

VARANADIGANA KASHAYA IN THE MANAGEMENT OF STHAULYA (OBESITY) – A CLINICAL TRIAL

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Abstract

“Sthaulya” (obesity) is such a disease, which leads to so many complications like Hypertension, Diabetes Mellitus, Osteo-arthritis, infertility, impotency as well as psychological disturbances like stress, anxiety, depression etc. Thus, the mortality and morbidity rate was high in obese person compared to others. This shows the importance of the disease and the need for further researches and adoption of effective measures in the management of the same. Effective treatment measures are needed for the successful management of Sthaulya. Hence in the present study a clinical trial was carried out with varanadigana kashaya in the management of sthauilya (obesity) and found intake of Varanadiganakashaya for 30 days gave good result in relieving the symptoms of Sthaulya.

Keywords: Ayurveda; Sthaulya; Obesity; Body Mass Index; Varanadigana kashaya.

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INTRODUCTION

Sthaulya (obesity) has been described since very early days in various Samhitas, Sangrahas, Nighantus of Ayurveda.^[1] It is one of the Santharpanajanya roga^[2] and also considered as one among the Kaphaja nanathmaja vyadhi^[3] and Ashtouninditeeya purusha.^[4] Asaatmya and Virudhaahara vihaaras (incompatible foods and activities) are the main cause for Sthaulya (obesity).^[5] There is increase in the meda (fat) and mamsadhatu (muscle) that causes Chala Sphik-Udara-Sthana (fat accumulation in buttocks, abdomen and breasts)^[6] and disproportionate body configuration. The Medoroga or Sthaulya and its Symptomatology could be correlated with Obesity. All the features and complications of Obesity strengthen the point of view of considering it as medoroga or Sthaulya.

The most common cause of obesity is excess calorie intake coupled with physical inactivity usually seen in modern sedentary life style. Obesity describes a weight of 120% or above.^[7] It is a state of excess adipose tissue mass.^[8] An abnormal growth of adipose tissue due to an enlargement of fat cell size or an increase in fat cell number or both is called obesity.^[9] Body Mass Index^[10] is considered as the standard measure for calculating Obesity. BMI is calculated by taking an individual weight (in kg) and dividing it by his or her height (in meters square). BMI between 25 and 29.9 kg/m² is called overweight and a BMI greater than 30 kg/m² is called obese.

There are many therapies and drugs which are available in Ayurveda and Modern science for the management of Sthaulya. But there are no promising results available. In modern medical science its management aspect remains symptomatic with troublesome side effects. Today it is a need to find the drug which is cost effective, easily available and has excellent results with zero side effects. In Ayurveda, the main line of treatment

explained is Apatarpana (depletion),^[11] where in ushna (hot potency), teekshna (penetrating), kaphahara, medohara drugs are administered. Ayurveda classics have quoted the use of Varanadigana kashaya^[12] in the management of sthauilya. Thus in the present study a clinical trial was carried out to prove scientifically the efficacy of Varanadi gana kashaya in the management of sthauilya (obesity).

MATERIALS AND METHODS

The formulation selected for research work Varanadi gana kashaya was prepared in the M.I.A.M.S., pharmacy as per the Standard Operative procedure. The study was carried out in 20 patients diagnosed as Sthaulya and selected randomly from the OPD and IPD of Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.

Inclusion criteria

- Patients of both the genders
- Patients aged between 20-55 years
- Diagnosed cases of Sthaulya according to the features told in classics
- Patients with BMI >30 (Kilograms per square meter).

Exclusion criteria

- Patients not fulfilling the inclusion criteria
- Associated with any systemic diseases like DM, HTN, and IHD.
- Pregnant & Lactating women.
- Associated with previous positive history of endocrinal pathologies such as Cushings syndrome.
- Patients who are using anti-hyperlipidemic drugs.

Laboratory Investigations

Lipid profile, Blood routine (Hb, TC, DC, ESR), FBS were carried out.

Design of Study

A single blind randomized clinical study.

Intervention

Varanadigana kashaya in a dose of 50ml was administered morning and evening minimum 1 hour prior to food. Total duration of the treatment was for 30 days and Follow up on 31st and 45th day of treatment

Diet and Regimen

Low fat diet, Moderate exercise and Daily walking for 30 minutes were advised for all the patients.

Assessment criteria

The assessment was done on the basis of following Subjective parameters and Objective parameters. The Subjective parameters were Sphik chalatva (movements of buttocks), Udara chalatva (abdomen movements), Sthana chalatva (breast movement), Kshudra shwasa (breathlessness), Dourgandhya (foul smell), Atikshuta (more hunger), Atipipasa (excess thirst), Angasadha (debility), Alpavyavaaya (loss of libido), Nidradhikya (excess sleep) and Swedaadikya (excess sweat). The Objective parameters were Body weight, Body mass index, Waist hip ratio, Anthropometrics (Measuring skin fold thickness by using Vernier calipers), Triceps, Biceps. Measurements are taken at various positions namely: Chest, Waist, Hips, Mid arm, Mid thigh and Mid calf. (Table 1)

Patients was assessed based on the assessment criteria and was observed for the symptomatic changes on 31st day. Follow up was taken on 45th day. The results obtained were analyzed statistically.

The list of clinical presentations of Sthaulya is given below and it was taken as the assessment criteria with scoring. (Table 1)

Objective criteria for assessment

A. Body Mass Index

The value of BMI >30 was considered as Obese

B. Measurement of Circumference

Chest – In normal expansion at the level of nipple

Abdomen – At the level of Umbilicus

Hips – At the level of highest point of distension of buttocks.

Mid thigh – Mid region of the thigh between pelvic and knee joints

Mid arm – Mid region of the arms between shoulder joint and elbow joint.

Mid-Calf – Mid portion of calf region

C. Skin fold Thickness

Skin fold thickness using vernier caliper was also recorded before and after the treatment.

1.Skin fold thickness of middle portion of biceps muscle

2.Skin fold thickness of middle portion of triceps muscle

D. Laboratory tests

Laboratory investigations of FBS, Total Cholesterol, Triglycerides were done before and after the treatment.

For the statistical calculation the recordings were categorized into grades based on Criteria's, it was included in the Case proforma for the study.

Statistical analysis

The scores of assessment criteria were analyzed statistically in the form of mean score B.T. (Before Treatment); A.T. (After Treatment);

Table 1: Assessment criteria with scoring

Sl.No.	Symptoms	Criteria	Scoring
1	Sphikchalatva	Absence of Chalatra	0
		Chalatra after fast movement or walking	1
		Chalatra after moderate movement or walking	2
		Chalatra after mild movement/Normal walking.	3
2	Udarachalatva	Absence of Chalatra	0
		Chalatra after fast movement or walking	1
		Chalatra after moderate movement or walking	2
		Chalatra after mild movement/Normal walking.	3
3	Sthanachalatva	Absence of Chalatra	0
		Chalatra after fast movement or walking	1
		Chalatra after moderate movement or walking	2
		Chalatra after mild movement/Normal walking.	3
4	Kshudrashwasa	Breathlessness during heavy work and relieved soon	0
		Breathlessness during heavy work and relieved by rest	1
		Breathlessness after little work but relieved soon and beyond tolerance.	2
		Breathlessness in resting condition.	3
5	Daurgandhya	Absence of foul smell	0
		Occasionally slight foul smell to close areas	1
		Persistent foul smell limited to close areas	2
		Persistent foul smell intolerable to companion/patient himself and felt from a long distance.	3
6	Athikshuda	Hunger induced 4 hourly	0
		Hunger within 4 hours of meal	1
		Hunger within 3 hours of meal	2
		Hunger within 2 hours of meal	3
7	Athipipasa	Average 2 litre water for drinking per day.	0
		2-3 litre water for drinking per day.	1
		3-4 litre water for drinking per day	2
		More than 4 litre water for drinking per day.	3
8	Angasada	No fatigue	0
		Fatigue after heavy work	1
		Fatigue after moderate work	2
		Fatigue after a little work	3
9	Alpavyavaya	Normal libido & sexual performance	0
		Decrease in libido but can perform sexual act	1
		Decrease in libido but can perform sexual act with difficulty.	2
10	Nidradhikya	Loss of libido&cannot perform sexual act.	3
		Normal sleep with 6-8 hours of sleep per day.	0
		Sleep upto 8-10 hours per day	1
		Sleep upto 10-12 hours per day	2
11	Swedadikya	Sleep more than 12 hours per day	3
		No Sweating	0
		Sweating after fast walking or heavy work	1
		Sweating after normal walk or a little work	2
		Sweating even in resting condition.	3

Difference of mean (B.T. - A.T); S.D. (Standard Deviation); S.E (Standard Error).

Students ‘t’ test was carried out. The results were considered Significant or Insignificant depending upon the value of P.

OBSERVATION AND RESULTS

Among 20 patients of Sthaulya, 55% of patients belongs to Body Weight ranging from 81-90 Kg’s, 20% belongs Body weight ranging from 71-80 Kg’s, 10% of patients

belongs to Body Weight ranging from 61-70 Kg's and 91-100 Kg's respectively, 5% belongs to Weight ranging from 100-110 Kg's. Among 20 patients of Sthaulya, 70% of patients belong to BMI ranging from 30-35Kg/m², 30% belongs BMI ranging from 35-40 Kg/m² and none of the patients belongs to BMI category ranging above 40 Kg/m². Details of the patient in the trial group according to the Body weight and BMI are shown in Table 2.

Before the treatment, the mean score of Sphikchalatva was 1.100, which was then reduced to 0.4000 after the treatment. There was 63.63% improvement. The Statistical analysis shows that the result was extremely significant at $p < 0.0001$. The mean score of Udarachalatva before the treatment was 1.050, which was reduced to 0.6500 after the treatment. There was 38.09% improvement. The statistical analysis shows that the result was very significant at $p < 0.0021$. The mean score of sthanachalatva was 0.8500 before the treatment which was reduced to 0.2500 after the treatment. There was 70.58% improvement. The statistical analysis shows that the result was extremely significant at $p < 0.0001$. The mean score of Thrishnadhikya before the treatment was 1.100 which was reduced to 0.7500 after the treatment. There was 31.81% improvement. The statistical analysis shows that the result was very significant at $P < 0.0047$. Before the treatment the mean score 52.38% improvement. The statistical analysis shows that the result was extremely significant at $p < 0.0001$. of Nidradhikya was 1.050 which was reduced to 0.5000 after the treatment. The mean score of Swedadhikya before the treatment was 1.400 which was reduced to 0.8500 after the treatment. There was 39.28% improvement. The statistical analysis shows that the result was extremely significant at $p < 0.0001$. The mean score before the treatment for the symptom Daurgandhya is 1.200 which was reduced to 0.8500 after the treatment. There was 29.16% improvement. The statistical

analysis shows that the result was very significant at $p < 0.0047$. The mean score before the treatment for Kshudraswasa is 1.200 which was reduced to 0.6000 after the treatment. There was 50% improvement. The statistical analysis shows that the result was extremely significant at $p < 0.0001$. The mean score before the treatment for Angasada is 1.600 which was reduced to 0.8000 after the treatment. There was 50% improvement. The statistical analysis shows that the result was extremely significant at $p < 0.0001$. Before the treatment the mean score of Alpavyavaya was 0.5000 which was improved to 0.1000 after the treatment. There was an improvement of 80%. The statistical analysis shows that the result was very significant at $p < 0.0021$. The mean score of Athikshudha before the treatment was 1.500 which was reduced to 1.100 after the treatment. There was an improvement of 26.66%. The statistical analysis shows that the result was highly significant at $p < 0.0021$. (Table 3)

The mean score of Chest circumference was 2.350 which were reduced to 1.950, with an improvement percentage of 17.02%. The statistical analysis shows that the result was very significant at $p < 0.0021$. The mean score of Waist circumference was 1.900 which was reduced to 1.550. 18.42% improvement was there. The statistical analysis shows that the result was very significant at $p < 0.0047$. The mean score of Hips circumference was 1.950 which was reduced to 1.700 with an improvement of only 12.82% and the statistical analysis shows that the result was significant at $p < 0.0210$. The mean score of Mid arm was 1.300 which was improved to 0.7500 with an improvement of 42.30%. The statistical analysis shows that the result was extremely significant at $p < 0.0001$. The mean score of mid thigh was 1.650 which was reduced to 1.350 with an improvement of only 18.18%. The statistical analysis shows that the result was significant at $p < 0.0102$. The mean score of mid calf was 1.200 which was having an improvement of 0.8000 after the treatment

with 33.33% improvement. The statistical analysis shows that the result was very significant at $p < 0.0021$. The mean score of Waist hip ratio before the treatment was 1.700 which was then improved to 1.150 with an improvement percentage of 32.35%. The statistical analysis shows that the result was extremely significant at $p < 0.0001$. (Table 4)

The mean score of Skin fold thickness for biceps before the treatment was 1.100 which was then improved to 0.7500 with 31.81%. The statistical analysis shows that the result was very significant at $p < 0.0047$. The mean score of Skin fold thickness for triceps before the treatment was 1.350 which was then improved to 0.9500 with 29.62% improvement. The statistical analysis shows that the result was very significant at $p < 0.0021$. (Table 5)

The mean score before treatment for weight is 1.500 which was improved to 1.150 after the treatment with an improvement of 23.33%. The statistical analysis shows that the result was very significant at $p < 0.0047$. (Table 6)

DISCUSSION

Sthaulya is considered as a burning problem of today's era caused due to sedentary life style, unwholesome food habits, lack of physical exercise, mental stress etc factors. Its importance lies in the fact that it is the doorway to other major health complications. The Sthaulya was discussed with great importance since Vedic period itself, the references of Sthaulya could be seen in Ayurvedic classics like Bruhatrayees and Laghutrayees. It was considered as one among the Astamahagadas. Sthaulya was referred to as Obesity in this context as the symptomatology, complications etc of Obesity is very similar to Sthaulya. Obesity describes a weight of 120% or above and is a state of excess adipose tissue mass. BMI between 25 and 29.9 kg/m^2 is called overweight and a BMI greater than 30 kg/m^2 is called obese.

Probable mode of action of drugs of Varanadigana kashaya: The Ingredients of Varanadigana Kashaya are bark of Varuna (*Crataeva nurvala* Buch-Ham.), roots of Sairyaka (*Nilgirianthus ciliatus*), tuber of Satavari (*Asparagus recemosus*), roots of purified Chitraka (*Plumbago zeylanica* Linn.), roots of Moorva (*Marsdenia tenacissima*), roots of Bilva (*Aegle marmelos*), roots of Vishanika (*Aristolochia bracteolata*), roots of Brihati (*Solanum indicum*), roots of Kantakari (*Solanum xanthocarpum*), bark of Karanja (*Pongamia pinnata* Linn.), bark of Pootikaranja (*Holoptelia integrifolia*), roots of Agnimantha (*Clerodendrum phlomidis* Linn.), fruit rind of Pathya (*Terminalia chebula*), bark of Shigru (*Moringa oleifera* Lam.), roots of Darbha (*Desmostachya bipinnata*), Purified fruits of Bhallathaka (*Semecarpus anacardium* Linn.). When considering the Doshagna karma of the drug majority of the drugs in the yoga were Kaphavatahara. Here Sthaulya is Kapha predominant Vyadhi. Due to its property it breaks down the samprapthi of Sthaulya. Drugs like Varana, Chitraka, Brihati, Pootikaranja, Pathya etc are having Deepana properties and Chitraka, Kantakari, Bhallataka are having pachana properties. In Sthaulya, both Jadaragni and dhatvagnis are affected and ama formation also occurs, here the drugs are deepana-pachana in action hence the action of agni is corrected. Proper dhatu pachana takes place, and it reduces the chances of excess meda formation thereby preventing the chances of Sthaulya. Apart from this, Pootikaranja is having Lekhana property and Bhallataka is having Chedana and Bhedana property. The properties of drugs help in breaking down the excess medas there by relieving the symptoms of Sthaulya. Also, the drugs like Chitraka, Bhallataka etc increases the BMR (Basal Metabolic rate) and helps in effective management of Sthaulya. Other than that some among these the drugs are also having the actions of Aamapachana, Anulomana, Grahi etc which helps in the correction of imbalance of Dosha's and to maintain a balanced state of Dosha's.

Table 2: Distribution of patients according to Body weight and BMI

Sl.No.	Criteria	Range	Total N=20	Percentage %
1	Weight	61-70	2	10
		71-80	4	20
		81-90	11	55
		91-100	2	10
		100-110	1	5
2	BMI	30-35	14	70
		35-40	6	30
		>40	0	0

Table 3: Effect on symptoms

Sl.No.	Symptoms	Mean		(%)	SD	SE	“t” Value	“P” Value
		BT	AT					
1	Sphikchalatva	1.100	0.4000	63.63	0.5712	0.1277	5.480	<0.0001
2	Udarachalatva	1.050	0.6500	38.09	0.5026	0.1124	3.559	<0.0021
3	Sthanachalatva	0.8500	0.2500	70.58	0.5026	0.1124	5.339	<0.0001
4	Thrishnadhikya	1.100	0.7500	31.81	0.4894	0.1094	3.199	<0.0047
5	Nidradhikya	1.050	0.5000	52.38	0.5104	0.1141	4.819	<0.0001
6	Swedadhikya	1.400	0.8500	39.28	0.5104	0.1141	4.819	<0.0001
7	Daurgandhya	1.200	0.8500	29.16	0.4894	0.1094	3.199	<0.0047
8	Kshudraswasa	1.200	0.6000	50	0.5026	0.1124	5.339	<0.0001
9	Angasada	1.600	0.8000	50	0.5231	0.1170	6.839	<0.0001
10	Alpavyavaya	0.5000	0.1000	80	0.5026	0.1124	3.559	<0.0021
11	Athikshudha	1.500	1.100	26.66	0.5026	0.1124	3.559	<0.0021

Table 4: Effect on body circumference

Sl.No.	Body circumference	Mean		(%)	SD	SE	“t” Value	“P” Value
		BT	AT					
1	Chest	2.350	1.950	17.02	0.5026	0.1124	3.559	<0.0021
2	Waist	1.900	1.550	18.42	0.4894	0.1094	3.199	<0.0047
3	Hips	1.950	1.700	12.82	0.4443	0.0993	2.517	<0.0210
4	Mid arm	1.300	0.7500	42.30	0.5104	0.1141	4.819	<0.0001
5	Mid thigh	1.650	1.350	18.18	0.4702	0.1051	2.854	<0.0102
6	Mid calf	1.200	0.8000	33.33	0.5026	0.1124	3.559	<0.0021
7	Waist hip ratio	1.700	1.150	32.35	0.5104	0.1141	4.819	<0.0001

Table 5: Effect on skin fold thickness

Sl.No.	Skin fold thickness	Mean		(%)	SD	SE	“t” Value	“P” Value
		BT	AT					
1	Biceps	1.100	0.7500	31.81	0.4894	0.1094	3.199	<0.0047
2	Triceps	1.350	0.9500	29.62	0.5026	0.1124	3.559	<0.0021

Table 6: Effect on weight

Symptoms	Mean		(%)	SD	SE	“t” Value	“P” Value
	BT	AT					
Weight	1.500	1.150	23.33	0.4894	0.1094	3.199	<0.0047

CONCLUSION

Based on the symptomatology, Sthaulya could be co-related to Obesity. An abnormal growth of adipose tissue due to an enlargement of fat cell size or an increase in fat cell number or both is called obesity. BMI between 25 and 29.9 kg/m² is called overweight and a BMI greater than 30 kg/m² is called obese. Intake of Varanadigana kashaya for 30 days gave better result in relieving the symptoms of Sthaulya. In relieving the symptoms of Sthaulya like Sthanachalatva, Nidradhikya, Kshudraswasa, Angasada, Alpavyavaya Varanadigana kashaya showed good results. In relieving the symptoms like Sphikchalatva, Udarachalatva, Trishnadhikya, Swedadhikya, Daurgandhya, Athikshudha Varanadigana kashaya showed average result. In the aspects like reduction in Waist circumference, mid arm circumference and Waist Hip ratio even though to a mild degree Varanadigana kashaya showed better results. In the reduction of Chest, Hip, Mid thigh and Mid calf circumference and in reduction of skin fold thickness of Biceps and Triceps, Varanadigana kashaya showed good result.

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