

Quality Assessment of Randomized Clinical Trials Reporting in Endodontic Journals: An Observational Study from 2012 to 2017



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Abstract

Introduction: Reports on randomized clinical trials (RCTs) are of critical importance because readers of research often do not access the full text. This study aimed to assess the reporting quality of RCTs in 2 leading endodontic journals. **Methods:** Issues of 2 endodontic journals, the *Journal of Endodontics* and the *International Journal of Endodontics*, dated from 2012 to 2017 were hand searched to identify RCT reports. A 37-item checklist based on the Consolidated Standards of Reporting Trials statement was used to examine the completeness of RCT reporting. **Results:** One hundred nine RCT reports were included in this study. The majority were published in the *Journal of Endodontics* (82%). The mean overall reporting quality score was 65.0% (95% confidence interval, 77.3–66.5). Most (80%–100%) RCTs clearly reported the author/contact details, trial design, participant characteristics, number of participants, and recruitment status as well as the study's intervention(s), objective(s), outcome(s), and conclusions. Conversely, only 56 of the 109 articles (51%) satisfactorily reported all 5 items related to the randomization method. Registration of reviews was not reported in any of the included abstracts. Most of the studies included in this analysis did not report their RCT registration (22%), funding (35%), or protocols (23%). **Conclusions:** The results of this study suggest that the reporting quality of RCTs in endodontic journals requires further improvement. Better reporting of RCTs is particularly important for ensuring the reliability of research findings and ultimately promoting the practice of evidence-based dentistry. Optimal RCT reporting should be encouraged, preferably by complying with the Consolidated Standards of Reporting Trials guidelines. (*J Endod* 2018;44:1246–1250)

Key Words

Endodontics, evidence-based dentistry, randomized clinical trials

We live in an era where research has become the core of many sciences, and accessing knowledge has never been easier. Randomized clinical trials (RCTs) are considered the most reliable type of research for evaluating medical interventions (1) and have been considered the gold standard for biomedical research for many years (2). The main problem with RCTs is that their findings rely on their internal validity, which is based on their methodology and execution. Therefore, high-quality reporting of the details of such research is essential.

Several scales have been developed over the years to evaluate the quality of RCTs. Most scales that objectively assess RCTs consist of a checklist with individual markers (3). In a systematic review by Olivo et al (4), 21 scales were identified that assess RCTs, but the review concluded that most scales had weak validity and reliability. An example of these scales is one developed by Jadad et al (5). Their scale uses an interstudy quantitative assessment that considers 3 main parts of the study: reporting randomization, double blinding, and dropouts. This scale was used to assess the quality of orthodontics RCTs published between 1989 and 1998 (6). The study concluded that the reporting of RCTs before 1996 was insufficient compared with studies published in the years after. The authors believe that the main reason for this discrepancy was the effect of a statement issued by the Consolidated Standards of Reporting Trials (CONSORT), which aimed to better control RCTs (7). CONSORT was developed in 1996 by an international group of clinical trialists, researchers, and editors to formulate guidelines for controlling RCT quality (www.consort-statement.org). These guidelines include the reporting of study design, abstract style, and findings of the study. The latest update of the guidelines was published in 2010 (8). Currently, there are 585 journals that have endorsed these guidelines. The aim of this study was to assess the quality of RCTs published from 2012 to 2017 in 2 leading endodontic journals with high impact factors and assess their compliance with the CONSORT guidelines.

Significance

Because randomized clinical trials are considered of great importance in evidence-based dentistry, the quality of reporting becomes essential. The CONSORT guidelines and checklist were made to control the quality of reporting; hence, adhering to them must be emphasized.

Materials and Methods

Two leading endodontic journals were selected for this study based on their impact factors: the *Journal of Endodontics* and the *International Journal of Endodontics*. RCTs were identified based on a hand search of all articles on human trials published in these 2 journals. *In vitro* studies, laboratory-based trials, and conference abstracts were excluded from this analysis. The key words “randomized controlled

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trial,” “randomised controlled trial,” “assigned,” “prospective,” and “comparative” were screened in the titles and abstracts; full texts of all articles fulfilling the inclusion criteria were then retrieved. The choice of conducting a hand search over using search engines was made to ensure that no RCT is excluded from this study for not mentioning the type of study in the title or not including the right key words. The literature search was undertaken independently and in duplicate by 2 authors (H.A. and F.A.); any disagreement was resolved by an open discussion between the authors until a mutual agreement was reached. One author (H.A.) screened and evaluated the potential RCTs using a piloted extraction sheet. The score value was assigned according to the CONSORT checklist guidelines (8). Each item was scored as “yes” if present, “no” if absent, or not applicable (NA) (9). An item was scored as NA if the design of the study made it impossible to include. The total score for each trial was calculated and converted to a percentage using the following equation: total score = (total number of “yes” items/[37 – total number of NA items])/100.

Additional information including the number of authors, the continent and country of the first author, and the clinical setting of the trial was also recorded for each article. Authors were calibrated by assessing the reporting of 10% of the included articles together by referring directly to the CONSORT checklist and associated explanations. A random sample of 10% of the articles was scored by a second examiner to assess interexaminer reliability of the CONSORT scores (10). Another random sample of 10% of the articles was scored a second time by the first examiner (H.A.) 3 months after the initial data collection was completed to test intraexaminer reliability.

Statistical Analysis

Descriptive statistics and percentage compliance with CONSORT checklist items were reported for published RCTs. Because of the small number and unbalanced cohort of trials, no formal statistical analyses were conducted between different cohorts of the sample except for tabulations. Descriptive statistics and tabulations were conducted using

SPSS Version 22.00 (IBM Corp, Armonk, NY). Bland-Altman plots were used to assess interexaminer reliability (11).

Results

From January 2012 to December 2017, 109 (approximately 4% of the total published articles) RCT reports were identified out of 2756 articles reviewed from the 2 endodontic journals (Table 1). The number of published RCTs in the 2 leading endodontic journals over the 6-year period was almost equally distributed across years (range from 12%–18%), except for the year 2017 (22%) (Table 1). Asia and Europe produced half of the published RCTs, with 44% and 23%, respectively; there was only 1 RCT in which the first author was based in Africa, and no RCT in this sample was conducted in Australia (Table 1). Most of the included RCTs were published in the *Journal of Endodontics* (82%) (Table 1).

In the majority of the included RCTs (86%), the first author worked in an academic institution; more than 69% of published trials had between 4 and 6 authors, but only a few RCTs reported the formal involvement of a statistician in the trials (4%) (Table 2). RCTs undertaken in university settings represented 86% of the total publications in this study, whereas RCTs undertaken in a hospital or private clinical setting represented only 14% of the included RCTs (Table 2).

The mean CONSORT score for all trial reports was 65.0% (95% confidence interval [CI], 77.3–66.5). From 2012 to 2017, the mean CONSORT score for RCTs by year of publication ranged from 63.5%–72.1% (Fig. 1). With few differences, RCTs that included more than 1 to 3 authors had the highest CONSORT scores for their reports (mean = 71.3%; 95% CI, 76.0–66.5). The European RCTs published in the 2 main endodontic journals had the best reporting quality for their abstracts (mean score = 72.2; 95% CI, 76.8–67.7), whereas South American RCTs had the lowest overall CONSORT scores (mean score = 64.1; 95% CI, 71.1–56.5) (Table 1).

With regard to the items on the CONSORT checklist, most RCTs (80%–100%) clearly reported and described the author/contact details, trial design, subject characteristics, number of participants, and recruitment status as well as the study intervention(s), objective(s),

TABLE 1. Characteristics of 109 Randomized Clinical Trials

Characteristic	Full-text publications	Percentage	Mean of total CONSORT scores	SD	95% CI
Journals					
IEJ	20	18	72.8	10.0	77.2–68.4
JOE	89	82%	67.4	10.1	69.5–65.3
Continent					
Africa	1	1	76.5	0.0	76.5
Asia	48	44	68.6	9.0	71.2–66.1
Europe	25	23	72.2	11.7	76.8–67.7
North America	22	20	65.8	7.3	68.8–62.7
South America	13	12	64.1	14.0	71.7–56.5
Year					
2012	20	18	65.0	10.6	69.9–60.4
2103	13	12	63.5	11.3	69.6–57.4
2014	15	14	67.6	10.9	73.1–62.1
2015	17	16	67.5	8.2	71.4–63.7
2016	20	18	72.1	7.7	75.4–68.7
2017	24	22	72.0	10.8	76.3–67.7
Number of authors					
<4	19	17	71.3	10.5	76.0–66.5
4–6	74	68	68.2	10.1	70.5–65.9
>6	16	15	65.9	10.5	71.1–60.7
Overall	109		68.4	10.2	70.3–66.5
Randomization	Overall	IEJ	JOE		
Adequate	51	65	48		
Inadequate	39	10	39		
No reporting	10	25	12		

CI, confidence interval; CONSORT, Consolidated Standards of Reporting Trials; JOE, Journal of Endodontics; IEJ, International Journal of Endodontics; SD, standard deviation.

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