The Effect of Auricular Acupuncture on the Pulse Rate: an Exploratory Randomised Controlled Trial

Adrian White, Edzard Ernst

Summary
Advocates of auricular acupuncture believe that the internal organs are represented in the concha of the ear and can be affected by needling the appropriate area. These two areas of the body have a common innervation from the vagus nerve. The aim of this randomised, single-blind study was to determine whether stimulation of the ear produced changes in the pulse rate, an indicator of vagal tone. Doctor volunteers were needled in either the vagus area or a control area of the ear, and pulse rate changes were measured over the following 30 minutes. No significant differences were found in the pulse rate changes of the two groups. This study, which was limited in size and in other respects, found no evidence to support the concept that the body is represented on the ear.

Key words
Auricular acupuncture, Pulse rate, Randomised controlled trial, Vagal tone.

Introduction
Auricular acupuncture is a method of treatment that involves needling the ear in order to produce relief of symptoms elsewhere in the body. In France in the early 1950s, Nogier first developed the concept that each part of the body is represented on the ear precisely, in a point-to-point fashion. This notion is referred to as somatotopic representation (1). There is some support for the concept of somatotopic representation when used for diagnosing patients with musculoskeletal problems (2) and heart disease (3), but it seems less effective when used as the basis for treatment (4).

Although the concept of somatotopic representation seems biologically implausible, the external auricle is richly innervated, and auricular stimulation can produce referred symptoms in remote parts of the body, at least in some patients (4). Many authors have commented on the fact that part of the skin of the ear is innervated by the vagus (5). In detail, the vagus nerve supplies the external auditory meatus and the concha, which is the depressed portion of the ear immediately anterior to the external auditory meatus. The concha is the site which Nogier believed represents the abdominal organs, whose function is partly under the control of the vagus nerve. It is a plausible hypothesis that stimulation of the sensory branch of the vagus might produce reflex alteration in vagomotor tone. Saxena reported an experiment in volunteers in which it was found that the radial pulse flow-rate, as measured by doppler probe, fell when the concha was squeezed (6). In the same report, he noted that the ancient Brahmins of India were in the habit of winding a sacred thread, the 7-stranded Janeu, around the ear before defaecation.

We decided to investigate, by means of a single-blind randomised trial, the hypothesis that auricular needling in the area of vagal innervation can induce an acute reduction in resting pulse rate, an easily measurable marker for vagal tone.

Method
Volunteers were recruited from doctors attending group discussion sessions on auricular acupuncture during an intermediate training course of the British Medical Acupuncture Society. All doctors had previously undertaken basic acupuncture training. Those with bleeding diathesis or unwilling to be needled were excluded, and informed consent was obtained before inclusion. Since this experiment's principal purpose was as part of experiential learning, ethical approval was not regarded as necessary.

Participants were seated at tables placed in a circle. On the table in front of each person was placed a data-recording form, the back of which was precoded with the letter A or B derived from a computer-generated random number list. Each doctor (subsequently called subject) was needled by the investigator on the right, according to the code on the subject's data form. This has been defined as the most appropriate place for a control
needling since it produces fewer local and distant symptoms than other needle sites (7). There was no attempt to hit any particular point. Needles used were size 15mm x 0.25mm (AcuMedic) and were inserted without any initial stimulation. After 5 minutes they were stimulated by gentle rotation, and after 30 minutes they were removed.

The main outcome measure was the pulse rate, which was recorded before needling, after 5min (before stimulation of needles), after 10min and after 30min. To achieve observer-blinding, all pulse measurements on each subject were made by the doctor who was seated to the subject’s left. Initial briefing included the instruction for all participants not to look at either the right ear or the data-recording form of the subject sitting to the right. Thus, each doctor treated the subject seated to the left, but observed the subject seated to the right. Blinding was confirmed by verbal questioning at the end of the study.

The secondary outcome measure was a questionnaire about 5 possible local symptoms caused by the needle (warmth, fullness, pain, activity, and radiation) rated on a 4 point scale from 0 to 3. This was scored 5 minutes after needle insertion and before stimulation. This method had been used by Margolin et al (7).

Statistical analysis was performed using $t$ tests for pulse rates, and chi-square tests for dichotomous data, in Microsoft Excel 97.

**Results**

Forty-one doctors (mean age 44 years, 6 females) volunteered to take part in the study; 19 subjects were needled in the vagus area and 22 in the control site. Apart from minor bleeding on removal of needles, no adverse events were noted.

The mean pulse rate fell marginally after needling in group A (vagus) and then remained below the baseline value, as shown in Table 1. None of these changes was statistically significant compared to baseline. In the control group B, the mean pulse rate remained constant. There were no statistically significant differences between the two groups at any time point ($p>0.2$). Figure 2 illustrates the mean pulse-rates together with 95% confidence intervals.

The groups were then compared with respect to the numbers of subjects whose pulse rate fell. This was done in order not to miss any large changes in small numbers of subjects who had responded differently. After 5 minutes, 6 subjects in each group had lower pulse rates than their baseline. After 10 minutes the numbers with a lower pulse rate (for vagus and controls, respectively) were 5 and 11, and after 30 minutes 8 and 9. None of these differences was statistically significant.

**Table 1**

<table>
<thead>
<tr>
<th>Acupuncture time</th>
<th>Vagus area mean (SD)</th>
<th>Control area mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>75.5 (5.7)</td>
</tr>
<tr>
<td></td>
<td>5min</td>
<td>73.8 (8.9)</td>
</tr>
<tr>
<td></td>
<td>10min</td>
<td>73.5 (9.2)</td>
</tr>
<tr>
<td></td>
<td>30min</td>
<td>74.1 (9.2)</td>
</tr>
</tbody>
</table>

**Figure 1.** Diagram of the ear showing the areas needled in an investigation into the vagal effects of auricular stimulation.

**Figure 2.** Pulse rate (mean and 95% CI) before and during auriculoacupuncture to either vagus or control area.
Mean (SD) scores for local symptoms from needling were 0.46 (0.71) in group A, and 0.68 (0.86) in the control group B. This difference failed to reach statistical significance (p=0.05).

Discussion
This randomised, single-blind trial in healthy volunteers failed to demonstrate a significant change in pulse rate in response to needling the part of the auricle which is innervated by the vagus. If a true effect exists, it is very small in relation to the standard deviation and therefore very prone to chance effects, confounding variables and measurement error. The very small trend towards a change in the anticipated direction allows a sample size calculation to be performed. Using an alpha value of 5% and beta of 80%, it was estimated that a total of 786 participants similar to those in this study would be required to provide a definitive answer. It is clear that the effect, if it exists, is too small to be clinically relevant.

The major limitation of this exploratory study is that the subjects were likely to have already been in autonomic balance in favour of vagal drive, as they were sitting in a pleasant, non-challenging environment. Therefore there may have been little scope for increasing the vagomotor tone and reducing the pulse rate. Further studies could use measures that involve an autonomic challenge such as the tilt-table, and might also use a more sensitive measure of autonomic response such as beat-to-beat variability. The latter measure was employed by Haker and revealed an increase in sympathetic tone after auricular needling, although it was considerably less than that induced by needling at LI.4 (8).

There is little published controlled research on physiological responses to auricular stimulation. Young and McCarthy compared the effect of needling the traditional Sympathetic point and a non-specific, placebo, auricular point on the electrodermal skin response to stressful stimuli in healthy volunteers (9). Stimulation of the Sympathetic point produced a significant change to the response in the predicted direction, although the results were complicated by unexpected rises in the responses in both groups. In another study, Choy and Eidenschenk found that pressure applied to the tragus (which is innervated by the vagus in some cases) significantly slowed stomach peristalsis (10). Thus, the present negative study is at odds with two other published controlled studies.

It is interesting that the local symptoms experienced by those participants who were needled in the helix region tended to be more marked than those of the vagus group. This is in contrast to the findings of Margolin et al (7). Other findings in the study of Margolin and colleagues, such as patient preference and general symptoms including relaxation, also demonstrate differences between the effects of needling these two areas. These findings validate the use of the upper helix area as the control procedure in a large study of auriculopuncture for cocaine addiction (11).

Conclusion
This study has not found a significant, acute reduction of heart rate as a result of needling the vagus area of the ear in seated, relaxed subjects.

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References
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