The Emperor’s sham – wrong assumption that sham needling is sham

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Abstract
During the last five years a large number of randomised controlled clinical trials (RCTs) have been published on the efficacy of acupuncture in different conditions. In most of these studies verum is compared with sham acupuncture. In general both verum and sham have been found to be effective, and often with little reported difference in outcome. This has repeatedly led to the conclusion that acupuncture is no more effective than placebo treatment. However, this conclusion is based on the assumption that sham acupuncture is inert. Since sham acupuncture evidently is merely another form of acupuncture from the physiological perspective, the assumption that sham is sham is incorrect and conclusions based on this assumption are therefore invalid. Clinical guidelines based on such conclusions may therefore exclude suffering patients from valuable treatments.

Keywords
Acupuncture, placebo, randomised controlled clinical trials, sham acupuncture.

Introduction
Clinical guidelines aim to be a base for recommended patient care, with safety and quality as the main objectives. They also aim to improve recommendations continually by providing clinicians with updated evidence of best practice. The drive to evaluate and analyse tools for the screening, diagnosis, management and monitoring of disease captured by the phrase ‘evidence-based medicine’ (EBM), has firmly entrenched itself as part of the recommendation for standard clinical care, and randomised controlled trials (RCTs) serve as one of the cornerstones of EBM. Results of RCTs have become important in evaluating pharmacological as well as non-pharmacological interventions. This is based on the concept that the effect of a treatment should be compared with the effect of an inert control procedure on patients randomly assigned to the treatment or the control group. Furthermore, the design of the study should also claim to be blinded, preferably both the patient and the person giving the treatment, to retain the highest score of scientific quality.

In applied RCTs the effects of verum acupuncture are commonly evaluated by comparison with a kind of sham acupuncture which is intended to be inert. The sham procedures in acupuncture studies are commonly described as placing the needle into a non-acupuncture point, inserting the needle superficially without further stimulation, or by using a placebo needle intended to produce a minor sensory stimulation without penetration of the skin. The crucial issue in analysing the results of such studies is whether the assumption that sham acupuncture is inert is true.

Review and analysis
We have argued that no sham procedure so far presented in acupuncture studies is truly inert. This is based on several lines of direct and indirect evidence:

Physiological findings
   a. Light touch on the skin, which is obtained during sham acupuncture, results in activity in the insular region of the brain.
   b. Mechanical ‘non-penetrating’, sham acupuncture (SA) as well as low frequency electroacupuncture (EA) evokes brain...
responses localised to the contralateral primary somatosensory cortex in healthy subjects

c. Superficial and deep acupuncture needle stimulation elicits similar BOLD responses in healthy subjects

d. Sham acupuncture (SA) and traditional Chinese acupuncture (TA) reduced both clinical and experimental pain in patients suffering from fibromyalgia; both modalities resulted in neural activity in the brain, as assessed with fMRI, though TA generally had a more pronounced effect

e. Reduction of serum cortisol concentration and anxiety level were observed following both verum (real) and sham (‘placebo’) acupuncture, although there were no significant differences in the changes between the two groups; also, these changes could not be attributed to rest

Clinical reports

g. Superficial needling and sham acupuncture is superior to a placebo pill, demonstrating that superficial and sham acupuncture is not inert

h. Superficial needling has been advocated as a treatment technique in its own right

i. Sham acupuncture has been proven to be as effective as verum acupuncture and dedicated analgesics, in headache and migraine

j. Sham acupuncture and verum acupuncture have been shown to be more effective than conventional therapeutic interventions in low back pain

k. Sham (‘placebo’) acupuncture was associated with a significantly higher overall pregnancy rate when compared with real acupuncture in IVF treatment

Because of the need to conduct high quality RCTs examining the effects of acupuncture that meet the conventions of good design, different sham acupuncture procedures have been introduced. However, the difficulty and complexity of finding a proper control for acupuncture is obvious, since all the sham alternatives so far presented induce a certain amount of sensory stimulation and thereby a possible therapeutic effect, ie no sham is totally inert. Consequently, there is a risk that there will be no statistical difference between the groups, which will lead to the conclusion that acupuncture is equal to placebo, and thereby without value. This type of conclusion is incorrect since real treatment effects from the light stimulation could be hidden by the assumption that the sham procedure will not affect the individual at all. Based on such assumptions, the clinical guidelines could then result in depriving patients of effective treatments with few side effects. As in the fairy tale ‘The Emperor’s New Clothes’ by Hans Christian Andersen, our striving for excellence has misled us.

The tale tells of an emperor who cares greatly about clothes. The emperor hires two weavers who promise him the finest suit of clothes from the most beautiful cloth. This cloth, they tell him, is invisible to anyone who is either stupid or unfit for his position, and so light it cannot be felt. The Emperor cannot see the (non-existent) cloth, but pretends that he can for fear of appearing stupid; his ministers do the same. When the weavers report that the suit is finished, they dress him in mime. The Emperor then goes on a procession through the capital to show off his new ‘clothes’. During the course of the procession, a small child cries out, ‘But he has nothing on!’ The people realise the child is telling the truth, but do not want to agree, for to do so would be to acknowledge that they, too, were ‘stupid’. In spite of the small child’s observation, the Emperor obliviously holds his head high and continues the procession. ‘The Emperor’s New Clothes’ is a simple story of seeing through the trappings of power to reveal ‘the truth’ of the Emperor’s vanity and the courtiers’ pusillanimity. Sham acupuncture was introduced to allow us to separate the specific from non-specific effects. But as with the Emperor’s clothes, there is no ‘sham’ acupuncture, and like the child in the fairy tale, we need to acknowledge this.

Conclusion

The randomised double blind placebo controlled trial has proved an invaluable tool for testing the efficacy of new drugs. In order to use a placebo or sham controlled design, an intervention has to be divided
into characteristic (specific) and incidental (placebo, non-specific) elements. However, recent research suggests that it is not meaningful to split complex interventions into characteristic and incidental elements. Elements that are categorised as incidental in drug trials may be integral to non-pharmaceutical interventions, such as patient-therapist interaction. If this is true, the use of placebo or sham controlled trial designs in evaluating acupuncture interventions may generate false (negative) results (if interpreted as sham) and treatments may be withheld that are safe and cost effective.

An assumption is a proposition that is taken for granted as if it were known to be true.

The assumption that sham acupuncture is inert is wrong. Sham acupuncture cannot and should not be considered a placebo procedure and should therefore not serve as a control for non-specific effects.

If we take the above suggestions into account, the interpretation of meta-analysis including those within Cochrane reviews should be reconsidered. Possibly the best way to assess the effects of acupuncture are studies using naturalistic protocols and/or observational studies.

Conflict of interest

TL chairs the not-for-profit charity ‘The Foundation of Acupuncture and Alternative Biological Treatment Methods’ which has received grants from AKAB Utbildning AB to support acupuncture research. The other authors have declared no conflict of interest.

Reference list

Education, practice and debate

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