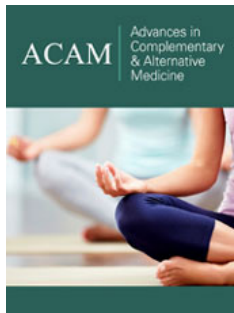


Efficacy of Agnikarma in Instant Pain Management for Sciatica: A Therapeutic Approach

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Abstract

Background: Low back pain, particularly sciatica, is a prevalent condition affecting 70-80% of the population. Sciatica, characterized by radiating pain along the sciatic nerve, is often caused by herniated discs and is associated with disability and increased healthcare costs. Ayurvedic treatments, including Agnikarma, have been proposed as effective interventions for managing sciatica symptoms.

Objective: The primary aim of this study was to clinically evaluate the efficacy of Agnikarma, based on Ayurvedic principles, in alleviating sciatica. Secondary objectives included examining potential untoward effects of Agnikarma in patients with sciatica.

Materials and Methods: A single-arm open-label clinical study was conducted at Dr. D.Y. Patil College of Ayurveda & Hospital, Navi Mumbai, with 50 participants. Patients with radiologically confirmed disc herniation and lumbo-sacral radicular syndrome lasting 6-12 weeks were selected. Agnikarma was performed using Rajat Shalaka (silver probe) for heat application on the affected area. The study employed weekly assessments of pain (Visual Analogue Scale - VAS), Straight Leg Raise (SLR) test, and other clinical parameters over 4 weeks.

Results: Statistically significant improvements were observed in pain reduction, range of motion (SLR), and pain intensity (VAS scores). The student's t-test and Wilcoxon signed-rank test revealed strong positive effects of the treatment with p-values < 0.0001, confirming that the intervention effectively reduced pain and improved mobility. No significant untoward effects were noted.

Discussion: Agnikarma showed promising results in the management of sciatica, with improvements in pain relief and functional mobility. The treatment's probable mode of action includes local heat stimulation, which enhances blood circulation, promotes healing, and stimulates the body's natural pain relief mechanisms.

Conclusion: This study supports the effectiveness of Agnikarma in treating sciatica, with statistically significant improvements in pain, mobility, and perceived pain intensity. Further research with larger sample sizes and longer follow-up periods is warranted to confirm the long-term benefits of this intervention.

Keywords: Sciatica; Agnikarma; Pain relief; Ayurvedic treatment; Visual analog scale; Straight leg raise test; Clinical study

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Introduction

Low back pain is a prevalent condition affecting 70% to 80% of the population, spanning all age groups, from children to the elderly. Among the various causes of low back pain, Sciatica is the most common. Sciatica involves pain that radiates along the sciatic nerve, extending from the lower back down one or both legs. The intensity of this pain often disrupts daily activities. According to Ayurvedic texts, the symptoms closely resemble those of Gridhrasi, a condition in which pain begins at the Sphik (hip) and extends to the Kati Prusta (lower back), Uru (thigh), Jaanu (knee), Jangha (calf), and Pada (foot). Along with pain, symptoms may include stiffness and heaviness, depending on the Dosha involved [1]. Sciatica has become one of the most common complaints across all age groups, both in India and abroad.

Contributing factors include improper sitting habits due to long hours of professional work, sudden jerky movements during travel or sports, the increasing trend of computer usage, mental stress, and weight gain, all of which exert undue pressure on the spinal structures and contribute to sciatica. Sciatica is characterized by radiating pain along the leg, typically affecting an area served by a single nerve root in the lumbar or sacral spine. The most common cause of sciatica is a herniated disc. In Western countries, the estimated annual incidence of sciatica is 5 cases per 1,000 adults. Disorders of the lumbar spine rank fifth in terms of hospital care costs and result in the highest expenses due to absenteeism from work and disability, surpassing other disease categories.

Aim & Objectives

- A. To clinically evaluate the efficacy of Agnikarma on the basis of scientific Ayurvedic principles in reversing or halting the process of Sciatica [2].
- B. To study the untoward effect of Agnikarma if any in the patients of Sciatica.

Materials & Methods

Source of materials

Rajat Shalaka (silver probe for Agnikarma) was used in the study conducted by the Department of Panchakarma.

Research place

A clinical survey was conducted on subjects attending the OPD and IPD of Unit 2, Department of Kaya-Chikitsa, Dr. D.Y. Patil College of Ayurveda & Hospital & Research Institute, Nerul, Navi Mumbai. Subjects who met the diagnostic criteria outlined in the Performa were selected for the study. Informed consent was obtained from all participants before initiating the interventions in each group. Ethical clearance for the study was granted by the IEC. The data collected during the clinical trial were statistically analyzed using Student's t-test & wilcoxon sign rank test.

Methods

Purva karma (pre-procedure measure)

Patient selection & consent: Only patients meeting the inclusion criteria for this procedure were selected. Written informed consent was obtained from the patient before proceeding.

Preparation of the affected area: The affected area, which is located about four angulas above or below the Janu (knee) on the back of the affected limb, was thoroughly cleaned with Triphala Kashaya (a medicinal decoction).

Dietary instructions: The patient was advised to take a Pichchhila diet before the procedure. A Pichchhila diet typically

consists of soft, moist foods that are easy to digest and soothing for the body.

Agropaharaniya (equipments required for Agnikarma) [3]

This term refers to the preparations made for the procedure. The following items were kept ready:

Rajat shalaka (silver probe): A specially designed, bindu-type (pointed) probe for applying heat.

Other instruments: Gas stove, candle, artery forceps, gauge pieces, spirits (for sterilization), Mahatiktaka Ghrita (a medicated ghee), Yashtimadhu (licorice), Gairik (a red powder used in Ayurvedic treatments), Haridra Churna (turmeric powder), and cotton were all prepared in advance.

Pradhana karma (Principal procedure)

Positioning: The patient was made to lie in a prone position (face down) for the procedure.

Area preparation: The affected area was thoroughly washed again with Triphala Kashaya and allowed to dry.

Heat application: The Shalaka was heated until it was red-hot, and small, burn-like marks were created on the marked points. This line covered the dorsal surface of the lower leg, either above or below the Janu Sandhi (knee joint).

Signs of correct procedure: The marks created on the skin should show Dagdha Lakshanas (burn-like symptoms) like:

- a) Shabdapradurbhava (sound or sensation),
- b) Durgandhata (foul smell),
- c) Twaka Sankocha (skin contraction) [4].

Paschata karma (post-procedure measure)

Post-procedure care: After the procedure, the area was treated with the application of Mahatiktaka Ghrita, Yashtimadhu, and Gairik to soothe and heal the affected area.

Observation: The patient was carefully monitored for any complications that might arise during or after the procedure.

Post-procedure instructions: The patient was advised to Table 1:

- a) Keep the treated area clean and dry,
- b) Avoid excessive physical exertion,
- c) Avoid any trauma to the area,
- d) Follow a wholesome diet conducive to healing.

Table 1: Methodology.

Details of Procedure	Agnikarma
Study design	Single Arm open labelled clinical study
Sample size	50

Ingredients	Rajat yukta Shalaka Agnisadhana (equipment's) required for agnikarm
Procedure	
a) Purvakarma	1) Written Consent
	2) Pichhil Annasevan
	3) Dhavan-Triphala kashaya
b) Pradhankarma	1) Identification of site
	2) Agnidagdha site:- 4 fingers above or below Janu sandhi (lateral aspect)
c) Paschyatkarma	1) Application of Mahatiktak Ghrita + Gairik + Yashtimadhu
	2) Observation of Dagdha Vrana
	3) Watch for any complication if any
Dose	One or two Bindu
Kala Type of Basti / Agnikarma	After Pichhil Annasevan Binduvata
Route of Administration	Bahya
Duration	After every 7 days for 4 weeks

Inclusion criteria

- Patients of any age, sex, race, or religion.
- Patients with a positive Straight Leg Raising (S.L.R) test.
- Radiologically confirmed disc herniation.
- Lumbo-sacral radicular syndrome lasting 6-12 weeks.

Exclusion criteria

- Patients with infectious diseases, such as HIV, HBs-Ag positive, or Koch's.
- Patients with Pott's disease, cauda equina syndrome, or muscle paralysis.
- Patients with metabolic disorders, including Diabetes Mellitus.
- Patients who have undergone previous spine surgeries, have bony stenosis, spondylolisthesis, or are pregnant.
- Patients with skin diseases.

Parameter of Assessment

The clinical assessment was performed based on the following key areas:

- Assessment of Efficacy

A) Subjective Improvement

This involved evaluating the patient's self-reported experience

of pain. This factor was assessed on a weekly basis over a 4-week period.

B) Objective Improvement

The objective improvement was evaluated using various clinical tests and scales:

- Straight Leg Raise (SLR) Test.
- Visual Analogue Scale (VAS).

Assessment of tolerability and other parameters

The assessment also focused on how well the patient tolerated the procedure and the treatment protocol. This included considerations such as

Premature discontinuation: Whether the patient stopped the treatment early, and the reasons for discontinuation.

Incomplete cases: Instances where the patient did not complete the treatment protocol.

Unsatisfactory or cured cases: Classification of cases based on the outcome of the treatment, categorizing them as either unsatisfactory or cured.

Assessment of efficacy (detailed guidelines)

Patients were evaluated weekly according to the following guidelines for 4 weeks:

A. Subjective Assessment (Tables 2-6)

Table 2: Gradation of clinical symptoms -Subjective Parameter.

Lakshana (Clinical Symptoms)	Grade 0	Grade 1	Grade 2	Grade 3
(Pain)	No pain	Mild (+) pain complained by patient when asked	Moderate (++) patient frequently complains of pain & has painful look	Severe (+++) excruciating pain associated with painful cries & agonizing look

Table 3: Gradation of clinical signs.

Sr. No.	Clinical Signs	Absent 0	Mild (+) 1	Moderate (++) 2	Severe (+++) 3
1	SLR Test	SLR 90	SLR 61-80	SLR 31-60	SLR 0-30 degree
2	VAS	0	0-3	04-Jun	07-Oct

Table 4: Gender wise distribution.

Sex	Male	Female
	18	32

Table 5: Age wise distribution.

Age	20-40	41-60	More than 60 years
	13	26	11

Table 6: Chronicity wise distribution.

Chronicity	0-6 months	6 months -2 years	More than 2years
	15	26	9

The pain was reviewed each week, and patients were asked to report any changes. Pain was measured using a four-grade scale (0-3) based on the following criteria

Severity: The intensity of pain or tenderness experienced.

Duration: How long the symptoms have been present.

Stage: The progression of symptoms from initial onset to current status.

The statistical analysis involved assessing various outcomes such as pain, Straight Leg Raising (SLR), and Visual Analog Scale (VAS) scores Before Treatment (BT) and After Treatment (AT). The statistical methods used for analyzing these outcomes were the Student's t-test and the Wilcoxon signed-rank test, and the results indicated statistically significant changes across all the measures [5].

B. Pain Assessment (Using Student's t-test) (Figures 1-3)

a) **Before Treatment (BT) Mean:** 2.24

b) **After Treatment (AT) Mean:** 0.54

c) **Mean Difference:** 1.4 (indicating a reduction in pain after treatment)

d) **t-value:** 17.324 (this is the test statistic value used to determine significance)

e) **One-tailed p-value:** <0.0001 (p-value indicates a very strong statistical significance)

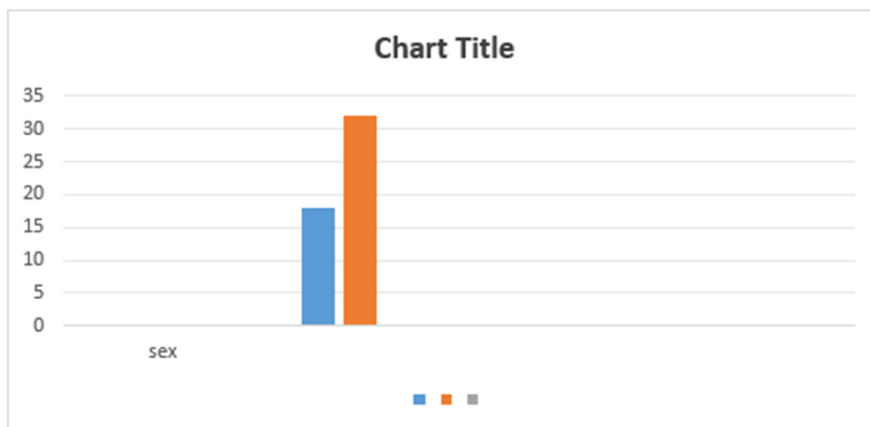


Figure 1: Gender wise distribution.

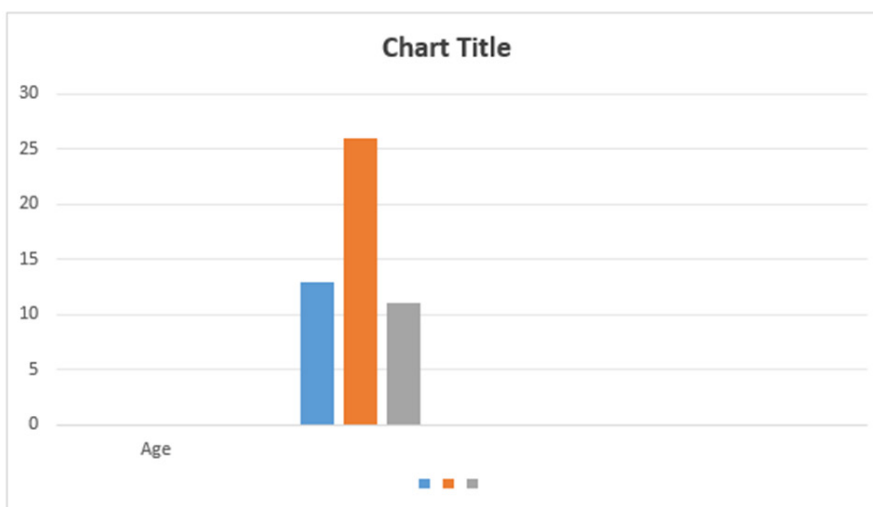


Figure 2: Age wise distribution.

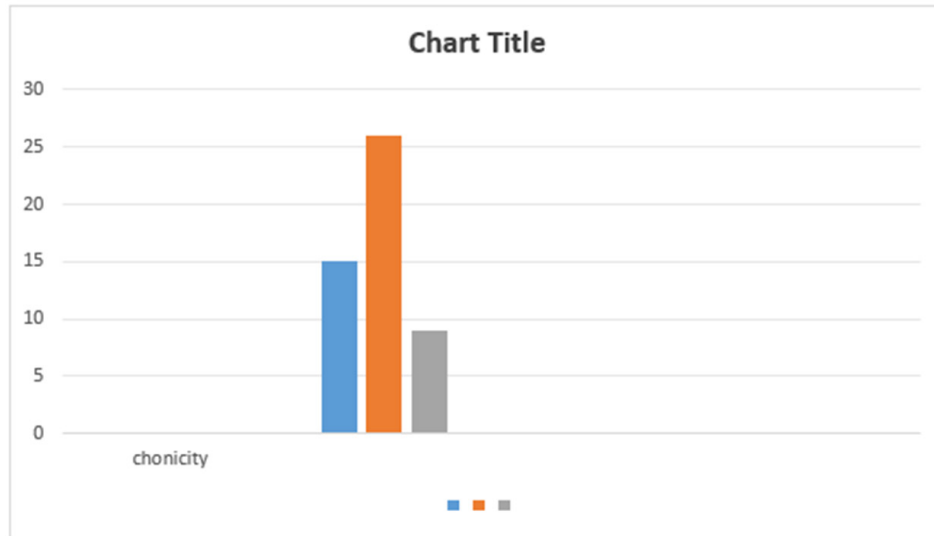


Figure 3: Chronicity wise distribution.

Interpretation

- The Student's t-test was applied to assess the difference in pain levels before and after treatment. A mean difference of 1.4 suggests a substantial reduction in pain following the intervention.
- The t-value of 17.324 is significantly high, which reflects the magnitude of the difference between the means.
- A p-value of <0.0001 indicates an extremely significant result, confirming that the observed reduction in pain is unlikely to have occurred by chance. Hence, this result is considered statistically significant.

I. Straight Leg Raise (SLR) Assessment (Using Wilcoxon Signed-Rank Test)

- Before Treatment (BT) Mean: 6.12
- After Treatment (AT) Mean: 3.68
- Mean Difference: 2.44 (indicating improvement in range of motion after treatment)
- Spearman Correlation Coefficient (r): -0.8147 (indicating a strong negative correlation between BT and AT scores)
- One-tailed p-value: <0.0001 (indicating statistical significance)

Interpretation

- The Wilcoxon signed-rank test was used to analyze the improvement in straight leg raising, a key indicator of lower back or leg mobility.
- The mean difference of 2.44 signifies a notable improvement in SLR after treatment.
- The Spearman correlation coefficient (r=-0.8147) indicates a strong negative correlation between BT and AT

values. This suggests that as the values of SLR before treatment increase, the values after treatment decrease, confirming improvement.

- A p-value of <0.0001 signifies that the observed improvement in SLR is statistically significant, further reinforcing the effectiveness of the treatment.

I. Visual Analog Scale (VAS) Assessment (Using Wilcoxon Signed-Rank Test)

- Before Treatment (BT) Mean: 2.42
- After Treatment (AT) Mean: 1.44
- Mean Difference: 0.98 (indicating reduction in perceived pain intensity)
- Spearman Correlation Coefficient (r): -0.4365 (moderate negative correlation)
- One-tailed p-value: <0.0001 (indicating statistical significance)

Interpretation

- The Wilcoxon signed-rank test was also applied to evaluate the reduction in pain intensity, as indicated by the VAS scores before and after treatment.
- The mean difference of 0.98 suggests that the treatment resulted in a reduction in perceived pain intensity.
- The Spearman correlation coefficient (r=-0.4365) indicates a moderate negative correlation, meaning that higher pain scores before treatment tend to correspond to lower pain scores after treatment.
- The p-value of <0.0001 confirms the statistical significance of the result, meaning the reduction in VAS scores is highly likely to be due to the treatment.

Discussion

The results of this study demonstrate a clear and statistically significant improvement in various outcome measures following the treatment. The key assessments involved evaluating pain reduction, improvement in Straight Leg Raising (SLR), and changes in Visual Analog Scale (VAS) scores. The findings from the statistical analyses, including the Student's t-test and Wilcoxon signed-rank test, suggest that the intervention provided substantial benefits to the participants in terms of pain relief and functional improvement.

Pain assessment

The reduction in pain, as measured by the mean difference of 1.4 (from 2.24 before treatment to 0.54 after treatment), highlights the efficacy of the intervention in managing pain. The student's t-test revealed a high t-value of 17.324 and an extremely low p-value (<0.0001), which indicates that the observed improvement is highly significant. This suggests that the treatment successfully alleviated pain and that the observed results are not due to random chance. Pain management is crucial in many clinical conditions, and these findings support the effectiveness of the intervention in addressing pain-related symptoms.

Straight Leg Raise (SLR) assessment

The SLR test measures the range of motion in the lower back and legs, which is an important indicator of mobility. The improvement in SLR, with a mean difference of 2.44 (from 6.12 before treatment to 3.68 after treatment), suggests that the treatment helped improve the range of motion. The negative correlation (Spearman's $r = -0.8147$) further strengthens the result, indicating that as the SLR values improved (lower values post-treatment), the mobility of participants significantly increased. The p-value of <0.0001 confirms that the improvement in SLR is statistically significant. This result demonstrates the positive impact of the treatment on the functional mobility of the participants, which could be crucial for individuals suffering from musculoskeletal or neurological conditions that impair lower limb mobility.

Visual Analog Scale (VAS) Assessment [6]

The VAS is a widely used tool for assessing the intensity of pain, and the reduction in VAS scores by 0.98 (from 2.42 to 1.44) indicates a moderate decrease in the perceived pain intensity. Although the Spearman correlation coefficient for VAS scores ($r = -0.4365$) suggests a moderate negative correlation between the pre-treatment and post-treatment scores, the observed reduction in pain is still statistically significant, as indicated by the p-value of <0.0001 . This suggests that the intervention had a meaningful impact on participants' perceptions of pain, and the moderate correlation suggests that the change in pain intensity was consistent across the sample, albeit to varying degrees.

Clinical implications

The findings of this study provide valuable insights into the efficacy of the treatment in managing pain and improving functional mobility. A reduction in pain is often the first step in improving

a patient's overall quality of life, and the improvement in SLR suggests that the treatment not only alleviates pain but also helps restore mobility, an important aspect of functional independence. The statistically significant improvements across all measures (pain, SLR, and VAS) underline the robustness of the intervention. The high statistical significance (p-values <0.0001) across all tests further validates the clinical effectiveness of the treatment.

Limitations and future research

While the results are promising, it is important to consider the limitations of the study. The sample size, gender, and age distribution, as well as the chronicity of the condition, may affect the generalizability of the findings. For instance, the majority of participants were female (32 vs. 18 males), and the majority had chronic conditions of varying durations. Future studies should explore the impact of the treatment across different demographics and conditions to assess its generalizability. Additionally, longer follow-up periods could provide insight into the long-term efficacy of the intervention.

Probable mode of action [7]

Application of Agni or local heat increases the local temperature which enhances the perfusion and does efficient delivery of oxygen to the tissues. Because of the better blood perfusion ischemia and degeneration related tissue injury gets healed. There is clearance of local inflammatory mediators and so inflammation is resolved and finally pain is reduced. Agnikarma also stimulates DPI (descending pain inhibiting mechanism) which further stimulates CNS. After this there is release of endogenous opioids in proopiomelanocortin (POMC) cells in the arcuate nucleus and in the brain stem and thus reduction of pain occurs. The probable mode of action of Agnikarma can also be explained through the gate control theory of pain. This theory explains that non-painful input closes the nerve gates to painful input which prevents pain sensation from travelling to the CNS. This theory explains how non-painful sensations can override and reduce painful sensations.

The local heat act as touch stimulus which increases large fiber activity and it has inhibitory effect on pain signals. According to Vant Hoff's principle the basal metabolism of the body increases by certain percentage for every 1 degree rise in body temperature. Rise in temperature induces relaxation of muscles and hence muscle spasm with inflammation and pain gets reduced. Muscle relaxes most readily when tissues are warm which in turn reduces the spasm, inflammation and pain. As per ayurveda principles Agnikarma removes Srotasavarodh (obstruction of micro-channels) and improves local blood circulation and neutralizes Sheeta, Chala, Khara, and Ruksha Guna of Vyana Vaya (responsible for all movements)

Effect on metabolism

Acc to scientist Dr. VenHanff, the place where heat burns the local tissue metabolism is improved, Thus various metabolic and rejuvenating changes takes places at the site of heat burns, thus it leads to increased demand of oxygen and nutrient of the tissues at

the site of heat burn. It also excretes the unwanted metabolites and toxins

Effect on the blood circulation

After performing Dahan the superficial sensory nerves get stimulated which leads to dilatation of local blood vessels, resulting in increased blood circulation. Apart from this it also decreases the viscosity of blood and thus leads to decreased blood pressure

Effect on pain

Due to increased local metabolism, the waste products (metabolites) which are produced gets excreted, which normalizes the blood circulation thus resulting in reduction in intensity of pain

Effect of heat on nerves

Provided that the heating is not excessive, it appears to reduce the excitability (quick response to stimuli) of nerves

Effect of heat on general rise temperature

There may be generalizing dilatation of the heated blood on the centres concerned with regeneration of the body temperature. Heating affects the vasomotor centres causing general rise in temperature.

Conclusion

This study provides strong evidence for the effectiveness of the treatment in reducing pain, improving straight leg raise mobility,

and decreasing the perceived pain intensity as measured by the VAS. The statistically significant changes observed in all outcome measures suggest that the intervention has the potential to improve both the functional and pain-related aspects of patients' conditions. These findings are consistent with previous studies in the field, further supporting the role of this treatment in clinical practice.

Competing interests

Author have declared that no competing interests exist.

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