

Acupuncture versus Homeopathy as a Complementary Therapy in Patients with Knee Osteoarthritis

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Abstract

Background: Osteoarthritis of the knee is a major cause of disability with treatment focused only on control of symptoms. The conservative non surgical management of knee osteoarthritis is to control the signs and symptoms. However, knee replacements are common for knee osteoarthritis. Despite the popularity of both acupuncture and homeopathy, evidence of their efficacy for treatment of osteoarthritis remains controversy.

Aim of the work: To assess the efficacy of Acupuncture compared with Homeopathy and with the usual conservative treatment (analgesics and physiotherapy) in patients with knee osteoarthritis.

Patients and Methods: Seventy-five patients who had had chronic pain for at least 6 months due to osteoarthritis of the knee (American College of Rheumatology [ACR] criteria and Kellgren-Lawrence score of 2) were admitted to the study. During the study, all of the subjects continued on their conservative therapy, which remained unchanged throughout the study. The subjects were randomly divided into three groups. Group I (Acupuncture group): Included 25 patients who were subjected to acupuncture at the standardized acu-point stimulation treatment without electrical stimulation. Sessions were done twice weekly from base line visit to week six. Group II (Homeopathy group): Included 25 patients who were given oral doses of homeopathic remedies that were commonly used for the treatment of osteoarthritis (Arnica Montana, Ruta graveolans and Rhus toxicodendron). Group III (Control group): Included 25 patients who continued only on their pre-study medications. Pain intensity on visual analog scale (VAS), the Health Assessment Questionnaire (HAQ) score and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score were recorded for each patient before the beginning of treatment, during each visit and at the end of the sessions. The results were statistically analyzed.

Results: Pain was significantly improved on both VAS and pain subscale of the WOMAC in group I. Also, the number of tender points decreased significantly and there was a significant decrease in the number of patients receiving analgesics for pain control at the end of the study ($p < 0.05$). In addition, a statistically significant improvement in knee function was detected ($p < 0.05$) on the total WOMAC score for knee osteoarthritis and both the function and stiffness subscales of the WOMAC, in addition a statistically significant decrease in knee swelling (knee circumference) was detected in group I. There was also a significant increase in patient quality of life assessed by the HAQ score for group I and this gain was significantly greater than the gain in the control group. There was a statistically significant improvement in the total WOMAC score, (both VAS and pain subscale of the WOMAC) and a significant reduction in the number of tender points in group II. Moreover, a significant decrease in the number of patients receiving analgesics for pain control was reported in this group ($p < 0.05$). In addition, the improvement of pain and function was statistically greater ($p < 0.05$) in comparison to the control group (group III).

Conclusions: Both Acupuncture and Homeopathy were effective in reducing pain and improving function of the knee compared to the usual care group but acupuncture was significantly more effective than homeopathy. Moreover, Acupuncture significantly decreased the knee circumference (swelling) while homeopathy and usual care did not significantly decrease the swelling.

Keywords: Osteoarthritis; Knee; Acupuncture; Homeopathy

Introduction

Osteoarthritis (OA) is the most common type of arthritis in humans. It is a major cause of pain and disability and has significant consequences for public health. The burden of OA is expected to

increase not only with aging of the population but particularly those who are aging and suffer from obesity [1]. The hip and knee are two commonly affected joints, having a significant impact on walking and other daily activities. The prevalence of OA is on the rise, and this trend is expected to continue [2].

Optimal management of patients with OA emphasizes conservative, nonsurgical strategies, combining non-pharmacological and pharmacological therapies [3]. The pharmacological modalities of treatment including acetaminophen, oral NSAIDs, topical NSAIDs, tramadol and intra-articular injections of corticosteroids. Unfortunately, the pharmacologic therapies used in treatment of OA may often cause unwanted and dangerous side effects [4]. the non-pharmacological modalities include: education, physical activities (e.g aerobic, strengthening, flexibility and aquatic exercise) , weight reduction, walking aids, footwear, physical therapy(e.g. specific isometric , isotonic, stabilization and plyometric training ,manual and soft tissue mobilizations , electrotherapeutic modalities, deep heat) and complementary therapies like Tai Chi ,Pilates, Yoga and Alexander programs as well as acupuncture [5].

Many studies have documented that acupuncture has a beneficial effect when treating many diseases and painful conditions. Therefore acupuncture is proposed to be a useful complementary therapy and may replace generally accepted pharmacological intervention [6]. It is proposed that acupuncture produces its effects by the conduction of electromagnetic signals at a greater-than-normal rate, thus aiding the activity of pain-killing biochemicals , such as endorphins and immune system cells at specific sites in the body [7]. In addition, acupuncture may alter brain chemistry by changing the release of neurotransmitters and neurohormones and affecting the parts of the central nervous system related to sensation and involuntary body functions, such as immune reactions and processes whereby a person's blood pressure, blood flow, and body temperature are regulated [8].

Homeopathy is a system of medicine which involves treating the individual with healthy substances, emphasizing natural foods as well as specific supplements in tablet form , with the aim of triggering the body's natural system of healing [9]. Homeopathy is based on the principle that an illness can be treated 'like with like', that is, a substance which causes symptoms when taken in large doses, can be used in small amounts to treat those same symptoms. The major difference between de- sensitization and Homeopathy is that with homeopathic medicines the substances are used in ultra-high dilutions, which makes them non-toxic [10]. Homeopathy is frequently tried by individuals with chronic problems such as chronic pain, arthritis, and extensive neurodegenerative diseases [11].

The aim of the present study was to evaluate the efficacy of Acupuncture compared with Homeopathy and with the usual conservative treatment (analgesics and physiotherapy) in patients with knee osteoarthritis.

Patients and Methods

Seventy five (75) individuals with knee osteoarthritis in one or both knees, diagnosed according to American College of Rheumatology (ACR) criteria [12], who had chronic pain for at least 6 months, were eligible to participate in this study. Staging of the knee OA was graded according to Kellgren-Lawrence grade 2 [13].

The patients were recruited from Ain Shams University Hospital rheumatology outpatient clinics, and the Outpatient Acupuncture Clinic of the Medical Service Unit of the National Research Centre, Cairo, Egypt.

After explaining the nature and details of the study, written informed consent was obtained from all subjects who agree to participate in this study. Individuals were excluded if he/she had other diseases affecting the knee, neurologic and psychiatric diseases, severe

coagulopathy, pregnancy, previous acupuncture treatment for osteoarthritis, had undergone knee surgery or intra-articular steroid injection within four weeks preceding the study,suffered arthritis due to other inflammatory conditions or experienced other medical causes of pains rather than knee OA.

All patients completed the following baseline evaluations

Full medical history and thorough clinical examination (general, systemic and musculoskeletal). Special emphasis as given to knee examination and knee circumference.

The body mass index (BMI): was calculated for each patients using the following equation: BMI= Weight\ (Height) 2 with weight in kilograms and height in meters [14].

Standard laboratory investigations were done including: complete blood picture (CBC), Erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], kidney function (BUN- serum creatinine), liver enzymes (AST-ALT), complete lipid profile, and urine analysis.

Plain X-ray of both knees (antro-posterior and lateral views) to determine the grade of knee osteoarthritis [13].

All the patients continued on the same dose and type of analgesic medications used before the study (including paracetamol or NSAID) according to patients' needs. After consent, the patients were randomly assigned to the following group.

Acupoints	Location	Needle manipulation
Stomach 35 (ST35) (Dubi)	With knee flexed, point at lower border of patella,in a depression lateral to the patellar ligament (the point is the lateral foramen of the patella)	0.5 to 1 cun obliquely in medial direction
Stomach 36 (ST36) (Zusanli)	3 cun below ST35, one finger breadth from anterior crest of tibia.,on tibialis anterior muscle.	Vertical 1 to1.5 cun
Gall bladder 34 (GB34) (yanglingquan)	On a depression anterior and inferior to the small head of fibula.	Vertical 1 to1.5 cun
Spleen 9 (SP 9) (yinlingquan)	On the lower border of the medial condyle of tibia,with the level of tibial tuberosity,in the depression posterior and inferior to medial condyle of tibia. 2 cun below the patella	Vertical 1 to1.5 cun
Spleen 10 (SP 10) (xuehai)	With knee flexed 2 cun above mediosuperior border of patella, on the bulge of medial portion of quadriceps femoris muscle (vastus medialis).	Vertical 1 to1.5 cun

Table 1: Standardized acupoints stimulation treatment (Berman et al.) [15]. N.B: 1 Cun is equal to the space between distal and proximal inter-pharyngeal joint on the middle finger.

Group I (Acupuncture group): Twenty five patients received acupuncture at the standardized acupoint stimulation treatment without electrical stimulation (Table 1 and Figure 1). Sessions were done twice weekly from base line visit to week six. All acupuncture treatments for a given patient were completed by the same physician. The patient was positioned supine with a pillow under both knees, with needles for 15-20 minutes. The acupuncture needles used for

treatment were 3 cm, 30 gauge solid disposable filiform stainless steel. The depth of needle insertion varied with thickness of the skin and subcutaneous fatty tissues at the site of the acupuncture points; it was usually 1 to 1.5 cm. Manual acupuncture treatment was given for 10 minutes for each site.



Figure 1: The standardized acupoint stimulation for knee osteoarthritis treatment.

Group II (Homeopathy group): Twenty five patients received oral doses of homeopathic remedies including:

- Arnica Montana 30c (5 drops in 30 ml water three times daily). This remedy was concerned specially with patients complained of pain.
- Ruta graveolans 30c, Rhus toxicodendron 30c (5 drops in 30 ml water once daily). These two remedies were concerned specially with patients who complained of stiffness.

The original form was in (pellets) prepared in National Research Centre, the pellets dissolved in 250 ml sterile water. The dose is given oral or sublingual of oral solution for 2 weeks, then patients come back for follow up the degree of pain and degree of improvement of knee function, then repeated same dose for another 2 weeks. Patients were not allowed to eat, smoke, and drink tea, coffee, or any food with special flavor half an hour before and after taking the homeopathic

drug. They were not allowed to put the drug in high temperature or in the sun light, and not beside any other drug.

Group III (Control group): Twenty five patients who continued only on their pre-study medications (NSAID and paracetamol).

All subjects were measured on a standardized test battery. Pain intensity on visual analog scale (VAS) [16]. Health status was measured on the Health Assessment Questionnaire (HAQ) score [17]. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score [18], were recorded for each patient before treatment, during each visit and at the end of the treatment sessions.

Statistical analysis

Analysis of data was carried out on an IBM using SPSS (statistical program for social science software version 12). Each dependent variable was described (mean, SD and range). The qualitative variables were described as numbers and percentages. The Chi-square test was used to compare the differences in qualitative variables between groups (%). The unpaired t-test was used for pairwise comparisons on the quantitative variables. One way Anova test (analysis of the variance) was used to compare more than two groups on the quantitative variables. Paired t-tests were used to compare pre-post test change scores on the dependent variables for each group.

A critical value <0.05 was considered statistically significant, p>0.05 was statistically insignificant and p<0.001 was considered highly statistically significant

Results

Seventy-five patients with osteoarthritis were included in the study (61 females and 14 males). Their age ranged from 44 to 57 years. Twenty six patients with bilateral knee osteoarthritis and twenty three patients with unilateral knee osteoarthritis (Table 2).

Variables	Acupuncture group I (n=25)	Homeopathy group II (n=25)	Controls group III (n=25)
	Mean ± SD	Mean ± SD	Mean ± SD
Age (years)	49 ± 7.6	51 ± 6 .0	50.5 ± 5.2
BMI (kg/m ²)	31.7±5.8	30.9±3.0	31.3±5
Gender			
Male n (%)	6 (24%)	5 (20%)	3 (12%)
Female n (%)	19 (76%)	20 (80%)	22 (88%)

Table 2: Demographic data of the different studied groups. Data are expressed as mean ± standard deviation or number with percent within parenthesis: no (%). BMI: Body Mass Index.

There were statistically significant gain scores in both the acupuncture and the homeopathy groups as regards: Pain on VAS of Pain, stiffness and physical function subscales of WOMAC, and the HAQ score (P<0.001). There was also a significant difference regarding the knee circumference in the acupuncture group (by paired t-test) (Table 3).

Characteristic	Acupuncture group I (n=25)			Homeopathy group II (n=25)			Controls group III (n=25)		
	Before	After	P Value	Before	After	P Value	Before	After	P value
	Mean ± S.D	Mean ± S.D		Mean ± S.D	Mean ± S.D		Mean ± S.D	Mean ± S.D	
VAS	9.38 ± 0.81	2.74 ± 0.98	<0.001	9.66 ± 0.62	5.16 ± 0.79	<0.001	9.50 ± 0.50	8.90 ± 1.03	>0.05
WOMAC Total	43.40 ± 0.49	25.04 ± 0.62	<0.001	44.20 ± 0.41	34.00 ± 0.99	<0.001	43.28 ± 0.50	41.81 ± 0.93	>0.05
WOMAC Pain	12.82 ± 0.51	4.72 ± 0.62	<0.001	13.52 ± 0.51	8.04 ± 0.99	<0.001	13.02 ± 0.51	12.06 ± 0.93	>0.05
WOMAC stiffness	4.64 ± 0.49	0.35 ± 0.62	<0.001	4.42 ± 0.41	2.06 ± 0.99	<0.001	4.30 ± 0.50	4.06 ± 0.93	>0.05
WOMAC physical function	26.08 ± 0.70	20.16 ± 0.62	<0.001	26.58 ± 0.64	24.92 ± 0.99	<0.001	25.94 ± 0.62	25.88 ± 0.93	>0.05
HAQ score	2.01 ± 0.28	0.94 ± 0.45	<0.001	1.80 ± 0.00	1.68 ± 0.48	0.003	1.98 ± 0.00	1.84 ± 0.37	0.051
Knee circumference	45.88 ± 1.97	45.19 ± 1.90	<0.001	45.51 ± 1.82	45.30 ± 1.89	0.054	44.40 ± 3.23	44.27 ± 3.09	0.052

Table 3: Comparison between the means of the studied parameters (before and after treatment) of the studied groups. Data are expressed as mean ± standard deviation. VAS: Visual Analogue Scale for pain; WOMAC: Western Ontario and McMaster University Osteoarthritis Index; HAQ: Health Assessment Questionnaire.

There was statistically significant difference (P<0.001) between the three studied groups at the end of the study as regards: Pain on VAS, stiffness and physical function subscales of WOMAC, and the HAQ

score. In contrast, there was non-significant difference between the three groups regarding the knee circumference (by one way ANOVA test) (Table 4).

group II vs. group III	group I vs. group III	group I vs. group II	P value, 1-way ANOVA	Controls group III (n=25) Mean ± S.D	Homeopathy group II (n=25) Mean ± S.D	Acupuncture group I (n=25) Mean ± S.D	Characteristic
<0.001*	<0.001*	<0.001*	<0.001*	8.90 ± 1.03	5.16 ± 0.79	2.74 ± 0.98	VAS
<0.001*	<0.001*	<0.001*	<0.001*	41.81 ± 0.93	34.00 ± 0.99	25.04 ± 0.62	WOMAC Total
<0.001*	<0.001*	<0.001*	<0.001*	12.06 ± 0.93	8.04 ± 0.99	4.72 ± 0.62	WOMAC Pain
<0.001*	<0.001*	<0.001*	<0.001*	4.06 ± 0.93	2.06 ± 0.99	0.35 ± 0.62	WOMAC Stiffness
0.305	<0.001*	<0.001*	<0.001*	25.88 ± 0.93	24.92 ± 0.99	20.16 ± 0.62	WOMAC physical function
0.403	<0.001*	<0.001*	<0.001*	1.84 ± 0.37	1.68 ± 0.48	0.94 ± 0.45	HAQ score
-	-	-	0.057	44.27 ± 3.09	45.30 ± 1.89	45.19 ± 1.90	Knee circumference

Table 4: Comparison between the outcomes of the studied groups at the end of week 6. *Data are expressed as mean ± standard deviation. ANOVA: Analysis of Variance; VAS: Visual Analogue Scale for pain; WOMAC: Western Ontario and McMaster University Osteoarthritis Index HAQ: Health Assessment Questionnaire.

There was a statistically significant difference between the studied groups (before and after treatment) regarding the number of patients

using analgesics and the number of patients having tender points (Table 5).

Variables		Acupuncture group I (n=25)	Homeopathy group II (n=25)	Controls group III (n=25)	X ²	P
Patients using analgesics	Before n (%)	25 (100%)	25 (100%)	25 (100%)	144	>0.05
	After n (%)	3 (12%)	10 (40%)	25 (100%)	59.83	<0.001
Patients having tender points	Before n (%)	25 (100%)	17 (68%)	17 (68%)	7	>0.05
	After n (%)	5 (20%)	6 (24%)	17 (68%)	30	<0.001

Table 5: Comparison between the studied groups (before and after treatment) regarding the number of patients using analgesics and the number of patients having tender points using the chi square test. Data are expressed as number with percent within parenthesis: n (%).

Discussion

Osteoarthritis is the most common joint disease, with many patients having persistent disability due to pain and stiffness. Analgesic and anti-inflammatory therapy are limited by side effects and not all patients are adequately controlled with life style changes [19].

In this study, pain has improved statistically on both VAS of pain and pain subscale of the WOMAC in group I (acupuncture treated group). The number of tender points decreased significantly, and moreover, there was significant decrease in the number of patients receiving analgesics for pain control. The positive findings for the acupuncture group were in agreement with a pilot study by Berman et al., where among 12 patients with knee osteoarthritis, pain showed statistically significant improvement with acupuncture [20]. Tukmachi et al., documented pain relief on applying acupuncture on 30 patients with symptomatic knee osteoarthritis [19]. Similarly, in another study that was conducted on 736 patients who received acupuncture for their knee osteoarthritis, a statistically significant improvement in pain was observed [21].

In our thesis, a statistically significant improvement in knee function was found in group I on the total WOMAC score for knee osteoarthritis and both the function and stiffness subscales of the WOMAC. In addition, a statistically significant decrease in knee swelling (knee circumference) was detected in this group. These findings agreed with Dai et al., where among 49 cases who completed their study, acupuncture affected both the VAS and the WOMAC in a significant manner [22]. Tukmachi et al., found that both manual and electro-acupuncture showed a significant improvement in the WOMAC pain and stiffness scores and the VAS score, either alone or as an adjunctive therapy to their symptomatic medications [19]. Also, acupuncture caused a decrease swelling and improved range of motion in patients with knee osteoarthritis [20]. Chen et al., found in their study done on 214 patients improvement in the WOMAC by using true acupuncture protocol versus non-penetrating acupuncture into exercise-based physical therapy[23].

In the present study, the acupuncture group showed significant decrease in pain intensity (VAS scores and pain subscale of WOMAC score) and better improvement in knee function (both stiffness and function subscales of WOMAC score), as well as the patient quality of life assessed by the HAQ score in comparison to the control group (patients receiving their usual analgesics and/or NSAIDs).

Interestingly, a significant decrease in the number of patients that continued on their usual medications was observed in the acupuncture group compared to the control group. This occurred in agreement with Berman et al., who found that patients on acupuncture improved on both WOMAC and Lequesne indices compared to those who received standard treatment alone [15].

The results of the present study are also consistent with the findings of Vas et al., who compared acupuncture plus diclofenac with sham acupuncture plus diclofenac and found that the former treatment was more effective in pain relief, stiffness reduction, physical function improvement and had better quality of life. Moreover the true acupuncture group exhibited a significant reduction of diclofenac consumption during treatment period [24].

A more recent single blinded, three armed, sham controlled study on 120 patients with knee osteoarthritis concluded that acupuncture as adjunctive therapy to pharmacological therapy with etoricoxib is more effective than sham acupuncture plus etoricoxib or etoricoxib alone in reducing pain and improving knee function after eight weeks and the benefits persisted for at least one month after the completion of treatment [25].

In the present study, the homeopathy treated group (group II) showed a statistically significant improvement in pain on both VAS and pain subscale of the WOMAC and significant decrease in the number of tender points. Moreover, a significant decrease in the number of patients receiving analgesics for pain control was reported in this group. Also, a statistically significant improvement in knee function was noticed in this group on the total WOMAC score for knee osteoarthritis and both the function and stiffness subscales of the WOMAC. However, the decrease in knee swelling assessed by the knee circumference was statistically insignificant in this group. In addition, we found that the improvement of pain and function was statistically significant in comparison to the control group (group III).

Our results go in agreement with the results of a previous controlled, double-blind clinical study that proved the clinical efficacy of Zeel compositum medication which contains (Arnica montana 4X, Rhus toxicodendron 4X, Sanguinaria canadensis 4X, Solanum dulcamara 5X and Sulphur 8X) to be equivalent to that of diclofenac in relieving pain of osteoarthritis of the knee, and has no dangerous side effects[25]. Another study by Binesser et al., who examined the effectiveness of Zeel versus Celebrex and Vioxx(cox-2 inhibitors) in 592 patients with osteoarthritis of the knee and found that after six weeks of treatment, scores indicated that the homeopathic medication and the cox-2 inhibitors were equally effective. Moreover, the test

medication (Zeel) scored significantly higher regarding to tolerability than the cox-2 inhibitors and costs less [27].

Different studies had documented the efficacy of Arnica gel preparation in osteoarthritis: Knuesel et al. investigated the efficacy and safety of Arnica Montana fresh plant gel applied twice daily in mild to moderate osteoarthritis (OA) of the knee. After 6 weeks, significant decreases in median total scores on the WOMAC by 12.6%, and decreased VAS score by 57% [28]. Similarly, Wriding et al, compared the effects of ibuprofen (5%) and arnica gel preparations in patients with osteoarthritis of inter-phalangeal joints of the hands. The mean of pain (VAS), number of tender joints, duration of morning stiffness and hand function all showed significant improvement [29]. Also, the results of the study conducted by Ross in 2008 that compared the efficacy of arnica gel with non steroidal anti-inflammatory gel in osteoarthritis of the hand showed that Arnica gel and ibuprofen gel were similar in their effect on osteoarthritis of the hands regarding hand function, pain, morning stiffness and number of tender joints with significant decrease in median total scores on the WOMAC, also decreased VAS score [30].

Conclusion

In conclusion, both Acupuncture and Homeopathy were effective in reducing pain and improving function of the knee compared to usual care. However, acupuncture was significantly more effective in pain reduction and increased function compared to Homeopathy. Moreover, Acupuncture significantly decreased the knee circumference. To our present available knowledge, this is the first study to compare the efficacy of acupuncture versus homeopathy in treatment of knee osteoarthritis. Further studies are required to assess the effectiveness of acupuncture for long-term outcomes. One potential limitation of this study is the small sample size. We believe, however, that this data will provided the basis for a power analysis of larger clinical trials in the future.

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