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Combined effectiveness of Maharasnadi Kashaya with Shunti Churna and Matra Basti with Ksheerabala Taila in Janu Sandhigata Vata (Osteoarthritis Knee): An open label, single arm clinical study

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ABSTRACT

Sandhi Gata Vata is a clinical condition that comes under the heading of Vata Vyadhi where Prakupita Vata affects Sandhi and causes specific signs and symptoms. Lakshanas of Sandhi Gata Vata of Janu Sandhi resembles the signs and symptoms of osteoarthritis of knee. Osteoarthritis of the knee is more commonly found in women than men, and the prevalence increases dramatically with age. The major risk factors associated with osteoarthritis knee joint are old age, obesity, excessive usage of knee joint (occupational), which makes it an important cause of disability. A clinical study was conducted on 31 subjects by administering combination of Maharsnadi Kashaya with Shunti Churna and Matra Basti with Ksheerabala Taila and the results obtained were statistically analysed. Statistically significant reduction in Lakshanas of Janu Sandhi Gata Vata and WOMAC scores were noted.

Key words: Janu Sandhi Gata Vata, Osteoarthritis Of Knee, Maharasnadi Kashaya, Shunti Churna, Ksheerabala Taila, Matra Basti.

INTRODUCTION

In normalcy *Vata Dosha* governs various body functions,^[1] but in morbid state (*Prakupita Vata*) can produce pathological conditions like *Vata Vyadhi*. The presentation of *Vata Vyadhi* depends upon factors like *Sthana* or structures involved.^[2,3] *Gatavata* is one such presentation of *Vata Vyadhi* where structures like *Sira*, *Snayu*, *Sandhi* etc. can be involved. *Sandhigata Vata* is a type of *Vata Vyadhi* where the pathology involves *Sandhi* and exhibit *Vata Poorna*

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Druti Sparsha Shotha (localized swelling similar to air filled bag), Vedana during Prasarana (flexion) and Akunchana (extension) of Sandhi, [6] Sandhi Stabdhata and Sandhi Atopa. [7]

Knee joint is one of the important weight bearing joints in the body and osteoarthritis of the knee is one of the common joint disorders. Osteoarthritis of knee has a prevalence of 22% to 39% in India. This condition is usually observed in the elderly people and the people who do excessive physical deeds. Knee pain especially with movement, pain after overuse of knee or after long period of inactivity, knee joint swelling and knee stiffness are the clinical features of osteoarthritis of knee, which resembles the clinical presentation of Sandhi Gata Vata of Janu.

Sandhigata Vata Chikitsa has to be planned, primarily aiming at the correction of morbid Vata Dosha, also considering involvement of morbid Kapha Dosha. Sandhigata Vata likely develops with an involvement of Dhatu Kshaya (Asthi) and the correction of Dhatu Kshaya is also a point of concern for the treatment.

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Maharasnadi Kashaya is a Shamana Yoga mentioned by Acharya Sharangadhara, [8] in Vatavyadhis like Gridhrasi, Pakshaghata, Janu Gata Vata [9] etc. Maharasnadi Kashaya is a combination of twenty six different herbal drugs and Rasna is the Pradhana Dravya used in this Yoga. Shunti Churna is one of the Anupanas mentioned for Maharasnadi Kashaya, which is known to have Shoolahara and analgesic actions. Both Maharasnadi Kashaya and Shunti have Vata-Kaphashamaka^[10] property and the combination can be used in a Vatakaphaja and Shoolapradhana Vata Vyadhi, like Sandhi Gata Vata. Matra Basti is a procedure which exerts Snehana and Vatashamana actions in the Shareera[11] and Ksheerabala Taila is a Vatashamaka^[12] Yoga which exerts Snehana and Brimhana in the body.

OBJECTIVE

To evaluate the combined effectiveness of *Maharasnadi Kashaya* with *Shunti* Choorna and *Matra Basti* with *Ksheerabala Taila* in the management of *Janu Sandhi Gata Vata* (osteoarthritis of knee joint)

MATERIALS AND METHODS

Source of Data

31 subjects of *Janu Sandhi Gata Vata* were recruited from In-patient department (IPD) of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Hassan.

Method of collection of data

Data was collected using specially prepared case proforma by incorporating the signs and symptoms of *Janu Sandhi Gata Vata*.

Diagnostic criteria

Diagnosis was made on the basis of signs and symptoms mentioned for *Janu Sandhi Gata Vata*^[13] and 'American College of Rheumatology revised criteria for early diagnosis of Knee O.A.'^[14]

Inclusion criteria

Subjects of age group 40 - 70 years,^[15] Male or female subjects, Osteo arthritis of unilateral or bilateral knee joints with chronicity less than 10 years, Radiologic changes in x-ray (Kellgren's Lawrence index >or =2),

Subjects fit for matra *Basti*, and who are willing to participate and sign the informed consent form were included for the study.

Exclusion criteria

Subjects with Knee pain caused by congenital dysplasia, rheumatoid arthritis, autoimmune diseases, external trauma to knee joint and knee surgeries and who had been on chondroprotective drugs, intra articular injections into the knee joint or systemic corticosteroid medication during 3 months preceding enrollment, Subjects who require surgical intervention to the knee joint, Subjects with Genu varum or Genu valgum, Subjects who are known case of HIV, HbSAg, Pregnant and breastfeeding subjects and Subjects with uncontrolled diabetes mellitus and essential hypertension were not included for the study.

Investigations: X-ray - Knee joint (AP view)

Study design:

- Type of study: Open label, single arm, prospective, clinical study.
- 2. Sampling method: Convenience sampling
- 3. Test: Pre test and Post test
- 4. Sample size: 31 subjects.
- 5. Study duration: 24 days

Medicines

Maharasnadi Kashaya, Shunti Choorna, Ksheerabala Taila was prepared in teaching pharmacy of SDM College of Ayurveda, Hassan.

Source and authentification of medicine

Raw materials for *Maharasnadi Kashaya*, *Shunthi Churna* and *Ksheerabala Taila* was purchased and authenticated from CKKM Pharmacy, Trippunithara, Kochi.

Treatment plan

 Maharasnadi Kashaya - 45 ml/day was given in divided doses (15 ml thrice a day) along with Shunti Choorna - 1 Karsha (12g) in divided doses (4g thrice a day) – After food orally for 24 days.

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2. *Matra Basti* was administered with *Ksheerabala Taila* - 70ml/day for initial 8 days.

Duration: *Matra Basti* - Initial 8 days, *Maharasnadi Kashaya* and *Shunti* Choorna - 24 days.

Assessment of Subject - was done on 1st Day (B.T), 8th Day and 24th Day (A.T).

Assessment criteria

Primary outcome measure : The effect of therapy was assessed on the basis of following subjective criteria - The signs and symptoms of *Janu Sandhi Gata Vata*, namely *Sandhi Shotha*, *Sandhi Vedana*, *Sandhi Atopa* and *Stabdhata*.

Secondary outcome measures: WOMAC osteoarthritis index (modified).

OBSERVATIONS AND RESULTS

The study was completed by including 31 subjects for the study. Statistical analysis was done using SPSS Ver. 20. Cochren Q and McNemar tests were used to analyse the significance of change in nominal data. Friedman's and wilcoxon sign rank tests were used to analyse the significance of change in ordinal data. Repeated Measure Anova test was used to analyse the significance of scale data.

Statistically significant reduction in *Lakshanas*, viz., *Shotha*, *Vedana* and *Atopa* was noted at both 8th day and 24th day intervals where P value is less than 0.05 in 62 number of knee joints (of 31 patients) (Table 1)

Statisticaly significant reduction in stiffness noted in stiffness of knee at both 8th day and 24th day intervals where P value is less than 0.05 in 62 number of knee joints (of 31 patients) (Table 2)

Statistically significant reduction in WOMAC scores noted in all the 3 pairs of instances under P value less than 0.05 in 62 number of knee joints (of 31 patients). (Table 3)

Table 1: Results of Wilcoxson Signed rank test for Shotha, Vedana and Atopa

Shotha	Negative ranks			Positive ranks			Ties	Total	z	Р	Remarks
	N	MR	SR	N	MR	SR					
Knee swelling on 8 th day-BT	15	8.0	120.0	0	0.0	0.0	47	62	-3.873	.001	S
Knee swelling on 24 th day-BT	28	14.50	406.0	0	0.0	0.0	34	62	-5.292	.001	S
Knee pain on 8 th day-BT	27	14	378.0	0	0.0	0.0	35	62	-5.11	.001	S
Knee pain on 24 th day-BT	39	20.0	781.0	1	39.0	39.0	22	62	-5.54	.001	S
Knee crepitus on 8 th day-BT	20	10.5	210.0	0	0.0	0.0	42	62	-4.47	.001	S
Knee crepitus on 24 th day-BT	28	14.5	406.0	0	0.0	0.0	34	62	-5.01	.001	S

Table 2: Mc Nemar test on stiffness of knee

Stiffness in knee BT	Stiffness of knee 8 th da	у	Stiffness of knee 24 th day			
	Absent	Present	Absent	Present		
Absent	16	0	16	0		
Present	10	36	23	23		

Table 3: Results of Repeated Measure Anova test on Womac scale- Pair wise comparison

Womac score	Womac score	Mean	Std Error	Sig.	95% Confidenc	Remarks	
(1)	(J)	difference (I-J)			Lower Bound	Upper Bound	
вт	8 th day	5.377	0.890	0.000	3.186	7.568	S
8 th day	24 th day	6.098	0.719	0.000	4.327	7.87	S
24 th day	ВТ	-11.475	0.859	0.000	-13.592	-9.359	s

DISCUSSION

Discussion on subjective and objective parameters

Discussion on Shotha: Vata Poorna Driti Sparsha Shotha is due to localised Vata Prakopa or Gatatwa of Vata in the Sandhi. This can be compared with knee effusion which happens due to chronic degenerative changes in joint structures. Drugs which have Shothahara or anti-inflammatory properties, help to reduce the Sandhi Shotha / effusion. Statistically significant improvement was noticed in Sandhi Shotha (90.32%) after treatment.

Discussion on *Vedana*: *Sandhi Vedana* during *Prasarana Akunchana* of *Janu Sandhi* is due to localised *Vata Prakopa*. This can be compared with knee pain caused by friction in the knee, due to cartilaginous degeneration. Drugs which have *Shoolahara* / analgesic properties help to alleviate knee pain. Drugs which exert *Snehana* action can help to reduce friction and improve joint mobility. Statistically significant improvement was noticed in *Sandhi Vedana* (61%) after treatment.

Discussion on *Atopa***:** *Vata* localised in *Janu Sandhi* causes *Stanika Shleshaka Kapha Kshaya* which causes

Rookshata in Sandhi. Rukshata in Sandhi affects Samshleshana Karma and causes Atopa in Sandhi. This can be compared with Crepitus / grating sensation in joint is produced by friction, due to reduction in synovial fluid and cartilaginous loss. Drugs which exert Snehana action can help to reduce Atopa in Sandhi. Statistically significant improvement was noticed in Atopa (75.67%) after treatment.

Discussion on Stambha: Stambha or Stabdhata in Janu manifests as a result of Sthanika Sheeta, Ruksha and Khara Guna Vruddhi and association of morbid Kapha causing restricted movement in knee joint. Snigdhata and Shlakshnata are very essential for free movement of knee joint. Joint stiffness is due to reduction in synovial fluid and cartilaginous loss. Drugs which exert Vata-kapha Shamana and Snehana action can help to reduce joint stiffness. Statistically significant improvement was noticed in Stambha (79.6%), after treatment.

Discussion on Womac Scale: WOMAC score consists of 3 assessment criterias. They are pain, stiffness and difficulty in movement. Improvement in these 3 criterias results in reduction of the total score. *Shoolahara, Shothahara, Snigdha* and *Vatakaphahara*

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properties of medicines administered help to alleviate pain, stiffness and difficulty in movement of knee joints. Statistically significant improvement was noticed in WOMAC scores after treatment.

Discussion on mode of action of *Maharasnadi* Kashaya and Shunti Churna

Majority of the drugs in Maharasnadi Kashaya have Snigdha Guna, Ushna Veerya and Vata-Kapha Shamaka properties. Snigdha Guna of drugs counter act Ruksha Guna Pradhanyata in case of Stabdhata and Atopa of Janu Sandhi and probably reduced the symptoms. Ushna Veerya drugs counteracts Sheeta Guna of Vata, and are also Shoolahara, which might have helped in reducing Stambha and Shoola in Janu Sandhi. Vata-Kapha Shamana property of drugs helps to alleviate Stambha of knee joint. Rasna has Quercetin and Isohamnetin as active chemical constituents. According to scientific studies, Quercetin is a potent anti-inflammatory agent. By targeting inflammatory response of macrophages, it helps to reduce knee swelling. Quercetin improves protein concentration, molecular size of hyaluronic acid and chondroitin 6 phosphate concentration in synovial fluid and reduces joint stiffness, grating sensation of Isohamnetin has anti-inflammatory and chondroprotective actions, helps to protect joint tissue from degeneration. Ashwagandha also has chondroprotective action by inhibition of gelatinase activity of collagenase type 2 enzyme. Shunti is Ushna Veerya and Vata-Kaphahara. This property helps to mitigate Prakupita Vata and Kapha Dosha in Sandhi and helps to reduce Stambha. Shunti is Shoolahara in nature, which helps to reduce Sandhi Vedana. Shunti is a known anti-inflammatory drug and the active components of Shunti are known to inhibit lipooxygenase resulting in suppression of synthesis of inflammatory leucotrienes, TNF-alpha in synoviocytes and reduces swelling in the joint. This can be a probable cause for reduction of Shotha in Janu Sandhi.

Discussion on mode of action of *Matra Basti* with *Ksheerabala Taila*

Matra Basti is given for the purpose of Snehana and Vatashamana. Taila / Ghruta given as Basti Dravya

helps to achieve *Snehana* in the body. It is mentioned that *Matra Basti* given for 8 days, can reach to all the *Dhatus* and causes *Snehana*.

Ksheerabala Taila given as Matra Basti does Snehana and Brimhana in the body including Sandhis. Ksheerabala Taila does nourishment of Kapha by the action of Snehana, which helps to counteract Ruksha, Khara Gunas of morbid Vata Dosha, does Sandhi Samshleshana and gives Sthirata for Sandhi. By the Brimhana action it counteracts the Asthi Dhatu Kshaya taking place in Janu Sandhi Gata Vata. Bala is proved to be having analgesic and anti-inflammatory activites which helps to alleviate Janu Shoola and Shotha.

Matra Basti is given through rectal route. Rectal route of administration has been given importance by considering drug assimilation, and bioavailability like the intravenous mode of administration. When the drugs are lipid soluble like Matra Basti Dravya, their active ingredients can get absorbed readily from the intestinal mucosa. Comparatively larger quantity of drug can be administered through Basti and the formulation of Basti Dravya is of minute size, which enables the drug to get absorbed readily and get assimilated freely in the body.

CONCLUSION

There was marked improvement in signs and symptoms of Janu Sandhi Gata Vata especially in Sandhi Shotha (90.32%) and Stambha (79.6%) after treatment. There was significant reduction in objective parameters like WOMAC scores after the treatment due to marked reduction in pain, stiffness and difficulty in movement. Maharasnadi Kashaya (15ml) with Shunti Churna orally thrice a day after food for a duration of 24 days and Matra Basti with Ksheerabala Taila (70ml) for a duration of 8 days is effective in Janu Sandhi Gata Vata (osteo-arthritis of knee).

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