

A CLINICAL STUDY ON THE MANAGEMENT OF SANDHIVATA (OSTEOARTHRITIS) WITH A POLYHERBAL OIL FORMULATION (AYUSHI OIL)

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ABSTRACT :

Sandhivata is a painful condition of joints due to vitiation of *Vata* and it is one among eighty types of *Vata* disorder described by acharya *Charaka*, which affects mostly the movable joints of elderly people, characterized by *shotha* (swelling) and *shula* (pain). It can be correlated with osteoarthritis with regard to sign and symptoms. Ayurvedic acharyas described *snehana* and *swedana* as main line of treatment in the management of *Sandhivata*. Keeping that in view a clinical trial was conducted in 100 patients of *Sandhivata* with a polyherbal oil formulation (Ayushi oil) as *bahya snehana* (external oleation) followed by *swedana* (fomentation) for a period of 20 days. To assess the effect of therapy objectively, all the signs and symptoms of *Sandhivata* were given a score depending upon their severity before and after treatment. The results were analyzed statistically and found highly significant in reducing all cardinal symptoms of *Sandhivata*.

Key words: *Sandhivata, snehan, swedana, Ayushi oil*

INTRODUCTION: Osteoarthritis (OA) is one of the most common forms of arthritis. It is a chronic condition in which the material that cushions the joints, called cartilage, breaks down. This causes the bones to rub against each other, causing stiffness, pain and loss of joint movement ^[1]. Globally approximately 250 million people have osteoarthritis of the knee (3.6% of the population) ^[2]. It is estimated that 80% of the population have radiographic evidence of OA by age 65, although only 60% of those will have symptoms ^[3]. OA can be judiciously compared to “*Sandhivata*” as per the description found in Ayurvedic Classics. *Sandhivata* comes under the 80 *Nanatmaj Vatavyadhi* described in *Charak Samhita*. This disease occurs mostly in movable joints where the “*khavaigunya*” is more

due to hyperphysical activity which leads to “*kshaya*” (degeneration) of *Dhatu* (tissue constituents) and “*Sleshak Kapha*” (comparable to synovial fluid of the joints). This “*dhatukshaya*” leads to aggravation of *Vata* and the aggravated *Vata* gets accumulated in the joints (*sandhi*) resulting in *Sandhivata*. Acharya *Charak* described this disease as “*Sandhigata Anila*” with symptoms of “*Shotha*” (which reveals as air filled bag on palpation) with *Shula* on “*akunchana*” and “*prasarana*” (flexion and extension of joints) ^[4].

The incidence of OA is ever increasing especially in the elderly population. Many theories have been advocated regarding its aetiology and treatment. But only temporary relief is possible in lieu of permanent recovery, thus posing a

challenge for medical profession. Ayurveda and Panchakarma therapies have been found very effective in the management of *Sandhivata*. “*Snehan & Swedan*” (Oleation and Sudation) are the prime line of treatment in different *Vata Vyadhi* [5]. Basing upon this logic we have taken Ayushi Oil, a novel polyherbal composition for external oleation followed by hot water fomentation to produce sudation in the management of *Sandhivata*.

AIM AND OBJECTIVE OF THE STUDY: The study was carried out with the approval of the Institutional Ethics Committee (IEC) at Sri Sai Ayurvedic Medical College & Hospital, Aligarh, U.P, India in order to evaluate the clinical efficacy of topical application of the polyherbal oil (Ayushi Oil) followed by gentle massage (*Abhyanga*) and hot water fomentation (*Swedan*) in the management of *Sandhivata* (Osteoarthritis).

MATERIAL AND METHOD:

REVIEW OF LITERATURE: The literature on *Sandhivata* and Osteoarthritis were reviewed from various sources like Ayurvedic Texts, Modern Medical Texts, Journals, internet etc before initiating the project. Detailed study of the constituent ingredients of the trial drug was also done.

Trial Drug: The Trial Drug “Ayushi Oil” is a poly herbal formulation. Each 100ml of “Ayushi Oil” is processed with following ingredients.

Asti Shrunkhla (<i>Cissus quadrangularis</i>)	
28 g	
Nirgundi (<i>Vitex negundo</i>)	23 g
Langali (<i>Gloriosa superba</i>)	06 g
Karpura (<i>Cinnamomum camphora</i>)	01 g
Ratan jot (<i>Geranium wallichianum</i>)	05 g
Til Oil (<i>Cessamum indicum</i>)	q.s

It was manufactured in the GMP certified pharmacy of Sri Sai Ayurvedic Medical College & Hospital, Aligarh, U.P, India with stringent quality control and as per the GMP norms. It was made available to patients in 200 ml packs (4 bottles were provided to each patient for completing the 20 days trial).

Study Design: This was a randomized, open, single group clinical trial.

Sample Size: 100 ambulatory patients of both the sex within the age group of 30 – 80 years were selected for the study as per the inclusion criteria (to follow here after) from the OPD and health camps of Sri Sai Ayurvedic Medical College & Hospital, Aligarh, U.P, India during the study period extending from August 2014 to January 2015 irrespective of their caste, religion etc. Out of them 8 patients dropped out of the study due to different reasons and 92 patients successfully completed the trial.

Inclusion Criteria:

- Age – 30 to 80 years
- Patients having at least one or more sign and symptoms of *Sandhivata* or Osteoarthritis like Pain in joints, stiffness, difficulty in flexion and extension, crepitus, swelling etc for more than 3 months prior to the study.

Exclusion Criteria:

- Patients who have taken long term steroid treatment
- Genetic Musculoskeletal disorder
- Autoimmune Musculoskeletal disorder
- Gouty Arthritis
- Severe osteoporosis
- Patients on Hormone replacement therapy
- Patients who are already advised Joint replacement surgery
- Morbidly obese patients

Investigations: Few routine laboratory tests like complete Haemogram, FBS, PPBS & X-Ray were carried out for every patient before beginning and after completion of the trial. CRP, RA Factor & serum Uric acid were carried out wherever required for differential diagnosis.

Method of administration of the trial Drug, Dose and Duration: The trial Drug was designed for topical use by gentle massage in rounded fashion on the affected part followed by hot water fomentation. The patients were advised to apply 10 ml of Ayushi oil on each affected part and continue massage till the oil was almost completely absorbed. They were also instructed to perform hot water fomentation (*swedan*) by using soft cotton towel till sweat appears on the affected part. The procedure was repeated twice in a day (Morning and Evening) for 20 consecutive days.

Dos and Don'ts during the trial: The patients were counselled to follow a standard dietary regimen rich in fibre. All the patients were motivated for 30 minutes of brisk walking every day for at least five days in week. The patients were also advised to avoid “*guru*” and “*abhisyandakarak*” food items. It was not

permitted to the patients to take any kind of Analgesic drugs during the trial period.

Follow up Schedule and Accumulation of Data: Each registered patient was thoroughly examined by either of the Investigators and the baseline information was recorded in the specially designed research case sheet. The patients were advised to report for follow up on 7th Day, 14th Day and the end of the trial.

Assessment Protocol: The magnitude and severity of the different sign and symptoms were measured by using a specially designed scale based on questionnaire. We referred the scale from a published article with minor modifications as per the requirement of the study ^[6]. On every follow up the patients were examined and interrogated for any improvement in the sign and symptoms and accordingly scoring was given. The scores at the end of the trial were compared to their baseline values to assess the improvement.

Statistical Analysis: The mean values of the scores before and after treatment were calculated and Paired t- test was applied as a statistical tool for the test of significance. All the statistical analysis was done online by using Graph pad scientific software ^[7].

Assessment Scale:

PARAMETER	SCORE
Sandhi Shula (Pain in Joints)	
No pain	0
Mild pain	1
Moderate pain, but no difficulty in walking	2
Slight difficulty in walking due to pain	3
Severe difficulty in walking	4
Sandhi Shotha (Swelling in joints)	
No swelling	0
Poorly appreciable slight swelling	1
Appreciably mild swelling	2
Moderate swelling	3
Severe swelling	4
Sandhi Graha (Stiffness in joints)	
No stiffness	0
Mild stiffness	1
Moderate stiffness	2
Severe difficulty due to stiffness	3
Severe stiffness for more than 10 minutes	4
Sandhi sphutana (Crepitus in joints)	
No crepitus	0
Crepitus on palpation of joints	1
Less frequent Audible crepitus	2
More frequent Audible Crepitus	3
Always audible crepitus	4
Sparsha Asahyata (Tenderness in joints)	
No tenderness	0
Mild Tenderness (Patients says tenderness)	1
Moderate tenderness (Felt on palpation of joints)	2
Severe tenderness (Wincing of face on touch)	3
Very Severe tenderness (Patient does not allow to touch the joint)	4
Akunchana Prasaranajanya Vedana (Pain during extension and flexion of joints)	
No pain	0
Pain without wincing of face	1
Pain with wincing of face	2
Prevent complete flexion	3
Patient does not allow passive movement	4

OBSERVATION & RESULT:

SL. No	PARAMETER	FREQUENCY (n)	MEAN (BT)	SD (BT)	MEAN (AT)	SD (AT)	↑	↓	t - Value	p - Value	Interpretation
1	Sandhi Shula (Pain in Joints)	92	2.74	0.96	1.48	0.85	↓		10.27	< 0.0001	Extremely Significant
2	Sandhi Shotha (Swelling in joints)	48	1.79	0.80	0.57	0.51	↓		5.66	< 0.0001	Extremely Significant
3	Sandhi Graha (Stiffness in joints)	69	2.42	0.89	1.26	0.82	↓		12.37	< 0.0001	Extremely Significant
4	Sandhi sphutana (Crepitus in joints)	32	2.00	0.97	0.75	0.68	↓		4.22	< 0.0001	Extremely Significant
5	Sparsha Asahyata (Tenderness in joints)	78	2.92	0.93	1.58	0.90	↓		9.95	< 0.0001	Extremely Significant
6	Akunchana Prasaranajanya Vedana (Pain during extension and flexion of joints)	92	2.90	0.79	1.32	0.70	↓		11.50	< 0.0001	Extremely Significant

Table – 1 : Effect of the Ayushi Oil on Different Sign & Symptoms of Sandhivata.

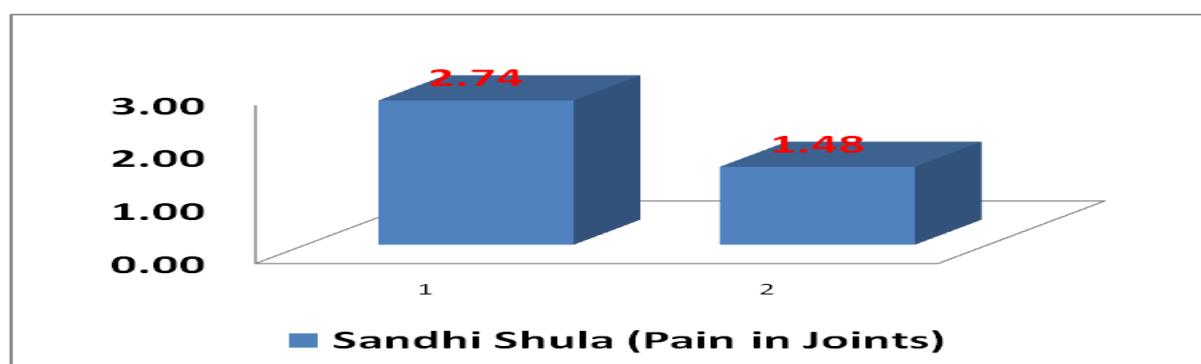


Chart – 1 : Effect of Ayushi Oil on Sandhi Shula (Pain in Joints)

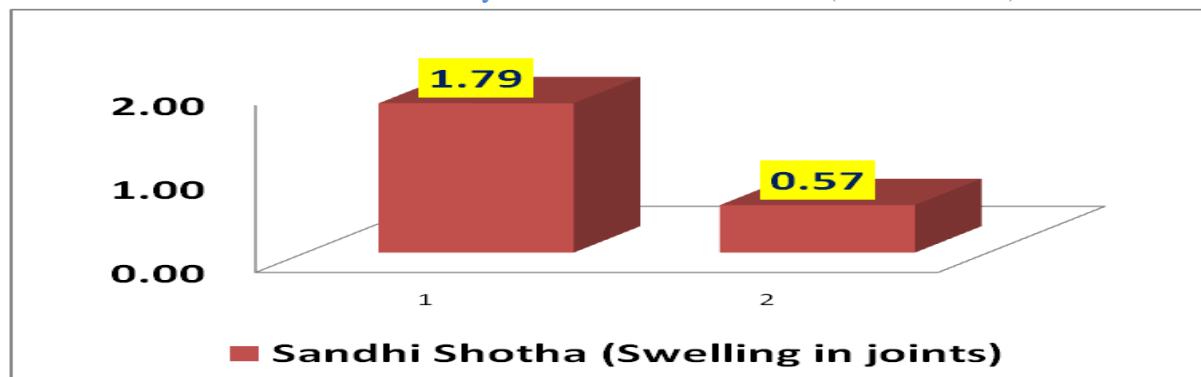


Chart – 2 : Effect of Ayushi Oil on Sandhi Shotha (Swelling in Joints)

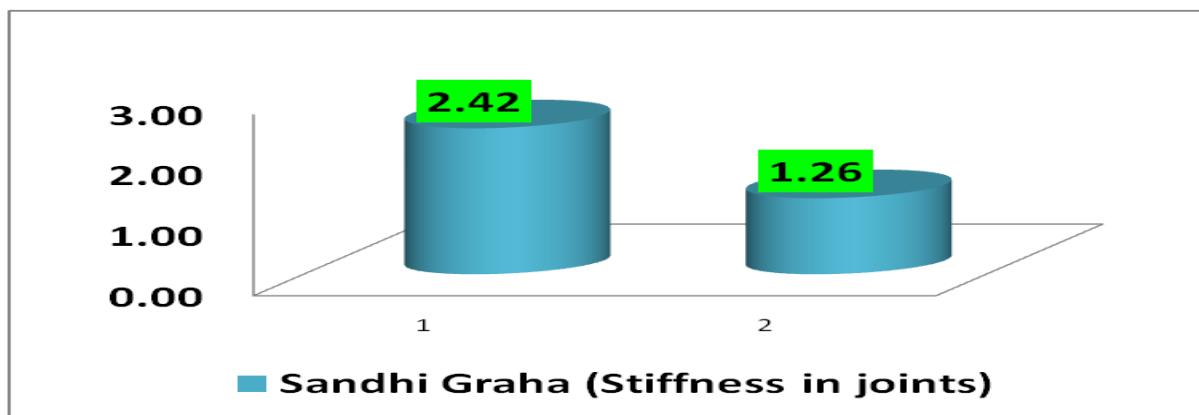


Chart – 3 : Effect of Ayushi Oil on *Sandhi Graha* (Stiffness in Joints)

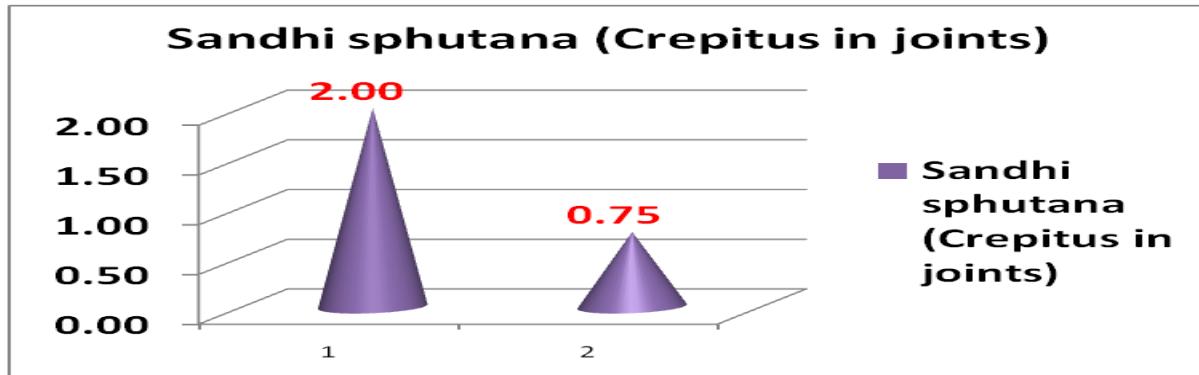


Chart – 4 : Effect of Ayushi Oil on *Sandhi Sphutana* (Crepitus in Joints)

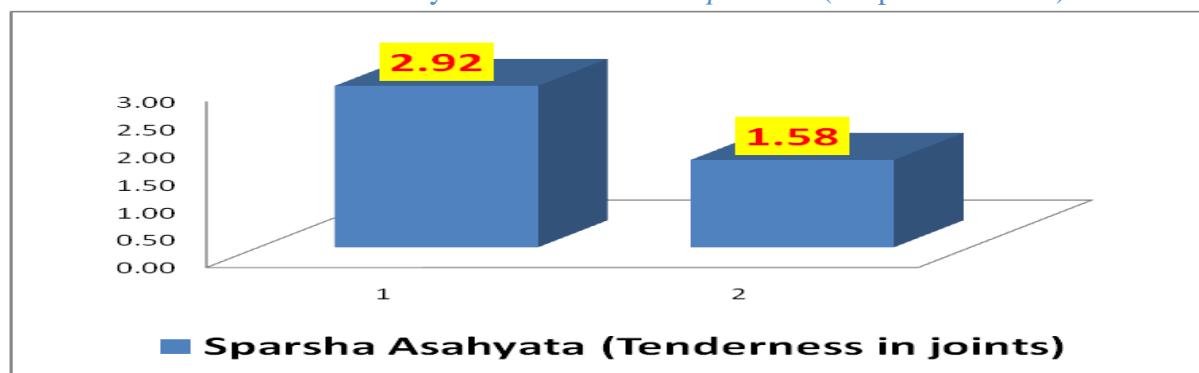


Chart – 5 : Effect of Ayushi Oil on *Sparsha Asahyata* (Tenderness in Joints)



Chart – 6 : Effect of Ayushi Oil on *Akunchana Prasharanajanya Vedana* (Pain during flexion and extension of Joints)

Overall Assessment:

Improvement Grid	No. of Patients	Percentage (%)
Excellent Improvement	57	61.96
Moderate Improvement	20	21.74
Mild Improvement	15	16.30
No Improvement	0	0.00
Total	92	100.00

Table – 2 : Overall effect of the Ayushi Oil on Sandhivata (OA)

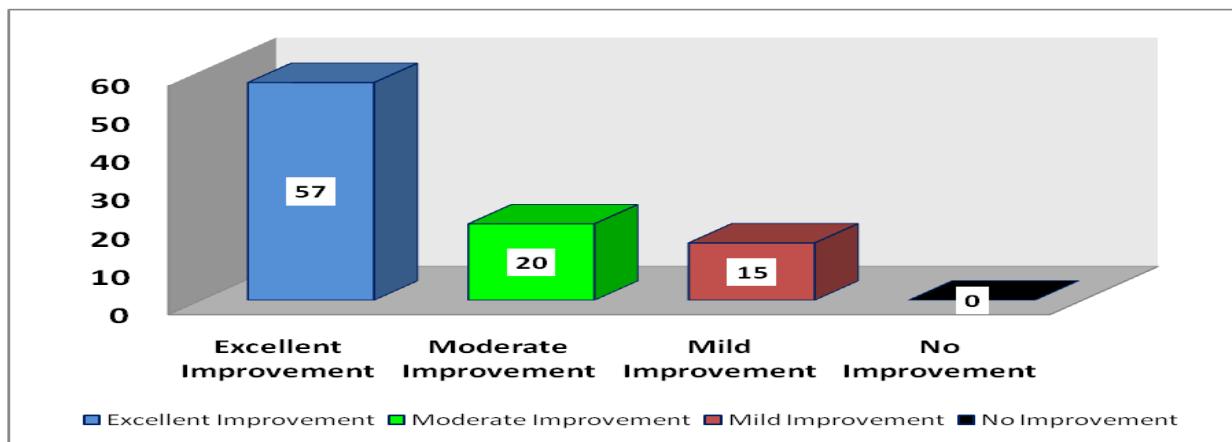


Chart – 7 : Overall effect of Ayushi Oil on Sandhivata (OA)

Key observation of the study:

- Ayushi oil was found significantly effective in reducing pain, tenderness, stiffness and pain during movement which are the main concern of a patient in osteoarthritis.
- Swelling and crepitus were found in relatively fewer numbers of patients of Osteoarthritis. But Ayushi oil was also found effective in improving both the symptoms with statistical significance.
- Ayushi oil provided excellent overall improvement in 61.96 % cases, Moderate Improvement in 21.74 % cases and Mild Improvement in 16.30 % of cases.
- No Improvement was marked not even in a single patient. Each and every patient got benefitted in some way or the other.

- The product offered excellent compliance and not even a single incidence of adverse event was noted during the study in any patient.

DISCUSSION: As per Ayurvedic principle, *Taila* (oil) is the best treatment for *Vata* dosha. Since *Sadhivata* is a disease with *Vata* predominance, choosing an oil formulation for its management is quite obvious. Ayushi oil fortified with herbs like *Nirgundi*, *Asthi shrunkhala*, *Langali*, *Ratan jot* etc. *Nirgundi* is best known for its *Vatahara* (analgesic) properties. *Asthi shrunkhala* is also a proven herb for bone health which increases the bone mineral density and arrests the degenerative process in the joints ^[8, 9]. This pharmacological property of *Asthi shrunkhala* is essentially useful in the management of *Sandhivata*

(Osteoarthritis) which occurs due to degenerative changes in the joints. *Langali* is a muscle relaxant (Nadkarni – 2002) and hence removes the stiffness of joints [10]. *Ratan jot* also exerts pain relieving effect. *Karpura* acts as a counter irritant. Therefore the synergistic effect of all these ingredients in Ayushi oil have been found useful in alleviating different sign and symptoms of *Sandhivata* (Osteoarthritis). The preparation was skin friendly on topical application as none of the ingredients has been found to produce any skin allergy.

SUMMARY & CONCLUSION: Topical application is often preferred in the management of *Sandhivata* (Osteoarthritis) as they are effective, easy to use, safe & economical. Ayushi Oil was also proven highly satisfactory in all these parameters. The novelty of the formulation makes this product stand out of the crowd in anti-arthritis oil segment. The investigators are of firm opinion that Ayushi Oil will prove a milestone in the management of *Sandhivata* (Osteoarthritis) in times to come. Further study is encouraged to evaluate its efficacy in other similar conditions.

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