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ORIGINAL ARTICLE Sept-Oct 2019

An open label single arm prospective clinical study on Vatagajankusharasa with Pippali Churna and Manjishta Kwatha as Anupana in Gridhrasi (Sciatica)

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ABSTRACT

Background - Low backache is the 2nd most common reason for all physician visits and it is a condition that affects as many as 80-90% of people during their life time.^[1] Sciatica is a relatively common condition with a life time incidence varying from 13-40%. Gridhrasi in Ayurveda is a Rujapradhana Nanatmaja Vatavyadhi, which has similar presentation of sciatica intervenes with the functional ability of low back and lower limbs. Vata Gajankusha Rasa is a potent medicinal preparation, which in classics have mentioned can cure severe form of Gridhrasi in a week. The present study is taken up with the hypothesis that Vata Gajankusha Rasa with Manjishta Kwatha and Pippali Churna as Anupana would be effective in the management of Gridhrasi. Objective - To evaluate the effectiveness of Vatagajankusha Rasa with Pippali Churna and Manjishta Kwatha as Anupana in the management of Gridhrasi (sciatica). Method - Among 40 registered patients 36 of them completed the course of treatment. They were administered with Vatagajankusha Rasa (125mg) twice daily with Pippali Churna (3grams) and Manjishta Kwatha (15ml) as Anupana before food for a period of 7 days. For stastistical analysis subjective and objective parameters were assessed by Wilcoxon signed rank and McNemar test. Result - In the parameters of Gridhrasi, the medicine was found to be statistically significant in relieving the assessment parameters like Ruk, Toda, Sthambha, Aruchi, Gourava (p<0.001). In Objective parameters like SLR and Lessagues test, significant relief was observed after statistical analysis. Conclusion - Vatagajankusha Rasa with Pippali Churna and Manjishta Kwatha as Anupana is effective in the management of symptoms of Gridhrasi.

Key words: Gridrasi, Lowback Ache, Sciatica, Vata Gajankusha Rasa, Pippali, Manjishta.

INTRODUCTION

Gridhrasi, one among 80 Vataja Nanatmaja Vyadhis is characterized by Stambha, Ruk, Toda, Spandana; initially affect Sphik, Kati and then gradually radiates

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to posterior aspects of Uru, Janu, Jangha and Pada.^[2] Two types of *Gridhrasi*, *Vataja* and *Vatakaphaja* can be seen, in Vatajagridrasishoola, Sthamba and Thoda prominent symptoms while in Vataare Kaphajagridrasi there will be more of Tandra, Gaurava and Arochaka.^[3] In Gridhrasi Lakshanas like 'Sakthi Utkshepam Nigruhnati' and gait similar to 'Gridha' not only depicts the difficulty in walking, but also inflicts the severity of pain.^{[4],[5]}

This condition is clinically very similar to sciatica, which is a condition where there is distribution of pain along the course of sciatic nerve i.e., radicular pain from low back to foot.^[6]

In this disease, mainly Apana Vata^[7] and Vyana Vata^[8] vitiation are observed, but most of the times Kapha remains as associated Dosha. So for, treatment of Dr. Vishnu M L. et al. An open label single arm prospective clinical study on Gridhrasi (Sciatica)

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Gridhrasi, drug of choice should have Vata -Kaphashamana, Dipana - Pachana and Shulaprashamana properties.

Vatagajankusha Rasa is a combination of Vyosha, Rasa Bhasmas, Vatsanabha, Karkatasringi, Haritaki etc. Of which Shunti, Maricha, Pippali has Deepana, Aamapachana action and improves the digestion. Vatsanabha has the property of Vikasi, Vyavayi, Yogvahi. Haritaki, Agnimantha, Karkatashringi works as Deepana, Vatanulomaka, Kaphanisaraka, Vatashamaka. Rasa-Bhasma's improves Agni and acts as Balya, Rasayana, Vatapradhana Tridosha Shamaka. So it will be very effective in Vatavyadhis.^[9]

Here the study was taken to find out the effectiveness of *Vatagajankusha Rasa* with *Manjishta Kwatha* and *Pippali Churna* as *Anupana* in the management of *Gridhrasi* (Sciatica).

OBJECTIVE OF THE STUDY

To evaluate the efficacy of *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* in the management of *Gridhrasi* (Sciatica)

MATERIALS AND METHODS

Source of data

Patients who attended the out-patient department of Kayachikitsa at Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan.

Method of collection of data

49 patients (Table 1) were screened and selected based on the screening form prepared. Data was collected using specially prepared case report form. The demographic details of 40 enrolled patients of *Gridrasi* such as age, gender, educational status etc. are represented in table below (Table 1).

Geographic Observation	Predominance	No of Patients (%)		
Age	31-40	12 (30 %)		
Gender	Male	22 (55%)		

ORIGINAL ARTICLE

Sept-Oct 2019

Marital status	Married	33 (82.5%)		
Educational status	Middle school	18 (45%)		
Occupation	Agriculture	12 (30%)		

The observations related to the disease details of the 40 patients of *Sciatica* are represented in table below (Table 2)

Table 2: Observations related to disease40patients of Sciatica

Parameter	Observation	No of Patients (%)		
Stambha	Present	37 (92.5%)		
Ruk	Present	40 (100%)		
Toda	Present	40 (100%)		
Spandana	Present	36 (90%)		
Gaurava	Present	20 (50%)		
Arochaka	Present	9 (22.5%)		
Tandra	Present	6 (15%)		
Duration	Chronic	19 (47.5%)		
H/O trauma to LS	Present	6 (15%)		

Diagnostic criteria

Diagnosis was made on the basis of Samanya Lakshanas of Gridrasi viz. Stambha, Ruk, Toda and Spandana starting from Sphika and extend through Kati, Prishta, Uru, Janu, Jangha, Padam in an order and on the basis of symptoms of sciatica.

Inclusion criteria

- 1. Positive Straight Leg Raising test (30 to 70 degree)
- 2. Patients aged between 20-70 years
- 3. Patients of either gender irrespective of caste, creed and religion
- 4. Patients who are willing to participate and sign the informed consent form

Exclusion criteria

- 1. Uncontrolled Diabetes Mellitus and Hypertension
- 2. Systemic disorders like Chronic Heart Disease, Chronic Renal Failure, Chronic Liver Disease
- 3. History of HIV, HbSAg, Carcinoma
- 4. Pregnant woman and lactating mother
- 5. History of major trauma causing fractures of pelvis and femur
- 6. Surgical indications such as progressive neurological deficit

Ethical clearance

Ethics clearance was obtained from Institutional Ethics Committee before initiation of the study (IEC No: SDM/IEC/17/2017-2018).

Study design

The study was open label, single arm, exploratory, prospective clinical on 30 patients of Sciatica selected using the convenience/ purposive (non-random) sampling technique with pre and post test design conducted in a tertiary Ayurveda hospital attached to quarters in southern India.

Intervention

Medicines - Vatagajankusha Rasa with Pippali Churna and Manjishta Kwatha as Anupana.

Source and authentification of drug

- Vatagajankusha Rasa (125mg each) tablets were purchased from VIRGO Pharmacy, Gujarat, which is a GMP certified pharmacy.
- Powdered *Pippali* was purchased from Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital pharmacy, Udupi, which is a GMP certified pharmacy.
- Raw drugs for Manjishta Kwatha were procured from Kajrekar pharmacy, Belagavi and were authenticated at Dravyaguna department of Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan.

ORIGINAL ARTICLE Sept-Oct 2019

Method of preparation of Manjishta Kwatha

Roots of *Manjishta* were cleaned and dried. They were coarsely powdered, weighed as per formula and then mixed well. 4 parts of water was added to 1 part of *Manjishta* coarse powder, boiled and reduced to $1/4^{\text{th}}$ part. Prepared *Kwatha* was packed in 210 ml bottles and labeled with name of the drug, reference, details of the manufacturer, batch number.

Treatment plan

Vatagajankusha Rasa tablet of 125mg after food with 3gm Pippali Churna and 15ml Manjishta Kwatha as Anupana twice daily.

Duration: 7 days

Assessment Criteria

Primary outcome measures

- Samanya Lakshanas of Gridrasi like Stambha, Ruk, Toda, Spandana, Tandra, Gauravata, Arochaka
- Symptoms of sciatica

Secondary outcome measures

- Gait
- Straight leg raising Test (goniometry)
- Lassegues sign

Table 3: Assesment criteria (self assessed scale)

SN	Subjective Parameter	Grade	Assessment
1.	Sthambha	0	No stiffness
		1	With up to 25% impairment in the range of movement of joint
		2	With 25-50% impairment in the range of movement of joints
		3	With 50-75% impairment in the range of the movement of joints
		4	With more than 75% impairment in the range of movements of the joints
2.	Ruk - VAS	0	No pain - Scale reading 0

		1	Mild pain - Scale reading >0-3 (Mild pain complained by patient when asked)
		2	Moderate pain - Scale reading >3-6 (Patient frequently complained of pain and has painful look)
		3	Severe pain - Scale reading >6-10 (Excruciating pain associated with painful cries and agonizing look)
3.	Toda	0	No pricking sensation
		1	Mild pricking sensation sometimes
		2	Frequent pricking sensation
		3	Severe pricking sensation all the time
4.	Spandana	0	Absent
		1	Present
5.	Gowrava	0	No heaviness
		1	Occasionally
		2	Daily and high in frequency but not persistent
		3	persistent
6.	Arochaka	0	No complains
		1	1-2 times weekly complains of no desire to eat anything
		2	3-4 times weekly complains of no desire to eat anything
		3	Always complains of no desire to eat anything
7.	Tandra	0	Absent
		1	Present
8.	SLR (Straight	0	SLR 90 degrees
	(Straight Leg Rising)	1	SLR 70-90 degrees

	2	SLR 50-70 degrees				
	3	SLR 30-50 degrees				
	4	SLR 0-30 degrees				
Lasegue's	0	absent				
Sign	1	present				
Tenderness	0	No tenderness				
	1	Subjective experience of tenderness				
		2	Wincing of face on expression			
	3 Wincing of face and withdrawa					
	4	Do not allow to touch				
	1	Abnormal				
	Sign	3 4 3 4 0 1 1 7 1 1 1 2 3 3 4				

Sept-Oct 2019

ORIGINAL ARTICLE

OBSERVATIONS AND RESULTS

Total 40 patients of *Gridhrasi* were registered for the study; out of which 4 were dropout and rest 36 patients completed the study. The effectiveness of the therapy in those 36 patients are being shown here under the separate headings.

Statistical analysis was done using SPSS VER. 23 using Wilcoxon signed rank test and McNemar test

Table 4: Results of Wilcoxon signed rank testshowing the effect of therapy.

Param eter	Negative ranks			Positive ranks		Ti e s	To tal	Z valu e	P valu e	
	N	M R	SR	N	M R	SR	,		2	-
Stamb ha Rt BT-AT	1 7	9. 00	15 3.0 0	0	0. 0 0	0.0 0	1 9	36	- 3.8 27	.000 *
Stamb ha Lt BT-AT	1 9	10 .5 0	19 9.5 0	1	1 0. 5 0	10. 50	1 6	36	- 4.0 25	.000 *
Ruk Rt	1 9	10 .0	19 0.0	0	0. 0	0.0 0	1 7	36	- 4.3	.000 *

ORIGINAL ARTICLE Sept-Oct 2019

BT-AT		0	0		0				59	
Ruk Lt BT-AT	1 2	6. 50	78. 00	0	0. 0 0	0.0 0	2 4	36	- 3.4 64	.001 *
Toda Rt BT-AT	1 6	9. 03	14 4.5 0	1	8. 5 0	8.5 0	1 9	36	- 3.5 78	.000 *
Toda Lt BT-AT	8	4. 50	36. 00	0	0. 0 0	0.0 0	2 8	36	- 2.7 14	.000 *
Gaura va Rt BT-AT	6	3. 50	21. 00	0	0. 0 0	0.0 0	3 0	36	- 2.4 49	.014 *
Gaura va Lt BT-AT	6	3. 50	21. 00	0	0. 0 0	0.0 0	3 0	36	- 2.4 49	.014 *
Arocha ka AT- BT	6	3. 50	21. 00	0	0. 0 0	0.0 0	3 0	36	- 2.3 33	.020 *
ASLR Rt BT- AT	2 2	12 .0 2	26 4.5 0	1	1 1. 5 0	11. 50	1 3	36	- 4.3 15	.000 *
ASLR Lt BT-AT	1 8	9. 50	17 1.0 0	0	0. 0 0	0.0 0	1 8	36	- 4.2 43	.000 *
PSLR Rt BT- AT	1 9	10 .0 0	19 0.0 0	0	0. 0 0	0.0 0	1 7	36	- 4.2 64	.000 *
PSLR Lt BT- AT	1 7	9. 59	16 3.0 0	1	8. 0 0	8.0 0	1 8	36	- 3.6 26	.000 *
Tender ness Rt BT- AT	2 0	10 .5 0	21 0.0 0	0	0. 0 0	0.0 0	1 6	36	- 4.4 72	.000 *
Tender ness Lt BT-AT	1 7	9. 50	16 1.5 0	1	9. 5 0	9.5 0	1 8	36	- 3.7 71	.000 *
* - Significant										

Table 5: Results of McNemar test showing the effect of therapy.

Parame ter	ВТ		AT	N	P valu	Remar ks	
ter	Prese nt	Abse nt	Prese nt	Abse nt		e	ĸs
Spanda na Rt BT-AT	25	11	11	25	3 6	.000	S
Spanda na Lt BT-AT	10	26	5	31	3 6	.063	NS
Tandra	5	31	0	36	3 6	.063	NS
Lassegu e test Rt BT-AT	26	10	17	19	3 6	.004	S
Lassegu e test Lt BT-AT	18	18	7	29	3 6	.001	S

DISCUSSION

Statistically significant improvements were observed in the primary and secondary outcome measures with administration of *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana*. Assessment of these parameters was done after 7 days of treatment.

Stambha was manifested as a result of Vataprakopa and Sheetaguna. Vata due to its Ruksha and Kharaguna produce dryness and decreases Snigdhata and Shlakshnata (Shleshaka Kapha) in Mamsa Dhatu, which is essential for proper contraction and relaxation of muscles. Ingredients of Vatagajankusha Rasa like Rasasindhura, Lohabhasma, Swarnamakshika, Gandhaka, Vatsanabha, Tankana, Trikatu etc. with the Bhavana of Nirgundi and Mundi Swarasa makes the drug more potent against Vata and Kapha disorders. Shudha Haratala, Shunti, Pippali act as Vatashamaka, due to its Ushnavirya and Snigdha Guna, which might have reduced the Stambha.

Ruk and Toda Lakshanas were manifested as a result of Prakopa of Vyanavata and Apana Vata and Sleshaka Kapha due to Nidanas like Atibharavahana, Vishama Cheshta and Divaswapna. Bhasmas, Hareetaki, Karkatasringi in Vatagajankusha Rasa are Vatashamaka Dravayas. Pippali, Maricha and Shunti are Shoola Prashamana Dravyas. Vatsanabha is Kaphavatahara and Rujapaha. Manjistha Kashaya helps in pacifying the Prakupitavata due to its Ushnavirya and Madhura Rasa. Pippali Manjishta Vatsanabha have analgesic activity due to glycosides, alkanoids and other bio active compounds present in them and helps in reducing the pain.^{[10],[11]}

Sanga of Vata and its increased Chalaguna can be held responsible for localised pulsations (Spandana). Vatagajankusha Rasa containing Vatahara drugs like Hareetaki and Vatsanabha having Ushnalaghu Guna might have removed Sanga by Vata Anulomana. Manjishta and Shunti acts as Srotoshodhaka and Raktaprasadaka.

Tandra is a Kaphaja Lakshana seen in Gridhrasi. Vatagajankusha Rasa containing Lohabhasma, Tankana, Pippali, Shunti, Karkatasringi on administration does Kaphaharana and reduces Tandra.

Gourava was manifested due to the Guru Guna predominantly found in Kapha Dosha. Aruchi is a Kaphajananathmaja Vyadhi. Vatagajankusha Rasa contains Shunthi and Pippali having Laghuguna and Ushnaveerya, helps in Kaphahara property. Haritaki, Agnimantha, Karkatshrangi works as Deepana, Vatanulomaka, Kaphanissaraka and Vatashamaka. Rasa Bhasmas increases the Agni. Manjisthakashaya having Rukshaguna, Ushnavirya, Katuvipaka reduced Gourava and Arochaka. Pippali Churna having Katu Rasa and Usnavirya did Kaphaharana and reduced above symptoms.

Reduction in the degree of SLR was manifested as a result of Vyana Vata vitiation, due to Prakupita Kapha Dosa. The Prakopa of Kapha Dosha was caused due to Guru Guna. The combination of Rasa Oushadhis in Vatagajankusha Rasa acts as Vatapradhana Tridoshahara. Karkatasringi, Haritaki, Agnimantha works as Agnideepaka, Vatanulomaka, Kaphanisaraka and Vatashamaka. Another cause for reduction in SLR is the Shoshana of Sira and Snayu. These are the Upadhatus of Raktadosha. Manjishta is Raktaprasadaka which nourishes the Rakta and its Upadhatus and improves the blood circulation. Manjishta being Pitta-Kapha Shamaka, can counteract the Pitta or Kaphaanubandha with Vata. Movements of the lower limbs are improved by Bhasmas and drugs like Pippali, Haritaki, Vatsanabha having Balya, Rasayana property by promoting Dhathu Poshana.

Tenderness was manifested as a result of *Raktadusti* and *Vataprakopa*. *Manjistha Kashaya* having *Madhuratikta Rasa* and *Ushna Virya* did *Sroto Shodhana* and *Rakta Prasadana*. Drugs *Like Hareetaki*, *Vatsanabha, Shunti, Pippali* in *Vataganjankusha Rasa* are having *Vatahara, Vedanasthapana* properties, which might have acted on tenderness.

Discussion on mode of action of drug

Vatagajankusha Rasa is a combination of Rasa Aushadhis like Rasa Sindhura, Lohabhasma, Swarnamakshika Bhasma, Gandhaka, Haratala, Tankana and Dravyas like Haritaki, Karkatasringi, Vatsanabha, Shunti, Pippali, Agnimantha with Bhavana in Nirgundi Swarasa and Mundi Swarasa. This combination of Rasa Oushadhis acts as Vatapradhana Tridoshahara. They increase the Jataragni and works as Balya and Rasayana.

After *Marana*, *Rasa Bhasmas* become microfine particles. They get easily absorbed into the body along with *Rasa Dhatu* and provides nourishment to the body. After *Marana* the particle size of *Bhasma* reduces into the size of "platelets" (1.5 чm) and it can be absorbed through the gap junctions and epithelial tissues in middle gut. Particles penetrate the intestinal barrier either by endocytosis, phagocytosis or persorption and transit to the blood stream.^[12]

Pippali, Maricha, Shunti are Shoolaprashamana Dravyas. They improve digestion by Deepanapachana Karma and thereby improves the overall nourishment of the body. Vatsnabha is Kaphavatahara and Rujapaha. It has Vikasi, Vyavayi, Yogvahi Guna makes it easy to reach the cellular level. Karkatasringi,

ORIGINAL ARTICLE Sept-Oct 2019

Haritaki, Agnimantha work as Agnideepaka, Vatanulomaka, Kaphanisaraka and Vatashamaka. Nirgundi, Agnimantha, Lauha Bhasma, Shudha Gandhaka and Tankana Bhasma act as Shothahara. Shunti acts as Srotoshodhaka and Raktaprasadaka. Pippali, Manjishta, Vatsanabha have analgesic activity due to glycosides, alkanoids and other bio active compounds present in them and helps in reducing the pain.

Pippali Choorna due to its Katu Rasa, Laghu Snigdha Guna and Madhura Vipaka acts as Deepaka, Vatanulomaka, Balya, Rasayana; improves the Jataragni and nourishes the body.

Manjishta Kwatha is having Tikta Rasa, Ushna Guna and Katu Vipaka. It's Raktaprasadaka action improves the blood circulation and it is Srotoshodhaka.

Thus Vatagajankusha Rasa with Pippali Churna and Manjishta Kwatha Anupana acts as Vata Pradhana Tridosha Shamaka, Deepaka, Pachaka, Shothahara, Srotovishodhaka, Raktaprasadaka, Balya and Rasayana.

CONCLUSION

Vatagajankusha Rasa contains the main ingredients like Rasa Sindhura, Loha bhasma, Swarnamakshika Bhasma, Shunthi, Pippali, Vatsanabha etc. and hence acts on Vata and Kapha Dosha which shows its action on both variants of Gridhrasi. Vatagajankusha Rasa with Pippali Churna and Manjishta Kwatha as Anupana showed marked effect on the signs and symptoms of Gridhrasi - Ruk, Toda, Stambha, Gourava and Aruchi. Medicines showed marked effect on objective parameters of Gridhrasi like - Straight leg raising test and lassegues test. Range of movements of lumbar spine showed significant improvement after treatment. Vatagajankusha Rasa orally in the dose of 125 mg twice daily with Pippali Churna (3gm) and Manjishta Kwatha (15ml) as Anupana for 7 days is effective in Gridhrasi.

ORIGINAL ARTICLE Sept-Oct 2019

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