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A Comparative Clinical Study To Evaluate The Efficacy Of *Pancha Tikta Ksheer Basti* And *Janu Dhara* In The Management Of *Janusandhigata Vata* W.S.R. To Osteoarthritis

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Abstract-

Ayurveda is a 'science of life' which provides not only curatives but also Preventive principle for healthy and long life of human beings. Vata, Pitta, and Kapha are Tridoshas which are responsible for health and disease depending on their normalcy and disequilibrium state. Among *Tridosha, Vata* is responsible for all *Chesta* and all disease. Abnormal Vata performs various afflictions to the body, thereby it produces various Vatavyadhi. When this deranged Vata lodges in Sandhi, it is characterized by pain, swelling and restriction of joint movements. Commonly this Sandhigata vata manifests in Janusandhi, which is a Marma and one among the most important weight bearing joints in body and it leads to Janusandhigata Vata. Janusandhigata vata is a Shoola and Shotha Pradhana Vatavyadhi affecting locomotor system and leaving the person disable and make him unable to do his daily routine activity. In contemporary medical science the similar condition of joint is explained as Osteoarthritis. Because it also produces the features such as, pain, inflammation, stiffness, limited movements and deformity in severe cases. Osteoarthritis is most common form of arthritis and also called degenerative joint disease. Due to similarities in signs and symptoms, it can be very much correlated to Janusandhigata Vata. The disease is managed by NSAIDs, Analgesic drugs, physiotherapy and corticosteroids etc. Above drugs are very costly and cause unwanted side effects. Even surgical treatment does not provide complete relief. Considering these facts, any new addition of herbal drugs in the clinical armamentarium is most welcome. Pancha Tikta Ksheer Basti and Janu Dhara (Local application) are believed to have appreciable role in the management of such degenerative conditions by imparting strength to the body musculature and nervous system.

Research study was carried out on 45 clinically diagnosed patients of *Janusandhigata Vata*. Total duration of Treatment was 48 days with the regular follow up every fort night up to 2 months for observing any side effect of drugs and symptomatic evaluation

Keywords: - Ayurveda, Janusandhigata Vata, Osteoarthritis, Basti, Pancha Tikta Ksheer Basti, Janudhara.

Introduction-

Ayurveda is a 'science of life' which provides not only curatives but also Preventive principle for healthy and long life of human beings. Vata, Pitta, and Kapha are Tridoshas which are responsible for health and disease depending on their normalcy and disequilibrium state. Among Tridosha, Vata is responsible for all Cheshta and all disease. Abnormal Vata performs various afflictions to the body, thereby it produces various Vatavyadhi. In old age, all Dhatu being to undergo Kshaya, thus leading to Vata Prakopa and making the individual prone to many Vatavyadhi. Among them Janusandhigata vata is having a higher incidence. When this deranged *Vata* lodges in *Sandhi*, it is characterized by pain, swelling and restriction of joint movements. Commonly this Sandhigata Vata manifests in Janusandhi, which is one among the most important weight bearing joints in body. The affliction of *Sandhis* by *Prakupita Vata* is the chief phenomena in *Samprapti* of Janusandhigata Vata. In Ayurveda, it is stated that any type of Shoola cannot be without presence of Vata¹. Hence, Janusandhigata Vata is a Shoola and Sothapradhana Vatavyadhi affecting locomotor system and leaving the person disable and make him unable to do his daily routine activity. One of the commonest disease seen in society is Janusandhigata Vata. Owing to distracting nature and difficult management Vatavyadhi has been included in *Aastamahagada*. Sandhi are one of the types of Marma and form a part of Madhyama Rogamarga. Thus, involvement of Marma, Madhyama Rogamarga, Vata dosha and Dhatukshaya make disease Kashta Sadhya.

Acharya Charak and Vagbhat has described the disease separately by the name of 'Sandhigata anila' under the chapter of Vatavyadhi. He defined it as a disease, with the symptoms of Swelling (Sandhishotha), which is palpable as air filled bag (Vatapurṇadrati Sparsaḥ) and pain on flexion and extension of the joints (Prasaraṇakuncanayoḥ savedana).

Acharya Sushruta described Pain (Shoola), Swelling (Shotha) and diminution of the movements at the joints involved (hantisandhigatah) as symptoms of Janusandhigata Vata.

Acharya Madhava described hanti sandhigatah (loss of functions), Pain (Shoola) and Atopa is symptom of this disease.

In *Ayurveda classics*, our *Acharya* have given so many special therapeutic procedures for specific disease along with thousands of medicaments. *Panchakarma* is a very unique therapeutic procedure, because of its preventive, promotive, prophylactic and rejuvenate properties as well as providing a radical cure. Among these *Panchakarma*, *Basti Karma* is such a *Chikitsa* that is applicable in all the *Vatavyadhis*. *Janusandhigata Vata* is a *Vatika* disorders and *Vata* also controls and regulator of other two *Dosha*, *Dhatu* and *Mala* and also all the body activities. Therefore, once *Vata* is controlled by *Basti*, all these factors are automatically regulated and total body equilibrium is achieved.

Acharya Charka has mentioned repeated use of Snehana, Svedana, Basti and Mridu Virechana for the treatment of Vatavyadhi. So, the plan of the management of diseases, in the study is based on the recommendations from classics for the treatment of Vatavyadhi. According to Ayurveda Snehana, Svedana, Dahana and Upanaha are the prime modalities of treatment in the management of Janusandhigata Vata. These are mostly aimed at Brimhana.

Sushruta has mentioned the treatment for Sandhigata Vata as Snehana, Svedana, Upanaha, Agnikarma, Bandhana and Unmardana.

Vagbhat explained that Sneha should be used according to Yukti for Bhakshana, Basti, Nasya, Abhyanga, Gandusha, Murdhni Taila, Karna Poorna and Akshi Tarpana.

Janu Dhara is one of the modalities of treatment commonly adopted in the management of *Janusandhigata Vata. Janu Dhara* procedures that have basically evolved from *Parisheka*, which is mentioned among type of *Svedana*. These also have *Brimhana* action due to the *Sneha* which is allowed to pouring over the affected joint for a stipulated duration.

In contemporary medical science the similar condition of joint is explained as Osteoarthritis. Because it also produces the features such as, pain, inflammation, stiffness, limited movements and deformity in severe cases. Osteoarthritis is most common form of arthritis and also called degenerative joint disease. It commonly presents unilaterally in the knee joint, which is the most important weight bearing joint in the body. Osteoarthritis of knee joint is the most common joint disorder seen in elderly people. Due to similarities in signs and symptoms, it can be very much correlated to *Janusandhigata Vata*.

Osteoarthritis refers to a clinical syndrome of joint pain accompanied by varying degrees of functional limitation and reduced quality of life. It is the most common form of arthritis, and one of the leading causes of pain and disability worldwide. Osteoarthritis is the most common by age 60. Studies reveal there is a steady rise in prevalence of OA from age 30 such that by 75 years, 80% of people have radiographic evidence of Osteoarthritis, although only 25-30% may have symptomatic. Osteoarthritis is a major cause of morbidity and disability, limiting activity and impaired quality of life especially among the elderly. The primary complaints of patients with Osteoarthritis are pain and difficulty in joint mobility. The etiology of pain is multi-factorial, including inflammatory and non-inflammatory causes. The disease is managed by NSAIDs, Analgesic drugs, physiotherapy and corticosteroids etc. Above drugs are very costly and cause unwanted side effects. Even surgical treatment does not provide complete relief. The most commonly affected peripheral joints are the knees, hips and small hand joints.

Osteoarthritis (OA) is the second most common rheumatological problem and is most frequent joint disease with prevalence of 22% to 39% in India ^{2,3,4}. This is the most common cause of locomotor disability in the elderly ⁵. ICMR sponsored multi-center study, 'Epidemiology of musculoskeletal conditions in India' according final report 2012 the prevalence of OA (screened positive in the sample size of 10 thousand) in Delhi was 3.28%, it was found to be 5.81% in Dibrugarh and 6.52% in Jodhpur ⁶.

NEED OF STUDY: -

- People of this era has changed his life style erroneously causing various physical as well as mental ailments out of which Osteoarthritis.
- Due to change in dietary habits, social structure, life style and environment factor joint disorders diseases have become the burning problem of society as well as medical community. Considering all the described facts it can be concluded that the complex cure of the disease is still having the status of miracle.
- The chronic pain of arthritis is a common presentation in clinical orthopedic practice. It presents not only with crippling and incapacitating effect but also with emotional, economic, and social problem. Often, the course of the diseases cannot be altered.
- Analgesics are the only mode of treatment.
- Commonly used analgesics and anti-inflammatory drugs have their limitations on short-term and prolonged use. In addition, there may be individual variation in analgesic effects.
- Considering these facts, any new addition of herbal drugs in the clinical armamentarium is most welcome.

This present research work undertaken is entitled as "A Comparative Clinical study to evaluate the efficacy of *Pancha Tikta Ksheer Basti & Janu Dhara* in the management of *Janusandhigata Vata* w.s.r. to Osteoarthritis" is focused in important techniques i.e. *Pancha Tikta Ksheer Basti* and *Janu Dhara* (Local application) are believed to have a appreciable role in the management of such degenerative conditions by imparting strength to the body musculature and nervous system. These drugs are proved to have *Vatahara*, *Shothahara* and *Vedanasthapana* properties by various research workers. *Vrihata Vishnu Taila* was given for *Janu Dhara* (local application).

AIMS AND OBJECTIVES: -

- Conceptual & Clinical study of Janusandhigata Vata w.s.r. to Osteoarthritis.
- To evaluate the efficacy of *Vrihata Vishnu Tail* in the form of *Janu Dhara* in the management of *Janusandhigata Vata*.
- To evaluate the efficacy of Pacha Tikta Ksheer Basti in the management of Janusandhigata Vata.
- * MATERIALS
- Clinical study materials: 45 Clinically diagnosed patients of Janusandhigata Vata
- Source of data: The data was collected from the patients, who were pre diagnosed and diagnosed patients of *Janusandhigata Vata* having age between 16 to 70 years were taken for the clinical trial from the (OPD, IPD unit of *Panchakarma* Department, NIA hospital Jaipur). Selection was carried out according to relevant history, sign, and symptoms including laboratory investigations to giving written informed consent. Special clinical proforma was prepared and findings were recorded at regular interval for proper assessment.

METHODS

Research design:

A comparative randomized clinical study.

Statistical method: Wilcoxon test and ANOVA test (Kruskal Wallis test), Dunn Multiple Comparison Test

✤ Diagnostic criteria:

The Patients were diagnosed on the base of both Ayurvedic and modern classical signs & symptoms of Janusandhigata Vata (Osteoarthritis).

CRITERIA: *

INCLUSION CRITERIA:

- Patients having clinical features of Janusandhigata Vata as described in Ayurvedic classics.
- All Patients having clinical symptoms of degenerative joint disease and suffering from moderate- tosevere Joint pain in large joints like knee etc. (with or without morning stiffness of <30 minutes duration).
- ◆ Patients having radiological evidence of OA with findings such as osteophytes, marginal lipping, narrowing of joint space, or sclerosis.
- Patients between age group 16-70 year.
- ◆ Patients belong to either gender, irrespective of religion, sex, socio-economic status, occupation are included for the study. JCRT
- ✤ Pain in the affective joints >6 weeks.
- Patient who are fit for Basti Karma and Janu Dhara karma.

EXCLUSION CRITERIA

- ◆ Patients with any anatomical deformity will be excluded.
- ✤ Patients with poorly control HTN, DM, Malignancy.
- * Patient with systemic condition such as Rheumatoid arthritis, Gouty arthritis, Psoriatic arthritis, Ankylosing spondylitis, were excluded for trial.
- ✤ Age group patient age below 16 years and above 70 years.
- ✤ H/O of any surgical intervention with reference to the affective joints.
- Bed ridden patient, confined to wheel chair, incapacitated. *
- ✤ Alcoholics, drug abusers, pregnant lactating women.

Duration of Trial/ Follow up schedule: Total duration of Treatment was 48 days with the regular follow up every fort night up to 2 months for observing any side effect of drugs and symptomatic evaluation.

Withdrawal criteria: - If any patient develops any adverse reactions or deterioration in condition, or could not report for regular follow up during clinical trial due to any reasons, he /she was withdrawn from the trial.

Treatment Schedule: - 45 clinically diagnosed patients of *Janusandhigata Vata* were registered for trial and they were divided randomly in three groups.

Group A: - In this group *Basti* will be given by *Pancha Tikta Ksheer* drugs for 16 days as *Kala Basti* pattern.Group B: - In this group *Janu Dhara* will be given by *Vrihata Vishnu Taila* on affected knee joint for 16 days.

Group C: - In this group both Pancha Tikta Ksheer Basti and Janu Dhara given to patients for 16 days.

+ ASSESEMENT CRITERIA: -

SUBJECTIVE CRITERIA:

✤ Grading of Janusandhigata Vata patients with reference to different symptoms: -

Sandhishoola (pain in joints)	
No pain	0
Pain during excessive movement	
Pain during little movement	2
Pain during rest, but tolerable	3
Continuous pain not tolerable	4
Sandhishotha (swelling over joints)	
No swelling	0
Swelling that can be seen with very careful observation	1
Swelling that can be obviously observed	2
Swelling very bulky, which can be observed clearly	3
Sandhigraha (Stambha) (stiffness in joints)	
No stiffness	0
Stiffness after first waking in the morning	1
Stiffness up to five minutes after waking, but is	
Relieved after movement	2
Stiffness continues for five minutes, with difficulty in	
Movement	3
Stiffness more than 15 minutes	4

Sparsasahyata (tenderness)

No tenderness	0
Pain on deep touch	1
Pain on superficial touch	2
Patient does not allow to touch	3
Sandhisphuțana (crepitus)	
No crepitus	0
Palpable crepitus	1
Audible crepitus	2

♦ WOMAC OSTEOARTHRITIS INDEX⁷

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The Western Ontario and McMaster Universities Arthritis Index (WOMAC) is widely used in the evaluation of Hip and Knee Osteoarthritis. It is a self-administered questionnaire consisting of 24 items divided into 3 subscales:

- Pain (5 items): during walking, using stairs, in bed, sitting or lying, and standing upright
- Stiffness (2 items): after first waking and later in the day
- Physical Function (17 items): using stairs, rising from sitting, standing, bending, walking, getting in / out of a car, shopping, putting on / taking off socks, rising from bed, lying in bed, getting in / out of bath, sitting, getting on / off toilet, heavy domestic duties, light domestic duties



Severity, on average, during the last 48 hours, of:

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	None	Slight	Moderate	Severe	Extreme
Pain – Walking					
Pain – Stair climbing					
Pain – Nocturnal					
Pain – Rest					
Pain – Weightbearing					
Stiffness:					
Morning Stiffness					
Stiffness occuring during the day					

Level of difficulty performing the following functions, on average, during the last 48 hours:

	None	Slight	Moderate	Severe	Extreme
Descending stairs					
Ascending stairs					
Rising from sitting					
Standing					
Bending to the floor					
Walking on flat					
Getting in/out of a car					
Going shopping					
Putting on socks					
Rising from bed					
Taking of socks					
Lying in bed					
Getting in/out of bath					
Sitting					
Getting on/off toilet					
Performing heavy domestic duties					
Performing light domestic duties					

The WOMAC parameters are:

0 - none, 1 - slight, 2 - moderate, 3 - severe, 4 - extreme.

The index is out of a total of 96 possible points, with 0 being the best and 96 being the worst

IMAGE- SHOWING QUESTIONNAIRE OF WOMAC SCORE

WOMAC OA Grading	WOMAC OA Scoring
0-None	Pain: 0-20
1-Mild	Stiffness: 0-8
2-Moderate	Physical function: 0-68
3-Severe	Total Scoring: 0-96
4- Extreme	

WOMAC OA INDEX

None: 0 Mild: 1-24 Moderate: 24-48 Severe: 48-72 Extreme: 72-96

Total Scoring from above reading is

OBJECTIVE CRITERIA:

Laboratory variables: The laboratory investigations were done those patients which are including clinical trial. The patients were assessed in clinical trial before and after treatment for the following laboratory investigations.

A. Routine Investigation of blood.

Hb%, TLC, DLC, ESR.

B. Radiological examination of joints- X-ray of affected part both anterior posterior & lateral view was done.

C. Serological Test & biochemical test - RA factor, CRP, ASLO Titre

RA Factor, CRP & ASLO Titer to exclude suspicious Rheumatoid arthritis and Gouty arthritis patients.

- STATISTICAL ANALYSIS: All the calculations were calculated through 'Graph-Pad Instat 3' Software.
- Paired 't' test- Applied to independent observation from one sample only when each individual gives a pair of observation, for parametric assessment. It was used on objective parameter of group 'A' and 'B' & group 'C'.
- ✓ Wilcoxon signed rank test- Non parametric test for the case of two related samples or repeated measurement on a single test. It was used for the assessment of improvement in symptom of group 'A', 'B'& 'C'.
- ✓ Inter Group comparisons, for nonparametric variables, Kruskal-Wallis Test & Dunn's Multiple Comparisons Test (Post Test) was used.
- ✓ ANOVA test- For the parametric data, ANOVA test was used and results were calculated.

All the observations made on various parameters were subjected to statistical analysis in terms of: -

Mean	
S.D.	- Standard Deviation
S.E.	- Standard Error
ʻt'	- Paired / Unpaired 't' test

Wilcoxon matched-pairs signed-ranks test for Non-parametric variables within group-

W	=	Sum	of all	signed	rank

P = Two tailed 'p' value

Kruskal-Wallis test for Non-parametric variables of different groups-

K.W. = Kruskal-Wallis-statistic

Interpretation of 'p' value-

>0.05	- insignificant (NS)
<0.05	- significant (S)
<0.001	- highly significant (HS)
<0.0001	- Extremely significant (ES)

OBSERVATIONS AND RESULTS

Demographic data

- The maximum number of patients i.e. 53.33% belonged to age group of 60-70 years, followed by 22.22% age group 49-59 years, 17.77% were from the age group of 48-58 years.
- Majority of patients i.e. 51.11% patients were Male, (84.44%) was Hindu, Urban (75.55%), Education status Secondary (26.66%), Middle socio-economy class (55.55%), Housewives (39.13%), married (97.77%), and were having mild physical activity (44.44%).
- Past history of gradual onset was reported in (64.44%) while Family history (20%) in patients.
- Among the female patients 81.81% were in menopausal state of life.
- Most of the patients i.e. 66.66% were tea addicts, followed by 20% tobacco addict and 13.33% Alcohol addicts.
- On considering the data of *Sharira Prakrti*, maximum i.e. 46.66% patients had *Vata -pitta Prakrti*, 40% had *Vata-Kapha Prakrti* and 13.33% patients had *Pitta-kapha Prakrti* while (62.22%) were having *Rajasika Manasa Prakrti*.
- Maximum patients have Samayaka Nidra (53.33%), Mandagni (51.11%), Madhyama Koṣṭha (53.33%), Madhyama Sara (51.11%), Madhyama Samhanana (57.77%), Sama Pramaņa (53.33%), Madhyama Satmaya (91.66%), Madhyama Satva (42.22%), Madhyama Ahara Abhyavarana Shakti (42.22%),Madhyama Ahara Jarana Shakti (48.88%) and 51.11% Madhyama Vyayama Shakti.

Data Related to disease: -

- Among the *Aharaja Nidana* of the disease taking excessively *Vata Prokopaka Ahara* was found in 35.55% patients. The other prominent *Nidanas* reported were *Ati Sheetahara* (15.55%), *Ati Rukshahara* (20%), *Visamasana* (8.88%), *Ati Alpahara* /fasting (13.33%) etc.
- According to Viharaja Nidāna most of the patients gave the history of Vega Sandharana (48.88%), Divasvapna (33.33%), Ratrijagaraņa (22.22%) etc.
- Involvement of bilaterally knee joint found in maximum number of patients (38.33%) Unilaterally, Left and Right knee joint involvement both (16.66%), Involvement of two joints found maximum Knee along with lumbosacral spine (8.33%), following 5% knee with cervical spine, 5% knee with foot joints etc.
- Most of the patients i.e. (38.33%) were suffering from *Januandhigata Vāta* from 1-2 years following 33.33% from 3-5 years.
- Gradual Onset of disease found in 73.33% of population and 53.33% of patients were having Aching type of nature of Pain.

- Among the chief complaints or *Rūpa* (Symptoms) of *Sandhigata Vāta*, all of population (100%) were having *Sandhiśūla* followed by (93.33%) *Sandhisphuṭana*, (85%) *Sandhigraha (Stabdhatā)*, (66.66%) *Sandhiśotha* and 58.33% were having *Sparśāsahyatā*.
- In the present study decrease joint space found in 53.33% patients followed by Subchondral bony sclerosis in 28.33%, osteophytes in 23.33%, altered shape of bone ending in 10% and Synovial effusion in 8.33% patients.

RESULTS-

Intra Group comparison -

Table No.-1: Showing Effect of Therapy in Subjective Parameters.

Variable	Cr	Me	ean	Mean	%	SD+	SD+ SF+	D	S
v al lable	61.	BT	AT	Diff.	Relief	5D±	SET	1	5
	Gr.	5.86	2.73	3.13	53.409	0.8338	0.2153	<0.0001	пс
	Α							<0.0001	115
Sandhishoola	Gr.	5.73	3.0	2.733	47.674	0.7988	0.2063	<0.0001	пс
Sananisnoola	В							<0.0001	115
	Gr.	<u>6.9</u> 3	2.53	4.40	63. <mark>461</mark>	0.9103	0.2350	<0.0001	110
	C					1	3	<0.0001	пз
	Gr.	3.60	1.93	1.66	46 <mark>.296</mark>	0.9759	0.2520	<0.0001	HS
	A								
Sandhiaraha	Gr.	3.2	1.86	1.33	41 <mark>.66</mark>	0.7237	0.1869	< 0.0001	HS
Sunanıgrana	В						6	8,	
C. C.	Gr.	3.76	1.46	2.27	60.714	0.5936	0.1533	< 0.0001	HS
	C)		3		
	Gr.	2.53	1.4	1.133	44.736	0.6399	0.1652	< 0.01	HS
	Α								
Sandhisotha	Gr.	2.46	1.46	1.0	40.540	0.5345	0.1380	< 0.001	HS
Sunanisoina	В								
	Gr.	2.93	1.13	1.8	61.363	0.4140	0.1069	< 0.0001	HS
	C								
	Gr.	2.0	1.06	0.933	46.666	0.5936	0.1533	< 0.0001	HS
	Α								
Sparasashvata	Gr.	2.06	1.20	0.866	41.935	0.6399	0.1652	< 0.001	HS
Spurususnyuu	В								
	Gr.	2.80	1.20	1.60	57.142	0.5071	0.1309	< 0.0001	HS
	C								

(Wilcoxon matched-pairs signed ranks test)

Sandhisphutana	Gr.	1.73	0.86	0.86	50	0.3518	0.0908	< 0.001	HS
	А								
	Gr.	1.4	0.73	0.666	47.619	0.4880	0.1260	< 0.001	HS
	В								
	Gr.	1.8	0.66	1.33	55.55	0.5164	0.1339	< 0.0001	HS
	С								
	Gr.	64.9	32.6	32.3	49.794	3.265	0.8432	< 0.0001	HS
WOMAC	А								
Index Score	Gr.	60.5	32.5	28.0	46.916	3.295	0.8548	< 0.0001	HS
muex Score	В								
	Gr.	67.6	26.7	40.93	60.492	4.182	1.079	< 0.0001	HS
	С								

(Gr.: Group, BT: Before treatment, AT: After treatment, Diff.: Difference, SD.: Standard Deviation, SE: Standard Error, P: P value, HS: Highly Significant, S: Significant, NS: Non-Significant)

Inter group comparisons- Showing Effect of Therapy in Subjective Parameters.

(Kruskal-Wallis Test & Dunn's Multiple Comparisons Test) (Post Test)

1	able 1002. Intel gio	up comparison i	y IXI uSKal-v	vallis test-
S. N.	Sign & symptoms	K.W.	P- Value	Significance
		statistic		
1.	<mark>Sand</mark> hishoola	19.020	< 0.0001	H.S.
2.	Sandhigraha	9.643	<0.001	H.S.
3.	Sandhisotha	14.772	< 0.0001	H.S.
4.	Sparasashyata	11.551	< 0.001	H.S.
5.	Sandhisphutana	3.53	>0.05	N.S.
6.	WOMAC INDEX	30.579	< 0.0001	H.S.
	SCORE			

Table No. -2: Inter group comparison by Kruskal-wallis test-

(P: P value, HS: Highly Significant, S: Significant, NS: Non-significant)

After this statistical analysis of inter group comparison we got that *Sandhishoola*, *Sandhigraha*, *Sandhisotha*, *Sparasashyata*, WOMAC Index Score have shown highly significant difference between the groups. While *Sandhisphutana* have shown just Non-significant changes.

Symptoms	Comparison	Difference	P- value	Significance
Sandhishoola	A Vs B	4.800	>0.05	N.S.
	A Vs C	-14.500	< 0.01	H.S.
	B Vs C	-19.233	< 0.001	H.S.
Sandhigraha	A Vs B	5.20	>0.05	N.S.
	A Vs C	-8.500	>0.05	N.S.
	B Vs C	-13.700	< 0.01	H.S.
Sandhisotha	A Vs B	2.733	>0.05	N.S.
	A Vs C	-12.733	< 0.01	H.S.
	B Vs C	-15.467	< 0.001	H.S.
Sparasashyata	A Vs B	1.067	>0.05	N.S.
	A Vs C	-12.067	< 0.05	S.
	B Vs C	-12.133	< 0.01	H.S.
WOMAC	A Vs B	10.33	>0.05	N.S.
INDEX	A Vs C	-15.933	< 0.01	H.S.
SCORE	B Vs C	-26.267	< 0.001	H.S.

Table No.- 3: Dunn multiple comparisons (post-test)-

(Gr.: Group, HS: Highly Significant, S: Significant, NS: Non-Significant)

On intergroup comparison, by the post test, group A Vs group B all sign & symptoms have shown nonsignificant difference. Thus, both the groups have shown similar effect.

On intergroup comparison of Group A Vs group C Sandhishoola, Sandhisotha, WOMAC Index score group C have shown highly significant difference. In Sparasashyata have shown significant difference. While Sandhigraha has shown non-significant difference. Thus, group C has shown better results than group A.

On intergroup comparison of group B Vs group C Sandhishoola, Sandhigraha, Sparasashyata, Sandhisotha, WOMAC Index Score have shown highly significant difference. Thus, group C has shown better results than group B.

Intra group comparisons- Showing Effect of Therapy in Objective Parameters. (Paired 't' Test)

 Table No.-4: Showing effect of Therapy on Lab Investigations (Objectives parameters):

Varia	Group	Me	ean	Mean	%	SD±	SE±	Т	Р	S
ble		BT	AT	-Diff.	Relie					
					f					
	Gr. A	11.71	12.24	-	-4.9%	0.5984	0.154	3.452	< 0.0	HS
Hb%			6	0.533			5		001	
(gm	Gr. B	13.22	13.18	0.040	0.30	0.5804	0.149	0.269	>0.0	NS
%)					%		9	9	5	
	Gr. C	13.32	13.63	-	-2.3%	0.7210	0.186	1.683	>0.0	NS
				0.313			2		5	
TLC	Gr. A	716 <mark>6</mark> .	6906.	260	3.62	970.86	250.6	1.037	>0.0	NS
		66	66		%		8		5	
	Gr. B	724 <mark>6</mark> .	6906.	340	4.69	686.40	177.2	1.918	>0.0	NS
		6	66	~~	%		3		5	
	Gr. C	683 <mark>3</mark> .	<mark>63</mark> 46.	48 <mark>6.6</mark>	6.92	1044.6	269.7	1.804	>0.0	NS
		33	66	7	%		2		5	
	Gr. A	20.3 <mark>3</mark>	16.8	3.533	17.3	3.50	2.715		>0 .0	NS
ESR					%			1.302	5	
5	Gr. B	17.73	16.26	1.467	8.27	4.60	2.133	0.687	>0.0	NS
R.S.	1.5				%			5	5	
N	Gr. C	23.06	15.93	7.133	30.93	8.831	2.280	3.129	< 0.0	HS
					%				001	
Neutr	Gr. A	5 9.8	58.33	1.467	2.45	5.792	1.496	0.980	>0.0	NS
ophils					%			7	5	
	Gr. B	57.46	57.8	-	-0.58	5.164	1.333	0.250	>0.0	NS
				0.333					5	
	Gr. C	56.4	59.6	-3.20	-5.67	4.263	1.101	2.907	< 0.0	S
									5	
Lymp	Gr. A	32.33	33.93	-	-4.94	5.654	1.460	1.096	>0.0	NS
hocyte				1.600					5	
	Gr. B	33.53	33.53	0.0	0.0	4.408	1.138	0.000	>0.0	NS
									5	
	Gr. C	35.66	35.2	0.466	1.30	3.461	0.893	0.522	>0.0	NS
							7	2	5	

Eosino	Gr. A	2.4	2.2	0.20	8.33	1.656	0.427	0.467	>0.0	NS
phils							6		5	
	Gr. B	3.4	2.66	0.73	21.55	0.9612	0.248	2.955	< 0.0	S
							2		5	
	Gr. C	3.06	2.26	0.800	26.09	1.320	0.340	2.347	< 0.0	S
							9		5	
Mono	Gr. A	4.06	4.06	0.0	0.0	1.964	0.507	0.000	>0.0	NS
cytes							1		5	
	Gr. B	5.06	4.73	0.33	6.58	1.234	0.318	1.046	>0.0	NS
							7		5	
	Gr. C	4.46	4	0.46	10.43	1.727	0.445	0.312	>0.0	NS
							8		5	

(Hb- Hemoglobin; **TLC-**Total Leucocytes Count; **ESR-**Erythrocyte Sedimentation Rate, Gr.: Group, BT: Before treatment, AT: After treatment, Diff.: Difference, SD.: Standard Deviation, SE: Standard Error, P: P value, HS: Highly Significant, S: Significant, NS: Non-Significant)

Inter Group comparisons- Showing Effect of Therapy in Objective Parameters -

To compare the effect of trial drugs in the groups, intergroup comparison was done. As the variables are parametric we used **ANOVA test**. The results were calculated & non-significant difference was observed between the groups that means the changes in groups were not different from each other.

Variable	P Value	S
		/ . C.
Hb%	< 0.05	S
TLC	>0.05	NS
ESR	>0.05	NS
Neutrophils	< 0.05	S
Lymphocyte	>0.05	NS
Eosinophils	>0.05	NS
Monocytes	>0.01	HS

		• T 100		•			
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Overall Effects of Therapy -

For assessment of overall improvement, following grading used-

Sr. No.	Observation	Grading	Percentage
1.	No relief	0	0-25%
2.	Mild relief	1	26-50%
3.	Moderate relief	2	51-75%
4.	Excellent relief	3	76-100%

Effects	Group A		Gr	oup B	Group C	
	No.	Percentage	No.	Percentage	No.	Percentage
	of		of		of	
	Patients		Patients		Patients	
No relief	0	0	0	0	0	0
Mild relief	07	46.66	11	73.33	01	6.66
Moderate	08	53.33	04	26.66	14	93.33
relief						
Excellent	0	0	0	0	0	0
relief						

Table no. -7: Showing the overall effect of therapy -

In Group A- Excellent relief was not found in any patients, while moderate relief in 53.33% whereas 46.66% were found mild relief, while in group B- Excellent relief was not found in any patients, while moderate relief in 26.66% whereas 73.34% were found mild relief. In group C- Excellent relief was not found in any patients, while moderate relief in 93.33% whereas 6.67% were found mild relief.

DISCUSSION: -

According to Ayurveda, treatment is 'Vighatana of Samprapti'' In the disease of Janusandhigata Vata, Vataprakopa and Khavaigunya i.e. Rikta Srotas (Snehadi Gunasunya) in Asthi-Sandhi are the main factors which leads the Samprapti of the disease. Rikta Srotas is filled by Sneha, correction of Khavaigunya and Vatshamana is achieved by treatment. Thus, For the present study, Pancha Tikta Ksheer Basti & Janu Dhara (Local application) was selected. The description of breakdown of Samprapti is discussed below.

DISCUSSION ON BASTI

Keeping the nature of disease i.e. Osteoarthritis, *Pancha Tikta Ksheer Basti* was planned as per the principle told by *Acharya Charaka* and it was given in the form of a *Yapana Basti*. *Yapana Basti* perform dual function of both *Anuvasana* and *Niruha Basti*, hence these *Bastis* are acting *Srotoshodhaka* as well as *Brihmana* at the same time. That's why there is no administered separate *Anuvasana* while giving *Yapana Basti*⁸.

Different meanings of word Yapana are-

- Pranadharana ⁹
- Dharanam –to maintain, Poshanam-to nourish, Rogashamanam ¹⁰-to cure disease.
- *Chakarpani* commented that *Yapana* means to maintain equillibrium.

Above points indicates that *Yapana Bastis* are *Mridu* in action, they promote *Dhatu* homeostasis and perform mild *shodhan* also. These *Bastis* are *Mridu* as it contains milk, *Ghrita* and *Madhu*¹¹. This stays for a long time in *Pakvashaya* and can be administered at any time ¹².

Pancha Tikta Ksheer Basti is a modification of *Yapana Basti*. The ingredients of *Bastis* contain *Ghee*, *Madhu*, *Saindhava* and milk which are *Ahara dravyas* along with other drugs. Thus, these are *Sahaja Satmya* (Wholesome) and do not produce any adverse action. Being *Ahara Dravyas* these drugs possess the most important *Pranadharana* (to keep continuity of life) quality.

Pancha tikta ksheer basti is a kalpita yog which are prepared by selecting drugs from the Tikta skandha mentioned in Charak Vimana Sthana. Almost all the drugs i.e. Nimba, Vasa, Patola, Amrita, Kantakari (Pancha Tikta) are having Tikta Rasa.so it was named Pancha Tikta Ksheer Basti. Other ingredients are milk, madhu, saindhav salt, Goghrita. Satapushpa kalka was added to increase the efficacy and to avoid any abdominal discomfort.

Mode of Action of Basti: -

Basti is the best treatment for *Vata* as said by *Acharya Charak "Bastihi Vataharanam" Basti* given through anal route firstly acts on *Apanavayu* and makes it normal. Then sequence it acts on *Samanavayu*, *Vyanavayu*, *Udanavayu* and *Pranavayu* and makes them normal *Apanavayu* takes *Basti virya* at *Urdhva Pradesha* of the body and *Vyanavayu* takes *Basti Virya* at the *Tiryaka Pradesha* of the body and makes them normal. *Samanavayu* acts on *Agni* and do *Agni Sandhuksana*, Thus, by getting *Vayu* and *Agni Samata* by *Basti*, health is achieved like tree fed with water at its root nourishes whole the tree, *Basti* nourishes whole the body.

Basti drug first reaches to the *Pakvashaya*. As we know *Pakvashaya* is *Mula Sthana* for *Vatadosha*. *Basti*, by destroying *Vatadosha* at its *Mula Sthana*, gets control on *Vata* all over the body. *Pakvashaya* is the site of *Purishadharakala*. Commentator *Dalhana* has said *Purishadhara* and *Asthidharakala* are one and same (*Su.Kal.-Dalhana*). *Basti* drugs directly acts on *Purishadharakala* so we can take its direct action on *Asthidharakala* also. After passing *Pakvashaya*,*Basti* drugs reach to *Grahani* which is the site of *Pittadharakala*. Here Commentator *Dalhana* has said *Pittadharakala* and *Majjadharakala* are one and same (*Su.Kal* 4-*Dalhana*) so by *Basti*, we can get direct benefit to the *Majjadharakala* also. *Basti* has direct effect on *Asthidharakala* and *Majjadharakala*.

Basti, may acts by increasing the *Asthi Dhatuagni* and *Majja Dhatuagni* and thus it nourishes the *Asthi* and *Majja Dhatu. Acharya Sushruta* has mentioned 6th *Basti* nourishes *Mamsa Dhatu*, 7th *Basti* nourishes *Meda Dhatu*, 8th *Basti* nourishes *Asthi Dhatu* and 9th *Basti* nourishes *Majja Dhatu*. (Su.Chi.37/71-76). Thus, through *Basti* we achieve *Vata dosha Shamana* and *Snehana* of *Asthi Dhatu*.So,we achieve the *shamana* of *Janusandhigatavata* by breaking the *Samprapti*.As *Vata dosha* is predominantly present in *Asthi Dhatu* and joints by *Asraya-asrayi* phenomenon.*Ksheera* used as *Basti dravyas* in the present clinical trial was prepared with *Tikta rasa* dominant drugs which are said to be effective in *Asthigata* and *Majjagata rogas.Ksheera* has *Snigdha* and *Madhura* properties which may further doing *Shamana* of *Vata Dosha*. *Tikta rasa* has tendency to go towards *Asthi Dhatu* after assimilation in body due to *Akasha* and *Vayu Mahabhuta*. The main site of pathology in *Janusandhigata Vata* degenerative changes occur in joints and bones itself. In early stages of *Janusandhigatavata* degenerative changes occur in joints and bones and at that time it treated inadequately or disease attains chronic course it is likely to disintegrates normal anatomical structure of joint in the form of degenerative changes and development of Osteophytes, demineralization of joint, sclerosis occurs which

adversely affects nomal physiological functions of joints and ultimately manifests in the form of *Janusandhigatavata* with joint pain, swelling, stiffness of joints, restricted movements. It was presumed that *ksheera* and *Tikta dravyas* when used together in the form of *ksheera basti* will act on the site of lesion in *Janusandhigatavata* i.e. joints will be in a position to breakdown chain of reactions occurring in the form of *Samprapti* at one hand and arrest the progress of the diseases on the other hand in addition to producing subjective improvement in patients. It was also observed during the current trial that those patients who had a very short history of development of *Janusandhigatavata* if managed with *Pancha Tikta ksheer Basti* showed significant symptomatic improvement.

Pancha Tikta ksheer Basti may also manifest its pharmacological actions in one or all the ways as mentioned below. These factors may act individually or in collaboration with each other to accomplish the task of *Basti* in the form of *Pancha Tikta ksheer Basti* and there by producing desired effects in the form of:

- 1. Arresting progress of the disease.
- 2. Delaying the degenerative changes in *Janusandhigata Vata*.

Pancha Tikta ksheer basti mitigates Vata-Pitta and maintains stability of Kapha. It acts on Rasa, Rakta , Mamsha, Medas, Asthi and Majja. It removes kleda and does aampachan, deepan therefore normalizes medagni and asthyagni and hence work as srotoshodhan as well as due to presence of milk, ghrit and tila taila does brihman and poshan of Asthi dhatu possess khara guna and tikta rasa is also khara in guna so on the basis of principle of samana guna and abhyas the composition of Pancha Tikta Ksheer Basti which is having *khara* and *snigdha guna* both has alleviated the symptoms and brought positive changes in the bone formation. It has worked in the accordance of principle told by Acharya Charak and Vagbhat for the treatment of Asthivikaras¹³. Pancha Tikta Ksheer Basti containing milk, Ghrita, tila taila and honey are used to cure the disease of *Vata* and these increases strength of body 14 . Its *Rasayana* property confirms its action on all body elements. Dhatu poshana depends upon unimpeded srotas, dhatvagni and Vayu if nourishing factors are properly provided ¹⁵. Pancha Tikta Ksheer Basti has nourishing factors for Asthi Dhatu in the form of Tikta drugs, milk, honey, ghrita. Maximum of Kwatha drugs possess Srotoshodhana property. It is stated that all Yapana Bastis can adversely suppress Agni if not appropriately administered ¹⁶. Thus, Janan (formation of body elements) property of Yapana Basti is due to Srotoshodhana quality and nourishing substances used in it. The drugs selected for Pancha Tikta Ksheer Basti have the property of anti-inflammatory, analgesic, antibacterial, anti-toxin, anti-oxidant and anti-tumour, immune-modulator, hepato-protetive. The compound formed by these drugs contained glycosides, saponins, essential amino acids like isoleusine, methionine etc. On the basis of above fact we can assume that the drugs compound thus formed affected the overall mechanism of Asthi formation and resorption by acting on hormonal level, absorption level and at the level of bone remodeling which is also being favored by the positive results in the signs and the symptoms of the patients of Osteoarthritis.

According to Modern medical science, as per *Basti*/Enema concerned in trans rectal route, the rectum has a rich blood and lymph supply and drug can cross the rectal mucosa like other lipid membrane. Thus, by entering in general circulation, *Basti* drugs acts on whole body. In the present study, the quantity of *Basti dravya* which comes out was less to the given *Basti dravya* in *Basti* which shows its absorption through the intestinal mucosa. May *Basti* acts through the nervous system or through the enteric receptors. May it increase the secretion of local enzyme or neurotransmitters. *Basti* influence the normal bacterial flora thus it increases the endogenous synthesis of Vitamin B 12, Vitamin K etc. *Basti* makes the whole metabolism normal.

• Probable mode of action of Janu Dhara

The external *Snehana* and *Svedana* therapies are extensively practiced in *Janusandhigata Vata*. The present clinical study has been conducted to evaluate the efficacy of *Vrihata Vishnu Tail* in the form of *Janu Dhara* in *Janusandhigata Vata*. The effect of therapy is being discussed here along with its efficacy on individual signs & symptoms of *Janusandhigata Vata*.

Janu Dhara is procedures evolved from Parisheka. It is a kind of Bahya Snehana and Svedana procedure. Snehana mainly acts against the Ruksha Guna caused by Vata and Svedana mainly acts against the Sheeta Guna. It also reduces the Stambha and Gauravata.

Sushruta explains that out of four Tiryak Dhamani, each Dhamani divides into hundred and thousand times and become innumerable. These Dhamani form a network and spread all over body. They have their openings in the Loma koopa. The Dravya applied over the skin is absorbed through these openings and undergo Pachana by the help of Bhrajaka Pitta which is situated in the skin. The Dravya can be applied in any forms such as Abhyanga, Parisheka, Avagaha etc. All the drugs applied in any of these forms undergo Pachana in the way explained above.

Vagbhata explained the same mode of absorption of the drugs applied over the skin.

Thus, by above references it can be said the *Dravya* used in *Janu Dhara* is absorbed through skin and produce an action according to the properties of drug.

The *Vata dosha*, which is the key factor in the causation of *Janusandhigata Vata*, has almost opposite quality of *Vrihata Vishnu Tail*.

Vrihata Vishnu tail ¹⁷ contains almost all of the drugs having *Uşṇa virya, Kaṭu, Madhura, Vipaka, Vatasamaka Vedanasthapana, Sothahara, Balya, Dipana, Pacana* and *Rasayana* Properties. *Janusandhigata vata* is a degenerative disorder so *Balya and Rasayana* action will clear the channels and enhance the *dhatu* production. Overall the drug *Vrihata Vishnu tail* is having dominance of *kapha-vata hara Doşhaghnata*. *Janusandhigata vata* is the disease of *Vata & kapha doşha* dominant hence the drugs having *kapha-vata hara* property showed highly significant result in clinical variables. *Vrihata Vishnu tail* is formed by *Til Tail* and *Til Tail* is also having *Vedanasthapana, Sothahara, Balya etc.* properties. *Sandhigata vata* is the disease of *Vata & kapha doşha* dominant hence the drugs having *kapha-vata hara* property showed significant result in clinical variables. Above properties of drugs helps in *Samprapti vightan* and prevents *Khavaigunya* which is main factor for Janusandhigata vata. Vatasamaka. Vedanasthapana, Sothahara effect of Vrihata Vishnu taila is explained in classics.

The relief shown in the present study is remarkable in this disease because this disease is progressive in nature and has tendency towards to incurability. The present study was a humble try in search of a cure and symptomatic relief of disease and improvement quality of life of patients.

CONCLUSION:

- ✓ The efficacy of Pancha Tikta Ksheer Basti along with Janu Dhara is more significant than Pancha Tikta Ksheer Basti and Janu Dhara alone. On comparing Pancha Tikta Ksheer Basti and Janu Dhara, Basti Karma is more effective than Janu Dhara Karma.
- ✓ Administration of *Bahirparimarjana Chikitsa (Janu Dhara)* is inevitable in the Osteoarthritis especially in *Janusandhigata Vata*.
- ✓ Thus, finally we can conclude that Pancha Tikta Ksheer Basti and Janu Dhara with Vrihta Vishnu Tail are effective in management of Janusandhigata Vata (Osteoarthritis) as it is safe, effective & free from any adverse effects. It also considerably prevents the relapse.

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