

## Assessment of the quality of randomized controlled trials in orthodontics published in PubMed indexed journals by Iranian authors from 2007 to 2017

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** Randomized controlled trials (RCTs) are the gold standard for providing evidence in clinical research. The present study was performed with the objective to assess the quality of reports of RCTs in orthodontics in PubMed-indexed journals published by Iranian authors from 2007 to 2017.

**METHODS:** All the articles on orthodontics published from 2007 to 2017 and indexed in PubMed with Iran affiliations were reviewed and quality evaluation was performed on them using JADAD checklist.

**RESULTS:** A total of 23 RCTs were evaluated. The mean of total score was 3.09 out of 5 and only 39.1% of the articles had appropriate methods of blinding and randomization. The cause for withdrawal was given in 65.2% of the articles.

**CONCLUSION:** The results of this study indicated that the quality of RCTs published by Iranian authors in orthodontics was acceptable, however improvements were necessary.

**KEYWORDS:** Randomized Clinical Trials; Quality Assessment; Orthodontics; Iran

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Evidence-based medicine (EBM) applies the outcomes of the scientific research to daily and routine clinical practice. Currently, this concept is popular among dentists and is known as evidence-based dentistry (EBD).<sup>1</sup> Clinical trials consist of scientific experiments involving subjects and/or patients designed to determine the most effective therapy for a disease condition. Generally, the results elicited from clinical trials help establish a protocol for populations affected by the same condition of the study sample or to choose from among different therapies available.<sup>2</sup>

The results of high-quality randomized clinical trials (RCTs) are considered to be strong

evidence in EBD.<sup>3,4</sup> In the field of dental science, like medicine, a new treatment procedure is rarely used in routine practice unless some randomized clinical trial(s) support it.<sup>5</sup> RCTs are the gold standard for providing evidence in clinical research. Quality of RCTs has recently been defined as “the likelihood of the trial design to generate unbiased results”.<sup>6</sup> However, even the RCT study design cannot eliminate all the bias, which can occur during designing, conducting, reporting, or application phase, hence causing incorrect results. In recent years, the need for predictable and effective dental treatments has prompted clinicians to look for therapeutic approaches validated by experimental trials; however,

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unfortunately, the quality of many published medical and dental RCTs is variable.<sup>7</sup>

It is important that RCTs, as the most valuable research method for assessing the efficacy of treatments, be reported with the highest possible level of quality.<sup>7</sup>

Although the number of RCTs by Iranian researchers has increased in recent years, the most important issue is the quality of these studies.

Badri et al. investigated orthodontic studies conducted in Iran and published in international and national journals, concluding that orthodontic research production has made significant progress in Iran in recent years up to 2012.<sup>8</sup>

Criteria and checklists have been prepared worldwide to assist readers in assessing the quality of studies regarding RCTs. The present study was investigated to assess the quality of RCT reports in the field of orthodontics published in PubMed-indexed journals conducted in Iran during 2007-2017 using the JADAD score.

## Methods

This study is a cross-sectional analytical study. In order to retrieve studies on RCTs in orthodontics conducted in Iran, an electronic search was conducted in the PubMed. First, keywords including orthodont, malocclusion, functional orthopedic, crossbite, open bite, deep bite, overbite, prognath, orthognath, retrognath, mandibular deficiency, mandibular excess, maxillary deficiency, maxillary excess, growth modification, dentofacial orthopedics, maxillary growth, mandibular growth, molar relationship, occlusal problem, occlusal anomaly, occlusal discrepancy, tooth problem, tooth anomaly, tooth discrepancy, vertical excess, vertical deficiency, tooth movement, tooth correction, teeth correction, tooth alignment, teeth alignment, distal movement, mesial movement, distalization, mesialization, functional appliance, removable appliance, and fixed appliance,<sup>9</sup> were entered in the "all fields" search box and clinical trials were

selected for article type and 3534 articles were found. Then, the word "Iran" was typed in the "affiliation" search box and 64 articles were found. In the next step, the "publication dates" was set to 2007 to 2017. Hence, 23 RCTs were identified.

Each article was read by two reviewers separately and the JADAD scale checklist was completed. Randomization, blinding, and accountability of all patients, including withdrawals, were 3 important factors of clinical trials based on which the results of the studies were scored. JADAD scale checklist consisted of 5 scores in total; 2, 2, and 1 of which in relation to randomization, blinding, and dropout rate, respectively.<sup>6</sup>

The scores were allocated as follows: 1, 1, -1, 1, 1, -1, and 1 for a/an randomized study, additional point for an appropriate method, inappropriate randomization method, subject blinded to intervention, evaluator blinded to therapy, inappropriate method of blinding, and description of withdrawals and dropouts, respectively.<sup>10</sup> The maximum achievable score was 5. Low-quality trials resulted in a score of < 3.<sup>11</sup>

Data were analyzed using descriptive statistics and Pearson correlation coefficient in SPSS software (version 18, SPSS Inc., Chicago, IL, USA).

## Results

23 articles were conducted on orthodontics in Iran and cited in PubMed from 2007 to 2017, as presented in table 1. The maximum number of articles was reported for the year 2014 (7 articles) (Figure 1).

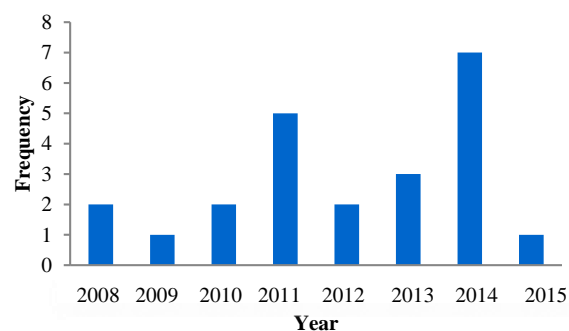


Figure 1. Number of articles published per year

**Table 1.** Studies on orthodontics conducted in Iran and cited in PubMed from 2007 to 2017

Affiliation	Author name	Title
Hamedan	Nasrin Farhadian	Streptococcus mutans counts among patients
Mazandaran University of Medical Sciences, Sari	Farhad Sobouti	Effects of laser-assisted cosmetic smile lift...
Shahid Beheshti University of Medical, Tehran	Ladan Eslamian	The effect of 810-nm low-level laser...
Tehran branch, Islamic Azad University	Haleh Hashemi	The effect of recommending a CPP-ACPF product on salivary...
Tehran branch, Islamic Azad University	Fariborz Amini	Effects of fixed orthodontic treatment using...
Shiraz University of Medical Sciences, Shiraz	Sepideh Torkan	Clinical and radiographic comparison of the...
Shiraz University of Medical Sciences, Shiraz	Hamidreza Eftekharian	Effect of Tranexamic Acid Irrigation on...
Hamedan	Amirfarhang Miresmaeili	Effect of carbon dioxide laser irradiation...
Mashhad University of Medical Sciences, Mashhad	Arezoo Jahanbin	Effectiveness of Er: YAG laser-aided fiberotomy...
Hamedan	Mohammad Zandi	Short-term skeletal and dental changes following...
Tehran branch, Islamic Azad University	Ladan Ansari	The effect of endotracheal tube cuff pressure co...
Shiraz University of Medical Sciences, Shiraz	Parisa Salehi	Comparison of survival time between two types of orthodontic...
Mashhad University of Medical Sciences, Mashhad	Fahimeh Farzanegan	Pain reduction after initial archwire placement in...
Shahid Beheshti University of Medical, Tehran	Rahman Showkatbakhsh	The effect of facemask and reverse chin cup...
Shahid Beheshti University of Medical Yazd	Rahman Showkatbakhsh	Treatment effects of R-appliance and Anterior...
Tabriz University of Medical Sciences, Tabriz	Soghra Yassaei	Comparison of the efficacy of calcium...
Tabriz	Koroush Taheri Taleh	Prevention of relapse following intraoral vertical ramus...
Tehran branch, Islamic Azad University	Behnam Bohluli	Trigemino-cardiac Reflex, Bilateral Sagittal Split Ramus...
Tehran branch, Islamic Azad University	Abdolreza Jamilian	Treatment effects of the R-appliance and twin block in Class II...
Shahid Beheshti University of Medical, Tehran	Rahman Showkatbakhsh	The effect of pulse electromagnetic...
Tabriz University of Medical Sciences, Tabriz	Javad Yazdani	Comparing the effect of 3 orthognathic surgical...
Mashhad University of Medical Sciences, Mashhad	Barat A. Ramezanzade	Histological changes in human dental pulp...
Hamedan	Nasrin Farhadian	Effect of fluoride varnish on enamel demineralization...

CPP-ACPF: Casein phosphopeptide-amorphous calcium phosphate fluoride

The articles were published in 16 scientific-research journals. The maximum number of articles was published in American Journal of Orthodontics and Dentofacial Orthopedics (AJODO) with 5 articles (Figure 2).

Of 23 articles, the maximum number was related to Shahid Beheshti University of Medical Sciences, Tehran, Iran, with 5 articles (Figure 3).

**JADAD quality assessment:** The results of JADAD quality assessment are presented in table 2.

Based on this assessment, the most frequent score in randomization was '1' in 52.2% of the articles. The mean randomization score was 1.30.

Assessment of blinding and its methods revealed that the most frequent blinding score (39.1%) was '2' with a mean of 1.13.

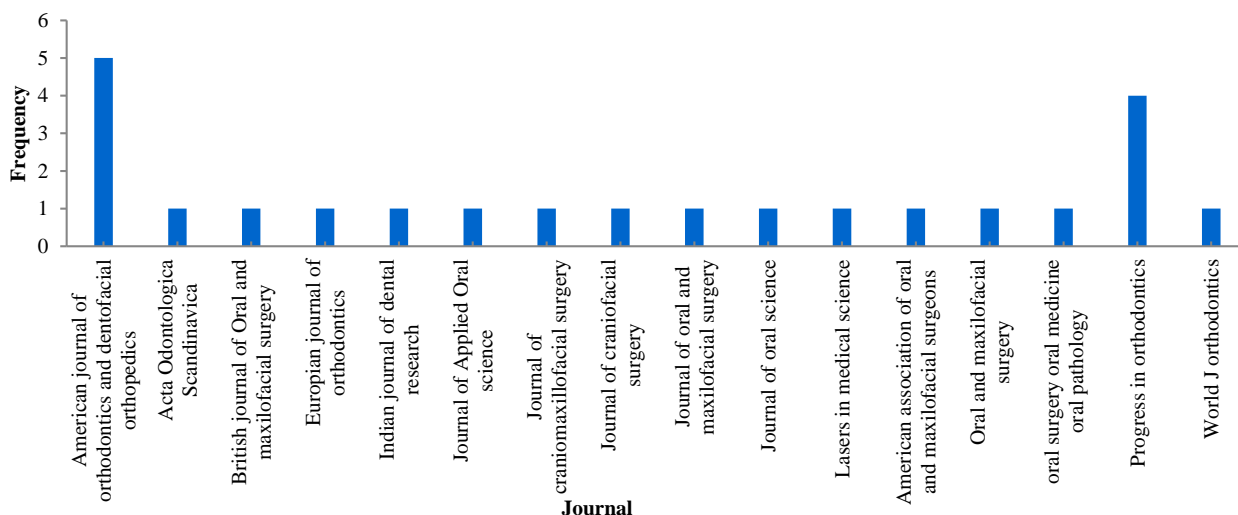


Figure 2. Rate of articles in terms of journals

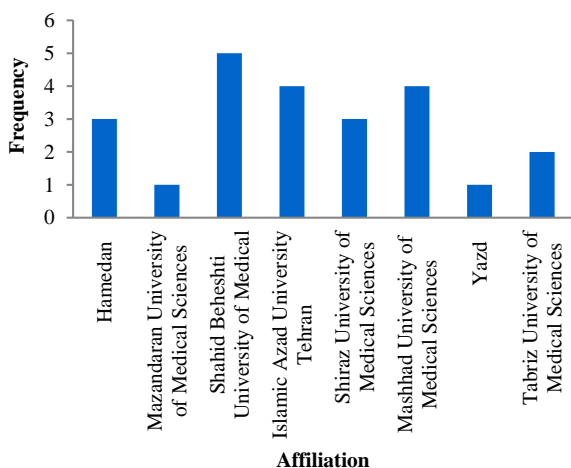


Figure 3. Rate of articles in terms of affiliation

In terms of dropout, the majority of the articles (65.2%) gained score 1 and the mean of dropout scores was 0.65.

Table 2. Rate of articles with score received in each item

Articles	0	1	2	3	4	5
Randomization	8.7	52.2	39.1			
Blindness	26.1	34.8	39.1			
Dropout	34.8	65.2				
Total score	4.3	8.7	21.7	26.2	21.7	17.4

The most frequent total score in JADAD quality assessment was '3' in 26.0% of articles and the mean of the total score for 23 articles was 3.09.

Correlation analysis showed no significant

correlation between the total score and year of publication ( $P = 0.281, r = 0.235$ ).

### Discussion

In the present study, quality assessment was performed on clinical trials in the orthodontics field indexed in PubMed on studies conducted in Iran in recent 10 years using the JADAD scale.

The investigation of the literature indicated that most of the articles published in recent 10 years were published in 2014. Regarding the inclusion of dental schools, the results showed that the Dental School of Shahid Beheshti University of Medical Sciences published the highest rate of RCTs in orthodontics indexed in PubMed. The type of journal is an important factor in the quality of articles

The majority of articles received a score of '1' in relation to randomization, which means that almost half of the studies did not use or describe suitable methods for randomization and more than half of the studies were poor in terms of randomization.

For blinding and its methods, more than half of the studies were poor and only 39.1% of the studies had employed adequate methods in blinding. Withdrawals/dropouts had been reported in most of the articles.

There are major concerns in relation to

blinding in certain disciplines like orthodontics. In fact, since orthodontic appliances usually have different shapes or configurations, clinicians usually realize which intervention the patients to receive. In some cases, for instance in trials involving functional removable appliances, a second blinded clinician should carry out the measurements after the patient has removed the appliance and the clinical chart has been hidden.<sup>12</sup>

4 articles, including the studies on "Comparison of survival time between two types of orthodontic fixed retainer", "The effect of recommending a Casein phosphopeptide-amorphous calcium phosphate fluoride (CPP-ACPF) product on salivary and plaque pH levels among orthodontic patients", "Clinical and radiographic comparison of the effects of two types of fixed retainers on periodontium" and "S. mutans counts among patients wearing removable retainers with silver nanoparticles compared to those wearing conventional retainers" gained maximum score of 5 and only one of the articles gained no score (0).

Maximum mean of total scores was contributed to 3 articles from Shiraz University of medical sciences that gained 4.6 points and articles that published on "Progress in Orthodontics" journal with mean score of 4.3.

Quality status of RCTs analyzed here did not significantly change over time.

In an investigation by Harrison, the quality of reporting of RCTs published in 3 orthodontic journals AJODO, British Journal of Orthodontics (BJO), and European Journal of Orthodontics (EJO), from 1989 to 1998 was assessed and the results revealed that the quality of reporting orthodontic clinical trials was insufficient to allow readers to assess the validity of the trials.<sup>14</sup>

In another study by Shimada et al., the quantity and quality of randomized controlled trials (RCTs) in orthodontic practice in PubMed from 2003 to 2007 was assessed and the results showed that the quality of RCTs was low and almost half of

the articles were found in AJODO.<sup>15</sup> In the present study, the maximum number of articles were also published in AJO-DO, however, the mean total score in the present study was 3.09, indicating that these RCTs had relatively high quality in terms of JADAD scale.

There has been a significant increase in the number of Iranian dental articles in recent years and during the last 2 decades indexed in the PubMed database.<sup>13</sup>

It is clear that a larger quantity of scientific studies is related to increased scientific development, however, the quality of publications is also important.

In a study by Habib Agahi et al. on critical appraisal of reporting RCTs published in Iranian dental journals during 2003-2010, the Consolidated Standards for Reporting Trials (CONSORT) scale was used for assessments. The results of this study showed that the quality of reporting RCTs in Iranian dental journals generally did not have the proposed standards, requiring improvements.<sup>16</sup>

With the development of EBM, RCTs have achieved a high status in the hierarchy for evaluation of the efficacy and safety of all the trials with an important role in decision making for clinicians.

RCTs are now considered as the best research design for comparison of therapeutic alternatives. Proper reporting of RCTs allows for easy determination of the RCT quality, which is important as low-quality RCTs might exaggerate the effects of treatment, potentially causing erroneous conclusions.<sup>17</sup> So far, only a few studies have been focused on the quality of RCTs and RCT was assessed in few dental disciplines.

Of all the RCT quality assessment tools, JADAD scale is the most commonly used one, providing an easy scoring procedure for quantitative evaluation of the quality of a trial and is often used for assessing the quality aspects of controlled trials method.<sup>18</sup>

To the best of our knowledge, no study is available on the assessment of the quality of RCTs published in orthodontics field in Iran



using JADAD criterion. The current study indicated that the quality of RCTs in studies regarding orthodontics conducted in Iran and published in 10 recent years, is a suitable level, however needing improvements, especially in terms of the randomization and blinding methods. The majority of studies conducted in Iran have not been indexed in PubMed, however, this source was used in the present study due to its open access and international visibility.

The limitation in the present study was review of few articles (23 articles), hence causing many statistical analyses not to be performed in order for inclusion of subgroups.

Since the number of studies conducted in Iran on orthodontics indexed in PubMed, was low and since no single resource can cover all the information, in addition, only relying on JADAD guidelines is not enough, further studies are suggested to be undertaken to evaluate the quality of RCTs indexed in other medical databases and with

other scales like the CONSORT.

### Conclusion

The findings of this study showed that the quality of clinical trials in orthodontics indexed in PubMed conducted in Iran in recent 10 years was fairly good. However, more attention is necessary regarding the methodological quality for randomization and blinding. Efforts, like compliance with the JADAD guidelines, should be made to minimize potential sources of bias and an increasing trend for improving the quality of RCTs.

### Conflict of Interests

Authors have no conflict of interest.

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