Clinical trials in Brazilian journals of ophthalmology: where we are

Ensaios clínicos em periódicos brasileiros de oftalmologia: onde estamos

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ABSTRACT

Purpose: To compare clinical trials published in Brazilian journals of ophthalmology and in foreign journals of ophthalmology with respect to the number of citations and the quality of reporting [by applying the Consolidated Standards for Reporting Trials (CONSORT) statement writing standards].

Methods: The sample of this systematic review comprised the two Brazilian journals of ophthalmology indexed at Science Citation Index Expanded and six of the foreign journals of ophthalmology with highest Impact Factor® according ISI. All clinical trials (CTs) published from January 2009 to December 2010 at the Brazilians journals and a 1:1 randomized sample of the foreign journals were included. The primary outcome was the number of citations through the end of 2011. Subgroup analysis included language. The secondary outcome included likelihood of citation (cited at least once versus no citation), and presence or absence of CONSORT statement indicators.

Results: The citation counts were statistically significantly higher (P<0.001) in the Foreign Group (10.50) compared with the Brazilian Group (0.45). The likelihood citation was statistically significantly higher (P<0.001) in the Foreign Group (20/20 - 100%) compared with the Brazilian Group (8/20 - 40%). The subgroup analysis of the language influence in Brazilian articles showed that the citation counts were statistically significantly higher in the papers published in English (P<0.04). Of 37 possible CONSORT items, the mean for the Foreign Group was 20.55 and for the Brazilian Group was 13.65 (P<0.003).

Conclusion: The number of citations and the quality of reporting of clinical trials in Brazilian journals of ophthalmology still are low when compared with the foreign journals of ophthalmology with highest Impact Factor®.

Keywords: Clinical trial; Ophthalmology; Citation databases; Journal Impact factor; Quality control

RESUMO

Objetivo: *Comparar ensaios clínicos publicados em periódicos brasileiros de oftalmologia e em periódicos estrangeiros de oftalmologia em relação ao número de citações e à qualidade da informação [através da aplicação do Consolidated Standards for Reporting Trials (CONSORT) statement].*

Métodos: *A amostra desta revisão sistemática abrangeu os dois periódicos brasileiras de oftalmologia indexaoas no* Science Citation Index Expanded *(Grupo Brasileiro) e seis dos periódicos estrangeiros de oftalmologia com maior fator de impacto de acordo com o ISI (Grupo Estrangeiro). Todos os ensaios clínicos, publicados entre janeiro de 2009 a dezembro de 2010, nos dois periódicos brasileiros e numa amostra aleatória 1:1 dos periódicos estrangeiros foram incluídos. O desfecho primário foi o número de citações até o final de 2011. A análise de subgrupos incluiu o idioma. O desfecho secundário incluiu a probabilidade de citação (citado ao menos uma vez versus não citado), e a presença ou ausência de indicadores da declaração CONSORT.*

Resultados: *O número de citações foi significativamente maior (P<0,001) no Grupo Estrangeiro (10,50) em comparação com o Grupo Brasileiro (0,45). A probabilidade de citação foi estatisticamente superior (P<0,001) no Grupo Estrangeiro (20/20-100%) comparado com o Grupo Brasileiro (8/20-41%). A análise de subgrupo sobre a influência da língua em artigos Brasileiros mostrou que o número de citações foi significativamente maior nos artigos publicados em Inglês (P<0,04). Dos 37 itens do CONSORT possíveis, a média para o Grupo Estrangeiro foi de 20,55 e para o Grupo Brasileiro foi 13,65 (P<0,003).*

Conclusão: *O número de citações e a qualidade da redação dos ensaios clínicos em periódicos Brasileiros de oftalmologia ainda são baixos quando comparados com os periódicos estrangeiros de oftalmologia com mais alto fator de impacto.*

Descritores: *Ensaio clínico; Oftalmologia; Bases de dados de citações; Fator de impacto de revistas; Controle de qualidade*

INTRODUCTION

The most used tool for measuring the insertion of a journal is an analysis of how often articles published in that journal were cited in other articles of the same or other journal, indexed in a particular database, in a given time. Although imperfect, this method is used as an indicator of the global inclusion of a journal. Few years ago, the "Arquivos Brasileiros de Oftalmologia (ABO)" and the "Revista Brasileira de Oftalmologia (RBO)" have become part of the Institute for Scientific Information (ISI) Web of Knowledge®, considered the most important database of scientific citations. The result of measurement of the citations made by ISI is published in the Journal Citation Reports® (JCR) which contains several indicators, the best known being the Impact Factor®. The Impact Factor® of a journal in a given year is calculated based on the number of times articles published in the journal in the two previous years were cited in that year by all journals in that database[1].

A clinical trial is a type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Clinical trials, when appropriately designed, conducted, and reported, represent the gold standard in evaluating healthcare interventions[2]. The Consolidated Standards of Reporting Trials Group (CONSORT) statement provides a 25-item checklist for a minimum set of recommendations for reporting the trial design, analysis, and results. It was

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developed to assist authors in writing reports of clinical trials, editors and peer reviewers in reviewing manuscripts for publication, and readers in critically appraising published articles. It gives guidance for reporting all clinical trials, but focuses on the most common design type-individually randomized, two group, parallel trials, which accounts for over half of trials in the literature[3].

The main purpose of this study is to compare clinical trials published in Brazilians ophthalmology journals and in foreign ophthalmology journals with respect to the number of citations and the quality of reporting (by applying the CONSORT statement writing standards).

METHODS

This study was a systematic review. Originals clinical trials phase III or phase IV were identified by retrospective review of articles published from January 2009 to December 2010 (2009/2010). Phase III trials compare the results of people taking a new treatment with the results of people taking the standard treatment. Phase IV trials are done using thousands of people after a treatment has been approved and marketed, to check for side effects that were not seen in the phase III trial.

One group (Brazilian Group) included the two Brazilian journals of ophthalmology indexed at Science Citation Index Expanded ("Arquivos Brasileiros de Oftalmologia" e "Revista Brasileira de Oftalmologia"), and the other group (Foreign Group) included six of the foreign journals of ophthalmology with highest Impact Factor® according ISI (Ophthalmology; American Journal of Ophthalmology; Archives of Ophthalmology; Investigative Ophthalmology and Vision Science; Journal of Cataract and Refractive Surgery; and British Journal of Ophthalmology)[4].

The Brazilian group included all 20 clinical trials published in 2009/2010[5-24]. The Foreign group included a randomized (random order with a computer generated random number) sample of 20 clinical trials among the 449 published in 2009/2010 [The Medline search strategies for clinical trial sought (publication type) was: "clinical trial"; or "clinical trial, phase III"; or "clinical trial, phase IV"; or "controlled clinical trial"][25-44]. All articles were carefully scrutinized to confirm the study design.

The primary outcome was the number of citations through the end of 2011[4]. Most articles are rarely cited, if at all, during the same year in which they were published, but the citation count of the 2 subsequent years is representative (it forms the basis of estimating journal impact factors). Subgroup analysis included language.

The secondary outcome included likelihood of citation (cited at least once versus no citation), and presence or absence of CONSORT statement indicators[3]. Although the CONSORT checklist has 25 items, our final grading scale had a maximum of 37 possible points, because there are general items divided in subparts. It was assigned 1 point per subpart.

Descriptive statistics were calculated. Continuous data were expressed as mean values, standard deviation (SD) and ranges. Independent sample t-test of equality of means was used to compare the 2 groups. Analyses were conducted using PSPP statistical software. P values are 2-tailed. Statistical significance was considered at the 0.05 level.

RESULTS

The citation counts were statistically significantly higher (P<0.001) in the Foreign Group (mean=10.50, SD=11.22, with a range from 1 to 42) compared with the Brazilian Group (mean=0.45, SD=0.60, with a range from 0 to 2) (Figure 1). The likelihood citation was statistically significantly higher (P<0.001) in the Foreign Group (20/20 - 100%) compared with the Brazilian Group (8/20 - 40%).

The subgroup analysis of the language influence in Brazilian articles showed that the citation counts were statistically significantly higher (P<0.04) in the papers published in English (mean=1.00, SD=0.82, with a range from 0 to 2) compared with the papers published in Portuguese (mean=0.31, SD=0.48, with a range from 0 to 1) (Figure 2).

Of 37 possible CONSORT items, the mean for the Foreign Group was 20.55 (54%), SD=5.07, with a range from 11 to 29 (30%-78%), and for the Brazilian Group was 13.65 (35%), SD=3.44, with a range from 8 to 21 (22%-57%). The difference was statistically significant (P<0.003) (Figure 3).

DISCUSSION

The results of this study demonstrated that the number of citations and quality of reporting of Brazilian journals of ophthalmology still are low when compared with the foreign journals of ophthalmology with higher Impact Factor. The situation is worse to the articles published in Portuguese. By analyzing the citation of articles according to the language in which they were published, it

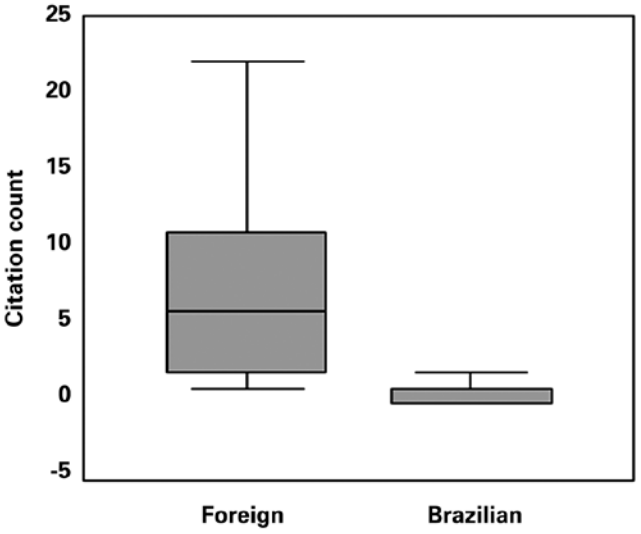

Figure 1. Citation counts of Foreign Group compared with the Brazilian Group.

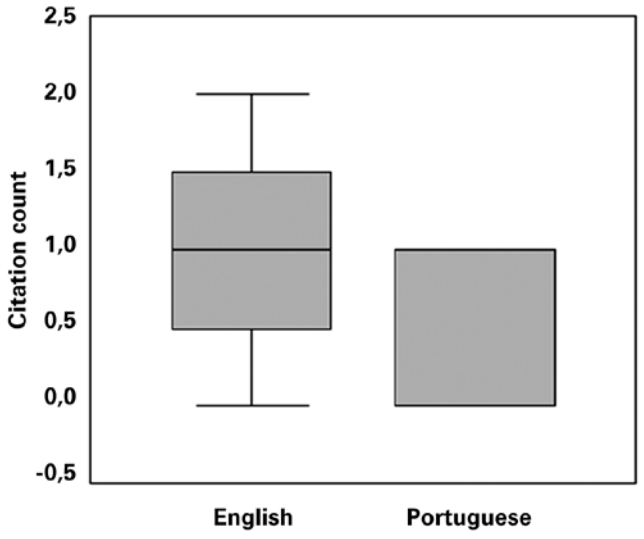

Figure 2. Subgroup analysis of the language influence in Brazilian articles.

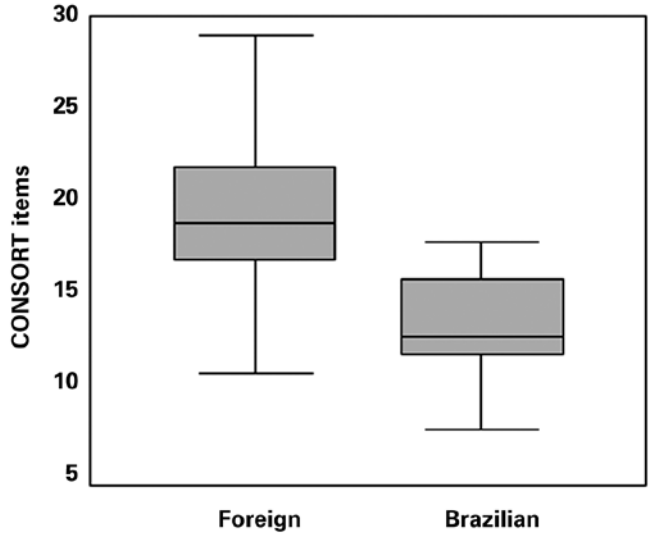

Figure 3. Presence of CONSORT statement indicators in the Foreign Group compared with the Brazilian Group.

is possible notice that the number of citations of papers written in English is higher[1].

Citation analysis of ophthalmology articles has rarely been reported. The impact of a published article can be estimated by evaluating how frequently the study is cited in subsequent peer-reviewed publications[45]. The number of times an article is cited over a given time period might indicates the level of importance attributed to its findings by research medical community[46]. Researchers around the world rank their choices of journals for publication according to Impact Factor®. The Coordination of Improvement of Higher Education Personnel (CAPES), which is the government agency in the Ministry of Education responsible for coordinating the post-graduation programs in Brazil, stratified the quality of the journals based exclusively from the ISI Impact Factor®[1].

One of the actions to reach a higher number of citations on CTs may be to embrace principles of the CONSORT[47]. The evidence-based approach that has been used for CONSORT also served as a model for development of other reporting guidelines, such as for reporting systematic reviews and meta-analysis of studies evaluating interventions (PRISMA)[48], and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[49]. However, as a potential drawback, a reporting guideline might encourage some authors to report fictitiously the information suggested by the guidance rather than what was actually done. Readers, peer reviewers, and editors should vigilantly guard against that potential drawback and refer, for example, to trial protocols, to information on trial registers, and to regulatory agency websites. Moreover, in some cases, the CONSORT can led to improvements in reporting but not in methodological conduct[50].

Some caveats of this study should be discussed. First, we compared the national journals versus a sample of the most important foreign journals. However, the encouragement of our Brazilian scientific community toward the highest standards of study conduct and reporting is a realistic and important goal. Second, we can not generalize the results because we analyzed only CTs. But this study design, jointly with meta-analysis, is considered the gold standard for clinical research[51]. Third, a citation does not guarantee the respect of the citing investigators. Occasionally a study may be cited only to be criticized or dismissed. Nevertheless, citation still means that the study is active in the scientific debate. Moreover, we should acknowledge that number of citation does not necessarily translate into clinical or scientific impact[40]. Fourth, a presumable circumstance that may had contributed to the low citation of papers from the Brazilian journals was its relative low IF [in 2011, the IF of ABO was 0.326, and the IF of RBO was 0.129] in comparison to the group of the foreign journals (in 2011, the average of IF was 3.692), because there is a tendency of authors to publish their best articles in journals with higher IF, perpetuating this situation[4]. Finally, for the same reason above, Brazilians authors used to publish its best articles in foreign journals. Amazingly, in a paper applying the CONSORT and STROBE statements to evaluate the reporting quality of neovascular age-related macular degeneration studies the highest reporting scores were achieved by Brazilians articles published in foreign journals[48].

The boards of the Brazilians journals of ophthalmology are doing efforts to change this current unfavorable picture because they know the editorial scenario is competitive[1,52-55]. Although the ABO and RBO have not yet officially adopted the CONSORT, neither the English language, they encourage its use as well as other protocols such as STROBE and PRISMA. This attitude may contribute to the improvement of Brazilian journals global insertion.

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