ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

OPEN LABEL COMPARATIVE CLINICAL TRIAL OF *DVIPANCHAMOOLADI TAILA* AND *KSHEERABALA TAILA MATRA VASTI* IN THE MANAGEMENT OF LOW BACK ACHE

Rabinarayan Tripathy[1]*, Parameswar Namboothiri[2], Susmita Priyadarshinee Otta[3]

*[1]Professor, P.G. Department of Shalya Tantra, Amrita School of Ayurveda, Vallikavu, Clappana P.O., Kollam

[2]Associate Professor, P.G. Department of Panchakarma, Amrita School of Ayurveda, Vallikavu, Clappana P.O., Kollam

[3]Research Officer, ARIMCHC, Poojappura, Thiruvananthapuram, Kerala.

ABSTRACT

Low back pain is a leading cause of disability, interferes with quality of life and work performance, and is the most common reason for medical consultations. Few cases of back pain are due to specific causes; most cases are non-specific. The most common presentation is acute back pain and is usually self-limiting, lasting less than three months regardless of treatment. Chronic back pain is a more difficult problem, which often has strong pathological and psychological overlay like work dissatisfaction, boredom, and a generous compensation system contribute to it. Among the diagnoses lumbar spondylosis is blamed. No single treatment is superior to others; even surgery is seldom successful at alleviating it. Hence a clinical study was conducted on 30 patients with classical sign and symptoms of *Katigraha* (LBA) with an aim to find out the effectiveness of *Dvipanchamooladi taila Matra basti* (oil enemata of an indigenous compound). The patients were randomly divided in to two groups 15 patients in each. Group I (Trial) administered with *Dvipanchamooladi taila matra basti* and Group II (Control) – *Ksheerabala taila Matra basti* (enemata prepared by processing *Sida Cordifolia* root with milk and sesame oil) for a total period of nine days. The trial drug being potentiated by its inherent properties like anti-inflammatory, anodyne etc. exhibited favorable result with an effectiveness of 87.30% to reduce the sign and symptom of low back ache & the effect of the trial therapy were statistically highly significant with a p-value of > 0.01 in the management of Low back ache.

KEYWORDS: Disc herniation, Coin test, S.L.R. test, F.N.S. test, L.S.M.test, Disc protrusion, Lumbar Spondylosis.

INTRODUCTION

Low back pain is a common disease manifested with pain and stiffness in the lumbar region, which hampers the normal activities of the person. With a review to Ayurvedic literature, the pathogenesis of this disease is not mentioned separately but included under *Vata vyadhi* (disease of locomotion & nervous system), which may be co-related to lumbar spondylosis that presents with degenerative changes in the lumbar region. Low back ache (LBA) affects approximately 60–85% of adults during some point in their lives[(2)]. In a large majority of individuals, though the symptoms are mild and transient, and 90% subsiding within 6 weeks, still for the minority with intractable symptoms, the impact on quality of life and economic implications are considerable. Chronic low back pain, defined as pain, persisting beyond 3 months, affects an estimated 15–45% of the population[(3)]. "*Katigraha*" etymologically derived as a disease where the patient feels pain and stiffness in the lumbar region, which hampers the normal activities of the person. Due to some clinico-pathological similarity, it can be co-related to Lumbar Spondylosis[(4)]. Varieties of diseases are mentioned in modern medical literature which present with pain and stiffness in the lumbar region amongst which Lumbar Spondylosis accounts 80% incidence in 3rd decades of life[(3)]. Hence *Katigraha* with a co-relation to lumbar spondylosis was proposed in the present study.

Lumbar spondylosis is a degenerative condition which affects the lower spine. In a patient with lumbar spondylosis, the spine is compromised by a narrowing of the space between the vertebrae, causing a variety of health problems ranging from back pain to neurological issues [(5)]. This condition is usually caused by old age, as the spine undergoes changes as people grow older, and many of these changes contribute to degeneration of the vertebrae.

Despite the high prevalence of low back pain within the general population, the therapeutic options are diverse and often inconsistent, resulting in rising costs and variability in management throughout the country. For complicated cases of *Katigraha* (lumbar spondylosis) Surgery is an option, but the expenditure of surgery may not be affordable by all individual. So the need arises to search for a better and safer treatment. The "*Basti" chikitsa* (a traditional treatment procedure, where the medicaments are infiltrated through anal route) has prime importance among *Pancha karma* (five types of treatment for the purification of body from metabolic toxins) because of its wide applicability in various conditions & forms. *Matra basti* (enema given in a low dose), the simple form of *Basti* which can be performed very easily even in OPD level without any complications. *Dvipanchamooladi taila* has been mentioned by *Vangasena Samhita* (An ancient book written by Vangasena, named as Chikitsa Sara samgraha in 1276 A.D.) for *Katigraha* [(6)]. So the clinical study was proposed.

Aims & objectives

- To assess the efficacy of *"Matra Basti"* with *Dvipanchamooladi taila* in *Katigraha*.

Materials and methods

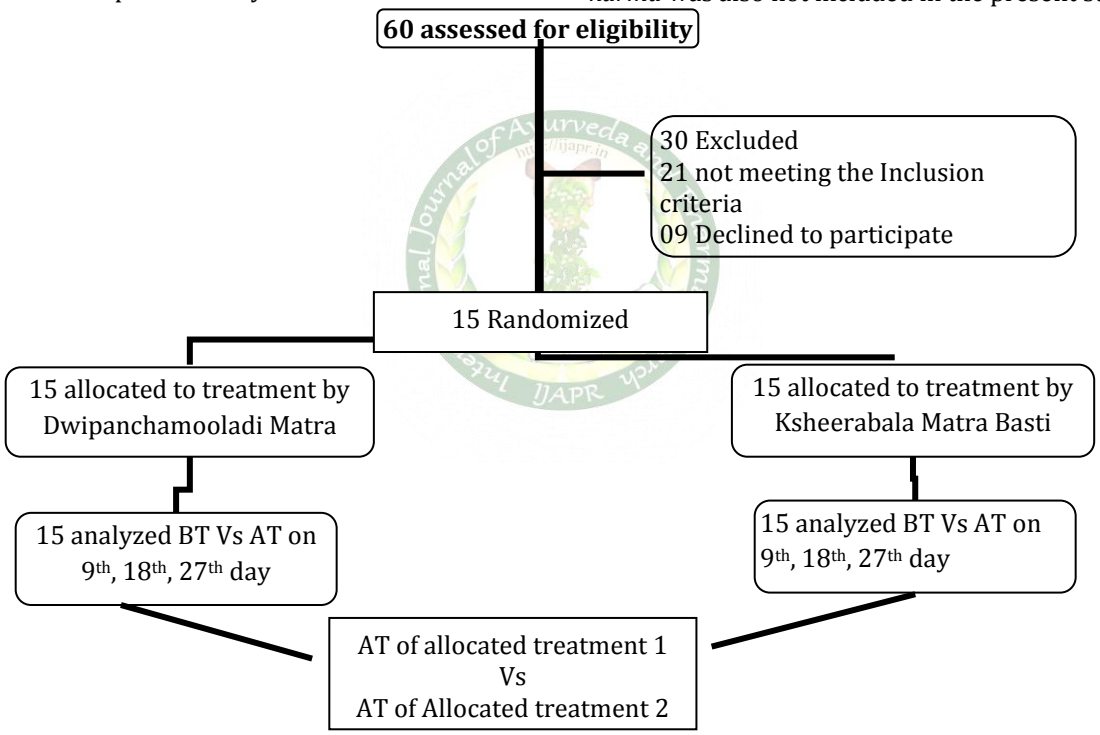
The study was a single blind clinical trial where 30 patients were selected by random sampling procedure, with a complaint of LBA attending the OPD (Outpatient department) & IPD (Inpatient Department) of NKJ. Ayurvedic Medical College, Bidar, Karnataka attached to Shri Siddharoodha charitable hospital and other associated hospital. The selected patients were divided into two groups, 15 in each. Initially, history of all patients were taken including age, sex, occupation, education, socio economic status, history of illness, family history, personal history including exercise, habits, diet etc. Physical examinations such as coin test, S.L.R (Slow Leg Rising), F.N.S (Femoral Nerve Stretching) along with vital statistics etc. routine hematological investigations such as Hb% (hemoglobin percentage), T.L.C (Total Leucocytes Count), D.L.C (Differential Leucocytes Count), E.S.R (Erythrocyte Sedimentation Rate), Blood sugar & urine were done to diagnose the cases provisionally & to rule out other pathology. Finally, X-Ray – Antero posterior & lateral view of Lumbo-Sacral spine was taken to diagnose lumbar spondylosis.

Group I (trial group): treated by *Dvipanchamooladi taila Matra basti* (70ml).

Group II (control group): treated by *Ksheerabala taila Matra basti* (70ml) once daily, for 9 days. Follow up period was 27days in total and observations recorded before the treatment, on 9th, 18th, and 27th day were assessed, statistically analyzed for *Matra basti* in both groups.

Inclusion criteria

Patients were selected between 30-60 yrs of age irrespective of sex, presenting with pain and stiffness, with positive Coin test, Lumbar Spine Mobility test, SLR test, FNS test and diagnosed as Lumbar Spondylosis by X-ray radiograph. Patients of spinal diseases like spinal tuberculosis, space occupying lesion, prolapsed disc, vertebral fracture & Spondylolisthesis, diagnosed case of cardiac disease, renal disease & other systemic disorders, Were excluded, from the study to avoid complication, drop out & biased result**.** Patient contra- indicated for *basti karma* was also not included in the present study.



Exclusion criteria

The indigenous compounds used for the purpose of clinical study, viz. trial drug, (*Dwipanchamuladi taila)*, control drug *(Ksheerabala taila)* and the drug used for pre measure *(Karpasastyadi taila)* were prepared in the college pharmacy.

Dvipanchamooladi taila: - *Dwipanchamoola taila* was prepared by sesame oil after being processed with curd, *Kanji* (sour gruel) & a number of herbal drugs as mentioned in the following table.

Table 1: Herbal drugs used in *Dwipanchamooladi Taila*

Drugs	Botanical name	Family name	Pharmacological Actions
Bilva	*Aegle marmelos*	Rutaceae	Laxative, expectorant, febrifuge
Agnimantha	*Premna corymbosa*	Verbinaceae	Anti-inflammatory, cardiotonic, expectorant, anti-bacterial, laxative, anodyne
Shyonaka	*Oroxylum indicum*	Bignoniaceae	Anti-inflammatory, anodyne, expectorant, diuretic, anti-arthritic

Patala	*Stereospermum colais*	Bignoniaceae	Anodyne, appetizer, constipating, diuretic, lithotriptic, anti-inflammatory, anti-bacterial
Gambhari	*Gmelina arborea*	Verbinaceae	Laxative, galactogogue, anthelminthic, anti-haemorrhoidal
Kantakari	*Solanum xanthocarpum*	Solanaceae	Diuretic, expectorant, anodyne, laxative, anti-inflammatory
Brihati	*Solanum indicum*	Solanaceae	Diuretic, expectorant, depurative
Shalaparni	*Pseudarthria viscid*	Fabaceae	Emmolient, anti-inflammatory, diuretic, cardiotonic, febrifuge
Prushniparni	*Desmodium gangeticum*	Fabaceae	Anti-inflammatory, expectorant, cardiotonic, carminative
Gokshura	*Tribulus terrestris*	Xygophyllaceae	Anti-inflammatory, laxative, lithotriptic, styptic, diuretic, expectorant
Madanaphala	*Randia dumatorum*	Rubiaceae	Antispasmodic, emetic, anti-inflammatory, abortificient, anodyne, antiseptic, antiostalgic

Karpasasthyadi Tailam: - *Karpasastyadi taila* was prepared by sesame oil after being processed with a number of herbal drugs as mentioned in the following table.

Table 2: Herbal drugs used in *Karpasastyadi Taila*

Drugs	Botanical name	Family name	Pharmacological Actions
Devadaru	*Cedrus deodara*	Pinaceae	Anti-cancerous, anti-inflammatory,
Bala	*Sida cordifolia*	Malvaceae	Aphrodisiac, strengthening, emollient
Rasna	*Pluchea lanceolata*	Zingiberaceae	Thermogenic, carminative, disinfectant, bronchodilator, anti-inflammatory, febrifuge
Kushtha	*Saussurea lappa*	Asteraceae	Diuretic, disinfectant, expectorant, carminative
Sarshapa	*Brassica juncca*	Brassicaceae	Anti-inflammatory, carminative, digestive, anthelmithic
Nagara	*Zingiber officinalis*	Zingiberaceae	Emollient, anthelminthic, aphrodisiac
Shatahwa	*Anethum sova*	Apiaceae	Cardiotonic, galactogogue, diuretic
Pippali mula	*Piper longum*	Piperaceae	Purgative, digestive, emmenogogue
Karpasa	*Gossypium berbaceum*	Malvaceae	Thermogenic, emollient, anti-dysentric, diuretic, anodyne
Masha	*Phaseolus mungo*	Fabaceae	Diuretic, galactogogue, appetizer
Kulatha	*Dolichos biflorus*	Fabaceae	Thermogenic, ophthalmic, diuretic, emmenogogue
Chavya	*Piper chava*	Araceae	Carminative, aphrodisiac, diphoratic
Sigru	*Moringa oliefera*	Moringaceae	Carminative, emmenagogue, expectorant, ophthalmic
Punarnava	*Boerhaavia diffusa*	Nictaginaceae	Cardiac stimulant, laxative, diuretic, anthelminthic

Ksheerabala taila: *Ksheerabala taila* was prepared by sesame oil after being processed with milk and *Sida cordifolia* which possesses the pharmacological actions as aphrodisiac, strengthening and emollient.

Nadi Swedana : Sudation given to the whole body or a part by boiling the following herbal drugs in a closed container and passing the vapour through a pipe.

Table 3: Herbal drugs used in *Nadi Sweda*

Drug	Botanical name	Family name	Pharmacological Actions
Lashuna	*Allium sativum*	Liliaceae	Anthelmithic, cardiotonic, aphrodisiac, expectorant, febrifuge, emmenagogue, anti-cholestrol, anti-bacterial, anti-fungal
Eranda	*Ricinus communis*	Euphorbiaceae	Thermogenic, purgative, Anthelmithic, emollient, diuretic, galactogogue
Nirgundi	*Vitex negundo*	Verbenaceae	Anthelmithic, expectorant, Thermogenic, carminative, anodyne, ophthalmic
Saindhava	Rock salt	-	
Arka	*Calotropis gigantia*	Asclepiadaceae	Expectorant, anthelminthic, rejuvenator, tonic

Assessment criteria (Subjective and Objective Parameters and Gradation)

The clinical assessment was made depending upon the improvement of sign & symptom as mentioned below.

1. Pain 2. Stiffness 3. Restricted Movements. 4. Inflammation 5. Tenderness 6. Coin Test 7. LSM Test 8. SLR Test & 9. FNS Test.

Pain: The intensity of pain was assessed by VAS (Visual Analogue Scale). In VAS a line of 10 mm length which was having marking at both ends (0 on the first end & 10 on the other end). Zero denotes no pain & 10 denote most excruciating pain. Further grading of pain was done as - 1mm-3mm – Mild, 4mm-6mm – Moderate & 7mm-9mm – Severe pain. The patients were advised to mark on the line to show the intensity of pain.

The other parameters like stiffness, restricted movements, inflammation, were assessed according to another grading as follows.

Table 4: Symptoms & its Grade points

Symptoms	Score					
Stiffness	0	1	2	3	4	0- Nothing specific(G0) 1- Mild (G1) 2.-Moderate(G2) 3- Severe(G3) 4 - Most excruciating.
Restricted movements	0	1	2	3	4	
Inflammation	0	1	2	3	4	
Tenderness	0	1	2	3	4	

Coin test : G0 – Easily pick the coin from the ground**,** G1 – Minimum difficulty to pick the coin**,** G2 – Moderate difficulty to pick the coin**,** G3 – Severe difficulty to pick the coin**,** G4 - Unable to pick the coin**;**

LSM (Lumbar Spine Mobility) test: G0 – Normal (5cm), G1 – Mild (4-5 cm)**,** G2 – Moderate (2-4 cm), G3 –Severe (0-2 cm), G4 - Unable to bend:

S.L.R. test: G0 – Angle between 70^0 - 90^0, G1 – Angle between 50^0 - 70^0, G2 – Angle between 30^0 - 50^0, G3 – Angle below 30^0, G4 - Unable to raise;

F.N.S. test: G0 – Leg can be stretched & flexed, G1 –Leg can be flexed at the knee but not forwardly stretched, G2 – Leg can be flexed with pain but not stretched, G3 – Leg can be flexed & cannot be stretched, G4 – Unable to do any movements.

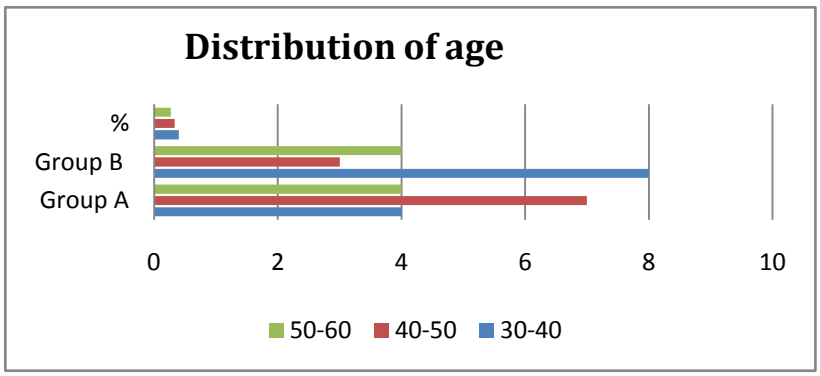
For the purpose of the assessment of result some grade points were used considering the severity of different sign and symptoms and Clinical assessment of result was done as: Cure: hundred percent; maximum improvement:75% to 99%; moderate improvement: 50% to 74%; mild Improvement: 25% to 49% and no improvement: less them 25% improvement of the cardinal sign and symptoms, like pain, stiffness, Restricted movements, inflammation, tenderness, Coin test, LSM test, SLR test & FNS test.

For clinical management of *Katigraha*, all the patients (trial & control) were initially managed by *Abhyanga* (whole body massage) with *Karpasasthyadi taila* for 35 minutes & *Nadi sweda* 10 minutes. In the treated group *Dvipanchamooladi taila*70 ml was administered as *Matra basti* where as *Matra basti* with *Ksheerabala taila* 70ml was done in the control group. All the patients were provided to take similar dietary regimen. The clinical assessment was done in every 9 days interval. The initial findings were compared with the result of progressive 9th day, 18th day and so on of findings. Grading/grouping according to the assessment criteria and measurement scale concerned to each item categorically differentiated the findings among the patients in the clinical study. And finally the assessment as a whole was presented in percent value.

Observations & Results

The patients were analyzed according to various factors like Age, Sex, Religion, Occupation, *Prakruti* (body constituent and temperament), Diet, Habitat, Chronicity, *Vyayama shakti* (exercise capacity) etc. & details of sign and Symptoms. The observations reveled that maximum patients were found in the age group 30- 40 yrs (40%). The incidence of *Katigraha* is more in females as compared to males in the present study.

Regarding the sign & symptom, initially pain was reported in 93.33% of patients, stiffness in 76.66%, restricted movement in 73.33% & inflammation in 60.00%. Whereas on examination it was evidenced that SLR test was +ve in 90.00% of patients, coin test +ve in 83.33%, LSM test +ve in 73.33% and FNS test +ve in 63.33% of cases. But after the treatment and 3rd follow up considerable relief was noticed in all sign and symptom. On 27th day observation pain reduced in 88.46 % patients in trial group, whereas in control group reduction of pain was seen in 68 % of cases. Inflammation reduced in 86.53 % of trial and 70 % cases in control; Stiffness 82.35% in trial & 65.38 % in control; Restricted Movement was reduced in 86 % cases in trial but 64.70 % cases in control. On examination Coin test, SLR, FNS & LSM was seen to be negative in 87.75 %, 87.5 %, 88 % & 86 % cases of group I, whereas in group II it was 67.34 %, 74.46 %, 64.58 %, 66.66 % respectively. (Table 2&3)



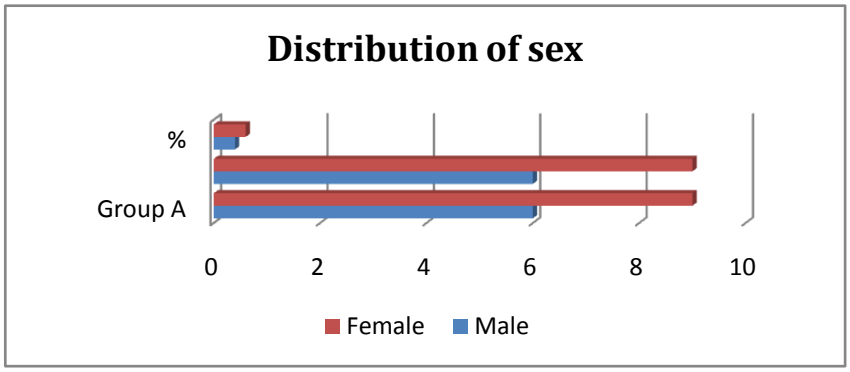


Table 5: Signs and symptoms in each group Before treatment

Incidence Parameters	Group I	Group II	Total	%
Pain	15	13	28	93.33 %
Inflammation	10	08	18	60.00 %
Stiffness	11	12	23	76.66 %
Restricted movements	12	10	22	73.33 %
Coin Test	13	12	25	83.33 %
S.L.R Test	12	10	27	90.00 %
F.N.S.Test	10	09	19	63.33 %
L.S.M.Test	14	13	22	73.33 %

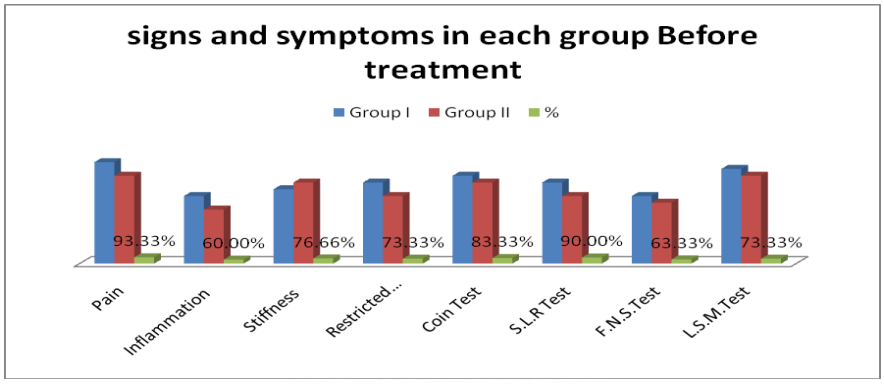
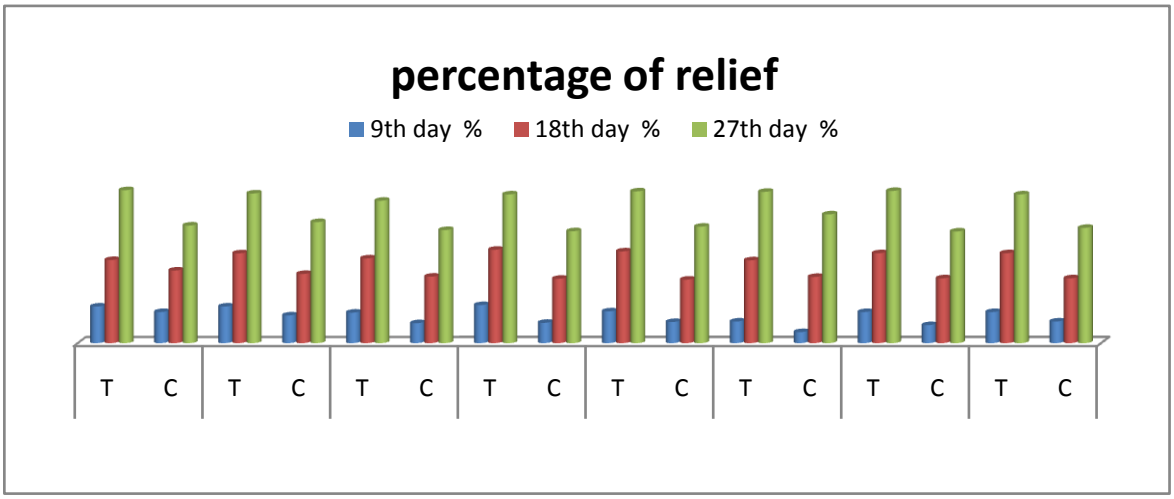


Table 6: Observation on different sign and symptom with percentage of relief

Sign & Symptom		9th day %	18th day %	27th day %
Pain	T	21.15 %	48.07 %	88.46 %
	C	18 %	42 %	68 %
Inflammation	T	21.15%	51.92 %	86.53 %
	C	16 %	40 %	70 %
Stiffness	T	17.64 %	49.01%	82.35%
	C	11.53 %	38.46 %	65.38 %
Restricted movement	T	22 %	54 %	86 %
	C	11.76 %	37.25 %	64.70 %
Coin test	T	18.36 %	53.06 %	87.75 %
	C	12.24 %	36.73 %	67.34 %
S.L.R. test	T	12.5%	47.91 %	87.5 %
	C	6.38 %	38.29 %	74.46 %
F.N.S. test	T	18 %	52 %	88 %
	C	10.41 %	37.5 %	64.58 %
L.S.M. test	T	18 %	52 %	86 %
	C	12.5 %	37.5 %	66.66 %



In order to present the study in a scientific manner the statistical assessment of the result was done. The mean ± S E of each sign and symptom, before treatment had been compared with mean ± S.E. value of after treatment. Paired t-test was used for significance and the effectiveness of the trial and control drug was assessed through p-value. (Tables 4-6). The statistical analysis signifies that the trail drug was effective in reducing pain, inflammation, stiffness, restricted movement and improving the clinical signs as compared to the control group. In the trail group, *Matra basti* with *Dvipanchamooladi taila* was effective 88.46% on pain, 86.53% on inflammation, 82.35% on stiffness, 86% on restricted movement, 87.75% on coin test, 87.5% on SLR, 88% on FNS, 86% on LSM & overall 87.30%.

Whereas on control group, *Ksheerabala taila matra basti* was effective 68% on pain, 70% on inflammation,65.38% on stiffness, 64.70% on restricted movement, 67.34% on coin test, 74046% on SLR, 64.58% on FNS, 66.66% on LSM & overall 68.22%. While comparing the effect of trial verses control it was found that, the trail drug was highly significant to reduce pain, LSM & FNS with p-value P<0.01 and significantly effective to reduce other sign symptoms with p-value <0.05. As an overall effect trial drug was also significantly high in improving *Katigraha* (Lumbar Spondylosis) with p-value of <0.01 (Table 6).

Table 7: Effectiveness of trial drug on different sign and symptom

S.No	Symptoms	B.T Mean±S.E	Follow up	A.T Mean±S.E	d.f	t value	p value	Remarks	Efficacy%
1	Pain	3.46±0.19	9th day	2.93±0.15	14	6.20	P<0.01	H.S	21.15%
			18th day	1.80±0.17		13.22	P<0.01	H.S	48.07%
			27th day	0.40±0.13		20.00	P<0.01	H.S	88.46%
2	Inflammation	3.46±0.19	9th day	2.73±0.15		6.20	P<0.01	H.S	21.15%
			18th day	1.66±0.15		16.83	P<0.01	H.S	51.92%
			27th day	0.46±0.13		17.74	P<0.01	H.S	86.53%
3	stiffness	3.4±0.19	9th day	2.8±0.2		4.58	P<0.01	H.S	17.64%
			18th day	1.73±0.18		13.22	P<0.01	H.S	49.01%
			27th day	0.60±0.16		19.34	P<0.01	H.S	82.35%
4	Restricted movement	3.33±0.21	9th day	2.6±0.16		6.20	P<0.01	H.S	22%
			18th day	1.53±0.13		16.83	P<0.01	H.S	54%
			27th day	0.46±0.13		21.5	P<0.01	H.S	86%
5	Coin test	3.26±0.20	9th day	2.66±0.15		4.58	P<0.01	H.S	18.36%
			18th day	1.53±0.16		11.30	P<0.01	H.S	53.06%
			27th day	0.4±0.13		14.93	P<0.01	H.S	87.75%
6	SLR	3.2±0.20	9th day	2.8±0.17		3.05	P<0.01	H.S	12.5%
			18th day	1.66±0.18		9.27	P<0.01	H.S	47.91%
			27th day	0.4±0.13		19.34	P<0.01	H.S	87.5%
7	FNS	3.33±0.18	9th day	2.73±0.18		4.58	P<0.01	H.S	18%
			18th day	1.6±0.16		11.30	P<0.01	H.S	52%
			27th day	0.4±0.13		19.13	P<0.01	H.S	88%
8	LSM	3.33±0.18	9th day	2.73±0.15		4.58	P<0.01	H.S	18%
			18th day	1.6±0.16		11.30	P<0.01	H.S	52%
			27th day	0.46±0.13		17.34	P<0.01	H.S	86%
9	overall	13.13±0.36	9th day	10.93±0.35		11	P<0.01	H.S	16.75%
			18th day	6.4±0.36		29.5	P<0.01	H.S	51.26%
			27th day	1.66±0.21		44.83	P<0.01	H.S	87.30%

Table 8: Effectiveness of control drug on different sign and symptom

Sl.no	Symptoms	B.T Mean±S.E	Follow up	A.T Mean±S.E	d.f	t value	p value	Remarks	Efficacy %
1	Pain	3.33±0.21	9th day	2.73±0.20	14	4.58	P<0.01	H.S	18%
			18th day	1.93±0.20		8.57	P<0.01	H.S	42%
			27th day	1.06±0.26		9.93	P<0.01	H.S	68%
2	Inflammation	3.33±0.18	9th day	2.8±0.22		4	P<0.01	H.S	16%
			18th day	2±0.21		7.13	P<0.01	H.S	40%
			27th day	1±0.21		12.48	P<0.01	H.S	70%
3	stiffness	3.46±0.16	9th day	3.06±0.22		3.05	P<0.01	H.S	11.53%
			18th day	2.13±0.21		8.36	P<0.01	H.S	38.46%
			27th day	1.2±0.27		10.98	P<0.01	H.S	65.38%
4	Restricted movement	3.4±0.21	9th day	0.84±0.21		3.05	P<0.01	H.S	11.76%
			18th day	2.13±0.19		6.14	P<0.01	H.S	37.25%
			27th day	1.2±0.31		9.05	P<0.01	H.S	64.70%
5	Coin test	3.26±0.20	9th day	2.86±0.21		3.05	P<0.01	H.S	12.24%
			18th day	2.06±0.20		6.87	P<0.01	H.S	36.73%
			27th day	1.06±0.22		11	P<0.01	H.S	67.34%
6	SLR	3.13±0.21	9th day	2.93±0.18		1.87	-	N.S	6.38%
			18th day	1.93±0.20		8.29	P<0.01	H.S	38.29%
			27th day	0.8±0.22		18.52	P<0.01	H.S	74.46%
7	FNS	3.2±0.20	9th day	2.86±0.19		2.64	P<0.05	S	10.41%
			18th day	2±0.19		8.29	P<0.01	H.S	37.5%
			27th day	1.13±0.21		13.48	P<0.01	H.S	64.58%
8	LSM	3.2±0.20	9th day	2.8±0.17		3.05	P<0.01	H.S	12.5%
			18th day	2±0.21		8.29	P<0.01	H.S	37.5%
			27th day	1.06±0.24		16	P<0.01	H.S	66.66%
9	overall	12.8±0.36	9th day	11.53±0.32		4.75	P<0.01	H.S	9.89%
			18th day	8±0.44		16.21	P<0.01	H.S	37.5%
			27th day	4.06±0.49		27.66	P<0.01	H.S	68.22%

Table 9: Effectiveness of Trial Vs control drug on different sign and symptom

S.No	Symptoms	Follow up	Trial Mean±S.E	Control Mean±S.E	d.f	t value	p value	Remarks
1	Pain	9th day	0.73±0.13	0.60±0.13	28	0.75	-	N.S
		18th day	1.66±0.12	1.40±0.16		1.29	-	N.S
		27th day	3.06±0.15	2.26±0.22		2.91	P<0.01	H.S
2	Inflammation	9th day	0.73±0.11	0.53±0.13		1.12	-	N.S
		18th day	1.80±0.10	1.33±0.18		2.16	P<0.05	S
		27th day	3±0.16	2.33±0.18		2.64	P<0.05	S
3	Stiffness	9th day	0.60±0.13	0.40±0.13		1.08	-	N.S
		18th day	1.66±0.12	1.33±0.15		1.64	-	N.S
		27th day	2.8±0.14	2.26±0.20		2.11	P<0.05	S
4	Restricted movement	9th day	0.73±0.11	0.40±0.13		1.88	-	N.S
		18th day	1.8±0.10	1.26±0.20		2.29	P<0.05	S
		27th day	2.86±0.13	2.20±0.24		2.40	P<0.05	S
5	Coin test	9th day	0.6±0.13	0.4±0.13		1.08	-	N.S
		18th day	1.73±0.15	1.2±0.17		2.29	P<0.05	S
		27th day	2.86±0.19	2.2±0.2		2.40	P<0.05	S
6	SLR	9th day	0.4±0.13	0.2±0.10		1.18	-	N.S
		18th day	1.53±0.16	1.2±0.14		1.51	-	N.S
		27th day	2.8±0.14	2.33±0.12		2.43	P<0.05	S
7	FNS	9th day	0.6±0.13	0.33±0.12		1.46	-	N.S
		18th day	1.73±0.15	1.2±0.14		2.52	P<0.05	S
		27th day	2.93±0.15	2.06±0.15		3.99	P<0.01	H.S
8	LSM	9th day	0.6±0.13	0.4±0.13		1.08	-	N.S
		18th day	1.73±0.15	1.2±0.14		2.52	P<0.05	S
		27th day	2.86±0.16	2.13±0.13		3.45	P<0.01	H.S
9	Overall	9th day	2.2±0.2	1.26±0.26		2.8	P<0.05	S

		18th day	6.73±0.22	4.8±0.29		5.17	P<0.01	H.S
		27th day	11.46±0.25	8.73±0.31		6.72	P<0.01	H.S

DISCUSSION

Katigraha is a pain dominant disorder, seems to be apparently non-serious but cripples the patient if not treated properly, and may lead to catastrophic complication. The pathogenesis according to Ayurveda is either by *Dhatukshaya* (depletion of tissue elements), *Margaavarana* (obstruction of nourishing channels) or due to *Abhighata* (trauma) [7,8]. In turn improper nourishment of *Rasadi dhatus* (nutritive part of metabolized food), leads into *Kshaya avastha* (depletion of tissue element), may be correlated to degenerative changes. Lumbar spondylosis is pain in lumbar region which begins as a result of degenerative changes.

In the present study maximum patients were registered in the age group of 30-40 years (40%). According to Sushruta these age groups are in middle age group where gradual decline of vitality of body and degenerative process (*Shrira bala* and *Dhatus)* starts, this provokes *Vata* (degenerative changes in spine & nervous system - Su.Su.35/35). Modern texts also say that, this is the beginning of the ageing process and degenerative changes in spine develop at this age.

Regarding Occupation, Maximum patients were house wife (46.67 %). 16.67% patients were belonging to labors. There was history of heavy weight lifting; standing for long time etc and 36.67% were belonging to serviced category.

The trail drug *Dvipanchamooladi taila* contains *Dashmoola, Kanjika, Dadhi, Madanaphala* and *Tila taila* which are *Vata-kapha shamaka* (alleviated degeneration and improves vitality), anti-inflammatory & analgesic. The photochemical screening indicates the presence of the phyto constituents such as Vitamins, Alkaloids, Saponins, Flavonids & Steroid have analgesic, anti inflammatory properties which explains the relief of pain in *Katigraha*.

It is proven fact that serum protein and fatty acid levels increase after *Basti Karma*. These are necessary for nourishment of the nervous tissue [9]. Also *Basti* acts on the natural bacterial flora of the intestines which is important for the synthesis of Vit. B6, B12. *Bastichikitsa* decreases the ketoacid and pyruvic acid levels, due to which Vit. B synthesis increases. This Vit. B restricts the demyelination process of the nerves and helps in regeneration. The potency of *Basti dravyas* (ingredients of enema) spreads through A.N.S (Autonomic nervous system) and expels out vitiated *Doshas* (metabolic toxins) from the body. This signifies its action on the nervous system[10] Regarding the acceptability of the trial drug it may be declared that the *Dvipanchamooladi taila* is a good medicine for *Katigraha* due to its pain relieving and anti inflammatory properties. Its use along with the procedure *Matra basti* found remedial in almost all the cases in the study though it did not give 100 % results.

CONCLUSION

Katigraha is a common disease & has complexity of pathology which makes the disease critical. Hence, the remedial field is not easier. After seeing the effect on all the patients, it is established that *Dvipanchamooladi taila Matra basti* efficiently reduces pain, stiffness, tenderness and restricted movements etc. It is observed that the therapy along with this drug acted mainly on pain in comparison to other parameters. The average retention time of *Matra basti* was noted around 9-10 hours. During the procedure, no complication had been noticed. However, It may not be claimed that, the work is of high proficiency in the field of research, but may shed a beam of ray in future study regarding the disease and its treatment.

REFERENCES

1. George E. Ehrlich, Low back pain, Bulletin of the World Health Organization 2003;81:671-676.
2. Sajitha, K, An Insight in to "Katigraha" (Low Back Ache), Ancient Science of Life, 2001; 21: 16-17
3. Balagué F, Mannion AF, Pellisé F, Cedraschi C. Non-specific low back pain. Lancet. 2012;379 (9814):482–91.
4. Murthy S.K., Charaka samhita with Chakrapanidatta commentary & Vidyotini, 1st Edn. Choukambha Sanskrit sansthan, Varanasi, 2009, page no - 617-619 sloka no - 28,46,47
5. http://www.wisegeek.com/what-is-lumbar-spondylosis.htm
6. Chikitsa Sara Samgraha, Bangasena Samhita, 1st Edn. Choukambha Sanskrit sansthan, Varanasi, 2004, Amavata Adhyaya, Page no 487, sloka no - 107
7. Gupta A, Ashtanga hridaya, 11th Edn. Choukambha Sanskrit sansthan, Varanasi, 1993. vata vyadhi Nidana, page no 627, sloka no -7
8. Tripathi Indradeva, Edited by Sri Ganga Sahaya Pandeya, Sodhala, Gadanigraha, Part II, Choukambha Sanskrit sansthan, Varanasi, 2005, Vata Vyadhi Chikitsa Adhayaya page no 535, Sloka No - 160
9. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2697338/
10. Pharmacodynamic understanding of Basti. a contemporary approach by Gyanendra D. Shukla, Shweta Pandey, and Anup.B. Thakar. International Journal of Pharmaceutical & Biological Archives 2012; 3(4):893-896.

Cite this article as:
Rabinarayan Tripathy, Parameswar Namboothiri, Susmita Priyadarshinee Otta. Open Label Comparative Clinical Trial Of Dvipanchamooladi Taila And Ksheerabala Taila Matra Vasti In The Management of Low Back Ache. International Journal of Ayurveda and Pharma Research. 2016;4(6):19-26.

Source of support: Nil, Conflict of interest: None Declared

***Address for correspondence**
Dr. Rabinarayan Tripathy
Professor
P.G. Department of Shalya Tantra,
Amrita School of Ayurveda,
Vallikavu, Clappana P.O., Kollam
Email: drrabi73@gmail.com
Ph - 08129292391