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A possible double-blind (practitioner-patient masking) acupuncture needle.

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Abstract

Background: The double-blind (practitioner-patient masking) placebo acupuncture needles have been considered almost impossible to develop until now.

Methods: We designed a double-blind non-penetrating placebo needle, the needle tip of which simply presses against the skin, and a matched penetrating needle. Validation test 1: To validate the masking effect for the practitioner, well-experienced 10 acupuncturists each applied 23 non-penetrating needles and 17 penetrating needles to the LI-4 point. After removing each needle, they judged whether the needle was 'penetrating,' 'non-penetrating' or 'unidentifiable.' Validation test 2: An acupuncturist who was pre-informed he will apply penetrating or non-penetrating needle applied penetrating/penetrating needle pairs at bilateral TE-5 points in 30 healthy volunteers. The acupuncturist guessed whether or not the needle was penetrating after removal of each needle. The acupuncturist provided clues to the needle's authenticity and rated his confidence in identification on a visual analog scale. Validation test 3: For the validation of uninformed patient masking, an acupuncturist randomly applied a non-penetrating/penetrating needle pair to the bilateral TE-5 points in 60 subjects. When both applications were completed, we asked them to write down anything that they noticed regarding the needle application and associated sensations. Validation test 4: For the validation of informed patient masking, an acupuncturist applied one of the following needle pairs －penetrating/non-penetrating, non-penetrating/non-penetrating, penetrating/penetrating－ randomly at bilateral TE-5 points in 114 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 whether they identified the needle to be non-penetrating or penetrating for each arm.

Results: Validation test 1: The mean ± SD of correct/unidentifiable/incorrect answers given by the 10 acupuncturists were 17.0 ± 4.1/6.4 ± 3.6/16.6 ± 3.0, respectively. Validation test 2: Of 60 needles, 44 were incorrectly identified by the acupuncturist. Most identifications were made based on the "feeling of needle insertion." Validation test 3: Regarding uninformed patient masking, none of the subjects commented in the questionnaire that they had received a non-penetrating needle. Validation test 4: Of the 114 non-penetrating needle applications, the informed subjects identified 64 incorrectly and 50 correctly. Most interestingly, the subjects identified 36 (32%) of 114 penetrating needle.applications incorrectly

Conclusion: These needles have the potential to mask both practitioners and patients from the type of needle used in acupuncture research.

Key words: *acupuncture, double-blind, placebo.*

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Introduction

The double-blind study design is generally employed as a methodological safeguard to satisfy the current criterion of minimizing bias in medical science[1-5]. However, in acupuncture trials the single-blind design had been only possible because practitioner masking in acupuncture studies has been considered as almost infeasible[4-11]. Therefore, randomized single-blind (patient masking) placebo controlled studies[12-17] have been acknowledged as the most rigorous methods in clinical acupuncture science. That is, the strongest evidence supporting the efficacy of acupuncture has been obtained using single-blind approaches[12-17] that fail to meet the methodological standards for study blinding in current medical science[1-5].

Several investigators recently invented and validated a patient masking, single-blind needle which to the patient looks and feels like a real needle[8-11]. These recently designed sham/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[4-8]. However, with studies in which only patients are blinded (single-blind studies), the specific effects of acupuncture beyond placebo cannot be fully clarified because the study subjects/patients may have been biased due to presence of unmasked practitioners[1-6,18-23]. As a result, the effectiveness of acupuncture has remained controversial, even though studies of the highest possible quality have been published in leading medical journals[5]. 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[4-8]. Double-blind trials using placebo needles are critically important to ensure that acupuncture research meets the methodological standards of medical science to provide stronger evidence of the effectiveness of acupuncture treatment using needles[1-6]. Only then will acupuncture be incorporated into generally accepted practice[1-6,19-21].

To solve this methodological conundrum of practitioner masking in acupuncture research x[4-8], we have designed a double-blind non-penetrating placebo needle and a matched penetrating needle[24-30]. Here, we report the design of double-blind (practitioner-patient masking) needles with a statistical evaluation of the masking effect of these needles[24-30].

Methods

Participants

We recruited well-experienced and licensed acupuncturists on the teaching staff and healthy volunteers who were familiar with receiving acupuncture as experimental subjects, and were familiar with the different sensations of needle penetration and *de qi*from Japan School of Acupuncture, Moxibustion and Physiotherapy. Before the study, the purpose and format were explained and the participants provided written consent. The Showa University Ethics Committee gave its approval.

Design of double-blind needles[24-30]

We designed a double-blind (practitioner-patient) non-penetrating placebo needle, the tip of which presses against the skin but cannot penetrate it, and a matched penetrating needle with a specified insertion depth to be used in acupuncture research. The non-penetrating needle is identical to the penetrating needle except for being shorter in the needle body and having a blunt tip. The appearance and feel of the non-penetrating and penetrating needles were indistinguishable from one another (Figure 1).

Validation test 1 for practitioner masking[25,26]

Ten highly experienced, licensed acupuncture practitioners (mean ± SD age: 41.7 ± 8.8 years; all men) with a mean ± SD duration of acupuncture experience of 12.4 ± 7.8 years participated in this study (Table 1). Forty needles consisted of 23 non-penetrating and 17 penetrating needles (10 mm insertion depth[31]) were used. Before the trial began, the practitioners were informed of possible use of both non-penetrating and penetrating needles. Each acupuncturist consecutively applied 40 needles at the LI-4 point[31], using the alternating twirling technique (alternating between rotating the needle clockwise and counterclockwise). Each needle was inserted and pulled out after the stopper had made contact with the top of the guide tube. Immediately after the removal of each needle, the practitioner recorded his judgment of the needle to be 'penetrating,' 'non-penetrating' or 'unidentifiable.'

Validation test 2 for practitioner masking[27]

We used 30 penetrating/penetrating needle (10 mm insertion depth[31]) pairs in this study (Figure 1). However, the subjects and the acupuncturist were informed that the

non-penetrating needle would be used in addition to the penetrating needle before the trial to perform this study under double-blind conditions.

An acupuncturist with 28 years of experience applied the pair of needles at bilateral TE-5 points, one needle on each side, in the 30 subjects (31.0± 9.8 years; 24 men, 6 women) using the alternating twirling technique. After removal of each needle the acupuncturist recorded whether he judged the needle to be penetrating or non-penetrating. He then reported clues that led to his identification of authenticity of the needle; these were "facial expression," "body movement," and "bleeding," in addition to the "feeling of needle insertion," "verval expression," "no bleeding," and "feeling of needle removal." He also rated his confidence in identification of the needle authenticity (i.e., the degree of certainty about his answer) on a visual analog scale (VAS), the end-points of which were 0 for no con fidence and 100 for complete confidence.

We asked the subjects to guess the authenticity of the needle and to rate skin penetration/penetration-like pain and deep dull sensation (*de qi*), that is considered essential for a successful acupuncture treatment[31] on a VAS after each removal of the needle. The VAS corresponded to a numerical scale of 0-100, where 0 represented no pain or *de qi* sensation and 100 the most intense skin penetration pain or *de qi* ever experienced during needle insertion.

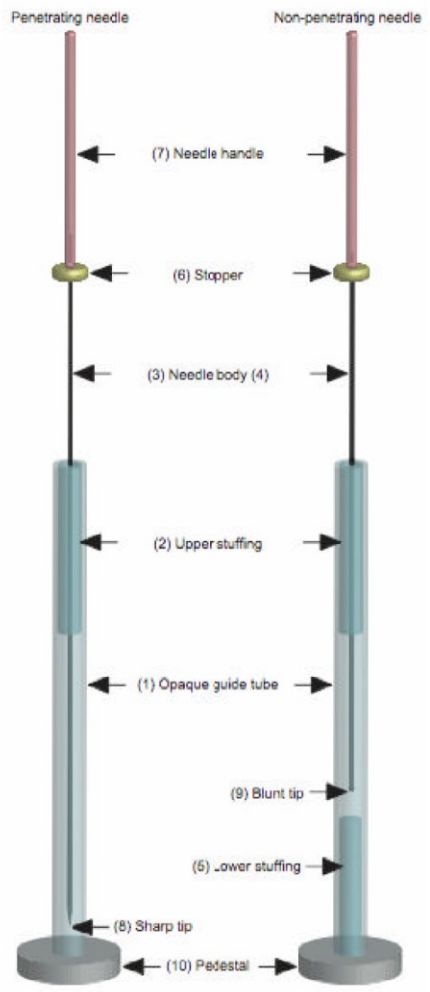

Figure 1 Double-blind non-peretrating placebo and matched penetrating needle[24-30].

Design of the double-blind acupuncture needles. Each needle assembly comprises an opaque guide tube (1) and upper stuffing (2) to provide resistance to the needle body during its passage through the guide tube. The body of the penetrating needle (3) is longer than the guide tube by an amount equal to the insertion depth, but the body of the non-penetrating needle (4) is long enough to allow its blunt tip to press against the skin when the needle body is made to advance to its limit. The non-penetrating needle contains lower stuffing (5) to give a sensation similar to that of skin puncture and tissue penetration. Both needles have a stopper (6) that prevents the needle handle (7) from advancing further when the sharp tip of the penetrating needle (8) or the blunt tip of the non-penetrating needle (9) reaches the specified position. The pedestal (10) on each needle is adhesive, allowing it to adhere firmly to the skin surface. The diameter of the needles in this series of studies was 0.16 mm. There should be no problem with use on the toes, fingers, and scalp[4]. It may be necessary to shave hairy skin sites to ensure firm adhesion. 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 and patients to avoid, in almost all cases, inadvertent risks to insert the needle deeper than is safe and therefore unnecessary tissue trauma. Use of a guide tube has added advantages as the sterility of the single use needle is maintained so preventing disease transmission from patient to practitioner and from practitioner to others because the needle body of the penetrating needle is enclosed in the guide tube before, during and after use.

Validation test 3 for uninformed patient masking[25,26)]

Sixty healthy volunteers (29.7 ± 7.5 years, 35 men, 25 women) were recruited. Before the trial began, the experimental procedure was explained to the subjects as follows: 'We will apply two needles, which may or may not differ in type, at bilateral TE-5 points[31)].'

The acupuncturist applied a pair of penetrating/ non-penetrating needles (10 mm insertion depth[31)]) to each of the 60 subjects at the bilateral TE-5 points, one needle in the right arm and the other in the left, using the alternating twirling technique. After each application, the subjects reported whether they felt a skin penetration sensation and *de qi* for each arm and wrote down anything that came to their notice. The practitioner guessed the authenticity of the needle after its removal.

Validation test 4 for informed patient masking[28,30)]

We recruited a well-experienced and licensed acupuncturist and 114 healthy volunteers (30.3±7.9 years; 73 men, 41 women). 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. The insertion depth of the penetrating needle was 5 mm[8)].

An acupuncturist with 8 years experience inserted a pair of needles, randomly taken from the shuffled 114 pairs, at bilateral TE- 5 points in the subjects and stimulated them using the alternating twirling technique. After each needle application, the subjects guessed the type of the needles. They also rated skin penetration/penetration-like pain and *de qi* on the VAS ranging from 0 to 10[8,27)]. The practitioner was also asked to guess the type of needle after each needle removal[25,27)].

Data Analysis[25,27,28)]

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 practitioner's confidence scores between correct and incorrect identifications and of the needle groups for VAS scores for skin penetration/penetration-like pain and *de qi* were made using Mann-Whitney's U test. Pearson's corre lation coefficient was used to indicate the relationship between the practitioner's confidence and skin penetration pain, and between the practitioner's confidence and *de qi*. All statistical analyses were performed using SPSS, version 15.0 J (SPSS Inc, Chicago, IL). The true identity of the needle was not revealed until after the results had been tabulated.

Results

Validation test 1 for practitioner masking[25,26)]

The number of correct/unidentifiable/incorrect answers given by the 10 acupuncturists had a mean± SD of 17.0 ± 4.1/6.4 ± 3.6/16.6 ± 3.0, respectively. Overall, the 170 correct and 166 incorrect identifications fitted a probability of 0.5 (χ^2 = 0.048, p = 0.827), excluding the 64 unidentifiable needles. Furthermore, 107 correctly

Table 1 Numbers of correctly identified, unidentified and incorrectly identified needles in 10 acupuncturists on 40 (23 non-penetrating/17 penetrating) needles[25)].

Acupuncturist	Years of experience	Number of correctly identified needles (non-penetrating/penetrating)	Number of unidentified needles (non-penetrating/penetrating)	Number of incorrectly identified needles (non-penetrating/penetrating)
No. 1	8	15 (10/5)	6 (2/4)	19 (11/8)
No. 2	25	21 (12/9)	7 (3/4)	12 (8/4)
No. 3	15	19 (13/6)	9 (3/6)	12 (7/5)
No. 4	13	22 (12/10)	1 (0/1)	17 (11/6)
No. 5	3	14 (12/2)	8 (4/4)	18 (7/11)
No. 6	5	13 (10/3)	12 (7/5)	15 (6/9)
No. 7	5	9 (7/2)	10 (3/7)	21 (13/8)
No. 8	25	19 (8/11)	3 (2/1)	18 (13/5)
No. 9	10	19 (9/10)	6 (4/2)	15 (10/5)
No. 10	15	19 (14/5)	2 (1/1)	19 (8/11)
Mean ± SD	12.4 ± 7.8	17.0 ± 4.1 (10.7/6.3)	6.4 ± 3.6 (2.9/3.5)	16.6 ± 3.0 (9.4/7.2)

identified non-penetrating needles and 94 incorrectly identified non-penetrating needles (χ^2 = 0.841, p = 0.359), and 63 correctly identified penetrating needles and 72 incorrectly identified penetrating needles (χ^2 = 0.600, p = 0.439) fitted a probability of 0.5 (Table 1).

Validation test 2 for practitioner masking[27)]

Of the 60 penetrating needles, 16 (27%) were correctly and 44 (73%) were incorrectly identified by the practitioner; these numbers did not fit a probability of 0.5 (χ^2 = 13.1, p < 0.001) (Figure 2). On the VAS, the mean confidence of the practitioner in identification of needle authenticity was 50.0 ± 19.7 for correctly identified needles, 73.6 ± 13.7 for incorrectly identified needles, and 67.3 ± 18.6 for all needles. Confidence in incorrect identification was significantly greater than that in correct identification (p < 0.001).

The practitioner guessed the authenticity of the needle principally depending on the "feeling of needle insertion" (Table 2). The second most frequently used determinant was "facial expression."

Of all the needles that were correctly and incorrectly identified by the practitioner, approximately 90% elicited skin penetration/penetration-like pain and/or *de qi* in the subjects (Table 3). The skin penetration/penetration-like pain and *de qi* scores for incorrectly identified needles were not significantly lower than those for correctly identified needles (skin penetration/penetration-like pain, p = 0.09; *de qi*, p = 0.13) (Figure 3). Further, no significant correlation between the VAS score of practitioner's confidence in identification and skin penetration/penetration-like pain or between the VAS score and *de qi* was observed for 16 correctly (skin penetration/penetration-like pain, r = 0.45, p = 0.08; *de qi*, r = 0.20, p = 0.47) and 44 incorrectly (skin penetration/penetration-like pain, r = 0.24, p = 0.12; *de qi*, r = 0.08, p = 0.63) identified needles.

Of the 60 needles, 40 (67%) were correctly and 20

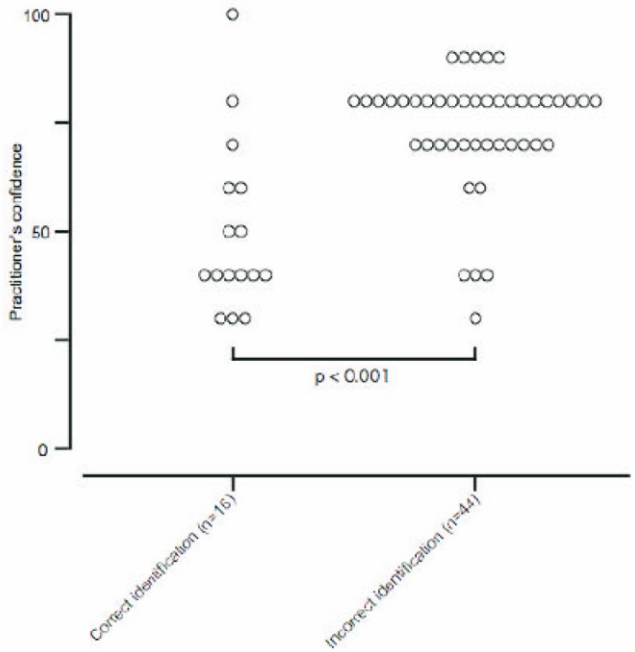

Figure 2 Practitioner's confidence in needle identification for correctly and incorrectly identified needles[27)].
Mean (SD) practitioner's confidence was 50.0 (19.7) for correctly and 73.6 (13.7) for incorrectly identified needles, and 67.3 (18.6) for all needles. Practitioner's confidence in incorrect identifications was significantly greater than that in correct identifications (p < 0.001).

(33%) were incorrectly identified by the subjects (Table 4). For the skin penetration/penetration-like pain and *de qi* scores, there was no significant difference between the 20 needles that were incorrectly and the 40 that were correctly identified (skin penetration/penetration-like pain, p = 0.162; *de qi*, p = 0.153).

Validation test 3 for uninformed patient masking[25,26)]

None of the subjects commented in the questionnaire that they had received a non-penetrating needle.

Of the 120 needles, the practitioner identified 65 (54.2%) correctly (penetrating needle = 35, non-penetrating needle = 30) and 55 (45.8%) incorrectly (penetrating needle = 25, non-penetrating needle = 30), which fits a probability of 0.5 ($\chi^2 = 0.833$, p = 0.361).

Validation test 4 for informed patient masking[28,30)]

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).

With regard to the ratings of the skin penetration/penetration-like pain and *de qi*, no significant differences were found in subjective intensity between the 114 non-penetrating and 114 penetrating needles (Table 5). Of

Table 2 Number of needles identified from clues and practitioner's confidence in identification[27)].

Clues for identification	Number of needles identified (correct/incorrect)	Practitioner's confidence, mean (SD)*
Feeling of needle insertion	20 (2/18)	74.0 (15.0)
Facial expression	7 (6/1)	40.0 (11.5)
Bleeding	1 (1/0)	100
Body movement	0	
Feeling of needle removal	0	
No bleeding	0	
Verbal expression	0	
Feeling of needle insertion + facial expression	24 (1/23)	70.8 (13.8)
Facial expression + body movement	4 (4/0)	62.5 (17.1)
Feeling of needle insertion + feeling of needle removal	3 (2/1)	50.0 (26.5)
Feeling of needle insertion + facial expression + feeling of needle removal	1 (0/1)	80

* Rated on a scale from 0-100.

Table 3 Relationship between needle sensations elicited in subjects and the practitioner's identification[27)].

Subjective sensation	Practitioner's identification Number (%) of needles (n = 60)	
	Incorrect	Correct
Neither SPP nor *de qi*	2 (3.3)	2 (3.3)
Both SPP and *de qi*	24 (40.0)	8 (13.3)
SPP or *de qi*	18 (30.0)	6 (10.0)
Total	44 (73.3)	16 (26.7)

SPP indicates skin penetration/penetration-like pain.

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*.

The distribution of the non-penetrating needles depicted according to the intensity of skin penetration/penetration-like pain or *de qi* was similar to that of the penetrating needles (Figure 4). Moreover, the frequencies that needle sensations were elicited in the case of the 114 non-penetrating needles were similar to those

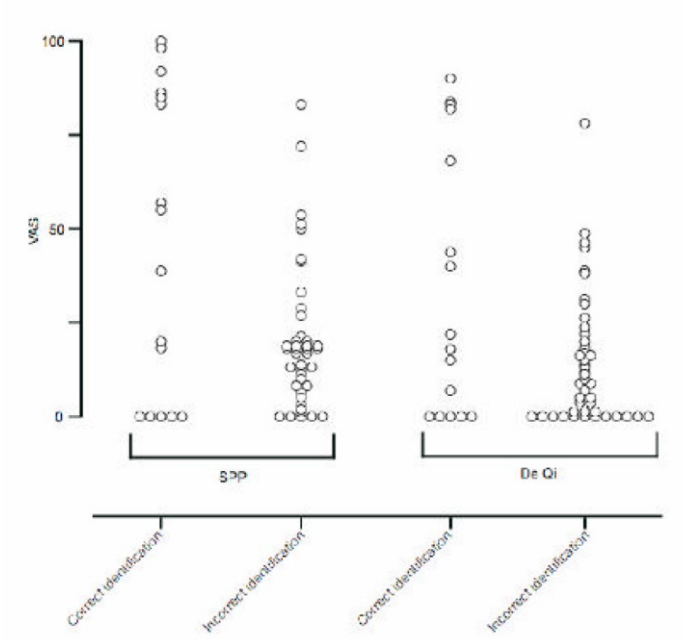

Figure 3 Needle sensations on a visual analog scale (VAS) in subjects[27].

Intensity of skin penetration/penetration-like pain (SPP) and *de qi* on a VAS in subjects for needles correctly and incorrectly identified by the practitioner. There was no significant difference between correctly identified and incorrectly identified needles for both skin penetration/penetration-like pain and *de qi* scores (skin penetration/penetration-like pain, p = 0.09; *de qi*, p = 0.13).

Table 4 Relationship between needle sensation and subjects' identification[27].

Subjective sensation	Practitioner's identification Number (%) of needles (n = 60)	
	Incorrect	Correct
Neither SPP nor *de qi*	1 (1.7)	3 (5.0)
Both SPP and *de qi*	8 (13.3)	24 (40.0)
SPP or *de qi*	11 (18.3)	13 (21.7)
Total	20 (33.3)	40 (66.7)

SPP indicates skin penetration/penetration-like pain.

Table 5 Skin penetration/penetration-like pain and *de qi* for 114 correctly and incorrectly identified non-penetrating and penetrating needles[28].

	Skin penetration /penetration-like pain Median (mean) [p-value]	*De qi* Median (mean) [p-value]
114 NP vs 114 P	1 (2.1) vs 1 (1.9) [0.872]	0 (1.0) vs 0 (1.3) [0.168]
50 correct NP vs 64 incorrect NP	0 (1.4) vs 2 (2.8) [< 0.001]**	0 (0.8) vs 0 (1.1) [0.095]
78 correct P vs 36 incorrect P	2 (2.1) vs 0.5 (1.3) [0.023]*	0 (1.7) vs 0 (0.3) [0.005]**
50 correct NP vs 78 correct P	0 (1.4) vs 2 (2.1) [0.001]**	0 (0.8) vs 0 (1.7) [0.005]**
50 correct NP vs 36 incorrect P	0 (1.4) vs 0.5 (1.3) [0.344]	0 (0.8) vs 0 (0.3) [0.949]
64 incorrect NP vs 78 correct P	2 (2.8) vs 2 (2.1) [0.142]	0 (1.1) vs 0 (1.7) [0.181]
64 incorrect NP vs 36 incorrect P	2 (2.8) vs 0.5 (1.3) [0.001]**	0 (1.1) vs 0 (0.3) [0.078]

Abbreviations: NP - Non-penetrating needles; P - Penetrating needles
* P < 0.05, ** P < 0.01 based on Mann-Whitney's U test.

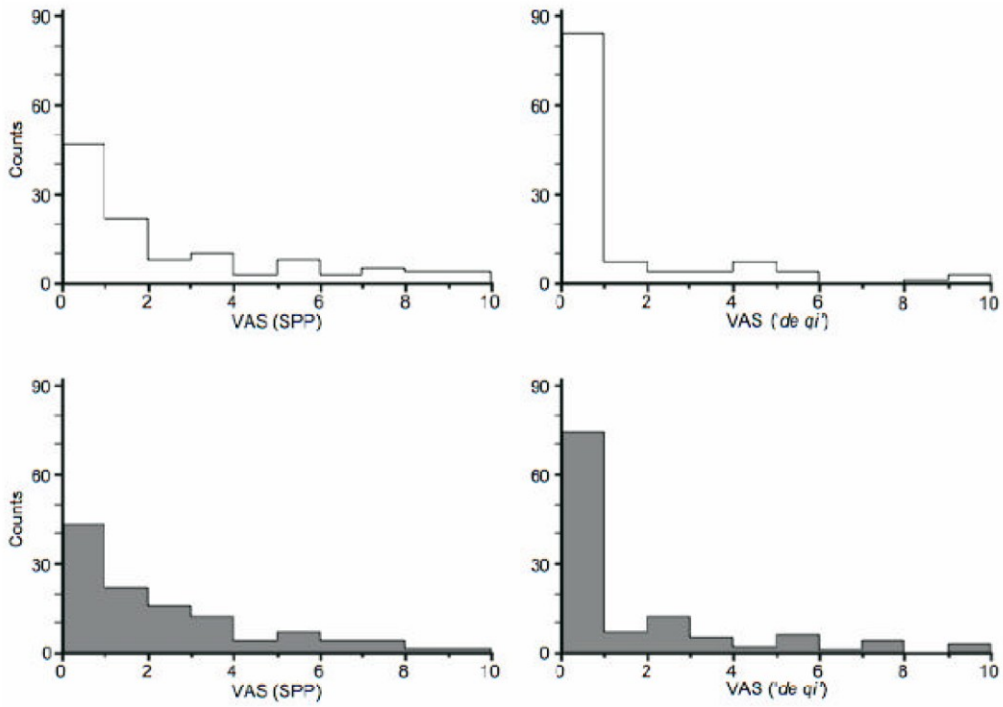

Figure 4 Histograms of the number of non-penetrating needles (white) or penetrating needles (gray) depicted according to intensity of skin penetration/penetration-like pain (SPP) and dull pain sensation (*de qi*)[28].

The vertical axis indicates the number of non-penetrating and penetrating needles. The horizontal axis indicates the score of SPP and *de qi* on a VAS (0-10). The distribution of counts on each VAS was similar between non-penetrating and penetrating needles (114 counts in total for each needle) for both SPP and *de qi*, suggesting that needle sensations elicited by the penetrating and non-penetrating needles are comparable.

in the case of the 114 penetrating needles (Table 6). 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 6).

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 (χ^2 = 2.854, p = 0.091). Nine (4%) needles were indistinguishable.

Discussion

Practitioner masking

The practitioners failed to distinguish between the penetrating and non-penetrating needles, regardless of their practical experience. The appearance and feel of the non-penetrating placebo and penetrating needles in this study were virtually identical, such that the needles caused well-experienced practitioners much difficulty in identifying the true nature of each needle. The fact that the practitioners made incorrect identifications approximately half of the times excluding the unidentifiable needles in the validation test 1, 3 and 4 shows that these needles are useful for masking even with a highly experienced acupuncturist. Further, the highly experienced acupuncturist failed to identify a large proportion of the total number of needles with the finding that a large proportion of needles were identified from the "feeling of needle insertion" in the validation test 2. This indicates that the non-penetrating needle and the penetrating needle were virtually indistinguishable in appearance and feel.

For the incorrectly identified needles in the validation test 2, the subjects' reactions were not expected to reveal the authenticity of the needle. Seven percent of all needles were identified by "body movement" with "facial expression," and all of these were correctly identified. However, for these needles, the practitioner's VAS scores of confidence in identification ranged from 40% to 80%. Thus, although these correctly identified needles were assumed to elicit penetration pain, withdrawal reactions suggesting the authenticity of the needles were obscure. We believe that the penetration pain elicited by an acupuncture needle is relatively weak, the authenticity of needles could not be revealed with 100% confidence. "Facial expression" gave the practitioner little clue about the needle authenticity because approximately two-thirds of needle identification from "facial expression" alone, together with other clues, were incorrect. In addition, the mean VAS score for the practitioner's confidence in identification of needles identified only from "facial expression" (86% of which were correctly identified) was only 40. Further, there was no significant positive correlation between the in tensity of skin penetration pain or *de qi* and the degree of the practitioner's confidence in correct identification of the penetrating needles, and a negative correlation for incorrectly identified penetrating needles. It is unlikely that the practitioner's identification was influenced by the subjects' reactions to the insertion of the needle. Considering that more than 90% of the needles correctly as well as incorrectly identified by the practitioner elicited non-significant different skin penetration/penetration-like pain and *de qi*, there were very few needles whose authenticity was revealed by the subject's reactions on needle insertion.

Table 6 Skin penetration/penetration-like pain (SPP) and *de qi* elicited by 114 non-penetrating and penetrating needles[28].

		Number of needles (% of 114 needles)	Number (%) of correctly identified needles	Number (%) of incorrectly identified needles
114 non-penetrating needles	Neither SPP nor *de qi* felt	30 (26.3)	25 (83.3)	5 (16.7)
	Only SPP felt	54 (47.4)	16 (29.6)	38 (70.4)
	Only *de qi* felt	12 (10.5)	5 (41.7)	7 (58.3)
	Both SPP and *de qi* felt	18 (15.8)	4 (22.2)	14 (77.8)
114 penetrating needles	Neither SPP nor *de qi* felt	24 (21.1)	9 (37.5)	15 (62.5)
	Only SPP felt	50 (43.9)	36 (72.0)	14 (28.0)
	Only *de qi* felt	18 (15.8)	15 (83.3)	3 (16.7)
	Both SPP and *de qi* felt	22 (19.3)	18 (81.8)	4 (18.2)

Patient masking

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 *de qi*. 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 5 mm insertion depth. Thus, subjects who were not informed of the potential use of non-penetrating needles did not suspect that they received a non-penetrating needle in the validation test 3, and the fully informed subjects in the validation test 4 misjudged nearly half of the non-penetrating needles. 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[8]. 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 non- and fully-informed subjects.

Although we expected it to be unlikely that a subject would misjudge a penetrating needle to be a non-penetrating one, surprisingly, 32% of 114 penetrating needles with 5 mm insertion depth in the validation test 4 and 33% of 60 penetrating needles with 10 mm insertion depth in the validation test 2 were incorrectly identified by the subjects. The skin penetration pain elicited by these needles was faint and nearly indistinguishable from the sensation elicited by the skin pressure associated with the non-penetrating needle in the validation test 4. Therefore, some penetrating needles were equally misjudged to be non-penetrating when the subjects were informed of the potential application of non-penetrating needles. These incorrect identifications, even though small in proportion, suggest that penetrating needles have some potential for double masking in study using one needle per patient like acupuncture at only the PC-6 point[32].

These results imply that this needle has the potential for in double blinding, but we must be cautious when extrapolating our results because of the following limitations of the study. These studies were 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 few bleeding occurred during this series of studies, 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 the validation test 2, 3 and 4, so inter-tester reliability should be tested. The subjects were confined to healthy acupuncture students who had previously experience that needle insertion or removal are not necessarily accompanied by pain. We examined only needle insertions to a 5 and 10 mm depth, using a needle of diameter 0.16 mm, at only two acupoints. 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. 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. It is not known for certain whether this placebo needle has any therapeutic effect or whether the action of acupuncture is point-specific, and these uncertainties should be taken into account when calling this needle placebo and designing studies with it as placebo[26,34,35].

Competing Interests

N.T. and The Educational Foundation of Hanada Gakuen hold US patent 6575992 B 1, Canadian patent CA 2339223, Korean patent 0478177, Taiwan patent 150135, Chinese patent ZL 00800894.9 and Japanese patent 4061397 for the needles described in this article. N.T. is a salaried employee of The Educational Foundation of Hanada Gakuen and has received research funding from The Educational Foundation of Hanada Gakuen.

Authors' Contributions

N.T. designed the double-blind needles and the study, performed the data collection and analysis, and wrote the manuscript. H.Y., M.T. and A.K. participated in the study design, the data collection and analysis, and manuscript preparation. N.T. is the guarantor. All authors have read and accepted the final version of the manuscript.

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