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A CLINICAL STUDY OF EFFECT OF VEDANASAMHARIKALPA LEPA IN SANDHIVATA – A FOLKLORE MEDICINE

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ABSTRACT

Sandhivata is one among the vatavyadhi and the commonest joint disorder affecting middle aged and elderly population. Acharya Charaka defined it as a disease with the symptoms as shotha, pain on flexion and extension. Sandhivata is accepted by Chakrapani as 'Gulpha vata' or 'Sandhigata vata'. By observing these symptoms we may compare Sandhigata vata to that of Osteoarthritis, which is a degenerative disorder that occurs when articular cartilage wears down. According to epidemiology the prevalence of osteoarthritis in India is 22-39%. Here an attempt is made to check the efficacy of the folklore medicine vedanasamhari kalpa lepa as upanaha in Sandhigatavata. Vedanasamhari kalpa comprises of following ingredients, Musaber (*Aloe vera*), Shunti (*Zingiber officinale)*, Haridra (*curcuma longa*), Shigru (*Moringaolefera*), Saindhava lavana (rock salt), Ajamoda (*Apium graveolans*), Katuki (*Pichorhiza kurroa*), Sambrani (Benzoin resin), Gairika (Fe2O3), Chinca patra swarasa (*Tamarind indica*). **Methodology:** Single group clinical study was conducted on a sample size of 25 with sandhigata vata affecting janu sandhi. Vedana Samhari Kalpa lepa was freshly prepared and applied over the affected knee joints of patients for 3hrs once daily for 20 days. **Interpretation and Results:** After the treatment there was significant relief in the main symptoms janusandhi shoola(pain), janusandhi shotha(oedema), janusandhistabdatha(stiffness). **Conclusion:** Vedanasamharikalpa lepa showed statistically significant effect on symptoms-jaanusandhi shoola(pain), jaanusandhi shotha(oedema), jaanusandhi stabdhata(stiffness) of sandhigata vata.

KEYWORDS: vedanasamhari kalpa lepa, Sandhigatavata, Osteoarthritis.

INTRODUCTION

Sandhivata is the most common joint disorder. Acharya charaka has described the disease separately by the name of ' sandhigata anila'. Acharya charaka defined it as a disease with the symptoms of shotha, which is palpable as an air filled bag (vata poorna driti sparsha) and pain on flexion & extension of that joint (akuncana prasarane vedana).[1] Sandhivata is accepted by chakrapani as 'Gulphavata' or 'Sandhigata vata'. In Allopathic science it can be correlated with osteoarthritis. It's a Degenerative joint disorder that occurs when flexible tissue at the end of a bone wears down.[2] According to Epidemiology the prevalence of OA in India is 22-39%. Radiographic evidence of this disease is present in the majority of persons by 65yrs of age & in about 80% of persons more than 75yr of age.[3]

VEDANASAMHARI KALPA is an herbo-mineral formulation comprises of Musaber(*Aloe vera*), Shunti(*Zingiber officinale)*, Haridra(*curcuma longa*), Shigru(*Moringa olefera*), Saindhava lavana(rock salt), Ajamoda(*Apium graveolans*), Katuki(*Pichorhiza kurroa*) Sambrani(Benzoin resin), Gairika(Fe2O3) are said to apply on affected joints along with chincha patra swarasa in kalka form.

Though sandhivata can be managed with Analgesics & NSAIDs, it has become a major problem of mankind and received progressive attention from the research works. However the prolonged use of these drugs has its own drawback. Recent works on NSAIDs suggest that these drugs do increase the risk of Renal disease. Such studies strongly indicate that to find safer Herbo-mineral drug for arthritis is the need of era. This study is aimed at scientifically validating the efficiency of VEDANA SAMHARI KALPA LEPA in the management of sandhivata under the title 'A Clinical study effect of VEDANA SAMHARI KALPA LEPA in sandhivata - A Folklore medicine'

Pharmaceutical Study

Vedanasamharikalpa is a herbo -mineral formulation. The drugs required were procured from Arya Pharmacy, Kerala on 18/11/2019 and authenticated from Dravyaguna Dept of SDM Institute of Ayurveda, Bangalore. The formulation was prepared in the

Teaching Pharmacy of Dept Of Rasashastra & Bhaishajya kalpana, SDM Institute of Ayurveda, Bangalore from 20/11/2019 – 23/11/2019. The raw drugs were made into fine powder and packed in a 135g packet for dispensing. While applying it was mixed with Chincha Patra Swarasa (Tamarind juice) and made in paste form and then heated and applied as Upanaha to the affected knee joint.

MATERIALAS AND METHOD

Materials

***** Raw drugs required for the preparation of Vedanasamharikalpa will be procured from the market and prepared in teaching pharmacy of SDM Institute of Ayurveda and Hospital, Bengaluru

* Clinical study will be conducted in hospital of SDM Institute of Ayurveda and Hospital, Bengaluru

Methods

• 25 Patients diagnosed with JanuSandhivata attending the OPD & IPD of SDM Institute of Ayurveda and Hospital was selected for the study.

Inclusion criteria

1) Patient aged 40-80 yrs
2) Clinical signs, symptoms of Sandhivata.
3) Patient of either sex.

Exclusion criteria

1) Patient having inconclusive diagnosis.
2) Patient having traumatic arthritis, Gouty arthritis, Cardiac disease, Renal failure, Diabetes

Study design

It is an Interventional study with before and after evaluation of the data in a single group. Here patient's status was noted before and after the treatment

Sample size - 25
Study period - 20 days

Intervention

The packet of Vedanasamharikalpa lepa was made into kalka (paste) by adding Chincha Patra swarasa(Tamarind juice) and heated and applied over the affected joints at morning for 3hrs, once daily for 20 days.

Assessment criteria

Scoring for different parameters was done as follow:

Subjective criteria

Gradation of pain by Visual Analogue Scale
0-1 = no pain
2-3 = mild pain
4-5 = uncomfortable
6-7 = distressing
8-9 = intense
10 = worst possible

Tenderness (Sparshaasahatwa)
0 No tenderness
1 Patient says tenderness
2 Wincing of face on touch
3 Does not allow to touch the joint

Stiffness (Graha)
0 No stiffness
1 Mild stiffness
2 Moderate stiffness
3 Severe difficulty due to walking

Sandhisphutana(crepitus)
0 No crepitus
1 Palpable crepitus
2 Audible crepitus

Oedema (Shotha)
Oedema was measured by measuring tape before and after the treatment.

Objective criteria

Improvement in range of movement was assessed before and after treatment with Goniometer.

A special Performa was prepared for data collection, incorporating all the relevant points. Written consent was taken from each patient for participation in the study. Follow up of patient was done after 8th day and 20th day. The assessment of signs and symptoms was done according to the gradation. The information gathered on the basis of observations was subjected to statistical analysis.

RESULTS AND DISCUSSION

Table No. 1: Showing the PAIN IN RIGHT KNEE JOINT of patients.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PAIN_LEFT_0thday	4.84	25	3.236	.647
	PAIN_LEFT_8thday	2.88	25	2.242	.448
Pair 2	PAIN_LEFT_8thday	2.88	25	2.242	.448
	PAIN_LEFT_20thday	.36	25	.757	.151
Pair 3	PAIN_LEFT_0thday	4.84	25	3.236	.647
	PAIN_LEFT_20thday	.36	25	.757	.151

Table No. 2: Showing the PAIN IN THE LEFT KNEE JOINT of patients.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PAIN_RIGHT_0thday	6.28	25	1.768	.354
	PAIN_RIGHT_8thday	3.60	25	1.732	.346
Pair 2	PAIN_RIGHT_8thday	3.60	25	1.732	.346
	PAIN_RIGHT_20thday	.52	25	.872	.174
Pair 3	PAIN_RIGHT_0thday	6.28	25	1.768	.354
	PAIN_RIGHT_20thday	.52	25	.872	.174

Table No. 3: Showing STIFFNESS IN RIGHT KNEE JOINT of patients.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	STIFFNESS_RIGHT_0thday	.52	25	.823	.165
	STIFFNESS_RIGHT_8thday	.32	25	.476	.095
Pair 2	STIFFNESS_RIGHT_8thday	.32	25	.476	.095
	STIFFNESS_RIGHT_20thday	.16	25	.374	.075
Pair 3	STIFFNESS_RIGHT_0thday	.52	25	.823	.165
	STIFFNESS_RIGHT_20thday	.16	25	.374	.075

Table No. 4: Showing STIFFNESS IN LEFT KNEE JOINT of patients.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	STIFFNESS_LEFT_0thday	.44	25	.768	.154
	STIFFNESS_LEFT_8thday	.28	25	.458	.092
Pair 2	STIFFNESS_LEFT_8thday	.28	25	.458	.092
	STIFFNESS_LEFT_20thday	.12	25	.332	.066
Pair 3	STIFFNESS_LEFT_0thday	.44	25	.768	.154
	STIFFNESS_LEFT_20thday	.12	25	.332	.066

Table No. 5: Showing the CREPITUS IN RIGHT KNEE JOINT of patient.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	CREPITUS_RIGHT_0thday	.72[a]	25	.458	.092
	CREPITUS_RIGHT_8thday	.72[a]	25	.458	.092
Pair 2	CREPITUS_RIGHT_8thday	.72	25	.458	.092
	CREPITUS_RIGHT_20thday	.44	25	.507	.101
Pair 3	CREPITUS_RIGHT_0thday	.72	25	.458	.092
	CREPITUS_RIGHT_20thday	.44	25	.507	.101

Table No. 6: Showing the CREPITUS IN LEFT KNEE JOINT of patient.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	CREPITUS_LEFT_0thday	.56[a]	25	.507	.101
	CREPITUS_LEFT_8thday	.56[a]	25	.507	.101
Pair 2	CREPITUS_LEFT_8thday	.56	25	.507	.101
	CREPITUS_LEFT_20thday	.36	25	.490	.098
Pair 3	CREPITUS_LEFT_0thday	.56	25	.507	.101
	CREPITUS_LEFT_20thday	.36	25	.490	.098

Table No. 7: Showing the OEDEMA IN KNEE JOINTS of patients.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	OEDEMA_0thday	1.16[a]	25	.374	.075
	OEDEMA_8thday	1.16[a]	25	.374	.075
Pair 2	OEDEMA_8thday	1.16	25	.374	.075
	OEDEMA_20thday	2.08	25	.277	.055
Pair 3	OEDEMA_0thday	1.16	25	.374	.075
	OEDEMA_20thday	2.08	25	.277	.055

Table No. 8: Showing the TENDERNESS IN KNEE JOINTS of patients.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TENDERNESS_0thday	.16	25	.374	.075
	TENDERNESS_8thday	.08	25	.277	.055
Pair 2	TENDERNESS_8thday	.08	25	.277	.055
	TENDERNESS_20thday	.00	25	.000	.000
Pair 3	TENDERNESS_0thday	.16	25	.374	.075
	TENDERNESS_20thday	.00	25	.000	.000

Detailed analysis of results is as follows based on different parameters

Age: In age the highest incidence was seen in the age group 51-60years (40%) followed by age group 61-70 yrs (32%). By this we can state that the disease is more prevalent between 51-70years. Osteoarthritis is a degenerative joint disease where the pathological event starts after 50 years of age. Our classical textual reference enumerates, Parihani avastha of vaya mentioned by acharya Sushrutha (40-70 years) is the stage which is dominated by vata, where degeneration starts. This may be the reason for the appearance of highest incidence.

Sex: Present study shows 72% of patients belonged to sex female where as 28% patients of belonged to male sex. This shows, in current study in this area of Bangalore female patients are affected more than male patients.

Religion: Maximum number of patients belonged to Hindu i.e 92%. This shows geographical dominance of Hindu in this area and nothing to do with disease.

Education: Majority of patients' i.e 28% are illiterate and also 28% have done post-graduation education. A definite conclusion cannot be drawn with educational status and occurrence of osteoarthritis.

Occupation: Majority of patients (56%) were housewives, followed by 20% teachers, 16% labourers and 2% Engineers. Overall analysis of the occupational status indicates higher incidence in house wives. However nature of work in patients of present study was, working in standing position, for long hours, lifting heavy weight etc which may exert stress on knee joints, leading to the damage in anatomical structures and manifestation of symptoms, since they are weight bearing joints, further leads the higher incidence of disease.

Ahara Quantity: Most of the patients' i.e 64% patients took Alpa Ahara whereas 24% took pramita ahara and 12% took in ati pramana. Alpa ahara can be a contributing factor for vata prakopa.

Diet Habit: Most of patients' i.e 76% patients were having vishamashana. 16% adhyashana and 4% were having samashana. Vishamashana may have caused imbalance in the vata dosha leading to sandhdigata vata.

Ahara type: 100% of patients in both groups belong to non-vegetarian diets. Non veg diet is heavy for digestion which may have led to agni vaishamya causing ama uttatpatti.

Socio-Economic Status: Study reveals that 44% of patients belonged to upper middle class and24% belonged to lower middle class. By this we cannot draw a definite conclusion over the socioeconomic status and the incidence of disease. But the socio–economic status and quality of food and nutrition are interrelated and intake amount of protein and calcium required can be related with bone health. Thus the food intake and quality food and incidence of disease can be interrelated.

Nature of work: Study reveals that 56% of the patients led a sedentary lifestyle whereas 20% of the patients were labour class and 20% were doing work that required standing. Thus it is quite clear that a sedentary lifestyle may have created vata prakopa so also long

standing and labour class work may have created pressure on the joints thus aggravating vata dosha.

Vyayama: Majority of patients i.e 52% did not do exercise at all, whereas 24% did less exercise and 24% did excessive exercise. This may be due to the age of the patients or the affliction of the joints with pain stiffness etc. which restricts the movements.

DISCUSSION

Sandhi Shoola: All the patients (100%) presented with symptoms of sandhi shoola. All the patients (100%) were having gradual onset of sandhi shoola. From this we may draw the conclusion as janu sandhigata vata has gradual onset of sandhi shoola. The chronic pathology involved may cause gradual changes in anatomical structures which lead to the onset of pain gradually.

Sandhi Shotha: 80% of patients presented with sandhi shotha whereas 20% did not have sandhi shotha. The patients (80%) were having Gradual onset of sandhi shotha. This concludes as even the sandhi shotha in janu sandhigata vata is having gradual onset with intermittent course of pain with chronicity.

Sandhi Sthabdhata: In 68% patients janusandhi sthabdhata was absent whereas 32% it was present. From this we may conclude that the patients are showing varying degrees of morning stiffness.

Sandhi atopa: In 68% patients janusandhi atopa was present whereas 32% it was absent. Majority of the patients were having joint crepitus of Palpable nature. From this we may conclude the nature of crepitus may depend on chronicity of disease or it may depend on other symptomatology also. Intensity of crepitus and chronicity of the disease are interdependent. The continuous damage to the internal structure leads to rubbing of inter condylar surfaces of bony edges and leads to atopa.

Prasarana and Akunchana Vedana (Painful movements): Majority of patients 96% had pain during flexion and extension of joints, followed by 4% did not have any pain during movement of joints. From this we may conclude that due to degenerative changes in the anatomical structures and due to the intensity of the pain and stiffness, patients may have restricted joint movement and even the painful joint movements.

Effect of therapy on following attributes

Sandhi Shoola (Pain in knee joint): Before the commencement of treatment100% patients had pain in the right knee joint of grade 6 which reduced to grade 4 on the 8th day of treatment and on 20th day it was of grade 1 in all the patients. Statistical analysis revealed that the improvement was highly significant with "P" value <0.001 and mean difference in means of severity score was 5.7. For the left knee before the commencement of treatment76% patients had pain in the knee joint of grade 5 which reduced to grade 3 on the 8th day of treatment and on 20th day it was of grade 1 in all the patients. Statistical analysis revealed that the improvement was highly significant with "P" value <0.001 and mean difference in means of severity score was 4.5.

Sandhi Shotha (Knee Joint Swelling): Before the commencement of treatment 84% of patients had shotha in the affected knee joint. On the 8th day of treatment there was no change in the shotha of the affected knee joint but on 20th day it was absent in 96% of patients having shotha and reduced in shotha was seen in 4% of patients. Statistical analysis revealed that the improvement was highly significant with "P" value <0.001.

Sandhi stabdhata(stiffness of joint): Before the commencement of treatment 32% patients had stiffness in right knee joint in which 12% of patients had mild stiffness whereas remaining 20% had moderate stiffness. On 8th day patients with moderate stiffness reduced to mild stiffness whereas those with mild stiffness remain the same. On 20th day stiffness reduced to 16% patients. Statistical analysis revealed that the improvement was highly significant with "P" value <0.009. For left knee before the commencement of treatment 28% patients had stiffness in knee joint in which 12% of patients had mild stiffness whereas remaining 16% had moderate stiffness. On 8th day patients with moderate stiffness reduced to mild stiffness whereas those with mild stiffness remain the same. On 20th day stiffness reduced to 12% patients. Statistical analysis revealed that the improvement was highly significant with "P" value <0.018.

Sparsha Asahishunta (Tenderness): It has been observed that the following values on the tenderness before treatment 16% patients had mild tenderness in both the knee joints and which reduced into 8% on 8th day. On the 20th day there was 100% cure in tenderness. Statistical analysis revealed that the improvement was highly significant with "P" value <0.04.

Range of movements (Goniometer): Before treatment 100 % patients had restricted range of movement on flexion of right knee joint in which 20% patients had flexion in between range of 1000 to 110^0 and 68% patients had flexion in between range of 111^0 to 120^0 and 12% patients had flexion in between range of 121^0 to 130^0 after treatment the flexion of right knee joint improved in all patients in which 36% patients improved by range of 121^0 to 130^0 and in 64% patients it improved by range of 1310 to 1400. Statistical analysis revealed, results were statistically significant with ("p<0.01). The restricted range of movement during extension of the right knee joint before treatment was 100% in which 80% patients had extension in between range of 5^0 to 9^0 and 20% patients had extension in between range of 0^0 to 4^0. After treatment the extension of the right knee joint improved in all patients in which 96% patients improved

by range of 0^0 to 4^0 and in 4% patients it remains by range of 5^0 to 9^0 .Statistical analysis revealed, results were statistically significant with ("p<0.01).

Before treatment 84% patients had restricted range of movement on flexion of left knee joint in which 12% patients had flexion in between range of 1000 to 1100 and 60% patients had flexion in between range of 1110 to 1200 and 12% patients had flexion in between range of 1210 to 1300 after treatment the flexion of left knee joint improved in all patients in which 32% patients improved by range of 1210 to 1300 and in 48% patients it improved by range of 1310 to 1400. Statistical analysis revealed, results were statistically significant with ("p<0.01). The restricted range of movement during extension of the left knee joint before treatment was 100% in which 56% patients had extension in between range of 50 to 90 and 44% patients had extension in between range of 00 to 40. After treatment the extension of the left knee joint improved in all patients .improved by range of 00 to 40. Statistical analysis revealed, results were statistically significant with ("p<0.01).

Sandhi Atopa (Crepitus): Before the commencement of treatment 72% patients had atopa in the right knee joint. Which remained the same on the 8th day of treatment and on 20th day it was reduced into 44% patients. Statistical analysis revealed that the improvement was highly significant with "P" value <0.005. For left knee before the commencement of treatment56% patients had atopa in the knee joint. Which remained the same on the 8th day of treatment and on the 20th day it was reduced into 32% patients. Statistical analysis revealed that the improvement was highly significant with "P" value <0.02.

Overall Improvement in assessment parameters: Overall assessment of improvement in assessment parameters shows marked improvement in 66% parameters, moderate improvement in 17% parameters, mild improvements in17% parameters' in assessment parameters of Sandhigata vata.

CONCLUSION

Sandhigata vata is one among the commonest form of articular disorders, which create a huge hindrance in day to day activities of the sufferer. Though it is a disease of old age, it can also affect the middle aged category as well. It mainly affects the major weight-bearing joints of the body especially knee. As per Ayurveda, it presents with shula, Sotha, Vata poornadruti sparsha and difficulty in flexion and extension of the Sandhi are the symptoms. Here the intervention as external Lepa was done to both the knee joints and it showed significant improvement in symptoms of pain, swelling, range of movement and walking distance after treatment. A large number of people prefer Ayurvedic way of treatments in conditions like this to return the flexibility and range of movements as it is a conservative way of management. Thus it can be concluded that sandhigata vata can be managed well by means of the combination vedanasamharikalpa lepa. It is cost effective and easily available ingredients, that emphasizes on the easy reach of the same intervention into the public.

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