



Comparative study of efficacy of *Swadamshtardi* (*Tribulusterrestris* etc) *taila* *Matrabasti* and *Katibasti* in *Katishool* (IVDP): A study protocol

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Abstract

Background: *Katishool* (Low back pain) is founding a very common symptom in early adult life and *madhyamavastha* of age. It is the most common symptom complex related to the muscular-skeletal system. Almost all adult can remember of having suffered from backache at least once in their life time. The low back region helps in the transmission of weight from upper extremity and trunk to the lower limb. In the process it takes lot of strain. Low back pain is a clinical condition in which lot of conditions can be interpreted ranging from spondylolysis, space occupying lesions, tuberculosis of spine, inter vertebral disc prolapsed [IVDP], etc. The term "prolapsed disc" means the protrusion or extrusion of the nucleus pulpous through a rent in the annulus fibrous. It is not a onetime phenomenon; rather it is a sequence of changes in the disc, which ultimately lead to its prolapsed. It is characterized by the commonest presenting symptom is low back pain with or without the pain radiating down the back of the leg (sciatica).

Aim and Objectives: to study the effect of *Swadamshtardi Taila Matrabasti* and *Katibasti* in *Katishool* (IVDP). To evaluate the effect of *Swadamshtardi Taila Matrabasti* and *Katibasti* on pain, stiffness, Straight Leg Rising Test (SLRT), Scobers Test and Modified Oswestry Low Back Pain Disability Questionnaire.

Methodology: In this study, total 30 patients will be divided randomly into two groups. In group A *Swadamshtardi Taila matrabasti* will be administered with dose form of 60 ml after food daily for nine days. In Group B, *Katibasti* will be advised daily for nine days

Result: Result will be assess base line of subjective and objective parameters and data will be compare after treatment.

Conclusion: *Swadamshtardi taila matrabasti* and *katibasti* will be reducing the symptoms of *katishool*.

Keywords: *swadamshtardi taila, matrabasti, katibasti, katishool, ivdp, pain, stiffness.*

Introduction: Rational

Katishoola is an ailment which is for the most part brought about by vitiation of *Vata Dosha*. Some old messages additionally depict *Katishoola* as an indication of certain issues, for example, *Katigraha, Trikagraha, Prushtagraha, Kativayu, Trikashoola, Prushtashool, Vataja Shoola, Trika Vedana, and Grudhrasi Vata* ^[1, 2, 3]. *Katishoola* (Low back pain) is a typical manifestation in early grown-up life and middle age. It is the commonest side effect complex identified with the musculo-skeletal framework. Practically everything grown-up can recollect of having experienced spinal pain at any rate once in their life time.

Low back pain is a clinical condition in which lot of conditions can be interpreted ranging from spondylolysis, space occupying lesions, tuberculosis of spine, inter vertebral disc prolapsed [IVDP], etc ^[4]. The expression "prolapsed plate" signifies the distension or expulsion of the core pulpous through a lease in the annulus sinewy. It's anything but a onetime marvel; rather it is an arrangement of changes in the circle, which eventually lead to its prolapsed. It is portrayed by the commonest introducing indication is low back torment with or without the agony emanating down the rear of the leg (sciatica) ^[5].

The prevalence of low back pain during school age approaches that seen in adults, increases from childhood to adolescence, and peaks between ages 35 and 55 years ^[6].

In Modern Medicine Treatment of low back pain includes Conservative Treatment like exercise, physiotherapy, rest and NSAID and Analgesics for temporary relief of pain. For low back pain permanent relief from the pain is needed. In this way Ayurveda *chikitsa* (treatment) that is *shodhana* can be given permanent relief from the pain in *Katishoola*.

Rational of the study

Maintenance of equilibrium of *dosha, dhatu* and *mala* is prime aim of the *tantra* and *vaidyas* ^[7]. And for this Panchakarma plays an important role in the *chikitsa* aspects of each and every disease. Among Panchakarma's, *basti* has been told as '*Ardhachikitsa/Sarvachikitsa*' in all *samhitas* and this *basti chikitsa* is mainly useful in disorders related to *vata dosha* ^[8]. *Matrabasti* is a type of *sneha basti* which can be given in all seasons without any strict regimen of *ahara-vihara*. It has preventive, promotive and potent rejuvenative action. Also it is *brumhana* and *vatahamaka* in nature ^[9]. Hence in present study *Matrabasti* and *Katibasti* is selected. *Swadamshtardi taila* mentioned by *Vangasena Samhita* &

Bharat Bhaishajya Ratanakar will be used for the *basti karma* which contain *Gokshur*, *Tila Tail*, *Kshir*, *Guda* (Jaggery) and *Adrak* (*Shunthi*)^[10, 11]. Which exert *vatahara*, *vedanasthapak* action^[12]. *Gokshur* acts as a *vatahara*, *shothahar* and also causes defensive action on pain^[13, 14]. Traditional medicine of *Swadamshtadi taila* is in various *vataj* disorders including *Katigraha*. The reason behind selection of '*Katibasti*' is that it comes under direct contact with painful region.

The purpose for determination of *Katibasti* is that it goes under direct contact with painful area. In this *vyadhi*, *samprapti* is at *kati*-area and is generally connected with auxiliary changes of lumbar vertebral section. There is unhinging in Lumbo-sacral joints and vertebrae, degeneration of intervertebral disc and oil capacity of *shleshmaka kapha* is influenced, which brings about pressure, aggravation or irritation of Sciatic Nerve, bringing about extreme pain. Along these lines, nearby *snehana* and *swedana* is viable and gives fast outcomes since they act at the site of *samprapti*.

Aim and Objectives

Aim

Study the effect of *Swadamshtadi Taila Matrabasti* and *Katibasti* on *Katishool*.

Objectives

1. To evaluate the effect of *Swadamshtadi Taila Matrabasti* on Straight Leg Rising Test, Scober Test and Modified Oswestry Low Back Pain Disability Questionnaire.
2. To evaluate the effect of *Swadamshtadi Taila Katibasti* on Straight Leg Rising Test, Scober test and Modified Oswestry Low Back Pain Disability Questionnaire.
3. To compare the effect of *Swadamshtadi Taila Matrabasti* and *Katibasti* on SLRT, Scober test and

Modified Oswestry Low Back Pain Disability Questionnaire.

Criteria for Diagnosis

A diagnosed case of Intervertebral Disc Prolapsed (IVDP) with the clinical symptoms from 6 months to 1 year without neurological deficit.

The signs & symptoms of *Katishoola* mentioned in the Ayurveda will be basis of diagnosis in addition to the criteria laid down for IVDP is as follows.

- *Shoola* in *katipradesha*.
- *Sthambana* in *katipradesha*.
- A known diagnosed case of IVDP.

Research Question

Whether *Swadamshtadi Taila matrabasti* and *Katibasti* are effective on *katishool* (IVDP).

Hypothesis

Swadamshtadi Taila matrabasti and *katibasti* are effective on *katishool* (IVDP).

Null Hypothesis

Swadamshtadi Taila matrabasti and *katibasti* doesn't effect on *katishool* (IVDP).

Study Type

Interventional

Trial Design

Randomized comparative clinical study

Methodology

Study Setting

Study will be conducted in academic hospital MGACH & RC, Salod (H), Wardha.

Table 1: Composition of the trail drugs

Sr. No.	Sanskrit Name	Botanical Name	Proportion
1.	Gokshur	Tribulusterrestris	2.56 lit (Decoction)
2.	TilaTaila	Sesame Oil (Sesamumindicum)	1.28 kg
3.	Kshir(Godugdha)	Milk	2.56 kg
4.	Adrak (Sunthi)	Zingiber officinale	200 gm (Paste)
5.	Guda	Jaggery	800 gm

Method of Preparation

All drugs will be well identified and will be collected from pharmacy. The above mention drug will be taken in equal quantity and will make in to a *kalk* (Paste) form & will add this into the 4 parts of *tila tail*, *swaras* of *Gokshur*, *Godugdha*, paste of *Adrak* (*Sunthi*) & *Guda* then will allow it to boil on the *mandagni* till the water will get evaporated. Then this oil will use for the purpose of *matrabasti* & *katibasti*.

Eligibility Criteria

1. Age of the patients between 20 to 60 years.

2. Patients suffering from the *katishoola* & IVDP having the Clinical symptoms.
3. Patients irrespective of their sex, religion, occupation and economic status.

Following Are Excluded From Study

Patients with other systemic condition such as Spondylithesis, Spina Bifida, Vertebral Fracture, Malignant disorder.

Patients with diabetes / hypertension, pregnant women. Associated with simple and compound fractures. Patients who are not fit for *matrabasti* and *katibasti*.

Table 2: Interventions of both groups

	Group A	Group B
Sample size	15	15
Intervention	<i>Matrabasti</i> with <i>Swadamshtardi Tail</i>	<i>Katibasti</i> with <i>Swadamshtardi Tail</i>
Duration	9 days	9 days
Timing of treatment	As per requirement	Up to 900 <i>matrakala</i> (around 35 min)
Follow up	28 days	28 days

Posology

60 ml of *Swadamshtardi Tail* for *matrabasti*.

Katibasti. 1 inches of brim of *katibasti* with 30 ml luke warm *Swadamshtardi Tail*

Criteria for Discontinuing or Modifying Allocated Interventions

Subject will be pulled back from the investigation if any untoward rate, highlights of medication affectability or some other malady or issue emerges, the subject will be offered free treatment till the issue dies down.

Follow up

28th days

Primary Outcomes

We will see the impact of *Swadamshtardi taila matrabasti* and *katibasti on shool* (Pain), *stambha* (stiffness).

Secondary Outcomes

We will see the effect of *Swadamshtardi taila matrabasti* and *katibasti* on Straight Leg Rising Test (SLRT), Scobers test and Modified Oswestry Low Back Pain Disability Questionnaire.

Discussion

Acharya Charaka mentioned *katishoola* in *Vata Nanatmaja Vyadhi*. In *katishoola*, *shoola* or *ruka* on lower back and lower limbs is the chief complaints associated with *stambha* (stiffness), in this disease *katishoola hetu dosha* will *vata sthansamshraya* in *Asthi-Sandhi* take place and produces *Asthivahasrotodusti* [15]. The drugs will be selected for the present study will predominantly of *Madhura Rasa*, *Guru*, *Snigdha* & *Brimhana* properties. Hence it will pacify *vata*. *Basti* has been considered as best treatment for *vata vyadhis* as mentioned by Acharya Charaka "*Basti Vataharanama*". As *Katishoola* is purely a *Vatavyadhi* so *basti* can be used as a treatment modality in *Katishoola*. Acharya Charaka has advised *basti* as principle of treatment in *Asthivaha strotasa vyadhis* [16]. As Acharya Vangasen mentioned *Swadamshtardi taila* in all types of *vatavyadhi*. So *Swadamshtardi taila* can be used through *basti* [17]. *Til taila* has been mentioned as prime *sneha* of vegetable origin and *Taila* has *vatashamaka* properties. *Taila* has got *Usna*, *Snigdha*, *Sukshma*, *Snigdha* properties by virtue of which it reaches deeper *dhatu* like *asthi* and *majja* by penetrating through minute channels. *Taila* is *Vedanasthapana*, *Snehana*, *Sandhaniya*, *Deepana*, *Balya*, *Rasayana* etc. As a result of these properties it can be used in *vatika* degenerative disorders like *katishool*. *Katibasti* can be nourishes the joints of the low back, pacifies the *dosha* causing pain or discomfort, soothes the nerves, relieves degeneration, stiffness and inflammation and cures pain. *Katibasti* is a procedure in which both the properties of *Snehana* & *Swedana* are incorporated. The reasons behind selection of *Katibasti* will that it comes under direct contact

with painful region. In the present study protocol, the compound drug '*Swadamshtardi taila*' which will be used for '*Matrabasti* and *Katibasti*' contains ingredients which will mainly having *vatahara* properties. *Tila taila*, which is the best *shamana auśadhi* for *vata* having *sukṣma*, *vyavayi* and *vikasi* gunas. *Tila taila* is used as the base of the drug, as a result the active principles of the drug will spreads very fast all over the body through the minute *strotas* when will be administered as *basti*.

Statistical Analysis

Data will be analyzed on the basis of appropriate statistics paired, unpaired test by using SPSS software.

Time Duration till Follow up 30th Days

The time duration for the patients will be 9th day and after that follow up for 18th days.

Follow up Period

On 9th 18th and 28th days after completion of treatment in both groups.

Patients will be observed during study period once in a week for 28th days in both groups, parameters will be assessed and recorded.

Time Schedule of Enrolment, Interventions

Matrabasti – will be administered after food at between 12 pm to 2pm

Katibasti – It will be advised at morning time 10am to 12pm.

Recruitment

15 (in each group) sample will be recruited by single randomizing sampling method.

Methods

Literature review search, preparation of drugs, plan of work, blue print in the form of flow chart, data collection, treatment and its effect, will be observe which route of administration is best and statistical analysis.

Data Collections Methods

Randomized sampling. Patients will be altogether analyzed both abstractly and dispassionately. Detailed history relating to the method of beginning (mode of onset), past sickness, past therapy history, family history, propensities, *ashtavidha pariksha* and *dashavidha pariksha* and physical assessment discoveries will be noted.

Routine examinations will be done to bar different pathologies. Radiological highlights likewise will be explored.

Subjective Criteria

1. Pain radiating from back to thigh, knee & calf
2. Stiffness radiating from back to thigh, knee & calf.
3. Restricted movements of back.

Objective Criteria

1. Straight Leg Raising Test.
2. Schober's Test.
3. Modified Oswestry Low Back Pain Disability Questionnaire.

Investigation

1. Hematological examination Hb%, TC, ESR.
2. X ray for diagnosis – Lumbosacral spine AP & Lateral view.
3. Urine- sugar, albumin and microscopic examination.
4. MRI of spine.(if necessary)
5. Other investigation if necessary.

The patients who will be satisfied the consideration rules will be oppressed for routine Hematological and Biochemical assessment and will exhorted Antero-Posterior and Lateral view X-ray of Lumbar Spine. Before initiation of the treatment an educated assent will be taken from the patients, and the patients will be assessed for both Subjective and Objective parameters and evaluating will be noted by Performa.

Data Management

The data coding will be done by principle investigator.

Statistical Methods

Paired and unpaired for objective criteria, non-parametric for subjective criteria, ANOVA for comparing between two groups.

Ethics and Dissemination

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

Consent or Assent

Patient will be given detail information regarding intervention in his own language. Then written consent will be taken from patients before starting the study. During study the confidentiality of each patient will be maintained.

Dissemination Policy

Data will be disseminated in the form of paper publication and presentation. Authorship eligibility guidelines and any intended use of professional writers. Informed consent material Informed

Strengths

Swadamshtradi taila will be work for the reducing symptoms of *katishool* and also changes the angle of Straight leg rising test, changes on Scober test. If proposed study results in the positive outcome then it will be established new mode of management for the *katishool*.

Limitations

It can be convincing the patient for *basti* and hospitalized for 28th day.

Conclusion

Conclusion will be mentioned after the deliberate and analyzing data.

References

1. Sharma PV, Charaka Samhita, Chikitsa Sthana, Vata Vyadhi, Chikithsa Adhyaya. 28/28. 2nd ed. Varanasi: Chaukhamba Sanskrit Sansthan, 1990, 225.
2. Murthy KR, Susruta Samhita, Nidanasthana, Vata Vyadhi Nidana. 1/20. Varanasi, India: Chaukhambha Orientalia, 2000, 102-10.
3. Murthy KR, Madhava Nidana, Vatavyadhi Nidana. 22/14, 57. Varanasi, India: Chaukhambha Orientalia, 1986, 65-90.
4. Bhende SV, Parwe S. Role of Ashwagandha Taila Matrabasti in the Management of Katigraha. International Journal of Ayurvedic Medicine. 11(2):310-3.
5. Maheshwari J. Essential Orthopaedics, chapter 31, 3rded revised reprint, Mehhta Publishers A-16 (east) Naraina-11New Delhi-110028, 2010, 228-229.
6. Nisargandha MA, Parwe SD, Wankhede SG, Deshpande VK. Comparison of nerve conduction studies on affected and non-affected side in the patients of sciatica. Int j basic appl physiol. 2020; 9(1):1.
7. Tripathi Brahmanand, Charaka Samhita, Brahmanand Tripathi, sutrasthana 1/53, 1st ed reprint, Chaukamba Sanskrit samsthan, 2005, 25.
8. Tripathi Brahmanand, Charaka Samhita, Brahmanand Tripathi, siddhi sthana 1/38-40, 1st ed reprint, Chaukamba Sanskrit samsthan, 2005, 1169-1170.
9. Tripathi Brahmanand, Charaka Samhita, Brahmanand Tripathi, siddhi sthana 4/54, 1st ed reprint, Chaukamba Sanskrit samsthan, 2005, 1224.
10. Nirmal Saxena. Vangasena Samhita of vangasena, vatavyadhi adhyaya shloka, 1sted, chaukhambha Sanskrit series office, Varanasi. 2004; 1(451):613-614
11. Shah rasavaiden Nagindas chaganlal, Bharat bhaishjya ratnakar panchmo bhag Tailaparakaranam 7430, 2nd edition reprint, B. Jain Publisher Pvt. Ltd. New Delhi, 2005, 69.
12. Vaidya Bapalal G. Nighantu Adarsa Uttaradha. Chapter -504 & 505,1sted Reprint, Chaukambha Bharti academy Varanasi. 2009; 2:567-576.
13. Vaidya Bapalal G. Nighantu Adarsa Purvardha Chapter -28,1sted Reprint, Chaukambha bharti academy Varanasi. 2007; 1:211.
14. Rande Subhas Dravyaguna Vigyana (part-1 & 2) Chapter -14, 1st ed Reprint, A. R. Nandurkar Proficient Publishing house pune, 2007, 308.
15. Tripathi Ravi Dutt, Charaka Samhita of Agnivesha Reprint, Vimansthan 5/16, Choukhambha Sanskrit Pratishtan, Delhi. 2009; 1:590.
16. Nirmal Saxena, Vangasena Samhita, of vangasena, vatavyadhi adhyaya shloka 1sted, chaukhambha Sanskrit series office, Varanasi. 2004; 1(451):613-614,
17. Tripathi Ravi Dutt, Charaka Samhita, of Agnivesha Reprint Sutrasthan 28/27, Choukhambha Sanskrit Pratishtan, Delhi. 2009; 1:431.