Commentary

Opinions on New Reporting Guidelines for Acupuncture Studies Using Sham Acupuncture as a Control Intervention: Advances Needed

Tae-Hun Kim *

Korean Medicine Clinical Trial Center, Kyung Hee University, Korean Medicine Hospital, Seoul, Republic of Korea

Received: March 28, 2024 Revised: April 23, 2024 Accepted: May 16, 2024

*Corresponding author: Tae-Hun Kim
Korean Medicine Clinical Trial Center, Kyung Hee University, Korean Medicine Hospital, 23, Kyungheedae-ro, Dongdaemun-gu, Seoul 02447, Republic of Korea
Email: rockandmineral@gmail.com
https://doi.org/10.56986/pim.2024.06.009

©2024 Jaseng Medical Foundation. This is an open access article under the CC BY-NC license (http://creativecommons.org/licenses/by-nc/4.0/).

The recently published article titled "The SHARE: SHam Acupuncture REporting Guidelines and a Checklist in Clinical Trials" offers valuable guidance on future acupuncture studies with sham controls [1]. As sham acupuncture is frequently employed in clinical trials to offer a fair evaluation of acupuncture efficacy and safety, the authors rightly express concerns about the problems arising from poor reporting of sham acupuncture details. A well-defined checklist of the necessary items would undoubtedly be helpful for researchers conducting clinical trials, those who read the articles, and the secondary research analysis to gain a clear understanding of the properties of sham acupuncture used in the study. In this regard, the authors successfully provide a comprehensive framework for reporting sham controls in acupuncture trials, adhering to the appropriate development methods of reporting guidelines – a significant contribution to the field. A similar, recently published reporting guideline “ACURATE: A Guide for Reporting Sham Controls in Trials Using Acupuncture” is very timely and provides researchers insight into sham acupuncture, which ultimately will greatly aid in establishing evidence for acupuncture treatment [2]. However, in both these reporting guidelines, there is no description on an equally important factor requiring attention in acupuncture trials: the details of “real” (verum) acupuncture.

When reviewing clinical trials employing sham acupuncture, it becomes apparent that the primary focus is on the selection of the type of sham acupuncture, specific implementation procedures, and areas of stimulation. The rationale for selecting sham acupuncture as the control group in acupuncture studies lies in the pursuit of an unbiased evaluation of the efficacy and safety of “real” acupuncture. This approach aims to provide a placebo control in a similar manner as conventional drug research to achieve blinding and minimize detection and performance biases [3].

The objective of this commentary is not to discuss whether sham acupuncture is as inert as a placebo in drug research, but rather to emphasize the importance of understanding the purpose of sham acupuncture in these studies. There is likely unanimous agreement that using sham acupuncture as a control group intervention enables the acquisition of information about the specific effects and safety of acupuncture. However, problems arise when researchers designing and conducting clinical trials with sham acupuncture, or those interpreting the results, assume that the acupuncture applied in the study resembles that commonly used in clinical practice or, at the very least, adheres to the acupuncture described in the study protocol.

In sham acupuncture research, particularly in studies utilizing sham devices, an important component often overlooked for “real” acupuncture used in clinical practice is the application of the base unit [4]. The base unit (that is the “assisted tools” in the checklist) is placed over the area where the needle stimulates the acupuncture point and is retained for the duration of either sham acupuncture or “real” acupuncture to achieve blinding in the study. Typically, the base unit comprises a small cylindrical piece of plastic with an adhesive layer which facilitates attachment to the skin, and sometimes there is a tube on the base unit for needle insertion. The blunt needle does not penetrate the skin. The cylinder is hollow, which allows for the insertion of the “real” acupuncture needle and the administration of acupuncture treatment. Typically, the base unit is situated over the area where the needle stimulates the acupuncture point and is retained for the duration of either sham acupuncture or “real” acupuncture to achieve blinding in the study. Typically, the base unit is placed over the area of interest in the study protocol.
research experience, there have been cases where the double-sided tape on the base unit obstructed the bottom of the cylinder, hindering the needle from puncturing the skin during “real” acupuncture. As a result, the acupuncture treatment in these studies may deviate somewhat from its real presentation in actual clinical settings [5].

This is not a hypothetical scenario but appears to be supported by empirical evidence. Upon analyzing network meta-analyses, we have observed that the effect size of “real” acupuncture in studies using sham devices is smaller than in studies using “non-acupuncture point” shallow needling control without sham devices. This appears to be consistent across various types of conditions. Where “non-acupuncture point” shallow needling is employed as a sham acupuncture control, it allows for administering stimulation similar to real world acupuncture practice without the need for a base unit in the “real” acupuncture group. It is not surprising to see different effects in studies using sham device controls with blunt needles compared with those reflecting effects similar to “real” acupuncture [6,7].

What is needed, then? The focus in reporting details should not be limited to the techniques of sham acupuncture, instead, it is essential to comprehensively describe the intricacies of “real” acupuncture. The Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (known as the STRICTA checklist) mandates the documentation of “real” acupuncture needling details in Item 2 and the description of other components associated with acupuncture treatment in Item 4 [8]. In sham device-controlled trials, if a base unit is employed during “real” acupuncture, its use in “real” acupuncture should be considered and reported in detail when documenting the actual insertion site, depth, direction, manual techniques, and response to acupuncture. Additionally, it is crucial to discuss the type of base unit used, any potential issues that may arise during the procedure, and the impact on treatment outcomes for other components.

It would be beneficial if the recently published sham acupuncture guidelines could include items or sections related to “real” acupuncture that is closely connected to sham acupuncture, ensuring accurate descriptions. Furthermore, concurrent mechanistic studies on the physiological effects of the base unit tube, pedestal, and adhesive tape are necessary. Following this, a fair evaluation of acupuncture effectiveness can be discussed.

Conflicts of Interest
There is no conflict of interest to declare.

Funding
None.

Ethical Statement
This article did not include any personal information and general research ethics guidelines were followed.

Data Availability
There is no usable data in this article.

References