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Research Article

AN OPEN LABEL RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALAUVATE THE EFFICACY OF TRAYODASHANGA GUGGULU WITH JALUKAVACHARANA IN THE MANAGEMENT OF JANU SANDHIGATA VATA

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Abstract

Sandhigata vata is a type of vatavyadhi which mainly occurs in elders. It being a vatavyadhi, located in marmasandhi and Vata Dosha plays main role in the disease. Ayurveda includes both the Bahya & Abhyantara Chikitsa for sandhigata vata. The bahya chikitsa includes Abhyangam, jalukavacharana Agnikarma, etc. The Abhyantara Chikitsa includes Guggulu, Vati, Ghruta etc. in this study, total of 40 patients of either gender who met the diagnostic and inclusion criteria were randomly assigned to two groups A and B, each with 20 patients. Group A was treated with Tryodashanga guggulu, while Group B was treated with Jaloukavacharana and Trayodashanga guggulu. After 30 days of treatment, the study reveals that Trayodashanga Guggulu with Jaloukavacharana gave better results in comparison with Trayodashanga Guggulu without Jaloukavacharana in clinically. Statistical analysis also supported this by concluding that the improvement after treatment is highly significant in Group B (Trayodashanga Guggulu with Jaloukavacharana) when compared with Group A (Trayodashanga guggulu).

Keywords: Sandhigata vata; Tryodashanga Guggulu; Jaloukavacharana.

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INTRODUCTION

Sandhigata vata is the most common joint disorder in the world, with the largest number of people affected. It is caused by the localisation of vitiated vata dosha in the asthi (bones), sandhi (joints) of the body, with symptoms such as sandhi shola (joint pain), sandhigraha (stiffness of the joints), and sandhi shotha (swelling in joints) and also prasarana ackunchana vedana (pain while movements). Sandhigata vata is most commonly noticed on janu sandhi (knee joint), because it is a weight-bearing and mobile joint of the body. This is due to increased physical activities such as long-standing jogging etc. Sandhigata vata samprapti (pathogenesis) can be separated into Dathukshaya janya (originates due to depletion of body tissues) and Avarana janya (originates due to obstruction). Consent use of vatakara ahara and vihara (food and activities which increases Vata) will quantitatively change the joint structure in due course of time, causing manifestation of Dathukshaya janya Sandhigata vata. It is commonly seen in old age population. Janu Sandhigata vata is produced by vata vridhi and kaphakshaya in janu sandhi. The other is that obesity may influence the joint, resulting in disease development. The same qualities, as well as other symptoms related to joint pain, have been documented by modern research. Osteoarthritis in the present view have considered weight bearing joints of knee, hip and intervertebral joints.

A direct specific line of treatment for Janusandigata vata is not explained. But the general line of treatment of Sandhigata vata is considered as a treatment modality for Janu Sandhigata vata. It includes both the Bahya (external) and Abhyantara Chikitsa (internal medication). The bahya chikitsa includes Abhyangam (oil application), jalukavacharana (leech therapy), Agnikarma (heat therapy) etc. The Abhyantara Chikitsa includes Guggulu (Medicines prepared with *Commiphora mukul)*, Vati (tablet), Ghruta (medicines prepared by Ghee) etc. The current study is a minor step towards finding a management modality for Janu Sandhigata vata. Both Bahya and Abhyantara Chikitsa are included here for quick and effective outcome. Acharya Vagbhata recommends Jalukavacharana in the janu sandhigata vata. Jalukavacharana (leech therapy) is supposed to relieve pain by having antinociceptive and counter-reaction effects. So in this clinical study Trayodashanga guggulu and jalouka avacharana was selected as Bahya and Abhyantara Chikitsa respectively.

MATERIALS AND METHODS

For the literary data all Ayurvedic classics, contemporary Ayurvedic literatures, modern textbooks, and online sites referencing the ailment, medicine, and administration were studied and documented. For the clinical data diagnosed Janu Sandhigata vata cases were taken from the Karnataka Ayurveda Medical College Hospital's OPD and IPD, along with referral sources, and special medical camps were organized for the purpose. The drug Trayodasanga guggulu for the trail was prepared classically and purchased from A.V.N Pharmacy, Madurai. For leech therapy the non-poisonous leeches (Nirvisha Jalukas) were purchased from Mangalore.

For the clinical study patients with any anatomical defect in bone, Sandhigata vata associated with any other systemic disorder interfering with the treatment, Pregnant and lactating mother, Intra articular fracture were excluded. X ray of knee joint both AP and LATERAL View, Blood clotting and bleeding time are the Investigation for the exclusion and diagnosis criteria. A minimum of 40 patients fulfilling the diagnostic criteria such as lakshanas (signs and symptoms) of janu sandhigata vata roga (diseases of knee joint), pain, Swelling, Crepitus in the knee joints, restricted movement of the knee joints Chronicity less than 5 years. Patient of either sex aged between 40-70 years and Patient's willing to participate the study were randomly

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assigned into two groups, Group A and Group B with 20 patients each. Group A 20 patients were administered Trayodashanga guggulu 2 g per day in two divided doses after food with hot water for 30 days. Group B 20 patients were treated with Jaluka avacharana on day 1 of intervention and Trayodashanga guggulu 2 g after food twice a day for 30 days. The assessment was done on the basis of subjective parameters like Severity of pain**,** Severity of crepitus**,** Severity of swelling**,** Severity of rigidity and objective parameters according to Radiological findings such as Osteophyte formation, Joint space narrowing and Subchondral sclerosis.

RESULTS

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank Test to test efficacy for Table 1. It was observed that P-Value is less than 0.05. Hence it was concluded that effect observed is significant. Statistical analysis in group A showed that the mean score which was 4.45 before the treatment was reduced to 1.45 after the treatment with 67% improvement and there was a statistically significant (P<0.05) result. In Group B, Statistical analysis showed that the mean score which was 4.80 before the treatment was reduced to 0.75 after the treatment with 84% improvement and there was a statistically significant (P<0.05) result.

On comparing the pain in knee joint between the Group A and Group B, Group B showed better results than Group A. It was statistically significant with p<0.001. Statistical analysis on swelling of knee joints showed that the mean score which was 1.35 before the treatment was reduced to 0.55 after the treatment with 59% improvement and there is a statistically significant (P<0.05). In Group B, Statistical analysis showed that the mean score which was 1.55 before the treatment was reduced to 0.15 after the treatment with 90% improvement and there is a statistically significant (P<0.05) results. (Table 1) On comparing the swelling of knee joint between the Group A and Group B, Group B shows better results than Group A. It was statistically significant with p<0.001. (Table 2)

Statistical analysis on the effect on rigidity of joints showed that the mean score which was 0.90 before the treatment was reduced to 0.30 after the treatment with 67% improvement and there is a statistically significant (P<0.05) result. Statistical analysis in Group B, showed that the mean score which was 0.90 before the treatment was reduced to 0.20 after the treatment with 78% improvement and there is a statistically significant (P<0.05) result. (Table 1) On comparing the rigidity of joints between the Group A and Group B, Group B shows better results than Group A. It was statistically no significant with p>0.005. (Table 2)

Group A Statistical analysis for symptom the crepitus of movement in knee joint showed that the mean score which was 0.55 before the treatment was reduced to 0.20 after the treatment with 64% improvement and there was a statistically significant (P<0.05) result. In Group B, Statistical analysis for the crepitus of movement in knee joint showed that the mean score which was 0.55 before the treatment was reduced to 0.15 after the treatment with 73% improvement and there was a statistically significant (P<0.01) result. (Table 1) On comparing the rigidity of joints between the Group A and Group B, Group B shows better results than Group A and it was statistically no significant with p>0.005. (Table 2)

In Group A, the oesteophytes in the knee joint Statistical analysis showed that the mean score which was 0.30 before and after the treatment with 0% improvement and there is a statistically no significant (P>0.05) result. In Group B, Statistical analysis showed that the mean score which was 0.35 before and after the treatment with 0% improvement and results were statistically no significant (P>0.05). (Table 1)

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Table 1: Effect of treatment on Different Parameters both within the group (N=20)

Parameters	Group	Paired Samples Descriptive Statistics					Wilcoxon Signed Rank Test within the group of A and B		
		B.T.		A.T.		% Change	Wilcoxon Z	p	Remarks
		Mean	SD	Mean	SD				
Pain	A	4.45	0.759	1.45	0.605	67%	4.18	<0.001	HS
	B	4.80	1.056	0.75	0.550	84%	3.97	<0.001	HS
Swelling of Joints	A	1.35	0.489	0.55	0.510	59%	4.00	<0.001	HS
	B	1.55	0.510	0.15	0.366	90%	4.05	<0.001	HS
Gradation of Rigidity of Joints	A	0.90	0.308	0.30	0.470	67%	3.46	<0.001	HS
	B	0.90	0.308	0.20	0.410	78%	3.74	<0.001	HS
Gradation of Crepitus of Movement	A	0.55	0.510	0.20	0.410	64%	2.65	<0.01	S
	B	0.55	0.510	0.15	0.366	73%	2.83	<0.01	S
Gradation of Oesteophytes	A	0.30	0.470	0.30	0.470	0%	0.00	>0.05	IS
	B	0.35	0.489	0.35	0.489	0%	0.00	>0.05	IS
Gradation of Joint Space Narrowing	A	0.35	0.489	0.15	0.366	57%	2.00	<0.05	MS
	B	0.40	0.503	0.15	0.366	63%	2.24	<0.05	MS
Gradation of Subchondral Sclerosis	A	0.40	0.503	0.30	0.470	25%	1.41	>0.05	IS
	B	0.40	0.503	0.30	0.470	25%	1.41	>0.05	IS

SD- Standard Deviation; IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant

Table 2: Effect of treatment on Different Parameters between groups A and B

Parameters	Group	Paired Samples Descriptive Statistics					Mann-Whitney U Test Between Groups A and B		
		B.T.		A.T.		% Change	Mann-Whitney Z	p	Remarks
		Mean	SD	Mean	SD				
Pain	A	4.45	0.759	1.45	0.605	67%	3.33	<0.001	HS
	B	4.80	1.056	0.75	0.550	84%			
Swelling of Joints	A	1.35	0.489	0.55	0.510	59%	2.62	<0.01	S
	B	1.55	0.510	0.15	0.366	90%			
Gradation of Rigidity of Joints	A	0.90	0.308	0.30	0.470	67%	0.72	>0.05	IS
	B	0.90	0.308	0.20	0.410	78%			
Gradation of Crepitus Of Movement	A	0.55	0.510	0.20	0.410	64%	0.41	>0.05	IS
	B	0.55	0.510	0.15	0.366	73%			
Gradation of Oesteophytes	A	0.30	0.470	0.30	0.470	0%	0.33	>0.05	IS
	B	0.35	0.489	0.35	0.489	0%			
Gradation of Joint Space Narrowing	A	0.35	0.489	0.15	0.366	57%	0.00	>0.05	IS
	B	0.40	0.503	0.15	0.366	63%			
Gradation of Subchondral Sclerosis	A	0.40	0.503	0.30	0.470	25%	0.00	>0.05	IS
	B	0.40	0.503	0.30	0.470	25%			

SD- Standard Deviation; IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant

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On comparing the oesteophytes between the Group A and Group B, Results observed were statistically in significant with p>0.005. (Table 2)

In Group A, the effect on joint space narrowing in the knee joint Statistical analysis showed that the mean score which was 0.35 before the treatment was reduced to 0.15 after the treatment with 57% improvement and there was a statistically significant (P<0.05). In Group B, the effect on joint space narrowing in the knee joint Statistical analysis showed that the mean score which was 0.40 before the treatment was reduced to 0.15 after the treatment with 63% improvement and there is a statistically significant (P<0.05). (Table 1). On comparing the joint space narrowing between the Group A and Group B, both the groups were showing same results and is statistically no significant with p>0.005. (Table 2)

In Group A, the subcondylar sclerosis in the knee joint statistical analysis showed that the mean score which was 0.40 before the treatment and 0.30 after the treatment with 25% improvement and results were statistically no significant (P>0.05). In Group B, the sub condylar sclerosis in the knee joint statistical analysis showed that the mean score which was 0.40 before the treatment and 0.30 after the treatment with 25% improvement seen and results were statistically no significant (P>0.05) (Table1) On comparing the subchondral sclerosis between the Group A and Group B, results observed were statistically no significant with p>0.005. (Table 2)

DISCUSSION

Guggulu regulates the body's inflammatory response by inhibiting the enzymes and activating the b cells.[1] Trayodashanga guggulu is very effective in sandhigata vata indicated by our Acharya Kaviraj govindas sen and Acharya Cakrapanidatta.[2][3] Jalukavacharana is indicated in Janu sandhigata vata by Acharya Vagbhata. Tryodashanga guggulu contains Aabha (stem barkof *Acacia nilotica*), Ashwagandha (roots of *Withania somnifera*), Hapusha (fruits of *Juniperus communis*), Guduchi (stem of *Tinospora cordifolia*), Shatavari (roots of *Aspargus recemosus*), Gokshura (fruits of *Tribulus terrestris*), Vriddhadaru (roots of *Argyeria nervosa*), Rasna (roots and leaves of *Pluchea lanceolata*), Shatapushpa (fruits of *Anethum sowa*), Karchur (rhizome of *Hidichium spicatum*), Yavani (*Trachyspermum ammi* fruits), Shunthi (rhizome of *Zingiber officinale*), shoditha Guggulu (purified exudates of *Commiphera mukul*) and Ghee. Vata and kapha are involved in the pathology of this disease. So a combination of snehana (oleation) and rookshana (dryness) is needed to break the pathology. Ghrta (ghee) which is an ingredient of this preparation is well known when Vata is concerned. It is most effective for balancing vata and supporting agni. In the combination of Tryodashanga guggulu, concentration of Guggulu is found to more, which has the pravabha (special action) of Vatahara (reduces Vata). In this formulation, all 10 Dravyas (drugs) have dominant Tikta rasa (bitter taste), 6 Dravyas, have dominant Kashaya Rasa (Astringent taste), 6 Dravyas having dominancy of Katu rasa (Pungent taste), and 4 dravyas having dominant of Madhura rasa (Sweet taste). Among these three, Katu Rasa has potential of Agnisandipana (digestive) & Mamsavilekhanam, which helps to normalize the Jatharagni to form nutritional Anna Rasa as substrate which further give qualitative nutrition to succeeding Dhatus & help in modification or normalization of Dhatwagni. It also helps to pacify Vata in the affected sandhi. As Dhatwagni increases, nutrition of all dhatus will be increased then asthi (bones) and majja (bone marrow) dathu may be get stable and asthi dhatu and majja dhatu kshaya will be decreased. So degeneration in asthi dhatu may not occur rapidly. Sandhigata vata is Madhyam Roga margagata Vatika disorder in which vitiated vata gets lodged in sandhi. Hence to treat Sandhigata vata drugs acting on both Vata and

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Asthi are needed. Acharya charaka mentioned the asthi dhatu dushti treatment as given tikta drvya and ghrita. In Trayodashanga Guggulu out of 13 dravyas 10 have dominant tikta rasa and also it contains ghrita. Tikta Rasa is having deepana, pachana and rochana properties. So it helps in the improvement of the general condition of health and thus strengthens the body as well as joints. Tikta Rasa is also having lekhana property, so it helps in the weight reduction of the patients and helps in the management of knee osteoarthritis. Tikta Rasa has vayu and akasha mahabhuta in dominance. It has affinity toward the body element like Asthi having a vayu and Akasha mahabhuta in dominance. Tikta Rasa has properties of Deepana (increases appetite), Pachana (digestive), Kleda-Meda Shoshaka (reduces fat), Srotovishodhaka (clears the passage) & potent in Lekhana (scrapping) property, thus helps to break the pathogenesis of Sandhigata vata. Kashaya Rasa also has property of Sharira-Kleda Shoshana. All these dominant Rasa in this formulation thus helps in breakage of pathogenesis of Disease. Besides this, there is dominancy of Laghu (easy to digest), Ruksha (dry) & Tikshna Gunas (penetrating property) in the Tryodashanga Guggulu which also helps in Sama dosa and Vata shamana.The formulation of Tryodashanga guggulu has 10 Dravyas with dominance of Ushnavirya (hot in potency) which also helps to pacify the Vata Dosha. With all these properties, Sukshma (minute) property of Guggulu helps in Bhedana (breaking) of Avarana (block), Vatanulomana, Vatasamana (reduces Vata). Ghrita is vata-pittashamaka, Vrishya and vayasthapaka, Madhura, Saumya, Sheetha (cold), Balya (strength), Agnivardhaka (kindles the digestive fire), Jwarahara (anti-pyretic) also, thus it pacifies vata, improves the general condition of the body and acts as rejuvenator of the body. Hence it helps in the samprapti vighatana of the janu sandhigata vata. The ghrita contains vit. D which plays an important role to utilize calcium and phosphorous in blood and bone building. The Ghrita has property like Yogavahi (Catalyst; The one that accelerates the properties of others) which is helpful in increasing bio-availability of other drugs without losing its own property.

Jalukavacharana (leech therapy) is said to induce pain relief via antinociceptive effects & counter reaction.[4] The saliva of leech has active biological substance (hirudin & hyaluronidase) which are proved to act as analgesic, anti-inflammatory and anaesthetic.[5] A comparative study conducted between leech therapy and transcutaneous electric nerve stimulation (TENS) showed that leech therapy produced a significant reduction in Lesquene's index for pain and physical function and VAS index.[6] Symptoms such as pain, swelling, rigidity, and crepitus, as well as movements, improved significantly after treatment. In Sandhigata vata, the main vitiated factor is Vata in sandhi. By the presence of sparsa sahishnuta (tenderness) the association of rakta in the Janu Sandhigata vata is elicited. By doing Jalukavacharana, the stagnant vitiated Rakta in the local area is removed which will help to retain the Chala Guna (movements) of Vata. By removing the stagnant vitiated rakta (blood) that had caused Sanga (obstruction), Jalukavacharana reduces intravascular pressure and volume, hence relieving Shoola (pain) and Shotha (swelling). The average amount of blood extracted per leech was 5 to 10 ml. Siraakunchana (vein dilation) is caused by vitiated Vata in Sira, which stimulates the smooth muscle of blood vessels, causing pain. After doing Jalukavacharana, the blood removed from the Sandhi, thus causing relief in pain. Jalukavacharana's therapeutic impact is caused not only to the elimination of blood, but also to secretions that serve as anticoagulants, local vasodilators, and local anesthetic, among other things. Anti-inflammatory chemicals such as bdellins and eglins help in inflammation reduction. In addition to hirudin, leech saliva contains calin, and destabilase-like substances that increase microcirculation by lowering blood viscosity.[7] Leech saliva also contains histamine-like compounds that act as a vasodilator. Leech saliva includes anaesthetic

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compounds that help to alleviate symptoms like pain and tenderness. The chemicals included in leech saliva improve microcirculation, reduce pain, and reduce inflammation in this way.

After the treatments as per protocol of the present study the pain in knee joint was reduced to 67% in Group A and 84% was reduced in Group B. Both were statistically highly significant. Severity of crepitus in knee joint was reduced to 64% in Group A and 73% was reduced in Group B. Both were statistically significant. The severity of swelling in knee joint was reduced to 59% in Group A and 90% was reduced in Group B. Both were statistically highly significant. The severity of rigidity in knee joint was reduced to 67% in Group A and 78% was reduced in Group B. Both were statistically highly significant. Out of the 40 patients in Group A and Group B 13 patients had osteophytes formation in knee joint. There was no difference in results observed. Which may be due to shorter period of intervention. Both results were statistically insignificant. Out of the 40 patients in Group A and Group B total 14 patients had joint space narrowing in knee joint. 57% were improved in Group A and 63% were improved in Group B. Both were statistically significant. Out of the 40 patients in Group A and Group B the subchondral sclerosis in knee joint not having any difference may be due to observation in short period. Both are statistically insignificant. The severity of pain, swelling in the knee joints reduced well and were statistically highly significant. The severity of crepitus, the severity of rigidity, joint space narrowing very less improvement were seen but were statistically significant. The oesteophytes formation, the joint space narrowing didn't have any difference and statistically in significant.

CONCLUSION

Both Tryodasanga Guggulu with and Without Jaloukavacharana showed good results in Janu Sandhigata vata. Trayodashanga Guggulu with Jaloukavacharana gave better results in comparison with Trayodashanga Guggulu without Jaloukavacharana clinically. Statistical analysis also supported the improvement after treatment is highly significant in Group B (Trayodashanga Guggulu with Jaloukavacharana) when compared with Group A (Trayodashanga guggulu).

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