

Electrical Stimulation of Auricular Acupuncture Points Is More Effective Than Conventional Manual Auricular Acupuncture in Chronic Cervical Pain: A Pilot Study

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In this prospective, randomized, double-blinded, controlled study, we tested the hypothesis that auricular electroacupuncture relieves pain more effectively than conventional manual auricular acupuncture. We studied 21 chronic cervical pain patients without radicular symptoms with insufficient pain relief (visual analogue scale >5) treated with standardized analgesic therapy. All patients received disposable acupuncture needles on the dominant side on the following acupuncture points: cervical spine, shen men, and cushion. In 10 patients, needles were continuously stimulated (2-mA constant current, 1 Hz monophasic) by using the electrical point stimulation device P-STIM™. In 11 control patients, no electrical stimulation was administered. All needles were withdrawn 48 h after insertion. Acupuncture

was performed once a week for 6 wk. Patients had to complete a questionnaire assessing pain intensity, psychological well-being, activity, sleep, and demand for rescue medication (lornoxepam and tramadol). The reduction in pain scores was significant in the electrical acupuncture group. Similarly, psychological well-being, activity, and sleep were significantly improved in patients receiving electrical acupuncture, and consumption of rescue medication was significantly less. These results demonstrate that continuous electrical stimulation of auricular acupuncture points by using the new point stimulation device P-STIM™ improves the treatment of chronic cervical pain in an outpatient population.

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Pain is a major complaint of patients with chronic cervical disorders (1,2). There are various treatment options, including conventional pharmacological and invasive pain therapy, physiotherapy, transcutaneous nerve stimulation, and manual treatment, as well as complementary approaches (3). Among them, acupuncture is widely available in Western chronic pain clinics (4). This traditional Chinese medicine technique dates back at least 2500 yr. The traditional theory of acupuncture is based on the concept that an imbalance of the energy flow, “Qi,” through the body in hypothesized channels called “meridians” can be corrected by manipulation of identifiable points close to the skin. In addition to the

designated acupuncture points located on the “meridians,” Nogier (5) described acupuncture points on the ear. Auricular acupuncture correlates a somatotopic map on the ear with other anatomical regions (5–7). The mechanism of acupuncture analgesia remains in question, but biological responses, such as the stimulation of A- δ fibers and activation of endorphins and monoamines by the stimulating “De qi” sensation, as well as psychological aspects, seem to be involved (8–11). The stimulation of acupuncture points can be achieved by either a mechanical action of needling or electrical point stimulation.

Among nonpharmacological treatment options, acupuncture has been found to be more effective than physiotherapy (12), transcutaneous nerve stimulation therapy (13), and massage (14,15) in chronic cervical pain patients. The cumulative evidence suggests that acupuncture represents a therapeutically beneficial and cost-effective treatment option in chronic cervical pain patients (9,16). This study was performed to test the hypothesis that continuous electrical stimulation

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of auricular acupuncture points is more effective than conventional manual auricular acupuncture in outpatients at home.

Methods

After we obtained approval from the local Ethics Committee at the University of Vienna and written, informed consent, 23 otherwise healthy adult patients with chronic cervical pain without radicular symptoms were investigated in a double-blinded, prospective, randomized study. Inclusion criteria were cervical pain with a duration of at least 6 mo, normal neurologic function of cervical nerves as confirmed by a neurologist, and no pain radiation. Pain arose from cervical spondylosis without nerve root impingement (confirmed by magnetic resonance imaging (MRI) and neurological examination), from pathologic structures due to osteoporosis and osteoarthritis of the intervertebral joints (radiograph and/or MRI), or from soft tissue with no evidence of skeletal or neural pathology and normal spinal structures.

Exclusion criteria were allergy to lornoxicam or tramadol, history of drug abuse, pregnancy, concomitant use of transcutaneous nerve stimulation or pacemaker, and history of acupuncture treatment.

After an initial physical and neurological examination and cessation of their previous analgesics, patients received oral pharmacotherapy with 8 mg of lornoxicam twice daily and rescue medication with up to 8×50 mg of tramadol daily. After 1 wk, the participants were reevaluated and asked to rate their pain intensity on a visual analog scale (VAS; 0 = no pain and 10 = worst pain imaginable). Patients were eligible for the next step in the study if, despite medication, their persisting pain intensity was at least 5 on the VAS.

All patients received Titan disposable acupuncture stimulation needles (27 gauge, 3-mm length; Fa. Biegler GmbH, Mauerbach, Austria), which were inserted on the dominant side. Standard references were consulted when choosing the following acupuncture points: cervical spine (37) shen men (55), and cushion (29, 19). These precise points were confirmed by determining the position of the least skin resistance by using electrical conductance meters (Multipoint Selection Pen™; Fa. Biegler GmbH). Needles were connected to the electrical point stimulation device P-STIM™ (Fa. Biegler GmbH, Mauerbach, Austria). This recently designed device consists of a rechargeable battery-powered stimulator (Fig. 1) that is positioned behind the ear of the patient like a hearing aid. The P-STIM™ model used in this study has a length of 49 mm, a height of 28 mm, and a weight of 11 g. The stimulator consists of a microcontroller and a bit-coded RS232 interface that produce appropriate wave

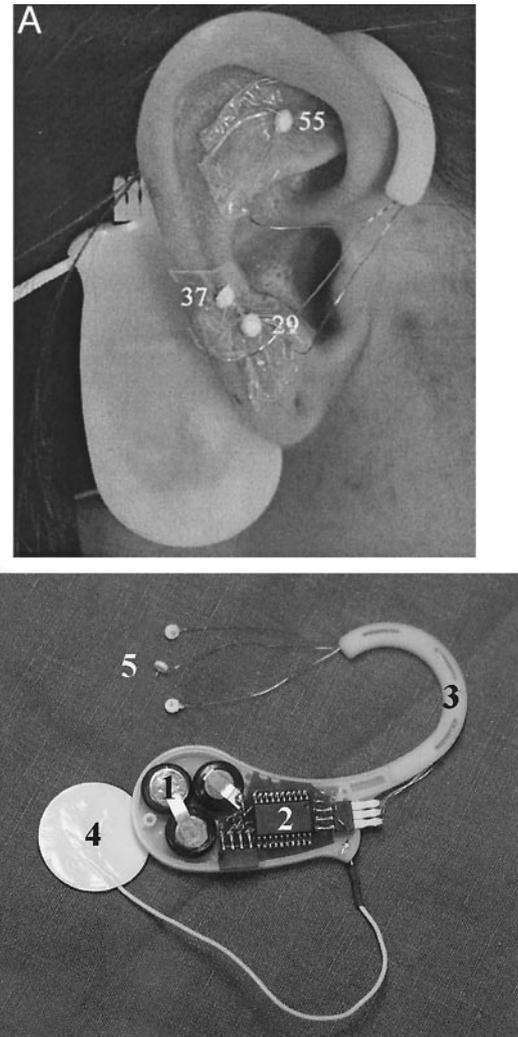
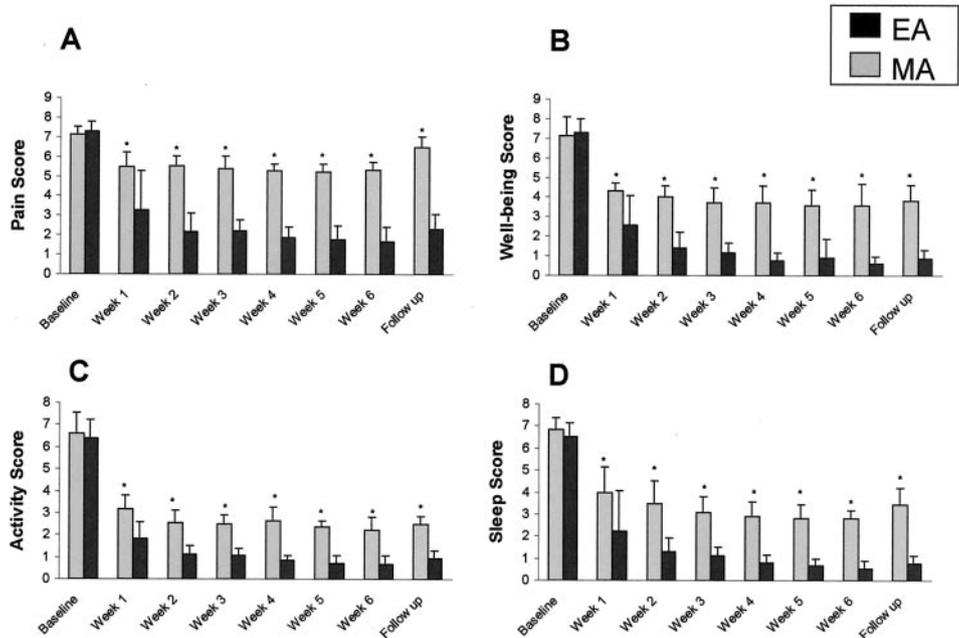


Figure 1. The electrical point stimulation device P-STIM™. A, acupuncture points are indicated by bullets and numbered according to the nomenclature of Nogier (5): cervical spine (37), shen men (55), and cushion (29). B, This device consists of an automated accumulator for the nickel metal hydride cells (1) and a microcontroller with a bit-coded RS232 interface (2). The constant current source guarantees equivalent stimulation energy (2 mA, 1 Hz monophasic) regardless of the individual impedance of the patient's skin. This preliminary P-STIM™ model is fixated via an anchor (3) behind the patient's ear, as well as with a bandage on the head. The neutral electrode (4) is positioned behind the ear. Three wires connect the P-STIM™ to the acupuncture needles (5).

forms of electrical stimuli. The constant current source guarantees equivalent stimulation energy regardless of the individual impedance of the patient's skin.

Patients were randomized into two groups by using computer-generated random tables. In 10 patients, needles were continuously stimulated with 2 mA of constant current at a low frequency of 1 Hz for 48 h. In 11 control patients, no electrical stimulation was administered. Patients and the investigator were blinded to the treatment allocated by randomization, and the P-STIM™ device was programmed by an independent technician.

Figure 2. Effect of manual auricular acupuncture (MA) and electrical auricular acupuncture (EA) on pain intensity, physical activity, psychological well-being, and sleep in chronic cervical pain patients. The reduction in pain scores was significantly higher in the electrical acupuncture group than in the conventional manual acupuncture group (A). Similarly, psychological well-being (B), activity (C), and sleep (D) were significantly improved in patients receiving electrical point stimulation during the study period of 6 wk of treatment and a follow-up 4 wk afterward. Data are reported as mean \pm SD of subjective scores ranging from 0 (no impairment) to 10 (worst deterioration imaginable). * $P < 0.05$ between the groups.



All needles were withdrawn 48 h after insertion. Acupuncture was performed once a week for 6 wk. A follow-up investigation was performed 4 wk after the last acupuncture analgesia. During the whole study period, patients had to complete a questionnaire assessing pain severity, psychological well-being, activity, sleep, and demand for rescue medication. Pain severity was scored with the VAS (0 = no pain and 10 = maximum pain). Similarly, psychological well-being, activity, and sleep were scored by the study patients by using a scale ranging from 0 (no impairment) to 10 (worst deterioration imaginable) (17). All patients received physiotherapy during the whole study period. The patients' overall satisfaction with the acupuncture treatment was documented at the end of the study period.

Analysis of covariance for repeated measures was used to assess differences between the two groups, taking into account the baseline values of age, sex, and body mass index as covariates. *Post hoc* group comparisons at each week were corrected by the Bonferroni-Holm method. P values < 0.05 were considered statistically significant. Data are presented as mean \pm SD or by frequencies, where appropriate.

Results

Twenty-three patients were enrolled in the study. Two patients were excluded: one control patient dropped out in the second week because of failed pain reduction, and one patient receiving electrical auricular acupuncture dropped out in the second week because of a local skin inflammation. Accordingly, 21 patients (15 women and 6

men) were analyzed. There were no significant differences in age (52 ± 12 yr versus 52 ± 9 yr), weight (68 ± 13 kg versus 76 ± 5 kg), or height (170 ± 6 cm versus 174 ± 8 cm) between the control group and the electrical acupuncture group, respectively.

There were no differences in pain duration or treatment between the two groups. Of the 21 included patients, 12 had common cervical pain, presumably of muscular origin, whereas 9 had additional severe structural changes observed on radiograph and MRI of the spine, including spondylarthrosis and localized protrusion of a disk. The mean duration of pain was 3.3 ± 1.2 yr, and most patients had experienced various treatment modalities before entering this study, including analgesic drugs, trigger point infiltrations, transcutaneous nerve stimulation, and passive physiotherapy, including massage, warmth, and galvanization. Pretreatment analgesic medication (nonsteroidal antiinflammatory drugs; NSAIDs) was the same in both groups.

The reduction in VAS pain scores was significantly larger in the electrical acupuncture group than in the conventional manual acupuncture group (Fig. 2A). No sex differences were found. Similarly, psychological well-being, activity, and sleep were significantly improved in patients receiving electrical point stimulation (Fig. 2B–D). The consumption of rescue medication was significantly more in the control group compared with the electrical acupuncture group (107 ± 5 tablets versus 47 ± 8 tablets needed during the whole investigation period).

No adverse effects of acupuncture (such as needle-induced hypotension or hematoma) were observed.

Whereas, not surprisingly, all patients in the electrical auricular acupuncture group correctly identified electrical stimulation, 10 (90%) patients in the control group also believed they were receiving electrical stimulation. Nine (90%) patients in the electrical auricular acupuncture group were satisfied and would repeat the treatment if necessary, and only one (10%) patient found the P-STIM™ design unpleasant and declined possible future treatment. All patients in the control group rejected further acupuncture treatment because of insufficient benefit, not because of discomfort. The comfort of wearing the P-STIM™ device was described as suitable by 65% of the patients and as sufficient by 35%.

Discussion

We found that chronic cervical pain patients treated with adjunctive auricular electroacupuncture during oral analgesic therapy with an NSAID and the weak opioid tramadol experienced a significant improvement in pain intensity, mobility, psychological well-being, and sleep (see Fig. 2). This finding is contradictory to some studies (16,18) but confirms numerous other trials that have found a beneficial effect of acupuncture (9,19-21).

As summarized in Figure 2, electrical stimulation of auricular acupuncture points by using the new electrical low-frequency stimulation device P-STIM™ further improved pain management in chronic cervical pain patients. Similarly, the analgesic effect of transcutaneous electrical stimulation of an auricular acupuncture point has recently been reported in acute pain patients (19). The mechanism of electrical auricular acupuncture analgesia is suggested to be mediated at least in part by the activation of descending inhibitory pain control systems (10,22), activation of the propriospinal heterosegmental antinociceptive system leading to the depression of long-lasting pain-induced changes of signal transduction in the spinal cord (11), and the release of endogenous opioid peptides (23). The specific electrical stimulation pattern influences the analgesic effects (24,25). Both low-frequency and high-frequency stimulation have been found to induce analgesia, but different types of endorphins are released (23,25,26). In this study, we used a preliminary model of the electrical stimulator device P-STIM™, which provided a monophasic 1-Hz stimulation. This preliminary model had to be worn like a hearing aid fixed with tape to guarantee the exact position throughout the stimulation period; despite some inconvenience, the possibility of continuous ambulatory treatment was very well received by the patients. In the meantime, a more comfortable, self-attaching design has become available. Another advantage of the second-generation P-STIM™ is the

production of a biphasic low-frequency current, which avoids polarization effects.

The use of electrical auricular acupuncture is safe (25,27). Contraindications against the use of an electrical stimulator device include the concomitant use of transcutaneous electrical nerve stimulation and a pacemaker.

Difficulty with blinding is one of the major problems for adequate validation of the effectiveness of acupuncture (16). Electrical stimulation of the auricular acupuncture points permitted a fully double-blinded study protocol in this study: the stimulator was activated or not by an investigator who was not otherwise involved in the study. The results show that patients of both groups (100% electrical acupuncture versus 90% control) believed they were receiving electrical stimulation, which proves that patient blinding was effective. One limitation of this study design is that the outcome variables are subjective. Another limitation is the lack of a placebo group, and therefore the data presented cannot refute the hypothesis that all the benefits from both treatments are due to non-specific effects of participation in the study, contact with the pain therapist, or patient expectation.

Chronic cervical pain is a common cause of suffering, disability, and consumption of medical health costs and social service utilization. Both manual and electrical acupuncture are inexpensive treatments with potential savings in analgesic drug costs. Our results clearly demonstrate the benefit of electroanalgesia, as previously documented. However—and this is the novelty—for the first time, a continuous stimulation in an outpatient setting with all the advantages of home-based therapy has been studied. Pain relief was significant, as was patient satisfaction. Furthermore, the need for analgesic drugs was considerably reduced in patients in the electrical acupuncture group, decreasing the risk of common drug-induced adverse effects of NSAIDs and opioids, such as gastrointestinal bleeding, nausea, vomiting, obstipation, and dizziness (28,29), which often lead to therapy cessation. For all these reasons, we believe that substantial savings in medical health care can be made through the adjuvant use of electroacupuncture.

Both options are demonstrably safe. According to these results, we recommend electrical stimulator acupuncture as an adjunct therapy in chronic cervical pain patients. Cumulative analgesic effects may be achieved by longer electrical stimulation periods (24). Further studies have to determine whether a stimulation period exceeding two days further improves treatment of chronic cervical pain.

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