

AYUSCRIPT

International Journal for Empirical Research in Ayurveda

www.ayuscript.com

Volume: 2 | Issue: 2

April-June 2023

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Clinical study on effect of Arogyavardhini vati in the management of Sthaulya w .r .t Obesity.

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ABSTRACT:

Background: Obesity is a global problem increasing progressively. It is an important disorder associated with number of potential fatal disease such as onset of diabetics mellitus and heart diseases and many more. Obesity is itself a disease and cause for many other diseases. Treating obesity has become a problem since safe drugs are not available for long term therapy. The herbal drug described by Ayurveda science are comparatively safe and have been used for many years. So, the following clinical study was undertaken using Ayurvedic medicine which are described in Ayurveda classics.

Aims and Objects: To study the disease Sthaulya w r t Obesity and to assess the efficacy of “Arogyavardhini vati ” in Sthaulya . **Methods:** It was a single arm, open, randomized clinical study. Patients with clinical sign and symptoms of Sthaulya were selected. **Results & conclusion :** The data was assessed on each sign and symptoms of obesity and most of the symptoms were found to be relieved after treatment with intervention of Arogyavardhini Vati in the patients of obesity. For more fruitful results, the study can be conducted for large sample size with long duration of time with additional parameters.

Key words: Sthaulya , Obesity , Arogyavardhini vati .

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How to cite article: Upadhyay K.G. Upadhyay A. G.Sharma R. Clinical study on effect of Arogyavardhini vati in the management of Sthaulya w .r .t Obesity. AYUSCRIPT 2023;2(2):41-52

Introduction :

Ayurveda is ancient science of life. This branch of medicine has a 5000 years' record of use in the Indian system of medicine. The concept and treatment of most of disease have been described in great depth relating with dosha ,dhatu ,mala of human body constituents .In Ayurvedic classics , Sthaulya (Obesity) is referred as 'Medoroga' and is considered to be a disease of Medodhatu vriddhi . A variety of different types of treatment have been detailed in Ayurvedic classics. Obesity is a condition in which excess body fat gets accumulated in body to an extent that it may impair health .It is a global problem increasing progressively .It occurs as a result of lack of physical activity with increased intake of food. More than 1.4 billion adults are overweight and more than half a billion are obese worldwide. Overweight and obesity are linked to more deaths worldwide than underweight. An increased consumption of highly calorific foods without an equal increase in physical activity leads to an unhealthy increase in weight.

Obesity is an important metabolic disorder associated with number of potential fatal disease such as onset of diabetics mellitus and heart diseases .Now a days ,treating obesity has become a problem since safe drugs are not available for long term therapy .In previous days ,some modern drugs were used to treat obesity but these drugs have undesirable side effect like pulmonary hypertension and depression (Galloway et .al. ,1984) .Thyroid hormones were once used to treat obesity but now are contraindicated due to their untoward systemic effect (Kyle et.al. 1966) . So the need for a safer drug for long term therapy is necessary for obesity. The use of a non-toxic compound with a capacity to hold the weight gain is needed. Sthaulya (Obesity) is a condition in which excessive consumption of fatty food without proper exercise routine leads to the accumulation of excessive fat in body .This leads to an imbalance of Mamas and Meda Dhatu which results in obesity. Arogyavardhini Vati is described as "Medovinashini " in Rasratnasamucchaya . It is an effective Ayurvedic preparation that helps to reduce weight by its Deepan (appetizer) and Pachana (digestive) properties. It also helps to eliminate the waste product from the body because of its Shodhan (detoxification) nature. Therefore, for this prospective single arm clinical study on Sthaulya (obesity), Arogyavardhini vati was administered in patients of obesity , which is well described in Ayurvedic classics as Medovinashini for this growing advance disease. Patients of Obesity were selected from OPD and IPD of Shri Ayurved Mahavidalaya eyam Rugnalaya , Nagpur .Results were assessed on the basis of fixed subjective and objective criteria and prove to be a good remedy for Obesity .

Aim and objectives:

- 1.To review all literature regarding Sthaulya and its co- relation with Obesity
2. To study the disease Sthaulya (obesity) and its management.
- 3.To evaluate the efficacy of Arogyavardhini vati in the management of sthauilya (Obesity)

Material and methods:

1. It was an open, single arm, randomized clinical study
2. The patience with clinical sign and symptoms of Sthaulya (obesity) and supporting laboratory data were selected.

Inclusive criteria :

1. Patient aged between 20 to 60 years, irrespective of sex, occupation, socio

- economic status.
2. All patients presenting with clinical sign and symptoms of Sthaulya (obesity) as mentioned in Ayurveda texts.
 3. BMI more than 25 were taken into consideration for the patient as obese. BMI can be measured by using formula.
 4. Standard height and weight chart was taken into consideration.

Exclusive criteria

1. Patients below age 20 and more than 60 years of age.
2. Patients suffering from hypothyroidism, C V disease, HTN, DM .
3. Patient with long term steroidal treatment.
4. Patient with other systemic illness.
5. Pregnant ladies and lactating mothers.
6. Patient not willing for trial.

Content of Arogyavardhini vati :

Name of the Ingredients(English Name) - Part / Proportion

1. Shuddha Parada (Processed Mercury) - 1Part
2. Shuddha. Gandhaka (Processed Sulphur) - 1Part
3. Lauha Bhasma (Calcinated Iron) - 1Part
4. Abharaka Bhasma (Calcinated Mica) - 1Part
5. Tamra Bhasma (Calcinated Copper) - 1Part
6. Triphala Churna
 - Haritaki (Terminalia chebula) -2 *3 parts
 - Bibhitaka(Terminalia bellirica Roxb)
 - Amalaki (Phyllanthus emblica)
7. Shuddha Shilajatu (Processed Black Bitumen) - 3part
- 8 Shuddha Gugguluu (Processed Commiphora) - 4part
- 9 Chitraka Moola (Plumbago zeylanica linn) - 4part
- 10 Katuki Moola (Picrorhiza kurroa) -22part
- 11 NimbaPatra Swarasa -for 2days Mardana (Azadirachta indica) (for wet Lavigation)

Time and Duration of study :45 days follow up for 15days.

Drug administration : 30 patients were given Arogyavardhini vati - 2 tab 500 mg each twice a day with Koshna jala (luke warm water) as anupan .

Criteria for assessment : (subjective assessment)

1. Angachalatya
 2. Atikshudha
 3. Kshudraswasa
 4. Daurgandhya
 5. Swedadhikaya
 6. Daurbalya
 7. Alasya
 8. Nidraadhikya
 9. Body mass index –BMI
- Completely absent:0
 - Mild presence:1
 - Moderate presence:2
 - Severe presence:3

Laboratory investigation (objective assessment) :

Following laboratory investigation was done at the time of screening and at the end of the study.

- 1.Hematological investigations - Hb%, TLC, DLC, ESR.
- 2.Urine analysis –Routine and Microscopic.
- 3.Biochemical examinations - PPBS, FBS.
4. Lipid profile - Sr. cholesterol, Sr. triglycerides, HDL, LDL.
- 5.Age specific weight for height table.

OBSERVATION & RESULTS:

The observations and results of the study 'Clinical study on effect of Arogyavardhini vati in the management of Sthaulya w .r .t Obesity' were as follows 45 days of administration of Arogyavardhini vati in the patients of Sthaulya. All the patients of this series were explored for investigations, which were carried out before the start of treatment. The status of all the symptoms & signs were also noted down after completion of treatment. Thus the change in the status of symptoms, sign & investigations were recorded.

1. Showing status of 30 patients Of Sthaulya .

Sr. No.	Study Period	Completed	LAMA	Total
1	Completed	29	01	30

2. Age wise distribution of patients Of Sthaulya.

Sr. No.	Age Group(Yrs)	No. of patients
1.	20 – 30	06
2	30 – 40	09
3	40 – 50	07
4	50 – 60	07
	Total	29

3. Gender distribution of patients Of Sthaulya .

Sr. No.	Gender	No. of patients
1	Male	12
2	Female	17
	Total	29

➤ 4. Religion distribution of patients of Sthaulya

Sr. No.	Religion	No. of patients
1	Hindu	26
2	Muslim	3
	Total	29

In 29 patients of sthaulya it was found that 6 patients were from age group of 20-30 yrs. 9 were from age group of 30-40 yrs & 7 were from 40-50 yrs age and 7 were from 50-60 yrs. It shows obesity can affect at any age group. As per sex distribution female patients were more. In religion wise distribution Hindu patients were more due to hindu dominating population in that region.

5.- Showing Economic status of patients Of Sthaulya :

Sr. No.	Economic status	No. of patients
1	Lower class	02
2	Middle class	16
3	Higher middle	09
4	Higher class	02
	Total	29

Most of the patients were from middle class and higher middle class .

➤ 6 - Occupation status wise distribution of sthaulya patients :

Sr. No.	Occupation status	No. of patients
1	House wife	14
2	Businessman	06
3	Serviceman	05
4	Retired	02
5	Student	02
	Total	29

In the study, most of the patients (female) were housewives whereas other dominating number of sthaulya patients were businessmen or serviceman.

7 -Marital status of patients Of sthaulya .

Sr. No.	Marital status	No. of patients
1	Married	27
2	Unmarried	02
	Total	29

Mostly patients were married .

8 - Dominant Rasas in Aahara of patients Of Sthaulya

Sr. No.	Dominant rasa in aahara	No. of patients
1	Madhura	14
2	Aamla	09
3	Lavana	06
4	Katu	00
5	Tikta	00
6	Kashaya	00
	Total	29

➤ 9 - Type of food ingested by patients Of Sthaulya

Sr. No.	Type of Diet	No. of patients
1	Pure Vegetarian	15
2	Mixed	14
	Total	29

In study population, both type i.e pure vegetarian and mixed diet consuming patients were there. Madhura, Aamla, Lavana rasa dominant in Aahara rasa were found .

➤ 10 - Showing Doshaja prakriti of patients

Sr. No.	Doshaja prakriti	No. of patients
1	Kaphaja	02
2	Vata Kaphaja	00
3	Pitta kaphaja	00
4	Kapha vataja	11
5	Kapha Pittaja	16
	Total	29

In this study, mostly patients were having Kaphaja Prakriti and Vata Kaphaja Prakriti were having Kapha vataja Prakriti showing sthaulya 's kapha dominance property.

11 - Agni-Parikshana wise distribution of sthaulya patients.

Sr. No.	Agni	No. of patients
1	Tikshana	00
2	Vishama	10
3	Mandagni	19
4	Samagni	00
	Total	29

Mostly patients were having Mandagni. Others have vishamagni.

12 - Sleep wise distribution of patients of sthaulya .

Sr. No.	Sleep Pattern	No. of patients
1	Sound	24
2	Disturbed	05
	Total	29

Mostly patients had sound sleep as nidraadhikya is also a symptom of sthaulya.

13. Stroto Drushti observed in 29 patients of Sthaulya .

Sr. No.	Stroto Drushti	No. of patients
1	Medovaha	29
2	Rasavaha	29
3	Swedavaha	11
4	Annavaha	02
5	Mamsavaha	01

Medovaha Stroto Drushti were in 100% of patients, Rasavaha Stroto Drushti also in 100% of patients.

14 - BMI of 29 patients of sthaulya .

Sr. No.	BMI	No. of patients
1	25 – 30	12
2	30 – 35	11
3	35 – 40	05
4	> 40	01
	Total	29

15 - Menstrual history in 17 female patients.

Sr. No.	Menstrual Nature	No . of patients
1	Regular	08
2	Irregular	06
3	Menopause	03
	Total	17

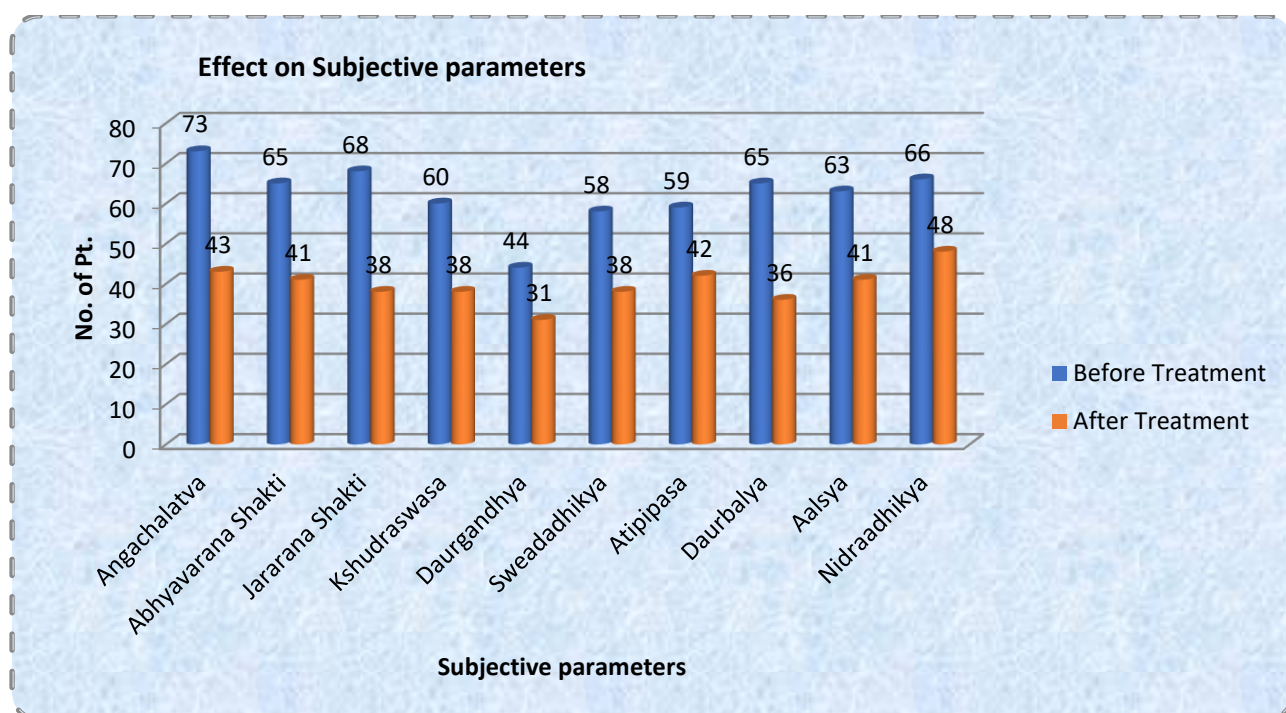
Results :

The data was statistically assessed on each sign and symptoms of obesity and most of the symptoms were found to be relieved after treatment with intervention of Arogyavardhini Vati in the patients of obesity .Appropriate statistical test were applied on the data.

16.Wilcoxon match paired sign rank test for subjective criteria

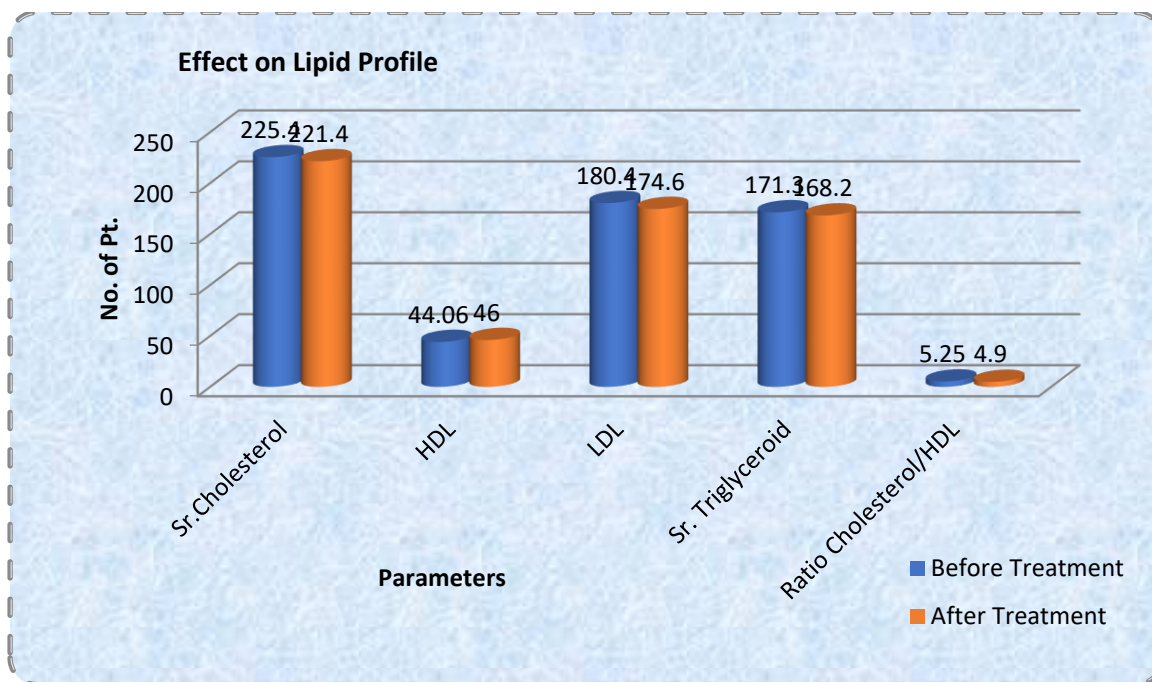
Sr no	Symptoms		Mean	SD	SE	W	N	P
1	Angachalatva	BT	2.48	0.5	0.09	276	23	<0.01
		AT	1.51	0.68	0.12			
2	Abhyavarana Shakti	BT	2.34	0.66	0.12	300	24	<0.01
		AT	1.44	0.68	0.12			
3	Jararana Shakti	BT	2.24	0.73	0.13	276	23	<0.01
		AT	1.37	0.72	0.13			
4	Kshudraswasa	BT	2.24	0.68	0.12	276	23	<0.01
		AT	1.14	0.68	0.12			
5	Daurgandhya	BT	1.37	0.62	0.11	105	14	<0.01
		AT	0.89	0.61	0.11			
6	Sweadadhikya	BT	2	0.75	0.14	153	17	<0.01
		AT	1.34	0.66	0.12			
7	Atipipasa	BT	2.03	0.73	0.13	153	17	<0.01
		AT	1.44	0.82	0.15			

8	Daurbalya	BT	2.24	0.73	0.13	325	25	<0.01
		AT	1.27	0.75	0.13			
9	Aalsya	BT	2.17	0.75	0.15	210	20	<0.01
		AT	1.41	0.73	0.13			
10	Nidraadhikya	BT	2.27	0.59	0.11	190	19	<0.01
		AT	1.62	0.62	0.11			



17. Effect of therapy on Lipid profile in Sthaulya patients(t test)

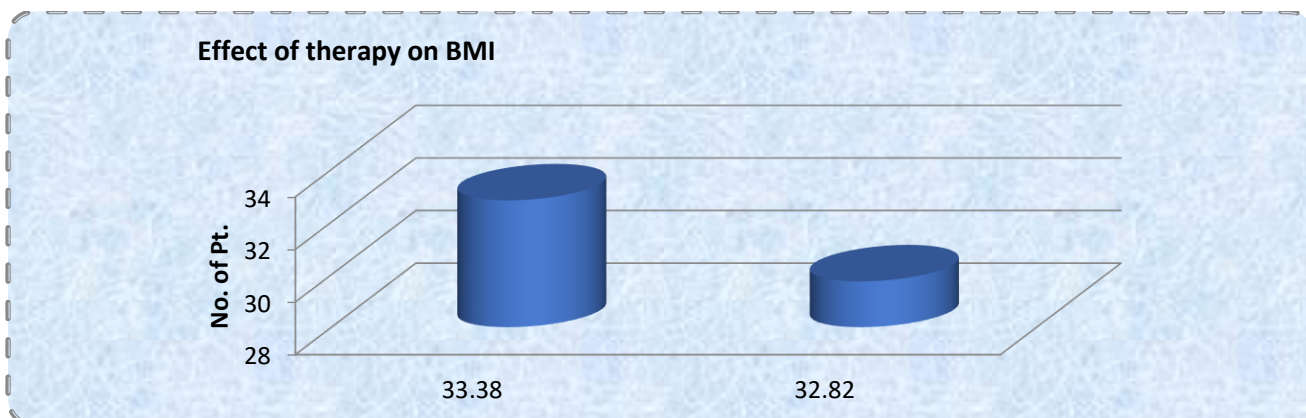
Sr. No	Investigation	Mean Score			S.D	S.E	't' Value	P Value
		B.T	A.T	Diff.				
1	Sr.Cholesterol	225.4	221.4	4	1.58	0.29	13.79	<0.001
2	HDL	44.06	46	-1.93	1.25	0.23	8.39	<0.001
3	LDL	180.4	174.6	5.86	2.11	0.39	15.02	<0.01
4	Sr. Triglyceroid	171.3	168.2	3.13	1.92	0.35	8.94	<0.01



18. Effect of therapy on BMI in Patients of sthaulya .(t test)

Sr.No	Investigation	Mean Score			S.D	S.E	't' Value	P Value
		B.T	A.T	Diff.				
1	BMI	33.38	32.82	0.55	0.47	0.08	7.12	<0.01

Average BMI score before treatment was 33.38 which decreased to 32.52 after treatment of 45 days .Decrease in BMI by 0.55 statistically tested by paired 't' test was 7.12 , p value <0.01 suggested that, Arogyavardhini vati is significant in decreasing BMI.



CONCLUSION:

Sthaulya is a predominant metabolic disorder, which is described by Charaka in Ashtaunindita Purusha. Excessive indulgence in oily and fatty food, sedentary life style, Divaswapana, Manasika factors like Harshanitya, Manasonivrita etc. along with genetic predisposition play a major role in aetiopathogenesis of Medo and mamans vridhi. In condition of Mandagni and Medo-Dhatvagni Mandya which leads to excessive formation of improper Meda-Dhatu leading to Sthaulya . Obesity occurs more in female than male and specially increases after marriage mostly might be due to use of IUCD, contraceptive pills, after delivery and in menopausal period etc. People of all age groups are equally affected by obesity, but the people belonging to age group of 30-40 years, are more prone to obesity. Most of the patients were married, as they were from middle age group and especially the females are more prone to obesity after marriage due to hormonal changes in the body. Occupation plays a major role as the causes of obesity. The people who are having sedentary work are more prone to obesity as compared to the people doing physical work. Socio economic conditions status greatly affect the prognosis of obesity. From the study conducted, we can see the people belonging to middle class are highly affected whereas people of higher middle class were also affected. Kapha-pittaja Prakriti persons were found more prone to Medovridhi, so they should be advised proper diet regimens and exercise. The obese people had dominant madhur ras in their diet and the dominant guna was guru. By applying the non-parametric test Wilcoxon Signed Rank Test, in the Study group, it is proved that the drugs play significant role in reduction of signs and symptoms of obesity. While considering effect of therapy on individual symptoms it is found that Arogyavardhini vati is more effective on Aangachalatva, Abhayavaran Shakti, Daurbalya, Atipipasa, Aalsya and Nidraadhikya. Applying paired "t" test, Sr.Cholesterol, HDL, LDL, Sr.Triglyceride, DL ratio, BMI were significant in the groups.

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Source of Support : None declared

Conflict of interest : Nil