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Is Ayurvedic effective in reducing osteoarthritis pain in adults?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

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Abstract

Objective: The objective of this selective EBM review is to determine whether or not Ayurvedic is effective in reducing osteoarthritis pain in adults.

Study Design: Review of three English language randomized controlled trials published between from 2004-2013.

Data Sources: Two double blind randomized controlled trials and one open label randomized controlled clinical trial were found using PubMed and Cochrane Library databases.

Outcomes Measured: To measure the effectiveness, the following parameters were utilized visual analog scale (VAS) reported by the patient to assess reduction in pain symptoms of osteoarthritis.

Results: Three randomized controlled studies results found that Ayurvedic medicine was beneficial in providing symptomatic pain relief in patients of osteoarthritis in adults.

Conclusions: The results of all three selected studies in this systemic review demonstrated that Ayurvedic provides some effectiveness in reducing osteoarthritis pain in adults when compared to conventional medications used for osteoarthritis.

Key Words: Ayurvedic medicine, Ayurveda, and Osteoarthritis

INTRODUCTION

Osteoarthritis is the most common type of arthritic disease, causing degenerative changes to the joints from everyday “wear and tear,” causing disability, pain and loss of function.^{3,4} This paper evaluates two double blind, randomized controlled clinical trials and an open label randomized controlled clinical trial comparing the efficacy of Ayurveda. For many centuries, in Eastern medicine, herbs have been used manage and treat osteoarthritis as an alternative form using conventional medicine. Ayurveda is a popular herbomineral drug in the Indian subcontinent that utilizes a holistic approach for alleviating symptoms of osteoarthritis pain in adults.^{1,2}

Approximately 27 million people in the United States have osteoarthritis. It is the leading cause of disability in non-institutionalized adults.^{4,5} Both incidence and prevalence of osteoarthritis are on the rise due to increasing age and obesity.⁵ Due to the growing populations that are effected with osteoarthritis it has a become a financial burden on both the healthcare system and patient population. The estimated average patient’s out of pocket cost is \$2,600 per year.⁴ Osteoarthritis accounts for 69.9% of all arthritis-related hospitalizations.⁴

Osteoarthritis develops gradually; however there are unknown parameters of causes, which contribute to degenerative changes resulting in an overall arthritic disease state of the joints.⁵ Osteoarthritis is characterized with following symptoms: pain, swelling, and stiffness, loss of flexibility, grating sensation, and development of bone spurs noted in radiographic images.⁶

The management of osteoarthritis requires a multidisciplinary approach.³ The use of acetaminophen, NSAIDs, narcotics, cortisone injections, engaging in physical and occupational therapy, exercise, proper weight management, and surgical options such as bone realignment and joint replacements can all help improve symptoms of osteoarthritis.^{1,2,3} Currently, there is no

cure for osteoarthritis; the above methods are utilized to help alleviate the symptoms of osteoarthritis.⁴ Due to its popular use in Eastern medicine and the growing trend for using herbal remedies, it is believed that Ayurveda may provide an alternative method of relief for osteoarthritis symptoms.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not Ayurvedic is effective in reducing osteoarthritis pain in adults.

METHODS

The criteria used for the selections of studies included the population of adult patients with osteoarthritis diagnoses with radiographic changes and an intervention of Ayurvedic medicine, with comparisons made with common conventional treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs), Celecoxib, and Diclofenac. The outcomes measured were reduction and improvement pain symptoms of osteoarthritis. The studies utilized in this systemic review included three randomized controlled trials, specifically two double blind randomized controlled clinical trials and one open label randomized controlled clinical trial.

The selections of this systemic review included a literature search using the Cochrane Library and PubMed databases and were limited search to the following keywords: “Ayurvedic medicine”, “Ayurveda”, and “osteoarthritis.” All articles were written in English and published in peer-reviewed journals between the years 2004 and 2013. All articles that were selected for this systemic review are based on their relevance to the topic and on the patient-oriented outcomes (POEMs). Inclusion criteria included that the studies selected for this systemic review were randomized controlled and either double blind or open label, adult patients with osteoarthritis pain with radiographic changes. Exclusion criteria included those patients less than 18 years of age, pregnant or lactating women. Table 1 outlines the demographics and

characteristics of the selected studies used in this systemic review. The statistics reported in the selected studies were p-values, confidence intervals (CI), ANOVA, and unpaired T-test.

Table 1 - Demographics & Characteristics of included studies

Study	Type	# pts	Age	Inclusion Criteria	Exclusion Criteria	W/D	Intervention
Chopra ¹ (2004)	Randomized controlled trial (double-blind)	358	>35 yrs	OA of knee classified via ACR and radiologic criteria. VAS \geq 40 mm. Patient on a stable dose of a NSAID. Female patients of child-bearing potential only if practicing contraception.	Pregnant or lactating women. Hx uncontrolled medical disease or abnormal renal and hepatic function. Received intra-articular corticosteroid injections in the knee joint within 3 months. Hypersensitivity to RA-11 or its components.	28	RA-11 (ARTREX, MENDAR) 2 capsules BID
Chopra ² (2013)	Randomized controlled trial (double-blind)	440	40-70 yrs	Diagnosis of knee OA with the ACR criteria. VAS score of 54 cm in one or both knees. Ambulant patients that required frequent analgesics.	Pregnant or lactating or women. Hx of non-DJD, severe disabling arthritis or spine and lower limb surgery, peptic ulcer bleed, or any unstable severe medical disease. Patients on medication that may influence efficacy evaluation.	123	Ayurvedic (SGCG) 400mg, 2 capsules TID Ayurvedic SGC 400mg, 2 capsules TID
Pengkhum ³ (2012)	Randomized controlled trial (open label)	60	\geq 50 yrs	OA diagnosed with radiographs and assessed by the Kellgren et al grading system. Patients using	Hx of severe RA inflammatory arthropathy, recent knee injury or received intra-articular	9	Ayurved Siriraj Wattana Recipe 900 mg/day

				acetaminophen for the most painful knee movement assessed by a VAS >4.	treatment. Patients that were expectation of future surgery.		
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OUTCOMES MEASUERED

Outcomes measured in the selected studies were based on patient-oriented outcomes (POEMs) of reduction in pain symptoms of osteoarthritis, at rest and during weight bearing activities. These outcomes were measure via the visual analog scale (VAS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Oxford-12, and global assessment by both the patients and physicians in the selected studies.

Both studies conducted by A. Chropra et al. utilized the visual analog scale, and WOMAC questionnaire to assess knee and/or hip pain in osteoarthritis patients. VAS assessed active pain on body weight-bearing activity, such as walking, and at rest of subjects with scores ranging from 0 for no pain and 10 for maximum pain.

Pengkhum et al. utilized the Oxford-12 questionnaire and the VAS for the assessment of function and pain of the knee in osteoarthritis patients judged by the patient. The VAS assessed pain during the most painful knee movement.

RESULTS

In the selected study conducted by Chopra et al. (2004) assessing the RA-11 (Ayurvedic) compared to a placebo taken twice a day after meals, in the treatment of patients with osteoarthritis of the knees. The study design was a randomized, double-blind, parallel efficacy and placebo-controlled trial for the duration of 32 weeks. Overall 90 subjects participated in the study and were randomly assigned that received the allocated treatments described above, and there were no significant difference between the groups. The study evaluation was made at

baseline and every week until completion of 32 weeks. Total of 28 subjects withdrew from trial. The study was presented in continuous data and intention to treat with the last observation carried out using analysis of variance (ANOVA). Active pain VAS and WOMAC pain were used to compare the two groups, with the focus on active pain VAS for RA-11 comparison to the placebo control demonstrated by Table 2.¹ The mean change in efficacy was measured at week 16 displaying the VAS for pain, for RA-11 -2.68 and placebo -1.30, with a p-value of 0.000 and for week 32, RA-11 -2.83 and placebo -1.80, with a p-value of 0.034, due to a plateau-like effect as the trial progressed.

Table 2: Mean change in efficacy at week 16 and week 32 (Mean and SD) from Chopra et al. (2004)

Variable e	Week 16 Treatment			Week 32 Treatment		
	Active	Placebo	P*	Active	Placebo	P*
VAS for pain	-2.68, (+/- 0.29)	-1.30, (+/- 0.31)	0.000	-2.83 (+/- 0.38)	-1.86, (+/- 0.36)	0.034

P analysis of variance.*

In the selected study conducted by Chopra et al. (2013) compared two standard Ayurvedic formulations (SGCG and SGC) to glucosamine (2 g daily) and Celecoxib (200 mg daily) which were given two capsules three times a day with plain water to assess effectiveness. SGCS formulation contained an additional plant extract, *B. serrata* allowing it to be of higher potency, which was not found in the SGC formulation of the Ayurvedic medicine. The study design was a randomized double-blind for the duration of 24 weeks. The study evaluation was made at baseline and weeks 2, 4, 8, 12, 16, 20 and 24. Overall 440 subjects participated in the study and were randomly assigned into four groups of 110 participants that received the allocated treatments described above, and there were no significant difference between the groups. Total of 126 (28.6%) subjects withdrew from trial. The study was presented in continuous data and intention to treat with the last observation carried out using analysis of variance (ANOVA).

Active pain VAS and WOMAC pain were used to compare the four groups, with the focus on active pain VAS for SGCS comparison to Celecoxib. Efficacy calculated that mean change of active body weight-bearing pain VAS from baseline to completion was fairly small for SGCG is -2.04 (CI 95% -2.47, -1.61) compared to Celecoxib is -1.82 (CI 95% -2.20, -1.44). The p-value is calculated at 0.21 indicating not statistically significant between SGCG and Celecoxib, as demonstrated by Table 3.²

Table 3: Efficacy from baseline to completion intent-to-treat analysis from Chopra et al. (2013)

	SGCS (Ayurvedic medicine)	Celecoxib	P (comparison, ANOVA)
Active pain VAS (mean change)	-2.04 (CI 95% -2.47, -1.61)	-1.82 (CI 95% -2.20, -1.44)	0.21

In the selected study conducted by Pengkhum et al. assessed the use of Ayurved Siriraj Wattana recipe (900 mg/day) comparing it with Diclofenac (75 mg/day), for providing symptomatic relief in patients with osteoarthritis of the knee. The study design was randomized, open-label, NSAIDs controlled trial for the duration of 12 weeks. Overall, there were 60 subjects participated in the study and were equally divided and randomly assigned to a treatment group. It was reported that 27 patients (90%) in Ayurved Siriraj Wattana recipe group and 24 patients (80%) in Diclofenac group completed the study, thus nine patients withdrew from the study. The study was presented in continuous data and statistical significant was evaluated by using unpaired T-test. VAS was utilized to assess the reduction in pain when Ayurved Siriraj Wattana recipe and Diclofenac are used at 2, 4, 8, and 12 weeks, as demonstrated by Table 4. On week 12, efficacy was calculated for VAS assessed pain the mean change for Ayurved Siriraj Wattana recipe at 4.37 compared to Diclofenac 4.42 as small, with the p-value calculated at 0.94 indicating not statistically significant.³

Table 4: Efficacy at baseline and follow-up visits from Pengkhum et al. (2012)

VAS assessed pain	Wattana (mean)	Diclofenac (mean)	95% CI	p-value
Baseline	6.63	6.58	-0.899, 0.807	0.91
Week 2	5.93	5.17	-1.594, 0.075	0.07
Week 4	5.48	5.58	-0.693, 0.896	0.79
Week 8	4.89	4.25	-1.568, 0.291	0.17
Week 12	4.37	4.42	-0.909, 0.973	0.94

For all three selected studies safety and tolerability of each intervention was measured via number of adverse events during each trial and recorded. Table 5 shows the overall adverse effects that result in Number Needed Harm (NNH) for the selected studies.

Table 5: Adverse Effects that result in NNH for the selected studies

Study	Ayurvedic Medicine's AE (%)	Placebo or Comparison Drug's AE (%)	RRI(%)	ARI(%)	NNH
Chopra ¹ (2004)	27.7	26.5	4.5	1.2	83
Chopra ² (2013)	28.16	32.38	12.9	4.2	24
Pengkhum ³ (2012)	6.6	9.9	33.3	3.3	30

DISCUSSION

Osteoarthritis is chronic condition that causes a wide range of problems in many patient population, and current conventional medication used have adverse side effects associated with them. Therefore, the goal of Ayurvedic medicine is to provide symptomatic relief from osteoarthritis pain.

Limitations exist in all the selected studies. The limitations of the selected studies are as follows: various formulations of Ayurvedic medicine were utilized, the studies used different

dosages, only Asian decent subjects participated in the study, and it is hypothesized that Ayurvedic medicine is considered safe, because of its long history of use in the Eastern culture but with limited evidence support. Specifically, Chopra et al. (2004) researchers were unable to explain the precise reason for the strong placebo response and a large number of patients withdrew from the study, Chopra et al. (2013) used a large number of participants (440) which would be harder to assess efficacy and follow-up, and Pengkhum et al. mostly females were enrolled in the study.^{1,2,3} Due to these limitations, there is a need for more research to be conducted to warrant the effectiveness of Ayurvedic medicine in reducing osteoarthritis pain in adults.

CONCLUSION

This systemic review investigated three studies of randomized control trials that demonstrated the effectiveness of Ayurvedic medicine used for managing pain in adults patients with osteoarthritis. The selected studies for this systemic review demonstrated Ayurvedic medicine is effective when compared to conventional treatments, such as Celecoxib and Diclofenac, and is statistical significant when compared to placebo.^{1,2,3} Ayurvedic medicine has been used for centuries and provides patients of osteoarthritis an alternative therapeutic option which can help decrease the side-effects of NSAIDs, such as gastrointestinal ulcers and co-morbidities. Future studies need to be conducted to determine the efficacy of Ayurvedic medicine in osteoarthritis patients, which are open globally and assess subjects from all origins to assess if Ayurvedic medicine is effective in reducing osteoarthritis pain in adults.

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