

How to Read a Clinical Trial Paper: A Lesson in Basic Trial Statistics

Shail M. Govani, MD, MSc, and Peter D. R. Higgins, MD, PhD, MSc

Dr. Govani is a Fellow and Dr. Higgins is an Assistant Professor of Internal Medicine, both in the Division of Gastroenterology of the Department of Internal Medicine at the University of Michigan in Ann Arbor, Michigan.

Address correspondence to:
Dr. Peter D. R. Higgins
1150 W. Medical Center Drive
SPC 5682
Ann Arbor, MI 48109;
Tel: 734-647-2964;
Fax: 734-763-2535;
E-mail: phiggins@umich.edu

Abstract: While the number of clinical trials performed yearly is increasing, the application of these results to individual patients is quite difficult. This article reviews key portions of the process of applying research results to clinical practice. The first step involves defining the study population and determining whether these patients are similar to the patients seen in clinical practice in terms of demographics, disease type, and disease severity. The dropout rate should be compared between the different study arms. Design aspects, including randomization and blinding, should be checked for signs of bias. When comparing studies, clinicians should be aware that the outcomes being studied may vary greatly from one study to another, and some outcomes are much more reliable and valuable than others. The definition of clinical response should also be scrutinized, as it may be too lenient. Surrogate outcomes should be viewed cautiously, and their use should be well justified. Clinicians should also note that statistical significance, as defined by a *P*-value cutoff, may be the result of a large sample size rather than a clinically significant difference. The treatment effect can be estimated by calculating the number needed to treat, which will demonstrate whether changes in clinical practice are worthwhile. Finally, this article discusses some common issues that can arise with figures.

In the last decade, the number of publications dedicated to research in gastroenterology has expanded dramatically.¹ In parallel, the number of clinical trials has been increasing, with more than 18,000 ongoing clinical trials in the United States alone.² With this rapid growth in research, clinicians find themselves trying to keep up with wave after wave of studies and trying to determine how these studies apply to their patients. As researchers learn more about disease processes, clinical trial design is also changing and becoming more complex. Medical school and subsequent clinical training provide limited education on how to evaluate these stud-

Keywords

Statistics; clinical trials; randomized controlled trials; outcomes; clinical research

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Michael Hoelscher



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