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CLINICAL EVALUATION OF RAKTAMOKSHANA BY MODIFIED SHRINGA YANTRA (WET CUPPING THERAPY) IN THE MANAGEMENT OF KATIGATAVATA (LUMBAR SPONDYLOSIS): A PROSPECTIVE SINGLE-ARM PILOT CLINICAL STUDY

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ABSTRACT

Background: Low back pain is one of the leading causes of disability worldwide and is frequently associated with lumbar spondylosis. Despite advances in pharmacological and rehabilitative management, recurrence, chronicity and adverse effects associated with long-term medication continue to challenge clinicians. In Ayurveda, the clinical presentation of lumbar spondylosis closely resembles Katigatavata, a Vata-dominant disorder characterized by pain, stiffness and restricted lumbar movements. Among the various therapeutic procedures described for Vatavyadhi, Raktamokshana occupies a unique place because of its rapid pain-relieving action. Modified Shringa Yantra (Wet Cupping Therapy) is a contemporary adaptation of the classical Shringa Raktamokshana technique; however, clinical evidence regarding its efficacy remains limited. **Aim:** To evaluate the clinical efficacy of Raktamokshana by Modified Shringa Yantra (Wet Cupping Therapy) in patients diagnosed with Katigatavata. **Materials and Methods:** A prospective, open-label, single-arm pilot clinical study was conducted on 20 patients fulfilling the diagnostic criteria of Katigatavata. All participants underwent two sittings of Modified Shringa Yantra at an interval of seven days. Clinical assessment was performed on Day 0,

Day 7 and Day 14 using the Visual Analogue Scale (VAS), Straight Leg Raising (SLR) test and Schober's test. Statistical analysis was carried out using paired t-test, Wilcoxon signed-rank test and McNemar test wherever appropriate. **Results:** The mean VAS score significantly decreased from 4.05 ± 1.57 at baseline to 1.05 ± 0.69 on Day 14 ($p<0.0001$). Significant improvement was also observed in SLR grading and VAS grading. Although Schober's test showed clinical improvement, the change was not statistically significant ($p=0.50$). The overall mean clinical improvement was 23.79%, and no serious adverse events were reported. **Conclusion:** Modified Shringa Yantra (Wet Cupping Therapy) demonstrated promising short-term efficacy in reducing pain and improving functional status among patients with Katigatavata. The procedure appears to be safe, minimally invasive and economically feasible. Larger randomized controlled trials are required to validate these findings.

KEYWORDS: Katigatavata, Raktamokshana, Wet Cupping Therapy, Modified Shringa Yantra, Lumbar Spondylosis, Low Back Pain.

INTRODUCTION

Low back pain (LBP) is a major global health problem and one of the leading causes of disability affecting individuals across all age groups. According to the World Health Organization (WHO), nearly 619 million people suffered from low back pain in 2020, and this number is projected to rise to more than 840 million by 2050, primarily due to population ageing, sedentary lifestyles and increasing obesity.[1] Low back pain contributes substantially to healthcare expenditure, work absenteeism and reduced quality of life, making it one of the most important musculoskeletal disorders worldwide.[2-4]

Lumbar spondylosis is among the most common causes of chronic mechanical low back pain. It represents a progressive degenerative condition involving intervertebral discs, vertebral end plates, facet joints and surrounding ligaments. Degeneration leads to chronic inflammation, muscle spasm, reduced spinal mobility and functional disability. Conventional management includes non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, physiotherapy, exercise therapy and surgery in selected cases. Although these interventions often provide symptomatic relief, prolonged medication is associated with gastrointestinal, renal and cardiovascular adverse effects, while recurrence and persistent disability remain common.[2-6]

Ayurveda describes disorders involving pain and restricted movement of the lumbar region under the broader spectrum of Vatavyadhi, with the clinical presentation closely resembling Katigatavata. The condition is characterized by Katishoola (low back pain), Stambha (stiffness), Graha (restriction of movement) and difficulty in performing routine activities. Although Katigatavata is not described as an independent disease entity in the classical Samhitas, its pathogenesis is well explained through the concepts of Dhatukshaya (degeneration of tissues) and Margavarana (obstruction to the normal movement of Vata). According to Charaka, aggravated Vata localizes in weakened tissues and produces pain, stiffness and functional impairment, which remarkably resembles the degenerative changes observed in lumbar spondylosis.[7]

Management of Vatavyadhi includes Shamana, Shodhana and Panchakarma therapies depending upon the stage and severity of disease. Among these, Raktamokshana occupies a distinctive place because of its ability to relieve localized pain and remove vitiated Rakta. Acharya Sushruta, widely regarded as the pioneer of surgery, has elaborately described Raktamokshana in Sutra Sthana, explaining its indications, contraindications and different methods such as Shringa, Alabu, Jalauka and Siravyadha.[8] Shringa is specifically recommended in disorders dominated by Vata because of its ability to evacuate vitiated blood through controlled suction. Similarly, Acharya Vagbhata, in Sutra Sthana, emphasizes Raktamokshana as an important Shodhana therapy for diseases associated with Rakta and Vata, highlighting its role in relieving pain, inflammation and obstruction.[9]

Modified Shringa Yantra, commonly known as Wet Cupping Therapy (Al-Hijama), is a modern adaptation of the classical Shringa Raktamokshana technique. The procedure combines controlled negative pressure with superficial scarification, facilitating removal of a small quantity of blood from the affected region. Experimental evidence suggests that wet cupping improves local microcirculation, enhances tissue oxygenation, reduces inflammatory mediators, relieves muscle spasm and activates endogenous analgesic pathways. Several clinical studies have reported its beneficial effects in chronic musculoskeletal disorders, including neck pain, osteoarthritis and chronic low back pain.[10-14] However, the available evidence remains heterogeneous because of variations in methodology, treatment protocols and outcome measures.

Furthermore, most published studies have evaluated wet cupping from the perspective of complementary and alternative medicine rather than within the framework of Ayurvedic

principles. Scientific studies integrating the classical concept of Raktamokshana by Modified Shringa Yantra with standardized Ayurvedic diagnostic criteria for Katigatavata are limited. This gap underscores the need for well-designed clinical studies that combine classical Ayurvedic knowledge with validated clinical assessment tools.

Research Gap

Although wet cupping therapy has been investigated in patients with chronic low back pain, very few studies have evaluated its efficacy as Raktamokshana by Modified Shringa Yantra based on classical Ayurvedic principles. Existing literature is limited by small sample sizes, heterogeneity in treatment protocols and inadequate incorporation of Ayurvedic diagnostic criteria. Moreover, only a few studies have assessed treatment outcomes using both subjective pain assessment and objective functional measures such as the Visual Analogue Scale (VAS), Straight Leg Raising (SLR) test and Schober's test. Therefore, further clinical evaluation using standardized methodology is warranted.

Rationale of the Study

Considering the increasing prevalence of chronic low back pain, the limitations associated with long-term conventional treatment and the classical indication of Raktamokshana in localized Vata disorders, the present study was undertaken to evaluate the clinical efficacy of Modified Shringa Yantra (Wet Cupping Therapy) in patients with Katigatavata. This pilot study aims to generate preliminary scientific evidence supporting a simple, minimally invasive, cost-effective and outpatient-based Ayurvedic parasurgical intervention, thereby laying the foundation for future large-scale randomized controlled trials.

MATERIALS AND METHODS

Study Design

The present study was designed as a prospective, open-label, single-arm interventional pilot clinical trial to evaluate the efficacy and safety of Raktamokshana by Modified Shringa Yantra (Wet Cupping Therapy) in patients diagnosed with Katigatavata.

A pilot study design was selected to assess the feasibility of the intervention, generate preliminary efficacy data, and provide baseline information for future randomized controlled trials.[15]

Study Setting

The study was conducted in the Department of Panchakarma (OPD/IPD) of SMBT Ayurved College and Hospital, Nashik.

Patients attending the Panchakarma outpatient and inpatient departments with complaints suggestive of Katigatavata were screened for eligibility.

Sample Size

The present investigation was conducted as a pilot clinical study involving 20 participants diagnosed with Katigatavata.

Since preliminary clinical evidence regarding Modified Shringa Yantra in Katigatavata is limited, a pilot sample was considered appropriate to evaluate feasibility, safety and preliminary therapeutic efficacy prior to conducting a large-scale randomized controlled trial.[15]

Patient Recruitment

Patients were recruited consecutively from the Panchakarma OPD and IPD after detailed clinical evaluation.

All eligible participants fulfilling the inclusion criteria and willing to participate voluntarily were enrolled after obtaining written informed consent.

Diagnostic Criteria

Diagnosis of Katigatavata was established based on classical Ayurvedic signs and symptoms supported by modern clinical examination.

The following features were considered

- Katishoola (Low back pain)
- Katistambha (Lumbar stiffness)
- Restricted lumbar movements
- Pain aggravated on movement
- Local tenderness
- Positive Straight Leg Raising (SLR) test whenever applicable

Radiological findings suggestive of lumbar spondylosis were considered supportive but not mandatory for diagnosis.

Inclusion Criteria

Patients fulfilling all the following criteria were included.

1. Age between 20 and 50 years.
2. Clinical diagnosis of Katigatavata.
3. Patients of either gender.
4. Willingness to undergo Modified Shringa Yantra.
5. Written informed consent.

Exclusion Criteria

Patients with the following conditions were excluded:

1. Acute traumatic low back pain
2. Prolapsed intervertebral disc with neurological deficit
3. Spinal tuberculosis
4. Malignancy involving the spine
5. Congenital spinal deformity
6. Severe osteoporosis
7. Bleeding disorders
8. Severe anemia
9. Uncontrolled diabetes mellitus
10. Pregnancy and lactation
11. Local skin infection at the treatment site
12. Patients receiving anticoagulant therapy
13. Unwillingness to participate

Withdrawal Criteria

Participants were withdrawn if they.

- Withdrew consent.
- Failed to complete follow-up.
- Developed serious adverse events.
- Violated the study protocol.

Baseline Assessment

A detailed clinical history was obtained from every participant.

General examination included.

- Pulse

- Blood pressure
- Respiratory rate
- Temperature

Systemic examination included.

- Musculoskeletal examination
- Neurological examination
- Lumbar spine examination

Laboratory Investigations

To assess fitness for the procedure and exclude associated pathology, the following investigations were performed.

Hematological

- Hemoglobin
- Total Leukocyte Count
- Differential Leukocyte Count
- ESR
- Complete Blood Count

Biochemical

- Random Blood Sugar
- Bleeding Time
- Clotting Time

Radiological

- X-ray Lumbosacral Spine (AP/Lateral View) wherever indicated.

Intervention

All enrolled participants underwent Raktamokshana by Modified Shringa Yantra (Wet Cupping Therapy).

The intervention consisted of.

- Two treatment sittings
- Interval of seven days
- Follow-up until Day 14

No other Panchakarma procedure was administered during the intervention period.

Materials Used

The following sterile materials were utilized:

- Disposable plastic cupping cups
- Manual vacuum suction pump
- Sterile No.11 surgical blade
- Sterile gauze pieces
- Cotton swabs
- Surgical gloves
- Kidney tray
- Povidone-iodine solution
- Surgical spirit
- Adhesive dressing

Procedure

The intervention of Raktamokshana by Modified Shringa Yantra (Wet Cupping Therapy) was performed under strict aseptic precautions by a trained Panchakarma physician. The procedure comprised three stages: Purva Karma (Pre-procedural measures), Pradhana Karma (Main procedure), and Pashchat Karma (Post-procedural measures).

1. Purva Karma (Pre-procedural Measures)

- The procedure, its benefits, possible risks, and post-procedure precautions were explained to each participant.
- Written informed consent was obtained before the intervention.
- The patient was positioned comfortably in the prone position on the procedure table.
- The lumbar region was exposed adequately.
- The treatment site was identified based on the maximum point of tenderness.
- The selected area was cleaned with 10% povidone-iodine solution, followed by 70% surgical spirit, maintaining strict aseptic precautions.

2. Pradhana Karma (Main Procedure)

- A sterile disposable cupping cup was placed over the identified treatment site.
- Negative pressure was created using a manual suction pump and maintained for approximately 3–5 minutes to produce localized hyperemia and congestion.

- The cup was gently removed.
- Multiple superficial skin incisions (approximately 1–2 mm in depth) were made using a sterile No. 11 surgical blade.
- The cupping cup was immediately reapplied over the scarified area.
- Negative pressure was recreated using the manual suction pump to facilitate controlled bloodletting.
- Approximately 20–30 mL of blood was allowed to collect, depending on:
  - Patient tolerance
  - Degree of local congestion
  - Clinical judgment of the treating physician
- The procedure was discontinued once adequate bloodletting was achieved or active bleeding ceased spontaneously.

3. Pashchat Karma (Post-procedural Measures)

- The cupping cup was removed carefully.
- The treated area was cleaned with sterile normal saline followed by 10% povidone-iodine solution.
- A sterile gauze dressing was applied over the treated site.
- Patients were observed briefly for any immediate adverse reactions, such as dizziness, excessive bleeding, or vasovagal symptoms.
- The following post-procedure instructions were provided:
  - Keep the dressing dry and intact for 24 hours.
  - Avoid strenuous physical activity for 24 hours.
  - Maintain proper local hygiene.
  - Report immediately if excessive bleeding, severe pain, fever, swelling, or signs of local infection develop.

Assessment Criteria

Clinical assessment was performed on.

- Day 0
- Day 7
- Day 14

Primary Outcome

Visual Analogue Scale (VAS)

Pain intensity was evaluated using a 10-cm Visual Analogue Scale.

Secondary Outcomes

Straight Leg Raising Test

Functional improvement was assessed using Straight Leg Raising test.

Schober's Test

Lumbar flexion was objectively assessed using Schober's test.

Safety Assessment

Participants were monitored throughout the study for.

- Excessive bleeding
- Hematoma
- Infection
- Vasovagal attack
- Dizziness
- Allergic reaction
- Persistent pain

All adverse events were documented.

No serious adverse events occurred during the study.

Statistical Analysis

Descriptive statistics were expressed as.

- Mean ± Standard Deviation (SD)
- Frequency
- Percentage

Inferential statistics included

- Paired t-test for normally distributed variables
- Wilcoxon Signed-Rank Test for non-parametric paired observations
- McNemar Test for paired categorical variables

A **p-value <0.05** was considered statistically significant.

Table 1. Schedule of Clinical Assessment

Assessment	Day 0	Day 7	Day 14
Informed Consent	✓	—	—
Clinical Examination	✓	✓	✓
VAS	✓	✓	✓
Straight Leg Raising Test	✓	✓	✓
Schober's Test	✓	✓	✓
Adverse Event Monitoring	✓	✓	✓

RESULTS

Study Population

A total of 20 patients fulfilling the diagnostic criteria for Katigatavata were enrolled in the study. All participants completed the treatment protocol and follow-up schedule. No participant was withdrawn from the study, and no serious adverse events were observed during the intervention period.

General Observation

1. Distribution of patients

Table No. 2: showing distribution of patients

Group	Complete Follow up	Withdrawals
Trial	20	00
Total	20	00

2. Age wise distribution of patients

Table No.3: Age wise distribution of patients.

Age Group	Frequency	%
21-30 Years	3	15%
31-40 Years	17	85%
Total	20	100%

In Trial group, 3 Patients belonged to 21-30 Years Age Group, 17 Patients belonged to 31-40 Years Age Group.

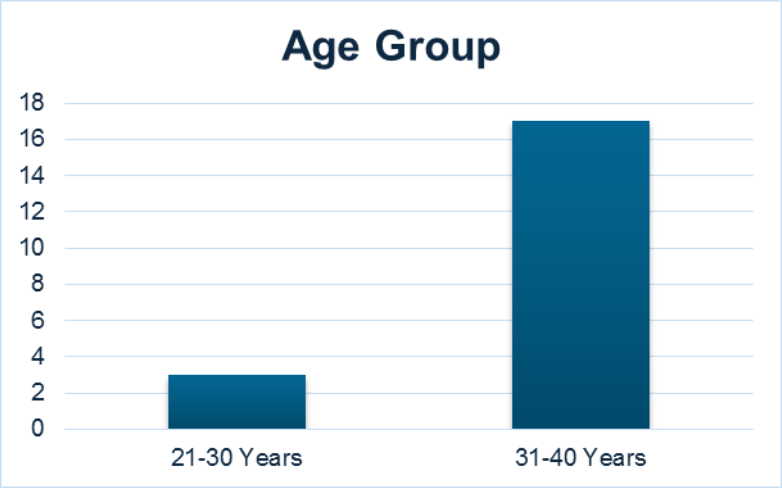

Figure No. 1: Age wise distribution of patients.

3. Gender wise distribution of Patients

Table No. 4: Gender wise distribution of patients.

Gender	Frequency	%
Female	8	40.00
Male	12	60.00
Total	20	100

In Trial group, 8 Patients belonged to Female Gender, 12 Patients belonged to Male Gender.

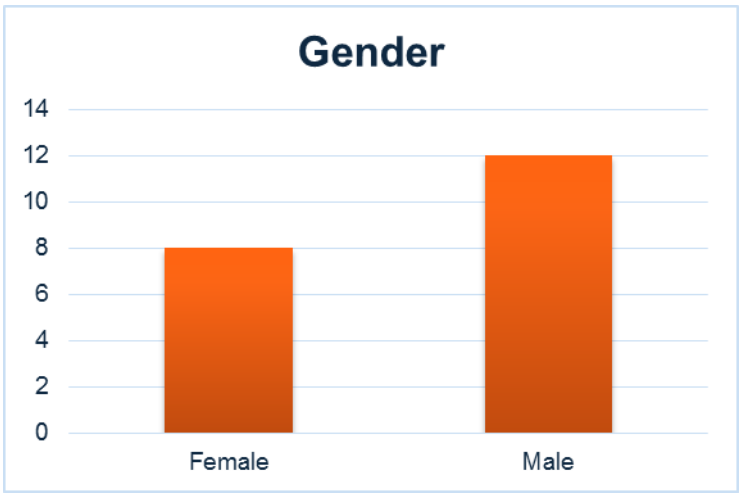

Figure No. 2: Gender wise distribution of patients.

4. Prakruti wise distribution of Patients

Table No. 5: Prakruti wise distribution of patients.

Prakruti	Frequency	%
Vatapitta	7	35.00
Pittakapha	11	55.00

Kaphapitta	2	10.00
Total	20	100

In Trial group, 7 Patients belonged to Vatapitta Prakruti, 11 Patients belonged to Pittakapha Prakruti, 2 Patients belonged to Kaphapitta Prakruti.

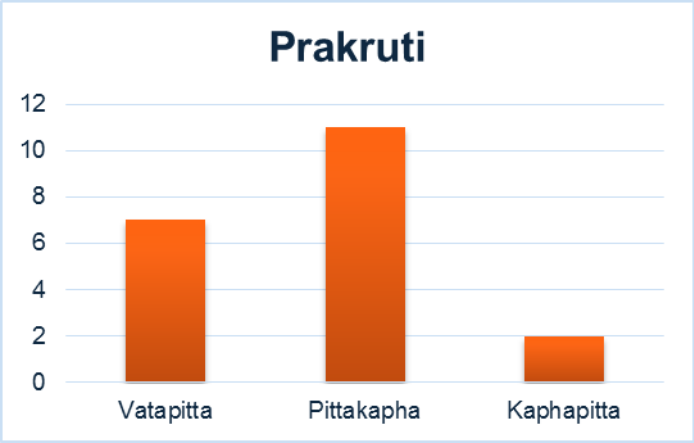

Figure No. 3: Prakruti wise distribution of patients.

5. Diet wise distribution of Patients

Table No. 6: Diet wise distribution of patients.

Diet	Frequency	%
Veg	9	45.00
Mixed	11	55.00
Total	20	100

In Trial group, 9 Patients belonged to Veg Diet, 11 Patients belonged to Mixed Diet.

Figure No. 4: Diet wise distribution of patients.

5.1 Descriptive Statistics of parameters:

1. VAS Score

Table No. 7: Descriptive Statistics For Parameter VAS Score.

VAS Score	D0	D7	D14
Mean	4.05	2.60	1.05
SD	1.57	1.35	0.69
Median	4	2.5	1
Mode	4	3	1

At day 0 (before treatment), the mean VAS score was 4.05 ± 1.57, indicating moderate pain intensity with moderate variability among patients.

At day 7, the mean VAS score reduced to 2.60 ± 1.35, reflecting a reduction in pain severity compared to baseline.

At day 14, the mean VAS score further decreased to 1.05 ± 0.69, indicating continued reduction in pain intensity with lower variability.

2. SLR

Table No. 8: Distribution of patients before and after treatment for parameter SLR.

SLR	D0	D7	D14
Grade 0	0	1	7
Grade 1	7	11	13
Grade 2	13	8	0
Grade 3	0	0	0

At day 0 (before treatment), no patients were observed in Grade 0, while 7 patients were in Grade 1 and 13 patients were in Grade 2. No patients were recorded in Grade 3. Thus, the majority of patients were in Grade 2, indicating moderate limitation at baseline.

At day 7, improvement was observed. Grade 0 appeared in 1 patient, while Grade 1 increased to 11 patients. Grade 2 reduced to 8 patients, and no patients were present in Grade 3 at this stage.

At day 14, further improvement was noted. Grade 0 increased to 7 patients, while Grade 1 increased to 13 patients. No patients were observed in Grade 2 or Grade 3 categories at this time point.

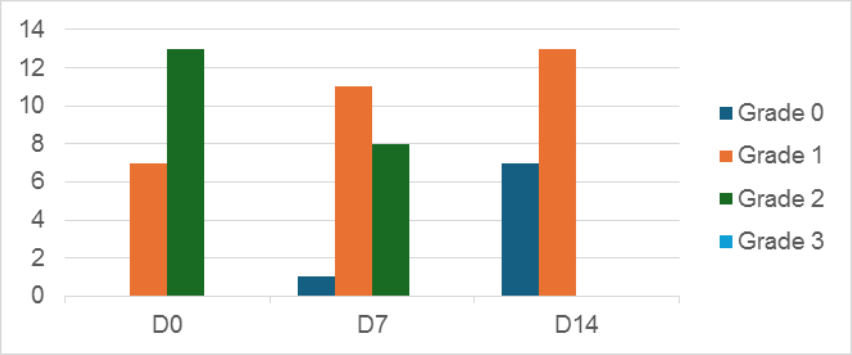

Figure No. 5: Distribution of patients before and after treatment for parameter SLR.

Table No. 9: Descriptive Statistics For Parameter SLR.

SLR	D0	D7	D14
Mean	1.65	1.35	0.65
SD	0.49	0.59	0.49
Median	2	1	1
Mode	2	1	1

At day 0 (before treatment), the mean SLR grade was 1.65 ± 0.49, indicating moderate limitation in Straight Leg Raising with low variability among patients.

At day 7, the mean SLR grade reduced to 1.35 ± 0.59, reflecting improvement in SLR with slightly increased variability.

At day 14, the mean further decreased to 0.65 ± 0.49, indicating continued improvement with reduced variability compared to day 7.

3. Schobers test

Table No. 10: Distribution of patients before and after treatment for parameter Schobers test.

Schobers test	D0	D7	D14
Grade 0	3	5	16
Grade 1	17	15	4

At day 0 (before treatment), 3 patients were in Grade 0, while the majority, 17 patients, were in Grade 1, indicating reduced lumbar flexion in most patients at baseline.

At day 7, improvement was observed. Grade 0 increased to 5 patients, while Grade 1 decreased to 15 patients.

At day 14, further improvement was noted. Grade 0 increased markedly to 16 patients, while Grade 1 reduced to 4 patients.

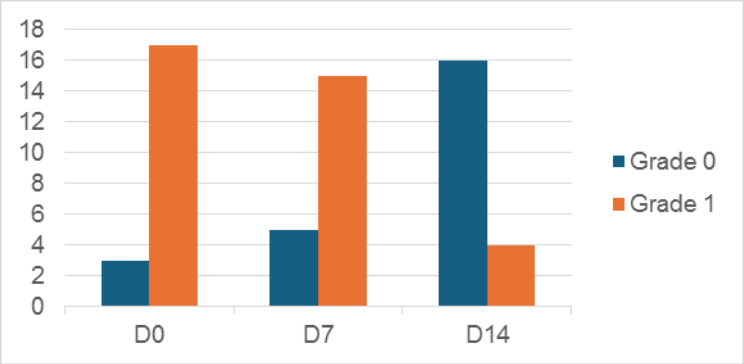

Figure No. 6: Distribution of patients before and after treatment for parameter Schobers test.

Table No. 11: Descriptive Statistics For Parameter Schobers test.

Schobers test	D0	D7	D14
Mean	0.85	0.75	0.20
SD	0.37	0.44	0.41
Median	1	1	0
Mode	1	1	0

At day 0 (before treatment), the mean Schober's test grade was 0.85 ± 0.37, indicating reduced lumbar flexibility with low variability among patients.

At day 7, the mean grade reduced to 0.75 ± 0.44, reflecting improvement in lumbar flexion with slightly increased variability.

At day 14, the mean further decreased to 0.20 ± 0.41, indicating marked improvement in lumbar flexibility with moderate variability.

4. VAS Grade

Table No. 12: Distribution of patients before and after treatment for parameter VAS Grade.

VAS Grade	D0	D7	D14
Grade 0	0	0	4
Grade 1	7	16	16
Grade 2	12	4	0
Grade 3	1	0	0

At day 0 (before treatment), no patients were observed in Grade 0, while 7 patients were in Grade 1, 12 patients in Grade 2, and 1 patient in Grade 3. Thus, the majority of patients were in Grade 2, indicating moderate pain at baseline.

At day 7, improvement was observed. No patients were in Grade 0, while Grade 1 increased to 16 patients. Grade 2 reduced to 4 patients, and no patients were present in Grade 3 at this stage.

At day 14, further improvement was noted. Grade 0 appeared in 4 patients, while Grade 1 remained in 16 patients. No patients were observed in Grade 2 or Grade 3 categories at this time point.

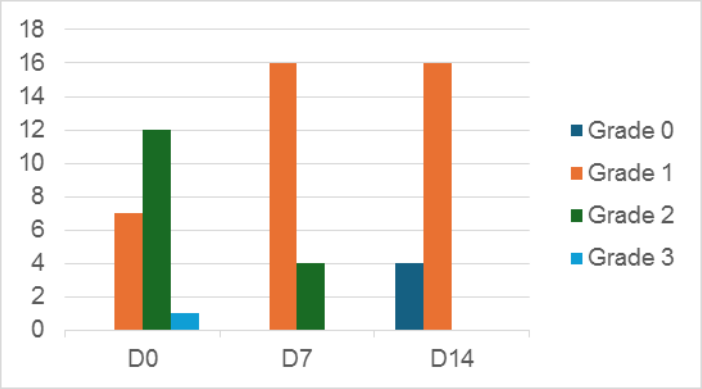

Figure No.7: Distribution of patients before and after treatment for parameter VAS Grade.

Table No. 13: Descriptive Statistics For Parameter VAS Grade.

VAS Grade	D0	D7	D14
Mean	1.70	1.20	0.80
SD	0.57	0.41	0.41
Median	2	1	1
Mode	2	1	1

At day 0 (before treatment), the mean VAS grade was 1.70 ± 0.57, indicating moderate pain severity with moderate variability among patients.

At day 7, the mean VAS grade reduced to 1.20 ± 0.41, reflecting improvement in pain severity with reduced variability.

At day 14, the mean further decreased to 0.80 ± 0.41, indicating continued reduction in pain with stable variability.

5.2 Statistical analysis within groups

Test of Normality

To determine whether the VAS Pain Score and other variables followed a normal distribution, the Kolmogorov-Smirnov & Shapiro–Wilk test was applied. A p-value less than 0.05 indicates deviation from normal distribution.

Table No. 14: Tests of Normality.

Parameter	Kolmogorov-Smirnov			Shapiro-Wilk		
	Statistic	df	p	Statistic	df	p
VAS Score	0.154	20	0.2	0.916	20	0.082
SLR	0.413	20	0.0001	0.608	20	0.0001
SCHOBERS Test	0.509	20	0.0001	0.433	20	0.0001
VAS GRADE	0.35	20	0.0001	0.736	20	0.0001

Interpretation

Significant p value indicates that Pain VAS Score data were normally distributed, whereas significant p value indicates that other variables were not normally distributed.

Inference

Non-parametric tests were considered appropriate for analysis of SLR, Schobers Test & VAS Grade, whereas parametric tests were considered appropriate for analysis of VAS Score.

Comparison of before and after treatment parameter values with Wilcoxon Signed Rank Test

To examine the effectiveness of Drug, a within-group analysis was conducted by comparing Before & After scores.

H0 (Null Hypothesis): There is no significant difference between Before & After Scores

H1 (Alternative Hypothesis): There is a significant difference between Before & After scores.

The Wilcoxon Signed-Rank Test was employed for the data on ordinal scale. This non-parametric test is appropriate for comparing paired observations before and after an intervention within the same group.

Table No.15: Analysis of Effect of treatment with Wilcoxon Signed Rank Test.

Parameter	N	Z value	p Value	Significance
SLR	20	-2.449	0.0001	Significant
VAS Grade	20	-3.162	0.0001	Significant

When comparing the values before treatment with those after treatment, significant difference was observed, with a p-value of less than 0.05, in SLR and VAS Grade. Hence treatment is effective in SLR and VAS Grade.

Comparison of before and after treatment parameter values with Paired T Test

The Paired t Test was employed for the data on continuous scale. Normality of the data was verified by Shapiro-wilk test. This parametric test is appropriate for comparing paired observations before and after an intervention within the same group.

Table No.16: Paired t test statistics for Group A parameters

VAS Score	Mean	N	Std. Deviation	Std. Error Mean
BT	4.05	20	1.57	0.35
AT	2.6	20	1.35	0.30

Table No.17: Paired t test analysis for Group A parameters.

Parameter	Mean	SD	SE	t	df	p
VAS Score	1.45	1.099	0.246	5.9	19	<0.0001

RESULT

Paired t-test was applied to assess the effect of treatment on VAS Score in Group A. The mean value decreased from 4.05 before treatment to 2.60 after treatment. The mean difference was 1.45 ± 1.099 with t = 5.9, df = 19, and p < 0.0001 (<0.05), which is statistically significant.

Interpretation

There is a statistically significant difference between before treatment and after treatment values of VAS Score in Group A.

Inference

Treatment in Group A significantly reduced VAS Score.

Comparison of before and after treatment parameter values with McNemar Test

The McNemar Test was employed for the data on Nominal scale with paired observations. This non-parametric test is appropriate for comparing paired observations before and after an intervention within the same group.

1. Schober's Test

Table No.18: Analysis of Effect of treatment with McNemar Test.

Before Treatment	After Treatment	
	0	1
0	3	0
1	2	15

N	20
P Value	0.5

Interpretation

There is no statistically significant difference between before treatment and after treatment distribution of Schober's Test. However, there is a slight improvement with increase in number of subjects in grade 0 after treatment.

Inference

Treatment showed no statistically significant improvement in Schober's Test, although a marginal improvement in distribution is seen after treatment.

5.3 Overall effect of treatment

Effect of therapy according to % relief in parameters

Table No.19: % relief in parameters.

Symptoms	BT	AT	Relieved	% Relief
VAS Score	81	52	29	35.80
SLR	33	27	6	18.18
Schobers test	17	15	2	11.76
VAS Grade	34	24	10	29.41
	Average % Relief			23.79

Average relief in symptoms was 23.79%.

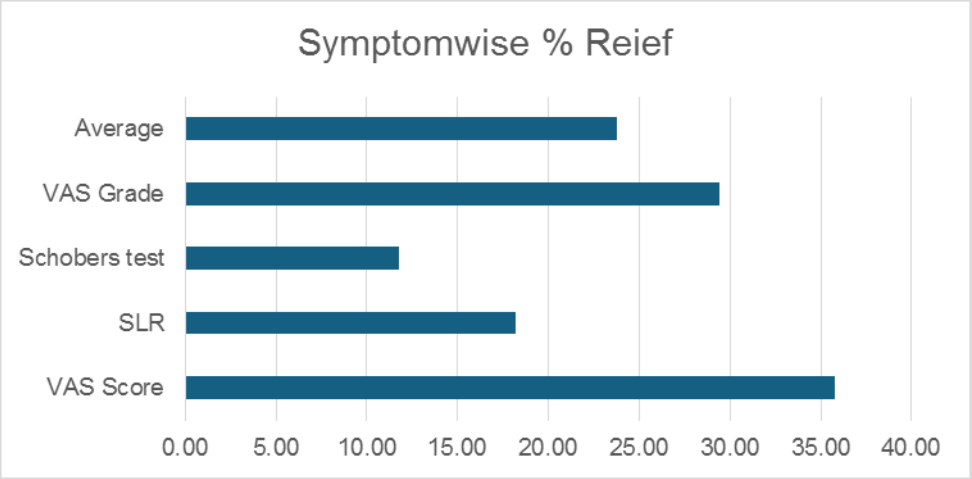

Figure No.8. % relief in parameters.

Effect of therapy according to % of relief in patients

Table No.20: Overall effect in all symptoms in patients.

SN	Total Before Treatment Score	Total After Treatment score	Relieved	% Relief	Overall Effect
1	5	3	2	40.00	Mild
2	4	3	1	25.00	Mild
3	5	3	2	40.00	Mild
4	5	4	1	20.00	Poor
5	2	1	1	50.00	Moderate
6	5	3	2	40.00	Mild
7	3	2	1	33.33	Mild
8	5	5	0	0.00	Poor
9	5	3	2	40.00	Mild
10	5	5	0	0.00	Poor
11	3	2	1	33.33	Mild
12	5	3	2	40.00	Mild
13	6	5	1	16.67	Poor
14	3	3	0	0.00	Poor
15	2	2	0	0.00	Poor
16	4	4	0	0.00	Poor
17	4	3	1	25.00	Mild
18	5	5	0	0.00	Poor
19	3	3	0	0.00	Poor
20	5	4	1	20.00	Poor

Average effect as per percent relief in patient= 21.17%

Distribution of Patients according to relief

Table No.21: Distribution of Patients according to relief.

Improvement	Trial Group	%
Poor	10	50%
Mild	9	45%
Moderate	1	5%
Marked	0	0%
Total	20	100%

Assessment of overall improvement in the trial group (n = 20) showed that 10 patients (50%) had poor improvement, representing the largest proportion.

Mild improvement was observed in 9 patients (45%), while moderate improvement was noted in 1 patient (5%). No patients were categorized under marked improvement.

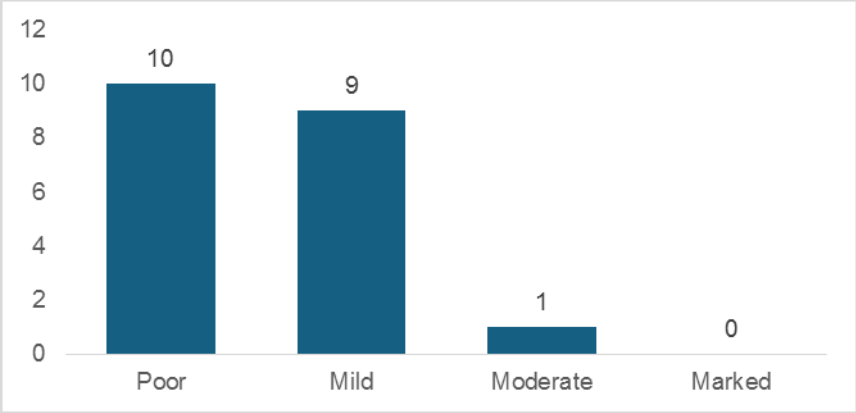

Figure No.9: Distribution of Patients according to relief.

DISCUSSION

The present prospective, open-label, single-arm pilot clinical study was undertaken to evaluate the clinical efficacy of Raktamokshana by Modified Shringa Yantra (Wet Cupping Therapy) in patients diagnosed with Katigatavata, a condition clinically comparable to chronic mechanical low back pain or lumbar spondylosis. All 20 enrolled participants completed the study, and no serious adverse events were observed, indicating that the intervention was feasible and well tolerated in an outpatient setting.

The principal finding of the study was a statistically highly significant reduction in pain intensity. The mean Visual Analogue Scale (VAS) score decreased from 4.05 ± 1.57 at baseline to 1.05 ± 0.69 on Day 14 ($p<0.0001$). Significant improvement was also observed in the Straight Leg Raising (SLR) test and VAS grading, whereas improvement in Schober's test did not achieve statistical significance. These findings suggest that Modified Shringa Yantra effectively reduces pain and improves functional ability in the short term.

Ayurvedic Interpretation

In Ayurveda, Katigatavata is understood under the broader spectrum of Vatavyadhi. According to Charak, aggravated Vata Dosha, either due to Dhatukshaya (tissue depletion) or Margavarana (obstruction to the normal movement of Vata), localizes in specific anatomical regions and produces pain, stiffness and restriction of movement.[7] The pathological process described in Ayurveda closely resembles the degenerative and inflammatory changes observed in lumbar spondylosis.

Among the Panchakarma procedures, Raktamokshana occupies a unique place in the management of localized painful disorders. Acharya Sushruta has described Shringa

Raktamokshana in Sutra Sthana, recommending it particularly in Vata-predominant disorders, where controlled suction removes vitiated blood and relieves localized pain.[8] Similarly, Acharya Vagbhata has emphasized Raktamokshana in Sutra Sthana, highlighting its role in alleviating pain, inflammation and obstruction by eliminating vitiated Rakta.[9]

The significant reduction in pain observed in the present study may therefore be explained by the removal of Dushta Rakta, reduction of Srotorodha, restoration of Vata Gati (Vatanulomana) and improvement in local tissue nutrition. Relief of Shoola, Stambha and Graha following Raktamokshana is consistent with the classical therapeutic principles described in the Ayurvedic texts.[7-9]

Interpretation of Clinical Findings

Pain is the predominant symptom of Katigatavata and has a direct impact on mobility and quality of life. In the present study, the highly significant reduction in VAS score suggests that Modified Shringa Yantra provides effective short-term analgesia. Improvement in the Straight Leg Raising (SLR) test further indicates reduction in muscular spasm and improvement in lumbar flexibility.

Although Schober's test demonstrated clinical improvement, statistical significance was not achieved. This finding may be attributed to the short follow-up period of only 14 days. While pain and muscle spasm may improve rapidly after intervention, restoration of lumbar mobility depends upon recovery of chronic soft tissue stiffness and degenerative structural changes, which generally require longer treatment duration and rehabilitation. Similar observations have been reported in previous clinical studies of chronic low back pain.[2-4]

Modern Scientific Interpretation

Wet cupping therapy has attracted increasing scientific interest because of its multiple physiological effects. Controlled negative pressure produces vasodilatation, increases local blood flow and enhances tissue oxygenation. Subsequent superficial scarification facilitates removal of stagnant blood together with inflammatory mediators and oxidative metabolites. Experimental studies have demonstrated that wet cupping may reduce levels of inflammatory cytokines, improve local microcirculation, decrease oxidative stress and stimulate endogenous opioid release, thereby producing analgesic and anti-inflammatory effects.[10-14][16]

Another proposed mechanism is activation of the Diffuse Noxious Inhibitory Control (DNIC) system, in which controlled nociceptive stimulation suppresses chronic pain perception through descending inhibitory neural pathways. In addition, improved lymphatic drainage and reduction of tissue edema may further contribute to pain relief and functional recovery.[16-17]

Comparison with Previous Studies

The findings of the present study are in agreement with previously published clinical trials and systematic reviews evaluating cupping therapy in chronic musculoskeletal disorders.

AlBedah et al. conducted a randomized controlled clinical trial in patients with persistent non-specific low back pain and reported significant reductions in pain and disability following wet cupping therapy compared with conventional management.[14]

Kim et al. performed a systematic review and concluded that cupping therapy may provide beneficial analgesic effects in patients with painful musculoskeletal conditions, although further high-quality randomized trials are required.[13]

Similarly, **Cao et al.** reviewed the available evidence and concluded that cupping therapy offers short-term pain relief in chronic musculoskeletal disorders but emphasized the need for improved methodological quality of future clinical studies.[12]

Mehta and Dhapte reviewed the biological mechanisms underlying cupping therapy and suggested that improved circulation, immunomodulation and activation of endogenous pain inhibitory pathways may explain its therapeutic effects.[11]

Rozenfeld and Kalichman highlighted the growing role of cupping therapy in musculoskeletal medicine and suggested that the procedure may be integrated safely with conventional rehabilitation strategies.[17]

Furthermore, **Teut et al.** demonstrated significant improvement in chronic low back pain using pulsatile dry cupping therapy in a randomized controlled trial, further supporting the therapeutic value of negative-pressure-based interventions in chronic spinal disorders.[18]

Unlike these studies, the present investigation evaluated the intervention within the classical Ayurvedic framework of Raktamokshana by Modified Shringa Yantra, employing

standardized Ayurvedic diagnostic criteria for Katigatavata together with validated clinical outcome measures. This integration of traditional Ayurvedic concepts with objective modern assessment tools enhances the scientific relevance of the present study.

Probable Mode of Action

The therapeutic effect of Modified Shringa Yantra is probably multifactorial.

From an Ayurvedic perspective, the procedure removes Dushta Rakta, reduces Srotorodha, relieves Margavarana, restores the normal movement of Vata, improves local tissue perfusion and ultimately alleviates Shoola, Stambha and Graha.[7-9]

From a modern biomedical perspective, negative pressure increases capillary perfusion, improves oxygen delivery, reduces local inflammatory mediators, facilitates removal of oxidative metabolites and activates endogenous analgesic mechanisms. These combined effects probably explain the significant reduction in pain and improvement in functional outcomes observed in the present study.[10-14] [16-18]

Clinical Implications

Recent international clinical practice guidelines recommend non-pharmacological interventions as first-line therapy for chronic low back pain because of the limited long-term benefits and potential adverse effects of prolonged analgesic therapy.[19-20] The findings of the present study suggest that Modified Shringa Yantra may serve as a safe, economical and minimally invasive outpatient procedure that can be integrated into multidisciplinary management of chronic mechanical low back pain corresponding to Katigatavata.

Strengths of the Study

The present study utilized standardized Ayurvedic diagnostic criteria together with validated clinical outcome measures including VAS, SLR and Schober's test. The intervention protocol was uniform for all participants, complete follow-up was achieved, and no serious adverse events occurred. The study also provides preliminary clinical evidence supporting the integration of classical Raktamokshana with contemporary clinical practice.

Limitations

The study has certain limitations. The sample size was relatively small and appropriate only for a pilot investigation. The absence of a control group limits direct comparison with conventional treatment or placebo. The follow-up period was limited to two weeks,

preventing evaluation of long-term efficacy and recurrence. Functional disability indices such as the Oswestry Disability Index, quality-of-life assessment, inflammatory biomarkers and radiological progression were not evaluated. Therefore, the findings should be interpreted as preliminary evidence requiring confirmation through adequately powered randomized controlled trials.

CONCLUSION

The present prospective single-arm pilot clinical study demonstrated that Raktamokshana by Modified Shringa Yantra (Wet Cupping Therapy) was associated with significant improvement in pain intensity and functional status among patients with Katigatavata (Lumbar Spondylosis). Statistically significant reductions were observed in the Visual Analogue Scale (VAS) score, Straight Leg Raising (SLR) grading and VAS grading following two treatment sittings administered one week apart. Although improvement was observed in Schober's test, statistical significance was not achieved, possibly because of the short duration of follow-up.

The procedure was well tolerated, and no serious adverse events were reported during the study period, suggesting that Modified Shringa Yantra is a feasible and safe intervention when performed under appropriate aseptic conditions by trained practitioners.

From the Ayurvedic perspective, the therapeutic effects may be attributed to the elimination of Dushta Rakta, relief of Margavarana, restoration of the normal movement of Vata (Vatanulomana), and improvement of local tissue perfusion as described in the classical texts. From a contemporary biomedical perspective, improved microcirculation, modulation of inflammatory mediators, reduction of oxidative stress, and activation of endogenous analgesic pathways may collectively contribute to the observed clinical benefits.

However, because this was a pilot study with a small sample size, no control group, and a short follow-up period, the findings should be interpreted as preliminary evidence rather than definitive proof of efficacy. Larger, adequately powered randomized controlled trials with longer follow-up, validated disability indices, quality-of-life assessment, imaging outcomes, and biomarker evaluation are required to establish the long-term effectiveness and mechanism of action of Modified Shringa Yantra in the management of Katigatavata.

Overall, the findings of the present study support the potential role of Raktamokshana by Modified Shringa Yantra as a safe, economical, minimally invasive, and clinically useful complementary intervention for the short-term management of Katigatavata, warranting further investigation through rigorous clinical research.

Clinical Significance

- Provides preliminary clinical evidence supporting the use of Modified Shringa Yantra in Katigatavata.
- Demonstrates significant short-term pain reduction with good patient tolerance.
- Offers a low-cost outpatient Panchakarma procedure that may reduce reliance on prolonged analgesic therapy.
- Supports integration of classical Ayurvedic principles with evidence-based clinical practice.

Strengths of the Study

- Prospective clinical study with predefined intervention and assessment schedule.
- Standardized protocol for Modified Shringa Yantra.
- Complete follow-up of all enrolled participants (100% retention).
- Use of validated outcome measures (VAS, SLR, and Schober's test).
- No serious adverse events, supporting procedural safety.
- Integration of classical Ayurvedic concepts with contemporary clinical assessment.

Limitations

- Small sample size (n = 20).
- Single-arm design without a control or comparator group.
- Open-label study, with potential for performance and observer bias.
- Short follow-up period (14 days), limiting evaluation of long-term outcomes and recurrence.
- Disability indices (e.g., Oswestry Disability Index), quality-of-life measures, imaging changes, and inflammatory biomarkers were not evaluated.
- Generalizability is limited because the study was conducted at a single center.

Future Scope

Future studies should focus on.

1. Multicenter randomized controlled trials with adequate sample size.

2. Longer follow-up to assess sustainability of clinical improvement.
3. Comparison with standard conservative management and sham cupping interventions.
4. Inclusion of validated disability scales such as the Oswestry Disability Index and Roland–Morris Disability Questionnaire.
5. Assessment of quality of life using standardized instruments (e.g., SF-36 or EQ-5D).
6. Evaluation of inflammatory biomarkers (CRP, IL-6, TNF-α) and oxidative stress markers.
7. Radiological assessment of lumbar degeneration where appropriate.
8. Cost-effectiveness analysis to evaluate feasibility in routine clinical practice.
9. Mechanistic studies exploring neurophysiological and microcirculatory changes induced by Modified Shringa Yantra.

Conflict of Interest

The authors declare no conflict of interest related to this study.

Informed Consent

Written informed consent was obtained from all participants before enrollment. Participants were informed about the study objectives, procedure, potential benefits, possible risks, confidentiality of data, and their right to withdraw from the study at any time without affecting their routine medical care.

Data Availability Statement

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request, subject to institutional policies and applicable ethical requirements.

Abbreviations

Abbreviation	Full Form
VAS	Visual Analogue Scale
SLR	Straight Leg Raising
IEC	Institutional Ethics Committee
ICMR	Indian Council of Medical Research
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
CRP	C-Reactive Protein
IL-6	Interleukin-6
TNF-α	Tumor Necrosis Factor-alpha

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