

A COMPARATIVE STUDY ON EFFICACY OF GOMUTRA HARITIKI AND VRIKSHAMLA(EXTRACT) IN THE MANAGEMENT OF STHAULYA. W.S.R. TO OVERWEIGHT

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ABSTRACT

Sthaulya is abnormal and excess accumulation of Meda Dhatu. In contemporary medical science it is compared with obesity and it is defined as excess body and visceral fat that poses health risk. As we see the Samprapti of Sthaulya, due to Meda-*Dhatwagni Mandya* there is excessive accumulation of Meda that leads to obstruction of Medovaha Strotasa. Due to this, there is Vimargagamana of Vata Dosha. The Vimargaga Vayu in Koshta ultimately increases the Jatharagni leading to an increase in appetite. This cycle goes on and on. This study was taken by looking at the present statistics of the incidence and prevalence of Obesity. In present study 30 patients were randomly selected and divided into two groups of 15 patients each. Gomutra Haritiki and Vrikshamla(extract) were given to Group I and Group II respectively for 60 days. After the completion of trial comparative efficacy and safety profile of both the formulations were assessed on different subjective and objective parameters. Result and Discussion revealed that both *Gomutra Haritiki* and *Vrikshamla(extract)* were quite effective in relieving both subjective and objective parameters after the course of 60 days.

Keywords: *Sthaulya, Meda Dhatu, Obesity, Gomutra Haritiki, Vrikshamla*

INTRODUCTION

Previously, the stigma of infectious diseases was the most common concern of the health sector, especially in the developing nation like India. But gradually with advancements in the medical health sciences, such infectious diseases are now more or less well under human control. More recently, there had been a major shift in the thrust area of medical concern from the infectious to non-infectious diseases or non-communicable diseases¹. Very rightly, such non-infectious diseases are, otherwise, known as the “lifestyle diseases” as their causation has been very

well studied and associated with the change in the lifestyle including the diet and activities². Obesity is one among such lifestyle diseases, which has been identified to be posing a major threat in the community in the recent years. Obesity is a leading preventable cause of death worldwide, with an increasing prevalence in adults and children, and authorities view it as one of the most serious public health hazard of 21st century. It’s like a sword hanging over one’s head tied in a weak thread which can strike at any time and create numerous difficulties and boundless miseries. Excess weight brings in increased mortality and morbidity. Among

Indian population 75% of women and 58% of male are obese³. Obesity is a state in which there is generalized accumulation of excess fat in the body leading to increased body weight in excess of 20% of desired weight for age and height. Obesity is no longer a problem in developed nations. Obesity is stigmatized in many of the modern world (particularly in Western world) though it was widely perceived as a symbol of wealth and fertility at other times in history and is in some parts of the world. People are getting fatter everywhere in almost all the parts of the world. There are various reasons for more and more people getting fatter by each day.

Obesity is the cause of various diseases particularly heart disease, diabetes, breathing difficulties during sleep, certain type of cancer and osteoarthritis.

Acharya Charaka has quoted *Sthaulya* under the eight varieties of impediments which are designated as *Astha ninditha*

2. Eligibility Criteria:

Inclusion Criteria:	Exclusion Criteria:
Diagnosed and confirmed cases of <i>Sthaulya</i> on the basis of clinical examination.	Patients suffering from diseases like nephrotic syndrome, hypothyroidism, jaundice, hepatitis, chronic infections and other serious diseases.
Age group 20-60 years of either sex.	Age below 20 years and above 60 years.
BMI in between 25 to 29.9.	BMI below 25 or over 29.9
Patients willing to sign the consent form.	Obesity due to secondary reason such as drug induced or hormonal imbalance.

3. Selection of Drugs: 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 drugs *Gomutra Haritiki* and *Vrikshamla* were preferred over others for present study.

4. Administration of Drug: 30 clinically diagnosed patients were randomly divided into 2 Groups of 15 each as below:

*purusha*⁴. It is one among the *santarpanotta vikara*⁵.

Many new researches and new efforts are being carried out in the path of solution for *Sthaulya*. An attempt has been made in the present study to compare the efficacy and safety profile of *Gomutra Haritiki*⁶ and *Vrikshamla* in the management of *Sthaulya*.

AIMS AND OBJECTIVE

1. To evaluate the efficacy of *Gomutra Haritiki* and *Vrikshamla*(extract) in *Sthaulya*(obesity) w.s.r. Overweight
2. To compare clinical efficacy of *Gomutra Haritiki* with *Vrikshamla*(Extract).

MATERIALS & METHODS:

1. Selection of Cases: The study was conducted on 30 clinically diagnosed patients of *Sthaulya*(Obesity) w.s.r. Overweight. The selection of patients was made from OPD/IPD of *Arogyashala*, National Institute of Ayurveda, Jaipur (Raj.).

Group A - 15 patients were administered *Gomutra Haritiki* in dose of 5gm twice in a day before meal with *Madhu* for 60days.

Group B - 15 patients were administered *Vrikshamla* (extract) 3 cap (500mg) twice a day before meal with lukewarm water for 60days.

5. Routine Examination and Assessment: -

The full details of history and physical examination of patients will be recorded as per the proforma. Clinical and physiological assessment were done on 0th day, 15th day, 30th day, 45th day & 60th day.

6. Pathyapathya:- Patients were advised to follow *Pathyapathya* as mentioned in *Ayurvedic* classics during the trial period.

1. PARAMETERS OF EVALUATION:

The effect of trial drug will be assessed in terms of Subjective, Anthropometry and Laboratory parameters.

A. Subjective parameters: - All the patients were registered for clinical trial and were looked for any changes in their clinical manifestations. Symptom rating scale was used for assessment of subjective parameters like *Atiksudha*, *Atipipasa*, *Daurgandhya*, *Swedadhikya*, *Daurbalya*, *Nidradhikya*, *Krichchavyavayta*, *Gaurava*, *Kshudraswasa* and *Angasada* before and after the treatment. Clinical trial was conducted by making a special research proforma.

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

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

ASSESSMENT OF SUBJECTIVE PARAMETERS

• 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

• 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

• 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

• Assessment of *Swedaadhikya* (Excessive sweating)

0 –	Normal perspiration
1 –	Mild perspiration after doing exertion

1) Subjective parameters: For subjective parameters following symptoms will be assessed:-

- *Kshudha aadhikya* (excessive hunger)
- *-Pipasa aadhikya* (excessive thirst)
- *-Kshudra swasa* (Breathlessness on exertion)
- *Sweda aadhikya* (excessive sweating)
- *-Atinidra* (excessive sleep)
- *-Dourbalya* (weakness)
- *-Gaurava* (Heaviness of body)
- *-Alasya* (letharginess)
- *-Angasada* (sluggishness of body)
- *-Krichchavyavayata*(difficulty in sexual intercourse)

2 –	Increased perspiration after doing little exertion
3 –	Profuse perspiration after doing little exertion
4 –	Perspiration without exertion

• **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

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

• **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.

• **Assessment of Alasya (Letharginess)**

- 0- Normally active.
- 1- Hesitate to start work but once started complete it.
- 2- Start work but does not complete it.
- 3- Doesn't have desire, works under compulsion.
- 4- Doesn't start work.

• **Assessment of Angasada (Sluggishness of the body)**

- 0- Absent
- 1- Occasional *Angasada*
- 2- Continuous *Angasada* but not interfere any activity
- 3- Continuous *Angasada* and sometimes interfere daily activity
- 4- Continuous *Angasada* which hamper daily activity and confined patient to complete rest.

• **Assessment of Krichchavyavayata (loss of libido)**

- 0- Absent
- 1- mild loss of libido
- 2- moderate loss of libido
- 3- severe loss of libido
- 4- complete loss of libido

B. Anthropometry Parameters: -

Following measurements were done; Weight, BMI and Waist Hip Ratio.

C. Laboratory Parameters: Following investigations were done to assess the changes of different regimes: -

✓ **Routine Blood Investigation**

- -Hemoglobin%
- -Total Leukocyte Count
- -Differential Leukocyte Count
- -Erythrocyte Sedimentation Rate

✓ **Renal Function Test**

✓ **Liver Function Test**

✓ **Lipid profile**

- Total cholesterol
- Sr.Triglycerides
- Sr.LDL
- Sr.HDL
- Sr.VLDL

D. Results:- Results were presented into three steps:-

- a) Effect of Therapy on Subjective Parameters.
- b) Effect of Therapy on Objective Parameters.
- c) Effect of Therapy on Laboratory Parameters.

- E. Statistical Analysis:-**
- a) **Unpaired t test** – baseline data comparison
 b) **Paired t test** – within group comparison
 c) **Unpaired t test** – between group comparisons

SUBJECTIVE PARAMETERS

Table1. Showing the pattern of clinical recovery in 15 patients of Sthaulya (Obesity) treated with Gomutra Haritiki i.e. Group I (paired't' test)

Signs & symptoms	Mean		Mean difference±SD	Relief in %	't' stat	'p' value
	BT ±SD	AT ±SD				
<i>Kshudhaadhikya</i>	1.8 ± 0.77	1.2 ± 0.67	0.6 ± 0.73	33.33	3.15	<0.01
<i>Pipasa</i>	2.13 ± 0.63	1.53 ± 0.63	0.6 ± 0.63	28.16	3.67	<0.01
<i>Daurbalya</i>	0.93 ± 0.79	0.6 ± 0.73	0.33 ± 0.48	35.48	2.64	<0.05
<i>Swedaadhikya</i>	1.26 ± 0.74	0.86 ± 0.51	0.4 ± 0.63	31.74	2.44	<0.05
<i>Atinidra</i>	1 ± 0.75	0.73 ± 0.7	0.26 ± 0.45	26	2.25	<0.05
<i>Kshudraswasa</i>	0.86 ± 0.63	0.6 ± 0.63	0.26 ± 0.45	30.23	2.25	<0.05
<i>Angasada</i>	1.06 ± 0.7	0.66 ± 0.72	0.4 ± 0.63	37.73	2.44	<0.05
<i>Krichhavyavaya</i>	0.26 ± 0.45	0.13 ± 0.35	0.13 ± 0.35	50	1.46	>0.05
<i>Gaurav</i>	1.13 ± 0.63	0.8 ± 0.67	0.8 ± 0.67	29.2	2.64	<0.05
<i>Aalsyata</i>	1.2 ± 0.67	0.86 ± 0.74	0.86 ± 0.74	27.5	2.64	<0.05

Table2. Showing the pattern of clinical recovery in 15 patients of Sthaulya (Obesity) treated with Vrikshamla i.e. Group 2 (paired' test)

Signs & symptoms	Mean		Mean difference ±SD	Relief in %	't' stat	'p' value
	BT ±SD	AT ±SD				
<i>Kshudhaadhikya</i>	1.8 ± 0.77	1.13 ± 0.74	0.66 ± 0.61	36.6	4.18	<0.01
<i>Pipasa</i>	2.26 ± 0.59	1.4 ± 0.63	0.86 ± 0.35	38.05	4.53	<0.001
<i>Daurbalya</i>	0.93 ± 0.79	0.46 ± 0.51	0.46 ± 0.51	49.4	3.5	<0.01
<i>Swedaadhikya</i>	1.33 ± 0.81	0.86 ± 0.74	0.46 ± 0.51	34.5	3.5	<0.01
<i>Atinidra</i>	1 ± 0.75	0.66 ± 0.61	0.33 ± 0.48	33	2.64	<0.05
<i>Kshudraswasa</i>	0.86 ± 0.74	0.46 ± 0.51	0.4 ± 0.5	46.51	3.05	<0.01
<i>Angasada</i>	1.06 ± 0.7	0.6 ± 0.5	0.46 ± 0.51	43.39	3.5	<0.01
<i>Krichhavyavaya</i>	0.26 ± 0.45	0.13 ± 0.35	0.13 ± 0.35	50	1.56	>0.05
<i>Gaurav</i>	1.13 ± 0.6	0.6 ± 0.5	0.53 ± 0.51	46.9	4	<0.01
<i>Aalsyata</i>	1.4 ± 0.73	0.8 ± 0.67	0.6 ± 0.5	42.8	4.58	<0.001

Table3. Inter group comparison of subjective parameters (unpaired't' test)

Subjective parameters	Mean difference		't' stat	'p' value
	Group 1	Group 2		
<i>Kshudhaadhikya</i>	0.6	0.66	0.26	>0.05
<i>Pipasa</i>	0.6	0.86	1.42	>0.05
<i>Daurbalya</i>	0.33	0.46	0.72	>0.05
<i>Swedaadhikya</i>	0.4	0.46	0.31	>0.05
<i>Atinidra</i>	0.26	0.33	0.38	>0.05
<i>Kshudraswasa</i>	0.26	0.4	0.75	>0.05
<i>Angasada</i>	0.4	0.33	0.32	>0.05
<i>Krichhavyavaya</i>	0.13	0.13	0	>0.05
<i>Gaurav</i>	0.33	0.53	1.09	>0.05
<i>Aalsyata</i>	0.33	0.6	1.46	>0.05

2. OBJECTIVE PARAMETERS

Table4. Showing the pattern of objective parameters in 15 patients of Sthaulya (Obesity) treated with Gomutra Haritki in Group I (paired't' test)

Signs & symptoms	Mean		Mean difference±SD	Relief in %	't' stat	'p' value	
	BT ± SD	AT ±SD					
Haemoglobin	12.7 ± 1.45	12.72± 1.48	0.24±0.38	1.88	4.36	<0.001	
ESR	26.4 ± 14.8	25.26± 13.49	1.13±7.87	4.28	0.31	>0.05	
Total Cholesterol	193.06±17.69	182.2±18.75	10.9±12.06	5.66	3.4	<0.01	
Serum Triglycerides	158.26±25.19	149.5±29.16	8.86±9.27	5.59	3.5	<0.01	
Serum HDL	50.61± 5.89	50.74±5.81	0.13±1.55	0.25	1.58	>0.05	
Serum LDL	96.88 ± 23.76	89.74±21.94	7.13±7.85	7.35	3.27	<0.01	
Serum VLDL	33.94 ± 9.6	30.48±8.51	3.35±5.52	9.87	2.09	>0.05	
RF	B.Urea	32.2 ± 4.44	29.26±4.18	2.93±0.03	9.09	3.1	<0.01
T	Sr.Creatinine	0.85 ± 0.1	0.76±0.14	0.08±0.13	9.41	11.8	<0.001
LF	SGOT	29.6 ± 7.06	27.93±4.26	1.66±4.25	5.6	1.06	>0.05
T	SGPT	30.06 ± 8.77	28.73±8.41	1.33±3.55	4.42	0.9	>0.05
	Al.Phos.	173.86±50.56	161.13±41.06	16.06±24.92	9.23	2.49	<0.05

Table 5 Showing the pattern of objective parameters in 15 patients of Sthaulya (Obesity) treated with Vrikshamla in Group 2 (paired' test)

Signs & symptoms	Mean		Mean diff.±SD	Relief in %	't' stat	'p' value	
	BT ± SD	AT ±SD					
Haemoglobin	12.76±1.67	12.79±1.76	0.24±0.4	1.88	4.27	<0.001	
ESR	23.93±15.51	20.13±12.17	3.8±5.6	15.87	2.27	<0.05	
Total Cholesterol	188.06±30.94	174.46±27.03	13.6±11.17	7.23	4.53	<0.001	
Serum Triglycerides	158.46±37.62	149.26±34.02	9.2±5.65	5.8	5.95	<0.001	
Serum HDL	53.13±6.88	50.86±6.9	2.53±3.6	4.76	1.8	>0.05	
Serum LDL	94.13±21.41	85.46±22.43	8.66±7.03	9.2	4.94	<0.001	
Serum VLDL	30.66±4.49	29.33±2.94	1.46±2.99	4.7	1.05	>0.05	
RFT	B.Urea	32.13±5.65	29.2±5.23	2.93±2.98	9.11	3.15	<0.01
	Sr.Creatinine	0.83±0.13	0.78±0.094	0.053±0.1	6.38	16.31	<0.001
LFT	SGOT	29.26±6.02	28±4.92	1.53±3.48	5.22	0.64	>0.05
	SGPT	27.8±6.1	27±4.92	1.46±1.92	5.25	0.5	>0.05
	Al.Phosphate	165.93±37.97	159.73±34.67	6.2±10.64	3.73	2.07	>0.05

Table6. Inter group comparison of objective parameters (unpaired' test)

Objective parameters	Mean difference		't' stat	'p' value
	Group 1	Group 2		
Haemoglobin	0.246	0.24	0.045	>0.05
ESR	1.13	3.8	1.06	>0.05
Total cholesterol	10.93	13.6	0.628	>0.05
Serum triglycerides	8.86	9.2	0.11	>0.05
Serum HDL	0.13	2.53	2.36	>0.05
Serum LDL	7.13	8.66	0.56	>0.05
Serum VLDL	3.53	1.46	1.16	>0.05
Serum urea	2.93	2.93	0	>0.05

Serum creatinine	0.086	0.053	0.75	>0.05
SGOT	1.66	1.53	0.093	>0.05
SGPT	1.33	1.46	0.12	>0.05
Alkaline phosphatase	16.06	6.2	1.409	>0.05

3. ANTHROPOMETRIC PARAMETERSTable No.7.Showing the pattern of physiological changes in 30 patients of Sthaulya(Obesity) among both Groups

Parameters	Groups	Mean		Mean dif-ference	Relief	't' stat	'p' value
		BT ± SD	AT ± SD				
Body Weight	Gp 1	72.6±8.77	70.56±8.31	2.03±1.74	2.79	3.39	<0.01
	Gp 2	70 ±7.53	68.06±7.26	1.93±1.03	2.75	5.37	<0.001
BMI	Gp 1	27.8±0.9	27.04±1.18	0.75±0.66	2.69	1.49	>0.05
	Gp 2	26.93±0.97	26.18±1.04	0.74±0.37	2.74	2.59	<0.05
WHR	Gp 1	0.99±0.03	0.95±0.05	0.043±0.045	4.343	39.04	<0.001
	Gp 2	1.002±0.027	0.95±0.03	0.042±0.02	4.19	68.01	<0.001

Table8. Inter group comparison of anthropometric parameters (unpaired't' test)

Parameters		Mean difference	't' stat	'p' value
Body Weight	Group 1	2.03 ± 1.74	0.19	>0.05
	Group 2	1.93 ± 1.03		
BMI	Group 1	0.757 ± 0.66	0.06	>0.05
	Group 2	0.745 ± 0.37		
WHR	Group 1	0.043 ± 0.045	0.04	>0.05
	Group 2	0.042 ± 0.02		

DISCUSSION:

A. Probable Mode of Action of

Drugs: In *Ayurveda*, the action of drugs is determined on pharmacodynamic factors as *Rasa*, *Guna*, *Veerya* and *Vipaka* along with certain specific properties called *Prabhava (Karma)*, which cannot be explained on these principles inherited by the drugs. These drugs in combination act as antagonist to the main morbid factors i.e. *Dosha* and *Dushya* to cause *Samprapti Vighatana* to all of the symptoms of the disease.

Gomutra Haritiki:

In *Gomutra Haritiki* the only constituents are *Gomutra* and *Haritiki*. *Gomutra* has *Tikshana*, *Ushana* and *Laghu Guna*, while *Haritiki* has *laghu* and *Ruksha Guna*. Both the constituents have predominance of *Vayu* and *Agni Mahabhuta*. So by means of such properties both drugs have a negative impact on *Kaphavidhi* and *Medovridhi*. Also *Gomutra Haritiki* have *Deepana*, *pachana* properties which stimulate *Jathargani* along with *Dhatvagni*

as well as it digest *Ama*, clears *Srotorodha*. Hence *Amasanchya* and *Srotorodha* are the fundamental cause of *Sthaulya*, So having such property of clearing *Amasanchaya* and *Srotorodha* in *Gomutra Haritiki* will lead to breakdown of pathology of *Sthaulya(Samprapti vighatana)*.

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 digest 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 on the basis of 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

In the present research work on the basis of facts, observations and result the whole study can be concluded in following steps:

- ✓ *Gomutra Haritiki* and *Vrikshamla* both showed significant improvement in all the subjective parameters except *Krichchvyavayta*.
- ✓ *Gomutra Haritiki* and *Vrikshamla* both showed significant improvement in all the anthropometric parameters like Body Weight, BMI and Waist Hip Ratio.
- ✓ *Gomutra Haritiki* and *Vrikshamla* both showed significant in all the considered biochemical investigative parameters except Sr. HDL.
- ✓ No side effect were noticed in any of the group which proves safety of *Gomutra Haritiki* and *Vrikshamla* for internal use.

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