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CLINICAL EVALUATION OF AN AYURVEDIC COMPOUND IN THE
MANAGEMENT OF JANU SANDHIGATA VATA W.S.R. TO OSTEOARTHRITIS OF
KNEE JOINT

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ABSTRACT:

Janusandhigatavata is one of the “Vata Vyadhi” which is described as a separate clinical entity even though it is not included in 80 types of Nanatmaja Vata Vikara. In modern science it can be correlated with osteoarthritis of knee joint which is a degenerative joint disease of fifth to sixth decade. Present treatment options in modern science have numerous untoward effects. Therefore an effective and side effect free solution was planned in the form of clinical study in which a hypothetical Ayurvedic compound was studied in 90 patients affected from Janusandhigatavata (osteoarthritis). For this study 90 patients of both sexes were randomly selected from O.P.D. of Department of Shalya Tantra, National Institute of Ayurved, Jaipur, Rajasthan, India and divided in to three groups having equal number of patients (30 patients in each group): Group A: Patients of this group were treated with an Ayurvedic compound, Group B: Patients of this group were treated with only Kalka Patra-Bandhan while Group C: Patients of this group were treated with combined therapy (i.e. an Ayurvedic Compound and Kalka-Bandhan). The dose of Ayurvedic compound was – 4 tablet TDS (500 mg each) and duration of treatment were of two months and the progress was evaluated weekly. Group C showed highly significant ($P<0.001$) improvement in overall symptoms while Group B showed significant improvement. It is concluded that combined therapy of Ayurvedic compound along with Kalka Patra Bandana are most effective in alleviating symptoms of osteoarthritis affected patients as compare to single therapy.

KEY WORDS: Janusandhigatavata, Kalka Patra Bandana, NanatmajaVataVikara, Osteoarthritis.

INTRODUCTION

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Ayurveda, an eternal science that deals physical, psychological as well as spiritual wellbeing of an individual covering all the facts of life. Now a day each and every treatment modality in any part of the world is looking towards *Ayurveda* and its herbals treasures for the less side effect and permanent cure of various ailments which present challenges before medical fraternity time to time.

Man of this era has changed his life style erroneously which has altered his *daushik* constitution and caused various physical as well as mental ailments, out of which *Janusandhigataavata* is one of them. On the basis of clinical features it can be correlated with osteoarthritis of the knee joint. Osteoarthritis is a chronic degenerative disease and is a leading cause of pain and disability in most of the countries.¹ It affects 5th - 6th decade of life in male while in females it affects younger age group.² Its ratio in male and female is 4:6. It involve mainly the weight bearing joints.³ It affects mostly major joints of the lower limb, frequently bilaterally, depending upon the daily activities of the population.⁴ Here the hip joint is the most common joint affected in population with western living habits, while the knee is involved more commonly in a population

with Asian living habits such as squatting and sitting cross-legged.^{5,6} In *Janusandhigataavata* pain, swelling, restricted movements of joints are common clinical features. The insidious starting is with aching pain in the joint and relieved by the rest. The other associated symptom is stiffness, which aggravated after a long rest and subsides after by active movement.⁷ The complete remedy of this disease is still not available in modern medicine. The drugs used are mainly Analgesics, Anti-Inflammatory and steroids, which cannot pacify the disease but provides only symptomatic relief.⁸ On other hand furious side effect like gastritis, ulceration of mucosal layer of stomach, heart burn and vomiting are added as the unwanted results.⁹ *Ayurveda* the science of life has its own methodology and hypothesis to manage all types of diseases. In this regard a clinical study is considered as a most important method to establish and revive all treatments hypothesis scientifically.

Keeping these views in mind this special mode of treatment to control *dhatukshaya* in geriatrics, an *Ayurvedic* compound having *Rasayana, Balya, Vatashamaka & AmaPachana* drugs are selected to treat the osteoarthritis of knee joint.

MATERIAL & METHODS

Selection of patients

90 Patients suffering from Osteoarthritis of knee joint were selected randomly as per the inclusion and exclusion criteria from O.P.D. of Department of Shalya, National Institute of Ayurved, Jaipur, Rajasthan, India on the basis of specific proforma prepared according to its description mentioned in *Ayurvedic* texts.

INCLUSION CRITERIA

Only following patients were registered for the study -

- Patients having clinical symptoms of Osteoarthritis.
- Patients having joint space reduction.
- Patients unfit for surgery.
- Patients with osteophytes formation.

EXCLUSION CRITERIA

- Patients affected with tuberculous arthritis, rheumatoid arthritis, gouty arthritis, diabetes mellitus and other secondary arthritis were excluded.
- Patients found associated with Hepatitis B and HIV was excluded from the study.
- If the condition of the patient deteriorated during the trial he/she will be excluded from the study.

DISCONTINUATION CRITERIA

Patient was not willing to continue treatment.

Grouping of patients

All the 90 patients were divided in three groups of 30 patients in each group.

- Group - A: This group of patients was treated with an *Ayurvedic* compound.
- Group - B: This group of patients was treated with only *Kalka Patra Bandhan*.
- Group - C: This group of patients was treated with combined therapy (i.e. an *Ayurvedic* Compound and *Kalka Patra Bandhan*).

Plan of clinical study

- Informed consent was obtained from every patient.
- Patients were managed on an outpatient department basis unless hospitalization is necessary.
- Monthly attendance for clinical evaluation and periodic assessment.
- Patients were instructed to avoid all other form of medicament during the course of treatment.
- In the event of any other illness, the patient must be directed to report the scholar immediately.

SELECTION OF DRUG

An *Ayurvedic* formulation was selected with the drugs having properties like *Sothahara*, *Vatashamaka*, *AmaPachana*, *Balya* and *Rasayana*.

Table no.-1: ingredients of ayurvedic compound

S.No.	Drug	Latin Name	Quantity
1	<i>Laksha</i>	<i>LacciferLacca</i>	1 part
2	<i>Asthishrnkhala</i>	<i>CissusQuadrangularis</i> Linn.	1 part
3	<i>Guggulu</i>	<i>Commiphoramukul</i> (Hook. ex Stocks) Engl.	1 part
4	<i>Shallaki</i>	<i>Bosweliaserrata</i> Roxb. (Salai)	1 part
5	<i>Ashwagandha</i>	<i>Withania somnifera</i> (L.) Dunal	1 part
6	<i>Suranjan</i>	<i>Colchiciumluteum</i> Baker	1/2 part
7	<i>Earanda</i>	<i>RicinusCommunis</i> Linn.	1/2 part
8	<i>Nirgundi</i>	<i>Vitexnegundo</i> Linn.	1/2 part
9	<i>Chopchini</i>	<i>Smilex-China</i> Linn.	1/4 part
10	<i>Sunthi</i>	<i>Zingiberofficinale</i> Roscoe	1/4 part

Ingredient of Kalka PatraBandhan

Fresh leaves of *Shigru*(*Moringa oleifera* Lam.), *Earanda*(*Ricinus Communis* Linn.)&*Nirgundi* (*Vitexnegundo* Linn.) collected daily from herbal garden of National Institute of *Ayurved*, Jaipur, Rajasthan, India.

Drug preparation

- *Ayurvedic* compound was prepared in the pharmacy of National Institute of *Ayurved*, Jaipur, Rajasthan, India.
- *Kalka* was prepared daily from the fresh leaves in the orthopedic O.P.D. unit of Shalya Tantra, , National Institute of *Ayurved*, Jaipur, Rajasthan, India.

Treatment

Dose of drug – 4 tablet TDS (each tablet is of 500 mg)

Duration of treatment

Duration of treatment was of two months and the progress will be evaluated after each 7 days.

Assessment Criteria

Assessment of therapy were done on the basis of functional and various laboratory parameters -

- **SUBJECTIVE PARAMETERS**

- Pain
- Walking distance

- **OBJECTIVE PARAMETERS**

- Pain (VAS)
- Walking distance
- Plain X-ray
- Laboratory Examinations

1. Routine haematological investigations - Hb %, TLC, DLC, E.S.R.
2. Biochemical investigation - Blood Sugar - Fasting and PP, Serum uric acid, RA factor.

The symptoms of Osteoarthritis of knee joint and joint activity were taken for the assessment results of clinical trial. Following four parameters were taken in account.

- Severity of pain
- Deep grading of tenderness
- Walking distance
- Movement of the knee joint (ROM)

OBSERVATION**Table -2: Demographic data**

S.No.	Observation	Maximum	Percentage
1.	Age	51-60 years	40.00
2.	Religion	Hindus	63.00
3.	Sex	Female	59.00
4.	Marital Status	Married	93.00
5.	Socioeconomic status	Middle	62.00
6.	Dietary pattern	Non vegetarian	68.00
7.	Habitat	Urban	60.00
8.	Occupation	House wives	59.00
9.	Education	Matriculation	33.00
10.	<i>SharirkaPrakrati</i>	<i>Vatapittaj</i>	50.00
11.	<i>Satva</i>	<i>Madhyam</i>	60.00
12.	<i>Kostas</i>	<i>Madhyam</i>	60.00
13.	<i>Jatharagni</i>	<i>Manda</i>	60.00

14.	Chronicities	1-2 yrs	31.00
15.	Family history	Negative	75.00
16.	Onset of disease	Gradual	70.00
17.	<i>Desha</i>	<i>Jangala</i>	68.00
18.	Addiction	Tea	70.00
19.	<i>Nidana</i>	<i>Dhatukshaya</i>	68.00
20.	Cardinal features	Deep grading of tenderness	67.00

RESULT

Table -3:Effect of Therapy on assessment criteria of Group A

Assessment criteria	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
Pain	2.73	1.53	43.90	1.24	0.23	5.29	<0.001
Deep grading of tenderness	2.63	1.57	40.51	1.17	0.21	4.98	<0.001
Walking distance	2.17	1.47	32.31	1.42	0.26	2.70	<0.01
Movement of the knee joint (ROM)	2.2	1.6	28.36	1.51	0.28	2.03	<0.05

Table- 4:Effect of Therapy on assessment criteria of Group B

Assessment criteria	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
Pain	2.27	1.53	32.35	1.48	0.27	2.71	<0.01
Deep grading of tenderness	2.23	1.77	20.90	1.36	0.25	1.88	<0.05
Walking distance	2.30	1.70	26.09	1.71	0.31	1.92	<0.05
Movement of the knee joint (ROM)	2.27	1.57	30.88	1.47	0.27	2.62	<0.01

Table -5: Effect of Therapy on assessment criteria of Group C

Assessment criteria	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
Pain	2.27	1.27	54.22	0.82	0.15	10.02	<0.001
Deep grading of tenderness	2.73	1.43	47.56	1.09	0.20	6.55	<0.001
Walking distance	2.77	1.27	54.22	0.82	0.15	10.02	<0.001
Movement of the knee joint (ROM)	2.77	1.17	57.83	0.89	0.16	9.80	<0.001

Table –6: Comparative effect of therapies on Pain

Groups	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
A	2.73	1.53	43.90	1.24	0.23	5.29	<0.001
B	2.27	1.53	32.35	1.48	0.27	2.71	<0.01
C	2.27	1.27	54.22	0.82	0.15	10.02	<0.001

Table –7: Comparative effects of therapies on deep grading of tenderness

Groups	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
A	2.63	1.57	40.51	1.17	0.21	4.98	<0.001
B	2.23	1.60	20.90	1.51	0.28	2.29	<0.01
C	2.73	1.43	47.56	1.09	0.20	6.55	<0.001

Table –8: Comparative effects of therapies on walking distance

Groups	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
A	2.17	1.47	32.31	1.42	0.26	2.70	<0.01
B	2.30	1.70	26.09	1.71	0.31	1.92	<0.05
C	2.77	1.27	54.22	0.82	0.15	10.02	<0.001

Table –9: Comparative effects of therapies on Range of movement

Groups	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
A	2.27	1.60	28.36	1.51	0.28	2.03	<0.05
B	2.73	1.43	47.56	1.09	0.20	6.55	<0.001
C	2.77	1.17	57.83	0.89	0.16	9.80	<0.001

Table –10: Comparative effect of therapies on X-Ray changes

Groups	Mean Score		% of Relief	S.D. (±)	S.E. (±)	t	P
	B.T.	A.T.					
A	1.87	1.77	5.36	0.31	0.06	1.80	<0.05
B	1.90	1.80	5.26	0.31	0.06	1.80	<0.05
C	1.97	1.77	10.17	0.41	0.67	2.69	<0.01

Table -11:Overall Effect of Therapy

Overall effect of Therapy	Group- A	Group- B	Group- C
Complete Remission	26.67	13.33	40.00
Marked Improvement	43.33	40.00	53.33
Moderate Improvement	26.67	40.00	6.67
No Improvement	3.33	6.67	0

Table -12: Recurrence of Symptoms (Follow up – 3 months)

Overall Recurrence of Symptoms	Group- A	Group- B	Group- C
Yes	30.00	40.00	23.33
No	70.00	60.00	76.67

DISCUSSION

All the main signs and symptoms were given scoring according to their severity as mentioned in the material and methods in clinical study. The effect of the therapy on signs and symptoms were assessed on the basis of scoring. Also X-ray examination was performed before and after the treatment to assess the effect of therapies.

Effect of therapies on Cardinal Symptoms

Group A

Effect of *Ayurvedic* compound was statistically highly significant in pain (43.90%). statistically highly significant relief was observed in deep grading of tenderness (40.51%), statistically significant relief was observed in walking distance (32.31%) and statistically insignificant relief was observed in movement of the knee joint (ROM) (28.36%).(Table no.3)

Group B

Effect of *Kalka PatraBandhan* was statistically highly significant in movement of the knee joint (30.88%).

Statistically significant relief was observed in pain (32.35%) statistically insignificant relief was observed in walking distance (26.09%) & deep grading of tenderness (20.90%). (Table no.4)

Group C

Effect of the *Ayurvedic* compound & *Kalka Patra Bandhan*, was statistically highly significant in movement of the knee joint (ROM) (57.83%). Statistically highly significant relief was observed in pain & walking distance i.e. (54.22%) statistically significant relief was observed in deep grading of tenderness (47.56%). (Table no.5)

Effect of therapies on X-Ray examination

Insignificant changes in X- Rays were seen ($P < 0.05$) in group A & B while in Group- C slight significant changes (10.07%) were observed.(Table no.10)

Total Effect of Therapies

In the group A- 26.67% patients showed complete remission, 43.33% patients were markedly improved, moderate improvement found in 26.67% patients

and no improvement was observed in 3.33% of patients.

In the group B- 13.33% patients showed complete remission, 40.00% patients were markedly improved, moderate improvement found in 40.00% patients and no improvement was observed in 6.67% of patients.

In the group C- 40.00% patients showed complete remission, 53.33% patients were markedly improved, moderate improvement found in 6.67% patients and no improvement was observed in 0% of patients. (Table no.11)

Recurrence of Symptoms

In Group-A, recurrence found in 30.00 % patients, Group-B recurrence found in 40.00% patients while in Group-C recurrence found in 23.33% patients during the follow up period i.e. 2 months after completion of therapy. (Table no.12) Here the patients who had moderate or marked improvement were more in number to get recurrence of symptoms.

PROBABLE MODE OF ACTION OF TRIAL DRUG

Ayurvedic compound is having contents which can be divided in to four categories according to their action-

Rasayana & Balya Ashwagandha and Guggulu come under it. These drugs increase the overall vitality of body thus making Dhatuposhana proper and help to hamper degenerative disease process in *Janusandhi* or helps in rebuilding of damaged cartilage.

Vedanasthapana, Vatashamaka, Sulaprashamana, Sothahara

Maximum all the drugs of the *Ayurvedic* compound comes under this category and these drugs mainly helps to alleviate *sandhisula, sandhisotha, sandhigraha* etc. by their particular action on joints due to their specific guna and karma.

Amapachana, Rochana, Deepana

Asthishrukhal, Suranjan, Chopchini and Sunthi etc. are helpful in maintaining digestive mechanism, which helps in assimilation of *Amadosha* in the body. This *Ama* formation is the major cause for disease according to *Ayurveda*.

So, from the above description we can conclude that the contents of the *Ayurvedic* compound having the properties to correct the pathology develop during the disease process of *Sandhigatavata* w.s.r. to Osteoarthritis of knee joint.

CONCLUSION

On the basis of above study it is concluded that total effect of therapies shows that in comparison to Group-B, Group-A shows better results this could be due to the *Sothahara, Vatashamaka, Amapachana, Balya* and *Rasayana* properties of the *Ayurvedic* Compound. In comparison to Group-A, Group-C showed better results

this could be the effect of combined therapy. Here, *Ayurvedic* compound helps to reduce degenerative changes in the Knee joints due to its *Rasayana* and *Vatashamana* properties while *Kalka PatraBandhan* works efficiently in relieving pain and other symptoms.

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