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Original research

External cold and vibration with BUZZY versus topical anesthetic gel for pain and anxiety associated with infiltrative anesthesia in pediatric dentistry: a double-blinded, split-mouth, randomized, controlled trial

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Purpose
A way to reduce the pain of injection is applying of external cold or vibrations with BUZZY, along with spinal cord gate control systems. We aimed to evaluate the effectiveness of this method in reducing children's pain and anxiety during infiltrative anesthesia.

Materials and Methods
This was a double-blinded, randomized, split-mouth, controlled, trial. Thirty 6 to 12-year-old children with decayed first permanent molar tooth on both sides of their maxilla were enrolled. Each side of the children's mouths was randomly allocated to either BUZZY or topical anesthetic gel prior to infiltrative anesthesia. Pain and anxiety during infiltrative anesthesia were measured with the Baker-Wong (BWS), FLACC (Face, Leg, Activity, Cry, Consolability), and heart rate (HR) scales.

Results
A generalized estimating equation (GEE) adjusted for age and baseline HR, indicated, significantly-lower intra-procedural HRs associated with BUZZY (aOR [95%CI]: 0.02 [0.00, 0.91], p=0.04). GEEs adjusted for age revealed the BWS (aOR [95%CI]: 0.59 [0.30, 1.14], p=0.12) and FLACC (aOR [95%CI]: 0.82 [0.62, 1.09], p=0.17) scores to be comparable between the study arms.

Conclusion
Our study failed to demonstrate the superiority of BUZZY over anesthetic gels regarding WBS and FLACC measures of pain and anxiety, but demonstrated a decrease in HR associated with BUZZY.

Keywords: *Pediatric dentistry, dental anxiety, behavioral control, pain, vibration*

Introduction

Pain management, particularly in pediatric populations, is a challenging aspect of a wide range of practices. Appropriate management of pain in pediatric patients is crucial for providing appropriate and timely interventions; this is subject to an appropriate understanding of the mechanisms underlying pain itself. The gate control theory, proposed by Melzack and Wall in 1965 (1), provides a theoretical framework according to which, the perception of pain is not solely determined by nociceptive input, but other inputs such as the ones from vibration and temperature receptors as well as psychological, social, and environmental factors resemble controlling a gate through which the pain inputs pass and by which could be modified. This theory offers valuable insights into how pain can be effectively managed, especially in children. Furthermore, appropriate identification and assessment of the degree pain are necessary for its proper management;

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in pediatric practice this could be performed via subjective measures such as the Wong-Baker Scale (WBS), and objective ones such as physiological measures e.g., the heart rate and behavioral measures such as the face, legs, activity, cry, consolability (FLACC) scale. Each of these standardized measures provides a unique insight on patients' perception of pain, and are used in current research and practices.

Non-pharmacological interventions exist aimed at alleviating pain based on the gate control theory. For instance, previous studies have shown, pain thresholds increase when skin temperature is reduced to 4°C (2, 3). Furthermore, besides the gate control theory, which states non-painful stimuli reduce the transmission of pain signals, this phenomenon could be explained by reduced sensitivity of terminal neurons, reduced edema, and slowing of signal transmission through nerves, due to vasoconstriction(4). A similar effect is observed for vibration; according to the gate control theory, activation of mechanoreceptors by external vibration, leads to blocking of the pain signals in the spinal cord, and/or their diversion to the spino-thalamic fibers (5-9).

The mentioned phenomena have been used, as bases of non-pharmacological management of injection-associated pain and/or anxiety, particularly in pediatric practices. For instance, Mohiuddin *et al*. (2) demonstrated that pre-cooling of the injection site with ice is more effective than topical anesthetic gel in reducting the pain perception in child (8–12 years) candidates of infiltration anesthesia and Albouni *et al*. (10) showed in a more recent study that a vibrating injection system reduces pain perception in child (6–9 years) candidates of intraoral injection. Consistently, simultaneous cooling and vibration has been shown to be effective as well, as indicated by Bilsin *et al*. (11) and a recent study by Nagpal *et al*. (12) demonstrated this effectiveness further increases by addition of a sound distraction. Yet, contrary evidence also exists, e.g., Smolarek *et al*. (13) conclude from their recent study on 5–8-year-old candidates of dental procedures that the vibrational technique is not associated with a reduced pain perception compared to the conventional method.

Among devices currently available that utilize "cold and vibration" for means of reduction of injection-associated pain/anxiety in pediatrics, VibraJect (VJ), DentalVibe (DV) and BUZZY could be cited (9). Among all, BUZZY (Pain Care Labs, USA) applies external vibration and cold simultaneously on the injection site. The device has a bee-like plastic body to transfer vibration, with a "wing" part accommodating 18 grams of ice, to apply cold (Figure 1). Furthermore, BUZZY has an attractive appearance to distract the child's attention during injection, and only a handful of contraindications exist regarding its use (8). Regarding the real-world effectiveness of BUZZY in reducing injection-associated pain/anxiety of children, results of previous studies have been contrary; the effectiveness seems to vary based on site of injection, and its type (14, 15). Particularly in pediatric dentistry, Faghihian *et al*. (16) concluded that inadequate data is available on the effectiveness of BUZZY in controlling injection pain, in their systematic review and meta-analysis study. Therefore, we aimed to contribute to the knowledge in this regard, with level-I evidence from a randomized trial. The null hypothesis is that there is no difference between the two anesthesia techniques.

Figure 1. *BUZZY device and its use in pediatric dentistry. (Images from: dentaquick.com).*

Materials and Methods

Study design, outcomes, and measurements

Herein reported in accordance with the CONSORT statement, is a double-blinded, randomized, split-mouth, active comparator-controlled, trial, with a 1:1 allocation ratio, conducted from 20 August 2021, until 20 December 2021, on children aged 6-12 years admitted to the clinics of the Isfahan Dental School, Isfahan, Iran. Participants were enrolled, whereby they met the following inclusion criteria: age from 6 to 12 years; adequate cooperation, with positive (+) or completely positive (++) Frankl classification; having first permanent molar tooth decayed on both sides of maxilla, requiring class I cavity preparation; being otherwise healthy, with no history of prior toothache and dental treatment; and no active use of painkillers and/or sedatives at the time of enrollment.

Participants were excluded after randomization, if any pathology and/or inflammation was discovered later in the face and/or the injection site; and/or if they were absent for the study procedures.

The primary outcome was pain during local anesthesia infiltration, measured by the following: the WBS, which is a subjective scale of pain; and the FLACC scale, which is an objective scale.

The WBS comprises 6 painted faces, each demonstrating a level of pain. Immediately after the injection, the child participant was asked to point to a face which demonstrates his/her subjective feeling of pain. The child's pain is then scored from 0 to 10, with 0 being the least, and 10 being the most severe pain.

In the FLACC scale, the pain, as demonstrated through involuntary movements and behaviors of the child during the painful procedure, is scored in accordance with a respective table. Score 0 suggests no pain, 1–3 shows mild pain, 4–6 indicates moderate pain, and 7–10 shows severe pain. The FLACC scores were assessed by a professional, based on video recordings of the procedures, whereby the sound was turned off for measuring of face, legs, and activity scores, and the sound was turned on for measuring of cry, and consolability scores.

Furthermore, the child's anxiety comprised a secondary outcome, measured by child's heart rate 5 minutes before, during, and 5 minutes after the painful procedure, monitored using a pulse oximeter device (Beurer PO80, Berlin Germany), in contact with the index finger of the children's left hand.

Sampling, randomization, and blinding

The sample size of 30 for each group was measured in order to detect significant difference for a type I error of 0.05 and power 0.8. Aiming to compensate for loss during follow-up, the sample size was increased by 36 percent, therefore a sample size of 41 was planned.

The recruitment of participants was from the clinics of the Isfahan Dental School, and in a simple random fashion. Randomization was in a split-mouth fashion with a 1:1 allocation ratio, with each side of each participant's mouth allocated to one of the study arms based on the results of an online coin flipper. Participants underwent their dental procedures in two sessions separated by a two-week interval, each session on one of the mouth sides.

The researchers, and the participants were all blinded to the results of random allocation. Random allocations and execution of procedures were done by a third person not involved in the study. Furthermore, the camera used for recording of treatment sessions was placed out of the child's vision, and recorded all procedures from the same angle. In order to further ensure blindness of the participants and the researchers, the BUZZY device (Pain Care Labs, USA) was placed on the child's face in all procedures, but it was turned off in the procedures of the comparator arm.

Intervention and comparator

The intervention arm underwent placement of BUZZY on the respective side of the face, with cold temperature, and vibration turned on, from two minutes before, until after infiltration of 1.8 ml lidocaine + 1:80,000 epinephrin. The comparator arm underwent placement of BUZZY on the respective side of the face, with ambient temperature, and vibration turned off, from two minutes before, until after infiltration of 1.8 ml lidocaine + 1:80,000 epinephrine, along with administration of a topical anesthetic gel (Benzocaine 20%, Prime Dental Gel) 30 seconds before the infiltration.

Statistical analysis

Data was analyzed in a per-protocol fashion, as outcome measurement was not possible for participants who were lost to follow up. Normality and/or lognormality of distributions were tested using the Kolmogorov–Smirnov method. Accordingly, continuous variables with normal distribution of measures were reported with mean and standard deviation (SD), and continuous variables without normal distribution were reported with median and range, and nominal variables were reported with count and percentage. Appropriate (non)parametric tests were used for comparisons involving study variables. Generalized estimating equations (GEE), adjusted for age were used to evaluate the adjusted effect of the BUZZY in comparison to active comparator; results were reported as adjusted odds ratio (aOR) along a 95% confidence interval (CI). Statistical analyses were carried out using SPSS IBM 25 software (IBM SPPS, Armonk, NY, USA) and p-value equal or below 0.05 was considered as the criterion of rejection of the null hypothesis.

Ethics, trial registration, and data availability

This study was approved by the research ethics committee (REC) of Isfahan University of Medical Sciences (approval ID: IR.MUI.RESEARCH.REC.1400.115), and was registered prospectively in the Iranian Registry of Clinical Trials (registration ID: IRCT20111219008458N3, 03/08/2021). The datasets originating from the current study are available upon request of qualified investigators, subject to approval of the REC of Isfahan University of Medical Sciences.

Results

As seen from the CONSORT flow diagram (Figure 2), a total of 44 children were assessed for eligibility, among whom, 41 underwent randomization. Of whom, 30 completed the study; they had a mean age (SD) of 8.9 (1.9) years, and 16 (53.3%) were girls. The baseline characteristics of the children and the measured outcomes in each group can be interpreted from Table 1. Moreover, no harms and/or unintended adverse effects were observed in either group. Furthermore, compared to active control, i.e., topical anesthetic

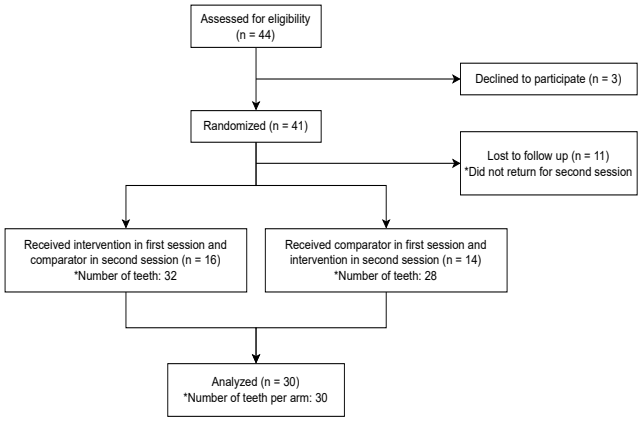

Figure 2. *CONSORT flow diagram.*

Table 1. *General demographics and outcomes.*

		Participants (n = 30)	
Mean age (SD)		8.9 (1.9)	
Female sex (n, %)		16 (53.3%)	
Study arm	BUZZY (n=30)	Topical Anesthetic Gel (n=30)	P-value
Mean heart rate (SD)			
• Before injection	104.0 (12.2)	100.8 (11.1)	0.06*
• During injection	107.7 (9.6)	109.9 (12.0)	0.33*
Median FLACC score (Range)	1 (0–3)	1 (0–4)	0.19**
Median Wong-Baker score (Range)	0 (0–8)	2 (0–10)	0.17**

Abbreviations: SD, standard deviation; FLACC, Face, Leg, Activity, Cry, Consolability scale.
* From paired samples T-test.
** From related-samples Wilcoxon signed rank test.

gel, a GEE adjusted for age and baseline heart rate, showed that usage of BUZZY is associated with significantly lower heart rates during the infiltration procedure (aOR [95%CI]: 0.02 [0.00, 0.91], P=0.04), yet, GEEs adjusted for age, showed that usage of BUZZY is associated with an insignificantly-decreased WBS (aOR [95%CI]: 0.59 [0.30, 1.14], P=0.12) and FLACC scores (aOR [95%CI]: 0.82 [0.62, 1.09], P=0.17) during the infiltration procedure.

Discussion

Our study failed to demonstrate the superiority of BUZZY over anesthetic gels regarding WBS and FLACC measures of pain and anxiety, but demonstrated a decrease associated with BUZZY, in the intra-procedural heart rate of child candidates of infiltrative anesthesia of teeth. These results, subject to replication by others, have implications for future practices in the field.

Feeling of pain is affected by different factors e.g., fear, anxiety, previous experiences, personality of the individual, confidence in the dentist; thus, it is difficult to measure (17, 18). Limited verbal communication further complicates the measurement of pain in pediatric practices. To counter this issue, and have an accurate measurement of the severity of pain, we used three different scales to measure the severity of pain, namely, a self-reported (WBS), a behavioral (FLACC scale), and a physiological (heart rate) scale. Regarding the usage of the FLACC scale, it should be noted that this scale is more frequently used, and therefore, optimized for children aged 6 months to 5 years; nevertheless, prior studies that were similar to the present study utilized this scale on children aged 5 to 12 years (10-13, 16, 19). Therefore, in order to maintain consistency and comparability with previous literature, we decided to use the FLACC scale as well.

Furthermore, we used a split-mouth design for the study; unlike parallel designs, this design could account for interpersonal differences that might exist in perception of pain between individuals. In other words, it could not be established whether two parallel group of people experience pain in a similar fashion, yet, it could be argued that the same person's perception of a specific pain in a specific setting remains similar. Nevertheless, the pain perceived in a situation may impact the pain perceived in the same situation in the future; we encountered this issue by splitting the participants into a group that received the intervention first and one that received the comparator first.

The BUZZY device, first invented for needle-related medical practices, has shown to be effective in reducing the pain and anxiety levels of children undergoing medical, needle injections; yet, its real-world effectiveness in dental injections is understudied. Recently, Faghihian *et al*. (19) and Sahiti *et al*. (17) demonstrated an additional level of pain reduction, associated with using the BUZZY device, in comparison to cold alone or counter simulation alone. Yet, our study hints that this additional level of pain reduction is not superior to using anesthetic gels, as per routine in dental injections. It could be argued that the vibrating device itself, along the vibrations and the sounds it produces, may be perceived as pain and increase the children's anxiety, thereby cancelling out the effects that it might have through stimulating temperature and vibration receptors. Furthermore, the topical anesthetic gels may also decrease the temperature of the site, thereby having a similar effect with the device. These points remain to be studied in the future, since they were not investigated in the present study.

Additionally, our study was limited in some aspects, including the number of participants, high loss to follow up, inclusion of only cooperative patients, and absence of minority populations. Particularly, whether the high loss to follow-up rate was associated with the intervention was not investigated, yet, this is deemed unlikely, since a split-mouth design was used, and the rate was similar between the participants in the intervention first and the ones in the comparator first arms. Nevertheless, further evidence is still warranted, to be used for evidence-driven practices. Future studies are encouraged to account for our limitations, especially the ones described supra.

Conclusion

Our study failed to demonstrate the superiority of BUZZY over anesthetic gels regarding WBS and FLACC measures of pain and anxiety, but demonstrated a decrease in HR associated with BUZZY.

Türkçe özet: *Pediatrik diş hekimliğinde infiltratif anestezi ile ilişkili ağrı ve anksiyete için topikal anestezik jelle BUZZY ile dışsal soğuk ve titreşim yönteminin karşılaştırılması: çift kör, split mouth, randomize, kontrollü çalışma. Amaç: Enjeksiyon ağrısını azaltmanın bir yolu, omurilik kapı kontrol sistemleriyle birlikte BUZZY ile dışsal soğuk veya titreşim uygulamaktır. Bu yöntemin çocukların infiltratif anestezi sırasında ağrı ve anksiyetelerini azaltmada etkinliğini değerlendirmeyi amaçladık. Denekler ve Yöntem: Bu, çift kör, randomize, split mouth, kontrollü bir çalışmaydı. Maksillalarının her iki tarafında çürümüş birinci daimi molar dişi olan 6 ila 12 yaş arasındaki otuz çocuk çalışmaya dahil edildi. Çocukların ağızlarının her iki tarafı, infiltratif anesteziden önce rastgele olarak ya BUZZY ya da topikal anestezik jel gruplarına ayrıldı. İnfiltratif anestezi sırasında ağrı ve anksiyete, Baker-Wong (BWS), FLACC (Yüz, Bacak, Aktivite, Ağlama, Teselli Edilebilirlik) ve kalp atış hızı (HR) ölçekleri ile ölçüldü. Sonuçlar: Yaşa ve başlangıç HR'sine göre ayarlanan genelleştirilmiş tahmin denklemi (GEE), BUZZY ile ilişkili olarak anlamlı derecede daha düşük işlem içi HR'ler olduğunu gösterdi (aOR [95%CI]: 0.02 [0.00, 0.91], p=0.04). Yaşa göre düzeltilmiş GEE'ler, BWS (aOR [95%CI]: 0.59 [0.30, 1.14], p=0.12) ve FLACC (aOR [95%CI]: 0.82 [0.62, 1.09], p=0.17) puanlarının çalışma kolları arasında karşılaştırılabilir olduğunu ortaya koydu. Sonuç: Çalışmamız, ağrı ve anksiyetenin BWS ve FLACC ölçümleri açısından BUZZY'nin anestezik jeller karşısındaki üstünlüğünü gösteremedi, ancak BUZZY ile ilişkili olarak HR'de bir azalma gösterdi. Anahtar kelimeler: pediatrik diş hekimliği, diş anksiyetesi, davranış kontrolü, ağrı, titreşim*

Ethics Committee Approval: This study was approved by the research ethics committee (REC) of Isfahan University of Medical Sciences (approval ID: IR.MUI.RESEARCH.REC.1400.115), and was registered prospectively in the Iranian Registry of Clinical Trials (registration ID: IRCT20111219008458N3, 03/08/2021).

Informed Consent: Participants provided informed consent.

Peer-review: Externally peer-reviewed.

Author contributions: RF, SZ participated in designing the study. MMT participated in generating the data for the study. RF, MMT, SZ participated in gathering the data for the study. SZ, participated in the analysis of the data. SZ wrote the majority of the original draft of the paper. MMT, SZ, SLA participated in writing the paper. RF, MMT, SZ, SLA has had access to all of the raw data of the study. RF, SZ, SLA

has reviewed the pertinent raw data on which the results and conclusions of this study are based. RF, MMT, SZ, SLA have approved the final version of this paper. SZ guarantees that all individuals who meet the Journal's authorship criteria are included as authors of this paper.

Conflict of Interest: The authors declared that they have no conflict of interest.

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