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An open label single arm prospective clinical study on *Vatagajankusharasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* in *Viswachi* (cervical spondylosis)

Dr. Moh Gulfam¹, Dr. Totad Muttappa², Dr Neelam Bisht³, Dr.Vishnu M L⁴, Dr.Yadu Gopan⁵

^{1,3,4,5}Final Year Post Graduate Scholar, ²Associate Professor, Dept. of Kayachikitsa, Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan, Karnataka, INDIA

ABSTRACT

Background: *Viswachi* is one among the 80 Nanatmaja Vata Vyadhi. This disease affects the neck and upper extremities with the signs and symptoms like Ruk, Stambha, Toda, Bahu Karmakshaya. *Vatagajankusha Rasa* is a combination of *Vyosha*, *Bhasmas*, *Vatsanabha*, *Karkatasringi*, *Haritaki* etc. It has *Vatakaphahara*, *Vikasi*, *Vyavayi*, *Rasayana* etc. properties. It is said to be effective in treating *Visawachi* in 7 days if given along with *Pippali Churna* and *Manjishta Kwatha*. **Aims and Objectives:** To evaluate the efficacy of *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* in the management of *Viswachi* (Cervical spondylosis). **Methodology:** Among 35 registered patients, 30 completed the course of treatment. They were administered with *Vatagajankusha Rasa* 1 tablet (125 mg) after food with *Anupana* 3gm *Pippali Churna* and 15 ml *Manjishta Kwatha* twice daily (morning and evening) for a period of 7 days. Nominal & ordinal data were analysed using non parametric tests like McNemar and Wilcoxon's signed rank tests respectively. **Result:** Assessment parameters like Ruk, Toda, Sthambha and *Bahukarma Kshya*. There was statistically significant improvement in the primary and secondary outcome measures ($p < 0.05$ was observed). **Conclusion:** *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* is effective in the management of *Viswachi* (Cervical spondylosis).

Key words: *Viswachi*, *Cervical spondylosis*, *Vatagajankusha Rasa*.

INTRODUCTION

Viswachi is one among the 80 vataja nanatmaja vikaras. It affects the neck and upper extremities. The symptoms as explained by different Acharya's are Ruk, Stambha, Toda, Karma Kshaya^[1] and Ceshtaharana of Bahu.^[2] Dalhana opinions that this

disease resembles Gridhrasi and is of two types, Vataja and Vata kaphaja.^[3]

The prevalence of degenerative neuronal diseases is about 6 in 1 lakh with a slight male dominance the onset is in middle life.^[4] Then by age 60, 70% of women and 85% of men show changes consistent with Cervical Spondylosis on x-ray.^[5]

The incidence of cervical spondylosis has been found to range from 83.2 to 202.9 persons per 1,000,000 with the peak incidence in the 50-54 years of age group. It is reported that in the US, 50-70% of the population will experience at least one significant episode of neck pain in their lives and 10% will suffer from neck pain at any given time.^[6]

Cervical Spondylosis is the most common spinal disorder in people over 55 years of age in the work, characteristic changes on spinal x-rays are present in majority of people aged over 70 years.^[7]

Address for correspondence:

Dr. Moh Gulfam

Final Year Post Graduate Scholar,
Dept. of Kayachikitsa, Sri Dharmasthala Manjunatheswara College
of Ayurveda and Hospital, Hassan, Karnataka, INDIA.

E-mail: drgulfamsaif@gmail.com

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Vatagajankusha Rasa is a combination of *Vyosha*, *Bhasmas*, *Vatsanabha*, *Karkatasringi*, *Haritaki* etc.^[8] of which *Shunti*, *Maricha*, *Pippali* works as *Deepana* and *Ama Pachana*. *Vatsanabha* has the properties like *Vikasi*, *Vyavayi*, *Yogavahi*; which makes it easy to digest along with all the drugs present in *Vatagajankusha Rasa*. It opens all the micro channels and easy to reach on cellular level. *Haritaki*, *Agnimantha*, *Karkatashringi* work as *Deepana*, *Vatanulomaka*, *Kapha Nissaraka*, *Vatashamaka*. All *Bhasmas* does *Agni Deepana* and work as *Balya*, *Rasayana*, *Vata Pradhana Tridosha Shamaka*.^[9] In this way the combination of these drugs acts in the management of *Viswachi*.

OBJECTIVE OF THE STUDY

To evaluate the efficacy of *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* in the management of *Viswachi* (Cervical spondylosis).

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

35 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 30 enrolled patients of *Viswachi* such as age, gender, educational status etc. are represented in table below (Table 1).

Table 1: Demographic detail of 35 patients of *Viswachi*.

Geographic Observation	Predominance	No of Patients (%)
Age	31-40 years	11 (31.4%)
	51-60 years	10 (28.6%)
Gender	Female	23 (65.7%)
Educational	High school	19 (54.3%)

Status		
Marital Status	Married	33 (94.3%)
Hard manual work	Present	19 (54.3%)

The observations related to the disease details of the 35 patients of *Viswachi* are represented in table below (Table 2)

Table 2: Observations related to disease.

Parameter	Observation	No of Patients (%)
<i>Shola</i>	Present	26 (74.3%)
<i>Stambha</i>	Present	23 (65.7%)
<i>Gourawa</i>	Present	22 (62.9%)
<i>Bahu Karma Kshya</i>	Present	17 (48.6%)
Spurling Test	Present	34 (97.1%)

Diagnostic Criteria

Diagnosis will be made on the basis of Samanya Lakshanas of *Vishwachi* viz. *Stambha*, *Ruk*, *Toda* and *Spandana* starting from *Greva* and extend through *Ansandhi*, *Bhuja*, *Angguli* in an order and symptoms of cervical spondylosis.

Inclusion Criteria

1. Patients who are willing to participate and sign the informed consent form.
2. Patients between 20-70 years of age.
3. Patients of either gender irrespective of caste, creed and religion.
4. Neurological assessments (reflexes).

- a. Triceps jerk
- b. Biceps jerk

Exclusion Criteria

1. Systemic diseases like diabetes mellitus, hypertension, tuberculosis and other chronic diseases.

2. Impaired renal function, Abnormal Liver function.
3. History of major trauma causing cervical vertebrae fracture, traumatic injury of cervical spine, cervical myelopathy.
4. Patients suffering from neoplastic and infective disorders.
5. Pregnant and lactating mothers

Ethical Clearance

Ethics clearance was obtained from Institutional Ethics Committee before initiation of the study. (IEC No: SDM/IEC/19/2017-2018).

Study Design

The study was open label, single arm, exploratory, prospective clinical on 30 patients of *Viswachi* 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

Medicine - *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana*

Source and authentication 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.

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 added to 1 part of *Manjishta* coarse powder, boiled and reduced to

1/4th 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 *Viswachi* like *Stambha*, *Ruk*, *Toda*, *Spandana*, *Tandra*, *Gauravata*, *Arochaka* and *Bahukarmakshya* and
- Symptoms of cervical spondylosis.

Secondary outcome measures

- ROM of neck (goniometry)
- Spurling test
- Lhermitte test
- Tenderness over cervical region

Table 3: Assesment criteria (self assessed scale)

SN	Subjective Parameter	Grade	Assessment
1.	<i>Sthambha</i>	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.	<i>Ruk – VAS</i>	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.	Spurling test	1	Present
		2	Absent

(Muscle Power) <i>Bahu karma kshaya</i> (loss of strength of Upper limb)	Grade
Complete paralysis	0
Flicker of contraction possible	1
Movement possible if gravity eliminated	2
Movement against gravity but not resistant	3
Movement possible against some resistant	4
Power normal (it is not normally possible to overcome a normal adult power)	5

OBSERVATIONS AND RESULTS

Total 35 patients of *Viswachi* were registered for the study; out of which 5 were dropout and rest 30 patients completed the study. The effectiveness of the therapy in those 30 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 test showing the effect of therapy.

Parameter	Negative rank			Positive rank			Ties	N	P value	Remarks
	N	MR	SR	P	MR	SR				
Shoola Right Upper Limb BT-AT	24	12.50	300.0	0	0.00	0.00	6	30	0.000	S
Shoola Left Upper Limb BT-AT	24	12.50	300.0	0	0.00	0.00	6	30	0.000	S
Sthamba Right BT-AT	22	11.50	253.0	0	0.00	0.00	8	30	0.000	S
Sthamba Left BT-AT	19	10.00	190.0	0	0.00	0.00	11	30	0.000	S
Toda Right	17	9.00	153.0	0	0.00	0.00	13	30	0.000	S

BT-AT										
Toda Left BT-AT	16	8.50	136.0	0	0.00	0.00	14	30	0.000	S
Gourava Right BT-AT	21	11.00	231.0	0	0.00	9	9	30	0.000	S
Gourava Left BT-AT	20	10.50	210.0	0	0.00	10	10	30	0.000	S

Parameter	Negative rank			Positive rank			Ties	N	P value	Remarks
	N	MR	SR	P	MR	SR				
Bahu Karma Kshaya Right - Proximal BT-AT	1	7.50	7.50	19	10.66	202.50	10	30	0.000	S
Bahu Karma Kshaya Right - Distal BT-AT	0	.00	.00	20	10.50	210.0	10	30	0.000	S
Bahu Karma Kshaya Right- Hand Grip BT-AT	1	9.00	9.00	19	10.58	201.0	10	30	0.000	S
Bahu Karma Kshaya Left - Proximal BT-AT	2	8.50	17.00	20	11.80	236.0	8	30	0.000	S
Bahu Karma Kshaya Left-Distal BT-AT	1	7.50	7.50	20	11.18	223.5	9	30	0.000	S
Bahu Karma Kshaya Left-Hand Grip BT-AT	1	8.00	8.00	16	9.06	145.0	13	30	0.000	S

Parameter	Negative rank			Positive rank			Ties	N	P value	Remarks
	N	MR	SR	P	MR	SR				
ROM Cervical Joint Flexion BT-AT	28	15.09	422.50	1	12.50	12.50	1	30	0.000	S
ROM Cervical Joint Extension BT-AT	28	14.50	406.0	0	.00	.00	2	30	0.000	S
ROM Cervical Joint Right Rotation BT-AT	24	12.50	300.0	0	.00	.00	6	30	0.000	S
ROM Cervical Joint Left Rotation BT-AT	23	12.00	276.0	0	.00	.00	7	30	0.000	S
ROM Cervical Joint Right Lateral Flexion BT-AT	23	12.50	276.0	0	.00	.00	7	30	0.000	S
ROM Cervical Joint Left Lateral Flexion BT-AT	19	10.00	190.0	11	.00	.00	.00	30	0.000	S

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

Parameter	BT		AT		N	P Value	Remarks
	Present	Absent	Present	Absent			
Spandana Right Upper Limb	21	9	11	10	30	0.02	S
Spandana Left Upper Limb	16	14	3	13	30	0.000	S
Tandra	17	13	1	16	30	0.000	S

Spurling Test Cervical Spine	29	1	12	17	30	0.000	S
Lhermitte test	27	3	1	26	30	0.000	S
MR = Mean Rank, SR = Sum of Ranks, S= Significant, NS = Non Significant							

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.

Statistically significant improvement was noticed in *shoola* after treatment. Wilcoxon signed rank test (P value=.000) showed improvements in mean after treatment.

This lakshanas were manifested as a result of prakopa of Vyana vata and sleshaka kapha due to nidanas like *Ati bhara vahana*, *Vishamacheshta* and *Divaswapnam*.

Manjistha Kasyam helps in pacifying the parakupita vata due to its *ushna virya* and *Katu Vipaka*. *Vatgajankusha Rasa* contains *Haritaki* which is *Laghu*, *ushna*, *Mdhura* and *Tridosahara* does the *Anulomana* of the *Vata*.^[17]

Statistically Significant reduction (p value < 0.000) of *Stambha*. At the end of therapy it was absent in patients in right and left upper limbs.

Stambha was manifested as a result due to the *Vata Prakopa* and due to the *sheeta* and *ruksha guna*. *Vatgajankusha Rasa* contains *Sudha Hartala* which acted as *Vatashamaka*, due to its *Ushna Virya* and *Snigdha Guna*. *Manjistha Kasyam* having *Madhura Rasa*, *Ushna Virya* reduced the *Vata*.

Statistically Significant Improvement (p value < .000) of *Bahu karmakshya* in Right proximal, distal, hand grip.

Statistically Significant Improvement (p value < .000) of *Bahu karmakshya* in left proximal, distal, hand grip.

Bahu Karmakshya can be understood as *Gati Sanga* manifested as a result of *Kapha Avarana* to the *Vyana Vata* in *Raktavaha Srotas* and *Mamsavaha Srotas*. *Vatgajankusha Rasa* helps in pacifying the *Kapha Avarana* by the *Usna Virya Tikta Rasa* and *Katu Vipaka*, *Pippali Choorna* contains, *Ushna Virya* administrated as *Anupana* with *Manjistha Kashayam* help in *Raktavaha Srotas* and *Mamsavaha Srotas*.

Statistically significant reduction (p value < 0.000) of Spurling test cervical spine. At the end of therapy it was absent patients. Reduction in the degree of ROM of cervical spine was manifested as a result of *Vyana Vata karmahani*, due to the *Prakupita Kapha Dosa*. The *Prakopa* of *Kapha Dosha* was caused due to the *Vridi* of *Guru Guna*. *Vatgajankusha Rasa* contains *Kapha-Vatahara* drugs like *Pippali*, *Shunthi*, *Vatsanabha* which is *Katu Rasa*, *Ushna Veerya* does *Kaphaharana* and brings *Vata Shamana* in *Greeva*, *Urdhwa Pradesha*.

Probable mode of action of *Vatgajankusha Rasa*

According to *Rasa Ratna Samuchhaya*, after *Marana*, *Bhasma* becomes microfine particles that easily absorb into the body along with *Rasa Dhatu*. Such absorbed *Bhasmas* provide nourishment to the body and cures all types of diseases.^[10]

Mode of action of different ingredients

The combination of *Rasa Oushadhis* act as *Kapha-Vata Pradhana Tridosahara*. They increase the *Jataragni* and works as *Balya* and *Rasayana*.^[11]

Shunti, *Maricha*, *Pippali* work as *Deepana*, *Pachana*. It improves digestion thereby improves the overall nourishment of the body.

Vatsanabha has *Vikasi*, *Vyavayi* and *Yogavahi Guna* which make it easy to be digested. It opens all the micro channels and reaches cellular level.^[12]

Karkatasringi, Haritaki and Agnimantha work as *Agni Deepaka, Vatanulomaka, Kapha Nisaraka* and *Vata Shamaka*.^[13]

Pippali is *Kapha-Vatahara* and *Urdhwa Bhagahara Dravya* due to which it can improve the brain functions. It is of *Madhura Vipaka* and *Ushna Veerya* which counter acts *Vata Dosha*. It is *Rasayana*.

Manjishta is *Pitta-Kapha Shamaka* due to which it can counteract the *Pitta* or *Kapha Anubandha* with *Vata*. It is *Rakta Prasadaka* which improve the blood circulation. It is *Swarakrut*.^[14]

CONCLUSION

Administration of *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* for 7 days shown statistically significant improvement in the clinical features of *Viswachi* namely - *Shoola, Stambha* and *Bahukarmakshya*. Statistically significant improvement was observed in the secondary outcome measure like spurling test. The study showed more improvement in "*Ruk*" followed by "*Stambha*" and *Gowrava*. Hence administration of *Vatagajankusha Rasa* (125 mg) twice daily with *Pippali Churna* (3gm) and *Manjishta Kwatha* (15ml) as *Anupana* after food for 7 days is effective in the management of *Viswachi* (Cervical spondylosis).

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