

**RANDOMIZED CONTROL CLINICAL TRIAL OF A NOVEL
COMPOUND DRUG *MEDONASHAK VATI AND CHIRBILVA*
(*HOLEPTELLIA INTREGRIFOLIA*) KWATH IN THE MANAGEMENT
OF *MEDOROGA* (OBESITY)**

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ABSTRACT

Nowadays obesity is a great problem in both developed and developing countries, affecting children as well as adults. Prevalence of obesity is increasing day by day due to alteration in eating habits, physical inactivity, emotional disturbances, increased alcohol consumption, smoking etc. Obesity is a major risk factor for many severe diseases like hypertension, diabetes mellitus, cardiovascular disorders, joint diseases, pulmonary diseases, endocrine disorders, cancer etc. Ayurveda deals with various dimensions of life and it is related to each and every living being present in the universe. Each and every activities of individual have been aimed to achieve *sukha*, by the right way of living. In Ayurvedic text eight types of body traits has been described. *Atisthaulya* is one of them, which deserves special attention, as it has been considered as a commonest risk factor for various

disorders. To evaluate the efficacy and safety aspects of a Novel Ayurvedic regimen ie *Medonashak vati* and *Chirbilva (Holeptellia integrifolia) kwath* in *medoroga*, a Randomized Control Clinical Trial was conducted in 50 patients of *medoroga* in Department of Swasthavritta, Patanjali Bharteeya Ayurvedigyan Avum Anusandhan Sansthan, Haridwar,

Uttarakhand. Assessment of efficacy was done by using a self designed proforma considering the the assessment of objective parameters such as Body mass index (BMI), Total Cholesterol, Triglycerides. High density lipid (HDL), Low density lipid (LDL) and Haemoglobin (Hb%) before and after the treatment. At the end of the treatment period, symptomatic improvement was found in the patients, statistically significant ($p < 0.001$) reduction in the parameters was noticed. No side effects were reported by the patients over the treatment period.

KEYWORDS: *Atisthauilya, Chirbilva, Medonashak vati, Medoroga,*

INTRODUCTION

It is well known that “Prevention is better than cure”. Previously it was thought that some drug formulations may prevent the *sthaulya* and serve the mankind, but now it has been observed that change in dietary regimen, life style have great role in prevention of obesity. For prevention and control of *sthaulya* Ayurveda has mentioned various life style measure and drugs.

Medoroga is described in the various classical texts of *Ayurveda* referring to excess fat deposition in the body resulting in flabby appearance.^[1] Faulty diet pattern, lifestyle and hereditary factors contribute to manifestation of *medoroga*.^[2] *Medoroga*, if not treated properly leads to certain diseases like *Prameha*, *Jwara*, *Bhagandara*, *Vrana* and *Vataroga*, and respective related complications.^[3] Diseases/complications that occur in patients of *medoroga* are more difficult to treat than in patients who do not have *medoroga*.^[4]

Acharya Charaka has defined the *Ati sthaulya* term as due to vitiation of *kapha dosha*, excess *medas* gets deposited in the body especially in the *stana/uras* (chest), *udara* (abdomen) and *sphik* (hip) regions in *medoroga*.^[5]

Sthauilya is the disease of abnormal *medodhatu*, Adhamala commentator of Sharangdhara Samhita has clearly mentioned that *medodosa ek prakar*.

Acharya Charaka(1500BC) has listed *atisthauilya* disease in *medodusti janya roga* and described its aetiopathogenesis, clinical features, complications.^[6] *Sthauilya* has been considered as a *Nanatamaj* or specific disease of *kapha* and it has been described in eight censurable personalities.

Acharya Sushruta (500BC) has classified *medoroga* in two groups, *Sthaulya* and *Karshya*. The proper *ahara rasa* has been claimed as a responsible factor for both conditions *sthaulya* and *karshya*. Its aetiology, clinical feature has been also described with complication like *prameha*, *prameha pidika*, *bhagandara*^[7] etc.

Acharya vagbhata (500 AD) has described *atisthaulya* disease under the title of *atibrinhanajanya roga*.^[8] The peculiarity of Vagabhata is that he has considered congenital *atisthaulya* disease produced through excess intake of *madhura rasa* by pregnant lady.

Acharya Madhavakara(700 AD) has described the sign and symptoms of *sthaulya* under title of *medoroga* in his text *Madhava Nidana*.^[9]

In 17th century A.D. Yoga Ratnakar has described a separate chapter on *Medoroga* and he has followed by the Bhava prakash.

In 18th Century Gobind Das Sen has described the management of *medoroga*.^[10]

The concepts of Aetiology, Pathogenesis, Clinical features, Complications, Management of *Medoroga* are in following manner.

AETIOLOGY

Avyāyāmadivāswapnaslēshmalāhārasēvinah|
Madhurōnnarasah prāyah snēhānmēdah pravardhayēt ||
Mēdasāvrutmārgatwāt pushyantyanyē na dhātavah|

In a person doing no physical exercise, enjoying day sleep, and taking *kapha*-provoking diet, sweet substances in the food juice are generally converted into *sneha* which leads to increase in the fat. Consequently, other body tissues do not get properly nourished in him because of the channels being blocked with fat.^[11]

PATHOGENESIS

By the *nidana sevana* i.e. excessive intake of *madhura*, *snighda*, *guru ahara* and activities like *divaswapna*, *avyayama* etc. *kapha* gets aggravated. The *ahara rasa* is homologous to the properties of *medodhatu*. The properties of *Kapha* is similar to the *medodhatu*, hence any increase in *kapha dosha* will constantly increase the *medodhatu*.

Due to the obstruction of Srotas (passage) by the fat, the movement of *vata* is specially confined to *kostha* (abdominal viscera) resulting in stimulation of the digestive power and absorption of the food. So the patient digests the food quickly and becomes a frequent eater.

If he does not get food (as and) when he needs it, he can be subjected to many diseases of serious nature¹². Among them the *agni* (*Pitta* responsible for digestion) and *vata* are the most troublesome factors. In the event of disproportionate increase of fat, diseases of very serious types are caused abruptly by *vata* dosha, which may lead to instantaneous death.

Owing to an excessive increase of fat and muscle tissue, the buttock, abdomen and breast become pendulous and strength of the person is rendered disproportionate with physical growth. Thus, the defects of the corpulent persons, their causes, signs and symptoms have been explained.^[12]

CLINICAL FEATURES

The *lakshana* of *medoroga* (clinical features) have been described in the *Ayurvedic* classical text *Madhava Nidana*.

Mēdastu chīyatē tasmādaśaktah sarvakarmasu ||

Kshudraswāstrushāmōhaswapna krathanasādanaih |

Yuktah kshutswēdadaurgandhyairalpaprānōl-pamāithunah ||

Mēdastu sarvabhūtānāmudarēnwastishu sthitam |

At evōdarē vruddhih prāyō mēdasvinō bhavēt ||

With the accumulation of fat, the person finds difficulty in doing all activities. *Medo roga* is associated with dyspnoea on exertion, thirst, drowsiness, sleepiness, sudden (momentary) obstruction to respiration, body ache, voracious appetite, excessive sweating and bad odour from the body. Life expectancy as well as sexual potency is decreased. Physiologically, there is a tendency for the fat to accumulate in the abdomen and in the bones (in the form of bone marrow). Pathologically, there is an excessive enlargement of the belly due to fat accumulation. Sudden obstruction to respiration is related to the Sanskrit word *krathana* in the verse. The word *krathana* also means snoring as given in the classical text *Basavarajeeyam*.^[13]

MATERIAL AND METHOD

A Randomized Control Clinical Trial was conducted in 50 patients of *medoroga* in Department of Swasthavritta, Patanjali Bharteeya Ayurvigyan Avum Anusandhan Sansthan, Haridwar, Uttarakhand.

Inclusion criterias

Patients of both sex with age group of 25 to 60 yrs.

Patients having BMI > 25

Patients who have rapid gain weight from past 6 months.

Exclusion Criterias

Patients with age < 25 and > 60 yrs.

Patients having obesity due to disorders of endocrine glands, genetic factors and drugs.

Patients suffering from serious complication like Diabetes mellitus, Hypertension, Coronary artery disease, Congestive Heart Disease, Osteoarthritis, Hyper ventilation syndrome, breathlessness, reproductive hormones abnormalities, impaired fertility, foetal anomaly associated with maternal obesity.

STUDY DESIGN

Pre treatment evaluation

All the persons were thoroughly enquired about age, sex, address, occupation, education, socio-economic status, life style, dietary habit at the time of registration.

After preliminary registration, persons were subjected to detailed case history and physical examination.

RANDOMISED CLINICAL TRIAL DESIGN

Out of 50 patient, 25 persons were randomized in each to two group I and II.

Group I: The persons received the trial drug "*Medonasak vati*" in a dose of 1gm twice a day and *Chirbilva kwath* 50 ml twice a day before meals.

Group II: The persons received the empty soft gelatine capsules in dose of two capsules twice a day before meals.

All groups received total treatment for three months with every 45 days follow-up.

Diet and lifestyle

All the patient were advised for normal diet and follow their normal daily routine.

(A) Assessment parameters

BMI-Body Mass Index

Total Cholesterol

Triglycerides.

HDL-High Density Lipid

LDL-Low Density Lipid

Hb%- Haemoglobin

DRUG DESIGN

Preparation of the Trial Drugs and Dose

“Medonasak vati” contains Amalaki Haritaki, Guruchi, Vidang, Mustaka, Shunthi, Puran Guggulu, Trikatu, one part each, Shilajatu and Shudha Lauha Bhasma 1/4th part each and the drug was administered orally in vati form. Each vati having the weight of 500mg.

Chirbilva kwath was made by adding 20gm of churna of Chirbilva powder in 400 ml of water and after heating when 100ml of decoction remained, 50 ml was taken two times in a day.

Results of Drug Trial

Assessment Parameters were taken in to consideration for evaluation of the drug effect. Response of treatment were assessed in each follow-up of 45 days (Total 2 follow up), In Parameter, BMI-body mass index, Total cholesterol, Triglycerides Lipid profile, and Hb% were assessed before and after the completion of treatment for 3 months. This selection is divided in to 2 categories.

Table 1: Showing the effect of drug on BMI.

Groups	BMI mean \pm SD			Within the group comparison (Paired 't' test)	
	BT	F ₁	F ₂	BT vs F ₁ (BT-F ₁)	BT vs F ₂ (BT - F ₂)
Group-I Drug (n=25)	31.23 \pm 4.25	29.39 \pm 3.42	28.99 \pm 3.58	1.85 \pm 1.40 t = 6.60 p < 0.001 HS	2.25 \pm 1.39 t = 8.10 p < 0.001 HS
Group-II Placebo (n=25)	31.16 \pm 4.04	30.93 \pm 3.51	30.85 \pm 3.39	0.23 \pm 2.40 t = 0.49 p > 0.05 HS	0.31 \pm 2.42 t = 0.65 p > 0.05 HS

According to above data mean decrease in BMI in 1st and 2nd follow up was 1.85 and 2.25 respectively and both were statistically highly significant, however mean decrease at 1st & 2nd followup in placebo group was observed statistically non significant.

Table 2: Showing the effect of drug on Total cholesterol.

Groups	Total cholesterol mean \pm SD			Within the group comparison (Paired 't' test)	
	BT	F ₁	F ₂	BT vs F ₁ (BT-F ₁)	BT vs F ₂ (BT - F ₂)
Group-I Drug (n=25)	234.80 \pm 30.65	222.44 \pm 37.68	216.88 \pm 36.13	12.36 \pm 27.48 t = 2.25 p < 0.05 S	17.92 \pm 33.26 t = 2.69 p < 0.02 S
Group-II Placebo (n=25)	247.28 \pm 26.26	247.84 \pm 27.31	247.48 \pm 26.64	-0.56 \pm 5.28 t = 0.53 p > 0.05 NS	-0.20 \pm 4.88 t = 0.20 p > 0.05 NS

In above data the initial mean of Total cholesterol in group-I was 234.80 \pm 30.65 which reduced to 222.44 \pm 37.68 after 1st follow up and 216.88 \pm 36.13 after 2nd follow up. In 3 months of treatment, the improvement in Total cholesterol was found statistically significant at 1st & 2nd follow up. While in group-II the initial mean was 247.28 \pm 26.26 which changed to 247.84 \pm 27.31 in 1st follow up and 247.48 \pm 26.64 in 2nd follow-up, the improvement in this group was not statistically significant [p > 0.05 (BT-F₁), p > 0.05 (B₂-F₁)]

Table3: Showing the effect of drug on Triglycerides.

Groups	Triglycerides mean \pm SD			Within the group comparison (Paired 't' test)	
	BT	F ₁	F ₂	BT vs F ₁ (BT-F ₁)	BT vs F ₂ (BT - F ₂)
Group-I Drug (n=25)	168.36 \pm 28.70	165.52 \pm 27.32	163.44 \pm 26.37	2.84 \pm 3.06 t = 4.63 p < 0.001 HS	4.92 \pm 4.04 t = 6.09 p < 0.001 HS
Group-II Placebo (n=25)	159.08 \pm 19.20	157.64 \pm 18.59	158.04 \pm 18.07	1.44 \pm 2.74 t = 2.63 p < 0.02 S	1.04 \pm 3.26 t = 1.60 p > 0.05 NS

In above data the initial mean of Triglycerides in group-I was 168.36 \pm 28.70 which reduced as 165.52 \pm 27.32 after 1st follow up and 163.44 \pm 26.37 after 2nd follow up. In 3 months of treatment the improvement in Triglycerides was found statistically highly significant at 1st and IInd follow up. While in group-II the initial mean was 159.08 \pm 19.20 which changed to 157.64

± 18.59 in 1st followup and 158.04 ± 18.07 in 2nd follow-up, the improvement in this group was statistically significant after 1st follow up and not significant at 2nd follow up [$p < 0.02$ (BT-F₁), $p > 0.05$ (B₂-F₁)].

Table 4: Showing the effect of drug on HDL.

Groups	HDL mean \pm SD			Within the group comparison (Paired 't' test)	
	BT	F ₁	F ₂	BT vs F ₁ (BT-F ₁)	BT vs F ₂ (BT - F ₂)
Group-I Drug (n=25)	38.28 \pm 2.84	38.76 \pm 2.52	39.88 \pm 2.49	-0.48 \pm 1.39 t = 1.73 p > 0.05 NS	-1.60 \pm 2.04 t = 3.92 p < 0.01 HS
Group-II Placebo (n=25)	37.68 \pm 2.23	37.72 \pm 2.46	38.52 \pm 2.02	-0.04 \pm 1.99 t = 0.10 p > 0.05 NS	-0.84 \pm 1.14 t = 3.67 p < 0.01 NS

In above data the initial mean of HDL in group-I was 38.28 ± 2.84 which reduced as 38.76 ± 2.52 after 1st follow up and 39.88 ± 2.49 after 2nd follow up. Here in 3 months of treatment the improvement in HDL was found not significant ($p > 0.05$) at 1st follow up but highly significant at 2nd follow up. While in group-II the initial mean was 37.68 ± 2.23 which changed to 37.72 ± 2.26 in 1st follow up and 38.52 ± 2.02 in 2nd follow up, the improvement in this group was not statistically significant [$p > 0.05$ (BT-F₁), $p < 0.01$ (B₂-F₁)].

Table 5: Showing the effect of drug on LDL.

Groups	LDL mean \pm SD			Within the group comparison (Paired 't' test)	
	BT	F ₁	F ₂	BT vs F ₁ (BT-F ₁)	BT vs F ₂ (BT - F ₂)
Group-I Drug (n=25)	134.00 \pm 18.72	131.16 \pm 17.69	129.12 \pm 16.11	2.84 \pm 2.37 t = 5.98 p < 0.001 HS	4.88 \pm 3.91 t = 6.24 p < 0.001 HS
Group-II Placebo (n=25)	135.16 \pm 14.55	134.08 \pm 14.67	133.48 \pm 14.63	1.08 \pm 3.08 t = 1.75 p > 0.05 NS	1.68 \pm 3.21 t = 2.62 p < 0.02 S

In above data the initial mean of LDL in group-I was 134.00 ± 18.72 which reduced as 131.16 ± 17.69 after 1st follow up and 129.12 ± 16.11 after 2nd follow up. In 3 months of treatment, the improvement in LDL was found highly significant at 1st and 2nd follow up. While in group-II the initial mean was 135.16 ± 14.55 which changed in 134.08 ± 14.67 in 1st

follow up and 133.48 ± 14.63 in 2nd follow up, the improvement was not significant at 1st follow up and significant at 2nd follow up.

Table 6: Showing the effect of drug on Hb%.

Groups	Hb% mean \pm SD			Within the group comparison (Paired 't' test)	
	BT	F ₁	F ₂	BT vs F ₁ (BT-F ₁)	BT vs F ₂ (BT - F ₂)
Group-I Drug (n=25)	11.94 \pm 1.22	12.25 \pm 1.14	12.58 \pm 1.07	-0.31 \pm 0.54 t = 2.88 p < 0.01 HS	-0.64 \pm 0.60 t = 5.38 p < 0.001 HS
Group-II Placebo (n=25)	11.92 \pm 1.38	11.76 \pm 1.38	11.91 \pm 1.33	0.16 \pm 0.73 t = 1.12 p > 0.05 NS	0.01 \pm 0.62 t = 0.10 p > 0.05 NS

In above data the initial mean of Hb% in group-I was 11.94 ± 1.22 which reduced as 12.25 ± 1.14 after 1st follow up and 12.58 ± 1.07 after 2nd follow up. In 3 months of treatment the improvement in Hb% was found statistically highly significant at 1st & 2nd follow up. While in group-II the initial mean was 11.92 ± 1.38 which changed to 11.76 ± 1.38 in 1st follow up and 11.91 ± 1.33 in 2nd follow-up, the improvement in this group was not statistically significant [$p > 0.05$ (BT-F₁), $p > 0.05$ (B₂-F₁)].

Inter Group Comparison of All Above Assessment Criteria.

When Mean difference of BMI of group I was compared with group II, both resulted statistically highly significant, the mean decrease in BMI in group-I was higher than group-II in both follow up.

The Mean decreases in total Cholesterol at 1st and 2nd follow up was higher as compared to group-II and difference was statically significant.

Mean decrease in Triglyceride of group-I when compared with group-II it was found not significant at 1st follow up where as highly significant at 2nd follow up.

Mean increase in HDL of group-I when compaired with group-II it was found not significant at 1st follow up where as highly significant at 2nd follow up.

Mean decrease in LDL of group-I when compared with group-II it was found not significant at 1st followup where as highly significant at 2nd follow up.

The Mean difference in Hb% of group-I when compared with group-II, It was found significant at 1st follow up while highly significant at 2nd follow up.

DISCUSSION

The aim of Ayurveda is to prevent the health of every person and to cure the diseases of patients. *Sthaulya* is an abnormal condition, so it needs prevention. It is a condition of increased body weight and dimensions. Persons having equal proportion of musculature and compactness of the body no doubt possess very strong sensory and motor organs and as such they are not overcome by the ambush of disease. They can stand hunger, thirst, the heat of the sun, cold and physical exercises. They can digest and assimilate properly.

Modern sciences of preventive and social medicine also defines obesity as an abnormal growth of adipose tissue due to enlargement of fat cell on an increase number of fat cells or a combined status of both may be present. In Ayurveda the physical inactivity, (*vihar*), eating habit (*ahara*) and psychological factors (*manasbhava*) have been considered as cause of obesity.^[14]

Acharya Charaka and Vagbhatta have stated a specific cause of obesity i.e. *bijadoshajanya* which is supported by modern science, because modern scientist consider genetic factor as a cause of obesity and they also consider the excessive eating habit of meals, sweet (*Madhura*), fat full diet (*Snigdha*) as a cause of obesity.^[15]

Adiposity is known to be associated with metabolic abnormalities. In most of the obese subjects metabolic alterations appear to be secondary to the obese state. Commonest abnormality is in the glucose metabolism resulting from an acquired insulin resistance at the periphery. Various lipid metabolism abnormalities are also recorded. Disorders in triglycerides and free fatty acid metabolism are the most significant. Obesity also alters the cholesterol metabolism to some extent.^[16]

An individual can take care to prevent the *sthaulata* by changing their life style but some people may require a therapeutic approach to prevent the disease, so the formulation named, “*Medonashak vati*” has been evaluated for management of *medoroga*. Its contents have been claimed as *medohara*, *Lekhan*, *Agni-varadhaka*, which may prevent the *sthaulyata*.^[17]

Amalaki is the *rasayana* (rejuvenating drug), it promotes the health and regulate the physiological phenomena of body. It has properties like *kapha*, *pitta samaka* and *bhedaka*. Due to *bhedaka guna* it is capable to destroying any type of obstruction in channels.

Haritaki is also *rasayana dravya*, *tridosha hara* and *lekhana*, it decreases the medodhatu by *lekhan karma*.

Guduchi has been regarded as a *rasayana* and it has been claimed to cure the visceral obstruction and it act on *medodhatu* directly.

Mustaka has been considered as a *lekhan dravya*. A lot of work has been done on mustaka and it has been found to reduce weight.

Vidang has *laghu*, *ruksha* and *tikshna* property so it increases gastric power and decreases the *meda* and *kapha*. It has been considered as *medohara*.

Guggulu is a great *medohara dravya* which has been proved by scientists.

Shilajatu has property of *lekhan* which reduces the weight and being a *rasayana* ultimately it is useful for body.

Trikatu and chirbilva have great power of *medonahsak* properties

Lauha is also *lekhan* and *rasayana*. In one hand it reduces the body weight, in other hand it maintains the normalcy of body by *rasayan* property.

Observation on BMI was found highly significant in group-I but in group-II it was found non-significant, It means this medicine is effective on BMI.^[18]

After use of medicine in group-I the decrease in Total cholesterol was observed significant and in group-II it was non-significant it means this drug prevent total cholesterol.

After use of medicine it was found that it is highly significant to control the triglyceride and in group-II it was found non-significant.

After using of “*Medonashak vati*” and “*Chirbilva kwath*” as a trial drug, The increase in HDL in group-I was highly significant while in group-II it was non-significant. Also it was found

that the drug was highly significant in decreasing LDL in group-I while in group-II it was found non-significant.

The drug was found capable in improving Hb%. It was found that after treatment it is highly significant in group-I and non-significant in group-II.

The effect of drug is good and it may be used by common person who are gaining weight because this drug is rasayana and has no any severe hazards. This is the concept of Ayurveda that rasayana may be used by common healthy person. The aim of rasayana is to control the abnormalities and to build up normal status of dhatu.^[19] It is stated in Ayurveda that Medo roga disease start on minor level and takes severity in later.^[20] So it will be better to control the *sthualata* in starting period with particular “Medonashak vati”. A common person can also use this rasayana in normal life which will prevent the some factor like cholesterol, triglyceride HDL etc. if taken in modern era.

CONCLUSION

The *Ayurvedic* regimen consisting of *Medonasak Vati* and *Chirbilva Kwath* as a medicine and diet pattern and walk exercise when administered for a 120-day treatment period to patients of *Medoroga* appears to be quite effective in terms of symptomatic improvement and reduction in physical parameters. The considered Assessment parameters were found to be within the respective normal ranges over the treatment period and so the regimen can be considered to be safe. No side effects were reported by any of the patients during the treatment period. The prescribed *Ayurvedic* regimen for a 120-day treatment period in *Medoroga* was found to be effective and safe.

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