Acupuncture for the Treatment of Pain of Osteoarthritic Knees

Wendy Takeda and Jean Wessel

Objective. *The purpose of this study was to determine whether acupuncture was more effective than sham acupuncture in the reduction of pain in persons with osteoarthritis (OA) of the knee.*

Methods. *Forty subjects (20 men, 20 women) with radiographic evidence of OA of the knee were stratified by gender and randomly assigned to either the experimental (real acupuncture) or control (sham acupuncture) groups. Subjects were treated three times per week for 3 weeks and evaluated at three test sessions. Outcome measures were: 1) the Pain Rating Index of the McGill Pain Questionnaire, 2) the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, and 3) pain threshold at four sites at the knee.*

Results. *The analyses of variance showed that both real and sham acupuncture significantly reduced pain, stiffness, and physical disability in the OA knee, but that there were no significant differences between groups.*

Conclusions. *Acupuncture is not more effective than sham acupuncture in the treatment of OA pain.*

Key Words: *Acupuncture; Pain; Osteoarthritis; Placebo; Knee.*

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Osteoarthritis (OA) is a very common disease, with the major complaint being pain [1]. This pain can lead to significant disability, particularly when the arthritis is in a weight-bearing joint [2]. Control of the pain obviously is crucial to the management of this disease. However, the treatment of the pain can be difficult. Antiinflammatory medications and analgesics such as acetaminophen are often used to treat OA but may be ineffective and/or produce side effects [3]. If these medications fail to adequately relieve the pain, replacement surgery is usually recommended [4,5]. However, surgery can be very risky for the OA population, where other health problems are frequent [4].

Acupuncture is a treatment that may provide adequate pain relief for OA without producing unwanted side effects. There is evidence to suggest that acupuncture can decrease pain by increasing production of endorphins and enkephalins [6], possibly through the stimulation of the afferent pathways [7]. Clinical reports support the use of acupuncture for the reduction of pain [8,9]. However, controlled trials are rare. There has been only one such study on the use of acupuncture in OA [10]. The results failed to demonstrate any significant differences between real and placebo acupuncture in the relief of pain in persons with OA in a variety of joints. Subjects were only treated once per week, a frequency that may not have been sufficient to produce analgesia. In addition, some subjects stopped medication as requested, whereas others continued.

It may be that more frequent treatments, as well as treatment of a specific joint, may result in effective pain relief for OA. The purpose of this study was to determine whether acupuncture decreased pain and stiffness and improved physical function in persons with OA of the knee.

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TABLE 1

Subject Characteristics for Control and Experimental Groups—Means and SDs (in parentheses)

	Group			
Variable	Control W = 10; M = 10	Experimental W = 10; M = 10	Women n = 20	Men n = 20
Age (years)	60.20 (9.75)	63.00 (8.78)	61.55 (9.68)	61.65 (9.09)
Height (cm)	163.70 (10.44)	166.25 (9.08)	157.95 (6.44)	172.00 (7.03)
Weight (kg)	88.22 (15.50)	92.12 (21.62)	86.53 (15.64)	93.81 (21.04)
BMI (kg/m²)	33.06 (6.26)	33.19 (6.19)	34.66 (6.09)	31.60 (5.98)
Grade I	n = 4	n = 1	n = 2	n = 3
Grade II	n = 8	n = 6	n = 8	n = 6
Grade III	n = 4	n = 8	n = 6	n = 6
Grade IV	n = 4	n = 5	n = 4	n = 5

W, women; M, men; BMI, body mass index.

MATERIALS AND METHODS

Research Design

The study was a double-blind, randomized, controlled clinical trial with one experimental group that received real acupuncture treatment and one control group that received placebo/sham acupuncture. Subjects were stratified by gender and randomly allocated to groups in blocks of four. Measurements of pain, stiffness, and function were taken before (pretest) and after (midtest) 3 weeks of treatment, and at follow-up 4 weeks later (posttest). The latter test period was included to examine the longer term effects of acupuncture, because clinical experience has suggested that the effects may not last. The study was approved by the Faculty Ethics Committee.

Subjects

Subjects were 40 volunteers (20 men, 20 women) with grade I–IV OA [11] of the affected knee. Based on pilot data on the intra- and inter-subject variability of the measurement of pain threshold, it was determined that a 1-kg difference between groups would be equivalent to an effect size of 0.30. To demonstrate a significant group × time interaction at an alpha level of 0.05 and a power of 0.80, 19 subjects per group were required [12].

Volunteers were included in the study if they had the following: pain in one or both knees, radiological evidence of OA, no change in medications for arthritis and other conditions in the last 3 weeks, and no previous experience with acupuncture of the knee. Potential subjects were excluded from the study if they had a serious systemic condition (such as diabetes), had any neurologic or musculoskeletal condition (including fibromyalgia), had hemophilia, received intra-articular steroid injections in the previous 2 months, were receiving any treatment other than medication for their arthritis, or had had reconstructive surgery on the affected knee. Subject characteristics are shown in Table 1.

Subjects signed a consent form prior to participation. They were told that they would be randomly assigned to one of two acupuncture groups and that the purpose of the study was to compare the effects of the two types of acupuncture on pain in the osteoarthritic knee. One subject from each group dropped out of the study because of personal/work commitments unrelated to the arthritis or treatment. These subjects were replaced by new recruits.

Testing

All measurements were performed by a professional assistant who was blind to group assignment of the subjects. Measurements were taken at approximately the same time of day and subjects were asked to keep their activity level and caffeine and alcohol intake constant during the study period. At each test session, the subjects were tested with the McGill Pain Questionnaire (MPQ) [13], the Western Ontario and McMaster Universities (WOMAC) OA Index [14], and a pain threshold dolorimeter [15]. Subjects determined which knee was the most painful, and only this knee was tested and treated.

The subjects described their pain using the MPQ. They were asked to choose a maximum of one word out of each category to describe the pain in their knee in the preceding 24 hours. The Pain Rating Index (PRI) [13], using the rank values of words, was calculated and used as a measure of pain intensity.

The WOMAC OA Index is a measure that was developed and tested specifically for subjects with OA of the hip and/or knee [14]. Subjects were instructed to rate, on 10-cm visual analogue scales (VAS), the pain and difficulty associated with different activities, and the stiffness experienced in the knee over the last 48 hours. Summated scores on each of the subscales—pain, stiffness, and difficulty—were used as the outcome measures.

The Pain Threshold Meter (Pain Diagnostics and Thermography, Great Neck, NY) was used to measure the pain threshold at the knee joint. This particular threshold meter had a rubber plunger tip with a 1-cm² surface. The dolorimeter was applied over four points

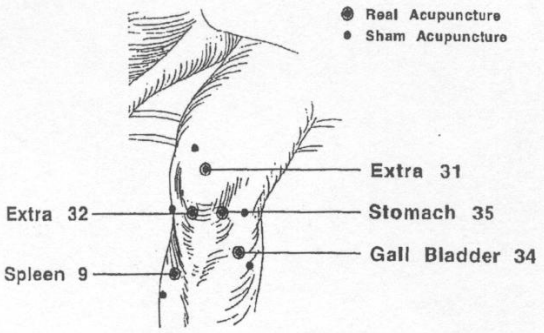

Figure 1. Acupuncture points and sham acupuncture points.

surrounding the knee: the medial and lateral joint lines and the distal musculotendinous junctions of vastus medialis (VM) and lateralis (VL). At each point, the assistant applied slow even force (approximately 1 kg per second) with the dolorimeter perpendicular to the skin surface, until the subject first felt discomfort. At this point, the assessor removed the dolorimeter and read the force on its gauge. The values were recorded as pressure (kg/cm^2).

Treatment

Subjects in both the experimental and control groups received treatment three times per week for 3 weeks from a physical therapist trained in acupuncture and certified by the Acupuncture Foundation of Canada. Zhang and Oetliker [16] indicated that a frequency of treatment of at least three times per week is the common practice of experienced Chinese acupuncturists, and that this frequency has rarely been met in previous acupuncture studies. In addition, the previous controlled trial on acupuncture for OA failed to demonstrate efficacy of acupuncture administered once per week [10].

Subjects were supine with a pillow under the knees during the treatment session. For the experimental treatment, the therapist inserted disposable 30-mm needles with 0.23 mm diameter into the five acupuncture points (Figure 1), specifically for knee and osteoarthritic pain [17]. The needles were inserted, rotated, and inserted deeper until the subject experienced Te chi (a local sensation of heaviness, numbness, soreness, or paresthesia) [18], or to the full depth of the needle if no Te chi was experienced. The needles were left in the subject for 30 minutes and each was rotated back and forth manually for 5 minutes.

For the placebo treatment, the same type of needles were inserted superficially (just enough to puncture the skin) approximately 1 inch from the acupuncture points (Figure 1), in areas not considered active acupuncture points. The needles were only touched periodically to give the impression that movement of the needles was taking place. The location of the points was the same for all control subjects.

Subjects in both groups were told they might experience prickling, aching, numbness, or tingling, and they were asked to report when they did have such sensations.

TABLE 2

Pain, Stiffness, and Function of Control and Experimental Groups at Pre-, Mid-, and Posttest—Means and SDs (in parentheses)

	Control group			Experimental group		
Variable	Pre	Mid[a]	Post[a]	Pre	Mid[a]	Post[a]
PRI	19.65 (13.01)	14.30 (12.15)	15.00 (17.51)	17.55 (13.16)	6.50 (5.39)	10.20 (7.43)
WOMAC pain index	21.93 (8.71)	14.84 (14.14)	19.44 (18.91)	19.44 (13.53)	11.15 (11.27)	14.01 (12.29)
WOMAC stiffness index	11.40 (6.12)	7.07 (5.96)	8.03 (6.22)	8.45 (5.53)	5.29 (4.52)	5.57 (5.68)
WOMAC function index	77.80 (36.55)	50.49 (42.49)	60.02 (45.85)	61.44 (43.15)	40.16 (34.72)	48.03 (43.56)

[a] Significantly ($P < 0.05$) different from pretest for all variables.

Data Analysis

Four separate 2-way ANOVAs with repeated measures (group vs time) were used to examine group and treatment effects on the pain, stiffness, and difficulty components of the WOMAC and the PRI of the MPQ. A 3-way ANOVA with repeated measures on two factors (group vs time vs location) was used for the pain threshold data. When the ANOVA revealed significant differences ($P < 0.05$), Newman Keul post hoc analyses were performed.

RESULTS

The results of the PRI and the three components of the WOMAC are shown in Table 2. All four outcome measures responded in a similar manner; there was a significant time effect ($P < 0.001$ for all measures) but no significant group or interaction effects. Post hoc results for all variables demonstrated that the pretest values were significantly different from mid- and posttest. There were no significant differences between mid- and posttest.

Table 3 illustrates the results for pain threshold measurements. The ANOVA revealed significant time ($P = 0.01$) and site ($P < 0.001$) effects but no group or interaction effects.

In examining the raw data, it appeared that the men may have had a greater response to treatment than women. Therefore, all the ANOVAs were repeated using an additional factor, gender, in the analyses.

TABLE 3

Pain Threshold (kg/cm²) of Control and Experimental Groups at Pre-, Mid-, and Posttest—Means and SDs (in parentheses)

	Control group			Experimental group		
Variable	Pre	Mid[a]	Post	Pre	Mid[a]	Post
Medial joint line[b]	3.64 (1.61)	4.19 (2.61)	3.69 (2.59)	4.06 (2.31)	4.69 (2.71)	4.38 (2.36)
Lateral joint line[b]	3.87 (1.59)	4.46 (2.34)	4.05 (2.42)	4.15 (2.02)	5.47 (2.40)	4.10 (1.73)
Vastus medialis	3.18 (1.43)	3.74 (2.14)	3.25 (2.48)	3.63 (1.78)	4.04 (2.09)	3.51 (1.87)
Vastus lateralis	3.32 (1.61)	3.79 (2.17)	3.57 (2.22)	3.87 (2.21)	4.34 (1.88)	4.04 (2.28)

[a] Significantly ($P < 0.05$) different from pretest.
[b] Significantly ($P < 0.05$) different from vastus medialis and lateralis.

There were significant gender effects on all variables except the PRI. Time × gender interaction was significant for the pain threshold measures and the WOMAC pain index—the men had greater improvement with treatment than the women.

Te chi was experienced regularly during treatment by 25 subjects (14 experimental, 11 control; 18 men, 7 women). The analyses were repeated using Te chi (rather than treatment), as the group factor. Significant group × time interactions were found for the WOMAC pain index and the pressure threshold scores. For both variables, only the Te chi group had significant improvement at mid- and posttest compared to pretest.

DISCUSSION

This study demonstrated that both the real and placebo acupuncture decreased pain, stiffness, and physical difficulty in persons with OA of the knee. There was a tendency for the true acupuncture group to show a greater response, but the difference was not significant. It is possible that both groups had a placebo response or that both groups responded in some physiological manner to their respective treatments.

There is some evidence to support a placebo response in both groups. Both improved with treatment, and the most objective measure, pain threshold, showed no significant difference between pretest and posttest. Subjects may have shown pain relief because they liked the therapist or because they expected to have a reduction in pain [6]. In fact, Wall [19] suggested that the expectations of the patient and the therapist are the best predictors of response to a placebo. It is possible that individuals who volunteered for the study believed that acupuncture would make a difference. However, the subjects were given no indication of which form of acupuncture was expected to give better pain relief. In addition, they were told that if their 'group' did not respond as well as the other, they would be offered a course of the 'better' treatment after the study was completed. Because the treating therapist was not blind to the group allocation of subjects, her expectations might also have influenced the results. However, one would have anticipated a greater pain relief in the experimental group compared to the control.

In all the pain measures, the men had greater changes than the women. The men may have experienced a greater placebo effect than the women because their pain coping strategies are different. Crisson and Keefe [20] found that women relied on internal loci of control or active coping strategies rather than outside forces to cope with pain. In contrast, men were more likely to utilize passive coping strategies. Considering acupuncture as an external force, it would then be expected that the men would respond better to treatment than the women. Kreitler et al. [21] demonstrated that symptom relief with acupuncture treatment could be predicted from subjects' beliefs, which could account for 85% of the variance in response to acupuncture. In the present study, however, subjects' beliefs were not measured. The greater response of the men could also be related to the fact that both the acupuncturist and the assessor were women.

An alternative explanation for the results is that physiological effects may have been occurring in both groups. First, Te chi occurred in a majority of subjects in both groups, and those who experienced Te chi had a better response. Second, the fact that men responded better than women may be due to physical rather than psychological differences in the genders. The women generally had more subcutaneous tissue around the knee and this may have hindered the insertion of the needles to a depth that would produce Te chi and possibly the desired physiological response. On the other hand, even the superficial insertion of needles in the control group subjects may have been adequate to produce a physiological response in individuals (mainly men) with less fat around the knee. Finally, some subjects may be physically incapable of responding to acupuncture. Stux and Pomeranz [22] found that 15–20% of mice failed to respond to acupuncture because they had insufficient opiate receptors.

Te chi may also have been experienced by subjects who expected to respond to acupuncture, i.e., Te chi was part of the placebo response. We have found in transcutaneous electrical nerve stimulation (TENS) studies that some subjects indicate that they feel current even when the power is shut off (unpublished observations). The response of the Te chi group may

simply be a reflection of the gender effect as more men experienced Te chi and men responded better to treatment.

The experience of Te chi in both groups was unexpected. The placebo acupuncture was designed to produce a minimal physiological effect [18] but still appear realistic to the subjects. Because the needles just pierced the skin, subjects were not expected to experience anything more than a momentary sharp prick. On the other hand, insertion of the needles to their full depth failed to elicit Te chi in some of the experimental subjects. If the Te chi sensation is related to the efficacy of acupuncture, it will be important to find ways to control this response in future studies. One approach may be to include subjects of only one gender or to increase the number of subjects and include gender as a factor. There should also be some attempt to measure 'Te Chi,' which in this study was a totally subjective report by the subjects. Finding a control treatment that does not produce Te chi may be problematic. Application of another treatment (e.g., placebo TENS) or insertion of needles in a remote location may not provide the realism necessary to provide a placebo effect.

The results of this study are similar to those of Gaw et al. [10], who also conducted a controlled, double-blind study on the treatment of OA with acupuncture. They reported pain relief in both control and treatment groups with no significant difference between them. They also concluded that the results could be due to similar physiological and/or placebo effects in both groups.

From the results of the present study, it is concluded that: 1) both the true acupuncture and sham acupuncture significantly reduced pain in the osteoarthritic knee; 2) there was no significant difference between the real and the sham acupuncture; 3) men responded better than women to acupuncture treatment; 4) subjects experiencing Te chi regularly during treatment responded better to acupuncture than those who did not experience this sensation; and 5) further study in acupuncture is warranted with better control of Te chi and a more homogeneous group.

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