A placebo acupuncture needle with potential for double blinding – a validation study

Nobuari Takakura, Hiroyoshi Yajima

Abstract

Background The double blind, non-penetrating placebo needle is effective in masking patients who are not informed that they may receive a placebo needle. In this study, we aimed to examine whether such needles are effective in masking subjects who have been so informed.

Methods One hundred and fourteen informed, consenting, healthy volunteers were recruited. An experienced acupuncturist applied one of the following needle pairs – penetrating/non-penetrating, non-penetrating/non-penetrating, penetrating/penetrating – randomly at bilateral TE5 points in subjects who were informed that they would receive either a non-penetrating or a penetrating needle. After the application of a pair of needles, the subjects reported for each arm on whether they identified the needle as non-penetrating or penetrating. The patients also rated skin penetration/penetration-like pain and the deep dull pain (de qi) associated with the needle application on a visual analogue scale (VAS). The chi squared goodness of fit test was used to determine the probability of the number of correctly and incorrectly identified needles. Statistical comparisons for VAS scores for skin penetration pain and de qi were made using Mann-Whitney’s U test.

Results Of the 114 non-penetrating needle applications, the subjects identified 64 incorrectly and 50 correctly, fitting a probability of 0.5 ($\chi^2 = 1.72, P=0.19$). Most interestingly, the subjects identified 36 (32%) of 114 penetrating needle applications incorrectly. Skin penetration/penetration-like pain and de qi scores did not differ significantly ($P=0.87$ and $P=0.17$, respectively) between the 114 non-penetrating and 114 penetrating needles.

Conclusions The non-penetrating placebo needle was effective in masking fully informed subjects. When used together with the matched penetrating needle, it has potential for use in double blind (patient and practitioner blind) studies.

Keywords

Double blind method, double blind needles, acupuncture, placebos.

Introduction

High quality acupuncture clinical trials using single blind methods have been reported, however, the results of these single blind studies are controversial. Several investigators recently invented and validated a subject masking, single blind needle which to the subject looks and feels like a real needle. These recently designed placebo devices, which overcome the inadequacies of previous control procedures, provide enhanced evidence in acupuncture studies when it is impossible to blind the practitioner to the intervention. However, the specific effects of acupuncture beyond placebo measured in such studies may still be biased due to presence of unmasked practitioners. Thus, there has been a call for a methodological advance beyond single blind studies, despite the inherent difficulties in masking the practitioner in acupuncture studies.

As a development in this field, we designed the double blind (practitioner and patient masking), non-penetrating, placebo needle together with the matched ‘real’ needle. The design of the placebo needle successfully masked the true nature of the needle from experienced acupuncturists, even though they were informed of their potential use. For patient masking, we showed that non-penetrating needles are effective when the patients are informed that two different types of acupuncture needles are being
compared. However, it remains questionable whether the placebo needle is effective in masking patients when they are informed of the potential use of a non-penetrating needle. In line with the modern day ethical requirement of full disclosure of experimental procedures, patients in clinical trials must be told that they may receive real or placebo needles. The aim of the present study, therefore, was to assess whether the double blind placebo needle is effective for blinding fully informed subjects.

**Methods**

*Double blind needles*

We described the details of the design of the needles and their effectiveness in masking the practitioners elsewhere. Briefly, the non-penetrating needle is identical to the penetrating needle except for being shorter and having a blunt tip (Figure 1). The guide is opaque, and has an adherent pedestal which attaches to the skin like the Park device. The lower part of the guide tube of the non-penetrating needle is stuffed and gives the practitioner the impression that the needle is penetrating the skin. The upper part of the guide tubes of both kinds of needle is also stuffed, to disguise the feel of the needle insertion. Both needles have a stopper that prevents the needle handle from advancing further when the sharp tip of the penetrating needle, or the blunt tip of the non-penetrating needle, reaches the specified position. In this way, the non-penetrating needle is indistinguishable from the penetrating needle in both appearance and feel. The insertion depth of the penetrating needle was 5mm. The diameter of the needles was 0.16mm.

*Participants*

We recruited an experienced and licensed acupuncturist on the teaching staff and 114 healthy volunteers (mean ± SD age: 30.3±7.9 years; 73 men, 41 women) who were familiar with receiving acupuncture as experimental subjects from Hanada College, and who were familiar with the different sensations of needle penetration and *de qi*. Before the study, the purpose and format of the study were explained and the subjects provided written consent. The Showa University Ethics Committee gave its approval.

*Validation of informed patient masking*

Before the trial, the subjects and the practitioner were informed that penetrating/penetrating, non-penetrating/non-penetrating, and penetrating/non-penetrating needle pairs would be used and that we would ask them about the nature of each needle after it had been removed. We prepared 38 pairs of each of these needle combinations. Each needle was sealed in a small opaque container. The 114 pairs of needles were shuffled in advance.

An acupuncturist with eight years experience inserted a pair of needles, randomly taken from the shuffled 114 pairs, at bilateral TE5 points in the subjects and manipulated them using the alternating (rotating clockwise and anticlockwise) twirling technique. TE5 is located three finger breadths above the wrist crease between the ulna and the radius on the posterior surface of the forearm.
application, the subjects guessed the type of the needles. They also rated skin penetration/penetration-like pain on a visual analogue scale (VAS) ranging from 0 (no skin penetration pain) to 10 (the most intense skin penetration pain ever experienced during needle insertion). In addition, we asked them to rate the acupuncture needle sensation of de qi, a deep dull pain sensation that is considered essential for a successful acupuncture treatment, on a VAS ranging from 0 (no de qi experienced during needle insertion) to 10 (the most intense de qi ever experienced during needle insertion). The practitioner was also asked to guess the type of needle after each needle removal. We asked the practitioner to report bleeding if this was noticed.

Data analysis
The chi squared goodness of fit test was used to determine whether the number of correctly and incorrectly identified needles fits a probability of 0.5. Statistical comparisons of the needle groups for VAS scores for skin penetration/penetration-like pain and de qi were made using Mann-Whitney’s U test. All statistical analyses were performed using SPSS, version 15.0J (SPSS Inc, Chicago, IL). The true identity of the needle was not revealed until after the results had been tabulated.

Results
The fully informed subjects guessed the nature of each of the 114 non-penetrating and 114 penetrating needles. Of the total 228 needles applied, the subjects identified 128 (56.1%) needles correctly (non-penetrating 50, penetrating 78) and 100 (43.9%) needles incorrectly (non-penetrating 64, penetrating 36), fitting the probability of 0.5 ($\chi^2=3.439, P=0.064$). For the 114 non-penetrating needles, the data also fits a probability of 0.5 ($\chi^2=1.719, P=0.19$).

With regard to the ratings of the skin penetration/penetration-like pain and de qi, no significant differences ($P=0.872$ and $P=0.168$, respectively) were found in subjective intensity between the 114 non-penetrating and 114 penetrating needles (Table 1). Of the 114 penetrating needles, 72 (63.2%, 54 correctly and 18 incorrectly identified) elicited skin penetration/penetration-like pain and 40 (35.1%) elicited de qi. Interestingly, 21.1% of the penetrating needles elicited neither response. Of the 114 non-penetrating needles, 72 (63.2%, 20 correctly and 52 incorrectly identified) elicited skin penetration/penetration-like pain and 30 (26.3%) elicited de qi.

For both non-penetrating and penetrating needles, the skin penetration/penetration-like pain score for the needles identified as penetrating was significantly larger than that for the needles identified as non-penetrating ($P<0.001$ and $P=0.023$, respectively) (Table 1). For de qi, the 36 penetrating needles identified as non-penetrating were associated with significantly less de qi than were the correctly identified 78 penetrating needles ($P=0.005$). Such a significant difference in de qi was not observed for the non-penetrating needles.

The skin penetration/penetration-like pain score for the correctly identified 50 non-penetrating needles was significantly less than that for the correctly identified 78 penetrating needles ($P=0.001$), but was not significantly different from that for the 36 penetrating needles identified as non-penetrating ($P=0.344$) (Table 1). The skin penetration/penetration-like pain score for the 64 non-penetrating needles

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Median (mean) scores for skin penetration pain/penetration-like pain and de qi for 114 correctly and incorrectly identified non-penetrating and penetrating needles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin penetration pain/penetration-like pain</strong></td>
<td><strong>De qi</strong></td>
</tr>
<tr>
<td>Median (mean)</td>
<td>[P value]</td>
</tr>
<tr>
<td>114 NP vs 114 P</td>
<td>1 (2.1) vs 1 (1.9) [0.872]^*</td>
</tr>
<tr>
<td>50 correct NP vs 64 incorrect NP</td>
<td>0 (1.4) vs 2.8 (2.8) [0.001]**</td>
</tr>
<tr>
<td>78 correct P vs 36 incorrect P</td>
<td>2 (2.1) vs 0.5 (1.3) [0.023] *</td>
</tr>
<tr>
<td>50 correct NP vs 78 correct P</td>
<td>0 (1.4) vs 2.8 (2.1) [0.001]**</td>
</tr>
<tr>
<td>50 correct NP vs 36 incorrect P</td>
<td>0 (1.4) vs 0.5 (1.3) [0.344]</td>
</tr>
<tr>
<td>64 incorrect NP vs 78 correct P</td>
<td>2 (2.8) vs 2.8 (2.1) [0.142]</td>
</tr>
<tr>
<td>64 incorrect NP vs 36 incorrect P</td>
<td>2 (2.8) vs 0.5 (1.3) [0.001]**</td>
</tr>
</tbody>
</table>

Abbreviations: NP – non-penetrating needles; P – penetrating needles
* P<0.05, ** P<0.01 based on Mann-Whitney’s U test
identified as penetrating was significantly greater than that for the 36 penetrating needles identified as non-penetrating (P=0.001), but was not significantly different from that for the correctly identified 78 penetrating needles (P=0.142) (Table 1).

The distribution of the non-penetrating needles depicted according to the intensity of skin penetration/penetration-like pain (SPP) and dull pain sensation (de qi) was similar to that of the penetrating needles (Figure 2). Moreover, the frequencies that needle sensations were elicited in the case of the 114 non-penetrating needles, ie 30 with neither skin penetration/penetration-like pain nor de qi, 54 with skin penetration/penetration-like pain only, 12 with de qi only and 18 with skin penetration/penetration-like pain, were similar to those in the case of the penetrating needles (Table 2). Furthermore, the frequencies that needle sensations were elicited in the case of non-penetrating needles that were incorrectly and correctly identified were quite similar to those in the case of the penetrating needles that were correctly and incorrectly identified (Table 2).

Of the total 228 needles, the practitioner identified 97 (42.5%) needles correctly (non-penetrating 54, penetrating 43) and 122 (53.5%) needles incorrectly (non-penetrating 54, penetrating 68), fitting the probability of 0.5 ($\chi^2=2.854$, P=0.091). Nine (4%) needles were indistinguishable. The number of non-penetrating needle applications which were correctly identified by both practitioner and subject was 24, and incorrectly identified by both was 34 (Table 3). The number of penetrating needle applications which were correctly identified by both practitioner and subject was 28, and incorrectly identified by both was 21.

**Discussion**

The fully informed subjects failed to correctly identify the non-penetrating needles even though they had previously received acupuncture and were familiar with the different sensations of needle penetration and...
Our non-penetrating needle group. blind placebo needle group were similar to that in who felt skin penetration pain or in the single blind study. The identity of the non-penetrating needle, as reported penetrating needles was too small to reveal the penetration-like pain between non-penetrating and in the present study. Therefore, skin penetration/penetration-like pain elicited by the non-penetrating needles did not suspect that they received a non-penetrating needle, and the fully informed subjects in the present study who were not informed of the potential use of non-penetrating needles did not identify whether the needles were penetrating or non-penetrating. The difference in skin penetration/penetration-like pain between non-penetrating and penetrating needles was too small to reveal the identity of the non-penetrating needle, as reported in the single blind study. The proportion of patients who felt skin penetration pain or de qi in the single blind placebo needle group were similar to that in our non-penetrating needle group. These similarities with the validated single blind needle confirm the effectiveness of patient masking by our needle. The double blind placebo needle with a blunt tip is a promising innovation that should allow double blind acupuncture studies to be undertaken in both naive and fully informed subjects.

Although we thought it unlikely that a subject would misjudge a penetrating needle to be a non-penetrating one, surprisingly, 32% of penetrating needles were incorrectly identified. The skin

de qi. Moreover, the highly experienced practitioner failed to identify both the penetrating and non-penetrating needles, as found in our previous study.21,24

The reason for the successful subject masking with the non-penetrating needle was that the sensations elicited by the needle were similar in frequency and intensity to those experienced with needle penetration to a 5mm insertion depth. Thus, subjects in the previous study who were not informed of the potential use of non-penetrating needles did not suspect that they received a non-penetrating needle, and the fully informed subjects in the present study misjudged nearly half of the non-penetrating needles. Interestingly, 70% of the non-penetrating needles that elicited skin penetration/penetration-like pain but not de qi were identified as penetrating needles. Therefore, skin penetration/penetration-like pain seemed to be the main factor used by the subjects to identify whether the needles were penetrating or non-penetrating. The difference in skin penetration/penetration-like pain between non-penetrating and penetrating needles was too small to reveal the identity of the non-penetrating needle, as reported in the single blind study. The proportion of patients who felt skin penetration pain or de qi in the single blind placebo needle group were similar to that in our non-penetrating needle group. These similarities with the validated single blind needle confirm the effectiveness of patient masking by our needle. The double blind placebo needle with a blunt tip is a promising innovation that should allow double blind acupuncture studies to be undertaken in both naive and fully informed subjects.

Although we thought it unlikely that a subject would misjudge a penetrating needle to be a non-penetrating one, surprisingly, 32% of penetrating needles were incorrectly identified. The skin

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Skin penetration pain/penetration-like pain (SPP) and de qi elicited by 114 non-penetrating and penetrating needles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of needles (% of 114 needles)</td>
</tr>
<tr>
<td>114 non-penetrating needles</td>
<td></td>
</tr>
<tr>
<td>Neither SPP nor de qi felt</td>
<td>30 (26.3)</td>
</tr>
<tr>
<td>Only SPP felt</td>
<td>54 (47.4)</td>
</tr>
<tr>
<td>Only de qi felt</td>
<td>12 (10.5)</td>
</tr>
<tr>
<td>Both SPP and de qi felt</td>
<td>18 (15.8)</td>
</tr>
<tr>
<td>114 penetrating needles</td>
<td></td>
</tr>
<tr>
<td>Neither SPP nor de qi felt</td>
<td>24 (21.1)</td>
</tr>
<tr>
<td>Only SPP felt</td>
<td>50 (43.9)</td>
</tr>
<tr>
<td>Only de qi felt</td>
<td>18 (15.8)</td>
</tr>
<tr>
<td>Both SPP and de qi felt</td>
<td>22 (19.3)</td>
</tr>
</tbody>
</table>
Since the needle is designed for use at all acupuncture point locations, there should be no problem with use on the toes, fingers, and scalp which Kaptchuk highlighted as popularly used sites. Insertion depth is adjustable realistically from 1 mm to 30 mm. Insertion direction is adjustable by altering the angle of the lower end of the guide tube. A penetrating needle with a stopper can enable acupuncturists to avoid, in almost all cases, inadvertent risks of inserting the needle deeper than is safe and causing unnecessary tissue trauma. Use of a guide tube has added advantages, as the sterility of the needle is maintained before, during and after use so preventing transmission of infection both to the patient and the practitioner. These results imply that this needle has the potential for double blinding, but we must be cautious when extrapolating our results because of the following limitations of the study. This study was not completed in a clinical setting with likely variables such as clinical improvement, adverse reactions and repeat treatments with multiple needles or points, which would risk the practitioner and patient unmasking. Although no bleeding occurred during this study, slight bleeding and patient reaction to strong pain elicited by real needle insertion in a few instances could break the blind. We used only one practitioner in this trial, so inter-tester reliability should be tested. The subjects were confined to healthy acupuncture students who had previously experienced the fact that needle insertion or removal are not necessarily accompanied by pain. The degree of manipulation of the depth or angle of the needle is restricted during needle insertion, although we believe that needle insertion and advancement are the most important components of acupuncture. Some degree of lack of control of the needle may be considered to increase the risk of pneumothorax for example, but we believe the needle is safe since its depth of insertion is restricted by the stopper. It is inevitable that any double blind needle is an artificial device for research that cannot fully reproduce all the conditions of real life acupuncture. Finally, it is not known for certain whether this placebo needle has any physiological activity, or whether the action of acupuncture is point specific, and these uncertainties should be taken into account when calling this needle a placebo and designing studies with it as placebo.

**Conclusions**

The non-penetrating placebo needle was effective in masking the fully informed subjects. When used together with the matched penetrating needle, it has potential for use in double blind (patient and practitioner blind) studies.

**Summary points**

- The double blind, non-penetrating placebo needle is effective in masking patients who are not informed that they may receive a placebo needle.
- In this study, the non-penetrating placebo needle was effective in masking the fully informed subjects.
- The practitioners were also effectively masked using this needle.
- Note that the needle was very fine (0.16 mm) and was set to penetrate only 5 mm deep.

**Conflict of interest**

NT and Hanada College possess a US patent 6575992B1, a Canadian patent CA 2339223, a Korean patent 0478177, a Taiwan patent 150135, a Chinese patent ZL00800894.9 (Title: Safe needle, placebo needle, and needle set for double blind) and a Japanese patent 4061397 (Title: Placebo needle, and needle set for double blinding) on the needles described in this manuscript. NT is a salaried

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**Table 3** Number of needles categorised according to needle identification by both practitioner and subject

<table>
<thead>
<tr>
<th>Practitioner’s identification</th>
<th>Subject’s identification</th>
<th>Number of 114 non-penetrating needles</th>
<th>Number of 114 penetrating needles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct</td>
<td>Correct</td>
<td>24</td>
<td>28</td>
</tr>
<tr>
<td>Correct</td>
<td>Incorrect</td>
<td>30</td>
<td>15</td>
</tr>
<tr>
<td>Incorrect</td>
<td>Correct</td>
<td>26*</td>
<td>50*</td>
</tr>
<tr>
<td>Incorrect</td>
<td>Incorrect</td>
<td>34*</td>
<td>21*</td>
</tr>
</tbody>
</table>

The totals of 60 (26*, 34*) non-penetrating needles and 71 (50*, 21*) penetrating needles incorrectly identified by the practitioner include 6 and 3 needles, respectively classified as unidentified.
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