

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SHUNTHYADI GUGGULU AND TRAYODASHANGA GUGGULU IN GRIDHRASI

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ABSTRACT

Gridhrasi is a pain predominant *Nanatmaja Vata Vyadhi* characterised by radiating pain through *Sphik, Kati, Prishtha, Uru, Janu, Jangha and Pada* in a sequential pattern. A number of medicines are available in market to treat this condition, but are associated with their side effects too. Hence, there arises a need for an effective, yet safe treatment for the suffering population to ease their problems of pain. In light of these considerations a comparative clinical study was planned to assess and compare the efficacy of two formulations, namely *Shunthyadi Guggulu* and *Trayodashanga Guggulu*. Statistically significant changes were observed in the symptoms like *Ruk, Stambha, Toda, Muhuspandana, Tandra, Gaurava, Aruchi*, Time taken to cover the distance of 50ft, SLR Active and Passive test (Affected leg).

Keywords: *Gridhrasi, Shunthyadi Guggulu, Trayodashanga Guggulu, Sciatica.*

INTRODUCTION

The basic difference between the living and non-living is the ability to move from one place to another and it

is hampered when an individual suffers from pain. A change in lifestyle and food habits along with

increased possibilities of daily injuries even at the micro-level affects every system of the human body including the Musculoskeletal and Nervous systems. *Gridhrasi*, a *Shoola Pradhana* (shooting pain predominant) *Nanatmaja Vata Vyadhi*¹ mentioned in *Ayurveda* explains one such disorder wherein, pain starts from *Sphik Pradesh* and radiates downwards to *Kati*, *Prishtha*, *Uru*, *Janu*, *Jangha*, *Pada* resulting with an inability of the patient to walk with ease. On the basis of symptoms, it can be correlated to Sciatica in modern medicine.

About 50 - 70 % of people get affected by low back pain with the incidence of Sciatica more than 40%². Administration of Analgesics, NSAIDs, Corticosteroids, Muscle relaxants gives temporary relief from pain. The surgical measures which are indicated are quite expensive and result in several complications. So, there is a need for a cost-effective and safer drug having an established efficacy.

Considering these aspects, two *Shamana Yoga* were selected for the study. *Shunthyadi Guggulu*³ is mentioned in *Vaidya Chintamani* having ingredients like *Shunti*, *Pippali*, *Devadaru*, *Rasna* etc. *Trayodashanga Guggulu*⁴ is mentioned in *Cakradatta* having ingredients like *Ashwagandha*, *Hapusa*, *Satapushpa*, *Yavani* etc. Both these formulations possess *Vata-Kaphahara*, *Deepana*, *Pachana* properties and are indicated in *Gridhrasi*.

Hence, this study is a sincere effort made to evaluate and compare the effect of *Shunthyadi Guggulu* and *Trayodashanga Guggulu* in the management of *Gridhrasi*.

OBJECTIVES OF THE STUDY: -

- To evaluate the therapeutic effect of *Shunthyadi Guggulu* in *Gridhrasi*.
- To evaluate the therapeutic effect of *Trayodashanga Guggulu* in *Gridhrasi*.
- To compare the therapeutic effect of *Shunthyadi Guggulu* and *Trayodashanga Guggulu* in *Gridhrasi*.

MATERIAL AND METHODS

IEC NUMBER: ICEC/KC/02

DRUG SOURCE: Raw drugs were collected from the source of procurement after proper identification by

experts. Medicines were prepared according to texts at Alva's Ayurveda Pharmacy, Mijar, Moodbidri.

SAMPLE SOURCE: Patients diagnosed with *Gridhrasi* were selected from the Outpatient Department and Inpatient Department of Post Graduate studies of *Kayachikitsa*, Alva's Ayurveda Medical College and Hospital, Moodbidri and also from Special medical camps and other referrals.

METHOD OF COLLECTION OF DATA: A case proforma was prepared with details of history taking, physical examination, necessary investigations and assessment parameters of signs and symptoms with their scores. This was analysed statistically.

SELECTION OF PATIENTS: Done irrespective of gender, religion, occupation, marital status, socio-economic status and educational status, fulfilling the diagnostic, inclusion and exclusion criteria of *Gridhrasi*.

SAMPLE SIZE AND GROUPING - A minimum of 40 patients in total, randomly allocated into 2 arms A and B comprising minimum of 20 patients in each group.

STUDY DESIGN - Parallel Group Comparative Clinical Study.

BLINDING - Single Blind.

METHOD OF SAMPLING - Lottery Method.

DIAGNOSTIC CRITERIA

1. Patients with radiating pain from *Sphik* and *Kati* to *Prishtha*, *Uru*, *Janu*, *Jangha* and *Pada*.
2. *Stambha* (*Stiffness*), *Toda* (*Pricking Sensation*), *Muhuspandana* (*Tingling Sensation*).
3. With or without *Tandra* (*Drowsiness*), *Gaurava* (*Heaviness*), *Aruchi* (*Anorexia*).
4. Positive SLR Test.

INCLUSION CRITERIA

1. Patients of age group between 20-60 years of either sex.
2. Patients fulfilling the diagnostic criteria as mentioned above.

EXCLUSION CRITERIA

1. Congenital, Neoplastic, Infective conditions of the spine.
2. *Gridhrasi* developed due to any post-surgical complications.

3. Patients who have lost the control on bladder and defecation.
4. Patients with any other systemic disorders which were felt to interfere with the clinical trial.
5. Pregnant women and Lactating mothers.

INTERVENTIONS

GROUP A (Trial group): *Shunthyadi Guggulu* in the dose of 500mg 2 tablets thrice a day after food with *Ushna Jala* for 30 days.

GROUP B (Standard group): *Trayodashanga Guggulu* in the dose of 500mg 2 tablets thrice a day after food with *Ushna Jala* for 30 days.

OBSERVATION PERIOD

- Treatment period - 30 days.
- Follow up - 15 days after completing the course of treatment.
- Total study duration - 45 days (30 days + 15 days).
- Days of assessments - Baseline, 16th day and after treatment i.e., on 31st day.

ASSESSMENT CRITERIA

- Based on detailed case proforma adopting standard scoring methods of subjective and objective parameters.
- Statistical test of significance - Analysed using paired 't' test and unpaired 't' test along with other suitable statistical methods wherever necessary.

SUBJECTIVE PARAMETERS: *Ruk, Stambha, Toda, Muhuspandana, Tandra, Gaurava, Aruchi*

OBJECTIVE PARAMETERS: SLR test (Active and Passive) and Distance of walking (Time taken to cover the distance of 50 Ft)

INVESTIGATIONS: Routine haematological investigations along with X-ray of Lumbo - Sacral Spine - AP and Lateral views were carried out whenever found necessary.

STATISTICAL TEST: Comparative analysis of the overall effect of the treatments in both the groups was done statistically with Mann-Whitney Rank Sum Test and within the group comparison with Wilcoxon Signed Rank Test.

RESULTS: -

Table 1: Demographic details

Demographic Characters	Highest Recorded	Reasons
Age	41 - 50 yrs.	Susceptibility of productive population is proven by the statistics.
Gender	52.5% (Males)	Man, to fulfil the needs of family, his body undergoes various kinds of stress which finally lands up in this painful disorder.
Socioeconomic status	50% (Lower Middle Class)	Due to subjective stress on the body secondary to their occupation.
Occupation	40% (Labour)	Nature of work has direct influence on the etiopathogenesis of <i>Gridhrasi</i> .
Addiction	80% (Tea, Coffee, Alcohol)	Addictions act as <i>Vata vyadhi Nidana</i> and further produce <i>Vata prakopa</i> producing <i>Gridhrasi</i> .
Nature of work	82.5% (Moderate nature of work)	Physical strain is an important <i>Vata Prakopa Nidana</i> to land a person to <i>Gridhrasi</i> .
<i>Prakruti</i>	72.5% (<i>Vata - Kapha</i>)	Susceptibility of persons with <i>Vata</i> as <i>Prakruti</i> to develop <i>Vataja</i> disorders like <i>Gridhrasi</i> .
Nature of Sleep	72.5 % (Disturbed Sleep)	It is quite evident that the character of pain in this disease disturbs the sleep of the patient which in turn caused <i>Vata Prakopa</i> .

Table 2: Effect of *Shunthyadi Guggulu* in Subjective and Objective Parameters in Group A.

CRITERIA	MEDIAN BT	MEDIAN AT	%	WSRT Value	p Value
<i>Ruk</i>	3.00	2.00	56.67	210.000	<0.001
<i>Stambha</i>	3.00	1.50	62.50	190.000	<0.001
<i>Toda</i>	3.00	1.00	50.00	210.000	<0.001
<i>Muhuspandana</i>	2.00	1.00	42.50	136.000	<0.001
<i>Tandra</i>	1.00	0.50	40.00	55.000	=0.002
<i>Gaurava</i>	1.00	0.50	48.28	55.000	=0.002
<i>Aruchi</i>	0.50	0.50	61.54	45.000	=0.004
Time Taken to Cover the Distance Of 50ft	3.00	1.00	59.62	210.000	<0.001
SLR Test (Right Leg - Active)	3.00	1.00	54.84	55.000	=0.002
SLR Test (Right Leg - Passive)	2.00	1.00	45.45	45.000	=0.004
SLR Test (Left Leg - Active)	3.00	1.50	50.00	55.000	=0.002
SLR Test (Left Leg - Passive)	2.00	1.00	47.62	36.000	=0.008

Table 3: Effect of *Trayodashanga Guggulu* in Subjective and Objective Parameters in Group B.

CRITERIA	MEDIAN BT	MEDIAN AT	%	WSRT Value	p Value
<i>Ruk</i>	3.00	2.00	51.52	210.000	<0.001
<i>Stambha</i>	3.00	1.00	60.00	210.000	<0.001
<i>Toda</i>	3.00	2.00	49.21	210.000	<0.001
<i>Muhuspandana</i>	2.00	1.00	45.83	171.000	<0.001
<i>Tandra</i>	0.00	0.00	43.75	15.000	=0.063
<i>Gaurava</i>	0.00	0.00	42.86	15.000	=0.063
<i>Aruchi</i>	0.00	0.00	57.14	10.000	=0.125
Time Taken to Cover the Distance Of 50ft	3.00	1.00	55.93	210.000	<0.001
SLR Test (Right Leg - Active)	3.00	1.00	56.67	55.000	=0.002
SLR Test (Right Leg - Passive)	2.00	1.00	50.00	55.000	=0.002
SLR Test (Left Leg - Active)	3.00	1.00	55.17	55.000	=0.002
SLR Test (Left Leg - Passive)	2.00	1.00	38.89	21.000	=0.031

Table 4: Comparative effect of Group A and Group B

Assessment Criteria	Group A	Group B	A - B	Percentage Relief		p Value
				Group A	Group B	
<i>Ruk</i>	2.000	2.000	0.000	56.67	51.52	<0.05
<i>Stambha</i>	1.000	2.000	1.000	62.50	60.00	>0.05
<i>Toda</i>	2.000	2.000	0.000	50.00	49.21	>0.05
<i>Muhuspandana</i>	1.000	1.000	0.000	42.50	45.83	>0.05
<i>Tandra</i>	0.500	0.000	0.500	40.00	43.75	>0.05
<i>Gaurava</i>	0.500	0.000	0.500	48.28	42.86	>0.05
<i>Aruchi</i>	0.000	0.000	0.000	61.54	57.14	>0.05
Time is taken to cover the distance of 50 Ft	2.000	2.000	0.000	59.62	55.93	<0.05
SLR Test - Rt. Leg (Active)	2.000	2.000	0.000	54.84	56.67	>0.05
SLR Test - Rt. Leg (Passive)	1.000	1.000	0.000	45.45	50.00	>0.05
SLR Test - Lt. Leg (Active)	2.000	1.000	1.000	50.00	55.17	>0.05
SLR Test - Lt. Leg (Passive)	1.000	1.000	0.000	47.62	38.89	>0.05

Table 5: Overall effect: -

Group	Grading	No. of patients
Group A	Moderate improvement	1
	Marked improvement	19
Group B	Moderate improvement	13
	Marked improvement	7

DISCUSSION

DISCUSSION ON RESULTS AND MODE OF ACTION OF DRUGS: -

SHUNTHYADI GUGGULU is mentioned in *Vaidya Chintamani* having ingredients like **Sunthi** has *Katu Rasa; Guru, Ruksha, Tikshna Gunas; Usna Virya; Madhura Vipaka; Vata-kaphahara, Dipana* properties and it acts on *Sula*. Anti-inflammatory, Anti-emetic⁵. **Pippali** has *Katu Rasa; Laghu, Snigdha, Tikshna Gunas; Usna Virya; Madhura Vipaka; Vata-Sleshmaha, Dipana* properties and it acts on *Sula*. Anti-inflammatory, Anti-bacterial⁶. **Pippali Mula** has *Katu Rasa; Laghu, Ruksha Gunas; Usna Virya; Katu Vipaka; Kapha-Vatahara, Dipana* and *Pachana* properties. Anti-inflammatory, Anti-bacterial, Anti-helminthic⁷. **Vidanga** has *Katu, Kashaya Rasas; Laghu, Ruksha, Tikshna Gunas; Usna Virya; Katu Vipaka; Dipana* property and it acts on *Sula*. Insecticidal, Antimalarial⁸. **Devadaru** has *Tikta, Katu, Kashaya Rasas; Ruksha, Laghu Gunas; Usna Virya; Katu Vipaka; Kapha-Vatahara, Dipana* properties. Spasmolytic⁹. **Saindhava Lavana** has *Madhura Rasa; Snigdha, Laghu Gunas; Sheeta Virya; Tridosha Hara, Rochana, Dipana* property and it acts on *Aruchi*¹⁰. **Rasna** has *Tikta Rasa; Guru Guna; Usna Virya; Katu Vipaka* and *Kapha-Vatahara* property. Anti-oedema, Analgesic¹¹. **Chitraka** has *Katu Rasa; Laghu, Ruksha, Tikshna Gunas; Usna Virya; Katu Vipaka; Vata-kaphahara, Dipana, Pachana* properties and it acts on *Sula*. Anti-pyretic, Appetizer¹². **Yavani** has *Katu Rasa; Laghu, Ruksha, Tikshna Gunas; Usna Virya; Kapha-Vatahara, Dipana, Pachana* properties and it acts on *Sula*. Antioxidant¹³. **Marica** has *Katu Rasa; Laghu, Tikshna Gunas; Usna Virya; Katu Vipaka; Kapha-*

Vatahara, Dipana properties and it acts on *Sula*. Sedative, Analgesic, Muscle relaxant¹⁴. **Vacha** has *Katu, Tikta Rasas; Laghu, Tikshna Gunas; Usna Virya; Katu Vipaka; Kapha-Vatahara* property. Analgesic¹⁵. **Haritaki** has *Pancharasas; Laghu, Ruksha Gunas; Usna Virya; Madhura Vipaka; Tridoshahara, Anulomana* properties and it acts on *Sotha*. Anti-stress, Anti-spasmodic¹⁶. **Guggulu** has *Tikta, Katu Rasas; Laghu, Ruksha Gunas; Usna Virya; Katu Vipaka; Tridoshahara* property it acts on *Vata vyadhi, Sotha*. Anti-oedema, Anti-inflammatory¹⁷.

TRAYODASHANGA GUGGULU is mentioned in *Cakradatta* having ingredients like **Abha** has *Kashaya Rasa; Guru, Ruksha Gunas; Sita Virya; Katu Vipaka; Kaphahara, Lekhana* and *Grahi* properties. Anti-constipative¹⁸. **Ashwagandha** has *Katu, Tikta, Kashaya Rasas; Snigdha, Laghu Gunas; Usna Virya; Katu Vipaka; Vata-kaphahara* properties and it acts on *Sotha*. Antioxidant¹⁹. **Hapusa** has *Katu, Tikta Rasas; Guru Guna; Usna Virya; Katu Vipaka; Vata-kaphahara, Dipana* properties and it acts on *Sula*. Anti-spasmodic, Anti-oedema²⁰. **Guduchi** has *Tikta, Kashaya Rasas; Guru, Snigdha Gunas; Usna Virya; Madhura Vipaka; Tridosha shamaka, Dipaniya, Grahi* and it acts on *Sula*. Anti-stress, Anti-spasmodic²¹. **Satavari** has *Madhura, Tikta Rasas; Guru, Snigdha Gunas; Sita Virya; Madhura Vipaka; Vata-pittahara* property. Antioxidant²². **Gokshura** has *Madhura Rasa; Guru, Snigdha Gunas; Sita Virya; Madhura Vipaka; Vata-pittahara* property. Spasmogenic, Analgesic²³. **Vridhadaraka** has *Kashaya, Katu, Tikta Rasas; Laghu, Snigdha Gunas; Usna Virya; Madhura Vipaka; Vata-kaphahara* property and it acts on *Sotha*. Anti-inflammatory²⁴. **Rasna** has *Tikta Rasa; Guru Guna; Usna Virya; Katu Vipaka* and *Kapha-Vatahara* property. Anti-inflammatory, Anti-oedema²⁵. **Shatapushpa** has *Katu, Tikta Rasas; Laghu, Tikshna Gunas; Usna Virya; Katu Vipaka; Vata-kaphahara, Dipana* properties and it acts on *Sula*. Antioxidant²⁶. **Sathi** has *Katu, Tikta, Kashaya Rasas; Laghu, Tikshna Gunas; Usna Virya; Katu Vipaka; Kapha-Vatahara* property and it acts on *Sula*. Anti-emetic, Anti-inflammatory²⁷. **Yavani** has *Katu Rasa; Laghu, Ruksha, Tikshna Gunas; Usna Virya; Kapha-Vatahara, Dipana, Pachana* properties

and it acts on *Sula*. Antioxidant, Hypolipidemic²⁸. **Sunthi** has *Katu Rasa*; *Guru*, *Ruksha*, *Tikshna Gunas*; *Usna Virya*; *Madhura Vipaka*; *Vata-kaphahara*, *Dipana* properties and it acts on *Sula*. Anti-inflammatory, Anti-atherosclerotic²⁹. **Guggulu** has *Tikta*, *Katu Rasas*; *Laghu*, *Ruksha Gunas*; *Usna Virya*; *Katu Vipaka*; *Tridosahara* property it acts on *Vata vyadhi*, *Sotha*. Anti-oedema, Spasmolytic³⁰. **Ghrita** has *Madhura Rasa*; *Guru*, *Snigdha Gunas*; *Mrudu Veerya*; *Madhura Vipaka*; *Vata-pittahara* property. Antioxidant³¹.

Dropouts: 2 patients in Group A discontinued the treatment due to their personal reasons.

CONCLUSION

40 Patients having the Signs and Symptoms of *Gridhrasi* / *Sciatica* and who were in the age group of 20 - 60 yrs. who attended the OPD and IPD of Alva's Ayurveda Medical College and Hospital were subjected to Parallel Group Comparative Clinical Study and were treated with *Shunthyadi Guggulu* and *Trayodashanga Guggulu*. After completion of the study, the following are the conclusions drawn.

- *Gridhrasi* is one among the *Vataja Nanatmaja Vyadhi*, *Vataja* and *Vatakaphaja* are the clinical types.
- Stiffness, pain and pricking sensation beginning from the buttock and then sequentially progressing to the back of the pelvis, hip, thigh, knee, leg and feet is the cardinal manifestation of the *Gridhrasi*.
- The clinical symptoms of *Gridhrasi* match with *Sciatica* of modern parlance.
- *Mithyacharana* of *Vyayama* was found to be a triggering factor in the pathogenesis of this disease.
- Clinical: Clinically, Group A - *Shunthyadi Guggulu* and Group B - *Trayodashanga Guggulu* equally showed effective changes in attributes within the group. When groups were compared there was no significant difference in results.
- Statistical: Statistically significant changes were observed in the symptoms like *Ruk*, *Stambha*, *Toda*, *Muhuspandana*, *Tandra*, *Gaurava*, *Aruchi*,

Time taken to cover the distance of 50ft, SLR Active and Passive test (Affected leg).

- From the above data and discussion, it can be concluded that both *Shunthyadi Guggulu* and *Trayodashanga Guggulu* are equally effective in relieving the signs and symptoms with the mild difference in terms of percentage in *Gridhrasi*.
- Treatment of *Shunthyadi Guggulu* is curative in patients suffering from *Gridhrasi* as the study revealed 19 patients had marked improvement and 1 patient had moderate improvement.
- *Trayodashanga Guggulu* study revealed moderate improvement in 13 patients and marked improvement in 7 patients.
- Both groups are effective in the remission of the symptoms of *Gridhrasi* as evidenced by a statistically significant reduction in the symptom score. So, hypothesis H1 is rejected and H0 is accepted.
- Patient Tolerance: There were no adverse effects found in the groups. Therefore, these formulations are effective and safe to be used in clinical practice.
- Quality of life is improved by both the medications as shown by improvement of functional ability, as well as a reduction in functional disability.

Suggestions for further studies:

- The research can be done in a larger sample size to evaluate the efficacy of *Shamana Aushadhi's* (Palliative treatment) in *Gridhrasi*.
- The study can be carried by undertaking radiological investigations like MRI, NCS.
- The subjects may be preferred to be treated in an IPD set-up, to obtain a comprehensive evaluation of both disease and diseased.

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