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Evaluation of pain, disruptive behaviour and anxiety in children aging 5-8 years old undergoing different modalities of local anaesthetic injection for dental treatment: a randomised clinical trial

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ABSTRACT

Objective: To evaluate the influence of different local anaesthetic techniques in pain, disruptive behaviour and anxiety in childrens dental treatment.

Material and methods: This was a randomised and parallel clinical trial. The sample consisted of 105 children (5–8 years old) that were divided into three groups ($n = 35$) according to the anaesthetic technique: conventional anaesthesia (CA); vibrational anaesthesia (VBA); computer-controlled local anaesthesia delivery (CCLAD). The outcomes were self-perception of pain (Wong-Baker Faces Pain Rating Scale – WBF; Numerical Rating Scale – NRS); disruptive behaviour (Face, Legg, Activity, Cry, Consolability Scale – FLACC); anxiety (Corah's Dental Anxiety Scale; modified Venham Picture test – VPTm) and physiological parameters (blood pressure – systolic – SBP and diastolic – DBP; heart rate – HR; oxygen saturation – SpO2; respiratory rate – RR). Data were statistically analysed with Kruskall-Wallis test and ANOVA for repeated measures with Tukey post hoc test ($\alpha = 0.05$).

Results: All the patients exhibited the same level of dental anxiety at baseline (Corah's Dental Anxiety Scale). There was no difference in self-perception pain, irrespective the evaluation tool used (WBF – $p = .864$; VAS – $p = .761$). No differences were detected in disruptive behaviour (FLACC – $p = .318$); anxiety (VPTm – $p = .274$); blood pressure (SBP – $p = .239$; DBP – $p = .512$); heart rate ($p = .728$); oxygen saturation ($p = .348$) and respiratory rate ($p = .238$) between anaesthetic techniques.

Conclusion: Different anaesthetic dental local techniques do not affect the levels of pain, disruptive behaviour, anxiety and physiological parameters in children aged 5–8 years old.

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Local anaesthesia; paediatric dentistry; pain management

Introduction

Pain control is critical to successful paediatric patient management and dental local anaesthesia is the most used method to eliminate pain during dental treatment. However, the use of needles is known as a trigger to fear and anxiety. Taking into account that local anaesthesia is the first phase of any invasive treatment, paediatric dentists must perform anaesthetic procedures without causing any adverse repercussions for behaviour management [1].

A significant number of patients still perceive local anaesthesia administration as a painful and anxiety-causing dental procedure [2]. For paediatric patients, the fear of dental treatment is usually linked to the psychological and physical trauma associated with needles and syringes for local anaesthesia; a painful injection during local anaesthetic administration may be considered the main reason for anxiety behaviours and defensive reactions [3].

To minimise or even to avoid the pain associated with local anaesthesia, different devices have been developed, with different technical and biological approaches.

Computer-controlled local anaesthetic delivery (CCLAD) has been firstly introduced in 1997 and since then it has been a topic for several clinical investigations. The theory behind the use of these computerised systems states that if the anaesthetic solution is delivered in specific flow and velocity rates, it will be compatible with tissue acceptance, resulting in reduced pain perception and, consequently, decreased patient anxiety levels [4].

The vibrational anaesthesia (VBA) is another alternative that seeks to minimise the discomfort during local anaesthesia. According to the pain gate theory, the stimulation of larger diameter nerve fibres by vibration stimulates mechanoreceptors to activate inhibitory neurons, which blocks smaller neurons and consequently prevents pain recognition [5]. The VBA promotes micro oscillations at the injection site and these pulsed oscillations close the gates of pain [6]. The device used for this purpose is the DentalVibe^{TM} (Accumedix, Grayslake, IL, USA).

There are different clinical trials that study the computerized [7–11] or the vibrational techniques [2,12–14] for local anaesthesia in children. Some studies evaluate pain and anxiety related to dental anaesthesia, comparing conventional

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anaesthesia (CA) and CCLAD [3,15,16] and others that compare CA and VBA analyzing only pain [6,12]. However, it is common to observe that these studies embrace large age ranges, including from preschoolers to teenagers [17–20] and age is a factor that must be taken into account because according to Oliveira *et al.* [21], the anxiety related to dental treatment is different between age ranges, whereas younger children have higher dental anxiety [21]. Also, to the knowledge of these researchers, this is the first study that compares CCLAD and VBA considering patient-reported outcomes and physiological parameters related to pain, disruptive behaviour and anxiety caused by different anaesthetic techniques in children.

Thus, the objective of this research is to evaluate the influence of different anaesthetic techniques in pain, disruptive behaviour and anxiety in dental treatment of children from 5 to 8 years old.

Material and methods

This paper has been prepared according to the protocol established by the Consolidated Standards of Reporting Trials statement – CONSORT [22].

Ethical approval

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for the accomplishment of this study (#1.941.369). All participants were informed about the nature and objectives of the study. After that, Informed consent forms were obtained from parents/guardians of the participating patients; all participating children that were alphabetised also signed assent forms.

Protocol registration

This clinical trial was registered in Clinicaltrials.gov, under protocol # 64773417.3.0000.5689.

Trial design, settings and locations of data collection

This was a randomised and parallel clinical trial with an equal allocation ratio. Three different study groups were defined, according to different anaesthetic techniques (conventional anaesthesia – CA, vibrational anaesthesia – VBA and computer control local anaesthesia delivery – CCLAD).

All procedures in selected volunteers were performed from November 2017, to November 2018. The study was conducted in the dental practice office at an elementary school called Integral Care Centre for Child and Adolescent Reitor Alvaro Augusto Cunha Rocha in Ponta Grossa State University (CAIC-UEPG) and paediatric dental clinics from the Department of Dentistry at Ponta Grossa State University (UEPG), Ponta Grossa, Paraná, Brazil.

Recruitment

The subjects were included in the study by convenience sampling. Children were invited to participate when seeking dental care at the university or the elementary school, according to eligibility criteria.

Inclusion criteria: Children aged 5–8 years, with cognitive conditions compatible with chronological age and in need of restorative treatment in the upper posterior teeth under local anaesthesia.

Exclusion criteria: children undergoing medical treatment at the moment of the intervention or who take drugs of continuous use that contraindicate the injection of local anaesthetics, children with a history of anaesthetic allergy, children with definitely negative behaviour according to the Frankl behaviour scale [23] and those who were not authorised by their parents or guardians.

Sample size

The sample size calculation was done considering the primary outcome 'pain'. In this way, the mean pain levels obtained by Palm [9] were used. Considering a power of 95% and a significance level of 5%, in a superiority clinical trial, the final sample was composed of 105 children, with 35 subjects per study group. The sample size calculation was done using the site sealedenvelope.com (Sealed Envelope Ltd, London, UK).

Random sequence generation and allocation concealment

A staff member not involved in the research protocol performed the randomisation and allocation processes.

Computer-generated tables with blocked randomisation (block size of 5) and an equal allocation ratio were obtained, considering the three study groups. The allocation concealment was accomplished by distributing the obtained codes in numbered black opaque envelopes, which were opened only on the day of the dental treatment, immediately before the local anaesthesia, consequently, the operator blinded until this moment.

These procedures were accomplished also in the site sealedenvelope.com (Sealed Envelope Ltd, London, UK).

Anaesthetic procedures

Anaesthesia

All local anaesthetic procedures were performed by the same experienced dentist (P.C.S.). The protocol included the use of topical anaesthesia with benzocaine 20% for 60 s, infiltrative anaesthetic technique with 1.8 mL of lidocaine 2% with epinephrine 1:100,000 anaesthetic and a flow rate of 1.0 mL per minute. All techniques used short needles of size 25 mm × 0.3 mm (30 G) (Unoject – DFL, Misawa Medical Industry Co. Ltd. Japan) for anaesthetic injection. For the puncture of the needle, the bevel was directed towards the alveolar mucosa, and through a light pressure it penetrated the soft tissue gradually and the local anaesthetic was delivered to the site of interest, according to the technique protocol. All anaesthetic injection procedures were controlled by a chronometer.

Conventional anaesthesia

For the puncture of the needle, the bevel was directed towards the alveolar mucosa, and through a light pressure, it penetrated the soft tissue, with bone contact avoided as it may cause discomfort. The local anaesthetic was delivered to the site of interest. Once it was confirmed negative aspiration, 1.8 mL of anaesthetic solution was injected over during 108 s. The needle was removed gently after the completion of the injection.

Vibrational anaesthesia

The VBA was performed with the aid of a device named DentalVibe^{TM} (Columbia Tech, Boston, USA). After topical anaesthesia, the device was positioned on the mucosa at the puncture site and turned on, transmitting a local vibration. After 10 s, the puncture was performed at the site located at the mean distance between the two ends of the vibrational device for anaesthetic delivery. The injection of the anaesthetic drug was done with a conventional syringe.

Computerised anaesthesia

For CCLAD, the equipment Morpheus^{TM} (Meibach Tech, São Paulo, Brasil) was used. A predetermined programme with a flow rate of 1.0 mL per minute was selected. After topical anaesthesia, the puncture was performed with the introduction pedal activated; shortly after, the aspiration button was selected, and if there was no positive aspiration, the injection pedal was activated for anaesthetic delivery. The injection of the anaesthetic drug was done with a syringe provided by the Morpheus manufacturer.

Outcomes and evaluation tools

Primary outcomes

Self-perception of pain. The self-perception of pain was evaluated with the Wong Baker Faces Pain Rating Scale (WBF) and Numerical Rating Scale (NRS). The Wong Baker Faces Pain Rating Scale (WBF) is scale when including pictures of facial expressions with correlating numbers of 0–10 (0 being 'no hurt' and 10 being 'hurts worst'). The Numerical Rating Scale (NRS), containing eleven points (0–10, where 0 means no pain, 10 means the worst possible pain) [17].

Disruptive behaviour. For the evaluation of children's disruptive behaviour during anaesthesia, the Faces, Legs, Activity, Cry, Consolability scale (FLACC) [24] was used. The results range from 0 to 10, originating the following classification: score 0 – the patient is considered relaxed and comfortable; score 1 to 3 – mild discomfort; score 4 to 6 – moderate pain; 7 to 10 – severe pain.

Secondary outcomes

Analysis of fear and anxiety related to dental treatment. All the children answered a specific questionnaire named Corah's Dental Anxiety Scale (Corah) [25,26] to identify and classify the level of fear and anxiety related to dental treatment. The author reported good reliability with the use of this questionnaire (internal consistency = 0.86; test-retest = 0.82) [25,26].

It is a four-item questionnaire with 4 questions to be answered by the patients that indicate their emotional reaction to a dental visit. The result ranges from 4 to 20. The scores classify the patient as 'anxiety-free' (score 4); 'moderate anxiety' (scores 5–10); 'high anxiety' (scores 11–15) and 'severe anxiety' (scores 16–20).

Analysis of the emotional state of anxiety. The Venham Picture Test modified (VPTm) [27] was performed to determine the child's emotional state of anxiety during different phases of the study.

VPTm consists of 8 pictures representing feelings ranging from anxiety to contentment. The children were asked to select the picture that better described their feelings at that specific moment. Negative feelings scored one point; positive feelings did not score. The sum of the responses ranges from 0 to 8 and the level of patient's anxiety is classified as 'anxiety-free' (score 0); 'low anxiety level' (scores 1–3); middle anxiety levels (scores 4–6) and 'high anxiety level' (7–8).

Physiological parameters. Volunteers were evaluated for systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), oxygen saturation (SpO_2) and respiratory rate (RR) by the Inmax^{TM} multiparametric monitor (Instramed, Porto Alegre, Brazil). SBP and DBP were measured before and during the anaesthetic procedures; for HR, SpO_2 and RR the values were recorded every 15 s during the procedure and the average was calculated and recorded in the individual file of the patient [7].

Intervention

The research protocol considered four moments to collect data about the patient-reported outcomes, patient-centred outcomes and physiological parameters. These moments were: T1 (before treatment); T2 (at the dental office, when the child is called out to take his/her place at the dental chair); T3 (during local anaesthesia) and T4 (immediately after local anaesthesia). All obtained data were recorded in a clinical file that was developed specifically for this research purpose. One assistant investigator was responsible for recording the data, as well as to guarantee the confidentiality of the patient's identification, which was replaced by a number. The sequence of the procedures is depicted in Figure 1.

T1 and T2 consisted in a pre-operatory evaluation that aimed to identify the baseline parameters regarding the volunteer's fear and anxiety related to dental treatment (Corah) and emotional state (VPTm), as well as the physiological parameters. The questionnaire regarding anxiety (Corah) was

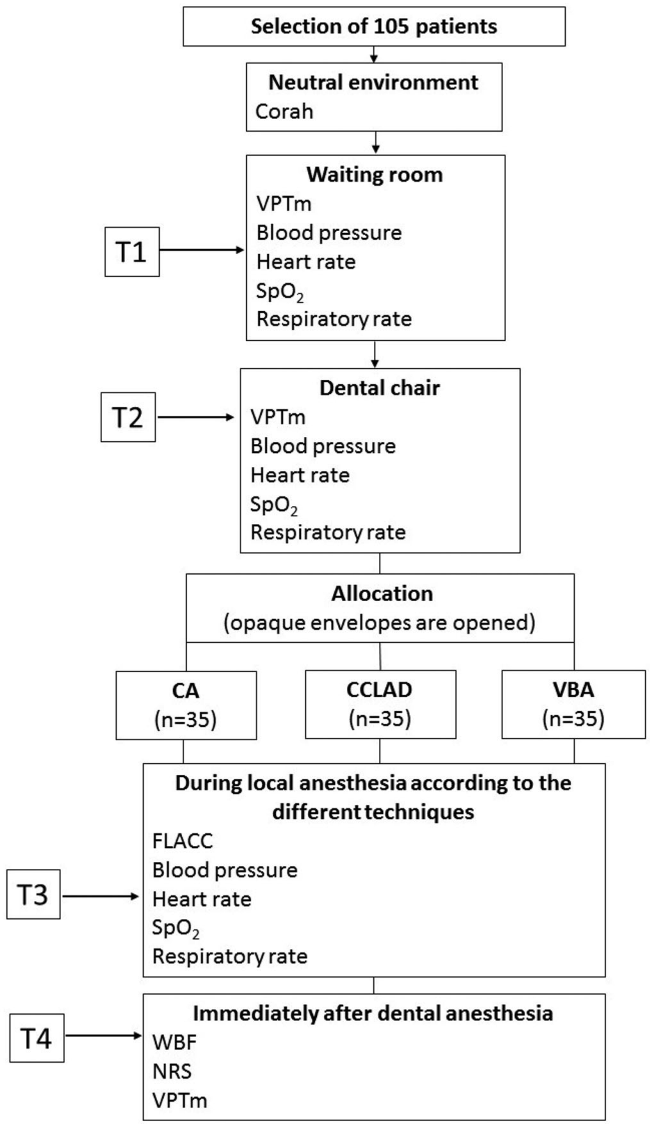

Figure 1. Flow diagram of the different phases of the study.

administered in a neutral environment; the other outcomes were measured at the waiting room of the dental office (T1). Once the child was sitting on the dental chair (T2), systolic and diastolic blood pressures, heart rate, oxygen saturation, respiratory rate and VPTm scores were recorded again.

After that, the main researcher, who was the single operator of this study, opened the opaque envelope to find out the anaesthetic technique that should be performed on that specific patient. This was the beginning of T3. During this trans-operatory phase, an assistant researcher recorded the anaesthetic procedure; this video was evaluated later, according to the FLACC criteria. The physiological parameters were recorded again.

Immediately after anaesthesia, at T4, the VPTm test was repeated and the pain self-perception tests (WBF and NRS) were also applied. At the end of the data collection, the dental treatment was done as usual. Usual measures of behavioural control, namely communication and communicative orientation, and behaviour management techniques such as tell-show-do, voice control, nonverbal communication, positive reinforcement and distraction, were used in all cases.

Blinding

The operator and the patients were not blinded to the anaesthetic techniques, since the devices that are needed to execute the techniques are very specific and cannot be disguised or hidden. Notwithstanding, the data analysis was done without the statistician knowing the study groups.

Evaluators

Evaluators were trained previously to apply the evaluation tools related to dental fear/anxiety, self-perception of pain, disruptive behaviour and physiological parameters. One auxiliary researcher applied the questionnaires Corah, VPTm, WBF, NRS and another one registered the physiological parameters.

A calibrated researcher performed the analysis of the recorded videos during anaesthesia application to determine the index of disruptive behaviour (FLACC). To gain reliable results, the evaluator was trained and calibrated (intra evaluator Kappa = 0.90) before analysis.

Statistical analysis

Statistical analysis was performed using the SPSS version 15.0 statistics programme (SPSS Inc., Chicago, IL, USA). A descriptive analysis was performed. The nonparametric data obtained after the application of the different tests (Corah, WBF, NRS, FLACC) were submitted to Kruskal-Wallis for unpaired analysis. ANOVA for repeated measures with post – hoc test of Tukey was used to compare the VPTm, SBP, DBP, HR, RR and SpO_2 data between the phases and groups of the study. Pearson correlation tests were also performed for Corah, VPTm, WBF, NRS and FLACC. All tests were performed with a significance level of 0.05.

Results

A total of 189 patients were examined and 84 were excluded from the sample because they didn't fulfil the inclusion criteria. A total of 105 children composed the research sample and all of them completed the study. The experimental protocols were implemented as planned (Figure 2). The mean age was 6.56 ± 0.9; the gender distribution was 53 males (50.47%) and 52 females (49.52%).

Dental anxiety (corah's dental anxiety scale)

It's important to mention that similar levels of dental anxiety were detected in the subjects at the baseline (Table 1). The majority of the research subjects showed moderate dental anxiety (40%), without differences regarding genders ($p = .976$) or between the study groups ($p = .283$) (Table 2).

Anxiety emotional state (VPTm)

To identify the child's emotional state of anxiety, the VPTm test was used at T1, T2 and T4. The sample remained

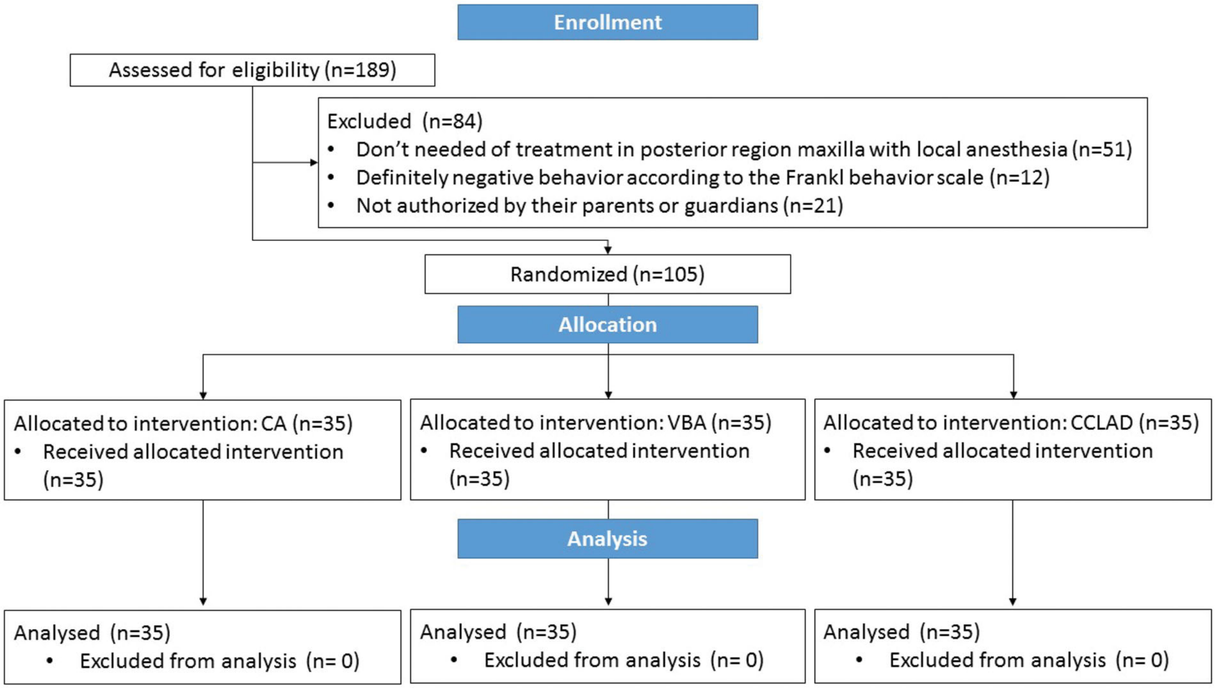

Figure 2. Sample analysed flow diagram (CONSORT).

Table 1. Dental anxiety at the baseline according to the study groups (Corah's Dental Anxiety Scale).

Dental Anxiety	CA	VBA	CCLAD	*p*-Value
Median (interquartile range)	2 (1–4)[a]	3 (1–4)[a]	2 (1–4)[a]	.283
Mean ± SD	2.31 ± 0.93[a]	2.62 ± 0.91[a]	2.31 ± 0.93[a]	

[a]Lowercase letters in the same line means no significant difference between groups ($p < .05$).

Table 2. Relative (absolute) frequencies of the fear and anxiety related to dental treatment (Corah) according to the patients̀ gender.

	Gender		
Dental Anxiety Levels	Male % (*n*)	Female % (*n*)	Total % (*n*)
Anxiety free	9.52% ($n = 10$)	6.66% ($n = 7$)	16.19% ($n = 17$)
Moderate anxiety	18.09% ($n = 19$)	21.90% ($n = 23$)	40.00% ($n = 42$)
High anxiety	17.14% ($n = 18$)	12.38% ($n = 13$)	52.00% ($n = 31$)
Severe anxiety	6.66% ($n = 7$)	7.61% ($n = 8$)	14.28% ($n = 15$)
p value	0.976		

Table 3. Anxiety emotional state (VPTm) according to study groups and study phases [median (interquartile range) and Mean + Standard Deviation].

	CA	VBA	CCLAD	*p*-Value
T1	1 (1–4)[a]	1 (1–3)[a]	1 (1–4)[a]	.487
	1.22 ± 0.59[a]	1.31 ± 0.52[a]	1.45 ± 0.85[a]	
T2	1 (1–4)[a]	1 (1–3)[a]	1 (1–4)[a]	.740
	1.42 ± 0.73[a]	1.42 ± 0.73[a]	1.57 ± 0.88[a]	
T4	2 (1–4)[a]	1 (1–4)[a]	1 (1–4)[a]	.274
	1.77 ± 0.87[a]	1.54 ± 0.88[a]	1.54 ± 0.81[a]	

Lowercase letters in the same line means no significant difference between groups ($p < .05$).

homogeneous, there was no difference in emotional state at T1 ($p = .487$), T2 ($p = .740$) and T4 ($p = .274$), in the same study group (Table 3).

Notwithstanding, when considering all the patients included in the sample, without group divisions, significant differences were observed between the moment before treatment (T1), at dental office (T2) and after anaesthesia (T4) ($p = .003$).

Self-perception of pain (WBF and NRS) and disruptive behaviour (FLACC)

The self-perception of pain was analysed through patient-reported outcome using WBF and VAS; disruptive behaviour was analysed using FLACC as a patient-centred outcome.

No difference between anaesthetic techniques was observed in self-reported pain, irrespective of the scale used (WBF – $p = .864$; NRS – $p = .761$) (Table 4). The same was observed regarding disruptive behaviour (FLACC – $p = .318$).

It was also observed that there is a poor correlation between disruptive behaviour and self-perception of pain (WBF – rho = .377, $p < .001$; NRS – rho = .300, $p = .002$).

Physiological parameters

No differences were detected in systolic and diastolic blood pressures, heart rate, respiratory rate or oxygen saturation when the three different anaesthetic techniques were used ($p > .05$).

The analysis of the overall sample showed that there is a difference in the means of SBP ($p = .022$), DBP ($p = .012$), HR ($p < .0001$) and RR ($p < .0001$) when the different moments (T1, T2, T3) of the dental appointment are considered (Table 5).

Table 4. Self-perception of pain (Wong Baker Faces and Numerical Rating Scale) according to study groups immediately after dental local anaesthesia (T4) [median (interquartile range) and Mean + Standard Deviation].

Evaluation of pain	CA	VBA	CCLAD	*p*-Value
WBF	2 (0–10)[a]	0 (0–10)[a]	0 (0–10)[a]	.864
	2.34 ± 3.0[a]	2.05 ± 2.88[a]	2.57 ± 3.31[a]	
VAS	2 (0–9)[a]	1 (0–10)[a]	1 (0–10)[a]	.761
	2.54 ± 2.94[a]	2.45 ± 3.22[a]	2.88 ± 3.39[a]	
FLACC	1 (1–3)[a]	1 (1–3)[a]	1 (1–3)[a]	.381
	0.80 ± 0.63[a]	1.08 ± 0.78[a]	1.00 ± 0.93[a]	

[a]Lowercase letters in the same line means no significant difference between groups ($p < .05$).

Discussion

This study aimed to verify if the use of different anaesthetic devices could improve the dental experience during anaesthetic procedures in children regarding anxiety, pain and disruptive behaviour. Also, to our knowledge, this is the first paper that compares vibrational and computerised anaesthesia in children. The obtained results favour the conventional anaesthetic technique as the most cost-effective procedure.

No difference in pain perception was observed when comparing conventional, computerised and vibrational anaesthesia in children aged 5–8 years old. This result is corroborated by several studies in the literature that compared conventional and computerised anaesthesia [7,10,11,17,20] or conventional and vibrational anaesthesia [6,28]. On the other hand, some papers state less pain perception with the use of computerised anaesthesia [8,18,29,30] or vibrational anaesthesia [5,31]. These conflicting results came from studies in which samples comprised children from 3 to 15 years old, and, the large age range in some of them may be a problem for self-reporting pain levels, introducing information bias to the study.

Pain perception is a multidimensional subjective response. Having said that, it is important to discuss the different aspects in a research that can influence this response.

It is known that toddlers and preschoolers do not understand abstract concepts; therefore, it may be difficult for them to discriminate the intensity of the pain because their descending control mechanisms are immature, limiting their ability to modulate the experience. Three or four years old children tend to select the extreme ends of pain scales, neglecting the middle portion of continuous or multiple-item scales. The ability to quantify pain experiences will be accurate only in 5 years old children. Conversely, adolescents tend to avoid manifestations of pain, because of fear of embarrassment, which may reflect in decreased reported levels of pain [32]. That is why the present study used a narrower age range, where the pain responses tend to present a similar analysis by the patients.

The level of dental anxiety at baseline is another variable that is not assessed by the studies usually. In this research, it was detected a moderate level of dental anxiety in the patients, resulting in a homogeneous sample. This is important because dental anxiety is a significant predictor for pain perception in children and adolescents [33] and anxious children tend to overestimate the intensity of pain [33,34],

Table 5. Physiological parameters according to the different anaesthetic techniques and dental appointment moments.

Physiological Parameters	CA T1	CA T2	CA T3	VBA T1	VBA T2	VBA T3	CCLAD T1	CCLAD T2	CCLAD T3	*p*-Value
Systolic blood pressure	107,48 ± 10,03[a]	102,40 ± 12,79[a]	102,17 ± 12,04[a]	106,20 ± 13,46[a]	105,74 ± 12,20[a]	106,22 ± 12,55[a]	103,40 ± 11,67[a]	102,94 ± 10,90[a]	99,88 ± 9,66[a]	.239
Diastolic blood pressure	81,60 ± 9,53[a]	76,77 ± 11,91[a]	75,31 ± 12,06[a]	80,71 ± 9,47[a]	78,45 ± 10,78[a]	81,08 ± 11,82[a]	78,42 ± 12,76[a]	77,74 ± 8,23[a]	76,80 ± 9,83[a]	.512
Heart Rate	93,45 ± 16,62[a]	92,00 ± 15,71[a]	95,20 ± 17,69[a]	92,02 ± 12,53a[a]	90,68 ± 11,65[a]	95,88 ± 12,66[a]	91,88 ± 14,29[a]	87,48 ± 12,98[a]	94,02 ± 14,26[a]	.728
SpO_2	96.68 ± 0.93[a]	96.97 ± 0.98[a]	96.77 ± 1.11[a]	95.74 ± 2.35[a]	96.60 ± 1.19[a]	96.40 ± 1.57[a]	96.68 ± 1.05[a]	96.51 ± 0.95[a]	96.48 ± 1.06[a]	.348
Respiratory rate	20.85 ± 3.89[a]	21.34 ± 3.94[a]	23.37 ± 5.24[a]	20.08 ± 3.52[a]	20.60 ± 3.95[a]	24.22 ± 5.61[a]	19.57 ± 2.86[a]	20.88 ± 3.37[a]	21.17 ± 4.08[a]	.238

[a]Lowercase letters in the same line means no significant difference between groups ($p < .05$).

including pain from local anaesthetic injection [35]. Therefore, in our sample, the reported pain data were obtained from patients with similar levels of anxiety at baseline.

Another aspect that needs to be addressed is the site and the technique of the anaesthesia. It is not uncommon in the literature studies that compare different anaesthetic techniques using different sites of injection. For instance, some papers included buccal and palatal infiltration [15,18,29,36] or buccal and palatal infiltration compared to inferior alveolar nerve block [11,17,37]. A palatal infiltration or a nerve block are much more painful than a buccal infiltration [38] and it probably would result in more intense responses. We used the infiltrative terminal anaesthetic technique in the posterior region of the maxilla for all study groups. This is a site of less anatomical variation that facilitate the anaesthetic procedure allowing to identify the real influence of the different anaesthetic devices in the patient's response to the anaesthesia.

Self-report methods are considered the gold standard for the assessment of pain [32]. Even so, to improve the assessment of pain, multiple tools, both patient-reported and centred, were used for a more accurate appraisal of children's pain experience: the Wong Baker Faces, which is a nonverbal tool with pictures; NRS, a numeric dimension tool; and FLAAC, an observational tool that identifies disruptive behaviour related to pain. The methodology was defined to favour a multidimensional assessment of pain.

Pain activates the compensatory mechanisms of the autonomic nervous system, which results in physiological responses like tachycardia, peripheral vasoconstriction, diaphoresis, pupil dilation, and increased secretion of catecholamines and adrecorticoid hormone [32]. Therefore, physiological parameters can complement the pain self-report, although they can not be the only indicators because they are not specific for pain response.

Physiological parameters such as heart rate and systolic blood pressure tend to increase in acute pain [39] with changes of 10% to 20% [32]. There is also an increase in the respiratory rate as a pain response [40]. Consequently, higher respiratory rates result in higher oxygen saturation. However, in the present study, this relation was not observed; besides, no correlations between these physiological parameters and pain self-perception were found.

It was identified that the systolic blood pressure decreased between the different moments of the study. This is probably due to the child's position. At T1, the child was sitting in a common chair; at T2 on the dental chair, but still at rest, and at T3 the child was lying down, which caused a gradual decrease in systolic blood pressure. Even without statistical differences, vibrational anaesthesia resulted in higher levels of systolic and diastolic blood pressures. This may be explained by the fact that physiological parameters are also influenced by anxiety levels, and vibrational anaesthesia is the technique that introduces greater changes to the conventional anaesthetic procedure when compared to computerised and traditional anaesthesia.

The different anaesthetic techniques did not influence the heart rate. This was corroborated by other studies that evaluated this parameter regarding computerised X conventional [10,41] or vibrational X conventional anaesthesia [5].

Taking all the former cited parameters together, we can state that the use of different local anaesthetic techniques will not contribute to minimise or eliminate the pain or anxiety related to dental anaesthesia in children of the 5 at 8 years old.

Notwithstanding, the emotional state of the patients is affected by the anaesthetic procedure itself, without the influence of the different devices used. The use of VPTm in different moments (at the waiting room, at the dental chair before anaesthesia and after anaesthesia) showed that anxiety increases after the local anaesthesia. In a secondary analysis, it was also observed a correlation between children's emotional state/anxiety and the self-reported pain levels.

Therefore, the behavioural response of children after dental anaesthesia is often a mixture of anxiety and pain [37]. Consequently, in a split-mouth design, the first procedure could influence the subsequent pain report after the anaesthesia in a second dental appointment. It's is known that early treatment sessions seem to exert influence on the behaviour and the perception of pain during dental anaesthesia, especially with highly anxious young [42]. This was observed in a clinical trial with 120 patients (7–11 years old), comparing computerised and conventional anaesthesia, that found difference in the disruptive behaviour only in the second anaesthetic procedure [43]. Considering that, a parallel design was implemented in this research. However, since we did not investigate the children's previous dental experience, our sample probably included children that have never been treated as well as patients with previous dental experiences, this situation could be a possible limitation of the study and demands further researches to corroborate our findings.

This study aimed to analyse the majority of the factors that influence the interpretation/measurement of pain in children (disruptive behaviour, anxiety, physiological parameters, as well as self – perception of pain) and how they would be related to the different anaesthetic techniques. To the authors' knowledge, this is the first paper that included all these parameters in a single clinical trial and we encourage similar future researches to clarify if our findings can be applied to other anaesthetic sites, techniques and age ranges.

Conclusion

In the light of the obtained results, there is no advantages in the inclusion of vibrational or computerised anaesthetic devices in paediatric dental practice, since different anaesthetic dental local techniques do not affect the levels of pain, disruptive behaviour, anxiety and physiological parameters in children aged 5–8 years old.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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