

Evidence-Based Practice Should Supersede Evidence-Based Medicine Through Consideration of Clinical Experience and Patient Characteristics in Addition to the Published Literature



Abstract: On the surface, the benefits of evidence-based medicine (EBM) seem self-evident. However, reliance on the scientific literature alone has limitations. Studies may be biased, statistically fragile, and/or not reproducible. Reliance solely on EBM may ignore physician clinical experience and individual patient characteristics and input. Reliance solely on EBM may overvalue quantitative, statistical significance, resulting in a false sense of certainty. Reliance solely on EBM may fail to consider lack of generalizability of published studies to individually unique patients. The concept of evidence-based practice goes beyond EBM and incorporates (1) EBM, (2) clinical expertise, and (3) individual patient characteristics, values, and preferences. Even if branded as evidence-based, a suggested treatment may not be the best treatment. Evidence-based practice must be considered before determining what is best for our patients.

I had come to an entirely erroneous conclusion, my dear Watson. How dangerous it always is to reason from insufficient data.¹

—*Sherlock Holmes*

Every clinician is faced with a common dilemma—how to best treat the illness or condition of the individual patient. Historically, determining the best treatment has evolved from being based primarily on conjecture to treatment decisions founded on scientific data. Few among us have not re-evaluated and changed treatments based on new, peer-reviewed original scientific articles, systematic reviews, or meta-analyses. We tout this practice as evidence-based medicine (EBM), which serves as a contemporary justification for calling into doubt long-established practices in favor of “evidence-based” treatments.

For example, in the late 1970s, a popular anterior cruciate ligament (ACL) surgical treatment was the “five one” reconstruction of the knee.² It addressed anteromedial rotatory instability, which was then thought to be the primary cause of anterior laxity in an ACL-deficient knee. However, after evaluating published evidence, this treatment was abandoned as an inappropriate approach for treating the pathology. Today, we reconstruct the ACL anatomically.

The Promise of EBM

On the surface, the benefits of EBM seem self-evident, and no longer are treatment algorithms based on anecdotal experience. The clinical trial has gained primacy. Consequently, treatment guidelines are based on data analysis, critical thinking, and hypothesis-driven investigation with clear objectives and conclusions. The goal of our research and its publication is to determine best practices, disseminate the evidence, and avoid unnecessary and perhaps harmful application of medical interventions.

A prototypical example of the application of EBM is the use of continuous passive motion (CPM) after knee surgery. At one time, it was a standard to use a CPM device after ACL reconstructive surgery.³ However, careful evaluation of the benefits of CPM revealed that, for the majority of patients, this device was neither necessary nor beneficial with respect to pain relief or functional motion.⁴ EBM resulted in a substantial decrease in the of routine use of CPM.^{5,6} Today, CPM for knee surgery continues to be evaluated, as clinicians and researchers refine the use of this device following certain knee surgeries.⁷⁻⁹

The Limitations of EBM

Today, we often state with confidence that our approach to clinical decision-making is based on the most recent scientific studies, i.e., EBM. Yet, all studies have limitations, and there is always the risk that some studies will be biased, fragile, and/or irreproducible.¹⁰⁻¹³ This could lead to guidelines and recommendations that are misdirected or wrong.

Thus, when deciding on the best treatment for our patients, we must review the medical literature with thoughtful scrutiny. Following every published recommendation without question or doubt may undervalue our individual and collective clinical experience—*anecdotal or otherwise*—and may similarly undervalue our patients' expectations. This narrow approach could result in a misapplication of EBM. Relying solely on medical algorithms or "evidence-based" Clinical Practice Guidelines may ignore both physician and individual patient characteristics and input.

EBM May Undervalue Clinical Experience and Patient Characteristics

The problem of blind adherence to decisions based only on published medical literature is shown in the controversy over arthroscopic outcomes in degenerative knees. "Evidence-based" reports have summarily claimed that an arthroscopic procedure results in outcomes that are no better than nonoperative management.¹⁴

As a result, the Centers for Medicare & Medicaid Services dictate regarding "Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee":

"A. Nationally Covered Indications. Not applicable."

"B. Nationally Noncovered Indications. The clinical effectiveness of arthroscopic lavage and arthroscopic debridement for the severe osteoarthritic knee has not been verified by scientifically controlled studies. After thorough discussions with clinical investigators, the orthopaedic community, and other interested parties, Centers for Medicare & Medicaid Services determines that the following procedures are not considered reasonable or necessary in treatment of the osteoarthritic knee and are not covered by the Medicare program: (1) Arthroscopic lavage used alone for the osteoarthritic knee; (2) Arthroscopic debridement for osteoarthritic patients presenting with knee pain only; or, (3) Arthroscopic debridement and lavage with or without debridement for patients presenting with severe osteoarthritis. Severe osteoarthritis is defined in the Outerbridge classification scale, grades III and IV. Outerbridge is the most commonly used clinical scale that classifies the severity of joint degeneration of the knee by compartments and grades. Grade I is defined as softening or blistering of joint cartilage. Grade II is defined as fragmentation or fissuring in an area less than 1 cm. Grade III presents clinically with cartilage fragmentation or fissuring in an area greater than 1 cm. Grade IV refers to cartilage erosion down to the bone. Grades III and IV are characteristic of severe osteoarthritis."

"C. Other. Apart from the noncovered indications above for arthroscopic lavage and/or arthroscopic debridement of the osteoarthritic knee, all other

indications of debridement for the subpopulation of patients without severe osteoarthritis of the knee who present with symptoms other than pain alone; i.e., (1) mechanical symptoms that include, but are not limited to, locking, snapping, or popping; (2) limb and knee joint alignment; and (3) less severe and/or early degenerative arthritis, remain at local contractor discretion. Medicare contractors may require submission of one or all of the following documents to define the patient's knee condition: Operative notes, Reports of standing x-rays, or, Arthroscopy results."¹⁵

Unfortunately, this ignores compelling physician experience and individual patient characteristics and expectations.^{16,17} We know from experience that arthroscopy helps many of our patients with degenerative knees.¹⁸⁻²²

EBM May Overvalue Statistical Significance

As we have previously published,^{23,24} the EBM movement is extremely over-reliant on quantitative, statistical significance, which can result in a false sense of certainty. When considering significance, the *P* value has almost mythical importance. $P < .05$ has been identified as the be-all and end-all of scientific truth. This ignores clinical significance, as well as uncertainty, and nuanced analysis of the true meaning of research data.

EBM May Fail to Consider Generalizability

Generalizability, or specifically the lack thereof, contributes to the fallibilities of EBM.^{22,25-28} In published studies, the included population may not reflect the demographics of other communities, including our communities. For example, urban versus rural differences, or differences in race or sex cannot be ignored. Misinterpretation of evidence due to the application of generalizations ignores population idiosyncrasies. The patient in front of us is an individual, and the results of the patient cases included in published studies may not be applicable.

Putting the Limitations of EBM All Together

Putting it all together, consider the example of viscosupplementation for the treatment of knee arthritis. The American Academy of Orthopaedic Surgeons has published guidelines that recommend against this treatment, stating that the current evidence does not identify a subset of patients who benefit.²⁹ Yet, some patients benefit.³⁰⁻³³ The benefit to certain patients may be undervalued despite clinical experience and individual patient characteristics as a result of over-reliance on statistical significance and failure to consider lack of generalizability. Guidelines based on EBM may overgeneralize statistically significant conclusions and ignore the benefits to some of our patients.

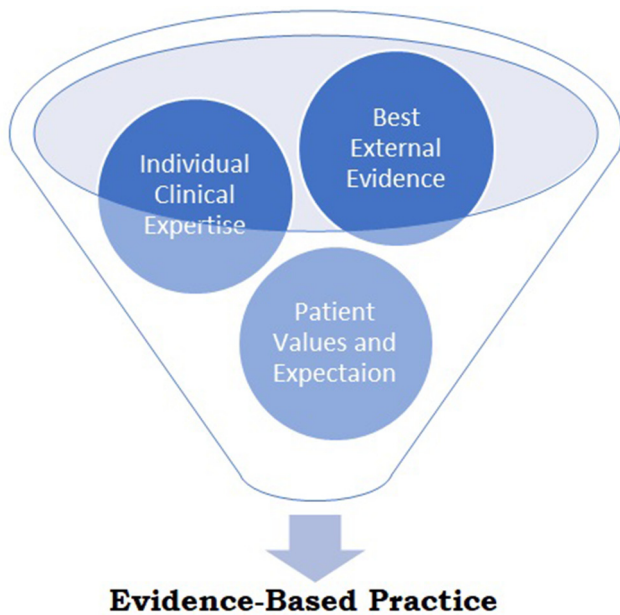


Fig 1. Evidence-based practice is based on a triad including the best external evidence-based medicine, individual clinical expertise, and patient values and expectations.

Evidence-Based Practice (EBP)

After further investigation, we have discovered a concept that goes beyond EBM and is known as EBP.³⁴ EBP is based on a triad of values, including (1) best external EBM, (2) clinical expertise, and (3) patient values and preferences. EBP applies value to all 3 aspects of the decision tree (Fig 1).³⁵

Analysis of the best external research evidence includes consideration of clinical and basic science studies including not only their conclusions, but their statistical fragility, generalizability, biases, and clinical significance. Next, consideration of individual clinical expertise includes one's own experience and knowledge, plus analysis of the collective opinion of other individual and groups of experts as a result of podium presentations, Level V evidence publications (expert opinion and Delphi consensus studies), and dissemination of such information using new or social media.³⁶⁻³⁸ Finally, we must consider individual patient characteristics such as race, sex, comorbidities, and activity levels; patient values such as return to sport or work; and patient expectations such as mitigation of pain, maximization of function, and ultimately, satisfaction, and substantial clinical benefit.³⁹⁻⁴¹

Conclusions

When a colleague, a payer, or an electronic medical record algorithm asserts that a treatment recommendation is "evidence-based," it is critical that the information behind the evidence be fully evaluated. Even if branded as evidence-based, a suggested treatment may

not be the best treatment. All research is inherently subject to bias, and EBM based on the best external evidence must be combined with individual clinical experience and consideration of individual patient characteristics, values, and expectations. In sum, this will result in EBP treatment recommendations and decisions to the benefit of each individual patient.

According to the fictional detective Sherlock Holmes, "There is nothing more deceptive than an obvious fact."⁴² Reliance on EBM alone, rather than the 3 pillars of EPB, is equally deceptive. Paradoxically, in our age of readily available data, the need to verify has never been more important when making medical decisions. Physicians face an avalanche of information as well as assertions as to the best path forward. This information is often misrepresented as being definitive on the basis of EBM. However, this information is often distorted. EBP must be considered before determining the best treatment for our patients.

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