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Devdarubaladi Tailam in osteoarthritis – open single arm clinical study.

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Abstract-

Osteoarthritis is a disease coming under the arthritis group of diseases described by modern science, which is almost identical to *Sandhigata vata* in etiology, pathology, and clinical features. According to WHO Osteoarthritis is the second commonest musculoskeletal problem in the world population. *Dhatukshayajanya Sandhigata Vata* (osteoarthritis) is the most common form of joint disorder that comes under the various *Gatavatas* explained in *Vatavyadhi Prakarana*. Owing to its morbidity, disability, and difficult management it has been placed under '*Ashtamahagada'* by *Sushruta*. It is common amongst the elderly and known to be a major cause of chronic disability. The traditional system of Indian and Asian countries treating this disorder for thousands of years. Ayurveda proves to be very effective in managing *Sandhigata vata* (Osteoarthritis). The objective of the study is to study the effect of *Devdarubaladi Tailam* described by *Sahastrayog* in the patients of *Sandhigata vata*. This was a prospective open single-arm clinical study conducted at Y.M.T. Ayurved Medical College and Hospital. 30 Patients having classical signs and symptoms of *Sandhigata vata* according to Ayurveda and Osteoarthritis according to modern science were selected. For the study, *Devdarubaladi Tailam* 20 ml was given orally twice daily before food with lukewarm water. The total duration of the study was 90 days in which treatment was given for 21 days and Follow-up was taken on every 7th day for the first month and then on every 15 days for the next 2 months. The study outcome included a gradation scale for classical Signs and symptoms of *Sandhigata vata*, VAS score, Flexion and extension goniometric scale, walking time, and swelling. Statistical analysis was performed using the student's t-test. Out of 30 patients treated, 21 (70%) got excellent results and 8 (26.66%) got Good results, one patient got a moderate result. There was extremely significant improvement seen in all classical symptoms of *Sandhigat vata* ($p < 0.0001$). The VAS score, Extension and flexion goniometric scale, swelling in mm, and

Walking time test showed statistically significant changes. The data showed that *Devdarubaladi Tailam* showed significant relief in classical signs and symptoms and modern parameters of *Sandhigata vata*.

Keywords- Osteoarthritis, Sandhigata vata, *Devdarubaladi Tailam,*

Introduction:

Sandhigata vata, a disorder of *Asthi–Majjavaha Srotas* is degenerative in nature where degeneration of *Asthi Dhatu* (osseous tissue) in the joints occurs. *Sandhigata Vata* is the most common form of joint disorder and comes under the various *Gatavatas* explained in *Vatavyadhi prakarana*.[1] It is caused by the localization of the vitiated *Vata dosha* in the *Asthi sandhis* of the body. It is characterized by the symptoms pertaining to the *Asthi sandhis* like *Sandhi shoola, Sandhi shotha, Sandhigraha,* etc. Owing to its morbidity, disability, and difficult management it has been placed under '*Ashtamahagada'* by *Acharya Sushruta.*[2]

Osteoarthritis is a disease coming under the arthritis group of diseases described by modern science, which is almost identical to *Sandhigatavata* in etiology, pathology, and clinical features. Osteoarthritis is the second most common rheumatologic problem and it is the most frequent joint disease with a prevalence of 22% to 39% in India. OA is more common in women than men. Nearly, 45% of women over the age of 65 years have symptoms while 70% of those over 65 years show radiological evidence of OA.[3] Globally, 595 million people had osteoarthritis in 2020, equal to 7·6% of the global population, and an increase of 132·2% in total cases since 1990. Compared with 2020, cases of osteoarthritis are projected to increase 74·9% for knee, 48·6% for hand, 78·6% for hip, and 95·1% for other types of osteoarthritis by 2050.[4] This disease keeps an insidious attack, which runs for many years causing the loss of function as well as deformity of the joints it cripples the patient's life makes him a burden on others, and hampers day-to-day activities. It does not cut the years of life but life of years.

There have been advances in the understanding of this disease. No longer is osteoarthritis, regarded as a simple consequence of aging and cartilage degeneration. Indeed, the former diagnostic label of 'degenerative joint disease' is now recognized to be a 'Misnomer'. A single definition of Osteoarthritis remains elusive. A workshop held in 1995 proposes the following consensus definition. "Osteoarthritis disease is the result of both mechanical and biological events, which destabilize the normal coupling of degradation and synthesis of articular cartilage chondrocytes and extracellular matrix and subchondral bone."[5]

Though there is a lot of advances in understanding this disease, day by day the disease has become a problem. As a constellation of clinical and anatomical features, analogous to heart failure, indeed 'OA' might with advantage be renamed 'joint failure'. Management of this disease is facing a lot of difficulties. In the contemporary system of medicine, NSAIDs, and surgery are practiced in the management of this disease, but have their own limitations. NSAIDs and anti-inflammatories carry an increased risk of gastric erosion, or haemorrhage in the elderly.[6] Intra-articular steroids are widely used, even though they provide marked relief from symptoms but they lose their effect from a week to month. Because studies in animal models have suggested that glucocorticoids produce cartilage, damage and frequent injections of large amounts of steroids have been associated with joint breakdown in humans.[7] Contemporary science has failed

to find a solution for this disease. It is said that current treatment for osteoarthritis is purely control of symptoms, as the underlying pathology is not managed because there is no disease-modifying osteoarthritis drug yet.

Hence it becomes essential to search for a new way for the treatment of *Sandhigata vata*- osteoarthritis which proves to be a ray of hope for further research works. Current clinical trial aims at arresting the progression of the disease and pacifying the pain without any side- effects.

Sandhigata vata is *pakwashaya udbhava vyadhi* and *Pakwashaya* is *uttpattisthan* of *Vata* and the site of action of tail is *Pakwashaya*. *Also, Vata Dosha* is predominantly present in *Asthi Dhatu* and joints. *Tikta Rasa* has a tendency to go toward *Asthidhatu* after assimilation in the body due to the dominance of *Akasha* and *Vayu Mahabhuta*. According to *Charak, Tail* is *Sarva Shrestha vataghna* and *Shoolaghna*.[8] *Susruta* beautifully delineates the importance of *Sneha* as *' sneho hi saroayam'*.[9] Human beings are composed of *Sneha*, and *Prana* predominantly contains *Sneha*. By keeping the above point in mind an attempt is made to assess the efficacy of *Devdarubaladi tailam* from *Sahasrayoga*[10] having action of *Agnideepan*, *Balya*, *Bruhana*, *Ojovardana*, *Rasayana*, *Vatashamak*, *Shoolaghna*, *Vedanasthapana*, *Shothhara* have been selected to evaluate its efficacy on *Dhatukshayajanya Sandhigata vata*. In the present context, *Tail* is used as *Shaman snehapana* which is prepared with *Tiktarasa pradhan dravyas* which proved to be effective in *Dhatukshaya janya sandhigata vata*

It is the hope that the present study will open new areas of research and provide the platform for further investigation drives in the Ayurveda field that are searching for a remedy for degenerative disorders by contemporary scientific methods. As such the demand and need for suggesting complete, complacent solace was felt. A sincere, dedicated research work was carried out.

The traditional knowledge is based upon the humeral theory that management is based upon the *Prabhava* of a *dravya*. Thus in Ayurveda presently many researches are undertaken with reference to pharmacodynamics and pharmacokinetics. The trends are changed when evidence-based therapeutics are to be shown to the scientific community. It is thought that there are no proper disease management techniques or medicaments available with Ayurveda. But many *Vedanasthapaka* and *Shothahara dravyas* were established and recorded over the ages. Thus an attempt was made to evaluate the efficacy of *Devdarubaladi tailam* in *Dhatukshaya janya sandhigata vata*.

Aim of the study:

To assess the efficacy of *Devdarubaladi tailam* in the management of *Sandhigata vata*. (Osteoarthritis).

Material and Methods:

This was a Prospective Open single arm nonrandomized clinical study. The study protocol was approved by the Institutional Ethics Committee (IEC) at Y.M.T. Ayurved Medical College. A total of 30 patients were selected out of 38 patients screened at OPD of Y.M.T. Ayurvedic Hospital, Mumbai. Each study participant provided written informed consent before participating in the study.

Type of Study: Open single-arm clinical study.

Place of study: Y.M.T Ayurvedic College & Hospital

Sample size: 30 patients

Name of the drug: *Devdarubaladi tailam*

Dosage & time: twice a day after meal for 21 days.

Follow-up – A total of 8 follow-ups were taken on 7th, 14th, 21st, 30th, 45th, 60th, 75th, and 90th day.

CRITERIA OF INCLUSION:

1. Patient selected irrespective of sex, occupation, education, and habitat.
2. Patient age group of 40 to 70 years of age.
3. Patient presenting Classical signs and symptoms of *Dhatukshayajanya sandhigata vata*.
4. Kellgren Lawrence radiographic grading scale of osteoarthritis.

CRITERIA OF EXCLUSION:

1. Patient with acute or chronic systemic, medical surgical ailment.
2. Patient with congenital or acquired abnormality related to joint.
3. Obese patient, diabetic patient
4. Patients with rheumatoid arthritis, psoriatic arthritis, gout, sciatica, tubercular bone disease etc.
5. Patient associated with simple or compound fracture, associated with Trauma
6. Immuno-compromised patients.
7. Patient on long-term steroids, chemotherapy
8. Pregnant women, lactating women.

CRITERIA OF WITHDRAWAL:

1. Any untoward symptoms seen in patients.
2. Any adverse drug reaction seen in patients.
3. If the patient is not willing.

CRITERIA OF ASSESSMENT:

A. Subjective criteria: Patients will be diagnosed on the basis of classical symptoms and signs of *Sandhigata Vata.* [11]

1) *Sandhishoola* (Knee joint pain)
2) Sandhishotha (Swelling over knee joint)
3) Sandhigraha (Stiffness at knee joint)
4) Sparasahtwa (Tenderness)
5) Vedana during akunchana and *prasarana* (Pain on flexion and extension of knee joint)
6) Sandhisphutana (Joint crepitus)
7) Gamankashtata (Difficulty in walking)

B. Objective criteria:

1. Universal pain assessment tool[17] grading 0 to 10.
2. Gradation of signs & symptoms mentioned in classics
3. Swelling in mm
4. Goneometric reading- Flexion and extension
5. Walking time in seconds

C. Case Record Form of each patient was prepared consisting of vital data, signs and symptoms, present history, past history, family history, *Samanya Parikshana, Dashavidha Parikshana, and Srotasa Parikshana.*

Drug Profile:

Drug ingredients are shown in Table 1.

Table 1: Shows the ingredients of *Devdarubaladi tailam* [10]

Sr. No.	Ingredients	Botanical Name	Quantity
1	*Devdaru*	Cedrus deodara	1 part
2	*Bala*	Sida cordifolia	1 part
3	*Rasna*	Alpinia	1 part

		galanga	
4	*Jatamansi*	Nardostachys jatamansi	1 part
5	*Sarshapa*	Brassica campestris	1 part
6	*Sunthi*	Zingiber officinale	1 part
7	*Til tail*	Sesame oil	4 parts

All *Vanaspati dravyas* were taken in equal parts and were subjected to grinding to obtain powder (coarse). This coarse powder was subjected to 16 parts of water and was boiled till 1\4th quantity of water remained. The medicine obtained after boiling was strained and the decoction thus obtained. This processed Decoction was then added to 4 parts of *Til tail* and the solid material of the above-mentioned *dravyas* which remains on the cloth was used for straining (i.e. *Kalka*) and was then added to this mixture and was again heated till all the decoction gets evaporated.[12] The *Siddha tail* thus obtained after straining was subjected to *Siddhi pariksha* as mentioned in the classics.[13]

Parameters and gradation for assessment of results:

Gradation of Ayurvedic Signs and symptoms has been done (Table 2)

Table 2: Gradation of sign & symptoms

Signs and symptoms		**Grade**
1) *Sandhi shoola* (Pain in knee joint)		
1	No Pain	0
2	Mild pain /occasional pain	1
3	Moderate/frequent pain	2
4	Severe pain	3
2) *Sandhi Shotha* (Swelling over the knee joint)		
1	No swelling	0
2	Mild, feeling of swelling with heaviness of joint	1
3	Moderate, apparent swelling	2
4	Severe, huge swelling	3
3) ***Sandhi graha* (Stiffness in the knee joint)**		
1	No stiffness	0
2	Stiffness for 30 minutes	1
3	Stiffness after sitting or walking forlong time	2
4	Stiffness whole day or whole night or both	3
4) ***Sparshasahatwa* (Tenderness)**		
1	No tenderness	0
2	Pain on pressure	1
3	Patient winches on pressure	2
4	Patient winches and withdraws affected part	3
5) *Akunchane Prasarana vedana* (Restriction on flexion and extension of knee joint)		

1	No restriction	0
2	Mild restricted	1
3	partially restricted	2
4	Fully restricted	3
6) *Sandhi sphutana* (Joint crepitus)		
1	No crepitus	0
2	Palpable crepitus	1
3	Audible crepitus	2
7) *Gamankashtata* (Difficulty in walking)		
1	No pain while walking	0
2	Mild pain while walking	1
3	Moderate pain while walking	2
4	Severe pain while walking	3

Assessment of drug response – (Table 3)

Table 3: Showing assessment of drug response

Excellent results	More than 75% relief in signs & symptoms was considered as Excellent results
Good results	signs & symptoms relieved between 50% to 75% was considered a Good results
Moderate results	signs & symptoms relieved in between 25% to 50% was considered as Moderate results.
No results	No change or less than 25% relief in signs & symptoms was considered as no results.

OBSERVATIONS & RESULT:

Table 4: Relief percentage in symptoms of 30 patients of Sandhigat vata.

	Symptoms	BT	AT	Diff.	Percentage
1	**Sandhi shoola**	**64**	**4**	**60**	**93.75%**
2	**Sandhi Shoth**	**26**	**0**	**26**	**100%**
3	***Sandhi graha***	**36**	**2**	**34**	**94.44%**
4	***Sparshasahatwa***	**55**	**4**	**51**	**92.73%**
5	**Akunchan Prasaran Vedana**	**60**	**16**	**44**	**73.33%**
6	**Sandhi sphutan**	**39**	**10**	**29**	**74.36%**
7	***Gamankashtata***	**62**	**22**	**40**	**64.52%**

Improvement in signs and symptoms –

Table 5: Showing improvement in signs and symptoms

Sr. No	Total effect of therapy	No. of patients	%
1.	Excellent result	21	70.00%
2.	Good result	8	26.67%
3.	Moderate result	1	3.33%
4.	No result	0	0%

Table 6: Improvement percentage in objective Parameters:

	Symptoms	BT	AT	Diff.	Percentage
1	VAS	173	12	161	93.06%
2	Goniometric Flexion of Knee joint	49	15	34	69.39%
3	Goniometric Extention of Knee joint	22	12	10	45.45%
4	Walking time in seconds	31	13	18	58.06%
5	Swelling in mm	385.78	372.64	13.14	3.40%

Statistical Analysis:

Table 7: Showing Statistical Analysis on subjective criteria (by Student's paired t-test)

Sr.no	Symptoms		B.T.	A.T.	Diff.	95% confidence interval of difference	t value	df	SE of diff	p-value
1.	*Sandhi shoola* (Pain in knee joint)	Mean	2.13	0.13	2	1.78-2.22	18.65	29	0.107	< 0.0001
		SD	0.68	0.35						
		SE	0.12	0.06						
2.	*Sandhi shoth* (Swelling over the knee joint)	Mean	0.87	0.00	0.87	0.56-1.17	5.79	29	0.149	< 0.0001
		SD	0.82	0.00						
		SE	0.15	0.00						
3.	*Sandhi graha* (stiffeness in knee joint)	Mean	1.20	0.67	0.53	0.74-1.52	5.95	29	0.190	< 0.0001
		SD	1.13	0.25						
		SE	0.21	0.05						
4.	*Sparshasahatwa* (Tenderness)	Mean	1.83	0.13	1.7	1.52-1.87	19.97	29	0.085	< 0.0001
		SD	0.65	0.35						
		SE	0.12	0.06						
5.	*Akunchana prasaran samay vedana* (Restriction on flexion and extension of knee joint)	Mean	2.00	0.53	1.47	1.19-1.73	11	29	0.133	< 0.0001
		SD	0.74	0.51						
		SE	0.14	0.09						
6.	*Sandhi sphutan*	Mean	1.30	0.33	0.97	0.78-1.14	10.80	29	0.089	< 0.0001

	(joint crepitus)	SD	0.47	0.48						
		SE	0.08	0.09						
7	*Gamankashtata* (Difficulty in walking)	Mean	2.07	0.73	1.34	1.06-1.59	10.26	29	0.711	< 0.0001
		SD	0.74	0.45						
		SE	0.14	0.08						

Table 8: Showing Statistical Analysis of the effect of drug on objective parameters. (by Student's paired t-test)

Sr.no	Symptoms		B.T.	A.T.	Diff.	95% confidence interval of difference	t value	df	SE of diff	p-value
1.	VAS	Mean	5.76	0.40	5.36	4.69-6.03	16.41	29	0.326	< 0.0001
		SD	2.25	0.81						
		SE	0.41	0.14						
2.	GONIOMETRIC READING – FLEXION OF KNEE JOINT	Mean	78.62	108.70	-30.08	(-35.49) - (-24.65)	11.40	26	2.638	< 0.0001
		SD	15.03	13.48						
		SE	2.89	2.59						
3.	GONIOMETRIC READING – EXTENSION OF KNEE JOINT	Mean	29.11	15.58	13.53	0.68-6.25	8.21	16	1.647	< 0.0001
		SD	23.26	23.10						
		SE	5.64	5.60						
4.	SWELLING IN MM	Mean	385.77	372.63	13.14	10.47-15.80	10.38	17	1.264	< 0.0001
		SD	17.86	16.25						
		SE	4.21	3.83						
5.	WALKING TIME IN SECONDS	Mean	27.24	22.24	5	3.98-6.01	10.20	24	0.489	< 0.0001
		SD	5.43	4.72						
		SE	1.08	0.94						

The use of *Devdarubaladi Tailam* was proved to be efficient in the management of *Sandhigata vata* with a '*p*'value less than 0.0001 **(Table 7,8)**. The percentage of relief on symptoms score of *Sandhi Shoola* was 93.75%, *Sandhi shoth* was 100%, *Sandhi graha* was 94.44%, *Sparshasahatwa* was 92.73%, *Akunchana prasarana Vedana* was 73.33%, *Sandhi sphutan* was 74.36%, and *Gamankashtata* was 64.52% **(Table 5)**.

The changes observed in objective criteria were also extremely significant ($p < 0.001$) **(Table 8)**

DISCUSSION:

Dhatukshayajanya type of *Sandhigata Vata* is the most common form of joint disorder. Owing to its morbidity, disability, and difficult management it has been placed under '*Ashtamahagada'* by *Sushruta*. It is

common amongst the elderly and known to be a major cause of chronic disability. It is caused by the localization of the vitiated *Vata dosha* in the *Asthi Sandhis* of the body. It is characterized by the symptoms pertaining to the *Asthi Sandhis* like *Sandhishoola*, *Sandhishotha*, etc. Osteoarthritis is a disease coming under the Arthritis group of diseases. Modern science explains the Pathogenesis of Osteoarthritis in two ways – 1. The sub-standard biomaterial of the joint and 2. Increased applied pressure over the joint.[14] The sub-standard biomaterial of the joint is almost identical to *Dhatukshayajanya Sandhigata Vata* in Etiology, Pathology, and Clinical features.

This clinical trial was a non-comparative clinical trial; the total study duration was 3 months. After informed written consent, 30 patients were enrolled for the clinical trial from IPD and OPD of Y.M.T Ayurvedic Medical College. Detailed history of every patient was taken and general and systemic examination was done and entered in specially designed case record form. In the present clinical study x-ray of the knee joint is taken into consideration as it is a major weight-bearing joint and susceptible to wear and tear and for statistical analysis to conclude

Dhatukshayajanya Sandhigata Vata being *Apatarpanjanya Vatavyadhi, Devdarubaladi Tailam* from *Sahasrayog* has been selected which has properties such as *Agnideepan*, *Balya*, *Bruhana Pushtikara*, *Rasayana*, *Shoolhara*, *Shothhara*.[15] According to *Sharangdhar Samhita Madhyama Matra* that is 3 *karsha* i.e 3 *tolas* equivalent to 36 gms must be given for *Dhatuposhan* and for *Sampurna Snigdhata* of *Sharir*.[16] According to *Dhatuposhan Nyaya* as described by *Sushruta Samhita* it takes 20 days for *Poshan* of *Asthi Dhatu*.[17] According to *Charak Sutra* and *Ashtanga Hrudaya Sutra*, *Shamana Sneha* should be administered when one feels hungry without taking food.[18,19] According to *Charak* in case of *Shamana Sneha*, *Ushnajala* is a universal *anupana*.[20] Hence it was decided to administer 40 ml in a divided dose for 21 days at *Annakaala* with *ushnajala*. Follow-up was taken after every 7 days for 1 month and later follow-up was taken after 15 days for the next 2 months to check the reoccurrence of the symptoms.

The improvement in the symptoms of diseases after the treatment was the main criterion of assessment. The total effects of the therapy were also assessed in terms of excellent, good, moderate relief, and no relief.

The study sample had 16 (53.30%) female and 14 (46.7%) male patients, 53.30% of patients were from the 51-60 age group. According to the nature of the work, 33.33% were in the sedentary group, 46.66% in the active group, and 20% were in the labor group. 53.33% were having *Vishama agni*, 33.33% were having *Teekshna agni* and 13.33% were having *Mandagni*. 53.33% were having *Madhyama koshta* and 33.33% were having *Krura koshta*. 46.67% were of *Vata pittaj prakruti*, 13.33% were of *pittaj-kaphaj prakruti*, and 40.00% were of *vata-kaphaj prakruti*.

Among 30 patients, all (100%) suffered from *Sandhishool*, *Sparshashayata*, *Sandhisphutan*, *Gamankashtata* with variable intensity and grade. 18 patients (60%) of them had *Sandhishotha* and *Sandhigraha* and 28 patients (93.33%) of had *Akunchana prasaran vedana*, that restricted their activities. 20 patients had bilateral and 10 patients had unilateral knee joint involvement. 7 patients had a duration of 4 to 5 years, 5 patients had 3 to 4 years, 5 patients had 2 to 3 years, 4 patients had 1 to 2 years, 3 patients had 6 months to 1 year, and 6 patients had a duration of 1 to 6 month. 50% of patients suffered from acute pain 40% was with chronicity and insidious was 10%.

Among 30 patients, 33.33% were consuming *Sheetanna*, 73.33% *Rookshanna*, 40% *Katu*, 30% *Tikta*, 40% *Kashaya Rasa pradhana ahara*. 46.66% used to take *Alpamatra*, while 66.66 followed *Upavasa* repeatedly. 16.66% had the practice of *Nishajagarana*, 33.33 % were involved in *Ativyama* and 13.33 % in *Atyuchha bhashana***.** Among 30 patients 20% suffer from *Bhaya*, *Dukh*, *Chinta*, 20% Shoka, and 26.67% *Krodha*.

Sandhigata vata is a *Vatapradhana vyadhi* which is being supported in this study, showing the higher values in particularly *Vatakara nidanas*. So the data of the present study support the existence of the pre-disposing factors of *Sandhigata vata*. *Sushruta* has described that the human body is *Snehmay* and *Sneha* is *Adhar* for *Prana*, *Sneha* does *Dharana* of *Prana*.[9] Due to *Sukshma*, *Snigdha gunas* it reaches till *anu parmanu* of *Sharir* and impacts *Snigdhata*, *Vishyandata*, *Mruduta*, and *Kledana* to *Sharir*.[21]

In this study 70% of patients got excellent results, 26.67% got good results, and 3.33% i.e. 1 patient got moderate results. Knee X-rays were done before and after treatment in all patients but no much change was observed.

The *Devdarubaladi Tailam* is significantly effective in *Sandhigat Vata* as the p-value is < 0.0001 at a 95% confidence level on all subjective and objective parameters. In *Sandhishool* the Mean score at 1st visit was 2.133 which was reduced to 0.9667 at 3rd follow-up. This indicates there has been significant improvement in *Sandhishool* from 1st visit to 3rd follow-up. The Mean score at the 8th follow-up was reduced to 0.1333. This again indicates there was a significant improvement in *Sandhishool* from the 3rd Follow-up to the 8th follow-up. In *Sandhishotha* the Mean score at 1st visit was 0.8667 and was reduced to 0.333 at 3rd follow-up. This indicates there was a significant improvement in *Sandhishotha* from 1st visit to 3rd follow-up. The Mean score at the 8th follow-up is reduced to 0.000. This indicates there is a significant improvement in *Sandhishotha* from the 3rd Follow-up to the 8th follow-up. In *Sandhigraha* the Mean score was reduced from 1.2000 to 0.6333 from 1st to 3rd follow up. The Mean score at the 8th follow-up was increased to 0.667 from 0.6333 at the 3rd follow-up. This indicates there is a significant improvement but is comparatively less than 3rd follow-up. In *Sparsahsahatva* the Mean score was reduced to 0.9333 from 1.8333 at 3rd follow-up, indicating significant improvement in *Sparsahsahatva* from 1st visit to 3rd follow-up. It was further reduced to 0.1333 at the 8th follow-up. This indicates there was highly significant improvement in *Sparsahsahatva* from the 3rd Follow-up to the 8th follow-up. In *Akunchan Prasaran Vedana* the Mean score was reduced to 1.2667 from 2.000 at 1st visit indicating significant improvement in *Akunchan Prasaran Vedana* at 3rd follow-up. The Mean score at the 8th follow-up was further reduced to 0.5333. This indicates a highly significant improvement in *Akunchan Prasaran Vedana* till the 8th follow-up. In *Sandhisputan* the Mean score at 1st visit is 1.3000 which is reduced to 0.6333 at 3rd follow-up. This indicates there has been a significant improvement in *Sandhisputan* from 1st visit to 3rd follow-up. The mean score at the 8th follow-up was reduced to 0.3333. This indicates there was a significant improvement but comparatively less from

the 3rd Follow-up to the 8th follow-up. In *Gamankashtata* the Mean score at 3rd follow-up was reduced to 1.1000 from 2.0667 at 1st Visit indicating there was a significant improvement in *Gamankashtata* from 1st visit to 3rd follow-up. The Mean score at the 8th follow-up was reduced to 0.7333. This indicates there is a significant improvement in *Gamankashtata* from the 3rd Follow-up to the 8th follow-up.

On objective parameters, the Mean score of the Visual Analogue scale at 1st visit was 5.7667 which was reduced to 3.0000 at 3rd follow-up. This indicates there is a significant improvement in VAS from 1st visit to 3rd follow-up. The Mean score at the 8th follow-up was reduced to 0.4000. This indicates there was a significant improvement in VAS from the 3rd Follow-up to the 8th follow-up.

The mean score of the Goneometric reading of the Flexion of the knee joint at the 1st visit was 78.6296 which was reduced to 0.9667 at the 3rd follow-up indicating there was a significant improvement in Flexion Reading from the 1st visit to 3rd follow-up. But there is no significant improvement from the 3rd follow-up to the 8th follow-up. Swelling and walking time also shows significant improvement on 8th follow-up.

CONCLUSION:

The study entitled "Clinical Evaluation of *Devdarubaladi Tailam* in the management of *"Sandhigata Vata"* was undertaken. Based upon the results of the clinical study were displayed in the form of tables, the discussion was made, and a conclusion was drawn. Marked relief was observed in chief complaints, and no side effect was observed. Out of 30 patients, only 1 patient had moderate relief, 21 (70%) patients had excellent results, and 8 (26.67%) patients had good results **(Table 5)**. There is a considerable improvement in the classical symptoms of *Sandhigat vata.* On completion of 90 days, the improvement in *Sandhi shool* was 93.75%, *Sandhi shotha* was 100%, *Sandhi graha was 94.44%, Sparsahatwa was 92.73%, Akunchan Prasaran Vedana* was 73.33%, *Sandhi sputan* was relieved by 74.36% and *Gamankashta was* relieved by 64.52%. All subjective and objective parameters were statistically analysed by the student's pair t-test which showed extremely significant ($p<0.0001$). The study shows inspiring results, but study design and sample size may be important limitations and could have led to an overestimation of the effect. It may be recommended that the study should be carried out on a large number of patients to Evaluate and analyse the results.

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