

## EVALUATION OF EFFICACY OF *PANCHAMRITA LAUHA GUGGULU (PLG)* IN MANAGEMENT OF CERVICAL SPONDYLOSIS (*MANYAGATA VATA*)

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### ABSTRACT

Cervical spondylosis is one of the most common diseases arising from change in life style, increased travelling on vehicles, continuous sitting & working on computers. Various single & compound herbal & herbo-mineral preparations are mentioned in *Ayurved* texts for management of cervical spondylosis. In this open randomized study 30 patients predominantly complaining of pain in cervical region (*Manya Shoola*) were screened for radiological evidence. Patients fulfilling inclusion criteria were recruited & treated with *Panchamrita Lauha Guggulu* [PLG] (250mg tds) for the period of 8 weeks. The percentage of relief for *Manya Shoola* proved to be 50%. *Manya Graha* (Spasm in cervical muscles) improved by 46.66%. The trial drug gave 43.33% relief in *Bhrama*. Percentage of relief in *Mansabala Kshaya* (muscular weakness in cervical region) was 46.66%. Thus the drug proved beneficial in all the symptoms of *Manyagata Vata*.

**Keywords:** Cervical spondylosis, *Manyagata Vata*, *Panchamrita Lauha Guggulu*, *Graha*

### INTRODUCTION

Speed has become the keyword of present day life. Besides this immense stress, unhealthy food habits, blindly following of westernized life style has contributed in destruction of quality of life considerably. The recent advantages in biotechnology & molecular biology may provide success in increasing the span of life but fail to improve the quality of life. Increasing percentage of degenerative diseases like Osteoarthritis, Diabetes, Hypertension, Ischemic Heart diseases, & Cerebro-vascular accidents in young individuals is the best example to prove this point. Cervical spondylosis is one of the most common diseases arising from change in life style, increased travelling on vehicles, continuous sitting & working on computers. *Manyagata Vata*<sup>1</sup> disease

shows similarity with this cervical spondylosis which is the topic of present study.

It impairs the routine activities of man. It may not lead to death but once occurred if not treated for prolonged period it may give rise to permanent deformity & many more complications. So right from the onset of the disease proper management is very essential. There are mainly two reasons described for vitiation of *Vata* in Ayurvedic texts, viz., *Margavarodha* (Obstruction) & *Dhatukshaya* (Degeneration).<sup>2</sup> *Manyagata Vata* (cervical spondylosis) being a degenerative disease comes under *Dhatukshayajanya Vataprakopa*. Generalized *Dhatukshaya* especially *Asthi dhatu kshaya* plays an important role in *Manyagata Vata*. *Asthi Dhatu* is contributed by *Prithvi* & *Vayu Mahabhutas*.<sup>3</sup>

*Prithvi* is responsible for stability, solidity & strength of *Asthi Dhatu* while *Vayu* is responsible for porous nature of *Asthi Dhatu*. With increasing age, *Vayu* increases resulting into gradual loss of *Prithvi Mahabhuta*, which makes the bone brittle in nature increasing its susceptibility for osteoarthritis of cervical spine. The patho-physiology of *Manyagata Vata* involves vitiation of *Vata Dosha*. *Rukshya* & *Chal guna* of *Vata* are chiefly involved in pathophysiology. Following points must be considered in pathophysiology of *Manyagata Vata* as-

- *Jatharagni Dushti*
- *Dhatvagni Dushti* (*Rasa, Rakta, Mansa & Asthi*)
- *Manya Sandhi Sthana Dushti*
- *Vata Vriddhi*
- *Dhatukshaya*

The treatment of *Manyagata* must include reduction of pain & inflammation along with correction of underlined pathophysiology hence the treatment should aim on –

- Normal functioning of *Jatharagni* (Digestive fire)
- Improve the function of *Dhatvagni* (Micro-digestion)
- Medicines to provide strength to joints
- Correction of *Dhatukshaya*

Various single & compound herbal & herbo-mineral preparations are mentioned in

*Ayurved* texts for management of *Vatavyadhi*. *Guggulu* is the most commonly used drug in the treatment of *Vatavyadhi* (*Guggulu* having *Snigdha, Ushna guna* which alleviates *Vata* & also reduces inflammation). PLG is mentioned in text *Bhaishajya Ratnavali* for management of *Mastishka Roga*, Various *Snayu Roga* & *Vata Vyadhi* which is a combination of 13 herbs viz. Purified Mercury, Purified Sulphur, *Rajata Bhasma*, *Abraka Bhasma*, *Makshika Bhasma*, *Lauha Bhasma* including *Guggulu* processed in *Sarshapa Taila* (mustard oil).<sup>4</sup> An attempt was made to evaluate efficacy of PLG to assess its effects in *Manyagata Vata*.

## MATERIALS & METHOD

### Preparation of PLG

#### *Guggulu Shodhana*

For this stone, glass, bark etc which are common impurities were first removed and then *guggulu* was broken into small pieces. Thereafter it was tied in a piece of cloth and boiled in *Dola-yantra* containing *Triphala* decoction. The boiling was continued till *guggulu* becomes soft mass. It was then taken out of the cloth and spread over smooth wooden board smeared with ghee. Then it was dried in the place free from dust. It was kept in glass jar free from moisture and heat and is used for PLG preparation.<sup>5</sup>

#### Table no. 1. Ingredients of PLG

Contents	Latin Name	Proportion
<i>Shuddha Parada</i>	Purified Mercury	1 part
<i>Shuddha Gandhaka</i>	Purified Mercury	1part
<i>Rajata Bhasma</i>	Calcinated Silver	1 part
<i>Makshika Bhasma</i>	Calcinated Chalcopryrite	1 part
<i>Abhraka Bhasma</i>	Calcinated Mica	1 part
<i>Lauha Bhasma</i>	Calcinated Iron	2 part
<i>Purified Guggulu</i>	<i>Commiphora wightii</i> (Arn.) Bhandari	7 part

<b>Mustard Oil</b>	<i>Brassica juncea</i> L. Czern.	Q.S.
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### Method of Preparation

The above mentioned drugs and purified *guggulu* put into the iron mortar and mixed well until homogenous mixture formed. While mixing above mentioned mustard oil also added for smoothening of the mixture. After formation of mixture pills were made. Criterion to determine the final stage before making pills is that it should not stick to the fingers when rolled. Pills dried in shed. These pills were kept in air tight containers. These pills were not exposed to sunlight.

### Design of Study; Ethical clearance; Institutional Ethics Committee Approval and Regulatory Compliance:

Before the initiation of the study, the study protocol and related documents were reviewed and approved by Institutional Ethics Committee at Smt. KGMP Ayu College, Mumbai. The study was conducted in accordance with Schedule Y of Drugs and Cosmetics act, India, amended in 2005 and ICMR ethical guidelines for biomedical research on human participants 2006.

**IEC No** - KGMP/NOTICE/1263/2009  
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**Type of study-** Randomized uncontrolled open study.

**No. of patients-** Total 30 patients were registered in this trial.

The study was carried out in following steps:-

### Criteria for Inclusion of patients

- Age- The patients of 20-65 yrs of age.
- Sex- Male & female both.
- Patients having signs & symptoms of *Manyagata Vata (Vatavyadhi)* mentioned in *Ayurvedic* texts.

- Patients with X-ray findings suggestive of cervical *spondylosis*.

### Criteria for Exclusion of patients

- The patients with signs & symptoms of *Vatavyadhi* related to bones other than cervical vertebrae.
- The patients with signs & symptoms of lumbar Spondylosis, Ankylosing Spondylosis, R.A., T.B. spine, osteoarthritis of other joints etc.
- Patients suffering from systemic diseases like DM, HTN & cardiac diseases etc.

**Diagnosis criteria:** The patients with X-ray finding suggestive of cervical spondylosis were taken for the study.

**Dose** - 250mg three times daily

**Anupana-** lukewarm water

**Duration of treatment-** 2 months (8weeks)

**Diet-** Patients were advised to take their usual diet.

**Follow up-** Follow up was advised after every one week.

### Investigations

Investigations like blood – CBC with ESR, Liver function test, renal profile, Blood sugar, Urine routine were done at the starting & at the end of the trial.

Radiological examination of cervical spine was done before the trial.

### Criteria for Assessment of the effect of drug

The efficacy of PLG was assessed mainly regarding the symptoms like Cervical pain (*Manya Shoola*), Stiffness (*Manya Graha*), Giddiness (*Bhrama*) and Weakness in neck muscles (*Mansabala Kshaya*). Also its effect on the other symptoms was assessed.

**The criteria for the assessment as per gradation was as follows**

***Manya Shoola (Pain in Cervical region)***

<b>Absent</b>	<b>0</b>
Occasional pain only on excessive work (>8hrs) or heavy work	1
Intermittent pain felt after 5-6hrs of work for slight excessive work	2
Continuous pain of high intensity felt after 1-2hrs of light work	3
Severe pain felt continuously, unable to do work for even ½hr	4

**Manya Graha (Muscle spasm in Cervical region)**

<b>Absent</b>	<b>0</b>
Felt occasionally on excess of work or in morning	1
Intermittently felt in morning & during work	2
Felt daily in morning & on doing work for 1 hr	3
Felt daily in morning & on doing work for 15-20mins	4

**Bhrama (Giddiness)**

<b>Absent</b>	<b>0</b>
Occasional felt once in week	1
Intermittently felt once after 3-4 days	2
Regularly felt once a day	3
Regularly felt more than once on every day	4

**Mansabala kshaya (Muscular weakness in cervical region)**

<b>Absent</b>	<b>0</b>
Occasional pain felt on carrying extra weight in hands or on shoulders etc.	1
Pain felt intermittently while carrying slightly extra weight in hands or on shoulders etc.	2
Pain felt immediately on carrying even normal weight that is bag etc. in the hand or on shoulders	3
Severe pain felt on carrying normal baggage etc.	4

**Observations and Results**

The collected data was analyzed under two headings i.e. demographic analysis & Clinical efficacy of the trial drug

**Demographic details**

Total 30 patients were registered for this study. The demographic analysis of these patients are shown as follows

**Table no. 2 Demographical findings in study group**

Demographic Parameters	No. of Patients (Total 30)	Percentage
<b>Age</b>		
20-29 yrs	02	6.66%
30-39 yrs	06	20%
40-49 yrs	15	50%
50-60 yrs	07	23.33%
<b>Sex</b>		
Male	12	40%

<b>Female</b>	18	60%
<b>Addiction</b>		
<b>Tea</b>	15	50%
<b>Tobacco</b>	03	10%
<b>Smoking</b>	03	10%
<b>Alcohol</b>	06	20%
<b>No Addiction</b>	03	10%
<b>Occupation</b>		
<b>Domestic work</b>	12	40%
<b>Clerk</b>	05	16.66%
<b>Sedentary</b>	06	20%
<b>Tailor</b>	04	13.33%
<b>Driver</b>	01	03.33%
<b>Labor</b>	02	6.66%

**Table no. 3 Symptom wise improvement in Manyagata Vata**

Sr. No.	Symptom	No. of Patients			Relief in %
		BT	AT	Relief	
1	<i>Manya Shoola</i>	30	15	15	50.00%
2	<i>Manya Graha</i>	30	16	14	46.66%
3	<i>Bhrama</i>	30	17	13	43.33%
4	<i>Mansabala Kshaya</i>	30	16	14	46.66%

The symptom *Manyagata Shoola* was Present in all The 30 pts. After treatment it remained in 15 patients i.e. 15 got relief. The percentage of relief was 50%. *Manya Graha* was present in 30 pts before treatment & remained in 16 pts after treatment i.e. 14 pts got improvement & percentage of

relief was 46.66%. *Bhrama*, *Mansabala Kshaya* were initially present in all the 30 pts & after treatment the patient got relief i.e. 43.33% (13 pts get relieved), 46.66% (14 pts get relieved) respectively.

**Table no. 4 Symptom Score wise improvement in patients of Manyagata Vata**

Sr. No.	Symptom	Symptom Score			Relief in %
		BT	AT	Relief	
1	<i>Manya Shoola</i>	92	32	60	65.21%
2	<i>Manya Graha</i>	47	21	26	55.31%
3	<i>Bhrama</i>	36	19	17	47.22%
4	<i>Mansabala Kshaya</i>	34	18	16	47.05%

Out of 4 symptoms of *Manyagata Vata* taken into consideration, regarding *Manya Shoola* before treatment the score was 92 & after treatment score was 32 i.e. relief score was 60 (65.21%). Relief score for *Manya*

*Graha* was 26 (55.31%), for *Bhrama* was 17 (47.22%), for *Mansabala Kshaya* was 16 (47.05%).

**Table no. 5 Total relief of trial drug**

Sr. No.	Relief in %	Result	No. of Pts.	Percentage
1	100	Totally Cured	2	6.66%
2	75-100	Cured	4	13.34%
3	50-75	Markedly improved	14	46.67%
4	25-50	Improved	7	23.33%
5	<25	Unchanged	3	10.00%

Out of 30 patients of *Manyagata Vata* treated with PLG, 2 pts (6.66%) got total relief in their signs & symptoms. 4 patients (13.34%) were cured i.e. they got 75-100% relief. Markedly improved pts were 14 in no.

(46.67%) while 7 patients (23.33%) were improved. 3 patients (10.00%) remained unchanged i.e. got relief <25%.

**Table no. 6 Statistical Analysis of symptoms of *Manyagata Vata***

Sr. No.	Symptom	Mean			S.D.	S.E.	t <sub>29</sub>	p
		BT	AT	Diff.				
1	<i>Manya Shoola</i>	3.1	1.1	2	1.05	0.19	10.42	< 0.001
2	<i>Manya Graha</i>	1.6	0.7	0.86	0.73	0.13	6.49	< 0.001
3	<i>Bhrama</i>	1.2	0.6	0.56	0.5	0.09	6.15	< 0.001
4	<i>Mansabala Kshaya</i>	1.1	0.6	0.53	0.5	0.09	5.75	< 0.001

**Manya Shoola:** The objective clinical evaluation of 30 patients showed the mean of difference as 2. This when subjected to statistical calculation showed the Std. Deviation 1.05 & Std. Error 0.19 respectively. The 't' value worked out to be 10.42 at d<sub>f</sub> 29 which means the probability of observing value of 't' 10.42 i.e. p<0.001 which is highly significant.

**Manya Graha:** For this symptom the mean of difference showed to be 0.86. The Std. Deviation was 0.73 with Std. Error 0.13. The 't' value worked out to be 6.49 at d<sub>f</sub> 29 which gives p<0.001 which is highly significant.

**Bhrama:** This symptom showed mean of difference 0.56 with Std. Deviation 0.50. The S.E. worked out for it was 0.09 with 't' value 6.15 at df 29 which gives p<0.001 i.e. highly significant.

**Mansabala Kshaya :** Mean of difference for this symptom worked out was 0.53 with S.D. 0.50. The S.E. value for it was 0.09

with 't' value 5.75 at d<sub>f</sub> 29 from which the probability worked out <0.001 which is highly significant.

## DISCUSSION

Though *Manyagata Vata* is included under the heading of *Vatavyadhi*, its description is not available in all the classics of Ayurveda. *Charak* had not mentioned specific etiological factors, *poorvarupa*, *roopa*, *Samprapti* and *chikitsa* of this disease. But the *nidanpanchak* and *chikitsa* described by him in *Vatavyadhi* chapter of *chikitsa sthana* in general is applicable to this *Manyagata Vata* as the vitiated *Vata dosha* is the main causative factor in this disease.<sup>6</sup>

*Manya Shoola* is the most prominent feature of this disease. The other signs & symptoms include *Manya Graha*, *Bhrama*, *Mansabala Kshaya*, etc. The incidence of this disease is increasing day by day due to speed & changes in life style, increased travelling, use of computers etc. Due to the pain in *Ma-*



nyagata Vata, daily routine work is efficiently hampered.

Satisfactory relief from pain & other symptoms without or with minimal side effects is the challenge that entire medical fraternity is facing. Panacea for pain is the prime demand of the patients of *Manyagata Vata*. As long term use of analgesics manifest undesired effects, search for medicine in indigenous system of medicine i.e. Ayurveda continues

PLG is mentioned in *Bhaishajya Ratnavali Mastishka Roga chikitsa*. It has been thoroughly studied with separate literary study of each drug i.e. herb. *Vata, Asthi, Sandhi* & related organs are also studied thoroughly with detailed references in all the classics.<sup>4</sup>

#### **The findings of clinical study are discussed shortly as follows**

Starting from the etiology of this disease we found that the major etiological factors which leads to this disease were *sheet Guna Sevana* i.e. excessive work in cold water, air conditioned offices, food preserved in refrigerators, cold drinks, kind of work i.e. housewives doing excessive domestic work, tailoring job, clerical job, increased traveling, sitting in front of computers, irregular dietary habits etc. physical as well as mental stress & strain causing vitiation of *Vata dosha*. Thus, all these play an important role in the generation of this disease.

#### **Demographic details of these patients suggests the following things**

**Age-** Age wise distribution showed that the maximum no. of patients i.e. 15 patients (50%) were from age group 40-49 yrs followed by 7 patients (23.33%) were of age group 50-60 yrs. This is because of in this age *Vata Dosha* in the body is very dominant giving rise to degenerative changes in

joints. From this we can conclude that there is increasing incidence of this disease in early forties as a result of speedy & changes in life style.

**Sex-** There was 18 female patients & 12 male patients. This is because the kind of work they doing i.e. domestic work, *sheet sevana* & also were in post menopausal age group.

**Occupation-** The incidence of this disease was seen higher in housewives i.e. 12 pts (40%). This may be due to their physical work, cleaning work in cold water, standing work in kitchen platforms, sweeping, bending kind of work. Next group i.e. 06 pts, because of their clerical job, sitting & working on computers, uncomfortable positions in chairs. Tailors also included due to their tailoring job etc.

**Addiction-** Maximum no. of patients was addicted to tea i.e.15 patients (50%) out of which maximum were housewives. So this data is not significant for any definite conclusion. Thus we can say that addiction does not play any important role in genesis of disease.

**Clinical efficacy of PLG:** In this trial, all the 30 patients were presented with the symptom *Manya Shoola*. The percentage of relief for *Manya Shoola* proved to be 50%. *Manya Graha* improved by 46.66%. The trial drug gave 43.33% relief in *Bhrama*. Percentage of relief in *Mansabala Kshaya* was 46.66%. Thus the drug proved beneficial in all the symptoms of *Manyagata Vata*.

**Results of Drug: - (PLG):** After completion of 8 weeks of trial, 2 patients (6.66%) had got relief in their signs & symptoms while 4 patients (13.34%) were cured i.e. 75% relief. Next to it 46.67% i.e. 14 patients showed markedly improvement while 7 patients

(23.33%) showed improvement & 3 pts remained unchanged, had not got relief at all.

**Statistical Analysis of results of PLG:** The clinical symptoms which showed significant improvement excluding associated symptoms i.e. *Manya Shoola*, *Manya Graha*, *Bhrama*, *Mansabala Kshaya* were subjected to statistical evaluation. The statistical analysis reveals that there is highly significant improvement in symptoms i.e. *Manya Shoola* ( $P < 0.001$  at  $t_{29}$ ) along with this, other symptoms *Manya Shoola*, *Manya Graha*, *Bhrama*, *Mansabala Kshaya*, are also having highly significant improvement ( $P < 0.001$  at  $t_{29}$ ). In the light of these observations it can be stated that the drug PLG has shown excellent results in the disease *Manyagata Vata*. From these results it can be concluded that the PLG possesses highly potent *Vata shamana* action (*vedanashamak*-analgesic) hence alleviates *Vata Dosha* in *Dhatukshayajanya Vatavyadhi Manyagata Vata*.

**Probable mode of action of Drug:** *Chikitsa* means nothing but the treatment given to disintegrate or destroy the *Samprapti* or pathogenesis of the disease. Generally *Samprapti* is found in the genesis of the disease. *Manyagata Vata* is produced mainly due to *Vata* with *Agnimandya*, *Asthimajjavaha Strotodushti*, *Dhatukshaya* like symptoms with vitiation of *Vata Dosha* giving rise to symptoms *Manya Shoola*, *Manya Graha*, *Bhrama*, *Mansabala Kshaya* etc. For the disintegration of *Samprapti* of *Manyagata Vata*, the drug must possess some essential properties like *Vata Shamaka*, *Vata Dushtihara*, *Agnivardhaka*, *Dhatvagnivardhaka*, strengthen the joints, *Dhatuvaradhan* along with *Vedanashamak* & *Snehana* actions. The drug PLG is a combination of Various

*Bhasmas* including *Guggulu* processed in Mustard Oil. The constituents like *Abhraka Bhasma*<sup>7</sup>, *Rajata Bhasma*<sup>8</sup> are known as rejuvenators & provides strength to *Dhatu*. *Makshika Bhasma*<sup>9</sup> & *Lauha Bhasma*<sup>10</sup> improves *Jatharagni* whereas *Guggulu*<sup>11</sup> is especially acting on *Asthidhatwagni* as mentioned by *Bhavaprakasha* under term “*Bhagna Sandhanakrit* (helps in reunion of fractured bones)”. Oil helps in better absorption & penetration of the drug by its *tiksha* property.<sup>12</sup> Thus, PLG directly impacts on the etiology of *Manyagata Vata* & helps in the disintegration of the *Samprapti* & settles down the vitiated *Vata dosha*. In *Manyagata Vata Dhatukshaya rodhaka*, *Dhatuvaradhaka*, *Daurbalyanashaka chikitsa* was essential as *Mansa* & *Asthi dhatu kshaya* were found with generalized weakness in *dhatu*, *sandhis* etc. The all *Bhasmas* act as *Balya*, *Rasayan*, *Vayasthapak* which is very essential in geriatric prone disease like *Vatavyadhi* (Osteoarthritis).

In *Manyagata Vatavyadhi Vataprakopa*, *dhatukshinata*, *Dhatu rukshata*, *Parushata*, *Asthidhatukshaya* generally founds. The contents of PLG were mainly *Guru*, *Snigdha gunatmak*, *Madhur rasa*, *Madhur vipaki* & *Ushna viryatmak* in properties, which corrects the above-mentioned symptoms.

Thus the contents of PLG directly took part in the *Samprapti vighatan* by their individual properties of each & every drug & as a whole medicine.

## CONCLUSION

The results of clinical trials proved that PLG shown good results in treating *Manyagata Vata*. This study had been done within a short span of time, the sample size & duration of treatment was also not so big. Be-



sides this the drug was seen very effective. Another project including large sample size & longer duration will be required to clear its future role in *Manyagata Vata*.

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