Acupuncture effect on thermal tolerance and electrical pain threshold: a randomised controlled trial

Marc Amand, Florence Nguyen-Huu, Costantino Balestra

ABSTRACT
Objective The aim of this study was to test whether acupuncture could modify the threshold of tolerance to thermal and electrical stimuli.

Methods A randomised placebo-controlled single-blind trial was conducted in 36 healthy volunteers randomly distributed to control (no treatment), conventional acupuncture and sham acupuncture groups. The subjects were blind to the group allocation. The authors measured before and after treatment the pain threshold with the Painmatcher (Cefar Medical AB, Lund, Sweden) and the cold tolerance with the cold pressor test, together with the Visual Analogue Scale pain score.

Results Electrical stimulation threshold and cold pressor tolerance both increased significantly in the control and the true acupuncture groups, but not the sham group. The changes in the true acupuncture group were highly statistically significant and amounted to 24% (pain threshold) and 44% (cold tolerance) increases in threshold. The changes in the true group were significantly greater than the control group but not significantly different from the sham group. The changes in the sham and control groups were not significantly different from each other.

Conclusion Acupuncture at true, appropriate points was more effective than no intervention in raising pain threshold and tolerance in volunteers, and acupuncture at inappropriate points had an intermediate effect which was not significantly different from either. Thus acupuncture analgesia may not be a point specific effect.

INTRODUCTION
Various non-invasive techniques are used to test variations in pain threshold. In this randomised controlled single-blind trial, a non-acupuncturist experimenter has observed whether needle insertion could modify threshold of tolerance to thermal and electrical stimuli.

Acupuncture (or electroacupuncture) is used as a complementary or alternative treatment of acute and chronic pain.1 Its effectiveness is sometimes questioned2–5 or even rebutted.4 Specific electrical,5 histological6–7 and physiological8 properties of classical acupuncture points have been discussed and the existence of the meridians’ remains hypothetical.8 Recent studies reveal that acupuncture seems to stimulate immune defences,9 generate a decrease in substance P10 and modulate the endogenous opioid systems (enkephalins, β-endorphin and endorphins).11 Sham acupuncture seems to have different effects: positron emission tomography scanning suggests that classical acupuncture induces an increase in opioid receptor activity both in long and short terms, which does not occur with sham acupuncture.11 Scanning with fMRI shows a reduced activity in the limbic system with classical acupuncture stimulation.12 The penetration of the needle leads to a significant reduction of blood flow in the ipsilateral frontal gyrus and, during the manual stimulation of the needle, changes are observed in the contralateral putamen with classical acupuncture group but not with the sham group.13

Our study aim was to test whether acupuncture induces hypoalgesia as measured by the cold pressor test (CPT) and electrical stimulation test (EST) using the Painmatcher (Cefar Medical AB, Lund, Sweden).

MATERIALS AND METHODS
Thirty-six subjects (16 women and 20 men), students in physiotherapy, healthy volunteers have been recruited from the Institut Supérieur d’Ergothérapie et de Kinésithérapie in Brussels. The study was approved by the Academic Ethical Committee (CE-2009-03-25-vs1), Brussels and informed consent form was obtained from each participant. The subjects were assigned by computer software (GraphPad StatMate V.1.0) in three groups: control, test acupuncture and sham acupuncture. The subjects had never had acupuncture training or treatment and met the inclusion criteria, for example, no recent or former upper limb trauma, or neurological disorders. They pre-

The EST was tested using the Painmatcher which delivers constant current up to a resistance of 13 kΩ, in a monophasic square pulse of 15 mA and 10 Hz, with intensity increasing randomly in steps of 4 μs–396 μs. The measurement-scale is calibrated from 0 to 99 steps. We used only one of the three available measures, the pain threshold. The subject had to press the electrode between the dominant thumb and index finger as long as possible to the maximum possible intensity which was then shown on the LCD display that was hidden from the subject. We took the average of three trials.

During the CPT, the subject was seated and had to maintain, as long as possible, the dominant hand, forearm and elbow immersed in circulating water kept at a constant temperature of 5°C. The time between the immersion and removal of the forearm was measured. The subject was unaware of the time spent.

After both the above tests, the subject recorded the maximum pain intensity experienced on a Visual Analogue Scale (VAS) from 0 to 100 mm (0 mm=no pain, 100 mm=maximum imaginable). The non-graduated side of the scale was shown to the subject.

The experimenter was a postgraduate student in physiotherapy. She received a short training to find certain defined points and to insert and manipulate needles. The subjects were blind to whether they were needled at classical acupuncture or sham points.

We did not use a classical approach to acupuncture but, to define acupuncture points, we have adopted the concept that needles need to be inserted precisely at defined points and manipulated to obtain their effect. The three acupuncture points (TE5, LI4 and SI4) were proposed by an experienced acupuncturist. These three points are used, inter alia, for treating pain of the upper limb. Their lower skin impedance was located by a point detector (Bersac’s Detectherapic, Colombes, France). Sham points were found as the nearest point (horizontally and medially) that showed normal skin impedance.

Acupuncture consisted of a single session using sterile brand (type B, 0.25×40 mm, batch 098436, TEWA, Maanshan Bond Medical Instruments Co., Ltd, China) needles introduced using a matching needle guide. The depth of insertion was 12 mm. The needles were manipulated in a bi-directional rotation and the sensation of de qi was elicited but not analysed. Each participant had a personal case which contained five needles (three were used). The control group received no puncture and the subjects remained seated for the same duration as needling before the forearm immersion. The acupuncture was given in the same side (dominant) as pain threshold tests.

The session consisted of baseline EST1, CPT1 measurements, insertion of acupuncture needles after skin cleaning with denatured ethanol (in test or sham groups only), manipulation of the needles for 20 min, followed by EST2 and CPT2, and finally removal of the needles, skin cleaning and pain VAS score.

Following the results of the D’Agostino and Pearson omnibus normality test, the data were treated using, when allowed, the one sample t test or the Wilcoxon Signed Rank Test for the intragroup comparison and the unpaired t test or the Mann–Whitney test for the intergroup comparison.

Table 1  Electrical stimulation threshold (EST) before (EST1) and after intervention or control period (EST2); mean of 3 trials each time

<table>
<thead>
<tr>
<th>Intragroup comparison</th>
<th>Control group</th>
<th>Test group</th>
<th>Sham group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men: n</td>
<td>6</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Women: n</td>
<td>6</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Age: mean, years (SD)</td>
<td>23.1 (± 2.5)</td>
<td>24.4 (± 3.6)</td>
<td>22.9 (± 3.2)</td>
</tr>
<tr>
<td>EST1: mean, 100 (SD)</td>
<td>18.8 (±11.2)</td>
<td>18.2 (±13.7)</td>
<td>17.5 (±8.8)</td>
</tr>
<tr>
<td>EST2: mean, 100 (SD)</td>
<td>19.4 (±10.9)</td>
<td>22.6 (±17.2)</td>
<td>19.4 (±8.9)</td>
</tr>
<tr>
<td>(EST2/EST1)*100 (%)</td>
<td>105.7 (±6.6)</td>
<td>124.3 (±23.1)</td>
<td>114.2 (±25.0)</td>
</tr>
<tr>
<td>p Value for change</td>
<td>0.0235</td>
<td>0.0039</td>
<td>0.1294</td>
</tr>
<tr>
<td>Minimum change (%)</td>
<td>96.8</td>
<td>96.8</td>
<td>88.9</td>
</tr>
<tr>
<td>Maximum change (%)</td>
<td>117.0</td>
<td>173.0</td>
<td>174.1</td>
</tr>
<tr>
<td>Decreased % (n)</td>
<td>3.0</td>
<td>1.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Table 2  Cold pressor tolerance (CPT) before (CPT1) and after intervention or control period (CPT2)

<table>
<thead>
<tr>
<th>Intragroup comparison</th>
<th>Control group</th>
<th>Test group</th>
<th>Sham group</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT1: mean (s)</td>
<td>112.9 (±61.2)</td>
<td>133.8 (±96.9)</td>
<td>106.9 (±70.8)</td>
</tr>
<tr>
<td>CPT2: mean (s)</td>
<td>123.2 (±65.5)</td>
<td>177.3 (±111.4)</td>
<td>122.2 (±75.7)</td>
</tr>
<tr>
<td>(CPT2/CPT1)*100 (%)</td>
<td>108.6 (±15.6)</td>
<td>144.8 (±37.2)</td>
<td>119.7 (±34.7)</td>
</tr>
<tr>
<td>p Value for change</td>
<td>0.0425</td>
<td>0.0016</td>
<td>0.0756</td>
</tr>
<tr>
<td>Minimum change (%)</td>
<td>88.9</td>
<td>104.0</td>
<td>61.5</td>
</tr>
<tr>
<td>Maximum change (%)</td>
<td>147.7</td>
<td>209.7</td>
<td>190.5</td>
</tr>
<tr>
<td>Decreased % (n)</td>
<td>3</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

Control group (CG): 30 min between the 2 measures
Test group (TG): measures before and after traditional acupuncture
Sham group (SG): measures before and after sham acupuncture.
The changes in the test acupuncture group were highly statistically significant and amounted to 24% (EST) and 45% (CTP) increases in threshold (Figures 1 and 2). The changes in the test group were significantly greater than the control group but not significantly different from the sham acupuncture group (Tables 1 and 2). The changes in the sham and control groups were not significantly different from each other. The maximum values of the VAS indicated that no individual had felt an intolerable pain (Table 3).

There were no meaningful statistically significant differences between the males and female volunteers (EST: p=0.11; CPT: p=0.49; VAS: p=0.41).

**DISCUSSION**

Our results show that experimental analgesia was greater with true acupuncture than with control (no treatment) but not than sham acupuncture at off-point locations.

Acupunctural hypoalgesia is the subject of many randomised clinical tests. These studies are often criticised for their experimental protocol. The difficulty of establishing a reproducible therapeutic protocol is inherent in classical acupuncture concepts in which pain is a sign of an ‘energy’ disturbance. An experimental pain applied to healthy subjects deviates therefore from classical acupuncture methods. We did not adopt the ‘Chinese laws’. The experimenter was not an acupuncturist. Her very brief training was limited to the anatomical identification and electrical localisation of points, and to the rudiments of puncture technique and needles handling.

The three points suggested were specified little compatible with an ideal intervention, but easy to find, without risk of injury and nevertheless deemed effective. These points should belong to Yang meridians and ‘disperse’ the cold. The needles were maintained 20 min. The recommended duration varies from 15–30 min.

Considering the subjective nature of pain, we have chosen three tests widely used: VAS, EST (Painmatcher) and CPT. Our test involved a single session. However, it seems that three sessions provide a better result. Furthermore, the CPT’s circulating water had a constant temperature of 5°C. However, the temperature should usually be ≤3°C. Mitchell et al showed that the increased level of cold tolerance is dependent on temperature. According to them, at 5°C, the average time of immersion is 140 s for men and 60 s for women. At the CPT 1, we obtain averages of 128 s (men) and 108 s (women). These differences are perhaps due to the geographical origin of the subjects.

In CPT, Downs et al do not obtain significant differences compared to the control and sham groups. In our study, only the test group gets a highly significant increase of the values between the first and the second series of tests in both EST (24%) and CPT (45%). This increase is significant for the control group too (EST: 6% and CPT: 9%). A habituation to pain can be raised but the sham group shows no significant variation. Four of the 12 subjects of this sham group had a negative difference at the EST and two are in this case at the CPT. These outcomes coupled with the importance of SDs in test and sham groups confirms a study which concluded that acupuncture’s analgesic effects on experimental pain may be dependent on both subject and mode. These elements show the difficulty to design and validate an acupunctural placebo technique without physiological activity.

In intergroup analyses, the difference between the increase of test and control groups is highly significant. The sham group shows no significant difference with both the control group than the test group. Thus, sham acupuncture effects are statistically inefficient but have no

### Table 3  Visual analogue scale

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Test group</th>
<th>Sham group</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS: / 10 (SD)</td>
<td>3.3 (±0.8)</td>
<td>3.3 (±1.6)</td>
<td>3.2 (±1)</td>
</tr>
<tr>
<td>Minimum /10</td>
<td>2.0</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>Maximum /10</td>
<td>4.5</td>
<td>7.0</td>
<td>5.0</td>
</tr>
</tbody>
</table>
statistically different action as treatment that has, itself, an action highly significant compared to no treatment. Recent systematic reviews reach to a similar conclusion. However, different physiological effects between classical acupuncture and sham acupuncture have been observed. The needle insertion, its depth, direction and manipulation seem to modify the results quality and a different effect in the deep cortical structures.

We have found no significant gender differences except for the VAS in the test group. The literature indicates a lower tolerance of women in EST which is variable to the CPT. But is the concept of pain not also an individual perception?

Our results show no correlation between EST, CPT and VAS. A study on the EST and the VAS concludes the same.

CONCLUSION
Acupuncture at true, appropriate points was more effective than no intervention in raising pain threshold and tolerance in volunteers, and acupuncture at inappropriate points had an intermediate effect which was not significantly different from either.

For specific thermal and electrical stimuli, true acupuncture induces a highly significant hypalgesia in the test group, a significant one in the control group and not a significant one in the sham group. There is thus an adaptation to pain between two successive tests which is curiously not found in the sham group. Compared to the control group, the results of test group are highly significant and those of the sham group are not. There is no significant difference between the test and sham groups but the absence of a truly inert placebo stays a major question.

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Competing interests None.

Ethics approval This study was conducted with the approval of the Academic Bio-

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Provenance and peer review Not commissioned; externally peer reviewed.

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