

A Clinical Comparative Study in Management of Sthoulya W.S.R. To Obesity with Triphala Churna And Trikatu Churna

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ABSTRACT-Sthoulya is the abnormal and excess accumulation of Medadhatu. Meda is the fourth tissue incorporates with weight gain. Weight gain is a natural physiological process but sometimes it increases to that point of development where it may impair health and invites a number of disorders with high morbidity and mortality. The derangement of Medadhatu leads to Medadhatugata diseases like Medovridhi, Medasvina, Sthoulya, Ati-Sthoulya etc., which is simulated with Overweight / Obesity in modern science. As regards its management priorance goes to Nidana-Parivarjanam (avoidance the ingestion of morbid factors) i.e. to change in eating habits and behavioral attitudes. According to Charaka, diet which is heavy to digest but low in nutrition value, desirable as it can subside or fulfill the need of aggravated digesting power, while low calorie doesn't increase fat anabolism. Various therapeutic modalities have been defined for Sthoulya in our classics. In all these Langhana, Swedana, Lekhana, Guru-Apatarpana, Vamana, Virechana, Basti are useful and Katu, Tikta and Kashaya Rasa dominant drugs, which are with Vataghna and Kaphaghna action has more importance. In Charaka Samhita Sutrasthana, there is elaboration of Triphala Churna for treatment of Sthoulya, which was taken here for trial. Another trial drug was Trikatu Churna which is elaborated in Bhavaprakasha Haritakyadi Varga as Sthoulyahara.

The clinical effect of therapy shows that in TG I, 1 (10%) patient was get moderate improvement while 9 (90%) patients were get mild improvement. In TG II, 7 (70%) patients were get mild improvement and 3 (30%) patients were get unsatisfactory improvement. In CG, 5 (50%) patients each were get mild improvement and unsatisfactory improvement. The comparative effect between all groups shows that TG I (Triphala

Churna with Pathyapathya) is more effective than TG II (Trikatu Churna with Pathyapathya) and CG (only Pathyapathya) where as TG II is more effective than CG.

KEYWORDS- obesity, Sthoulya, Trikatu Churna, Triphala Churna

I. INTRODUCTION-

Overweight and obesity kills more people than underweight and act as a predisposing factor for non-communicable diseases such as cardiovascular diseases (heart attack and stroke), diabetes, hypertension, musculoskeletal disorders (osteoarthritis), some cancers (including breast, ovarian, prostate, liver, gallbladder, kidney, and colon). According to W.H.O¹, most of the world's population lives in countries where overweight and obesity kills more people than underweight. In 2016, more than 1.9 billion adults, 18 years and older, were overweight. Of these over 650 million were obese. 39% of adults aged 18 years and over were overweight, and 13% were obese. 41 million children under the age of 5 were overweight or obese. Over 340 million children and adolescents aged 5-19 were overweight or obese in 2016.

Sthoulya (obesity) has been known to Indian physicians since very primitive era. Meda (fat) is the essential element of our body as it provides 30-40 % of total energy intake but too much of it causes various disorders like Sthoulya (obesity) etc. Sthoulya described as notorious disorder is mentioned by Acharya Charaka in Ashta-Nindita Purusha². Acharya Charaka and Vagbhata mentioned that Karshya (thin) is better than Sthoulya, because there is no perfect remedy for the Sthoulya. The severity gradations described in Ayurveda i.e. Hina-Sthoulya, Sthoulya, Ati-Sthoulya may be correlated with Overweight, Obesity and Morbid obesity based on BMI but

there is no accurate parameter available to destinate this.

The etiopathogenesis highlights on eating habits, sedentary life styles and up to some extent genetic and endocrinal factors. Madhura Rasa (sweet in taste), Snigdha (unctuous), Guru (heavy), Kapha Vriddhikara (diet which increases Kapha), Prithvi Jala Mahabhuta dominant diet, are generally rich in carbohydrate and fat contents, which have higher nutrition values usually. This leads to more calories production and ultimately storage as depot fat. Viharaj Nidana like Divaswapna (day sleep) or Ati Nindra (excess sleep), less exercise, less sexual act can able to diminish direct Medodhatvagni without create Jatharagni Mandya also, which can create a base for dietary fault to create etiopathogenesis.

Various therapeutic modalities have been defined for Sthoulya in our classics. In all these Langhana, Swedana, Lekhana, Guru-Apatarpana, Vamana, Virechana, Basti are useful and Katu, Tikta and Kashaya Rasa dominant drugs, which are with Vataghna and Kaphaghna action has more importance. In Charaka Samhita Sutrasthana³, there is elaboration of Triphala Churna for treatment of Sthoulya. Trikatu Churna elaborated in Bhavaprakasha Haritakyadi Varga⁴ has also indicated in Sthoulya. Ayurveda emphasized on Pathya (Ahara-Vihar) and Apathya for management of Sthoulya in various Samhitas like Charaka (Cha.Su. 21/25-28), Sushruta (S.S.Su.15/38), Vagbhatta (A.H.Su 14/36), Bhaishajya Ratnavali⁵ etc.

In Triphala Churna, properties of individual ingredients shows majority of Kashaya Rasa, Laghu, Ruksha Guna, Ushna Virya. Sthoulya requires reduction in the states of Kapha, which is considered to be possible with the trial drug, innervated with the above properties. In Trikatu Churna, properties of individual ingredients shows majority of Katu Rasa, Laghu, Snigdha Guna, Ushna Virya. These properties may reduce the states of Kapha. So, the present work is a further step in the field of Kayachikitsa entitled "A clinical comparative study in management of Sthoulya w.s.r. to Obesity with Triphala Churna and Trikatu Churna" which has been taken with following aims and objectives-

AIMS AND OBJECTIVES-

- To study the efficacy of Triphala Churna in Sthoulya (Obesity).
- To study the efficacy of Trikatu Churna in Sthoulya (Obesity).

- To study the efficacy of Pathyapathya (Ahara-Vihar) in Sthoulya (Obesity).
- To compare the effect of all three groups i.e. Triphala, Trikatu and Pathyapathya in Sthoulya (Obesity).

II. MATERIALS & METHODS-

- **Study type** - Randomized open comparative clinical study.
- **Place of study** - Clinical study was conducted on patients in OPD/IPD of P.G. Dept. of Kayachikitsa, V.Y.D.S Ayurveda Mahavidyalaya, Khurja.
- **Selection of patients** - The patients with symptoms of Sthoulya (Obesity) were randomly selected who were agreed for giving consent.
- **Sample size** - 30 (Total 33 patients were screened, 30 patients completed the trial).
- **Study design** - Selected patients were divided into 3 groups (TG I, TG II and CG) with 10 patients in each group.
 1. In Trial group-I (TG I), Triphala Churna along with Pathyapathya was implemented.
 2. In Trial group-II (TG II), Trikatu Churna along with Pathyapathya was implemented.
 3. In group-III i.e. Control group (CG), only Pathyapathya was implemented.
- **Diagnostic criteria** - The criteria by which we can make diagnosis of Sthoulya are included in inclusion criteria for which assessment grading were done.
- **Inclusion criteria** –
 1. Age – Patients in between 30 and 50 years of age were selected irrespective of their gender, social and economical status.
 2. Sex – Both male and female
 3. **Subjective parameters**
 - Chala Sphik Udara Sthana (Pendulous movement of buttock, abdomen, chest / breast)
 - Sramaswasa/ Kshudraswasa (Exertional dyspnoea)
 - Ati-Pipasa (Excessive thirst)
 - Ati-Kshudha (Excessive hunger)
 - Ati-Nidra (Excessive and Untimely sleep)
 - Ati-Sweda (Excessive sweating)
 - Sweda Daurgandhya (Foul smelling)
 4. **Objective parameters**
 - Body weight in excess (Actual weight – Ideal weight)
 - Body mass index (BMI – 25 –29.99 Kg/m²)
 - Skin fold thickness (Male ≥ 40 mm, Female ≥ 50 mm)

- Waist –Hip ratio (W.H.R.) (Male \geq 1, Female \geq 0.8)
- High Lipid Profile
- **Exclusion criteria**
- ✦ Patients not fulfilling inclusion criteria.
- ✦ Patients age below age 30 and above 50 years.
- ✦ Patients having BMI \geq 30 Kg/m² and \leq 25 Kg/m²
- ✦ Obesity of hereditary/genetic origin or endocrinal involvement.
- ✦ Obesity due to any secondary causes like patients with long term steroid treatment.
- ✦ Cases having medical emergencies or suffering from major systemic disorders like cardiac diseases (IHD), IDDM, uncontrolled hypertension, renal and hepatic diseases etc.
- ✦ Pregnant females and lactating women.
- **Laboratory investigations -**
- ✦ Lipid profile (S. Cholesterol, S. Triglyceride, H.D.L., L.D.L.)
- ✦ Wherever required complete blood count (CBC), Blood sugar, L.F.T, K.F.T., Thyroid profile etc. were done.
- **Selection of drug -**
- ✦ **Triphala Churna** (Charaka Samhita Sutrasthana 21/22)
- ❖ **Ingredients** –Haritaki, Bibhitaki, Amalaki
- ❖ **Dose**- 5gm twice daily after meal
- ❖ **Dosage form** – Powder
- ❖ **Route of Administration** – Oral
- ❖ **Anupana**- Luke warm water
- ✦ **Trikatu Churna** (Bhavaprakasha Haritakyadi Varga Sloka 62-63)
- ❖ **Ingredients** –Sunthi, Pippali, Maricha
- ❖ **Dose**- 3gm twice daily before meal
- ❖ **Dosage form** – Powder

- ❖ **Route of Administration** – Oral
- ❖ **Anupana**- Luke warm water
- ✦ **Pathyapathya** (Ahara-Vihar)-In this research study, special diet and regimen adopted for weight reduction.
- **Duration of treatment** – Three months (90 days)
- **Follow up (Observation period)** – 6 follow ups every 15 days for 3 months.

ASSESSMENT ON RESULTS -Assessment of progress was done before and after treatment on the basis of subjective and objective parameters every month biweekly. Grading was given for all the symptoms according to severity.

- **General observations**- Various demographic parameters like age, sex, marital status, religion etc. were analyzed in the present trial.
- **Statistical assessment of results**- The statistical assessment was done on subjective and objective parameters. The obtained results were analyzed with the use of Wilcoxon signed rank method to check the significance of subjective parameters and Paired ‘t’ test for objective parameters. The effectiveness of the trial drug to different sign and symptoms of each group will be assessed through P-value. ANOVA for comparison between three groups was also implemented.
- **Clinical assessment of results**- The clinical assessment of results will be noted after treatment upon the cardinal clinical features of subjective and objective parameters. The result in view of percentage of improvement will classify as follows-

1	Maximum improvement	-	> 75% improvement
2	Moderate improvement	-	> 50% to 75% improvement
3	Mild improvement	-	> 25% to 50% improvement
4	Unsatisfactory	-	Negligible (\leq 25%) improvement

III. OBSERVATIONS AND RESULTS-

In the study total 33 patients were screened, among them 2 patients were dropped out from TG II, 1 patient was dropped out from CG. Hence 30 patients completed the course.

- ❖ The demographic data in this study reveals that maximum numbers of patients were observed between the age group of 46-50 years. Maximum patients found in female group, married group. Maximum patients were Hindu and were living in rural areas. Maximum patients found in housewife group, upper class

group. All patients were in BMI of 25 - < 30. Maximum patients have found positive family history group, were of up to 1 yr chronicity group, onset in adult age group and occasional medication group. Maximum patients were of intermediate level of educational status, tea/coffee addiction group, pleasure mood, day sleep, non-veg diet, overeating (Ati-Sampurana) habit, 05-06 times / day periodicity of diet, fats and fast foods preference of diet group.

- ❖ Maximum patients were found in Madhura Rasa dominancy group, Sannipataja Prakruti group, Avara Sara group, Madhyam Samhanana group, Adhika Pramana group, Sarvarasa Satmya group, Avara Satva group, Pravara Ahara Abhyavarana Shakti group, Pravara Jaran Shakti group, sedentary Vyayama Shakti group, Madhya Kostha group, Tikshnagni group, regular bowel habit group.
- ❖ **Presence of clinical features** - Chala Sphik Udara Sthana (Pendulous movement of buttock, abdomen, chest / breast), Sramaswasa / Kshudraswasa (Exertional dyspnoea) was present in all groups i.e. 10 (100%).

(Excessive thirst) was present in 7 (70%), 5 (50%), 6 (60%) where as Ati-Kshudha (Excessive hunger) in 9 (90%), 9 (90%), 8 (80%), Ati-Nidra (Excessive and Untimely sleep) in 8 (80%), 5 (50%), 7 (70%), Ati-Sweda (Excessive sweating) in 8 (80%), 6 (60%), 7 (70%), Sweda Daurgandhya (Foul smelling) in 8 (80%), 6 (60%), 7 (70%) in TG I, TG II and CG group respectively. Weight in excess, Body mass index (BMI), Skin fold thickness, Waist-Hip ratio, Lipid profile was assessed in all patients i.e. 10 (100%) in all groups.

Table 1-Statistical analysis showing the effectiveness of trial drug in TG I

Sign & Symptoms	N	Mean Score			Mean diff.	± S.D.	± S.E.	w-value/ t-value	p - value	Remark
		B.T.	A.T.							
Chala Sphik Udara Sthana (Pendulous movement)	10	2.6	A.T.1	2.5	0.1	0.316	0.1	1	> 0.9999	N.S.
		2.6	A.T.2	2.3	0.3	0.483	0.153	6	0.25	N.S.
		2.6	A.T.3	2	0.6	0.516	0.163	21	0.0313	S.
		2.6	A.T.4	2	0.6	0.516	0.163	21	0.0313	S.
		2.6	A.T.5	1.6	1	0.817	0.258	28	0.0156	S.
		2.6	A.T.6	1.4	1.2	0.633	0.2	45	0.0039	V.S.
Sramaswasa / Kshudraswasa (Exertional dyspnoea)	10	2.4	A.T.1	2.3	0.1	0.316	0.1	1	> 0.9999	N.S.
		2.4	A.T.2	2.1	0.3	0.483	0.153	6	0.25	N.S.
		2.4	A.T.3	2	0.4	0.516	0.163	10	0.125	N.S.
		2.4	A.T.4	1.7	0.7	0.483	0.153	28	0.0156	S.
		2.4	A.T.5	1.6	0.8	0.422	0.133	36	0.0078	V.S.
		2.4	A.T.6	1.3	1.1	0.568	0.18	45	0.0039	V.S.
Ati-Pipasa (Excessive thirst)	7	1.86	A.T.1	1.714	0.1429	0.378	0.143	1	> 0.9999	N.S.
		1.86	A.T.2	1.714	0.1429	0.378	0.143	1	> 0.9999	N.S.
		1.86	A.T.3	1.429	0.4286	0.535	0.202	6	0.25	N.S.
		1.86	A.T.4	1.286	0.5714	0.535	0.202	10	0.125	N.S.
		1.86	A.T.5	1	0.8571	0.378	0.143	21	0.0313	S.
		1.86	A.T.6	0.8571	1	0.577	0.218	21	0.0313	S.
Ati-Kshudha (Excessive hunger)	9	1.89	A.T.1	1.778	0.1111	0.333	0.111	1	> 0.9999	N.S.
		1.89	A.T.2	1.667	0.2222	0.441	0.147	3	0.5	N.S.
		1.89	A.T.3	1.556	0.3333	0.5	0.167	6	0.25	N.S.
		1.89	A.T.4	1.333	0.5556	0.527	0.176	15	0.0625	N.Q.S.
		1.89	A.T.5	1.222	0.6667	0.5	0.167	21	0.0313	S.
		1.89	A.T.6	1.111	0.7778	0.441	0.147	28	0.0156	S.
Ati-Nidra (Excessive and Untimely sleep)	8	2.25	A.T.1	2.125	0.125	0.354	0.125	1	> 0.9999	N.S.
		2.25	A.T.2	2	0.25	0.463	0.164	3	0.5	N.S.
		2.25	A.T.3	1.75	0.5	0.756	0.267	6	0.25	N.S.
		2.25	A.T.4	1.75	0.5	0.756	0.267	6	0.25	N.S.
		2.25	A.T.5	1.25	1	0.756	0.267	21	0.0313	S.
		2.25	A.T.6	1	1.25	0.463	0.164	36	0.0078	V.S.
Ati-Sweda	8	2.25	A.T.1	2	0.25	0.463	0.164	3	0.5	N.S.

(Excessive sweating)		2.25	A.T.2	1.75	0.5	0.535	0.189	10	0.125	N.S.
		2.25	A.T.3	1.5	0.75	0.463	0.164	21	0.0313	S.
		2.25	A.T.4	1.5	0.75	0.463	0.164	21	0.0313	S.
		2.25	A.T.5	1.375	0.875	0.354	0.125	28	0.0156	S.
		2.25	A.T.6	1.125	1.125	0.641	0.227	28	0.0156	S.
Sweda Daurgandhya (Foul smelling)	8	2.5	A.T.1	2.25	0.25	0.463	0.164	3	0.5	N.S.
		2.5	A.T.2	2	0.5	0.756	0.267	6	0.25	N.S.
		2.5	A.T.3	1.875	0.625	0.744	0.263	10	0.125	N.S.
		2.5	A.T.4	1.625	0.875	0.641	0.227	21	0.0313	S.
		2.5	A.T.5	1.25	1.25	0.886	0.313	21	0.0313	S.
		2.5	A.T.6	1	1.5	0.926	0.327	28	0.0156	S.
Weight excess	10	72.4	A.T.1	70.5	1.9	1.449	0.458	4.146	0.0025	V.S.
		72.4	A.T.2	69.2	3.2	1.317	0.416	7.686	< 0.0001	E.S.
		72.4	A.T.3	66.4	6	1.886	0.596	10.062	< 0.0001	E.S.
		72.4	A.T.4	65.4	7	2.055	0.65	10.773	< 0.0001	E.S.
		72.4	A.T.5	63.7	8.7	3.234	1.023	8.508	< 0.0001	E.S.
		72.4	A.T.6	62.4	10	2.944	0.931	10.742	< 0.0001	E.S.
Body mass index (BMI)	10	29.1	A.T.1	28.314	0.753	0.568	0.18	4.191	0.0023	V.S.
		29.1	A.T.2	27.765	1.302	0.531	0.168	7.758	< 0.0001	E.S.
		29.1	A.T.3	26.653	2.414	0.758	0.24	10.074	< 0.0001	E.S.
		29.1	A.T.4	26.257	2.81	0.801	0.253	11.095	< 0.0001	E.S.
		29.1	A.T.5	25.578	3.489	1.248	0.395	8.843	< 0.0001	E.S.
		29.1	A.T.6	25.059	4.008	1.139	0.36	11.130	< 0.0001	E.S.
Skin fold thickness (Male)	3	58.3	A.T.1	56	2.333	1.528	0.882	2.646	0.1181	N.S.
		58.3	A.T.2	54.333	4	3	1.732	2.309	0.1472	N.S.
		58.3	A.T.3	53.333	5	3.606	2.082	2.402	0.1383	N.S.
		58.3	A.T.4	52	6.333	3.055	1.764	3.591	0.0696	N.Q.S.
		58.3	A.T.5	49	9.333	3.786	2.186	4.270	0.0507	N.Q.S.
		58.3	A.T.6	47.333	11	2.646	1.528	7.201	0.0187	S.
Skin fold thickness (Female)	7	71.4	A.T.1	69.714	1.714	1.496	0.565	3.032	0.023	S.
		71.4	A.T.2	67.143	4.286	2.215	0.837	5.120	0.0022	V.S.
		71.4	A.T.3	65.571	5.857	2.116	0.8	7.325	0.0003	E.S.
		71.4	A.T.4	63.571	7.857	3.388	1.28	6.136	0.0009	E.S.
		71.4	A.T.5	62.857	8.571	3.552	1.343	6.384	0.0007	E.S.
		71.4	A.T.6	61.714	9.714	3.147	1.19	8.167	0.0002	E.S.
Waist-Hip ratio (Male)	3	1.03	A.T.1	1.017	0.0133	0.012	0.007	2	0.1835	N.S.
		1.03	A.T.2	0.01528	0.0088	0.043	0.987	4.914	0.039	S.
		1.03	A.T.3	0.9567	0.0733	0.015	0.009	8.315	0.0142	S.
		1.03	A.T.4	0.94	0.09	0.03	0.017	5.196	0.0351	S.
		1.03	A.T.5	0.9267	0.1033	0.015	0.009	11.717	0.0072	V.S.
		1.03	A.T.6	0.9133	0.1167	0.015	0.009	13.229	0.0057	V.S.
Waist-Hip ratio (Female)	7	0.9614	A.T.1	0.95	0.0114	0.009	0.003	3.361	0.0152	S.
		0.9614	A.T.2	0.9329	0.0286	0.02	0.008	3.714	0.0099	V.S.
		0.9614	A.T.3	0.9129	0.0486	0.019	0.007	6.893	0.0005	E.S.
		0.9614	A.T.4	0.9057	0.0557	0.018	0.007	8.132	0.0002	E.S.
		0.9614	A.T.5	0.89	0.0714	0.016	0.006	12.01	< 0.0001	E.S.
		0.9614	A.T.6	0.8786	0.0829	0.018	0.007	12.182	< 0.0001	E.S.
S. Cholesterol	10	279.8	A.T.1	270.6	9.2	4.417	1.397	6.586	0.0001	E.S.
		279.8	A.T.2	258.7	21.1	5.705	1.804	11.696	< 0.0001	E.S.
		279.8	A.T.3	247.7	32.1	8.412	2.66	12.067	< 0.0001	E.S.
		279.8	A.T.4	238.8	41	9.238	2.921	14.035	< 0.0001	E.S.
		279.8	A.T.5	228.7	51.1	8.252	2.61	19.582	< 0.0001	E.S.

		279.8	A.T.6	225.4	54.4	8.884	2.81	19.363	< 0.0001	E.S.
S. Triglyceride	10	220.5	A.T.1	210.9	9.6	5.337	1.688	5.688	0.0003	E.S.
		220.5	A.T.2	201	19.5	7.892	2.496	7.814	< 0.0001	E.S.
		220.5	A.T.3	193.2	27.3	10.55	3.337	8.181	< 0.0001	E.S.
		220.5	A.T.4	186.3	34.2	12.5	3.952	8.654	< 0.0001	E.S.
		220.5	A.T.5	181.5	39	13.76	4.351	8.963	< 0.0001	E.S.
		220.5	A.T.6	177.2	43.3	14.29	4.519	9.581	< 0.0001	E.S.
H.D.L.	10	35.9	A.T.1	36.8	-0.9	0.876	0.277	3.25	0.01	V.S.
		35.9	A.T.2	37.5	-1.6	0.966	0.306	5.237	0.0005	E.S.
		35.9	A.T.3	38.8	-2.9	1.101	0.348	8.333	< 0.0001	E.S.
		35.9	A.T.4	40.3	-4.4	1.35	0.427	10.307	< 0.0001	E.S.
		35.9	A.T.5	41	-5.1	1.524	0.482	10.583	< 0.0001	E.S.
		35.9	A.T.6	41.9	-6	1.491	0.471	12.728	< 0.0001	E.S.
L.D.L	10	181.5	A.T.1	175.7	5.8	2.974	0.94	6.167	0.0002	E.S.
		181.5	A.T.2	169.5	12	3.83	1.211	9.909	< 0.0001	E.S.
		181.5	A.T.3	161.5	20	3.83	1.211	16.514	< 0.0001	E.S.
		181.5	A.T.4	156.9	24.6	6.569	2.077	11.842	< 0.0001	E.S.
		181.5	A.T.5	151.6	29.9	7.651	2.42	12.357	< 0.0001	E.S.
		181.5	A.T.6	148.2	33.3	7.732	2.445	13.619	< 0.0001	E.S.

Table 2- Statistical analysis showing the effectiveness of trial drug in TG II

Sign & Symptoms	N	Mean Score			Mean diff.	± S.D.	± S.E.	w-value/ t-value	p - value	Remark
		B.T.	A.T.							
Chala Sphik Udara Sthana (Pendulous movement)	10	2.5	A.T.1	2.2	0.3	0.483	0.153	6	0.25	N.S.
		2.5	A.T.2	2	0.5	0.527	0.167	15	0.0625	N.Q.S.
		2.5	A.T.3	1.9	0.6	0.516	0.163	21	0.0313	S.
		2.5	A.T.4	1.8	0.7	0.675	0.213	21	0.0313	S.
		2.5	A.T.5	1.7	0.8	0.789	0.249	21	0.0313	S.
		2.5	A.T.6	1.6	0.9	0.738	0.233	28	0.0156	S.
Sramaswasa / Kshudraswasa (Exertional dyspnoea)	10	2.5	A.T.1	2.4	0.1	0.316	0.1	1	> 0.9999	N.S.
		2.5	A.T.2	2.1	0.4	0.516	0.163	10	0.125	N.S.
		2.5	A.T.3	2	0.5	0.707	0.224	10	0.125	N.S.
		2.5	A.T.4	1.8	0.7	0.675	0.213	21	0.0313	S.
		2.5	A.T.5	1.6	0.9	0.738	0.233	28	0.0156	S.
		2.5	A.T.6	1.5	1	0.667	0.211	45	0.0039	V.S.
Ati-Pipasa (Excessive thirst)	5	1.4	A.T.1	1.2	0.2	0.447	0.2	1	> 0.9999	N.S.
		1.4	A.T.2	1.2	0.2	0.447	0.2	1	> 0.9999	N.S.
		1.4	A.T.3	1	0.4	0.548	0.245	3	0.5	N.S.
		1.4	A.T.4	1	0.4	0.548	0.245	3	0.5	N.S.
		1.4	A.T.5	1	0.4	0.548	0.245	3	0.5	N.S.
		1.4	A.T.6	0.8	0.6	0.548	0.245	6	0.25	N.S.
Ati-Kshudha (Excessive hunger)	9	1.67	A.T.1	1.444	0.2222	0.441	0.147	3	0.5	N.S.
		1.67	A.T.2	1.333	0.3333	0.5	0.167	6	0.25	N.S.
		1.67	A.T.3	1.222	0.4444	0.527	0.176	10	0.125	N.S.
		1.67	A.T.4	1.222	0.4444	0.527	0.176	10	0.125	N.S.
		1.67	A.T.5	1.111	0.5556	0.527	0.176	15	0.0625	N.Q.S.
		1.67	A.T.6	1.111	0.5556	0.527	0.176	15	0.0625	N.Q.S.
Ati-Nidra (Excessive)	5	2.2	A.T.1	2	0.2	0.447	0.2	1	> 0.9999	N.S.
		2.2	A.T.2	2	0.2	0.447	0.2	1	> 0.9999	N.S.

and Untimely sleep)		2.2	A.T.3	2	0.2	0.447	0.2	1	> 0.9999	N.S.
		2.2	A.T.4	1.8	0.4	0.548	0.245	3	0.5	N.S.
		2.2	A.T.5	1.6	0.6	0.548	0.245	6	0.25	N.S.
		2.2	A.T.6	1	1.2	0.447	0.2	15	0.0625	N.Q.S.
Ati-Sweda (Excessive sweating)	6	2.17	A.T.1	1.833	0.3333	0.516	0.211	3	0.5	N.S.
		2.17	A.T.2	1.5	0.6667	0.817	0.333	6	0.25	N.S.
		2.17	A.T.3	1.5	0.6667	0.817	0.333	6	0.25	N.S.
		2.17	A.T.4	1.5	0.6667	0.817	0.333	6	0.25	N.S.
		2.17	A.T.5	1.5	0.6667	0.817	0.333	6	0.25	N.S.
		2.17	A.T.6	1.167	1	0.753	0.307	15	0.0625	N.Q.S.
Sweda Daurgandhya (Foul smelling)	6	2.67	A.T.1	2.167	0.5	0.548	0.224	6	0.25	N.S.
		2.67	A.T.2	2	0.6667	0.516	0.211	10	0.125	N.S.
		2.67	A.T.3	1.833	0.8333	0.753	0.307	10	0.125	N.S.
		2.67	A.T.4	1.667	1	0.633	0.258	15	0.0625	N.Q.S.
		2.67	A.T.5	1.5	1.167	0.753	0.307	15	0.0625	N.Q.S.
		2.67	A.T.6	1.167	1.5	1.049	0.428	15	0.0625	N.Q.S.
Weight excess	10	73.6	A.T.1	72.7	0.9	1.101	0.348	2.586	0.0294	S.
		73.6	A.T.2	71.7	1.9	1.595	0.504	3.767	0.0044	V.S.
		73.6	A.T.3	70.2	3.4	2.319	0.733	4.636	0.0012	V.S.
		73.6	A.T.4	68.9	4.7	3.129	0.989	4.750	0.001	V.S.
		73.6	A.T.5	67.3	6.3	3.592	1.136	5.547	0.0004	E.S.
		73.6	A.T.6	66.4	7.2	4.158	1.315	5.476	0.0004	E.S.
Body mass index (BMI)	10	28.7	A.T.1	28.341	0.346	0.426	0.135	2.568	0.0303	S.
		28.7	A.T.2	27.96	0.727	0.609	0.193	3.777	0.0044	V.S.
		28.7	A.T.3	27.362	1.325	0.911	0.288	4.601	0.0013	V.S.
		28.7	A.T.4	26.86	1.827	1.207	0.382	4.785	0.001	E.S.
		28.7	A.T.5	26.231	2.456	1.436	0.454	5.410	0.0004	E.S.
		28.7	A.T.6	25.875	2.812	1.65	0.522	5.391	0.0004	E.S.
Skin fold thickness (Male)	5	53.8	A.T.1	53	0.8	0.837	0.374	2.138	0.0993	N.Q.S.
		53.8	A.T.2	52.2	1.6	1.817	0.812	1.969	0.1202	N.S.
		53.8	A.T.3	49.8	4	2.828	1.265	3.162	0.0341	S.
		53.8	A.T.4	49.2	4.6	3.05	1.364	3.373	0.028	S.
		53.8	A.T.5	47.6	6.2	3.899	1.744	3.556	0.0237	S.
		53.8	A.T.6	46.2	7.6	3.847	1.72	4.417	0.0115	S.
Skin fold thickness (Female)	5	68.2	A.T.1	66.6	1.6	1.517	0.678	2.359	0.0777	N.Q.S.
		68.2	A.T.2	65.2	3	1.581	0.707	4.243	0.0132	S.
		68.2	A.T.3	63.4	4.8	2.49	1.114	4.311	0.0125	S.
		68.2	A.T.4	62.2	6	2.121	0.949	6.325	0.0032	V.S.
		68.2	A.T.5	60.8	7.4	2.881	1.288	5.744	0.0046	V.S.
		68.2	A.T.6	60	8.2	3.271	1.463	5.605	0.005	V.S.
Waist –Hip ratio (Male)	5	1.154	A.T.1	1.138	0.016	0.011	0.005	3.138	0.0349	S.
		1.154	A.T.2	1.11	0.044	0.005	0.002	7.963	< 0.0001	E.S.
		1.154	A.T.3	1.096	0.058	0.02	0.009	6.328	0.0032	V.S.
		1.154	A.T.4	1.082	0.072	0.022	0.01	7.426	0.0018	V.S.
		1.154	A.T.5	1.062	0.092	0.032	0.014	6.441	0.003	V.S.
		1.154	A.T.6	1.042	0.112	0.033	0.015	7.656	0.0016	V.S.
Waist –Hip ratio (Female)	5	0.968	A.T.1	0.958	0.01	0.01	0.004	2.236	0.089	N.Q.S.
		0.968	A.T.2	0.942	0.026	0.019	0.009	2.982	0.0406	S.
		0.968	A.T.3	0.926	0.042	0.026	0.012	3.628	0.0222	S.
		0.968	A.T.4	0.916	0.052	0.023	0.01	5.099	0.007	V.S.
		0.968	A.T.5	0.912	0.056	0.026	0.012	4.802	0.0086	V.S.
		0.968	A.T.6	0.898	0.07	0.026	0.011	6.139	0.0036	V.S.

S. Cholesterol	10	267.8	A.T.1	259.2	8.6	5.892	1.863	4.616	0.0013	V.S.
		267.8	A.T.2	251.9	15.9	6.773	2.142	7.423	< 0.0001	E.S.
		267.8	A.T.3	242.9	24.9	8.621	2.726	9.134	< 0.0001	E.S.
		267.8	A.T.4	235.6	32.2	9.065	2.867	11.233	< 0.0001	E.S.
		267.8	A.T.5	228.7	39.1	10.65	3.368	11.609	< 0.0001	E.S.
		267.8	A.T.6	220.6	47.2	11.82	3.738	12.627	< 0.0001	E.S.
S. Triglyceride	10	197.7	A.T.1	192.6	5.1	2.685	0.849	6.006	< 0.0001	E.S.
		197.7	A.T.2	184.1	13.6	5.06	1.6	8.500	< 0.0001	E.S.
		197.7	A.T.3	177.8	19.9	7.923	2.505	7.943	< 0.0001	E.S.
		197.7	A.T.4	171.8	25.9	10.57	3.341	7.751	< 0.0001	E.S.
		197.7	A.T.5	166.2	31.5	12.43	3.931	8.014	< 0.0001	E.S.
		197.7	A.T.6	164.7	33	12.81	4.05	8.149	< 0.0001	E.S.
H.D.L.	10	37.1	A.T.1	38.1	-1	0.943	0.298	3.354	0.0085	V.S.
		37.1	A.T.2	38.7	-1.6	0.966	0.306	5.237	0.0005	E.S.
		37.1	A.T.3	39.6	-2.5	1.179	0.373	6.708	< 0.0001	E.S.
		37.1	A.T.4	40.7	-3.6	1.713	0.542	6.647	< 0.0001	E.S.
		37.1	A.T.5	42.2	-5.1	1.287	0.407	12.534	< 0.0001	E.S.
		37.1	A.T.6	42.9	-5.8	1.317	0.416	13.931	< 0.0001	E.S.
L.D.L	10	175	A.T.1	169.4	5.6	2.989	0.945	5.925	0.0002	E.S.
		175	A.T.2	165.2	9.8	4.315	1.365	7.181	< 0.0001	E.S.
		175	A.T.3	161.4	13.6	5.641	1.784	7.624	< 0.0001	E.S.
		175	A.T.4	157.3	17.7	7.025	2.221	7.968	< 0.0001	E.S.
		175	A.T.5	151.6	23.4	8.017	2.535	9.23	< 0.0001	E.S.
		175	A.T.6	145.5	29.5	7.502	2.372	12.435	< 0.0001	E.S.

Table 3- Statistical analysis showing effectiveness (only Pathyapathya) in CG

Sign Symptoms &	N	Mean Score		Mean diff.	± S.D.	± S.E.	w-value/ t-value	p - value	Remark	
		B.T.	A.T.							
Chala Sphik Udara Sthana (Pendulous movement)	10	2.4	A.T.1	2.2	0.2	0.422	0.133	3	0.5	N.S.
		2.4	A.T.2	2	0.4	0.516	0.163	10	0.125	N.S.
		2.4	A.T.3	1.8	0.6	0.516	0.163	21	0.0313	S.
		2.4	A.T.4	1.7	0.7	0.675	0.213	21	0.0313	S.
		2.4	A.T.5	1.6	0.8	0.789	0.249	21	0.0313	S.
		2.4	A.T.6	1.6	0.8	0.789	0.249	21	0.0313	S.
Sramaswasa / Kshudraswasa (Exertional dyspnoea)	10	2.2	A.T.1	2.1	0.1	0.316	0.1	1	> 0.9999	N.S.
		2.2	A.T.2	1.9	0.3	0.483	0.153	6	0.25	N.S.
		2.2	A.T.3	1.9	0.3	0.483	0.153	6	0.25	N.S.
		2.2	A.T.4	1.7	0.5	0.527	0.167	15	0.0625	N.Q.S.
		2.2	A.T.5	1.6	0.6	0.516	0.163	21	0.0313	S.
		2.2	A.T.6	1.4	0.8	0.422	0.133	36	0.0078	V.S.
Ati-Pipasa (Excessive thirst)	6	1.33	A.T.1	1.167	0.1667	0.408	0.167	1	> 0.9999	N.S.
		1.33	A.T.2	1	0.3333	0.516	0.211	3	0.5	N.S.
		1.33	A.T.3	0.8333	0.5	0.548	0.224	6	0.25	N.S.
		1.33	A.T.4	0.8333	0.5	0.548	0.224	6	0.25	N.S.
		1.33	A.T.5	0.8333	0.5	0.548	0.224	6	0.25	N.S.
		1.33	A.T.6	0.8333	0.5	0.548	0.224	6	0.25	N.S.
Ati-Kshudha (Excessive hunger)	8	1.63	A.T.1	1.5	0.125	0.354	0.125	1	> 0.9999	N.S.
		1.63	A.T.2	1.375	0.25	0.463	0.164	3	0.5	N.S.
		1.63	A.T.3	1.25	0.375	0.518	0.183	6	0.25	N.S.
		1.63	A.T.4	1.125	0.5	0.535	0.189	10	0.125	N.S.

		1.63	A.T.5	1.125	0.5	0.535	0.189	10	0.125	N.S.
		1.63	A.T.6	1.125	0.5	0.535	0.189	10	0.125	N.S.
Ati-Nidra (Excessive and Untimely sleep)	7	2	A.T.1	1.857	0.1429	0.378	0.143	1	> 0.9999	N.S.
		2	A.T.2	1.857	0.1429	0.378	0.143	1	> 0.9999	N.S.
		2	A.T.3	1.857	0.1429	0.378	0.143	1	> 0.9999	N.S.
		2	A.T.4	1.571	0.4286	0.535	0.202	6	0.125	N.S.
		2	A.T.5	1.143	0.8571	0.69	0.261	15	0.0625	N.Q.S.
		2	A.T.6	1	1	0.577	0.218	21	0.0313	S.
Ati-Sweda (Excessive sweating)	7	2.14	A.T.1	1.857	0.2857	0.488	0.184	3	0.5	N.S.
		2.14	A.T.2	1.714	0.4286	0.535	0.202	6	0.25	N.S.
		2.14	A.T.3	1.714	0.4286	0.535	0.202	6	0.25	N.S.
		2.14	A.T.4	1.714	0.4286	0.535	0.202	6	0.25	N.S.
		2.14	A.T.5	1.714	0.4286	0.535	0.202	6	0.25	N.S.
		2.14	A.T.6	1.286	0.8571	0.69	0.261	15	0.0625	N.Q.S.
Sweda Daugandhya (Foul smelling)	7	2.43	A.T.1	2.143	0.2857	0.488	0.184	3	0.5	N.S.
		2.43	A.T.2	2	0.4286	0.535	0.202	6	0.25	N.S.
		2.43	A.T.3	1.857	0.5714	0.535	0.202	10	0.125	N.S.
		2.43	A.T.4	1.714	0.7143	0.488	0.184	15	0.0625	N.Q.S.
		2.43	A.T.5	1.571	0.8571	0.69	0.261	15	0.0625	N.Q.S.
		2.43	A.T.6	1.143	1.286	0.488	0.184	28	0.0156	S.
Weight excess	in 10	74.4	A.T.1	74.2	0.2	0.422	0.133	1.500	0.1679	N.S.
		74.4	A.T.2	73.7	0.7	1.252	0.396	1.769	0.1108	N.S.
		74.4	A.T.3	72.6	1.8	1.619	0.512	3.515	0.0066	V.S.
		74.4	A.T.4	71	3.4	2.366	0.748	4.543	0.0014	V.S.
		74.4	A.T.5	70.3	4.1	2.644	0.836	4.904	0.0008	E.S.
		74.4	A.T.6	69.4	5	2.828	0.894	5.590	0.0003	E.S.
Body mass index (BMI)	10	28.6	A.T.1	28.563	0.077	0.163	0.051	1.499	0.1682	N.S.
		28.6	A.T.2	28.379	0.261	0.461	0.146	1.789	0.1072	N.S.
		28.6	A.T.3	27.97	0.67	0.602	0.19	3.518	0.0065	V.S.
		28.6	A.T.4	27.372	1.268	0.82	0.259	4.892	0.0009	E.S.
		28.6	A.T.5	27.109	1.531	0.902	0.285	5.370	0.0005	E.S.
		28.6	A.T.6	26.764	1.876	0.95	0.3	6.244	0.0002	E.S.
Skin fold thickness (Male)	6	55.7	A.T.1	54.833	0.8333	0.983	0.401	2.076	0.0925	N.Q.S.
		55.7	A.T.2	53.333	2.333	2.251	0.919	2.539	0.0519	N.Q.S.
		55.7	A.T.3	52.167	3.5	2.588	1.057	3.312	0.0212	S.
		55.7	A.T.4	51.833	3.833	2.483	1.014	3.781	0.0129	S.
		55.7	A.T.5	50.5	5.167	2.483	1.014	5.096	0.0038	V.S.
		55.7	A.T.6	50.167	5.5	2.739	1.118	4.919	0.0044	V.S.
Skin fold thickness (Female)	4	66.5	A.T.1	64.25	2.25	1.708	0.854	2.635	0.078	N.Q.S.
		66.5	A.T.2	63.25	3.25	0.957	0.479	6.789	0.0065	V.S.
		66.5	A.T.3	62.5	4	1.414	0.707	5.657	0.0109	S.
		66.5	A.T.4	62	4.5	2.38	1.19	3.781	0.0324	S.
		66.5	A.T.5	60.75	5.75	2.754	1.377	4.176	0.025	S.
		66.5	A.T.6	59.75	6.75	2.986	1.493	4.521	0.0202	S.
Waist–Hip ratio (Male)	6	1.123	A.T.1	1.118	0.005	0.008	0.003	1.464	0.2031	N.S.
		1.123	A.T.2	1.113	0.01	0.013	0.005	1.936	0.1106	N.S.
		1.123	A.T.3	1.075	0.0483	0.013	0.005	8.907	0.0003	E.S.
		1.123	A.T.4	1.068	0.055	0.012	0.005	11	0.0001	E.S.
		1.123	A.T.5	1.058	0.065	0.023	0.01	6.789	0.0011	V.S.
		1.123	A.T.6	1.037	0.0867	0.032	0.013	6.625	0.0012	V.S.
Waist–Hip	4	0.95	A.T.1	0.9475	0.0025	0.005	0.003	1	0.391	N.S.

ratio (Female)		0.95	A.T.2	0.945	0.005	0.006	0.003	1.732	0.1817	N.S.
		0.95	A.T.3	0.9225	0.0275	0.013	0.0063	4.371	0.0029	S.
		0.95	A.T.4	0.915	0.035	0.019	0.01	3.656	0.0354	S.
		0.95	A.T.5	0.905	0.045	0.024	0.012	3.781	0.0324	S.
		0.95	A.T.6	0.8875	0.0625	0.029	0.014	4.352	0.0224	S.
S. Cholesterol	10	267.2	A.T.1	256.8	10.4	5.641	1.784	5.830	0.0002	E.S.
		267.2	A.T.2	250.2	17	7.674	2.427	7.005	< 0.0001	E.S.
		267.2	A.T.3	243	24.2	12.7	4.016	6.026	0.0002	E.S.
		267.2	A.T.4	233.2	34	13.89	4.392	7.742	< 0.0001	E.S.
		267.2	A.T.5	227	40.2	15.22	4.812	8.355	< 0.0001	E.S.
		267.2	A.T.6	223	44.2	16.15	5.107	8.654	< 0.0001	E.S.
S. Triglyceride	10	205	A.T.1	200	5	2.16	0.683	7.319	< 0.0001	E.S.
		205	A.T.2	194	11	4.447	1.406	7.822	< 0.0001	E.S.
		205	A.T.3	188.6	16.4	6.31	1.996	8.218	< 0.0001	E.S.
		205	A.T.4	184.2	20.8	6.925	2.19	9.498	< 0.0001	E.S.
		205	A.T.5	180.6	24.4	8.449	2.672	9.133	< 0.0001	E.S.
		205	A.T.6	176.2	28.8	10.16	3.214	8.961	< 0.0001	E.S.
H.D.L.	10	37.5	A.T.1	37.9	-0.4	0.699	0.221	1.809	0.1039	N.S.
		37.5	A.T.2	38.9	-1.4	0.699	0.221	6.332	0.0001	E.S.
		37.5	A.T.3	40.1	-2.6	1.35	0.427	6.091	0.0002	E.S.
		37.5	A.T.4	41	-3.5	1.179	0.373	9.391	< 0.0001	E.S.
		37.5	A.T.5	41.7	-4.2	1.619	0.512	8.202	< 0.0001	E.S.
		37.5	A.T.6	43.1	-5.6	1.43	0.452	12.385	< 0.0001	E.S.
L.D.L	10	171.7	A.T.1	166.5	5.2	1.989	0.629	8.268	< 0.0001	E.S.
		171.7	A.T.2	159.9	11.8	4.849	1.533	7.696	< 0.0001	E.S.
		171.7	A.T.3	155	16.7	4.644	1.469	11.372	< 0.0001	E.S.
		171.7	A.T.4	151	20.7	6.584	2.082	9.943	< 0.0001	E.S.
		171.7	A.T.5	148.7	23	8.097	2.56	8.983	< 0.0001	E.S.
		171.7	A.T.6	146	25.7	9.696	3.066	8.382	< 0.0001	E.S.

❖ **Response** - Response has been defined in lieu of improvement in the sign & symptoms. After 90 days of treatment (AT6) in Chala Sphik Udara Sthana (Pendulous movement), the % of improvement was 46.15% in TG I, 36% in TG II and 33.33% in CG. In Sramaswasa/Kshudraswasa (Exertional dyspnoea), the % of improvement was 45.83% in TG I, 40.00% in TG II and 36.36% in CG. In Ati-Pipasa (Excessive thirst), the % of improvement was 53.85% in TG I, 42.86% in TG II and 37.51% in CG. In Ati-Kshudha (Excessive hunger), the % of improvement was 41.18% in TG I, 33.33% in TG II and 30.77% in CG. In Ati-Nidra (Excessive and Untimely sleep), the % of improvement shows 55.56% in TG I, 54.55% in TG II and 50.00% in CG. In Ati-Sweda (Excessive sweating), the % of improvement shows 50.00% in TG I, 46.15% in TG II and 40.00% in CG. In Sweda Dargandhya (Foul smelling), the % of improvement shows 60.00% in TG I, 56.24% in TG II and 52.94% in CG. In Weight in excess, the % of improvement shows 13.81% in TG I, 9.78% in TG II and 6.72% in CG. In Body mass index

(BMI), the % of improvement shows 13.79% in TG I, 9.80% in TG II and 6.55% in CG. In Skin fold thickness (male), the % of improvement shows 18.86% in TG I, 14.13% in TG II and 9.88% in CG. In Skin fold thickness (female), the % of improvement shows 13.60% in TG I, 12.02% in TG II and 10.15% in CG. In Waist-Hip ratio (male), the % of improvement shows 11.33% in TG I, 9.71% in TG II and 7.72% in CG. In Waist-Hip ratio (female), the % of improvement shows 8.62% in TG I, 7.23% in TG II and 6.58% in CG. In S. Cholesterol, the % of improvement shows 19.44% in TG I, 17.63% in TG II and 16.54% in CG. In S. Triglyceride, the % of improvement shows 19.64% in TG I, 16.69% in TG II and 14.05% in CG. In H.D.L., the % of improvement shows 16.71% in TG I, 15.63% in TG II and 14.93% in CG. In L.D.L., the % of improvement shows 18.35% in TG I, 16.86% in TG II and 14.97% in CG.

❖ **Comparison of effects on different parameters of both drugs** - Comparison between TG I vs. TG II vs. CG shows that TG I is more

effective than TG II and CG where as TG II is more effective than CG.

Table 4- Overall assessment (clinical results)

Clinical assessment of result	TG I		TG II		CG	
	f	%	f	%	f	%
Maximum improvement	0	0%	0	0%	0	0%
Moderate improvement	1	10%	0	0%	0	0%
Mild improvement	9	90%	7	70%	5	50%
Unsatisfactory improvement	0	0%	3	30%	5	50%

IV. CONCLUSION-

In this randomized open clinical study, considering the sign and symptoms, all patients attained improvement, which was evaluated in various percentages against different objectives. The clinical effect of therapy shows that in TG I, 1 (10%) patient was get moderate improvement while 9 (90%) patients were get mild improvement. In TG II, 7 (70%) patients were get mild improvement and 3 (30%) patients were get unsatisfactory improvement. In CG, 5 (50%) patients each were get mild improvement and unsatisfactory improvement. The comparative effect between all groups shows that TG I (Triphala Churna with Pathyapathya) is more effective than TG II (Trikatu Churna with Pathyapathya) and CG (only Pathyapathya) where as TG II is more effective than CG. So, along with Pathyapathya, medications like Triphala Churna may add in the management of Sthoulya (Obesity).

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