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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF 'TIKTA GHṚTA KṢĪRA VASTI' IN THE MANAGEMENT OF 'KAṬIGRAHA' W.S.R. TO 'LUMBAR SPONDYLOSIS'

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ABSTRACT

Today is the era of modernization and fast life. Faulty dietetic habits and irregular life styles are responsible for early degenerative changes in bodily tissue and play a vital role in the manifestation of such degenerative disorder like Lumbar spondylosis. In this way, this disease is now becoming a significant threat to the working population. *Kaṭigraha* as a separate disease has been described in the classical text *Gada Nigraha*. It has been correlated in the present study with Lumbar Spondylosis due to similarity of clinical manifestation and pathogenesis. Keeping in mind the high prevalence, intensity of symptoms of disease, lack of current effective treatment and considering classical reference of *Tikta* (bitter) *Ghṛta* (prepared with *Tikta Dravyas of Vāgbhata's Vātaśodhagna Gaṇa) Kṣīra Vasti* in *Kaṭigraha*, an open label, clinical trial was conducted to assess the efficacy of *Tikta Ghṛta Kṣīra Vasti* (enema prepared with milk and *Tikta Ghṛta*) in the management of *Kaṭigraha* with special reference to Lumbar Spondylosis. Observation and results assessed by using SLRT, Walking time, Aberdeen Low Back Pain Disability Scale, Roland Morris Low Back Pain Disability Questionnaire. Statistical test for comparison was done by ANOVA. The clinical study gives statistically significant results in reducing the symptoms and further improving quality of life of individual.

Key words: Lumbar spondylosis, *Kaṭigraha, Vātaśodhagna Gaṇa* (drugs pacifying vata), *Tikta Ghṛta Kṣīra Vasti*.

INTRODUCTION

Recent busy, professional, social life, improper sitting posture in offices, continuous working in one posture, over-exertion, jerking movements during travelling, agricultural work and sports – all these factors create undue pressure and stress injury to the spine and play an important role in producing disease like Lumbar Spondylosis .

Lumbar Spondylosis is present in 27-37% of the asymptomatic population. In the United States, more than 80% of individuals older than 40 years have Lumbar Spondylosis, increasing from 3% of individuals aged 20-29 years. Low back ache (LBA) affects approximately 60–85%

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of adults during some point in their lives [1]. Chronic low back pain, defined as pain symptoms persisting beyond 3 months, affects an estimated 15–45% of the population.

Kaṭigraha as a separate disease has been described in the classical text *Gada Nigraha*[2]. It has been correlated in the present study with Lumbar Spondylosis due to similarity of clinical manifestation and pathogenesis.

This existence of constant pain urges one to find a remedy. But, there is no current concrete, gold-standard treatment approach to the diverse range of patient presentations of *Kaṭigraha* (Lumbar Spondylosis) despite substantial research efforts to identify conservative and more invasive methods of managing symptoms and slowing progressive degeneration**.** According to the principle of *Āśṛayāśrayī Bhāva* (mutual relation of bony tissue and *Vāta*), when *Vāta* increases *Asthi* (bony tissue) decreases because, both are inversely proportional to each other. *Pañcakarma* therapy (five folds of treatment) of *Āyurvēda* has attracted the attention of the people worldwide as it is an unique type of treatment of various chronic, autoimmune, hormonal, degenerative disorder etc, where other sorts of treatments have no satisfactory answer as well as equally beneficial for the promotion and preservation of health. *Ācārya Caraka* mentioned *Trikagraha (Kaṭigraha)* in *Vāta Nānātmaja Vyādhi* (diseases caused only by vitiation of *Vāta*) in *Mahārogādhyāya.* He further describes the treatment of *Asthi Āśraya Vyādhi* as *Tikta Ghṛta Kṣīra Vasti*. [3] *Ācārya Vāgbhaṭa* also mentioned in *Asthidhātu Kṣaya Vikāra* is *Tikta Ghṛta Kṣīra Vasti*[4]. He also quoted *Vāta Śodhan Gaṇa*[5] for disease produced by *Vāta.*

So in present study *Tikta Dravyas* are taken from *Vāta Śodhana Gaṇa* of *Vāgbhata* that is *Bhadradārvādi, Vīratarvādi, Vidāryādi Gaṇa*. *Ghṛta* prepared by *Tikta Dravyas* and also *Kwātha* prepared by *Tikta Dravyas* as per classics for *Vasti. Tikta Ghṛta Kṣīra Vasti* which is selected for present study is a type of *Yāpana Vasti* which comes under *Nirūha Vasti* that has *Bṛhmaṇa* (strength promoting), *Rasāyana* (rejuvenating) and *Vāta Śāmaka* effects. Milk added as adjuvant augments its properties.

MATERIAL AND METHODS:

It is an open label efficacy trial on 60 subjects for 10 days duration procedure naming *Tikta Ghṛta Kṣīra Vasti* used in the patients of Lumbar Spondylosis. Total 60 patients were selected and registered from O.P.D. and I.P.D. of Department of Pañcakarma, S. V. Ayurvedic Hospital, Tirupati, based on the criteria. Study was approved by Institutional Ethics Committee with approval no. IEC SVAYC/15/PK/12 dated 26/03/15.

Inclusion criteria:

- Age between 30 to 70 years.
- Low back pain less than 8 month's duration.
- Low back stiffness (short duration) less than 8 months duration.
- Early changes in Lumbar Spine X-ray findings.
- Loss of range of movement of lumbar spine.
- Weakness, numbness or tingling in low back, legs or feet may be present.

➢ **Exclusion criteria:**

- Hypertension (uncontrolled)
- Diabetes mellitus (uncontrolled)
- Obesity (>85Kg)
- Pott's spine
- Post spinal surgical case
- Severe metabolic disorder

- Psychiatric disorder
- Space occupying lesion of brain
- Paget's disease of bone
- Malignancy
- LBA due to inflammatory causes
- LBA due to congenital causes
- LBA due to gynaecological causes
- LBA due to problems in other body parts

Laboratory Evaluation:

- Following laboratory investigations were carried out in each patient only before treatment to rule out any other systemic diseases.
- **Blood:** Haemoglobin, TLC, DLC, ESR, BT, Sugar- Fasting & P.P.
- **Urine:** Routine & Microscopic.
- X-ray, C.T. Scan and MRI of lumbar region if required.

Assessment criteria:

Patients will be clinically assessed basing on the-

1. S.L.R. Test
2. Average walking time.
3. Quality of Life (qol)Scoring Methods –

- Aberdeen Low Back Pain Disability Scale.
- Roland Morris Low Back Pain Disability Questionnaire.

Design of the clinical study:

Patients were given *Tikta Ghṛta Kṣīra Yāpna Vasti* for 8 days.

The assessment is done at base line, immediately after treatment and after one month of treatment.

Contents of *Tikta Ghṛta Kṣīra Vasti*:

• *Madhu* (Honey) – 50 gm
• *Saindhava lavaṇa* (Rock salt) – 3 gm
•*Tikta Ghṛta*– 50 ml
• *Kalka (Śatapuṣpā* paste*)* – 6 gm
• *Kwātha (Tikta Kṣīrapāka/* decoction*)* – 250 ml

Statistical analysis:

Statistical test for comparison was done by ANOVA followed by one way analysis of variance and Turkey-Kramer multiple comparison test. Graph Pad In Stat software used for statistical analysis.

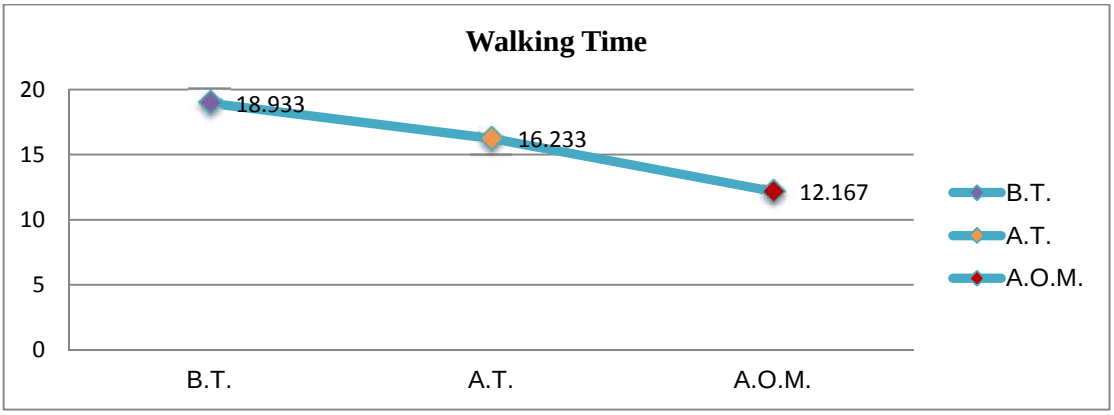
OBSERVATIONS AND RESULTS:

Out of the 60 registered patients included in the study, maximum 33.33 % patients belonged to age group of 50 -60 years, females 66.66%, married 86.66 %, Hindus 83.33 %, primary educated 40%patients, 50% patients field worker with physical labour, 66% lower middle class, *Vāta-Kapha Prakṛti* (one's body composition) patients 60% and majority of patients were mixed diet i.e. 83.33 % .

Table No.1 Showing ANOVA summary of walking time (average):

ANOVA summary of walking time (average)			
Groups	**A-Before treatment**	**B- After treatment**	**C-After one month of treatment**
Mean	18.933	16.233	12.167
Std. Deviation	3.654	3.154	3.004
Sample size	60	60	60
Comparison	A vs B	A vs C	B vs C
Mean Difference	2.700	6.767	4.067
Q value	24.736	61.992	37.256
P value summary	*** P<0.001	*** P<0.001	***P<0.001

Graph No.1showing walking time (average):

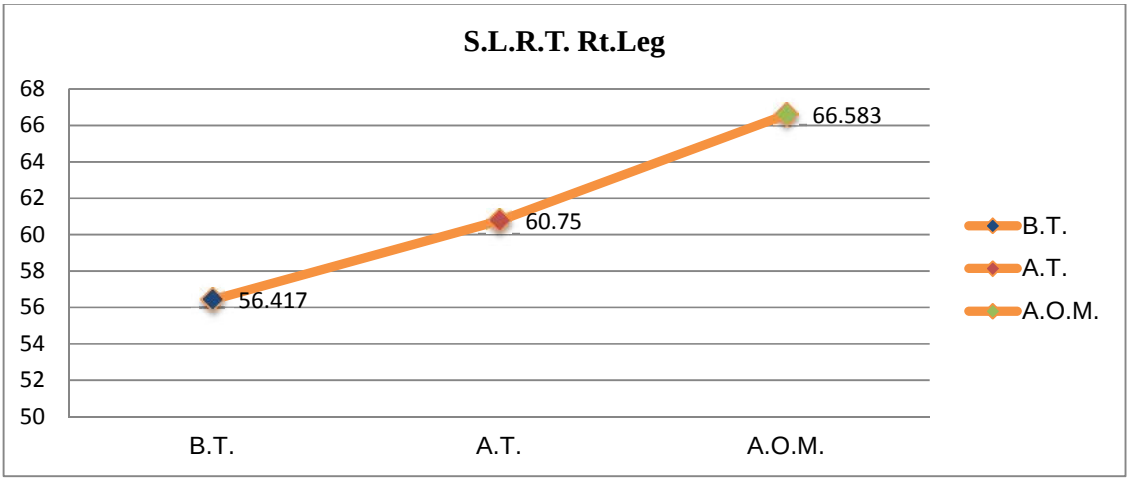


There were more than two groups for comparison of average walking time. So, ANOVA test with Turkey-Kramer multiple comparison test was applied. In one way analysis of variance and Turkey-Kramer multiple comparison test, q > 24.736 for all the groups and highest for comparison between 0 and 30 days and P < 0.001 which is extremely significant. The test is also significant just after treatment.

Table No.2 Showing ANOVA summary of S.L.R.T. Rt. lower limb:

ANOVA summary of S.L.R.T. Rt. lower limb			
Groups	**A-Before treatment**	**B- After treatment**	**C-After one month of treatment**
Mean	56.417	60.750	66.583
Std. Deviation	15.129	13.013	11.553
Sample size	60	60	60
Comparison	A vs B	A vs C	B vs C
Mean Difference	4.333	10.167	5.833
Q value	11.768	27.610	15.842
P value summary	*** P<0.001	*** P<0.001	*** P<0.001

Graph No.2 showing S.L.R.T. Rt. lower limb:

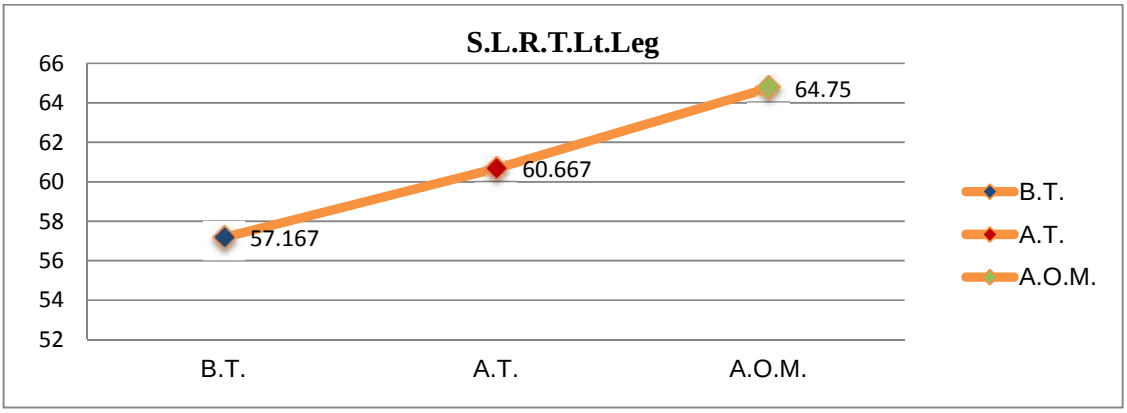


There were more than two groups for comparison of S.L.R.T. Rt. leg. So, ANOVA test with Turkey-Kramer multiple comparison test was applied. In one way analysis of variance and Turkey-Kramer multiple comparison test, q > 11.768 for all the groups and highest for comparison between 0 and 30 days and P < 0.001 which is extremely significant. The test is also significant just after treatment.

Table No.3 Showing ANOVA summary of SLRT Lt. Lower limb:

ANOVA summary of SLRT Lt. lower limb			
Groups	**A-Before treatment**	**B- After treatment**	**C-After one month of treatment**
Mean	57.167	60.667	64.750
Std. Deviation	14.940	13.761	12.400
Sample size	60	60	60
Comparison	A vs B	A vs C	B vs C
Mean Difference	3.500	7.583	4.083
Q value	10.603	22.974	12.371
P value summary	*** P<0.001	*** P<0.001	*** P<0.001

Graph No.3 showing S.L.R.T. Lt. Lower limb:



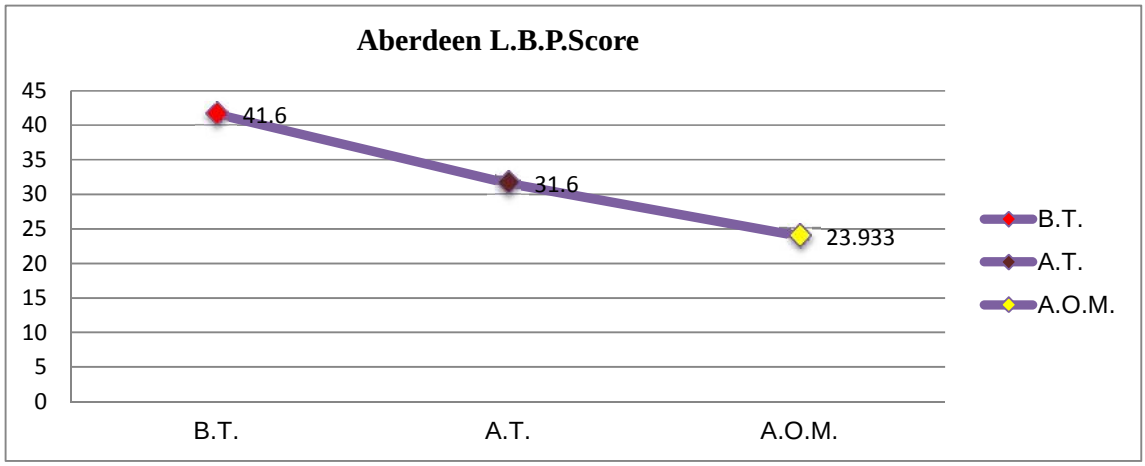
There were more than two groups for comparison of S.L.R.T. Lt. Leg. So, ANOVA test with Turkey-Kramer multiple comparison test was applied. In one way analysis of variance and Turkey-Kramer multiple comparison test, q > 10.603 for all the groups and highest for comparison between 0 and 30 days and P < 0.001 which is extremely significant. The test is also significant just after treatment.

Table No.4 Showing ANOVA summary of Aberdeen L.B.P. scale:

ANOVA summary of Aberdeen L.B.P. scale			
Groups	**A-Before treatment**	**B- After treatment**	**C-After one month of treatment**
Mean	41.600	31.600	23.933
Std. Deviation	8.183	7.883	6.947
Sample size	60	60	60
Comparison	A vs B	A vs C	B vs C

Mean Difference	10.000	17.667	7.667
Q value	25.785	45.553	19.768
P value summary	*** P<0.001	*** P<0.001	*** P<0.001

Graph No.4 showing Aberdeen L.B.P. scale:

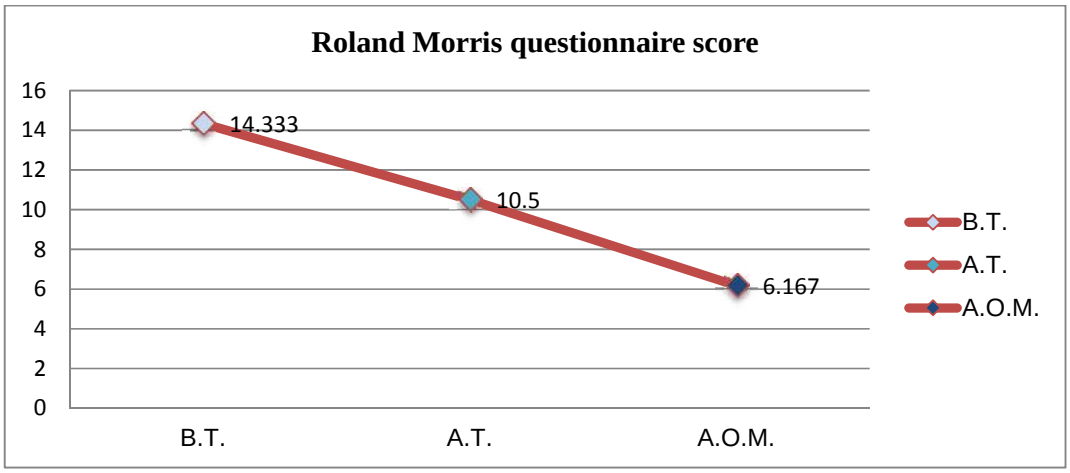


There were more than two groups for comparison of Aberdeen low back pain score. So, ANOVA test with Turkey-Kramer multiple comparison test was applied. In one way analysis of variance and Turkey-Kramer multiple comparison test, $q > 19.768$ for all the groups and highest for comparison between 0 and 30 days and $P < 0.001$ which is extremely significant. The test is also significant just after treatment.

Table No.5 Showing ANOVA summary of Roland Morris Questionnaire score:

ANOVA summary of Roland Morris Questionnaire Score			
Groups	**A-Before treatment**	**B- After treatment**	**C-After one month of treatment**
Mean	14.333	10.500	6.167
Std. Deviation	3.986	3.744	3.232
Sample size	60	60	60
Comparison	A vs B	A vs C	B vs C
Mean Difference	3.833	8.167	4.333
Q value	22.153	47.195	25.042
P value summary	*** P<0.001	*** P<0.001	*** P<0.001

Graph No.5 showing Roland Morris Questionnaire score:



There were more than two groups for comparison of Rolland Morris questionnaire score. So, ANOVA test with Turkey-Kramer multiple comparison test was applied. In one way analysis of variance and Turkey-Kramer multiple comparison test, $q > 22.153$ for all the groups and highest for comparison between 0 and 30 days and $p < 0.001$ which is extremely significant. The test is also significant just after treatment.

DISCUSSION:

In *Kaṭigraha Hētu Doṣa* (causative factor) is *Vāta*, *Sthānsamśrya* (seat of disease) takes place in *Asthi-Sandhi* (bony joints) and it produces *Asthivahaśrotoduṣti* (vitiation of bony tissues). *Śamana Auṣadhas* are not enough to treat the severity of *Kaṭigraha* because it is a *Kṛcchrasādhya* (cured with difficulty), *Madhyam Rogamārga vyādhi* so need of *Pañcakarma* therapy particularly *Tikta Ghṛta Kṣīra Vasti* having the *Bṛmhaṇa* affect and pacify *Vāta* effectively in *Kaṭigarha* (Lumbar Spondylosis) is chosen for treatment.

The clinical study revealed some magnificent facts that Lumbar Spondylosis can be taken under or compared almost completely with *Kaṭigraha* and *Tikta Ghṛta Kṣīra Vasti* used in this disease gives significant results in reducing the symptoms and further improving quality of life of individual. It can also be used in the *Asthi Kṣayaja Vyādhi* like *Khālitya* (alopecia) and other degenerative diseases like osteoarthritis, avascular necrosis etc, which involves bony tissue.

CONCLUSION:

- A plethora of studies have been done on the role of *Vasti* in *Kaṭigraha*, but here the problem has been addressed with a *Vasti* that consist of a unique combination of *Tikta Dravyas* anticipating better therapeutic dividends.
- Conclusion can be made from the present study that *Tikta Ghṛta Kṣīra Vasti* can offer extremely significant relief in cardinal features of Lumbar Spondylosis such as pain, stiffness and restricted movements along with reasonably good improvement in associated manifestations like tingling sensation and numbness.
- No major adverse or side effects were encountered during this treatment period.

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