

**A RANDOMIZED COMPARATIVE CLINICAL STUDY ON THE
EFFECT OF DVATRIMSAKA GUGGULU AND RASNA GUGGULU IN
THE MANAGEMENT OF GRIDHRASI W.S.R TO SCIATICA**

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ABSTRACT

Objective: To compare the therapeutic effects of *Dvatrimśaka Guggulu* and *Rasna Guggulu* in reducing the signs and symptoms of *Gridhrasi/Sciatica*. **Design:** Open randomized comparative clinical-study with pre and post-test design. Setting: O.P.D. and I.P.D. of Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Udupi. **Interventions:** The patients selected were randomly divided into 2 groups of 15 each by adapting the permuted block randomization method. Selected patients were treated with oral administration of *Dvatrimśaka Guggulu* for a period of 14 days with the *Anupana* of warm water in one group and another group was administered with *Rasna Guggulu*. **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. **Results:** *Dvatrimśaka Guggulu* and *Rasna Guggulu* are effective in the remission of the symptoms of *Gridhrasi* as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters. **Conclusion:** The effectiveness of the *Dvatrimśaka Guggulu* is supreme

comparing to that of *Rasna Guggulu* as evidenced by the various outcome measures and the statistical analysis shows that it is significant.

KEYWORDS: *Gridhrasi, Dvatrimśaka Guggulu, Rasna Guggulu, Sciatica.*

INTRODUCTION

Gridhrasi is one among 80 types of *Nānatmaja Vatavyadhi*.^[1] Action of walking is the function of *Karmendriya* especially both the *Pada*. Site of *Gridhrasi* is usually both the lower limbs. *Gati* of affected person is altered like that of *Gridhra* bird referred to vulture due to extreme pain similar to vulture piercing its beak into prey.^[2] Most of the Clinical features of *Sciatica* resemble to that of *Gridhrasi*. *Sciatica* can be defined as the radicular pain related to the sciatic nerve trunk.^[3] *Sciatica* causes pain, burning sensation, numbness, tingling sensation, radiating from the lower back and upper buttock down the back of the thigh, calf and to the foot, that is along the course of Sciatic nerve.^[11] Pain is the cardinal symptom of *Sciatica*. The lifetime incidence of this condition is estimated to be between 13% to 40%.^[4] Most commonly found in people age 25 to 45 years, men are more frequently affected than women. Highest incidence is found in 5th decade and the disease has been reported to occur in 1% to 10 % of population. Conventional medicine treatment of *sciatica* is limited to NSAID's, Opioid and non opioid analgesics, muscle relaxants, corticosteroid injections, physiotherapy and surgery.^[5] Despite of these expensive treatments and hospitalization the relapse of conditions intensify the gravity of problem. On other hand our science suggests cost effective and beneficial approach.

Shamana and *Shodhana Chikitsa* are explained for *Gridhrasi*. *Shodhana* includes mainly *Snehana, Swedana, Basti, Virechana etc.* Specific treatment modalities like *Siravyadha, Agnikarma, Katibasti*. *Shamana Chikitsa* includes medicinal preparations which are proved to be effective, one among that is *Guggulu*. It has *Vatashamaka* and *Shulahara* property.^[6] *Shamana* treatment is cost effective as well as convenient to patients as it does not require hospitalization. Some of the *Shamana Yoga* specifically been mentioned for *Gridhrasi* itself include *Dvatrimśaka Guggulu*^[7] and *Rasna Guggulu*.^[8] *Dvatrimśaka Guggulu* contains most potent 32 different drugs and there is no much research work carried on this formulation, Hence an effort will be put in this regard to compare the effect of *Dvatrimśaka Guggulu* and *Rasna Guggulu* in *Gridhrasi*.

Objectives

- ☉ To compare the therapeutic effects of *Dvatrimśaka Guggulu* and *Rasna Guggulu* in reducing the signs and symptoms of *Gridhrasi*/Sciatica.

MATERIALS AND METHODS

Source of data

The patients suffering from *Gridhrasi* will be selected for the study from OPD and IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi. *Dvatrimśaka Guggulu* and *Rasna Guggulu* will be obtained from SDM Ayurveda Pharmacy, Kuthpady, Udupi.

Study design

- ☉ Study Type : Interventional with pre and post - test design
- ☉ Estimated enrolment : 30 participants
- ☉ Allocation : Randomized
- ☉ Endpoint Classification : Comparative Study
- ☉ Intervention Model : Double group assignment
- ☉ Masking : Open label study
- ☉ Primary Purpose : Treatment

Intervention

The patient selected will be randomly divided into 2 groups of 15 each by adapting the permuted block randomization method.

Group A: Recruited subjects will be treated with oral administration of *Dvatrimśaka Guggulu* in the dose of 500mg 2 TID after food along with *Usna Jala*.

Group B: Recruited subjects will be treated with oral administration of *Rasna Guggulu* in the dose of 500mg 2 TID after food along with *Usna Jala*.

Patients will be reviewed on the 0th day - 14th day for recording the changes and asked to undergo follow up after 28days of treatment.

Duration

Group A: The study includes 14 days of medication with *Dvatrimśaka Guggulu* followed by another 28 days of follow up period. Total duration of study: 42 days.

Group B: The study includes 14 days of medication with *Rasna Guggulu* followed by another 28days of follow up period. Total duration of study: 42 days.

Follow up: 28 days after treatment.

Diagnostic criteria

- ⊙ Symptoms of *Gridhrasi* like radiating pain which radiates from back of thigh, leg and foot stiffness, pricking sensation, twitching in buttocks , heaviness of the legs, drowsiness and tastelessness.
- ⊙ Presence of radicular pain of sciatica that includes sudden or gradual onset of low back pain radiating to lower limb from buttock , thigh, calf and foot.

Inclusion criteria

- ⊙ Patients with *Prathyatma Laxana* of *Gridhrasi*.
- ⊙ Patients of *Gridhrasi* - Sciatica between the age of 16 to 70 years.
- ⊙ Patients having signs and symptoms of Sciatica.
- ⊙ Patients with or without evidences of Lumbar Spondylosis.
- ⊙ Patients with or without evidences of Disc Prolapse

Exclusion criteria

- ⊙ Patient with Infective conditions of the spine.
- ⊙ Neoplastic and Metastatic conditions of the spine with radicular pain.
- ⊙ Patient with other systemic disorders associating Sciatica.
- ⊙ Sciatica with Congenital deformities of spine.
- ⊙ Pregnancy and lactating mother.

Assessment criteria**Subjective parameters:**

- ⊙ Pain(*Ruk*) - Greenough & Fraser Scoring method
- ⊙ Stiffness (*Sthambha*)
- ⊙ Pricking type of pain(*Toda*)
- ⊙ Twitching (*Spandana*)
- ⊙ Functional Ability- Sugar baker & Barofsky Clinical Mobility Scale
- ⊙ Functional Disability - Oswestry Disability Assessment Questionnaire.

Objective parameters

- ⊙ Restricted limb movement-SLR Test (*Sakthiutkshepa nigraha*)
- ⊙ Neurological deficit-Herron and turners rating.

- ⊙ The parameters of signs and symptoms along with investigations will be scored on the basis of standard method and will be analyzed statistically using paired and unpaired t test and Wilcoxon's signed rank test and Mann Whitney U test.

Investigations

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

RESULTS

Table 1: Effect of *Dvatrimśaka Guggulu* and *Rasna Guggulu* on the symptoms of *Gridhrasi*.

Group p N=15	BT Mea n	AT Mean	Diff D BT-AT	% of Relief	Wilcoxon Signed Rank Test					Mann-Whitney U test		
					SD	SEM	Median	Z Value	P Value	T Value	U Value	P Value
Effect of Treatment on <i>Stambha</i>												
Group 1 <i>Dvatrisaka</i>	2.53	0.46	2.06	81.5	BT: AT:	BT: AT:	BT: AT:	3.53	<0.00 1	307	38	<0.00 1
Group 2 <i>Rasna</i>	2.53	1.33	1.20	47.3	BT: AT:	BT: AT:	BT: AT:	3.44	<0.00 1			
Effect of Treatment on <i>Toda</i>												
Group 1 <i>Dvatrisaka</i>	2.53	0.53	2	78.9	BT:0. 51 AT:0. 51	BT:0. 13 AT:0. 13	BT:3.00 AT:1.00	3.49	<0.00 1	315	30	<0.00 1
Group 2 <i>Rasna</i>	1.93	1.00	0.93	48.2	BT:0. 96 AT:0. 84	BT:0. 24 AT:0. 21	BT:2.00 AT:1.00	3.27	<0.00 1			
Effect of Treatment on <i>Spandana</i>												
Group 1 <i>Dvatrisaka</i>	0.93	0.13	0.80	85.7	BT:0. 96 AT:0. 35	BT:0. 24 AT:0. 90	BT:1.00 AT:0.00	2.58	0.008	259.5	85.5	0.222
Group 2 <i>Rasna</i>	0.53	0.13	0.4	75	BT: AT:	BT: AT:	BT: AT:	2.44	0.031			

***Dvatrimśaka guggulu* group** - The study proves that there was a remission by 81.5% in *Stambha*, recording a remission by 78.9% in *Toda*, and a remission by 85.7% in *Spandana*. 100% improvement was noted in case of *aruchi* and *Tandra*. 86.65 improvement was found

remission of *Gaurava*. **Rasna guggulu group** – The study proves that there was a remission by 47.3% in *Stambha*, recording a remission by 48.2% in *Toda*, and a remission by 75% in *Spandana*. 100% improvement was noted in case of *Aruchi* and 60% in *Tandra*. 52.6% improvement was found remission of *Gaurava*

Table 2: Effect of *Dvatrimśaka Guggulu* and *Rasna Guggulu* on various outcome measures.

Group P N=15	BT Mean	AT Mean	Diff D BT- AT	% of Relief	Wilcoxon Signed Rank Test					Mann-Whitney U test		
					SD	SEM	Median	Z Value	P Value	T Value	U Value	P Value
Effect of Treatment on Pain												
Group 1 <i>Dvatrimśaka</i>	25.5	51.9	26.4	40	BT: 7.06 AT: 6.05	BT: 1.82 AT: 1.56	BT: 25.0 AT: 54.0	3.42	<0.00 1	318	27	<0.00 1
Group 2 <i>Rasna</i>	27.2	45.2	17.9	27	BT: 8.04 AT: 6.61	BT: 2.07 AT: 1.70	BT: 23.0 AT: 47.0	3.41	<0.00 1			
Effect of Treatment on Neurological deficit												
Group 1 <i>Dvatrimśaka</i>	56.3	12.6	43.6	36.3	BT: 13.9 AT: 7.03	BT: 7.03 AT: 1.81	BT: 60.0 AT: 10.0	3.42	<0.00 1	281	64.0	0.045
Group 2 <i>Rasna</i>	56.0	21.6	34.3	28.6	BT: 20.5 AT: 10.9	BT: 5.30 AT: 2.83	BT: 45.0 AT: 20.0	3.41	<0.00 1			
Effect of Treatment on Functional ability												
Group 1 <i>Dvatrimśaka</i>	16.5	22.5	6	25	BT: 2.53 AT: 0.91	BT: 0.65 AT: 0.23	BT: 17.0 AT: 23.0	3.42	<0.00 1	317	28.0	<0.00 1
Group 2 <i>Rasna</i>	16.8	20.6	3.74	15.5	BT: 2.61 AT:1 .84	BT: 0.67 AT:0. 47	BT: 18.0 AT: 21.0	3.45	<0.00 1			
Effect of Treatment on Functional Disability												
Group 1 <i>Dvatrimśaka</i>	22.4	3.93	18.5	37	BT: 5.15 AT: 1.87	BT: 1.33 AT: 0.48	BT: 24.0 AT: 4.00	3.41	<0.00 1	318	26.5	<0.00 1
Group 2 <i>Rasna</i>	21.4	9.86	11.5	23	BT: 5.84 AT: 4.38	BT: 1.50 AT: 1.13	BT: 20.0 AT: 10.0	3.419	<0.00 1			

Dvatrimśaka guggulu group -A remission by 40% was found in Pain Criteria with statistically significant difference ($P = <0.001$). Neurological deficits improvement were 36.3% with highly significant P value < 0.001 , Functional ability increased by 25% and Functional disability decreased by 27% . **Rasna Guggulu Group** – A remission by 27% was found in Pain Criteria with statistically significant difference ($P = <0.001$). Neurological deficits improvement were 28.6% with highly significant P value < 0.001 , Functional ability increased by 15.5% and Functional disability decreased by 23% .

Table 3: Effect of Dvatrimśaka Guggulu and Rasna Guggulu on various Test for Sciatica.

Effect of treatment on SLR Test Active										
	BT Mean	AT Mean	Diff D BT-AT	% of Relief	Paired t test				Unpaired t test	
					SD	SEM	T VALUE	P VALUE	T VALUE	P VALUE
Group 1 <i>Dvatrimśaka</i>	38.3	69.6	31.3	81.7	BT: 6.98 AT: 11.4	BT: 1.80 AT: 2.94	14.194	<0.001	2.88	0.07
Group 2 <i>Rasna</i>	36.3	58.0	21.6	59.6	BT: 7.43 AT: 11.4	BT: 1.91 AT: 2.96	8.599	<0.001		
Effect of treatment on SLR Test Passive										
Group 1 <i>Dvatrimśaka</i>	41	73.6	32.6	79.6	BT: 5.73 AT: 9.90	BT: 1.48 AT: 2.55	14.00	<0.001	1.76	0.08
Group 2 <i>Rasna</i>	44.3	70	26.6	57.9	BT: 7.28 AT: 14.6	BT: 1.88 AT: 3.78	8.034	<0.001		
Effect of treatment on Lasegue’s test										
Group 1 <i>Dvatrimśaka</i>	36.3	70.0	33.6	92.6	BT: 7.43 AT: 14.1	BT: 1.91 AT: 3.92	12.11	<0.001	2.08	0.04
Group 2 <i>Rasna</i>	39.3	68.0	28.6	72.8	BT: 6.23 AT: 10.4	BT: 1.60 AT: 2.70	13.31	<0.001		
Effect of treatment on Schober’s test										
Group 1 <i>Dvatrimśaka</i>	16.8	21.0	4.2	25	BT: 3.16 AT: 4.24	BT: 0.81 AT: 1.09	11.03	<0.001	0.97	0.33

Group 2 <i>Rasna</i>	17.1	21.8	4.7	27.4	BT: 2.35 AT: 2.80	BT: 0.60 AT: 0.72	16.24	<0.001		
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***Dvatrimśaka guggulu* group** –The improvement in SLR Active and Passive were 81.7% and 79.6% respectively. There were 92.6% improvement in Lasegue's test and 24% improvement in Schober's test with P value <0.001. 33% improvement in time taken for walking 30 feet's, 38.7% in time taken for 10 sit ups, 36.3% improvement in time taken for climbing 10 steps, 41.3% remission in distance between floor and finger on forward bending with each having P value <0.001. ***Rasna guggulu* group** –The improvement in SLR Active and Passive were 59.6% and 57.9% respectively. There were 72.8% improvement in Lasegue's test and 27.4% improvement in Schober's test with P value <0.001. 40.3% improvement in time taken for walking 30 feet's, 32% in time taken for 10 sit ups, 30% improvement in time taken for climbing 10 steps, 27.5% remission in distance between floor and finger on forward bending with each having P value <0.001.

Comparison between the groups using Mann whitney U test showed that the results were statistically significant with $p < 0.001$ and percentage of relief showed that *Dvatrimśaka Guggulu* benefitted better.

Table no. 4: Overall effect of the treatment.

Extent of Change	Change Category	Number of Patients			% of Patients		
		<i>Dvatrimśaka Guggulu</i>	<i>Rasna Guggulu</i>	Total	<i>Dvatrimśaka Guggulu</i>	<i>Rasna Guggulu</i>	Total
0%	No	0	0	0	0%	0%	0%
1%-25%	Mild	0	0	0	0%	0%	0%
26%-50%	Moderate	1	9	10	6.6%	60%	33.3%
51%-75%	Marked	3	5	8	20%	33.3%	26.6%
76%-100%	Excellent	11	1	12	73.3%	6.6%	40%

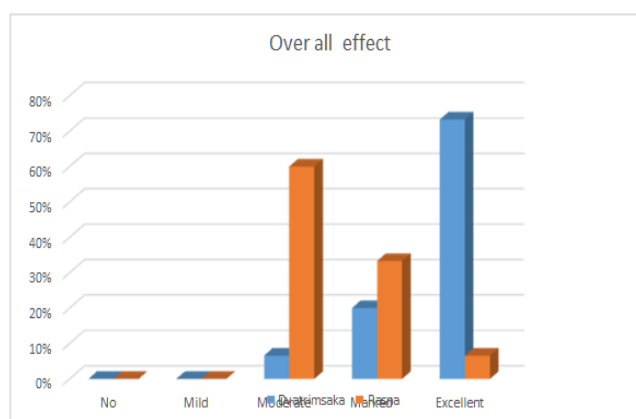


Figure no. 1: Overall effect of the treatment.

In *Dvatrimśaka Guggulu* Group it is found that 73.3% patients had complete improvement, 20% of patients had marked improvement and 6.6% of them had moderate improvement. In *Rasna Guggulu* Group 40% patients had complete improvement, 26.6% of them had mild improvement, 33.3% of patients had moderate improvement. In both Groups, none of them had any adverse reaction or symptoms unchanged.

DISCUSSION

Dvatrimśaka guggulu is mentioned in *Yogaratanakara Vatavyadhi adbhikara*. As the name indicates the *Yoga* consists of thirty-two ingredients including *Guggulu*. Among that thirty – one ingredients are taken in equal proportion and same quantity of *Guggulu* is added. *Dvatrimśaka Guggulu* is a herbo mineral combination, most the drugs in the formulation are having *Vata kapha hara* property which alleviates both morbid *Vata* and *Kapha Dosha*. This *Yoga* is explained by Lord *Danwantari* himself, indicated in all types of *Vatavyadhi* especially *Gridhrasi*.

Due to *Ushna veerya* of drugs such as *Chavya*, *Chitraka*, *Vacha* and all morbid *Vata* get pacified. The *Deepana pachana* property of *Maricha*, *Pippali*, *Shunti Amapachana* action will be fulfilled. *Haritaki* and *Bibitaki* have *Vatanulomana* property that have in *Mridu Virechana* thereby helps pacifying the excessive *Vata* and *Kapha* in the body. Drugs like *Devadaru*, *Tumburu*, *Vatsanabha*, have *Shoolahara* property that provides symptomatic relief to the patient. *Guggulu* is excellent anti-inflammatory drugs which act as *Kapha vatashamaka* and also *Vendana shamaka* due to its *Ushana veerya*. *Amalaki* and *Pippali* will act as *Balya* and provides *Rasayana* effect to the *shareera*. *Dvatrimśaka guggulu* as effective in all patients despite of suffering from *Vataja* or *Vatakaphaja Gridhrasi* without any undesirable effects.

Rasna Guggulu is the herbal formulation which consist of *Rasna* and *Guggulu* in equal quantity. *Rasna* is well known *Vatahara* drug which is also have a *Kaphahara* property and *Guggulu* act as *Kapha vata shamaka* thus alleviating both *Kapha* and *Vata Dosha*. *Rasna* have *Guru snigdha guna* and *Ushna Veerya* and it act as *Vayastapana*. Due to *Vata anulomana* property it provides a *mridu rechana* action and helps to pacify morbid *Vata*. The agalanga content of *Rasna* act as analgesic as well as anti-inflammatory. *Guggulu* is also one of the main ingredient which have anti-inflammatory and analgesic property due to its

Ushna veerya. *Guggulu* is a *Rasayana* drug having *Kaphavata shamaka* and *Vedanashamaka* property. So *Rasna Guggulu* was beneficial in both type of *Gridhrasi* despite of any complication.

Vataprakopa is evident in *Gridhrasi* as it causes severe pain, stiffness and altered sensation of the limbs. One of the important *Prathyanga* of *Shareera* is *Snayu*. *Utkshepa* and *Apakshepa* is one among its *Karma*. In *Gridhrasi* this *Snayu* will be affected by the morbid *Vata* and causing impairment. The improvement in the functions are evident from the increased functional ability, reduced functional disability and improvement in time taken for walking, climbing stairs and sit ups after treatment. There was remarkable reduction in all these signs and symptoms of *Gridhrasi* in both groups. But Group A administered with *Dvatrimśaka guggulu* had better results statistically and found to be efficacious in reducing morbidity of *Vata*. The efficacy of *Dvatrimśaka Guggulu* is beyond doubt rectifying the etiopathogenesis of *Gridhrasi* irrespective of its cause as *Dhatukshaya* or *Margavarana*. Similar is the outcome related to *Rasna Guggulu* also.

CONCLUSION

Dvatrimśaka Guggulu and *Rasna Guggulu*, both have shown improvement in almost all the parameters, but comparatively *Dvatrimśaka Guggulu* showed better results. A maximum 73.3% and minimum 20% of patients showed complete and moderate remission in *Dvatrimśaka Guggulu* group respectively. Whereas in *Rasna Guggulu* group complete and mild remission has been seen equal to 26.6%, 33.3% respectively.

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