

# Auriculotherapy Fails to Relieve Chronic Pain

## A Controlled Crossover Study

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● Enthusiastic reports of the effectiveness of electrical stimulation of the outer ear for the relief of pain ("auriculotherapy") have led to increasing use of the procedure. In the present study, auriculotherapy was evaluated in 36 patients suffering from chronic pain, using a controlled crossover design. The first experiment compared the effects of stimulation of designated auriculotherapy points, and of control points unrelated to the painful area. A second experiment compared stimulation of designated points with a no-stimulation placebo control. Pain-relief scores obtained with the McGill Pain Questionnaire failed to show any differences in either experiment. It is concluded that auriculotherapy is not an effective therapeutic procedure for chronic pain.

ENTHUSIASTIC reports<sup>1-3</sup> of the effectiveness of electrical stimulation of the outer ear for the relief of pain ("auriculotherapy") have led to increasing use of the procedure. Nogier<sup>4</sup> proposed that (1) the body surface and visceral structures are represented at the auricle in a somatotopic organization that resembles an inverted fetus, (2) disease or pain at any body structure is reflected by increased tenderness and skin conductance at a corresponding point at the ear, and (3) electrical stimulation or acupuncture of the appropriate ear-point leads to a dramatic abolition or decrease in pain in the corresponding part of the body.

These remarkable claims appear to be supported by the observation<sup>5</sup> of a highly complex neural and vascular organization of the auricle. Furthermore, a well-designed double-blind trial of patients with musculoskeletal pain<sup>6</sup> reports a concordance of 75.2% between the spatial location of pain in the body determined by medical diagnosis and elevated auricular tenderness and conductance at the points designated by Nogier. Moreover, Pert et al<sup>7</sup> found that auricular electro-

stimulation produced naloxone hydrochloride-reversible analgesia in the rat accompanied by increased endorphin levels in the CSF and depletion of endorphin in the periaqueductal gray matter.

Despite the positive evidence, the claim that auriculotherapy is effective for the relief of pain has never been systematically investigated. The purpose of this study was to evaluate auriculotherapy in patients suffering from chronic pain.

### PATIENTS AND METHODS

#### Patients

The subjects were 36 patients (19 women, 17 men), 21 to 87 years of age (mean, 55.5 years), who suffered from chronic pain. They had been referred to the Pain Center of the Montreal General Hospital for treatment by transcutaneous electrical nerve stimulation. The number of patients in each diagnostic category included the following: peripheral nerve injury, 14; low-back syndromes, 12; musculoskeletal pain syndromes, seven; and miscellaneous pain syndromes, three.

#### Apparatus

A transcutaneous electrical nerve stimulator (MRL Neuroprobe II) was used for stimulation and for recording skin conductance and pain tolerance thresholds. It produces a maximum current output of 200  $\mu$ amps and has a built-in meter that displays current output and permits a recording of skin conductance. The spring-

loaded probe tip, which exerted a constant pressure when applied to the skin, was also used to obtain tenderness ratings. The probe tip had a diameter of 2 mm and exerted a pressure of 50 g/sq mm.

#### Pain Ratings

Pain ratings were obtained by means of both the pain rating index and the present pain intensity of the McGill Pain Questionnaire (MPQ),<sup>8</sup> which have been found to provide valid, reliable measures of pain.<sup>9,10</sup> The pain rating index is the sum of the rank values of the words chosen from 20 sets of qualitative words, each set containing two to six words that describe the sensory, affective, and evaluative properties of pain. The lists of pain descriptors were read to the patient, who was asked to choose the word in each set that best characterized his pain at the moment. The present pain intensity was rated on a scale of 0 to 5 as follows: 0=none, 1=mild, 2=discomforting, 3=distressing, 4=horrible, and 5=excruciating.

#### Experimental Design

The study used a randomized, crossover design in which the effects of stimulation of designated auricular points—which will henceforth be called "Nogier points"—were compared with the effects of stimulating control points. Two types of controls were used: group 1 received electrical stimulation of distant, nonrelated auricular points and group 2 received gentle, tactile stimulation of distant points in which the probe tip was placed at auricular points but no electrical stimulation was given. In group 1, half the subjects received stimulation of Nogier points for two sessions, followed by two sessions of stimulation of distant control points. The remaining half received the stimulation sessions in the reverse order. The same design was used in group 2 except that tactile "placebo" stimulation was applied at distant control points.

The Figure shows the somatotopic map used in this study. It is based on the maps described by Nogier,<sup>4</sup> and others.<sup>11</sup> During treatment of Nogier points, the patients received electrical stimulation at the regions that are shown in the Figure to represent the body parts that were painful. Control points were selected at a distance from the designated Nogier points and bore no relationship to the painful body parts.

#### Procedure

The study was carried out by two experimenters, experimenter 1 and experimenter 2. Each patient was greeted by experimenter 1 and was asked to follow him into the treatment room where he was informed of the nature of the study. After he consented to participate, experimenter

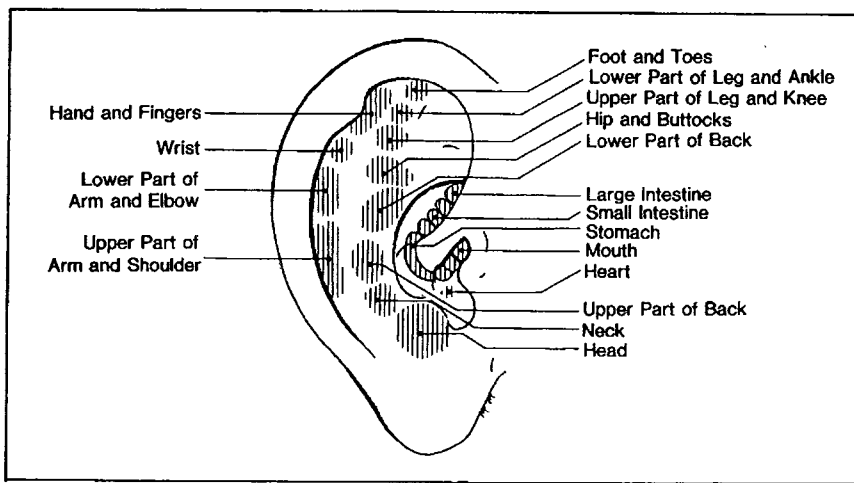


Diagram of presumed somatotopic representation on auricle based on maps described by Nogier,<sup>4</sup> Oleson et al,<sup>6</sup> and Wexu.<sup>11</sup>

Mean Percentage Decreases in Pain*				
	% Decrease in PRI†	% Reporting ≥33% Decrease in PRI†	% Decrease in PPI‡	% Reporting ≥33% Decrease in PPI‡
Group 1 (N=23)				
Nogier points	30.5	43	29	41
Control points	41.3	52	33.8	55
	<i>t</i> (22)=-1.86, NS	...	<i>t</i> (21)=-.6, NS§	...
Group 2 (N=10)				
Nogier points	32.5	50	29.8	50
Control points	24.4	40	31.5	60
	<i>t</i> (9)=-.85, NS	...	<i>t</i> (9)=.71, NS	...

\*After auricular stimulation and percent of patients reporting a decrease in pain of 33% or more.

†PRI indicates pain rating index.

‡PPI indicates present pain intensity.

§*t* test based on N=22.

1 evaluated the patient's pain problem, chose the appropriate Nogier and control stimulation points, and marked the points on two maps of the auricle (shown in the Figure), one designated as Nogier points and the other as control points. Experimenter 1 left the room, handed experimenter 2 the two maps, and told him which ear to treat first. Experimenter 1 then returned to the treatment room to obtain a pretreatment pain score using the MPQ.

During this time, experimenter 2 opened an envelope that had been prepared previously for each prospective patient and read the order of treatments (Nogier followed by control or vice versa) for the patient. The order was based on the Gellerman<sup>12</sup> series, which ensures random assignment to groups.

After the patient completed the MPQ, experimenter 1 informed him that he was not to discuss the pain problem with experimenter 2, who was ready to enter the room and begin treatment. Experimenter 1 then asked the patient to lie in a supine position on the examination table and left the room. Experimenter 2 entered a few minutes later. He cleaned the patient's ears with alcohol and measured the skin conductance and tenderness at each of the designated points on both ears. Pain-tolerance thresholds were obtained

during the course of stimulation. Stimulation time was fixed at five minutes for each ear and was equally apportioned among the designated treatment points. After experimenter 2 had stimulated all of the points, he cleaned the patient's ears, asked him to sit in a chair, and left the room. Experimenter 1 then returned to collect the MPQ pain scores after treatment.

This treatment procedure was carried out for all four sessions, with a change in stimulation from Nogier points to control points (or vice versa) at the third session. When the patients in group 2 received the control treatment, the probe was disconnected during the control stimulation period.

This procedure provides a satisfactory control for auricular stimulation. The patient was blinded with respect to the hypothetical map on the ear, and he was unaware that he would receive placebo stimulation during two of the four treatment sessions. At the same time, experimenter 1, who administered the MPQ before and after treatments, was blinded to the order of stimulation. Furthermore, the method of application of current to the ear precluded any possible effect by E2's biases. The probe was spring-loaded so that a constant pressure was applied to all points. The amount of electrical current

was determined by feedback from the patient who stated that it was felt but was not painful. Furthermore, the duration of stimulation—a total of five minutes for each ear—was identical for all patients. Finally, the number of points stimulated for Nogier and control sessions was the same.

### Skin Conductance, Tenderness Ratings, and Pain Tolerance Thresholds

Skin conductance was measured at each point on the patient's ears by the spring-loaded probe and the meter on the electrical stimulator. The point that registered the highest skin conductance within each designated region shown in the Figure was recorded. The points were then identified with a felt-tipped pen for later recording of tenderness ratings and pain-tolerance thresholds.

Tenderness ratings were obtained by asking the patient to rate the tenderness of each point, in turn, as either "not at all tender," "somewhat tender," "moderately tender," or "very tender," in response to equal pressure applied with the spring-loaded probe. For scoring and subsequent data analysis, rank values of 0, 1, 2, or 3, respectively, were assigned to the aforementioned descriptions.

Pain-tolerance threshold was defined as the highest intensity of current the patient was willing to tolerate, and was obtained during the course of stimulation. It was determined by beginning the stimulation with the lowest possible intensity and then gradually increasing the intensity until the patient said it reached an intolerable level and asked experimenter 2 to stop. The pain-tolerance threshold was recorded and the intensity was lowered to a comfortable level for the remaining stimulation time. The procedure for patients in group 2 who received the tactile placebo stimulation was identical to that mentioned herein except that the probe was disconnected during stimulation. The probe tip was placed gently on each point for the allotted time. Although pain-tolerance thresholds for these patients were not obtained, the patients were nevertheless asked to indicate when they considered the stimulation to have reached a painful level. Because these patients had been anticipating electrical stimulation, the tactile pressure of the probe seems to have fulfilled this expectation.

### RESULTS Pain Ratings

The Table indicates that electrical stimulation of Nogier points on the auricle does not produce greater decreases in pain than identical stimulation of distant control points

(group 1). Similarly, stimulation of Nogier points does not produce more pain relief than tactile placebo stimulation (group 2). The pain relief scores in groups 1 and 2 fall within the expected range of placebo effects reported by Beecher.<sup>13</sup> Because the percentage change in pain scores produced by treatment is partly determined by the initial pain intensity,<sup>8</sup> it is important to note that the mean pain rating index and present pain intensity scores at the beginning of the first treatment and crossover session were similar for both groups, and statistical analyses disclosed no significant differences.

The pain-relieving effects of transcutaneous electrical nerve stimulation applied to trigger points or acupuncture points of the body have been shown to be most pronounced in patients suffering from low-back pain and peripheral nerve injury.<sup>14,15</sup> Because these findings might also hold true for auricular stimulation, we examined these two subgroups individually. The nine patients with low-back pain who received stimulation of Nogier and control points reported mean decreases in the pain rating index of 24% and 30%, respectively. A *t* test for matched pairs showed that the difference was not significant ( $t(8)=0.48$ ). Only two patients with low-back pain were in group 2, therefore precluding statistical analysis. Of the 14 patients with peripheral nerve injury, eight were assigned to group 1 and five to group 2. For the former group, the mean decrease in the pain rating index after stimulation was 30% for Nogier points and 50% for control points. A two-tailed *t* test for matched pairs comparing these means was not significant ( $t(7)=-1.95$ ).

#### Skin Conductance, Tenderness Ratings and Pain Tolerance Thresholds

To avoid possible confounding effects of previous stimulation at each point, only measurements obtained on the first session of each treatment order (ie, sessions 1 and 3) were analyzed. The results showed that there were no differences in skin conductance, tenderness ratings, or pain-tolerance thresholds between Nogier and control points. When these data were examined for syndrome subgroups, the Nogier points

of the patients with low-back pain were rated as being significantly more tender than control points ( $t(11)=3.09$ ;  $P<.01$ ), although no differences were found in skin conductance or pain-tolerance thresholds, and even this single difference was not found in patients with peripheral nerve injuries.

#### Referred Sensations

During electrical stimulation, ten patients reported feeling a number of unusual sensations referred to different parts of their bodies. A patient with low-back pain, for example, complained of pain in her groin shortly after stimulation began—a pain she had never felt before—and which disappeared when stimulation ended. Among these reported sensations were tingling, stabbing, pulsing, warmth, and “glowing.” All of these reports were unsolicited and completely spontaneous. The sensations were reported only during actual stimulation and never when the placebo was given. They were usually felt at a distance from the actual site of pain and were unrelated to the presumed somatotopic organization of the auricle.<sup>4</sup>

#### COMMENT

The results show that auriculotherapy does not relieve chronic pain more effectively than a placebo control. It is reasonable to conclude that patients' reports of pain relief after auriculotherapy may be attributed to placebo effects. The data refute Nogier's<sup>4</sup> assumption that the external ear is an effective site for the modulation of pain at remote areas of the body. The robustness of these results is reinforced by the fact that they were obtained, in large part, from patients with low-back pain and peripheral nerve injuries—two populations that respond well to transcutaneous electrical stimulation.<sup>14,15</sup> Even in these groups, auriculotherapy was no more effective than the placebo in alleviating pain. These results provide a striking demonstration of the “powerful placebo.”<sup>11</sup>

We observed that the Nogier points were more tender than the control points in patients with low-back pain. However, this is an isolated result that was not supported by records of skin conductance or pain-tolerance thresholds and was not found in the

patients with peripheral nerve injuries. Our results, taken together, do not support the notion of a somatotopic map on the auricle.

The reports of referred sensations from ten patients during stimulation suggests that there is a convergence and summation of somatosensory inputs from the external ear at excitatory neuron pools in the CNS.<sup>16</sup> It is possible that, in some patients at least, the referred sensations during stimulation reinforce the pain relief produced by the placebo effect. This may underlie the conviction by therapists and patients alike that auricular stimulation relieves pain.

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