

## The dilemma of placebo needles in acupuncture research

In the era when randomised controlled trials were considered to be the 'gold standard', placebo needles were originally developed for use in acupuncture trials to determine the specific effects of needling. They were designed using the principle of visual illusion; needles of similar appearance that do not penetrate the skin, but retract telescopically into the needle handle, were used.<sup>1,2</sup> In early research studies, these non-penetrating placebo needles were thought to control for bias and the contextual and psychological components of healing in acupuncture research.

In clinical trials, the placebo control should be indistinguishable from the active treatment (ie, achieve blinding) and yet be physiologically inert. In the case of acupuncture, however, it

is difficult to meet both criteria. To develop and validate placebo needles in terms of both blinding and physiological inertness, one is faced with a dilemma.

To explain this further, consider two hypothetical settings of placebo needles, depicted in figure 1. A placebo needle that produces unnoticeably small differences in *de qi* sensations compared with a real acupuncture needle would ensure successful blinding, although it is unlikely that this placebo needle would be physiologically inert. By contrast, a placebo needle that produces distinctly different *de qi* sensations compared with a real acupuncture needle may come closer to being physiologically inert, but it is highly unlikely it would be successful at blinding. Simultaneously considering the issues of blinding and physiological inertness of the placebo needle, it is clear that none adequately meets both criteria.

Studies using placebo needles have generated different results according to their aims and hypotheses. When researchers have wanted

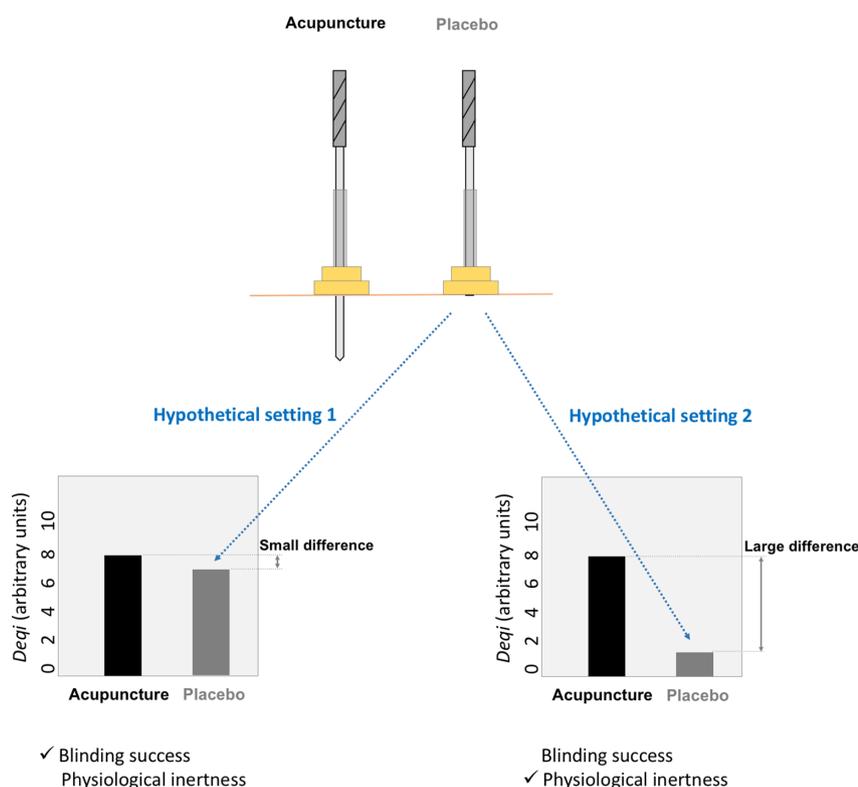
to evaluate the successful blinding of placebo needles, they have demonstrated small differences in the *de qi* sensations associated with real and placebo needles.<sup>3,4</sup> In such cases, the placebo needles might have directly activated the somatosensory system and affected multiple brain systems as they produce *de qi* sensations similar to those of real acupuncture. Conversely, when researchers have wanted to use placebo needles as a sham control and thereby demonstrate they were physiologically inert, they have encountered large differences between the *de qi* sensations associated with real and placebo needles.<sup>1,5</sup> In such cases, the placebo needles may not always be successful at blinding, as patients might correctly guess their identity owing to the differences in sensory information produced by the two types of needles. This inconsistency of results according to the underlying purpose of the study supports the assertion that no placebo needle is able to satisfy both criteria simultaneously under various conditions.

Several clinical trials have found that real and placebo acupuncture are equally effective and superior to usual care in patients with chronic pain.<sup>6</sup> As placebo needles do not constitute proper controls in acupuncture research, we should avoid drawing premature conclusions that acupuncture treatment is no more effective than a placebo control or that acupuncture itself is a placebo. Because acupuncture functions as a somatosensory-guided mind-body therapy, placebo needles could similarly enhance bodily sensations around the treatment site and induce potential effects related to endogenous pain modulation in the brain. Should we rest here or should we attempt to escape from the dilemma of the placebo needle?

### Younbyoung Chae

Acupuncture & Meridian Science Research Center, College of Korean Medicine, Kyung Hee University, Seoul, South Korea

**Correspondence to** Professor Younbyoung Chae, Acupuncture & Meridian Science Research Center,



**Figure 1** The dilemma of placebo needles (schematic diagram showing two hypothetical scenarios). Consideration of the issues of blinding and the physiological inertness of the placebo needle simultaneously indicates that no type of placebo needle is likely able to satisfy both criteria.

College of Korean Medicine, Kyung Hee University, 1 Hoegi-dong, Dongdaemun-gu, Seoul, South Korea; ybchae@khu.ac.kr

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