

Comparative Evaluation Related to Pain in Children Submitted to Dental anesthesia with or Without Vibration

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Abstract

Experience: The effect of the action of vibration in pain analgesia is relatively well established, however little is known about the real effect of vibration on pain reduction.

Objective: To compare children's reactions when undergoing dental local anesthesia using an anesthesia device that produces micro-vibrations.

Method: Thirty children underwent two types of anesthesia: with and without vibration. The anesthetic procedures were filmed and consisted of maxillary posterior infiltration anesthesia. A combination of tests was used to evaluate the multidimensional character of fear, anxiety, and pain. The tests were applied before and after the anesthetic procedures. At the end of the second anesthesia session, the children reported their preferences regarding the use of vibration or not.

Results: It was found that 90% of the children preferred anesthesia with vibration. A statistically significant difference was found in the Visual Analogue Scale (VAS) when comparing the mean values ($p=0.04$) using selective criteria at a 5% significance level.

Conclusion: Vibration seems to have a positive influence on the children's perception during local anesthetic procedures.

Keywords: Pediatric dentistry; Anesthesia; Vibration

Introduction

Dentistry has made great scientific advances, however people continue to correlate dental procedures with pain. Local anesthesia is frequently used to minimize pain, although the anaesthetic technologies cause considerable discomfort to patients. Fear of pain associated with the dentist is strongly related to the application of intraoral local anesthesia, which is the most common method for pain block during dental procedures. There are electronic injection systems on the market that have been developed to promote less uncomfortable local anesthesia in dentistry [1,2].

These systems control the anesthesia flow-rate delivery into the perioral tissues which, according to the manufacturers, promotes less painful anesthesia [3]. In addition to the computerized systems that control flow rate during the administration of dental local anaesthesia, there are other techniques that use vibratory stimuli to alleviate pain [4,5]. Research on vibration to control pain began in 1965 when Ronald Melzack and Charles Patrick Wall proposed the concept of Gate Control Theory of Pain. The mechanism of pain inhibition using vibratory stimuli is based on mechanical stimuli in which A- β nerve fibers transmit information from vibration receptors and touch receptors on the skin. They stimulate inhibitory interneurons in the spinal cord that in turn act to reduce the amount of pain signal transmitted by A- σ and C fibers from the skin to second-order neurons that cross the midline of the spinal cord and then ascend to the brain [6,7]. Since then, research on the use of vibration in analgesia has grown significantly. Nowadays, there are devices on the market that vibrate during dental local anesthesia which, according to the manufacturers, provide less painful anesthesia [7-11].

Studies have shown divergent results as to the effectiveness of using syringes with micro-vibrations developed for dental local anesthesia. The SMV (syringe micro vibrator), patent registered by Iran National Patent number 63765, is a device in development intended to reduce

stress and pain during anesthetic administration⁸ and it is similar to Vibraject® (vibrating dental local anesthesia attachment available on the market) [9], however, argue that Vibraject® is not effective in reducing pain of local anesthetic in children. Other studies found no significant results in pain reduction during local anesthesia when using vibration [10,11].

In view of the above, the aim of this study was to analyze the effectiveness of vibration using a device developed at the School of Pharmacy, Dentistry, and Nursing, Federal University of Ceará (UFC-FFOE), patent pending at INPI-BR (National Institute of Industrial Property) No 1020130230740 (Figure 1). The device uses vibration during the procedure of dental local anesthesia, and although it produces micro-vibrations, its design is different from Vibraject®.

Materials and Methods

This is a random clinical trial with a control group and the null hypothesis is that the vibration produced by the device during administration of local anesthesia in children would not influence pain reduction. The primary conclusion of the study was to assess patients' pain and discomfort.

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Figure 1: Dental local anesthesia device developed by the School of Pharmacy, Dentistry and Nursing of the Federal University of Ceara, Brazil.

Participants

The study began after it was approved by the Ethics Research Committee of the Federal University of Ceara (report No 240/202). Thirty girls and boys with ages between 7 and 12 attended at the School of Pharmacy, Dentistry, and Nursing of the Federal University of Ceara during the first semester of 2013, were invited to participate in the study.

The children consented verbally and the parents or guardians signed a term of free and informed consent. The inclusion criteria for the child to participate in the study were as follows: no systemic alterations such as psychological or developmental disorders (motor, sensorial or cognitive), and at least one tooth in each maxillary hemiarch (54, 55, 64, 65 and/or 14, 15, 16, 24, 25, 26) [12,13] that required dental treatment using local anesthesia.

Those who were undergoing medical treatment, using medications that alter sensitivity to pain perception, presented any signs of hypersensitivity to any component of the anesthetic solution, or presented ulcers or alterations in the mucosa were excluded.

Clinical Procedures

We used different scales to assess anxiety and amount of pain during local anesthesia using the device that produced micro-vibrations. The application of the scales occurred at three distinct phases: anamnesis and clinical examination, 1st anesthetic session, and 2nd anesthetic session, with one week interval between each phase.

During the anesthetic sessions, all performed by a pediatric dentist, the same type of needle and anesthetic were used: short gingival needle (short Unoject 30G, DFL Indústria e Comércio SA, Rio de Janeiro, Brazil), and local anesthetic 2% Novocol 100 containing lidocaine and phenylephrine hydrochlorides (SS White). Information on the medical and dental history of the patient was collected during anamnesis in the first phase, before the clinical examination, using the Dental Subscale of the Children's Fear Survey Schedule, (CFSS-DC).

After the application of the questionnaire, a clinical exam was performed to introduce the child to the clinical dental environment, but without any treatment. The questionnaire has been used in other studies [14-18] and it consists of [15] items related to dental and medical situations.

Each item can be scored on a 5 point scale from 1 (not afraid) to 5 (very afraid). Total scores thus range from 15 to 75 points. It was established that children who scored below 32 points presented 'non-clinical dental fear and anxiety'; between 32 and 39 points 'medium dental fear and anxiety'; and above 39 points 'high dental fear or anxiety' [19].

In this experiment, the questionnaire was administered directly to the children, irrespective of age, and each item was explained verbally to assure comprehension. The children in this study were at the beginning of puberty.

In the second and third phases, clinical procedures such as infiltration anesthesia and dental treatment were performed, according to patient's needs. In each anesthetic session, the same type of local anesthetic was used administered by a device with a computer-controlled local anesthetic delivery system, in a way that each child received anesthetic from the same device, whether using vibration in the first session or not. Considering that people have the same probability of being selected in the sample regarding the use of the device with vibration in the first session and to prevent any possible preferences of the operator, we used random drawing. The probabilistic sampling occurred as follows: the names of the individuals were assigned to a number in an Excel® sheet, drawing one by one until the calculated sample was completed.

The application of the evaluation scales of fear, anxiety, and pain during the anesthetic procedure was applied in the second and third phases of the study, when a single calibrated researcher applied the scales at two distinct times of the anesthetic session: before and after anesthesia. The second application of the scales occurred after anesthesia before the dental procedure, so that anesthesia did not alter value of pain and anxiety perception during the data collection of the scale. All the procedures were filmed, since the introduction of the needle into the mucosa until its removal. At the end of the second anesthetic session, the patients were asked whether they preferred the anesthetic device with or without vibration. The presence of parents in the dental office during the procedures was optional [20-22].

The following scales were applied to measure fear, anxiety, and pain in the participants of the study: Frankl Scale, FAS (Facial Anxiety Scale), SEM (sound, eye, and motor scale), and VAS (Visual Analogue Scale).

The Frankl scale, developed by Frankl, Shiere and Fogelis in 1962, used in other studies [23,24], describes the four types of behavior that a patient can present during dental treatment. The four types of behavior are as follows:

Definitely negative: when a child refuses to be treated, possibly demonstrates forced crying and expresses fear or any other negative characteristics. It is considered the worst possible behavior.

Negative: the child is reluctant to accept treatment, sulky and withdrawn, does not cooperate, and there is evidence of a negative attitude, yet not constant.

Positive: when the child accepts treatment, yet shows slight caution, wants to cooperate with the dental surgeon, sometimes shows reserved attitudes, but follows instruction cooperatively.

Definitely positive: the child fully collaborates, communicates well with the dentist, shows interest in the procedures, smiles, and appreciates the situation.

In the present study, the calibrated researcher classified the behavior of the child in accordance with the above-mentioned scale during the anesthetic session at two distinct times: before and after anesthesia, whether using micro-vibrations or not.

The Facial Anxiety Scale (FAS) is a self-reported measure that displays six faces, ranging from 'very happy' to 'very sad'. The control

the deviation because of the cognitive difference among difference ages it was through the child's first choice.

The level of anxiety is indicated by a number ranging from 0 to 5, represented by six different facial expressions [24,25]. The children were asked to indicate which face represents their feelings at the two distinct times (before and after each anesthesia) (Figure 2).

The sound, eyes and motor scale (SEM) is used to evaluate the efficiency of pain control during the anesthetic procedure. The slightest manifestation of the eyes, sound or motion of the patient is graded in four levels: comfort, slight discomfort, moderate pain, and pain [22-24]. The scale was applied while filming the anesthetic procedure, which was analyzed by the researchers according to the criteria established in previous studies [22-24].

The Visual Analogue Scale (VAS) measures children's pain experience and it consists of a straight line, 100mm in length, that ranges from 0 (no pain) to 100 (worst pain possible) [26,27]. In the present study, the line was vertical to facilitate the children's understanding and it was only applied once per anesthetic session, soon after anesthesia. Thus, the bottom end corresponds to 0 (no pain) and the upper end to 100 (worst pain possible) (Figure 3).

Statistical Analysis

The sample size calculation was based on the fact that the anesthetic sessions occurred during the first half of 2013. A total of

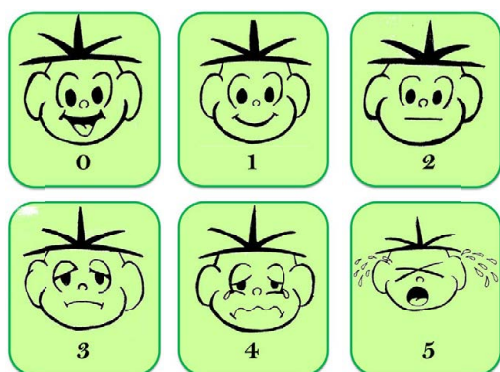


Figure 2: Facial Anxiety Scale (FAS) is a self-reported measure that displays six faces ranging from 'very happy' to 'very unhappy'.

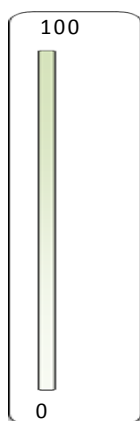


Figure 3: Visual Analogue Scale (VAS).

250 patients aged between 7 and 12 years were treated at the Clinic of Pediatric Dentistry, School of Pharmacy, Dentistry, and Nursing of the Federal University of Ceará throughout the semester. Thus, we used convenience sampling and simple random sampling, considering a finite population of 250 individuals. Given that the population is finite, composed of 250 patients, and adopting 5% significance level with a margin of error of 0.61 and sample standard deviation of 1.799, we needed a minimum sample of 30 patients.

Considering the population sample in the study, the group of participants was composed of 30 children (15 girls and 15 boys) who underwent two anesthetic sessions, totaling 60 anesthetic sessions.

For the statistical analysis, the following were used: descriptive analysis; Mann-Whitney nonparametric test (Mann-Whitney U test for independent samples), Wilcoxon signed-ranks test for related samples, t-test for independent samples, cross-reference tables, and association test (chi-square test) at a level of significance of 0.05.

Results

After obtaining the results of the CFSS-DS (Table 1), an analysis of the CFSS-DS was performed using cross-reference tables and the association test (chi-square). For better precision, we applied the values expressed by Fisher's exact test in the results of chi-square tests. We choose the values from the Fisher's exact test due to the amount of individuals in the contingency table. Thus, these comparisons aimed to demonstrate whether there is any association between the values found in the Frankl, FAS, VAS, SEM scales with the level of anxiety found in the responses of the CFSS-DS. In the comparison test, considering the selection criterion at a 5% significance level, the null hypothesis was that there was no association among the Frankl, FAS, VAS, SEM variables with the CFSS-DS. The alternative hypothesis was when there was association of these variables with the CFSS-DS. After analyzing the results, it was found that in none of the cross-references there was association among the variables since the p-value > 0.05 was found, accepting the null hypothesis (Table 2).

For the analysis of the data in the Frankl, FAS, and SEM scales, the Mann-Whitney nonparametric test for independent samples was used, using the selection criteria at a 5% significance level. For the application of this test, the null hypothesis was considered when the median values among the groups were equal, and the alternative hypothesis when the median values among the groups were different. Thus, after analyzing the results of the scales, the null hypothesis was not rejected as there was no difference among the individuals who had undergone anesthesia with vibration from those who had not (p-value>0.05) (Table 3). The data distribution of the Frankl, FAS, and SEM scales are shown in (Tables 4-6).

Considering the need to analyze the presence of different median values in the Frankl and FAS scales when comparing the before and after local anesthetic procedure in the same session, the Wilcoxon signed-ranks test for related samples was used with the selection criteria at a 5% significance level. Therefore, when comparing the

	CFSS-DS			Total
	Not Anxious	Moderate anxiety	High anxiety	
Count	26	2	2	30
% within the total group sample	86.70%	6.70%	6.70%	100%

Table 1: Distribution of children according to the level of anxiety presented at the administration of CFSS-DS during anamnesis and clinical exam, without any anesthetic procedure.

	Values for Fisher's Exact test (p-value)
Frankl before anesthesia with vibration	0.676
Frankl before anesthesia without vibration	1.245
Frankl after anesthesia with vibration	1.555
Frankl after anesthesia without vibration	0.986
FAS before anesthesia with vibration	2.29
FAS before anesthesia without vibration	6.345
FAS after anesthesia with vibration	5.79
FAS after anesthesia without vibration	4.875
Visual Analogue Scale (VAS) with vibration	8.799
Visual Analogue Scale (VAS) without vibration	18.527
Sound, eye, and motor scale (SEM) with vibration	2.237
Sound, eye, and motor scale (SEM) without vibration	3.561

Table 2: Values of Fisher's Exact Test when the chi-square test was applied. The values are a comparison of the scales with CDSS-DS.

Null hypothesis	Test	Significance	Decision
The distribution of Frankl after anesthesia is the same between the categories with or without vibration	Mann-Whitney U test for independent samples	0.576	Null hypothesis accepted
The distribution of FAS after anesthesia is the same between the categories with or without vibration	Mann-Whitney U test for independent samples	0.795	Null hypothesis accepted
The distribution of SEM is the same between the categories with or without vibration during the anesthetic sessions	Mann-Whitney U test for independent samples	0.305	Null hypothesis accepted

Table 3: Significance values for Mann-Whitney nonparametric test (Mann-Whitney U test for independent samples). The table shows the comparison of the Frankl, FAS and SEM scales among groups that underwent anesthesia with or without vibration. Asymptotic significance is shown and a significance level of 0.05 was adopted.

Frankl before anesthesia without vibration	Definitely Positive*	Positive*	Total
Count	9	21	30
% within the group without vibration	30%	70%	100%
Frankl after anesthesia without vibration	Definitely positive*	Positive*	Total
Count	8	22	30
% within the group without vibration	26.70%	73.30%	100%
Frankl before anesthesia with vibration	Definitely Positive*	Positive*	Total
Count	12	17	29**
% within the group with vibration	41.40%	58.60%	100%
Frankl after anesthesia with vibration	Definitely positive*	Positive*	Total
Count	10	20	30
% within the group with vibration	33.30%	66.70%	100%

*The table shows only the values of the Frankl Scale for behaviors considered 'definitely positive' and 'positive' as it was reported that only one child presented 'negative' behavior, and no children showed 'definitely negative' behavior.

**One child presented a 'negative' behavior profile during the application of the scale before anesthesia with vibration. For the Mann-Whitney U-Test for independent samples, this variable was excluded.

Table 4: Distribution of variables of the Frankl scale according to the time before and after anesthesia and use of vibration or not.

FAS before anesthesia without vibration	0	1	2	3	4	5	Total
Count	11	12	5	2	0	0	30
% within the group without vibration	36.70%	40.00%	16.70%	6.70%	0%	0%	100%
FAS after anesthesia without vibration	0	1	2	3	4	5	Total
Count	8	13	8	1	0	0	30
% within the group without vibration	26.70%	43.30%	26.70%	3.30%	0%	0%	100%
FAS before anesthesia with vibration	0	1	2	3	4	5	Total
Count	16	8	6	0	0	0	30
% within the group with vibration	53.30%	26.70%	20%	0%	0%	0%	100%
FAS before anesthesia with vibration	0	1	2	3	4	5	Total
Count	9	13	6	2	0	0	30
% within the group with vibration	30%	43.30%	20%	6.70%	0%	0%	100%

Table 5: Distribution of variables of the FAS scale, according to the time before and after anesthesia and use of vibration or not.

median differences of the Frankl scale before and after anesthesia in the same session without using vibration, asymptotic significances ($p=0.655$, $p>0.05$) were found, the same as in the sessions when vibration was used ($p = 0.414$, $p>0.05$). The median differences of the FAS scale before and after anesthesia in the same anesthetic session

without vibration were also compared and asymptotic significances ($p = 0.490$, $p>0.05$) were found, the same as in sessions when vibration was used ($p=0.109$, $p>0.05$).

To analyze the results of the VAS scale, the t-test for independent

SEM scale anesthesia without vibration		Comfort	Slight discomfort	Moderate pain	Pain	Total
Count		27	3	0	0	30
% within the group without vibration		90%	10%	0%	0%	100%
SEM scale anesthesia with vibration		Comfort	Slight discomfort	Moderate pain	Pain	Total
Count		29	1	0	0	30
% within the group with vibration		96.70%	3.30%	0%	0%	100%

Table 6: Distribution of the variables of the SEM scale, according to the data collected in each anesthetic session and recorded in accordance with the use of vibration or not during the anesthetic session.

Group statistics					
		N	Mean	Standard-deviation	Mean standard error
Visual Analogue Scale	No use of vibration	30	2.17	2.35	0.429
	Use of vibration	30	1.07	1.507	0.275

Table 7: Mean values, Standard Deviation, Mean Standard Error of VAS.

samples was used, considering a selection criteria at a 5% significance level. For this test, the null hypothesis was considered when the mean values of the two groups were equal and the alternative hypothesis when the mean values of the two groups were different. Thus, the null hypothesis was rejected and the alternative hypothesis was accepted, that is, the mean values of the two groups (the group in which vibration was used and the group in which it was not) were different. The p -value < 0.05 was found in the independent sample tests using the Levene test for equality of variations at a significance level of 0.040. Therefore, a difference among the mean values was found. Considering that the mean values on the VAS scale in the group in which vibration was used was 2.17 and the mean values of group in which no vibration was used was 1.07, higher values were found in the VAS scale in the group in which no vibration was used (Table 7).

After performing all associations and statistic analyses regarding the application of the scales, the goal was to know if the children in the study preferred the use of vibration during the anesthetic session or not. A simple percentage calculation was performed and it was concluded that 90% (N=27) of the children preferred vibration, while 10% (N=3) preferred anesthesia without vibration.

Discussion

In literature, divergences have been observed regarding the effectiveness of anesthesia with vibration [4-12]. The main objective of the present study was to evaluate reactions concerning anxiety, fear, and pain in children submitted to local anesthesia with controlled flow-rate delivery of the anesthetic solution with low intensity vibration, in comparison with other sessions in which anesthesia was applied without vibration.

We compared the level of anxiety found in the previously mentioned Dental Subscale of the Children's Fear Survey Schedule with the values expressed in the Frankl, FAS, VAS, and SEM scales to determine whether children showing higher anxiety in the CFSS-DS would present the same high values in the Frankl, FAS, VAS, and SEM scales.

After the comparisons, significant values were not obtained (due to the presence of p -values higher than 0.05) (Table 2). Therefore, it was concluded that there was no relationship of predicted anxiety analyzed by CFSS-DS before the anesthetic procedure with the scales applied to verify anxiety, fear, and pain before and after anesthesia with or without vibration.

In the analysis of the level of anxiety after the use of anesthesia, the Facial Anxiety Scale (FAS) was used to compare anxiety shown after the anesthetic procedures between the sessions with or without vibration. A significance value of 0.795 ($p > 0.05$) (Table 3) was obtained, so it was concluded that there was no difference on the Facial Anxiety Scale (FAS) after the anesthetic sessions. Therefore, it can be concluded that there was no difference in the results in the analysis of anxiety level after local anesthetic procedures using vibration in comparison with the local anesthetic procedure in which vibration was not used. Thus, we are in agreement with the studies that claim that vibration does (not) reduce pain in children who undergo local anesthesia [9-11].

In the behavior analysis, we used the Frankl scale 19-22 to verify possible behavior changes after the use of vibration during dental local anesthesia in comparison with no vibration. A significance value of 0.576 ($p > 0.05$) (Table 3) was obtained, so it may be concluded that there was no behavior difference between using vibration or not when performing the anesthetic procedures. According to the analysis of the scale, we are in agreement with the studies that claim that vibration does (not) reduce pain in children who undergo local anesthesia [9-11].

When analyzing the mean values of the Frankl and FAS scales before and after anesthesia in the same anesthetic sessions, no differences in the mean values between the two scales were found, with a predominance of values that did not indicate fear, anxiety, or bad behavior. Therefore, it may be concluded that the device with a computer-controlled local anesthetic delivery system was well accepted, both in the case of local anesthetic with vibration as without vibration concerning its effectiveness to promote less discomfort during local anesthesia due to the controlled flow-rate delivery of the anesthetic solution into the perioral tissues [2]. It is important to point out that the non-difference in behavior and fear when we compared the records before and after anesthesia is because all anesthetic procedures were performed by a pediatric dentist.

To analyze the experience of pain, we used the SEM scale (Sound, Eyes and Motor scale) [22-24] to observe if the children experienced pain during local anesthesia with vibration in comparison with the session without vibration. The results of the comparison obtained a significance value of 0.305 (Table 3), concluding that there was no difference whether vibration was used or not in the experience of pain. According to the scale, the children experienced a degree of 'comfort' when anesthesia was administered without vibration (90%, N=27) and with vibration (96.7%, N=29) (Table 6). Therefore, when the data of the SEM scale were analyzed, we agree with the studies that claim that vibration does (not) reduce pain in children who undergo local anesthesia [9-11].

The Visual Analogue Scale 25-27 was also used to analyze the pain experience comparing local anesthesia with or without vibration. The result of the comparison obtained a significance value of 0.040 ($p < 0.05$) and we found a difference in self-reported pain experience regarding the use of vibration or not. Considering the mean values of the group in which vibration was used with those in which no vibration was

used (Table 7), it was concluded that the use of vibration promotes less pain than when it is not used in local anesthesia. According to the scale and literature, vibration during local anesthesia is effective in pain reduction [4-8].

According to the children researched, vibration in dental local anesthesia was well accepted, as 90% (N=27) chose vibration during the local anesthetic procedure claiming that vibration during anesthetic administration reduces pain. Therefore, we agree with literature that vibration is effective in reducing pain sensitivity [4-8].

Conclusion

According to the results, vibration does not seem to influence anxiety or fear when the tested device was used. The use of vibration, however, seemed to have had a positive influence on the children's perception as practically all of them chose the device with vibration.

Conflict of Interest

The authors state no conflicts of interest.

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