

Applying Evidence-Based Medicine to Traditional Chinese Medicine: Debate and Strategy

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ABSTRACT

Drawing on recent paper published literature in both English and Chinese, this explores reactions to the evaluation of Chinese medicine using randomized controlled trials (RCTs) and the standards of evidence-based medicine (EBM). The literature review revealed a few sources which contend that Chinese medicine should not be evaluated on the basis of RCTs, but a far greater number which advocate for applying RCT and EBM standards to Chinese medicine. This paper describes the position of the detractors and points out ways in which their arguments contain oversimplified representations of Chinese medicine, biomedicine, EBM, and RCTs. In describing the position of the proponents, the analysis outlines some of the numerous innovative techniques they are developing for dealing with issues of control and standardization in efficacy research. Overall, the analysis indicates that important refinements are being generated in Chinese medicine research and clinical trial design in response to the challenges posed by the forced encounter of these two paradigms.

INTRODUCTION

Over the past decade biomedical health care institutions have increasingly united around evidence-based medicine (EBM) as the preferred method for determining the most efficacious way to provide health care to patients. EBM has been constructed as an empirical challenge to conventional assumptions about treatment efficacy, which have often been based more on untested theories of mechanism, the authority of mentors, or clinical experience, rather than on scientific evidence.¹ The “gold standard” of evidence for treatment efficacy within EBM has come to be a systematic review of randomized clinical trials (RCTs) with double-blinding and placebo or sham procedures.² Although not discounted entirely, other forms of evidence, such as that resulting from observational research or case studies, are considered much lower down on the evidentiary hierarchy.

Considerable debate has arisen concerning whether EBM constitutes a truly legitimate approach to find the best ways to care for patients, or instead represents a naive view of scientific objectivity, a depersonalized bureaucratization of “care,” or a veiled calculus for cutting costs and wresting control from clinicians.^{3,4} Difficulties have been raised for

biomedicine and complementary and alternative medicine (CAM) alike, but more so for the latter. Some sources have argued that CAM can be “evidence based,”^{5,6} while others have refuted this assertion.⁷ Some have contended that only certain forms of CAM have the potential to be “evidence based” or that current EBM standards are more appropriate to some forms of CAM than others. A suggested compromise is that CAM can be “evidence based” if certain modifications are made either to CAM practices⁸ or to EBM standards of evidence.² Those who have suggested either considerable or insurmountable challenges to making CAM “evidence based” have differed on whether they place responsibility for these obstacles more with CAM practices⁸ or current formulations of EBM.⁹ Disagreement also exists as to whether CAM should, in fact, be “evidence based,” that is, whether current EBM standards constitute a fair arbiter for non-biomedical forms of healing.¹⁰

Chinese medicine provides an important vantage point from which to explore this debate. Chinese medicine is a broad set of healing theories and practices whose practitioners trace its origins to ancient Chinese texts dating back over 2000 years. Today Chinese medicine is not only widely practiced in China through an officially sanctioned refor-

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mulation known as Traditional Chinese Medicine (TCM) dating back to the late 1950s, but is frequently used by Chinese in diaspora, and is becoming increasingly popular among non-Chinese in many countries. Theories commonly associated with Chinese medicine include notions of the flow of *qi* and the balancing of complementary opposites; associated therapeutic practices include acupuncture and herbal medicine.

Recent literature on Chinese medicine addresses epistemological, ontological, methodological, and strategic challenges involved in incorporating RCTs and the standards of EBM. A

few authors contend that Chinese medicine should not be evaluated based on RCTs, detailing their reasons against modern Western scientific methods of determining efficacy. A far greater number of sources advocate for applying RCT and EBM standards to Chinese medicine and propose a variety of innovative strategies of mutual accommodation. This paper describes these positions and points out limitations on both sides. Overall, the analysis suggests that the challenges posed by the forced encounter of these two very different paradigms are generating important refinements in both Chinese medicine research and clinical trial design.

SOURCE MATERIALS

Journals consulted

Alternative Therapies in Health and Medicine
American Journal of Acupuncture
American Journal of Chinese Medicine
Annals of Internal Medicine
Archives of Otolaryngology—Head and Neck Surgery
British Medical Journal
Chinese Journal of Integrated Traditional Chinese and Western Medicine (Zhongguo Zhong Xi Yi Jiehe Zazhi)
Clinical Acupuncture and Oriental Medicine
The Cochrane Database of Systematic Reviews
Complementary Therapies in Medicine
European Journal of Oriental Medicine
Evaluation and the Health Professions
Health Technology Assessment
Hong Kong Medical Journal
Journal of Alternative and Complementary Medicine
Journal of Chinese Medicine
Journal of Clinical Pharmacology
Journal of Law and Medicine
Journal of Law, Medicine, and Ethics
Journal of Traditional Chinese Medicine
Journal of Chinese Integrative Medicine (Zhong Xi Yi Jie He Xue Bao)
Journal of Evidence Based Medicine (Xuzheng Yixue Zazhi)
Pain
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See also reference list (pp. 262–263).

MATERIALS AND METHODS

I enter this research as a cultural anthropologist who has studied the Chinese language, culture, and history for two decades and has lived in China for several years during that time. I reviewed a variety of journal articles on Chinese medicine and efficacy issues, including items written in both English and Chinese (see box entitled Source Materials). While emphasis was placed on journal articles, several books were also consulted. This literature was accessed mainly through the bibliographic databases MEDLINE, Expanded Academic ASAP, and WorldCat, using the search terms evidence based, complementary and alternative medicine, and Chinese medicine.

THE CASE AGAINST

Articles arguing that Chinese medicine should not be assessed by the standards of EBM and RCTs are in a minority, and issue from both Chinese and non-Chinese authors. Churchill, for example, argues that “EBM is not neutral” and is biased toward the “biomedical paradigm” and against Chinese medicine.⁹ Freuhauf criticizes how Chinese medicine “feels compelled to scour for legitimacy by conducting ‘scientific’ tests that conform to the parameters of Western medicine.”¹¹ Fan maintains that “randomized clinical trials” were inappropriate as the “standard method” by which to assess Chinese medicine.¹⁰ These authors ground their resistance against the evaluation of Chinese medicine based on EBM standards and RCTs in a contention that these frameworks presume the “objectivity” of the evidentiary practices of modern Western science and privilege the epistemologies, ontologies, and practices that underlie biomedicine. They hold that notions of evidence underlying EBM standards and RCTs entail a series of assumptions that are incompatible with theories and practices central to Chinese medicine.

In alluding to the ways in which they feel that Chinese medicine is fundamentally different from modern Western science and biomedicine, these authors point to numerous dimensions. These dimensions include Chinese medicine’s emphasis on real-life observation, personal experience, the therapeutic encounter, the subjective basis of diagnostic procedures, syndrome differentiation, myriad diagnostic categories, tailoring treatment to individual differences, situation-specific flexibility, attention to time and place, natural healing through balancing bodily processes, qualitative measurement of outcomes, holism, complexity, multiple influences, interconnected processes, interdependent connection between person and macrocosm, the body as an ever-changing nexus of functional processes, and legitimacy grounded in ancient wisdom. In contrast, they assert that modern Western science and biomedicine place priority on artificially controlled settings, external technical measurements, diagnosis of disease, limited diagnostic categories, standardization, group averages, technological interventions, quantita-

tive technical measurement of outcomes, disarticulated anatomical structures, reductionism, isolated causes, the microscopic level of bodily biochemistry and molecular physiology, separation of person from their environment, the body as an assemblage of material structures, and legitimacy based on modern science.¹⁰

In eschewing the evidentiary priorities of EBM, these authors advance a constructionist view of knowledge based on the premise that it is impossible to perceive an objective material reality; instead, all observations of the world must be mediated through perceptual lenses afforded by cultural concepts or theoretical ideas. Drawing upon classical notions linked with philosophy of science and citing scholars such as Kuhn,¹² they argue that biomedicine, EBM, and RCTs are based on a theoretical framework or “paradigm” entirely “incommensurable” with that of Chinese medicine. Taking a relativist stance, they insist that neither paradigm is more objective than the other; rather, each theoretical framework merely contains different conceptual tools through which to attain a distinct vantage point on the world we inhabit. With regard to the notion of evidence, Fan elaborates that “every theory conforms with some, but not all, empirical evidence. More importantly, empirical evidence is itself theory-laden. A piece of empirical information taken by one theory as its supporting evidence may not be accepted by another theory as evidence at all.”¹⁰ Churchill adds that since no paradigm has “universal applicability” and “all understanding is relative, limited and provisional,” it is inappropriate to use research techniques from the biomedical paradigm to evaluate Chinese medicine or other forms of CAM.⁹

In making their case, Fan, Churchill, and Freuhauf relate the history through which the rhetoric of “science” has been used over the last century in China to strengthen the position of biomedicine relative to Chinese medicine.^{9–11} They portray Western scientific research methods as being used to subordinate Chinese medicine in China and abroad, and each call for various forms of resistance. Churchill, for example, writes: “The ‘biomedicine is scientific’ argument has been used continuously and mainly successfully in this century to suppress competition, and one can suspect that the call for evidence based medicine is the latest manifestation of this.”⁹ Advocating passive resistance, Churchill suggests that practitioners of Chinese medicine and those in other “CAM professions. . . should not casually consent to EBM as the basis of regulatory decisions, and should question its . . . possible implicit intention to subjugate CAM disciplines to the biomedical agenda.” Fan suggests a more proactive strategy, arguing that while “modern scientific medicine’s use of randomized clinical trials” may be appropriate for biomedicine, “use of individual-sensitive observational studies” would be a more suitable main method for evaluating Chinese medicine.¹⁰ Fan thus calls on the Chinese government to reform the health care system from a “mono-standard integration to a dual standard integration, where modern scientific medicine will be practiced and developed according to the modern scientific standard, and Traditional

Chinese Medicine will be allowed to practice and develop in terms of its own standard.”¹⁰

Limitations

While possessing compelling logic in many respects, these arguments against applying the standards of RCTs and EBM to Chinese medicine are limited in at least three respects. First, although the case against RCTs for Chinese medicine is attentive to power in the sense of tracing the history of biomedical science’s rise to dominance, it is arguably unrealistic when suggesting that Chinese medicine practitioners either simply refuse to go along with current formulations of EBM or propose a dual standard system. This involves ignoring the current “legitimizing context”^{4,13} in which both biomedicine and Chinese medicine are currently embedded both in China and abroad. Refusing to participate is becoming increasingly difficult as the value placed on RCTs spreads globally through channels such as the Cochrane database project.¹⁴ Churchill’s suggestion that this is an issue of “the individual’s freedom of choice in health issues and paradigm choices”⁹ does not resolve the dilemma since policies, regulations, and funding that create the context for individual practice are becoming increasingly indexed to EBM criteria both in China and elsewhere. Attempting to establish a dual standard for efficacy is also unlikely to be viable since it would be easily construed as a double standard that sets inferior criteria for Chinese medicine. Also, in practice many biomedical clinicians strive to tailor treatments to individual patient circumstances and feel that there are treatments not yet formally researched which clinical experience has shown to be effective.¹⁵ Since individual case observations are not foreign to biomedical practice, it is difficult to justify not counting them as equally valid evidence for biomedicine as for Chinese medicine.

Second, the arguments against RCTs for Chinese medicine presented above tend toward an oversimplified view of Chinese medicine, biomedicine, EBM, and RCTs. The tendency to exaggerate differences and underestimate similarities between Chinese medicine and biomedicine has been remarked upon in broader context by China scholars such as Unschuld¹³ and Scheid.¹⁶ In this case, the above arguments overlook the fact that EBM and the priority it places on RCTs were initially instituted precisely because biomedical clinicians were engaged in many of the practices that are typically aligned with Chinese medicine—acting on the basis of subjective experience, case observations, and the advice of mentors.¹ They also fail to note how effects of EBM on the regulatory environment are frustrating for many biomedical clinicians who want to maintain control over clinical decision-making and provide personalized care.³ In the process of comparison, they forget the diversity that sits under the umbrella of biomedicine.

These arguments rejecting RCTs also gloss over much of the social complexity that has constituted Chinese medicine both at present and in the past. This is related to not ade-

quately distinguishing between ideals and practice and between representations and reality. While Chinese medicine is popularly viewed today as a longstanding unitary tradition constituting a “coherent body of knowledge,”¹⁷ in fact, Chinese medicine is a continually evolving *mélange* comprised of a wide diversity of theories and practices which have only recently been recognized as one “tradition.”^{13,16,18–20} While often presented as ancient tradition, Chinese medicine today is very different from what it was prior to concerted contact and competition with biomedicine over the last century.^{11,16} Although represented as tailoring treatment to individuals and to multiple situational factors in a virtuoso-like manner, in clinical practice Chinese medicine is sometimes dispensed in a rather woodenly formulaic way.¹⁶ Observations in contemporary China show that some practitioners who work in busy clinics have little time to spend with each patient. Some past and present physicians have prided themselves on gaining all the information they need for a diagnosis from the pulse, without requiring the patient to tell them their complaint.²¹ In addition, some Chinese medicine practitioners in China today see incorporating more technology and laboratory tests into their practice as a way to advance Chinese medicine.¹⁶

Emphasis in these arguments on the importance of syndrome differentiation in determining treatment is a prime example of the mismatch between representations and reality. Presented by many contemporary practitioners as a unified approach central to Chinese medicine since its origins,¹⁶ *bianzheng lunzhi* can be translated as “determining treatment on the basis of discerning the syndrome.” China scholars have elaborated that this entails deciding on treatment based on the complex pattern of symptoms and signs observed in the patient within the context of his or her distinctive constitution, current circumstances such as the season, and the present constellation of his or her bodily processes.^{16,19} As in Fan’s paper, the special efficacy of Chinese medicine is commonly said today to be rooted in *bianzheng lunzhi*.¹⁰ In this vein, discussions of the difficulty of applying the RCT design to Chinese medicine stress that while biomedicine assigns standardized treatment based on disease categories such as diabetes, Chinese medicine tailors individualized treatment based on syndromes, such as *shen xu* or deficiency of the process translated as the “kidney.”²² As a result, diseases seen as distinct in biomedicine may be diagnosed as the same syndrome in Chinese medicine, and distinct syndromes in Chinese medicine may be diagnosed as the same disease in biomedicine. RCT detractors such as Fan assert that it is impossible to conduct valid RCTs on Chinese medicine because if syndrome differentiation was used, its radical individualization would result in small numbers in the same treatment group, yielding results lacking statistical significance.¹⁰ Yet, if, to avoid the $N = 1$ problem, Chinese medicine treatments were tested within a biomedical diagnostic framework, the results would be equally meaningless because Chinese medicine’s fundamental essence would be violated.

Scheid provides historical and ethnographic research data to show that *bianzheng lunzhi* was not a central orthodoxy or a coherent conceptual system in Chinese medicine in ancient China.¹⁶ Rather, a wide variety of diagnostic traditions coexisted in imperial China, and some practitioners “openly questioned the necessity of patterns to guide treatment” and advocated one standard medicine for each disease.¹⁶ The central position of *bianzheng lunzhi* as a long-standing, coherent, defining feature of Chinese medicine is a twentieth-century Chinese creation in which the “eight rubrics” (*yin/yang*, cold/heat, interior/exterior, and depletion/repletion) came to subordinate the myriad other historical diagnostic traditions.¹⁶ Over the past five decades, this emphasis has been used to differentiate Chinese medicine from biomedicine, stress its scientific character, assert a distinctive basis for its efficacy, and establish a palatable patriotic association with China’s “heritage.”¹⁶ In turn, the stress on syndrome differentiation has also involved cultivating public consciousness of Chinese medicine as superior to biomedicine in getting at the root cause of a problem, preventing illness and treating chronic conditions, and avoiding side effects.¹⁶ Scheid’s ethnographic research has shown that in “clinical practice. . . *bianzheng lunzhi* remains but one of a number of diagnostic and therapeutic strategies employed by physicians,” and “many textbooks” and much research is moving away from “syndrome differentiation” and toward “type differentiation” in which biomedical disease categories are used as the main rubric and then “subdivided into several distinct Chinese medicine patterns.”¹⁶

The anti-EBM case presented above also caricatures EBM and RCTs in a manner that overstates the limitations inherent in these techniques. Despite intimations to the contrary, while RCTs provide the highest level of evidence in current EBM criteria, evidence obtained from other research designs such as case studies is not excluded.¹ Current formulations of EBM clearly note that sometimes case observation studies or clinical experience will be “the best evidence available,” whatever form of therapy is being examined.⁴ Furthermore, despite assumptions otherwise, patient perspectives on treatment efficacy and experiential aspects of a clinician’s craft can be taken into account in RCTs through systematic questioning.²³ Detractors underestimate the creativity possible in accommodating Chinese medicine and RCTs to each other. While some RCTs on Chinese medicine therapies are conducted entirely within biomedical diagnostic categories and Western constructs of the body, others strive for a design more in tune with the paradigm of Chinese medicine.

Beyond issues of power, legitimacy, and ideals versus practice, a final limitation is that opponents of EBM do not provide a viable alternative. While offering important criticism, they lack a detailed method of assessment to systematically support their vision of efficacy. Without a clearly delineated alternative mode of evaluation, their notions of evidence remain abstract without clear guidelines for implementation.

THE CASE FOR

While numerous scholars have argued that modern Western science and its evidentiary standards and evaluative procedures are a historical and cultural product based on contingent social values,^{12,24,25} this has not prevented researchers from striving to develop research frameworks that minimize ethnocentric bias. While recognizing certain challenges, articles published by scholars of Chinese medicine from China and other countries are far more likely than not to support using EBM standards and RCTs to evaluate Chinese medicine therapies. Many practitioners and researchers in China and elsewhere view RCT confirmation as a way to advance Chinese medicine, provide better treatment to patients, maintain a respected position alongside biomedicine, and/or work toward a new integrated medicine of best practices.^{14,26}

In this vein, some authors in China have recently criticized Chinese medicine for settling for a low standard of evidence and stressed the importance of complying with EBM standards in order to enhance patient health and increase Chinese medicine’s stature nationally and internationally.^{8,14,22,27} A study in the late 1990s was pivotal in stimulating criticism of the evidence available on the safety and efficacy of Chinese medicine.²⁸ Conducted by Chinese University of Hong Kong researchers, it examined the frequency and quality of RCTs in papers published in Chinese journals between 1980 and 1997. Drawing from a hand search of a stratified random sample of 28 Chinese journals of Chinese medicine (out of 100 extant), together with additional perusal of electronic bibliographic databases including biomedical journals, they estimated a total of 10000 RCTs on Chinese medicine. Scrutinizing the *Chinese Journal of Integrated Traditional Chinese and Western Medicine*, a venue with higher-quality trials and ten times as many RCTs as the other journals, the researchers frequently found problems with methodological quality, including inadequate sample size, inappropriate randomization method, unsuitable control treatments, few blinded trials, inadequate time span, and publication bias such that exceedingly few negative results were reported. The authors concluded that there was a rather large and rapidly increasing number of RCTs on Chinese medicine therapies, but that their quality was usually quite low.²⁸

Referring to the study cited above, recent articles in China have pointed to the questionable quality of evidence in many publications on Chinese medicine. Such articles criticize those Chinese physicians who retain an attitude of “seeing but not acknowledging”²⁸ the shortcomings of certain Chinese medicine treatments. Drawing on idioms important in the history of modern science in twentieth-century China, they urge TCM practitioners to “seek truth from facts,”¹⁴ rather than base their views on unsubstantiated theory or blind loyalty to Chinese medicine. These critics observe a common occurrences of reporting only positive findings, fabricating results, and using specious reasoning to make negative results seem positive.⁸ These authors see compli-

ance with the standards of EBM as critical to the survival, modernization, development, and global extension of Chinese medicine by establishing a more objective, scientific basis for its therapeutic efficacy and safety.^{14,22,26,29-32}

Many authors of these sorts of critiques hail from the China Cochrane Center (CCC).¹⁴ Established in 2000 in the city of Chengdu, this research center is one of 13 sites worldwide, comprising the international Cochrane Collaboration for meta-analyses in EBM. Among other institutionalizing moves that have been made to solidify EBM standards in medical research, teaching, and practice in China, in 2001 the Chinese Ministry of Health inaugurated the *Journal of Evidence-Based Medicine* and launched graduate courses in EBM.³³ CCC member Li Ming has cogently argued that the problem of applying aggregate statistics to individuals does not trump the value of RCTs and meta-analyses.³⁴ Rather, customization should be addressed at the point of treating an individual patient, at which time the clinician should check whether the patient is significantly different from the subjects tested, a point also made by Sackett et al.¹

Advocates of RCTs offer numerous methodological innovations to accommodate the characteristics of Chinese medicine. These discussions generally deal with two main areas: designing appropriate control measures and developing means of standardization. Discussions of control measures have tended to focus on acupuncture, although the complex experience afforded by herbal decoctions raises some similar issues. Berman,^{35,36} Lao et al.,³⁷ Birch and Felt,³⁸ Hammerschlag,^{39,40} and other leading acupuncture researchers have provided excellent reviews of the numerous specialized control measures that have been developed for acupuncture trials. These include nonacupuncture inert controls, placebo acupuncture, sham acupuncture, real acupuncture with a decoy treatment, waiting list controls, standard care controls, and adjunctive care comparisons. I will focus my remarks on issues involving standardization, using examples from both acupuncture studies and herbal trials.

The ideal of customization in Chinese medicine is challenging to reconcile with the RCT requirement of standardization. In the current ideal, Chinese medicine is predicated on the need to tailor both diagnosis and treatment to the individual patient and circumstances. Practitioners are expected to tailor specific herbal combinations and/or acupuncture treatments to the patient's individual mind-body constitution, as well as to their social and natural environment. Thus, two patients coming into a clinic with the same biomedical ailment may receive different diagnoses due to perceived etiological differences, or to patients having different physical constitutions, combinations of ailments, ages, genders, or lifestyles. Furthermore, the same patient with the same problem might receive a somewhat different prescription depending on the season. While this ideal is difficult to achieve within an RCT, nu-

merous creative strategies have been developed that strive to respect the character of Chinese medicine.

Tang and Leung criticize the argument that RCTs "cannot be applied to TCM as such trials require similar patients requiring similar treatments."²² They point out a similar criticism of the use of RCTs in biomedicine, which states that there is too much individual variation for aggregate statistical results to be useful in clinical practice. They argue that while much individual variation exists, often it is not relevant to treatment efficacy. Since TCM has a "limited number of identified 'syndromes'" and patients with similar syndromes are often prescribed similar treatments, it is just as possible to apply RCTs to Chinese medicine as it is to biomedicine.²² This point is underscored by Scheid's observation that in the mid-1990s China enacted national standards for "diagnosis and therapeutic efficacy" for 406 diseases and syndrome patterns and instituted an official manual of "clinical terminology."¹⁶ As Scheid also points out, official TCM reformulations in mainland China cannot represent the complexity of other extant styles of Chinese medicine, thus constraining the broad applicability of Tang and Leung's arguments.¹⁶

Standardization

Approaches to standardization can be divided into micro and macro. Microstandardization involves the amounts, composition, quality, and strength of the treatments being tested in an RCT. Macrostandardization involves the manner in which treatments are assigned to patients: whether the same treatment is assigned to all patients with a certain biomedical disease, or individually tailored treatments are assigned based on the Chinese medicine diagnostic category into which each patient fits.

Strategies for microstandardization include methods of ensuring that acupuncture needles are all inserted in the same manner in the same bodily locations with the same depth and pattern of manipulation, and herbal ingredients and mixtures all have the same contents and are all prepared in the same manner. This entails stretching RCT norms away from testing simple chemical compounds or stripped-down procedures to figure in the intricacies involved in testing complex herbal substances, combinations of multiple herbs,^{31,32,41} use of multiple acupuncture points, detailed needle manipulation patterns, or a combination thereof.

There are two main approaches to the issue of macrostandardization: the conventional approach of testing a treatment's efficacy for ameliorating disease states as defined by biomedicine, and a second, innovative approach of testing the efficacy of treatments for syndrome patterns. Under the conventional approach, standardized acupuncture and herbal treatments are given to patients diagnosed with a biomedical disease. This first approach arguably puts Chinese medicine at a disadvantage since many of its therapies were ideally designed to address syndrome patterns, at least in the case of the TCM style of Chinese medicine. Under the in-

novative approach, standardization occurs at the level of following Chinese medicine's principles for customizing treatment for various syndrome patterns and for each individual patient in context. This approach is more consonant with the current ideals of Chinese medicine since it evaluates efficacy within an indigenous theoretical framework.

Examples of macrostandardization vary in their details: one might test the efficacy of various therapies for ameliorating the condition of patients with deficiency of the kidney syndrome (*shen xu*), for which there is no biomedical equivalent; in other cases, one might investigate treating a condition which has a biomedical parallel but which Chinese medicine divides into subtypes. Critchley et al. suggest comparing one standard biomedical treatment of asthma against Chinese medicine treatments differentiated by "cold" and "heat" types.⁴¹ Another variation is to test whether Chinese medicine's customization of subjects, into different treatment subtypes is appropriate. Wei suggests that herbal preparations be randomly assigned to research subjects, and then see if those subjects in which efficacy is observed have different characteristics than nonresponders.¹⁴ Langevin et al. are investigating ways to assign *yin* and *yang* scores to research subjects in order to classify and divide them into subgroups to investigate whether, for example, "different groups of patients respond differently to acupuncture treatments or Chinese herb formulas."⁴² As proliferation of subtypes constitutes a challenge to adequate sample sizes, such analyses could help in assessing the empirical legitimacy of reducing the number of subcategories of signs and symptoms into which TCM divides its diagnoses (*jianhua bianzheng fenxing*).³¹

In other cases, treatment outcomes of individualized Chinese medicine therapies are compared with outcomes of standard biomedical treatment. For example, outcomes from herbal combinations tailored to each patient according to the theoretical principles of Chinese medicine are compared with results from a standard biomedical medication. Alternatively, results from biomedical treatment combined with individualized Chinese medicine therapies are compared with biomedical treatment alone to see if they produce better outcomes.^{36,39} Such cases usually employ a standard biomedical diagnosis.

Berman points out that use of a standardized approach in clinical trials need not be exclusive of utilizing individualized treatments in those same trials.³⁶ Researchers can use some combination of both, depending on research phase, for example, a formulaic phase I, and a customized phase II. Alternatively, instead of using one treatment for one biomedical diagnosis, researchers can devise a meta-formula which offers different treatments to individual patients according to the pre-specified traditional Chinese diagnostic category into which the person falls. Along these lines, Schnyer and Allen have proposed that acupuncture trials can use a detailed instruction manual to combine elements of "standardization and replicability" with "flexibility to tailor treatments to individuals."⁴³

Melding concerns about controls and standardization, MacPherson recommends conducting "pragmatic rather than explanatory trials."^{44,45} Similar to "outcomes research,"³⁸ a pragmatic trial is designed to assess the "overall effectiveness" of a treatment, often comparing "a new intervention with the best existing one," in order to "inform decisions about procedures and interventions in normal clinical practice."⁴⁴ By contrast, explanatory trials are designed to evaluate "efficacy" of a treatment "over and above" any "non-specific effects" in order to "evaluate a scientific hypothesis."⁴⁴ Observing that acupuncture research in the West has been "dominated" by explanatory trials, MacPherson criticizes how "artificial" and "far removed from clinical reality" they are. Instead of asking if acupuncture is better than placebo, a pragmatic trial inquires: "Is acupuncture of better value than what is currently on offer?"⁴⁴ MacPherson argues that pragmatic trials are more appropriate for acupuncture because they more closely mirror the everyday concerns and practices of clinicians and patients and are thus more likely to be applied to patient care. Pragmatic trials allow practitioners to individualize treatment, patients to make informed choices, and treatment-placebo synergies to be maximized.⁴⁴ Examples include two recent large-scale acupuncture trials supported by the National Health Service in Great Britain, focused on treating headaches⁴⁶ and low-back pain.⁴⁷

Limitations

While efforts are being made to increasingly incorporate theoretical elements from Chinese medicine into the design of RCTs, the vast majority of papers still tend to be based around biomedical diagnostic categories. This is the case not only in articles published in Western journals but articles published in Chinese journals. In an extensive review of Chinese journal articles on efficacy trials of Chinese medicine, Tang and colleagues found that most Chinese medicine trials to date have conformed to a western biomedical bias with regard to diagnostic categories and measurements. Although these biomedical measurements were "often complemented by traditional Chinese methods," they were not the primary focus.²⁸

In addition, immense epistemological and ontological differences remain between theories in Chinese medicine and those underlying biomedicine and much of modern Western science. As a result, much current RCT research is still open to charges that it does not take seriously constructs within Chinese medicine, including not only diagnostic categories but also bodily constructs, such as the triple burner (*san jiao*) and the "kidney" (*shen*), which have no clear correlates in biomedical anatomy or physiology.²² While research on acupuncture channels (*jingluo*) and points (*xuewei*) has recently found intriguing links with connective tissue^{48,49} and neurophysiology,^{50,51} other phenomena such as *yin* and *yang* and *qi* have remained more elusive with regard to finding correspondences with biomedical constructs.^{38,42}

Part of the evidential crisis may rest in the biomedical metaphors into which concepts from Chinese medicine have typically been translated. For example, Birch and Felt describe how *qi* has been commonly glossed as “energy,” encouraging a fruitless search to measure its physical presence in the neural structures of the nervous system.³⁸ They suggest that *qi* may be translated better as “a subtle global operating system, . . . human software not human hardware” or as “a generative matrix in which all things interact with all other things through the exchange of information.”³⁸ They argue that a software metaphor may encourage research that investigates whether predicted responses to a *qi* paradigm are found in observations of the world, rather than seeking to find *qi* itself. This may result in a better fit with both Chinese medical practice and current biomedical sensibilities.

Birch and Felt also raise questions concerning the strategic utility of outcomes research (pragmatic trials) for enhancing the legitimacy of acupuncture.³⁸ They argue that until acupuncture has proved its efficacy within many standard RCTs, the results of outcomes research will mean little to many arbiters. For the paradigm of Chinese medicine to be seriously considered by skeptics, several of its therapies must first be shown efficacious within MacPherson’s “explanatory trials.” Only then “perhaps whole person approaches, rooted in systems and information theory, will find greater acceptance and utilization” in the assessment of efficacy.³⁸

CONCLUSIONS

While offering compelling arguments concerning paradigm incommensurability, those opposed to using RCTs and EBM criteria to evaluate Chinese medicine tend to oversimplify Chinese medicine, biomedicine, RCTs, and EBM. The detractors make overly polarized contrasts between Chinese medicine and biomedicine, and restrict their role to criticizing without offering a systematic evaluative alternative. While it is a challenging venture fraught with issues of paradigm differences and medical politics, researchers have found numerous strategies for designing RCTs in ways that strive to respect the spirit of Chinese medicine, although there is much improvement yet to be made. Concerted ongoing accommodation is needed between the practice of Chinese medicine and the design of efficacy research. Through the alchemy of the interaction of the two, I believe that both have been, and will continue to be, strengthened.

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