

# Evaluation of the Efficacy and Safety of Ayuraksha Vati in the Management of Sthaulya (Obesity): A Pilot Clinical Study

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## Abstract

Obesity is increasingly recognized as an important metabolic disorder resulting from unhealthy eating habits, sedentary routine, inadequate physical activity, and rising psychological stress. It is frequently associated with several health problems such as diabetes mellitus, hypertension, dyslipidemia, cardiovascular diseases, infertility, and diminished quality of life. In Ayurvedic science, obesity is comparable to *Sthaulya*, a condition produced by weakened digestive and metabolic functions (*Agnimandya*), vitiation of Kapha Dosha, abnormal increase of Medo Dhatu, and blockage of body channels (*Srotorodha*).

The present pilot clinical study was carried out to assess the therapeutic efficacy and safety of **Ayuraksha Vati**, a *Ghan Vati* formulation prepared from **Kutki (Picrorhiza kurroa)**, **Guggulu (Commiphora mukul)**, and **Haritaki (Terminalia chebula)**, in patients suffering from Sthaulya. The selected participants received the trial medicine along with advised dietary regulation and lifestyle modifications for the planned treatment period. Clinical assessment was performed through subjective parameters such as breathlessness (*Kshudra Shwasa*), excessive appetite (*Atikshudha*), excessive sleep (*Atinidra*), laziness (*Alasya*), weakness (*Daurbalyata*), fatigue (*Klama*), reduced enthusiasm (*Utsahahani*), and sensation of heaviness in the body (*Gaurava*). Objective assessment included body weight, body mass index, waist circumference, waist-hip ratio, and biochemical investigations including lipid profile.

The intervention demonstrated notable improvement in both symptomatic complaints and measurable clinical parameters after completion of therapy. No significant adverse reactions or unwanted effects were observed during the treatment period, suggesting good safety and tolerability of the formulation. On the basis of these observations, Ayuraksha Vati may be considered a safe, effective, and comprehensive Ayurvedic approach for the management of obesity by targeting the underlying metabolic imbalance.

**Keywords:** *Sthaulya*; *Obesity*; *Ayuraksha Vati*; *Ghan Vati*; *Ayurveda*; *Medoroga*

## 1. Introduction

Obesity is presently recognized as one of the major public health concerns worldwide, with a continuously increasing prevalence in both developed and developing countries. As per global health estimates, more than **1.9 billion adults were overweight in 2022**, and among them, over **650 million were obese**. Since 1975, the incidence of obesity has risen nearly threefold, mainly due to urbanization, sedentary routine, unhealthy food choices, and decreased physical activity. If this trend persists, a large segment of the world population may become overweight or obese in the future. India is also facing a rapidly growing burden of obesity and is counted among the nations with a high number of affected individuals. Recent surveys indicate that nearly **24% of adult women** and **23% of adult men** fall under the category of overweight or obesity, demonstrating the increasing prevalence in both sexes.

Obesity should not be considered only as excess body weight; rather, it is a multifactorial metabolic disorder that predisposes individuals to several complications such as diabetes mellitus, hypertension, dyslipidemia, cardiovascular diseases, osteoarthritis, infertility, polycystic ovarian syndrome, sleep disturbances, and reduced longevity. In addition

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to physical illness, it may also lead to emotional and social problems including poor self-confidence, anxiety, depression, and diminished quality of life. Therefore, proper prevention and management strategies are essential.

In Ayurvedic literature, obesity can be correlated with *Sthaulya* or *Medoroga*. Acharya Charaka has included *Atisthauilya* among the *Ashta Nindita Purusha* and described it as a condition resulting from excessive accumulation of *Meda* and *Mamsa Dhatu*. Such individuals may suffer from lethargy, reduced physical capacity, breathlessness on exertion, excessive appetite, excessive thirst, and shortened lifespan. The pathogenesis of *Sthaulya* primarily involves *Agnimandya* (diminished digestive and metabolic activity), vitiation of Kapha Dosha, increase in Medo Dhatu, formation of *Ama*, and obstruction of body channels (*Srotorodha*).

Ayurveda advocates management by correcting the basic pathology through *Nidana Parivarjana* (elimination of causative factors), *Deepana*, *Pachana*, *Lekhana*, *Langhana*, dietary discipline, and healthy lifestyle practices. Although modern treatment modalities include anti-obesity medications and surgical procedures, these approaches may be associated with side effects, recurrence, and higher cost. Hence, there is increasing interest in safer and more sustainable therapeutic alternatives.

**Ayuraksha Vati** is a *Ghan Vati* preparation composed of **Kutki (Picrorhiza kurroa)**, **Guggulu (Commiphora mukul)**, and **Haritaki (Terminalia chebula)**. These drugs are traditionally known for their *Deepana*, *Pachana*, *Lekhana*, *Medohara*, and *Srotoshodhaka* properties, which may help regulate metabolism and reduce excess adiposity.

Therefore, the present pilot clinical study has been designed to evaluate the therapeutic role of **Ayuraksha Vati** in the management of *Sthaulya*. The formulation will be administered and its effects will be assessed systematically according to Ayurvedic clinical principles through subjective symptoms, anthropometric parameters, and biochemical investigations.

## 2. Aim

To evaluate the efficacy and safety of **Ayuraksha Vati** in the management of *Sthaulya* (Obesity) through clinical and measurable assessment parameters.

## 3. Objectives

- To assess the therapeutic effect of **Ayuraksha Vati** in the management of *Sthaulya* (Obesity).
- To observe the changes in anthropometric measurements such as body weight, BMI, waist circumference, and waist-hip ratio after treatment.
- To evaluate the influence of the trial drug on biochemical parameters including lipid profile.
- To determine improvement in associated clinical features through regular follow-up.
- To study the safety and tolerability of **Ayuraksha Vati** during the course of treatment.

## 4. Importance of Present Study

- Obesity is an increasingly prevalent metabolic disorder that is linked with complications such as diabetes mellitus, hypertension, dyslipidemia, cardiovascular diseases, and impaired quality of life. Therefore, effective and safe treatment approaches are highly essential.
- **Ayuraksha Vati**, prepared with Kutki, Guggulu, and Haritaki, is known for its *Deepana*, *Pachana*, *Lekhana*, and *Medohara* actions, which may be useful in the management of *Sthaulya*. Clinical evaluation of this formulation may help to validate its therapeutic role.

- The present study is intended to provide evidence regarding the efficacy and safety of Ayuraksha Vati, which may support the use of a cost-effective, holistic, and sustainable Ayurvedic approach for obesity management.

## 5. Materials and Methods

### Selection of Sample

Patients fulfilling the diagnostic and inclusion criteria of *Sthaulya* (Obesity) were selected irrespective of sex, religion, occupation, and socioeconomic status.

### Source of Patients

10 clinically diagnosed patients of obesity were selected from the OPD/IPD of the Department of Kayachikitsa, Shri Khudadad Dungaji Government Ayurved College and Hospital, Raipur, Chhattisgarh.

### Drug Preparation

The trial drug **Ayuraksha Vati** was prepared in the form of *Ghan Vati* using the ingredients **Kutki, Guggulu, and Haritaki** in appropriate proportion as per classical pharmaceutical procedure under proper supervision.

## 6. Treatment Schedule

### 1. Patient Preparation

Before starting the trial drug, *Deepana, Pachana, and Koshtha Shuddhi* were done. For this, **Sanjeevani Vati** was given in a dose of **2 tablets twice daily** with lukewarm water for **7 days**. Along with this, **Triphala Churna 5 gm** was given at bedtime with lukewarm water. After proper preparation of the patient, the trial medicine was started.

### 2. Posology

S.No	Medicine	Route	Form	Dose/ Frequency	Anupana	Time	Durat ion	During treatment follow up	Post trial follow up
1.	<b>Ayuraksha vati</b>	Oral	Ghanvati	1gm * 3 times =3gms 500mg 2 tab/3 times a day	Lukewarm water	Morning, afternoon, evening before meal	60 days	15 days	30 days

## 7. Inclusion Criteria

- Age above 20 and below 60 years.
- Both male and female
- Patients must have features described under *sthaulya* in Ayurvedic texts i.e. *medo vriddhi* (excess fat deposition), Reduced physical activity tolerance, excessive sweating, laziness, heaviness, *kshudra shwasa*, *Atikshudha*, *Atitrishna*, etc
- BMI >30KG/M<sup>2</sup>, Uncomplicated case of Obesity grade I, Obesity grade II, Obesity grade III.

- v. Willing patients who are ready to follow Ayurvedic treatment protocol, have signed written informed consent to participate in the study.
- vi. Those who are physically and mentally capable to adhere dietary advise , attend regular follow-ups.

### 8. Exclusion Criteria

- i. Grade IV obesity & Uncontrolled medical conditions like hypertension, diabetes mellitus (FBS>200mg/dl), hypothyroidism, Pcod, heart diseases, chronic kidney disease, liver disorders, acute T.B., obstructive pulmonary disease.
- ii. Primary cardiac conditions like acute coronary syndrome , myocardial infarction , cardiac arrhythmias, and /or cardiac failure in last 6 months will be excluded from study
- iii. Pregnant and lactating women.
- iv. Psychiatric or cognitive disorder.
- v. Person with Alcohol or drug dependency

### 9. Termination of Study

The case with following complications will be withdrawn from the study

- i. If any type health emergency in the patient.
- ii. If any kind of adverse effect of medicine patient quit with own choice.
- iii. Aggravation of the disease during the course of the trial period.
- iv. Discontinuation of the treatment during trial.

### 10. Criteria of Assessment of Patient

#### Subjective Parameter-

No.	SYMPTOMS	NO OF PATIENTS	BEFORE TREATMENT					AFTER TREATMENT					%RELIEF
			G0	G1	G2	G3	TOTAL	G0	G1	G2	G3	TOTAL	
1	Breathlessness	10	2	2	3	3	17	5	4	1	0	6	64.75%
2	Excessive hunger	10	3	3	3	1	12	7	3	0	0	3	75%
3	Excessive sleep	10	9	1	0	0	1	10	0	0	0	0	100%
4	laziness	10	3	6	1	0	8	10	0	0	0	0	100%
5	weakness	10	2	2	4	2	16	5	4	1	0	6	62.5%
6	Fatigue	10	2	3	4	1	14	9	1	0	0	1	92.86%
7	Loss of enthusiasm	10	4	4	1	1	9	7	3	0	0	3	66.67%
8	Heaviness of body	10	3	2	3	2	14	7	1	2	0	5	64.28%

#### Result-

Parameter	Mean		MD	% Relief	SD	SE	P-VALUE	Conclusion
	BT	AT						
Weight(kg)	92.700	87.100	5.600	6.04%	1.075	0.340	0.00000	S
BMI(kg/m <sup>2</sup> )	34.720	32.620	2.100	6.05%	0.359	0.114	0.00000	S

Waist Circumference(cm)	108.500	102.000	6.500	5.99%	1.080	0.342	0.00000	S
Waist Hip Ratio	0.981	0.939	0.042	4.28%	0.004	0.001	0.00000	S

**Objective Parameter-**

No. of Patients	Weight(kg)		BMI(kg/m <sup>2</sup> )		Waist Circumference(cm)		Waist Hip Ratio	
	BT	AT	BT	AT	BT	AT	BT	AT
1	92	86	34.8	32.5	108	101	0.98	0.94
2	88	84	33.6	32.1	105	100	0.97	0.93
3	96	90	35.5	33.2	112	105	1.00	0.96
4	102	95	37.2	34.7	116	108	1.02	0.97
5	90	85	34.1	32.3	107	101	0.96	0.92
6	85	81	32.8	31.1	103	98	0.95	0.91
7	94	88	35.0	32.8	110	103	0.99	0.95
8	89	83	33.4	31.2	104	98	0.96	0.92
9	91	86	34.3	32.4	106	100	0.97	0.93
10	100	93	36.5	33.9	114	106	1.01	0.96

**Result-**

Parameter	Mean		MD	% Relief	SD	SE	P-VALUE	Conclusion
	BT	AT						
-			-	-	-	-	-	
<b>Breathlessness</b>	<u>1.700</u>	<u>0.600</u>	<u>1.100</u>	<u>64.71%</u>	<u>0.738</u>	<u>0.233</u>	<u>0.00110</u>	<u>S</u>
<b>Fatigue</b>	<u>1.400</u>	<u>0.100</u>	<u>1.300</u>	<u>92.86%</u>	<u>0.949</u>	<u>0.300</u>	<u>0.00190</u>	<u>S</u>
<b>Laziness</b>	<u>0.800</u>	<u>0.000</u>	<u>0.800</u>	<u>100.00%</u>	<u>0.633</u>	<u>0.200</u>	<u>0.00311</u>	<u>S</u>
<b>Weakness</b>	<u>1.600</u>	<u>0.600</u>	<u>1.000</u>	<u>62.50%</u>	<u>0.6667</u>	<u>0.211</u>	<u>0.00105</u>	<u>S</u>
<b>Excessive Sleep</b>	<u>0.100</u>	<u>0.000</u>	<u>0.100</u>	<u>100.00%</u>	<u>0.316</u>	<u>0.100</u>	<u>0.34344</u>	<u>NS</u>
<b>Excessive Hunger</b>	<u>1.200</u>	<u>0.300</u>	<u>0.900</u>	<u>75.00%</u>	<u>0.738</u>	<u>0.233</u>	<u>0.00386</u>	<u>S</u>
<b>Loss of enthusiasm</b>	<u>0.900</u>	<u>0.300</u>	<u>0.600</u>	<u>66.67%</u>	<u>0.699</u>	<u>0.221</u>	<u>0.02386</u>	<u>S</u>
<b>Heaviness of body</b>	<u>1.400</u>	<u>0.300</u>	<u>1.100</u>	<u>64.29%</u>	<u>0.876</u>	<u>0.277</u>	<u>0.00324</u>	<u>S</u>

**Statistical Interpretation of Results****Objective Parameters**

The study demonstrated a statistically significant improvement in all objective parameters following the intervention. **Body weight** showed a reduction from 92.7 kg (BT) to 87.1 kg (AT), with a mean difference (MD) of 5.6 kg and 6.04% relief. This change was **highly significant (p < 0.001)**. **Body Mass Index (BMI)** decreased from 34.72 to 32.62, with an MD of 2.10 and 6.05% improvement, which was also **highly significant (p < 0.001)**. **Waist circumference** reduced from 108.5 cm to 102.0 cm (MD = 6.5 cm, 5.99% relief), showing **high statistical significance (p < 0.001)**. **Waist-hip ratio** decreased from 0.981 to 0.939 (MD = 0.042, 4.28% relief), which was

again **highly significant (p < 0.001)**. These findings indicate that the intervention had a **significant effect on reducing overall and central obesity**.

### Subjective Parameters

All major subjective symptoms showed statistically significant improvement after treatment.

**Breathlessness** reduced by 64.71% (p < 0.01), **Fatigue** showed marked improvement of 92.86% (p < 0.01), **Laziness** improved by 100% (p < 0.01), **Weakness** reduced by 62.5% (p < 0.01). This reflects a **clinically meaningful improvement in functional capacity and quality of life**, **Excessive hunger (75%)**, **loss of enthusiasm (66.67%)**, and **heaviness of body (64.29%)** showed **statistically significant improvement (p < 0.05)**, **Excessive sleep** showed 100% relief; however, it was **statistically non-significant (p > 0.05)**. This may be due to, Low baseline severity, Small sample size (n=10), Reduced variability affecting statistical power

The statistical analysis reveals that the intervention produced:

**Highly significant improvement in objective parameters** (weight, BMI, waist circumference, WHR) **Significant to highly significant improvement in subjective symptoms**, **Clinically meaningful reduction in signs and symptoms of Sthaulya (obesity)**. The results suggest that the therapy is **effective in both anthropometric reduction and symptomatic relief**.

“Statistical analysis was carried out using paired t-test, and significance was assessed at p < 0.05 level.”

## 11. Discussion

### Discussion on Mode of Action of Ayuraksha Vati

Ayuraksha Vati, formulated as *Ghan Vati*, is a herbo-mineral/polyherbal preparation containing **Kutki, Guggulu, and Haritaki**. The combination is likely to produce therapeutic benefits in *Sthaulya* (Obesity) through the collective action of its ingredients. The formulation is mainly known for its *Deepana, Pachana, Lekhana*, and *Medohara* properties, which help in correcting the disturbed metabolic state associated with obesity.

**Guggulu** is traditionally recognized for its ability to reduce excess *Meda Dhatu* and promote proper metabolism. It possesses *Lekhana* and *Amapachana* actions, which may help in mobilizing accumulated fat and improving lipid metabolism. It is also described as *Rasayana* and *Shothahara*, supporting overall health and reducing inflammatory changes.

**Haritaki** is widely used for its cleansing and rejuvenating properties. It has *Anulomana, Deepana, Pachana*, and *Srotoshodhana* actions, which help maintain bowel regularity, improve digestion, and remove metabolic waste products. These effects may indirectly support healthy weight management.

**Kutki** is known for its *Deepana, Pachana, Bhedana*, and liver-stimulating properties. It assists in improving digestive efficiency, enhancing metabolism, and correcting Kapha-Meda imbalance. It may also be beneficial in maintaining healthy lipid levels.

Most of the ingredients possess *Laghu* and *Ruksha Guna* with predominance of *Katu* and *Tikta Rasa*, which are useful in reducing Kapha Dosha and the heaviness or excessive unctuousness commonly seen in obesity. These qualities oppose the *Guru* and *Snigdha* attributes responsible for increased fat accumulation.

The observations of the present study showed noticeable improvement in symptoms such as breathlessness, increased appetite, laziness, weakness, fatigue, excessive sleep, and heaviness of body. Favorable changes were also noted in objective parameters including body weight, BMI, waist circumference, waist-hip ratio, and lipid profile.

The therapeutic response may be explained by the action of the formulation on *Agnimandya*, *Ama*, Kapha aggravation, and excess Medo Dhatu, which are considered major factors in the pathogenesis of *Sthaulya*. By improving digestive power, clearing obstructed channels, and supporting proper metabolism, the formulation may assist in gradual reduction of obesity.

Another important finding of the study was the tolerability of the drug. No significant adverse effects were reported during the treatment period, indicating that Ayuraksha Vati appears safe when used in the recommended dose and duration. However, as this was a pilot study with a limited number of participants, larger controlled trials are necessary for further confirmation.

## 12. Conclusion

Ayuraksha Vati, administered in *Ghan Vati* form, showed promising results in the management of *Sthaulya* (Obesity). Improvement was observed in clinical symptoms along with beneficial changes in body weight, BMI, waist circumference, waist-hip ratio, and lipid profile. The probable mode of action may be related to its *Deepana*, *Pachana*, *Lekhana*, and *Medohara* properties, which help address the underlying metabolic disturbance responsible for obesity.

No significant adverse reactions were observed during the study, suggesting good safety and tolerability of the formulation. Hence, Ayuraksha Vati may be considered a safe, effective, affordable, and holistic Ayurvedic option for obesity management. Further studies with a larger sample size are recommended to validate these findings more conclusively.

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