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RESEARCH ARTICLE

Clinical Efficacy/Safety of Therapeutic Combination; *Kshirbala Taila Matra Basti*, *Vatari Guggulu*, *Maharasnadi Kwatha* and *Narayan Taila* in the Management of Osteoarthritis Knee (*Sandhivata*): A Prospective Open Label Study

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ABSTRACT

Introduction: Osteoarthritis (OA) knee is the most frequent joint disease encountered in the clinical practice and a leading cause of disability in the elderly**.** It is a chronic degenerative disorder of multi-factorial etiology characterized by loss of articular cartilage, hypertrophy of bone at the margins, sub-chondral sclerosis and range of biochemical and morphological alterations of the synovial membrane and joint capsule. The clinical presentation of OA is similar to *Sandhivata* described under *Vatavyadhi* in *Ayurveda.*

Objectives: To evaluate the clinical efficacy and safety of *Kshirbala Taila Matra Basti chikitsa* along with *Vatari Guggulu, Maharasnadi Kwatha* internally and local application of *Narayan Taila* in the management of OA knee.

Materials and Methods: A prospective, interventional, open-label study was carried out at the Regional Aryuveda Research Institute for Mother and Child Health (RARIMCH), Nagpur. Sixty patients in the age group 35-65 years with primary OA of knee joint fulfilling the diagnostic criteria were enrolled. A combination of *Kshirbala Taila Matra Basti* for 27 days in three courses (each of 9 days) along with *Vatari Guggulu, Maharasnadi Kwatha* orally and local application of Narayan Taila locally, was administered for 12 weeks. Subjects were followed every fortnightly during treatment and after 4 weeks of completion of treatment. Assessment was done at every two weeks on the basis of the change in pain, stiffness and physical function using the validated modified western ontario and McMster Universities osteoartharitis index (WOMAC) questionnaire, visual analog scale (VAS) scale and global Assessment of disease activity scale.

Observations and Results: A significant reduction in total WOMAC score (p-value < 0.001) was observed after the treatment of 12 weeks and also at the end of 16th week. The mean knee joint pain score assessed on VAS was 8.05 which reduced significantly to 5.52 on 84th day and 5.37 on follow-up (p < 0.001). The mean score of global assessment of disease activity at baseline was 80.17, which reduced to 51.17 on 84th day and 49.00 on follow up (p < 0.001). No adverse events were reported during the course of treatment.

Conclusion: The therapeutic regimen *Kshirabala Taila, Matra Basti and Vatari Guggulu, Maharasnadi Kwatha* along with topical application of Narayana Taila is safe and significantly effective (P < 0.001) in all the cardinal symptoms of OA of knee joint.

Keywords: Global assessment of disease activity score, *Kshirbala Taila*, *Maharasnadi Kwatha, Matra Basti*, *Narayana Taila*, OA knee, *Sandhivata*, *Vatari Guggulu,* WOMAC Score,

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INTRODUCTION

OA or degenerative joint disease is characterized by degradation of joints, articular cartilage and sub-chondral bone.[1] It is one of the major health concerns in India, with a prevalence of 22 to 39%.[2]

As per European league against rheumatism (EULAR) recommendations; treatment of OA knee varies from person to person, taking into account factors such as age, co-morbidity and the presence of inflammation. Optimal management of OA knee requires a combination of pharmacological and non-pharmacological treatment modalities. Non-pharmacological treatment of OA knee includes regular education, exercise, appliances (sticks, insoles) and weight reduction. Exercises, especially those directed towards increasing strength of quadriceps and/or preserving normal mobility of the knee are strongly

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recommended.[3] Traditional non-selective non-steroidal anti-inflammatory drug (NSAIDs) and cyclooxygenase Type 2 selective NSAIDs (COX-2s) are commonly used to treat arthritis and inflammatory conditions, as well as acute and chronic pain. However, non-selective NSAIDs can cause a variety of gastrointestinal (GI) toxicities.[4] Further, the American College of Rheumatology (ACR) guidelines for the management of osteoarthritis knee recommended non-pharmacologic therapies as a first line course of treatment.[5]

Arthritis (both OA and rheumatoid arthritis) is one of the foremost diseases for which patient seeks complementary or alternative medicine option[6]. Because of the limitations of conventional medicine, there is an uptrend among patients for use of alternative therapies, like herbal medicine, acupuncture, etc., according to reports about 60–90% of non-satisfied arthritis patients are likely to use the complementary and alternative medicine (CAM) approach for their disease.[7]

The clinical presentation of osteoarthritis is similar to *Sandhivata* described under *Vatavyadhi* in Ayurveda.[8] The etiology of *Sandhivata* is attributed to improper diet, lifestyle and old age, etc., leading to degeneration of body tissues (*Dhatu kshaya*) which causes aggravation of *Vata* (humour responsible for all movements in the body) and reduction in *Shleshak Kapha* (fluid present in joints) The aggravated *Vata* causes degeneration, pain and inflammation in joints. There is increased *Vata dosha* in old age. *Basti* (medicated enema) is considered superior amongst *Panchakarma* (five treatment for elimination of vitiated *Dosha* from the body) and treatment of choice in *Vata Dosha* and *Vatapradhana* (mainly due to vitiation of *vata dosha*) diseases.[9] *Matra Basti* is very beneficial for the persons suffering with *Vatavyadhi*.[10] Keeping in view the literature about the role of aging and *Vatadosa* in the manifestation of *Sandhivata*, *Matra basti* with *Ksirabala Taila*,[11] was taken into consideration along with *Vatari guggulu*,[12] *Maharasnadi Kwatha*,[13] and *Narayana taila*,[14] for this study to evaluate the efficacy and safety of this therapeutic combination in the patients of OA of knee.

OBJECTIVES

Clinical evaluation of efficacy and safety of the therapeutic combination of *Kshirbala Taila Matra Basti* along with *Vatari Guggulu*, *Maharasnadi Kwatha* and *Narayan Taila* in the management of OA knee.

MATERIALS AND METHODS

Study Design and Setting

It was an open label, non-controlled, prospective, interventional trial, conducted at RARIMCH, Nagpur RARIMCH under CCRAS, Ministry of AYUSH, as per the good clinical practices (GCP) guidelines and the declaration of helsinki. The study protocol was approved by the Institutional Ethical Committee of the institute, and registered with Clinical Trial Registry of India (CTRI/2013/12/004241 Registered on 24/12/2013).

Study Participants

Total 60 patients of OA of the knee were recruited from the outpatient department of Regional Ayurveda Research Institute, Nagpur after obtaining informed written consent. Patients were screened in accordance with inclusion and exclusion criteria mentioned in the protocol.

Inclusion Criteria

Patients of either sex aged between 35 and 65 years; having pain in the affected knee joint(s) for >3 months with radiological changes as per Grade I to III of Kellgren and Lawrence radiological scale; fulfilling the diagnostic criteria of osteoarthritis knee recommended by the American College of Rheumatology (ACR), who were willing to participate in the study for 16 weeks were included.

Exclusion Criteria

Patients with the history of knee joint trauma/fracture; surgical/diagnostic intervention with reference to the affected knee joint(s) were excluded. Further, the patients with any deformity of knee, hip or back altering the gait and posture of the patient, gross disability in performing daily normal routine, i.e., bedridden patients or confined to wheelchair were also excluded. Patients with other comorbidities such as gouty arthritis, rheumatoid arthritis, and psoriatic arthritis were excluded. Moreover, patients with uncontrolled hypertension (>160/100 mm of Hg) and uncontrolled diabetes mellitus B.S. (F) >126 mg% and/or B.S. (2 hr PP) >200 mg% and or HbA1c > 6.5%, evidence of malignancy were also vetoed from the study. The patients on prolonged (>6 weeks) medication with corticosteroids, antidepressants, anti-cholinergic, etc. were excluded. Patients with past history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke or severe arrhythmia in the last 6 months, severe renal or hepatic damage, and pregnant/lactating women were also excluded.

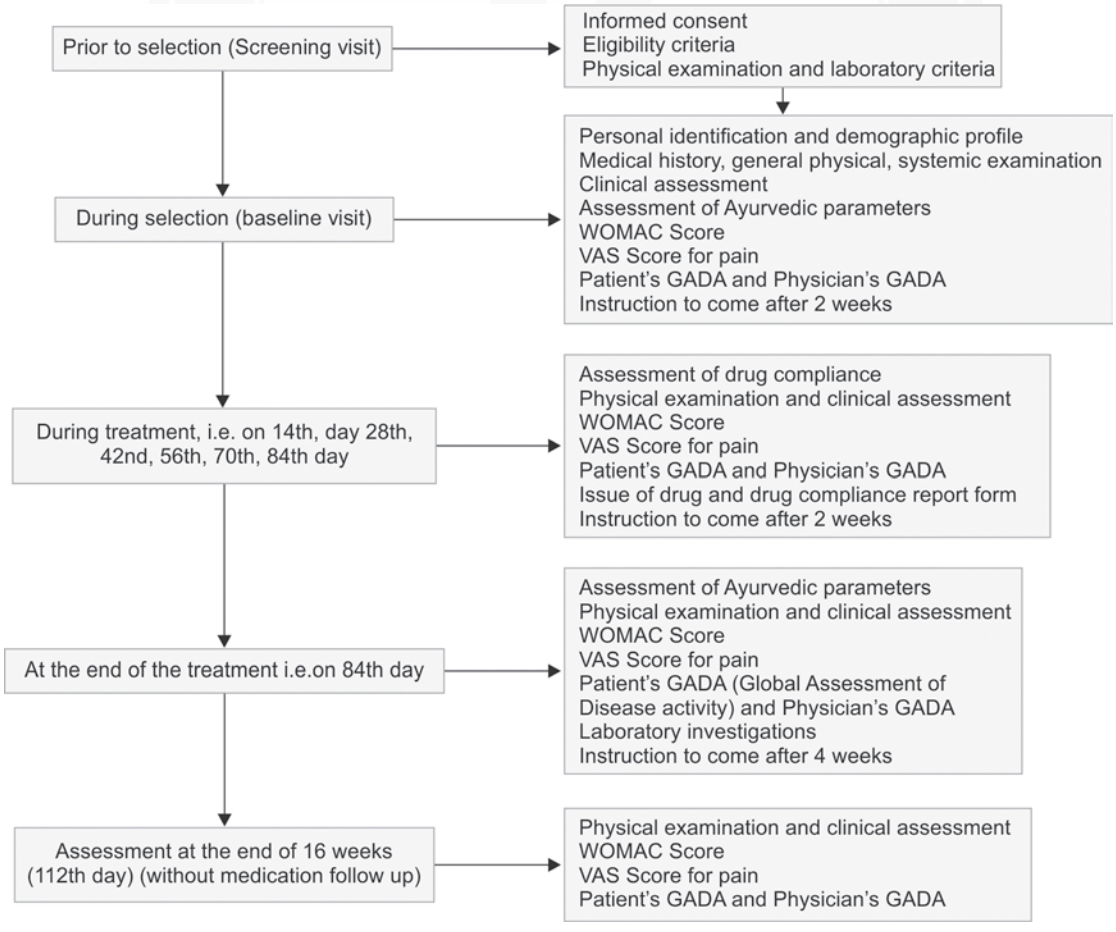
Study Interventions: The trial drugs prepared as per Ayurvedic Formulary of India (AFI) were taken from good manufacturing practices (GMP) certified Ayurvedic pharmaceutical company for the study. Total 27 *Matra Basti* (60 ml oil enema) with *Kshirbala taila* was given in

three courses of nine days each (i.e., from day 1st to 9th and 30th to 38th and 60th to 68th day). The therapeutic regimen of *Matra Basti* consisted of *Snehana* (oleation) with *Narayana Taila, Svedana* (hot fomentation) with *Baspa Sveda* (water steam) and *Matra Basti* with 60 ml of *Kshirbala Taila* (AFI–Part I, 8:11; PP 132). *Kshirbala Taila Matra Basti* was administered during the daytime after a meal in IPD at the institute. *Vatari Guggulu* (AFI–Part I, 5:10; PP 70–71) was administered orally in the dose of 500 mg. two tab thrice a day with lukewarm water after food for 12 weeks. *Maharasnadi Kwatha* (AFI - Part I, 4:28; PP 60–61) was administered orally in the dose of 20 ml twice a day with lukewarm water after food for 12 weeks. *Narayana Taila* (Ayurvedic Formulary of India (AFI)–Part I, 8:23; PP 138) was applied twice a day on affected knee joints for 12 weeks. To monitor drug compliance, relief in symptoms and adverse drug events the subjects were assessed biweekly, (i.e., at the end of 14th day, 28th day, 42nd day, 56th day, and 70th day and 84th day) and assessment of post-treatment effect without intervention was carried out in the follow-up visit on 16th week (112th day).

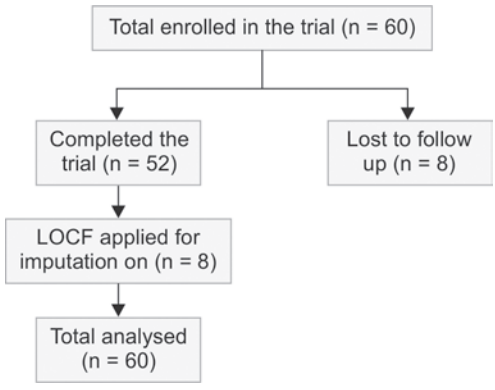
Study Procedure: On the enrolment day at baseline (Visit 1), patient's demographic profile, medical history, general physical and systemic examination, assessment of clinical/Ayurvedic parameters were recorded. Assessment of severity of affected knee joints was done by recording the scoring on WOMAC questionnaire, VAS, patient's global assessment of disease activity scale (PGADA) and physician's global assessment of disease activity scale (GADA). The patient was then admitted in the (indoor patient department) IPD at the institute and *Kshirbala Taila Matra Basti* were administered for nine days. After discharge, the oral and local component of the trial drugs and drug compliance report form were handed over to the patients for taking at home. Total 27 *Matra Bastis* were given in three courses of nine days each (i.e., from day 1st to 9th and 30th to 38th and 60th to 68th day). Subsequent visits were planned at an interval of two weeks 14th day (Visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (Visit 5), 70th day (visit 6) and 84th day (visit 7). The patients were assessed and study medications were given at each subsequent visit till 84th day. The patients were assessed without medication in follow-up visit on day 112th (visit 8) to monitor the lasting effects of the trial drugs. Details of clinical assessment and study schedule are given in Flow Chart 1.

The data of all the patients were recorded in predesigned case report forms (CRFs) and were also entered

Flow Chart 1: Study schedule



Flow Chart 2: Outflow of the patient in the study



in electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The e-formats and xerox of the CRFs along with the scorings and laboratory investigation reports were sent to the councils headquarter on a monthly basis for the purpose of clinical trial monitoring.

Out of the total 60 patients enrolled in the study eight dropped out during the course of the study. Intention-to-treat analysis was done, and the data of all those patients who have completed at least 14th day visit were imputed by last observation carried forward method (LOCF). Hence, the data of a total 60 patients was used for statistical analysis. Flow Chart 2 shows the outflow of the patients in the study.

Efficacy evaluation through Outcome

The primary outcome measure was changed in WOMAC total score and was assessed at baseline and thereafter biweekly in each visit. The WOMAC questionnaire used in this study has three sections; section 1 was for assessment of knee joint pain (5 Qs), section 2 was for assessment of joint stiffness (2 Qs) and section 3 was for the assessment of difficulty in physical function (17 Qs); total of 24 symptoms and each was rated on a 5-point scale of severity. The secondary outcome measures changed in WOMAC stiffness and physical function scores, change in knee pain on the VAS, change in Global Assessment of Disease Activity (GADA) scores as per patient and physician. The change in specific symptoms of *Sandhivata mentioned in Ayurveda* has also been assessed at baseline and after completion of the treatment (84th day) and (112th day) 4 weeks after stopping the intervention.

Statistical Analysis

The efficacy and safety parameters were analysed according to the intention-to-treat analysis. Missing values were imputed by the LOCF method. Statistical analysis was performed using Statistical packages for Social Sciences version 15.0. Statistical significance was defined as p-value <0.05. Primary and secondary outcome measures; change in the scores of WOMAC, VAS and GADA from the baseline to 12 weeks were analysed by using paired t-test. Symptomatic relief was assessed in terms of presence and absence of the symptoms at baseline and at 84th day and 112th day.

OBSERVATIONS AND RESULTS

Data of total 60 patients (16.7%) males and (83.3%) females were used for statistical analysis. The baseline demographic data of the participants are summarized in Table 1. Data revealed that maximum patients (46.7%) were in the age group of 60 to 65 years followed by (26.7%) in the age group of 54 to 59 years. 60% of the patients were above the poverty line; most of the patients (93.3%) cases belonged to an urban area; 70% patients were housewives and most of the patients (81.7%) had emotional stress.

Table 1: Baseline characteristics of study participants (n=60)

Variables	*n (%)*
Age	
36– 41	1 (1.7%)
42– 47	7 (11.7%)
48– 53	8 (13.3%)
54– 59	16 (26.7%)
60– 65	28 (46.7%)
Sex	
Male	10 (16.7%)
Female	50 (83.3%)
Marital status	
Married	49 (81.7%)
Widow(er)	11 (18.3%)
Educational status	
Illiterate	7 (11.7%)
Read and write	53 (88.3%)
Occupation	
Desk work	11 (18.3%)
Field work with physical labour	5 (8.3%)
Field work	2 (3.3%)
House wife	42 (70.0%)
Socio-economic status	
Above poverty line	36 (60.0%)
Below poverty line	24 (40.0%)
Habitat	
Urban	56 (93.3%)
Semi-urban	1 (1.7%)
Rural	3 (5.0%)
Emotional stress	
Average	49 (81.7%)
Moderate	9 (15.0%)
Too much	2 (3.3%)

Effect of Trial Drugs on Total WOMAC Score and its Different Domains, i.e., Pain, Stiffness and Physical Function Domain Scores

The effect of treatment is shown in Table 2, and Graphs 1 and 2. The mean total WOMAC score on the baseline was 66.82, which reduced to 41.47 on 84th day and 40.08 on 112th day (follow-up without medication). A significant reduction in total WOMAC score (p-value <0.001) was observed after the treatment of 12 weeks and also at the end of 16th week in comparison to the baseline advocating that the therapy is significantly effective in the patients of osteoarthritis knee (*Sandhivata*).

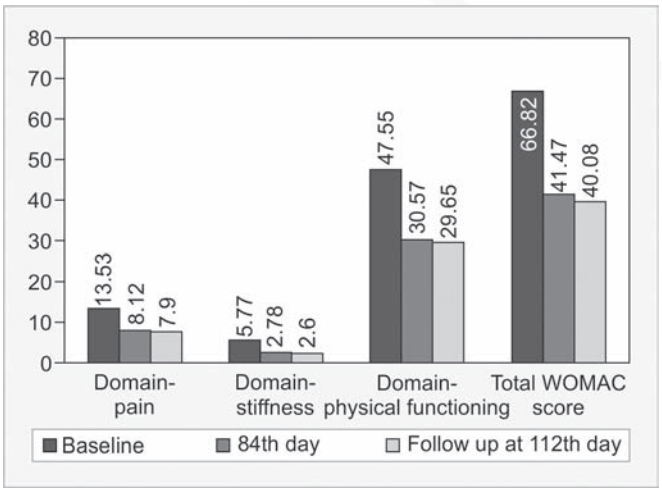
The mean of WOMAC pain score reduced from 13.53 to 8.12 on 84th day and 7.90 on follow-up visit showing highly significant improvement in joint pain (p <0.001). Further, in WOMAC stiffness domain, the mean at baseline was 5.77 which reduced to 2.78 on 84th day and 2.60 on follow-up visit, showing highly significant (p <0.001) reduction in joint stiffness. Similarly, in WOMAC physical functioning domain, the mean at baseline was 47.55, decreased to 30.57 on 84th day and 29.65 on follow-up visit which is showing highly significant (p <0.001) improvement in physical functions.

At the baseline visit, the mean knee joint pain score assessed on VAS was 8.05 which reduced significantly to 5.52 on 84th day and 5.37 on follow-up visit, showing significant relief in joint pain (p <0.001). The mean score of patient's global assessment of disease activity at baseline was 80.17, which reduced to 51.17 on 84th day and 49.00 on follow-up visit showing highly significant improvement (p <0.001). Further, the mean score of physician's global assessment of disease activity at baseline was 78.17, which reduced to 50.33 on 84th day and 47.17 on follow-up visit showing highly significant relief (p <0.001). The results in disease-specific Ayurvedic parameters were satisfactory; 25% of patients got relief in *Sandhisula* (knee pain), 42.5% patients got relief in *Sandhi sotha* (swelling in knee joint), 11.7% of patients got relief in *Vatapurnadruti Sparsa* (Crepitation), only 1.7% patients got relief in *Prasarana Akuncana Vedana* (Painful movements of the affected joint) and 15.0% of patients got relief in *Apravrutti* (restricted movement).

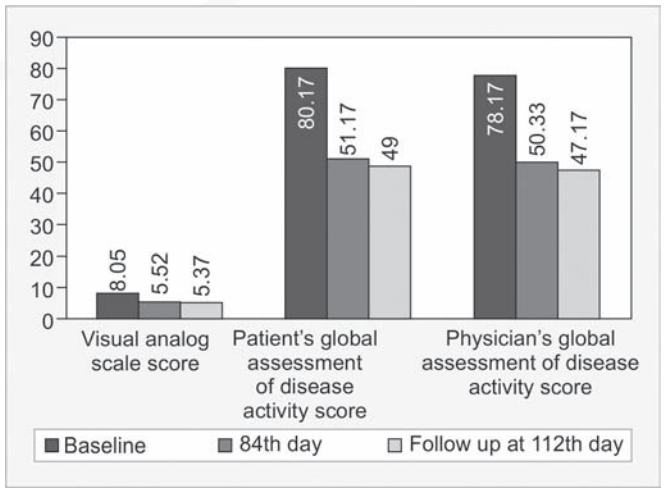
Table 2: Effect of trial drugs on outcome parameters

Outcome parameters (n = 60)	*Baseline*	*84th day*	*Follow up at 112th day*	*t-valu$*	*p-value*
Total WOMAC Score	66.82 (10.651)	41.47 (12.357)	40.08 (12.431)	19.054	<0.001
Domain–Pain	13.53 (2.696)	8.12 (2.656)	7.90 (2.589)	14.888	<0.001
Domain–Stiffness	5.77 (1.345)	2.78 (1.316)	2.60 (1.304)	15.056	<0.001
Domain–Physical functioning	47.55 (7.599)	30.57 (8.990)	29.65 (9.089)	18.652	<0.001
Visual analog scale (VAS) score	8.05 (1.199)	5.52 (1.742)	5.37 (1.895)	10.095	<0.001
Patient's global assessment of disease activity score	80.17 (11.273)	51.17 (16.374)	49.00 (18.567)	12.672	<0.001
Physician's global assessment of disease activity score	78.17 (10.969)	50.33 (15.510)	47.17 (17.281)	13.167	<0.001

Values are reported as mean (SD); $compared using paired t-test at baseline and 84th day; *p-value < 0.05 considered as significant



Graph 1: Effect of trial drug on outcome parameters

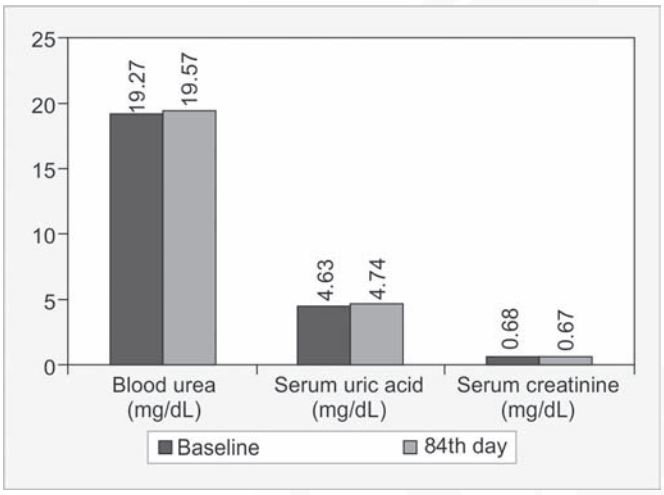


Graph 2: Effect of trial drug on outcome parameters

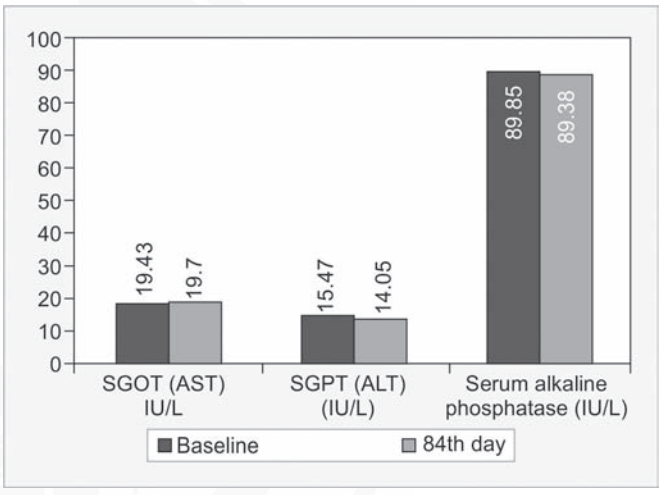
Table 3: Effect of Trial drugs on safety parameters

Parameters (n = 60)	*Baseline*	*84th day*	*t-value*[$]	*p-value*
Blood urea (mg/dL)	19.27 (5.446)	19.57 (6.269)	0.444	0.658
Serum uric acid (mg/dL)	4.632 (1.1597)	4.747 (1.1568)	1.431	0.158
Serum creatinine (mg/dL)	0.682 (0.1338)	0.677 (0.1454)	0.318	0.751
SGOT (AST) IU/L	19.43 (5.673)	19.70 (4.670)	0.334	0.740
SGPT (ALT) IU/L	15.47 (6.806)	14.05 (4.374)	2.065	0.043
Total protein (gm/dL)	7.412 (0.3992)	7.452 (0.3886)	0.843	0.402
S. Albumin (g/dL)	4.500 (0.2307)	4.482 (0.2709)	0.480	0.633
S. Globulin (g/dL)	2.91 (0.407)	2.970 (0.3993)	1.315	0.194
Conjugated bilirubin (mg/dL)	0.1615 (0.05168)	0.4615 (2.43440)	0.952	0.345
Unconjugated bilirubin (mg/dL)	0.1827 (0.11244)	0.6235 (3.59537)	0.946	0.348
Serum alkaline phosphatase (IU/L)	89.85 (24.142)	89.38 (26.801)	0.242	0.810

Values are reported as mean (SD); [$]compared using paired t-test; *p-value < 0.05 has been considered as significant; SGOT: Serum glutamic oxaloacetic transaminase; SGPT: Serum glutamic pyruvic transaminase



Graph 3: Effect of trial drug on safety parameters



Graph 4: Effect of trial drug on safety parameters

Effect of Trial Drugs on Safety Parameters

The effect of this treatment on various safety parameters, such as liver function tests and renal function tests, was assessed on the baseline and at 84th day visit. The values were within normal limits during the entire trial period (Table 3, and Graphs 3 and 4). Further, no adverse events or adverse drug effects were reported during the indoor and outdoor course of treatment. These observations validate that these classical drugs are safe for human use.

DISCUSSION

The primary objective of this study was to evaluate the efficacy of the age-old combination of classical Ayurvedic therapy *Kheerbala Taila Matra Basti* and *Vatari guggulu* along with *Maharasnadi kwatha* and local application of *Narayan Taila* in the management of osteoarthritis the knee. In the present study 83.3% of the patients were female, this supports that osteoarthritis of knee is more commonly found in women than men.[15] Sex hormones have long been considered a possible factor in the systemic predisposition to osteoarthritis, especially in women.[16-18] As per agewise distribution, maximum numbers of patients (46.7%) were in the age group of 60 to 65 years followed by (26.7%) in the age group of 54 to 59 years. This is the age wherein deterioration of *Dhatu* (tissues) starts. These observations support the causative pathology of disease which involves *Vataprakopa* (vitiation of *Vata*) due to aging and *Asthi Dhatu Kshya* (degeneration of Bone tissue) leading to *Sandhivata*.

The *Basti chikitsa* (treatment) was employed as per classical references with the standard protocol. *Snehana* with *Narayana Taila* and *Svedana* with *Baspa Sveda* together produced *Vatasamaka* (pacification of *Vata*), *Balya* (strengthen-

ing), *Anulomaka* and *Pachana* (tissue metabolism) effect. It emphasizes the classical principle of repeated *Snehana-Svedana* for *Vata* disorders the standard in relieving the stiffness of joints thus making them more flexible. *Kshirabala Taila* contains *Kshira* (milk), *Bala* (*Sida cordifolia*) and *Tila Taila* (Sesamum indicum oil). All these drugs possess mainly *Snigdha Guna* (unctuous property) and *Vatahara* (alleviates vitiated *Vatadosa*) properties, which might have helped in controlling the vitiated *Vata* resulting in relieving the joint pain in osteoarthritis knee. *Kshirabala Taila Matra Basti* due to its *Brimhana* (nourishing) action might have provided the nourishment to the *Dhatu* resulting in an improvement in physical functions of the knee joint.

Sida cordifolia is the main content of *Kshirabala Taila*, and one of the important contents of *Narayana Taila* and *Maharasnadi Kwatha*. Pharmacological studies have demonstrated that *Bala* possesses vaccine and vasicinone, which are having anti-inflammatory and analgesic activity.[19–22] *Vatari guggulu was given orally which contains Eranda Taila (Ricinus communis), Sudha Gandhaka (*Sulphur purified*), Sudha Guggulu (Commiphora wightii), Haritaki (*terminalia chebula*), Vibhitaka (*terminalia belerica*)*, and *Amlaki (*Emblica officinalis*). Most of* these drugs have *Tikta*, *Katu*, *Kasaya Rasa*, *Usna Virya*, and *Katu Vipaka with Vata Kapha Samana* (pacification of *Vata* and *Kapha)* properties. *Vatari guggulu* has *Guggulu* (Commiphora wightii) as its base, it has demonstrated anti-inflammatory activity of crude drug and standardized extract containing guggulsteron in animal models.[23] Clinical studies have also shown effectiveness of *Commiphora wightii* in the management of osteoarthritis.[24] Castor oil is another important constituent of *Vatari guggulu*. Ricinoleic acid present in castor oil has anti-inflammatory effect.[25] *Maharasnadi Kwatha* contains *Rasna* (*Pluchea lanceolata*), *Dhanvayasa* (*Fagonia cretica*), *Bala* (*Sida cordifolia*), *Eranda-Mula* (*Ricinus communis*), *Devadaru* (*Cedrus deodara*) and *Shati* (*Hedychium spicatum*) etc and all these drugs possess *Vata* pacifying (*shamana)* properties. A study by *Vandita Shrivastawa* et.al on ethanolic extract of *Rasna* exhibited significant anti-inflammatory activity.[26] A new quaternary base chloride called pluchine was isolated from *Pluchea lanceolata.* This substance harbours smooth muscle relaxing, spasmolytic and anti-inflammatory effects.[27] *Maharasnadi Kwatha* has significant analgesic and anti-inflammatory properties.[28] *Simhanada Guggul* and *Narayana Taila* studied in albino rats has shown significant anti-inflammatory effect.[29] This therapeutic combination of *Ksheerbala Taila Matra Basti*, *Vatari Guggulu*, *Maharasnadi Kwatha* and gentle local massage with *Narayan Taila* is collectively having *Vata-shamak* (palliation of *Vata* humour), *Kapha-shamak* (palliation of *Kapha* humour), *Aam-pachan* (digestion of toxic wastes), *Deepan* (empowering agni/ digestive fire.), *Vedna-sthapan* (subsidence of pain) and *Rasayana* (rejuvenation) properties. Due to these properties, it normalizes vitiated *Vata* and helps to relieve joint pain and stiffness in osteoarthritis knee.

CONCLUSION

The study concluded that the therapeutic regimen *Kshirabala taila matra basti* and *Vatari guggulu*, *Maharasnadi kwatha* along with topical application of *Narayana taila* is safe and significantly effective ($p < 0.001$) in all the cardinal symptoms of osteoarthritis knee.

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हिंदी सारांश

क्षीरबला तैल मात्रा बस्ति, वातारि गुग्गुलु, महारास्नादि क्वाथ एवं नारायण तैल से संयुक्त चिकित्सा का संधिवात प्रबंधन में चिकित्सीय प्रभाव/सुरक्षा मूल्यांकन

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भूमिकाः जानुगत संधिवात क्लिनिकल प्रैक्टिस में सबसे अधिक पाये जाने वाली संधिगत व्याधि है। यह सामान्यतः वृद्धावस्था में पायी जाने वाली व्याधि है। यह एक बहुपादीय निदान वाली जीर्ण व्याधि है जो संधिगत कार्टिलेज का क्षय, संधि के किनारों पर हड्डी की वृद्धि, सबकोंड्रल स्क्लेरोसिस तथा साइनोवियल झिल्ली और संयुक्त कैप्सूल के जैव रासायनिक और अकारिकिय परिवर्तन की श्रेणी द्वारा परिलक्षित होती है। आयुर्वेद में इसका वर्णन वातव्याधि में किया गया है।

उद्देश्यः क्षीरबला तैल मात्रा बस्ति, वातारि गुग्गुलु, महारास्नादि क्वाथ एवं नारायण तैल से संयुक्त चिकित्सा का जानुगत संधिवात से ग्रसित रोगियों पर प्रभाव एवं निरापदता का अध्ययन।

साधन एवं विधिः वर्तमान अध्ययन के लिए अमेरिकन कॉलेज ऑफ़ रियूमेटोलोजी के द्वारा संधिवात के लिए निर्धारित नैदानिक मापदंडों को पूरा करने वाले कुल 60 रोगियों (35 और 65 वर्ष के मध्य) का चयन क्षेत्रीय आयुर्वेदीय मातृ एवं शिशु स्वास्थ्य अनुसंधान संस्थान, नागपुर के बहिरंग रोगी विभाग से किया गया।

चयनित रोगियों में नारायण तैल से सर्वांग स्नेह तथा वाष्प स्वेद देने के पश्चात क्षीरबला तैल की 27 मात्रा बस्तियां दी गई (प्रथम दिन से नवे दिन तक, 30वें दिन से 38वें दिन तक तथा 60वें से 68वें दिन तक)। वातारि गुग्गुलु कोष्ण जल से, महारास्नादि क्वाथ का पान तथा नारायण तैल का स्थानिक प्रयोग 12 सप्ताह तक किया गया। रोगियों की हर 15 दिन पर जांच की गयी तथा चिकित्सा बंद करने के उपरान्त चार सप्ताह के बाद पुनः जांच की गयी।

परिणामः इस अध्ययन के अंत में यह पाया गया की उपचार के प्रभाव स्वरूप कुल वोमेक स्कोर (जिसमे संधि पीड़ा, संधि में जड़ता तथा शारीरिक कार्य क्षमता) में सांख्यिकीय रुप से महत्वपूर्ण सुधार पाया गया ($p < 0.001$) तथा संधि पीड़ा की तीव्रता में वास (VAS) स्केल में सांख्यिकीय रूप से महत्वपूर्ण कमी पायी गई ($p < 0.001$)। पेशेंट ग्लोबल असेसमेंट ऑफ़ डिजीज एक्टिविटी स्कोर तथा फिजिशियन ग्लोबल असेसमेंट ऑफ़ डिजीज एक्टिविटी स्कोर में भी सांख्यिकीय रूप से महत्वपूर्ण कमी पायी गई ($p < 0.001$)। जो की सिद्ध करता है कि यह आयुर्वेदीय संयुक्त चिकित्सा, जानुगत संधिवात में अत्यधिक प्रभावी है। इस चिकित्सा में प्रयुक्त औषधियों का रुग्ण पर कोई दुष्प्रभाव भी नहीं पाया गया।