

A CLINICAL STUDY EVALUATING THE EFFECT OF SANDHIVATARI GUTIKA ON JANU SANDHIGATA VATA WSR TO O A KNEE

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ABSTRACT

Objective: To evaluate the effect of *Sandhivatarigutika* in reducing the symptoms in patients suffering from *Janu Sandhigata Vata/ OA Knee*. To assess the change in the Quality of Life. **Design:** Open Non- randomized clinical-study with pre and post-test design. **Setting:** OPD and I.P.D. of Shri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Udupi. **Participants:** 30 patients diagnosed with *Janusandhigata vata* **Interventions:** The 30 patients were selected based on diagnostic criteria, inclusion criteria and exclusion criteria. Patients were treated with *Sandhivatarigutika* one thrice a day after food with lukewarm water as *Anupana* (post prandial drink) for a period of 28 days. **Main outcome measures:** Pain, Tenderness, Swelling, Stiffness, Range of movement, *Sandhishula* (joint pain), *Prasaranaakunchanasavedana* (pain felt while flexion and extension of joint) and KOOS **Results:** *Sandhivatarigutika* is effective in the remission of the symptoms of *Janusandhigata vata* as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters. **Interpretation & Conclusion:** *Sandhivatarigutika* is effective in the remission of the symptoms of *Janusandhigata vata* as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters.

Keywords: *Janusandhigata vata; Sandhivatarigutika; Osteoarthritis Knee.*

INTRODUCTION

Health is a basic prerequisite for the materialization of social and spiritual evolution of an individual. But present era is of modernization and fast life. Everyone is busy and living stressful life. Changes in lifestyle in the form of busy professional and social life, improper sitting posture in offices, incessant work in one posture and over exertion, jerking movements during travelling and sports have created several disharmonies in his natal system. All these lopsided life style

factors will end up in early degenerative changes of body tissues and play a vital role in manifestation of degenerative disorders.

To live with pain is the worst tragedy that can happen to any living being. There are many reasons for pain. *Sandhigata vata* is one of the diseases where joint pain is a cardinal feature. It is included and explained in the *Vatavyadhichikitsita*. *Vatadosha* (one of three biological elements, one which move things) is con-

sidered to play a major role in maintaining homeostasis of *Tridosha* (three basic biological elements of body)¹. The above mentioned faulty life styles will lead to *Prakopa* (aggravation) of *vata dosha* either by *Margaavarana* (obstruction) or by *Dhatu kshaya* (depletion of body tissues)². When *Vatadosha* is aggravated and undergoes *Kopa* (vitiation) and then hosts in the *Sandhis* (joints) leads to manifestation of *Sandhigata vata* (osteoarthritis) and when such a *kopa* of *Vata* affect the *Janusandhi* (knee joint) the condition is known as *Janusandhigata vata* which is characterised by the symptoms- *Vata Purnadhritisparasatha* (fluctuating swelling felt identical to a leather bag filled with air), *Prasarnaakunchanpravritisavedana* (pain felt while flexion and extension of joint)³, *Hanti Sandhi* (destruction of joint), *Sandhi Sula* (pain in the joints) *Sandhi Atopa* (crackling or popping sound in joint)⁴.

Osteoarthritis can be considered as similar to *Sandhigata vata* based on similarities in terms of their, aetiology, etiopathogenesis, presentation of the disease. It is a degenerative joint disorder characterized by degeneration of joint cartilage and adjacent bone that can cause joint pain and stiffness.⁵ The disease is managed by NSAIDs, analgesic drugs, physiotherapy and corticosteroids etc. But these medicines are very costly and cause unwanted affects. Even the surgical treatment does not endow with absolute relief. However, a permanent aid is not provided by any of these and the same is still under research.

OBJECTIVES

1. To evaluate the effect of *Sandhivartarigutika* in reducing the symptoms in patients suffering from *Janusandhigata Vata/ OA Knee*.
2. To assess the change in the Quality of Life.

MATERIALS AND METHODS

Source of data:

A minimum of 30 patients diagnosed as *Janu Sandhigata vata/ OA Knee* will be taken for the study from the OPD & IPD of S.D.M Ayurveda Hospital, Udupi, irrespective of caste and sex. The medicines required will be procured from SDM pharmacy, Udupi.

Method of collection of data:

A Proforma will be prepared with all points of history taking, Symptoms and physical signs of *Janusandhigata vata/ OA Knee* and laboratory investigations will be carried out as mentioned in conventional sciences. Accordingly, patients are selected and then subjected to detailed complete history and clinical examinations. A minimum of 30 patients with *Janusandhigata vata/ OA knee* will be selected as per the diagnostic, inclusion and exclusion criteria.

Design of the study:

This is an open label non randomized single group assignment interventional model clinical study with pre-test and post-test design. The patients were selected irrespective of gender, cast, race, based on the diagnostic inclusion and exclusion criteria. All the parameters of signs, symptoms are scored as enlisted in the assessment criteria and the result obtained was statistically analysed using the paired t test or Wilcoxon signed rank test.

Study Type: Interventional. Allocation: Non – Randomized. Endpoint Classification: Efficacy Study Intervention Model: Single group Assignment. Masking: Open label. Primary Purpose: Treatment

Diagnostic criteria:

- Patient fulfilling the diagnostic criteria according to ACR diagnostic guidelines of osteoarthritis of the knee.
- Patient presenting with symptoms diagnostic of *Janusandhigata Vata – Janusandhigatasoola* (joint pain), *Sopha* (swelling) and *Stabdhattha* (stiffness).

Inclusion criteria:

- All patients fulfilling diagnostic criteria.
- Age groups between 16 years to 70 years (both ages inclusive) are selected irrespective of gender & religion.
- Socio-economic status eligible for Study: all categories who had signed a written informed consent form.

Exclusion criteria:

- Patients suffering from diseases like psoriatic arthritis, Rheumatoid arthritis, Tuberculosis, Carcinoma, Liver Diseases, Renal diseases and SLE are excluded.

- Patients suffering from other systemic disorder.
- Women who are pregnant or nursing an infant.
- History of hypersensitivity to any of the ingredients of trial drug.

Assessment criteria:

- Signs and symptoms of Janusandhigata Vata (OA knee) are evaluated before, during and after treatment on the baseline, 14th day and 28th day. Analysis of the subjective and objective parameters will be done.

a. Subjective parameters

1. Prasarnaakunchanpravritisavedana
2. Pain (Sandhi Shoola)-Visual Analogue Scale (VAS)
3. Knee joint tenderness
4. KOOS-Index for Osteoarthritis

b. Objective parameters

1. Swelling
2. Range of movement
3. Walking - time required to cover 50 meters in seconds.

Intervention:

Study group: - Patients of this group will be given Sandhivatarigutika as under:

- Dose - 3 x 500mg/day
- Dosage form - Capsule of 500mg (1capsule of 500mg each thrice a day)
- Route of Administration - Oral
- Time of Administration - Thrice a day after food
- Anupana - Lukewarm Water
- Duration - 28 days

Duration of study:

- 28 days of intervention and 14 days of follow up period
- Assessment: - once in 14 days i.e. on 0th day, 14th day, 28th day and 42nd day.

Follow up: Follow up will be done after 14 days of treatment.

OBSERVATIONS

Among the 30 patients taken for the study 3.3% of the patients belonged to the age group 31-40 years. This is followed by 13.3 % of the patients in 41-50 and

33.3% of patients in 51-60 years of age group. In 61-70 years of age group 50% of patients were present. Out of 30 patients, 53 % patients were females and 47 % were males. Maximum number of patients recorded in this study was Hindus. 83.3% belonged to Hindu religion. 13.3% of patients belonged to Christianity; Muslims were 3.3%. 100 % of patients were married in the present sample. Majority of patients comprising 40% in this study had completed their higher secondary education. Rest of the educational status is Graduation 36.7% and contributing Matriculation 13.3%. This is followed by 3.3 % illiterate, 3.3% primary school and 3.3% post graduates. Maximum numbers of patients were home-makers i.e., 56.66%, 30% of patients were manual laborers, 10% were employees and 3.33% were businessmen. Out of 30 patients, only 23.3% of the patients were restricted to vegetarian diet, and the remaining 76.7% of the patients had the habit of taking mixed diet. 50% patients among the 30 patients followed *Samashana* (sufficient quantity of food), 20% patients followed *Vishamashana* (irregular quantity of food) and 30 % patients followed *Adhyasana* (more quantity of food). An enquiry about the addiction revealed that only 23.3 % of the patients had the addiction of consuming alcohol. 36.7 % of the patients had the habit of taking coffee or tea regularly and 13.3% of the patients had the addiction of smoking. 56.7% patients had no addictions. Out of 30 patients, 33.3 % had the history of oral NSAID intake before the commencement of the study, 66.6% of the patients had not taken any treatment. Maximum number of patients i.e. 36.7 % had their body weight between 71 to 80 kg. 33.3% % of the patients had their body weight between 61 to 70 kg. It may be inferred that the incidence of Osteoarthritis Knee may be directly proportional to the body weight of the individual along with other predisposing factors. Maximum number i.e. 56.6% of patients had BMI between 18.5 – 24.99, which add to the fact that overweight can predispose to knee joint pain and Osteoarthritis Knee. Majority of Patients belonged to *VataKaphaPrakruti* i.e. 50.0 % and 20.0 % belonged to *VataPitaPrakruti*, 30.0 % belonged to *PittakaphaPrakruti*. This observation supports the susceptibility of persons with *Vata* as

Prakruti to develop *Vataja* disorders like *Sandhigatavata*, which is accordingly to the general principles mentioned in the literature. 50.0% patients exhibited *Madhyama Sara*, 43.3 % patients had *Pravara Sara* and 6.7% had *Avarasara*. Among 30 patients, 50 % recorded as *MadhyamaSamhanana*, 43.3 % patients showed by *PravaraSamhanana* and 6.7% as *AvaraSamhanana*. The assessment of *Pramana* of the body in 30 patients revealed that 53.3% patients had *Madhyama Pramana*, 40.0% patients shown *Pravarapramana* and 6.7% patients shown *Avarapramana*. Analysis of *Satmya* revealed that 73.33 % had *MadhyamaSatmya*, 23.3% had *Pravarasatmya* where as 3.3% patient had *Avarasatmya*. The assessment of *Abhyavaharana Shakti* majority of patients had *Pravaraabhyavaharana Shakti* 63.3%. This indicates *Abhyavaharana Shakti* is not indulged in the manifestation of *Janusandhigata vata* in the sample of patients considered. As per literature improper digestion leads to the production of *Ama* (improperly digested metabolic residue) and further production of *vata prakopa* and *Vatavyadhi*. Majority of patients had *Pravarajarana Shakti* 56.7%, shows *Jaranasakthi* had no direct relation in the development of *Janusandhigatavata* in the selected sample from the population. 93.3% patients showed by *Avaravyayama shakthi* (severe weakness by exercise).

RESULTS:

Statistical analysis of the parameters was done (Table No 1). Pain (*sandhi shula*) was recorded separately for both left and right knee joint using visual analogue scale before and after treatment. Remission of pain (*sandhi shula*) was 60% on right knee and 58.16% on left. The change in *sandhishula* was statistically highly significant with P value <0.001. Remission of stiffness was by 56.70% on right knee and 54.72 % on left knee. The change in stiffness was statistically highly significant with P value <0.001. Remission of tenderness was by 56.70% on right knee and 54.72% on left knee with statistically highly significant P

value (<0.001). Swelling was measured by measuring the girth of right and left knee separately on before treatment and after treatment. Remission in swelling was 5.33% on right knee and 5.07% on left knee with statistically highly significant P value (<0.001). Range of movement was recorded separately on right and left knee separately using Goniometer. Improvement in range of movement was 4.62 % on right knee joint and 3.65% on left knee joint with statistically highly significant P value (<0.001). Time taken for walking 50 meters was recorded using stopwatch in terms of seconds. An improvement of 4.62 % in time taken to walk 50 meters was noted with statistically highly significant P value (<0.001). *Prasaranaakunchanapravrutisavedana* indicates pain on movements. It was also recorded separately for right and left leg. Remission by 60.0% on right knee joint and 60.0% on left knee joint with statistically highly significant P value (<0.001). Knee injury and Osteoarthritis Outcome Score was recorded for each patient on baseline, 14th day, 28th day and on 42nd day for KOOS Pain, KOOS Symptoms, Function in daily living (KOOS ADL), Function in Sport and Recreation (KOOS Sport/Rec), and knee-related Quality of Life (KOOS QOL). The statistical analysis revealed that score of KOOS Symptoms after treatment recorded an improvement by 27.57% with statistically highly significant P value (<0.001). The statistical analysis revealed that score of KOOS Pain after treatment recorded an improvement by 28.33% with statistically highly significant P value (<0.001). The statistical analysis revealed that the score of KOOS ADL after treatment recorded an improvement by 30.72% with statistically highly significant P value (<0.001). The statistical analysis revealed that the initial mean score of KOOS SPORTS/ REC after treatment recorded an improvement by 29.17% with statistically highly significant P value (<0.001). The statistical analysis revealed that the initial mean score of KOOS QOL after treatment recorded an improvement by 34.38% with statistically highly significant P value (<0.001).

Table 1: Statistical analysis of the objective and subjective parameters

Effect Of Treatment On Pain (Sandhi Sula) (Right Knee)								
BT Mean	AT Mean	Diff D BT-AT	% OF Relief	Wilcoxon Signed rank test				
				SD	SEM	MEDIAN	Z VALUE	P VALUE
3.233	1.400	1.833	56.70%	BT: 0.900	BT:0.164	BT: 4.000	-4.656	<0.0001
				AT:0.855	AT:0.156	AT: 1.000		
Effect of Treatment on Pain (Sandhi sula) (Left knee)								
3.267	1.367	1.900	58.16%	BT: 0.900	BT:0.225	BT: 4.000	-4.532	<0.0001
				AT: 0.928	AT:0.169	AT: 1.000		
Effect of Treatment on morning STIFFNESS (right knee)								
3.233	1.400	1.833	56.70%	BT: 1.135	BT:0.207	BT: 4.000	-4.410	<0.0001
				AT:18.715	AT:0.163	AT: 1.000		
Effect of Treatment on morning STIFFNESS (left knee)								
3.533	1.600	1.933	54.72%	BT: 0.937	BT:0.171	BT: 4.000	-4.500	<0.0001
				AT: 1.070	AT:0.195	AT: 1.000		
Effect of Treatment on TENDERNESS (right knee)								
3.533	1.600	1.9333	54.72%	BT: 0.776	BT:0.142	BT: 0.142	-4.565	<0.0001
				AT: 0.855	AT:0.156	AT: 0.156		
Effect of Treatment on tenderness (left knee)								
3.467	1.733	1.933	55.75%	BT: 0.973	BT:0.171	BT: 4.000	-4.549	<0.0001
				AT: 0.980	AT:0.195	AT: 2.000		
Effect of Treatment on swelling (right knee)								
				SD	SEM	MEAN	t-VALUE	P VALUE
51.950	49.180	2.770	53.3%	BT: 7.894	BT:1.441	BT: 52.500	-4.401	<0.0001
				AT: 7.954	AT:1.452	AT:50.000		
Effect of Treatment on swelling (Left knee)								
51.623	49.007	2.617	50.7%	BT: 8.156	BT:1.489	BT: 52.750	-4.236	<0.0001
				AT: 8.022	AT:1.465	AT:48.750		
Effect of Treatment on Range of movement (Right knee)								
BT Mean	AT Mean	Diff D BT-AT	% of Relief	Paired t-Test				
				SD	SEM	t-value	P VALUE	
121.233	127.467	-6.233	46.2%	BT: 5.859	BT: 1.070	-8.732	<0.0001	
				AT: 3.748	AT:0.684			
Effect of Treatment on Range of movement (Left knee)								
122.067	127.633	-5.567	36.5%	BT: 6.633	BT:1.211	-6.174	<0.0001	
				AT: 3.662	AT:0.669			
Effect of Treatment on Time taken to walk 50 meters								
83.300	64.000	19.300	23.16%	BT: 9.997	BT: 1.825	11.571	<0.0001	
				AT: 8.964	AT:1.637			
Effect of Treatment on Prasarana Akunchanasavedana (right knee)								
BT Mean	AT Mean	Diff D BT-AT	% OF Relief	Wilcoxon Signed rank test				
				SD	SEM	MEDIAN	Z VALUE	P VALUE
3.667	2.000	1.667	45.5%	BT: 0.884	BT:0.161	BT: 4.000	-4.691	<0.0001

				AT: 0.159	AT:0.156	AT: 2.000		
Effect of Treatment on PrasaranaAkunchanasavedana (Left knee)								
3.433	1.967	1.467	42.72%	BT: 1.251	BT:0.228	BT: 4.000	-4.556	<0.0001
				AT: 0.999	AT:0.182	AT: 2.000		
Effect of Treatment on KOOS symptoms								
17.103	44.675	-27.571	27.57%	BT: 8.934	BT:1.631	BT: 14.286	4.685	<0.0001
				AT:11.934	AT:2.179	AT:46.429		
Effect of Treatment on KOOS Pain								
24.630	52.963	-28.333	28.33%	BT: 8.373	BT:1.631	BT: 22.220	4.762	<0.0001
				AT:10.211	AT:2.179	AT:52.778		
Table No 78: Effect of Treatment on KOOS ADL								
29.755	60.471	-30.716	30.72%	BT: 7.242	BT:1.322	BT: 27.941	4.742	<0.0001
				AT: 9.595	AT:1.752	AT:61.765		
Table No 79: Effect of Treatment on KOOS SPORTS/ REC								
3.667	32.833	-29.167	29.17%	BT: 6.814	BT:1.244	BT: 0.000	4.733	<0.0001
				AT:11.423	AT:2.086	AT:30.000		
Table No 80: Effect of Treatment on KOOS QOL								
13.333	47.708	-34.375	34.38%	BT: 10.854	BT:1.982	BT: 12.500	4.653	<0.0001
				AT:11.777	AT:2.150	AT:50.000		

KOOS outcome profile

The mean KOOS subscales are presented and reported as an outcome profile for the Janusandhigata vata patients selected for the study. Preferably in a graph with scores from 0-100 on the y-axis and the five subscales

on the x-axis. The order of the subscales from left to right should be: KOOS Pain, KOOS Symptoms, KOOS ADL, KOOS Sport/Rec and KOOS QOL. The separate mean scores of the five dimensions can be visualized in the outcome profile (Figure No 1).

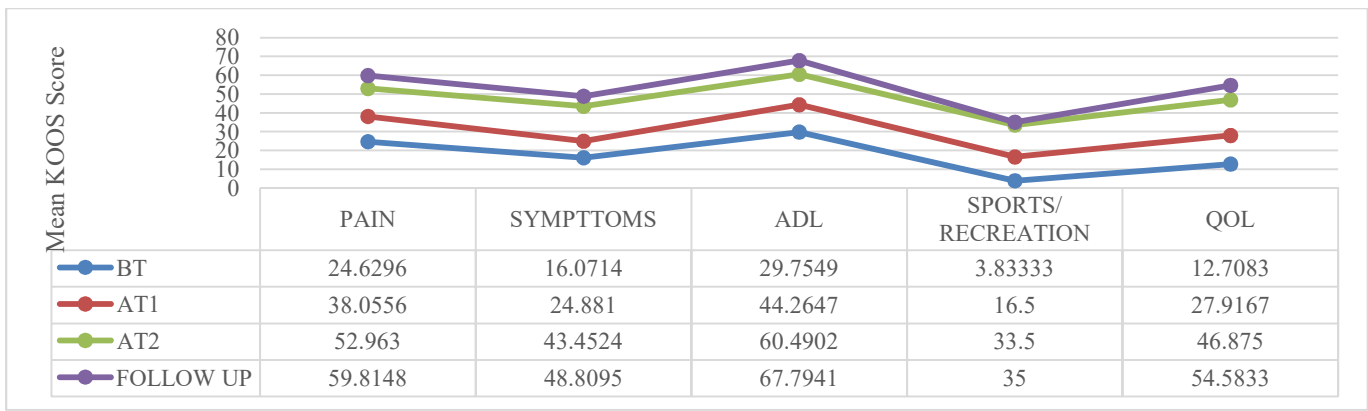


Figure No 1: KOOS OUTCOME PROFILE

DISCUSSION

Vatavyadhi is explained in the literature and has its aetiology as specific nidana, dhatukshaya as well as Margavarana. Sandhigata vata a vata dominant disease, in which Dhatu Kshaya, Asthivahasrotosdushti, and Vata prakopa are the key factors. Asthi-sandhi (bony joint) and shleshakakaphakshaya are the basic

pathological processes, which are characterised by sandishula, sandhi sotha (swelling of joint), Akunchanprasaranavedana, Sandi-Sphutanaan Sanghigraha. According to textual references, it has been clearly quoted that the vatakaphashamaka and srotoshodhakadravyaare generally advised for the management of Sandhivata. In the present study, San-

dhivatarigutika was given internally. it has provided highly significant relief in most of the cardinal signs and symptoms of *Janusandhigata vata*.

As *Sandhivartarigutika* is concerned, the ingredients are *Hingula*, *Guggulu* (*Commiphora mukul*) and *bola* (*cinnabar*) (*Commiphora myrrha*) triturated with cow's milk. The three major ingredients of *Sandhivartarigutika* possess *Katutikta Rasa*, *Ushnaveerya* and *Vata-kaphashamaka*. *Tikta rasa* increases *dhatvagni* (metabolism), consequently nutrition to all the dhatu will be restored. This gradual transformation of dhatu leads to correct *asthi dhatu kshaya*. Therefore, degeneration in the *asthi dhatu* may not be occurred rapidly. Thus, it could be said that *sandhivartarigutika* slows down the degenerative processes. Though, *Tikta rasa* (bitter taste) aggravates *vayu*, the main principle of Ayurvedic treatment is "*Sthanamjayatepurvam*". The main site of *sandhigata vata* is *sandhi* which is the seat of *Sleshakapha*. By decreasing the vitiation of *kaphadosha*, *Tikta rasa* acts according to the above principle. *Sandhigata vata* is a *vatavyadhi*, where some association of *kaphacan* also be traced, which is evident by symptoms like restricted movements, joint swelling and stiffness. Due to *Tikta* and *Katurasa* of *sandhivartarigutika* and *kaphadosha* are brought to normalcy in general and particularly at sandhi region. By the correction of vitiated vata, re-arrangement of *shleshakapha* may be taken place and thereby improvement of symptoms is observed. *Sandhigata vata* and osteoarthritis are quite similar diseases found in clinical practice, in which etiopathogenesis and symptoms are overlapped. Guggulsterone, a major constituent in *guggulu* has been found to potently inhibit the activation of nuclear factor-kappaB (NF-kappaB), a critical regulator of inflammatory responses. Such repression of NF-kappaB activation by guggulsterone has been proposed as a mechanism of the anti-inflammatory effect of guggulsterone.⁵ So, guggulu reduces pain and inflammation significantly. Various studies had been proved the anti-rheumatic effect of *Hingula* (*cinnabar*). Prostaglandins and leucotrienes are the mediators of pain and inflammation. *Hingula* reduces pain and inflammation significantly that may be due to its inhibitory effect on these inflammatory me-

diators. *Bola* contains high content of bioactive furanodienes. It results in analgesic activities against some of the most prevalent and distressing pain symptoms, particularly headaches, muscle aches, joint pain, lower back pain, fever-dependent pain, and menstrual cramps.⁶ *Godugdha* (cow's milk) used for trituration of main ingredients has high nutritive value. It has been proved scientifically that usage of cow's milk can reduce the progression of osteoarthritis.⁷ It is the major source for calcium supplement. From the above-mentioned evidences, it is very evident that the *Sandhivartarigutika* can act on *Janusandhigata vata vis-à-vis* Osteoarthritis knee efficiently.

CONCLUSION

As to put together improvement in quality of life and remission of symptoms, the effectiveness of *Sandhivartarigutika* is acceptable as evidenced by the various outcome measures. The statistical analysis shows that results are highly significant in most of the parameters.

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