Considerations for Assessment and Applicability of Studies of Intervention

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KEYWORDS

• Evidence-based practice • Hierarchy of evidence • Quality of evidence
• Applicability of evidence • Evidence-based medicine • Levels of evidence

KEY POINTS

- There are different study designs to test the benefits or harm of an intervention. Randomized clinical trials and systematic reviews are the strongest designs to minimize threats to validity.
- Quality indicators that impact the validity of intervention studies are sample representativeness, randomization, blinding, completeness of follow-up, data presentation, and chronology of data collection.
- The continuum between efficacy and effectiveness studies helps to determine the applicability of the evidence to individual patients.
- Efficacy studies are well-controlled and determine whether the intervention works under ideal circumstances; thus, treatment effects are greater than expected in clinical practice.
- Effectiveness studies sacrifice control to answer whether the intervention works under real clinical conditions and their treatment effects are similar to those expected in clinical practice.

INTRODUCTION

When evidence-based medicine emerged as a new approach to teach medical practice, the challenge to clinicians was clear: "Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence to evaluate the clinical literature."[1] Since then, the

Disclosure Statement: The authors have nothing to disclose.
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Clin Sports Med 37 (2018) 427–440
https://doi.org/10.1016/j.csm.2018.03.008
sportsmed.theclinics.com

evidence-based medicine approach has crossed beyond the borders of medicine and, as Guyatt and colleagues[2] stated, this approach "applies to all clinical care provisions and the rubric evidence-based health care is equally appropriate." Despite all the good intentions of teaching the evidence-based practice approach to health care professionals, many clinicians do not have the necessary knowledge to evaluate the validity and usefulness of the medical literature.[3] The barriers experienced in the United States to implement evidence-based practice[4] are the same experienced in many other countries[5,6] and across the spectrum of health professions including sports medicine, physical therapy, and athletic training, just to mention a few.[4,7–9]

Several narratives have been published[10–13] with the intent to guide users of the evidence (ie, health care practitioners) on how to appraise the results of clinical research and apply to individual patients in everyday clinical practice. The goal of this review is to refresh clinicians' knowledge of the most important considerations while appraising the evidence of studies of intervention. This article first reviews the hierarchy of evidence and discuss the strengths and weaknesses of different study designs. Then, it discusses the elements of clinical studies that impact their validity followed by a description of the balance between internal and external validity. We hope this review helps clinicians, whatever their areas of practice, to feel empowered to be more active participants in the process of critically appraising and applying evidence to improve patient outcomes in their clinical practice.

HIERARCHY OF EVIDENCE FOR INTERVENTION STUDIES

The basis for clinical decision making relies on the interaction of evidence from clinically relevant research, clinical expertise, and patients' values. Health care practitioners must have the skills to distinguish high-quality from low-quality clinical research. To that end, hierarchies of evidence were developed to facilitate the work of busy clinicians in ranking research studies based on their study design and ability to minimize bias (ie, any tendency that prevents unprejudiced consideration of a question).[14] Hierarchies (or levels) of evidence are grades of recommendations for classifying studies based on research design, using internal validity as criterion for the rankings. Levels of evidence provide a short cut to finding the best evidence. For example, suppose a clinician wants to find evidence for exercise programs to prevent knee ligament injuries, but a search on the topic yields dozens of hits. The clinician then uses the levels of evidence to guide as to which articles are the most valid and useful for the purpose, and focuses first on systematic reviews (SRs). If those are not available, he goes down in the hierarchy and looks for randomized clinical trials (RCTs), and so on. Herein we present a summary of a hierarchy of evidence for intervention studies.[15] This hierarchy includes 5 levels, the lowest being mechanism-based reasoning studies and the highest being SRs of RCTs, which will be described from the bottom to the top level (**Fig. 1**).

Level V

Mechanistic studies establish the pathophysiologic basis for treatment and may be used to generate hypotheses or rule out implausible hypotheses and may provide preliminary evidence to support treatment efficacy in the absence of higher levels of evidence.[16] However, there is controversy regarding using mechanistic studies as a form of evidence to guide clinical practice.[15,16] Considering the purpose of this review, mechanistic studies are not discussed further.