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Research Article

SAPTHASARAM KASHAYAM AND KOTTAM CHUKKADI TAILA IN THE MANAGEMENT OF KATIGRAHA (LUMBAR SPONDYLOSIS) – A CLINICAL TRIAL

Pooja Sharada Jagadeesh Shanbough[1]*, Shripathi Acharya[2], Naveen K[3]

1. *PG Scholar, Dept. of Kayachikitsa, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.*
2. *Professor and Head, Dept. of Kayachikitsa, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.*
3. *Assistant Professor, Dept. of Kayachikitsa, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.*

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Abstract

Low back pain (LBP) affects approximately 60–85% of adults during some point in their lives. The lifestyle changes in diet and habits of individuals have made Katigraha a very common disease now- a- days. In most of the cases, people are not able to manage the disease with modern medicines and also by quitting their diet and habits or changing their lifestyle. So, keeping these points in view, here an attempt has been made with Sapthasaram kashayam (internal) and Kottam chukkadi taila (external application) mentioned in Sahasrayoga. 20 Subjects diagnosed as Katigraha and who fulfil the inclusion criteria was randomly selected. Sapthasaram kashayam was given in two divided doses of 50ml each; morning and evening 1 hour before food and Kottam chukkadi taila applied at Kati region twice daily for 30 days. Results showed that there was relief in pain (27.3%), stiffness (39.9%), tenderness (44.7) and difficulty in walking (23.8), Schober's test (20%), VAS (24.3%) and Oswestry test (17.2%) which was statistically significant. (P = <0.001). To conclude, the patients had shown improvement in most of the assessment criteria of Katigraha. According to this study Sapthasaram kashaya and kottam chukkadi taila can be opted for all the Katigraha i.e. lumbar spondylosis.

Keywords: Katigraha; Sapthasaram kashayam; Kottam chukkadi taila.

***Address for correspondence:**
Dr. Pooja Sharada Jagadeesh Shanbough,
PG Scholar,
Dept. of Kayachikitsa,
Muniyal Institute of Ayurveda Medical Sciences,
Manipal, Karnataka, India – 576 104
E-mail: pooja.jagadeesh9@gmail.com

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INTRODUCTION

Back pain, one of the major musculoskeletal pain problems, has plagued humans since we evolved the upright bipedal position from that of the quadruped. The vast majority of us will have at least one bout of debilitating back pain in our lives, and many of us live with chronic symptoms. Low back pain (LBP) affects approximately 60-85% of adults during some point in their lives and Lumbar Spondylosis (LS) is responsible for about 10% of these.

In Ayurveda, Katigraha is the term given for Low Back Ache. The term Kati means low back region and Graha means stiffness with gripping pain. Terms like Kati, Trika, and Shroniare not been described as a separate disease entity by any text except Gada Nigraha,[1] it has been categorized under Vataja Nanatmaja Vyadhi in Charaka Samhita as Prishta Graha.[2] In lumbar spondylosis, low back pain, difficulty in walking, tenderness has been told as the prominent feature. Lumbar spondylosis is a degenerative condition affecting the discs, vertebral bodies, and/or associated joints of the lumbar spine.[3]

Kati shoolais mentioned as a symptom in different types of vataja disorders and not as a separate disease in classical texts. Kati ruja or shoola is also present as a symptom of Kati graha.

Based on this statement the hypothesis has been framed for the study, which states that Sapthasaram kashayam (internal)[4] and Kottam chukkaditaila (external application)[5] is capable in controlling Katigraha.

MATERIALS AND METHODS

All Ayurveda, Modern literatures and contemporary texts including the journals, Previous research works, websites etc. were reviewed pertaining to the drug and diseases in the intended study.The formulation selected for the research work Sapthasaram kashayam and Kottam chukkadi taila was prepared in Muniyal Institute of Ayurveda Medical Sciences and Hospital, Manipal, pharmacy as per the standard operative procedure. The study was carried out in 20 patients diagnosed as Katigraha and selected from the OPD and IPD of Muniyal Institute of Ayurveda Medical Sciences, Manipal Karnataka after obtaining the Institutional Ethical Committee clearance. (IEC/KC/02; IEC/MIAMS/2016-2017/Date: 15/4/2016)

Preparation of Kottam chukkadi taila

The Kalka dravya and dravadravya for the preaparation of Kottamchukkadi taila are Kottam, Chukku, Vayampu, Sigru, Lasuna, Devadaru, Karotti, Siddhardha, Suvaha and Dadhi, Chincha rasa respectively. Tila taila was used as the base. 1 part of kalka (all the kalka dravya mixed together), 4 parts of oil (tilataila), and 16 parts of Drava dravya were added together boiled and reduced to the quantity of oil.[6]

Preparation of Sapthasaram kashayam choorna:

Varshabhu, Bilwa, Khalvo, Ruba, Sahachara, Sunthi, Angimantha were taken in equal quantity and pounded to coarse power form and packed.

Method of preparation

10 grams Sapthasaram Kashayam choorna is taken and added with 16 parts (800 ml) of water and reduced to 1/8th part (100 ml) and taken at morning and evening before food.

Inclusion Criteria

- Subjects of age group- 30 to 60 years (Irrespective of gender).
- L.S.M (Lumbar spine mobility) tests[7][8][9]

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- If flexion of the spine is less than6cm
- If lateral flexion of the spine is less than35^{o}
- If extension of the spine is less than30^{o}
- If spinal rotation from the waist on either side is less than 45^{o} (perside).

Exclusion Criteria

- Subjects having complicated diseases like spinal tumor, fracture of vertebrae, Malignancy and Tuberculosis of spine etc.
- Subjects with known case of diabetes mellitus and hypertension.
- Subjects with history of trauma to the spine and with marked deformities of spinal cord and disc prolapse.
- Ankylosing spondylosis, Rheumatoid Arthritis, Psoriatic Arthritis, Gouty Arthritis, Pregnancy, Epilepsy or any other serious systemic illness.
- Subjects aged below 30 yrs. and above 60 yrs.

Laboratory Investigations

- Complete blood test
- Fasting blood sugar
- Plain X-ray of lumbar spine (AP and LAT)
- RA factor (To rule out Rheumatoid arthritis)
- Serum uric acid (To rule out Gout)
- Mantoux test (Only if necessary- to rule out TB of spine)
- HLAB27 (if necessary)
- MRI (if necessary)

Design of Study

A single blind clinical study

Interventions

Sapthasaram kashayam (internally) and Kottam chukkadi taila (external application) in a dose of 50ml (Kashaya) & 10-15 ml (Taila) was administered morning and evening minimum 1 hour prior to food. Total duration of the study was 30 days and Follow up on 31st and 45th day of treatment.

Diet and Regimen

Avoid Potatoes, Brinjals, Chanaka (chana dal), Beans, Green peas, Shushkaahara (dry food items), Viruddhaahara (foods having opposite quality), Fast food, Aerated drinks, and Bakery items. Mainly laghu (light), ruksha (roughness) and sheeta (cold) gunaahara. Avoid Ativyayama (excess exercise); mild to moderate exercises can be done. Avoid Atimaithuna (excess sexual intercourse).

Assessment criteria

The assessment was done on the basis of following Subjective parameters and Objective parameters. The Subjective parameters were Katiruja (pain), Katigraha (stiffness), Tenderness and Difficulty in walking. The Objective parameters were Schober'stest,[10] Visual analogue scale and Oswestry low back disability assessment questionnaire.[11]

Patients was assessed based in the assessment criteria and was observed for the symptomatic changes on 31st day. Follow up was taken on 45th day. The results obtained were analyzed statistically. The list of clinical presentation of Katigraha is given below and it was taken as the assessment criteria with scoring. (Table 1 and Table 2) (Figure 1)

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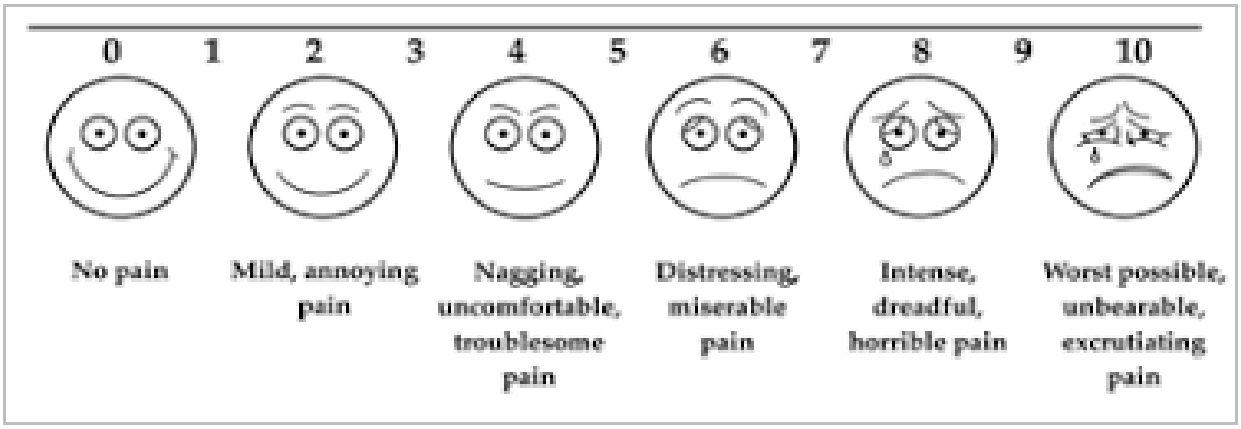
Table 1: Scoring pattern

Signs and Symptoms	Parameters	Score
Kati ruja (Pain)	No pain	0
	Localized, recurrent, mild pain in back, not radiating to legs, exaggerated by Walking & lifting weight, completely relieved by rest.	1
	Recurrent, Mild but uncomfortable pain in back, radiating to one/ both leg, Exaggerated by movements, subsided by rest.	2
	Moderate but dreadful pain in the back, with/ without radiation, exaggerated by bending, not relieved by rest, relieved by fomentation & massage, not Disturbing sleep.	3
	Severe (Horrible) pain in the back with / without radiation to legs, unchanged by rest, disturbing the sleep, relieved by fomentation, lotions or lower analgesics	4
	Severe(Agonizing) continuous pain in the back, radiation to both legs, disturbs sleep, requires higher analgesics or major injections for spinal block	5
	Intense degree of continuous pain not relieved by any measures	6
Kati graha (Stiffness)	no restriction of movements	0
	restriction in any one movement of above	1
	restriction in any 2 movements	2
	restriction in any 3 movements	3
	restriction in all 4 movements	4
Tenderness	No tenderness	0
	mild tenderness without any sudden response on pressure	1
	wincing of face on pressure due to tenderness	2
	wincing of face withdrawal of affected part on pressure	3
	resists touch due to tenderness	4
Difficulty in walking	No difficulty in walking	0
	Pain restrict walking more than 1 mile	1
	Pain restrict walking more than ½ mile	2
	pain restrict walking more than ¼ mile	3
	Not able to walk at all	4
Schobers test	No restrictions > 5 cm	0
	Mild restriction upto 4cm	1
	Moderate restriction upto 3cm	2
	Severe restriction < 2cm	3

Figure 1: Visual analogue scale (for pain assessment)



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Ayurpharm Int J Ayur Alli Sci., Vol. 7, No. 6 (2018) Pages 92 – 100

Table 2: Oswestry low back disability assessment questionnaire

Signs and Symptoms	Parameters	Score
Section 1 – Pain intensity	I have no pain at the moment	0
	The pain is very mild at the moment	1
	The pain is moderate at the moment	2
	The pain is fairly severe at the moment	3
	The pain is very severe at the moment	4
	The pain is the worst imaginable at the moment	5
Section 2 – Personal care (washing, dressing etc)	I can look after myself normally without causing extra pain	0
	I can look after myself normally but it causes extra pain	1
	It is painful to look after myself and I am slow and careful	2
	I need some help but manage most of my personal care	3
	I need help every day in most aspects of self-care	4
	I do not get dressed, I wash with difficulty and stay in bed	5
Section 3 – Lifting	I can lift heavy weights without extra pain	0
	I can lift heavy weights but it gives extra pain	1
	Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table	2
	Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned	3
	I can lift very light weights	4
	I cannot lift or carry anything at all	5
Section 4 – Walking*	Pain does not prevent me walking any distance	0
	Pain prevents me from walking more than 1 mile	1
	Pain prevents me from walking more than ½ mile	2
	Pain prevents me from walking more than 100 yard	3
	I can only walk using a stick or crutches	4
	I am in bed most of the time	5
Section 5 – Sitting	I can sit in any chair as long as I like	0
	I can only sit in my favourite chair as long as I like	1
	Pain prevents me sitting more than one hour	2
	Pain prevents me from sitting more than 30 minutes	3
	Pain prevents me from sitting more than 10 minutes	4
	Pain prevents me from sitting at all	5
Section 6 – Standing	I can stand as long as I want without extra pain	0
	I can stand as long as I want but it gives me extra pain	1
	Pain prevents me from standing for more than 1 hour	2
	Pain prevents me from standing for more than 30 minutes	3
	Pain prevents me from standing for more than 10 minutes	4
	Pain prevents me from standing at all	5
Section 7 – Sleeping	My sleep is never disturbed by pain	0
	My sleep is occasionally disturbed by pain	1
	Because of pain I have less than 6 hours sleep	2
	Because of pain I have less than 4 hours sleep	3
	Because of pain I have less than 2 hours sleep	4
	Pain prevents me from sleeping at all	5
Section 8 – Sex life (if applicable)	My sex life is normal and causes no extra pain	0
	My sex life is normal but causes some extra pain	1
	My sex life is nearly normal but is very painful	2
	My sex life is severely restricted by pain	3
	My sex life is nearly absent because of pain	4
	Pain prevents any sex life at all	5
Section 9 – Social life	My social life is normal and gives me no extra pain	0
	My social life is normal but increases the degree of pain	1
	Pain has no significant effect on my social life apart from limiting my more energetic	2

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	interests eg, sport	
	Pain has restricted my social life and I do not go out as often	3
	Pain has restricted my social life to my home	4
	I have no social life because of pain	5
	I can travel anywhere without pain	0
	I can travel anywhere but it gives me extra pain	1
Section 10 – Travelling	Pain is bad but I manage journeys over two hours	2
	Pain restricts me to journeys of less than one hour \	3
	Pain restricts me to short necessary journeys under 30 minutes	4
	Pain prevents me from travelling except to receive treatment	5

Laboratory parameters

- Radiological evidences (X-ray lumbar spine) X-rays were assessed as per Kellegren and Lawrance scale for degenerative changes. (Table 3)
- Hemoglobin percentage
- ESR

Statistical analysis

The scores of assessment criteria were analysed statistically in the form of mean score B.T (Before Treatment), A.T. (after Treatment), Difference of mean (B.T. - A.T), S.D. (Standard Deviation), S.E (Standard Error). Students paired 't' test and Mann Whitney U test was carried out. The results were considered Significant or Insignificant depending upon P value.

RESULTS

Among 20 subjects of Katigraha, 9% belonged to age group 51-60 years, 6% belonged to age group 41-50 years and 5% belonged to age group 30-40 years. Among 20 subjects of Katigraha, 10% were male and 10% subjects were female. Among 20 subjects of Katigraha, 13% subjects were married and 7% were unmarried. 8% subjects were house wife, 1% farmers, 2% were businessman, 8% were doing desk work and 1% field workers.

Before the treatment, the mean score of Kati ruja (pain) was 2.58, which was then reduced to 1.88 after treatment. There was 27.3% improvement.

The statistically analysis shows that the result was extremely significant (P= 0.0001). After Follow-up value reduced further to 1.76, the effect of treatment showed 31.8 % improvement in pain score which is statistically extremely- significant (P=0.0003).

Before the treatment, the mean score observed in Stiffness was 2.75, which after treatment value reduced to 1.90, the effect of treatment showed 30.9 % improvement in stiffness score which was statistically extremely- significant (P<0.0001). After Follow-up value reduced to 1.65, the effect of treatment showed 40 % improvement in stiffness score which is statistically extremely- significant. (P<0.0001)

Mean score observed in Tenderness before the treatment was 1.05. After Treatment value reduced to 0.60, the effect of treatment showed 44.7 % improvement in tenderness score which is statistically very- significant (P=0.0039).After Follow- up value reduced to 0.45 , the effect of treatment showed 61.6 % improvement in tenderness score which is statistically extremely- significant (P=0.0005).

Mean score observed in Difficulty in walking before the treatment was 1.05. After Treatment value reduced to 0.80, the effect of treatment showed 23.8 % improvement in difficulty in walking score which is statistically significant (P=0.0210).After Follow-up value reduced to 0.70, the effect of treatment showed 33.3 % improvement in difficulty in walking score which is statistically significant (P=0.0156).

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Before the treatment, the mean score in Schober's test was 1.25. After Treatment value reduced to 1.00, the effect of treatment showed 20 % improvement in Schober's test score which is statistically significant (P=0.0210).After Follow-up value reduced to 0.95, the effect of treatment showed 24 % improvement in Schober's test score which is statistically significant (P=0.0102).

Mean score observed in VAS before the treatment was 3.70. After Treatment value reduced to 2.80, the effect of treatment showed 24.3 % improvement in VAS score which is statistically extremely- significant (P<0.0001).After Follow-up value reduced to 2.40, the effect of treatment showed 36.6 % improvement in VAS score which is statistically extremely- significant. (P<0.0001)

Before the treatment, the mean score observed in Oswestry low back disability assessment questionnaire score was 28.44. After Treatment value reduced to 23.54, the effect of treatment showed 17.2 % improvement in Oswestry low back disability assessment questionnaire score which is statistically extremely- significant (P<0.0001). After Follow-up value reduced to 20.65 , the effect of treatment showed 27.3 % improvement in Oswestry low back disability assessment questionnaire score which is statistically extremely- significant (P<0.0001). (Table 4 and Table 5)

DISCUSSION

Katigraha is considered as a major musculoskeletal problem of today's era. Because of the lifestyle changes in diet and habits of individuals, Katigraha is spreading as a very common disease now a day. In most of the cases, people are not able to manage the disease with modern medicines and also by quitting their diet and habits or changing their lifestyle. Katigraha was referred to as Lumbar spondylosis in this context as the symptomatology, complications etc of lumbar spondylosis is very similar to Katigraha.

Probable mode of action of trial drugs[12]

Sapthasaram kashayam is mentioned in Sahasrayoga. Its ingredients are Varshabhu (Rakta Punarnava - *Boerhavia diffusa*), Bilwa (*Aegel marmelos*), Khalvo (Kulatha - *Dolichos biflorus*), Ruba (Eranda - *Ricinus communis*), Sahachara (*Barleria prionitis*), Sunthi (*Zingiber officinale*) and Angimantha (*Clerodendrum phlomidis*). When considering the Dosha karma of the drug majority of the drugs in the yoga are having Vatakaphahara properties. Punarnava, Kulatha, Sahachara, Shunti and Agnimantha have vatakaphahara karma. Bilwa has tridoshahara property and Sahachara has kaphahara property. Shunti has deepana and pachana properties whereas Eranda has amapachana and anulomana property. In Katigraha there is dominance of vata and kaphadosha and there is pain and stiffness due to vata avarutakapha (specifically shleshaka kapha). All these drugs have the property of Vatakaphahara which does samprathi vighatana of the disease and helps to bring back the normal conditions of the vitiated doshas.

Kottam chukkadi taila is mentioned in Sahasra yoga. Its ingredients are

Kalka dravya: Kottam (Kushta - *Saussuria lappa*), Chukku (Shunti - *Zingiber officinale*), Vayampu (Vacha - *Acorus calamus*), Sigru (*Moringa oleifera*), Lasuna (*Allium sativum*), Devadaru (*Cedrus deodara*), Kardhotti (Govindhaphala - *Capparis sepiaria*), Siddhardha (Sarshapa - *Brassica campestris*), Suvaha (*Alpinia officinarum*).

Drava dravya: Dadhi (Curd), Chincha rasa (Tamarind leaf juice - *Tamarindus indica*). Sneha dravya: Tila taila (sesame oil - *Sesamum indicum*).

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Table 3: Kellegren and Lawrance scale

Grade	Parameters
Grade 1	Doubtful narrowing of joint space and possible osteophytic lipping.
Grade 2	Definite osteophytes, definite narrowing of joint space.
Grade 3	Moderate multiple osteophytes, definite narrowing of joints space, some sclerosis and possible deformity of bone contour.
Grade 4	Large osteophytes marked narrowing of joint space, severe sclerosis and definite deformity of bone contour.

Table 4: Effect of symptoms after treatment

Symptoms	BT	AT	%	SD	SE	"t"value	"P" value
Kati ruja	2.58	1.9	27.3	0.78	0.18	4.951	0.0001
Kati graham	2.75	1.90	30.9	0.96	0.21	5.667	<0.0001
Tenderness	1.05	0.60	0.47	0.68	0.15	t/r=0.815	p=0.0039
Difficulty in walking	1.05	0.80	23.8	0.89	0.20	t/r=2.517	p=0.0210
Schober's test	1.25	1	20	0.72	0.16	2.517	0.0210
Visual analogue scale	3.70	2.80	24.3	1.19	0.26	7.285	<0.0001
Oswestry questionnaire	28.44	23.54	17.2	16.02	3.58	5.505	<0.0001

Table 5: Effect of symptoms after follow-up

Symptoms	BT	AF	%	SD	SE	"t"value	"P" value
Kati ruja	2.58	1.76	31.8	0.66	0.16	4.667	0.0003
Kati graham	2.75	1.65	40	0.87	0.19	6.242	<0.0001
Tenderness	1.05	0.45	61.6	0.60	0.13	t/r=0.839	p=0.0005
Difficulty in walking	1.05	0.70	33.3	0.80	0.17	t/r=2.517	P=0.0156
Schober's test	1.25	0.95	24	0.68	0.15	2.854	0.0102
Visual analogue scale	3.70	2.40	36.6	0.94	0.21	7.255	<0.0001
Oswestry questionnaire	28.44	20.65	27.3	16.31	3.64	7.362	<0.0001

All the drugs in mentioned in the yoga have Vatakaphahara properties. Shunti, Vacha, Shigru, Lashuna, Kardhotti, Sarshapa, Rasna, Chinch rasa and Tilataila have deepana karma. Shunti and Rasna have ama pachana property. Lasuna has asthi – mamsa sandhanakara property all this will help in the breaking of the pathogenesis of the disease Katigraha.

CONCLUSION

Lumbar Spondylosis due to its clinical manifestation, pathogenesis and complication can be positively correlated with Katigraha mentioned in Gada Nigraha.

The Samanya Nidana mentioned for Vata Prakopa stand true even for Lumbar Spondylosis.

A review of the therapeutics revealed that most of the drugs were Vata Kapha Shamaka, Agni deepaka, Aamahara, Vaata anulomaka, Vedanasthapana. Some even are proven to have a rasayana effect.

Bahya Snehana adds to the Vatashamaka or Vatahara action and hence helped to obtain a better Improvement. This also proves the role of additional modalities with internal medications in the management of Katigraha and hence Vatavyadhi or any other disease.

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Ayurpharm Int J Ayur Alli Sci., Vol. 7, No. 6 (2018) Pages 92 – 100

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