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A PARALLEL COMPARATIVE CLINICAL TRIAL OF GUDUCHYADI CHURNA WITH TRIFALA CHURNA IN THE MANAGEMENT OF STHAULYA

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ABSTRACT

Background: Obesity (Sthaulya) is a widespread lifestyle disorder affecting people globally. In Ayurveda, Medoroga is classified as a chronic, yapya condition necessitating prolonged management.

Objectives: To evaluate and compare the clinical effectiveness of Guduchyadi Churna versus Trifala Churna in treating Sthaulya.

Methods: A randomized clinical trial involved 300 patients with BMI ranging from 25–30. Participants were divided into two groups, receiving either Guduchyadi Churna or Trifala Churna for 45 days. Subjective and objective parameters were assessed at baseline and every 15 days.

Results: Both groups exhibited notable improvements, but the Guduchyadi group showed superior reductions in BMI, body weight, abdominal girth, and subjective symptoms.

Conclusions: Guduchyadi Churna proved more effective than Trifala Churna in managing Sthaulya and is safe for extended use.

KEYWORDS: Guduchyadi Churna, Trifala Churna, Sthaulya, Obesity, Ayurveda, Clinical Trial

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INTRODUCTION

Obesity, a major global health issue, ranks as the fifth leading cause of death worldwide. The World Health Organization (WHO) defines obesity as excessive or abnormal fat accumulation that harms health, resulting from an energy imbalance between calories consumed and expended. Body Mass Index (BMI), calculated as [(weight in kg)/(height in m^2)], is a widely used index to categorize adults as underweight, overweight, or obese. The WHO employs specific BMI thresholds to identify obesity, aiding in recognizing individuals at higher risk of morbidity and mortality (Table 1). Over the past two decades, obesity rates (BMI above 30 kg/m^2) have surged in developing nations, with 641 million obese adults in 2014 compared to 105 million in 1975, indicating a dramatic rise. Studies show obesity as a complex condition driven by individual factors like genetics and learned behaviors, combined with societal issues such as unhealthy eating habits and food deserts. Researchers agree that obesity, though influenced by genetics and epigenetics, is largely an acquired condition tied to lifestyle choices, including sedentary behavior and excessive food intake. Various obesity types, particularly abdominal obesity, elevate risks for chronic conditions like asthma, cancer, diabetes, hypercholesterolemia, and cardiovascular diseases, worsening existing health issues and triggering new ones.

Obesity impacts nearly all organ systems, including the cardiovascular, endocrine, central nervous, and gastrointestinal systems. It is linked to a rising incidence of cardiovascular conditions such as hypertension, coronary heart disease, atrial fibrillation, and heart failure. According to India's NFHS-3 survey, 13% of women and 9% of men aged 15–49 were overweight or obese. Over the past two decades, overweight prevalence in India has doubled, becoming an epidemic in urban areas and rapidly increasing in rural regions.

Classification	BMI (kg/m2)	Risk of co-morbidities
Underweight	<18.5	Low (but risk of other clinical problems increased)
Normal weight	18.5–24.9	Average
Overweight	25.0–29.9	Mildly increased
Obese	≥30	
Obese I	30.0–34.9	Moderate
Obese II	35.0–39.9	Severe
Obese III	≥40	Very Severe

Table 1. BMI classification of adult weights based on the WHO schema (BMI = weight in kg/height in $meters^2$).

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Ayurveda is the only system of Medicine which not only deals with the health but also shows an ideal path to lead a successful life. Ayurveda has given utmost importance to preventive, curative and rejuvinative methods.

Now a days we are getting patient's having symptoms of diseases due to lifestyle changes, bad eating habits, lack of exercise, etc. Some metabolic diseases like Medoroga (hyperlipidemia) are the real challenges to treat in this modern lifestyle. Ayurveda tells about Dinacharya and Rutucharya for the prevention of diseases, but today, very few people live according to Ayurvedic rules. Sometimes we don't have solutions to change our lifestyle because there is a rat race for life, everybody is so anxious and works around the clock. Mental health is another major issue, a lot of pressure about work, manasik doshas like anger, lust, jealousy, sluthishness, fascination, etc., are there. So, people are unsatisfied with life and have lost their mental health. Also, due to work culture, people don't do daily exercise, which leads to Medaovriddhi. Bad eating habits are a major factor in such metabolic diseases. fast food, spicy, oily food, viruddh Anna Sevan, overeating, preserved food, and food containing excess fat are the major habits of food taken. According to Ayurveda, Medaoroga means Medavriddhi, that is, excess Meda dhatu. It is a chronic and contagious disease. It is a bahya margashrit vyadhi. It is included in Ashtonindit vyadhi. According to Charakacharya, causes are excess sweet, oily, cold, preserved food, lack of exercise, genetic causes, daytime sleep, excess food, etc.

Samprapti: - Hetu sevan – Medaovriddhi – Strotovrodha – Vimargag vata – Vat goes in Koshtha – Jatharagnisandhukshan – Excess hunger – Medao vriddhi – Except Meda all dhatu shoshan. Also, due to the excess burden on Medao dhatu Agni, it gets disturbed, so Medao dhatwagnimandya is there, so there is no production of prakrut Meda dhatu, instead there is only vikrut Medaovriddhi.

Consequences: -

1. Daurbalya (Weakness) – As we saw, there is no dhatu poshan except Meda; all dhatu kshay is there, so we observed daurbalya.

2. Daurgandhya – Sweda (Sweat) is an excretory product of Meda. Here, Vikrut Medao vriddhi is seen, so Swed also gets disturbed. & excess sweat is there. Due to improper production, there is an offensive smell.

3. Excess hunger & Thirst: - Due to jatharagni sandhukshan we observed excess hunger & thirst.
4. Libido: - Due to shukrakshaya, there is a loss of libido.

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5. Early aging: - There are all dhatuksheenata except Meda, so the patient feels an early aging condition. (Javoparodh) 6. Decreased life span: - due to dhatu asaratva, life span gets decreased.

MATERIAL & METHOD: -

Material: -

Drug Review: - □□□□□□□5□□™□□□□□ □□□ ™□ □□™□□ l □ □□f□J □□□□ □□□□□□ □□□ □4 □ ll □□□□ □□ □□ A) GuduChyadi churna - It contains guduchi and musta in same proportion. Take guduchi and musta fine powder in the same proportion and mix them thoroughly. B) Trifala churn- It contains Aamala ki, Bibhitak, Haritaki. Take the above three contents, fine powder in the same proportion, and mix them thoroughly.

1) Guduchi - (Teno spora Cordifolia)- It has tikta,katu ras.Madhur vipak and ushna virya. Due to tikta ras it is good dhaatuaagni deepan and due to Madhur vipak it is dhaatu poshak. It reduces rasa gat dosh and kled. It has yakrutotejak property. It increases Meda dhaatu Agni. It digests vikrit Meda.It is used for all dhaatus as dhaatu poshak so used as Sanshaman rasayan. It is used in Jirna Vyadhi as dhatu poshak.

2) Musta - (Cyperus Rotundus)- It has tikata ras,katu vipak and Sheeta virya. Due to tikta,kayu ras it is deepan, pachan, grahi so used in Agnimandya, Ajeerna, Atisara. It is used as aampachak. It is kledaghna. It is kafapittaghna and vatakar.It is dhaatu Agni Deepak.

3) Aamalaki-(Emblica officinalis)- It has Lavan varjit panch ras, Madhur vipak,sheet virya. It is Agni Deepak, aam pachak, anulomak. It is kledaghna, dhaatu shodhak. It digests dhaatugat dosh, throws them out. And used as vayasthapak, it does lekhan of excess meda.

4) Haritaki -(Terminalia Chebula)- It has Lavan varjit kashaya ras Pradhan ras, Madhura vipak and ushna virya. It is digestive, Agni Deepak, aam pachak, kledaghna, lekhan on Meda dhaatu. It removes strotorodh, so used as rasayan.

5)Bibhitak -(Terminalia Belerica)- It has kashaya ras, madhura vipak, ushn virya. It isDeepak, pachak, Anuloma,dushta kafaghna. It is khafapittaghna. It is shothahar.

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Methods: - Trial design: -

1. Select 300 patients from the OPD having Medaovriddhi.

2. They are separated randomly into 2 groups, namely A & B.

3. Multistage simple randomization method used.

4. Firstly, select patients according to the inclusion criteria and then divide into two groups. Odd-number patients like 1, 3, 5 will be added to group A, and even-number patients

5. Patients like 2,4,6 will be added to group B.

6. Guduchyadi Churna 3 gm given to group A. Dose is 3 g 1 hour before food with koshna water two times a day.

7. Trifala Churna 3gm given to group B. Dose is 3 g 1 hour before food with koshna water two times a day.

8. Instruct the patients about diet. Avoid a Fatty, oily diet. Light breakfast, lunch, and dinner include two rotis with subji.

9. Instruct patients to maintain a daily diary about diet and exercise.

10. Record subjective & objective criteria on day O.

11. Continue the Medicines up to 45 days.

12. Record subjective & objective criteria after 0, 15, 30, 45 days. 13. We will collect, segregate & analyse the data afterwards. 14. Will conclude the use of a proper statistical test

Inclusion criteria: - 1. Male & Female patients aged between 20 to 50 years. 2. Patients having symptoms of Medaovriddhi like excess fat under skin, udar vruddhi, stan vruddhi, sfig vruddhi 3. Patients having a BMI between 25 to 30.

Exclusion criteria: - 1. Patients having chronic diseases of the Kidney, Liver, Heart & Brain. 2. Patients having diseases of Endocrine disorders. 3. Patients having genetic disorders.

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Pre-Inclusion Investigation: - 1. CBC with ESR 2. Lipid Profile 3. T3, T4, TSH 4. BSL

RANDOM WITHDRAWAL CRITERIA:

1) A Patient willing to quit during the project will be allowed to quit and will be replaced.

2) If any serious adverse effect develops, the patient will be excluded.

SUBJECTIVE CRITERIA:

Changes in Sthaulya's subjective parameters (signs & symptoms) will be evaluated using the Gradation method:

1. Atikshudha: Grade 0 – Hunger after 6 hours. Grade I – Hunger between 4–5 hours. Grade II – Hunger between 3–4 hours post-meal. Grade III – Strong hunger 2–3 hours post-meal. Grade IV – Intense hunger within 2 hours post-meal.
2. Atisweda: Grade 0 – Sweating after intense activity or in hot weather. Grade I – Heavy sweating after moderate activity. Grade II – Sweating after minimal activity. Grade III – Excessive sweating after minimal activity. Grade IV – Sweating at rest or in cold weather.
3. Atinidra: Grade 0 – Normal 6–7 hours sleep daily. Grade I – Up to 8 hours sleep with body heaviness. Grade II – Up to 8 hours sleep with heaviness and yawning. Grade III – Up to 10 hours sleep with drowsiness. Grade IV – Over 10 hours sleep with drowsiness and fatigue.
4. Sweda Durgandhi: Grade 0 – No body odor. Grade I – Occasional odor persisting after bathing. Grade II – Constant odor in close proximity, resistant to deodorants. Grade III – Strong odor noticeable from a distance, unaffected by deodorants. Grade IV – Intense odor, unbearable even to the patient.
5. Aalasya: Grade 0 – No laziness, work done efficiently and timely. Grade I – Work done well but started late. Grade II – Work done poorly, delayed, with mental strain. Grade III – Reluctant to start work, minimal effort, very slow. Grade IV – No initiative, avoids work even under pressure.
6. Shrama Shwasa: Grade 0 – Shortness of breath after heavy activity, quickly relieved, tolerable. Grade I – Breathlessness after moderate activity, later relieved, tolerable. Grade

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II – Breathlessness after light activity, later relieved, tolerable. Grade III – Breathlessness after light activity, later relieved, intolerable. Grade IV – Breathlessness at rest.

7. Atipipasa: Grade 0 – Normal thirst. Grade I – Up to 1 liter excess water intake. Grade II – 1–2 liters excess water intake. Grade III – 2–3 liters excess water intake. Grade IV – Over 3 liters water intake.

OBJECTIVE CRITERIA:

1. Weight
2. BMI: Body Mass Index (BMI) is calculated as weight (kg) divided by height (m^2).
3. Abdomen circumference: Abdominal obesity is measured by the circumference of the abdomen, taken between the lowest rib and the top of the hip bone, at the umbilicus.
4. Waist-to-Hip Ratio: This measures abdominal obesity by dividing waist circumference by hip circumference (widest part of buttocks). Normal values are 0.75 for men and 1.10 for women.
5. Lipid Profile
6. Skin Fold Thickness
7. Mid-arm Circumference
8. Mid-thigh Circumference

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PROCEDURE:

300 patients were divided into two groups randomly.

Group A received Guduchyadi Churna (3 gm twice daily with lukewarm water).

Group B received Trifala Churna (3 gm twice daily with lukewarm water).

Diet and lifestyle guidance was provided.

Follow-ups occurred on days 0, 15, 30, and 45.

Data collected included subjective parameters (Atikshudha, Atisweda, etc.) and objective measures (Weight, BMI, Waist-Hip Ratio, Lipid Profile).

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