ORIGINAL ARTICLE

A Clinical evaluation of Raktamokshana and Trayodashanga Guggulu in management of Katigata vata w.s.r. to Lumbar spondylosis.

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ABSTRACT:

Background: Stressful life, travelling, workout or ageing, all of them lead to one of the most common health problem known as low back pain. It is becoming a major health issue all over the world. Based upon the pathophysiology and symptoms of Katigatavata is equated with lumbar spondylosis which is a Vata dominant Sandhiroga affecting the Katee region. Kapha Kashya in the Pristha-asthisandhis leads to Rukshta and Vatakopa. To study the etio-pathogenesis and to evaluate effectiveness of Raktamokshana and Trayodashanga Guggulu in Katigata Vata (Lumbar spondylosis) Methods: A total of 30 patients of Katigata Vata were enrolled and randomly allocated into two groups (15 in each group). In Group A (n = 15), Raktamokshana (cupping) was done at an interval of 15 days in two sittings along with placebo (roasted suji powder) capsules (PC) for one month. In Group B (n = 15), Raktamokshana (cupping) was done at an interval of 15 days in two sittings along with Trayodashanga Guggulu (TDG) for one month. Results: Raktamokshana along with Trayodashanga Guggulu (Group B) has shown better result in compare to Raktamokshana along with placebo (Group A). Percentage relief in forward flexon was same in both groups, and complete remission of symptoms of Katigatavata was more in patients treated with Raktamokshana along with Trayodashanga Guggulu. Conclusion: Clinically Raktamokshana along with Trayodashanga Guggulu (Group B) has shown better result in compare to Raktamokshana along with placebo (Group A).

Keywords: Katigatavata, cupping, Raktamokshana, Trayodashanga Guggulu, Lumbar Spondylosis.

INTRODUCTION

Nonspecific low back pain usually refers to pain at lumbar regions and aren’t attributable to a recognizable, known specific pathology (e.g. infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorders, radicular syndrome, or cauda syndrome). Low back pain became one of the biggest problems for public health systems in the western countries during middle of the 20th century, and now seems to be extending worldwide. Some of the common known causative factors of low back pain are stressful life, travelling, workouts or ageing. Based upon the pathophysiology and related symptoms, Katigata vata can be correlated with lumbar spondylosis which is a Vata dominant Sandhiroga affecting the Kati region. Kapha kashya (…….) in the pristha asthi sandhi leading to

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**MATERIAL AND METHODS**

**Selection of patients**

Patients of Katigata Vata presented with sign and symptoms of Kati Shoola (pain in lumbar area) measured according to VAS scale, Kati Stambha (stiffness/rigidity of lumbar joint), Kati Suptata (numbness), Akunchan Prasarane Pravrruti Savedana (restricted movement) were selected and enrolled in the study randomly, irrespective of their caste, sex gender, religion, etc. The patients were selected from O.P.D. & I.P.D. of Shalya Tantara I.P.G.T. & R.A., Jamnagar. The registered patients were randomly allocated into two groups. The study was approved by Institutional Ethics Committee,(IEC), vide letter no; PGT/7/-A/ Ethics/2016-17/2735 dated 21/11/16 before starting the clinical trial. The study was also registered in clinical trial registry of India vide, registration number: CTRI Reg. No. CTRI/2016/12/012877.

**Inclusion criteria**

Patient suffering from Katigata Vata (Lumber spondylosis) with age group between 40-70 years of either sex were included. Patients of Katigata Vata with controlled cases of diabetes maliitis were also included in the study..

**Exclusion Criteria**

- Age below 40 years and above 70 years.
- Patients of uncontrolled diabetes mellitus
- R.A. (Rheumatoid arthritis) positive.
- Other diseases like paralysis, Parkinson’s disease, severe anaemia, malignancy.
- Pregnancy
- Protrusion of lumbar disc & disc prolapsed.

**DIAGNOSTIC CRITERIA**

A standard research proforma was developed on basis of principles of Ayurveda & modern medicine. The details description regarding clinical history and examination, techniques were included to assess the mode of onset & progress of the disease. The supportive investigations were also noted to establish degeneration and to exclude other diseases related to Lumbo sacral joints. Routine & microscopic haematological, urine & stool examination were carried out.

**Subjective Criteria:**

1. **Kati Shoola** (pain in lumbar area)/ VAS scale
2. **Kati Stambha** (stiffness of lumbar joint)
3. **Kati Suptata** (numbness)
4. **Akunchan Prasarane Pravrruti Savedana** (restricted movement)

**Objective Criteria:**

1. Range of movement (ROM)
2. X-ray of lumbar spine (KAL Scale)
3. ODI Scale (Oswestry Disability Index)
Laboratory Investigations:
1. Routine Haematological, biochemical and urine investigations were carried out before commencement and after completion of the study.
2. Haemoglobin
3. TLC, DC, ESR
4. Serum calcium
5. HIV, VDRL, HBsAg, HCV
6. Urine routine and microscopic examinations.

Radiological Investigations:
X-Ray Lumbo-sacral spine Antero-posterior and Lateral view, were carried out before commencement and after completion of the study.

Materials
Among 30 registered patients in first group (Group A, n=15) were treated with Raktmokshana along with placebo, while second group (Group B, n=15) patients were treated with Raktmokshana along with Trayodasha Guggulu.

| S.No. | Group A | Group B |
|-------|---------|---------|
| No. of patients | 15 | 15 |
| Intervention | Raktamokshana followed by Placebo capsule (Rosted suji powder) | Raktamokshana followed by Trayodasha Guggulu |
| Drug | Placebo capsule (Rosted suji powder) | Trayodasha Guggulu Vati |
| Dose | 500mg 2 caps tds after meal for one month | 500mg 2 Vati tds after meal for one month |
| Anupan | Ushna Jala | Ushna Jala |
| Instrument | Modified Shringa Yantra (Hijama therapy) | Modified Shringa Yantra (Hijama therapy) |
| Site | Lumbar region | Lumbar region |
| Duration | Two sittings in 15 days interval | Two sittings in 15 days interval |
| Follow up | 1 Month | 1 Month |

Common methodology for Group A & Group B

Purva Karma: Mudgayusaha pan and local Snehana and Nadi sweden.

Pradhana Karma
- At first modified Shringa Yantra (MSY; Hijama instrument) were cleaned with hypochlorite solution and dried with sterile gauge piece then applied to demarcate the site on Lumbo-sacral region.
- After visible changes in colour all MSY were removed.
- 20-25 pricks were made in skin by using disposable needle no.18
- Re-application of MSY were done by pricking the site. Due to negative pressure oozing of blood started letting into the cup.
- Cups were kept at the site till complete cessation of oozing of the blood.
- In one sitting minimum 30 ml and maximum 50 ml vitiated blood was removed, and on average 40 ml blood was removed.

Paschata Karma
- Aseptic dressing was done with Haridra powder after the procedure.
- Patients were advised to avoid water contact to pricked site for 24 hours.
- Honey mixed with water was given to patient for drinking.
- Patients were observed up to half an hour after procedure for any complication.
- Patients were called after 15 days for second sitting.

Assessment
The signs and symptoms were assessed every week for one month and noted in the Clinical assessment performa. Scoring patterns were allocated for subjective parameters and objective parameters. Assessment of VAS Scale, KL sign, Schober’s test, SLR test, Lassegue’s sign, ROM were done before treatment, during treatment at every week and after treatment.

Follow Up:
After completion of one month treatment, patients were advised to visit after every 07 days for follow up for at least one month.

Pathya- Apathya
Pathya: Patients were advised to take foods which shouldn’t be very cold, light(easily digestible), unctuous, promoting blood formation and either slightly sour or devoid of sour.

Apathya: After bloodletting, patients were advised to avoid strenuous exercise, copulation, cold breeze, day sleep, use of alkalis, pungent substances in food. Patients should avoid...
grief and much more conversation or speech. The condition indigestion shouldn’t be created in the patient/s till he/she attains good strength.  

Assessment Criteria.

The improvement was assessed on the basis of relief found in the cardinal features of the disease. To assess the effect of therapy, all the signs and symptoms were assigned score depending upon their severity as elaborated in table no.13-20.

**Duration of Treatment**

Patients were assessed weekly (interval of 7days) up to 4 weeks.

**Follow up Period**

After completion of one month of the treatment protocol, patients were further observed for reoccurrence and any untoward effect of the treatment in one month of follow up.

**Statistical tests**

Wilcoxon Signed-Rank test was used for intra-group statistical analysis of result. The Mann-Whitney Rank Sum Test was used for inter-group comparison.

**OBSERVATIONS**

**General observations**

Majority of the patients (56.66%) were found between 40-50 years, and both sex were equally participated. Among the patients, 73.33% belonged to middle economic class, and 40% were house-hold ladies. About 90% patients belonged to Hindu religion. In this study, 80% patients were reported from urban area. In this study, patients having Krura kostha, no-addiction, history of Diwaswapana, history of menopause and Vata-Pitta Prakriti were reported 53.33%, 70%, 53.33%, 53.33% and 60% respectively. Patients belonging to Madhayama Sara, Madhyama Samhanana and Madhyama Satva were estimated 83.33%. Madhayama Pramana, Madhyama Satmya were estimated 83.33%, and Madhayama Pramana and Madhyama Satmya were 93.33% and 76.67% respectively. Patients of Madhyama Ahara Shakti and Samashana were found 76.67% and 43.33% respectively, and patients taking Katu Dravya predominant diet was also 76.67%.

All the participated patients were complaint of Kati Shula, while patients having Kati Stambha, Kati Suptata and Akunchana Prasaran Pravrutti Savedana were found 90%, 73.33% and 83.33% respectively. Gradual onset of pain was found in 60% patients, intermittent pain episodes was found in 70% patients, and dull aching type of pain was felt by 75% patients. Among them, 60 % patients had the history of aggravation of pain due to seasonal change, 80% patients noticed aggravation of pain during weight lifting, 73.33% during standing position for more than 10 minutes and working; and 66.67% during walking. Among the participated patients, 93.33% felt relief in pain on lying down in supine position. About 66.67 % patients had Kati Stambha for 10-15 minutes; and 73.33% had Akunchana Prasaran Pravrutti Savedana occasionally. For the pain management, 53.33% patients had found history of conservative treatment. On examination, tenderness was found in all of the patients of Katigata Vata, 70% had difficulty in forward flexion, whereas 90% was categorized under moderate level of VAS Scale, 33.33% was found positive Lassegue’s test. Similarly, 66.67% patients were categorized under moderate level of ODI Scale, 43.33% was found grade 1 Schober’s test; and 53.33% was found grade 1 deformity in KL scale.

**RESULTS**

**On Subjective and Objective Parameters**

In group A, Raktamokshana along with placebo, highly significant result (p<0.001) was found in Kati Shula, Kati Stambha whereas significant in Kati Suptata ,Akunchana Prasaran Pravrutti Savedana. Similarly, the results were observed highly significant with VAS Scale and ODI Scale. However, it was observed significant with Flexion, SLR & Schober’s test; and non-significant (P > 0.05) with Extention and Laseague Sign. In group B, Raktamokshana along with Trayodashanga Guggulu exhibited highly significant (p< 0.001) in Kati Shula, Kati Stambha, KatiSuptata & Akunchana Prasaran Pravrutti Savedana. Raktamokshana exhibited highly significant (P<0.001) in VAS scale, SLR, ODI scale & Schober’s test, whereas it was significant in forward flexion and Rt & Lt lateral flexion; and non-significant in extension and Lassegue’s sign.

**Comparative effect of Therapy**

Comparatively Raktamokshana along with Trayodashanga Guggulu was found better effect in compare to Raktamokshana along with placebo in Kati Suptata and Akunchana Prasaran Pravrutti Savedana. Group B showed better effect on Schober’s test and SLR. Equal improvement was found in both the groups in Forward flexion. In group A and group B, no significant changes were found in lab investigations except hemoglobin; where significant change was observed in both the groups of Raktamokshana with placebo and Raktamokshana along with Trayodashanga Guggulu.

**Overall Result of Therapy**

In case of overall effect in Group A, patients (n=5, 33.33%) were found moderate improvement; patients (n=7, 46.67%) were improved markedly; and patients (n=3, 20%) were recovered completely with sign and symptoms of lumbar spondylisis. In Group B, patients (n=5, 33.33%) were improved moderately; patients (n=5, 33.33%) were improved markedly; and patients (n=5, 33.33%) were recovered completely with sign and symptoms of lumbar
spondylosis. The recurrence of symptoms was found in 20% patients that was 3 patients in Group A and 3 patients in Group B during follow up period.

**DISCUSSION:**

Acharyas describe Katigata Vata as the most common joint disorder. In this disorder, Kati Sandhi is primarily affected due to provocation of Vata Dosha. All Vataprapakopa Nidanas and Dhatu Kshaya in Vardhakaya Avastha (Old age) are responsible for Katigatavata. The clinical features are Sandhi Shoola (pain), Sandhi Shopha (disc-herniation), Karmahani (restricted movement), Shunya (numbness).

Katigata vata is predominant in adult female population of middle economic class belonging to Hindu religion and reside in urban area. This disease has been found prevalent among Krura Kostha, non-addiction, history of menopause, history of Diwaswapna, Vata-Pitta Prakriti, Madhayama sara, Madhyama Samhanana, Madhymya Satva, Madhymaya Pramana, Madhymya Satmaya, Madhyama Ahara Shakti and Katu Dravyas predominant diet taking individual.

In this study, patients of Katigata Vata had major complaints of Kati shoola, Kati Stambha, Kati Suptata and non-significant in extension test, whereas it was significant in forward flexion and (P<0.001) in V AS scale, SLR, ODI scale & Schober’s Savedana. Raktamokshana exhibited highly significant (p< 0.001) in KL scale. In group A, Rasayana Prasaranene Pravrutti Savedana. Characteristics of pain in the disease has been found gradual onset or intermittent pain episodes or dull aching type of pain. Some of the patients showed history of aggravation of pain due to seasonal change and aggravation of pain during weight lifting becomes severe on standing position for more than 10 minutes or on working. In some cases, pain of the patients might be increased on walking. Occasionally, most of the patients encountered Akunchana Prasarane Pravrutti Saedana. It was found that patients felt relief of pain on lying down in supine position. Majority of the patients were undergone conservative treatment. Most of the Katigata vata’s patients was found tenderness on examination, tenderness and difficulty in forward flexion; moderately affected VAS scale having positive Lassegue’s test; moderately affected ODI Scale having grade 1Sober’s test; and had grade 1 deformity in KL scale. In group A, Raktamokshana along with placebo was found highly significant (p<0.001) in Kati Shula, Kati Stambha whereas significant in Kati Suptata, Akunchana Prasarna Pravrutti Savedana. Similarly, the results were observed highly significant with VAS scale and ODI Scale. However, it was observed significant with Flexion, SLR & Schober’s test; and non-significant (P > 0.05) with Extention and Lassegue Sign. In group B, Raktamokshana along with Tryodashanga Guggulu exhibited highly significant (p< 0.001) in Kati Shula, Kati Stambha, Kati Suptata & Akunchana Prasaran Pravrutti Savedana. Raktamokshana exhibited highly significant (P<0.001) in VAS scale, SLR, ODI scale & Schober’s test, whereas it was significant in forward flexion and Rt & Lt lateral flexion; and non-significant in extension and Lassegue’s sign. In case of overall effect of Group B was found significant when compared with group B. Raktamokshana along with Tryodashanga guggulu was effective in Katigata vata, then Raktamokshana alone. The other observations in both the groups were non-significant. Raktamokshana: In Dhatukshaya Janya Samprapti, application of modified Shringa Yantra helps to remove Vata vitiated blood, other pain producing chemicals and toxins from the circulation. It helps to enhance fresh blood supply to the affected lumbar region. Thus, it acts as local level Shodhana therapy which purifies Pravartaka Mula of Rasa and Rakta Vaha Srotas (blood vessels). In Margavaranajanya Samprapti, Raktamokshana removes Avarana of Kapha Dosh over Vayu Vayu which helps to re-establish Prakrit Rasa-Rakta Samvahana and provides nutritional support to the affected parts. The blood which was let-out (in the range between 30-50 ml in one sitting) by Shringa Yantra having the similar classical qualities of Dushta Rakta mentioned in Samhita like Phenila, Aruna, Krishna, etc which is characteristically matches with that of mentioned by Acharya Sushruta. This Dushta Rakta can be assumed as source of inflammatory mediators. Modified Shringa Yantra resembles with ancient Shringa Yantra mentioned by Acharya Sushruta and it works with similar principle. Tryodasanga Guggulu: Tryodasanga Guggulu is combination of Vedanasthapak, Shoolaharu and Rasayana properties. In pathophysiology of Katigata Vata, Vata is vitiated by Atishrama, Bharvahana, Veggavidhara, etc. Due to vitiated Vata degenerative changes occures in intervertebral disc of lumbar spine and Mamsa Dhatu of lower limb. Intervertebral disc regeneration requires Glycosoaminoglycan (GAGs), collagen and protein which is possible by Madhur VIPaka and Rasayana property of Tryodashanga Guggulu. It is observed that due to Rasayana property and Madhur VIPaka of Tryodashanga Guggulu, physical strength, muscular strength and nerve strength increases and recovers the functional disability of patients. On the basis of Dosha, Dhatwagni, Ama, Srotas level, mode of action of Tryodashanga Guggulu can be explained. From above findings both the modules of therapy have definite role in relieving pain whereas Raktamokshana along with Tryodashanga Guggulu has shown better result.

**CONCLUSION**

In this study, Raktamokshana along with Tryodashanga Guggulu has shown effective in the management of Katigata vata. The treatment modalities has no side effect noted during the study period and follow up.

**ABBREVIATIONS:** Not Applicable

**ACKNOWLEDGEMENTS:** Not Applicable

**CONFLICT OF INTEREST:** Author declares that there is no conflict of interest.

**SOURCE OF SUPPORT:** None
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Table 2: Organoleptic characters of Tryodashanga Guggulu Vati

| Parameters     | Result    |
|----------------|-----------|
| Color          | Black     |
| Odor           | Characteristic |
| Taste          | Pungent   |
| Touch          | Hard      |

Table 3: Physicochemical analysis of TrayodashangaGugguluVati

| Parameters         | Value  |
|--------------------|--------|
| Loss on drying at 110°C | 12.7%  |
| Ash value           | 11.1%  |
| Acid in soluble ash | 0.077% |
| Parameters                  | Value     |
|---------------------------|-----------|
| Water soluble extract     | 24.3%     |
| Methanol soluble extract  | 16.8%     |
| pH                        | 6.0       |
| Average weight of Vati    | 509.5 mg  |
| Highest weight            | 578 mg    |
| Lowest weight             | 425 mg    |
| Hardness                  | 2.8 kg/cm²|

**Table 4:** $R_f$ values of Trayodashangaguggulu Vati (Plate 2)

| HPTLC Value | $R_f$ values at 254 (nm) | $R_f$ values at 366 (nm) |
|-------------|--------------------------|--------------------------|
|             | 0.02, 0.33, 0.43, 0.62, 0.70, 0.76, 0.88, 0.94, 0.98 | 0.02, 0.33, 0.62, 0.73 |

**Table 5:** Gradation of subjective criteria:

| Kati Shula                                                                 | Grades |
|---------------------------------------------------------------------------|--------|
| No-pain                                                                   | 0      |
| Bearable pain relieved by without medication                              | 1      |
| Moderate pain relieved by medication                                      | 2      |
| Severe pain with disturbed routine work and relieved by strong analgesics| 3      |
| Patient cannot tolerate                                                  | 3      |

| Kati Stambha                                                             | Grades |
|-------------------------------------------------------------------------|--------|
| No stiffness                                                            | 0      |
| Stiffness for few minutes after sitting for long duration but relieved by mild movements | 1      |
| Stiffness more than 1 hour or more than once in a day but routine works are not disturbed | 2      |
| Stiffness lasting for more than 1 hour or many times a day, mildly affecting the daily routine | 3      |
| Episodes of stiffness lasting for 2-6 hours, Daily routines are hampered severely | 4      |

| Suptata (numbness)                                                       | Grades |
|-------------------------------------------------------------------------|--------|
| No numbness                                                             | 0      |
| Occasionally once in a day for few minutes                              | 1      |
| Daily once in a day for few minutes                                    | 2      |
| Daily for 2 or more times/30-60 minutes                                 | 3      |
| Daily more than 1 hour/Many times a day                                 | 4      |

**Table 6:** AkunchanaprasaraneAkshamta (Restriction of Movement):

| AkunchanaprasaraneAkshamta (Restriction of Movement):                   | Grades |
|------------------------------------------------------------------------|--------|
| No restriction of movement.                                            | 0      |
| Restriction in any one movement.                                       | 1      |
| Restriction in any two movements.                                      | 2      |
| Restriction in any three movements.                                    | 3      |
| Restriction in all four movements.                                     | 4      |
| Type of Pain | Description                                                                 | Grade of Pain | Description                        |
|-------------|------------------------------------------------------------------------------|---------------|------------------------------------|
| Mild        | Does not interfere with most activities. Able to adopt to pain psychologically and with medication or devices such as cushions. | 0             | No pain                            |
|             |                                                                               | 1             | Very light, barely noticeable pain. |
|             |                                                                               | 2             | Mild pain, Discomforting           |
|             |                                                                               | 3             | Very Noticeable pain, but patient groused to it. |
| Moderate    | Interfere with many activities, requires lifestyle changes, but patient remained independent unable to adapt to pain. | 4             | Strong deep, continuous pain       |
|             |                                                                               | 5             | Strong deep pain. Patient notice the pain all the time and it affects normal life style. |
|             |                                                                               | 6             | Very strong, deep piercing pain partially dominating the senses and causing trouble holding a job. |
| Severe      | Unable to engage in normal activities. Patient is disabled and unable to function independently | 7             | Very strong, deep piercing pain completely dominating the senses. |
|             |                                                                               | 8             | Very strong, deep piercing pain with severe personality changes. Demand for surgery |
|             |                                                                               | 9             | Patient cannot tolerate it and demand pain killers or surgery |
|             |                                                                               | 10            | Unimaginable unspeakable           |

Table 7: Gradation of VA scale (Visual analogue scale)

| Gradation | Grades |
|-----------|--------|
| No pain   | 0      |
| Mild (0-3)| 1      |
| Moderate (4-6) | 2    |
| Severe (7-10) | 3     |

Table 8: Oswestry Disability Index (ODI):

| INTERPRETATION | Grades |
|----------------|--------|
| 0%-20%: Minimal disability: | 0      |
| 20%-40%: Moderate disability | 1      |
| 40%-60%: Severe disability | 2      |
| 60%-80%: Crippled | 3      |
| 80%-100%: Disability | 4      |

Table 9: Range of Motion L-S Spine:

| Movement | Grades |
|----------|--------|
| Forward flexion (normal 80 degree) |        |
| Grade 0: 80 degree | 0      |
| Grade 1: 80-50 degree | 1      |
| Grade 2: 50-30 degree | 2      |
| Grade 3: <30 degree | 3      |
| Right lateral flexion: (normal approx.35°) |        |
| Grade 0: 35 degree | 0      |
| Grade 1: 25 degree | 1      |
| Grade 2: 15 degree | 2      |
| Grade 3: <15 degree | 3      |
| Left lateral flexion: (normal approx.35°) |        |
|
| Movement                        | Grades |
|--------------------------------|--------|
| Grade 0: 35degree              | 0      |
| Grade 1: 25degree              | 1      |
| Grade 2: 15 degree             | 2      |
| Grade 3: <15 degree            | 3      |
| Extension: (normal approx. 20-30°) |        |
| Grade 0: 20-30 degree          | 0      |
| Grade 1: 10-20 degree          | 1      |
| < 10 degree                    | 2      |
| Rotation towards right: (normally approx. 45°) |        |
| Grade 0: 45 degree             | 0      |
| Grade 1: 30 degree             | 1      |
| Grade 2: 15 degree             | 2      |
| Grade 3: <15 degree            | 3      |

**Table 10**: Straight leg raise test (SLR):

In 1880 Serbian doctor LazaLazarević described the straight leg raise test as it is used today, so the sign is often named Lazarević’s sign.

| SLR Test Angle          | Grades |
|-------------------------|--------|
| Equal to or greater than 90° | 0      |
| 71-<90°                  | 1      |
| 51-70°                   | 2      |
| 31-50°                   | 3      |
| <30°                     | 4      |

**Table 11**: Schober’s test

| Schobertest              | Grades |
|--------------------------|--------|
| Distance increases 5cm   | 0      |
| Distance increases 4cm   | 1      |
| Distance increases 3cm   | 2      |
| Distance increases 2cm   | 3      |
| Distance increases 1cm   | 4      |
| No change in the distance| 5      |

**Table 12**: Gradation of Kellgren- Lawrence test

| Kellgren- Lawrence Test                                           | Grades |
|-------------------------------------------------------------------|--------|
| No radiographic features of OA presentation                      | 0      |
| Doutful joint space narrowing (JSN) and possible osteophytes lipping | 1      |
| Definite osteophytes and possible joint space narrowing on antero-posterior weight bearing radiograph. | 2      |
| Multiple osteophytes marked JSN, severe sclerosis and possible bony deformity. | 3      |
| Large osteophytes, marked joint space narrowing, severe sclerosis and definite bony deformity | 4      |

**Criteria for Overall Assessment**:

Patients were graded into 5 groups to assess the overall effect of therapy.

1. **Cured**: 76-100% improvement in subjective and objective parameters.
2. **Marked Improvement**: 51-75% improvement in subjective and objective parameters.
3. Moderate Improvement: 26-50% improvement in subjective and objective parameters.
4. Mild improvement: < 25% improvement in subjective and objective parameters.
5. Unchanged: No improvement in subjective and objective parameters.

Table 13: Effect of Raktamokshana along with Placebo (Group A) on Chief Complaints (N=15)

| N  | Chief Complain          | Mean score | % of Relief | SD  | SE   | W   | Z   | P        | S |
|----|------------------------|------------|-------------|-----|------|-----|-----|----------|---|
| 15 | Katishula              | 2.06       | 51.63       | 0.59| 0.15 | -105| -3.63| <0.001   | HS|
| 14 | Katistambha            | 1.35       | 78.94       | 0.26| 0.07 | -105| -3.63| <0.001   | HS|
| 10 | Katisuptata            | 1.6        | 69.44       | 0.31| 0.1  | -55 | -3.05| 0.002    | S |
| 10 | AkunchanaPrasaraPravrittiSavedana | 1.1 | 72.72       | 0.42| 0.13 | -36 | -2.82| 0.008    | S |

Table-14: Effect of Raktamokshana along with Trayodashanga Guggulu (Group B) on Chief Complaints (N=15)

| N  | Chief Complain          | Mean score | % of Relief | SD  | SE   | W   | Z   | P        | S |
|----|------------------------|------------|-------------|-----|------|-----|-----|----------|---|
| 15 | Katishula              | 2.26       | 52.94       | 0.41| 0.10 | -120| -3.62| <0.001   | HS|
| 13 | Katistambha            | 1.61       | 85.71       | 0.50| 0.14 | -91 | -3.28| <0.001   | HS|
| 12 | Katisuptata            | 1.75       | 71.42       | 0.62| 0.17 | -78 | -3.27| <0.001   | HS|
| 15 | AkunchanaPrasaraPravrittiSavedana | 1.26 | 73.68       | 0.45| 0.11 | -91 | -3.50| <0.001   | HS|

Table-15: Effect of Raktamokshana along with Placebo (Group A) on Clinical Examination N=15

| N  | Clinical Examination  | Mean score | % of Relief | SD  | SE   | W   | Z   | P        | S |
|----|-----------------------|------------|-------------|-----|------|-----|-----|----------|---|
| 10 | Forward Flexion       | 1.2        | 66.66       | 0.42| 0.13 | -36 | -2.88| 0.008    | S |
| 09 | Rt. L. Flexion        | 1.1        | 70          | 0.44| 0.14 | -28 | -2.64| 0.016    | S |
| 08 | Lt. L. Flexion        | 1.12       | 77.77       | 0.64| 0.22 | -21 | -2.33| 0.031    | S |
| 07 | Extension              | 1          | 42.85       | 0.53| 0.20 | -6  | -1.73| 0.250    | NS|
| 15 | VAS                    | 1.93       | 44.82       | 0.35| 0.09 | -91 | -3.60| <0.001   | HS|
| 15 | SLR                    | 1.53       | 43.78       | 0.48| 0.12 | -55 | -3.16| 0.002    | S |
| 05 | Leseague Sign          | 1          | 60          | 0.54| 0.24 | -6  | -1.73| 0.250    | NS|
| 15 | ODI                    | 1.33       | 70          | 0.25| 0.06 | -105| -3.74| <0.001   | HS|
| 15 | Schober’s test         | 1.61       | 47.61       | 0.72| 0.21 | -36 | -2.64| 0.008    | S |

Table-16: Effect of Raktamokshana along with TrayodashangaGuggulu (Group B) on Clinical Examination N=15

| N  | Clinical Examination  | Mean score | % of Relief | SD  | SE   | W   | Z   | P        | S |
|----|-----------------------|------------|-------------|-----|------|-----|-----|----------|---|
| 2  | Forward Flexion       | 1.25       | 66.66       | 0.38| 0.11 | -55 | -3.16| 0.002    | S |
| 8  | Rt. L. Flexion        | 1.12       | 77.77       | 0.35| 0.12 | -28 | -2.64| 0.016    | S |
| 8  | Lt. L. Flexion        | 1          | 87.5        | 0.35| 0.12 | -28 | -2.64| 0.016    | S |
| 7  | Extension              | 1          | 57.14       | 0.53| 0.20 | -10 | -2.01| 0.125    | NS|
| 15 | VAS                    | 2.2        | 51.51       | 0.35| 0.09 | -120| -3.64| <0.001   | HS|
| 14 | SLR                    | 1.92       | 44.44       | 0.53| 0.14 | -66 | -3.20| <0.001   | HS|
| 8  | Leseague Sign          | 1          | 62.5        | 0.51| 0.18 | -15 | -2.23| 0.063    | NS|
| 15 | ODI                    | 1.26       | 73.68       | 0.25| 0.06 | -105| -3.74| <0.001   | HS|
| 15 | Schober’s test         | 2          | 50          | 0.65| 0.16 | -78 | -3.21| <0.001   | HS|
Table-17: Effect of Raktamokshana along with Placebo (Group A) on Investigation N=15

| N  | Lab Investigation | Mean score | % of Relief | SD  | SE   | t    | P    | S |
|----|-------------------|------------|-------------|-----|------|------|------|---|
| 15 | Hb                | 13.42      | 13.06       | 2.682 | 0.594 | 0.153 | 2.34 | 0.034 | S |
| 15 | FBS               | 85.8       | 92.33       | -0.761 | 22.83 | 5.89  | -1.10 | 0.28  | NS |
| 15 | TLC               | 6866       | 7040        | -0.252 | 1760.8 | 454.65 | -0.38 | 0.70  | NS |
| 15 | Neutrophils       | 56.93      | 55.6        | 2.34  | 11.31 | 0.45  | 0.65  | NS  |
| 15 | Lymphocytes       | 34.26      | 33.73       | 1.55  | 5.85  | 0.35  | 0.72  | NS  |
| 15 | Eosinophil        | 5.6        | 4.66        | 1.66  | 4.21  | 1.08  | 0.85  | 0.40  | NS |
| 15 | Monocytes         | 3.2        | 2.93        | 2.08  | 1.22  | 0.31  | 0.84  | 0.41  | NS |
| 15 | ESR               | 15.46      | 19.6        | 40.5  | 14.17 | 3.65  | -1.13 | 0.27  | NS |
| 15 | S. Calcium        | 9.83       | 9.70        | 1.28  | 1.11  | 0.28  | 0.44  | 0.66  | NS |

Table-18: Effect of Raktamokshana along with (Group B) on Lab Investigation N=15

| N  | Lab Investigation | Mean score | % of Relief | SD  | SE   | t    | P    | S |
|----|-------------------|------------|-------------|-----|------|------|------|---|
| 15 | Hb                | 13.40      | 13.04       | 2.686 | 0.574 | 0.148 | 2.428 | 0.029 | S |
| 15 | FBS               | 97.33      | 95.8        | 1.57  | 17.74 | 4.58  | 0.33  | 0.743 | NS |
| 15 | TLC               | 8446.6     | 7233.3      | 14.36 | 3270.83 | 844.52 | 1.43  | 0.173 | NS |
| 15 | Neutrophils       | 62.2       | 57.66       | 7.28  | 19.22 | 4.96  | 0.91  | 0.376 | NS |
| 15 | Lymphocytes       | 33.33      | 32.2        | 3.4   | 13.46 | 3.47  | 0.32  | 0.74  | NS |
| 15 | Eosinophil        | 3.13       | 4.93        | -63.82| 3.07  | 0.79  | -2.26 | 0.04  | NS |
| 15 | Monocytes         | 2.6        | 2.53        | 2.56  | 1.10  | 0.28  | 0.23  | 0.81  | NS |
| 15 | ESR               | 29.2       | 21.4        | 26.55 | 23.44 | 6.05  | 1.28  | 0.21  | NS |
| 15 | S. Calcium        | 9.74       | 10.19       | -4.65 | 0.93  | 0.24  | -1.88 | 0.08  | NS |

Table-19: Comparitive Effect of Raktamokshana along with placebo and Raktamokshana along with Trayodashanga Guggulu

| Symptoms                              | Mean score | % of Relief | U   | P   | Significant |
|---------------------------------------|------------|-------------|-----|-----|-------------|
|                                       | Group A    | Group B     | Group A | Group B |             |
| Katishula                             | 1.066      | 1.2         | 51.63 | 52.94 | 132         | 0.224 | NS |
| Katistambha                           | 1.0714     | 1.384       | 78.94 | 85.71 | 62.5        | 0.059 | NS |
| Katisuptata                           | 1.111      | 1.25        | 69.44 | 71.42 | 57.50       | 0.726 | NS |
| Akunchana Prasarana Pravrutti Savedana| 0.8        | 0.933       | 72.72 | 73.68 | 84.0        | 0.498 | NS |
| Forward Flexion                       | 0.8        | 0.833       | 66.66 | 66.66 | 62.0        | 0.882 | NS |
| Rt. L. Flexion                        | 0.78       | 0.875       | 70    | 77.77 | 32.50       | 0.663 | NS |
| Lt. L. Flexion                        | 0.875      | 0.875       | 77.77 | 87.5  | 32.50       | 0.959 | NS |
| Extension                              | 0.428      | 0.571       | 42.85 | 57.14 | 28          | 0.710 | NS |
| VAS                                   | 0.867      | 1.133       | 44.82 | 51.51 | 140.50      | 0.053 | NS |
| SLR                                   | 0.667      | 0.857       | 43.78 | 44.44 | 87.50       | 0.358 | NS |
| Lesseague Sign                        | 0.6        | 0.625       | 60    | 62.5  | 20.50       | 0.943 | NS |
| ODI                                   | 0.933      | 0.933       | 70    | 73.68 | 112.5       | 0.962 | NS |
| Schober’s test                        | 0.769      | 1           | 47.61 | 50    | 115.5       | 0.373 | NS |
### Table-20: Overall Effect of Therapy on Clinical Assessments

| Improvement          | Group A | Group B |
|----------------------|---------|---------|
|                      | No. of Patients | %       | No. of Patients | %       |
| Unchanged            | -       | -       | -               | -       |
| Mild improvement     | -       | -       | -               | -       |
| Moderate improvement | 05      | 33.33   | 05              | 33.33   |
| Marked improvement   | 07      | 46.67   | 05              | 33.33   |
| Complete remission   | 03      | 20      | 05              | 33.33   |

### Table -21: Recurrence of symptoms (Follow up period – 1 month)

| Recurrence of symptoms | No. of patients | Total | % |
|-------------------------|-----------------|-------|---|
|                         | Group A | Group B |     |
| Yes                     | 03      | 03      | 06  | 20|
| No                      | 12      | 12      | 24  | 80|