Systematic Review
Pediatric Dentistry

Adherence to the CONSORT statement of randomized clinical trials on ART restorations in children: current status and reporting characteristics

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Abstract: Appropriate research reports are important to facilitate the evaluation of studies and the decision-making by dentists and policymakers. This meta-research study assessed the conformity of randomized clinical trials (RCTs) on atraumatic restorative treatment (ART) restorations with the CONSORT recommendations and their risk of bias (RoB). Cochrane Library, MEDLINE, BBO, LILACS, Scopus, and Web of Science databases were searched from April 2019 to June 2021 for RCTs that assessed the longevity of ART restorations in children. A specific tool was used to assess adherence to the CONSORT recommendations; RoB was evaluated with the Cochrane risk-of-bias tool. Descriptive analyses included the number of studies by journal, follow-up period, country, and quality assessments. A total of 2,181 papers were retrieved and 36 of them were analyzed qualitatively. The overall CONSORT mean score (CONms) was 22.52 ± 6.17 out of 32 points. The best described items were intervention and outcomes, whereas allocation concealment was described in only 22% of the papers. Significant differences in CONms were detected in the analysis by country and publication dates. High CONms were observed in recently published papers (26.7 ± 3.1) when compared to first ART studies (18.1 ± 4.6; $p < 0.001$). RoB was low in four studies, unclear in 11, and high in 21. Adherence of the papers to the CONSORT recommendations was not fully achieved and most of the papers had unclear and high RoB (PROSPERO registration #CRD42020201460).

Keywords: Dental Atraumatic Restorative Treatment; Systematic Review; Randomized Controlled Trial.

Introduction

Atraumatic restorative treatment (ART) is a minimally invasive approach for the management of dental caries. Since its development in the mid-1980s and its endorsement by the World Health Organization (WHO) in 1994, the number of clinical trials on this technique has increased, assessing the longevity of ART restorations and their efficacy in controlling dental caries.

ART, which began as an alternative for restoring teeth in underserved communities, has been currently used around the globe in public health dentistry as well as in private practices. This restorative approach is based on principles of minimally invasive dentistry, which recommends the preservation of the tooth structure, the maintenance of pulp vitality, and the prevention of pain and discomfort for the patient.[1]

To include the ART approach in their recommended protocols, clinicians and policymakers are greatly encouraged to make their treatment decisions based on the concepts of evidence-based dentistry (EBD). These concepts aim to increase the success of the intervention and to maximize its benefits to the patients.[2]

EBD is "grounded on a systematic process of establishing the level and the quality of the evidence" and the systematic reviews are the foundation of this process.[3]

Different systematic reviews about the ART protocol have been published. According to these reviews, ART can be successfully used for occlusal restorations in deciduous and permanent teeth[4,5] and occlusal-proximal cavities may have a higher risk of failure.[4,5] However, the statement that "new randomized clinical trials are needed to corroborate the findings" is common in systematic reviews, especially in those on occlusal-proximal cavities.[6,7,8] Also, it is not uncommon to read that systematic reviewers were not able to find the information needed in a certain paper,[7] which hampers the evaluation of potential bias.

One of the cornerstones of EBD is to minimize bias and provide reliable results. Systematic reviews and meta-analyses are based on primary studies to evaluate data qualitatively and quantitatively, aiming for the development of clinical practice guidelines.[9] By combining primary studies, the final sample is enlarged, providing enhanced power to the results when compared to a single trial. However, the inclusion of papers irrespective of their veracity can originate misleading conclusions.

Publication of RCTs is as important as their accomplishment, with transparent and complete reporting so that readers can identify if the study has potential sources of systematic and random errors. To standardize the reporting of RCTs, in the early 1990s, a group of researchers and medical journal editors developed the CONSORT statement (Consolidated Standards of Reporting Trials). This statement was published in 1996[10] and consists of a set of recommendations to improve the quality of RCT reports. The CONSORT statement provides the authors with a standardized and complete sequence of key components for reporting clinical trials, facilitating the reading and interpretation of the findings. Indirectly, the completeness of reporting could improve the methodological quality of RCTs.

Since the CONSORT statement was published, different dental journals have endorsed and recommended its use in RCTs.[11] Nevertheless, it has been demonstrated that compliance with the CONSORT statement has not been fully adopted in different areas of dentistry, including implant dentistry,[12] restorative dentistry,[13-15] endodontics,[16] orthodontics,[17] and public health dentistry.[18]

In this way, it is important to identify possible flaws and improve practices associated with ART research to promote reproducibility and transparency in the research and in its reports. Meta-research is a tool that can be used to accomplish this goal. It is defined as the "study of the research itself"[19] and it has five major areas of interest: methods, reporting, reproducibility, evaluation, and incentives.[20] In the present research, we focused our efforts on methods and reporting, *i.e.*, on the identificationg of biases and questionable practices in conducting and communicating the ART research. To our knowledge, this is the first study to do that.

Therefore, the objective of this study was to perform a meta-research analyzing the compliance of RCTs on the longevity of atraumatic restorations in primary and permanent teeth with the CONSORT statement and the RoB of these studies according to the Cochrane tool for evaluation of RoB.

Methodology

Protocol and registration

This systematic review of the literature followed the recommendations of PRISMA 2020 for writing the research report[21] and was carried out between April

2019 and June 2021 at the State University of Ponta Grossa, Paraná, Brazil. This study was registered with PROSPERO (CRD42020201460).

Sources of information and search strategy

The eligible studies were searched in different electronic databases, namely Cochrane Library, MEDLINE via PubMed, Brazilian Library in Dentistry (BBO), and Latin American and Caribbean Literature in Health Sciences (LILACS). Citation databases such as Scopus and Web of Science were also searched. Reference lists for all primary studies were also manually searched. Gray literature was not consulted because this research evaluated the quality of studies published in indexed peer-reviewed journals and we did not aim to estimate the efficacy of the ART protocol.

The search strategy was assembled initially for MEDLINE via PubMed. For this purpose, the terminology for indexing biomedical information (MeSH terms) and free terms presented in titles and abstracts were combined using the Boolean operator "OR" within concepts of the search strategy and the Boolean operator "AND" for different concepts. Subsequently, the search strategy was adapted for other databases (Figure 1).

Eligibility criteria

Randomized clinical trials that evaluated the longevity of ART restorations on children's deciduous and permanent teeth were included. Considering the date of the first publication of the CONSORT statement, we only included studies published from 1996 to 2021. Reports published in any media other than peer-reviewed journals were excluded. No language restriction was applied.

Selection of studies and data collection process

The papers were selected by title and abstracts; duplicates were considered once. If the title and abstract did not provide enough information to make a clear decision, full-text articles were obtained. Subsequently, two reviewers (A.D.R.G. and L.M.W.) classified those articles that met the inclusion criteria. Data were extracted using customized forms including information about the name of the journal, year of publication, country of the main author, study design, follow-up period of the trial, and number of patients/teeth, among other information. When multiple papers from the same research were found (reports with different follow-up periods), the data were extracted from the newest report; if information about CONSORT adherence was still missing, the previous reports from the same research could be searched for the lacking information; in this case, the set of papers was considered to be one entry.

Compliance with the consort statement

Compliance with the CONSORT statement was evaluated through a previously tested instrument applied to other studies (Table 1).[14,15] The CONSORT assessment tool is based on the items "material and methods" and "results" from the CONSORT Declaration of 2010.[22]

The tool includes a total of 12 criteria from the CONSORT statement. Given that some of them have subdivisions, a total of 16 items were assessed. Each item received a score from 0 to 2 (score 0 = no description, score 1 = poor description; score 2 = adequate description). Before paper evaluation, the instrument was revised and all items were discussed between two authors (A.C.R.C and L.M.W). Both authors then evaluated the included studies with the CONSORT tool. In case of a discrepancy in the scoring process for any item, a third author was contacted (D.S.W.).

Evaluators were not blinded to authorship of the paper. This was not possible because they were familiar with the theme and publications; also, the research center could be easily discovered after article reading.

Risk of bias in individual studies

Risk of bias assessment was performed by two independent reviewers (A.D.R.G and L.M.W), using the Cochrane Collaboration's tool version 1.0.[23] The RoB tool contains six domains: sequence generation, allocation concealment, blinding of patients/masking of evaluators, incomplete outcome data, selective outcomes reporting, and other possible sources of bias.

The judgment of each entry involved 'yes', indicating low risk of bias; 'no', indicating high risk of bias; and

Pubmed= 903 (17/02/2020)	
#1 ((((((((((((((((((molar[MeSH Terms]) OR dental caries[MeSH Terms]) OR tooth, deciduous[MeSH Terms]) OR dentition, permanent[MeSH Terms]) OR dentition, mixed[MeSH Terms]) OR molar[Title/Abstract]) OR "dental caries"[Title/Abstract]) OR "tooth deciduous"[Title/Abstract]) OR "dentition permanent"[Title/Abstract]) OR "dentition mixed"[Title/Abstract]) OR "occlusal surfaces"[Title/Abstract]) OR "posterior teeth"[Title/Abstract]) OR "posterior tooth"[Title/Abstract]) OR "Class II"[Title/Abstract]) OR "Class I"[Title/Abstract]) OR "Class 2"[Title/Abstract]) OR "Class 1"[Title/Abstract]))))	**#2** (((((((((dental atraumatic restorative treatment[MeSH Terms]) OR "dental atraumatic restorative treatment"[Title/Abstract]) OR "atraumatic restorative treatment"[Title/Abstract]) OR ART[Title/Abstract]) OR IRT[Title/Abstract]) OR "minimal intervention"[Title/Abstract]) OR "partial caries removal"[Title/Abstract]) OR "ART restorations"[Title/Abstract]))
#1 AND #2	
Scopus= 571 (17/02/2020)	
#1(TITLE-ABS-KEY (*molar*) OR TITLE-ABS-KEY (*"dental caries"*) OR TITLE-ABS-KEY (*"t??th deciduous"*) OR TITLE-ABS-KEY (*"dentition permanent"*) OR TITLE-ABS-KEY (*"dentition mixed"*) OR TITLE-ABS-KEY (*"occlusal surfaces"*) OR TITLE-ABS-KEY (*"posterior t??th"*) OR TITLE-ABS-KEY (*"class II"*) OR TITLE-ABS-KEY (*"class I"*) OR TITLE-ABS-KEY (*"class 1"*) OR TITLE-ABS-KEY (*"class 2"*))	**#2** (TITLE-ABS-KEY (*"dental atraumatic restorative treatment"*) OR TITLE-ABS-KEY (*"atraumatic restorative treatment"*) OR TITLE-ABS-KEY (*art*) OR TITLE-ABS-KEY (*irt*) OR TITLE-ABS-KEY (*"minimal intervention"*) OR TITLE-ABS-KEY (*"partial caries removal"*) OR TITLE-ABS-KEY (*"ART restorations"*))) AND (LIMIT-TO (SUBJAREA , *"DENT"*))
#1 AND 2 AND #3	
Web of Science- 393 (17/02/2020)	
#1 TOPIC: (molar) *OR***TOPIC:** ("dental caries") *OR***TOPIC:** ("t*th deciduous") *OR***TOPIC:** ("dentition permanent") *OR***TOPIC:** ("dentition mixed") *OR***TOPIC:** ("occlusal surfaces") *OR***TOPIC:** ("posterior t*th") *OR***TOPIC:** ("class I") *OR***TOPIC:** ("class II") *OR***TOPIC:** ("class 1") *OR***TOPIC:** ("class 2")	**TOPIC:** ("dental atraumatic restorative treatment") *OR***TOPIC:** ("atraumatic restorative treatment") *OR***TOPIC:** (ART) *OR***TOPIC:** (IRT) *OR***TOPIC:** ("minimal intervention") *OR***TOPIC:** ("partial caries removal") *OR***TOPIC:** ("ART restorations") AND (DENTISTRY ORAL SURGERY MEDICINE)
#1 AND #2	
Lilacs and BBO= 41 (17/02/2020)	
#1 (mh:(molar)) OR (mh:(dental caries)) OR (mh:(tooth, deciduous)) OR (mh:(dentition, permanent)) OR (mh:(dentition, mixed)) OR (tw:("occlusal surfaces")) OR (tw:("posterior teeth")) OR (tw:("posterior tooth")) OR (tw:("class II")) OR (tw:("class I")) OR (tw:("class 2")) OR (tw:("class1")) OR (tw:("superfíciesoclusais")) OR (tw:("dentesposteriores")) OR (tw:("dente posterior")) OR (tw:("classe II")) OR (tw:("classe I")) OR (tw:("classe 1")) OR (tw:("classe 2")) OR (tw:("superficies oclusales")) OR (tw:("dientesposteriores")) OR (tw:("diente posterior")) OR (tw:("clase II")) OR (tw:("clase I")) OR (tw:("clase 2")) OR (tw:("clase 1"))	**#2** (mh:(dental atraumaticrestorativetreatment)) OR (tw:("atr aumaticrestorativetreatment")) OR (tw:(ART)) OR (tw:(IRT)) OR (tw:("minimalintervention")) OR (tw:("partial caries removal")) OR (tw:("ART restorations")) OR (tw:("tratamiento de restauración atraumático")) OR (tw:("intervención mínima")) OR (tw:("extirpación parcial de caries")) OR (tw:("restauraciónes ART")) OR (tw:("restauraciónes TRA")) OR (tw:(TRA)) OR (tw:("tratamento restaurador atraumático")) OR (tw:("mínima intervenção")) OR (tw:("remoção parcial de cárie")) OR (tw:("restaurações ART"))
#1 AND #2 AND #3	
Cochrane Library = 259 (17/02/2020)	
#1 MeSH descriptor: [Molar] explode all trees **#2** MeSH descriptor: [Dental caries] explode all trees **#3** MeSH descriptor: [Tooth, deciduous] explode all trees **#4** MeSH descriptor: [Dentition, permanent] explode all trees **#5** MeSH descriptor: [Dentition, mixed] explode all trees **#6** molar:ti,ab,kw or "dental caries":ti,ab,kw or t*thdeciduous:ti,ab,kw or "dentition permanent":ti,ab,kw or "dentition mixed": ti,ab,kw(Word variations have been searched) **#7** "occlusal surface":ti,ab,kw or posterior t*th:ti,ab,kw or "class II":ti,ab,kw or "class I": ti,ab,kw(Word variations have been searched) **#8** "class 1":ti,ab,kw(Word variations have been searched) **#9** #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	**#1** MeSH descriptor: [Molar] explode all trees **#2** MeSH descriptor: [Dental caries] explode all trees **#3** MeSH descriptor: [Tooth, deciduous] explode all trees **#4** MeSH descriptor: [Dentition, permanent] explode all trees **#5** MeSH descriptor: [Dentition, mixed] explode all trees **#3** #1 OR #2 **#4**"Atraumatic restorative treatment":ti,ab,kw orART:ti,ab,kw or ART near technique*:ti,ab,kw orART near restoration*:ti,ab,kw or ART near sealant*:ti,ab,kw(Word variations have been searched) **#5**IRT:ti,ab,kw or "interim restorative technique":ti,ab,kw or "ART approach":ti,ab,kw or "dental restoration":ti,ab,kw or "minimal intervention":ti,ab,kw(Word variations have been searched) **#6** ionomer:ti,ab,kw or "partial caries removal":ti,ab,kw(Word variations have been searched) **#7** #3 OR #4 OR #5 OR #6
#9 AND #7 AND #6	

Figure 1. Search strategy in the different databases (February 17, 2020).

Table 1. Evaluation tool for assessment of adherence of studies to CONSORT recommendations.[14,15]

CONSORT item	Sub item	Score	Adherence of methods and results items to the CONSORT statement
			Description
Study design		Positive [2]	The drawing of the essay is clearly written in the text (split mouth, parallel, factorial, cluster).
		Negative [0]	This information is not reported.
		Poor [1]	1. Information can be obtained during the reading of the manuscript, although this is not explicitly reported by the authors. 2. There is a lack of consistency between the sections of the article (examples - the abstract does not correspond to the material and methods section; the presentation of the results does not correspond to the description of the study design; the flowchart presents different information, etc.).
Participants	Eligibility criteria	Positive [2]	The inclusion and exclusion criteria are clear, so readers can know exactly know which population the data can be extrapolated to.
		Negative [0]	This information is not reported.
		Poor [1]	1. Incomplete information oneligibility criteria compared to most field studies. 2. Presence of inconsistencies in the inclusion/exclusion criteria that prevent readers from knowing the population in which the intervention/control groups were performed.
	Search field and location	Positive [2]	Clear description of the scenario (academic, practice-based research, university, private clinics, etc.), as well as the date on which the intervention was implemented.
		Negative [0]	The setting and/or location are not reported in the text.
		Poor [1]	1. The authors describe the scenario or date, but never both. 2. This information can be obtained indirectly in the text.
Interventions		Positive [2]	The interventions for each group are described in sufficient detail to allow replication, including how they were actually administered.
		Negative [0]	No description.
		Poor [1]	Missing information that prevents replication of interventions/comparators.
Outcomes		Positive [2]	At least the primary results were defined in detail, including how and when they were evaluated. Consider this to be clear when the details are clear, but the authors did not use the term "primary result" or related synonyms.
		Negative [0]	There is no definition of primary outcome and/or secondary outcomes.
		Poor [1]	The authors only report having used specific criteria without providing details about the most important results of these criteria.
Sample Size		Positive [2]	The sample size calculation method is described, allowing replication. The primary result for each calculated sample size should be identified. The elements of sample size calculation are (1) the estimated results in each group (implying the clinically important target difference between the intervention groups); (2) the error level α (type I); (3) statistical power (or β error level (type II)); and (4), for continuous results, the standard deviation of the measurements should be reported. For equivalence runs, the equivalence limit instead of the size of the effect size should be reported.
		Negative [0]	There is no description in the article.
		Poor [1]	The sample size is described, but some parameters are missing, avoiding replication.
Randomization	Sequence generation	Positive [2]	1. Clear description of random sequence generation. 2. Or clear description of a non-random sequence method.
		Negative [0]	There is no information in the text.
		Poor [1]	The authors only provide a very superficial description (such as the "groups were randomly allocated") or do not provide enough information to allow replication of the randomization process.
	Allocation concealment	Positive [2]	Clear description of allocation concealment. See the next columns for risk of bias assessment.
		Negative [0]	There is no information in the text.
		Poor [1]	Not applicable.

Continue

Continuation

CONSORT item	Sub item	Score	Adherence of methods and results items to the CONSORT statement
			Description
Blinding		Positive [2]	1) The authors describe who is blinded to the study.2. In blinded studies (when this is clearly reported by the authors), the description of the participant or evaluator (the blinded one) is sufficient; However, when the study is double-blind or triple-blind, all blinded people should be described. 2) The study describes only the participant or blinded examiner, but one of these people cannot be blinded by resources intrinsic to the study design.
		Negative [0]	There is no description of blinding.
		Poor [1]	Poor/partial information. For example, (1) the authors describe the blinding of examiners or the blinding of participants, but never both. (2) The authors describe the study as blind or double-blind, but do not specify who was blinded.
Statistical methods	Hypothesis testing	Positive [2]	Statistical methods are described in sufficient detail, allowing a knowledgeable reader to have access to the original data and verify the reported results. In addition, the statistical tests employed by the authors seem to be appropriate for the type of study and the nature of the data collected.
		Negative [0]	Statistical methods are not described.
		Poor [1]	There is insufficient information to evaluate the statistical method used by the author and/or the type of statistical tests employed by the authors are inappropriate for the design and/or nature of the data (*e.g.*, tests that do not take into account the paired nature of the data when this is the case). 2) The authors describe several statistical tests, but do not specify to which outcome they were applied.
	Effect size estimation	Positive [2]	The authors report, at least for the primary result, the size of the effect and its accuracy (as a 95% confidence interval). Odds ratio, risk ratio, risk difference, mean difference, etc.
		Negative [0]	No description of effect size and confidence interval.
		Poor [1]	Incomplete information.
Flow of participants	Flowchart	Positive [2]	For each group, the number of participants who were randomly assigned, received the desired treatment, and were analyzed for the primary result is described in the flowchart.
		Negative [0]	The flowchart is not presented in the article.
		Poor [1]	1.There are inconsistencies between the numbers described in the flowchart and other parts of the manuscript. 2. Incomplete diagram with missing information.
	Losses/ Exclusions	Positive [2]	1. For each group, losses and exclusions after randomization and their reasons are described. 2.During the reading, the reviewer notes that there are no losses in the follow-up period.
		Negative [0]	No description of losses or exclusions.
		Poor [1]	Incomplete information. For example, 1. The authors describe the overall percentage of losses, but this information is not specified by group. 2. The authors describe the losses and exclusions, but do not specify the reasons.
Baseline data		Positive [2]	A description of the table/text containing the demographic and clinical characteristics of the baseline of each group is presented in the article.
		Negative [0]	There is no table/text description with baseline or description data in the body of the text.
		Poor [1]	1. A table/description of text with baseline data is displayed, but the data are not distributed between the study groups and/or data as percentages instead of raw numbers. 2. Poor information about the participants. 3. Inconsistencies may be observed in the data.
Numbers analyzed		Positive [2]	For each group and for each result, the number or participants (denominator) included in the analysis is clear.
		Negative [0]	The authors do not report the numbers analyzed.
		Poor [1]	1. There is no clear description of the number of participants (denominator) included in the analysis of at least one of the results. 2. Instead of reporting the raw number of participants, the authors report their data as percentages. 3. The authors do not report the baseline number of patients included in each analysis. 4. Data can be obtained indirectly in the study.

Continue

Continuation

CONSORT item	Sub item	Score	Adherence of methods and results items to the CONSORT statement
			Description
Registration and Protocol		Positive [2]	The study was recorded in a test record and the protocol number is provided.
		Negative [0]	This information is not available in the manuscript. Registration with the Ethics Committee is not valid as a study record.
		Poor [1]	The authors describe that the study was registered, but did not provide the registration number and/or the registration number is not linked to the study.

'unclear', indicating lack of information or uncertainty about the potential bias. During the quality assessment of individual studies, any differences between reviewers were solved through discussion and, when necessary, by consulting a third reviewer (A.C.R.C.).

The studies were considered to have a "low" risk of bias if all the domains showed a low risk. If one or more criteria showed a high risk of bias, the study was considered to have a "high" risk of bias. The study was judged as "unclear" when one or more domains had an unclear risk of bias.

Scoring system and statistical analysis

Data on the included papers were assigned to four categories: journal of publication, year of publication, follow-up periods, and country of the first author, including descriptive data and mean scores obtained with the CONSORT tool.

After the normality test (Shapiro-Wilk), the comparison within each factor for the CONSORT scores was performed by ANOVA with Tukey's post-hoc test (95% confidence intervall; and significance level of 0.05) (SigmaPlot, Systat Software Inc., Germany).

Correlation analysis was performed between the CONSORT mean score and: a) the 2020 ISI impact factor of the journal in which the paper was published; b) the risk of bias of the paper; c) year of publication (Spearman's linear correlation). Correlation analysis was also used to assess the impact factor of the journal with the Cochrane RoB toolscore (Friedman linear correlation) (Medcalc, Medcalc Software Ltd, Belgium).

Results

Characteristics of the included studies

Initially, a total of 2,181 studies were retrieved. After removing the duplicates, 1,256 papers remained. The reading of titles and abstracts lowered this number to 50 articles. From these, 14 were excluded for the following reasons: a) three studies were study protocols;[24,25,26] b) four studies were only about ART sealants;[27,28,29,30] c) two studies did not evaluate the longevity of ART restorations;[31,32] d) one study was a review of another paper;[33] e) two studies included adult patients;[34,35] and f) two studies associated ART with other techniques in the same research arm[36,37] (Figure 2). Therefore, the study included 36 papers.

Included RCTs investigated different follow-up periods (from 6 months to 6 years); in most studies, the follow-up period ranged from 0 to 24 months (63.9%). Most of the included RCTs were published in the following journals: Clinical Oral Investigations (16.7%), Caries Research (11.1%), International Journal of Paedriatric Dentistry (11.1%), and Community Dentistry Oral Epidemiology (8.3%). The other papers (52.8%) came from 16 different journals (Table 2).

Brazil accounted for more than one-third of the publications worldwide (41.7%); other countries were China (13.9%), the Netherlands (8.3%), and Turkey (8.3 %). The remaining papers were from India, Kenya, Tanzania, South Africa, Kuwait, Syria, and Australia, which together represented 27.8% of the publications (Table 2).

The periods with the largest number of published articles were from 1999 to 2004 (33.3%) and 2015 to 2021 (38.9%). The 2005-2009 and 2010-2014periods encompassed 27.8% of the publications (Table 2).

Most of the studies exhibited a parallel or split-mouth design. Glass ionomer cement was usually compared with composite resin, stainless steel crowns (Hall technique), different brands of glass ionomer cements (including resin-modified GIC and low-cost GICs), and amalgam. The number of restorations in the studies varied from 59 to 1,891,

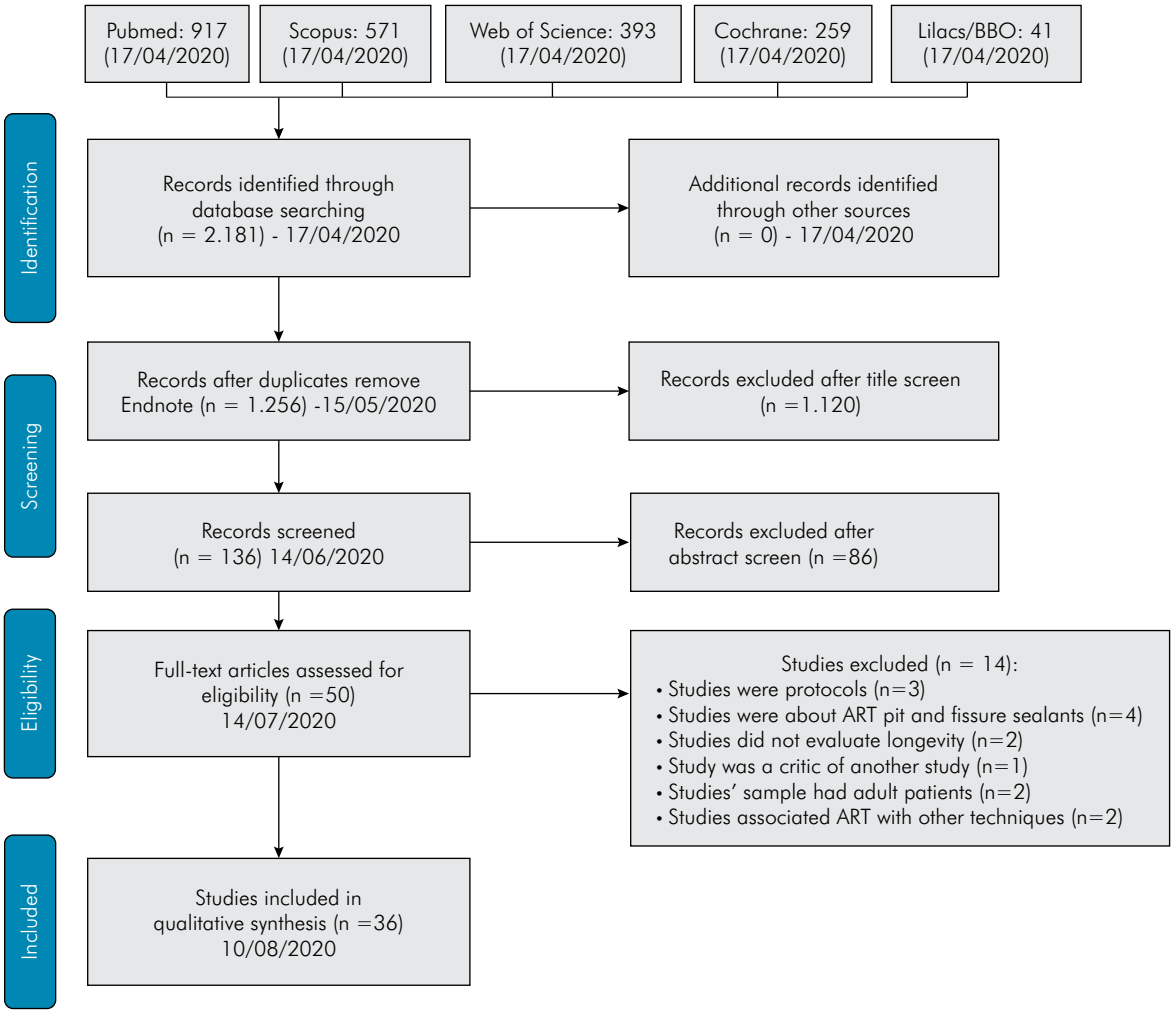

Figure 2. Flowchart of the search strategy steps in databases.

and most of them were performed on primary teeth. Both occlusal and occlusal-proximal restorations were performed in 16 studies; only occlusal restorations were included in 10 studies; only occlusal-proximal restorations were performed in nine studies; and occlusal, occlusal-proximal cavities and class III restorations were tested in one study (Table 3).

Compliance with the consort tools

Figure 3 shows the percentage of compliance of included studies with each item of the CONSORT evaluation tool. The best described items were intervention and outcomes, which were appropriately reported by all included papers, followed by hypothesis testing, effect size, and numbers analyzed, which were well described by more than 70% of the included studies. Criteria such as eligibility, blinding of participants or evaluators, and losses/exclusion were described by approximately 60% of the papers. Allocation concealment was described by only 22.2% of the papers; protocol registration was present in 36.1% of the papers and flowchart in 41.7%.

Consort mean scores according to study characteristics

The overall score for CONSORT items in the studies included in this review was 22.52 ± 6.17, which represents 70.37% of the maximum CONSORT score (32 points). There are significant differences in the CONSORT mean scores of the studies when the data were analyzed by country and publication dates (Table 4).

Table 2. Characteristics of the included studies by category.

Category	Number of studies	Percentage
Journal		
Clinical Oral Investigation	6	16.7
Caries Research	4	11.1
Int. Journal of Paedriatric Dentistry	4	11.1
Community Dent. Oral Epidemiol.	3	8.3
Other*	19	52.8
Countries		
Brazil	15	41.7
China	5	13.9
Netherlands	3	8.3
Turkey	3	8.3
Other **	10	27.8
Time period		
1999 - 2004	12	33.3
2005 – 2009	4	11.1
2010 – 2014	6	16.7
2015 - 2021	14	38.9
Follow-up time (year)		
0 to 12 months	12	33.3
13 to 24 months	11	30.6
25 to 36 months	8	22.2
37 to 48 months	3	8.3
more than 48 months	2	5.6

*Other: 16 journals (BMC Oral Health; Brazilian Dental Science, Pediatric Dentistry, Journal of the Indian Society of Pedodontics and Preventive Dentistry, Journal of Applied Oral Science, Journal of Public Health Dentistry, Contemporary Clinical Dentistry, Journal of Dentistry for Children, Journal of the South African Dental Association, Brazilian Oral Research, Journal the American Dental Association, International Dental Journal, Medical Principles and Practice, Nigerian Journal of Clinical Practice, Journal of Clinical Paediatric Dentistry, Quintessence International, and Journal of Dentistry); **Other: 7 countries (Kenya, Tanzania, South Africa, Australia, Kuwait, India, and Syria)

Regarding the journals, no significant differences were detected between the CONSORT mean scores when different journals were analyzed (Table 4). Clinical Oral Investigations presented the best scores with a total of 6 papers (27.5 ± 3.4), followed by Caries Research (four papers; 22.5 ± 3.9) and International Journal of Paediatric Dentistry (four papers; 21.5 ± 3.9).

When the country of the first author was considered, a significant difference was observed ($p < 0.001$; Table 4). Brazil had the highest number of papers and the highest CONSORT mean score (26.8 ± 3.2), which was statistically different from China, Turkey, and other countries, except for the Netherlands, which received the second-best CONSORT mean score. Besides Brazil and the Netherlands (21.6 ± 4.5), the highest mean scores were achieved by a group of papers from different countries such as India, Kuwait, Kenya, Syria, Tanzania, South Africa, and Australia (20.8 ± 4.5).

An increase in the CONSORT mean scores was observed in more recently published papers (2015–2021) (26.7 ± 3.1) when compared to first ART studies conducted from 1999 to 2004 (18.1 ± 4.6; $p = 0.001$) (Table 4).

When analyzing the follow-up period of the restorations, no differences were observed in the CONSORT mean scores ($p = 0.274$; Table 4). The follow-up periods varied between studies; most of the included studies had a follow-up period between 0 and 24 months (Table 2).

Risk of BIAS of the included studies

Only four studies included in the review were considered to have a lowRoB;[38-41] 11 papers were judged to have an unclear risk,[42-52] and 21 had a high RoB[25, 53-67] (Figure 4).

Adequate random sequence generation and allocation concealment were achieved by 47% and 25% of the studies, respectively. Blinding of the examiners was more common than blinding of the participants. Selective reporting was the only domain in which all the studies presented a "low RoB" with an appropriate description (Figure 5).

Correlation between variables

Weak and non-significant correlations were found between the CONSORT mean scores and the journal's impact factor [r = - 0.03 (95%CI -0.35–0.30) ; $p = 0.87$]; the RoB in the studies and the impact factor of the journals in which they were published [r = -0.19 (95%CI -0.49–0.15); $p = 0.26$), and the RoB scores in the studies and the CONSORT scores [r=-0.03 (95%CI -0.35–0.30); $p = 0.88$]. The only strong correlation was found between CONSORT mean scores and publication year [r=0.67 (95%CI 0.46–0.82) $p < 0.0001$].

Discussion

In the dental literature and in the biomedical literature in general, it is not uncommon to detect failures, both in designing and reporting clinical trials[68].

Table 3. Characteristics of the included studies.

Identification of articles (author, date)	Country of the first author	Protocol registration	Journals (Impact Factor-ISI 2020)	Study design	Restorative materials / (test group - ART x control)	Number of research subjects/ number of teeth	Type of tooth	Classification of cavities	CONSORT included in the Journal guidelines/ CONSORT Score
Akman, Tosun 2020[53]	Turkey	n.r.	Nigerian Journal Clinical Practice (0.42)	Parallel	Composite resin (Filltec Z350) x Bulkfill resin (Sonic fill) x GIC (Equia Fill) x composite resin (X-tra fill)	30 / 160	Deciduous molars	Class II	YES/20
Araújo et al. 2020[54]	Brazil	Yes	BMC Oral Health (0.86)	Parallel	GIC (GIC EQUIA Forte) x Preformed metal crowns (3M/ESPE) cemented with encapsulated GIC (Fuji I)	131 / 131	Deciduous molars	Class II	YES/30 CONSORT extension for abstracts
Arrow, Forrest 2016[37]	Australia	Yes	Caries Research (2,32)	Parallel	GIC X composite resin, steel crown	220 / 597	Deciduous molars	Class I, II	YES/28
Bonifácio et al. 2013[55]	Netherlands	n.r.	International Journal of Paediatric Dentistry (2,05)	Parallel	Maxxion R (FGM, Rio de Janeiro, Brazil), Hi-Dense (Shofu, Ratingen, Germany), or Fuji IX (GC Europe, Leuven, Belgium)	262/262	Deciduous molars	class II	YES/20
Cefaly et al. 2013[56]	Brazil	n.r.	Brazilian Dental Science (0,2)	Parallel	GIC (Ketac Molar-3M ESPE) X (Fuji VIII-GC Corp).	n.r / 60	Permanent molars	class I and class II	NO/20
Amorim et al. 2014[57]	Brazil	Yes	Clinical Oral Investigations (-2,45)	Parallel	GIC (Ketac Molar Easymix®; 3M ESPE) X Amalgam (Permite Regular set®; SDI)	258 / 750	Deciduous molars	class I and class II	YES/32
D'Costa, Singhal, Acharya 2020[57]	India	n.r.	The Journal of Clinical Pediatric Dentistry (0.94)	Parallel	GIC (GC Gold Label 9) x GC Miracle Mix® (Metal-Reinforced Crown & Core Build-Up)	89/92	Permanent molars or premolars	class I and class II	
Lopes et al. 2018[38]	Brazil	Yes	Pediatric Dentistry (2,05)	Multiple restorations per patient	Equia Fil, GC Europe, Leuven, Belgium X GCP Glass Fill, GCP-Dental, Ridderkerk, Netherlands)	children 33 / teeth 59	Deciduous molars	class II	YES/32
Serpa et al. 2017[58]	Brazil	n.r.	Journal of the Indian Society of Pedodontics and Preventive Dentistry (0,53)	split mouth	Ketac Molar Easy Mix – 3M ESPE X Filtek Z250 – 3M ESPE	children 86/ cavities 216	Deciduous molars	occlusal and occlusa	YES/24
Ersin et al. 2006[59]	Turkey		Journal of American Dental Association (2.49)	split mouth	GIC (Fuji IX GP) x packable resin-based composite (SureFil)	Children 219/ cavities 419	Deciduous molars	Class I and II	YES/17
Faustino-Silva, Figueiredo 2019[43]	Brazil	yes	Clin Oral Investigation (2,45)	split mouth	KetacMolar Easymix® (3MESPE) X VitroMolar® (DFL)	children 25/ teeth 100	Deciduous molars	class I	YES/25
Freitas et al. 2018[44]	Brazil	Yes	Journal of Applied Oral Science (1,5)	split mouth	GIC (Riva Self-Cure, SDI Limited, Bayswater, VIC, Australia) X encapsulated GIC (Riva Self-Cure, SDI Limited, Bayswater, VIC, Australia)	children 40 / teeth 80	Permanent molars	class I	YES/27

Continue

Continuation

Identification of articles (author, date)	Country of the first author	Protocol registration	Journals (Impact Factor-ISI 2020)	Study design	Restorative materials / (test group - ART x control)	Number of research subjects/ number of teeth	Type of tooth	Classification of cavities	CONSORT included in the Journal guidelines/ CONSORT Score
Frencken, van't Hof, Taifour 2007[60]	Netherlands	n.r.	Community Dentistry and Oral Epidemiology (2,27)	Parallel	Avalloy® (Cavex, Haarlem, The Netherlands) X Fuji IX® (GC Europe, Leuven, Belgium) and Ketac Molar® (3MESPE, Seefeld, Germany)	children 681/ restorations 1,117	Permanent molars	class I e class II	YES/22
Gao et al. 2003[61]	China	n.r.	Quintessence International (1,39)	Multiple restorations per patient	Fuji IX GP (GC) X Ketac-Molar (3M Dental) X encapsulated amalgam (Central Iron and Steel Research Institute)	adults 68 / teeth 149	Permanent molars	class I	YES/16
Gurunathan, Tandon 2010[80]	India	n.r.	International Journal of Paediatric Dentistry (-2,05)	split mouth	Amalgomer (CR Advanced Health Care) X Fuji IX (GC Corporation Tokyo)	children 100/ teeth 200	Deciduous molars	class I and class II	YES/23
Hilgert et al. 2016[81]	Brazil	Yes	International Journal of Paediatric Dentistry (-2,05)	Parallel	Amalgam(Permite (SDI) X Ketac Molar Easymix (3M ESPE)	children n.r / teeth 681	Deciduous molars	class I and class II	YES/28
Ho et al. 1999[45]	China (Hong-Kong)	n.r.	Community Dentistry and Oral Epidemiology (2,27)	Multiple restorations per patient	Fuji IX (GC Int. Corp) X ChemFil Superior (DeTrey/Dentsply)	adults 23 / teeth 100	Permanent molars	class I	YES/12
Honkala et al. 2003[46]	Kuwait	n.r.	International Journal of Paediatric Dentistry (2,05)	split mouth	Chem-Flex (Dentsply/DeTrey) X Megalloy (Dentsply/DeTrey)	children 35 / teeth 70	Deciduous molars	class I, class II	YES/17
Kalf-Scholte et al. 2003[82]	Netherlands	n.r.	Journal of Public Health Dentistry (1,35)	split mouth	Chelon Silver (ESPE) x Chelon Fil (ESPE a) + amalgam powder (Cavex)	children 83/ teeth 178	Permanent molars	class I	YES/17
Kemoli et al. 2014[47]	Kenya	n..r.	Contemporary Clinical Dentistry (0,69)	Multiple restorations per patient	Fuji IX (GC Europe) x Ketac Molar Easymix (3M ESPE) x Ketac Molar Applicap (3M ESPE)	children n.r / teeth 804	Deciduous molars	occlusal I	YES/18
Lo et al. 2001[48]	China	n.r.	Caries Research (2,32)	split mouth	ChemFlex (Dentsply DeTrey) x Fuji IX GP (GC)	children 89 / teeth 202	Deciduous molars and permanent molars	class I and class II	YES/20
Mandari et al. 2003[83]	Tanzania	n.r.	Caries Research (2,32)	split mouth	non-gamma-2 amalgam (ANA 200, Nordiska Dental Ab) x Fuji II (GC International Corp.)	children 114 / teeth 341	Permanent molars	class I	YES/25
Menezes, Rosenblat, Medeiros 2006[39]	Brazil	n.r.	Journal of Dentistry for Children (0,3)	Multiple restorations per patient	Vidrion R GIC (SS White) x Ketac-Molar GIC (3M ESPE)	children 110 / teeth 245	Deciduous molars	class I and class II	YES/24
Menezes-Silva et al. 2019[84]	Brazil	Yes	Clinical Oral Investigations (2,45)	Parallel	Equia system (GC Co.) X Filtek Z350 XT (3M ESPE)	children 154 / teeth 154	Permanent molars	class II	YES/30
Mickenautsch, Yengopal, Banerjee 2000[8]	South Africa	n.r.	Journal of the South African Dental Association (0,19)	Multiple restorations per patient	Fuji IX (GC) X Ketac Molar (ESPE)	113 / 163	Permanent molars	class I	NO/15

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Continuation

Identification of articles (author, date)	Country of the first author	Protocol registration	Journals (Impact Factor-ISI 2020)	Study design	Restorative materials / (test group - ART x control)	Number of research subjects/ number of teeth	Type of tooth	Classification of cavities	CONSORT included in the Journal guidelines/ CONSORT Score
Mijan et al.2014[63]	Netherlands/ Brazil	correction of 2014 results data / Yes	Clinical Oral Investigations/ Clinical Oral Investigations(2,45)	Parallel	amalgam (Permite Regular Set®; SDI) x GIC (Ketac Molar EasyMix®, 3M ESPE) x ultraconservative treatment (nonrestorative approach)	302 / 866	Deciduous molars	class I and class II	YES/29
Moura et al. 2019[40]	Brazil	Yes	Brazilian Oral Research (1,77)	Multiple restorations per patient	GIC (Ketac Molar, 3N ESPE) x GIC (Vitro Molar, DFL)	243 / 728	Deciduous molars	class I, class II and class III	YES/30
Olegario et al. 2019[85]	Brazil	Yes	Clinical Oral Investigations (2,45)	Parallel "3-arm"	GIC (Equia Fil, GC Europe) x compomer (Dyract Extra, Dentsply International) x glass carbomer (Glass Carbomer Cement, GCP)	578 / 568	Deciduous molars	class I and class II	YES/30
Olegário et al. 2020[41]	Brazil	Yes	Journal of Dentistry (3,24)	Parallel "3-arm"	GIC (Fuji IX Gold Label, GC Corp) x GIC (Vitro Molar, nova DFL) x GIC (Maxxion R,FGM)	150 /150	Deciduous molars	Class I	YES/31
Pacheco et al. 2017[67]	Brazil	Yes	Brazilian Oral Research (1,77)	Parallel	Ketac Molar EasyMix (3M ESPE) X Vitro Molar (DFL)	117 / 117	Deciduous molars	class II	YES/28
Taifour et al. 2002[65]	Syria	n.r.	Caries Research (2,32)	Parallel	Fuji IX (GC Europe, Leuven) and Ketac Molar (3MESPE, Seefeld) X Avalloy® (Cavex)	children 835 / teeth 1891	Deciduous molars	class I and class II	YES/18
Taifour et al. 2003[64]	Syria	n.r.	Community Dent Oral Epidemiol (2,27)	Parallel	Fuji IX (GC Europe, Leuven) and Ketac Molar (3MESPE, Seefeld) X Avalloy® (Cavex)	children 679 / teeth 1118	Permanent molars	class I and class II	YES/18
Topaloglu et al. 2009[49]	Turkey	n.r.	Clinical Oral Investigations (1,45)	Parallel	Filtek Z250 (3MESPE) X Filtek Z250 (3MESPE) + Carisolv™ (Mediteam)	children 327 / teeth 568	Deciduous molars	class II	YES/21
Yip et al. 2002[50]	China	n.r.	Journal of the American Dental Association (2,49)	Multiple restorations per patient	Fuji IX GP (GC) x Ketac-Molar Aplicap (3M ESPE) x encapsulated GK Amalgam Alloy (Advanced Technology & Materials Co. Ltd. Beijing)	adults 68/ teeth 149	Permanent molars	class I	YES/12
Yu et al. 2004[51]	China	n.r.	International Dental Journal (1,62)	Multiple restorations per patient	Fuji IX GP (GC) x Ketac Molar Aplicap (3M ESPE) x Encapsulated non-gamma 2 GK amalgam alloy (Central Iron & Steel Institute)	children 60/ teeth 167	Deciduous molars	class I and class II	YES/16
Ziraps, Honkala 2002[52]	Kuwait	n.r.	Medical Principles and Practice (1,53)	n.r	Chem Flex TX (Dentsply) X Fuji IX (GC)	children 41 / teeth 63	Permanent molars	class I	YES/13

n.r. = not reported

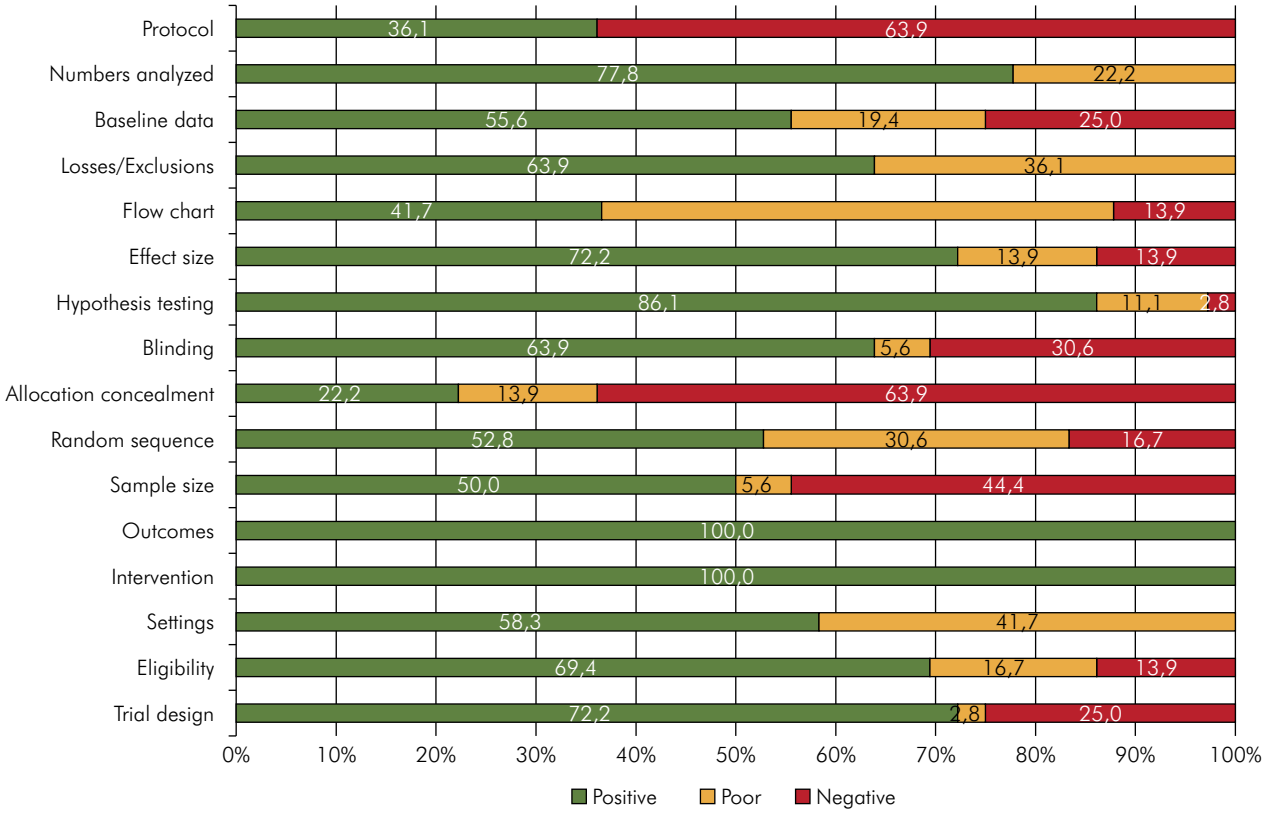

Figure 3. Percentage of studies according to CONSORT scores for each analyzed criterion.

With the increasing number of journals that encourage authors to follow CONSORT recommendations, research reports would be expected to present clearer and more complete information.[69] In our study, the mean CONSORT score was 22.52 ± 6.17, which represents moderate compliance with CONSORT recommendations (70% of the maximum CONSORT score – 32 points).

The CONSORT recommendations are not an instrument to assess the quality of RCTs,[69] but a guide to help authors write research reports. The quality of RCTs can be assessed with the Cochrane ROB tool. In this meta-research, we combined both tools, focusing on items related to the description of the methodology and research results.

Our results showed THAT the largest number of papers focused on the longevity of ART restorations WERE published in four journals. Among the other 16 journals with publications on this topic, only three did not recommend the use of the CONSORT statement in the authors' guidelines for publication (Table 2). Even considering that most of the journals encourage adherence to the CONSORT statement, the mean average score did not reach the maximum possible score of the evaluation tool. This means that peer-reviewed processes are not detecting incomplete reporting of some of the published articles.

However, there has been a significant trend towards an increase in adherence to CONSORT recommendations in more recent studies: the mean score in the 1999-2004 period was 18.1 ± 4.6, whereas in the 2015 to 2021 period, it rose to 26.7 ± 3.1 (approximately 82.2% of the maximum possible score), with a positive correlation ($r = 0.6883$; $p < 0.0001$). The increase in mean CONSORT scores over time certainly reflects the influence of the reviewers and editors of different journals, who encourage and demand a more complete description of the different stages of the studies. Also, the authors have become acquainted with the CONSORT recommendations and improved their research reporting skills.

Table 4. Analysis of the scores obtained from CONSORT according to different categories (journals, countries, time period, and follow-up time (ANOVA by posts with Dunn's post-test).

Category	Mean ± Standard Deviation	Median (interquartile range)	p-value*
Journal			
Clinical Oral Investigations	27.5 ± 3.4	27.5 (23-28)	
Caries Research	22.5 ± 3.9	22.5 (19-25.5)	
Int. Journal of Paediatric Dentistry	21.5 ± 3.9	21.5 (18.5-24.5)	p = 0.218
Community Dent. Oral Epidemiol.	18 ± 5	18 (13.5-21)	
Other*	24 ± 5.9	24 (17.3-26)	
Country			
Brazil	26.8 ± 3.2[a]	27 (24.3-30)	
China	16.4 ± 4.5[b]	16 (12-20.5)	
Netherlands	21.6 ± 4.5[a,b]	22 (18.3-25)	p < 0.001
Turkey	19.3 ± 2.08[b]	20 (17.8-20.8)	
Other **	20.8 ± 4.5 [c,b]	20.5 (18-25)	
Publication date			
1999 – 2004	18.1 ± 4.6 [b]	17.5 (14.5-22)	
2005 – 2009	22.7 ± 1.5 [a,b]	23 (21.5-24)	p < 0.001
2010 – 2014	23.0 ± 4.6 [a,b]	21.5 (20-27.0)	
2015– 2020	26.7 ± 3.1[a]	26 (25-30)	
Follow-up period (year)			
0 to 12 months	24.3 ± 4.8	24 (23.5 – 27)	
13 to 24 months	20.0 ± 6.4	18 (16.3 – 24.8)	
25 to 36 months	21.1 ± 4.7	20 (18.0 – 22.5)	p = 0.274
37 to 48 months	25.3 ± 2.1	26 (23.7 -26.7)	
more than 48 months	23.5 ± 2.1	23.5 (22 – 25.0)	

*Other: 16 journals (BMC Oral Health; Brazilian Dental Science, Pediatric Dentistry, Journal of the Indian Society of Pedodontics and Preventive Dentistry, Journal of Applied Oral Science, Journal of Public Health Dentistry, Contemporary Clinical Dentistry, Journal of Dentistry for Children, Journal of the South African Dental Association, Brazilian Oral Research, Journal the American Dental Association, International Dental Journal, Medical Principles and Practice, Nigerian Journal of Clinical Practice, Journal of Clinical Paediatric Dentistry, Quintessence International, and Journal of Dentistry); **Other: 7 countries (Kenya, Tanzania, South Africa,Australia, Kuwait, India, and Syria).

Knowing that the CONSORT group started their activities in 1996, this finding shows a relatively long period should be allowed before new modalities of research reports are adopted. As with translational research, which requires some time before moving from basic science discoveries into daily practice, the appropriation of the CONSORT recommendations by the subjects involved in the publication process also requires some time before full compliance.

Our study showed that, despite the moderate degree of adherence to CONSORT recommendations, this did not have a strong impact on the quality of papers included in the present study regarding the domains of the Cochrane RoB tool. This can be explained because adherence to the CONSORT statement does not evaluate the quality of RCTs, but it encourages a complete report. We observed there were a large number of papers considered to have an unclear RoB and this is directly linked to a flawed report. If the report is complete, even when some phase of the research is not accomplished correctly, the reader will be able to judge and the unclear scoring would not be applied. This problem probably will be solved with full compliance with the CONSORT statement.

An appropriate randomization process was only achieved by 25% of the papers, given that it consists of two stages: sequence generation and allocation concealment. Sequence generation is essential so that participants in the test and control groups could

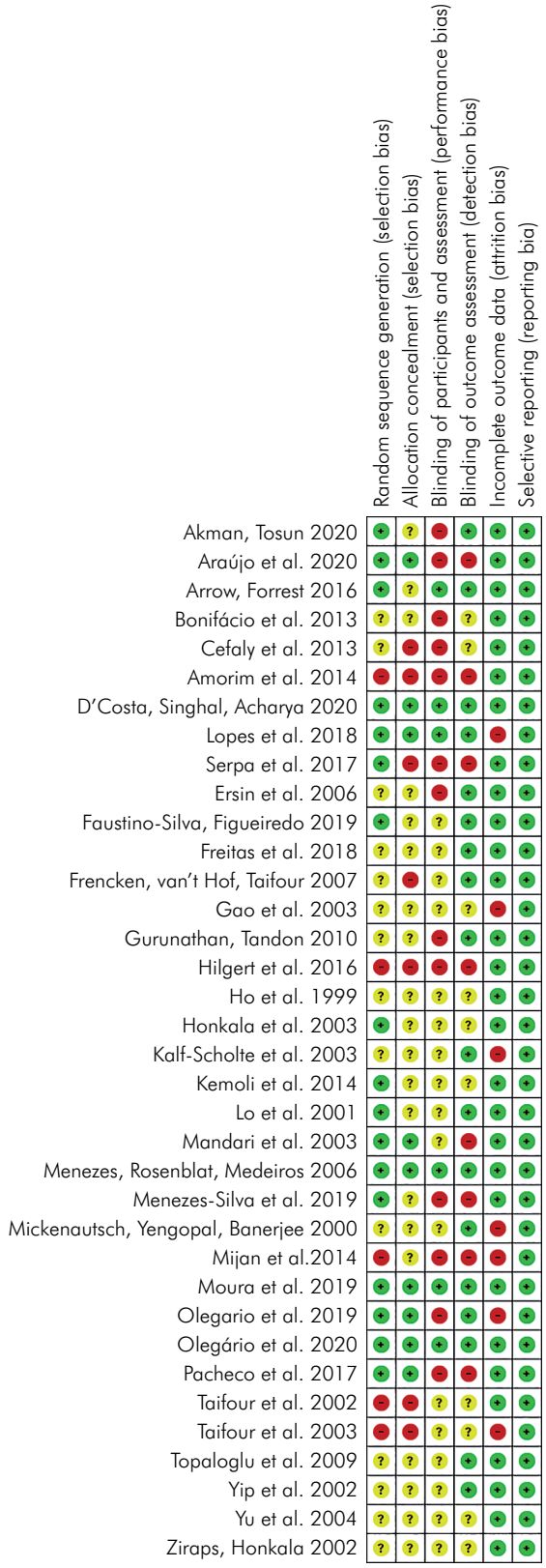

Figure 4. Summary of risk assessment of bias according to the Cochrane tool.

have similar characteristics at the beginning of the study and could be exposed to the same chance of receiving the intervention; allocation concealment ensures that neither patients nor operators are aware of the intervention before the study is implemented.[70] Thus, the insertion of systematic errors or random bias in RCTs may reduce the confidence we have in the study results, as bias may distort the truth towards greater benefit or harm of the intervention. Therefore, we recommend that clinical decision-making should be taken based not on individual RCTs, but on systematic reviews, which are a research design that analyzes the RoB of papers, but also the certainty of the evidence as a whole.

We expected journals with higher impact factors to be more rigorous during the review process, resulting in higher CONSORT scores. However, the impact factor of the journals did not show a significant correlation with the CONSORT scores, nor with the RoB in the included studies. The impact factor reflects the average number of citations of scientific articles published in a given journal. Consequently, the ideal scenario would have been to have those studies with the most complete research reports and better quality papers in the most cited journals. A complete report is fundamental, as it would make the experiment reproducible, a requirement that is inherent to any scientific research, and also would ease up the risk of bias analysis and the confidence in the results.

Among the analyzed CONSORT criteria, protocol registration, study flowchart, and allocation concealment were the least reported items (Figure 3). The registration protocol for clinical trials has been a recommendation from the International Committee of Medical Journals since 2005[71]. Protocol registration was reported only by 13 papers (36.1%). It prevents the selective reporting of outcomes, which distorts the evidence available for decision-making[72]. Every researcher must, before the beginning of the study, register their research protocol in one of the available databases to make it public to all interested parties, including other researchers in the field, reviewers, and editors of scientific journals and even patients that are participating in clinical trials. Examples of digital platforms for registering clinical trials

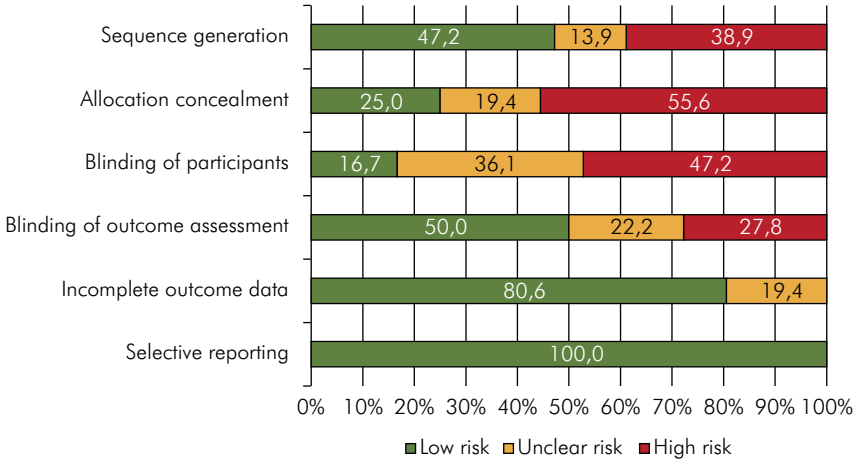

Figure 5. Relative frequencies of studies according to the risk of bias assessment (Cochrane tool).

include ClinicalTrials.gov (https://clinicaltrials.gov/) and EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/).

The lack of a flowchart was detected in approximately 60% of the studies. The function of the flowchart is to present, quickly and directly, all phases of the clinical trial, including the recruitment of patients, their allocation, and follow-up periods, with the respective patient losses to follow-up. The flowchart allows analyzing the internal and external validity of the trial and it is usually related to better reporting of clinical research.[73] It is an important criterion that needs to be present in all ART research reports.

Another very important criterion for the quality of the results obtained is the sample size calculation, which was not reported by 50% of the papers. A recent study reported an even higher percentage (79.1%) for the period from 1955 to 2013[74], among RCTs taken from systematic reviews in dentistry. A study with a small sample size has limited test power and less chance of detecting a true effect in the comparison between groups, and when they detect a difference, this positive finding may be due to chance alone. Likewise, a very large sample represents unnecessary expenses and an ethical challenge when including excess patients in a clinical trial[75]. This stage is part of the planning and the statistical treatment of the study and numerous factors need to be considered, such as the primary outcome of the study, the type of trial (superiority, non-inferiority, or equivalence), the desired power for the study, among other characteristics. As it has a direct influence on the study result of the clinical trial, this step needs to be carefully described in the study reports.

Our study showed that more than 60% of the included papers accomplished a follow-up period of 24 months or more. However, one-third of the clinical trials reported a 12-month follow-up (33.3%), which is probably a very short period to evaluate the longevity of restorations, even for deciduous teeth. Therefore, we certainly encourage the authors to plan longer follow-up periods in future research studies, particularly if permanent teeth are included.

Most studies were published in the 1999–2004 and 2015–2021 periods. The first period coincides with the years following the dissemination of the ART technique to the world dental community and the endorsement by the World Health Organization in 1994.[76] In recent years, an increased number of publications have been justified by the recognized effectiveness of the selective removal of decayed tissue techniques and the growth of minimal intervention dentistry,[77] which has the ART protocol as one of its most common procedures.

There are some limitations to the present study. Despite a very comprehensive search in different databases with specific vocabulary and keywords, we may have missed some articles. For instance, no Japanese, Chinese, or Korean database was searched. Also, we did not identify papers that fulfilled the eligibility criteria in languages other than English.

A large number of publications about ART are by Brazilian authors; they also showed the highest mean CONSORT scores, which reflects the methodological evolution of Brazilian dental research and the acceptance ART has gained in Brazilian dentistry, particularly in pediatric dentistry. ART is part of the national oral health program in Brazil, with the inclusion of the technique in the curricula of Brazilian dental schools. This is probably connected to the fact that untreated dental caries is the main component in the dmf-t index (2.43) in 5-year-old children in Brazil, affecting mainly the low-income population and their access to healthcare services,[78] and ART is a protocol with the potential to expand service and dental assistance coverage for this population,[79] and it is also a key component of WHO's Basic Package of Oral Care (BPOC) for making restorative dental treatment more reachable to communities in developing nations.[66]

It is encouraging to note that adherence to CONSORT recommendations has increased over time. Notwithstanding, this does not mean that ART research in pediatric dentistry is free of bias and thoroughly reported. By providing quantitative data about ART research, we hope to encourage a deeper analysis that may lead authors to refine their methodology and research reports and improve the peer-review process. Thus, future RCTs should be targeted on non-inferiority designs with a high test power and low random error to corroborate the advantages of adopting the ART approach over "conventional restorative techniques".

Conclusion

Regarding RCTs on the longevity of ART restorations, it may be concluded that adherence to the CONSORT statement was not fully achieved, despite the inclusion of CONSORT guidelines in the publication guidelines of different journals. Also, most of the included papers have unclear and high RoB. These findings indicate that adherence to the CONSORT recommendations should be encouraged, which may indirectly refine the research methodology and reporting and improve RoB in RCTs.

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