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Pursuit of a genuine effect of acupuncture: development of placebo acupuncture needles

Acupuncture has been used to treat a wide range of health conditions. The efficacy of acupuncture has not conclusively been established because only randomized control trials using single-blind needles have been reported. Single blinding is problematic because it is insufficient to prevent practitioner bias. In acupuncture research, practitioner blinding had been considered virtually impossible.

Addressing this methodological shortfall, we developed acupuncture needles to blind both patients and acupuncturists, namely double-blind acupuncture needles (Fig. 1). The visco-elastic stuffing inside the guide tube of both the double-blind real and placebo needles renders the needle insertion into the skin indiscernible to the acupuncturists. The placebo needle has a blunt tip which presses the skin but does not penetrate the skin, like placebo needles for single blinding. However, the double-blind needles have a stopper mechanism that controls the depth of the needle insertion and skin press, unlike single-blind needles. This prevents the acupuncturist from adjusting the pressure against the skin or the depth of the needle insertion, which is another advantage over the single-blind needles.

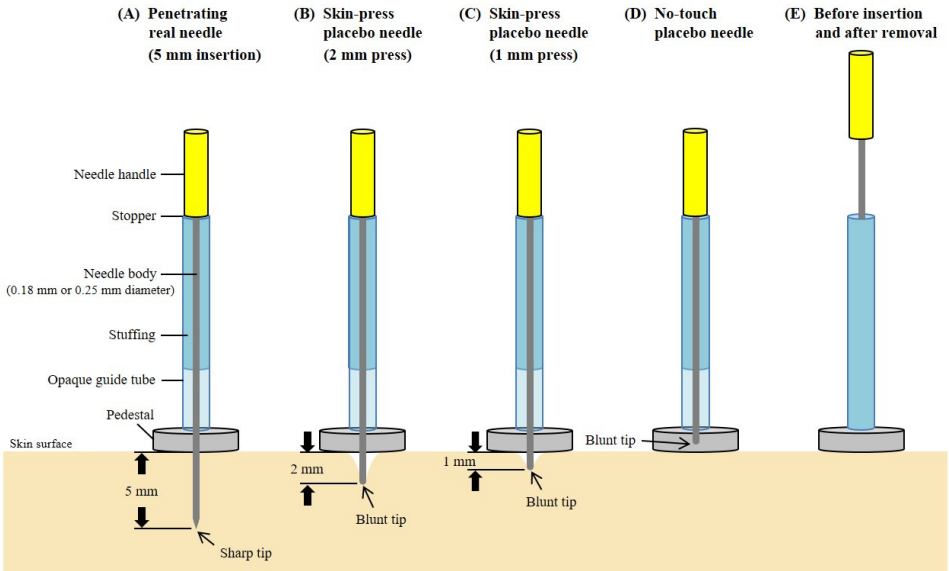

Fig. 1. Acupuncture needles for double blinding.

The penetrating real (A), skin-press placebo (B and C) and no-touch placebo (D) needles comprise an opaque guide tube and upper stuffing to give resistance to the needle body during its passage through the guide tube. Each needle has a stopper, which prevents the needle handle from advancing further when the tip of the needle reaches the specified position. The pedestal on each needle is adhesive, allowing it to stick firmly to the skin surface. Nobody can distinguish the type of the needle before insertion and after removal of the needle (E).

In acupuncture trials using single- or double-blind needles, the majority of patients in the real treatment arm where they receive needle insertion, don't believe they receive placebo acupuncture. In order for patients in the placebo arm to have the same degree of expectancy, a placebo needle must provide similar sensations as a real needle insertion. Then patients may guess the placebo needle as 'penetrating' at a similar rate as a penetrating needle in the real arm. In order to develop an ideal placebo needle, research should focus on the intensity of sensations felt by patients and its association with the depth of skin press using the blunt tip needle.

This is the first study to investigate the effects of patient blinding and needle sensations in patients with different lengths of the blunt tip of placebo needle that presses the skin to compare with needle insertion. We used double-blind needles which are able to preset fixed depths of needle insertion or skin press. Needles of both 0.18 mm and 0.25 mm diameter, which are commonly applied in acupuncture treatments, were used in this study for 5 mm insertion (Fig. 1A), 1 mm press (Fig. 1B) and 2 mm press (Fig. 1C). These six types of needles were applied randomly at three points in each forearm in 40 healthy volunteers. We compared effects of patient blinding and needle sensations such as pain and/or *de qi*, that is the characteristic constellation of sensations felt by patients during acupuncture needling. Results revealed the percentage of patients who felt needle sensations (Fig. 2A) and the needles guessed as 'penetrating' (Fig. 2B) with the 2 mm skin-press placebo needles were similar to the percentage of patients who felt needle sensations and the needles guessed as 'penetrating' with real needles, as compared to the 1 mm skin-press placebo needles. These findings suggested that 2 mm skin-press placebo needles are more promising for patient blinding than 1 mm skin-press placebo needles. Also, the use of smaller diameter needles enhanced the effect of patient blinding.

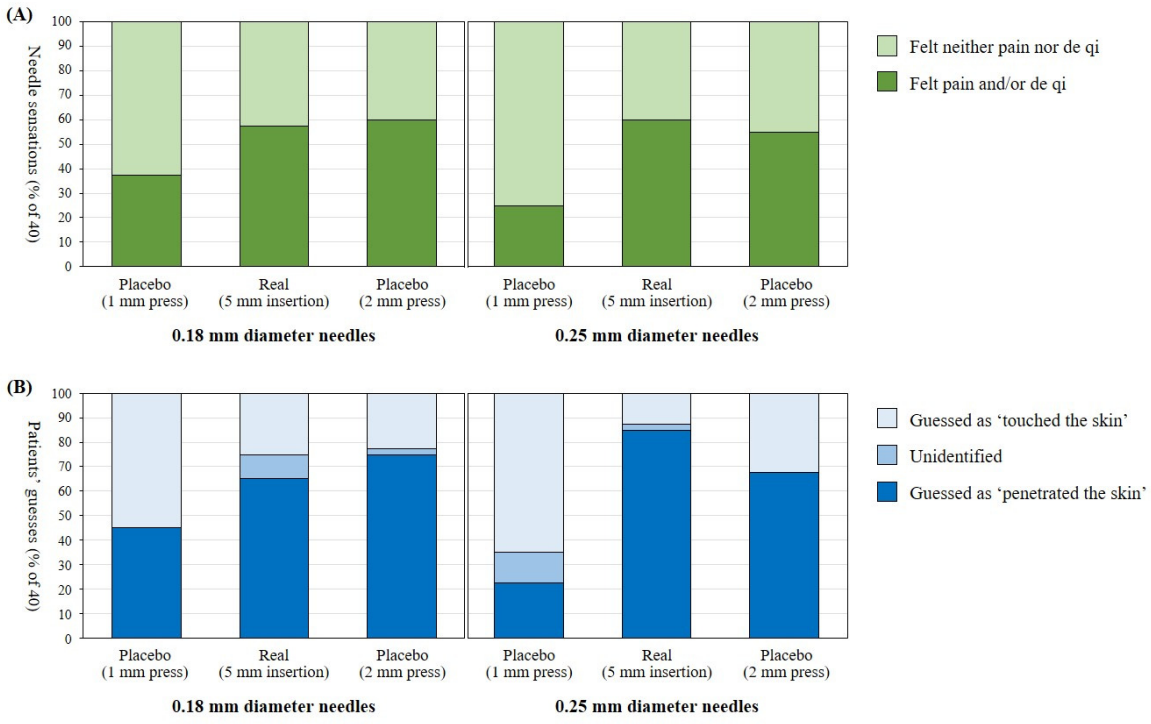

Fig. 2A. Percentage of needle sensations with 40 needles each. 2B. Percentage of patients' guesses for 40 needles each.

We believe the skin-press placebo needle is an important device to enable the determination of the specific effects of skin penetration. However, there is a possibility that the skin-press placebo needle because of its somatosensory stimulation to the skin is not a placebo and clinically active. Future studies comparing the skin-press placebo needle to another type of placebo needle such as a no-touch needle (Fig. 1D), where the tip of the needle does not touch the skin, need to be performed to conclude whether the skin-press placebo needle is clinically an inert placebo.

Nobuari Takakura[1,2]***, Miho Takayama***[1,2]***, Morihiro Nasu***[1]***, Masako Nishiwaki***[1]***, Akiko Kawase***[2]***, Hiroyoshi Yajima***[1,2]

[1]*Department of Acupuncture and Moxibustion, Faculty of Health Sciences, Tokyo Ariake University of Medical and Health Sciences, Japan*

[1]*Japan School of Acupuncture, Moxibustion and Physiotherapy, Japan*

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