10.5005/jp-journals-10064-0034

RESEARCH ARTICLE

Evaluation of *Vyoshadi Guggulu* and *Haritaki Churna* in the Management of Dyslipidemia: A Multicenter Prospective Clinical Study

[1]Meda M Rao, [2]Paravazhi Radhakrishanan, [3]Varanasi Subose, [4]Sarada Ota, [5]Guru C Bhuyan, [6]Pradeep Dua
[7]Shruti Khanduri, [8]Babita Yadav, [9]Rakesh Rana, [10]Richa Singhal, [11]Narayanam Srikanth

ABSTRACT

Introduction: Dyslipidemia (DL) is a principal risk factor in the pathophysiology of cardiovascular diseases (CVD) and diabetes mellitus (DM). It may correlate with *Medoroga*, which is a risk factor for diseases like *Prameha*, *Hridroga Jwara*, *Bhagandara*, *Vrana*, *Vataroga,* etc.

Aim: To assess the clinical efficacy of *Vyoshadi Guggulu* (VG) and *Haritaki Churna* (HC) in the management of DL and changes in the quality of life of the study participants.

Materials and methods: It was a prospective, multicenter, single-arm study. The Ayurvedic formulations VG (2 tablets of 500 mg each TDS) after food with lukewarm water and HC (3 gm bd) were administered for 12 weeks with a follow-up of 2 weeks without interventions. Totally, 146 participants belonging to either sex, 18 to 70 years with low-density lipoprotein (LDL) 100 to 160 mg/dL and/or serum cholesterol 200 to 250 mg/dL and/or serum triglycerides (TG) 150 to 250 mg/dL and those willing and able to participate were included in the study. The outcome measures were changes in lipid profile, clinical safety, and changes in the quality of life.

Results: There was a significant reduction ($p<0.005$) in the mean serum cholesterol level, i.e., 214.8 reduced to 208.3 after 84 days of treatment and ($p<0.001$) in the mean high-density lipoprotein (HDL), i.e., 46.3 reduced to 44.04 after 84 days of treatment. There was no significant change in the serum TG, LDL, and very-low density lipoprotein (VLDL) value. There is also improvement in the quality of life ($p<0.001$) of the participants. There are no significant changes observed in the laboratory safety parameters. This corroborated that drugs are safe to use.

Conclusion: *Vyoshadi Guggulu* and *Haritaki Churna* are effective in the management of DL and are safe to use.

Clinical significance: The use of these drugs may lower the complications of DL.

Keywords: Ayurveda, Dyslipidemia, *Haritaki Churna*, *Medoroga*, Quality of life, *Vyoshadi Guggulu.*

How to cite this article: Rao MM, Radhakrishanan P, Subose V, Ota S, Bhuyan GC, Dua P, Khanduri S, Yadav B, Rana R, Singhal R, Srikanth N. Evaluation of *Vyoshadi Guggulu* and *Haritaki Churna* in the Management of Dyslipidemia: A Multicenter Prospective Clinical Study. J Res Ayurvedic Sci 2018;2(1):12-19.

Source of support: Nil

Conflict of interest: None

[1]Director (Ayurveda), [2]Assistant Director (Ayurveda), [3-8]Research Officer (Ayurveda), [9]Statistical Officer, [10]Statistical Assistant [11]Deputy Director General

[1,4,6-11]Central Council for Research in Ayurvedic Sciences, New Delhi, India

[2]National Ayurveda Research Institute for Panchakarma Cheruturuthy, Kerala, India

[3] Regional Ayurveda Research Institute for Drug Development Gwalior, Madhya Pradesh, India

[5]Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Odisha, India

Corresponding Author: Sarada Ota, Research Officer (Ayurveda), Central Council for Research in Ayurvedic Sciences New Delhi, India, Phone: +9101128525410, e-mail: sarada_ota@yahoo.com

INTRODUCTION

Dyslipidemia is a principal risk factor in the pathophysiology of CVD and DM.[1] Across the globe, CVD and DM are the conditions with increase in mortality.[2] It is studied that for every 1% reduction in lipid levels the risk of heart diseases reduces by 2.5%.[3] In India, there has been alarming increase in the prevalence of CVD (sample registration system) and DM.[4] In Ayurveda, DL can be correlated with *Medoroga*. Faulty diet pattern, lifestyle, and hereditary factors contribute to manifestation of *Medoroga*.[5] Although not an independent disease entity, it is a risk factor for diseases like *Prameha, Jwara, Bhagandara, Vrana, Vataroga*, etc.[6] According to *Acharya Susruta*, *Medovaha Srotas dusti* leads to *Sthaulya* (obesity). As mentioned in *Ayurvedic* classic, due to vitiation of *Kapha Dosha*, excess *Medas* gets deposited in the body, especially in the *Stana Uras* (chest), *Udara* (abdomen), and *Sphik* (hip) regions that cause *Medoroga*.[7] There are so many compound and single drugs that have been described in Ayurvedic classics, including the trial drugs VG and HC for the management of Medoroga and lowering its complications. As VG and HC are commonly used in practice for the management of Medoroga and the pharmacopoeial standards also have been incorporated in Ayurvedic Pharmacopoeia of India (API), both the drugs were selected in this study with the following objectives.

OBJECTIVES

The primary objective of the study was to assess the clinical efficacy of VG and HC in the management of DL, and the secondary objective was to assess the changes in the quality of life of the subjects of DL.

OUTCOME MEASURES

The primary outcome measure was to assess the changes in lipid profile at 84th day from baseline and secondary outcome measure was to assess the changes in the quality of life of the subjects at 84th day from baseline by using SF-36 Health Survey (RAND) score. It is a widely used standardized questionnaire for measuring self-reported physical and mental health status. This questionnaire consists of 36 questions (items) measuring physical and mental health status in respect of eight health domains, viz., (1) physical functioning, (2) role limitations due to physical health, (3) bodily pain, (4) general health perceptions, (5) vitality (energy/fatigue), (6) social functioning, (7) role limitations due to emotional health, and (8) general mental health (psychological distress/well-being).

The responses to each of the SF-36 items are scored and totaled according to a standardized scoring protocol.[8] The summed-up scores are expressed as a score on a 0 to 100 scale for each of the eight domains. Higher scores represent better self-perception of health. Among the eight domains, the domains 1, 2, 3, 6, and 7 represent health status as absence of disability, whereas domains 4 and 8 represent health status in terms of both positive and negative health states.

MATERIALS AND METHODS

Study Design and Setting

It was a prospective, multicenter, single-arm study. The study was conducted at three peripheral institutes of Central Council for Research in Ayurvedic Sciences (CCRAS), viz., National Research Institute of *Panchakarma* (NRIP), Cheruthuruthy, National Institute for *Ayurvedic* Pharmaceutical Research (NIAPR), Patiala, and National Ayurvedic Research Institute for Vector Borne Diseases (NAIRVBD), Vijayawada under the Intra Mural Clinical Research (IMR) program of CCRAS.

The trial drugs were administered for 12 weeks with a follow-up at the end of 14th week without any interventions. A total number of 146 individuals (from all three participating centers) of clinically diagnosed cases of DL were enrolled in the study.

Before the enrolment process the written consents of the participants were obtained and all were also informed about the study in detail. The trial drugs were standardized as per the standards and standard operational procedures lay down in the API. The study protocol was approved by the Institutional Ethics Committee of each participating institute and also registered in Clinical Trial Registry of India, CTRI/2012/03/002527.

Inclusion and Exclusion Criteria

Participants of DL belonging to either sex, aged between 18 and 70 years having LDL between 100 and 160 mg/dL and/or serum cholesterol 200 and 250 mg/dL and/or serum TG 150 to 250 mg/dL and those who were willing and able to participate in the 14 weeks long study were included in the study. Those participants who received any cholesterol-lowering medication within last 8 weeks before the screening, having type III and type IV hypercholesterolemia, poorly controlled hypertension (≥160/100 mm Hg), evidence of malignancy, on prolonged (≥6 weeks) medication with corticosteroids, antidepressants, anticholinergics, immunosuppressants, estrogen replacement therapy, etc., or any other drugs that may to have an influence on the outcome of the study were excluded from the study.

Further, the participants who were suffering from major systemic illness necessitating long-term drug treatment (rheumatoid arthritis, tuberculosis, psycho-neuro-endocrinal disorders, etc.), heart diseases, those having uncontrolled DM (blood sugar fasting >250 mg/dL), concurrent serious hepatic disorder [defined as aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT), total bilirubin or alkaline phosphatase (ALP) >2 times upper normal limit], or renal disorders (defined as serum creatinine > 1.2 mg/dL), severe pulmonary dysfunction (uncontrolled asthma and chronic obstructive pulmonary disease), inflammatory bowel disease, pregnant and lactating females, those with history of hypersensitivity to any of the trial drugs were also excluded from the study.

Criteria for Withdrawal

All the participants were free to withdraw from the study at any time on their own. The effort was made to collect the data of such participants by making phone calls.

Trial Interventions

As mentioned in API, part-II, Volume-II, VG[9] was administered orally in a dose of 1 gm (2 tablets of 500 mg each) thrice daily after food with lukewarm water and HC[10] was administered in a dose of 3 gm twice daily for 12 weeks as mentioned in API, part-I, Volume-I. Vyoshadi *Guggulu* contains *Trikatu* (*Sunthi*, *Pippali*, and *Maricha*), *Triphala* (*Haritaki, Vibhitaka*, and *Amalaki*), and *Trimada* (*Chitraka*,

Vidanga, and *Musta*) in one part each and *Guggulu* contains nine part in the formulation.

Both the drugs were procured in a lot from the selected good manufacturing practices certified company for three centers to avoid the batch variation. The drugs were prepared following the pharmacopoeial standards for each ingredient as well as finished products.

Laboratory Investigations

Laboratory investigations, such as Hb%, total leukocyte count, differential leukocyte count, erythrocyte sedimentation rate (ESR), fetal bovine serum, serum uric acid, serum urea, serum creatinine, aspartate transaminase, alanine transaminase, total protein, serum albumin, serum globulin, serum cholesterol, serum TG, LDL, HDL, VLDL were carried out at baseline and at the end of the study. The investigations were carried out with same methods at three participating centers to avoid the investigation error. The method along with the reagent details is annexed in Supplementary File-1.

STUDY PROCEDURE

All the participants had signed the informed consent form prior to their screening. After their enrolment demographic data, medical history, personal history, family history, and chief complaints were enquired and recorded in the case report form. The *Prakriti* of the participants was also assessed by a specific questionnaire.

Supplementary File-1 Methodology details pertaining to biochemistry and pathology investigations of dyslipidemia study

Biochemistry/Pathology Investigation	*Methodology*
Hemoglobin	Electrical impedance/Drabkin's method
Total leukocyte count	DC detection method
Differential leukocyte count	DC detection method
Erythrocyte sedimentation rate	Westergren's sodium citrate Westergren's Apparatus
Blood sugar	Glucose oxidase and peroxidase
Cholesterol	CHOD-PAP method (with LCF), endpoint (modified Roeschlaub's method)
TG	Glycerol phosphate oxidase/ PAP method
HDL cholesterol	Direct enzymatic method
Total protein	Direct biuret
Serum albumin	BCG dye method
Blood urea	GLDH-Urease
Serum creatinine	Modified Jaffe
Serum uric acid	Trinder
Bilirubin	Modified Jendrassik and Grof's
SGOT (AST)	IFCC method kinetic
SGPT (ALT)	IFCC method kinetic
Serum alkaline phosphatase	Tris-carbonate buffer kinetic

Further, hematological and biochemical investigations were carried out at baseline and end of the intervention period and recorded in the case report form. Participants were followed up on 14th, 28th, 42nd, 56th, 70th, and 84th day (12 weeks) and at the end of 98th day (14 weeks) for clinical assessment. During every follow-up, VG packed in separate containers and HC packed in sachets (3 gm each) were issued to the participants. Drug compliance form was also issued to each participant for filling up to ensure the consumption of medicines and the patients were also instructed to return the empty containers and sachets (Flow Chart 1).

Statistical Analysis

The data were analyzed using Statistical Package for Social Sciences 15.0 version. Clinical symptoms and laboratory parameters were analyzed by repeated measures analysis of variance to elicit the within subjects and between subjects effects at baseline and different time points of follow-up.

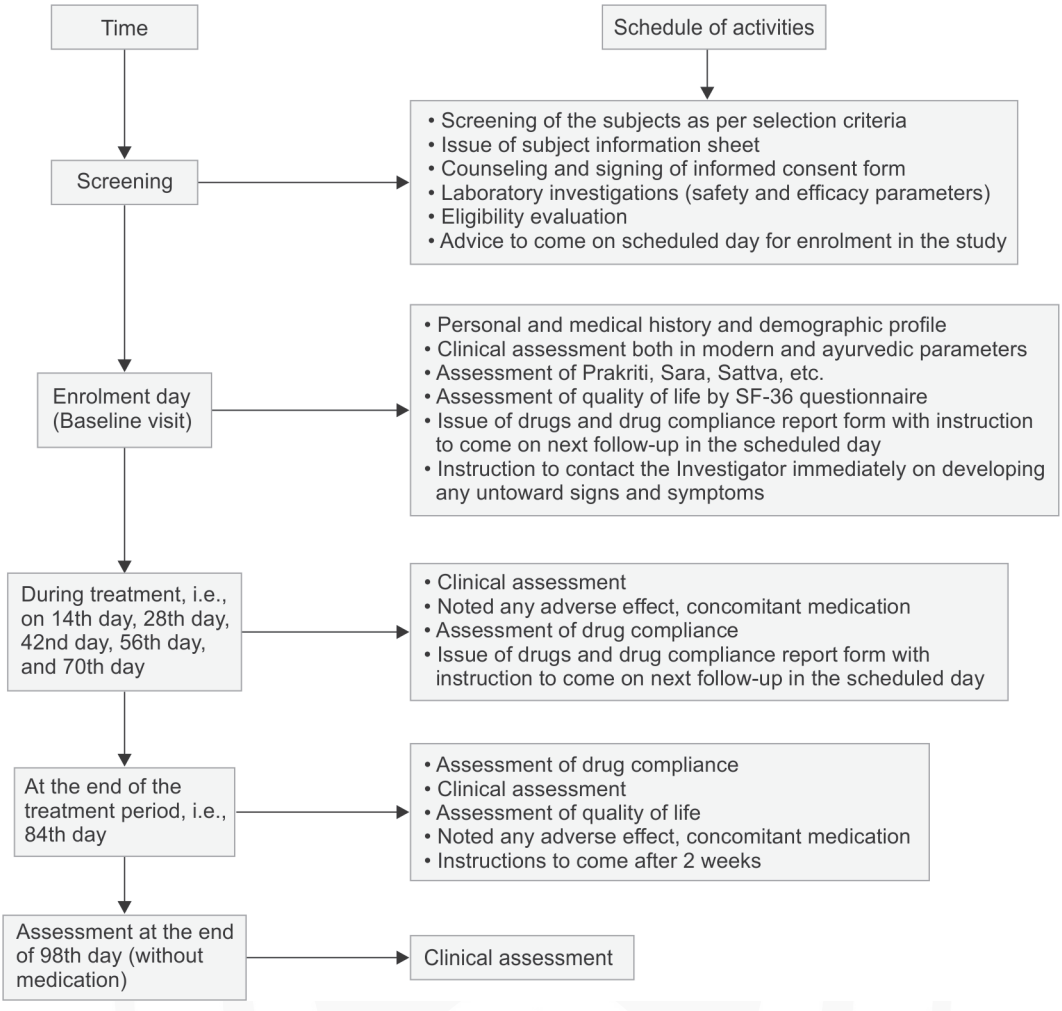
RESULTS

Totally, 146 subjects were enrolled in the study. The details of enrolled subjects are depicted in Flow Chart 2. The detail demographic data and other baseline characteristics of analyzed patients are presented in Table 1. It is revealed that 27.4% of patients belonged to the age group of 45 to 53 years followed by 26.7% in the age group of 54 to 65 years; among them, 79.7% were males and 87.0% patients were married. 95.5% patients were having no addiction, 71.9% patients had normal sleep and 80.8% had regular bowel habits.

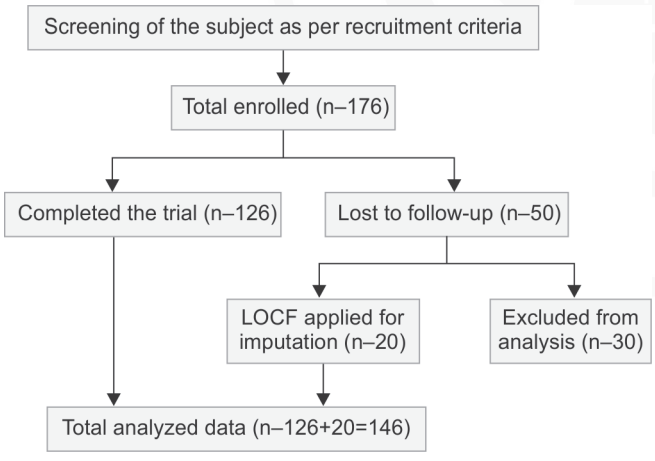
Effect of the Drugs on Clinical Signs and Symptoms

Graph 1 shows the effect of VG and HC on clinical symptoms of DL. The mean breathlessness score which was 38.7 ± 29.4 before the treatment reduced to 19.5 ± 17.7 and 17.8 ± 17.85 at the end of the treatment, i.e., 84th day and after follow-up, i.e., 98th day respectively. The mean score of paresthesia which was 26.2 ± 26.15 at baseline reduced to 9.8 ± 15.9 and 9.25 ± 16.1, respectively, at the end of the treatment and after follow-up without intervention. The mean score of confusion which was 21.9 ± 27.5 at baseline reduced to 7.2 ± 14.96 at the end of the treatment period and 6.5 ± 14.1 at the end of follow-up period; and the mean score of fatigue which was 42.1 ± 27.0 before the treatment reduced to 16.6 ± 19.1 at the end of the treatment and 15.75 ± 18.8 at the end of 98th day. The result is statistically significant ($p < 0.001$).

Flow Chart 1: Study procedures



Flow Chart 2: Outflow of the subjects in the study.
LOCF: Last observation carried forward



Effect of Trial Drugs on Outcome Measures

Table 2 shows the effect of trial drugs on lipid profiles. There was a significant reduction ($p = 0.003$) in the mean serum cholesterol (mg/dL) levels, which was 214.8 at the baseline and reduced to 208.3 at the end of treatment period. There was no significant difference in the parameters, viz., serum TG, serum LDL, and serum VLDL.

Effect of Drugs on Safety Parameters

Table 3 shows the effect of trial drugs on biochemical parameters, i.e., liver function and renal function and it reveals that all the parameters were within the limits, both at baseline and after the trial interventions. Further, no adverse events/reactions were reported during treatment period. This result established the safety of the trial drugs.

Effect of the Trial Drugs on Quality of Life of the Participants

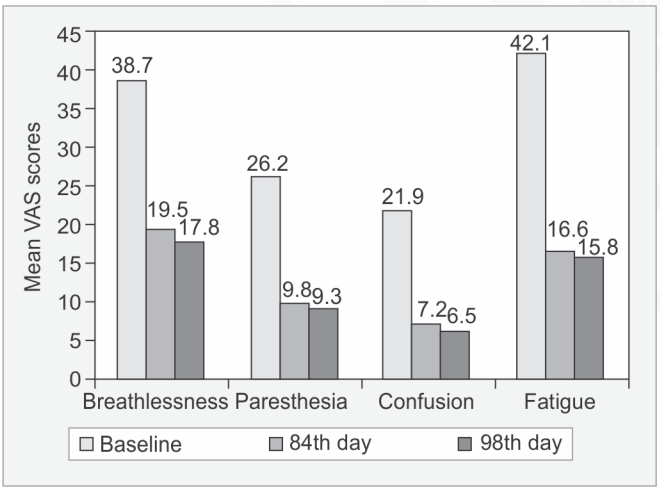
The finding of the study shows that the scores received on eight domains of SF-36 health survey questionnaire, viz., physical functioning, limitation due to physical health, limitation due to emotional problems, energy/fatigue, social well-being, emotional well-being, pain, and general health improved than at the baseline and were statistically significant ($p < 0.001$) at the end of treatment period, i.e., 84th day and 98th day follow-up period (Graph 2).

DISCUSSION

The purpose of this clinical study was to evaluate the efficacy of VG and HC in DL. The finding of the study

Table 1: Demographic and baseline characteristics of the participants (n = 146)

Variables	*N (%)*	*Mean ± SD*
Age		49.6 ± 10.3
Gender		
Male	52 (35.6)	
Female	94 (64.4)	
Marital status		
Married	140 (95.9)	
Unmarried	6 (4.1)	
Educational status		
Illiterate	18 (12.3)	
Read and write	128 (87.7)	
Habitat		
Urban	81 (55.5)	
Semi-urban	27 (18.5)	
Rural	52 (32.9)	
Economic status		
Above poverty line	121 (82.9)	
Below poverty line	25 (17.1)	
Occupation		
Desk work	34 (23.3)	
Fieldwork with physical labor	14 (9.6)	
Housewife	76 (52.1)	
Dietary habits		
Vegetarian	41 (28.1)	
Nonvegetarian	105 (71.9)	
Weight		69.65 ± 27.84
BMI (kg/m2)		27.84 ± 5.03
Sharirika prakriti		
Pitta-Kaphaja	105 (71.9)	
Vata-Pittaja	35 (24)	
Vata-Kaphaja	3 (2.1)	



Graph 1: Effect of trial drugs on symptoms of dyslipidemia (n = 146)

shows significant change in correcting DL by reducing serum cholesterol levels and reduction (under normal limits) in systolic blood pressure. The above formulations have also brought in significant amelioration of chief complaints, such as breathlessness, paresthesia, confusion,

Table 2: Effect of trial drugs on lipid profile (n = 146)

Variable	*Baseline (mean ± SD)*	*84th day (mean ± SD)*	*t-value*	*p-value*
Serum cholesterol (mg/dL)	214.8 ± 33.5	208.3 ± 35.1	3.05	0.003*
Serum triglyceride (mg/dL)	164.1 ± 67.75	158.3 ± 77.1	1.2	0.23
Low density lipoprotein (mg/dL)	135.7 ± 32.8	132.85 ± 37.8	1.3	0.2
Very low density lipoprotien (mg/dL)	32.8 ± 13.5	31.6 ± 15.4	1.2	0.23

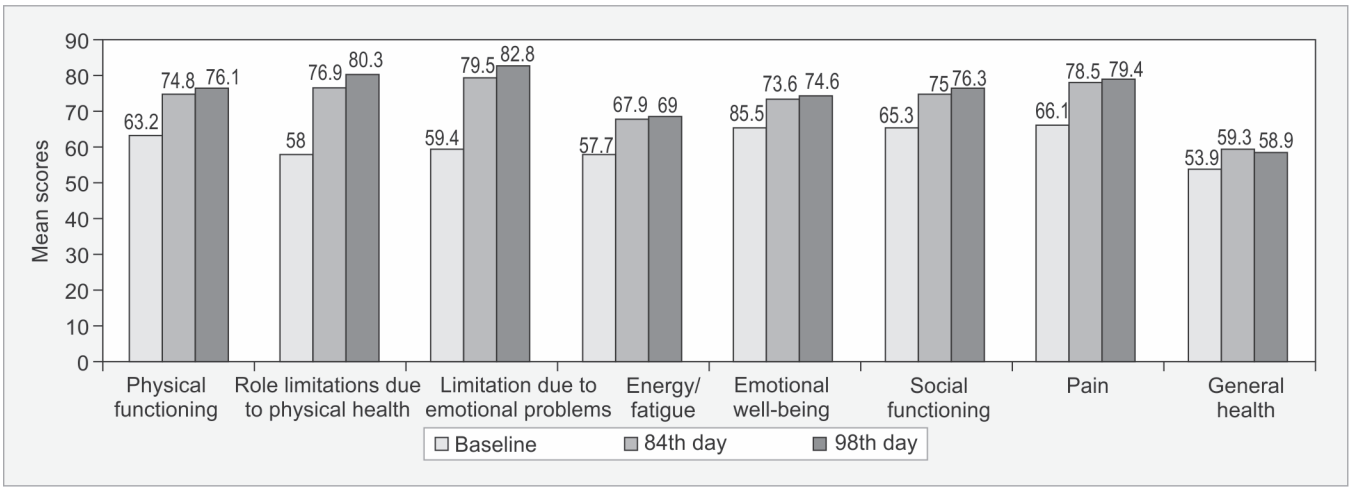
Table 3: The effect of trial drugs on safety lab parameters

Variables	*Baseline (mean ± SD)*	*84th day (mean ± SD)*
Serum urea (mg/dL)	20.7 ± 5.7	19.6 ± 6.0
Serum uric acid (mg/dL)	5.0 ± 5.0	4.9 ± 5.0
Serum creatinine (mg/dL)	1.15 ± 2.1	1.1 ± 2.1
SGOT (AST) (U/L)	25.6 ± 10.5	23.6 ± 14.5
SGPT (ALT) (U/L)	28.6 ± 18.9	27.7 ± 23.1
Total protein (gm/dL)	7.5 ± 0.5	7.4 ± 0.5
Serum albumin (gm/dL)	4.4 ± 0.4	4.24 ± 0.4
Serum globulin (gm/dL)	3.1 ± 0.4	3.15 ± 0.4
Conjugated bilirubin (mg/dL)	0.2 ± 0.2	0.17 ± 0.1
Unconjugated bilirubin (mg/dL)	0.5 ± 0.2	0.4 ± 0.2

fatigue, and also have improved quality of life of the participants. In addition, there were no significant changes found in the safety laboratory parameters, i.e., hepatic and renal parameters.

Dyslipidemia is a condition with abnormal raised levels of cholesterol and/or fat in the blood. It is an established risk factor too for the coronary artery diseases.[11] It can be correlated with the *Medoroga* in Ayurveda. *Medoroga* is a *Santarpanotha vyadhi* caused due to consumption of *Sleshmala Ahara*, *Diwaswapna*, and inadequate physical activities, which leads to incomplete processing of *Anna Rasa* (consumed food); is converted into *Ama Dosh*.[7] It leads to *Medo dhtavagni Mandyata*, *Medovaha Srotodushti*, and accumulation of *Apakwa Medas*. Similar to *Medoroga*, sedentary lifestyle and faulty diet habit are also main causes for DL. In addition to this, it is also known that *Kapha Dosha* and *Meda Dhatu* are mutually dependent on each other, so if any causative factor which increases *Kapha dosha* will result in increase of *medas*, resulting in DL.

There are several Ayurvedic formulations that have been studied in patients of *Medoroga*. In a study, a combination of *Navaka Guggulu, Sthaulhara Kashaya,* prescribed diet and physical exercise produced some significant reduction in chest–abdomen–hip circumference. There was some



Graph 2: Effect of trial drugs on quality of life of the study participants (n = 146)

improvement in subjective symptoms, but lipid parameters and quality of life were not studied.[6] In a study conducted at Institute of Postgraduate Training and Research Centre for Research in *Ayurveda* Jamnagar with the same drugs, i.e., VG and HC produced considerable symptomatic improvement in the subjects affected with DL but the changes in the quality of life were not assessed.[12]

In the present study, both the trial drugs are having the ingredients with *Medoghna, Lekhana* and *Kaphaghna* property, i.e., Triphala, i.e., three myrobalans, viz., *Amalaki* (*Emblica officinalis* Gaertn.), *Haritaki* (*Terminalia chebula* Retz.), *Vibhitaki* (*Terminalia bellerica* Roxb.); *Trikatu* viz. *Shunthi* (*Zingiber officinale Rosc.*), *Maricha* (*Piper nigrum Linn.*), *Pippali* (*Piper longum Linn.*), and *Trimada*, i.e., *Vidang* (*Embelia ribes* Burn.f.), *Musta* (*Cyperus rotundus* Linn.), *Chitrak* (*Plumbago zeylanica* Linn.).

According to Ayurveda, *Haritaki* possesses *Katu Tikta rasa*, *Laghu Ruksha guna*, and *Ushna Virya*; *Vibhitaki* possesses *Kashaya Rasa*, *Ruksha Guna*, and *Ushna virya*; and *Amalaki* possesses *Katu Tikta Kashaya Rasa*, *Laghu Ruksha Guna*, and *Ushna Virya*. Trikatu and *Trimada* are predominantly *Katu Rasa* and *Ushna Virya*.[13] *Purana Guggulu* has been described as "*Atilekhana*" and "*Medohara*"; it also acts as *Agnivardhaka* and *Srotoshodhaka* due to its *Teekshna Guna*. Being *Vishad* it eliminates the *Snigdha* and *Picchila Meda* and *Kapha*.[14]

Further, some experimental studies on the ingredients of VG and HC have also established hypolipidemic, hypocholesterolemic, and antidyslipidemic action. 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.[15,16] *Guggulu* has been found to be effective in the treatment of hyperlipidemia.[17] Triphala has also been found to have potent hypolipidemic effect and have shown to be potent in reducing hypercholesteremia and atherosclerosis.[18,19] *Pipali* (*Piper longum*) has demonstrated significant antidiabetic and antihyperlipidemic activity; it has a high potential as an effective dietary supplement in the management of DL.[20-22] *Maricha* (*Piper nigrum Linn.*) extracts have shown effect in reducing the body weight, fat, ameliorated high fat diet-induced hyperlipidemia and its constituents.[23] Ginger and pepper have shown to modulate oxidative stress caused by hypercholesterolemia.[24] Ginger has demonstrated decrease in all lipid profile parameters.[25,26] Also, in a clinical study the results show that ginger has a significant lipid lowering effect compared with placebo.[27] Therefore, the pharmacological action of VG and HC could be deduced by the *rasa panchaka* as described above and there are ample properties to elicit *Kaphamedohara* action of the formulations of VG and HC, which might have contributed to the amelioration of the symptoms of *medoroga* (DL) and reduction in the serum cholesterol levels.

Hence, 12 weeks administration of VG and HC produces antidyslipidemic action. However, long-term administration of VG and HC can throw more light on this phenomenon of elevation of HDL levels.

CONCLUSION

This study, therefore, proves that administration of VG and HC has affirmative action in ameliorating chief complaints of DL (*Medodosha*), enhancing quality of life of affected person and is safe to use.

ACKNOWLEDGMENTS

The authors are highly indebted to the Director General and Deputy Director (Technical), CCRAS, New Delhi,

for their timely support and are thankful to the members of the Institutional Ethical Committees of the participating centers. They acknowledge the services extended by Dr N Thameez Selavam, RO (Bio-chem.); Dr VC Deep RO (Ay.); Dr Aarti Sheetal, Senior Research Fellow (Ayu), CCRAS Hqr.; Dr C Sanjeev and Dr Afsal, Junior Consultants of NRIP, Cheruthuruthy; Smt Sukjinder Kaur, sister-incharge; Smt Gitanjali, Staff Nurse; Smt Asha Verma, Hindi Assistant, and Sh Aniya Singh, Stenographer of NRIADD Bhubaneswar for their technical and secretarial support during the study and preparation of the manuscript. The authors are also thankful to all the study participants for their cooperation to carry out and complete the study.

REFERENCES

1. Enas A, Vishwanathan M, Mohan D, Sayed F, Pazhoor S, Chennikkara H. The metabolic syndrome and dyslipidemia among Asian Indians: a population with high rates of diabetes and premature coronary artery disease. J Cardiometab Syndr 2007 Sep;2(4):267-275.
2. Alberti KGMM, Eckel RH, Grundy SM, Zimmet PZ, Cleeman JI, Donato KA, Fruchart JC, James WP, Loria CM, Smith SC Jr. Harmonizing the metabolic syndrome: a joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; And International Association for the Study of Obesity. Circulation 2009 Oct;120(16):1640-1645.
3. Lichtenstein AH, Appel LJ, Brands M, Carnethon M, Daniels S, Franch HA, Franklin B, Kris-Etherton P, Harris WS, Howard B, et al. Diet and lifestyle recommendations revision 2006. A scientific statement from the American Heart Association Nutrition Committee. Circulation 2006 Jul;114(1):82-96.
4. Anjana RM, Ali MK, Pradeepa R, Deepa M, Datta M, Unnikrishnan R, Rema M, Mohan V. The need for obtaining accurate nationwide estimates of diabetes prevalence in India: rationale for a national study on diabetes. Indian J Med Res 2011 Apr;133:369-380.
5. Ramsubba Rao KV, Laxmu NM. Management of Hyperlipidaemia (Medoroga) in Ayurveda—a review. Int Res J Pharm 2011;2(11):6-10.
6. Prasad SVLN, Rao V Prahalad, Punita V, Murali Manohar Raju Y, Sharmila UV, Anand B. Efficacy and safety of an Ayurvedic regimen in Medoroga. Indian J Traditional Knowl 2009 Jul;8(3):379-386.
7. Singhal GD. Ayurvedic clinical diagnosis based on Madhava Nidana, Part II. Chowkhamba Sanskrit Pratishthan: Delhi; 1996. p. 593-594 (Chapter 34, verse 34.1-2/1, 34.2/2-4).
8. Ware JE, Snow KK, Kosisnki M, Gandek B. SF-36 Health Survey Manual and Interpretation Guide. Boston, MA: The Health Institute; 1993.
9. Anonymous. The Ayurvedic Pharmacopeia of India (API), Part-II, Vol-II. 1st ed. The Controller of Publications; New Delhi: Ministry of Health and Family Welfare, Govt. of India; 2007. pp. 138-140
10. Anonymous. The Ayurvedic Pharmacopeia of India (API), Part-II, Vol-II. 1st ed. The Controller of Publications; New Delhi: Ministry of Health and Family Welfare, Govt. of India; 2007. pp. 47-48.
11. Pooja BA, Bhatted S, Chaturvedi N, Deekshit S, Bhojani MK. Role of atorvastatin in dyslipidemia: a clinical study. Indian J Clin Practice 2013 Dec;24(7):620-622.
12. Ragvani H, Bhatt N, Thakar AB. Clinical evaluation of Vyoshadi Guggulu and Haritaki Churna in the management of dyslipidemia. Int J Pharm Biol Arch 2013 Aug;4(4): 643-646.
13. Bhāvamiśra. Bhāvaprakāśa Nighaṇṭu—Hindi Commentary by Shastri Brahmashankara Vaidhya Rupalalji. 9th ed. Vol. I. Chaukhumbha Sanskrit Bhawan: Varanasi; 1999. p. 959.
14. Upadhyay BN. Studies on role of Commiphora mukul (Gugullu) in management of IHD. PhD Thesis, Department of Kayachikitsa, Varanasi: IMS BHU; 1979.
15. Maruthappan V, Shree KS. Hypolipidemic activity of Haritaki (*Terminalia chebula*) in atherogenic diet induced hyperlipidemic rats. J Adv Pharm Technol Res 2010 Apr;1(2):229-235.
16. Rathore HS, Soni S, Bhatnagar D. Hypocholesterolemic effect of Terminalia chebula fruit (Myrobalan) in mice. Anc Sci Life 2004 Apr;23(4):11-15.
17. Hasani-Ranjbar S, Nayebi N, Moradi L, Mehri A, Larijani B, Abdollahi M. The efficacy and safety of herbal medicines used in the treatment of hyperlipidemia; a systematic review. Curr Pharm Des 2010;16(26):2935-2947.
18. Saravanan S, Srikumar R, Manikandan S, Jeya Parthasarathy N, Sheela Devi R. Hypolipidemic effect of Triphala in experimentally induced hypercholesteremic rats. Yakugaku Zasshi 2007 Feb;127(2):385-358.
19. Thakur CP, Thakur B, Singh S, Sinha PK, Sinha SK. The Ayurvedic medicines Haritaki, Amala and Bahira reduce cholesterol-induced atherosclerosis in rabbits. Int J Cardiol 1988 Nov;21(2):167-175.
20. Kumar S, Sharma S, Vasudeva N. Screening of antidiabetic and antihyperlipidemic potential of oil from *Piper longum* and piperine with their possible mechanism. Expert Opin Pharmacother 2013 Sep;14(13):1723-1736.
21. Vijayakumar RS, Nalini N. Piperine, an active principle from Piper nigrum, modulates hormonal and apo lipoprotein profiles in hyperlipidemic rats. J Basic Clin Physiol Pharmacol 2006 Jun;17(2):71-86.
22. Bao L, Bai S, Borijihan G. Hypolipidemic effects of a new piperine derivative GB-N from Piper longum in high-fat diet-fed rats. Pharm Biol 2012 Aug;50(8):962-967.
23. Parim B, Harishankar N, Balaji M, Pothana S, Sajjalaguddam RR. Effects of Piper nigrum extracts: restorative perspectives of high-fat diet-induced changes on lipid profile, body composition, and hormones in Sprague-Dawley rats. Pharm Biol 2015 Apr;53(9):1318-1328.
24. Otunola GA, Oloyede OB, Oladiji AT, Afolayan AJ. Selected spices and their combination modulate hypercholesterolemia-induced oxidative stress in experimental rats. Biol Res 2014 Mar;47:55.
25. El-Rokh el-S, Yassin NA, El-Shenawy SM, Ibrahim BM. Antihypercholesterolaemic effect of ginger rhizome (*Zingiber officinale*) in rats. Inflammopharmacology 2010 Dec;18(6): 309-315.
26. Bhandari U, Kanojia R, Pillai KK. Effect of ethanolic extract of Zingiber officinale on dyslipidaemia in diabetic rats. J Ethnopharmacol 2005 Feb 28;97(2):227-230.
27. Alizadeh-Navaei R, Roozbeh F, Saravi M, Pouramir M, Jalali F, Moghadamnia AA. Investigation of the effect of ginger on the lipid levels. A double blind controlled clinical trial. Saudi Med J 2008 Sep;29(9):1280-1284.

हिंदी सारांश

डीसलिपिडेमिया के प्रबंधन में व्योषादी गुग्गुलु एवं हरीतकी चूर्ण के प्रभाव पर चिकित्सकीय मूल्यांकन–एक बहुकेंद्रीय प्रत्याशित अध्ययन

[1]मेदा एम. राव, [2]पारवाजी राधाकृष्णनन, [3]वारणसी सुबोस, [4]शारदा ओता, [5]गुरु सी. भूयां
[6]प्रदीप दुआ, [7]श्रुति खंडूड़ी, [8]बबिता यादव, [9]राकेश राणा, [10]रिचा सिंघल, [11]नारायणम श्रीकांत

भूमिकाः डीसलिपिडेमिया, हृदय रोगों एवं डायाबेटिस मलाइट्स जैसे अन्य रोगों के लिए एक प्रधान कारण है। यह पाया गया है की लिपिड स्तरों में 1% तक की कमी होने पर हृदय रोगों का जोखिम 2.5% तक घट जाता है।

उद्देश्यः डिसलिपिडेमिया जन्य लक्षणों के प्रबंधन में व्योषादी गुग्गुलु एवं हरीतकी चूर्ण (आयुर्वेदिक औषधियों) की प्रभावकारिता के साथ ग्रसित व्यक्तियों के जीवन की गुणवत्ता में सुधार का चिकित्सीय मूल्यांकन।

सामग्री एवं विधिः यह चिकित्सीय अध्ययन बहु-केंद्रीय स्तर पर किया गया था। इस में व्योषादी गुग्गुलु 2–2 गोली (प्रत्येक गोली 500 मि.ग्रा. की) को दिन में तीन बार खाना खाने के बाद हल्के गुनगुने पानी के साथ एवं हरीतकी चूर्ण 03 ग्राम की मात्रा में दिन में दो बार 12 सप्ताह तक दिया गया था। कुल 146 रोगी जिनकी वय 40–70 वर्ष के अन्तराल की थी और जांचानुसार जिनका LDL का स्तर 100–160 मि.ग्रा./डीएल, Serum Cholesterol का स्तर 200–250 मि.ग्रा./डीएल और Serum Triglycerides का स्तर 150–250 मि.ग्रा./डीएल था और वे इस चिकित्सीय अध्ययन में भाग लेने के इच्छुक थे उन्हें ही अध्ययन में सम्मिलित किया था। Lipid profile में देखे गये बदलाव इस अध्ययन का प्राथमिक परिणाम था जबकि SF–36 (RAND) QOL द्वारा मूल्यांकन किये गये जीवन की गुणवत्ता में परिवर्तन तथा नैदानिक सुरक्षा सहायक परिणाम थे।

परिणामः अध्ययन के अंत में उपचार के प्रभाव स्वरूप सिरम कॉलेस्ट्रोल (Serum Cholesterol) का स्तर घट कर 208.3 ± 35.1 हो गया जिसका स्तर बेसलाइन पर 214.8 ± 33.5 था। अध्ययन में उपचार के 84 दिनों उपरान्त एच.डी.एल.(HDL) का औसत लगभग 46.3 ± 8.3 से घट कर 44.04 ± 8.1 हो गया यह एक अच्छा परिणाम था । जबकि Serum TG, Serum एल.डी.एल. (LDL) और सीरम वी.एल.डी.एल. (Serum VLDL) के स्तर में कोई महत्वपूर्ण अंतर नहीं पाया गया था। परिणाम के आधार पर यह भी पाया गया था की व्योषादि गुग्गुलु एवं हरीतकी चूर्ण के प्रयोग का ग्रसित व्यक्तियों की जीवन की गुणवत्ता में भी सुधार था। इसके अतिरिक्त लिवर और किडनी के प्रयोगशाला मापदण्डों में कोई महत्वपूर्ण अन्तर नहीं पाया गया था। अतः यह परिणाम औषधियों के प्रभाव को सत्यापित करता है साथ ही आयुर्वेद की उपयोगिता को मुख्य धारा में लाने की सम्भावना को दर्शाता है।

निष्कर्षः इस अध्ययन से स्पष्ट होता है कि डिसलिपिडेमिया में व्योषादि गुग्गुलु एवं हरीतकी चूर्ण जैसी आयुर्वेदिक औषधियों का उपयोग प्रभावकारी व सुरक्षित है।

सूचांकः अतः व्योषादि गुग्गुलु एवं हरीतकी चूर्ण के प्रयोग से डिसलिपिडेमिया रोग के कारण होने वाली अन्य समस्याएँ (रोग) कम हो सकती है।

संकेत चिन्हः आयुर्वेद, डिसलिपिडेमिया, मेदोरोग, व्योषादि गुग्गुलु, तथा हरीतकी चूर्ण।