

Reporting Number Needed to Treat and Absolute Risk Reduction in Randomized Controlled Trials

Jim Nuovo, MD

Joy Melnikow, MD, MPH

Denise Chang, BA

RANDOMIZED CONTROLLED TRIALS (RCTs) are the gold standard in the assessment of a treatment effect.¹ The magnitude of this effect can be presented in various ways, eg, relative risk reduction (RRR), absolute risk reduction (ARR), and odds ratio (OR). In 1988, Laupacis et al² reported the number needed to treat (NNT), an expression of the number of patients who must be treated to prevent one adverse event. Mathematically, NNT equals the reciprocal of the ARR. Reporting this value provides readers with additional information to help them decide whether a treatment should be used. Failing to report NNT may influence the interpretation of study results. For example, reporting RRR alone may lead a reader to believe that a treatment effect is larger than it really is.³⁻⁶ We examined the frequency of explicit reporting of NNT and ARR in RCTs.

METHODS

Five frequently cited journals were selected for investigation: *Annals of Internal Medicine*, *BMJ*, *JAMA*, *The Lancet*, and the *New England Journal of Medicine*. For each journal, 4 years were assessed: 1989, 1992, 1995, and 1998. The index year was designated 1989 because it represented 1 year after publication on NNT by Laupacis et al.² Three-year intervals were selected to obtain a representative sample to observe for changes over time. All issues of each journal were manually reviewed for the specific years of in-

Context Ongoing efforts to improve the quality of reporting for randomized controlled trials (RCTs) include the Consolidated Standards of Reporting Trials (CONSORT) statement. We examined the frequency of explicit reporting of the number needed to treat (NNT) and the absolute risk reduction (ARR) in RCTs.

Methods Five frequently cited journals were investigated: *Annals of Internal Medicine*, *BMJ*, *JAMA*, *The Lancet*, and the *New England Journal of Medicine*. For each journal, 4 years were evaluated: 1989, 1992, 1995, and 1998. All issues of each journal for each year were reviewed manually. Eligible articles were those in which an RCT was conducted on the use of a medication showing a significant treatment effect. Elements abstracted from each eligible article were the condition investigated, event being treated or prevented, intervention, study results, and reporting methods (relative risk reduction, NNT, and ARR).

Results Of 359 eligible articles, NNT was reported in 8 articles. Six of the 8 studies were from 1998. Absolute risk reduction was reported in 18 articles, 10 of which were from 1998.

Conclusions Despite CONSORT recommendations, few authors expressed their findings in terms of NNT or ARR. Consideration should be given to including these values in reports of RCTs.

JAMA. 2002;287:2813-2814

www.jama.com

terest. Eligible articles included studies that reported a randomization process, presented binary outcome or survival data, and reported a statistically significant treatment effect. All eligible articles were reviewed independently by 2 of the authors. A data collection form was used to abstract the following information from each article: condition investigated, event being treated or prevented, intervention, study results, and reporting methods (RRR, NNT, and ARR). The complete article was reviewed to assess the use of NNT and ARR. After completing the data abstraction process, findings were compared.

RESULTS

There was complete agreement between the 2 reviewers. The summary of findings and journal-specific results is presented in the TABLE. Five hundred sixty-four articles met the criteria for a

randomized trial. Of these, 359 met the additional inclusion criteria. The NNT was reported in 8 articles, and ARR was reported in 18. All 8 articles reporting NNT also presented ARR. Six of the 8 studies reporting NNT and 10 of the 18 reporting ARR were from 1998.

COMMENT

The best evidence on the efficacy of medical interventions comes from well-conducted RCTs, but unless the results of such trials are reported adequately, assessing that information is difficult. The methods by which data are displayed can influence the interpretation of the study results.³ The widespread practice of stressing important findings from RCTs

Author Affiliations: Department of Family and Community Medicine, University of California, Davis.

Corresponding Author and Reprints: Jim Nuovo, MD, Department of Family and Community Medicine, University of California, Davis, 4860 Y St, Sacramento, CA 95817 (e-mail: jim.nuovo@ucdmc.ucdavis.edu).

Table. Reporting Number Needed to Treat (NNT) and Absolute Risk Reduction (ARR) in Randomized Controlled Trials (RCTs) of 5 Journals

Journal	No. of Articles		
	Eligible RCTs	NNT	ARR
1989*			
<i>Annals of Internal Medicine</i>	5	0	0
<i>BMJ</i>	15	0	0
<i>JAMA</i>	9	0	0
<i>The Lancet</i>	24	0	0
<i>New England Journal of Medicine</i>	2	6	7
Total	55	6	7
1992			
<i>Annals of Internal Medicine</i>	14	0	1
<i>BMJ</i>	15	0	0
<i>JAMA</i>	8	0	0
<i>The Lancet</i>	24	1	1
<i>New England Journal of Medicine</i>	30	0	1
Total	91	1	3
1995			
<i>Annals of Internal Medicine</i>	17	0	0
<i>BMJ</i>	8	1	1
<i>JAMA</i>	9	0	0
<i>The Lancet</i>	25	0	2
<i>New England Journal of Medicine</i>	34	0	2
Total	93	1	5
1998			
<i>Annals of Internal Medicine</i>	11	0	2
<i>BMJ</i>	8	0	1
<i>JAMA</i>	17	1	1
<i>The Lancet</i>	22	3	3
<i>New England Journal of Medicine</i>	38	2	3
Total	96	6	10
Total Eligible RCTs			
<i>Annals of Internal Medicine</i>	47	0	3
<i>BMJ</i>	46	1	2
<i>JAMA</i>	43	1	1
<i>The Lancet</i>	95	4	6
<i>New England Journal of Medicine</i>	128	2	6
Total	359	8	18

*1989 was chosen as the index year for comparison of change over time.

in terms of RRRs may potentially mislead the reader.⁴ The NNT and ARR express efficacy by incorporating the baseline risk without therapy and the risk reduction with therapy. Also, NNT allows physicians to understand how much effort is needed to prevent one event, thus allowing comparisons with the amount of effort needed to prevent the same or other events in patients with other disorders.

Despite NNT's potential, there have been concerns expressed about its limitations. Cook and Sackett⁵ note that NNT presents a problem when the results of an RCT with patients at one baseline risk

are applied to a particular patient at a different risk. Chatellier et al⁶ express concern on extrapolating NNT to time points not considered in trials.

There have been ongoing efforts to improve the quality of reporting results of RCTs, including the Consolidated Standards of Reporting Trials (CONSORT) statement, first published in 1996.⁷ A subsequent revision of the CONSORT statement encouraged reporting of absolute values and NNT.⁸ Although the use of CONSORT improves the quality of reporting in some areas,⁹ the results of our study raise concerns, specifically, that NNT and

ARR are underused in the medical literature. These results are consistent with those of similar studies showing that inadequate description of randomization¹⁰ and participant flow¹¹ are common. Junker¹² described the adherence to published standards of reporting on an 18-item scale; the mean score among 121 reports was 8.4. The results of our study and others suggest the need for additional measures to ensure compliance with reporting standards. These measures should continue to improve the reporting of an RCT and enable readers to better interpret the results.

Author Contributions: Study concept and design: Nuovo, Melnikow, Chang.
Acquisition of data: Nuovo, Chang.
Analysis and interpretation of data: Nuovo, Melnikow.
Drafting of the manuscript: Nuovo, Melnikow.
Critical revision of the manuscript for important intellectual content: Nuovo, Chang.
Administrative, technical, or material support: Nuovo, Chang.
Study supervision: Nuovo.

REFERENCES

- Moher D, Jadad AR, Nichol G, Penman M, Tugwell P, Walsh S. Assessing the quality of randomized controlled trials. *Control Clin Trials*. 1995;16:62-73.
- Laupacis A, Sackett DL, Roberts RS. An assessment of clinically useful measures of the consequences of treatment. *N Engl J Med*. 1988;318:1728-1733.
- Elting LS, Martin CG, Cantor SB, Rubenstein EB. Influence of data display formats on physician investigator's decisions to stop clinical trials. *BMJ*. 1999;318:1527-1531.
- Naylor CD, Chen E, Strauss B. Measured enthusiasm: does the method of reporting trial results alter perceptions of therapeutic effectiveness? *Ann Intern Med*. 1992;117:916-921.
- Cook RJ, Sackett DL. The number needed to treat: a clinically useful measure of treatment effect. *BMJ*. 1995;310:452-454.
- Chatellier G, Zapletal E, Lemaitre D, et al. The number needed to treat: a clinically useful nomogram in its proper context. *BMJ*. 1996;312:426-429.
- Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting randomized controlled trials: the CONSORT statement. *JAMA*. 1996;276:637-639.
- Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting randomized trials. *Ann Intern Med*. 2001;134:663-694.
- Moher D, Jones A, Lepage L. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. *JAMA*. 2001;285:1992-1995.
- Hotopf M, Lewis G, Normand C. Putting trials on trial: the costs and consequences of small trials in depression. *J Epidemiol Community Health*. 1997;51:354-358.
- Egger M, Juni P, Bartlett C. Value of flow diagrams in reports of randomized controlled trials. *JAMA*. 2001;285:1996-1999.
- Junker CA. Adherence to published standards of reporting: a comparison of placebo-controlled trials published in English or German. *JAMA*. 1998;280:247-249.