# Critical Issues in Evidence-Based Research Verifying Efficacy of Acupuncture

### Abstract

The 11th version of the ICD effective in January 2022 suggests that the status of acupuncture is going to change from the complementary and alternative medicine in the West, showing acupuncture has the access to the main health system. However, the misunderstandings like whether or acupuncture is a science, pattern identification, needling depth, manipulation deserve evidence-based researchers to consider in research design to verify the efficacy of acupuncture.

Keywords: ICD; Opioid Crisis; Pattern Identification; Extra Acupoints

## Introduction

Morphine and opiates have been considered "wonder drugs" as relief of pain caused by wounds among many options for more than one hundred years. However, President Trump's declaration that opioid crisis has become a "health emergency" on October 26, 2017 deserves attention because the nation is urgently in need of non-pharmacologic strategies in order to decrease the public's opioid dependence. In the meanwhile, more and more patients and the medical professional are turning to acupuncture, trying to understand what role it can play in the integrative medicine in the West to solve the opioid epidemic [1,2]. It is noted that the quality of the research methodology need attention and the awareness of some issues like "real" acupuncture against a "sham" acupuncture control in the controlled trials must be raised [3]. It is reported that the Traditional Chinese Medicine (TCM) is going to be included for the first time in the 11th revision of the World Health Organization's (WHO) International Statistical Classification of Diseases and Related Health Problems (ICD), which will be effective on January 1, 2022 [4]. This information surely encourages both acupuncture and the TCM to make more contributions to the public health in the future.

# **Challenging Issues**

### Science or Pseudoscience

Whether or not the acupuncture is science remains controversial because it's been argued academically and clinically for long. It needs more discussion if the so-called "scientific evidence" with modern techniques, such as fMRI and CT, can really examine the efficacy of the acupuncture.



Compared to deductive reasoning in the West, the Chinese are often used to the inductive reasoning, which enables the TCM and acupuncture features similarities with Yin-Yang, Qi-Blood, the Five Elements, and Pattern identification in theories. In addition, the philosophical principles and thoughts placing the human body into a large system through the observation of nature make traditional Chinese Medicine (TCM) and acupuncture more complex and harder for those who are used to inductive reasoning to get the whole picture. Pattern, for example, is the key and unique concept serving as the key role in diagnosis. However, a pattern may encompass broad symptoms recognized and discussed in the Western medicine [5]. The Chinese history shows that the TCM and acupuncture had been the major roles in the health system for more than twenty centuries in China until the Qing dynasty (1644-1912). On the other hand, the answer has been given with the objective evidence that the population of China increased from forty-two million in the Qin dynasty (221-206 BC) to 150 million in the earlier period of the Qing dynasty (1644-1912) [5].

### **Pattern Identification**

Ying-Yang is the top concept and the Yin-Yang balance is understood to be the key to the health. This concept has been the dominating role of acupuncture and the traditional Chinese medicine (TCM) throughout the history of Chinese medicine for many centuries. Among the acupoint combinations, the Four Gates (LV 3, Yin and LI 4, Yang) is the classic and well known protocol used. This combination is used to treat the subhealth case successfully in the Qi deficiency and Blood stasis pattern, demonstrating the application of the concept and highlighting the importance of Yin-Yang balance [6]. Pattern, which is based on Yin-yang, is the unique concept in the acupuncture and the TCM. In addition, pattern identification plays the most critical factor for the successful treatment outcomes. However, studies [7-10] show that patterns were not included in the research designs in which extra acupoints can be selected for use together with traditional acupoints in

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clinical practice. It is worth discussing that diseases rather than patterns are included in most of the evidence-based research. The expected results cannot occur for sure when the patterns are not taken into consideration.

Liver qi stagnation is the most important and common pattern in clinic. The channel route of Liver channel, and the functions of Liver in the TCM show that the insulting sequence plays a key to understanding the relationship between Liver and Lung in the treatment of cough effectively. Current scientific studies of depression, which is the presentation of negative Shen in the TCM, show that the stagnated Liver qi can dysregulate the neurotransmitter signaling in transforming macronutrients into molecules. In other words, the stagnated Liver qi can lead the molecules to be delivered insufficiently to the brain with the disrupted mitochondrial ATP production in neurons. In addition, the failure in controlling the ratio of lymphocytes seen as Yin and granulocytes seen as Yang by the autonomic nervous system is viewed as Liver qi stagnation. On the other hand, the sympathetic nervous system viewed as Yang controls the Natural Killer cell while the parasympathetic nervous system viewed as Yin is assumed to be connected closely to the release of cytotoxic substances [11].

### Sam Acupuncture

Sham acupuncture has been used for more than 30 years in clinical trials of acupuncture as a common tool to test the efficacy of acupuncture. As a matter of fact, whether or not the channel system, which is established on the experience and knowledge of the use of extra acupoints and Ashi points, exist within the body remains uncertain because there is no scientific evidence to verify it. In other words, various forms of current sham acupuncture conducted for verifying the efficacy of acupuncture seems questionable. There are in general two kinds of acupoints: acupoints on the twelve regular channels and extra acupoints not included in the regular channels. With the specific indications, actions, and the great effect in the acupuncture theory and treatment, extra acupoints distinguish themselves from the regular acupoints on the traditional twelve channels, even though most of them have not been discovered and verified with scientific evidence [12]. However, the acupuncture history suggests that extra acupoints can be discovered at any time like the new extra acupointGangshui (肝水) discovered and used for sub-acute cough, which demonstrates there may be numerous extra acupoints undiscovered [7]. To some extents, acupoints selected in the sham acupuncture trials may be the locations of new extra acupoints that have not been discovered to affect the results.

# To Combine or Not to Combine Regular Acupoints with Extra Acupoints

Since whether or not the channel system exists has not yet been proved, forming the most effective acupoint protocol remains an issue. The challenge experienced acupuncture practitioners face is when it is the best time to consider including extra acupoints in a protocol. It is believed that the protocol Canadian Journal of Biomedical Research and Technology

following the TCM theories can bring about the best results. Unfortunately, not all of the actions and indications of extra acupoints have been and verified as traditional regular acupoints in scientific research. The historical developments of extra acupoints show that an extra point can surely play an essential role in acupuncture and be used alone or with the traditional regular acupoints for the treatments [12]. In other words, there is not sufficient scientific evidence at present to understand the actions and indications of extra acupoints.

### **Needling Depth**

'Deqi' is the sensation required for the better outcomes. In order to obtain "deqi" in practice, the needles must be inserted into specific acupoints to the required depth. Two primary factors like the nature of the stimulation and the location of the stimulation are varied in the sham acupuncture trials. Unfortunately shallow needling is often conducted by current research teams but in fact cannot be considered to be inert [13].

### **Manipulations**

In addition to correct pattern identification, exact needling depth, and the location selections, manipulation also deserves attention. One of the key factors that can influence acupuncture effects in the TCM theory is manipulation of needles [14]. Tonification and sedation are two major techniques in acupuncture treatments performed in either lifting-thrusting or twisting-rotating. It is presented in the study that the skin temperature increased continually during stimulations and decreased later in the last phase. The increased temperature caused by lifting-thrusting stimulation is proved to be higher significantly than that of twisting-rotating manipulation [15].

#### Discussion

Complementary and alternative medicine (CAM) refers to therapies that scientific evidence has not shown to be safe or effective in large scientific studies. Different amounts and levels of scientific evidence, however, support various CAM therapies. It is true to some extents that acupuncture has not yet been proved with the Western scientific evidence to be effective in treating all the diseases and disorders. With extensive evidence-based research, it has demonstrated the benefits of acupuncture for various illnesses, which resembles the fact that not all the diseases can be treated and cured with the Western medicine up to now.

Compared to the Western medicine, symptoms in the acupuncture and the TCM are believed to be broader with the pattern identification. A disease in the acupuncture and the TCM is believed and understood to be the imbalance of Yin and Yang. How to make acupuncture treatments effectively requires an accurate diagnosis following Zang-Fu organs, channel theories, Yin-Yang, and acupoint indications. The pathological classifications of diseases in the Western medicine are not generally followed by TCM physicians and

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acupuncturists, but they strictly depend on the patterns developed with the Yin- Yang balance, Qi-Blood, and the meridian theory. It deserves attention that the safety and effectiveness of acupuncture have been verified with scientific evidence and acupuncture is highly recommended by the WHO for the pain management and various diseases, such as dysmenorrhea, neck disorders, vomiting, migraine, tension headache, and postoperative nausea [16,17].

These issues in this study represent that there are some misunderstandings for evidence-based researchers to consider in designing a scientific research. In the Bible, the Earth is described in many ways; it is a circle (Is. 40:22) and also suggested that the Earth has 4 corners in the Revelations, which shows that the "fact" can be defined from the different perspectives. The inductive reasoning of the Chinese is the foundation for the developments of the acupuncture and the TCM, which is totally different from the deductive reasoning in the West. Whether or not it is the time to judge the acupuncture or the TCM are sciences remain uncertain and controversial because the criteria established by the West used to judge an apple pie cannot apply to stinky tofu in the Chinese communities at all [18].

### Conclusion

Scientific evidence provides the explanations of the abstract concepts, showing the direction for the accurate interpretations of the acupuncture. However, the present developments of the evidence-based research show there is a long way to go because there exist some misunderstanding and gaps. The new version of the ICD by the WHO suggests that whether or not the acupuncture and the Western medicine can co-work with each other in the future for the better healthcare needs more attentions and efforts.

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