

Evaluation of efficacy and safety of *Vrikshamlaadi yog* in *Sthaulaya*

Research Article

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Abstract

Obesity (*Sthaulaya*) is one of the commonest disease which affects adults and children equally. Obesity is not simply aesthetically ugly but is associated with a large number of metabolic disorders like hypertension, diabetes, ischemic heart diseases, osteoarthritis, etc. In 21st century, continuous changing life styles, environment and dietary habits have made man victim of many diseases. *Sthaulaya* (Obesity) is one of the most common disease which affects someone's social, physical and mental features. In Ayurveda *Sthaulaya* has been described since early days. *Acharaya Charaka* has mentioned *Sthaulaya* among eight undesirable persons (Ch.su.21) & *Santarpanjanitaroga* (Ch.su.23). There are more than a billion overweight people in the world.

Present study was conducted to explore evidence based therapeutic potential of *VRIKSHAMLAADI YOG* in *Sthaulaya*. The patients fulfilling the inclusion criteria and voluntarily willing for trial were registered from O.P.D. & I.P.D. Dept. of Kayachikitsa R.G.G.P.G.AYU Hospital, Paprola. Total 20 Patients were registered & turned for follow up after 8 weeks. The trial drug "*Vrikshamlakadi yog*" a combination of several herbal extract was given in fixed dose combination. As per assessment criteria 15 patients showed moderate Improvement, 4 showed mild/no improvement and 1 patient did not come for follow up. Statistical analysis showed all variables kept in assessment & evaluation criteria have significant positive improvement ($p < 0.001$). *Vrikshamlaadiyog* proved to be an effective and safe remedy for *Sthaulaya*.

Keywords: *Sthaulaya*, *Vrikshamlaadiyog*

Introduction

In Ayurveda *Sthaulaya* and medoroga (obesity) has been described in detail. *Acharaya Charaka* has mentioned *Sthaulaya* among eight undesirable persons (1) and considered it as *santarpanjanitaroga* which means diseases associated with excessive intake of food (2). There are more than a billion overweight people in the world.

Changing life styles, environment and dietary habits especially high carbohydrates diet, fats in diet, sedentary habits, stress, etc have made man victim of many non communicable diseases. Obesity (*Sthaulaya*) is one of the commonest disease which affects adults and children equally. Obesity is not simply aesthetically ugly but is associated with a large number of metabolic disorders like hypertension, diabetes, ischemic heart diseases, osteoarthritis, etc.(3)

Reports shows that obesity is killing more than 2,20,000 people in USA and Canada alone annually. The World Health Organization report 2002 represents

one of the largest projects ever undertaken by W.H.O., in collaboration with "expert's world wide" describes obesity a wakeup call to the global community"(4)

Obesity is a complex disorder involving an excessive amount of body fat. It is not just a cosmetic concern, it increases risk of diseases and health problems, such as heart diseases, Diabetes etc. Dietetic corrections, physiotherapy, drugs and surgery have been given options to obese patients to correct and control obesity. Expectations from herbal formulation are high because the use of anti- obesity drugs have to be prolonged and safety can only be assured by herbal formulations(5).

Current research proposal is small step to explore evidence based therapeutic potential of Ayurvedic herbal formulation "*Vrikshamlaadiyog*" in correction of obesity as an Anti-obesity formulation. In present short term clinical trial *Vrikshamlaadiyog*, shall be used in a dose of one capsule thrice a day in volunteers.

The trial formulation "*Vrikshamlaadiyog*" was prepared by Rudra Remedies Pvt. Ltd. It contains hydro-alcoholic extracts well known Ayurvedic herbs which are advised for use in obesity by Ayurvedic classics.

Aims and Objectives

1. To evaluate the efficacy of *Vrikshamlaadiyog* in management of Obesity on various subjective and objective parameters.
2. To evaluate the safety of Drug.

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Material and Methods

20 volunteers were selected from OPD and IPD of Post Graduate Department of Kayachikitsa Department of Rajiv Gandhi Govt. P.G. Ayurvedic College Hospital, Paprola. The selected volunteers were fulfilling the criteria irrespective of their age, sex, religion etc.

The selected obese volunteers were between age group of 18-65 years. Routine blood examination was carried out in order to rule out any other pathology and monitor their normal values of blood. The parameters were applied to confirm that the enrolled volunteers were obese on established criteria.

Since the constituents of the trial drug are well described in Ayurvedic classics for their use in obesity, Ethical Approval was not required as per guidelines of Ministry of Ayush, Government of India. Enrolled volunteers were fully made aware with nature of trial, trial drug, its constitutions and the fact that they shall have to stay in trial for desired trial duration. However they had liberty to withdraw from clinical trial as and when they feel so and for this they shall not require any type of permission.

Selection criteria

Inclusion criteria

A. **Subjective Criteria-** Registered volunteers need to have following signs and symptoms given in Ayurvedic classics:

- *Chalaspikudarasthana* - Pendulous buttocks, abdomen and breasts.
- *Kshudrashwasa* – Dyspnoea on effort.
- *Kshudhaatimatra* – Excessive appetite.
- *Pipasaatiyoga* – Excessive thirst.
- *Nidraadhikya* – Excessive sleep.

B. Objective criteria

- Body Mass Index (BMI)-
- It is calculated by formula:
- $BMI = \text{Weight (kg)} / \text{Height}^2 (\text{m}^2)$
- Volunteers having BMI more than 25 were included for study.
- Raised WAIST-HIP ratio.
- Body weight.
- Skin Fold Thickness.

Exclusion criteria

- Patient not willing for trial.
- Patient below age 18 and above age 65.
- Patient with advanced chronic disease.
- Alcohol and drug abuse.
- Patient with acute disorders.
- Drug induced Obesity/Secondary Obesity.
- Any other reason seems essential to not to include patient in trial.

Criteria of Assessment

Assessment was done on various subjective and objective criteria.

1. *KsudraShwasa* (Shortness of Breath)

No shortness of Breath	G0
Slight shortness of Breath after hard physical exertion	G1
Shortness of breath after mild physical exertion	G2
Shortness of breath even at rest	G3

2. *Pipasaatiyoga* (Excessive Thirst)

<1.5 litre/day	G0
1.5-2 litre/day	G1
2-3 litre/day	G2

3. *Kshudaatimatra* (Excessive hunger)

<2 chapati/day	G0
2-4 chapati/day	G1
4-6 chapati/day	G2
>6 chapati /day	G3

4. Weight reduction

No weight loss	G0
Upto 2 kg	G1
2-5 kg weight	G2
>5 kg weight	G3

5. *Nidraadhikya*

6-8hours/day	G0
8-10hours/day	G1
10-12hour/day	G2
12-14 hours/day	G3

6. *Chalaspikaudara Stanam* (Movements of body parts)

Absence of movements	G0
Little movements after fast activity	G1
Movement after mild activity	G2
Movement even an changing posture	G3

7. Skin fold Thickness Mid Bicep (in cms)

<2cm	G0
2.0-2.5	G1
2.6-3.0	G2
3.1-3.5	G3
>3.5	G4

Table no.1: Trial Drug “Vrikshamlaadiyog” and its constituents

Formulation Name	Vrikshamlaadiyog
Pharmaceutical form	Capsule
Dose	1 capsule
Route of administration	Oral
Frequency of administration	Thrice a day
Duration of administration	8 weeks
Ingredients	In table below
Storage	Moisture free environment

Constituents:

The trial formulations contained following herbs as their hydroalcoholic extracts and in the quantity mentioned. Two chemicals namely Tankan and Sphatika were also present in formulation. The formulation was prepared by Rudra Remedies.

Table no.2

S.no	Ingredients	QTY in mgm.	Latin name	Local name	Part used
1.	Sonth	35	<i>Zingiber officinale</i> Rosc.	Sonth	Rhizome
2.	Kallimirch	15	<i>Piper nigrum</i> Linn.	Kallimirch	Fruit
3.	Peepali	30	<i>Piper longum</i> Linn.	Peepali	Fruit
4.	Chitrakmool	35	<i>Plumbago zeylanica</i> Linn.	Chitrakmool	Root
5.	Harrarh	30	<i>Termanalia chebul a</i> Retz.	Harrarh	Fruit
6.	Vrikshaamla	100	<i>Garcinia indica</i> Chois	Kankushta	Fruit
7.	Vaivaring	35	<i>Verbena officinalis</i> L.	Vaivaring	Fruit
8.	Punarnava	40	<i>Boerhavia diffusa</i> Linn.	Punarnava	Root
9.	Shudhguggal	65	<i>Commiphora mukul</i> Engl.	Shudhguggal	Gum resin
10.	Tankan	40	<i>Sodii biboras</i>	Sodiibiboras	
11.	Phitkariphoola	40	Burned alum	Burned alum	
12.	Pipalamool	35	<i>Piper longum</i> Linn.	Piper longum	Root

Duration of Trial: 8 Weeks

Period of clinical study-

Start date: October 2015

Completion date- March 2016

Trial Group

The study was done in single trial group. It was an open trial with voluntary participation of subjects.

Study, Visits & Assessment-

The subjects visited the hospital at screening and enrollment and after 8 weeks of trial period.

Lipid profile was done at the time of enrollment and necessary laboratory investigations repeated at the time of completion of trial.

The efficacy of Vrikshamlaadiyog in weight reduction was evaluated by special proforma for assessment and evaluation which included grading for Shortness of breath, Pipasaatiyoga, Excessive hunger, Weight reduction, Nidraadhikya, Movements of body parts, Skin fold Thickness, BMI(kg/m²) etc.

Improvement categorized as GOOD, MODERATE & MILD.

Good Improvement:-

- No side effect
- Minimum 2 Grades improvement in 5 out of 8 other parameters.
- Reduction of >4 kg body weight
- >30% Reduction in >2 out of Serum cholesterol, Serum Triglyceride, LDL, VLDL.

Moderate Improvement

- Minimum 2 Grades improvement in 3-4 out of 8 other parameters.
- Reduction of 2-4kg body weight
- 15-30% Reduction in >2 out of Serum cholesterol, Serum Triglyceride, LDL, VLDL.

No Improvement

- Minimum 2 Grades improvement in 1-2 out of 8 other parameters.
- Reduction of <2kg body weight
- Upto 15% Reduction in >2 out of Serum cholesterol, Serum Triglyceride, LDL, VLDL.

Observations and Results:

20 Patients were registered & turned for follow up every 15 days.

As per assessment criteria out of 20 patients, 15 patients showed moderate Improvement & 4 showed mild/no improvement and 1 patient did not come for complete follow up. Statistical analysis shows all variables kept in Assessment & evaluation criteria have significant positive improvement (p<0.001).

The patients of all ages and both the sex groups reported improvement in their complaints.

No side/adverse effect found in any patient.

Symptom wise details-

1.KshudraShwasa (Shortness of Breath)-

Mean Score before treatment was 2.105 which fell to 1.105 showing improvement of 47.08% which was highly significant with t value of 9.25 and P<0.001

2.Pipasaatyoga(Excessive Thirst) -

Mean Score before treatment was 1.105 which fell to 0.31 showing improvement of 71.94% which was highly significant with t value of 4.84 and P<0.05

3.Kshudha(Excessive appetite)-

Mean Score before treatment was 2.57 which fell to 1.0 showing improvement of 61.08% which was highly significant with t value of 12.81 and P<0.001

4.Nidraadhikya(Excessive sleep)-

Mean Score before treatment was 1.526 which

fell to 0.42 showing improvement of 72.42 which was highly significant with t value of 7.31 and P<0.001

5.Chalaspikaudarasthana (Pendulous body)-

Mean Score before treatment was 1.368 which fell to 1.15 showing improvement of 21.8% which was not significant with t value of 1.711 and P>0.05

6.Body weight

Mean Score before treatment was 72.21 which fell to 69.15 showing improvement of 4.23% which was highly significant with t value of 15.86 and P<0.001

7.BMI(Kg/m2)-

Mean Score before treatment was 27.74 which fell to 26.60 showing a improvement of 4.10% which was highly significant with t value of 10.63 and P<0.001

8.Hip-Waist ratio-

Mean Score before treatment was 0.84 which fell to 0.82 showing a improvement of 23.80% which was highly significant with t value of 6.976 and P<0.001

9.Skin fold thickness-

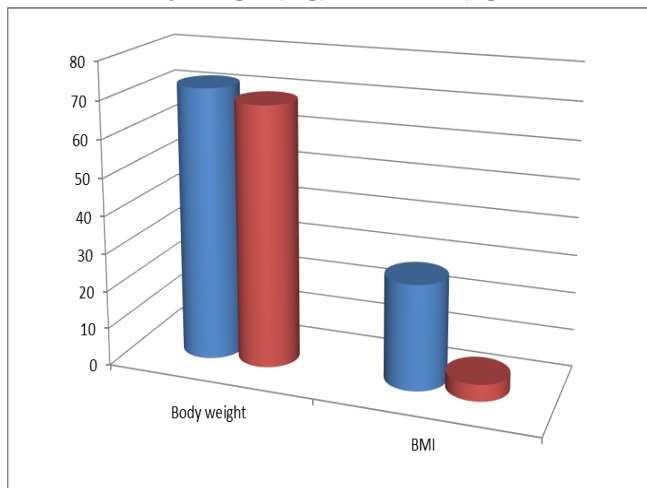
- **Mid-Bicep thickness-** Mean Score before treatment was 2.256 which fell to 2.17 showing a improvement of 3.81% which was highly significant with t value of 6.46 and P<0.001

- **Mid-Triceps thickness-** Mean Score before treatment was 2.35 which fell to 2.301 showing a improvement of 20.0% which was highly significant with t value of 3.0 and P<0.001

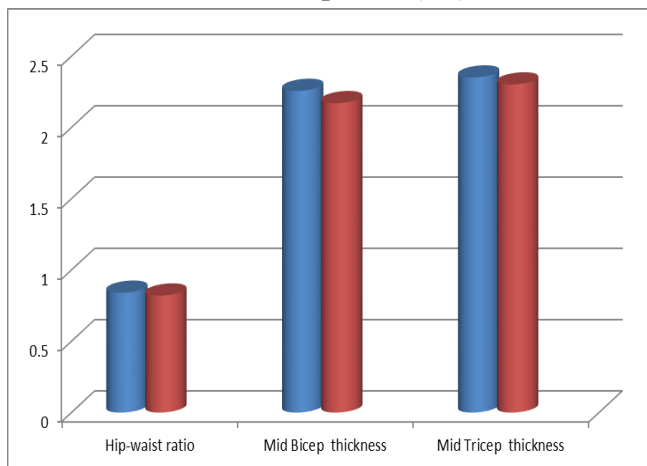
Table no.3: Showing above results shown in tabular & graph form

S.no.	Symptom	MEAN		% DIFF.	S.D.	S.E.	“t”	P
		BT	AT					
1	<i>Kshudrashwasa</i>	2.105	1.105	47.0	0.471	0.1080	9.25	<0.001
2	<i>Pipasa</i>	1.105	0.31	71.94	0.7132	0.163	4.84	<0.001
3	<i>Kshudha</i>	2.57	1.0	61.08	0.507	0.1165	12.81	<0.001
4	<i>Nidraadhikya</i>	1.526	0.42	72.47	0.42	0.657	7.31	<0.001
5	<i>Chalaspikaudharasthana</i>	1.368	1.15	21.8	0.5353	0.123	1.711	<0.05
6	Body weight	72.21	69.15	4.23	0.811	0.186	15.86	<0.001
7	BMI	27.74	26.60	4.10	0.422	0.097	10.63	<0.001
8.	Hip-waist ratio	0.84	0.82	23.80	0.019	0.0043	6.976	<0.001
9.	Mid Bicep thickness	2.256	2.17	3.81	0.0602	0.013	6.46	<0.001
10	Mid Triceps thickness	2.35	2.301	20	0.083	0.019	3.0	<0.001

Bar graph no.1: Showing improvement in Body weight(Kg) and BMI (kg/m²)



Bar graph no.2: Showing improvement in Hip-waist ratio(cm),Mid Bicep ratio(cm) and Mid Tricep ratio (cm)



Discussion-

The word Obesity is derived from Latin word ‘OBESUS’ which means having eaten. Obesity is defined as abnormal growth of adipose tissue due to enlargement of fat cell size or increase in cell number or combination of both (6).

It is also defined in terms of Body Mass Index. BMI>25 is categorized as overweight and BMI>30 is obese. Some authorities have considered BMI>27 as obese but studies suggest that morbidity begins to rise when BMI is above 25. Suggesting that the cut off for consideration of obesity should be lowered. (7)

Worldwide there has been an increasing trend in prevalence of obesity in developed as well as developing countries. The Trend is obviously being reflected in increasing prevalence of Metabolic Syndrome worldwide, which has important implication for future patterns of prevalence of Diabetes, Hypertension and Cardiovascular disease and their complications. Metabolic syndrome is highly prevalent clinical entity. Looking at various studies around the world , which included population sample aged from 20 -25 and upwards ,the prevalence varies from up to 80% (India) to 24%(US) in men and from 7% (France)to

46%(India) in women. Most genetic factors account for only one third of variance in body weight.(8)

Environmental factors involving both energy intake and energy output contributes to obesity. The fundamental cause of obesity epidemic are sedentary lifestyle and high fat energy dense diet.(9)

Obesity is associated with increased food consumption .Fat provides more energy than proteins and carbohydrates per unit weight and contributes to obesity. High fat food are preferentially selected by individuals because of their high palatability and weak satiety effect (10). Various researches have been carried out and many theories have been postulated as to how the fats lead to obesity. Researchers in Michigan University indicate that taste is responsible for High fat intake. There is relationship between dietary fat, membrane phospholipids and obesity. Modification in dietary fat profile have been shown to affect body weight gain and obesity. This may occur through changes in partitioning between oxidation , storage and alteration in membrane structure which in turn influences metabolic rate. (11)

A strong link exists between physical inactivity and weight gain. There is a possibility that this relation is bidirectional with obesity discouraging physical activity and inactivity promoting weight gain. Similarly there is strong relation between socio-economic status and obesity. Cultural factors are also important as these relate to both availability and composition of diet and changes in level of physical activity. (12)

Various ayurvedic formulations have been clinically tried to evaluate their effect on obesity in past e.g. Srivastava R.et.al.(2004) studied the effect of *Lashun* and *Vidanga* 2gm BD with water for 60 days and *Guggal yoga* 2gm BD for 60 days with water.

In the present study total 20 patients were registered, out of which 19 turned for follow up. *Vrikshamlakadiyog* was given in dose of one capsule thrice a day. The capsule had a fixed dose of herbal formulations in each capsule. All the criteria’s designed for evaluation of efficacy were evaluated and studied statistically.The data of present study establishes an excellent improvement in *Pipasa* (Thirst) and *Nidraadhikya* (excessive sleep). Patients also showed improvement in *kshudrakwasa* (Breathlessness), *Kshudha* (appetite). Marked improvement was found in weight loss and BMI. Slight improvement was found in Waist-Hip ratio and skin fold thickness. The patients of all ages and both the sex reported improvement in their complaints and lost weight.

No side/adverse effect contributable to trial formulation was reported by any volunteer.

Conclusion:

Findings of this study suggest that “*Vrikshamlakadiyog*” is effective in weight reduction. *Vrikshamlakadiyog* provide good results in term of efficacy on subjective and objective parameters.

No side/adverse effect was observed any volunteer which establishes the safety of trial formulation.

Financial support and sponsorship-

- Rajiv Gandhi Govt.P.G.Ayu.College and Hospital
- Rudra Remedies Pvt. Ltd.

Conflicts of interest

There are no conflicts of interest.

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