



Evidence-Based Medicine and Research for Shiatsu practitioners

By Stergios Tsiormpatzis MSc

During our Shiatsu training, independent of the specific school or style we are trained in, we learn things like 'in order to help a receiver with x problem or imbalance, we could use this technique or that approach'. Some of us might be attracted to Shiatsu as a means of relaxation, others as a system of care or medicine. Some prefer to highlight that Shiatsu is an art, a concept that is no more straightforward than the meaning of medicine or the significance of Shiatsu itself. Yet most of us would at least agree that Shiatsu is something that can really help someone who is sick.

Our training usually consists of many hundreds of hours of hands-on practical experience as well as conceptual theories upon which those practical skills are based. We are confident in this knowledge, due to what our teachers said and what different masters of Shiatsu have taught them, as well as due to our own hands-on practice. Or, for those who choose to explore written sources too, because the founding masters of Shiatsu have written so in their books. In other words, we are confident about the knowledge coming from the experts in our field and our subjective experience. Sometimes it happens that our experience does not justify what we have learned, and then we might question our skills or the knowledge that has been transferred to us. Sometimes it happens that we discover something new that exceeds the limits of what we have learned and we try to find out how it could fit in theory. Sometimes we are so confident in what we have been trained, that when our practical experience goes against it, we just choose to close our eyes and ignore it, secretly hoping that this will not happen again. Or we are willing to just erase all that knowledge because of its apparent failures.



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A few Drops of History

Similar to Shiatsu, with its century-long history, other methods that 'can really help someone who is sick' are based on such knowledge resources – expertise and experience. Medicine, with its pluralistic millennia of history worldwide, is no different to that: a written accumulation of expert opinion and written documentation of clinical experience. Whether we look at the remaining documents of the medical approach developed at the Hippocratic school of Kos in Ancient Greece¹ or the one that was developed from, let's say, the Huang Di school of Ancient China², we discover the beginning of a medical approach based on reason in the understanding of the natural order of things and a framework of scientific knowledge, elements of which we can recognise in our own Shiatsu learning experience. A kind of 'scientific' background can be traced to medical practice ever since, alongside the 'scientific' paradigm of each time and place. Thus, it was not until the 17th century that in Britain the first unplanned comparative experiment with a patient was reported³, and not until the 18th century that a systematic critical effort 'to improve the evidence of medicine' was developed by British doctors⁴.

The term Evidence-Based Medicine (EBM) first appeared in a 1991 editorial⁵, while the origin of the EBM approach probably can be traced to the late 1970s⁶. The notion of critical appraisal of the evidence was central to it – and still is for the paradigm as a whole. Since then, healthcare has been extensively



transformed in a way that the need for scientific research is a fundamental requirement of medicine⁷. EBM came to take the place of what could be called 'expert-based medicine'⁸. The EBM Working Group wrote in a 1992 paper: 'Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research' (Guyatt et al., 1992). While this early downgrading of expertise has been considerably modified during the years, 'the young physicians realized that they could challenge their seniors in a way that was not possible with expert-based medicine. It was liberating and democratizing' (Smith and Rennie, 2014). Being a 'tool' that could be used to promote the sharing of and control of professional medical power as had been developed during the ages, it is not strange that the EBM approach was resisted by the medical profession⁹.

What is EBM?

A common misconception among Shiatsu practitioners is that Shiatsu is so unique that it cannot be investigated using a scientific approach. Below we will try to correct that misconception by exploring what EBM is and trying to highlight the relevance of its research methods to Shiatsu.

According to what some pioneers of the EBM paradigm wrote in an editorial for the British Medical Journal back in 1996, EBM is about '**integrating individual clinical expertise and the best external evidence**'¹⁰. In that editorial titled: 'Evidence based medicine: what it is and what it isn't', (a highly recommended read) they wrote, among other things:

'Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. {...} **Good doctors**

use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients.¹¹

Yet, as is the case with science in general, the concepts of EBM are continually developing [11], and if we want to reach a working definition, we will need to accept the scientific approach of following the most recent evidence and rejecting previous notions when proved unsatisfactory. Thus, in a 2002 publication, some of the EBM pioneers stated:

‘The concepts of evidence-based medicine are evolving as limitations of early models are addressed. [...] we present a **new model for evidence-based clinical decision making based on patients’ circumstances, patients’ preferences and**

actions, and best research evidence, with a central role for clinical expertise to integrate these components’ (Fig 1).¹²

The role of expertise has been advanced, without discounting the original intentions of the EBM approach:

‘Clinical expertise includes the general basic skills of clinical practice as well as the experience of the individual practitioner. Clinical expertise must encompass and balance the patient’s clinical state and circumstances, relevant research evidence, and the patient’s preferences and actions if a successful and satisfying result is to occur¹².

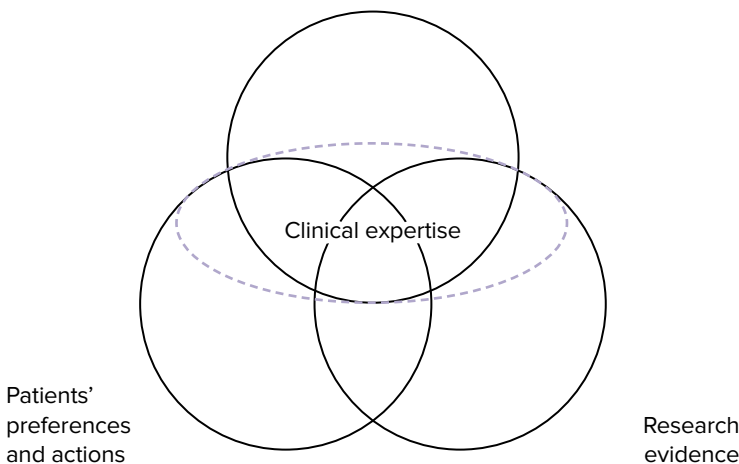
A detailed discussion of various misconceptions about EBM, which are often well-justified, exceeds the purpose of this article. EBM today faces many challenges, and it needs to develop further to bypass them. However, it is clear that EBM is the paradigm of healthcare that dominates current and future practice¹³⁻¹⁴. But is it compatible with Shiatsu? From the brief discussion of some basic

concepts above, we believe that we can answer positively. But let’s have a look at some of the possible issues.

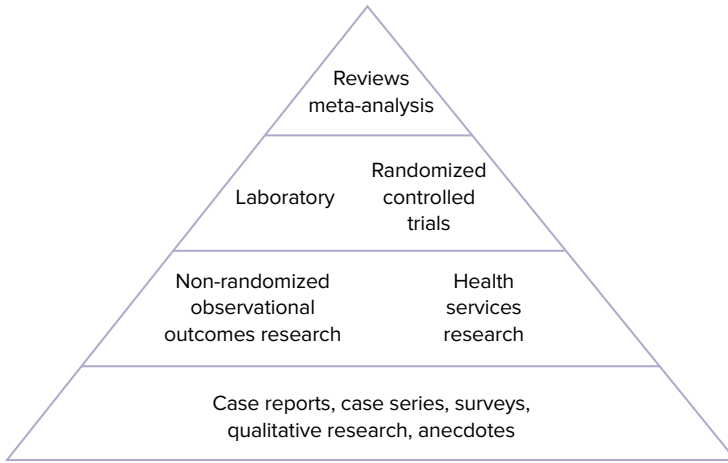
EBM research methods are not easily adopted by some complementary modalities, which in many cases are of a complex nature, involving a combination of multiple traditional or novel interventions¹⁵⁻¹⁷. In addition, the commonly perceived focus of EBM on the ‘gold standard’ of randomised controlled trials (RCTs, especially the placebo-controlled ones) - which is a research method designed to answer questions about the efficacy and safety of pharmaceuticals¹⁸ - can cause problems when researching clinical medical fields including Shiatsu^[18-20]. But, as you might already grasp, RCTs are not what EBM is about, nor is statistical data.

EBM research includes evidence of many types and from many sources. Sources of evidence are often put in hierarchical order according to their **internal validity**. An early version of the ‘**standard evidence hierarchy pyramid**’ used by the EBM approach is in figure 2. Yet there are plenty of versions of that pyramid and, even more important, there are alternatives that seem to be more relevant to complex interventions, such as the **Evidence House** (figure 3)²¹ or the **circular approach**²². Those consider not only the internal validity but **external validity** and **model (or ecological) validity**. Even the traditional pyramid was modified by the EBM Working Group in 2000, by putting at the top of it the randomised n-of-1 trials²³.

Clinical state and circumstances - Figure 1



The Evidence Hierarchy - Figure 2



Internal validity: whether the study results are valid for the patients of the study, whether the results obtained by our study design could be attributed to what we did in the research rather than to some irrelevant factor.

External validity: whether the study results can be used for patients other than the study patients, whether they are generalisable.

Model (or ecological) validity: whether the study results can be used in real-life situations, with different practitioners, facilities, context, etc.

Table 1: Evidence validities

Types and Domains of Research

As described above, EBM is not about RCTs. It is not only about quantitative evidence either. Numerical approaches to assess the effects of medical interventions were already in use during the early 18th century²⁵. The quantitative approach of inquiry has indeed dominated clinical health research for some decades²⁶.

Quantitative RCTs are usually considered the gold standard of medical knowledge because they can efficiently control confounding variables, isolating the effect of the tested treatment, achieving high levels of internal

validity and implying causality. Unfortunately, this is often at the cost of the external and model validity of the

study²⁷, making this approach unfavourable for assessing the efficacy of complementary medicine²⁸ or patients with multiple comorbidities²⁹.

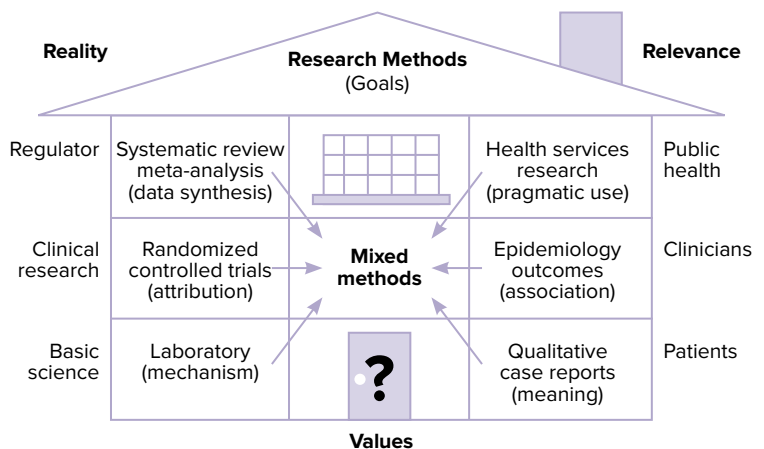
But if not numbers and statistics, then what are we talking about?

Qualitative research methods

- aim to seek answers by asking non-quantifiable questions and are more appropriate for ‘what?’, ‘how?’, and ‘why?’ types of questions³⁰, exploring subjects subjective experiences³¹. Their relevance to EBM lies in their ability to examine questions that are not easily answerable by the quantitative approach^{32,33}.

Mixed methods research - is an approach in which the researcher collects and analyses data using both qualitative and quantitative approaches in a single study³⁴. It focuses on research questions that require an understanding of the real-life context, multiple perspectives and handling of cultural influences. By utilising multiple methods (for example, both doing a clinical trial and using in-depth interviews too) it intentionally integrates or combines these methods to

The Evidence House - Figure 3



draw on the strengths of each and frames the investigation within philosophical and theoretical positions³⁵. It is able to generate evidence containing both statistically causal inferences and more complex, non-reductive qualitative explanations and...

Is it still something that seems incompatible with the possibility of researching Shiatsu using the EBM approach?

Basic Domains of Research.

Let's look at some basic domains of research that we could consider useful for Shiatsu. The accumulated experience of modalities more advanced in their evidence-base is always an excellent place to look for a possible future for Shiatsu as well. What follows is an adaptation from work on the area of therapeutic massage and bodywork³⁶:

Sociocultural - includes questions that deal with demographics, satisfaction, costs of care, epidemiology, education and outreach (training, public information), law and politics, history of the field, and anything related to how patients perceive and experience their care, how practitioners evaluate and explain the practice to themselves and others, and why

people become motivated to study or receive Shiatsu.

How effective and safe it is - includes questions that deal with issues about the practice of Shiatsu - comparisons of intervention techniques, appropriate time spent in each session, appropriate frequency of sessions, how long the effects of a session are likely to last and how this can be measured, what safety issues concern its practice, what is the practitioner's effect on the result of care, and other such questions.

How it compares to others - includes questions that aim to compare the effectiveness of Shiatsu at relieving symptoms or maintaining functionality with the effectiveness of other practices at doing the same thing. Here researchers will compare their interventions with other bodywork modalities, such as acupuncture or tuina or different styles of massage, or other healthcare methods, such as those of medicine, psychology, Chinese medicine, and so on.

How it works - includes research on underlying physiological mechanisms, such as seeking evidence of how Shiatsu causes an effect

to the autonomic nervous system and produces changes in the pupil diameter, heart rate, pulse rate and blood pressure, or how Shiatsu influences the hypothalamus-pituitary-adrenocortical axis functioning, and similar questions.

But is Research about Shiatsu Feasible?

'But doesn't this kind of research require large studies, many researchers and a lot of money? How can we do that? We are not big pharma...'. While this is true, it's only half right. There are both studies where you would need a large group of patients, and studies where just a single patient is enough. There are both studies that require the collaboration of many researchers, and studies that can be done by just one. There are studies that require a lot of money, and there are... let's say that there are people ready to partly volunteer the required time and skills to run a study that will not require a lot of money. Even more important, there are ways for each practitioner to contribute to developing the evidence-base for Shiatsu. In the next article by the Shiatsu Research Network, we will provide you with more details about that.

References:

1. Bulger RJ, Barbato AL. On the Hippocratic Sources of Western Medical Practice. The Hastings Center Report 2000;30:S4. doi:10.2307/3527655.
2. Unschuld PU. Huang Di Nei Jing Ling Shu: The Ancient Classic on Needle Therapy. Journal of Chinese Medicine 2016;111:5–18.
3. Mirza R, Punja S, Vohra S, Guyatt G. The History and Development of N-of-1 Trials. Journal of the Royal Society of Medicine 2017;110:330–40. doi:10.1177/0141076817721131.
4. Tröhler U. "To improve the evidence of medicine": The 18th century British origins of a critical approach. Edinburgh, UK: Royal College of Physicians of Edinburgh; 2000.
5. Guyatt GH. Evidence-based medicine. ACP Journal Club 1991;114:A16. doi:10.7326/0003-4819-114-2-165.
6. Sur R, Dahm P. History of evidence-based medicine. Indian Journal of Urology 2011;27:487. doi:10.4103/0970-1591.91438.
7. Kamath S, Guyatt G. Importance of Evidence-Based Medicine on Research and Practice. Indian Journal of Anaesthesia 2016;60:622–5. doi:10.4103/0019-5049.190615.



8. Smith R, Rennie D. Evidence Based Medicine - An Oral History. *BMJ* 2014;348. doi:10.1136/bmj.g371.
9. Grahame-Smith D. Evidence Based Medicine: Socratic Dissent. *BMJ* 1995;310:1126–7. doi:10.1136/bmj.310.6987.1126.
10. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence Based Medicine: What it is and What it isn't. *BMJ* 1996;312:71–2. doi:10.1136/bmj.312.7023.71.
11. Claridge JA, Fabian TC. History and Development of Evidence-Based Medicine. *World Journal of Surgery* 2005;29:547–53. doi:10.1007/s00268-005-7910-1.
12. Haynes RB, Devereaux PJ, Guyatt GH. Clinical expertise in the era of evidence-based medicine and patient choice. *Vox Sanguinis* 2002;83 Suppl 1:383–6. doi:10.1111/j.1423-0410.2002.tb05339.x.
13. Sheridan DJ. The Future of Evidence-Based Medicine. Evidence-Based Medicine, London, UK: Imperial College Press; 2016, p. 197–214. doi:10.1142/9781783267637_0009.
14. Sheridan DJ, Julian DG. Achievements and Limitations of Evidence-Based Medicine. *Journal of the American College of Cardiology* 2016;68:204–13. doi:10.1016/j.jacc.2016.03.600.
15. Veziri Y, Leach MJ, Kumar S. Barriers to the Conduct and Application of Research in Complementary and Alternative Medicine: A Systematic Review. *BMC Complementary and Alternative Medicine* 2017;17. doi:10.1186/s12906-017-1660-0.
16. Walker BF, Stomski NJ, Hebert JJ, French SD. Evidence-Based Practice in Chiropractic Practice: A Survey of Chiropractors' Knowledge, Skills, Use of Research Literature and Barriers to the Use of Research Evidence. *Complementary Therapies in Medicine* 2014;22:286–95. doi:10.1016/j.ctim.2014.02.007.
17. Coulter ID, Lewith G, Khorsan R, Kirk R, Mittman B. Research Methodology: Choices, Logistics, and Challenges. *Evidence-Based Complementary and Alternative Medicine* 2014;2014. doi:10.1155/2014/780520.
18. Bothwell LE, Greene JA, Podolsky SH, Jones DS. Assessing the Gold Standard — Lessons from the History of RCTs. *New England Journal of Medicine* 2016;374:2175–81. doi:10.1056/NEJMms1604593.
19. Jones DS, Podolsky SH. The History and Fate of the Gold Standard. *The Lancet* 2015;385:1502–3. doi:10.1016/S0140-6736(15)60742-5.
20. Vickers A. Methodological Issues in Complementary and Alternative Medicine Research: A Personal Reflection on 10 Years of Debate in the United Kingdom. *The Journal of Alternative and Complementary Medicine* 1996;2:515–24. doi:10.1089/acm.1996.2.515.
21. Jonas WB. The Evidence House: How to Build an Inclusive Base for Complementary Medicine. *The Western Journal of Medicine* 2001;175:79–80.
22. Walach H, Falkenberg T, Fønnebo V, Lewith G, Jonas WB. Circular Instead of Hierarchical: Methodological Principles for the Evaluation of Complex Interventions. *BMC Medical Research Methodology* 2006;6. doi:10.1186/1471-2288-6-29.
23. Guyatt GH, Haynes RB, Jaeschke RZ, Cook DJ, Green L, Naylor CD, et al. Users' Guides to the Medical Literature: XXV. Evidence-Based Medicine: Principles for Applying the Users' Guides to Patient Care. *JAMA* 2000;284:1290–6. doi:10.1001/jama.284.10.1290.
24. Lewith GT, Jonas WB, Walach H, editors. *Clinical Research in Complementary Therapies: Principles, Problems and Solutions*. 2nd ed. Edinburgh: Elsevier; 2011.
25. Tröhler U. The introduction of numerical methods to assess the effects of medical interventions during the 18th century: a brief history. *JLL Bulletin: Commentaries on the History of Treatment Evaluation* 2010. <https://www.jameslindlibrary.org/articles/the-introduction-of-numerical-methods-to-assess-the-effects-of-medical-interventions-during-the-18th-century-a-brief-history/>.
26. Britten N. Making Sense of Qualitative Research: A New Series. *Medical Education* 2005;39:5–6. doi:10.1111/j.1365-2929.2004.02024.x.
27. Khorsan R, Crawford C. External Validity and Model Validity: A Conceptual Approach for Systematic Review Methodology. *Evidence-Based Complementary and Alternative Medicine* 2014;2014. doi:10.1155/2014/694804.
28. Verhoef MJ, Casebeer AL, Hilsden RJ. Assessing Efficacy of Complementary Medicine: Adding Qualitative Research Methods to the "Gold Standard." *The Journal of Alternative and Complementary Medicine* 2002;8:275–81. doi:10.1089/10755530260127961.
29. Fortin M. Randomized Controlled Trials: Do They Have External Validity for Patients With Multiple Comorbidities? *The Annals of Family Medicine* 2006;4:104–8. doi:10.1370/afm.516.
30. Green J, Thorogood N. *Qualitative Methods for Health Research*. London: SAGE; 2004.
31. Pope C, Mays N. *Qualitative Methods in Health Research. Qualitative Research in Health Care*, Oxford, UK: Blackwell Publishing Ltd; 2006, p. 1–11. doi:10.1002/9780470750841.ch1.
32. Green J, Britten N. Qualitative Research and Evidence Based Medicine. *BMJ* 1998;316:1230–2. doi:10.1136/bmj.316.7139.1230.
33. Pope C, Mays N. Qualitative Research: Reaching the Parts other Methods cannot Reach: An Introduction to Qualitative Methods in Health and Health Services Research. *BMJ* 1995;311:42–5. doi:10.1136/bmj.311.6996.42.
34. Tashakkori A, Creswell JW. Editorial: The New Era of Mixed Methods. *Journal of Mixed Methods Research* 2007;1:3–7. doi:10.1177/2345678906293042.
35. Creswell JW, Klassen AC, Plano Clark VL, Smith KC. *Best Practices for Mixed Methods Research in the Health Sciences*. 2011.
36. Cassidy CM, Hart JA. Methodological issues in investigations of massage/ bodywork therapy: Part III: *Journal of Bodywork and Movement Therapies* 2003;7:136–41. doi:10.1016/S1360-8592(03)00035-4.