Quality of reporting and risk of bias of randomized clinical trials published in Spanish and Latin American journals

Vivienne C. Bachelet[a,*], Hector Pardo-Hernandez[b]

[a] Escuela de Medicina, Facultad de Ciencias Médicas, Universidad de Santiago de Chile (USACH), Santiago, Chile

[b] Iberoamerican Cochrane Center, Biomedical Research Institute Sant Pau (IIB Sant Pau) - CIBER Epidemiología y Salud Pública (CIBERESP), Barcelona, Spain

*Corresponding author vbachelet@medwave.cl

Citation Bachelet VC, Pardo-Hernandez H. Quality of reporting and risk of bias of randomized clinical trials published in Spanish and Latin American journals. *Medwave* 2019;19(1):e7573

Doi 10.5867/medwave.2019.01.7573

Submission date 25/1/2018
Publication date 29/1/2019

In the pyramid of the evidence quality to assess efficacy, effectiveness, and adverse reactions to interventions, randomized clinical/controlled trials (RCT) are conventionally at the top, right below systematic reviews of clinical trials and n-of-1 trials.[1] When RCTs are conducted properly, randomization of participants to treatments ensures that confounding by both known and unknown covariables will be controlled, thus reducing the risk of bias.[2] This is why we use RCTs to decide on the best interventions for our patients, which can be pharmacological, surgical, psychological, educational, informational or manual therapies, as well as changes in processes or the use of devices or medical devices.

Since the advent of the evidence-based medicine movement and the Cochrane Collaboration at the end of the eighties and beginning of the nineties, respectively, there has been a growing interest to improve the quality of the evidence from RCTs. Two main focuses have arisen: the methodological quality of the trials and the quality of the reporting of the findings. The former is concerned about the design and conduct of the RCT to reduce the risk of bias starting from the planning stage[3,4] and for which a variety of scales, systems, and classifications have been developed to assess internal validity.[5] The latter concerns how the findings are published in the biomedical literature and how the methods and the results of an RCT are actually reported—imprecisions and gaps in the reporting will hinder the correct assessment of the internal validity of the trials[6], the consequence being that much of the medical literature is rendered useless and wasteful. As Chalmers and Glasziou bluntly stated: "Without accessible and usable reports, research cannot help patients and their clinicians."[7]

Methodological quality of clinical trials has been defined as a set of parameters in the design and conduct of a study that reflects the validity of the outcome of interest[8] and primarily depends on the selection of the participants and sample size; on the random allocation of treatment; on blinding and masking; on patient follow-up with accounting for losses and drop-outs; and on the non-selective reporting of planned endpoints and outcomes.[9] Depending upon how each one of these phases of the clinical trials is planned, conducted, analyzed, and reported, the risk of bias may be higher or lesser. The most commonly used method to assess the risk of bias of RCTs is the Cochrane Collaboration tool.[5]

Acknowledging the need to improve the quality of reporting of the published clinical trials, in 1993 a meeting was held in Ottawa, Canada, that brought together editors of medical journals, trialists, epi-

demiologists, and methodologists. From this first effort, the first version of the Consolidated Standards of Reporting Trials (CONSORT) Statement came out, which was published in 1996. Subsequently, two other versions have been published, in 2001 and 2010. This last statement was published simultaneously in nine high-impact medical journals and is the version currently in use.[10] The CONSORT guideline sets minimum required standards for an adequate reporting of an RCT. It contains 25 items distributed in six topics: 1) title and abstract, 2) introduction, 3) methods, 4) results, 5) discussion, and 6) ancillary analyses.[11,12]

After the publication of each CONSORT statement, the leading biomedical journals have gradually incorporated the recommendation to use CONSORT when reporting trial results in their author guidelines. How these recommendations and the integration of CONSORT adherence into the editorial workflow (endorsement and enforcement) have impacted the quality of publications has also been extensively studied. Two systematic reviews evaluated reporting completeness and concluded that journal endorsement and enforcement to CONSORT could lead to favorable results regarding reporting completeness, but that more research is needed.[13,14] Likewise, another study with a research-on-research design concluded that while poor-quality reporting prevalence has gradually decreased, there is still much to be done, especially in lower impact factor journals.[15]

There are few studies on randomized clinical trials of Latin America. While the region accounts for a significant share of global disease burden, it does not have a corresponding number of published clinical trials in the five top biomedical journals.[16] One study looked at the prevalence of registration in the clinical trials databases of Latin American RCTs in 2010 and compared the methodological characteristics of the articles that reported registration before trial commencement versus those that did not.[17] The authors found that only 4% of the trials were prospectively registered. Another study compared methodological quality with funding source of trials conducted in Latin America but published elsewhere[18]—no statistically significant associations were found. Another descriptive study found that only 13% of a random sample of 101 RCTs published in 56 journals mentioned the CONSORT guideline.[19] More recently, a systematic hand search of RCTs published in dermatology journals in Spanish found a high risk of bias due to gaps in reporting and methodological deficiencies.[20]

The Iberoamerican Cochrane Network currently leads a large project to identify all Spanish-language journals that publish original clinical research in Spain and Latin America. In 2012, 1498 journals had been identified, of which only 3% had an impact factor; 4.1% were indexed in MEDLINE/PubMed; 3.7% were included in EMBASE.[21] Those journals are currently being hand-searched by Cochrane collaborators in order to identify all RCTs published in Spain and Latin America, by specialty. Additionally, an online database has been developed to centralize all hand searching activities and to facilitate submission of references to CENTRAL (*Cochrane Collaboration Central Register of Controlled Trials*) thus potentially feeding into the systematic reviews that Cochrane conducts on different health topics. This database is BADERI (Base de Datos de Ensayos y Revistas Iberoamericanas) and was officially launched in October 2015.[22] Until 2017, BADERI had included 6583 references to RCTs published in over 400 journals from Spain and Latin America on 46 medical specialties, covering a period from 1957 to 2017.[22] To date, manual hand searching has completed the following specialties: Obstetrics and Gynecology,[23] Dermatology,[20] Physiotherapy,[24] Ophthalmology,[25] Orthopedics and Traumatology,[26] and Dentistry.[27] Methodological quality of these clinical trials has been assessed only for Dermatology[20], Ophthalmology,[25] Orthopedics and Traumatology,[26] and in the clinical trials on reproductive techniques in obstetrics.[23]

We are currently beginning to undertake a broad research project that will assess both the methodological and the reporting quality of randomized controlled trials published in Spain and Latin America included in Cochrane's BADERI database. The results of this research project will help journal editors, funders, and research communities of the region in their decision-making process on the planning, conduct, and publication of clinical trials.

Notes

Acknowledgement
DICYT Project 021901BN

Competing interests
None

References

1. Guyatt G, Rennie D, Meade MO, Cook DJ. User's Guides to the Medical Literature - A Manual for Evidence-Based Clinical Practice. 5th ed. The American Medical Association; 2015.
2. Newman TB, Browner WS, Cummings SR, Hulley SB. Designing an observational study: cross-sectional and case-control studies. In: Designing clinical research. Lippincott Williams & Williams, a Wolters Kluwer business; 2013. | Link |
3. Haynes RB, Sackett DL, Guyatt GH, Tugwell P. Clinical Epidemiology - How to Do Clinical Practice Research. 3rd ed. Lippincott Williams & Wilkins; 2006.
4. Altman DG, Machin D, Bryant TN, Gardner M. Statistics with confidence: confidence intervals and statistical guidelines. 2nd ed. BMJ Books 2000.
5. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011 Oct 18;343:d5928. | CrossRef | PubMed |
6. Moher D, Altman DG, Schulz KF, Simera I, Wager E. Guidelines for Reporting Health Research: A User's Manual. 1st ed. BMJ Books 2014.
7. Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. Lancet Lond Engl 2009;374:86–9. | CrossRef |
8. Verhagen AP, de Vet HC, de Bie RA, Kessels AG, Boers M, Bouter LM, et al. The Delphi list: a criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. J Clin Epidemiol. 1998 Dec;51(12):1235-41. | PubMed |
9. Delgado-Parra I. Identificación, descripción y análisis crítico de ensayos clínicos controlados publicados en revistas odontológicas de habla hispana. Memoria para optar al grado de Doctora. Universidad Complutense de Madrid, Facultad de Odontología; 2017. | Link |

10. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011 Oct 18;343:d5928. | CrossRef | PubMed |
11. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Trials. 2010 Mar 24;11:32. | CrossRef | PubMed |
12. Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. PLoS Med. 2007 Oct 16;4(10):e297. | PubMed |
13. Cobos-Carbó A, Augustovski F. [CONSORT 2010 Declaration: updated guideline for reporting parallel group randomised trials]. Med Clin (Barc). 2011 Jul 23;137(5):213-5. | CrossRef | PubMed |
14. Perel P, Miranda JJ, Ortiz Z, Casas JP. Relation between the global burden of disease and randomized clinical trials conducted in Latin America published in the five leading medical journals. PLoS One. 2008 Feb 27;3(2):e1696. | CrossRef | PubMed |
15. Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, et al. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. Cochrane Database Syst Rev. 2012 Nov 14;11:MR000030. | CrossRef | PubMed |
16. Stevens A, Shamseer L, Weinstein E, Yazdi F, Turner L, Thielman J, et al. Relation of completeness of reporting of health research to journals' endorsement of reporting guidelines: systematic review. BMJ. 2014 Jun 25;348:g3804. | CrossRef | PubMed |
17. Dechartres A, Trinquart L, Atal I, Moher D, Dickersin K, Boutron I, et al. Evolution of poor reporting and inadequate methods over time in 20 920 randomised controlled trials included in Cochrane reviews: research on research study. BMJ. 2017 Jun 8;357:j2490. | CrossRef | PubMed |
18. Reveiz L, Bonfill X, Glujovsky D, Pinzon CE, Asenjo-Lobos C, Cortes M, et al. Trial registration in Latin America and the Caribbean's: study of randomized trials published in 2010. J Clin Epidemiol. 2012 May;65(5):482-7. | CrossRef | PubMed |
19. Reveiz L, Sangalang S, Glujovsky D, Pinzon CE, Asenjo Lobos C, Cortes M, et al. Characteristics of randomized trials published in Latin America and the Caribbean according to funding source. PLoS One. 2013;8(2):e56410. | CrossRef | PubMed |
20. Reveiz L, Villanueva E, Iko C, et al. Compliance with clinical trial registration and reporting guidelines by Latin American and Caribbean journals. Cad Saude Publica 2013;29:1095-100. | CrossRef |
21. Sanclemente G, Pardo H, Sánchez S, Bonfill X. Analysis of the Quality of Clinical Trials Published in Spanish-Language Dermatology Journals Between 1997 and 2012. Actas Dermosifiliogr. 2016 Jan-Feb;107(1):44-54. | CrossRef | PubMed |
22. Bonfill X, Osorio D, Posso M, Solà I, Rada G, Torres A, et al. Identification of biomedical journals in Spain and Latin America. Health Info Libr J. 2015 Dec;32(4):276-86. | CrossRef | PubMed |
23. Pardo-Hernandez H, Urrútia G, Barajas-Nava LA, Buitrago-Garcia D, Garzón JV, Martínez-Zapata MJ, et al. BADERI: an online database to coordinate handsearching activities of controlled clinical trials for their potential inclusion in systematic reviews. Trials. 2017 Jun 13;18(1):273. | CrossRef | PubMed |
24. Gutarra-Vilchez RB, Pardo-Hernandez H, Arévalo-Rodríguez I, Buitrago D, Bonfill X. Identification and description of controlled clinical trials published in Spanish Gynaecology and Obstetrics journals and risk of bias assessment of trials on assisted reproductive techniques. Eur J Obstet Gynecol Reprod Biol. 2016 Aug;203:5-11. | CrossRef | PubMed |
25. Sanclemente G, Pardo H, Sánchez S, Bonfill X. Analysis of the Quality of Clinical Trials Published in Spanish-Language Dermatology Journals Between 1997 and 2012. Actas Dermosifiliogr. 2016 Jan-Feb;107(1):44-54. | CrossRef | PubMed |
26. Turrillas M, Sitjà-Rabert M, Pardo H, Vilaró Casamitjana J, Fort-Vanmeerhaeghe A, Morral Fernández A, et al. Identification and description of controlled clinical trials published in Physiotherapy journals in Spain. J Eval Clin Pract. 2017 Feb;23(1):29-36. | CrossRef | PubMed |
27. Villanueva J, Delgado I, Saldarriaga JR, Gargallo MG, Amaro Y, Zapata S, et al. Identification and description of controlled clinical trials in Spanish language dental journals. Health Info Libr J. 2018 Sep;35(3):192-201. | CrossRef | PubMed |

Correspondencia a
Alameda Bernardo O'Higgins 3363
Estación Central
Santiago
Región Metropolitana
Chile