



The combined effect of extraoral vibratory stimulus and external cooling on pain perception during intra-oral local anesthesia administration in children: a systematic review and meta-analysis

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This study aimed to assess the combined use of extraoral vibratory stimulation and extraoral cooling in reducing the pain (subjective and objective) of dental local anesthesia administration in children.

PubMed, Cochrane Central Register of Controlled Trials, and Ovid SP databases were searched up to July 2021. Article titles were screened and full-text evaluations of the selected articles were performed. Finally, seven studies (391 children, aged 4 – 12 years) were included in this qualitative and quantitative analysis. The pooled data determined the combined effect of extraoral vibration and extraoral cooling as a single measure. Extraoral vibration or cooling alone were not compared. The measured primary and secondary outcomes were pain perception and subjective and objective pain, respectively. When compared with the control, extraoral vibration and cooling resulted in significant differences in the mean combined data for the variables, pain perception, and pain reaction. Children's subjective pain as measured by pain scores were reduced when extraoral vibration and cooling was used during local anesthesia administration (mean difference -3.52; 95% confidence interval [-5.06 - 1.98]) and objective pain (mean difference -1.46; 95% confidence interval [-2.95 - 0.02] ; mean difference -1.93; 95% confidence interval [-3.72 - 0.14]).

Within the confines of this systematic review, there is low-quality evidence to support the use of combined extraoral vibration and cooling for reducing pain (subjective and objective) during intraoral local anesthesia administration in children.

Keywords: Children; Cooling; External; Intraoral; Local Anesthesia; Vibration.



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INTRODUCTION

Fear of pain due to needle pricks is high among children [1]. Reducing the discomfort during intraoral

local anesthesia administration is considered the most challenging aspect of dentistry, especially in pediatric dental patients. Physical, psychological, and pharmaceutical methods, and their combinations have tried to address this pain. Pharmaceutical approaches include the

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application of topical anesthetics [2]. Psychological and behavioral modification methods including active distractions, deep breathing [3], Witaul [4], and eye movement distractions [5] have been tried. Passive distraction methods, such as audiovisual glasses and video distraction [6], have also been attempted with some success [7]. Other methods, such as precooling the injection site [8], warming the local anesthesia [9], buffering the local anesthesia [10], and camouflaging the syringe, have also been suggested [11]. Physical methods, such as vibration, are among the oldest methods and the most widely used, to alleviate needle prick discomfort during local anesthesia administration in children. The gate control theory by Melzak and Wall is a widely accepted pain theory that explains the mechanism underlying the vibratory effects in reducing pain perception. According to Melzak and Wall, vibration activateS A-beta fibers whose diameters are larger than A-delta and C fibers that transmit pain sensation from the periphery to the brain [12].

Vibratory stimuli can be delivered to the desired site, that is, the site of the needle prick, using both direct and indirect methods. Direct vibratory stimuli can be applied intraorally at the site of the needle prick. Direct vibratory stimulation can be achieved manually using a cotton roll [13], an SMV-Syringe Micro Vibrator instrument that snaps onto a syringe[14], or a dental vibrate [12].

Indirect vibratory stimuli through extraoral vibratory stimulations may also be useful in alleviating pain during intraoral local anesthesia delivery, as reported in various studies.

Previous systematic reviews of direct intraoral vibration using different vibratory devices have shown that direct intraoral vibratory stimulations can reduce pain perception during intraoral local anesthesia administration [12]. Previous systematic reviews have suggested that precooling the injection site has the potential to reduce discomfort due to injection pain and local anesthesia administration [8].

Indirect extraoral vibratory stimulations are effective in reducing pain due to intraoral local anesthesia

administration in a few studies. No systematic review has been conducted on the effects of indirect extraoral vibratory stimulations and extraoral cooling on injection pain. This systematic review aimed to evaluate the combined effect of extraoral vibration and cooling on pain during intraoral local anesthesia administration in children.

METHODS

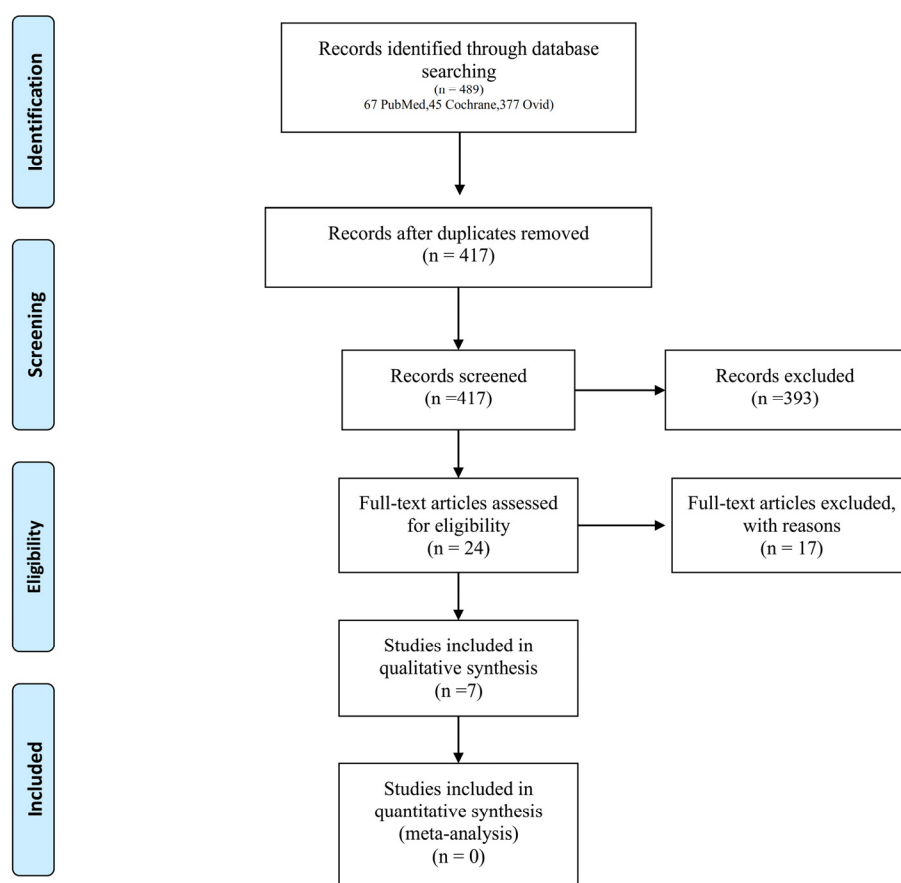
Protocol and registration: This study was registered under the Prospero registration number CRD42021282192, and followed the PRISMA guidelines.

Eligibility criteria: The strategic search question was evaluated in PICO format “Does the combination of extraoral vibration and cooling have any effect on pain perception and reaction during dental injections in children”. Patients were children, aged between 3 and 17 years. The intervention consisted of a combined extraoral vibratory stimulus and cooling during an intraoral needle prick. The control group consisted of children who did not receive an extraoral vibratory stimulus or patients who received any other method of counter stimulation. An electronic database search was conducted. The search included all articles up to July, 2021. The search was based on a strategic question using the relevant MeSH terms ["extraoral vibration"] AND ["dental"] AND ["child"]. Quantitative data were analyzed using RevMan software, and a random-effects model was applied to calculate the mean difference.

Only studies that combined extraoral vibratory devices and cold application during intraoral local anesthesia delivery in children were included. Observational data, reviews, and case reports were omitted from the analysis. Articles on oral vibratory devices were omitted. Title and abstract outlines were screened, and relevant articles were imported to citation software (www.zotero.org) from the selected databases. Duplicates were removed. Titles that met our criteria were included in the qualitative analysis. Information extraction and analysis were performed

Table 1. Table showing Excluded articles and reasons for exclusion

No	Excluded articles	Reasons for exclusion
1.	Felemban, et al 2021 [20]	Intra-oral vibration was used
2.	Menni, et al 2020 [22]	Intra-oral vibration was used
3.	Salma, et al 2021 [25]	Intra-oral vibration was used and too in adults
4.	Smorarek, et al 2020 [16]	Intra-oral vibration was used
5.	Hassanein, et al 2020 [21]	Intra-oral vibration was used
6.	Veneva, et al 2019 [30]	Intra-oral vibration was used
7.	Tandon, et al 2018 [28]	Intra-oral vibration was used
8.	Tung, et al 2018 [29]	Intra-oral vibration was used
9.	Erdogan, et al 2018 [19]	Intra-oral vibration was used
10.	Raslan, et al 2018 [24]	Intra-oral vibration was used
11.	Shaefer, et al 2017 [26]	Intra-oral vibration was used
12.	Bagherian, et al 2016 [13]	Intra-oral vibration was used
13.	Shilpapiya, et al 2015 [27]	Intra-oral vibration was used
14.	Elbay, et al 2015 [18]	Intra-oral vibration was used
15.	Nasehi, et al 2015 [23]	Intra-oral vibration was used
16.	Difelice, et al 2014 [17]	Intra-oral vibration was used
17.	Ching, et al 2014 [15]	Intra-oral vibration was used

**Fig. 1.** Flow chart

independently by two examiners. The outcome measure was “pain perception and reaction”. Means and standard deviations were collected from individual studies.

Data synthesis: Fixed-or random-effect models were used to analyze the pooled mean data. The significance level was set at five percent.

Table 2. Characteristics of the included studies

No	Author-year	Study design	Sample characteristics	Type of injection	Gauge of manual syringe used	Topical anesthesia	Intervention characteristic and comparison groups	Vibration instrument	Measuring Scales	Outcomes
1.	Sahiti, et al 2021 [34]	Randomized parallel-arm, single blinded, interventional, clinical trial	100 children, aged 4 to 11 years	Infiltration	23 gauge needle	20% benzocaine	50 – Extra oral Vibration + Cooling 50 – Counter stimulation	Buzzy Counter stimulation with gentle mucosal vibration	WBFP RS VAS VPT VCARS	Extra oral Vibration + Cooling better
2.	AlHareky, et al. 2021 [31]	Randomized parallel-arm, interventional, clinical trial Parlell arm design.	51 children, aged 5 to 12 years	Maxillary buccal infiltration	30 gauge needle	20% benzocaine	25 – Extra oral Vibration + Cooling 26 – No Extra oral Vibration + Cooling	Buzzy	VAS FLACC SEM	Extra oral vibration + Cooling better
3.	Subramaniam and ghai 2021 [35]	Randomized parallel-arm, interventional, clinical trial	40 children, aged 4 to 8 years	Both infiltrations and blocks	26 or 30 gauge needle	Not mentioned	20 – Extra oral Vibration 20 – No Extra oral Vibration	Custom device	SEM	Extra oral vibration better
4.	Suohu, et al. 2020 [36]	Randomized parallel-arm, interventional, clinical trial	50 children, aged 5 to 12 years	Infiltrations	Not mentioned	Not mentioned	25 – Traditional syringe with Extra oral Vibration + Cooling 26 – Traditional syringe without Extra oral Vibration + Cooling	Buzzy	WBFP RS FLACC	Extra oral vibration + Cooling better
5.	Bilsin, et al. 2019 [32]	Randomized parallel-arm, interventional, control trial	60 children, aged 7 to 12 years	Mandibular infiltrations	30 gauge needle	-	30 – Extra oral Vibration + Cooling 30 – No Extra oral Vibration + Cooling	Buzzy	WBFP RS	Extra oral vibration + Cooling better
6.	Alanazi, 2018 [37]	Split mouth randomised crossover study	60 children, aged 7 years	Maxillary infiltrations	30 gauge needle	20% benzocaine	30 – Extra oral Vibration + Cooling 30 – No Extra oral Vibration+ Cooling	Buzzy	Heart rate WBFP S FLACC	Extra oral vibration+ Cooling better
7.	Hegde, 2019 [33]	Randomized crossover, split-mouth, clinical study	30 children, aged 6-11 years.	Bilateral inferior alveolar nerve block	Not mentioned	Not mentioned	30 – Extra oral Vibration 30 – No Extra oral Vibration	Custom device	Heart rate WBFP S FLACC	Extra oral vibration better

*Abbreviations used in this table: FLACC, face, legs, activity, cry, and consolability scale; G1, group 1; G2, group 2; G3, group 3; SEM scale, sound, eye, motor scale; VAS, visual analog scale; VCARS, Venham's clinical anxiety rating scale; VPT, Venham's picture test; WB-FPR Scale, The Wong Baker faces pain rating scale.

Risk of bias [RoB] assessment: RoB was assessed using the Cochrane criteria.

RESULTS

In the evaluated electronic databases, 489 articles were retrieved. Duplicates were excluded. A total of 417 articles were screened by the title and abstract. Of these, 24 articles were included for the full-text review. After the full-text analysis, 17 articles were excluded [13, 15-30]. The details of the excluded articles are listed in Table 1. Seven studies were included in the final analysis [31-37]. The search results are presented as a flowchart

in Fig. 1.

Characteristics of the included studies: All published studies from 2018-2021 are shown in Table 2. Five of the seven studies followed a parallel-arm design [31,32, 34-36], and two used the split-mouth design [33,37]. A total of 391 children, aged 4-12 years, received different dental injections, including infiltrations (both maxillary and mandibular) [34,36], maxillary infiltration alone [37], mandibular infiltration alone [32], infiltration and blocks [35], or inferior alveolar nerve block alone [33]. Extraoral vibration and precooling were compared with no extraoral vibration and no precooling in 5 studies [31-33,36,37]. Extraoral vibration and precooling were compared with counter stimulation in one study [34]. Only extraoral

vibration was performed in one study [35]. Extraoral vibration and cooling were delivered using the BUZZY device in 5 studies [31,32,34,36,37]. A custom device was used to deliver vibration in two studies [33,35]. Pain perception was evaluated in six studies [31,32,34,36,37]. Of these, four studies used the Wong Baker faces pain rating scale (WB-FPRS) alone [32,36,37], and one study used the Visual Analog Scale (VAS) only [31]. Furthermore, one study used both the WB-FPRS and VAS [34].

Pain reactions were evaluated in six studies [31,33-37]. The face, legs, activity, cry, and consolability scale (FLACC) and sound, eye, motor scale (SEM) were the most commonly used scales to measure pain reactions. Only FLACC was used in three studies [33,36,37]. Only SEM was used in one study [35]. Another study used both FLACC and SEM [31]. Moreover, heart rate was measured in two studies [33,37].

Risk of bias: Cochrane guidelines were followed to evaluate the risk of bias (Fig. 2 and Fig. 3). Randomization was performed in all included studies (n = 7) [31-37]. There was a single-blinded study [34]. In our opinion, blinding of participants is not feasible because the stimulation due to vibration can be perceived by children, and blinding of outcome assessment was not mentioned in any of the studies. All studies were free from other forms of bias.

Effects of extraoral vibration and cooling on the primary outcome: Children’s perception of pain was evaluated in six studies [31-34,36,37]. Of these, four studies used the WB-FPRS alone [32,33,36,37], and one study used the VAS only [31]. One study used both the WB-FPRS and VAS [34]. Considering all three studies, a significant decline in self-reported pain scores was reported with the use of extraoral vibration and precooling during local anesthesia administration with a mean difference of -3.52; 95% confidence interval [-5.06 -1.98] (Fig. 4).

Effects of extraoral vibration and cooling on the secondary outcomes: Only a few studies reported pain reactions (objective pain, n = 6). FLACC was exclusively

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Alanazi et al 2018	+	?	-	?	+	+	+
AlHareky et al 2021	+	+	-	-	+	+	+
Bilsin et al 2019	+	?	-	-	+	+	+
Hegde et al 2019	+	+	-	-	+	+	+
Sahiti et al 2021	?	?	-	-	+	+	+
Subramaniam and ghai 2021	+	?	-	-	+	+	+
Suohu et al 2020	+	?	-	-	+	+	+

Fig. 2. Risk of bias summary

used in three studies [33,36,37]. SEM was used in one study [35]. Another study used both FLACC and SEM [31]. Few studies included a quantitative analysis. In the pooled mean results of two of the studies, a significant decline in pain reaction was reported with the use of extraoral vibration and precooling during local anesthesia administration, with a mean difference of -1.46; 95% confidence interval [-2.95 0.02], and SEM mean difference -1.93; 95% confidence interval [-3.72 -0.14] (Fig. 5 and Fig. 6).

DISCUSSION

Multiple modalities have been used to mitigate injection pain among children . Vibration is one such modality. The direct intraoral vibratory method has been proven to have a positive effect on pain reduction due

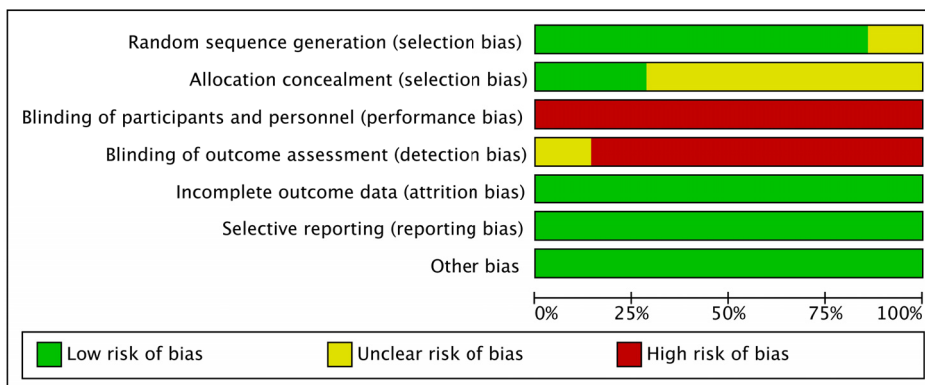


Fig. 3. Risk of bias graph

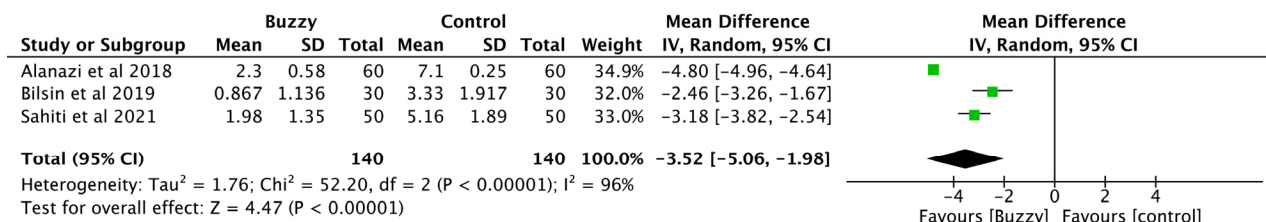


Fig. 4. Pain perception (The Wong Baker FACES scale)

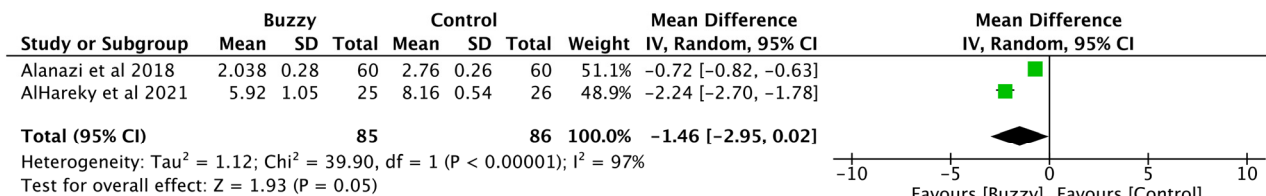


Fig. 5. Pain reaction (Face, Legs, Activity, Cry, and Consolability Scale)

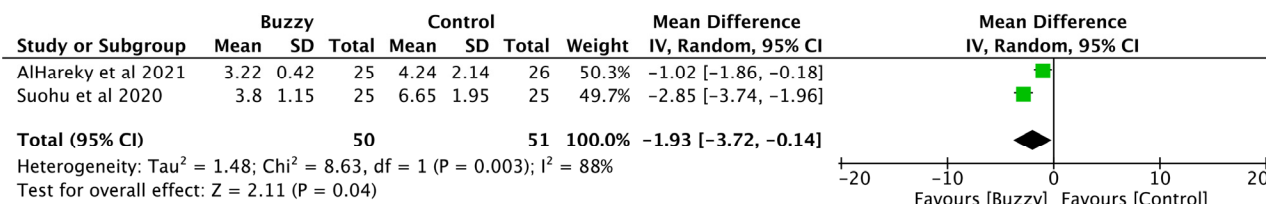


Fig. 6. Pain reaction (Sound, Eye, Motor scale)

to needle prick during intraoral injections [12]. This systematic review aimed to evaluate and quantify the effects of extraoral vibration and pre-cooling on pain reduction during local anesthesia administration in children.

Seven studies qualified for the final qualitative analysis. All studies were randomized controlled trials

[31-37]. Five followed a parallel-arm design [31,32, 34-36], and two used a split-mouth design [33,37]. Children in the qualified studies ranged in age, from 4 to 12 years.

The type of intraoral local anesthesia injections varied across the included studies, and included infiltration (both maxillary and mandibular) [34,36], maxillary infiltrations

alone [37], mandibular infiltrations alone [32], infiltrations and blocks [35], and inferior alveolar nerve block alone [33]. The intervention groups used extraoral vibration with cooling [31-33,36,37], the control groups had no intervention [31-33,36,37], or use counter-stimulation [34]. Most of the studies used 26-or 30-gauge needles, apart from Sahiti et al. (2020). Sahiti et al. reported using 23-gauge needles [34]. The use of topical anesthesia (20% benzocaine) was reported in only two studies [31,34].

Child-reported pain scores for intraoral dental injections were assessed with and without extraoral vibration and cooling. Child-reported pain scores were assessed in six studies using the WB-FPRS scale. In these studies, self-reported pain scores were significantly lower in the extraoral vibration and cooling group than in the control group. In the pooled results of the three studies, a significant reduction in self-reported pain scores by the child was found to be associated with the use of extraoral vibration and precooling during local anesthesia administration mean difference -3.52; 95% confidence interval [-5.06 -1.98] (Fig. 4).

Pain reaction was evaluated in a few studies using FLACC and SEM [33,36,37]. In all the evaluated studies, the pain reaction was significantly lower in the extraoral vibration and cooling group than in the control group. In the pooled results of the two studies, a significant reduction in pain reaction by the child was found to be associated with the use of extraoral vibration and precooling during local anesthesia administration (FLACC, mean difference -1.46; 95% confidence interval [-2.95 0.02]; SEM mean difference -1.93; 95% confidence interval [-3.72 -0.14]) (Fig. 5 and Fig. 6).

Summary of evidence: Extraoral vibration plus cooling is a feasible and effective measure for pain reduction during local dental anesthesia administration in children. In comparison with the control group, significant differences were found in the pooled results of pain perception and reaction when combined extraoral vibration and cooling was used.

Limitations of the review: Blinding of participants is not feasible. In the included studies, extraoral vibration

and cooling can be sensed by the children. The sources of extraoral vibration and cooling varied between the included studies. Combined extraoral vibration and cooling was delivered using BUZZY device in 5 studies [31,32,34,36,37] and a custom device was used to deliver vibration in two studies [33,35]. The location of intraoral local anesthesia administration was not the same in all studies. Few studies evaluated block injections, a few evaluated infiltrations alone, and other studies evaluated both infiltrations and blocks (both maxillary and mandibular) [34,36], maxillary infiltrations alone [37], mandibular infiltrations alone [32], infiltrations and blocks [35], and inferior alveolar nerve block alone [33]. Furthermore, only a few studies evaluated pain reactions [33,36,37].

Strengths of this study: Only studies reporting extraoral vibration plus cooling at the site of local anesthesia administration were assessed. To the best of our knowledge, this is the first systematic review to report an association between extraoral vibratory stimulus plus cooling, and pain perception during dental local anesthesia administration in children.

Directions for Future Research: 1. Future research should aim to optimize the magnitude of extraoral vibration for alleviating pain due to intraoral injections. 2. Studies on the effect of extraoral vibration plus cooling on the inferior alveolar nerve block exclusively, in children or adults, with adequate sample size, should be considered.

Conclusions: Based on the available results, the conclusions are as follows.

1. The use of extraoral vibration plus cooling as a counter-stimulatory measure is effective in reducing the pain perceived by children during intraoral local anesthesia administration.
2. The risk of bias was high in most of the studies. Therefore, the quality of evidence was considered low.

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