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Clinical study to evaluate the efficacy of Abhaya Choorna and Abhaya Choorna with Vyayam in Sthaulya.

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Abstract:

The burden of lifestyle disorder is rapidly increasing day by day. Now a days with continuous changing of lifestyle and dietary habits made man the victim of many diseases and “Sthaulya” is one of them. Sthaulya is a state of increased vikrut vruddhi of Medadhatu. Or it is defined as abnormal or excessive fat accumulation that may impair health of individual. Studies have shown that over the past four decades, consumption of food eaten away from home has also risen alarmingly. It is well known that this rise of obesity among the word population could be attributed to an increase in calorie intake coupled with lack of adequate physical activity. The available data is based on the clinical findings only.

KEY-WORDS: Obesity, *Sthaulya, Santarpanjanya vikar*, *Medoroga,* Lifestyle disorder

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INTRODUCTION:

Sthaulya (obesity) is a state of the increased *medodhatu* (fatty tissue). India is currently witnessing rising number of people who are obese. Many among the Indian population have started relying on processed food that contain a huge percentage of trans-fat, sugar and other unhealthy and artificial ingredients. *Sthaulya* is one such lifestyle disorder. Sedentary lifestyles are leading people to silent self-destruction, making one in every five Indian men and women obese. It has reached epidemic properties globally 39% of adults in the world are overweight. One-in-five children and adolescents, globally, are overweight. In Ayurveda, obesity has been described as *Sthoulya* or *Medoroga* in *Santarpanottha Vikara*. i.e the disease caused by over nourishment.[2] *Kapha* which is heavy and dense in nature abnormally accumulates in weaker channels of the body, causing their blockage. [3] Metabolic disturbances in an obese individual is *Medho dhatu* caused mainly due to excess intake of *Madhura* and *Snigdha Ahara*[4]. *Nidana* (causative factors) of *Sthoulya* can be classified as *Aharatmaka Nidana*, *Viharatmaka Nidana*, *Manasika Nidana* and Anya *Nidana.* [5] Acharya Charaka has mentioned *Guru* (heavy to digest) and *Apatarpana* (with no or less nutrition value) diet as treatment for *Medoroga*.[6]

Aim and Objective:

1. To evaluate the efficacy of *Abhaya Choorna* and *Abhaya Choorna* with *Vyayam* in *sthaulya*.
2. To treat the patient of Sthaulya according to ayurvedic classics.

Materials and Methods: Clinical study was performed on group of randomly selected 60 patients. Patients were categorised in two groups, Group A and Group B. Group A was given Abhaya Choorna whereas Group B was treated with Abhaya Choorna with Vyayam was given for 21 days and follow up of patient was taken on the day of examination, 7th day, 14th day and 21th day. All the patients were examined before and after the treatment. No adverse effects were observed during the entire procedure.

Plan of study:

It was comparative clinical study, where 60 patients were randomly selected on which study was carried out. Patients were divided randomly in two equal groups named Group A (*Abhaya Choorna*) & Group B (*Abhaya Choorna with Vyayam*). Total duration of study is 21 days. where clinical study was performed on group of randomly selected 60 patients from OPD of our institute.

Inclusion Criteria: -

1) Patients of age group 16 to 40 years.
2) Body Mass Index (BMI) above 30 were selected.
3) Predominant *kapha prakruti* patients were selected.
4) Uncomplicated *sthaulya* patients were selected.
5) Diagnosed patients of *sthaulya.*
6) Patients willing to take treatment

Exclusion Criteria: -

1) Patient not willing for treatment
2) Any discomfort found during treatment
3) Obesity due to certain secondary cause like pregnancy, drug induced.
4) Sthaulya with *jwara, prameha, pramehapeedaka* etc.
5) Who have undergone bloodletting therapy.

Criteria for assessment

Total Assessment of the Therapy was done on the basis of relief in the signs and symptoms as well as objective criteria Body weight, BMI, Abdomen, Hip, W/H ratio. The efficacy of the therapy was assessed on the basis of the following subjective as well as objective criteria.

Subjective criteria

The patients were assessed twice by giving a score before and after the therapy according to the severity of the symptoms.

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Statistical analysis was carried out to obtain the efficacy of the therapy. The details of the scoring pattern adopted for the main signs and symptoms in the present study were as follows.

Table no.1 Subjective criteria:

No.	Parameters	Grade	Finding
1.	Chala Udara	0	Absence of Chalatva
		1	Presence of Chalatva
2.	Chala Stana	0	Absence of Chalatva
		1	Presence of Chalatva
3.	Daurgandhya	0	Absence of bad smell
		1	Occasional bad smell in body even after bathing
		2	Persistant bad smell in body even after bathing suppressed by deodorants
		3	Persistant bad smell is not suppressed by deodorants even after bathing
4.	Kshudrashwasa	0	Absent
		1	Dysponea on moderate work
		2	Dysponea on slight work
		3	Dysponea even at rest
5.	Anga Gaurava	0	No feel heaviness in body
		1	Feels heaviness in body but it does not hamper
		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
6.	Kshudhaatimatra	0	Feels hunger at next annakala only
		1	Feels hunger for once in between annakala
		2	Feels hunger more than twice
		3	Feels hunger always
7.	Pipasaatiyoga	0	Normal thirst
		1	Up to 1 litre excess intake of water
		2	1-to-2-liter excess intake of water
		3	2-to-3-liter excess intake of water
8.	Daurbalya	0	Can do mild & moderate work without difficulty
		1	Can do only mild & moderate work with difficulty
		2	Can do mild work with very difficulty
		3	Cannot do even mild work
9.	Swedadhikya (At normal temperature in normal condition)	0	No sweating
		1	Profuse sweating after moderate work
		2	Profuse sweating after slight work
		3	Sweating even in resting condition

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10.	Alasya	0	No alasya (doing work satisfactory with proper vigour in time)
		1	Does not have any initiation & not wants to work even after pressure
11.	Vyayamshakti		Plane surface
			Ascending surface
			Descending surface

Objective Criteria:

Weight: Reduction of weight was compared in comparison before treatment and after treatment.

Body mass index (BMI):

The body mass index (BMI) is a statistical measurement which compares a person's weight and height. The frequent use of the BMI is to assess how much an individual's body weight departs from what is normal or desirable for a person of his or her height. For a given height, BMI is proportional to weight. However, for a given weight, BMI is inversely proportional to the square of the height. The B.M.I. is the actual body weight divided by the height squared in meter (kg/m^2). This index provides a satisfactory measure of obesity in people who are not hypertrophied athletes. The classification of obesity as per B.M.I. by W.H.O. Criteria is as:

- Under weight- <18.5 kg/m^2
- Normal weight- 18.5 - 24.9 kg/m^2
- Over weight- 25 - 29.9 kg/m^2
- Obesity (Class-I)- 30 - 34.9 kg/m^2
- Obesity (Class-II)- 35 - 39.9 kg/m^2
- Morbid Obesity (Class-III) - > 40 kg/m^2

Body Circumference Measurements: Abdominal Girth, Hip Girth, Waist to Hip Ratio

Table no.2 Treatment protocol:

Groups	Drug and Vyayam	No. of patients	Time	Dose and Anupana
Group A	Abhaya Choorna	3o	Morning-Evening *Apankaal* 30 mins Before meals	3 gms orally with madhu
Group B	Abhaya Choorna with Vyayam	30	Morning-Evening *Apankaal* 30 mins Before meals	3 gms orally with madhu
			Walking minimum 30 min.	Vyayam as Walking Exercise

Assessment of Overall effect of therapy: -

The overall effect was decided on the basis of Improvement in Subjective parameters and reduction in Objective criteria i.e., Weight, BMI, Abdomen, Hip and W/H Ratio. In this part, percentage improvement in Objective criteria i.e., Weight, BMI, Abdomen, Hip and W/H ratio were assessed and then average of all the percentage improvement was taken. Similarly for subjective parameters percentage improvement in each subjective parameter present in the patient was assessed and then average of all the percentage improvement of subjective parameters was taken. Finally, to assess the total effect of the Therapies an average of

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Subjective and objective parameter was taken. Thus, the total effect of the Therapies was markedas following:

Table no.3 Improvement in Group-A & Group -B

Sr. No.	Criteria	ImprovementGrade	No. of patients		No. of symptoms	
			Gr. A	Gr. B	Gr. A	Gr. B
1	75% to 100%	Marked	00	12	00	00
2	50% to 74%	Moderate	25	18	00	10
3	25% to 49%	Mild	05	00	09	00
4	00% to 24%	Poor	00	00	01	00

In this study, In Group-A, no patient gets marked improvement, 25[83.33%] patients get moderate improvement while 5[16.67%] patients are mild improved. In group B, 12[40%] patients have good improvement while 18[60%] patients where moderately improved.

Statistical Estimation of results:

The Wilcoxon signed-rank test is applied to the statistical data for evaluating the Subjective Criteria. Students Paired‘t’ applied to the statistical data for evaluating the difference in the B.T. and A.T. scores of Objective parameters. Students Unpaired‘t’ test is applied for evaluating the difference in the effects of two therapies Objective Parameter wise. Overall Effect of Therapy as per Statistical analysis

Table no.4 Comparison in both group

Sr. No.	SubjectiveParameters	Within Groups (Wilcoxon test)		Comparison (Mann-Whitney’s test)
		Group A	Group B	
1	*Chala udara*	Significant	Significant	Insignificant (A ≈ B)
2	Chala stana	Significant	Significant	Insignificant (A ≈ B)
3	*Daurgandhya*	Significant	Significant	Insignificant (A ≈ B)
4	*Kshudrashwasa*	Significant	Significant	Insignificant (A ≈ B)
5	Abga gaurava	Significant	Significant	Insignificant (A ≈ B)
6	Khudatimatra	Significant	Significant	Insignificant (A ≈ B)
7	*Pipasatiyoga*	Significant	Significant	Insignificant (A ≈ B)
8	*Daurbalya*	Significant	Significant	Insignificant (A ≈ B)
9	*Swedadhikya*	Significant	Significant	Insignificant (A ≈ B)
10	*Alasya*	Significant	Significant	Insignificant (A ≈ B)

(≈ - means no significant difference)

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Table no.5 Overall Effect of Therapy

Sr. No.	Objective Parameter	Within Groups (Paired t test)		Comparison (Unpaired't'test)
		Group A	Group B	
1	**Weight**	Significant	Significant	Insignificant (A ≈ B)
2	**BMI**	Significant	Significant	Insignificant (A ≈ B)
3	**Abd girth**	Significant	Significant	Insignificant (A ≈ B)
4	**Hip girth**	Significant	Significant	Insignificant (A ≈ B)
5	**Waist:Hip**	Significant	Significant	Insignificant (A ≈ B)

(≈ - means no significant difference)

Observations:

In the present study of 36 patients of *Sthaulya*, maximum number of patients were in the age group of 31-40 years(60%), females (78.33%), Hindu by religion (91.67%), married (66.67%), belonging to middle socioeconomic class (60%), and Literate.(100%), Housewife's (35.00%) Further, in this study maximum number of patients were of *Kapha pitta Prakriti* (53.33%), patients of this study were having mix diet(51.67%), 55 % patients were having vishamagni,71.67% patients were having no stress, 100% patients were not doing exercise.

Table no. 6 According to % Relief in Symptoms -

Sr. No.	Symptoms	% Relief	
		Group A	Group B
1	*Chala udara*	53.85	72.00
2	*Chala stana*	41.67	64.00
3	*Daurgandhya*	59.42	71.43
4	*Kshudrashwasa*	55.71	72.86
5	*Anga gaurava*	60.29	73.53
6	*Khudatimatra*	55.70	71.62
7	*Pipasatiyoga*	57.53	72.22
8	*Daurbalya*	60.29	73.53
9	*Swedadhikya*	53.33	67.80
10	*Alasya*	58.06	69.35
11	**Avg. % Relief**	**55.58**	**70.83**

Table no. 7 According to Avg. Change in Parameters:

Sr. No.	Parameters	Difference in Avg. Decrease	
		Group A	Group B
1	**Weight**	1.81	2.13
2	**BMI**	0.81	0.92

3	**Abd Girth**	0.79	1.00
4	**Hip Girth**	1.22	1.53
5	**Waist: Hip**	0.011	0.012

Table no. 8 Change in *Vyayam shakti* of Group B:

Sr. No.	*Vyayam shakti*	BT	AT	Avg. Increase (minutes)
1	Plane surface	22.17	27.10	4.93
2	Ascending surface	12.10	17.40	5.30
3	Descending surface	13.50	20.47	6.97

DISCUSSION:

Study shows that mostly patients were having sedentary lifestyle, unhealthy diet, fast food (Abhishayandi ahar,Snigdha) this causes vitiation of kapha dosha and medodushti which leads to increase in weight. Viharaj hetu specifically Vyayam have not found in any of patients, which make man physically inactive causes Sthaulya. Hence with the help of both Aushadh and Vihara chikitsa Group B shows better results. In the present clinical study, a total of 60 i.e. Is divided in two groups of 30 patient in each, suffering from Sthaulya (obesity) were taken and all completed the course of the treatment. The disease is mainly diagnosed based on signs and symptoms of Sthaulya (obesity) as mentioned in the Ayurvedic texts. Body Weight, Body Mass index, Abdominal Girth,Hip Girth, waist-Hip ratio, Vyayamshakti (plane surface, Ascending surface, Descending surface) were used as the objective parameters to evaluate obesity status.

General Observations:

Age wise distribution

In the present study, maximum no. of patients i.e., 36 were fromthe age group 31-40 yrs. Followed by 23 in 31-40 yrs.

Gender: In the present study, maximum no. of patients i.e., 47 were femalewhile remaining 13 were male

Occupation: According Occupation wise distribution it was found that, maximum no. of patients i.e.,21 was housewife and followed by 20 were service, 18 were Student and 1 was Farmer.

Diet: On the observation it was found that, maximum no. of patientsi.e.,31 was taking mix diet while remaining 29 were taking veg diet.

Prakruti: On the observation it was found that, maximum no. of patients i.e., 32 were of *Kapha-Pitta prakruti* and 28 were having *Kapha-Vata sharira prakruti.*

Agni: On the observation it was found that, maximum no. of patient's i.e., 33 were having *vishamagni* followed by 27 having *tikshnagni*.

Exercise: On the observation it was found that, maximum no. of patients i.e,60 were have not done Exercise.

Mode of action of *Abhaya*:

In the disease *Sthaulya*, *Tikshnagni* is occurs. Here, Jatharagni is found in excessive condition whereas Medodhatvagni is found in Manda condition. It is due to *Avarana* of *Vayu* in *Kostha*. So, person indulges more food, which produce excessive Meda and vitiated cycle go on. This cycle is broken (*Samprapti Vighatana*) by *Katu-Rasa* & *Ushna-Virya Pradhana* drugs – *Haritaki* is one of the contents of *Triphala* which decreases Meda by its Lekhana, Shoshana and Kaphanashaka properties, *Kaphanashaka* properties due to Agni and Vayu *Mahabhuta* dominance in them. *Haritaki* due to

deepan activities it digests ama in the body and it also having *Medakaphahar* properties *along with* it enhances agni and ultimately it helps in increasing lekhan and dhatwagni so the samprapti is broken for further *meda* preparation. Ushna-Virya also helps in Kleda and *Meda Vilayana* action. *Katu-Rasa, Ushna-Virya* encounters *Dhatwagnimandya* and potentiates the weakened Dhatwagni and help in *Amapachana* thereby alleviates Aparipakwa and Ama dhatu. Ultimately act as *medohar* and breaks the *Samprapti* of *Sthaulya*.

Mode of action *Vyayam*:

By practicing *Vyayam*, means stage of being one canremain physically and mentally steady and fit. Exercise, a nonpharmacologic intervention that is available to most of the public, may play an essential role in the treatment of Obesity. Physical exercise (*Vyayam*) has been traditionally considered as a strategy to burn calories, but physical exercise particularly '*Ardhashakti Vyayam*' (exercise till increased rate of respiration, perspiration is much more than that. It is a stimulus that, when properly managed, contributes to a significant improvement in energy and macronutrient balance regulation and body functioning, that is, a precise regulation of body homeostasis. All the *Aharaja Nidana* (fast food, junk food, sweet food etc) decreases physical activity, which increases *Kapha* and leads accumulation of Meda, however *Vyayam* regain, due to *Vyayam* there is sharir laghavat due to kapha dosha vilayan, due to *Vyayam* there is increase in metabolic rate and veryless deposition of fat into the body as *Vyayam* help to reduce meda and kapha, there is increase in calory burn while *Vyayam*.

CONCLUSION:

The total effect of *Chikitsa* is evaluated by taking relief in percentage of each patient. Out of 30 patients in Group a Moderate improvement was seen in 25 patients. Mild improvement was seen in 5 patients. In Grp B out of 30 patient's good improvement was seen in 12 patients. Moderate improvement was seen in 18 patients. For *Chala udara*, symptom 53.85 % in Grp A and 72.00 % in Grp B,for *Chala stana* 41.67 % in Grp A and 64.00 % in Grp B, for *Daurgandhya* 59.42 % in Grp A and 71.43 % in Grp B, for *Kshudrashwasa* 55.71 % in Grp A and 72.86 % in Grp B *Anga gaurava*60.29% in Grp A and 73.53 % in Grp B, *Kshudatimatra* 55.70% in Grp A and 71.62 % in Grp B, *Pipasatiyoga* 57.53 % in Grp A and 72.22%in Grp B, *Daurbalya* 60.29 % in Grp A and 73.53 % in Grp B,*Swedadhikya* 53.33 % in Grp A and 67.80 % in Grp B, *Alasya* 58.06% in Grp A and 69.35 % in Grp B. By using *Abhaya choorna* by using *Abhaya choorna* with *Vyayam* on Sthaulya (obesity) symptoms as *Chala udara, Chala stana, Daurgandhya, Kshudrashwasa, Angagaurava, Kshudatimatra, Pipasatiyoga, Daurbalya, Swdadhikya, Alasya* were got the 55.58 % to 70.83 % relief. In view of Observations and based on results obtained, statistical analysis, we concluded that *Abhaya choorna with Vyayam* showing significant results compared to *Abhaya choorna* in some symptoms of Sthaulya (obesity). The present study was conducted with limited time, limited facilities and limited number of patients. A study of larger group of patients may help to comprehend the mode of action of the trial drug. In the future, additional studies may be performed to take the present issue further in a proper perspective and future possibilities of reduction of modern drug requirement.

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