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**Research Article****EVALUATION OF EFFICACY OF TRAYODASHANG GUGGULU IN MANAGEMENT OF CERVICAL SPONDYLOSIS (MANYAGATA VATA)**Rathod H. S.¹, Sawant R. S.^{2*}¹Lecturer, Dept. of Kayachikitsa, Dhanwantri Ayurvedic Medical College, Hospital and Research Centre, Nipani, Karnataka, India²Assistant Professor, Dept. of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Nanded, M.S. India

*Correspondence	Abstract
<p>Dr. R. S. Sawant, M.D (Ayu), Assistant Professor, Dept. of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Nanded, M.S. India</p> <p>DOI: 10.7897/2321-6328.01206</p> <p>Article Received on: 07/06/13 Accepted on: 11/08/13</p>	<p>Cervical spondylosis or Manyagata Vata is one of the most common diseases arising from change in life style, increased travelling on vehicles, continuous sitting and working on computers. Various single and compound herbal and 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. Such patients were recruited and treated with Trayodashang Guggulu (500 mg tds) for the period of 8 weeks. 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.</p> <p>Keywords: Cervical spondylosis, Manyagata Vata, Trayodashang Guggulu, Manya Shoola, Manya Graha</p>

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 and 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 and 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 and working on computers. Manyagata Vata 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 and 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) and Dhatukshaya (Degeneration).¹ 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 and Vayu Mahabhutas.² Prithvi is responsible for stability, solidity and 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 and 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 and Asthi)
- Manya Sandhi Sthana Dushti
- Vata Vriddhi
- Dhatukshaya

The treatment of Manyagata must include reduction of pain and 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 and compound herbal and 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 and also reduces inflammation). Trayodashang guggulu is mentioned in text Chakradatta for management of Vata Vyadhi which is a combination of 13 herbs viz. Aabha, Ashwgandha, Hapusha, Guduchi, Vrudhadaruk, Shatavari, Gokshur, Rasna, Shatapushpa, Karchoor, Ajawayan, Shunthi including Guggulu processed in Cow Ghee.³ An attempt was made to

evaluated efficacy of Trayodashang Guggulu to assess its effects in Manyagata Vata.

MATERIALS AND METHOD

Preparation of Trayodashang Guggulu

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 Trayodashang guggulu preparation.⁴

Table 1: Ingredients of Trayodashang Guggulu

Contents	Latin Name	Proportion
Aabha (Babbul)	<i>Acacia arabica</i>	1 part
Ashwagandha	<i>Withania Somnifera</i>	1 part
Hapusha	<i>Juniperus communis</i>	1 part
Guduchi	<i>Tinospora cordifolia</i>	1 part
Shatavari	<i>Asparagus recemosus</i>	1 part
Gokshur	<i>Tribulus terrestris</i>	1 part
Vridhdharu	<i>Argyria speciosa</i>	1 part
Rasna	<i>Pluchea lanceolata</i>	1 part
Shatapushpa	<i>Foeniculum valgare</i>	1 part
Karchur	<i>Curcuma zedoaria</i>	1 part
Yavani	<i>Trachhyspermum ammi</i>	1 part
Shunthi	<i>Zingiber officinale</i>	1 part
Guggulu	<i>Commiphora mukul</i>	13 parts
Ghee	Clarified butter	1/2 part

Method of Preparation

The above mentioned herbal drugs [Figure 1 and 2] are dried and made into fine powders separately. These drugs and purified guggulu put into the iron mortar and mixed well until homogenous mixture formed. While mixing above mentioned; ghee 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 GAC, Nanded, India. 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.

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 and female both.
- Patients having signs and 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 and symptoms of Vatavyadhi related to bones other than cervical vertebrae.
- The patients with signs and symptoms of lumber spondylosis, ankylosing spondylosis, R.A., T.B. spine, osteoarthritis of other joints etc.
- Patients suffering from systemic diseases like DM, HTN and cardiac diseases etc.

Diagnosis Criteria

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

Dose – 500 mg 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 and 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 Trayodashang guggulu was assessed mainly regarding the symptoms like Cervical pain (Manya Shoola), Siffness (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

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

Manya Graha

Absent	0
Felt occasionally on excess of work or in morning	1
Intermittently felt in morning and during work	2
Felt daily in morning and on doing work for 1 h	3
Felt daily in morning and on doing work for 15-20 minutes	4

Bhrama

Absent	0
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

Absent	0
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 and 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 2: Demographical Findings in Study Group

Demographic Parameters	No. of Patients (Total 30)	Percentage
Age		
20-29 yrs	02	6.66 %
30-39 yrs	06	20 %
40-49 yrs	15	50 %
50-60 yrs	07	23.33 %
Sex		
Male	12	40 %
Female	18	60 %
Addiction		
Tea	15	50 %
Tobacco	03	10 %
Smoking	03	10 %
Alcohol	06	20 %
No Addiction	03	10 %
Occupation		
Domestic work	12	40 %
Clerk	05	16.66 %
Sedentary	06	20 %
Tailor	04	13.33 %
Driver	01	03.33 %
Labor	02	6.66 %

Table 3: Symptom Wise Improvement in Manyagata Vata

Symptom	No. of Patients			Relief in %
	BT	AT	Relief	
Manya Shoola	30	15	15	50.00 %
Manya Graha	30	16	14	46.66 %
Bhrama	30	17	13	43.33 %
Mansabala Kshaya	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 and remained in 16 pts after treatment i.e. 14 pts got improvement and percentage of relief was 46.66 %. Bhrama, Mansabala Kshaya were initially present in all the 30 pts and after treatment the patient got relief i.e. 43.33 % (13 pts get relieved), 46.66 % (14 pts get relieved) respectively.

Table 4: Symptom Score Wise Improvement in Patients of Manyagata Vata

Symptom	Symptom Score			Relief in %
	BT	AT	Relief	
Manya Shoola	92	32	60	65.21 %
Manya Graha	47	21	26	55.31 %
Bhrama	36	19	17	47.22 %
Mansabala Kshaya	34	18	16	47.05 %

Out of 4 symptoms of Manyagata Vata taken into consideration, regarding Manya Shoola before treatment the score was 92 and 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 5: Total Relief of Trial Drug

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

Out of 30 patients of Manyagata Vata treated with Trayodashang Guggulu, 2 pts (6.66 %) got total relief in their signs and 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 6: Statistical Analysis of Symptoms of Manyagata Vata

Symptom	Mean			S.D.	S.E.	t ₂₉	p
	BT	AT	Diff.				
Manya Shoola	3.1	1.1	2	1.05	0.19	10.42	<0.001
Manya Graha	1.6	0.7	0.86	0.73	0.13	6.49	<0.001
Bhrama	1.2	0.6	0.56	0.5	0.09	6.15	<0.001
Mansabala Kshaya	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 and Std. Error 0.19 respectively. The 't' value worked out to be 10.42 at d_f 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_f 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 d_f 29 which gives $p < 0.001$ i.e. highly significant.

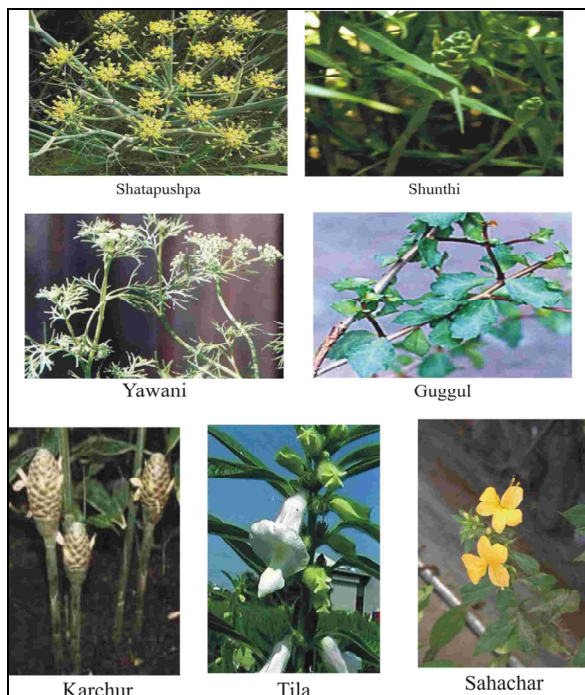


Figure 1: Ingredients of Trayodashang Guggulu

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_f 29 from which the probability worked out < 0.001 which is highly significant.



Figure 2: Ingredients of Trayodashang Guggulu

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 sthan in general is applicable to this Manyagata Vata as the vitiated Vata dosha is the main causative factor in this disease.⁵ Manya Shoola is the most prominent feature of this disease. The other signs and symptoms include Manya Graha, Bhrama, Mansabala Kshaya, etc. The incidence of this disease is increasing day by day due to speed and changes in life style, increased travelling, use of computers etc. Due to the pain in Manyagata Vata, daily routine work is efficiently hampered. Satisfactory relief from pain and 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 Trayodashang guggulu is the combination of 13 herbs mentioned in Chakradutta Vatavyadhi chikitsa. It has been thoroughly studied with separate literary study of each drug i.e. herb. Vata, Asthi, Sandhi and related organs are also studied thoroughly with detailed references in all the classics.³

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 and 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 and changes in life style.

Sex- There was 18 female patients and 12 male patients. This is because the kind of work they doing i.e. domestic work, sheet sevana and 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 and 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 Trayodashang Guggulu

In this trial, all the 30 patients were presented with the symptom Many Shoola. The percentage of relief for Many Shoola proved to be 50 %. Many 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 (Trayodashang Guggulu)

After completion of 8 weeks of trial, 2 patients (6.66 %) had got relief in their signs and 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 and 3 pts remained unchanged, had not got relief at all.

Statistical Analysis of results of Trayodashang Guggulu

The clinical symptoms which showed significant improvement excluding associated symptoms i.e. Many Shoola, Many Graha, Bhrama, Mansabala Kshaya were subjected to statistical evaluation. The statistical analysis reveals that there is highly significant improvement in symptoms i.e. Many Shoola ($P < 0.001$ at t_{29}) along with this, other symptoms Many Shoola, Many 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 Trayodashang Guggulu has shown excellent results in the disease Manyagata Vata. From these results it can be concluded that the Trayodashang Guggulu 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 Many Shoola, Many 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 and Snehana actions. The drug Trayodashanga Guggul is a combination of 13 herbs including Guggulu processed in ghee. The constituents like Shatavari, Ashwagandha, and Guduchi are known as rejuvenators and provides strength to Dhatus. Shunthi and Ajamoda improve Jatharagni whereas Babbul is especially

acting on Asthidhatwagni. Ghee with its yogavahi property helps in better absorption and penetration of the drug. Thus, Trayodashang guggulu directly impacts on the etiology of Manyagata Vata and helps in the disintegration of the Samprapti and settles down the vitiated Vata dosha. According to the Ayurvedic principles Agnimandya always creates anulom dhatukshaya and this ultimately produces Vatavyadhi. Being Vatavyadhi Agnimandya plays an important role in Manyagata Vata. Agnimandya was corrected by the Dipan- Pachan dravyas Shunthi, Ajawayan and Shatapushpa. They were also act as Vatanulomaka, Vatashamaka and Vedanasthapaka. In Manyagata Vata Dhatukshaya rodhaka, Dhatuvaradhaka, Daurbalyanashaka chikitsa was essential as Mansa and Asthi dhatu kshaya were found with generalized weakness in dhatu, sandhis etc. The drugs like Ashwagandha, Shatavari, Guduchi, Guggul, Vriddhadaru, Babbul, Hapusha and Goghrit were 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 Trayodashang Guggulu were mainly Guru, Snigdha gunatmak, Madhur rasa, Madhur vipaki and Ushna viryatmak in properties, which corrects the above-mentioned symptoms. Thus the contents of Trayodashang Guggulu directly took part in the Samprapti vighatan by their individual properties of each and every drug and as a whole medicine.

CONCLUSION

The results of clinical trials proved that Trayodashang Guggulu shown good results in treating Manyagata Vata. This study had been done within a short span of time, the sample size and duration of treatment was also not so big. Besides this the drug was seen very effective. Another project including large sample size and longer duration will be required to clear its future role in Manyagata Vata. This study was a sincere effort for bringing the drug stated by our Acharyas as 'Mahaushadi of Vatavyadhi' in limelight but the major part is still in dark light which the great challenge is. It needs to do further study on this drug to establish its analgesic action, Vatashaman action in other painful conditions. On this conclusion the dissertation itself ends but the quest for the betterment of the human beings never ends.

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