



Research Article

A CLINICAL TRIAL TO EVALUATE THE COMBINED EFFECT OF *EKAVIMSHATIKA GUGGULU* AND *BALA TAILA MATRA VASTI* IN SCIATICA

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ABSTRACT

Ekavimshatika Guggulu is mentioned in Bhavaprakasha Madhyamakhanda Kushta Adhyaya and Bala Taila mentioned in Bhela Samhita Vata Vyadhi Adhyaya. Most of the drugs in Ekavimshatika Guggulu are of Vata-kapha Shamana and also mitigate Gridhrasi as per the Phalasruthy. Bala Taila is having Vatahara property and is Balya in nature. Matra Vasti possess the qualities of Vata Anulomana and Snehana properties. The study was an interventional study with pre and post-test, without control group. Subjects of either gender with age group 20-60 years registered in Pankajakasthuri Ayurveda Medical College & Post Graduate Centre, satisfying the inclusion and exclusion criteria were subjected to positive sampling and total of 27 subjects were selected and 27 subjects completed the clinical trial. The selected subjects were administered Ekavimshatika Guggulu in a dosage of 2 tablets orally thrice daily before food along with 75ml Bala Taila as Matra Vasti for 14 days. Assessment of the subjects was done on 0th day, 15th day and follow up done on 30th day with subjective and objective parameters. **RESULTS**: On analysing the results, it has been found that subjective parameters like tenderness, radiating pain, ODI scale, Sciatica Bothersomeness Index Scale, Sciatica Frequency Index Scale and objective parameters like SLR, Lessigues sign, also other parameters like Gridhrasi lakshanas got statistically significant improvement. Friedman test was used to assess the overall significance between three points. P-value <0.05 was found to be significant. Wilcoxon Sign Rank test was used to find out overall difference between before treatment and after follow up in subjective parameters. Significance in range of movements was assessed by repeated measures of Anova. CONCLUSION: Based on the observations and results of the clinical study, the alternate hypothesis, Ekavimshatika Guagulu and Bala Taila Matra Vasti is effective in the management of sciatica is accepted and null hypothesis is rejected.

INTRODUCTION

Sciatica is a condition stemming from the pathology related to sciatic nerve or its roots. Impingement of this nerve can lead to sharp, shooting pain along its pathway, accompanied by difficulties in walking, leg numbness, a burning sensation, and muscle weakness. This condition often arises from mechanical compression of the L5-S1 nerve root,



commonly due to disc protrusion, disc prolapse, or degenerative changes. The prevalence of sciatica varies widely, ranging from 49% to 70% in the general population. Fortunately, about 90% of patients recover through conservative treatment, which may include bed rest, analgesics, and local anesthetic or corticosteroid injections. The onset of sciatica can be sudden or gradual, often preceded by repeated episodes of low back pain that may last for months or even years. This condition has become one of the most significant ailments in society, severely impacting the daily activities of individuals during their most productive years.

The clinical features of sciatica closely resemble those of *Gridhrasi* in Ayurveda, presenting as aching pain that begins in the lumbar region and

radiates to the buttock, thigh, calf, and foot. In Avurvedic terms, degenerative conditions and disc protrusions are categorized as Dhatukshava and Maraavarodha. To address these issues, formulations with properties such as Vatahara, Kaphahara, Agni Deepana, Shoolahara, Vatanulomana, Dhatuposhana, and Balva have been selected. This approach aims to prevent the advanced limping stage of sciatica through conservative Ayurvedic treatment. Ekavimshatika Guggulu, a formulation from Bhavaprakasha in the Madhyamakhanda Kushta Adhyaya, consists ingredients primarily aimed at Vata-Kapha shamana and Deepana properties. Bala Taila is noted for its Balva, Rasavana, and Vatahara qualities as described in Bhela Samhita. Additionally. *Matravasthi* offers Shamana for Vatadosha and Snehana for Dhatus, making it a suitable choice for treatment. Despite the rapid advancements and successes in other medical systems, the efficacy of this Ayurvedic formulation remains significant. The tolerability of commonly prescribed analgesics and adjuvant drugs for managing sciatica has not been thoroughly established. Most guidelines advocate for a course of conservative care, which can help treat the condition and prevent its progression to advanced chronic stages. Experiencing pain is often regarded as one of the most challenging things in life, impacting not only functional ability but also mental well-being. Along with pain, symptoms such as numbness, weakness in the foot must also be considered, as they collectively define the sciatica syndrome. Therefore, the selected procedures and the chosen drug aim to serve as effective alternatives for alleviating this condition.

OBIECTIVES OF THE STUDY

- 1. To study sciatica in Ayurvedic view.
- 2. To evaluate the combined effect of *Ekavimshatika Guggulu* and *Bala Taila* as *Matra Vasti* in the subjective and objective parameters of sciatica.

MATERIALS AND METHODS

Source of Data

a) Literary Source: The main text books for literary search includes:

Charaka Samhita, Sushruta Samhita, Ashtanga Sangraha, Ashtanga Hridaya, Madhava Nidana, Bhavaprakasha, Sharangadhara Samhita, Chakradatta, Bhaishajya Ratnavali, Yogaratnakara

b) Drug Source

The medicine used in this study was prepared in a GMP certified company following all pharmacopoeia quality standards. CoA obtained from CARe KERALAM.

c) Sample Source

The subjects of age group 20 to 60 years, who satisfied the inclusion criteria, attending the OPD & IPD of Pankajakasthuri Ayurveda Medical College and PG Centre Hospital, Kattakada, were taken for study. Subjects were enrolled into the study after necessary investigations from a recognized standard laboratory. Dose and dosage regimens were fixed according to Ayurvedic classic.

Method of Collection of Data

Sample Size: 27 subjects irrespective of gender, religion, occupation, marital status, socioeconomic status, educational status, fulfilling the diagnostic criteria, inclusion criteria, and exclusion criteria were selected.

Study Design: Interventional study, pre- and post- test without control group

Inclusion Criteria

- 1. Subjects of either gender aged between 20 to 60 years.
- 2. Subjects presenting with signs and symptoms of Sciatica.
- 3. Subjects presenting with SLR grading < 90 degree.
- 4. Subjects who are willing to sign the consent form and agreeing to follow the protocol of the study.

Exclusion Criteria

- 1. Pregnant women, lactating mothers and mentally challenged persons.
- 2. Sciatica developed due to post-surgical complications.
- 3. Congenital deformity of spine.
- 4. Infective conditions and inflammatory conditions of spine.
- 5. Vertebral fractures/known case of IVDP.
- 6. Neoplastic conditions of spine.
- 7. Anarhas of Matravasti
- 8. Bilateral Sciatica.

Intervention

Sample Size	27 Subjects
Intervention	Ekavimshatika Guggulu + Bala Taila Matra Vasti
Dose	Gutika- 500mg, Vasti- 75ml
Anupana	Warm water
Time of Administration	2 tablets thrice daily before food, <i>Vasti</i> afternoon 1.30 P.M
Duration	14 days

Observation Period

Treatment period: 14 days

Days of assessment: Observations were done at baseline i.e., 0^{th} day, 15^{th} , 30^{th} day

Assessment Criteria

Assessment of the condition was done based on detailed case proforma adopting standard scoring methods of subjective and objective parameters.

Subjective Parameter

Lumbo Sacral Tenderness Radiating pain towards lower limb

Oswestry Disability Index Scale (ODI Scale)

Roland- Morris Low back pain and Disability Ouestionnaire (RMO)

Sciatica Bothersomeness index scale

Sciatica Frequency index scale

Objective Parameter

SLR

Lessigue's test

Investigations

Specification of safety parameters: Laboratory test was performed before and after the trial Blood routine examination – CBC, RBS, LFT, CRP and RFT.

Radiological investigation – X ray of Lumbo Sacral spine- AP and lateral view, whenever found necessary.

Grading of the Combined Effect of Ekavimshatika Guggulu and Bala Taila in Subjective Parameters

	Case 1			Case 2			Case 3			Case 4			Case 5		
	BT A	T AF		BT AT AF		BT AT AF			BT AT AF			BT AT AF			
Lumbosacral tenderness (Grade)	2	0	0	2	0	0	2	0	0	3	1	1	2	0	0
ODI scale	21	7	7	22	7	7	20	4	4	24	10	12	14	3	3
RMQ	14	4	4	21	4	4	15	3	3	21	10	12	16	3	3
SBI	16	4	4	20	4	4	20	4	4	24	12	12	16	4	4
SFI	12	4	4	20	4	4	12	4	4	24	12	12	12	4	4

	Case	6		Case	7		Case	8		Case	9		Case	10	
Lumbosacral tenderness	3	0	0	2	0	0	2	0	0	2	0	0	3	0	0
ODI scale	21	7	7	15	5	5	22	5	5	25	6	6	24	8	8
RMQ	19	5	5	17	13 DA	3	20	6	6	18	4	4	22	10	10
SBI	20	4	4	12	4	4	20	4	4	24	4	4	20	8	8
SFI	20	4	4	12	4	4	20	4	4	20	4	4	12	8	8

Grading of the Combined Effect of Ekavimshatika Guggulu and Bala Taila in Objective Parameters

Case 1			Case 2			Case 3			Case 4			Case 5			
SLR	3	1	1	3	1	1	3	1	1	3	2	2	3	1	1
Lessigues sign	1	0	0	1	0	0	1	0	0	1	1	1	1	0	0

	Case	Case 6 Case 7		Case 8			Case 9			Case 10					
SLR	3	0	0	3	1	1	3	1	1	3	0	0	3	0	0
Lessigues sign	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0

RESULT

Subjective Parameters	Mean BT	Mean AT	Mean AF	Chi- square Value	P Value
Lumbosacral tenderness	3.00	1.50	1.50	54.000	< 0.001
ODI	3.00	1.50	1.50	52.699	< 0.001
RMQ	3.00	1.50	1.50	52.669	< 0.001
SBI	3.00	1.50	1.50	54.000	< 0.001
SFI	3.00	1.52	1.48	53.366	< 0.001

Objective Parameters	Mean BT	Mean AT	Mean AF	Chi-square value	P Value
SLR	3.93	1.54	1.54	50.000	< 0.001
Lasegue's Sign	2.89	1.56	1.56	48.000	< 0.001

ROM	Mean BT	Mean AT	Mean AF	F value	P value
Flexion	33.77	43.81	46.70	1436.573	< 0.001
Extension	16.51	24.85	26.70	1383.218	< 0.001
Lateral Flexion	18.07	23.22	24.62	3475.589	< 0.001
Rotation	3.88	6.33	8.29	975.683	< 0.001

DISCUSSION

Discussion on Sciatica and Gridhrasi

Sciatica is considered to be a debilitating condition which affects the day-to-day life of an individual. Sciatica cases can be treated to an extent and advanced limping stage can be prevented. In this study sciatica was correlated to *Gridhrasi*. *Gridhrasi* occurs due to *Dhatukshaya* and *Margasyavarana*. Based on the symptoms, *Gridhrasi* was analysed in two forms: *Vataja* and *Vata-Kaphaja*. Among the subjects, symptoms of sciatica were mostly due to disc herniation and degenerative changes.

Sciatica due to disc herniation can be correlated to Vata-Kaphaja type. According to the etiopathogenesis, the continuous exposure to *Nidanas* such as Bharaharana, Vegadharana, leads to Vata Prakopa and intake of Madhura Rasa, Divasvapna results in Kapha Prakopa. Increased Sheeta Guna of Vata and Kapha in Koshta leads to Agnimandhya which in turn causes vitiation of Rasa Dhatu and exhibits Lakshanas like Gaurava, Aruchi, Tandra. Vitiated Vata reaches the Kati Pradesha as it is the main Sthana of Vayu which further vitiates Asthi Dhatu due to the Asraya Asrayi relation of Vata with Asthi at the same region. The Chala, Ruksha, Sheeta Guna of Vata is affected here which hampers the normal Gati of Vata. The Sheeta Guna further vitiates the Kapha along with Vata. The Vitiated Vata displaces the vitiated Kapha from its normal place. This causes Lakshanas such as Toda. Sthambha. Muhuspandana Ruk. Sakthiutshepanigraha.

Degenerative changes in the vertebrae can be correlated with the *Vataja* type of condition. According to the etiopathogenesis of *Vatika Gridhrasi*, continuous exposure to *Vata Prakopa Nidhanas* and *Vardhakya janya Dhatukshaya* might result in increased *Ruksha Sheeta Guna* of *Vata*. Vitiated *Vata* reaches the *Asthi* and *Majja Dhatu* in the *Kati Pradesha* due to the *Asraya-Asrayi Bhava*. This results in increased *Ruksha* and *Sheeta* qualities of *Vata* in the *Asthi* and *Majja*, along with decreased *Snigdhamsha* of *Shleshaka Kapha*

in the *Majja Vaha Srotas*. Consequently, this leads to symptoms such as *Ruk*, *Toda*, *Muhuspandana*, and *Sakthiutshepa Nigraha*.

Discussion on Chikitsa

In Vata-Kaphaja Gridhrasi, the Ruksha and Sheeta Guna of Vata, as well as the Guru and Sheeta Guna of Kapha, need to be corrected. To address this, formulations with Ushna Guna and Snigdha Guna are utilized. The Ushna Guna helps to mitigate the Sheeta Guna of Vata and the Guru Guna of Grathitha Shleshaka Kapha. Following this, to restore the Snigdha aspect of Prakrutha Kapha, the Madhura Rasa, Snigdha Guna, and Brimhana Karma of the medicine are employed. Pratiloma Gati of Vata is maintained through Anulomana Karma of Vasti.

In Vatika Gridhrasi, the Ruksha and Sheeta Gunas of Vata need to be mitigated, while the Snigdha Guna of Kapha has to be restored. The Ushna and Snigdha Gunas of the drugs in this formulation, along with Vatanulomana Karma, helps to mitigate the Sheeta and Ruksha Gunas of the Dosha and restore the Snigdha Guna of Shleshaka Kapha.

Discussion on Drug

Samprapthi Vighatana is considered to be the main aim of *Chikitsa*.

Probable Mode of Action of Ekavimshatika Guggulu

Ekavamishatika Guggulu possesses action on both Vata Kaphaja and Vatika type of Gridhrasi. In Vata Kaphaja type of Gridhrasi, Deepana Karma of Chitraka, Hareetaki, Shunti, Maricha, Pippali, Ajaji, Chavya, Musta, and Amaradharu increases Agni, which in turn corrects the Rasa Dhatu and thus reduces symptoms such as Gaurava, Tandra, Aruchi. Laghu, Ushna Virya, and Katu Vipaka of Chitraka, Hareetaki, Bibhithaki, Shunti, Ajaji, Chavya, Vacha, Vidanga, and Guggulu helps to reduce the Vaikritha Guru Guna of Kapha. The Ushna Virya of Chitraka, Hareetaki, Bibhithaki, Shunti, Maricha, Pippali, Ajaji, Chavya, Karavi, Vacha, and Guggulu mitigates the Sheeta Guna of Vata. The Anulomana property of Hareetaki, Karavi, Maricha, and Ajamoda also helps in

normalizing the *Chala Guna* of *Vata*. Obstruction of *Vata* by *Kapha* is hence removed. *Guggulu* also possess *Rasayana* property enhances the *Asthi Majja Dhatu Poshana*. In *Ekavamishatika Guggulu*, chemical constituents such as gallic acid and ellagic acid, present in *Haritaki, Bibhithaki*, and *Amalaki*, and piplartine in *Pippali* and *Chavya*, along with Quercetin and E-Guggulusterone in *Guggulu*, possess analgesic properties.

In Vatika type of Gridhrasi Sheeta Guna of Vata might be reduced by Ushna Virya of most of the drugs in Ekavimshatika Guggulu like Chitraka, Hareetaki, Bibhithaki, Shunti, Maricha, Pippali, Chavya, Karavi Vacha, Athivisha, Kushta, Guggulu. Madhura Vipaka of Haritaki, Bibhithaki, Amalaki, Shunti, Pippali Enhances the Snigdhamsha of Shleshaka Kapha.

Probable Mode of Action of Bala Taila

In Vata Kaphaja Gridhrasi - Ruksha Sheeta Guna of Vata and Guru Sheeta Guna of Kapha has to be mitigated. Bala Taila is Vata Kapha Shamana in nature and does the Anulomana of Vata in Pakvashaya and also helps in correcting *Vishamagni* which in turn does proper Dhatu Parinama. Rasayana Property of Ksheera also does the Asthi Majja Dhathu Poshana. In Vatika Gridhrasi Snigdhamsha of Shleshaka Kapha has to be maintained which is achieved by Guru, Snigdha Guna, and Brimhana property of Bala and Ksheera. In Bala constituents Taila chemical like Ephedrine, Ouinazolines in *Bala* and chemical constituents in *Tila* Taila like oleic acid and linoleic acid possess analgesic property.

Probable Mode of Action of Bala Taila as Mathra Vasthi

Matra Vasthi acts as Shamana, Brahmana and Anulomana. Ingredients in Bala Taila possess drugs of Ushna Virya which acts against both Vata and Kapha Dosha. In Matra Vasti Oushadha Virya reaches Pakwashaya and there it corrects the Apana Vayu and Virya in Oushadha is taken by Samana Vayu since it is near to the Jataragni, Pachana of Oushadha takes place and it reaches the Asthi Majja Dhatu where Sheeta Guna of Vata and Kapha gets corrected and due to Guru Snigdha Guna of Bala and Ksheera it enhances the Snigdhamsha of Shleshaka Kapha. As a whole Vasthi is involved in Pakvashayasthitha Dosha Nirharana and Apana Vata Anulomana and hence the normal Gathi of Vata is attained.

Discussion on Methodology

This was an interventional study with pre and post test without control group intended for getting a statistical outcome. Subjects of age group 20–60 were selected because of the more prevalence rate of this disease during this age. Both Genders were taken for study because it does not influence the treatment. LFT and RFT were assessed on 0th and 15th day to avoid the adverse drug reactions. In this study Subjects with

symptoms of *Vataja* and *Vata Kaphaja* symptoms like *Ruk, Toda, Muhuspandana, Sakthiutshepa nigraha, Tandra, Aruchi, Gaurava* was assessed with grading. Dosage form of *Ekavimshatika Guggulu* was taken as *1 Shana (3g)* which was considered to be the maximum dosage in (AFI). *Guggulu Shodana* was done on *Triphala Kashaya* which also acts as *Rasayana* which gives add on benefit to *Guggulu. Matra Vasti* was administered afternoon. At this time *Agni* is involved in the *Pachana* of *Ahara* and *Srotomukha* is opened. If *Matra Vasti* is administered at this time *Veerya* of the medicine circulates throughout the body.

Known cases of IVDP, Vertebral fractures were excluded because study period was for a shorter duration and also investigations such as MRI, X ray were not included in this study. Pregnancy, lactating mothers were excluded from the study as they were belonging to vulnerable groups.

Sample size of the subjects was 27 including drop out and it was calculated based on previous study. Certificate of Analysis was obtained for the study. Higher metals and microbial study and also physicochemical parameters were done on both the formulations which was under the normal limit.

CONCLUSION

This study had shown highly significant results for subjective parameters and objective parameters. Moreover, the safety parameters of the drugs were evaluated, ensuring their safe internal use. Hence the combined use of *Ekavimshatika Guggulu* and *Bala Taila* as *Matravasthi* can be utilized in the management of Sciatica.

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