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Original Research Article

Patient blinding with blunt tip placebo acupuncture needles: comparison between 1 mm and 2 mm skin press

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ABSTRACT

Objective: To investigate the influence of the depth of skin press in blunt tip placebo acupuncture needles on patient blinding and its relationship to needle diameter.
Methods: Forty healthy volunteers were enrolled as subjects for patient blinding. Four acupuncturists applied the following needles randomly at three points in each forearm: 0.18 mm and 0.25 mm diameter penetrating needles inserted to a depth of 5 mm, and 0.18 mm and 0.25 mm diameter skin-touch needles depressing the skin at the acupoint to a depth of 1 mm and 2 mm from the skin surface. The subjects reported their guesses at the nature of needles they received, and rated needle pain and de qi. A blinding index was calculated to define the success of blinding for subjects.
Results: The blinding status of subjects for 1 mm press needles of 0.18 mm diameter was "random guess", but "unblinded" for 1 mm press needles of 0.25 mm diameter. For 2 mm press needles of both diameters, the blinding status was "opposite guess" and the blinding status for penetrating needles of both diameters was "unblinded." The percentages of "felt pain" with 2 mm press needles of both diameters were similar to that with penetrating needles, but those were not similar for 1 mm press needles. The frequency of de qi occurrence with 2 mm press needles of 0.18 mm diameter was similar to that of penetrating needles of both diameters.
Conclusion: Placebo needles of 2 mm press made more subjects guess that the needles penetrated the skin than 1 mm press needles. The use of small diameter needles increased patient blinding.

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1. Introduction

Acupuncture is one of the most prominent treatments in complementary and alternative medicine, and has great potential for supplementing Western medicine. Although indications for acupuncture were reported by the World Health Organization [1], scientific evidence for acupuncture has been insufficient [2,3]. The quality of acupuncture trials has not been rigorous enough because of methodological flaws [3]. To meet the standards of evidence-based medicine, placebo needles have been developed to blind patients [4–8] or to blind both practitioners and patients [9–12]. In these needles, a blunt tip touches the skin to give patients a pricking sensation without skin penetration. Approximately 55%–95% of patients who received placebo needles for single blinding reported that they guessed that the needles penetrated the skin [13–23]. In contrast, approximately 40%–55% of subjects or patients who received skin-touch placebo needles for double blinding, in which the blunt tip depressed the skin by 1 mm from the surface, reported that they guessed that the needles had penetrated the skin [24–26]. In needles used for single blinding, there is no mechanism, such as the stopper built into the needles for double blinding [24–26], that controls the depth to which the blunt tip depresses the skin or the needle penetrates the skin,

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allowing acupuncturists to adjust the pressure themselves [4–6]. The difference in the intensity of skin pressure with the blunt tip between placebo needles for single and double blinding could be a major factor affecting the number of patients who guessed placebo needles had "penetrated." Further, the diameter of the needle body in needles for single blinding is more than 0.25 mm [5,6,8], which is thicker than that in needles for double blinding [9–12].

Pain and de qi associated with needle administration are important factors in subjects' or patients' belief in the needle penetration [4,25–28]. The intensity of needle sensation, such as pain and de qi, is influenced by insertion depth of the penetrating needle, skin pressure from the blunt tip of skin-touch placebo needles and the diameter of these needles. However, studies on the influence of slight differences in the depth of skin press on patient blinding and its relationship with the diameter of penetrating and skin-touch placebo needles have not been conducted. Hence, we employed needles for double blinding that were equipped with a stopper to control the length of needle tip that could extend from the bottom of the guide tube and insert into or press on the skin.

The aim of this study was to determine the effect of patient blinding with 1 mm and 2 mm press from the skin surface with a blunt tip, compared with penetration of the skin with penetrating needles and the role of needle diameter in double blinding.

2. Materials and methods

2.1. Study subjects

The study included 40 healthy volunteers as subjects (23 males and 17 females, and (23.6 ± 7.5) years of age (mean ± standard deviation)) who were familiar with receiving acupuncture and de qi for patient blinding. They had no neurological disorders to cause loss or abnormal sensation in the arms. Four licensed acupuncturists, experienced in using needles for double blinding, were recruited for acupuncture administration (1 male and 3 females, (48.0 ± 8.0) years of age, and (8.0 ± 1.7) years of acupuncture experience). We provided a written explanation of the study protocol, including the use of penetrating and non-penetrating needles. We did not explain the insertion depth of penetrating needles or depth of press from the skin surface of skin-touch placebo needles. All participants provided a written consent prior to the treatment. The study was approved by the Ethics Committee of Tokyo Ariake University of Medical and Health Sciences (Registration number 156).

2.2. Setting

The study was conducted at the Tokyo Ariake University of Medical and Health Sciences and the Japan School of Acupuncture, Moxibustion and Physiotherapy, Tokyo, Japan.

2.3. Study design and interventions

Study design was a clinical research with four types of skin-touch placebo needles, the tips of which press against the skin but do not penetrate, and two types of penetrating needles (Fig. 1) as described below:

(1) Skin-touch placebo needle of 0.18 mm diameter to depress the skin 1 mm from the surface (1 mm press skin-touch needle of 0.18 mm diameter).
(2) Skin-touch placebo needle of 0.18 mm diameter to depress the skin 2 mm from the surface (2 mm press skin-touch needle of 0.18 mm diameter).

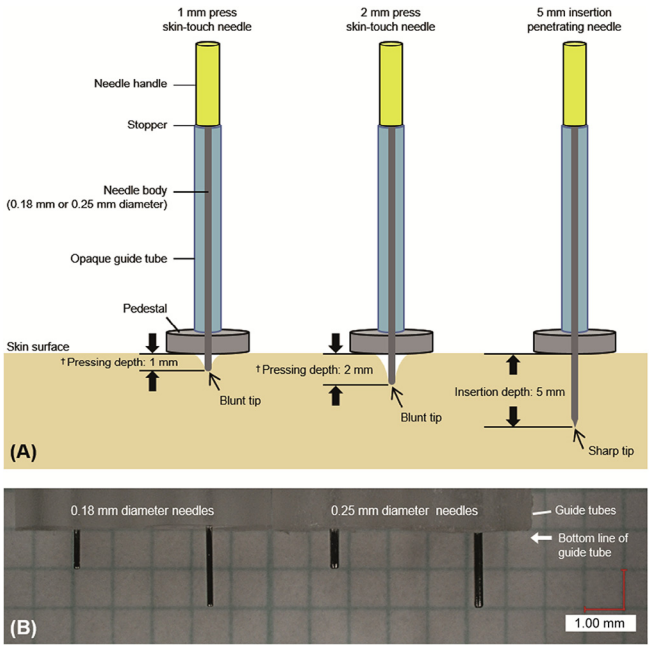

Fig. 1. Takakura needles for double blinding. (A) Skin-touch placebo needle to depress the skin 1 mm from the skin surface (left), 2 mm from the skin surface (middle) and a penetrating needle to insert to a depth of 5 mm from the skin surface (right). †The length of needle tip protruding from the bottom of the guide tube when the needle is fully advanced. (B) The pictures of blunt tips for 1 mm and 2 mm press skin-touch needles with 0.18 mm and 0.25 mm diameters (Digital microscope VHX-6000, KEYENCE CORPORATION, Tokyo, Japan). The needles were handmade as commercialized needles for double blinding were not available. A caliper with 1/20 mm accuracy (530-102 N15R, Mitutoyo Corporation, Kanagawa, Japan) was used to measure the lengths of skin-touch placebo needles under an optical microscope (Stereo Microscope LZ-LED-T, KENIS LIMITED, Osaka, Japan).

(3) Skin-touch placebo needle of 0.25 mm diameter to depress the skin 1 mm from the surface (1 mm press skin-touch needle of 0.25 mm diameter).
(4) Skin-touch placebo needle of 0.25 mm diameter to depress the skin 2 mm from the surface (2 mm press skin-touch needle of 0.25 mm diameter).
(5) Penetrating needle of 0.18 mm diameter to insert the needle 5 mm in the skin (penetrating needle of 0.18 mm diameter).
(6) Penetrating needle of 0.25 mm diameter to insert the needle 5 mm in the skin (penetrating needle of 0.25 mm diameter).

The appearances of these six types of needles are indistinguishable [9,24–32]. In skin-touch placebo needles, the blunt tip protrudes from the bottom of the guide tube, inducing skin pressure, when the needle is advanced to the maximum depth (Fig. 1B). In both needles, a stopper restricts the length of the needle tip that can protrude from the guide tube.

We prepared 40 bags for sterilization, and put a set of the six types of needles into each bag. The sealed bags were then sterilized using gaseous ethylene oxide. The six types of needles in an envelope were administered to each subject in a random order. The details of skin-touch placebo and penetrating needles for double blinding have been previously described [9,24–32].

2.4. Points to apply needles

Based on previous studies, six points (three points each on the right and left forearms) at one-fourth (distal), two-fourths (middle) and three-fourths (proximal) of the length from the skin crease in the posterior surface of the wrist joint to the elbow (olecranon) on

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