



Research Article

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COMPARATIVE CLINICAL EVALUATION OF JANU VESTANA AND JALAUKAVACHARANA IN JANUSANDHIGATAVATA

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ABSTRACT

Living system has an ability to maintain itself by means of repair and reconstruction. Ageing process leads to a decrease in this efficiency of the body. The autonomous Vayu governs this change and gives rise to various Vatavyadhi as the age advances. Sandhigatavata is one such condition that occurs when provoked Vata enters the asthisandhi owing to gatavata pathology. Pain typically present on joint mobilisation with features like swelling, stiffness, crepitus etc are the clinical manifestations of this condition. It can be well correlated with Osteoarthritis described in modern science. Knee joint is an easy target and the degenerative changes in knees is termed as Janusandhigatavata. Various procedures performed on the knee are in vogue. Local application, intra-articular injections and non pharmacological treatments are some widely used approaches among them. Yet, an additional cavernous review is indispensable to bring out a precise outcome of these procedures. Hence, the particular study was done with Nirgundi taila Janu Vestana and Jalaukavacharana in Janusandhigatavata. It was a parallel group comparative clinical study, conducted and completed on 62 patients suffering from Janusandhigatavata within 70 years of age, irrespective of gender, randomly allocated into 2 groups with 31 patients each subjected to Nirgundi taila Janu Vestana and Jalaukavacharana. The therapeutic effect was assessed based on specific clinical parameters and statistically analysed for test of significance using paired and unpaired 't' test. Both groups showed statistically highly significant improvement in the primary outcome parameters with $p < 0.001$. However the effect of Jalaukavacharana was appreciated instantly when compared to Vestana.

Keywords: Janusandhigatavata, Nirgundi taila, Janu Vestana, Jalaukavacharana.

INTRODUCTION

An essential property of the living system is its ability to maintain itself, by means of repair, reconstruction and reconstitution. This capacity for self synthesis sets off the living from the nonliving. Then, if the living organism can and does reconstitute itself continuously, it would not have worn out. Therefore it is necessary to postulate that wearing out or ageing process involves a decrease in efficiency of the body mechanism for reconstruction and reconstitution. All these functions are controlled by vata; the prime among the tridosha, due to its six –fold distinguishing features like spreading, quick action, vigour, capacity to vitiate other dosha, autonomy and power to create maximum number of diseases¹. Sandhigatavata is a condition of gatavata, wherein provoked vata dosha enters the asthisandhi and causes vedana typically on joint mobilisation along with features like stambha, shotha², atopa³ etc. Sandhigatavata can be compared with osteoarthritis (OA) due to its outstanding similarities to this degenerative joint disease. Osteoarthritis is a generalised phenomenon that can occur in certain predisposed joints of the body. The pattern of joint involvement in OA is influenced by prior vocational or avocational overload⁴. When the degenerative changes occur in the knee joint, sandhigatavata is prefixed with 'Janu' and called as 'Janusandhigatavata'. The reported prevalence of osteoarthritis from a study in rural India is 5.78 %. Indians are said to have an increased risk of knee osteoarthritis. The major risk factors associated with knee Osteoarthritis seen in a population study were: age, female sex, obesity, occupational knee bending, physical labour and chondrocalcinosis⁵. Janusandhigatavata can impair physical health of an individual predominantly due

to pain and can cause a complexity in locomotion in the form of diminishing the ability to walk. If untreated for long, it can cripple the locomotion of an individual to a greater extent. Hence a timely and suitable treatment would enable a patient of Janusandhigatavata to maintain the near intactness of locomotion for longer duration. Various treatment procedures that can be performed on the knee for Janusandhigatavata are in vogue. Local application, intra-articular injections and non pharmacological joint treatments are some widely approached modalities of treatment. Research activities have been undertaken in various disciplines of medical science in these areas. Yet, an additional cavernous review is indispensable to bring out a precise outcome of these procedures. Keeping this vision in mind, it was planned to conduct a clinical study to evaluate and compare the efficacy of Janu Vestana using Nirgundi Taila⁶ and Jalaukavacharana in patients suffering from Janusandhigatavata.

MATERIALS AND METHODS

Key materials for the study

Janu Vestana group - Nirgundi Taila and 60 cm × 15 cm strip of cotton cloth.

Jalaukavacharana group – Nirvisha Jalauka

Method of study

The patients who attended the OPD, IPD and arthritis special camps with signs and symptoms of Janusandhigatavata were screened. Among these, 68 patients who fulfilled all necessary criteria and gave a written consent for the clinical trial were enrolled for the trial as study volunteers. The selection and allocation of

patients were done at random, irrespective of gender, occupation, educational status, socio economical status and marital status considerations. They were subjected to parallel group comparison clinical study. Blinding was not done, as the clinical trial involved procedures which were to be explained to the volunteers before conducting the trial and the volunteers would be the eye witnessing the same when the treatment was done. The study was carried out as per the Ethical clearance number: SDMCAU/ACA15/EC11/09-10. Out of 68 patients, 35 patients were registered in Janu vestana group and 33 patients were registered in Jalaukavacharana group. Finally 62 patients completed the study. There were 31 patients in each group who completed the study. Among the 06 dropouts, 04 patients were from Janu Vestana group and 02 patients were from Jalaukavacharana group.

Study duration

Janu vestana was done daily for approximately six hours for a time period of two weeks. Jalaukavacharana was done for one sitting and the patients were followed up for a period of two weeks. Clinical assessments were done at baseline, 7th and 14th day of treatment. Total study duration was for two weeks.

Diagnostic criteria

- Pain in knee joint with/without other features like stiffness, swelling and joint crepitus
- Evidence of radiological changes suggestive of osteoarthritis of knee

Inclusion criteria

- Patients fulfilling the diagnostic criteria
- Patients of either sex with age 70 years or below
- Both fresh and already treated cases (with no or negligible response to earlier treatments)
- Patients who agreed to sign the informed consent form and follow up the protocol

Exclusion criteria

- Patients who refused to give a written consent.
- Janusandhigatavata secondary to other joint diseases like Rheumatoid Arthritis, Psoriatic arthritis and Gouty arthritis.
- Janusandhigatavata as a consequence of trauma and fractures.
- Patients suffering from systemic illness which would decline the general condition of the patient and interfere with the clinical trial.
- Patients unfit for Raktmokshana.
- Vulnerable group like lactating mothers, pregnant and mentally challenged persons.

Specific investigations

- X-ray knee antero-posterior view and lateral view before treatment to know the extent of radiological changes before commencing the intervention.
- Clotting time and bleeding time before commencing the intervention (Jalaukavacharana group).

Intervention

Method of Janu Vestana

Preparation phase

Patients were explained the procedure and written consent was obtained from all study volunteers. Patients were subjected to routine investigations before commencing the treatment. A strip of thin cotton cloth, measuring 60 cm × 15 cm was taken and rolled into a cylindrical shape. Approximately 70 ml of Nirgundi taila was made warm by heating it in a hot water bath. The temperature of the oil was according to the skin tolerance of individual patient.

Main procedure

The patient was made to lie in supine position with a mackintosh spread under the knees. The affected knee/knees were exposed. The role of cotton cloth was dipped in warm Nirgundi taila until it was fully soaked and the excess oil was gently squeezed out. The cotton cloth roll soaked in warm oil was wrapped around the knee in a circular manner. Care was taken that the cloth was not wrapped too tightly or too loosely. The free end of the cloth was fastened in position using a safety pin, so as to enable the cloth stay in position. The time duration for retention of the medicine on the knee, per sitting was approximately 6 hours. Night time was selected for the treatment so that the patient could follow-up the treatment conveniently.

After procedure

The patient was advised to open up the wrapped cotton cloth the next morning when awakened from bed and wash the knee with warm water. The procedure was continued on a daily basis for the entire course of the treatment phase (14 days).

Method of Jalaukavacharana

Preparation phase

Preparation of Jalauka

Two leeches for each affected joint were removed from the preservation container and put in turmeric water until they were active. They were then transferred to a bowl containing clean water and were ready for use.

Preparation of Patient

The patient was explained the procedure and written consent was obtained. CT and BT were done apart from the routine investigations to all patients of this group before commencing the treatment.

Main procedure

A single sitting of Jalaukavacharana using one leech on medial aspect and one on lateral aspect of index knee joint/joints were carried out. The leeches were covered with thin cotton pads dipped in room temperature water while sucking the blood. Each leech was allowed to suck from the area of its application as long as it sucked and was allowed to detach by itself.

After procedure**In Patient**

The oozing blood was cleaned up with sterile gauze and the area of bite was dusted with turmeric powder. When the bleeding reduced, a loose bandage was tied around the knee so as to avoid inconvenience to the patient from the oozing blood.

In Jalauka

The leeches were induced emesis immediately after detachment by applying turmeric at their mouth end. They were cleaned in fresh water and later transferred into clean containers with fresh water.

Assessment criteria

Clinical evaluation was done at baseline, 7th day and 14th day to assess the efficacy variables Pain (Knee function assessment chart of the British Orthopaedic Association Research subcommittee) and Crepitus (Criteria of Altman for the diagnosis of idiopathic Osteo Arthritis of Knee using clinical and X-Ray data). Patients were asked to complete the WOMAC⁷ questioner (Western Ontario Mac mister index) at each visit.

OBSERVATIONS AND RESULTS**Demographic distribution**

The distribution of 62 patients according to age, gender and occupation is shown in Table 1. It was observed that the maximum number of patients belonged to age group 51-55 years and 66-70 years. Age wise distribution showed 25.81 % (n = 16) patients belonged to age group of 51-55 and 66-70 each. Out of 62 patients 69.35 % (n = 43) were females and 30.65 % (n = 19) were males. Considering occupational impact on Janusandhigatavata, the present study had 48.38 % (n = 30) housewives in the study. Field labourers and people in service like teachers, drivers were the second highest in the study accounting 14.52 % (n = 09) each.

Outcome measures

The scores of outcome variables which were assessed at the evaluating time points, that is baseline, 7th and 14th day were tabulated and subjected to statistical analysis. SPSS 16 was the statistical software used for the analysis. Paired't' test was used to evaluate the statistical significance of the efficacy of treatment within the groups; before, during and after treatment. Independent sample't' test was used to evaluate the statistical significance of the efficacy of treatments between the groups. On evaluation at pre and post treatment phases within the groups, the clinical parameter Pain and WOMAC showed improvement in both the groups. The same was supported by statistical analysis, showing highly significant difference in the efficacy variables from baseline measures to 7th and 14th day (p < 0.001) in both the groups. Table 2 and 3 show the means of efficacy variables at baseline, 7th and 14th day, percentage of relief, mean difference along with standard error, t value and p value of efficacy variables from baseline to 14th day of study period in Janu Vestana and Jalaukavacharana groups respectively. While comparing the outcome variables between the groups, it was observed that Jalaukavacharana group appreciated rapid decline in pain and WOMAC immediately after treatment in comparison to Janu Vestana group. The same was also supported statistically. There was statistically highly significant difference in the effect of treatment between the groups (p < 0.001), except for WOMAC stiffness on 14th day which was statistically significant (p = 0.01). Hence the mean of differences of outcome variables in both groups were compared and it was found that Jalaukavacharana group responded instantly and vigorously to treatment in comparison with Janu Vestana group. Table 4 shows the Mean of difference, Standard deviation, Mean difference, Standard error of difference of means, t value and p value of efficacy variables at 7th and 14th day of treatment period. Joint crepitus was appreciated in all patients. It remained unchanged throughout the study period in both the groups. Hence this data was not subjected to statistical analysis.

Table 1: The demographic profile of 62 patients

Variable	Vestana group		Jalaukavacharana group		Total	
	n(31)	Percentage	n(31)	Percentage	n (62)	Percentage
Age						
46-50	07	22.58	04	12.90	11	17.74
51-55	06	19.36	10	32.26	16	25.81
56-60	04	12.90	04	12.90	08	12.90
61-65	06	19.35	05	16.13	11	17.74
66-70	08	25.81	08	25.81	16	25.81
Gender						
Male	08	25.81	11	35.48	19	30.65
Female	23	74.19	20	64.52	43	69.35
Occupation						
Peasants	03	9.68	02	6.45	05	8.06
Housewives	13	41.94	17	54.83	30	48.38
Labourers	06	19.35	03	9.68	09	14.52
Service	04	12.90	05	16.13	09	14.52
Business	02	6.45	03	9.68	05	8.06
Landlord	01	3.23	01	3.23	02	3.23
Professional	02	6.45	NIL	-	02	3.23

Table 2: Comparison of Efficacy measures in Janu Vestana group

Variable	Mean Baseline	Mean 7 th day	Mean 14 th day	% of relief on 14 th day	MD + SE	't' value	P value
Pain	2.77	2.03	1.97	28.88	.806 + .086	9.404	< 0.001
WOMAC pain	7.42	5.26	5.03	32.21	2.387 + .244	9.784	< 0.001
WOMAC stiffness	1.94	1.16	1.03	46.91	.903 + .176	5.141	< 0.001
WOMAC function difficulty	37.42	32.94	32.13	14.14	5.290 + .455	11.631	< 0.001
WOMAC Combined	46.77	39.29	38.13	18.47	8.645 + .715	12.095	< 0.001

MD - Mean Difference, SE - Standard Error, 't' value - value got after applying 't' test, P value- Probability

Table 3: Comparison of Efficacy measures in Jalaukavacharana group

Variable	Mean Baseline	Mean 7 th day	Mean 14 th day	% of relief on 14 th day	MD + SE	't' value	P value
Pain	2.61	0.74	1.03	60.54	1.581 + .765	11.507	< 0.001
WOMAC pain	7.45	2.84	3.26	56.24	4.194 + .326	12.864	< 0.001
WOMAC stiffness	1.97	0.26	.39	80.20	1.581 + .184	8.582	< 0.001
WOMAC function difficulty	37.65	25.23	26.26	30.25	11.387 + .972	11.710	< 0.001
WOMAC Combined	47.03	28.29	29.90	36.42	17.129 + 1.334	12.838	< 0.001

MD - Mean Difference, SE - Standard Error, 't' value - value got after applying 't' test, P value- Probability

Table 4: Comparative effect of Janu Vestana and Jalaukavacharana

Variable	Group	n	Mean (BT-AT)	SD	MD	SE Diff	't' value	P value
Pain 7 th day	1	31	0.74	0.514	1.129	0.145	7.813	< 0.001
	2	31	1.87	0.619				
Pain 14 th day	1	31	0.81	0.477	0.774	0.162	4.781	< 0.001
	2	31	1.58	0.765				
WOMAC pain 7 th day	1	31	2.16	1.186	2.452	.359	6.838	< 0.001
	2	31	4.61	1.606				
WOMAC pain 14 th day	1	31	2.39	1.358	1.806	.407	4.436	< 0.001
	2	31	4.19	1.815				
WOMAC stiffness 7 th day	1	31	0.77	0.956	0.935	0.241	3.889	< 0.001
	2	31	1.71	0.938				
WOMAC stiffness 14 th day	1	31	0.90	0.978	0.677	0.255	2.661	= .010
	2	31	1.58	1.025				
WOMAC function difficulty 7 th day	1	31	4.48	2.365	7.935	0.927	8.560	< 0.001
	2	31	12.42	4.588				
WOMAC function difficulty 14 th day	1	31	5.29	2.532	6.097	1.074	5.679	< 0.001
	2	31	11.39	5.414				
WOMAC Combined 7 th day	1	31	7.48	3.623	11.258	1.277	8.819	< 0.001
	2	31	18.74	6.115				
WOMAC Combined 14 th day	1	31	8.65	3.980	8.484	1.514	5.605	< 0.001
	2	31	17.13	7.429				

n- number, SD- Standard Deviation, MD - Mean Difference, SE Diff- Standard Error of the difference in mean, 't' value - 't' test value, P value- Probability

DISCUSSION

Demographic profile

Maximum number of patients in the study belonged to age group 51-55 years and 66-70 years. Steady rise in the prevalence of osteoarthritis is observed in people between the age group of 30 to 65 years, where 80 % of the population have radiological evidence⁸. Majority of study volunteers belonged to female gender. This observation is supported by the universal observation that prevalence of osteoarthritis in elderly females is more. During and after menopause the falling levels of oestrogen and progesterone combined with the natural ageing process makes women more susceptible to osteoarthritis⁹. Symptomatic and radiographic OA increases with age. The age related increase is more in females. The disease is more severe in females with more symptoms, more extensive involvement, and increased prevalence of knee¹⁰. Considering occupation influence, more physical

activity in the individual and house hold activities in females showed a relationship in the manifestation and aggravation of this condition as majority were housewives in the study. Epidemiological surveys suggest that physical factors involved in occupations are important determinants of the condition¹¹.

Treatments

Janu Vestana

This is a treatment specially meant for vata dosha¹². Nirgundi taila is a sneha indicated for vata vyadhi. This taila was made warm before use. Hence the treatment was a combination of vestana, snehana and mild svedana which is indicated in the treatment of vata vyadhi¹³. This effect is supported by the Molecular Transdermal transport system¹⁴ which relies on the mechanism of the human body to pick a drug molecule through skin. A

molecular Transdermal transport vehicle should have at least 4 components.

- Blood flow enhancer through vaso dilatory action. (Achieved by svedana in this study)
- Penetration enhancer/ permeation enhancer where vegetable oil or vegetable oil alcohol mixes serve as suitable enhancer.
- Active ingredient- the drug molecule
- Water soluble adhesive that links the above three.

Jalaukavacharana

The effectiveness of this treatment may be attributed to the analgesic, anti inflammatory and anaesthetic activity of the leech saliva which contains a number of pharmacologically active biological substances like hirudin, hyaluronidase, inhibitors of kallikerine, fibrinases, collagenase etc. These substances are injected into the body during the bite which brings about the effect¹⁵.

Adverse events

No major adverse events were observed during and after the intervention. Few patients complained of mild itch around the bit on the third and fourth day after application of leech in Jalaukavacharana group which gradually subsided on dusting the bite area with turmeric powder. No other medicines were given for this purpose. One patient complained of itch which tiny red rashes on the knee for the first two days in Vestana group. These rashes gradually disappeared from the third day.

CONCLUSION

This study concludes that both treatments were effective in bringing down the pain in knees and reducing the WOMAC scores in Janusandhigatavata. Further it was observed that Jalaukavacharana had instant and vigorous pain relieving effect in comparison to Janu vestana. But the mean scores showed that the effect of Jalaukavacharana retained at the end of second week was reduced compared to the effect obtained in the first week. On the other hand the effect obtained by Janu Vestana gradually increased by the end of second week in comparison with the effect obtained towards the end of first week. There was no change in joint crepitus in both the groups before and after treatment. Both the procedures were found safe for practice. They were accepted and well tolerated by patients. No obnoxious side effects were observed except for a mild local itching in few patients. The overall compliance to the therapy was good. Thus it can be concluded that Janu Vestana using Nirgundi taila and Jalaukavacharana are effective and safe treatments in symptomatic management of Janusandhigata Vata; where in Jalaukavachana has instant effect which declines gradually, while Janu Vestana has gradual increasing

effect in symptomatic management of Janusandhigatavata.

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