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TO EVALUATE THE EFFICACY OF MADHAVIMOOLA (HIPTAGE BENGHALANSIS ROOT) AS STRI KATIBHAGA KSHEENAKA YOGA – A PILOT STUDY

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ABSTRACT

Background: Obesity (*Medo Roga)* is a *Kapha Pradhana, Atibrimhana Janya Vyadhi*, where *Shleshma Dosha* seated in (*Medodhatu).* According to Ayurvedic perspective, it is clear that *Kledaka Kapha, Samana-Vyana Vata, Pachaka Pitta, Medo Dhatu* and *Medodhatwagni* are involved in the pathogenesis of *Medo Roga*[1]. The excessively increased *Asthayi Medo Dhatu* is *Ama* in nature, due to which it is retained in the body for a longer period resulting in further complications. For this *Langhana* treatment is mainly highlighted in *Grantha*[2]. The challenging nature (relapsing) of the disease makes it difficult to be treated. **Aim and Objective:** The aim of the present study was to evaluate the efficacy of *Madhavimoola* in the reduction of female waist circumference. **Settings and Design:** Single arm, Open Randomised clinical trial. **Materials and Methods:** Here, *Madhavimoola* is selected for the study to evaluate its efficacy over female's waist circumference, on 30 patients for 45 days on empty stomach with (*Nisneha Takra*) fat-free buttermilk, early in the morning, in single group. **Results:** The results were highly significant (p<0.001) in the objective criteria → Waist Circumference, Hip Circumference, Waist-Hip Ratio, Weight, except than in BMI = 0.161. In subjective criteria Abdomen-Breast movements (*Udara-Stana Chalatva*) and symptom of weakness (*Daurbalya*) showed significant difference (p=0.016). **Conclusion:** The study showed good results in reducing waist circumference (*Katibhaga*) in female subjects.

Keywords: *Madhavimoola*, Obesity.

INTRODUCTION

Obesity is widely regarded as a pandemic with potentially disastrous consequences for human health. It may lead to profound social and psychological consequences for individuals. The prevalence of obesity has increased threefold with in the last 20 years and continues to rise[3]. When *Meda* (fat) is greatly increased in the body it leads to *Margavrodha* (channel obstruction) of *Vata*. The *Vata Dosha* gets vitiated and gives rise to various dreadful diseases[4]. In India, 12.1% of males and 16% of females were recorded as overweight/obese (National Family Health Survey-2007). Many studies in India have reported higher prevalence of obesity among women[5]. However, what is not generally recognized is the fact that obesity also has a great impact upon health outcomes for women than for men. This impact is seen in the physical, psychological and social well-being of women compared to men[6]. Studies show, circulating oestrogen stores lipid deposits in gluteo-femoral region and menopause associated oestrogen deficiency results in an accumulation of adipose deposits around the abdomen and waist area. Waist circumference and Waist-Hip Ratio are both related to increased risk of all-causes mortality, throughout the range of adult BMI's[7]. Considering this in mind, Madhavimoola, a drug mentioned in a classic *Chakradutta*, is selected for the study that helps reducing the *Strikati* (waist) *Bhaga*[8], when administered with *Nisneha Takra* (fat free buttermilk) which has *Ruksha, Laghu Guna* that acts as *Kaphamedohara*[9].

Objectives: To evaluate the efficacy of Madhavimoola in the reduction of female waist circumference.

Study design: Single Arm Open Clinical Trial.

Sample size: minimum 30 females.

Methodology

Drug Distribution: After taking consent and detailed history, a special case sheet proforma was prepared and filled. On every 15th day (0th, 15th, 30th day) the measurements as per the study criteria was taken till 45th day. The study subjects told to take *Kalka* (trial drug) on daily bases, with *Nisneha Takra* (fat free buttermilk).

Source of Data:

a) **Sample Source:** 30 patients fulfilling the diagnostic and inclusion criteria, attending the OPD, camps and another referral were selected randomly. Ethical clearance number **IEC No: ICEC/KC/05**

b) **Drug Source:** Raw drug identified, collected and authenticated by the botanist, from Kunjargiri (Udupi) and Manda forest (Jammu-J&K).

Figure 1: Roots of Hiptage benghalansis

Method of Collection of Data

i) **Selection of Patients:** Females fulfilling the diagnostic and inclusion criteria, irrespective of religion, occupation, socio economic status, educational status was randomly selected for the study.

ii) **Diagnostic Criteria:** Waist circumference > 80 cm (31.49 inches) -Waist-Hip Ratio > 0.85

iii) **Inclusion Criteria:**
- Females fulfilling the diagnostic criteria between the age group of 16-60 years were selected.
- Increased Waist-Hip Ratio.
- Participants who gave the written consent for the clinical trial on them.

iv) **Exclusion Criteria:**
- Vulnerable female groups.
- Patients having major systemic disorders or other illness which may interfere with the present clinical study.
- Secondary Obesity.

v) **Intervention:**
- *Madhavi Moola Kalka*, 1 *Karsha* (12 gms), on empty stomach in the morning with *Takra* (fat free buttermilk).

vi) **Observation Period:**
- Total course of treatment was of 45 days

- Assessment was done at baseline, 15th, 30th, 45th day of the study.

vii. **Assessment Criteria: primary and secondary outcome**

- Assessment of the condition was done on the basis of detailed case proforma, adopted standard scoring methods of assessment parameters.
- **Objective Criteria** - Waist Circumference, Hip Circumference, Waist-Hip Ratio, BMI.
  Objective parameters-

Waist circumference (cm); Hip circumference (cm); Waist-Hip ratio >0.80[10]; Weight (kg); Height (mt^2); BMI[11]

Overweight = 25-30 kg/m^2, Obese grade I = 30-35 kg/m^2, Obese grade II = 35-40 kg/m^2, Obese grade III = >40 kg/m^2

Subjective Criteria - *Sphik Chalatva, Udara Chalatva, Stana Chalatva, Aalasya, Krichra Vyavaya, Daurbalya, Daurgandha, Swedabadha, Kshudha Atimatra, Pipasa Atiyoga, Gourava.*

Table 1: Subjective parameters-

1.Sphik, Udara, *Stana Chalatva:*	Grade
Absent	0
Visibility of chalatva after fast movements	1
Visibility of chalatva after moderate movements	2
Visibility of chalatva after mild movements	3
Visibility of chalatva after postural change	4
2.Aalasya:	
No aalasya	0
Satisfactory work done with late initiation	1
Unsatisfactory work under mental pressure and takes time	2
Not starting any work on her own responsibility and doing little work	3
Does take any initiation and not want to work even after pressure	4
3.Nidra adhikya:	
Sleep 6-7 hrs/day	0
Sleep up to 8 hrs/day + anga gaurava	1
Sleep up to 8-9 hrs/day + anga gaurava + jrimbha	2
Sleep up to 10 hrs/day + tandra	3
Sleep > 10 hrs/day + tandra + klama	4
4.Krichra vyavaya:	
Unimpaired libido and sexual performance	0
Decrease in libido but, can perform sexual act	1
Decrease in libido but, can perform sexual act with difficulty	2
Loss of libido and cannot perform sexual act	3
**5.Daurbalya/ *Krichra Vyayama:* **	
Can do routine exercise	0
Can do moderate exercise without difficulty	1
Can do only mild exercise	2
Can do mild exercise with difficulty	3
Cannot do even mild exercise	4
6.Daurgandha:	
Absence of foul smell	0
Occasional bad smell from body, removed after bathing	1

Persistent bad smell limited to close areas, difficult to supress with deodorant	2
Persistent bad smell limited to close areas, difficult to supress with deodorant	3
Persistent bad smell felt from long distance even intolerable to the patient herself	4
7.Swedabadha:	
Sweating after heavy work/ fast movement/ in hot season	0
Profuse sweating after moderate work and movement	1
Sweating after little work and movement	2
Profuse sweating after little work and movement	3
Sweating even at rest or in cold climate	4
8.Pipasa atiyoga:	
Able to withstand thirst for more than 5 hrs.	0
Able to withstand thirst for not > 4 hrs.	1
Able to withstand thirst for not > 3 hrs.	2
Able to withstand thirst for not > 2 hrs.	3
Able to withstand thirst for not > 1 hr.	4
9.Kshudha atiyoga:	
Tolerate hunger above 3 hrs.	0
Tolerate hunger up to 3 hrs. with irritability	1
Tolerate hunger up to 2 hrs.	2
Tolerate hunger up to 2 hrs. with irritability	3
Cannot tolerate hunger for 1 hr.	4
10.Gaurava:	
No heaviness in the body	0
Heaviness in the body does not hampers routine work	1
Heaviness in the body hampers routine work	2
Heaviness in the body restricts routine work	3
Heaviness in the body destroys the routine work	4

Statistical analysis: Statistical Test of Significance - **paired 't' test** was implemented to test the hypothesis of the study, where the objective criteria was assessed statistically, and conclusion drawn on the basis of before and after completion of treatment. For the subjective criteria, Wilcoxon Signed Rank Test was implemented.

Observations & Results: Among the 30 patients, maximum patients belonged to age group 31-45 years. Most of them belonged to Hindu religion (25 patients), married (26 patients) with the positive family history (21 patients) and sedentary lifestyle (26 patients). Maximum were recorded with *Adhyashana,* *Mandagni, Madhyama Koshtha, Kapha Vata Prakruti, Madhyama - Satwa, Satmya, Sara, Samhanana, Pramana, Aahara Shakti* and *Avara Vyayama Shakti.* Results obtained after the clinical trial were analysed statistically and interpreted on the basis of assessment criteria before and after treatment. The final result showed that on 45th day of treatment, 12 patients (40%) showed minimal relief, 9 patients (30%) showed mild relief, 5 showed (16.66%) moderate relief, 1 patient (3.33%) showed marked relief and 3 patients showed (0%) no improvement. The clinical results for objective criteria were found to be statistically significant at p<0.001, except for BMI = 0.161.

Table 2: Effect of treatment on 45th day, on 30 patients in objective criteria:

Criteria	BT mean	AT mean	Difference in mean	%	SD	SE	t- value	P value (95% CI)
WC	41.23	38.30	2.93	7.10	3.534	0.645	7.150	<0.001
HC	45.25	44.31	0.94	2.07	4.617	0.843	4.296	<0.001
WHR	0.90	0.86	0.04	4.44	0.0799	0.0146	4.993	<0.001
BMI	32.09	31.74	0.35	1.09	4.526	0.826	1.439	=0.161
Wt.	78.21	76.88	1.33	1.70	12.319	2.249	4.431	<0.001

Table 3: Effect of treatment on 15th, 30th, 45th day on 30 patients in Udara chalatva:

Criteria	BT mean	AT mean	Difference in mean	%	SD	SE	z- value	P value
15th day	44	44	0	0	1.0080	0.1840	0.000	=1.000
30th day	44	37	7	15.90	0.9353	0.1708	-2.646	=0.016
45th day	44	34	10	22.72	0.8604	0.1571	-3.162	=0.002

Statistical analysis of single group study, showed that the mean of Udara Chalatva was 44 before treatment and after 15th day it was same, after analysing statistically, the change that occurred with the treatment is not great enough to exclude the possibility that it is due to chance (P = 1.000). After 30th day it was reduced to 37 after treatment. When these values were analysed statistically, the change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant difference (P = 0.016). On 45th day reduction was observed up to 34 and after analysing statistically, the change that occurred with the treatment is greater than would be expected by chance, there is a statistically significant difference (P = 0.002).

Table 4: Effect of treatment on 15th, 30th, 45th day on 30 patients in Stana Chalatva:

Criteria	BT mean	AT mean	Difference in mean	%	SD	SE	z- value	P value
15th day	42	42	0	0	1.0700	0.1953	0.000	=1.000
30th day	42	38	4	9.52	1.0148	0.1853	-2.000	=0.125
45th day	42	35	7	16.66	0.9499	0.1734	-2.646	**=0.016**

Statistical analysis of single group study, showed that the mean of Stana Chalatva was 42 before treatment and after 15th day it was same, after analysing statistically, the change that occurred with the treatment is not great enough to exclude the possibility that it is due to chance (P = 1.000). After 30th day it was reduced to 38 after treatment. When these values were analysed statistically, the change that occurred with the treatment is not great enough to exclude the possibility that it is due to chance (P = 0.125). On 45th day reduction was observed up to 35 and after analysing statistically, the change that occurred with the treatment is greater than would be expected by chance, there is a statistically significant difference (P = 0.016).

Table 5: Effect of treatment on 15th, 30th, 45th day on 30 patients in Daurbalya:

Criteria	BT mean	AT mean	Difference in mean	%	SD	SE	z- value	P value
15th day	45	45	0	0	1.2798	0.2337	0.000	=1.000
30th day	45	42	3	6.66	1.2205	0.2228	-1.732	=0.250
45th day	45	39	6	13.33	1.1492	0.2098	-2.449	=0.031

Statistical analysis of single group study, showed that the mean of Daurbalya was 45 before treatment and after 15th day it was same, after analysing statistically, the change that occurred with the treatment is not

great enough to exclude the possibility that it is due to chance (P = 1.000). After 30th day it was reduced to 42 after treatment. When these values were analysed statistically, the change that occurred with the treatment is not great enough to exclude the possibility that it is due to chance (P = 0.250). On 45th day reduction was observed up to 39 and after analysing statistically, the change that occurred with the treatment is greater than would be expected by chance, there is a statistically significant difference (P = 0.031).

Table 6: Overall improvement observed after treatment in 30 patients on 45th day:

Improvement	No. of patients	Percentage
Complete improvement (100%)	0	0
Marked improvement (75-99%)	1	3.33
Moderate improvement (50-74%)	5	16.66
Mild improvement (25-49%)	9	30
Minimal improvement (1-24%)	12	40
No improvement (0%)	3	10

The patients who reduced waist circumference up to 1-2 inches, were considered to be minimally improved, on reducing 3-4 inches mildly improvement was recorded. Moderate improvement was documented if patient reduced 5-6 inches, only 1 patient showed marked improvement with the reduction of 6.4 inches and no improvement was recorded when no marked change (less than 1 inch) was observed on 45th day (last day).

Untoward Symptoms: 1 patient out of 30 patients complained of pustules over axilla, thigh and abdomen, but continued the treatment as she was responding to the trial drug. Pustules subsided after the 3 days of the treatment completion.

DISCUSSION

On Trial Drug: The trial drug (*Madhavilata*) have *Laghu* and *Sheeta Guna, Katu-Tikta-Kashaya* and *Madhura Rasa, Sheeta Virya, Madhura Vipaka* and *Tridoshaghana* properties. [qualities of the above *Guna* → *Rooksha, Ushna, Laghu, Teekshna, Vishada, Kaphaghana, Langhana Karaka, Srotas Shodhaka, Karshaya Karaka, Agni Deepaka, Utsaha Karaka* all these acts opposite to the properties of *Kapha* and *Meda*, that leads to *Medoroga*.][12] Phytochemicals in root bark - Alkaloids (a bioactive component having promising effect in tackling obesity), Tannins (tannic acid is a major component of tannins, documented to stimulate the glucose transport and inhibits adiposity), Reducing sugar[13].

On Kala: The medicine has to be administered in the period of *Ananna/Abhakta Kala* (on empty stomach, early in the morning). Since, this is the time of administration for drug in *Kaphaudreka, Balwan Roga* and *Rogi* (*Anaanna Kala* – empty stomach), *Apana Vayu Vaigungya*, on empty stomach before food[14].

On Anupana: Here, *Takra* is taken as *Anupana*. According to *Acharya Sushruta*[15], *Takra* prepared by adding the water in curd (1/2: 1), after churning it properly extract the whole butter, the left fluid is *Nisneha Takra*. Having the properties *Madhura-Amla-Kashaya Rasa, Laghu-Rooksha Guna, Ushna Virya, Madhura Vipaka* and *Kapha-Vatahara.* Moreover, it is well known for its digestive property and administration in *Kapha-Medo Roga*.

Effect of Therapy on objective criteria:
The result of the study/clinical trial suggests that there is a significant change in all the objective criteria except BMI, which was also proved statistically.
Waist circumference- Test showed highly significant change with P value <0.001., Hip circumference- Test showed highly significant change with P value <0.001., Waist-Hip Ratio- Test showed highly significant change with P value <0.001., BMI- Test showed non-significant change with P value =0.161., Weight- Test showed highly significant change with P value <0.001.

Effect of therapy on *Lakshana* (Subjective Criteria): After the therapy, mild improvement on *Lakshana* was recorded like in *Udara-Stana Chalatva* and

Daurbalya. Statistical analysis by using Wilcoxon Signed Rank Test, Stat-32, Sigma Stat 4.0 version was done on the data collected showed, HS (highly significant) = 0.002 effect seen in *Udara chalatva* on 45th day. In *Stana Chalatva, Daurbalya, Swedabadha* and *Atikshudha* significant effects seen statistically, on 45th day.

CONCLUSION

Medo roga is *Santarpanotha Shleshmaja Vikara* considered as an independent *disease*, placed under the umbrella of lifestyle disorders, but it is the cause for *various* diseases too. It is characterised by excessive fat accumulation in different body parts, especially *Udara-Stana-Sphik,* causing its *Chalatva*. In this study, the main cause for increased female waist size was observed to be due to *Beejaswabhavaja*, followed by *Avyayama*. Maximum number of patients in the study belonged to service class followed by housewives, irregular, untimely eating and sleeping lead to this disease. Mixed diet, sedentary lifestyle, family history for the *Medoroga* and increased waist circumference was documented during the trial. As said "Prevention is better than cure" the phrase fits for this *Roga* well, hence, *Medoroga* is a *Krichra Sadhya Vyadhi*, (cured with difficulty) by following healthy regimen the disease can be prevented.

Limitation of the study: The patients were allowed to continue their regular routine (except additional sugar consumption).

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