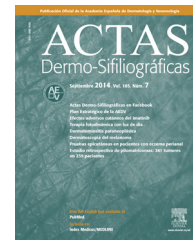




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ORIGINAL ARTICLE

Analysis of the Quality of Clinical Trials Published in Spanish-Language Dermatology Journals Between 1997 and 2012[☆]



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Received 17 June 2015; accepted 31 July 2015

Available online 18 December 2015

KEYWORDS

Randomized clinical trial;
Bias;
Methodology;
Dermatology journals;
Spanish

Abstract

Introduction: The value of randomized clinical trials (RCTs) undertaken to identify an association between an intervention and an outcome is determined by their quality and scientific rigor.

Objective: To assess the methodological quality of RCTs published in Spanish-language dermatology journals.

Methods: By way of a systematic manual search, we identified all the RCTs in journals published in Spain and Latin America between 1997 (the year in which the CONSORT statement was published) and 2012. Risk of bias was evaluated for each RCT by assessing the following domains: randomization sequence generation, allocation concealment, blinding of patients and those assessing outcomes, missing data, and patient follow-up. Source of funding and conflict of interest statements, if any, were recorded for each study.

Results: The search identified 70 RCTs published in 21 journals. Most of the RCTs had a high risk of bias, primarily because of gaps in the reporting of important methodological aspects. The source of funding was reported in only 15 studies.

Discussion and conclusions: In spite of the considerable number of Spanish and Latin American journals, few RCTs have been published in the 15 years analyzed. Most of the RCTs published had serious defects in that the authors omitted methodological information essential to any evaluation of the quality of the trial and failed to report sources of funding or possible conflicts of interest for the authors involved. Authors of experimental clinical research in dermatology published in Spain and Latin America need to substantially improve both the design of their trials and the reporting of results.

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[☆] Please cite this article as: Sanclemente G. Análisis de la calidad de los ensayos clínicos publicados en revistas dermatológicas publicadas en español entre 1997 y 2012. Actas Dermosifiliogr. 2016;107:44–54.

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PALABRAS CLAVE

Ensayo clínico aleatorizado; Sesgos; Metodología; Revistas dermatológicas; Español

Análisis de la calidad de los ensayos clínicos publicados en revistas dermatológicas publicadas en español entre 1997 y 2012**Resumen**

Introducción: La relevancia del ensayo controlado con asignación aleatoria (ECA) para determinar si existe una asociación entre una intervención y un desenlace está determinada por su calidad y rigor científico.

Objetivo: Evaluar la calidad metodológica de los ECA publicados en revistas dermatológicas en español.

Métodos: Se realizó una búsqueda manual y sistemática de los ECA publicados en las revistas de Dermatología españolas y latinoamericanas entre 1997 (publicación de los criterios CONSORT) y 2012. Se determinó el riesgo de sesgo de cada ECA, evaluando los siguientes dominios: generación de la secuencia aleatoria, ocultamiento de la asignación, cegamiento de los pacientes/evaluadores de desenlaces, datos faltantes y seguimiento de pacientes. Se identificaron la fuente de financiación de los estudios y el reporte de conflictos de interés.

Resultados: Se identificaron 70 ECA publicadas en 21 revistas. La mayoría de los ECA tuvo un alto riesgo de sesgo, principalmente por falta de reporte de los aspectos metodológicos importantes. Solo 15 estudios declararon fuentes de financiación.

Discusión y conclusiones: A pesar del número considerable de revistas existentes en España y Latinoamérica, en los 15 años estudiados se han publicado pocos ECA. La mayoría de los estudios presentó problemas de calidad importantes, al carecer de información metodológica que permitiera evaluar su calidad y a las falencias en el reporte de las fuentes de financiación y de los conflictos de interés de los autores. La investigación clínica experimental dermatológica que se publica en Ibero-Latinoamérica debe mejorar ostensiblemente tanto en su diseño como en su reporte de resultados.

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Introduction

The randomized controlled trial (RCT) is the most rigorous type of methodological design and the best way of determining whether a cause-effect relation exists between an intervention and the result or outcome being assessed. RCTs also provide the raw material for systematic reviews and meta-analyses. However, the value of such studies depends on the quality and methodological rigor of their design and implementation.

In recent decades, the field of dermatology has seen a substantial increase in experimental clinical research. However, this upturn in the volume of research has not been accompanied by a corresponding improvement in trial design and methodology. Several studies have reported that the RCTs published in the dermatology literature tend to fall below acceptable standards.¹⁻⁴

The Consolidated Standards of Reporting Trials (CONSORT) statement was first published in 1996 to improve the quality of reporting of clinical trials worldwide.⁵ The CONSORT statement includes a checklist designed to improve the reporting of RCTs, which also, indirectly, throws light on the study's quality and scientific rigor.

An improvement in the scientific quality and reporting of RCTs might have been expected following the implementation of CONSORT and the publication of the Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials (available from: <http://www.fda.gov/downloads/Drugs/>

<http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf> and <http://www.mrc.ac.uk/documents/pdf/good-clinical-practice-in-clinical-trials/>).

However, the evidence reveals the continued presence after 1997 of serious flaws in the design and reporting of clinical trials.⁶ The problem has also been observed in trials in the Spanish-language dermatology literature published after 1997. A study carried out in Spain found that only 6 (25%) of the 24 clinical trials found in the dermatology journal with the highest impact in that country—*ACTAS Dermo-Sifiligráficas*—were classified as being of high quality.³

In this context, the aim of the present study was to assess the methodological quality of the experimental clinical research in dermatology published in Spanish to facilitate an analysis of the strengths of these studies and the challenges that must be overcome. We analyzed the RCTs identified by a recent study that handsearched Spanish-language dermatology journals.⁷

The present study complements that work by analyzing the methodological quality of the RCTs published between 1997 and 2012 using the appropriate Cochrane Collaboration tools and a review of the reporting of conflicts of interest and funding sources.

Objective

To assess the methodological quality of the RCTs published in Spanish-language dermatology journals between 1997 and 2012.

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