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Research Article

A PILOT CLINICAL STUDY ON THE EFFICACY OF *STHOULYAHARA CHOORNAM* IN THE MANAGEMENT OF *STHOULYA* W.S.R. TO OBESITY

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ABSTRACT

Obesity is a condition in which excess body fat has accumulated in different parts of the body mainly in the subcutaneous tissues. It hurts health and leads to reduced life expectancy as well as increased health problems. The World Health Organization has identified obesity as a global epidemic. The term "*Sthoulya*" is described in Ayurveda as "Overweight and Obesity". This study was undertaken to identify the efficacy of *Sthoulyahara Choornam (Anubhuta Yoga* of SJSAC & H, which is in use for its in-house patients since 25 years). The ingredients of *Sthoulyahara Choornam* are mentioned in *Charaka Samhita* in the treatment of *Medoroga*. A total of 10 patients of either sex of age group 20-60 years were randomly selected from OPD & IPD of Sri Jayendra Saraswathi Ayurveda College & Hospital, Nazarethpettai, Chennai, 600123. They were treated with *Sthoulyahara Choornam* in doses of 2mg thrice a day after food with lukewarm water for 30 days (one month). *Sthoulyahara Choornam* was found to have a significant effect in reducing the symptoms of *Medodushti* and in the reduction of objective parameters like Bodyweight, B.M.I., skinfold thickness, and lipid profile.

INTRODUCTION

Health has a relationship between the mind, soul, and body, but nowadays the equilibrium state between mind and body is disturbed due to lots of physical, mental, and psychological issues. Obesity is one of the increasing health issues of today's life, and even patients are not aware of this. Obesity (*Sthoulya*) is frowned upon by society for both social and medical reasons. *Sthoulya* is *Santarpanjanya Vikara* means overnutrition. *Sthoulya* is classified as *Medoroga* in *Ayurveda*[1]. When *Agni* or digestive power, is disturbed, *Ama* is produced, followed by disturbed *Dhatwagni* (tissue fire) into the fatty tissues and impeded the normal development of new tissues. Obesity is the result of accumulating improperly produced subcutaneous fatty tissue in the body. The reason behind the *Chala Guna* of *Vata*, accumulated fats disrupt *Vata's* mobility, which in turn promotes hunger. As a result, patients will take more meals again it converted into improper fatty tissue[2]. In *Charaka Samhita*, *Sthoulya* is considered as the *Ashtanindita Purusha* while explaining anthropology[3]. Both these persons the obese and the emaciated are to be deprecated always, among the obese and the emaciated, the emaciated is better[4]. Obesity is an unhealthy nutritional health problem that affects not only low and middle-income countries but also urban and rural areas.

Obesity and overweight are caused by an imbalance between calories consumed and used. In the 21st century, Obesity becomes one of the most serious public health. The prevalence has increased at an alarming rate. Globally in 2010, the number of overweight patients is estimated to be over 42 million. Close to 35 million of these are living in developing countries[5]. Obesity has spread rapidly over the world, in the middle and upper classes are the worst affected. The main reason is the excess deposition of body fat, which makes a person sluggish and decreases their power and side-by-side immunity also. In behind patients become overweight and obese having many different causes. The most common causes are a genetic factor, lack of physical activities, a sedentary

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lifestyle, excessive sleep, sleeping during the day after a meal, and unhealthy food habits.

Need of Study: In *Charaka Samhita*, the uses of these ingredients which is having in *Sthoulyahara Choornam*, are claimed effective for the *Sthoulya*. In the present study, *Sthoulyahara Choornam* is taken for the Clinical trial which is been used since 25 years on in-house patients of SJSAC&H. *Sthoulyahara Choornam* is quoted from *Charaka Samhita Sutrastana Ashta Ninditiya Adhya*[6]. *Sthoulyahara Choornam (Anubhuta yoga)* has *Haritaki*, *Bibhitaki*, *Amalaki*, *Sunthi*, *Vidanga*, *Yava Kshara*, and *Louha Bhasma* in equal quantity. Almost all the Drugs are having *Katu, Tikta, Kashaya, Madhura Rasa, Laghu Ruksha Guna, Ushna Virya*, and *Tidoshashamaka* especially *Kaphavata Shamaka* properties which may help disintegrate the *Samprapti* of *Sthoulya*. These showed encouraging results in the reduction of weight, skin fold thickness, body circumference, and associated signs and symptoms.

Aims & Objectives

- To evaluate the efficacy of *Sthoulyahara Choornam* in the management of obesity.
- To collect literature on *Sthoulya* W.S.R. to obesity from *Ayurveda* and modern.

Materials and methods

Clinical study Source of Data: A total of 10 Patients of either sex of age group 20-60 years were randomly selected from OPD & IPD of Sri Jayendra Saraswathi Ayurveda College & Hospital, Nazarethpettai, Chennai. (IEC) clearance was obtained before the study. Ref. IEC NO: IEC/SJSACH/16/2021 and CTRI Registered No: CTRI/2022/10/046110

Selection of Patients

A. Inclusion criteria

- Age groups from 20-60 years of either sex were selected for the study.
- Patients having cardinal features of obesity were selected.
- Patients having a BMI of 25 to 40 kg/m^2 were included in this present study.

B. Exclusion criteria

- Age below 20 years & above 60 years of age was excluded from the study.
- Patients receiving drugs like steroids and antidepressants etc were excluded from the study.
- Obesity due to any endocrinal disorders like Cushing syndrome, hypothyroidism, etc. was excluded.
- Patients having BMI below 25 kg/m^2 and more than 40 kg/m^2 were not considered.

C. Discontinuation Criteria

- Parents are not willing to continue.
- During the clinical trial, if a patient develops any serious condition which requires urgent treatment.
- A patient her/his self wants to withdraw from the clinical trial.

D. Protocol of Research

- The patient's consent is obtained after making him/her aware of the merits or demerits of the trial drugs along with the proposed trial duration.
- Fulfillment of inclusion criteria.
- Registration of obese patients.
- Investigations mentioned were advised to her/ him before presenting Ayurvedic formulation.

Posology- *Sthoulyahara Choornam (Anubhuta yoga)*

- **Doses:** 2 gm of *Choornam* thrice a day will be taken with lukewarm water, after intake of food.
- **Time of administration:** Morning, Noon, and night
- **Anupana:** *Ushnodaka*[7]
- **Duration:** 30 Days

Table 2: Composition of *Sthoulyahara Choornam*

Drug name	Botanical Name	Parts use	*Dosha Karmas*	Ratio
Amalaki[8]	*Embelica officinalis* Gaertn	Fruit pulp	*Tridoshahara*, Specially *Pittahara*	1part
Haritaki[9]	*Terminalia chebula* Retz.	Fruit pulp	*Tridoshahara*, Specially *Vatahara*	1part
Bibhitaka[10]	*Terminalia belerica* Roxb.	Fruit pulp	*Tridoshahara*, Specially *Kaphahara*	1part
Sunthi[11]	*Zingiber officinale* Rose.	Rhizome	*Kaphavatasamak*	1part
Vidanga[12]	*Embelia ribes* Burm.f.	Fruit	*Kaphavatasamak*	1part
Yava Kshara[13]	Mixture of Potassium Salts	Whole plant	*Kaphapittahara*	1part
Louha Bhasma[14]	Ferrous Oxide		*Tridoshahara*, Specially *Kapha-pittahara*	1part

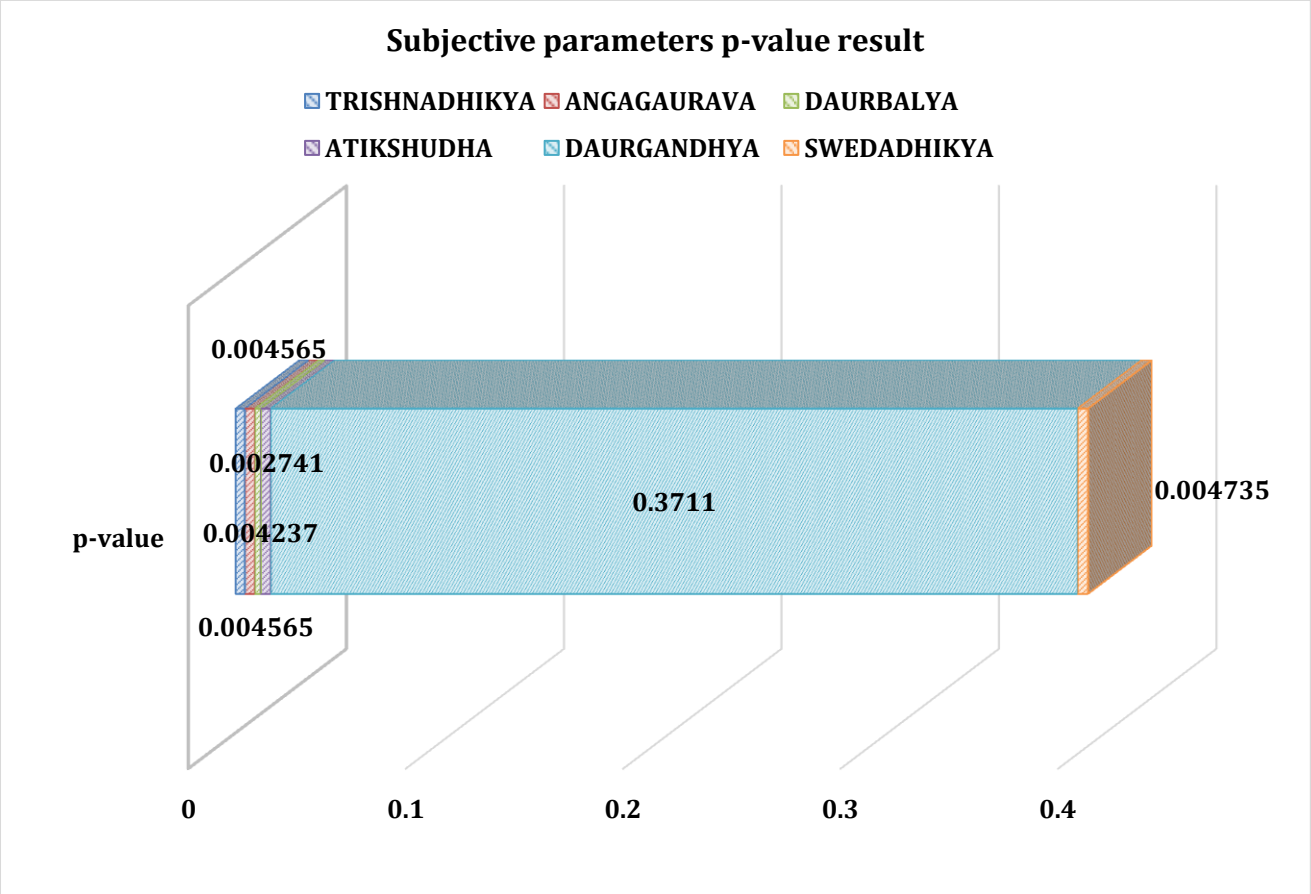
Statistical Analysis: All the results were calculated by using Software: R

For score variables, Wilcoxon signed-rank test was used while for continuous variables Paired t-Test was used and results were calculated.

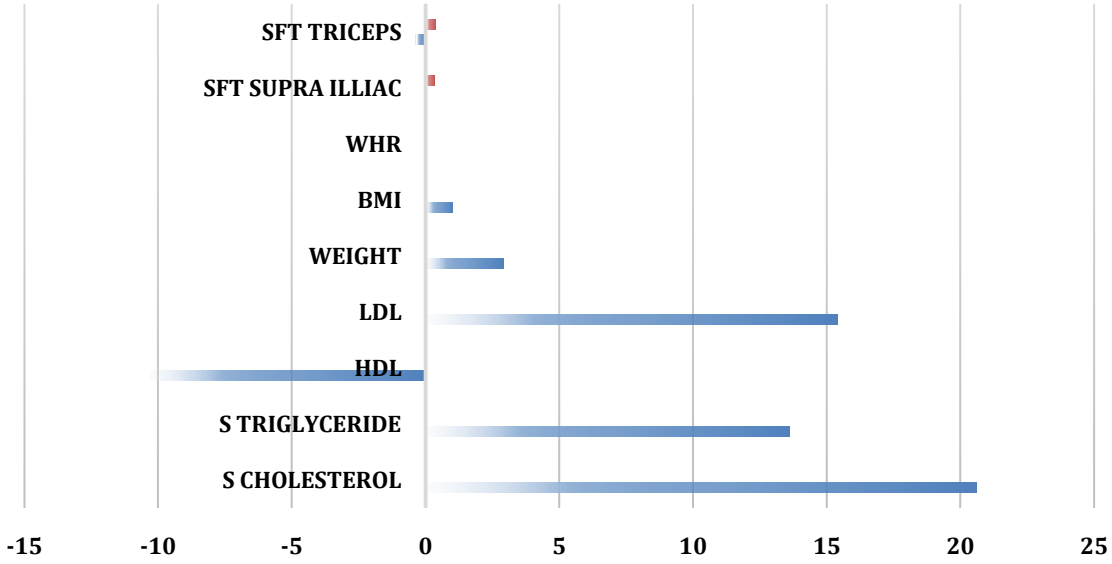
Result: Showing the P value used in the result

Subjective Parameters				
S.No	**Variable**	**Test Statistics**	**p-value**	**Remarks**
1	*Trishnadhikya*	10	0.004237	S
2	*Angagaurava*	10	0.004565	S
3	*Daurbalya*	10	0.002741	S
4	*Atikshudha*	10	0.004565	S
5	*Daurgandhya*	10	0.3711	NS
6	*Swedadhikya*	10	0.004735	S

Objective Parameters					
S.No	**Variable**	**Mean difference**	**Test Statistics**	**p-value**	**Remarks**
7	S Cholesterol	20.6	10	7.471e-08	S
8	S Triglyceride	13.6	10	4.552e-06	S
11	HDL	-10.3	10	1.27e-05	S
12	LDL	15.4	10	1.567e-08	S
13	Weight	2.9	10	2.431e-06	S
14	BMI	1.02	10	2.228e-06	S
15	WHR	0.008	10	0.00311	S
16	SFT Supra Illiac	0.01	10	0.3434	NS
17	SFT Triceps	-0.359	10	0.3856	NS



Objective parameters p-value & mean difference result



	S CHOLESTEROL	S TRIGLYCERIDE	HDL	LDL	WEIGHT	BMI	WHR	SFT SUPRA ILLIAC	SFT TRICEPS
p-value	7.47E-08	4.55E-06	1.27E-05	1.57E-08	2.43E-06	2.23E-06	0.00311	0.3434	0.3856
Mean difference	20.6	13.6	-10.3	15.4	2.9	1.02	0.008	0.01	-0.359

p-value Mean difference

Age: A maximum of 60 % of patients in the study were 20-40 years, and 40 % number of patients belong to the age group 41-60 years in the study. It means that youngsters are more likely to become obese. It is *Madhyama Kala*, according to *Ayurveda*, it leads to "*Paripurnata*" in all *Sharir Dhatus*. In this source, obesity is more common in adults due to a sedentary lifestyle and food habits.

Sex: Male predominance was evident in the study (50 % of patients were male, and 50 % of patients were female.

Religion: The majority of the population i.e., 80 % of patients were Hindu in the study, Muslim community at 1 %, followed by other communities at 1 % in the study. This does not refer to the total obesity community in and around Nazarethpettai, among them, I take the patients who come to my hospital.

Socio-Economic Status: A maximum of 20% of patients were from rich status, 20% of patients were from upper middle status in the study, 40% of patients were from middle status, and 20% of patients were from lower middle status in the study.

Habitat: 70% of patients were from the urban area in both groups while 30% of patients belong to rural habitat in this study. Over nutrition is one of the reasons for patients who have easy access to their sedentary occupations, and live-in calm, non-violent environments.

Dietary Habits: Both dietary habits have the same contribution to obesity in the study.

***Dosha*:** In this study, 70% of patients had *Pitta Kapha* and 30% of patients had *Vata Kapha* which shows *Kapha* predominancy in *Sthoulya*.

***Satva*:** *Satva* was of *Pravara* type in 40% of patients in respectively, while it was *Madhyama* type in 50% and of patients found 10% *Avara* type *Satva* respectively in the study.

***Ahara Shakti*:** 30% of patients had *Madhyam Ahara Shakti*, 60% of patients had *Pravara Ahara Shakti*, and 20% of patients had *Pravara Ahara Shakti* in the study.

***Jarana Shakti*:** In the study, 10% of patients had *Avara Jarana Shakti*, 20 % of patients had *Madhyam Jarana Shakti* and 70 % of patients had *Pravara Jarana Shakti*.

***Vyayama Shakti*:** 60 % of patients had Avara *Vyayama* and 40% of patients had *Madhyam Vyayama* in the study. It shows how etiological factors, *Avyayamam* have a role in the occurrence of *Sthoulya*. Obesity is mostly caused by a lack of physical activity. This assertion is validated by both ancient and modern medical knowledge.

***Desha*:** In the study, 10% of patients had *Anupa Desha* and 90% of patients had *Jangala Desha*.

***Agni*:** 50% of patients had *Tikshna Agni*, 40% of patients had *Sama Agni* in this study and 10% of patients had *Vishama Agni*. *Medoroga* patients had an increased *Jatharagni*, which leads to increased food

consumption. According to *Acharya Charaka*, the *Avaran* of *Vayu* causes excessive hunger in *Medoroga* and generates a desire to eat more frequently. It is also characterized by rapid food digestion, which perpetuates the cycle of increased hunger. *Vishamagni* and *Tikshnagni* in patients could be caused by *Koshthastha Vayu* and *Sandhukshita Agni*.

***Kostha*:** In the study, 70% of patients had *Madhyam Kostha*, and 30% of patients had *Mridu Kostha*. Here most of the patients had *Madhyam Kostha*, which is the *Kapha* dominancy *Koshtha* that forms the foundation for Obesity. According to *Ashtanga Hridaya Madhyama Kostha* is mostly caused by *Kapha* dominance.

***Nidra*:** 60 % of patients had *Atinidra* and 40 % of patients had *Samyak Nidra* in the study. Excess sleep is one of the main reasons for obesity, as it produces *Kapha Prakopa* and increases the *Meda Dhatu*, therefore acting as an etiological factor.

Duration: 70% of patients had a 0 to 18 months duration of disease, and 30% of patients had a 19 to 36 months duration of disease. World health organization has listed obesity as a diet-related chronic disease.

Results:

Effect of Therapy on *Trishnadhikya*

Willcoxon Signed Rank test shows a statistically significant outcome. A P-value is 0.004237. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on *Angagaurava*

Willcoxon Signed Rank test shows a statistically significant outcome. The P-value is 0.004565. The alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on *Daurbalya*

Willcoxon Signed Rank test shows a statistically significant outcome. A P-value is 0.002741. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on *Atikshudha*

Willcoxon Signed Rank test shows a statistically significant outcome. The P-value is 0.004565. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on *Daurgandhya*

Willcoxon Signed Rank test shows a statistically significant outcome. A P-value is 0.3711. The alternative hypothesis is true location shift is not equal to 0. There is no significant difference between the two outcomes.

Effect of Therapy on *Swedadhikya*

Willcoxon Signed Rank test shows a statistically significant outcome. The P-value is 0.004735. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

No.of patients	*Trishnadhikya*		*Angagaurava*		*Daurbalya*		*Atikshudha*		*Daurgandhya*		*Swedadhikya*	
	BF	**AF**	**BF**	**AF**	**BF**	**AF**	**BF**	**AF**	**BF**	**AF**	**BF**	**AF**
1	3	1	3	1	1	0	3	1	0	0	1	0
2	4	2	2	0	2	1	2	1	1	0	2	0
3	3	1	2	1	1	0	3	2	2	0	3	0
4	2	1	1	0	2	1	2	0	0	0	2	0
5	3	1	2	1	2	1	2	1	1	1	2	1
6	2	1	2	1	2	1	3	2	0	0	1	0
7	3	1	2	1	3	2	2	0	0	0	1	0
8	3	1	1	0	3	2	3	1	0	0	2	1
9	3	0	2	0	1	0	2	0	1	1	3	2
10	3	1	3	1	2	1	4	2	0	0	2	0

* For comparison between before treatment and after treatment for *Trishnadhikya, Angagaurava, Daurbalya, Atikshudha,* and *Swedadhikya* there was a significant difference observed for *Daurgandhya* was no significant difference observed.

Effect of Therapy on Serum Cholesterol

Paired t-test shows the statistically significant outcome. Here t value is 15.728, the P-value is 7.471e-08, and the mean difference is 20.6. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on Serum Triglyceride

Paired t-test shows a statistically significant outcome. Here t value is 9.7143, the P-value is 4.552e-06, and the mean difference is 13.6. The alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on HDL

Paired t-test shows a statistically significant outcome. Here t value is -8.5668, the P-value is 1.27e-05, and the mean difference is -10.3. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on LDL

Paired t-test shows a statistically significant outcome. Here t value is 18.799, the P-value is 1.567e-08, and the mean difference is 15.4. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

No.of patients	Serum Cholesterol		Serum Triglyceride		HDL		LDL	
	BF	AF	BF	AF	BF	AF	BF	AF
1	261	247	166	157	35	46	156	142
2	253	238	171	162	32	39	180	164
3	212	190	154	139	37	43	153	137
4	198	173	169	146	29	38	162	147
5	211	195	183	171	34	42	178	159
6	197	174	179	163	28	37	183	163
7	221	198	167	158	31	48	165	151
8	193	170	180	163	30	45	158	143
9	208	183	193	179	29	36	175	161
10	196	176	175	163	32	46	187	176

* For comparison between before-treatment and after-treatment for Serum Cholesterol, Serum Triglyceride, HDL, and LDL there was a significant difference observed.

Effect of Therapy on Weight

Paired t-test shows a statistically significant outcome. Here t value is 10.474, the P-value is 2.431e-06, and the mean difference is 2.9. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on BMI

Paired t-test shows a statistically significant outcome. Here t value is 10.583, the P-value is 2.228e-06, and the mean difference is 1.02. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on WHR

Paired t-test shows a statistically significant outcome. Here t value is 4, the P-value is 0.00311, and the mean difference is 0.008. An alternative hypothesis is true location shift is not equal to 0. There is a significant difference between the two outcomes.

Effect of Therapy on S.F.T SUPRA ILLIAC

Paired t-test shows the statistically significant outcome. Here t value is 1, the P-value is 0.3434, and the mean difference is 0.01. An alternative hypothesis is true location shift is not equal to 0. There is no significant difference between the two outcomes.

Effect of Therapy on S.F.T. TRICEPS

Paired t-test shows the statistically significant outcome. Here t value is -0.91182, the P-value is 0.3856, and the mean difference is -0.359. The alternative hypothesis is true location shift is not equal to 0. There is no significant difference between the two outcomes.

No.of patients	Weight		BMI		WHR		S.F.T SUPRA ILLIAC		S.F.T. TRICEPS	
	BF	AF	BF	AF	BF	AF	BF	AF	BF	AF
1	79	77	29	28.3	1.16	1.15	23.6	23.6	14.08	14.07
2	96	93	31.7	30.7	1.27	1.27	21.9	21.5	14.3	14.3
3	104	101	33.2	32.2	1.23	1.22	25	25	14.6	14.5
4	90	89	32.7	32.3	1.21	1.21	24.1	24.1	15.03	15.03
5	88	85	30.4	29.4	1.31	1.30	23.5	23.5	14.5	14.5
6	95	91	30	28.7	1.28	1.27	21	20.9	15.8	15.7
7	85	82	33.2	32	1.11	1.11	22.9	22.9	15.1	15
8	88	84	32.7	31.2	1.15	1.14	21.7	21.7	14.3	14.3
9	98	95	33.1	31.1	1.25	1.23	24.2	24.2	14.7	14.7
10	89	86	33.1	32	1.05	1.04	21.3	21.3	14.9	14.8

* For comparison between before-treatment and after-treatment Weight, BMI, and WHR there was a significant difference observed and for S.F.T. Supra Illiac, and S.F.T. Triceps there was no significant difference observed.

DISCUSSION

Sthoulya is a metabolic disorder caused by a lack of exercise, improper diet, stress, and genetic predisposition which leads to an increase in *Kapha Dosha* (bio element) followed by excessive adipose tissue accumulation (which belongs to *Prithvi* and *Jala Mahabhoota*) in the body along with poor digestive fire, and toxin accumulation. Overeating and a sedentary lifestyle, excessive sleep, use of steroids, and psycho-emotional illnesses like grief, stress, and anxiety, all contribute to the accumulation of *Prithvi* and *Jala Mahabhoota* in the body. *Prithvi* and *Jala Mahabhoota* present heavy, dense, slow, and cold and are hostile to *Dhatvagni* (metabolic fire), which is sharp, light, and hot, resulting in a sluggish metabolism and accumulation of fat. So, the drugs chosen should be of *Kaphahara* properties to break the etiopathogenesis of Obesity[15]

This study showed the efficacy of *Sthoulyahara Choornam*, as stated in *Anubhuta Yoga*, respectively, on obesity. Many Ayurvedic medicines for the treatment of obesity have been listed in *Ayurvedic* scriptures. So, in this study, the oral drug *Sthoulyahara Choornam*, which is *Anubhuta Yoga* ingredient maintained in Charaka Samhita, had been chosen for the trial study. This formulation was presented in the form of *Choornam* to improve their palatability and make them easier to administer to patients.

Probable Mode of Action

The mode of action of *Sthoulyahara Choornam* on *Sthoulya* can be explained as follows –

Sthoulya is a disease caused by the ingestion of *Kapha Vriddhikara Ahara*, *Vihara*, and *Manasa Nidana*. These elements disrupt *Jatharagni*, resulting in *Ama Annarasa* and *Medodhatvagnimandya*. *Sthoulya* is caused by excessive development and accumulation of *Medodhatu* because of this condition.

Here *Sthoulyahara Choornam*, is an *Anubhuta Yoga* of *Ayurvedic* herbs and minerals used for the treatment of obesity. *Sthoulyahara Choornam* contains 7 ingredients *Amalaki, Bibhitaki, Haritaki, Vidanga, Sunthi, Yava Kshara*, and *Loha Bhasma*. *Acharya Charaka* recommends all ingredients for *Medoroga* (hyperlipidemia), *Sthoulya* (obesity), and other *Kaphajaroga* (*Kapha*-related disorders). *Medo Dhatu's* obstruction by *Kaphavrita Vata* causes symptoms including exhaustion, exertional dyspnea, thirst, increased sleep, and increased perspiration among *Medorogi*. It is an *Anubhuta Yoga*, with properties like *Ruksha* (dry), *Laghu* (light in digestion), *Tikshna, Sara, Katu*, *Kashaya Rasa*, *Deepana* (appetizer), *Medohara* (decreases Medodhatu), and so on.

This medication's digestive (*Ama Pachana*), appetitive, scraping, lightening, and *VataKapha* palliative effects aid in the relief of the symptoms. As a result, via scraping activity, it removes *Medoja* blockage and restores *Vata* balance. Reduction in exertional dyspnea and fatigue can also be attributed to the loss of body weight caused by the administration of *Anubhuta Yoga*.

The *Katu* and *Kashaya rasa*, light and dry qualities, and dominant medications *Ushna Virya*, and *Tridoshasamaka*, *Kaphavatasamaka* in *Sthoulyahara Choornam* have all the properties to break down the etiology of hyperlipidemia.

CONCLUSION

From the above study, this was concluded that etiological factors i.e., Dietary, Psychological & lifestyle related mainly vitiate *Kapha* and *Meda* which obstruct the path of *Vata* and causes its *Avarana* which results in provocation of *Vata*. That's why genetic factors, sedentary lifestyle & *Kapha*-predominant *Prakriti Purush* were found to increase the prevalence of Obesity. Therefore, the line of treatment should be *Kapha-Vata-Medo Hara* & *Apatarpanakara*. Hence, a clinical study was done to evaluate the efficacy *Sthoulyahara Choornam* in the management of *Sthoulya* w.s.r. to obesity. The outcome of this study revealed the results of overall in 10 patients advocated in the study. *Sthoulyahara Choornam* was found to have a significant effect in reducing the symptoms of *Medo Dushti* and in the reduction of objective parameters like weight, BMI, and lipid profile.

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