A comparative study of Ayurvedic medicine and modern medicine treatment in *Medoroga* (overweight)

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**Abstract**---*Medoroga* (obesity) is one of the most important risk factors for the development of hyperlipidemia, atherosclerosis, cardiovascular disease, renal disease etc. and the leading cause of death. To compare the efficacy as Ayurvedic medicine and Modern medicine treatment modality on BMI, BMR, Waist Circumference & lipid profile in Overweight (*Medoroga*). Newly diagnosed *Medoroga* (Overweight) patients will be selected and divided into two groups. In both groups, dietary, physical therapy, and behavioral therapy will be recommended. According to modern medicine, it is the treatment protocol of overweight. Ayurveda also included *pathyaahar*, *vyayam* and *satvajay* in the treatment principle of *Medoroga*. In group A, *Jayantyadi churna* is given in a dose of 3 grams twice a day before meal for 180 days and as no medicine is advised in modern medicine for overweight, placebo will be given for 180 days. Follow up were performed on 0, 30th, 60th, 90th, 120th, 150th and 180th. Our hypothesis is that Group A can be found to be more effective than...
Introduction

Obesity is defined as abnormal or excessive body fat accumulation. It is an important health problem associated with a number of illnesses which leads to a variety of life-threatening illnesses and results in a reduction in a person’s lifespan.\(^1\)\(^-\)\(^2\)

According to the India-3 National Family Health Survey (NFHS-3), 13% of women (15-49 years) and 9% of men (15-49 years) were overweight or obese by 2005-06. The prevalence of overweight has doubled in last two decades in India.\(^3\) It has become epidemic in urban areas and is increasing at an alarming rate in rural areas. Prevalence of overweight was higher in urban areas than in rural areas and decreased in people involved in agriculture or handicrafts.\(^4\)

Rationale of study

In this era of modernization, Overweight is a curse to the human beings. In spite of advancement in treatment of overweight, its prevalence is increasing significantly. According to modern medicine, Diet, physical activities and behaviour therapy are the first line treatment modalities in the management of overweight.\(^5\)\(^-\)\(^9\)

In Ayurveda, the correlated condition to overweight is (Medoroga) which is mentioned in Madhavnidan\(^10\) and Sharangdhara\(^11\)Samhitas. The fundamental approach of Ayurveda to treat Medorogais to correct dhatvagnimandya leading to proper formation of dhatu.\(^12\) Guru, Apatarpanahar(diet therapy), Vyayama(exercise) and Shleshma-medohar medication. To keep this in mind, the current study is designed to evaluate the effectiveness of Ayurved and modern medicine treatments in the management of Medoroga (Obesity).\(^13\)\(^-\)\(^14\)

Aim – Objectives

Aim

To compare the efficacy as Ayurvedic medicine and Modern medicine treatment modality in Overweight (Medoroga).
Objectives

Primary Objectives:
- To study the efficacy of Ayurvedic medicine treatment on BMI, BMR & Waist Circumference in Overweight.
- To study the efficacy of Modern medicine treatment on BMI, BMR & Waist Circumference in Overweight.
- To compare the effectiveness of both treatment modalities in BMI, BMR, and Waist Circumference at Overweight
- To compare the effectiveness of both treatment modalities on Lipid profile

Secondary objectives
To study the correlation of prakruti in the pathogenesis of Medoroga (Overweight).

Case Definition
A patient having BMI in the range of 25-29.

Research Question
Whether Ayurvedic medicine treatment is more effective than Modern medicine treatment in Medoroga (Overweight)?

Hypothesis
Null hypothesis (H0): Ayurvedic medicine and Modern medicine treatment has similar effect in the management of Medoroga (Overweight).
Alternate hypothesis (H1): Ayurvedic medicine treatment modality is more effective than Modern medicine treatment in the management of Medoroga (Overweight).

Materials and Methods

Study Type:

Trial Design: A randomized double blind placebo controlled trial.
Sampling methods: Simple random technique by lottery method.
Blinding: Double blinding

Place of Study: This study will be conducted in Mahatma Gandhi Ayurved Hospital, Research Center DMIMS (DU), Salod (H), Wardha.

Material

1. Selection of patients – Patients will be selected as per inclusion criteria from O.P.D. and I.P.D. of Kayachikitsaof Mahatma Gandhi Ayurved Hospital, Research Center DMIMS (DU), Salod (H), Wardha.

2. Selection of Drug: All raw drugs required to manufacture the drug will be collected from local market and it will be authenticated by experts of Dravyaguna. Medicine will be prepared in the Rasashala of Mahatma Gandhi Ayurved Hospital, Research Center DMIMS (DU), Salod (H), Wardha.
3. Number of groups

- Group-A: (Ayurvedic medicine treatment) Diet therapy, Physical exercise, behavior therapy and *Jayantyadi Churna* (n=38).
- Group-B: (Modern medicine treatment) Diet therapy, Physical exercise, behavior therapy and Placebo (n=38).

<table>
<thead>
<tr>
<th>Group</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>Drug</td>
<td><em>Jayantyadi Churna</em></td>
<td>Placebo</td>
</tr>
<tr>
<td>Route of administration</td>
<td>Oral</td>
<td>Oral</td>
</tr>
<tr>
<td>Doses</td>
<td>3 cap. (1 gram each) twice a day</td>
<td>3 cap. (1 gram each) twice a day</td>
</tr>
<tr>
<td>Aushadhi sevan Kaal</td>
<td><em>Pragbhakta</em> (Two Hour Before Meals)</td>
<td><em>Pragbhakta</em> (Two Hour Before Meals)</td>
</tr>
<tr>
<td>Total Duration</td>
<td>180 days</td>
<td>180 days</td>
</tr>
</tbody>
</table>

**Diet Therapy**

The patients of both groups will be advised the daily calories as per their working pattern

- For female patient 1,000 to 1,200 kcal/day,
- For male patient 1,200 to 1,600 kcal/day.
  (The diet plan will be advised by Dietician)

**Physical Activity**

30 minutes daily walk for 6 months as per individual capacity.

**Behavior therapy**

Counseling regarding diet and physical activity will be done by Dietician and principal investigator on every visit.

**Inclusion criteria**

- Age group from 20-50 years, irrespective of sex, with similar socioeconomic status.
- BMI in the range of 25-29 (Weight in Kg / Height in m²).

**Exclusion criteria:**

- Patients of Coronary Heart disease, Atherosclerosis, Myocardial infarction, renal failure, Diabetes mellitus, Hypothyroidism
- Pregnancy and lactating women.
- Psychiatric illness.
- Patients with a history of anorexia nervosa or bulimia nervosa.
• Patients on steroids and *Guggul* therapy.
• Smokers.

**Withdrawal criteria:**
• Patient unwilling to continue the treatment.
• If any types of adverse effect seen

**Investigation:**
• Fasting blood sugar
• Lipid profile

**Sample size:**

\[
N > \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2/r)}{(\mu_1 - \mu_2)^2}
\]

Alpha (\(\alpha\)) 0.05
Beta (\(\beta\)) 0.2
Mean in group 1 (\(\mu_1\)) 1.768
Standard deviation in group 1 (\(\sigma_1\)) 1.722
Mean in group 2 (\(\mu_2\)) 0.653
Standard deviation in group 2 (\(\sigma_2\)) **1.346**
Ratio (Group 2 / Group 1) 1

Minimum sample size needed for group 1: 31
Minimum sample size needed for group 2: 31
38 patients needed in each group in the study. (Considering 20% as dropout)
N= **31**
= **38** patients needed in each group in the study. (Including 20% as dropout)

**Expected outcome**
Expected difference of BMI of 0.5kg/m\(^2\) will be considered as significant.

**Assessment Criteria**
• **BMI:** Weight will be measured in fasting state with same clothes on each visit.

<table>
<thead>
<tr>
<th>Improvement</th>
<th>Reduction in BMI (in kg/m(^2))</th>
</tr>
</thead>
<tbody>
<tr>
<td>I(_1) (&lt; 25 %)</td>
<td>-</td>
</tr>
<tr>
<td>I(_2) (25-50 %)</td>
<td>-</td>
</tr>
<tr>
<td>I(_3) (50-75 %)</td>
<td>-</td>
</tr>
<tr>
<td>I(_4) (&gt;75 %)</td>
<td>-</td>
</tr>
</tbody>
</table>

• **Waist circumference**

Follow up were performed on 0, 30\(^{th}\), 60\(^{th}\), 90\(^{th}\), 120\(^{th}\), 150\(^{th}\) and 180\(^{th}\) day.
Statistical Analysis: Data will be analyzed on the basis of appropriate statistics paired and unpaired test and ANOVA by using SPSS software. Time duration till follow up: The treatment duration will be of 180 days. Time schedule of enrolment, intervention:

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Gantt chart</th>
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<tbody>
<tr>
<td>Medicine Preparation</td>
<td>Q1</td>
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<tr>
<td>Patients Enrolment</td>
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<tr>
<td>Data Collection</td>
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<td>Data Analysis</td>
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<td>Thesis Writing</td>
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<td>Thesis submission</td>
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Recruitment: patients will be randomly recruited in group A & B by simple random sampling method.
Method: Literature review search, plan of work, Blueprint in the flow chart, preparation of medicine, data collection, treatment and its effect, will be observe which route of administration is best and statistical analysis.
Screening visit

Selection (Baseline Visit)

Follow up were performed on 0, 30th, 60th, 90th, 120th, 150th and 180th day.

On 180th day

Assessment at the end of 24th weeks

- Eligibility evaluation as per inclusion criteria

- Randomization- Group A (n=38), a trial Group. Group B (n=38), a placebo control Group.

  Assessment of BMI, BMR, Fasting Blood Sugar Waist circumference & PrakritiParikshan & lipid profile.

- Assessment of BMI, BMR, Waist circumference

- BMI, BMR, Waist circumference & Lipid profile

- Clinical Assessment
- Statistical Analysis
- Results and Conclusion

Figure 1. Schematic Diagram of Study Methodology
Data collection methods – Randomized sampling.

Objective parameters
- Body mass Index (kg/m²)
- Waist Circumference
- Lipid Profile

Investigations Routine
Lipid Profile (To rule out Hyperlipidemia and dislipidemia)

Data Management
Data coding will be done by principal investigator.

Statistical Method
Statistical analysis will be done using chi-square tests and unpaired ‘t’ student tests.

Ethics and dissemination
This study was approved by the Institutional Ethics Committee of MGACHRC/IEC/February-2021/192 Dt. 16/02/2021, all participants will ask to read and sign the informed consent. The study results will be disseminated to study participants and published in peer-reviewed publications.

Consent OR Assent
Before starting the intervention patient will be given detail information regarding intervention, preparation of medicine and drug doses accordingly in his own language then the written consent will be taken from patients before starting the study. During study confidentiality will be maintain.

Dissemination policy
The data will be spreading in the form of paper publication and Monograph. Authorship eligibility guidelines and any intended use of professional writers.

Informed consent materials
The subjects will be given all consent materials in the form of hard copy, and other related documents.

Discussion
Jatharagni (digestive fire) plays a major role in proper nutrition of Dhatu. The etiopathogenic factor of Medovridhhi is hypofunctioning of Jatharagni results in production of Ama (undigested toxic substances) This condition may enhance the medodushti leading to medoroga. Protocol reviewed 18, 19 Various Acharya’s like Charak, Sushruta, Vagbhata described numerous herbal combinations to correct Jatharagni & medo dhatvagni..Jayantyadi churna is selected for this study. It contains following medicine 20. It may helpful to reduce BMI in Medoroga due to their following properties.

Haritki (TerminaliaChebula) – In previous study, it showed effect on adiponectin and leptineventually work as lipolytic 21.
Agnimanth corrects agni and reduce BMI because of its dipana, pachana, medohara and kaphahara properties.\(^{22}\)

Amalki is Kaphahar & medohar in one study; it showed significant reduction in triglycerides, LDL total cholesterol and VLDL along with significant increases in HDL levels.\(^{23}\)

Kutaj possesses Katu, Tikta and kashaya rasa along with Laghu and Ruksha gunas reduces vitiation of Kapha and Medodushti. It removes Amaivisha by its Deepaniya, Pachaniya, and Vishaghn aproPERTIES.\(^{24}\) A number of studies from modern medicine\(^{25-28}\) and Ayurveda on obesity and dyslipidemia\(^{29-30}\) were reported.

**Conclusion**

On the basis of data analysis, observation and results, conclusion will be drawn.

**References**

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