

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL



Research Article

ISSN: 2320-5091

Impact Factor: 6.719

A CLINICAL RANDOMIZED OPEN STUDY ON THE MANAGEMENT OF SANDHIGATAVATA W.S.R. TO OSTEOARTHRITIS BY PATOLA (TRICOSANTHUS DIOCA) KSHIR BASTI

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https://doi.org/10.46607/iamj0809032021

(Published online: March 2021)

Open Access © International Ayurvedic Medical Journal, India 2021 Article Received: 24/02/2021 - Peer Reviewed:02/03/2021 - Accepted for Publication:06/03/2021

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ABSTRACT

Osteoarthritis is the leading causes of arthritis in adult population. The word "Osteoarthritis" correlate as "Sandhigatavata" which is describe under 'Vatvyadhi" in Ayurveda. Osteoarthritis (OA) may be perhaps the oldest of all known diseases. In this present era there is no definite cure for OA. Ayurvedic management of SandhigataVata, include BahyaSnehan (external oliation), Swedana (fomentation), Abhyantara TiktaSnehapana (ingestion of medicated ghee), Basti (medicated enema) treatment and GugguluPrayoga(drug containing comiferamukul). Aim: To assess the efficacy of 'Patola (Tricosanthusdioca) Kshir Basti' in the patients of 'Sandhigatavata'. To study the efficacy of 'Guduchi (Tinusporacordifolia) Kshir Basti' in the patients of 'Sandhigatavata'. Materials and Methods: In the present study 60 patients of Sandhigatavata were studied. These patients were classified randomly into two groups termed as Trial Group and Control Group. Diagnosis of Sandhigatavata was done on the basis of classical signs and symptoms mentioned in Ayurvedic text, as well as the diagnostic criteria for osteoarthritis of knee Result: Significant results (P < 0.05) were found in all the cardinal symptoms – Pain (Sandhiruja), Swelling (Shotha), tenderness, crepitus and pain on extension and flexion. Haematological findings showed significant result in sr. calcium, Haemoglobin percentage and ESR (Erythrocyte sedimentation rate) changes. **Conclusion:** At 5% level tabulated Chi Square suggested that both of the groups are same.

Keywords: Sandhigatvata, Osteoarthritis, PatolKshir Basti, Guduchi (Tinusporacordifolia) kshirbasti

INTRODUCTION

Osteoarthritis (OA) is the most common type of arthritis. Its high prevalence, especially in the elderly, and the high rate of disability related to disease make it a leading cause of disability in the elderly.^[1] Osteoarthritis (OA) is the second most common rheumatologic problem in India and has a prevalence rate of 22-39%.^[2]OA is joint failure, a disease in which all structures of the joint have undergone pathologic change, often in concert. The pathological changes of disease is hyaline articular cartilage loss, present in a focal and, initially, nonuniform manner.^[3]Several factors heighten the risk of incident OA, including age, gender, joint injury, and obesity. Although the clinical manifestations of OA can begin as early as the fourth and fifth decades of life, the incidence of OA continues to increase with each decade of aging. Moreover, women in their 50s, 60s, and 70s have a greater prevalence of OA in the hands and knees than do men.^[4]Although OA itself is not a life-threatening disease, but it significantly alters quality of life and loss of mobility causing disability. In those <55 years, the joint distribution of OA in men and women is similar ^[5]. In Avurveda, the disease SandhigataVata resembles with OA, which is described under Vatavyadhi. Since Osteoarthritis is a most commonly disturbing joint disease those with more severe OA, especially of knee or hip a spectrum of non-pharmacologic measures supplemented by an analgesic and or NSAID is appropriate.^[6]However, concern over the use of NSAIDs in OA has grown in recent years because of the adverse effect of these agent, especially those related to gastrointestinal tract.^[7] Patient's life is crippled. Therefore, people of the present era are looking forward towards Ayurveda for relief.

The management of Sandhigatavata is described in various Avurvedic text, Charaka has stated the management of 'AsthipradoshajaVvadhi'(Disease related

to skeletal system) in which use of Kshira (Milk) processed by Tikta Rasa in the form of Basti(medicated enema) is advised.^[8]Tikta Rasa has properties of Dipana-Pachana (Increase digestive power), Stanva-Shodhana, Lekhana, kleda – Meda-Vasa Upashoshanam.^[9]the drugs having Tikta Rasa are responsible to increase Vata, except Guduchi (Tinusporacordifolia) and Patola (Tricosanthusdioca).^[10]Because of all these properties PatolaPatra (Leaves of Tricosanthusdioca)was selected and Kshira was processed with Patola (Tricosanthusdioca), this Patola (Tricosanthusdioca) Kshira was used in the form of Kshira Basti in 'AsthipradoshajaVyadhi' like Sandhigatavata. It is probable that Tikta Rasa along with milk by virtue ofits properties such as Vishad, Parush, Khara, and Ruksha acts on Meda Dhatu, which is converted into Parthiva Dravya, so that Asthi is formed. To achieve the maximum effect, drug is administered in the form of Basti which directly acts on Purishdharakala, also to be considered as Asthidharakala.[11]Basti stands for main management of vata and Sandhigatavata is one of the Vatavyadhi^[12] Thus study entitled" Clinical Randomized Open Study On the Management of Sandhigatavata by Patola (Tricosanthusdioca)Kshira Basti". **Materials and Method**

A total of 60 subjects with OA knees were recruited for the study all the patients of SandhigataVata were selected irrespective of Sex, Religion and Economical status. However there were two groups one having 28 patients (Trial group) which were given Patola (Tricosanthusdioca) Kshir Bastiand another comparative group having 26 patients (Control group) were given Guduchi (Tinusporacordifolia) kshir Basti during the treatment course. Among which 60 subjects (34 female and 26 male) completed the whole course and 6 dropped out. The study was approved by the Institutional Ethical Committee (IEC) and Institutional Ethics Committee (IEC) (Ref No.: IEC/GACN/PGD/200/2013). Signed informed consent was obtained from all the participants.

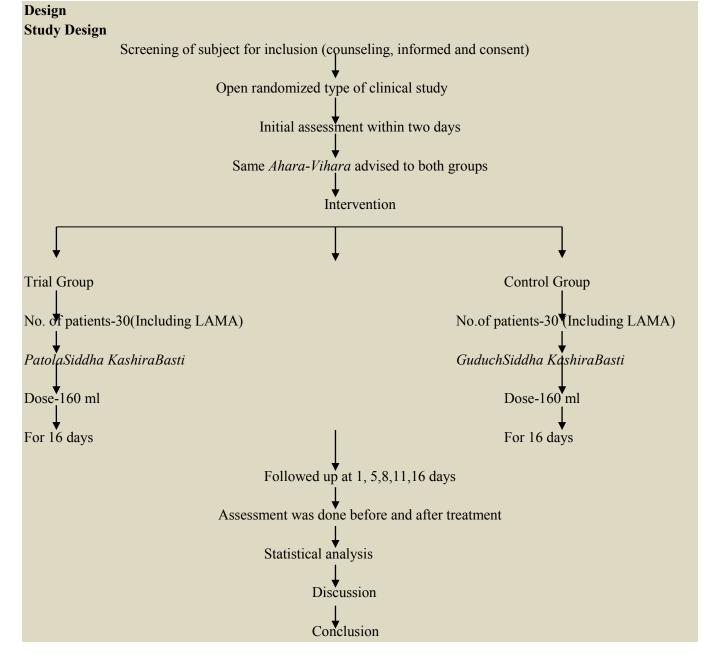
Inclusion Criteria: Age group primarily above 40 years. Patients of both sexes will be considered Established cases mainly of knee joint by clinical and radiological findings

Exclusion Criteria: Secondary OA due to rheumatoid arthritis, gout, septic arthritis, tuberculosis, tumor, trauma, or hemophilia, Major medical or psychiatric disorders. Congenital bone and joint deformity. Ster-

oid dependent patients for relief. Patients not willing for trial. Patients with ano-rectal pathologies like fissures, piles, fistula etc.

Washout Period

There was washout period of 2 weeks only if the patients give previous history of taking Allopathic/Ayurvedic/Any medicine (Any oral or local application was withdrawn gradually within a week time and subject had not given any medicine for next week and then he/she was registered for the trial.



Trial Group:

30 patients fulfilling the criteria of diagnosis were selected randomly for the study in this group. Patients were selected according to criteria of diagnosis. Those patients who were willing to get the treatment from I.P.D of allied hospital were admitted prior to start the treatment. Patients were under observation for about two days. During these two days of observation vital data, chief complaints and history of patients were recorded. All the clinical examinations as mentioned in case proforma were carried out. Routine Blood and other related investigations were carried out to rule out other pathologies. Patients were sent for X-ray examination of the joint to confirm the diagnosis and to exclude other pathology. Early in the morning patients were sent for Abhyanga (oil massage) and Svedana (hot fomentation) in Panchakarma Department. Then patients were advised to eat light Diet. Patola (Tricosanthusdioca) Kshir Basti was prepared as mentioned in Sharangdhar Samhita.^[13] After that prepared basti was given in the quantity of 160 ml to the patient. Procedure of giving Bastiwas done according to Charaka as mentioned in Siddhi Sthan^[14]. The duration of the treatment was 16 days.

Control group: In this group 26 patient were given *Guduchi (Tinusporacordifolia)Kshir Basti* as mentioned in trial group.

Procedure of Basti Therapy:

1) **Preparation of The Patients** (*Purva karma*): The patients were mainly subjected for *Abhyanga*

and *Nadi Sveda* at the sight of *Kati Pradesh*, prior to the administration of *Basti*.

Abhyanga: The *Abhyang* was done by lukewarm *Tila tail* for about 15 to 20 minutes.

Nadi Sveda: After *Snehana* the patients was subjected for *Sveda* by using *NadiSvedana* (by using *Dashmula* and *Nirgundikwatha*) for about 15 to20 minutes.

Procedure of Kshir Basti:

First *TilaTalia* was applied to *Kati, ShroniPradesh* (*Lumber region*) of the patient and massage was done. Then *Nadi-Sveda* was given to the massaged part for about 10 minutes. Left-lateral position was given to the patients and his left knee Joint was flexed up to chest as possible to the patient^[23] 50 ml prepared *Kshir* was taken into plastic syringe which was attached to the simple rubber catheter having no.10. *Kshira* was pushed gently with the same force as mentioned in science. After that, patient was instructed to take rest, at least for 15 minutes.

Pashchat Karma (After procedure):

After giving *Basti*, instruction was given to patients to lie down on abdomen for 20-25 minute. Patients were asked to hold *Basti Dravya* for possible maximum period. Hot water bath was advised after *Basti Pratyagaman (time period between basti given and it expel from anal root)*. Patients were suggested to avoided heavy work, running, day sleep and exercise. Whole procedure was followed to all patients in both groups.

Preparation of Kshir Basti:

Table 1: Table Showing Management of Groups

Control group-Guduchi (Tinusporacordifolia) Kshir Basti			Trial Group-Patola (Tricosanthusdioca) Kshir Basti			
1. <i>Kshir</i> – 160 ml			1. Kshir–160mll			
2.	Guduchi (Tinusporacordifolia)Kand in Bharad Form –	2. Patola (Tricosanthusdioca) Patra in Bhara				
	20 gm		Form–20 gm			
3.	Water –640ml	3. Water – 640 ml				
4.	Saidhav and Shatapushakalk each of 2 gmswas add-	4.	Saidhav and Shatapushakalk each of 2 gms was			
	ed.		added			
5.	<i>Ghrita</i> 10 ml	5.	Ghrita 10 ml			

For *Guduchi (Tinusporacordifolia) Kshir Basti*, 20 gms of crushed *Guduchi (Tinusporacordifolia)Kand* was taken in a pot, then 160 ml of milk was added with 640ml of water, boiled until the half of the liquid was left and then 2 gms of *Saidhav*, 2 gms*ShatapushaKalka* and 10 ml of caw Ghee was added. In the

same way Patola (Tricosanthusdioca) Kshir Ba	<i>asti</i> was	Wincing of face	- 2	
prepared. Duration of treatment was of 16 day	Wincing of face and patient withdraws the affected			
was administered in the morning at about 9	part - 3			
A.M. after light diet, once a day.		Not allow to touch the joint	- 4	
Criteria of Assessment:	7) Nature of Pain			
Subjective criteria: ^[15] Visual analogue scale	(VAS)	No pain	- 0	
was used for assessing pain		Only in morning	- 1	
1) Pain (<i>Shoola)</i>		In morning and evening	- 2	
No Pain	- 0	Pain present at whole day	- 3	
Mild Pain	- 1	8) Roentological Gradation		
Moderate pain but no difficulty in walking	- 2	Normal Roentogram	- 0	
Moderate pain and slight difficulty in walking	- 3	Marginal osteophytes/sclerosis/reduced		
Severe pain which prevents walking	-4	joint space	-1	
Pain on Extension and Flexion (Passive		Joint space markedly reduced,		
movement)		subchondral sclerosis osteophytes	-2	
a) No pain	-0	Bony cyst formation, osteoporosis		
b) Pain without wincing of face	-1	and joint deformity	- 3	
c) Pain with wincing of face	- 2	9) Angle of flexion of joint before and aft	er treat-	
d) Prevents complete flexion	- 3	ment done.		
e) Doesn't allow passive movement	-4	10) Body Mass Index (B.M.I) was assessed.	,	
3) Stiffness (Graha)		B.M.I. =Weight in kg		
No stiffness	- 0	Height in m ²		
Mild stiffness	- 1	11) Weight		
Moderate stiffness	- 2	Objective parameters		
Severe stiffness (more than 10 minutes)	- 3	Radiological findings		
4) Shotha (swelling) on Joint		The Kellgren-Lawrence index was used to a	issess the	
No Shotha	- 0	changes in radiological finding.		
Slight Shotha	- 1	• Grade 1 - Doubtful narrowing of joint s	space and	
Moderate Shotha	- 2	possible osteophytic lipping		
Severe Shotha	- 3	• Grade 2 - Definite osteophytes, definite	e narrow-	
5) Crepitus		ing of joint space		
No	- 0	• Grade 3 - Moderate multiple osteophy	tes, defi-	
Palpable Crepitus	- 1	nite narrowing of joints space, some scle	rosis and	
Audible crepitus	- 2	possible deformity of bone contour		
6) Tenderness at Joint ("Ritchie Articular Ind	ex.")	• Grade 4 - Large osteophytes, marked r	arrowing	
No	- 0	of joint space, severe sclerosis and de	finite de-	
Patients says tenderness	- 1	formity of bone contour		

Overall effect of therapy

No improvement:	• 0-25%,
Mild improvement:	• >25-50%,
Moderate improvement:	• >50-75%,
Marked improvement:	• >75-<100%
Complete remission:	• 100%.

Sr. no.	Range of B.M. I	Trial Group		Control Group		Total no. of patients.	%
		No. of patients.	%	No. of patients.	%		
1	<18.5(Underweight)	00	00	00	00	00	00
2	22-24.9(Normal)	12	40%	09	30%	21	35%
3	25-30(Overweight)	17	56.67%	20	66.67%	37	61.67%
4	>30Obese	01	3.33%	01	3.33%	02	3.33%

Observations Table2: Table Showing Body Mass Index of 60 patients of *Sandhigatavata*

B.M.I = Weight in (Kg) /Height in meter ²Table-1 showed that most of the patients studied were overweight (61.67% patients). While gross obese person having B.M.I above 30 were 3.33% patients. No one patient was recorded in category of underweight. Patients having B.M.I between 22- 24.9 were also observed (35%).In this study, none of the patients of *Sandhigatavata* were categorized in 'complete remission and markedly relieved'. However, 90% patients from Trial Group were relieved and 3.33% patients were unchanged after completing the treatment. In case of Control group 80% patients were relieved and 6.66% patients were unchanged. Comparison between two groups was statistically evaluated by Chi-square test using Yates correction as depicted in Table-03 because condition of almost five units in each cell of criteria of effect of therapy was not fulfilled. Table-03

Table 3: Table Showing Comparison B	Between Two Group WRT to To	otal Effect of Therapy by Chi Square Test

S. N.	Total Effect	Treated Group		Control Group		Total No. of Patients
			No. of Patients		No. of Patients	
1	Relieved	Observed-	27.0	Observed-	24.0	51
		Expected-	26.44	Expected-	26.44	
		Chi Sq. of Cell-	0.000136	Chi Sq. of Cell-	0.1423	
2	Unchanged	Observed-	01	Observed-	02	03
		Expected-	1.44	Expected-	1.44	
		Chi Sq. of Cell-	0.0025	Chi Sq. of Cell-	0.0025	
Total No. of Patients			28		26	54

Total Chi Square =

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0.000136 {+} 0.0025 {+} 0.1423 {+} 0.0025
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$$= 0.1474$$

At 5% level tabulated Chi Square at said degree of freedom [(C-1) (R-1)]=1 is 3.841 which is much more than calculated Chi Square value, hence the result is insignificant at 5% level. To calculate Chi Square following formula was used.[|O-E| - 1/2]²/O-E Yate's correction was used. This test suggested that both of the groups are same.

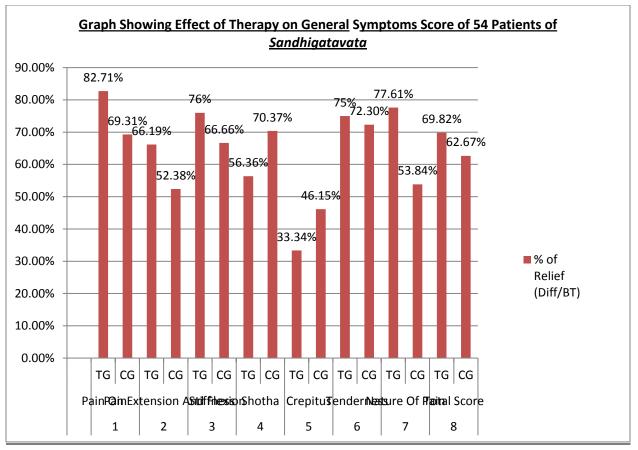
DISCUSSION

Sandhigatavata(Osteoarthritis) is described in all Samhita and SangrahaGrantha(Ayurvedic literature) as a separate clinical entity under the heading of *VataVyadhi*. It is included in 80 types of *Nanatmaja-VatikaVikara*by *Charaka*by mentioning the name of *Gulphavata*. While commenting on "*Gulphavata*" *Chakrapani* explains the meaning of "*GulphaVata*" as *Sandhigatavata* or *Khudvata*^[16] The main symptoms and signs of *Sandhigatavata* (Osteoarthritis) include pain on flexion and extension of the affected joint, swelling, stiffness, crepitus, and tenderness. The swelling described by Charaka is of special type which is felt like a bag filled with air (*VataPurnaDriti Sparsha*)^[17]. *Sandhigatavata* is similar to the osteoarthritis with respect to the symptom. Not only had that, but degenerative changes, termed as *Kshayajanya* vitiation of *Vayu* is also similar. The most commonly affected parts are knee, hip, sacroiliac, ankle, distal

interphalangeal, metatarso phalangeal joints, which are weight bearing parts of the body. Osteoarthritis can also occur as a complication of some other disease. Modern medicine prescribes nonsteroidal antiinflammatory medicines and analgesics drugs most of the times.^[18]Sometimes oral steroids or intra-articular steroids are needed. These medicines have dreaded side effects.^[19] Sometimes these medicines also fail to give the relief in symptoms. Further surgical innervations are needed to give the relief in crippled life which disturbs the economic health of the patients that too in the middle or old age. Therefore, patients suffering from Sandhigatavata have the ray of hope from the Ayrveda. Ayrveda has the successful answers up to certain extent. Taking foresaid facts into consideration thought was in mind to evaluate the effect of some of the concepts of treatment in Sandhigatavata in which Dushti(imbalance) of Vata, Meda, Asthi and Majja are main factors which are generally seen among the patients of Sandhigatavata. It is manifested because of two main causes, termed as causes responsible for Dhatukshay (Degenerative) and Marga- Avarodha (Obstructive). Treatment of Sandhigatavata is same as that of the treatment of Asthidushti. Charaka has advised to follow Panchakarma, treatment. KshiraBasti processed with the help of TiktaRasa, has also been advised.^[20]Tikta Rasa is included in different causes

responsible for the vitiation of Vayu. Vagbhat in AsthangHridaya has mentioned a characteristic of Tikta Rasa. He is of the opinion that use of Tikta Rasa in general might cause vitiation of Vayu. But, Arunadatta is of the opinion that use of Kshira Basti processed with TiktaRasa does not aggravate Vayu because of use of Sneha(Lubricant) along with Tikta^[21]Therefore use of Tikta Rasa along with one of the Sneha by oral route or by anal route in the form of Basti is advised. In the same manner Kshira processed with Tikta Rasa is also advised by Charaka^[22]Keeping these facts in mind, people in the society are looking forward to Ayurveda to design effective management of Sandhigatavata. Considering these views, it was thought to evaluate effect of Patola (Tricosanthusdioca)Kshir Basti on Sandhigatavata.

Effect of Therapy on General Symptom Score: It has been explained in the criteria of assessment that the effect of therapy will be evaluated on clinical features by adopting score system which is described in the criteria of assessment. These symptoms were pain, pain on extension and flexion, Stiffness, *Shotha*, Crepitus, Tenderness, and Nature of pain. Each of these symptoms was assessed with respect to the symptom for general symptom score before the start of treatment as well as after the completion of treatment.



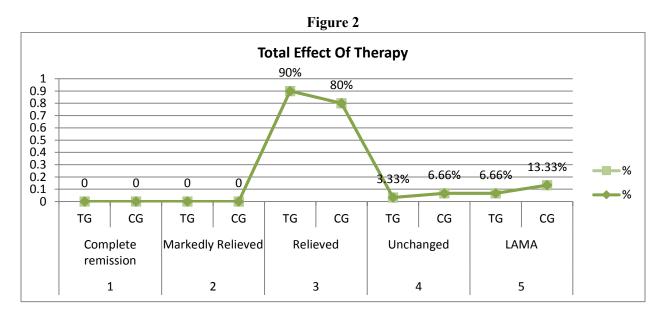


Total Effect of Therapy: In this study, none of the patients of *Sandhigatavata* were categorised in 'complete remission and markedly relieved'. However, 90% patients from Trial Group were relieved and 3.33% patients were unchanged after completing the treatment. In case of Control group 80% patients were relieved and 6.66% patients were unchanged. Comparison between two groups was statistically evaluated by Chi-square test using Yates correction because condition of almost five units in each cell of criteria of effect of therapy was not fulfilled.

Total Chi Square = 0.000136+0.0025+0.1423+0.0025 = 0.1474

At 5% level tabulated Chi Square at said degree of freedom [(C-1)(R-1)]=1 is 3.841 which is much more than calculated Chi Square value, hence the result are insignificant at 5% level. To calculate Chi Square following formula was used.

 $[O-E] - 1/2]^2/O-E$ Yate's correction was used. This test suggested that both of the groups are same. Kshir Bastiin the management of Sandhigatavatais one of the useful, cost effective, treatment having less side effects. So, drugs having Tikta Rasalike Patola (Tricosanthusdioca) and Guduchi (Tinusporacordifolia) were used in this study in the form of KshirBasti for the patients of Sandhigatavata having Sthula Constitution. Tikta Rasa present in Basti might be beneficial in MedaPachana. By virtue of Ruksha, Khara, Parushaguna of Tikta Rasa might be helpful in forming the Asthi Dhatu from Sthula part of Meda Dhatu. Sandhigatavata as described earlier is the major problem of the today's era. It is very important to manage such patients with the help of Ayurveda. The course of Kshir Basti processed with Tikta Rasa should be used for more prolonged time in future.



Probable mode of action of Basti: *Basti Chikitsa* is the prime treatment modality of *Ayurveda*. It is also considered as *ArdhaChikitsa* (half treatment). Though *Basti* is administered in the *pakvashaya*, it has action throughout the body. According to *Shushruta*, a properly given *Basti*, remains in the *pakvashaya*, *shroni* and below *nabhi* (umbilicus) and through the *srotases* the *Virya* (potency) of *Basti Dravya* spread to the entire body. *Basti* is having two action, expelling the *Doshas* and nourishing the body. First, potency of the Basti drugs get absorbed to have its systemic action. Its second major action is related with the facilitation of excretion of morbid substances responsible for the disease process into the colon, from where they are evacuated^[24].

CONCLUSION

Osteoarthritis is a disease in which degeneration of joint cartilage and adjacent bone that can cause joint pain and stiffness. This is the most common of all joint disorders affects men and women. The prevalence of this joint disease is estimated to be 1-2% world-wide. Since Osteoarthritis is a most commonly disturbing joint disease a number of analgesics and anti-inflammatory drugs are prescribed in it. *Kshir Basti* in the management of *Sandhigatavata* is one of the useful, cost effective, treatment having less side effects.

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Source of Support: Nil Conflict of Interest: None Declared

How to cite this URL: Gulhane Harshad et al: A Clinical Randomized Open Study On The Management Of Sandhigatavata W.S.R. To Osteoarthritis By Patola (Tricosanthus Dioca) Kshir Basti. International Ayurvedic Medical Journal {online} 2021 {cited March, 2021} Available from: http://www.iamj.in/posts/images/upload/562_571.pdf