RESEARCH PAPER

A Randomized Open-Label Controlled Clinical Study to Evaluate the Efficacy of Siravedha and Gunja Beej Lepa in the Management of Gridhrasi (Sciatica)

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Abstract
Background: *Gridhrasi* is an obstinate *Vataja Nanatmaja* disorder characterized by radiating pain, stiffness, and restricted movement in the lower limbs, closely correlating with Sciatica in modern medicine. Contemporary medical management predominantly relies on temporary analgesics or surgical interventions that carry significant limitations and risks. **Aim:** This randomized, open-label, two-arm comparative clinical study aims to evaluate and compare the therapeutic efficacy of *Siravedha* (venesection) and *Gunja Beej Lepa* (topical application) in the management of *Gridhrasi.* **Methods:** 40 patients were randomly assigned to either the *Siravedha* group or *the Lepa* group. The clinical assessment criteria included subjective parameters *(Toda, Stambha, Spandana)* and objective parameters (SLR, VAS, Lasegue's sign). **Results:** Both intragroup and intergroup statistical analyses demonstrated that while both interventions produced significant improvements, *Siravedha* yielded a markedly superior therapeutic benefit across all clinical outcomes. **Conclusion:** *Siravedha* offers highly significant and superior symptomatic and functional relief in patients with *Gridhrasi* compared to *Gunja Beej Lepa.*

Keywords: Gridhrasi,Sirvedha,Gunja beja Lepa,Sciatica,VAS
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Introductions

Health is the supreme foundation for the achievement of a happy life, yet modern sedentary lifestyles, physical stress, and postural inconsistencies place undue strain on the spinal column. These factors play a major role in the development of low back pain and Sciatica, rendering it a prominent affliction that heavily impacts daily activity and socioeconomic productivity. In Ayurveda, this severe debilitating condition is described as *Gridhrasi*—a term derived from the vulture-like (*Gridhra*) altered gait of the patient experiencing extreme pain.

Sciatica is characterized by pain, numbness, and tingling radiating from the low back down to the foot due to compression or irritation of the sciatic nerve roots. Conventional modern treatments provide primarily symptomatic relief via NSAIDs and analgesics, while surgical interventions are often feared and possess varying limitations. Consequently, finding a quick, cost-effective, and robust Ayurvedic treatment protocol is highly relevant. This study evaluates two distinct classical modalities: the surgical/para-surgical procedure of *Siravedha* and the topical application of *Gunja Beej Lepa*.

Aims and Objectives

Primary Aim:

- To compare the overall efficacy of *Siravedha* and *Gunja Beej Lepa* in the management of *Gridhrasi* (Sciatica).

Objective :

- To study the independent therapeutic effects of *Siravedha* in *Gridhrasi.*
- To study the independent therapeutic effects of *Gunja Beej Lepa* in *Gridhrasi.*
- To observe and document any complications arising from either intervention.

Hypothesis

- **Null Hypothesis (H_0):** There is no significant difference between the therapeutic effects of *Siravedha and Gunja Beej Lepa* in managing *Gridhrasi.*
- **Research Hypothesis (H_1)*:*** *Siravedha* is more effective than *Gunja Beej Lepa* in the management of *Gridhrasi.*
- **Research Hypothesis (H_2):** *Gunja Beej Lepa* is more effective than *Siravedha* in the management of *Gridhrasi.*

Disease Review

Ayurvedic Perspective (*Gridhrasi)*

Gridhrasi is explicitly categorized under the 80 types of *Nanatmaja Vata Vyadhi* (diseases caused exclusively by Vata vitiation). The pathogenesis (*Samprapti*) involves the vitiation of *Vyana* and *Apana Vayu* localizing in the *Sphik* (buttocks), *Kati* (waist), and *Prishtha* (back), subsequently affecting the *Kandara* (ligaments/tendons) of the lower limbs.

- ***Vataja Gridhrasi:*** Characterized by *Ruka* (pain), *Toda* (pricking sensation), *Stambha* (stiffness), *Muhurspandana* (twitching), and *Deha Pravakrata* (sciatic scoliosis).
- ***Vata-Kaphaja Gridhrasi:*** Presents with the above Vataja symptoms alongside *Tandra* (drowsiness), *Gaurava* (heaviness), and *Arochaka* (anorexia).

Modern Perspective (Sciatica)

Sciatica is a symptom complex resulting from mechanical pressure on the sciatic nerve or its roots (L4, L5, S1, S2, S3). The most prevalent cause is a prolapsed or herniated intervertebral disc (occurring in 90% of cases at the L4-L5 or L5-S1 levels), which leads to nerve root compression. Pathophysiologically, extreme vertical stress leads to the bulging and extrusion of the *nucleus pulposus* through the *annulus fibrosus*, compressing the adjacent nerve root and eliciting sharp, lancinating radicular pain down the leg.

Drug and Procedure Review

***Gunja Beej Lepa* (Topical Drug Application)**

Gunja (*Abrus precatorius* Linn.), classified under the *Upavisha* group, acts as a potent, deep-penetrating herb.

- **Pharmacodynamics:** Possesses *Laghu*, *Ruksha*, and *Tikshna* Gunas with *Ushna Virya* and *Katu Vipaka*.
- **Clinical Action:** Directly antagonizes *Sita* (cold) and *Stambha* (stiffness), acting as a *Kapha-Vata Shamaka* to clear channel obstructions (*Srotorodha*). Medieval texts, including the *Vangasena* Samhita and *Yogaratnakara,* highly extol its immediate pain-relieving properties when applied as a paste over the sciatic nerve path.

***Siravedha* (Venesection Procedure)**

Siravedha is a para-surgical (*Anushastra Karma*) blood-letting procedure utilized for rapid pain relief.

- **Anatomical Site:** Performed at the *Antara-kandara-gulpha* (the vein situated between the Achilles tendon and the malleolus of the ankle joint), as instructed by Acharya Charaka.
- **Mechanism:** Rapidly eliminates localized morbid humors, relieves mechanical pressure on the *Kandara*, and provides instantaneous relief from *Toda* and *Stambha*.

Methodology

- **Study Design:** Open randomized controlled trial; Phase 2 clinical trial.
- **Sample Size:** 40 patients (20 in Group A: *Siravedha;* 20 in Group B: *Gunja Beej Lepa).*
- **Duration & Follow-up:** 30 days, with clinical follow-ups on days 3, 5, 7, 15, and 30.
- **Intervention Group A *(Siravedha):*** Executed using a disposable scalp vein No. 20 at the *antra-kandra gulf* for a total of 4 sittings (1 sitting per week).
- **Intervention Group B *(Gunja Beej Lepa):*** Paste applied approximately 1 cm thick over the sciatic nerve roots until dry (15–30 minutes).
- **Inclusion Criteria:** Patients aged 20–70 years exhibiting subjective complaints of *Ruka*, *Toda*, *Stambha*, and *Spandana*, accompanied by a positive Straight Leg Raise (SLR) test.
- **Exclusion Criteria:** Major illnesses (e.g., DM, TB), pregnancy, severe anemia (Hb < 10 mg/dl), and surgical indications like progressive neurological deficits.

Results and Interpretation on Each Parameter

Intragroup analysis was conducted using the Wilcoxon signed-rank test, while intergroup analysis utilized the Mann–Whitney U test. Both groups demonstrated baseline comparability ($p > 0.05$) across all parameters prior to intervention.

Intragroup analysis: The Wilcoxon signed-rank test demonstrated a significant improvement in Walking Time within the *Siravedha* group (**W = 210.00, p < 0.001**). The Lepa group also demonstrated a significant improvement (**W = 190.00, p < 0.001**).
Overall interpretation: Both *Siravedha and Lepa* resulted in significant improvement in Walking Time. However, the **significant intergroup difference after treatment, lower post-treatment median, complete reduction of the median score to zero, and greater percentage improvement (100% vs. 66.67%) demonstrate that *Siravedha* was more effective than *Lepa* in improving Walking Time**.
Table no. 1: Intergroup Effect Size (*Siravedha vs. Lepa)*

Parameter	Effect Size (r)	Interpretation
Aruchi	0.035	Negligible
Gaurava	0.275	Small
Lasegues	0.175	Small
SLR	-0.135	Small (favors Lepa)
Spandana	0.163	Small
Stambha	0.053	Negligible
Suptata	0.238	Small
Tandra	0.385	Small to Medium
Toda	0.263	Small
VAS	0.325	Small to Medium
Walking Time	0.363	Small to Medium

Intergroup Effect Size Analysis *(Siravedha vs. Lepa)*
The table presents the **intergroup effect sizes (r)** for the different clinical parameters comparing the *Siravedha* and *Lepa* groups. The effect size indicates the magnitude of the difference between the two groups, with larger absolute values representing a greater magnitude of between-group effect.
The effect size for ***Aruchi* (r = 0.035)** and ***Stambha* (r = 0.053)** was negligible, indicating very little difference between the Siravedha and Lepa groups for these parameters. For **Lasegues (r = 0.175), *Spandana* (r = 0.163), *Gaurava* (r = 0.275), *Suptata* (r = 0.238), and *Toda* (r = 0.263)**, the effect sizes were small, indicating a modest advantage of Siravedha over Lepa.
A **small-to-medium effect** was observed for **Tandra (r = 0.385), VAS (r = 0.325), and Walking Time (r = 0.363)**. Among these parameters, Tandra showed the largest effect size, followed by Walking Time and VAS, suggesting a comparatively greater treatment advantage for Siravedha in these outcomes.
For **SLR, the effect size was r = −0.135**, which was classified as small and favoured the Lepa group according to the direction of the calculated effect size. However, this effect was relatively small in magnitude.
Overall, the effect-size analysis indicates that the **intergroup differences generally favoured the Siravedha group**, with the strongest effects observed for **Tandra, Walking Time, and VAS**. Although some parameters showed negligible or small effects, the overall pattern, when considered alongside the significant post-treatment intergroup differences and percentage improvements observed in the preceding tables, supports a **greater overall therapeutic benefit of *Siravedha* compared with *Lepa***.
Table no.2: Intragroup Effect Size (Pre- vs. Post-Treatment)

Parameter	*Siravedha (*r)	*Lepa* (r)
Aruchi	0.877	0.793
Gaurava	0.877	0.856
Lasegues	0.568	0.188
SLR	0.877	0.818
Spandana	0.877	0.818
Stambha	0.877	0.793
Suptata	0.86	0.831
Tandra	0.877	0.793
Toda	0.835	0.793
VAS	0.877	0.793
Walking Time	0.877	0.793

Intragroup Effect Size (Pre-treatment vs. Post-treatment)

The table presents the intragroup effect sizes (r) for the *Siravedha and Lepa* groups across the different clinical parameters. The effect size indicates the magnitude of change within each group following treatment. In the ***Siravedha* group**, large effect sizes were observed for almost all parameters. The effect size was **r = 0.877** for *Aruchi, Gaurava, SLR, Spandana, Stambha, Tandra, VAS,* and Walking Time, indicating a **large treatment effect**. Similarly, *Suptata* showed a large effect size of **r = 0.860**, while Toda showed **r = 0.835**, also indicating a large effect. Lasegues showed an effect size of **r = 0.568**, representing a moderate-to-large effect.

In comparison, the Lepa group also demonstrated positive treatment effects, with effect sizes ranging from **r = 0.188 to 0.856**. The largest effect was observed for Gaurava (**r = 0.856**), followed by *Suptata* (**r = 0.831**) and SLR and *Spandana* (**r = 0.818**). However, the effect sizes *for Aruchi, Stambha, Tandra, Toda, VAS,* and Walking Time were **r = 0.793**, while Lasegues showed a comparatively smaller effect (**r = 0.188**).

Overall, the intragroup effect-size analysis demonstrates that ***Siravedha* produced large effects across all assessed parameters**, with particularly strong effects for Aruchi, Gaurava, SLR, *Spandana, Stambha, Tandra,* VAS, and Walking Time. Although Lepa also produced improvement, the effect size was generally lower than that observed with *Siravedha.* These findings indicate a **strong and consistent therapeutic effect of *Siravedha* across the clinical outcomes**.

Table no.3 Interpretation of Result :

Parameter	*Siravedha* (% Improvement)	*Lepa* (% Improvement)	Intergroup p-value (After)	Significant
Aruchi	100.00%	33.33%	<0.001	Yes
Gaurava	71.43%	33.33%	0.03	Yes

Lasegues	100.00%	0.00%	0.03	Yes
SLR	100.00%	50.00%	<0.001	Yes
Spandana	100.00%	50.00%	<0.001	Yes
Stambha	100.00%	66.67%	<0.001	Yes
Suptata	100.00%	50.00%	<0.001	Yes
Tandra	100.00%	33.33%	<0.001	Yes
Toda	100.00%	66.67%	0.01	Yes
VAS	75.00%	33.33%	<0.001	Yes
Walking Time	100.00%	66.67%	<0.001	Yes

Comparative Percentage Improvement and Post-treatment Intergroup Significance

The table compares the percentage improvement achieved by the *Siravedha and Lepa* groups and presents the corresponding post-treatment intergroup p-values.

The findings demonstrate that **Siravedha produced greater percentage improvement than Lepa across all assessed parameters**. Complete **100% improvement** was observed in the *Siravedha* group for ***Aruchi,* Lasegues, SLR, *Spandana, Stambha, Suptata, Tandra, Toda,* and Walking Time**, whereas the corresponding improvement in the Lepa group ranged from **0% to 66.67%**.

For **Gaurava**, the percentage improvement was **71.43% in the Siravedha group compared with 33.33% in the Lepa group**. Similarly, for **VAS**, the Siravedha group demonstrated **75% improvement**, compared with **33.33% in the Lepa group**. These findings indicate a greater reduction in symptom severity and pain intensity following Siravedha treatment.

The post-treatment intergroup comparisons were **significant for all parameters**, with p-values ranging from **<0.001 to 0.03**. Significant differences were observed for Aruchi (**$p < 0.001$**), Gaurava (**$p = 0.03$**), Lasegues (**$p = 0.03$**), SLR (**$p < 0.001$**), Spandana (**$p < 0.001$**), Stambha (**$p < 0.001$**), Suptata (**$p < 0.001$**), Tandra (**$p < 0.001$**), Toda (**$p = 0.01$**), VAS (**$p < 0.001$**), and Walking Time (**$p < 0.001$**).

Thus, the findings consistently demonstrate a **significant advantage of Siravedha over Lepa across all evaluated parameters**. The combination of **greater percentage improvement and statistically significant post-treatment differences** supports the superior therapeutic effectiveness of Siravedha in improving the assessed clinical manifestations and functional outcomes.

Overall Statistical Conclusion

The present statistical analysis was carried out to compare the therapeutic effectiveness of ***Siravedha*** and ***Lepa*** in the management of the assessed clinical signs and symptoms. The analysis included both **intragroup comparison** of pre-treatment and post-treatment scores using the Wilcoxon signed-rank test and **intergroup comparison** between the Siravedha and Lepa groups using the Mann–Whitney U test. The magnitude of treatment response was further assessed using percentage improvement and effect-size analysis.

At baseline, the Siravedha and Lepa groups were comparable across all the assessed parameters. The intergroup Mann–Whitney U test showed **no significant difference before treatment** for Aruchi ($p = 0.85$), Gaurava ($p = 0.12$), Lasegues Sign ($p = 0.88$), SLR ($p = 0.44$), Spandana ($p = 0.73$), Stambha ($p = 0.77$), Suptata ($p = 0.18$), Tandra ($p = 0.19$), Toda ($p = 0.56$), VAS ($p = 0.09$), and Walking Time ($p = 0.54$). This baseline comparability is important because it indicates that the differences observed after treatment are less likely to be attributable to initial differences between the groups.

The **intragroup analysis demonstrated significant improvement in both groups**. The Wilcoxon signed-rank test showed significant pre- to post-treatment improvement in the Siravedha group for all assessed parameters, with $p < 0.001$. The Lepa group also demonstrated significant improvement for all parameters, with $p < 0.001$. Therefore, both interventions were effective in producing improvement from baseline.

However, statistical significance within a group alone does not establish superiority of one treatment over another; therefore, the post-treatment intergroup comparison and magnitude of improvement provide important evidence regarding comparative effectiveness.

The **post-treatment intergroup analysis consistently favoured the Siravedha group**. Significant differences were observed between Siravedha and Lepa for every assessed parameter. The p-values were **<0.001 for Aruchi, SLR, Spandana, Stambha, Suptata, Tandra, VAS, and Walking Time; 0.03 for Gaurava and Lasegues Sign; and 0.01 for *Toda*.** The post-treatment median scores were also lower in the *Siravedha* group across all parameters. This consistent pattern indicates that the improvement achieved following *Siravedha* was greater than that achieved following *Lepa.*

The percentage improvement further strengthens this finding. The *Siravedha* group demonstrated **100% improvement in *Aruchi,* Lasegues Sign, SLR, *Spandana, Stambha, Suptata, Tandra, Toda,* and Walking Time**. For Gaurava, the improvement was **71.43%**, while VAS showed **75% improvement**. In comparison, the Lepa group demonstrated **33.33% improvement in *Aruchi, Gaurava, Tandra* and VAS; 0% in Lasegues Sign; 50% in SLR, *Spandana and Suptata;* and 66.67% in Stambha, Toda and Walking Time**. Thus, Siravedha produced a greater percentage improvement in **every assessed parameter**.

The effect-size analysis also provides evidence regarding the magnitude of the treatment response. The intragroup effect sizes in the *Siravedha* group ranged from **0.568 to 0.877**, indicating moderate-to-large or large effects across the assessed outcomes. Particularly large effects were observed for *Aruchi,* Gaurava, SLR, *Spandana, Stambha, Tandra,* VAS and Walking Time (r = 0.877), while Suptata (r = 0.860) and Toda (r = 0.835) also demonstrated large effects. Lasegues Sign showed an effect size of **r = 0.568**, representing a moderate-to-large effect. In comparison, the *Lepa* group also showed positive effects, but the effect size was comparatively lower for most parameters, particularly Lasegues Sign (r = 0.188).

The intergroup effect-size analysis further demonstrated a generally favourable effect for *Siravedha.* Small effects favouring *Siravedha* were observed for *Gaurava,* Lasegues Sign, *Spandana, Suptata and Toda,* while small-to-medium effects were observed for **Tandra (r = 0.385), Walking Time (r = 0.363), and VAS (r = 0.325)**. *Aruchi* and *Stambha* demonstrated negligible intergroup effect sizes. The SLR effect size was small and its direction was reported as favouring *Lepa* (**r = −0.135**); however, the corresponding percentage improvement and post-treatment comparison showed greater improvement in the *Siravedha* group. Therefore, the direction of the effect-size statistic for SLR should be interpreted together with the underlying scoring direction and the other outcome measures rather than in isolation.

Parameter-wise Overall Findings

The analysis of ***Aruchi*** showed complete improvement in the *Siravedha* group compared with 33.33% improvement in the Lepa group, with a significant post-treatment intergroup difference ($p < 0.001$). This indicates a clear advantage of *Siravedha.*

For ***Gaurava,*** improvement was 71.43% with *Siravedha* compared with 33.33% with Lepa. The post-treatment difference was significant ($p = 0.03$), demonstrating greater improvement with *Siravedha.*

For **Lasegues Sign**, the *Siravedha* group achieved 100% improvement, while no improvement was observed in the Lepa group. The post-treatment difference was significant ($p = 0.03$), providing strong evidence in favour of *Siravedha.*

For **SLR**, the *Siravedha* group demonstrated 100% improvement compared with 50% in the Lepa group, with a significant post-treatment difference ($p < 0.001$). Thus, despite the small negative direction of the calculated intergroup effect-size statistic, the observed clinical improvement and post-treatment comparison favoured *Siravedha.*

For ***Spandana,*** complete improvement was observed in the *Siravedha* group compared with 50% in the *Lepa* group, with a significant intergroup difference ($p < 0.001$).

For ***Stambha,*** the *Siravedha* group showed 100% improvement compared with 66.67% in the Lepa group, with a significant post-treatment difference ($p < 0.001$).

For ***Suptata,*** the Siravedha group achieved 100% improvement compared with 50% in the Lepa group. The post-treatment difference was significant ($p < 0.001$), indicating greater improvement following *Siravedha.*

For ***Tandra,*** the *Siravedha* group demonstrated complete improvement (100%), whereas the Lepa group showed 33.33% improvement. The intergroup difference was significant ($p < 0.001$), and the intergroup effect size was among the larger effects observed (r = 0.385).

For ***Toda,*** improvement was 100% in the Siravedha group compared with 66.67% in the Lepa group. The post-treatment difference was significant ($p = 0.01$), favouring Siravedha.

For **VAS**, which represents pain intensity, the median score decreased from 8.00 to 2.00 in the Siravedha group, whereas it decreased from 9.00 to 6.00 in the Lepa group. The corresponding percentage improvement was **75% versus 33.33%**, respectively, and the post-treatment difference was significant ($p < 0.001$). The intergroup effect size of **r = 0.325** also indicates a small-to-medium effect favouring *Siravedha.*

For **Walking Time**, the *Siravedha* group achieved 100% improvement compared with 66.67% in the *Lepa* group. The post-treatment difference was significant ($p < 0.001$), with an intergroup effect size of **r = 0.363**, indicating a small-to-medium effect favouring Siravedha.

In conclusion, the statistical findings demonstrate that **both *Siravedha and Lepa* produced significant improvement in the assessed clinical parameters**. However, the evidence from the **post-treatment Mann–Whitney U tests, percentage improvement, median scores, intragroup effect sizes, and intergroup effect sizes consistently indicates a greater therapeutic benefit with *Siravedha***.

The absence of significant baseline differences between the groups establishes comparability before treatment, while the significant post-treatment differences across **all 11 parameters** demonstrate that the improvement was significantly greater in the Siravedha group. Furthermore, *Siravedha* achieved **100% improvement in 9 of the 11 parameters**, while also producing greater improvement in Gaurava and VAS. The large intragroup effect sizes observed in the *Siravedha* group further demonstrate the magnitude and consistency of the treatment response.

Therefore, based on the overall statistical evidence, ***Siravedha* can be considered more effective *than Lepa* in improving the assessed clinical signs, symptoms, pain intensity and functional outcomes in the present study**. The findings provide statistical support for the **superiority of *Siravedha* over *Lepa*** for the outcomes evaluated in this study.

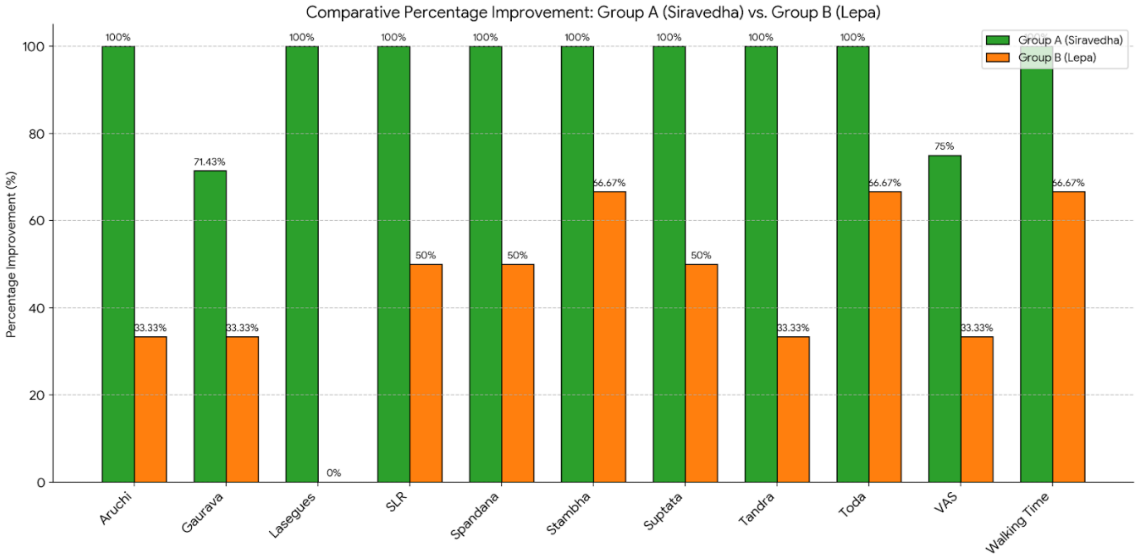

Figure no.1 Comparative Percentage

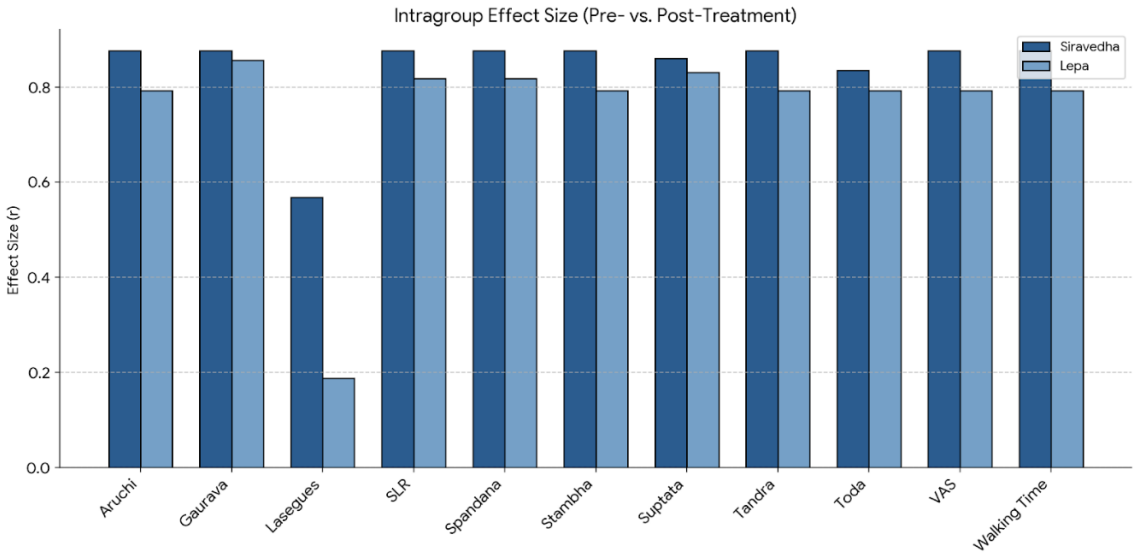

Figure no.2 Intragroup result

Discussion

The statistical analysis rigorously evaluated the comparative efficacy of Siravedha and Gunja Beej Lepa. Intragroup analyses utilizing the Wilcoxon signed-rank test confirmed that both interventions independently produced statistically significant improvements ($p < 0.001$) across all 11 evaluated signs and symptoms. This indicates that both modalities are viable conservative treatments for mitigating the effects of Gridhrasi.

However, intergroup analysis via the Mann-Whitney U test consistently and definitively favored Siravedha. Siravedha achieved an extraordinary 100% median improvement in 9 out of 11 clinical parameters (including crucial structural/functional tests like SLR and Lasegue's sign), whereas Lepa's improvements plateaued between 0% and 66.67% across the same markers. Intragroup effect size (r) analyses corroborated this, revealing large effects (ranging from 0.835 to 0.877) for almost all parameters in the Siravedha group, compared to more moderate effects in the Lepa group. The intergroup effect sizes identified small-to-medium therapeutic advantages specifically favoring Siravedha in mitigating Tandra ($r = 0.385$), restoring Walking Time ($r = 0.363$), and reducing VAS pain scores ($r = 0.325$).

The superiority of Siravedha can be attributed to its classical mechanism of action. As an *Anushastra Karma*, *Siravedha* directly intervenes in the *Srotodushti*. By performing venesection at the designated *antra-kandra gulf*, the localized morbid humors are rapidly evacuated. This instantaneous decompression relieves pressure on the *Kandara*, restoring the normal *Gati* (movement) of *Vata* and providing immediate relief from *Toda* and *Stambha*. While *Gunja Beej Lepa* successfully acts as a *Kapha-Vata Shamaka* by penetrating tissues and inducing local vasodilation, its topical nature cannot match the rapid mechanical decompression provided by venesection.

Conclusion

While both Siravedha and Gunja Beej Lepa act as effective Ayurvedic modalities for mitigating the symptoms of Gridhrasi (Sciatica), the clinical evidence strongly validates the rejection of the null hypothesis in favor of the first research hypothesis. Siravedha produced significantly larger intragroup effect sizes, profound percentage improvements (achieving 100% resolution in 9 out of 11 evaluated parameters), and lower post-treatment median scores than Lepa. Based on the comprehensive statistical evidence, Siravedha is definitively more effective than *Gunja Beej Lepa* in reducing pain intensity, correcting neurological deficits, and restoring functional locomotor impairments associated with Gridhrasi.

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