




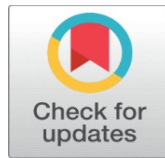
# A RANDOMIZED, OPEN LABELED, CONTROLLED EQUIVALENCE PILOT DRUG TRIAL TO EVALUATE EFFECT OF POLYHERBAL FORMULATIONS, EFFICACY AND SAFETY OF MODIFIED PANCHAKARMA TREATMENT PLAN OBETOX IN PATIENTS WITH OBESITY (MEDOROG)

Dr. Smita Naram <sup>1</sup> , Deepak Mahajan <sup>2</sup> , Dr. Hemang Parekh <sup>3</sup> 

<sup>1</sup> Department of Research and Development, Ayushakti Ayurveda Pvt Ltd, Bhadran Nagar Cross Road, Malad, Mumbai-64, India

<sup>2</sup> Research Head, Ayushakti Ayurveda Pvt Ltd, Bhadran Nagar Cross Road, Malad, Mumbai-64, India

<sup>3</sup> Medical Head, Ayushakti Ayurveda Hospital, Bhadran Nagar Cross Road, Malad, Mumbai-64, India



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## Corresponding Author

Deepak Mahajan,  
[drdeepakm@ayushakti.com](mailto:drdeepakm@ayushakti.com)

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## ABSTRACT

A chronic complex diseases with excessive fat deposition is called as Obesity. It can lead to many metabolic disease like Type II diabetes, heart diseases, thyroid, hypertension, increased blood cholesterol level, liver disease, sleep apnoea and certain cancers. It can lead to increase the risk of co morbid conditions specially heart diseases. Weight loss can improve or prevent many health issues related to Obesity. Ayurveda says that Obesity is Vikrita Vriddhi (Abnormal increase) of Medodhatu (Fatty Tissue).

**Aims and Objective-** This study was planned to evaluate the efficacy of Ayurvedic treatment Tab Mednil, Tab Suhruday & Obetox Treatment Plan in the treatment of Obesity (Medorog) and to assess the change in various biochemical markers.

**Method-** This is a proof-of-concept study in which a sample size of 60 participants (30 in each group) was considered sufficient to achieve the study objectives. Participants were randomly assigned to two groups according to a computer-generated randomization list.

**Results-** The results show that participants observed a lighter body image, more energy and enthusiasm, and a reduction in obesity-related complications, in terms of weight, H/W ratio, BMI and lipid profile.

**Conclusion-** Obetox protocol along with herbal remedies gives significant results in the Obesity.

**Keywords:** Medorog, Obesity, Detox, Virechan, Obetox

## 1. INTRODUCTION

A change in diet and an inactive lifestyle have led to an obesity epidemic in several Asian countries: The consumption of fat and high-fat foods has increased significantly, while at the same time physical activity has decreased. With the rapid

pace of industrialization and economic progress, more and more jobs are now sedentary, and dietary habits are also changing with a decrease in grain consumption and an increase in sugar and fat intake. All this has led to an increase in obesity and the problems associated with it. According to a survey conducted by the Nutrition Foundation of India, 45% of women and 29% of men in urban areas of the country are overweight. Globally, India ranks 7th on the obesity index [Nayak \(2018\)](#). Obesity used to be a lifestyle issue, but now the World Health Organization has classified it as a disease. Ayurveda has placed more emphasis on a balanced state of body tissues in the definition of health. According to Ayurveda, obesity is a condition in which medodhatu (adipose tissue) is in a state of vikrita vridhhi (abnormal increase). Definition of Atisthaulya (obesity) A person who is incapacitated and disfigured with sagging buttocks, abdomen and breasts due to extensive growth of fat and flesh is called Atisthula (obese) and the condition is termed as Atisthaulya (obesity) [Jadavaji \(2001\)](#). The term obesity is defined as an excessive storage of energy in the body in the form of fat. Obesity is an increase in body weight beyond the limit of skeletal and physical requirements as a result of excessive accumulation of body fat. A BMI (Body Mass Index) between 25 and 29.9 kg/m<sup>2</sup> is considered overweight, and over 30 kg/m<sup>2</sup> is diagnosed as obesity. In the Charaka Samhita [Ibidem Charaka Samhita](#), the causative factors for obesity are described as bijadosha (hereditary component) in addition to dietary, nutritional and psychological factors. Apart from these factors, the components affecting meda (Fatty Tissue) and kapha (one of the three humors) can be considered as causative factors for Obesity. Dhatvagni Mandya (weak digestive fire at the level of body tissues) is the main cause among other components in the etiopathology of sthaulya [Vagbhata, Ashtang Sangraha Sutrasthana Adhyaya 24/15 \(1991\)](#). In the context of obesity, the exogenous causes are meda-potentiating diets and cures, while dosha (three humors), dhatu (body tissues), mala (excretions), srotas (body channels) etc. belong to the endogenous factors. This small randomized trial was conducted to check the effectiveness of Ayurvedic treatment Tab Mednil, Tab Suhruday & Obetox Treatment Plan in the management of Obesity (Medorog) and various biochemical markers.

## 2. AIMS AND OBJECTIVES

- **Primary objective:**

To evaluate the efficacy of Ayurvedic treatment Tab Mednil, Tab Suhruday & Obetox Treatment Plan in the treatment of Obesity (Medorog).

- **Secondary objectives:**

To evaluate the change in various biochemical markers (Sr. Cholesterol, Sr. Triglycerides, HDL and LDL) between the two study groups at the end of treatment.

To Evaluation of the clinical safety of the Ayurvedic treatment packages.

## 3. METHODOLOGY

### **Ethical considerations.**

Approval by the ethics committee.

### **Informed consent**

Written informed consent was obtained from each participant in the prescribed format prior to performing any study-related procedures (i.e., physical examination, laboratory screening, or other investigational procedures) and prior to performing

any study-related procedures. The procedure for obtaining written informed consent from participants was carried out by the investigator

### **Study design**

#### **Sample size considerations**

As this is a proof-of-concept study with no previous clinical results available, a sample size of 60 participants (30 in each group) was considered adequate to meet the study objectives.

#### **Criteria for randomization**

Participants were randomized into two groups using a computer-generated randomization list.

**Group I:** (30 patients) received Tab Mednil, Tab Suhruday (Metaboost) taken orally twice daily.

**Group II:** (30 patients) received Tab Mednil, Tab Suhruday (Metaboost) were taken orally DOSE twice daily along with Obetox treatment plan (Virechana +Basti)

### **Study Population**

#### **Inclusion Criteria:**

- 1) The patients with generalized obesity (GO) with BMI  $\geq 25$  kg/m
- 2) Patients of either sex between the age group of 25- 65 years (both years inclusive)
- 3) Ready to abide by trial procedures and to give informed consent

#### **Exclusion criteria:**

- 1) Patients who have genetic history of obesity.
- 2) Subjects with severe comorbidities, heart disease, stroke, insulin-treated diabetes and chronic renal insufficiency (eGFR & lt; 60 ml/minute/1.73 m<sup>2</sup>).
- 3) Patients current treatment with a weight loss medication (or list under or Phentermine)
- 4) Patients Impaired mobility or confined to a wheelchair or bed and unable to perform self-care activities.
- 5) Previous Bariatric surgery in the past is also excluded.
- 6) Planned bariatric surgery in the next 12 months.
- 7) Any condition that, in the opinion of the investigator, does not justify the patient's inclusion in the study.

#### **Study drug-**

Each participant was supplied with the tab Mednil 625 mg thrice a day after food with lukewarm water at each visit and Tab Suhruday (Metaboost) 510 mg twice a day after food with lukewarm water at each visit.

#### **Study Duration**

Each participant was in the study for 6 months.

#### **Herbal remedies –**

Mednil 625 mg three times daily after food with lukewarm water and Tab Suhruday (Metaboost) 510 mg twice daily after food with lukewarm water. All the medicines were purchased from the pharmacy of Ayushakti Ayurveda Pvt Ltd, Plot Number 78, Stice, Musalgaon, Sinnar, Nashik 422112.

### **Study Procedures**

Potential trial participants were screened at Ayushakti Ayurveda Pvt Ltd Malad and Borivali branch, following written informed consent, eligible participants were enrolled in the study. The trial drugs and obetox treatment was advised according to the randomization list.

#### **Statistical analysis –**

Mean (X), standard deviation (S.D), standard error (SE), paired TDS test were performed at the 0.05, 0.01 and 0.001 p level. The results were then interpreted as follows:

- $P > 0.05$  = insignificant.
- $P < 0.05$  = significant
- $P < 0.01$  = significant result
- $P < 0.001$  = highly significant result.

#### **Plan of studies-**

##### **Purvakarma (Preoperative)-**

Herbal remedies like Hingashtak churna  $\frac{1}{4}$  tea spoon before food and supachak churna  $\frac{1}{4}$  tea spoon after food with luke warm water were used for Deepana Pachana (to improve appetite and digestion).

Rukshana therapy (Dry therapy) with Sidhdha massage followed by Potali sweda (medicated bolus) was done on full body for 5 days to improve the superficial circulation and to lose the Aam (toxins) from superficial strotas.

Snehapan (internal oleation) with Pachak ghee, Medhya ghee and Mahatriphala ghee was done till all the features of proper oleation described in ayurvedic texts are not achieved. During these days full body massage with Mahanarayan oil and Balada oil was continue to lose the internal toxins at deeper level and bring them in stomach to remove through anal canal by a procedure of Virechana (Purgation).

##### **Pradhan Karma (Operative)-**

Virechana Karma (detoxification) was done on empty stomach by administering tablets like Virechan and Virechan plus. All expected complications and outcomes were explained to the patient in writing before starting the procedure.

##### **Paschat karma (Post-operative)-**

Samsarjan karma (diet plan) was recommended for 3 to 7 days depending on the shuddhi (cleansing signs) during Virechana karma (detoxification).

## **4. RESULTS AND DISCUSSION**

For participation in the study, 98 patients were screened to reach the target of 60 patients. Of these, 21 patients were not included in the study for the reasons indicated in the flowchart. 77 patients were enrolled in the study, 53 of whom completed the study. 25 patients dropped out of the study at various stages of the project, mainly due to poor follow-up. The results show that there was a feeling of lightness and energy, enthusiasm and a reduction in complications of obesity.

The demographic distribution of patients participating in the study was: women  $n=25$  with a mean age of 53.08 years and men  $n=28$  with a mean age of 54.43 years.

### Changes in Weight-

The average weight changes were significant in both groups, but highly significant weight loss was observed in group II, i.e. 13.2 kg in 3 months and 4.54 kg in one month after detoxification. The mean weight loss after Obetox and Basti (enema) was highly significant compared to that observed in patients receiving medication only, i.e. 5.6 kg weight loss in 3 months and 2.89 kg in one month. (P-value- <0.0001). The results are shown in Table 1.

### Change in BMI-

The difference in BMI was significant in both groups. The P value was <0.0001 in both groups, yet a BMI difference of 5.03 was found in group II compared to 2.2 in group I. The results are shown in Table 1.

### Waist Hip ratio-

Highly significant difference was found in the waist and Hip ratio in both the groups. 5.03 cms difference was found in group II and 2.27 cms difference was found in group I in waist and Hip ratio. The results are mentioned in table-1.

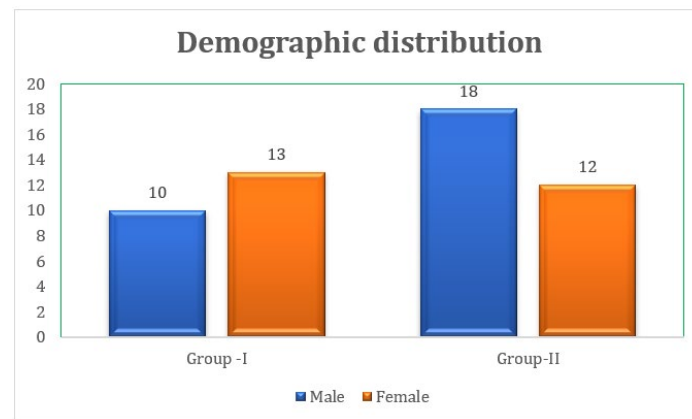
### Serum Cholesterol levels-

In both the groups' highly significant difference was observed in serum Cholesterol levels. In group II Obetox programme along with medicines gives better result in serum cholesterol levels as compared with Group I. The results are mentioned in table-1.

### Serum Triglyceride level-

Highly significant difference was found in both the groups. Still serum triglyceride was better reduced with Obetox and medicines P value 0.0044 as compared to group with only medicines P value 0.008. The results are mentioned in table-1.

**Chart 1**



**Chart 1** Demographic Distribution

**Table 1**

**Table 1 Changes in the body parameters and lipid profile.**

	Difference in Weight (In Kg)							
	BT	V2	AT	Diff in 1 month	Mean (In 3 months)	SD	SEM	P value
Group-1 (n=23)	74.86	71.96957	69.21304	2.89043478	-5.648	3.014	0.6284	<0.0001
Group-II(n=30)	74.48	69.94	66.24	4.54	-13.2	3.26	0.5952	<0.0001
Difference in BMI								
	BT	V2	AT	Diff in 1 month	Mean (In 3 months)	SD	SEM	P value

Group-1 (n=23)	30.47	29.30042	28.18866	1.16542678	-2.278	1.252	0.2612	<0.0001
Group-II(n=30)	28.39	26.11832	23.36326	2.27571473	-5.03	1.225	0.2236	<0.0001
Difference in W/H Ratio								
	BT	V2	AT	Diff in 1 month	Mean (In 3 months)	SD	SEM	P value
Group-1 (n=23)	0.921	0.921712	0.921588	-0.0005135	-2.278	1.252	0.2612	<0.0001
Group-II(n=30)	0.963	0.96571	0.96456	-0.0027374	-5.03	1.225	0.2236	<0.0001
Difference in Cholesterol level								
	BT	V2	AT	Diff in 1 month	Mean (In 3 months)	SD	SEM	P value
Group-1 (n=23)	181.5	157.4739	137.4391	24.0652174	-44.1	46.04	9.6	0.0001
Group-II(n=30)	187.1	156.49	131.2167	30.5933333	-55.87	45.38	8.285	<0.0001
Difference in Triglycerides level								
	BT	V2	AT	Diff in 1 month	Mean (In 3 months)	SD	SEM	P value
Group-1 (n=23)	137	124.7087	117.9565	12.273913	-19.03	28.71	5.987	0.0044
Group-II(n=30)	168.7	138.9433	109.13	29.7833333	-59.6	114.5	20.91	0.008
Difference in LDL level								
	BT	V2	AT	Diff in 1 month	Mean (In 3 months)	SD	SEM	P value
Group-1 (n=23)	138.9	116.7304	108.2348	22.1347826	-30.63	24.52	5.113	<0.0001
Group-II(n=30)	125	96.85667	90.22333	28.1173333	-34.75	38.37	7.005	<0.0001
Difference in HDL level								
	BT	V2	AT	Diff in 1 month	Mean (In 3 months)	SD	SEM	P value
Group-1 (n=23)	48.77	49.02609	50.95217	-0.2565217	-2.183	8.472	1.766	0.2296
Group-II(n=30)	47.37	48.75333	50.23333	-1.3866667	-2.86667	11.12	2.031	0.008

## 5. DISCUSSION

*Charakacharya* has given a detailed description of Obesity in his *Charaksamhita* under the heading *Medorog*, which contains details of causative factors, etiopathogenesis, signs and symptoms. Acharya Sushruta has described the complications of obesity in his *Sushruta Samhita*.

*Nidan parivarjan* (to avoid causative factors) is the first line of treatment stated by the *Charaka*. Obesity (*Medorog*) can be treated with two major therapies *Shodhana* and *Shamana*. In *Shodhana* bio purification therapies are used like *Vamana* (Medicated emesis) and *Virechana* (Medicated purgation) and are advisable according to the *Dehbala* (strength of the patient) and *Vyadhibala* (strength of the disease). *Virechana* karma normalizes the agni (digestive fire) and brings the tridosha in balance state also it clears the *Srotavarodha* (obstruction in micro channels) [Acharya \(2008\)](#). Panchakarma is a specially designed five procedures of bio-purification of the entire body. These procedures bring the biological system into normal homeostasis, rejuvenate the body and also help to achieve the expected pharmacotherapeutic effect of herbal medicines [Chaturvedi \(2019\)](#).

During the treatment, Rukshana therapy (dry therapy) with *Sidhdha* massage followed by *Potali sweda* (medicinal bolus) was performed on the whole body, which can lead to an increase in lymphatic drainage, and lymphatic massage has been shown to help in water loss and ultimately weight loss [Lulla & Prasad \(2013\)](#). During the *virechana* process, cellular fluid is drained through the interstitial fluid into the vascular compartment and from there into the gastrointestinal tract for removal through the anal canal. This means that this process causes a biochemical



change by modulating the fluid compartments [Acharya \(2008\)](#), [Arthur & John \(n.d.\)](#). *Cuminum cyminum* (Shwet jirak) contains essential fatty acids, volatile oils, phenolic compounds therefore it has an anti-obesity effect and it has effect on weight, BMI, waist circumference and H/W ratio [Mohseni et al. \(2021\)](#). *Cuminum cyminum* (Shwet jirak) is associated with significant decrease in serum insulin level hence has an impact on weight and BMI [Taghizadeh et al. \(2015\)](#). *Enicostemma littorale* blume (Mamejava) has alkaloids which reduces weight, BMI, serum lipids hence possesses anti-lipase and anti-obesity potential [Garg & Singh \(2015\)](#). *Ciccus quadrangularis* (Gokshur) have significant anti hyperlipidaemic effect [Talreja \(2015\)](#). Trikatu is a polyherbal combination contains Maricha (*Piper nigrum*), Pippali (*Piper longum*), Shunthi (*Zinziber officinalis*) is mostly used in all the medicines used in Obesity (Medorog) as it has anti-obesity and anti hyperlipidaemic effect [Thakkar & Jadhav \(2022\)](#). Guggulu resin significantly decreases weight and ultimately BMI and obesity it also reduces serum cholesterol, triglycerides, and LDL level [Gupte et al. \(2020\)](#).

## 6. CONCLUSION

Causative factors for Obesity (Medorog) mentioned in the ayurveda texts are changing now a days. Stress, altered faulty food habit, lack of exercise, sedentary life style is becoming prominent causative factors. The result indicates that both Virechana Karma and the preparatory procedures to correct lipid metabolism have an effect against the metabolic syndrome caused by insulin resistance and reduce body weight, BMI, serum triglycerides and blood glucose levels. Obetox protocol along with herbal remedies gives significant results in the Obesity.

## CONFLICT OF INTERESTS

None.

## ACKNOWLEDGMENTS

None.

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