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Is Topical Anesthesia Effective to Reduce the Intensity of Pain in Children for Placement the Clamp Before Rubber Dam Isolation for Sealant Application? A Systematic Review and Meta-Analysis

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Abstract

Aim: A systematic review/meta-analysis was performed to evaluate the use of topical anesthesia for reducing the intensity of pain for the placement the clamp used in rubber dam compared to a placebo or benzocaine in patients undergoing preventive treatment?

Methods: A search was performed in PubMed, Scopus, Web of Science, LILACS, BBO, Cochrane Library and Grey literature. IADR abstracts, unpublished trials registries, dissertations and theses were also searched for randomized clinical trials comparing the clinical effectiveness of intra-pocket anesthesia and placebo. Risk/intensity of pain was the primary outcome. The risk of bias tool from the Cochrane Collaboration was used for quality assessment. Meta-analysis was performed on studies considered at low risk of bias. Quality of the evidence for each outcome was assessed using the GRADE tool.

Results: The 2,114 articles were identified. Six remained in the qualitative synthesis, 2 studies were considered at "low" risk of bias and 4 studies were considered at "unclear" risk of bias. Standardized mean difference for intensity of pain using Faces Scale compared a topic x placebo was - 0.69 (95% CI = -1.23 to -0.15; p=0.01) and for Faces Scale compared a topic x benzocaine was 0.00 (95% CI = -0.32 to 0.32; p=1.00). For VRS pain scale compared topic x placebo it was - 0.50 (95% CI = -0.84 to -0.16; p=0.004).

Conclusion: The anesthetic gel compared to placebo decreases the intensity of pain during the placement the clamp used in rubber dam for preventive treatment, but when compared to another topic there are no differences.

Keywords: Meta-analysis; Anesthetics; Pit and fissure sealants; Dental anxiety

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Introduction

Local anesthesia is essential in Dentistry for pain control, however, many patients report anxiety, pain from injections and 18% of patients are "very" afraid of the needle and 31% are "moderate" afraid [1-3]. Only the visual stimulus, such as the needle in the syringe, is already a triggering factor of insecurity, because even without previous negative experience with local anesthesia, subjective fear can occur [4,5].

Topical anesthesia is a strategy that minimizes patient pain caused by needle puncture and can be an alternative to replace local anesthesia [6,7], and has already been tested in some dental procedures such as scaling and root planning [6,8], adaptation of the clamp for absolute isolation for applying sealants [9,10] and carrying out restorations [11,12].

In Pediatric Dentistry it is essential to think about ways to replace local anesthesia since the most prevalent disease in the pediatric population is caries [7,12,13]. Around 60% to 90% of students have already had caries lesions on their permanent teeth [14,15]. A way to prevent and treat initial carious lesions and the use of pit and fissure sealants that when adapting the rubber dam and the clamp

requires the use of an anesthesia [9,10,16].

Topical anesthetics are available in the form of gels, solutions, ointments, adhesives and aerosols, with superficial effectiveness in the tissues, around 2 mm to 3 mm deep [17,18]. Some studies have shown that the topical anesthetic is capable of reducing the risk and intensity of pain during the adaptation of the clamp of rubber dam in children [7,9,10], other studies have not shown a significant difference between different anesthetic salts [16,19] or differences between the topical anesthetic and the use of a placebo [20].

Due to these divergences in the literature, the objective of this study was to carry out a systematic review to evaluate the use of topical anesthesia for reducing the intensity of pain for the placement the clamp used in rubber dam compared to a placebo or benzocaine in patients undergoing preventive treatment?

Materials and Methods

Protocol and registration

This study protocol was registered in the PROSPERO database (CRD42019137301) and the recommendations of the PRISMA statement were followed [21]. It was accomplished from February to August of 2020 at State University of Ponta Grossa, Paraná, Brazil.

Information sources and search strategy

The controlled vocabulary (MeSH terms) and free keywords in the search strategy were defined based on the PICOS question: The use of topical anesthesia is effective for reducing the intensity of pain for the placement the clamp used in rubber dam compared to a placebo or benzocaine in patients undergoing preventive treatment?

1. P: Patients undergoing preventive treatment
2. I: Other topical anesthetics other than benzocaine
3. C: Use the placebo or benzocaine anesthesia
4. O: Risk and intensity of pain for the placement the clamp
5. S (Study design): Randomized clinical trials.

To identify the trials to be included, we searched the electronic databases MEDLINE *via* PubMed, Scopus, Web of Science, the Latin American and Caribbean Health Sciences Literature Database (LILACS), the Brazilian Library in Dentistry (BBO) and the Cochrane Library (Table 1). We also hand-searched the reference lists of all primary studies for additional relevant publications and investigated the related article links for each primary study in the PubMed database. No restrictions on publication date or languages were involved.

Abstracts of the annual conference of the International Association for Dental Research (IADR) and its regional divisions (1990-2020) were used; the authors of relevant abstracts were contacted for further information. The grey literature was explored using the database System for Information on Grey Literature in Europe (SIGLE). Dissertations and theses were searched using the ProQuest dissertations and theses full text data bases and the Periodicos capes theses database.

To locate unpublished and ongoing trials, the following clinical trials registries were searched: Current Controlled Trials (www.controlled-trials.com), International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/), the ClinicalTrials.gov (www.clinicaltrials.gov), Rebec (www.rebec.gov.br) and EU Clinical Trials Register (https://www.clinicaltrialsregister.eu).

The search strategy and the date of search for all databases were included in Table 1. The search strategy developed for PubMed was modified for the other databases to identify eligible studies. Full-text versions of the papers that appeared to meet the inclusion criteria were retrieved for further assessment and data extraction.

Eligibility criteria

We included Randomized Clinical Trials (RCTs) with parallel or split-mouth designs that compare the intensity of pain using topical anesthesia after the placement the clamp for rubber dam versus placebo or benzocaine in children patients.

RCT studies were excluded if: 1) other types of procedure were performed; 2) anesthetic gels were not compared with a placebo; 3) participants took analgesics or anti-inflammatory drugs before probing and/or SRP.

Study selection and data collection process

The articles were selected by title and abstracts according to the described search strategy. Articles appearing in more than one database were considered once. Full-text articles were obtained when there was insufficient information in the title and abstract to make a clear decision.

Subsequently, full-text articles were acquired, and two reviewers (L.M.W. and J.L.G.) classified those that met the inclusion criteria. To handle such a large number of studies, we created an ID for each eligible study, combining first author and year of publication. Relevant information about the study design, participants, interventions and outcomes were extracted using customized extraction forms by three authors (L.M.W., J.L.G. and A.R.) (Table 2).

When there were multiple reports of the same study (i.e., reports with different follow-ups), data from all reports were extracted directly into a single data collection form to avoid overlapping data. The collection form was pilot tested using a sample of study reports to ensure that the criteria were consistent with the research question.

When more than two anesthetic gels were tested, data were combined to make a single entry. When the pain was reported in different time periods after a single clinical session of probing and/or SRP, we collected the data from the most immediate period. If data from multiple clinical sessions of probing and/or SRP were reported, we averaged the values.

Risk of bias in individual studies

Quality assessments of the included trials were evaluated by two independent reviewers (L.M.W. and J.L.G.), using the Cochrane Collaboration tool for assessing risk of bias in randomized trials [22]. The assessment criteria contained six items: Sequence generation, allocation concealment, blinding of the outcome assessors, incomplete outcome data, selective outcome reporting, and other possible sources of bias. During data extraction and quality assessment, any disagreements between the reviewers were resolved through discussion, and if needed, by consulting a third reviewer (A.R.).

For each aspect of the quality assessment, the risk of bias was scored following the recommendations described in the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 (http://handbook.cochrane.org). The judgment for each entry consisted of recording "yes" (low risk of bias), "no" (high risk of bias) or "unclear" (either lack of information or uncertainty over the potential for bias).

Table 1: Electronic databases and search strategy.

Pubmed=618		
#1	**#2**	**#3**
dentition, permanent[MeSH Terms] OR Dentition, Mixed[MeSH Terms] OR molar[Title/Abstract] OR "permanent mandibular first molar"[Title/Abstract] OR "permanent maxillary molars"[Title/Abstract] OR "first molars"[Title/Abstract] OR "posterior molars"[Title/Abstract] OR "permanent teeth"[Title/Abstract] OR "permanent tooth"[Title/Abstract] OR "permanent dentition"[Title/Abstract] OR "permanent mandibular molars"[Title/Abstract] OR "mixed dentition"[Title/Abstract]	rubber dams[MeSH Terms] OR Placebos[MeSH Terms] OR Pit and Fissure Sealants[MeSH Terms] OR "rubber dam isolation"[Title/Abstract] OR "rubber dam"[Title/Abstract] OR "minimal intervention"[Title/Abstract] OR "Topical Anesthetic"[Title/Abstract] OR "Sealant Placement"[Title/Abstract] OR "clamp placement"[Title/Abstract] OR EMLA[Title/Abstract] OR "anesthetic gel"[Title/Abstract] OR "dental anesthesia"[Title/Abstract] OR "dental sealants"[Title/Abstract] OR "Gingival Anesthesia"[Title/Abstract] OR "preventive resin restorations"[Title/Abstract] OR placebos[Title/Abstract] OR Oraqix[Title/Abstract]	(randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies as topic[mh] OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospective*[tw] OR volunteer*[tw]) NOT (animals[mh] NOT humans[mh]))
#1 AND #2 AND #3		
Scopus= 1690		
#1		#2
TITLE-ABS-KEY ("dentition permanent") OR TITLE-ABS-KEY ("dentition mixed") OR TITLE-ABS-KEY (molar) OR TITLE-ABS-KEY ("permanent mandibular first molar") OR TITLE-ABS-KEY ("permanent maxillary molars") OR TITLE-ABS-KEY ("first molars") OR TITLE-ABS-KEY ("posterior molars") OR TITLE-ABS-KEY ("permanent t??th") OR TITLE-ABS-KEY ("permanent mandibular molars")		TITLE-ABS-KEY ("rubber dam*") OR TITLE-ABS-KEY (placebos) OR TITLE-ABS-KEY ("pit and fissure sealants") OR TITLE-ABS-KEY ("rubber dam isolation") OR TITLE-ABS-KEY ("minimal intervention") OR TITLE-ABS-KEY ("topical anesthetic") OR TITLE-ABS-KEY ("Sealant Placement") OR TITLE-ABS-KEY ("clamp placement") OR TITLE-ABS-KEY ("anesthetic gel") OR TITLE-ABS-KEY (emla) OR TITLE-ABS-KEY ("dental anesthesia") OR TITLE-ABS-KEY ("dental sealants") OR TITLE-ABS-KEY ("Gingival Anesthesia") OR TITLE-ABS-KEY ("preventive resin restorations") OR TITLE-ABS-KEY (oraqix))) AND (LIMIT-TO (SUBJAREA , "DENT")
#1 AND #2		
Web of Science=595		
#1		#2
TOPIC: ("dentition permanent") OR TOPIC: ("dentition mixed") OR TOPIC: (molar$) OR TOPIC: ("permanent mandibular first molar") OR TOPIC:("permanent maxillary molars") OR TOPIC: ("first molars") OR TOPIC: ("posterior molars") OR TOPIC: ("permanent t*th") OR TOPIC: ("permanent mandibular molars")		TOPIC: ("rubber dam*") OR TOPIC: (placebos) OR TOPIC: ("pit and fissure sealants") OR TOPIC: ("rubber dam isolation") OR TOPIC: ("minimal intervention") OR TOPIC: ("topical anesthetic") OR TOPIC: ("Sealant Placement") OR TOPIC: ("clamp placement") OR TOPIC: ("anesthetic gel") ORTOPIC: (emla) OR TOPIC: ("dental anesthesia") OR TOPIC: ("dental sealants") OR TOPIC: ("Gingival Anesthesia") OR TOPIC: ("preventive resin restorations") OR TOPIC: (oraqix) AND (DENTISTRY ORAL SURGERY MEDICINE)
#1 AND #2		
Lilacs and BBO = 31		
#1		#2
MH:"dentition, permanent" OR MH:"dentition, mixed"OR "permanent dentition" OR "dentición permanente" OR "dentição permanente"OR "mixed dentition" OR "dentición mixta" OR "dentição mista" OR molar OR molars OR molares OR "permanent mandibular first molar" OR "primer molar permanente mandibular" OR "primeiro molar permanente mandibular"OR "permanent maxillary molars" OR "molares permanentes maxilares" OR "first molars" OR "primeros molares" OR "primeiros molares" OR "posterior molars" OR "molares posteriores" OR "permanent teeth" OR "dientes permanentes" OR "dentes permanentes" OR "permanent tooth" OR "diente permanente" OR "dente permanente" OR "permanent mandibular molars" OR "molares permanentes mandibulares"		MH:"rubber dams" OR MH:Placebos OR MH:"Pit and Fissure Sealants"OR Anesthesia, Dental OR "rubber dam" OR "rubber dams" OR "Dique de borracha" OR "diques de borracha" OR "diques de goma" OR "dique de goma" OR "goma dique" OR rubber dam isolation OR "aislamiento con goma dique" OR "aislamiento con dique de goma" OR "isolamento com dique de borracha" OR "placebos" OR "Pit and Fissure Sealants"OR "Pit and Fissure Sealant" OR "Selantes de Fossas e Fissuras" OR "Selante de Fossas e Fissuras" OR "Selladores de Fosas y Fisuras" OR "Sellador de Fosas y Fisuras" OR "Sellantes de Fosas y Fisuras" OR "Sellante de Fosas y Fisuras" OR "minimal intervention" OR "mínima intervenção" OR "intervenção mínima" OR "intervención mínima" OR "mínima intervención" OR "Topical Anesthetic" OR "anestésico tópico" OR "Sealant Placement" OR "aplicación de sellante" OR "aplicação de selante" OR "clamp placement" OR "colocação do grampo" OR "colocación de clamps" OR EMLA OR anesthetic gel OR "gel anestésico" OR "dental anesthesia" OR "anestesia dentária" OR "anestesia dental" OR "dental sealants" OR "Selantes dentarios"OR "Selante dentario" OR "Selladores dentales" OR "Sellante dental" OR "Gingival Anesthesia" OR "anestesia gingival" OR "anestesia gengival" OR "preventive resin restorations" OR "restauración preventiva de resina" OR "restauración de resina preventiva" OR "restauração preventiva de resina" OR "restauração de resina preventiva" OR Oraqix
#1 AND #2		
Cochrane Library = 394		

MeSH descriptor:[Dentition, Permanent] explode all trees; MeSH descriptor:[Dentition, Mixed] explode all trees; (molar):ti,ab,kw OR ("permanent mandibular first molar"):ti,ab,kw OR ("permanent maxillary molars"):ti,ab,kw OR ("posterior molars"):ti.ab,kw OR ("permanent t*th"):ti,ab,kw OR ("permamnent mandibular molars"):ti,ab,kw #1 OR #2 OR #3 OR #4 (4981)	MeSH descriptor: [Rubber Dams] explode all trees; MeSH descriptor: [Placebos] explode all trees; MeSH descriptor: [Pit and Fissure Sealants] explode all trees; ("rubber dam isolation"):ti,ab,kw OR ("minimal intervention"):ti,ab,kw OR ("Topical Anesthetic"):ti,ab,kw OR ("Sealant Placement"):ti,ab,kw OR (clamp):ti,ab,kw OR (EMLA):ti,ab,kw OR ("anesthetic gel"):ti,ab,kw OR ("dental anesthesia"):ti,ab,kw OR ("Gingival Anesthesia"):ti,ab,kw OR ("reventive resin restoration"):ti,ab,kw OR (Oraqix):ti,ab,kw #6 OR #7 OR #8 OR #9 OR #10 OR #11 (25633)
#5 AND #12 (395)	

Table 2: Summary of the studies included in this systematic review.

Study ID	Study design/ Country	Subjects' age mean ± SD [range]	No. of male subjects [%]	Total No. patients [drop-outs]	Topical Anesthetic Used	Control group	Time anesthetic topic was left before the treatment/n. clamp	Outcomes evaluated		
								Rescue Anesthesia/ (n.) / type	N. events/ total Risk Intensity of pain	Scale
Lim et al. 2004	Split-mouth/ USA	9 ± n.r (6-12)	13. [42]	31 [0]	Emla®: 5% a	Vaseline	n.r/#14/	n.r	EMLA : 0.47 ± 0.27/ 31 Vaseline: 0.64 ± 0.24/31	FPS
Olopes et al. 2018	Split-mouth/ Brazil	n.r ± n.r. [7-11]	12 [41]	29[1]	Tetracaine hydrochloride 1% with 0.1% phenylephrine hydrochloride	Benzotop®: 20%	2 min/#26;# 200; #203; #204	Yes (0)/ injectable anesthesia	VRS: Tetraine: 1.06 ± 2.29/29 Benzocaine: 1.82 ± 2.56/29 Flacc: Tetraine: 0.0 ± 0.30/29 Benzocaine: 0.0 ± 0.46/29 Wong Baker: Tetraine: 0.0 ± 1.05/29 Benzocaine: 0.0 ± 1.22/29	Wong Baker; Flacc; VRS
Stecker et al. 2002	Split-mouth/ USA	11.3 ± 3.5 [5-17]	16 [60]	28 [0]	DentiPatch® (20%, Lidocained)	Hurricaine Dry Handle Swab (Benzocaine 20%)	Hurricaine: 1 min Patch: 5 min/#n.r	No	Hurricaine: 33.9 ± 25.1/28; DentiPanch: 31.0 ± 25.7/28	VAS
Wambier et al. 2018	Split-mouth/ Brazil	10.8 ± 0.5 [8-12]	38 [48]	81 [0]	handled topical liposomal thermo-sensitive gel: 0,5%	Placebo	2 min/#26	No	VRS: Gel: 1.2 ± 1.15 / 81 Placebo: 1.8± 2.3/ 81 Wong Baker: Gel: 0.7 ± 0.9/ 81 Placebo: 1.0±1.1/ 81	Wong-Baker FACES scale and VRS
Wambier et al. 2018	Split-mouth/ Brazil	10.4± 1.0 [8-12]	42 [52]	82 [0]	handled Light-cured anesthetic gel: 5%	Light-cured Placebo	30 s/#26	Yes (infiltrative anesthesia)	VRS: Gel: 1.4 ± 1.6/ 82 Placebo: 2.7 ± 2.2/ 82 Wong Baker: Gel: 0.9 ± 1.0/ 82 Placebo: 1.7 ± 1.3/ 82 Flacc: Gel: 0.4 ± 0.7/82 Placebo: 1.0 ± 1.1/82	Wong-Baker FACES Scale; VRS ; Flacc
Yoon et al. 2009	Split-mouth/ USA	n.r ± n.r. [7-12]	18 [40]	45 [0]	cOraqix® 5%,	Benzocaine 20%	2 min/#14A	n.r	Oraqix: 0.76 ± 1.17/45 Benzocaine: 0.76 ± 1.17/45	FPS

ID: Identification; SD: Standard Deviation; n.r.-Not Reported; VAS: Visual Analog Scale; VRS: Verbal Rating Scale; FSP: Facial Scale Pain
[a]Emla® 5%, AstraZeneca, RɛD Södertälje, Sweden
[b]Tetracainehydrochloride 1% with 0.1%phenylephrinehydrochloride: Allergan; SP, SP
[c]DentiPatch® 20% lidocaine: not report
[d]Oraqix® 5%, Dentsply, York, PA, USA
[b]Benzotop® 2%, DFL, Rio de Janeiro, RJ
[g]Benzocaine gel: 20%: not report

Summary measures and synthesis of the results

Data from eligible studies were either dichotomous (absolute risk of pain) or continuous (pain intensity). Only studies classified at "low" and "unclear" risk of bias in the key domains were entered into the meta-analysis. We calculated the risk ratio and the 95% Confidence Interval (CI).

The random-effects models were employed. Heterogeneity was assessed using the Cochran Q test and I2 statistics. All analyses were conducted using Revman 5.3 (Review Manager Ver. 5.3, The Cochrane Collaboration, Copenhagen, Denmark).

GRADE analysis

The quality of the evidence was graded for each outcome across studies (body of evidence) using the Grading of Recommendations: Assessment, Development and Evaluation (GRADE) (http://www.gradeworkinggroup.org/) to determine the overall strength of evidence for each meta-analysis. The GRADE approach is used to contextualize or justify intervention recommendations with four levels of evidence quality, ranging from high to very low.

The GRADE approach begins with the study design (RCTs or observational studies) and then addresses five reasons (risk of bias, imprecision, inconsistency, indirectness of evidence, and publication bias) to possibly rate down the quality of the evidence (1 or 2 levels) and three to possibly rate up the quality (large effect; management of confounding factors; dose-response gradient). Each one of these topics was assessed as "no limitation"; "serious limitations" and "very serious limitations" to allow categorization of the quality of the evidence for each outcome into high, moderate, low, and very low. The "high quality" suggests that we are very confident that the true effect lies close to the estimate of the effect. On the other extreme "very low quality" suggests that we have very little confidence in the effect estimate and the estimate reported can be substantially different from what it was measured.

Results

Some studies did not contain all the information needed and not send e-mails to the authors for further information. After the database screening and removal of duplicates, 2,114 studies were identified (Figure 1). After title screening, 422 studies remained. This number was reduced to 7 after examination of the abstracts and their full texts were assessed to check eligibility. Among them, one study was excluded because not compared to placebo group [23].

Characteristics of included articles

The characteristics of the 6 selected studies are listed in Table 2. All studies included in this systematic review had the study design as a split-mouth [7,9,10,16,19,20]. Three studies were realized in Brazil [7,9,20] and three in USA [10,16,19].

The number of children included in the primary studies ranged from 29 to 82, just one patients drop-out in one study [20]. The mean age of all the participants included in the clinical trials was approximately 7 years. The percentage of males ranged from 40% to

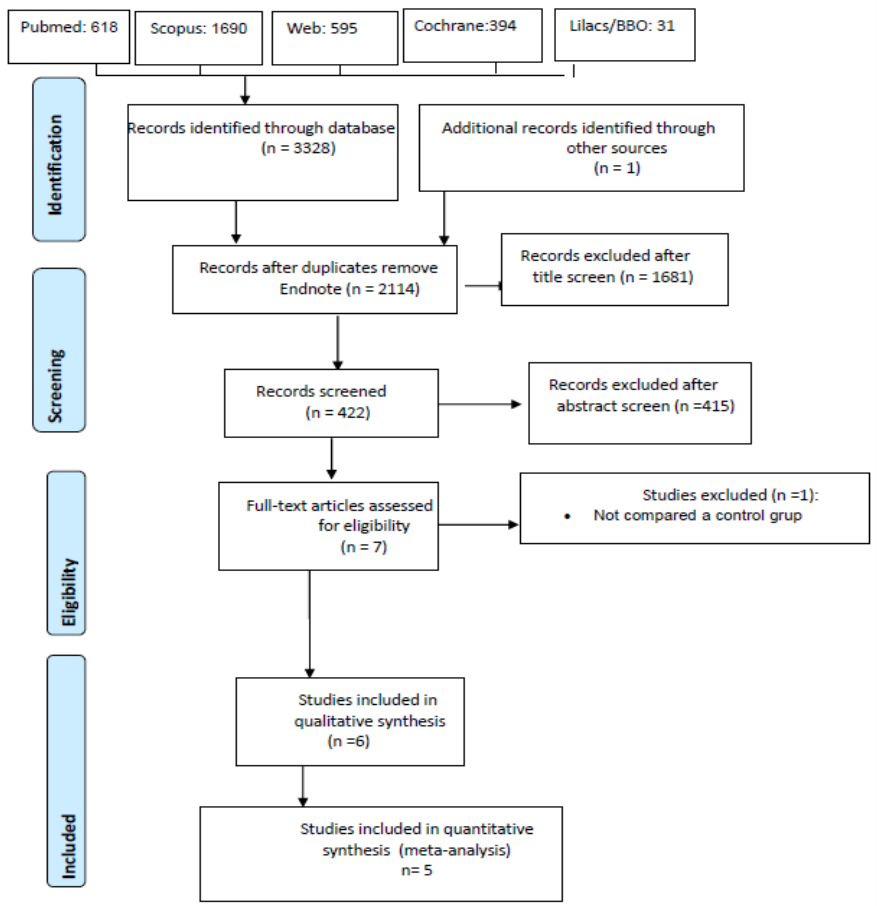

Figure 1: Flow diagram of study.

60%.

The topical anesthetics used in the experimental groups varied between studies, 4 studies [10,16,19,20] used commercial anesthetics and 2 studies [7,9] used manipulated anesthetics. The control group varied between placebos with aspects similar to the experimental groups in 3 studies [7,9,10]; another 3 studies [16,19,20] used 20% benzocaine as a control.

The waiting time for adapting the clamp in most cases was 2 min [7,16,20], one study [9] waited only 30 sec, another waited one minutes for the control and 5 min for the experimental group [19], only one study [10] did not report the waiting time.

The clamp used for the rubber dam of the first permanent molars in most studies was 26 [7,9,20], studies 2 used clamp 14 [10,16] and one study [19] did not report this information. Of all studies included, only 2 used rescue anesthesia which was infiltrative anesthesia [9,20], studies [7,19] did not have rescue anesthesia and studies [10,16] are did not report this data.

The scales to verify pain intensity varied between studies, the most used was SPF [7,9,10,16,20], Followed by VRS [7,9,20], VAS was used in only one study [19] and the same was seen with the Flacc scale [9].

Assessment of the risk of bias

The assessment of the risk of bias of the included studies is presented in Figure 2. Some full-text studies did not report the method of randomization and how the allocation concealment was done. Blinding was adequately described in these studies. In the Cochrane risk of bias tool, 2 of these studies [7,9] were judged as at "low" risk of bias and 4 studies [10,16,19,20] were judged as at "unclear" risk of bias.

Meta-analysis

All meta-analyses were performed on studies from which the information could be extracted.

Intensity of pain using Faces Scale compared a topic x placebo: This analysis was based on three studies [7,9,10]. The standardized mean difference was -0.69 (95% CI = -1.23 to -0.15; p=0.01), showing superiority for topics anesthetics. The data were heterogeneous (chi^2 test p=0.002; I^2=84%) (Figure 3).

Intensity of pain using Faces Scale compared a topic x benzocaine: This analysis was based on two studies [16,20]. The standardized mean difference it was 0.00 (95% CI = -0.32 to 0.32; p=1.00), showing no superiority for different topics anesthetics. The data not were heterogeneous (chi^2 test p=1.00; I^2=0%) (Figure 4).

Intensity of pain using VRS compared a topic x placebo: This analysis was based on two studies [7,9]. The standardized mean difference it was -0.50 (95% CI = -0.84 to -0.16; p=0.004), showing superiority for the topic anesthetic. The data were heterogeneous (chi^2 test p=0.13; I^2=57%) (Figure 5).

Assessment of the quality of evidence

In the summary-of-findings (Table 3), the meta-analysis was

Figure 2: Summary of the risk of bias assessment according to the Cochrane Collaboration tool.

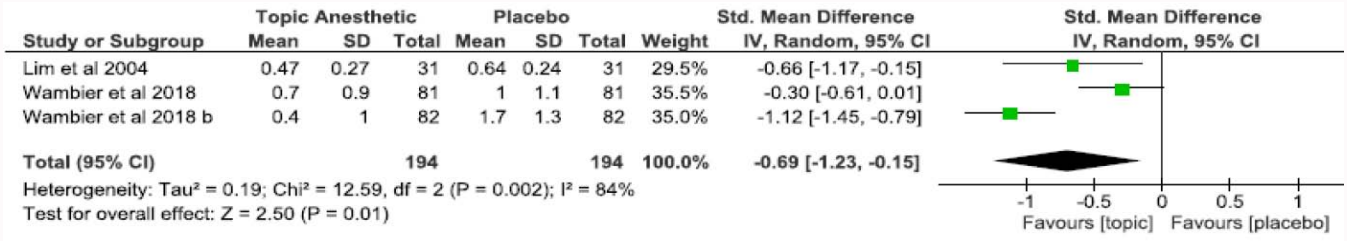

Figure 3: Forest plots of Faces scale- topic x placebo.

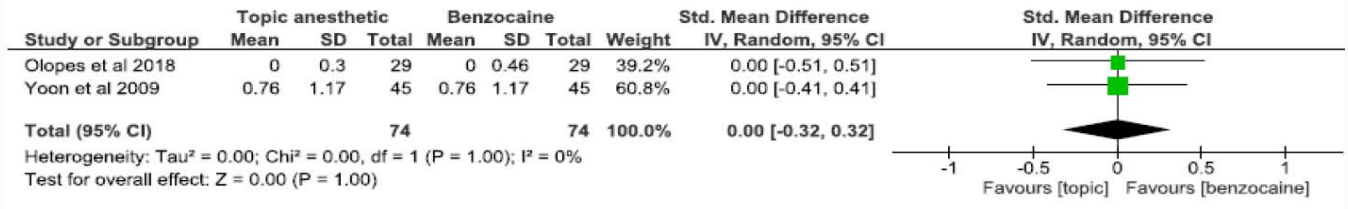

Figure 4: Forest plots of Faces scale -topic x benzocaine.

Figure 5: Forest plots of VRS scale- topic x placebo.

graded as moderate in the quality of evidence for intensity of pain using Faces Scale and low in the quality evidence for intensity of pain using VRS scale. The reasons for downgrading the evidence were that the RCTs are at "unclear" risk of bias.

Discussion

This is the first systematic review that assesses the effectiveness of topical anesthetics to be used in pediatric dentistry to placement the clamp used in rubber dam. It is known that many children report pain when used clamps for perform clinical procedures [10,12], and the most common procedure to remedy this pain is still infiltrative anesthesia [24,25].

Among the various clamps used to rubber dam the first permanent molars, the most used is still clamp 26, which has the advantage of being supragingival but is indicated when the tooth is already completely erupted [7,9]. Clamp 14 A is also indicated for the first permanent molars but it is more subgingival as it is indicated

Table 3: Summary of findings table.

Patient or population: Children					
Intervention: Topic anesthetic					
Comparison: Placebo or benzocaine					
Outcomes	**Anticipated absolute effects** †(95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)
	Topic anesthetic	**Placebo/Bencaine**			
Faces Scale (Topic x placebo)	SMD -0.69 SD lower (-1.23 to -0.15)	-	-	194 (3 RCTs)	⊕⊕◯◯ MODERATE‡
Faces Scale (Topic x benzocaine)	SMD 0.00 SD lower (-0.32 to 0.32)	-	-	74 (2 RCTs)	⊕⊕◯◯ MODERATE‡
VRS Scale (Topic x placebo)	SMD -0.50 SD lower (-0.84 to -0.16)	-	-	163 (2 RCTs)	⊕◯◯◯ Low

†The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group
‡Imprecision and high risk of bias. CI: Confidence Interval; RCT: Randomised Clinical Trials; SMD: St. Means Difference

for teeth that are in the eruption phase [16]. In these cases, most clinicians perform infiltrative anesthesia [26] and we can see from the results of this systematic review that topical anesthetics can be indicated in these cases.

Infiltrative anesthesia has a longer duration compared to topical anesthesia [27,28] and also produces a vasoconstrictor effect that increases the time of anesthetic action [29,30], while topical anesthetics have a limited capacity of penetration, since they need to overcome the keratinized cells that protect the outer layer of the oral mucosa [31]. They still have a short action time around 15 min to 20 min [18], while infiltrative anesthesia remains for more than an hour [32]. Therefore, this brief period of analgesia may limit the use of topical anesthetic gels in certain procedures that determine a longer procedure time or that is more invasive [33].

Depending on the anesthetic salt present in the topical anesthetic, it will directly interfere in the duration of action that is related to its hydrophobicity, allows the drug to remain in the tissue that surrounds a nerve for a long period [17]. Hydrophobicity promotes a prolonged interaction with the binding site in the sodium channel determining greater potency than other anesthetic salts [18,29].

There is a variety of topical anesthetics that can be used although benzocaine-based ointment is the most used in dentistry [17,19]. This type of anesthetic salt has a lower analgesia potential compared to lidocaine and prilocaine [34,35]. Than these salts are less efficient and less potent than products based on tetracaine [9,36].

For non-invasive procedures in pediatric dentistry a potent topical anesthetic is effective in reducing the intensity of pain during the procedure [9,13]. Preventive procedures like pit and fissure sealants in which the child has active movement of the tongue or a lot of saliva production a topical anesthetic can be used, as observed in the meta-analyzes of this study [16,37,38].

In Meta-analyzes different pain scales can be compared by comparing topical anesthetics with different anesthetic salts and a placebo, showing superiority to topical anesthetics. Although there were no significant differences when comparing different topical anesthetics in pain intensity, it can be seen that both are effective for adapting the absolute isolation clamp.

The evolution of topical anesthetics represented a major advance in dentistry providing comfort to patients who are afraid of infiltrative anesthesia so studies on this topic must continue so that professionals have options to choose according to the real need of their patients.

Conclusion

The anesthetic gel compared to placebo decreases the intensity of pain during the placement the clamp used in rubber dam for preventive treatment, but when compared to another topic there are no differences.

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