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A CLINICAL EVALUATION OF LEKHANIYA GHANVATI IN THE MANAGEMENT OF STHAULYA (OBESITY)

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ABSTRACT

Background: Obesity is considered the world's oldest metabolic disorder. It is not a single disease entity but a syndrome with many causes including combination of genetic, nutritional and sociological factors. The WHO considers obesity as "Insidious, creeping pandemic which is now engulfing the entire world". Obesity develops as a result of a complex interaction between a person's genes and the environment characterize by long-term energy imbalance due to excessive caloric consumption, insufficient energy output (sedentary lifestyle, low resting metabolic rate) or both. Diet and life style play a significant role both in development and control of obesity. Obesity increases the likelihood of various diseases, particularly heart disease, type 2 diabetes, breathing difficulties during sleep, certain types of cancer, and osteoarthritis. In modern medicine no exact treatment is available if present has adverse effects but in Ayurvedic system of medicine various measures are given so, we selected Lekhaniya dravyas for management of Sthaulya (obesity). **Method:** Total 60 registered patients were divided into 2 groups having 30-30 patient in each group and out of them 26 and 27 patients respectively completed the course. **Result**: In Group I B.M.I. and W.H.R.(Waist hip ratio) were decreased significantly, but in Group II B.M.I. and W.H.R. were not decreased significantly. It is also useful in reducing *Atishudha, Kshudraswasa, Angachalatva, Swedadhikya, Gatrasada* which were the chief complaints of the patients.

Keywords: Obesity, *Sthaulya, Pathya-Apathya*, Metabolic disorder, *Lekhaniya dravya*

INTRODUCTION:

Obesity is a global problem, affecting an estimated 300 million people worldwide [1]. Its prevalence is increasing in both developed and developing countries throughout the world. It is a worldwide epidemic [2] which is characterized by excess adipose tissue and that contributes to numerous chronic diseases [3] and early mortality [4,5]. This epidemic has received both national and international attention because of obesity's detrimental impact on health, the enormous economic burden it imposes[6]. The present epidemic of overweight and obesity in the whole world is an unintended consequence of the economic, social, and technological advances realized during the past several decades [7]. With the onset of the industrial revolution increase in the average body size of the population was an additional concern to health care professional. The food supply is low in cost and abundant and palatable foods with high caloric density are readily available in prepackaged forms and in fast-food restaurants. Labour-saving technologies have greatly reduced the amount of physical activity that used to be the part of everyday life in olden days. The widespread

availability of electronic devices in the home have further promoted a sedentary lifestyle, particularly among children. Elevated body mass index, particularly caused by abdominal or upper-body obesity, has been associated with a number of diseases and metabolic abnormalities and these individuals are highly stigmatized and face multiple forms of prejudice and discrimination because of their weight.[15,16]

Objective: To evaluate the efficacy of Lekhaniya Ghanvati in Patients of Sthaulya on subjective, objective and biochemical parameters.

Material and Methods:

The present study was carried out at Kayachikitsa O.P.D and I.P.D. of Sir Sunder Lal Hospital, Institute of Medical Sciences, Banaras Hindu University Varanasi between the period of June 2009 to July 2010. A total of 60 patients of Sthaulya were divided into 2 groups in each group 30 patients were registered, in I group out of 30 patients 26 and in II group out of 30 patients 27 completed the follow up. The institutional ethical review Committee of B.H.U. approved the study.

Study design:

This is a randomized controlled stratified, single blind, clinical trial phase II study.

Inclusion criteria:

1. The patients age range between 20 – 60 years.
2. The patients having clinical signs and symptoms of Sthaulya.
3. The patients having B.M.I. in between 25 - 39.99 kg/m^2

Exclusion criteria:

1. Patients below the age of 20 years and above 60 years.
2. Patients with Hypothyroidism.
3. Patients undergoing long term Steroid therapy.
4. Patients with Diabetes and severe Hypertension.
5. Patients with evidence of severe Renal, Hepatic and Cardiac involvement.
6. Patients with B.M.I. more than 40 kg/m^2 and less than 25 kg/m^2.

FOLLOW UP STUDY- Every patient was registered after fulfilling the inclusion criteria, patients are underwent assessment of symptoms and also assessment of different components of weight, BMI, anthropometric parameters. A total of three follow ups were done at the interval of one month each. All the patients were subjected to comprehensive, therapeutic, regimens as per classical description and all the subjective and objective parameter were recorded each time.

Study Groups:

TREATMENT SCHEDULE FOR GROUP I (N=26): **Lekhaniya Ghanvati** in dose of 50 mg/kg/ bodyweight in three divided doses with Luke warm water. In this group total 30 patients were registered and out of them 26 completed the course.

Duration: Total duration of therapy was 3 months with 3 follow ups of one month.

TREATMENT SCHEDULE FOR GROUP II (N=27): In this group the Pathya-Apathaya Ahar-vihar was given. In this group total 30 patients were registered and out of them 27 completed the course. Patients of this group have been advised to adhere to the Pathya Ahara and Vihara prepared according to the principles of Ayurveda and calorie value calculation of food items and calorie demand of the individual.

Contents and Preparation of the Lekhaniya Ghanvati-

Lekhaniya Ghanvati contents: Chitrak[9,10,11] 200gm, Mustak[9] 200gm, Shun-

thi[9] 200gm, Aamalaki[9,11] 200gm, Haritaki[9,11] 200gm, Bibhitaki[9,11] 200gm, Vidang[9] 200gm, Guggul[10,11] 300gm, Apamarga tandul[9] 200gm, Guduchi[9] 200gm, Arjun[12] 200gm, Shilajit[10,11] 50gm, Bilwa[9,10,11] 200gm, Vacha[9,13] 50gm, Kutki[9] 50gm, Lauhabhasma[10,11] 50gm.

Bhavana Dravya: Gomutra[10]

Method of Preparation:

All the dravyas were broken till yavkut, then Kwath was prepared with Gomutra as bhawna dravya. After this Guggul was dissolved in Kwath, then it was condensed up to Ghan form then Ghanvati were made of 500 mg by pills making machine**.**

Clinical Assessment of the Disease:

Subjective Criteria:

1. ***Angachalatva:***

- Absence of Chalatva -0
- Little visible movement after fast movement -1
- Little visible movement even after moderate movement - 2
- Movement after mild movement -3
- Movement even after changing posture -4

2. ***Kshudraswasa :***

- No Dyspnoea - 0
- Dyspnoea after heavy works but relieved soon and up to tolerance - 1
- Dyspnoea after moderate works but relieved later and up to tolerance-2
- Dyspnoea after little works but relieved later and up to tolerance - 3
- Dyspnoea after little works but relieved later and beyond tolerance- 4
- Dyspnoea in resting condition - 5

3. ***Gatrasada :***

- No fatigue - 0
- Little fatigue in doing hard work - 1
- Moderate fatigue in doing routine work - 2
- Excessive fatigue in doing routine work - 3
- Excessive fatigue even in doing little work - 4

4. ***Atishudha:***

- Person not at all taking food - 0
- Person taking food in less quantity once a day - 1
- Person taking food in less quantity twice in a day - 2
- Person taking food in moderate quantity twice in a day - 3
- Person taking food in normal quantity twice in a day -4
- Person taking food in excessive quantity thrice in a day – 5

The assessment was done before starting the treatment and at each 3 follow ups of 30 days and the improvement was assessed on the basis of percentage relief and statistical evaluations.

CRITERIA FOR ASSESSMENT OF OVERALL EFFECTS

For the gross assessment of the result obtained with the clinical trial, the response of the treatment was determined in terms of:

***Subjective improvement*:** Patients were specifically asked about growing feeling of wellbeing and improvement in angachalatva, atishudha, atipipasa, nidraadhikya, kshudrashwasa, gatrasada at each follow ups of treatment.

Clinical improvement: Reduction in weight, BMI, arm circumference, hip circumference and waist circumference was noted at each follow ups.

Hematological and Biochemical assessment*:* Lipid profile, Liver Function test value were recorded before and after the treat-

ment in registered cases to evaluate the nature and extent of change in relation to course of disease Sthaulya. Hb%, TLC, DLC ESR, Serum Creatinine, blood urea and Blood sugar value were recorded before and after the treatment in registered cases to evaluate the safety profile of the drug.

STATISTICAL ANALYSIS

Statistical Analysis: The data collected were transferred on master chart showing various items/variables in columns and subjects in rows. The analysis of data was done using statistical software SPSS version 16.0.

Intra-group (within the group) comparison:

To test the significance of mean of difference of paired observations (BT versus AT) paired t test was applied

Inter-group comparison (Between the group):

In case of more than two independent groups, one-way ANOVA (Analysis of Variance) was applied and value of F test was determined, whenever F test resulted statistically significant, post–hoc test was applied for multiple comparisons, identifying significant pairs of groups.

Statistical Significance

$p < 0.05$ was considered statistically significant

$p < 0.01$ or $p < 0.001$ as statistically highly significant and

$p > 0.05$ as not statistically significant.

RESULTS OF THERAPEUTIC TRIAL

Table No. 1 Mean change in Weight (in Kilogram) in 53 patients of Sthaulya(Obesity):

Groups	BT	FU1	FU2	FU3	Within the group comparison Paired 't' test BTvsAT Mean± SD	Between the group comparison on difference of BT & AT One Way ANOVA	Post Hoc Test Significant pairs of group (p< 0.05)
Group I (n=26)	75.35± 12.16	73.40± 11.90	71.40± 11.81	69.60± 11.65	5.95±1.33 t = 16.57 p < 0.05	F = 67.26 p < 0.001	**(1,2)**
Group II (n=27)	**74.40± 9.16**	**74.25± 9.30**	**74.60± 9.25**	**74.95± 9.16**	**5.50±2.21 t = 1.11 p > 0.05**		

BT-Before Treatment, FU-Follow up

Table No. 2 Mean change in BMI in 53 patients of Sthaulya(Obesity):

Groups	BT	FU1	FU2	FU3	Within the group comparison Paired 't' test BTvsAT Mean±SD	Between the group comparison on difference of BT & AT One Way	Post Hoc Test Significant pairs of group (p< 0.05)

						ANOVA	
Group I (n=26)	31.11± 3.58	30.04± 3.34	29.21± 3.28	28.37± 3.33	2.73±1.09 t = 11.19 p < 0.01	F = 21.68 p < 0.001	**(1,2)**
Group II (n=27)	**31.43± 3.53**	**31.20± 3.94**	**31.57± 3.64**	**31.73± 3.65**	**2.99±.97 t = 1.37 p > 0.05**		

Table No 3.Mean change in Waist Hip Ratio in 53 patients of Sthaulya(Obesity):

Groups	BT	FU1	FU2	FU3	Within the group comparison Paired 't' test BTvsAT Mean±SD	Between the group comparison on difference of BT & AT One Way ANOVA	Post Hoc Test Significant pairs of group (p< 0.05)
Group I (n=26)	0.88 ±0.08	0.87± 0.07	0.85± 0.07	0.84± 0.06	0.03±0.02 t = 6.18 p < 0.05	F = 20.86 p < 0.001 HS	**(1,2)**
Group II (n=27)	**0.88 ±0.05**	**0.88± 0.05**	**0.88± 0.05**	**0.89± 0.05**	**0.01±0.02 t = 1.82 p > 0.05**		

Table No.4 Mean change in Angchalatva in 53 patients of Sthaulya(Obesity):

Groups	BT	FU1	FU2	FU3	Within the group comparison Paired 't' test BTvsAT Mean± SD	Between the group comparison on difference of BT & AT One Way ANOVA
Group I (n=26)	1.90± 1.16	1.55± 1.09	1.00± 0.85	0.45± 0.60	1.45±0.94 t = 6.87 p < 0.05	**F = 2.37 p > 0.005 NS**
Group II (n=27)	**1.75± 0.91**	**1.25± 0.97**	**0.80± 0.83**	**0.70± 0.66**	**1.05±0.76 t = 6.18 p < 0.05**	

Table No. 5 Mean change in Kshudrashwasa in 53 patients of Sthaulya(Obesity):

Groups	BT	FU1	FU2	FU3	Within the group comparison	Between the group comparison	Post Hoc Test Significant pairs of group

					Paired 't' test BTvsAT Mean±SD	on difference of BT & AT One Way ANOVA	(p< 0.05)
Group I (n=26)	1.65± 0.98	1.40± 0.75	0.80± 0.76	0.40± 0..59	1.20±0.69 t = 7.71 p < 0.05	F = 6.81 p< 0.001 HS	**(1,2)**
Group IV (n=27)	**1.80± 1.00**	**1.30± 0.87**	**0.65± 0.81**	**1.45± 0.94**	**0.35±0.87 t = 1.79 p > 0.05**		

Table No. 6 Mean change in Gatrasada in 53 patients of Sthaulya(Obesity):

Groups	BT	FU1	FU2	FU3	Within the group comparison Paired 't' test BTvsAT Mean±SD	Between the group comparison on difference of BT & AT One Way ANOVA	Post Hoc Test Significant pairs of group (p< 0.05)
Group I (n=26)	2.50± 1.05	0.95± 0.76	0.30± 0.57	0.35± 0.93	2.15±1.22 t = 7.84 p < 0.05	F = 7.65 p < 0.001 HS	**(1,2)**
Group II (n=27)	**2.50± 1.14**	**2.00± 0.72**	**1.60± 1.09**	**1.85± 1.18**	**0.65±1.09 t = 2.67 p < 0.05**		

Table No. 7 Mean change in Atishudha in 53 patients of Sthaulya(Obesity):

Groups	BT	FU1	FU2	FU3	Within the group comparison Paired 't' test BTvsAT Mean±SD	Between the group comparison on difference of BT & AT One Way ANOVA
Group I (n=26)	3.95± 1.19	3.65± 0.74	3.95± 0.22	4.00± 0.00	0.05±1.19 t = 0.19 p > 0.05	**F = 0.99 p > 0.005 NS**
Group II (n=27)	**3.50± 1.35**	**3.70± 1.03**	**3.70± 0.73**	**3.95± 0.88**	**0.45±1.46 t = 1.37 p > 0.05**	

Table No. 8 Mean change in Lipid profile test in 53 patients of Sthaulya(Obesity):

Group	Components	BT	AT	AT~BT	Within comparison 't'test	Group Paired
I (n=26	HDL	42.25±8.41	42.85±5.54	60.50±9.44	t=0.28, p>0.05	
	Triglyceride	207.82±79.55	148.13±21.98	59.68±63.41	t=4.20, p<0.05	
	Cholesterol	199.25±32.45	196.12±16.97	3.13±21.18	t=3.13, p>0.05	
	LDL	122.09±22.89	121.96±20.05	0.13±7.33	t=0.08, p>0.05	
	VLDL	42.36±15.68	39.85±17.82	2.51±9.05	t=1.24, p>0.05	
II (n=27)	HDL	39.78±4.09	39.14±3.86	0.63±0.64	t=1.26, p>0.05	
	Triglyceride	162.41±54.44	162.44±46.93	0.04±32.33	t=0.006, p>0.05	
	Cholesterol	214.59±38.76	221.63±30.15	7.04±23.18	t=1.35, p>0.05	
	LDL	123.49±30.07	126.89±27.01	3.40±12.57	t=1.21, p>0.05	
	VLDL	39.25±13.84	42.92±14.23	3.66±11.00	t=1.49, p>0.05	

Variables	Between the group comparison on difference of BT&AT One Way Anova Test	Post Hoc Test significant pairs of group p<0.005
HDL	F =0.42, p>0.005	
Triglyceride	F =6.84, p<0.005	(1,2)
Cholesterol	F =0.84, p>0.005	
LDL	F=7.59, p<0.005	(1,2)
VLDL	F = 3.72, p>0.05	

Table No.9 Mean change in Liver Function test in 53 patients of Sthaulya(Obesity):

Group	Components	BT	AT	AT~BT	Within Group comparison Paired 't'
I (n=26)	S. Bilirubin	0.73±0.14	0.68±0.11	0.05±0.19	t=1.31, p>0.05
	SGOT	35.70±3.28	30.61±5.31	2.45±3.25	t=3.37, p<0.05
	SGPT	36.25±3.04	33.05±2.05	3.20±2.93	t=4.88, p<0.05
	S. Alk.Phos	62.10±16.18	60.15±15.07	1.95±2.81	t=3.09, p<0.05
II(n=27)	S.Bilirubin	0.68±0.22	0.71±0.14	0.02±0.29	t=0.31, p>0.05
	SGOT	31.20±7.10	27.45±5.96	3.75±5.38	t=3.11, p>0.05
	SGPT	31.50±5.81	30.00±5.09	1.50±2.03	t=3.29, p<0.05
	S.Alk.Phos.	65.21±18.28	62.94±15.72	2.26±5.53	t=1.78, p>0.05

Variables	Between the group comparison on difference of BT &AT Post Hoc test

S.Bilirubin	F =0.61, p>0.005
SGOT	F=1.25, p>0.005
SGPT	F=2.09, p>0.005
S.Alk.Phos.	F=0.15, p>0.005

Table No.10 Mean change in Blood Urea in 53 patients of Sthaulya(Obesity):

Groups	BT	AT	Within the group comparison Paired 't' test BTvsAT Mean±SD	Between the group comparison on difference of BT & AT One Way ANOVA
Group I (n=26)	28.95±6.91	27.55±5.16	1.40±8.88 t = 0.71 p > 0.05	F = 0.25 p > 0.005 NS
Group II (n=27)	29.70±6.66	28.94±5.42	1.45±9.22 t = 0.71 p > 0.05	

Table No.11 Mean change in Serum creatinine in 53 patients of Sthaulya(Obesity):

Groups	BT	AT	Within the group comparison Paired 't' test BTvsAT Mean±SD	Between the group comparison on difference of BT & AT One Way ANOVA
Group I (n=26)	0.69±0.16	0.65±0.16	0.40±0.17 t = 1.04 p > 0.05	F = 0.53 p > 0.005 NS
Group II (n=27)	0.71±0.16	0.63±0.17	0.08±0.16 t = 0.71 p > 0.05	

Table No. 12 Mean change in Blood Sugar in 53 patients of Sthaulya(Obesity):

Groups	BT	AT	Within the group comparison Paired 't' test BTvsAT Mean±SD	Between the group comparison on difference of BT & AT One Way ANOVA
Group I (n=26)	102±7.61	94.40±12.48	7.60±13.29 t = 2.55 p < 0.05	F =0.78 p > 0.005 NS
Group II (n=27)	100.15±6.93	92.55±11.75	7.60±12.97 t = 2.62 p < 0.05	

DISCUSSION

Overweight and obesity are defined as "abnormal or excessive fat accumulation that may impair health". For an individual, obesity is usually the result of an imbalance between calories consumed and calories expended. It is no.2 worldwide preventable cause of death and disability. There is associated risk of heart disease, stroke, gallbladder disease, cancer, osteoarthritis, sleep apnea and there is multifactorial etiology components related with obesity. In obesity it is difficult to change dietary habits. Mostly people ignore the initial stages of obesity. hence group of lekhaniya dravyas were selected which are present in above trial drug.

Probable mode of action of Action of trial drug Lekhaniya Ghanvati:

- Trial drug possess cholagogue property, *tikta, katu rasa, tiksnaguna* properties irritate the intestine leading to increased propulsive movement of intestine.[8] Hence, provides less time for absorption of fat from intestine
- Dravyas present in the trial drug possess Choleretics action which causes excretion of bile which further leads to decrease absorption of fat from intestine [8].
- Trial drug has, *Kutki,* have irritant property which damage the structure of villi in intestine hence causes decreased capacity for absorption.
- Trial drug increases the bile secretion which decreases cholesterol level.[9]
- Trial drug increases the bile production due to katu and ushna properties. [9]
- Tikta dravyas are ama[9] pachak therefore restores the manda medodhatvagni.
- Katurasa is Chedaka, Margavivaraka[9] and Kapha Shamaka
- Tikta, Katu Rasa, Laghu, Ushan properties present in trial drug are very useful for Ama Pachana, so by means of these properties digestion of Ama, restoration of Agni (Deepana) at the dhatu level, removal of excessive Kledaka Kapha takes place.
- Tikta & Katu Rasa are also Kleda and Meda Nashaka[9]
- Tiksna guna acts on Srotas (channels) immediately and pierces the smallest cells of the vessels and removes the obstruction caused by lipids[14].
- Tikta and Kashaya rasas have Lekhana guna [9] that scraps out excessive Kapha and Meda from srotas.
- In addition to Lekhana, Kashaya rasa also has the property of Soshana[9] which absorbs the excessive fluids and lipid substances caused by hypercholesterolaemia.
- Lagu guna acts as kaphahara, reduces the tissue weights (Langana)[15] and clears the channels of the body (Srotoshodhana).
- All dravyas are Ushna in Virya, which oppose any increment of kapha and medas by the vilayan property[9].

CONCLUSION:

The present work it may be concluded that-

- The Lekhaniya Ghanvati is very useful for reducing Atishudha, Kshudraswasa, Angachalatva, Swedadhikya and Gatrasada which were the chief complaints of the patients.
- Use of Lekhaniya Ghanvati the markedly brings lightness of body,improves knee joints pain, and ankle joints pain.
- The trial drug in this study is supposed to be very good combination of Me-

doghna, Vedanashamak and Amapachak Dravyas.

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