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 *Katigata vata* 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 flexion was same in both groups, and complete remission of symptoms of *Katigata vata* 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: *Katigata vata*, 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. ¹Some 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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rukshata and *vatakopa* and vitiated *Vayu* becomes localized in *Kati Pradesha* (Lumbar region). The symptoms like *Shoola* (Pain), *Shoph* (Inflammation), *Stambha* (Rigidity) are developed later on.² Low back pain is now ranked second to headache, as the most common location of pain. Four out of every five adults experience at least one bout of back pain during their life time. In India, nearly 60 % of the people have significant back pain. Lumbar spondylosis is responsible for about 10 % of all back pain. Prevalence of low back Pain in the world and India are 60-85%, and 25-30% respectively.³ Patients of lumbar spondylosis are bound to choose analgesics, anti-inflammatory drugs, steroid injections and physiotherapy as conservative management to improve the quality of life. In advanced stage, the surgical therapies like spinal fusion, spinal decompression etc. are the only option. These procedures are not fulfilling the goal of patients because of very high cost and its therapeutic limitation.⁴ Treatment modalities like *Raktamokshana* and *Trayodashanga Guggulu* are result-oriented therapies recommended in *Ayurveda* to manage painful conditions.⁵ Therefore, the study has been planned to evaluate the effectiveness of *Raktamokshana* and *Trayodashanga Guggulu* in management of *Katigata vata with special reference to lumbar spondylosis*.^{6,7,8}

सिराव्यधश्चिकित्सार्थं शल्यतन्त्रे प्रकीर्तितः ।

यथा प्रणिहितः सम्यग्बस्तिः कायचिकित्सेते ॥ Su.Sa 8/23 ॥

Raktamokshana is an important Para-surgical procedure recommended by *Acharyas* for treatment of *Snayu Sandhigata Vata*. *Shringa* (Cow horn) is an ideal instrument for pacification of vitiated *Vata Rakta Dosha*. At present, *Shringa* is difficult to manage for the procedure, so that many modified *Shringa Yantras* have been developed and are available in the market and are being used for it. It is very simple and easy to use even at OPD level. Hence, in this study, this Modified *Shring Yantra* (MSY; Hijama instrument) had been selected for the purpose of *Raktamokshana*.^{9,10,11} To control the degenerative process of an individual, *Rasayana*, *Balya*, *Vatasamak Amapachana* drugs should be preferred. For the purpose of it, *Trayodashanga Guggulu* is selected for internal use to pacify the vitiated *Vata Kapha Dohsa*. Majority of *Dravyas* of *Trayodashanga Guggulu* contains *Vatashamaka*, *Rasayana*, *Balya*, *Amapachana* property.^{12,13} *Trayodashanga Guggulu* having *Vatashamaka*, *Dipana*, *Balya* properties, are desirable with *shodhana karma*. Because of high prevalence and disability rate in productive life span, lack of available effective treatment and considering classical reference for the management of *Katigata Vata* (Lumbar Spondylosis), *Raktamokshana* and *Trayodashanga Guggulu* had been conducted.¹⁴

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 Pravrutti 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* (Lumbar spondylosis) with age group between 40-70 years of either sex were included. Patients of *Katigata Vata* with controlled cases of diabetes mellitus 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 Pravrutti 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 *Trayodashanga Guggulu*.

S.No.	Group A	Group B
No. of patients	15	15
Intervention	<i>Raktmokshana</i> followed by Placebo capsule (Rosted suji powder)	<i>Raktmokshana</i> followed by <i>Trayodashanga Guggulu</i>
Drug	Placebo capsule (Rosted suji powder)	<i>Trayodashanga Guggulu Vati</i>
Dose	500mg 2 caps tds after meal for one month	500mg 2 <i>Vati</i> tds after meal for one month
Anupan	<i>Ushna Jala</i>	<i>Ushna Jala</i>
Instrument	Modified <i>Shringa Yantra</i> (Hijama therapy)	Modified <i>Shringa Yantra</i> (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: *Mudgayusha 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.²

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.³

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 sign 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 kosta, 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 *Akunchane Prasarane 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 Prasarana Pravrutti Saedana* 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 Prasarana 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*, *Kati Suptata* & *Akunchana Prasarane 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 Prasarane 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 spondylosis. 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 *Vataprakopaka Nidanas* and *Dhatu Kshaya* in *Vardhakya Avastha* (Old age) are responsible for *Katigata vata*. The clinical features are *Sandhi Shoola* (pain), *Sandhi Shopha* (disc-herniation), *Karmahani* (restricted movement), *Shunyata* (numbness).¹⁵ *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, Madhyama Satva, Madhayama Pramana, Madhyama Satmaya, Madhyama Ahara Shakti and Katu Dravyas predominant diet taking individual.¹⁶ In this study, patients of *Katigata Vata* had major complaints of *Kati shoola*, *Kati Stambha*, *Kati Suptata* and *Akunchane Prasarane 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 Prasarana Pravrutti Saedana*. It was found that patients felt relief of pain on lying down in supine position.¹⁷ 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 1 Schober'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 Laseague Sign. In group B, *Raktamokshana* along with *Trayodashanga Guggulu* exhibited highly significant ($p < 0.001$) in *Kati Shula*, *Kati Stambha*, *Kati Suptata* & *Akunchana Prasarane 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 *Margavarana janya Samprapti*, *Raktamokshana* removes *Avarana* of *Kapha Dosha* over *Vyana 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*.¹ 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. *Trayodashanga Guggulu*: *Trayodashanga Guggulu* is combination of *Vedanasthapak*, *Shoolahara* and *Rasayana* properties. In pathophysiology of *Katigata Vata*, *Vata* is vitiated by *Atishrama*, *Bharvahana*, *Vegavidharana*, etc. Due to vitiated *Vata* degenerative changes occurs 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 *Trayodashanga Guggulu*. It is observed that due to *Rasayana* property and *Madhur Vipaka* of *Trayodashanga 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 *Trayodashanga Guggulu* can be explained. From above findings both the modules of therapy have definite role in relieving pain whereas *Raktamokshana* along with *Trayodashanga Guggulu* has shown better result.

CONCLUSION

In this study, *Raktamokshana* along with *Trayodashanga 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 <i>Vati</i>	509.5 mg
Highest weight	578 mg
Lowest weight	425 mg
Hardness	2.8kg/ cm ²

Table 4: R_f values of *TrayodashangaGugguluVati*(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,	0.02, 0.33, 0.62, 0.73
	0.76, 0.88, 0.94, 0.98	

Table 5: Gradation of subjective criteria:

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

<i>Kati Stambha</i>	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

<i>Suptata</i> (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):

<i>AkunchanaprrasaraneAkshamta</i> (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
		0	No pain
Mild	Does not interfere with most activities. Able to adopt to pain psychologically and with medication or devices such as cushions.	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: 35degree	0
Grade 1:25degree	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 Laza Lazarević 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

Schoberstest	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 test⁶

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
		BT	AT							
15	<i>Katishula</i>	2.06	1	51.63	0.59	0.15	-105	-3.63	<0.001	HS
14	<i>Katistambha</i>	1.35	0.28	78.94	0.26	0.07	-105	-3.63	<0.001	HS
10	<i>Katisuptata</i>	1.6	0.5	69.44	0.31	0.1	-55	-3.05	0.002	S
10	<i>AkunchanaPrasaraPravrittiSavdana</i>	1.1	0.3	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
		BT	AT							
15	<i>Katishula</i>	2.26	1.06	52.94	0.41	0.10	-120	-3.62	<0.001	HS
13	<i>Katistambha</i>	1.61	0.23	85.71	0.50	0.14	-91	-3.28	<0.001	HS
12	<i>Katisuptata</i>	1.75	0.5	71.42	0.62	0.17	-78	-3.27	<0.001	HS
15	<i>AkunchanaPrasaraPravruttiSavdana</i>	1.26	0.33	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
		BT	AT							
10	Forward Flexion	1.2	0.4	66.66	0.42	0.13	-36	-2.88	0.008	S
09	Rt. L. Flexion	1.1	0.33	70	0.44	0.14	-28	-2.64	0.016	S
08	Lt. L. Flexion	1.12	0.25	77.77	0.64	0.22	-21	-2.33	0.031	S
07	Extension	1	0.57	42.85	0.53	0.20	-6	-1.73	0.250	NS
15	VAS	1.93	1.06	44.82	0.35	0.09	-91	-3.60	<0.001	HS
15	SLR	1.53	0.86	43.78	0.48	0.12	-55	-3.16	0.002	S
05	Leseague Sign	1	0.4	60	0.54	0.24	-6	-1.73	0.250	NS
15	ODI	1.33	0.33	70	0.25	0.06	-105	-3.74	<0.001	HS
15	Schober's test	1.61	0.84	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
		BT	AT							
2	Forward Flexion	1.25	0.41	66.66	0.38	0.11	-55	-3.16	0.002	S
8	Rt. L. Flexion	1.12	0.25	77.77	0.35	0.12	-28	-2.64	0.016	S
8	Lt. L. Flexion	1	0.12	87.5	0.35	0.12	-28	-2.64	0.016	S
7	Extension	1	0.42	57.14	0.53	0.20	-10	-2	0.125	NS
15	VAS	2.2	1.06	51.51	0.35	0.09	-120	-3.64	<0.001	HS
14	SLR	1.92	1.07	44.44	0.53	0.14	-66	-3.20	<0.001	HS
8	Leseague Sign	1	0.37	62.5	0.51	0.18	-15	-2.23	0.063	NS
15	ODI	1.26	0.33	73.68	0.25	0.06	-105	-3.74	<0.001	HS
15	Schober's test	2	1	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
		BT	AT						
15	Hb	13.42	13.06	2.682	0.594	0.153	2.34	0.034	S
15	FBS	85.8	92.33	-7.61	22.83	5.89	-1.10	0.28	NS
15	TLC	6866	7040	-2.52	1760.8	454.65	-0.38	0.70	NS
15	Neutrophils	56.93	55.6	2.34	11.31	2.92	0.45	0.65	NS
15	Lymphocytes	34.26	33.73	1.55	5.85	1.51	0.35	0.72	NS
15	Eosinophil	5.6	4.66	16.6	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
		BT	AT						
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: Comparative 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			
<i>Katishula</i>	1.066	1.2	51.63	52.94	132	0.224	NS
<i>Katistambha</i>	1.0714	1.384	78.94	85.71	62.5	0.059	NS
<i>Katisuptata</i>	1.111	1.25	69.44	71.42	57.50	0.726	NS
<i>Akunchana Prasarana</i> <i>Pravrutti Savedana</i>	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
Leseague 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