A Double-dlind Placebo Needle for Acupuncture Research

Takakura Nobuari

Professor, Department of Acupuncture and Moxibustion

Faculty of Health Sciences

Tokyo Ariake University of Medical and Health Sciences

Japan

Double-blind (practitioner-patient masking) evaluation of acupuncture treatment has been considered almost impossible because placebo needles aimed at masking practitioners have been considered unfeasible.

Several investigators recently invented patient-masking single blind placebo/sham needles of which to the patient look and feel like a real needle. Those recent designed placebo/sham devices, which overcome the insufficiencies of previous control procedures, provide enhanced evidence in acupuncture studies when it is impossible to blind the practitioner to the intervention. However, with studies in which only patients are blinded (single-blind studies), the specific effects of acupuncture other than placebo cannot be fully clarified since the subjects/patients are still exposed to possible bias due to the expectations, enthusiasm, suggestions and attitude of unmasked practitioners. As a result, the effectiveness of acupuncture has remained controversial.

Single-blind methods fail to meet the methodological standards for study blinding in conventional medicine. It is critically important to develop double-blind (practitioner-patient masking) procedures to demarcate veracious effect of acupuncture from non-specific effects. Only then will acupuncture be incorporated into generally accepted practice. However, in the literature, no procedure or placebo needle had been developed to blind the practitioner.

To solve the methodological conundrum of practitioner masking, we have designed a pair of double-blind (practitioner-patient masking) needle. Here, we report the design of double-blind (practitioner-patient masking) non-penetrating placebo and matched needles with a statistical evaluation of the masking effect of these needles.