10.5005/jp-journals-10064-0016

RESEARCH ARTICLE

Clinical Safety of Selected Ayurvedic Formulations in Obesity and Dyslipidemia

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ABSTRACT

Introduction: Obesity is a condition of abnormal or excessive fatness, and dyslipidemia is a condition with abnormal raised levels of any one or all lipids in the blood. Ayurveda compares signs and symptoms of obesity and dyslipidemia with the disease *Sthaulya/Medoroga*. *Vyoshadi Guggulu* and *Haritaki Churna* are the most commonly used medicines in the management of *Sthaulya*. However, the safety of these drugs was not evaluated until now through clinical trials.

Objective: The objective of this study was to assess clinical safety of *Vyoshadi Guggulu* and *Haritaki Churna* in the management of obesity (*Sthaulya*) and dyslipidemia.

Materials and methods: A prospective, open-label multicentric study was carried out at peripheral institutes of the Central Council for Research in Ayurvedic Sciences (CCRAS). Total 306 patients satisfying selection criteria were randomly selected from the outpatient department of respective centers and were administered *Vyoshadi Guggulu* (3 tablets of 500 mg) and *Haritaki Churana* (3 gm twice daily) in case of obesity, and *Vyoshadi Guggulu* (2 tablets of 500 mg thrice in a day) and *Haritaki Churana* (3 gm twice daily in cases of dyslipidemia) with lukewarm water for 12 weeks. So, the daily intake of the medicine was similar in all these cases. Hematological parameters, viz., lipid profile, and safety parameters were assessed at baseline and at the end of 12 weeks. Paired sample t-test was applied to compare the changes.

Results: At the end of 12 weeks, compared with baseline, no statistically significant difference was observed in liver function tests (LFTs) and kidney function tests (KFTs) in the subjects.

Conclusion: The findings clearly indicate that *Vyoshadi Guggulu* and *Haritaki Churna* are clinically safe and tolerable in subjects with obesity and dyslipidemia belonging to different age groups, gender, geographical area, and different *Prakrti*.

Keywords: Dyslipidemia, *Haritaki Churna*, Obesity, Sthaulya, *Vyoshadi Guggulu*.

How to cite this article: Sharma BS, Ota S, Khanduri S, Yadav B, Dua P, Kumar K, Ravte RK, Nair PKS, Rao MM, Sannd R, Radhakrishnan P, Subhose V, Giri SK, Kumari R, Rana RK. Clinical Safety of Selected Ayurvedic Formulations in Obesity and Dyslipidemia. J Res Ayurvedic Sci 2017;1(3):142-149.

Source of support: Nil

Conflict of interest: None

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INTRODUCTION

Obesity is a state in which weight exceeds a standard based on height. The risk of obesity appears to increase as the percent fat content in the body rises above an upper limit of normal. The definition of overweight and obesity is based on body mass index (BMI), which is measured as weight (in kilograms) divided by square of height (in meters). A healthy BMI range is 18.5 to 24.9 kg/m^2. Overweight is defined as a BMI from 25 to 29.9 kg/m^2, and obesity is defined as BMI $\geq$ 30 kg/m^2. BMI value with combination of waist circumference can be used to evaluate health risk for individuals.[1] Obesity can lead to hazardous health consequences including type II diabetes, coronary artery disease, dyslipidemia, stroke, heart failure, hypertension, fatty liver disease, sleep apnea, osteoarthritis, and reproductive and gastrointestinal cancers.[2] Lipoprotein metabolism disorders, viz., overproduction and deficiency of lipoprotein, is known as dyslipidemia. These disorders may be manifested in the body due to the elevation of the serum total cholesterol, low-density lipoprotein cholesterol, and triglyceride concentrations, and a decrease in the concentration of

high-density lipoprotein (HDL) cholesterol.[3] Dyslipidemia is a main risk factor in the pathophysiology of cardiovascular diseases and diabetes mellitus.[4] It is reported that the abnormality in cholesterol level causes 18% of the global cardiovascular diseases and 56% of the global ischemic heart diseases. It is also studied that for every 1% reduction in lipid levels, the risk of heart diseases reduces by 2.5%.[5] This study was undertaken by the National Foundation of India among the middle class (officers), lower class (clerks and peons) in a large office establishment and the poor class from a slum in New Delhi. Obesity of 1% for males and 4% for females was found in slums; the corresponding figures in the middle class were 32.3% and 50%. More females than males have been found to be overweight (BMI > 25) in all age groups, 44.5% females *vs* 19.6% males. Incidence of obesity was higher in people above 40 years of age. The prevalence of obesity (BMI > 30) was about 3% in males and about 14% in females above 40 years of age.[6] About 20 million Indians are obese and by 2025 the expected number shall be 68 million.[7]

The different texts of *Ayurveda* have explained the disease *Sthaulya/Medoroga* in detail which is symptomatically similar with obesity and dyslipidemia. With the current "back to nature" thrust, many obese subjects also look for some help from the traditional systems like *Ayurveda*.[8] The societal factors that promote sedentary lifestyles and the consumption of high-fat, energy-dense diets are mainly responsible for global epidemic of obesity.[9] Apart from this, genes also play an important role in the determination of a person's susceptibility to weight gain.[10] *Ayurveda* classical texts also consider dietetic, behavioral pattern, and psychological factors as causes of *Sthaulya*. *Ahara Atisampurna* (excessive intake of food) plays the major role in the causation of obesity. As per *Acharya Charak*, *Sthaulya* is mainly due to vitiation (*Dushti*) of *Rasa* and *Meda dhatu*. The aggravated *Kapha Dosha* and *Medas* obstruct the *Vata* in *Kostha* (alimentary canal) causing *Vata* to be hyperactive, which stimulates *Agni* resulting in digestion of food rapidly, and vitiated or hyperactive *Vata* absorbs it rapidly which increases the craving for food. So, a person requires food frequently. *Medas* causes *Srotorodha* (obstruct the nourishment pathway), thus the other *Dhatus* do not get nourishment properly resulting in the disproportionate increase of *Medas* (adipose tissue).[11] The impairment of *Jathragni* also leads to the impairment of *Dhatwaagni*. The *Medadhatwagnimandya* leads to *Vriddhi* of *Medadhatu* and associated dyslipidemia in *Sthaulya*.

The contents of *Vyoshadiguggulu* are mainly *Ushna Virya* (hot potency), *Agnideepaka* (promotes digestive fire) and *Kapha-Vatashamaka* (alleviating *Kapha* and *Vata dosha*). Both *Vyoshadi Guggulu* and *Haritaki Churna* are given with lukewarm water. The lukewarm water and *Haritaki* are *Kapha-vataghna* (alleviating *Kapha* and *vata*) *Haritaki* is *Kaphghna* (alleviating *Kapha*) and *Vatahgna* (alleviating *Vata*). Thus, both drugs help in reversing the *Samprapti* (pathogenesis) of *Sthaulya*, obesity associated with dyslipidemia.

The objective of the studies was to assess the safety of *Vyoshadi Guggulu* and *Haritaki Churna* in obese and dyslipidimic subjects.

Drug Profile

The composition of the drug is given in Table 1.

OBJECTIVE

Critical analysis of clinical safety of classical Ayurvedic formulations, viz. *Vyoshadi Guggulu* and *Haritaki Churna*, in the management of obesity (*Sthaulya*) and dyslipidemia.

MATERIALS AND METHODS

The formulations fulfilling the physicochemical standards and quality parameters, and prepared as per standard operating procedures, were procured from good manufacturing practices-certified companies for the studies. These two different clinical studies were approved by institutional ethics committee of all the participating centers and done in accordance with WHO Good Clinical Practice Guidelines. Both clinical trials were registered under Clinical Trial Registration of India. Open-label, multicenter clinical trial was carried out in selected peripheral institutes of CCRAS. Follow-up was done every 2 weeks to record the onset of any adverse reaction during the intervention.

Table 1: Composition of *Vyoshadi Guggulu* and *Haritaki Churna*

Sanskrit name	*Ratio*	*Botanical name*	*Part used*
Vyoshadi Guggulu[12]			
Shunthi	1 part	*Zingiber officinale Roscoe.*	Dried tuber
Maricha	1 part	*Piper nigrum* L.	Dried fruit
Pippali	1 part	*Piper longum* L.	Dried fruit
Chitraka	1 part	*Plumbago zeylanica* L.	Root
Musta	1 part	*Cyperus rotundus* L.	Rhizome
Vidanga	1 part	*Embelia ribes* Burm.f.	Dried fruit
Haritaki	1 part	*Terminalia chebula* Retz.	Dried fruit
Bibhitaki	1 part	*Terminalia bellirica* (Gaertn.) Roxb.	Dried fruit
Amalaki	1 part	*Emblica officinalis* Gaertn.	Dried fruit
Guguulu	9 parts	*Commiphora mukul* (Hook. ex Stocks) Engl.	Resin
Haritaki Chura[13]			
Haritaki	100 parts	*Terminalia chebula*	Dried fruit

The data obtained were analyzed to assess the safety of *Vyoshadi Guggulu* and *Haritaki Churna* through LFTs and KFTs.

Study I—Clinical Evaluation of *Vyoshadi Guggulu* and *Haritaki Churna* in the Management of Obesity (*Sthaulya*) (CTRI/2012/03/002527)

A total of 160 participants were enrolled in the trial from three peripheral institutes. Patients were screened in accordance with the inclusion and exclusion criteria and were recruited after obtaining the written informed consent. The patients were administered *Vyoshadi Guggulu* in a dose of 1.5 gm (3 tablets of 500 mg each) twice daily and *Haritaki Churna* in a dose of 3 gm twice daily for a period of 12 weeks (i.e., 84 days). Both the drugs were advised before food and with lukewarm water. After the end of treatment period of 12 weeks, patients were also followed without medications till 14 weeks to check any adverse reaction. Out of the total 160 patients enrolled in the study, 20 dropped out during the course of the study. Intention-to-treat analysis was done and the data of all those patients who have completed at least 14th day visit were imputed by last observation carried forward (LOCF) method. Patients who dropped out after baseline visit only were excluded from analysis. Hence, data of a total 160 patients were used for statistical analysis.

Study II—Clinical Evaluation of *Vyoshadi Guggulu* and *Haritaki Churna* in the Management of Dyslipidemia—(CTRI/2012/03/002528)

A total of 146 individuals were enrolled in the study conducted at 3 peripheral research institutes. Patients were screened in accordance with the inclusion and exclusion criteria and were recruited after obtaining the written informed consent. *Vyoshadi Guggulu* was administered orally in a dose of 1 gm (2 tablets of 500 mg each) thrice daily after food with lukewarm water and *Haritaki Churna* in a dose of 3 gm twice daily for 12 weeks. The trial drugs were administered for 12 weeks with a follow-up at the end of 14 weeks without any interventions. Total 146 subjects were enrolled in the study. Fifty dropped out during the course of the study. Intention-to-treat analysis was done, and the data of all those patients who have completed at least 14th day visit were imputed by LOCF method. Patients who dropped out after baseline visit only were excluded from analysis. Hence, data of a total 146 patients were used for statistical analysis.

Statistical Analysis

Laboratory parameters at the beginning and at the end of the trial period were compared using paired t-test. A p-value of <0.05 was considered significant. All statistical analysis was performed using Statistical Package for the Social Sciences (SPSS), version 15.0.

OBSERVATIONS

Effect of *Vyoshadi Guggulu* and *Haritaki Churna* on Obesity

Total 160 subjects completed the trial. The majority of the subjects were females (80.6%). About 91.3% knew how to read and write, 80% patients belonged to above poverty line, and 84.4% were non-vegetarian. It was also observed that maximum number of subjects (56.3%) were of *Pitta-Kaphaja Prakriti*. Table 2 shows the basic information and demographic profile of the subjects. Combination of *Vyoshadi Guggulu* and *Haritaki Churna* was found effective in the management of obesity which could be ascertained by its effect on the outcome parameters, viz., BMI, waist circumference, hip circumference, waist-hip ratio, lipid profile, and all the eight domains of Short form 36 (SF-36[14] Health Survey Questionnaire; $p < 0.001$). The effect of this treatment on LFTs and renal function tests was assessed at baseline and at day 84 of the trial. The values were within stipulated

Table 2: Demographic profile of the subjects in both clinical trials

Demographic profile	*Subject enrolled for obesity*	*Subject enrolled for dyslipidemia*
Sex		
Male	31 (19.4%)	52 (35.6%)
Female	129 (80.6%)	94 (64.4%)
Education		
Not able to read and write	14 (8.8%)	17 (11.6%)
Literate	146 (91.3%)	128 (87.7%)
Socioeconomic status		
Below poverty line	32 (20%)	25 (17.1%)
Above poverty line	128 (80.0%)	121 (82.9%)
Diet		
Vegetarian	25 (15.6%)	41 (28.1%)
Non-vegetarian	135 (84.4%)	105 (71.9%)
Prakriti		
Vataja		
Pittaja		2 (1.4%)
Kaphaja	42(26.3%)	1 (0.7%)
Vata-Pittaja	20 (12.5%)	35 (24.0%)
Pitta-Kaphaja	90 (56.3%)	105 (71.9%)
Vata-Kaphaja	8 (5.0%)	3 (2.1%)
Subjects completing the trial from different geographical locations		
Karnataka (Bengaluru)	55 (34.3%)	
Kerala (Cheruthuruthy)	54 (33.7%)	54 (37.0%)
West Bengal (Kolkata)	51 (31.8%)	
Punjab (Patiala)		51 (34.9%)
Andhra Pradesh (Vijayawada)		41 (28.1%)
Total	160	146

Values are expressed as n (%)

Table 3: Safety profile of the subjects of both clinical trials

	Effect of Vyoshadi Guggulu *and* Haritaki Churna *in obesity*				*Effect of* Vyoshadi Guggulu *and* Haritaki Churna *in dyslipidemia*			
Parameters	*BT*	*AT*	$*t-value*	*p-value*	*BT*	*AT*	$*t-value*	*p-value*
Liver function test								
SGOT (IU/L)	24.83 (10.372)	21.85 (8.550)	4.017	<0.001	25.60 (10.529)	23.60 (14.486)	2.462	<0.05
SGPT (IU/L)	28.49 (16.397)	23.29 (11.618)	5.962	<0.001	28.62 (18.921)	27.72 (23.120)	0.794	<0.5
Total protein (gm/dL)	7.29 (0.561)	7.24 (0.511)	1.151	<0.5	7.50 (0.511)	7.40 (0.515)	3.290	<0.001
Serum albumin (gm/dL)	4.25 (0.281)	4.09 (0.366)	6.344	<0.001	4.37 (0.386)	4.24 (0.421)	4.202	<0.001
Serum globulin (gm/dL)	3.03 (0.496)	3.15 (0.435)	2.659	<0.1	3.11 (0.401)	3.14 (0.377)	1.068	<0.5
Conjugated bilirubin (mg/dL)	0.17 (0.072)	0.16 (0.087)	1.705	<0.001	0.19 (0.160)	0.17 (0.090)	1.352	<0.5
Unconjugated bilirubin (mg/dL)	0.43 (0.198)	0.38 (0.180)	3.153	<0.002	0.46 (0.180)	0.43 (0.187)	0.958	<0.5
Serum alkaline phosphatase (U/L)	75.64 (25.948)	74.52 (24.327)	1.106	<0.5	–	–	–	–
Kidney function test								
Blood urea (mg/dL)	20.12 (5.417)	20.88 (15.491)	0.607	<1	20.66 (5.733)	19.62 (6.014)	2.386	<0.05
Serum uric acid (mg/dL)	4.84 (1.392)	4.68 (1.266)	2.252	<0.05	5.02 (5.035)	4.92 (5.000)	1.317	<0.5
Serum creatinine (mg/dL)	0.78 (0.180)	0.80 (0.676)	0.431	<1	1.15 (2.078)	1.09 (2.110)	0.718	<0.5

Values are expressed as mean (standard deviation), compared using paired t-test. *p-value of <0.05 has been considered significant; SGOT: Serum glutamic oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase

range during the entire trial period (Table 3, Graphs 1 to 3). Further, no adverse drug effect or adverse events were reported during the treatment period.

Effect of *Vyoshadi Guggulu* and *Haritaki Churna* on Dyslipidemia

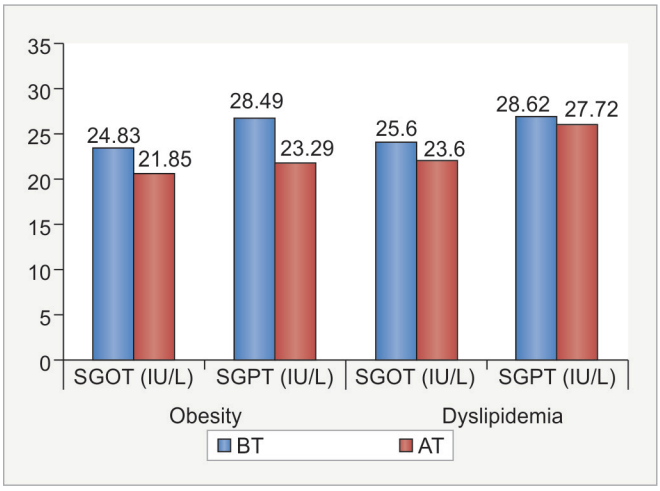
Total 146 subjects completed the trial. The majority of the subjects were females (64.4%), and 87.7% knew how to read and write. About 82.9% belonged to above poverty line, and 71.9% were non-vegetarian. It was also observed that maximum number of subjects (71.9%) were of *Pitta-Kaphaja Prakriti*. Table 2 shows the basic information and demographic profile of the subjects. Combination of *Vyoshadi Guggulu* and *Haritaki Churna* was found effective in the management of dyslipidemia which could be ascertained by its effect on the outcome parameters. There was a significant reduction ($p = 0.003$) in the mean serum cholesterol level. Moreover, mean HDL and mean scores of all the eight domains of SF-36 Health Survey Questionnaire were also statistically significant (p-value < 0.001) as compared before and after treatment. The effect of this treatment on LFTs and renal function tests was assessed at baseline and at day 84 of the trial. The values were within range during the entire trial period (Table 3, Graphs 1 to 3). Further, no adverse drug effect or adverse events were reported during the treatment period.

The data, regarding demographic profile and safety, obtained from both studies are given in Tables 2 and 3 and Graphs 1 to 3.

Open-label multicenter clinical trials were done in selected peripheral institutes of CCRAS to evaluate the safety and efficacy of *Vyoshadi Guggulu* and *Haritaki Churna* in the subjects of obesity and dyslipidemia, and the details are briefed in Table 4. Follow-up was done every 2 weeks to record the onset of any adverse reaction during the intervention and also after completing the study. The data, regarding demographic profile, efficacy, and safety, obtained from the both studies are given in Tables 2 and 3 and Graphs 1 to 3.

DISCUSSION AND CONCLUSION

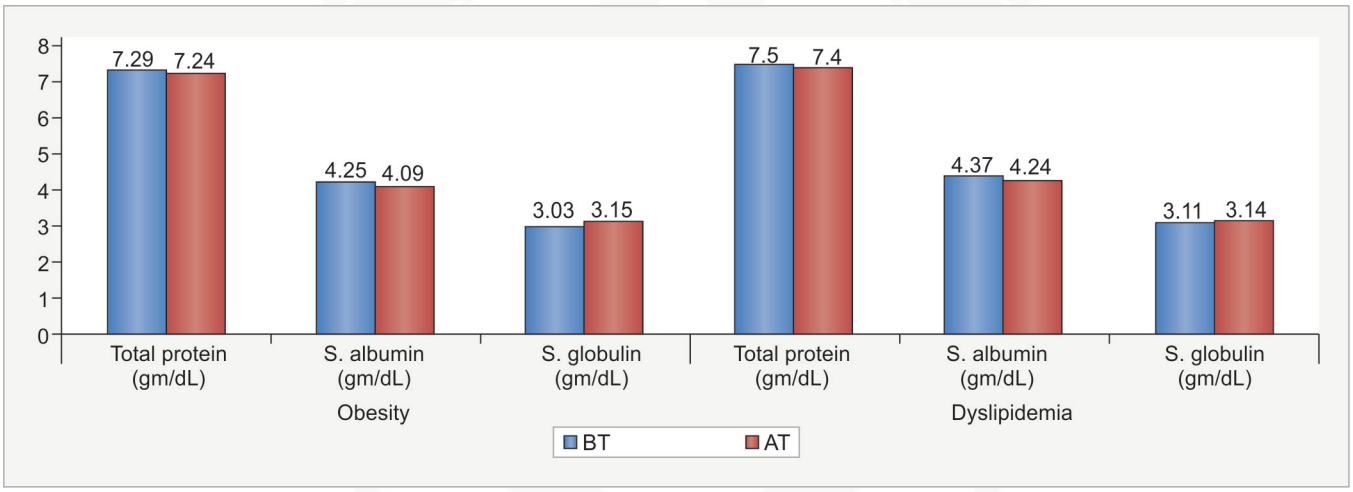
Kapha and *Medadhatu* play vital role in the pathogenesis of the *Sthaulya*. *Kaphavardhaka Ahara* (*Kapha* elevating food), absence of physical activities, and *Diwaswapna* (day sleep) leads to incomplete processing of *Anna Rasa* (consumed food), which is converted into *Ama Dosha*.[15] It leads to *Medodhtavagni Mandyata*. In the case of *Sthaulya*, the *Medadhatwagnimandya* leads to *Vriddhi* of *Medadhatu* and associated dyslipidemia. *Charaka* described *Sthaulya* is a *Santarpan janya vyadhi* and he recommended "*Guru cha Aptarpana*" *Chikitsa*. *Kapha Dosha* and *Meda Dhatu* are the main causative factors and mutually dependent on each other. So, any causative factor which increases *Kapha dosha* will result in the increase of *Medas* resulting to dyslipidemia. Apart from these two, *Vata* and *Agni* also plays an important role in pathogenesis of these diseases.[11] Hence the treatment must be focused on alleviating the *Vata* and *Kaphadosha,* besides taking care of increased *Medadhatu* and impaired *Agni*. The contents of *Vyoshadi Guggulu* and *Haritaki Churna* act as *Medoghana* (*Meda* alleviating), *Lekhana* (scraping), and *Kaphaghna* (*Kapha* alleviating). The contents of *Vyosadi Guggulu*, viz., *Triphala*, *Trikatu*, and *Trimada* are mainly *Ushna Virya*



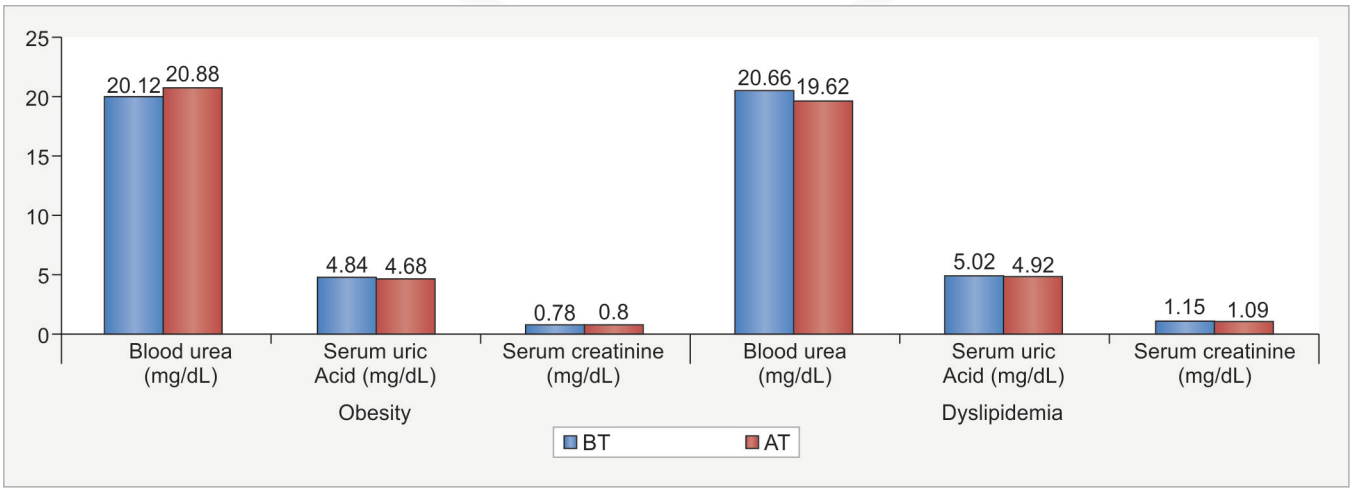
Graph 1: Comparison of LFT [SGOT (IU/L) and SGPT (IU/L)] before and after the trial in both the studies. SGOT: Serum glutamic oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase

and *Katu Rasa*.[16] *Purana* (old) *Guggulu* is mentioned as "*Atilekhana*: (drastic scraping) and "*Medohara*" (Meda alleviating), which possesses *Teekshna* (sharp/irritant) and *Vishada* guna. It acts as *Agnivardhaka* (promoter of digestive fire) and *Srotoshodhaka* (purifier of *Srotas*) due to its *Teekshna guna* (sharp/irritant property) and being *Vishada* (clear) it eliminates the *Snigdha* (unctuous) and *Picchila* (slimy) *Meda* and *Kapha*.[17]

Modern studies on the ingredients of *Vyoshadi Guggulu* and *Haritaki Churna* also have established their hypolipidemic, hypocholesterolemic, and anti-dyslipidemic actions. Oleo gum resin of *Guggulu* has been found to be effective in reducing serum cholesterol, estrogen-induced hyperlipidemia, and hypercholesterolemia.[18] Guggulsterone has reported to reduce serum cholesterol, triglyceride,[19] and having cardioprotective action.[20] 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. *Triphala* has also been found to have potent hypolipidemic effect and have shown to be potent in reducing hypercholesterolemia and atherosclerosis.[21,22] Piperine significantly possesses a lipid-lowering effect and anti-obesity activity without any change in appetite.[23] *Piper nigrum* L. extracts have shown results in reducing the



Graph 2: Comparison of LFT (total protein, serum albumin, and serum globulin) before and after trial in both studies



Graph 3: Comparison of KFTs (blood urea, serum creatinine, and blood urea) before and after the trial in both studies

Table 4: Brief description of studies conducted in the management of obesity and dyslipidemia

Name of study	*Study period*	*Study design*	*Number of centers*	*Current names*	*Sample size*	*Study interventions*	*Dosage schedule*	*Intervention period*
Clinical evaluation of *Vyoshadi Guggulu* and *Haritaki Churna* in the management of obesity (*Sthaulya*) CTRI/2012/03/002527	2011–2012	Open-label multicenter study	3	1 NARIP, Cheruthuruthy 2 CARIDD, Kolkata 3 RARIMD, Bengaluru	146	*Vyoshadi Guggulu* *Haritaki Churna*	Three tablets (500 mg each) BD with lukewarm water before food Three grams BD with lukewarm water before food	12 weeks
Clinical evaluation of *Vyoshadi Guggulu* and *Haritaki Churna* in the management of dyslipidemia CTRI/2012/03/002528	2011–2012	Open-label multicenter study	3	1 NARIP, Cheruthuruthy 2 CARIRD, Patiala 3 RARISD, Vijayawada	160	*Vyoshadi Guggulu* *Haritaki Churna*	Two tablets (500 mg each) TDS with lukewarm water after food Three grams BD with lukewarm water after food	12 weeks

NARIP: National Ayurveda Research Institute for Panchakarma, Cheruthuruthy; CARIDD: Central Ayurveda Research Institute for Drug Development, Kolkata; RARIMD: Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru; CARIRD: Central Ayurveda Research Institute for Respiratory Disorders, Patiala; RARIS: Regional Ayurveda Research Institute for Skin Disorders, Vijayawada

body weight, fat percentage, ameliorated HFD-induced hyperlipidemia, and its constituents.[24] Ginger (*Zingiber officinale* Roscoe, Zingiberaceae) has been reported to ameliorate hyperlipidemia, hyperglycemia, oxidative stress, and inflammation.[25] It has potential in managing obesity, accompanying with an intervention-genotype interaction effect.[26] The inhibition of intestinal absorption of dietary fat was reported by the active compounds of *Z. officinale*.[27]

Both drugs have *Kaphamedohara* (*Kapha* and *Meda* alleviating) action according to *Ayurveda*, and also there are evidences of these drugs having activity on lipid profile. Hence, administration of *Vyoshadi Guggulu* and *Haritaki Churna* for 12 weeks is very commonly used to cure conditions like hypercholesterolemia and obesity.

The purpose of these studies was to assess the safety profile of these formulations by comparing LFTs and KFTs before and after the treatment. Both formulations were given in different disease conditions, obesity and dyslipidemia, in different clinical studies executed in peripheral institutes of CCRAS. Although there was slight change in LFT and KFT before and after the *Ayurvedic* interventions, but the change was within normal limits. None of the patients complained of any adverse reaction or side-effects during these studies.

It can be concluded from these studies that these two *Ayurvedic* formulations are safe as far as liver and renal functions are concerned, and these were well tolerated by the participating subjects.

These studies ascertain that the *Ayurvedic* formulations are safer for short term and long term consumption as far as renal functions are concerned. The data collected from these studies provide a positive conclusion that the *Ayurvedic* medicines are safe. The *Ayurvedic* medicines are safe if each ingredient is procured after fulfilling standard guidelines and prepared under proper guidance. Further exploration with larger samples can be taken to establish the safety concern.

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हिंदी सारांश

स्थौल्य एवं डिस्लिपिडिमिया में चयनित आयुर्वेदिक योगों की निरापदता

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भूमिका: स्थौल्य शरीर में वसा की अत्यधिक मात्रा है। स्थौल्य कई बिमारियों के बढ़ते संकटों से जुड़ा हुआ है जैसे मधुमेह, हृदयरोग, डिस्लिपिडिमिया, स्ट्रोक आदि। सामान्यतया स्थौल्य में ट्राइग्लिसराइड्ज, कोलेस्ट्रोल, न्यून घनत्व वसा सामान्य से अधिक मात्रा में और महत्घनत्व वसा सामान्य से कम मात्रा में पाये जाते हैं। डिस्लिपिडिमिया में रक्त में लिपिड, ट्राइग्लिसराइड्ज, कोलेस्ट्रोल, न्यून घनत्व वसा तथा महत्घनत्व वसा सामान्य से अधिक मात्रा में पाये जाते हैं। हरीतकी चूर्ण एवं व्योषादि गुग्गुलु सामान्य रूप से स्थौल्य और डिस्लिपिडिमिया की चिकित्सा में प्रयुक्त होते हैं।

उद्देश्य: शास्त्रीय आयुर्वेदीय योगों यथा हरीतकी चूर्ण एवं व्योषादि गुग्गुलु का स्थौल्य और डिस्लिपिडिमिया के रोगियों में निरापदता के परिणामों का सांख्यकीय विश्लेषण द्वारा स्थापित करना है।

सामग्री व विधि: स्थौल्य और डिस्लिपिडिमिया प्रबंधन की दो औषधियों, हरीतकी चूर्ण एवं व्योषादि गुग्गुलु, का विशेष रूप से सुरक्षात्मक प्रोफाइल जांच करने के लिए सीसीआरएएस के विभिन्न परिधीय संस्थानों में पूर्ण किये गये दो विभिन्न चिकित्सकीय अध्ययनों से एकत्रित किये गये आंकड़ों के पूर्वव्यापी विश्लेषण से यह अध्ययन किया गया है। यह सुरक्षात्मक आंकलन यकृत कार्य परीक्षण एवं वृक्क कार्य परीक्षण के परीक्षण अवधि से पूर्व व पश्चात उपलब्ध आंकड़ों से किया गया है। प्रथम दिवस तथा अध्ययन अवधि पूर्ण पर औसत परिवर्तन में तुलना करने के लिये युग्मित नमूना टी–परीक्षण प्रयुक्त किया गया। इस अध्ययन से यह ज्ञात हुआ कि सभी मापदंड पूरी अध्ययन अवधि के दौरान निर्दिष्ट सीमाओं के भीतर थे।

निष्कर्ष: दो विभिन्न चिकित्सकीय अध्ययनों का निष्कर्ष स्पष्ट रूप से इंगित करता है कि हरीतकी चूर्ण एवं व्योषादि गुग्गुलु चिकित्सकीय रूप से सुरक्षित है। यह विभिन्न आयु समूहों, लिंग, भौगोलिक क्षेत्र व प्रकृति से जुड़े प्रतिभागियों के अच्छी तरह से नियोजित अनुसंधान अध्ययनों के परिणामों के माध्यम से समझा जा सकता है।