Relief of Chronic Shoulder and Neck Pain by Electro-Acupuncture and Transcutaneous Electrical Nervous Stimulation: A Randomized Crossover Trial

Madoka Yoshimizu, MPH,1 Alan R. Teo, MD,2 Masahiko Ando, MD,1 Kosuke Kiyohara, DPH,1 and Takashi Kawamura, MD1

ABSTRACT

Background: Chronic neck and shoulder pain is common and disabling.
Objective: The aim of this study was to compare the effectiveness of electro-acupuncture and transcutaneous electrical stimulation (TENS) for relief of shoulder and neck pain.
Materials and Methods: Design: This was a randomized crossover trial. Subjects: Ninety patients were enrolled, with a mean age of 34 years, and with females slightly outnumbering males. All subjects completed the study. Intervention: For electro-acupuncture, acupuncture needles were placed in four different acupoints in the trapezius muscle and each subject underwent a 15-minute session of low-frequency electrical stimulation. TENS treatment was similar and used as an active comparator, with a 2-week washout period between treatments. Outcome Measures: The primary outcome was reduction in pain as measured by a 100 cm visual analogue scale. Secondary outcomes included quality-of-life (QoL) measures.
Results: Electro-acupuncture produced significantly greater reduction in pain than TENS did the first 2 days after treatment (p=0.001 and p=0.003, respectively), with pain decreasing from 56 to 33 and 34 versus from 55 to 42 and 42. Electro-acupuncture also produced a significant improvement in the vitality subscale of the Short Form-36. No adverse effects or carryover effect were detected.
Conclusions: The results of this study offer preliminary evidence for the comparative effectiveness of electro-acupuncture over TENS for the acute relief of chronic shoulder and neck pain in adults.

Key Words: Electro-Acupuncture, Transcutaneous Electrical Nerve Stimulation, Crossover Trial, Neck Pain, Shoulder Pain

INTRODUCTION

Shoulder and neck complaints are extremely common in developed countries. A Swedish study of combined neck and shoulder pain estimated a prevalence of 18% in a random adult population.1 A large French study of a working population found the prevalence of chronic neck and shoulder pain in women was 15%–18% and 8%–10% in men.2 Health surveys in Japan have found shoulder–neck to be the most common physical complaint affecting 13% of the population.3 Such complaints cause a significant disease burden, including chronic disability, diminished work productivity, and decreased ability to perform activities of daily living.4–6 Shoulder–neck pain is an extremely broad term, but careful studies of more precise descriptors have shown that, by far, the most common form of pain is a dull muscle

1Kyoto University Health Service, Kyoto, Japan.
2Robert Wood Johnson Foundation Clinical Scholars Program, University of Michigan, Ann Arbor, Michigan.
achievable by TENS; or TENS followed by electro-acupuncture. Because patients received two distinct active treatments making masking unfeasible, this study was conducted as an open trial.

Patients

Patients between the ages of 20 and 65 who self-identified (as confirmed by written history) as having chronic pain in the neck and/or shoulder region and had minimal experience with acupuncture or TENS were eligible for inclusion. Patients were recruited from the university community, including both students and staff. The clinical definition used for neck–shoulder pain (i.e., katakori) was “tightness or stiffness in the shoulder and lower neck, especially the trapezius and semispinalis muscles.” Patients were excluded if they met any of the following criteria: (1) concurrently undergoing regular (one or more times a week) treatment for neck–shoulder pain; (2) fear of acupuncture techniques; (3) history of a neurologic condition; (4) history of a significant orthopedic condition; and (5) any other factor that would impair involvement in a clinical trial (e.g., inability to complete the follow-up). Baseline characteristics were collected for age, gender, history of myofascial pain, related symptoms, and past medical history. Patients were allocated to one of two groups using block randomization with a block size ranging from 2 to 6. Randomization was performed by a researcher who was uninvolved with the interventions and data analysis. This study was approved by the ethics committee of the Kyoto University Faculty of Medicine, and written informed consent was obtained from all patients before enrollment. A total of 90 patients were enrolled, with a mean age of 34 years, and females slightly outnumbered males.

Interventions

Interventions were performed with patients in a prone position in an examination room at the Kyoto University Health Service. No special environmental interventions, including aromatics, music, or lighting, were used. A single licensed acupuncturist (M.Y.), with 5 years of professional experience and trained in both modalities, performed all treatments. For the electro-acupuncture treatment, four 0.20 × 50–mm stainless-steel, disposable acupuncture needles (Yamasho® NEO, Nagahama-shi, Shiga-ken, Japan) were inserted at four sites in the upper back and shoulder of each subject. Japanese-style acupuncture was used. This style has two major distinctions from Chinese acupuncture: first, a technique of acupuncture needle insertion called kanshinhou utilizes a hollow tube through which the needle is guided; and second, Japanese acupuncture needles are shorter (3–60 mm) and thinner (0.16–0.24 mm) than Chinese needles.

The clinician first palpated for four acupoints associated with neck–shoulder pain and positioned in the trapezius: the left and right Jianjing (GB 21) and Jianwaishu (SI 14). For
Electro-acupuncture, needles were then inserted into the Ah Shi point within a 1-cm radius of these acupoints. Needles were inserted perpendicular to the skin, and not twirled. Both acupuncture points and Ah Shi points have been shown to have a high degree (71%) of correspondence. Consistent with previous research protocols and actual clinical practice, needles were inserted into muscle tissue to a depth of between 10 and 15 mm. The needles were then connected to a low-frequency electrical generator (Techno Link® Techtron DSP, Niigata-shi, Niigata-ken, Japan) set to an electrical frequency of 0.5–10 Hz, a current of 4–4.1 mA, and a resistance of 500 Ω (ohms); then, the patients underwent 15 minutes of stimulation. This duration was chosen based on standard clinical practice. Electrical strength was adjusted to the highest level that each patient could tolerate comfortably (typically creating muscle contraction) and readjusted after the first 5 minutes. For the TENS treatment, patients had four gel-type electrode pads placed at the same points (bilateral GB 21 and SI 14), using the same electrical generator set to an electrical frequency of 1–1.5 kHz, a current of 60–63 mA, and a resistance of 500 Ω (ohms). Duration of stimulation and adjustment were the same as with electro-acupuncture.

Participants received a single treatment session for each intervention. There was a 2-week washout period before the second randomized treatment but no washout prior to the first. Any subject who developed an adverse reaction was treated appropriately and study treatment was stopped. Patients continued taking their routine medications for any chronic medical conditions (e.g., antihypertensives), but were instructed to abstain from taking any new medications (over-the-counter or prescription), including analgesics, during the study period.

Outcome Measures

Previous articles have commented on the difficulty of establishing objective outcome measures for myofascial pain syndromes, but from the patient’s perspective (which, after all, is the most clinically relevant), subjective functional improvement is often measured. Thus, the primary outcome for this study was pain relief as measured by a 100-mm visual analogue scale (VAS), ranging from 0 (“no pain at all”) to 100 (“worst neck and shoulder pain I have experienced”). Subjects drew a hash mark at the point along the line that best represented their pain level at the time referenced in the question. Patients were asked to provide VAS scores for a total of eight timepoints per intervention: immediately before and after treatment and once daily on the second through seventh day after treatment. To exclude recall bias, patients completed separate questionnaires at each of these timepoints.

Secondary outcome variables included QoL measures and safety. QoL was assessed using a subset of 15 questions derived from the Short Form (SF-36) Japanese, version 2. Four of the subscales in the SF-36 acute form (symptoms over the last week) were utilized: (1) role physical (4 items); (2) bodily pain (2 items); (3) vitality (4 items); and (4) mental health (5 items). These scores were transformed linearly to range from 0 (worst score) to 100 (best score). Patients provided answers twice per intervention, once before treatment and once per week afterward. Safety of the treatment was assessed by report of adverse events, and by monitoring of blood pressure (BP) and heart rate (HR) before and after each intervention.

Statistical Analysis

The average reduction in pain was calculated as the mean difference between the VAS score immediately before treatment and those from immediately after through 6 days after treatment. A total of 90 subjects (45 for each group) were planned to be accrued into this study, which assured at least 90% statistical power to detect a 4.5-mm difference in the average VAS score at a 5% significance level. The improvement of QoL was calculated as the difference between pretreatment and post-treatment QoL scores. The effect on vital signs was also evaluated based on the pretreatment and post-treatment values. Analyses were performed on an intention-to-treat (ITT) basis.

RESULTS

Study Population

Patient flow through the study is illustrated in Figure 1. Ninety patients were enrolled in the study from September 2005 through November 2006 and all completed the planned treatment. According to the randomization procedure, 45 patients were allocated to each group. Subjects in group A received electro-acupuncture followed by TENS, while those in group B received TENS followed by electro-acupuncture. Because of a technical error, two group A patients underwent the group B protocol, but were analyzed on an ITT basis.
Baseline characteristics of the study patients are shown in Table 1. The mean age was 34 years and females slightly outnumbered males. Most patients complained of pain or stiffness in both shoulders and in the neck, and these patients’ symptoms were chronic.

Reduction in Pain

Shoulder and neck pain over time by treatment is shown in Figure 2. Patients had moderate pain at baseline (a VAS of 55 for TENS and a VAS of 56 for electro-acupuncture), which substantially decreased immediately after treatment in both treatment arms (VAS of 34 for both TENS and electro-acupuncture). Electro-acupuncture then produced sustained pain reduction on days 2 and 3 (VAS scores of 33 and 34, respectively), whereas TENS produced a more-rapid decay in effect (VAS scores of 42 on days 2 and 3). Electro-acupuncture provided significantly more relief of pain, compared to TENS on days 2 and 3 (p = 0.001 and p = 0.003, respectively).

In the standard crossover-design analyses, there was neither a significant carryover effect (p = 0.508) nor a period effect (p = 0.108) on pain reduction. Because there was no evidence of systematic bias caused by order of treatment, pooled data from both periods were used to estimate treatment effect. For the treatment effect, which was assessed using the average reduction in pain from immediately after treatment through day 7, electro-acupuncture showed a further 5.3-mm improvement in VAS, score compared with TENS (p = 0.025). In an analysis of covariance, the treatment-period interaction term was not significant (p = 0.296).

The pain-relief effect of electro-acupuncture remained significantly greater (p = 0.010) after adjustment for pretreatment VAS score, gender, age, and period. No covariates,

<table>
<thead>
<tr>
<th>Table 1. Baseline Characteristics of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Electro–acupuncture followed by TENS n = 45</td>
</tr>
<tr>
<td>Age, yr ± SD</td>
</tr>
<tr>
<td>Female/male</td>
</tr>
<tr>
<td>Previous acupuncture for shoulder/neck symptom</td>
</tr>
<tr>
<td>Previous acupuncture for other complaints</td>
</tr>
<tr>
<td>Pain and stiffness location, no. (%)</td>
</tr>
<tr>
<td>Shoulder</td>
</tr>
<tr>
<td>Neck</td>
</tr>
<tr>
<td>Both</td>
</tr>
<tr>
<td>Duration of symptoms, no. (%)</td>
</tr>
<tr>
<td>&lt;1 year</td>
</tr>
<tr>
<td>1–4 years</td>
</tr>
<tr>
<td>5–9 years</td>
</tr>
<tr>
<td>10–19 years</td>
</tr>
<tr>
<td>&gt;20 years</td>
</tr>
</tbody>
</table>

TENS, transcutaneous electrical nerve stimulation; yr, years; SD, standard deviation.
except pretreatment VAS scores, were significantly correlated with pain reduction.

QoL measures showed that vitality was similar pretreatment (54.2 for electro-acupuncture and 56.9 for TENS), but that QoL only improved post-treatment for electro-acupuncture (61.5) and not for TENS (56.6). In the analysis of covariance, electro-acupuncture produced a significantly greater improvement in vitality \( (p = 0.005) \) than TENS did after adjustment for pretreatment score, gender, age, and period (Table 2). For role physical, bodily pain, and mental health subscales, there were no significant differences in improvement between electro-acupuncture and TENS. The treatment-period interaction term was not significant in either of these analyses.

Safety

No serious adverse events were reported. BP and HR were stable for both electroacupuncture and TENS (Table 3). There were no significant carryover effects in systolic BP, diastolic BP, and HR \( (p = 0.213, 0.189, \) and \( 0.825, \) respectively). Systolic and diastolic BP readings were similar between electro-acupuncture and TENS, and no significant treatment effects \( (p = 0.307 \) and \( 0.312, \) respectively) were found. In terms of HR, a slightly increased pretreatment value in electroacupuncture, probably because of a fear of pricking pain, decreased to the same level as TENS after treatment, yielding a small, but significant treatment-related change \( (p = 0.021) \). In the analysis of covariance, electro-acupuncture was associated with a significantly larger change in HR \( (p = 0.021) \) than TENS after adjustment for pretreatment score, gender, age, and period. There were no such differences in systolic or diastolic BP between electro-acupuncture and TENS in the analysis of covariance. The treatment-period interaction term was not significant in either of these analyses.

**DISCUSSION**

To the authors’ knowledge, this is the first randomized trial that compared electro-acupuncture and TENS for shoulder and neck pain. The results suggest that both electro-acupuncture and TENS are effective short-term therapies for chronic shoulder and neck pain, but electroacupuncture is preferable because its pain-relieving effect is more durable. Specifically, the superiority of electro-acupuncture continued for at least 2 days after treatment and then gradually attenuated.

The effect size of electro-acupuncture, while not large, was clinically significant. Specifically, electro-acupuncture produced a 41% reduction in pain 1 day after treatment, whereas TENS produced only a 24% reduction at that same time point. For patients with chronic pain, a 16% benefit for a treatment modality is meaningful and similar to results

**Table 2. Quality of Life Measurements Before and After Treatment**

<table>
<thead>
<tr>
<th>Subscale of SF-36</th>
<th>Electro-acupuncture</th>
<th>TENS</th>
<th>p-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role physical</td>
<td>Before</td>
<td>83.3±19.2</td>
<td>84.2±19.4</td>
</tr>
<tr>
<td></td>
<td>After</td>
<td>89.0±14.8</td>
<td>86.1±17.4</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>Before</td>
<td>67.5±23.0</td>
<td>66.7±23.2</td>
</tr>
<tr>
<td></td>
<td>After</td>
<td>72.5±21.4</td>
<td>68.4±20.7</td>
</tr>
<tr>
<td>Vitality</td>
<td>Before</td>
<td>54.2±21.1</td>
<td>56.9±19.5</td>
</tr>
<tr>
<td></td>
<td>After</td>
<td>61.5±18.1</td>
<td>58.6±21.7</td>
</tr>
<tr>
<td>Mental health</td>
<td>Before</td>
<td>70.9±17.6</td>
<td>70.3±20.5</td>
</tr>
<tr>
<td></td>
<td>After</td>
<td>72.3±17.3</td>
<td>70.6±20.2</td>
</tr>
</tbody>
</table>

SF-36, Short-Form–36; TENS, transcutaneous electrical nerve stimulation.

*Comparison was made for the pre- and post-treatment difference between electroacupuncture and TENS.

**Table 3. Vital Signs Before and After Treatment**

<table>
<thead>
<tr>
<th>Vital sign</th>
<th>Electro-acupuncture</th>
<th>TENS</th>
<th>p-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>Before</td>
<td>109.4±16.4</td>
<td>110.0±14.5</td>
</tr>
<tr>
<td></td>
<td>After</td>
<td>109.0±14.9</td>
<td>108.6±14.4</td>
</tr>
<tr>
<td>Systolic</td>
<td>Before</td>
<td>66.4±13.7</td>
<td>66.2±13.1</td>
</tr>
<tr>
<td></td>
<td>After</td>
<td>67.5±11.8</td>
<td>66.0±13.7</td>
</tr>
<tr>
<td>Heart rate</td>
<td>Before</td>
<td>66.2±9.8</td>
<td>64.9±8.7</td>
</tr>
<tr>
<td></td>
<td>After</td>
<td>62.6±7.9</td>
<td>62.5±8.0</td>
</tr>
</tbody>
</table>

TENS, transcutaneous electrical nerve stimulation.

*Comparison was made for pre- and post-treatment difference between electroacupuncture and TENS.
found in other studies, such as in acupuncture for low-back pain. Improvement in vitality was more modest, at 13% for electro-acupuncture versus –1% for TENS; we suspect this was the result of post-treatment measurement not occurring until 1 week later.

The relative simplicity and uniformity of the electro-acupuncture treatment protocol makes it amendable to both clinical application and reproducibility. Only four needle locations, standardized to easily identifiable anatomical landmarks on the easily accessible trapezius muscle, with just 15-minute electrical stimulation was enough to produce both a clinically and statistically significant difference. Physicians and researchers have noted that the efficacy of acupuncture may depend on the individual skill of the practitioner, and interpatient variation in placement of needles is widely regarded by acupuncturists as essential to treatment. Electro-acupuncture requires less technical expertise than manual acupuncture, because even a deviation off an acupoint is partially accommodated for by the regional effect of the electrical current. With relatively limited training, even non-acupuncturist clinicians working in primary care or pain clinics could be capable of performing the electroacupuncture treatment protocol used in this study.

Strengths of this study included its randomized design, perfect follow-up rate, lack of interoperator bias, and relatively larger sample size (especially when considering the effective doubling of data with a crossover design), compared to similar studies. A crossover design was well-suited to this trial for two reasons. One, treatment for myofascial neck and shoulder complaints being among the most prevalent in primary care, few high-quality studies have compared the results of the many treatment choices available. By suggesting the superiority of an acupuncture technique to a technique similar in all ways, except for use of needling, this study helps fill in the gap of knowledge necessary for clinicians to make good, evidence-based treatment decisions.

Another major strength of this study is its clinical applicability. Designed to be a practical comparison, this study was a head-to-head comparison of two reasonable, comparable therapeutic options used in clinical practice. Despite neck and shoulder complaints being among the most prevalent in primary care, few high-quality studies have compared the results of the many treatment choices available. By suggesting the superiority of an acupuncture technique to a technique similar in all ways, except for use of needling, this study helps fill in the gap of knowledge necessary for clinicians to make good, evidence-based treatment decisions.

Because this was an open trial, a placebo effect could have accounted for observed differences. However, the authors find this unlikely for two reasons. First, the pain trend observed in this study argues against a simple placebo effect. TENS provided significant immediate relief; indeed, pain relief from TENS was essentially identical to electro-acupuncture immediately after treatment. This trend changed, however, a day after treatment when electro-acupuncture showed that it was more effective. If subjects improved merely because of an anticipatory effect, it would be quite odd for this delayed peak in the effectiveness of acupuncture, but it is consistent with acupuncturists’ clinical experience. In short, the authors suggest that the relief from TENS served as an effective control intervention. Second, both interventions were given equal consideration with equal one-on-one therapeutic care, which should have equalized any psychological benefits intrinsic to undergoing treatment. The authors felt that it was not feasible to create a believable placebo treatment group with electro-acupuncture. Moving needle placement away from acupuncture points, though used sometimes in sham manual acupuncture, was also felt to be too similar to real treatment because the larger area of effect provided by electrical stimulation.

This study has some other noteworthy limitations. First, because it did not include a placebo control, it was not possible to evaluate the magnitude of change relative to no treatment at all in this study population. Second, lack of blinding limited the internal validity of the study. Third, treatment was limited to a single session for each modality, whereas in actual clinical practice most patients would undergo repeated treatments. Studies with longer treatment and follow-up periods to evaluate how long-lasting a benefit can be achieved are warranted. Fourth, outcomes reflected subjective data, based on a VAS and the SF-36. In future experiments, adding more physiological measures as well as use of validated tools, such as a pressure algometer, would complement subjective measures.

CONCLUSIONS

Taken together, these results provide preliminary evidence supporting the use of electro-acupuncture for relief of neck and shoulder pain. It is notable that a single, simple, and short form of electro-acupuncture treatment can make a significant reduction of chronic symptoms, compared to TENS treatment. More research, including longitudinal follow-up, a placebo treatment arm, and other outcome measures are essential to strengthen and validate these findings.

ACKNOWLEDGMENTS

Dr. Teo wishes to acknowledge support for this study provided by grants from the Robert Wood Johnson Foundation Clinical Scholars program and the University of California, San Francisco School of Medicine Office of International Programs.

DISCLOSURE STATEMENT

No competing financial interests exist.
REFERENCES


Address correspondence to:
Alan R. Teo, MD
Robert Wood Johnson Foundation Clinical Scholars Program
University of Michigan
6312 Medical Science Building I
1150 West Medical Center Drive
Ann Arbor, MI 48109-0604

E-mail: alan.teo@stanfordalumni.org