Evaluating blinding effectiveness of a novel Ryodoraku sham needle device

BACKGROUND

Ryodoraku electroacupuncture (REA) uses a single needle inserted into a targeted body region or acupuncture point, after which a cathode conductor is placed in contact with the needle handle to introduce a direct current into the body, while the patient holds a cylindrical anode conductor.[1] In Japan, 80% of physicians who practise acupuncture use REA to treat various illnesses.[2] However, when conducting clinical trials involving REA, it is difficult to choose a sham control. The aim of the present project was to create and evaluate a sham needle device for REA, by testing whether or not participants were able to judge correctly if the needle was inserted.

SUBJECTS AND PROCEDURES

Forty-three healthy males with a mean age of 29 years (range 19–42 years), who had experienced REA during their training as rehabilitation assistants, voluntarily participated in the project. Written informed consent was obtained in accordance with the ethical standards of the Declaration of Helsinki. Two types of disposable, disinfected and non-commercially produced devices for real and sham needle insertion were created (figure 1).

Due to the preliminary nature of the project, only the sham device was used and a single experienced acupuncturist was involved. In all 43 participants, the sham device was placed at ST36 on the right leg using double-sided adhesive. All participants were allowed to observe the whole procedure, in which a stainless steel acupuncture needle (diameter 0.15 mm, length 40 mm, Taiho Medical Products, Japan) was inserted to a depth of 15 mm and direct current (12 V, 200 μA) was applied for 10 s using a ES-160 EA device (ITO, Japan),[1] before withdrawal of the needle. The participants were asked if they thought the acupuncture needle had been inserted and were instructed to respond 'yes', 'no' or 'uncertain'. The participants' responses were documented on a record sheet. A video of the above experimental methods is available (see online supplementary material).

FINDINGS

While the sham device prevented the needles from actually being inserted into the body, 41 of 43 participants (95%) believed they had received real needling and answered 'yes'. The remaining two participants replied 'no'.

COMMENTARY AND CONCLUSION

Sham acupuncture has been used as a control treatment in clinical trials, with the aim of testing the efficacy of acupuncture for the treatment of various illnesses.[3] In an ideal, double-blind, controlled acupuncture study, patients should not know whether they are receiving true or sham needling in order to exclude a potential placebo effect. REA has two components: mechanical stimulation by invasive needling; and intramuscular electrical stimulation by direct current. The present study has demonstrated that this novel sham REA needle device is an effective single-blind control with the presence of epidermal electrical stimulation, and thus may help determine the efficacy of REA in clinical trials. We are inclined to believe that the epidermal electrical stimulation contributed to the effectiveness of blinding; however, it remains unknown whether blinding effectiveness would be diminished if no electrical stimulation were applied, and whether surface stimulation itself may be associated with potential therapeutic effects. It should also be noted that our evaluation was limited to male adults and lower limbs only; therefore, it may not be possible to extrapolate the findings to mixed gender populations or other body regions.

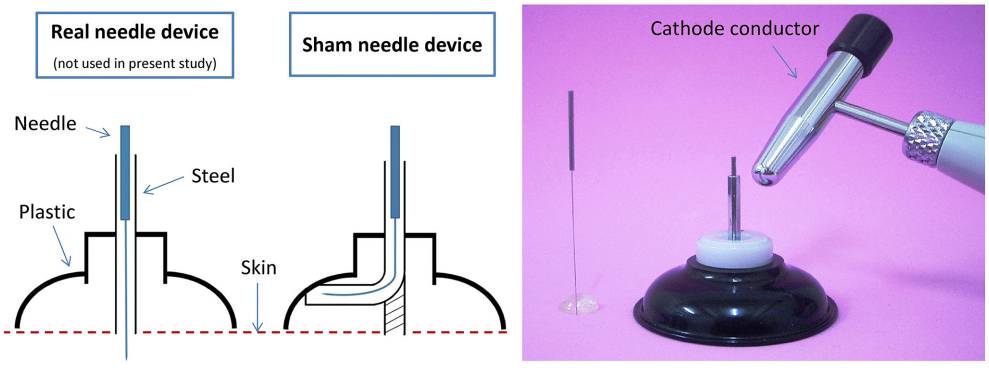

Figure 1 Left panel: schematic diagrams of real and sham needle devices for Ryodoraku electroacupuncture. Right panel: photograph of equipment.

Accordingly, these findings and their potential limitations warrant further investigation.

Yiu Ming Wong

Health Science Unit (PEC), Hong Kong Physically Handicapped & Able Bodied Association, Kowloon, Hong Kong

Correspondence to Dr Yiu Ming Wong, Health Science Unit (PEC), Hong Kong Physically Handicapped & Able Bodied Association, S102, G/F, Lai Lo House, Lai Kok Estate Shamshuipo, Kowloon, Hong Kong; pt@hkphab.org.hk

Funding This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests We have no significant competing financial, professional or personal interests that might have influenced the performance or presentation of the work described in this manuscript.

Patient consent Obtained.

Ethics approval The study protocol was approved by the Human Research Ethics Committee, Health Science Unit, Hong Kong Physically Handicapped and Able Bodied Association and all study procedures were performed in compliance with relevant laws and institutional guidelines in accordance with the ethical standards of the Declaration of Helsinki.

Provenance and peer review Not commissioned; internally peer reviewed.

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/acupmed-2016-011328).

To cite Wong YM. *Acupunct Med* 2018;**36**:56–57.

Accepted 23 April 2017

Acupunct Med 2017;**36**:56–57. doi:10.1136/acupmed-2016-011328

REFERENCES

1 Okazaki K, Sadove MS, Kim SI, *et al*. Ryodoraku therapy for migraine headache. *Am J Chin Med* 1975;3:61–70.
2 Yamashita K. The Japanese system of acupuncture. *The Japanese Journal of Ryodoraku Medicine* 1979;10:312–21.
3 Vincent C, Lewith G. Placebo controls for acupuncture studies. *J R Soc Med* 1995;88:199–202.