



## RESEARCH ARTICLE

# Clinical Evaluation of *Yogaraj Guggulu*, *Gandharvahasta Taila*, and *Dhanwantara Taila* in the Management of Osteoarthritis Knees

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## ABSTRACT

**Background:** Osteoarthritis (OA) is a chronic degenerative joint disease and is the most common form of arthritis. It is the fourth leading cause of disability worldwide. Most of this disability burden is attributable to the involvement of hips or knees.

**Objective:** The aim of the present study was to assess the clinical efficacy of Ayurvedic formulations in the management of OA knees.

**Materials and methods:** It was an open label, multicenter, prospective, and clinical study. One hundred and twenty subjects of primary OA knees aged between 35 and 65 years, fulfilling the diagnostic criteria of the American College of Rheumatology (ACR) and showing radiological changes, were enrolled in the study. *Yogaraj guggulu* (500 mg) thrice a day with lukewarm water after food along with *Gandharvahasta taila* (6 mL) orally with lukewarm water just before bedtime and *Dhanwantara taila* for external application twice a day were given for 12 weeks. The assessment was done every 4 weeks. The primary outcome was assessed by seeing the change in the total Western Ontario and McMaster University osteoarthritis (WOMAC) score.

**Results:** WOMAC score and clinical symptoms were reduced significantly from baseline to the end of the treatment.

**Conclusion:** This study revealed the efficacy of *Yogaraj guggulu* along with *Gandharvahasta taila* and *Dhanwantara taila* in the management of OA knees.

**Keywords:** *Dhanwantara taila*, *Gandharvahasta taila*, Osteoarthritis, *Sandhigatavata*, Western Ontario and McMaster University osteoarthritis score, *Yogaraj guggulu*.

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## INTRODUCTION

Osteoarthritis (OA) is a chronic degenerative joint disease and is the commonest form of arthritis. It is the fourth leading cause of disability worldwide. Most of this disability burden is attributable to the involvement of hips or knees.<sup>1</sup> It progresses slowly with usual signs and symptoms of joint pain and swollen and deformed joints with limitation of movement.

The risk factors in high-risk population include female gender, old age, overweight, history of previous injuries, or surgeries of knees.<sup>2</sup> It has been estimated that, in Asia, the percentage of people aged 65 years and above will double in the next two decades, from 6.8% in 2008 to 16.2% in 2040. It is estimated that during the period 2008 to 2040, in India alone the proportion of people aged 65 and over will increase by 274%. In 2008, Japan had the world's oldest population, and India and China were ranked the top two countries in the absolute number of people aged 65 years and more.<sup>3</sup>

In Ayurveda, OA can be regarded as a specific variety/form of *Vata vyadhi*, which is manifested due to the aggravation of *Vata*. The conventional diagnosis "osteoarthritis of the knee" cannot be directly translated into the Ayurvedic diagnostic system. As an approximation, the Ayurvedic term "[Janu-] sandhigatavata" (literal translation from Sanskrit: "Vata is seated [has moved] in [into] the [knee-] joint") is most commonly used by the Ayurveda physicians. Ayurveda has

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its own sophisticated diagnostic system: it generally belongs to a cluster of diseases in which the aggravation of *Vata* prevails.<sup>4,5</sup>

As mentioned above, the prevalence of OA is high worldwide, and in conventional therapy, nonsteroidal anti-inflammatory drugs (NSAIDs) are still used for the initial treatment in primary care: however, these are associated with a number of side effects, such as upper gastrointestinal bleeding and renal failure as well as myocardial infarction and stroke. Nowadays, patients with OA often seek alternative medicine as it has fewer side effects and is considered to be safer. The present study was undertaken with an objective to assess the efficacy of Ayurvedic formulations, *Yogaraj guggulu*, *Gandharvahasta taila*, and *Dhanwantara taila*, in the management of osteoarthritis knees.

## MATERIALS AND METHODS

An open label, multicenter, noncomparative, prospective, and pragmatic trial was used. The clinical trial was carried out at three peripheral institutes of Central Council for Research in Ayurvedic Sciences (CCRAS). Prior to commencement of the study, ethical clearance was obtained separately by each institute from the Institutional Ethical Committee on 8th March 2013 (F. No. 6-21/2012-ACRI/Tech/IEC). The study was conducted in accordance with Schedule Y of Drugs and Cosmetics Act, India, amended in 2005 and Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human participants, adopted from World Medical Association (WMA)—Declaration of Helsinki. The trial had been registered in the clinical trial registry of India (CTRI/2016/01/006552).

### Inclusion Criteria

- Patients of either sex aged between 35 years and 65 years.
- Patients of primary OA knees (unilateral/bilateral) as per at least three of the following American College of Rheumatology (ACR) clinical categories of diagnostic criteria, i.e., (i) crepitus on active motion, (ii) <30 minutes of morning stiffness, (iii) bony tenderness, (iv) bony enlargement, and (v) no palpable warmth.
- Radiographical changes as per grades I to III of the Kellgren and Lawrence radiological scale.
- Able and willing to participate and provide signed informed consent.

### Exclusion Criteria

- Patients with the grade IV Kellgren and Lawrence radiological scale.

- History of any trauma/fractured joint/surgical/diagnostic intervention with reference to the affected joint(s).
- Patients with comorbidities, such as gouty arthritis, rheumatoid arthritis, and psoriatic arthritis.
- Patients having any deformity of knees, hips, or back altering the gait and posture of the patient.
- Any unstable cardiovascular disease.
- Patients with diabetes mellitus HbA<sub>1c</sub> >6.5%.
- Any other chronic systemic illness.
- Patients with evidence of malignancy.
- History of knee arthroscopy/knee replacement surgery.
- Patients with concurrent hepatic disorder (defined as aspartate amino transferase (AST) and/or alanine amino transferase (ALT) >2 times the upper normal limit or renal disorders (defined as serum creatinine > the upper limit of the laboratory value), pulmonary dysfunction (bronchial asthma and/or chronic obstructive pulmonary disease [COPD]).
- Patients administered with any chondroprotective drugs, intra-articular injection into the affected joint, or systemic medication with corticosteroids during the preceding 3 months.
- Pregnant/lactating women.
- Patients with an acute mental disorder.
- Patients who are currently participating in any other clinical trial.

Any other condition which the principal investigator thinks may jeopardize the study.

### Trial Interventions

- *Yogaraj guggulu*—500 mg (thrice a day) orally (crushed into powder) with lukewarm water after food for 12 weeks
- *Gandharvahasta taila*—6 mL orally with lukewarm water just before bedtime for 12 weeks
- *Dhanwantara taila*—20 mL locally for 12 weeks (twice a day)

### Procurement of Drugs

Trial drugs were procured from good manufacturing practice (GMP) certified company—Indian Medicine Pharmaceutical Corporation Limited (IMPCL), Mohan, Almora district, Uttaranchal.

### Primary Outcome Measures

Any changes in the total Western Ontario and McMaster University osteoarthritis (WOMAC)<sup>6</sup> score from baseline to the end of 4th, 8th, 12th, and 16th week.

## Secondary Outcome Measures

- Assessment of the changes in symptoms of *Sandhi Vata* (such as joint pain and stiffness, restricted movement of joints, crepitus in joints, swollen joints, and bony tenderness of joints) from baseline to the end of the 12th week.
- Assessment of the quality-of-life by using the World Health Organization Quality-of-Life (WHOQOL) BREF<sup>7</sup> scale questionnaire from baseline to end of 12th week.

## Study Procedures

Patients approaching the outpatient department and having pain in knee joint/s were screened for the study. The participant was explained adequately about the study. All subjects of this study were also provided a patient information sheet and consent form describing this study and providing sufficient information to make decision about their participation in this study. The voluntary written consent was obtained from each participant, and the patients were informed that all trial results recorded will be treated in strict confidence.

After clinical assessment, the patients were sent for laboratory investigations and X-ray of the most affected knee joint. Thereafter, the patients were assigned into a single group taking into consideration the inclusion and exclusion criteria. Their complete medical history and demographic data were recorded in a specially designed case record form (CRF). Physical examination and clinical assessment of all the subjects were carried out and recorded in the CRF. The 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 joints. The subject's answers were graded on a quantitative scale (0 = none, 1 = mild, 2 = moderate, 3 = severe, and 4 = extreme). The maximum possible WOMAC score was 96 (pain = 20, stiffness = 8, and physical function = 68). The QOL was assessed by using the WHOQOL BREF questionnaire.

Study medicines for 4 weeks were dispensed and the subjects were advised to return empty containers of trial medicines on every follow-up visit in order to check the drug compliance.

## Follow-up Assessment

The subjects were called every fourth week for twelve weeks (i.e., 28th, 56th, and 84th day) to ensure the drug compliance, to give them study medication for the next 4 weeks and to enquire whether there was any adverse effect. The follow-up was done at the end of the 16th week to see the long-term effects of the treatment.

## Laboratory Investigations

Laboratory parameters, such as liver function tests (LFT), renal function tests (RFT), complete blood count (CBC), erythrocyte sedimentation rate (ESR), hemoglobin (Hb)%, rheumatoid (RA) factor, glycosylated hemoglobin (HbA1c)%, and digital X-ray, of the most affected knee joint were done at baseline. All the laboratory investigations except HbA1C%, X-ray, and RA factor were done at the end of the 12th week also.

## Statistical Analysis

The data collected at baseline, mid treatment, and after the treatment were tabulated and analyzed by using appropriate statistical methods. Clinical symptoms, subjective parameters, and laboratory parameters were subjected to univariate and multivariate analysis using statistical package for social sciences (SPSS), 15.0 version, with appropriate statistical methods.

## RESULTS

### Demographic Profile of Study Subjects

The study was conducted on 120 subjects (40 in each center). Out of these, 111 subjects completed the study, 9 dropped out, and the imputation technique was applied on 4 cases. The data of four subjects were taken for analysis along with the data of the completed cases by the last observation carried forward method for intention-to-analysis.

Maximum numbers of subjects (52.5%) were found to be in the age group of 46–55 years followed by 26.1% in the age group of 35–45 years. It was found that females (81.7%) were more sufferers than males (18.3%). A literacy rate of 89.6% was recorded among the total number of patients. Maximum numbers of subjects were house wives (67.0%) followed by 20% subjects involved in field work with physical labor. Among the total subjects, 82.6% were above the poverty line. The majority of the subjects (63.5%) were urban followed by rural (33.0%). Maximum numbers of subjects were Hindus (85.2%) followed by Muslims (12.2%). About 75.7% were nonvegetarians while 24.3% were vegetarians. According to the available data, 82.6% of the subjects were having no addiction while 14.8% were addicted to tobacco chewing. It was found that 75.7% of the subjects had normal sleep and 80% had regular bowel habit. The average emotional stress was observed in 53% of the subjects whereas moderate emotional stress was noted in 39.1% of the subjects. The mean body weight was  $65.54 \pm 10.956$  kg, the height was  $156.33 \pm 8.013$  cm, and BMI was  $19.3028 \pm 11.44379$  kg/m<sup>2</sup>. It was observed that the maximum numbers of subjects

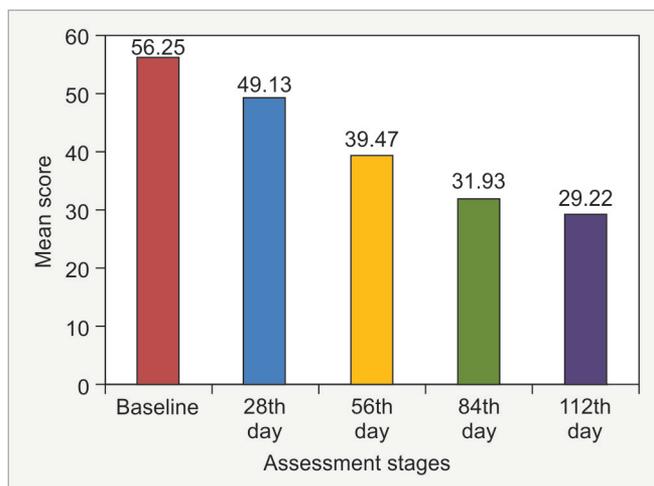
**Table 1:** Demographic profile and baseline characteristics of study subjects (n = 115)

Variables	n (%)
<b>Age (in years)</b>	
35–45	30 (26.1)
46–55	60 (52.2)
56–65	25 (21.8)
<b>Gender</b>	
Male	21 (18.3)
Female	94 (81.7)
<b>Educational status</b>	
Illiterate	12 (10.4)
Read and write	103 (89.6)
<b>Habitat</b>	
Urban	73 (63.5)
Semiurban	4 (3.5)
Rural	38 (33)
<b>Economic status</b>	
Above poverty line	95 (82.6)
Below poverty line	20 (17.4)
<b>Occupation</b>	
Desk work	15 (13.0)
Fieldwork with physical labor	23 (20.0)
Housewife	77 (67.0)
<b>Dietary habits</b>	
Vegetarian	28 (24.3)
Nonvegetarian	87 (75.7)
<b>Religion</b>	
Hindu	98 (85.2)
Muslim	14 (12.2)
Christian	3 (2.6)
<b>Addiction</b>	
Smoking	2 (1.7)
Tobacco	17 (14.8)
Alcohol	1 (0.9)
None	95 (82.6)
<b>Sharirika Prakriti</b>	
Vataj	5 (4.3)
Pittaj	20 (17.4)
Kaphaj	1 (0.9)
Vata-Pittaja	43 (37.4)
Vata-Kaphaja	7 (6.1)
Pitta-Kaphaja	33 (28.7)
Sama	6 (5.2)

were of *Vata-Pittaja Prakriti* (37.4%) followed by *Pitta-Kaphaja Prakriti* (28.7%) (Table 1).

### Effect of the Drugs on Outcome Measures on the Total WOMAC Score

The mean total WOMAC score was found to reduce subsequently from baseline to 28th, 56th, and 84th day (Fig. 1). A significant reduction in the mean total WOMAC score ( $p < 0.001$ ) was observed after 12 weeks of treatment and



**Fig. 1:** Effect of therapy on the total WOMAC score

also at the end of the 16th week in comparison to baseline (paired *t* test) (Table 2).

### Effect of the Drugs on Chief Complaints of the Study Subjects

Significant improvement in cardinal features of OA knees, i.e., joint pain and stiffness, restricted movement of joints, crepitus in joints, bony tenderness of joints, etc., was observed at the end of therapy (84th day) and follow-up (112th day) in comparison to baseline (McNemar test) (Table 3).

### Effect of the Drugs on the QOL of the Subjects

The mean QOL score assessed by the WHOQOL BREF scale improved from baseline to the end of the treatment (84th day) and follow up (112th day) (Fig. 2). The improvement in the QOL score was found on all the four domains of QOL viz. physical health, psychological health, social relationships, and environment and was highly statistically significant ( $p < 0.001$ ) (paired *t* test) (Table 2).

### Effect of the Drugs on Safety Laboratory Parameters

It is observed that safety laboratory parameters, such as the total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), LFT, and RFT, were not changed significantly from baseline to the end of the treatment (Table 4).

## DISCUSSION

*Sandhigata vata* (OA), described under *Vata vyadhi* (diseases arising due to humor *Vata*) in Ayurveda,<sup>8</sup> requires the proper line of treatment of *Vata dosha*, such as *Snehana* (oleation), *Swedana* (fomentation), and *Mridu*

**Table 2:** Effect of treatment on outcome parameters (n = 115)

Parameters	Baseline	84th day	112th day	<sup>§</sup> t value	*p value
Total WOMAC score	56.25 ± 14.45	31.93 ± 14.56	29.22 ± 17.84	21.382	<0.001
WHOQOL-BREF Score					
Domain 1 (physical health)	43.60 ± 13.10	62.98 ± 12.45	63.60 ± 16.44	15.063	<0.001
Domain 2 (psychological)	48.60 ± 12.20	58.17 ± 13.06	58.48 ± 14.40	8.794	<0.001
Domain 3 (social relationships)	64.16 ± 13.96	65.97 ± 13.60	66.25 ± 13.83	4.058	<0.001
Domain 4 (environment)	58.50 ± 11.80	62.43 ± 12.20	62.76 ± 62.80	6.292	<0.001

Values are reported as mean ± SD

<sup>§</sup>Compared using the paired t test at baseline and 84th day

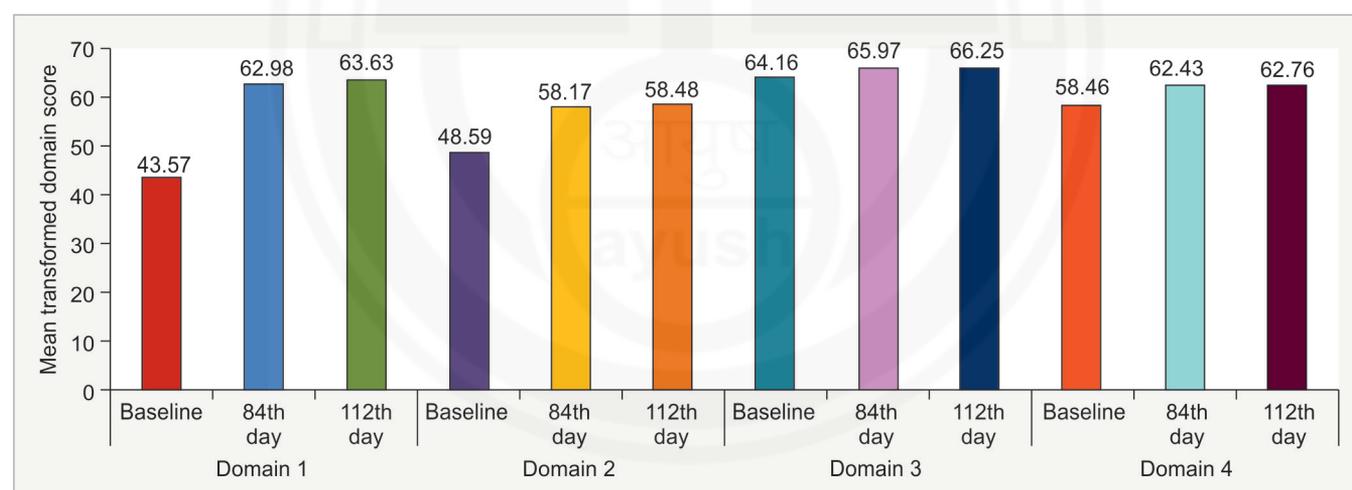
\*p value <0.05 has been considered as significant

**Table 3:** Effect of treatment on chief complaints

Chief complaint	n (baseline)	n (84th day)	% of relief	p value	n (112th day)	% of relief	*p value
Joint pain at rest	87	10	88.5	<0.001	14	83.9	<0.001
Joint pain on movement	115	99	13.9	–	85	26.1	<0.001
Restricted movement of joint(s)	104	53	49.03	<0.001	41	60.6	<0.001
Joint stiffness	113	54	52.2	<0.001	55	51.33	<0.001
Crepitus/crunching in the joint(s)	115	107	6.9	0.008	104	9.6	0.001
Weakness of affected joint(s)	83	36	56.6	<0.001	35	57.8	<0.001
Swollen joint(s)	48	23	52.1	<0.001	21	56.2	<0.001
Bony enlargement of the joint	4	4	0	–	4	0	–
Bony tenderness	109	81	25.7	0.000	64	41.3	0.000
Palpable warmth of the affected knee joint	8	1	87.5	0.016	3	62.5	0.125

Compared using the McNemar test

\*p value <0.05 has been considered as significant

**Fig. 2:** Effect of therapy on the WHOQOL-BREF score

*samshodhana* (mild purgation)<sup>9</sup> along with *Shamana* therapy (palliative treatment). In *Sandhigata Vata*, there is aggravation of *Vata dosha* and *kshaya* (decrease) of *Kapha dosha* (*Shleshaka Kapha*). The aggravated principle of *Vata* brings *rukshata* (dryness), *laghutva* (lightness), *saushirya* (porosity), and *kharatva* (coarseness)<sup>10</sup> into the joints. It destroys the structure and function of the joints. Oil used in *Abhyanga* (massage) has *Snigdha* (unctuous), *Guru* (heavy), and *Mridu* (soft) properties which are opposite to the properties of *Vata*. *Abhyanga* alleviates the provoked *Vata* responsible for the degeneration and manifestation of features of

pain and stiffness. It brings the *Kapha dosha* to the normal state. Moreover, *Abhyanga* of *Taila* stimulates local blood circulation. The ingredients of *Dhanwantara taila* have *Vata* pacifying *Brihmana* (nourishing) properties. It is indicated in *Vata roga* and *Dhatu kshaya* (degeneration of tissues).<sup>11</sup>

*Gandharvahasta taila* causes *Mridu virechana* (mild purgation). It cleanses the *Srotas* (body channels), which improves the nourishment to body tissues. It helps in restoring the normal path (*Anuloma gati*) of *Vata*. *Gandharvahasta taila* contains *Eranda beej* (seed of *Ricinus Communis* L.) as one of the ingredients. *Eranda* is *madhura*

**Table 4:** Effect of the drugs on safety laboratory parameters

Laboratory parameters	Baseline	84th day	t value	*p value
Blood urea (mg/dL)	21.8 ± 5.5	21.7 ± 5.60	0.211	0.833
Serum uric acid (mg/dL)	4.97 ± 1.2	4.9 ± 1.30	0.469	0.640
Serum creatinine (mg/dL)	0.8 ± 0.13	0.82 ± 0.20	1.104	0.272
Serum glutamic-oxaloacetic transaminase (AST) (IU/L)	24.5 ± 8.60	24.2 ± 8.80	0.429	0.669
Serum glutamic-pyruvic transaminase (ALT) (IU/L)	25.1 ± 10.8	25.3 ± 11.3	0.135	0.893
Total protein (g/dL)	7.27 ± 0.60	7.23 ± 0.50	0.746	0.457
Serum albumin (g/dL)	4.34 ± 0.33	4.3 ± 0.30	0.220	0.826
Serum globulin (g/dL)	2.94 ± 0.70	2.9 ± 0.60	0.802	0.424
Conjugated bilirubin (mg/dL)	0.34 ± 0.15	0.3 ± 0.10	4.062	0.000
Unconjugated bilirubin (mg/dL)	0.36 ± 0.21	0.35 ± 0.21	0.490	0.625
Serum alkaline phosphatase (IU/L)	77.23 ± 28.1	77.07 ± 29.82	0.130	0.897

Values are reported as mean ± SD

\*p value <0.05 has been considered as significant

(sweet), *snigdha* (unctuous), and *ushna* (hot) in properties, which are opposite to *Vata dosha*.<sup>12</sup> It has anti-inflammatory and analgesic properties.<sup>11</sup> *Eranda beej* has *Vibhedana* (purgative), *Srotoshodhana* (channel cleansing), and *Anulomana* (the direction of *Vata* in the right path) actions.<sup>13</sup> Acharya Charaka described it under *Bhedaniya* and *Angamardaprashamana* groups.<sup>14,15</sup> *Eranda taila* is indicated for *Mridu virechana* in *Vata vyadhi chikitsa*.<sup>13</sup> *Sunthi* (*Zingiber officinale* Roscoe), one of the ingredients of *Gandharvahasta taila*, is *Ushna*, *Snigdha*, and *Pachaka* (digestive). It pacifies *Vata* and *Kapha* and has analgesic and anti-inflammatory properties.<sup>16</sup>

*Yogaraj guggulu* alleviates all the three *Doshas* and has *Rasayana* (rejuvenative) action. It is indicated in the management of all *Vata rogas*.<sup>17</sup> *Guggulu* possesses anti-inflammatory and analgesic actions. It prevents degenerative changes in bones and joints. It reduces inflammation, pain, and stiffness of joints.<sup>18</sup> Earlier pharmacological studies on *Guggulu* have established its anti-inflammatory and anti-arthritis activities in formaldehyde-induced arthritis, in albino rats.<sup>19</sup> A study, presented at the ACR, has shown that herbal Ayurvedic therapy, consisting of *Guggulu*, is equally effective in treating OA knees as a commonly prescribed medication (Celebrex) and glucosamine with fewer side effects. In addition, *Guggulu* has been shown to be a potent inhibitor of the enzyme, Nuclear Factor Kappa-light-chain-enhancer of activated B cells (NFkB), which regulates the body's inflammatory response. There are several studies that show decreased inflammatory joint swelling after administration of the extracts of the *Guggulu* resin.<sup>20,21</sup>

In the present study, highly significant improvement was found in joint pain, joint stiffness, and the QOL. The improvement remained steady at the end of the follow-up without treatment. This shows the long-term effect of the treatment. The Ayurvedic formulations had no adverse consequences on liver and kidney functions during the

study as evident from safety parameters. The drug was well tolerated by the majority of the patients.

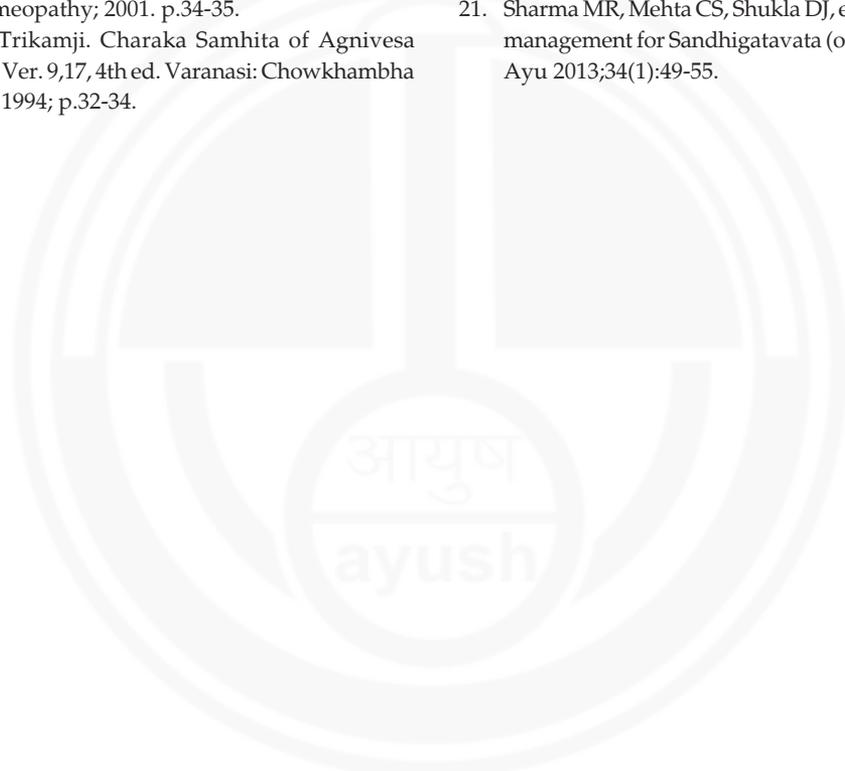
## CONCLUSION

The Ayurvedic formulations, *Yogaraj guggulu*, *Gandharvahasta taila*, and *Dhanwantara taila*, are safe and significantly reduce joint pain, joint stiffness, and improves the QOL. The present study reveals that Ayurvedic treatment according to the line of treatment of *Vata* provided highly significant relief from OA of knee joints. The improvement remained steady even after four weeks of the completion of treatment. This shows the efficacy and long-term benefits of the treatment.

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## हिंदी सारांश

### योगराज गुग्गुलु, गन्धर्वहस्त तैल व धान्वंतर तैल का जानुसंधिगतवात में चिकित्सात्मक अध्ययन

दीपा माखीजा, दिनेश बरुआ, पी राधाकृष्णन, वी सी दीप, शारदा ओता, तापसी बोरा, रिचा सिंघल, श्रुति खण्डूड़ी, भगवान सहाय शर्मा, भारती गुप्ता, नारायणम श्रीकांत

**भूमिका:** संधिगतवात एक धातुक्षयजन्य संधिरोग है। दुनियाभर में यह विकलांगता का चौथा प्रमुख कारण है। यह विकलांगता अधिकांश जानु या वंक्षण संधि के प्रभावित होने के कारण पायी जाती है।

**उद्देश्य:** योगराज गुग्गुलु, गन्धर्वहस्त तैल व धान्वंतर तैल के प्रभाव को जानुसंधिगतवात रोगियों में अध्ययन करना।

**साधन एवम विधि:** यह एक बहु केंद्रीय अध्ययन है जो कि केंद्रीय आयुर्वेदिक अनुसंधान परिषद के तीन केन्द्रों पर १२० रोगियों में चयन प्रक्रिया के अनुसार बहिरंग विभाग में किया गया तथा इन रोगियों को योगराज गुग्गुलु ५०० मिग्रा दिन में तीन बार खाने के बाद, गन्धर्वहस्त तैल ६ मिली रात में व धान्वंतर तैल दिन में दो बार बाह्य प्रयोगार्थ १२ सप्ताह तक दिया गया। साथ ही रोगियों को बिना औषधि दिये १२ सप्ताह के पश्चात ४ सप्ताह तक और निरीक्षण किया गया। १२० में से केवल ११५ रोगियों के आकड़ों का ही आंकलन किया गया।

**परिणाम:** १२ सप्ताह होने पर वोमेक स्कोर एवम संधिगतवात के लक्षणों में प्रभावकारी परिणाम पाया गया यकृत एवम वृक्क के कार्य पर किसी भी प्रकार का हानिकारक परिणाम नहीं पाया गया। इसके अंतर्गत कोई भी दुष्प्रभाव नहीं प्राप्त हुआ।

**निष्कर्ष:** योगराज गुग्गुलु, गन्धर्वहस्त तैल व धान्वंतर तैल के जानुसंधिगतवात की चिकित्सा में प्रभावकारी एवम सुरक्षित परिणाम प्राप्त हुए।