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A controlled clinical study to evaluate the efficacy of Janu Basti and Asthi Shrinkhala in management of Janusandhigata Vata w.s.r to Osteoarthritis

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ABSTRACT

Background : Sandhigata Vata is characterized by Shoola (pain), Shopha (swelling) and restricted movement of affected joints. Osteoarthritis is characterized by inflammation of joints, marked by progressive cartilage damage as a result of age related degenerative change or trauma. Sandhigata Vata correlates with Osteoarthritis. **Objectives** - The present study was intended to evaluate and compare the efficacy of Asthishrinkhala (Trial drug) and Glucosamine sulfate (Control drug) in Janusandhigatavata w.s.r to Osteoarthritis. **Materials and Method** - 40 subjects diagnosed with Janusandhigatavata were randomly assigned into two equal groups comprising of 20 subjects each. Subjects of Group A received Janubasti with Mahavishagarbha Taila and Tab. Glucosamine sulfate 500mg 1 T.I.D after food and subjects of Group B received Janubasti with Mahavishagarbha Taila and Tab. Asthishrinkhala 500mg 1 T.I.D after food for a duration of 30 days. **Observation and Results** - In the present study, Asthishrinkhala and Glucosamine sulfate both were beneficial in reducing the symptoms of Janu Sandhigata Vata. On comparison between the groups, Glucosamine sulfate was more in beneficial in reducing the symptom of Janu Sandhigata Vata compared to Asthishrinkhala. However there was a statistically non significant result between groups, overall the subjects on glucosamine sulfate expressed greater benefit compared to Asthishrinkhala. **Conclusion** - Both the drugs were beneficial in managing the symptoms of Sandhigatavata, but overall the subjects treated with glucosamine sulfate expressed greater benefits compared to subjects treated with Asthishrinkhala.

Key words: Asthishrinkhala, Glucosamine sulfate, Janubasti, Osteoarthritis, Sandhigata Vata.

INTRODUCTION

Ayurveda is an ancient and holistic science. Aim of Ayurveda is "Swasthasya Swasthya Rakshanam Aturasya Vikara Prashamanam"^[1] (i.e.) maintenance of health in a healthy individual and cure of disease in diseased. Tridosha's are basic substratum of the body.

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Samyavastha of Tridosha keeps an individual healthy. Among Tridoshas, Vata is considered to be superior as it is Atibalavan (strength), Ashukari (swiftness), Gariyasi (supremacy), Atyayikatva (acuteness), Dushchikitsa (difficult to manage) and Vishitachikitsa (special management). Because of which our Acharyas have explained diseases concerned to Vata separately and their management in detail.

The etiopathogenesis of Vatavyadhi, has dual pathways -Gatavata and Avaranajanya Vataroga. By various Nidanans, Vata gets Prakopa and leads to vitiation of various components of body like Mamsa, Meda, Asthi etc. and Upadhatu like Sira, Snayu etc. When Sandhi gets involved it leads to the manifestation of Sandhigatavata and produces symptoms like pain, swelling and restricted movements of the affected joint.

Osteoarthritis (OA) is characterized by inflammation of Joints, marked by progressive cartilage damage. Its prevalence is high especially in elderly. It is associated with high rate of disability.

According to world health organization, OA is the 2nd most common musculoskeletal problem in the world population (30%) after low back pain (50%). Major risk factors associated with OA of knee joint are age, gender, obesity, occupational knee bending.^[2] Treatment modalities in contemporary science is broadly divided into pharmaco-therapeutic and non-pharmacological therapy. Pharmaco-therapeutic include Non steroidal anti-inflammatory drugs, corticosteroids, medications that stops the bone loss and increases bone strength E.g.: calcitronin, medications which increase the bone formation e.g.: teriparatide. Much of these have their own limitations and side effects. If the pharmaco therapy fails then the last resort is surgery. Surgical approaches apart from being invasive and palliative are extremely expensive and unaffordable to a large number of patients especially from India. Hence patients seek alternate medicine. It is the need of the hour to explore an effective, safe, domiciliary mode of management in this disorder. *Asthisrinkhala* has the property of *Shothahara* (Anti-inflammatory), *Vedanasthapan* (Analgesic), *Vatahara* (mitigate Vata)^[3] helps in pain management and in improving the status of degeneration in joints.

With above intention, the present study was undertaken to evaluate the efficacy of *Asthisrinkhala* in the management of *Janusandhigata* w.s.r to osteoarthritis.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of *Asthisrinkhala* in the management of *Janusandhigatavata* w.s.r to osteoarthritis.
2. To re-evaluate the efficacy of Glucosamine sulfate in the management of *Janusandhigatavata* w.s.r to osteoarthritis.
3. To compare the efficacy of *Asthisrinkhala* with glucosamine sulfate in the management of *Janusandhigatavata* w.s.r to osteoarthritis.

MATERIALS AND METHODS

Subjects attending OPD, IPD and special camp conducted at Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru were selected and randomly assigned into two groups.

Ethical Clearance and Consent

Institutional ethical committee clearance and signed informed consent from subjects was obtained prior to the commencement of the study.

Sampling Method and Research Design

Total 40 patients were selected and randomly assigned into two groups Group A and B respectively comprising 20 subjects in each.

Diagnostic Criteria

Diagnosis was based on classical sign and symptoms of *Janusandhigatavata* and Osteoarthritis and was confirmed by X ray OA findings of knee joint.

Inclusion Criteria

- Subjects between age group of 35-70 years
- Subjects with classical signs & symptoms of *Janu Sandhigata Vata*
- Subjects with osteophytic changes in X-ray.
- Subjects having joint space reduction

Exclusion Criteria

- Subjects suffering from *Janu Sandhigata Vata* with bony deformity.
- Subjects suffering from diseases like rheumatic heart disease, rheumatoid arthritis, Gouty arthritis and other inflammatory joint conditions.
- Any systemic illness that would interfere with the course of disease and treatment.

Laboratory Investigation

X ray of Knee joints - AP and Lateral View.

Intervention

Group A : Patients were treated with *Janubasti* with *Mahavishgarbha Taila* for 7 days and Tab.

Glucosamine sulfate 500 mg 1 tid after food with lukewarm for 30 days.

Group B : Patients were treated with *Janubasti* with *Mahavishagarba Taila* for 7 days and *Cap. Asthishrinkhala* 500 mg 1 tid after food with lukewarm for 30 days.

Assessment Criteria

- *SandhiShoola* (Pain)
- *SandhiSthamba* (Stiffness)
- *SandhiSputana* (Crepitus)
- Range of Movement
- Tenderness

Assessment was done on 0th, 7th, 15th, 21st and 30th day. Follow up assessment was done on 45th day.

Statistical Analysis

Statistical Analysis was done with - Unpaired 't' test, Paired 't' test for parametric data and Mann-Whitney U Test and Wilcoxon Sign Rank test for non-parametric data.

OBSERVATIONS

The incidence of *Janusandhigatavata* is found between 40 years to 60 years. The same has been observed in the present clinical study. (Table 1).

The incidence of *Janusandhigatavata* is more in Female compared to male. The same has been observed in the present clinical study. (Table 2)

Continuous usage of joint is the cause for manifestation of Osteoarthritis. In the present study most of the female subjects were Housewife where continuous standing and weight bearing of joint takes place (Table 3).

Over weight and obesity are the other cause for development of Osteoarthritis. Same has been observed in the present study. (Table 4)

The incidence of distribution according to the symptomatology is shown in (Table 5)

Table 1: Showing the incidence of disease with relation with age.

Age	Group A	Group B	Total
35-45	3	1	4 (10%)
46-55	3	6	9 (22.5%)
56-65	9	11	20 (50%)
66-75	5	2	7 (17.5%)

Table 2: Showing the incidence of disease with relation to gender.

Gender	Group A	Group B	Total
Male	10	4	14 (35%)
Female	10	16	26 (65%)

Table 3: Showing the incidence of disease with relation to occupation.

Occupation	Group A	Group B	Total
House wife	8	14	22 (55%)
Agriculture	4	0	4 (10%)
Business men	3	1	4 (10%)
Others	5	5	10 (25%)

Table 4: Showing the incidence of disease with relation to BMI.

BMI	Group A	Group B	Total
Normal Index	5	3	8 (20%)
Over weight	9	12	21 (52.5%)
Obesity	6	5	11 (27.5%)

Table 5: Incidence of observation of patients according to symptomatology .

Symptom	No of Patients		Total	%
	Group A	Group B		
Pain	20	20	40	100%
Stiffness	6	6	12	30%
Crepitus	20	20	40	100%
Range of movement	20	20	40	100%
Tenderness	3	4	7	17.5%

RESULTS

The effect of the treatment in both the groups was statistically highly significant result ($p < 0.001$) in assessment parameter like Range of movement, Stiffness and *Sandhi Shoola*. Whereas on tenderness the result was statistically significant in Group B ($p < 0.05$) and it was statistically non-significant in Group A. Statistically non-significant result was seen in group A and Group B in the assessment *Sandhi Sputana*. (Table 6&7).

Table 6: Effect of medicine on chief complaints in the patients of Sandhigata Vata in Group A.

Symptoms	Mean Score		P value
	B.T	A.T	
<i>Sandhi Shoola</i>	5.45	2.95	0.000
<i>Sandhi Sthamba</i>	0.25	0.05	0.046
<i>Sandhi Sputana</i>	1.10±0.308	0.95±0.394	0.083
Range of movement	9.85±5.008	5.85±3.265	0.000
Tenderness	0.15±0.366	0.05±0.224	0.163

Table 7: Effect of medicine on chief complaints in the patients of Sandhigata Vata in Group B.

Symptoms	Mean Score		P value
	B.T	A.T	
<i>Sandhi Shoola</i>	5.55	3.15	0.000
<i>Sandhi Sthamba</i>	0.40	0.05	0.034
<i>Sandhi Sputana</i>	1.05±0.224	1.00±0.324	0.330
Range of movement	13.05±7.695	8.60±5.384	0.000
Tenderness	0.35 ±0.671	0.05±0.224	0.05

Table 8: Showing the Over All Improvement

Symptom	Group	UN	ML	MD	MR
Pain	A	4	10	4	2
	B	5	9	6	0
Stiffness	A	18	0	0	2
	B	15	0	0	5
Crepitus	A	20	0	0	0
	B	20	0	0	0
ROM	A	5	11	3	1
	B	7	10	1	2
Tenderness	A	20	0	0	0
	B	16	0	0	4

UN=unchanged, ML= mild, MD= moderate, MR= marked Relief. A=Group A, B= Group B.

By assessing overall improvement through Chi Square Test Group A shows better result compared to Group B. P values for overall changes from pre to post within

the groups was highly significant in assessment parameter like stiffness, range of movement and tenderness ($p < 0.01$). Whereas parameter like *Sandhi Shoola* shows non-significant with p Value > 0.05 (Table 8).

DISCUSSION

Sandhi Shoola

Both groups showed statistically highly significant result with slight better results in group A. At the Completion of treatment 28 patients were in Grade 1 and 12 patients were in Grade 2. (Table 9 & 10). This effect of the therapy was probably due to glucosamine sulfate possessing pro-inflammatory and joint degenerating effect of interleukin-1.^[4]

Sandhi Sthamba

Both groups showed statistically significant result with slight better results in group B.

At the Completion of treatment 38 patients were in Grade 0 and 2 patients were in Grade 1 (Table 9&10). This effect was probably due to *Shothahara* and *Vedanasthapana* property of *Asthishrinkala*.^[3]

Sandhi Sputana

Both groups showed statistically non-significant result with slight better results in group B. At the completion of treatment 38 patients were in Grade 1, 1 patient in Grade 0 and one in Grade 2 respectively (Table 9&10). This effect was probably due to *Ashtishrinkhala* possessing *Madhurarasa* and *Mahdurarasa* had *Pruthvi* and *Apmahabhutapradhana* because of these quality it will help in increases the *Snigdha* and *Picchilaguna* in the *Sandhi* region

Tenderness

The results was statistically significant in Group B and statistically non significant in Group A. At the completion of treatment 38 patients were in Grade 0 and 2 patients were in Grade 1 (Table 9&10). This effect was probably due to it has *Shothahara* property and *Vedanasthapana* property of *Asthishrinkala*.^[3]

Range of Movement

Both groups showed statistically highly significant result with slight better results in group B. At the

completion of treatment 38 patients were in Grade 1 and 2 patients were in Grade 2. (Table 9&10) This effect was probably due to it has *Shothahara* property and *Vedanasthapana* property of *Asthishrinkala*.^[3]

Table 8: Showing the results of interventions on Symptoms in Group A.

Symptom	B.T				15 th day				A.T			
	G	G	G	G	G	G	G	G	G	G	G	G
C.F.	R	R	R	R	R	R	R	R	R	R	R	R
	0	1	2	3	0	1	2	3	0	1	2	3
Pain	0	3	1	6	0	7	1	2	0	1	6	0
			1				1			4		
Stiffness	1	5	0	0	1	3	0	0	1	1	0	0
	5				7				9			
Crepitus	0	1	2	0	0	1	1	0	1	1	1	0
		8				9				9		
ROM	0	1	2	0	0	1	2	0	0	2	0	0
		8				8				0		
Tenderness	1	3	0	0	1	1	0	0	1	1	0	0
	7				9				9			

Table 9: Showing the results of interventions on Symptoms in Group B.

Symptom	B.T				15 th day				A.T			
	G	G	G	G	G	G	G	G	G	G	G	G
C.F.	R	R	R	R	R	R	R	R	R	R	R	R
	0	1	2	3	0	1	2	3	0	1	2	3
Pain	0	0	1	5	0	7	1	0	0	1	6	0
			5				3			4		
Stiffness	1	5	0	1	1	4	0	0	1	1	0	0
	4				6				9			
Crepitus	0	1	1	0	0	1	1	0	0	1	1	0
		9				9				9		
ROM	0	1	4	1	0	1	4	0	0	1	2	0
		5				6				8		

Tenderness	15	3	2	0	16	4	0	0	19	1	0	0
GR- Grade , BT- Before Treatment, AT- After Treatment, C.F- Clinical Features												

CONCLUSION

Janu Sandhigata Vata is a very chronic condition. As age progress the structure of the joint get affected more. There is a need for extensive research on the subject, owing to its influence on the quality of life. Its progressive nature can affect movements of the joint and hence can affect the patient's daily life. Such conditions require more preventive line of management. *Chikitsa* of *Sandhigatavata* mentioned in classics contains *Snehana*, *Svedana*, *Bandana*^[5] etc. Hence in the present study *Janubasti* was selected as external procedure it acts in form of both *Snehana* as well as *Swedana*.

Asthishrikhala and Glucosamine Sulfate were administered orally to the subjects. Compared to subjects treated with *Astishrinkhala*, subjects treated with glucosamine sulfate showed better clinical improvements in Range of movement, *Sandhishoola* and stiffness. Group B patients showed better clinical improvements in Range of Movement, *Sandhishoola*, Stiffness and Tenderness. Though on comparing between the groups there was statistically non significant results. On overall assessment it can be concluded that, the subjects administered with Glucosamine sulfate showed better results compared to subjects administered with *Astishrinkhala* in the management of *Sandigathavata* with special reference to Osteoarthritis.

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