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A Clinical Study on Medovaha Srotodushti W.S.R. to Sthoulya and its Management with Mustadi Kashaya: A Study Protocol

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ABSTRACT

Introduction: Sthoulya(Obesity) is a well-described disorder with a long-standing history, which continues to be a significant health concern in the present day. The condition has its impact from Jataragni(digestive fire) to Dhatwagni(metabolic fire), involving multiple systems. Madhavakara called it Meda Roga(fat disorder) and other acharyas also support this view by citing its link with the Medovaha Srotas. WHO identifies obesity as a major risk factor for cardiovascular diseases, hypertension, type 2 diabetes mellitus, atherosclerosis, impaired reproductive health, cancer etc. As Ayurveda has proven to give better lifestyle changes and effective therapies, a simple herbal formulation Mustadi Kashaya mentioned in the Charaka Samhita, Sutra Sthana, Santarpaniya Adhyaya is selected. Objective: Study on Medovaha Srotas through evaluating the efficacy of Mustadi Kashaya in Sthoulya, lipid profile and Agni(fire). Methods: Non randomized open label single arm clinical study recruiting 100 eligible participants(age 21-60) with BMI > 25kg/m^2 fulfilling inclusion criteria selected for study. Discussion: Data analysed using repeated measures ANOVA and paired-t test to check efficacy of formulation in Sthoulya and association of Medovaha Srotas with obesity through subjective and objective parameters. Conclusion: This trial is to validate the treatment for Medovaha Sroto Dushti through an easy herbal formulation to manage NCDs. World Obesity Day was celebrated on 4th March 2026 with the theme 8 billion reasons to act on obesity, where this trial is a short step to highlight the role of correction in digestion and metabolism and managing complications of obesity to improve the quality of life in society.

Keywords: Sthoulya, non-communicable diseases, BMI, Mustadi Kashaya, Medas

INTRODUCTION:

Obesity is a chronic, multifactorial condition associated with excess adiposity and an increased risk of several non-communicable diseases. Its development and progression are influenced by interacting biological, behavioural, environmental and social determinants. Contemporary assessment commonly uses anthropometric measures such as body mass index (BMI), waist circumference and waist–hip ratio together with metabolic indicators as clinically indicated. The World Health Organization identifies overweight and obesity as major public-health concerns because of their association with conditions including

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cardiovascular disease and type 2 diabetes mellitus[1]. Reports also emphasise the continuing burden of obesity and the need for preventive and therapeutic strategies[2,3].

In Ayurveda, Sthoulya is discussed in the context of Santarpana Janya Vyadhi-disease developed due to excessive but inappropriate nutrition and Ashta Nindita Purusha- the eight undesirable health conditions. The classical description includes increased accumulation of Meda evident by pendulousness of body parts such as Sphik, Udara and Stana, reduced enthusiasm and limitations in physical activity. The description of Medovaha Srotas and its Dushti Lakshana provides a disease-oriented framework for examining the clinical presentation and associated Nidana in Sthoulya. Concepts such as Jatharagni, Dhatwagni, Meda Dhatu and Srotodushti are relevant in understanding manifestation of Sthoulya in development of metabolic syndromes.

The present study is designed to examine Medovaha Srotodushti in relation to Sthoulya using predefined clinical scoring along with anthropometric and laboratory values. The protocol includes assessment of Medovaha Sroto Dushti Nidana through Ahara, Vihara, Manasika Bhava and Beeja Dushti. The Medovaha Srotodushti Lakshana, Atisthoola Lakshana and Sthoulya-related Ashta Dosha Lakshana is also recorded to find out the extend of association of Meda Dushti in Obesity. The Agni-related domains like Agni Bala, Abhyavaharana Shakti, Jarana Shakti and Vyayama Shakti in participants provide a clear understanding on role of digestive and metabolic fire.

A formulation Mustadi Kashaya described in the Charaka Samhita, Sutra Sthana, Chapter 23, Santarpaniya Adhyaya has been selected for this study because of its classical context in the management of Santarpana Janya conditions[4]. Previous clinical studies has explored the efficacy of Mustadi-based formulations in Sthoulya[5]. A single-arm prospective design is proposed to document changes during treatment and explore associations among the selected Ayurvedic and biomedical variables. The present protocol additionally places emphasis on the relationship between Medovaha Srotodushti, Agni-related domains and measurable clinical and biochemical variables.

AIM AND OBJECTIVES:

Primary Objectives

1. To study the role of Medovaha Srotodushti in Sthoulya.
2. To evaluate changes in clinical features of Sthoulya following administration of Mustadi Kashaya.
3. To evaluate changes in lipid profile following administration of Mustadi Kashaya.

Secondary Objectives

4. To assess changes in Medovaha Srotodushti Lakshana following the intervention.
5. To examine the relationship between Agni-related parameters and Medovaha Srotodushti.
6. To explore associations between selected Nidana, clinical features, anthropometric measures and biochemical parameters.

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MATERIALS AND METHODS:

Study Design

The study is planned as a prospective, single-centre, non-randomised, open-label, single-arm interventional clinical study. No parallel control group or random allocation is included. The treatment period is two months followed by a one-month follow-up.

Study Setting and Recruitment

Participants will be recruited from the outpatient department of the Central Ayurveda Research Institute, Bhubaneswar, Odisha through an obesity camp. Screening will be performed against the predefined eligibility criteria. Relevant demographic details, medical history, dietary and lifestyle history, clinical findings and investigation results will be recorded in a case record form.

Eligibility Criteria

Inclusion Criteria

- Adults aged 21–60 years, irrespective of gender.
- Clinical features of Sthoulya- pendulousness of the abdomen, breasts or buttocks and reduced enthusiasm.
- BMI of greater than 25 kg/m² up to 40 kg/m²
- Corpulence Index greater than 12 kg/m³
- Willingness to provide written informed consent and attend scheduled assessments and follow-up visits.

Exclusion Criteria

- Individuals younger than 21 years or older than 60 years.
- Pregnant or lactating women.
- Impaired liver function SGOT/SGPT ratio greater than 2 or impaired renal function with serum creatinine greater than 1.4 mg/dL.
- Non-insulin-dependent diabetes mellitus
- Insulin-dependent diabetes mellitus with HbA1c greater than 8%.
- Unstable cardiovascular or cerebrovascular conditions.
- Current corticosteroid therapy.
- Individuals unwilling to provide consent.
- Illiterate participants without a literate relative or guardian able to explain the procedures and assist with consumption of medication and follow up visits.
- Any other condition considered unsuitable for recruitment by the investigator.

Study Intervention

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Mustadi Kashaya mentioned under Santarpana Adhyaya context included drugs like Musta, Aragwada, Pata, Amalaki, Haritaki, Vibhitaki, Devadaru, Shvadamshtra, Khadira, Nimba, Haridra, Daruharidra, Twak and Kutaja. Quality-assured raw drugsin coarse form is procured from GMP certified organization Ashtavaidyan Thaikkattu Mooss Vaidyaratnam, Thrissur, Kerala. The raw materials are properly cleaned, washed and dried at 50–60°C. The dried materials are mixed and coarsely powdered using a disintegrator with a 1/8-inch mesh. Quality analysis of the raw materials carried out by CARe KERALAM Ltd, Koratty, Thrissur, an AYUSH-approved facility.

The protocol describes preparation using 48 g of coarse powder boiled with sixteen times quantity of water, reduced to one-eighth and filtered[6]. A daily dose of 96 mL, administered as 48 mL twice daily on an empty stomach for two months followed by a one month follow up without medication, where assessments of parameters done on every 30th day.

Outcome Measures

Primary Clinical and Anthropometric Measures

- Medovaha Srotodushti Lakshana assessed using the study scoring proforma.
- Atisthoola Lakshana and Sthoulya-related Ashta Dosha Lakshana assessed using the study scoring proformas.
- Body weight and BMI.
- Waist–hip ratio.
- Total skinfold thickness.

Biochemical Measures

The biochemical outcomes include lipid profile and liver enzymes (SGPT and SGOT). Complete blood count, fasting blood sugar, postprandial blood sugar, HbA1c,liver function tests, kidney function tests and thyroid profile as laboratory investigations also checked at screening and at the end of intervention.

Agni and Functional Measures

Agni-related assessment includes Agni Bala through a validated tool[7], Abhyavaharana Shakti, Jarana Shakti and Vyayama Shakti are also assessed.

DISCUSSION

Statistical Analysis

The collected data will be entered in SPSS software for analysis and interpretation. Descriptive statistics will be used to summarise demographic and baseline characteristics, including age, sex, marital status, occupation and relevant personal history. Frequency distributions will be prepared for selected Nidana, clinical features, weight, BMI, waist circumference, waist–hip ratio, total skinfold thickness, lipid profile and liver enzyme values.

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Continuous variables will be summarised using mean and standard deviation, together with minimum, maximum and 25th, 50th (median) and 75th percentiles. Categorical and ordinal variables will be summarised using frequencies and percentages.

Repeated measurements like weight, body mass index, corpulence index, waist circumference, hip circumference, waist–hip ratio, skinfold thickness measurements of supra-iliac, subscapular, triceps, biceps and total skinfold thickness, lipid profile parameters (total cholesterol, LDL, triglycerides, HDL and VLDL) and liver enzymes (SGPT and SGOT) will be analysed using repeated-measures analysis of variance (ANOVA) comparing baseline with the first, second and third follow-up assessments.

For the ordinal Ayurvedic clinical parameters like Chala Sphik-Udara-Stana, Ayata Upachaya Utsaha, Madhuryam Asye, Anga Saithilya, Alasya, Shrama Swasa, Ati Pipasa, Ati Kshudha, Ati Nidra, Sweda Adhikya, Gatra Dourgandhya, Kruchra Vyavayata, Java Uparodha and Agni Bala through scoring entry done and repeated-measures ANOVA they will be assessed. Jarana Shakti, Abhyavaharana Shakti and Vyayama Shakti were assessed between screening and the second follow-up using the Wilcoxon signed-rank test.

For laboratory parameters assessed at screening and the second follow-up—haemoglobin, total leukocyte count, red blood cell count, platelet count, erythrocyte sedimentation rate, fasting blood sugar, post-prandial blood sugar, HbA1c, urea, serum creatinine and thyroid-stimulating hormone the statistical output assessed through paired t-test.

All tests are interpreted at a 5% level of significance, with $p < 0.05$ considered statistically significant.

Safety Monitoring and Withdrawal

Participants will be monitored for adverse drug events during the intervention. If a serious complication requiring urgent treatment with other medicines or therapies develops, the participant may be withdrawn from the study. Any adverse drug reaction occurring during the study will be documented and reported in accordance with the applicable institutional and regulatory requirements.

Stages of Study

- Screening at CARI outpatient department through obesity camp
- Eligibility assessment against inclusion and exclusion criteria
- Written informed consent and enrolment (planned n = 100)
- Baseline assessment: clinical scores, anthropometry, laboratory and Agni-related parameters
- Mustadi Kashaya intervention for two months
- Interim assessment on Day 30
- End-of-treatment assessment on Day 60
- One-month follow-up
- Statistical analysis and interpretation

The trial has been registered with the Clinical Trials Registry–India (CTRI) after getting the IEC approval from the IEC committee. Written informed consent will be obtained from each participant before enrolment along with maintenance of confidentiality. The approved participant information sheet and consent form in multiple languages will be used to ensure the understanding of participant about the study.

This protocol is designed to examine Sthoulya through an integrated Ayurvedic and modern framework. The central focus is on the association between Medovaha Srotas and Sthoulya through the clinical, anthropometric and biochemical factors. The assessment of Nidana scoring also compared alongside Medovaha Srotodushti Nidana to support their interrelationship.

The inclusion of anthropometric measures such as BMI, waist circumference, hip circumference, waist–hip ratio and total skinfold thickness provides measurable indicators of body size and fat distribution. Lipid profile and liver enzyme assessments add biochemical dimensions to the clinical evaluation. Agni-related domains are included to explore whether changes in digestive and functional assessments occur alongside changes in clinical and biochemical parameters.

Mustadi Kashaya is selected on the basis of its classical description in the Santarpaniya Adhyaya of Charaka Samhita. Proper raw-drug sourcing, processing and quality assessment is important for reproducibility of efficacy. The single-arm, open-label design is feasible for an exploratory clinical assessment and permits repeated measurements within the same participants.

CONCLUSION

The study is expected to provide a structured description of the association between Medovaha Sroto Dushti Nidana, Medovaha Srotodushti Lakshana and clinical features of Sthoulya. It will also estimate changes in anthropometric, biochemical and Agni-related parameters during a two-month course of Mustadi Kashaya. As the majority of raw drug in the formulation is Tikta Katu Kashaya with Laghu Ruksha Guna may dries up the Kledata, scrape the Sroto Lepana and clear the obstruction developed due to Meda Avarana. Through the changes in Sthoulya Lakshana, Meda Dushti Lakshana, anthropometric measurements and biochemical parameters this action can be assessed. As removal of Avarana control the Prakopa of Vata Dosha, a normalcy in Ahara Shakti and Jarana Shakti also can be expected. If the formulation is able to correct the metabolism of Meda Dhatu then patient may feel relief in Anutsaha, Shrama Shwasa, Gourava etc. Thus clear understanding of involvement of Medovaha Srotas, its metabolism and its significance in Obesity is expected from the trial.

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