ADA CE Program ARTICLE 2

Reporting quality of randomized controlled trial abstracts

Survey of leading general dental journals

Fang Hua, DDS, MS; Lijia Deng, DDS, MS; Chung How Kau, BDS, MScD, MBA, PhD; Han Jiang, DDS, PhD; Hong He, DDS, MS, PhD; Tanya Walsh, MSc, PhD

ABSTRACT

Background. The authors conducted a study to assess the reporting quality of randomized controlled trial (RCT) abstracts published in leading general dental journals, investigate any improvement after the release of the Consolidated Standards of Reporting Trials (CONSORT) for Abstracts guidelines, and identify factors associated with better reporting quality.

Methods. The authors searched PubMed for RCTs published in 10 leading general dental journals during the periods from 2005 to 2007 (pre-CONSORT period) and 2010 to 2012 (post-CONSORT period). The authors evaluated and scored the reporting quality of included abstracts by using the original 16-item CONSORT for Abstracts checklist. The authors used risk ratios and the *t* test to compare the adequate reporting rate of each item and the overall quality in the 2 periods. The authors used univariate and multivariate regressions to identify predictors of better reporting quality.

Results. The authors included and evaluated 276 RCT abstracts. Investigators reported significantly more checklist items during the post-CONSORT period (mean [standard deviation {SD}], 4.53 [1.69]) than during the pre-CONSORT period (mean [SD], 3.87 [1.10]; mean difference, −0.66 [95% confidence interval, −0.99 to −0.33]; $P < .001$). Investigators reported 3 items—interventions, objective, and conclusions—adequately in most of the abstracts (> 80%). In contrast, the authors saw sufficient reporting of randomization, recruitment, outcome in the results section, and funding in none of the pre-CONSORT abstracts and less than 2% of the post-CONSORT abstracts. On the basis of the multivariate analysis, a higher impact factor ($P < .001$) and a publication date in the post-CONSORT period ($P = .003$) were associated significantly with higher reporting quality.

Conclusions. The reporting quality of RCT abstracts from leading general dental journals has improved significantly, but there is still room for improvement.

Practical Implications. Joint efforts by authors, reviewers, journal editors, and other stakeholders to improve the reporting of dental RCT abstracts are needed.

Key Words. Randomized controlled trials; abstracts; dentistry; CONSORT; research design; data reporting.

JADA 2015:146(9):669-678

http://dx.doi.org/10.1016/j.adaj.2015.03.020

In evidence-based medicine, high-quality, well-designed, and well-conducted randomized controlled trials (RCTs) are considered evidence of the highest grade in the hierarchy of research design,[1] the criterion standard to investigate benefits and harms of medical interventions,[2] and the ideal research design in dental clinical trials.[3] Because of the substantial effect of RCTs on health care, the Consolidated Standards of Reporting Trials (CONSORT) was introduced and updated to improve reporting quality and standardize the conduct of RCTs.[4-7]

Supplemental material is available online.

Because abstracts are the first and usually the only part of a research report that is read, good reporting of abstracts is vital.[8] Investigators in previous studies have shown that only 45% of conference abstracts will be published subsequently in full length,[9] and approximately 50% of biomedical research is behind the paywall.[10] Thus, readers often rely on abstracts to assess a study initially, decide whether

This article has an accompanying online continuing education activity available at: http://jada.ada.org/ce/home.

to retrieve more information (for example, the full text), or even inform their health care decision making. A well-written abstract, therefore, should contain sufficient information regarding the study, help readers to assess the validity and applicability of the findings, and aid the retrieval of research reports from databases.[6]

Considering the importance of abstracts, an extension of the CONSORT statement specifically for reporting RCT abstracts in journal and conference proceedings was developed and published in 2008.[6] However, after the release of these guidelines, the reporting quality of RCT abstracts in leading medical and dental specialty journals remained suboptimal.[11-16]

RCTs from "high-impact general medical journals" are considered to have high potential to influence clinical practice.[17] Similarly, with their high impact factors and wide readership, RCTs published in "high-impact" general dental journals are likely to affect dental practice to the same extent. However, the reporting quality of RCT abstracts from leading general dental journals has not yet been assessed. Thus, the aims of this study were to evaluate the reporting quality of RCT abstracts from leading general dental journals, to investigate any improvement in reporting quality after the release of CONSORT for Abstracts, and to identify possible predictors of better abstract reporting quality.

METHODS

Selection of journals. Among general dental journals that publish articles from all dental specialties, 10 journals with the highest impact factors in the 2012 Journal Citation Report[18] were selected: *Journal of Dental Research* (JDR, impact factor of 3.826), *Journal of Dentistry* (JOD; 3.2), *International Journal of Oral Science* (IJOS; 2.719), *Oral Diseases* (OD; 2.377), *Clinical Oral Investigations* (COI; 2.2), *The Journal of the American Dental Association* (JADA; 1.822), *Odontology* (ODT; 1.576), *European Journal of Oral Sciences* (EJOS; 1.42), *Australian Dental Journal* (ADJ; 1.371), and *Acta Odontologica Scandinavica* (AOS; 1.358).

Search strategy. As the CONSORT extension for Abstracts was released in January 2008, we planned to retrieve RCT abstracts published before or at least 2.5 years after this date, allowing for the dissemination and endorsement of these guidelines. Therefore, we obtained all RCT abstracts published during the period from July 2005 to June 2007 (pre-CONSORT group) and July 2010 to June 2012 (post-CONSORT group) in the 10 selected journals. We searched the MEDLINE database via the PubMed search engine on December 25, 2012. We modified and used an extended version of the Cochrane Highly Sensitive Search Strategy for retrieval of randomized studies (eTable, available online at the end of this article).[19]

Inclusion and exclusion criteria. According to the Cochrane criteria for selection of RCTs, predefined inclusion criteria were as follows: human participants, interventions associated with health care, experimental studies, presence of a control group, and random assignment of participants to the study or control group.[16] We excluded articles of the following kinds: editorials, letters, and case reports; reviews, systematic reviews, and meta-analyses; laboratory-based studies; articles that were not RCTs (observational or controlled clinical studies); studies not conducted on humans; and methodology studies (studies that dealt with the design and conduct of RCTs).

We compiled all references retrieved into reference manager software (NoteExpress 2; AegeanSoftware) with all identifiers (journal name and author name and address) removed to ensure masked study selections and quality assessments. Two authors (F.H. and L.D.) performed the selection process independently by using the specified inclusion and exclusion criteria. They resolved any disagreement by means of consultation with 2 experts (H.J. and H.H.) until they reached consensus. For studies whose abstracts did not enable their identification as RCTs, we retrieved and scrutinized the full texts.

Pilot study. Before assessing the quality of included abstracts, we performed a pilot study to indicate necessary refinements of the checklist and calibrate reviewers. Of the original 17 items of the CONSORT for Abstracts checklist, 1 item (*authors*) specific to conference abstracts was excluded.[6] After initial calibration, the 2 reviewers (F.H. and L.D.) independently evaluated 10 randomly selected abstracts by referring directly to the checklist and associated explanations.[6] The interrater agreement assessed using the Cohen κ statistic was good (0.903).

Data extraction and evaluation. We evaluated the reporting quality of included abstracts by checking whether the criteria for the 16 items were met adequately. We scored an individual item 1 if it was reported adequately and 0 if the reporting was inadequate. For each abstract, we totaled the scores for all 16 items to calculate an overall CONSORT score (OCS). For the OCS, possible scores ranged from 0 to 16. During the quality assessment, we also recorded the reporting of 10 subitems of applicable CONSORT quality items, as suggested in the explanation of the CONSORT for Abstracts checklist,[6] to provide supplementary information. In addition, we extracted the following data and descriptive information from each abstract for reporting quality predictor analyses: number

ABBREVIATION KEY. **ADJ:** *Australian Dental Journal.* **AOS:** *Acta Odontologica Scandinavica.* **COI:** *Clinical Oral Investigations.* **CONSORT:** Consolidated Standards of Reporting Trials. **EJOS:** *European Journal of Oral Sciences.* **IJOS:** *International Journal of Oral Science.* **JADA:** *The Journal of the American Dental Association.* **JDR:** *Journal of Dental Research.* **JOD:** *Journal of Dentistry.* **MeSH:** Medical Subject Headings. **OCS:** Overall CONSORT score. **OD:** *Oral Diseases.* **ODT:** *Odontology.* **RCT:** Randomized controlled trial.