

How to Incorporate Clinical Experience Into Evidence-Based Medicine

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Evidence-based medicine (EBM) represents a paradigm change in the way in which medicine is practiced. On one level, evidence-based medicine is a formalism for integrating “research evidence with clinical expertise and patient values.”⁵ It is not intended to supplant clinical experience, but rather to augment and strengthen it. There has been a concern voiced within the neurosurgical community that EBM will reduce patient care to a set of protocols and lead to a cookbook approach to patient care. There is a temptation to allow EBM and its emphasis on the literature to cut discussion short rather than to broaden clinical considerations. Not to recognize the fundamental importance of clinical experience, however, is a clear distortion of the original intent of EBM.

The passions that are inflamed by the EBM movement are fanned by questions of what it means to know something. Contemporary clinical medicine is an exercise in reasoning with uncertainty. The data that we collect are imprecise and often subjective. It is well accepted that a diagnosis is a prerequisite for effective treatment. Yet at the same time we use the concept of a *differential diagnosis* to acknowledge the fact that our final determination may be incorrect and that other etiologies are possible. In the end, however, we have a need to know that the treatment plan that we are implementing is correct, and this desire drives us to assert more certainty than we know to be the case. To be wrong is unacceptable.

In this context, it is helpful to point out that a paradigm of absolute reliance on the literature is no more likely to lead to optimal management decisions than a blind adherence to clinical experience alone. Literature reviews can be conducted using a meaningful, reliable, and repeatable methodology. The fundamental question, however, is whether an article or body of work is applicable to a particular clinical question. Often the answer is unclear. Some decisions are driven more by the efficacy of treatment, whereas others are more closely tied to the risk of side effects. The first step in implementing EBM is for-

mulating an appropriate clinical question. This is where much of the art of EBM resides and also where fundamental and important assumptions creep into the process. The contention that EBM is an objective process and without bias should be debunked once and for all. Just as it is possible for a decision to be steeped too heavily in the clinical experience of one expert, it is also possible for a decision to rely excessively on the medical literature without accommodating the unique particulars of the individual case. How then are we to proceed?

Stephen Haines has observed that the salient insight of the EBM paradigm is that the quality of evidence is of vital importance when applying conclusions from the literature to solve clinical problems.³ It is well accepted in the neurosurgical community that 100 case reports do not carry the same weight as one well-implemented, randomized, controlled trial (RCT). Central to EBM is a system for categorizing the importance of the data (*Table 10.1*). When well-designed and well-executed RCT studies that speak to the clinical problem in question exist, they obviously bring significant clarity to clinical decision making. Unfortunately, the likelihood of such an occurrence on a typical neurosurgical service is rare. There are few questions in neurosurgery, as in the other medical specialties, for which RCTs have been performed. There are many obstacles to the implementation of an RCT. In addition, there are some situations that make the institution of an RCT unnecessary or ill advised.⁶ Sackett⁵ identified a clinical situation called *all or none* in which before the institution of a particular treatment, a disease is universally fatal, whereas with the treatment, some patients survive.⁷ He has argued that an RCT is unethical in the study of an *all-or-none* disease. Another example of an all-or-none situation occurs when some patients die of the disease before treatment, but all survive after treatment is initiated. In other less stark situations in which there is a lack of clinical equipoise, it is unethical to randomize patients. Fortunately, RCTs are not a requirement to practice sound EBM that incorporates clinical experience.

As mentioned above, one of the first steps in EBM is determining whether the evidence is applicable to the current clinical situation.⁷ It is important to ask whether the patient

TABLE 10.1. Levels of evidence (from Sackett⁵)

Level of Evidence	Therapy	Prognosis	Diagnosis
1	Systematic review of randomized, controlled trials	Systematic review of inception cohort study or validated clinical practice guideline	Systematic review of level 1 diagnostic study
2	Systematic review of cohort study or individual cohort study	Retrospective cohort study	Independent blind comparison of nonconsecutive cases or subgroup analysis
3	Case-control study		Independent comparison with incomplete use of reference standard
4	Case series	Case series	Reference standard was not applied correctly
5	Expert opinion or conclusion based on “first principles”	Expert opinion or conclusion based on “first principles”	Expert opinion or conclusion based on “first principles”

being treated is similar to the experimental group in the study. The treatment must be compatible with the patient's values. A determination must be made that the treatment is feasible and that the benefits of the proposed treatment outweigh the potential harm. The National Acute Spinal Cord Injury Study provides an example of a well-designed RCT that demonstrated a statistically significant benefit in the use of methylprednisolone for the treatment of spinal cord injury.¹ Soon after the article was published, its recommendations were incorporated into the standard of care. More thoughtful analysis soon drew attention to some of the study's limitations. Although the study successfully demonstrated efficacy, Hurlburt's group pointed out that the treatment effect was not clinically significant. Also overlooked was the morbidity of treatment including a sixfold increase in the risk of deep venous thrombosis and pulmonary embolism.⁴ This opinion was reiterated by the article in the article “Pharmacological Therapy After Acute Cervical Spinal Cord Injury.”² The Spine Patient Outcomes Research Trial of herniated lumbar discs is another example of a well-designed RCT that ultimately did not have an impact on clinical practice.⁸ This trial funded by the National Institutes of Health looked at the important question of whether surgery or nonoperative treatment was preferable in the treatment of lumbar disc herniation. Unfortunately, the high degree of crossover between the experimental and control groups made application of the results to clinical practice unwarranted. That study was also limited by a bias toward the null hypothesis by excluding the cases that were most likely to benefit from surgery. This was unavoidable, however, because it would have been unethical to randomize patients with a footdrop to nonoperative treatment.

Barriers to the adoption of EBM more widely are typically seen as external factors. Before the Internet age, up-to-date sources of evidence were not as widely disseminated. The process of assessing the quality of evidence is

laborious and time-consuming. The medical literature is always changing and growing at an exponential rate. High-quality and dependable assessments require training. Ultimately, the literature itself is limited by a lack of class I evidence. One real but often unstated limitation of EBM is an internal factor, a heavy discounting of the value of clinical experience. The framers of EBM envisioned a more balanced approach, but contemporary EBM often devalues clinical experience as anecdotal. Both clinical experience and a rigorous assessment of the literature have an important role to play in the formulation of a clinical plan. Clinical experience is incorporated early in the process in which the question to be considered is being formulated. This is the place where a patient's headache after a lumbar discectomy suggests the possibility of a cerebrospinal fluid leak or, in another scenario, leg pain in a patient with degenerative disc disease is considered to be radicular rather than referred. It is clinical experience that alerts us to a problem and tells us where to look. Late in the process, clinical experience will alert us to the possibility that a patient will not tolerate a potential therapy, either because of his or her overall state of health or personal values. Ultimately, clinical experience informs not only the care that we deliver, but also a prudent interpretation of the literature.

In summary, the conflict between clinical experience and EBM is a false one. EBM in its truest form is not only based on a rigorous analysis of the literature but also incorporates clinical experience throughout the process. Individualized patient care should not be disparaged but rather represents our highest calling as physicians.

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