

## • Review

# Can a science-based definition of acupuncture improve clinical outcomes?

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### ABSTRACT

Research on acupuncture has been muddled by attempts to bridge the ancient with the modern. Barriers to effectiveness research are reflected in recurring conflicts that include disagreement on use of the most basic terms, lack of standard intervention controls, and the absence of functional measures for assessing treatment effect. Acupuncture research has stalled at the “placebo barrier” wherein acupuncture is “no better than placebo.” The most widely recognized comparative effectiveness research in acupuncture does not compare acupuncture treatment protocols within groups, thereby, mutating large scale effectiveness studies into large scale efficacy trials. Too often research in acupuncture attempts to tie outcomes to traditional belief systems thereby limiting usefulness of the research. The acupuncture research paradigm needs to focus more closely on a scientific definition of treatments and outcomes that compare protocols in terms of prevalent clinical issues such as relative effectiveness for treating pain.

**Keywords:** acupuncture; research; medicine, traditional Chinese

**Citation:** Priebe T, Stumpf SH, Zalunardo R. Can a science-based definition of acupuncture improve clinical outcomes? *J Integr Med*. 2017 April; Epub ahead of print.

### 1 Introduction

Acupuncture as a modern profession should be a straightforward modality that involves the placement of needles at strategic points on the body to promote a healing response. Acupuncture remains intertwined with centuries old non-scientific healing arts known as traditional Chinese medicine (TCM). For example, Hui et al.<sup>[1]</sup> emphasized “the inseparable nature of body–mind–spirit, the centrality of dynamic homeostatic balance, the importance of energetic flow, and self-healing”. This is a confounder in acupuncture research. Research in acupuncture is compromised when the modality is tied to explanations that belong with TCM. Our argument is to unwind this entanglement and conduct acupuncture research according to biomedical principles.

There continue to be forces attempting to drive change, but they have not yet elevated acupuncture to the level of mainstream practice. Avoiding prescientific arguments is one approach towards explaining acupuncture mechanism of action, efficacy and effectiveness. The most widely recognized comparative effectiveness research in acupuncture does not compare acupuncture treatment protocols within groups, thereby, mutating large scale effectiveness studies into large scale efficacy trials. *Acupuncture Medical Treatment Guidelines* describe updated standard scientific methodology for assessing practice outcomes and effectiveness.<sup>[2]</sup>

Acupuncture, like knives, has evolved over millennia. They have ancient origins, modern utility, varied history, and even today, spiritual value. The manufacture of knives has evolved further than has the application of



acupuncture. Acupuncture needs to migrate from a mind-body-spirit medicine described by Hui et al.<sup>[1]</sup> to a healing art based on science. Knife construction has moved past a “hand me down” craft to a precise, replicable, and standardized industry where quality is measured scientifically. Although knife making and acupuncture still value the traditional master-apprentice teaching practices, it is time for acupuncture, like knife manufacture, to advance towards scientific methodology for assessing practice outcomes and effectiveness.

Kendall<sup>[3]</sup> scientifically described the mechanisms of action of acupuncture as based upon early Chinese descriptions of “blood circulation, organization of the cardiovascular system, somatovisceral relationships (communication between the external body and the internal organs), immune system function and the organization of the musculoskeletal system.” The American College of Occupational and Environmental Medicine Guidelines recognized the effectiveness of needling without providing evidence of “meridians” or defining vital energy flow (qi).<sup>[4]</sup>

Acupuncture needles are inserted manually and either “twiddled” by the practitioner or, alternatively, attached to an electric current. These are the only two types of needling procedures that are recognized and reimbursed by insurers.<sup>[5]</sup> As is the case with other health professions, acupuncturists are not necessarily protected by laws that govern their scope of practice.<sup>[4-6]</sup> The most forthright recognition that acupuncture is a mainstream enterprise is the willingness of many insurers to pay acupuncturists for needling therapy.

In the biomedical world (which we refer to as the mainstream in this paper), research is an important driver for assessing cultural and social authority of a health profession.<sup>[7-9]</sup> It is therefore imperative that acupuncture research adheres to research principles as well as mainstream expectations for research models. Fealty to traditional themes may add complexity, raising the bar and occluding the picture. The research process should be straightforward and unencumbered by prescientific notions. We review four domains of acupuncture research—placebo, comparative effectiveness, Deqi and linguistics—to illustrate how fealty to traditional themes needlessly confounds acupuncture research.

Research bolsters the credibility of any health profession. Since being legally recognized as a medical profession in the 1970s acupuncture has relied on a legacy of “ancient tradition” to establish its credentials as a valid intervention. Training programs prepare practitioners to deliver outcomes based upon “thousands of years” of practice. This approach holds little value in the biomedical world. Until the Age of Enlightenment, when science emerged as a competing paradigm for understanding the

world, traditional medicines were orthodoxy in healthcare. Traditional medicines were based upon observation of the patient. Systems such as Ayurveda, TCM, and mesmerism were typically tied to the cosmos and other poetic schemes that reflected paradigms of understanding in ancient times. By the early 20th century, biomedicine had established objective scientific theory which vigorously rejected cultural differences, effectively replacing folk medicines as the authoritative healing model.<sup>[7]</sup>

When considered as a single modality instead of a “whole system,” acupuncture is easily adaptable to the biomedical model, fitting nicely into comparative effectiveness research. Variables that might distinguish models for comparison include stimulation—electric or manual, point selection, biomedical responses, and functional measurement of outcomes. Acupuncture treatments are based upon placing needles in combinations of specific points on the body. The ancient correspondence of these points to perennial seasons and cosmological phenomena is incompatible with the scientific method. Biomedical science locates acupuncture points along biological structures. Specific acupuncture points mapped in ancient records have been replicated according to biomedical neurovascular anatomy.<sup>[10]</sup> Combinations of points are specified as treatment strategies for specific injuries. The mechanism of action has been described in scientific terms as the movement of blood, stimulation of nerve points, and release of other bodily fluids to injured areas.<sup>[10]</sup> Physical effects and outcomes have been demonstrated in studies of needling therapy; however, outcomes are rarely correlated to common variations in technique: e.g., the insertion of the needles according to particular locations of particular points for a particular diagnosis, depth of needle insertion, and stimulation by “twiddling” versus electric current. Interestingly, there are numerous studies comparing acupuncture to the use of drugs and surgery to treat pain; however, the acupuncture treatment protocol frequently fails to meet standards of actual practice. Acupuncture is not researched as it is practiced by acupuncturists.

In this paper we describe investigative areas in acupuncture that illustrate efforts to make the transition to a biomedical model. In certain cases, such as linguistics, that transition may be inherently contrary to the study of language rules. If this is the case, then it is fair to conclude the examination of linguistics in the study of acupuncture should be paradigmatically neutral. In other cases, such as the investigation of the Deqi phenomenon, the transition from the traditional to the biomedical model illustrates how the transition can be successfully undertaken. In fact, the number of studies may be growing that focus on a biomedical approach, to test the effectiveness of incorporating specific acupuncture points

to yield specific outcomes.<sup>[10]</sup>

## 2 Placebo research in acupuncture

Acupuncture research has reached as far as the “placebo barrier” wherein acupuncture is “no better than placebo”.<sup>[11]</sup> Kaptchuk is the foremost researcher who focuses on acupuncture as placebo. He is recognized as one of the most prolific among acupuncture and complementary medicine researchers since publishing his classic book synthesizing Chinese and mainstream contemporary medicine.<sup>[12]</sup> Since 1996, Kaptchuk’s interest in the placebo effect has expanded. His early position seemed to focus on whether any positive effects other than placebo could be attributed to acupuncture. His current interest has grown to include placebo in the history of medicine.<sup>[13]</sup> He argued that placebo research must move beyond the view wherein placebo signifies a failure, instead investigating it as a straightforward clinical outcome; “We need more research involving clinical interventions designed to elicit placebo effects in participants without deception ... we need to know precisely when, how and in what dose ... these interventions can provide therapeutic benefit.”<sup>[14]</sup> Kaptchuk applied the “dose × frequency × duration” model to a meta-analysis of complementary and alternative medicine (CAM) therapies limited to supplements and herbs used for treating irritable bowel syndrome.<sup>[15]</sup> The study is of interest here because it pooled CAM interventions excluding acupuncture and discussion of traditional, non-scientific considerations.

Despite Kaptchuk’s best arguments, placebo effectiveness is viewed as damaging to clinical outcomes research. By contrast, comparative effectiveness research occupies one of the highest rungs on the research ladder. In our view, the most renowned studies of comparative effectiveness in acupuncture research, i.e., the “German studies” did not measure up to Kaptchuk’s standard of when, how and what dose.<sup>[16]</sup> Comparative effectiveness research in clinical applications should demonstrate cost savings and improved outcomes when comparing techniques or procedures. The model must be specific, as acupuncturists and researchers will attest.<sup>[17]</sup> Standardization is necessary when comparing outcome measures, targeted points, diagnoses, and experimental/control models.

## 3 Comparative effectiveness research in acupuncture

Placing acupuncture within traditional medicine leads research away from the medical mainstream. The result is a continuing struggle for acupuncture research to demonstrate consistent, prevailing treatment impact as

a modality. Effectiveness studies require sample sizes larger than those used in efficacy or mechanism of action studies.<sup>[18]</sup> A set of controlled trials by Witt<sup>[16]</sup> claimed to demonstrate acupuncture effectiveness for the first time on large scale single studies and without combining studies. These large scale studies were superior to meta-evaluations that combined results from smaller studies. The German studies included treatment for acute and chronic osteoarthritis of the knee, headaches and low back pain.<sup>[19,20]</sup> Witt<sup>[16]</sup> described her studies as “pragmatic research” which she interpreted as comparative effectiveness research (CER). This description is imprecise. CER is concerned with what works best for patients given existing health care interventions. The purpose is to compare benefits and harms within groups.

The German studies sidestepped testing particular acupuncture protocols. Witt and co-authors left the treatment protocol—whether “traditional” or “biomedical”—to the treating clinicians. The clinicians selected acupuncture points, treatment frequencies, and diagnostic paradigms that diverged on how, when and dosage. Studies that strictly adhere to the study of acupuncture as a modality that employs the use of acupuncture points are uncommon. Napadow et al.<sup>[17]</sup> compared frequency of use for points and point clusters in two Beijing hospitals where acupuncture was commonly practiced. The researchers standardized on specific points; however, they did not standardize on illness or “complaint”. Data were collected in the milieu as practice actually occurs. They found practitioners used a “core of very frequently used points across many different conditions.” They concluded some acupuncture points were helpful for many conditions while other points had very narrow uses.

## 4 Deqi studies split on biomedical science versus cultural tradition

Arbitration of the Chinese word “qi” is a cultural and not a scientific activity. The arguments are long lived. The *Chinese Medical Terminology* textbook commonly used in acupuncture training programs states the following. Qi has a science and evidence-based meaning as “air or gas” and a cultural implied meaning of “energy or life force”, with reference to human physiology or anatomy.<sup>[21]</sup> The antipodal arguments are visible in recent research on a related traditional concept. Deqi is an ancient concept viewed as an indicator of a powerful response to acupuncture needling. Zhou et al.<sup>[22]</sup> conducted research to distinguish Deqi as something other than “neurophysiological aspects.” He pointed out that “Indeed, one of the main criticisms of acupuncture remains the lack of scientifically acceptable data and quantifiable efficacy.” Zhu et al.<sup>[23]</sup> explained that Deqi was a “needling sensation” which



they attributed to subjective feelings of the patient. The traditional view is that Deqi can also be attributed to the practitioner who is regarded as the more powerful source for eliciting Deqi. They used survey methods common in scientific research to capture the descriptions of the patients' feelings. They pointed out that common Deqi survey scales, i.e., the Massachusetts General Hospital Acupuncture Sensation Scale, the Subjective Acupuncture Sensation Scale, and the Southampton Needle Sensation Questionnaire, failed to correlate with each other as well as with the most commonly used medical pain scales, e.g., the visual analog scale.<sup>[24,25]</sup>

Recent Deqi research has attempted to cross the subjective with the objective experience, and the traditional with the scientific views.<sup>[26]</sup> Outcomes which might verify the Deqi experience were measured by observed clinical outcomes. For example, Zhou et al.<sup>[27]</sup> tested for soreness when acupuncture was applied to acupuncture points along the spine. They found significant differences in the patient's experience of "soreness, fullness and heaviness" which are classic Deqi descriptors. These conditions were specifically tied to specific acupuncture points (ST28–ST36 and CV4–CV12). They could not attribute "obtaining the Deqi sensation" to needling along the points; however significant differences of Deqi intensity were found in soreness, fullness, and heaviness between ST28–ST36 and in fullness between CV4–CV12. Streitberger et al.<sup>[28]</sup> conducted an ultrasound imaging study in an attempt to link the Deqi sensation to a specific acupuncture point, PC6. He found no correlation even when the needle was inserted directly in the nerve. Zhou et al.<sup>[27]</sup> concluded it was possible Deqi was elicited through the central nervous system where regular neuronal activity of the paralimbic system and subcortical structure of the brain may initiate a series of cascade reactions to ultimately restore homeostasis.

Tian et al.<sup>[29]</sup> observed increases in blood flow, tissue displacement and the amplitude of myoelectricity along key acupoints after Deqi had been elicited. They concluded that quantitative measurement of these biophysical phenomena presents the best opportunity to confirm the validity of acupuncture. They also observed that other Chinese acupuncture researchers commonly aspire to demonstrate the "existence of ancient concepts" and their medical effect on health. Tian et al.<sup>[29]</sup> concluded the historical failure to describe Deqi in scientific terms is not a failure of science. It is an insistence in adhering to cultural concepts that do not easily translate to science. These failures are the function of belief systems and cultural homogeneity. Shiro et al.<sup>[10]</sup> explained the Deqi phenomenon in biomedical language: *In conclusion, acupressure at three distal acupuncture points, LI4, LI10 and LI11, maintained higher level of the high frequency*

*components of heart rate variability and blood flow and oxygenation of the trapezius muscle, compared with acupressure at three distal acupuncture points, ST34, ST36 and ST41.*

## 5 Linguistics in acupuncture research

Chinese "words" frequently have more than one meaning.<sup>[21]</sup> The symbol for "qi" can mean air or gas as well as "energy or life force". For acupuncture traditionalists the word "qi" implies a dynamic functional view of all body systems.<sup>[30,31]</sup> The word "energy" is central to the cultural description of acupuncture and cannot be separated from Chinese medicine.<sup>[32,33]</sup> According to this view acupuncture works by releasing blocked energy circulating through invisible meridians. Use of these and similar terms when describing needling therapy is central to the claims, beliefs and practices among a cohort of TCM and acupuncture practitioners unconcerned these ideas have not been demonstrated scientifically. Schnorrenberger<sup>[30]</sup> has argued acupuncture finally needs an anatomical nomenclature for daily practice and scientific research. Yang et al.<sup>[34]</sup> has attempted to resolve the mysterious balance of yin and yang with the biophysical, i.e., positive and negative charge or matter and anti-matter.

*These are not prejudices if one takes it as sun and moon, positive and negative charge, or matter and anti-matter. However, we must focus on the science alone as there were quite a bit of superstitions, mystics, voodoo, and philosophical musing in the ancient world that should have no place in our scientific thoughts.*<sup>[34]</sup>

Kendall, Kavoussi and Unschuld are among multiple cultural/historical researchers who argue that roots of acupuncture are European.<sup>[3,32,33]</sup> Dorfer is one of several medico-anthropologists who have argued that antecedents to Chinese medicine can be documented in the discoveries of preserved ancient peoples with tattoos located close to or at Chinese acupuncture points.<sup>[35]</sup> Another argument challenging foundations of Chinese medicine is that Chinese language frequently provides for multiple meanings of a term. Therefore, pinning one meaning to any single word or pictograph such as qi requires considerable parsing. The non-traditional views of historical medico-anthropologists, including those referenced above, are regarded as competitive, even, heretical among certain Chinese medicine cultural/historical stalwarts.<sup>[36,37]</sup>

A more nuanced and less contentious view is argued by the linguists. Pritzker<sup>[38]</sup> argued that Chinese medicine is embedded within social relationships. The very nature of translating Chinese medical terms is fraught with secondary and tertiary agenda such as social positioning



and interpersonal relationships. An appraisal of key terms and their roots in Chinese medicine is neither antithetical nor oppositional to a unique Chinese view of medicine and the treatment of illness. Pritzker<sup>[38]</sup> has described similarities in the ways in which Chinese medicine views a patient and how that holistic view is arguably close to the current Western patient-centered view.

*... illness is understood as a constellation of patterns and presentations that together reflect the unique interaction of constitutional, environmental, lifestyle and psychosocial processes in each individual. In Chinese medicine, diagnosis is thus made as an assessment of the particular “set” of disharmonies affecting a given individual. These disharmonies are ascertained through a combination of diagnostic techniques, including detailed history taking, close observation, tongue and pulse diagnosis and palpation.*<sup>[38]</sup>

The question is to what extent the linguistic approach aligns with the biomedical or the cultural/historical view. Pritzker was engaged with the dual approach that we have described as historical/cultural and biomedical. She acknowledged that “language standardization” translation was “central in efforts to integrate Chinese medicine into a global, mainstream medical framework.” She also pointed out that language was a source of variability as students “grapple with multiple translations” attempting to fit Chinese medicine into a framework of personal meaning.<sup>[38]</sup> For linguists such as Pritzker, Chinese medicine is a fluid practice that, when properly translated, captures “human interactions, political and moral commitments, and theoretical stances” that are in play when translating Chinese medical texts.<sup>[39]</sup> Linguists who align with this point of view argue that translation standards are important given the globalization of Chinese medicine.

Pritzker describes a “tension” between “biomedical” and “anti-biomedical” camps that has proved “contentious” for more than a decade. In our view, this tension extends into the research domain. Rather than struggle to identify a plausible or even popular approach or method for treating with acupuncture, e.g., this set of points for this particular symptom, acupuncture researchers such as Witt elect to work with a very simplified point standard or allow providers to use whatever approach they prefer. Is this not the same phenomenon among rival translation camps, each of which supports their particular set of terms and understandings? Ambivalence and variability on this scale will predictably undermine outcomes in research.

## 6 Acupuncture and regulation

Points of view that might guide acupuncture research are irrelevant in the legislatively defined Workers Compensation healthcare system in California which

specifically includes acupuncturists as eligible providers.<sup>[2]</sup> Within the Workers Compensation world acupuncture and acupuncturists are legally obligated to provide evidence-based treatment. The California Medical Treatment Utilization Schedule and the Acupuncture Medical Treatment Guidelines are science-based, and considered to be presumptively correct in describing acupuncture effects.<sup>[2]</sup> Workers Compensation and Personal Injury cases require that approved medical modalities and procedures be legally defensible. Treatment must be assessed by measuring functional outcomes for all interventions. Guidelines for chronic pain and guidelines for intra-disciplinary practice require medication documentation, weekly functional progress reports, and monthly reports assessing strength, endurance, range of motion and behavioral changes. “Functional improvement” is indicated by a clinically significant improvement in activities of daily living or a reduction in work restrictions. The baseline is measured at the outset and repeated with each treatment cycle.

## 7 Discussion

The German studies were successful in showing that acupuncture effectiveness can be demonstrated when the sample is sufficiently large. However, these studies did not test for effectiveness in terms of specific treatment models; modalities yes, but models no. Research that has helped identify which models of treatment, e.g., electrical versus manual, or which sets of points work best for this disorder or that disorder, is rare. By contrast, the Deqi studies specifically compared acupuncture points that would be most likely to produce the Deqi effect. The German studies avoided the divided camps while the Deqi researchers made a point of utilizing traditional, mixed and exclusively biomedical models. The linguists recognize the role of context in translating essential historical and cultural concepts. Language translation is influenced by numerous factors that change meaning and understanding. When it comes to healthcare, these factors confound rather than simplify or pinpoint effective treatment. This is a shortcoming for the profession as a whole.

The absence of scientific research standards in acupuncture research can lead to claims that test one’s belief in acupuncture. Community acupuncture is a business model that treats patients in group settings wherein multiple patients are experiencing needling therapy collectively, i.e., in the same room at the same time. This is a viable approach which could actually improve economic benefit for licensees. However, some of these clinics have claimed that treatment in groups creates “communal qi” thereby elevating the therapeutic



value of acupuncture treatment. Consumer advocates have challenged advertisements about the existence and the benefits of “communal qi”.<sup>[40]</sup> Without a scientific platform such claims are likely in violation of Section 5 of The Federal Trade Commission (FTC) Act which “empowers the FTC to address deceptive or unfair acts or practices about any product intended to affect consumers’ behavior and/or assessments about that product.”

## 8 Conclusion

Chinese medicine is rife with conflict and issues of ownership. Such differences have profound effects. For example, the terms biomedicine or Western medicine are commonly used by the field instead of simply medicine. Acupuncture is used interchangeably with the terms traditional Chinese or Oriental medicine. The battles over clinical terms and translation of Chinese texts remain a healthy exercise for many experts. However, the widespread use of traditional terms confounds the ability of acupuncture, or needling therapy, to find a useful place in US medicine. Description and explanation of acupuncture’s therapeutic effects as a neurochemical phenomenon along with otherwise medico-scientific conventions is hardly novel.<sup>[41]</sup> Despite decades of scientific arguments that support a biomedical model, steadfast insistence on the use of traditional terms remains a standard in the conduct of acupuncture research. The use of prescientific language in place of medical language commonly used in mainstream healthcare is harmful to the profession, practitioners and the public. It is our view that this insistence frequently dissolves into a defensive posture that places the patient at risk. This same view compromises and hamstring practical outcomes in acupuncture research.

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