

## CLINICAL EVALUATION OF VYOSHADI GUGGULU AND HARITAKI CHURNA IN THE MANAGEMENT OF DYSLIPIDEMIA

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<https://doi.org/10.46607/iamj0509042021>

(Published Online: April 2021)

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Article Received: 31/03/2021 - Peer Reviewed: 03/04/2021 - Accepted for Publication: 05/04/2021



### ABSTRACT

Modern 20<sup>th</sup> century is the era of many lifestyle disorders and diseases due to them owing to stress, unhealthy lifestyles, lack of exercise, pollution etc. One such prominent disorder Dyslipidemia is investigated in this study. Owing to the detrimental effects like liver damage, nausea, bowel upset etc. of modern medicine, Ayurveda which is a booming area in the field of medical science is chosen for this work. The present study is a part of Ayurvedic Clinical Trials (ACT) project as a multicentric study on the norms of CCRAS to standardize the trial drugs. The effect of *Vyoshadi Guggulu* and *Haritaki Churna* on body lipids and other subjective-objective parameters is evaluated in this study. The present work has been designed as before and after study without a control group.

**Keywords:** *Medoroga, Sthaulya, Dyslipidemia, Vyoshadi Guggulu, Haritaki Choorna, SF-36*

### INTRODUCTION

The fast-paced human life in today's world with unhealthy lifestyle is prone to many different lifestyle disorders like Coronary artery diseases, Diabetes Mellitus, Atherosclerosis, Cerebrovascular Accident etc.<sup>1</sup> Studies have shown that people from South Asian

Lineage have higher risk of cardiovascular diseases. The common risk indicators are Dyslipidemia and Hypertension<sup>2</sup> Dyslipidemia is a condition caused due to abnormal amounts of lipids [i.e. cholesterol, triglycerides or both are raised in the plasma] in the

human body. This often results in symptoms such as pressure in chest, leg pain, indigestion, heart palpitations, queasiness, etc. Primary dyslipidemia is caused due to genetic factors and is often inherited, and Secondary dyslipidemia is an effect of lifestyle disorders and a byproduct of hypothyroidism, obesity, alcoholism etc<sup>3</sup>. Such lifestyle disorders which impact the wellbeing of a person are summarized in the context of *Janapadodwamsaneeya Adhyaya* in classics, where in disastrous impact of overeating, lack of exercise is illustrated.<sup>4</sup> Natural treatments for the said condition include incorporating a healthier living with regular exercise, avoiding junk fats, getting proper sleep, consumption of fibers and water on regular basis, eluding smoking and alcoholism etc. One of the common forms of Dyslipidemia is Hyperlipidemia wherein there is a high level of fat or cholesterol in the body, leading to increased chances of stroke. The prescribed medicines such as statins suffer from side effects such as muscle pains and when taken in huge amounts can even cause muscle breakdowns. The closest Ayurveda dialect to this disease is *Atisthauilya* or *Medoroga and Prameha*. Charaka has described the definition, etiopathogenesis, principal symptoms, *Ashtadosha* and complications of *Sthauilya*<sup>7</sup> due to its ignorance in detail. Vagbhata has first time mentioned types of *Sthauilya*<sup>5</sup> as *Atisthauilya, Madhya Sthauilya and Heena Sthauilya* along with their management. *Adhamalla* differentiated<sup>6</sup> the 2 types as *Medoroga*- the Adiposity including its clinical features of *Sthauilya* and *Medodosha*- as the Lipid disorders where *meda* acts as an etiological factor in the genesis of other diseases. *Sushrutha* mentioned the management of *Sthauilya*.<sup>8</sup>

#### d. Intervention

**Table 1:** Showing the details of Intervention

Drug	<i>Vyoshadi Guggulu</i>	<i>Haritaki Churna</i>
Dose	1 gm (2 Tablets of 500mg each) thrice daily	3 gm twice daily
Dosage form	Tablet of 500 mg	Powder
Route of Administration	Oral	Oral
Time of Administration	Thrice a day after food	Twice a day after food
<i>Anupana</i>	Lukewarm Water	Lukewarm Water

*Vyoshadi Guggulu*<sup>9</sup> is explained by *Vagbhata* as a *Shamanaushadhi* for the treatment of *Medoroga*. *Vyoshadi Guggulu and Haritaki Churna*<sup>10</sup> are two drugs chosen in the study to counter the disease for their easily and cost effectively available ingredients.

#### Objectives:

- To assess the clinical safety and efficacy of *Vyoshadi Guggulu and Haritaki Churna* in patients of *Medoroga*.
- To assess the change in the Quality of Life (SF-36 Health Survey) Score.

#### Materials and Methods

##### a. Source of data:

- Minimum 30 patients diagnosed with *Medoroga/ Dyslipidemia* from OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka.

##### b. Method of Collection of Data:

- A special Proforma with details about familial history, signs and symptoms was prepared and the patients were subjected to physical examinations and regular observations. (Protocol projected by CCRAS)<sup>11</sup>

##### c. Study Type - Interventional

- *Design* - Pre-test and Post-test design
- *Purpose* - Treatment
- *Masking* - Open label
- *Control* - Not controlled
- *Timing* - Prospective
- *End Point* - Efficiency and Safety
- *No. of Groups* - One
- *Duration of Study* - 4 Weeks

### e. Drug Review<sup>12</sup>

**Table 2:** Showing the ingredients of trial drugs

<b>Shunti</b>	<i>Zingiber officinale</i> Rosc. Zingiberaceae	Anulomana, Dipana, Hridya, Pachana, Vatakaphahara, Amadoshahara
<b>Maricha</b>	<i>Piper nigrum</i> Linn. Piperaceae	Sleshmahara, Dipana, Medohara, Pittakara, Ruchya, Kaphavatajit, Vatahara, Chedana, Jantunasana, Hridroga, Vataroga
<b>Pippali</b>	<i>Piper longum</i> Linn Piperaceae	Dipana, Hridya, Kaphahar, Ruchya, Vrishya Rechana Tridoshahara, Vatahara, Rasayana,
<b>Chitraka</b>	<i>Plumbago zeylanica</i> Linn Plumbaginaceae.	Sothahara, Dipana, Grahi, Pachana, Kaphavatahara, Arsohara, Sulahar
<b>Musta</b>	<i>Cyperus rotundus</i> Linn. Cyperaceae	Sothahara, Dipana, Grahi, Krimighna, Pachana, Vishaghna, Pittakaphahara, Sthaulyahara, Trishnanigrahana, Twakdosahara, Jwaraghna
<b>Haritaki</b>	<i>Terminalia chebula</i> Retz. Combretaceae	Chakshya, Dipana, Hridya, Medhya, Sarvadoshaprasamana, Rasayana, Anulomana
<b>Vibhataka</b>	<i>Terminalia belerica</i> Roxb. Combretaceae	Chakshushya, Kesya, Kaphapittajit, Bhedhaka, Kriminasana, Kasahara
<b>Amalaki</b>	<i>Emblica officinalis</i> Gaertn. Euphorbiaceae	Tridoshajit, Vrishya, Rasayana, Chakshushya
<b>Vidanga</b>	<i>Embelia ribes</i> Burm. Myrsinaceae	Anulomana, Dipana, Kriminasana, Vatakaphapaha
<b>Guggulu</b>	<i>Commiphora mukul</i> Engl. Burseraceae	Balya, Rasayana, Varnya, Vatabalasajit, Bhagnasandhanakrit, Medohara

### f. Inclusion Criteria:

- Patients presenting with *Pratyatma lakshana of Medoroga*
- Patients of either sex aged 18 –70 years.
- Patients having
  - LDLc 100mg/dL - 160mg/dL and / or
  - Total cholesterol 200mg/dL - 250mg/dL and / or
  - Triglycerides –150mg/dL - 250 mg/dL

### g. Exclusion Criteria

- Age below 25 years and above 60 years
- Patients - received any cholesterol lowering medication within the last 8 weeks.
- Patients having
- Type III and Type IV hypercholesterolemia
- Poorly controlled Hypertension (> 160 / 100 mm Hg)
- With evidence of malignancy
- Uncontrolled Diabetes Mellitus
- Patients under medication with Corticosteroids, Antidepressants, Anticholinergic, Immunosuppressants.

- Patients suffering from major systemic illness Rheumatoid arthritis, Tuberculosis, Psycho-Neuro-Endocrine disorders, Atrial Fibrillation, Acute Coronary Syndrome, Myocardial Infarction, Stroke, Severe Arrhythmia, Renal disorders, serious hepatic disorder, and severe pulmonary dysfunction.
- Alcoholics and/or drug abusers.
- H/o hypersensitivity to any of the trial drugs or their ingredients.

### h. Assessment Criteria

- *Subjective Parameters*
- *Lakshana of Medoroga* assessed after scoring.
- *Objective Parameters*
- Lipid profile values
- Liver function tests
- Renal function tests
- SF-36-Health Survey Score

### i. Investigations

- *Hematology:* Haemoglobin, T.L.C, D.L.C, E.S.R., FBS & HbA1c

- *Biochemistry*: Blood Urea, Serum Uric Acid, Serum Creatinine, S.G.O.T. & S.G.P.T., Total protein, S. Albumin, S. Globulin, A/G ratio, Serum Bilirubin: Conjugated bilirubin, Unconjugated bilirubin
- Serum Alkaline Phosphatase
- Serum Lipid Profile - Total Cholesterol, Serum Triglycerides, Low Density Lipoprotein (LDLc), High Density lipoprotein (HDLc), Very Low-Density Lipoprotein (VLDL), Total Cholesterol/HDLc ratio
- Electrocardiography (ECG)

## Observations & Results

**Table 3:** Showing the demographic profile

Observations	Maximum	No. of Patients	Percentage
Age	41-50	15	50
Sex	Male	19	63
Marital status	Married	29	96.7
Religion	Hindu	23	77
Domicile	Rural	25	83
Education	Post matric	23	77
Height (cms)	146-155	20	67
Body weight (kg)	61-70	9	30
Built	Stout	12	40
Activities	Sedentary	20	57
Dietary habits	Mixed	26	87
Prakriti	Pittakapha	22	73

### j. Demographic Profile

The incidence of Dyslipidaemia in 41-50.yrs age groups shows a positive relation between Dyslipidemia and age. Majority of patients were males. The high

prevalence among the rural population and of *Pittakaphaprakrithi* tends to predominate in Dyslipidaemics.

**Table 4:** Showing the effect on Subjective & objective parameters

Parameter	BT	AT	D	S.D	't'	p
Total cholesterol	218.4	151.16	66.3	45.53	8.013	<0.0001
Triglyceride level	203.5	190.33	13.43	110.28	0.6655	0.511
HDL level	35.35	35.33	0.033	0.7071	0.04446	0.9648
LDL level	125.56	123.53	1.63	33.807	0.246	0.7932
Atherogenic index	4.5	4.05	0.45	0.0707	4.771	<0.0001
Body mass index	23.81	23.53	0.27	0.4949	3.158	3.518
Body weight	74.16	71.3	2.63	0	1.329	0.1943
Breathlessness	35	33.3	1.66	11.24	1.425	<0.0001
Paresthesia	4.1	0.83	3.33	8.64	2.11	<0.0001
Confusion	5.83	1.66	4.1	9.4762	2.4	<0.026
Fatigue	1.66	4.64	3	10.064	1.36	0.164

**k. Effect of Therapy**

**i. Effect on Lipid profile and Atherogenic Index:**

Present study shows a non-significant decrease of Serum triglycerides with a ‘t’ value of 0.6655. HDL was found to have significant increase with ‘t’ value showing 0.04446. However, the significant decrease in serum LDL after completing 28 days of treatment. Serum cholesterol levels were decreased significantly with ‘t’ value 0.246. There was a significant decrease in Atherosclerotic Index with ‘t’ value 4.771 on account of the duration of treatment these values are beneficial.

**ii. Effect on Subjective Parameters**

Subjective criteria of the clinical manifestation of Dyslipidemias and its correlation with Medoroga

showed significant reduction of Breathlessness with ‘t’ value 1.425. Parasthesia had significant reduction with ‘t’ value 2.11. There was a significant reduction in Confusion with ‘t’ value 2.4 and there was a non-significant reduction in Fatigue with ‘t’ value 1.36.

**iii. SF – 36 Scoring**

Physical component summary showed significant decrease in the Physical Functioning with ‘t’ value 3.488, Limitation due to physical health with ‘t’ value 12.034, Social functioning with ‘t’ value 4.879 pain with ‘t’ value 2.766 and fatigue with ‘t’ value 8.102 parameters. The limitation due to emotional problems showing ‘t’ value 8.32 and emotional wellbeing with ‘t’ value 2.133 indicates an improvement in the parameters of quality of life.

**Table 5:** Showing the effect on SF-36 Health Survey Score

Parameter	BT	AT	D	S.D	‘t’	p
Physical Functioning	89.56	96.33	3.5355	6.67	3.488	0.0016
Physical Health	67	89	22	0	12.034	<0.0001
Emotional Problems	86.66	95.86	9.1	3.5355	8.32	<0.0001
Energy/Fatigue	91.66	74.66	17	24.749	8.102	<0.0001
Social Functioning	81.66	92.5	9.82	0	4.879	<0.0001
Pain	92	88	4	0	2.776	<0.0001
General Health	69.66	89.5	19.83	0	8.337	<0.0001
Emotional Well Being	78.06	76.9	1.16	0	2.133	0.415

**l. Probable mode of action of Vyoshadi Guggulu and Haritaki Churna:**

- The trial drugs are virtue of *deepana, pachana and rochana guna* which modulates metabolism at the *Dhatu* level by *agni deepana and ama pachana*. The drugs possessing *deepana* properties enhance the bioavailability of the combination drugs such as that of *Trikatu. Trimada and Triphala* augment the action of natural cleansing which further brings about the scavenging of free radicals.
- *Medoroga*, is due *Medodhatvagnimandya* that results in *Avarana of Vata in Koshta and atikledana by Kaphadosha*. *Vyoshadi Guggulu* acts in *samprapti vighatana* by decreasing *medas* by its *lekhana, shoshana and kaphanashaka* properties, as the drugs are of *Agni and Vayu Mahabhoota* dominance.

- *Haritaki churna* contains sennosides to treat constipation and tannins treat diarrhea, when used in a high dose [6g] for the former and low dose [2 g] for the latter. Its *Prabhava* is that while it is a laxative, it is also nourishing.

**CONCLUSION**

Demographic data showed that the males with *Pittakapha Prakriti* aging between 30 -50 were more prone to have Dyslipideamia. The combination of drugs tried in this study, *Vyoshadi Guggulu and Haritaki Churna*, was effective in lowering total cholesterol level and triglycerides with maximum therapeutic efficacy. The drug helps in reducing LDL and improving HDL after treatment. Other symptomatic effects like breathlessness, confusion, parasthesia and fatigue showed significant reduction.

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**Source of Support: Nil**

**Conflict of Interest: None Declared**

How to cite this URL: Veeraj Praveen & Jonah. S: Clinical Evaluation Of Vyoshadi Guggulu And Haritaki Churnain The Management Of Dyslipidemia. *International Ayurvedic Medical Journal* {online} 2021 {cited April, 2021} Available from:

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