Quality of reporting of randomized controlled trials in ten academic Indian dental journals

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ABSTRACT

Background: Biased results from poorly reported trials can mislead decision-making in health care at all levels, from treatment decisions for the individual patient to formulation of national public health policies.

Objective: To evaluate the quality of reporting of randomized controlled trials (RCTs) in ten Indian dental journals over the period 2011–2012.

Materials and Methods: This study included all RCTs published as full-text articles reported in ten Indian dental journals over the period from 2011 to 2012. The relevant trials were identified by searching Medline. Hand searching of the journals was also carried out by three of the authors to check if any potential trial was missing. Each article was assessed against the Consolidated Standards of Reporting Trials criteria tool, as described by Schulz et al. (2010).

Results: The mean number of criteria present per article was 12.2 (standard deviation [SD] = 2.2) and only 5 of 106 articles got total possible score. Most of the articles (69%) did not mention about justification for sample size calculation, 89% of the articles did not mention about allocation concealment, 86% of the articles did not mention about funding and 63% of the articles did not mention about limitations of the study.

Conclusion: The quality of reporting of Randomized clinical trials in ten Indian academic journals was poor.

Key words: Clinical trials, Consolidated Standards of Reporting Trials statement, Indian dental journals, quality of reporting, randomized controlled trials

Research as a part of curriculum is not new to dental and medical education in India but efforts to incorporate clinical research into academics has been accelerated from mid-1990’s in India. Randomized controlled trials (RCTs) were considered gold standard in evaluating health care intervention.[1]

However, randomized trials can yield biased results if they lack methodological rigor. Only high-quality research, in which proper attention has been given to design, will consistently eliminate bias. The design and implementation of an RCT require methodological as well as clinical expertise; meticulous effort; and a high index of suspicion for unanticipated difficulties, potentially unnoticed problems, and methodological deficiencies. Reports of RCTs should be written with similarly close attention to minimizing bias. To assess a trial accurately, readers of a published report need complete, clear, and transparent information on its methodology and findings.

Recent methodological analyses indicate that inadequate reporting and design are associated with biased estimates of treatment effects. Such systematic error is seriously damaging to RCTs, which boast the elimination of...
systematic error as their primary hallmark. Systematic error in RCTs reflects poor science, and poor science threatens proper ethical standards. For example, information on the method used in a trial to assign participants to comparison groups was recorded in only 21% of 519 trial reports indexed in PubMed in 2000,\(^2\) and only 34% of 616 reports indexed in 2006.\(^3\) Similarly, only 45% of trial reports indexed in PubMed in 2000\(^2\) and 53% in 2006\(^3\) defined a primary end point and only 27% in 2000 and 45% in 2006 reported a sample size calculation.

Reporting is not only often incomplete but also sometimes inaccurate. To rectify this problem of improper reporting of RCT, researchers have prepared a Consolidated Standards of Reporting Trials (CONSORT) statement for the first time in 1996\(^4\) and the objective of CONSORT is to facilitate critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials. Later this CONSORT statement was updated in 2010.\(^5\)

Biased results from poorly designed and reported trials can mislead decision-making in healthcare at all levels, from treatment decisions for the individual patient to formulation of national public health policies. Little research has been conducted on reporting of RCTs in important dental journals in India; hence, the aim of this study was to evaluate the quality of reporting of RCTs in ten Indian dental journals over the period 2010–2011.

**MATERIALS AND METHODS**

This study included all RCTs published as full-text articles reported in ten Indian dental journals over the period from 2010 to 2011. The journals included were:

1. Indian Journal of Dental Research
2. Journal of Indian Association for Public Health Dentistry
3. Journal of Indian Society for Pedodontics and Preventive Dentistry
4. Journal of Indian Society of Periodontology
5. Journal of Maxillofacial and Oral surgery
6. Journal of Conservative Dentistry
7. Journal of Indian Academy of Oral Medicine and Radiology
8. Journal of Indian Prosthodontic Society
9. Journal of Indian Orthodontic Society
10. Journal of Oral and Maxillofacial Pathology

We decided to include trials published in these journals because they are leading dental journals, published by their respective national associations and their methodological reporting has not been systematically studied until date. We studied the trials published in 2010–2011 since the revised CONSORT statement was published in 2010 to improve the quality of reporting of RCTs.\(^5\)

**Search strategy**

Medline and PubMed databases were searched and trials were considered to be RCTs if the words “random,” “randomly,” “randomization,” or “randomized” were used to describe the allocation method in the text. The relevant trials were identified by searching Medline using a highly sensitive search strategy developed and validated by Robinson and Dickersin\(^6\) and all phases of the search strategy are shown in Table 1. Hand searching of these journals was also carried out by three of the authors to check if any potential trial was missing.

**Inclusion and exclusion criteria**

Abstracts of all the articles were read first and if the articles appeared to be describing an RCT, then the full-length paper was obtained. RCTs were defined as controlled experiments designed to evaluate an intervention using a random method to assign study units to a test or comparison group. All RCT’s which met this definition were included. Articles reporting studies that did not meet this definition were excluded. The following exclusion criteria were then applied:

1. Articles that were found during the quality assessments to be nonrandomized trials or in vitro experimental studies were excluded from further analysis
2. Articles reporting pilot studies
3. Articles describing secondary analysis of primary data
4. Articles which describes only part of the methodology and in detail methodology described elsewhere

After applying the inclusion and exclusion criteria, the journal and date of publication of each included study was recorded. Each article was assessed against the CONSORT criteria tool, as described by Schulz et al.\(^5\) This tool evaluates the presence of 25 item checklist and provides guidance for reporting all randomized controlled trials, but focuses on the most common design type-individually randomized, two groups, parallel trials. Other trial designs, such as cluster randomized trials and noninferiority trials, require varying amounts of additional information. For each criterion, the

| Journal                                          | Mean (SD) | Range |
|--------------------------------------------------|-----------|-------|
| Indian Journal of Dental Research                | 14.3 (2.9) | 11–25 |
| Journal of Indian Association for Public Health Dentistry | 11 (2)   | 09–16 |
| Journal of Indian Society for Pedodontics and Preventive Dentistry | 11.6 (2.8) | 08–15 |
| Journal of Indian Society of Periodontics         | 13.2 (3.4) | 10–25 |
| Journal of Maxillofacial and Oral Surgery         | 9.5 (2.3)  | 08–12 |
| Journal of Conservative Dentistry                | 12.6 (3.8) | 10–19 |
| Journal of Indian academy of Oral                 | 11.8 (2.9) | 09–14 |
| Medicine and radiology                            | 10 (1.2)   | 09–13 |
| Journal of Indian Orthodontic Society             | 13 (2.2)   | 11–17 |
| Journal of Oral and Maxillofacial Pathology       | 09 (1.1)   | 08–14 |
| Overall                                          | 12.2 (2.2) | 08–25 |

SD=Standard deviation
articles were given a score of “1” when the criterion was assessed as being present and “0” for those that did not meet the criterion. A total score was, therefore, obtained for each article. A data collection sheet, containing the criteria, was developed and piloted. All the reviewers then applied the criteria to eight papers, for training purposes. The interobserver agreement of the three authors (VS, ASKB, GP) was rated by calculation of Kappa values (0.88, 0.76, 0.80). Any disagreement was resolved by discussion between the reviewers; if the disagreement could not be resolved by discussion, the opinion of the senior reviewer was sought.

RESULTS

One hundred and twenty articles were found from the PubMed and Medline databases and sixty four articles were found through hand search which made the pool of 184 articles. Of these 184 articles, 29 were found to be non-RCTs, eight articles were pilot studies and 11 articles involved secondary analysis of data [Flow chart 1].

The remaining 106 articles were derived as follows: 25 from Indian Journal of Dental Research, 10 from Journal of Indian Association for Public Health Dentistry, 9 from Journal of Indian Society for Pedodontics and Preventive Dentistry, 14 from Journal of Indian society of Periodontology, 10 from Journal of Maxillofacial and Oral Surgery, 18 from Journal of Conservative Dentistry, 4 from Journal of Indian Academy of Oral Medicine and Radiology, 6 from Journal of Indian Prosthodontic Society, 8 from Journal of Indian Prosthodontic Society, 2 from Journal of Oral and Maxillofacial Pathology.

The mean number of criteria present per article was 12.2 (standard deviation [SD] = 2.2) and only 5 of 106 articles got total possible score. The mean number of criteria per articles published in Indian Journal of Dental Research was 14.3 (SD = 2.9), Journal of Indian Association for Public Health Dentistry was 11 (SD = 2), Journal of Indian society for Pedodontics and Preventive Dentistry was 11.6 (SD = 2.8), Journal of Indian Society of Periodontology was 13.2 (SD = 3.4), Journal of Maxillofacial and Oral Surgery was 9.5 (SD = 2.3), Journal of Conservative Dentistry was 12.6 (SD = 3.8), Journal of Indian Academy of Oral Medicine and Radiology was 11.8 (SD = 2.9), Journal of Indian Prosthodontic Society was 10 (SD = 1.2), Journal of Indian Orthodontic Society was 13 (SD = 2.2) and Journal of Oral and Maxillofacial Pathology was 09 (SD = 1.1) [Table 1].

Most of the articles (69%) did not mention about justification for sample size calculation, 47% of the articles had not mentioned about statistical methods, 89% of the articles had not mentioned about allocation concealment, 86% of the articles had not mentioned about funding and 63% of the articles had not mentioned about limitations of the study [Table 2].

DISCUSSION

This study was intended to assess the quality of reporting of randomized controlled trails in ten Indian dental journals. There are no published studies to answer this research question; this is the first study in India. 106 articles published in ten journals were assessed using the CONSORT statement proposed by Shultz, Altman, and Moher. The consort tool used in this study was proposed in the year 2010; before it many similar studies were reported using CONSORT statement described by Scherer and Crawly (1998). This revised CONSORT statement provides guidance for reporting of all randomized controlled trials.

The quality of reporting of randomized clinical trials in ten Indian academic journals were poor with mean number of criteria 12.2 which is similar to the study conducted by Pandis et al. where the authors has assessed the quality of Randomized clinical trials in six major dental journals. One of the reasons in deficiencies in the reports may be due to the word limits imposed by the journals and none of these ten journals mentioned about CONSORT statement in their guidelines for authors.

When the results of this study and previous Chinese studies were compared, the Indian reports had a higher reporting rate of each key methodological item. The study evaluating 7422 Chinese RCT studies published during 1999–2004 (13 Chinese medical journals extracted by hand search) revealed that 1.1% of the studies reported sample size determination, 7.9% reported random sequence generation, and 0.3% reported allocation concealment. According to another study evaluating 142 RCT papers from 2004 to 2007 published in five leading Chinese medical journals, none of the studies reported sample
Table 2: Adherence of randomized controlled trial reports to Consolidated Standards of Reporting Trials statement

| CONSORT (number and criteria) | Articles described each item (%) |
|-----------------------------|----------------------------------|
|                            | Present | Absent |
| Title and abstract          |         |        |
| Identification as a randomized trial in the title | 89      | 11     |
| Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) |         |        |
| Introduction                |         |        |
| Background and objectives   |         |        |
| Scientific background and explanation of rationale | 18      | 82     |
| Specific objectives or hypotheses |         |        |
| Methods                     |         |        |
| Trial design                |         |        |
| Description of trial design (such as parallel, factorial) including allocation ratio | 24      | 76     |
| Important changes to methods after trial commencement (such as eligibility criteria), with reasons |         |        |
| Participants                |         |        |
| Eligibility criteria for participants | 56      | 44     |
| Settings and locations where the data were collected |         |        |
| Interventions               |         |        |
| The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 32      | 68     |
| Participants                |         |        |
| Eligibility criteria for participants | 56      | 44     |
| Settings and locations where the data were collected |         |        |
| Interventions               |         |        |
| The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 32      | 68     |
| Outcomes                    |         |        |
| Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed | 37      | 63     |
| Any changes to trial outcomes after the trial commenced, with reasons |         |        |
| Sample size                 |         |        |
| How sample size was determined | 31      | 69     |
| When applicable, explanation of any interim analyses and stopping guidelines |         |        |
| Randomization               |         |        |
| Sequence generation         |         |        |
| Method used to generate the random allocation sequence | 35      | 65     |
| Type of randomization; details of any restriction (such as blocking and block size) |         |        |
| Allocation concealment mechanism | 11      | 89     |
| Implementation              |         |        |
| Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 17      | 83     |
| Blinding                    |         |        |
| If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 39      | 61     |
| If relevant, description of the similarity of interventions |         |        |
| Statistical methods         |         |        |
| Statistical methods used to compare groups for primary and secondary outcomes | 53      | 47     |
| Methods for additional analyses, such as subgroup analyses and adjusted analyses |         |        |
| Results                     |         |        |
| Participant flow (a diagram is strongly recommended) | 62      | 38     |
| For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome |         |        |
| For each group, losses and exclusions after randomization, together with reasons |         |        |
| Recruitment                 |         |        |
| Dates defining the periods of recruitment and follow-up | 29      | 71     |
| Why the trial ended or was stopped |         |        |
| Baseline data               |         |        |
| Table showing baseline demographic and clinical characteristics for each group | 79      | 21     |
| Numbers analyzed            |         |        |
| For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | 46      | 54     |
| Outcomes and estimation     |         |        |
| For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | 31      | 69     |
| For binary outcomes, presentation of both absolute and relative effect sizes is recommended |         |        |
| Ancillary analyses          |         |        |
| Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | 22      | 78     |
| Harms/adverse effects       |         |        |
| All important harms or unintended effects in each group | 57      | 43     |
| Discussion                  |         |        |
| Limitations                 |         |        |

Contd...
Quality of reporting of randomized controlled trials in ten dental journals

Table 2: Contd...

| CONSORT (number and criteria) | Articles described each item (%) |
|-------------------------------|----------------------------------|
|                               | Present | Absent |
| Generalizability              |         |       |
| Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |         |       |
| Other information             |         |       |
| Registration                  |         |       |
| Registration number and name of trial registry |         |       |
| Protocol- Where the full trial protocol can be accessed, if available |         |       |
| Funding - Sources of funding and other support |         |       |
| CONSORT=Consolidated Standards of Reporting Trials |         |       |

size determination, 26.8% reported random sequence generation, 4.2% reported allocation concealment, 10.6% reported blinding, and 0.7% contained flow diagrams. Our study showed that the reported percentages for all key methodological items were greater than those reported in either Chinese studies.

Another important finding of this study is that only 14% articles adequately mentioned about source of funding and conflict of interest which is less compared to another study reported from India wherein the sources of funding and conflicts of interest were not declared in over three-fourths.10

One of the limitations of this study is that we evaluated the quality of reporting, which is not the same as the methodological quality of the study. It is possible that a poorly reported study is well designed and executed, and a well-reported one may have several shortcomings. However, empirical evidence exists that indicates poorly reported studies are associated with larger estimates of intervention effect, i.e. poor reporting reflects poor methodology, which in turn is associated with biased results.11

Poor adherence of RCT reports from India to the CONSORT reporting guidance may involve a variety of factors. The most likely reason is unfamiliarity with the CONSORT statement. To improve familiarity, more journals should include the CONSORT statement in their “Information for Authors” and require adherence to the statement for RCT reports. Similarly, increased education and training in the designing and reporting of RCTs may also help improve reporting quality. We believe that deficiencies in RCT reporting might reflect poor research. Although it is evident that education in clinical trial methodology and biostatistics is essential to better adhere to the CONSORT statement, such resources have been limited in India. Previous studies reported that the involvement of a trial methodologist (epidemiologist or biostatistician) improves reporting quality.12 In addition, the skills of good medical content writers may help to improve the quality of reports. Future studies to assess the quality of RCT’s should include barriers preventing the diffusion of CONSORT adoption and ways to improve reporting quality should further be explored.

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Conflicts of interest
There are no conflicts of interest.

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