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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<table>
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<th>ABSTRACT</th>
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| **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. 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 vatajana nanatmajavyadhi should be more beneficial for quality of life. Kevalavataja and vatakaphaja are the two clinical variations in presentation of gridhrasishoola. Khalli is also considered as a variant form of the gridhrasi shoolad. 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 symptoms. 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, vrushhya, tridoshahara, oral administration of Rasnaguggulu is said to be very effective and curative in vatyadvhi especially in gridrasi which includes katisshool 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. Swedana is best advised in Gridrasi when symptoms like stambha, 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 Vishagarbhataila 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(Spadana)
5. Functional Ability- Sugar baker & Barofsky Clinical Mobility Scale
6. Functional Disability - Oswestry Disability Assessment Questionnaire

Objective Parameters
1. Restricted limb movement/SLR Test (Sakhikshepanigraha)
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 7 days with vishagarbhataila. Samyaklaxanas are noted accordingly and also observed for ayoga and atiyoga of katibasti.
   - Follow up Period: 14 days. Duration of study: 21 days.

**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 undergone 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 Abhyavahara 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 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 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., apatarpāṇa for the margavaranajanya vatavyadhi and santarpāṇa treatment procedures for dhautukshayajāya vatavyadhi. Kati basti stands as an supportive therapy indicated in the both margavaranajāya and dhautukshayajāya vatavyadhi. Rasna Guggulu is a Herbo mineral compound with ingredients like Rasna, Shudha Guggulu in equal quanti- ties. As the drugs are having Tridoshaghna and dominantly Vatakaphahara qualities, they help in alleviating both Vata and kaphaDosha. Due to the Snigdha, guruGuna and UshnaVeerya, Rasna pacifies Vata and kapha. Rasna is a well known drug for vayasthāpana and kaphavatara 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 VaiḍanShamaka. 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 Śnehan a and Śvedana are said to be effective, has been indicated for the conditions which are said to be incurable among the Vatavyadhī and Gridhrasī is a fine example of it. During the whole course of the treatment all patients were extremely comfortable with no undesir- able 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 speed- ing 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 Vastī is a procedure of SnigdhaSweda, while defining Śvedana it has been said that Stambha, Gaurava, Seeta are going to be re-duced and it induces Śvedana. Kati Vastī also does the same thing, of course, in reduced intensity. Here Vishagarbhathaila is used for the purpose of Kati basti which is considered as snigdhravaswedā. The ingredients of Vi- shagarbhathaila are Maricha, Vacha, Swarnaksheeri, Tila, Vatsanabha, Dattura, Kushta, Saindha. KatiBasti is explained under the heading of swedana among the Bahrpirasī 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. Gridhrasī being a vatavyadhī and also presence of association of morbid kapha- dosha at times, katibasti has its local action over gridhrasī. Kati bastī is regarded as a type of sweda.

It subsequent the similar action of sweda as it is classically cited. The addition of ushna and tikshndravya like that of tila, saindhvalavana, maricha, vacha as ingredients of visha-garbhathaila 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 30 minutes 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 gridhrasi 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 entrap 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 vishagarbhattaila 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.

**REFERENCES**

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>BT-AT</th>
<th>%Relief</th>
<th>Paired t' test</th>
<th>Comparison</th>
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<tbody>
<tr>
<td></td>
<td>BT(±SD)</td>
<td>AT(±SD)</td>
<td></td>
<td>SD</td>
<td>SEM</td>
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<tr>
<td>Effect of Treatment on Stambha</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Rg group</td>
<td>3(±0.000)</td>
<td>1.26 (±0.458)</td>
<td>1.73</td>
<td>57.66</td>
<td>0.45</td>
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<tr>
<td>Kb group</td>
<td>2.26(±0.594)</td>
<td>1.06(±0.704)</td>
<td>1.2</td>
<td>53.09</td>
<td>0.41</td>
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<td>Effect of Treatment on Toda</td>
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<tr>
<td>Rg group</td>
<td>1.93(±0.704)</td>
<td>0.93(±0.704)</td>
<td>1</td>
<td>51.81</td>
<td>0.00</td>
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<tr>
<td>Kb group</td>
<td>2(±0.458)</td>
<td>0.66(±0.724)</td>
<td>1.06</td>
<td>53</td>
<td>0.79</td>
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<td>Effect of Treatment on Spandana</td>
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<tr>
<td>Rg group</td>
<td>1.66(±0.617)</td>
<td>0.6(±0.507)</td>
<td>1.06</td>
<td>63.85</td>
<td>0.25</td>
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<tr>
<td>Kb group</td>
<td>1.66(±0.488)</td>
<td>0.6(±0.507)</td>
<td>1.06</td>
<td>63.85</td>
<td>0.25</td>
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<td>Effect of Treatment on Aruchi</td>
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<tr>
<td>Rg group</td>
<td>1.4(±0.986)</td>
<td>0.53(±0.516)</td>
<td>0.86</td>
<td>61.4</td>
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<td>Kb group</td>
<td>1.33(±0.724)</td>
<td>0.46(±0.516)</td>
<td>0.86</td>
<td>64.66</td>
<td>0.352</td>
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Table 2: Effect of Rasna Guggulu and Kati Basti on Variaous Outcome Measures

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>BT-AT</th>
<th>%Relief</th>
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<tr>
<td></td>
<td>BT(±SD)</td>
<td>AT(±SD)</td>
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<td>SEM</td>
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<tr>
<td>Effect of Treatment on Pain</td>
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<tr>
<td>Rg group</td>
<td>41.13(±8.790)</td>
<td>49.73(±6.954)</td>
<td>8.6</td>
<td>20.9</td>
<td>7.189</td>
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<tr>
<td>Kb group</td>
<td>33.06(±12.561)</td>
<td>46.8(±9.041)</td>
<td>13.73</td>
<td>41.53</td>
<td>7.440</td>
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Effect of Treatment on Neurological deficit

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<tr>
<th>Group</th>
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<th>Mean (±SD)</th>
<th>p-value</th>
<th>2-tailed p-value</th>
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<tbody>
<tr>
<td>Rg</td>
<td>24.66 (±5.164)</td>
<td>11.33 (±5.164)</td>
<td>13.33</td>
<td>54.05</td>
</tr>
<tr>
<td>Kb</td>
<td>34 (±10.036)</td>
<td>18.66 (±5.164)</td>
<td>15.33</td>
<td>45.08</td>
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Effect of Treatment on Functional Ability

<table>
<thead>
<tr>
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<th>Mean (±SD)</th>
<th>p-value</th>
<th>2-tailed p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rg</td>
<td>19.4 (±1.765)</td>
<td>21.26 (±1.438)</td>
<td>1.86</td>
<td>9.58</td>
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<td>Kb</td>
<td>17.4 (±4.171)</td>
<td>20 (±2.976)</td>
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<td>14.94</td>
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Effect of Treatment on Functional Disability

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<tr>
<td>Rg</td>
<td>13.8 (±3.489)</td>
<td>9.13 (±2.503)</td>
<td>4.66</td>
<td>33.76</td>
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<tr>
<td>Kb</td>
<td>19.2 (±6.614)</td>
<td>12.06 (±3.494)</td>
<td>7.13</td>
<td>37.13</td>
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Table 3: Effect of Rasna Guggulu And Kati Basti on Various Tests For Sciatica

Effect of treatment on SLR Test Active

<table>
<thead>
<tr>
<th>Group</th>
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<th>Mean (±SD)</th>
<th>p-value</th>
<th>2-tailed p-value</th>
</tr>
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<tbody>
<tr>
<td>Rg</td>
<td>53 (±9.024)</td>
<td>70 (±6.268)</td>
<td>17</td>
<td>32.07</td>
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<tr>
<td>Kb</td>
<td>44.66 (±10.601)</td>
<td>62 (±8.619)</td>
<td>17.33</td>
<td>38.80</td>
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Effect of treatment on SLR Test Passive

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<th>Mean (±SD)</th>
<th>p-value</th>
<th>2-tailed p-value</th>
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<tbody>
<tr>
<td>Rg</td>
<td>61.33 (±8.338)</td>
<td>78 (±6.492)</td>
<td>16.66</td>
<td>27.16</td>
</tr>
<tr>
<td>Kb</td>
<td>54 (±11.680)</td>
<td>69.33 (±11.62)</td>
<td>15.33</td>
<td>28.38</td>
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Effect of treatment on Lassegues Test

<table>
<thead>
<tr>
<th>Group</th>
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<th>Mean (±SD)</th>
<th>p-value</th>
<th>2-tailed p-value</th>
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<tbody>
<tr>
<td>Rg</td>
<td>66.66 (±6.172)</td>
<td>85.33 (±6.114)</td>
<td>18.67</td>
<td>28.00</td>
</tr>
<tr>
<td>Kb</td>
<td>63.33 (±10.465)</td>
<td>79.66 (±8.550)</td>
<td>16.33</td>
<td>25.78</td>
</tr>
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Table 4: GRADINGS

GRADINGS

1. Stambha (Stiffness):
   i. No stiffness - 0
   ii. Mild stiffness - 1
   iii. Moderate stiffness - 2
   iv. Severe stiffness - 3

2. Ruk (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. Toda (Pricking Sensation):
   i. No pricking sensation - 0
   ii. Mild pricking sensation - 1
   iii. Moderate pricking sensation - 2
   iv. Severe pricking sensation - 3

4. Spandana (Twitching):
   i. No twitching - 0
   ii. Mild twitching - 1
   iii. Moderate twitching - 2
   iv. Severe twitching - 3

5. Aruchi (Anorexia):
   i. No anorexia - 0
   ii. Mild anorexia - 1
   iii. Moderate anorexia - 2
   iv. Severe anorexia - 3

6. Tandra (Stupor):
   i. No stupor - 0
   ii. Mild stupor - 1
   iii. Moderate stupor - 2
   iv. Severe stupor - 3

7. Gaurava (Heaviness):
   i. No heaviness - 0
   ii. Mild heaviness - 1
   iii. Moderate heaviness - 2
   iv. Severe heaviness - 3

Source of Support: Nil
Conflict Of Interest: None Declared