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CLINICAL STUDY TO ASSESS THE EFFICACY OF GANDHA TAILA ORALLY IN THE MANAGEMENT OF JANU SANDHIGATA VATA WITH SPECIAL REFERENCE TO KNEE JOINT OSTEOARTHRITIS

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Abstract

INTRODUCTION: Sandhigatavata is one among the vatavyadhi. It may be correlated to osteoarthritis. Osteoarthritis is a degenerative joint disorder characterized by breakdown of joint cartilage and produces the symptoms like joint pain, swelling etc. due to resemblance in signs and symptoms. Though, many treatments are available for osteoarthritis, pain management is essentially preferred. Gandha taila has been widely described in the ayurvedic texts and it is said to be very beneficial for degenerative bone and joint disorders. So this clinical study is planned to evaluate the efficacy of gnadha taila in the management of janusandhigatavata (OA of knee) as, it has vatahara, shothahara (antiinflammatory), shoolahna (analgesic) action.

METHODOLOGY: 50 patients fulfilling the diagnostic and inclusion criteria belonging to either sex were selected for this open uncontrolled clinical study. Gandha taila was prepared and administered orally with milk or warm water in a dose of 20ml twice a day for 45 days.

RESULT: Subjective parameters were suitably graded to assess the results based on clinical observations before and after treatment. Statistically results were highly significant ($P < 0.001$) in criteria like pain, swelling, crepitation, pain during extension & flexion of joint.

CONCLUSION: Gandha tail prepared by using of Sesame seeds, Cow milk, Kakolyadi gana and Eladi gana is found very effective in the context of shool (<0.001- highly significant), shotha (<0.001- highly significant), Vatapurnadrutisparsha (<0.001- highly significant), Akunchana prasarana janya vedana (<0.001- highly significant).

Key Words : Knee joint osteoarthritis, Janusandhigata vata, Gandha taila

INTRODUCTION

Osteoarthritis is a degenerative joint disorder characterized by breakdown of joint cartilage. It is caused by the mechanical stress to the joints and produces the symptoms like joint pain, swelling etc. Even though the disease effects any joint in the body, most commonly involved joint and weight bearing joint of the body is knee joint. The incidence of this disease increases with the age and the prevalence is more in females (25%) when compared to the males (16%).^[1] According to WHO Osteoarthritis is the 2nd commonest problem in the world population i.e 30%. The major risk factors associated with Knee joint are Age, female, sex, obesity, occupational Knee bending, & making it an important cause of disability. There is no treatment available which can prevent or reverse or block the disease process. The disease is manage by NSAID'S, analgesic drugs, physiotherapy & corticosteroids etc. These drugs are very costly & cause unwanted side effects. Even the surgical treatment does not provide complete relief. This disease simulates to the sandhigata vata. In sandhigatavata mostly janusandhi and some other major joints i.e. hip, knee, shoulder etc. are involved. Out of these janusandhi is commonly involved since it is weight bearing joint. Janusandhigata vata is most common joint disorder world wide especially amongst the elderly and obese person. Till date janusandhigata vata is a challenging disease and it is the one cause of disability in industrialized countries. While working in hospital we came across large number of patients suffering from janusandhigata vata. To overcome all above limitation & side effect of surgery & conservative management this disease still have ray of hope and ayurveda could be solution. Hence janusandhi gata vata had been the subject of study in previous year and reasearch scholars have shown enthusiatic results with help of ayurvedic preparations. Gandha taila has been widely described in the ayurvedic texts and it is said to be very beneficial for degenerative bone and joint disorders. With the Aim of this to keep step forward the present study had been planned and taken up as a research.

AIM OF THE STUDY: clinical study to assess the efficacy of gandha taila orally in the management of janu sandhigata vata with special reference to knee joint osteoarthritis.

OBJECTIVES OF THE STUDY :

1) To review & study the complete literature available on knee joint osteoarthritis

according to ayurveda and modern aspect.

2) To review & study the complete literature available on Gandha taila.

MATERIALS AND METHODS :

Method of preparation for Gandha Tail :^[2]

1. In present era it is not possible to follow procedure as mentioned in Sushruta samhita for "Gandha tail" preparation.

2. We have modified same procedure feasible to todays condition without distracting basic involved by Sushruta while preparation of "Gandha tail".

3. As per the reference given in text the method of preparation start with pouch of "Black till" kept in following water for seven days. But now days it is difficult to find a clean following water in urban areas.

4. So we have placed the pouch of "Black till" in full of water vessel overnight and dried in the sun during the day time for seven days. In second week the pouch of "Black till" had been dipped in "Cow's milk" overnight than in the day time it was placed under the sunlight to dry.

5. Then after in third week "Black till" pouch had been dipped in the decoction of yestimadhu like the same way and than again it was dried under the sunlight in day time this was done for another seven days,

6. Finally the pouch containing "Black till" was again dipped in "Cow's milk" and kept overnight and dried under the sunlight in day time. After drying the "Black till" was made in to powder form and than powder of "Kakolyadi drugs" was added to it.

7. Further we had made "Eladi gana" kwatha by adding cow's milk to it than adding all the drugs (powder of black till and kakolyadi drugs) and added adequate amount of water to it.

8. The Gandha taila was prepared by keeping these mixture on low flame and than the siddhi lakshana of oil was checked.

Dose :^[3] 1 pal = 40ml, So for patient convenient we have divided same as

20ml twice a day. Before meal With milk / warm water.

Type of study : open uncontrolled clinical study.

Samples size:- 50 Patients who fulfill the inclusive criteria had been selected with irrespective of sex from D.Y. Patil Ayurvedic Hospital.

Follow up :- The follow up of patients had been taken on weekly basis.

Duration of study :- 45 days.

Investigation:- (Pre-clinical study) CBC, ESR ,BSL, Sr.Creat

X-ray of Knee joint Ap-Lat.

SELECTION CRITERIA:

Inclusion criteria:

- Patients in the age group of 40-65 years of both male & female.
- Patients with symptoms like shool (pain),shotha (swelling), Vatapurnadrutisparsha (crepitation), Akunchana prasarana janya vedana.(pain during extension & flexion of joint).

Exclusion criteria:

- patients suffering from diseases like amavata, vatarakta,& kroshtukshirsha.
- patients with condition like AID'S,tuberculosis,uncontrolled diabetes,uncontrolled hypertension and pregnancy.
- patients with secondary osteoarthritis of diseases such as rheumatoid arthritis, malignancy & trauma are excluded.

Assessment Criteria: Assessment had been made with the following parameters.

SUBJECTIVE PARAMETERS:

1. shool (pain)
2. shotha (swelling)
3. Vatapurnadrutisparsha (crepitation)
4. Akunchana prasarana janya vedana.(pain during extension & flexion of joint)

GRADATION CHART FOR SUBJECTIVE PARAMETERS:

1. **Shoola (pain)** : pain had been assessed on the basis of visual analogue scale.

Table No:1

Shoola (Pain)	Grade
No Shoola	0
Mild Shoola	1-3
Moderate Shoola	4-6
Severe Shoola	7-10

I have used VAS (Visual Analogue Scale) for pain gradation. Pain intensity 0 = no pain ; 1 - 3 = mild pain (patient has no difficulty while walking) ; 4 - 6 = moderate pain (patient has slight difficulty while walking) ; 7 - 10 = severe pain (patient has difficulty while walking).

2. **Shotha (swelling)** :- It is typically the result of inflammation. Swelling can occur internally, or it can affect the outer skin and muscles.

Table No:2

Shotha (Swelling) in joints	Grade
No Swelling	0
Mild Swelling	1
Moderate Swelling	2
Severe Swelling	3

Gradation for Shotha (Swelling) – [0] gradation is no swelling ; Gradation [1] is mild swelling i.e slight pitting disappears rapidly ; Gradation [2] is moderate swelling i.e somewhat deeper pitting disappears in 10-25 second ; Gradation [3] is severe swelling i.e pitting is noticeably deep may last more than a minute.

3. **Vatapoornadrutisparsha (crepitation)** :- A clinical sign had been characterized by a crackling sensation or sound felt under the joints.

Table No:3

Vatapoornadrutisparsha (Crepitation)	Grade
No Crepitus	0
Palpable Crepitus	1
Audible Crepitus	2

Gradations of crepitation – Gradation [0] is no crepitus (No crackling sensation or sound) ; Gradation [1] - Palpable crepitus (cracking sensation under the joint) ; Gradation [2] - Audible crepitus (crackling sound under the joints).

4. **Akunchana prasarana janya vedana** :- Pain during extension and flexion of joint will be assessed on the basis of visual analogue scale.

Table No:4

Akunchan Prasaranjanya Vedana	Grade
No pain	0
Pain without winching of face	1-3
Pain with winching of face	4-6
Prevent complete flexion	7-10

I have used VAS (Visual Analogue Scale) for pain gradation. Pain intensity 0 = no pain ; 1 - 3 = mild pain (Pain without winching of face) ; 4 - 6 = moderate pain (Pain with winching of face) ; 7 - 10 = severe pain (Prevent complete flexion).

OBSERVATION :

In this clinical study a total number of 50 patients were screened all the patients were examined before and after the treatment. It was observed that majority of the patients suffering with osteoarthritis of knee joint were elderly above 45 years among them 70% were female. which affects the people with increased physical activity and vatakaphapradhana prakruti. Majority of the patients were belonging to hindu community with normal body weight, disease chronicity of more than three year with gradual onset of the disease in which continuous generalised pain was observed.

RESULTS :

The signs and symptoms were assessed before, after the treatment based on the assessment criteria. The effect of the therapy statistically analysed by Wilcoxon's signed rank test.

Table No:5 Showing effect of Gandha taila on pain:

SR. NO.	VARIABLES		MEAN	SD	MEDIAN	N	W	p	RESULT
1	Shoola (PAIN)	BT	5.14	1.14	6	50	127 5	<0.001	HIGHLY SIGNIFICANT
		AT	0.76	0.96	1				
		DIFFERENCE	4.38	0.6	4				

During this clinical study we were observed there was highly significant decrease in Pain observed on last day of study (45th day) i.e Initially, Mean score of pain was 5.14 and after given Gandha taila orally to the patients it reduced up 0.76. This result is statistically highly significant (P<0.001), In Janusandhigata vata.

Table No:6 Showing effect of Gandha taila on swelling:

SR. NO.	VARIABLES		MEAN	SD	MEDIAN	N	W	p	RESULT
2	Shohta (SWELLING)	BT	2.36	0.48	2	50	127 5	<0.001	HIGHLY SIGNIFICANT
		AT	0.36	0.53	0				
		DIFFERENCE	2	0.29	2				

During this clinical study we were observed there was highly significant decrease in swelling observed on last day of study (45th day) i.e Initially, Mean score of swelling was 2.36 and after given Gandha taila orally to the patients it reduced up 0.36. This result is statistically highly significant (P<0.001), In Janusandhigata vata.

Table No:7 Showing effect of Gandha taila on crepitation:

SR. NO.	VARIABLES		MEAN	SD	MEDIAN	N	W	p	RESULT
3	Vatapoorna drutisparsha CREPITATION	BT	1.38	0.49	1	50	127 5	<0.001	HIGHLY SIGNIFICANT
		AT	0.38	0.49	0				
		DIFFERENCE	1	0	1				

During this clinical study we were observed there was highly significant decrease in crepitation observed on last day of study (45th day) i.e Initially, Mean score of crepitation was 1.38 and after given Gandha taila orally to the patients it reduced up 0.38. This result is statistically highly significant ($P < 0.001$), In Janusandhigata vata.

Table No:8 Showing effect of Gandha taila on pain during extension & flexion of joint:

SR. NO.	VARIABLES		MEAN	SD	MEDIAN	N	W	p	RESULT
4	Akunchana prasarana janyavedana (PAIN DURING EXTENSION & FLEXION OF JOINT)	BT	5.14	1.14	6	50	127 5	<0.001	HIGHLY SIGNIFICANT
		AT	0.76	0.96	1				
		DIFFERENCE	4.38	0.6	4				

During this clinical study we were observed there was highly significant decrease in pain during extension & flexion of joint observed on last day of study (45th day) i.e Initially, Mean score of pain during extension & flexion of joint was 5.14 and after given Gandha taila orally to the patients it reduced up 0.76. This result is statistically highly significant ($P < 0.001$), In Janusandhigata vata.

DISCUSSION:

Discussions had been under the following headings:-

1. Discussions on Janusandhigata vata.
2. Discussion on clinical study.
3. Discussion on demographical data.

1) Discussions on Janusandhigata vata:-

The description of sandhigata vata is available in almost all the ancient literature, begins from vedic literature to today's recent advancement of ayurveda and when janusandhi is involved it may be called as janusandhigata Vata. This disease simulates to the Osteoarthritis of knee joint, osteoarthritis also called as degenerative joint disorder, it is most common form of chronic disorder of synovial joints. It is characterized by

progressive degenerative changes in the articular cartilages over the years, particularly in the weight bearing joints, which shows a strong association with aging and is a major cause of pain and disability in the elderly. OA of the knee joints is the most common form of OA; hence the present study was designed on management of Janusandhigata Vata (OA of Knee Joint).

2) Discussion on clinical study:-

50 patients were registered for the study. All the patients were subjected to thorough Pre-clinical laboratory and radiological examinations. All the patients appeared for the assessment of results. The laboratory tests like routine blood viz: CBC, ESR, BSL and Sr.Creat were done to assess the general condition of the patient and to exclude the other systemic diseases. The radiology of the affected joint was performed in each patient as diagnostic criteria and also to exclude the conditions associated with simple or compound fractures. After scrutinizing the whole literature of ayurveda and modern Medicine, the subjective parameters for clinical assessment whereas shool (pain), shotha (swelling), vatapurnadrutisparsa (crepitation) and akunchana prasarana janya vedana (pain during extension & flexion of joint). All the patients were subjected to administered the Gandha taila orally with milk or warm water in a dose of 20ml twice a day and later each patients were observed for samyaka/ayoga anuvasita Lakshanas and final assessment was done on 45th day.

3) Discussion on demographical data:-

The **observations** obtained during the clinical study are discussed below :-

Age:- Eligibility criteria for patients for the study between 40-65 years. 30% Patient were belongs to the age group of 46-50 years. This indicates that the disease Janusandhigata Vata is known fact in the old age group. After reaching the age of 45 there was natural degeneration of the Śarira Dhatu and Bala which in turn aggravates the Vata generating the pathology.

Sex:- 70% of the patients of this study were females and 30% was male. Even the universal data says the prevalence of osteoarthritis is more in elderly women. In females, menopause contributes the degenerative changes. Even in males the degenerative process starts from the age of 50.

Religion:- This study shows a greater prevalence of Janusandhigata vata in Hindus 39 patients (78%) and 11 patient (22%) Muslim. The greater incidence may be due to more population of Hindus in and around this area.

Education:- In this study, maximum number of patient i.e. 62% were primary educated, 22% illiterate, 12% graduate, and 4% Post graduate. It was revealed from the study that due to lower education, people have to do more strenuous work and don't take proper diet, which may lead to Dhatukshaya.

Occupation:- Majority of the patients (52%) were occupied with Physical labor which involves long hours of working in fields, lifting weights, standing for long hours and traveling, while (40%) patients were from sedentary lifestyle, and only 8% were Executive. Knee joint is a weight bearing joint, hence the constant standing, walking long distances, lifting weights etc activities exerts stress on the joints and accelerates the process of degeneration.

Prakruti:- 34% were belonged to Vata-Pitta Prakruti. And 56% patients were Vata kapha Prakruti. It specifies that Asthi Kṣay is more common in Vata –kapha Pradhana Prakruti. Hence, majority of the patients were having the existence of Vata dosha in their prakriti constitution. This shows the Vata prakriti person is more prone to vataja set of diseases.

Knee joints affected:- Majority of patients 78% were affected with bilateral knee involved, only 22% with unilateral involvement. The bilateral involvement may be because of lack of treatment at initial stage as it is told that in long standing O.A leads to bilateral involvement which is unilateral initially.

Duration of Illness:- Maximum number of patients (62%) gave 3 years of history of illness, 10% less than 1yr, 28% between 1-3yrs of History. Which suggest that the disease is yapyya/Asadhya and progression will be continuing till we check the disease process and give proper line of treatment.

Further, During this clinical study we were observed that near about 3 patients were dropped out, as per our observation in this context test of medicine was major factor. None of our patient were developed any adverse drug reaction during my clinical study.

CONCLUSION :

During this clinical study while reviewing various references we have noticed that vata is essential factor for the development of janu sandhigata vata. Moreover, cardinal features of janu sandhigata vata are similar to cardinal features of osteoarthritis. Gandha tail prepared by using of Sesame seeds, Cow milk, Kakolyadi gana and Eladi gana is found very effective in the context of shool (<0.001- highly significant), shotha (<0.001- highly significant), Vatapurnadrutisparsha (<0.001- highly significant), Akunchana prasarana janya vedana (<0.001- highly significant). During our clinical study we have not observed any adverse drug reaction. As sample size for this study was only 50 and medicine test factor was responsible for 3 dropped out needs to be conducted on more sample size with multicentric, controlled trial by adding appropriate flavour in prepared medicine for patients convenience.

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