

The Webscout

SECTION EDITOR



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Observational studies

Observational studies are better than their reputation. They have their place in the continuum of clinical research. The following recommended reading will give you an overview of the types of observational studies and their role.

Song and Chung have published a review on two types of observational studies: cohort studies and case-control studies. They highlight the role of these studies in research and discuss methodological issues. In cohort studies, a population with defined characteristics is followed for the occurrence of an outcome of interest. Such studies can be conducted prospectively or retrospectively. The concept of case-control studies is to select patients with a defined disease (case) and subjects without the defined disease (control), and to compare their characteristics to identify prognostic factors for the disease. You can find the review by Song and Chung at www.ncbi.nlm.nih.gov/pmc/articles/PMC2998589.

C.J. Mann has also published a review on observational study designs. In addition to describing cohort and case-control studies, the article also reviews the advantages and disadvantages of cross-sectional studies. You can read the full article at <http://emj.bmj.com/content/20/1/54>. The main purpose of cross-sectional studies is to analyse prevalence at a given time point. However, such studies only measure simple associations and cannot be used to differentiate the effect from the cause.

Randomised controlled studies are of course considered the gold standard in clinical research due to the control for bias and the high validity they offer. So why should you use observational studies? Mariani and Pêgo-Fernandes have summarised their thoughts on the importance of observational studies in an editorial, which you can find here: <https://tinyurl.com/mariani-peggo>. The great advantage of observational studies is that they are far closer to clinical practice than a randomised controlled trial.

Sometimes they might even be more suitable than randomised controlled trials. This is often the case when it comes to investigating surgical interventions. Concato et al. have systematically analysed the validity of observational studies in comparison to randomised controlled studies. They conclude that observational studies, if well-designed, do not overestimate effects. The results of observational studies and randomised trials were quite similar for every clinical topic examined, and observational studies were less prone to heterogeneity. According to the authors, this might in part be because, in observational studies, patients are treated according to their individual needs. You can find the full article here: <https://tinyurl.com/Concato-NEJM>.

Although observational studies may be better than their reputation, you still need to be careful when interpreting the results. An "Open Learning Textbook" on biostatistics published by University of Florida Health (<https://tinyurl.com/causation-and-observational>) shows why this is so important. In an observational study, you are much more restricted in your possibilities to control for confounding variables than you are in the conduct of a randomised controlled trial.

This means that you cannot be sure whether an observed outcome is the consequence of your method or treatment or whether another factor has confounded the results. Of course, this can happen in randomised controlled trials as well, but you have more options to control for confounders.

The peer-reviewed journal *Observational Studies* (<http://obsstudies.org>) is a resource on all aspects of observational studies. The journal aims to cover study protocols, methodological aspects, software, descriptions of and access to data sets, and data analyses. An interesting piece I found here is a reprint of an article from 1965 that was authored by William Cochran, a prominent statistician deeply involved in the statistics of observational studies. The reprint is accompanied by comments from leading current researchers in observational studies. You can read the article here: http://obsstudies.org/files/cochran_and_comments.pdf. Cochran saw the potential of observational studies to establish causal relationships when controlled trials are not feasible. But he also urged caution in the interpretation of results: "A claim of proof of cause and effect must carry with it an explanation of the mechanism by which the effect is produced."

Inadequate interpretation and reporting of results from observational studies may have contributed to their bad reputation. To ensure adequate reporting of the results of an observational study, you should follow the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Statement: www.strobe-statement.org. Similar to the CONSORT statement, which applies to randomised controlled studies, the STROBE statement gives you a checklist of items that you should include when you write a manuscript on the results of an observational study.

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