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An observational pilot study on the effect of *Gomutra Haritaki*, diet control and exercise in the management of *Sthaulya* (obesity)

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Abstract

Background: India is currently witnessing rising numbers of people in the middle-class who are obese. A lot of the Indian population has started relying on processed foods that contain a huge percentage of trans-fat, sugars, and other unhealthy and artificial ingredients. Obesity is considered the core of many diseases. Increased weight carries significant health risks for some cancers, diabetes, heart diseases and strokes. Junk food, alcohol and sedentary lifestyle are leading us to silent self destruction, making one in every five Indian men and women either obese or overweight. **Aim:** To determine the effect of *Gomutra Haritaki* on *Sthaulya*. **Materials and Methods:** An observational pilot study on the effect of *Gomutra Haritaki*, diet control and exercise in the management of *Sthaulya* (obesity) was conducted on 21 patients. Enrolled patients were screened on the basis of clinical findings and allocated into two groups. Trial group received *Gomutra Haritaki* (6 g/day in three divided doses) while control group received placebo capsules in the same dose for 8 weeks. **Result:** Statistically highly significant relief was found in weight reduction ($P < 0.001$), and body mass index (BMI) ($P < 0.01$) in both groups. Control group has shown better results against trial group. **Conclusion:** These results prove the impact of diet and exercise in the management of *Sthaulya*.

Key words: Cow's urine, *Gomutra, Haritaki,* obesity, *Sthaulya, Terminalia chebula*

Introduction

Sthaulya (obesity) is a state of increased *Medodhatu* (fat).[1] It is one of the *Santarpanottha Vikaras*[2] (diseases of excess nourishment) where a physician needs to apply the principle of *Vishesha* (dissimilarity), which can restore the unhealthy increase of components to the healthy form. Prevalence of *Sthaulya* in society is increasing day by day due to decreased awareness regarding exercise and faulty dietary habits. It has reached up to epidemic level. *Sthaulya* is a disease in which there is abundant growth of *Medodhatu* in the body beyond normal limits. The present study is aimed to determine the effect of *Gomutra Haritaki*[3] on *Sthaulya*.

Materials and Methods

All the patients were selected for the present study by keeping in views, the symptomatology of *Sthaulya* as mentioned in Ayurvedic texts as well as criteria mentioned in modern texts for diagnosis of obesity, irrespective of age, sex, religion and economic status.

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Criteria for diagnosis

1. Patients with signs and symptoms of *Sthaulya* in Ayurvedic classics supported by symptomatology of obesity. i.e. *Chala Sphik/Udara/Stana* (pendulous buttock/abdomen/breast), *Swedadhikya* (excessive sweating), *Angadaurgandhya* (bad body odor), *Angagauravata*, *Ati Kshudha* (excessive hunger), *Ati Pipasa* (excessive thirst), *Kshudra Shwasa* (dyspnoea on exertion), *Utsaha Hani* (lack of enthusiasm), *Ati Nidra* (excessive sleep)
2. Detailed examinations to exclude other pathologies were carried out. For the diagnosis of obesity, standard height weight chart, which was recommended by the courtesy of "Life Insurance Corporation of India", was adopted.[4] On this basis, a person carrying about 10% more weight for the ideal weight for a particular age (11-60 years), sex and height was considered as *Sthula* (obese)
3. Moreover, the value of Body Mass Index (BMI) was also taken into consideration while making to the final diagnosis. The person whose value of BMI was more than 25 kg/m^2[5] was considered as a case of *Sthaulya*

4. In addition to this, abdomen, chest, buttocks, mid-arm and mid-thigh circumference was taken. To exclude any other pathology; routine investigations of blood, urine analysis, stool analysis and bio-chemical investigations such as blood sugar level, serum cholesterol and total lipid estimation were carried out.

Grouping

All the selected patients were randomly divided into two groups.

Trial group (Gomutra Haritaki)

Patients of this group were treated with 500 mg tablets of *Gomutra Haritaki*. The drug was administered in a dose of 6g per day (4 tablets thrice a day) with luke warm water during *Abhakta* (early morning) and *Prakbhakta Kala*[6,7] (before lunch and dinner) for eight weeks.

Control group (placebo group)

Patients of this group were treated with placebo capsules, filled with fried *Rawa* (wheat flour). The dose, *Anupana*, *Kala* and duration were kept the same as that of the trial group.

Diet and physical exercise

Patients of both groups were given a chart comprising diet restrictions and exercises.

Criteria of assessment

For assessing the changes, patients were examined at weekly intervals. Suitable scoring method for the symptoms and signs was adopted. The efficacy of the therapy was assessed on the basis of subjective as well as objective criteria.

Subjective criteria

Most of the signs and symptoms of *Sthaulya*[8-10] described in Ayurveda are subjective in nature.

The details of the scores adopted for the main signs and symptoms in present study are as follows:

1. *Chala Sphik - Udara - Stana*

Absence of *Chalatva*	- 0
Little visible movement (in the areas) after fast movement	- 1
Little visible movement (in the areas) even after moderate movement	- 2
Movement (in the areas) after mild movement	- 3
Movement (in the areas) even after changing posture	- 4

2. *Utsaha Hani*

No *Alasya* (doing work satisfactory with) proper vigour in time	- 0
Doing work with desire with initiation late in time	- 1
Doing work without desire with lot of mental pressure and late in time	- 2
Not starting any work with own responsibility, doing little work very Slowly	- 3
Does not have any initiation and not wants to work even after pressure	- 4

3. *Kshudra Shwasa*

No Dyspnoea even after heavy work (movement)	- 0
Dyspnoea after moderate work but relieved later and upto tolerance capacity.	- 1
Dyspnoea after little work but relieved later and upto tolerance capacity	- 2
Dyspnoea after little work but relieved later and beyond tolerance capacity	- 3
Dyspnoea in resting condition	- 4

4. *Atinidra*

Sleep upto 6 to 7 hours per day	- 0
Sleep upto 8 hours/day with *Angagaurava*	- 1
Sleep upto 8 hours/day with *Jrumbha*	- 2
Sleep upto 10 hours/day with *Tandra*	- 3
Sleep more than 10 hours/day with *Tandra* and *Klama*	- 4

5. *Swedadhikya* (Sweating at normal temperature in normal condition)

Sweating after heavy work and fast movement or in hot season	- 0
Profuse sweating after moderate work and movement	- 1
Sweating after little work and movement	- 2
Profuse sweating after little work and movement	- 3
Sweating even at rest or in cold season	- 4

6. *Anga Daurgandhya*

Absence of bad smell	- 0
Occasional bad smell in the body removed after bathing	- 1
Persistent bad smell limited to close areas, difficult to suppress with deodorants	- 2
Persistent bad smell felt from long distance not suppressed by deodorants	- 3
Persistent bad smell felt from long distance even intolerable to the patient himself	- 4

7. *Anga Gauravata*

No heaviness in body	- 0
Feels heaviness in body but it does hot hamper routine work	- 1
Feels heaviness in body which hampers daily routine work	- 2
Feels heaviness in body which hampers movement of the body	- 3
Feels heaviness with flabbiness in all over body which causes distress to the person	- 4

8. *Ati Pipasa*

Upto 1 to 1.5 litres of intake per day	- 0
Upto 1 litre excess intake of water	- 1
1 to 2 litre excess intake of water	- 2
2 to 3 litre excess intake of water	- 3
More than 3 litre intake of water	- 4

9. *Ati Ksudha*

Normal diet with lunch and dinner	- 0
Morning break fast with lunch and dinner	- 1
Supplementary food with above mentioned articles	- 2

Objective criteria

It was assessed on body weight, measurement of circumference and BMI before and after the treatment.

Statistical analysis

To assess results objectively and for statistical analysis, multidimensional scoring system was adopted. This scoring was

obtained before and after the treatment through statistical analysis, percentage relief was taken to assess the efficacy of therapy.

Criteria for overall effect of therapy

Overall effect was decided on the basis of scores given to the following parameters.

- Body weight and BMI reduction – 33.333%
- Girth circumference – 33.333%
- Improvement in signs and symptoms – 33.333%.

Observations and Results

In the present study, a total of 44 patients of *Sthaulya* were registered. Out of which, 21 patients (13 from trial group and 8 from control group) have completed the course of treatment; whereas 23 patients have left the course against medical advice at different stages.

Enrolled patients were in the range of 15-60 years. Maximum numbers of patients (36.32%) were from the age group of 31-40 years. Sex wise distribution shows that the maximum number of patients (83.99%) were females.

Distribution of 44 patients of *Sthaulya* according to their *Nidana Sevana* is shown in Table 1.

Effect of therapy

Effect of therapy in Trial Group on Subjective criteria is shown in Table 2, while its effect on weight reduction, BMI and girth circumference is shown in Table 3.

Effect of placebo in subjective criteria is depicted in Table 4. Effect of placebo on weight reduction, BMI and girth circumference is depicted in Table 5.

Overall effect of therapy

Maximum numbers (38.46%) of patients were found to be moderately improved followed by the same number of patients as improved, 15.38% patients were markedly improved and 7.69% patients remain unchanged in the trial group.

Maximum numbers (50%) of patients were found as moderately improved followed by 37.50% patients as improved and 12.50% patients observed as markedly improved and none of the patient remains unchanged in this group [Table 6].

Discussion

The term "*Sthula*" itself indicates the deposition of *Prithvi* and *Apa Mahabhuta* dominant factors in the body.[11] *Nidana* (causative factors) of *Sthaulya* is divided into four categories i.e. *Aharatmaka* (food), *Viharatmaka* (behavioral), *Manasa* (psychological) and *Anya* (others). Intake of highly refined food with maximum percentage of carbohydrates and working with high-tech machineries, which makes a person less active and prone to *Sthaulya*. Now-a-days, *Nidanas* of *Sthaulya* are changing, e.g. previously *Manasonivrtti* (reduced mental exercises) and *Harshanityatva* (cheerfulness) were said to be the *Nidanas* of *Sthaulya*, but these are now changing to increasing stress, which causes episodes of binge eating leading to *Sthaulya*. Hereditary factor is also the prominent cause for *Sthaulya*.[12]

Samprati (etiopathogenesis) of *Sthaulya* can be interpreted in two ways. According to Charaka, increased *Jatharagni* (digestive power) causes maximum ingestion and leads to maximum absorption of *Prithvi* and *Apa Mahabhuta* dominant factors in the body leading to increased *Medodhatu* in the body.[13] According to Dalhana, there is a state of *Medodhatvagnimandya* (reduced status of a type of metabolic component situated at the level of *Medodhatu*), which leads to excessive formation of improper *Medodhatu* leading to *Sthaulya*.[14]

Here, *Sthaulya* is taken for study because there is abundant growth of *Medodhatu* in the body which is having *Prithvi*

Table 1: Distribution of 44 patients of *Sthaulya* according to their *Nidana Sevana*

***Nidana* (causative factors)**	**Trial group**	**Control group**	**Total**	**Percentage**
Bijadoshaswabhavat (heredity)	15	6	21	47.67
Aharatmaka (food)				
Ati Bhojana (over intake)	12	4	16	36.32
Ati Guru	6	3	9	20.43
Ati Snigdha	12	4	16	36.32
Ati Sheeta	4	2	6	13.62
Ati Madhura	22	8	30	68.18
Dadhi (curd)	22	10	32	72.72
Mamsa (meat)	2	-	2	4.54
Viharatmaka (daily regimen)				
Avyayama (lack of physical exercise)	25	12	37	83.94
Diwaswapa (day sleeping)	25	11	36	81.72
Ati Nidra (excessive sleeping)	7	2	9	20.43
Cheshtadvesha (aversion towards physical movements)	12	4	16	36.32
Asana Sukha (excessive seating)	22	7	29	65.83
Manasa (psychological)				
Achintana (lack of mental exercise)	22	7	29	65.83
Harshanityatva (cheerfulness)	20	8	28	63.56

Table 2: Effect of *Gomutra Haritaki* on subjective criteria (*n*=13)

Symptoms	Mean BT	Mean AT	Mean difference	Percentage of relief	SD	SE	*t*	*P*
Chala Sphik/Udara/Stana (pendulous buttock/abdomen/breast)	1.46	1.30	0.16	10.95	0.37	0.104	1.46	>0.05
Swedadhikya (excessive sweating)	1.76	1.07	0.68	38.81	0.48	0.133	5.17	<0.001
Angadaurgandhya (bad body odor)	1.53	0.92	0.6	39.66	0.50	0.14	4.33	<0.001
Angagauravata	1.61	0.69	0.91	56.99	0.49	0.137	6.71	<0.001
Ati Kshudha	1.30	0.61	0.68	52.66	0.48	0.133	5.17	<0.001
Ati Pipasa	1.46	0.76	0.69	47.31	0.48	0.133	2.25	<0.01
Kshudra Shwasa	1.38	0.76	0.61	44.25	0.50	0.14	4.33	<0.001
Utsaha Hani (lack of enthusiasm)	1.53	0.38	1.14	74.86	0.68	0.19	6.02	<0.001
Ati Nidra	1.15	0.61	0.53	46.48	0.51	0.144	3.67	<0.01

SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment

Table 3: Effect of *Gomutra Haritaki* on objective criteria (*n*=13)

Parameter	Mean BT	Mean AT	Mean difference	Percentage of relief	SD	SE	*t*	*P*
Weight (kg)	78.11	74.69	3.42	4.37	2.84	0.78	4.33	<0.001
BMI (kg/m^2)	32.56	31.11	1.45	4.45	1.27	0.35	4.06	<0.01
Circumference								
Chest	97.46	96.03	1.43	1.46	1.73	0.41	2.95	<0.05
Abdomen	95.78	92.23	3.54	3.70	4.49	1.24	3.99	<0.01
Buttocks	106.9	104.3	2.59	2.42	2.45	0.68	4.39	<0.001
Mid-arm	31.38	30.37	0.64	2.06	0.59	0.16	3.94	<0.01
Mid-thigh	58.62	28.30	0.31	0.52	1.39	0.38	1.54	>0.05

SD: Standard deviation, SE: Standard error. BMI: Body mass index, BT: Before treatment, AT: After treatment

Table 4: Effect of placebo on subjective criteria (*n*=8)

Symptoms	Mean BT	Mean AT	Mean difference	Percentage of relief	SD	SE	*t*	*P*
Chala Sphik/Udara/Stana	1.5	1.318	0.125	8.33	0.35	0.125	1	>0.05
Swedadhikya	1.625	0.75	0.825	53.84	0.53	0.189	5.27	<0.01
Angadaurgandhya	1	0.125	0.875	87	0.83	0.29	2.956	<0.05
Angagauravata	1.5	0.5	1	66.66	0.53	0.18	5.27	<0.01
Ati Kshudha	1.375	1	0.375	27.27	0.517	0.183	2.04	>0.05
Ati Pipasa	1.25	0.625	0.625	50	0.517	0.183	3.90	<0.05
Kshudra Shwasa	1	0.375	0.625	62.50	0.517	0.183	3.91	<0.05
Utsaha Hani	1.75	0.375	1.375	78.57	0.517	0.183	7.49	<0.001
Ati Nidra	1.375	0.875	0.50	36.36	0.53	0.18	2.63	<0.05

SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment

Table 5: Effect of placebo on objective criteria (*n*=8)

Parameter	Mean BT	Mean AT	Mean difference	Percentage of relief	SD	SE	*t*	*P*
Weight (kg)	77.18	73.56	3.62	4.69	2.68	0.99	4.41	<0.01
BMI (kg/m^2)	31.51	30.07	1.44	4.55	1.06	0.37	4.40	<0.01
Circumference								
Chest	98.31	95.75	2.56	2.60	1.86	0.66	4.72	<0.01
Abdomen	95.78	92.08	3.69	3.85	2.90	1.03	3.84	<0.01
Buttocks	108.3	105.3	3.03	2.80	2.13	0.75	5.08	<0.01
Mid-arm	31.87	31.25	0.62	1.99	0.75	0.26	2.52	>0.05
Mid-thigh	61.17	59.21	1.95	3.20	0.98	0.348	1.54	>0.05

SD: Standard deviation, SE: Standard error, BMI: Body mass index, BT: Before treatment, AT: After treatment

and *Apa Mahabhuta* dominance. It is a condition of *Vriddha* (increased) *Medodhatu*. It requires the drug which can cause a diminution of *Medodhatu* for its cure. Keeping this in view *Gomutra Haritaki* was selected. *Gomutra* and *Haritaki*

Table 6: Overall effect of therapy

Assessment	Trial group (%)	Control group (%)	Total	Percentage
Cured (100% relief)	0	0	0	0
Markedly improved (75-99% relief)	2 (15.38)	1 (12.50)	3	14.28
Moderately improved (50-74% relief)	5 (38.46)	4 (50)	9	42.84
Improved (25-49% relief)	5 (38.46)	3 (37.5)	8	38.08
Unchanged (<25% relief)	1 (7.69)	0 (0)	1	4.76

both are having *Kapha Medoghna* (reducing *Kapha* and *Meda*) properties due to *Agni* and *Vayu Mahabhuta* dominance in them. Hence, it was thought that *Gomutra Haritaki* will reduce *Medodhatu*. In this study, control group also planned to rule out the psychological effects of medicine, to rule out the changes occurring seasonally and to assess the effect of medicine other than diet restrictions and exercise.

Abhakta and *Pragbhakta Kala* were decided for the administration considering the involvement of *Doshas* in the disease. Therefore, the dose was divided into 3 equal parts, i.e. 2 g for each Kala and administered in *Abhakta* (early morning) and *Prakbhakta Kala* (before lunch and dinner).

Strict diet and exercise schedules were advised to all patients. As the observations show, nearly 68% patients were housewives. Least awareness about following proper dietary habits and lack of time to follow exercise might be reasons behind increased prevalence of obesity in housewives and also dropout rates in the present study. The dropout rate of obese individuals is a point of concern observed in the present pilot study. This might be due to two reasons. Attraction towards diet (*Laulya*) is observed in patients, owing to which the patients do not agree to follow prescribed guidelines for a longer duration. Limited efficacy of trial drug may be the second reason as the patient's psyche expects faster weight reduction rate in shorter duration. When the medicine shows less effect than the expectations of patient, the psyche tries to divert towards vicious cycle of weight gain and obesity. The dropout rate itself indicates the need of a faster acting medicine for weight reduction in obesity.

In this study, 84% patients were females. The reason behind this observation might be the factors such as puberty, menstrual disturbances, menopause, post-operative and consumption or intake of oral contraceptives. In the observations almost 48% patients were found to have the family history of *Sthaulya* [Table 1]. Charaka has also stated *Beejaswabhava* as one of the important causes of *Sthaulya*.[15] Observations from the present study confirms these statements from modern science as well as from Ayurveda. Better results were found in symptoms such as *Atikshudha* (excessive hunger) and *Atinidra* (excessive sleep) in the trial group than the control group which shows that *Gomutra Haritaki* might breaking the obstruction caused by *Medodhatu* in *Koshtha* and establishing normal pathway of *Vatadosa* in the *Koshtha*. Due to this reason, *Atikshudha* was found to be relived. This is also evidenced in classics that *Gomutra* with its *Ushna* (hot), *Tikshna* (sharp) properties and *Haritaki* with its own properties dose the role of *Srotovibandhanashana* (reliving the obstructions in the body channels).

Better results were found in symptoms such as *Swedadhikya* (excessive sweating), *Angagauravata* (heaviness of the body), *Angadaurgandhya* (bad body odor), *Atipipasa* (excessive thirst), *Utsahahani* (loss of enthusiasm), and *Kshudra Swasa* (dyspnoea on exertion), in Control Group than Trial Group. Trial group has shown better results in symptoms such as *Chala Sphik-Udara-Stana* (pendulous buttock/abdomen/breast), *Atikshudha* and *Atinidra*. Mild response was noted in weight reduction and BMI in the control group than trial group.

Probable mode of action of *Gomutra Haritaki* in *Sthaulya*

Gomutra and *Haritaki* has got the predominance of *Agni* and *Vayu Mahabhuta*. One can see the predominance of *Laghu* (light), *Ushna*, *Tikshna* and *Ruksha* (ununctuous) *Gunas* (properties) in both of them. Where as in case of *Sthaulya*, there is abundant increase of *Medodhatu* and this *Medodhatu* has the predominance of *Prithvi* and *Apa Mahabhuta*. In case of *Sthaulya* one can see the saturation of *Guru* (heavy to digest), *Sheeta* (cold in potency) and *Snigdha* (unctous) *Gunas* in the body. Due to the opposite properties, *Gomutra Haritaki* might have reduced the increased *Medodhatu* in cases of *Sthaulya*.[16]

Gomutra Haritaki was prepared by giving only three *Bhavanas* (a process in which herbs are triturated with liquid material) of *Gomutra* to *Haritaki Churna* (powder). If more *Bhavanas* of *Gomutra* were given then the results would have been more significant.

Conclusion

Causative factors of *Sthaulya* mentioned in classics are now changing. Increasing stress, faulty dietary habits and decreased awareness regarding exercise are becoming the prominent causative factors for *Sthaulya*. *Kapha Prakrti* persons were found more prone to *Sthaulya* so they should be advised proper diet regimens and exercise. In society, percentage of the population suffering from *Sthaulya* is increasing day by day so they should made aware regarding the disease and its severe complications before it reaches to epidemic level. Study shows that placebo has shown better results than the trial group. This also reflects the impact of diet restrictions and exercise in the management of *Sthaulya*.

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हिन्दी सारांश

स्थौल्य चिकित्सा में गोमूत्र हरीतकी के प्रभाव का अध्ययन

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स्थौल्य के २१ रोगियों में रेण्डमाइज्ड क्लिनिकल ट्रायल किया गया । इस अध्ययन मे स्थौल्य के नैदानिक मानकों को पूर्ण करनेवाले रोगियों को दो वर्गों मे विभाजित कर औषधियाँ दी गयी । १. वर्ग–एम (मेनेजमेन्ट ग्रुप) इसमे स्थौल्य के १३ रोगियों को गौमूत्र हरितकी (६ ग्राम प्रतिदिन– तीन विभाजित मात्रा में), २. वर्ग–सी (कंट्रोल ग्रुप) इसमे स्थौल्य के ८ रोगियो को प्लेसिबो (भूने हुए रवे से युक्त कैप्सूल) (६ ग्राम प्रतिदीन–तीन विभाजीत मात्रा में) औषधी दी गयी । चिकित्सा की अवधि ८ सप्ताह थी । दोनों वर्गों के रोगीयों को आहार तथा व्यायाम निर्देशित करनेवाला समयपत्रक दिया गया था, जिसका उन्हे प्रस्तुत अध्ययन के दौरान पालन करना था । इस अध्ययन मे व्याधि के प्रमुख लक्षणों के रुप मे भारवृद्धि, अंगगौरवता, क्षुद्र श्वास, अतिक्षुधा तथा अतिपिपासा पाए गए । ग्रुप एम में ४.३७% लाभ वजन कम होने मे तथा ४.४५% जितना लाभ बी.एम.आई. कम होने मे पाया गया । ग्रुप सी में ४.६९% लाभ वजन कम होने मे तथा ४.५५% लाभ इचख बी.एम.आई. कम होने मे पाया गया । प्रस्तुत अध्ययन में कंट्रोल ग्रुप की अपेक्षा मेनेजमेन्ट ग्रुप में बेहतर परिणाम मिले है । प्रस्तुत अध्ययन में मिले परिणाम स्थौल्य चिकित्सा में आहार तथा व्यायाम के महत्व को स्थापित करते है ।