



## The therapeutic efficacy of somatic acupuncture is not increased by auriculotherapy: A randomised, blind control study in cervical myofascial pain

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### KEYWORDS

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Double blind;  
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**Summary** Auriculotherapy (ear acupuncture) is a therapeutic technique in which points on the auricle are stimulated with needles. Usually it is combined with somatic acupuncture because of possible synergy, although the efficacy of this pairing has neither been confirmed nor disproved. The aim of this study was to verify: (1) if somatic acupuncture can reduce myofascial cervical pain; (2) if concomitant auriculotherapy improves the efficacy of somatic acupuncture. A group of 62 patients affected by cervical myofascial pain was randomly divided into two groups of 31. Group A (6 males and 25 females) underwent eight sessions of somatic acupuncture. Group B (7 males and 24 females) underwent eight sessions of somatic acupuncture in the same way as group A, paired with auriculotherapy. Pain was scored using the McGill Pain Questionnaire before and at the end of treatment, and 1 and 3 months later. The results showed that both somatic acupuncture and somatic plus ear acupuncture have a positive effect in reducing pain. The pain intensity score was  $40.70 \pm 17.78$  in group A before therapy and  $13.32 \pm 9.62$  after therapy; in group B it was  $38.90 \pm 15.31$  and  $13.43 \pm 10.96$ . Somatic plus auriculotherapy was therefore not statistically significantly superior to somatic therapy alone in the treatment of cervical myofascial pain.

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### Introduction

The principle of auriculotherapy is based primarily on the somatotopic representation on the

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auricle of several somatic and visceral structures. The existence of this correlation has been suggested by morphological and electrophysiological studies. Morphological changes on the auricle, e.g. telangiectasis, desquamation, pigmentation, erythema and hyperaemia, have been related to chronic organic conditions. Some authors<sup>20,12</sup> observed a lowering of electrical resistance at particular points on the auricle after stimulation of specific body parts, both in animals and man. Oleson et al.<sup>19</sup> evaluated the increased sensitivity to pressure and electrical conductance in certain areas of the auricle in patients afflicted by somatic pain, demonstrating a somatotopic representation of different body areas on the auricle itself. Similar results were obtained on palpation with a pressure detector. These painful points are localised in similar areas in patients with the same disease.<sup>23,5</sup> Indeed, the creation of the microsystem of auriculotherapy was based on this theory<sup>17</sup>: that visceral dysfunction and pain in a particular body structure are detectable on the auricle through an increase in pain sensitivity and electrical conductance in particular areas. Electrical or acupunctural stimulation of these areas leads to a lessening of pain in the corresponding structures of the body.<sup>6,10,18,25</sup>

Auricular stimulation is now often paired with somatic acupuncture in the treatment of painful conditions, a pairing justified by suggestions of greater clinical improvement. However, this hypothesis is yet to be tested in a blind, placebo-controlled clinical trial. The only published observation<sup>15</sup> on the possible benefits of pairing somatic and auricular stimulation found no substantial differences between the two, though the study principally concerned the efficacy of electrical stimulation (transcutaneous electrical nerve stimulation; TENS) and not that of paired somatic and auricular acupoint stimulation.

Our aims here were: (1) to evaluate the analgesic efficacy of somatic acupuncture in the treatment of cervical myofascial pain; (2) to ascertain whether the pairing of somatic acupuncture and auriculotherapy can produce a better clinical result than the use of somatic acupuncture alone.

## Materials and methods

The trial involved 70 patients fulfilling the diagnostic criteria for myofascial cervical pain,<sup>9</sup> chosen from those attending our pain therapy unit over a 12-month period (see 'Exclusion criteria' next). Sixty-two patients (46 women and 16 men, with ages ranging from 25 to 55 years) completed the study; eight dropped out for various reasons

during the trial. All the patients selected were new to acupuncture treatment, as to execute correctly a blind study those who had already undergone acupuncture in the past had to be excluded. Any treatment being given before the trial was suspended, but 1 g paracetamol was permitted in acute episodes of pain. Patients gave their informed consent, and the study was planned according to the suggestions of the Helsinki Declaration. Patients were divided randomly into two groups: group A, somatic acupuncture; group B, somatic acupuncture paired with ear acupuncture.

## Exclusion criteria

- A diagnosis of primary and secondary fibromyalgia;
- Patients with severe systemic illnesses, in particular asthma, emphysema, chronic bronchitis, severe myocardial failure and disturbances of cardiac rhythm under treatment; patients undergoing hypotensive treatment with reserpine or clonidine;
- Radiographic evidence of severe, bridge-like osteophytes; osteoporosis;
- Patients under psychotropic drug treatment (major and minor tranquillisers);
- Patients under benzodiazepine treatment were admitted only if an interruption of treatment for 2 weeks was clinically appropriate;
- Drug and alcohol abuse;
- Patients affected by concomitant central and peripheral neurological illnesses that could interfere with the aim of the study (multiple sclerosis, epilepsy or brain injuries with chronic impairment, polyneuropathies due to diabetes, alcohol, etc. radiculopathy);
- Presence of an adipose panniculus.

## Randomisation

After being accepted for the study, each patient was assigned to one of the two groups using a previously constructed randomisation table. A detailed explanation of the procedure was given, and all the patients were requested to participate, and to have their pain monitored at one and three months after the therapy. Patients were free to drop out of the study at any time. The doctor who carried out the pain measurements did not know to which group the patients belonged.

## Blindness

The diagnostic procedures and acupunctural treatments were carried out by two different doctors;

both were expert in acupuncture. Data were statistically evaluated by a third part of our research team, whose members were aware of the aim of the research but not of the type of treatment used in each group.

### Therapeutic procedure

#### Acupuncture group (A)

The 31 patients in this group [mean age  $45.5 \pm 10.28$  years (S.D.)] underwent eight sessions of somatic acupuncture of 20 min each, once a week, according to the following scheme. Two trigger points or the two more tender points and the following acupuncture points were treated:

- 3 SI (Houxi), 5 TE (Waiguan), 4 LI (Hegu), 10 BL (Tianzhu), 20 GB (Fengchi), which were embedded bilaterally; points 14 GV (Dazhui) and 15 GV (Yamen), embedded only in the median line. All the needles, except the 3 SI, were stimulated, two at a time, with a rotary movement dx/sx (clockwise and anticlockwise alternately) for 20 s only at the moment of embedding and toward the appearance of the de-qi sensation.

#### Acupuncture + auriculotherapy group (B)

In this group, 31 patients (mean age  $39.8 \pm 9.01$  years) underwent acupuncture treatment, as set out for group A, paired with auriculotherapy. Auricular needles, four points for each ear (Fig. 1), were embedded as follows in all the patients after somatic acupuncture:

- Shen menn point;
- Lung point;
- Cervical column area;
- Cephalaea point.

#### Needles

Different sets of needles were used for somatic and auricular stimulation.

#### Somatic stimulation

Disposable Sedatelec® needles were used,  $300 \mu\text{m}$  in diameter and of two different lengths: type 34.30 needles (useful length 18 mm) for superficial insertion (3 SI, 20 GB, 14 GV and 15 GV) and type 52.30 needles (useful length 29 mm) for deep insertion when the subcutis was thin (4 LI, 5 TE, 10 BL); type 72.30,  $300 \mu\text{m}$  in diameter (useful length 49 mm) for deep insertion when the fatty cushion in the subcutis was at least 3 cm thick. The puncture reached muscular level for all the points; points 14 and 15 GV were embedded in the interspinous ligament.

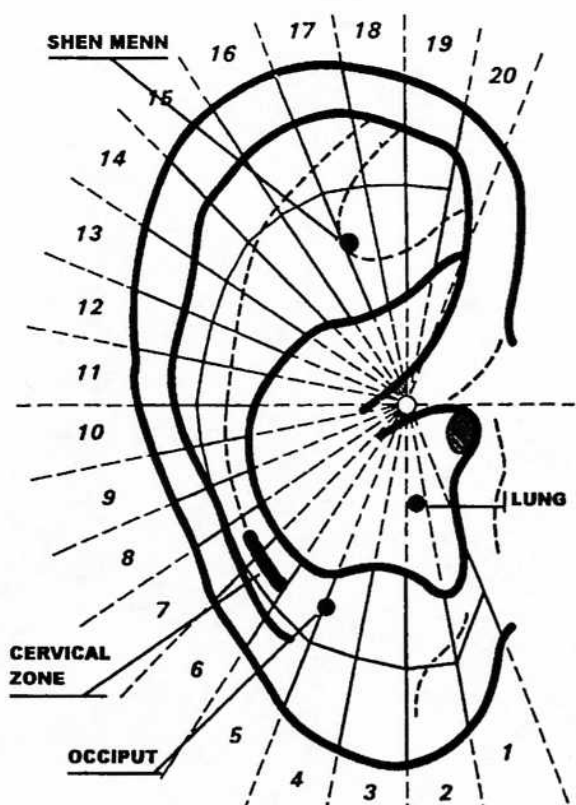


Figure 1 The auricle map—the points selected.

#### Auricular stimulation

Disposable Sedatelec® 34.30 needles were used,  $300 \mu\text{m}$  in diameter (useful length 18 mm). The auricular needles were also stimulated, two at a time, with a rotary movement dx/sx for 20 s only at the moment of embedding.

#### Pain measurement and statistical analysis

Pain was evaluated before and after therapy, and one and three months later, using the Italian version of the McGill Pain Questionnaire (MPQ)<sup>16</sup> for spontaneous pain and the Visual Analogue Scale (VAS) for pain provoked by movement during the examination.

The MPQ is made up of 20 groups of words that describe various pain characteristics. The patient is invited to choose the most suitable terms for his or her pain. Each word is correlated with a number, which accords a value to the word. After completing the test, the intensity of pain is correlated with the number of words chosen (number of words) and the sum of all the numbers (total score). The mean and S.D. of the number of words and total score for the two groups at the end of the therapy and in the two follow-ups were compared with the data obtained before therapy by the *t*-test for paired data. The

statistical significance of the differences between the two groups was evaluated by the Mann–Whitney test.

## Results

The pain scores, together with the statistical significance of the differences between the two groups, are set out in Table 1. Somatic acupuncture either by itself or paired with auriculotherapy was equally effective in the treatment of cervical myofascial pain. Pain at the end of treatment, measured by both MGPQ and VAS, was statistically significantly less than before treatment; pain relief was constant at 1 month and 3 months after the end of treatment. There were no statistical differences in pain experience between the two groups before or at the end of therapy, or at follow-up. Twenty-two patients who were treated with somatic acupunc-

ture paired with auriculotherapy (group B) had more than 50% pain relief after treatment, as did 26 patients treated with somatic acupuncture alone (group A).

## Discussion

Myofascial cervical pain is one of the more frequent forms of myofascial pain. Unfortunately its treatment is very often disappointing. The lack of definitive therapies is evident from the wide range of therapeutic and rehabilitative approaches, both conventional and complementary, that have been used in this disabling pain syndrome. In this context, somatic as well as auricular acupuncture has been used, with contrasting results. In an open study,<sup>1</sup> 34 out of 42 patients (80.8%) affected by chronic cervical pain reported a significant reduction in pain after somatic acupuncture. In another

**Table 1** Results for the McGill Pain Questionnaire (total score and number of words), and Visual Analogue Scale at various times in group A (somatic acupuncture only) and group B (somatic and auricular acupuncture).

	Before treatment	After treatment	1 month later	3 months later
<b>McGill Pain Questionnaire</b>				
<b>Total score—group A</b>				
Mean	40.70	13.32	14.17	15.64
S.D.	17.78	9.62	10.99	11.43
<i>p</i> -value vs. before therapy		<0.05	<0.05	<0.05
<b>Total score—group B</b>				
Mean	38.90	13.43	11.36	12.90
S.D.	15.31	10.96	12.16	13.87
<i>p</i> -value vs. before therapy		<0.05	<0.05	<0.05
<i>p</i> -value—group A vs. B	NS	NS	NS	NS
<b>No of words—group A</b>				
Mean	12.12	5.87	6.03	6.41
S.D.	3.76	3.43	4.06	4.43
<i>p</i> -value vs. before therapy		<0.05	<0.05	<0.05
<b>No of words—group B</b>				
Mean	11.36	5.33	5.10	5.10
S.D.	3.02	3.57	4.06	4.82
<i>p</i> -value vs. before therapy		<0.05	<0.05	<0.05
<i>p</i> -value—group A vs. B	NS	NS	NS	NS
<b>Visual Analogue Scale</b>				
<b>Group A</b>				
Mean	57.90	15.64	15.34	18.96
S.D.	18.87	12.69	15.69	15.60
<i>p</i> -value vs. before therapy		<0.05	<0.05	<0.05
<b>Group B</b>				
Mean	61.00	19.50	18.50	21.00
S.D.	20.73	19.31	17.96	19.88
<i>p</i> -value vs. before therapy		<0.05	<0.05	<0.05
<i>p</i> -value—group A vs. B	NS	NS	NS	NS

open study, Petrie and Langley<sup>21</sup> compared somatic acupuncture with sham TENS in the treatment of cervical pain, and reported a significantly better result in patients treated with acupuncture. The same outcome was obtained by, Coan et al.<sup>8</sup> while later, Petrie and Hazlemann<sup>22</sup> repeating the same controlled study, obtained different results, finding no difference between acupuncture and control groups.

In a randomised, controlled study in patients affected by cervical myofascial pain the treating of acupuncture areas and trigger points with a diodic laser had greater efficacy than placebo.<sup>4</sup> However, recent meta-analyses and systematic reviews<sup>28,26</sup> have concluded that there is no convincing proof justifying the use of acupuncture in the treatment of cervical or lumbar pain.

Sator-Katzenschlager et al.<sup>24</sup> found that electrical stimulation as well as manual acupuncture of auricular acupoints was effective in chronic cervical pain, with more positive results for electrical stimulation. Ceccherelli et al.<sup>3</sup> compared the efficacy of somatic acupuncture and auriculotherapy in the treatment of cervical myofascial pain, and found that both techniques were equally effective.

Nevertheless, there are still some uncertainties surrounding the use of reflex therapies in the management of myofascial cervical pain. These concern the efficacy of somatic acupuncture in this condition, and whether the combined use of somatic and auricular acupuncture can improve on the pain control eventually reached by somatic acupuncture alone. These doubts prompted us to try to confirm the efficacy of somatic acupuncture and to compare it with the combined use of somatic and auricular acupuncture.

Data from our trial strongly support previous observations that acupunctural stimulation is effective in the treatment of myofascial cervical pain, and that the combined use of somatic and auricular acupuncture does not bring about any change in the quality of the therapeutic outcome, as pairing these two techniques did not elicit better analgesia. In other words, the clinical results achieved using somatic stimulation only are not susceptible to further improvement, at least when another stimulation technique is adopted. This can be explained by the concept of stimulation adequacy, a theory shared by all the therapies using physical energies to produce therapeutic effects. In order for a stimulus to be effective it should be of adequate intensity, as only with adequate activation of neural networks and ascending pathways can appropriate antinociceptive responses, such as the so-called diffuse noxious inhibitory controls (DNIC),

be activated. This has been clearly demonstrated in animals<sup>13,14</sup> as well as in man.<sup>2</sup>

In rats Le Bars et al. were able to demonstrate a linear correlation between the intensity of electrical acupuncture and the inhibition of pain responses in spinal-cord cells. They were also able to demonstrate that different somatic areas are more or less able to trigger this antinociceptive effect when stimulated by electroacupuncture.

In humans, variations in pain-relieving effects induced by electroacupuncture at different acupoints with different stimulus intensities have been demonstrated. This observation emphasises the fact that in humans also an appropriate stimulus intensity, together with a somatotopic stimulation area, are essential for the best activation of DNIC, suggesting further that a weak stimulation intensity only activates  $\alpha$ - $\beta$  fibres, while only more intense and suprathreshold stimulations are able to activate DNIC.<sup>27</sup>

In the present study the intensity of the stimulation applied was confirmed clinically by the presence of the de-qi sensation. This sensation, classically described in all books on traditional Chinese acupuncture, is believed to be evoked via the activation of unmyelinated, small-diameter sensory fibres of the same type involved in the activation of DNIC.<sup>11</sup>

Stimulation adequacy in the acupuncture field depends on several variables,<sup>7</sup> ranging from the therapeutic scheme adopted to the number and frequency of therapeutic sessions, the duration of each session and its characteristics, as well as the size of the needles used. Moreover, of great importance are variables such as the depth of the puncture and the type of stimulation used: in manual stimulation, the type, duration and number of stimulations in any one session; in electrostimulation, the frequency and intensity of the electrical stimulus applied throughout the needle.

The lack of further improvement with concurrent somatic and auricular acupuncture in our study may be explained by the fact that the intensity of the somatic acupunctural stimulation was sufficient for therapeutic activation of endogenous pain-control systems, with the production of the de-qi sensation. Possible improvements in therapeutic effects obtained in other clinical studies were probably due to the inadequacy of the somatic stimulation, which was able to evoke an afferent barrage in the  $\alpha$ - $\beta$  myelinated fibres but was insufficiently intense to stimulate unmyelinated, small-diameter sensory fibres and therefore unable to activate the DNIC. This possibility strongly indicates the need for a rigorous and complete description in scientific publications of the acupunctural stimu-

lation employed and of the sensation evoked, in order to allow comparison of results obtained in different studies. The ultimate aim is to substitute the energetic philosophical theory of traditional Chinese medicine with a modern theory based only on scientific evidence and reproducible experiments.

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