

# Efficacy of *Medohar Arka* in *Sthaulya* (Overweight) – A single blind placebo controlled clinical study

#### Research Article

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#### Abstract

In Ayurveda, Sthaulya is santarpanothha vyadhi caused by excessive accumulation of Meda resulting in pendulous appearance of Sphik, Udara and Stana. It can be correlated with overweight or obesity. Obesity is characterized by abnormal growth of adipose tissue due to enlargement of fat cell size or number which is expressed in BMI, 24.9 kg/m² to 29.9 kg/m² indicates overweight and >30 kg/m² indicates obesity. Studies have been conducted on medications like *medohar guggulu*, *navaka guggulu* but *Medohar Arka* was relatively unexplored. It is a low cost medicine described by *Ras Tantra Saara and Siddha Prayoga Sangraha* for *sthaulya*. Material and Methods-Study comprised of 66 participants between age group of 20-50 years, either sex, having B.M.I. between 25-30 kg/m². Group M was treated with Medohar Arka 15ml twice daily before food with equal amount of water whereas Group P was treated with Placebo 250 mg twice daily before food with equal amount water for 90 days. Pathyapathya and vyayama was advised to both groups in the form of Ahar (Diet) and Vihar(30 min brisk walk). Assessment was done on day 0 and day 90 (completion of treatment). Participants were assessed for objective parameters like Body Mass Index, Waist Hip Ratio(WHR) and Mid Arm circumference(MAC). On comparing both the groups, statistically significant improvement was observed in Body Mass Index, Waist Hip Ratio, Mid Arm circumference in Medohar arka group. Conclusion- Medohar Arka was effective in managing overweight. Further study could be conducted on obese patients for generalized use of this medicine.

Keywords: Sthaulya, Overweight, Medohar arka, BMI.

#### Introduction

In Ayurveda, "sthaulya" is defined as a person with a bulbous Stana (Chest) ,Sphika (Hip) and Udara (Abdomen), and caused by excessive Meda deposition in those areas, as well as disproportionate or aberrant distribution of Meda and a lessened enthusiasm for life(1). Meda obstructs the srotas and Vata primarily moves into Aamashya, where it strengthens the Agni and assimilates the food. As a result, the obese individual digests meals quickly and has intense hunger. Overeating causes Meda Dhatu to grow too quickly, which results in Sthulata. Furthermore, in his emphasis on the etiopathogenesis of Sthaulya, Acharya Sushruta stressed the role of metabolic abnormalities (Dhatvaagnimandya)(2). The patient of Sthaulya displays an odd occurrence where their appetite is excessive and their food is swiftly broken down, which suggests that the Jatharaagni is overworking. In addition to this, the patient exhibits laziness, which may be brought on by a lack of energy or a Bhutaagni that is

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not operating properly. Additionally, *Dhatvaagni* appears to be disturbed, as in *Sthaulya*, mostly *Medo-Dhatu* forms and there is a shortage of other *dhatus*. Thus, *Jatharaagni* is *Tikshna* in *Sthaulya*, *Bhutaagni* is *Manda*, and *Dhatvaagni* is disturbed in its respective roles.

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As per the clinical features of *Sthaulya*, it can be correlated with overweight or obesity.

Being overweight is defined as having a BMI of 24.9-29.9 kg/m<sup>2</sup>, whilst obesity is characterized as having a BMI more than 30 kg/m<sup>2</sup>. (Class I 30-34.9 kg/m<sup>2</sup>, Class II 35.0-39.9kg/m<sup>2</sup>, Class III. >40 kg/m<sup>2</sup>).

In the survey of WHO conducted in 2016, over 1.9 billion people having the age of 18 and above were found overweight, and over 650 million were obese. Additionally, India is experiencing a quicker rate of growth in overweight and obesity than the rest of the world. For instance, between 1998 and 2015, the prevalence of obesity climbed from 2.2% to 5.1%, and the prevalence of overweight increased from 8.4% to 15.5% among women (3). Coronary artery disease, hypertension, type 2 diabetes, cholelithiasis, osteoarthritis, Deep Vein Thrombosis, and depression have all been linked to obesity (4). In a study, it was observed that risk of cardiovascular disease increases in people who are overweight, especially when there is central deposition of adipose tissue (5). Additionally, abdominal obesity has been ascertained as a risk factor for cardiovascular disease globally (6). Consequently,



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being obese increases the risk of hypertension along with cardiovascular disease, which becomes a point of serious concern (7). Chronic kidney disease, myocardial infarction, stroke and aneurysm can all be caused by long standing hypertension.

Medications in modern medicine such as orlistat, sibutramine, and naltrexone are being used to manage weight. FDA recommends it for a BMI of 30 kg/m2 or more or of 27 kg kg/m2 with a related risk factor such as hypertension, diabetes and its use is not recommended for more than 12 weeks if there is not a reduction in baseline body weight by 5% (8). These medicines have limitations due to its side effects such as hypertension, tachycardia, constipation, fecal incontinence, bloating, and poor fat-soluble vitamin absorption (9).

According to Ayurveda, Sthaulya is considered as Santarpanottha Vyadhi. The treatment principle includes shodhana and shamana for sthaulya which cause aptarpana. Based on the pathogenesis of Sthaulya facts and mentioned above, it can be stated that a medication that decreases Jatharaagni, especially Abhyavaharana shakti, increases Bhutaagni, corrects Dhatvaagni's functions, and has simultaneous Medohara, Kapha-hara, and Vatahara actions may be effective in treating it.

There are various *shamana* medications for *sthaulya* and *MedoharArka* is one such medication mentioned in *Rastantra Saar and Siddha Prayog Sangraha* which could be useful for people who are overweight. Additionally, it was discovered to have considerable weight-loss benefits in animal(10) and human experiment (11).

#### **Materials and Methods**

**Material -** Material related to the disease as well as the drug was appraised by collecting data from *Samhitas*, other classical books of Ayurveda and several books of modern science

#### **Procurement of medicine**

Medohar arka-It was procured from Prakriti Nutanvann Gausadan (Prakriti Pharma) Bulandshahar, Uttar Pradesh and its analytical test was conducted at Dattatreya Rasashala of MGACH&RC, Salod(H), Wardha.

# Composition of Medohar arka-

- Gomutra-12 L,
- Kesar (Crocus sativus L.) stigma 2gm

#### Placebo

Placebo capsules of 250 mg were prepared in *Dattatreya Rasashala*.

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**Clinical source:** Subjects visiting outdoor and indoor of *Kayachikitsa* department and from the specialty camps were registered for the study.

**Methodology:** Approval of Institutional Ethics Committee (Ref no. MGACHRC/IEC/July- 2021/330) was obtained.

The study was started after CTRI registration-Reg.no. CTRI/2021/10/037336.

Before commencement of study written informed consent was taken from each patient .

**Study Type:** Clinical Study

Study design: Randomized single blind (assessor

blinded) Placebo controlled clinical trial.

**Sample size**: 60 (30\*2)

#### **Inclusion Criteria**

Following participants were included in the study

- between the age group of 20-50 years of either sex
- who were in the BMI range of 25-30 kg/m<sup>2</sup>
- who were keen to participate in the study and sign the consent form

#### **Exclusion Criteria**

Following participants were excluded from the study

- who had drug induced obesity
- who were on anti-lipidemic medication
- K/C/o Hypothyroidism, Diabetes mellitus, Cardiovascular, Renal disorder
- Pregnant and lactating women.

#### Withdrawal Criteria

- Participant who was not willing to continue treatment.
- Participants who had features of any drug sensitivity or any other disease or problem during study were withdrawn.

# **Grouping and Posology**

Table 1: Grouping and Posology

				00		
Group	p Sample size Intervention		Dose & Frequency	Anupana	Duration	Follow up
Group M	30	Medohar arka	15 ml twice a day before meals	With equal quantity of water	90 days	On 30th, 60th, 90th day
Group P	30	Placebo	250 mg twice a day before meals	With equal quantity of water	90 days	On 30th, 60th, 90th day

Along with the medications, participants of both the groups were advised diet and physical activity during treatment period.

**Diet Therapy:** Participants were advised to restrict diet which may cause weight gain such as fried-junk food, baked food, maida, etc.

Physical activity: Daily 30 min. walk

Screening Parameters (Baseline): BMI, Waist Hip

ratio, Mid arm circumference **Treatment Period:** 90 days

**Follow up period**: On 30th, 60th, 90th day

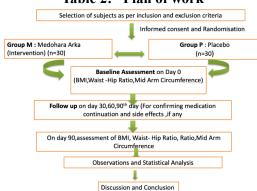


#### **Assessment Criteria**

The following Anthropometric assessment was done before and after treatment

- Body Mass Index (BMI)
- Waist-Hip ratio(WHR)
- Mid arm circumference(MAC) (mid of arm from shoulder joint to elbow joint) with measuring tape.

Table 2: Plan of work



# **Observations and Results**

A total of 66 participants were enrolled for the study. Participants in Group M and Group P were treated with *Medohar Arka* and Cap. Placebo respectively for 90 days. Out of the total participants, 3 dropped out from Group M due to characteristic smell of medicine and Group P due to non compliance in follow up. It was observed that 3 participants who had been prescribed *Medohar Arka* had burning sensation in abdomen after its intake which might be due to predominance of *pitta* in those individuals and *ushna guna* of the medicine could also be attributed to it. Also, 4 participants had frequent bowel movements post its intake which could be due to its *teekshna guna*.

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Objective parameters were assessed after completion of treatment and data was statistically analyzed using the student's paired t-test test.

Considering the factors affecting overweight, data regarding age, gender, Family history, *vyayam*,

type of meal were collected and analyzed along with the objective parameters.

Table 3: Distribution of participants according to age in both the groups

Croup	Age Group (in years)							
Group	21 - 30	31 – 40	41 - 50	Total				
Medohar Arka (Group M)	9 (30.0%)	10 (33.3%)	11 (36.7%)	30 (100.0%)				
Placebo (Group P)	16 (53.3%)	6 (20.0%)	8 (26.6%)	30 (100.0%)				
Total	25 (41.7%)	16 (26.7%)	19 (31.6%)	60 (100.0%)				

In the present study, participants between the age group of 20-50 years were included. 41.7% participants were in the age group of 21-30 yrs., 26.7% in the age group of 31-40, and 31.6% were in the age group of 41-50 yrs.

Table 4: Gender wise Distribution of participants in both groups

Cwann		Ge	Total	0/		
Group	Male	%	Female	%	Total	%
Medohar Arka (Group M)	9	30.0%	21	70.0%	30	100.0%
Placebo (Group P)	16	53.3%	14	46.7%	30	100.0%
Total	25	41.7%	35	58.3%	60	100.0%

In this study, gender-wise distribution of participants showed that 41.7% were male and 58.7% were females.

Table 5: Distribution of patients according to Family History

Group		Family	Total	%		
Group	Yes	%	No	%	Total	/0
Medohar Arka (Group M)	9	30.0%	21	70.0%	30	100.0%
Placebo (Group P)	10	33.3%	20	66.7%	30	100.0%
Total	19	31.7%	41	68.3%	60	100.0%

In the present study, it was observed that, out of 60 participants, family history of obesity was present in 31.7% patients and in 68.3% patients it was absent.

Table 6: Distribution of natients according to nature of diet in both groups

Table 6. Distribution of patients according to nature of dict in both groups									
Group		Nature	Total	%					
Group	Mixed	%	Veg	%	Totai	70			
Medohar Arka (Group M)	24	80.0%	6	20.0%	30	100.0%			
Placebo (Group P)	25	83.3%	5	16.7%	30	100.0%			
Total	49	81.7%	11	18.3%	60	100.0%			

Distribution of participants according to nature of diet showed that out of 60 participants, 18.3% were vegetarian, and in 81.7% took mixed diet.

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Table 7: Distribution of participants according to *Vyayam* in both the groups

Croun		Vya	Total	%					
Group	Yes	%	No	%	Total	70			
Medohar Arka (Group M)	8	26.7%	22	73.3%	30	100.0%			
Placebo (Group P)	9	30.0%	21	70.0%	30	100.0%			
Total	17	28 3%	13	71.7%	60	100.0%			

In this study, out of 60 participants, *Vyayam* was already practiced by 28.3% participants and maximum participants, 71.7% did not indulge in any *vyayama* prior to the study.

Table 8: Distribution of participants according to Prakruti in both groups

Prakruti	Group								
Trakrati	Medohar Arka (Group M)	%	Placebo (Group P)	%					
KP(Kapha-Pittaj)	13	43.3%	12	40.0%					
KV(Kapha-vataj)	2	6.7%	6	20.0%					
PK(Pitta-kaphaj)	8	26.7%	8	26.7%					
PV(Pitta-vataj)	1	3.3%	1	3.3%					
VK(Vata-kaphaj)	4	13.3%	3	10.0%					
VP(Vata-pittaj)	2	6.7%	0	0.0%					
Total	30	100.0%	30	100.0%					

Prakruti wise distribution showed that, out of 60 participants, maximum 41.7% participants had Kapha-Pittaja Prakruti, 26.7% had Pitta-Kaphaj Prakruti, 13.3% had Kapha-Vataj Prakruti, 11.7% had Vata-Kaphaj Prakruti, 33.3% had Pitta-Vataj Prakruti and only 6.7% subjects had Vata-Pittaj Prakruti.

Table 9: Distribution of participants according to Agni in both groups

Agni	Group								
Agni	Medohar Arka (Group M)	%	Placebo (Group P)	%					
Manda	2	6.7%	7	23.3%					
Tikshna	19	63.3%	16	53.3%					
Vishama	9	30.0%	7	23.3%					
Total	30	100.0%	30	100.0%					

In this study, out of 60 participants, 15% had *Mandagni*, 58.3% had *Tikshnagni* and 26.7% participants had *Vishamagni*.

Table 10: Mean comparisons of BMI before and after treatment in both groups

BMI		Mean	S.D.	Std. Error	Mean Diff.	% Decrease	Paired t Statistic	P Value
Medohar Arka (Group M)	BMI 0 day BMI 90 day	28.93 27.61	1.348 1.440	0.246 0.263	1.32	4.56%	9.904	0.001* Significant
Placebo (Group P)	BMI 0 day BMI 90 day	28.26 28.07	1.814 1.875	0.331	0.190	0.67%	1.289	0.208 Nonsignificant

\* indicate significant difference at 5% level of significance

Before treatment in Group M, mean value of BMI was  $28.93\pm1.348$  which was reduced to  $27.61\pm1.440$  and showed a statistically significant improvement(p value 0.001). In Group P, before treatment, mean value of BMI was  $28.26\pm1.814$  which reduced to  $28.07\pm1.875$  and did not show statistically significant improvement (p value 0.208). The comparison of both groups showed statistically significant result in Group M in BMI.

**Table 11: Reduction in BMI of participants** 

	No. of Patients									
BMI range (kg/m²)	Group	M	Group P							
	0 day	90th day	0 day	90th day						
< 25	-	1(3.3%)	-	0						
25.0-27.5	5 (16.6%)	11(36.6%)	8(26.6%)	10(33.3%)						
27.6- 30.0	25 (83.3%)	18 (60%)	22(73.3%)	20 (66.6%)						

In the present study, BMI of participants, who were treated with *Medohar arka*, reduced significantly as compared to Placebo. Out of 30 participants in Group M, 16.6%(5) were in the BMI range of 25-27.5 kg/m<sup>2</sup> on the initial day of treatment which increased to 39.9%(12) at the end of treatment. Thus, there was 23.3% rise in number of participants in the category of 25-27.5 kg/m<sup>2</sup> as compared to Placebo which was mere 6.7%.



Table 12: Mean comparisons of Mid Arm Circumference from 0 to 90 days

Mid Arm Circumference (MAC)		Mean	S.D.	Std. Error	Mean Diff.	% Decrease	Paired t Statistic	P Value
Medohar Arka (Group M)	MAC 0 day MAC 90 day	32.40 30.93	3.013 2.876	0.550 0.525	1.47	4.54%	14.060	0.001* Significant
Placebo (Group P)	MAC 0 day MAC 90 day	31.43 31.12	2.596 2.741	0.474 0.492	0.31	6.03%	0.4018	0.654 Non Significant

<sup>\*</sup> indicate significant difference at 5% level of significance

Mean value of MAC before treatment in Group M was 32.40±3.01 which reduced to 30.93±2.87 on 90th day and was statistically significant (p value 0.001). In Group P, before treatment, mean value of MAC was 31.43±2.59 which reduced to 31.12±2.74 on 90th day which was statistically non significant. Thus, Medohar Arka was effective in reducing MAC.

Table 13: Mean comparisons of WHR from 0 to 90 days

WH	WHR		S.D.	Std. Error	Mean Diff.	% Decrease	Paired t Statistic	P Value
Medohar Arka	MAC 0 day	0.94	0.050	0.009	0.02	2.13%	4.382	0.001*
(Group M)	MAC 90 day	0.92	0.045	0.008				Significant
Placebo	MAC 0 day	0.92	0.056	0.010	0.00	0.0%	0.162	0.873
(Group P)	MAC 90 day	0.92	0.055	0.010	0.00	0.070	0.102	Non Significant

<sup>\*</sup> indicates significant difference at 5% level of significance

Before treatment in group M mean value of WHR was 0.94±0.05 which reduced to 0.92±0.04 90th day and was statistically significant. (p value 0.001).

In group P, before treatment, mean value of WHR was  $0.92\pm0.05$  which almost remained same to  $0.92\pm0.05$  on 90th day. The p value 0.87 shows statistically non-significant on 90th day. The comparison of both groups, group M showed significant improvement in WHR than group P.

#### Discussion

This study evaluated the therapeutic efficacy of *Medohar Arka* in overweight patients having a Body Mass index in the range of 25 kg/m2 to 30 kg/m2.

Participants in group M were treated with *Medohar Arka* 15 ml twice a day with equal quantity of water on empty stomach whereas participants in group P were treated with Placebo capsules 250 mg twice a day before meals for 90 days. Individuals were assessed for objective parameters like Body Mass Index(BMI), Waist-Hip ratio (WHR) and Mid arm circumference (MAC) during and after the treatment.

According to the demographic data included in the current study, being overweight was prevalent in the age group of 21-30 years. Agrawal Ashish et al. found more incidence between the age group of 21-30 years, which was similar to this study(12). According to modern science obesity and overweight can occur at any age and it increases with advanced age. The study population of this trial comprised of the age group 21-30 years hence prevalence might be more in this age group. And also, it might be due to faulty dietary habits and the sedentary lifestyle of this age group people.

In the present study, more incidence of obesity was observed in females (58.7%) as compared to males. Sunanda Math, et.al. reported more incidence of obesity in females (73%) which was comparable to this

study(13). According to modern science, females are more prone to obesity and overweight than males due to sedentary lifestyles, eating high-calorie food, hormonal changes, and use of contraceptive devices(14)

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Out of the total of 60 participants enrolled for the study the evidence of family history was absent in 68.3% of patients. Pardhekar et.al found absence of evidence of family history in 66.67% of participants which was similar to our study(15). But, Acharya Charak has mentioned Beejadosha (Genetic factor) as one of the important factors in the pathogenesis of Sthaulya and as per modern science genetic component is present in the etiology of obesity(16). Since the patients enrolled were overweight and not obese, thus family history was not evident in this study.

Out of the 60 participants enrolled in the study maximum (81.7%) were taking a mixed type of diet. Anjali et.al. reported higher (70%) incidence of obesity in individuals taking a mixed diet which supports the finding of our study(17). Excessive consumption of an oily and fatty diet is one of the causative factors of Sthaulya mentioned by Acharya Charak(18). Additionally, since subjects were recruited from a region where people consumed mixed diet more, hence the incidence of Sthaulya was more in such subjects.

In the present study out of 60 participants,71.7% did not practice any Vyayam (physical exercise). Jayasiri et.al. found similar finding (86.70%) which is comparable to present study(19). Avyayam (physical inactivity) is major causative factor for Sthaulya as per Ayurveda(20)and modern science. Due to lack of physical activities and sedentary lifestyle energy expenditure of the body reduced as compared to energy intake which leads to obesity.

Among the 60 participants, 41.7% had Kapha-Pittaj Prakruti. This showed that Sthaulya is prevalent in Kapha-pitta Pradhan Prakruti and there is dominance of Kapha Dosha. A study conducted by Jatin et.al. showed



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more incidence of obesity in Kapha-Pittaja Prakruti which was comparable to our study(21).

In this study, majority 58.3% of participants had Tikshnagni. Barman et.al. conducted study on Sthaulya and found more incidence of Tikshnagni (52.5%) in their study which was supportive to this study(22). Tikshnagni causes Atikshudha which is one of the causes of Sthaulya(23).

In this study, mean score of BMI before treatment was 28.93±1.34 and 28.26±1.81 in group M and group P respectively which reduced to 27.61±1.44 and 28.07±1.87 in group M and group P respectively after treatment which showed statistically significant improvement in group M (p-value 0.001). Study conducted by Kumar Saini et.al showed similar results where mean BMI score of patients treated with gomutra reduced from 38.1±0.81 to 35.8±0.9 which was statistically significant (p-value <0.001)(24).

In this study, before treatment mean score of MAC was 32.4± 3.01 and 30.93±1.41 in group M and group P respectively which reduced to 30.93±2.87 and 30.77±2.73 in group M and group P respectively after treatment. MAC showed statistically significant improvement after treatment group M with a p-value of 0.001.Similar findings were observed in study conducted by Kumar Saini, et.al where MAC reduced from 31.8±0.54 to 30.3±0.48 at the end of treatment which was statistically significant(p-value <0.001)(25).

In this study, the mean score of WHR before treatment was 0.94±0.05 and 0.92±0.05 in group M and group P respectively which was reduced to 0.92±0.04 and 0.92±0.05 in group M and group P respectively after treatment. WHR showed statistically significant improvement after treatment in group M(p-value 0.001) and statistically non significant result in group P (p value 0.87). In the study conducted by Pankaj kumar et.al, where patients were treated with gomutra haritaki revealed that there was significant reduction(p-value <0.001) in Waist Hip ratio from 0.99±0.03 to 0.95±0.05 at the end of treatment which was similar to the findings obtained in the present study(26).

Characteristics of *Medohar Arka* like *Deepana*, *Vatanuloman*, *Kaphamedohar*, *Lekhana*, and *Sthaulyahar* would have contributed to the statistically significant reduction in objective parameters like BMI, Mid arm circumference, and Waist-Hip Ratio. All of these characteristics contributed to the dissolution of *Sthaulya's Samprapti* and the removal of excess *Kapha* and *Meda* through the action of *lekhana* (scraping), which could have lowered BMI, MAC, and WHR.

#### **Probable Mode of Action**

Medohar Arka contains Gomutra Arka and Kesar. *Kapha dosha* is involved in the pathogenesis of *Sthaulya*. *Medohar Arka* due to its *Ushna virya* alleviated *Kapha dosha*. Also, *Kaphahara* action could be attained by *Katu rasa* and *rooksha-laghu guna*.

Meda being the chief cause of Sthaulya, Medoahar Arka performed Medo-shoshaana karma due to Katu rasa and Rooksha guna. Ushna veerya could also have helped in dissolution of Meda. Medohara Arka could have, Pachana ,Deepana and Lekhana properties by virtue of Ushna veerya and Katu rasa.

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Thus, it ignited Agni and helped in pachana of Ama, thereby, alleviating improperly formed Ama dhatu. Katu rasa and Ushna veerya also encountered weakened Dhatwagni and ignited it. Due to Katu rasa, Medohar Arka caused dilatation of all the channels involved i.e Srotansivivrunoti. Ushna veerya and Katu rasa checked over Mamsavaha and Medovaha srotodushti.

Phytochemical screening of *Medohar Arka* showed that flavonoids, tannins, polyphenol and saponin were present in considerable amount. Antiangiogenic activity of Polyphenols suppresses the growth of adipose tissue and modulates adipocyte metabolism.

While small intestinal absorption of dietary fat is inhibited by saponin, which also reduces the pancreatic lipase activity(27). Crocetin produced by disintegration of crocin in the gut—reduces fat absorption and as a result reduces energy intake and body weight through pancreatic lipase inhibition(28). Thus, presence of both these phytochemicals could have played a critical role in the observed anti- obesity activity. Thus, through the above mode of action *Medohar Arka* could have helped in combating *sthaulya*.

## Conclusion

From this study, it could be concluded that female patients were more prone to overweight than males. Kapha-Pittaj Prakruti with Tikshna agni was also found to be a factor for being overweight. Significant improvement was observed in objective parameters like Body Mass Index (BMI), Waist Hip Ratio (WHR), Mid Arm circumference (MAC) in group that was prescribed Medohar Arka. So, it could be concluded that Medohar Arka is effective in the management of Sthaulya (Overweight) and is a cheaper alternative to other medications without adverse effects.

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