Discussion Sections in Reports of Controlled Trials Published in General Medical Journals

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ANYONE WISHING TO INTERPRET a trial needs to know how its results compare with those of similar studies, a fact recognized by the original CONSORT (Consolidated Standards of Reporting Trials) statement, which recommended that the report of a randomized trial discuss its findings in light of the totality of relevant evidence.1 In May 1997, Annals of Internal Medicine, BMJ, JAMA, The Lancet, and The New England Journal of Medicine published 26 reports of randomized trials. Reports of apparently similar trials were found for 25 of these. In only 2 were a trial’s results placed in the context of an up-to-date systematic review of relevant studies. Thus, only a small proportion of the reports provided sufficient information to permit reliable interpretation of the new results.2 We repeated our study in May 2001 to assess whether there had been any detectable improvement since then. In 1997, and again in this study, it was not our aim to assess the overall quality of the discussion sections of trial reports but simply to assess how well the results of the new trial had been placed in the context of other relevant research.

METHODS

A report was eligible for inclusion as a trial if it met the following criteria. First, it was published during May 2001 as a full report or article (that is, not in the editorials, news, research letters, short reports, or correspondence sections) in Annals of Internal Medicine, BMJ, JAMA, The Lancet, or The New England Journal of Medicine. Second, on the basis of the best available information, the individuals (or other units) observed in the trial were assigned prospectively to 1 of 2 or more forms of health care by using random allocation or some quasi-random method of allocation, such as alternation, date of birth, or case record number, that is, randomized and quasi-randomized trials, as defined by the Cochrane Collaboration.3

If the discussion section of an eligible report contained an explicit attempt to identify and discuss all other similar trials, whether or not an attempt was made to combine their results quantitatively with those of the new trial, it was considered as a systematic review.

Each of us searched the relevant issues of the journals in different random order. Any reports judged to be eligible by at least 1 of us were considered for inclusion. We resolved any outstanding disagreements by discussion and included reports on which all 3 of us agreed.

Other trials that seem to have addressed the question concerned in the index report were sought by searching the Cochrane Controlled Trials Register (CENTRAL). We did not systematically search for all such trials or judge whether there was sufficient similarity between the new trial and other trials to combine them in a formal meta-analysis.

We independently assessed the discussion section of each eligible report to decide whether an attempt had been
made within it to integrate the results of the new trial within a systematic review, either qualitatively or quantitatively. Such a review could have been one done previously or one done especially by the authors of the report. We resolved any disagreements in our assessments by discussion.

RESULTS

Thirty-three reports of randomized trials, available in the online reference list (http://www.jama.com), were identified in the 19 issues of these 5 journals published in May 2001. In 4 reports, the authors claimed that their study was the first to have addressed the question concerned. Reports of apparently similar trials were found for 1 of these 4.

None of the 30 reports for which there appear to be similar trials contained a discussion of the trial’s results in the context of an up-to-date systematic review of earlier trials. Relevant systematic reviews were mentioned in the discussion section of 3 reports, but the results of the new trial had not been integrated either qualitatively or quantitatively into an update of these reviews. However, one trial was reported in the same issue of The Lancet as a systematic review of other relevant trials. In the remaining 27 reports, there was no evidence that any systematic attempt had been made to set the results of the new trials in context (Table).

COMMENT

More than 35 years ago, Austin Bradford Hill suggested that the structure of a scientific paper could usefully be conceptualized in terms of 4 questions: Why did you start? What did you do? What answer did you get? And what does it mean anyway? These questions are reflected in a common structure for scientific reports (sometimes called IMRaD) comprising an introduction, a description of the materials and methods, the results, and a discussion of the findings. The introduction should clarify why the study was worth starting. The discussion should indicate the contribution of the new findings to the evidence available at reporting.

The public would be served better if systematic reviews were always available before new clinical studies began, which would reduce unwanted duplication of research and help ensure that new research had been designed to build on lessons from earlier research. Another consequence would be the automatic establishment of the basis for preparing a more informative discussion section when the new study is reported.

In our 2 studies, separated by 4 years, we have been unable to detect any increase in the extent to which the results of new randomized trials published in 5 prestigious general medical journals have been presented within the context of updated systematic reviews of other relevant studies (Table). We have not identified any other reports of empirical research assessing the extent to which this issue has been addressed. Some articles have considered other issues about the quality of discussion sections, but the fundamental and important issue addressed in our studies seems to have been ignored. Perhaps even more worrying, the CONSORT group appears to have weakened its initial guidance on this matter by deleting their earlier reference to the need to interpret the data from a trial “in the light of the totality of the available evidence.”

The expectation that the results of a new randomized trial will be reported in the context of an up-to-date systematic review of earlier trials does not imply that the discussion section of every report of a randomized trial should contain a full account of the material, methods, and findings of such a review. The technology already exists to enable a brief review to be included in the discussion section, with links to relevant, up-to-date, systematic reviews published elsewhere. The encouraging development by the BMJ of including a summary with each report of new research to show what is already known on a topic and what the new study adds could be extended to provide links to the evidence, such as systematic reviews, upon which these summaries are based.

Because our expectations imply radical changes in the way that research is done and reported, we expect that not all researchers, journal editors, or publishers will agree with them. However, science is cumulative, and everyone, including the public, has a right to expect that this principle will be reflected more effectively in the way that science is conducted and reported. We feel that this imposes a duty on researchers to present their results in proper context and on journal editors to require researchers to do so.

DISCLAIMER: All 3 authors are employed at the UK Cochrane Centre, which is part of the Cochrane Collaboration. The views expressed in this article represent those of the authors and are not necessarily the views or the official policy of the Cochrane Collaboration.

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Quality of Reporting of Randomized Trials as a Measure of Methodologic Quality

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The randomized controlled trial (RCT) is the design of choice for evaluating the effectiveness of health care interventions, but trials are not immune to bias. The validity of their results is threatened by the subversion of randomization, resulting in biased allocation to comparison groups, the unequal provision of care apart from the intervention under evaluation, the biased assessment of outcomes, and the inadequate handling of dropouts and losses to follow-up. Several studies have recently documented these biases. For example, Schulz et al demonstrated, for trials with binary outcomes included in meta-analyses from the Cochrane Pregnancy and Childbirth Database, that trials in which randomization was inadequately concealed yielded exaggerated estimates of treatment effect in comparison with trials that reported adequate concealment and found a similar (but smaller) overestimation of treatment effects for trials that were not adequately blinded.

Information on trial quality is important for peer review, when considering the results from individual trials and for the conduct of unbiased systematic reviews. The assessment of the methodologic quality of a trial is closely intertwined with the quality of reporting, that is, the extent to which a report provides information about the design, conduct, and analysis of the trial. Trial reports often omit important methodologic details. A widely used approach to this problem consists in treating reporting quality as a proxy measure for methodologic quality. This could be justified if the assumption were correct that faulty reporting reflects faulty methods. The objective of our study was to examine the relationship between the quality of reporting and the methodologic quality of RCTs.

Context The evaluation of the methodologic quality of randomized controlled trials (RCTs) is central to evidence-based health care. Important methodologic detail may, however, be omitted from published reports, and the quality of reporting is therefore often used as a proxy measure for methodologic quality. We examined the relationship between reporting quality and methodologic quality of published RCTs.

Methods Study of 60 reports of placebo-controlled trials published in English-language journals from 1985 to 1997. Reporting quality was measured using a 25-item scale based on the 1996 issue of the Consolidated Standards of Reporting Trials (CONSORT). Concealment of allocation, appropriate blinding, and analysis according to the intention-to-treat principle were indicators of methodologic quality. Methodologic quality was compared between groups of trials defined by reporting quality scores of low, intermediate, and high. Reporting quality scores were compared between groups defined by high and low methodologic quality.

Results Among 23 trials of low reporting quality (median score, 9 [range, 3.5-10.5]), allocation concealment was unclear for all but 1 trial, but there were 16 trials (70%) with adequate blinding and 9 trials (39%) that had been analyzed according to the intention-to-treat principle. Among 18 trials of high reporting quality (median score, 18 [range 16.5-22.0]), there were 8 trials (44%) with adequate allocation concealment, 16 trials (89%) with adequate blinding, and 13 trials (72%) analyzed according to the intention-to-treat principle. The median reporting score was 15.0 for the 33 trials that were analyzed according to intention-to-treat principle and 14.5 for the 14 trials with on-treatment analyses ($P = .67$).

Conclusions Similar quality of reporting may hide important differences in methodologic quality, and well-conducted trials may be reported badly. A clear distinction should be made between these 2 dimensions of the quality of RCTs.

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