

CLINICAL EVALUATION OF HARI JIWAN OIL IN THE TREATMENT OF SANDHIVATA (OSTEOARTHRITIS)

****Prof. (Dr.) Sudarsan Behera and *Dr. Sushanta Sahu**

****Principal and HOD, Dept of Kayachikitsa, Gopabandhu Ayurveda Mahavidyalaya, Puri Odisha.**

***Asst. Professor, S.S.N. Ayurved College & R.I., Nrusinghnath, Paikmal.**

***Corresponding Author: Dr. Sushanta Sahu**

S.S.N. Ayurved College & R.I., Nrusinghnath, Paikmal, Bargarh, Odisha, India.

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INTRODUCTION

Osteoarthritis (OA) is the most common form of arthritis in human beings. It is the most prevalent and disabling amongst chronic diseases. The incidence increases with age. Approximately 80 percent of the population gets afflicted by the age of 65 yrs. Pain and limitation of movement restrict the independence of older adults by impairing their performance of activities in day to day living. As a result, dependence becomes common for ambulation, stair climbing and other lower-extremity functions. The precise etiology of osteoarthritis is unknown. The biochemical and biomechanical factors may play an important role in the etio-pathogenesis. OA can be classified as a primary (idiopathic) or secondary depending upon the absence or presence of an underlying local or systemic condition respectively. Secondary OA may develop at any age in a joint damaged by trauma, disease (such as tuberculosis, gout, RA), and deformity (such as congenital dislocation of the hip) Conversely, Primary OA is without discernable relation to any other disease process. It occurs mainly in middle-aged or elderly individuals & typically involves distal joints i.e. interphalangeal region of fingers (forming Heberden's nodes) But it may involve hip, knee, vertebral, and other joints.

Osteoarthritis can be defined as a gradual loss of articular cartilage combined with thickening of the sub-chondral bone, bone outgrowths (called osteophytes) at joint margins and mild, chronic non-specific synovial inflammation. The difference between "physiological ageing of the cartilage" and "O.A. cartilage" is not sharp. However, cartilage can be identified in typically three stages i.e. Stage I: Normal cartilage. Stage II: Ageing cartilage. Stage III: OA. cartilage. Ayurveda is basically based on the tridosha theory.

Tridoshas are Vata, Pitta and Kaph. When these tridosha remains in their physiological limits they help in nourishment and maintenance of the body. Both increase and decrease (Vridhhi & Ksya) of these tridoshas produces various pathological conditions in the body. In all of the three doshas vata is power in its activating others and putting them to work. This vata when provoked can cause many diseases like *Sandhigatavata* (Osteoarthritis), Amavata, Panguta, Khanjata etc. All of these vatic disorders are included in the Maharoga 4. Among these vatic disorders *Sandhigatavata* (Osteoarthritis) is very common diseases. The description of *Sandhigatavata* (Osteoarthritis) is briefly depicted in Ayurvedic texts. This disease is characterized by Shool (Pain), Prsaranakunchanvedna (Pain on

movement) and Sopha (Swelling) in Sandhies (Joints). Here, provoked vata effect the Sandhies.

Clinical Manifestation

Osteoarthritis is primarily assessed through a history and physical examination. The cardinal symptom of osteoarthritis⁵ is pain that worsens during activity and improves with rest. Instability of joints is a common finding, especially of the knees joints. Stiffness may occur following periods of inactivity. Musculoskeletal examination may reveal swelling, deformities, bony overgrowth (referred as Heberden's nodes when involving the distal interphalangeal joints and Bouchard's nodes when involving the proximal interphalangeal joints of the hands), crepitus and limitation of motion. Muscle spasm, and tendon and capsular contractures also may be observed, depending on the site and duration of involvement. Pain caused by osteoarthritis may develop in any part of the involved joint or tissue. Typically, pain progresses gradually over time and increases with weight bearing. A patient with primary osteoarthritis seldom has any attributing systemic symptoms (e.g., fatigue or generalized weakness). The progression of symptoms in patients with osteoarthritis is fairly consistent. Mild discomfort first occurs in a joint when it is in high use, but the pain is relieved by rest. Symptoms progress to constant pain on use of the affected joint and finally,

with more advanced joint involvement, pain occurs at rest and at night. Generally, little tenderness occurs outside the joint, but pain can occur with extreme range of motion. Limitation of motion is often prominent.

In context to Ayurvedic literature OA may be known as *Sandhigatavata* (Osteoarthritis). In *Sandhigatavata*

(Osteoarthritis) as like to other vata disorders when *Avyaktalakshana* of *Poorvarupavastha* becomes *Vyakta*, the various symptoms as according to different Acharyas is tabulated below:

Sl. No	Symptoms	Charak	Sushrut	A.Samgrah	A.Hridaya	M.Nidan
1	Sandhi soola	+	+	+	+	+
2	Sandhi Sotha	+	+	+	+	-
3	Vatapurnadruti Sparsh	+	-	+	+	-
4	Prasaran-akunchanayo vedana	+	-	+	+	-
5	Hanti Sandhi	-	+	-	-	+
6	Atopa	-	-	-	-	+

DRUG REVIEW

The trial drug is a Poly Herbal oil formulation manufactured by M/S Harijiwan Ayurvedic Pharmacy, Khadapali, P.O.-Rajgangpur, Sundargarh, Odisha

Each 100 ml. of Hari Jiwan oil contains

1. Garlic (*Allium sativum*) 3 mg. Ref-Bhabaprakash,
2. Clove (*Syzgium aromaticum*) 0.5 mg. Ref- Bhabaprakash,
3. Camphor (*Cinamomumcamphora*) 1 mg. Ref- Bhabaprakash,
4. Castor oil (*Ricinus communis*) 1 mg. Ref- Bhabaprakash,
5. Black Pepper (*Piper nigrum*) 1 mg. Ref- Bhabaprakash,
6. Ajwain (*Trachyspermum ammi*) 1 mg. Ref- Bhabaprakash,
7. Nutmeg (*Myristica fragrans*) 0.5 mg. Ref- Bhabaprakash,
8. Pippali (*Piper longum*) 0.5 mg. Ref- Bhabaprakash,
9. Cinamomun(*Cinamomum Zeylenicum*) 1mg. Ref-Bhabaprakash,
10. Nilgiri oil(*Eucalyptus globulus*) 1 mg. Ref- Bhabaprakash,
11. Phenol (Carbolic acid) 0.15 ml ,Ref- Indian pharmacopeia
12. Sunthi (*Zingiber officinale*) 5 mg. Ref-Bhabaprakash,
13. Dashamool oil 30 ml Ref-Bhabaprakash,
14. Mustard Oil q.s. Ref-Bhabaprakash,

All the drugs present in Hari Jiwan are having *Vedanahara* (Analgesic), *Sothara* (Anti-inflammatory), *Vatahara* (Nurvine) and nutritive properties and Dashamoola taila is already a pain relieved oil described in Ayurvedic literature. By applying it locally it reduces the pain and inflammation of the joint.

CLINICAL STUDY

MATERIALS AND METHOD

Patients attending the OPD or IPD of Gopabandhu Ayurveda Mahavidyalaya & Hospital, Puri, and Odisha were screened for Osteoarthritis irrespective of their sex, religion, cast etc. Only those patients who fulfilled the inclusion criteria and were ready to give informed consent for the study were registered for the trial in between the age group of 30 to 65 year. A specially designed research case sheet was used for collecting and maintaining different data. 30 patients were randomly allocated for trial with Hari Jiwan oil. The entire study was completed in a span of 3 months (Jun-2017 to August-2017).

Selection criteria

Inclusive criteria

- 1) All the patients presenting with the clinical features of osteoarthritis
- 2) Patients diagnosed to be suffering from osteoarthritis.
- 3) Patient of osteoarthritis who has gone for any type of treatment with no or sub optimal relief.

Exclusive Criteria

- 1) Severe and complicated cases of osteoarthritis.
- 2) Patient not complying with direction of the physician.
- 3) Any condition which cannot be rendered as a case of osteoarthritis.

B) Criteria for Diagnosis

The diagnosis of these patients of *Sandhigatavata* (Osteoarthritis) was confirmed on the basis of clinical features & radiological investigation described in ayurvedic and modern texts, which are as follows:-

Main Symptoms

SandhiShool (Pain of rest), SandhiSoth (Swelling), SandhiHanti (Restriction of joint movement), PassaranakunchanVedna (Pain on movement), Jadya (Stiffness), Saphutan (Crepitation)

Concomitant Medication

Concomitant medications were monitored throughout the study and recorded in the research case sheet. 25 patients took no other drugs, 3 took laxatives, 2 took antacids. Most of these medications were taken for very short periods. None of the patients took any known arthritis related medication other than trial drug.

Investigation

All patients were investigated for their Complete Blood Count (CBC) and X-Ray of the Knee joints before starting and after the completion of the trial. All the tests were performed in NABL accredited laboratory.

Study Design

The current study was design with single group design. The study was started after obtaining the approval of the Institutional Ethical Committee (IEC). Informed written consent was obtained from every patient before registering them in to the trial.

Drugs and Posology

10 ml. of Hari Jiwan oil was massage to the affected part twice daily for 30 days and improvement was assessed in every 15 days interval.

Assessment of the study**Criteria of Assessment**

The following objective and subjective criteria were follows to assess the improvement of the cases before and after treatments.

Six point Osteoarthritis rating scale and X-Ray of the involve knee was done for every patient included in the trial before starting and after completion of the study. Change in these parameters were analysed to get the outcome of the study by using suitable statistical method.

Statistical Analysis

The values of Osteoarthritis rating scale before and after treatment and radiological change before and after were compared using Students Paired t-test. If the p – value was found to be < .05 the result was interpreted as insignificant. If the p – value was found to be < .01 the result was interpreted as significant. If the p – value was found to be < .001 the result was interpreted as extremely significant. All the calculations were done by using Graph pad statistical software.

The overall benefit of the drug was assessed by a specially designed scoring system. A percentage reduction in overall score after treatment (AT) was calculated for every patient. The percentage reduction in overall score was interpreted as per the following grid.

Scores > 80% – Excellent Result

Scores between 56% to 80% – Good Result

Scores between 31% to 56% – Moderate Results

Scores between 6% to 30% – Mild Results

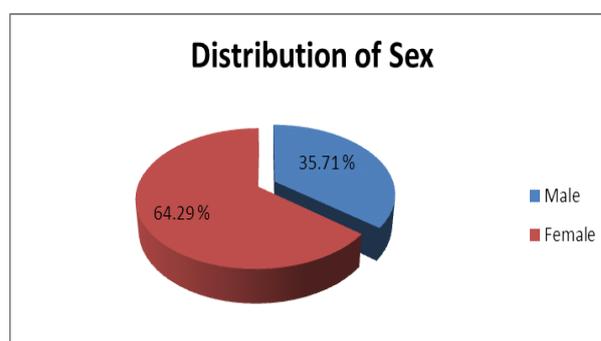
Scores ≤ 5% – Unsatisfactory Result

OBSERVATION AND RESULT

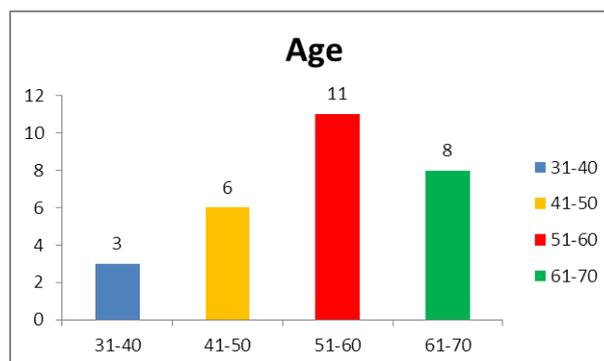
30 patients were registered for the trial but there was a drop out of 2 patients due to different reasons, so total 28 patients have completed the trial.

Demographic Data**1. Sex Wise Distribution of Subject**

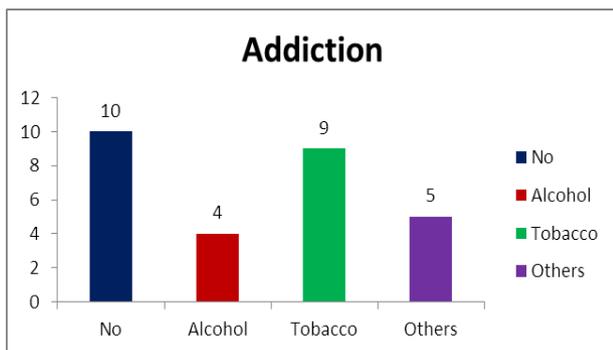
Sex	No.	%
Male	10	35.71
Female	18	64.29

**2. Age group wise distribution of Subject**

Age	No.	%
31-40	3	10.71
41-50	6	21.42
51-60	11	39.28
61-70	8	28.57

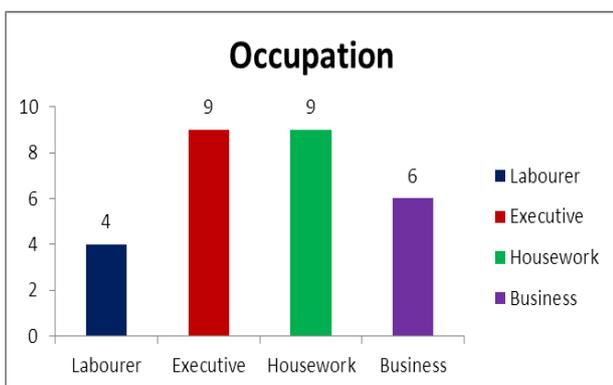
**3. Addiction Wise Distribution of Subject**

Addiction	No.	%
No	10	35.71
Alcohol	4	14.28
Tobacco	9	32.21
Others	5	17.85



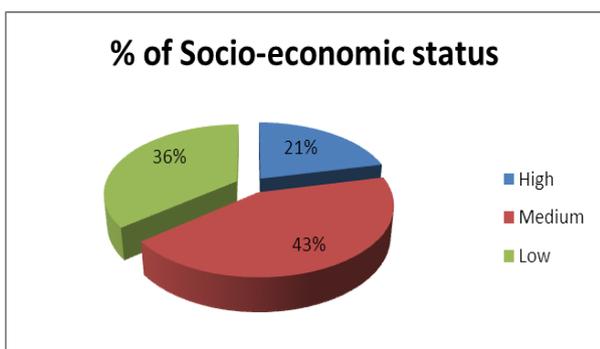
4. Occupation Wise Distribution of Subject

Occupation	No	%
Labourer	4	14.28
Executive	9	32.32
Housework	9	32.32
Business	6	21.42



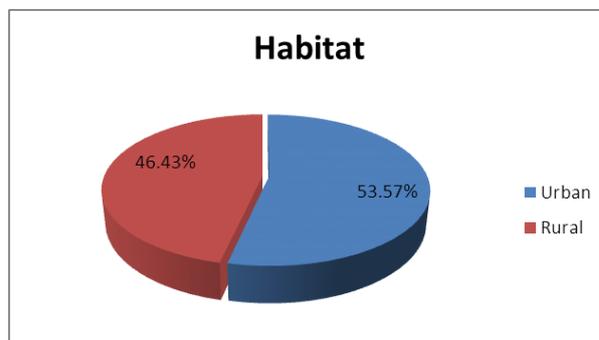
5. Socio-economic status Wise Distribution of Subject

Socio-economic Status	No	%
High	6	21.43
Medium	12	42.86
Low	10	35.71



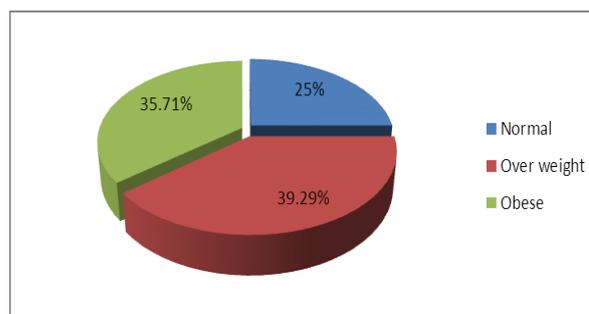
6. Habitat

Habitat	No.	%
Urban	15	53.57
Rural	13	46.43



7. Body Built

Body Built	No.	%
Normal	7	25
Over weight	11	39.29
Obese	10	35.71

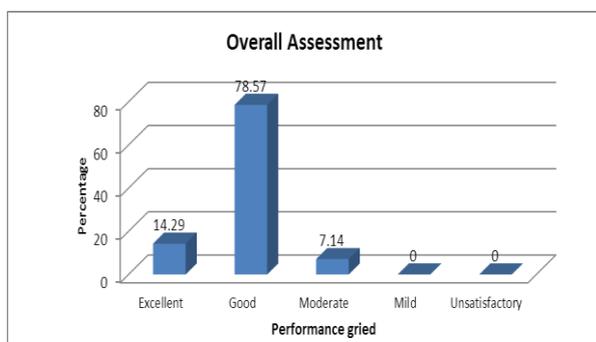


EFFECTIVENESS OF TRIAL DRUG

Parameter	Frequency (N)	Degree of Freedom (df)	Mean		Standard Deviation (SD)		↑	↓	t-value	P-value	Interpretation
			B.T.	A.T.	B.T.	A.T.					
Pain	27	26	2.89	0.89	± 0.51	± 0.51		↓	26.49	< 0.0001	Extremely significant
Swelling	27	26	2.74	0.84	± 0.45	± 0.60		↓	17.00	< 0.0001	Extremely significant
Stiffness	27	26	2.70	0.74	± 0.61	± 0.66		↓	17.37	< 0.0001	Extremely significant
Crepitation	24	23	2.63	0.79	± 0.58	± 0.51		↓	14.09	< 0.0001	Extremely significant
Pain during Extension & Flexion	28	27	2.82	0.89	± 0.39	± 0.57		↓	18.91	< 0.0001	Extremely significant
Tenderness	26	25	2.69	0.96	± 0.74	± 0.53		↓	10.66	< 0.0001	Extremely significant
Over all	28	27	15.61	4.86	± 1.99	± 1.65		↓	32.01	< 0.0001	Extremely significant

Performance Grid in 3 different treatment groups

Performance Grid	Criteria	Group-A	
		No.	%
Excellent	> 80%	4	14.29
Good	56% - 80%	22	78.57
Moderate	31% - 55%	2	7.14
Mild	6% - 30%	0	0.00
Unsatisfactory	< 5%	0	0.00



Assessment of adverse effect of trial drug

No patients during the trial reported any type of adverse reaction.

OBSERVATION HIGHLIGHTS

- The study included both male (10 nos.) and female (18 nos.) patients. But females are more than male patients.
- The Study included patients in the age limit of 30 to 65 years (both inclusive). Patients in the age group of 51 – 60 years were maximum (11) and in the age group of 31 – 40 years were minimum (3).
- Osteoarthritis was found to be well distributed among different occupation. However patients with executive life style and house job were found to be

maximum (9 nos each.) & people with hard labour were found to be minimum (4 nos.).

- Osteoarthritis affects all types of Socio-economic classes from society. Medium class being the maximum (42.86%) followed by low and high classes.
- Out of the total registered patients 64.29 % reported some or the other kind of addiction. However tobacco users were maximum among them (32.21 %).
- Osteoarthritis affects both urban (53.57%) and rural (46.43%) population nearly in equal proportion.
- Among 28 nos. of patients 36.84% were normal, 33.33% were overweight and 29.83% were obese.
- The trial drug Hari Jiwan oil was found effective in improving all the sign and symptoms of OA. The mean scores of pain was reduced from 2.89 to 0.89, swelling reduced from 2.74 to 0.84, stiffness reduced from 2.70 to 0.74, crepitation reduced from 2.63 to 0.79, pain during extension & flexion reduced from 2.82 to 0.89 and tenderness reduced from 2.69 to 0.96. The mean overall score reduced from 15.61 to 4.86. All the above mentioned changes were found to be extremely significant statistically with $p < 0.0001$.
- On overall rating of the effectiveness of Hari Jiwan oil we got Good results in 78.87 % cases, Excellent result in 14.29% cases and Moderate result in 7.14 % cases.
- On analysing the incidence of adverse effects we got that none of the patients report any type of adverse effects.

DISCUSSION

In the present study we observed that patients in the age group 51- 60 years were highest in number. This may be due to the fact that in this period of life degenerative and

senile changes start taking their toll. Females also reach menopause by this age leading to osteoporosis which is a potential risk factor for OA.

Patients with Executive work and House hold works (particularly females) mostly have a sedentary life style which leads to weight gain. We also observed that approximately 63 % of patients were either overweight or obese. This further proves a positive co-relation between body weight and risk of developing OA.

It was further observed that OA is well distributed among all socio-economic groups and urban/rural population.

We observed highly significant result in improving the different sign and symptoms of OA with massage with Hari Jiwan Oil which is a combination of Garlic, Clove, Camphor, Castor oil, Black Pepper, Ajwain, Nutmeg, Pippali, Cinamomun, Nilgiri oil, Phenol, Sunthi, Dashamool oil and Mustard Oil. Dashamula oil is a proven antiarthritic preparations from Ayurvedic Pharmacopia. Their efficacy has been proven beyond doubt in multiple clinical trials. *Sunthi, Ajwain, Black pepper and Pippali* are having agnidipaka action (enhancing effect on both *kosthagni* and *dhatwagni*). *Castor oil, Nilgiri oil* and *Mustard oil* are important *Vata shamak* (pacifying action on Vata dosha) drugs as described in Ayurvedic texts. Modern science has also proved the analgesic, anti-inflammatory, anti-oxidant and anti-artritic effect of these drugs.

CONCLUSION

The investigators are quite sure on the efficacy of Hari Jiwan oil in the management of OA basing on the outcomes of the present study. Therefore only mild cases should be prescribed with oil massage. But moderate, severe and chronic cases should be prescribed this drugs some oral anti arthritis drugs simultaneously for predictable results. Moreover the therapy was found safe in long term use which is an essential condition in the management of OA requiring long term treatment. We further invite large sample and extended study for more accuracy.

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SOURCE OF SUPPORT

Nil.

CONFLICT OF INTEREST

None Declared.

REFERENCES

1. Daniel J. McCarty and William J. Koopman.; Arthritis and allied conditions. Twelfth edition, Edited by Philadelphia, Lea &Febiger, 1993; 2: 151.
2. Crain, Darrell C.; The Arthritis Handbook, Second revised edition, Published by Arco Publishing Co. Inc, USA
3. Michael Mason & H.L.F. Currey; Introduction to Clinical Rheumatology; 2nd Revised edition edition; Pitman Medical.
4. TripathiBrahmanad; AstangHridayam; Chaukhambha Sanskrit pratisthan, 2007; 487.
5. Michael Doherty, John Doherty; Clinical Examination in Rheumatology; Wolfe Pub, 1992.
6. TripathiBrahmanad; CharakSamhita- II; Chaukhambhasurbhartipratisthan, 1998; 942.
7. ShastriAmbikadutta; Sushrutsamhita Ni 1/28; Chaukhambha Sanskrit sansthan, 2000.
8. Gupta Atridev; Astana Sangraha-I/ Ni; Chowkhambakrishnadas Academy, 2005; 400.
9. TripathiBrahmanad; AstangHridayam; Chaukhambha Sanskrit pratisthan, 2007; 539.
10. UpadhyayaYadhunandana; MadhavNidana; Chaukhambha Sanskrit Bhawan, 2003; 463.
11. Shah NagindasChhagganlal; Bharat Bhasajya Ratnakar, 5(8129).
12. Chunekar K.C.: Bhabaprakash Nighantu.
13. Chandanwale A.S. & Kala Suhas Kulkarni- Clinical evaluation of Rumalaya forte in osteoarthritis.
14. *Pain*, Vol 1, Melzack R, The McGill Pain Questionnaire: major properties and scoring methods, 277-299.
15. <http://graphpad.com/quickcalcs/ttest1/>: Calculation of Data.
16. Krunal et.al: Phytochemical evaluation of the wild and cultivated varieties of Eranda Mula (Roots of *Ricinus communis* Linn.)- AYU, Apr-Jun 2013; 34(2).