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Research Article

RECEPTOR ACTIVATOR OF NF-κB LIGAND INDUCED OSTEOCLASTOGENESIS IN CERVICAL SPONDYLOSIS - ROLE OF *BALAMULA GHRITAM* (A POWERFUL ANTIOXIDANT DRUG) AS *UTTARABHAKTIKA SNEHA*

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Cervical spondylosis, Oxidative stress, RANKL activation, Disc dehydration, *Balamula,* Antioxidant.

ABSTRACT

The discs which are located in between the vertebras to act as shock absorbers during jolts to prevent spine injuries get either dislocated, bulged out or get thinned on continuous pressure being exerted upon them either by travel or a posture that is unsuitable to their alignment. In cases of discs getting thinned out and the height of these discs get reduced due to various causes produce undue pressure over the cervical spine resulting in oxidative stress and production of free radicals in the body causing deterioration of bone tissue and bone mass leading to regulation of RANKL/OPG ratio levels causing degeneration of bone. It is possible to resurrect the dehydrated discs with rehydration using *Balamula* (*Sida cordifolia* root) with the help of its properties and actions that it can positively act upon the area by refilling the gaps of erosions and assure a recovery with the proper administration of it in the form of ghee which has been processed with it and its intake being after food. **Material & Methods:** Various Ayurvedic classical textbooks and published journal articles were reviewed and analysed. **Results:** Evidences from various studies show that the phytochemicals obtain from *Balamula* (*Sida cordifolia* root) and *Go- Ghritam* (cow's ghee) acts as antioxidant, 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. It is defined as "vertebral osteophytosis secondary to the degenerative disc disease "mainly due to the osteophytic formations that occur with progressive degeneration of spinal segment. [1]

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Prevalence Rate: Survey conducted among bike riders in South India revealed that 62% of males and 36% of females had cervical spondylosis.[2] Research studies reveal that long lasting work on computers, long bending of head puts undue pressure on the cervical spine and the muscles of the neck, shoulder and upper limb becomes overloaded and finally injured.

Study conducted among computer users result showed that 73% respondents had neck and shoulder pain considered as one of the risk factors for the development of cervical spondylosis. Research report says that rise in number of professionals confined to desk or in front of computers working for long hours in one posture is one of the major causes for early degeneration of cervical spine causing cervical spondylosis.[3]

Incidence: More common in middle aged or elderly patients, **Age-** Over 40– 50 years of age more people tend to develop degenerative conditions in the cervical spine. **Sex-** Women are more affected due to hormonal

fluctuations. **Most Common Affected area–** Between third and seventh cervical vertebra (C3 – C7).[4]

Role of Free Radicals (Reactive Oxygen Species) in Cervical Spondylosis[5]

Cervical spondylosis is said as osteoporosis of cervical spine where there is deterioration of bone tissue, loss of bone mass leading to enlarged bone fragility and risk of fracture. It is due to the change in the balance between osteoblasts and osteoclasts. The activities of bone cell are influenced by a lot of cellular and nutritional factors include supply of oxygen, nutrients, endocrines, cytokines, growth factor and free radical formation. Research studies prove that 70-80% of the degenerative diseases are caused due to the generation of free radicals in the body and cervical spondylosis is one among them.

Effect of ROS at the Level of Bone: ROS induces apoptosis of osteoblasts and osteocytes cells localized in bone matrix leading to osteoclastogenesis. Excessive osteocytes apoptosis correlates with oxidative stress causing imbalance of osteoclastogenesis leading to increase in bone remodelling and bone loss. Recent research evidences/clinical studies have shown that ROS and antioxidant systems are involved in the pathogenesis of bone loss several factors mainly produced by osteoblast and osteocytes that regulate osteoclast and osteoblast activity and then bone remodelling. Most important are ligand of receptor activator of NF-κB (RANKL) and osteoprotegerin (OPG). A central component of the interaction between immune and skeletal system is mainly by TNF receptor family molecule, receptor activator of NF-κB ligand (RANKL). This protein also called (TNF–related activation cytokine) TRANCE was first identified as surface marker for regulatory effects on immune cell function. Later shown to be essential for differentiation, activation, and survival of osteoclasts. RANKL now known to be secreted by activated T-lymphocytes studied extensively on the context of bone loss in osteoporosis. It activates the differentiation and activity of osteoclasts by interacting with specific receptors and mediates osteoclasto-genesis and bone resorption. OPG is a soluble receptor capable of binding and blocking RANKL→ inhibition of osteoclast activity. Due to oxidative stress, it blocks the activation of osteoclast by this bone remodeling process increases and regulation of RANKL/OPG ratio levels (which is responsible for maintaining balance between bone resorption and formation) are increased resulting in inadequate and proper bone formation leading to various bone diseases, various skeletal diseases mainly degenerative conditions of bone. A very important factor underlying the pathogenesis of osteoporosis is receptor activator of NF-κB ligand. RANKL plays a crucial role in osteoclast differentiation and activation. The ROS are involved in the regulation of RANKL dependent osteoclast differentiation. It acts as intracellular signalling compounds have cytotoxic effects, including lipid peroxidation and DNA damage.

Role of RANKL Receptor in Osteoporosis: Recent research studies prove that inhibition of RANKL receptor appears to be promising new treatment of osteoporosis condition.

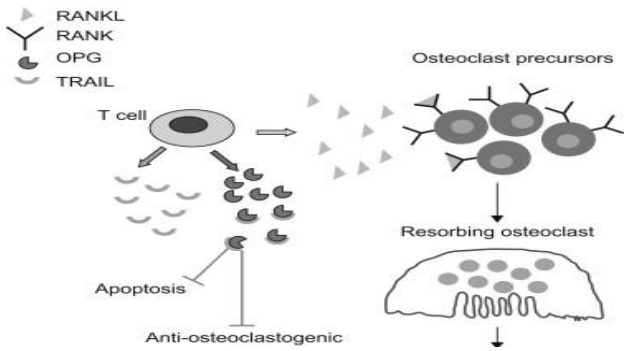


Fig 1: Mechanism of T cell Activation Inducing RANKL/ OPG Leading to Bone

Antioxidant as "free radical scavengers"[6]: To stop the free radical formation in the body antioxidant are needed. Antioxidant acts as free radical scavengers that inhibit or decreases the oxidation of compounds and reduces oxidative stress and prevent the harmful effects of free radicals. Studies suggest that decrease in plasma antioxidants are seen in osteoporotic women and this loss leads to accelerated bone loss through activation of tumour necrosis factor (TNF- alpha) dependant signalling pathway. It prevents osteoclast formation, NF-κB activation and TNF–alpha expression involved in osteoclast activation.

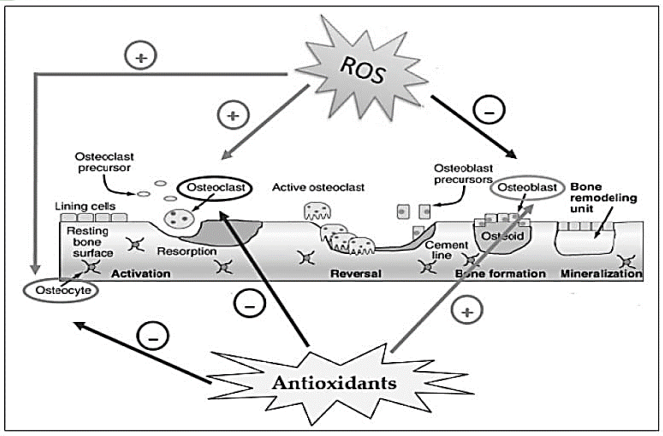
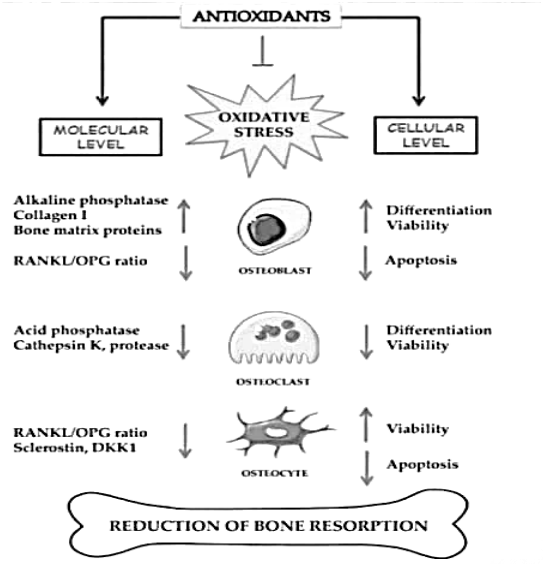


Fig 2: ROS and Antioxidant Activity on Bone Cells

- Effect of antioxidant at molecular level– prevents RANKL and OPG by inhibiting the enhancement of RANKL/ OPG ratio in osteoblast and osteocytes, inhibits the increase of bone acid phosphate and protease activity.
- Effect of antioxidant at cellular level– counteract excessive apoptosis of osteoblast and osteocytes, reduce the differentiation of activation of osteoclasts.

ROS (Reactive oxygen species) activates osteoclast differentiation and osteocyte apoptosis (+), and inhibit osteoblast activity (-) inducing bone resorption,

Antioxidant- activate osteoblast differentiation (+), inhibit osteoclast activity and osteocyte apoptosis (-) induing bone formation



MATERIALS AND METHODS

IEC and CTRI number:e -(IEC NO – IEC/SJSACH/05/2021, CTRI NO – CTRI/2021/07/034968)

Taxonomical Classification[8]

- Kingdom: Plantae
- Subkingdom: Tracheobionta
- Super division: Spermatophyta
- Division: Magnoliopsida
- Class: Eudicots
- Subclass: Dilleniidae
- Order: Malvales
- Family: Malvaceae
- Genus: Sida (Linn.)
- Species: *Sida cordifolia* Linn.

Figure 3: (a) diagrammatic representation of plant (b) original plant (c) *Sida cordifolia*

A perennial, short erect shrub with much stellate soft and covered with densely matted wooly hairs all over, pubescent wooly herb growing about 60cm with short stem and branches.

Regional Names[9]

- **Tamil:** Nilatutti, Chithamutti, Arivalmanaippundu
- **English:** Country mallow
- **Telugu:** Antisa, Chirubenda, Muttavapulgamu, Suvarnamu, Chitimutti, Tutturabenda
- **Hindi:** Barial, Bariar, Khareti, Kharenti, Kungyi
- **Malayalam:** Katturam, Velluram
- **Marathi:** Chikana, Khiranti
- **Bengali:** Bala, Barila, Brela, Svetberela
- **Gujarati:** Baladana

Various Ayurvedic Classical textbooks and published research article journals were reviewed and analysed. A search in the pharmacodynamics pertaining to *Bala* (*Sida cordifolia*) as a whole plant from various classics reveal that the taste of this drug is *Madhura* (sweet) and its *Guna* (property) is light, slimy, and unctuous which is a very vital information for us to confirm its superiority over the deranged, crumbled, crest fallen organs to get rearranged in their full form to perform their action again with full capacity. A critical analysis of this drug is required for its action in an Ayurvedic way to know how it can reach to the remotest areas of the body to deliver its properties and actions to bring out a positive result to the one who is afflicted with internal damages of the structural elements.

General Description about the drug *Bala* (*Sida Cordifolia* Linn.)

Bala has been widely used since ancient time for treating various ailments and considered to be one of the *Rasayana* plants that have great medicinal importance. It is mentioned under *Balya* and *Bramhaniya dashaimani* according to *Caraka*[7], and under *Madhura skandha* and *Vatasamsamana* by *Susrutha.*

Synonyms

Table 1: Below describes the Synonyms of *Bala* mentioned in various *Nighantus*

Synonyms	*D.N*[10]	*B. N*[11]	*R. N*[12]	*K. N*[13]	*M.P. N*[14]	*P. N*[15]
Badiyalaka	+	-	-	-	-	-
Baladhya	-	-	+	-	-	-
Balini	-	-	-	+	-	-
Bhadra	-	-	+	-	-	-
Bhadrabala	-	-	+	-	-	-
Bhadrodani	+	-	+	+	+	-
Kharakakashtika	-	-	-	+	-	-
Kharayashtika	+	+	+	-	-	-
Vataghni	-	-	-	-	+	-
Vatyalaka	-	+	-	+	+	-
Vatyali	-	-	+	-	-	-
Vatyapushpi	-	+	-	-	-	-
Kanaka	-	-	-	-	-	+
Krura	-	-	-	+	-	-
Motapati	-	-	+	-	-	-
Ōdanavha	+	-	+	-	-	-
Ōdanika	+	-	-	-	-	-
Phanijivaka	-	+	-	-	-	-
Prahasa	-	-	-	-	-	+
Raktatandula	-	-	+	-	-	-
Samanga	+	-	+	+	+	-
Shītapaki	+	-	-	+	+	-

Varieties of *Bala*[16]

Table 2: Below Describe the Varieties of *Bala* Mentioned in Classical Textbooks

Varieties	Name	Botanical Name
Baladvaya (C.S)	*Bala* *Atibala*	• *Sida cordifolia* Linn. • *Abutilon indicum* Linn.
Balatraya (A.H)	*Bala* *Atibala* *Nagabala*	• *Sida cordifolia* Linn. • *Abutilon indicum* Linn. • *Grewia hirsute* Vanb.
Balachatustaya (K.N) and *(B.N)*	*Bala* *Atibala* *Nagabala* *Mahabala*	• *Sida cordifolia* Linn. • *Abutilon indicum* Linn. • *Grewia hirsute* Vanb. • *Sida rhombifolia* Linn.
Balapanchaya (R.N) and *(P.N)*	*Bala* *Atibala* *Nagabala* *Mahabala* *Rajabala*	• *Sida cordifolia* Linn. • *Abutilon indicum* Linn. • *Grewia hirsute* Vanb. • *Sida rhombifolia* Linn. • *Sida veroniceafolia* Lom.

Classification of *Bala* based on different *varga*

Table 3: Below Describes the *Varga* based Classification of *Bala* Mentioned in *Nighantus*

Nighantus	*Vargas*
Dhanvantari Nighantu (D.N)	*Guduchyadi Varga*
Bhavaprakasha Nighantu (B.N)	*Guduchyadi Varga*
Raja Nighantu (R.N)	*Shatahwadi Varga*
Kaiyadeva Nighantu (K.N)	*Oushadhi Varga*
Madanapala Nighantu (M.P.N)	*Abhayadi Varga*
Priya Nighantu (P.N)	*Shatapushpadi Varga*

Chemical composition[17,18]

- Alkaloid part of whole plant– 0.085%
- Alkaloid mostly found in seeds with 0.32%
- Fatty acids, mucilaginous matter, phytosterol, potassium nitrate and resin are also present.
- Study conducted on chemical constituents of root it has alkaloids like-beta- phenethylamine, hypaphorine, vasicine, vasicinone and vasicinol, liberal amounts of choline and betaine are also present.
- Studies have proven that *Bala* root has (anti-inflammatory, hepatoprotective, analgesic, antioxidant, neuroprotective, anti-osteoarthritis) properties.
- Highest antioxidant property- Among all types of *Bala*– *Sida cordifolia* root has rich content of polyphenols. The phenolic compound has excellent free radical scavenging property.
- The flavonoids, a group of polyphenolic compounds have free radical scavenging activity, inhibition of hydrolytic and oxidative enzyme and have anti-inflammatory action.

Parts Used– Official part used in all formulations is *Root (Balamula).*

The roots of this drug are cooling, astringent, aromatic, bitter, demulcent, febrifuge, stomachic, nervine, and cardiac tonic, anti- arthritic, anthelmintic, antipyretic and immunomodulator.[19]

Research Studies on *Sida cordifolia* root and its unique Phyto-pharmacological properties are mentioned below:

1. Root of *Sida Cordifolia* reported to have high antioxidant property. [20]
2. Ghosal et al. isolated alkaloids from the roots of *S. cordifolia* contains high amounts of choline and betaine compounds. [21]
3. According to Franzotti et al. and Sutradhar et al. root possess analgesic and anti-inflammatory properties.[22,23]
4. In another study by Sutradhar et al. authors isolated and investigated two new bioactive flavones and it shown significant analgesic and anti-inflammatory activity. [24]
5. Momin et al. performed phytochemical screening which showed the antioxidant, antimicrobial and analgesic activity of *Bala*. [25]
6. Kanth and Diwan et al. studied hypoglycaemic, analgesic, and anti-inflammatory activities with roots of *S. cordifolia* extracts and it was founded to have anti-diabetic properties. [26]
7. Mahrukh et al. evaluated hypoglycaemic, anti–hyperlipidaemic and antioxidant activities of *S. cordifolia* root and highly significant results were seen. There was a significant increase observed in this study in the antioxidant enzymes such as CAT and SD (Superoxide – dismutase). [27]
8. Sumath & Mustafa et al. conducted research on anti-stress and adaptogenic property of S. cordifolia root results showed the reduced plasma cortisol and blood glucose levels. [28]
9. Rao & Mishra et al. studied the hepatoprotective activity of S. cordifolia root against carbon tetrachloride, paracetamol, rifampicin induced toxicities and highly significant results were seen. [29]
10. Rejitha et al. studied the hepatoprotective activity of roots against alcohol induced liver toxicity and found to reduce the oxidative stress in the body. [30]

Pharmacodynamics[31]

Table 4: describes the *Rasa panchaka* of *Bala* mentioned in various *Nighantus*

Rasa Panchaka		***D.N***	***B.N***	***R.N***	***K.N***	***M.P.N***	***P.N***
Rasa	*Madhura*	+	+	-	+	+	+
	Atitikta	-	-	+	-	-	-
Guna	*Snigdha*	+	+	-	+	+	+
	Laghu	-	-	+	-	-	-
Virya	*Shita*	+	+	-	+	+	+
Vipaka	*Madhura*	+	+	+	+	+	+
Dosha karma	*Tridoshahar*	+	-	-	+	-	-
	Vatapittahar	-	+	-	-	+	+

Properties and Action

Bala is considered as one of the important chief ingredients used in various Ayurvedic formulations and it has been used in different forms in current medical practice. The drug has got many properties and action as mentioned below:

Karma: *Vata- pitta hara, Bramhana, Balya, Vrshya, Ojovardhaka, Rasayana, Hrdya, Rakta-pitta Samaka, Jwaraghna, Vishamajwarahara, Krimighna, Snehana, Anulomana, Nadībalya, Vatahara* and *Vishagna.*

Roga Karma: Abyantara Roga*- Kshayaja Rogas, Krshata, Dourbalya.* All *Vatavikaras* having *Dathukshaya, Adhmana, Vibandha, Hrddourbalya, Raktapittahara, Prameha, Vatarakta, Rajayakshma, Garbhasaya Dourbalya, Mutrakruccha* and *Mutravikaras.*

Bahya Rogas: *Vranashotha, Netrarogas.*

Go-Ghritam: It is mentioned under the class of clarified butter or anhydrous milk fat obtained by heating butter or cream of milk over 100°C, melts at 35°C water content is removed by evaporation and the residual content is then filtered and stored as pure ghee. [32]

Regional Names

- Sanskrit: *Ghrta, Ajya, Havi, Sarpi*
- English: Clarified butter, Ghee
- Tamil: Pasu Nei
- Hindi: Gaya ghī
- Malayalam: Pasu Ney
- Telugu: Nei, Neyyi
- Kannada: Tuppa
- Bengali: Gava ghee
- Gujarati: Ghee
- Marati: Tupa

Fig 4: Shows cow's ghee (*Go Ghritam*)

Classification of *Ghirta* According to Various Classical Textbooks

Table 5: Below Describes the Types of Classification of *Ghritam*

Classification Type	*C.S* [33]	*A.H* [34]	*S.S* [35]	*Sh. S* [36]	*Bh. Pa*[37]	*Ka. S* [38]
Yoni bheda - Jangama sneha dravya	+	+	+	+	+	+
Chaturvidha sneha (Ghritam as Uttama sneha)	+	+	+	+	+	+
Special property- *Samskarasyanuvartana* property, Given from birth *"Janmadhyeva cha shīlanath"* *"Sahasra vīrya"* (increases the potency of the drug used) and *"Karmasa hasrakrit"* (enhances the therapeutic action to cure various ailments) *"Sanskarath"* and *"Sarvasatmyatccha"* (due to the ability of its process and generalized acceptability).	+	+	-	-	-	+
Based on digestion Least *Guru* and *Vatahara*	-	+	+	-	-	+

Properties of *Ghrta* [39]

1. *Rasa: Madhura*
2. *Guna: Snigdha, Mridu, Saumya, Yogavahi, Alpabhishyandi*
3. *Virya: Sheta*
4. *Vipaka: Madhura*
5. *Doshakarma: Tridoshas hara*

Pharmacological Actions of *Ghrta*

Table 6: Describes Various Classical References of Pharmacological Properties of *Ghritam*

Roga Karma	*C.S*	*S. S*	*A.H*	*D.N*	*B. P*	*K. N*	*K. S*
Ojovriddhi	+	+	+	--	+	+	+
Rasayana	--	--	--	--	+	--	--
Vayasthapana	--	+	+	--	+	+	+
Aayushya	--	+	+	+	+	--	+
Balakara	--	+	+	+	+	+	+
Agidepana	+	+	+	+	+	+	+
Brimhana	--	--	--	--	--	+	+

Alpabhishyandi	--	+	--	--	--	--	--
Sleshmabhivardhana	+	+	--	--	--	--	--
Medovriddhi	--	+	--	--	--	--	--
Pitta- vata hara	+	+	--	--	+	--	+
Mridukara	+	+	--	--	--	--	--

Major Properties Considered Under my study are

- *Pitta - Vata hara*
- Beneficial for *Datuposhana*
- Useful in *Datukshayajanya vatavikara*
- Has *Agnidepana* property (enhances digestive power)
- Gives *Snehana* (nourishes upto cellular level)
- *Mridukara* (internally as well as externally imparts softness)
- *Balayur vardana (*provides strength and increases lifespan of an individual)
- *Vayasthapana* (delays ageing)
- *Sleshmabhivardhana* (replaces the lost content of *Kapha*) and beneficial for *Ojas* (enhances immunity power)

Chemical composition of *Go-Ghrta*[40]

- Free fatty acids – 0.1-0.44%
- Triglycerides – 97-98%
- Diglycerides – 0.25-0.4%
- Monoglycerides – 0.016-0.038%
- Sterols – 0.22-0.41%

It also contains high number of vitamins like A, D, E, K

Reported Researches on *Go Ghrta*

Lipophilic Action of Ghee: Ghee is the most edible fat and has only 8% of saturated fatty acids. Ghee formulations are easily digested, absorbed and the drug target organ system is very fast due to the lipophilic nature. Human cell membrane is made up of lipid molecules the lipophilic action of ghee facilitates the active drug molecules into the cell into the mitochondria, microsome and nuclear membrane and the targeted effect are produced.

Antioxidant Effect of Ghee: It has got free radical scavenging capacity. Since it contains high amounts of beta- carotene and vitamin E are considered as powerful anti-oxidants. When Free radicals are produced in the body due to oxidative stress it oxidizes the lipid present in cell membrane and blood and are called as lipid peroxides highly injurious to health. Due to high content of anti-oxidants present in ghee this has capacity to arrest this mechanism and prevent the body from oxidative damage.

Animal studies reported the effects of ghee[41]

Ghee is superior to other oils/ fats because of (MCFAs) medium chain fatty acids content directly absorbed by the liver to generate energy. Also helps to burn unwanted fats from the body. (St-Onge & Jones, 2008: Nokasa et al, 2009)

- Decreased the serum total cholesterol level, low density lipoprotein (LDL), very low-density lipoprotein (VLDL) and triglycerides
- Decreased liver total cholesterol, triglycerides, and cholesterol esters
- Lower the level of non-enzymatic induced lipid peroxidation in liver homogenate. [42]
- Research shows that adequate production of butyric acid supports the production of T killer cells in gut and maintain strong immune system
- *Go-Ghritam* comprises polyunsaturated fatty acids (PUFA) are essential fatty acids which helps to carry the medicament in micelle form to penetrate in any normal cell followed by β oxidation releases the active components of the medicaments with high rate of absorption and to reach the target cell to show their effects.

Recent studies shown that cow's ghee contain Conjugated Linoleic Acid (CLA), Butyric acid, sphingomyelin, lipids and vitamins like A, D, E, and it increases the retention of calcium up to 45% and phosphorous up to 57% (Kehar 1956, Steggarada 1951)

Preparation of *Balamula Ghritam*[43]

Detailed preparation of medicated ghee has been mentioned in the classical textbook of *Sarangadhara Samhita* and *Bhaisajya kalpana vijnanam*. The medicine selected for the study (*Balamula Ghritam*) prepared by following the methods mentioned in these textbooks.

Standard Rule - One part of *Kalka,* four parts of *Ghrta/Taila* and four parts to *Taila/Ghrta* of any liquid (*Drava dravya*). [44]

Requirements

Materials Required

1. Broad mouthed stainless steel vessel
2. Gas burner with stove
3. Weighing machine
4. Measuring jar
5. Pulverizer
6. Stirrer or spoon/ spatula
7. Strainer or clean piece of cloth– 2 in number
8. Air tight storage containers with sealing

Ingredients Required

Table 7: List of Ingredients Required for *Balamula Ghritam*

Drugs	Part Used	Quantity
Kvatha Dravya		
Balamula (*Sida cordifolia* Linn)	*Sida cordifolia* root	7 kg
Water	-	56 litres
Kalka Dravya		
Balamula (*Sida cordifolia* Linn)	*Sida cordifolia* root	1750 grams
Sneha Dravya		
Go Ghritam	Cow's ghee	8 litres

Collection of Raw Drugs: Dry and good quality raw drugs were procured from local vendor and were preserved properly before the start of medicine preparation. The medicinal preparation was carried out in batches at Sri Sankara Ayur Pharmacy of Sri Jayendra Saraswathi Ayurveda College and Hospital, after obtaining Drug Authentication Certificate from the expert of Dravya Guna Department.

Fig 5: *Balamula* (Sida cordifolia root)

Fig 6: Cow's ghee (*Go Ghritam*)

Preparation of *Kvatha* for *Balamula Ghritam*

7000 grams of *Balamula* was made into coarse powder and to those 8 times of water was added then kept in a wide mouthed vessel, was allowed to boil till it was reduced to 1/4th quantity. Obtained 14 litres of *Balamula kvatha* was filtered and used for the preparation of *Ghritam.*

Fig 7: *Balamula* made coarse powder added in to 8 times of water and boiled well

Fig 8: obtained 14 liters of *Balamula kvatha*

Preparation of *Kalka*

1750 grams of *Balamula* was made into fine powder by using pulverizer. The obtained *Balamula churnam* was mixed with sufficient quantity of water and made into a fine paste.

Fig 9: *Balamula* added into Pulverizer made into fine paste Fig 10: Prepared *Balamula Kalka*

Preparation of *Balamula Ghritam*

A broad mouthed stainless steel was taken and 8 litres of *Go Ghritam* was added and it was kept *in Mandagni*. To which 14 litres of prepared decoction *Balamula kvatha* was added and mixed well. Then prepared

Balamula Kalka was added into the *Sneha* preparation and the process was carried out in *Mandagni* and uniform temperature maintained. The contents are frequently stirred and boiled well. The entire preparation of *Balamula Ghritam* took 3 days (03.09.2021 to 05.09.2021) and on 4th day (06.09.2021) packing was done.

Fig 11: *Go Ghritam* added into broad vessel and kept in *Mandagni*

Fig 12: *Balamula kvatha* added to *Ghritam*

Fig 13: *Balamula Kalka* added to *Ghritam*

Fig 14: *Madhyama paka lakshanas* of *Balamula Ghritam (phena shanti lakshanas)*

Test for Completion– (*Madhyama paka lakshanas* observed)

- Disappearance of foam in *Balamula Ghritam kalpana (Phena shanti)* was observed.
- *Kalka* of the drug was rolled into *Varti* form (*Vartivat snehakalkaha*).
- Good color and pleasant smell of the drug were tested (*Gandavarna rasotpatti*).
- *Varti* when put on fire does not produce any crackling sound *(Sabdaheno agninishiptaha).*

Fig 15: *Kalka* rolled into *Varti* Form (*Madhyama Paka Lakshanas*)

Storage of *Balamula Ghritam*

The prepared *Balamula Ghritam* was filtered using a clean plain white cloth and after cooling it was packed in a 200ml air tight container bottle with label containing– name of medicine in English, and regional language, dose, batch number, manufacturer, manufactured date, expiry date was mentioned and was properly sealed.

Fig 16: *Balamula Ghritam* filtered using clean white cloth

Fig 17: *Balamula Ghritam* (final product)

Administration of *Balamula Ghritam* as *Uttarabhaktika Sneha*

Uttarabhaktikasneha- *"Indriyasthiratamurdhvamurdhvajatrugadakshayam"* when *Sneha* is given after food it causes stability of the sense organs and cures the disorders of upper parts of body.

Synonyms of *Uttarabhaktika Sneha*– *Bhojanothara sneha, Uttarabhakta sneha, Bhaktopari sneha.*

Present study focuses on the management of cervical spondylosis which is considered as *Urdwajatrugata vikara*, hence *Uttarabhaktika snehapana* is selected as the best treatment choice. As mentioned above the effects and indications of *Brimhana snehapana* when prescribed after food has the power of rendering nourishment up to cellular level.

Administration of *Uttarabhaktika Sneha* Time and Dosage

- ***Pratah Bhojana Kala***– *Sneha* prescribed after morning meals indicated in *Vyana vayu vikaras*. In cervical spondylosis also *Vyana vayu* involvement seen (sensory and motor functions are guided by *Vyana vayu*).
- According to *Acharya Vagbhata* he mentioned *Beshaja kala* for *Urdhwa jatrugata vikaras* is *Nishi ("Urdhwajatruvikareshu Swapnakale Prashasyate").*[45]

Selection of *Matra* for *Uttarabaktikasneha*[46]

Table 8: Describes the Selection of *Matra* for *Acchapeya Sneha prayoga*

Matra prayoga	*Yama*	Digestion time
***Uttamamatra Prayoga* - 24 hours Totally**		
Hrasiyasi matra	*4 Yama*	12 hours
Hrasva matra	*6 Yama*	18 hours
Uttama matra	*8 Yama*	24 hours (ahoratra)
***Madhyama Matra Prayoga* – 12 hours Totally**		
Hrasiyasi matra	*2 Yama*	6 hours
Hrasva matra	*3 Yama*	9 hours
Madhyama matra	*4 Yama*	12 hours
***Hrswa Matra Prayoga* – 6 hours Totally**		
Hrasiyasi matra	1 *Yama*	3 hours

Based on the above tabular column the *Balamula Ghritam* which was prescribed 10ml quantity morning and night after food was aimed to get digested in 3 hours (*Hrasiyasi matra*). For a prescription of a *Sneha dravya*, one should have a good digestive capacity, with that in mind *Trikatu churnam* 1tsp (5gm) was given morning and night with 1 ounce (30ml) of hot water ½ hour after food for 3 days prior to the prescription of *Balamula Ghritam.*

Trikatu Churnam- As a whole it possesses *Katu rasa, Ushna vīrya → Agnidepana → Kapha Vatahara* [47]

Qualities of *Ushnajala* – has qualities like *Dīpana* (carminative*), pacana* (digestive) *Laghu* (light), *vata kapha shamana.* [48]

With the perfect rectification of *Jataragni* into *Samagni avastha*, only the contemplation of prescribing *Balamula Ghritam* was thought of.

DISSCUSSION

Digestion and Metabolism of Lipids – Modern View [49,50]

At the level of GI– Digestion, absorption, and transportation of lipids: Lipids consumed are in the form of triglycerides and cholesterol. Digestion of triglycerides into monoglyceride occurs in buccal cavity by lipase reaches the stomach where the gastric lipase released by chief cells further breakdown fat molecules converted to monoacylglycerol and free fatty acids. Fat molecules then reach duodenal part of small intestine by the action of bile and pancreatic lipase absorption of lipids take place. Liberated fatty acids can either be short chain fatty acids or long chain fatty acids. Short chain fatty acids are hydrophobic and hence they dissolve in watery intestinal chyme and enter blood capillary.

Large chain fatty acids are not water soluble hence require bile salts for emulsification. Inside the absorptive cells, the long chain fatty acids+ monoglycerides are recombined to form triglycerides, which aggregate into globules along with the phospholipids and cholesterol become coated with proteins. Large spherical masses about 80mm in diameter called as chylomicrons. Chylomicrons are formed in the endoplasmic reticulum in absorptive cells of small intestine. Newly secreted chylomicrons are from the basolateral membrane onto lacteals where they join to become a chyle. Lymphatic vessels carry the chyle to venous return of systemic circulation. This is the transportation unit and amphipathic in nature helps to transport the lipids absorbed from intestine to adipose tissue, cardiac and skeletal muscle tissues.

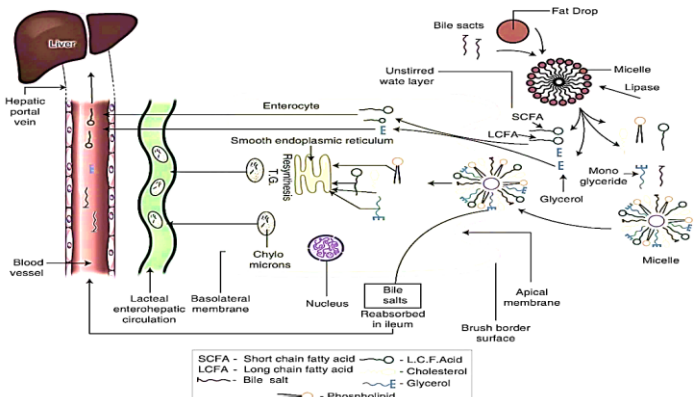


Fig 18: Shows the Digestion, Absorption and Transportation of Lipids

***Balamula Ghritam* contains 2 ingredients *Balamula* (*Sida cordifolia* root) and Cow's ghee (*Go – Ghritam*)**

Sida cordifolia root said to possess anti-inflammatory, analgesic, antioxidant, neuroprotective and anti-osteoarthritic properties considered as best nervine tonic and immunomodulator.[51] The abundant phyto chemical contents of choline and betaine helps in maintaining proper brain and nervous system functions, healthy structural integrity of cell membrane, DNA synthesis, inhibits osteoclastogenesis, prevents osteoporosis and helps in maintaining bone strength.[52,53]

Cow's Ghee: 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 are needed for maintain the structural integrity of bone. [54]

Antioxidative Effect of *Balamula Ghritam* and its Action on Neuro Degenerative Condition w.s.r Bone Degeneration (Osteoporosis)-[55,56] Oxidative stress that is produced in cervical spondylosis majorly exist between the generation of reactive oxygen species and damage limitation by the antioxidant system, it is a phenomenon that produce an imbalance between ROS and antioxidants in a biological system. Loss of antioxidant leads to accelerated bone loss through activation of tumour necrosis factor alpha (TNF – α) and RANKL through NF-κB dependent signalling pathway. Administration of dietary/plant-based antioxidants with rich amount of vitamin C, E, alkaloids, flavonoids, polyphenols, carotenoids, phenolic acid, linolic acid found to be very effective in the treatment of osteoporotic conditions.

Phenolic compounds like flavonoids present in plants inhibit lipid peroxidation and lipoxygenases. Antioxidants derived from plants are natural products with radical scavenging capacity. These plant-based antioxidants have been reported to donate protons and thereby reducing the ROS and prevent oxidative stress in human health. [57]

Recent research reveals that *Balamula* (*Sida cordifolia* root) possess high amount of polyphenolic content with abundant antioxidative property in it and they are considered to have an excellent role in the prevention of degeneration of bone. It also contains rich source of alkaloids, flavonoids which are essential dietary antioxidant supplement exerts various biological effects like anti-inflammatory, anti-ageing and neuroprotective properties. [58]

Go-Ghritam also contain rich source of Vitamin A, D, E and beta-carotene possess high antioxidant property.

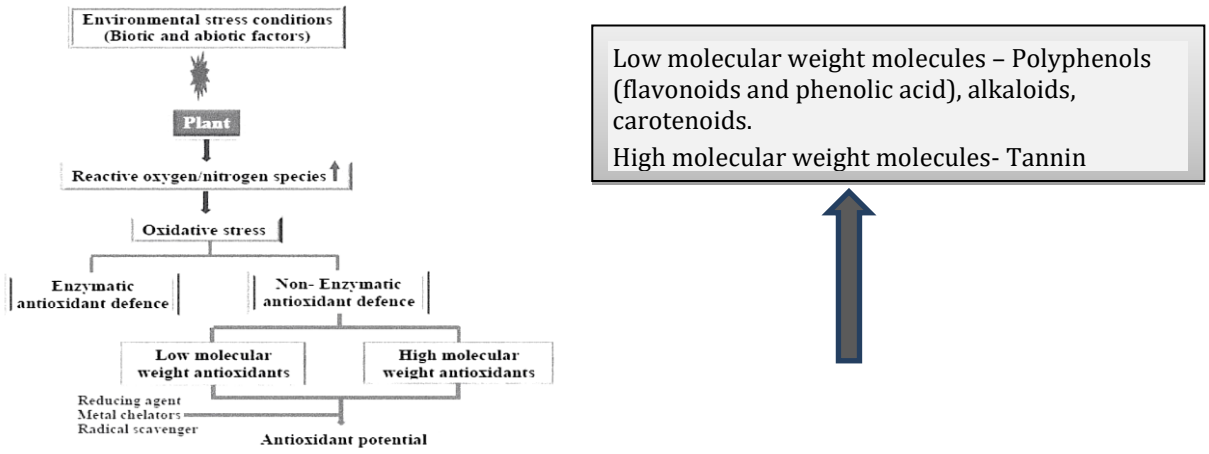


Fig 19: Describes Mechanism of dietary/plant-based Antioxidant with low Molecular Weight Molecules and high Molecular Weight Molecules

Mode of Action of *Abhyantara Sneha (Uttarabhaktika Sneha*) [59]

Milk fat globule membrane (MFGM) is a highly structural membrane that surrounds the milk fat globules and contains unique beneficial lipids and specific proteins. The primary lipids of MFGM are polar lipids and significant amount of neural lipids like cholesterol, triglycerides, diglycerides and monoglycerides (Walstra, 1974, 1985; Kwak et al., 1989) MFGM polar lipid fractions consisting mainly of sphingolipids and glycerophospholipids. Under the sphingophospholipids the most representative being sphingomyelin found to be high in brain and neural tissues, plays a vital role in various cell activities such as regulation, proliferation, and growth (Futerman & Hannun, 2004). Phospholipids are essential fatty acids and are essential for the biological functions of cell membrane their functions including signalling and transport and provides stability to bones. It also reduces the inflammatory reactions by inhibiting the prostaglandins helps to reduce joint stiffness and correct the functional impairment. [60]

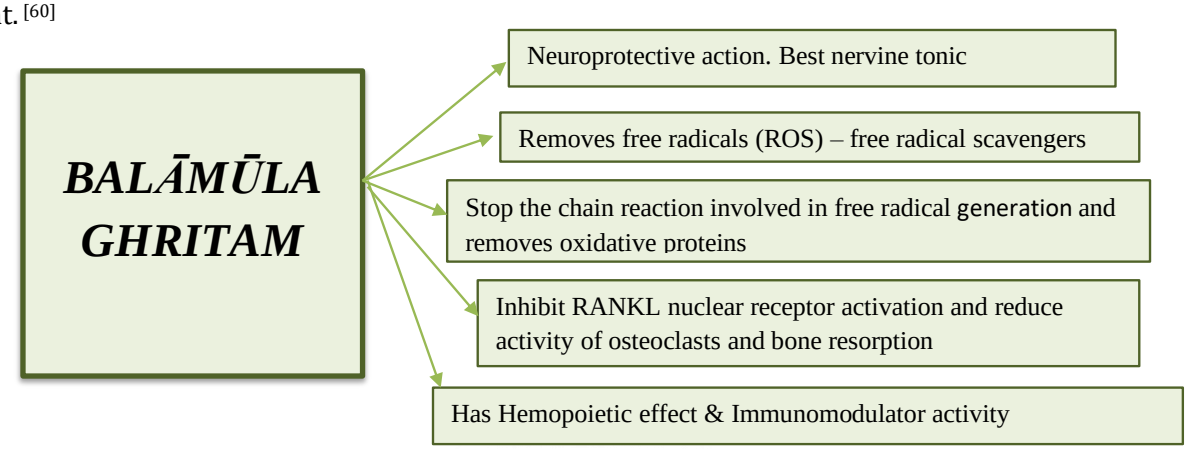


Fig 20: Antioxidative Effect of *Balamula Ghritam*

***Balamula Ghritam* Digestion and Absorption– Ayurvedic View**

The food ingested at the proper time is drawn into the alimentary tract by *Prana vata*; its hard/big masses split and made soft by the liquid; then the *Audaryagni (Jataragni)* activated by the *Shamana vata* cooks the food present in the *Amashaya* (stomach) just like external fire cooks the rice and water kept in the pot. Although the food consists of all the taste, it first becomes *Madhura* (sweet) and it gives raise to the production of *Kapha*, of frothy nature, next undergoing further cooking it becomes *Amla* (sour) and gives raise to the production of *Pitta,* then getting expelled from the *Amashaya* (stomach) it gets dried, becomes solid and *Katu* (pungent) and gives raise to the production of *Vata*.

The three successive stages of transformation the *Madhura, Amla, Katu* are known as *Avastha paka* each on leading to the production of *Kapha, Pitta* and *Vata* respectively. All these three stages together form the first phase of digestion of food. [61] The *Go-Ghritam* which contains *Balamula* has *Madhura rasa, Snigdha guna, Shita Virya, Madhura vipaka* and it is having qualities like *Brimhana, balya, Vrishya, Vata- pitta hara, Ojovardhaka, Rasayana, Snehana* and *Anulomana.* On the other hand, the *Go Ghritam* contains has a special property like *Samskarasyanuvartana, Sahasravīrya* 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 *Dīpana, 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.

Transportation of *Balamula Ghritam* to the Targeted Site

The properties of *Balamula Ghritam* on its rapid absorption become finest essence and attach to micelles which are small droplets and form the micelle- component complex called chylomicrons. From this it is further taken by the lymph vessels and is released into the blood stream, reaches the damaged site – cervical spine and replaces the lost qualities of *Prthvi* and *Jala mahabhuta* to get filled up with this new arrival of the essence of *Balamula Ghritam.*

After undergoing a curious transformation process, a "baptism" occurs in liver by which the exogenous *Balamula Ghritam* essence *(Vijathīya*) is converted to endogenous *(Sajathīya)* 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 (*Vijathī*ya), whereas the *Balamula Ghritam* essence with blood in systemic circulation is *Sthaye/Poshya aushadam* and is endogenous (*Sajathīya).*

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 *Greva pradesha* with the new arrival of the essence of *Balamula Ghritam*. [62]

CONCLUSION

It is quite possible for the drug to reach any spot of the body provided it is prescribed at the right time with appropriate dose to be delivered accurate. The above concept is an example for the drug delivery with its capsulated properties to get aligned with the spot of damage there by rectifying the damage caused due to dehydration. 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 signalling 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. The mucilaginous nature of this drug is the most vital part of drug dispensation here to get the result on a positive note.

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