

**CURRENT RESEARCH TRENDS IN MANAGEMENT OF SANDHIGATA VATA**¹Saroj Devi

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Received on 11/07/2016*Accepted on* 12/05/2016*Published on* 19/07/2016**ABSTRACT**

Musculoskeletal disorders are the common cause of disability in world. Further, among these disorders *Sandhigata Vata* (osteoarthritis) is the most common joint disorder. In allopathic system of medicine, the management mainly based on symptomatically relief of painful conditions, but still there is need for such therapeutic regimen that could retard the disease progression. Until now, no such regimen is present. For the search of such agents, Herbal remedies and dietary supplements have become an important area of research and clinical practice in orthopedics and rheumatology. In Ayurveda, *Sandhigata Vata* described under *Vata Vyadhi*. This disease occurs by vitiation of *Vata Dosha*. Symptomatically *Sandhigata Vata* is much close to osteoarthritis (OA). This review framed to discuss the recent advancement in use of Ayurvedic drugs for management of osteoarthritis. Several Ayurvedic drugs used by physicians to treat osteoarthritis demonstrated significant biological and immunological effects in clinical drug trials, hence providing a new platform for development of new effective treatment regimens and better patient care. Main aim of this review article is to find out such evidence-based medicine so that we can have a way for further studies

Keywords: *Sandhigata Vata*, osteoarthritis, *Zingiber officinale*, *Boswellia serrata*, *Tinospora cordifolia*, *Withania somnifera*

INTRODUCTION

Ayurveda is a holistic ethical medicine system. It is being practiced in Indian subcontinent for thousands of years. This traditional medicine system mainly based on experience and firm clinical evidences and uses herbs, minerals and animal product for therapeutic purpose. Ayurveda approaches each individual as different entity and follows the basic principal of maintaining harmony among three *dosha* of the body. According to this system, no two persons are alike and hence their management is different according to their body constitutions. Many of chronic diseases are managed and treated by these ancient treatment modalities, *Sandhigata Vata* (osteoarthritis) is one of them. *Sandhigata Vata* is described in *Charaka samhita* under *Vata vyadhies*.¹ (chapter describing diseases of *Vata* dosh vitiation). Later more or less the same description is found in various texts. Osteoarthritis (OA) is the most common joint disorder among all musculoskeletal disorders. According to WHO musculoskeletal and rheumatic disorders are the leading cause of disability in present world.² A high prevalence of OA among older people and women and its moderate to severe impact on daily life poses a significant public health problem. Limitation of conventional system of medicine in management of these disorders indicates a strong need to find out other safer and effective measures; here Ayurvedic medicine may provide a possible solution. In modern system of medicine, the pharmacological management is limited to symptomatic relief of painful conditions³ and hence there is strong need of such treatment modalities, which could retard cartilaginous degeneration and disease progression. Many of research scholars of Ayurveda are working toward this goal. This review is to compile all such research work done and to find out a combined

approach for better management of disease via Ayurvedic medicines.

MATERIAL AND METHODS

Identification of clinical trials

Thirty-eight papers collected for review purpose from computer literature and three from library of institute of medical sciences Banaras Hindu University. Computer database used were Medline, Springer India, Biosis, Oxford journals, eCAM, IJAR, JAIM, AYU etc. Manual search for additional trials then performed through various computer search engines.

Inclusion criteria

1. Study should be a randomized control trial involving any herbal or herbo-mineral compound.
2. Study should advocate efficacy of Ayurveda.
3. Study involving human subjects with osteoarthritis.
4. Study published in peer-reviewed journal and should be in English language.

Exclusion criteria

1. Studies done on such herbal drugs not found in Indian subcontinent and not a part of Ayurvedic system are excluded.
2. Animal based model studies.
3. Trial lacking essential methodological details

Data extraction and quality assessment

Data related to sample size of study; study design, interventions used, primary outcome, results etc. recorded in tabular form for easy understanding of the articles. Methodological quality of articles are validated by jaded scoring system.⁴

After evaluating articles on above criteria, a total of 12 research articles and 2 review articles selected for the study.

Results

Lakshadi guggulu

A clinical trial was done by Sharma *et al* to evaluate role of *Lakshadi guggulu*, *kalka patra bandhan* and knee traction in management of osteoarthritis.⁵ The study was open label clinical trial with sample size of 10 patients. Diagnosis made on clinical and radiological basis. Assessment criteria were severity of pain, deep grading of tenderness, walking distance and degree of flexion of knee joint. *Lakshadi guggulu* was given in *vati* form at dosing of two *vati* twice daily, with *anupana* of hot milk or hot water for 28 days. *Kalka patra bandhan* and traction therapy were also used as adjuvant to the *Lakshadi guggulu*. Results showed a significant ($p < 0.001$) decrease in symptoms of disease. Maximum effect (76%) was observed in deep grading of tenderness.

Shunthi (Zingiber officinale), *Guduchi (Tinospora cordifolia)*, *Amalaki (Emblia officinalis)*, *Ashwagandha (Withania somnifera)*, *Gokshur (Tribulus terrestris)* in various combined dosage forms

A. Chopra *et al* did a randomized, double blind, placebo controlled, metacentric trial of 16-week duration under NMITLI (New Millennium Indian Technology Leadership Initiative) project.⁶ Sample size consists of 245 patients, randomized into seven arms (35 patients in each arm). Five oral formulations (coded as A, B, C, D, and E) with a common base of *Zingiber officinale* and *Tinospora cordifolia* with maximum of 4 plant extract were evaluated. Clinical evaluation was done on basis of active pain VAS (Visual Analog Score) and WOMAC

(Western Ontario and McMaster Universities Arthritis Index). Amongst all the groups, “C” formulation (containing *Shunthi* 1000mg + *Guduchi* 220mg + *Amalaki* 500mg) showed the best response in reducing pain. There was no statistically significance difference in the mean changes from baseline to completion in active-pain VAS and WOMAC index between the groups. “C” arm also demonstrated least consumption of oral paracetamol tablet as rescue drug. “C” arm also showed best efficacy in comparison to placebo and Glucosamine sulphate. Mean RIDIT (relative to identified distribution) analysis of “C” versus placebo was 0.652 and “C” versus Glucosamine sulphate was 0.618. “C” formulation also recorded a comparatively lesser frequency of adverse effects related to abdominal symptoms. “C” formulation was chosen for further development and validation.

Matra Vasti

A randomized clinical trial done by Mayuri R. Shah *et al* shown the effect of *Matra Vasti* in *Sandhigata vata* (osteoarthritis).⁷ Study consists of 35 patients, divided into 2 groups. One group was treated with *sarvanga abhyanga-Swedana* + *Matra Vasti* and other with *sarvanga abhyanga-Swedana* + *Matra Vasti* + indigenous compound drug. *Matra vasti* was given with 60 ml of *Bala tail* (oil of *Sida cordifolia*) for 3 weeks at 3 days interval. Results obtained were highly significant in reduction of pain scores, joint swelling, pain in extension flexion and walking time. Complete remission was observed in 43.75% of cases in group A and 23.52% in group B.

Lepidium sativum (chandrashura)

Nita D. Rawal and T.N. Pandya conducted a randomized placebo controlled clinical trial on *Lepidium sativum* (*Chandrashura*) in the management of *Sandhivata*.⁸ Seed powder of *Lepidium sativum* was given in a dose of 6gm per day in two divided doses for 30 days. The results obtained were highly significant ($p < 0.001$) for cardinal symptoms of *Sandhivata*. No major adverse effects were noticed during the study.

***Shunthi* (*Zingiber officinale*) and *Guduchi* (*Tinospora cordifolia*) based drugs.**

A study was done under NMITLI arthritis project to evaluate higher doses of *Shunthi-Guduchi* based drugs in osteoarthritis knees.⁹ *Shunthi-Guduchi* was taken as base drugs and when these are combined with *Amalaki* (*Embllica officinale*) and administered with *Bhallataka Parpati* shown a marked decrease in joint pain.

Another study was done by Zahra Zakeri *et al* to evaluate effect of ginger extract on knee pain, stiffness and difficulty in osteoarthritis knee.¹⁰ Patients treated with ginger extract showed a significant reduction in pain VAS ($p < 0.05$) as compared to placebo group. Reduction in morning stiffness and difficulty were also greater in ginger group ($p < 0.05$). Although there was reduction in pain according to WOMAC score but the results were not statistically significant. Similar study done by Anousheh Haghighi *et al* compared ginger extract with indomethacin^[11] and shown that both drugs have significant reduction in pain scores and WOMAC scores and ginger can be used as safe alternative to non-steroidal anti-inflammatory drugs in knee osteoarthritis.

RA-11, a standardized multiple Ayurvedic drug

A randomized, double blind, placebo controlled study was done by A. Chopra *et al* to evaluate efficacy and safety of RA-11 which was an Ayurvedic drug consisting of *Withania somnifera*, *Boswellia serrata*, *Zingiber officinale* and *Curcuma longa*.¹² When compared with placebo the mean reduction in pain in active group was significantly better. This controlled drug trial demonstrated the potential efficacy and safety of RA-11 in symptomatic treatment of osteoarthritis knee.

Articulin-F

Articulin-F, an Ayurvedic herbomineral formulation containing *Withania somnifera* root (450mg), *Curcuma longa* rhizome (50mg), *Boswellia serrata* gum resin (100mg) and Zinc (50mg) was clinically evaluated by Kulkarni *et al*.^[13] 42 patients were randomized into two groups in which first group is given two capsule of formulation and other received identical placebo. Treatment with this formulation significantly improved the severity of pain ($p < 0.001$) and disability score ($p < 0.05$). Morning stiffness, grip strength etc. also improved but not up to significant levels.

Boswellia serrata extract

Boswellia serrata gum (*Salai guggulu*) was evaluated for its anti-inflammatory and anti-arthritic activity by N. Kimmatkar *et al*.¹⁴ A randomized, double blind, placebo controlled study was done on 30 patients. Two groups of 15 patients each were designed and given either *Boswellia serrata* extract (333mg) or placebo drug, 3 times a day for 8 weeks. Decrease in

severity of pain and improvement in loss of function were statistically significant ($p < 0.001$) in the group treated with *Boswellia* extract as compared to placebo.

Another study was done by Sontakke S, V. Thawani *et al* to compare efficacy of *Boswellia serrata* extract with Valdecoxib in osteoarthritis knee.¹⁵ This randomized open label trial consists of two groups of 33 patients each. Group 1 received *Boswellia* extract (333mg) three times a day and group 2 received Valdecoxib 10mg once a day for total duration of 6 months. Results showed decrease in WOMAC score in both groups up to significant levels. Valdecoxib group showed early lowering in WOMAC as compared to group treated with *Boswellia* extract but WOMAC score in *Boswellia* extract treated group remained persistently lower even after 1 month of discontinuation of therapy. No such post treatment effects noticed in Valdecoxib treated group.

Combination of Guggulu, Ashwagandha and Madhuyasti

We have conducted a similar trial to evaluate the role of selected Rasayana in

management of janu sandhigata vata (Osteoarthritis of knee joint). This study was single blind prospective cross sectional clinical trial conducted in Sir Sunderlal hospital, Banaras Hindu University. Total 100 patients were selected for trial and randomly divided into 4 groups. Ethical clearance was taken from institute ethical committee and an informed consent was acquired from all the patients under this trial. Patients of Group 1 were advised to take 500mg tablet of Glucosamine sulphate once a day for continuous 3 months. In Group 2 patients were advised to take 1 capsule of pure Guggulu two times a day. Patients in Group 3 had taken 2 capsules of Rasayana A+B (Guggulu + Yastimadhu), two times a day for three months. Similarly in Group 4, patient had taken 2 capsules of Rasayana A+C (Guggulu + Ashwagandha), two times a day for three months. We have observed that all the four groups yielded statistically significant results but patients in group 4 who have taken guggulu and Ashwagandha have shown a better clinical outcome in sign and symptoms of the disease.

Tabular presentation of review data:

Table no. 1

S. No.	Jadad Score	Sample size	Study design	Interventions/control	Primary outcome Criteria	Main result
1.	05	245	Double blind, placebo control, parallel group, multicenter.	1. <i>Shunthi</i> (<i>Zingiber officinale</i>) 100mg 2. <i>Guduchi</i> (<i>Tinospora cordifolia</i>) 220mg 3. <i>Amalaki</i> (<i>Emblica officinalis</i>) 500mg 4. <i>Ashwagandha</i> (<i>Withania somnifera</i>) 600mg 5. <i>Gokshur</i> (<i>Tribulus terrestris</i>) 216mg 6. Glucosamine sulphate 7. Placebo	1. Active pain VAS, 2. WOMAC index scores, 3. WOMAC difficulty scores.	'C' arm showed best efficiency in comparison to Placebo and Glucosamine sulphate. 'C' versus Placebo Mean RIDIT value was 0.652. Z score = 2.185 P value = 0.029 C' versus Glucosamine sulphate Mean RIDIT value was 0.618 Z score = 2.185 P value = 0.090
2.	02	35	Randomized	Group A - <i>Matra basti</i> with	1. Five	Highly significant values

			clinical trial	60ml <i>bala tail</i> for 3 weeks at 3 days interval. Group B – <i>Matra basti</i> (3 weeks) along with indigenous compound drug for 4 weeks.	point Pain score. 2. Four point X-ray examination score.	($p < 0.001$) in various scores of joint swelling, <i>akunchana prasarana vedana</i> (pain in extension flexion) and walking time. Complete remission in 43.75% of patients in Group A and 23.52% in Group B.
3.	02	98	Randomized placebo controlled.	Group D -52 patients given <i>Lapidum sativum</i> seed powder 6gm/day q 12hr for 30 days. Group C –placebo (starch) 2 capsules BD for 30 days.	<i>Sandhivata</i> pain score grading and total effect of therapy.	Complete remission of disease symptoms in 30% cases of group D and 05.26% of group C. Highly significant ($p < 0.001$) relief was observed in symptoms of <i>Sandhishoola</i> , <i>Sandhigraha</i> , <i>Sandhishotha</i> , and <i>Sparshasahyata</i> , in Group D.
4.	03	92	Randomized, blind, parallel efficiency, 4 arm, multicenter trial.	<u>Group I-</u> <i>Guduchi</i> -330mg <i>Ashwagandha</i> -900mg <i>Gokshura</i> -324mg <i>Sunthi</i> -1500mg <u>Group II-</u> <i>Guduchi</i> -440mg <i>Ashwagandha</i> -1200mg <i>Gokshura</i> -432mg <i>Shunthi</i> -2000mg <u>Group III</u> <i>Sallaki guggul</i> -2000mg <i>Shunthi</i> -1000mg <i>Guduchi</i> -220mg <u>Group IV</u> <i>Bhallataka parpati</i> -1125mg + <i>Shunthi</i> 1500mg, <i>Gokshura</i> 330mg, <i>Ashwagandha</i> 750mg	VAS WOMAC Index WOMAC difficulty Index.	
5.	05	90	Randomized Double blind, placebo controlled, parallel group, single center trial	<u>Group I</u> 2 capsules of RA11 twice daily <u>Group II</u> 2 capsules placebo twice daily for 32 weeks	VAS WOMAC Index WOMAC difficulty Index Likert scale	The mean reduction in pain VAS at 16 week Active group- 2.70 Placebo group- 1.30 At 32 Week- Active group- 2.80 Placebo group- 1.80
6.	03	42	Double blind, crossover, placebo controlled	Articulin F (Roots of <i>Withania somnifera</i> , stem of <i>B. serrata</i> , Rhizome of <i>C. longa</i> and zinc complex) and placebo every 8 hrs. for 3 months	Severity of pain, Morning stiffness score, grip strength, disability score	Articulin F improved pain severity and disability scores significantly
7.	03	204	Double blind placebo controlled randomized clinical trial	2 Groups Group 1- <i>Ginger</i> extract 250 mg 1 cap. BD for 6 weeks Group 2- Placebo 1 cap. BD for 6 months	Knee joint pain on standing, VAS index, WOMAC index, pain, stiffness	In VAS score: pain reduction was significant in <i>Ginger</i> group (mean 1.75 on standing and 2.054 on walking after treatment), WOMAC also improved significantly

					and difficulty on walking	
8.	03	56	Double blind, placebo control, double dummy, crossover study	3 Groups Group 1- <i>Ginger</i> extract 1 cap. (170mg) TDS for 21 days Group 2- Ibuprofen 400mg TDS for 21 days Group 3- Placebo 1 cap. TDS for 21 days	Pain score, VAS index	Pain relief was significant and graded as Ibuprofen> <i>Ginger</i> Extract> Placebo No significant difference between placebo and <i>ginger</i> extract.
9.	03	66	Randomized, open label, comparative study	2 groups of 33 patient each Group 1- <i>Boswellia</i> extract 333mg TDS for 6 months Group 2- Valdecoxib 10mg OD for 6 months	WOMAC Index, pain scores, difficulty in walking and stiffness scores	Decrease in WOMAC scores in both groups was statistically significant; Valdecoxib group showed early lowering in WOMAC scores but WOMAC scores in <i>Boswellia</i> extract treated group remained persistently lower even after one month of discontinuation of therapy. No such post treatment effect was shown in Valdecoxib treated group.

DISCUSSION

From this review, we found very much promising evidence which support use of these Ayurvedic drugs in management of *Sandhigata Vata*. More of the reviewed drugs are potentially useful in reducing joint pain and improved joint mobility. Most of selected studies were of good methodological quality as assessed by *Jadad scale*. Although most of the studies having drugs for oral use but one study also showed prominent evidences in support of *Vasti* treatment. Most of the studies used VAS and WOMAC index as their assessment criteria. Diagnostic criteria were also based mainly on clinical and radiological features of disease. Most of the studies have excluded traumatic arthritis from the study criteria. Most significant finding is that none of the clinical trial had shown potential side effect due to these drugs and hence can be used safely in pain management in osteoarthritis knee.

Promising evidences from many clinical trials above have shown that *Shunthi* (*Zingiber officinale*), *Guduchi* (*Tinospora cordifolia*), *Ashwagandha* (*Withania somnifera*) and *Boswellia serrata* are the most potent drugs that have good analgesic effects and may use safely in *Sandhigata Vata*. Although only one study have supported use of *Lepidium sativum* in *Sandhivata* but results obtained are promising and need to be evaluated by further studies on large sample sizes.

Incidences of adverse events for these drugs appear to very low and these drugs may provide a much-needed alternative to NSAIDs in chronic cases of osteoarthritis. Although there are hundreds of other drugs classically used in Ayurveda for management of *Sandhigata Vata* but still we need more clinical evidences in support of those drugs. This evidence recommends that all Ayurvedic medicines promoted for management of *Sandhigata Vata* require rigorous scientific scrutiny. Along with that, a long-term safety, data of these drugs

needed and we hope that in near future we can find more such evidences in support of Ayurvedic drugs. Considering the large number of people suffering from joint diseases and known adverse effects of NSAIDs we assume that this area of research in Ayurveda drugs can be a boon for those suffering from these diseases.

CONCLUSION

From above review, we may conclude that Ayurvedic drugs have a very much potential to treat osteoarthritis pain in much holistic way. We assume more such research works needed in near future so that we can find an alternative to NSAIDs with lesser adverse effects. There is strong need of scientifically approved clinical development of Ayurvedic formulations in management of *Sandhigata Vata* and these drugs can be a platform for this work. All of the studies have demonstrated a great safety profile and this is the most considerable fact in support of these drugs. We suggest for further studies done at larger sample sizes in near future so that we can have a more holistic approach to the management of this disease.

References

1. Shastri K. Chaturvedi G. ed. Charaka Samhita of Agnivesha .Vidhyotani Tika. Chapter 28 verse 37 Varanasi: Choukhambha Sanskrit Sansthan; 2007
2. Siddharth K. Das, Anand N Malvaliya, Osteoarthritis and crystal deposition disease, API Textbook of Medicine by S.N. Shah. 7th edition.
3. OARSI recommendations for the management of Hip and Knee OA. Part II, OARSI evidence based, expert guidelines.
4. Jadad AR, Moore RA, Carrol D *et al*. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control clin trial 1996; 17:1-12.
5. Sharma V, Sharma A, Kushwah HK, An indigenous approach to manage the Osteoarthritis of knee joint with Lakshadi Guggulu, Kalka-patra bandhan and knee traction. Ancient Science of Life. Vol. XXVI (3) 2007.
6. Chopra A, Saluja M, Tillu G *et al*. A randomized controlled exploratory evaluation of standardized Ayurvedic formulation in symptomatic Osteoarthritis knees: a government of India NMITLI project. Evidence Based Complimentary and Alternative Medicine, volume 2011, article ID 724291.
7. Shah MR, Mehta CS, Shukla VD, Dave AR, Bhatt NN, A clinical study of Matra Vasti and ayurvedic indigenous compound drug in management of Sandhigatavata (Osteoarthritis). AYU journal September 19, 2012 IP: 117.224.140.180
8. Neeta D Raval, Pandya TN, Clinical trial of Lepidium Sativum (Chandrashura) in management of Sandhivata (Osteoarthritis). AYU vol. 30, No. 2 (april-june) 2009.
9. Chopra A, Saluja M, Tillu G *et al*. Evaluation of higher doses of Shunthi-Guduchi formulation for safety in treatment of Osteoarthritis knees: a government of India

- NMITLI arthritis project. JAIM. September 19, 2012 IP; 117.224.140.180
10. Zakeri Z, Izadi S, Bari Z *et al*, Evaluating the effect of Ginger extract on knee pain, stiffness and difficulty in patient with knee Osteoarthritis. Journal of Medicinal Plant Research vol. 5(15), pp.3375-3379, 4 august 2011.
 11. Haghighi A, Tavalaei N, Owlia MB, Effect of Ginger on primary knee Osteoarthritis. Indian Journal of Rheumatology 2006 june, volume 1, number 1; pp 3-7.
 12. Chopra A, Lavin P, Patwardhan B, Chitre D. A 32 week randomized, placebo controlled evaluation of RA-11, an Ayurvedic drug on osteoarthritis of the knees. J. clinical rheumatology 2004; 10:236-45.
 13. Kulkarni RR, Patki PS, Jog VP, Gandage SG, Patwardhan B. Treatment of osteoarthritis with the herbo-mineral formulation: a double blind, placebo controlled, cross-over study. J ethnopharmacology 1991; 33:91-5.
 14. Kimmatkar N, Thawani V, Hingorani L, Khiyani R. Efficacy and tolerability of Boswellia serrata extract in treatment of osteoarthritis of knee- a randomized, double blind, placebo controlled trial. Phytomedicine 2003; 10:3-7.
 15. Sontakke S, Thawani V, Pimpalkhute S, Kabra P, Babhulkar S, Hingorani S, Hingorani L. Open, randomized, controlled clinical trial of Boswellia serrata extract as compared to valdecoxib in osteoarthritis of knee. Indian J Pharmacology 2007; 39:27-9.

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