



Research Article

## CLINICAL EVALUATION OF *ANGAMARDAPRASHAMANA MAHAKASHAYA* AND *KATIVASTI* IN THE MANAGEMENT OF LUMBAR SPONDYLOSIS (*KATIGRAHA*)

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### ABSTRACT

Lumbar spondylosis is a degenerative disease where degeneration occurs in lumbar vertebrae, intervertebral disc and in intervertebral joints, characterized by loss of hydration of disc followed by formation of osteophytes and transdiscal bridging. It involves the entire joint including the nearby muscles, underlying bone, ligament, disk and give rise to symptoms of Lumbar spondylosis. *Katigraha* is a *Vataja nanatatmaja vyadhi* mentioned by Sharangadhar and *Shodala*. As per Acharya *Shodala*, *Vata* situated in *Asthi* of *Kati* region, increased due to various *Nidana* (causes) and produce symptoms of vitiated *Vata* as *Shula* (pain), *Pangutwa* (disability) both the lower limbs known as *Katigraha*. Hence for treatment of lumbar spondylosis is correlated and treatment given according to *Chikitsa* modalities of *Katigraha* (*Vatavyadhi Chikitsa*). To evaluate the efficacy of *Angamardaprashamana Mahakashaya* and *Kativasti* in the management of lumbar spondylosis clinically a open, random, clinical trial is carried out on 100 patients in one group, as intervention *Angamardaprashamana Mahakashaya Churna* (powder form) is given orally and *Kativasti* (a type of sudation therapy) on lumbar region is given externally. Follow up taken in every 20<sup>th</sup> day upto 60 days. After treatment for statistical analysis of data paired t test is done and data shows highly significant result and shows remarkable changes in signs and symptoms. But its result of radiological changes are found not significant statistically. The relief % is analysis by using Oswestry Disability Index which shows 91% respond to treatment and 74% got major improvements. Thus, the study says that trial drug and therapy have capacity to improve lumbar spondylosis (*Katigraha*) significantly.

### INTRODUCTION

'A man is as strong as his back': the quote clearly indicates the importance of back. Lumbar Spondylosis is degenerative condition of the lumbar vertebrae or spine and intervertebral disc, patients often complain of back pain that increases with movement, is associated with stiffness and better when inactive.<sup>[1]</sup> It is a chronic degenerative disorder of multifactorial etiology characterized by loss of hydration of disc and leads to space reduction and

weakens the annulus fibrosus which leads to approximation of zygapophyseal and facet joints and compression of annular ligament, Then continuous disc space narrowing and fibrosis occurs along with the formation of osteophytes and transdiscal bridging. It involves the entire joint including the nearby muscles, underlying bone, ligament, disk and give rise to symptoms of Lumbar Spondylosis.

In Ayurveda lumbar spondylosis is correlated with *Katigraha*, In Sanskrit *Kati* means waist or part of body which is covered with cloths and *Graha* means one which supports.<sup>[2]</sup> *Katigraha* indicates a disease condition of the lower back associated with stiffness (*Stambha* or *Graha*) and pain (*Katishoola*). *Katigraha* is one of the 80 types of *Vataja Nanatatmaja vyadhi* described by *Shodala* and *Sharangdhar* <sup>[3,4]</sup>. *Angamarda* is a *Lakshana* (sign) of *Vayu*, which only occurs in *Dhatukshya* (degenerative) condition. *Angamarda*

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*prashmana Mahakashaya* is a group of 10 number of herbs described in Charak Samhita [5]. These drugs together having quality to pacify vitiated *Vata Dosha*, causing muscular, bony, ligamentous pain and also have the quality to restore the painless condition from painfulness.

*Kativasti* is a *Ekanga, Snigdha, Samshamaniya, Sagni, Drava Swedan* and its direct references were not present in the *Samhitas* but can take references from *Vranavasti* and *Shirovasti* as their external *Dharana* (retention) of oil, because it have also external application of oil like *Shiro* or *Vranavasti*.

#### AIMS AND OBJECTIVES

- To evaluate the efficacy of *Angamardaprashamana Mahakashaya* and *Kativasti* the management of lumbar spondylosis (*Katigraha*).
- To make effective Ayurvedic treatment for Lumbar Spondylosis clinically.

#### MATERIAL AND METHODS

The study comprised of 100 patients of lumbar spondylosis were registered in OPD & IPD of *Angamardaprashamana Mahakashaya*

**Table 1: Contents of *Angamardaprashamana Mahakashaya* its Botanical name, part used, *Doshakarma* and ratio taken for Making of Medicine**

Classical name	Botanical name [7]	Part used [7]	<i>Doshakarma</i> [7]	Ratio [7]Per Kg
<i>Vidarigandha</i>	<i>Desmodium gangeticum</i>	Leaf and stem	<i>Tridoshashamak</i>	1000g
<i>Prishniparni</i>	<i>Uraria picta</i>	Root	<i>Tridoshashamak</i>	1000g
<i>Brihati</i>	<i>Solanum indicum</i>	Fruit & <i>Panchanga</i>	<i>Vatakaphahara</i>	1000g
<i>Kantakari</i>	<i>Solanum xanthocarpam</i>	Fruit	<i>Vatakaphahara</i>	800g
<i>Chandana (Sweta)</i>	<i>Santalum album</i>	Heartwood	<i>Kaphapittahara</i>	1000g
<i>Usheer</i>	<i>Veteveria zizanooides</i>	Fruit	<i>Kaphapittahara</i>	166g
<i>Eranda</i>	<i>Ricinus communis</i>	Roots	<i>Vatahara, Vatakaphahara</i>	1000g
<i>Kakoli/Pratinidhi dravya" (Ashwagandha)"[8]</i>	<i>Roscoea purpurea</i>	Rhizome	<i>Vatahara</i>	1000g
<i>Ela (Sukshma)</i>	<i>Elettaria Cardamomum</i>	Fruit	<i>Kaphavatahara</i>	166g
<i>Madhuka</i>	<i>Glycorhyza glabra</i>	Stem	<i>Tridoshashahara</i>	1000g

The 10 herbs of the *Angamardaprashamana Mahakashaya* are collected by myself from the botanical gardens, local market and vendors, as *Kakoli* is not available due its unavailability so its *Pratinidhi dravya Ashwagandha* is taken as per Acharya Bhavprakash, then it is made in *Churna* form in State Ayurvedic pharmacy, Govt. Ayurvedic College and Hospital, Jalukbari, Guwahati.

Procedure of the external therapy *Kativasti*: After checking the vital of patients he is asked to lie on bed on prone position, a ring made by dough is put on the lumbar area of patients where maximum degeneration occur, which is assessed by X-ray of LS

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**Ethical Clearance:** The research has been approved by the institutional Ethical committee. Written consent taken from all the patients before the trial. Ref No. IEC/2020/227.

**Selection of Drug and its Testing:** Drugs are collected manually and made it in *Churna* form in State Ayurvedic pharmacy of Govt. Ayurvedic College Guwahati, and then tested for its authenticity in State Drug Testing laboratory (Ayush), Jalukbari, Guwahati. Report NO. DTL (AY)/06/2021

The study has been registered in Central trial Registry-India (CTRI) and got reference number as, CTRI trial Ref No -CTRI/2021/09/036690.

**Intervention:** *Angamardaprashamana Mahakashaya churna* is given orally and *Kativasti* with *Mahavishagarbha taila* is given externally.

**Duration:** 60 days.

**Dose:** 3gm B.D with lukewarm water after food.

spine, in one bowl the oil is kept for warming, then the lukewarm medicated oil is poured into the ring and when it becomes cold then it is replaced by another bowl of hot oil by using 50ml syringe the process is repeated upto 30 minutes. After removing the oil the ring is also removed them a gentle massage is given for 5minutes over the back and thigh. The oil is taken for *Kativasti* is *Mahavishagarbha Taila*[6]. It is done regularly upto 14 days and also repeated for some patients who need.

**Study Design:** The clinical study was compromised 100 subjects of lumbar spondylosis were selected randomly from OPD and IPD of Kayachikitsa

Department of Govt. Ayurvedic College and Hospital, Guwahati, Assam. Their history was in clinical proforma sheet with special reference to habitat, occupation, work life, *Kostha*, *Prakriti* during history and physical examination.

#### Inclusion Criteria

1. Patient with low back pain, stiffness, tenderness of back, thigh and legs with radiological changes.
2. Lumbar spondylosis with spondylolisthesis.
3. Age of patients between 20 to 75 years of age.
4. Duration of illness >3 months

#### Exclusion Criteria

1. Patient associated with cardiac problem & CKD.
2. Ankylosing spondylitis
3. Pregnant woman
4. Patient associated with infectious arthritis
5. Congenital anomalies like spina bifida, dysplastic spondylolisthesis etc.
6. Pathologic spondylolisthesis like due to tumor, metastasis, osteoporosis, cuadaequina syndrome.
7. Spondylolisthesis
8. Sciatica

#### Laboratory Investigation

- Blood routine test
- X-Ray Lumbosacral spine AP and Lateral view

#### Diagnostic Criteria

Sign and symptom of lumbar spondylosis with positive radiological changes like narrowing of intervertebral disk, definite osteophytes and possible deformity of Bone ends.

**Assessment Criteria:** The assessment of the trial was done on the basis of following parameters.

#### Subjective Criteria

##### Duration of Pain

- No pain- 0
- Occasional pain- 1
- Frequent pain - 3
- Continuous pain- 4

##### Stiffness

- No Stiffness- 0
- Stiffness lasting 5 min to 2 hour - 1
- Stiffness lasting for 2 to 8 hour- 2
- Stiffness 2 hour to 8 hour- 3
- Stiffness more than 8 hour- 4

##### Oswestry lumbar back pain questionnaires [9]

1. Pain intensity- (0-5)
2. Personal care (washing, dressing etc)- (0-5)
3. Lifting- (0-5)
4. Walking- (0-5)
5. Sitting- (0-5)
6. Standing- (0-5)
7. Sleeping - (0-5)
8. Sex life- (0-5)
9. Social life- (0-5)

##### 10. Travelling- (0-5)

#### Objectives Criteria

##### Modified Schobers test: [10]

- >5cm & No restriction- 0
- Mild restriction Upto 4cm - 1
- Moderate restriction Upto 3cm - 2
- Severe restriction, <2cm- 3

**Statistical Analysis:** Study carried on 100 patients before and after treatment data's were collected and Mean, Standard Deviation, Standard Error, t and p values are observed to know statistically significant or not.

#### OBSERVATION AND RESULT

Study was done on 100 patients. Results of observation on demographic profile:

- It was observed that, more number of patients are female (56%). The major age group effected is 36-50yrs of age contributing 45% followed by 51-65 years (21%), 20-35years (18%) and in age group between 66-75 years (16%).
- Majority numbers of the patients were housewives i.e., (51%), followed by 10 patients (10%) are there who do business and daily wage work and 16 patients were farmer that occupy 16%.
- The study of *Prakriti* showed that 60 patients (60%) are *Vatik prakriti*, 12 patients were *Paittik prakriti* i.e., (12%) and 28 patients were *Sleshmik prakriti* i.e., 28%.
- After analysis of *Kostha* of the patients it is found that who have *Madhyam kostha* are effected more, that is 62% followed by 24% *Krura kostha* and only 14% have *Mridu Kostha*.
- Study shows medium build patients were more effected by *Katigraha* i.e., 59% (59) followed by obese patients which are 27% (27), and patients have thin build were 14% (14) of the sample.
- On the distribution of lifestyle, it shows 64 patients i.e., 64% follow active lifestyle and 36 patients follow sedentary lifestyle i.e., 36%.
- Study shows lower middle class people were more sufferers i.e., 43%, (43 patients), followed by poor class 28% (28 patients), upper middle class 26% (26 patients), rich class suffering the disease only by 3% of the population i.e., 3 no of Patients.
- Among the symptoms, most of the patient have low back pain i.e., 81% and difficulty in walking- 80%, followed by 60% have stiffness of back and thigh, 43% of patients have tenderness over lumbar region and 36% of patients have difficulty in walking and 100% patients have radiological changes.
- Statistical analysis of data along with results are tabulated-

**Table 2: Statistical Result of Pain (over low back)**

Symptoms	N	BT Mean	Mean			Paired t test				Significance
			Mean	df(n-1)	Mean ±SD	SEM	t	p		
Pain over Low back	100	3.41								
			FU1	3.29	99	3.29±0.57	0.06	2.7715	0.0067	Significant
			FU2	3.01	99	3.01±0.27	0.03	6.0000	<0.001	Highly significant
			FU3	2.70	99	2.70±0.46	0.05	8.9294	<0.001	Highly significant

**Table 3: Statistical result of stiffness (over lower back)**

Symptoms	N	BT Mean	Mean			Paired t test				Significance
			Mean	Df(n-1)	SD	SEM	t	P		
Stiffness over back and gluteal muscle	100	2.37								
			FU1	1.96	99	0.73	0.09	4.86	<0.001	Highly significant
			FU2	1.87	99	0.48	0.06	5.0419	<0.001	Highly significant
			FU3	1.49	99	0.79	0.09	7.4058	<0.001	Highly significant

**Table 4: Statistical result of Tenderness over low back**

Symptoms	N	BT Mean	Mean			Paired t test				Significance
			Mean	df(n-1)	Mean±SD	SEM	t	P		
Tenderness over Low back	100	1.17	FU							
			FU1	0.98	99	0.98±0.85	0.09	3.1778	0.0020	Significant
			FU2	0.97	99	0.97±0.74	0.07	4.2426	<0.0001	Highly significant
			FU3	0.85	99	0.85±0.69	0.07	4.1894	<0.0001	Highly significant

**Table 5: Statistical Result of Modified Schober's test**

Criteria	N	BT Mean	Mean			Paired t test				Significance
			Mean	df(n-1)	Mean ±SD	SEM	t	P		
Modified Schober's test	100	2.20	FU							
			FU1	2.10	99	2.10±0.83	0.08	3.3166	0.0013	Significant
			FU2	1.89	99	1.89±0.84	0.08	6.3777	<0.001	Highly significant
			FU3	1.59	99	1.59±1.08	0.11	6.4052	<0.001	Highly significant

**Table 6: Statistical Result of Oswestry lumbar back pain disability questionnaires Symptoms**

Symptoms	N	BT Mean	Mean			Paired t test				Significance
			Mean	Df (n-1)	Mean±SD	SEM	t	P		
OLBPDQ	100	63.2562	FU							
			FU1	57.7730	99	57.7730±11.2135	1.1213	4.9466	<0.001	Highly significant
			FU2	34.8149	99	34.81±16.5883	1.6672	18.27771	<0.001	Highly significant
			FU3	26.6267	99	26.6267±17.5177	1.7518	19.0464	<0.001	Highly significant

**Table 7: Statistical result of radiological changes in Lumbar X-ray before and after treatment**

Radiological changes	n	Mean	Df (n-1)	Mean ±SD	SEM	t value	p value	Significant
BT	100	3.23	99	3.23±0.92	0.09	1.214	0.1583	
AT/FU3	100	3.21	99	3.21±0.98	0.10			Not significant

**DISCUSSION**

As in Lumbar Spondylosis, degeneration occurs in lumbar vertebrae, intervertebral disc and in the intervertebral joints and in Ayurveda *Vata* and *Asthi* (bone) are have *Asraya Asrayi Sambandha*, thus *Samprapti* (pathogenesis) of *Katigraha* defined as *Vata* situated in *Asthi* of *Kati* region, increased *Vata* due to various *Nidana* diminishes *Sneha* from *Asthidhatu* by

its opposite qualities to *Sneha*. Due to this diminution of *Sneha*, *Khavaigunya* occurs in *Asthi* and leads to *Dhatu kshaya* and produce symptoms of vitiated *Vata* as *Shula*, *Stambha* etc known as *Katigraha*.

According to Ayurvedic pharmacopeia of India, the trial drugs have pharmacological properties mostly have *Madhur Snigdha Guna*, *Balya*, *Deepaneeya*,



*Rasayana* and *Vatashamak* properties. Charaka Samhita described that these drug has restorative and pain palliative action on diseases.

*Kativasti* stimulate the trans dermal drug delivery systems through which drug get entered by hair follicles, sweat glands and cellular route. Due to use of oil that is heated upto 40-45 degree Celsius it does vasodilatation and increase absorption through skin where drug goes to circulation and through which it nourishes the skin muscles, ligament's, disc and bones, when skin absorption time is more it increases the local blood flow, it increase local cellular metabolism and it also stimulate endogenous pain inhibiting system by releasing of opioids peptides and do vasodilatation thus it relives from pain and give flexibility to joints.

It was observed that patients disability got major improved by 74% and mild improvement got by 7%, moderate improvement got by 10% and was analyses by Oswestry lumbar disability index. Thus, both the trial drug and therapy have quality to reduce pain, to repair tissue and to give nutrition to the tissue. After full course of treatment 9% patients did not get fully relived but their flexibility and mobility of spine increases and they feel light and can do their daily work without any difficulty.

Result of radiological changes found statistically not significant thus it need research for longer duration and on large number of sample size.

The treatment procedure can easily give a life to patients NSAIDS, antidepressants, muscle relaxant, and injection therapy type of medication free life and helps them to stay away from their side effects. Because most of the diagnosed patients took pharmacotherapy to control pain, swelling, and minimize disability like oral NSAIDS, opioid medications, antidepressants, muscle relaxant and some other took injection therapy like- epidural steroid injections and facet injections.<sup>[11]</sup>

## CONCLUSION

The clinical study of *Angamardaprashamana Mahakashaya* and *Kativasti* with *Mahavishagarbha taila* on lumbar spondylosis with special reference to *Katigraha* shows significant result on its symptoms

and severity of the disease. By this method of treatment we can easily treat the lumbar spondylosis disease and can prevent disability of the patients. During the treatment period, no adverse effects were seen clinically, this indicate the non toxicity and safety of the trial drug. Thus, the study is concluded that trial drug and therapy both have capacity to improve or cure Lumbar Spondylosis (*Katigraha*) significantly.

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