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A Randomised Controlled Trial to Evaluate the Effect of Agnikarma with Guda (Jaggery) and Panchaloha Shalaka in Janusandhigata Vata on Pain

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ABSTRACT

Osteoarthritis is the second most common rheumatologic problem in India and has a prevalence rate of 22-39%. It is well correlated with *Janusandhigata vata*. *Agnikarma* with *kshoudra*, *guda* and *sneha* are mainly indicated in the management of pain emerged from *gambheer dhatu*. The pain management modality which is easy to perform with lesser complications and better rate of success should be the criteria in choosing the management of this disease. Moreover *tapta dravas* are considered to have more penetrating power than *rooksha* instruments such as *Shalaka*. Hence, *tapta Guda* is taken in the present study, to compare its efficacy with *panchaloha Shalaka* and its feasibility in *agnikarma*. *Agnikarma* with *Guda*(Jaggery) gives significant results in relieving the signs and symptoms of *Janusandhigata vata*.

KEYWORDS

Ayurveda; Shalyatantra; Agnikarma; Janusandhigatavata



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INTRODUCTION

Shalyatantra is one of the eminent branches of Ayurveda, which consists of major therapies like *Bheshaja karma*, *Kshara Karma*, *Agnikarma*, *Shastra karma* and *Raktamokshana*. “*Agninakritvayat karma, agnesambandhivayat karma, tad Agnikarma*” -procedure followed in curative measures adopted through *agni* or are related to *agni* is called as *Agnikarma*¹. *Agni karma* is superior among all of them and has proved to be a boon where local involvement of *Vata* and *Kaphadoshas* are observed in the disease. It is indicated in many critical diseases like *Arsha*, *Arbuda*, *Bhagandara*, *Apachi*, *Antravidhi*² *Gridhrasi*, etc. and in many other disorders of *Sira*, *Snayu*, *Asthi* and also in *Sandhigata Vata Prakopa*.³ The diseases treated with *Agni karma* do not recur⁴, no fear of bleeding, putrefaction and ultimately it produces balancing effect on vitiated *Vata Dosha*. For easy transfer of heat and to produce *SamyakDagdhaVrana* (Therapeutic Burn), in classics *Dahanaupkaranas* (devices) like *Pippali*, *Ajashakruth*, *Godanta*, *Shara*, *Shalaka*, *Jambaustha*, *Madhu*, *Guda*, *Sneha* are mentioned for the particular *Dhatu* involved in the disease⁵. The profound influence of *Agnikarma* becomes clear from the wide description about Para – surgical

procedure in various diseases. Even in the modern surgery the principles of *Agnikarma* have been adopted with advanced technology like Cauterisation, in order to stop bleeding and to prevent reoccurrence of the disease in current days. Osteoarthritis is the most common type of arthritis or degenerative joint disorder where the knee joint is more susceptible for wear and tear⁶. It is the second most common rheumatologic problem in India and has a prevalence rate of 22-39%. Worldwide prevalence rate of osteoarthritis is 20% for men, 41% for women, and it causes pain or dysfunction in 20% of the elderly⁷. It is major social problem as large percentage of population suffer from this condition⁸.

A classical text explains the symptoms like *shotha*, *vatapoornadrithisparsha*, *akunchanaprasaranevedana* for *sandhigata vata* under *vatavyadhi*⁹ which resembles the symptoms of osteoarthritis. In contemporary science osteoarthritis treatment is confined to NSAIDs, analgesics, steroids (hydrocortisone), surgical decompression and traction. But this condition reappears if the precipitating activities are followed and next option is arthroscopic surgery¹⁰. The pain management modality which is easy to perform with lesser complications and better rate of success should be the criteria



in choosing the management of this disease. Moreover *taptadravas* are considered to have more penetrating power than *rooksha* instruments such as *shalaka*¹¹. Hence *tapta Guda* is taken in the present study its efficacy was compared with *Panchadhatu shalaka*.

MATERIALS AND METHOD S

Ethical Committee Approval No.
BMK/12/PG/SL/10

Source of Data

Thirty patients diagnosed with Janusandhigata vata, were taken for the study from KLEU's Shri. BMK Ayurveda Hospital Patients and were randomly selected into two Groups viz., Group A (control group) & Group B (trial group) irrespective of their sex, religion, socio-economic status etc. Each patient was selected for the trial after voluntary consent.

Study design

Randomized Controlled trial

Diagnostic criteria

The diagnosis is mainly based on clinical presentation of the patient according to signs and symptoms of *JanuSandhigata Vata* mentioned in classical texts like *Shotha*, *Vatapurnadrithisparsha*, *Akunchanaprasaranevedana*.

Inclusion Criteria:

- Patients with *prathyatma lakshana* of *JanusandhigataVata* will be selected irrespective of their sex, religion, occupation, and socioeconomic status
- Age groups between 40 years to 70 years are selected.

Exclusion Criteria:

- Deformity of the joint
- History of previous surgery on knee joint
- Acute Exacerbation of osteoarthritis is excluded
- Patients with systemic diseases like Diabetes mellitus, Tuberculosis
- Patients on any analgesic, antipsychotics, anxiolytic drugs
- Patients with addictions like narcotics

LABORATORY INVESTIGATIONS:

X-ray- to exclude the other pathology

Intervention: The total study period is of 7 days

Group A- Patients were subjected to *Agnikarma* with *Panchaloha Shalaka* on 1stday.

Group B- Patients were subjected to *Agnikarmawith Guda* on 1st day.

DURATION OF TREATMENT:

Agnikarma was performed in a single sitting and assessment was done before the application of *Agnikarma* with *panchaloha Shalaka* and *Guda*, soon after application(after15mins), after 3 hours of



application and on 1st, 2nd, 3rd & 7th day of Agnikarma.

LATENT HEAT STUDY: This was performed to see the thermal regulation of individual *dahanopakarana* (Table no.9).

PROCEDURE OF AGNIKARMA:

The patient was made to lie on table in supine position then *Agnikarma* was performed on the predetermined most painful and tender point of the affected Knee joint.

PRE-OPERATIVE PROCEDURE –

Picchilaanna (Unctuous food) was advised to take orally. Well Informed consent for the procedure

Collection of materials for the Procedure

Sterile Gloves 1pair, Gauze pieces-1pair, Sponge holding forcep-1, sterile drapes-1, Stove-1, *Panchaloha Shalaka*, *Guda* (jaggary), *Guda agnikarma* instrument (Figure No.1), *Ghritakumari* (Aloe vera) pulp.

OPERATIVE PROCEDURE-

Group A: *Agnikarma* with *Panchadhatu shalaka*: The *shalakais* heated to red hot over a stove. It is then applied on a cleaned and predetermined site.

Group B: *Agnikarmawith Guda*:

- Instrumentation- Instrument was designed and developed with Copper having 13 cm length, 1.5cm Diameter and is having piston for expulsion of the heated *guda*(Figure No.1).



Fig 1 Instrument for *Gudaagnikarma*

Under all aseptic precaution painting and draping was done, most tender point was selected and marked then 5 gm. of *Guda* was loaded in the instrument chamber. Instrument has placed over the electric stove for heating until the drop of *guda* pops out. Immediately a drop of *guda* is allowed to fall over predetermined site from a distance of 1inch by holding an instrument at 40⁰ angle and cleaned with cotton after cooling of the drop of *guda*.

POST-OPERATIVE PROCEDURE-

The *Agnikarma* site was anointed with *Ghritakumari* pulp in both the group.

CRITERIA OF ASSESSMENT-

- Subjective: pain(Assessed by VAS Scale)
- Objective: Range of movements(flexion) by Goniometer

Grading was given for every clinical feature and it is presented in the Table No.1 & 2

Table 1Assessment of pain (VAS Scale)

Grades	Details
Grade 0	No pain
Grade 1-2	Mild pain (Mild)
Grade 3-4	Moderate Pain (Discomforting)
Grade 5-6	Severe Pain (Distressing)



Grade 7-8	Very severe Pain (horrible pain)
Grade 9-10	worst Pain (excruciating pain)

Table 2 Assessment of Range of movements (Flexion)

Grades	Details
Grade 0	Normal flexion 130 ⁰ -150 ⁰
Grade 1	Lesser than 130 ⁰ & More than 100 ⁰
Grade 2	Lesser than 100 ⁰ & More than 75 ⁰

Grade 3	Lesser than 75 ⁰
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RESULTS

Observation of the results on pain with respect to the group A (Control group) and Group B (Trial group) are denoted in the table No. 3 and 4 respectively.

Table 3 Effect of *Agnikarma* with *Panchaloha Shalaka* in Pain

Post-operative days	Mean \pm SD		% in the reduction of Pain	Mean Df	95% CI of diff	Significantly different? (P < 0.05)	P value summary
	BT	AT					
Soon After	3.6 \pm 1.1	2.9 \pm 1.5	19.44	0.67	-0.29 to 1.6	No	Ns
3 rd hour	3.6 \pm 1.1	1.5 \pm 1.4	58.33	2.1	1.2 to 3.1	Yes	***
1 st day	3.6 \pm 1.1	1.5 \pm 1.2	58.33	2.1	1.2 to 3.1	Yes	***
2 nd day	3.6 \pm 1.1	1.9 \pm 0.92	47.22	1.7	0.78 to 2.7	Yes	***
3 rd day	3.6 \pm 1.1	2.5 \pm 0.92	30.55	1.1	0.11 to 2.0	Yes	*
7 th day	3.6 \pm 1.1	3.3 \pm 0.98	8.33	0.27	-0.69 to 1.2	No	Ns

Table 4 Effect of *Agnikarma* with *Guda* in Pain

Post-operative days	Mean \pm SD		% in the reduction of Pain	Mean Df	95% CI of diff	Significantly different? (P < 0.05)	P value summary
	BT	AT					
Soon After	4.1 \pm 0.92	2.8 \pm 1.5	31.70	1.3	0.50 to 2.2	Yes	***
3 rd hour	4.1 \pm 0.92	1.1 \pm 1.3	73.17	3.1	2.2 to 3.9	Yes	***
1 st day	4.1 \pm 0.92	1.1 \pm 1.0	73.17	3.1	2.2 to 3.9	Yes	***
2 nd day	4.1 \pm 0.92	1.9 \pm 0.52	53.65	2.3	1.4 to 3.1	Yes	***
3 rd day	4.1 \pm 0.92	2.3 \pm 0.70	43.90	1.9	1.0 to 2.7	Yes	***
7 th day	4.1 \pm 0.92	3.7 \pm 0.70	9.75	0.40	-0.43 to 1.2	No	Ns

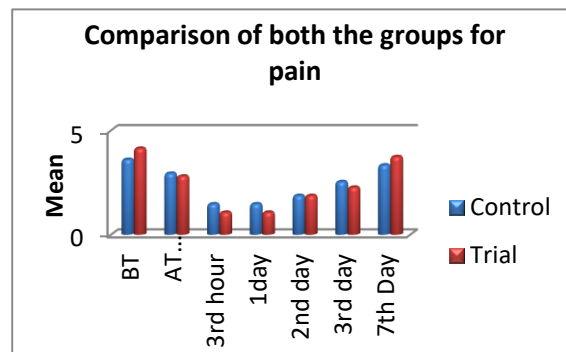
Effect on pain- In control group significant reduction in pain was observed from 3rd hour to 3rd day which ranged from 58% reduction to 30 % respectively; this suggests that *agnikarma* is effective in reduction of pain immediately. In trial group significant reduction in pain was observed from soon after

application(after 15mins) of *agnikarma* with *Guda* to 3rd day which ranged from 73% reduction to 43.33% respectively; Prolonged effect with one sitting of *agnikarma* was up to 3rd day of treatment and on 7th day pain assessed with VAS scale remained same as before treatment. Effect on Flexion of knee joint with respect to the

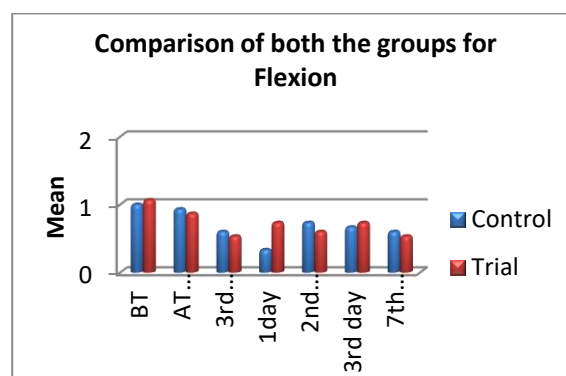


group A (Control group) and Group B (Trial group) are denoted in the table no. 5 and 6, respectively. In control group significant improve in flexibility was observed - at 3rd hour 40%, 1st day 67% and on 2nd day onwards gradual decrease was seen in flexibility, on 7th day remained same as before treatment. In trial group significant improvement in flexibility was observed at 3rd hour and 1st day 52%, and on 2nd day 45.45% on 7th day remained same as before treatment. It shows that the treatment of the *janusandhigata vata* in both the groups has got result in marked improvement which is statistically significant. Clinically there was a great improvement with respect to morning stiffness and pain during movement in trial group compared to control group. Overall

comparison of the effect of the therapy is presented in Table No 7 and 8 (Graph 1 and 2).



Graph 1 Comparison of both the groups for pain



Graph 2 Comparison of both the groups for pain

Table 7 Comparison of both the groups for pain

Days	Agnikarma with Panchaloha (Mean)	Agnikarma with Guda (Mean)	Difference	T	P value	Result
BT	3.600	4.133	0.5333	1.347	P > 0.05	Ns
AT soon af	2.933	2.800	-0.1333	0.3368	P > 0.05	Ns
3rd hour	1.467	1.067	-0.4000	1.010	P > 0.05	Ns
1day	1.467	1.067	-0.4000	1.010	P > 0.05	Ns
2nd day	1.867	1.867	0.0	0.0	P > 0.05	Ns
3rd day	2.533	2.267	-0.2667	0.6736	P > 0.05	Ns
7th day	3.333	3.733	0.4000	1.010	P > 0.05	Ns

Table 8 Comparison of both the groups for Flexion

Observations	Agnikarma with Panchaloha (Mean)	Agnikarma with Guda (Mean)	Difference	T	P value	Result
BT	1.000	1.067	0.06667	0.3026	P > 0.05	Ns
AT soon af	0.9333	0.8667	-0.06667	0.3026	P > 0.05	Ns
3rd hour	0.6000	0.5333	-0.06667	0.3026	P > 0.05	Ns
1day	0.6000	0.5333	-0.06667	0.3026	P > 0.05	Ns



2nd day	0.7333	0.6000	-0.1333	0.6053	P > 0.05	Ns
3rd day	0.6667	0.7333	0.06667	0.3026	P > 0.05	Ns
7th Day	0.3333	0.7333	0.4000	1.816	P > 0.05	Ns

When we compare individually, the effect on pain relief was better in trial group as compared to control group on 3rd hr, 1st day, 2nd day and on 3rd day of *agnikarma*, and eventually the effect of *agnikarma* in pain and flexion was statistically same in both the groups hence statistically no difference is seen comparatively.

DISCUSSION

Table 9 Latent Heat Study of Individual *Dahanopakarana*

Sl. no	Materials	Average heat /boiling point	Immediate dissipation removing from fire	heat after from the	Subsequent heat dissipation/1min	Superficial tissue destruction
1	Pippali	55-60 ⁰ c	10-12 ⁰ c		20 ⁰ c	Less
2	Ajashakruta	65-70 ⁰ c	10-15 ⁰ c		15 ⁰ c	Less
3	Godanta	70-80 ⁰ c	10-15 ⁰ c		15 ⁰ c	Less
4	Shara (Arrow)	140-150 ⁰ c	18-20 ⁰ c		25 ⁰ c	Less
5	Jambousta(stone)	215-220 ⁰ c	20-22 ⁰ c		8-10 ⁰ c	Moderate
6	PanchalohaShalaka	250-255 ⁰ c	18-20 ⁰ c		6-8 ⁰ c	Moderate
7	Madhu	120-130 ⁰ c	0 ⁰ c		2-3 ⁰ c	More
8	Guda	155-165 ⁰ c	0 ⁰ c		2-3 ⁰ c	More
9	Tail	140-160 ⁰ c	0 ⁰ c		1-2 ⁰ c	More
10	Ghrita	180-190 ⁰ c	0 ⁰ c		1-2 ⁰ c	More

It was conducted to see the heat retaining capacity of individual *dhahanopakarana*. Among those *Panchaloha Shalaka* had considerably higher temperature (average heat is 250-255⁰c and immediate dissipation after removing from the fire is

Instrumental Design for gudaagnikarma

Usage methodology of *Guda* in classics was not found, for that we designed an innovative instrument that consisted of hollow body, a piston with handle made up of copper to make a uniform application of *guda* and to avoid creation of large wound. Latent heat study (Table No. 9)

18-20⁰C and after 1minute further 6-8⁰C reduction occurs) than that of the *guda* (average boiling point is 155-165⁰C and immediate dissipation after removing from the fire is 0⁰c and after 1minute further 2-3⁰C reduction occurs), but *Snigdha dravya*



owing to its higher latent heat can affect a greater fluctuation in the temperature of the tissue surface and also that of the subsequent layers¹⁵.

Agnikarma with *Guda* shows a high efficacy than *Panchaloha Shalakain* reduction of pain, and restricted movement (Flexion), but no statistical difference was seen. When we compare individually, the effect of pain relief is more (73%) seen in trial group as compared to control group on 3rd hr ,1st day, 2nd day and on 3rd day of *agnikarma*, and eventually the effect of *agnikarma* in pain and flexion was statistically same in the both the groups.

Pain relief in trial group was more, which may be due to more heat penetration through the subsequent layers of the skin due to its higher latent heat which causes destruction of the free nerve endings. This tends to close the "gate" and prevent the sensory transmission of pain¹².

Probable mode of action of Agnikarma

Agnikarma cures all the *vataja* and *kaphaja* disorders as *ushna guna* of *agnikarma* is opposite to that of *Vata* and *Kapha doshas*. According to Ayurveda, every *Dhatu* (tissue) has its own *Dhatvagni* and when it becomes low, diseases begins to manifest. In this condition, *Agnikarma* works by giving external heat thereby increasing the *Dhatvagni* which helps to digest the

aggravated *dosha* and hence cures the disease¹³.

The local thermo therapy may increase tissue metabolism which may leads to excretion of the unwanted metabolites and toxins. Heat may stimulate lateral spinothalamic tract (SST) which leads to stimulation of descending pain inhibitory fibres (DPI) with release of endogenous opioid peptide that binds with opioid receptors at substantia gelatinosa of rolando and inhibit release of p-substance (pre-synaptic inhibition) a neuropeptide acting as a neurotransmitter and blockage of transmission pain sensation occurs¹⁴.It is hypothetically stated that after *samyak dagdha* some local antibodies or non-specific immunoglobulin may act as a disease modifying activity.

Raising the temperature of damaged tissue through red hot *shalaka* may speed up the metabolic process, improves circulation by vasodilatation, reduce edema, accelerate repair, which can reduce painful stiffness in joints like arthritis. Thus *Agnikarma* may help in reducing the pain and stiffness of the joints¹⁴.

It was observed that there was a great improvement in acute cases and moderate response in chronic cases. Compared to *Panchadhatu Shalaka* the incidence of blebs and ulcer formation at the site of *Agnikarma* is more in case of *Guda*. It is



due to the sticky nature of *Guda* and it was healed within a few days of the application of a mixture with *Madhu* and *Ghritha*.

CONCLUSION

Agnikarma with *guda* reduced pain up to 73% immediately after application and the effect was observed up to 3rd day (prolonged). So *agnikarma* with *guda*(jaggary) acts as a immediate pain relieving modality. Latent heat of *guda* (jaggary) has shown more heat retaining capacity than that of *panchaloha Shalaka*. The effect on pain relief was better in trial group as compared to control group. Continuation of treatment for a further few weeks can expect more significant results in chronic conditions and also adjuvant therapies like *snehana*, *swedana*, and *basti* may give a disease modifying results.



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