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A Comparative Efficacy Study of the *Panchtikta Ghrita Matra Vasti* and *Panchtikta Ghrita Marsha Nasya* in Cervical Spondylosis

Research Article

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Abstract

Introduction- Cervical Spondylosis is now becoming a significant threat to the working population due to its progressive nature of the disease. Modern science provides various types of medical and surgical therapies for Cervical Spondylosis but it is realized that more research is needed for the treatment of Cervical Spondylosis satisfactorily.Aim - To study the efficacy of *Panchtikta Ghrita Matra Vasti* and *Panchtikta Ghrita Marsha Nasya* in Cervical Spondylosis. Material & Method- Open randomized parallel comparative clinical study, Phase 2 trial. 30 patients were randomly equal number (n=15) recruited in the study in two groups. In Group A, patients were treated with *Panchtiktaghrita Matravasti*and in Group B with *Panchtiktaghrita Marsha Nasya.* Subjective criteria for the study was *Manya Shool* and *Manya Stambha* whether objective criteria were CBC, ESR and Neck disability index (NDI). Observation & Result- With respect to the blood investigation CBC and ESR was not found significant ($P<0.05$). Moreover, radiological changes in X-ray also not found significantly notable. NDI score was found better in both the groups, but mean score of NDI was suggestively improved in Group B (before 45.03, after 13.06) compare to Group A (before 46.26, after 23.06). Conclusion- Both the treatment modalities i.e. *Basti* and *Nasya* was effective in Cervical Spondylosis. *Panchtikta Ghrita Marsha Nasya* was given good results clinically in the patients compare to *Panchtikta Ghrita Matra Vasti*, but significant conclusion was not calculated with small sample data. So, large population research study is recommended for further research.

Key Words: *Panchatikta ghrit, Matra basti, Nasya, Cervical spondylosis.*

Introduction

Cervical Spondylosis is now becoming a significant threat to the working population due to its progressive nature of the disease. Modern science provides various types of medical and surgical therapies for Cervical Spondylosis but it is realized that more research is needed for the treatment of Cervical Spondylosis satisfactorily.

A healthy life has been cherished wish of man since ages, but now a day due to fast developing technological era, sedentary lifestyle and lack of time, people cannot concentrate on their proper regimens and facing so many hurdles. One such hurdle is Cervical Spondylosis (1). Occupational stress, poor posture in sitting or sleeping, day sleep, excessive travelling etc. lead to spondylitic changes in cervical spines.

Treatment is usually conservative in nature; Surgery is occasionally performed and taking long term treatment of modern medicine the chronic use of analgesic affects body badly (2).

Many of the treatment modalities for cervical spondylosis have not been subjected to rigorous, controlled trials. Surgery is advocated for cervical radiculopathy in patients who have intractable pain, progressive symptoms, or weakness that fails to improve with conservative therapy. Surgical indications for cervical spondylotic myelopathy remain somewhat controversial, but most clinicians recommend operative therapy over conservative therapy for moderate-to-severe myelopathy.

According to Ayurveda, *Manyasthambha* is correlated with Cervical spondylosis which is *Vatakapha* predominant disorder as it resides in *Kasherukagata sandhi* and *Majja*. So, *Vatahara* and *Brumhana Chikitsa* are advised in this entity by our Acharyas. *Charakacharya* described *Panchatikta Dravyas and Panchatikta Ksheer and Ghrita Basti in Asthyashrit Vyadhi* (3). In *Asthivaha Strotodushti Chikitsa Panchatikta Dravya Siddha Ksheer Basti and Sarpi* are mentioned and since all these are *Rasayana* for *Asthi Dhatu.* He had also mentioned the importance of *Sthanic Snehana, Swedana* and *Basti* in *Vatdosha Upkramass*.(4)

The *Nasya Karma* is also considered as the best and the most specific procedure for diseases of the head and neck- "*Urdhwa Jatru-Vikaresu*

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Visesannasyamisyate" (5). The rich vascular plexus of nasal cavity provides a direct route into blood stream for medications that easily cross mucus membrane. According to Acharya *Charaka*, Nose is the gateway of Shira (6). Same is stated by *Vagbhatta* the nasal passage is considered as the portals of the head "*Nasa hi Siraso Dwaram"* (7).

According to above concepts all drugs measures introduced through the nose spread throughout the head and its constituent parts and may accordingly influence all the *Doshas* and diseases situated in these parts (8). *Manya shoola lakshana* is explained as *Greevayah Paschatbhaga Shoola* (9). *Sushruta* had used the words *Manyagraha* and *Manyastambha* synonymously and described *Manyastambha* in *Urdhvajatrugata Vata nanatmaja vikara* (10) as *Manyaha kriyahani*. He described the involvement of *Kaphavruta Vata* in the pathogenesis of *Manyasthambha*(11). *Manyastambha* is told as *Vata kaphaja* even though it is included in *Vataja nanatmaja Vyadhi* according to *Sharangadhara* (12).

Bhavaprakasha, *Yogaratnakara*, *Sushruta Samhita*, *Bhaishajya Ratnavali* all advised the use of *Nasya* for its management. *Panchatikta Dravyas* i.e. *Guduchi* (*Tinospora cordifolia (Thunb.) Miers*), *Nimb* (*Azadirachta indica* A. Juss), *Vasa* (*Adhathoda vasica Nees.*), *Kanatakari* (*Solanum Xanthocarpum* Schard. Wendl), *Patol* (*Trichosanthes* dioica ROXB) involved in *Panchtikta Ghrita* preparation are *Rasayana for Asthidhatu. Charakacharya* described *Panchatikta Dravyas* in *Asthivaha Strotodushti Chikitsa in the form of Ksheerbasti and Sarpi* (13).

Rationale

In this period of modernization and fast life, people undergo many unwanted practices like improper sitting posture for long time in offices, continuous work in one posture and over exertion, load bearing movements during travelling and sports – all these factors create undue pressure and compressive injury to the spine and play an important role in producing disease like cervical spondylosis. Cervical spondylosis is a degenerative condition of the cervical spine where it may lead to Cervical spondylotic myelopathy (14).

Main symptoms are Pain & Stiffness in neck, radiating pain into arms, headache, vertigo, tingling sensation, numbness etc. It disturbs daily routine & overall life of patient.

This disease is now becoming a significant threat to the working population due to its progressive nature. Modern medical science provides various types of medical and surgical therapies but is seen that none of therapy is satisfactory in cervical Spondylosis. All treatment modules just provide symptomatic relief for short period of time. Hence Ayurveda now coming into focus for chronic types of conditions.

Here in initial stages of the disease *Kapha Dosha* involvement is present. The *Kapha* vitiation causes obstruction of *Vata*. Main factors involving in its pathogenesis are *Vata* (*Vyanavata*) and *Kapha* (*Shleshaka Kapha*). *Dushyas* occurring in it are *Asthi, majja, snayu, mamsa.* Hence, the drugs having *Vata Kaphahara* properties should be administered. They should have property to prevent the degeneration of bones and promote the regeneration. According to *Charakacharya*, *Basti* is prime treatment for *Vata* diseases (15). By taking into consideration all above facts, in this study use of Panchtikta ghrita(16) was used for *Vasti* and *Nasya* in patients having cervical spondylosis.

Specific objectives

- To study the effect of *Panchtikta Ghrita Matra Vasti* in Cervical spondylosis
- To study the effect of Panchtikta *Ghrita Marsha Nasya* in Cervical spondylosis
- To compare effects of the *Panchtikta Ghrita Matra Vasti* and *Panchtikta Ghrita Marsha Nasya* in Cervical Spondylosis

Methods

Trial design- Open randomized parallel comparative clinical study (Phase 2/3). 30 patients were randomly (n=15 in each group) recruited in the study in two groups. In group A, patients were treated with *Panchtikta Ghrita Matra Vasti* and in group B with *Panchtikta Ghrita Marsha Nasya.* Not a single change was done after trial commencement.

Participants

Eligibility criteria for participants:

Inclusion criteria - Patients of either sex with presenting classical symptoms of cervical spondylosis (17), X-ray suggesting cervical spondylosis (18) confirmed by qualified radiologist, Patients above 20 years and <60 years, Patient who can make neck extension up to 45-degree angle.

Exclusion Criteria - Age group below 20 years and above 60 years, Cervical Spondylosis with myelopathy and radiculopathy (ICD 10 criteria M47.8), Contraindication and previously treated with *Vasti therapy* (19), *Nasya Anarha* (20), *Matra Sneha Vasti Anarha*, Pregnant and lactating mothers, Recent cervical, spinal, or shoulder surgery or implanted instrumentation or previous surgery for cervical spondylotic myelopathy, Stenosis of the spinal canal, Patients suffering from any infectious disease (like tuberculosis), metabolic disease (like diabetes mellitus and hypothyroidism), or chronic diseases (such as rheumatoid arthritis, systematic lupus erythromatous and ankylosing spondylitis)

Settings and locations where the data were collected:

Concerned patients were selected from the *Panchakarma* OPD and IPD of MGACH & RC, Salod (H) with preset diagnostic criteria and who were willing to give informed consent.

Panchtikta Ghrita which is trail drug is supplied by Kamdhenu Panchgavya Govidnyana Anusandhana Kendra, Deolapar, Nagpur, Maharashtra where it was prepared as per *Snehapaka vidhi* mentioned by *Sharangdhara* in Sh. Sam. Madh. Kh. – ch.9.

Table 1: Intervention of *Panchatikta Ghrita* in both the groups

	Group A	Group B
Intervention	Panchtikta Ghrita Matra Vasti was administered after preparatory procedure	Administration of *Marsha Nasya* with lukewarm *Panchtikta Ghrita (Mrudu paka)* with the dose of 8 *Bindu* (approximate 4 ml) in each nostril one by one with the help of dropper at 8:30 am for 7 consecutive days (21).
Root of administration	Anal	Nasal
Dosage	60 ml per day for consecutive 7 days	8 drops (4 ml) in each nostril per day for consecutive 7 days
Duration of intervention	7 days	7 days
Follow up Period:	21 days	21 days
Total Study duration	28 days	28 days

Outcomes

Primary outcome of this trial was to compare efficacy of *Panchtikta Ghrit Marsha Nasya* and *Panchtikta Ghrit Matra Basti* in *Manya Stambha* (Spondylosis) in terms of relief in symptoms of Cervical Spondylosis and Improvement(reduction) in Neck Disability Index (NDI) score & Secondary outcome was to find out radiological changes in cervical spondylosis in both groups. Assessment of the patients was done before intervention, just after completion of interventions (on 8th day) and on the follow up day i.e. 21th day as follows.

7.1 Subjective Parameters:

1) *Manya shoola* (Pain in cervical region):
- 0=No Pain
- 1=Pain in neck only after neck movements
- 2=Continuous pain in neck which further worsen after neck movements
- 3= Continuous Pain in neck and it radiates towards either upper limb and disturbed the sleep

2) *Manya sthambha* (Stiffness in Cervical region):
- 0=No Stiffness,
- 1=Stiffness up to 1 hour
- 2=Stiffness up to 2-3 hours
- 3=Stiffness up to more than 4-6 hours

Objective Parameters:

Neck disability Index:

It is a questionnaire used to find out the level of disability of neck before and after treatment. It consists 10 questions such as pain intensity, personal care (like washing dressing), lifting, reading, headache, concentration, work, driving, sleeping, recreation, etc., each having 6 questions (0-5 points). This index was assessed before the day of intervention, just after completion of interventions (on 8th day) and on the follow up day i.e. 21st day as follows.

X-ray cervical spines (Anteroposterior and lateral view):

Degenerative changes of Cervical spondylosis with mark reduction in cervical spines was assessed through X-ray Cervical regions (AP & Lateral view) before intervention and on the follow up visit i.e. on 21st day.

Sample size: Total 30 patient were recruited in the study, 15 patients per group.

Randomization/ Sequence generation: Randomization was done by simple lottery method

Implementation- Maintenance of sequence of random allocation, enrollment of patients and assignment of intervention to patients was done by principal investigator.

Statistical methods

Statistical methods used to compare groups for primary and secondary outcomes. The data obtained in clinical study was subjected to statistical tests paired, unpaired t-test (software sigma stat version 0.2) and analyzed in two parts as; the subjective criteria were assessed before treatment (V1), after treatment(V2), after 14 days (at follow up –V3) by the Wilcoxon signed Rank test. Neck disability index was also assessed on same visits with Paired & unpaired t-test (for comparison before &after treatment in same group & to compare between group respectively) using Graph pad prism software version 7.0 version. P value < 0.05 was considered significant. Radiological findings of X-ray were assessed before starting treatment and on 28th day of study.

All patients were instructed to take analgesic according to their choice if pain was aggravated during trial & If there was further or any complication such as tingling or vertigo arises then such patient will be allowed to undergo physiotherapy. But there were no such incidences occur for any patient.

Results

30 patients recruited in this clinical trial (15 in each group), all patients received intended treatment for allotted duration and were analyzed for the primary & secondary outcomes. No patient was drop out from the study and no any adverse event was noted. From the collected data from all 30 patients registered in this trial reflected that there was maximum patients 20 (66.66%) were from age group 40-50, 18 patients (60%) were females & from urban population, 25 (83.33%) were had sedentary job,20 patients (67%) were Hindus, 11 patients (37%) were patients suffered from disturbed sleep, 16 patients (55%) had disturbed bowel habit & 21 patients (78%) were of *vatapradhan pittanubandhi prakruti*.

Assessment of the total effect of the therapy

Table 2: Showing Statistical analysis of effect of both interventions on *Manyashoola* (Pain in cervical region)

Manya shoola	Before t/t	After t/t	Follow Up Period
Group A			
Grade 0	0(0%)	13(70%)	10(66.66%)
Grade 1	0(0%)	2(30%)	5(33.33%)
Grade 2	3(20%)	0(0%)	0(0%)
Grade 3	8(53.3%)	0(0%)	0(0%)
Grade 4	4(26.7%)	0(0%)	0(0%)
Fisher Exact	-	3.600	3.733
p-value	-	<0.001, S	<0.001, S
Group B			
Grade 0	0(0%)	11(80%)	15(100%)
Grade 1	0(0%)	4(20%)	0(0%)
Grade 2	6(40%)	0(0%)	0(0%)
Grade 3	6(40%)	0(0%)	0(0%)
Grade 4	3(20%)	0(0%)	0(0%)
χ2-value	-	2.933	3.333
p-value	-	<0.001, S	<0.001, S
Comparison between Group A and Group B			
Fisher Exact	2.39	2.400	2.333
p-value	0.30, NS	0.011, S	0.026, S

*S- Significant, NS- Not Significant

Inference:

From above table and graph, it reflects that in Group A, there were 3, 8 and 4 patients had *Manyashoola* having Grade 2, 3 and 4 respectively. While in Group B, there were 6, 6 and 3 patients with *Manyashoola* having Grade 2, 3 and 4 respectively. From the observation, it is clear that in Group A, the maximum number of patients with *Manyashoola* having Grade 3. However, in Group B, there were maximum patients with *Manyashoola* having Grade 2 and 3. In group A,70 % patients got relief just after intervention & 80% persons got relief after intervention in group B.

The non significant Chi-square value (2.39) and P value (P= 0.30) while comparison between Group A and Group B before treatment, it shows that there was uniform distribution.

On comparing just after intervention between Group A and Group B, significant Fisher Exact value (2.40) and P value (P= 0.011) shows that there is significance between two groups, that means *Marsh Nasya* with *Panchtikta Ghrita* is more effective than Matra Vasti with *Panchtikta Ghrita* to reduce the symptom of *Manya shoola*.

In Follow up visit, though there was significant relief in *Shirashoola* after intervention in each group, but after comparison between two groups, the significant Fisher Exact value (2.33) and P value (P= 0.026) shows that comparative more effect of Marsh Nasya with *Panchtikta Ghrita* than the effect of *Matra Vasti* with *Panchtikta Ghrita* even after 21 days also.

Table 3: Showing Statistical analysis of effect of both interventions on *Manyasthambha* (Stiffness in Cervical region)

Manya Sthambha	Before t/t	After t/t	Follow Up Period
Group A			
Grade 0	0(0%)	12(80%)	15(100%)
Grade 1	0(0%)	3(20%)	0(0%)
Grade 2	2(13.3%)	0(0%)	0(0%)
Grade 3	8(53.3%)	0(0%)	0(0%)
Grade 4	5(33.3%)	0(0%)	0(0%)
Fisher Exact	-	3.333	3.600
p-value	-	<0.001, S	<0.001, S
Group B			
Grade 0	1(6.7%)	14(90%)	15(100%)
Grade 1	0(0%)	1(10%)	0(0%)
Grade 2	5(33.3%)	0(0%)	0(0%)
Grade 3	7(46.7%)	0(0%)	0(0%)
Grade 4	2(13.3%)	0(0%)	0(0%)
Fisher Exact	-	3.733	3.933
p-value	-	<0.001	<0.001
Comparison between Group A and Group B			
Fisher Exact	3.63	2.50	2.40
p-value	0.30, NS	0.021, S	0.103, NS

*S- Significant, NS- Not Significant

Inference:

From above table and graph, it reflects that in Group A, there were 2, 8 and 5 patients had *Manyasthambha* having Grade 2, 3 and 4 respectively. While in Group B, there were 1, 5, 7 and 4 patients with *Manyasthambha* having Grade 0, 2, 3 and 4 respectively. From the observation, it was clear that in both groups, the maximum number of patients with *Manyasthambha* having Grade 3.

From the above table, it again reflects that there were 6, 6 and 3 patients with *Manyasthambha* in Group A having Grade 1, 2 and 3 respectively which shows that after *Matra Vasti with Panchtikta Ghrita*, there were 80% patients got relief from *Manyasthambha*. This means after intervention in control group, the intensity of *Manyasthambha* was reduced significantly. In the follow up visit of same group, the effect was going on and total number of patients got relief from Manyasthambha.

From the above table, it again reflects that there were 1, 8, 5 and 1 patient with *Manyasthambha* in Group B having Grade 0, 1, 2 and 3 respectively. After *Marsh Nasya with Panchtikta Ghrita* there were 90 % patients got relief from *Manyasthambha.* This means after intervention in trial group, the severity of *Manyasthambha* was reduced significantly. In the follow up visit of same group, the effect was going on and there was not a single patient with *Manyasthambha* and there was no recurrence.

The non-significant Fisher Exact value (3.63) and P value (P= 0.30) while comparison between Group A and Group B before treatment shows that there was uniform distribution.

On comparing just after intervention between Group A and Group B, the significant Fisher Exact value (2.50) and P value (P= 0.021) shows that there was significant difference between two groups, that means *Marsh Nasya with Panchtikta Ghrita* was more

effective than group A to reduce the symptom of *Manyasthambha*.

In Follow up visit, though there was significant relief in *Manyasthambha* after intervention in each group and after comparison between two groups, the non-significant Fisher Exact value (2.40) and P value (P= 0.103) shows that group with *Marsh Nasya with Panchtikta Ghrita* was as effect as that of group A for relief in Manya Sthmbha after 21 days.

Table 4: Calculation of Neck Disability Index (NDI) score before and after the treatment in both groups

	Group A			Group B	
SN	**Before**	**After**	SN	**Before**	**After**
1	23	13	1	23	4
2	24	13	2	24	8
3	21	12	3	23	11
4	24	14	4	22	11
5	23	12	5	24	11
6	21	11	6	22	4
7	23	12	7	23	4
8	22	11	8	24	10
9	22	8	9	24	4
10	23	11	10	20	4
11	21	11	11	22	8
12	23	13	12	19	1
13	22	12	13	23	4
14	21	8	14	22	4
15	22	10	15	23	10
NDI	46.26	23.06	**NDI**	45.06	13.06

Table 5: Statistical analysis of NDI score in both the groups

NDI score before treatment in both Groups						
Group	N	Median	25%	75%	T Value	P Value
A	15	22	21.25	23	212	0.418
B	15	23	22	23.75		
Before & After the treatment NDI score in Group A						
Treatment	N	Median	25%	75%	T Value	P Value
Before TT	15	22	21.25	23	-120.000	<0.001, S
After TT	15	12	11	12.75		
Before & After the treatment NDI score in Group B						
Treatment	N	Mean	Std Dev	SEM	T Value	P Value
Before TT	15	22.533	1.457	0.376	20.992	<0.001, S
After TT	15	6.533	3.42	0.883		
NDI score after treatment in both Groups						
Group	N	Median	25%	75%	T Value	P Value
A	15	12	11	12.75	323	<0.001, S
B	15	4	4	10		

*S- Significant, NS- Not Significant

The neck disability index was found significant in both the groups. However, more significant in group B.

There was no restriction of food or regimen while administering *Matra Basti*; it can be administered continuously in all seasons. Unlike *Anuvasana* Basti, *Matrabasti* can be administered to *Bala*, *Vriddha* and in *Alpagni* conditions. There is no *Pariharakala* for this type of *Basti*. There were not a single excluded or withdrawn from the study after randomization.

Recruitment: Total duration of intervention was 7 days which was followed by visit after 14 days i.e. on the 21st day.

Outcomes and estimation

The symptoms were Cervical spondylosis was significantly reduced after interventions in both groups and this relief in symptoms was persisted even on the follow up visit also in both groups. NDI score was found better in both the groups, but mean score of NDI was suggestively improved in Group B (before 45.03, after 13.06) compare to Group A (before 46.26, after 23.06) .But there was no significant changes in radiological findings even just after interventions and on follow up visit (P<0.05). Though there was significant relief in symptoms of Cervical spondylosis as well as significant reduction in Neck disability index in both groups. However, both these positive findings were significantly more in Group B i.e. Marsh Nasya with Panchtikta Ghrita.

Table 6: Observations of Hematological parameters in Group A (Matra Vasti treatment)

Parameter	Treatment Name	N	Mean	Std Dev	SEM	T value	P value
HB%	BT	15	12.567	1.607	0.415	0.786	0.445
	AT	15	12.387	1.603	0.414		
	Difference	15	0.18	0.887	0.229		
TLC	BT	15	6226.667	1084.611	280.045	-0.579	0.572
	AT	15	6440	1501.808	387.765		
	Difference	15	-213.333	1427.719	368.635		
N	BT	15	56.8	6.603	1.705	-2.219	0.043
	AT	15	59.867	6.278	1.621		
	Difference	15	-3.067	5.351	1.382		
L	BT	15	37.6	6.045	1.561	0.935	0.366
	AT	15	36.267	5.97	1.541		
	Difference	15	1.333	5.525	1.427		
Total RBC	BT	15	4.753	0.691	0.178	-0.783	0.447
	AT	15	4.803	0.672	0.174		
	Difference	15	-0.0507	0.251	0.0647		
T. Platelet	BT	15	260733.3	96703.87	24968.83	-0.217	0.831
	AT	15	262466.7	90590.02	23390.24		
	Difference	15	-1733.33	30918.02	7982.998		
ESR	BT	15	29	22.656	5.85	2.098	0.055
	AT	15	24.067	19.998	5.163		
	Difference	15	4.933	9.106	2.351		
MCH	BT	15	25.9	5.487	1.417	0.301	0.768
	AT	15	25.8	5.343	1.38		
	Difference	15	0.1	1.286	0.332		

Table 7: Observations of Hematological parameters in Group B (Marsh Nasya treatment)

Parameter	Treatment Name	N	Mean	Std Dev	SEM	T value	P value
HB%	BT	15	13.313	2.14	0.552	-0.289	0.777
	AT	15	13.373	1.921	0.496		
	Difference	15	-0.06	0.805	0.208		
TLC	BT	15	6800	1424.781	367.877	0.466	0.648
	AT	15	6633.333	1468.073	379.055		
	Difference	15	166.667	1384.437	357.46		
N	BT	15	58.533	6.046	1.561	-1.208	0.247
	AT	15	61.4	8.007	2.067		
	Difference	15	-2.867	9.187	2.372		
L	BT	15	34.467	5.317	1.373	0.787	0.444
	AT	15	32.8	7.58	1.957		
	Difference	15	1.667	8.2	2.117		
B	BT	15	3.4	2.501	0.646	0.000	1.000
	AT	15	3.4	1.882	0.486		
	Difference	15	0	2.591	0.669		
E	BT	15	3.267	2.282	0.589	0.837	0.417
	AT	15	2.933	1.668	0.431		
	Difference	15	0.333	1.543	0.398		
Total RBC	BT	15	4.611	0.676	0.175	-0.235	0.817
	AT	15	4.625	0.688	0.178		
	Difference	15	-0.014	0.23	0.0595		
ESR	BT	15	27	20.231	5.224	0.137	0.893
	AT	15	26.533	22.627	5.842		
	Difference	15	0.467	13.228	3.415		

MVC	BT	15	89.047	8.641	2.231	-1.237	0.236
	AT	15	90	7.819	2.019		
	Difference	15	-0.953	2.984	0.77		
MCHC	BT	15	32.567	1.375	0.355	0.216	0.832
	AT	15	32.459	2.074	0.536		
	Difference	15	0.107	1.925	0.497		

Table 8: Observations of Hematological parameters in Group A (Basti) & Group B (Nasya) before treatment

Parameter	Treatment Name	N	Mean	Std Dev	SEM	T value	P value
HB%	Group A	15	12.567	1.607	0.415	-1.081	0.289
	Group B	15	13.313	2.14	0.552		
TLC	Group A	15	6226.667	1084.611	280.045	-1.240	0.225
	Group B	15	6800	1424.781	367.877		
N	Group A	15	6226.667	1084.611	280.045	-0.750	0.460
	Group B	15	6800	1424.781	367.877		
L	Group A	15	37.6	6.045	1.561	1.507	0.143
	Group B	15	34.467	5.317	1.373		
Total RBC	Group A	15	4.753	0.691	0.178	0.569	0.574
	Group B	15	4.611	0.676	0.175		
MCH	Group A	15	25.9	5.487	1.417	-1.869	0.072
	Group B	15	29.013	3.396	0.877		
MCHC	Group A	15	32.44	2.224	0.574	-0.188	0.853
	Group B	15	32.567	1.375	0.355		

Table 9: Observations of Hematological parameters in Group A (Basti) & Group B (Nasya) after treatment

Parameter	Treatment Name	N	Mean	Std Dev	SEM	T value	P value
HB%	Group A	15	12.387	1.603	0.414	-1.527	0.138
	Group B	15	13.313	2.14	0.552		
N	Group A	15	59.867	6.278	1.621	-0.584	0.564
	Group B	15	61.4	8.007	2.067		
L	Group A	15	36.267	5.97	1.541	1.392	0.175
	Group B	15	32.8	7.58	1.957		
Total RBC	Group A	15	4.803	0.672	0.174	0.719	0.478
	Group B	15	4.625	0.688	0.178		
MCV	Group A	15	77.067	11.56	2.985	-3.589	0.001
	Group B	15	90	7.819	2.019		
MCH	Group A	15	25.8	5.343	1.38	-2.151	0.040
	Group B	15	29.167	2.86	0.739		
MCHC	Group A	15	33.113	2.658	0.686	0.751	0.459
	Group B	15	32.459	2.074	0.536		
ESR	Group A	15	18	9	45	226.500	0.820
	Group B	15	25	8.25	33.75		

There was not significant difference found in hematological parameters and all the hematological values found normal during both the intervention.

ESR was decreased insignificantly just after interventions in both the groups. But there was no statistically significant difference seen between the groups. (*p<0.05)

Overall effect of therapy with Subjective Criteria:

Table 10: Assessment on the basis of relief in subjective criteria

	Range	Group A	Group B	Total
Controlled	100%	0(0%)	0(0%)	0(0%)
Marked Relief	≥75%	12(80%)	13(86.67%)	25(83.33%)
Moderate Relief	≥50-74%	3(20%)	2(13.33%)	5(16.67%)
Mild Relief	≥25-49%	0(0%)	0(0%)	0(0%)
No Relief	<25%	0(0%)	0(0%)	0(0%)

From the above table, it reflects that when both groups responses were summarized, the patients got marked relief were 12 (80%) and 13 (86.67%) from Group A and B respectively. There were 3 (20%) and 2 (13.33%) patients who got moderate relief from Group A and B respectively.

Harms

No any types of adverse event were noted in both groups during this trial which shows the safety nature of both interventions.

Discussion

Probable Mode of action of Panchatikta Ghrita

As cervical spondylosis is *Asthi majja pradoshaja Vikara* as per description of Acharya Charaka that *Basti* with *Sarpi* medicated with *Panchtikta dravya* is more beneficial in such entities. *Matrabasti* is one of the types of *Snehabasti* which does *snehana* as a first line of treatment in *Sandhigata vata* told by *Acharya Sushruta*. As *Goghrita* is *Vatapittahara* and when it is medicated with *Panchtikta dravya* it becomes *Tridoshahara*. The ingredients of the *Panchtikta Ghrita* is chiefly having *Vedanasthapana / Shoolaprashamana* effect (*Guduchi, Nimba, Vasa, Kantakari, ksheerasarpi*) *Shothahara* (*Nimba, Vasa, Kantakari*) *Vatahara* (Patola, Kantakari, Ksheerasarpi) *Balya/Bhrimana* (*Guduchi, Nimba, Patola, ksheerasarpi*) *Rasayana* effect (*Guduchi, Nimba, Vasa, Ksheerasarpi*). The *Ghrita* is nullifies the effect of *Rukshata* and *Laghuta* of *Tikta rasa* retaining the *Kharatva*, which is absolutely helpful to correct the *Asthi Dhatu* which then corrects the disease progress (21).

Ghrita is *Vata-pittashamaka, Balya, Agnivardhaka, Madhura, Saumya, Sheeta Virya, Shula, Jwarahara, Vrishya and Vayasthapaka* also. Thus, it pacifies the *Vata*, improve the general condition of the body and acts as a rejuvenator of the body. Thus, helps in the *Samprapti Vighatana* of the *Manyasthmbha*. As well it is having property like *Yogavahi* which is helpful in increase bio-availability of other drugs without losing its own property. It also contains vitamin D which plays an important role to utilize calcium and phosphorous in blood and bone building. In addition to above antioxidant properties of *Ghrita*, it prevents the oxidative damage of various tissues & thus provides protection from various degenerative conditions (22).

As *Panchtikta Ghrita* is main medication in both groups nourishes the nerves due to its *Snigdha* property. As it is a type of ketogenic diet and prevents stiffness of the nerves, muscles in regions of neck, shoulders and arms which ultimately results in significant reduction in Stiffness &Pain. Consistency in relief even after stoppage of procedures in both groups & significant reduction in severity of symptoms as well as reduction in neck disability shows that *Panchtikta Ghrita* is anti-inflammatory in nature, it may reduce or checks over further degenerative changes of the cervical spines due to its *Bruhana* nature also (23).

Probable mode of action of Matra Vasti

Matravasti with *Panchtikta Ghrita* is helpful to induce *Anulomana* of the vitiated *Vata Dosha* which is responsible for Pain i.e. *Manyashoola*. Dalhana says that *Pureeshadhara Kala* and *Asthidhara Kala* are one and the same. So, we can assume that if we administer drug to the rectum (*Pureeshadhara Kala*); the *Asthivaha Srotas* also get nurtured (24).

Probable mode of action of Nasya

Nasya therapy is considered as best therapy for the diseases or pathologies lying above the clavicle (25). As nose is gateway of brain as per *Acharya Vagbhata* and all medications administered to nasal orifice, it gets passed to brain & reaches to the surrounding areas of head & neck, after that it affects over various *Dosha* in those areas and checks over pathologies situated in particular region (26).

In the present study maximum patients were females & incidence rate of cervical spondylosis is more in female which is supported by Ali M. Alsham et .al.2015 stating that Cervical spondylosis is common (~30%) in the >30 age groups & prevalence of it is more in women (7.8% and 76.2%) than in men (73.9% and 3.3%) (27).

Insignificant result in radiological improvement in Cervical X -ray spines was found due to due to minimum duration of intervention and study. As both interventions in two groups in current clinical study was given for only 7 days for sample size. As minimum 21 days are required to reach medicine through *Rasa dhatu* to *Asthi dhatu* which is assessed through X-ray cervical spines (28).

Statistically reduction in ESR in both the groups just after interventions reflects the anti-inflammatory action of *Panchtikta Ghrita* since there is no significant difference between both the groups.

More significant effect found in Group B may be due to additional local massage & sudation therapies over face, neck & shoulder which was done as a preprocedural of *Marsh Nasya* & which ultimately improve blood circulation in local area, which provides greater nourishment to this part. Both these therapies alleviate the *Rukshata* & *Sthmabha* induced due to *Vata* & *Kapha Prakopa*. Local *Swedana* therapy with *Nirgundi qwatha* over cervical region may helpful to relieve pain, which decreases the intensity of *Manyashoola* due to its *Vata-Kapha hara* properties (29).

Simultaneously *Dhoomapana* with *Haridra* was also given to all patients recruited in group B for 7 days as a part of post-procedure protocol of *Nasya* therapy. Likewise, it may be helpful to pacify *Kapha Dosha* in Cervical region.

Generalizability

From this clinical trial, considering the significant effectiveness of both interventions in patients with Cervical spondylosis, further multicentric study can be planned with large sample size. Duration of both interventions can be increased by 14 to 21 days for perusal the significant changes in Radiological investigation i.e. X Ray cervical spine.

Interpretation

Both groups have given a highly significant improvement in reducing symptoms of cervical spondylosis & reduction in Neck disability index. While comparing between two groups, it was also statistically proved that *Nasya* with *Panchtikta Ghrita* is more effective *than Matra Vasti* with *Panchtikta Ghrita* in

reducing symptoms of cervical spondylosis & improvement in NDI scale. Both interventions are proved as safe i.e. without causing any undue effects.

Though rectal route of drug administration is more effective than other routes, however, many conditions such as anal fissure or piles, proctitis are certain contraindications for this type of therapy i.e. this principle is exactly applicable for *Matra Vasti* also. Many times, especially female patients are more reluctant to undergo such type of anal root therapy. In such cases, *Nasya* therapy will be the alternative option for the patients. In addition to above, *Nasya* therapy is quite cost effective than that of *Matra Vasti* as it requires comparative less amount of drug as well as dietic restrictions, only lifestyle modification advised during *Nasya* therapy is quite easy to follow in comparison with *Matra Vasti*. Duration of such restrictions are also less as compared to that of *Matra Vasti*. Because in *Matra Basti,* restrictions should be double the duration of intervention of therapy.

Conclusion

With reference to all findings it is concluded that in Group B, intervention with *Marsh Nasya* with *Panchtikta Ghrita* is more effective to reduce the severity of symptoms of Cervical spondylosis as well as effective in reducing neck disability index than that of Group A, intervention of *Matra Vasti* with *Panchtikta Ghrita*.

Registration: Registration number and name of trial registry-
Ethical clearance number: DMIMS (DU)/IEC/ June-2017-18/6991
Registration in Clinical trial registry of India (CTRI): CTRI/2019/10/021748

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Conflict of Interest

No conflict of interest

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