

Rising to the Challenges of Evidence-Based Medicine: A Way Forward for Acupuncture

Jacob Godwin, DAOM, Dipl OM, LAc

Abstract

Evidence-based medicine offers important opportunities and poses critical challenges to the acupuncture profession. Having a clear understanding of what evidence-based medicine is and what it is not is necessary to understanding how the acupuncture field might benefit by adopting evidence-based medicine as its paradigm. This article discusses the need for the acupuncture field to retool its professional, academic, and clinical apparatuses to produce, critically appraise, and use high-quality scientific evidence in order to develop acupuncture as an evidence-based procedure. Development of evidence-based acupuncture procedures, practice guidelines, and research directives may help acupuncture become a standard therapeutic procedure rather than a complement or alternative to conventional medicine.

Introduction

SCIENCE AND TECHNOLOGY HAVE CHANGED the world forever. Biology and medical science have not been immune to these changes and have been shaped by frequent and profound discoveries over the past two centuries. In fact, medical science is currently experiencing the emergence of its newest paradigm—that of evidence-based medicine (EBM). All paradigms eventually fail and are replaced by new ones through scientific revolutions.¹ EBM is one such revolution. It has radically changed the way medicine is taught to physicians and how it is delivered to patients. EBM has become the fundamental basis for clinical practice around the world.² The revolution of EBM is that it shifts value away from the authority of experts and senior practitioners toward the independent critical appraisal of the evidence for any given clinical question by the physician.³ This shift emphasizes the patient's individual needs and values, the physician's own clinical judgment, and the best current evidence. This type of revolution is necessary to the establishment and continued evolution of any normal science. As a paradigm comes to its natural end, a new paradigm emerges to answer critical questions.

Acupuncture has operated under a paradigm articulated in the classical texts of the Han dynasty without scientific revolution for more than 2000 years.⁴ Interestingly, the Han physicians who established the paradigm laid out in the *Huangdi Neijing* and contemporaneous texts were in a position similar to that of modern acupuncturists. The Han physicians and the authors of the *Huangdi Neijing* revolutionized medicine in their time by calling for a move toward

a paradigm based on natural laws rather than temperamental spirits^{5,6}—a step toward science, as we know it now.

Coincidentally, modern doctors of acupuncture and of biomedicine are experiencing a revolution similar to that of the Han, in that they are both recognizing the need to move away from *expert*-based medicine toward *evidence*-based medicine. Both acupuncturists and biomedical physicians are grappling with the issue of ensuring that they are delivering care that is supported by high-quality evidence. When the Han physicians found themselves tyrannized by an intellectually stifling paradigm, they overthrew it and established a paradigm in the *Huangdi Neijing* that has endured more than 2000 years. When biomedical physicians realized that they had become mired in anecdotal expert-based practices, they developed the hugely successful model of evidence-based medicine. As acupuncturists come to realize that they, too, may be languishing under an anecdotal expert-based paradigm, what will be the response?

This article discusses the need for the acupuncture field to retool its professional, academic, and clinical apparatuses to produce, critically appraise, and use high-quality scientific evidence in order to develop acupuncture as an evidence-based procedure. Development of evidence-based acupuncture procedures, practice guidelines, and research directives may help acupuncture become a standard therapeutic procedure rather than a complement or alternative to conventional medicine.

Evidence-Based Medicine

EBM, while still controversial, is the dominant paradigm within medicine.² The term *evidence-based medicine* was

first used in publication by Gordon Guyatt⁷ in 1991 when he described a “way of the past” wherein clinical decisions were based primarily on the authority of experts. Guyatt argued that decisions in the “way of the future” should be based on independent critical appraisal of the highest-quality evidence available. He described evidence-based medicine as requiring, of each clinician, the ability to retrieve, critically appraise, and synthesize research data. Along with these skills, a clinician practicing EBM should be able to determine the applicability of the data to individual patients. Should direct evidence not be available, an EBM clinician should follow a systematic approach to decision making.

EBM has evolved over the past 23 years. Its tenets have many incarnations, but Sackett’s brief description is the one most often cited: “Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”⁸

Other definitions exist. Most of them offer the same basic ideas in different forms. Greenhalgh, however, offers an interesting summary of EBM ideals that highlights an important component—the need to estimate the risk of benefit and harm: “Evidence-based medicine is the use of mathematical estimates of the risk of benefit and harm, derived from high-quality research on population samples, to inform clinical decision-making in the diagnosis, investigation or management of individual patients.”⁹

Greenhalgh’s addition of the idea of estimating the benefit and harm of a particular intervention based on current evidence is important to acupuncture because, for many conditions, supporting evidence may be weak or nonexistent regarding effectiveness, but the evidence for acupuncture’s safety is strong.^{10,11} In these cases, acupuncture might be considered after other treatments have failed, or in conjunction with them simply because it is a very safe option with at least *some* evidence supporting it. Although this is an important point, it is not enough for acupuncture to just be a safe *alternative* or *complement* to better-supported therapies. Evidence must be developed to fully support acupuncture as an option rather than an alternative. From its inception, EBM has been about applying the best evidence available to an *individual* patient. EBM considers the physician’s clinical reasoning, the available evidence, and the values of the individual patient as factors in making clinical decisions.⁸ Nevertheless, many critics of EBM see it as a tyrannical imposition when it is quite the opposite. If anything, EBM requires more individualized care than does expert-based medicine, whereby patients are treated on the basis of evidence that may be outdated, anecdotal, or not applicable to the present patient’s specific situation—or all of the above. Sackett addresses this misconception:

Evidence based medicine is not “cookbook” medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients’ choice, it cannot result in slavish, cookbook approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision.⁸

EBM brings the expertise of the clinician and the individual needs of the patient into a well-articulated relation-

ship with the best current evidence. The point of EBM is to clarify this relationship so that each of these three components can be used at their fullest capacity. Expert-based medicine can wander too far from scientific reality and remain vulnerable to bias if best current evidence is not fully considered. Meanwhile, if clinical expertise or patient values are ignored, tyrannical impositions of evidence-based conclusions can be arbitrarily used to develop “cookbook” approaches to medicine (as addressed by Sackett). The aim of EBM is to create a logical structure that can maintain a productive and balanced working relationship among these three components. Although this is the ideal, it is not always the reality.

EBM, as with any idea, can be abused and executed poorly. Many critics of EBM rightly point out that health-care management and third-party payers erroneously equate a lack of evidence with lack of effectiveness in order to restrict patient care. In addition, these third-party entities often use the moniker of EBM to justify the imposition of guidelines or procedures on physicians. This is, of course, diametrically opposed to the principles of EBM. In EBM, the physician, not a third party, is the one who applies a critical appraisal of the evidence to his or her patient. EBM does require discipline on the part of the physician to base clinical decisions on the best evidence, but it does not give license to third parties to supplant the physician’s clinical expertise with policy. Again, it is a common misconception that EBM devalues clinical expertise. By making the relationship between the physician’s expertise and the best evidence clearer, EBM ensures that the value of individual patient needs, physician expertise, and best evidence are all accounted for in the clinical decision.

Some critics call for the development of an “evidence-informed practice” to counter the problem of EBM misapplication.¹² However, as Sackett and others have already explained, EBM is already a revolution against such authoritative tyrannies. The fact that people and organizations misuse and misrepresent EBM is not a reason to abandon it, or even modify it. EBM already allows for clinical decisions to be made in the absence of high-quality evidence, and does not equate a lack of evidence with a lack of efficacy.

The evidence base for acupuncture as a therapeutic intervention capable of treating many causes and types of pain is strong,¹³ and evidence that it can treat many of the complex diseases it is purported to treat is emergent.^{14,15} The globalization of acupuncture and continued integration of acupuncture into the modern healthcare apparatus make critical the need to establish a comprehensive biological model of acupuncture. However, basic questions of mechanism remain unanswered, and significant research problems need to be solved before such a model can be realized.¹⁶ In addition, the field is largely operating under the same sort of authoritarian expert-based medicine that EBM seeks to overthrow.

EBM can provide for acupuncture physicians and researchers a single, well-defined goal. This clearly articulated and established objective could unite like-minded acupuncture physicians and researchers. It could also unite the acupuncture field with other healthcare disciplines working toward the same objective. This will allow the sharing of information and foster collegiality between acupuncturists and their biomedical counterparts. EBM can be a banner

under which those wishing to develop acupuncture into a fully accepted therapeutic intervention can rally.

Scientific Research Is Imperative

EBM relies on the machinery of a mature normal science to provide demonstrable, repeatable, and dependable evidence for the use of any given therapeutic intervention. Only practitioners operating a science described by Kuhn¹ as *normal* are able to develop and maintain an evidence base capable of supporting acupuncture as a fully accepted therapeutic procedure. Normal science refines and perfects valid theories under an established paradigm. Acupuncturists and researchers are not currently operating a normal science—we cannot refine or perfect what we do not have.

Critical problems regarding mechanisms of action for acupuncture and basic science remain unsolved.¹⁷ Solutions must be found and developed into sound scientific theories that can be refined through repeated research before acupuncture can enjoy the benefits of a normal science. The development and maintenance of an acupuncture evidence base are the most important challenge posed by EBM and are the key to acupuncture's future in the modern world. It is a challenge that the field must embrace whole-heartedly without asking for concessions. Although creative solutions may need to be found, acupuncturists must be willing to be held to the same standards as other healthcare professionals. Much of the groundwork has already been done to move acupuncture in the right direction. However, much work remains.

Working toward evidence-based acupuncture provides the acupuncture field a path to full integration with modern healthcare, but there are barriers. Currently, acupuncture is considered a modality of complementary and alternative medicine and is very rarely included in standard care guidelines despite clear evidence that it is more effective than current guideline-based interventions for many conditions.^{14,18} Medical doctors are uncomfortable referring patients to acupuncturists because of a perceived lack of high-quality research.¹⁹ It is difficult for physicians to trust a procedure with an unknown mechanism, especially one often conflated with metaphysical ideas already rejected by science.^{5,20}

One of the greatest barriers to the full acceptance of acupuncture as a valid therapeutic procedure is the question of mechanisms of action.^{19,21} Sharp lines are being drawn between acupuncture based on modern science and acupuncture based on ancient Chinese ideologies.²⁰ Neither Traditional Chinese Medicine nor the Han paradigm from which it sprung offers a coherent (let alone scientifically valid) theory of how acupuncture works. Moreover, both are fraught with critical errors in anatomy and physiology. Biological models will eventually supplant the Han paradigm. It is critical that degreed acupuncturists construct these biological models. If this work is done without a deep understanding of what acupuncture is, and what it has been for the past 2500 years, the product will probably only partially explain acupuncture.

The Doctor of Acupuncture and Oriental Medicine degree programs are a huge step forward for the field and hold great promise for solving many of these problems by introducing acupuncturists to scientific research and preparing them to contribute to the knowledge base. Researchers have been calling for acupuncturists to get involved in research for

years now, with little success.²² Without clearly articulated objectives regarding what research needs to be done and how that research affects the field at professional, clinical, educational, and legislative levels, the call to support scientific research will likely continue to go unanswered by acupuncturists. If acupuncture is to evolve into an accepted evidence-based therapeutic intervention, support for scientific research is no longer just a suggestion—it is imperative.

The Building of a Biological Model of Acupuncture

A comprehensive biological model must be established if acupuncture is to become an option rather than an *alternative* or a *complement*. Such a model may be within reach. Acupuncture research has been slow and challenges remain, but key sets of evidence have already been established. Work on several key acupuncture puzzles has seen progress over the past 10 years. There is also a nascent, but rather robust, evidence base built on hard data from high-quality clinical trials for the use of acupuncture for a wide variety of conditions.^{13,15,23–25} Effectiveness trials and meta-analyses are critically important, and must continue. However, a plausible comprehensive biological mechanism of action must also be established for acupuncture.

Effectiveness trials can tell us whether acupuncture is an effective treatment option for a given condition. They can also compare different acupuncture procedures with each other, to standardized care, to a placebo control, or to all three. They are a highly flexible mainstay of research. Thus, effectiveness trials are a top priority for research. There are many examples in medicine of an intervention being known to be effective before the mechanisms of action are fully understood. Many pharmaceuticals are used despite having unclear mechanisms. However, effectiveness trials do not tell us *how* acupuncture gets these results. Without the *how*, we cannot improve upon the results we get, nor can we fully integrate acupuncture with other therapies. Knowing the mechanisms of action for acupuncture will allow us to develop other technologies related to acupuncture and to better integrate acupuncture with pharmaceutical treatments and surgical procedures. Knowing the mechanisms will also help to develop new, more effective point selection and needling methods. We need the *how*.

Advanced neuroimaging has emerged as the most promising tool for discovering the mechanisms of action behind acupuncture.²⁶ Already, a handful of researchers have found evidence for three primary claims of acupuncture: (1) that acupuncture can modulate complex physiologic processes directly;^{26,27} (2) that acupuncture treatment locations have specific effects;^{28–30} and (3) that different methods of stimulation and different manipulations of the needle have measurably different effects on the body.^{26,27,29,31} Only 15 years ago, many of these claims were considered pseudo-scientific fantasy. Today they are features of a cutting-edge therapeutic intervention supported by good science. Acupuncture produces profound changes in the central nervous system along with local tissue responses.^{26,27,29} If acupuncture continues to prove to be a means of directly accessing and modulating a physiologic system as important as the central nervous system, acupuncture could be developed into much more than an *accepted* intervention—it might be one of the most important developments in

medicine in recent years, opening doors to entirely new approaches to treating many complex diseases.

Demanding More

Acupuncture is currently an expert-based medicine, and it has been for more than 2000 years. Professional discourse among acupuncturists, the clinical practice of acupuncture, and acupuncture education rely on sourcing information from classical texts that are notoriously difficult to translate and interpret, from contemporary textbooks that are rarely subjected to a systematic peer-review process, and from various experts. These sources are anecdotal. This is a critical problem that must be addressed immediately. Acupuncture students should demand more than anecdotal expert opinion as evidence from their professors; likewise, physicians should demand more from their colleagues—and themselves.

Case studies, expert opinion, and other forms of anecdotal evidence can inform a physician's decision under the evidence-based paradigm. These forms of evidence are not excluded from consideration in EBM. However, this should not discourage acupuncturists from developing higher-quality evidence. Anecdotal evidence is given a place in the accepted evidence hierarchy of EBM. It is important evidence. It is the frontline of research and evidence gathering. Expert opinion, case studies, research into classical texts, and so forth can point researchers in the right direction. These unfiltered forms of evidence can give researchers a target for more rigorous inquiry by articulating a particular research question to be answered, or a hypothesis to be tested. Acupuncturists are sitting on 2000 years of ideas waiting to be tested. Anecdotal evidence from classical texts, textbooks, or seasoned practitioners is simply too vulnerable to bias and error to be considered sufficient on its own. These forms of evidence can provide novelty and nuance under a well-established model, but they can never replace high-quality critical appraisals of scientific research.^{2,9} These forms of evidence can point out a new idea or a flaw in the system, but they cannot support the system on their own.

Support for sources of expert opinion should be minimized while higher-quality forms of evidence, such as randomized controlled trials, systematic reviews, and meta-analyses, should be demanded, developed, and used. The acupuncture field outside of China is nascent and has limited resources. These resources are desperately needed for scientific acupuncture research and development. If the acupuncture field could shift but a fraction of what it spends yearly on expert-based symposiums, books, webinars, and workshops into peer-reviewed and critically appraised evidence-based sources of information, acupuncture might see a period of expansion and development not seen since the Han dynasty.

Conclusion

Contemporary acupuncturists find themselves in the same position their biomedical colleagues and the Han physicians did—with a practice and a profession built largely on expert opinion. The biomedical community responded with EBM and the Han with the texts of the *Huangdi Neijing*. With what will the modern acupuncture community respond?

If the acupuncture profession can redirect at least some significant portion of its intellectual and financial resources

toward meeting the clearly defined objectives of evidence-based medicine, a comprehensive biological model could be developed. With such a model supported by a robust scientific evidence base, acupuncture becomes a vital part of modern healthcare. Current epistemologic barriers dividing acupuncturists from other healthcare professionals would be eroded. Acupuncturists would be able to reap the benefits of research and developments in other fields of science, taking advantage of new technologies and new theories.

Acupuncture physicians and researchers interested in developing acupuncture into an evidence-based intervention must work together toward that specific goal. Simply *doing research* is no longer enough. It is time the field molds existing research data, and those yet to come, into a sound evidence base capable of supporting clinical and professional guidelines. Following these guidelines will create a demand for higher educational and professional standards across the field. The research that is being done is not finding its way into the field at either of these levels. College curricula are not based on the evidence base, physicians do not practice acupuncture based on current scientific research, and practice guidelines are almost nonexistent. The time has come for acupuncture to embrace modern science as its paradigm and to put to use the valuable research being done. Only then can the academic, professional, and clinical standards be raised to meet the needs of a modern healthcare system operating under an evidence-based medicine paradigm.

Author Disclosure Statement

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Address correspondence to:
Jacob Godwin, DAOM, Dipl OM, LAc
 1625 W. 4th Avenue
 Suite 100
 Spokane, WA 99201

E-mail: jacobgodwinlac@gmail.com

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