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YOGARAJA GUGGULU IN THE MANAGEMENT OF MEDOROGA WITH SPECIAL REFERENCE TO DYSLIPIDEMIA: A RANDOMIZED OPEN-LABELLED CONTROLLED CLINICAL STUDY

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ABSTRACT

Background & Objectives: Dyslipidemia is a disorder of lipoprotein metabolism characterized by abnormalities in serum total cholesterol, low-density lipoprotein cholesterol (LDL-C), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C) and very-low-density lipoprotein (VLDL). In Ayurveda, the condition has been correlated with Medoroga, associated with Medo Dhatu Vriddhi and abnormality of Meda. The present study was undertaken to clinically evaluate the efficacy of Yogaraja Guggulu in the management of Medoroga with special reference to dyslipidemia and to compare its effect with Navaka Guggulu. **Methods:** A randomized, open-labelled, parallel-group, active-controlled clinical study was conducted in 30 subjects fulfilling the diagnostic criteria for dyslipidemia. Subjects were randomly allocated into Group A (n=15), was given Yogaraja Guggulu, and Group B (n=15), was given Navaka Guggulu. Both interventions were administered orally for 30 days, followed by a 15-day drug-free follow-up. Fasting serum lipid profile was assessed on Day 0, Day 30 and Day 45. Within-group analysis was performed using the

Wilcoxon signed-rank test and between-group analysis using the Mann-Whitney U test. Effect size was also assessed. **Results:** Group A showed highly significant reductions in total cholesterol, LDL, VLDL and triglycerides after 30 days of intervention, while improvement in HDL was non-significant. Group B showed highly significant reductions in total cholesterol, LDL and triglycerides and a significant reduction in VLDL; improvement in HDL was non-significant. Changes between the groups were non-significant for all assessed lipid parameters at Day 30 and Day 45. The overall effect was reported as 46.76% in Group A and 43.18% in Group B. **Conclusion**: In the present study, Yogaraja Guggulu showed significant improvement in most lipid parameters within the group and showed no statistically significant difference in between the group comparison. The findings support further evaluation of Yogaraja Guggulu in larger clinical studies of Medoroga with special reference to dyslipidemia.

KEYWORDS: Medoroga, Dyslipidemia, Yogaraja Guggulu, Navaka Guggulu, Lipid profile.

1. INTRODUCTION

Dyslipidemia is a disorder of lipoprotein metabolism that may involve increased total cholesterol, LDL-C and triglycerides, together with reduced HDL-C. It is an important risk factor associated with coronary artery disease, atherosclerosis and cardiovascular disease.

Contemporary pharmacological management includes statins, cholesterol absorption inhibitors, fibrates and nicotinic acid. But their use is associated with adverse effects such as myalgias, arthralgias, dyspepsia, hepatic toxicity and renal toxicity.

From the Ayurvedic perspective, dyslipidemia has been understood in relation to Medoroga, a condition associated with Medo Dhatu Vriddhi and abnormalities described as Bahutwa and Abaddhatwa of Meda. Several Ayurvedic formulations have been investigated for their possible antihyperlipidemic effects.

Yogaraja Guggulu, described in the source as a Medohara Yoga mentioned by Acharya Sharangadhara, was selected as the trial formulation because of its reported hypolipidemic, cardioprotective and hepatoprotective activities. Navaka Guggulu, consisting of Maricha, Pippali, Shunti, Haritaki, Vibhitaki, Amalaki, Chitraka and Musta being a proven drug in Medoroga, was selected as the control intervention.

The present study was therefore designed to evaluate the clinical efficacy of Yogaraja Guggulu in Medoroga with special reference to dyslipidemia and compare its effect with Navaka Guggulu.

2. RESEARCH QUESTION

Whether oral administration of Yogaraja Guggulu is effective in Medoroga with special reference to dyslipidemia?

3. AIM AND OBJECTIVES

Aim: To clinically evaluate the efficacy of Yogaraja Guggulu in the management of Medoroga with special reference to dyslipidemia.

Primary objectives

- To evaluate the efficacy of Yogaraja Guggulu in Medoroga with special reference to dyslipidemia using the lipid profile.
- To re-evaluate the efficacy of Navaka Guggulu in Medoroga with special reference to dyslipidemia using the lipid profile.
- To compare the efficacy of Yogaraja Guggulu and Navaka Guggulu in Medoroga with special reference to dyslipidemia using the lipid profile.
- Secondary objective: To undertake a detailed literary review of Medoroga with special reference to dyslipidemia.

4. HYPOTHESIS

Null hypothesis (H0): There is no significant difference between the efficacy of Yogaraja Guggulu and Navaka Guggulu in Medoroga with special reference to dyslipidemia.

Alternative hypothesis (H1): The efficacy of Yogaraja Guggulu is better than Navaka Guggulu in Medoroga with special reference to dyslipidemia.

Alternative hypothesis (H2): The efficacy of Navaka Guggulu is better than Yogaraja Guggulu in Medoroga with special reference to dyslipidemia.

5. MATERIALS AND METHODS

5.1 Study Design and Ethical Considerations

The study was a randomized, open-labelled, parallel-group, active-controlled clinical study. Thirty subjects diagnosed with Medoroga with special reference to dyslipidemia were

randomly allocated into two groups of 15 subjects each. The study was prospectively registered in the Clinical Trials Registry–India on 10/07/2024 with CTRI number CTRI/2024/07/070818. The source material states that written informed consent was obtained from participating subjects.

5.2 Source of Data

Literary source: Ayurvedic classical literature, contemporary textbooks, authentic digital sources and reputed journals were referred for information regarding the disease and drugs.

Sample source: Subjects fulfilling the inclusion criteria was selected from the OPD/IPD of Sri Sri College of Ayurvedic Science and Research Hospital, Kanakapura Road, Bengaluru.

5.3 Sample Size and Randomization

The sample size calculation estimated 118 subjects using the stated RCT formula. Because the work formed part of the postgraduate academic curriculum and there were time and feasibility constraints, a standard sample size of 30 was taken. Randomization was performed using a randomization table generated through www.randomizer.org.

Thirty subjects were randomized into Group A (n=15) and Group B (n=15).

5.4 Drug Source.

Drug	Manufacturer / Source	Batch	Manufacturing / Expiry
Yogaraja Guggulu	GMP-certified AIM WELL PHARMA; procured from Sarvahitha Ayurvedalaya Pvt. Ltd., Bengaluru	T01	07/2024 – 06/2027
Navaka Guggulu	GMP-certified AIM WELL PHARMA; procured from Sarvahitha Ayurvedalaya Pvt. Ltd., Bengaluru	T02	07/2024 – 06/2027

5.5 Diagnostic Criteria

Subjects were diagnosed based on fasting serum lipid profile. The source material used the following diagnostic ranges.

Parameter	Range considered for diagnosis	Range for exclusion
Total cholesterol	>200 mg/dL	>400 mg/dL
LDL	>129 mg/dL	>189 mg/dL
Triglycerides	≥150 mg/dL	>400 mg/dL
HDL	≤40 mg/dL	>40 mg/dL
VLDL	>30 mg/dL	>100 mg/dL

5.6 Inclusion Criteria

- Subjects of either gender between 21 and 60 years of age.
- Subjects fulfilling the diagnostic criteria.
- Subjects willing to participate with written informed consent in a language understood by them.
- Both obese and non-obese subjects were included.

5.7 Exclusion Criteria

- Pregnant and lactating women.
- Subjects with uncontrolled systemic illness including diabetes mellitus and hypertension.
- Subjects receiving medication for dyslipidemia.
- Subjects with serum lipid values beyond the specified exclusion ranges.

5.8 Intervention and Posology.

Feature	Trial Group – Group A	Control Group – Group B
Sample size	15	15
Intervention	Yogaraja Guggulu	Navaka Guggulu
Dosage	2 tablets TID (500 mg tablets)	2 tablets TID (500 mg tablets)
Anupana	Honey	Lukewarm water
Time of administration	TID, before food	TID, before food
Treatment period	30 days	30 days
Drug-free follow-up	15 days	15 days
Total study duration	45 days	45 days
Route	Oral	Oral

5.9 Assessment Criteria and Schedule

Assessment was based on fasting serum lipid profile.

Assessment point	Assessment
Day 0	Pre-test fasting serum lipid profile
Day 30	Post-test fasting serum lipid profile
Day 45	Follow-up fasting serum lipid profile

5.10 Statistical Analysis

Data were presented in tables, diagrams and charts. Statistical analysis was performed using SIGMASTAT software version 3.1. The Wilcoxon signed-rank test was used to assess before-and-after treatment differences within groups, while the Mann-Whitney U test was used for comparisons between groups. $P > 0.05$ was interpreted as non-significant, $P \leq 0.05$ as significant and $P \leq 0.01$ as highly significant. Effect size was calculated to assess the magnitude of clinical improvement.

6. RESULTS

6.1 Study Flow and Safety

Thirty-two subjects were screened. Two were excluded for not meeting the inclusion criteria. Thirty subjects were randomized, with 15 subjects allocated to each group. All 30 subjects received the allocated interventions, completed follow-up and were included in analysis. No adverse drug reaction was reported in either group and no rescue medication was administered.

6.2 Baseline Observations

Among the study participants, reported following observations: 51–60 years constituted 33.33%; females constituted 56.66%; 73.33% were from Sadharana Desha; 100% were Hindu; 60.00% were graduates; 56.66% were salaried employees; 66.66% belonged to upper-middle socioeconomic status; 100% were married; 63.33% consumed a mixed diet; 80% consumed coffee; 56.66% had a sedentary lifestyle; 56.66% had a family history; 63.33% had Vata Shleshmala Prakriti; and prominent Nidana included Snigdha Ahara Sevana (60%) and Avyayama (56.70%).

6.3 Total Cholesterol.

Group	Day 0 Median (IQR)	Day 30 Median (IQR)	Day 45 Median (IQR)	Between-group P
A	215 (192–226.25)	176 (159.75–208.50)	174 (166.50–208.00)	0.392 / 0.636
B	215 (209.25–229.00)	201 (174.50–213.75)	192 (173.50–201.00)	

Within Group A and Group B, reduction on Day 30 was highly significant and change from Day 30 to Day 45 was non-significant. Between-group differences were non-significant at Day 30 and Day 45.

6.4 LDL

Group	Day 0	Day 30	Day 45	Between-group P
A	140 (130.75–163.50)	122 (88–134.25)	118 (85.50–130.00)	0.740 / 0.753
B	136 (122.50–162.25)	112 (90.25–137.25)	111 (90.25–134.25)	

Both groups showed highly significant reduction by Day 30 and non-significant change during follow-up. Between-group differences were non-significant.

6.5 HDL

Group	Day 0	Day 30	Day 45	Between-group P
A	46 (38.50–60.00)	48 (40–57.50)	55 (42.75–60.00)	0.648 / 0.898
B	45.9 (32.75–56.50)	45 (35–60.00)	46 (40.25–68.75)	

Improvement in HDL was non-significant within both groups at Day 30 and Day 45, and inter-group differences were non-significant.

6.6 VLDL

Group	Day 0	Day 30	Day 45	Between-group P
A	34 (27.25–60.00)	30 (24.50–40.50)	30 (25–39.90)	0.468 / 0.561
B	38 (31.50–41.00)	37 (28.25–39.75)	34 (28.25–37.75)	

Group A showed a highly significant reduction at Day 30 and non-significant change during follow-up. Group B showed a significant reduction at Day 30 and non-significant change during follow-up. Inter-group differences were non-significant.

6.7 Triglycerides

Group	Day 0	Day 30	Day 45	Between-group P
A	170 (155.25–195.75)	150 (141.25–162.00)	148 (140–161.00)	0.629 / 0.763
B	172.6 (126–232.75)	128 (107.50–174.75)	128 (106.75–176.00)	

Both groups showed highly significant reduction by Day 30 and non-significant change during follow-up. Inter-group differences were non-significant.

6.8 Summary of Statistical Analysis

Parameter	Group A Day 0–30	Group A Day 30–45	Group B Day 0–30	Group B Day 30–45	Between groups
Total cholesterol	Highly significant	Non-significant	Highly significant	Non-significant	Non-significant
LDL	Highly significant	Non-significant	Highly significant	Non-significant	Non-significant
HDL	Non-significant	Non-significant	Non-significant	Non-significant	Non-significant
VLDL	Highly significant	Non-significant	Significant	Non-significant	Non-significant
Triglycerides	Highly significant	Non-significant	Highly significant	Non-significant	Non-significant

6.9 Overall Effect

Parameter	Group A	Group B
Total cholesterol	45.45%	66.66%
LDL	68.75%	64.28%
HDL	57.14%	33.33%
VLDL	12.5%	23.07%
Triglycerides	50%	28.57%
Total	46.76%	43.18%

The overall assessment of objective parameters showed similar overall effects in the Trial and Control groups, reported as 46.76% and 43.18%, respectively.

6.10 Effect Size.

Parameter	Group A 0–30	Group A 30–45	Group B 0–30	Group B 30–45
Total cholesterol	0.86 (Large)	0.56 (Large)	0.74 (Large)	0.46 (Medium)
LDL	0.81 (Large)	0.30 (Medium)	0.66 (Large)	0.32 (Medium)
HDL	0.54 (Large)	0.36 (Medium)	0.73 (Large)	0.27 (Small)
VLDL	0.68 (Large)	0.37 (Medium)	0.67 (Large)	0.30 (Medium)
Triglycerides	0.88 (Large)	0.47 (Medium)	0.88 (Large)	0.32 (Medium)

effect size was calculated for repeated measures using $r = Z/\sqrt{N}$ for the Wilcoxon signed-rank analysis.

7. DISCUSSION

7.1 Ayurvedic and Modern Correlation

The study considers dyslipidemia in the context of Medoroga, associated with Medo Dhatu Vriddhi and abnormality of Meda. Yogaraja Guggulu is described in the source as a Medohara formulation possessing Deepana, Pachana and Lekhana actions. The observed reductions in total cholesterol, LDL, VLDL and triglycerides after 30 days are discussed in the PPT in relation to these properties.

7.2 Probable Mode of Action of Yogaraja Guggulu

Yogaraja Guggulu is described as a herbo-mineral formulation containing Triphala, Shunti, Pippali, Guggulu, Chavya, Hingu, Chitraka, Ajamoda, Sweta Jeeraka, Krishna Jeeraka, Renuka, Indrayava, Patha, Vacha, Murva, Sarshapa, multiple Bhasma preparations and Rasa Sindhura. attributes Deepana, Pachana, Lekhana and Medohara actions to the formulation.

Triphala contains tannins, flavonoids, polyphenols and ascorbic acid with antioxidant and lipid-metabolism effects. Shunti contains gingerol, shogaol and zingerone and is described as having anti-inflammatory, antioxidant and lipid-metabolism effects. Pippali contains piperine and alkaloids and is described as enhancing bioavailability and influencing thermogenesis and lipid metabolism. Guggulu contains guggulsterone and sterols and is described as influencing cholesterol and fat metabolism.

Other ingredients are described as contributing carminative, antioxidant, hepatoprotective and lipid-modulating effects. The source attributes lipid-related activities to Chavya, Hingu, Chitraka, Ajamoda, Jeeraka, Renuka, Indrayava, Patha, Vacha, Murva, Sarshapa, Vidanga and Katuki. The Bhasma components and Rasa Sindhura are contributing to bioavailability and lipid-modulating effects.

7.3 Comparison with Navaka Guggulu

Within-group analysis showed significant reductions in several lipid parameters in both groups. However, between-group comparisons at Day 30 and Day 45 were non-significant for total cholesterol, LDL, HDL, VLDL and triglycerides. Thus, the study data did not demonstrate a statistically significant difference between the two interventions for the assessed lipid outcomes.

8. SAFETY AND CONFIDENTIALITY

No adverse drug reaction was reported in either group and no rescue medication was required during the study. The source material states that study data would be kept confidential and preserved for a period of five years.

9. LIMITATIONS

The study had a small sample size of 30 subjects, which limits generalization to a larger population. also states that Yogaraja Guggulu could not be prepared in the college because it contains Rasoushadis and requires a long preparation period; therefore, the formulation was procured from a GMP-certified pharmacy.

10. SCOPE FOR FURTHER STUDY

Larger studies can be done to establish more conclusive results. It also proposes future treatment protocols incorporating classical Virechana and Udwartana in Medoroga and suggests assessment using advanced lipoprotein testing.

11. CONCLUSION

In the present randomized open-labelled controlled clinical study, both Yogaraja Guggulu and Navaka Guggulu produced significant improvements in several lipid parameters within their respective groups. Yogaraja Guggulu produced highly significant reductions in total cholesterol, LDL, VLDL and triglycerides after 30 days, while HDL improvement was non-significant. Between-group comparisons showed no statistically significant difference in the assessed lipid parameters at Day 30 or Day 45. The study therefore reported Yogaraja Guggulu as clinically as effective as Navaka Guggulu for the studied parameters. null hypothesis was accepted there was no significant difference between the two interventions.

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