

# A phytochemical study of bala dwayam (*Sida cordifolia* & *Abutilon indicum* linn.) And clinical evaluation of its moola churna ksheerapaka in Sandhigata vata with special reference to janu sandhi

## Research Article

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## Abstract

Joint pain is a world wide problem. Almost 70 to 80% of the world population suffer from it. Statistical analysis shows that by the age of 60 to 75 years, 80% of the population shows radiographic evidences of osteoarthritis. Osteoarthritis of the knee joint is characterised by gradual increase of pain in the joint, 'grating' may be felt or heard on movement. A plain radiograph is the only useful investigation. This may show some typical features of osteoarthritis, namely focal narrowing of joint space, marginal osteophyte, subchondral sclerosis cysts and osteochondral bodies. According to Ayurveda it is coined as *Sandhigata vata* where in *Vata* takes on the *sandhisthana*, it leads to the degeneration of *asthi dhatu* and decreases *shleshaka kapha* disturbing the normal structure and functions of the joints involved. As age advances *Vatadosha* triggers and accelerates *dhatukshaya* and *balakshaya*. *Sandhigata vata* is a *madhyama rogamarga vyadhi* involving the *sandhi marma*. *Dhatukshaya* is highly prevalent in *vridhdhavastha*. Thus the involvement of *Marma*, *Madhyama roga marga*, *vata dosha* and *dhatukshaya* adds to the *kashtasadyata* of the disease.

**Key Words:** *Sandhigata vata*, *Janu Sandhi*, *Bala*, *Atibala*, *Rasayana*, Musculoskeletal disorder.

## Introduction

Musculoskeletal disorders are the most commonest self-reported ailment in the community. It has a substantial influence on health and quality of life and impose an enormous burden of cost on the healthcare system. Prevalence of musculoskeletal disorders varies with the change of climatic conditions and geographic region. It also identifies advancing age and female sex as the factors associated with increased incidence of Musculoskeletal pain. Arthritis affects 15% people i.e. over 180 million people in India. This prevalence is higher than many well known diseases such as diabetes, AIDS and cancer.

*Bala* (*Sida cordifolia* Linn.) and *Atibala* (*Abutilon indicum* Linn.) both together are called as *Bala Dwayam* (1,2,3). Qualities of both are nearly identical. Both the Medicinal plants are said to be *Vatapittahara*. *Ksheerapaka* refers to medicated milk which is prepared by boiling the milk with drug and water until only milk part remains (4). When drugs like *Bala* and *Atibala* are added in the preparation of *ksheerapaka*, it will have an add on effect of nutritional

value along with its medicinal property of *Vatapittahara*.

## Aims and Objectives

### Aim

- To compare the effect of *Bala moola churna ksheerapaka* and *Atibala moola churna ksheerapaka* in *Janu Sandhigata vata*.

### Objective

- To study the disease *Sandhigata vata*.

## Materials and Methods

### Materials

In this study two herbal drugs and its milk preparations (*ksheerapaka*) are used.

- Bala moola* (*Sida cordifolia* Linn.) *ksheerapaka* – Group A
- Atibala moola* (*Abutilon indicum* Linn.) *ksheerapaka* – Group B

Table no. 1 - Group A

Drug	Botanical name	Rasa
<i>Bala</i> (Root)	<i>Sida cordifolia</i> Linn.	<i>Madhura</i>

Table no. 2 - Group B

Drug	Botanical name	Rasa
<i>Atibala</i> (Root)	<i>Abutilon indicum</i> Linn.	<i>Madhura</i>

Standardization & authentication of raw drugs were done at a standard pharmacognosy laboratory and

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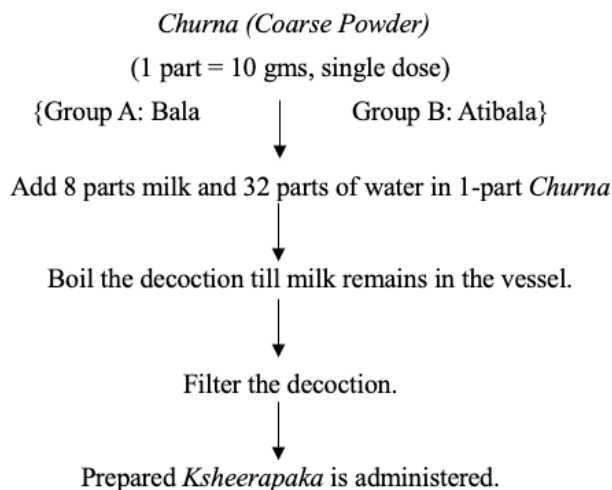
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the prepared *ksheerapaka* was also subjected to phytochemical analysis.

### Method of Preparation of Ksheerapaka



**Table no. 3 - Dosage schedule**

Drug	Group A <i>Bala Moola Ksheerapaka</i>	Group B <i>Atibala Moola Ksheerapaka</i>
Dose	80 ml	80 ml
Route	Oral	Oral
Sevan kala	Apana kaal	Apana kaal
	Morning and evening before meals	Morning and evening before meals
Duration	30 days	30 days
Follow up	On day 15 and day 30	On day 15 and day 30

### Ethical Clearance

Permission of Institutional Ethics Committee was sought before starting the clinical study.

**CTRI Registration:** CTRI/2019/03/018183

### Selection Criteria

#### Inclusion Criteria

- Classical sign and symptoms of *Janu Sandhigatavata* are *Shula, Shotha, Stambha, Sparsha-asahyata, Sphutana, Akunchana prasarana vedana* etc. at the joints.
- Patients between age group of 45 - 70 years.

#### Exclusion Criteria

- Patients below 45 and above 70 years of age.
- Patients with other joints deformities or diseases which are not related to *Sandhigatavata*, such as *Amavata, Vatarakta*, fracture of joints, and needs surgical care will be excluded.
- Autoimmune diseases like SLE, Ankylosing Spondylitis.

#### Withdrawal Criteria

- If patients develop any adverse effect.
- If patient is not responding to treatment and aggravation of symptoms.
- If patient refuses to continue with the treatment.

### Informed Consent

Written valid, informed consent of the patient was taken prior to the enrolment of the trial.

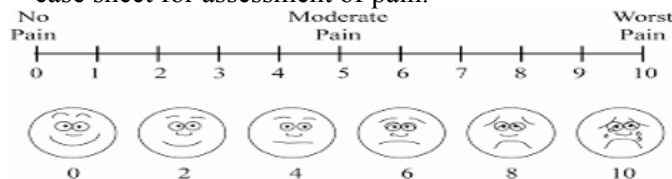
### Criteria of assessment

#### A.Parameters for Subjective criteria

- Pain
  - No pain - 0
  - Mild pain - 1
  - Moderate pain but no difficulty in walking - 2
  - Slight difficulty in walking due to pain - 3
  - Severe difficulty in walking - 4
- Sandhigraha (stiffness)
  - No stiffness - 0
  - Mild stiffness - 1
  - Moderate stiffness - 2
  - Severe difficulty due to stiffness - 3
  - Severe stiffness more than 10 minute - 4
- Akunchanprasaranjanya Vedana (Pain during flexion & extension)
  - No pain - 0
  - Pain without winching of face - 1
  - Pain with winching of face - 2
  - Prevent complete flexion - 3
  - Does not allow passive movement - 4
- Sparsha Asahyata (Tenderness)
  - No tenderness - 0
  - Patient says tenderness - 1
  - Winching of face on touch - 2
  - Does not allow to touch the joint - 3
- Sandhisphutuna (Crepitus)
  - No crepitus - 0
  - Palpable crepitus - 1
  - Audible crepitus - 2

### Objective Criteria

- Range of Movements will be measured with the help of Goniometer.
- Walking Test
- Climbing Stair Test
- WOMAC Scale
- Visual Analogue Scale (VAS) will be added in the case sheet for assessment of pain.



**Table no. 4 - Visual Analogue Scale (Pain)**

Pain	Range	Grade
No Pain	0	0
Mild Pain	1 - 3	1
Moderate Pain	4 - 6	2
Severe Pain	7 - 9	3
Worst Pain	10	4

**Table no. 5 - Range of Movements – Flexion of knee joint**

Range of Movement	Movement Angle	Grade
None	>130	0
Mild	130 - 120	1
Moderate	120 - 110	2
Severe	110 - 100	3
Extreme	100 - 90	4

**Table no.6 - Climbing Stair Test – Time taken to climb 10 steps**

Criteria	Time	Grade
Easily	0	0
With mild difficulty	0-30 sec	1
Moderate	30 sec -1min	2
With marked difficulty	1min -1min 30 sec	3
Impossible	1min 30 sec - 2min	4

**Table no. 7 - Walking Test – Time taken to walk 30 mts**

Criteria	Time	Grade
Easily	0	0
With mild difficulty	0-30 sec	1
Moderate	30 sec -1min	2
With marked difficulty	1min - 1min 30 sec	3
Impossible	1min 30 sec - 2min	4

**Table no. 8- WOMAC Score Grading**

None	0	0
Mild	0-24	1
Moderate	25-48	2
Severe	49- 72	3
Extreme	73- 96	4

**Table no. 9 - Criteria for overall assessment**

Cured	100% relief in sign and symptoms
Best Improvement	>75% and <100% relief in sign and symptoms
Moderate Improvement	>50% and <75% relief in sign and symptoms
Mild improvement	>25% and <50% relief in sign and symptoms
Unchanged	< 25% relief in signs and symptoms

**Lab. Investigations**

1. Routine investigations : CBC, Sr. Calcium
2. X-Ray of Knee Joint AP/ Lat view of patients will be done, if necessary.

**Observations**

The distribution of patients in both the groups showed a maximum number of male patients in the age group of 45-50 years having upper middle socio economic status with more of service going people. Majority of the patients had gradual and progressive involvement of knee joint pain with *vata-pitta prakruti* along with *madhyam sara samhana dashavidha pariksha bhavas*.

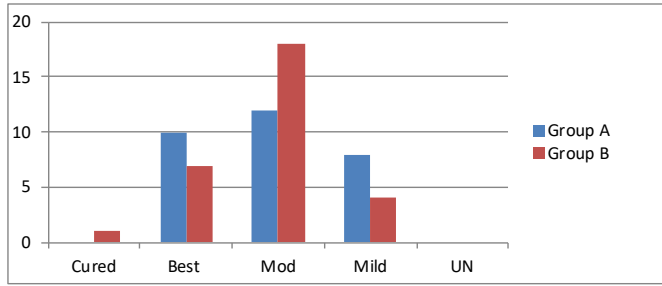
**Table no. 10 Results – Group A & Group B**

Sr.No.	Effect of Treatment on Symptoms	Group	Difference In Means	Standard Deviation ( S.D.)	SEM	t	p value
1	Effect on <i>Sandhishula</i>	A	1.333	0.547	0.0998	1.254	0.215
		B	1.133	0.681	0.124		
2	Effect on <i>Sandhi Shotha</i>	A	0.333	0.547	0.0998	3.120	0.003
		B	0.800	0.610	0.111		
3	Effect on <i>Sandhigraha</i>	A	0.667	0.802	0.146	0.348	0.729
		B	0.600	0.675	0.123		
4	Effect on <i>Akunchana Prasaran Vedana</i>	A	0.667	0.661	0.121	2.926	0.005
		B	1.133	0.571	0.104		
5	Effect on <i>Sparshasahatva</i>	A	0.433	0.568	0.104	0.0333	0.820
		B	0.400	0.563	0.103		
6	Effect on <i>Sandhisphutana</i>	A	0.400	0.498	0.0910	2.380	0.021
		B	0.733	0.583	0.106		
7	Effect on Range of Movement	A	0.667	0.547	0.0998	0.249	0.804
		B	0.633	0.490	0.0895		
8	Effect on Walking Test	A	1.567	0.728	0.133	0.549	0.585
		B	1.467	0.681	0.124		
9	Effect on Climbing stair Test	A	1.900	0.712	0.130	1.270	0.209
		B	1.667	0.711	0.130		
10	Effect on VAS	A	1.167	0.379	0.0692	2.660	0.010
		B	1.500	0.572	0.104		
11	Effect on WOMAC Scale	A	1.067	0.254	0.0463	1.523	0.133
		B	1.200	0.407	0.0743		

**Table no. 11: Showing the Overall Effect of Treatment Group A & Group B on basis of VAS**

Effect	No. of patients Group A	%	No. of patients Group B	%
Cured	0	0	1	3.33
Best improvement	10	33.33	7	23.33
Moderate improvement	12	40	18	60
Mild improvement	8	26.66	4	13.33
Unchanged	0	0	0	0

**Graph no: 1 Showing the Overall Effect of Treatment**



### Comparison of Over All Effect of Treatment in both the Groups A & B

On comparison between both the Groups A & B on overall effect of treatment on basis of VAS showed that 3.33% from Group B had attained full cure rate, while 33.33% and 23.33% patients attained best improvement in Group A and Group B respectively. Moderate improvement was experienced by 40% in Group A and 60% in Group B while 26.66% and 13.33% patients received mild improvement in Group A and Group B respectively. Group A and Group B both showed statistically significant results in nearly all the parameters accessed. In the parameters of *sandhi shula*, *sandhi graha sparshasahatva* Group A had significant results while in parameters of *sandhi shotha*, *akunchana prasaran vedana* and *sandhisputana* Group B had significant results. Considering VAS scale and WOMAC scale Group B had an edge over to Group A statistically with p value 0.010 and p value 0.133 respectively. However the dominance of Group B ie. the patients who received *Atibala moola ksheerapaka* presumed to have received better results than Group A ie the patients who received *Bala moola ksheerapaka* in comparison to the over all effect of treatment.

### Discussion

On the basis of the above mentioned results, it is clear that *Bala moola Ksheerapaka* and *Atibala moola Ksheerapaka* produced significant improvement on various symptoms and signs including pain, tenderness, stiffness and swelling. Marked improvement in WOMAC score was also significant. But there was not much significant changes observed in X-rays and Sr. calcium levels of pre and post treatment done. Besides the treatment was found to be safe, palatable and well tolerated. No obnoxious side effects were observed.

### Conclusion

*Bala* is the most common drug mentioned in many preparations of Ayurvedic formulations and widely described with its classification in almost all ancient classical texts. In the present study *Bala* and *Atibala* both belonging to Malvaceae family are chiefly considered as sources of *Bala* with respect to different

aspects of drug assay. Pharmacognostical study reveals almost common root anatomy with slight distinguishing characters.

Milk (*Ksheer*) is easily available and described as *jivana*, *brimhana*, *nitya rasayana* and *pathyatama*. (5) Thus it is good in prevention and curative aspect of many disorders, especially those having chronic nature. Milk has properties similar to that of ojas and hence it improves immunity and body defense mechanism. Milk contains Vitamins, fat. Protein carbohydrate, minerals etc. which is needed for physical and mental well-being. *Ksheerapaka kalpana* or medicated milk is an ayurvedic dosage form and is been potentially used as a medicine by combining it with different herbs which nourishes the tissues and have more anabolic effects.

*Sandhigata vata* is a degenerative disorder generally occurring in the adults. As the age increases *Vata* with its *ruksha khara guna* afflicts the joint causing more degeneration of the bone as well as the cartilage and the surrounding tissues. The synovial fluid is also reduced which causes the rubbing of the bones and the disease progresses with pain and reduced movements of the joint. Early diagnosis of this disease, foundation of remedial measures to prevent debilitating orthopedic problem and giving support and guidance to the family members helps to definitely improve the prognosis for the patients suffering from *sandhigatavata*

Thus it may be concluded that the research study of *Bala Moola Ksheerapaka* and *Atibala Moola Ksheerapaka* is an effective and safe regimen in the symptomatic relief of *Janu Sandhigatavata* (knee osteoarthritis).

### Acknowledgement

Department of Dravyaguna and Department of Kayachikitsa of Dr. D.Y.Patil Vidyapeeth, Pune

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