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EFFECT OF THERMO MECHANICAL STIMULATION DURING LOCAL ANESTHESIA IN PEDIATRIC DENTISTRY: A PILOT RANDOMIZED CLINICAL TRIAL

Efeito de estimulação termomecânica durante anestesia local em odontopediatria: um ensaio clínico randomizado piloto

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ABSTRACT

Aim: To evaluate the effectiveness of a thermo mechanical stimulation device (Buzzy®) in relation to pain, fear and anxiety during local anesthesia in children. **Materials and methods:** Study carried out from May 2018 to July 2019, with children aged 7 to 11 years, without previous experience involving anesthesia in the last 2 years and who needed dental treatment (extraction, restoration or endodontic) under local anesthesia in deciduous molars. The sample was randomized into a control group, which received conventional anesthesia, and an intervention group, which received anesthesia with Buzzy®. The levels of anxiety, fear and pain perception of both groups were verified using: Come Modified Picture Test (VPTM); heart rate; Behavioral Scale Come; Faces Pain Scale – Revised (FPS-R) and Face, Legs, Activity, Cry, Consolability (FLACC). **Results:** Most children (55%) had low anxiety before and after treatment ($P<0.05$). The acceptability of the children to Buzzy® was 100% and the majority (90%) would like to use it again. **Discussion:** The tested device is an interesting tool to complement management techniques during consultations, in view of the excellent acceptability and interest on the part of patients and family members. **Conclusion:** This study demonstrated that the use of thermo mechanical stimulation is feasible in the dental clinic, due to its easy use and good acceptability in the clinical environment, in addition to not presenting risks in its use.

Keywords: Anesthesia, local. Anxiety. Pain management. Fear. Pediatric dentistry.

RESUMO

Objetivo: Avaliar a eficácia de um dispositivo de estimulação termomecânica (Buzzy®) em relação à dor, medo e ansiedade durante anestesia local em crianças. **Materiais e métodos:** Estudo realizado no período de maio de 2018 a julho de 2019, com crianças de 7 a 11 anos, sem experiência prévia envolvendo anestesia nos últimos 2 anos e que necessitassem de tratamento odontológico (extração, restauração ou endodontia) sob anestesia local em molares decíduos. A amostra foi randomizada em grupo controle, que recebeu anestesia convencional, e grupo intervenção, que recebeu anestesia com Buzzy®. Os níveis de ansiedade, medo e percepção de dor de ambos os grupos foram verificados por meio de: Venham Modified Picture Test (VPTM); frequência cardíaca; Escala Comportamental Venham; Faces Pain Scale – Revised (FPS-R) e Face, Legs, Activity, Cry, Consolability (FLACC). **Resultados:** A maioria das crianças (55%) apresentou baixa ansiedade antes e depois do tratamento ($P<0,05$). A aceitabilidade das crianças ao Buzzy® foi de 100% e a maioria (90%) gostaria de usar novamente. **Discussão:** O aparelho testado é uma ferramenta interessante para complementar as técnicas de manejo durante as consultas, tendo em vista a excelente aceitabilidade e interesse por parte dos pacientes e familiares. **Conclusão:** Este estudo demonstrou que o uso da estimulação termomecânica é viável na clínica odontológica, devido ao seu fácil uso e boa aceitabilidade no meio clínico, além de não apresentar riscos em seu uso.

Palavras-chave: Anestesia local. Ansiedade. Manejo da dor. Medo. Odontopediatria.

INTRODUCTION

Painful experiences lived by the child at the dentist are determining factors in the occurrence of fear of dental treatment[1-3], and may lead to dental treatment avoidance in the future. Thus, pain, as well as anxiety, management is essential to offer a successful treatment in dentistry, aiming to reduce the chances of aversion to the dental environment.

Local anesthesia is widely used in dentistry, avoiding the painful sensation during consultations. However, the use of the needle is considered an important source of pain and anguish in children, which can lead to future trauma, usually developed between the ages of 5 to 10 years after a negative painful experience[4, 5]. In the context of assisting in pain management during procedures involving needles, the Buzzy® device was created (MMJ Labs, Atlanta, GE, EUA) aiming to assist in the control of pain in children. Although it was not developed for Dentistry, its use is recommended by the manufacturers, being a fast and easy to use intervention[5]. The device consists of a vibrating motor with ice that combines multiple approaches, providing cold analgesia, tactile stimulation and distraction[6]. In this sense, it acts according to the “Gate Control” theory developed by Ronald Melzack and Patric Wall, since it activates the large diameter nerve fibers responsible for the touch and vibration stimuli, enabling the reduction of pain due to the fact that the brain recognizes only one stimulus at a time (painful or tactile), and the first impulse to reach the nervous system is the sensation of vibration[7].Furthermore, due to its bee shape, it is hoped that it is a playful material and facilitates its acceptability by the child in the clinical environment[8].

A systematic review and meta-analysis[9] on the effectiveness of Buzzy® for pain management, during needle procedures, found that the device shows promise in the management of childhood pain. However, the results are still uncertain due to the low methodological quality of the current evidence[9]. Although there is a range of studies related to the device, different studies have assessed the efficacy of vibrating devices in children dental injections and have showed conflicting results[10]. Therefore, the objective of this pilot study is to evaluate the acceptability and effectiveness of thermomechanical stimulation (Buzzy®) during local anesthesia in pediatric dentistry. The hypothesis is that

the Buzzy® appliance will provide the pediatric patient to reduce the perception of pain, anxiety and fear during dental treatment and will be well accepted by children.

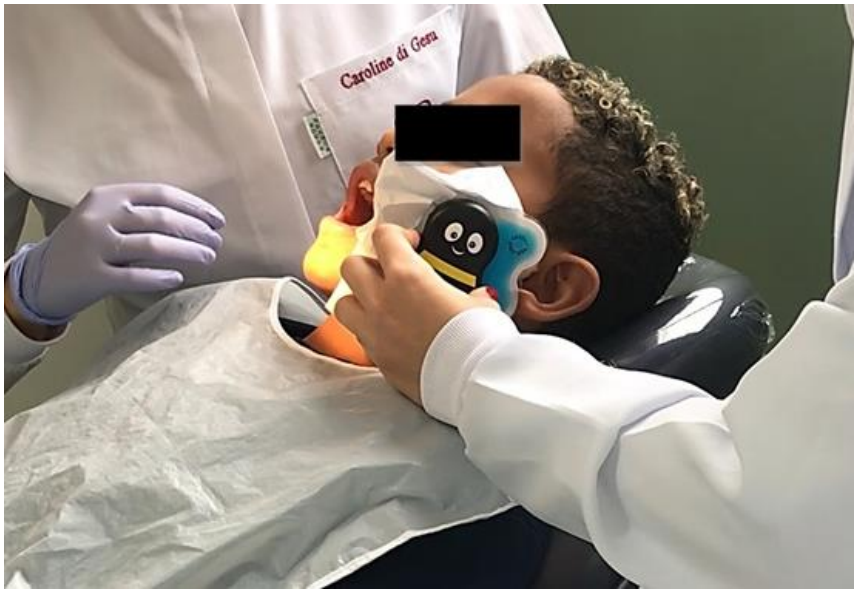
MATERIALS AND METHODS

Study design and sample selection

This randomized controlled pilot study was carried out in the behavior laboratory of the Children's Clinic of the Faculty of Dentistry of the Federal University of Pelotas (FO - UFPel), in the city of Pelotas/RS, Brazil. Twenty children were included according to the following inclusion criteria: being between 7 and 11 years old (specific operational period of Piaget); general good health; no previous dental experience involving anesthesia in the past 2 years; lack of behavioral cooperation according to the VENHAM Picture Test Modified (VPTM) test[11]; and need for treatment in at least one deciduous molar, which required local anesthesia. Children who had one of the following characteristics were excluded: physical or mental disability; neural damage prior to the branch to be anesthetized; history of hypersensitivity to the drug used (3% lidocaine).

After clinical evaluation, the selected children were divided into 2 groups: Intervention, which received care with the use of Buzzy® during local anesthesia (figure 1); and Control, which received conventional assistance. Randomization was performed with 20 brown envelopes, divided equally between the groups, in the first dental evaluation visit. Afterwards, it was excluded. Thus, the balance between the groups and the random allocation of the selected sample was guaranteed.

Figure 1 - Image of the Buzzy® device positioned prior to anesthesia



Experimental design

In the first consultation, parents were interviewed and demographic (sex and age) and socioeconomic (family income and maternal education) information was collected.

The children were treated by two calibrated undergraduate students enrolled in the last year in Dental School, supervised by Pediatric Dentistry professors. The procedure consultation consisted of performing any procedure (extraction, restoration or endodontic) in deciduous molars under local anesthesia. Both groups received the behavioral management technique used in the clinical routine (“tell-show-do technique” and positive reinforcement) explaining the process involved in the injection in a playful way and, prior to this, the use of topical anesthetic.

In the intervention group, there was also, at this moment, the presentation of Buzzy® (MMJ Labs, Atlanta, GE, EUA), which is a bee-shaped device that consists of two components: the bee's body, the place responsible for the vibration; and the removable ice wings kept in the freezer between procedures. The device was placed by the assistant on the child's face, externally, in the region close to the place to be anesthetized and kept in position throughout the anesthetic procedure. Each pair of wings keeps frozen for about 10 minutes at room temperature and can be used up to 100 times.

To measure the level of anxiety, during the time of anesthesia, heart rate was assessed using the Choice MMed® MD300C1 Finger Pulse Oximeter. Measurement was performed at the beginning, during and at the end of the injection. In order to assess the levels obtained, the following cutoff points were used: 75 to 118 beats per minute (bpm), considered normal for the age group[12], and oxygen saturation above 92%. Frequency above 118 bpm was considered a high rate and below 75 bpm, a low level; oxygen saturation was considered low when less than 92%[13].

The consultations were recorded using 2 cameras (one for face and one for body) placed on tripods, for later assessment of behavior and painful sensation .By agreeing to participate in the study, the children were aware of the footage. The perception of pain during the anesthesia procedure was made through FLACC (face, legs, activity, cry, consolability)[14]. Each category can be scored on a scale of zero to two, in a total result ranging from zero to ten. It is considered "zero", as relaxed or comfortable, "one to three", small discomfort, "four to six", moderate pain and "seven to ten", severe discomfort or pain or both. The higher the score, the greater the intensity of the pain behavior shown by the child. Behavior was assessed using the VENHAM Behavioral Scale during the time of anesthesia[15]. The score is calculated according to the patients' body response. Scores range from zero (cooperative) to five (widespread protest). The most negative level observed during anesthesia was considered.

Anxious was assessed following a projective self-analysis test from eight pairs of human figures with different emotional reactions through VPTM[11]. When questioning the child about his feelings, a point in the assessment was scored for each negative image choice. The sum of all pairs of figures can vary from zero to eight, with zero representing anxiety-free children; one to three - low level of anxiety; four to six - average anxiety level and seven to nine - highly anxious[16].

After attendance, through the Faces Pain Scale - Revised (FPS-R)[16] the intensity of pain perceived by the child was evaluated by presenting six faces aligned with an expression of pain in an increasing ordinal gradation, whose score ranges from one (no pain) to six (strong pain), without expression of crying or smile. It should be noted that it must be explained according to the degree of understanding and age of the minor, and

also should not use words such as "cheerful" and "sad" during the assessment. Once this was done, the behavioral level was measured again through the VPTM.

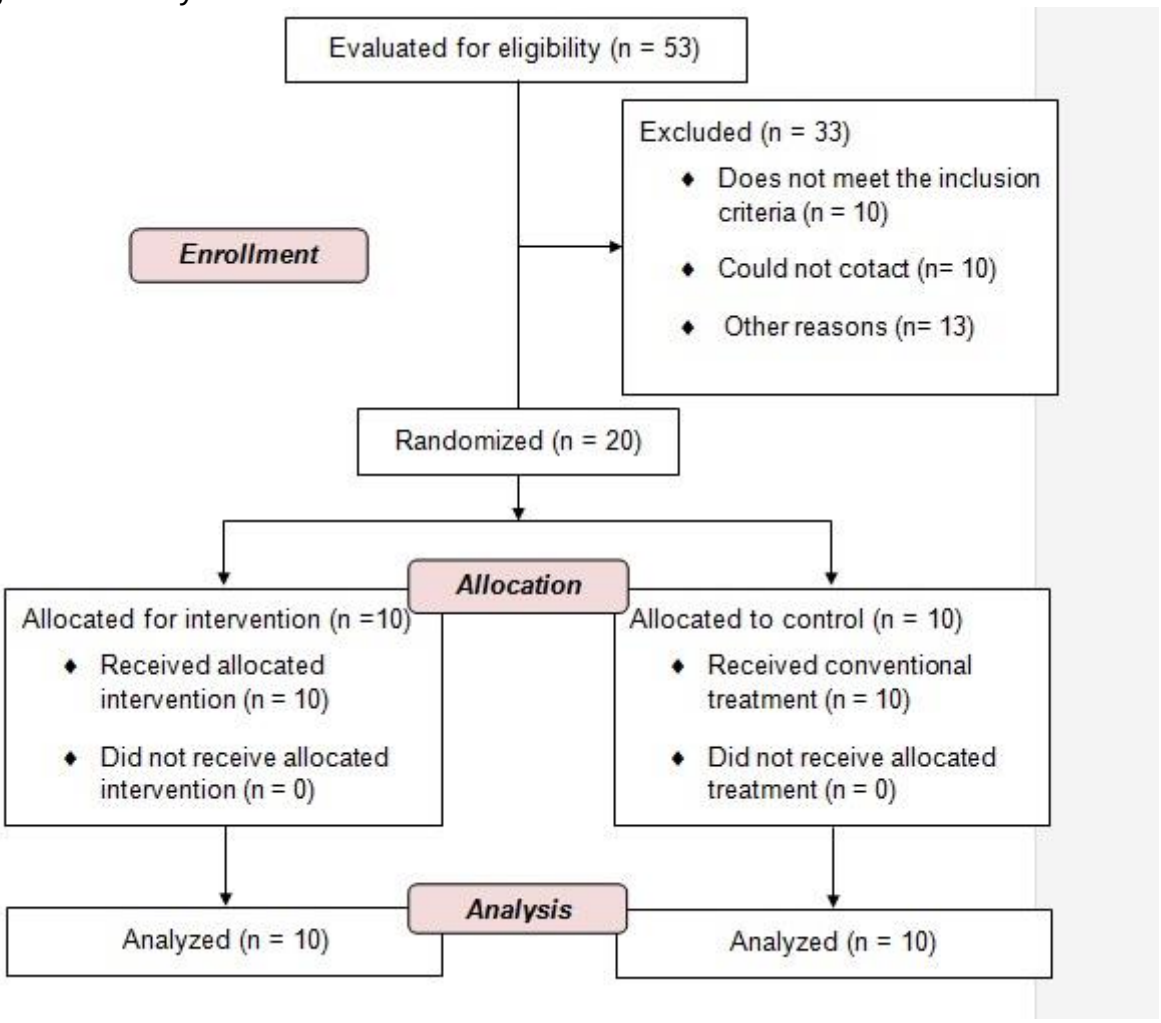
Data analysis

The data were entered into a spreadsheet in the Microsoft® Excel® 2010 program and analyzed using the Stata 14.0 program. Due to the data distribution, the variables of the VPTM, FLACC, VENHAM Behavioral and FPS-R were dichotomized. Thus, children were classified as: collaborative and non-collaborative behavior; anxious and anxiety-free; and as the absence or presence of pain. Descriptive analysis of the data was performed, obtaining the absolute and relative frequencies; and comparisons between groups. The outcomes of interest were analyzed using the chi-square test for dichotomous variables and the Mann-Whitney test for means. A significance level of 5% was adopted for all analyzes.

RESULTS

Figure 2 represents the sample flowchart of the present study, which shows the total number of children selected, excluded, interviewed and/or examined and patients completed/analyzed.

Figure 2 – Study flowchart



The selected sample consisted of 20 children, 11 of whom were male and 9 were female. The mean age was 8.65 years, with a standard deviation of ± 1.35. About the procedures performed, 70% of these were tooth extractions. Regarding the degree of anxiety reported by the patients, at the start of the first consultation according to the VPTM, it was observed that 13 of them were free from anxiety. These and other descriptive characteristics of the sample are shown in Table 1.

Table 1 - Descriptive characteristics of the sample (n = 20)

	Total	Buzzy® Intervention Group	Control Conventional Treatment
Number	20	10	10
Average age (± dp)	8.65(±1,35)	9.20 (±1,40)	8.10 (±1,10)
Gender N (%)			
Male	11 (55%)	5(50%)	6 (60%)
Female	9(45%)	5 (50%)	4 (40%)
Procedure N (%)			
Tooth extraction	14 (70%)	6 (60%)	8 (80%)
Restoration	6 (30%)	4 (40%)	2 (20%)
Maternal perception			
Fear of dentist N (%)			
No	15 (75%)	8 (80%)	7 (70%)
Yes	5 (25%)	2 (20%)	3 (30%)
Anxiety (VPTM) N(%)			
Low	13 (65%)	6 (60%)	7 (70%)
High	7 (35%)	4 (40%)	3 (30%)

As for the behavior of patients during anesthesia, assessed through the recordings, table 2 shows that 75% of the children cooperated. Regarding self-report, 11 children remained free from anxiety, and the intervention group remained with values equal to those of the first consultation; while in the control group, 2 children were classified as non-collaborator, according to VENHAM behavior scale.

Table 2 - Behavior of children according to VENHAM behavior scale during local anesthesia and anxiety after the consultation evaluated according to the VENHAM Picture Test Modified (VPTM).

	Total n (%)	Intervention Group Buzzy® n (%)	Group control Conventional Treatment n (%)	*P**
Behavior				0.605
Collaborator	15 (75%)	7 (70%)	8 (80%)	
Non-Collaborator	5 (25%)	3 (30%)	2 (20%)	
Anxiety (VPTM)				0.653
Low	11 (55%)	6 (60%)	5 (50%)	
High	9 (45%)	4 (40%)	5 (50%)	

* chi-square test

In reference to heart rate, it was noted that 85% of the entire sample was within the normal range, 5% had high and 10% low hearth rate, with no statistically significant difference between the groups (Table 3).

Table 3 - Heart rate and oxygenation level during local anesthesia.

	Total n (%)	**Intervention Group Buzzy®** n (%)	**Group control Conventional Treatment** n (%)	***P****
Heart rate				0.217
Low	2 (10%)	0 (-)	2 (20%)	
Normal	17 (85%)	9 (90%)	8 (80%)	
High	1 (05%)	1 (10%)	0 (-)	
Oxygenation				1.000
Normal	18 (90%)	9 (90%)	9 (90%)	
Low	2 (10%)	1 (10%)	1 (10%)	

* chi-square test

Table 4 shows results on the child's perception of pain during anesthesia, according to the FPS-R. It was found that 13 of the patients reported that they did not feel any pain, of which 6 were from the intervention group and 7 from the control group, with no difference between groups.

Table 4 - Perception of pain after the procedure according to Faces Pain Scale - Revised (FPS-R) applied after the consultation.

FPS- R Scale	**Total**	**Intervention Group Buzzy®**	**Group control Conventional Treatment**	***P****
Variation	1-6	1-6	1-6	
Medium (± dp)	1.95 (1.79)	2.20 (2.00)	1.70 (1.60)	
Median	1	1	1	
Pain N (%)				0.639
Absent	13 (65%)	6 (60%)	7(70%)	
Present	7 (35%)	4 (40%)	3 (30%)	

* chi-square test

Considering table 5, it was verified by analyzing the videos collected that 11 children expressed some painful reaction, among them 5 used the Buzzy® device and 6 underwent conventional treatment, according to the FLACC scale (p = 0.65).

Most children, who used the Buzzy® device, when questioned, reported that enjoyed the experience, but when asked if they would use it again, 1 said no.

Table 5 - Pain assessment using the Face, Legs, Activity, Cry and Consolability (FLACC) scale during local anesthesia.

FLACC pain scale	**Total** **n (%)**	**Intervention Group Buzzy® n (%)**	**Group control Conventional Treatment n (%)**	***P- value****
				0.653
Absent	9 (45%)	5 (50%)	4 (40%)	
Present	11 (55%)	5 (50%)	6 (60%)	

* chi-square test

DISCUSSION

The present pilot study sought to assess the acceptability and effect of using a thermo mechanical stimulation device during local anesthesia of deciduous molars. Randomized controlled clinical studies are the ideal design to test the effectiveness of a particular treatment or intervention. There was no difference between the groups in the evaluated outcomes. However, it was noted that the tested device is an interesting tool to complement the handling techniques during pediatric consultations, in view of the excellent acceptability and interest on the part of patients and family members to Buzzy®. This is in agreement with a study on immunization, where in interviews with parents, they demonstrated satisfaction and endorsed the preference for use in another opportunity[9].

To date, few studies have evaluated its use in the face region for local anesthesia in children. A study found that the use of Buzzy® in children undergoing local anesthesia in dentistry resulted in a reduction of fear and discomfort[17]. However, as it is a randomized crossover study with a split mouth, the methodology adopted in this research may not be the most suitable, since it can generate positive or negative

influences and expectations between consultations, making it difficult to compare data between first and second care.

The literature does not report any adverse reactions during the use of this tool[9,16], as in the present study, there were no adverse reactions. It is suggested, therefore, that there is no contraindication, being safe to use in several procedures. Other facilities, observed by different researchers, are: the easy use of this material; its quick action; negligible interference in clinical time; and the economic factor, considering that it can be reused numerous times (cost approximately U$ 0.09 per use)[9,17]. In line with the above reports, it was observed during the visits that the device facilitated the child's distraction during analgesia, in addition to providing a more playful intervention, generating greater comfort for the patient, since he does not feel threatened by friendly Buzzy® design. Thus, there is the possibility of preventing future fears of needles due to the well-being generated with this equipment, since several studies in different areas have shown to be effective in relieving pain and anxiety in children[18, 19].

It is important to highlight the use of behavioral management techniques, which are widely used in pediatric dentistry and are fundamental to create rapport with patients[4]. Thus, in this study, some of these techniques were used in both sample groups in order to obtain better results in relation to pain, fear and anxiety of the minor in relation to the treatment. Also, topical anesthetic (Benzocaine) was used prior to anesthetic injections, adopted as a routine in the children's clinic. Therefore, one of the hypotheses for the absence of difference between the intervention and control groups is due to the effectiveness of behavioral management performed in all consultations, as well as the correct application of the anesthetic gel, thus equating conventional treatment with treatment using Buzzy®. In contrast, the results of two studies[17,20] revealed that Buzzy is an effective device to reduce pediatric injection pain perception. This can be interpreted by the combination effect of cooling and vibration. However, the positive impact of Buzzy can be partially related to its distractive feature and distraction can play a major role in diverting the attention, especially among children.

Among the approaches available to minimize the perception of pain, the use of vibrotactile devices or jet injectors has been discussed in the literature[21]. However, specific studies with larger samples and anxious children must be carried out.

Devices similar to the one tested in this work are available on the market. However, they do not associate mechanical action with thermal action, such as Dental Vibe® (Vibration), specific for local dental anesthesia, and Vapocoolant Spray (Ice)[22]. A systematic review included four articles for the Dental Vibe device[22-25] and two articles for the Buzzy device[17, 20]. The results of the present meta-analysis showed that the use of DentalVibe does not have a positive impact on reducing the perception of dental injection pain. This could be due to the sound or vibration sensation caused by the device, which can induce pediatric fear and anxiety. Vibration was considered a stressor in children. Furthermore; a positive relationship was demonstrated between anxiety and pain perception in pediatric dentistry. Another explanation for the results of this meta-analysis is that children can interpret DV-induced pressure and vibration as a kind of pain or discomfort.

CONCLUSION

Children who used Buzzy® had similar perception of pain, anxiety and fear between groups. The device proved to be easy to use, playful and well accepted by patients, in addition to not having contraindications. Consequently, this device can be used or not, depending on the professional choice.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interest.

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