



Research Article

**EFFICACY OF GUDUCHYADI YOGA IN THE MANAGEMENT OF MEDOROGA WITH SPECIAL REREFERENCE TO DYSLIPIDEMIA- A RONDONIZED CLINICAL TRIAL**

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ABSTRACT

*Medoroga*, a condition which arises due to *Medo dhatu vriddhi* which may lead to *Bahutwa* and *Abaddhatwa* of *Poshaka medo dhatu*. It can be correlated to disease dyslipidemia based on pathophysiology. It is the need of the hour to contribute safer, effective and economical medicines to manage the condition. Main aim of the study was to evaluate the efficacy of *Guduchyadi yoga* and *Navaka Guggulu* in the management of *Medoroga* with special reference to dyslipidemia. **Methods:** The present study implemented an open-labelled, active controlled pre and post-test clinical study with 30 subjects (who fulfilled the diagnostic and inclusion criteria). A convenience sampling method was used for the selection. Subjects were randomly assigned into two groups, Group A (trial) and Group B (control) comprising of 15 subjects each. Subjects of Group A received *Guduchyadi Yoga* (50ml *Kashaya* with 1.5g of *Guggulu*) and Group B received *Navaka Guggulu* (2 tablets with warm water). Both interventions were given twice daily before food for duration of 30 days. A twelve-hour fasting sample of serum lipid profile and BMI were used to measure the efficacy before and after the treatment. Statistical analysis of parameters was assessed using Wilcoxon signed rank test (W), Friedman's test, Mann Whitney U test (U), by paired t-test, repeated measures ANOVA test, unpaired t-test. **Results:** The trial drug showed statistically significant result in improving serum lipid profile and reducing BMI ( $P < 0.05$ ). **Conclusion:** The polyherbal formulation (*Guduchyadi yoga*) is effective in the management of *Medoroga* (dyslipidemia).

INTRODUCTION

Dyslipidemia is a disorder of lipoprotein metabolism, which may include lipoprotein overproduction or deficiency, or both. This leads to elevated total cholesterol (TC), low density lipoprotein cholesterol (LDL-C) and triglyceride (TG) concentrations, and a decrease in the high-density lipoprotein cholesterol (HDL-C) concentration in the blood [1].


5C8Z is the ICD-11 code used for unspecified disorder of lipoprotein metabolism.

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 development of atherosclerosis and associated cardiovascular events [2]. In India approximately 25-30% of urban and 15-20% rural subjects are suffering from dyslipidemia.[3]

The commonly used drugs in the pharmacological intervention in dyslipidemia include statins, cholesterol absorption inhibitors, bile acid sequestrants, fibrates, nicotinic acid, etc but the use of these drugs are associated with considerable adverse effects like-myalgias, arthralgias, dyspepsia, hepatic toxicity, renal toxicity etc.[4]

In Ayurveda, dyslipidemia, based on the pathophysiology, can be understood in terms of *Medoroga*, a condition which arises due to *Medo dhatu vriddhi*[5,6] which may lead to *Bahutwa* and *Abaddhatwa* of *Poshaka medo dhatu* [7].

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Considering the prevalence and adverse effects on long term use of contemporary interventions, it is the need of the hour to contribute safer, effective and economical medicines to manage the condition and serve the society. Thus, *Guduchyadi yoga*<sup>[8]</sup>, a *Medohara yoga*, mentioned by *Acharya Vangasena* consisting of *Guduchi*, *Triphala* and *Guggulu*, was taken for the present study.

*Navaka guggulu*<sup>[9]</sup> being a proven drug for *Medoroga* was taken as control drug, to compare and establish its efficacy levels.<sup>[10]</sup>

## MATERIALS AND METHODS

### Trial design

This study was an open- labelled, active controlled pre and post-test clinical study with 30 subjects. The ethical clearance was obtained from the Institutional Ethics Committee with registration number- SSIEC/229/2022. The study was registered under the Clinical Trial Registry India, prospectively with registration number-CTRI/2023/05/052460.

### Participants

#### Diagnostic Criteria

Subjects were diagnosed based on serum lipid profile <sup>[11]</sup> with increased levels of any of the serum lipids, as mentioned in table 1.

**Table 1: Diagnostic Criteria**

Lipid	Range
Total cholesterol	>200mg/dL
LDL-C	>129mg/dL
VLDL-C	>30mg/dL
Triglycerides	≥150mg/dL
HDL-C	≤40mg/dL

#### Inclusion Criteria

Subjects of either gender between the age group of 21-60 years and those who full filled the diagnostic criteria. Subjects who were inclined to

participate with written informed consent, which was conveyed in the language which the subject could understand were included. Both obese and non-obese subjects were included.

#### Exclusion Criteria

Pregnant and lactating women, subjects with any uncontrolled systemic illness including diabetes mellitus, hypertension, with any condition interfering with the course of disease and treatment. Subjects who are on any medication for dyslipidemia. Subjects with any of the following serum lipid levels as mentioned in table 2 were excluded.

**Table 2: Exclusion Criteria**

Lipid	Range
Total cholesterol	>400mg/dL
LDL-C	>189mg/dL
VLDL-C	>100mg/dL
Triglycerides	>400mg/dL
HDL-C	>40mg/dL

The study individuals diagnosed with dyslipidemia were recruited from OPD, IPD, and special camps conducted at our institution.

#### Intervention

The subjects in trial group (Group A) were administered with *Guduchyadi Yoga* and subjects in control group (Group B) were administered *Navaka Guggulu*. Ingredients of *Guduchyadi yoga* was procured from GMP certified pharmacies, (Fig. 1, 2, 3) was mixed in institutional pharmacy and stored in air tight containers (Fig. 4). *Navaka guggulu* was procured from GMP certified pharmacy (Fig. 5). Ingredients of the trial drug are given in Table 3. Method of preparation of *Guduchyadi Yoga*- 24gm of *Kwatha churna* was added with 400ml of water and boiled in an open vessel until it is reduced to 50ml. To this *Kashaya* 1.5gm of *Guggulu* is added, mixed well and administered<sup>[12]</sup>.

**Table 3: Ingredients of Trial Drug-Guduchyadi yoga**

Sanskrit name	Botanical name	Family	Part used	Quantity used
<i>Guduchi</i>	<i>Tinospora cordifolia</i> (Wild.) Miers. ex Hk. f. & Th.	Menispermaceae	Root, Stem, Leaf	1 part
<i>Amalaki</i>	<i>Emblica officinalis</i> Gaertn.	Euphorbiaceae	Fruits	1 part
<i>Haritaki</i>	<i>Terminalia chebula</i> Retz.	Combretaceae	Fruits	1 part
<i>Vibhitaki</i>	<i>Terminalia bellirica</i> (Gaertn.) Roxb.	Combretaceae	Fruits	1 part
** <i>Guggulu</i> ( <i>Shodhita purana</i> )	<i>Commiphora mukul</i> (Hook. Ex Stocks)	Burseraceae	Gum resin	1.5g for every 50ml of <i>Kashaya</i>

\*\**Guggulu* is added as a *Prakshepaka Dravya* to *Kashaya* in 1 *Shana Matra* <sup>[12]</sup>

## Outcomes

### Assessment criteria

The assessment was made on fasting sample of serum lipid profile with grading as given in Table 4 and on Body Mass Index (BMI). The outcomes were accessed on baseline, 30<sup>th</sup> day (after treatment) and 45<sup>th</sup> day (drug free follow up).

**Table 4: Assessment criteria of lipid profile**

Lipid	Grade- I	Grade- II
Total cholesterol	201-240mg/dL	241-400mg/dL
LDL-C	130-159mg/dL	160-189mg/dL
HDL-C	20-40mg/dL	1-20mg/dL
Triglycerides	150-199mg/dL	200-400mg/dL
VLDL-C	31-65mg/dL	65-100mg/dL

### Sample size

Sample size was determined based on the appropriate sample size estimate formula of Superiority clinical interventional studies  $(n) = 2 \times \{Z(1-\beta) + Z(1-\alpha)/\delta - \delta_0\}^2 \times p \times (1-p)$ . Here  $(1-\beta)$ - 0.84,  $(1-\alpha)$ - 1.645,  $\delta$ -0.21,  $\delta_0$ - 0.10,  $p$ = 30% (0.30) Considering 10% attrition rate,  $n = 212.6 + 21.26 = 233$ . It was estimated to be 84 samples in each group total of 233. As the duration for the present study was of short period, sample size was limited to 15 subjects in each group, total of 30.

### Randomization-Sequence generation

Eligible subjects were assigned to either group in a 1:1 ratio using the lottery method of simple randomization. A list of random numbers was generated by picking up the chits mixed in a box. The chits were same in size, shape and colour to minimize bias.

### Randomization-Allocation, Concealment mechanism and Implementation

The sequentially numbered, opaque, sealed envelope (SNOSE) technique was used for allocation concealment. Principal investigator generated the allocation sequence, enrolled participants, and assigned participants to interventions.

### Statistical Methods

Statistical analysis was done using Statistical Package for Social Sciences (SPSS) software for Windows, Version 26.0. Armonk, New York: IBM Corp and SIGMASTAT software for Windows, version 3.1. San Jose, California: Systat.

The data were analyzed initially to ascertain whether they pass normality test or not with Shapiro-Wilk test – if normality test is passed then analysis for parametric data was employed if not then non-parametric test were employed to determine the level of significance.

For the assessment of parametric values (TC, TG, LDL-C, HDL-C, VLDL-C and BMI) Paired t-test was applied to assess before and after treatment results, whereas for the outcome of 3 or more assessments,

repeated measures ANOVA test was used to assess results within the group. Unpaired t-test was applied to assess results between the groups.

Mann Whitney U test (U) was applied to assess results between the groups. The corresponding p value was noted and obtained results were interpreted as non-significant for p value >0.05, significant for p value ≤0.05, significant for p value ≤0.01. To ascertain whether the statistical analysis correlates with clinical improvement, Effect size determination was carried out for all the parameters respectively. Obtained results were interpreted as very large effect band (>0.8), large effect band (>0.5-≤0.8), medium effect band (>0.3-≤0.5), small effect band (≤0.2), no effect band (0).

## RESULTS AND DISCUSSION

In this study, 38 participants were screened, out of which 30 were enrolled for the trial. All 30 participants completed the study. No subjects dropped out during the trial and follow-up period. The study flow diagram is given in Fig. 5.

### Baseline data, Numbers analyzed

#### Observations

It was observed that among 30 subjects who completed the study, 10 (33.33%) were in the age group of 41-51 years and 51-60 years each and 16 (53.33%) of them were males. 15 (50%) subjects were graduates with executive line of work. 21 (70%) subjects had a moderate physical activity followed by 9 (30%) subjects had sedentary lifestyle. *Vata-Pitta Prakruti* was mainly observed in 19 (63.33%) subjects and *Pitta-Kapha Prakruti* in 5 (16.66%) and 6 (20%) subjects had *Vata-Kapha Prakruti*. 23 (76.66%) subjects reported having family history of dyslipidemia. 13 (43.33%) subjects were overweight. 18 (60%) subjects had *Nidana* of *Atisnigdha*hara *sevana*, 17 (56.70%) subjects had *Atimadhura*hara *sevana* and 13 (43.33%) had *Atimamsaha*hara *sevana* as *Nidana*.

**Outcomes and estimation, Ancillary analyses**

**Effect of Intervention- Results on Serum Lipid Profile (Primary Outcome)**

Effect of interventions on fasting serum lipid profile in 15 subjects of both groups is given in Table 5. On comparing the statistical results within group after treatment period, both the groups showed statistically highly significant results on 30<sup>th</sup> day and statistically

non-significant results on 45<sup>th</sup> day in reducing TC, LDL-C, VLDL-C and TG along with improvement in HDL-C. On comparing the statistical results between the groups after treatment period, statistically significant results in reduction of TC, and statistically non-significant result in reduction of LDL-C, VLDL-C, TG and in improvement of HDL-C on 30<sup>th</sup> day and 45<sup>th</sup> day was seen. (Table 6 and 7).

**Table 5: Effect of intervention on Fasting Serum Lipid Profile**

Parameter	Grade *Range (mg/dL)	Group A (No. of Subjects)			Group B (No. of Subjects)		
		0 <sup>th</sup> Day	30 <sup>th</sup> Day	45 <sup>th</sup> Day	0 <sup>th</sup> Day	30 <sup>th</sup> Day	45 <sup>th</sup> Day
TC	201- 240 (Grade-I)	3	8	9	1	4	4
	241- 300 (Grade-II)	10	6	6	11	10	10
	301- 350 (Grade-II)	1	1	0	3	1	1
	351- 400 (Grade-II)	1	0	0	0	0	0
LDL-C	130- 159 (Grade-I)	4	10	10	3	11	11
	160- 189 (Grade-II)	11	5	5	12	4	4
VLDL-C	31- 65 (Grade-I)	5	12	13	1	10	10
	65-100 (Grade-II)	10	3	2	14	5	5
TG	151- 199 (Grade-I)	6	8	8	5	9	9
	200- 249 (Grade-II)	5	5	5	7	5	5
	250- 349 (Grade-II)	3	2	2	2	1	1
	350- 400 (Grade-II)	1	0	0	1	0	0
HDL-C	21- 40 (Grade-I)	2	9	9	10	12	12
	1- 20 (Grade-II)	13	6	6	5	3	3

\*Range based on Assessment criteria given in Table-4

**Table 6: Results of intervention on Serum Lipid Profile (Primary outcome)- within the groups**

Parameter	Group	Mean-baseline	S. D	Mean 30 <sup>th</sup> day	S. D	p-value	Effect size 30 <sup>th</sup> day	Mean 45 <sup>th</sup> day	S. D	p-value	Effect size 45 <sup>th</sup> day
TC	A	219.178	22.171	165.521	18.983	<0.001	0.33	165.733	18.866	0.910	0.2
	B	224.752	23.045	188.438	29.270	<0.001	0.33	187.567	28.789	0.375	0.2
LDL-C	A	146.153	28.699	95.620	30.787	<0.001	0.35	95.800	30.709	0.938	0.17
	B	137.962	30.665	105.333	30.962	<0.001	0.57	105.800	30.727	0.250	0.17
VLDL-C	A	43.507	20.261	34.920	18.454	<0.001	0.55	34.840	17.939	0.297	0.22
	B	41.707	16.380	33.180	12.538	<0.001	0.33	33.087	12.592	0.875	0.13
TG	A	203.804	48.986	147.527	46.415	<0.001	0.33	147.167	46.492	0.125	0.11
	B	188.489	85.004	143.467	49.298	<0.001	0.33	144.000	49.567	0.219	0.15
HDL-C	A	43.840	12.994	37.027	8.777	0.004	0.44	38.000	8.089	0.012	0.25
	B	47.806	13.894	37.395	10.772	<0.001	0.25	37.920	10.575	0.063	0.13



**Table 7: Results of intervention on Serum Lipid Profile (Primary outcome)- between the groups**

Parameter	Assessment day	p-value	Effect size
TC	30 <sup>th</sup> day	0.003	0.46
	45 <sup>th</sup> day	0.020	0.44
LDL-C	30 <sup>th</sup> day	0.396	0.22
	45 <sup>th</sup> day	0.380	0.22
VLDL-C	30 <sup>th</sup> day	0.917	0.44
	45 <sup>th</sup> day	0.967	0.48
TG	30 <sup>th</sup> day	0.818	0.48
	45 <sup>th</sup> day	0.858	0.06
HDL-C	30 <sup>th</sup> day	0.919	0.05
	45 <sup>th</sup> day	0.982	0.05

**Effect of Intervention- Results on BMI (Secondary Outcome)**

Effect of interventions on fasting serum lipid profile in 15 subjects of both groups is given in Table 8. On comparing the statistical results within group after treatment period, both the groups showed statistically highly significant results on 30<sup>th</sup> day and statistically non-significant results on 45<sup>th</sup> day in reducing BMI. On comparing the statistical results between the groups after treatment period, statistically non-significant result in reduction of BMI on 30<sup>th</sup> day and 45<sup>th</sup> day was seen. (Table 9 and 10).

**Table 8: Effect of intervention on BMI**

Parameter	Range (kg/m <sup>2</sup> )	Group A (No. of Subjects)			Group B (No. of Subjects)		
		0 <sup>th</sup> Day	30 <sup>th</sup> Day	45 <sup>th</sup> Day	0 <sup>th</sup> Day	30 <sup>th</sup> Day	45 <sup>th</sup> Day
BMI	18.0- 24.9	3	4	4	3	4	4
	25.0- 29.9	10	10	10	7	5	5
	30.0- 40.0	2	1	1	5	3	3

**Table 9: Results of intervention on BMI (Secondary outcome)- within the groups**

Parameter	Group	Mean-baseline	S. D	Mean 30 <sup>th</sup> day	S. D	p-value	Effect size 30 <sup>th</sup> day	Mean 45 <sup>th</sup> day	S. D	p-value	Effect size 45 <sup>th</sup> day
BMI	A	28.340	4.952	27.820	4.707	<0.001	0.47	27.733	5.024	0.575	0.01
	B	26.860	2.682	26.353	2.760	0.002	0.44	26.320	2.649	0.648	0.01

**Table 10: Results of intervention- BMI (Secondary outcome)-between the groups**

Parameter	Assessment day	p-value	Effect size
BMI	30 <sup>th</sup> day	0.307	0.33
	45 <sup>th</sup> day	0.343	0.33



**Figure 1: Triphala**



Figure 2: *Guduchi*



Figure 3: *Shodita Purana Guggulu* with measuring spoon of quantity 1.5g



Figure 4: A-Trial Drug; B-Control Drug

## DISCUSSION

Previous studies performed over larger population indicate that the risk of developing dyslipidemia increases with age and often affects adults. Similar observations were made in the present study [13].

In the present study, it was noted that there was 70% incidence in males. This indicates the prevalence of dyslipidemia more in males than in females[13]. Previous studies conducted on larger population on the prevalence of dyslipidemia in India showed more prevalence in males than in females. Estrogen levels in young women have a protective effect against high cholesterol which might be the reason for less incidence of dyslipidemia in women. Sedentary lifestyle, calorie rich diet, and lack of

equilibrium between energy intake and energy expenditure can lead to impaired metabolism and result into metabolic disorders [14]. In the present study, most of subjects reported history of dyslipidemia in the family. Like previous works, risk of dyslipidemia being high in people with a family history was supported in the present study too [14].

Though *Medoroga* is *Kapha Pradhana Vyadhi*, the incidence on *Prakruti* cannot be substantiated in the present study. Majority of the subjects had *Atisnigdhabhara sevana* and *Atimadhura ahara sevana* as *Nidana* along with *Avyayama*, these are considered as major *Aharaja nidana* according to classics. Excessive consumption of these food items causes vitiation of *Kapha dosha* and these possesses similar

properties to that of *Medo dhatu*, thus causing *Medodhatu vrudhi* leading to *Medo roga*. *Avyama* is considered as a *Viharatmaka nidana* for *Medoroga*.

Both the groups showed statistically highly significant results in reducing LDL-C, VLDL-C, TG, BMI and improvement of HDL-C. From this, it can be inferred that both the interventions were equally effective in treating these parameters. Trial group had higher efficacy in reduction of TC than the control group. The effect size calculation shows that trial group was clinically efficacious than control group, with medium effect band.

*Guduchyadi yoga* is a polyherbal preparation with ingredients namely, *Guduchi*, *Triphala* and *Guggulu*, mentioned in *Vangasena Samhita* in the context of *Medoroga Chikitsa* having *Kashaya*, *Tikta Rasa*; *Laghu Ruksha Guna*; *Tridosahara* property with *Deepana Pachana Karma*.

*Guduchi* has *Tikta kashaya rasa*, *Laghu ruksha guna*, *Ushna veerya* and aids in *Deepana* and *Pachana*. It has hypolipidemic, hepatoprotective and cardio-protective pharmacological actions<sup>[15]</sup>.

*Triphala* with *Laghu*, *Ruksha guna*, has *Deepana*, *Vatanulomana*, *Kaphagna karma*. It contains anti-hyperlipidemic and hepatoprotective constituents<sup>[16,17,18]</sup>.

*Guggulu* has *Katu*, *Tikta rasa*, *Laghu ruksha teekshna guna*, *Ushna veerya*. It has *Medohara*, *Deepana*, *Lekhana*, *Raktaprasadaka karma* and is a proven hypolipidemic<sup>[19]</sup>.

The research design is randomized and controlled clinical study with 30-day intervention duration and 15-day follow up duration. A treatment protocol consisting of all the components of *Medoroga Chikitsa* can be taken as future study for better management of dyslipidemia. Further studies can be conducted by assessing advanced lipoprotein testing.

## CONCLUSION

The present study showed that both the interventions, namely, *Guduchyadi yoga* and *Navaka Guggulu* were equally effective in the management of *Medoroga* (dyslipidemia).

Compared to *Navaka guggulu*, *Guduchyadi yoga* has shown slightly better results in reduction of TC, LDL-C, VLDL-C, TG, BMI, and in improvement of HDL-C. However, the current sample size is insufficient to conclude which formulation is better. A similar study with a larger sample size is needed to draw further conclusions. No adverse drug reactions were reported in the study population, which concludes the safety of both formulations under the study duration. Further studies incorporating advanced lipoprotein testing and adopting treatment principles of *Medoroga* can be done.

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