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A COMPARATIVE CLINICAL STUDY ON VEDANA SHAMAKA (ANALGESIC) EFFICACY OF AGNIKARMA AND RASONADI GUGGULU IN THE MANAGEMENT OF SANDHIGATA VATA OF JANUSANDHI W.S.R. TO OSTEOARTHRITIS OF KNEE JOINT

Anoop Kumar K[1], S K Bannigol[2], Siddanagouda A Patil[3]

[1]MS (AYU), Assistant Professor,
Dept of Shalya Tantra, Shiva Ayurvedic Medical College, Bilaspur, Himachal Pradesh
[2]MD (AYU), Prof and HOD, [3]MS (AYU), Reader
Department of Shalya Tantra, Ayurveda Mahavidyalaya, Hubli, Karnataka, India
Email: dranoopkumark123@live.com

ABSTRACT

Vatavyadhi is one among *Ashtamahagada, Sandhigatavata* is listed as one amongst *Vatavyadhi*. When vata gets vitiated in the joints, *Sleshakakaphavruthavyanavata* condition occurs in joints which hampers the normal function. *Shoola* or Pain is a main factor in all diseases. The condition can be correlated to Osteo – Arthritis knee joint as its having same clinical features mentioned in *Sandhigatavata*. Eventhough pain is only a symptom, it hampers the normal daily activities. Pain is an inevitable symptom in *Sandhigatavata*. Knee joint is one of the weights bearing joint. Pain in knee joint restricts movement of the body. Thus, this clinical work has given importance in achieving Analgesia in Patients suffering from *Janusandhishoola*. Vitiation of *vata* is prime causative factor for *Sandhishoola*. So keeping in view this clinical study, *Agnikarma* and *Rasonadiguggulu* were selected in the management of pain. Ayurvedic classics have given prime importance and direct reference for *Agnikarma* and its Analgesic effect. *RasonadiGuggulu* is another drug mentioned specially for *sandhigatavata* where each of its components is having *Shoolahara* properties. In the present study total 40 patients were selected and randomly divided into two groups. In Group A 20 patients were treated with *Agnikarma* with *panchalohashalaka* followed by *shatadhouthagruthalepana*. In Group B, 20 patients were administered *Rasonadiguggulu* thrice daily. As Analgesic efficacy has to be achieved fast, follow up was done on 7th day after treatment. Only one sitting of *Agnikarma* was performed. After the completion of clinical trial it was found that *Agnikarma* works efficiently tan *RasonadiGuggulu*. In both the groups, it was found that the improvement of mean score of Pain relief (McGills Pain index) at the end of *Agnikarma* by *Panchalohashalaka* in Group A shows (Mean BT-3.8, Mean AT- 0.0) 100% relief. Whereas at the end of 7days in Group B treated with *RasonadiGuggulu* shows (Mean BT-3.65, Mean AT-2.95) 19.17% relief. Comparative analysis of both groups reveals that *Agnikarma* is superior as a *VedanaShamaka*.

Keywords: *Sandhigatavata, Janusandhishoola*, Osteo arthritis knee, *Agnikarma, Rasonadiguggulu, Vedanashamaka*, Analgesia.

INTRODUCTION

Sandhigatavata is one among those diseases where pain is inevitable, one among those which creates temporary or permanent loss of joints mainly because of *Sandhishoola* or joint pains, among which *janusandhishoola* is having more importance as it hinders walking. As *Janumarma* is residing in *Janusandhi*, pain will be severely elicited on injuries or diseases. *Vatavyadhi* is one among *Ashtamahagada, Sandhigatavata* is listed as one amongst *Vatavyadhi* . *Sandhigatavata* is a clinical condition in which structural and functional derangement of joints occurs because vitiated *vata* gets lodged in the joints. *Sleshakakapha* is residing in every *sandhi*. All movements of the body is controlled by *vyanavata.* When *vata* gets vitiated in the joints, *Sleshakakaphavruthavyanavata* condition occurs in joints which hampers the normal function. *Susruta* specifically mentions that in *Sandhigatavata*, *shoola* and *sopha* are the main clinical features .So reducing pain plays an important role in *Sandhigatavata*. With the same clinical features modern science has explained the disease Osteo Arthritis. Osteoarthritis is defined as a non-inflammatory degenerative joint disease marked by degeneration of articular cartilage, hypertrophy of bones at margins, and changes in the synovial membrane, accompanied by pain and stiffness of joints. Hence, an inflammatory change in the joints of bone is known as Osteoarthritis. Osteoarthritis is the commonest form of joint disease which is a painful and disabling in advancing years of life. It occurs in old age, mainly in the weight-bearing joints (knee, hip). Osteoarthritis, also known as degenerative arthritis, or degenerative joint disease is a clinical syndrome in which low-grade inflammation of joints is caused by abnormal wearing of the cartilage that covers and act as a cushion inside the joints. Because of the decrease of synovial fluid, patient experiences pain upon weight bearing joints during walking and standing. The decreased movement because of joint due to pain, regional muscles of joint may change to atrophy and ligament may become more lax. Further, O.A. is an articular abnormality of synovial joints characterized by splitting and fibrillations of articular cartilage of joints. This is usually accompanied by subchondral sclerosis, bony cyst, joints space narrowing and any bony overgrowth at tissue joint margins. Thus, *Sandhigatavata* can be correlated with Osteoarthritis as both are having the same clinical features where pain is primary.

IMPORTANCE OF AGNIKARMA

In Ayurvedic literatures several methods of treatment like *Snehana, Upanaha, Agnikarma, Raktamoksana* etc. are advised for *Vatavyadhis*. Among these *Agnikarma* due to its *UshnaSuksma, Asukariguna* pacifies the *VataKaphaDosa* and removes *Srotavarodha*. Patient is effectively relived from stiffness, pain and other associated symptoms. *Teekshna, Ushnagunadravyas* can also be used for pain reduction instead of *Agnikarma*. This work is to find out how much effective is *Agnikarma* in inducing Analgesia.

THE DRUG *RASONADI GUGGULU*

Rasonadi Guggulu is a combination of six drugs indicated in *Sandhigatavata*. Selection of this drug was done as all the individual drugs in this combination is ***Shoolahara (Vedanashamaka),*** *Vatahara* and *Vata-kaphahara*. Reference of *Rasonadiguggulu* is available in ***Rasatantra Sara vaSiddhaprayoga Sangraha***[1]**.**

METHODOLGY

Present study was a randomized comparative clinical study. A Minimum of 40 subjects were selected incidentally and randomly categorized into two Groups as Group A and Group B.

Group A:

Sample size : Minimum of 20 subjects.

Procedure: *Agnikarma* on knee joint in *bindu pramana* followed by *Shatadhoutagritha alepana.*

The tenderest point on the knee joint was elicited in completely flexed position. The points were marked with a marker. Painting of the area was done with antiseptic solution. Mental support for the patient was given and vitals were recorded. *Agnitapta* (Redhot) *panchaloha shalaka* was used with high precision on the marked tender region and *agnikarma* was done in *bindu pramana*.

Duration : One sitting.

Group B:

Sample size : Minimum of 20 subjects.

Internally : *Rasonadiguggulu*.

Dose : 500mg, thrice daily.

Anupana : *Ushnodaka*

Duration : 7 days.

Follow-up: The subjects of the above two groups were followed up for 7days.

MATERIALS USED FOR STUDY

Group A: *PANCHALOHA SHALAKA* And *SHATADHOUTA GRITHA*

Metals	**Weight**	**Percentage**
Tamra	20gms	40%
Loha	15gms	30%
Rajat	5gms	10%
Yashada	5gms	10%
Vanga	5gms	10%
Total	**50gms**	**100%**

Group B: *RASONADI GUGGULU*

Sl No.:	**Drugs**	**Quantity**
1	*ShodithaGuggulu*	10 parts
2	*Lasuna*	5 parts
3	*Maricha*	2 parts
4	*Pippali*	2 parts
5	*Rasna*	2 parts
6	*Eranda*	2 parts

ASSESMENT CRITERIA:

Assessment criteria:

Assessment was done on subjective and objective parameters before and after the treatment.

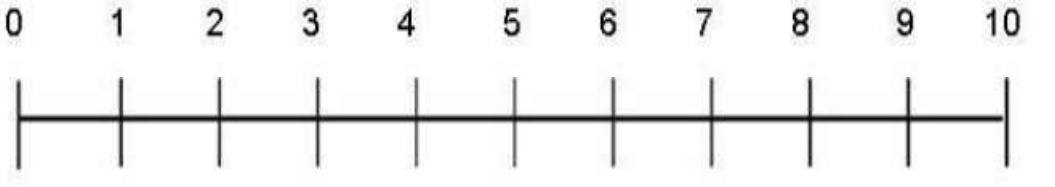
Subjective parameters: Pain.
Objective parameters: Tenderness.
Subjective parameters
Pain: - Pain was assessed on McGill's Pain Index Score.

McGill's Pain index Score

No Pain	-	0
Mild Pain	-	1
Discomforting pain	-	2
Distressing Pain	-	3
Horrible Pain	-	4
Excruciating Pain	-	5

Numerical Rating Scale Score
Pain was assessed on the basis of visual analogue scale

NO PAIN WORST PAIN



Objective parameters
Local tenderness

Definition	Grade
No tenderness -	0
Tenderness to palpation without grimace or flinch. -	1
Tenderness with grimace and / or flinch to palpation. -	2
Tenderness with withdrawal (+ "jump sign") -	3
Withdrawal (+ "jump sign") to non-noxious stimuli (i.e. Superficial palpation, pin prick, gentle percussion) -	4

Overall assessment of parameters
Changes observed in the subjective and objective parameters were analysed before and after the treatment, and then results were categorized as,

No relief -- less than 25 % improvement.
Mild relief -- 25 to 50 % improvement.
Moderate relief -- 50 to 75% improvement.
Marked relief -- more than 75% improvement.

Overall assessment was done based on the improvement in subjective and objective parameters before and after treatment which were subjected to statistical analysis by applying student 't' test.

OBSERVATIONS AND RESULT
Group A showed 100% relief of pain in the post operative period which was statistically highly significant at the level of $p < 0.001$ ($t = 16.90$) where as Group B showed relief of pain of 19.17% which was statistically highly significant at the level of $p < 0.001$ ($t = 4.76$) at the end of treatment.

Table 1: Showing the comparative reduction in Pain at the end of the treatment in the groups based on McGill's Pain Index score.

Groups	Mean		% Relief	S.D	S.E	't'	P	Remarks
	B.T	A.T						
Group A n1=20	3.8	0	100%	1.00	0.22	16.90	<0.001	HS
Group B n2=20	3.65	2.95	19.17%	0.65	0.14	4.76	<0.001	HS

At the end of treatment, Group A showed 100% relief in the intensity of pain over B.T. Mean of 3.8 in patients who had undergone *Agnikarma* with *PanchalohaShalaka* whereas Group B in the same duration had relief of pain of 19.17% over B.T. Mean of 3.65 in patients who had undergone treatment with *RasonadiGuggulu*.

Table 2: Showing overall Relief of Pain at the end of treatment in Group A & Group B by McGill's Pain Index score.

Groups	**Mean B.T**	**Mean A.T**	**% Relief**
Group A	3.8	0	100
Group B	3.65	2.95	19.17

The intensity of pain experienced by patients of Group A was lesser than Group B which was statistically highly significant at the level of $p < 0.001$ ($t = 11.54$).

Table 3: Showing the Comparison between Group A and Group B in Relief of Pain end of treatment according to McGill's Pain Index score.

Groups	**S.D**	**S.E**	**'t'**	**P**	**Remarks**
Group A	0.84	0.26	11.54	<0.001	HS
Group B					

The mean score of the objective parameter '**Tenderness',** the comparative efficacy of Group A with Group B was statistically Highly significant ($p<0.001$) with S.D 0.62, S.E 0.19 and 't' value of 6.85. . Group A had more efficacy of treatment on **tenderness** compared to Group B.

Table 4: Comparative Efficacy of Therapies on objective Parameter tenderness in Group A and Group B using Unpaired Student's 't' test:

Assessment Parameters	**Group A**			**Group B**			**Unpaired 't' test (Group A vs Group B)**				**Remarks**
	Mean Diff	**S.D**	**S.E**	**Mean Diff**	**S.D**	**S.E**	**S.D**	**S.E**	**T**	**P**	

Tenderness	1.9	0.71	0.16	0.55	0.51	0.11	0.62	0.19	6.85	<0.001	HS

In this study in Group A treated with *Agnikarma* by *PanchalohaShalaka,* all subjects (100%) got **Moderate Relief.**

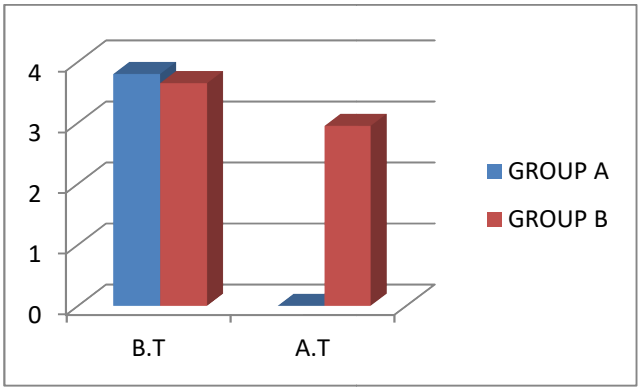
Whereas in Group B treated with *RasonadiGuggulu*, 06 subjects (30%) got **Mild Relief** and 14 subjects (70%) got **No Relief.**

Table 5: The Overall effect of study on 40 subjects of *Sandhigata vata* :

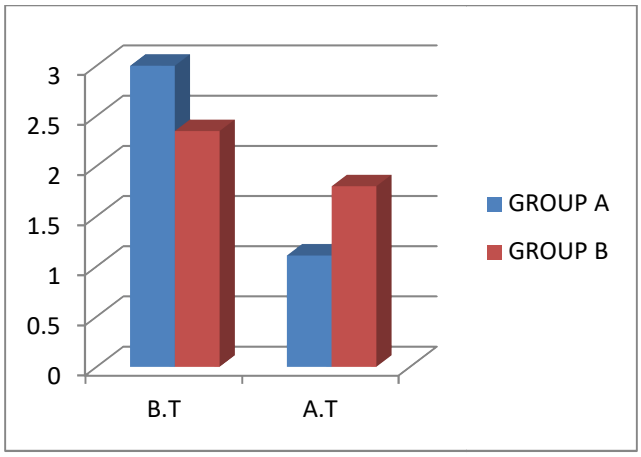
Remarks	Group A		Group B		Total	
	No	%	No	%	No	%
Complete relief – 100%	0	0	0	0	0	0
Marked relief-- more than 75% improvement	0	0	0	0	0	0
Moderate relief -- 50 to 75% improvement	20	100%	0	0	20	50%
Mild relief-- 25 to 50 % improvement	0	0	6	30%	6	15%
No relief-- less than 25 % improvement	0	0	14	70%	14	35%

The overall pain relief in Group A and B with Mc Gill's pain index provided 100.00 % and 19.17 % respectively. However the comparative efficacy of Group A with Group B was statistically Highly significant ($p<0.001$). Even though the comparative efficacies of therapies were statistically highly significant, the percentage relief was more in Group A.

The therapies in Group A and B provided **63.33%** and **23.40 %** improvement on Tenderness. However the comparative efficacy of Group A with Group B was statistically highly significant ($p<0.001$). Even though the comparative efficacies of therapies were statistically insignificant, the percentage relief was more in group A. In this present study in Group A, all subjects got **Moderate Relief (100.00%).** In this present study in Group B, 06 subjects got **Mild Relief (30.00%)**, 14 subjects did not got any **Relief (70.00%).**It strongly indicates that effect of *Agnikarma* by *Panchalohashalaka* is more benficial in *Janusandhishoola* of *Sandhigatavata.*



Graph showing average pain index before and after treatment.



Graph showing average tenderness before and after treatment.

CONCLUSION

Conclusion is the final outcome of any study. It is derived out after a thorough scientific study succeeded by a discussion about the literary and practical work. Following conclusions are drawn after scientific discussion is being presented here.

- *Sandhigata vata* is a type of *vatavyadhi* which commonly occurs in old age. In this clinical trial higher incidence of *Janusandhishoola* was observed in males .The incidence of the disease based on occupation was also found. People who are/were indulged in long standing and walking works which create more wear and tear to the weight bearing knee joint are more prone for *Sandhigata vata* in *Janu sandhi.*
- *Sandhigata vata* being correlated with Osteo- arthritis knee of contemporary science is justifiable.
- The *nidanas* told in Ayurveda coincides with that of modern medicine which ultimately leads to wear and tear of Knee joint and its ligaments.
- The subjects of Group A showed better results in all the parameters compared to Group B. So *Agnikarma* by *Panchaloha Shalaka* has a much contributory effect in *Sandhigata vata* even though *Rasonadi Guggulu* internally also has a significant role in this disease.

To compare the analgesic efficacy of *Agnikarma* by *Pancha Loha Shalaka*, A similar combination of *shoolahara* drugs which can induce analgesia was required, thus selected *Rasonadi guggulu.*

- **Mode of Action of *Agnikarma*** : *Agni* having *ushna guna* which pacifes *Vata* and *kapha* & increases *dhatvagni* , pacifies the *mandagni* , also performs the *Ama Pachana* , removes the accumulated toxins , enhaces nourishment & formation of good newer tissues.
- By *Agnikarma* procedure symptomatic relief of pain was obtained appreciably. For complete cure of the disease multiple sittings of *agnikarma* along with internal medication is necessary.
- Proper knee joint exercises are also required in future for increasing the strength of ligaments and knee joint muscles which plays a major role in supporting knee joint. No complications were seen during the course of study. The following are the advantages of the *Agnikarma* by *Pancha Loha Shalaka* .

A. *Pancha Loha Shalaka* retains heat for longer period.
B. Performance of procedure is easy.
C. Cuts the mass fast.
D. Less post-operative pain.
E. Less healing period.
F. Nil post-operative complication.

Recommendations for further study

- *Agni karma* therapy has lot of potential, hence extensive study based on scientific pa-

rameters in the management of Pain in *Sandhigatavata* as well as in other diseases by *Agnikarma* is need of the hour.

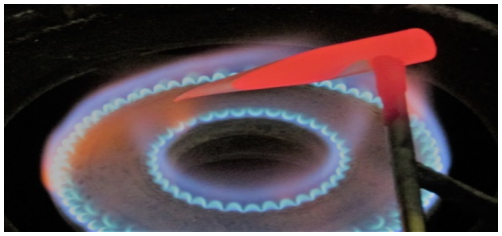
- ❖ Larger sample size and multiple sittings of *agnikarma* may give complete relief. Designing of different *AgnikarmaShalakas*, suitable for performing *Agnikarma* in different diseases is an absolute necessity.

REFERENCES

1. Sri Krishnanandaji Maharaj; Rasatantra Sara va Siddhaprayoga Sangraha Volume II; 1st edition 1947; Reprint 2012; Krishnagopala Ayurveda Bhavan (DT) Ajmer, Rajasthan; Vatavyadhi 18/11; Page No.197.

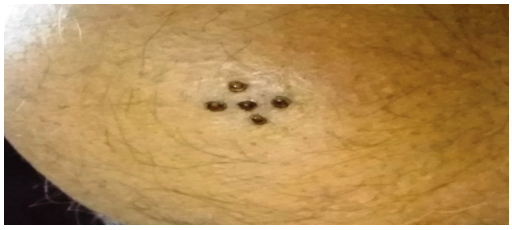
Picture No.1 – *Pancha loha Shalaka*

Picture No.2 - *Agnitapta*



Picture No.3 – Painting of tender area

Picture No.4 – After *Agnikarma*



Picture No.4 – *Shatadhouta gritha alepana*

Picture No.5 – *Rasonadi guggulu.*

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