

AN OPEN RANDOMIZED COMPARATIVE CLINICAL STUDY ON RASNA GUGGULU AND KATIBASTI WITH VISHAGARBHA THAILA IN GRIDRASI W.S.R SCIATICA SYNDROME

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ABSTRACT

Objective: To evaluate the therapeutic efficacy of *RasnaGuggulu* in the remission of the symptoms of *Gridhrasi/Sciatica*, to evaluate the therapeutic efficacy of *Kati Basti* with *Vishagarbha thaila* in the remission of the symptoms of *Gridhrasi/Sciatica* and to compare the effect of *RasnaGuggulu* and *KatiBasti* in bringing symptomatic relief and functional improvement in the patients of *Gridhrasi/Sciatica*. **Design:** Open randomized comparative clinical-study with pre and post-test design. **Setting:** I.P.D. of Shri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Udupi. **Participants:** 30 patients diagnosed as *gridhrasi*. **Interventions:** The patients selected were randomly divided into 2 groups of 15 each by adapting the permuted block randomization method. *RasnaGuggulu* Group: 15 patients were treated with *RasnaGuggulu* for a period of 7 days with the *anupana* of 150 ml of *Ushnajala*. *KatiBasti* Group: 15 patients were treated with *KatiBasti* during morning or day time after evacuation of bowel or bladder for 7days consistently. **Main outcome measures:** Pain – Greenough & Fraser scoring method; Stiffness, Functional ability by Sugarbaker & Barofsky Clinical Mobility Scale; Functional Disability by Oswestry Disability Assessment Questionnaire; Restricted Limb Movement/SLR Tests; Neurological Deficit- Herron & Turners Rating. **Results:** *RasnaGuggulu* and *Katibasti* 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. **Interpretation & Conclusion:** *RasnaGuggulu* and *Katibasti* 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.

Keywords: Gridhrasi, RasnaGuggulu, KatiBasti, Vishagarbha thaila, Sciatica.

INTRODUCTION

As walking is an integral part of the routine since man learnt walking, the infirmity which hamper the movement of the limbs are as old as the learning of walking. As per estimation 80% of Americans will experience low back pain, the annual prevalence is 15-45% with a point prevalence of approximately 30%. The causes of low back ache may range from trivial mechanical inflict to more severe lingering or fatal illnesses. *Gridhrasi* is considered as most common cause of low back ache mostly affecting the people at their most productive age. *Gridhrasi* is paralleled to Sciatica Syndrome in the modern parlance.

Vatavyadhi is one of the most prevailing health problems in the clinical practice and *Gridhrasi* is one among them. *Kandara* or else termed as *gridhrasi snayu* is affected in *gridhrasi* causing *ruja* (pain) as the dominant feature. Pain is felt in the region of *sphik*, *prush-ta*, *jaanu*, *jangha*, and *pada*¹. The typical diagnostic method mentioned for the sciatica, straight leg raising test (SLR), is explained as *sakthiutkshepanigraha* in the classics. *Gridhrasi* is one among the 80 *vatajananatmajavyadhi* enumerated in the classics and the treatment for *vataja nanatmajavyadhi* should be more beneficial for quality of life. *Kevala-vataja* and *vatakaphaja* are the two clinical variations in presentation of *gridhrasishoola*. *Khalli* is also considered as a variant form of the *gridhrasi shoola*⁴. *Vataja gridhrasi* is characterized by *stambha* (stiffness), *ruk* (pain), *toda* (pricking sensation) and *muhurspandana* (twitching), while, *vatakaphajagridhrasi* has

features of *tandra* (drowsiness), *gaurava* (heaviness in the legs) and *arochaka* (tastelessness) along with the above symptoms². *Snigdhasweda*, *virechana karma*, *niruhabasti*, *anuvasanabasti*, *agnikarma*, *siravyadha*, *shamana* medications and *rasayana* are the complete treatment principles of *gridhrasi* in both the varieties with a little difference. As *rasna* and *guggulu* have unique properties like *vatakaphahara*, *vayasthapana*, *rasayana*, *vrushya*, *tridosahara*, oral administration of *Rasnaguggulu* is said to be very effective and curative in *vatavyadhi* especially in *gridrasi* which includes *katishoola* as a main symptom. This medication with *rasnaguggulu* is indicated both in *vataja* and *vatakaphaja* variants of *gridhrasi*. Likewise the *bahirparimarjanachikitsa* also promotes an equal contribution for the treatment of *Gridrasi*. *Katibasti* is one among the *drava sweda*⁵. *Swedana* is best advised in *Gridrasi* when symptoms like *sthambha*, *ruk*, *gourava* are present. As the disease is *vata* and *vatakapha-pradhana*, the *swedana* selected is to be *snigdha/ruksha* with *vata/vatakaphahara* drugs.

OBJECTIVES

1. To evaluate the therapeutic efficacy of *RasnaGuggulu* in the remission of the symptoms of *Gridhrasi/Sciatica*.
2. To evaluate the therapeutic efficacy of *Kati Basti* in the remission of the symptoms of *Gridhrasi/Sciatica*.

3. To compare the effect of *RasnaGuggulu* and *Kati Basti* in bringing symptomatic relief and functional improvement in the patients of *Gridhrasi/Sciatica*.

MATERIALS AND METHODS

Source of data: 30 patients diagnosed as *Gridhrasi/Sciatica* fulfilling the diagnostic/inclusion and exclusion criteria were taken for study from OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka. The *guggulu* each containing 500 mg of *rasna* and *guggulu* and ingredients of *Vishagarbhathaila* for *katibasti* were obtained from SDM Ayurveda Pharmacy Udyavara, Udupi.

Method of collection of data:

A special proforma was prepared incorporating all the clinical manifestation and assessment criteria including laboratory investigation findings of the *Gridhrasi/Sciatica* with Complete data including detailed clinical history and complete physical examination.

Diagnostic criteria

1. Presence of symptoms of *Gridhrasi* that include stiffness, pain, pricking sensation, twitching in waist, buttocks & then radiating to back of the thigh, leg, ankle, foot suggestive of *VatajaGridhrasi*. The additional symptoms like heaviness in the legs, drowsiness and tastelessness may be present.
2. Presence of radicular pain of *Sciatica* that includes sudden/gradual onset of low back ache radiating to buttock, thigh, calf and foot.

Inclusion Criteria

1. Patients of *Gridhrasi/Sciatica* between the age of 16 to 70 years.
2. Patients with/without radiological evidence of Lumbar Spondylosis.
3. Patients of with/without radiological evidence of Disc Prolapse.

Exclusion Criteria

1. *Sciatica* with congenital deformities of spine
2. Neoplastic conditions of the spine with radicular pain.
3. Infections of the spine with *Sciatica*.
4. Patients with any other systemic illness associating *Sciatica*.
5. Patients contraindicated for *Kati Basti Karma*.

Assessment Criteria

Subjective Parameters

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

Objective Parameters

1. Restricted limb movement/SLR Test (*Sakthikshepanigraha*)
2. Neurological Deficit- Herron & Turners Rating

Intervention

The patients selected were randomly divided into 2 groups of 15 each by adapting the permuted block randomization method.

1. Group A – RASNA GUGGULU GROUP

15 patients were treated with *Rasnaguggulu* for a period of 7 days. Following are the details of the medication:

Dosage: 500mg 2TID

Anupana: *Ushnajala*

Follow up Period: 14 days. Duration of study: 21 days.

2.Group B – KATI BASTI GROUP

15 patients were treated with a sitting of *Kati-Basti* during morning for about 7days with *vishagarbhathaila*. *Samyaxanaxas* are noted accordingly and also observed for *ayoga* and *atiyoga* of *katibasti*.

Follow up Period: 14 days Duration of study: 21days

INVESTIGATIONS:

Complete Hemogram, ESR, RBS, X-Ray Lumbosacral spine

OBSERVATIONS: Among the 30 patients taken for the study 33.33 % of the patients belonged to the age group of 41-50 and 51-60 years. 56.66% patients were females and 43.33% were males.73.33% of the patients belonged to Hindu Religion. 93.33% of patients were married compared to 6.66% of Unmarried individuals in the present sample. Majority of patients comprising 23.33% in this study had completed their Graduation education followed by Primary school education contributing 16.66 %. 36.66% of the patient belonged to upper middle class, 26.66% were from lower middle class, 20% from middle

class and 16.66 % of patients hailed from poor socio-economic status. Maximum numbers of patients 63.33 % of were manual laborers, 13.33% were employees, 13.33% were employee and home maker. 10 % of businessmen and none were students. 46.66 % of the patients complained of disturbed sleep. Enquiry about the previous treatment revealed that among 30 patients, 96.66 % had the history of oral NSAID intake before the commencement of the study, 3.33 % of the patients had underwent Laminectomy and dissection and none other patients give any history of treatment done.40 % had their body weight between 51 to 60 kg. 30 % of the patients had their body weight between 61 to 70 kg , and 23.33% of patients had their body weight 41-50kgs.63.33 % had BMI between 18.5 – 24.99 by which it can be predicted as none among 30 patients had overweight as predisposing factor to the low back ache and Sciatica. Analysis of the *Prakruti* reveals that majority of patients were of *VatakaphaPrakruti* i.e. 40 % and 20 % belonged to *VataPrakruti*, 13.33 % belonged to *Pittakapha Prakruti*. This observation supports the susceptibility of persons with *Vata* as *Prakruti* to develop *Vataja* disorders like *Gridhrasi*. Analysis of the symptoms revealed that 80 % patients exhibited *KevalaVatajaGridhrasi*, and 20% patients had *vata-kaphaja* type of *gridhrasi*. 86.66 % recorded *Madhyama Samhanana*, 10% patients showed *Pravara Samhanana* and 3.33% patients showed *avarasamhanana*. An appropriate correlation cannot be made out regarding the incidence of the disease and influence of *Samhanana* of the individual. But individuals with *Avara Sara* and *Samhanana* may have

more tendencies to develop *Vatavyadhi*. The assessment of the *Satva* in 30 patients showed 90 % patients having *Madhyama Satva*. Individuals with profound psychological stress along with the mechanical stress over the body may have more tendencies to develop or to precipitate *Vata* disorders. Analysis of *Satmya* revealed that 96.66 % had *Madhyama Satmya*. This confirms that the individuals do not take a proper balanced diet which can result in the morbidity of the *vatadosha*. The assessment in 30 patients revealed that, 96.66 % of patients had *Madhyama Abhyavaharana Shakti*. The assessment of *Jarana Shakti* in 30 patients revealed that, 96.66 % of patients had *Madhyama Jarana Shakti*. 10 % of the patients had *pravara Vyayama Shakti*, 90 % had *Madhyama Vyayama Shakti* and none had *avara Vyayama Shakti*. This denotes the severity of the pain in *Gridhrasi*. In this study, 96.66% patients were of *Madhyama Vaya*.

RESULTS:

Rasnaguggulu group: The study proved that there was 57.66 % improvement in *stambha*, 51.81 % and 61.4% improvement in *toda* and *aruchi*, 63.85% improvement in *spandana*, 20.9 % improvement in the pain which were statistically highly significant with P value < 0.001. Neurological deficit was improved by 54.05% with P < 0.001, Functional ability increased by 9.58% and functional disability decreased by 33.76%. The improvement in SLR test Active and Passive was by 32.07 % and 27.16% respectively with P value < 0.001. The outcome measures like walking for 30 feet, duration of 10 sit ups, time taken to climb 10 steps, and distance between finger

and floor showed an improvement of 15.24%, 12.18%, 12.46% and 40.66% respectively, each having a P value < 0.001. It was found that 100% of patients had moderate improvement, none had mild improvement and none of the patients had the symptoms unchanged. [Table No. 1, 2 and 3] **KatiBasti Group** -The study proved that there was 53.09% improvement in *stambha*, 53% improvement in *toda* and 64.66% improvement in *aruchi*, 63.85% improvement in *spandana*, 41.53% improvement in the pain which were statistically highly significant with P value < 0.001. Neurological deficit was improved by 45.08 % with P < 0.001, Functional ability increased by 14.94% and functional disability decreased by 37.13%. The improvement in SLR test Active and Passive was by 38.80% and 28.38% respectively with P value < 0.001. The outcome measures like walking for 30 feet, duration of 10 sit ups, time taken to climb 10 steps, and distance between finger and floor showed an improvement of 14.32 %, 16.51 %, 14.33 %, and 30.08% respectively, each having a P value < 0.001. It was found that 6.66% of patients had major improvement, 80 % had moderate improvement, 13.33% had mild improvement and none of the patients had the symptoms unchanged. [Table No. 1, 2 and 3] Comparison between the groups shows that *Rasnaguggulu* Group had more improvement compared to *KatiBasti* Group which was statistically significant.

DISCUSSION

Vatavyadhi is elaborated in the literature and has its etiology as specific *nidana*, *dhatukshaya* as well as *margavarana*. The line of

treatment explained in the literature is also specific in this regard, i.e., *apatarpana* for the *margavaranajanya vatavyadhi* and *santarpana* treatment procedures for *dhatukshayaja vatavyadhi*. *Kati basti* stands as an supportive therapy indicated in the both *margavarana* and *dhatukshayaja vatavyadhi*. *Rasna Guggulu* is a Herbo mineral compound with ingredients like *Rasna*, *Shudha Guggulu* in equal quantities. As the drugs are having *Tridoshaghna* and dominantly *Vatakaphahara* qualities, they help in alleviating both *Vata* and *KaphaDosh*. Due to the *Snigdha*, *guruGuna* and *UshnaVeerya*, *Rasna* pacifies *Vata* and *kapha*. *Rasna* is a well known drug for *vayasthapana* and *kaphavatahara* thus it also helps in *VataAnulomana* and also *Rasna* contains *agalanga* as chemical component which acts as anti-inflammatory and analgesic. *Guggulu* is also having *Kaphavata Shamaka* and anti-inflammatory property by its *UshnaVeerya* and is proved to be *VedanaShamaka*. *RasnaGuggulu* to relieve the symptoms like *Toda*, *Sup-tata*, *Ruk* etc from the affected parts of the body, the external measures in the form of *Snehana* and *Swedana* are said to be effective, has been indicated for the conditions which are said to be incurable among the *Vatavyadhi* and *Gridhrasi* is a fine example of it.. During the whole course of the treatment all patients were extremely comfortable with no undesirable effects. *Rasna* has the *Acetoxychavicol acetate* as its content thus owing to the fact that the local inflammation is being cleared by its anti-inflammatory action along with speeding up of the disc desiccation. *Rasna* possess *ushna* and *snigdha* properties which pacifies morbidity of the *vatadosha*. On other side

guggulu has the properties of *kaphavatashamaka* and it has proved with its analgesic and anti-inflammatory activity where in further to add it has properties like anti-atherosclerotic, hypolipidemic which helps to pacify the vitiated *vata* and *kapha*.

Kati Vasti is a procedure of *SnigdhaSweda*, while defining *Swedana* it has been said that *Stambha*, *Gaurava*, *Seeta* are going to be reduced and it induces *Swedana*. *Kati Vasti* also does the same thing, of course, in reduced intensity. Here *Vishagarbhathaila* is used for the purpose of *Kati basti* which is considered as *snigdhadravasweda*. The ingredients of *Vishagarbhathaila* are *Maricha*, *Vacha*, *Swarnaksheeri*, *Tila*, *Vatsanabha*, *Dattura*, *Kushta*, *Saindhava*. *KatiBasti* is explained under the heading of *swedana* among the *Bahirparimarjana* therapy primarily indicated for *vatavyadhi*. The action of *katibasti* is the rectification of *vata* chiefly and also reducing the morbidity of *kapha* and *vatadosha*. The ingredients of the *vishagarbhathaila* have the therapeutic action of alleviating the morbid *vatadosha* and also *kapha*. *Gridhrasi* being a *vatavyadhi* and also presence of association of morbid *kaphadosha* at times, *katibasti* has its local action over *gridhrasi*. *Kati basti* is regarded as a type of *sweda*.

It subsequent the similar action of *sweda* as it is classically cited. The addition of *ushna* and *tikshnadravya* like that of *tila*, *saindhavalavana*, *maricha*, *vacha* as ingredients of *vishagarbhathaila* may lead to the *atiyoga* as a risk factor when a luke warm oil is poured and if the constant temperature is not maintained. And the risk is doubled if the patient has not instructed about the procedure, restricted diet

and restricted activity. As such the risk factor was expressed by a single patient for first 3 consistent days, the study conducted revealed that the administration of the *Kati basti* for a period of 7 days was safe. The duration of the procedure depends upon the severity of the illness which in turn patient can able to be in a particular position for about 30minutes and also the sensitivity to heat as even constant temperature is maintained. Further to be more cautious it is not advised if patient has fever , fractures or any infective pathologies and hence considered as effective and safe.

Meanwhile considering the etiology of *gridrasi kevatavataja, margavarana* and *dhatukshaya*, or else to say the treatments adopted in this present study will negate the effect of *margavarana* and also rectify the *Dhatukshaya* by reducing the symptomatology of the illness. On the other hand, during the course of the illness affliction of the same *snayu* and *kandara* by any of the pathological factors entraps the *gridhrasinadi* leading to the *avarana* pathology. Almost maximum patients has shown moderate response in remission of the *sthambha, toda, spandana*, pain and also in functional disability and neurological deficits and other symptom parameters along with the improvement in the functional ability. This proves the efficacy of *RasnaGuggulu* beyond doubt in rectifying the etiopathogenesis of *gridhrasi* irrespective of its cause as *Dhatukshaya* or *margavarana*. But as to consider in *Kati basti* major improvement is the outcome. Though *katibasti* has reduced the symptom complex and other outcome measures irrespective of the cause, its efficacy is less without

the prescription of *shamana* and *rasayana* medications.

CONCLUSION

As to put together considering the improvement in quality of life, the effectiveness of the *Katibasti* with *vishagarbhataila* is more acceptable comparing to that of *RasnaGuggulu* as evidenced by the various outcome measures and the statistical analysis shows that the results are highly significant in most of the parameters.

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Table 1: Effect of Rasna Guggulu and Kati Basti on The Symptoms of Gridhrasi

Group	Mean		BT-AT	%Relief	Paired 't' test				Comparison	
	BT(±SD)	AT(±SD)			SD	SEM	t	P	t	P
Effect of Treatment on <i>Stambha</i>										
Rg group	3(±0.000)	1.26(±0.458)	1.73	57.66	0.458	0.118	14.66	<0.001	225.00	0.653
Kb group	2.26(±0.594)	1.06(±0.704)	1.2	53.09	0.414	0.107	11.225	<0.001		
Effect of Treatment on <i>Toda</i>										
Rg group	1.93(±0.704)	0.93(±0.704)	1	51.81	0.00	0.00	14.000	<0.001	202.500	0.141
Kb group	2(±0.458)	0.66(±0.724)	1.06	53	0.799	0.206	6.141	<0.001		
Effect of Treatment on <i>Spandana</i>										
Rg group	1.66(±0.617)	0.6(±0.507)	1.06	63.85	0.258	0.0667	16.000	<0.001	232.500	0.962
Kb group	1.66(±0.488)	0.6(±0.507)	1.06	63.85	0.258	0.0667	16.000	<0.001		
Effect of Treatment on <i>Aruchi</i>										
Rg group	1.4(±0.986)	0.53(±0.516)	0.86	61.4	0.743	0.192	4.516	<0.001	243.000	0.593
Kb group	1.33(±0.724)	0.46(±0.516)	0.86	64.66	0.352	0.0909	9.539	<0.001		

Table 2: Effect of Rasna Guggulu and Kati Basti on Various Outcome Measures

Group	Mean		BT-AT	%Relief	Paired test				Unpaired test	
	BT(±SD)	AT(±SD)			SD	SEM	t	P	t	P
Effect of Treatment on Pain										
Rg group	41.13(±8.790)	49.73(±6.954)	8.6	20.9	7.189	1.856	4.633	<0.001	281.000	0.046
Kb group	33.06(±12.561)	46.8(±9.041)	13.73	41.53	7.440	1.921	7.149	<0.001		

Effect of Treatment on Neurological defecit										
Rg group	24.66(±5.164)	11.33(±5.164)	13.33	54.05	4.88	1.26	10.583	<0.001	215.000	0.412
Kb group	34(±10.036)	18.66(±5.164)	15.33	45.08	7.188	1.856	8.262	<0.001		
Effect of Treatment on Functional Ability										
Rg group	19.4(±1.765)	21.26(±1.438)	1.86	9.58	0.915	0.236	7.897	<0.001	1.513	0.141
Kb group	17.4(±4.171)	20(±2.976)	2.6	14.94	1.639	0.423	6.145	<0.001		
Effect of Treatment on Functional Disability										
Rg group	13.8(±3.489)	9.13(±2.503)	4.66	33.76	3.457	0.893	5.228	<0.001	1.738	0.093
Kb group	19.2(±6.614)	12.06(±3.494)	7.13	37.13	4.274	1.104	6.464	<0.001		

Table 3: Effect of Rasna Guggulu And Kati Basti on Various Tests For Sciatica

Effect of treatment on SLR Test Active										
Rg group	53(±9.024)	70(±6.268)	17	32.07	7.020	1.813	9.379	<0.001	242.500	0.682
Kb group	44.66(±10.601)	62(±8.619)	17.33	38.80	5.300	1.369	12.665	<0.001		
Effect of treatment on SLR Test Passive										
Rg group	61.33(±8.338)	78(±6.492)	16.66	27.16	7.943	2.051	8.126	<0.001	225.500	0.771
Kb group	54(±11.680)	69.33(±11.62)	15.33	28.38	6.114	1.579	9.713	<0.001		
Effect of treatment on Lassegues Test										
Rg group	66.66(±6.172)	85.33(±6.114)	18.67	28.00	6.673	1.723	10.835	<0.001	209.000	0.295
Kb group	63.33(±10.465)	79.66(±8.550)	16.33	25.78	6.114	1.579	10.347	<0.001		

Table 4: GRADINGS

GRADINGS		
1. <i>Stambha</i> (Stiffness):		
i.	No stiffness	- 0
ii.	Mild stiffness	- 1
iii.	Moderate stiffness	- 2
iv.	Severe stiffness	- 3
2. <i>Ruk</i> (Pain):		

i.	No pain	- 0
ii.	Painful, walks without limping	- 1
iii.	Painful, walks with limping but without support	- 2
iv.	Painful, can walk only with support	- 3
v.	Painful, unable to walk	- 4
3. <i>Toda</i> (Pricking Sensation):		
i.	No pricking sensation	- 0
ii.	Mild pricking sensation	- 1
iii.	Moderate pricking sensation	- 2
iv.	Severe pricking sensation	- 3
4. <i>Spandana</i> (Twitching):		
i.	No twitching	- 0
ii.	Mild twitching	- 1
iii.	Moderate twitching	- 2
iv.	Severe twitching	- 3
5. <i>Aruchi</i> (Anorexia):		
i.	No anorexia	- 0
ii.	Mild anorexia	- 1
iii.	Moderate anorexia	- 2
iv.	Severe anorexia	- 3
6. <i>Tandra</i> (Stupor):		
i.	No stupor	- 0
ii.	Mild stupor	- 1
iii.	Moderate stupor	- 2
iv.	Severe stupor	- 3
7. <i>Gaurava</i> (Heaviness):		
i.	No heaviness	- 0
ii.	Mild heaviness	- 1
iii.	Moderate heaviness	- 2
iv.	Severe heaviness	- 3

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