

PRISMA 2020 Checklist

Section Topic	and	Item #	Checklist item	Location where item is reported
TITLE				
Title		1	Identify the report as a systematic review.	<p>"Conscious and Deep Sedation Drugs in Pediatric Dentistry: A Systematic Review of Randomized Controlled Trials (2019–2024)"</p> <p>Please refer to Page 1 of manuscript</p>
ABSTRACT				
Abstract		2	See the PRISMA 2020 for Abstracts checklist.	<p>Abstract</p> <p>Introduction:</p> <p>Dental anxiety in children is a common issue that hinders dental treatment, generates negative experiences, and perpetuates dental fear. This highlights the importance of finding effective solutions. Conscious and/or deep sedation techniques are key tools to improve the pediatric patient's experience and facilitate complex procedures. However, their application requires careful analysis due to the wide variety of available protocols, recommendations and administration routs.</p> <p>Materials and Methods:</p> <p>A systematic review was conducted following the "Regulations for the Master's Final Project in Pediatric Dentistry and Interceptive and Functional Orthodontics at the Universidad San Pablo CEU" as well as the PRISMA 2020 guidelines. The review has been registered into Prospero and PRISMA guidelines have been followed. The electronic search for this systematic review was conducted from October to January (2024-2025). Articles were selected from three databases: PubMed, Scopus, and Web of Science. More specific filters were applied from each of them Eight terms were used for the search strategy and selection criteria were followed. Studies that performed any dental treatment on pediatric patients aged 2 to 12 years who underwent conscious or deep sedation to reduce their anxiety during treatment were selected. The Cochrane Risk of Bias Tool for Randomized Controlled Trials was used to assess the risk of biased of the selected articles.</p> <p>Results:</p> <p>The initial electronic search generated 1,697 titles from the MEDLINE/PubMed database, 1,563 from Web of Science, and 1,437 from Scopus. Filtering allowed us to eliminate a large number of articles, and with the help of the bibliographic manager Zotero, we were able to eliminate duplicates. After analyzing the titles and abstracts of 196 articles, we selected 14 Randomized Controlled Trials (RCTs) that were published during the last 5 years to include in our review. during the last 5 years were selected for this review.</p> <p>Conclusions:</p> <p>The fastest onset of action is determined by the route of administration. Reported adverse effects were not statistically significant. Nitrous oxide shows the fastest recovery, but drug selection should always be based on the type of dental procedure, its duration, and the child's specific needs. Further research is needed to evaluate parents' level of satisfaction when their children undergo these types of procedures.</p>

PRISMA 2020 Checklist

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			Keywords: (dental care for children), (pediatric dentistry), (separation anxiety), (deep sedation), (conscious sedation), (anti-anxiety agents), (anesthetics, dissociative), (in-office sedation)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Dental anxiety in children is a common issue that hinders dental treatment, generates negative experiences, and perpetuates dental fear. This highlights the importance of finding effective solutions. Conscious and/or deep sedation techniques are key tools to improve the pediatric patient's experience and facilitate complex procedures. However, their application requires careful analysis due to the wide variety of available protocols, recommendations and administration routs.
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	<p>Main Objective: To deepen the understanding of different conscious and/or deep sedation techniques used in pediatric dentistry commonly used to relieve anxiety and manage behavior in pediatric patients undergoing dental procedures, and to analyze which sedative agent is mostly recommended.</p> <p>Secondary Objectives:</p> <ol style="list-style-type: none"> 1. Identify the drug with the fastest onset of action. 2. Determine which agent presents the fewer side effects. 3. Indicate which drug allows for the best recovery. 4. Evaluate what is the most effective method or technique of administration. 5. Evaluate parents' personal experience after their children underwent sedation.
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Clinical studies in children under 12 y/o • Randomized controlled trials • Published in the last 5 years • Articles in English or Spanish <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Animal or in vitro studies • Letters to the editor • Case reports • Systematic reviews

PRISMA 2020 Checklist

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				<ul style="list-style-type: none"> Observational or comparative studies Meta-analyses Studies including general anesthesia <p>Studies were grouped for the syntheses based on the type of study (RCT) that adapted to the selection criteria.</p> <p>Materials and method section of manuscript</p>
Information sources		6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	<p>A narrative review was conducted between the months of October, 2024 and January, 2025, through an advanced search in the following databases: PubMed, Scopus, and Web of Science.</p> <p>Materials and method section of manuscript</p>
Search strategy		7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	<p>The electronic search for this systematic review was conducted from October to January (2024-2025). Initially, to approach the topic, a preliminary search was performed in the EBSCO Discovery metasearch engine, which retrieved an excessively high number of results from different databases. Therefore, it was decided to focus on three of them: PubMed, Scopus, and Web of Science. More specific filters were applied from each of them, allowing us to further narrow the search and identify potentially relevant studies. Eight terms were used for the search strategy, including the Boolean operators "OR" and "AND" to limit the search to the desired result. The search was performed as follows:</p> <p>((dental care for children) OR (pediatric dentistry) OR (separation anxiety)) AND ((deep sedation) OR (conscious sedation) OR (anti-anxiety agents) OR (anesthetics, dissociative) OR (in-office sedation)).</p> <p>Materials and methods section</p>
Selection process		8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	<p>After searching for articles in the various electronic databases mentioned above, the studies were exported to the bibliography manager Zotero® to facilitate the detection of duplicate articles. After eliminating duplicate articles, the titles and/or abstracts of the studies were read and analyzed, discarding those that were not relevant for this systematic review according to the inclusion and exclusion criteria. The full text was then read to assess eligibility and perform a qualitative synthesis.</p> <p>Materials and method</p>
Data collection		9	Specify the methods used to collect data from reports, including how many	To summarize the most relevant data from the studies, the following clinical

PRISMA 2020 Checklist

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process			reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	data were extracted: authors, year of publication, study design, number and age of patients, type of drug used and distribution of patient groups, time at which anxiety was measured, onset of side effects, patient recovery, parental satisfaction, and type of anxiety measurement
Data items		10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Anxiety measures were classified into two groups. First, physiological measures included heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), noninvasive blood pressure (NIBP), and the bispectral index (BIS), which assesses the degree of hypnosis by estimating the level of brain electrical activity and oxygen saturation (SpO2).
		10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Second, measures were made using scales or questionnaires, such as the Modified Observer Assessment of Alertness and Sedation Scale (MOAAS), the Visual Analogue Scale (VAS), the FLACC (Face, Legs, Activity, Cry, Controllability) scale, the OSUBRS (Ohio State University Behavioral Rating Scale), and the Houpt, Ramsay, and Frankl scales.
Study risk of bias assessment		11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	The Cochrane Risk of Bias Tool for Randomized Controlled Trials was used to assess the risk of biased of the selected articles, all of which were randomized controlled trials. This scale evaluates seven domains: random sequence generation, allocation concealment, selective reporting, other biases, masking of participants and personnel, masking of outcomes, and incomplete outcome data. The articles were classified as "high risk of bias," "low risk of bias," and "fair risk of bias." The results were then tabulated. Page 5 manuscript
Effect measures		12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Not available
Synthesis methods		13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Please refer to page 3-5, Materials and Method section
		13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Please refer to page 3-5, Materials and Method section Data was collected by the same two investigators who worked as a continuously as team preparing and editing the manuscript, creating the tables and diagrams. All the relevant data pertaining to the selected articles was summarized into tables.
		13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Please refer to page 3-5, Materials and Method section
		13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Please refer to page 3-5, Materials and Method section. No meta-analysis was carried out.
		13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Please refer to page 3-5, Materials and Method section, All the selected articles were RCT.
		13f	Describe any sensitivity analyses conducted to assess robustness of the	Not available

PRISMA 2020 Checklist

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		synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	The Cochrane Risk of Bias Tool for Randomized Controlled Trials was used to assess the risk of biased of the selected articles, all of which were randomized controlled trials. This scale evaluates seven domains: random sequence generation, allocation concealment, selective reporting, other biases, masking of participants and personnel, masking of outcomes, and incomplete outcome data. The articles were classified as “high risk of bias,” “low risk of bias,” and “fair risk of bias.” The results were then tabulated. Page 5 manuscript
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Not available
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	The initial electronic search generated 1,697 titles from the MEDLINE/PubMed database, 1,563 from Web of Science, and 1,437 from Scopus. Filtering allowed us to eliminate a large number of articles, and with the help of the bibliographic manager Zotero, we were able to eliminate duplicates. After analyzing the titles and abstracts of 196 articles, we selected 14 to include in our review, as shown in Tables 2-4.
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	One study was excluded for sample age discrepancy. The article is included on Table 6 and is the following: “The intranasal dexmedetomidine plus ketamine for procedural sedation in children, adaptive randomized controlled non-inferiority multicenter trial (Ketodex): a statistical analysis plan.”
Study characteristics	17	Cite each included study and present its characteristics.	Please refer to Tables 2-4
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Please refer to Tables 5
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Please refer to Tables 2-4
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Please refer to Tables 2-4
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Please refer to Tables 2-4. No meta-analysis was carried out.
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Not available
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Not available

PRISMA 2020 Checklist

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Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Please refer to Table 5
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Not available
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Please refer to the result section of the manuscript (pages 5-6)
	23b	Discuss any limitations of the evidence included in the review.	<p>In most reviewed studies, children were healthy or had mild systemic conditions, consistent with ASA physical status classifications I and II (22). However, some techniques may be more suitable for children with more complex medical conditions, as in the study conducted by Garret-Bernardin et al., which included patients with physical and psychological impairments and thus provides a broader view of the types of patients managed under nitrous oxide sedation (23).</p> <p>Another aspect to point out is that there was limited information on regard to the dental restoration procedures performed in the studies, although some mentioned the use of local anesthesia, bite blocks, and rubber dams. Undoubtedly, we believe this detail is important to be added in these kind of studies as the type of procedure performed can influence both behavior and anxiety levels (21).</p> <p>Initially, we intended to exclude articles allocated to deep sedation, but this was not feasible due to ambiguity in many studies regarding the type of sedation used. In several[GR1] cases, it was not specified whether the sedation was conscious or deep, and patient drowsiness was vaguely described (21). In some studies[GR2], children reportedly fell asleep, and oral devices were used, suggesting the sedation may have been deeper than indicated. This highlights the need to establish a standardized definition of conscious sedation, or at the very least, use universally accepted terminology. Without clear classification, it is difficult for researchers to properly interpret and apply published data (21).</p>
	23c	Discuss any limitations of the review processes used.	<p>The main limitation of this work is the lack of uniformity among clinical trials in the literature, particularly regarding the scales used to measure sedation levels, which vary significantly. Most studies lacked a placebo-controlled group or comparisons with a known-effective sedative. Future research should consider using oral midazolam or nitrous oxide sedation as standard references to evaluate the efficacy of other methods.</p> <p>It's also important to consider the age of the children included in the studies as limitation. Children should ideally be segmented into three broad age groups, as recommended by the British National Formulary (BNF) for pediatric prescriptions: 1–6 years, 6–12 years, and over 12 years, since reasons for sedation may vary notably across these groups</p>
	23d	Discuss implications of the results for practice, policy, and future research.	Although few studies evaluated parental satisfaction, it is evident in the few studies that reported it that parents tend to favor approaches that balance

PRISMA 2020 Checklist

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			efficacy, safety, and comfort for their children. The lack of information on this regard entails that further research is needed to evaluate parental comfort and satisfaction when their children undergo these types of interventions.
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Prospero registration number: CRD420250637249
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	No protocol was originally required for the study.
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	There is no amendment.
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	No sources of funding for the research were received. The authors declare that no funds, grants, or other support were received during the preparation of this manuscript
Competing interests	26	Declare any competing interests of review authors.	The authors declare no competing interests.
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	None of these data are publicly available.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. This work is licensed under CC BY 4.0. To view a copy of this license, visit <https://creativecommons.org/licenses/by/4.0/>

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