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Assessment of the quality of reporting of randomized clinical trials in paediatric dentistry journals

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Introduction. Reporting of randomized controlled trials (RCTs) should be of high quality to support the conclusions reached by the authors. Poor-quality reporting has been associated with an overestimation in intervention efficacy. Within the field of paediatric dentistry, no study has assessed the quality of reporting.

Objective. The aim of this study was to assess published RCTs in paediatric dental journals between 1985 and 2006 for: (i) whether quality of reporting allows readers to assess the validity of trials; and (ii) whether quality of reporting has improved since the introduction of the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Methods. Hand search of the main paediatric dentistry journals; inclusion criteria were: the trial was performed on children, and RCT. CONSORT guidelines were made into an operational checklist. Trials published between 1985 and 1997, and between 1998 and 2006 were compared to determine any improvement since the publication of the CONSORT guidelines.

Results. One hundred and seventy-three of 5635 articles met the inclusion criteria. Reporting quality was poor overall and showed heterogeneity. It had improved slightly since the publication of CONSORT. Few trials were reported adequately.

Conclusion. The quality of reporting of clinical trials is poor, and often not adequate to allow readers to assess trial validity. Overall quality of reporting has not substantially improved since the publication of CONSORT.

Introduction

Evidence-based medicine is defined as 'the integration of best research evidence with clinical expertise and patient values'[1]. Although the evidence-based approach was originally developed in medicine, its principles can be applied to all fields in health care including dentistry. In dentistry, the approach is known as evidence-based dentistry (EBD).

Research evidence is crucial to EBD as it allows practitioners to decide which interventions are most effective. The highest level of evidence for an intervention is considered to be a systematic review of a number of high-quality randomized controlled trials (RCTs)[2]. After this, the next level in the hierarchy is evidence from individual high-quality randomized controlled clinical trials. The quality of these trials is crucial because poor-quality trials have been shown to lead to an overestimation of the effects of interventions by as much as 30–41%[3].

Evidence has shown that the quality of reporting of trials and their design and conduct are often highly correlated. Poor-quality reporting of trials has been found to lead to an overestimation in intervention efficacy by 35% in meta-analyses in medicine[4]. Therefore, when a clinician has to evaluate the quality of a trial, they usually must rely solely on the quality of the reporting[5].

Given the importance of reporting trials properly, a checklist has been developed for authors to follow before publishing their research to improve the quality of reporting of RCTs[6]. This checklist is known as the Consolidated Standards of Reporting Trials (CONSORT) statement, and was first published in 1996. The checklist has since been revised by various authors[7,8]. CONSORT is a checklist that should be followed with the publication of a

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randomized clinical trial. The checklist items require clear and thorough descriptions of hypothesis, protocol, randomization, blinding (masking), follow-up, and analysis. One hundred and fifty-two journals have now adopted the CONSORT statement and will only publish trials which follow CONSORT[9].

Within the field of paediatric dentistry, no study has been undertaken to assess the quality of reporting of published clinical trials. Therefore, the aim of this study was to assess the quality of reporting of published randomized clinical trials in paediatric dental journals in relation to their compliance with the CONSORT guidelines.

Materials and methods

Preliminary investigation confirmed that before 1985, there were few dedicated paediatric dentistry journals. Therefore, the search was restricted to between 1985 and 2006. The following paediatric dental journals were included: (i) *Journal of Paediatric Dentistry* (1985–1990); (ii) *International Journal of Paediatric Dentistry* (1991–2006); (iii) *Journal of Dentistry for Children* (1985–2006); (iv) *Paediatric Dentistry* (1985–2006); (v) *European Journal of Paediatric Dentistry* (2000–2005); (vi) *European Archives of Paediatric Dentistry* (2006); (vii) *The Journal of Pedodontics* (1985–1990); and (viii) *The Journal of Clinical Pediatric Dentistry* (1990–2006).

Some of these journals are actually the same, but their title changed as they developed. Therefore, data from the journals *European Journal of Paediatric Dentistry* and *European Archives of Paediatric Dentistry* will be described under the heading of *European Journal of Paediatric Dentistry*. In the same way, data from the journals *Journal of Paediatric Dentistry* and *International Journal of Paediatric Dentistry* will be described under the heading of *International Journal of Paediatric Dentistry*, and data from the journals *The Journal of Pedodontics* and *The Journal of Clinical Pediatric Dentistry* will be described under the heading of *The Journal of Clinical Pediatric Dentistry*.

The first stage of the study was the hand-screening of the included journals to identify RCTs which would be included in the assessment. Hand-searching was preferred to electronic searching of databases for RCTs, as it has been shown to identify more trials compared with electronic searching[5].

The inclusion criteria for a trial were: (i) the trial was a randomized clinical trial; (ii) the trial was published between 1985 and 2006, and in English; (iii) the trial participants were infants and children, aged 18 years or under; and (iv) the article had been published in one of the paediatric dental journals specified.

The screening of titles, abstracts, and full-text articles was conducted in duplicate by AA with either SP or PA. Photocopies of all relevant articles were obtained in order to assess their compliance with the CONSORT guidelines. The compliance assessment was undertaken using an operational version of the CONSORT checklist (Table 1), whereby the 22 items of the CONSORT statement checklist were converted into 34 questions[7]. Each included trial was assessed independently by two researchers using the scoring system 'yes', 'no', and 'not applicable'. The level of agreement between reviewers for the checklist items was measured, and kappa scores were calculated for inter-examiner agreement. Disagreements were resolved by subsequent discussion.

Trials published between 1985 and 1996 were compared to trials published between 1997 and 2006, to assess whether there had been any improvement in quality of reporting since the publication of the CONSORT guidelines. In particular, compliance with key items of quality was evaluated. These key items were: randomization, concealment of treatment allocation, masking (blinding), and patient follow-up, as these are the factors most likely to be associated with empirical evidence of bias[10].

The results were collated and analysed using SPSS version 14.0 (Chicago, IL, USA). Checklist items that were not applicable in the trials were excluded from the analysis (and appropriately noted). The overall proportion of reported items complying with the CONSORT checklist was reported. Chi-squared tests were used to compare the proportion of articles which complied with the checklist items, before and after the publication of CONSORT to ascertain any changes since the publication of CONSORT. Chi-squared tests were also used

Table 1. The modified 34-item Consolidated Standards of Reporting Trials checklist.

Article section and topic	
Title and abstract	1. Were the words 'random allocation', 'randomized', or 'randomly assigned' mentioned in the abstract?
Background	2. Were the nature, scope, and severity of the problem described?
Participants	3. Were the eligibility (and exclusion) criteria of the trial participants described: age, gender, clinical diagnosis, and comorbid conditions?
	4. Were the settings and locations of the data collection reported?
Interventions	5. Were precise details of the interventions intended for each group given? Was it described how and when they were actually administered?
Objectives	6. Were the specific objectives and/or hypotheses mentioned?
Outcomes	7. Were there clearly defined primary and secondary outcome measures (provenance and properties of the scales), and did they distinguish between first- and second-degree outcomes?
	8. Were any methods used to enhance the quality of measurements (e.g. multiple observations, training of assessors)?
Sample size	9. Is there a description of how sample size was calculated, identification of the primary outcome on which the calculation was based, and the resulting target sample size per comparison group?
	10. Did they provide any explanation on interim analyses or stopping rules?
Randomization sequence generation	11. Was the method used to generate the random allocation sequence reported?
	12. If applicable, did the authors provide details of any restriction (e.g. blocking, stratification)?
Randomization allocation concealment	13. Was the method used to implement the random allocation sequence (e.g. numbered containers or central telephone) reported, clarifying whether the sequence was concealed until interventions were assigned?
Randomization implementation	14. Did the authors explain who generated the allocation sequence?
	15. Did the authors explain who enrolled the participants?
	16. Did the authors explain who assigned the participants to their groups?
Blinding (masking)	17. Did the authors report whether participants were blinded to group assignment?
	18. Did the authors report whether those administering the interventions were blinded to group assignment?
	19. Did the authors report whether the assessors were blinded to group assignment?
	20. If blinded, did they report how the success of blinding was evaluated?
Statistical methods	21. Did the authors specify which statistical procedure was used for primary outcomes?
	22. When applicable, were the methods of subgroup analysis or adjusted analyses given, and/or did the authors clarify the choice of variables that were adjusted for and specify whether the analysis was planned or suggested by the data?
Participant flow	23. Did the authors report the flow of each participant through each stage (or if there is no flow chart included in the study report, is it possible to fill into the CONSORT flow diagram the number of participants randomly as signed to each group, receiving intended treatment, completing the study protocol, and analysed for primary outcome?
	24. Did the authors describe study protocol violations together with reasons?
Recruitment	25. Are the dates defining the periods of recruitment and follow-up given?
Baseline data	26. Are the baseline demographic and clinical characteristics of each group (mean, SD, or categories) reported?
Numbers analysed	27. Is the number of participants (denominator) in each group included in each analysis (e.g. in binary outcomes, the results should be stated in absolute numbers, not in proportions)?
	28. Was it an 'intention-to-treat' analysis (the participants were analysed in the same groups to which they were randomized)?
Outcomes and estimation	29. Is there a summary of results and the estimated effect size and precision (e.g. 95% confidence interval) for each group reported for each primary and secondary outcome?
Ancillary analyses	30. When undertaken, did the authors indicate which ancillary analyses (subgroup or adjusted analysis) were prespecified in the protocol?
Adverse events	31. Are the estimates of the frequency of all important adverse or side effects in each intervention group reported?
Discussion – interpretation	32. Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.
Generalizability	33. Generalizability (external validity) of the trial findings.
Overall evidence	34. General interpretation of the results in the context of current evidence.

to compare the compliance of the key items in the checklist, between journals, in order to determine any significant differences in reporting quality between journals.

Results

In the initial screening phase, 5365 published abstracts were identified in the target journals

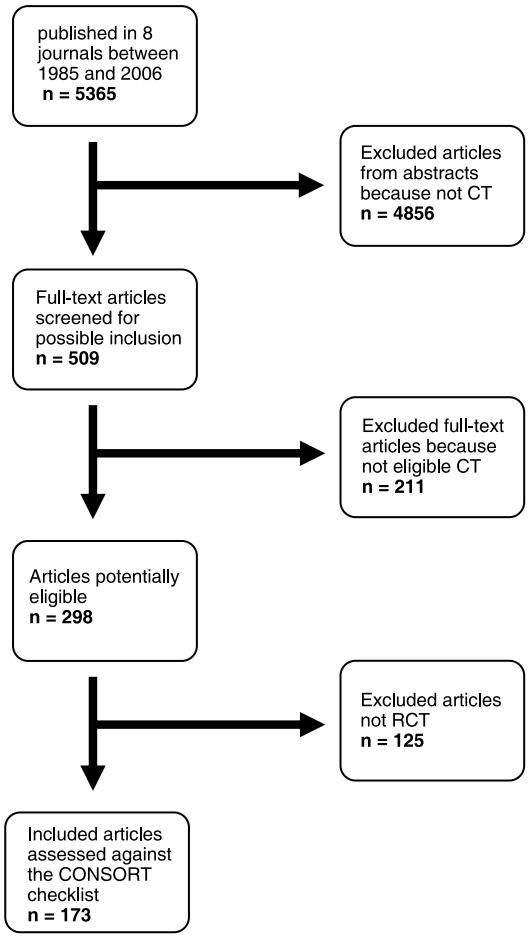

Fig. 1. Flow of number of articles. CT, clinical trial; *N*, number of articles; RCT, randomized clinical trial.

over the defined date range. However, 4856 were excluded because they were case reports, reviews, or observational studies. Of the 509 full-text articles subsequently identified as clinical trials, 211 of these were excluded because they were clinical trials performed in adults, animals, or *in vitro* leaving 298 were potentially eligible for inclusion. Before the assessment stage, 125 (42%) of the 298 clinical trials were excluded because they were not randomized clinical trials. Therefore, 173 articles (3%) were included and assessed against the CONSORT checklist. The flow of articles throughout the study is shown in Fig. 1.

Inter-reviewer agreement

The inter-reviewer agreement kappa score for compliance of articles using the CONSORT checklist was 0.95. This represents excellent agreement.

Compliance of articles against the CONSORT checklist

The percentage of reported trials which complied against items of the CONSORT checklist varied considerably among articles, and also between the different sections of the CONSORT checklist.

Good levels of compliance with CONSORT were found in the reporting of the introductions, which included the title, abstract, and background of the studies (96–98%), and also in the discussion, interpretation, generalizability, and overall evidence sections (97%, 98%, and 96%, respectively). Reporting of randomization methods was poor, ranging from 5 to 9% compliance. Only 8 of 173 (4%) of published articles provided a description of how the sample size was calculated. An 'intention-to-treat' analysis was only reported in 2 of 173 (1%) published articles. These data are summarized in Fig. 2.

Compliance before and after CONSORT

The quality of reporting showed better results after 1997 in the titles/abstracts and discussion sections. Compliance with item 18, which asked if authors report whether those administering the interventions were masked (blinded) to group assignment, worsened. There was little change in other checklist items pre- and post-CONSORT. A comparison of compliance with the CONSORT checklist until 1996 and after 1997 is illustrated in Fig. 3.

Chi-squared tests were used to compare the proportions of articles that complied with the 34 questions in the CONSORT checklist between those that were published up to the end of 1996 (before CONSORT) and those articles that were published in 1997 or later (after CONSORT).

Item 1 asked specifically if the words 'random allocation', 'randomized', or 'randomly assigned' were mentioned in the title or abstract. The result showed a significant improvement from 45% before CONSORT to 71% after ($P = 0.003$). Item 11 questioned if the method used to

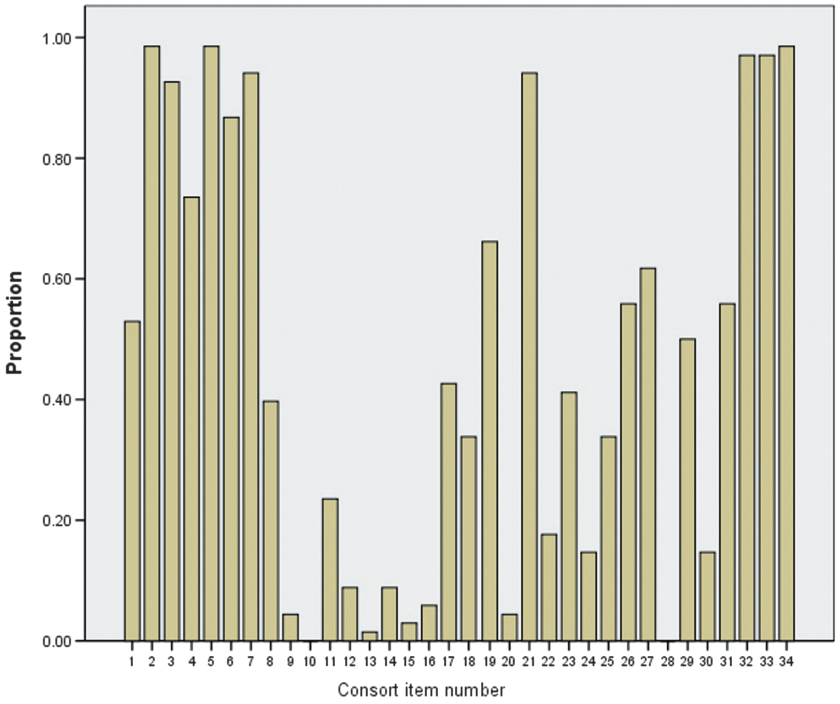

Fig. 2. Compliance of articles against the Consolidated Standards of Reporting Trials (CONSORT) checklist.

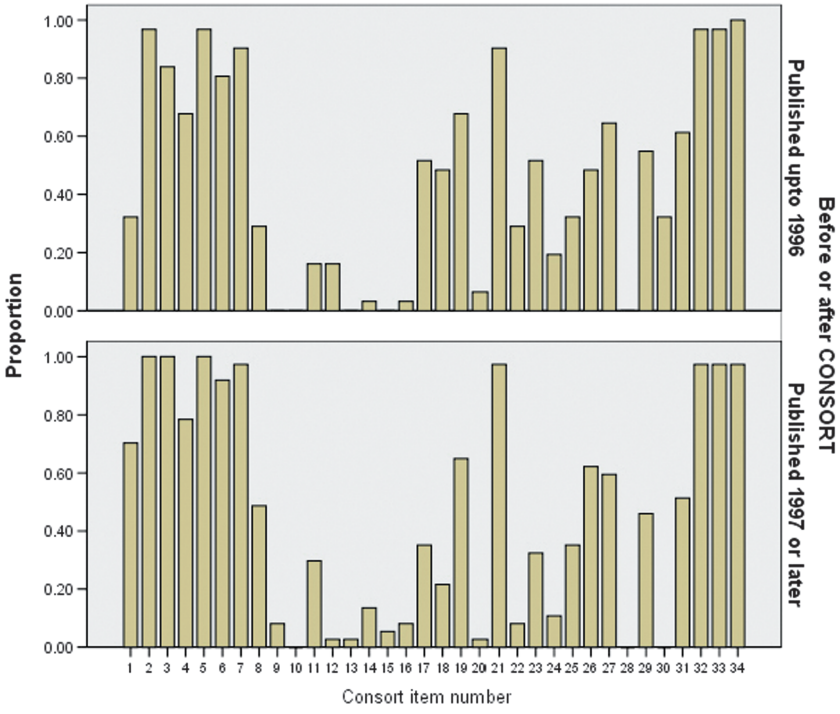

Fig. 3. Compliance with Consolidated Standards of Reporting Trials (CONSORT) before and after 1997.

generate the random allocation sequence was reported. The result showed that there was no significant difference before (22%) and after (28%) the introduction of CONSORT ($P = 0.481$).

Item 13 concerned randomization allocation concealment, specifically if the method used to implement the random allocation sequence (e.g. numbered containers or central telephone) was concealed until interventions were assigned. The result showed that there was no significant improvement before and after CONSORT, 5% and 6%, respectively ($P = 1.00$). Item 17 regarded authors reporting whether

participants were blinded to group assignment. The results showed that there was no significant difference, in fact reporting actually decreased from 42% before CONSORT to 34% after ($P = 0.416$).

Item 18, which asked if authors reported whether those administering the intervention were blinded to group assignment, demonstrated a reduction in compliance, with a decrease from 44% before CONSORT to 27% after, which was statistically significant ($P = 0.050$). Item 19 questioned if authors reported whether the assessors were blinded to group assignment. The result showed that there was no significant difference ($P = 1.00$) before and after CONSORT, with reporting remaining at 58%.

There was no significant difference between the journals with respect to compliance with the CONSORT items.

Discussion

The objective of this study was to assess the quality of reporting of published RCTs in paediatric dental journals between 1985 and 2006. The number of included RCTs was 173. The quality of reporting of RCTs was generally poor and even after the publication of the CONSORT statement, the quality of reporting only improved negligibly.

These results come as no surprise when looking at similar studies carried out in both medical and dental literature. A study looking at the quality of the reporting of clinical trials in orthodontics concluded that 'the quality of reporting orthodontic clinical trials was insufficient to allow readers to assess the validity of the trials'[11].

Obviously, RCTs involving children are published in.dental publications other than those relevant to paediatric dentistry. We decided to restrict our search to paediatric dentistry journals first to make this exercise manageable. Large numbers of children have taken part in RCTs looking at fluoride and other anti-caries agents. Inclusion of all these trials would potentially have led to an unmanageable number of RCTs to assess. In addition, we were particularly interested in the adoption of CONSORT which is a function of the editorial board of a journal.

A potential criticism of the study is that only articles published in English were included, which may not be representative of all published articles. The journals chosen represent the major journals in the field. Indeed, it is possible (although untested) that trials published in lower impact paediatric dentistry journals might be even less likely to follow CONSORT guidelines.

What are the implications of this study? This study indicates that reporting of RCTs in paediatric dentistry journals is poor, and this suggests that the original study design was poor as well. If this is the case, then there are profound ethical implications. Patients taking part in any research study should expect that the study is carried out in a rigorous and an appropriate manner to ensure results are meaningful and applicable. This is particularly true of child patients. If we assume that many of these studies were not run to the highest possible standards, then these child patients may have been exposed to potential harmful experimental interventions for possibly limited benefit. Clearly, this situation should not be allowed to continue. Those responsible for designing and reporting on clinical trials should implement the CONSORT guidelines.

Readers of RCTs published in the major paediatric dentistry journals should also be aware that, in general, the quality of the reporting is poor. Thus, a reader may not be able to assess the validity of a trial. Caution should be used when reading a published report of the efficacy of interventions. Readers should also consider assessing the quality of a report, using the operational checklist, if the subject of the RCT is of particular interest.

A study by Plint *et al*. showed that journal adoption of CONSORT is associated with improved reporting of RCTs[12]. Only two of the five active paediatric dentistry journals used for this study confirmed that they had not enforced authors to comply with CONSORT in order for a trial to be published. The other three journals did not provide any information regarding compliance with CONSORT. It has been over 10 years since the publication of the CONSORT statement, and at the time of writing, the authors are not aware of any paediatric dentistry journals that have adopted

it yet. Journal editors and editorial boards have an opportunity to take the lead in improving the quality of reporting by adopting the CONSORT statement and only publishing reports which adhere to CONSORT.

Letters were sent to the journals included in the study, to ascertain their status regarding the adoption of the CONSORT guidelines. Only two of the five journals responded to the letter, the *European Archives of Paediatric Dentistry*, which stated that they have not yet adopted CONSORT statement yet, but they were considering adopting it in volume 9 of 2008, and the *International Journal of Paediatric Dentistry* who were considering adopting it in 2008.

Conclusion

The quality of reporting of clinical trials is generally poor, and is often not adequate to allow readers to assess the validity of the trial. The overall quality of reporting of clinical trials has not substantially improved since the publication of the CONSORT guidelines.

Paediatric dentistry journal editorial boards are encouraged to actively engage in discussion regarding the potential to adopt CONSORT if they are not already doing so. There is good evidence in the literature that the adoption of CONSORT improves the quality of both the conduct and reporting of trials in journals that have taken the decision to make it a requirement for submission acceptance.

What this paper adds

- The overall quality of reporting of clinical trials has not substantially improved since the publication of CONSORT.
- Paediatric dental journals are encouraged to adopt CONSORT.

Why this paper is important to paediatric dentists

- The quality of reporting of clinical trials is generally poor, and is often not adequate to allow readers to assess the validity of the trial.
- Researchers are encouraged to adopt CONSORT when undertaking clinical trials.

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