

Data interpretation in analgesic clinical trials with statistically non-significant primary analyses: An ACTION systematic review

Jennifer S. Gewandter^a, Andrew McKeown^a, Michael P. McDermott^b, Jordan D. Dworkin^c, Shannon M. Smith^a, Robert A. Gross^d, Matthew Hunsinger^f, Allison H. Lin^e, Bob A. Rappaport^e, Andrew S. C. Rice^g, Michael C Rowbotham^h, Mark R. Williams^a, Dennis C. Turkⁱ, Robert H. Dworkin^a

^aDepartment of Anesthesiology, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA (AM: Andrew.Mckeown@URMC.Rochester.edu; SMS: Shannon1.Smith@URMC.Rochester.edu; MRW: Mark1.Williams@URMC.Rochester.edu; RHD: Robert_Dworkin@URMC.Rochester.edu)

^bDepartments of Biostatistics and Computational Biology and Neurology, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA, mikem@bst.rochester.edu.

^cHaverford College, Haverford, PA, jdworkin@haverford.edu

^dDepartments of Neurology and Pharmacology and Physiology University of Rochester School of Medicine and Dentistry, Rochester, NY, USA, Robert_Gross@URMC.Rochester.edu

^eUnited States Food and Drug Administration, Silver Spring, MD, USA (SHH: Sharon.hertz@fda.hhs.gov; AHL: Allison.Lin@fda.hhs.gov; BAR: bob.rappaport@fda.hhs.gov)

^fSchool of Professional Psychology, Pacific University, Hillsboro, OR, USA, matthewh@pacificu.edu

^gPain Research, Department of Surgery and Cancer, Imperial College, London, UK, a.rice@imperial.ac.uk

^hCalifornia Pacific Medical Center, San Francisco, CA, USA, mcrowbotham@gmail.com

ⁱDepartment of Anesthesiology and Pain Medicine, University of Washington, Seattle, WA, USA, turkdc@u.washington.edu

****The work was performed at the University of Rochester, Rochester, NY****

***Corresponding author:**

Jennifer Gewandter

Tel: +1 585 276 5661

Fax: +1 585 244 7271

E-mail: Jennifer_gewandter@urmc.rochester.edu

Running Title: Spin in analgesic clinical trials

Abstract

Peer-reviewed publications of randomized clinical trials (RCTs) are the primary means of disseminating research findings. “Spin” in RCT publications is misrepresentation of statistically non-significant research findings to suggest treatment benefit. Spin can influence the way readers interpret clinical trials and use the information to make decisions about treatments and medical policies. The objective of this study was to determine the frequency with which 4 types of spin were used in publications of analgesic RCTs with non-significant primary analyses in 6 major pain journals. In the 76 articles included in our sample, 28% of the Abstracts and 29% of the main texts emphasized secondary analyses with p-values <0.05; 22% of Abstracts and 29% of texts emphasized treatment benefit based on non-significant primary results; 14% of Abstracts and 18% of texts emphasized within-group improvements over time, rather than primary between-group comparisons; and 13% of Abstracts and 10% of texts interpreted a non-significant difference between groups in a superiority study as comparable effectiveness. When considering the article Conclusion sections, 21% did not mention the non-significant primary result, 22% were presented with no uncertainty or qualification, 30% did not acknowledge that future research was required, and 8% recommended the intervention for clinical use.

Perspective: This article identifies relatively frequent “spin” in analgesic RCTs. These findings highlight a need for authors, reviewers, and editors to be more cognizant of how analgesic RCT results are presented and attempt to minimize spin in future clinical trial publications.

Key words: spin, misrepresentation, randomized clinical trials, ACTION, systematic review