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A Comparative Clinical Evaluation Of Effect Of Agnikarma With Tamra Shalaka Over Siravyadhana Along With Trayodashanga Guggulu In The Management Of Gridrasi – A Clinical Trial

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Abstract: Background: Gridhrasi (Sciatica) is a prevalent condition marked by pain, numbness, and functional limitation along the sciatic nerve, impacting daily activities. Ayurveda offers targeted therapies such as Agnikarma (therapeutic cauterization) and Siravyadhana (therapeutic venesection), often combined with oral formulations like Trayodashanga Guggulu.

Objective: To evaluate and compare the clinical efficacy of Agnikarma with Tamra Shalaka versus Siravyadhana, both alongside Trayodashanga Guggulu, in the management of Gridhrasi.

Methods: In this randomized comparative clinical trial, 48 patients diagnosed with Gridhrasi were equally allocated into two groups. Group A received Agnikarma with Tamra Shalaka plus Trayodashanga Guggulu, while Group B received Siravyadhana with Trayodashanga Guggulu. Treatment outcomes were assessed using subjective parameters (Ruk, Sthamba, Toda, Gaurava) and objective parameters (SLR) at baseline and post-treatment.

Results: Both groups demonstrated statistically significant improvement in pain relief, functional mobility, and overall patient satisfaction. Group A exhibited slightly faster onset of relief and slight reduction in pain scores and disability indices compared to Group B, indicating a superior therapeutic effect of Agnikarma with Tamra Shalaka. No major adverse effects were reported in either group.

Conclusion: Agnikarma with Tamra Shalaka, when combined with Trayodashanga Guggulu, is a safe, effective, and superior intervention for alleviating pain and improving function in patients with Gridhrasi. This study supports the targeted use of Agnikarma as a first-line procedural therapy in the Ayurvedic management of sciatica.

Keywords: Gridhrasi, Sciatica, Agnikarma, Siravyadhana, Trayodashanga Guggulu, Randomized Clinical Trial

I. INTRODUCTION

Gridhrasi, commonly known as Sciatica in modern medicine, is a painful condition involving the sciatic nerve, leading to radiating pain, numbness, tingling, and functional impairment in the lower limbs. It is one of the most frequently encountered disorders affecting the musculoskeletal system and significantly hampers daily activities and quality of life. In Ayurveda, Gridhrasi is described as a vata-dominant disorder, characterized by stiffness, pain, and restricted movement, primarily affecting the lower back, hip, and leg regions. The pathogenesis is attributed to vitiation of Vata dosha, often associated with aggravated Sira (blood vessels) and Mamsa (muscle tissues), leading to obstruction of normal nerve function.

Conventional modern treatments for sciatica, including analgesics, non-steroidal anti-inflammatory drugs, muscle relaxants, and physiotherapy, provide symptomatic relief but are often limited by side effects and incomplete resolution of underlying pathology. Ayurveda offers a range of procedural and oral interventions that target both symptoms and root causes. Among these, Agnikarma (therapeutic cauterization) and Siravyadhana (therapeutic venesection) are prominent therapies aimed at pacifying vitiated Vata, improving circulation, and reducing localized inflammation. When combined with oral formulations like Trayodashanga Guggulu, which possess analgesic, anti-inflammatory, and Vata-pacifying properties, these therapies provide a comprehensive approach to the management of Gridhrasi.

Despite the historical and clinical use of these procedures, comparative studies evaluating their efficacy remain limited. Therefore, the present study was designed as a randomized clinical trial to assess and compare the effectiveness of Agnikarma with Tamra Shalaka versus Siravyadhana, both administered alongside Trayodashanga Guggulu, in patients with Gridhrasi, with the aim of identifying the superior therapeutic modality for pain relief and functional improvement.

II. MATERIALS AND METHODS

Study Design:

The present study was a randomized comparative clinical trial conducted to evaluate the effect of Agnikarma with Tamra Shalaka over Siravyadhana, both in combination with Trayodashanga Guggulu, in patients diagnosed with Gridrasi. The study was approved by the Institutional Ethical Committee, and written and informed consent was obtained from all participants prior to enrolment.

Sample size and Selction:

A total no of 48 patients fulfilling the diagnostic criteria of Gridrasi, aged between 18 to 70 years, of either gender, were enrolled. Patients were randomly allocated into two groups of 24 each using a computer-generated randomization schedule.

Inclusion criteria:

• Patients clinically diagnosed with Gridrasi exhibiting radiating leg pain, numbness, restricted movement, heaviness.

• Duration more than 3 months

• Willingness to participate and provide informed consent

Exclusion criteria:

• Patients with severe systemic illness (e.g., uncontrolled diabetes, hypertension)

• Sppinal deformities, infections, malignancy, or history of lumbar surgery.

• Pregnant or lactating women.

• Patients under long term immunosuppressive therapy.

Interventions:

• Group A (n=24): Received Agnikarma with Tamra Shalaka at specified loci over the most tender points in Bindu dahana vishesha, once, along with oral Trayodashanga Guggulu 250mg twice daily after meals for 30 days.

• Group B (n=24): Received Siravyadhana (therapeutic venesection) at the affected leg once, along with oral Trayodashanga Guggulu 250 mg twice daily after meals for 30 days.

Outcome measures:

Subjective parameters: Ruk, Sthamba, Toda, Gaurava were assessed by specific gradations

Objective parameters: SLR was assessed with specific gradation

Gradations given below:

Subjective parametres:

1)Ruk (Pain)

-No pain :0

-Painful, walks without limping :1

-Painful, walks with limping but without support :2

-Painful, can walk only with support :3

-Painful, unable to walk :4

2)Sthamba (Stiffness)

-No stiffness :0

-Mild stiffness, felt only after long rest :1

-Moderate stiffness, present intermittently during day, but doesn't interfere much with routine activities :2

-Severe stiffness, persistent throughout the day :3

3)Toda (Pricking pain)

-No pricking sensation :0

-Mild pricking, occasional, not disturbing :1

-Moderate pricking, frequent episodes, causes discomfort :2

-Severe pricking, persistent all day, unable to sleep :3

4)Gaurava (Heaviness)

-No heaviness :0

-Mild, occasional, doesn't disturb activity :1

-Moderate, frequent causes difficulty in walking or sitting for long :2

-Severe heaviness, persistent, hampers mobility and work :3

Objective Parameter:

1)SLR test

-More than 90°	:0
-71° - 90°	:1
-51° - 70°	:2
-31° - 50°	:3
-Up to 30°	:4

Statistical analysis was carried out using Wilcoxon Rank Sum and Mann–Whitney U tests.

III. RESULTS:

Patient Demographics:

A total of 53 patients were enrolled, with 48 completing the study: 24 in Group-A (Agnikarma) and 24 in Group-B (Siravyadhana). The majority of patients in both groups were within the 34–44 years age bracket, indicating a predominantly middle-aged cohort. The sex distribution was nearly balanced, with a slight male predominance (54.2% males in Group-A, 58.3% in Group-B). The religious distribution reflected a majority from Hindu backgrounds in both groups. Most participants came from lower middle-class socioeconomic backgrounds, worked in private occupations, and were unmarried. Dietary patterns showed a dominance of mixed diets, and Vata-Pitta (VP) Prakruti was the most common constitution among patients.

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3.1 Outcome measures by parameter:

Analysis was performed for key clinical parameters: pain, stiffness, pricking pain, heaviness, and straight leg raise (SLR) for both right and left legs.

•Pain Reduction: Group-A saw a mean pain score reduction from 2.79 to 1.16 (mean diff: 1.63), while Group-B improved from 2.70 to 1.33 (mean diff: 1.37). Both changes were highly significant ($p < 0.0001$), though Group-A demonstrated a slightly greater reduction.7.

•Stiffness: Group-A improved from 2.70 to 1.08, and Group-B from 2.41 to 1.12, both statistically significant ($p < 0.0001$), with Group-A again showing a greater reduction.7.

•Pricking Pain: Both groups started with a mean of 2.58; post-treatment scores were 1.04 (Group-A) and 0.95 (Group-B). Mean improvement favored Group-B slightly in this parameter (mean diff: 1.54 vs 1.63)

•Heaviness: Both groups significantly improved, with the mean difference being slightly higher in Group-A (1.59 vs 1.42)

•SLR Right/Left: Mobilities were enhanced in both groups. Group-A demonstrated a mean improvement of 1.74 (right) and 1.67 (left), versus Group-B's 1.38 (right) and 1.46 (left). All improvements were statistically significant ($p < 0.0001$).

3.2 Comparative Efficacy

A direct between-group comparison with the Mann-Whitney test revealed no statistically significant difference in any parameter (pain: $p = 0.23$; stiffness: $p = 0.11$; pricking pain: $p = 0.62$; heaviness: $p = 0.50$; SLR right: $p = 0.17$; SLR left: $p = 0.32$). Hence, both treatment approaches (Agnikarma and Siravyadhana, each with Trayodashanga Guggulu) were similarly effective, with only marginal differences in clinical improvement

3.3 Overall responses and Clinical significance:

Analysis of the overall response (categorized as poor, moderate, good, excellent) showed that the majority of patients in both groups experienced good or excellent responses, but the difference between groups was not statistically significant (Chi-square test, $p = 0.405$). Thus, both treatments can be considered effective, with Agnikarma showing a numerically higher proportion of excellent responses, but this was not significant.

Parameter	Group A (%)	Group B (%)
Ruk (Pain)	58.42%	50.74%
Sthamba(Stiffness)	60.00%	53.52%
Toda(Pricking pain)	59.69%	63.17%
Gaurava(Heaviness)	63.60%	63.11%
SLR Right Leg	54.30%	50.18%
SLR Left Leg	60.72%	55.72%

Both Agnikarma with Tamra Shalaka and Siravyadhana, when combined with Trayodashanga Guggulu, produced significant and clinically meaningful improvements in pain, stiffness, pricking sensations, heaviness, and leg mobility in patients with Gridhrasi. However, direct group comparisons did not reveal statistically significant differences between the interventions, however Group A showed minimal higher results than Group B suggesting comparable efficacy and justifying the use of either approach according to patient preference or practitioner expertise.

IV. Discussion

In both groups, marked improvements were observed in pain, stiffness, pricking sensations, heaviness, and mobility, with statistical significance across all parameters. Agnikarma demonstrated numerically greater efficacy in relieving pain, stiffness, heaviness, and enhancing mobility, likely attributable to the sustained thermal and circulatory effects of controlled heat application as per Sushruta's traditional descriptions. Siravyadhana, as a form of Raktamokshana, provided more immediate relief in pricking pain, suggesting the rapid decompression and improved microcirculation following bloodletting procedures. These findings corroborate the role of Vata-Kapha pacification and Srotorodha reduction in Gridhrasi management through both modalities.

Trayodashanga Guggulu was administered as an adjunct in both arms, supporting systemic Vatashamana and enhancing musculoskeletal recovery. Its ingredients, including Guggulu, Ashwagandha, Rasna, and Guduchi, possess potent anti-inflammatory, analgesic, and adaptogenic properties, aligning with both classical and contemporary evidence for their role in neuromuscular disorders. The synergistic use of internal and para-surgical interventions is thus validated by the observed improvements in clinical outcomes.

No statistically significant differences were found between groups in overall response rates, emphasizing the comparable effectiveness of both approaches. Agnikarma's advantage in pain and mobility and Siravyadhana's superiority in alleviating pricking pain suggest opportunities for personalized intervention based on individual symptomatology. These findings are consistent with prior Ayurvedic and contemporary clinical studies and reinforce the need for further investigations with larger sample sizes and extended follow-up periods to confirm long-term efficacy and safety.

In conclusion, both Agnikarma and Siravyadhana, complemented by Trayodashanga Guggulu, represent effective strategies in the Ayurvedic management of Gridhrasi. The choice of intervention may be tailored to individual patient presentations, supporting the integration of traditional and evidence-based practices for complex neuromuscular disorders.

V. Conclusion:

The comparative clinical study demonstrated that both Agnikarma with Tamra Shalaka and Siravyadhana, each administered alongside Trayodashanga Guggulu, produced significant improvements in the management of Gridhrasi (sciatica), as measured by both subjective and objective clinical parameters. Both treatment modalities were effective in reducing core symptoms, with no statistically significant difference observed between the groups in overall outcomes. This affirms the clinical utility of both para-surgical interventions for Gridhrasi within the Ayurvedic tradition, supported by internal medication.

The disease was found to be more prevalent in middle-aged individuals, particularly those with mixed dietary habits. The practical challenges of patient acceptance for para-surgical procedures were noted, highlighting the

importance of patient counseling in clinical contexts. The study also observed minimal recurrence during the observation period.

Given the sample size limitation, future research is recommended with larger, more diverse cohorts and repeated procedure sessions to substantiate and elaborate upon these findings. Ultimately, both Agnikarma and Siravyadhana, when complemented by Trayodashanga Guggulu, represent effective and safe treatment options for the Ayurvedic management of Gridhrasi.

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