

Reporting and Interpretation of Randomized Controlled Trials With Statistically Nonsignificant Results for Primary Outcomes

Isabelle Boutron, MD, PhD

Susan Dutton, MSc

Philippe Ravaud, MD, PhD

Douglas G. Altman, DSc

ACCURATE PRESENTATION OF the results of a randomized controlled trial (RCT) is the cornerstone of the dissemination of the results and their implementation in clinical practice. The Declaration of Helsinki states that “Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports.” To help enforce this principle, trial registration is required,¹ and reporting guidelines are available.² However, investigators usually have broad latitude in writing their articles³; they can choose which data to report and how to report them.

Consequently, scientific articles are not simply reports of facts, and authors have many opportunities to consciously or subconsciously shape the impression of their results for readers, that is, to add “spin” to their scientific report.⁴ Spin can be defined as specific reporting that could distort the interpretation of results and mislead readers.^{3,5,6} The use of spin in scientific writing can result from ignorance of the scientific issue, unconscious bias, or willful intent to deceive.³ Such distorted presentation and interpretation of trial results in published articles has

Context Previous studies indicate that the interpretation of trial results can be distorted by authors of published reports.

Objective To identify the nature and frequency of distorted presentation or “spin” (ie, specific reporting strategies, whatever their motive, to highlight that the experimental treatment is beneficial, despite a statistically nonsignificant difference for the primary outcome, or to distract the reader from statistically nonsignificant results) in published reports of randomized controlled trials (RCTs) with statistically nonsignificant results for primary outcomes.

Data Sources March 2007 search of MEDLINE via PubMed using the Cochrane Highly Sensitive Search Strategy to identify reports of RCTs published in December 2006.

Study Selection Articles were included if they were parallel-group RCTs with a clearly identified primary outcome showing statistically nonsignificant results (ie, $P \geq .05$).

Data Extraction Two readers appraised each selected article using a pretested, standardized data abstraction form developed in a pilot test.

Results From the 616 published reports of RCTs examined, 72 were eligible and appraised. The title was reported with spin in 13 articles (18.0%; 95% confidence interval [CI], 10.0%-28.9%). Spin was identified in the Results and Conclusions sections of the abstracts of 27 (37.5%; 95% CI, 26.4%-49.7%) and 42 (58.3%; 95% CI, 46.1%-69.8%) reports, respectively, with the conclusions of 17 (23.6%; 95% CI, 14.4%-35.1%) focusing only on treatment effectiveness. Spin was identified in the main-text Results, Discussion, and Conclusions sections of 21 (29.2%; 95% CI, 19.0%-41.1%), 31 (43.1%; 95% CI, 31.4%-55.3%), and 36 (50.0%; 95% CI, 38.0%-62.0%) reports, respectively. More than 40% of the reports had spin in at least 2 of these sections in the main text.

Conclusion In this representative sample of RCTs published in 2006 with statistically nonsignificant primary outcomes, the reporting and interpretation of findings was frequently inconsistent with the results.

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been highlighted in letters to editors criticizing the interpretation of results⁷ and in methodological reviews evaluating misleading claims in published reports of RCTs^{8,9} or systematic reviews.¹⁰ However, to our knowledge, the strategies used to create spin in published articles have never been systematically assessed.

Author Affiliations: Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom (Drs Boutron and Altman and Ms Dutton); INSERM, U738, Paris, France (Drs Boutron and Ravaud); Assistance Publique des Hôpitaux de Paris, Hôpital Hôtel Dieu, Centre d'Épidémiologie Clinique, Paris (Drs Boutron and Ravaud); and Université Paris Descartes, Faculté de Médecine, Paris (Drs Boutron and Ravaud).

Corresponding Author: Isabelle Boutron, MD, PhD, Centre d'Épidémiologie Clinique, Hôpital Hôtel Dieu, 1, Place du Parvis Notre-Dame, 75181 Paris CEDEX 4, France (isabelle.boutron@hntd.aphp.fr).