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Comparative Efficacy Of Vidangadi Lauha And Orlistat In The Management Of Sthaulya: A Randomized Controlled Clinical Trial

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Abstract-

Background- *Obesity is a major global health concern, resulting from an imbalance between energy intake and expenditure, which leads to excessive fat accumulation and reduced life expectancy. In Ayurveda, this condition is described as Sthaulya, one of the Ashta Nindita Purusha. With it's growing prevalence worldwide, the need for effective and sustainable management strategies has become increasingly important.* ***Aim:*** *To evaluate the efficacy of Vidangadi Lauha in the management of Sthaulya (obesity).****Objectives:*** *To observe the adverse effects of Vidangadi Lauha in Sthaulya.* ***Methodology:*** *A randomized controlled clinical study was conducted with two groups. The trial group received Vidangadi Lauha 1 g thrice daily, and the control group received Orlistat 60 mg twice daily for a duration of three months.****Results:*** *Both Vidangadi Lauha and Orlistat demonstrated a reduction in weight and BMI. However, Vidangadi Lauha was more effective, showing a significant reduction in body fat, visceral fat, body circumferences, cholesterol, and triglycerides, along with relief in the symptoms of Sthaulya. In the Vidangadi Lauha group, 40% of patients showed marked improvement and 60% showed moderate improvement, whereas Orlistat produced mostly mild improvement.****Conclusion:*** *Both treatments were effective in reducing weight, BMI, body fat, and visceral fat. Vidangadi Lauha was superior to Orlistat in improving body fat percentage, visceral fat, skinfold thickness, body circumferences, lipid profile, and Ayurvedic symptoms of Sthaulya. Vidangadi Lauha also demonstrated better patient compliance and fewer adverse effects, establishing it as a safer and more holistic option for obesity management.*

Keywords- *vidangadi lauha, orlistat, sthaulya, obesity.*

INTRODUCTION- Obesity is a complex metabolic disorder marked by excess fat accumulation, increasing the risk of hypertension, diabetes, cardiovascular diseases, osteoarthritis, and cognitive decline.[1] According to the National AYUSH Morbidity Code (NAMC), Sthaulya is classified under ICD-326 ACB-1.[2] WHO (2016) reports indicate that 39% of adults were overweight and 13% obese, reflecting its rising prevalence and significant healthcare burden.[3]

When lifestyle changes fail, pharmacological options are considered, but most anti-obesity drugs have been withdrawn due to serious side effects. Orlistat, a gastrointestinal lipase inhibitor reducing fat absorption by ~30%, remains widely approved but is limited by steatorrhea, flatulence, and fat-soluble vitamin malabsorption, highlighting the need for safer alternatives.[4]

Given the rising obesity burden and limitations of current therapies, there is growing interest in validating Ayurvedic formulations. Vidangadi Lauha, a classical preparation from *Bhaishajya Ratnavali*, is traditionally indicated for Medoroga and Sthaulya.[5]

Most *Ayurvedic* obesity studies are limited by small samples, short duration, non-standardized assessments, and lack of controls. Evidence for formulations like *Vidangadi Lauha* using modern tools is scarce. This study evaluates its efficacy with validated parameters, aiming to bridge classical *Ayurvedic* knowledge with contemporary research for safe and cost-effective obesity management.

METHODOLOGY-

Study design A randomized clinical trial with a 2:1 allocation ratio was conducted following Institutional Ethics Committee approval and prospective registration in the Clinical Trials Registry of India (CTRI/2024/03/063592). Eligible participants were monitored for 90 days, with assessments of anthropometry, lipid profile, and blood sugar to evaluate therapeutic and metabolic outcomes.

Drug -

The study involves two groups: a trial group and a control group. The trial group will receive *Vidangadi Lauha*. In contrast, the control group will receive Tablet Orlistat, a standard drug. **Sample size–**

A 2:1 allocation ratio was adopted, with 45 participants divided into Group A (*Vidangadi Lauha*, n=30) and Group B (Orlistat, n=15), considering Orlistat as the control.

Intervention -

In this study, the trial intervention consisted of *Vidangadi Lauha* administered in a dose of 1 g orally before meals with *Godugdha* (15 ml) as *Anupan*, while the control group received Orlistat in a dose of 60 mg orally before meals. The duration of drug administration in both groups was 90 days.

***Vidangadi lauha* formulations –**

Vidangadi Lauha is a classical Ayurvedic formulation cited in *Bhaishajya Ratnavali (Medoroga Adhyaya* 22/25)[5], indicated for *Sthaulya* and related metabolic disorders. For this study, the preparation was procured from *Shree Dhootapapeshwar* Limited, a GMP-certified *Ayurvedic* company, and underwent authentication and standardization per company guidelines to ensure quality, safety, and clinical efficacy.

Tablet orlistat –

Orlistat, an FDA-approved anti-obesity drug, inhibits gastric and pancreatic lipases by covalently binding their active serine site, blocking triglyceride hydrolysis and reducing fat absorption by ~30%. This promotes weight loss and improves lipid profile and glycemic control.[8]In the study, a dose of 60 mg twice daily[6] was used, balancing efficacy with minimal risk of gastrointestinal side effects.

Measuring trial outcomes –

The study assessed primary outcomes—body weight, BMI, body fat percentage, abdominal girth, and waist–hip ratio—and secondary outcomes, including lipid profile and *Sthaulya* symptoms. Participants underwent baseline clinical exams and investigations (blood sugar, lipid profile). Study drugs were given for 90 days, with 15-day follow-ups for anthropometry, and biochemical tests at baseline and completion, ensuring close monitoring of efficacy and compliance.

Eligibility criteria –

Participants of either gender, aged 18–60 years, with Sthaulya symptoms, BMI 25–34.9 kg/m2, and waist–hip ratio ≥0.81 (females) or ≥1.0 (males) were eligible. Controlled comorbidities like dyslipidemia, hypertension, and type 2 diabetes were allowed. Exclusions included pregnant or lactating women, hypothyroidism, PCOS, psychiatric or eating disorders, recent weight-altering drugs or supplements, prior obesity-related surgery, and type 2 diabetics on metformin.

Assessment criteria –

The diagnostic framework for the study included both subjective and objective criteria. Subjective parameters such as *Daurgandhya, Kshudra Shwasa, Trishna, Nidra Adhikya, Kshudhadhikya, Swedadhikya, Daurbalya*, and *Chal Sphik-Stana-Udara Lambanam*. Objective parameters included body weight, BMI (25–34.9 kg/m2, overweight to Grade I obesity), waist–hip ratio (>0.8 in males, >0.81 in females)[7], body fat percentage, body circumferences, lipid profile, and fasting and postprandial

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OBSERVATION AND RESULT –

Data were presented as mean ± SD, with $p \leq 0.05$ considered statistically significant. Paired t-test was used for within-group comparisons, unpaired t-test for between-group comparisons, and Wilcoxon signed-rank test for non-parametric data. Statistical analyses were performed using standard software to assess therapeutic efficacy.

EFFECT OF *VIDANGADI LAUHA* AND ORLISTAT ON OBJECTIVE PARAMETERS BEFORE AND AFTER TREATMENT

Variable	Group	N	Mean Diff	SD	SE	t-Value	P-Value	Result
Weight	Group A	30	7.16	1.45	0.27	3.710	0.001	Sig
	Group B	15	5.65	0.81	0.21			
BMI	Group A	30	3.12	1.00	0.18	2.986	0.005	Sig
	Group B	15	2.23	0.80	0.21			
Abdominal girth	Group A	30	6.07	2.60	0.47	1.910	0.063	NS
	Group B	15	4.60	2.03	0.52			
Waist hip ratio	Group A	30	0.06	0.06	0.01	-0.281	0.780	NS
	Group B	15	0.07	0.05	0.01			
Body fat percentage	Group A	30	3.45	0.94	0.17	5.645	0.000	Sig
	Group B	15	1.93	0.63	0.16			
Lean muscle mass	Group A	30	3.18	2.56	0.47	2.793	0.008	Sig
	Group B	15	1.28	0.77	0.20			
Visceral fat	Group A	30	3.47	0.97	0.18	4.650	0.000	Sig
	Group B	15	2.23	0.49	0.13			

Variable	Group	N	Mean Diff	SD	SE	t-Value	P-Value	Result
Biceps	Group A	30	1.53	0.51	0.09	4.293	0.000	Sig
	Group B	15	0.93	0.26	0.07			
Triceps	Group A	30	1.5`0	0.68	0.12	2.822	0.007	Sig
	Group B	15	1.00	0.00	0.00			
Subscapular	Group A	30	1.53	0.57	0.10	3.279	0.002	Sig
	Group B	15	0.93	0.59	0.15			
Suprailiac	Group A	30	1.53	0.63	0.11	3.533	0.001	Sig
	Group B	15	0.93	0.26	0.07			
Neck circumference	Group A	30	1.50	0.57	0.10	0.167	0.869	NS
	Group B	15	1.47	0.74	0.19			
Mid arm circumference	Group A	30	3.20	1.35	0.25	0.500	0.620	NS
	Group B	15	3.00	1.07	0.28			
Mid-thigh circumference	Group A	30	5.07	1.55	0.28	4.074	0.000	Sig
	Group B	15	3.20	1.21	0.31			

Variable	Group	N	Mean Diff	SD	SE	t-Value	P-Value	Result
BSL (Fasting)	Group A	30	9.03	9.67	1.77	1.631	0.110	NS
	Group B	15	3.53	12.48	3.22			
BSL (Post prandinal)	Group A	30	17.90	10.34	1.89	0.837	0.407	NS
	Group B	15	15.20	9.91	2.56			
Sr. cholesterol	Group A	30	35.27	12.01	2.19	2.280	0.028	Sig
	Group B	15	25.67	15.67	4.05			
Triglycerides	Group A	30	32.93	11.30	2.06	5.263	0.000	Sig
	Group B	15	14.87	9.86	2.55			
HDL	Group A	30	2.37	2.93	0.53	2.834	0.007	Sig
	Group B	15	-0.13	2.47	0.64			
LDL	Group A	30	24.17	15.03	2.74	-0.197	0.845	NS
	Group B	15	25.13	16.46	4.25			

EFFECT OF *VIDANGADI LAUHA* AND ORLISTAT ON DIFFERENT SUBJECTIVE PARAMETERS

Patients were monitored at 15-day intervals throughout the 90-day study period; however, for clarity of presentation, only the baseline and end-of-study (day 90) measurements have been reported.

KSHUDRASHWAS-

GROUP	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	2.17 ± 0.70	1.57 ± 0.82	27.69%
Group B	1.47 ± 0.52	1.40 ± 0.51	4.55%

DAURANDHYA –

Group	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	1.90 ± 0.71	0.50 ± 0.51	73.68%
Group B	1.73 ± 0.46	1.00 ± 0.00	42.31%

TRISHNA –

Group	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	1.90 ± 0.48	0.27 ± 0.45	85.96%
Group B	1.93 ± 0.26	0.40 ± 0.51	79.31%

NIDRADHIKYA –

Group	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	1.97 ± 0.41	0.20 ± 0.41	89.83%
Group B	2.00 ± 0.00	0.40 ± 0.51	80.00%

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KSHUDHADHIKYA –

Group	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	1.90 ± 0.40	0.10 ± 0.31	94.74%
Group B	1.73 ± 0.59	1.73 ± 0.59	0.00%

SWEDADHIKYA -

Group	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	2.07 ± 0.52	0.27 ± 0.45	87.10%
Group B	1.93 ± 0.26	1.00 ± 0.00	48.28%

DAURBALYA –

Group	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	2.17 ± 0.46	0.27 ± 0.45	87.69%
Group B	1.80 ± 0.41	1.00 ± 0.00	44.44%

CHAL SPHIK STAN UDAR

Group	Baseline (Mean ± SD)	Day 90 (Mean ± SD)	% Improvement
Group A	0.87 ± 0.90	0.83 ± 0.91	3.85%
Group B	1.13 ± 0.83	1.13 ± 0.83	0.00%

OVERALL EFFECTS OF *VIDANGADI LAUHA* AND ORLISTAT

Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	12	40.00%	0	0.00%
Moderate Improvement	18	60.00%	2	13.33%
Mild Improvement	0	0.00%	13	86.67%
No Improvement	0	0.00%	0	0.00%
TOTAL	30	100.00%	15	100.00%

DISCUSSION-

The study evaluated the efficacy of *Vidangadi Lauha* compared with Orlistat in managing *Sthaulya*. In its pathogenesis, *Kapha*-dominant *Tridosha* imbalance leads to *Medodhatu* aggravation, *Vata* obstruction, and heightened *Koshta Agni*, resulting in increased appetite and excessive intake.[9] Despite strong *Agni*, *Adhyashana* Sheela causes formation of *Ama Rasa*, which nourishes *Meda* and drives *Medoroga* progression.[10] Management therefore focuses on balancing *Agni*, pacifying *Kapha*, and reducing excess *Meda. Vidangadi Lauha*, described in *Bhaishajya Ratnavali*, is a classical formulation targeting these factors effectively.[11]

Vidangadi Lauha contains ingredients predominantly having *Tikta–Kashaya Rasa, Laghu–Ruksha Guna, Sheeta Veerya*, and *Madhura Vipaka*. In *Medoroga*, where *Kapha* is aggravated and *Meda* is vitiated, *Tikta–Kashaya Rasa* and *Laghu–Ruksha Guna* help pacify *Kapha* and induce *Rukshana*, thereby facilitating *Meda* reduction.[12,13]

The ingredients of *Vidangadi Lauha* act synergistically to correct the pathogenic factors of *Sthaulya* by enhancing digestion, metabolism, and fat reduction. *Pippali* stimulates *Agni*, digests *Ama*, promotes *Lekhana*, and reduces *Meda*, including visceral fat, while also improving the lipid profile.[14] *Amalaki*, a

potent *Rasayana*, boosts metabolism, reduces adiposity, and exerts antioxidant, antihyperlipidemic, and antidiabetic effects.[15,16] *Bibhitaki* and *Haritaki* facilitate *Lekhana* and *Medohara*,[17,18] regulate lipid metabolism, and aid weight reduction; *Haritaki* additionally supports gut health through *Deepana–Pachana* and mild *Rechana* actions. *Musta* and *Shunthi* enhance digestion, correct metabolism, reduce *Meda*, and support lipid-lowering activity,[19,20] with *Shunthi* and *Hrivera* also providing anti-inflammatory and cardioprotective effects[21,22]. *Bilva* and *Patha* improve digestion, regulate metabolism, and offer hypoglycemic and antioxidant benefits, aiding weight and gut health.[23,24] *Chandana* and *Usheer* pacify *Pitta–Kapha*, purify blood, and help reduce visceral fat and systemic inflammation.[25,26] *Bala* strengthens tissues, regulates lipid and glucose metabolism, and supports weight management.[27] *Lauha Bhasma* enhances Agni, assimilation, and tissue strength, while regulating glucose and lipid metabolism with additional antioxidant and hepatoprotective effects.[28]

Collectively, these ingredients target the core pathology of *Sthaulya*—excess *Kapha*, impaired *Agni*, *Meda* accumulation, and metabolic imbalance—by improving digestion, promoting lipid and glucose metabolism, reducing visceral fat, enhancing gut function, and supporting sustainable weight loss.

Phytochemical and experimental studies on *Vidangadi Lauha* ingredients demonstrate significant hypolipidemic effects, lowering TC, TG, and LDL-C while increasing HDL-C. Their antioxidant and free radical scavenging properties protect against lipid peroxidation and oxidative damage. Some components also down-regulate lipogenesis and promote lipolysis in visceral fat, thereby reducing the atherogenic index. Collectively, these actions suggest that Vidangadi Lauha not only improves lipid levels but also helps prevent metabolic complications.[29]

Orlistat is a widely used anti-obesity drug that acts by reversibly inhibiting gastric and pancreatic lipases. By binding to the active serine site of these enzymes, it blocks triglyceride hydrolysis into absorbable fatty acids and monoglycerides, thereby reducing fat absorption by about 30%. This results in a negative energy balance, promoting gradual weight loss, especially of visceral fat linked to metabolic disorders. In addition to weight reduction, Orlistat improves glycemic control, lipid profile, and cardiovascular health. Its minimal systemic absorption ensures localized action in the gut with a favorable safety profile.[30]

The study demonstrated significant reductions in body weight, BMI, body fat percentage, abdominal girth, and waist–hip ratio in both groups. Notably, *Vidangadi Lauha* exhibited superior efficacy in alleviating the subjective symptoms of *Sthaulya*. Phytochemical and experimental studies of its ingredients support hypolipidemic, antioxidant, lipolytic, and lipogenesis-modulating activities, which likely contributed to improvements in lipid profile and reduction of visceral fat. Overall, the findings suggest that *Vidangadi Lauha* is a safe and effective, providing both metabolic and symptomatic benefits.

Conclusion - The clinical study showed significant improvement in both subjective and objective parameters of *Sthaulya. Vidangadi Lauha* effectively reduced BMI, body weight, abdominal girth, waist–hip ratio, body fat, visceral fat, body circumferences, skinfold thickness, and lipid levels, demonstrating its *Medohara, Lekhana*, and *Deepana–Pachana* properties. Both *Vidangadi Lauha* and Orlistat produced statistically significant results; however, *Vidangadi Lauha* offered greater symptomatic relief, better compliance, higher patient satisfaction, and minimal adverse effects. In contrast, Orlistat's efficacy was limited by gastrointestinal disturbances. Thus, *Vidangadi Lauha* emerges as a safe, effective, and holistic therapy for *Sthaulya*, providing a promising alternative or complementary option to conventional treatment.

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