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Research Article

COMBINED EFFECT OF *VAJIGANDHADI GANA KASHAYA* AND *KOLAKULATHADI CHURNAM LEPAM* IN THE MANAGEMENT OF *JANU SANDHIGATA* VATA W.S.R. TO OSTEOARTHRITIS OF KNEE JOINT

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ABSTRACT

Sandhigata vata is one of such disease commonly affecting a large number of individuals occurs usually after midlife stage. *Sandhigata vata* can be compared with osteoarthritis of contemporary medical science. In this study, the combined efficacy of *Vajigandhadi gana Kashaya churna* and *Kolakulathadi churna* as *Lepam* in *Janu Sandhigata vata* having properties like *Ushna virya*, *Vatahara*, *Ama pachana*, *Sothahara*, *Shulahara* and *Vedana sthapana* was evaluated. The textual reference for *Vajigandhadi gana* is only present but in this study the *Gana* is prepared in the form of *Kwath churna. Kolakulathadi churna* was used as external application in the study. The study was designed for the improvement of the cardinal symptoms of *Janu Sandhigata vata* among the ageing population and marked improvement was noticed. **Aim:** To study the efficacy of *Vajigandhadi gana Kashaya* and *Kolakulathadilepam* in the management of *Janu sandhigata vata* w.s.r. Osteoarthritis of knee joint. **Materials and Methods:** 40 patients fulfilling the inclusion criteria after signing the informed consent form were selected from the OPD and IPD of SJSACH. It is a single arm prospective open randomized clinical study. Patients were administered with 50ml of *Vajigandhadi gana Kashaya* morning and evening after food for 21 days and *Kolakulathadi churna* as *Lepam* (external application) over the affected knee joint for 07 days with two assessments on 8th day and 22nd day & follow up after one month. **Results:** Subjective parameters were assessed using Friedman's test and Wilcoxon signed rank test and objective parameters were assessed using Paired sample t test. All the parameters had highly significant and significant results with p value. **Conclusion:** The combined effect of *Vajigandhadi gana Kashaya* and *Kolakulathadilepam* was very effective in the management of *Janu sandhigata vata* (osteoarthritis of knee joint) as most of the drugs in both the formulations possess properties such as *Shula hara*, *Shotha hara*, *Vedana sthapana*, *Ama pachana, Balya* and *Rasayana*.

INTRODUCTION

Janu sandhigata vata is one such disorder where *Janu sandhi* is involved and the locomotive functions are affected. In Ayurveda, the *Vyadhi* is explained under *Sthana visheshakruta Vata vyadhi.*[1] When the *Vata dosha* is increased, it is prone to get lodged in the *Asthis* and *Sandhis*.

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In old age, all *Dhatus* are deranged leading to *Vata prakopa* and making the individual prone to many *Vataja vyadhi*. *Sandhigata vata* is a *Dhatu kshayajanya vyadhi* where *Asthivaha* and *Majjavaha srotodushti* is mainly seen.[2] It occurs usually after midlife stage.

Vata prakopakara nidanas in the generation of *Janu sandhigata vata* includes: *Vata prakopa ahara-Ruksha*, *Sheeta, Alpa, Laghu* etc and *Vihara-Pradhavana, Bhara harana* or *Abhighata* due to *Prapatana, Marma abhighata, Dukha shayya* and *Asana.*[3] Due to *Nidana* (*Vata prakopa nidana* and *Vardhakya avastha*), there is aggravation of *Vata dosha* leading to *Dhatu kshaya* which in turn reduces *Sneha bhava* in the body, the increased *Vata dosha* gets

vitiated and occupies the *Rikta sthanas* in the body along with other *Doshas.* Thereby, resulting in *Karma hani* of the *Sandhis. Prakupitha Vata dosha* creates *Sandhi shula* (pain), while due to *Shleshmaka kapha kshaya*, *Sandhi garshana* (crepitation) take place and symptoms like *Sandhi shotha* (inflammation) occurs.[4]

In modern science, Osteoarthritis is described among arthritis group causing joint disorder. It is almost identical to *Sandhigata vata* in etiology, pathology and clinical features. Osteoarthritis is the second most common musculoskeletal disorder in the elderly population after back pain. Due to etiological factors, there will be loss of cartilaginous matrix leading to focal loss of chondrocytes along with proliferation of chondrocytes at other places. Gradually there will be loosening and breaking of articular cartilages. As a result, the subchondral bony part becomes exposed followed by deformation of micro cyst. It further leads to subarticular sclerosis, changes in shape of joint surface and osteophyte formation.[5]

Hence in this study, *Vajigandhadi gana Kashaya*[6] internally and *Kolakulathadi lepam*[7] was applied externally in the management of *Janu sandhigata vata* (osteoarthritis of knee joint) as most of the drugs in both the formulations possess properties such as *Shula hara*, *Shotha hara*, *Vedana sthapana*, *Ama pachana* and *Rasayana*.

AIMS AND OBJECTIVES

The study has been conducted with following aims and objectives:

To study the efficacy of *Vajigandhadi gana Kashaya* and *Kolakulathadilepam* in the management of *Janu sandhigata vata* w.s.r. Osteoarthritis of knee joint.

Hypothesis

H_0–*Vajigandhadi gana Kashaya* and *Kolakulathadi lepam* are not effective in the management of *Janu sandhigata vata* (Osteoarthritis of knee).

H_1–*Vajigandhadi gana Kashaya* and *Kolakulathadi lepam* are effective in the management of *Janu sandhigata vata* (Osteoarthritis of knee).

MATERIALS AND METHODS

Sample source

A total of 40 patients diagnosed with *Janu sandhigata vata* (Osteoarthritis of knee) those who satisfied the inclusion criteria of the Osteoarthritis of knee and willing to sign the informed consent form were selected from OPD and IPD of Sri Jayendra Saraswathi Ayurveda College and Hospital, Nazarathpet, Chennai. Institutional Ethical Committee (IEC) clearance was obtained prior to the study.

Ref. IEC NO: IEC/SJSACH/06/2021 and CTRI Registered No. CTRI/2021/08/035827.

Sample size: 40 patients

Method of Sampling: Single Random Sampling

Duration of the Study: 21 days

Design of the Study

- Day 0: assessment done
- Day 1st to 7th: *Vajigandhadi gana kashaya* administered orally & *Kolakulathadi lepam* applied over affected joint
- Day 8th to 21th: Internal medication continued
- First assessment on: 8th day
- Second assessment on :22nd day
- Post treatment follow up: After one month (51st day)

Plan of the Treatment

Included patients were treated as follows:

Internal Administration

Oral administration of *Kashaya* prepared (50ml) twice a day after food for 21 days.

External Application

Lepam will be applied of thickness app. 2cm mixed with *Chinch Patra rasa*; once in a day time over the knee joint for 7 days.

Drug Source

Drugs required for the preparation of medicines were collected from the local market and grinded from the Sankara Ayur Pharmacy of Sri Jayendra Saraswathi Ayurveda College and Hospital for the present study.

Preparation of *Vajigandhadi Gana Kashaya Churna* and *Kolakulathadi Lepa Churna*

Table 1: shows the ingredients of *Vajigandhadi gana Kashaya churna*

Drugs	Botanical name	Quantity
Aswagandha	*Withania somnifera*	1 Part
Bala	*Sida cardifolia*	1 Part
Atibala	*Abutilon indicum*	1 Part
Nagabala	*Sida veronicaefolia*	1 Part
Bilva	*Aegel marmelos*	1 Part
Agnimantha	*Premna integrifolia*	1 Part
Syonaka	*Oroxylum indicum*	1 Part

Patala	*Stereospermum suaveolens*	1 Part
Gambhari	*Gmelina arborea*	1 Part
Prshni parni	*Uraria picta*	1 Part
Shala parni	*Desmodium gangeticum*	1 Part
Gokshura	*Tribulus terrestris*	1 Part
Kanthakari	*Solanum xanthocarpum*	1 Part
Brihati	*Solanum indicum*	1 Part
Himsra	*Capparis separia*	1 Part
Vyagranakha	*Capparis zeylanica*	1 Part
Rasna	*Alpania galangal*	1 Part
Sunthi	*Zingiber officinale*	1 Part

Table 2: Shows the ingredients of *Kolakulathadi lepa churna*

Drugs	Botanical name	Quantity
Kola	*Ziziphus jujube*	1 Part
Kulatha	*Dolichos biflorus*	1 Part
Suradaru	*Cedrus deodara*	1 Part
Yava	*Hordeum vulgare*	1 Part
Shatahva	*Anethum sowa*	1 Part
Masha	*Vigna mungo*	1 Part
Atasi	*Sesbania grandiflora*	1 Part
Vacha	*Acorus calamus*	1 Part
Kushta	*Saussurea lappa*	1 Part
Rasna	*Alpinia galangal*	1 Part
Tailaphala	*Ricinus communis*	1 Part

Fig 1: *Vajigandhadi gana kashaya choornam* **Fig 2: *Kolakulathadi churnam***

Inclusion Criteria

- Diagnosed cases of *Janu Sandhigata Vata* w.s.r. to Osteoarthritis of knee willing to participate in the study and have completed the consent form were selected.
- Patient between the age group 50-70 years.
- Sex- All genders

Exclusion Criteria

- Any history of osteotomy/arthroplasty
- Auto-immune origin disease (rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus).
- Tuberculosis of knee
- Paget disease
- Fractures
- Pregnancy

Diagnostic Criteria

Diagnosis will be made on the basis of ACR criteria (American College of Rheumatology) [8]

- Using history, physical examination and radiographic findings:
- Pain in the knee + and 1 of the following –
    1. Over 50 years of age
    2. Less than 30 min of morning stiffness, crepitus on active motion and osteophytes

Assessment Criteria[9]

Based on subjective and objective parameters including grading and standard scoring method were assessed before and after treatment.

Subjective Parameters

Subjective Parameters	Grades	
Sandhi Shoola	0	No pain
	1	Mild pain
	2	Moderate pain without difficulty in walking
	3	Moderate pain with difficulty in walking
	4	Severe pain with difficulty in walking
Sandhi Shotha	0	No swelling
	1	Slightly
	2	Covers well over the bony prominence
	3	Marked and elevated
	4	Severe and elevated
Sandhi Stabdata	0	No stiffness
	1	< 5 min
	2	5-10 min
	3	10-15 min
	4	>15 min
Sandhi Atopa	0	No crepitus
	1	Occasional crepitus
	2	Persistent crepitus
	3	Persistent and palpable crepitus
	4	Persistent and audible crepitus

Objective Parameters

Objective Parameters	Grades	
Range of Movements	0	Normal Flexion 130 degree
	1	<130 and 110 degree
	2	< 110 and 90 degree
	3	< 90 and 70 degree
	4	< 70 degree

Womac Score (ref: WOMAC Questionnaire Index)[10]

Grade 1	None	0
Grade 2	Mild	1- 24
Grade 3	Moderate	25- 48
Grade 4	Severe	49 – 72
Grade 5	Extreme	73 – 96

Laboratory Investigations

Investigations were performed in all patients before the treatment

- Hb gm%, ESR, CRP
- RBS

Statistical Analysis

The data obtained were recorded for the statistical analysis with presentation in tables, diagrams and graphs. Statistical analysis was done with IBM spss software 15.

a) Assessment of subjective parameters – Friedman's test and Wilcoxon signed rank test

b) Assessment of objective parameters – Paired sample t test

OBSERVATION AND RESULTS

48 patients who came to the OPD and IPD with the complaints of *Janu Sandhigata vata* were screened with the assessment criteria and 40 patients who fulfilled the inclusion criteria were selected and registered for the study.

The observation was done on 40 patients in which maximum patients were i.e., 30% were found between 50-55 years of age group and majority of the patients i.e., 72.5% were found females. About 30% were belonging to lower socioeconomic status and 57.5% were literate but primary educated. Maximum number of patients i.e., 27.5% were house wives and most of the patients i.e. 32.5% were doing long standing nature of work. In the present study, majority of patients i.e., 50% were suffering from more than 1 year and 65% had incidence of gradual mode of onset. In the present study, majority of the patients i.e., 37.5% had aggravation due to standing for long time. Maximum number of the patients i.e. 67.5% had mixed diet and 32.5% had *Katu, Tikta, Kashaya rasa pradhana ahara.* In the present study, maximum number of patients i.e., 50% had disturbed sleep and 40% had constipation. Majority of the patients, i.e., 47.5% were having BMI of 25-30 (over weight) and most of the patients i.e., 52.5% were doing no exercise. In the present study, most of the patients i.e., 35% were *Vata* predominant *Kapha prakriti*.

RESULTS

Table 3 Showing the Summary of Significant Results in Subjective Parameters

Parameters	N	Mean score		X^2	P- value	Remarks
		BT	AT			
Sandhi Shula	38	13.88	7.45	73.041	.000	HS
Sandhi Shopha	32	11.68	6.13	59.00	.000	HS
Sandhi Stabdata	33	11.81	6.74	59.815	.000	HS
Sandhi Atopa	36	12.29	6.55	63.795	.000	HS

Table 4 Showing the Summary of Significant Results in Objective Parameters

Parameters	Mean score		Diff of Mean	% of relief	SD	SE Mean	T- value	P- value	Remarks
	BT	AT							
Range of Movements	1.98	.73	1.25	63.13	.840	.133	9.415	.005	S
Womac Score	3.95	2.13	1.82	46.07	.385	.061	29.995	.013	S

DISCUSSION

Probable mode of action of *Vajigandhadi gana Kashaya*: Most of the drugs in this formulation are *Vata - kapha hara, Shula hara, Shotha hara, Vedana sthapana*. Some drugs like *Bala*[11], *Atibala*[12], *Nagabala*[13], *Aswagandha*[14], *Gambhari*[15], *Gokshura*[16], *Prishni parni*[17] act as *Balya* and *Rasayana*. Drugs like *Shunthi*[18], *Shala parni*[19], *Syonaka*[20] acts as *Deepana* and *Pachana*. This formulation contains *Dashamoola* which is *Tridosha hara* especially *Vata shamaka*. It possesses qualities like *Shula hara, Shotha hara*. Most of the drugs possess *Tikta rasa*. *Tikta rasa* have properties like – *Deepana, Pachana* and *Rochana*.

Probable Mode of Action of *Kolakulathadi Churnam* as *Lepam*: Most of the drugs in the formulation contain properties like *Ushna virya, Vata hara, Sotha hara*. *Chincha patra swarasa* which is used as the base for the *Lepa churnam* contain properties like *Sopha hara, Vata – Kapha hara.* When the *Lepam* is applied mixed with *Chincha patra swarasa*, the active principles of ingredients of *Lepa* are released in the base. This combination gets absorbed through the

Swedavaha srotas and thereafter, it is subjected for *Pachana* by *Bhrajaka pitta* present in skin. Further, new transformation takes place which pacifies the provocated *Dosha* locally and thus breaks the *Samprapti* leading to alleviation of the symptoms.[21]

The Pathway of Topical Drug Application to Reach Target Tissue– The pharmacological action of topical drug relies on penetration through the stratum corneum and permeation into the lower layers of the skin. The topically applied drugs may have depot effect such that they accumulate for a prolonged time in the stratum corneum, epidermis, dermis and subcutaneous tissue to form a reservoir, from which there is a sustained release of drug into the surrounding tissues. The drug may travel from the surface of skin via hair follicles or sweat glands to reach the lower layers.

At the dermal layer level, the drug may enter into the local blood vessels for distribution to deeper tissues. Thereafter, the uptake of the drug from the dermal microcirculation into the systemic circulation occurs. Ultimately, the drug diffuse deeper into inflamed tissues and gets absorbed via lymphatic drainage.[22]

Discussion on Results

Effect of Therapy on Subjective Parameters (Table 3)

***Sandhi shula*:** The mean rank of the symptom *Sandhi shula* before treatment (day 0) was 13.88 and after treatment (day 8) it was reduced to 11.49 and further (Day 22) it was reduced to 7.45. The p value was <0.001 and it was statistically highly significant.

Sandhi Shotha: The mean rank value of symptom of *Sandhi shotha* before treatment (day 0) was 11.68 and after treatment (day 8) it was reduced to 9.36 and further (day 22) it was reduced to 6.13. The p value was <0.001 and it was statistically highly significant.

***Sandhi Stabdata*:** The mean rank value of symptom of *Sandhi stabdata* before treatment (day 0) was 11.81 and after treatment (day 8) it was reduced to 10.01 and further (day 22) it was reduced to 6.74. The p value was <0.001 and it was statistically highly significant.

***Sandhi Atopa*:** the mean rank value of symptom of *Sandhi atopa* before treatment (day 0) was 12.29 and after treatment (day 8) it was reduced to 9.59 and further (day 22) it was reduced to 6.55. The p value was <0.001 and it was statistically highly significant.

Effect of Therapy on Objective Parameters (Table 4)

Range of Movements: The mean score of the parameter before treatment (day 0) was 1.98, after treatment (day 8) was 1.35 and further (day 22) it was .73. The percentage of relief was 31.81% (day 8) and further 63.13% (day 22) and it was statistically significant with p value 0.005.

WOMAC Index: The mean score of the parameters before treatment (day 0) was 3.95, after treatment (day 8) was 3.08 and further it was 2.13. The percentage of relief was 22.02% (day 8) and further 46.07% (day 22) and it was statistically significant with p value 0.013.

CONCLUSION

Janu sandhigata vata is commonly associated with *Vardhakya Avastha*. It is a *Madhyama rogamarga vyadhi*. The prognosis of the disease is considered to be *Kashta sadhya*. The *Lakshanas* of *Janu sandhigata vata* explained in the classics has resemblance to the signs and symptoms of osteoarthritis of knee joint explained in contemporary science. Sedentary lifestyle, strenuous work, occupation, fault dietary habits are main contributing factors in the pathogenesis of the disease. It leads to the vitiation of *Vata dosha* along with *Kapha dosha.* Most of the drugs in *Vajigandhadi gana kashaya* have *Ushna virya, Vata – kapha hara* property, *Shula hara, Sotha hara*, *Balya* and *Rasayana. Kolakulathadi churna* possess *Vata – kapha hara, Sotha hara, Shula hara* properties. *Lepa churna* has *Ama pachana* property also. So by their potency, they help in putting down the *Samprapti* of *Janu sandhigata vata*. *Chincha patra swarasa* which is used as base for *Kolakulathadi lepam* possess qualities like *Shula hara, Shotha hara, Ushna virya, Kapha - vata hara* hence it enhance the properties of the *Lepa churna* and helps in reducing the symptoms. The trial drugs showed marked improvement in improving the symptoms of patients; hence many patients got symptomatic relief during the study. These drugs showed highly significant results on *Sandhi shula*, *Sandhi shotha, Sandhi stabdata* and *Sandhi atopa* and significant results on Range of movements and WOMAC score index. This suggests that there was considerable improvement. No complications were observed during study.

Scope for Further Studies

- Radiological investigations like X- ray, MRI can be done before and after therapy for better understanding of the therapy.
- Study can be done with other *Shamana aushadhi* along with *Kashaya* for better result.
- Scientific tools are not available for assessment of *Janu sandhigata vata*; hence in future studies assessment tools can be developed for the disease.

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