



# An Open Label Single Arm Interventional Study To Evaluate The Efficacy Of *Bilvadi Gutika* On Raised Level Of ESR In Musculoskeletal Disorders

Sanjana P \* Dr. Beena MD\*\* Dr. P.Sudhakar Reddy\*\*\*

\*IV BAMS \*\* Associate professor, Department of PG Studies in Kayachikitsa, \*\*\*Prof& Head, Dept.of PG Studies in Swasthavritta , JSS Ayurveda Medical College, Mysuru-570028

## Abstract.

**Background:** Health is state of having equilibrium of *dosha*, *dhatu* and *mala* in the body and disease is termed when they are deranged<sup>1</sup>. Ayurveda strongly believes that the diseases are originated due to *Agnimandya* (unable to digest even a light food) which in turn leads to the formation of *Amavisha* or *amadasha* produced out of improper digestion. It is also stated that the formation of *Ama* need not necessarily be due to *Jatharagnimandyajanya* but may be due to impairment in the *dhatwagnivyapara* also. The clinical features of musculoskeletal disorders are closely related with the different diseases mentioned under *vatavyadhi* and *amavata* wherein there is involvement of *ama* or *amavisha* is responsible for the production of diseases.. Musculoskeletal disorder is one of the major causes for morbidity & 2nd most common cause for disability worldwide. According to WHO 40% people over age of 60 suffer from musculoskeletal diseases & 80% of people have low back pain at some point of life. The presence of raised level of ESR which is seen in inflammatory conditions of musculoskeletal disorders if addressed in the early stage will be helpful in breaking the pathology. **Objective:** To evaluate the efficacy of *BilvadiGutika* in raised level of ESR in Musculoskeletal Disorder. **Materials & Methodology:** *Bilvadi gutika* was administered in the dose of one tablet three times daily before food for 14 days in the 21 subjects suffering from musculoskeletal disorders has raised ESR more than 20mm/1 hour.**Result:** The study showed significant reduction of symptoms of musculoskeletal disorders and the paired t-test for ESR showed statistically insignificant with p value-0.360. **Conclusion:** The study showed- *Bilvadi gutika* has moderate effect in decreasing the raised ESR in musculoskeletal disorders. *Bilvadi gutika* has significant effect in reduction of symptoms of musculoskeletal disorders.

**Key words:** *Bilvadigutika*, *Amavisha*, musculoskeletal disorders, ESR

**Corresponding author:** Dr.Beena MD - drpbsreddy@yahoo.com

**Introduction:**

“*Rogastudoshavaishamyamdoshasamyamarogata*”: When the dosha, dhatu and mala in the body are in equilibrium it is said to be the state of health and disease when they are deranged<sup>1</sup>. Ayurveda strongly believes that the diseases are originated due to *Agnimandya* (unable to digest even a light food) which in turn leads to the formation of *Aamavisha* or *Amadosha* produced out of improper digestion<sup>2</sup>. It is also stated that the formation of *Ama* need not necessarily be due to *Jatharagnimandyajanya* but may be due to impairment in the *Dhatwagnivyapara* also<sup>3</sup>.

The clinical features of musculoskeletal disorders are closely related with the different diseases mentioned under *Vatavyadhi* and *Amavata* wherein there is involvement of *Ama* or *Amavisha* is responsible for the production of diseases. Musculoskeletal disorder is one of the major causes for morbidity & 2<sup>nd</sup> most common cause for disability worldwide. According to WHO 40% people over age of 60 suffer from musculoskeletal diseases & 80% of people have low back pain at some point of life<sup>4</sup>.

The laboratory investigations like ESR, CRP, and presence of certain Antibodies are diagnostic criteria in musculoskeletal disorders. The presence of raised level of ESR which is seen in inflammatory conditions of musculoskeletal disorders if addressed in the early stage will be helpful in breaking the pathology.

*Bilwadigutika* is best given in *Ajeerna, Ama, Garavisha, Jwara, visha* mentioned in *AstangaHridaya*<sup>5</sup>. We find references of all Musculoskeletal diseases like Rheumatoid arthritis, Osteoarthritis, Sciatica, polymyalgia etc in which ESR will be raised<sup>6,7</sup> Hence to evaluate the efficacy of *BilwadiGutika* in raised level of ESR in musculoskeletal disorder has been studied.

**Objective:**

To evaluate the efficacy of *BilwadiGutika* in raised level of ESR in Musculoskeletal Disorder

**Material and Method:**

**Source of data:** Subjects visiting IPD and OPD of Kayachikitsa

**Collection of data:**

- a. Clinical study design: Single group, open label, interventional, clinical study
- b. Sample size: A single group of 21 subjects diagnosed with musculoskeletal disorders having *Amalakshana* with increased ESR more than 20mm/1 hour irrespective of the gender fulfilling the inclusion criteria were selected for the study.

**Sample size:** 21 subjects

**Inclusion criteria:**

1. Any Musculoskeletal diseases presents with clinical features.
2. Patients of age group between 20 to 70 years with raised ESR levels irrespective of the gender

**Exclusion criteria:**

- 1 Any systemic diseases which interfere with the administration of *Bilwadi Gutika*.
2. The patients with severe pain.

**Diagnostic criteria:**

- 1) Clinical features in musculoskeletal disorders having
  - ✓ Shotha in sandhi(Swelling in joints)
  - ✓ Shoola in sandhi(Pain in joints)
  - ✓ Agnimandya (Loss of appetite)
  - ✓ Alasya (Tiredness)
  - ✓ Stabdhatta (Stiffness in joints)
  - ✓ Angamardha (Body pains)
  - ✓ Aruchi (Tastelessness)
- 2) Raised ESR more than 20mm/ 1 hour.

**Materials & Methods:**

Bilvadigutika : *Bilwadi Gutika* is an Ayurvedic medicine used for the treatment of snake bite, scorpion sting, spider bite, rodent bite, gastroenteritis, cholera, indigestion, and fever. Generally, it is a drug of choice for toxic effects developed in human body due to any underlying cause or toxic substance of animal origin. The present drug has been taken from *Ashtanga Hrudaya utara Sthana* 36/84-85). The ingredients of Gutika : The *Bilwa moola* — Root of *Aegle marmelos* ,*Surasa Pushpa* (Tulasi) — flower of *Ocimum sanctum* , *Karanja Bija* — *Pongamia pinnata* ,*Phalatraya* — *Amalaki* (*Embllica officinalis*) + *Haritaki* (*Terminalia chebula*) + *Bhibhitaki* (*Terminalia bellerica*) , *Vyosha* (*Trikatu*) — *Sunthi* (*Zingiber officinale*) + *Maricha* (*Piper nigrum*) + *Pippali* (*Piper longum*) , *Haridra Dwya* — *Haridra* (*Curcuma longa*) + *Daru haridra* (*Berberis aristata*) , *Basta Mutra* — *Aja mutra* (Goat Urine)

Indications: *Sarpa Visha* — Snake bite, *Luta, Gara visha* , *Vrischika Visha* — Scorpion Bite ,*Mushika Visha* — Rodent bite , *Visuchika* — Gastroenteritis ,*Ajirna* — Indigestion , *Jwara* — Fever & *Bhuta Badha Nashaka*

For the present study *Bilvadigutika* has been procured from GMP certified pharmaceuticals .

**Methodology:**

**Ethical clearance :** SPL5/JSSAMC/Research project/2021-22

23 subjects suffering from musculoskeletal disorders were selected from OPD of Kayachikitsa, after clinical assessment, subjects were sent to lab investigation for ESR. ESR more than 20 mm/hour has been recruited for study. *Bilvadigutika* were administered 1 tab three times daily before food for 15 days. Two subjects were dropped out, so total 21 subjects were analyzed for assessment.

**Assessment criteria**

The assessment of result was made based on subjective and objective parameters before and after treatment.

**Subjective Parameters:** The following subjective parameters were graded and assessed before and after treatment

*Shoola, Shotha, Stabdhatta, Angamarda, Agnimandhya, Aruchi, Alasya, Trishna Nidraviparyaya and Jwara*

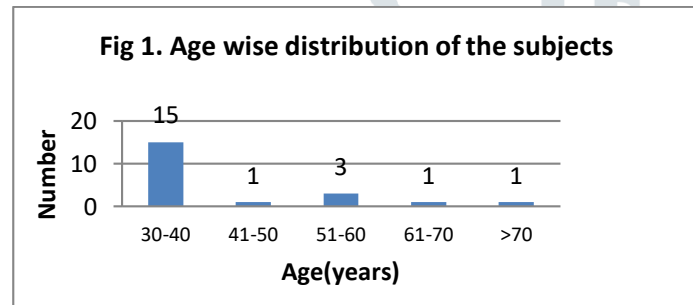
**Objective Parameter:** ESR estimation was carried out before and after treatment

## OBSERVATIONS

Age of the participants ranges from 31 years to 71 years with mean (SD) age is 41.43(11.54) years.

Table 1. Age wise distribution of the subjects

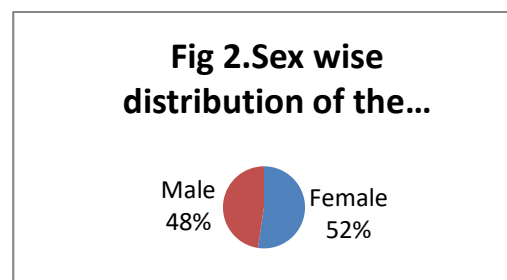
Age(Years)	Number	Percentage
30-40	15	71.4
41-50	1	4.8
51-60	3	14.3
61-70	1	4.8
>7	1	4.8
Total	21	100.0



Among the 21 subjects majority (15) (71.4) were belongs to age group of 30-40 years

Table 2: Sex wise distribution of the participants.

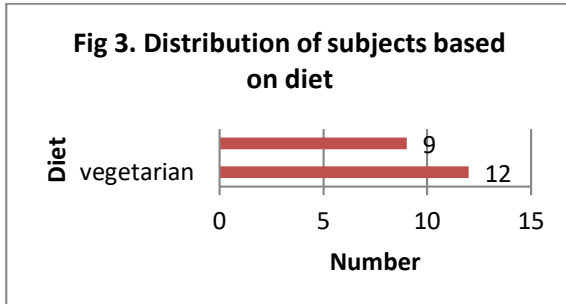
Sex	Frequency	Percentage
Female	11	52.4
Male	10	47.6
Total	21	100.0



Among the 21 subjects ,11(52%) were female

Table 3: Distribution of subjects based on diet

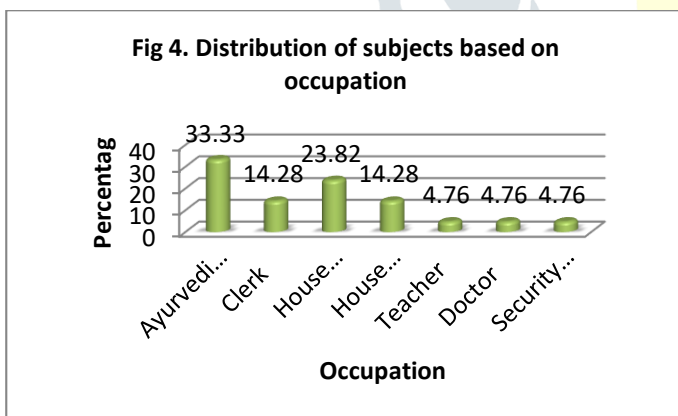
Diet	Number	Percentage
vegetarian	12	57.15
Non vegetarian	9	42.85
Total	21	100



Among 21 subjects, 12 (52%) were vegetarians

Table 4. Distribution of subjects based on occupation

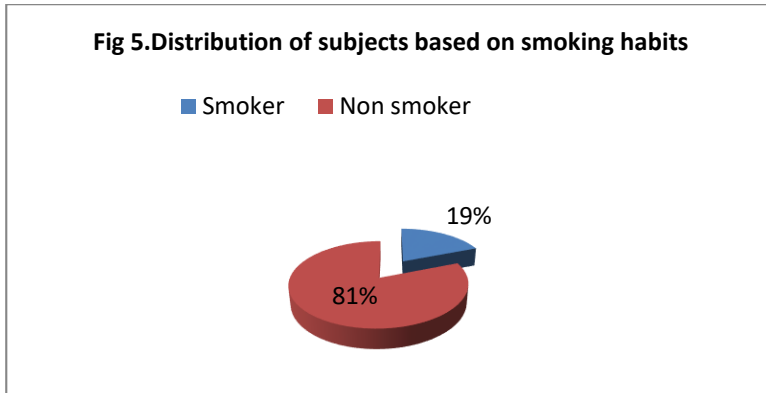
Occupation	Number	Percentage
Ayurvedic therapist	7	33.33
Clerk	3	14.28
House keeping	5	23.82
House maker	3	14.28
Teacher	1	4.76
Doctor	1	4.76
Security guard	1	4.76



Among the 21 subjects, Ayurveda therapist were 33.33%, Housekeeping were 23.82%, clerks & House makers were 14.28%, & teachers, doctors & security guard were 4.76% each

Table 5. Distribution of subjects based on smoking habits

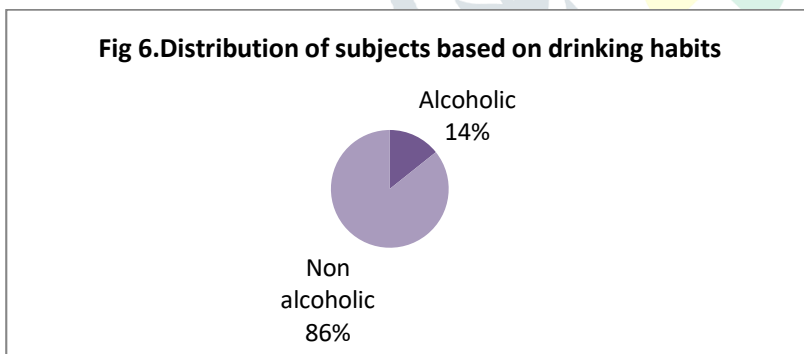
Smoking	Number	Percentage
Smoker	4	19.05
Non smoker	17	80.95



Among the 21 subjects non- smokers were 81% and smokers were 19%

Table 6. Distribution of subjects based on drinking habits

Drinking	Number	Percentage
Alcoholic	3	14.28
Non alcoholic	18	85.72



**Results:** Statistical analysis performed by using Paired Sample t-Test for objective parameter (ESR) and descriptive statistics i.e percentage has been used for symptoms calculation

Table 7: Comparison of ESR readings before and after the treatment

ESR	Before (Mean(SD))	After (Mean(SD))	t-value	p-value*
	40.76(14.68)	37.71(17.47)	0.938	0.360

\*Paired t test

There is no statistical significance difference in the mean ESR before and after the treatment. This could be because of small sample size.

Table 8: Symptoms Before &amp; After

Sl No	Symptoms		BEFORE (Number)	AFTER (Number)
1	Shula (Pain)			
		Severe	14 (66.67%)	5(23.81%)
		Moderate	5(23.81%)	2(9.52%)
		Mild	2(9.52%)	1(4.76%)
		No Pain	0	13(61.90%)
2	Shotha (Swelling)			
		More than 10 joints involved	0	0
		6-10 joints	11(52.38%)	4(19.04%)
		1-5 joints	10(47.62%)	3(14.28%)
		No joints involved	0	14(66.67%)
3	Sthabdata(Stiffness)			
		More than 8hours	3(14.28%)	2(9.52%)
		2-8 hours	5(23.81%)	1(4.76%)
		5min- 2hours	8(38.09%)	3(14.28%)
		Less than 5min	3(14.28%)	2(9.52%)
		No sthabdata	2(9.52%)	10(47.62%)
4	Angamarda(Body Pain)			
		Severe	11(52.38%)	3(14.28%)
		Constant	5(23.81%)	3(14.28%)
		Occasionally	4(19.04%)	3(14.28%)
		Absence	1(4.76%)	12(57.14%)
5	Agnimandya(Loss Of Appetite)			
		Present	11(52.38%)	4(19.04%)
		Absent	10(47.62%)	17(80.95%)
6	Aruchi (Loss Of Taste)			
		Present	11(52.38%)	4(19.04%)
		Absent	10(47.62%)	17(80.95%)
7	Alasya			
		Present	14(66.67%)	6(28.57%)
		Absent	7(33.33%)	15(71.43%)

The above table suggests that majority of the symptoms are reduced after treatment.



## DISCUSSION:

Musculoskeletal disorders are common and it is affected by age, occupation, activity level, lifestyle, family history. According to WHO, 40% over the age of 60 suffer from musculoskeletal diseases. Musculoskeletal are the conditions that can affect muscles, bones and joints. It includes various arthritis, tendinitis, carpal tunnel syndrome, fibromyalgia, bone fractures which can affect any major area of musculoskeletal system including neck, shoulders, wrists, back, hips, legs, knee, feet. The severities of musculoskeletal disorders vary. Main symptoms include recurrent pain, stiff joints; swelling, dull aches which can be some signs of inflammation. Diagnosis of musculoskeletal disorders can be made based on history, using the physical examinations by evaluating the severity of pain, redness, swelling, muscle weakness, muscle atrophy, restricted joint movements, by laboratory tests, imaging test or other diagnostic procedures.

One such laboratory technique which stands as a basic pillar for detection of inflammatory process taking place in body is the ESR. An raise in ESR will be usually seen when inflammation is present and when person is exhibiting the symptoms of inflammatory disorder which includes Fever, Headache, Weight loss, anemia, Joint stiffness, aches, pain in joints, loss of appetite and in major diseases like vascular diseases, heart diseases, kidney disorders and in cancer condition.

In Ayurveda, the inflammatory *lakshana's* are explained under the heading of *Ama*<sup>8,9</sup>, as *Strotorodha*, *Balabramsha*, *Gourava*, *anilamoodata*, *alasya*, *Apakti*, *nisteeva*, *malasanga*, *aruchi*, *klama*<sup>10</sup> which can be in turn assumed as a signs of toxins obstructing the channels of body and interrupting the bodily functions.

*Bilwadi gutika* is one of the effective Ayurvedic formulation which is indicated in our classics for providing healing effects from problems arising due imbalance of *Kapha* and *Vata Dosha*. It helps to curb the acute toxic pathological conditions and also having analgesic, anti-inflammatory action. The ingredients of *Bilvadigutika* drugs like *Bilva*<sup>11</sup>, *Haridra*<sup>12</sup>, *Tulasi*<sup>13</sup>, *Pippali*<sup>14</sup>, *Shunthi*<sup>15</sup>, *Amalaki*<sup>16</sup>, *Daruharidra*<sup>17</sup>, *Gomutra*<sup>18</sup>, *Maricha*<sup>19</sup>, *Karanjabeeja*<sup>20</sup>, *vibhitaki*<sup>21</sup>, *haritaki*<sup>22</sup> have showed anti-inflammatory action in previous animal experimentations. The present study showed the reduction in severity of symptoms of anti-inflammatory like *Shoola* (Pain), *Shotha* (Swelling), *Angamardha* (body pains) *Stabdhatta* (stiffness). The study results shows 90 % increase in appetite and change in the symptom of loss of taste i.e before treatment 11 were having loss of taste, after treatment 7 got improvements and improvement in taste were observed in 17 subjects. Regarding the symptom of *Alasya* (tiredness) there was a significant improvement has been observed.

On analyzing objective parameter ESR, the study shows statistically insignificant with p value -0.360. Even though statistically it is insignificant, clinically it is observed that, 11 subjects got good reduction in ESR and 10 subjects were moderate increase of ESR seen after treatment. Statistical significant can be achieved with large sample size with longer duration.

## CONCLUSION:

Based on the observation, results and discussion of the study titled- An open labeled single arm interventional study to evaluate the efficacy of *Bilwadi gutika* on raised level of ESR in musculoskeletal disorders, the following conclusion is drawn.

1. *Bilwadi gutika* has moderate effect in decreasing the raised ESR in musculoskeletal disorders
2. *Bilwadi gutika* has significant effect in reduction of symptoms of musculoskeletal disorders.



**Acknowledgement:** We are extremely thankful to Rajeev Gandhi University of Health Sciences, Bengaluru for providing financial support to conduct this project under UG Student research Scheme.

**References:**

1. Gupta atrideva, Ashtangahridayam of Vagbhata, chaukhambha Sanskrit samsthan, Varanasi, Sutrasthana, edition 12<sup>th</sup>, 1997, 1<sup>st</sup> chapter, 19<sup>th</sup> sloka, page no 10
2. Acharya Trikamji Jaddav, Carakasamhita of Agnivesha, chaukhambha Surabharatiprakashan, Varanasi, edition 2008, Chikitsasthana 15<sup>th</sup>, 44, cakrapani commentary, page no. 517.
3. Sharma PV, Susrutasamhita, Nibandhasangraha of Dalhana, Chaukhamba orientalia, Varanasi, reprint edition 2014, Sutra sthana 15<sup>th</sup>, 32, Dalhana commentary page no. 73-74
4. Harrison's principles of internal medicine 19<sup>th</sup> addition Chapter 380, Page no 2143-2189
5. Gupta atrideva, Ashtangahridayam of Vagbhata, chaukhambha Sanskrit samsthan, Varanasi, edition 12<sup>th</sup>, 1997, Uttarasthana 36<sup>th</sup> chapter, 84-85, page no 585.
6. Ravi KGolghate, comprehensive study of ESR and samathain amavathavyadhi, ISSN:0976-0075 Ayurveda e journal rasamruta-7:16 September, 2015
7. Malcolm I Brigden M. D, clinical utility of the erythrocyte sedimentation rate, am fam physicians 1999 oct 1;60(5):1443-1450
8. Dr. Bulusu Sitaram; Astanga Hridaya, Varanasi, Chaukhambha Orientalia. 2008 (Sutrasthan Chapter 13/25) Page No. 176 4. Prof. Yadundana Upadhyay: Madhava Nidana; The Madhukosha Sanskrit Commentary, Varanasi, Part 1 Chaukhambha Prakashana: 2013 (Chapter 25/1-5) Page No. 509
9. Dr. Brahmanand Tripathi; Ashtanga Hridaya, (Sutrasthana Chapter 13/23-24) Delhi, Chaukhamba Sanskrit Pratisthana; 2012 Page No. 188
10. Gupta atrideva, Ashtangahridayam of Vagbhata, chaukhambha Sanskrit samsthan, Varanasi, edition 12<sup>th</sup>, 1997, Uttarasthana 36<sup>th</sup> chapter, 84-85, page no 585.
11. Mrutyunjaymirje, Evaluation of the anti-inflammatory activity of ocimum sanctum in albino rats, international journal of current microbiology and applied science, 2014
12. Julies juneka, Anti-inflammatory properties of curcumin, A major constituent of curcuma longa: A review of preclinical and clinical research, alternative medicine review, 2009
13. Mrutyunjaymirje, Evaluation of the anti-inflammatory activity of ocimum sanctum in albino rats, international journal of current microbiology and applied science, 2014
14. Dhana lakshmi mamaheswari, Phyto chemistry and pharmacology of piper longum, a systemic review, world journal of pharmaceutical science, 2016
15. Raji. Y, Udoh, Anti-inflammatory and analgesic properties of the rhizome extract of Zingiber officinale, African journal of biomedical research, 2002
16. Anti-inflammatory and analgesic activities of water extract from the fruit of Phyllanthus embelica, international journal of applied research in natural products 2010

17. Vijender singh, gunjan, deepthi katiyar, anti- inflammatory activity of alcoholic and aqueous heart wood extract of *Berberis aristata*, Asian journal of pharmaceutical and clinical research,2014
18. <https://www.slideshare.net>, Date:2/2/2017
19. Katina suhana Andrade, Sandra regina, Anti -oxidant activity of black pepper oil-obtained by superficial  $CO_2$ , oberoamerican conference on supercritical thids cartagena de Indians 2013
20. Maniganesh, mani vasudevan, kalippan, Anti -inflammatory and analgesic effect of *Pongamia glabra* leaf gall extracts, pharmacologyonline,2008
21. Alam firoj, Siddiqui.h, cardio protective activity of *Terminalia bellerica* on isoprenaline induced myocardial necrosis in rats, Asian journal of chemical and pharmaceutical research 2014
22. Alam firoj, Siddiqui.h, cardio protective activity of *Terminalia bellerica* on isoprenaline induced myocardial necrosis in rats, Asian journal of chemical and pharmaceutical research 2014

