Randomized Control Trial

# The Effect of Acupuncture and Physiotherapy on Patients with Knee Osteoarthritis: A Randomized Controlled Study

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**Background:** Osteoarthritis is the most prevalent form of joint disease, and the most common location is the knee.

**Objectives:** The aim of this study was to determine the effect of acupuncture treatment and physiotherapy on pain, physical function, and quality of life (QOL) in patients with knee osteoarthritis (KOA).

**Study Design:** This study was a prospective, randomized, controlled clinical trial.

**Settings:** The research took place in the interventional pain unit of a tertiary center in a university hospital.

**Methods:** One hundred patients with KOA were randomly divided into the acupuncture group and the physiotherapy group. Both treatments were given in 12 sessions over 6 weeks. Thirteen acupuncture points were selected for the knee. Local points were GB34, SP10, SP9, ST36, ST35, ST34, EX-LE2, EX-LE5, EXLE4, and distal (distant) points were defined as KI3, SP6, LI4, and ST41. The Visual Analog Scale (VAS) was used to measure pain intensity. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the 36-Item Short Form Health Survey (SF-36) were used to determine functional status and health-related QOL, respectively. All patients were evaluated at baseline, after the last treatment, and at the 12-week follow-up period.

**Results:** There was no statistically significant difference between the acupuncture group and physiotherapy group in terms of pain, total WOMAC, and SF-36 levels at baseline, after treatment, and at the 12th week after treatment ($P > 0.05$). Both treatments significantly improved functional status (acupuncture, from 63.8 ± 20.81 to 53.72 ± 19.43; and physiotherapy, from 59.04 ± 21.49 to 52.28 ± 19.54; $P < 0.05$) and decreased the level of pain assessed by VAS (acupuncture, from 8.32 ± 1.61 to 5.54 ± 2.34; and physiotherapy, from 7.86 ± 1.9 to 5.68 ± 2.42; $P < 0.05$) at the 12-week follow-up of the study. There was no adverse advent related to therapeutic methods.

**Limitations:** Sham or placebo control groups are lacking in this study.

**Conclusions:** The acupuncture and physiotherapy performed twice weekly for 6 weeks have similar effects with regard to pain, functional status, and QOL. There were no significant differences between the acupuncture and physiotherapy groups in relief of pain, improved functional status, and QOL in the treatment of KOA. Both acupuncture and physiotherapy treatments were found to yield significantly superior results when compared with baseline values.

**Key words:** Knee osteoarthritis, acupuncture, physiotherapy, randomized clinical trial

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Osteoarthritis (OA) is a chronic, noninflammatory, and degenerative disease. The most commonly affected joints are the knees (1), and the disease is characterized by progressive cartilage destruction, osteophyte formation, and subchondral sclerosis, especially in load-bearing joints. It has been reported that knee pain caused by OA is the most common cause of physical disability in the elderly (2-4). The most important and debilitating symptom of OA is the pain. However, stiffness in the joint, reduced range of movement, crepitation, locking, deformity, quadriceps atrophy, and loss of function are also common (5).

There is no proven treatment method that reverses structural changes in knee osteoarthritis (KOA). The aim of the treatment is to reduce pain, preserve and improve the quality of life (QOL) and joint functions, increase muscle strength, prevent injuries, and complications related to the treatment (6). Nonpharmacologic, pharmacologic, and, when necessary, surgical methods are used for the treatment of KOA (7). Pharmacologic treatments include analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), intraarticular injections, and so forth. Nonpharmacologic treatments mainly comprise lifestyle changes, weight loss, physiotherapy, acupuncture, low-intensity aerobic exercises, and orthoses. Surgical treatment is recommended for patients with intractable pain and disability despite conservative treatment methods. NSAIDs are frequently used in the treatment of OA, but the prescription is limited owing to serious side effects (gastric ulcers, gastrointestinal bleeding, and kidney damage) in long-term use (8). Because of the high cost and risks of surgical treatments and the side effects of pharmacologic drugs, patients are seeking alternative and complementary treatment methods (9).

Acupuncture is the best-known alternative and complementary treatment method, which is basically applied to certain body points (acupuncture points) with disposable sterile needles (10). According to common knowledge, these points are found on meridians or channels following energy flows. The World Health Organization has also included OA in the group of diseases that acupuncture therapy has proven to be effective in controlled clinical trials (11). The effect of acupuncture on KOA has been shown in many reviews and meta-analyzes (12,13).

Physiotherapy, which encompasses a number of modalities, is a noninvasive conventional treatment option in the management of KOA. There are several physiotherapeutic modalities such as therapeutic ultrasound (US), shortwave diathermy, transcutaneous electrical nerve stimulation (TENS), laser, hotpack (HP), hot water baths, paraffin, and infrared, which are frequently used in patients with KOA. Previous studies indicated that combined physical therapy agents reduced pain and swelling and were very useful in the treatment of functional disorders in patients with degenerative diseases (14,15).

Thermal US is one of the widely used physiotherapeutic modalities as a deep tissue heater. The effects of US include increment of metabolic rate, nerve transmission, circulation, and soft tissue flexibility, leading top pain reduction and muscle spasm improvement. It also has a chondroprotective effect on the osteoarthritic cartilage in KOA. US are sound waves with a much higher frequency, and the frequency of US waves used for treatment is generally between 0.5 and 3.5 MHz. The frequency of US waves that are used as a therapeutic modality is 0.8 to 3 MHz, and the average treatment dose is 1.5 W/cm$^2$ (16).

Physiotherapy, such as TENS and muscle stimulation, may be used to improve quadriceps strength and has some evidence that shows it can help with pain reduction. TENS is a low-frequency electrical current for pain relief, applied through superficial electrodes placed on the skin. The analgesic mechanism of action of TENS, which is widely used in musculoskeletal pain, is through the activation of inhibitory pathways descending from the midbrain and brain stem, and thus inhibition of nociceptive neurons in the spinal cord (17). In addition, it has been determined that TENS has a positive effect on local tissue healing and could reduce the inflammatory processes. There are several studies indicating the effects of TENS on patients with musculoskeletal pain.

Hot pack is a fabric bag filled with silicate gel. After the silicate gel is heated up to 60°C to 70°C by tap water, it can be applied for 20 to 30 minutes without losing its heat by wrapping it in a towel. It is generally used as a superficial heating modality in musculoskeletal pain disorders.

There are few studies that have compared acupuncture and physiotherapy agents in the literature. Most of these studies are low quality with small study groups. Randomized controlled studies are needed to demonstrate the comparative effectiveness of acupuncture with other physiotherapeutic modalities in the treatment of KOA. The aim of this study was to compare the effect of acupuncture and physiotherapy on pain, physical function, and health-related QOL in patients with KOA.

## Methods

Our study was planned as a prospective, randomized, and controlled study. Local ethics committee approval (B.10.1.TKH.4.34.H.GP.0.01/111) was obtained for this study. Written and verbal information about the study and procedures were given, and informed consents were obtained from the patients. The study was carried out in accordance with the Declaration of Helsinki. Patients aged 38 to 80 years were recruited from the department of outpatient physical medicine and rehabilitation clinic of a training and research hospital between January 2018 and September 2018.

### Inclusion Criteria

Patients aged 40 years and older who have chronic knee pain (for more than 6 months) and diagnosed with KOA according to the American College of Rheumatology (ACR) diagnostic criteria (18), and patients with stage 2 or stage 3 OA in both knees according to Kellgren-Lawrence (KL) criteria were included in the study.

### Exclusion Criteria

Patients with previous knee surgery; those who have had intraarticular injection (steroid, prolotherapy, platelet-rich plasma, etc.), acupuncture, or physiotherapy in the last 6 months; patients with rheumatoid arthritis or other systemic, autoimmune, and rheumatic diseases; secondary KOA; senile dementia; severe psychiatric and psychological disorders; allergic skin diseases, ulcer, or infection; pregnant and lactating patients; patients receiving anticoagulant therapy; hearing aids or pacemakers; abnormal hepatic or renal dysfunction; and neuropathic pain were excluded.

### Patients

Our study was conducted with a total of 100 patients aged between 38 and 80 years. Detailed knee examinations were performed, and demographic and clinical data comprising age, gender, marital status, employment status, education level, duration of pain (month), and stage of KOA were recorded. The severity of the disease was determined according to the radiologic stage. Two-way anteroposterior knee radiographs were taken on the feet. Anteroposterior radiographs were classified according to KL criteria (19,20). The study flow chart is shown in Fig. 1.

We used G* Power version 3.1.2 (Heinrich Heine-Universität Düsseldorf, Düsseldorf, Germany) to calculate the sample size. Power analysis revealed that 50 patients were needed for each group for 80% statistical power at 20% significance level. We used data from a pilot study in which acupuncture affected Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores (standard deviation [SD] = 16.60), which corresponded to an estimated effect size of 0.396 (21).

### Randomization

According to the ACR criteria, 200 knees of 100 patients were included in the study. Acupuncturists were not included in the randomization process. The patients were divided randomly into 2 groups, acupuncture and physiotherapy (TENS, HP, US), grouped in a ratio of 1:1, using sequentially numbered, opaque, sealed envelopes. All measurements before (at baseline) and after treatment (at 6 weeks and at 12 weeks) were evaluated by

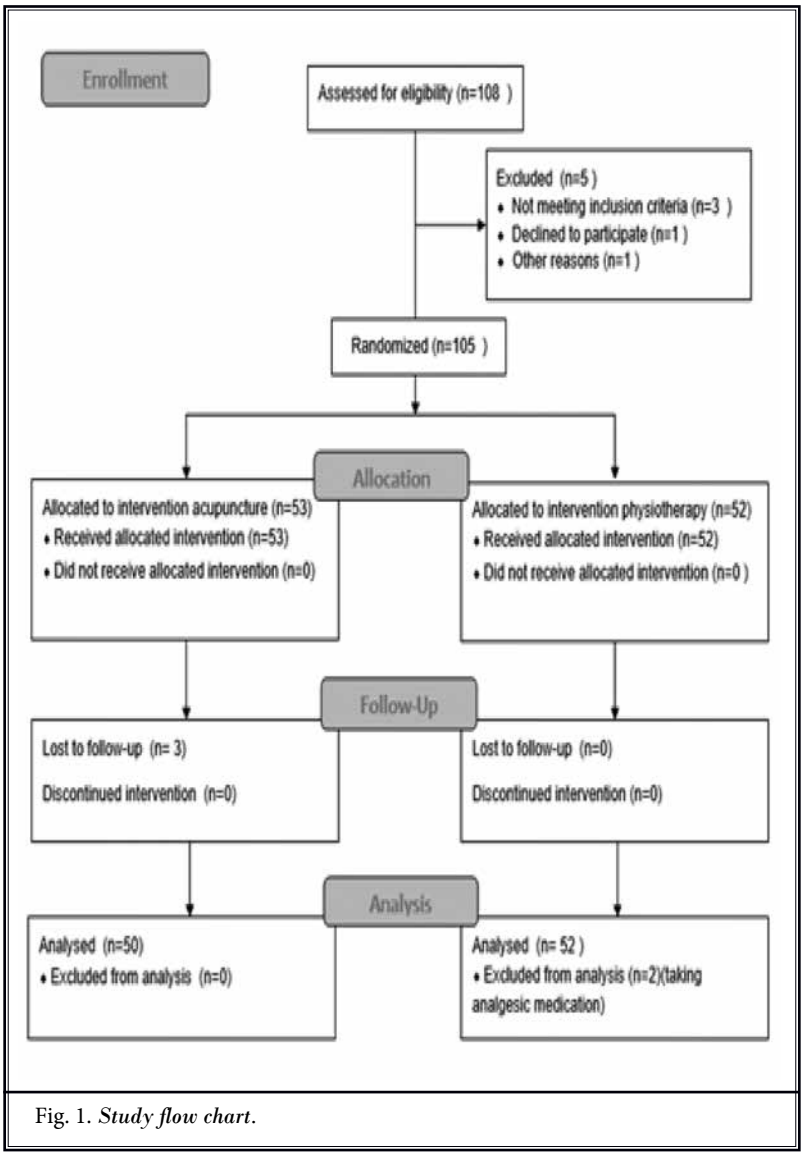


Fig. 1. *Study flow chart.*

the same researcher. All the patients were advised not to take any other treatment for KOA.

### Acupuncture Intervention

Acupuncture treatment was applied to all cases in group 1 by the same physician who is experienced and certificated in this field for 8 years. Acupuncture treatment was performed as 20 minutes per session twice weekly for 6 weeks with a total of 12 session. For patients with bilateral KOA, both knees were needled, and for patients with unilateral KOA, the acupuncturist needled only the affected knee. In patients with KOA affected by bilateral knee, the acupuncture protocol followed the CONSORT and STRICTA guidelines (22). Routine disinfection was performed by an acupuncturist with a 75% alcohol pad. The patient sat in a position in which the knee joint would be most comfortable, and the patient could not see the needle. Patients in the acupuncture group were treated with disposable, sterile, single-use, steel acupuncture needles (0.30: 25 mm, or 0.30: 40 mm), and 0.8 to 3 cm was used as penetration depth for 20 minutes. Thirteen acupuncture points were selected for the knee. (The physicians have chosen at least 5 local points and 3 distant points.) Local points were GB34, SP10, SP9, ST36, ST35, ST34, EX-LE2, EX-LE5, EXLE4, and the distal (distant) points were KI3, SP6, LI4, and ST41. After the acupuncture treatment, the patients were asked to state any negative feeling caused by the needles such as nausea, feeling faint, or discomfort in the needle-stuck area.

### Physiotherapy Intervention

A total of 12 sessions of HP for 20 minutes, US 1.5 W/cm$^2$ for 6 minutes, and TENS for 20 minutes were applied to the patients in the physiotherapy group.

US (Enraf-Nonius B.V., Rotterdam, Holland) was applied to the knee joint, a with 5-cm diameter head, at a dose of 1 MHz, 1.5 W/cm$^2$. It was applied for 6 minutes in each session to both knees. The US head was applied to both knee joint distances from the mediolateral direction by small circular movements of the head.

The TENS (EN-Stim 4, Enraf-Nonius) device was applied to both knees for 20 minutes with a frequency of 100 Hz, and a stimulation time of 300 μs for 10 sessions. Patients were positioned in the supine position with their knees extended, and electrodes for the electrical stimulation were placed on the anterior medial and lateral painful areas of the affected knee. HPs were placed on the affected knees for 20 minutes.

A home exercise program, including quadriceps strengthening, isometric, and isotonic exercises, were also given to patients in both treatment groups. The patients were instructed to perform the exercises daily for 10 repetitions. Patients included in the study were evaluated at baseline, at the end of treatment (6 weeks), and 12 weeks after treatment. During the study, the patients in both groups were asked to state any negative situation or side effect.

### Primary Outcome Measurement

Pain assessed by Visual Analog Scale (VAS) and WOMAC scores indicating functional status of the knee were the primary outcome measures. The success rate was based on changes in pain and function at baseline and at the 12th week. WOMAC function subscale will be used to evaluate physical function (23). In WOMAC index, pain was evaluated with 5 questions, stiffness with 2 questions, and functional status with 17 questions. For each measurement, questions were scored between 1 and 10, and the total score was determined for each section, WOMAC function subscale (17 titles with a score between 0 and 68), and pain subscale (5 titles with a score from 0–20). Higher scores showed worse pain and function. The knee pain was assessed by VAS (0–10 cm). The patients were asked to mark their subjective pain levels on a 10-cm scale. Accordingly, the value 0 indicates that there is no pain, and the value 10 indicates the most severe pain. The distance between the baseline and the marked point is recorded as centimeters (24).

### Secondary Outcome Measurement

The health-related QOL was our secondary outcome measure. QOL scale short form (36-Item Short Form Health Survey [SF-36]) was used to assess the QOL. The SF-36 evaluates many aspects of health and includes 36 questions consisting of 8 subtitles such as physical function, social function, physical role function, emotional role function, mental health, energy fatigue, pain, and general health. The first 4 subtitles evaluate the physical health QOL, and the last 4 subtitles evaluate the mental health QOL. The evaluation is made considering the last 4 weeks, and the scale is evaluated between 0 and 100. High score indicates better health level, and low score indicates poor QOL (25).

Adverse events were monitored and reported by a physician via an open-ended questionnaire. The presence of redness, itching, hemorrhage, swelling, brushing, pain, and peripheral neuritis was noted as the adverse events. Patients were requested to voluntarily report adverse effects, and the researchers

confirmed the occurrence by an interview or physical examination.

### Statistical Analyses

SPSS Statistics Version 22 software (IBM Corporation, Armonk, NY) was used for statistical analysis in the study. In the evaluation of the data, suitability of parameters to normal distribution were assessed by the Shapiro-Wilks test, the Student t-test was used for the comparison of descriptive statistical methods (mean, standard deviation, frequency), as well as the comparison of parameters that showed normal distribution, and the Mann-Whitney U test was used for the comparison of parameters that did not show normal distribution. Paired sample t-test was used for intragroup comparisons of quantitative data with normal distribution, and the Wilcoxon signed-rank test was used for intragroup comparison of non-normally distributed parameters. In the comparison of qualitative data, the $\chi^2$ test, the Fisher exact test, the Fisher-Freeman-Halton test, and Continuity (Yates) Correction were used. Significance was evaluated at the level of $P < 0.05$.

## Results

The study was conducted with 100 patients, 63 (63%) women and 37 (37%) men, aged between 38 and 80 years. The study was examined under 2 treatment groups, 50 (50%) patients in the acupuncture group (group 1) and 50 (50%) patients in the physiotherapy group (group 2). The mean age of our patients was 57.5 ± 7.81 years, and the average body mass index (BMI) was 32.4 ± 5.78. There was no significant difference between groups in terms of age, gender, marital status, educational status, and stage of KOA ($P > 0.05$). The baseline characteristics and outcome measurements are shown in Table 1.

According to our primary outcome results, there was no significant difference between the 2 groups with regard to pain by VAS and WOMAC scores, and WOMAC pain scores at baseline, posttreatment, and 12th week control ($P > 0.05$). Both groups were improved at the end of the therapy, and the improvement was continued in both groups up to the 12th week. According to secondary outcome measures, significant difference was observed between groups with regard to scores at baseline, posttreatment, and 12th-week values ($P > 0.05$). Both groups had significant improvements in SF-36 scores at the end of treatments and at 12th-week follow-up ($P < 0.05$).

Table 2 shows the results for VAS pain and WOMAC

Table 1. *Demographic data and clinical characteristics in the groups.*

| | | Treatment Group | | *P* value |
|---|---|---|---|---|
| | | Acupuncture (n = 50) (mean ± SD) | Physiotherapy (n = 50) (mean ± SD) | |
| Age (yrs) | | 57.82 ± 7.15 | 57.18 ± 8.48 | [1]0.684 |
| BMI (kg/m$^2$) | | 33.54 ± 6.17 | 31.26 ± 5.17 | **[1]0.049*** |
| Duration of pain in KOA (month) (median) | | 55.74 ± 42.03 (48) | 27.5 ± 22.7 (24) | **[2]0.001*** |
| Gender n (%) | Female | 31 (62%) | 32 (64%) | [3]1.000 |
| | Male | 19 (38%) | 18 (36%) | |
| Marital status n (%) | Married | 46 (92%) | 46 (92%) | [4]1.000 |
| | Single | 4 (8%) | 4 (8%) | |
| Education level n (%) | Primary | 37 (74%) | 32 (64%) | [5]0.634 |
| | Single | 10 (20%) | 14 (28%) | |
| | University | 3 (6%) | 4 (8%) | |
| Employment status n (%) | Employed | 9 (18%) | 16 (32%) | [3]0.166 |
| | Unemployed | 41 (82%) | 34 (68%) | |
| KOA stage n (%) | 2 | 28 (56%) | 28 (56%) | [6]1.000 |
| | 3 | 22 (44%) | 22 (44%) | |

[1]Student t-test. [2]Mann-Whitney U test. [3]Continuity (Yates) correction. [4]Fisher exact test. [5]Fisher-Freeman-Halton test. [6]$\chi^2$ test.
*$P < 0.05$ is considered statistically significant.

pain scores for acupuncture and physiotherapy over time. Posttreatment and 12th week WOMAC scores were significantly lower than the baseline values. ($P < 0.05$). In the physiotherapy group, total WOMAC scores were not significantly changed posttreatment compared with the baseline ($P > 0.05$), whereas the decrease in total WOMAC scores at the 12th week was statistically significant ($P < 0.05$). WOMAC total scores were improved in both short and long terms in the acupuncture group, whereas the scores were improved only at 12th week control in the physiotherapy group.

In the acupuncture group, the decrease in WOMAC pain scores at posttreatment and 12th week was statistically improved. There was no significant change in the physiotherapy group after the treatment, but reduction of pain at the 12th week after treatment was statistically significant ($P < 0.05$).

In the acupuncture group, decreased WOMAC stiffness scores were statistically significant at posttreatment and at the 12th week ($P < 0.05$), however, no statistical significance was observed in the physiotherapy group ($P > 0.05$).

There was no significant difference between the treatment groups in terms of improvement in WOMAC physical function at baseline, posttreatment, and posttreatment at the 12th week. The improvement in WOMAC physical function values after treatment and at 12th-week follow-up were statistically significant (physiotherapy; $P < 0.05$ and acupuncture; $P < 0.05$).

There was no significant difference between the

Table 2. *Severity of pain and subgroup of WOMAC scores over time according to group.*

| WOMAC | | Treatment Group | | *P* |
|---|---|---|---|---|
| | | Acupuncture (n = 50) (mean ± SD) | Physical therapy (n = 50) (mean ± SD) | |
| WOMAC Total | Pretreatment | 63.8 ± 20.81 | 59.04 ± 21.49 | 0.263 |
| | Posttreatment | 55.47 ± 21.49 | 55.93 ± 19.43 | 0.909 |
| | Week 12 | 53.72 ± 19.43 | 52.28 ± 19.54 | 0.712 |
| | Pre/posttreatment, $P^2$ | **0.001*** | **0.127** | |
| | Pre/posttreatment week 12, $P^2$ | **0.000*** | **0.001*** | |
| WOMAC Pain | Pretreatment | 13.02 ± 4.44 | 11.78 ± 4.4 | 0.164 |
| | Posttreatment | 11.18 ± 4.57 | 11.26 ± 4 | 0.926 |
| | Week 12 | 10.88 ± 4.69 | 10.5 ± 4.14 | 0.668 |
| | Pre/posttreatment, $P^2$ | **0.005*** | **0.245** | |
| | Pre/posttreatment week 12, $P^2$ | **0.001*** | **0.005*** | |
| WOMAC Stiffness | Pretreatment | 4.9 ± 2.29 | 4.46 ± 2.33 | **0.343** |
| | Posttreatment | 4.22 ± 2.48 | 4.34 ± 1.95 | **0.789** |
| | Week 12 | 4.14 ± 2.43 | 4.08 ± 2.04 | **0.894** |
| | Pre/posttreatment, $P^2$ | **0.006*** | **0.624** | |
| | Pre/posttreatment week 12, $P^2$ | **0.012*** | **0.192** | |
| WOMAC Function | Pretreatment | 44.26 ± 14.23 | 40.86 ± 15.17 | **0.251** |
| | Posttreatment | 38.2 ± 15.21 | 37.92 ± 13.71 | **0.923** |
| | Week 12 | 37.58 ± 14.23 | 35.5 ± 13.9 | **0.461** |
| | Pre/posttreatment, $P^2$ | **0.001*** | **0.045*** | |
| | Pre/posttreatment week 12, $P^2$ | **0.000*** | **0.001*** | |
| VAS Pain | Pretreatment | **8.32 ± 1.61 (8)** | **7.86 ± 1.9 (8)** | **[1a]0.231** |
| | Posttreatment | **6.04 ± 2.16 (6)** | **5.81 ± 2.26 (6)** | **[1a]0.628** |
| | Week 12 | **5.54 ± 2.34 (5)** | **5.68 ± 2.42 (5)** | **[1a]0.929** |
| | Pre/posttreatment, $P^2$ | **< 0.05*** | **< 0.05*** | |
| | Pre/posttreatment week 12, $P^2$ | **< 0.05*** | **< 0.05*** | |

[1]Student t-test. [2]Paired sample t-test. *$P < 0.05$ is considered statistically significant.

treatment groups in terms of SF-36 subscales of physical function, physical role difficulty, emotional role difficulty, and energy/fatigue at baseline, after treatment, and at the 12th week ($P > 0.05$). There was no significant change in the SF-36 physical function scores in the acupuncture group after treatment and at 12th-week control ($P > 0.05$), although the improvement in the physical function was statistically significant in the physiotherapy treatment group ($P < 0.05$). SF-36 pain values at baseline were similar between 2 groups. A statistically significant improvement was found in the SF-36 general health, posttreatment and at 12th-week in the acupuncture group than in the physiotherapy group. Table 3 shows comparison of SF-36 scores between treatment groups.

Both acupuncture and physiotherapy methods were well tolerated in our study and no side effects were observed. Most patients completed the study except those who left because of personal reasons. Five patients dropped out after completing acupuncture and physiotherapy; 3 did not follow up after treatment because of personal reasons, and 2 were taking concomitant analgesic and anti-inflammatory medication, contrary to the study protocol.

## Discussion

KOA is one of the most common musculoskeletal diseases. In KOA, QOL is impaired owing to pain and limited physical functions (26). The aim of this study was to compare the effects of acupuncture and physical therapy agents on pain, physical function, and health-

Table 3. *Comparison of SF-36 scores between treatment groups.*

| SF-36 | | Treatment Group | | *P* |
|---|---|---|---|---|
| | | Acupuncture (n = 50) (mean ± SD) | Physical therapy (n = 50) (mean ± SD) | |
| Physical function | Pretreatment | 31.5 ± 19.2 | 31.6 ± 19.44 | [1a]0.979 |
| | Posttreatment | 34 ± 21.67 | 38.7 ± 22.13 | [1a]0.286 |
| | Week 12 | 35.3 ± 19.55 | 38.1 ± 23.41 | [1a]0.518 |
| | Pre/posttreatment, $P^{2a}$ | 0.349 | **0.026*** | |
| | Pre/posttreatment week 12, $P^{2a}$ | 0.091 | 0.022* | |
| Role physical (median) | Pretreatment | 18.5 ± 32.66 (0) | 21 ± 35.12 (0) | [1b]0.987 |
| | Posttreatment | 30 ± 37.8 (12.5) | 20.5 ± 35.96 (0) | [1b]0.080 |
| | Week 12 | 29.9 ± 39.08 (0) | 21.2 ± 37.76 (0) | [1b]0.143 |
| | Pre/posttreatment, $P^{2b}$ | 0.070 | 0.930 | |
| | Pre/posttreatment week 12, $P^{2b}$ | 0.106 | 0.965 | |
| Role emotional (median) | Pretreatment | 43.34 ± 45.82 (33) | 35.2 ± 45.8 (0) | [1b]0.332 |
| | Posttreatment | 52.86 ± 43.73 (67) | 40.3 ± 44.05 (29) | [1b]0.188 |
| | Week 12 | 45.2 ± 45.39 (33) | 46.16 ± 45.08 (33) | [1b]0.880 |
| | Pre/posttreatment, $P^{2b}$ | 0.277 | 0.274 | |
| | Pre/posttreatment week 12, $P^{2b}$ | 0.806 | **0.048*** | |
| Energy/fatigue | Pretreatment | 39.7 ± 21.79 | 46.26 ± 21.87 | [1a]0.136 |
| | Posttreatment | 44.32 ± 21.85 | 43.98 ± 18.69 | [1a]0.934 |
| | Week 12 | 43.76 ± 21 | 49.66 ± 19.43 | [1a]0.148 |
| | Pre/Posttreatment, $P^{2a}$ | 0.066 | 0.429 | |
| | Pre/Posttreatment week 12, $P^{2a}$ | 0.101 | 0.270 | |
| Emotional well-being | Pretreatment | 59.86 ± 17.77 | 64.44 ± 17.09 | [1a]0.192 |
| | Posttreatment | 62.52 ± 16.49 | 65.66 ± 17.86 | [1a]0.363 |
| | Week 12 | 63.28 ± 15.53 | 63.52 ± 16.79 | [1a]0.941 |
| | Pre/posttreatment, $P^{2a}$ | 0.105 | 0.557 | |
| | Pre/posttreatment week 12, $P^{2a}$ | 0.062 | 0.672 | |

Table 3 con't. *Comparison of SF-36 scores between treatment groups.*

| SF-36 | | Treatment Group | | *P* |
|---|---|---|---|---|
| | | Acupuncture (n = 50) (mean ± SD) | Physical therapy (n = 50) (mean ± SD) | |
| Social function | Pretreatment | 51.44 ± 24.43 | 46.58 ± 27.23 | [1a]0.350 |
| | Posttreatment | 55.06 ± 23.58 | 55.36 ± 27.84 | [1a]0.954 |
| | Week 12 | 55.38 ± 23.15 | 56.84 ± 27.91 | [1a]0.776 |
| | Pre/posttreatment, $P^{2a}$ | 0.283 | **0.020*** | |
| | Pre/posttreatment week 12, $P^{2a}$ | 0.268 | 0.006* | |
| Body pain | Pretreatment | 35.4 ± 21.78 | 33.9 ± 24.29 | [1a]0.746 |
| | Posttreatment | 51.74 ± 25.02 | 38.8 ± 27.63 | [1a]0.016* |
| | Week 12 | 52.46 ± 26.17 | 42.92 ± 27.32 | [1a]0.078 |
| | Pre/posttreatment, $P^{2a}$ | **0.000*** | 0.094 | |
| | Pre/posttreatment week 12, $P^{2a}$ | **0.000*** | **0.002*** | |
| General health | Pretreatment | 47 ± 18.07 | 48.3 ± 18.78 | [1a]0.725 |
| | Posttreatment | 50.7 ± 19.01 | 49.16 ± 21.22 | [1a]0.703 |
| | Week 12 | 52.8 ± 19.77 | 49.3 ± 19.19 | [1a]0.371 |
| | Pre/posttreatment, $P^{2a}$ | 0.088 | 0.628 | |
| | Pre/posttreatment week 12, $P^{2a}$ | **0.019*** | 0.610 | |
| Health change (median) | Pretreatment | 31 ± 22.9 (25) | 27 ± 21.92 (25) | [1b]0.390 |
| | Posttreatment | 43 ± 23.71 (25) | 30.6 ± 23.73 (25) | **[1b]0.013*** |
| | Week 12 | 43.5 ± 24.65 (37.5) | 35.6 ± 25.67 (25) | [1b]0.134 |
| | Pre/posttreatment, $P^{2b}$ | **0.002*** | 0.316 | |
| | Pre/posttreatment week 12, $P^{2b}$ | **0.003*** | 0.021* | |

[1a]Student t-test. [1b]Mann-Whitney U test. [2a]Paired sample t-test. [2b]Wilcoxon signed-rank test. *$P < 0.05$ is considered statistically significant.

related QOL in patients with mild to moderate severity of KOA.

Previous studies have shown that advanced age and increase in BMI are important risk factors for OA (27-29). The mean age and BMI of our patients were compatible with the literature, in which the mean age and BMI of our patients was 57.5 and 32.4, respectively.OA is generally known to affect women more than men (30). In our study respectively, the number of female patients was statistically higher than men, in both groups.

In acupuncture, the impulses that start with nociceptors by immersion of needle activates the analgesic system by stimulating enkephalinergic and serotonergic neurons in the mesencephalon as they travel from the medulla spinalis to the cortex. Thus beta-endorphin, enkephalin, serotonin, and norepinephrine, which have anti-inflammatory and immune modulatory effects, increase in the central nervous system and plasma by acupuncture. Beta-endorphin has analgesic and anti-inflammatory effects (31).

In a meta-analysis, patients with KOA who were treated with acupuncture had decreased pain intensity, improved physical function, and improved QOL (11).

In a randomized, controlled, clinical study, Zhang et al (21) found acupuncture treatment superior to physiotherapy in KOA with regard to scores of total WOMAC and 3 subscales for pain, stiffness, and physical function. Acupuncture was also found to be more effective than sham acupuncture in patients with KOA (32). Contrary to these studies, Takeda and Wessel (33) did not find a significant difference in terms of pain, stiffness, and physical activity between acupuncture and placebo acupuncture applications for patients with KOA.

In our study, acupuncture treatment twice weekly, 12 sessions in total, statistically improved the VAS pain, WOMAC, and SF-36 scales at the end of the treatment and at the 12th-week control. Pain intensity levels of patients decreased and their physical function and their QOL improved after the acupuncture treatment.

Physiotherapy is generally used in clinic as a combination of several treatment agents. Previous reports indicated that applications using more than one physical therapy agent generally gave more successful results (14). In our study, we have combined HP, US, and TENS with exercises on therapeutic physiotherapy approach.

Previous studies indicated that physiotherapy reduced pain and increased physical functions. During absorption of US waves in tissues and reflection on interfaces, heat energy is released and thus provides deep heating. It was determined that US caused a marked increase in intraarticular temperature, which creates analgesic, circulatory accelerator, and nutritional correction effects. It was determined that US caused a marked increase in intraarticular temperature, which creates analgesic, circulatory accelerator, micromassage and nutritional correction effects (16,34).TENS application increases the secretions and plasma levels of adrenocorticotropic hormone, as well as beta-endorphin. TENS has been reported in previous studies to reduce analgesic consumption for postoperative pain (35). In our study, statistically significant improvements were observed in the VAS pain, WOMAC, and SF-36 scores in patients with applied combined physiotherapy agents at the end of the treatment and at the 12th-week follow-up.

Both acupuncture and physiotherapy improved pain by VAS in similar proportion at the end of 12 weeks. WOMAC subscales and WOMAC total scores were significantly improved in the acupuncture group at both posttreatment and 12th-week follow-up, however, the improvement in WOMAC pain, stiffness, and total scores were significant only at the 12-week follow-up in the physiotherapy group.

With regard to QOL assessed by SF-36, the body pain and health change subgroups were improved similarly in both treatment groups, however, physical function, emotional, and social function scores were improved only in physiotherapy, whereas general health scores were improved only in acupuncture treatment groups.

These results indicate that acupuncture has a great treatment effect on KOA in both short and long term, whereas physiotherapy has only the long-term effect on the symptoms of KOA up to 12 weeks. In addition, some of the SF-36 subscores (body pain, health change) were similarly improved in both groups, general health was improved only in the acupuncture treatment group, and physical, emotional, and general health scores were improved in the physiotherapy group at the 12-week control.

### Limitations

The major limitation of this study was the lack of sham control and placebo groups. The placebo effect may not be well dispersed to the groups because of the control group's deficiency. However, our primary goal was to compare acupuncture and physiotherapy treatments. Overall, patient and practitioner contacts were less intense in the physiotherapy treatment group than the acupuncture group.

The second limitation was that the significant difference within the group was not attributable only to acupuncture or physiotherapy, as exercises were performed by both groups, and we cannot exclude the effect of home exercise programs. Another limitation may be the effect of different BMI values between the 2 groups. Although the significance was not striking, we cannot exclude the effect of BMI as a risk factor. The size of study group and the presence of long-term follow-up to 3 months and randomization are the advantages and valued points of our study.

## Conclusions

Acupuncture and physiotherapy have similar efficacy in the treatment of KOA in both the short and long terms. It was determined that the effect of both methods continued after the treatment and 12 weeks later. The WOMAC pain, stiffness, and total score indicating functional status are improved in both short and long term only in the acupuncture treatment group. In addition, QOL general health subscores were improved only in the acupuncture group, whereas physical and social function was improved only in the physiotherapy group. Both treatment groups had improvement in different aspects of QOL up to 3 months.

Acupuncture and physiotherapy have comparable effects on pain of KOA, but improvement in functional status and QOL may be different with regard to variable subgroups.

### Author Contributions

SGA, AD, and OG conceptualized and designed the study. Acquisition of data were performed by SGA, AD, and OG. SGA, AD, and OG performed the further interpretation of data and drafted the manuscript, and revised the manuscript for intellectual content. All authors read and approved the final manuscript.

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