CLINICAL STUDY

Clinical Evaluation of Hypolipidaemic Activities of Certain Herbo-Mineral Drugs with special reference to Obesity

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ABSTRACT :

Sthaulya Roga contributes too much morbidity in the patients and it has been named the mother of Diabetes, Hypertension, Cerebro-vascular disease, Joint-disorders, Hyperlipidaemias & other problems. Sthaulya Roga strikingly resembles with disease entity termed as obesity in Modern system of medicine. The basic principles of treatment of Sthaulya Roga (Obesity) as described in Ayurvedic classics & modern texts of medicine are Nidana parivarjana & Apatarpana cikitsa in the form of consumption of low caloric diet and increase in exercise. In this context, Sodhana cikitsa in the form of Lekhana Basti & Samana cikitsa in the form of Medohara Bati have been used in the present trial as the remedies for the management of Sthaulya (Obesity). Diet & modified life styles were also advised to the patients of Sthaulya Roga for correction of their body weight & Lipid Profile.

The study was conducted in 45 clinically diagnosed patients of Obesity with an objective of clinical evaluation of Hypolipdaemic effect of Medohara Bati & Lekhana Basti (Both Kalpita yoga) on the basis of various scientific parameters.

It was observed that the patients treated with trial drugs separately and together showed statistcally highly significant reduction in their body weight & correction in Lipid profile. The percentage of improvement was minimum in MedoharaBati treated group & maximum in mixed group. No side/toxic effects were noted in any of the patients during the trial period.

Key Words : Sthaulya, Obesity, meda, Lipid profile, BMI, Basti

INTRODCTION

The Lipids, as described in modern science possess properties which closely resembe that of "Sneha Dravayas" i.e. Meda; Vasa & Majja etc. Any increase in their levels above their physiological range in the body are capable of producing various lipid disoders in human body. In Ayurvedic classics, in reference to "Sthaulya Roga", two types of Meda (fat) are described viz.

1. **Baddha Meda**—The fat which is not mobile and is stored in the form of fat at various places [fat depots/muscles in the body].
2. **Abaddha Meda**—The fat which is mobile & circulates in the body along with blood in the form of lipids [Cholesterol,Triglycerides, LDC, HDL and VLDL etc.].

Abaddha Meda is stored as fat [Baddha meda] in the body in the form of serum triglycerdies in adipose tissues, resulting in accumulation of more adipose tissue & increased adiposity in the body whichis termed as Sthaulya (Obesity).

The basic principlesof treatement for Sthaulya Roga (Obesity) can be categorized in three groups :

1. Nidana Parivarjana (Avoidance of causative factors)
2. General principlesof management, which include
   - A. Apatarpana cikitsa
   - B. Sodhana cikitsa
   - C. Samana cikitsa
3. Pathya & Apathya (Modified Diet & Life Style)

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AIMS & OBJECTIVES

The main objective was to undertake clinical and laboratory evaluation of Hypolipaemic effects of certain Herbo-mineral drugs inthe form of "Medohara Bati" & "Lekhana Basti" in a series of patients of Sthaulya Roga (Obesity)

MATERIALS & METHODS

1. Selection of Drugs

"Medohara Bati" & "Lekhana Basti" possess the properties like Dipana, Pacana, Chedana, Medohara and also possess the properties of pacification of Kapha & Vata dosa. Thus the selection of drugs aimed to achieve control over the aetiological factors & Samrapti Vighatama of Sthaulya Roga (Obesity).

Method of Preparation of Medohara Bati

All ingredients of Medohara Bati were taken in equal quantity and were powdered . 16 times water was added and boiled till the mixture remained to 1/8th. This decoction was filtered and reminant of drugs were removed. Then decoction was boiled again till it was converted into Ghana Satva form. Then pure Guggula and Rasanjana were added to the Ghana Satva and mild heat was applied at the time of preparation. Lastly Bhasma [1/4th part] was added to this Ghana Satva and Bhavana of Gomutra was given to the Ghana Satva. Mixture of the whole drug was kept in electric oven for drying. Finally tablets of 500 mg. in weight were prepared. This drug was prepared at the pharmacy of N.I.A. Jaipur.

Table 1 : Contents of Medohara Bati

	Drug.	Botanical Name		Qty.
1.	Vidanaga	Emblia ribes	-	1 Part
2.	Mustaka	Cyprus rotundus	-	1 Part
3.	Haritaki	Terminalia chebula	-	1 Part
4.	Amalaki	Embelica belerica	-	1 Part
5.	Vibhitaki	Terminalia belerica	-	1 Part
6.	Pippali	Piper longum	-	1 Part
7.	Kutha	Saussurea lappa	-	1 Part
8.	Sunthi	Zingiber officinale	-	1 Part
9.	Kutaki	Picrorrhira kurroe	-	1 Part
10.	Purana Guggulu	Commifera mukul	-	1 Part
11.	Apamarga Tandula	Achyranthus aspera	-	1 Part
12.	Basanjana	Baberis aristata	-	1 Part
13.	Bilva Chhala	Aegle marmelous	-	1 Part
14.	Haridra	Curcuma longa	-	1 Part
15.	Rasona	Attium sativum	-	1/2 Part of all drugs [7 parts]
16.	Lauha Bhamsa	Ferrum	-	1/4 Part of drugs [3 1/2 parts]

Table - 2 : Contents of Lekhana Basti

Triphala Kvatha (Decoction of T.Chebula, E. Officinale & T. Belerica)	- 250 ml
Gaumutra (Cow's urine)	- 150 ml
Madhu (Honey)	- 40 gm.
Saindhava Lavana (Mineral Salt)	- 10 gm.
Yavaksara (?)	- 10 gm.
Vaca (A.Calamas) + Yasthi Madhu (G.Glabra) Kalka (Paste)	- 20 + 20 gm.
Sarsapa Taila (?)	- 50 ml
Quantity	- 300-400 ml.
Retention time	- 10 to 12 min

I. Study Design

45 clinically diagnosed patients of Sthaulya Roga(Obesity) reporting to OPD/IPD of NIA Hospital were randomly divided into following three groups.

(1) Group A - 15 obese patients were given "Medohara Bati" in the dose of 4 Tablets (2 gms) T.D.S. With Lukewarm Water for 30 days.

(2) Group B - 15 obese patients were administered " Lekhana Basti" for 15 days. Basti was prepared in the manner of Astanga Hridaya Sutra Sthana 19/45 and administered as per Caraka Siddhi Sthana : 3/ 24-25.

(3) Group C - 15 patients were administered "Medohara Bati" & "Lekhana Basti" together, Bati was given for 30 days & Basti was administered for 15 days.

All the patients were advised Pathya [controlled diet] as per descriptions available in Ayurvedic Classics, during and after the course of therapy.

Patients were followed up after 15 & 30 days

II. Selection of Patients

A. Inclusion Criteria

1. All Patients of either sex and of any age suffering from clinical condition of Sthaulya (Obesity) without any complications.
2. Patients having BMI>24.
3. Patients having normal Thyroid functions.

B. Exclusion Criteria

1. Drug induced obesity.
2. Hereditary indispoistion.
3. Obesity due to certain secondary causes.
4. Hormonal disoders e.g. Hypothyrodism.
5. Pregnant Women.

Criteria of Assessment

1. Subjective Improvement - Physical and mental fitness.

2. Clinical - Following classical symptoms of Sthaulya Roga were assessed in patients before and after the trial.

- Cala, Sphiga, Udara & Stana (Pendulous buttocks, Abdomen & Breasts)
- Gaurava (Heaviness)
- Ati Ksudha, Ati Trisa and Ati Nidra (Excessive Hunger, Thrist & Sleep)
- Svedadhikya & Daurgandhya (Excessive Perspiration & Emits bad odour)
- Krchavyavayata (Difficulty in sexual intercourse)
- Ayathopacaya (Disproprtionate body)
- Daurbalaya (Weakness)
- Udara Vridhi (Enlargement of abdomen)
- Alasya & Angasad (Lassitude)
- Ksudra Svasa (Dyspnoea on exertion)

3. Objective

- Body weight
- Body Mass Index (BMI)
- Raised Hip and Waist Ratio.
- Skin fold thickness at the level of Biceps, Triceps & Nape of the Neck.

4. Laboratory Investigations

- Hb gm%
- Blood Sugar Fasting & Post Prandial
- Serum Cholesterol.
- Serum Triglycerides.
- HDL.
- LDL
- VLDL
- Serum T3, T4, TSH-To rule out Hypothyrodism

DISCUSSION

Medohara Bati by virtue of its ingredients posseses dipana (55.5%), Pacana (44.4%), Chedana (16.6%), Lekhana (72.2%), Kapha-Vatahara (55.5%) & Srotosodhaka (33.3%) and potent Hypolipidaemic (62.5%) Properties.

Medohara Bati with these pharmacotherapeutic properties was likely to break down the chain of reaction essential for the Samprapti (pathogenesis) of Sthaulya Roga & check its progress without producing weakness or any side effects in the body.

Various types of Lekhana Basti are described in different Ayurvedic texts. The drugs used in present Lekhana Basti have Lekhana (75%), Kaphavatahara (62.5%), Dipana (62.5%), Pacana (37.5%), Vrisya (37.5%) & Srotosodhaka (37.5%) Properties.

Probable mode of action of Lekhana Basti

1. Lekhana Basti dravyas when introduced through rectum reach up to the level of Nabhi, Kati, Parswa & Udara Pradesa and produce cleansing effects by its Lekhana (scrapping) action —

   नाभि प्रदेशं कटि पार्श्व कुक्षिं गत्वा शकृतदोषचयं विलोडय्।
   संस्नेह काय सुपरीषदोषः सम्यक् सुखैनेति च यः स बस्तिः।
   (च.सि. १/४०)

2. It is possible that Basti dravya may produce local effects by irritating & stimulating the nerve endings of colon and rectum. The Lekhana Basti dravyas may acts by its Usna Virya, which spreads throughout the body with the help of Apana, Udana

and Vyana Vayu when administered through rectum.

3. Parasympathetic stimulation in general, increases the overall degree of activity of the G.I.T. by allowing rapid propulsion of contents along the tract. This propulsive effect is associated with simultaneous increase in rates of secretion of many of gastro-intestinal glands (Gyton Physiology, 774).

4. Except Saindhava all drugs of Lekhana Basti are having Tiksna Guna and Lekhana properties. Saindhava contains NaCl and other ions, which fulfils the requirement for generating action potential by which ion exchange takes place through the semi permeable membrane of the intestine. This exchange of ions may help in taking out vitiated doshas from the body. Sarshapa Taila is basically Snigdha, Usna and Tiksna Guna Pradhana, which can control vitiated Kapha and Vata Dosa and can disolve the Meda dhatu by its Tiksna Guna. By the Usna Virya and Lekhana properties of these Basti dravyas it spreads through out the body and expels out the vitiated Dhatu, and Dosa by Kekhana (Scraping action).

A Lekhana Basti with these drugs was likely to check the actiopathogenesis of Sthaulya and arrest the progress of the disease.

Observations & Results:

1. Vital Statistics

Majority of the patients belonged to the age group of 30-60 yrs., were predominantly females (84.5%), married (73.3%), hindus (80%), housewives (46.6%), belonging to lower-middle class consuming mixed diet with lower incidence of family history, consuming Pravara Ahara Matra (93.3%) with Ati Nidra (84.5%), Madhyama (55.5%) & Avara (31.2%) Vyayama Sakti having Krura Kostha with Tiksnagni (71.2%), Kapha-Vata Prakriti (55.5%) & Tamasika Prakriti (75.5%), belonging to Mamsa & Medasara, Asamhata Samhanana (Sthula-57.8%).

TABLE No.1

PATTERN OF CLINICAL RECOVERY IN 15 PATIENTS OF STHAULYA (OBESITY)

S. No	Symptoms	Group-A				Group-B				Group - C			
		n	Imp. %	*t*	*p*	*n*	Imp. %	*t*	*p*	*n*	Imp. %	*t*	*p*
1.	*C.S.U.S.*	9	60.24	5.92	<0.001	15	44.44	16	<0.001	14	41.16	4.07	<0.001
2.	*Caurava*	15	53.49	11.50	<0.001	15	43.48	10.58	<0.001	15	60.42	10.64	<0.001
3.	*Ksudhi Vriddhi*	15	56.10	11.5	<0.001	14	49.82	8.61	<0.001	15	56.10	7.99	<0.001
4.	*Trausa Vriddhi*	8	52.83	5.01	<0.001	7	53.09	5.40	<0.001	6	66.67	4.83	<0.001
5.	*Ali Nidra*	15	43.48	10.58	<0.001	14	48.02	11.45	<0.001	14	64.03	7.40	<0.001
6.	*Sveddhikya*	8	55.60	4.92	<0.001	8	55.20	4.89	<0.001	5	66.47	4.29	<0.001
7.	*Daurbalya*	13	70.53	7.48	<0.001	13	59.13	7.47	<0.001	13	64.75	8.20	<0.001
8.	*Kriccha Vyavdhyatd*	4	83.33	-	-	4	83.33	-	-	7	80.42	4.75	<0.001
9.	*Ayaheopacaya*	15	54.55	11.22	<0.001	15	48.48	16	<0.001	15	45.65	11.50	<0.001
10.	*Udara Vriddhi*	15	50.00	11.00	<0.001	15	47.73	10.69	<0.001	15	51.11	11.50	<0.001
11.	*Daurgandhya*	2	66.67	-	-	2	66.67	-	-	1	100	-	-
12.	*Tandra*	15	58.00	8.29	<0.001	15	58.06	8.29	<0.001	14	61.11	7.90	<0.001
13.	*Alasya*	15	64.52	10.58	<0.001	15	61.29	10.72	<0.001	14	61.29	8.71	<0.001
14.	*Angasdda*	3	67.00	-	-	9	67.16	2.27	<0.05	8	66.67	7.15	<0.001
15.	*Ksudra Svasa*	15	64.29	11.22	<0.001	15	60.71	12.47	<0.001	15	60.71	12.22	<0.001
16.	*Depression*	6	49.92	4.83	<0.001	9	75.19	5.92	<0.001	6	60.24	4.83	<0.001

C.S.U.S. - Cala Sphiga Udara & Stana.

Table No. 2 PATTERN OF OBJECTIVE CHANGES (REDUCTION) IN VARIOUS PARAMETERS IN 15 PATIENTS OF *STHAULYA* (OBESITY)

S. No	Objective Parameters	Group-A			Group-B			Group - C		
		Imp. %	*t*	*p*	Imp. %	*t*	*p*	Imp. %	*t*	*p*
1.	Body Weight	4.43	11.13	<0.001	6.79	24.58	<0.001	6.52	10.89	<0.001
2.	BMI	4.84	1.58	<0.005	6.48.	15.09	<0.001	5.25	9.07	<0.001
3.	Hip Circumference	5.39	6.36	<0.001	6.60	10.43	<0.001	7.88	10.40	<0.001
4.	Waist Circumference	6.59	14.53	<0.001	6.65	11.13	<0.001	7.34	10.43	<0.001
5.	Biceps S.F.T.	17.38	4.89	<0.001	26.50	7.64	<0.001	34.04	7.64	<0.001
6.	Trickeps S.F.T.	15.85	2.66	<0.05	21.01	7.47	<0.001	22.95	7.47	<0.001
7.	Nape of the neck	34.07	5.20	<0.001	52.76	8.26	<0.001	35.86	8.26	<0.001

S.F.T. - Skin Fold Thickness.

Table No. 3 THE PATTERN OF BIO-CHEMICAL CHANGES IN 15 PATIENTS OF *STHAULYA* (OBESITY)

S. No	Objective Parameters	Group-A			Group-B			Group - C		
		Imp. %	*t*	*p*	Imp. %	*t*	*p*	Imp. %	*t*	*p*
1.	Hb%	4.08	4.56	<0.001	4.72	2.97	<0.01	8.37	4.22	<0.001
2.	B.S. (Fasting)	3.35	2.26	<0.05	7.49	4.03	<0.01	7.91	2.27	<0.05
3.	B.S. (P.P.)	7.00	3.22	<0.01	7.80	5.28	<0.01	8.61	3.93	<0.01
4.	Serum Cholesterol	3.87	3.96	<0.05	4.46	1.77	<0.05	13.20	4.00	<0.01
5.	Serum Triglycerides	5.35	2.16	<0.05	2.32	1.13	<0.05	15.89	4.76	<0.001
6.	HDL	12.91	4.49	<0.01	18.26	2.81	<0.02	11.73	3.97	<0.001
7.	LDL	12.69	5.52	<0.001	17.11	5.55	<0.001	28.90	4.99	<0.001
8.	VLDL	5.37	2.17	<0.05	3.35	1.41	<0.05	17.05	5.79	<0.001

2. Subjective Improvement

All the patients of all the three groups revealed considerable growing feeling of well being after the course of therapy, it was more so in the patients treated with Lekhana Basti.

3. Clinical Recovery

- In all three groups highly significant response (p<0.001) was found in the Symptoms of C.S.U.S., Gaurava, Ksudha Vriddhi, Trsa Vriddhi, Ati Nidra, Svedadhikya, Daurbalya, Ayathopacaya, Udara Vriddhi, Tandra, Alasya, Ksudra Svasa & Depression. Statistically Insignificant reduction (p<0.05) was noted in the Symptom of Angasada in the patients of group B. Clinical resonse could not be defined statistically in symptom of Kriccha Vyavayata, Daurgandhya & Angasada because of the less number of patients in respective groups.
- Patients of all the three groups showed highly significant correction in subjective observation. The percentage of improvement was mild (51.8%) in group A, moderate (55.4%) in group B and maximum (60.49%) in group C.

3. Objective Parameters

- In group A, highly significant response (p<0.001) was observed in Body weight, Hip & Waist circumference, Biceps & Nape of the neck skin fold thickness and insignificant response (p<0.05) in BMI & Triceps skin fold thickness.
- In the patients of group B & group C highly signifcant response (p<0.001) was observed in all objective parameters.
- An average of 12.65% improvement in group A, 15.25% in group B & 17.12% in group C was seen in objective parameters.

4. Laboratory Parameters

- Statistically insignficant changes were observed in observations like Blood suger (Fasting) in group A & group C, although there was a trend of clinical

reduction of Blood sugar level. Whereas in all three groups statistically signficant change was observed in the form of reduction in the levels of Blood sugar (PP). Highly significant change ($p<0.001$) was observed in Hb% in all three groups. This may be attributed to the prabhava (effect) of the contents of the preparations used for the clinical trial.

- The patients of group A & group B showed insignificant reduction ($p<0.05$) in the level of S. Cholesterol, S. Triglycerides & VLDL, although there was a clinicial trend of reduction. Significant elevation in HDL levels & highly significant reduction in the level of LDL was also seen in group A & B. This shows Hypolipidaemic effect of these drugs on one hand and strong cardioprotective effect on the other.

- The patients of group C reported significant reduction in the levels of S.Chelesterol & significant elevation in the level of HDL. There was highly significant reduction in the levels of S.Triglycerides, LDL & VLDL. These findings suggest potent hypolipidaemic activities of the trial drugs. This may be termed as Lekhana Prabhava of these drugs. As a result there was statistically significant correction in most of the clinical manifestations of Sthaulya (Obesity). These drugs have revealed strong cardioprotective effect in the patients of group C also.

- Correction in lipid profile was maximum (17.35%) in group C, moderate in group B (8.89%) & miniumum (8.03%) in group A.

- It is note worthy that the average reduction in body weight in group A was 1-3 Kg. in group B it was 3-7 Kg. and in group C it was 5-10 Kg. These finding strongly support the Ayurvedic concepts that Lekhaniya Drugs and Sodhana Tereaphy (Lekhana Basti) produce Lekhaniya Prabhava (Hypolipidaemic activites) in the body. None of the patients complained of weakness after teh therapy.

All the patients tolerated Lekhaniya drugs in the form of Medohara Bati & Lekhana Basti very well & no side effects/toxicity effects were reported by any of the patients, thus they are absolutely safe for internal use by the patients of Sthaulya Roga (Obesity)

Several patients reported passing out of intestinal worms through rectum when they were administered Lekhana Basti or Medohara Bati. This may have been because of Vidanga-a known & potent antihelminthic drug. The elimination of intestinal worms further helps in improving the normal physiological functions of the gut, which are supplemented by various Dipana & Pacana drugs.

CONCLUSIONS

1. Medohara Bati & Lekhana Basti separately and in combination have produced statistically highly significant improvement/correction in various parameters.
2. The percentage of improvement was higher when a combined therapy was administered.
3. The trial drugs have shown significant Hypolipidaemic activities on various laboratory parameters.
4. Thus Medohara Bati & Lekhana Basti when used separately or simultaneously are good remedies for the management of Sthaulya Roga (Obesity).

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