



## ORIGINAL ARTICLE

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## Methodological quality of clinical trials in pediatric dentistry research published in ISI journals, 2008-2012.

**Abstract:** There are many studies about the methodological quality of articles in pediatric dentistry. However, there is no up-to-date information or the use of measurement guidelines designed and validated for this purpose. The aim of this article is to determine the methodological quantity and quality of clinical trials (CT) in pediatric dentistry published in four Web of Knowledge (ISI-indexed) journals between 2008 and 2012. Clinical trials published in four ISI pediatric dentistry journals were evaluated. Name of the journal, year of publication, country of the corresponding author, type of CT and main subject were registered. A scale of methodological quality (MINCIR) from 11 to 36 points was applied to evaluate each article, establishing 18 points as the cutoff for “good methodological quality”. The quality was calculated by country, subject area and journal. Of 1,151 published articles, 149 (12.5%) clinical trials were selected. Their methodological quality was  $15.7 \pm 2.7$  points. 17% of the CT achieved a score equal to or greater than a methodological quality considered “acceptable”. One in every 6 published clinical trials was of good methodological quality. This would actually make it difficult to adopt the results of these investigations into routine clinical practice or to include them in future systematic reviews and meta-analyses.

**Keywords:** *Pediatric Dentistry, Evidence-Based Dentistry, Clinical Trial*

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### INTRODUCTION.

Evidence-based dentistry (EBD) represents a treatment approach that integrates the use of the best evidence available for clinical decision making<sup>1</sup>, helping professionals to stay informed about the areas of work prior to the treatment choice<sup>2</sup>. This approach requires measurement tools and reports of methodological quantity and quality, such as bibliometric analyses<sup>3</sup>, which can characterize the scientific production of people and institutions both in quantitative and qualitative terms, reducing the subjectivity inherent in the indexing of knowledge in a determined field of science to a minimum<sup>4</sup>.

In pediatric dentistry, bibliometric analyses have been

performed on clinical trials (CT) and their results are varied. Nainar<sup>5</sup> reports that three out of four articles published between 1968 and 1998 were studies considered as having a low level of evidence (descriptive studies, case reports and expert opinions); while Poletto & Faraco<sup>6</sup> analyzed articles published in a Brazilian journal of pediatric dentistry, finding a frequency of only 4.3% in CT. For his part, Al-Namankany<sup>7</sup> analyzed the quality of CT publications, basing it on the CONSORT (Consolidated Standards of Reporting Trials) guideline, concluding that these articles were of poor quality and contained insufficient information to evaluate the validity of the study. All this indicates that studies in pediatric dentistry are in the main anecdotal in

nature with a poor methodological quality.

Although the reports conclude that there is a need to evaluate and improve the quality of the evidence<sup>5,7,8</sup>, the instruments used to measure methodological quality do not present validity and reliability studies when determining this quality, which must be seen as a multidimensional concept<sup>9,10</sup>. One of the scales that measures the methodological quality of CT is the MINCIR (Methodology and Research in Surgery) scale, which has demonstrated its validity<sup>9</sup> and reliability<sup>11</sup> and proven its use in the bibliometric analysis of articles in dental therapy research<sup>12</sup> and oral-maxillofacial surgery<sup>13</sup>. Its use in pediatric dentistry would make it possible to quantify the methodological quantity and quality of CT, minimizing the chances of error in the determination of the quality of the scientific literature<sup>14</sup> and contributing to the most current quantification of the evidence obtained

in this specialty.

The aim of this study is to determine the quantity and methodological quality of CT in pediatric dentistry published in four ISI-indexed journals between 2008 and 2012.

## MATERIALS AND METHODS.

A bibliometric study was designed for CT published between 2008 and 2012 in the pediatric dentistry journals belonging to the SCI-Expanded database of the Thomson-Reuters (ex ISI) collection: Journal of Clinical Pediatric Dentistry; Pediatric dentistry; International Journal of Paediatric Dentistry and European Journal of Paediatric Dentistry.

### Information search and compilation

One of the principal investigators (AJ) searched the SCI-Expanded database ([www.isiwebofknowledge.com](http://www.isiwebofknowledge.com))

**Table 1.** Search strategy and limits used in the study.

Database	Search strategy <sup>1</sup>	Limits
SCI-Expanded. Thompson Reuters-ISI.	(SO=(Journal of Clinical Pediatric Dentistry) OR SO=(PEDIATRIC DENTISTRY) OR SO=(International Journal of Paediatric Dentistry) OR SO=(European Journal of Paediatric Dentistry)).	Search time=2008-01-01 / 2012-12-31. Use of Lemmatization=On.Document type: article.

1. Used in the search bar of the "advanced search" tool. Conducted June 14, 2013.

**Table 2.** Variables used for the analysis of selected articles.

Journal name	Year of publication	Country of corresponding author:	CT design type	Main subject area <sup>1</sup>
Journal of Clinical Pediatric Dentistry. Pediatric Dentistry. International Journal of Paediatric Dentistry European Journal of Paediatric Dentistry	2008-2012	Name of country attached	Growth and development. Simple CT (those with simple blinding, CT with randomization and without masking, CT without randomization and with masking. Uncontrolled CT (CT without a group control such as quasi-experimental studies, before -after CT	Multicenter CTPediatric Dentistry. Disability/medically compromised. Disturbances in dental development. Periodontal disease. Cleft lip-palate/Head and neck syndromes. Dental materials/ Restorative dentistry. Oral medicine/Oral surgery. Occlusion/Orthodontics. Prevention/Dental education. Radiology. Sedation/Pain management. Trauma. Temporomandibular disorders. Miscellaneous

1. Defined according to the publication criteria of the International Journal of Paediatric Dentistry.

**Table 3.** Scale of methodological quality for treatment articles (Manterola *et al.*<sup>9</sup>) used in this study.

	Score
<b>Study design</b>	
Multicenter clinical trial	12
Controlled randomized clinical trial w/ double masking*	9
Clinical trial (w/o masking or simple, w/o randomization)**	6
Concurrent or prospective cohort	4
Historical or retrospective cohort	3
Cross-sectional	3
Series of cases	1
<b>Study population by factor and justification***</b>	
≥201	6 or 12
151-200	5 or 10
101-150	4 or 8
61-100	3 or 6
31-60	2 or 4
≤30	1 or 2
<b>Description of the methodology employed</b>	
<i>Aim</i>	
Clear and concrete aims are given	3
Vague aims are given	2
No aims are given	1
<i>Design</i>	
The design used is mentioned and justified	3
The design used is mentioned	2
The design used is not mentioned or justified	1
<i>Sample selection criteria</i>	
Inclusion and exclusion criteria are described	3
Inclusion or exclusion criteria are described	2
Selection criteria not described	1
<i>Size of the sample</i>	
Sample is justified	3
Sample is not justified	1
<b>Final score</b>	<b>6 to 36</b>

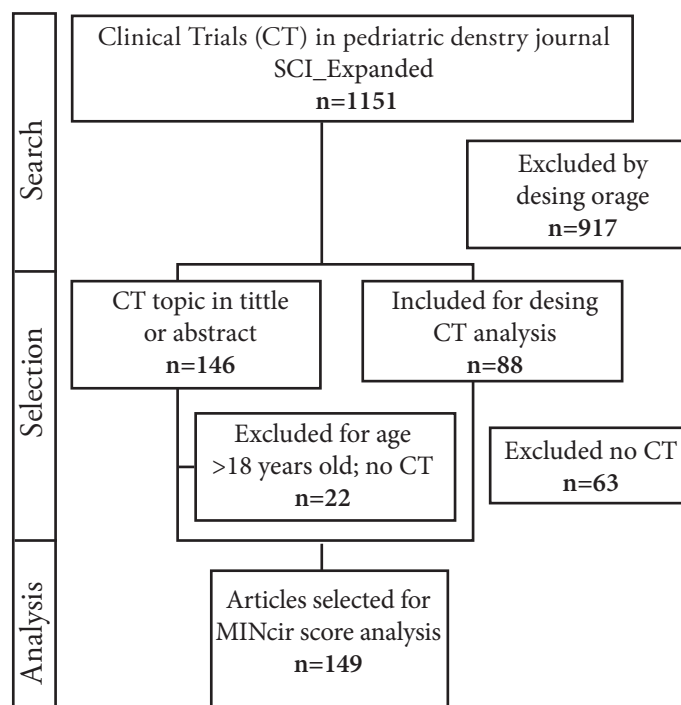
\*Includes clinical trials with restricted randomization and quasi-experimental studies.

\*\*Includes experimental studies (before and after).

\*\*\*Multiplied x2 if there is justification of the sample size.

using a strategy and search limits recommended for the four pediatric dentistry journals (Table 1). Two investigators (JA, AP) selected the articles that had the CT design or something similar in their title or abstract<sup>15</sup> (“clinical trial/study”, “randomized-single/double/triple-blind/masked-control/controlled trial”, “randomized trial”, “split mouth design/study”, “crossover/parallel trial/study/design/ intervention”, “cluster randomized trial”, “randomized placebo controlled study) and whose participants were under 18

**Figure 1.** Flow chart of selection and analysis of clinical trials (CT) published in pediatric dentistry journals.



years of age. Articles were excluded where the design was descriptive or analytical, as well as literature reviews, letters to the editor and technical notes.

The selected articles were analyzed by having two investigators (AJ, PA) read the complete text; these two ultimately selected those articles where the authors controlled one or more interventions on a population of subjects selected according to a properly designed protocol. Then, both investigators analyzed and independently tabulated the variables: i) journal name; II) publication year (2008-2012); III) country of corresponding author; IV) type of CT and v) main subject area of the article. (Table 2)

For those articles where there was a discrepancy between the two reviewers in recording the type of CT and main subject area, a second investigator (PA) analyzed the document and classification was agreed by consensus.

### Methodological quality

For the analysis of the methodological quality (MQ) of each CT, the “MINCIR Therapy” instrument described by Manterola *et al.*<sup>9</sup> was used, which presents 3 domains (Study design; Size of study population and Methodolo-

**Table 4.** Number and methodological quality of clinical trials published according to year in 4 ISI journals of pediatric dentistry 2008-2012.

Journal	Year of publication					Total (%)	MINCIR scale score		
	2008	2009	2010	2011	2012		mean±SD	min	max
European Journal of Paediatric Dentistry	7	1	4	4	10	26 (17)	14.8±2.4	11	22
International Journal of Paediatric Dentistry	8	10	6	14	1	39 (26)	17.1±3.7	13	29
Journal of Clinical Pediatric Dentistry	8	11	11	12	9	51 (34)	14.8±1.7	12	19
Pediatric dentistry	5	5	9	10	4	33 (22)	15.8±1.8	13	20
<b>Total</b>	<b>28</b>	<b>27</b>	<b>30</b>	<b>40</b>	<b>24</b>	<b>149 (100)</b>	<b>15.7±2.7</b>	<b>11</b>	<b>29</b>

**Table 5.** Countries that have published clinical trials in ISI journals of pediatric dentistry 2008-2012 and their average score of methodological quality.

Country	Nº	Articles		Score MQ <sup>1</sup>
		%		mean±SD <sup>2</sup>
India	25	16.8		14.8±1.9
Brazil	18	12		14.9±1.3
Italy	18	12		14±1.7
United States	16	10.7		14.6±2.1
Turkey	10	6.7		16.6±2.6
Iran	8	5.4		16± 2.7
Thailand	5	3.4		17±3.4
Israel	5	3.4		17.4±3.8
Finland	5	3.4		21.6±5.5
Germany	4	2.7		14.7±1.5
Mexico	4	2.7		16.7±1.5
Egypt	4	2.7		14±3.1
Sweden	4	2.7		18.4±2.5
Others <sup>3</sup>	23	15.4		16.1±2.7
<b>Total</b>	<b>149</b>	<b>100</b>		<b>15.7± 2.7</b>

1. Methodological quality

2. Standard deviation.

3. Countries with three articles selected (Saudi Arabia, Spain, the United Kingdom), two (Kenya) and only one article (Albania, Canada, Korea, Croatia, France, Iraq, Ireland, Japan, Lebanon, Serbia, Syria and Switzerland).

gy used) and six items (Table 3). A score within a range of 11 (worst methodological quality) to 36 points (best methodological quality) was assigned to each article, establishing 18 points as the cutoff for “good methodological quality”.

### Data analysis.

In order to verify interobserver reliability, two investigators (AJ and PA) analyzed, using the methodological quality instrument chosen for this study, 15 articles published in 2007 in the same four journals, determining an interobserver reliability in designs and MQ scores

**Table 6.** Subject area and methodological quality of clinical trials published in 4 ISI journals of pediatric dentistry 2008-2012.

Subject area <sup>1</sup>	Nº articles	Score MQ <sup>2</sup>		
		mean±SD	min	max
Radiology	1	12	-	-
Cleft lip-palate/Head and neck syndromes	1	14	-	-
Miscellaneous	1	14	-	-
Temporomandibular disorders	2	12.5±0.7	12	13
Occlusion/Orthodontics	15	14.4±1.7	11	18
Periodontal disease	2	15±1.4	14	16
Oral medicine/Oral surgery	3	15±1.7	14	17
Prevention/Dental education	36	15.7±3.5	12	29
Disability/medically compromised	2	16±1.4	15	17
Dental materials/Restorative dentistry	54	16.1±2.5	13	24
Sedation/Pain management	32	16.4±2.7	13	24

1. Based on the “Journal of Clinical Pediatric Dentistry”.

2. Methodological quality

with a Kappa above 0.8. The variables journal name, publication year, country of corresponding author and main subject area of the article were analyzed using descriptive statistics. The average MQ score of each article was related to the country of origin, subject area and journal using tables. The data were tabulated in MS Excel 2009, from which the results tables were created.

## RESULTS.

1,151 titles were identified in total from the search strategies: 234 articles were described as CT but ultimately

149 (12.5%) were selected and classified as CT (Figure 1).

### Number of articles

Of the articles selected, the journal with the highest number of CT in the analyzed period was the Journal of Clinical Pediatric Dentistry (50 articles) and the year with the most publications was 2011 (40 articles) (Table 4). The country with the most corresponding authors was India (16.8%), followed by Brazil and Italy (12%) (Table 5). According to the subject area, most of the selected CT were categorized as Dental materials/Restorative Dentistry and Prevention/Dental education (Table 6).

### CT Quality

All the articles reviewed presented an average  $\pm$ standard deviation ( $\pm$ SD) of  $15.7 \pm 2.7$ . The journal with the highest average MQ score was the International Journal of Pediatric Dentistry with  $17.1 \pm 3.7$  (Table 4). Only 26 of all the articles reviewed obtained a score of 18 points or more. Among the countries, Finland shows the greatest average MQ with 21.6 points (Table 5). The discipline with the highest MQ score was Sedation/Pain management, with an average of 16.4 points. No subject area reached 18 points (Table 6).

The MQ instrument made it possible to classify 92% as simple CT, 2% presented clear objectives suitable to the study design, and 8.7% used calculation strategies for determining sample size.

## DISCUSSION.

Our results show that in the last five years an average of 30 CT have been published every year, which is 12.9% of all the articles published from 2008 to 2012 by the four pediatric dentistry journals selected, a percentage similar to the 12.4% shown by Manterola *et al.*<sup>12</sup> in their study of MQ in surgery publications, but much higher than the 4.3% reported by Poletto & Faraco<sup>6</sup> for pediatric dentistry articles published by a Brazilian journal and the 3.6% for endodontics articles reported by Shafiei & Shahravan<sup>16</sup>.

### About the quantity

The frequency of published CT has been increasing

over the past few years; but many of these, together with the contribution of new scientific writing guidelines, has not been enough to have any real impact on improving the quality of CT.

The Journal of Clinical Pediatric Dentistry published the greatest number of CT; however, despite the quantity, the frequency per year of CT was observed as being homogenous in all the journals. If we compare the results with those of Nainar<sup>5</sup>, we observe that Pediatric Dentistry has published a steady number of CT over the years.

51.5% of the CT in the four journals analyzed are from India (16.8%), Brazil (12%), Italy (12%) and the United States (10.7%); these values are similar to the scientific productivity of these countries in other dental disciplines such as prosthodontics<sup>17</sup> and orofacial pain<sup>18</sup>, and are associated with public policies to incentivize publication, the presence of advanced research centers or the collaboration of researchers from other countries advanced in each area<sup>17</sup>.

The most published subject area in pediatric dentistry is "Dental material and Restorative dentistry", followed by "Prevention and Dental education", results very similar to those obtained by Poletto & Faraco<sup>6</sup>, but somewhat different from those reported by Nainar<sup>5</sup>, which reports that the main subject area studied is "Medicine, Pathology and Oral Surgery", which may be due to this author integrating every type of article design, of which the greatest proportion is descriptive studies, studies with no intervention risk.

### About the quality

In terms of the MQ, in general an average score of  $15.7 \pm 2.7$  was obtained. Only 26 CT (17%) obtained a score higher than the construct of good methodological quality proposed by the instrument (18 points). Independent of the instrument used to evaluate the MQ, the results are very similar to previous bibliometric reports in pediatric dentistry<sup>7,8</sup> and in other areas of dentistry<sup>12,13,19,20</sup>.

The countries with the greatest number of CT publications do not achieve a satisfactory methodological quality (Table 5). India has shown an increase in CT over the past few years, which has not correlated with its quality score as presented in this report (14.8). Finland reaches a mean that

exceeds the cutoff of the scale, which is why as a country, its articles present a good methodological quality; nevertheless, the number of published articles is low, because in 2010 and 2011 only one article per year was chosen.

Although these results present data similar to the reports previously mentioned<sup>7,8</sup>, it is important to consider some limitations of the present study. First, the journals analyzed do not include all the CT generated worldwide in pediatric dentistry, and second, the low number of CT selected could be due to search and indexing errors as well as measurement bias on the part of the researchers. Small variations in the number of CT could have a great impact in the final figures. However, we consider it useful to present these results to the dentistry community, responding to the suggestions of previous reports<sup>5,7,8</sup> and using a completely valid and reliable MQ measuring instrument<sup>11</sup>.

The systems used to assess the quality of scientific publications have been varied; nevertheless, the MQ must be seen as a multidimensional concept. Although there are guidelines for the publication of results such as CONSORT (randomized clinical studies) and STARD (diagnostic accuracy studies), none of these was designed specifically for the evaluation of MQ and they have not been validated for this purpose<sup>9</sup>. In their report, Da Silva *et al.*<sup>10</sup> analyzed several psychometric scales and lists of methodological quality in clinical articles, observing that the CONSORT guideline reports only analysis of appearance, content and agreement between reviewers<sup>10,21</sup> which entails limitations, since they can be used in the evaluation of different types of studies, for different populations and different approaches in health care<sup>10</sup>. As a result, it becomes important to identify valid and reliable scales to use for a specific topic, thereby decreasing

the possibility of errors in determining the quality of scientific literature<sup>14</sup>.

The MINCIR scale used in this study presents reports of reliability and validity in dental therapy research<sup>12</sup>, permitting analysis of the MQ based on the three basic concepts that the report must explicitly mention within a CT: type of study design, study population size and how it was calculated, and presentation of aims and clear and replicable selection criteria<sup>9</sup>; for this reason, our study revealed that 92% of the CT were simple CT, and only three articles (2%) presented clear aims suitable to the study design. As a result, inadequate methodological quality was observed most frequently when the study design, the study population size and its justification were mentioned and when the aims were clearly and specifically outlined.

Despite the recommendation by editorial bodies concerning the use of scientific writing guidelines for CT such as CONSORT, their quality has not improved substantially since the publication of the guideline<sup>7</sup>. This implies repeating patterns of quality: instead of improving, they continue with a clear deficit in the generation of CT of good methodological quality, neglecting the editorial recommendations in the improvement of reporting quality.

In conclusion, the quantity and quality of clinical trials in pediatric dentistry research in the last five years has remained low. There is therefore a critical need to develop methodological strategies to improve the volume and quality of the scientific production in this area of dentistry. In light of these results, it is suggested that these assessment scales be disseminated more widely in order to verify the different items that can doubtless be corrected or improved.

### Calidad metodológica de ensayos clínicos en odontología pediátrica en revistas ISI publicados entre 2008-2012.

**Resumen:** Existen estudios sobre la calidad metodológica de los artículos en la odontología pediátrica. Sin embargo, no hay ninguna información a la fecha sobre el uso de instrumentos diseñados y validados para este propósito. El objetivo

de este estudio es determinar la cantidad y calidad metodológica de ensayos clínicos (EC) en odontología pediátrica publicados en cuatro revistas indizadas en Web of Knowledge (ISI) entre los años 2008 y 2012. Se evaluaron ensayos clínicos publicados en 4 revistas ISI de odontología pediátrica. Se registró el nombre de revista, año de publicación, país de autor de correspondencia, tipo de EC y temática principal de

odontología pediátrica. Se aplicó una escala de calidad metodológica (MINCIR) entre 11-36 puntos para evaluar cada artículo, estableciendo un corte de 18 puntos como buena calidad metodológica. Se calculó la calidad por país, área temática y revista. De 1151 artículos publicados en 4 revistas de odontología pediátrica entre 2008-12, se encontraron 149 (12,5%) ensayos clínicos. La calidad metodológica de estos fue de  $15.7 \pm 2,7$  puntos. El 17% de los EC lograron un pun-

taje igual o superior a una calidad metodológica considerada como "aceptable". Uno de cada 6 ensayos clínicos publicados obtuvieron una buena calidad metodológica. Esto dificultaría la adopción de los resultados de estas investigaciones en la práctica clínica rutinaria, así como su futura inclusión en revisiones sistemáticas y meta-análisis.

**Palabras clave:** *Odontología pediátrica; Odontología Basada en Evidencia; Ensayo Clínico.*

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