Original Article

Critical Appraisal of Reporting Randomized Clinical Trials Published in Iranian Dental Journals During 2003-2010

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Abstract
Objective: Considering the importance of randomized clinical trials (RCTs) in the evidence-based approach, the objective of this study was critical appraisal of reporting RCTs in Iranian dental journals.
Materials and Methods: After adequate searching, 113 RCT articles published during 2003-2010 were reviewed for quality of reporting with the CONSORT scale. The quality of each paper was assessed on 20.
Results: Although statistical analysis was described in 93.8%, acceptable methods for randomization and blinding were found in only 8% and 11.5% of the papers, respectively. Reasons for withdrawal were also given in just 20.4% of the articles.
Conclusion: This study revealed that the quality of reporting RCTs in Iranian dental journals does not meet the recommended standards generally and needs to be improved.
Key Words: Randomized Clinical Trials; Dentistry; Iran

INTRODUCTION

Randomized clinical trials (RCTs) are human studies in which the effects of two treatment modalities are compared [1, 2]. RCTs are somehow considered the "gold standard" of clinical research into the effect of different treatment modalities and they provide the clinician with the highest level of evidence for therapeutic interventions [2, 3]. RCTs are extensively used by medical and dental researchers [4]. In the dental science, similar to the medical field, a new treatment modality is seldom used in routine treatment procedures unless one or several randomized clinical trial(s) provide hard evidence in favor of it [2]. In fact, the basic fundamentals and the structural principles observed in designing an RCT minimize bias in the results [5]. These basic fundamentals include randomization, allocation, blinding and a control group receiving placebo, the careful observation of which in a properly guided RCT yield the most reliable prediction of treatment results [6]. In recent years, scientific advances have resulted in the review and summarization of the evidence provided by clinical trials during systematic reviews,

resulting in realization of the importance of carrying out accurate clinical trials and as a result, of the significance of evaluating the validity of the results of clinical trials. Therefore, the quality of designing and the way RCT is carried out have a definite effect on the validity of its results; the reports of weakly designed RCTs show the therapeutic results of those interventions with unreal magnification and the consequence of defective methodology will be patient treatment failure [7,8]. Since 1980 researchers have focused on evaluating the quality of RCTs and several published articles have indicated the presence of defective methodology in reporting the results of clinical trials. These reports indicate that low-quality RCTs estimate the efficacy of therapeutic interventions up to 30% higher than the real level in comparison to high-quality RCTs [9, 10]. Clinical epidemiologists have designed a process referred to as "critical appraisal" to assess RCTs [11, 12]. To this end, checklists and criteria have been designed and prepared all over the world to help readers evaluate the quality of RCT reports [4,7,13], of which CONSORT is the most valid tool [14]. CONSORT is a tool introduced in the form of a checklist of items that should be observed in an RCT; the aim of its designing is to facilitate critical appraisal and interpretation of RCTs by journal reviewers and readers and to provide a guideline for authors so that they can have an understanding of how to improve the quality of RCT reports [8]. There is ever-increasing evidence indicating that use of CONSORT by journals and researchers improves the quality of RCT reports [8, 15].

A large number of RCTs are carried out annually in academic centers in Iran. In many cases selective reporting of the studies with positive outcomes results in biases in making judgments about the evidence available [16]. The present study was carried out using the valuable CONSORT tool in order to evaluate the quality of RCT reports in the field of dentistry, published in the scientific-research journal in Iran in a 7-year period (2003-2010). To date various studies have been carried out regarding critical appraisal of RCTs on dental implants (Esposito, 2001; Dumbrigue, 2006) [17,18], dental prosthesis (Dumbrigue, 2001; Jokstad, 2002; Vere, 2011) [19-21], orthodontics (Harrison, 2003) [7], community dentistry (Richards, 2011) [22], periodontology (Mantenegro, 2002) [3], pediatric dentistry (Al-Namankany, 2009; Hurst, 2011) [23,24]. The present study is the first critical appraisal of RCTs published in the field of dentistry in Iran.

MATERIALS AND METHODS

In the present study, first the full texts of all the RCT articles published in Iranian scientific-research journals from 2003 to the end of 2010 were collected. To this end, the website of the Ministry of Health and Medical Education at www.HBI.ir and also the www.SID.ir website were evaluated for a list of journals with a scientific-research status approved by the Journals' Committee of Medical Sciences of Iran. The list was used to extract the list of dental journals. Then the website of each journal and the website of Iranmedex were checked for full texts of all the RCT articles published in the time interval specified in the present study.

Iranmedex is a non-specialized databank that provides research articles in medical sciences and encompasses articles published in scientific journals of Iran. The strategy of the search was based on the keywords. In this case, the medical keywords of "Randomized Clinical Trial" or "Clinical Trial" or "RCT" were searched in combination with the words "Dentistry" or "Dental". In addition, after searching the electronic resources, we started hand searching for non-electronic resources including all related original articles published in all available Iranian dental journals during the above-mentioned period.

The outcome was the clinical trial research in the sciences of dentistry.
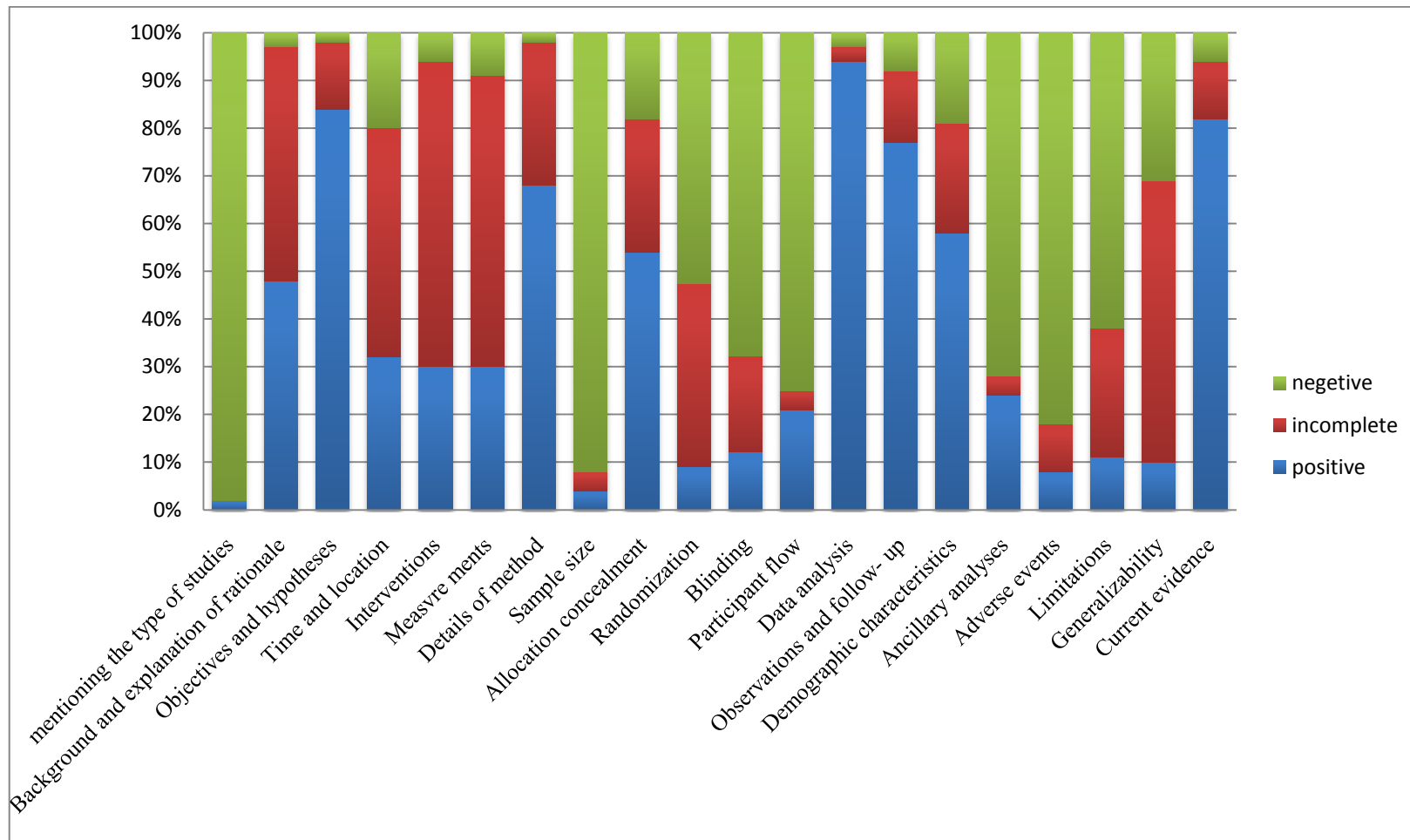
Graph 1. Comparison of Observed CONSORT Items Among 113 Articles

Moreover, the reference lists of retrieved studies were also used for finding additional relevant studies. Two reviewers reviewed all identified titles and abstracts independently. The full texts were collected, their data were recorded and the evaluation was initiated. The following data were collected for all the articles and recorded in special forms: journal name, publication year, article title, and the article field [3]. The researcher-designed form was separately completed for each article; the form consisted of a CONSORT checklist that was completed for each article. During evaluation of the full text, two reviewers separately read through each article and the latest version of CONSORT checklist (2010) was separately completed for each article. This checklist consists of 22 items in five sections that evaluate the different parts of the articles. Item number 1 addresses the title and abstract; item number 2 evaluates the introduction; items 3-12 deal with the materials and methods; items 13-19 are concerned with the results; and items 20-22 are related to the discussion. For example, in the items addressing the materials and methods, sample size, blinding, randomization and statistical methods each is considered a separate item and the reviewer should read through the article to evaluate whether each item has been observed or not [12-14]. In the present study, like some other similar studies, some minor changes were made to the original version of the tool, i.e. modified CONSORT was used. To this end, twenty main items of this tool were selected and for each item three different situations of "without", "with" and "incomplete/unacceptable" were considered. In other words, the completed list for each article indicated the items of CONSORT that had been observed in each article [10]. At the beginning of the study, a pilot stage was carried out between the two reviewers and the checklist was separately filled out for ten articles randomly selected from the articles collected.

Then a session was held between the two reviewers and the items over which they had no agreement were determined. Then an agreement was reached regarding these items after a series of discussions [10]. At the end of the article review stage, inter-rater reliability was measured by ICC (Intra-Class Correlation) and a measured ICC of 0.88 (CI 95% :0.80-0.93) was considered acceptable. Data were analyzed by SPSS 17. Descriptive statistics were used to evaluate the distribution of RCT articles; One-way ANOVA analysis of variance was used to analyze differences regarding classification of articles; linear regression model with significant level of 0.05 and OR (odds ratio) were used at 95% confidence interval to analyze the difference between the mean scores of the articles and the year of publication.

RESULTS

A total of 113 relevant articles were collected in the present study. The minimum and maximum number of articles published were related to 2003 (8 articles) and 2006 (23 articles), respectively. The articles were collected from 12 scientific-research journals. The maximum number of published articles was from one journal with 31 articles (Journal of Dentistry Tehran University of Medical Sciences) and the minimum was related to three journals (one article in each: Dentistry journals of Yazd, Babol and Tabriz). The articles were classified into ten groups after they were thoroughly read. The most numerous articles were related to periodontics with 45 articles, comprising almost 40% of all the clinical trials in dentistry; the least number of articles were on infection control and oral pathology, each with one article (Table 1 and Graph 2). Graph 1 presents the rate of reporting of the 20 items evaluated in all the articles assessed as "observed", "not observed", and "incomplete/unacceptable" cases separately shown for each items.

Table 1. Main Characteristics of 113 Mentioned Articles

Journal Name	*Tehran University*	*Behshti University*	*Islamic Association*	*Mashhad University*	*Shiraz University*	*Isfahan University*	*Qazvin*	*Yazd University*	*Babol University*	*Tabriz University*
Number of Articles (percent)	36(31.8)	22(19.5)	7(15)	16(14.2)	12(10.6)	5(4.4)	2(1.8)	1(0.9)	1(0.9)	1(0.9)
Field of Articles	*Periodontics*	*Pediatrics*	*Oral Medicine*	*Surgery*	*Orthodontics*	*Endodontics*	*Prostho-dontics*	*Operative Dentistry*	*Infection Control*	*Pathology*
Number of Articles (percent)	45(39.8)	16(14.2)	14(12.4)	10(8.8)	10(8.8)	9(8)	5(4.4)	2(1.8)	1(0.9)	1(0.9)
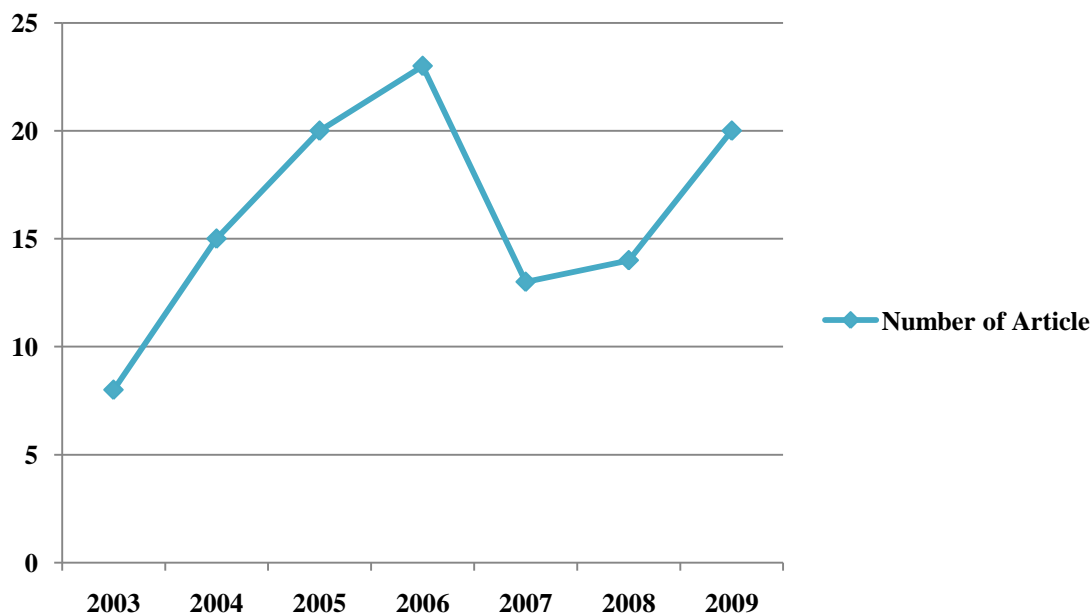
Graph 2. Trend of publishing RCT articles between 2003-2009.

As the graph shows, the least-reported item in the articles was item number 1 (mentioning the type of the article in the title), with 98.2% of the articles failing to report it. The highest rate of reporting was related to item number 13, which is related to an appropriate method of analysis and 93.8% of the articles had reported it. It is noteworthy that only eight items depicted in this graph have been observed in more than 50% of the articles evaluated, with a reporting rate higher than 80% for half of the items (four items). In addition, except for item number 1, a reporting rate of less than 10% was achieved for the three remaining items.

One-way ANOVA analysis of variance showed no significant relationship between the publication year of the journals and the specialty field of the article on one hand and all the items from the checklist that had been reported on the other (P=0.35). In other words, the articles that had reported a greater number of CONSORT items were not significantly different from other articles regarding the two above-mentioned items.

Linear regression model showed that each consecutive year of publication from 2003 to 2010 has witnessed a 0.34-unit increase in the rate of reporting of all the items with no statistically significant differences (P=0.081). In the checklist used, items 9-12 evaluated the most important structural components of RCTs; the items have been reported as follows: concealment of allocation, 53.1%; randomization, 8%; blinding, 11.5%; and reporting of dropouts, 20.4%. On the whole, the articles have observed a mean score of 8.8±2.23 out of 22.

DISCUSSION

The present study was undertaken to carry out a critical appraisal of the RCT articles in the dental field published in Iran and the overall results showed that the necessary criteria for clinical trials have not been observed in an acceptable level in the works published.

In the present study, an inclusion criteria for the journal was their scientific research status; however, in such studies other criteria such as being indexed in databases such as PubMed

can be considered as one of the inclusion criteria that seems to restrict the number of dental articles for evaluation in Iran. However, Cioffi and Farella (2011) believe that the quality of the RCT published has no relationship with the impact factor of the journal involved [25]. In the present study, almost 40% of the articles were in the field of periodontics. Moles et al. (2002) too reported more RTCs in periodontics compared to other dental specialty fields [26]. However, Nocini et al. (2010) reported that it is difficult to gather evidence and data in some dental fields such as surgery because the superiority of one surgical technique to another, contrary to the effect of one specific drug, has a direct relationship with the expertise and dexterity of the surgeon, which is difficult to evaluate [27]. In the present study, only 8.8% of the articles evaluated were related to maxillofacial surgery.

In the present study, almost all the items for the evaluation of RCTs in the comprehensive CONSORT tool were included to evaluate the articles in question, which is similar to the methodology used by Hurst et al. (2011) because these researchers, too, used a modified and simplified version of CONSORT [24], while Richards and Al-Namankany used the original version of CONSORT for the critical appraisal of the articles in their studies [22, 23]. In some similar studies in recent years, more simple tools have been used for critical evaluation of articles; Sjogren (2002) and Harrison (2003) used Jadad criteria, which does not seem to be justified in the face of comprehensive CONSORT tool [7, 27]. Researchers in the majority of studies similar to the present study have focused on the main structural principles of RCT. Studies carried out to date on various RCTs published in the field of dentistry in relation to the evaluation of randomization have shown that it has been observed in 17-54.8% of cases [3,7,17-21]. In other words, under the best circumstances all over the world, half of the dental studies have properly executed randomization in RCTs.

In the present study, only 8% of the articles evaluated had properly used randomization. Evaluation of studies at an international level for the application of blinding shows that it has been correctly applied in 6.5-40% of studies [3, 7, 17-21]. It appears it has been more difficult to properly apply blinding in comparison with randomization all over the world. The results of the present study showed that blinding has been executed in 11.5% of the articles under study, which is consistent with the results of similar studies in other countries [7]. The results of the present study showed that in 20.4% of the studies evaluated there have been some dropouts from studies, decreasing the accuracy and reliability of the results. In a study conducted by Dumbrigue et al., in 98% of the studies evaluated all the subjects had been preserved up to the end of the study without any dropouts [18].

At present, more than 40000 clinical trials all over the world are actively including patients in such studies and certainly a large amount of energy and human resources should be utilized to improve the quality of reports of these RCTs [4]. The results of the present study showed that irrespective of the low rate of observation of the main structural principles of RCTs, the numeric values regarding observation of other CONSORT items are significant; for example, item number 8, which evaluates "reporting the method used to determine the sample size", has been properly observed only in 3.7% of the studies.

Therefore, it is suggested that research centers implement more supervision in relation to better designing processes and execution of such studies and Iranian journals should introduce the reliable CONSORT tool to the authors and reviewers so that their application might increase the quality of articles published in the future.

It is also suggested that CONSORT tool should be more properly introduced in research workshops and seminars to the researchers in the dental field.

Since some of the articles derived from studies carried out in Iran are published in English journals, a deficiency is evident regarding these studies in the present study and it is suggested that future studies should evaluate these studies too.

CONCLUSION

In conclusion, the quality of reporting clinical trials was insufficient to allow readers to assess the validity of the trials. We have shown that greater attention to quality aspects of design and reporting of RCTs in Iranian dental Journals is needed and the dental research community should view these results with concern.

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