Validation of a simplified sham acupuncture technique for its use in clinical research: a randomised, single blind, crossover study

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ABSTRACT

Objectives The validity of a new sham acupuncture technique was tested on acupuncture naïve healthy subjects.

Methods The procedure was tested in acupoints LI4 and ST6 in a randomised, single blind and crossover study. The participants were blind to which technique they received. 32 healthy volunteers (15 men, 17 women, aged between 20 and 62 years, mean age 34 years) were recruited at the Universidad de la República, Uruguay. Interventions Participants were randomly assigned to one of two groups: (1) real acupuncture or (2) sham acupuncture. After 30 min, the patients were ‘needled’ again in a crossover design. Main outcome measures A yes/no questionnaire was used to assess the credibility and characteristics of the procedure.

Results For the credibility question (do you think you received real acupuncture?) no statistically significant group differences were evident before or after the crossover. Subjects who answered yes to this question ranged from 14/16 (87.5%) before crossover to 10/16 (62.5%) after crossover for the sham and 12/16 (75%) before crossover to 15/16 (93.8%) after crossover for the real acupuncture. The question that showed a significant difference (only after crossover) was the question, “did you feel the needle penetrating the skin?”; after crossover 12/16 (75%) subjects in the real acupuncture group said yes and 2/16 (12%) subjects in the sham group said yes to this question (p<0.01).

Conclusions These data suggests that this method is credible and constitutes a simple and inexpensive technique for use as a control in clinical research in acupuncture naïve subjects.

INTRODUCTION

Evidence based medicine requires well-controlled research studies with adequate placebo techniques that mimic all aspects of the active intervention but are inert. Acupuncture therapy is used world wide for the treatment of several diseases but the lack of research studies with acceptable controls has been a major methodological problem.1 2

The lack of adequate sham procedure in the past has led researchers to compare real acupuncture with a wide variety of other interventions. For example, it is still common to see published peer-reviewed research in which the sham procedure consists on needling non-acupuncture points or minimal subcutaneous stimulation in acupuncture points.3 4 It was argued that procedures which imply needle insertion are not acceptable as controls because they can elicit neurobiological responses at various levels in the central nervous system, including the primary and secondary somatosensory cortex, anterior cingulated cortex and the insula region.5 6

The National Institutes of Health already recognised this methodological problem a decade ago during the Consensus Conference on Acupuncture1 and concluded that “Although there have been many studies of its potential usefulness, many of these studies provide equivocal results because of design, sample size, and other factors”. Furthermore, it was specifically stated that the lack of appropriate controls such as placebos and sham acupuncture groups is problematic. During the past decade new solutions were presented and ‘single-blind’ acupuncture needles were introduced. These kinds of devices allow patients to be blind to the treatment but not the acupuncturist. Streitberger and Kleinhenz7 introduced a ‘placebo’ needle with a blunt tip and a retractile handle and tested this in the acupuncture point LI4 on the hand. This needle moves inside the handle, touches the skin and appears to be shortened in order to mimic a real acupuncture procedure. An independent validation of the credibility of this placebo needle was performed8 and it was concluded that even if the needle has limitations it is a convincing control for single blind studies. The main limitation discussed in this study9 was that almost 40% of patients did not find that the sham and real intervention were similar. Slight changes have been made to this device since its original presentation, including the development of an adhesive guide tube to hold the sham needle more firmly in place.9 Another ‘placebo’ needle was recently presented by Takakura and Yajima.10 The authors claim that this is a double-blind device, masking both the patient and the practitioner. The main problem with those devices is that they are not available for researchers world wide since they are custom fabricated. Another sham acupuncture needle made with an improved blunting technique process was recently presented.11

A simplified and less expensive sham acupuncture method for use in single blind trials used regular blunted acupuncture needles and adhesive foam to keep them in place.12 13 The main problem with this technique is that the acupuncturist has to manually perceive when the sham needle touched the skin and be careful not to penetrate the skin.

The ideal sham acupuncture device should mimic all aspects of real acupuncture but be inert. However, the sham devices previously presented in the literature would usually ‘prick’ the skin even if they are ‘non-penetrating’. It can be argued that the...
blunted needle touching the skin may elicit a biological response by stimulating afferent fibres.5 6

The aim of our study was to develop and evaluate the validity of an improved, simplified, non-penetrating and inexpensive sham acupuncture technique in healthy human subjects. We tested the method in a randomised and crossover design study on acupuncture LI4 in the hand and ST6 in the face. Both points are commonly used for treating headaches, trigeminal neuralgia, temporomandibular disorders and other craniofacial pain syndromes. We hypothesised that the sham intervention would be as credible as the real, even after crossover.

METHODS
Study sample
The subjects were healthy volunteers recruited from students and staff at the Universidad de la República, School of Dentistry, Uruguay. Thirty-two subjects (15 male and 17 women, aged between 20 and 62 years, mean age 34 years) were included according to the following inclusion and exclusion criteria:

Inclusion:
1. They were between the ages of 18 and 70 years old.
2. Willing to participate in a study in which acupuncture needles were inserted and kept in place for 5 min.

Exclusion criteria:
1. Obvious acute or chronic medical diseases.
2. Prior treatment with any acupuncture technique.
3. Needle phobia.
4. Elevated blood pressure (≥140/90).
5. Pregnancy.

Sample size estimation
Sample size calculations were performed assuming a power of 80% and accepting a statistical difference at the 5% level. The estimated total sample size needed was 30 patients.

Ethics
The protocol and the consent form were approved by the Ethics Committee of the Universidad de la República, School of Dentistry, Uruguay.

Group assignment
The subjects were randomly assigned to one of two experimental groups: (1) acupuncture or (2) sham acupuncture, using a computerised randomisation program. After 30 min, the patients were ‘needled’ again in a crossover design using the same points in the opposite side of the body. The side of the body which received acupuncture first was also randomised.

Bias control
Blinding
All subjects consented and signed a consent form which informed them that we were testing two different acupuncture techniques. The methods and verbal instruction used during the experiment were identical for all individuals in an effort to minimise any bias between the two methods. The patients were blind to which kind of procedure they were receiving. In order to minimise bias an independent investigator was in charge of the randomisation process and the preparation of the patients and needles. When the acupuncturist approached the patient he was blind to which procedure the subject would receive.

Real acupuncture technique
In the acupuncture group, two acupuncture needles (25 × 0.22 mm, manufactured by Wujiang City Cloud & Dragon Medical Device Co, Ltd, China) were inserted in acupuncture points, LI4 and ST6. In all situations the skin area was disinfected with 70% alcohol. An adhesive patch was made using two pieces of 13 mm length of high density foam tape 5 mm thick, 12.7 mm wide (MD brand, Georgia, USA). One of the foam pieces was perforated in order to hold a needle-guidance tube (figure 1). The whole device (foam, tube and needle) was double sealed and sterilised using an ethylene oxide sterilisation system. The needle was kept in place within the tube when the patch was placed on the skin so that the subjects were not able to distinguish whether they were getting real or sham acupuncture. A certified acupuncturist with 18 years of experience tapped the needle and after the insertion the tube was taken out. Then, the acupuncturist made the classic rotation manoeuvre of the needle for 5 s, without inserting it any further. After 5 min the needles were removed and the subjects were asked to fill out a standardised questionnaire.

Sham acupuncture technique
In the sham acupuncture group the same skin disinfection technique and the same two-piece sterile adhesive patch were used.
A regular acupuncture needle was used with the tip blunted and shortened, in order that after the needle was tapped it would not prick the skin. The same visual setting, manipulations, stimulation procedures, time and questionnaires as in the real acupuncture group were used in order to have the same psychological impact, but the sham needle just moved inside the foam pad providing the same visual appearance that in the real acupuncture (figure 2). During the rotation manoeuvre the acupuncturist had to be careful not to advance the depth of the needle any further, in order to avoid the needle making contact with the skin.

Outcome measures
1. Questionnaires: after each needle removal the subjects were asked to fill a standard questionnaire. They were asked five yes/no specific questions. Four questions were about the specific sensations they might have experienced during the experiment (including needle penetration). De qi sensations were indirectly explored in these questions using a typical set of quality descriptors that were shown to characterise this sensation (eg, dull, aching, pressure, numbness, etc).
2. One credibility question asked them to state if they felt that the procedure was real acupuncture or not.
3. Visual analogue scales (VAS): finally, each patient rated the pain sensation they experienced at each site using a 100 mm VAS immediate after each procedure.

Data analysis
In this study the primary outcome was a dichotomous variable (yes/no). For this reason, we analysed the two groups for differences in response to this variable using a χ² analysis for each site and for each type of acupuncture (sham and real). Statistical significance was accepted for any response below the 5% level.

RESULTS
Drop outs
There were no drop-outs in this study. All 32 enrolled subjects completed both arms of the experiment after randomisation.

Questionnaire
For the procedure credibility question (do you think you received real acupuncture?), no statistically significant group differences were evident before (p=0.365) or after the crossover (p=0.144). The number of subjects who answered yes to this question ranged from 14/16 (8.5%) before crossover to 10/16 (62.5%) after crossover for the sham and 12/16 (75%) before crossover to 15/16 (93.8%) after crossover for the real acupuncture.

For the remaining four questions regarding specific characteristics of the sensations experienced during acupuncture, three of these questions showed no statistically significant group differences in either arm of the study (table 1). The only question that showed a significant group difference (and only after crossover) was the question ‘did you feel the needle penetrating the skin?’. After crossover 12/16 (75%) subjects in the real acupuncture group said yes and 3/16 (18.8%) subjects in the sham group said yes to this question. The VAS score was 0 in the great majority of cases: two participants scored above 0 (4 and 6) after real acupuncture.

DISCUSSION
The development of a credible, simple and inexpensive sham acupuncture device is still a methodological concern in acupuncture research. Our data suggests that the sham acupuncture method used in this study is credible and a high proportion of the subjects believe they were receiving real acupuncture. Moreover, the sensory experiences that the subjects report also support the idea that our sham acupuncture is credible. The method we used does not require a custom made retractile needle device and constitutes a simple and inexpensive sham acupuncture technique for use as a control condition in clinical research. The major limitations of the study are that we used acupuncture naïve subjects and we only tested the system at two sites, namely LI4 and ST6 points. It remains to be seen if the credibility of our method will be sustained in experienced acupuncture subjects. If non-acupuncture naïve subjects are able to distinguish sham from real stimulation, this would expand the exclusion criteria to eliminate subjects with prior acupuncture experience.

Previous sham acupuncture devices would usually ‘prick’ the skin and cannot be considered physiologically inert. Our device has improved this methodological problem because the needle was shortened and blunted in such a way that would not prick the skin. It is plausible that this methodological ‘advantage’ was responsible for the statistical significant difference for the yes response to the question of the needle penetration of the skin after crossover. However, it is important to note that the credibility question remained non-significant even after crossover. Even some patients that did not report needle penetration perceived that they received real acupuncture. A possible limitation of the technique is that the foam pad touching the skin may elicit a biological response by activating A-β and C fibres. However, it can be argued that this biological response is less intense than a pricking or penetrating needle.

Our data agrees with Park et al’s study which reported on the validity of a new non-penetrating sham acupuncture device. They reported that their procedure was indistinguishable from the same procedure using real needles in acupuncture naïve subjects. Our data also agrees with the results presented by Goddard et al who also concluded that their subjects were not able to reliably differentiate between real and placebo acupuncture. Finally, a study by Takakura and Yajima used a penetrating (real) and non-penetrating needle (sham) acupuncture on 114 healthy volunteers who were informed that they would receive either a non-penetrating or a penetrating needle. They found that 78/114 (68.4%) of subjects who had real acupuncture reported they felt the needle penetrate the skin. In contrast, they reported that 64/114 (56.1%) of the sham acupuncture subjects reported they felt needle penetration of the skin. While these data were found to be non-significant, it is possible that because their subjects were informed that one device was non-penetrating, this influenced the outcome.

The sham needle study method used by Goddard et al was quite similar to our method with the main difference being that in their study the acupuncturist had to manually perceive when the shortened (sham needle) needle touched the skin and they would have to be careful not to push hard enough to allow the needle to penetrate the skin. In our study, we used a fixed length clear guide tube with the bottom portion of the tube covered by the foam. We then cut the sham needle so that it would move inside the foam pad when fully depressed into the tube but would not prick the skin. It was interesting to find that some participants reported de qi sensations and needle penetration during the sham procedure even if the needle was not supposed to touch the skin. Besides the placebo effect it is possible that the pressure that the acupuncturist made while tapping the tube may be responsible for a mechanical stimulation of the skin. The
acupuncturist reported that his tactile sensations of quickly tapping the needle into the tube were the same for the sham and for the real acupuncture needle.

Two more differences need to be noted between our study and the Goddard study. First, we tested our method on two points (LI4 and ST6) which are located on both the hand and the face while they evaluated it only on the LI4 point on the hand. Second, our study was a crossover study and we discovered a difference between the groups after crossover on the question, ‘did you feel the needle penetrate the skin?’ This observation suggests that sham acupuncture studies may not work well in experimental studies that have a crossover design.

In conclusion, the method presented in this paper constitutes a credible, simple, inexpensive and relatively indistinguishable sham acupuncture technique for its use as a control in clinical research. Our findings are limited to LI4 and ST6 points, and in young healthy acupuncture-naive subjects, although there is no reason to expect that these results would not generalise to other subjects and other points. The only drawback is that subjects generally can feel the needle penetrate the skin, when asked this question directly, which may be problematic if the experimental design is a crossover study. Future research must test the device in symptomatic participants, which may reflect a population that would be included in a randomised clinical trial.

**Table 1** Per cent of ‘yes’ answers to the five questions

<table>
<thead>
<tr>
<th>Five questions</th>
<th>Before crossover</th>
<th>After crossover</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LI4† ST6‡</td>
<td>LI4† ST6‡</td>
</tr>
<tr>
<td>1. Did you feel the needle penetrate your skin?</td>
<td>9/16 10/16</td>
<td>12/16 12/16</td>
</tr>
<tr>
<td></td>
<td>56% 62%</td>
<td>75% 75%</td>
</tr>
<tr>
<td>2. Do you feel that you received real acupuncture?</td>
<td>12/16 12/16</td>
<td>15/16 15/16</td>
</tr>
<tr>
<td></td>
<td>75% 75%</td>
<td>94% 94%</td>
</tr>
<tr>
<td>3. Were there any qi sensations?</td>
<td>8/16 7/16</td>
<td>6/16 8/16</td>
</tr>
<tr>
<td></td>
<td>50% 44%</td>
<td>37% 50%</td>
</tr>
<tr>
<td>4. Was the procedure painful?</td>
<td>1/16 2/16</td>
<td>0 0</td>
</tr>
<tr>
<td></td>
<td>6% 12%</td>
<td>12% 12%</td>
</tr>
<tr>
<td>5. Do you consider this procedure comfortable?</td>
<td>15/16 16/16</td>
<td>16/16 16/16</td>
</tr>
<tr>
<td></td>
<td>94% 100%</td>
<td>94% 100%</td>
</tr>
</tbody>
</table>

*p* chi square, real vs sham for each point; †Hand acupuncture point (LI4); ‡Facial acupuncture point (ST6).

**REFERENCES**

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