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Comparative Evaluation of Efficacy of Gomaya Mashi Udvartana with Petiswedana and Rodhradi Gana Udvartana with Petiswedana in the Management of Sthoulya (Obesity) – A study Protocol

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Abstract--Obesity is a metabolic condition associated with the abnormal accumulation of fat in the body, resulting in multiple adverse effects on health. Generally, it occurs due to an imbalance between the intake of calories and its utilization in the body. Patients with a body mass index (BMI) of more than 25–30 kg/m are considered obese². The prevalence rate of Obesity is 11.8% to 31.3% as per observations of ICMR-INDIAB in 2015. It can be correlated with *Sthoulya* mentioned in *Ayurveda* that occurred due to vitiated *Kapha* and *Meda*. *Sthoulya* is one of the major diseases under *Santarpanotha Vyadhi* (Nutritional Disorders) caused due to *Dushti of Medovaha Srotasa*. It is an abnormal and excessive accumulation of

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Meda Dhatu in the body. According to *Acharya Charaka*, *Udvardana* has *Kaphhar* and *Medohar* properties. It is of 2 types, i.e. *Snigdha Udvardana* and *Ruksha Udvardana*. Among them, *Ruksha Udvardana* is used in the management of *Sthoulya*. To evaluate the comparative efficacy of *Rodhradi Gana Udvardana* with *Petiswedana* and *Gomaya Mashi Udvardana* with *Petiswedana* in the management of *Sthoulya* (Obesity). A total of 60 patients will be enrolled and divided randomly into two equal groups. In group (Control group), *Udvardana* with *Rodhradi Gana* followed by *Peti Swedana* will be prescribed for 14 days. In group B i. e. Interventional group, *Udvardana* with *Gomaya Mashi* followed by *Peti Swedana* will be advised to obese patients for 14 days. Subjective and objective outcomes will be statistically analyzed by appropriate methods. Conclusions will be drawn based on observations and results obtained in this study.

Keyword: Sthoulya, Udvardana, Obesity, Rodhradi Gana, Gomaya Mashi, Petiswedana.

Introduction

The World health organization has defined Obesity as a condition with excessive fat accumulation in the body to the extent that health is adversely affected [1]. It results from a positive energy imbalance expressed by body mass index (BMI) of 25–29.9 and ≥ 30 kg/m², respectively[2,3]. In 2000, WHO labeled Obesity as the most blatantly visible but most neglected public health problem worldwide [4]. It has become a major public health problem in both developed and developing countries. It is causally related to a wide spectrum of chronic non-communicable diseases, including Type 2 Diabetes, Cardiovascular diseases, and Cancer [5]. Both generalized Obesity and Abdominal Obesity are associated with an increased risk of morbidity and mortality [6]. Moreover, several studies reported Obesity as the well-documented major risk factor for many non-communicable diseases and health conditions, including Hypertension, High Lipid Concentrations, Type-2 Diabetes, Coronary Heart Disease, Stroke, and certain Cancers.[7-11]. According to WHO, in 2016, more than 1.9 billion adults aged 18 years and older were Overweight or Obese [12]. The global burden of Obesity is recorded to be 4 million deaths and 40 million disability-adjusted life years among adults globally in 2015[13]. The prevalence of obesity in urban areas of Maharashtra is 6.6% and 2.2%. The prevalence of obesity in rural areas is 3.4% and 0.6%. The prevalence of Obesity is higher in urban areas as compared to the rural areas. Lack of physical activities, family factors, frequent and overeating habits are important risk factors for this disease [14].

Certain factors e.g.age, gender, geographical variations, socio-economic status, etc., affect the prevalence of Obesity in India. The prevalence rate of central Obesity is 16.9%-36.3%, as per observations of a study conducted by ICMR-INDIAB in 2015. In India, Abdominal Obesity is the most contributing factor for developing cardiovascular complications [15]. Most persons with middle-age suffer from such type of Obesity, but it can occur at any stage of life. Normally, women

are more prone than men [16], but men suffer from this disease at 20-30 years [17].

There are different treatment modalities described by modern science for the management of Obesity like Diet, Exercise, Drug therapy, and Surgery. However, there are certain limitations of pharmacological options due to their certain neurological and psychiatric side effects. Moreover, non –pharmacological modalities like Diet lead to fatty/ oily stool, fecal urgency, and fat-soluble vitamins [18]. So, it is necessary to search for simple but effective treatment modalities in alternative science, i.e., Ayurveda to manage such conditions.

According to *Ayurveda*, Obesity can be correlated with *Sthoulya* that originated from *Kapha* and *MedaDushti*. *Sthoulya* is one of the major diseases under *SantarpanothaVyadhi* (Nutritional Disorders) caused due to the *Dushti* of *MedovahaStrotasa*. It is an abnormal and excessive accumulation of *Meda Dhatu* in the body [19]. *Acharya Charak* considered *Atisthula* as one among *Astonindita Purusha*, [20] *Meda*s increased in the body due to lack of physical exercises, sleeping during the daytime, and consuming food, which increases *Kapha Dosh*a, ingestion of excess fats/oils and substances that are predominantly sweet. All the channels that continuously supply nutrients to other tissues are blocked by *Medas* (Fats), so further tissues are not properly formed, and only *Medas* get accumulated. Because of this unequal distribution of fats in the body, the person is called *Sthula*. In *Sthoulya*, the person suffers from mild dyspnoea, thirst, drowsiness, excessive sleep & appetite, the offensive smell from the body, incapability to work and participate in sexual intercourse.

Ayurveda vividly elaborates *the Ayurvedic* line of treatment through various *Shaman* and *ShodhanChikitsa*. Among *Shodhana*, it can be classified based on the route of administration, e.g., external and internal. Among them, *Udvardana* and *Petiswedana* these are *BahyaShodhana* procedures that eliminate Vitiated *Dosha* through the skin and help melt fat. *Udvardana* has *Kaphhar* and *Medohar* properties. According to *Acharya Charaka*, *Udvardana* is of two types, *SnigdhaUdvardana* and *RukshaUdvardana*. Among them, *Ruksha Udvardana* is used in treating *Sthula* (obese patients), in which dry powder of herbs without oil is generally used for this procedure. The previous clinical evidence shows that many herbal drugs can be used for *Udvardana*. Still, through this study, novel efforts are made to study the comparative efficacy of *Udvardana* with *GomayaMashi*, i.e., cow dung ash powder (Animal product) and herbal powder in the management of Obesity.

Background & rationale

Treatment of Obesity includes Diet therapy, Exercise, and drugs. Peripheral acting weight-reducing drugs possess some adverse effects such as fatty/ oily stool, flatulence, fecal urgency, and deficiency of fat-soluble vitamins. Drug acting over an endocannabinoid system such as Rimonoban has side effects such as multiple Neurological and psychiatric ailments [21]. On the other hand, patients are generally unwilling to undergo surgeries, e.g., bariatric surgery, due to fear. Therefore, alternative treatment options in Ayurveda for the same should be searched due to the above scenario.

In *Ayurvedic* literature regarding the management of *Sthoulya* (Obesity), it is observed that extensive work has been carried out regarding the efficacy of various treatment measures in *Ayurveda*. However, these measures have certain limitations. Among *Panchakarma*, through *Vamana* and *Virechana* offers significant results in weight reduction, many patients have poor compliance rate towards the consumption of medicated ghee before administration of these procedures that is their mandatory criteria. There is a misbelief about the lipid elevating effects of this medicated ghee also. Therefore, obese patients get deprived of their miraculous results.

Moreover, most patients are reluctant and deny to undergo *Vasti* (*Medicated Vasti*), e.g., *Lekhana Vasti*, due to hesitancy. There is also much apprehension regarding *Vasti* formulations that contain many herbo-mineral combinations that may adversely affect the liver and kidney. Therefore, external treatments are quite popular among society for the management of this clinical condition. *Udavartna*, i.e., dry powder massage, is considered the best therapy for encouraging results in inches loss. On extensive review of Ayurvedic trials, it is found that many studies have been carried out regarding *Sthoulya* (Obesity). Still, research work on *Gomaya Mashiudvartana* in *Sthoulya* (Obesity) and comparative analysis is not done yet.

There are many rural areas and villages in India where cows are kept for milk and dairy product purposes. Thus, the cow dung can easily be procured from such rural areas and villages at a very low cost compared to other herbal drugs, for which one has to search a lot, and the herbal drugs are costly enough for one's reach. Hence, this study is planned to study the comparative efficacy of *Rodhradi Gana Udvartana* with *Petiswedana* and *Gomaya Mashi Udvartana* with *Petiswedana* in the management of *Sthoulya* (Obesity).

Aim and Objectives

Aim:

Evaluation of Comparative efficacy of *Rodhradi Gana Udvartana* with *Petiswedana* and *Gomaya Mashi Udvartana* with *Petiswedana* in the management of *Sthoulya* (Obesity).

Objectives:

- To assess & compare the efficacy of *Rodhradi Gana Udvartana* with *Petiswedana* and *Gomaya Mashi Udvartana* with *Petiswedana* over Weight in Kg & B.M.I. in Obesity
- To assess & compare the efficacy of *Rodhradi Gana Udvartana* with *Petiswedana* and *Gomaya Mashi Udvartana* with *Petiswedana* over anthropometric parameters, e.g., Mid arm circumference, abdominal circumference, Mid-thigh circumference, Waist-Hip Ratio, & Skinfold thickness in Obesity.
- To assess & compare the efficacy *Rodhradi Gana Udvartana* with *Petiswedana* and *Gomaya Mashi Udvartana* with *Petiswedana* over biochemical parameters, e.g., Serum Lipid Profile in Obesity

Material and Methods

Type of Study: Interventional Study

Study design: Randomized, single-blind controlled clinical trial

Case definition- Diagnosed case of *Sthoulya* (Obesity)

Diagnostic Criteria:

- Lipid profile (S. Total cholesterol, S. triglycerides, S. HDL, L.D.L, V.L.D.L)
- Fasting Blood Sugar

Research Question: Whether *Gomaya Mashi Udvartana* with *Petiswedana* is more efficacious than the *Rodhradi Gana Udvartana* with *Petiswedana* in managing *Sthoulya* (Obesity)?

Ethics & Dissemination: IEC Certificate, obtained vide IEC Ref No. MGACHRC/IEC/July-2021/341 dated 30.07.2021, CTRI registration under process.

Methodology

Study Setting: The study will be conducted in Panchakarma OPD & IPD, Mahatma Gandhi Ayurved college hospital & Research Centre (MGACH&RC), Salod (Hirapur) Wardha, Maharashtra.

Eligibility criteria

Inclusion criteria:

- Subjects between the age group of 20-40 years of either sex
- Patients having B.M.I. of 25 to 39.9 kg/m² with or without comorbidity of Obesity as per ICD Criteria for obesity[22]
- Subjects willing to participate in the study and sign the consent form

Exclusion criteria

- Patients having B.M.I. equal or > 40 kg/m²
- K/c/o Hypothyroidism, Diabetes mellitus, Cardiovascular, Renal Disorder, and Drug-induced Obesity, etc.
- Pregnant lady and Lactating mother.
- Individuals showing unsuitability of Drug or ADR
- Patients not willing to continue due to any reason
- Patient contraindicated for *Udvartana* and *Petiswedana* [23]

Interventions

Group-wise details of intervention in this study are given in table no.1.

- Group A (Control Group): *Rodhradi Gana Udvartana* with *Petiswedana*
- Group B (Trial Group) : *GomayaMashiUdvartana* with *Petiswedana*

Methodology of the study: The methodology of the study is mentioned in Figure no.1.

Criteria for discontinuing or modifying allocated interventions:

- Patients willing to quit in between will be allowed to quit & will be replaced.
- If a patient develops an acute illness during the trial, which may hamper the study.
- Withdrawn patients will be replaced
- If any untoward incidence, features of drug sensitivity, or any other disease or problem arises, the subject will alleviate the problem without taking charge.

Follow up: 16th day of study.

Assessment Criteria

The following Anthropometric assessment will be done before & after the treatment using a weighing machine & measuring tape.

- Body Weight of the patient in kg (Weight will be taken on an empty stomach with the same cloths)
 - B.M.I. (calculated by International criteria of B.M.I.)
 - Anthropometric Assessment/Body circumference (The girth measurements of certain regions, e.g., Chest- Abdomen – Hip – Mid-thigh –Mid arm using measuring tape before and after the Treatment)
 - ❖ Chest circumference – In normal expansion at the level of nipple
 - ❖ Abdomen circumference – At the level of the umbilicus
 - ❖ Hip circumference – At the level of the highest point of distension of the buttock
 - ❖ Mid-thigh circumference – Mid of the thigh between pelvic and knee joints
 - ❖ Mid arm circumference – Mid of the arm between shoulder joint and elbow joint
 - ❖ Waist-Hip Ratio
- In case of all circumferences, the mean values will be taken before and after treatment.

Biochemical test

Lipid profile (S. Total cholesterol, S. triglycerides, S. HDL, L.D.L, V.L.D.L)

Consent: The written informed consent will be taken from the patient before starting the study. During the study, the confidentiality of each patient will be maintained.

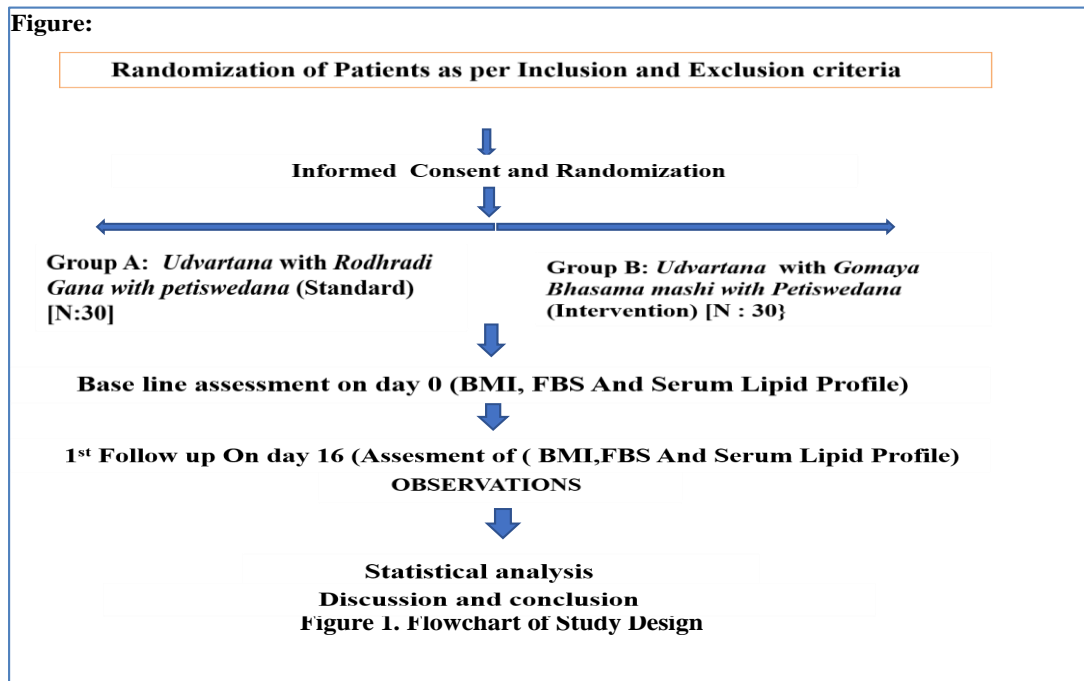


Table 1
Group-wise details of Intervention

Group	Sample Size	Intervention	Quantity and Frequency	Duration	Follow up
A	30	Udvartana with Rodhradi Gana with Petiswedana	100 gm Daily once	15 days	0day(baseline)16 th day
B	30	Udvartana with Gomaya Mashi with Petiswedana	100 gm Daily once	15 days	0day (baseline)16 th day

Result and Observations

Data obtained from baseline & follow-up visits will be used for analysis, and the results will be reflected based on various charts, graphs, and tables. To verify the significance of the results: Reduction in Body Weight by more than 3 Kg, more than 5 cm reduction in Anthropometric measurements & Skinfold thickness (each in cms) after the intervention will be considered significant.

Discussion

Mainly *Kapha-Meda* is a prime pathological factor involved in the pathogenesis of the *Sthoulya*(Obesity). Therefore, drugs exhibiting *Katu-TiktaRasa* (pungent-bitter), *Ushna Virya*, *LaghuRuksha-TikshnaGunaDravya* should be mainly used to

induce the *Medovilayana* and pacify *Kapha Dosha*. *Udvardana* is, a type of massage of the body which subsides or normalizes *Kapha*, liquefies, and dissolves excess fat, is helpful for a good structural framework of the musculoskeletal system. It has *Kapha-Medovilayana* property due to the *Veerya* of drug entering the body and opening the *Mukha* of *Siras*, thereby creating *Paka* of *Kapha* and *Meda* [24]. *Udvardana* is one of the readily available, eco-friendly procedures used to strengthen the locomotor system. As *ApatarpanChikitsa* is the most appropriate line of treatment in *Sthoulya* to prevent *Amasanchaya* and *Srotavarodha*, *Twakasta Agni* gets stimulated after applying drugs used for *Udvardana*, which leads to absorption and digestion of these drugs and further does *Pravilayana* of *Medha Dhatu* (liquefaction of subcutaneous fat) below the skin. In *Sthoulya*, there is an increase in *VikrutaMeda Dhatu*, which stimulates the formation of *Kledain* excess quantity that obstructs circulatory channels, and *AbaddhaMeda Dhatu* (loose fat) is formed. This process may lead to *Dhatvagnimandya* (decreased metabolism of *MedaDhatu* at cellular level). *Medohara* property of drug used for *Udvardana* can be justified based on its *Ushna*, *Tikshna*, *Laghu* properties. Due to *Rukshaguna* of *Dravya* and *Ruksha Udvardana*, absorption of *Kleda* takes place [25]. Thus, *Abaddhatva* of *Meda* and *Kapha* might be reduced. *Gomaya* is *Kaphashamakin* nature, and it is indicated in mostly *Kapha Dosha PradhanaVyadhi* such as asthma, cough, hiccup, eye disorders, mouth disorders, Obesity, etc [26-28]. Other related studies were reviewed [29-44]. *Gomaya* being *Kaphasamak* and *Medohara*, best serves the purpose of *Samprapti Vighatan* of *Sthoulya*.

Conclusion

Conclusions will be drawn according to the observations based on various assessment parameters obtained in this study.

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