

## A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF SHUNTYADI GUGGULU IN GRIDHRASI W.S.R TO SCIATICA SYNDROME

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### ABSTRACT

**Objective:** To evaluate the therapeutic effect of *Shuntyadi Guggulu* in *Gridhrasi/Sciatica* syndrome. **Methodology:** An open labelled interventional study with pre and post-test design was planned to evaluate the effect of *Shuntyadi Guggulu* in *Gridhrasi/Sciatica* syndrome. The study was conducted on patients suffering from *Gridhrasi* selected from OPD and IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udipi, Karnataka. *Shuntyadi Guggulu* obtained from SDM Ayurveda Pharmacy, Udipi, Karnataka. The 30 patients were treated with *Shuntyadi Guggulu*, 2 capsules, each of 500 mg TID after food for 30 days with *UshnaJala Anupana*. The main outcome measures: Pain - Greenough and Fraser Scoring method; Stiffness, pricking type of pain, Twitching, Functional ability by Sugarbaker and Barofsky Clinical Mobility Scale; Functional Disability by Oswestry Disability Assessment Questionnaire; Restricted Limb Movement/SLR Tests; Neurological Deficit - Herron and Turners Rating and are analyzed statistically using paired T test

and Wilcoxon's method. **Results:** The study shows an excellent response in most of the subjective and objective criteria. It is evident by statistically significant reduction in the symptom scores of various subjective and objective criteria's and analyzing the calculated overall result. In the study 96.7% had excellent improvement, 3.3% had moderate improvement. Among the 18 parameters which are taken for the study, in 7 parameters ie. *Ruk, Stambha, Toda, Spandana, Aruchi, Tandra, Gaurava*, a greater number of patients showed excellent response recording more than 75% improvement. This study proved the excellent effect of *Shuntyadi Guggulu* in both *Vata* and *Vata Kaphaja Gridhrasi*. **Conclusion:** *Shuntyadi Guggulu* is very effective in remission of the signs and symptoms of *Gridhrasi* as evidenced by improvement in the ability of activities and quality of life and by statistically significant improvement in score of various subjective and objective parameters.

**KEYWORDS:** *Gridhrasi, Shuntyadi Guggulu, Sciatica.*

## INTRODUCTION

According to Indian mythology, the essence and concept of *Ayurveda* came into existence by *Lord Brahma*. *Ayurveda*, the science of life which is originated from *Atharva Veda* explains a series of concepts and provides the knowledge of how to prevent disease and how to eliminate its root cause if it does occur. We can say a person is healthy only if his *Dosha, Dhātu, Mala* and *Agni* are in equilibrium state.<sup>[1]</sup> The health is not only a physical aspect but also a mental and spiritual aspect. Our lifestyle plays a big role in health, wellness and fitness of body and mind. Nowadays, in the lives of people new challenges are emerging and compelling them to sit for hours and hours in front of computer and TV or making them to carry heavy bags on shoulders overtime, or lifting of objects in awkward positions etc.

These abnormal activities cause strain in spinal column (*Prustavamsha and Kati*) results in the vitiation of *Vata Dosha* and sometimes the *Kapha Dosha* with the association of *Kandara* of *pada* resulting in altered gait which is similar to the walking of vulture.<sup>[2]</sup> The excessively aggravated *Vata* impairs the *Kandara* of the ankles and toes and results in *Kshepa* (pain and inability to extend) in the thighs.<sup>[3]</sup> These are the same symptoms which is explained under the sciatica syndrome. Sciatica syndrome usually affects only one side of the lower body. The pain originates from the lower back and radiates through the posterior aspect of thigh and down the leg. Depending on the site where the sciatic nerve is affected, the pain may also extend to the foot or toe. This incidence is related to age, rare before 20 years. Sciatica syndrome is reported to affect 1% to 10% of the population, most commonly in the

age group of 25 to 45 years.<sup>[4]</sup> The prevalence of sciatica symptoms reported in literature varies considerably ranging from 1.6% in the general population to 43% in a selected working population.<sup>[5]</sup> As many as 40% of people will get sciatica during their life and people who suffer from acute or chronic back pain tend to be more susceptible to sciatica. In general, an estimated 5% to 10% of patients with low back pain have sciatica syndrome.<sup>[6]</sup>

Ayurveda literature have included *Gridhrasi* under the category of *Vataja Nanatmaja Vyadhi* (80 types of *Vataja Nanatmaja Vikaras*) on the basis *Dosha* predominance.<sup>[7]</sup> Excessively aggravated *Vata* in gluteal region produces *Stambha*(stiffness), *Ruk*(pain), *Toda* (pricking sensation) and *Muhurspandana* (twitching) and is known as *Vataja Gridhrasi* while *Vatakaphaja Gridhrasi* has features such as *Tandra* (drowsiness), *Gaurava* (heaviness in the legs) and *Arochaka* (tastelessness) along with features of *Vataja Gridhrasi*.<sup>[8]</sup> These symptoms can be correlated with Sciatica syndrome. In about 90% of patients, the cause for sciatica is spinal disc herniation and other possible causes are spondylolisthesis, spinal stenosis, piriformis syndrome, pelvic tumours, pregnancy etc. The straight-leg-raising test is helpful in diagnosing and we can get the same explanation in the *Samhita* by the word, *Sakthiutkshepa Nigraha*. Sciatica is treated initially by painkillers, anti-inflammatory drugs, corticosteroid injections etc. and if pain is severe and lasts for more than six months, surgery is the option which is comparatively expensive and needs hospitalization. In *Ayurveda*, *Gridhrasi* treatment is explained under *Vatavyadhi Chikitsa* by *Acharyas*. They included treatments like *Shamana*, *Swedana*, *Virechana*, *Niruha Basti*, *Anuvasana Basti*, *Agnikarma*, *Siravyadha*.<sup>[9,10]</sup> The formulation *Shuntyadi Guggulu* is mentioned for *Gridhrasi* in *Vaidya Chindamani*, *Vataprakarana Adhyaya* which contains 13 ingredients.<sup>[11]</sup> A main ingredient of formulation is *Guggulu* which has *Vatashamaka* and *Shulahara* property. A clinical trial was taken up to evaluate the effect of *Shuntyadi Guggulu* in *Gridhrasi*.

The study entitled –“A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF *SHUNTYADI GUGGULU* IN *GRIDHRASI* W.S.R. TO SCIATICA SYNDROME.”

## MATERIALS AND METHODS

Ethical Committee clearance has been done.

Reference number SDMCAU/ACA-49/ECH 12/2020-21.

**Objectives of the study**

1. To evaluate the therapeutic efficacy of *Shuntyadi Guggulu* in bringing symptomatic relief in patients of *Gridhrasi*.
2. To evaluate the functional improvement by *Shuntyadi Guggulu* in the patients of *Gridhrasi*.

**Source of data**

Minimum 30 patients diagnosed as *Gridhrasi*/Sciatica syndrome fulfilling the diagnostic/inclusion and exclusion criteria taken for study from OPD and IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi, Karnataka. The oral medication *Shuntyadi Guggulu* given in dose of 1g TID with warm water. Trial drug *Shuntyadi Guggulu* is obtained from Shri Dharmasthala manjunatheshwara Ayurveda Pharmacy Kuthpady, Udupi.

**Method of collection of data**

A special proforma is prepared incorporating all the clinical manifestation and assessment criteria including laboratory investigation findings, if any, of the *Gridhrasi*/Sciatica syndrome. Complete data including detailed clinical history and complete physical examination was collected from all the selected patients as per this proforma.

**Design of the study**

- Study type: Interventional with pre and post-test design
- Estimated enrollment: 30 Participants
- Allocation: Non-Randomized
- Endpoint classification: Efficacy study.
- Intervention Model: Single group assignment
- Masking: Open Label study
- Primary purpose: Treatment

**Intervention**

Dosage: 1g TID

*Anupana- Ushnodaka*

Duration of study: 30days.

Follow up period- 15days

Administration-After food

**A) Diagnostic criteria**

1. Symptoms of *vataja Gridhrasi* such as radiating pain starting from gluteal region, back of thigh to leg and foot, stiffness, pricking sensation, twitching in buttocks. *Vatakaphaja Gridhrasi* features like heaviness of the legs, drowsiness and tastelessness.
2. Patient suffering from low back ache with radiating pain towards the lower limb.

**B) Inclusion criteria**

1. Patients having low back ache with radiation to lower limbs.
2. Patients having sciatica syndrome with mild to moderate osteoporotic changes in lumbosacral spine where surgical interventions are absolutely not necessary and medical management is suggested.
3. Patients with or without radiological evidence-MRI, CT of disc-prolapse.
4. Patients with or without radiological evidence-MRI, CT of lumbar spondylosis.
5. Patient between the age group of 20-60 years and of either sex.

**C) Exclusion criteria**

1. Deformities and Congenital defects of spine
2. Tuberculosis of spine.
3. Neoplasm of spine.
4. Pregnancy and lactating mother
5. Fracture of lumbosacral vertebrae.

**D) Assessment criteria****Primary outcome measures**

1. Pain (*Ruk*) – Visual analogue scale<sup>12</sup> & Greenough and Fraser Scoring method.<sup>13</sup>
2. Stiffness (*Sthambha*)
3. Pricking type of pain (*Toda*)
4. Functional Ability- Sugar baker & Barofsky Clinical Mobility Scale.<sup>14</sup>
5. Functional disability - Oswestry Disability assessment questionnaire.<sup>15</sup>

**Secondary outcome measures**

1. SLR Test (*Sakthiutkshepa Nigraha*)
2. Neurological deficit-Herron and turners rating. The parameters of signs and symptoms along with investigations scored on the basis of standard method and analyzed statistically using paired T test and Wilcoxon's method.

## Investigations

- **Radiological:** X-ray of Lumbo-sacral spine AP & lateral view if necessary.
- **Routine:** Hematological investigations-Hb%, TC, DC, ESR, RBS. Urine routine and microscopic to rule out other condition.

## OBSERVATIONS

In the present study among 30 patients of *Gridhrasi*, it was observed that 7 patients came under *Vatakaphaja* and 23 patients came under *Vataja* type. A maximum number of patients ie. 60% belonged to 51-60 age group, but there is no much difference in the count of male and female patients ie. 43% male and 57% female and all patients who participated in this study were married. In the study, 37.7% were office workers, 26.7% were home maker, 33.3% were doing business and 3.3% were working in manual labour field. On observing diet, it was found that 80% were following vegetarian diet. Out of 30 patients, 77% of the patients complained of disturbed sleep and about 43% of patients had a treatment history of NSAIDs. The number of participants with body weight bellow 50kg and more than 70kg were very less.

Out of 30 patients, about 57% of patients belonged to *Vatapitta Prakruti*, 30% were of *Vatakapha Prakruti*, 10% had *Pittakapha Prakruti* and only 3% belonged to *Kapha Prakruti* and a maximum of 80% patients had *Madhyama Vikruti* of *Dosha Dushti*. A maximum of participants had *Madhyama* in case of *Sara*, *Samhanana*, *Pramana*, *Satva*, *Satmya*, *Abhyavaharana Shakti*, *Jarana Shakti* and *Vyayama shakti*. Among 30 patients, 10% had sudden onset of disease and 90% of patients had gradual onset.

## RESULTS

**Table 1: Effect of *shuntyadi guggulu* on the symptoms of *gridhrasi*.**

	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
Effect of Treatment on <i>Stambha</i>								
BT	2.367	2.167	91.5%	0.490	0.0895	2.000	-5.066	P = <0.001
AT	0.200			0.484	0.0884	0.000		
Effect of Treatment on <i>Toda</i>								
BT	2.300	2.233	97.1%	0.466	0.0851	2.000	-5.002	P = <0.001
AT	0.0667			0.254	0.0463	0.000		
Effect of Treatment on <i>Spandana</i>								
BT	2.533	2.233	88.1%	0.571	0.104	3.000	-4.950	P = <0.001
AT	0.300			0.466	0.0851	0.000		
Effect of treatment on <i>Aruchi</i>								

BT	0.367	0.367	100%	0.718	0.131	0.000	-2.428	P =0.016
AT	0.000			0.000	0.000	0.000		
Effect of treatment on <i>Tandra</i>								
BT	0.400	0.400	100%	0.770	0.141	0.000	-2.460	P = 0.016
AT	0.000			0.000	0.000	0.000		
Effect of treatment on <i>Gaurava</i>								
BT	0.533	0.4663	87.4%	1.074	0.196	0.000	-2.392	P = 0.016
AT	0.0667			0.254	0.0463	0.000		

Table 2: Effect of *shuntyadi guggulu* on various outcome measures.

Outcome	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
Effect of Treatment on Pain								
BT	26.333	26.534	100%	4.901	0.895	25.000	4.791	P = <0.001
AT	52.867			3.148	0.575	52.000		
Effect of Treatment on Neurological Deficit								
BT	20.000	10.000	50%	0.000	0.000	20.000	-5.477	P = <0.001
AT	10.000			0.000	0.000	10.000		
Effect of Treatment on Functional ability								
BT	14.533	7.734	53.2%	3.857	0.704	13.000	4.820	P = <0.001
AT	22.267			1.172	0.214	22.000		
Effect of Treatment on Functional disability								
BT	27.333	24.2	88.5%	9.378	1.712	32.000	-4.809	P = <0.001
AT	3.133			3.026	0.552	2.500		

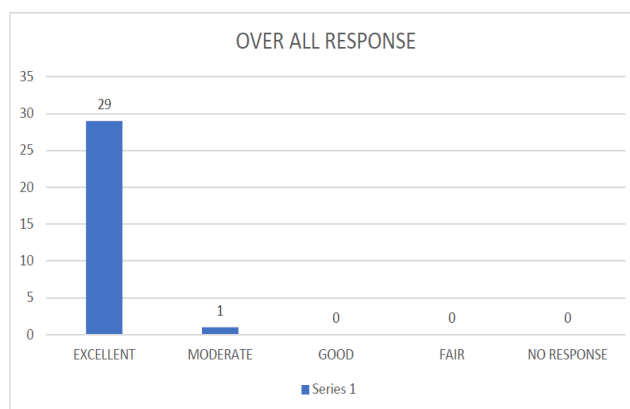
Table 3: Effect of *shuntyadi guggulu* on various test for sciatica.

	Mean	Mean difference	% of relief	SD	SE	Median	t value	P value
Effect of treatment on SLR active test								
BT	38.833	34.667	89.2%	9.886	1.805	45.000	-18.228	P = <0.001
AT	73.500			6.967	1.272	70.000		
Effect of treatment on SLR passive test								
BT	43.833	31.167	71.1%	11.647	2.127	45.000	-13.291	P = <0.001
AT	75.000			7.768	1.418	77.500		
Effect of treatment on Lasegue's test								
BT	38.833	38.834	100%	9.886	1.805	45.000	-13.514	P = <0.001
AT	77.667			13.880	2.534	80.000		

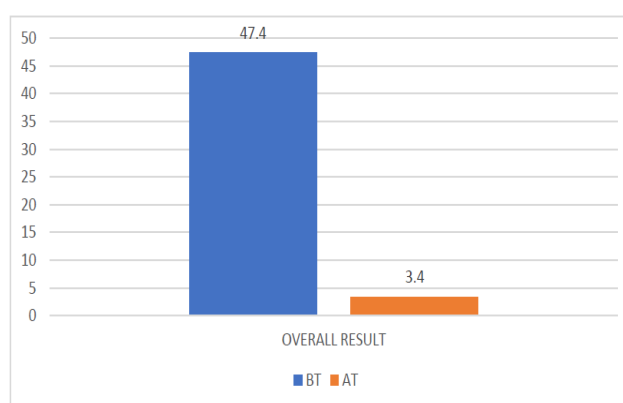
Table no. 4: Overall effect of the treatment.

Extent of change	Change category	Number of patients	Percentage of patients
0%	No	0	0%
1%-25%	Mild	0	0%
26%-50%	Moderate	0	0%
51%-75%	Marked	1	3.3%
76%-100%	Excellent	29	96.7%





**Figure No. 1: Over all response.**



**Figure No. 2: Individual assessment in graph.**

## DISCUSSION

The incidence and prevalence of *Gridhrasi* is high now a days and observation showed the incidence is almost same in both gender and we can say that, *Gridhrasi* can affect both the gender equally. Here the study also proves that the mentally and mechanically stressed middle class persons are more affected with *Gridhrasi*. The common cause for Sciatica syndrome observed from this study is life style ie. office workers who are travelling a lot, improper sitting postures etc. will result in the strain and stress in spine and this leads to the pathology of *Gridhrasi*. From the study, we observed, the onset is gradual and can conclude that, the common pathology is degenerative in *Gridhrasi* patients.

Results of this study displayed noticeable improvement in tests like Straight leg raising test, Lasegue's test etc. explains the excellent effect of *Shuntyadi Guggulu* in containing the pathology of sciatica syndrome i.e., in nerve root compression. The study showed improvement in activities like time taken for walking, climbing steps, situps, functional



ability and disability. This highlighted the improvement in quality of life in *Gridhrasi* patients after this treatment.

### Probable mode of action

*Gridhrasi* is *Vataja Nanatmaja Vyadhi*. *Theevra Ruja* is the main symptom of *Gridhrasi*. Excessively aggravated *Vata* in *Sphik Pradesha* causes *Stambha* (stiffness), *Ruk* (pain), *Toda* (pricking sensation) and *Muhurspandana* (twitching), while *Vatakaphaja Gridhrasi* has features of *Tandra* (drowsiness), *Gaurava* (heaviness in the legs) and *Arochaka* (tastelessness) along with the above symptoms. *Acharya Charaka* has explained the track of pain and it is similar to the sciatic nerve pathway. Here the *Vyana Vata* is vitiated along with *Apana Vata* and the locomotor action is affected. According to references *Sakthikshepa Nigraha* ie. the restricted movement of the affected limb, will also be there.

*Shuntyadi Guggulu* is said in *Vaidya Chindamani, Vataprakarana Adhyaya*. The *Shuntyadi Guggulu Yoga* has the direct reference for *Gridhrasi*. Twelve herbs except *Guggulu* are taken and powdered in a portion of one part each. Fine powder of these drugs is mixed with 24 parts of *Guggulu Paka* and filled in capsules after cooling off. *Ushna Jala* is given as *Anupana*.

The drugs like *Shunti*, *Maricha*, *Pippali*, *Pippalimula*, *Haritaki* etc. have the *Deepana-Pachana Karma*. All drugs of *Shuntyadi Guggulu* are having *Ushna Veerya*. This can act on vitiated *vata* and also most of them have *ShoolaPrashamanaproperty*. Analgesic and Anti-inflammatory property of drugs like *Guggulu* will reduce the pain which is the main symptom of *sciatica*. *Rasna* and *Guggulu* are well known for their action in pacifying vitiated *Vata* and *Guggulu* as the main ingredient of *Shuntyadi Guggulu* also controls morbid *vata*. The *Laghu*, *Ushna*, *Sukshma* and *Srotoshodhanaproperties* of *Guggulu* results in the *Kapha Shamana* and it removes the *Kapha* obstruction and opens the path, then relieves the *Stambha* and *Tandra*.

The *Sanga* and *Margavarodha* type of *Srotodushti* is present in *Gridhrasi*. The *Kapha Prakopa Nidana* results in *Agni Mandhya* and there by production of *Ama*. This leads to vitiation of *Agni*, *Rasa Dhatu* and resulting in production of *Kapha* as it is the *Mala* of *Rasa dhatu*. The *Shuntyadi Guggulu* helps in removing the *Margavarana* and also in reducing the *Dhatukshaya*. Study confirms effect of *Shuntyadi Guggulu* on neurological deficit and improving functional ability. This shows the ability of *Yogato* provide symptomatic relief and also in the *Samprapti Vighatana*.

The drugs *Pippali* and *Guggulu* have the *Rasayana* property and improves the *Poshana* of *dhatu* or provide strength to nerve and ligaments.

*Haritaki* is having *Deepana*, *Vatanulomana*, *Kaphanisaraka* and *Vatashamaka* properties. It acts on both *Vata* and *Kapha*, thereby effective in *Vata* as well as *Vata-Kaphaja Gridhrasi*. The *Rechana* or *Mridu Virechana* effect of *Pippali*, *Rasna* and *Haritaki* helps in pacifying morbid *vata*. *Pippali* is having an add on effect i.e., helps in increasing the effect of other drugs.

Sciatica also known as sciatic neuritis, sciatic neuralgia, lumbar radiculopathy or radicular leg pain. Referred pain typically felt like shooting or shock starts from the lower back and radiates along the sciatic nerve pathway. Pain typically occurs in the distribution of a dermatome and goes below the knee to the foot and is associated with neurological dysfunction, such as weakness and numbness. Sciatica is caused by injury or pressure on the sciatic nerve. In 90% of sciatica patients, disc bulge or herniation will be the cause. The disc pathology or nerve root irritation by the stress in lumbosacral level results in this condition. *Haridra* prevents the release of inflammatory mediators such as TNF- $\alpha$ . The volatile oil, curcumin and its derivatives, are the active anti-inflammatory constituents of the herb. The chemical constituent quercetin is having the anti-inflammatory effect. Piperine, which is the prime constituent of *Pippali* fruit, is reported to be having significant anti-inflammatory activity and its root is having anti-inflammatory and analgesic activity. About 89% remission in the SLR test shows the effect of *Shuntyadi Guggulu* in this pathology. The anti-inflammatory action of *Yoga* helps in reducing the pain. The main symptom of sciatica syndrome is severe pain and is relieved by *Guggulu* which is having analgesic property.

The *Ushna Jala* is having the properties like *Deepana*, *Pachana*, *Srotoshodhana* etc. and this helps in correcting the *Agni* and opens the *Srothomukha*. The *Ushna Jala Anupana* helps in increasing the action of main drug.

## CONCLUSION

The ingredients of *Shuntyadi Guggulu* are easily available, preparation and administration were simple, palatable, free from adverse effects, therapeutic effectiveness was good and cost effective. So, it can be adopted as a medication for treatment of *Gridhrasi*/Sciatica Syndrome. *Shuntyadi Guggulu* is very effective in remission of the signs and symptoms of *Gridhrasi* and in improving the functional ability and quality of life as evidenced through statistically

significant improvement in score of various subjective and objective parameters. This study proved the excellent effect of *Shuntyadi Guggulu* in both *Vata* and *Vata Kaphaja Gridhrasi*. Further study with more number of patients may give more annotations regarding the effect of *Shuntyadi Guggulu* in *Gridhrasi/Sciatica Syndrome*.

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