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Research Article

A CLINICAL STUDY TO COMPARE THE EFFECT OF *LEKHNIYA MAHAKASHAY* THROUGH ORAL ADMINISTRATION AND *SARWANG SWEDAN* IN CASES OF *STHAULYA* W.S.R TO OBESITY

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KEYWORDS: *Sthaulya,* Hypertension, Hyperlipidemia, BMI, *Lekhaniya mahakashay, Sarwang swedan.*

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ABSTRACT

Today 2.1billion people nearly 30% of world population are either obese or overweight. The rise in global obesity rates over the last 3 decades has been wide spread presenting a major public health epidemic both for the developed and developing world. In Ayurveda obesity is referred as *Sthaulya*. Excessive truncal adiposity is very well correlated with risk for diabetes, hypertension and cardiovascular disease obese people are 20% more likely to develop pancreatic cancer, number of GI disorder and hepatobiliary disorder. Mostly obesity is primary i.e., no obvious cause exists other than imbalance in energy intake and energy expenditure. Importantly modest losses of 5% to 10% of body weight have been shown to reduce health risk such as hyperlipidemia, hypertension and insulin resistance. In this research drugs are selected from Ayurvedic classics and the effect of *Lekhaniya mahakashay* is compared in *Sarwang swedan* as well as in oral medication. Overall goals of this weight loss management are, to prevent further weight gain, to lose weight to achieve a realistic target BMI and to maintain a lower body weight over the long term.

INTRODUCTION

Ayurveda is the oldest science ever since serving the world. In Modern era with continuous changing life styles and environment, changed diet habits, man has become the victim of many diseases and *Sthaulya* is one of them. *Acharya Charaka* has quoted *Sthaulya* under *Ashta-nindita Purusha,*[1] *Acharya Charaka* also lists this problem under *Santarpanajanita Vyadhi.*[2] *Dalhana* seems to be more explicit while commenting on *Medo Roga* and specified *Dhatvagnimandya*[3] in pathogenesis of the disease. An individual whose increased *Meda* and *Mamsa Dhatu* make his hips, abdomen and breasts pendulous and whose vitality is much less than his body size is *Sthaulya*. In contemporary medical science it is compared with obesity and it is defined as an excess of adipose tissue that imparts health risk, body weight of 20% excess over ideal weight for age, sex and height is considered as health risk.[4] It is defined by body mass index and further evaluated in terms of fat distribution via the waist hip ratio. It is most commonly caused by a combination of excessive food intake, lack of physical activity and genetic susceptibility. A few cases are caused primarily by genes, endocrine disorders, medication or mental illness and insufficient sleep. Obesity in India has reached epidemic proportion in the 21st century with mortal obesity affecting 5% of country population. In *Samprapti* of *Sthaulya*, due to *Meda-Dhatwagni Mandya*, there is excessive accumulation of *Meda* that leads to obstruction of *Medovaha Strotasa*. Due to this, there is *Vimargagamana* of *Dosha Vata*. The *Vimarga Vayu* in *Koshta* ultimately increases the *Jatharagni* leading to an increase in appetite. But because of the obstruction created by *Medovaha Strotasa,* all other *Dhatus* remain malnourished and only *Meda Dhatu* increases.

So here we made an endeavour to evolve a safe and complete solution for this problem with the help of Ayurvedic medicine and *Swedan karma*

therapy. For this research entitled "A clinical study to compare the effect of *Lekhaniya mahakashay through oral administration* and *Sarwang swedan* in cases of *Sthaulya* w.s.r. obesity" medicine are selected from Ayurvedic classics.

1. *Lekhaniya mahakashay kwath* (Ch.su.4/3)
2. *Dashang gugglu* (Bha.Pr.Chi. 8/30)

Dashang gugglu helps to balance *Vata* and *Kapha* disorder. It helps to promote healthy weight loss combats obesity and *Ama* formation and improves basic metabolic rate so it is considered to have a better result in overcoming obesity or *Sthaulya*. According to *Sharangdhara* any drug possessing *Laghu* and *Tikshna* properties *Katu vipaka* and *Ushna virya* performs *Lekhan karma* that is curative and absorptive action on *Dosh, Dhatu*, and *Mala* along with *Lekhan karma*. Owing to above said attributes these drugs improve strength of *Agni* particularly *Jathragni* and *Dhaatwagni* which further reduces and ultimately stops production of dust *Medo dhatu* in body. *Lekhaniya mahakashay* possess above mentioned character so its oral use is considered in decoction form.

Sthaulya is a *Santarpanoth vyadhi* and *Aptarpan* therapy is prescribed. In *Sthaulya Aptarpan* itself contains *Langhan, Rukshan* and *Swedan upkrama*. So *Sarvanga swedan* is a better option for treatment of *Sthaulya* under concept of *Aptarpana*.

In this research the effect of *Lekhaniya mahakashay* is compared in *Sarwang swedan* as well as in oral medication because it may be very convenient to patient to use it as oral medication rather than *Sarwang swedan*.

Total 64 patients of *Sthaulya* were registered in a specialized research proforma along with informed consent from OPD and IPD of state Ayurvedic College and Hospital Lucknow, all the selected patients were divided into two Groups. Among these 5 patients were drop out.

Group A - Patient were treated with *Dashang gugglu* 2 *Vati* (500mg each) T.D.S + *Lekhaniya mahakashay decoction* 40ml (BD) orally.

Group B - Patient were treated with *Dashang gugglu* 2 *Vati* (500mg each) T.D.S+*Sarwang swedan* by *Lekhaniya mahakashay kwath.*

Patients were interrogated, examined and investigated thoroughly by following the exclusion and inclusion criteria. Treatment period was of three months. The response of the treatment was recorded by periodical check up. At the end of the treatment Group A shows more significant result than treatment of Group B.

MATERIAL AND METHODS

Sample Size: Total 64 patients of *Sthaulya* were registered for the present study from OPD and IPD of R.A.C.H LKO. Among these 5 patients were drop out.

Grouping: The enrolled patients of *Sthaulya* for the present clinical study were kept into two groups i.e. Group A with 31 patients and Group B with 28 patients.

Sample design

Group A- *Dashang gugglu* 2 *Vati* (500mg each) T.D.S +*Lekhaniya mahakashay* decoction 40ml (BD) after meal.

Group B- *Dashang gugglu* 2 *vati* (500mg each) T.D.S +*Sarvang sweda* with *Lekhaniya mahakashay* for two weeks daily with one week gap.

Period of Study Trial period was of 3 months, an assessment of clinical feature and lab investigation was done after.

***Swedana* Method:** *Samyaka Taila abhyanga* was followed by *Sarwangavaspaswedana* in the *Vashpaswedanayantra* till the *Samayakaswinna lakshan* i.e., *Swed-pradurbhava, Gaurava-nigraha* and *Mardava* appeared. After 10-15 minutes of *Swedana karma* patients were advised to take rest at least for one hour.

A. Inclusion Criteria

1. BMI is between 30 and 45
2. W.H.R. i.e. > 1.0 in men and > 0.85 in women.
3. Patients between the age group of 16-60 years of either sex.
4. Patient having more than 50% of the following major clinical symptoms was included in the trial (Ch.Su. 21/4).

i) *Chala Sphik Udara Stana* (pendulous buttocks, belly and breasts)
ii) *Javoparodha* (sluggishness in movement)
iii) *Krichvyavayta* (difficulty in intercourse)
iv) *Swedabadha* (excessive sweating)
v) *Kshudatimatrama* (excessive appetite)
vi) *Daurbalyam* (weakness)
vii) *Pipasatiyogam* (excessive thirst)
viii) *Daurgandhyam* (Foul smell)

B-Exclusion Criteria

Following cases were not included for the research study:

a) Patients < 16 years and >60 years.
b) Patients having BMI > 45.
c) Patients having obesity due to secondary reasons such as drug induced or hormonal imbalance.

d) Patients with hypothyroidism and Diabetes mellitus.
e) Patients having uncontrolled HTN (SBP> 110mmhg), CHD, IHD and highly obese and evidence of Renal, Hepatic involvement.
f) Patients having history of hereditary obesity.
g) Patients not willing for consent.

Criteria of Assessment

1. Subjective Parameters

i) *Chala Sphik Udara Stana* (Pendulous buttocks, belly and breasts)

0 (Nil): Absence of movement.
1 (Mild): Little movement after fast activity.
2 (Moderate): Movement after mild activity.
3 (Severe): No movement

ii) *Javoparodha* (Sluggishness in movement)

0 (Nil): Unimpaired movements
1 (Mild): On desire can work sluggishly but properly
2 (Moderate): on desire can work sluggishly but improperly
3 (Severe): on desire cannot work

iii) *Krichvyavayta* (Difficulty in intercourse)

0 (Nil): Normal sexual performance without exertion.
1 (Mild): Sexual performance with exertion.
2 (Moderate): Sexual performance with exertion and breathlessness.
3 (Severe): Sexual performance occasionally or monthly with exertion and breathlessness.

iv) *Daurbalyam* (weakness)

0 (Nil): No tiredness
1 (Mild): Mild fatigue after doing work
2 (Moderate): Tired after doing work
3 (Severe): Works with great difficulty

v) *Daurgandhyam* (Bad body odour)

0 (Nil): Absence of odour
1 (Mild): Occasional bad odour
2 (Moderate): Persistent bad odour
3 (Severe): Persistent bad odour intolerable to patient

vi) *Swedabadha* (excessive sweating)

0 (Nil) : Normal perspiration
1 (Mild): Mild perspiration after doing exertion
2 (Moderate): Heavy perspiration after doing little exertion
3 (Severe): Perspiration without exertion

Vii) *Kshudatimatrama* (excessive hunger)

0 (Nil): Normal appetite
1 (Mild): Intake of food in excess amount
2 (Moderate): Feels hungry even after taking meal 3 times a day.
3 (Severe): Feels hungry even after taking meals 4 times a day.

viii) *Pipasatiyogam* (excessive thirst)

0 (Nil): Normal intake (about 2.5 lt/day of fluid
1 (Mild): 2.5 - 3.5 lt/day of fluid
2 (Moderate): 3.5 - 4.5 lt/day of fluid
3 (Severe) :> 5 lt/day of fluid

2. Objective Parameters

For objective parameters following examinations were done:

a) B.M.I. (Body Mass Index)

0 (Nil): B.M.I is less than 30
1 (Mild): B.M.I is in between 30-35
2 (Moderate): B.M.I is in between 35-40
3 (Severe): B.M.I is between 40-45 or > 45

b) Body weight: According to height.

c) W.H.R. (Waist Hip Ratio)- WHR i.e., > 1.0 in men and > 0.85 in women indicates abdominal fat accumulation.

Laboratory Investigations

i) Routine Blood Investigation

-CBC- GBP - Hb%
-TLC
-DLC
-ESR

ii) Urine - a) Routine (R) b) Microscopic (M)
iii) Stool - for ova and cyst
iv) Blood Sugar - a) Fasting b) PP
v) Lipid profile

Sr. Total Cholesterol
Sr. Triglycerides
Sr. LDL
Sr. VLDL
Sr. HDL

vi) Thyroid Function Test: For exclusion
vii) Liver function test: For exclusion and side effects
viii) Renal function test: For exclusion and side effects

Assessment of Result

The result is assessed on the basis of symptoms relief and improvement in terms of laboratory investigations. The result of present clinical trial is grouped in following categories:

1) Relieved

i) Patients having >75% relief in terms of clinical symptom.
ii) B.M.I. is less than 25.
iii) Markedly change in Waist - hip ratio.

2) Improved

i) Patients having improvement between 45-75% in clinical symptoms.
ii) B.M.I. is in between 25 to 30.
iii) Slight changes in Waist-hip ratio.

3) No Improvement

i) Patients having improvement less than 40% in clinical symptoms.
ii) No change in B.M.I.
iii) No change in waist-hip ratio.

Observation and Result

Table 1: Comparison of change in *Chala Sphik, Udara, Stana* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	2.35±0.75	1.16±0.93	1.19±.70	4.41	0.0001*
Group B	2.29±0.66	1.71±0.98	.58±.50	2.13	0.0001*
Z-value	.54	-1.98			
p-value[2]	.58	0.04*			

[1]Wilcoxon rank sum test, [2]Mann-Whitney U test, *Significant

Table 2: Comparison of change in *Javoparodha* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	2.39±0.76	0.32±0.48	2.07±.62	6.32	0.0001*
Group B	2.36±0.78	0.64±0.78	1.72±.65	5.33	0.0001*
Z-value	.12	-1.30			
p-value[2]	.90	0.19			

[1]Wilcoxon rank sum test, [2]Mann-Whitney U test, *Significant

Table 3: Comparison of change in *Krichhavyavayata* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	1.90±01.08	.13±0.34	1.77±.99	5.25	0.0001*
Group B	1.79±01.07	0.68±0.77	1.10±.78	3.62	0.0001*
Z-value	0.46	-2.58			
p-value[2]	0.645	0.009			

[1]Wilcoxon rank sum test, [2]Mann-Whitney U test, *Significant

Table No. 4: Comparison of change in *Swedabadha* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	1.81±1.01	.23±0.50	1.58±.15	5.29	0.0001*
Group B	2.11±0.69	.43±0.79	1.68±.54	5.34	0.0001*
Z-value	-0.94	-0.68			
p-value[2]	0.342	0.496			

[1]Wilcoxon rank sum test, [2]Mann-Whitney U test,

Table 5: Comparison of change in *Kshudatimatrama* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	1.26±1.03	.19±0.40	1.07±.14	4.03351	0.0001*
Group B	1.68±1.02	.36±0.49	1.32±.77	4.44903	0.0001*
Z-value	-1.51	-1.07			
p-value[2]	0.13	0.28			

[1]Wilcoxon rank sum test, [2]Mann-Whitney U test, *Significant

Table 6: Comparison of change in *Daurbalyam* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	2.19±0.83	0.68±0.83	1.51±.72	5.11	0.0001*
Group B	2.07±0.90	0.75±0.65	1.32±.61	4.67	0.0001*
Z-value	0.47	-.67			
p-value[2]	0.63	0.49			

[1]Wilcoxon rank sum test, [2]Mann-Whitney U test, *Significant

Table 7: Comparison of change in *Pipasatiyogam* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	1.94±0.93	0.32±0.75	1.62±.16	5.20	0.0001*
Group B	2.18±0.98	0.64±0.73	1.53±.79	4.76	0.0001*
Z-value	0.39	-2.79			
p-value[2]	0.25	0.06			

Table 8: Comparison of change in *Daurgandhyam* before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	2.03±0.87	0.35±0.66	1.68±.70	5.52	0.0001*
Group B	1.89±0.99	1.11±1.03	.78±.68	2.63	0.0001*
Z-value	0.39	-2.79			
p-value[2]	0.69	0.001			

[1]Wilcoxon rank sum test, [2]Mann-Whitney U test

Table 9: Comparison of change in Weight before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	84±11.74	76.13±10.61	7.87±2.34	3.01	0.0001*
Group B	83.64±14.42	79.25±14.59	4.39±1.28	1.54	0.0001*
Z-value	.54	-.59			
p-value[2]	0.91	0.34			

[1]Wilcoxon rank sum test, [2]unpaired t test, *Significant

Table 10: Comparison of change in BMI before to after treatment

Groups	Before treatment	After treatment	Mean change	z-value	p-value[1]
Group A	33.99±3.09	30.75±2.66	3.24±.17	3.90	0.0001*
Group B	34.51±3.41	32.67±3.38	1.84±.55	2.11	0.0001*
Z-value	.54	-2.24			
p-value[2]	.54	0.01			

[1]Wilcoxon rank sum test,, [2]unpaired t test, *Significant

Table 11: Comparison of change in WHR before to after treatment

Groups	Before treatment	After treatment	Mean- change	z-value	p-value[1]
Group A	0.91±.05	0.89±0.06	0.02±.009	1.71	0.0001
Group B	0.93±0.14	0.91±0.12	0.02±.03	.57	0.0001
Z-value	-.46	-.74			
p-value[2]	.43	.43			

[1]Wilcoxon rank sum test, [2]unpaired t test, *

Table 12: Comparison of biochemical parameters from before to after treatment between the groups

Time interval	Group A	Group B	p-value[1]
Hb (gm/dl)			
Before	11.2±1.40	11.43±1.58	0.54
After	11.67±1.20	11.82±1.226	0.64
Mean change, p-value[2]	0.62±.92, 0.0001*	0.32±.54, .0008*	
TLC (cells/mm^3)			
Before	7645.16±1746.78	7639.29±1586.83	.98
After	6654.84±1115.3	6921.43±1108.34	.36
Mean change, p-value[2]	-990.32±1158.3, 0.0001*	-717.86±1080.8, .0016*	
Neutrophil (%)			
Before	61.87±7.84	61.43±7.88	0..82

After	61.39±7.48	60.54±7.42	0.66
Mean change, p-value[2]	-0.48±.88, 0.005*	-0.89±1.1, 0.0002*	
Eosinophil (%)			
Before	1.94±2.10	1.57±1.45	0.44.
After	1.10±1.49	1.00±1.05	0.77
Mean change, p-value[2]	-0.83±1.18, 0.0005*	-0.57±.92, 0.002*	
Basophil (%)			
Before	0.35±0.55	0.32±0.55	.81
After	0.26±0.44	0.29±0.46	.81
Mean change, p-value[2]	-0.09±.39, 0.18	-0.03±.33, 0.57	
Monocytes (%)			
Before	1.06±1.71	.46±.92	0.10
After	0.74±1.32	0.75±1.27	0.98
Mean change, p-value[2]	-0.32±.59, 0.005	-0.29±1.08, 0.17*	
Lymphocytes (%)			
Before	32.35±9.45	34.50±11.82	0.44
After	31.52±8.86	33.46±11.06	0.45
Mean change, p-value[2]	-.83±1.18, 0.04*	-1.04±2.0, 0.01	
ESR (mm/hr.)			
Before	19.32±6.85	22.86±7.31	0.06
After	16.65±3.41	16.79±4.15	0.88
Mean change, p-value[2]	-2.67±5.00, 0.00057*	-6.07±5.4, 0.0002*	

[1]Unpaired t-test, [2]Paired t-test, *Significant

Table 13: Comparison of Lipid Profile from before to after treatment between the groups

Time interval	Group A	Group B	p-value[1]
TC(mg/dl)			
Before	218.71±23.02	215.14±23.84	0.56
After	189.88±21.88	195.71±18.59	0.17
Mean change, p-value[2]	28.48±15.4, 0.0001*	19.43±12.4, 0.0001*	
TG(mg/dl)			
Before	171.68±44.82	166.21±41.02	0.62
After	146.68±37.4	151.64±36.57	0.60
Mean change, p-value[2]	25.00±28.7, 0.0001*	14.57±12.7, 0.0001*	
HDL(mg/dl)			
Before	42.00±10.11	40.29±5.83	.43
After	44.14±10.90	41.71±10.90	.28
Mean change, p-value[2]	1.41±5.25, 0.0003*	2.14±2.75, 0.1424*	
LDL(mg/dl)			
Before	128.06±18.72	125.36±11.68	0.51
After	115.65±16.78	115.86±11.08	0.42
Mean change, p-value[2]	12.49, ±6.70.0001*	12.7±6.3, 0.0001*	
VLDL(mg/dl)			
Before	46.23±10.72	33.18±8.09	0.0001*

After	39.06±9.27	29.91±7.07	0.0001*
Mean change, p-value[2]	7.17±4.7, 0.0001*	3.17±2.32, 0.0001*	

[1]Unpaired t-test, [2]Paired t-test, *Significant

Table 14: Comparison of Blood Sugar level from before to after treatment between the groups

Time interval	Group A	Group B	p-value[1]
Fasting(mg/dl)			
Before	82.43±10.10	83.57±9.74	0.66
After	81.12±9.92	82.21.±9.80	0.67
Mean change, p-value[2]	1.31±2.8, 0.0149*	1.35±0.82, 0.0001*	
PP(mg/dl)			
Before	134.16±13.58	142±15.27	0.04
After	130.68±12.85	139.39±15.24	0.02*
Mean change, p-value[2]	3.48±2.9, 0.0001*	2.61±2.5, 0.0001*	

[1]Unpaired t-test, [2]Paired t-test, *Significant

Table 15: Overall improvement in the severity of symptoms

	Group A		Group B	
	No.	%	No.	%
Relieved	21	67.74	10	35.72
Improved	10	32.26	15	53.57
Not improved	0	0	3	10.71

Overall Effect of the Trial Drugs

There was significant relief in both the treatment of group A and group B, but treatment of group A is more significant than group B.

DISCUSSION

Acharya Charaka has mentioned *Sthaulya* as a *Santarpan janya vyadhi*, *Charak Samhita* has also considered *Sthaulya* one among the *Astanindita vyadhi. Sushruta Samhita* has considered it as *Rasa Nimittaja Vyadhi*. *Madhavakara* has described *Medoroga* as individual entity in 34th chapter of *Madhava nidana* and used *Medosvina, Atisthula* and *Sthula* words as synonym.

Nidana* of *Sthaulya

Nidana of *Sthaulya* is divided in four categories *Aharatmaka, Viharatmaka, Manasa* and *Anya.* The modern lifestyle in terms of fast foods, increased luxury, lack of physical work, have contributed to the etiology of *Sthaulya*. *Achintanach* and *Harsanityatva* are the *Mansika* causes but now a day's stress is also a causative factor because its leads to the vigorous demand for the food which leads to the *Sthaulya*.

Samprapti

Samprapti of *Sthaulya* can be divided in to two categories.

1) *Samprapti*, according to *Charaka samhita* is Due to obstruction of *Srotas* by *Meda*, the *Vata* moving mainly into stomach, whips up the Agni (*Tikshnagni*) and absorbs the food. The diseased man digests food speedily. Excessive eating produces more production of *Rasa* which causes over growth of *Meda Dhatu* leading to *Sthaulya*, increased *Jatharagni,* which leads to excessive formation of improper *Medodhatu* leading to *Sthaulya*.
2) According to *Acharya Sushruta Ama Rasa* is produced due to *Kaphavardhaka Ahara, Adhyashana, Avyayama, Divaswapa.* The *Madhura Bhava Ama Rasa* moves with in the body, *Snigdhamsha* of this *Anna Rasa* causes *Sthaulya,* which produces excessive *Medodhatu* and this is according to *Dalhana* in which there is a state of *Medodhatvagni mandya* which leads to excessive formation of improper *Medodhatu* leading to *Sthaulya.*

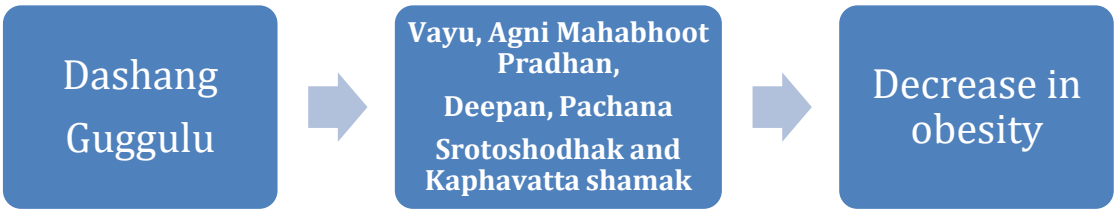
The hypothesis decided for the study was if we treat the *Santarpan janya vyadhi* by *Apatarpana dravyas, Vyadhi* will automatically get treated. To prove this hypothesis a conceptual and clinical study was performed in the patients of *Sthaulya*.

***Roopa*:** *Rupas* of *Sthaulya* are compiled from various classics. Out of them, 8 most common symptoms of *Sthaulya* occur due to excessive accumulation of *Meda* in fat depots leading to *Chalatva* of the various organs, *Daurabalya*, *Dauragandhya, Kshudhaadhikya, Pipasatiyoga, Swedaadhikyata, Nidraadhikya, Kshudra shwasa, Angagauravata* Su.su.15/37 other various signs and symptoms. Regarding the differential diagnosis of

the disease, *Sthaulya* can be easily spotted by just *Darshana Pariksha.*

Mode of Action of Drug as Per Modern View- constituent of *Lekhaniya mahakashay* has choleretic and purgative action since bile salt are required for absorption of fat and lipid from gut, their excretion would lead to decreased absorption of fat and lipids in gut increasing faecal fat and bile salt content leading to decrease in obesity.

Mode of Action of *Dashang Gugglu*



Mode of Action of *Lekhaniya Mahakashay*

Discussion on Clinical Symptoms

Chala Sphik Udara Stana

Considerable relief in the symptoms of *Chala sphika–udara- stana* was observed in patients of Group A (Z=4.41, p<0.0001) and in patient of group B (Z=2.213, p<0.0001). This might be due to *Sphik-Udara –Stana* are the main site of excess *Medo* deposition and maximum contents of *Dashang gugglu* and *Lekhaniya mahakashay* have *Medohara* properties which lead to reduction of excess *Medo Dhatu* from these sites.

Javoparodha

Considerable relief in the symptoms of *Javoparodha* was observed in patients of Group A (Z=6.32, p<0.0001) and in patient of group B (Z=5.33, p<0.0001). The *Shaithilya* (flabbiness), *Saukumarya* (delicacy) and *Guruta* properties of *Meda Dhatu* causes *Javoparodh* along with raised *Alasya* because of vitiated *Kapha*. Thus these persons are slow to initiate the work.

Due to *Ama Pachana, Kapha Nashaka* and *Medohara* effect of trial drugs helped in minimizing this symptom.

Krichvyavayta

Considerable relief in the symptoms of *Krichhavyavayata* was observed in patients of Group A (Z=5.25, p<0.0001) and in patient of group B (Z=3.62, p<0.0001). The trail drugs have *Dipana*, *Pachana, Medohara* and *Strotoshodhak* property which causes *Ama Pachana* by virtue of which *Uttar Dhatu* got nourishment and reduced *Medodhatu* over the *Sphika, Udara, Stana* also helps to reduce the *Krichhavyavayata*. However, modern researchers have studied the relation between weight loss and improvement in sexual functions also.[5]

Swedabadha

Considerable relief in the symptoms of *Swedabadha* was observed in patients of Group A (Z=4.03, p<0.0001) and in patient of group B (Z=4.44, p<0.0001). This is due to the fact that *Sweda* (sweat) is a *Mala* (metabolic by product) of *Medodhatu*. During normal metabolism of this tissue sweat is produced but in normal quantities to maintain the normal physiological phenomenon. However, in Obesity, the metabolism of *Medas* is greatly hampered due to a *Medodhatvagnimandya*. As a result, the *Dhaturupa medas* is formed less and *Malarupa Sweda* is formed in excess. With the trial regimen, as already seen, this *Dhatvagnimandya* is corrected and the normal metabolism process is re established so that the *Medodhatu* is formed qualitatively and there occurs a decrease in the *Malarupa Sweda.*

More over Obesity is a condition associated with physiological increase in the sympathetic arm of the autonomic nervous system.[6] The excessive sweating observed in the subjects may be attributed to this increased sympathetic activity. Further, It is also demonstrated that parasympathetic activity increased with weight loss in obese.[7] Thus, the decrease in the symptom excessive sweating may be explained in terms of reestablishment of sympathetic-parasympathetic balance due to weight loss.

Kshudatimatrama

Considerable relief in the symptoms of *Kshudatimatrama* was observed in patients of Group A (Z=4.03, p<0.0001) and in patient of group B (Z=4.44, p<0.0001).

The status of *Agni* in *Atisthaulya* needs a precise understanding. The indulgence in *Kapha* vitiating etiological factors initially results in a *Jaṭharagnimandya*. This in turn leads to the formation of *Amasamyukta annarasa* (improperly digested *Annarasa*). This poorly formed *Annarasa* initiates *Dhatvagnimandya* at the level of *Rasa dhatu*. Subsequently, *Ama* accumulation takes place at the *Dhatu* level and the *Rasadhatu* formed is qualitatively not sufficient to perform its function of *Prinana* (nourishment of other tissues). This *Amasamyuktarasadhatu* sequentially diminishes the strength of succeeding *Dhatvagnis* and as a result, there occurs a morbid *Amasancaya* resulting in *Srotorodha* at the *Kostha* with a resultant *Vatakopa*. This, secondarily, causes a pathological flaring up of the *Jaṭharagni*.[8] Due to maximum content of trial drug have *Dipana Pachana* Properties with *Kashaya, Katu* and *Tikta Rasa*. These are *Kapha Shamaka* and *Ama Pachaka*, as a result *Jatharagni* and *Dhatvagni* are normalized.

Daurbalyam

Considerable relief in the symptoms of *Daurbalyam* was observed in patients of Group A (Z=5.11, p<0.0001) and in patient of group B (Z=4.67, p<0.0001). Due to *Srotorodha* of different (Rasa and *Meda*) *Srotas* by *Ama*, nourishment of rest of *Dhatu* are diminished, thus it will not transport nutrient to Uttar *Dhatu*. Hence, it causes *Dhatu Kshaya* which results in to *Ojakshaya* which may lead to *Daurbalya*.

The trial drugs have *Dipana, Pachana*, *Medohara* and *Strotoshodhak* property which causes *Ama Pachana* by virtue of which *Uttar Dhatu* got nourishment.

Pipasatiyogam

Considerable relief in the symptoms of *Pipasatiyogam* was observed in patients of Group A (Z=5.11, p<0.0001) and in patient of group B (Z=4.67, p<0.0001). In patients of obesity *Pipasadhikya* is because of *Pitta dosha* and *Prakupit vata dosha*, the trial drugs have *Tikta, Kashaya rasa* and *Ama Pachana* properties by that *Medodhatu* reduced and the *Avarana* break down which lead to normalize *Pitta* and *Vata* so the symptom may got reduced.

Daurgandhyam

Considerable relief in the symptoms of *Daurgandhyam* was observed in patients of Group A (Z=5.52, p<0.0001) and in patient of group B (Z=2.63, p<0.0001). *Sweda* is stated as *Mala* of *Meda*.[9] Due to excessive *Vikriti medodhatu, Gatra dauragandhya* present in obese patients. Trial drugs have property of *Strotoshodana* leads to the formation of normal *Medodhatu* and decrease the above symptoms.

Discussion on Objective Parameters

Body Weight

There was highly significant (p=0.0001) mean change in the weight from before to after treatment in both group. The mean change in weight between the groups was not found to be significant (p>0.05). The decrease was found to be higher in Group A (p=.002, z= 3.01) than Group B (p= .12, z=1.54). The decrease in the body weight attributed to the choleraetic and purgative action[10] of constituent of *Lekhaniya mhakashay*. Since bile salt are required for absorption of fat and lipids in gut their excretion would lead to decreased absorption of fat and lipids in gut increasing faecal fat and bile salt content leading to decrease in weight.

Body Mass Index (BMI)

There was significant mean change in the BMI from before to after treatment in both the groups. The mean change in BMI between the groups was also found to be significant (p=0.01). The decrease was found to be higher in Group A (mean change=3.24±.17) than Group B (mean change=1.84±.55).

Due to reduction of weight and *Medo dhatu* BMI is also reduced.

Waist hip ratio

There was insignificant (p>0.05) mean change in the WHR from before to after treatment in both the groups. The difference in the mean change in WHR between the groups was found to be insignificant (p>0.05). The decrease was found to be slightly higher in group A (z=1.71) than group B (z=.57). waist (*Udara*) and hip (*Sphik*) are also the main site of deposition of *Meda*, so reduction in *Meda* may causes the reduction in waist and hip ratio.

Discussion on Laboratory Parameters

Hemoglobin

There was an increase in the Haemoglobin concentration at the end of the intervention, however the change was significant (P<0.001) in both the groups. Under normal physiology, the *Rasadhatu* is transformed into the *Raktadhatu*. In *Atisthaulya* with a malfunctioning of *Dhatvagni*, specifically *Raktadhatvagni* here, this transformation is impaired evident by the decreased Haemoglobin concentration before the intervention. After the intervention, due to reestablishment of the normal physiological functioning of the *Dhatvagnis* the mobilization of the *Ahararasa* to corresponding *Dhatus* is ensured, thereby yielding a qualitative and quantitative improvement in *Raktadhatu* as observed with the increase in Hemoglobin concentration.

Renal Function Tests

All the Renal Function Tests were observed to be within physiological normal limits on Day 0. At the end of intervention, significant change was seen in the values.

B. Urea

There was significant (p=0.0001) decrease in both the groups from pre to post treatment. Thus, the safety of the trial drugs with respect to renal functioning can be assured.

Liver Function Test

In the present study the liver functions were found to be within physiological normal limits on Day 0. This indicates that the obesity in the study subjects was not an outcome of a pathological metabolic error, rather was a consequential of an energy imbalance.

A significant (p<0.05) decrease was observed from pre to post treatment in alkaline phosphate, SGOT and SGPT. However, all the changes were within the normal physiological limits confirming the hepato-protective action of the trial drug.

Lipid Profile

S. Cholesterol in patients of both the Group A and B the decrease was statistically highly significant (p=0.0001).

S. Triglyceride in patients of both the Group A and B the decrease was statistically highly significant (p=0.0001).

S. HDL in patients of Group A, the increase was statistically highly significant (p<0.001). The change was not significant in between the Groups. HDL is considered as good cholesterol because of its effectiveness in cholesterol removal from periphery to liver (reverse cholesterol transport).

S.LDL in patients of both the Group A and B the decrease was statistically highly significant (p=0.0001).

VLDL in patients of both the Group A and B the decrease was statistically highly significant (p=0.0001).

Meda, Majja, Vasa which are *Sneha Dravya* can be correlated with lipids since they have properties and function similar to that of lipids. The trial drugs have *Ruksha Guna* and *Laghu Guna* like properties which are known for its *Dhatu Shoshaka, Rukshana* and *Lekhana Karma*. Due to their *Rukshana Lekhana* properties they results in reduction of lipids from body which might help in minimizing these biochemical matters.

Discussion on Final Result

In Group A, 21 patients (67.74%) were relieved and 10 patients (32.26%) were improved by administration of the trial drugs.

In Group B, 10 patients (35.72%) were relieved, 15 patients (53.57%) were improved and 3 patients (10.71%) were not improved by the administration of the trial drugs. The comparison between Group A and B reveals that the percentage of relieved patients is higher in Group B than in Group A. This difference is statistically significant as (p=0.01).

CONCLUSION

- *Sthaulya* is a *Dushya* dominant *Vyadhi*.
- *Medo* is the main *Dushya* and *Kapha* is the main *Dosha* of *Sthaulya*.
- *Acharya Charaka* considered *Atisthaulya Purusha* as one out of the *Asthanindtiya Purusha*.
- Excessive indulgence in oily and fatty food, sedentary life style, *Divaswapna*, *Manasika* factors like-*Harshanitya*, *Manasonivrita* etc., along with genetic predisposition play a major role in aetiopathogenesis of *Sthaulya*.
- *Acharya Charaka* has specially mentioned *Beejadosha* as the *Nidana* for *Sthaulya.*
- *Sushruta Samhita* has considered *Rasa* as the major pathological factor involved in obesity.
- The etiological factors lead to *Kapha* and *Meda vraddhi* which block the micro channels causing *Samana vayu* vitiation in the *Koshtha* and causes *Jatharagni Sandhukshana* thereby increasing the person's appetite and increased intake of food ultimately leading to *Sthaulya Roga (Medodhatu vriddhi).*
- Due to obstruction by *Meda, Vyana vayu* could not transport nutrient to other *Dhatu* so *Medadhatu* is increased and *Uttara dhatu* are decreased.
- Restoration of Agni to normal physiological states, removal of *Medaavarana* and accumulated *Sama meda* from the body are the main principle of treatment of this disease.
- On basis of the Etiopathogenesis and literary meaning *Sthaulya* can be correlated with Obesity.
- Obesity is widespread in almost all socio-economic classes.
- Majority of the patients i.e., 12 (35.29%) of group A and 9 (30%) of group B belong to third and fourth decade of life.
- Females were more prone to obesity i.e., 27 (79.41%) in group A and 24 (80%) in group B were females.
- Maximum number of the patients i.e., 29 (85.3%) in group A and 26 (86.67%) of group B were married.
- *Sthaulya* is more common in people addicted to tea (61.76% in group A and 56.67% in group B) and taking mixed food (64.70% in group A and 70%in group B).
- *Vishamasan* (55.8% in group A and 50% of group B) is observed as main dietary habit in patients of obesity.
- In females, menstrual disorder is more common among associated disease i.e., 29.41% (10) of group A and 26.67% (8) of group B were having menstrual disorder.
- *Acharya Charaka* explanation of *Sthaulya* matches with phenotype of density. W.H.R and skin fold thickness can be taken as parameter to assess the *Sthaulya*, as W.H.R helps to check the abdominal fat (*Chala udara*)and gluteal fat (*Chala sphika*) and skin fold thickness helps to measure regional fat (*Chala stana*).
- The trial drug *Lekhaniya Mahakashay* is effective in the disease due to their *Deepana, Pachana, Lekhana, Rukshana, Medohara, Srotoshodhana, Aamapachana, Vatanulomana, Kaphaghna* etc. properties.
- As Sthaulya it is a *Santarpanoth vyadhi* and also *Kashtasadhya* so *Apatarpana chikista* like *Swedan* is prescribed for *Sthaulya*.
- As *Gugglu* has *Srotosodhak* property and *Medoanil haranam* property so it plays a great role in treatment of obesity.
- Therapeutic efficacy of Group A was significantly higher than Group B.
- In Group A, 21 patients (67.74%) were relieved and 10 patients (32.26%) were improved by administration of the trial drugs.
- In Group B, 10 patients (35.72%) were relieved, 15 patients (53.57%) were improved and 3 patients (10.71%) were not improved.
- Both the group showed significant improvement in all subjective parameter.

  Both the group showed significant improvement on body weight, BMI and WHR.
- No any biochemical abnormalities have been observed in registered cases after completion of trial it indicates safety of the trial drug.
- Both the trial drug was found effective as lipid lowering agent so can be used in dyslipidemia.
- The response of treatment in Group A is more than Group B, the intergroup comparison was statistically significant. So, the therapeutic

response among the patients included in this study was encouraging.

- Thus it can be concluded that *Lekhaniya Mahakashay kwath* along with *Dasang gugglu* is proved to be an effective therapy and this regimen should be tested on large scale for long duration of trial.

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