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Evidence-Based Surgery Defined

“It is the mark of an educated mind to be able to entertain a thought without accepting it.”

– Aristotle

Summary

In this chapter, evidence-based medicine (EBM) is defined and the necessity and challenges of practicing EBM in sur-

gery are presented. Resources are provided to aid the surgeon in obtaining the best available evidence.

Introduction

The term “evidence-based medicine” (EBM) first appeared in autumn 1990 in a document for applicants to the Internal Medicine Residency Program at McMaster University that described EBM as an attitude of “enlightened skepticism” toward the application of diagnostic, therapeutic, and prognostic technologies. As outlined in the text *Clinical Epidemiology*¹ and first described in the literature in the *ACP Journal Club* in 1991,² the EBM approach to practicing medicine relies on an awareness of the evidence upon which a clinician’s practice is based and the strength of inference permitted by that evidence. The most sophisticated practice of EBM requires, in turn, a clear delineation of relevant clinical questions, a thorough search of the literature relating to the questions, a critical appraisal of available evidence and its applicability to the clinical situation, and a balanced application of the conclusions to the clinical problem. The EBM model integrates research evidence, clinical circumstances, patients’ values/preferences, and clinical experience (Fig. 2.1).

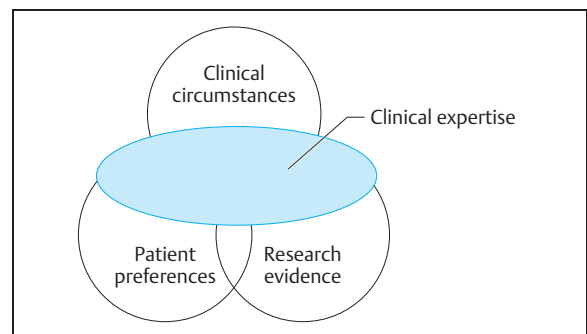


Fig. 2.1 Current model of evidence-based medicine.

Jargon Simplified: Evidence-Based Medicine

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 requires integration of individual clinical expertise and patient preferences with the best available external clinical evidence from systematic research.”³

How Evidence-Based Medicine Differs from Traditional Approaches to Health Care

According to the traditional paradigm, clinicians evaluate and solve clinical problems by reflecting on their own clinical experience or the underlying biology and pathophysiology or by consulting a textbook or local expert. For many traditional practitioners, reading the Introduction and Discussion sections of a research article is sufficient for gaining relevant information, and observations from day-to-day clinical experience are a valid means of building and maintaining knowledge about patient prognosis, the value of diagnostic tests, and the efficacy of treatment. Because this paradigm places high value on traditional

scientific authority and adherence to standard approaches,⁴ traditional medical training and common sense provide an adequate base for evaluating new tests and treatments, and content expertise and clinical experience are sufficient to generate guidelines for clinical practice.

Evidence-based practice posits that although pathophysiology and clinical experience are necessary, they alone are insufficient guides for practice. These evidence sources may lead to inaccurate predictions about the performance of diagnostic tests and the efficacy of treatments. Like the traditional approach to health-care, the evidence-based

health-care paradigm also assumes that clinical experience and the development of clinical instincts (particularly with respect to diagnosis) are crucial elements of physician competence. However, the EBM approach includes several additional steps. These steps include using experience to identify important knowledge gaps and information needs, formulating answerable questions, identifying potentially relevant research, assessing the validity of evidence and results, developing clinical policies that align research evidence and clinical circumstances, and applying research evidence to individual patients with their specific experiences, expectations, and values.⁵

Key Concepts: The Five As of Evidence-Based Medicine

1. Ask – Formulate your question.
2. Acquire – Conduct an efficient search for the best available research evidence.
3. Appraise – Is the evidence you found valid?
4. Apply – Use the best available evidence and decide whether it is applicable to your specific patient question
5. Act – When evidence is valid, take what you have learned back to your patient.

Unfortunately, practicing EBM is not easy. Practitioners must know how to frame a clinical question to facilitate use of the literature in its resolution. Typically, a question should include the population, the intervention, and relevant outcome measures. The question, “What is the role of internal fixation of tibial fractures?” is vague. The question should be “In patients presenting to the emergency room

with open tibial diaphyseal fractures (*population*), what is the effect of external fixators versus nonreamed intramedullary nails (*interventions*) on reoperation rates (*outcome*)?”

EBM practitioners (i.e., clinicians who work under the EBM paradigm) regularly consult original literature, including the Methods and Results sections of research articles.⁶ Correctly interpreting literature on prognosis, diagnostic tests, and treatment and potentially harmful exposures (medications’ side effects, environmental exposures) requires an understanding of the hierarchy of evidence. For example, in making treatment decisions, EBM practitioners may conduct an *n*-of-1 randomized trial (randomized trial in an individual patient, with the patient repeatedly treated with active intervention or placebo) to determine the optimal treatment for an individual patient.⁷ Alternatively, they may seek a systematic review of randomized trials of treatment alternatives. If a systematic review is not available, they will look for individual randomized trials and high-quality observational studies of relevant management strategies. If the literature is lacking altogether, EBM practitioners will fall back on the underlying biology and pathophysiology, and clinical experience.

Jargon Simplified: *n*-of-1 Trials

“‘*n* of 1’ trials are conducted by systematically varying the management of a patient’s illness during a series of treatment periods (alternating between experimental and control interventions) to confirm the effectiveness of treatment in the individual patient.”⁸

The Need for Evidence-Based Medicine

Over the last several years, the concepts and ideas attributed to and labeled collectively as evidence-based medicine have become a part of daily clinical lives, and clinicians increasingly hear about evidence-based guidelines, evidence-based care paths, and evidence-based questions and solutions. The controversy has shifted from whether to implement the new concepts to how to do so sensibly and efficiently, while avoiding potential problems associated with several misconceptions about what EBM is and what it is not. The EBM-related concepts of hierarchy of evidence, meta-analyses, confidence intervals, study design, and so on, are so widespread, that clinicians to understand today’s medical literature have no choice but to become familiar with EBM principles and methodologies.

The skills associated with EBM should allow clinicians to function more rationally. The ability to follow the path from research to application should also provide more control over what we do, and more satisfaction from our

daily practice. Although learning to locate, assess, and use new evidence in the original literature can improve our daily practice, limited access to that information and limited time allocated to continuing education may cause our up-to-date clinical knowledge to deteriorate with time. EBM-related skills provide solutions to deal with this problem by allowing us to access, appraise, and apply information much more efficiently.⁹

Critics of EBM have mistakenly suggested that EBM equates evidence with results of randomized trials, statistical significance with clinical relevance, evidence (of whatever kind) with decisions, and lack of evidence of efficacy with the evidence for the lack of efficacy. Other critics argue that EBM is not a tool for providing optimal patient care, but merely a cost-containment tool.¹⁰ All these statements represent a fundamental mischaracterization of EBM.