

REVIEW ARTICLES

Observational studies often make clinical practice recommendations: an empirical evaluation of authors' attitudes

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Abstract

Objectives: Although observational studies provide useful descriptive and correlative information, their role in the evaluation of medical interventions remains contentious. There has been no systematic evaluation of authors' attitudes toward their own nonrandomized studies and how often they recommend specific medical practices.

Study Design and Setting: We reviewed all original articles of nonrandomized studies published in 2010 in *New England Journal of Medicine*, *Lancet*, *Journal of the American Medical Association*, and *Annals of Internal Medicine*. We classified articles based on whether authors recommend a medical practice and whether they state that a randomized trial is needed to support their recommendation. We also examined the types of logical extrapolations used by authors who did advance recommendations.

Results: Of the 631 original articles published in 2010, 298 (47%) articles were eligible observational studies. In 167 (56%) of 298 studies, authors recommended a medical practice based on their results. Only 24 (14%) of 167 studies stated that a randomized controlled trial (RCT) should be done to validate the recommendation, whereas the other 143 articles made a total of 149 logical extrapolations to recommend specific medical practices. Recommendations without a call for a randomized trial were most common in studies of modifiable factors (59%), but they were also common in studies reporting incidence or prevalence (51%), studies examining novel tests (41%), and association studies of nonmodifiable factors (32%).

Conclusion: The authors of observational studies often extrapolate their results to make recommendations concerning a medical practice, typically without first calling for a RCT. Published by Elsevier Inc.

Keywords: Epidemiology; Clinical trials; Observational studies; Randomized trials; Hierarchy of research design; Reversal

1. Introduction

Observational studies play an important role in advancing medical knowledge. They yield crucial data on incidence, prevalence, correlation, association, prognosis, and natural history. Their role, however, in answering questions regarding medical practices—for example, the use of treatments and diagnostic and screening tests—has long been a contentious issue. One early empirical evaluation compared the results of historical studies with those of historical controls vs. randomized controlled trials (RCTs) [1]. For six different therapies tested in 50 RCTs and 56 studies

with historical controls, the authors found that a particular agent was considered effective in 79% of studies with historical controls but only in 20% of RCTs. In 2000, two high-profile empirical evaluations [2,3] found remarkable agreement between the two types of design. These conclusions met with criticism [4,5], and a greater proportion of disagreement was found in the largest empirical evaluation [6] (of 45 topics and 408 studies), with differences in the effect size exceeding 50% seen in 62% of the topics. Other empirical evaluations have found that five of the six most cited observational studies were refuted or found to have exaggerated results when tested in RCTs [7]. The discrepancy rate between observational studies and randomized trials may vary according to topic, with greater discordance in some fields such as nutrition and cancer and better agreement in other types of questions such as appraisal of harms of medical interventions [8–11].

Conflict of interest statement: The authors declare no conflicts of interest.

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What is new?

- The majority of authors (56%) of observational studies in high impact journals make medical practice recommendations. These extrapolations may not logically follow from the authors' own research, and may instead be best supported by prospective, randomized studies. Nevertheless, only a minority (14%) of these authors call for a randomized controlled trial to support their recommendation prior to implementation.

Biases may exist in both RCTs and observational studies [12], and both types of studies are useful. However, making inferences about medical treatments and management based on observational studies alone may be precarious. Even large well-done observational studies may be frequently wrong [13], and the association does not prove causation. Although these limitations are recognized, it is unknown whether the authors of observational studies acknowledge them and abstain from making recommendations regarding medical practice.

It is also worth noting that not all observational studies address medical treatments. Some observational studies may provide estimates of incidence and prevalence of a disease. Other types of observational studies may address the performance of a diagnostic or screening test or demonstrate that some agent is a risk factor for (or protects against) disease. Yet, even in these cases, authors may recommend a clinical practice in their article. Such recommendations often do not logically follow from the data they have presented. It would thus be interesting to systematically appraise the authors' attitudes toward their own nonrandomized studies.

Here, we sought to investigate the authors' attitudes toward observational studies. We examined all original articles from four major general medicine journals in 2010. We aimed to evaluate how often authors state that their work supports a stance toward a medical practice, and if so, whether they stated that a randomized trial would be necessary to support their recommendation.

2. Methods

2.1. Eligible studies

We examined all original articles published in one calendar year in *New England Journal of Medicine (NEJM)*, *Journal of the American Medical Association (JAMA)*, *Lancet*, and *Annals of Internal Medicine*, the four general medicine journals with highest impact factor according to *Journal Citation Reports* 2010 edition. Articles considered were listed under the heading "Articles" in *Annals of Internal Medicine*, "Original Contribution" in *JAMA*, "Original

Article" in *NEJM*, and "Original Research Article" in *Lancet*. We chose 2010 as it represents the last complete year at the time we started our investigation. Articles were reviewed independently by two reviewers (V.P. and J.J.). We excluded all RCTs, meta-analyses, systematic reviews, decision and cost-effectiveness analyses, studies using non-human subjects, and studies whose main data were derived from modeling. We included only case series with $N > 5$. Both retrospective and prospective and controlled and uncontrolled observational studies were included. This review was performed in duplicate, with strong intrarater agreement (Cohen kappa, 0.97).

2.2. Data extraction

For each included study, we assessed whether the authors recommended some course of medical practice, and if so, what their recommendation(s) is (are). Medical practice was defined broadly and included screening, diagnostic, and treatment-guiding tests; medications; interventions; other therapeutics; behavioral or counseling recommendations; changes to hospital or systems structure; or, broadly, any activity that might be performed by some member of a health care team. Specific recommendation statements were evaluated independently by two investigators with strong agreement (Cohen kappa, 0.96) and recorded verbatim. Furthermore, we recorded whether the authors' stated that an RCT was needed to support the proposed recommendation. This too was performed in duplicate (Cohen kappa, 0.92).

2.3. Classification

One reviewer (V.P.) classified each included study as one of four types: incidence/prevalence studies (those that reported the incidence or prevalence of some medical illness or practice), treatment association studies (those that examined associations or correlations between modifiable factors and outcomes), testing studies (those that examined diagnostic, screening, or stratification tests), and all other association studies involving nonmodifiable factors. The distinction between treatment association and other association studies is that the former examines associations between some factor or practice, which is under the control of health care personnel or patients, and some outcome (for instance, the administration of a therapy with mortality), whereas "other associations" examine the association between two phenomena outside the control of health care personnel or patients (for instance, the relationship between one illness and another).

When nonrandomized studies made recommendations for medical practices, four kinds of logical leaps (extrapolations) were noted. In incidence/prevalence studies, authors may have used their article to argue that some specific remedy should be performed regarding the illness or practice being studied. However, simply because something is prevalent does not mean it is alterable, and furthermore,

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