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Is acupuncture effective in improving pain in patients with knee osteoarthritis?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not “Is acupuncture effective in improving pain in patients with knee osteoarthritis?”

Study design: A systematic review of three randomized controlled trials (RCTs) published in between 2015-2018.

Data sources: All three RCTs were discovered using PubMed. The articles were published in English in peer-reviewed journals and selected based on applicability to the clinical question.

Outcome measured: Based on the studies done by Lin et al. and Chen et al., using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a self-reported measure of lower extremity pain, stiffness, and function. In the RCT led by Helianthi et al., the Lequesne index was used, an interview format that includes pain, maximum distance walked, and activities of daily living. Higher scores indicate an increase in worse symptoms and function.

Results: In the RCT led by Lin et al., there were no significant differences among the treatment groups between traditional acupuncture and sham acupuncture two weeks post intervention ($p=.684$). In the RCT led by Helianthi et al., laser acupuncture led to a decrease in pain and an increase in function by an improvement of the Lequesne Index compared to the control group ($p<.0001$), indicated by a mean change from baseline of 6.48. In the RCT led by Chen et al. both groups showed improvement from therapy with no significant differences between penetrating acupuncture and non-penetrating acupuncture in WOMAC response at ($p=.148$).

Conclusion: Only the study led by Helianthi et al., demonstrated that acupuncture led to significantly reduced symptom severity as measured by the Lequesne index. This suggests that acupuncture may not be an effective and beneficial treatment for all patients for the treatment of knee osteoarthritis. Future studies should include a large sample size.

Key words: acupuncture, osteoarthritis of the knee

Introduction:

Knee osteoarthritis is the most common form of arthritis, characterized by degeneration of joint cartilage and the bone that causes pain and stiffness, especially in the elderly. It is classified as a progressive disease that may lead to various forms of disability in the future for patients. Symptoms can typically include knee pain that has a gradual onset and can worsen with activity, knee stiffness, joint swelling, pain after sitting for prolonged periods of time, and pain that gradually worsens over time.¹ An evaluation of knee osteoarthritis can be made with a thorough history and physical, as well as radiographic imaging. The views for knee osteoarthritis that are recommended are standing anteroposterior, standing lateral in extension, and a skyline view of the patella. Radiographic findings that are characteristic of osteoarthritis include joint space narrowing, osteophyte formation, subchondral sclerosis, and subchondral cysts.¹

Knee arthritis is the most common form of arthritis in the elderly, with prevalence of knee osteoarthritis expected to increase with longer life expectancy.¹ For example, in Indonesia, 5% of the population are over 65, and by 2035, that number is expected to increase by 10.6%, which results in a longer life expectancy, meaning more of the population will have osteoarthritis. Among those over the age of 70, the prevalence of knee osteoarthritis can reach as high as 40%.² The estimated prevalence in adults is 240 cases per 100,000 people per year.¹ The estimated lifetime costs for people who were diagnosed with knee osteoarthritis are estimated to be \$140,000, due to most people needing a total knee replacement after ten years of failed medical therapy.³ It is unknown how many healthcare visits are attributed to knee osteoarthritis; however, it is estimated that by 2032, 26,000 individuals per 1,000,000 aged greater than 45 years old, are estimated to have seen a provider for osteoarthritis.⁴

Knee osteoarthritis can be categorized as either primary or secondary. Primary knee osteoarthritis is the result of knee degeneration without any specific cause, and it is unknown

how the articular cartilage degenerates; however, it is believed to be caused by overuse over time. Secondary arthritis is further classified into osteoarthritis due to a known reason, such as posttraumatic, postsurgical, congenital, scoliosis, rickets, or hemochromatosis to name a few.¹

Current treatment for knee osteoarthritis is classified as nonpharmacologic and pharmacologic. Nonpharmacologic therapy includes avoidance of activities that worsen the pain, physical therapy, weight loss to decrease the amount the joints have to hold, acupuncture, heat and cold compresses. If unbearable pain continues, pharmacological therapy would be the next step for the patient. Oral NSAIDs, such as ibuprofen, is first line treatment for patients with symptomatic knee arthritis.⁵ There are also topical options such as capsaicin cream or topical NSAIDs, like diclofenac gel. Another alternative could be intra-articular corticosteroid injections. One example is triamcinolone that can be used up to 3-4 times a year. ¹Since osteoarthritis is a degenerative disease, few of the population with this condition have no pain, but most undergo possible surgery.

Acupuncture has been widely used for pain for over 3,500 years, and introducing acupuncture to a condition with limited forms of relief may help symptomatic patients. This paper evaluates three randomized controlled trials (RCTs) to assess the efficacy of acupuncture as management for knee osteoarthritis. Acupuncture is a technique that has been around for over 3,000 years and has benefits to patients to treat their pain. ⁷ Over the years, pharmacologic treatment has been the mainstay of treating osteoarthritis, with eventually turning to surgical measures to try to fix an incurable problem. Acupuncture was seen as an alternative because of its ability to suppress the body's inflammatory response, improve blood flow, and relax muscle tone in the patient. It is also believed that acupuncture causes the body to release more

endorphins, which lessens the pain. *Some contraindications to acupuncture may include an active infection, bleeding disorders like hemophilia, or a pacemaker. ⁵

OBJECTIVE

The objective of this EBM review is to determine “is acupuncture effective in improving pain in patients with knee osteoarthritis?”

METHODS

The studies chosen were based on applicability to the clinical question, and incorporation of patient-oriented outcomes. The studies chosen were selected if they fulfilled criteria based on population, intervention, comparisons, and the outcome measured. It was required that all studies were directed at patients who were diagnosed with knee osteoarthritis. The studies referenced in this review were found on PubMed using key words “osteoarthritis” and “acupuncture.” It was required that the studies were published in peer reviewed journals and employed randomization. The articles were all published in English. Inclusion criteria consisted of articles that were dated from 2011-present, the English language only, and RCTs. The exclusion criteria included Rheumatoid arthritis, studies published before 2011, and observational studies. Statistical analysis utilized in these studies include the mean change from baseline of the pain in the patient’s knee in the Western Ontario and McMaster Universities Osteoarthritis Index and the Lequesne Index as well as evaluating statistical significance using p-values.

The population of the studies targeted in this selective EBM review included women and men with knee osteoarthritis >40 years old. The demographics and characteristics of these studies can be found on Table 1. The intervention used in these studies was acupuncture vs. the control group who used sham acupuncture.

OUTCOME MEASURED

The studies by Lin et al. and Chen et al., utilized the Western Ontario and McMaster Universities Osteoarthritis Index. The WOMAC is a self-reported measure of lower extremity pain (which includes 5 items during walking, using stairs, in bed, sitting or lying, and standing upright), stiffness (two items which includes after first walking and later in the day), and function (17 items which includes using stairs, rising from sitting, standing, bending, walking, getting in/out of a car, shopping, putting on/taking off socks, rising from bed, lying in bed, getting in/out of bath, sitting, getting on/off toilet, heavy domestic duties, light domestic duties). All points are rated on a 5 point scale ranging from none to extreme. Total scores of the WOMAC ranged from 0-96 with higher scores indicating worse symptoms and function.⁵ In the study led by Helianthi et al., the Lequesne index was used, which is an interview format. This index consists of three aspects including: pain, maximum distance walked, and activities of daily living. The score for pain contained questions for each scale which ranged from 0 (no pain or functional limitation) to 2 (pain at rest). The maximum distance walked aspect is graded from 0=unlimited to 6=less than 100 m. The score was upgraded one point if the participant used one walking stick or two points if the participant used two walking sticks or crutches. The activities of daily living are graded from 0 (no limitation), .5 (able with mild limitation), 1 (able with moderate limitation), 1.5 (able with severe limitation), 2 (unable). This index aggregates symptoms and functions which ranges from a scale of 0-24. The higher the score, the worse the symptoms and function.

Table 1. Demographics & Characteristics of Included Studies

Study	Type	#Pts	Age (yrs)	Inclusion criteria	Exclusion criteria	W/D	Interventions
Lin (2018)	RCT	42	45-75	Patients 45-75 with knee osteoarthritis, chronic knee pain during the past six month, radiologic confirmation or unilateral or bilateral knee osteoarthritis, and agree to refrain from analgesic during this trial.	History of knee surgery, pain in the knee due to other conditions, acute disease, mental disorder, pregnancy, or breastfeeding.	6	Acupuncture vs. sham acupuncture
Helianthi	RCT	62	>60	Patients older than 60 diagnosed with grade 2 or 3 arthritis and pain intensity greater than 4/10.	Previous knee replacement, consumed opioids, had a previous corticosteroid injection in the last 4 months, or oral NSAID medication in the last 3 days. Also those who had conditions that would interfere with the study.	3	Laser acupuncture vs. sham acupuncture
Chen 2013	RCT	214	>45	Patients older 40, pain in 1 or both knee joints for more than 6 months, pain >4/10.	Any other disease that affect the joint like gout, rheumatoid arthritis, and significant trauma, pregnancy, significant coagulopathy,	61	Puncture acupuncture vs. sham acupuncture

RESULTS

Only Helianthi et al., provided significant statistical evidence that acupuncture decreased the severity of pain and overall function in patients with knee osteoarthritis. Helanthei et al., conducted a double blind randomized controlled trial in geriatric patients with knee osteoarthritis. The authors enrolled patients who were 60 years of age and older and have been diagnosed with grade 2 and grade 3 knee osteoarthritis based on the Kellgren-Lawrence grading scale which is based on radiographic evidence.²A randomization list was created using a computer generated number. Both the investigators and the participants were unaware of who received laser treatment or a placebo treatment. Laser acupuncture can be described as a single-probe gallium aluminum arsenide laser device that was performed on certain acupuncture points. It provides the same results as traditional acupuncture, but it is less invasive. The treatment was given twice a week for ten sessions for both the treatment and control group. The authors used the Lequesne Index to compare pain levels. 62 individuals first enrolled in this study; however, only 59 completed it due to one participant having a cerebrovascular accident and two refusing to complete the treatments. A worst case analysis was not done in this group. The demographic and baseline clinical characteristics of the group were similar. The Lequesne Index improved significantly in scores of the treatment group compared to the control group from baseline to 2 weeks post intervention with a mean difference of 6.48. ($p < .001$).²The results are summarized in table 2 below. The study also found that laser acupuncture treatment has a beneficial effect on reducing pain intensity and improving functional outcome.

Table 2. Changes in Lequesne index between groups from baseline to two week post intervention in Helianthi et al. ²

Characteristics	Active laser acupuncture group n=30	Placebo acupuncture group (n=29)	Mean difference (95% CI)	P-value
Changes in Lequesne index mean between baseline and at 2 weeks post intervention (SD)	5.3 (4.5)	-1.2 (3.7)	6.48 (4.34 to 8.46)	p<0.001

Lin et al. provided a similar study using a randomized, participant-blinded, sham acupuncture controlled pilot trial. The authors included participants who were 45-75 years old and diagnosed with knee osteoarthritis according to the National Institute for Health and Clinical Guidelines 2014 Edition criteria, and radiologic evidence of a score of II or III according to the Kellgren-Lawrence scale. Randomization sequence was stratified with a 1:1 allocation using random block sizes of six. Also, outcome assessors and data analysts were blinded to the allocation; however, the acupuncturists delivering the interventions were not blinded. The groups were split up into Group A and group B. The acupuncturists used traditional Chinese acupuncture using needles and points on channels that traverse the area of pain. ⁷ This study utilized the WOMAC, which is a self-reported measure of lower extremity pain, stiffness, and function. This was the primary outcome. The secondary outcomes included the WOMAC, intensity of pain measured by the visual analogue scale, and the quality of life assessment on physical and mental component scores. Patients completed the questionnaires at baseline and at weeks 8, 16, and 26. The study aimed to analyze the effectiveness of an eight week acupuncture including three sessions per week. The sample size included 42 subjects; however, 6 participants dropped out due to relocation, violation of treatment protocols, and loss of contact. ⁷ There were

no significant differences among the treatment conditions on any baseline demographic and clinical characteristics. Overall, the average pain score and the WOMAC function score decreased over the 26 weeks period; however, there was no statistically significant difference in scores between the groups. For the WOMAC at week 26, $p=.684$ with a mean change of 9.7 between the groups.⁷The results are summarized below in table 3.

Table 3. Outcomes, differences between groups and changes over time ⁷

Variable	Traditional Chinese acupuncture (n=21)	Sham acupuncture (n=21)	P value
WOMAC pain and function score Baseline (SD)	25.9 (12.1)	28.8 (12.7)	0.451
WOMAC pain and function score week 26	16.2 (13.1)	18.6 (12.3)	0.684

Chen et al., also did similar studies as the authors in the other two articles. The authors used a randomized, participant blinded, controlled center at three physical therapy centers. The criteria for entry consisted of patients who were 40 year of age or older and radiologically confirmed knee osteoarthritis, a score of 2 or 3 by the Kellgren-Lawrence score. 214 patients were analyzed. By week 26, 61 patients were lost due missing treatments, withdrawals, violations, and losing contact. Patients received 12 sessions of acupuncture directly following exercise-based therapy. All participants received treatment once or twice a week. Acupuncture was administered with puncturing and non- puncturing needles following every exercise-based physical therapy. There were nine acupuncture points for each knee. Patients were randomized with a block of 6, stratified by an acupuncturist. The patients, physical therapist, data collectors, and statistician were blinded throughout the study period. The outcome measured the change in the WOMAC between baseline and at 26 weeks with a telephone follow-up. A clinically

important patient response was defined as a change of at least 36% in the WOMAC score. Patients were evaluated during week 6 (mid-treatment) and at week 12. For the 26 week assessment, a questionnaire was mailed with telephone follow-up. There were 214 eligible patients, and there were no pretreatment differences found to be clinically relevant among the two experimental groups in any sociodemographic or other clinical factors. 74% considered their knee OA symptoms to be at least slightly better; however, there were no appreciable clinical or statistically significant differences observed.⁶ The mean change from baseline was 6.8 for the non-penetrating acupuncture. For the true acupuncture, the mean change from baseline was 6.1. This means between the groups, the non-penetrating acupuncture improved by .7 points more than the true acupuncture, and there was no statistically significant difference between the groups at 26 weeks ($p=.148$).⁶ The results are summarized in the table below in table 4.

Table 4. Outcomes, differences between groups and changes over time ⁶

Variable (WOMAC)	Non-penetrating acupuncture (n=109)	True acupuncture (n=104)	p-value
Mean of WOMAC at baseline	44.0 (41.0, 46.9)	47.6 (44.8, 50.5)	.080
Mean at WOMAC at 26 weeks	37.2 (32.8, 41.6)	41.5 (37.6, 45.4)	.148

DISCUSSION

Osteoarthritis is a life-altering condition that most people will come across at some point in life. Unfortunately, osteoarthritis is a progressive condition with no cure. There are options that can simply slow the progression down. Acupuncture may have a benefit to certain patients, or perhaps it acts as a placebo effect; however, it has been difficult for researchers to produce evidence that renders acupuncture a guaranteed way to reduce pain in patients with knee osteoarthritis.

This review evaluated the efficacy of acupuncture as treatment resulting in a reduction in pain severity and increase in overall quality of life in those with knee osteoarthritis. One study compared laser acupuncture vs. sham acupuncture, one compared true needle acupuncture vs. sham acupuncture, and one compared true needle acupuncture vs. sham acupuncture with all participants receiving physical therapy. All three studies have found improvement using their respective measurements with Lin et al., and Chen et al., using the WOMAC and Helantheni et al using the Lequesne index. However, only Helantheni et al, had statistically significant evidence with a statistically significant p value and large effect sizes between the treatment and control group. Also, the studies by Chen et al., also showed slightly more improvement with the non-penetrating (sham acupuncture) than the true acupuncture with a larger mean change from baseline. Unfortunately, this information does not single handedly prove that acupuncture is an effective treatment to decrease severity in pain in the knee and improve overall quality of life. The evidence is inconclusive and conflicting. All three studies had limitations. The limitations in Chen et al., included that there was a lack of physical therapy group; which meant it was hard to tell if it was physical therapy improving the patient's symptoms or the acupuncture itself. Another limitation that was present across all three studies, was the smaller than proposed sample size due to slow recruitment. In Helantheni et al., the limitation was the short term follow-up which made it difficult to assume when the effects of laser acupuncture will wear off. In Lin et al., the limitation was the small sample size affecting the validity and reliability of these results as well as the inability to do treatment blinding, as well as blinded raters or objective measures. In all three studies, limitations included that participants were on a mild-moderate pain level rather than moderate-severe. Patients also started acupuncture later in their disease progression rather than earlier.

CONCLUSION

This systematic review showed that it is difficult to tell if acupuncture would have an effect for patients with knee osteoarthritis in reducing their symptoms and improving their quality of life. Only Helianthi et al., found that acupuncture caused a statistically significant mean decrease in the Lequesne Index after nine sessions total and two weeks post intervention. The potential improvement in those individuals with knee osteoarthritis is worth further exploration as quality of life can be improved if symptoms of knee osteoarthritis are improved. Lin and Chen et al., also found an decrease in symptoms; however, the results were not statistically significant between the two groups, which may be attributed to their small sample size. In order to further demonstrate the potential benefits that acupuncture has, it is important to perform these studies with a large sample size and a longer duration. Also, it is important that a worst-case analysis is done to account for potential defects and deficiencies and to identify the most critical components that will affect the study. This was not done in the study by Helianthi et al or Chen et al. It was determined from Chen and Lin et al., that acupuncture does not cause any harm, and it is deemed feasible and safe, however effectiveness in treating osteoarthritis is still undetermined. Another possibility to explore is studying a sample size when their pain is moderate to severe, because a mild to moderate pain level will give low baseline scores, which could give a ceiling effect with little to no improvement. Another beneficial method for the study would be the timing given of acupuncture to determine if there could potentially be a difference if acupuncture was given right when patients were diagnosed with knee osteoarthritis. It could be beneficial if acupuncture was started earlier instead of pharmacotherapy, as it could potentially slow progression of the disease.

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