A Comparative Study to Evaluate the Efficacy of Lekhana Basti and Modified Vachadi Gana Basti in Combination with Navaka Guggulu in Sthaulya (Obesity) - A Study Protocol

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Authors’ contributions

This work was carried out in collaboration among all authors. Author AB designed the study, performed the statistical analysis, wrote the protocol and first draft of the manuscript. Authors SP and MN managed the analyses of the study. Author MN managed the literature searches. All authors read and approved the final manuscript.

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Study Protocol

ABSTRACT

Background: Sthaulya described as Obesity occurs due to the vitiation of Kapha & Vata. The signs and symptoms of Sthaulya can be correlated with Obesity. This has been said in Ayurveda and Sthaulya purusha (Obese person) is considered one of the nindita Purusha. Lekhaniya gana contains the drugs like Triphala, Shatpushpa, Madhu (Honey), Ushaka, Kasis, Tuttha, Shilajit, Saindhava (Salt), Yavakshar, Gomutra (Cow Urine) which are having specially lekhaniya (Scrapping) properties. Kapha and Meda (fat) hara property, in sthaulya increased kapha and meda (fat) is seen, the medicine having these lekhaniya property helps to scrap the excess fat from the body so this medicine is helpful to reduce fat. While Modified Vachadi Gana (Group of herbs) contains Devdaru (Cedrus Deodara), Shunthi (Zingiber Officinale), Vacha (Acorus Calamus), Haritaki

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INTRODUCTION

Obesity is known as ‘Sthaulya’ in Ayurveda and is characterized as the condition in which unreasonable measure of fat is aggregated in the body. At the point when the Agni (digestive fire) is being vitiated, the ama (morbid material) is developed in the body [1]. This has been said in Ayurveda, and Sthaulya Purusha (Obese person) is considered one of The Nindita Purusha (despicable person) [2]. Obesity has become epidemic in some developed countries, and it is usually caused by a combination of constitutional, social factors, Biological factors like genetic & hormonal, psychological factors like individual & family [3]. Overweight and Obesity have reached epidemic proportions in India in the 21st century affecting 5% of its population.

As per the World Health Organization (2016), there are around 2 billion grown-ups overweight; of those, 650 million are viewed as influenced by heftiness (BMI>30 kg/m2). That equates to (39% of men and 40% of ladies) of grown-ups matured 18 or over overweight, with 13 % fat. The overall pervasiveness of heftiness almost significantly increased somewhere in the range of 1975 and 2016. It is assessed since the vast majority of the total population lives in nations where overweight and Obesity slaughters a more significant number of individuals than underweight [4].

Basti (Medicated Enema) is one of the five processes explained in Panchakarma; if we use it in different drugs combinations with medohara and lekhaniya property, it reduces Meda Vriddhi (excessive fat). The morbid humours are expelled out of the body from the Rectal route during this procedure with the help of medicines in Classical Vachadi Gana Basti & Modified Vachadi Gana Basti the lekhana (Scraping), medohar(fat reducing property), Vata kapha hara hara property.

Bariatric surgery carries risks of having short and long-term complications to be an option for patients with Severe Obesity. The most common complication after surgery is peritonitis, herniation, and pulmonary complications [5]. Some of the co-morbidities related to overweight and Obesity include cancers (cancer of breast, endometrial, ovarian, colorectal, oesophageal, kidney, pancreatic, prostate), Coronary artery diseases, type 2 diabetes, arthritis, asthma and also premature morbidity and mortality. Although there is no cure for Obesity, there are multiple treatment options.

In Ayurveda, Sthaulya has been described as fatal for ages. Charaka has described the Sthaulya as one among the eight Ashto ninditha (eight despicable) and Samtarpanajanita roga (over nourishment). Kapha, Vata and Meda are responsible factors for the pathogenesis of Sthaulya. Thus the therapy is based on neutralization of said factors along with weight and fat reduction [6].
Saindhava, Yavakshar, Gomutra [7]. While Modified Vachadi Gana contains devdaru, Shunthi, Vacha, Haritaki, Ativisha, Nagarmotha, Ushaka, Kasis, Tuttha, Shilajit, Saindhava, Yavakshar [8]. Modified Vachadi Gana having Vata and Kapha hara property & used in Vata kaphaja vikara and sthaulya is one of the vata kaphaja vikara so to treat it Vata Kapha reducing medicine is to use. Modified Vachadi Gana having those above properties apart from that also having lekhaniya property. Hence, it also helps to scrap the excess fat from the body so that this medicine may reduce fat.

1.1 Rationale

Medoroga (Obesity) is increasing global attention by its increasing prevalence. Globally it is becoming a life-threatening problem. Ayurveda a wonderful old tradition has contributed many methods to combat this lifestyle disorder. The main Samprapti (pathogenesis) Ghatak of medoroga (fat related disease) is accumulated Kapha in the body, which we have to expel out through purification.

1.2 Aim

To study the effect of Lekhana Basti & Modified Vachadi Gana Basti along with Navaka guggulu in the management of Sthaulya (Obesity).

1.3 Objectives

- To study Lekhana Basti’s effect on body mass index, body circumference measurements, skin fold thickness, and lipid profile.
- To study the effect of Modified Vachadi Gana yoga basti on body mass index, body circumference measurements, skinfold thickness & lipid profile
- To compare the efficacy of Lekhana Basti and Modified Vachadi Gana yoga basti on body mass Index, body circumference measurements, skinfold thickness & lipid profile.

2. METHODOLOGY

2.1 Research Question

Wheather Modified Vachadi Gana Basti along with Navaka Guggulu is more efficacious than Lekhana Basti and Navaka Guggulu in the management of Sthaulya (Obesity)?
Table 1. Methodology

<table>
<thead>
<tr>
<th>Grouping</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>35 Lekhan Basti</td>
<td>35 Modified Vachadi gana basti</td>
</tr>
<tr>
<td>Intervention</td>
<td>8 days yoga basti + 16 days panihara kala + Navaka guggulu</td>
<td>8 days yoga basti + 16 days panihara kala + Navaka guggulu</td>
</tr>
<tr>
<td>Duration</td>
<td>8 days yoga basti + 16 days panihara kala + Navaka guggulu</td>
<td>8 days yoga basti + 16 days panihara kala + Navaka guggulu</td>
</tr>
<tr>
<td>Follow up</td>
<td>24th, 60th, 90th days</td>
<td>24th, 60th, 90th days</td>
</tr>
</tbody>
</table>

Table 2. Drugs for basti composition of trial drugs

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Group</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Standard group</td>
<td>Lekhan Basti: Saindhavam- 1/2 aksha + Makshika- 100 ml (1 prasrut) mixed well then add Sneha- 150 ml (11/2 prasruti), kalka- 48 gm (1/2 prasruti), Kwatha- 200 ml (2prasruti), Gomutra-100 ml (1 prasrut), Prakshepa -1 Kashu 12 gm (Yavakshara, shuddha shilajit, Kasus, Hingi, Tuttha, ushaka)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decoction of Lekhaniya Gana: Decoction of Lekhaniya Gana – 100 gm Kwatha churna( Lekhaniya Gana) + 800 ml water = boiled = and reduced to 200ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anuvasa Basti: Tila Taila Dose 72 ml (11/2 Pala) Saindhavam &amp; Satahava- 2 g.m (2 masha)</td>
</tr>
<tr>
<td>2.</td>
<td>Experimental Group</td>
<td>Modified Vachadi Gana Basti: Saindhavam- 1/2 aksha + Makshika- 100 ml (1 prasrut) mixed well then add Sneha- 150 ml (11/2 prasruti), kalka- 48 gm (1/2 prasruti), Kwatha- 200 ml (2prasruti), Gomutra-100 ml (1 prasrut), Prakshepa -1 Kashu 12 gm (Yavakshara, shuddha shilajit, Kasus, Hingi, Tuttha, ushaka)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decoction of Vachadi gana Basti: Decoction of Vachadi gana – 100 gm Kwatha churna( Vachadi) + 800 ml water = boiled = and reduced to 200ml</td>
</tr>
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<td>Anuvasa Basti: Tila Taila Dose 72 ml (11/2 Pala) Saindhavam &amp; Satahava- 2 g.m (2 masha)</td>
</tr>
</tbody>
</table>
The abhyanga will be done with plain tila taila to the whole body, and sweda will be given only on the area below the ribs to foot.

2.6 Pradhana Karma

1) Patient will be asked to lie on the Panchakarma droni (Specific table for procedure) in vama parshwa (left lateral position with right leg flexed) and asked to take a deep breath, sukoshna (luke warm) basti dravya (Enema drugs) administered slowly with the help of a glycerin syringe fitted with a rubber tube (anuvasana basti) or enema can fitted with soft rubber tube (niruha basti).

2) Extreme care will be taken to avoid all the basti vyapats (Complication of enema). Then the patient was asked to shift from right to left lateral and vice-versa repeatedly for five minutes in the case of anuvasana (oil enema), mrudhu tadana (tapping) was done over kati (back region), prushta (Buttock) and uru pradesha (Thigh region).

3) The time of administration, the time of retention and any complication present will be noticed at the spot.

2.7 Paschat Karma

1) Basti pratayagamana kala (retention of enema time) will be recorded carefully and vital data of the patient will be recorded by the examination.

2) Then the patient will be advised with all pathyapathy (Dos and Don’ts) to maintain the basti pariharakala.

2.8 Selection, Composition & Preparation of Material

For Massage – Sesame oil – 100 ml
For fomentation by steam – Raw Dashamoola (Roots of Ten herbs) – 50 gm

2.8.1 Criteria for discontinuing or modifying allocated interventions

If subjects will observe any side effects and issues will stop medicine, they will be windrows from the study. If any adverse effects watch, they will get free medication from the principal investigator.

Follow up – 90th days

Secondary outcome-Lekhan Basti and modified Vachadi Gana Basti will reduce the values 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.

Statistical analysis- Data will be analyzed based on appropriate statistics paired with unpaired t-test and ANNOVA by using SPSS software.

Time duration till follow up – The subjects' treatment duration will be 16th days and after that follow up for 90th days.

Follow up period- 90th days.

Time schedule of enrolment, interventions- Subjects will be recruited for the study after clearance of the Institutional Ethical Committee. Interventions will be lekhan and modified vachadi gana basti.

Recruitment-35 subjects in each group will be recruited by a single randomizing sampling method.

2.9 Methods

Literature review search, plan of work, blueprint in the form of flow chart, row materials collection, preparation of medicine, data collection, treatment and its effect will be observed and statistical analysis.

Data collections methods- Randomized sampling

2.10 Subjective Parameters

1. Chala sphika [9] (excessive fat on buttocks)
2. Chala stana [9] (Excessive fat on Breast)
3. Chala udara [9] (Excessive fat on abdomen)
4. Dourbalya [10] (Weakness)
6. Kshudati matra [10] (Excessive hungry)
8. Pipasati [10] (Excessive Thrust)

2.11 Objective Parameters

1. Body Mass Index (k.g/m2)
2. Body circumference measurements
Measurement of the circumference of the following areas, where adipose tissue is generally found to be more, was taken:

a. Chest: In normal expansion, at the level of the nipples
b. Waist: At the level of the umbilicus
c. Pelvis: At the level of the anterior superior iliac spine
d. Hip: At the level of the highest point of distension of the buttocks
e. Mid-arm: Middle of the arm between the shoulder joint and the elbow joint
f. Mid-thigh: Middle of the thigh between the hip joint and the knee joint
g. Mid-calf: Middle of the calf between the knee joint and the ankle joint

3. Skinfold thickness:-

The effectiveness of therapy on body fat was assessed by measuring the skinfold thickness using Harpenden Calipers before and after treatment; measurement was taken in the following areas:

a. Skinfold thickness over the middle portion of the biceps muscle
b. Skinfold thickness over the central part of the triceps muscle
c. Skinfold thickness over the abdomen
d. Skinfold thickness over the middle portion of the arm
4. Lipid profile
5. Weight

2.12 Assessment of Basti [12]

1. Prasrushta Vitkata , mutra, samira(Passing urine, stool, flatus)
2. Laghavta (Lightness in the body)
3. Ruchi (appetite)
4. Agni vriddhi (Increased digestive power)
5. Asaya Laghuta (lightness of organs)

2.13 Investigations Routine

2.13.1 Serological investigations

Complete blood count with Erythrocytes Sedimentation Rate (To exclude an infectious condition)

- Random Blood Sugar (To rule out Diabetes Mellitus)
- Lipid profile (To rule out Hyperlipidemia)

2.13.2 Data management

Data coding will be done by the principal investigator.

2.13.3 Statistical method

Chi square test, Paired and Unpaired for objective criteria, nonparametric for subjective criteria, ANNOVA for comparing between two groups.

2.13.4 Dissemination policy

Data will be disseminated in the form of paper publication and Monograph. Authorship eligibility guidelines and any intended use of professional writers.

2.13.5 Informed consent materials

Subjects will be given all consent material in the form of hard copy and other related documents. Before starting the interventions, subjects will be given detailed information regarding intervention, preparation of medicine and study in his /her language. Then written consent will be taken from patients.

3. DISCUSSION

Sthaulya (Obesity) is a state of increased Medodhatu (fat) [13]. Sthaulya is a disease in which there is abundant growth of Medodhatu in the body beyond normal limits. It is one of the Santarpanottha Vikaras(Disease due to consumption of excessive calories) [14].

Based on Nidanas, there lies a significant similarity in Medorog and Hyperlipidemia. Aharaja (dietary causes), Viharaja (lifestyle factors), Manasika(Psychological factors) and Beeja Doshaja (Genetic factors) Nidanas (diagnosis) observed in both the disease are almost similar being primarily Santarpankaraka. In this manner, the Samprapti (pathogenesis) likewise goes the same for both the conditions up somewhat. It contrasts in the last part because of ‘Medo Dhatvagnimandya’, ‘Asthayi Medodhatu’ increments: because of the absence of change to Sthayi Meda prompting ascends in flowing Lipids.

Kapha dosha’ is associated mainly due to its ‘Ashrayashrayi Sambhandha’ to Meda. Similarly, vitiated Pitta is involved as seen by impairment of proper Agni function. Vata has a role in pathogenesis as seen from the impaired Dhatwaagni, which is appropriate Vayu's function. ‘Asthayi Medo Dhatu’ is transported via Rasa Dhatu, and Meda Dhatu has a direct
quantitative increase due to ‘Dhatvagnimandya’. Hence both these Dhatu shows a qualitative impairment seen on clinical grounds.

Sthaulya is a ‘Kapha-Vata pradhana Tridoshaj vyadhi’, and Acharyas has recommended vataghna and Kaphaghna annapana and aushadhi for this disease. Lekhana Basti is selected as it has for most action on Lekhana Karma. In Group 02 Modified Vachadi Gana Basti is chosen as it having Vata Kapha & lekhan karma Both. We have chosen Lekhana Basti & Modified Vachadi Gana Basti for Sthaulya. It has less risk, safe and easy for Sthaulya as it has less chance, safe and easy for administration than Vamana and virechana.

Studies on basti were reported by Hiware et al. [15] and Bhende et al. [16] Studies on Obesity and different assessment tools were reviewed [17-19]. Related aspects of Obesity were also addressed in the studies of Dixit et al. [20], Khatib et al. [21] and Regmi et al. [22].

3.1 Probable Action of lekhan basti & Modified Vachadi Gana Basti

Lekhan Basti & Modified Vachadi Gana Basti was prepared by combining the taila, madhu, gomutra, lavana, which cosist ushana and tikhna guna. Taila has anupravana bhava. Due to that it passes through illoceacal valve and reaches up to Grahan, where it absorbed. Basti inhibits the fat absorption by reaching upto grahan. Hence, it pacified Saman vayu and brought Jatharagni to its average level and activated the vyana vayu to break the Sroto sang and synergize the action of Lekhan therapy at the cellular level. The basti drug consists of kasaya, tikta and katu rasa, so that properties potentiate the action of lekhan medicine.

3.2 Strength

Lekhan Basti and modified Vachadi Gana Basti will be work for reducing BMI, Weight and Lipid profile

3.3 Limitations

Specific geographical area, convincing the patients for basti.

4. CONCLUSION

It will be concluded that Modified Vachadi Gana Basti will help to reduce weight and may decrease the value of lipid profile. Further conclusion will be mentioned after the deliberate analysis of data.

CONSENT

It is not applicable.

ETHICAL APPROVAL

Research ethical approval, after critical evaluation and presentation in front of SRC and then IEC, the ethical committee has approved the research topic. IEC letter no. MGACHRC/IEC/February-2021/189.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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