

Title :	A comparative efficacy study of the Panchtikta Ghrita and Go Ghrita (Placebo) Nasya in Manyasthambha (Cervical Spondylosis)	
1]	Introduction:	
a]	<p>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 Manyasthambha. Manyastambha can be co-related with Cervical Spondylosis in modern perspective [1]. Occupational stress, poor posture in sitting or sleeping, day sleep, excessive travelling etc. lead to spondylotic changes in cervical spine.</p> <p>Treatment is usually conservative in nature; Surgery is occasionally performed. 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.</p> <p>The <i>Nasya Karma</i> is considered as the best and the most specific procedure for diseases of the head and neck- “<i>Urdhwa Jatru-Vikaresu Visesannasyamisyate</i>”[2]. 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, Nasa is the gateway of Shira[3]. Same is stated by <i>Vagbhatta</i> the nasal passage is considered as the portals of the head “<i>Nasa hi Siraso Dwaram</i>”[4]. 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 <i>Doshas</i> and diseases situated in these parts[5].</p>	
	Need for study:	
	<p>This disease is now becoming a significant threat to the working population due to its progressive nature. Modern medical science provide various types of medical and surgical therapies but is seen that none of therapy is satisfactory in cervical Spondylosis. All treatment module just provide symptomatic relief for short period of time. Hence Ayurveda now coming into focus for chronic types of conditions.</p>	
b]	Literary Review:	
	<p>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</p>	

overexertion, 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 spondylosis Myelopathy[6]. 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.

Manya shoola laxana is explained as Greevayah Paschatbhaga Shoola[7].Sushruta has used the words Manyagraha and Manyastambha synonymously and described Manyastambha (Urdhvajatrugata Vata nanatmaja vikara)[8] as Manyaha kriyahani. He told involvement of Kaphavruta Vata in the pathogenesis of Manyastambha[9].Manyastambha is told as *Vata kaphaja* even though it is included in Vataja nanatmaja Vyadhi according to Sharangadhara[10]. Bhava Prakasha, Yoga Ratnakara, SushrutaSamhita, Bhaishajya Ratnavali all advised use of nasya karma for its management.

Here in initial stages of the disease Kapha Dosha involvement is present. The Kapha prakopa nidanas causes kapha prakopa which 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.

By taking into consideration all above facts, in this study use of Panchtikta ghrita[11] will be used for nasya in patients having cervical spondylosis.

Panchatikta Dravyas involved in Panchtikta ghrita preparation are *Rasayana for Asthidhatu*. Charakacharya described *Panchatikta Dravyas* in *Asthivaha Strotodushti Chikitsa in the form of Ksheerbasti and Sarpi*[12].

S.N.	Ingredient	Pharmacological Action
1	Guduchi	Tinospora cordifolia
2	Nimb	Azadirachta indica
3	Vasa	Adhatoda Vasica
4	Kanatakari	Solanum xanthospermum
5	Patol	Trichosanthes patola

All drugs in Panchatikta ghrita having Tikta rasa and Ushnavirya which facilitate dhatvagni, nutrition and stableness of all dhatus. It helps in improvement of general condition, also act as anti-inflammatory agent. Yogvahiguna of ghrita increase bioavailability of other drugs, so

	<p>degeneration may not occur rapidly. It does dhatuposhana due to Tikta rasa & ushnavirya help in pacification of aggravated vata.</p> <p>They rejuvenate the <i>Dhatus</i>, repair them, remove <i>Kha Vaigunya</i>, give <i>Bala</i> (strength) to the <i>Dhatu</i>, maintain their healthy condition and restricts/slow down the progress of disease[13].</p>	
c]	Previous work done:	
	<ul style="list-style-type: none"> • A clinical study on the development of subtype of Abhyanga with reference to its role in the management of Griva-hundana (cervical spondylosis). By-Dr. Kalapi Patel Department of Panchkarma I.P.G.T. & R.A.Gujarat Ayurved University, Jamnagar. • Effect of <i>Tikta Kshira Basti</i> and <i>Patrapinda Sweda</i> In The Management Of Cervical Spondylosis (<i>Asthigata Vata</i>). By- Dr. Jayadipkumar P. Shah Department Of Panchkarma, I.P.G.T. & R.A. Gujarat Ayurved University, Jamnagar. • In 1992, S. Hebbar from G.A.M.C. Mysore worked on Manyasthamba with special reference to its management by Nasya. • In 2006, Ashwin Dev from DGMAMC Gadag worked on management of Manyasthamba by Rookshasweda and Nasya. <p>In 2009, Mukta Hiremath from DGMAMC Gadag worked on evaluation of the comparative efficacy of Greeva basti and Nasya karma with Karpasthyadi taila in Manyasthamba.</p>	
2]	Aim and Objectives:	
2a]	Aim of study:	To study effect of nasya with Panchtikta ghrita and ghrita in Manyashoola and manyagraha in Cervical spondylosis
2b]	Objectives of study:	
	<ol style="list-style-type: none"> 1. To study the effect of nasya with Panchtikta ghrita Manyashoola and manyagraha in Cervical spondylosis 2. To study the effect of nasya with goghrita in Manyashoola and manyagraha in Cervical spondylosis 3. To Compare the effect of nasya with Panchtikta ghrita and goghrita in Manyashoola and manyagraha of Cervical spondylosis 4. Pain management with nasya 	
3]	Material And Methods:	The informed consent of the participants will also be obtained before participation in the study.
3a]	Source of study:	The study area will be Mahatma Gandhi Ayurvedic College, Hospital and Research Centre. Salod (H), Wardha

3b]	Study Design:	Randomized parallel Comparative Clinical study		
3c]	Study Type:	Interventional		
	Phase of Study:	Phase 1 / Phase 2		
3d]	Sample size:	30 patients		
3e]	Grouping: 2 groups	Group A – 15 Patient (Panchtikta ghrita Nasya) Group B - 15 Patient (Goghrita Nasya [Placebo])		
3f]	Inclusion criteria:	<ul style="list-style-type: none"> • Age group above 20 years and below 60 years • Manyasthambha Signs and symptoms • Cervical spondylosis-signs & symptoms 		
3g]	Exclusion criteria:	<ul style="list-style-type: none"> • Age group below 20 years and above 60 years • Known Patients of serious disorders of head • Cervical Spondylosis with myelopathy and radiculopathy (ICD 10 criteria M47.8) • Nasya anarha[14] • Pregnant females 		
3h]	Selection of Material:	Subjects are selected from the <i>Panchakarma</i> OPD and IPD of MGACH & RC Salod (H) with preset diagnostic criteria and distributed randomly by Lottery method into two groups.		
3h1]	Composition of Material:			
	Panchtikta ghrita (Cow ghee medicated with Guduchi,Vasa,Nimba,kantakari and Patola)is prepared in Rasashala of Go anusandhna Kendra,Devalapar,madhyapradesh after proper identification according to Ghrita Kalpana and methods directed by textual reference (Sharangadhara samhita) and cow ghee is procured from local sources.			
	S. N	Sanskrit	Botanical Name	Useful part
	1	Guduchi	<i>Tinospora cordifolia</i>	Root bark
	2	Nimba	<i>Azadaricta indica</i>	Stem bark
	3	Vasa	<i>Adhataoda Vasica</i>	Leaves
	4	Kanatakari	<i>Solanum xanthospermum</i>	Root bark
	5	Patola	<i>Trichosanthes patola</i>	Root
	6	Goghrita	Cow ghee	-
	7	Water		-
				4 part
				16 part
	Toxicity studies:		No known toxicity reported either for Panchtikta ghrita or	

		Plane ghee which is Edible in nature.
3h2]	Preparation of Material:	
	Group A – Panchtikta Nasya group patients will subjected to <i>Uttam matra of Marsha Nasya</i> [15] Group B –Goghrita Nasya group patients will subjected to <i>Uttam matra of Marsha Nasya</i> a) Poorva Karma Local <i>Snehana</i> with <i>Til Tila</i> (Sesame Oil) and local <i>Nadi Sveda</i> . b) Pradhana Karma <i>Marsha Nasya</i> with <i>Panchtikta Ghrita</i> and <i>plane goghrita</i> for respected group (<i>Mradu paka</i>) with the dose of 8 <i>Bindu</i> (approximate 4 ml) in each nostril at 8:30 am for 7 consecutive days. <i>Panchtikta ghrita</i> and <i>plane goghrita</i> should be made lukewarm before administration. c) Paschat karma: <i>Dhoomapaana</i> with <i>haridradi varti</i> and <i>Kavala</i> are practiced.	
3i]	Dosage:	8 drops in each nostrils
3j]	Study duration:	7 days
3k]	Follow up Period:	7 days
3l]	Screening Investigations:	CBC ESR
3m]	Specific Investigations:	X -Ray Cervical spines (AP –Lateral View)
3n]	Subjective Parameters:	Both pre and post assessments of the patients will be done on the basis of clinical symptoms- 1]Shula (Pain) in cervical region: 0=No Pain 1=Pain in the neck, 2=Pain in neck, mild aggravates with movement 3=Pain in neck, severe aggravates with movement 4=Pain in neck, radiation and disturbed the sleep 2]Stambha (Stiffness) in Cervical region: 0=No Stiffness, 1=Stiffness up to 1 hour 2=Stiffness up to 2-3 hours 3=Stiffness up to 4-6 hours 4=Stiffness more than 6 hours 3]Graha (Restricted movement) of neck 0= Normal range of movement

		1= ROM reduced up to 25%					
		2= ROM reduced to 26% -50%					
		3= ROM reduced 51% - 75%					
		4= ROM reduced 76% - 100%					
3o]	Objective Parameters:	<ul style="list-style-type: none"> • Neck disability Index • Goniometer Scoring (Assessment in degrees). 					
3p]	Statistical Methods:						
	The subjective criteria were assessed before treatment, after treatment, after first follow up and after second follow up. The data obtained in clinical study is subjected to statistical test and analyzed in two parts as; <ol style="list-style-type: none"> 1. The Wilcoxon signed Rank test 2. Paired t-test using Graphpad prism software. 						
3q]	Assessment of Results:						
	Assessment of study will be done for clinical and Assessment parameters on the basis of Before and After assessments.						
3r]	PICO model:						
	Population	Patients suffering from Manyasthambha (Cervical spondylosis)					
	Intervention	<i>Panchtikta ghrita Nasya</i>					
	Comparison	<i>Goghrita Nasya</i>					
	Outcome	Pain relief with <i>Panchtikta ghrita nasya</i> in Cervical Spondylosis					
3s]	Intervention Table						
	Group	Group A	Group B				
	Sample size	15 patients	15 patients				
	Intervention	<i>Panchtikta ghrita Nasya</i>	<i>Goghrita Nasya</i>				
	Dose	8 drops in each nostrils	8 drops in each nostrils				
	Duration	7 days	7 days				
	Follow up period	7 days	7 days				
	Total duration	14 days	14 days				
3t]	Gnat Chart						
		Q1	Q2	Q3	Q4	Q5	Q6
	Enrolment of Patients						
	Medicine preparation						

Data collection						
Data analysis						
Writing the Article						
Submission						

4]	References (Vancouver)					
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5a]	Annexure -1:	Case Sheet
5b]	Annexure -2:	Consent Form (Bi-Lingual)
	Annexure -3:	NDI SCALE (Scale for objective criteria)
	Annexure -4:	Budget Proposal (separate tables for Investigation & trial Medicine)