Study Protocol

"Comparative evaluation of efficacy of modified *Ashmaghnasveda* (Stone Therapy) and *Choornapindasveda* in management of *Katigraha* (Lumbar spondylosis)"

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 GroupA(Interventional). *Churnapindasveda* will be performed for 14 days in GroupB (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.

Keyword: *Ashmaghnasveda*, *Katigraha*, Lumbar spondylosis, *Ashmaghnasveda*

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 Sharangadhara, who placed it under the heading of *NanatmajaVatavyadhi*. [2]

*Katigraha*is 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 *Vatakaphaghna* measures including both oral medication as well as *Panchakarma* procedures displayed highly significant results in all the subjective and objective parameters of *Katigraha*.*Panchakarma*includes 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]

Amongst these, *Svedana* is one which is defined as one which relieves one of *Stambha, gaurava, sheeta* and also produces *Sveda* (Sweat).[7] While explaining its benefits, *Acharya Charaka* states that it induces sweating, relieves one of pain, stiffness, heaviness and

brings softness in the body.[8] While *Acharya Sushruta* states that it helps in achieving improved mobility of the joints which have stiffness.[9] Itis indicated in diseases of many systems like respiratory, neuromuscular diseases, musculoskeletal system such as *Gridhrasi, Stambha* (stiffness), *Khalli* etc.[10] and also found useful in Ankylosing spondylitis[11], Osteoarthritis[12], Sciatica[13].

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, Parisheka, 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 *RasnadiTaila* along with *Shunthi-Erand Yoga"* were found to be very effective in the management of *Katishoola*.[16]*;* use of*Churnapindasveda*in *Katigraha* was also found to have significant results. [17], [18]*Churnapindasveda*is a type of *rukshasankarasveda*which is beneficial in *vatakaphaja* or *samavataja* diseases.[19]*Ashmaghnasveda (Charaka)*[20]*/ GhanshmaSveda (Vagbhatta)*[21],[22]is one of the major *svedana* procedures which is especiallybeneficial in *Sama vataja* and *vatakaphaja* diseases.[23] In its traditional form *Ashmaghnasveda*is 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.

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 bedrest, 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/ Vatakaphaghna* 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 *kolakulatthadichurna*, *karpasasthyadichurna* etc. in high quantity for daily use and leads to escalated treatment cost.*Ashmaghna (Charaka)/ Ghanshma (Vagbhatta) Sveda*in 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 *Vatavyadhi*. *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 DvipanchamooladiTaila and Ksheerabala Taila Matra Vasti in the Management of Low Back Ache established that Dvipanchamooladitaila Matrabasti efficiently reduces symptoms like pain, stiffness, tenderness, andrestricted 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 *GodhumadiUpanahaSweda* In *NiramajaKatigraha*: An Open Clinical

Trial[28] concluded that PanchakoladiUpanaha 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 takeaway 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 Sveda*in 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 Comparitive Clinical Study of *ArohanaMatra Basti* And Standard *Matra Basti* In *KevalaVatajaKatigraha* Vis-À-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.

Aims and Objectives:

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 *churnapindasveda* in management of *Katigraha* (lumbar spondylosis).

Objectives

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

Study Type: Interventional study

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

Case definition-Diagnosed cases of Katigraha(Lumbar spondylosis).

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

Research Question:
Whether modified *Ashmaghnasveda*(stone therapy)is more effective than *churnapindasveda* in patients of *Katigraha* (Lumbar spondylosis)?

Methodology:

Study setting: The study will be conducted in Panchkarma OPD & IPD,MahatmaGandhiAyurvedaCollegeHospitalandResearchCentre(MGACH&RC),Salod(Hirapur)Wardha, Maharashtra.

Eligibility criteria:
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 back ache for more than 12 weeks
- Patients willing to give informed consent.

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 (*Abhighatajanya Katigraha*).
- Contraindicated for *Svedana*.[10], [31]

Interventions:
Table 1.Methodology of the study

Figure 1.Flowchart of study design or methodology

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.

Followup:28thday of study.

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.

Outcomes:

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

Participant timeline: 14 days treatment and follow up on 28th day of study.

Figures:

Figure 1

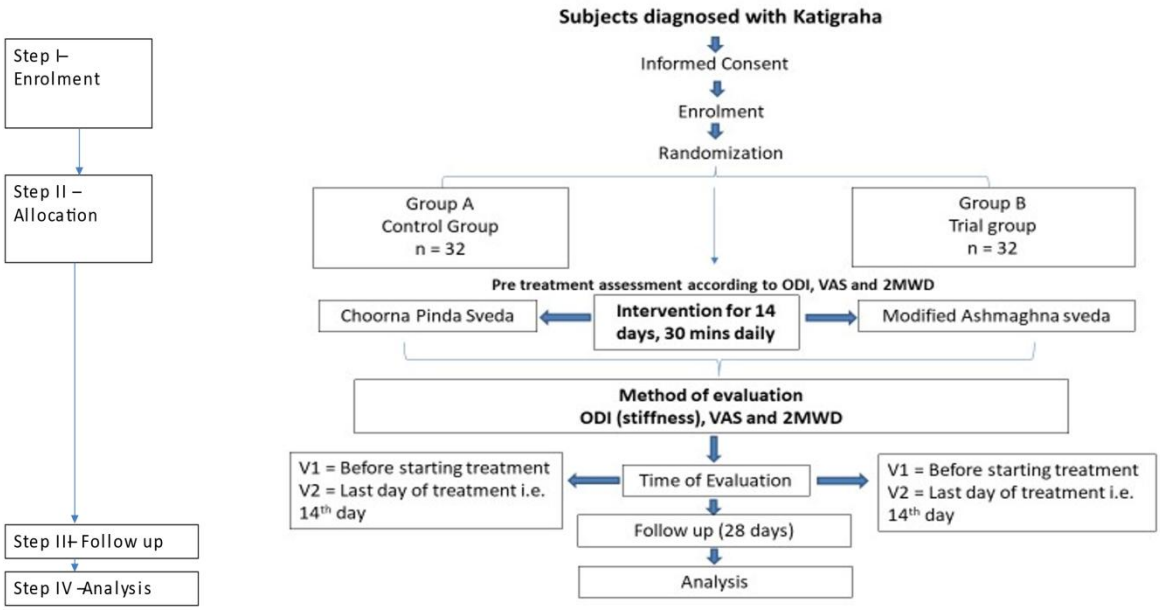

Figure 2. Gnatt Chart

Title	"A Comparative randomized control clinical study on effect of modified *Ashmaghnasveda* (stone therapy) with *Choornapindasveda*in management of *Katigraha*(Lumbar spondylosis)"							
Steps	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**
Enrolment of Participants								
Data collection								
Writing the thesis parts up to methods								
Data analysis								
Writing the thesis parts up to results & Conclusions								
Submission								

Tables:

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	
2	Intervention	*Churna Pinda Sveda*	*AshmaghnaSveda (Ekanga)*
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 *kolakulatthadichurna* 300gms heated in 600ml *dhanyamla* till cooked and two boluses prepared. Step2- *Pinda sveda* given locally on Kati pradesh Step3- *Svedana* is done for 30 minutes Step4- Body sponged with towel dipped in hot water	Step1- Basalt stone is first heated in burning *dashmulapanchanga* and then dipped in normal temperature *dashmulakvath* to bring it to bearable heat level Step2- *Svedana* is done for 30 minutes Step3- body sponge with towel dipped in hot water

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.

$n = f(\alpha/2, \beta) \times [p1 \times (100 - p1) + p2 \times (100 - p2)] / (p2 - p1)2$

Where, n- Sample Size, α – level of significance, β – power, p1- percentage of success in control group, p2 - percentage of success in trial group. α -5%, β -90%, p1-32 %, p2-70 %, therefore n= 32 in each group i.e. 64

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].

Data monitoring: The Data coding will be done by PI and supervisor.
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). Apvalueoflessthan0.05willbeconsidered as significant.
Ethics and dissemination: IEC certificate, obtained vide Ref No. MGACH/IEC/Oct2020/128 dated 10.10.2020.
Consent or assent: 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.
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).

Discussion will be done and conclusion(s) drawn according to the observations made in the case registration and follow up forms.

Trial Registration: IEC Ref No. MGACH/IEC/Oct2020/128 dated 10.10.2020,
CTRI registration REF/2021/06/044865

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