IAMJ

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL

Research Article ISSN: 2320-5091 Impact Factor: 6.719

A RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF VISHWADI GUGGULU AND RASNA GUGGULU IN GRIDHRASI

Saniya K K[1], **Susheel Shetty**[2]

[1]P.G. Scholar; [2]Professor and HOD
Department of Kayachikitsa, Alva's Ayurveda medical college and Hospital, Vidyagiri, DK- 574227, Karnataka, India

Corresponding Author:drsaniyakk@gmail.com

https://doi.org/10.46607/iamj0710072022

(Published Online: July 2022)

Open Access

Article Received: 10/06/2022 - **Peer Reviewed:** 28/06/2022 - **Accepted for Publication:** 02/07/2022

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ABSTRACT

Background: *Gridhrasi* is a Ruja Pradhana Nanatmaja Vata Vyadhi, characterized by *Ruk* radiating from *Sphik, Kati, Prishta, Uru, Janu, Jangha* and *Pada* along with *Stambha, Toda* and *Muhuspandana*. It may be correlated to Sciatica, in which neuralgia along the course of the sciatic nerve frequently produces radiating pain into the buttock and lower limbs. Lifetime incidence of low back pain is said to be 50-70% with the incidence of Sciatica more than 40%. In modern science, various treatment modalities are available which will help to a certain extent and are not the ultimate cure. In light of these considerations, the study aimed to assess the efficacy of the two Ayurvedic formulations Vishwadi guggulu from Brihat Nigantu Ratnakara and Rasna Guggulu from Gada Nigraha in the treatment of *Gridhrasi*.

Methodology: 60 patients fulfilling the diagnostic and inclusion criteria were selected and randomly allocated into Group A (Vishwadi Guggulu) and Group B (Rasna Guggulu). Comparative analysis of the overall effects of the treatment in both groups was done statistically with Mann- Whitney Rank Sum Test and Unpaired t-Test. Within the group, a comparison was done by Wilcoxon Signed Rank Test and Paired t-Test.

Result: Within the group, the comparison showed statistically significant results for all parameters in Group A and Group B.

Conclusion: On statistical comparison between the two groups there is no significant difference in the effect of both Vishwadi Guggulu and Rasna Guggulu. Thus, H_1 is rejected and H_0 is accepted.

Keywords: *Gridhrasi*; Sciatica; Vishwadi Guggulu; Rasna Guggulu.

INTRODUCTION

The biological system has been disrupted by a sedentary lifestyle, poor sitting posture, constant and excessive effort with jerky movements during travel and sports. This discord will have an impact on the locomotor system, which will significantly reduce human activity in terms of social and professional life.

Gridhrasi is one of the 80 types of nanatmaja vata vyadhi[1] that has been mentioned in the Ayurveda classics. It is of two types that is *Vataja* and *VataKaphaja Gridhrasi*. *Vataja Gridhrasi* is characterized by *Sthamba*, *Toda*, *Muhuspandana*, and *Ruk* radiating from *sphik pradesha*[2] and radiating down the *Kati*, *Prushta*, *Uru*, *Janu*, *Janga*, *Pada* and the gait of the patient is like a vulture due to severe pain. In addition, *Vata Kaphaja Gridhrasi* present with *Tandra*, *Gourava*, and *Aruchi*.

As per modern science, *Gridhrasi* can be closely correlated to Sciatica. Sciatica is a condition where there is a pain in the distribution of the sciatic nerve or its component nerve roots[3]. The pain is often worsened with flexion of the lumbar spine, twisting, bending, or coughing. The most common cause is a herniated or bulging lumbar intervertebral disc[4]. Patients with Sciatica usually experience pain in the lumbar spine. The discomfort will often be unilateral and radicular to the ipsilateral afflicted extremity. Patients typically express pain or a burning sensation deep in their buttocks, as well as parasthesia that occurs in conjunction with the pain.

In developing countries, low back pain is the most common cause of the inability to work[5]. About 50% - 70% of people get affected by low back pain with the incidence of Sciatica more than 40% [6]. The prevalence of sciatic symptoms varies considerably ranging from 1.6% in the general population to 43% in a working population[7].

Various therapeutic approaches such as analgesics, corticosteroids, immobilization, physiotherapy, surgical procedures and so on are available in modern science. This will help to some extent but is not a complete cure. Some therapies are considerably more costly, and they can lead to consequences.

Taking these aspects into concern, two Ayurvedic formulations are taken for the present study. *Vishwadi Guggulu*[8] is taken as a trial drug from Brihat Nigantu Ratnakara which have ingredients like *Shunti*, *Pippali*, *Chitraka*, *Maricha*, *Vidanga*, *Rasna*, etc. *Rasna Guggulu*[9] is taken as a standard drug from Gada Nigraha with the ingredients *Rasna* and *Guggulu*. Both of these formulations have *Katu rasa*, *Ushna virya*, *Vatakaphahara*, and *Dipana* properties which aid in samprapti vigatana, restoring the equilibrium of doshas and alleviating *Gridhrasi* symptoms.

As a result, the purpose of this study was to evaluate and compare the effects of Vishwadi Guggulu and Rasna Guggulu in *Gridhras*i.

MATERIALS AND METHODS:

OBJECTIVES OF THE STUDY:

- To evaluate the therapeutic effect of *Vishwadi Guggulu* in *Gridhrasi*.
- To evaluate the therapeutic effect of *Rasna Guggulu* in *Gridhrasi*.
- To compare the therapeutic effect of *Vishwadi Guggulu* and *Rasna Guggulu* in *Gridhrasi*.

SOURCE OF DATA:

a) LITERARY SOURCE:

All the available Ayurvedic literature, modern medical literature, and contemporary texts including journals, and websites about the disease and drugs were reviewed and documented for the intended study.

b) DRUG SOURCE:

The formulations selected for this work, Vishwadi Guggulu and Rasna Guggulu were prepared in

the Alva's Pharmacy, Mijar as per the literature reference. Raw drugs were collected from authenticated dealers after proper identification.

c) SAMPLE SOURCE:

Patients diagnosed with *Gridhrasi* were randomly selected from

- OPD and IPD of Alva's Ayurveda Medical College and Hospital, Moodbidri
- Medical Camps and other referrals.

METHOD OF COLLECTION OF DATA:

- SAMPLE SIZE AND GROUPING: A minimum of 60 patients irrespective of gender, religion, occupation, marital status, socio-economic status and educational status, fulfilling the diagnostic criteria and inclusion criteria were selected. They were randomly divided into 2 groups A and B comprising a minimum of 30 patients in each group.
- STUDY DESIGN: Parallel group comparative clinical study
- BLINDING: Single Blind
- METHOD OF SAMPLING: Lottery Method

DIAGNOSTIC CRITERIA

- Patient with pain in *Kati pradesha* and radiating to *Sphik, Uru, Janu, Janga* and *Pada* along with *Stambha, Toda, Muhuspandana* with or without *Tandra, Gourava and Arochaka.*
- SLR Test – Positive

INCLUSION CRITERIA

- Patients within the age group of 20-60 yrs of either sex.
- The patient who had given their written consent and who agreed to follow the protocol of the study.
- Patient fulfilling the diagnostic criteria.

EXCLUSION CRITERIA

- Vulnerable groups like pregnant women, lactating mothers and mentally challenged persons.
- Patients having any other systemic disorders that will interfere with the course of study.
- *Gridhrasi* developed due to post-surgical complications.
- Congenital, infective, traumatic, and neoplastic conditions of the spine.

INTERVENTION

Table 12: Intervention of Group A

SAMPLE SIZE	30 Patients
INTERVENTION	*Vishwadi Guggulu*
DOSE	500mg
ANUPANA	Ushna jala
TIME	2 tablets three times a day after food
DURATION	30 Days

Table 13: Intervention of Group B

SAMPLE SIZE	30 Patients
INTERVENTION	*Rasnadi Guggulu*
DOSE	500mg
ANUPANA	Ushna jala
TIME	2 tablets three times a day after food
DURATION	30 Days

OBSERVATION PERIOD

- **Treatment period:** 30 days

Follow up: 15 days after completing the course of treatment i.e., 46th day

- **Total study duration:** 45 days
- **Days of assessment:** Observations were done at baseline i.e., 0th day, 16th day, 31st day, and on the 46th day

ASSESSMENT CRITERIA

- Assessments of the condition were done based on detailed case proforma adopting standard scoring methods of subjective and objective parameters.
- Statistical test of significance:

i) Comparative analysis of the overall effect of the treatments in both the groups was done statistically using Mann-Whitney Rank Sum Test and Unpaired t-Test.

ii) Within the group, a comparison was done using Wilcoxon Signed Rank Test and Paired t-Test.

SUBJECTIVE PARAMETER

- *Ruk*
- *Stambha*
- *Toda*
- *Muhuspandana*
- *Tandra*
- *Gourava*
- *Aruchi*

OBJECTIVE PARAMETER

- SLR Test (Active and Passive)
- Bragard's Test
- Distance of walking (Time taken to cover the distance of 50 feet)

INVESTIGATIONS

- Hematological Investigation: Hb, Total Count, Differential Count, ESR, RBS
- Radiological Investigation: X-ray of Lumbo Sacral spine – AP and Lateral view, other investigations whenever found necessary.

RESULTS

Table 3: Effect of Group A

CRITERIA	Median BT	Median AT	%	S.D. (±)	S.E. (±)	WSRT Value	p-Value
Ruk	3.00	1.00	56.31	0.450	0.082	465.00	<0.001
Stambha	3.00	1.00	59.75	0.305	0.055	465.00	<0.001
Toda	3.00	1.50	48.33	0.626	0.114	465.00	<0.001
Muhuspandana	2.00	1.00	46.26	0.407	0.074	351.00	<0.001
Tandra	3.00	1.00	57.56	0.389	0.112	78.00	<0.001
Gaurava	3.00	1.00	63.63	0.739	0.213	78.00	<0.001
Aruchi	3.00	1.00	56.24	0.389	0.112	78.00	<0.001
Bragard's Test	1.00	0.00	81	0.346	0.063	190.00	<0.001
Time taken to cover the distance of 50ft	3.00	1.00	50.62	0.535	0.097	465.00	<0.001

Table 4: Effect of Group A on SLR Test:

CRITERIA	Mean BT	Mean AT	%	S.D. (±)	S.E. (±)	t Value	p-Value
SLR Test (Right Leg-Active)	26.33	31.50	19.63	24.003	4.382	6.360	<0.001
SLR Test (Right Leg-Passive)	29.667	34.833	17.39	26.277	4.798	6.360	<0.001
SLR Test (Left Leg- Active)	22.833	26.667	16.78	26.207	4.785	4.892	<0.001
SLR Test (Left Leg- Passive)	25.500	29.333	15.03	28.670	5.234	4.898	<0.001

Table 5: Effect of Group B

CRITERIA	Median BT	Median AT	%	S.D. (±)	S.E. (±)	WSRT Value	p-Value
Ruk	3.00	1.00	48.21	0.679	0.124	465.00	<0.001
Stambha	3.00	1.00	51.78	0.568	0.104	435.00	<0.001
Toda	3.00	1.00	48.77	0.498	0.091	465.00	<0.001
Muhuspandana	2.00	1.00	43.10	0.430	0.078	325.00	<0.001
Tandra	3.00	1.00	60.61	0.669	0.193	78.00	<0.001
Gaurava	3.00	1.00	58.07	0.793	0.229	78.00	<0.001
Aruchi	3.00	1.00	47.21	0.497	0.133	105.00	<0.001
Bragard's Test	1.00	0.00	63.57	0.450	0.082	190.00	<0.001
Time taken to cover the distance of 50ft	2.50	1.00	51.32	0.479	0.087	465.00	<0.001

Table 6: Effect of Group B on SLR Test

CRITERIA	Mean BT	Mean AT	%	S.D. (±)	S.E. (±)	t Value	p-Value
SLR Test (Right Leg-Active)	21.33	24.50	14.81	27.429	5.008	4.289	<0.001
SLR Test (Right Leg-Passive)	23.667	26.667	12.67	29.663	5.416	4.039	<0.001
SLR Test (Left Leg- Active)	30.000	34.500	15	24.891	4.544	6.496	<0.001
SLR Test (Left Leg- Passive)	33.500	36.833	9.94	25.980	4.743	6.021	<0.001

Table 7: Comparative effect of Group A and Group B

CRITERIA	Group A	Group B	t Value	p-Value	Remarks
Ruk	2.00	1.00	1050.00	0.046	SS
Stambha	2.00	1.00	1022.50	0.113	NS
Toda	1.00	1.00	965.00	0.463	NS
Muhuspandana	1.00	1.00	953.50	0.573	NS
Tandra	2.00	2.00	144.00	0.749	NS
Gaurava	1.50	1.00	186.00	0.224	NS
Aruchi	2.00	1.50	165.00	0.400	NS
SLR Test (Right Leg-Active)	5.167	3.167	1.822	0.074	NS
SLR Test (Right Leg-Passive)	5.167	3.000	1.968	0.054	NS
SLR Test (Left Leg- Active)	3.833	4.500	0.637	0.526	NS
SLR Test (Left Leg- Passive)	3.833	3.333	0.521	0.604	NS
Bragard's Test	1.00	1.00	915.00	0.994	NS
Time taken to cover the distance of 50ft	1.00	1.00	975.00	0.377	NS

Table 8: Comparative result of Symptom wise relief in Group A and Group B

Assessment Criteria	Group A	Group B
Ruk	56.31%	48.21%
Stambha	59.75%	51.78%
Toda	48.33%	48.77%
Muhuspandana	46.26%	43.10%
Tandra	57.56%	60.61%
Aruchi	63.63%	58.07%
Gaurava	56.24%	47.21%

SLR Right Leg – Active	19.63%	14.81%
SLR Right Leg – Passive	17.39%	12.67%
SLR Left Leg – Active	16.78%	15%
SLR Left Leg – Passive	15.03%	9.94%
Bragard's Test	81%	63.57%
Time taken to cover the distance of 50 ft	50.62%	51.32%

Table 9: Overall Effect of Group A and Group B

EFFECT OF TREATMENT		GROUP A	GROUP B
CLASS	GRADING	NO OF PATIENTS	NO OF PATIENTS
0%	No Improvement	0	0
1-25%	Mild Improvement	0	0
26-50%	Moderate Improvement	10	17
51-75%	Marked Improvement	20	13
76-99%	Significant Improvement	0	0
100%	Complete Relief	0	0

DISCUSSION

In this study, maximum (35%) of patients were between the age group 41-50 yrs. This is because the incidence peak is in the fifth decade and declines thereafter[10]. Predominance is seen in the working-age group that travels more and engages in strenuous physical activity. Because of their lifestyle, they are more prone to lumbosacral strain. Maximum (28%) of the patients are labourers. Occupational predisposition has been seen in machine operators, drivers and jobs where workers are subject to physically awkward positions and activities especially flexion/torsion of the trunk[11,12]. Most patients (66.67%) had disturbed sleep, this may be due to the intensity of pain. Lying down can increase pressure on the irritated nerve especially if you sleep on a soft mattress. 51.67% of patients had *Vishamagni* and 55% of patients had *Krura koshta* which may be due to the predominance of *Vata dosha*. The increase in *Ruksha guna* of *Vata* produces hard faeces with the difficulty of elimination or even non- elimination.

Samprapti vighatana is the aim of Chikitsa and individual drugs in the formulation should be effective in attaining this objective. *Vata* and *Kapha* are the two major doshas involved in the manifestation of the disease *Gridhrasi*. The ingredients of Vishwadi Guggulu are Shunti, Pippali, Pippalimoola, Vidanda, Devadaru, Saindhava, Rasna, Chitraka, Yavani, Maricha, Vacha, Harithaki, and Guggulu. Rasna, Guggulu, and Ghrita are the main ingredients of Rasna Guggulu.

Most of these drugs are *Ushna Virya* which helps in *Vata shamana*. *Laghu, Ruksha, Tikshna guna, Ushna Virya* and *Katu Vipaka* helps in *Kapha nirharana*. *Dipana* and *Pachana* action of the drugs helps in *Amapachana* and also stabilizes the *Agni*. *Lekhana karma* of the drugs like Vacha, Harithaki, and Guggulu helps in *Srotoshodan*a, it removes the adhered *Dosha* from the *Dushita Srotas*. Saindhava possesses *Sheetha virya, Laghu-Snigdha guna* and it is *Tridoshagna*, that helps in Agnidipana and relieves Aruchi. It also reduces inflammation and thereby reduces pain. Vishwadi Guggulu additionally has *Vatagna* and *Shoolahara properties*. Rasna is especially known to have properties like *Vatanulomana, Kaphavatahara*, and *Vayasthapana*. *Laghu guna* and *Katu rasa* of Guggulu, *Tikta rasa* of Rasna help in suppressing *Kapha*, and due to the *Vishad guna* of Guggulu, it clears S*rotoavarodha* thus rectifying symptoms like *Stambha*[13]. Guggulu having properties like *Laghu guna, Katu rasa* and *Ushna virya* helps to promote the quality of *jatharaagni*, helps in *Amapachana* and relieves symptoms like *Aruchi, Gaurava*. The formulation contains Guggulu which gives the best results in *Vatavyadhi*. It is *Raktaprasadaka, Sothahara* and *Vedanasthapaka*.

The oleoresins of Guggulu have high anti-inflammatory, analgesic and anti-arthritic activity. It increases leukocytes in the blood and stimulates phagocytosis. It reduces pain and stiffness because of the suppression of the inflammatory cytokines NF-k B and its target molecules by reducing inflammation. It also suppresses the activation of interleukins and prostaglandins and acts as a pain killer. It plays a good role in managing conditions like nerve damage due to its antioxidant effect[14]. Guggulsterone, Gingeron, Embelin, and Piperine possess analgesic activity. The aqueous extract of Devadaru, hydroalcoholic extract of Harithaki and piperine in Maricha possess anti-inflammatory and anti-arthritic activity. Piperine increases the bioavailability of other drugs in the formulations. Many research study shows that Rasna has Anti-inflammatory, Immunosuppressive, Antioxidant and Anti-arthritic properties.

The dose was 2 tablets (500mg each) thrice daily after food. According to AFI, 2-4g matra is mentioned for Guggulu[15]. *Gridhrasi* is a condition where *Vyanavayu* is affected and *adhobhakta aushada kala* is indicated in *Vyanavayu vikriti* and *Udanavayu vikriti*[16]. For *Vata* and *Kapha dosha* vitiation, *Ushna Jala* is the best anupana[17].

CONCLUSION

Gridhrasi is one of the 80 types of nanatmaja vata vyadhi that has been mentioned in the ayurveda classics. Aharaja, Viharaja, Manasika and Agantuja Nidana plays an important role in the manifestation or aggravation of the disease condition.

The medicines which have *Katu rasa, Ushna virya, Vatakaphahara* and *Dipana* properties will help to bring back the equilibrium of doshas and helps to relieve the symptoms of *Gridhrasi.*

When comparing the two drugs clinically, Vishwadi Guggulu showed effective changes in all parameters and the effect was sustained longer than Rasna Guggulu. On statistical comparison within the group, both Vishwadi Guggulu and Rasna Guggulu showed highly significant results at $p<0.001$. In comparison between the two Groups, there was no statistically significant difference in the effect of treatment with $p>0.05$. Hence, the null hypothesis **(H_0)** is accepted i.e., there is no significant difference between the effect of Vishwadi Guggulu and Rasna Guggulu in Gridhrasi.

REFERENCES

1. Agnivesha, Caraka Samhita with Ayurveda Dipika Commentry of Cakrapanidatta, edited by Vaidya Jadaraji Trikamji Acharya, Published by Choukhamba Krishnadas Academy, Sutra sthana, 20th Chapter, Maharoga Adhyaya, sloka no:11, pgno:113.
2. Agnivesh, Caraka Samhita with Ayurveda Dipika Commentry of Cakrapanidatta, edited by Vaidya Jadaraji Trikamji Acharya, Published by Choukhamba Krishnadas Academy, Chikitsa sthana, 28th Chapter, Vatavyadhi chikitsa, sloka no: 56-57, pgno:519.
3. Aspi F Golwalla and Sharukh a Golwalla, Medicine for Students, 20th edition, published by Dr, A F Golwalla, Mumbai, Chapter 7th, Neurology, pgno:574,575,576,577.
4. B. M. Koes, M.W. Van Tulder, W C Peul, Diagnosis and treatment of Sciatica, 2007, june 23, 334(7607):1313-1317, doi:10.1136/bmj.39223.428495.BE
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC/1895638
5. SirStanleyDavidson, Davidson's Principles and Practice of Medicine, 20thedition, Edited by Nicholas A Boon, Nicki R Colledge, Brian R Walker, Churchill Livingstone Elesenier publication, Neurological Diseases Chapter, pgno:1242.
6. Sai Krishna C V, Praveen B S, Vikram kumar, Mathew Joseph; A Clinico Comparative Study of Patra panda Sweda with and without Interferential Therapy (IFT) in Gridhrasi with special reference to Sciatica; IAMJ, September 2017;5(9): pgno:3307.
http://www.jaims.in/index.php/jaims/article/view/334
7. Shri Dattarama Srikrishnalala Mathur, Brihat Nigandu Ratnakara, published by Khemaraja Srikrishnadas Prakashan, Vol 5-6, Vatavyadhi Karma Vipaka, pg no:485.
8. Shri Vaidya Sodhala, Gada Nigraha with The Vidyotini hindi commentry by Shri Indradeva Tripathi, edited by Shri Gangasahaya Pandeya, published by Chaukambha Sanskrit Samsthan, 21st Chapter, Vataroga Adhikara, Sloka no:146, pg:506.
9. M.A Stafford, P. Peng, D.A Hill Sciatica: A Review of History, Epidemiology, Pathogenesis and the Role of Epidural Steroid Injection in Management. British Journal of Anaesthesia, Volume 99, Issue 4, October 2007, Page 461-473.
http://doi.org/10.1093/bja/aem238

10. Davis D, Maini K, Vasudevan A. Sciatica (updated 2021 sep 2). In: StatPearls (internet). Treasure Island (FL): StatPearls Publishing; 2022 Jan.
11. M.A Stafford, P. Peng, D.A Hill Sciatica: A Review of History, Epidemiology, Pathogenesis and the Role of Epidural Steroid Injection in Management. British Journal of Anaesthesia, Volume 99, Issue 4, October 2007, Page 461-473.
http://doi.org/10.1093/bja/aem238
12. M.A Stafford, P. Peng, D.A Hill Sciatica: A Review of History, Epidemiology, Pathogenesis and the Role of Epidural Steroid Injection in Management. British Journal of Anaesthesia, Volume 99, Issue 4, October 2007, Page 461-473.
http://doi.org/10.1093/bja/aem238
13. Alman Anupam Ashok. Clinical study of effect of rasnadi gutika in the management of gridhrasi. IAMJ: volume 3; issue 10: October 2015
14. Alman Anupam Ashok. Clinical study of effect of rasnadi gutika in the management of gridhrasi. IAMJ: volume 3; issue 10: October 2015
15. Ayurvedic Formulary of India, Part 1, Part B, Published by G.O.I., Ministry of health and family welfare, 2003, 58pp
16. Archana R Belge, Omprakash W Talokar, Raman S Belge. Critical study of Aushadhi Sevana Kala with special reference to Chronopharmacology. IOSR-JPBS, vol 4, issue 4(nov- dec 2012). Pp 45-53.
17. Prof. jyotirmitra, Ashtangasangraha Induvirachitasheshilekhavyakya, Publisher Chaukambha Sanskrit Samstan, Varanasi, Edition 2005, Chapter 10, Sloka No.31, P.No. 105.

Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Saniya K & Susheel Shetty: A Randomized Controlled Clinical Study to Evaluate the Efficacy of Vishwadi Guggulu and Rasna Guggulu in Gridhrasi. International Ayurvedic Medical Journal {online} 2022 {cited July 2022} Available from: http://www.iamj.in/posts/images/upload/1665_1672.pdf