



Research Article

EFFECT OF *BALAMULA GHRITA UTTARABHAKTIKA SNEHA* AND *MASHASAINDHAVA TAILA PICHU* IN THE MANAGEMENT OF CERVICAL SPONDYLOSIS-A SINGLE ARM PROSPECTIVE OPEN RANDOMIZED CLINICAL STUDY

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ABSTRACT

In Ayurveda prevalence of *Vayu mahabhuta* is considered as prime factor that causes deterioration of qualities of *Kapha* in *Greeva stana* hence prescription of drugs having *Vatanuloma* and qualities of *Prithvi* and *Jala mahabhuta* would be very effective. In the present study humble attempt is made to evaluate the effect of *Balamula Ghritam* internally and combined with *Mashasaindhava Tailam* as external pack in arresting further degeneration. **Materials and methods:** 40 patients fulfilling the inclusion criteria after signing the informed consent form were selected from SJSACH [IEC NO-IEC/SJSACH/05/2021, CTRI NO - CTRI/2021/07/034968]. It is a single arm prospective open randomized clinical study. Patients were administered with 10ml of *Balamula Ghritam* morning and night after food and *Mashasaindhava Tailam* as *pichu* (external pack) over the cervical area for 21 days with two follow ups after the completion of the trial. **Result:** Subjective parameters were assessed using Friedman test and Wilcoxon signed rank test and objective parameters were assessed using paired sample t test. All the parameters had highly significant results with significant p value at the end of the treatment. **Conclusion:** The combined effect of *Balamula Ghritam* and *Mashasaindhava Tailam* was very effective in the management of cervical spondylosis. The critical analysis of the contents of *Balamula Ghritam* and *Mashasaindhava Tailam* acts as antioxidant, removes free radicals ROS, reduces the activity of osteoclast and bone resorption by inhibiting RANKL receptor pathway. It also has anti-inflammatory, anti-arthritic, anti-analgesic effect that found to be effective in reducing the symptoms of cervical spondylosis.

INTRODUCTION

Cervical spondylosis is a degenerative condition that occurs in the cervical spine and leading to changes in the intervertebral discs with disc degeneration, osteophyte and spur formation, ligamentous hypertrophy, vertebral subluxation, decreased in the height of disc and facet joint arthropathy all these contribute to narrowing of spinal canal and intervertebral foramina.

The wear and tear of the spine related disorder is on the rise now, especially more on the cervical vertebrae, where there is an abnormal damage to the cartilage and bones of the neck. The normal adult skull weighs around 4.5-5kg and it continuously exerts a pressure on the cervical spine during the sitting posture and in standing erect for humans.^[1]

Problem Statement: A survey conducted in young adults from South India revealed the prevalence of cervical spondylosis. About 62% of males, 36% of females are facing cervical spondylosis.^[2] The prevalence of cervical spondylosis is about 13% in the third decade of males rising to 100% by age 70 years and in females the prevalence ranged from 5 % in the fourth decade to 96% in women older than 70 years.

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The radiographic changes are more severe in men than women.^[3]

Need for the Study: To reach distant places across the globe has been made easy now a days due to improvement in the overall infrastructure of Roadways, Railways and Airways and though this is a welcome move for the commuters to make their plan of improving their business standards or for their career development, there also occurs health hazards in the form of long travel leading to physical and mental agony of an individual. Also due to occupational stress, improper sitting postures, sitting in air conditioners and adopting continuously one posture, over exertion causes pressure over cervical spine with a damage to the flexibility of the surrounding tissues, cushion structures called the discs protecting the vertebrae from friction and acting as shock absorbers leading to the cause of cervical spondylosis. All these factors cause oxidative stress with the generation of free radicals altering the balance between osteoblasts and osteoclasts leading to osteoclastogenesis and bone loss. This further activates RANKL (NF- κ B signaling pathway) and blocks the activation of osteoclast resulting in degenerative conditions of bone. Recent studies prove that 70 – 80% of degenerative diseases are caused due to generation of free radicals. The medicine possessing more of Antioxidant property has a been proven to be highly effective in inhibition of RANKL signaling pathway thereby preventing the bone from further degeneration.^[4]

In Ayurveda, *Vata dosha* gets aggravated due to various *Nidana* factors due to “*Dosha sanchara*” of *Vayu* and *Akasha mahabhuta* to *Kapha stana (Greeva pradesha)* causing deterioration of *Prithvi* and *Jala mahabhuta* along with qualities of *Kapha (Snigdha, Sheta, Guru, Slaksna, Sthira)*. Based on the *Panchaboutika Siddhanth* and *Guna – Karma vikalpa* theory of Ayurveda. Medicine should have *Snehana* property along with *Prithvi* and *Jala mahabhuta pradhana oushadha* and *Vatanulomana* considered as best choice.^[5,6]

To strengthen the cervical area with the reduction of pain and to get overall improvement in the mobility of cervical spine *Bala* root having properties of *Snigdha, Madhura, Balya, Picchila, Vatahara, Rasayana, Tridosahara, Bala ojovardhanam*

properties as per Ayurvedic classics shall be a best drug for administration when used in the form of ghee preparation preferably after food after a careful analysis of the *jataragni* of an individual.

As an external therapy *Masha* and *Saindhava* processed with *Tila Tailam* shall be used warm as *pichu* on the cervical spine area would not only stabilize but also enhances a free movement of an affected site. Hence this study is planned to bring out the efficacy of *Balamula Ghritam* internally and *Mashasaindhava Tailam* externally in the management of cervical spondylosis with special reference to pain management by nourishing the disc.

AIMS AND OBJECTIVES

- To study the combined effect of *Balamula Ghritam* as *Uttarabakthika Sneha* and *Mashasaindhava Tailam* as external *Pichu* on cervical spondylosis
- To understand the conceptual aspect of cervical spondylosis in modern and Ayurveda.

H₀- *Balamula Ghritam* and *Mashasaindhava Tailam* are not effective in the management of cervical spondylosis.

H₁- *Balamula Ghritam* and *Mashasaindhava Tailam* are effective in the management of cervical spondylosis

MATERIALS AND METHODS

Source of Data and Drug

The patients who attended the O.P.D and I.P.D of Sri Jayendra Saraswathi Ayurveda College and Hospital, Nazarathpettai, Chennai having the signs and symptoms of cervical spondylosis were screened. 40 patients who fulfilled the inclusion criteria after signing the informed consent form were taken for the clinical study. A comprehensive case sheet proforma was prepared for all these selected patients which incorporates the relevant data like personal details, history of illness, signs and symptoms, laboratory investigations, reports and examinations (based on subjective and objective parameters) for the confirmation of diagnosis.

Drug Source: drugs that are required for the preparation of medicine were identified and collected from the Sankara Ayur pharmacy of Sri Jayendra Saraswathi Ayurveda College and Hospital. After the standardization of prepared medicines, it was used in the present study.

Ingredients of Balamula Ghritam and Mashasaindhava Tailam

Balamula Ghritam and *Mashasaindhava Tailam* preparation was carried out in two batches following standard methods from Sarangadhara Samhita^[7]

Table 1: Shows Balamula Ghritam Ingredients

Drugs	Part Used	Quantity
Kvatha Dravya		
<i>Balamula</i> (<i>Sida cordifolia</i> Linn)	<i>Sida cordifolia</i> root	7 kgs
Water	Purified water	56 litres
Kalka Dravya		
<i>Balamula</i> (<i>Sida cordifolia</i> Linn)	<i>Sida cordifolia</i> root	1750 grams
Sneha Dravya		
<i>Go Ghritam</i>	Cow's ghee	8 litres

Table 2: Shows Masha Saindhava Tailam Ingredients

Drugs	Part used	Quantity
Kvatha Dravya		
<i>Masha</i> (<i>Vigna mungo</i> (Linn.) Hepper)	Black gram seed	7 kgs
Water	Purified water	56 liters
Kalka Dravya		
<i>Masha</i> (<i>Vigna mungo</i> (Linn.) Hepper)	Black gram seed	875 grams
<i>Saindhava Lavana</i>	Rock salt	875 grams
Sneha Dravya		
<i>Tila Tailam</i>	Sesame oil	8 liters

Final Product of Balamula Ghritam and Mashasaindhava Tailam**Fig 1: (a) Balamula Ghritam final product (b) Mashasaindhava Tailam final product****Diagnostic Criteria**

Patients between the age group of 25-60 years of any sex with radiological evidence and other clinical features such as radiating pain along the course of C5-C6, C6-C7 dermatome, numbness, paresthesia, tingling sensation, stiffness, dizziness, weakness are considered.

Plan of the Study

- Sample Size - 40
- No. of Group - One
- Method of Sampling - Simple Random Sampling Technique.

Inclusion Criteria

- Pre-diagnosed cases of cervical spondylosis with supporting radiographic reports e.g., MRI of cervical spine and presence of osteophytes and reduced joint space in x-ray.
- Diagnosed patients of cervical spondylosis willing to participate and sign the informed consent form will be selected for the study.
- Age – Between 25 – 60 years
- Sex- All genders
- Chronicity less than 3 years will be included in the study.

Exclusion Criteria

Cervical spondylosis due to trauma, spinal surgery will be excluded.

Cervical spondylosis associated with autoimmune diseases rheumatoid arthritis, systemic lupus erythematosus, ankylosing spondylitis.

Conditions like-

- Spondylolisthesis
- Tumours of spine
- Facet joint arthropathies
- Haemangioma
- Syringomyelia
- Osteomyelitis
- Paget’s disease
- Scleroderma
- Tuberculosis of spine
- Fibromyalgia
- Polymyositis
- Fractures
- Whiplash injury
- Amyotrophic lateral Sclerosis
- Pregnancy, multiple sclerosis
- Renal and Cardiac failure

Subjective Parameters

Table 3: Shows Assessment of subjective parameters

Neck pain	Grade 0	No pain
	Grade 1	Mild pain relieved on rest
	Grade 2	Moderate pain relieved on taking rest
	Grade 3	High intense pain not relieved on rest
Neck Stiffness	Grade 0	No stiffness
	Grade 1	Mild stiffness
	Grade 2	Moderate stiffness
	Grade 3	Severe stiffness
Radiating pain	Grade 0	No radiation
	Grade 1	Radiation of pain from neck to arm occasionally present
	Grade 2	Radiation of pain from neck to any one side of extremity
	Grade 3	Radiation of pain to both the sides of the extremity

Plan of Treatment

Posology: 40 patients administered with *Balamula Ghritam* as *Uttarabhaktika Sneha* internally and *Mashasaindhava Tailam* as *Pichu* externally for a period of 21 days.

Dosage

Balamula Ghritam: Was prescribed with 10ml morning and 10ml night as *Uttarabhaktika Sneha* (after food).^[8]

Anupana- *Ushna jala* ^[9] taken after the intake of *Balamula Ghritam*.

*Prior to the prescription of *Balamula Ghritam Trikatu churnam* was given for 3 days to rectify the *Agni* of the patient and for the proper digestion and absorption of *Balamula Ghritam*.

Mashasaindhava Tailam: Was used as external pack (*Pichu*) in empty stomach in morning. ^[10] Depending upon the surface area of neck and site of lesion quantity of the oil varied from 50- 80 ml.

Duration of Study Period: Clinical study carried for a period of 21 days

Follow Up

- Day 0 – assessment done – Before treatment
- Day 22 – assessment done – After treatment
- Day 30- follow up

Laboratory Investigation: Routine Blood investigation

Radiological Investigations: X – ray of cervical spine Anteroposterior and lateral view

Assessment Criteria: It includes subjective and objective parameters for assessment based on clinical grading and standard scoring methods. These criteria were used for assessing the patient before the treatment on Day 0, after 21 days of treatment on Day 22nd and one follow up without medications on Day 30th was done.



Numbness	Grade 0	No numbness
	Grade 1	Numbness from neck to arm occasionally present
	Grade 2	Numbness from neck to any one side of extremity
	Grade 3	Numbness from neck to both the sides of the extremity
Weakness in arms	Grade 0	No weakness
	Grade 1	Weakness in any one side of the extremity, occasionally present
	Grade 2	Weakness in any one side of the extremity
	Grade 3	Weakness in both the sides of the extremity
Dizziness	Grade 0	No dizziness
	Grade 1	Occasionally present
	Grade 2	On movements of neck patient feels dizziness
	Grade 3	Constantly dizziness is present

Objective Parameters

- Muscle power assessment [11]
 - Grade 0- No movement
 - Grade 1- Flickering movements
 - Grade 2- Active movement with gravity
 - Grade 3- Active movement against gravity
 - Grade 4- Active movement against gravity and resistance
 - Grade 5- Normal power
- Assessment of reflexes (biceps and triceps) [12]
 - Grade 0- Absent (Areflexia)
 - Grade 1- Diminished (hyporeflexia)
 - Grade 2- Average (normal)
 - Grade 3 – Exaggerated (brisk)
 - Grade 4- Clonus, very brisk (hyper reflexia)
- Neck disability index questionnaire (NDI Score)
- CROM (Cervical Range of Motion) Assessment using Goniometer readings. [13]

Table 4: Shows Cervical range of motion with the normal degree (ROM)

CROM (Cervical range of motion)	Normal Range
Right lateral flexion (RLF)	Normal = about 43 degrees
Left lateral flexion (LLF)	Normal = about 43 degrees
Right lateral rotation (RLR)	Normal = about 45 degrees
Left lateral rotation (LRL)	Normal = about 45 degrees
Forward flexion (FF)	Normal = about 38 degrees
Backward extension (BE)	Normal = about 38 degrees

OBSERVATIONS AND RESULTS

In the present study - Total no of patients Screened = 48
 Total no of patients registered for the study = 48
 No of patients completed the study = 40
 Total no of drop outs = 08

Pre-treatment observation: All the patients have been studied along with the registration by noting down their demographic profile including their age, address, occupation, education, socioeconomic status, habits etc. After preliminary registration, patient was subjected to detailed case history taking, physical, general, systemic and musculoskeletal system examination. During this all-other relevant information like *Astavidha* and *Dashavidha pareeksha* were noted.

Combined Effect of *Balamula Ghritam* and *Mashasaindhava Tailam* on Subjective and Objective Parameters

Assessment of subjective parameters was carried out using Friedman test and Wilcoxon test and objective parameter assessment was done using paired sample t test

Among 40 patients who completed the study 35 patients had neck pain, 27 patients had neck stiffness, 35 patients had radiation of pain, 26 patients had numbness, 26 patients had weakness in arms, 31 patients had dizziness and 30 patients had complaints of muscle power, 15 patients had complaints of biceps reflex, 13 patients had complaints of triceps reflex and 40 patients had complaints with restricted cervical range of motion (CROM) and neck disability index score (NDI Score) all these symptoms results after treatment are represented below (Table 5)

Table 5: shows the summary of highly significant results in the subjective parameters after treatment

Symptom	N value	Mean Rank		P value	Remarks
		BT-D0	AT- D30		
Neck pain	35	1.94	1.06	0.000	HS
Neck stiffness	27	1.84	1.16	0.000	HS
Radiating pain	35	1.94	1.06	0.000	HS
Numbness	26	1.83	1.18	0.000	HS
Weakness in arms	26	1.83	1.18	0.000	HS
Dizziness	31	1.89	1.11	0.000	HS

Table 6: shows the summary of significant results in objective parameters after treatment

Symptom	N value	Mean		Diff of Mean	% Of relief	SE Mean	T value	P value	Remarks
		BT	AT						
Muscle power	30	3.45	4.28	- 0.83	-24.05	0.094	-8.780	0.000	HS
Biceps reflex	15	1.63	1.95	-0.32	-19.63	0.075	-4.333	0.000	HS
Triceps reflex	13	1.68	1.95	-0.27	-16.07	0.071	-3.846	0.000	HS
Right lateral flexion	06	40.45	42.58	-2.12	-5.26	0.831	-2.556	0.015	S
Left lateral flexion	08	39.90	42.38	-2.48	-6.21	0.837	-2.958	0.005	HS
Right lateral rotation	05	42.93	44.20	-1.27	-2.95	0.570	-2.239	0.031	S
Left lateral rotation	06	42.63	44.40	-1.77	-4.15	0.699	-2.538	0.015	S
Forward flexion	07	36.08	37.75	-1.67	-4.62	0.611	-2.740	0.009	S
Backward flexion	08	36.73	37.75	-1.02	-2.77	0.518	-1.978	0.055	S
NDI Score	40	2.03	1.03	1	49.26	0.062	16.125	0.000	HS

From (Table 6) results the symptoms like neck pain, neck stiffness, radiation of pain, numbness, weakness in arms, dizziness, muscle power, reflex power and left lateral flexion (LLF), NDI Score had highly significant results with P value (<0.001). Symptoms like Right lateral flexion (P value - 0.015), Right lateral rotation (P value - 0.031), Left lateral rotation (P value - 0.015), Forward flexion (P value - 0.009) and Backward extension (P value - 0.055) had significant results after treatment.

Overall Treatment Result of Clinical Signs and Symptoms of Present Clinical Study

Based on subjective and objective parameters assessment was carried out in 40 patients. The observation was made based on before treatment assessment followed by day 22nd assessment (after treatment) and finally observation after 1 week on day 30th (follow up) assessment without medications was done and treatment results were concluded as follows:

Table 7: represents total no of patients with grades before and after treatment

Patients Completed The Study = 40							
Symptom	N value	Treatment effect represented using grades					
		BT - DAY 0			AT - DAY 30		
		Gr-1	Gr-2	Gr-3	Gr-0	Gr-1	Gr-2
Neck pain	35	12	15	08	16	18	01
Neck stiffness	27	07	12	08	13	11	03
Radiation of pain	35	12	15	08	22	11	02
Numbness	26	09	11	06	16	08	02
Weakness in arms	26	09	11	06	17	09	0
Dizziness	31	12	14	05	27	04	0

N= total no. of patients, Gr-0 - no symptom, Gr-1 - mild, Gr-2 - moderate, Gr-3- severe

Based on Muscle Power Assessment - Before Treatment (BT - Day 0)

10 patients had grade- 2 (active movement with gravity), 12 patient had grade-3 (active movement against gravity), 08 patients had grade 4 (active movement against gravity and resistance)

After Treatment - Day 30th - Marked statistical improvement seen in all the patients after treatment, 07 patients had grade 5 (normal power), 17 patients had grade 4 (active movements against gravity and resistance) and 06 patients had grade 3 (active movements against gravity), there were no patients with grade 2 complaints after treatment.

Based on Biceps and Triceps Reflex Assessment- Before Treatment (BT - Day 0)

Assessment on biceps and triceps reflex - grade 1 (diminished biceps reflex) was observed in 08 patients on right side and 07 patients on left side. Grade 1 - diminished triceps reflex - 07 patients on right side and 06 patients on left side.

After Treatment - Day 30th - significant improvement was observed in both reflexes after treatment. On assessment of biceps reflex 13 patients had grade 2 (normal power), 02 patients still had grade 1 (diminished reflex). On triceps reflex 12 patients had grade 1 (normal power) and 01 patient had grade 1 (diminished reflex) after treatment.

Based on NDI Score Assessment- Before Treatment - Day 0

Among 40 patients 10 patients had mild disability, 22 patients had moderate disability, 05 patients had severe disability and 03 patients had complete disability.

Assessment Made After Treatment- Day 30th- There was marked improvement observed after the treatment was done 06 patients had no disability (complete relief), 26 patients had mild disability, 08 patients had moderate disability.

Summary of Overall Assessment of Patients Observed After Treatment

Table 8: shows the effect of treatment and number of patients based on relief of clinical symptoms

Observed Number of patients with relief after treatment			
Symptoms	Complete relief	Mild relief	Moderate relief
Neck pain	16	18	01
Neck stiffness	13	11	03
Radiation of pain	22	11	02
Numbness	12	08	02
Weakness in arms	17	09	0
Dizziness	27	04	0
Muscle power assessment	07	17	06
Biceps & Triceps Reflex assessment	25	03	0
NDI Score	06	26	08

With the above table it is clear that maximum number of patients had complete relief from the clinical symptoms after treatment.

DISCUSSION

Effect of *Bala Mula Ghritam* in Cervical Spondylosis

Balamula Ghritam contains 2 ingredients *Balamula* (*Sida cordifolia* root) and Cow's ghee (*Ghritam*). The root is said to possess anti-inflammatory, analgesic, antioxidant, neuroprotective and anti-osteoarthritic properties and the root acts as best nervine tonic and immunomodulator.^[14] The chemical compounds especially the choline maintains brain and nervous system functions and needed for proper liver functions, healthy brain development, muscle movement and metabolism of fat. It maintains the structural integrity of cell membrane, DNA synthesis and a healthy nervous system.^[15] Another compound called betaine inhibits osteoclastogenesis and prevents osteoporosis and helps in maintaining bone strength.^[16]

Cow's ghee on the other hand is a complex lipid of glycerides (mixed), free fatty acids, phospholipids, sterols, fat soluble vitamins high amount of Vitamin A, carbonyls, hydrocarbons, carotenoids and E, conjugated linoleic acid, oleic acid that are needed for maintaining the structural integrity of bone.^[17]

Mode of Action of *Ābhyantara Sneha* (*Uttarabhaktika Sneha*)^[18]

The *Ghritam* which contains *Balamula* has *Madhura rasa*, *Snigdha guna*, *Shita virya*, *Madhura vipaka* and it is having qualities like *Brimhana*, *Balya*, *Vrishya*, *Vata-pittahara*, *Ojovardhaka*, *Rasayana*, *Snehana* and *Anulomana*. On the other hand, the *Go Ghritam* contains has a special property like *Samskarasyanuvartana*, *Sahasravirya* and *Karma hasrakrit* by which it enlightens the property, potency and therapeutic action of the drug with which it is processed without compromising its own properties. When the *Balamula Ghritam* was prescribed 10ml after the breakfast and dinner as *Uttarabhaktika Sneha* in the case of cervical spondylosis with an intention of digesting in 3 hours time to enhance its digestion 30ml of *Ushna jala* (hot water) was prescribed. Hot water has a nature of liquefying any solid material due to its *Dipana*, *Pacana* property and by making an enroute entry into the solid material thereby bringing its disintegration. This *Balamula Ghritam* on digestion gets converted as an essence which is addressed as *Asthaye/Poshakamsham* which is exogenous, gets absorbed into the portal circulation and taken to liver to be detoxified.

Metabolization of *Bala Mula Ghritam* in *Yakrit*^[19]

After undergoing a curious transformation process, a "baptism" occurs in liver by which the exogenous *Balamula Ghritam* essence (*Vijathiya*) is converted to endogenous (*Sajathiya*) tissue component into the blood, thus contain not only endogenized *Balamula Ghritam* essence (*Sthaye/ Poshya*) which is the precursor for nourishment to come. Thus, the portion of *Balamula Ghritam* inside the portal system is *Asthaye* or *Poshaka aushadam* and is exogenous (*Vijathiya*), whereas the *Balamula Ghritam* essence with blood in systemic circulation is *Sthaye/ Poshya aushadam* and is endogenous (*Sajathiya*). When *Vijathiya* essence transforms into *Sajathiya* attains new functional status (*Varna*) responsibility, it is a part of body and instrumental in providing nutrition to all other tissues of body.

Transformation of *Bala Mula Ghritam* to the Targeted Site (Cervical Spine)

Further the part of *Balamula Ghritam* in the form of essence by mixing with the food essence it is being continuously transformed to erythropoietin factors of blood with the help of *Rasadhatwagni* and *Ranjaka pitta*. All the properties of *Balamula Ghritam* on its rapid digestion and absorption becomes the first essence for its onward transmission through the blood stream to the site of damage and it replaces the lost qualities of *Prthvi* and *Jala mahabhuta* to get filled up in the *Grēva pradesha* with the new arrival of the essence of *Balamula Ghritam* the functions and properties such as *Sandhisansleshana*, *Snehana*, *Ropana*, *Purana*, *Bala*, *Sthairya* gets enhanced.

Action of *Bala Mula Ghritam* at the Level of Targeted Site (Cervical Spine)

The *Balamula Ghritam* contains high antioxidant properties hence protect against cell death and disease prevention. It acts as free radical scavengers and removes the oxidative stress that is been developed in cervical spondylosis. Antioxidants have opposing effects contribute to differentiation of osteoblasts and bone formation by maintaining vital osteocytes that contribute to osteoblast activity and osteogenesis. It reduces the osteoclast differentiation and their activity and acts as direct scavengers of ROS and the conjugated linoleic acid inhibits osteoclast differentiation by modulating RANKL signaling. It influences the calcium and bone metabolism and thus has an important role in treating osteoporotic conditions. Since gene detection studies have shown that the receptor activator of nuclear factor - kappa B ligand (RANKL) is considered as crucial mediators of osteoclastogenesis this antioxidants prevent osteoclast formation, NF-κB activation and TNF alpha expression involved in osteoclast activation and help in restoring

the physiological bone remodeling process. [20] *Balamula Ghritam* also has Anti - ageing action by immune stimulation, removing the free radicals, enhancing cellular detoxification, repair the damaged

cells, self-renewal of damaged proliferating tissues and restore them by eliminating damaged or muted cells with fresh cells.[21]

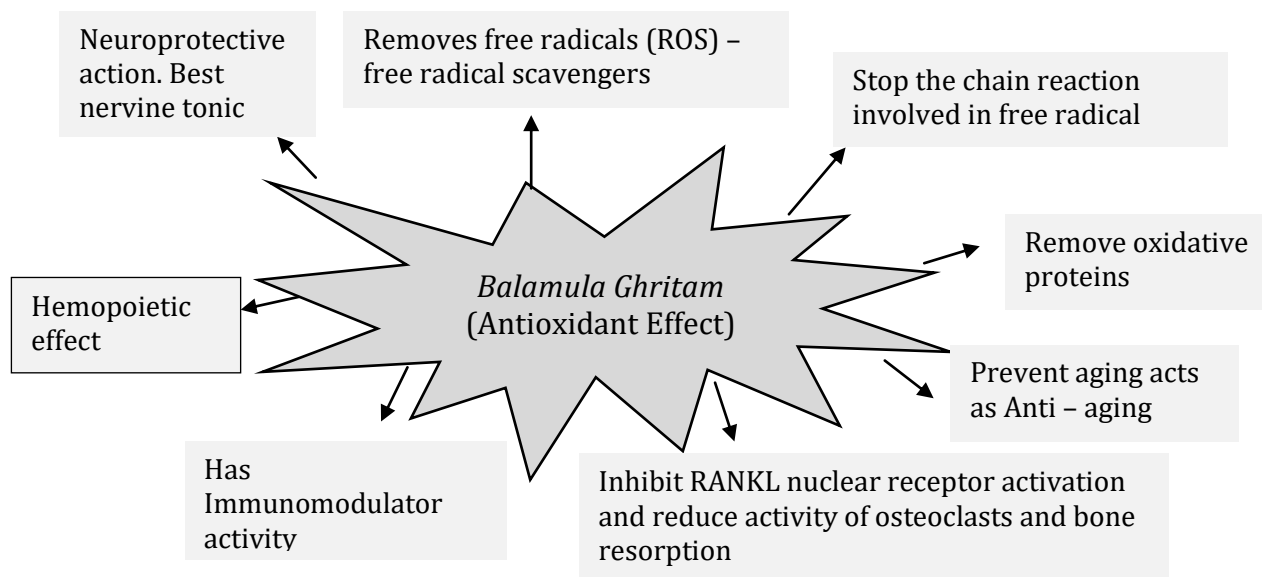


Fig 2 shows the antioxidative effect of *Balamula Ghritam*

Effect of *MaShasaindhava Tailam Pichu* in Cervical Spondylosis

Mashasaindhava Tailam when applied as *Pichu* enhances the penetration of lipid vesicles through its lipid fluidizing property and allows the direct carrier skin exchange of collision complex transfer of the molecules of the oil through appendage pathway. Liposomes, Niosomes provide a localized action of lipid molecules and allow the transmission of polyunsaturated fatty acids and its contents like linoleic acid, oleic acid, and palmitic acid through the skin.

The *Mashasaindhava Tailam* contains 3 ingredients - *Masha*, *Saindhava* and *Tila Tailam*.

Masha seed contains high antioxidant properties and anti-analgesic property that reduces the oxidative stress and pain produced in the body. It has high anti-inflammatory effects that help in reducing the inflammation by inhibiting prostaglandin synthesis. It has a specific type of flavonoid (C- glycosal), high amount of minerals like calcium, phosphorous and iron present in this drug has a crucial role in preventing bone loss and osteoporosis that helps to correct the reduced bone mineral density. [22]

Saindhava Lavana- Also contains high amounts of minerals like calcium, iron, zinc, magnesium, potassium, copper, lithium, chromium and phosphorous helps to correct bone loss and increases the bone mineral density and prevent osteoporosis. It

helps in strengthening the bones and connective tissue. It has high antioxidant property helps to stimulate blood circulation and mineral balance. It has free radical scavenging property. It has anti - inflammatory effect hence reduces muscle cramp, relief in joint stiffness, rheumatic pain and inflammation. [23]

Tila Tailam- The alkaloid content of *Tila Tailam* possess high anti-inflammatory effect, flavonoids and phenols acts as anti - oxidants, content of tannin present in the drug helps to repair tissue damage and possess best wound healing property. Minerals like phosphorous, potassium, calcium, zinc, iron has anti-arthritis effect helps to increase bone mineral density and strengthen the bones and nerves. The unique chemical compound "sesamol" a natural lignans contain lignan aglycones and lignan glycosides plays a vital role in removing the free radicals, corrects oxidative stress and helps in tissue repairment. It inhibits osteoclastogenesis and RANKL mediated NF-κB ligand pathways and shows promising effect in treatment of osteoporosis. [24] A study on *Mashasaindhava Tailam* in frozen shoulder revealed that the *Tailam* had significant results in reduction of pain, stiffness, numbness and improved the overall ROM. [25]

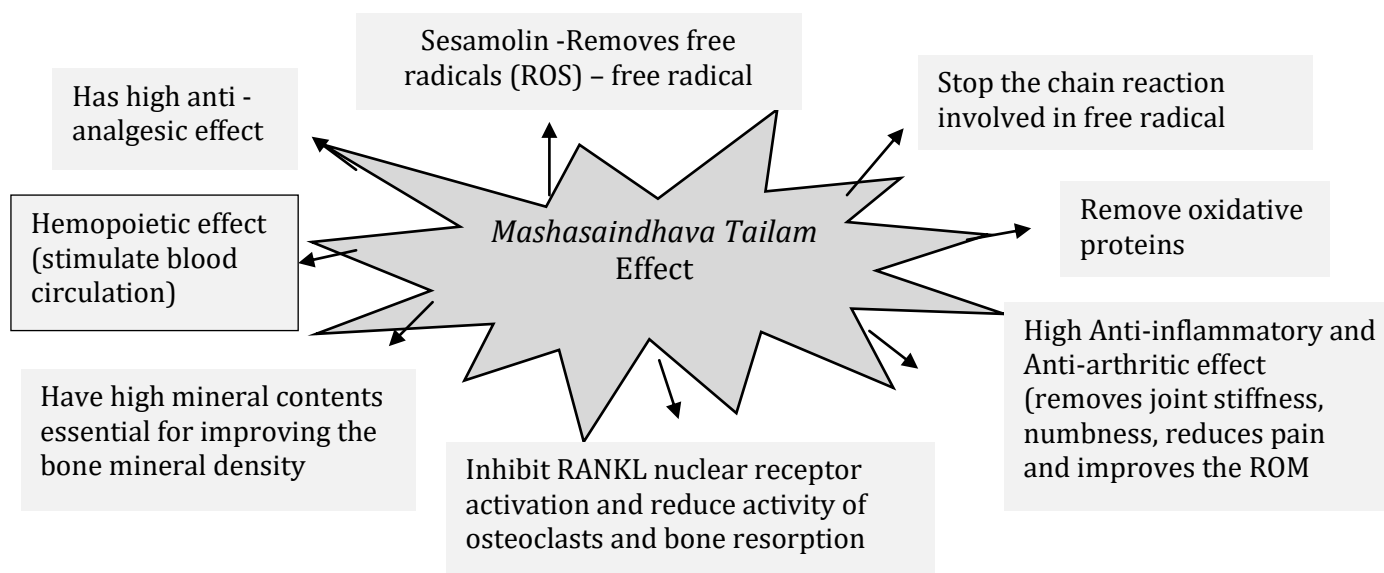


Fig 3: Shows various pharmacological actions of *Mashasaindhava tailam*

Combined Effect of *Balamula Ghritam* and *Mashasaindhava Tailam* on the Above Parameters after Treatment

Cervical spondylosis caused by various intrinsic and extrinsic factors induces oxidative stress thereby leading to circulatory free radicals (ROS) in the body. These produce degenerative and inflammatory changes by osteoclastogenesis and activation of cytokines respectively. Hence symptoms such as neck pain, neck stiffness, numbness, radiating pain, weakness in arms, dizziness and neurological impairment including muscle power, reflex and Cervical range of movement (CROM) are produced.

- Administration of *Balamula Ghritam* internally and application *Mashasaindhava Tailam pichu* considerably reduces these deteriorative changes through its various properties. The root of *Balamula Ghritam* possesses anti-inflammatory, analgesic, antioxidant, neuroprotective and anti-osteoarthritic properties and acts as best nervine tonic and immunomodulator. On the other hand, the *Mashasaindhava Tailam pichu* application and its absorption through Trans epidermal layers with its compound like linoleic, oleic acid etc. helps to repair the tissue damage and have an effect on reduce the inflammatory changes and promotes the bone mineral density and strengthens the bone. There by the neurological and locomotory functions are enhanced. [26]

CONCLUSION

Cervical spondylosis is not only a mechanical defect but also an anatomical fault which ends up with radiculopathy, myelopathy etc. If not treated in time as the wear and tear is so rapid to occur due to factors like skull weight, sedentary postures and due to

occupation. Conditions like herniated disc, thinning of disc, nerve cord compression, hypertrophy of facet joints etc. need an immediate attention. In Ayurveda management the tissue repair and nutritional supply to the cervical spine can be made possible with the prescription of medicated ghee prepared with *Balamula* administered after food by considering the *jataragni's* digestive capacity, place a vital role in the supply of nutrients in the form of properties and action to the required site is the need of the hour. A critical analysis of the product *Balamula* in *Balamula Ghritam* has been proved beyond doubt to acts as an antioxidant, free radical scavenger, inhibit the RANKL receptor signaling pathways thereby reduce the activity of osteoclast and bone resorption. With the internal prescription of *Balamula Ghritam*, the internal arrival of the property enhancement at the site of loss of those properties is made for the replacement of lost properties by treating the spot with the external therapy also. For this purpose, *Mashasaindhava Tailam* has the result of recovery on a very positive note as *Mashasaindhava Tailam* is said to possess anti-inflammatory, anti-arthritic, anti-analgesic effect, acts as free radical scavengers and inhibit RANKL nuclear receptor activation and reduces the activity of osteoclasts and bone resorption. The above concept state that the replacement of depleted deposit with the replenished ones is the key to success which is made possible with the in-depth study of the above internal and external prescriptions given to my patients.

Limitations of Present Clinical Study

- The dose of *Balamula Ghritam* can be made into *Madhyama matra* for quick results.
- The period of study shall be extended to observe changes in radiological investigations.

- The sample size of the study could have been increased to attain highly significant results with more accurate mean values.

Scope of Further Studies

- Standard Ayurvedic assessment criteria should be prepared for future study purpose
- Appropriate research designs should be prepared for conducting future research works and that should enable to follow more of Ayurvedic concepts.
- A biomedical study of *Balamula Ghritam and Mashasaindhava Tailam* in collaboration with the concepts of the principles of Ayurveda is required to make it more evidence-based research and to take it to a global level

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