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STRICTA and the Traditional Acupuncture Paradigm: Time to Update?

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ABSTRACT

Introduction: Although acupuncture is an ancient therapeutic technique of inestimable value, it currently still adopts its intact traditional model, despite all technological developments and elucidated mechanisms of action. We aimed to critically analyze the Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) based on contemporary science and health contexts.

Discussion: We evaluated the content of STRICTA guidelines published in 2001, and updated in 2010, and compared it to that of published articles that address acupuncture mechanisms of action, in light of science, acupuncture research methodology, and scientific communications of acupuncture efficacy studies in different clinical conditions seeking to identify gaps, congruencies, and dissonances. We then developed a critical analysis of the line of thought adopted by STRICTA. After analyzing the STRICTA guidelines dated 2001 and 2010, we identified gaps that deserve to be revisited and reformulated.

Conclusion: We make suggestions for consideration by the STRICTA working group highlighting the urgency of a new review, among which that they consider abolishing the reference to “acupuncture points” and “meridians”, as well as the unfounded use of “sham acupuncture”. We also suggest the adoption of contemporary medical rationale for acupuncture prescription and dosage based on Nosological diagnosis. We hope that these suggestions are capable of bringing the guidelines closer to the currently prevailing health context.

Keywords: Acupuncture therapy; Chinese traditional medicine; STRICTA statements; Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture

INTRODUCTION

"The prohibitive and imperative powers of paradigms, official beliefs, sovereign doctrines, and established truths combine to determine cognitive stereotypes, unquestioned received ideas, uncontested stupid beliefs, triumphant absurdities, and rejections of evidence in the name of evidence to expand their reign of intellectual and cognitive conformism in all latitudes" [1].

It is estimated that 80% of the world's population uses traditional practices to prevent and treat diseases, guided by the belief that they are effective and harmless [2]. Stimulated by the growing interest in this subject, several institutions of excellence have been engaged in teaching and developing regulations and protocols to demonstrate the effectiveness and safety of traditional and complementary medical products and practices. Their main goal is to promote the incorporation of such techniques into official health systems [3]. Among these institutions, the World Health Organization (WHO) stands out given that in 2018 88% of the member states already supported the expansion of traditional medicine outside East Asia [4].

Quoting WHO, “Indigenous traditional medicine is defined as the sum total of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental and social diseases. This knowledge or practice may rely exclusively on past experience and observation handed down orally or in writing from generation to generation. These practices are native to the country in which they are practiced” [4].

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Thus, herbal medicine, homeopathy, osteopathy, chiropractic, naturopathy, Ayurvedic and Chinese medicine, and acupuncture are accommodated under this umbrella.

Considering that acupuncture has been practiced in China for more than 3,000 years and that the dissection of corpses was prohibited in that country from Antiquity until the beginning of the 18th century, the traditional model of acupuncture was necessarily built on empirical foundations [5]. In 2008, WHO established alphanumeric nomenclature in English for acupuncture points, maintaining the classic Chinese unit of length named Cun for locating such points, corresponding to the width of the patient's thumb, measured at the level of the interphalangeal joint, or by dividing the patient's height by 75 [6]. Parallel to the movement of WHO is the lucrative traditional Chinese medicine industry, which generates around US $ 5 trillion annually. For instance, China invests US $ 122.4 billion in this area per year, a third of its total pharmaceutical industry, Australia, US $ 3.97 billion, and the United States, US $ 311 million [2].

The increasing number of papers, multiplicity of acupuncture techniques, inconsistency of comparators, and heterogeneity of results for the same clinical conditions motivated an attempt to standardize the minimum content of communications on the field of acupuncture by the Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) in 2001 [7], an extension of the Consolidated Standards of Reporting Trials (CONSORT) [8]. In the present article, based on contemporary science and health contexts, we aimed to critically analyze the guidelines recommended by STRICTA.

EASTXWEST/TRADITIONXMODERNITY

The concept of acupuncture adopted by WHO basically alludes to the etymology of the word, i.e. “Acupuncture literally means to puncture with a needle. However, the application of needles [...] may also involve the application of other kinds of stimulation to certain points” [9]. The same concept has been repeated in more recent publications [10]. For the National Institutes of Health, “acupuncture describes a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques” [11].

These concepts have gained other contours in the light of science, such as “Western medical acupuncture is a therapeutic modality involving the insertion of fine needles; it is an adaptation of Chinese acupuncture using current knowledge of anatomy, physiology and pathology, and the principles of evidence-based medicine” [12]. Information to develop a more robust concept is abundant. The link between acupuncture and the release of endorphins, for example, has been made long ago, more precisely in 1976 [13]. Despite this evidence, until now, the term “vital energy” is adopted in some supposedly scientific publications.

Acupuncture constitutes a minimally invasive, non-surgical therapeutic procedure. Its input is generated in the periphery, from the percutaneous insertion of filiform metal needles (non-concentric electrodes) in neuro-reactive anatomical sites for bottom-up modulation at the supra-segmental level [14]. This elicits neuro-modulatory adaptive responses of the central and autonomic nervous system, expressed through different pathways such as opioidergic, endocannabinoid, serotonergic, cholinergic, GABAergic, and noradrenergic systems, converging to repair the homeostasis of the hypothalamic-pituitary-adrenal axis [12,15,16].

STRICTA GAPS

The recommendations of STRICTA, an extension of CONSORT, were firstly published in 2001 and updated in 2010 with the aim of ensuring greater methodological rigor and transparency, in addition to allowing interpretation of results and reproducibility [7,8,17-19]. They also brought together a series of guidelines aimed at reporting clinical studies on the effectiveness of acupuncture. It would be desirable for the scientific standard of communications to eclipse the folkloric perspective of acupuncture, and to be positioned in line with the current model of evidence-based health. Nonetheless, so far, this has not been the reality [20]. Because of this, we discuss below some weaknesses of STRICTA.

Mentioned in subitem 2b of STRICTA [19], acupuncture points and meridians do not find anatomical counterparts in the human body [12,21-23]. They are just allegories of Chinese tradition standardized by WHO in an attempt to facilitate scientific communication. If “acupuncture points” do not have a reliable concept, let alone “non-acupuncture points”, often used as comparators in clinical studies at the whim of the authors!

In addition to describing the location of “acupuncture points”, STRICTA also recommends detailing the material and equipment used, rationale for prescription, needle insertion depth, retention time, as well as quality and reactions generated by stimuli applied to the needles. As far as we are concerned, though, more important than the depth of needling, what really matters is the anatomical target of the stimulus rationally defined and based on diagnosis, whether it is a nerve, a motor point, or certain trigger points. Above all, the definitions of dose and quality of stimulation in association with needles appear to be closely related to therapeutic results [24-27].

It would be desirable for STRICTA to also recommend the reporting of adverse events related to acupuncture, since most needles are inserted blindly and, therefore, not without risk. The adverse outcomes with the least impact are bleeding, pain and hematoma at the insertion site and needle fracture [28], whereas those with the greatest impact are pneumothorax, hemothorax, pinna perichondritis, discitis, and post-dural puncture headache. Based on this, ultrasound image-guided needling is an irrefutable reality in clinical practice and a tool to be immediately incorporated into acupuncture offices, although not even mentioned in STRICTA [29-36].

In its item 5, STRICTA recommends a description of the acupuncturist’s expertise, in terms of training and years of experience [19]. However, it is well known that a great inter-professional variability prevails regarding the location of traditional acupuncture points [37]. Therefore, the imaging resources available to practice good medicine should be used to guide acupuncturists. In its sub-item 6b, STRICTA reinforces the need to detail sham interventions [19], which whether penetrating or not, can generate neurophysiological, immune, and circulatory responses to some extent, not at all

characterizing an inert comparator. Verum acupuncture itself, as it has been practiced, raises doubts regarding its alleged effectiveness in treating various clinical conditions, reflected inconclusive systematic in countless reviews [38,39]. Both have their effect influenced by non-technical factors listed in item 2 of STRICTA [19], such as professional/patient relationship, patient expectations, therapeutic environment, and ritual [40,41]. Additionally, a wide range of acupuncture techniques is described, from the most subtle such as minimal acupuncture to the most invasive such as fire-needle or acupotomy, making the possibility of comparison between treatment groups and analysis of effectiveness even more difficult [42,43].

Regarding sham acupuncture, we are probably witnessing the transgression of the Declaration of Helsinki as "The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances: Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or [...] Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention" [44,38].

It is necessary to emphasize that the points discussed in this article are not new, nor exclusive of the authors' thoughts. Over time, several other authors have expressed their points of view about the paradoxes involving practice, research, and scientific communication in acupuncture. We quote a relevant article published by Langevin et al. [45], with the collaboration of several respected researchers, including Hugh MacPherson, after the STRICTA update was published, "It is now the important responsibility of acupuncture researchers to face these results squarely and move the field forward." Thus, why not move forward?

EMERGING ISSUES

It is impressive that acupuncture has been practiced in China for more than 3,000 years and despite the technological evolution of humankind it has kept its model practically intact, based solely on its long history [46]. This fact takes on even more prodigious contours considering that this same model has been serving, over time, the most populous nation on the planet. Nonetheless, in 2019, only 16.4% of the healthcare services in China were provided by traditional medicine [47], signaling a gradually increasing interest in "Western medicine".

DISCUSSION

In a permanent movement, WHO has been disseminating traditional Chinese medicine services and products for basic health care, promoting their supposed safety, efficacy, and quality, despite the universal scientific knowledge, culture, and legislation of the member nations. Traditional acupuncture insists and persists isolated from scientific development and the evidence-based health model, essential for decision-making [48], surviving the interesting split between Western and Eastern medicine. Fueled by pseudoscientific concepts, acupuncture claims its legitimacy alongside integrative health practices, endorsed by WHO, which took on the responsibility of translating concepts and standardizing techniques and protocols, with the mission of promoting communication between medicines from both halves of the globe.

Clearly this matter goes beyond the linguistic barrier or difficulty to translate, as we have AI technology available for this and other purposes in professional training and clinical practice [49,50]. In the context of acupuncture, the insistent effort to disguise traditional concepts as scientific language sounds puerile [3]. The paradigmatic rupture is necessary. After all, in the 21st century anesthetists do not use a bow and arrow prepared with curare in their daily practice in the name of tradition! An extremely relevant question emerges from this: Does the traditional model of acupuncture meet the most basic ethical principles of beneficence and non-maleficence, as well as the application of the best scientific knowledge available in research and basic health care?

The guidelines established by STRICTA are notoriously traditionalist and contradict basic knowledge of anatomy, electrophysiology, and neurophysiology accumulated over the centuries, failing in their objective of ensuring transparency and reproducibility of scientific communications in this area of knowledge, as they assume, for example, "acupuncture points" and "sham acupuncture" [51]. Far from being an extension of the CONSORT, which recently updated recommendations for publishing clinical study results [52], STRICTA guidelines do not reflect the quality of publications [53], nor achieve the desired engagement or respectability, even though they are committed to the mission of providing scientificity to the traditional Chinese acupuncture.

Waiting for a solution of purely conceptual nature, also highlighted by other authors [38], editors remain exposed to unintelligible traditional language, compelled to create their own rules and limits, often not made explicit, in the arduous exercise of balancing reasonableness, ethics, and traditional medicine without compromising the reputation of their journals, final disseminators of the pseudoscientific practice of traditional acupuncture. More than a set of guidelines, it is expected that STRICTA recommendations provide resistance to the establishment, a counter system movement, which has probably been frustrated by the power of the tradition industry. Therefore, it is high time STRICTA corrected their mistakes and finally opted for scientific acupuncture.

CONCLUSION

In conclusion, we would like to present some suggestions that could eventually be taken into consideration by the STRICTA working group:

- Adopt the terms "scientific acupuncture" and "traditional acupuncture" instead of "Western acupuncture" and "Eastern acupuncture", respectively;
- Allow the citation of "acupuncture point" and "meridian" exclusively accompanied by anatomical references;
- Adopt "neuro-reactive point" in place of "acupuncture point" with prescription and dosage linked to a Nosological diagnosis;
- Abolish the use of "sham acupuncture" and "non-

acupuncture point" in clinical studies under any justification;

- Abolish the use of minimal or superficial acupuncture as comparators;
- Evaluate the safety of fire needle, warm needle, acupotomy, and ablative techniques;
- Emphasize the fact that electrical stimulators can be programmed, making comparison and reproducibility possible, while manual stimulation cannot;
- Promote the use of ultrasound-guided needling in the routine practice of scientific acupuncture.

The best scenario would be having the format of scientific communications influencing the clinical practice!

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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