

Blinding Effect of Non-penetrating Sham Needle in the Randomized Controlled Trials of Acupuncture: A Systematic Review

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Abstract

The aim of this article was to assess the clinical evidence for or against the blinding effect of non-penetrating sham needle as placebo needle. This systematic review included randomized controlled trials (RCTs) of acupuncture taking non-penetrating sham acupuncture as placebo needle. Systematic searches were conducted in 13 electronic databases up to July 2012: Medline, PubMed, the Cochrane Library, CINAHL, EMBASE, a Chinese medical database. All parallel or cross-over RCTs of acupuncture for the blinding effect of non-penetrating needle were chosen without language restrictions. Finally, totally 7 RCTs met the inclusion criteria. In conclusion, our systematic review and meta-analysis demonstrate that the non-penetrating needle is an effective instrument for placebo control in the acupuncture RCTs.

Key Words

Acupuncture Therapy; Review, Systematic; Meta-analysis; Placebo Effect; Sham Needle

In the field of acupuncture research, an appropriate control treatment is rather important to exclude the placebo effect of acupuncture. In the year 1998, Streitberg's method was designed using a blunt needle inserted into a prop to give the presentation that acupuncture was being administered through the skin when it was not. From then on, more and more randomized clinical trials (RCTs) about the blinding effect of non-penetrating needle had been coming out. This review is going to assess the clinical evidence and credibility of the blinding effect of non-penetrating sham needle in RCTs.

1 Materials and Methods

1.1 Identification of relevant studies and eligibility criteria

All studies related to the RCTs of acupuncture for the blinding effect of non-penetrating needle were chosen and identified independently by three investigators through searching the following databases up to July 2012: PubMed (from 1967), Medline (from 1968), EMBASE (from 1966), the Cochrane Library (Issue 7, 2012), Biosis Preview (BP) (from 1990), and the China Biological and Medical Database (CBMdisc, from 1979).

The following key words were used in our search strategies: 'Rct' or 'sham needle' or 'placebo needle' and 'sham acupuncture' or 'placebo acupuncture'.

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1.2 Data extraction

The data were extracted according to pre-defined criteria. The Cochrane risk-of-bias tool and the Physiotherapy Evidence Database (PEDro) scale were used to assess the methodological quality of the trials. The same two authors independently assessed the quality of the acupuncture technique as described previously. Disagreements were resolved by discussion with the other authors.

1.3 Data analysis and statistical methods

We calculated the odds ratio (OR) with 95% confidence interval (95% CI) by the Cochrane Review Manager (RevMan, version 4.2) to assess the blinding effect of the non-penetrating needle. Pooled ORs with corresponding 95% CI were calculated by both fixed-effects model and random-effects model. Heterogeneity among studies was evaluated using the Chi-square test based on Cochrane Q statistic.

Quantification of heterogeneity was made by the I² metric, which is independent of the number of studies included in the meta-analysis. A *P* value of <0.05 was considered to be statistically significant, except for the Q statistic, which was considered significant if *P*<0.10. In this review, A *P* value of >0.05 was considered to be statistically insignificant, which meant that the subjects had the same subjective sensation by the stimulation of verum and sham acupuncture and the sham acupuncture had successfully blinded the subjects.

2 Eligible Studies and Study Characteristics

The excluding process is shown in Figure 1, and the information of the included studies is present in Table 1.

Table 1. The included studies

Study	Study design	Method	Outcome measures	Result
Enblom A, et al ^[1]	Single-blind	Verum acupuncture (<i>n</i> =109) versus sham acupuncture (<i>n</i> =106) with a non-penetrating telescopic sham needle	Bang's blinding index (BI)	Most patients in the verum (74 of 95; 78%, BI 0.72) and the sham (68 of 95; 72%, BI -0.60) acupuncture group believed they had received verum acupuncture
Lee H, et al ^[2]	Subject-blind	Real acupuncture (<i>n</i> =39) versus non-penetrating sham acupuncture (<i>n</i> =40)	BI	41% of participants in the real acupuncture group made correct guesses for Hegu (LI 4); 21 participants in the sham acupuncture group (<i>n</i> =40) made correct guesses
Takakura N, et al ^[3]	Double-blind	To validate the masking effect for the practitioner, 10 acupuncturists applied 40 needles (23 non-penetrating/17 penetrating); for the validation of patient masking, an acupuncturist randomly applied a non-penetrating/penetrating needle pair to bilateral Waiguan (TE 5) in 60 volunteers	Questionnaire; BI	The ($\bar{x} \pm s$) of correct/unidentifiable/incorrect answers given by the 10 acupuncturists were (17.0±4.1)/ (6.4±3.6)/ (16.6±3.0) respectively. Regarding patient masking, none of the subjects commented in the questionnaire that they had received a non-penetrating needle
Goddard G, et al ^[4]	Single-blind	24 subjects received real Acupuncture; 25 subjects received placebo acupuncture.	BI	22 (88%) of the 25 subjects who received placebo acupuncture believed they had received real acupuncture; 19 (79.2%) of the 24 subjects who received real acupuncture correctly determined they had received real acupuncture
Enblom A, et al ^[5]	Single-blind	80 individuals were randomized to one single needling given by one of four physiotherapists using either an invasive needle or a non-penetrating telescopic sham needle	BI	BI was 0.20 (95% CI 0.03-0.36) in the acupuncture group and 0.10 (95% CI 0.09-0.29) in the sham group (interpretation: 20 and 10% identified needling type beyond statistical chance)

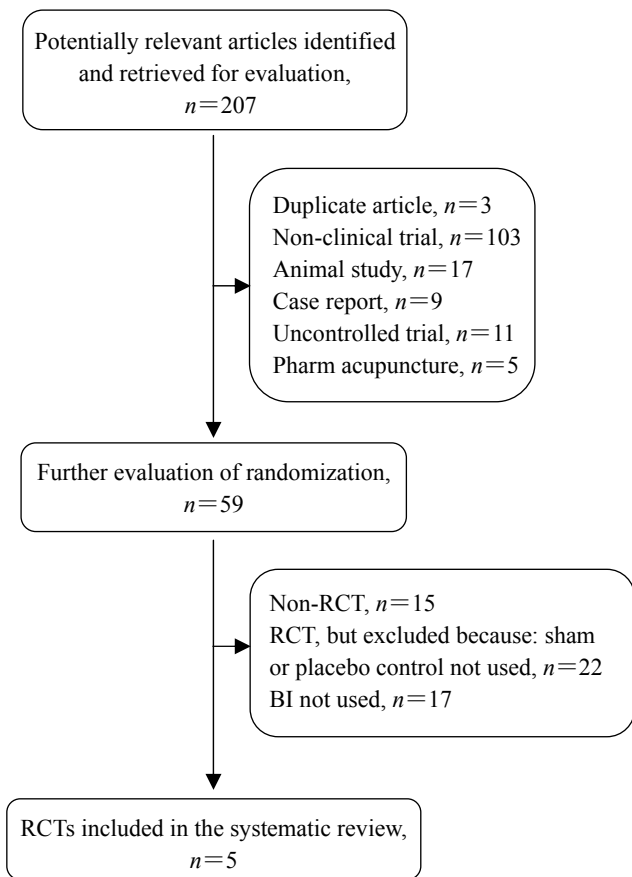


Figure 1. The excluding process

3 Results

See the forest plots (Figure 2) of the comparison of acupuncture group versus sham acupuncture group. We can see that a P value of <0.05 was considered statistically significant. The calculated 2-tailed P value was 0.06. This P value indicated a statistical difference between the two treatment groups. This supports the null hypothesis that subjects were not able to differentiate between real and placebo acupuncture.

4 Limitations of This Review and the Direction of the Future

Some limitations in this review need to be addressed. First of all, one limitation of using a meta-analytic approach for population-based observational studies is that these studies only yield estimates of associations that are influenced by confounding factors such as age, sex or ethnic admixture, either between studies or between cases and controls within each study. Maybe it is necessary to focus on the influence of age, sex, ethnic admixture, and other factors on the result of this kind of research. Second, no prospective study was found in the present review, and all included studies used a retrospective case-control design, which is subjective to certain bias, especially survival bias. What's more, the blinding method of the double-blind researches included in this review has not been described clearly enough.

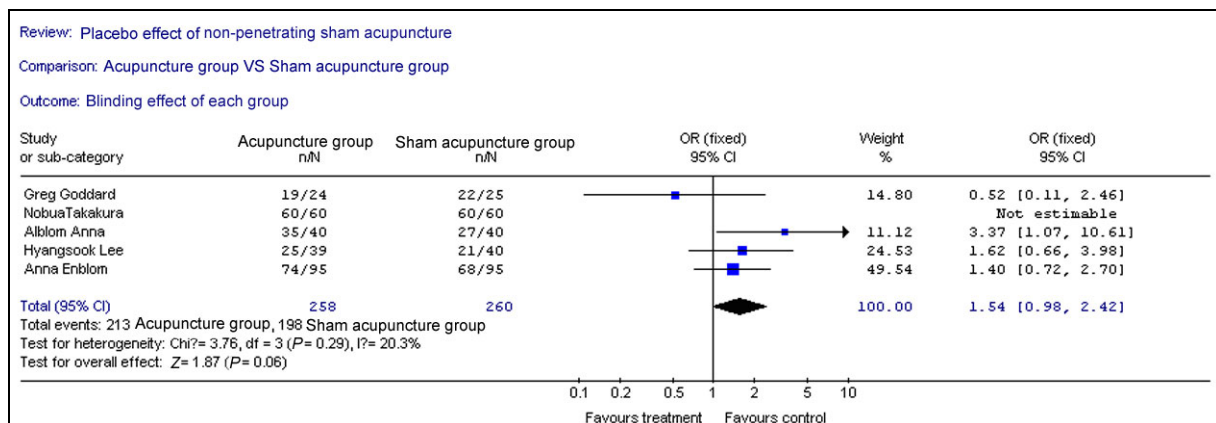


Figure 2. The forest plots

5 Discussion

During the exclusion of references, one research of double-blind acupuncture placebo^[6] is impressive. Although this research is not a randomized controlled trial, it explored the blinding effect of non-penetrating needle from the respect of appearance researches, the biomechanical properties as well as the MRI characteristics between acupuncture and

and sensation. It revealed that the subjects correctly identified 55.8% of treatments from appearance and 56.7% from skin sensation. As a double-blind research, it also explored the blinding effect on the acupuncturists. The result was that acupuncturists identified 45.0% of treatments from appearance and 55.0% from skin sensation. Besides these clinical non-penetrating sham needle have also been explored^[7-8]. They have revealed a marked difference

in the biomechanical properties and brain metabolic changes between true and non-penetrating sham needling. Placebo acupuncture control has been widely used in clinical research, and the purpose is to reduce the psychological factor to the minimum. The ideal placebo/sham acupuncture has a crucial role in the design of acupuncture studies. Therefore, many clinical acupuncture researches haven't met the design standard of conventional clinical trials. Clarifying the difference between the comforting effect of acupuncture and the drug studies is the key to answering such a challenging question. To avoid the failure in clinical design, we should consider appropriately the concept of placebo and sham acupuncture points, as well as acupuncture points and meridians.

Ideal placebo acupuncture control should abide by three principles:

First, a placebo needling has no or almost no specific therapeutic effect.

Second, needling the position that does not has therapeutic effect.

Last, subjects should not aware difference between placebo acupuncture and true acupuncture^[9].

However, it's not been confirmed whether this placebo acupuncture is suitable for Chinese acupuncture researches. The purpose of the West to do acupuncture clinical research is to verify whether or not the acupuncture is effective, which is different from the Chinese situation. The Chinese have admitted that the acupuncture is effective. At the premise that the effect of acupuncture is not sure, the Western studies have especially set up placebo-controlled acupuncture studies^[10-11].

There are still many problems with the placebo acupuncture, while as an essential part in the contemporary acupuncture study, it should get greater attention^[12-13]. We look forward to the development of a more reasonable design to help the acupuncture research.

Conflict of Interest

There is no potential conflict of interest in this article.

Acknowledgments

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