Comparative Evaluation of Efficacy of Modified Ashmaghnasveda (Stone Therapy) and Choornapindasveda in Management of Katigraha (Lumbar spondylosis)

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Authors’ contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

ABSTRACT

Background: Katigraha is one of the most common illnesses affecting the Kati area, in which Vata gets are unbalanced in their own sthana (seat), resulting in Graha (stiffness) and Ruja (pain). Lumbar Spondylosis is a disease that causes back discomfort caused by spine movement and is accompanied by rigidity. Ashmaghnasveda is a key svedana treatment that helps with vataja, particularly Sama vataja and vatakaphaja illnesses. In this project, a structurally modified form of Ashmaghnasveda will be employed to produce ekangasveda. The goal of this study was to assess the efficacy of modified Ashmaghnasveda (stone therapy) and churnapindasveda in the treatment of Katigraha (lumbar spondylosis).

Methodology: A total of 64 patients will be enrolled, and they will be evenly divided into two groups. Modified Ashmaghnasveda will be performed for 14 days in Group A (Interventional). Churnapindasveda will be performed for 14 days in Group B (comparator group). Expected Results: The objective parameters will be monitored and documented as they change. Conclusion: Based on the information gathered, conclusions will be reached.
Keywords: Ashmaghnasveda; katigraha; lumbar spondylosis; ashmaghnasveda.

1. INTRODUCTION

Katigraha is a disease that affects the Kati region and causes Vata to become imbalanced in its own sthana. According to Gadanigraha, when Vata is impacted by Ama and lands in Kati pradesh, it manifests Katigraha symptoms such as Graha (stiffness) and Ruja (pain) in Kati pradesh (lower back). [1] Katigraha was also emphasised by Acharya Sharangadharana, who placed it under the heading of NanatmajaVatavyadhi. [2]

Katigrahas often compared with chronic low back pain due to similarity in clinical manifestations. Lumbar Spondylosis is a similar disease which is diagnosed as back pain induced by spine movement and associated with stiffness.[3] Chronic low back pain is diagnosed when pain lasts more than 12 weeks and accounts for almost 50% of total back pain costs. Risk factors include obesity, females, old age, history of back pain and restricted spinal mobility due to any other reason.[4] Various studies have been performed with low back pain as a major complaint, in which Vataghna and Vatakaphaghnna measures including both oral medication as well as Panchakarma procedures displayed highly significant results in all the subjective and objective parameters of Katigraha. Panchakarmaincludes proceduresnamely Vamana, Virechana, Niruha Basti, Anuvasana Basti and Nasya. But, along with these there are vital purvakarma viz. Snehana and Svedana which are also part of Shadvidhaupkrama [5] and therefore are both, purva as well as pradhana karma in various disorders including Vatavyadhi [6].

Out of various classification of svedana, Sagnisveda is one where there is direct contact of Agni and is of 13 types viz. Sankara, Prastara, Nadi, Parishkeha, Avagaha, Jentaka, Ashmaghna, Karshu, Kuti, Bhu, Kumbhika, Kupa and Holaka.[14] Other major classification of Svedana include, according to the area/ part(s) of the body involved i.e. Ekanga (one part of body) and Sarvanga (whole body) [15].

Many studies have been done on effects of localized treatments on Katigraha, Katishula etc. e.g. “Katibasti with RasndiTalai along with Shunthi- Erand Yoga” were found to be very effective in the management of Katishoola.[16]; use of Churnapindasvedain Katigraha was also found to have significant results. [17], [18] Churnapindasvedais a type of rukhasankarasvedawhich is beneficial in vatakaphaja or samavataja diseases,[19] Ashmaghnasveda (Charaka)[20]/ GhanshmaSveda (Vaghhatta)[21],[22]is one of the major svedana procedures which is especiallybeneficial in Sama vataja and vatakaphaja diseases.[23] In its traditional form Ashmaghnasvedais a type of sarvangasveda, in which a stone slab of the size of height of a person is used to induce sarvangasveda and is one of the mahana(strong) svedana karma.[24] This treatment is not being used frequently due to various reasons like tedious and prolonged process, needing a lot of medicinal resources and manpower thereby increasing the cost of treatment due to which it is gradually becoming a lost treatment modality.

Stone massage/ stone therapy being used in various Spa centres and other traditional system of medicine is a relaxing treatment which can be considered as a modified alternative of Ashmaghnasveda, which incorporates the benefits of massage, heat therapy and acupressure all at the same time. The stone massage has a form of impact on the body which uses mechanical stimuli viz. pressure on the tissues to induce desired physiological reactions.[25] In many countries hot stone therapy for whole body or spine is also being used for treatment of stiffness, aches, stress and anxiety etc. in which a stone slab is directly heated while a person lays on it and has shown very good results.[26] This hot stone therapy lacks the use of medicinal effects of herbs which
are used in the case of AshmaghnaSveda. Considering all this it will be beneficial to find out if AshmaghnaSveda can be structurally modified to be given locally with the help of smaller stones instead of a stone bed which can provide a better treatment option while reducing medical costs.

2. RATIONALE

Treatment of Lumbar spondylosis includes anti-inflammatory, analgesics, muscle relaxants, Non-steroidal anti-inflammatory drugs or NSAIDs, exercises, traction, absolute bed rest and invasive treatments such as surgeries.[27]Limitations of these therapies include various side effects in pain relieving group of medicines like NSAIDs, reduced work output and change in lifestyle of the patients in case of bed rest, patients not willing to undergo surgeries due to fear etc.

Due to this we shall explore the treatment options for the same in Ayurveda. Various studies have been performed under different headings for management of Katigraha/ Lumbar spondylosis, in which Vataghna/ Vatakaphaghnaha measures including both oral medication as well as Panchakarma procedures such as Basti, Snehadhara, Patrapindasveda, Churnapindasveda etc. have displayed significant results in all the subjective and objective parameters of. These treatments have various limitations like, requirement of admission in IPD for treatments like Basti and snehadhara. Patients refusing for treatments like basti due to fear. Treatments such as Snehadhara and churnapindasveda involving high cost. Patrapindasveda requires higher quantity of resources daily. Churnapindasveda although anon-invasive modality requires medicated powder like kolakulathadhichurna, karpasasthyadichurna etc. in high quantity for daily use and leads to escalated treatment cost. Ashmagnah (Charaka)/ Ghanshma (Vagbhatta) Svedain its traditional form is a tedious and prolonged process and not cost effective either, as it needs a lot of resources.

Considering all this a structurally modified technique of AshmaghnaSveda; providing it in the form of ekangasveda(stone therapy) will be utilized in the current study. Stone therapy/ stone massage can be done with small stones to induce localised effects but lack the use of medication unlike in the case of Ashmaghna Sveda. Ashmaghnasveda is one of the mahansveda mentioned in the Ayurvedic literature and is mentioned to be useful in various types of Vatavyadh. Mahan sveda is given in conditions where the vyadhibala is strong, is associated with kapha or Ama like in Katigraha and patient is also strong enough to take the treatment.

In clinical practice Ashmaghnasveda has been becoming obsolete due to very high requirement of raw herbs, specific pre- and post-procedure requirements, and increasing cost of medicinal herbs which are burned to heat the stone slab. Stone massage therapy is a traditional treatment practiced in various countries and has shown promising results in reducing pains and relaxing muscles and stress. But in this therapy the stones are not heated with the herbs of medicinal properties.

Considering the above literature, it will be beneficial to modify the Ashmaghnasveda into localized treatment which will not only help in reviving a treatment which is becoming obsolete but also provide for new treatment option which is beneficial to society. , it will be beneficial to find out if modified Ashmaghnasveda can be given to Ekanga (locally) which will help in reducing the waste generated at the hospital & to reduce the need of IPD admissions as the treatment can be carried out as a day care treatment.

Thus, considering the prevalence, disability rate in productive part of life, intensity of symptoms of disease and considering classical reference of efficacy of Ashmaghnasveda, and reference of use of Churnapindasveda[15]in Katigraha a randomised clinical study will be conducted to assess its efficacy in Katigraha. Some of the previous studies done on same topic have shown results and limitations like Fernando et al in Clinical Efficacy of Erandamuladi Yapana Basti in the Management of Katigraha (Lumbar Spondylosis) concluded that 35% patients had marked improvement, 25% had mild improvement and 15% had complete remission and moderate improvement each. 10% of the patients showed improved state, but it had limitations like only one group was used and treatment duration was also very long, of 30 days. Treatment used was basti for which many patients show hesitation and non-compliance. Tripathy et. al. in Open Label Comparative Clinical Trial of DvipanchamoooladiTaila and Kesheerabala Taila Matra Vasti in the Management of Low Back Ache established that Dvipanchamoooladita taila Matrabasti efficiently
redduces symptoms like pain, stiffness, tenderness, and restricted movements. It was observed that the therapy along with drug acted mainly on pain as compared to other parameters, but it had similar limitations as above. Kumavat et al in A clinical study to evaluate the efficacy of kativasti and sunthi-erand yoga in the management of katishoola with special reference to lumbosacral arthropathy concluded that Katibasti with RasnadiTailaalongside Sunthi-Erand Yoga are very effective treatment modalities and can be used with good results in the management of Katishoola (lumbosacral arthropathy) but it had various limitations like the study was performed including oral intake of shunthieranda yoga. Important take away from the study was that local treatment which is used for svedana is having better results. Kumar T et al in Evaluation of Effect of GodhumadiUpanahaSveda In NirajamaKatigraha: An Open Clinical Trial[28] concluded that PanchakoladilUpanaha was effective in relieving Samaja stage of Katigraha and Avasthanusara treatment is more effective in the management of Katigraha than that of Anavasthanusara treatment, important takeway from this study was Upnaha is a localized treatment which showed promising result and author highlights the fact that localized treatment holds good results in the treatment of Katigraha. Mishra G et al in Clinical Study to Evaluate the Effect of Modified Choorna Pinda Svedain the Management of Katigraha (Lumbago) maximum patients got marked improvement which is statisticallysignificant; neither any patient got complete remission, norremains unchanged however, the limitations on this study were that only one treatment group was used and Svedana was performed on whole body, while author also agrees that the disease is localized, in such case localized treatment can show better results. Sharma P et al in Comparative Clinical Study of ArohanaMatra Basti And Standard Matra Basti In KevalaVatajKatigraha Vis-Á-Vis Lumbar Spondylosis[29]and Bhende et al Comparative clinical study of Ashwagandha and Chincha tail Matrabasti [30] concluded that statistically significant results were seen in both the groups which confirm effect of Matra Basti in Kevalavatajakatigraha to be veryeffective, but it had limitations of having a small sample size and treatment administered being basti for which there is hesitation and non-compliance.

From the above-mentioned works done we can see that plenty of work has been done on katigraha, but no work has been done on ghanashmasveda or stone therapy in Ayurveda. It can also be inferred than many authors insist on use of local treatment in the cases of Katigraha. The limitations of the above established treatment have already been discussed which makes it essential to look for a cost effective, non-invasive treatment modality which can be done at OPD level with minimal generation of hospital waste. Therefore, Modified form of Ashmaghnasveda (stone therapy) is being chosen for evaluation in this study.

2.1 Aims and Objectives

2.1.1 Aim

To evaluate the efficacy of modified Ashmaghnasveda (stone therapy) in management of Katigraha (lumbar spondylosis).To evaluate the comparative efficacy of modified Ashmaghnasveda (stone therapy) and churnapindsasveda in management of Katigraha (lumbar spondylosis).

2.1.2 Objectives

1. To evaluate the efficacy of modified Ashmaghnasveda (stone therapy) in the management of Katigraha (lumbar spondylosis).
2. To evaluate the efficacy of Churnapindsasveda in the management of Katigraha (lumbar spondylosis).
3. To compare the effects of Ashmaghnasveda and Churnapindain Katigraha(lumbar spondylosis).

2.2 Study Type

Interventional study.

2.3 Trial Design

Superiority clinical trial i.e. A randomized control trial(RCT) – Reference standard control trial, open study.

2.4 Case Definition

Diagnosed cases of Katigraha (Lumbar spondylosis).

2.5 Diagnostic Criteria

1. Katigraha (Stiffness in lower back)
2. Katishoola (Low back pain) for more than 12 weeks
3. Reduced walking capacity due to pain

2.6 Research Question

Whether modified Ashmaghinasveda (stone therapy) is more effective than churnapindasveda in patients of Katigraha (Lumbar spondylosis)?

3. METHODOLOGY

3.1 Study Setting

The study will be conducted in Panchkarma OPD & IPD, Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACH & RC), Salod (Hirapur) Wardha, Maharashtra.

CTRI registration REF/2021/06/044865

3.2 Eligibility Criteria

3.2.1 Inclusion criteria

- Patients without barring any gender between 21 to 40 years of age.
- Patients diagnosed as a case of Katigraha (Lumbar spondylosis ICD code M 47.8) will be selected irrespective of gender/occupation and socio-economic status.
- Patients having low backache for more than 12 weeks
- Patients willing to give informed consent.

3.2.2 Exclusion criteria

- Patients Reporting with low backache due to spinal tumour, malignancy of the pelvis, tuberculosis of vertebral bodies, Ankylosing Spondylitis, Rheumatoid Arthritis, Psoriatic Arthritis, Gouty Arthritis and congenital deformity.
- Low backache associated with Myelopathy and radiculopathy
- Post-surgical backache and history of lumbar surgery or implanted instrumentation or prostheses.
- Pregnant women, lactating mother and women undergoing menstruation.
- Patients with the history of trauma (Abhighatayana Katigraha).

- Contraindicated for Svedana.[10], [31]

3.3 Interventions

3.3.1 Criteria for discontinuing or modifying allocated interventions

- Patients willing to quit in between will be allowed to quit and will be replaced.
- If patient develops any 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 be offered free treatment till the problem subsides.

3.4 Followup

28th day of study.

3.5 Assessment Criteria

The improvement will be assessed on the basis of relief in sign and symptoms of Katigraha. All the sign and symptoms will be assigned score depending upon their severity to assess the effect of treatment, the details of which are given below:

A. For Katigraha: Oswestry’s Disability index [32]

B. For Katishoola: Visual Analogue Scale [33], [34]

C. For difficulty in walking: Two minutes’ walk distance test (2MWD) [35] will be used to measure the functional improvement in walking capacity.

3.6 Outcomes

3.6.1 Primary

Primary outcome is reduction in pain, stiffness and difficulty in walking in cases of Katigraha.

3.6.2 Participant timeline

14 days treatment and follow up on 28th day of study.
Fig. 1. Study procedure of the study

Title
“A Comparative randomized control clinical study on effect of modified Ashmaghnasveda (stone therapy) with Choornapindasveda in management of Katigraha (Lumbar spondylosis)”

Steps
Enrolment of Participants Q1
Data collection Q2
Writing the thesis parts up to methods Q3
Data analysis Q4
Writing the thesis parts up to results & Conclusions Q5
Submission Q6

Fig. 2. Gnatt Chart

Table 1. Methodology of the study

| S.N. | Head                          | Group A (Control) | Group B (Trial) |
|------|-------------------------------|-------------------|-----------------|
| 1    | Sample size                   | To be evaluated as per pilot study | Ashmaghnasveda (Ekanga) |
| 2    | Intervention                  | Churna Pinda Sveda | 14 days         |
| 3    | Duration of treatment         | 14 days           | 14 days         |
| 4    | Schedules                     | 1 – 14 days       | 1-14 days       |
| 5    | Follow up period              | 28th day          | 28th day        |
| 6    | Total duration                | 28 days           | 28 days         |
| 7    | Dose                          | 30 minutes or till samyaksvinnalakshana are achieved.[35] | 30 minutes or till samyaksvinnalakshana are achieved.[35] |
| 8    | Preparation and Procedure     | Step1- Kulattha and Step1 - Basalt stone is first heated in burning dashmulapanchanga and then dipped in normal temperature dashmulakvath to bring it to bearable heat level dashmulakvath to bring it to bearable heat level |
|      |                               | kolakuladdichuruma 300gms heated in 600ml dhanyamla till cooked and two boluses prepared. | dashmulapanchanga and then dipped in normal temperature dumbmulakvath to bring it to bearable heat level |
|      |                               | Step2- Pinda sveda given locally on Kati pradesh | Step2- Svedana is done for 30 minutes |
|      |                               | Step3- Svedana is done for 30 minutes | Step3- body sponge with towel dipped in hot water |
|      |                               | Step4- Body sponged with towel dipped in hot water |
3.7 Methods: Assignment of Interventions (for Controlled Trials)

Recruitment: Patients will be recruited by randomization sampling method. The PI and Supervisor will allocate and enrol the patient.

Phase I - Pilot Study – 12 patients were taken for treatment as thumb rule according to which sample size was calculated.

Phase II - Main trial for which sample size was calculated according to Pilot study. 64 patients are required to have a 90% chance of detecting, as significant at the 5% level, an increase in the primary outcome measure from 32% in the control group to 70% in the experimental group.

\[ n = \frac{f(\alpha/2, \beta) \times [p_1 \times (100 - p_1) + p_2 \times (100 - p_2)]}{(p_2 - p_1)^2} \]

Where, \( n \) - Sample Size, \( \alpha \) – level of significance, \( \beta \) – power, \( p_1 \)- percentage of success in control group, \( p_2 \) - percentage of success in trial group.

\( \alpha \)-5%, \( \beta \)-90%, \( p_1\)-32 %, \( p_2 \)-70 %, therefore \( n=32 \) in each group i.e. 64

3.8 Data Collection, Management, and Analysis Methods

Observations will be made after completion of study, according to the data collected with the help of following:

I. Case registration Form with detailed history and examination (Annexure I)
II. Follow Up Assessment Performa (Annexure II)

Related studies from modern medicine were reviewed [36-39].

3.9 Data Monitoring

The Data coding will be done by PI and supervisor.

3.10 Statistical Methods

Data obtained will be calculated by using Student’s Paired and Unpaired ‘t’ test. Data on continuous variables will be analysed using parametric tests. The data on discrete variables will be presented as n (%). The continuous data will be presented as mean (SD)/Median (Min-Max). A p value of less than0.05will be considered as significant.

4. DISCUSSION

Discussion will be drawn according to the observations made in the case registration and follow up forms.

5. CONCLUSION

The modified Ashmaghnasveda (stone therapy) will be more effective in management of Katigraha (lumbar spondylosis) as compare to churnapindasveda in management of Katigraha (lumbar spondylosis).

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.

ETHICAL APPROVAL

Ethical approval has taken, IEC certificate, obtained vide Ref No. MGACH/IEC/Oct2020/128 dated 10.10.2020.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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