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**AN OPEN LABEL DOUBLE ARM CONTROL CLINICAL STUDY TO
EVALUATE THE ADD ON EFFECTIVENESS OF SHIGRUVAADI
UDARA BANDHANA IN CENTRAL OBESITY- PILOT STUDY**

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ABSTRACT

Obesity is the major health care challenge that we are facing today. In addition to overall obesity, central obesity is associated with a statistically higher health risk, even among individuals with normal weight. Sthoulya is the nearest clinical entity in Ayurveda comparable to obesity. The lakshana of sthoulya is chalatwa of udara caused due to increase in the size of udara. The treatment modalities recommended for sthoulya includes Langhana, apatarpana, rookshana. Swedana being a type of langhana therapy. In this astudy, the drugs from swedopaga gana of charaka are used as mrudu swedana to remove the mala of the meda that is sweda, in the form of udara bandhana. Udvartana is a procedure which does rookshana along with kapha medo shaman and is a well-established treatment for Sthoulya. Patients were divided into 2 groups (N= 14) and clinical study was conducted. Study group (N=7) patients were given Udvartana and udara bandhana. Control group (N=7) patients were given Udvartana. Study conducted for 7 days. Waist circumference and waist height ratio is assessed before and after the treatment. The findings were recorded using T-test was used find the Significance between the groups. On analysing the data of the study group, there was statistically significant change in the assessment criteria in the study group but when analysed with the control group there was no much statistically significant changes. This may be due to

less sample size taken for pilot study and the actual study might give a significant result. Though there is no statistically significant result seen in study group when compared to control group, still there is a negative mean difference obtained and a significant result with a single group is seen. Also, changes were physically appreciated. On increasing the sample size, statistically significant result may be obtained.

Keywords: shigruvaadi udara bandhana, swedopaga ganas, central obesity

INTRODUCTION

Obesity is the major health challenge that occupies the first place among non-communicable diseases creating an enormous socioeconomic and public health burden in most countries (Mohan *et al.*, 2015). It is reported in the recent studies that, more than 1.9 billion adults are overweight, 650 million are obese and approximately 2.8 million deaths occur as a result of being overweight or obese. (O'Dowd, 2006) The study reveals that overall prevalence of generalized obesity is 50.1 %, while that of abdominal obesity is 68.9% in India. In addition to overall obesity, central obesity is associated with a statistically higher risk of heart disease, hypertension, insulin resistance, type 2 diabetes, and increased risk of developing cardiovascular disease, even among individuals with normal weight. Sthoulya is the nearest clinical entity in Ayurveda comparable to obesity. The characteristic of sthoulya is being explained as laxity of abdomen (Acharya, Y. 2021)

The treatment modalities recommended for sthoulya includes langhana, apatarpana,

rookshana. Swedana is one of the treatments of the santarpanajnya vikaras, which can be considered for obesity also (Acharya, Y. 2021). Though saagni swedana is not indicated in sthoulya, niragni swedana or mrudu swedana is indicated. In this study swedopaga dravyas are used as rookshana and mrudu swedana to remove the mala of the meda that is sweda, in the form of udara bandhana along with udvartana.

Though there are many established treatments in the management of overall obesity, there are few treatments established to reduce central obesity. Thus, considering the risks and importance of reducing central obesity, in this study we tried to evaluate the add on effectiveness of udara bandhana with shigruvaadi swedopaga dravyas along with udvartana in reducing central obesity.

MATERIALS AND METHODS

SOURCE OF DATA:

Patients from the OPD and IPD of swasthavritta and yoga, Sri Dharmasthala college of Ayurveda and hospital.

METHODS OF COLLECTION OF DATA:

14 patients fulfilling the diagnostic criteria and inclusion criteria were selected.

DIAGNOSTIC CRITERIA

1. Waist circumference :>40 inches (102 cm) in males and >35 inches (88 cm) in female
2. Waist height ratio :>0.50 cm (R, A. 2012)

INCLUSION CRITERIA

1. Age :25-60 yrs.
2. Waist circumference :>40 inches (102 cm) in men and >35 inches (88 cm) in women.
3. Waist height ratio :>0.50 (R, A.2012)

EXCLUSION CRITERIA

1. Visible wounds over the abdomen and lower back.
2. Pregnant and post-partum woman.
3. Inflammatory skin conditions over the abdomen and lower back.
4. Known case of abnormal abdominal enlargements.
5. Known case of any organomegaly.

D. LABORATORY INVESTIGATIONS:

USG-abdomen to rule out any major pathologies.

STUDY DESIGN:

It is a two-group interventional clinical study of 14 patients. 7 patients in each group. Study conducted for 7 days.

PLAN OF STUDY:

Source and authentication of raw drugs

The raw drugs are collected from the local market and authentication is taken from the dravya guna department of Sri Dharmasthala Manjunatheshwara college of Ayurveda Hassan.

Grouping

14 patients fulfilling the inclusion criteria was selected and divided into 2 groups of 7 in each using convenient sampling method. Group 1(N=7) patients will be given udvartana with udvartana churna- 30 min. Group 2(N=7) patients will be given udvartana with udvartana churna -30 min and udara bandhana-4 hours.

Study duration-7 days.

INGREDIENTS

Table 1: Shigruvaadi swedopaga dravyas (Acharya, Y. 2021)

Name of the drugs	Botanical name	Part used	Proportion
<i>Shigru</i>	<i>Moringa olifera</i>	Stem bark	1 part
<i>Yava</i>	<i>Hordium vulgare</i>	Seeds	1 part
<i>Kulatta</i>	<i>Cassia absus</i>	Seeds	1 part
<i>Tila</i>	<i>Sesamum indicum</i>	Seeds	1 part
<i>Masha</i>	<i>Vigna mungo</i>	Seeds	1 part

Cotton cloth-2 pieces-1st piece-12*100 inch for binding around the abdomen.

2nd piece-12*70 inch to cover the area, where lepa is applied.

Table 2: Udvartana churna

Name of the drugs	Botanical name	Matra	Part used
<i>Kulatha</i>	<i>Cassia absus</i>	4 parts	Seeds
<i>Yava</i>	<i>Hordium vulgare</i>	4 parts	Seeds
<i>Triphala,</i> <i>Haritaki</i> <i>Amalaki</i> <i>Vibhitaki</i>	<i>Terminellia chebula,</i> <i>Embellica officinalis,</i> <i>Terminellia bellarica</i>	1 part each	Fruits
<i>Mudga</i>	<i>Vignus radiata</i>	1 part	Seeds
<i>Methika</i>	<i>Trigonella foenum grecum</i>	1 part	Seeds
<i>Sarshapa</i>	<i>Brassica compestri</i>	¼ part	Seeds

METHODS OF MEASUREMENT OF WAIST CIRCUMFERENCE

Patient's abdomen is palpated in an erect position to locate the last rib, the waist is measured at a vertical level below the lower rib in the narrowest part of the abdomen. Measuring tape is placed horizontally encircling around the patient's abdomen in the waist region. The tape is gently tightened around the patient's abdomen without depressing the skin. Measurement is taken from the zero line of the tape (to the nearest millimeter) at the end of a normal expiration. (VMC", 2021)

METHOD OF PREPARATION OF LEPA FOR UDARA BANDHANA

Fine powders of drugs from 1 to 5(of table 1) are taken in equal proportion (approximately 5 grams each) and added to 250ml of boiling water and stirred continuously, so that it becomes a thick paste without lumps.

INTERVENTION

Udvartana is done with udvartana churna for 30 min all over the body, once daily in the morning and hot water bath is advised.

2 cm thick shigruvaadi lepa having lukewarm temperature is applied over the abdomen (below the xyphoid process till pubic symphysis, covering the area between lower border of the last rib and the upper border of the iliac crest on both sides) The cotton cloth of 12*70 inches is used to cover over the applied lepa. Another cotton cloth of 12*100 inches is used to cover over the first piece and tied around the abdomen so that it does not hampers the regular respiratory activity. It is left for 4 hours and then removed and washed with warm water.

ASSESSMENT CRITERIA

- Waist circumference
- Waist height ratio

FOLLOW UP DURING TREATMENT:

Patients were assessed before and after the treatment.

STATISTICAL METHOD:

Data was collected using specially designed case report form (CRF). Data was tabulated and analysed by using statistical software. The statistical analysis included descriptive

statistics and paired t test and unpaired t test.

RESULTS

A paired sample t-test was conducted to compare the waist circumference, to evaluate the add on effectiveness of shigruvaadi udara bandhana in central obesity. On analysing the data before and after the udara bandhana along with udwartana, there is statistically significant difference in the scores. For waist circumference before intervention (M=101.143, SD=15.337) and after intervention (M=96.500, SD=15.2014); t(6)=6.839, p=0.0005 that is <0.005.

This result suggests that the udara bandhana when done along with udwartana reduces waist circumference. A paired sample t-test was conducted to compare the waist height ratio, to evaluate the add on effectiveness of shigruvaadi udara bandhana in central obesity. The waist height ratio before and after the udara bandhana along with udwartana, there is

statistically significant difference in the scores for waist height before intervention (M=0.6443, SD=0.08997) and after intervention (M=0.6129, SD=0.8789); t (6) =6.181, p=0.01 that is <0.005. This result suggests that the udara bandhana when done along with udwartana reduces waist height ratio.

Leven’s test for equality of variances was applied to assess homogeneity of the groups. This revealed that the two groups were homogeneous. The results were given assuming the equal variance between the groups.

In order to evaluate the add on effectiveness of shigruvaadi udara bandhana in central obesity, the independent sample t test was conducted. In the test it was found that there was no statistical significance in waist circumference, t (12) = -2.049, p=0.63 that is > 0.05 and also in waist height ratio also has no statistical significance that is, t (12) = -1.486, p=0.163 that is >0.05.

Table 3: Paired sample test of waist circumference (study group)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Waist circumference in cm - BT - Waist circumference in cm - AT	4.6429	1.7962	.6789	2.9817	6.3040	6.839	6	0.000

Table 4: Paired sample test of waist height ratio (study group)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Waist Height Ratio - BT - Weight Height Ratio - AT	.03143	.01345	.00508	.01899	0.04387	6.181	6	0.001

Table 5: Paired sample test of waist circumference (control group)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Waist circumference in cm - BT - Waist circumference in cm - AT	2.4286	2.2254	0.8411	.3704	4.4867	2.887	6	0.028

Table 6: Paired sample test of waist height ratio (control group)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Waist Height Ratio - BT - Weight Height Ratio - AT	0.02000	0.01528	0.00577	0.00587	0.03413	3.464	6	.013

Table 7: Independent Samples Test of waist height ratio - Levene's Test for Equality of Variances

		Levene's Test for Equality of Variances	
		F	Sig.
Waist height Ratio Mean Difference	Equal variances assumed	0.090	0.769
	Equal variances not assumed		

Table 8: Independent Samples Test of waist height ratio - t-test for Equality of Means

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Waist height Ratio Mean Difference	Equal variances assumed	-1.486	12	0.163	-0.11429	0.07693	-0.28190	0.05333
	Equal variances not assumed	-1.486	11.811	0.164	-0.11429	0.07693	-0.28220	0.05363

Table 9: Independent Samples Test of waist circumference - Levene's Test for Equality of Variances

		Levene's Test for Equality of Variances	
		F	Sig.
Waist circumferences mean difference	Equal variances assumed	0.001	0.976
	Equal variances not assumed		

Table 10: Independent Samples Test of waist circumference - t-test for Equality of Means

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Waist circumference mean difference	Equal variances assumed	-2.049	12	0.063	-2.21429	1.08091	-4.56939	0.14082
	Equal variances not assumed	-2.049	11.488	0.064	-2.21429	1.08091	-4.58108	0.15250

DISCUSSION:

The statistically less significant result may be due to less sample size taken for pilot study and the actual study might give a significant result. Though there is no statistically significant result seen in study group when compared to a standard group, still there is a negative mean difference seen and there is a significant result with a single group. The changes were also physically appreciated.

CONCLUSION:

There are many established treatments in the management of overall obesity, there are few treatments established to reduce central obesity. Though the statistically significant result is not seen in the above study the result was clinically appreciated. And we may get a statistically significant result in the actual study. Inculcating this procedure in clinical practice would be of great use to the people having central obesity.

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