

# The Role of Scalp Acupuncture for Relieving the Chronic Pain of Degenerative Osteoarthritis: A Pilot Study of Egyptian Women

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## ABSTRACT

**Background:** Osteoarthritis (OA) is a common chronic and painful condition secondary to deterioration of cartilage. OA-related pain can be managed pharmacologically together with complementary therapies, such as acupuncture.

**Objective:** The aim of this trial was to evaluate the effectiveness of Yamamoto New Scalp Acupuncture (YNSA) for relieving pain associated with OA in Egyptian women.

**Design and Setting:** At the Female Outpatient Pain Clinic, of the National Research Centre, in Cairo, Egypt, between March 2008 and June 2009, 30 females (ages 27–80) presenting with chronic pain caused by OA were studied.

**Intervention:** The affected YNSA points were treated for 20 minutes in a single session.

**Main Outcome Measure:** Pain was assessed by a visual analogue scale (VAS) prior to, and 1 hour after, the intervention.

**Results:** Preintervention VAS scores were: 3–10 (mean  $7.43 \pm 1.9$ ;  $P > 0.05$ ). Postintervention VAS scores ranged from 0 to 8 (mean  $3.37 \pm 2.1$ ) with a statistically significant positive correlation between these scores and pretreatment values ( $P = 0.01$ ). Postintervention VAS scores were significantly related to pain locations. *Post-hoc* analysis showed statistically significant lower postintervention VAS scores for cervical OA, compared to those of lumbosacral OA.

**Conclusions:** YNSA acupuncture is effective in immediate pain relief among females suffering from degenerative OA.

**Key Words:** Chronic Pain, Osteoarthritis, Scalp Acupuncture

## INTRODUCTION

**O**STEoarthritis (OA) IS A CLINICAL SYNDROME of joint pain accompanied by varying degrees of functional limitation and reduced quality of life (QoL). OA is one of the most common of all chronic conditions. It is characterized by the degeneration of cartilage and its underlying bone within a joint as well as bony overgrowth. The breakdown of these tissues eventually leads to pain and joint stiffness.<sup>1</sup>

Joints most commonly affected are: knees; hips; hands; and spine. Overall, OA affects 13.9% of adults ages 25 and older and 33.6% (12.4 million) of people who are 65 years old. An estimated 26.9 million U.S. adults in 2005 of 21 million in 1990 had OA—and this is believed to be a conservative estimate.<sup>2</sup> Women between ages 65 and 74 were twice as likely as men to have knee OA. Men have a 45% lower incident risk of knee OA and a 36% reduced risk of hip OA than do women.<sup>3</sup>

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There is currently no cure for OA. Treatment for OA focuses on relieving symptoms and improving function. Treatment should be multidisciplinary, including a combination of patient education, physical therapy, weight control, and use of medications. Nonpharmacological and pharmacological management of symptoms are approached according to established guidelines.<sup>4</sup> The 2000 update of the American College of Rheumatology (ACR) recommendations has mentioned acupuncture as a viable therapeutic approach for OA.<sup>4</sup>

Acupuncture is one of the oldest treatment modalities, and has been successfully practiced in China for 4000 years. Traditionally, acupuncture has been used to treat various mental and physical disabilities.<sup>5</sup> Classical acupuncture is based on the theory that vital energy (Qi), flows through the body along meridians. There are specific points along these meridians (acupuncture points or acupoints) at which Qi may be accessed. Inserting needles into these points permits a practitioner to restore harmony to a patient's system by rebalancing the flow of Qi within that patient.<sup>6</sup>

In 1996, the U.S. Food and Drug Administration reclassified acupuncture needles from Class III (investigational use) to Class II (general acupuncture use).<sup>7</sup> The National Institutes of Health stated that acupuncture might be useful as an adjunct or alternative treatment for osteoarthritis.<sup>8</sup>

In the Western medical model, acupuncture is thought to relieve pain through the gate-control mechanism or through the release of neurochemicals.<sup>9</sup> Pomeranz and Berman<sup>10</sup> described the possible neural mechanisms of acupuncture analgesia as follows: Small diameter muscle afferents are stimulated, sending impulses to the spinal cord, which then activates 3 centers (spinal cord, midbrain, and pituitary gland) to release neurochemicals (endorphins and monoamines) that block pain messages.

Chronic disorders of the locomotor system are important fields of indication for Yamamoto New Scalp Acupuncture (YNSA).<sup>11</sup> This is an acupuncture method that provides rapid relief of pain of the locomotor system. YNSA, used since 1973, is a complete acupuncture microsystem.

While relatively unknown in the United States, YNSA deserves recognition and further research into its reliability and validity as well as its compatibility with other forms of treatment. YNSA is providing new insights into the electromagnetic circuitry of the body.<sup>12</sup>

## MATERIALS AND METHODS

### Selection Criteria

After institutional approval, between March 2008 and June 2009, 30 female patients with chronic degenerative OA were randomly selected from a list of patients with the same pathology who were referred to the Outpatient Women's

Pain Clinic, of the National Research Institute, in Cairo, Egypt. Inclusion criteria were: women between ages 27 and 80; presence of neck, shoulder, and/or low-back pain diagnosed by plain X-ray, computed tomography scan, or magnetic resonance imaging; no motor deficits (noted during a neurological examination); and chronic symptoms of more than 12 weeks' duration.

Written informed consent was obtained from the patients prior to the study. The Human Ethics Research committee of the National Research Centre granted the treatment approval.

Women were excluded if they refused to sign the informed consent form or had had previous treatments with acupuncture for any reason in the past 3 months. Women with conditions, such as cancer, metastasis of cancer, vertebral fractures, herniated discs, and bone infections, were also excluded.

Certain concomitant treatments were not permitted during the 4 weeks prior to the study treatment (opioids, invasive-therapy methods, or neuromuscular blocks in the region of treatment and parenteral or oral corticosteroids); during the week prior to treatment (nonsteroidal anti-inflammatory drugs, topical antirheumatics, topical corticosteroids, and muscle relaxants); or during the day prior to treatment (analgesics, heat, massage, and cold or rheumatism bath therapy).

### Procedure

Patients were examined clinically by a trained physician, who informed them about the visual analogue scale (VAS) that was to calculate each patient's VAS score before therapy and 1 hour after receiving treatment. The latter was calculated for the main pain location for patients with multiple pain sites.

The VAS enables patients to adjust a red slide in a white visual field to represent their sensation of pain subjectively on a scale between "no pain" (the red bar is withdrawn completely from the window) and "most intense pain" (the red bar completely fills the window). On the reverse of the VAS, hidden from the patient, the therapist can read the person's subjective assessment in figures on an 11-number scale between 0 and 10 (0 means no pain; 10 means most intense pain).<sup>1,2</sup>

The trial was based on revised *Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)* guidelines.<sup>13</sup>

YNSA was given to all patients in the trial. The affected scalp points were defined by the treating clinician, who was a medical physician licensed to perform acupuncture.

### Details of Needling

The intervention was conducted as follows:

- Only one session was given to each patient.
- Sterile, stainless-steel disposable acupuncture needles, sized 0.15 × 0.15, were used.

- 4–6 needles were inserted, mainly in the basic points and the brain area (according to the YNSA protocol), during the session.
- The depth of insertion was 5 mm–15 mm, until De Qi was attained.
- The needles were retained for 15–20 minutes.
- Manual stimulation only was applied to the needles.

The primary outcome measure was pain relief, as measured by the VAS.

### Statistical Analysis

Statistical analysis was performed, using PASW Statistics 18, Release 18.0.2, Serial Number 10146966. Data were presented as mean  $\pm$  standard deviation or numbers and percentages, as necessary. The distribution of qualitative data among groups was evaluated by a *chi-square* test or a Fisher's exact test, as necessary. A Spearman's test was used for evaluating the correlation between continuous variables.

Pre- and postintervention differences were calculated for each patient and the statistical significance of this difference was evaluated by a paired Student's *t*-test. However, the means of the differences were compared among patients' pain locations and multiplicity of these locations, using an unpaired Student's *t*-test or analysis of variance, as indicated. The Bonferroni test was used for *post-hoc* analysis for a two-by-two comparison of any statistically significant differences among the compared groups. A *P*-value of  $< 5$  was necessary for establishing statistical significance.

## RESULTS

This study included 30 females. Their ages ranged from 27 to 80, with a mean value of  $50.1 \pm 11.6$  years. Duration of pain among these patients ranged from 12 weeks to 4 years (mean value of 18 months  $\pm$  4 months). The main pain locations were the cervical region ( $n=12$ , 40%), the lumbosacral region ( $n=11$ , 36.7%), the shoulder region ( $n=4$ , 13.3%), and the knee ( $n=3$ , 10%). Seven patients (23.3%) had multiple pain locations that were: cervical and lumbar regions in 3 patients (43%); cervical and shoulder regions in 2 patients (28.6%); shoulder and knee in 1 patient (14.3%); and shoulder and lumbar regions in another patient (14.3%).

Preintervention VAS scores ranged from 3 to 10, with a mean value of  $7.43 \pm 1.9$ , and the scores calculated for OA affecting the knee, lumbosacral region, cervical region, and shoulder were  $9 \pm 1$ ,  $7.6 \pm 1.6$ ,  $7.3 \pm 1.8$ , and  $6.3 \pm 3$ , respectively ( $P > 0.05$ ). A high preintervention VAS score was significantly related to the presence of multiple pain locations; with this latter group of patients having a score of  $8.7 \pm 1.9$ , compared to only  $7.04 \pm 1.74$  for patients presenting with a single pain location ( $P = 0.038$ ).

However, the pre-VAS score was not significantly related to patients' ages ( $P > 0.05$ ).

Postintervention VAS scores ranged from 0 to 8, with a mean value of  $3.37 \pm 2.1$  and a statistically significant positive correlation between postintervention and preintervention values ( $P = 0.01$ ). Postintervention VAS scores were significantly related to pain location; values calculated for patients with OA affecting the lumbosacral, knee, shoulder, and cervical regions were:  $4.8 \pm 1.6$ ;  $4.33 \pm 1.2$ ;  $2.75 \pm 1.71$ ; and  $2 \pm 1.95$  ( $P = 0.005$ ), respectively. *Post-hoc* analysis showed a statistically significantly lower postintervention VAS scores for patients presenting with OA of the cervical region, compared to those with pain in the lumbosacral region ( $P = 0.004$ ). In addition, post-intervention VAS scores were not related to patients' age nor to multiplicity of pain locations ( $P > 0.05$ ).

The VAS score difference calculated for each patient ranged from 2 to 8, with a mean value of  $1.77 \pm 0.43$ , indicating a high, statistically significant improvement after therapy for the whole group of patients ( $P = 0.001$ ). There was a statistically significant relationship between relative pain relief, as indicated by a higher VAS score difference, and location of pain ( $P = 0.032$ ). The score differences calculated for patients presenting with OA affecting the cervical, knee, shoulder, and lumbosacral regions were:  $4.8 \pm 2$ ;  $4.7 \pm 1.5$ ;  $3.5 \pm 1.7$ ; and  $2.8 \pm 0.9$ , respectively. *Post-hoc* analysis showed a more statistically significant improvement in patients presenting with OA of the cervical region, compared to patients with chronic lumbosacral pain ( $P = 0.031$ ).

In Summary:

- (1) Patients presenting with OA affecting multiple locations had significantly higher preintervention VAS scores, compared to patients with OA affecting only one location ( $P = 0.038$ ).
- (2) There was a statistically significant positive correlation between the pre- and post-VAS scores ( $P = 0.01$ ). In other words, the higher the preintervention values were, the more higher postintervention values were expected.
- (3) All participants benefited from this single-session treatment, as indicated by a statistically significant VAS score difference ( $P = 0.001$ ).
- (4) Both calculated postintervention VAS scores and VAS score differences were significantly related to pain location ( $P = 0.005$  and  $P = 0.032$ , respectively). Patients with cervical OA had significantly lower post-VAS scores and score differences, compared to patients with lumbosacral pain ( $P = 0.004$  and  $P = 0.031$ , respectively).

## DISCUSSION

The aim of this study was to determine the effectiveness of YNSA for relieving pain of the locomotor system among

women seeking pain relief at the Outpatient Clinic. The trial was intended to show how rapidly YNSA produces pain-relieving effects. The data presented here offers support that YNSA is a form of microsystem acupuncture that is successful for relieving acute and chronic nonspecific musculoskeletal pain secondary to a variety of causes. YNSA is another form of acupuncture that complements the Traditional Chinese Medicine (TCM) teachings while providing new insights into the electromagnetic circuitry of the body.<sup>14</sup>

The VAS score difference calculated for each patient revealed a high, statistically significant improvement after therapy for the whole group of patients, as indicated by the *P*-value (*P*=0.001). This was in accordance with the study by Shaladi et al. in 2010.<sup>15</sup> The degree of reduction of pain was 71%, as evaluated with a VAS used in that study to evaluate the effectiveness of YNSA for relief of neck pain; this study also used a 1-session technique. Another study conducted by Feelyin 2006<sup>11</sup> emphasized the results obtained in the current study: Where YNSA was applied for treating pain and dysfunction, secondary to different diagnoses, YNSA showed very promising results for relieving back pain immediately, even with the use of a minimal number of needles.<sup>11</sup>

In a survey of experts performed by Schokert in 2009,<sup>16</sup> therapists were asked which indication for YNSA they regarded as being the most important. The rapid and reliable effects of YNSA for producing immediate pain relief was emphasized in the survey responses, recommending YNSA's global application in integrative medicine and fostering further studies to prove the value of this technique for pain management.

In the current study, neither the site of pain nor the diversity of the underlying pathological diagnoses predisposing to pain limited the application of the modality. Patients with neck, low-back, and knee pain were treated equally. In all of the studied conditions, the patients had significant reductions of pain, as measured by the VAS. This was in accordance with a study carried out by Schokert and colleagues in 2003<sup>17</sup> to evaluate the effectiveness of YNSA for relieving pain of the locomotor system, with no pathological specificity. The rapidity of the onset of relief was studied subjectively using a VAS and objectively applying topometry. In addition, YNSA's long term effects were evaluated.<sup>17</sup> In that study, the average VAS values calculated for 104 German people were 63/100 points before treatment and 19/100 points after treatment (measured on a 100-point scale), as expressed by treated patients immediately after an acupuncture session of 3–9 minutes duration. The difference in the mean before/after values was 44. Of those 104 patients, a total of 45 (43.3%) reported relief, and 52 participants (50%) reported freedom from symptoms for different periods of time. One important advantage of that study<sup>17</sup> was that the needles were left in place for only for

3–9 minutes, with the aim of evaluating YNSA's its effectiveness in emergency conditions. In the current study, this point was not addressed; only a single session of YNSA was applied. However, it was also concluded, that YNSA is effective, in a single session, for immediate pain relief secondary to upper and lower locomotor chronic pain. In another pilot study, performed at the Mayo clinic,<sup>18</sup> involving participants with chronic refractory musculoskeletal pain, it was demonstrated that acupuncture stimulation provided pain relief. That study used laser needles, which appeared to be clinically equivalent to the metal needles used in the current study.

In a review article of randomized controlled trials reporting on the role of acupuncture for managing knee OA,<sup>1</sup> 10 trials, representing 1456 patients, provided evidence that this modality is effective for pain relief and physical dysfunction associated with OA.<sup>1</sup> In accordance with the current study, these studies had pain in common as an outcome measure; mostly grading pain using a VAS. Other outcome measures studied had included: QoL measures; physician global assessment; examination-based measures, such as joint range-of-motion; and performance-based measures, such as walk times. Pain was the main outcome reported in all the studies, with an observed significant reduction recorded by a VAS scale. One of these studies also found that the reduction in pain was significantly greater for an acupuncture group versus a medication treatment (diclofenac) group.

## CONCLUSIONS

YNSA is an effective modality for immediate relief of chronic pain. Although results are promising, still larger studies are required to assess this acupuncture modality further and widen its application, teaching, and accreditation. YNSA deserves recognition and further research into its reliability and validity as well as its compatibility with other forms of treatment.

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