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RESEARCH ARTICLE

AN OPEN LABELLED CLINICAL TRIAL TO EVALUATE THE COMBINED EFFICACY OF MATRA BASTI, GODHUMA UPANAHA AND LAKSHADI GUGGULU IN THE MANAGEMENT OF JANU SANDHIGATA VATA VIS-À-VIS OSTEOARTHRITIS OF KNEE IN PERIMENOPAUSE WOMEN”

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Abstract

Sandhigatavata is a disease in which Vata affects the joint causing pain and swelling, this is also characterized by palpation which feels like a bag filled with air and pain experienced during extension and flexion of joint. The disease Janu Sandhigata Vata is described as Osteoarthritis (OA) which manifests the abnormality of the synovial joints characterized by softening, splitting and fragmentation of articular cartilage not attributable to direct contact with inflammatory tissue. Osteoarthritis tends to have a stronger association with women during perimenopause (Rajonivrutti). The prevalence rate of OA in perimenopause women is 31.6%. Perimenopause is a menopausal transition phase to a nonproductive stage in women. It includes somatic, psychological and uro-genital symptoms. The somatic symptoms make the phase difficult to cope with routine life. In Ayurveda it can be understood as Rajonivrutti is Jarakalaja Swabhavikaavastha during this phase Kshaya of Bala, Utsaha, Veerya leads to Vata Prakopa. Considering all these, the present study was undertaken to evaluate the combined efficacy of Matrabasti, Godhuma Upanaha and Lakshadi Guggulu in the management of Janu Sandhigata Vata.

Objective of the study: To evaluate the combined efficacy of Matrabasti, Godhuma Upanaha and Lakshadi Guggulu in the management of Janu Sandhigata Vata vis-a-vis Osteoarthritis of knee in Perimenopause women.

Methods: The data was collected on 0th day, on the day of completion of Matra Basti and Upanaha Karma and Shamanoushadhi. i.e. on 0th, 9th, 31st day.

Results: Matrabasti, Godhuma Upanaha and Lakshadi Guggulu showed clinical improvement and statistically highly significant results in reduction of Pain, Swelling, Stiffness, Crepitus and WOMAC-Index for Osteoarthritis with p value 0.000. in the management of Janu Sandhigata Vata in perimenopause women.

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Introduction:-

Sandhigata Vata is the one among the eighty types of Vataja nanatmaja vyadhi¹ which mainly occurs in Variddhavastha due to Dhatukashya and other VataprakopaNidana. Main symptoms are Vaturandritisparsha (swelling), PrasaranakunchanaVedana (pain on movement), Sandhishoola (pain in joint), cracking sound which limits daily life activities. Osteoarthritis (OA) is an abnormality of the synovial joints characterised by softening, splitting and fragmentation of articular cartilage not attributable to direct contact with inflammatory tissue. This is usually accompanied by subchondral sclerosis and bony cysts, joint space narrowing and bony outgrowths at tissue joint margins². The prevalence of osteoarthritis among elderly as per the recent study is 56.6%, making it a leading cause of disability⁶. The prevalence of OA in female is 31.6% it rises strikingly with age⁹. It is highly prevalent in those over age of 45 to 60 years. Also in women, osteoarthritis tends to have a stronger association with obesity and is frequently bilateral.

Perimenopause is a physiological process and it is time of menopausal transition, a period around menopause (40-55 years)⁸ where the estrogen level decreases in the circulating system results in physical, somatic, vasomotor, psychological and urogenital presentations. Somatic and manifestations are more common with the musculoskeletal abnormalities which includes irregular menstrual cycle, headache, feeling dizzy, pain and stiffness of the muscle and joint, symptoms. In Ayurveda classical texts the Kala of Rajonivrutti is mentioned as 50 years. This last stage of age corresponds to Parihani of Madhya Vaya as Perimenopause stage that is transition from Pitta Pradhana kala to Vata Pradhana kala. During this phase Sapta Dhatu, Indriya, Bala, Veerya, Uthsaha starts to decline, Vata dosha starts to aggravate where both Sharirika and Manasika Bala is affected.³

In modern medical science, OA can be managed with analgesics and NSAIDs, injection glucocorticoids. Long term usage of above medicines causes gastrointestinal toxicity, renal and hepatic metabolism impairment². Hence an alternative, effective, safer and cost effective management needs to be explored for this disorder.

In the course of Ayurvedic therapy provides symptomatic relief of pain also it reduces need for surgical intervention hence management protocol for Janu Sandhigata Vata includes therapeutic methods like Snehana, Upanaha, Agnikarma, Bandhana and Mardana Bhahyabhyantara Snehaprayoga especially with Tiktadravyasiddhagrita as proposed line of treatment for Asthi-Majjagata vata⁵. Basti is considered to be the best treatment for Vata vyadhi. Matrabasti is a type of Snehabasti which is effective in Kevalavata condition because of its Snehana, Bruhmanaproperties. Due to Sarvakalam Niratyayaya Matrabasti is more compliant to patient.

Aims and Objectives:-

To Evaluate the Combined Efficacy of Matra Basti, Godhuma Upanaha and Lakshadi Guggulu in The Management of Janu Sandhigata Vata Vis-A-Vis Osteoarthritis of Knee in Perimenopause Women.

Materials and Methods:-

Literary material — A detailed study of Sandhigata Vata and Osteoarthritis of knee in perimenopause women was done along with a study of selected drugs. Various books of Ayurveda, contemporary Science, and peer reviewed journal of PubMed and Google Scholar, related to the subject, were referred.

Source of Drugs

Mahanarayanataila, Guggulutiktakaghrita, Gandhataila, Dhanyamla and Saindavalavana was manufactured by Vaidyaratnam Oushadhalaya a GMP certified company were procured from Ashwini Ayurvedic centre, New Sayyajirao road Mysuru.

Godhumaupanaha

Godhuma and Yava Churn were procured from G. Abdul Ravoof Pansari, Unani and Herbal shop and general store, Mandi Mohalla Mysuru.

Lakshadiguugulu

Lakshadi Guugulu manufactured by Shree Dhootapapeshwar private Limited (a GMP Certified company), 135, Nanubhai Desai Road, Khetwadi, Mumbai, Maharashtra and was procured from Ashwini Ayurvedic Centre, New Sayyajirao road Mysuru.

Study design –

A single group open labelled clinical trial with Pre and Post-test design.

Source of data

Subjects were selected from the OPD and IPD of Government Ayurveda Medical College and Hospital Mysuru, and Government Hi-Tech Panchakarma Hospital Mysuru.

Sample size-

A minimum of 30 subjects were selected who were fulfilling the criteria for the diagnosis of the disease were registered for the study in prescribed preform.

Inclusion Criteria

1. Perimenopause women between the age group of 40-55 years with the signs and symptoms of Janu Sandhigata Vata vis-a-vis osteoarthritis of knee.
2. Subjects with the symptoms of Janu Sandhigata Vata for at least one month of duration and Subjects fulfilling the diagnostic criteria were included. Both fresh and treated cases were taken for the study.

Exclusion Criteria

1. Subjects of OA suffering with other diseases like Rheumatoid Arthritis, Systemic Lupus Erythematosus, Psoriatic Arthritis, Gouty Arthritis Subjects, co-morbidities like Pseudo-gout, Osteonecrosis of the knee, Ruptured Baker cyst, Anserine Bursitis (knee), Post-surgical and Prosthetic knee joints, acute trauma (<3 months) and fracture of knee joint.
2. Subjects of OA suffering from any other systemic disorders such as uncontrolled DM (RBS>250mg/dl) HbA1c>9, and Hypertension (BP>150/100mmhg), renal disorder etc, obesity (grade II) BMI >35.
3. Pregnant and lactating women and having organic pathology of reproductive system like carcinoma, fibroid, ovarian cysts, surgical menopause were excluded.

Diagnostic criteria

1. Presence of signs and symptoms of Janu Sandhigata Vata such as Janu SandhiShoola, JanuSandhi Shotha, Stiffness and Crepitus, X ray AP and Lateral view of knee joint was taken for the confirmation of diagnosis, Severity of the Osteoarthritis knee joint was assessed with the help of Kellgren–Lawrence Radiographic Grading Scale of Osteoarthritis.
2. Perimenopause stage was decided based on STRAW⁹ scale (irregular menstrual cycle and amenorrhea not more than 12 months)
3. Haematological investigations namely Haemoglobin%, TC, DC, ESR, Random blood sugar, and Urine examinations namely Sugar, Albumin & Microscopic were carried out to rule out other systemic diseases in all the cases, Rheumatoid factor was done for ruling out Rheumatoid arthritis, Imaging tests (USG) were done in doubt full cases.

Assessment Parameters:

Assessment was done based on following parameters:

1. WOMAC index for osteoarthritis⁶.
2. Clinical grading of signs and symptoms of the disease Janu Sandhigata Vata .

Subjective parameters:**Pain:**

SandhiShoolalike Vedana on Akunchana and Prasarana

No pain: P0

Mild pain: P1

Moderate pain: P2

Severe pain: P3

Swelling:

SandhiShotha like Vatapurna Druthi parshavat

No Swelling :S0

Mild Swelling :S1

Moderate Swelling :S2
Severe Swelling :S3

Stiffness:

Sandhi Stabdhata
No Stiffness :ST0
Mild Stiffness :ST1
Moderate Stiffness :ST2
Severe Stiffness :ST3

Knee joint Crepitus

No crepitus : C0
Mild palpable crepitus : C1
Moderate palpable crepitus : C2
Audible crepitus : C3

Table : SHOWING WOMAC SCORE GRADING:

	SCORE	GRADE
None	0	Grade 0
Mild	1-26	Grade 1
Moderate	27-52	Grade 2
Severe	53-78	Grade 3
Extreme	79-104	Grade 4

Assessment schedule:

In the present Clinical trial, three assessments of the subjects were done. Pre test assessment was done on 0 day i.e., before starting the intervention. Mid-test assessment was done on 9th day i.e., on the day of completion of MatraBastiand Upanaha procedure and post-test assessment was done on 31st day i.e., after the completion Shamanoushadhi.

Pre and Post test assessment were considered for overall result.

Statistical methods:

The data was collected on 0 day, 9th day and 31st day. The result was analysed statistically by using Descriptive statistics, Inferential statistics by Chi - square test, Paired- 't' test, Wilcoxon Signed Rank test and Friedman test using Service product for Statistical Solution (SPSS) for windows software. The 't' test and 'p' values were calculated by using paired 't' test and considered at the level of $P < 0.05$ and $P < 0.05$ and $P < 0.10$ (Insignificant), $P < 0.01$ (significant), and $P < 0.001$ (highly significant), to carry out the results.

Intervention Protocol

1. **MatraBasti:** 70ml for 8 days
(Mahanarayanataila 30ml, Guggulutiktakagritha 30ml, Gandhataila 10ml).
2. **GodhumaUpanahais** applied to the knee joint about 12 hours for 8 consecutive days.
3. **LakshadiGuggulu** 1000mg per day in two equally divided doses during morning and night after food with Luke warm water for 21 days.

Total duration of intervention- 31 days

Results:-**Result on Womac Score Grading**

In the present study out of 30 subjects, 15 subjects (50%) had score of grade IV, 5 subjects (16.6%) had score of grade III, 6 subjects (20%) had score of grade II and 4 subjects (13.4%) had score of grade I in pre-test assessment.

Post assessment, on 30th day of intervention 1 subjects (3.4%) had score of grade IV, 1 subjects (3.4%) had score of grade III, 3 subjects (10%) had score of grade II, 8 subjects (26.6%) had score of grade I and 17 subjects had found complete relief from symptoms.

The result obtained regarding the parameter of WOMAC score showed statistically highly significant with p value 0.001

Descriptive Statistics

	Mean	N	Std. Deviation	Std. Error Mean
WOMAC 0	62.3333	30	24.34286	4.44438
WOMAC 9	33.0000	30	22.18884	4.05111
WOMAC 30	14.9000	30	21.84325	3.98801

Results on Janu Sandhi Shoola /Pain.

In the present study out of 30 subjects, 19 subjects (63.4%) had extreme feeling of knee joint pain, 9 subjects (30%) had moderate pain and 2 subjects (6.7%) had mild pain in pre test assessment.

Post assessment on 30th day of intervention 1 subjects (3.4%) had severe pain, 5 subjects (16.7%) had moderate pain and 14 subjects (46.7%) had mild pain and 10 subjects (33.4%) had been completely relived from pain.

Therefore, the parameter on the results of knee joint pain showed highly significant with p value of 0.000.

Friedman Test:

	Mean Rank	N	Chi-Square	df	Significance
Pain 0 th day	2.90	30	49.723	2	0.000
Pain 9 th day	1.85				
Pain 30 th day	1.25				

P-value = 0.000HS

Results on Janu Sandhi Shotha / Swelling

Out of 30 subjects, 5 subjects (16.7%) had extreme feeling of knee joint swelling, 16 subjects (53.4%) had moderate swelling, 6 subjects (20%) had mild swelling and 3 subjects (0.0%) had no swelling in pre-test assessment.

Post assessment on 30th day of intervention 0 subjects (0.0%) had no swelling, 3 subjects (10%) had moderate swelling and 10 subjects (33.4%) had mild swelling and 17 subjects (56.7%) had been completely relived from swelling.

Therefore, the parameter on the results of knee joint swelling showed highly significant with p value of 0.001.

Friedman Test:

	Mean Rank	N	Chi-Square	df	Significance
Swelling 0 th day	2.73	30	44.000	2	0.001
Swelling 9 th day	2.00				
Swelling 30 th day	1.27				

P-value = 0.001HS

Results on Knee joint Stiffness

Out of 30 subjects, 3 subjects (10%) had extreme feeling of Knee Joint Stiffness, 17 subjects (56.7%) had moderate Stiffness, 10 subjects (33.4%) had mild Stiffness in pre-test assessment.

Post assessment on 30th day of intervention, 1 subjects (3.33%) had moderate Stiffness and 4 subjects (13.3%) had mild Stiffness and 26 subjects (86.6%) had been completely relived from Stiffness.

Therefore, the parameter on the results of Knee joint Stiffness showed highly significant with p value of 0.000.

Friedman Test:

	Mean Rank	N	Chi-Square	df	Significance
Stiffness 0 th day	2.93	30	50.420	2	0.000
Stiffness 9 th day	1.75				
Stiffness 30 th day	1.32				

P-value = 0.000HS

Results on Knee Joint Crepitus:

Out of 30 subjects, 20 subjects (66.6%) had extreme feeling of knee joint Crepitus, 6 subjects (20%) had moderate Crepitus and 4 subjects (13.3%) had mild Crepitus in pre-test assessment.

Post assessment on 30th day of intervention 0 subjects (0.0%) had no Crepitus, 4 subjects (13.3%) had moderate Crepitus, 12 subjects (40%) had mild Crepitus and 14 subjects (46.6%) had been completely relived from Crepitus.

Therefore, the parameter on the results of knee joint Crepitus showed highly significant with p value of 0.001.

Friedman Test:

	Mean Rank	N	Chi-Square	df	Significance
Crepitus 0 th day	2.85	30	53.850	2	0.001
Crepitus 9 th day	2.08				
Crepitus 30 th day	1.07				

P-value = 0.001HS

Overall Assessment

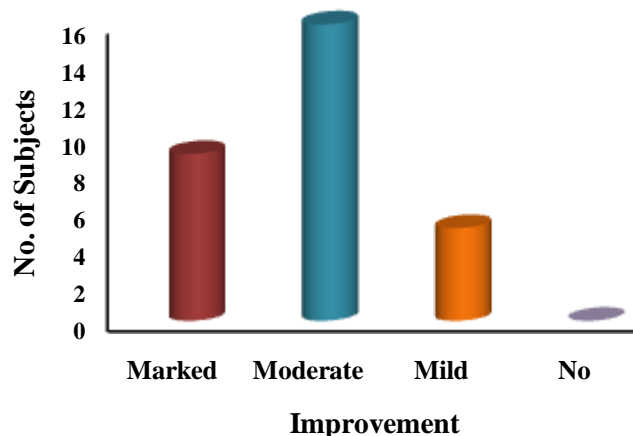
In the present study among 30 subjects, 16 subjects (53.4%) had moderate improvement, 9 subjects (30%) had marked improvement and 5 subjects (16.7%) had mild improvement.

Thus result obtained by the study shows highly significant with p value 0.000

Overall assessment	Number of subjects	percentage
Marked improvement	9	30%
Moderate improvement	16	53.4%
Mild improvement	5	16.7%
Total	30	100%

Overall assessment	Chi square test	df	significance
	33.800	2	0.000

Overall Assesment



Discussion:-**1) Mahanarayanataila⁵**

Mahanarayanataila is indicated for the management of Vata Vyadhi. The main ingredients are Shatavari, Kwatha and Ksheera. Individual ingredients of Mahanarayanataila possess Katu, Tikta Rasa, Laghu, Rukshaguna, Ushna Virya and Katu Vipaka ultimately lead to karma such as Deepana, Pachana, Asthi Poshaka, Vedana Sthapaka, Santarpana and Vata Kapha Pradhana Tridosha. The phytoconstituent present in this taila are phenolic acids, terpenoids, flavonoids, phytosterol which contains phytoestrogen activity balancing the estrogen, thus reducing cholesterol by preventing osteoporosis, anti-inflammatory and anti-arthritis properties.

2) Guggulu Tikta Gritha⁴

It is mentioned as treatment for Sandhigata Vata in Vata Vyadhi Adhikara. The ingredients are Nimba, Amruta, Vasa, Patola, Nidigdika, Patha, Kushta, Shuddha Guggulu, Ghrita etc. Charaka, in Asthi Dhatu Dushti the treatment should be given Tikta Dravya, Ghrita and Kshira. Tikta Rasa has Vayu and Akasha Mahabhuta in dominance. Hence it has affinity towards the Asthi having Vayu and Akasha Mahabhuta. In Guggulu Tikta Ghrita predominance of Tikta Rasa Ushna Virya Deepana, Lekhana, Pachana properties which facilitates increase Dhatvagni, property acts as anti-inflammatory, immunomodulatory and anti-lipidemic action which may help to prevent the any degenerative changes in the body.

3) Gandha Taila¹⁰

Gandhataila is explained in the context of Bhagnachikitsa. It possesses properties like guru, snigdha guna and ushnaverya, Vatahara, Bruhamana, Asthi Dhatu vardhaka. The main ingredients of gandhataila are tila, cow milk. Sesum seeds possess a rich content of calcium, proteins, vitamins, oil. Hence Gandhataila acts primarily on the Asthi Dhatu. It provides shape and support to the body as a whole. According to the principle of ashraya-ashrayee bhava vatavridhi leads to sushirata in asthi dhatu causing asthikshaya. In perimenopause women due to decrease of oestrogen causes osteoporosis, Regular intake of Gandhataila can prevent all these symptoms by nourishment to the Asthi Dhatu.

Probable Mode Of Action Of Matra Basti

Basti karma is mentioned as an important treatment modality of Vata Vyadhi¹. It is considered to be the half the treatment for Vatapradanavyadhi because Pakwashaya is the Mula Sthana of Vata. In Charaka Samhita has described the effect of basti with a simile that as active principles in the water when poured at the root of the tree reaches the whole plant. Matra Basti is the variety of Snehabasti. Anuvasanabasti, it is indicated particularly in balavridhi and Dhatu Kshaya Janya Vata vyadhi where Bhramana effect is intended. The dose of Sneha is equal to Hrsva Matra of Snehapana which get easily absorbed in the body without coming out. In the present study Mahanarayanataila, Guggulu Tikta Gritha and Gandhataila was used as Basti dravya when enters pakwashaya by its veyra, removes the morbid dosha which is lodged anywhere (shiras) in the body. Because Rectum with its vascularity and venous plexus provides a good absorbing surface. The intervention selected with a view that it should act as Shothahara, Sulahara, Balya and Asthi Dhatu poshaka, Sandhanakara and Rasayana.

Mode Of Action Of Upanaha

Swedana is a procedure which relieves stiffness, heaviness, cold and induces sweda. Upanahasweda³ used in vedana predominant and vata dosha samshrutavyadhis.

Upanahasweda may reduce pain by acting over the joint by raising local temperature and increasing local blood circulation which opens the pores of the skin to permit the medicines towards the affected site removing the metabolic waste products. The ingredients of Godhumaupanaha¹⁰ are Godhumachurna, Yavachurna, Saindavalavana, Dhanyamala and Snehadravya is Mahanarayanataila. madhura, guru, ushna & snigdha gunasandhanakara, sthairyakarabruhamana and it pacifies vata and pitta relieves the pain, stiffness by producing sweda and nourishes the joints by analgesic and anti-inflammatory activity.

Lakshadiguggulu¹⁰

The ingredients of lakshadiguggulu are Laksha, Asthi shrunkala, Nagabala, Kakubha, Ashwagandha, each 1 part and Shuddhaguggulu 5 part, most of these drugs having vata kapha shamaka, deepana, balya, rasayana, shotagna, vedana shamaka and shulaprashamaka. Guggulu is shothahara and bhagnasandhanakara Rasayana. Experimental and clinical studies showed that it is having antioxidant, analgesic, anti-inflammatory and antimicrobial activities because it contains natural steroids and vitamin helpful for reducing degeneration of bone.

Conclusion:-

On the basis of concepts, analysis and clinical observations made in this study, the following conclusions were drawn: Based on literature review the disease Janu Sandhigata Vata can be correlated in Osteoarthritis of knee in Modern science. The Osteoarthritis in Perimenopausal Women is a variety of primary osteoarthritis mediated by estrogen deficiency.

The statistical analysis of the data regarding parameter of WOMAC index for Osteoarthritis disease showed statistically significant. The statistical analysis of Subjective parameters also showed highly significant with p value 0.000. Hence, it can be concluded that combined effect of Matrabasti with Mahanarayanataila, Guggulutiktakagritha, Gandhataila, Godhumaupanaha and LakshadiGuggulu is having vatashamaka, rasayana and brihmana property shows effective in the management of Janu Sandhigata Vata Vis-à-Vis in Osteoarthritis of knee in Perimenopause women. No adverse or side effects were observed during the study period.

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