Research Article

www.ijrap.net

(ISSN Online:2229–3566, ISSN Print:2277–4343)

A RANDOMISED COMPARATIVE CLINICAL STUDY TO EVALUATE THE RELATIVE EFFECT OF PRAGBHAKTA AND ADHOBHAKTA AUSHADHA SEVANA KALA IN GRIDHRASI

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Received on: 18/1/26 Accepted on: 28/2/26

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DOI: 10.7897/2277-4343.17255

ABSTRACT

Background: Aushadha Sevana Kala (time of drug administration) is an important Ayurvedic principle that optimizes drug efficacy by aligning treatment with physiological rhythms. Chronopharmacology supports time-dependent variations in disease activity and drug response. Despite detailed classical descriptions, clinical validation of this concept remains limited. Aim: To evaluate the clinical impact of Aushadha Sevana Kala on therapeutic outcomes using Vatagajankusha Rasa in Gridhrasi (Sciatica). Materials and Methods: A randomized comparative clinical study was conducted on 30 Gridhrasi patients, divided into two groups (n=15 each). Group A received Vatagajankusha Rasa in Pragbhakta Kala (before food), while Group B received it in Adhobhakta Kala (after food) for 15 days. Assessments were done at baseline, post-treatment, and one-week follow-up, with intra- and inter-group statistical analysis. Results: Both groups showed statistically significant improvement in all clinical parameters. Group A (Pragbhakta Kala) demonstrated comparatively better clinical improvement. Inter-group comparison revealed a statistically significant difference only in stiffness ($P < 0.05$), while other parameters did not show statistically significant differences. Conclusion: The study supports the classical concept of Aushadha Sevana Kala, emphasizing the role of proper drug timing in improving therapeutic outcomes in Gridhrasi. Further large-scale studies are needed to validate these findings across different conditions.

Keywords: Aushadha Sevana Kala, Chronotherapeutics, Circadian rhythm, Gridhrasi, Vatagajankusha Rasa, Drug Administration Timing.

INTRODUCTION

Kala (time) is a fundamental Ayurvedic principle governing biological rhythms that influence health and disease[1]. It regulates Dosha (bio-regulatory principle) dynamics—Chaya (Accumulation), Kopa (Aggravation), and Prashama (Alleviation)-thereby affecting disease onset, progression, and resolution[2]. Therapeutic success depends not only on drug selection but also on appropriate timing with respect to disease stage, Agni (Digestive fire), Ṛtu (Season), and Prakrti (Body constitution)[3].

Aushadha Sevana Kala is an important clinical application of Kala[4]. Classical texts describe multiple timings—ten Kalas by Charaka and Sushruta, eleven Kalas by Vagbhata[5], and five explained by Sharngadhara.Despite strong textual support, clinical validation remains limited. Pragbhakta Kala (before food) is indicated in Apana Vata (downward-moving subtype of Vata) disorders and diseases of the lower body. Gridhrasi, a Vatavyadhi(Disease caused by Vata), presents with radiating pain from Sphik (gluteal region) to Pada (Ankle), along with Ruk (Pain), Toda (Pricking Pain), Stambha (Stiffness), Spandana (Fasciculation), and restricted movements[6].

Vatagajankusha Rasa[7], a classical formulation for Vata (one of the three fundamental bio-regulatory principles) disorders, is commonly used in Gridhrasi. Hence, this study evaluates the clinical impact of Aushadha Sevana Kala using Vatagajankusha Rasa in Gridhrasi.

Aim and Objectives

- To evaluate the efficacy of Vatagajankusha Rasa administered in Pragbhakta Kala in patients of Gridhrasi.
- To evaluate the efficacy of Vatagajankusha Rasa administered in Adhobhakta Kala in patients of Gridhrasi.
- To compare the therapeutic efficacy of Vatagajankusha Rasa administered in Pragbhakta Kala and Adhobhakta Kala in patients of Gridhrasi.

MATERIALS AND METHODS

Study Design: The present study was an open-label, randomized, comparative, interventional clinical trial with parallel group assignment.

Study Settings: The study was conducted in the Outpatient Department (OPD) of the institute.

Sample Size: A total of 30 clinically diagnosed patients of Gridhrasi were enrolled in the study.

Randomization: Patients fulfilling the inclusion criteria were randomly allocated into two groups (Group A and Group B) with 15 patients in each group, using computer-generated random numbers.

Intervention

Group A: Vatagajankusha Rasa was administered in a dose of 125 mg twice daily (BD) in Pragbhakta Kala for 15 days along with Ushna Jala (Warm Water) as Anupana (adjuvant).

Group B: Vatagajankusha Rasa was administered in a dose of 125 mg twice daily (BD) in Adhobhakta Kala for 15 days along with Ushna Jala as Anupana.

Assessment Criteria: Detailed clinical history and physical examination were carried out in all patients using a pre-designed and pre-validated case proforma.

Outcome Measures: Clinical assessment was performed at baseline (before treatment), after completion of treatment, and at one-week follow-up after cessation of therapy. The following parameters were assessed:

- Pain (Visual Analogue Scale – VAS)[8]
- Stiffness
- Tenderness
- Straight Leg Raising Test (SLR)
- Oswestry Disability Index (ODI)[9]

Diagnostic Criteria: Diagnosis of Gridhrasi was made based on classical signs and symptoms, including:

- Radiating pain extending from Sphik → Kaṭi (Hip) → Uru (Thigh) → Janu (Knee) → Jangha (Calf) → Pada
- Associated symptoms such as Toda, Stambha, and Spandana.

Inclusion Criteria

- Patients presenting with classical signs and symptoms of Gridhrasi
- Pain intensity ≤ Grade 5 on Visual Analogue Scale (VAS)
- Age between 30 and 60 years, irrespective of gender
- Patients willing to participate and comply with study protocol, after obtaining informed consent from them.

Exclusion Criteria

- Congenital anomalies of the spine.
- Fracture, neoplastic conditions, or tuberculosis of the spine.
- Cauda equina syndrome or entrapment neuropathy.
- Uncontrolled Diabetes Mellitus, Hypertension, or severe neurological deficits.

Statistical Analysis

- The collected data were analysed for intra-group and inter-group significance.
- Wilcoxon Signed-Rank Test was applied for intra-group analysis.
- Mann–Whitney U test was used for inter-group comparison.
- $P < 0.05$ was considered statistically significant.

OBSERVATIONS AND RESULTS

Effect of Treatment on Pain

On intra-group analysis, both Group A and Group B demonstrated statistically significant reduction in pain scores at both Before Treatment (BT)–After Treatment (AT) and Before Treatment (BT)–After follow up (AF) intervals. In both groups, all patients showed improvement with no negative ranks, and Wilcoxon Signed Rank Test revealed highly significant results ($p < 0.01$ to $p < 0.001$). Inter-group comparison using the Mann–Whitney U test showed no statistically significant difference between Group A and Group B at BT–AT ($p = 0.509$) and BT–AF ($p = 0.726$) intervals.

Effect of Treatment on Stiffness

Intra-group analysis revealed that both Group A and Group B showed statistically highly significant reduction in stiffness at BT–AT and BT–AF intervals ($p < 0.001$). Inter-group comparison demonstrated a statistically significant difference favouring Group A at both BT–AT ($p = 0.0182$) and BT–AF ($p = 0.025$) intervals.

Effect of Treatment on Oswestry Disability Index (ODI)

Both Group A and Group B exhibited statistically highly significant improvement in functional disability as assessed by the Oswestry Disability Index at BT–AT and BT–AF intervals ($p < 0.001$). However, inter-group comparison revealed no statistically significant difference between the two groups at BT–AT ($p = 0.131$) and BT–AF ($p = 0.262$).

Effect of Treatment on Tenderness

Intra-group analysis showed statistically significant to highly significant reduction in tenderness scores in both Group A and Group B at BT–AT and BT–AF intervals ($p < 0.01$ to $p < 0.001$). Inter-group comparison revealed no statistically significant difference between the two groups at BT–AT ($p = 0.631$) and BT–AF ($p = 0.726$).

Effect of Treatment on Straight Leg Raising (SLR)

Both groups showed statistically highly significant improvement in Straight Leg Raising test values at BT–AT and BT–AF intervals ($p < 0.001$). Inter-group comparison did not show any statistically significant difference between Group A and Group B at BT–AT ($p = 0.645$) and BT–AF ($p = 0.222$).

Table 1: Comparison of Percentage Improvement Between Groups

Parameter	Group A		Group B	
	BT-AT	BT-AF	BT-AT	BT-AF
Pain	28.11%	50.55%	38.77%	48.77%
Stiffness	47.11%	62.22%	38.33%	53.88%
Oswestry	24.33%	33.88%	20.11%	28.78%
Tenderness	41.66%	56.11%	35%	46.88%
SLR	43.88%	69.44%	31.33%	46.22%

BT: Before Treatment, AT: After Treatment

Table 2: Overall Therapeutic Effect of Treatment in Both Groups

Overall effect	Group A		Group B	
	Numbers	%	Numbers	%
Marked improvement	3	20%	0	0%
Moderate improvement	6	40%	1	6.66%
Mild improvement	4	26.66%	12	80%
No improvement	2	13.34%	2	13.34%
Total	15	100%	15	100%

DISCUSSION

Effect of Aushadha Sevana Kala

The present study evaluated the clinical relevance of Aushadha Sevana Kala, specifically Pragbhakta and Adhobhakta Kala, in the management of Gridhrasi using Vatagajankusha Rasa. Group A (Pragbhakta Kala) clinically demonstrated comparatively better improvement in pain, although inter-group comparison was not statistically significant, possibly due to enhanced Agni bala and improved drug absorption when administered before food. Statistically significant relief in stiffness was also observed in Group A, indicating better Srotoshodhana and Vata–Kapha pacification. Both groups showed comparable improvement in the Oswestry Disability Index (ODI); however, Group A exhibited a higher mean reduction and better clinical improvement, suggesting relatively faster restoration of functional ability. Improvement in tenderness was clinically more pronounced in Group A, and Straight Leg Raise (SLR) assessment also revealed better clinical improvement in Group A compared to Group B. These findings indicate that drug administration before food may

enhance therapeutic efficacy, particularly in conditions involving Apana Vata and the lower part of the body, as described in classical texts.

Probable Mode of Action of Vatagajankusha Rasa in Gridhrasi

The formulation studied Vatagajankusha rasa, prepared using 8 parts each of Parada (Mercury) and Kupilu *(Strychnos nux-vomica)*, 3 parts each of Gandhaka (Sulphur), Triphala, Trikatu was found to be clinically effective in improving symptoms of Gridhrasi. This action is due to the judicial combination of ingredients present in the product. Trikatu and kupilu act as vata kapha hara (Correcting Vata and Kapha, 2 amongst 3 fundamental bio-regulatory principles), kajjali and triphala are tridoshahara(Correcting all 3 fundamental bio-regulatory principles). Kajjali acts as yogavahi (Bio-enhancer) and as per Rasatarangini reference and it improves the action of ingredients with which it is administered showing its bio-efficacy. So, these factors help in samprapti vighatana of Gridhrasi.

Kupilu has been documented to have analgesic and anti-inflammatory properties[10]. Kupilu contains compounds like Brucine, which can inhibit pre-inflammatory factors like TNF-α and prostaglandin synthesis. These were reducing pain and inflammation. *Strychnos nux-vomica* seeds may help alleviate symptoms by reducing oxidative stress, enhancing antioxidant capacity, restoring muscle mass, and improving motor and sensory functions[11]. Trikatu are known to have anti-inflammatory, analgesic and antioxidant properties[12]. Triphala exhibits anti-inflammatory, antioxidant and neuroprotective effects in sciatica, improving nerve conduction and reducing hyperalgesia and allodynia. It lowers pro-inflammatory cytokines (TGF-β, TNF-α, IL-1β) and enhances NGF expression, with histopathological evidence supporting its neuroprotective action[13]. Kajjali is used as a bio-enhancer. In traditional formulations, it acts as a catalyst to boost the bio-availability, absorption and effectiveness of drugs, it acts as a catalyst of other medicinal ingredients and effectiveness of other medicinal ingredients.[14,15]

In total it can be said that Vatagajankusha rasa acts in Gridhrasi through aamahara (Ama-digestive) and Vata-Kapha hara actions as well as by providing anti-inflammatory, analgesic, neuroprotective, and nerve strengthening effect, in addition to overcoming circulation and offer muscle relaxing properties.

CONCLUSION

The present study substantiates the classical Ayurvedic concept that Aushadha Sevana Kala significantly influences therapeutic outcomes. Although Vatagajankusha Rasa was effective in both administration timings, Pragbhakta Kala demonstrated superior clinical efficacy, particularly in reducing stiffness, improving functional outcomes, and achieving sustained therapeutic benefits in Gridhrasi. These findings provide clinical validation for classical textual references and emphasize the need to incorporate appropriate drug timing into routine Ayurvedic practice. However, a large sample study is required to draw an effective conclusion.

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Cite this article as:

Parikshith K, Satyanarayana B and J Dinesh Nayak. A randomised comparative clinical study to evaluate the relative effect of Pragbhakta and Adhobhakta aushadha sevana kala in Gridhrasi. Int. J. Res. Ayurveda Pharm. 2026;17(2):78-80
DOI: http://dx.doi.org/10.7897/2277-4343.17255

Source of support: Nil, Conflict of interest: None Declared