



**Protocol**

## **Evaluation of the Efficacy of Pippalyadi Basti and Lekhan Basti in the Management of Medoroga with Special Reference to Obesity – A Protocol**

Ritu Wadhwa<sup>1</sup>, Sonali Wairagade<sup>2,\*</sup>, Dnyaneshwar Padavi<sup>3</sup>, Ranjit S. Ambad<sup>4</sup>, Shriram Kane<sup>5</sup> and Jayant Giri<sup>6</sup>

<sup>1</sup>Dept. of Panchkarma, D Y Patil University, School of Ayurveda, Nerul, Navi Mumbai, India

<sup>2</sup>Dept. of Kayachikitsa, Datta Meghe Ayurved Medical College Hospital and Research Centre, Wanadongri, Nagpur (MS), India

<sup>3</sup>Dept. of Kayachikitsa, D Y Patil University, School of Ayurveda, Nerul, Navi Mumbai, India

<sup>4</sup>Dept of Biochemistry, Datta Meghe Medical College, Shalinitai Meghe Hospital & Research Centre, Nagpur, Maharashtra, India

<sup>5</sup>Dept. of Medicine Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Wardha, India

<sup>6</sup>Dept. of Mechanical Engineering, Yeshwantrao Chavan College of Engineering, Nagpur, India

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### \*CORRESPONDING AUTHOR

Dr. Sonali Wairagade, Professor & HOD, Dept. of Kayachikitsa, Datta Meghe Ayurved Medical College Hospital and Research Centre, Wanadongri, Nagpur (MS), India.

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### ABSTRACT

**Background:** The conventional concept of etiopathogenesis, prognosis, and management of obesity is very similar and equally advanced to the Medoroga/Sthaulyaroga of Ayurveda, which was conceived in 1500 BC by Acharya Charaka. Overweight or obesity is mostly found in people with predominantly Kapha-type constitutions. According to Acharya Charak, apart from the genetic factors, diet (like shleshmakar, abhishayandi) & lifestyle (like avyayam, divaswapna) are the main contributing factors in the aetiopathogenesis of Medoroga. As per previous study Lekhana Basti was found to have moderate results in obesity. Pippalyadi has Chitraka and Pippali in addition to the other components of Lekhan basti so could have better results in correcting the vitiated Agni. Therefore, Pippalyadi basti is chosen for the current study.

**Objectives:**

- To evaluate efficacy of Pippalyadi Basti in the management of Medoroga.
- To compare the efficacy with Lekhana Basti
- Conceptual study of Medoroga in Ayurvedic texts and Obesity in modern medicine.
- Effect of Pippalyadi Basti & Lekhan Basti on B.M.I.

**Methodology:** D.Y. Patil Ayurved Hospital, Samhitas & modern books of medicine, Pharmacy attached to college for the preparations of the drugs, international & national medical journals and magazines, OPD, IPD, Labs, other provisions of the hospitals will be availed to do this intended work.

**Expected Results:** Changes will be observed in objective outcomes.

**Conclusion:** Conclusion will be drawn by suitably analyzing data.

**Keywords:** LekhanBasti; Medoroga; Obesity; Pippalyadibasti

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## Introduction

**Rational justification:** The prevalence of obesity has increased threefold within the last 20 years & continuous to rise. The management of obesity with modern drugs is quite unsatisfactory as most of the modern drugs employed in the treatment of the obesity possess serious side and toxic effects as or list at, which is approved for use in obesity leads to a modest weight loss of 29 kg after 1 to 2 yr and its use is associated with many gastrointestinal side effects. For the extremely obese patient with established complications, surgery may be the most appropriate intervention and may be lifesaving. However, due to its cost and the risk of complications, the search is still on for other effective and safe treatments.

*Sthoulya* is one among the major diseases that falls under the category of *santarpanottha* vyadhis [1]. This condition can lead to the association of many other disorders in its course. Hence, it gains high significance from the medical point of view.

To overcome the seriousness of the disease it is decided to launch the clinical trial which has role in *sampraptivighatan* (breakdown the pathogenesis of disease). A drug that is administered rectally will, in general (depending on the drug) have a faster onset, higher bioavailability, shorter peak, and shorter duration than the oral route [2,3]. Hence *Basti* is taken for the study. Acharaya Charak has said in sutra *sthanrukshatikshnabasti* and *udavartan* is beneficial for the management of *Medoroga* (*Atishul*) [4].

“वातध्वन्यन्नपानानि श्लेष्मदोहराणि चारुक्षोष्णा बस्तयस्तिक्षणा रुक्षाणयुद्वर्तनानि च॥”  
(च. सु.२१/२१)

Keeping this point in mind *pippalyadibasti* [5] is taken as *rukshatikshana basti* which is advocated by Acharya Charak, and beneficial for *Shleshmyikar*.

“पिप्पल्यश्चित्रकश्चेतित्रयस्तेश्लेष्मरोगिषु सक्षारक्षोद्रगोमुत्राना तिस्तेहान्विताहिताः॥” (च. सि.१०/२४)

*Pippalyadibasti* does *strotas shodhan* and will be effective in the reduction of body weight & other associated symptoms of obesity. In one group *Pippalyadi Basti* and another group *Lekhan Basti* [6] will be given. *Lekhan Basti* is a type of enema which contains *ayurvedic* drugs that cause the excoriation of the excessive fat from the body.

“त्रिफलाकाथगोमुत्रक्षोद्रक्षारसमायुताः

। ऊषकादिप्रतीवपा वस्तयो लेखनाः स्मृताः॥” (सु. चि.३८/८२)

As per previous study *Lekhana Basti* was found to have moderate results in obesity. *Pippalyadi* on the other hand has *Chitraka* and *Pippali* in addition to the other components of *Lekahanbasti*, this could have better

Results in correcting the vitiated Agni. Therefore, *Pippalyadibasti* is chosen for the current study. Approach of this study is to provide safer, effective, comprehensive and rational option for management of *Medoroga*.

## Aim

To compare the efficacy of *Pippalyadi Basti* and *Lekhan Basti* in the management of *Medoroga*.

## Objectives

- To evaluate efficacy of *Pippalyadi Basti* in the management of *Medoroga*
- To compare the efficacy with *Lekhana Basti*
- Conceptual study of *Medoroga* in Ayurvedic texts and Obesity in modern medicine.
- Effect of *Pippalyadi Basti* and *Lekhan Basti* on B.M.I.

## Hypothesis

### Null hypothesis

There is no significant difference between efficacy of *Pippalyadi basti* and *lekhambasti* in the management of *Medoroga*.

### Alternative hypothesis

*Pippalyadi Basti* is more effective than *lekhambasti* in the management of *Medoroga*

*Pippalyadi Basti* is less effective than *lekhambasti* in the management of *Medoroga*

## Material and Method

### Inclusion Criteria

- The patients having clinical signs and symptoms of *Sthoulya*
- The patients whose age >18 and <50 years will be selected
- B.M.I criteria (30-40 kg/m<sup>2</sup>), Waist and hip ratio
- The patients who are eligible for *Basti* and ready to give consent

### Exclusion Criteria

- Patients with long term Steroid treatment & anti-psychotic drugs.
- Patients with severe Hypertension, Diabetes & Hypothyroidism.

- Patients with evidence of Renal, Hepatic and Cardiac involvement.
- Pregnant and lactating woman
- Associated with any rectal pathology like hemorrhoids, fissure etc.

### **Sample Size**

The sample size of the study is 60.

### **Place of the trial**

D.Y. Patil School of Ayurved & Hospital, Nerul Navi Mumbai

### **Diagnostic criteria**

Diagnosis will be based on: Body Mass Index (BMI)  
Patients with BMI >30, <40 (Kilograms per square meter).

Increased weight for specific height as per Height – Weight chart

### **Laboratory investigations**

- Complete blood count includes CBC & ESR
- Serum T3, T4 & TSH
- Blood Sugar Level
- Blood Lipid Profile

### **Methodology**

#### **Source and Data**

D.Y. Patil Ayurved Hospital, Samhita's & modern books of medicine, Pharmacy attached to college for the

preparations of the drugs, international & national medical journals and magazines , OPD , IPD , Labs , other provisions of the hospitals will be availed to do this intended work.

**CRF-A** case proforma will be specially designed with all points of history-taking, physical signs, lab investigations as mentioned in classics and allied sciences. The parameters of signs and symptoms will be scored as mentioned in the proforma.

### **Sample size**

60 patients will be divided in to 2 groups

30 patients for each group

Group A - *Pippalyadi Basti* will be given

Group B - *Lekhan Basti* will be given

### **Material/Drug**

Drugs of *Pippalyadi Basti* - *Gomutra, Madhu, Shatpushpa, chitrak* and *Pippali* will be purchased from standardised Pharmacy.

Consecutive *Niruhabasti*(*Pippalyadi Basti* and *Lekhan Basti*) for 3 days and *Anuvasan* will be given with *triphaladi tail* (100ml) on first day, fourth day and again 3 *Niruh* and last day *Anuvasan* will be given.

*Pippalyadibasti* and *Lekhanbasti* is type of *niruhabasti* and will be prepared as per standard operative procedure.

### **Duration and Doses**

Table 1 enlists duration and doses.

**Table 1:** List of drugs, dose, kal, duration and follow-up.

1	Drug	<i>Niruha- Pippaliadiniruhabasti &amp; LekhanBasti</i> (no. of basti 6) <i>Anuvasan with triphaladi tail</i> (no. of basti 3) <i>SthanikSnehan</i> with til oil and <i>Sthanik Swedan</i> with <i>Triphala kwath Nadi Sweda</i>
2	Dose	<i>Niruha</i> – 560 ml <i>Anuvasan</i> - 100 ml
3	Kal	<i>Niruha- abhukta</i> <i>Anuvasan - adrapaninambhojan</i> (immediately after meals)
4	Duration	<i>Basti karma-</i> D1, D5 and D 9- <i>Anuvasan basti</i> D2, D3, D4 then D6, D7 and D8 means 3 days Continuous <i>Niruhabasti</i> .
5	Follow up	0, 10 <sup>th</sup> , 27 <sup>th</sup> , 38 <sup>th</sup> and 56 <sup>th</sup> day (8 weeks)

### **Assessment Criteria**

The assessment of overall effect of the therapy was based on the following grading -

### Subjective parameters

Clinical symptoms of the patient as described in *Charak Samhita* (ca. su. 21/4) (Table 2).

- *UtsahaHani / Aalasya*

- *Atikshudha*
- *Atipipasa*
- *Atisweda*
- *Dourbalya*
- *Dourgandhya*

**Table 2:** List of subjective parameter, observation and scale of the clinical symptoms.

S. No.	Subjective Parameter	Observations	Scale
1	<i>Alasyal/ utsahahani</i>	No <i>alasya</i> (doing work satisfactorily with proper vigor in time)	Grade 0
		Doing work satisfactorily with late initiation	Grade I
		Doing work unsatisfactorily under mental pressure and takes time	Grade II
		Not starting work on his responsibility and doing little work very slowly	Grade III
		Does not take any initiation does not want to work even after pressure	Grade IV
2	<i>Atikshudha – (on the basis of aharmatra)</i>	Normal appetite 2-3 times daily	Grade 0
		Excess appetite 2-3 times daily	Grade I
		3-4 times daily	Grade II
		4-5 times daily	Grade III
		More than 5times daily	Grade IV
3	<i>Atipipasa</i>	Normal thirst	Grade 0
		Up to 1liter excess intake of water	Grade I
		1 to 2-liter excess intake of water	Grade II
		2–3-liter excess intake of water	Grade III
		More than 3liter intake of water	Grade IV
4	<i>Atisweda</i>	Sweating after heavy work and fast movement or in hot season	Grade 0
		Profuse sweating after moderate work and movement	Grade I
		Sweating after little work and movement	Grade II
		Profuse Sweating after little work and movement	Grade III
		Sweating even at rest or in cold season	Grade IV
5	<i>Daurbalya/Alpa vyayam</i>	Can do routine exercise	Grade 0
		Can do moderate exercise without difficulty	Grade I
		Can do only mild exercise	Grade II
		Can do mild exercise very difficulty	Grade III
		Cannot do even mild exercise	Grade IV
6	<i>Daurgandhya</i>	Absence of bad smell	Grade 0
		Occasional bad smell from the body which removed after bathing	Grade I
		Persistent bad smell limited to close areas difficult to suppress with deodorants.	Grade II
		Persistent bad smell felt from long distance and is not suppressed by deodorants	Grade III
		Persistent bad smell felt from long distance even tolerable to the patient himself.	Grade IV

### Objective Parameters

- Body weight.
- BMI (BMI or Quetelet's Index) BMI=Weight in kg / Height in meter<sup>2</sup>

**According to the BMI, patients can be divided into different degrees of obesity as follows:**

BMI classification:

1. Overweight: 25-29.9 kg/m<sup>2</sup>

2. Obesity (Class I): 30-34.9 kg/m<sup>2</sup>
3. Obesity (Class II): 35-39.9 kg/m<sup>2</sup>
4. Obesity (Class III or morbid obesity): >40kg/m<sup>2</sup>

#### **Criteria for overall assessment of the therapy**

Table 3 enlists the grades for overall assessment of the therapy.

**Table 3:** Grades for overall assessment of the therapy.

Grade 1	Complete remission	100% relief of signs and symptoms
		>20% reduction in body weight
Grade 2	Marked improvement	>75% relief in sign and symptoms
		>15% reduction in body weight
Grade 3	Moderate improvement	50 -70% relief in sign and symptoms
		10-15% reduction in body weight
Grade 4	Mild improvement	25-50% relief in sign and symptoms
		6-10% reduction in body weight
Grade 5	Negligeable improvement	<25% relief in sign and symptoms
		<6% reduction in body weight
Grade 6	Stable	Undiminished sign and symptoms
		No reduction in body weight

#### **Criteria for discontinuing or modifying allocated interventions**

Subject will be withdrawn from the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises, the subject will be offered free treatment till the problem subsides.

**Follow up:** 0, 10<sup>th</sup>, 27<sup>th</sup>, 38<sup>th</sup> and 56<sup>th</sup> day (8 weeks)

#### **Primary Outcomes:**

##### **Outcome of Both the Treatment will be seen in**

*UtsahaHani / Aalasya, Atikshudha, Atipipasa, Atisweda, Dourbalya, Dourgandhya, Body Weight Quality of life, and Adverse effects of treatment if any*

#### **Discussion**

Obesity is a serious concern which directly or indirectly influences pathophysiology of many other diseases especially endocrine disorders [7-13]. Hence, the based on the protocol the following points will be discussed.

- To overcome the seriousness of the disease it is decided to launch the clinical trial which has role in *sampraptivighatan* (breakdown the pathogenesis of disease).
- A drug that is administered rectally will have a faster onset, higher bioavailability, shorter peak, and shorter duration than the oral route.
- Hence *Basti* is taken for the study.
- *Pippalyadibasti* which is *rukshatikshanabasti* does *strotas shodhan* & will be effective in the

reduction of body weight & other associated symptoms of obesity.

- One group will be treated with *Pippalyadi Basti* and another group with *Lekhan Basti*.
- *Lekhan Basti* is a type of enema which contains *ayurvedic* drugs that cause the excoriation of the excessive fat from the body.
- As per previous study *Lekhana Basti* was found to have moderate results in obesity.
- *Pippalyadi* on the other hand has *Chitraka* and *Pippali* in addition to the other components of *Lekhanbasti* this could have better results in correcting the vitiated Agni. Therefore, *Pippalyadibasti* is chosen for the current study.
- Approach of this study is to provide safer, effective, comprehensive and rational option for management of Medoroga.

#### **Statistical Analysis**

#### **Probable Method of Data Analysis**

Pairedt-test will be applied for the assessment of individual group on objective parameters whereas unpaired t-test will be applied to assess the comparative efficacy of the *Pippalyadi Basti* & *LekhanBasti* in Group A with Group B. For subjective parameters Wilcoxon signed rank test will be applied within the groups (Before/After) Mann-Whitney Test will be used between the groups.

**Time duration till follow up:** 8 weeks

**Recruitment:** 60 (30 in each group) patients will be recruited by simple random sampling Lottery method, and PI will allocate and enrol the patient.

### **Method**

#### **Data collection methods**

##### **Assesement criteria**

*UtsahaHani / Aalasya, Atikshudha, Atipipasa, Atisweda, Dourbalya, Dourgandhya*

Body weight, BMI (BMI or Quetelet's Index) BMI=Weight in kg / Height in meter<sup>2</sup> will be assessed before and after treatment.

We will stay in touch with patient by taking contact no. and timely advise them for medication and follow up and data of follow up patient will be stored in documentation with reason.

**Data management:** The data entry coding will be done by PI

**Statistical methods:** Statistical assessment will be done through Mann – Whitney U test

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

**Dissemination policy:** The data will be disseminated by paper publication.

Authorship eligibility guidelines and any intended use of professional writers

**Informed consent materials:** With all the information model consent form and other related documentation will be given to participants.

**Limitations:** This study will not be conducted on major systemic diseases, post traumatic conditions.

### **Expected Results**

- Observation will be recorded during *pippalyadi basti* and *lekhana basti*
- Result will be drawn on the basis of data recorded

### **Conclusion**

Conclusion will be drawn on the basis of observations in clinical study, results & statistical analysis during study after experts (Supervisor) discussion.

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The authors did not receive any financial sponsorship for the research.

### **Conflict of Interest**

The author declares no conflict of interest.

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