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CLINICAL EVALUATION OF VATARI GUGGULU, MAHARASNADI KWATHA AND NARAYAN TAILA IN THE MANAGEMENT OF OSTEOARTHRITIS KNEE

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ABSTRACT

In present era, pharmacological, biochemical and surgical interventions are not successful remedy for osteoarthritis (OA). Ayurveda and complementary medicine have medication for OA. **Objectives**: The main aim of the study was to assess the efficacy and safety of therapeutic combination of vatari guggulu along with Maharasnadi kwatha and Narayan taila with gentle massage for 15 min daily up to 12 weeks on affected knee joint pain assessed on Visual analogue scale (VAS) and Western Ontario and McMaster University Osteoarthritis Index (WOMAC). **Materials and methods**: It was an open label, multicenter, prospective, clinical study conducted on 142 patients of OA Knee, Vatari guggulu 500 mg thrice in a day along with Maharasnadi Kwatha 20 ml with equal amount of water twice daily and Narayan taila 20 ml twice in a day for external application with gentle massage for 15 min up to 12 weeks were used to all the study participants. **Results**: VAS, WOMAC score and clinical symptoms were reduced significantly from baseline to end of the treatment. **Conclusions**: The study provides good evidence in support of the efficacy and safety of the Vatari guggulu along with Maharasnadi Kwatha and Narayan taila in the management of Osteoarthritis knee.

1. INTRODUCTION

Osteoarthritis (OA) is a chronic degenerative disorder of multifactorial etiology characterized by loss of articular cartilage, hypertrophy of bone at the margins, subchondral sclerosis and range of biochemical and morphological alterations of the synovial membrane and joint capsule. Pathological changes in the late stage of OA include softening, ulceration and focal disintegration of the articular cartilage; synovial inflammation also may occur. Typical clinical symptoms are pain, particularly after prolonged activity and weight bearing; whereas stiffness is experienced after inactivity. It is also known as degenerative arthritis, which commonly affects the hands, feet, spine and large weight bearing joints, such as the hips and knees. It can present as localized, generalized or as erosive osteoarthritis. Most cases of osteoarthritis have no cause and are referred to as primary osteoarthritis. Primary osteoarthritis is mostly related to aging. Secondary osteoarthritis is caused by another disease or condition. Epidemiological of this disease in India is not clear but it is estimated that osteoarthritis is the second most common rheumatologically problem and is most frequent joint disease with prevalence of 22%-39% India. Osteoarthritis prevalence increases with age, so that 11% of all women over the age of 60 years have symptoms due to knee OA.

The guidelines for treatment of the OA of the knee from the National institute of health and clinical excellence (NICE), the American college of rheumatology and the European league against rheumatism recommend non-drug treatments including the education of the patients, social support, physical exercises and weight loss. Non-steroidal anti-inflammatory drugs (NSAIDs) are still used as the initial treatment in primary care as anti-inflammatory and analgesic agents by inhibiting the synthesis of prostaglandins. NSAIDs are associated with a number of side effects, most importantly the increased risk of gastrointestinal (GI) bleeding and renal failure as well as increasing risk of myocardial infarction and stroke especially in the COX-2 inhibitor category. The intra articular injections of corticosteroid and sodium hyaluronate etc. are also in practice but have limited role. Finally end stage forms OA are treated with knee replacement therapy. This is frequently associated with pain relief but however hold a substantial post-operative risk and financial burden. On the basis of limitations, the use of alternative therapies, such as acupuncture, medicinal herbs is on the rise and according to reports; about 60-90% of dissatisfied arthritis patients are likely to use the complementary and alternative medicine (CAM) approach to overcoming pain and associated problems. An increasing number of people in U S are adopting complementary or alternative medicine

approaches to meet their personal health problems. Arthritis (both OA and RA) is one of the foremost diseases for which patient seeks option of complementary or alternative. In treating osteoarthritis, glucosamine and chondroitin sulfate, two of the molecular building blocks found in articular cartilage, are the most commonly used alternative supplements.

Sandhivata nomenclature available in Ayurvedic literatures for this clinical entity, which is similar to Osteoarthritis. The cause of Sandhivata in Ayurveda is attributed to improper diet, life style, and old age etc leading to degeneration of body elements (dhatu kshaya), aggravation of vata; the humor responsible for all the v movements and functions of the body and reduction in shleshaka kapha; a slimy substance present in the joints. The aggravated vata brings rukshyata (dryness), laghutva (lightness), kharatva (coarseness) in the joints causing degeneration. In sandhivata sandhi shula is the main feature. The other features are including shotha (swelling), stabdata (stiffness) ana atopa (crepitus) and difficulty in performing the functions of the involved joint.

On the basis of literature and day to day clinical practice evaluate to scientifically rule out efficacy and safety of this combination. Primary and secondary objective was to assess the efficacy and safety of therapeutic combination of Vatari guggulualong with Maharasnadi Kwatha and Narayan taila in the management of osteoarthiritis simultaneously.

2. MATERIALS AND METHODS

It was an open label, multicenter, non-comparative, perspective, pragmatic trial. The trial protocol and related documents were reviewed and approved by the institutional Ethics committee of each participating center. The study was conducted in accordance with schedule Y of Drugs and Cosmetic Act, India, amended in 2005 and (ICMR) ethical guidelines for biomedical research on human participants, adopted from World Medical Association (WMA) – Declaration of Helsinki.

2.1 Primary and Secondary outcome measures

Primary outcome measure of study was to evaluate efficacy of Ayurvedic formulations Vatari guggulu, Maharasnadi skwatha and Narayan taila in the subjects suffering from OA knee by assessing change in WOMAC total score. The secondary outcome measures were to evaluate the changes in the score of three sub scales i.e. WOMAC pain subscale and global assessment of disease activity by the patients and physicians by using visual analogue scale (VAS) for pain in last 48 h from the date of assessment. Laboratory parameters such as LFT, RFT, complete blood count (CBC), ESR, hemoglobin, RA factor, blood sugar fasting and urine examination were done, X-ray of the affected knee joint was also performed.

2.2 Trial interventions

Therapeutic Combination of Vatari guggulu 500mg thrice in a day along with Maharasnadi Kwatha 20 ml twice daily with equal amount of lukewarm water and Narayan taila 20 ml twice in a day for external application with gentle massage for 15 min up to 12 weeks were used in this study.

2.3 Washout period

There was wash out period of 2 weeks only if the patient gives previous history of taking allopathic/ Ayurvedic /any medicine.

2.4 Inclusion criteria

Subjects of either sex, age between 35 and 65 years, having symptoms of OA and willing able to participate in the study for 12weeks were included in the study.

2.5 Exclusion criteria

The subjects having rheumatoid arthritis, gouty arthritis, history of any trauma or fractured joint or surgical history to the joint in the previous 6 months before the screening visit were not included in the study. Further, patients who are bed ridden or confined to wheel chair, having any deformity of knee, hip or back altering the gait and posture, uncontrolled hypertension, uncontrolled diabetes mellitus, prolonged medication with corticosteroids, antidepressants, anticholinergics, past history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke or severe arrhythmia in the last 6 months, severe renal or hepatic disorders, pregnant and lactating woman were also excluded from the study.

2.6 Study procedures

Total 142 subjects who fulfilled the inclusion and exclusion criteria were enrolled in the study. All enrolled subjects were given combination of Vatari guggulu 500 mg thrice in a day along with Maharasnadi Kwath 20 ml twice in a day with equal quantity of warm water orally and Narayan taila 20 ml twice in a day for external application with gentle massage for 15 min up to 84 days. Recruited subjects were advised to carry on their daily activities and exercises that they had been doing before enrollment. Pain was measured in a visual Analogue Scale (VAS) (subject mark the location on the 10-cm line corresponding to the amount of pain they experienced during last 48 h). VAS data of this type was recorded as the no. of millimeters from the left of the line with the range 0-100. WOMAC Index (Modified – CRD Pune Version) containing 24 questions (Q) was used to grade pain (Q.1-5), stiffness (Q.6-7), and physical function difficulty (Q.8-24) pertaining to the knee joint. The max possible WOMAC score was 96(pain= 20, stiffness =8 and Physical Function = 68). The knees were examined for the swelling/synovitis (grades:0 = none, 1 = detectable synovial thickening without loss of bony contours, 2 = synovial thickening with loss of bony contours and 3 = bulging synovial proliferation with cystic characteristics). Subjects were advised to return

empty containers of trial medicines on every follow up visit in order to check the drug compliance.

2.7 Follow-up assessment

Subjects were visited for follow-up visits on day 14 (visit 1), day 28(visit 2), day 42 (visit 3), day 56(visit 4), day 70(visit 5) and day 84 (visit 6). On each follow up visit, patients general and systematic physical examination were done. Assessment of the symptoms of assessment of disease severity score was assessed by both the investigators and subjects on every follow up visit to know the efficacy of the treatment. Labortary investigations i.e CBC, Hb%, ESR,Renal Function Test,Liver Function Test were performed at baseline and at the end of 84th day for safety evaluation of the drugs.

3. RESULTS

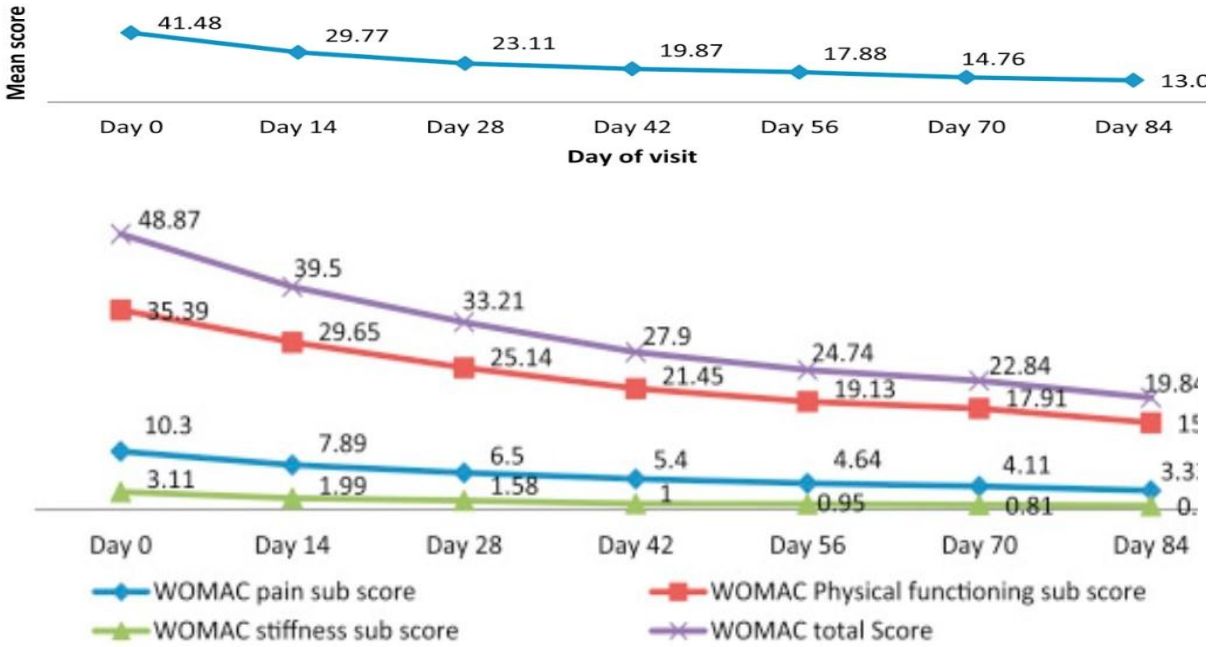
The study was conducted on 142 subjects. Out of these, 126 have completed the study and 16 were dropped out due to loss to follow up and amputation technique applied on 15 cases. The data of 15 subjects were taken for analysis along with the data of completed cases by last observation carry forward method for intention to analysis. In this study, Age 54-59 and 60-65 were more affected 37 (26.2%) and 50 (35.4%) respectively. Further most of the subjects (95.7%) have no addiction, 62.4% have normal sleep, 78% were having regular bowel habit. No significant changes were observed at the end of the therapy i.e. pulse rate, body temperature, respiratory rate, systolic and diastolic blood pressure, appetite and body weight.

3.1 Effect of therapy on outcomes measures

At baseline visit, the mean knee joint pain score assessed on Visual Analogue Scale (VAS) was 41.48±2.59. The mean knee joint pain score (VAS) reduced significantly from base line to 29.77±2.15 after 14th day treatment with this medicines. The mean pain score further reduced significantly from baseline to 23.11 ±1.75; 19.87±1.704; 17.88±1.61;14.76±1.43 and 13.03±1.50 on days 28th, 42nd, 56th, 70th and 84th respectively. At baseline visit, the mean score of (WOMAC) was 48.87±0.99 which was reduced significantly to 19.43 ±01.25 at the end of the study. The mean WOMAC pain sub sore reduced significantly from baseline 10.30 ±0.27-3.33±0.25 at the end of the study. The mean WOMAC stiffness sub score reduced significantly from baseline 03.11±00.1-0.68±0.1 at the end of the study. At baseline visit, the mean WOMAC Physical functioning sub score 35.39±0.71, which was reduced significantly to 15.39±0.95 at the end of the study.

4. DISCUSSION

The key objective of this study was to evaluate the efficacy of combination of classical Ayurvedic drugs Vatari guggulu with Maharasnadi kwath and gentle massage of Narayana taila in the management of Osteoarthiritis knee.The subjects were selected as per the criteria of American college of rheumatology, and the effect of therapy was assessed by WOMAC combined score, three WOMAC sub scales, pain by visual analogue scale, global assessment of disease severity both by the physicians as well as patients. The hematological and biochemical parameters were done for the safety evaluation of the trial drugs; X-rays of knee joints was also done before the treatment.



Results of the study showed that 35.40% subjects were foun in 60- 65 year of age group. The results are encouraging at the end of the study. Statistically results are highly significant ($p<0.0001$). Mean knee joint pain score was decreased on every follow up visit. WOMAC sub scales (pain, stiffness, physical functioning) decreased significantly from their baseline values. The need of rescue medicine for pain management was reduced as study progressed. Findings show that combination of these Ayurvedic drugs reduced joint pain; joint stiffness and improved physical function. (Table 1).

Table 1: Effects of therapy on chief complaints in the subjects of OA knee.

Clinical Symptom	No. of patient		Percentage of patients who got the relief
	Before treatment	After treatment	
Joint pain on movement	141	19	86.52
Joint pain at rest	96	107	-11.45
Restricted movement of joints	114	40	64.91
Crepitus/crunching in the joints	140	94	32.85
Weakness of affected joints	95	58	38.94
Swollen joints	84	13	84.52
Bony enlargement of the joints	13	04	69.23
Joint stiffness	126	38	69.84

In this study, the global assessment of drug tolerability assessed by the physician, most of the subjects had feeling of good to excellent tolerability of drugs. Drawer's test, test for medical a lateral collateral ligaments and McMurray's test of meniscal tears were normal. Baseline to end of the study values were observed in safety laboratory parameters such as total leucocyte count, neutrophil, eosinophil, ESR, serum uric acid, serum creatinine. No changes were observed in X-ray of knee joints. Basically osteoarthritis knee or degenerative joint disease start at the age of 40 which is declining stage of middle age. The symptoms, such as pain and inflammation, appear in middle age. Till the age of 55 it occurs equally in both sexes; after 55 the incidence is higher in women. Aggravated vata brings rukshyata, laghutva, kharatva in the joints causing degeneration. Sandhi shula is the predominantly main feature. The other features are shotha, stabdata, atopa.

Composition of Vatari guggulu is collectively having vatashamaka, kaphashamaka, aamapachana, dipan, vedanasthapana and rasayana properties. Due to ushna virya and vatanulomana propertie, it normalizes the movement of apana vaayu and vyana vaayu which in turn helps to relieve pain. Furthermore, the kaphashamaka properties of Eranda and Guggulu by its laghu, ushna, sukshma, strotoshudhikara properties;it checks blockage of path occurred due to kapha dosha and so helps to relieve stambha and shotha. Maharasnadhi kwatha is a polyherbal formulation proved to be safe ana nontoxic has the potential for providing relief to arthritis patients. Narayan taila is also a potent vatashamaka properties. In this study we use for its massage locally on knee joints.

5. CONCLUSION

It is concluded that the effect is of treatment package of trial is effective in the management of Osteoarthritis knee. This prospective study provides the evidence in support of the potential efficacy and safety of Ayurvedic medicines. It is a safe and effective treatment of OA knee.

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