Protocol

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

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ARTICLE INFO
Received 18 November 2022
Revised 20 December 2022
Available Online 05 January 2023

ACADEMIC EDITOR
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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 Lekhan 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
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 santaranpanth 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. Acharya Charak has said in sutra sthanrakshatikshnabasti and udavartan is beneficial for the management of Medoroga (Atishthul ) [4].

“वातश्लेष्मनानि श्लेष्मेदोहराणी चारुक्षीणा बलविद्यितिक्रिया रक्षायणुद्वरतानानि च”
(च. सू. २१/२१)

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

“पिप्पल्यायदिवत्रक्षेत्रित्रयस्तोष्णस्तरोशारस्तरोष्णक्षोर्गुमुखनाति भीलितेविविधातिः॥”
(च. सू. ३०/३८)

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 excoration of the excessive fat from the body.

“पिप्पल्यायदिवत्रक्षेत्रित्रयस्तोष्णस्तरोशारस्तरोष्णक्षोर्गुमुखनाति भीलितेविविधातिः॥”
(च. सू. ३०/३८)

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 Lekhan 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 lekhanbasti in the management of Medoroga.

Alternative hypothesis

Pippalyadi Basti is more effective than lekhan Basti in the management of Medoroga

Pippalyadi Basti is less effective than lekhan Basti 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/m²), Waist and hip ratio
- The patients who are eligible for Basti and ready to give consent

Exclusion Criteria

- 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 *triphala 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>
<thead>
<tr>
<th></th>
<th>Drug</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1 | *Niruha* - 560 ml | *Pippaliadiniruhabasti & LekhanBasti (no. of basti 6)*  
*Anuvasan* with *triphaladi tail* (no. of basti 3)  
*SthanikSnehan* with *til oil* and *Sthanik Swedan* with *Triphala kwath Nadi Sweda* |
| 2 | *Niruha* - 100 ml | *Anuvasan*  |
| 3 | *Niruha*- abhukta | *Anuvasan - adrapaninambhojan (immediately after meals)* |
| 4 | Basti karma- D1, D5 and D 9- *Anuvasan basti*  
D2, D3, D4 then D6, D7 and D8 means 3 days Continuous *Niruhabasti*. | 0, 10th, 27th, 38th and 56th day (8 weeks) |

**Assessment Criteria**

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

e-ISSN: 2583:3332

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Subjective parameters

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

- Utsah/Hani / Aalasya
- Atikshudha
- Atipipasa
- Atisweda
- Dourbalya
- Dourgandhya

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

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

Objective Parameters

- Body weight.
- BMI (BMI or Quetelet’s Index) BMI=Weight in kg / Height in meter²

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

BMI classification:
1. Overweight: 25-29.9 kg/m²
2. Obesity (Class I): 30-34.9 kg/m²
3. Obesity (Class II): 35-39.9 kg/m²
4. Obesity (Class III or morbid obesity): >40kg/m²

Criteria for overall assessment of the therapy

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

<table>
<thead>
<tr>
<th>Grade 1</th>
<th>Complete remission</th>
<th>100% relief of signs and symptoms</th>
<th>&gt;20% reduction in body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 2</td>
<td>Marked improvement</td>
<td>&gt;75% relief in sign and symptoms</td>
<td>&gt;15% reduction in body weight</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Moderate improvement</td>
<td>50-70% relief in sign and symptoms</td>
<td>10-15% reduction in body weight</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Mild improvement</td>
<td>25-50% relief in sign and symptoms</td>
<td>6-10% reduction in body weight</td>
</tr>
<tr>
<td>Grade 5</td>
<td>Negligible improvement</td>
<td>&lt;25% relief in sign and symptoms</td>
<td>&lt;6% reduction in body weight</td>
</tr>
<tr>
<td>Grade 6</td>
<td>Stable</td>
<td>Undiminished sign and symptoms</td>
<td>No reduction in body weight</td>
</tr>
</tbody>
</table>

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, 10th, 27th, 38th and 56th 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 striotas 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 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.

Statistical Analysis

Probable Method of Data Analysis

Paired t-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

Assessment criteria

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

Body weight, BMI (BMI or Quetelet’s Index)

BMI=Weight in kg / Height in meter2 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 lekhan 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.

Funding

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

Conflict of Interest

The author declares no conflict of interest.

References

10. VSS P, Adapa D, Vana DR, Choudhury A, Jahangir MA, Chatterjee A. Nutritional components relevant

