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Study the effect of *Rodhradi Gana Basti* and *Udvartana* in *Sthaulya* (Obesity): A Study Protocol

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Abstract
Background: *Sthoulya* (Obesity) has become a burning problem of the day caused by untraditional dietary habits. Obesity is considered as global epidemic, which is increasing due to sedentary life styles and improved socio-economic conditions. In India, in the interim, ongoing information finds that in 2005, almost 14 percent of ladies ages 18 to 49 were overweight or hefty, with higher rates among urban ladies (25 percent) than provincial ladies (8 percent).
Aim and Objective: To study the effect of *Rodhradi gana Basti* and *Udvartan* in *sthauly* (Obesity) and to compare the effect of *Rodhradi gana basti* and *udvartan* on BMI, waist hip ratio, Lipid profile.
Methodology: In this study, 30 patients will be divided randomly into 2 groups (15 in each). In Group a *Rodhradi gana* drugs *basti* as like pattern of *yogbasti* will be administered. In Group B, *udvartan* will be administered with *Rodhradi gana* drugs for 15 days.
Results: Changes will be observed in objective parameters.
Conclusion: *Basti* and *Udvartan* will be lowering the lipid levels, waist hip ratio and BMI too.

Keywords: *Rodhradi gana*, *Niruha basti*, *udvartan*, *sthaulya*, obesity

Introduction: Rational

Sthoulya (Obesity) has become a burning problem of the day caused by untraditional dietary habits. Obesity is considered as global epidemic, which is increasing due to sedentary life styles and improved socio-economic conditions. In India, in the interim, late information finds that in 2005, about 14 percent of ladies ages 18 to 49 were overweight or stout, with higher rates among urban ladies (25 percent) than provincial ladies (8 percent). The pace of overweight and heftiness in ladies, generally speaking, expanded by 3.5 percent a year from 1998 to 2005 [1].

Niruha Basti is one of the most important and commonly used therapies having wide range of therapeutic action. *Niruha Basti* is one which eradicates *dosha* (Humors) from the body, increases strength of the body and has *Achintya shakti* (unpredictable effects) [2]. In *Ayurveda Sthoulya* has been described as a fatal from ages.

Charaka has described the *Sthoulya* is one among the eight *Asto ninditha* [3] (eight despicable) and *Samtarpanajanita roga* [4] (over nourishment). *Kapha*, *Vata* and *Meda* [5,6] are responsible factors for pathogenesis of *Sthaulya*,. Thus the therapy is based on neutralization said factors along with weight and fat reduction.

Foods and drinks alleviating *vata* and reducing *kapha* and fat where in *ruksha, ushna, and tikshna basti* are some of the line of treatment indicated in *sthoulya*. Hence the line of treatment explained for *Sthoulya* includes *udavartana*, where in *ushna, teekshna, kaphahara*, therapeutic lines are followed [7]. The present study will be taken up to compare the effect *Udvartana* and *basti* in *Sthoulya* with *Rodradi gana dravyas.*

The *Sthoulya* is explained in context of *medoroga*. In Ayurveda *Sthoulya* has been described since very early days in various *Samhitas*, *Sangraha granthas*, *Nighantu*, etc. As Charaka has described *Sthoulya* is one among the eight *Asto ninditha*s [8] and *Samtarpanajanita roga* [9]. In pathogenesis of *Sthaulya*, *Kapha*, *Vata* and *Meda* [10, 11] are main responsible factors. Thus the therapy should be based on all these factors i.e. *Vata Kapha hara* and *medohara*.

Etiology and treatment of *Sthoulya* are dealt in detail in *Charaka* [12] *and Sushruta Samhita* [13]. Information regarding the detail description of Obesity based on BMI, causes and complications are observed from the contemporary texts [14].

Rational of the Study

In this disease; the excessive production of abnormal *Meda Dhatu* is clearly visualized. It is proved that the main culprit of pathogenesis of *Medoroga* is *Kapha* and *Meda*. Therefore, the first line of treatment is considered to restrict the excess production of *Kapha* and *Meda*. Many theory and medicament put toward us for the management of the disease but till now perfect therapy for this problem is not found. Even by the use of modern medicine, unwanted effects and long term complications are commonly seen but in *Ayurveda* obese persons reduce their weight without any side effects. Also *Sushruta* has underscored on metabolic unsetting influences in the etiopathogenesis of *Sthaulya*. Looking in to the realities of pathogenesis of *sthaulya* referenced in old style messages, it tends to be said that the medications, which diminishes satiety, amends the elements of *Bhutagni* and *Dhatvagni* (digestion) and simultaneously

have weight or fat or cholesterol decreasing activities (*Medohara*, *Kaphahara*), might be appropriate for the administration [15].

Aim and Objectives

Aim

Study the effect of *Rodhradi gana basti* and *Udvartan* in *Sthaulya* (Obesity)

Objectives

1. To evaluate the effect of *Rodhradi gana basti* on Lipid profile, Anthropometric and BMI.
2. To evaluate the effect of *Rodhradi gana Udvartan* on Lipid profile, Anthropometric and BMI.
3. To compare the effect of *Rodhradi gana Udvartan* and *Basti* on Lipid profile, Anthropometric and BMI.

Case Definition

Analyzed and Confirmed instances of either sex between the age gatherings of 20 to 50 years having stoutness. As per WHO corpulence is a BMI more noteworthy than or equivalent to 30. And overweight is a BMI more noteworthy than or equivalent to 25. Patient with overweight (E66.0 of ICD-10 criteria) of preset will be included in to the study.

Research Question

Whether *Rodhradi gana basti* and *udvartan* is effective on *sthaulya* (obesity)?

Hypothesis

Rodhradi gan basti and *Udvartan* is effective on *sthaulya* (obesity)

Null Hypothesis

Rodhradi gan basti and *Udvartan* doesn't effect on *sthaulya* (obesity)

Study Type

Interventional

Trial Design

Randomized comparative clinical trial

Methodology

Study Setting

The study will be conducted in academic hospital MGACH and RC, Salod (H), Wardha.

Table 1: Composition of the trail drugs

Sr. No.	Sanskrit Name	Botanical Name	Proportion
1	*Lodhra*	Symplocos recemosa	1 part
2	*Palash*	Butia monosperma	1 part
3	*Shonaka*	Oroxylum indicum	1 part
4	*Asoka*	Saraca Indica	1part
5	*Bharangi*	Clerodendrum serratum	1 part
6	*Kayaphala*	Myrica esculenta	1 part
7	*Yelvaluka*	Prnus serasus	1 part
8	*Shalmali*	Salmalia malabarica	1 part
9	*Manjishta*	Rubia Cordifolia	1 part
10	*Kadamba*	Anphocephalus cadamba	1 part

Eligibility criteria

Primary obesity (E66.0 of ICD- 10 criteria) Patients with overweight where BMI > 25-30kg/m^2 Patients of age between 20 to 50 years.

Following Are Excluded From Study

Drug induced obesity (E66.1 of ICD – 10 criteria) Extreme obesity with alveolar hypoventilation (E23.6 of ICD – 10 criteria) Obesity due to any secondary causes.
Adiposogenital dystrophylipomatosis (E23.6of ICD- 10 criteria) Dolorosa (E88.2 of ICD -10 criteria)
Other systemic diseases which intervenes with the course of treatment Patients of age under 20 and above 50 years.

Table 2: Interventions of both groups

Grouping	Group A	Group B
Sample size	15	15
Intervention	*Rodhradi gana basti*	*Rodhradi gana udvartan*
Duration	15 days	15 days
Follow up	15 days	15 days

Criteria for Discontinuing or Modifying Allocated Interventions

Subject will be pulled back from the investigation if any untoward rate, highlights of medication affectability or some other malady or issue emerges, the subject will be offered free treatment till the issue dies down.
Follow up: 15th days

Primary Outcomes

We will see the impact of *Rodhradi gana basti* and *Rodhradi gana udvartan* on BMI, Waist hip proportion and Anthropometrics boundaries when treatment. Information will be communicated as standard mistake of mean at 5 % level of noteworthiness. It is hypothesized that *Rodhradi gana* will be more effective through *basti* and *udvartan* and we will compare the effect between the *basti* and *udvartan* in BMI, Waist hip ratio.

Secondary Outcomes

We will see the effect of *Rodhradi gana* through *basti* and *udvartan* on all parameters of lipid profile (Serum total cholesterol, Serum triglycerides, low density lipoproteins (LDL), High density lipoproteins (HDL), Very Low density lipoproteins (VLDL), and HDL Cholesterol ratio.

Discussion

The *Lekhana* (Scraping /lancing) in Ayurveda liquefies and eliminates the excessive deposited *dosha* and deformed *dhatu*, thus the *basti* and /or *udvartana* has the adequate effect on reducing the obesity/ overweight. *Basti*, nourishes and strengthens all the *dhatus* [16]. *Vagbhata* [17]. defined *Udvartana* as massage of the body subsides or normalizes *kapha*, liquefies and dissolve excess fat, best owes steadiness and strength to the organ of body and makes the skin healthy and smooth. *Udvartana* is having the *qualities* of *Kapha-Medovilayana* property. Due to *ushna* and *teekshna guna* of *dravya* and forceful massage effect and, the *Veerya* of drug enters into body through. There after it opens the *mukha* of *siras*, thereby making *paka* of *Kapha*

and *Medas*. Due to this, there will be liquification of *Kapha* and *Medas*. *Rodradradi gana dravyas* mentioned in *Susruta Samhitaa* [18]. are *kaphahara* and *medahara*. *Basti* has been mentioned by *Susruta* [19]. in specific *Lekhan basti* for removal of overweight and fat accumulations. Components of *Rodhradi gana* are having *ushna* and *tikshna* properties there by acting as *kaphahara* and *medohara* hence they may prove to be a useful in *Sthoulya* (obesity). Reviewed study for discussion [20, 21, 22].

Statistical Analysis
Data will be analyzed on the basis of appropriate statistics paired unpaired t-test and ANOVA by using SPSS software.

Time Duration till Follow up- 30th Days
The treatment duration for the patients is 15th days and after that follow up for 15th days.

Follow up Period
15th days

Time Schedule of Enrolment, Interventions
Subjects will be enroll in the study after clearance of Institutional Ethical Committee. Interventions will be *Basti* and *Udvartan.*

Recruitment
15 (in each group) sample will be recruited by single randomizing sampling method.

Methods
Literature review search, plan of work, blue print in the form of flow chart, row materials collection, preparation of medicine, data collection, treatment and its effect will be observe which route of administration is best and statistical analysis.

Data Collections Methods
Randomized sampling

Objective Criteria
1. Calculation of BMI(weight in kg divided by height in meter sqare)
2. Waist Hip ratio
3. Anthropometrics (Measuring skin fold thickness by using Harpenden calipers) Tricep, biceps, Intra scapular, sub scapular, abdomen, thighs

- Measurements are taken at various position namely, chest, Abdomen, Buttocks, Thighs

1. Lipid profile (12 hours fasting)

a. Serum total cholesterol
b. Serum triglycerides
c. Low density lipoproteins (LDL)
d. High density lipoproteins (HDL)
e. Very Low density lipoproteins (VLDL)
f. HDL Cholesterol ratio

Data Management
The data coding will be done by principle investigator

Statistical Methods
Paired and unpaired for objective criteria, non-parametric for subjective criteria, ANNOVA for comparing between two groups.

Ethics and Dissemination
Research ethical approval, after critical evaluation and presentation the ethical committee has approve the research topic.

Consent or Assent
Patient will be given detail information regarding intervention in his own language. Then written consent will be taken from patients before starting the study.
During study the confidentiality of each patient will be maintained.

Dissemination Policy
The data will be disseminated in the form of paper publication and Monograph. Authorship eligibility guidelines and any intended use of professional writers.
Informed consent material- patient will be given all consent material in the form of hard copy, and other related documents.

Strengths
Rodhradi gana will be work for the reducing BMI, waist hip ratio, mainly on Lipid profile. If proposed study results in the positive outcome then it will be established new mode of management for the *Sthauly* (Obesity).

Limitation
Specific geographical area, convincing the patients for *basti*.

Conclusion
Conclusion will be mentioned after the deliberate and analyzing data.

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