Perspective

Two Evidence-Based Acupuncture Models

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ABSTRACT   Modern clinical trials have produced controversial data interpretation which refutes conventional standard teachings and practices. Acupuncture scholars and practitioners have been stimulated to scrutinize these trials and analyze conventional practices. This paper presents two acupuncture models which address these issues. One rationalizes the clinical trial results with newer understanding of acupuncture points and techniques, while the other reconciles these results with rediscovered techniques of palpating points and performing needling. These two models indicate that acupuncture is in transition from classical model to evidence-based models.
KEYWORDS   acupuncture model, evidence-based, LI Yong-ming's Balloon model, LENG San-hua's C-Nerve Network Counter-Stimulation model

Classical acupuncture theory is based on the circulation of qi and blood along a meridian network system, mediated through yin and yang, interior and exterior, organs and tissues. Yin and yang imbalance, qi and blood blockage, interior/exterior disharmony, and organ and tissue impairment cause illness. Acupuncture treats illness by needling points on the meridians and obtaining qi sensation, with the objective of eliminating imbalances, blockages, disharmony and impairment. Scholars and practitioners who adhere to the theories and tenets of classical acupuncture have encountered challenges in the shape of acupuncture clinical trials that have generated massive data to dispute this classical model. Clinical trials have generated data which brings into question some of the following issues: the obfuscation or lack of precision for classical acupuncture points; the fact that "sham" acupuncture produces real clinical effects; the non-existence of specific anatomical structures for acupuncture points and meridians; therapeutic effects elicited by stimulating non-acupuncture points; and the effectiveness of acupuncture treatment without obtaining qi sensation, among others.

This paper presents two acupuncture models developed by LI Yong-ming and LENG San-hua that address these challenges and establish new theories to guide acupuncture practice.

LI Yong-ming's Balloon Model

Researchers and scientists have a bias to determine specific effects from specific causes: they always want to find the acupuncture-point-specific effect. Failing to achieve this goal, they claim that the intervention is nothing more than placebo effect. Numerous well designed clinical trials in the Western countries demonstrate these challenges. Among the 10 selected clinical trials[1-10] (Appendix 1), 6 originated from Germany's Acupuncture Trials[1-3] (GERAC) and Acupuncture Randomized Trials[4-6] (ART), 2 parallel research programs established by German researchers. Both programs chose low back pain, knee osteoarthritis, migraine prophylaxis, and tension-type headache as their study subjects for clinical trials. Collectively, 3,873 German patients participated in the GERAC studies, and 1,170 German patients participated in the ART studies. Physicians, clinicians, researchers and statisticians were jointly involved in these studies, making them the largest clinical trials so far to assess acupuncture's effectiveness in treating pain conditions. Research results were published in prestigious mainstream medical journals such as *Lancet*, *Journal of the American Medical Association*, *British Medical Journal*, *Archives of Internal Medicine*, *Annals of Internal Medicine*, and *Journal of Headache Pain*. In the 8 German trials[1-6,11,12] (4 for each group), they reached the following conclusions: (a) acupuncture is effective; (b) acupuncture is superior to conventional pain management; and (c) 6[1-6] out of the 8 trials

demonstrated that true acupuncture with classical protocols is not significantly different from minimal/superficial acupuncture. The other 4 popularly-cited acupuncture clinical trials also support the conclusion that there is no significant difference between true acupuncture and sham control acupuncture.

LI Yong-ming's Balloon model[13] of interacting effects goes directly to the heart of these problems (Figure 1). The Balloon model provides a schematic representation of 5 effective therapeutic layers: spontaneous recovery, placebo effect, mind-body connection effect, pan-acupuncture effect, and acupuncture-point-specific effect. This model was based on his 3 decades clinical experiences and observations on numerous practitioners in the United States. In the United States, patients visit acupuncture practitioners with various conditions. They are treated in a private, quiet and nicely decorated room. One-time disposable thin needles are applied to the patients with little or none stimulations. A good relationship between patients and practitioner is nurtured during the treatment course. Most patients have low tolerance to strong needle stimulations.
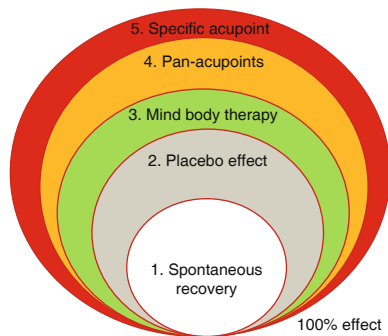

Figure 1.   LI Yong-ming's Balloon Model

In this model, acupuncture's total effect is compounded from 5 sources which are layered around each other. The 5 effects are dynamic in the sense that all of them together can not exceed 100%, so if one effect is more prevalent, the other effects will be variously mitigated. The spontaneous recovery comes from the body itself, even without any intervention. The placebo effect is a beneficial physiological effect in response to a placebo. The mind-body connection effect encompasses how the mind affects the body. The pan-acupuncture point effect is based on the idea that acupuncture points universally exist all over the body, and therefore any stimulation will have an effect. The acupuncture-point-specific effect emphasizes the effectiveness of the classical acupuncture points and

specifically-identified acupuncture points such as Ashi points, trigger points, motor points and reflexive points.

Modern science looks for an arrow-like trajectory from cause to effect; Chinese medicine is based on circularity and reciprocal adjustments. Placebo or sham acupuncture was designed with the intention to provide a clear-cut distinction between "real," point-specific acupuncture and non-point-specific acupuncture, which was considered non-acupuncture by researchers and most traditional practitioners. However, if the 5 effects cited by LI Yong-ming are always in play, studies incorporating placebo and sham acupuncture will always be inconclusive because they implicitly embed the effect resulting from the spontaneous recovery effect, placebo effect, mind-body connection effect, and pan-acupuncture effect. The listed studies above are examples of separating the point-specific acupuncture effect from the spontaneous recovery effect, placebo effect, mind-body connection effect, and pan-acupuncture effect. This becomes the essential problem with many other modern acupuncture clinical trial studies. A well-designed trial must take into account the difficulty of constructing a true control for acupuncture.

In LI Yong-ming's model, a practitioner applies an acupuncture point combination and selects acupuncture stimulation techniques, such as western-style "soft" acupuncture (acupuncture at pan-acupoints without stimulation) or comfortable acupuncture, or traditional Chinese hard acupuncture (acupuncture at acupoints with stimulation),[14] in an attempt to maximize the total effect of acupuncture intervention. The patient's response to that treatment will be idiosyncratic to the patient. It is unlikely that the practitioner will be able to isolate the acupuncture-point-specific effect from the total effect of the treatment, and it is even more challenging to separate the acupuncture-point-specific effect from the combined the spontaneous recovery effect, placebo effect, mind-body connection effect, and pan-acupuncture effect. Facing these quandaries and dilemmas, the Balloon model of acupuncture effectiveness has attracted much attention recently. It seems that this model encompasses the challenges and dilemmas encountered from the clinical trials cited. Soft acupuncture and hard acupuncture are two styles of acupuncture practice which could produce equivalent effect on many conditions.[12] This equivalency in clinical practice is translated into statistical indifference in clinical trial comparisons between treatment group (hard acupuncture) and control group (soft acupuncture).

Another implication of the Balloon model is to avoid over-treatment. If soft or comfortable acupuncture is sufficient to treat a condition (many pain conditions are in this category), then an acupuncture-point-specific effect from hard acupuncture, or strong stimulation with qi sensation is redundant. If pan-acupuncture points can achieve the treatment effect, it is not necessary to choose inconvenient points. Based on the observed idiosyncratic reactions of the patient and understanding of the patient's conditions, practitioners can select the optimal combinations of acupuncture points and needling techniques for each patient.

C-Nerve Network Counter-Stimulation Acupuncture

Why can't acupuncture always deliver expected outcomes? Why do so many clinical trials[1-6,8,9] challenge the conventional teachings and practices based on national and international standards? We present LENG San-hua's C-Nerve Network Counter-Stimulation model[15] to address these issues.

The C-Nerve Network Counter-Stimulation model focuses on pain conditions. Appendix 2 includes all the clinical trials presented in Appendix 1, minus the one that is not pain related, and adds 3 more trials: one from Germany Acupuncture Trials; one from Acupuncture Clinical Trials; and one that used by LENG San-hua to illustrate his theory.[16]

It should be noted that the acupuncture protocols in the treatment group in these 3 added trials are different from others: they used scalp acupuncture, trigger points, and Ashi points respectively, especially the last two. Identifying the sensitization points such as trigger points and Ashi points in each patient is the key element in LENG San-hua's C-Nerve Network Counter-Stimulation model.

In C-Nerve Network Counter-Stimulation acupuncture, meridians of the human body are seen as lines drawn to describe the functional interactions between body parts, and are used as guidelines to find distal acupoints for treatment. LENG San-hua notes that meridians are not anatomic structures of the human body that perform physiological function of the body. Rather, it is the anatomical structures of skin, vessels, fascia, muscle and bone which determine the acupoints and receive mechanical stimulation from needles (or needles and heat together). C-nerve receptors are the structures that transfer the stimulation of needle manipulation into electronic impulses. C-nerve pathways are the structures that conduct the electronic impulses to the brain's functional centers. Trans-axonal electronic conduction of electric impulse mediates the functional relation between body parts (this is the mechanism expressed by the meridian system). Brain centers produce the treatment signals (efferent electronic impulse).

Sensitization is the scientific term for "tenderness at the acupuncture points" which is essential for clinicians to locate the most effective stimulation points. C-nerve sensitization is a universal protective mechanism which evolved in animals, including human beings. C-nerve sensitization is differentiated as peripheral sensitization and central sensitization. Peripheral sensitization means that C-nerve endings are exposed to inflammatory mediators, or the responsive threshold of the nerve decreased, resulting in expansion of pain signaling. Central sensitization means enhancement in the function of neurons and circuits in C-nerve pathways caused by increases in membrane excitability and synaptic efficacy as well as to reduced inhibition. Sensitization is a manifestation of the remarkable plasticity of the somatosensory nervous system in response to activity, inflammation, and neural injury. LENG San-hua differentiates acupuncture points as physiological points and pathological points. Physiological acupoints are where Shen (Kidney) qi enters and exits. C-nerve receptors transfer stimulation at physiological acupoints into electric signals, conduct the signals to brain centers, and produce efferent nerve signals, which arrive at the peripheral effectors. Pathological acupoints are where true qi and pathogenic qi meet and flow together; where injury and anti-injury mechanisms occur; where nerve sensitization occurs. C-nerve sensitization includes different types of response to different stimulations: sensitization to mechanical stimulation produces the response of tenderness; sensitization to cold produces the response of affinity to warmth and dislike of cold; sensitization to warmth produces the response of affinity to cold and dislike of heat; sensitization to specific chemicals or antigens produces the response of allergy, itching, sneezing, asthma, rashes, etc.; sensitization to sound produces the response of tinnitus; sensitization to light produces the response of photophobia or tears.

Traditional textbooks and acupuncture standards do not differentiate between physiological acupuncture points and pathological acupuncture points. Attempts to

locate acupoints based solely on theory, without knowing a patient's exact condition, often leads practitioners to disregard the techniques that incorporate palpation, body part positioning and movements to locate acupoints, and results in reduction of the acupuncture area. These techniques, however, are mentioned and recommended in the *Huangdi's Internal Classic* (Huang Di Nei Jing).

In C-Nerve Network Counter-Stimulation acupuncture, physiological and pathological acupoints are differentiated. Physiological acupoint location includes the 5 layers of skin, vessels, fascia, muscle, and bone. Pathological acupoints can be in one or multiple layers of skin, vessel, fascia, muscle, and bone. Physiological acupoints present with pain, tenderness, abnormal changes of color, temperature, pulse and texture, while pathological acupoints do not. Both physiologic and pathologic acupoints are dynamic. Palpation can generally locate acupoints precisely, determining subtle differences in the 5 tissue layers. In C-Nerve Network Counter-Stimulation acupuncture, classical concepts noted in the *Huangdi's Internal Classic* are still relevant: tenderness of Xu (dificiency) means pain, but the patient is comfortable; tenderness of Shi (excess) means pain, and the patient is uncomfortable; vessels demonstrating change to Shi means a strong and big pulse; vessels demonstrating change to Xu means a thin and weak pulse; warm syndrome carries a warm sensation; cold syndrome carries a cold sensation; Biao (Exterior) or Li (Interior) decide the location of the problem; texture changes produce tender nodules and tender muscle bands.

Five-body palpations are the most important component of assessment in C-Nerve Network Counter-Stimulation acupuncture. In skin/hypodermis palpation, the hypodermis is movable with the skin. Tenderness, tender nodules and bands are identified using the following palpation methods and signifiers: gentle pressure; pinch; pinch and roll; change of tissue temperature, test with the back side of the hand. In pulse palpation, the intensity, depth, and length of pulse are compared; the same pulse in the contralateral side is compared; pulses in different body parts are compared. Deep fascia palpation differentiates areas of muscle tenderness or fascial tenderness: positive for resistive isometrics contraction in muscles; negative for resistive isometrics contraction in fascia. Tension changes are identified through testing with pressure and testing with motion of joint. Muscle palpation assesses tenderness,

pain with resistive isometrics, tense muscles, nodules and bands, painful nodules and bands (active), and non-painful nodules and bands (latent). In bone palpation, nodules in bone membrane can be identified through movability of nodules. The deeper the nodule, the less mobile it is, with a progression of: superficial fascia > deep fascia > bone membrane. To differentiate tenderness at the deep facia level from tenderness in the bone membrane, practitioners can apply different vectors of pressure: vertical pressure and oblique pressure produce the same tenderness at deep fascia level, while vertical pressure feels more tender than oblique pressure at the bone membrane level.

C-Nerve Network Counter-Stimulation acupuncture also emphasizes the use of distal acupoints. Generally, known meridian theory is the clue to identify the distant acupoint. However, finding distal acupoint can also go beyond the known meridian system. Instant effect is the key to finding distal acupoint: Biao-Ben (branch-root) relation is demonstrated when a distal acupoint reduces the tenderness of the local acupoint instantly. Distal points can be found using the following techniques: locating distal acupoints in the same meridian (the Five-Shu acupoints in the same meridian; other acupoints in the same meridian); locating distal acupoints in the same-name meridian (the Five-Shu acupoints in the same-name meridian, and other acupoints in the same-name meridian); locating distal acupoints in other body parts (ear acupoint, scalp acupoint, navel acupoint).

Adjustment of body position is important in identifying treatment sites and performing treatment on the sites/points. The goal is to adjust the patient's position so that the tissue can be stimulated in relaxed condition. This technique is not only used in locating He-sea acupoints (which is documented in the *Huangdi's Internal Classic*), but other points too, especially five-shu points. The fact that patient position is important to improve therapeutic effects is well-known in both Chinese and Western medicine. Counter Stimulation therapy can be taken as a diagnosis procedure to identify the affected meridian and acupoints. Counter Stimulation therapy can also be employed as a therapeutic procedure, used in manual therapy, acupuncture and moxibustion. Instant effect is the criteria of diagnosis and treatment. C-Nerve Network Counter-Stimulation acupuncture increases therapeutic effect, repeatability of outcomes, compliance of patients, and confidence of practitioners.

C-Nerve Network Counter-Stimulation acupuncture does not consider the issue of sham acupuncture versus true acupuncture to be significant. It focuses on applying effective stimulation to points/sites using the correct techniques. It emphasizes the identification of local sensitive points through five-body (sinew, vessel, flesh, skin and bone) palpation techniques, and the identification of distal sensitive points with guidance from the meridian network and adjustment of body positions. All these protocols are partially documented in the *Huangdi's Internal Classic* and can be explained by C-nerve network theory. LENG San-hua's C-Nerve Network Counter-Stimulation model rationalizes those seemingly-contradictory findings in the clinical trials, and his clinical experience and teaching validates his C-Nerve Network Counter-Stimulation model. It is a model that reconciles modern clinical trial data and classical acupuncture techniques. It demonstrates that locating dynamic acupuncture points with correct rediscovered palpating techniques resolves those clinical trial quandaries and improves clinical effectiveness. No statistical difference in clinical trials 1–9 is explained by their violating C-Nerve Network Counter-Stimulation model principles in treatment protocols of treatment groups and significant statistical difference among clinical trials 14–16 is explained by their following C-Nerve Network Counter-Stimulation model principles in protocols of treatment groups.

Conclusion

Modern clinical trials have produced controversial data interpretation which refutes conventional standard teachings and practices. Acupuncture scholars and practitioners have been stimulated to scrutinize these trials and analyze conventional practices. LI Yong-ming's Balloon model and LENG San-hua's C-Nerve Network Counter-Stimulation model addressed these issues. LI Yong-ming's Balloon model rationalizes the clinical trial results with newer understanding of acupuncture points and techniques and how acupuncture works, while LENG San-hua's C-Nerve Network Counter-Stimulation model reconciles these results with rediscovered techniques of palpating points and performing needling. Li Yong-ming's Balloon model explains well why clinical trials 1–9 demonstrated no statistical difference between the treatment group and control group. Just as significantly, LENG San-hua's C-Nerve Network Counter-Stimulation model explains well why clinical trials 11, 12 and 16 did demonstrate a statistical difference between the treatment group and the control group. These two models are indications that acupuncture is in transition from classical model to evidence-based models.

Electronic Supplementary Material Supplementary material (Appendixes 1 and 2) is available in the online version of this article at https://doi.org/10.1007/s11655-019-3177-5

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