



Comparative effect of *Ashwagandha* (*Withania Somnifera*) and *Chincha* (*Tamarindusindica*) *Matrabasti* in *Katigraha* (Low backache): A study Protocol

Shweta Parwe¹, Milind Nisargandha^{2*}, Snehal Bhende³

¹ Professor and Head, department of Panchakarma, MGACH and RC, Datta Meghe Institute of Medical Sciences, Wardha, Nagpur, Maharashtra, India

² Department of Physiology, Ashwini Rural Medical College, Hospital and Research Centre, Kumbhari, Solapur, Maharashtra, India

³ PG scholar, Department of Panchakarma, MGACH and RC, Datta Meghe Institute of Medical Sciences, Wardha, Nagpur, Maharashtra, India

Abstract

Background: *Katigraha* is the common type of problem the present world is facing. *Katigraha* is one of the *vatavyadhi* which is the problem of lumbar region. Even though this disease is not life threatening but it hampers the daily activity of person. It is described as a separate disease in the classical text *Gadanigraha* and *Acharya Sharangdhar* considered it as a *nanatmaja vatavyadhi*. *Acharya Shodhayla* described it is a condition characterized by pain and restricted movement of *kati* (back region). *Kati* itself is one of the seats of *vatadosha* and the root cause of disease is aggravated by *vata*.

Aim and Objectives: to study the comparative effect of *Ashwagandha* and *Chincha* in *Katigraha* and to compare the effect of *Ashwagandha* and *Chincha* on Functional Disability of Index, ROM and Schober's Test.

Methodology: We will plan that 30 patients will be divided randomly into two groups (15 in each). Group A- *Ashwagandha* oil *matrabasti* 60 ml will administer for seven days after food and Group B- *Chincha* oil *matrabasti* 60 ml will administer for seven days after food.

Results: Changes will be observed in subjective and objective parameters.

Conclusion: *Ashwagandha* oil and *Chincha* oil *matrabasti* will reduce the symptoms of *katigraha* and will be lowering the scoring on functional disability index, reduce the length of Schober's test and will changes on range of motion.

Keywords: *ashwagandha*, *chincha*, *matrabasti*, *katigraha*, *withania somnifera*, *tamarindusindica*.

Introduction: Rational

Katigraha is the commonest encountered disease. It is one of the *Nanatmaja Vatavyadhi* which is the problem of lumbar region. Even though this kind of disease is not life threatening but it makes a huge impact on daily activity of people facing such disease. *Bruhatrayi* has considered *katigraha* as a symptom in various diseases such as *Atisaar*, *Arshas*, *Ashmari*, *Bhagandara* etc. *Archarya Shodhayla* and *Acharya Sharangdhar* considered *Katigraha* as a separate disease as *Nanatmaja Vatavyadhi* [1].

Acharya Shodhayla described that it is a condition characterized by pain and restricted movement of *Kati*. *Kati* itself is one of the seats of *Vatadosha* and the root cause of disease is aggravated by *Vata* [2].

Katigraha is a *Sthambha Shula*, and *Shosha* predominant *Vyadhi*. As correctly said by *Acharya Sushruta* without vitiation of *Vata*, *Shula* cannot be produced. *Gada Nigraha* clearly states that the pain arises due to *Stiffness*, which is by produced *Sama* or *Nirama Vayu* movement into *Kati* hence this suggests of presence *Dhatu Khsayatmak* and *Marga Avarodhaka* type of *Samprapti* [3].

About 60-80 % of world population experience low back pain at some time in their lives. The highest prevalence is among people aged 35- 60 years [4].

Low back torment is a clinical condition wherein parcel of conditions can be deciphered running from spondylolysis, space involving injuries, tuberculosis of spine, entomb

vertebral circle prolapse, and so on low back agony is not an onetime wonder; rather it is described by the commonest introducing indication is low back torment with or without the agony emanating down the rear of the leg (*sciatica*) [5].

Rational of the Study

Lower back region helps in the transmission of weight from upper extremity and trunk to the lower limb. In Present day lifestyle Mostly everyone is living a stressful life. False sitting posture in the workplace, overexertion and continuous work in a single posture may lead to lumbar pain. *Katigraha* is the disease affects daily, routine activity of a person life as it restricts the back movements. In modern medical treatment of low back pain includes conservative treatment like exercise, physiotherapy, rest and NSAID and analgesics that will help to a certain extent but it is not ultimate cure [6].

Surgeries for this condition are moreover expensive and there are chances of recurrence [7].

For low back pain permanent relief from the pain is needed. *Ayurveda* offers multiple options for the management of painful condition. In condition of *Katigraha* mainly *Vata* and *Kapha Dosh* get vitiated.

So for the treatment of *Katigraha*, drug of choice should have *Vatakaphashamak*, *Vatanulomaka*, *Shulaprashaman*, *Balya* and *Brumhana* properties. As per the above reference reflect that *Vata* is the main causative factor for *Katigraha*

and the *Ashwagandha* and *Chincha Taila* it become more potent to pacifying *Vatadosha* and pacifying pain, *Matrabasti* is indicated for *Vata* disorders so it is necessary to know the efficacy of *Ashwagandha Taila* and *Amla Chincha Taila Matrabasti* in *Katigraha*-For resolving pain, improving the functionality as well as ability of the body within the cost effectiveness is required so this study will choose for better find out and will need to know the drug effect.

Aim and Objectives

Aim

Compare the effect of *Ashwagandha* oil and *Chincha* oil *matrabsti* in *katigraha*

Objectives

1. To evaluate the effect of *Ashwagandha* oil *matrabasti* on Functional Disability Index, Range of Motion, SLRT and Scober's Test.
2. To evaluate the effect of *Chincha* oil *matrabasti* on Functional Disability Index, Range of Motion, SLRT and Scober's Test.
3. To compare the effect of *Ashwagandha* oil and *Chincha* oil *matrabasti* on Functional Disability Index, Range of Motion, SLRT and Scober's Test.

Case Definition

A diagnosed case of *Katigraha* with clinical symptoms of *Shoola* in *Katipradesha* (Lumbar Pain) and *Stambhana* in *Katipradesha* (Lumbar Stiffness) from 6 months to 1 year without neurological deficit.

Diagnostic Criteria of *Katigraha*

The sign and symptoms of *Katigraha* mentioned in Ayurved will be basis of Dignosis Criteria is follows.

1. *Shoola* in *Katipradesha*
2. *Sthambhana* in *Katipradesha*

Research Questions

Whether the *Ashwagandha* oil *Matrabasti* is as effective as *Chincha* oil *Matrabasti* to reduce the symptoms of *Katigraha*?

Hypothesis

Null hypothesis

Ashwagandha oil *Matrabasti* is not as effective as *Chincha* oil *Matrabasti* to reduce symptoms of *Katigraha*.

Alternate Hypothesis

Ashwagandha oil *Matrabasti* and *Chincha* oil *Matrabasti* have remarkable effect in reduction of symptoms of *Katigraha*.

Study Type

Interventional

Trial Design

Randomized Open Interventional Comparative Clinical Trial.

Sample Selection Technique

Simple Randomization by lottery method.

Methodology

Study Setting

The study will be conducted in MGACH and RC, Salod (H), and Wardha.

Table 1: composition of material

Sr. No.	Drug name	Botanical name	Part used
1	Ashwagandha	Withaniasomnifera	Root
2.	TilaTaila	Sesamumindicum	Beeja
3.	Chincha	Tamarindusindica	Patra
4.	TilaTaila	Sesamumindica	Beeja

Posology

60 ml of *Ashwagandha* oil *Matrabasti*.

60 ml of *Chincha* oil *Matrabasti*.

Inclusion Criteria

1. Patients of *Katigraha* age between 25 to 65 years, irrespective of their sex, religion, occupation and economic status.
2. A diagnosed case of *katigraha* with the clinical symptoms from 6months to 1year without any neurological deficit.

Exclusion Criteria

1. Patients having neurological deficit.
2. Lumbar and other vertebral disc disorder with myelopathy, other disc degeneration radiculopathy (M51.0+ of ICD-10).
3. Pregnant women, Traumatic Patients.
4. Associated with simple and compound fracture.
5. *Matrabasti* *Ayoga*-Patients suffering from Piles, debility anaemia.

Table 2: Interventions of the groups

Grouping	Group A	Group B
Sample size	15	15
Intervention	<i>Ashwagandha</i> oil <i>matrabasti</i>	<i>Chincha</i> oil <i>matrabasti</i>
Dose	60ml	60ml
Duration	9 days	9 days
Fallow up	18 days	18 days

Criteria for Discontinuing or Modifying Allocated Intervention

Patient will withdrawal from the study if there will be any adverse effect was occurs and then he or she will be treated from the same in free of cost till becomes alright.

Follow up: 18 days

Primary Outcome

We will see the effect of *Ashwagandha* oil *matrabasti* and *Chincha* oil *matrabasti* on pain and *stambha*

Secondary Outcome

We will see the effect of *Ashwagandha* oil *matrabasti* and *Chincha* oil *matrabasti* on Schober's Test, Lumbar Flexion, Lumbar Extension, Right Lateral Movement, Left Lateral Movement, Rotation, Functional Rating Index Questionnaire and Straight leg raising test (SLRT).

Discussion

"*Katigraha* is the condition in which vitiated *Vata Dosha* gets situated in the *Katipradesha* and proceeding *Shoola*

(Pain) and *Stambha* (Stiffness). Due to the consumption of *Vata Vardhak Ahar* and *Vihar Vata dosha* get Vitiated and this Vitiated or aggravated *Vata* moves all over the body and finds a suitable place for its lodgment in the *Khavaigunya Yukta Srotas*. Low back pain is becoming a major health problem now a day due to faulty posture and living habits; this is the main causative factors for the producing disease like low back pain. *Stambha* (stiffness) and *shoola* (pain) are caused by vitiated *vata* which incapacitates the patients. By giving treatment through *basti* irritation is diminished and the fit of the muscles is calmed. This decrease in irritation and fit encourages better blood flexibly and improved nerve conduction to the influenced territory prompting suggestive improvement furthermore, eventually to improved practical status of the tolerant [8]. Barely any examinations explicitly inspect sciatica, however some low back torment contemplates remember information for sciatica pervasiveness, hazard components, and regular history. Low back-related leg torment, or sciatica, is one of the most widely recognized varieties of low back agony [9, 10]. In the disease *Katigraha Hetu Dosha* is *Vata Sthansamshraya* in *Asthi* and *Sandhi* takes place and produces *Asthivahasrotasdushti* [11]. *Shamana Aushadhi* are not enough for the severity of disease *Katigraha* because it is a *Kricchrasadhya*, *Madhyam Rogamarga* disease so need of the *Panchakarma* is needed, hence for the pacification of *Vata dosha Basti* has been considered as best treatment for *Vatavyadhi* as mentioned by *Acharya Charak* “*Basti Vataharanama Sheshatatham*” [12]. As *Katigraha* is a *Vatavyadhi* so *Basti* can be used as a treatment modalities. *Basti* is one of the purification process by which all the three vitiated *Doshas* are expelled from the anal canal and especially *Vata Dosha* get pacified [13]. *Ashwagandha* is best drug in *kevalavata*, *Krurakoshta*, *Dhatu kshaya*, *Vridha* in *Apan Vayu Dushti* it can be given best relief and overall improvement of health of patients. *Ashwagandha Taila* is with *Madhur*, *Tikta Rasa*, *Snigdha Guna*, *Ushna Virya* and *Madhura Vipaka* having *Vatapitta Shamak* [14]. *Vatanulomana Balya*, *Brumhana*, *Rasayana* [15, 16]. *Tila taila* is having *Sukshma*, *Vyavayi*, and *Vikasi Gunas*. *Tila taila* is used as a base of the *Ashwagandha Taila*. *Ashwagandha Taila* is *Vataghna* by its *Ushna Virya* begin *Shothahara* and *Vednasthapana*, *Sidha Taila* can be used for *Matrabasti* in *Vatavyadhi* [17]. By virtue of all these qualities of *Ashwagandha* oil *Matrabasti* can be *alliviates Vata*, and can be reduce symptoms of *Katigraha*, it can also increases *Snigdha Guna* of body and kindles the *Dhawagni* especially of *Rasa*, *Mamsa* and *Medas* thus acting as a *Vatashamak* and reduces the *shoola and stambha*. *Chincha* oil has *Rasa-Amla*, *Madhur*, *Guna –Laghu*, *Ruksha*. *Virya - Ushna*, *Vipak - Amla*, action *Vatashamak*, *Sarak*, *Anulomak*, *Vibandhanashak*, *Roachaka*. Hence *Chincha Taila* is mentioned best drug in *kevalavata*, *Krurakoshta*; In *Apan Vayu Dushti*, hence it gives best relief and overall improvement of health of patients [18]. Study drugs are *Shothhara* and *Vedanasthapana* [19].

Statistical Analysis

Data will be analyzed on the basis of appropriate statistics Paired t-test, unpaired test and Chi square test by using SPSS software, 24.0 version and Graph Pad Prism 7.0 version and $p < 0.05$. will considered as level of significance.

Time Duration till Follow up

18th days.

Total treatment duration will be nine days after treatment follow up will be 18th days.

In both groups initially nine days of treatment and follow up period after nine days.

Follow up Period

Nine days

Time Schedule of Enrolment, Interventions

Matrabasti with the help of *Ashwagandha* oil and *Chincha* oil with dose 60ml will be given after CTRI registration. From 0 days to nine days continuously after food.

Recruitment

15 (in each group, Group A and Group B) will be recruited randomizing sampling method. Total 30 Subjects (15 subjects in each group)

Group A

15 subjects will given an established procedure of *Matrabasti* with *Ashwagandha* oil for nine days.

Group B

15 subjects were given an established procedure of *Matrabasti* with *Chincha* oil for nine days.

Methods

First we will search literature review, then frame plan of work, medicine collection, authentication of raw drugs, medicine preparation both *Ashwagandha* oil and *Chincha* oil, recruitment of patients, data collection, adverse effects observe if any and analysis.

Data Collections Method

Randomized sampling

Subjective Parameters

- a) *Shoola* (Pain)
- b) *Sthambha* (Stiffness)

Objective Parameters

1. Schober's Test
2. Range of Motion
 - a. Lumbar Flexion
 - b. Lumbar Extension
 - c. Right Lateral Movement
 - d. Left Lateral Movement
 - e. Rotation
3. Functional Rating Index Questionnaire
4. Straight leg raising test (SLRT)

Investigations

The patients who will be fulfilled the inclusion criteria will be subjected for haematological investigations and will advise X-ray of lumbar spine anterior and posterior view and lateral view before initiation of treatment an informed consent will be taken from the patient and his relatives and after that patient will be evaluated for the both subjective and objective parameters and grading will be noted according to the case Performa.

Data Management

Data coding will be done by Principle investigators.

Statistical Methods

Paired t- test and unpaired for objectives parameters, non-parametric and Chi square test for subjective parameters.

Ethics and Dissemination

Research ethical approval, after critical evaluation and presentation the ethical committee has taken the research topic.

Consent or Assent

Subjects will be given detail information regarding their treatment in their own language. Then written consent will be taken from patients before starting the study.

Dissemination Policy

Will be in the form of paper publication, presentation and Monograph.

Strengths

If proposed study will results in the positive outcome then it will be established new mode of management for the *katigraha*. In society, we will be provided economical and effective for pain reduction and stiffness.

Limitations

Will be convincing the patients for *matrabasti* and for hospitalization.

Conclusion

Conclusion will be mentioned after the analyzing data.

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