



A Comparative Clinical Study of The Efficacy Of Amritadya Guggulu With Triphala Kwatha And With Madhudak In The Management Of Medoroga (Obesity)

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ABSTRACT –

Obesity is currently an increasingly prevalent metabolic disorder affecting more than 1.9 billion adults globally in 2014. In *Ayurveda*, *Medoroga* or *Sthaulya* (obesity) is considered as a *medo doshaja vyadhi* and also one among the *kaphaja nanatmaja vyadhis*. *Kapha* and *meda* are having *ashrayashrayi bhava* and *Amritadya Guggulu* is having *Kapha* and *Medanashaka* Properties. Hence the present study was under taken to assess the effect of this drug. The study was a prospective comparative Clinical Trial of two groups each of 20 patients. All the 40 patients of obesity taken from OPD section of Desh Bhagat Ayurvedic Hospital, Mandi Gobindgarh fulfilling the inclusion and exclusion criteria were included in the trial. They were divided into two groups randomly. The patients of Group A received *Amritadya Guggulu* 1 gm. BD with lukewarm water with honey for 60 days and patients of Group B received *Amritadya Guggulu* with *Triphala Kwatha* mixed with honey for 60 days.

In Group A, among 20 patients 2.5% patients showed marked response, 45% patients showed moderate response and 51% patients showed mild response. In Group B among 20 patients, 5% patients showed good response, 59.4 % patients showed moderate response and 35.6% has shown highly significance. In this present study, *Amritadya Guggulu* with two different *anupaans* was tried and in both groups , significant results were found but more significant results were found in Group B.

Key words: *Sthaulya*, BMI, obesity, *meda doshaja*, *kaphaja nanatmaja vyadhi*, *Amritadya Guggulu*.

INTRODUCTION –

Ayurveda defines health as a state of equilibrium of Dosha, Dhatu, Agni & Mala and tranquillity of the Soul, Sense organs & the mind; not mere absence of disease. Imbalance in dosha dhatu poshana kriya lead to risk of *Medoroga* (obesity) & other Metabolic diseases. Obesity can no longer be regarded simply as cosmetic problem affecting certain individuals but must be considered an epidemic requiring effective measures for its prevention and management.

Medoroga has become an increasing health concern internationally. It is one among the major diseases of Modern era. In Modern era with continuous changing life styles and environment, changed diet habits, man has become the victim of many disease and Obesity is one of them. In *Ayurveda*, *medoroga* is considered as *Santarpanjanya vyadhi* (over nutritional) due to excessive accumulation of *Meda* (depot fat) in body. Acharya Charaka had given the appropriate and precise definition of *Sthaulya*¹. Acharya Charaka mentioned that a person in whom excessive and abnormal increase of *Medodhatu* along with *Mamsadhatu* is found which results into pendulous appearance of buttocks, belly and breasts and whose increase bulk is not matched by a corresponding increase in energy is called *sthulapurusha*.

According to W.H.O. overweight and obesity are the fifth leading risk for Global death.² In 2008, more than 1.4 billion adults were overweight of these over 200 million men and nearly 300 million women were obese.³ Worldwide obesity has nearly doubled since 1980.

According to a study published in the noted Journal Lancet, India is the 3rd most obese country in the world. Obesity not only reduces the life span of an individual but also leads to life threatening complications like stroke and Ischemic heart disease (IHD). It also poses a serious risk for the development of diabetes

mellitus, hypertension, reproductive disorders, pulmonary diseases, gall stones, renal failure, muscular skeletal disorders especially osteoarthritis and certain forms of cancer.⁴

Many remedies have been put forwarded till now like Surgical lipisection, lipid lowering medicines etc. but they have so many complications, so it is necessary to implement the *chikitsa sutras* mentioned by our *Acharyas* in reducing the *Sthaulya/medovridhi*. So that one can lead a happy life without misery. In Ayurveda classics so many treatments are said for this *Sthaulya*. In this context our aim is to reduce excess weight along with *doshashaman* and *strotoshodhan*. In present study an attempt is made to find suitable remedy for *Sthaulya* as mentioned by *Chakradatta*⁵ i.e. *Amritadya Guggulu*. It was given to the patients with two different *Anupaans*; with honey mixed lukewarm water & with *Triphala Kwatha* mixed with honey mentioned by *Yogaratanakara*⁶. Both *Amritadya Guggulu* and *Triphala Kwatha* are having *Kapha* and *Medanashaka* properties. In this clinical trial, patients were divided into two groups. The duration of trial was 60 days and follow up duration was 15 days. After completing the trial the results of both groups were statistically analysed.

AIMS AND OBJECTIVES –

To assess the effect of *Amritadya Guggulu* with two different *anupaans*

- To compare the result of both the groups.

MATERIAL AND METHODS –

Material required –

Amritadya Guggulu and *Triphala Kwatha* –

Table no.1 – Showing ingredients of *Amritadya Guggulu* –

Sr.No.	Drug	Latin Name	Part Used	Quantity
	<u>Amrita</u>	<u>Tinospora cordifolia</u>	Stem	1 part
	<u>Ela</u>	<u>Elettaria cardamomum</u>	Seed	2 part
	<u>Vaividanga</u>	<u>Embelia ribes</u>	Fruit	3 part
	<u>Kutaja</u>	<u>Holarrhena antidysenterica</u>	Bark	4 part
	<u>Vibhitaki</u>	<u>Terminalia bellirica</u>	Fruit	5 part
	<u>Haritaki</u>	<u>Terminalia chebula</u>	Fruit	6 part
	<u>Amalaki</u>	<u>Embelia officinalis</u>	Fruit	7 part
	<u>Shudh Guggulu</u>	<u>Commiphora mukul</u>	Gum resin	8 part

Table no.2 - Showing ingredients of *Triphala Kwatha* –

	Haritaki	<u>Terminalia chebula</u>	Fruit	1 part
	Vibhitaki	<u>Terminalia bellirica</u>	Fruit	1 part
	Amlaki	<u>Embelia officinalis</u>	Fruit	1 part

Method of preparation of *Amritadya Guggulu* –

Purification of *Ashudh Guggulu* was done with *Dola Yantra Swedan vidhi* with the help of *Triphala Kwatha*. *Triphala Kwatha* was made by making coarse powder of *Haritaki*, *Vibhitaki* and *Amlaki* and then add 16 parts of water, boiled and reduced to 1/4th part, filtered and used. Fine coarse powder of above seven ingredients was made and mixed with *shudhh Guggulu*. And then *Amritadya Guggulu* vaties of 375 mg. were made.⁷

Sample Size:-

Total number of patients taken for study was 40 excluding dropouts. The patients selected for the study was divided into two groups i.e. Group A and Group B. Each consisting of 20 patients each.

Group A: 20 patients of obesity was given drug “*Amritadya Guggulu*” in the dose of 1gm. two times a day with honey mixed lukewarm water along with *pathya ahara-vihara* for 60 days.

Group B: 20 patients was given” *Amritadya Guggulu*” same as in first group with *Triphala kwatha* mixed with honey along with *pathya ahara-vihara* for 60 days

Study Design: - Prospective, Randomized and Parallel

Ethical clearance :-

The study was approved by IEC (Institutional Ethics Committee) under ref. no. DBU/PGSAR/2403A-2014-15 dated 24/03/2014.

Criteria for the selection of patients:

Patients fulfilling the criteria of *Sthaulya* (obesity) from OPD & IPD of Kaya Chikitsa Dept. & cases referred by other departments of DBAC&H, Mandi Gobindgarh; were selected randomly with coin toss method irrespective of race, cast, sex, religion etc.

Inclusion criteria:-

1. Patients aged: 16 to 60 yrs.
2. Sex: either sex.
3. Patients suffering from obesity due to acquired reasons.
4. Patients having –

BMI - 25-35 Kg/meter²

Waist / hip ratio > 0.8

Skin fold thickness at triceps –14 to 28 mm

Exclusion criteria:

1. Patients suffering from obesity due to hereditary indisposition
2. Patients suffering from drug induced obesity.
3. Obesity and dyslipidemia due to injudicious use of drugs such as diuretics, corticosteroids etc.
4. Increased abdominal girth due to other disease like ascites.
5. Having hormonal disorders like diabetes mellitus.
6. Pregnant and lactating women.

Investigations Required:-

Blood - Hb_{gm}%, T.L.C., D.L.C., E.S.R., F.B.S. ,LFT,RFT

Bio-Chemistry -S. Uric acid, S. Cholesterol, S. Low density lipoprotein (S.LDL) , S. High density lipoprotein (S.HDL) , S. Very low density lipoprotein (S.VLDL)

Urine Examination – Routine and Microscopic examination of urine.

Diagnostic Criteria of Assessment –

Patients were diagnosed on the basis of performa prepared with signs and symptoms of *Sthaulya* in Ayurvedic classics. The results were assessed on the basis of improvement recorded, in clinical findings and laboratory investigations. Changes observed in signs and symptoms were assessed by adopting suitable scoring method.

Subjective criteria –

Ati Kshudha, Ati Pipasa, Ati Nidra, Ati Sweda, Alasya, Kshudra shwasa, Dourbalya, Chala sphik udara stana

Scoring was given according to the severity of symptoms.

- Grade 0 - Absence of symptoms
- Grade 1 - Mild degree of symptoms
- Grade 2 - Moderate degree of symptoms
- Grade 3 - Severe degree of symptoms

Objective criteria :-

A. Weight –Weight measured using only the same standard electronic weighing machine.

B. BMI :The body mass index (BMI), or Quetelet index, 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. B.M.I. is the actual body weight in Kg.divided by square of the height in meter (Kg /met²).⁸

C. The waist circumference is measured half way between the superior iliac crest and the rib cage in the mid axillary line; whereas the hip circumference is measured one third of the distance between the superior iliac spine and the patella.

D. Waist Hip Ratio

E. Skin Fold Thickness at Tricep

Overall assessment -

Marked Response	=	75-100 %
Moderate Response	=	50-74 %
Poor Response	=	26-49 %
No Response	=	0-25 %

RESULTS AND DISCUSSION :-

Overall from the study conducted on 40-patients for duration of 60 days, Following observation was made before and after treatment in subjective and objective parameters in both groups.

Table No.3:- Showing effect on Subjective parameters in patients of Group A –

Subjective parameter	MEAN			Change In %	± SD	± SE	t-value	p-value	Remarks
	BT	AT	Diff.						
Ati kshudha	2.15	1.05	1.1	51.1	0.45	0.11	10.0	<0.05	S.
Ati pipasa	2.45	1.25	1.2	49.1	0.49	0.11	10.9	<0.001	H.S.
Daurbalya	2.75	1.25	1.5	54.4	0.65	0.11	13.6	<0.001	H.S.
Swedadhikya	2.7	1.35	1.35	50.0	0.41	0.12	11.25	<0.001	H.S.
Ati Nidra	2.5	1.15	1.35	54.1	0.44	0.13	10.18	<0.001	H.S.
Alasya	2.35	1.15	1.2	51.8	0.48	0.13	9.23	<0.001	H.S.
Kshudra shwas	2.05	1.0	1.05	51.6	0.52	0.10	10.5	<0.001	H.S.
Chala sphik udara stan	2.35	1.1	1.25	53.1	0.48	0.121	10.4	<0.05	S.

Table No. 4 :- Showing effect on Objective parameters in patients of Group A

Objective Parameter	Mean	Std. Dev	Std. Err. Mean	t value	P-value
WeightBT-WeightAT	7.250	1.446	0.323	22.416	0.396 x 10 ⁻¹⁴
BMIBT-BMIAT	2.555	0.565	0.126	20.217	0.261 x 10 ⁻¹³
WaistBT-WaistAT	1.600	0.820	0.183	8.718	0.457 x 10 ⁻⁰⁷
Skin Fold thicknessBT-Skin Fold thicknessAT	2.085	0.850	0.190	10.963	0.117 x 10 ⁻⁰⁸
Waist Hip RatioBT-Waist Hip RatioAT	0.042	0.018	0.004	10.140	0.420 x 10 ⁻⁰⁸

Table No. 5 :- Showing effect on Subjective parameters of patients of Group B

Subjective parameter	MEAN			Change In %	± SD	± SE	t-value	p-value	Remarks
	BT	AT	Diff.						
Ati kshudha	2.35	0.85	1.5	63.8	0.41	0.12	12.5	<0.001	H.S.
Ati pipasa	2.35	0.95	1.4	59.6	0.64	0.11	12.72	<0.001	H.S.
Daurbalya	2.25	0.8	1.45	64.4	0.65	0.10	14.5	<0.001	H.S.
Swedadhikya	2.95	1.35	1.6	54.3	0.52	0.13	12.3	<0.001	H.S.
Ati Nidra	1.85	0.8	1.05	56.7	0.59	0.11	9.53	<0.001	H.S.
Alasya	2.15	0.7	1.45	67.4	0.61	0.12	12.07	<0.001	H.S.
Kshudra shwas	2.3	0.9	1.4	60.8	0.54	0.10	14.0	<0.001	H.S.
Chala sphik udara stan	2.05	0.9	1.15	56.1	0.49	0.10	11.5	<0.001	H.S.

Table No.6:- Showing effect on Objective parameters of patients of Group B

Objective Clinical Parameter	Mean	Std. Dev	Std. Err. Mean	t value	P-value
WeightBT-WeightAT	9.550	1.395	0.312	30.626	0.123 x 10 ⁻¹⁶
BMIBT-BMIAT	3.490	0.762	0.170	20.477	0.207 x 10 ⁻¹³
WaistBT-WaistAT	2.750	0.638	0.142	19.256	0.633 x 10 ⁻¹³
Skin Fold thicknessBT-Skin Fold thicknessAT	2.310	0.567	0.126	18.205	0.174 x 10 ⁻¹²
Waist Hip RatioBT-Waist Hip RatioAT	0.054	0.040	0.009	5.968	0.000009

In patients of Group A, 51.1% relief was assessed in *Ati Kshudha* at $p < 0.05$ and in Group B, 63.8 % relief was assessed at $p < 0.001$.

In *Ati Pipasa*, 49.1% relief was assessed in patients of group A at $p < 0.001$ and 59.6% relief was assessed in Group B at $p < 0.001$.

In *Daurbalya*, 54.4 % relief was assessed in patients of group A at $p < 0.001$ and 64.4 % relief was assessed in patients of group B at $p < 0.001$.

In *Swedadhikya*, 50 % relief was assessed in patients of group A at $p < 0.001$ and 54.3 % relief was assessed in patients of group B at $p < 0.001$.

In *Ati nidra*, 54.1 % relief was assessed in patients of group A at $p < 0.001$ and 56.7 % relief was assessed in patients of group B at $p < 0.001$.

In *Alasya*, 51.8 % relief was assessed in patients of group A at $p < 0.001$ and 67.4 % relief was assessed in patients of group B at $p < 0.001$.

In *Kshudra shwas*, 51.6 % relief was assessed in patients of group A at $p < 0.001$ and 60.8 % relief was assessed in patients of group B at $p < 0.001$.

In *Chalaspikaudarastana*, 53.1 % relief was assessed in patients of group A at $p < 0.001$ and 56.1 % relief was assessed in patients of group B at $p < 0.001$.

In Group A, mean difference in weight was 7.25 and in Group B was 9.550 at $p < 0.001$.

In BMI, the mean difference in Group A was 2.6 and in Group B was 3.490 at $p < 0.001$.

In Waist hip ratio, the mean difference in Group A was 0.042 and in Group B was 0.054 at $p < 0.001$ and

In skin fold thickness, the mean difference in Group A was 2.09 and in Group B was 2.310 at $p < 0.001$.

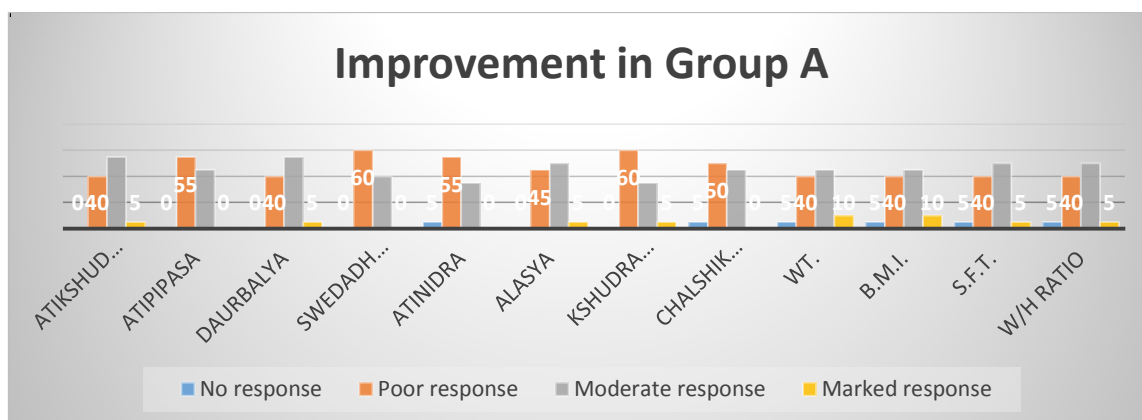
In both Groups, among the lipid profile serum cholesterol level decreases after treatment. In Group A Serum Cholesterol level decreases with mean of 1.250 and t value 6.140 more but serum Triglyceride shows less significance. S.LDL level decreases with mean of 1.40 and t value 2.864 .It shows significant effect ($p < 0.05$). In Group B , Serum Cholesterol level decreases with mean of 2.3 and t value 4.124.It shows more highly significant ($p < 0.001$) than Group A but serum Triglyceride shows less significance. S.LDL level decreases with mean of 1.75 and t value 6.254.It shows highly significant ($p < 0.001$) than Group A. Serum VLDL value decreases in both groups with $p < 0.05$ and Serum HDL level slightly increase but it is not significant ($p > 0.05$)

Group A improvement –

Table No.7 – Showing improvement in Group A –

Subjective and objective criteria	No Response(%)	Poor Response(%)	Moderate Response(%)	Marked Response(%)
Atikshudha	0	40	55	5
Atipipasa	0	55	45	0
Daurbalya	0	40	55	5
Swedaadhikya	5	55	40	0
Atinidra	5	55	35	0
Alasya	0	45	50	5
Kshudra shwasa	0	60	35	5
Chala Sphikaudarastana	5	50	45	0
Wt.	5	40	45	10
B.M.I.	5	40	45	10
S.F.T.	5	40	50	5
W/H Ratio	5	40	50	5

Graph no.1:- Showing improvement in Group A

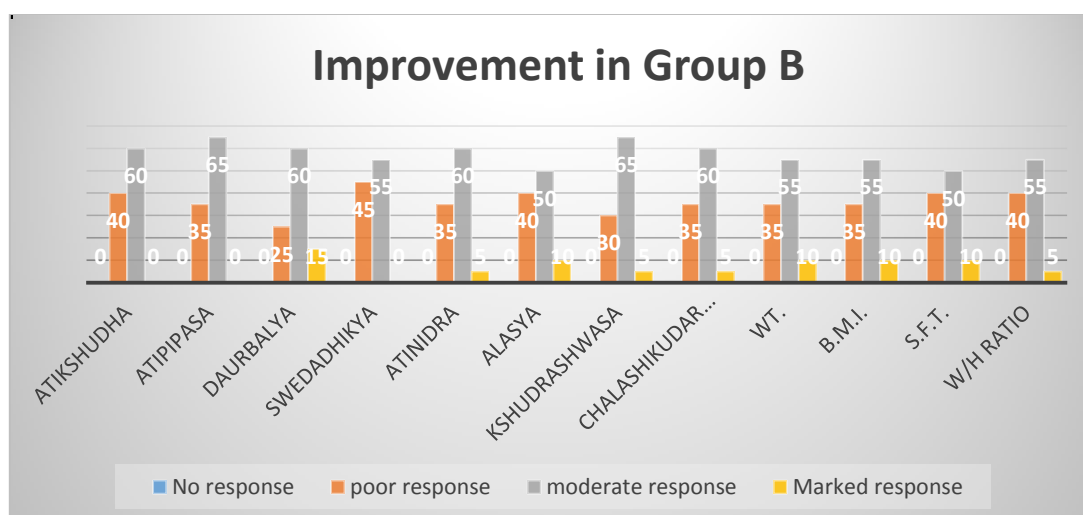


Group B -

Table No. 8 :- Showing Improvement in Group B

Subjective & objective Improvement	No Response (%)	Poor Response (%)	Moderate Response (%)	Marked Response (%)
Atikshudha	0	40	60	0
Atipipasa	0	35	65	0
Daurbalya	0	25	60	15
Swedaadhikya	0	45	55	0
Atinidra	0	35	60	5
Alasya	0	40	50	10
Kshudra shwasa	0	30	65	5
Chalaspikaudarastana	0	35	60	5
Wt.	0	35	55	10
B.M.I.	0	35	55	10
S.F.T.	0	40	50	10
W/H ratio	0	40	55	5

Graph no.2:- Showing improvement in Group B



Overall assessment -

In the overall assessment in Group A , among 20 patients 2.5% patients showed good response i.e. above 70% relief in signs and symptoms, 45% patients showed moderate response i.e. 50-70% relief in signs and symptoms and 51% patients showed mild response i.e. below 30-50% relief in signs and symptoms. The statistical evaluation showed all parameters, both subjective and objective has shown highly significance.

In Group B among 20 patients, 5% patients showed good response i.e. above 70% relief in signs and symptoms, 59.4 % patients showed moderate response i.e. 50-70% relief in signs and symptoms and 35.6% patients showed mild response i.e. below 30-50% relief in signs and symptoms. Here by, from the above-mentioned results, it is obvious that *Amritadya Guggulu* with *Triphala Kwatha* is more effective in the management of *Medoroga* than *Amritadya Guggulu* with lukewarm water.

Mode of Action of Trial Drug –

Amritadya Guggulu contain drugs which are mainly *ushna viryatmaka* having *katu, tikta rasa* and *laghu, Ruksha* and *ushna guna* which possess *lekhana , bhedan karma*. By virtue of these properties this *yoga* is *Kapha-vaat shamaka* as well as *medoghana*. Most of the drugs i.e. *guduchi, amalaki, haritaki, and ela* exhibit *deepana guna* due to *pradhanata* of *vayu and agni mahabhoota*. As *agnimandya* is one of the factor in causation of disease, it corrects abnormality in *jatharagni*

Anupaana of *Triphala Kwath* with honey potentiate the action of this drug by its laxative effect. *Triphala* is one of the best natural colon cleanser. It stimulates the metabolism in our body and encourage the digestive system to work efficiently so that the fat taken in can be consumed in proper manner and no necessary storage of fat can take place in the body, it also purify blood and improve blood circulation, and increase immunity.

Antiobesity effect of Triphala⁹ –

Triphala has been reported to contain gallic acid. Gallic acid is a widely occurring phenolic compound of plant origin. Gallic acid is selected as a bioactive marker due to its easy availability, common presence in these fruits and as anti obesity property. Gallic acid is maximum in *amalaki* (*emblica officinalis*).

Medoghana effect of Guggulu¹⁰ -

The major ingredient of the trial drug is *Guggulu*. Guggulsterone content of *Guggul* have lipid-lowering effect. Guggulsterone inhibit the synthesis of cholesterol in the body while also speeding up the degradation and excretion of cholesterol.

To do this, the active phytochemicals in guggul inhibit the farnesoid X receptor which is a bile acid receptor needed for the controlling the levels of cholesterol in the body. More specifically, *Guggulu* reduces the production of cholesterol in the liver, and Guggulsterone can block the oxidation of LDL. Instead, guggulu enhances the activities of receptors that bind LDL in the liver and, therefore, increases the rate at which LDL is broken down into simpler and safer compounds.

CONCLUSION –

Treatment modality *Amritadya Guggulu* with *Triphala Kwatha* shows better efficacy in reliving subjective features as well as objective features than *Amritadya Guggulu* with lukewarm water. *Karshana* and *lekhana* property of this medication probably responsible for the *karshana* of *medadhatu*, leading to *srotoshodhana* thus reducing the *meda*.

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