Clinical Efficacy and Safety of *Vyoshadi Guggulu* and *Haritaki Churna* in the Management of Obesity: A Prospective Open-label Multicenter Study

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**ABSTRACT**

**Background:** Obesity is a medical condition in which excess body fat has accumulated to the extent that it may have a negative effect on health. Obesity is most commonly caused by a combination of excessive food intake, lack of physical activity, and genetic susceptibility. Obesity can be compared with a condition called *sthalya* in Ayurveda.

**Aims and objectives:** To evaluate the efficacy and safety of *Vyoshadi Guggulu* and *Haritaki Churna* in patients suffering from obesity (*sthalya*).

**Materials and methods:** A prospective, open-label multicenter study was carried out at three peripheral centers of the Central Council for Research in Ayurvedic Sciences. A total of 165 obese patients satisfying the selection criteria were enrolled from the outpatient department of these centers and were administered *Vyoshadi Guggulu* (1.5 gm) twice daily before food with lukewarm water and *Haritaki Churna* (3 gm) twice a day before food for 12 weeks. Patients were also followed after 2 weeks of without medication period. Body mass index (BMI), waist circumference, hip circumference, and 36-item Short Form (SF-36) health survey questionnaire were assessed at an interval of 14 days each till 12 weeks (i.e., 84 days) and at the end of without drug follow-up period at 14th week. Paired sample *t*-test was used to compare mean change in BMI, waist circumference, and hip circumference from baseline to the 84th day. A *p*-value <0.05 was considered significant.

**Results:** At the end of treatment period of 84 days as compared with baseline, a statistically significant change in BMI, waist circumference, hip circumference, and waist–hip ratio was observed (*p*-value <0.001). A significant reduction in serum cholesterol level was also observed from a mean value of 187.79 at baseline to 183.84 at 84th day (*p*-value <0.022). Moreover, a significant improvement in all the eight domains of SF-36 health survey questionnaire was also observed (*p*-value <0.001)

**Conclusion:** *Vyoshadi Guggulu* and *Haritaki Churna* administered together in the above-mentioned dose were found effective and safe in patients suffering from obesity.

**Keywords:** 36-Item short form, Ayurveda, *Haritaki churna*, Obesity, *Sthaulya*, *Vyoshadi guggulu*.


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**INTRODUCTION**

Obesity is a condition analogous to descriptions of an Ayurvedic clinical condition called as “*Sthaulya*” in Sanskrit language. If a person’s weight is at least 10% in excess of the normal or desirable weight and with a body mass index (BMI) of 30 or more, then that person is considered obese. Lean but very muscular individuals may be overweight by arbitrary standards without having increased adiposity. It is a chronic disorder with complex interaction between genetic and environmental factors. It is characterized by high cholesterol, fatty acid levels, insulin desensitization, high blood pressure, and excessive adipose mass accumulation.1 A total of 2.8% Indian women and 1.3% Indian men are found to be obese, even overweight has been seen in 9.8% and 8.4% women and men respectively.2 In addition, there are predictions that by the year 2015, the prevalence of overweight subjects will reach around 40% (31% of men and 29% of women).3 Obesity is a major risk factor for a number of chronic diseases, including diabetes, cardiovascular diseases, and cancer.4 The most commonly found comorbidity is metabolic syndrome, which includes diabetes mellitus (type II), high blood pressure, high blood cholesterol, and high triglyceride levels.5
Obesity is currently on a dramatic rise in low and middle-income countries, particularly in urban settings. It has been predicted that by the year 2020, noncommunicable diseases will contribute to 43.3% of all deaths in India. At the global level according to the World Health Organization (WHO), in 2005, there were about 1.6 billion overweight persons aged 15 years and above, and among them at least 400 million adults were obese. Current obesity levels range from below 5% in China, Japan, and certain African nations to over 75% in urban Samoa, and it has been estimated that obesity contributes to 6 million deaths every year worldwide. Obesity can be understood in line with the description of sthālya or medoroga in Ayurveda. In this particular pathology, vata which is obstructed by meda dhatu enhances the activity of Agni in koshita, resulting in rapid digestion of food which in turn increases the craving for food. As medas obstruct the nourishment pathway, the other dhatus do not get nourished properly, resulting in the disproportionate increase of medas. Charaka Samhita describes the symptoms of sthālya as Ayuhrasa (decrease of life span), Javoparodha (decrease in enthusiasm and activity), Krichravyavayata (difficulty in sexual act), Dowrbalya (decrease of strength), Dowrgandhya (bad odor), Swedabadha (excess perspiration), and Kshut Pipasadhyaka (excessive hunger and thirst). This results mainly due to rasa and medo dushti.

These drugs were selected considering their special indication in obesity. Contents of Vyoshadi Guggulu are largely having uslma virya, mitigate kapha and vata, and improve agni, which helps in the management of sthālya. Both Vyoshadi Guggulu and Haritaki Churna (powder of Haritaki) are part of Ayurvedic prescriptions for overweight, obesity, hypercholesterolemia, and related conditions. This study was an attempt to comprehensively conduct a multidimensional evaluation (clinical, laboratory, and quality of life parameters) on the effect and safety of this combination on obesity.

OBJECTIVES

To evaluate the efficacy and safety of two classical Ayurvedic formulations Vyoshadi Guggulu and Haritaki Churna in the management of obesity.

MATERIALS AND METHODS

Study Design

The study was a prospective open-label multicenter trial executed at three peripheral centers of the Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH. The study was approved by the Institutional Ethics Committee of all the three participating centers and was done in accordance with WHO Good Clinical Practice guidelines. The clinical trial has also been registered in the Clinical Trial Registry of India (CTRI/2012/03/002527).

Study Participants

A total of 165 participants were enrolled in the trial from three peripheral institutes of the Central Council for Research in Ayurvedic Sciences, viz., Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru; Central Ayurveda Research Institute for Drug Development, Kolkata; and Central Ayurveda Research Institute for Neuromuscular & Musculo-Skeletal Disorders, Cheruthuruthy.

Patients were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol and were recruited in the study after obtaining written informed consent.

Inclusion Criteria

Patients of either sex aged between 18 and 65 years and with BMI $\geq$30 kg/m² and $<40$ kg/m², who were willing to participate in the study for 14 weeks were included.

Exclusion Criteria

Patients taking weight-losing drugs, appetite suppressants, pathophysiologic/genetic syndromes, having malignancy, uncontrolled diabetes mellitus (blood sugar fasting >250 mg/dL), poorly controlled hypertension (>160/100 mm Hg), on prolonged medication with corticosteroids, antidepressants, anticholinergics, etc., were excluded from the study. Further, persons suffering from major systemic illnesses like rheumatoid arthritis, tuberculosis, psychoneuroendocrinal disorders, etc., were also not included in the study. Persons with a past history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke or severe arrhythmia, clinical evidence of heart failure, concurrent serious hepatic disorder, renal disorders, severe pulmonary dysfunction, alcoholics, and/or drug abusers were not included.

Persons with prior surgical therapy for obesity and history of hypersensitivity to any of the trial drugs or their ingredients, pregnant/lactating women, and those who have participated in any clinical trial during the past 6 months were also excluded from the study.

Study Interventions

The patients were administered Vyoshadi Guggulu [Ayurvedic Pharmacopoeia of India (API) – Part II, Vol II; pp. 117–118] in a dose of 1.5 gm (3 tablets of 500 mg each) twice daily and Haritaki Churna (API – Part I, Vol I; pp. 62–63) in a dose of 3 gm twice daily for a period of
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12 weeks (i.e., 84 days). Both the drugs were advised before food and with lukewarm water. Both the Ayurvedic formulations were procured from Good Manufacturing Practice-certified Ayurvedic pharmaceutical industries and standardized following the standard laid in the API. After the end of the treatment period of 12 weeks, patients were also followed without medications till the 14th week.

Study Procedure

On the enrolment day at baseline (visit 1), patients’ demographic profile, medical history, family history particularly related to obesity, sharirik prakriti, and vital parameters were recorded. Subsequent visits were planned at an interval of 2 weeks [14th day (visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (visit 5), 70th day (visit 6), and 84th day (visit 7)]. Patients were assessed and given study medications at each subsequent visit till 84th day. There was also a without medication follow-up after 2 weeks of 84th day visit. Details of clinical assessment and study schedule are given in Flow Chart 1.

At the study site, data of all the patients were recorded in predesigned case report forms (CRFs) and were also entered in electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The e-formats and xerox of the CRFs along with the laboratory investigation reports of the patients were sent by the participating centers to the Council’s headquarters on a weekly basis for the purpose of clinical trial monitoring.

Out of the total 165 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 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. Flow Chart 2 shows the outflow of the patients in the study.

Outcomes

Primary outcome measure was change in BMI at 84th day from baseline. The secondary outcome measure was change in waist circumference and waist–hip ratio, change in lipid profile, and improvement in quality of life as assessed by 36-item Short Form (SF-36) health survey questionnaire compared at 84th day with baseline.

Statistical Analysis

Primary outcome and secondary outcome measures, i.e., BMI, waist circumference, waist–hip ratio, serum lipid profile, and all the eight domains of SF-36 health survey questionnaire were analyzed as mean change in the
response from baseline to 84th day by using paired t-test. A p-value <0.05 was considered significant. Analysis was carried out using Statistical Package for Social Sciences 15.0 version.

RESULTS

Data of a total 160 patients were used for statistical analysis. Majority of the patients were females, i.e., 80.6%. Demographic profile of the patients showed that 8.8% of the patients were illiterate and 91.3% knew how to read and write; 10.6% of the patients used to do desk work, 10.6% of the patients each either did fieldwork or fieldwork with physical labor, and 55% of the patients were housewives. It was also observed that maximum number of patients (56.3%) were of Pitta-kaphaja prakriti.

Table 1 shows the basic information and demographic profile of the patients.

Chief complaints faced by the patients suffering from obesity were assessed by visual analog scale (VAS) (0–100 cm). Table 2 gives the mean VAS score at baseline, at 84th day, and at follow-up at the end of 14th week for various chief complaints faced by the patients with obesity.

It was observed that Vyoshadi Guggulu and Haritaki Churna have been very effective in overcoming the chief complaints. It is evident from Table 2 that mean VAS score for the complaint of polyphagia reduced significantly from 33.5 at the baseline to 15.4 at 84th day (p-value <0.001). The mean VAS score for the complaint of mental stress reduced from 26.4 at baseline to 14.0 on 84th day (p-value <0.001) and reduced further to 12.4 at the end of without drug follow-up at 14th week. Statistically significant reduction (p-value <0.001) was also seen in all the other complaints like excessive sweating, body fatigue, loss of libido, palpitation, and excess sleep. It was also observed that the mean VAS score for all the complaints also reduced during the without medication follow-up period at the end of 14th week.

Combination of Vyoshadi Guggulu and Haritaki Churna has been found effective in the management of obesity, which could be ascertained by its effect on the outcome parameters, viz., BMI, waist circumference,
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A significant increase in BMI, waist circumference, hip circumference, and waist–hip ratio was observed (p-value <0.001) (Graph 1). A significant decrease in serum triglyceride level was also observed (p-value <0.05). Moreover, serum triglyceride level also decreased from a mean value of 125.64 at baseline to 121.34 at 84th day. However, the decrease was not statistically significant.

Vyoshadi Guggulu and Haritaki Churna have also been found effective in improving the quality of life of the patients as assessed by SF-36 health survey questionnaire. A statistically significant improvement in all the eight domains of SF-36 health survey questionnaire, viz., physical functioning, role limitations due to physical health, limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health, was observed (p-value <0.001). Moreover, it was also observed that mean score of all the eight domains was higher at 14th week (follow-up without medication) as compared with baseline scores (Graph 2).

**Effect of the Drugs on Safety Parameters**

The effect of this treatment on liver function tests and renal function tests was assessed at baseline and at 84th day. The values were within range during the entire

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**Table 3: Effect of the treatment on outcome parameters**

<table>
<thead>
<tr>
<th>Parameters (n = 160)</th>
<th>Baseline</th>
<th>84th day</th>
<th>Follow-up at the end of 14th week</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body mass index (kg/m²)</td>
<td>33.58 (2.62)</td>
<td>32.99 (2.67)</td>
<td>33.13 (2.72)</td>
<td>6.947</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>105.82 (7.96)</td>
<td>100.62 (7.93)</td>
<td>100.84 (7.85)</td>
<td>11.617</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Hip circumference (cm)</td>
<td>114.60 (7.35)</td>
<td>110.68 (6.95)</td>
<td>110.55 (7.08)</td>
<td>10.321</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Waist–hip ratio</td>
<td>0.923 (0.06)</td>
<td>0.907 (0.06)</td>
<td>0.910 (0.06)</td>
<td>4.889</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

**Lipid profile**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Baseline</th>
<th>84th day</th>
<th>Follow-up at the end of 14th week</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum cholesterol (mg/dL)</td>
<td>187.79 (33.76)</td>
<td>183.84 (34.59)</td>
<td>–</td>
<td>2.318</td>
<td>0.022*</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>125.64 (51.80)</td>
<td>121.34 (51.35)</td>
<td>–</td>
<td>1.977</td>
<td>0.064</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>118.03 (29.00)</td>
<td>118.80 (30.44)</td>
<td>–</td>
<td>0.344</td>
<td>0.733</td>
</tr>
<tr>
<td>VLDL (mg/dL)</td>
<td>26.56 (10.85)</td>
<td>25.36 (11.30)</td>
<td>–</td>
<td>1.383</td>
<td>0.169</td>
</tr>
</tbody>
</table>

**SF-36 health survey questionnaire**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Baseline</th>
<th>84th day</th>
<th>Follow-up at the end of 14th week</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>69.67 (22.98)</td>
<td>81.23 (18.74)</td>
<td>81.07 (18.98)</td>
<td>7.585</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Role limitation due to physical health</td>
<td>68.93 (43.18)</td>
<td>87.11 (31.04)</td>
<td>86.32 (31.66)</td>
<td>6.494</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Limitation due to emotional problems</td>
<td>75.47 (40.47)</td>
<td>87.00 (29.51)</td>
<td>88.67 (27.52)</td>
<td>4.229</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Energy/fatigue</td>
<td>56.16 (16.20)</td>
<td>67.04 (15.55)</td>
<td>66.67 (15.04)</td>
<td>9.054</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Emotional well-being</td>
<td>65.51 (17.69)</td>
<td>73.51 (16.05)</td>
<td>74.69 (14.78)</td>
<td>6.715</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Social functioning</td>
<td>79.62 (25.65)</td>
<td>87.68 (19.86)</td>
<td>87.64 (19.19)</td>
<td>5.060</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Pain</td>
<td>72.04 (21.48)</td>
<td>82.31 (19.96)</td>
<td>80.74 (20.40)</td>
<td>7.134</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>General health</td>
<td>49.22 (14.15)</td>
<td>56.00 (14.73)</td>
<td>57.92 (14.19)</td>
<td>7.694</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Values are expressed as mean (standard deviation); *Compared using paired t-test at baseline and 84th day; "p-value <0.05 has been considered as significant; HDL: High-density lipoprotein; LDL: Low-density lipoprotein; VLDL: Very low-density lipoprotein

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[Image: Graph 1: Effect of the drug on physical parameters]
trial period (Table 4, Graphs 3 to 5). These observations validate that these classical drugs are safe for human use. Further, no adverse drug effect or adverse events were reported during the treatment period.

**DISCUSSION**

Obesity is analogous to “Sthaulya” mentioned by Ayurvedic lexicons. *Sthaulya* has been considered as ninditiya (an impediment). In general, the etiology can be

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**Table 4: Effect of the treatment on safety parameters**

<table>
<thead>
<tr>
<th>Parameters (n = 160)</th>
<th>Baseline</th>
<th>84th day</th>
<th>t-value&lt;sup&gt;4&lt;/sup&gt;</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Urea (mg/dL)</td>
<td>20.12 (5.417)</td>
<td>20.88 (15.491)</td>
<td>0.607</td>
<td>0.544</td>
</tr>
<tr>
<td>Serum Uric acid (mg/dL)</td>
<td>4.84 (1.392)</td>
<td>4.68 (1.266)</td>
<td>2.252</td>
<td>0.026*</td>
</tr>
<tr>
<td>Serum Creatinine (mg/dL)</td>
<td>0.78 (0.180)</td>
<td>0.80 (0.676)</td>
<td>0.431</td>
<td>0.667</td>
</tr>
<tr>
<td>SGOT (IU/L)</td>
<td>24.83 (10.372)</td>
<td>21.85 (8.550)</td>
<td>4.017</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>SGPT (IU/L)</td>
<td>28.49 (16.397)</td>
<td>23.29 (11.618)</td>
<td>5.962</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Total Protein (g/dL)</td>
<td>7.29 (0.561)</td>
<td>7.24 (0.511)</td>
<td>1.151</td>
<td>0.251</td>
</tr>
<tr>
<td>Serum Albumin (g/dL)</td>
<td>4.25 (0.281)</td>
<td>4.09 (0.366)</td>
<td>6.344</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Serum Globulin (g/dL)</td>
<td>3.03 (0.496)</td>
<td>3.15 (0.435)</td>
<td>2.659</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Conjugated Bilirubin (mg/dL)</td>
<td>0.17 (0.072)</td>
<td>0.16 (0.087)</td>
<td>1.705</td>
<td>0.090</td>
</tr>
<tr>
<td>Unconjugated Bilirubin (mg/dL)</td>
<td>0.43 (0.198)</td>
<td>0.38 (0.180)</td>
<td>3.153</td>
<td>0.002*</td>
</tr>
<tr>
<td>Serum Alkaline Phosphatase (IU/L)</td>
<td>75.64 (25.948)</td>
<td>74.52 (24.327)</td>
<td>1.106</td>
<td>0.271</td>
</tr>
</tbody>
</table>

Values are expressed as mean (standard deviation); <sup>4</sup> Compared using paired t-test at baseline and 84th day; *p-value <0.05 has been considered as significant; SGOT: Serum glutamic oxaloacetic transaminase; SGPT: Serum glutamic pyruvic transaminase
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CONCLUSION

Vyoshadi Guggulu and Haritaki Churna form a part of the prescription of Ayurvedic doctors in the treatment of Sthautya and deranged lipid metabolic disorders. But till date, there has not been any systematic attempt to document the effect of this combination on specific subjective and objective outcome measures, and this study, therefore, attempts to document the same. The study proved that 84 days of treatment with a combination of Vyoshadi Guggulu and Haritaki Churna in patients with obesity has a significant role in reducing BMI, hip circumference, waist circumference, and serum cholesterol. Further, it improves the self-perceived status of health as assessed by SF-36 scale and significantly ameliorated clinical symptomatology of obesity. Nevertheless, a long-term treatment with Vyoshadi Guggulu and Haritaki Churna might have more substantial effects for achieving minimal risk in obese persons for noncommunicable disorders like cardiovascular disorders, diabetes, etc.

REFERENCES

सारांश

स्वास्थ्य की चिकित्सा में योगादि गुरुगुल एवं हरितकी चूर्ण की आलूर्ची ग्राह्यकारिता एवं सुरक्षा: एक प्रत्याशित बहुकेन्द्रीय ऑपेन लेबल अध्ययन

'के आर किशोर, "सोहित के रावत, "पी के एस नायर, "एस के निर्द, "बी एस शर्मा
"प्रदीप गुप्ता, "शुभि खण्डकी, "ब्रस्पा यादव, "प्रकेरेश राय, "आचा सिंधव,
"एन भीकार, "एन एम पाठक, "कश्यप लिंड भीमान

मूलिका: अध्ययन एक बहुकेन्द्रीय अध्ययन है जिसका स्वास्थ्य पर उत्तराधिकार पड़ता है। मूलान्तरण यह रोग अधिक्षर योगादि के जल्द करने के साथ योगादि के तथा उनके अनुप्रयोगिक तौर पर अध्ययन है। भौतिकीय के अलावा स्वास्थ्य का भी एक अहंकार अध्ययन है जो इस परिपथ के 3 सेंटी मी तक विश्लेषण के 165 रोगियों में दिखा गया।

अभिगत्व एवं चुनाव: हरितकी चूर्ण, योगादि गुरुगुल एवं सुरक्षा को अंग्रेजी वा रोगियों में देखा।

संख्या एवं विवरण: यह एक बहुकेन्द्रीय अध्ययन है जो इस परिपथ के 3 रोगियों पर विश्लेषण के 2 साल तक रोगियों की आवश्यकता की।

परिणाम: 54 दिनों का समाप्त होने पर पाए गए हैं कि सदिवाली तौर पर बी.एम.आई.। कमर परिसंपत्ति तथा निवेश परिसंपत्ति में महत्वपूर्ण परिवर्तन प्राप्त हुए।

प्रकाश: योगादि गुरुगुल एवं हरितकी चूर्ण इस अध्ययन के दौरान प्रभावशाली तथा स्वास्थ्य के रोगियों में सुतनित पाए गए।