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A PILOT STUDY TO COMPARE THE THERAPEUTIC EFFECTS OF BRIHAT AGNIMANTH (PREMNA INTEGRIFOLIA LINN) AND LAGHU AGNIMANTH (CLERODENDRUM PHLOMIDIS LINN F.) MOOL KWATH IN THE MANAGEMENT OF STHAULYA WSR OBESITY

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ABSTRACT

Obesity, a global health epidemic, is closely linked to increased morbidity and mortality. In Ayurveda, it is correlated with *Sthaulya*, caused by *Medo Dhatu Vriddhi* (excess fat accumulation) mention in *Astonindita Purushaadhaya*. This pilot study aimed to compare the therapeutic effects of *Brihat Agnimanth* (*Premna integrifolia Linn.*) and *Laghu Agnimanth* (*Clerodendrum phlomidis Linn. f.*) *mool kwath* in managing *Sthaulya (obesity)*. A randomized, parallel clinical trial was conducted on 30 patients aged 18–60 years with BMI ≥25 kg/m². Group A received *Brihat Agnimanth mool kwath*, and Group B received *Laghu Agnimanth mool kwath* for 60 days. Anthropometric (weight, BMI, abdominal circumference), clinical (*Kshudaadhikya, Pipāsādhikya, Swedādhikya, Daurbalya*), and biochemical (cholesterol, triglycerides, LDL, HDL) parameters were assessed statistically. Both groups showed significant intragroup improvements in all parameters. Intergroup analysis revealed no significant difference ($p > 0.05$) in weight, BMI, or lipid

levels, except for HDL cholesterol, where *Brihat Agnimanth* showed significantly higher improvement ($p < 0.05$). The findings suggest that both *Brihat* and *Laghu Agnimanth* are effective in reducing obesity and improving metabolic health. *Brihat Agnimanth* demonstrated superior lipid-modulating activity, while *Laghu Agnimanth* showed slightly better BMI reduction. Both can be considered safe and beneficial Ayurvedic formulations for obesity management.

INTRODUCTION

The number of people dealing with obesity has increased in developing nations during the last twenty years.[1] India, the world's third most populated country, has felt the heavy blow of obesity, which the World Health Organization (WHO) calls a global epidemic.[2] The WHO states that obesity stands as one of the most widespread public health issues, yet it often receives little attention in both developing and developed regions. The WHO's World Health Statistics Report from 2020 reveals that one in eight adults worldwide struggles with obesity. It also reports that around 2.8 million people lose their lives every year because of being overweight or obese. With its strong link to increased illness and death, obesity is now viewed as a disease by itself.[3]

In Ayurveda Obesity is correlated with *Sthaulya*.[4] Various medicines help treat *Sthaulya* (obesity). Among these, *Agnimanth* is considered one of the preferred drugs for managing *Sthaulya.*[5] Over the last several decades, researchers have studied the qualities of different kinds of *Agnimanth* used in *Sthaulya.*[6] This idea focuses on understanding the therapeutic value of two types of *Agnimanth—Brihat Agnimanth* (*Premna integrifolia*) and *Laghu Agnimanth* (*Clerodendrum phlomidis*)—to treat *Sthaulya* (obesity).

MATERIAL AND METHODS

Study design

Type of Study- A randomized open clinical trial

The study was conducted as a randomized, parallel trail. At institutional outpatient department. The study protocol was approved by the institutional ethical committee SKAU/Acad/2025/432-35.

And University ethical committee SKAU/Acad/2025/428-31. The study was conducted according to good clinical practices and registered in the clinical trial registry; India vide CTRI Reg. No. CTRI/2024/08/072187. The written informed consent was obtained from each

of the patient prior to enrollment.

Study Participants- Total 30 patients (15-15 in each group A and group B) of *Sthaulya*, fulfilling inclusion criteria was randomly selected.

Inclusive criteria

1. Patient having Clinical sign & symptom of Sthaulya as per Ayurvedic text.
2. Patient either sex between the Age group of 18 - 60year
3. Patient having BMI more than or equal to 25kg/m2

Exclusive criteria

1. Patient below the age of 18 years and above 60 years
2. Patient of any chronic diseases
3. Pregnant and lactating women

Discontinuation criteria

Any acute or severe illness.

Patient not willing to continue the treatment.

Posology: Both the Drugs were selected for observe the therapeutic effect on Sthaulya wsr Obesity. Brihat Agnimanth (Premna integrifolia) mool kwath was given to the group A patients. While Laghu Agnimanth (Clerodendrum phlomidis) mool kwath was given to the patients of group B. **Dose**-80 ml *kwath* two times when food is digested was given in case of both drugs.[7]

Method of preparation of trial drug formulation:

Brihat Agnimanth (Premna integrifolia) root powder and Laghu Agnimanth (Clerodendrum phlomidis) root powder were prepared in Department of Rasashastra and Bhaishajya Kalpana following guidelines of GMP mention in AFI part 1,2nd edition page no 202.

METHODOLOGY

Eligibility of patients for the study was checked and recorded in a case Performa.

On the enrollment at visit, the demographic profile medical history, general and systemic examination ayurvedic parameters and modern parameters of Sthaulya wsr Obesity were observed. Follow up had been done at every week during study and assessment was done on every visit on the basis of parameters.

Criteria for assessment[8]

The assessment of *Sthaulya* wsr Obesity *was* done before and after the treatment. Grading of the signs and symptoms of *Sthaulya* wsr Obesity was given as follows.

1. ***Kshudhaadhikya*** **(Excessive Hunger)**

Severity of sign & symptoms	Score
Taking diet 2 times in a day without any supplementary diet.	0
Taking diet 2 times in a day with any supplementary diet.	1
Taking diet 3 -4times in a day without any supplementary Diet.	2
Taking diet 3 -4times in a day with any supplementary diet.	3
Taking irregular or intermittent diet.	4

2. ***Pipasaadhikya*** **(Excessive Thrust)**

Severity of sign & symptoms	Score
Normal thirst (1-2liter intake of water)	0
Up to 1liter excess intake of water.	1
1-2liter excess intake of water.	2
2-3liter excess intake of water.	3
More than 3liter excess intake of water.	4

3. ***Swedaadhikya*** **(Excessive Sweating)**

Severity of sign & symptoms	Score
Sweating after heavy work and fast movements or in hot season.	0
Profuse sweating after moderate work and movements	1
Sweating after little work and movements.	2
Profuse sweating after little work and movements.	3
Sweating even at rest or in cold season.	4

4. ***Daurbalya*** **(Weakness).**

Severity of sign & symptoms	Score
Person Can do routine exercise.	0
Can do moderate exercise without difficulty.	1
Can do only mild exercise.	2
Can do only mild exercise with difficulty.	3
Cannot do even mild exercise.	4

Data presentation and statically analysis

At the study site, data of all the patient were recorded in case Performa and were also entered in master chart design in excel with many data validation check to ensure correct data entry. Outcome measures were analyzed as a mean change in response from baseline to 60^{th} day.

The parameters of group A (Brihat Agnimanth) and group B (Laghu Agnimanth) were analyzed using unpaired t test to compare the before and after treatment scores.

Comparison of Weight Reduction Between Group A and Group B was analyzed. (Table no.1).

Comparison of Abdominal Circumference Between Group A and Group B was analyzed. (Table no.2).

Comparison of BMI between Group A and Group B was analyzed. (Table no.3).

Comparison of Kshudaadhikya between Group A and Group B was analyzed. (Table no.4).

Comparison of Pipāsādhikya between Group A and Group B was analyzed. (Table no.5). Comparison of Swedādhikya between Group A and Group B was analyzed. (Table no.6).

Comparison of Daurbalya between Group A and Group B was analyzed. (Table no.7).

Comparison of Serum Cholesterol Between Group A and Group B was analyzed. (Table no.8).

Comparison of Serum Triglycerides Between Group A and Group B was analyzed. (Table no.9).

Comparison of LDL Cholesterol Between Group A and Group B was analyzed. (Table no.10).

Comparison of HDL Cholesterol Between Group A and Group B was analyzed. (Table no.11).

All statical analysis was performed using SPSS software with appropriate statical methods.

OBSERVATION AND RESULTS

In total 35 patients were registered in both groups out of which group A contains 18 and group B contains 17 patients and out of total 35 patients 5 patients (2 patients from group A

and 3 patients from group B) were discontinued due to personal reasons and 30 patients completed trail.

After follow up assessment changes in the result were found in its symptoms associated with *Sthaulya* like weight, abdominal circumference, BMI, *Kshudhaadhikya, Pipasaadhikya, Swedaadhikya, and Daurbalya*.

Anthropometric Parameters

- **Weight**
  - Group A (Brihat): ↓ 1.23 kg → **1.44% reduction**
  - Group B (Laghu): ↓ 1.34 kg → **1.63% reduction**

- **Abdominal circumference**:
  - Group A: ↓ 1.53 cm → **1.64% reduction**
  - Group B: ↓ 1.53 cm → **1.71% reduction**

- **BMI**
  - Group A: ↓ 0.73 units → **2.40% reduction**
  - Group B: ↓ 1.17 units → **4.01% reduction Clinical Symptoms**

- **Kshudaadhikya (Excessive hunger)**:
  - Group A: ↓ 65.8%
- Group B: ↓ 62.9%

- **Pipāsādhikya (Excessive thirst)**:
  - Group A: ↓ 68.2%
  - Group B: ↓ 69.7%

- **Swedādhikya (Excessive sweating)**:
  - Group A: ↓ 72.8%
  - Group B: ↓ 60.9%

- **Daurbalya (Weakness)**:
  - Group A: ↓ 53.8%
  - Group B: ↓ 60.9%

Biochemical Parameters

- **Serum Cholesterol**
  - Group A: ↓ 5.8%
  - Group B: ↓ 5.3%

- **Serum Triglycerides**
  - Group A: ↓ 6.2%
  - Group B: ↓ 6.0%

- **LDL (Bad cholesterol)**
  - Group A: ↓ 11.3%
  - Group B: ↓ 10.6%

- **HDL (Good cholesterol)**
  - Group A: ↑ 7.3%
  - Group B: ↑ 8.4%

- Both *Brihat Agnimanth* and *Laghu Agnimanth* produced highly significant intragroup improvements in weight, BMI, abdominal circumference, clinical symptoms, and lipid profile.

- Intergroup comparisons showed no significant differences in most parameters (weight, BMI, abdominal circumference, cholesterol, triglycerides, LDL, and symptoms).

The only statistically significant difference was in HDL cholesterol improvement, where *Brihat Agnimanth* demonstrated greater efficacy than *Laghu Agnimanth*.

DISCUSSION

- Both drugs are effective in the management of *Sthaulya* (Obesity) with comparable results in most domains.
- *Laghu Agnimanth* showed a slight edge in BMI reduction and symptom relief (*Daurbalya*).
- *Brihat Agnimanth* showed superior effect in elevating HDL ("good cholesterol"), suggesting better cardiovascular protection.

Table no- 1: Comparison of Weight Reduction Between Group A and Group B.

Unpaired T Test	Comparison			
	Weight			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	85.38	82.04	84.15	80.70
S.D.	7.193	7.706	7.279	7.810
Number	15	15	15	15
Mean Difference	3.34		3.45	
Unpaired T Test	1.227		1.253	
P value	0.2300		0.2206	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

This indicates that although both *Brihat Agnimanth* and *Laghu Agnimanth* groups showed significant weight reduction individually (as per paired t-tests), the difference in weight reduction between the two groups was not statistically significant when compared directly. Thus, both formulations appear equally effective in reducing body weight, with no clear superiority of one over the other in this parameter based on intergroup comparison.

Table no 2: Comparison of Abdominal Circumference Between Group A and Group B.

Unpaired T Test	Comparison			
	Periphery of abdomen (in cm)			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	93.27	89.33	91.73	87.80
S.D.	7.186	7.413	7.216	7.213
Number	15	15	15	15
Mean Difference	3.93		3.93	
Unpaired T Test	1.476		1.493	
P value	0.1512		0.1466	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

The results indicate that although both *Brihat Agnimanth* and *Laghu Agnimanth* produced significant reductions in abdominal circumference individually (as shown by paired t-tests), the intergroup difference was not statistically significant. This suggests that both formulations were equally effective in reducing central obesity (abdominal girth), with no significant superiority of one over the other when compared directly.

Table No. 3: Comparison of BMI between Group A and Group B.

Unpaired T Test	Comparison			
	BMI			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	30.36	29.17	29.63	28.00
S.D.	2.187	2.309	2.125	2.449
Number	15	15	15	15
Mean Difference	1.19		1.63	
Unpaired T Test	1.447		1.951	
P value	0.1590		0.0612	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Although both groups showed highly significant intragroup reductions in BMI (as per paired t-tests), the intergroup comparison was not statistically significant ($p>0.05$). This indicates that neither *Brihat* nor *Laghu Agnimanth* demonstrated clear superiority over the other in reducing BMI, although Laghu Agnimanth showed a trend toward slightly better reduction (mean difference of 1.63 vs. 1.19 units).

Table No.4 Comparison of *Kshudaadhikya* (Excess Hunger) between Group A and Group B

Unpaired T Test	Comparison			
	Kshudaadhikya			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	2.93	3.07	1.00	1.13
S.D.	0.884	0.884	0.845	0.915
Number	15	15	15	15
Mean Difference	0.13		0.13	
Unpaired T Test	0.413		0.414	
P value	0.6826		0.6817	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Although both Brihat and Laghu Agnimanth produced highly significant reductions in *Kshudaadhikya* individually (as shown by paired t-tests), the intergroup comparison did not reveal a significant difference. This indicates that both formulations were equally effective in reducing excessive hunger, and neither showed superiority in this parameter.

Table No. 5: Comparison of *Pipāsādhikya* (Excess Thrust) between Group A and Group B.

Unpaired T Test	Comparison			
	Pipasaadhikya			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	3.33	2.87	1.07	0.87
S.D.	0.900	0.915	0.704	0.743
Number	15	15	15	15
Mean Difference	0.47		0.20	
Unpaired T Test	1.408		0.757	
P value	0.1701		0.4555	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Both *Brihat* and *Laghu Agnimanth* showed highly significant intragroup reductions in *Pipasadhikya* (as per paired t-tests). However, the intergroup comparison revealed no statistically significant difference, suggesting that both formulations were equally effective in reducing excessive thirst among obese patients.

Table No. 6: Comparison of *Swedādhikya* (Excess Sweating) between Group A and Group B.

Unpaired T Test	Comparison			
	Swedaadhikya			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	3.20	3.07	0.87	1.20
S.D.	0.862	0.704	0.743	0.676
Number	15	15	15	15
Mean Difference	0.13		0.33	
Unpaired T Test	0.464		1.285	
P value	0.6462		0.2094	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Both *Brihat* and *Laghu Agnimanth* demonstrated highly significant intragroup reductions in *Swedadhikya* (as per paired t-tests). However, the intergroup comparison did not reveal any significant difference, suggesting that both formulations were equally effective in reducing excessive sweating, with no clear superiority of one over the other.

Table No. 7: Comparison of *Daurbalya* (Weakness) between Group A and Group B.

Unpaired T Test	Comparison			
	Daurbalya			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	2.60	3.07	1.20	1.20
S.D.	0.737	0.704	0.862	0.862
Number	15	15	15	15
Mean Difference	0.47		0.00	
Unpaired T Test	1.774		0.000	
P value	0.0870		1.0000	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Although both *Brihat* and *Laghu Agnimanth* produced highly significant intragroup improvements in *Daurbalya* (as shown by paired t-tests), the intergroup comparison revealed no significant difference. This indicates that both formulations were equally effective in reducing weakness among obese patients, with no clear superiority of one over the other.

Table No. 8: Comparison of Serum Cholesterol Between Group A and Group B.

Unpaired T Test	Comparison			
	Serum Cholesterol			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	198.23	190.46	186.79	180.46
S.D.	16.644	14.446	14.506	11.960
Number	15	15	15	15
Mean Difference	7.77		6.33	
Unpaired T Test	1.365		1.303	
P value	0.1832		0.2031	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Both *Brihat* and *Laghu Agnimanth* demonstrated highly significant intragroup reductions in serum cholesterol (as shown by paired t-tests). However, the intergroup comparison did not reveal a statistically significant difference. This indicates that both formulations were equally effective in reducing cholesterol levels, with neither showing clear superiority in lipid-lowering efficacy.

Table No. 9: Comparison of Serum Triglycerides Between Group A and Group B.

Unpaired T Test	Comparison			
	Serum Triglycerides			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	153.34	143.85	143.80	135.27
S.D.	14.761	12.846	12.456	11.562
Number	15	15	15	15
Mean Difference	9.49		8.53	
Unpaired T Test	1.879		1.943	
P value	0.0707		0.0621	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Both *Brihat* and *Laghu Agnimanth* showed highly significant intragroup reductions in serum triglycerides (as per paired t-tests). However, the intergroup comparison did not reach statistical significance, though the p-values were close to 0.05, suggesting a trend toward greater reduction in Group B (*Laghu Agnimanth*). Thus, while both formulations are effective in lowering triglyceride levels, *Laghu Agnimanth* may have a slight edge, though this requires confirmation in a larger sample.

Table No. 10: Comparison of LDL Cholesterol Between Group A and Group B.

Unpaired T Test	Comparison			
	LDL			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	117.30	115.23	104.03	103.00
S.D.	9.312	11.323	8.646	9.073
Number	15	15	15	15
Mean Difference	2.07		1.03	
Unpaired T Test	0.546		0.319	
P value	0.5894		0.7522	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Interpretation

Both *Brihat* and *Laghu Agnimanth* produced highly significant intragroup reductions in LDL cholesterol (as shown by paired t-tests). However, the intergroup comparison did not reveal any significant difference, indicating that both formulations were equally effective in lowering LDL cholesterol levels.

Table No. 11: Comparison of HDL Cholesterol Between Group A and Group B.

Unpaired T Test	Comparison			
	HDL			
	Before		After	
	Group A	Group B	Group A	Group B
Mean	50.20	46.13	53.87	50.00
S.D.	5.532	4.086	4.627	3.723
Number	15	15	15	15
Mean Difference	4.07		3.87	
Unpaired T Test	2.290		2.522	
P value	0.0297		0.0176	
Table Value at 0.05	2.05		2.05	
Result	Significant		Significant	

Interpretation- Both *Brihat* and *Laghu Agnimanth* significantly improved HDL levels individually. However, the intergroup comparison showed a significant difference, suggesting that *Brihat Agnimanth* had a relatively stronger effect in improving HDL ("good cholesterol") compared to *Laghu Agnimanth*. This highlights that while both drugs were effective in enhancing protective lipid fractions, *Brihat Agnimanth* demonstrated superior efficacy in elevating HDL levels, thereby potentially offering greater cardiovascular protection in obese patients.

CONCLUSION

Overall, both formulations can be considered beneficial, with *Brihat Agnimanth* having a stronger impact on lipid modulation, while *Laghu Agnimanth* slightly better on BMI and *Daurbalya*.

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