Original Article

Efficacy of external cold and a vibrating device in reducing pain and anxiety during local anaesthesia

Nivedita Jain[1], Preene Juneja[1], Updesh Masih[1], Bharath Bhushan A.K.[1], Upendra Singh Bhaduaria[2], Khushboo Badjatya[1]

[1]Department of Pediatric and Preventive Dentistry, Sri Aurobindo College of Dentistry, [2]Department of Public Health Dentistry, Sri Aurobindo College of Dentistry, Indore, Madhya Pradesh, India

Abstract

Background and Aim: To evaluate and compare the efficacy of external cold and a vibrating device in reducing the pain and anxiety amidst children receiving maxillary infiltration anaesthesia over conventional methods. **Method:** A sum of thirty subjects aged between 5 and 10 years who had undergone dental procedures requiring maxillary infiltration were enrolled in the current split-mouth randomised control study. The control intervention constitutes infiltration of 1.8 mL of 2% lignocaine in addition to 1:100,000 adrenaline (Lox, Neon Laboratories Mumbai, India) whereas, the experimental group used external cold and a vibrating device (Buzzy®, MMJ Labs, Atlanta, GA, USA) in annexation to the control protocol. Simultaneous to LA administration, pulse rate was employed as an objective measure and the subjective measure was recorded using RMS Pictorial Scale (RMS-PS) for the child's discomfort. To document the child's pain as anticipated by the dentist the revised face, limbs, arms, cry and consolability (FLACC-R) scale was employed. **Result:** Lower pain sensation and anxiety was recorded in the experimental group using Buzzy when compared to control. **Conclusion:** External cold in adjacent with vibrations might be efficient in lowering pain as well as anxiety in children experiencing infiltration dental anaesthesia though further research work is requisite with a larger sample size.

Keywords: Buzzy, gate control theory, local anaesthesia, pain

Introduction

The International Association for the study of pain defines pain as "unpleasant sensory and emotional experience associated with definite or potential tissue damage or described in respect to such damage."[1] Needle phobia is contemplated amongst the foremost fear inducing and painful procedure in paediatric dentistry.[2] Pain during an injection and associated bodily injury are amongst the two most prevalent dimensions of fear of dental injection with infrequent being acquired disease and fear related to LA.[3]

Address for correspondence: Dr. Nivedita Jain, 12 Ravindra Nagar, Palasia, Near PWD Office, Indore – 452018, Madhya Pradesh, India
E-mail: drnivedita4@gmail.com

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Psychological interventions for managing anxiety in children are primarily cognitive-behavioural treatments (CBT).[4]

Multifarious methods may be utilised to curtail pain with an anaesthetic amidst which few routinely used are application of topical anaesthesia (ex . Lidocaine),[5] modifying rate of the infiltration by lowering the speed of injection,[6] distraction techniques,[7] vibrating the encompassing tissue while administering the injection applying pressure to site of injection and precooling.[8]

Temperature (peculiarly cold) has been owning to possess a massive effect to mitigate pain in treatment procedure and is practiced for odontogenic pain management. Lately, cold gel beneath a vibrating device has been acknowledged and practiced

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among dental professionals.[9,10] The theory for utilisation of cold (temperature) in adjunct with vibration (stimulation) falls under the psychological segment, conveying that the pain is reliant on the patient's scrutiny and perception.[11] Studies state that vibrating devices distracts the patient, inflicting the brain cells to relay the vibrations thereby giving room for the delivery of analgesia.[9,11,12] The augmentation of cold element, further confuses the perceptions of signals by the pain pathway thereby facilitating a "masking effect of pain".[9,13]

In spite of the device Buzzy being first used in the year 2009 following its approval by FDA in the year 2006, limited studies stand reported in respect to its effectiveness while delivering LA for dental procedures in paediatric patients.

This prevailing study compares a commercially available device that amalgamates cold and vibration (Buzzy®, MMJ Labs, Atlanta GA, USA) in abbreviating the pain and anxiety amidst children receiving maxillary infiltration anaesthesia over conventional method, using a split-mouth randomised control trial.

Material and Methods

The present study was executed in the Department of Paediatric and Preventive Dentistry, Sri Aurobindo College of Dentistry, Indore following clearance from the ethical committee of the institution.

With children visiting the department for dental treatment being the primary source of samples, 34 children aged 5–10 years were a part of our study. Written informed consent was achieved from parents of the child for partake in our study.

Sample selection and sample power calculation, using the G-Power sample size calculator (Universitat Kiel, Kiel, Germany).

Inclusion criteria

Subjects

Patients in age group of 5 to 10 years experiencing their first dental anaesthesia requiring dental procedure in the maxillary posterior that use bilateral buccal infiltration anaesthesia

- aged between 5 and 10 years
- no previous experience of dental anaesthesia
- requiring dental procedures in the maxillary posterior teeth that use bilateral buccal infiltration anaesthesia
- Classified initially as potentially cooperative according to Wright classification of 1975 and after further screening were graded as either positive (+) or negative (-) accordant with the scale of Frankl given in 1962.

Exclusion criteria

Subjects with

- known systemic disease
- behavioural management problem
- known allergy to local anaesthetic agents

Intervention

Subjects who qualified the inclusion standard were recruited into the study and by the usage of flip coin method, we determined intervention type that subject undergoes first.

A pre-structured proforma was used to document socio-demographic characteristics and risk factors that might influence patient's pain perception. The characteristics enclosed self-reported variables like subjects' age, gender, residence, chief complaint, arch and region affected, medical history and personal history. The assessed variables included teeth requiring pulp therapy and mobile teeth.

The appointments to be implemented for procedure including and excluding Buzzy were scheduled at a gap of 15 days and a strict sterilisation protocol was ensured throughout the course of the study.

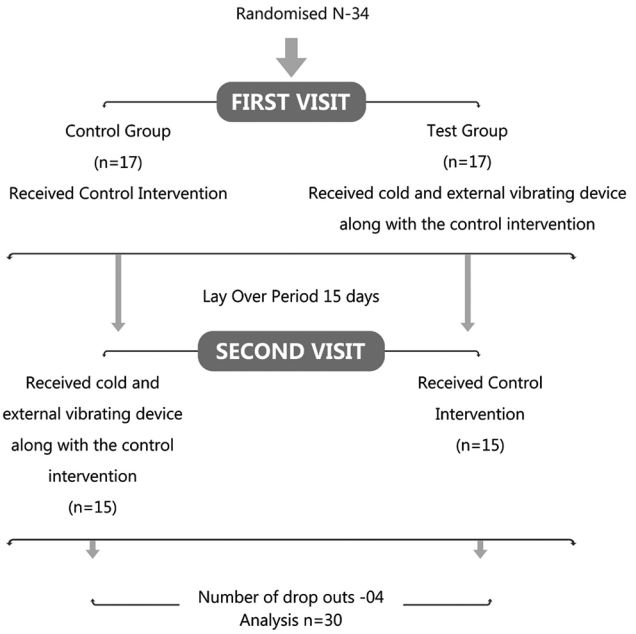
Initially the area to be injected was anaesthetised by applying 2% w/v lignocaine hydrochloride topical gel for 15–20 s (CALIGNO Jelly, Cachet Pharmaceuticals, Mumbai, India) before the using either intervention.

The control group comprised administration of 1.8 mL of 2% lidocaine with 1:100,000 adrenaline (Lox, Neon Laboratories Mumbai, India) using manual injector with the help of a 26 gauge 24 mm needle.

A gel ice pack comprising of water, sodium polyacrylate and mixed isothiazolinones cooled to 5°Celsius for 30 s followed by the application of an external vibrating device (Buzzy®, MMJ Labs, Atlanta, GA, USA) [Figure 1] comprised of the test intervention along with control protocol. A single clinician performed all procedural work to avoid variations that could arise from injection technique.

While performing the procedure, a fingertip digital pulse oximeter was placed on the index finger to record the pulse rate.

Study design and execution



Outcomes

Assessment of external cold with vibrating device at the injection site with respect to sensation of pain on basis of rating using RMS-PS.

Subject's pain response was selected using picture ticked among the five faces ranging from very happy to very unhappy which determined the magnitude of pain felt.

Recording of pulse rate the objective assessment during administration of lignocaine using a fingertip digital Pulse Oximeter.

FLACC-R scale was used to record the child's pain as perceived by the examiner. FLACC-R scores were coded as mild (scores 0–3), moderate (4–6) and severe (7–10), based on formerly defined clinically significant pain categories. A professional was trained to record patient's vitals and note the FLACC-R as observed by the examiner.

Statistical analysis

The data collected was tabulated and entered in Microsoft Excel and subjected to statistical analysis using Statistical Package for Social Sciences (SPSS, IBM version 20.0). The statistical significance level was set at 5% and $P \leq 0.05$ was statistically significant. Kolmogorov- Smirnov test and Shapiro-Wilks test were employed to test the normality of data. Mann–Whitney *U* test was performed for quantitative variables.

Results

34 children who require dental procedures in the posterior teeth that warrant the use of bilateral maxillary buccal infiltration analgesia was used. This study was successfully completed by thirty children with a total of four dropouts.

Percentage of Male: Female ratio in our study was 58.8: 41.2 and the difference was statistically insignificant.

Table 1 shows a comparative evaluation of mean pain perception and pulse rate between control and intervention group in both the genders which revealed no significant gender predilection in our study for all the parameters assessed in both the groups.

Table 2, Graph 1 shows a comparative mean pain perception between the conventional and interventional group which revealed highly significant difference in FLACC-R and RMS-PS with scores in the intervention group using Buzzy being lower than the control group.

Comparison of mean pulse rate between the control and intervention group revealed no significant difference between the two with lower pulse rate recorded in subjects of the intervention group.

Discussion

The sequel of dental fear and anxiousness comes from different sources and can be contemplated as undesirable understandings with hearing negative remarks from family, friends, and others playing a pivotal role. Fear analogous with the needle is strongest.[14]

Procedures involving needle are considered as the main source of pain in paediatric patients in different settings.[15]

In a cross-sectional study by Colares *et al*.[16] 970 children between 5 and 12 years old showed 14.4% prevalence of dental fear and anxiety.[16]

Pain management during invasive and noninvasive dental procedures is of absolute importance as pain could result in noncompliance and evasion of treatment.[17] Numerous methods are suggested to curtail the discomfort of LA injection for dental procedures amidst which desensitising the injection site is a recommended strategy.[18]

Bhadauria US, *et al*. reported in a study that precooling the site of injection before LA delivery served as an effective, reasonable and reliable method in alleviating pain especially in subjects with fear and anxiety during dental procedures.[8]

Buzzy® is a vibrating plastic made device with appearance of a bee with cooled wings. It is a versatile and economic product. It is hypothesised to work based on the gate control theory, on the principle that pain modulation is carried from peripheral nervous system to the central nervous system through a gating system in the dorsal horn of the spinal cord.[19]

The vibration element of Buzzy can induce excitation of A-beta fibres (fast non-noxious motion nerves), which eventually causing blockage of A-delta (afferent pain receptive nerves).[20] However, the cold element will excite the C fibres; and if applied prior to the pain stimulant, will block A-delta pain signal as well. Buzzy® has presented in studies

Table 1: Gender -wise comparison of mean pain perception and pulse rate between control and intervention group

Parameter	Control group *n*=30 Mean±S.D		*P*	Interventional group (buzzy) *n*=30 Mean±S.D		*P*
	Male	Female		Male	Female	
FLACC-R	6.20±2.04	7.14±1.21	0.294 (NS)	2.20±1.47	3.00±1.15	0.250 (NS)
RMS-PS	3.80±1.03	3.71±0.755	0.854 (NS)	2.10±0.87	2.00±0.57	0.796 (NS)
Pulse Rate	111±12.89	112.2±14.06	0.848 (NS)	107.00±14.98	105.48±12.59	0.824 (NS)

NS=Non-Significant (P<0.05). *Measured using Mann Whitney U Test

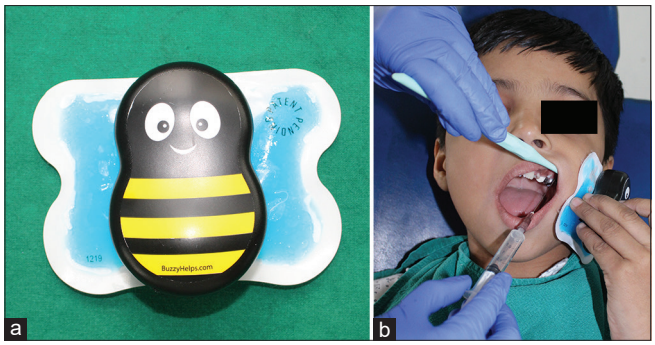


Figure 1: Buzzy (a) and its application (b)

to be superior to placebo and to vapocoolants and analgesic creams.[9,21]

This study assessed pain and anxiety perception in 30 children with need of maxillary buccal infiltration anaesthesia bilaterally in a split-mouth randomised control trial and observed the practice of Buzzy® as a potent method to diminish the pain during administration of local anaesthetic agents when compared with conventional treatment. This will instil positive attitude of the patient and will help gain cooperation level from the child.

The age-group of 5–10 years was considered as it since this age-group has been proposed as an age where cognitive development begins to manifest itself.[22]

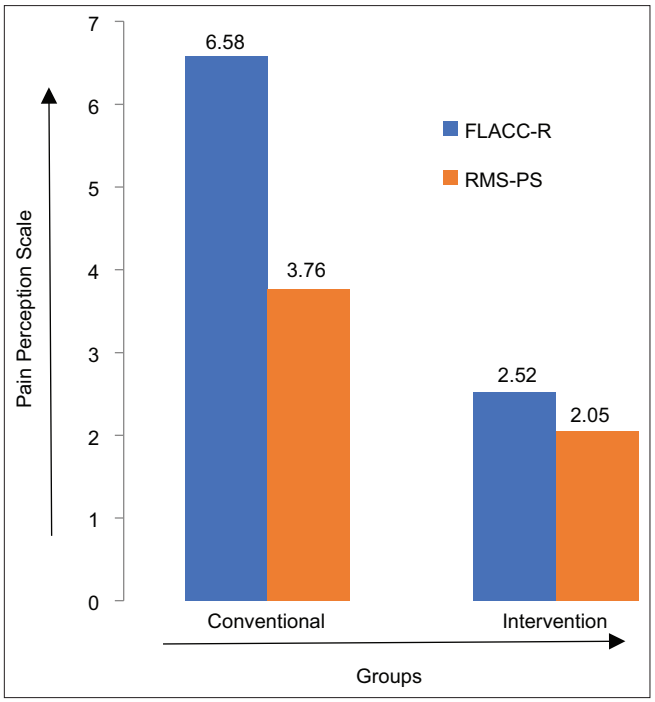
Buccal infiltration was preferred mode of anaesthesia in comparison with others as it is least painful.[23,24] Further, the technique is not considered challenging to the dental surgeon, and hence ensures minimum variability in the method of administration of injection.[23]

Studies conducted by Beck and Weaver,[25] and Guinot Jimeno *et al*.[26] stated usefulness of pulse oximeter in gauging the extent of stress and anxiety in patients undergoing dental treatment. Hence, pulse rate and oxygen saturation levels were recorded prior to local anaesthetic agent administration.

RMS-PS was preferred for subjective measurement of pain for the patient since it has advantages like it is simple, quick, efficient to evaluate anxiety in a paediatric speciality dental clinic. It also aids in endowing a good dental experience and a confiding relationship between paediatric dentists, patients, and parents.[27] In present study, RMS-PS scores recorded were found to be statistically lower in interventional group when correlated to the control group.

The FLACC-R scale was used as it has definite descriptors and unique behaviour as identified by parents for every child.[28] Statistical analysis revealed FLACC-R scores to be lower significantly in the intervention group when compared to control group.

Sahebkar Moeini *et al*.[29] (2020) investigated the effect of cold and warm vibration on pain caused by IV catheterisation in



Graph 1: Mean Pain Perception recorded using FLACC-R and RMS-PS in Conventional and Buzzy group

Table 2: Comparison of Mean Pain Perception and Pulse Rate recorded in Conventional and Buzzy group

Parameter	Conventional Group *n*=30 Mean+S.D	Interventional Group (Buzzy) *n*=30 Mean+S.D	*P*
FLACC-R	6.58+1.76	2.52+1.37	0.001 (HS)
RMS-PS	3.76+0.90	2.05+0.74	0.001 (HS)
Pulse rate	111.52+12.96	106.35+13.65	0.202 (NS)

HS=Highly Significant (*P*>0.05). NS=Non-Significant (*P*<0.05). *Measured using Mann-Whitney U test

3- to 6-year-old children and stated that both cold and warm vibrations could reduce the pain caused by injection, but cold vibration showed greater effect on reducing pain. Therefore, cold or warm vibrating devices are suggested in management of aggressive painful procedures in children.

Erdogan B, *et al*.[30] (2021) aimed to determine the effect of the distraction cards, virtual reality and Buzzy® methods on venipuncture pain and anxiety in children aged 7–12 years and concluded that Buzzy® group had the lowest mean Visual Analogue Scale and mean Wong Baker FACES score.

Buzzy helps children distract and get the better of their negative perception to pain instead of actually fixing the child behaviour. This result is in line with a study by Alanazi KJ, *et al*.[31] and is discordant to the recordings of a study by Elbay *et al*.[32]

The observations noted by us our concurrent with studies conducted by Alanazi KJ, *et al*.[31] Bilsin E, *et al*.[33] and Suohu T, *et al*.[34] reported that application of combination of external cold and vibration at the anaesthesia site resulted in children

experiencing a significant lower injection pain during dental injection.

Our study to the best of our knowledge is a pioneer study of its kind which used RMS pictorial scale and revised FLACC-R to assess pain and anxiety in paediatric dental patients while administering local anaesthesia using Buzzy.

Even though, sample size considered stands out as a limitation of this study, technically a larger sample may have provided a stronger support to our hypothesis.

Conclusion

- The application of the "BUZZY" was effective in reducing pain perception during injection and perceived anxiety of children.
- The intervention of Buzzy before administration of LA can be practiced as an efficient, reasonable and reliable method in alleviating pain chiefly in paediatric patients.

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Conflicts of interest

There are no conflicts of interest.

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