



ISSN 2456-3110

Vol 8 · Issue 9

September 2023

Journal of
**Ayurveda and Integrated
Medical Sciences**

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences



Maharshi Charaka
Ayurveda

Indexed

A randomized controlled clinical study to evaluate the efficacy of *Gomutra Triphala Vati* in the management of *Sthoulya*

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ABSTRACT

Background: *Sthoulya* is considered as one of the *Kaphaja Nanatmaja Vyadhi*. Overweight and Obesity are defined as an abnormal, excessive fat accumulation that may impair health. The aim of the study was to assess the efficacy of the two Ayurvedic formulations, *Gomutra Triphala Vati* which is one of the unexplored *Aushadha yoga* explained in Vangasena Samhita, *Medorogaadhikaara* and *Navaka Guggulu* explained in Chakradatta, *Sthoulya Chikitsa* in the management of *Sthoulya*. (Overweight and Class One Obesity). **Materials and Methods:** 60 patients fulfilling the Diagnostic and Inclusion criteria were selected for a Single Blind Comparative study. They were randomly allocated into 2 equal groups A & B. Group A and Group B subjects received *Gomutra Triphala Vati* and *Navaka Guggulu* in a dosage of 500mg, two tablets, twice daily, after food with *Ushna Jala* (Warm water) for 45 days, respectively. Assessment was done at baseline i.e.; 0th day, 16th day, 31st day, after treatment on 46th day and after follow up on 61st day. **Results:** While comparing both the drugs clinically, *Gomutra Triphala Vati* and *Navaka Guggulu* showed effective results in *Sthoulya*. On statistical comparison within the groups, both the groups showed significant effect ($P < 0.05$) in *Atinidra*, *Alpavyayama*, *Alasya*, Body weight, BMI, Circumferences of Midarm, Waist, Chest, Hip and Thigh. **Conclusion:** On statistical comparison between the two groups there is no significant difference in the effect of both *Gomutra Triphala Vati* and *Navaka Guggulu*. Thus, H_1 is rejected and H_0 is accepted.

Key words: *Gomutra Triphala Vati*, *Navaka Guggulu*, *Sthoulya*, Overweight, Class one Obesity.

INTRODUCTION

Sthoulya is considered as one of the *Santarpanottha Vikara*^[1] and classified under *Kaphaja Nanatmaja Vyadhi*.^[2] Acharya Charaka defines *Sthoulya* as increase of *Medomamsa Dhatu* which causes *Chala Sphik*, *Chala Udara* and *Chala Stana*. There will be *Ayatha Upachaya* and *Utsahahaani* in the individual. Such persons are

called *Atisthoola* and considered as one among *Ashta Nindita Purusha*.^[3]

Sthoulya is been co-related to Overweight and Obesity in this study.

Overweight and Obesity are defined as a state of excess adipose tissue mass that adversely affects health.^[4] According to WHO, Overweight is a BMI ranging between 25-29.9 Kg /m² and Class one Obesity is a BMI ranging between 30-34.9 Kg/m².^[5]

The World Health Report of WHO listed Obesity under top ten risks to the health. Obesity is one of the burning problems globally as it will hamper the different systems in the body.^[6] According to WHO estimation in 2016 more than 1.9 billion adults are Overweight; of these, over 650 million are Obese. These include 12.6% women and 9.3% men in India. Prevalence of Obesity is more in women when compared to men.^[7]

In contemporary science, there are only limited treatments for Obesity like use of weight loss

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Submission Date: 28/08/2023 Accepted Date: 20/09/2023

Access this article online

Quick Response Code



Website: www.jaims.in

DOI: 10.21760/jaims.8.9.2

medications and Bariatric surgery. But these medications have got multiple contraindications and side effects.^[8]

In the *Chikitsa* of *Sthoulya*, various texts of Ayurveda have given wide range of options which includes many of *Aushadha yogas* like *Navaka Guggulu*,^[9] *Amritadya Guggulu*,^[10] *Loharishta*^[11] etc.

In order to explore new formulation by taking reference as mentioned in our Classics, *Gomutra Triphala Vati*^[12] is one of the unexplored *Aushadha Yoga* explained in Vangasena Samhita *Medorogaadhikaara*. The ingredients include *Gomutra* and *Triphala Choorna*.

Gomutra is *Teekshna*, *Laghu*, *Ushna*, *Kapha-Vata Shamaka*, being *Kshareeya* it has *Medonaashaka* property also.^[13] *Triphala* is *Kapha-Pitta Shamaka*, *Agnideepaka*, *Ruchya*.^[14]

In the present study, for the preparation of *Gomutra Triphala Vati*, freshly collected *Gomutra* from Indigenous Cow Breed Malnad Gidda is being used keeping in mind the Medicinal Values.^[15]

Hence, in this study an attempt is been done to evaluate the efficacy of *Gomutra Triphala Vati* in comparison with *Navaka Guggulu* which is taken as a Standard Drug in the management of *Sthoulya*.

AIM OF THE STUDY

To evaluate the therapeutic effect of *Gomutra Triphala Vati* in the management of *Sthoulya*. (Overweight and Class one Obesity)

OBJECTIVES OF THE STUDY

1. To evaluate the therapeutic effect of *Navaka Guggulu* in the management of *Sthoulya* as standard drug. (Overweight and Class one Obesity)
2. To compare the therapeutic effect of *Gomutra Triphala Vati* and *Navaka Guggulu* in the management of *Sthoulya*. (Overweight and Class one Obesity)

METHODOLOGY

Source of sample: A minimum of 60 patients attending the OPD and IPD of Alva's Ayurveda Hospital, Moodubidire, and nearby clinics who were diagnosed

as *Sthoulya* (Overweight and Class One Obesity) and fulfilling the inclusion criteria were selected. Data was collected based on a detailed case proforma designed for the study.

- **Study design** - Randomized Controlled Clinical Study
- **Blinding** - Single blind
- **Allocation** - Random allocation
- **Method of sampling** - Lottery method
- **Groups** - 2 groups
 - Group A - *Gomutra Triphala Vati*
 - Group B - *Navaka Guggulu*
- **Sample size** - 30 patients in each group
- **Total sample size** - 60 patients

Diagnostic criteria

Patients having BMI ranging from

- 25 to 29.9 Kg/m² (Over weight)
- 30 to 34.9 Kg/m² (Class One Obesity)

Associated with any two of the below mentioned features

<i>Atikshudha</i> (Excessive Hunger)	<i>Atisweda</i> (Excessive Sweating)
<i>Atipipasa</i> (Excessive Thirst)	<i>Dourgandhaya</i> (Bad Odour)
<i>Atinidra</i> (Excessive Sleep)	<i>Chala Sphik</i>
<i>Alpashwasa</i> (Difficulty in breathing)	<i>Chala Udara</i>
<i>Alpavyayama</i> (Reduced Activities)	<i>Chala Stana</i>
<i>Alasya</i> (Lethargy)	

Inclusion criteria

1. Subjects of both genders.
2. Subjects from age group 18 to 60 years.
3. Subjects having BMI between 25-34.9 Kg/m².
4. Subjects who are ready to give written informed consent.

5. Subjects fulfilling the diagnostic criteria.

Exclusion criteria

- Subjects who are known case of Diabetes Mellitus, Hypertension, any other systemic diseases.
- Obese patients with known endocrine dysfunctions.
- Pregnant women and lactating mothers.

Subjective parameters

Table 1: Subjective parameters

<i>Atikshudha</i>	<i>Atisweda</i>
<i>Atipipasa</i>	<i>Dourgandhya</i>
<i>Atinidra</i>	<i>Chala Sphik</i>
<i>Alpashwasa</i>	<i>Chala Udara</i>
<i>Alpavyayama</i>	<i>Chala Stana</i>
<i>Alasya</i>	

Objective parameters

- Body Weight
- BMI
- Midarm Circumference
- Thigh Circumference
- Chest Circumference
- Waist Circumference
- Hip Circumference
- Waist Hip ratio

Intervention

The patients fulfilling the criteria for inclusion are randomly assigned into 2 groups, each comprising of 30 patients.

Table 2: Intervention

	Group A	Group B
Study Drug	<i>Gomutra Triphala Vati</i>	<i>Navaka Guggulu</i>

Dose	500mg 2 Tablets Twice daily	500mg 2 Tablets Twice daily
<i>Anupana</i>	<i>Ushna Jala</i>	<i>Ushna Jala</i>
Route of administration	Oral	Oral
Time of administration	After food	After food
Duration of treatment	45 days	45 days

Ingredients of formulations

Gomutra Triphala Vati: Gomutra, Amalaki, Hareetaki, Vibheetaki.

Navaka Guggulu: Shunti, Maricha, Pippali, Amalaki, Hareetaki, Vibheetaki, Musta, Vidanga, Chitrakamoola and Shuddha Guggulu.

Observation Period

The patients will be assessed clinically before treatment on day 0 and during treatment, on 16th day, on 31st day and on 46th day.

Follow Up

Follow up of the patient will be done on 61st day, after the intervention period.

Total Study Duration

Total study duration including follow up will be 60 days.

Investigations

Routine Blood Investigations, Lipid profile, Thyroid function test, USG of Abdomen and Pelvis and any other relevant investigations if necessary.

OBSERVATIONS AND RESULTS

Table 3: Observation of 60 Patients

Characteristics	Predominance	Percentage
Age	41-50 years	40%
Gender	Female	61.66%
Religion	Hindu	76.6%

Marital status	Married	86.6%
Occupation	House wife	35%
Diet	Vegetarian	55%
Prakriti	Kapha Vata	68.3%
Saara	Medo Saara	58.3%
Abhyavaharana Shakti	Pravara	56.6%
Jarana Shakti	Madhyama	56.6%
Vyayama Shakti	Madhyama	63.3%
Weight	Overweight	85%
	Class I obesity	15%

Statistics

Statistical tests applied

Descriptive Statistics was applied to each parameter first. RM Anova on Ranks and One way RM Anova was performed to prove the effectiveness of the medicine before and after trial and all pair wise Multiple comparison within the group. Mann-Whitney Rank Sum Test and Unpaired t-Test was performed for comparative analysis of the overall effect of the treatments in between the groups. The summarized form of Statistical Analysis is presented below.

Table 4: Effectiveness of the medicine before and after the trial on Subjective Parameters

Assessment criteria	Group	Mean Value		RM Anova on Ranks	
		BT	AT	Q Value	P<0.05
Atikshudha	Group A	0.933	0.267	4.272	Yes
	Group B	0.933	0.333	3.695	yes
Atipipasa	Group A	0.333	0.066	1.328	No

	Group B	0.067	0.033	0.231	No
Atisweda	Group A	0.5	0.167	2.021	No
	Group B	1.267	0.333	5.484	No
Atinidra	Group A	1.3	0.4	5.427	Yes
	Group B	1.1	0.2	4.907	Yes
Alasya	Group A	1.467	0.367	6.697	Yes
	Group B	1.567	0.333	7.217	Yes
Alpashwasa	Group A	0.567	0.1	2.54	No
	Group B	0.233	0.0667	1.386	No
Alpa Vyayama	Group A	0.767	0.167	6.12	Yes
	Group B	1.3	0.3	3.464	Yes
Dourgandhya	Group A	0.167	0.0333	0.693	No
	Group B	0.967	0.433	3.853	No
Chala Sphik	Group A	0.333	0.167	0.924	NO
	Group B	0.633	0.333	2.483	NO
Chala Udara	Group A	0.533	0.2	2.136	NO
	Group B	0.533	0.3	2.021	NO
Chala Stana	Group A	0.267	0.133	0.924	No

	Group B	0.333	0.167	1.443	No
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Table 5: Effectiveness of the medicine before and after the trial on Objective Parameters

Assessment criteria	Group	Mean Value		RM Anova on Ranks	
		BT	AT	Q Value	P<0.05
Body weight	Group A	75.247	73.02	10.335	Yes
	Group B	75.44	72.51	10.508	Yes
B.MI	Group A	27.993	27.133	10.277	Yes
	Group B	28.073	27.33	10.392	Yes
Midarm Circumference	Group A	30.09	29.577	9.18	Yes
	Group B	30.183	29.613	9.295	Yes
Thigh Circumference	Group A	45.617	45.217	7.852	Yes
	Group B	46.63	46.197	9.007	Yes
Waist Circumference	Group A	104.7	104.2	8.545	Yes
	Group B	99.298	98.83	8.198	Yes
Chest Circumference	Group A	102.813	102.593	5.081	Yes
	Group B	104.407	104.093	6.928	Yes
Hip Circumference	Group A	103.017	102.867	4.561	Yes
	Group B	102.153	102.063	4.561	Yes

Waist - Hip Ratio	Group A	0.977	0.975	1.443	No
	Group B	0.976	0.974	2.021	No

Table 6: Comparative analysis of the overall effect of the treatments on Subjective and Objective Parameters

Assessment criteria	Median Value BT-AT		Mann-Whitney Test		Remark
	Group A	Group B	T Value	P Value	
<i>Atikshudha</i>	0	0	938	0.739	Non-Significant
<i>Atipipasa</i>	0	0	961.5	0.494	Non-Significant
<i>Atisweda</i>	0	0	752	0.116	Non-Significant
<i>Atinidra</i>	1	0.50	926.5	0.871	Non-Significant
<i>Alasya</i>	1	1.5	867.5	0.487	Non-Significant
<i>Alpashwasa</i>	0	0	972.5	0.398	Non-Significant
<i>Alpa Vyayama</i>	2	0	801	0.093	Non-Significant
<i>Dourgandhya</i>	0	0	769	0.131	Non-Significant
<i>Chala Sphik</i>	0	0	844.5	0.299	Non-Significant
<i>Chala Udara</i>	0	0	925.5	0.882	Non-Significant
<i>Chala Stana</i>	0	0	887.5	0.688	Non-Significant
Body weight	2.050	2	1006.5	0.178	Non-Significant

BMI	0.800	0.700	988.5	0.280	Non - Significant
Midarm Circumference	0.500	0.400	954	0.569	Non - Significant
Thigh Circumference	0.500	0.400	918	0.965	Non - Significant
Waist Circumference	0.500	0.300	1014	0.145	Non - Significant
Chest Circumference	0.150	0.200	863.5	0.451	Non - Significant
Hip Circumference	0.200	0	995	0.239	Non - Significant
Waist – Hip Ratio	0	0	885	0.661	Non - Significant

Effect of Therapy

60 patients of *Sthoulya* were randomly divided into two groups : Group A and Group B . The effects on Subjective Parameters are analyzed here, percentage wise relief compared here with respect to BT at all time points of Observation.

Table 7: Percentage wise relief in Subjective Parameters

Subjective Parameters	Group-A				Group-B			
	D16	D31	AT 46	FU 61	D16	D31	AT 46	FU 61
<i>Atikshudha</i>	21.4 3%	53.5 9%	71.3 8%	89.28 %	14.2 2%	42.7 %	64.3 %	78.56 %
<i>Atipipasa</i>	19.8 1%	60%	79.9 6%	90%	0%	50 %	50.0 7%	100 0%
<i>Atisweda</i>	7.8%	46.6 %	66.6 %	86.66 %	18.4 %	52.6 %	73.7 %	86.81 %

<i>Atinidra</i>	17.9 %	53.8 %	69.2 %	97.4 %	21.1 %	51.5 %	98.2 %	100 %
<i>Alpashwas</i>	25%	56.8 %	74.9 8%	100 %	21.3 %	55.7 %	78.7 %	89.3 %
<i>Alpavyaya</i>	23.6 %	29.4 5%	82.3 6%	94.12 %	14.16 %	14.6 %	71.3 7%	85.7 %
<i>Alasya</i>	17.4 7%	47.8 4%	78.2 %	100 %	28.23 %	56.8 %	76.9 2%	92.3 %
<i>Dourgandhya</i>	20.3 %	40.1 1%	80.0 5%	80.05 %	13.85 %	41.6 %	55.2 2%	62.04 %
<i>Chalaspshik</i>	0%	30.0 3%	49.8 4%	30.03 %	0%	21.1 %	47.3 9%	68.4 %
<i>Chalaudara</i>	12.3 %	49.9 %	62.4 %	31.33 %	0%	18.7 %	43.7 %	56.28 %
<i>Chalastana</i>	12.7 %	37.4 5%	50.1 8%	50.18 %	0%	19.1 %	49.8 %	60 %

Table 8: Percentage wise relief in Objective Parameters

Body weight	21.4 3%	53.5 9%	71.3 8%	89.2 8%	14.2 %	42.8 7%	64.3 %	78.5 6%
BMI	19.8 1%	60%	79.9 6%	90%	0%	50%	50.0 7%	100 %
Chest circumference	7.8 %	46.6 %	66.6 %	86.6 6%	18.4 %	52.6 %	73.7 %	86.8 1%
Midarm Circumference	17.9 %	53.8 %	69.2 %	97.4 %	21.1 %	51.5 %	98.2 %	100 %
Waist Circumference	25%	56.8 %	74.9 8%	100 %	21.3 %	55.3 %	78.7 %	89.3 %

Hip Circumference	23.6 %	29.4 5%	82.3 6%	94.1 2%	14.1 6%	14.1 6%	71.3 7%	85.7 %
Thigh Circumference	17.4 7%	47.8 4%	78.2 %	100 %	28.2 3%	56.3 8%	76.9 2%	92.3 %
Waist - hip ratio	20.3 %	40.1 1%	80.0 5%	80.0 5%	13.8 5%	41.3 6%	55.2 2%	62.0 4%

DISCUSSION

A total of Eleven Subjective Parameters were taken for the study. Most of the patients who complained of subjective *Lakshana* are responded well in general. Some of the parameters like *Chalatva* of *Sphik*, *Udara*, *Stana*, *Atisweda*, *Dourgandhya*, *Atipipasa* were responded mildly as the patients were mildly affected by these symptoms and in this study after Randomization, majority of them were Overweight who had 2-3 Subjective Symptoms, but those who were of Class One Obesity had more Subjective Symptoms. The *Aoushadha Yogas* are having *Meda Vilayana* and *Shoshana*, *Amapachana* properties. The vitiated *Meda* which gets deposited in *Sphik*, *Stana*, *Udara*, *Urdhwa* and *Adha Shakha* can be easily reduced by this treatment thus acting on reduction of Body weight, BMI and Circumferences.

Discussion on mode of action of Gomutra Triphala Vati

In the *Samprapti* of *Sthoulya*, there is *Kaphavridhi*, *Medodhatvagnimandya* and vitiated *Vata* due to *Avarana*.

Gomutra due to its *Laghu*, *Ushna*, *Teekshna Guna* and *Ushna Veerya* does the *Shoshana* of *Prithvi* and *Jala Mahabhuta Pradhana Medo Dhatu*.

Triphala has the action of *Deepana*, *Ruchya*, *Sara Guna* and *Tridosha Shamaka*.

Gomutra and *Triphala* both have shown Anti-obesity action in various studies individually.^[16]

Probable action on Dosha

Sthoulya is a *Kapha Vataja Vyadhi*. The *Gomutra Triphala Vati* mainly acts on *Kapha-Vata* by virtue of its *Ushna Veerya*.

Gomutra Triphala Vati is found to be effective *Kapha-Vatahara Aoushadha Yoga* which is targeted in the *Samprapti Vighnana* of *Sthoulya Roga*.

Probable action on Dooshya

There is *Meda* and *Mamsa Vriddhi* in *Sthoulya Roga* and also there is production of *Ama Rasa*. The *Gomutra Triphala Vati* breaks the *Srotosanga*. Hence the active principles can reach to the cellular level. As *Gomutra Triphala Vati* is having *Tikta*, *Katu* and *Kashaya Rasa*, they cause *Shoshana*, *Lekhana*, and *Amahara*. Due to this *Malarooopi Kapha* is removed, excessive *Medas* is scraped away and *Ama* is removed from the body.

Probable action on Agni

Gomutra and *Triphala* both are having *Deepana* and *Pachana Gunas*. *Deepana* has the action to reduce the *Mandagni* at *Kostha* and also correcting the *Dhatvagnimandya* at the level of *Medodhatu* which has become *Mandatva* by the *Avarana* of *Ama*. This *Amapachana* is achieved and *Medodhatvagni Deepana* is simultaneously achieved by the use of *Gomutra Triphala Vati*.

Probable action on Srotas

Due to *Laghu*, *Teekshna*, *Rooksha Guna* of the drugs in this *Aoushadha*, the *Gomutra Triphala Vati* breaks the *Sanga* in *Medavaha Srotas*. So, the *Uttarottara Dhatu* are nourished and the process of *Medo Vriddhi* is stopped. Hence accumulation of deranged *Medas* is inhibited by this *Aoushadha*.

Discussion on mode of action of Navaka Guggulu

- Due to *Katu Rasa*,^[17] it has *Sneha*, *Meda* and *Kleda Upashoshana* property.
- Trikatu*, *Triphala* are having *Deepana* and *Pachana Karma*.
- Hence it is *Amapachaka* and reduces the increased *Kleda*.
- Due to *Laghu*, *Rooksha*, *Teekshna Guna* and *Ushna Veerya* it improves *Jataragni* and *Dhatwagni* and *Kapha Vatahara* in nature.
- Katu Vipaka* reduces the increased *Medo Dhatu* and have *Sroto Vishodhana* action.

- Various studies showed that *Navaka Guggulu* formulation possess Antihyperlipidemic, Anti-obesity activities^[18] and beneficial in weight reduction.

CONCLUSION

While comparing both the drugs clinically, *Gomutra Triphala Vati* and *Navaka Guggulu* showed effective results in *Sthoulya*. On statistical comparison within the groups, both the groups showed significant effect ($p < 0.05$) in *Atinidra*, *Alpavyayama*, *Alasya*, Body weight, BMI, Circumferences of Midarm, Waist, Chest, Hip and Thigh. After treatment there was significant effect on all the parameters except *Atipipasa*, *Atisweda*, *Dourgandhya*, *Chala Sphik*, *Udara*, *Stana* and Waist hip ratio, where statistically insignificant result was seen. The effect of the drugs were maintained even after the treatment till the period of follow-up. On comparing between two groups, there was no statistical significant difference in the effect of treatment with $p > 0.05$. Hence null hypothesis (H_0) is accepted.

H_0 - There is no Statistically significant difference in the efficacy of *Gomutra Triphala Vati* and *Navaka Guggulu* in the management of *Sthoulya*. (Overweight and Class one Obesity).

ACKNOWLEDGMENTS

I would like to express my gratitude to my institution and hospital who gave me the possibility to complete this project. Also, I take this opportunity to express my gratitude to my Guide and Co-guide for their valuable guidance.

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How to cite this article: Prithvi N Bhat, Susheel Shetty, Nikel Kumari. A randomized controlled clinical study to evaluate the efficacy of Gomutra Triphala Vati in the management of Sthoulya. J Ayurveda Integr Med Sci 2023;09:07-15.

<http://dx.doi.org/10.21760/jaims.8.9.2>

Source of Support: Nil, **Conflict of Interest:** None declared.
