

## A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF SHUDDHA GUGGULU RASAYANA IN VISWACHI W.S.R TO CERVICAL SPONDYLOSIS

<sup>\*1</sup>Dr. Ananthalekshmi R., <sup>2</sup>Dr. Veerakumara K. and <sup>3</sup>Dr. Shrilatha Kamath T.

<sup>1</sup>Final Year Pg Scholar, Department of Kayachiitsa.

<sup>2</sup>Professor and Guide, Department of Kayachiitsa and Manasa Roga.

<sup>3</sup>Professor and Head of The Department, Department of Kayachiitsa and Manasa Roga.

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**\*Corresponding Author**

**Dr. Ananthalekshmi R.**

Final Year Pg Scholar,  
Department of Kayachiitsa.

### ABSTRACT

**Objectives:** To evaluate the therapeutic effect of *Shuddha Guggulu Rasayana* in *Viswachi* W.S.R. to cervical spondylosis. **Methodology:** an open labelled clinical study was planned to evaluate the therapeutic effect of *Shuddha Guggulu Rasayana* in *Viswachi* W.S.R. to cervical spondylosis. The patients suffering from *Vishwachi* w.s.r to cervical spondylosis will be selected for the study from OPD & IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi. *Shuddha Guggulu Rasayana* capsules will be obtained from SDM Ayurveda Pharmacy, Kuthpady, Udupi. The subjects suffering from *Vishwachi*

W.S.R to cervical spondylosis will be screened under strict diagnostic, inclusion and exclusion criteria and will be selected for the study. Eligible subjects then will be invited to participate in the study after signing a detailed informed consent and then registered for this clinical trial. Thus registered participants will be treated with the medication as per the plan of intervention. The outcome measures will assessed at baseline, on 7<sup>th</sup> Day, 14<sup>th</sup> Day and 42<sup>th</sup> Day after the *Rasayana*. The selected patients were administered with 4 capsules of *Shuddha Guggulu Rasayana* in TID dosage before food with 1 glass of warm milk for a period of 14 days and follow up after 28 days were told which in total makes 42 days of treatment. Later were analysed statistically using paired t test for numerical values and Wilcoxon signed rank test for ordinal data comparing before treatment and after treatment. **Results:** statistically significant results are obtained in this clinical study. **Conclusion:** the patients who were treated with shuddha guggulu rasayana got an excellent relief after the treatment.

**KEYWORDS:** *viswachi*, *vatavyadhi*, *shuddha guggulu rasayana*, cervical spondylosis

## INTRODUCTION

Ambulation is one of the important functioning of the vertebrates, flexibility of the skeletal structures plays a major role in ambulation as well as all the motor function. The lifestyles specifically, maintaining posture plays vital role in maintaining the health of the spine. Cervical spondylosis is a burning issue related to the spine in this era of technical advancement and sedentary lifestyle. Most of the time it seeks a medical attention only after pain and stiffness become persistent.

As this disease is pain predominant, as well as mobility of the part of the body is affected this is understood under the heading of *Vatavyadhi*. To be more precise this disease is understood under the topic of *Vishwachi*<sup>[1]</sup> where due to the compression over the *Kandara* that is running from the neck to that of the hand causes the pain over the course of that *Kandara* as well as loss of motor function. This has been listed as *Shoola*, *Sankocha* and *Bahu Karma Kshaya*.

Cervical spondylosis<sup>[2]</sup> is degeneration of the intervertebral disc which is characterized by the pain in the neck then radiates into the shoulders or arms. The roots which is most likely to affects are C5 and C6. It is most commonly seen in old age people but nowadays young people are also affected by the disease because of continuous work having impact over the neck area and adopting the sedentary life styles. The incidence of cervical spondylosis is, 60-70% in females and 85% in males by the middle age.<sup>[3,4]</sup>

Out of many treatment modalities such as analgesic, anti-inflammatory and parenteral steroid therapy may have immediate relief, but they play a minimum role in rectifying the pathology. So an alternate treatment for the long term benefit is needed. To enlist some of the treatment modalities such as *Shodhana*, *Shamana* and *Rasayana* are proved beneficial in observing results with minimum or no discomfort. In this study *Shuddha Guggulu Rasayana* has been selected as it is *Shothahara*, *Vedana Sthapana* and *Rasayana* which is indicated in *Vatavyadhi*. An attempt is made to evaluate the effect of *Shuddha Guggulu Rasayana* in *Vishwachi*.<sup>[5]</sup>

## METHODOLOGY

Ethical committee clearance has been done, Reference number: SDMCAU/ACA-49/ECH12/2020-21.

## OBJECTIVES

To evaluate the therapeutic effect of *Shuddha Guggulu Rasayana* in *Viswachi* W.S.R. to cervical spondylosis.

## DESIGN OF THE STUDY

study type	Interventional
Estimated enrolment	30 participants
End point classification	Efficacy study
Interventional model	Single group study
Masking	Open labelled
Primary purpose	Treatment

**SETTINGS:** Shri Dharmasthala Manjunatheswara college of Ayurveda, Udupi, Karnataka.

### Study selection.

30 patients suffering from *Viswachi* (cervical spondylosis) were selected for the study.

### Intervention

The selected patients were administered with 4 capsules of *Shuddha Guggulu Rasayana* in TID dosage before food with 1 glass of warm milk for a period of 14 days and follow up after 28 days were told which in total makes 42 days of treatment.

## DIAGNOSTIC CRITERIA

The diagnostic criteria includes the clinical presentation of *Vishwachi* W.S.R. to cervical spondylosis i.e. pain in the neck and stiffness, radiation of pain, degeneration of spine supported by X ray findings based on cervical degenerative index.<sup>[6]</sup>

## INCLUSION CRITERIA

- Patients presenting with signs & symptoms of *Vishwachi* (cervical spondylosis) supported with Radiological findings with X-ray.
- Patients of either sex aged between 25 to 70 years.
- Able to cooperate in the completion of study.
- Willing and able to comply with study protocol.

- Patients who fulfill all eligibility criteria.

### EXCLUSION CRITERIA<sup>[7]</sup>

- Patients showing the features of cervical spondylosis due to fracture and osteoporosis
- Ankylosing spondylitis
- Rheumatoid Arthritis
- Motor neuron disease
- Metabolic and infectious bone disease
- Syringomyelia
- Malignancy

### ASSESSMENT CRITERIA

#### Primary Outcome Measures

Scores of the visual analogue scale [Time Frame: on day 0, day 7, Day 14 & Day 42 after *Rasayana*] Clinical effects will be evaluated based on scores of the visual analogue scale (VAS<sup>8</sup>).

Range of the motion of Cervical segments and adjacent segments [Time Frame: on day 0, day 7, Day 14 & Day 42 after *Rasayana*] Standard dynamic flexion and extension lateral cervical segments will be obtained to evaluate range of motion of C2-C7 and adjacent segments.

#### Secondary Outcome Measures

Scores of the Neck Disability Index<sup>[9]</sup> [Time Frame: on day 0, day 7, Day 14 & Day 42 after *Rasayana*] Clinical effects will be evaluated based on scores of the Neck Disability Index (NDI).

Neutral head position test (NBPT) [Time Frame: on day 0, day 7, Day 14 & Day 42 after *Rasayana*] NBPT will be evaluated using the CROM (cervical range of motion) device, which is a special goniometer for the neck. NBPT will be started when the cervical region is in a neutral position, the individual will be asked to turn his head completely to the left or right and return to the neutral position in a controlled manner. The angular difference will be recorded in degrees.

## RESULTS

Statistical analysis of the results was done on sigma plot software version 14 using paired t test and Wilcoxon sign rank test, the effect of treatment are as follows.

Table no 1: effect on pain.

Criteria	time	mean	SD	SE	Median	Difference In mean	% improvement	Wilcoxon Signed Rank test	
Visual analogue scale	BT	6.867	0.196	0.401	7	2.967	43%	Z value	P value
	AT	3.900	0.194	0.397	4			-4.856	P= <0.01
	FU	3	0.983	0.179	3	3.867	56%		

Table no 2: effect on flexion of neck.

Criteria	time	Mean	SD	SE	median	Difference In mean	% improvement	Paired t test	
Flexion of neck	BT	32.833	7.621	1.391	30	7.667	23%	T value	P Value
	AT	40.500	6.611	1.207	40			12.324	P= <0.01
	FU	44	6.352	1.160	45	11.167	34%		

Table no 3: effect on extension of the neck.

Criteria	Time	mean	SD	SE	median	Difference In mean	% improvement	Paired T test	
Extension of the neck	BT	33.00	5.663	1.034	35	7.00	21%	T value	P value
	AT	40.0	5.724	1.045	40			9.424	P= <0.001
	FU	43.833	4.292	0.784	45	10.83	31%		

Table no 4: effect on lateral flexion of the neck.

Criteria	time	mean	SD	SE	median	Difference In mean	% improvement	Paired t test	
Lateral flexion of neck	BT	27.33	6.661	1.216	27.500	8.5	31%	T value	T value
	AT	35.833	5.584	1.019	35.00			12..420	P= <0.001
	FU	38.333	5.622	1.026	40.00	11	40%		

Table no 5: effect on lateral rotation of the neck.

Criteria	Time	mean	SD	SE	median	Difference In mean	% improvement	Paired t test	
Lateral rotation of neck	BT	28.167	5.645	1.031	25	7.66	27%	T value	P value
	AT	35.833	6.170	1.127	35			-10.82	P= <0.01
	FU	39.167	6.444	1.176	40	11	39%		

Table no 6: effect on neck disability index.

Criteria	time	mean	SD	SE	median	Difference In mean	% improvement	Wilcoxon Signed Rank test	
Neck disability index	BT	30.833	3.281	0.599	31	18.33	59%	P value	Z value
	AT	12.500	3.298	0.602	12			P=	-4.807
	FU	8.167	2.984	0.545	8.00	22.666	73.5%	<0.001	

Table no 7: effect on NDPT.

Criteria	time	mean	SD	SE	median	Difference In mean	% improvement	Paired t test	
NDPT	BT	32.833	7.621	1.391	30	7.667	23%	T value	P Value
	AT	40.500	6.611	1.207	40			12.324	P=
	FU	44	6.352	1.160	45	11.167	34%		<0.01

### BASED ON SYMPTOMS

After the treatment in 30 patients, 43% of improvement is seen visual analogue scale- pain, 23% improvement is seen in flexion of the neck, 21% of improvement is seen in extension of neck, 31% of improvement in lateral flexion of the neck and 27% improvement is seen lateral rotation of the neck, 59% of improvement in neck disability index and 23% improvement in neutral head position test.

### OVERALL IMPROVEMENT

By assessing the overall effect of shuddha guggulu rasayana in viswachi among 30 patients, 80% of the patients shows good improvement and 20% of the patients shows excellent improvement.

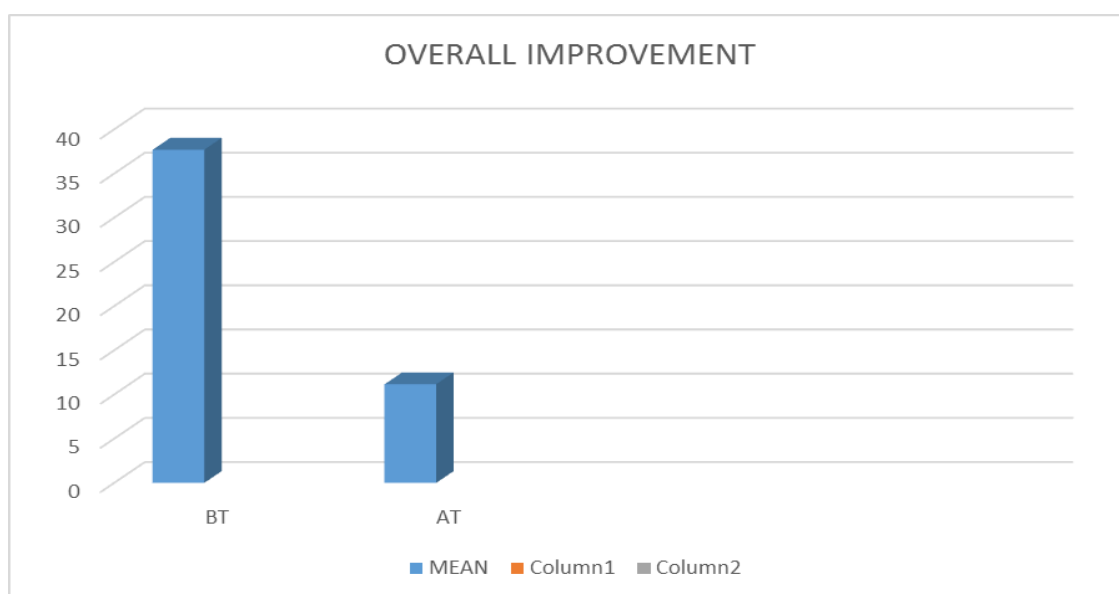


Diagram no 1: patient wise improvement.

## DISCUSSION

*Acharya* have explained in separate chapter for *Vata Vyadhi* which shows the importance of *Vata Dosha* in manifesting disease. As *Vata* have property of *Chala Guna* and it also has the work of transferring the other remaining *Dosha* to different *Sthana* of the *Sharira*. Due to *Nidana Vata Dushti* happens and finally resulting in *Vatavyadhi*. Hence a study on *Viswachi*, one of the *Vatavyadhi* was taken under the consideration.

Cervical spondylosis is a degenerative condition happening in the cervical spine causing in the reduction of space between the disc and finally resulting in the nerve compression. Previously around 25 to 30 years back occurrence of cervical spondylosis was restricted to the older generation, but now a days, due to the more impact of excessive use of mobile phones, computers and sedentary life styles, such diseases are most commonly now seen even in younger generations.

The treatment started with *mrudu koshta shodhana* with *eanda thaila* and *shunti Kashaya* which acts as *vata anulomana* and it will also help to get muscle relaxation. *Shuddha guggulu* is *sookshma*, *ushna guna*, *katurasa* and *katu vipaka*. *Katu vipaka dravya* is of *vatakaphahara* in nature. *Guggulu* works as anti inflammatory, anti obesity and also has lipidomodulatory in nature. *Shuddha guggulu* is indicated in *vata vyadhi* as *rasayana*, according to *charaka* in *vatavyadhi* condition *shuddha guggulu* should be taken along with milk which is nourishing and is the natural source of calcium. Hence *shuddha guggulu* in *rasayana* dosage along with milk as *anupana* helps in *viswachi* caused due to *margavaranajanya* and *dhathukshayajanya* as well as *vataja* and *vatakaphaja viswachi*.

## CONCLUSION

*Shuddha guggulu rasayana* shows the statistically significant improvement with  $p < 0.001$  in the parameters of pain, neck degerative index, neutral head position test and overall range of movements. There was reduction in the symptoms from moderate to mild on AT that is on 14<sup>th</sup> day, Further during the follow up there was marginal reduction in symptoms, on 42<sup>nd</sup> day. On comparing the overall effect on symptoms, there was an overall improvement in pain, 56 % of improvement in neck disability index, 25% improvement in range of movements, 34 % improvement in neutral head position test. On comparing the overall effect of treatment all the 30 patients had marked improvement within 50-75%. Adverse drug reaction was not reported or observed in any of the patients during the treatment period or during follow up.

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