39.700	10.05	22.6↓	6.270	1.402	7.168	<0.001	HS
6. .	SGOT	G – I	15	33.867	32.933	0.933	2.75↓	6.850	1.769	0.528	0.606	IS
		G – II	15	37.067	29.000	8.067	21.76 ↓	15.295	3.949	2.043	0.060	IS
7.	SGPT	G – I	15	35.200	33.933	1.267	3.59↓	12.981	3.352	0.378	0.711	IS
		G – II	15	35.200	30.600	4.600	13.06 ↓	10.861	2.804	1.640	0.123	IS
8.	FBS	G- I	15	93.200	92.600	0.600	0.64↓	6.967	1.799	0.334	0.744	IS
		G- II	15	93.33	87.467	5.86	0.90↓	7.029	1.815	3.232	0.006	IS
9.	B. Urea	G- I	15	31.533	26.533	5.000	15.85↓	9.366	2.418	2.068	0.058	IS
		G -II	15	26.200	27.800	-1.600	6.10↑	6.905	1.783	-0.897	0.385	IS
10.	S.Creatinine	G – I	15	0.833	0.733	0.100	12↓	0.136	0.035	2.842	0.013	IS
		G – II	15	0.773	0.800	-0.026	3.36↑	0.162	0.041	-0.636	0.535	IS

*↑ - Increase, ↓- Decrease, HS – Highly Significant, S – Significant, IS – Insignificant

Intergroup Comparison on biochemical parameters

Table 5: Inter group comparison of effect on biochemical parameters

SN	Symptoms	% Relief		Diff. in% age	SD ±	SE ±	't' value	'p'Value	Sig
		G – I	G- II						
1.	Cholesterol	21.5	1.61	19.89↓	50.95	18.93	2.742	0.918	IS
2.	Triglycerides	21.2	19.8	1.4↓	36.81	13.68	0.579	0.708	IS
3.	HDL	6.15	17.07	-10.92↑	12.08	4.491	1.217	0.218	IS
4.	LDL	33.80	21.4	12.4↓	14.062	5.225	0.995	0.3111	IS
5.	VLDL	24.7	22.6	2.1↓	8.470	3.147	0.889	0.507	IS
6.	SGOT	2.75	21.76	-19.01↑	12.06	4.48	-1.5906	0.117	IS
7.	SGPT	3.59	13.06	-9.47↑	12.18	4.529	0.7359	0.48	IS
10.	FBS	0.64	0.90	-0.26↑	7.126	2.648	-1.988	0.072	IS
11.	B. Urea	15.85	6.10	9.75↓	8.378	3.113	2.119	0.503	IS
12.	S. Creatinine	12	3.36	8.64↓	0.152	0.056	2.23	0.606	IS

*↑ - Increase, ↓- Decrease, HS – Highly Significant, S – Significant, IS – Insignificant

Effect of therapy based on Objective parameters

Table 6: Effect of therapy based on Objective parameters

SN	Category	Groups	Mean		% Change	SD±	SE±	't' value	'p' value	Sig
			BT	AT						
1.	Weight	G-I	64.46	63.580	1.36% ↓	1.448	0.374	2.353	0.034	S
		G-II	61.66	60.08	2.57% ↓	1.658	0.428	3.706	0.002	S
2.	BMI	G-I	25.227	24.587	3.47% ↓	0.876	0.226	2.831	0.013	S
		G-II	24.913	24.367	2.17%↓	0.993	0.257	2.131	0.051	IS
3.	Waist Circumference	G-I	90.600	86.800	4.19↓	3.144	0.812	4.681	<0.001	HS
		G-II	93.933	93.000	0.99 ↓	3.081	0.796	1.173	0.260	IS
4.	Hip Circumference	G-I	97.600	95.533	2.11↓	2.120	0.547	3.775	0.002	S
		G-II	95.607	95.200	0.42↓	0.907	0.234	1.736	0.105	IS
5.	Skin fold thickness biceps	G-I	10.093	9.487	6.07↓	0.920	1	2.554	0.023	S
		G-II	10.322	10.035	2.78↓	0.497	0.128	2.241	0.042	S
6.	Skin fold thickness triceps	G-I	11.563	10.883	5.88 ↓	0.795	0.205	3.314	0.005	S
		G-II	12.493	11.667	6.61 ↓	0.849	0.219	3.771	0.002	S
7.	Skin fold thickness Supra-iliac	G-I	13.969	13.572	2.84 ↓	0.712	0.184	2.158	0.049	S
		G-II	14.420	13.740	4.71↓	0.728	0.188	3.617	0.003	S
8.	Waist hip ratio	G-I	0.97	0.918	5.36↓	0.035	0.009	2.277	0.039	S
		G-II	0.985	0.984	0.101↓	0.036	0.009	0.0707	0.945	IS

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

Table 7: Inter group comparison of effect on objective parameters

SN	Symptoms	% Relief		Diff. in %	SD±	SE±	't' value	'p' value	Sig
		G-I	G-II						
1.	Body Weight	1.36%	2.57%	0.75↓	1.58	0.58	-1.243	0.224	IS
2.	BMI	3.47%	2.17%	1.3↓	0.988	0.367	-0.889	<0.001	HS
3.	Waist circumference	4.19 %	0.99	3.2↓	3.170	2.866	2.433	0.761	IS
4.	Hip Circumference	2.11 %	0.42 %	1.69↓	1.786	0.663	2.099	0.726	IS
5.	Skin fold thickness Biceps	6.07 %	2.78 %	3.29↓	0.752	0.279	-1.141	0.149	IS
6.	Skin fold thickness Triceps	5.88	6.61	-0.73↑	0.837	0.311	-0.471	0.426	IS
7.	Skin fold thickness Supra iliac	2.84	4.71	-1.87↑	0.733	0.272	-1.039	0.267	IS
8.	Hip waist Ratio	5.36	0.101	5.25↓	0.036	0.013	1.474	0.761	IS

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

Table 8: Effect of therapy on Haematological parameters

SN	Category	Group	Mean		% Change	SD±	SE±	't' value	'p' value	Sig
			BT	AT						
1.	Hb	G-I	12.727	12.873	1.15%	0.843	0.218	-0.674	0.511	IS
		G-II	12.987	13.040	0.40%	0.698	0.180	-0.296	0.772	IS
2.	TLC	G-I	6473.68	6226.99	3.81%	1480.76	382.33	0.645	0.529	IS
		G-II	7566.6	7320.00	3.25%	1478.35	381.70	0.646	0.529	IS
3.	Neutrophils	G-I	56.883	56.007	6.67%	11.48	2.96	1.814	0.091	IS
		G-II	59.433	61.413	0.3%	5.639	1.456	-1.360	0.195	IS
4.	Lymphocytes	G-I	30.147	32.173	6.2%	8.078	2.086	-0.972	0.348	IS
		G-II	33.180	30.947	6.72%	7.136	1.843	1.212	0.246	IS
5.	Mixed Cells	G-I	7.720	7.427	3.79%	1.336	0.345	0.850	0.409	IS
		G-II	7.387	7.507	1.62%	3.277	0.846	-0.142	0.889	IS
6.	ESR	G-I	20.200	15.067	25.41%	12.592	3.25	1.579	0.137	IS
		G-II	15.800	11.733	13.67%	6.307	1.629	2.497	0.026	S

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

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

SN	Symptoms	% Relief		Diff. in%	SD±	SE±	't' value	'p' value	Sig
		G-I	G-II						
1.	Hb	1.15	0.40	0.75 ↓	0.787	0.292	-0.318	0.453	IS
2.	TLC	3.81	3.25	0.56 ↓	1506	559	0.047	0.603	IS
3.	Neutrophils	6.67	0.31	6.36 ↓	9.21	3.424	2.14	0.014	S
4.	Lymphocytes	6.2	6.72	-0.52 ↑	7.593	2.821	-1.660	0.099	IS
5.	Mixed Cells	3.79	1.62	2.17 ↓	2.548	0.946	0.436	0.654	IS
6.	ESR	25.41	13.67	11.74	10.31	3.832	0.574	0.557	IS

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

Prepared Trial Drugs

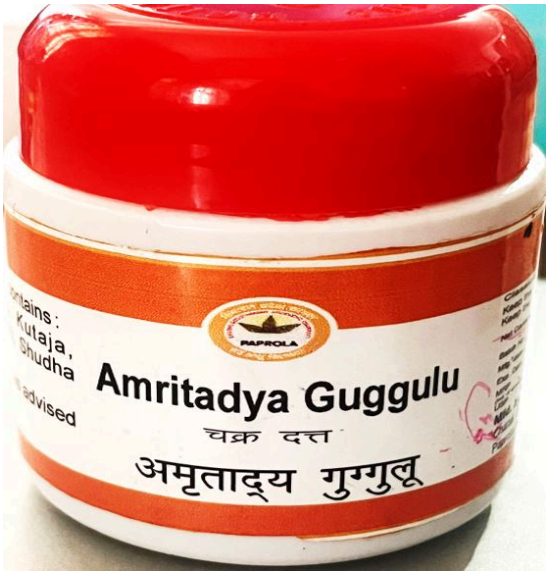

Figure 1: Amrityadya Guggul

Figure 2: Haritaki Churna

Effect of Therapy on Subjective Criteria Signs and symptoms (Table no. 4)

Chala-Sphik-Udara-Stana: There was statistically significant decrease *(p value =0.041)* in *Chala-Sphika-Udara-Stana* by 28.5% in group I while in group II 10.0% decrease was observed after the therapy which was statistically insignificant *(p value 0.334).*

Kshudra Shawasa: There was statistically highly significant decrease *(p value < 0.001)* in *Kshudra Shawasa* by 71.3% in group I while in group II 17.9% decrease was observed after the therapy which was statistically insignificant *(p value = 0.080).*

Sandhi Shoola: In Group I, *Sandhi Shoola* was decreased by 25% and changes were statistically insignificant *(p value = 0.).* In group II only 20% decrease in *Sandhi Shoola* was observed after the therapy which was statistically insignificant *(p value = 0.433).*

Kshudha Atimatra: There was a statistically highly significant decrease (p *value<0.001)* in *Kshudha Ati Matra* by 81.8 % in group I. In group II there was only 29.9% decrease in *Kshudha Atimatra* which was statistically insignificant.

Pipasa Atiyoga:There was statistically highly significant decrease *(p value < 0.001)* in *Pipasa Atiyoga* by 83.3% in group I. In group II only 44.5 % decrease in *Pipasa Atiyoga* was observed after the therapy was insignificant statistically *(p value = 0.104).*

Nidraadhikya: There was statistically highly significant decrease *(p value < 0.001)* in *Nidradhikya* by 68.7% in group I. In group II 29.9% decrease in was observed after the therapy which was statistically insignificant *(p value = 0.271).*

Javoprodha: There was statistically highly significant decrease *(p value < 0.001)* in *Javoprodha* by 83.3% in group I. In group II 26.7% decrease was observed after the therapy which was statistically significant *(p value = 0.041).*

Swedabadha: In Group I, *Swedabadha* decreased by 59.9% and changes were statistically significant *(p value 0.009).* In group II only 29.9% decrease in *Swedababha* was observed after the therapy which was statistically insignificant *(p value = 0.334).*

Daurgandya: There was statistically significant decrease of 46.7% *(p value=0.004) in Daurgandhya* of group I. In group II only 18.1% decrease in *Daugandya was* observed after the therapy which was statistically insignificant *(p value = 0.164).*

Effect of therapy on Objective Criteria

Body weight (Kgs): The mean body weight of study subjects before therapy was 64.46kg,

Reduced to 63.580kg after intervention with a change of 1.36% with p-value =0.034 that shows a statistically significant result in Group-I. While in Group-II, the mean body weight before treatment was 61.66kg that reduced to 60.08kg after the therapy with 2.57% change that was statistically significant (p value =0.002).

BMI (Kg/m2): In Group-I study subjects, mean BMI before treatment was 25.227 Kg/m2 that reduced to 24.587 Kg/m2 with a change of 3.47%. The result was statistically significant with p-value=0.013. The mean BMI was 24.913 Kg/m2 before treatment that reduced to 24.367 Kg/m2 with change of 2.17% that implies statistically significant result as p-value=0.051 in Group-II.

Waist Circumference (cm): In Group-I the mean value of waist circumference before treatment was 90.600 cm that reduced to 86.800 cm after treatment with a change of 4.19%. The change was statistically significant with p-value < 0.001. While in Group-II, the mean value of 93.933 dropped to 93.00 with a change of 0.99%. The change was statistically insignificant with p value=0.260.

Hip Circumference (cm): The mean value of hip circumference in Group-1, before treatment was 97.600 cm that reduced to 95.533cm with a change of 2.11% that was statistically significant with p-value 0.002. While in Group-II, there was a 0.42% change from mean value of hip circumference with 95.607cm before treatment to 95.200 cm after treatment. The change was statistically insignificant with p-value=0.105.

Skin fold thickness biceps (mm): The mean value of Skin fold thickness biceps in Group-1, before treatment was 10.093mm that reduced to 9.487mm with a change of 6.07% that was statistically significant with p-value 0.023.

While in Group-II, there was 2.78% of change from mean value of Skin fold thickness biceps with 10.322mm before treatment to 10.035 mm after treatment. The change was statistically significant with p-value=0.042.

Skin fold thickness triceps (mm): The mean value of Skin fold thickness triceps in Group-1, before treatment was 11.563 mm that reduced to 10.883mm with a change of 5.88% that was statistically significant with p-value 0.005.

While in Group-II, there was 6.61% of change from mean value of Skin fold thickness triceps with 12.493 mm before treatment to 11.667mm after treatment. The change was statistically significant with p-value=0.002.

Skin fold thickness Supra-iliac (mm): The mean value of Skin fold thickness Supra-iliac in Group-1, before treatment was 13.969mm that reduced to 13.572mm with a change of 2.84% that was statistically significant with p-value 0.049. While in Group-II, there was 4.71 % of change from mean value of Skin fold thickness Supra-iliac with 14.420 mm before treatment to 13.740 mm after treatment. The change was statistically significant with p-value=0.003.

Waist-Hip ratio (cm): The mean value of waist-hip ratio in Group-1, before treatment was 0.97 cm, reduced to 0.91cm with a change of 5.36 % that was statistically significant with p-value 0.039. While in Group-II, there was a 0.10 % of change from mean value of waist-hip ratio with 0.985cm before treatment to 0.984 cm after treatment. The change was statistically insignificant with p-value=0.945.

Effect of therapy on Haematological Parameters (Table no. 8)

Hemoglobin: The hemoglobin level in group I increased by 1.15% and 0.40% in group II. But the results were statistically insignificant in group I and in group II (p value > 0.05)

Total Leucocyte Count: There was a decrease in TLC count by 3.81% in group I and 3.25% in group II respectively. But the changes were statistically insignificant (p value >0.05).

Differential Leucocyte Count: In Neutrophils, there was a decrease of 6.67% was observed in group I and in group II a decrease of 0.3% was observed. But the changes were insignificant (p value >0.05). In the case of Lymphocytes, there was a decrease by 6.2% in group I value and by 6.72% in group II value. But both the results were statistically insignificant (p value >0.05). But in group I mixed cell decreased by 3.79% and the changes were statistically significant (p value =0.019). In group II mixed cell value increased by 1.62 % and this change was statistically insignificant (p value >0.05).

Erythrocyte Sedimentation Rate: ESR value decreased by 25.41% and by 13.67% in Group I and Group II, respectively. The changes were statistically insignificant for group I with p values =0.137and statistically significant group II (p value<0.05).

Discussion

Major steps in the *Samprapti* of *Medo Rogas* are *Kapha Dosha* and *Meda Dhatu* increase due to the various *Aharatmaka, Viharatmaka* and *Manasika Nidana Sevana* and then *Sthana Samshraya* takes place in *Medovaha Srotas*. The increase in *Kapha* and *Medodhatu* causes vitalization of *Agni* at different levels in the body, which results in *Medodhatvagnimandya.* All these things together lead to *Medovaha Srotodusti. Srota Avarodha* of different *Srotasa* is caused by increased *Meda,* which affects the *Poshana* of different *Dhatus* and it again leads to *Medodhatu Vriddhi.* Due to the reduced *Poshana* (nutrition) of different *Dhatus*, *Ashtadosha* of *Medoroga* i.e., *Ayushohrasa, Kshudraswasa, Daurbalya* etc. are produced. *Srotosanga* causes the *Margavarodha* of *Vayu*. This *Avarodhita Vayu* reaches *Kostha* and causes *Jatharagni Sandhukshana,* which leads to *Atikshuda* and *Vishamagni.* Further, it contributes in the aggravation of the disease.

The probable mode of action *Amritadya Guggul* and *Haritaki Churna* in *Samprapti Vighatan* of *Medo Rogas* can be explained on the following basis-

At the level of *Dosha*: *Amritadya Guggulu* encounters *Vata & Kapha Dosha* by virtue of its *Katu-Rasa* dominance & *Ushna-Virya*. *Vatahara* action is also achieved by *Laghu* and *Snigdha* property.

At the level of *Dushya*: *Meda & Kleda* are the chief culprits in *Sthaulya, Katu-Rasa* performs *Medo-Kledopa-Shoshana* action *Sthairya Guna* of *Madhura Rasa* combats *Sharira Shaithilya, Ushna-Virya* also helps in *Kleda* and *Meda Vilayana* action.

At the level of *Agni* and *Ama*: *Katu-Rasa, Ushna-Virya* encounters *Dhatwagni Mandya* & potentiates the weakened *Dhatwagni* and help in *Ama Pachana* thereby alleviates *Ama Medo Dhatu*.

At the level of *Srotas:* Due to *Katu-Rasa*, all the involved channels are dilated i.e., "*Srotansi Vivrunoti* action.

Katu-Rasa and Ushna Virya check over *Medovaha and Mamsavaha Srotodushti*. In nutshell in *Amritadya Guggulu* maximum ingredient have *Katu Rasa, & Laghu, Ruksha* and *Ushna Virya, Katu Vipak, Vata-Kaphashamak Karshana, Lekhaniya, Medorogahara, Amapachana, Dhatu Shoshana* properties, which normalize the state of *Agni.* Thus, regulated *Jatharagni,* checked the excessive growth and accumulation of *Medodhatu* and thereby causing *Lakshana Upshamana of Sthaulya.* → An important point is during the clinical study very interesting findings were found. Most of the female patients who had irregular menstruation earlier were improved to regular menstruation. This may be due to the *Agni Mahabhuta Pradhana* (Su. Su 15/16) and *Ushna Virya, Dipana, Pachana* effects of *Amritadya Guggulu* as claimed by our classics.

Haritaki

Vayu Mahabhoota in *Kashaya Rasa* absorbs *Kleda, Kashaya Rasa* being most *Ruksha* may facilitate *Shoshana* (absorption) of liquefied or detoxified *Kapha* and *Medodhatu*. *Tikta* and *Katu Rasa* are *Srotas-Shodhak.* Due to *Vayu* and *Agni* predominance, *Katu Rasa* absorbs the fluid and stimulates *Agni*, digests *Aama* and *Vilayana* property of *Agni* helps to expel the obstructive material.

Because of *Sookshma Guna* it permeates even to minute channels, thus helping the drug to reach at cellular level and depleting the accumulated *Kleda*. *Haritaki* is an exceptional drug as it has got *Madhur Vipaka* and *Ushna Veerya* along with *Kashaya Rasa* which exerts *Anulomana Karma. Madhura Vipaka* is responsible for alleviation of *Vata* and *Pitta.*

Ushna Veerya stimulates *Agni* consequently corrects the *Dhatvagnimandya* and improves digestion and metabolism. It opposes any increment of unwanted *Kapha* by the *Vilayana* property and helps in *Srotas-Shodhan*. It alleviates *Vata* which is the predominant *Dosha* in an old age.

Thus, *Rasapanchaka* of *Haritaki* is responsible for *Agnideepan* (stimulating Agni), *Amapachan* (digesting toxic waste of metabolism) and *Srotaoshodhana* (clearing the micro channels). Hence, by means of these actions, it normalizes the functions of *Jatharagni*, results in restoration of *Agni* at the *Dhatu* level (*Dhatwagni-deepan*), removal of excessive *Kleda* as well as *Dhatu Poshana Karma.*

Experimental study reveals that *Haritaki* contains alkaloids phytosterols, saponins, tannins, ellagic acid, gallic acid, chebulinic acid, chebugalic acid and corilagin. High amount of saponins, phytosterols, chebulinic acid and corilagin present in *Haritaki* may be responsible for the hypolipidemic effect.

Anti-oxidant constituents of *Haritaki* also prevent the endogenous oxidation of cholesterol resulting in decrease in the concentration of low-density lipoprotein and again confirm the hypolipidemic activity. Tannins have been reported to increase fecal bile acid excretion, thereby leading to reduction in cholesterol levels. The hypolipidemic action of *Haritaki* has been explained through inhibition of cholesterol biosynthesis, increased fecal bile acid excretion and enhanced plasma cholesterol acyl transferase activity. It has also shown significant effect in reducing total cholesterol (hypocholesterolemic effect), TG, total protein, and elevation of HDL levels. *Haritaki* also helps in regulating blood sugar levels and increases insulin sensitivity in the body. Various animal studies showed that *Haritaki* and *Madhu* brought significant reductions in Serum Cholesterol, T.G., LDL, and VLDL along with reduction in body weight.**[1-8]**

Conclusion

In group-I treated with *Amritadya Guggul* and *Haritaki Churna* showed statistically highly significant improvement was found in subjective parameters like *Kshudra Shwasa. Kshudha Atimatra, Pipasa Atiyoga, Nidradhikya* and *Javoprodha* and statistically significant improvement was found in *Chala Sphika Udara Stana, Sandhi Shoola, Swedabadha* and *Daurgandhya.* While in group-II Tab. Atorvastatin showed statistically insignificant improvement was found in all the subjective parameters except *Sweabhadha.* Result of trial drug (*Amritadya Guggul* and *Haritaki Churna*) given in group I showed. Statistically highly significant reduction in levels of Serum Cholesterol, Serum Triglycerides and LDL, VLDL. Statistically insignificant results are seen in HDL. Result of standard control (Tab. Atorvastatin) given in group II showed. Statistically highly significant improvement in levels of Triglycerides, LDL and VLDL were observed. Statistically insignificant improvement seen in HDL level and serum cholesterol. Trial drug is as effective as standard control in improving S. Lipid Profile level.

Amritadya Guggul had an upper edge on correcting Body weight, and BMI as compared to Atorvastatin.

No untoward effect of therapy was observed during the entire trial period. Therefore, the present study confirms the efficacy and safety of *Amritadya Guggul* and *Haritaki Churna* as hypolipidemic agents. However, as the present study has been conducted on a small sample size and/or a short duration of time, further studies are required to be conducted in large number of patients of Dyslipidemia for a longer duration to confirm the therapeutic benefits *Amritadi Guggul*.

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