Published in final edited form as:

Plast Reconstr Surg. 2010 July ; 126(1): 286–294. doi:10.1097/PRS.0b013e3181dc54ee.

How to Practice Evidence-Based Medicine

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Abstract

Evidence-based medicine (EBM) is defined as the conscientious, explicit and judicious use of current best evidence, combined with individual clinical expertise and patient preferences and values, in making decisions about the care of individual patients. In an effort to emphasize the importance of EBM in plastic surgery, ASPS and PRS have launched an initiative to improve the understanding of EBM concepts and provide tools for implementing EBM in practice. Through a series of special articles aimed at educating plastic surgeons, our hope is that readers will be compelled to learn more about EBM and incorporate its principles into their own practices. As the first of the series, this article provides a brief overview of the evolution, current application, and practice of EBM.

Keywords

evidence-based medicine; critical appraisal; levels of evidence; health policy

Evidence-based medicine (EBM) is rooted in the words of Archie Cochrane (1909–1988), a British epidemiologist, who understood the importance of synthesizing high-quality evidence to inform clinical decisions. (1) In 1979, he wrote: “It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomised controlled trials.” However, it was not until the early 1990s that the term “evidence-based medicine” first appeared in the medical literature. In a 1992 *JAMA* article, (2) the Evidence Based Medicine Working Group introduced EBM to the wider medical community:

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There are no products mentioned in this article.

The authors have no conflicts of interest related to the contents of this article.

"A new paradigm for medical practice is emerging. Evidence-based medicine deemphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature."

Shortly thereafter, the Users' Guides to the Medical Literature series was published by JAMA,(3) the Cochrane Collaboration, a group aimed at publishing a database of systematic reviews, was founded, and EBM was on its way to becoming the next revolution in modern medicine. (4;5)

In an effort to emphasize the importance of EBM in plastic surgery, ASPS and PRS have launched an initiative to improve the understanding of EBM concepts and provide tools for implementing EBM in practice. Since 2007, ASPS has published two evidence-based practice guidelines and six evidence-based patient safety advisory documents. In 2009, "Outcomes" appeared on the PRS masthead, and the editorial, *Introducing Evidence-Based Medicine to Plastic and Reconstructive Surgery*,(6) was published. Moving forward, ASPS and PRS will collaborate on a series of special articles aimed at educating plastic surgeons about several EBM topics such as research design, research bias, biostatistics, research reporting guidelines, and critical appraisal of research studies. In addition, ASPS and PRS are partnering with the American Board of Plastic Surgeons to write a series of Maintenance of Certification (MOC) articles on a variety of common plastic surgery topics by having each of the Directors synthesize the best available evidence in the literature to guide practice. These efforts will showcase high-quality articles and systematic reviews on various topics in plastic surgery. Our hope is that readers will be compelled to learn more about EBM and incorporate its principles into their own practices, through these EBM articles.

Evolution of EBM

Modern EBM is composed of 5 main components (Table 1) (7) and is defined as the conscientious, explicit and judicious use of current best evidence, combined with individual clinical expertise and patient preferences and values, in making decisions about the care of individual patients.(8) Although EBM may be considered a relatively modern concept in healthcare, the practice is far from new. An example of early EBM practices is James Lind's (1716–1794) treatment of scurvy, an ailment that often plagued sailors during the eighteenth century. In his 1753 paper, *Treatise of the Scurvy*, Lind describes his experience as the ship's surgeon aboard the *HMS Salisbury* where he designed a study to compare six remedies being used to treat scurvy. He chose 12 men with similar cases of the illness and divided them into six groups of two. Each group was given a particular treatment: cider, elixir of vitriol (ie, sulfuric acid), vinegar, sea-water, citrus (oranges and lemons), nutmeg, or a mixture of garlic, mustard seed and other herbs. The groups were treated for 14 days. Although this trial was small, Lind's results suggested that citrus was superior over the other scurvy treatments, even those recommended by the Royal College of Physicians (sulfuric acid) and the Admiralty (vinegar). (9;10) Thus, this trial serves not only as an early account

of randomization and a defined treatment period, but also as an example of a fair test that refuted expert opinion.

Early scientific methods are also found in surgical references. In the eighteenth century, the British surgeon William Cheselden (1688–1752), introduced a new method of lithotomy, a surgical procedure used to remove bladder stones, and was credited with another important feature of valid evidence—comparable treatment groups. Cheselden put forth considerable effort to keep accurate records of his operations. In what would now be considered a case series, he included the ages and dates of operation for all patients undergoing lithotomy between March 1727 and July 1730. In 1740, he wrote:

”What success I have had in my private practice I have kept no account of, because I had no intention to publish it, that not being sufficiently witnessed. Publicly in St. Thomas's Hospital I have cut two hundred and thirteen; of the first fifty, only three died; of the second fifty, three; of the third fifty, eight, and of the last sixty-three, six.”

Evaluating the increase in mortality rates over time, Cheselden noticed that the average age of patients in the later operative groups was higher than that of the earlier groups, noting that in the later groups: “...even the most aged and most miserable cases expected to be saved by it.” After Cheselden’s realization that dissimilarities in patients’ ages could contribute to differences in treatment outcomes, John Yelloly (1774–1842), another British physician, emphasized that the gender of patients and size of bladder stones should also be documented, as these characteristics could also influence mortality rates after lithotomy. (9;11) Comparability of treatment groups is now a critical measure of a study’s validity.

Numerous examples of early EBM exist in the literature, but despite the innovative ideas of our predecessors, treatments and practices are still being recommended without evidence that they actually improve outcomes.(10) In their book, *Testing Treatments*, Evans et al. describe several contemporary examples that shed light on the consequences of using unproven practices.(12) We can certainly remember the devastating example of expert opinion gone wrong, when Dr. Benjamin Spock (1903–1998), American childcare specialist and author of the best-selling book *Baby and Child Care*, recommended that infants sleep in the prone position. Dr. Spock was considered an “expert” in child care, and his reasoning seemed quite logical— infants sleeping on their backs may be more likely to choke on vomit. Without question, millions of healthcare workers and families began following Dr. Spock’s advice, and placing babies to sleep in the prone position became standard practice. Unfortunately, no conclusive evidence existed that sleeping on the stomach was safer for infants than sleeping on the back, and as a result of this untested practice, thousands of children died of sudden infant death syndrome. (13)

Examples of untested treatments are also present in the surgical literature. In this particular example, a commonly used invasive treatment was later found to provide no better outcome than less invasive treatments. Radical mastectomy, developed in the early nineteenth century by William Halsted (1852–1922), was the most common method for treating breast cancer. At the time, cancer specialists believed that breast cancer grew slowly from the tumor outward toward the lymph nodes and that extensive removal of the affected area should cure

the cancer. Based on the belief that “more is better,” the radical mastectomy involved complete removal of the affected breast and pectoralis muscles, and in the most severe cases, splitting of the breast bone and removal of ribs to access the lymph nodes. Unfortunately, after widespread use of this extremely invasive procedure, survival rates did not improve. This caused cancer specialists to revise their original theory, prompting the use of lumpectomy, a less invasive surgical procedure, followed by systemic treatments such as radiation and chemotherapy. However, even with this new theory, many surgeons still advocated for the radical procedure, and it was not until the mid-1950s that the less invasive treatments became widely accepted. Two American surgeons, George Crile and Bernard Fisher, were credited with bringing this issue to the forefront. While Crile was promoting the less radical procedures, Fisher and his colleagues began conducting randomized controlled trials to compare the effectiveness of radical mastectomy and lumpectomy followed by radiation for breast cancer treatment. After a 20-year follow up, their results suggested that lumpectomy followed by radiation was equally effective as radical mastectomy at treating breast cancer. If not for this new found evidence, more women would have undergone the unnecessary and highly mutilating procedure without added benefit. After Fisher’s work, additional trials were conducted in the UK, Sweden, and Italy, paving the way for the very first systematic review on breast cancer treatment. (12)

These and many other examples emphasize the importance of using valid evidence to inform clinical decisions. Although it would be incorrect to assume that “pre-EBM” medicine was unscientific, modern EBM provides a framework and cultural standard for applying the evidence, and this guidance is necessary for all specialties, including plastic surgery.

Current Application of EBM

EBM is now widespread throughout the United States and is utilized in multiple ways by legislators, policy makers, and payers. Government- and employee-sponsored health plans are driving these initiatives. According to a June 2009 Health Care Reform Survey conducted by Aon Consulting, EBM was cited as a top initiative to improve the quality of care. Of 1,100 U.S.-based employers surveyed, 80 percent of all respondents and 94 percent of respondents with over 10,000 employees agreed that provider reimbursement should be based on EBM. (14)

EBM is often a key component of pay for performance programs that reward physicians for meeting predetermined outcomes or performance measures. There is no universal set of performance measures shared by all payers. However, one of the best known pay for performance programs is the Centers for Medicaid and Medicare Services (CMS) Physician Quality Reporting Initiative (PQRI). Physicians who meet the PQRI requirements and report their performance measures through claim submission or a qualified PQRI registry are eligible for incentive payments. In 2010, physicians who meet the PQRI reporting requirements are eligible to earn bonuses of up to 2 percent of their total CMS charges. It is anticipated that physicians who do not meet PQRI requirements will face reduced Medicare payments.

Health plan benefit design is another area where EBM is playing an increasingly important role. Health plans, both public and private, are using evidence-based guidelines to determine which clinical procedures, therapies, medical devices, and drugs will be covered. Comparative effectiveness research (CER) takes this one step further by comparing treatment options to determine the appropriateness of treatments for a specific condition or disease. CER analyzes the medical benefits, risks, and costs associated with each treatment. CER is likely to have a huge impact in the future as the American Recovery and Reinvestment Act of 2009 invested \$1.1 billion in this federal initiative. Due to the up-front costs associated with generating, coordinating and disseminating the CER findings, it unclear if or how soon cost savings will be realized.

EBM is also playing a prominent role in the development of Continuing Medical Education (CME) content. The Accreditation Council for Continuing Medical Education (ACCME) guidelines require that educational activities address gaps in practice, physician education, patient care or patient education so as to change physician competence, performance and patient outcomes. Educational objectives and patient care recommendations are poised to strengthen the effectiveness of CME activities and provide physicians with practical tools to improve their practices.

Despite the push by institutions and organizations, some clinicians are still reluctant to practice EBM. Implementing EBM is no doubt a daunting task—biomedical publications contain an overwhelming amount of information, only a fraction of which is valid, important and applicable to clinical care. However, numerous resources on EBM are now available, including books, critical appraisal checklists, web tutorials, and workshops. Table 2 provides several useful resources for learning and practicing EBM skills.

Practice of EBM

The first step toward becoming an effective practitioner of EBM is determining what is meant by “best evidence.” Although the randomized controlled trial (RCT) is often touted as the be-all and end-all of clinical evidence, one can still practice EBM without such information. In fact, EBM involves using the best available evidence at the time, and what qualifies as “best evidence” differs by clinical question. Randomized controlled trials (RCTs), though desirable for clinical questions about therapy, may not be appropriate for all clinical questions. (15) For example, to investigate if smoking increases the risk of lung cancer, researchers cannot ethically randomize one group of patients to smoking and one to placebo. Thus, questions about risk are usually best answered by observational studies, eg, a study comparing people who already smoke to those who do not.

Therefore, various types of evidence can be used to develop the best treatment plan for a patient, and this evidence is ranked by its strength or level of evidence; the more rigorous the study design, the higher the level of evidence. Moreover, this evidence can be synthesized into practice recommendations that are graded according to the strength of the supporting evidence. In their 1989 manuscript, *Rules of Evidence and Clinical Recommendations on the Use of Antithrombotic Agents*, Sackett, et al. published the very first scales for rating levels of evidence and grading recommendations.(8) As more

specialties adopted EBM, the scales were modified for each specialty. Table 3 depicts ASPS' evidence rating scales, which were modeled after the scales published by the Journal of Bone and Joint Surgery (16) and the Centre for Evidence Based Medicine. (17) Even though most rating scales are relatively similar, there are differences in ranking systems (eg, alphabetic: A–D; numeric: I–V; or alphanumeric: 1.a., 1.b., etc.) and qualifying evidence at each level; therefore, level I evidence on one scale may not equate to level I evidence on the other. In addition, scales do not always account for differences in the type of clinical question that the evidence is attempting to answer. Study designs can be assigned different levels of evidence depending on the type of clinical question. For example, a well-designed prospective cohort study about therapy would be level II evidence on ASPS' therapeutic scale, whereas the same design used for a study about prognosis or risk would be level I on ASPS' prognosis/risk scale. Inconsistencies can also be found in scales for grading practice recommendations. Therefore, developers of evidence-based articles should include a clear description of the rating scales that were used to rate level of evidence and grade recommendations.

Importantly, level of evidence depends not only on the study design, but also on the methodological quality. All studies, even RCTs, are susceptible to some form of bias; thus, it is necessary to appraise each study for potential biases and overall validity. (18) Table 4 includes a list of questions that can be used to evaluate the quality of an RCT. Additional tools are available for appraising other study designs. Similar to evidence rating scales, inconsistencies also exist in the critical appraisal process. In a recent study assessing the ability of orthopedic surgeons to rate their own research, (19) Schmidt et al. found substantial inconsistencies in the levels of evidence assigned to research articles by different reviewers. In addition, authors often rated their own studies more favorably than independent reviewers. Lack of inter-rater reliability may be due to inadequate training in critical appraisal skills, ambiguity in evidence rating scales, whether reviewers appraised the full-text articles or the abstracts only, or poorly written manuscripts with inadequate methods sections. Numerous organizations have developed critical appraisal tools and tutorials aimed at standardizing the process; though, even with these tools, there remains some subjectivity. Therefore, to reduce inconsistency and bias in the critical appraisal process, studies should be appraised by several reviewers who can then come to a consensus on the final rating. In addition, critical appraisal may become easier as authors begin to consider new standards for reporting their research. The EQUATOR network—Enhancing the Quality and Transparency of Health Research—aims to improve the transparency and reporting of original research. Reporting standards for randomized controlled trials (CONSORT), (20) observational studies (STROBE),(21) and many other research designs can be found on the EQUATOR website.(22)

At times, and especially in surgery, clinicians are faced with clinical questions for which no high-level evidence exists. Although “expert opinions” may seem obsolete in the realm of EBM, they do qualify as evidence and can be very helpful when no other evidence is available. However, when relying on expert opinion in clinical decision making, one must consider how the opinions were developed, not how persuasive the experts are! Expert opinions are evidence when they were developed with an unbiased method for evaluating facts (ie, clinicians' experiences or observations) and forming conclusions that are supported

by those facts. Developers of evidence-based guidelines are now required to use a formal consensus process (eg, Delphi Method, Nominal Group Technique) for developing expert opinion recommendations.

Even with the best tools for practicing EBM, there is not enough time in the day for the busy clinician to acquire and appraise research studies for every clinical question. However, several efforts are underway to streamline the process. Systematic reviews, meta-analyses, and evidence-based guidelines can be huge time savers, and when developed with a prospective, transparent and reproducible method, can be powerful tools in evidence-based practice.(23;24) Initiatives for improving the quality of these documents are in full force, including reporting standards for systematic reviews and meta-analyses, such as the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), formerly Quality of Reporting of Meta-Analyses (QUOROM),(25) and groups such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group (24) and the Physicians Consortium for Performance Improvement (PCPI) for guideline development. Though guidelines are often criticized for being “cookbook” medicine, (8;26) evidence alone cannot answer clinical questions about individual patients; clinical expertise and patient values and preferences are key elements of EBM and are equally important in clinical decision making. Therefore, when it comes to practice guidelines, one size does not fit all, and recommendations will not apply to every patient, yet well-developed guidelines can be helpful for developing individualized treatment plans.

As with any new process, EBM is no stranger to growing pains, and the increase in EBM practice has revealed obstacles in implementation. Knowledge translation, the act of integrating the best available evidence into practice, is the newest challenge in EBM. (10;27;28) Even though evidence is available, there is often a lag between its discovery and actual practice. Iain Chalmers, Editor of the James Lind Library, wrote, “Although science is cumulative, scientists rarely cumulate scientifically,” and emphasized that even our predecessors had difficulty in this area, as James Lind’s “proven” treatment of scurvy took 42 years to become standard practice.(29) Clinicians may be hesitant to implement evidence for various reasons, including institutional issues such as reimbursement, time constraints, liability, and organizational standards, or their own knowledge and attitudes about patient care such as lack of self confidence in clinical skills or inability to appraise and/or apply the evidence. Current research is aimed at developing guidelines to help clinicians translate evidence into practice effectively. The Johns Hopkins Quality and Safety Research Group has developed a large-scale model for knowledge translation that not only provides the evidence, but also envisions how the evidence can be implemented within the entire healthcare system.(28) By engaging and educating all stakeholders about the new intervention, identifying barriers to implementation, providing actual tools for executing the intervention, and measuring performance, this model promotes a collaborative culture, a necessary element for effecting change. Therefore, individual clinicians must learn EBM skills, but institutions and organization must provide them with essential tools for practicing EBM in the real world.

As the newest revolution in modern medicine, EBM has the potential to improve patient care. Past experience has shown us that better outcomes can be achieved with better

knowledge. However, as we embark on this new journey, we must be cautious. EBM can be a useful tool when practiced properly, but it can also be dangerous if attempted hastily. Therefore, we must be mindful that the information on which we base our decisions is not always created equal, and misinformation can certainly be worse than no information. We also must realize the limitations of EBM and understand what it can and cannot do. Nevertheless, we should be ever vigilant in our quest to identify the best evidence and improve patient care. Silverman, (30) citing the philosopher Karl Popper (1902–1994), observes:

”There is no way to know when our observations about complex events in nature are complete. Our knowledge is finite, but our ignorance is infinite. In medicine, we can never be certain about the consequences of our interventions, we can only narrow the area of uncertainty.”

It is time to embrace this new direction in medicine; even small steps toward learning and practicing EBM will bring us closer to the truth.

Acknowledgment

The authors would like to thank Karie O'Connor of the American Society of Plastic Surgeons for her assistance with research for this project.

Supported in part by a Midcareer Investigator Award in Patient-Oriented Research (K24 AR053120) from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (To Dr. Kevin C. Chung).

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Table 1

The Five Basic Components of Evidence-Based Medicine

Step 1	Converting the need for information (about prevention, diagnosis, prognosis, therapy, causation, etc.) into an answerable question
Step 2	Tracking down the best evidence with which to answer that question
Step 3	Critically appraising that evidence for its validity (closeness to the truth), impact (size of effect), and applicability (usefulness in our clinical practice)
Step 4	Integrating the critical appraisal with our clinical expertise and with our patient's unique biology, values, and circumstances
Step 5	Evaluating our effectiveness and efficiency in executing steps 1-4 and seeking ways to improve for next time

Table 2**Resources for Learning and Implementing Evidence-Based Medicine**

Websites	Centre for Evidence-Based Medicine, Oxford (CEBM), http://www.cebm.net/ Centre for Evidence-Based Medicine, Canada http://www.cebm.utoronto.ca/ Grading of Recommendations Assessment, Development and Evaluation (GRADE), http://www.gradeworkinggroup.org/ McMaster University, Surgical Outcomes Research Centre (SOURCE). Evidence-Based Surgery http://fhs.mcmaster.ca/source/EBS/ebs-1.htm
Books	Fletcher, R. W., Fletcher, S.W. Clinical epidemiology: The essentials, Fourth Ed. Baltimore: Lippincott Williams & Wilkins, 2005. Greenhalgh, T. How to read a paper: the basics of evidence-based medicine, Third Ed. Oxford: Blackwell Publishing, 2006. Sackett, D.L., Straus, S.E., Richardson, W. S., Rosenberg, W., Haynes, R. B. Evidence-based medicine: How to practice and teach EBM, Second Ed. Philadelphia: Elsevier Churchill Livingstone, 2000. Straus, S. E., Richardson, W. S., Glasziou, P., Haynes, R. B. Evidence-based medicine: How to practice and teach EBM, Third Ed. Philadelphia: Elsevier Churchill Livingstone, 2005. The evidence-based medicine working group. Users' guides to the medical literature. Essentials of evidence-based clinical practice. Chicago: American Medical Association, 2002.
Workshops	Centre for Evidence Based Medicine, Oxford From the main website, http://www.cebm.net, click on "Courses" and/or "Conferences" The Cochrane Collaboration workshops, http://www.cochrane.org/news/workshops.htm Rocky Mountain Evidence Based Health Care workshop, http://ebhc.uchsc.edu/index.php
Online Tutorials	Introduction to Evidence-Based Medicine Fourth Edition. Duke University Medical Center Library and Health Sciences Library, UNC-Chapel Hill http://www.hsl.unc.edu/services/tutorials/ebm/index.htm Understanding Evidence-based Healthcare: A Foundation for Action. United States Cochrane Center http://apps1.jhsph.edu/cochrane/CUEwebcourse.htm
Critical Appraisal Tools	Critical Appraisal Skills Programme (CASP) http://www.phru.nhs.uk/Pages/PHD/resources.htm Centre for Evidence-Based Medicine (CEBM) http://www.cebm.net/index.aspx?o=1157 Appraisal of Guidelines for Research and Evaluation (AGREE) http://www.agreecollaboration.org/pdf/agreeinstrumentfinal.pdf
Research Reporting Guidelines	Enhancing the Quality and Transparency of Health Research (EQUATOR) Main website: http://www.equator-network.org/ Library for Health Research Reporting: includes links to the guidelines/ checklists below and other useful resources, http://www.equator-network.org/index.aspx?o=1037 Consolidated Standards of Reporting Trials (CONSORT) Main website: http://www.consort-statement.org/ The home page provides links to a reporting checklist, flow diagram, and free online flow diagram generator. Standards for Reporting Diagnostic Accuracy (STARD) Main website: http://www.stard-statement.org/ The home page provides links to a reporting checklist and flow diagram. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Main website: http://www.strobe-statement.org/index.html Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), formerly QUOROM Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. QUOROM Group. Br J Surg 2000; 87(11):1448-1454. PMID: 11091231 Meta-analysis of Observational Studies in Epidemiology (MOOSE) Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, Moher D, Becker BJ, Sipe TA, Thacker SB. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000; 283(15):2008-2012. PMID: 10789670 Standards for Reporting Literature Searches (STARLITE) Booth A. "Brimful of STARLITE": toward standards for reporting literature searches. J Med Libr Assoc 2006; 94(4):421-9, e205. PMID: 17082834

Table 3**ASPS Scales for Rating Levels of Evidence and Grading Recommendations**

Evidence Rating Scale for Therapeutic Studies	
Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
III	Retrospective comparative study; case-control study; or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research or “first principles”

Evidence Rating Scale for Diagnostic Studies	
Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with “gold” standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with “gold” standard as reference) in a series of consecutive patient; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied “gold” standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted “gold” standard
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research or “first principles”

Evidence Rating Scale for Prognostic/Risk Studies	
Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, prospective cohort study with adequate power; or a systematic review of these studies
II	Lesser-quality prospective cohort study; retrospective cohort study; untreated controls from a randomized controlled trial; or a systematic review of these studies
III	Case-control study; or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research or “first principles”

Scale for Grading Recommendations			
Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision- making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V: Little or no systematic empirical evidence	Clinicians should consider all options in their decision- making and be alert to new published evidence that clarifies

Scale for Grading Recommendations			
Grade	Descriptor	Qualifying Evidence	Implications for Practice
			the balance of benefit versus harm; patient preference should have a substantial influencing role.

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Table 4**Critical Appraisal of a Randomized Controlled Trial****Important Questions to Ask When Critically Appraising an RCT**

Screening Questions:

- Did the study ask a clearly-focused question?
- Was this a randomized controlled trial (RCT) and was it appropriately so?

Should I continue?

Detailed Questions:

- Were participants appropriately allocated to intervention and control groups?
- Were participants, staff and study personnel “blind” to participants’ study group?
- Were all of the participants who entered the trial accounted for at its conclusion?
- Were the participants in all groups followed up and data collected in the same way?
- Did the study have enough participants to minimize the play of chance?
- How are the results presented, and what is the main result?
- How precise are these results?
- Were all important outcomes considered so the results can be applied?