

AN OPEN LABELED CLINICAL TRIAL ON THE EFFECT OF VRIKSHAMLA IN STHAULYA (OBESITY) WITH SPECIAL REFERENCE TO HYPERLIPIDAEMIA

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ABSTRACT

Obesity is one of the leading causes for more than 53 diseases and in India around 30 million peoples are suffering with *Sthaulya* (obesity), individual habits with stressful life, wrong dietary habits and sedentary life is the main cause of disease and no satisfactory treatment is available in conventional system. Hence there is need explore alternative system of Indian medicine like Ayurveda for the benefits of sufferers Ayurveda dealt this disease as *sthaulya* (obesity) under *medoroga* (Adipose tissue disorder) and many treatment modalities have been explained number of drugs in *Brahatrayi* (Charaka shastra & Vagbhat) were cited *Bhavamishra* was the author of *Bhavaprakash Nighantu* (Lexicon) which is one of the *Laghutrayis* (*Sharanghadara, Madhavanidhama & Bhavaprakash*) text is highlighted with *Karmaoushadi* (action based drug) such as *Amradi phala varga* explained Vrikshamla considered as drug index of Ayurveda thus present study was designed to screen the drug with properties of *Kapha medohara* (ability to reduce *Kapha* & Fat) *Medorogahara* (reduces Adipose tissue) *Sthaulya-nashaka* (Anti-obesity) and *Karshyakara* (ability to make lean) from *Bhavaprakasha nighantu* in Ayurveda.

Keywords: Obesity, *Sthaulya*, drug *Vikshamla*, *Bhavaprakasha Nighantu*, Ayurveda.

INTRODUCTION

“Ancient Indian Vedic thought has now become globally acceptable with its universal terminology. Ayurveda believes that human being is an epitome of universe. And is basically composed of same elements that are known as five basic elements, namely *Prithvi, Aap, Teja, Vayu* and *Akasha*, all the five elements are called as *panchamahabhuta*, around the axis of *Panchamahabhuta* the three pillars of life are revolved. Ayurveda is based on the principle of *Tridoshas Vata*,

Pitta and *kapha*, these *tridoshas* are the basic constituents of the physiological system, and these *tridoshas* are basic metabolic elements constituting the body and mind of the living organisms. As we moved into rapid modernization by providing almost luxury to our day- to- day life, an average of person is unable to maintain individual’s health by not adopting proper dietary and daily activities as a result of which many diseases such as *sthaulya* or *medoro-*

ga/Hyperlipidemia occur. Therefore, Hyperlipidemia may be correlated with the conditions of *Santarpana-janya-vikara* as explained in our classics². So, for Concept of Hyperlipidaemia is the excess accumulation of lipids (Especially plasma lipids) in the body, leading various acute or chronic condition. "Ayurveda classics have also referred that "prayahasnehatmedaha-pravardhayet" Implies the fact that excess sneha is responsible for excess production of meda and such excessively produced meda causing avarodha or avarana of other, Dhatu leading to Medoroga/sthaulya-laxana as well as upadrava, here we can link the vikruti which is explained in Ayurveda with present modern knowledge about lipids. Therefore, need and relevance of proposed research study for obesity/ Hyperlipidemia is a common disorder of recent days, it affects about 25% of total population, mostly the people of developed countries as well as developing countries are said to be suffering from this condition. Blood levels of cholesterol and triglycerides give valuable information for the assessment of errors in lipids-metabolism. Various surveys in USA and European countries have shown a definite correlation between a high incidence of coronary heart diseases and raised cholesterol and triglyceride levels in the body, conversely in some eastern countries the average of cholesterol level is low, as well as the incidence of coronary heart diseases. In India the incidence of Hyperlipidemia and related disorders are increasing every year as the evidence of positive correlation between LDL cholesterol and cardiovascular diseases. There is even stronger negative correlation with HDL higher the plasma HDL level, the lower risk of cardiovascular diseases. Diagnosis of Hyperlipidemia is done by clinical and laboratory investigations, If Hyperlipidemia is diagnosed the prime aim is to bring back the high cholesterol level to normal levels, the LDL triglycerides and total cholesterol levels should be lowered and HDL level should be increased by diet control and drug therapy which has equal importance in controlling the disease. Impairment of various enzymes is the cause for Hyperlipidemia, Ayurveda considers that the cause of all these conditions are Agni-vikruti, here Jatharagni, Bhutagni and

Dhatwagni are involved. In this regard approach of ayurveda is safer, comprehensive and rational. In this present study the drug or medicine is selected Vrikshamla which is indicated in sthaulya/ medovriddhi/santarpana-janya-vikaras. Accumulation of ama and vitiated dhatus are seen in this condition, these drugs have Deepana –Amapachana-kaph & meda shaman-Anulomana properties. Which forcefully clears the accumulated and improper dhatus and malas from the Dhatus and removes deposited malas from the srotas and make dhatus and srotas clear and normal which can be used in this condition. In the pathology of Sthaulya, Kapha is main Dosha and Meda is main Dushya, while Agnimandya takes place at Medodhatvagni level. So, that type of drug therapy should be selected which 'have Kapha and Medohara property and have efficacy to correct the function of Medodhatvagnimandya. So many preparations have been mentioned in our texts for the treatment of Medodhatu Vridhi. But keeping in mind easy availability, compatibility, cost and preparation of drug Vrikshamla⁸ were preferred & select for present study.

Aim and Objectives

1. To evaluate the Therapeutic effect of Vrikshamla in Sthaulya (Obesity).
2. To evaluate the Therapeutic effect of Vrikshamla in Medoroga/Santarpanajanya- Vikaras.

Materials and Methods

A) Inclusion criteria:

- 1) Both Males & females will be selected
- 2) Patient will be selected from the age group 20-50 years
- 3) Lipid profile level
 - a) Serum ch. Above -200 mg/dl
 - b) Serum tri. above -165mg/dl
 - c) LDL above – 150mg/dl
 - d) HDL below – 70mg/dl
- 4) Patient of sthaulya diagnosed according to classical features.
- 5) Patients with BMI above -30

B) Exclusion criteria

- 1) Patients below the age of 20 years and above the 50 years.

- 2) Patients undergoing other treatment for *sthaulya* (obesity).
- 3) Known cases of Diabetes mellitus (*Madhumeha*), Hyperthyroidism, Thyrotoxicosis, Nephrotic syndrome, Hypertension, Cardiac patients, Gouty arthritis, Infectious diseases, Endocrinal and CNS disorders.
- 4) Hepatic Disorders

Diagnostic Criteria

Assessment of Subjective Parameters for Subjective Parameters Following Symptoms Will Be Assed

- *Kshudha Aadhikya* (Excessive hunger)
- *Pipasa Aadhikya* (Excessive thirst)
- *Kshudra Shwasa* (Breathlessness)
- *Swedaadhikya* (Excessive sweating)
- *Atinidra* (Excessive sleep)
- *Daurbalya* (General debility)
- *Gaurava* (Heaviness of the body)
- *Alasya* (Letharginess)
- *Angasada* (Sluggishness of the body)
- *Krichchavyavayata* (difficulty in sexual intercourse)

Objective Parameters:

- 1) Body weight- BMI= Kg/m²
- 2) Body Mass Index (BMI)
- 3) Body circumference measurements (at upper mid arm, chest, abdomen, waist-hip)
- 4) Blood pressure
- 5) Lipid profile Test.

Serum ch. Above -200 mg/dl

Serum tri. above -165mg/dl

LDL above – 150mg/dl

HDL below – 70mg/dl

Design of Study

➤ Single Arm trial

➤ Sample size 60

Statistical analysis: Paired ‘t’ test & other appropriate statistical tests will be adopted

Intervention

Vrikshamla Capsule 500mg BD before meal with Lukewarm water

Duration of the Study

60 days

Follow up

Follow up will be done in every 15 days

Drug *Vrikshamla* (*Garcinia cambogia*)

Ayurvedic Pharmacodyanamic

Rasa: *Madhura, Amla, Katu* (*Amlarasa* dominant)

Gana: *Ruksha, Laghu*

Virya: *Ushna*

Vipaka: *Amla*

Karma: *Hridya, Medohara*

Doshaghnata: *Kapha-Vatahara*



***Vrikshamla* (*Garcinia Cambogia*)**

Botanical Classification

Kingdom	Plantae	Order	Malpighiales
Subkingdom	Tracheobionta	Family	Clusiaceae
Division	Magnoliophyta	Genus	Garcinia
Class	Magnoliopsida	Species	<i>Garcinia cambogia</i>
Subclass	Dilleniidae		

Chemical Composition

The fruits of *Vriksamala* contain 10% maleic acid and very little quantity of tartaric and citric acid. Garcinia is a rich source of active compounds including garcinol, isogarcinol, xanthochymol, isoxanthoehymol and Hydroxy citric acid. These are flavonoids, benzophenones, xantho-

nes, lactones and phenolic acids. Xanthenes are oxygenated heterocyclic compounds present in higher plants. Xanthone nucleus is symmetric and is known as xanthen-9H-ones or 9- xanthenone or dibenzo-γ-pyrone. The biological activities of these compounds depend on the different substituent's position and nature. Flavonoids are polyphenolic

compounds, which are remarkable group of plant metabolites. The antioxidant and free radical scavenging activity of flavonoids depend on the position of hydroxyl groups and other chemical features. Benzophenones are organic group of aromatic ketones having the parent compound diarylketone, which have wide applications in pharmaceutical industry as the plant has a wide range of biologically active compounds showing broader activity range.

Ayurvedic Pharmacodynamic

Rasa : Madhura, Amla, Katu (Amlarasa dominant)

Gana : Ruksha, Laghu

Virya : Ushna

Vipaka : Amla

Prabhava: Hridya,

Doshagnata: Kapha-Vatahara



Vrikshamla (Garcinia Cambogia)

Parts Used: Fruits, Seed oil, Root bark

Dose: 2 to 4 gm powder. Fruit Juice-10 to 20 ml,

Fruit extract- The usual dose of Garcinia extract is 300 to 500mg BD before meal with water.

Vrikshamla (Extract): The extract (water based) of *Vrikshamla* fruits has *Amla, Katu* and *Madhura Rasa*. It also has *Laghu* and *Ushna Guna* with predominance of *Vayu* and *Agni Mahabhuta*. The *Deepana, Pachana* and *Kapha-Medohara* properties of *Vrikshamla* are also mentioned in Ayurvedic literature. Due to its *Laghu* and *Ushana Guna* it digests the *Amasanchaya* and clears the *Srotorodha*. It contains mainly *Amla Rasa* which has the property of *Agnideepana* also predominance of *Vayu* and *Agni Mahabhuta* makes it *Laghu Dravya* having inherent tendency of *Agnisamdhuksana* (Ch.Su.-5/6). So, based on these factors it is quite acceptable that *Vrikshamla* digest the *Amasanchaya*, clears the *Srotorodha* and improves the status of *Jatharagni* and *Dhatvagni*. Moreover, modern science has also shown interest in *Vrikshamla*. Many studies have shown that intake of HCA present in *Kokam* reduces appetite, inhibits lipogenesis and reduces body weight.

Assessment Criteria (It is Review of Literature)

Clinical-Grading (subjective parameters)

In the present clinical study, all the cases of *sthaulya* (obesity) Will be assessed with the specific subjective and objective parameters at a regular interval of 15 days.

All the above symptomatic assessment will be done by using Symptom Rating Scale as following:

Table 1: Assessment of Subjective Parameters

Symptoms:	Score:
Absent	0
Mild (Irregular)	1
Mild (Regular)	2
Moderate	3
Severe	4

Table 2: Assessment of *Kshudha Aadhikya* (Excessive hunger)

0 — becomes hungry after about 6hrs
1 — becomes hungry after about 4-5 hrs
2 — becomes hungry after about 3hrs
3 — becomes hungry after about 2-3hrs
4 — becomes hungry after about 2hrs

Table 3: Assessment of *Pipasa Aadhikya* (Excessive thirst)

0-	Drinks about 8-10 glass of water daily
1-	Drinks about 10-15 glass of water daily
2-	Drinks about 15-20 glass of water daily
3-	Drinks about 20-25 glass of water daily
4-	unable to have a sound sleep for his thirst

Table 4: Assessment of *Kshudra Shwasa* (Breathlessness)

0-	No shortness of breath
1-	Mild Dyspnoea after physical exertion relieved on rest
2-	Moderate Dyspnoea after physical exertion
3-	Dyspnoea even after daily routine
4-	Breathless even at rest

Table 5: Assessment of *Swedaadhikya* (Excessive sweating)

0-	Normal perspiration
1-	Mild perspiration after doing exertion
2-	Increased perspiration after doing little exertion
3-	Profuse perspiration after doing little exertion
4-	Perspiration without exertion

Table 6: Assessment of *Atinidra* (Excessive sleep)

0-	— 6-8 hrs/day sleep
1-	— 8-10hrs/day sleep
2-	— 10-12 hrs/day sleep
3-	— 12-14 hrs/day sleep
4-	- >14 hrs/day sleep

Table 7: Assessment of *Daurbalya* (General debility)

0-	— Feeling of well being
1-	— Tired after doing strenuous physical activity
2-	— Tired after doing moderate physical activity but can-do daily activity
3-	— Perform daily activity with difficulty
4-	— Extremely tired to carry out daily routine activity

Table 8: Assessment of *Gaurava* (Heaviness of the body)

0-	— No feeling of heaviness.
1-	— Occasional feeling of heaviness.
2-	— Continuous feeling of heaviness, but patient does usual work.
3-	— Continuous feeling of heaviness which hampers usual work.
4-	— Unable to do any work due to heaviness.

DISCUSSION

In Ayurveda the action of drug is determined on pharmacodynamic factors as *Rasa-Guna-Veerya* and *Vipaka* along with certain specific properties called as *Prabhava*

(Karma) *Vrikshamla (Extract)*: The extract (water based) of *Vrikshamla* fruits has *Amla, Katu* and *Madhura Rasa*. It also has *Laghu* and *Ushna Guna* with predominance of *Vayu* and *Agni Mahabhuta*. The *Deepana, Pachana*

and *Kapha-Medohara* properties of *Vrikshamla* are also mentioned in Ayurvedic literature. Due to its *Laghu* and *Ushana Guna* it digests the *Amasanchaya* and clears the *Srotorodha*. It contains mainly Amla Rasa which has the property of *Agnideepana* also predominance of Vayu and *Agni Mahabhuta* makes it *Laghu Dravya* having inherent tendency of *Agnisamdrukshana* (Ch.Su.-5/6). So, based on these factors it is quite acceptable that *Vrikshamla* digest the *Amasanchaya*, clears the *Srotorodha* and improves the status of *Jatharagni* and *Dhatvagni*. Moreover, modern science has also shown interest in *Vrikshamla*. Many studies have shown that intake of HCA present in *Kokam* reduces appetite, inhibits lipogenesis and reduces body weight.

CONCLUSION

The present review on Anti-Obesity drug *Vrikshamla* mentioned *Bhavaprakasha Nighantu*. The management of *Sthaulya*/Metabolic syndrome in conventional system of medicine is still not satisfactory and warranting newer strategies from other resources, it seems to explore an Ayurveda inspired line of management for treating *Sthaulya* (Obesity) or Metabolic syndrome and preventing its life threatening complications in the present clinical work *Vrikshamla* (*garcinia combogia*) is selected as trail drug for treatment of *Sthaulya* (Obesity) because of its *Medohara* (Reduce fat) cardio protective, Anti-Oxidant and lipid per oxidation, in habitation properties. This review of literature may be further evaluated for clinical utility and planning of the treatment of *Sthaulya* (obesity).

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