ORIGINAL RESEARCH

# Effectiveness of an External Cooling and Vibrating Device vs Counterstimulation in Reducing Discomfort of Inferior Alveolar Nerve Block in Pediatric Dental Patients: A Single-blinded Randomized Controlled Trial

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## Abstract

**Background:** Pain management in pediatric patients during dental procedures is very important. Here, the traditional method of behavior management is compared with novel methods.

**Aim:** To compare and determine the effectiveness of an external cooling and vibrating device vs counterstimulation with the conventional technique in reducing the fear and discomfort of pediatric dental patients aged 5–7 years during inferior alveolar nerve block (IANB).

**Materials and methods:** The study population consisted of children aged 5–7 years, rated as positive (+) or negative (–) on the Frankl behavior rating scale, who reported to the Department of Pediatric and Preventive Dentistry and required dental procedures in posterior teeth that warranted the use of IANB.

Anxiety measurement was conducted by both objective and subjective means. The subjective measures included Wong–Baker Faces Pain Rating Scale (WBFPRS), as chosen by the patient, and Face, Legs, Activity, Cry, Consolability Scale (FLACC), as recorded by the observer, while the objective measure was pulse rate, recorded by a pulse oximeter.

**Group A:** External cooling and vibrating device (Buzzy).

**Group B:** Counterstimulation group.

**Group C:** Control group.

**Results:** The WBFPRS score and FLACC score reduced following the intervention in the counterstimulation group, indicating a reduction in pain perception and anxiety compared to the application of Buzzy and the conventional technique.

**Conclusion:** Counterstimulation was the most effective in reducing pain perception and anxiety during the administration of IANB.

**Clinical significance:** The injection of local anesthetic remains one of the painful and fear-inducing procedures in pediatric dentistry. This study provides evidence that counterstimulation is effective in reducing pain perception and anxiety during the administration of IANB.

**Keywords:** Behavior modification, Counterstimulation, Dental anesthesia, Randomized controlled trial, Vibration.

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## Introduction

In pediatric dentistry, the delivery of local anesthetic continues to be a painful and frightening procedure.[1] Reduction of pain can promote a good rapport between the pediatric dentist and the child.[2]

No studies could be found in the literature comparing the Buzzy device and counterstimulation with the conventional technique for behavior management of the child during inferior alveolar nerve block (IANB) procedure. Hence, the study was conducted to compare and determine the effectiveness of an external cooling and vibrating device versus counterstimulation with the conventional technique in reducing the fear and discomfort of pediatric dental patients aged 5–7 years during IANB.

The objectives were:

- To evaluate the perception of pain and anxiety level of patients pre- and post-operatively by recording Wong–Baker Faces Pain Rating Scale (WBFPRS) score by the child, pulse rate of the child using a finger pulse oximeter, and Face, Legs, Activity, Cry, Consolability (FLACC) scale score by the evaluator.
- To compare the mean pulse oximeter, WBFPRS, and FLACC scale readings between the study groups before and after the procedure.

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**Conflict of interest:** None

## Materials and Methods

The study was conducted as a single-blinded randomized controlled trial over 1 year after obtaining ethical clearance (IEC no.: 207/2020/DCC). It was registered in the Clinical Trials Registry—India (CTRI reg. no. CTRI/2021/04/033124).

Children aged 5–7 years, who belong to Frankl's behavior rating positive (+) or negative (–), requiring dental procedures that warranted the use of IANB, were included in the study.

Children with systemic illness, allergies, congenital syndromes, and a history of neurobehavioral disorders, those with any problem associated with the site of application of the cooling and vibrating device, and children who exhibited Frankl's definitely negative behavior during the intervention were excluded from the study.

The sample size was 41 in each group, determined by a prior study conducted by Alanazi et al.[1] The consecutive selection method was employed for sampling.

Using block randomization with a block size of 6 (1:1:1 ratio of allocation to each group), selected children were equally distributed into three groups.

Group A: External cooling and vibrating device group.

Group B: Counterstimulation group.

Group C: Control group.

In each group, pulse rate was recorded using the pulse oximeter. The child chose a face from the WBFPRS that described how he or she felt at that moment. Pulse rate and FLACC scale readings were recorded by an independent observer blinded to the study group. The injection site was dried using sterile gauze, and anesthetic gel (2% lignocaine hydrochloride gel) was applied for 1–2 minutes (Figs 1 to 4).

### Group A: External Cooling and Vibrating Device Group

The device was first introduced to the child to familiarize them with it. The frozen wing was attached to Buzzy and placed extra-orally closer to the injection site. Using a 25-mm, 28-gauge needle and 1.8 mL of 2% lignocaine, IANB was administered, during which the child held the device.

### Group B: Counterstimulation Group

Counterstimulation was done by gently vibrating the mucosa near the injection site using the thumb while administering IANB.


**Fig. 2:** Child choosing a face from the WBFPRS

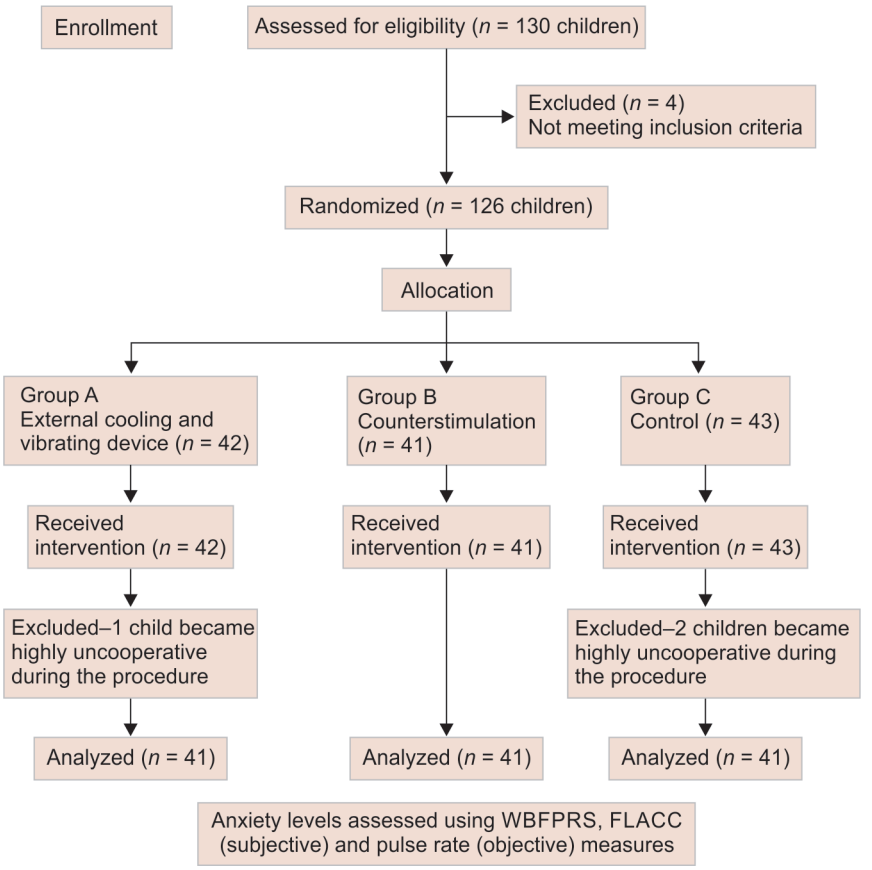


**Fig. 1:** Consolidated Standards of Reporting Trials flow diagram

**Fig. 3:** Applying external cooling and vibrating device (Buzzy)

**Fig. 4:** Applying counterstimulation

Mild pressure was applied using the forefinger over an equivalent extra-oral site.

### Group C: Control Group

The children in this group were given topical anesthesia followed by IANB. In each group, immediately after the IANB, the child again chose a face from the counterstimulation. Readings from the FLACC scale and pulse rate were recorded by the same independent observer.

### Statistical Analysis

Data analysis was done using the software Statistical Product and Service Solutions (SPSS) version 22. The Shapiro–Wilk test was used to check the normality of distribution. For comparing baseline values with follow-up values in the groups, the paired *t*-test or Wilcoxon signed-rank test was used, based on the normality of distribution. The statistical significance of the difference between the means of variables among different independent groups was tested using the Kruskal–Wallis test. To determine the significance between the groups, the Bonferroni *post hoc* test was used.

## Results

In group A, the increase in pulse rate was statistically significant ($p$-value = 0.003).

The increase in WBFPRS ($p$-value = 0.960) and FLACC score ($p$-value = 0.066) following the intervention was not statistically significant.

In group B, the decrease in WBFPRS ($p$-value = 0.828) and FLACC ($p$-value = 0.096) scores following the intervention was not statistically significant.

An increase in the pulse rate was observed after the intervention ($p$-value = 0.020; statistically significant).

In group C, the increase in WBFPRS ($p$-value = 0.002), FLACC ($p$-value = 0.001) scores, and pulse rate ($p$-value = 0.001) following the intervention was statistically significant.

After the intervention, the WBFPRS score reduced in the counterstimulation group, and the change in the WBFPRS score shows a negative value of −0.24 ± 4.43. This is indicative of a reduction in pain perception and anxiety following the application of counterstimulation compared to the conventional technique. The FLACC score also showed a reduction in the counterstimulation group compared to both the external cooling and vibrating device (Buzzy) group and the control groups, with a negative value of change in the FLACC score of −0.46 ± 1.67.

The change in pulse rate was lowest in the external cooling and vibrating device (Buzzy) group, followed by the counterstimulation group. Therefore, there was a reduction in pain perception and anxiety in the external cooling and vibrating device (Buzzy) group compared to counterstimulation according to the objective scale, but it was not statistically significant.

## Discussion

To minimize pain and anxiety associated with the administration of local anesthesia, many methods have been described. Vibration stimulus is one of the nonpharmacologic methods used to mitigate the unpleasant sensations of local anesthesia injection.[3]

The effectiveness of the intervention used during dental procedures to reduce fear and pain in an anxious child needs to be assessed by evaluating the anxiety levels. This can be done either by using subjective measures (Wong–Baker Faces Pain Rating Scale, FLACC, Facial Image Scale, Venham's Clinical Anxiety Rating Scale) or objective measures (pulse rate, respiratory rate, oxygen saturation, etc.).

In this study, anxiety was measured using both objective and subjective means. The subjective measures were WBFPRS, as chosen by the patient, and FLACC, as recorded by the observer. The objective measure was pulse rate, recorded by a pulse oximeter.

The present study focused on two techniques to reduce the pain and anxiety associated with the delivery of local anesthesia, which were compared with the conventional technique. The participants were assigned to three groups: a group where the Buzzy® device was used while administering local anesthesia, a group that employed counterstimulation, and finally a group where the conventional method was used.

The WBFPRS score reduced following the intervention in the counterstimulation group, and the change in the WBFPRS score showed a negative value, indicative of a reduction in pain perception and anxiety following the application of counterstimulation compared to the conventional technique. These inferences were in accordance with those of a systematic review by Tirupathi and Rajasekhar (2020).[4] Seven studies were included in that study, and the effectiveness of vibration in reducing pain due to local anesthesia was evaluated in children. In most of the studies, the pain scores reported by children in the vibratory counterstimulation group were

**Table 1:** Comparison of change in WBFPRS score, pulse rate, and FLACC score before and after the intervention among three groups

| *Variable* | *Group A (N = 41)* | *Group B (N = 41)* | *Group C (N = 41)* | *Test* | *p-value* |
|---|---|---|---|---|---|
| Change in WBFPRS score | | | | | |
| Mean ± SD | 0.04 ± 2.94 | −0.24 ± 4.43 | 1.75 ± 3.13[c] | Kruskal–Wallis test | 0.019 |
| Median (IQR) | 0 (−2 to 1) | 0 (−4 to 4) | 20 to 4 | | |
| Change in pulse rate-beats per minute | | | | | |
| Mean ± SD | 3.02 ± 6.76 | 3.75 ± 9.89 | 5.04 ± 9.01 | Kruskal–Wallis test | 0.804 |
| Median (IQR) | 4 (−2 to 7) | 5 (−3 to 9.5) | 4 (−1 to 11) | | |
| Change in FLACC score | | | | | |
| Mean ± SD | 0.51 ± 1.91 | −0.46 ± 1.67[a] | 1.02 ± 1.63[c] | Kruskal–Wallis test | 0.004 |
| Median (IQR) | 0 (−1 to 2) | 0 (−2 to 1) | 10 to 2 | | |

[a]Statistically significant between groups A and B; [c]Statistically significant between groups B and C

significantly lower than in the control group. In six studies, the pain reported was evaluated using the WBFPRS scale. The study concluded that during the administration of local anesthesia, the use of intraoral vibration as a counterstimulatory measure was effective in alleviating the pain perceived by the child (Table 1).

While correlating the results of the present study with those of the systematic review and meta-analysis, the reduction in scores of subjective parameters might be attributed to intraoral vibration as a counterstimulatory measure, whether manual or motorized. Whether the mode of applying vibration (intraoral vs extraoral) matters in reducing pain perception is open for further research.

The FLACC score also showed a statistically significant reduction in the counterstimulation group when compared to both the Buzzy and control groups, with a negative value of change in the FLACC score, indicative of a reduction in pain perception and anxiety following the application of counterstimulation compared to the application of Buzzy and the conventional technique. This is in agreement with the study conducted by Aminabadi et al. (2008),[5] where counterstimulation was found to be effective in minimizing pain during the delivery of local anesthetic.

In contrast, Sahithi et al. (2021)[6] evaluated the efficacy of counterstimulation and external vibrating devices in reducing children's dental anxiety and pain perception during the injection of local anesthetic. Based on the mean scores of WBFPS and VAS, a delay in pain perception following the administration of local anesthetic was more prominent in the Buzzy group when compared to the counterstimulation group. The study concluded that using a Buzzy® device for external vibration is better compared to the application of counterstimulation in reducing apprehension in children during a painful dental procedure.

The change in FLACC score in the Buzzy group is lower when compared to the control group, which does not show any statistical significance. Children in the counterstimulation group reported less pain when compared to the control group, as per the FLACC score.

In all three groups, the pulse rate showed a statistically significant increase. The elevation in pulse rate was lower in group A, where the Buzzy device was used, followed by the counterstimulation group. The increase in pulse rate was highest in the control group. However, the change in pulse rate between the groups was statistically nonsignificant. This is consistent with the results of the study conducted by Suohu et al. (2020),[7] where the oxygen saturation levels and the pulse rate values were the same before and after the procedure when comparing Buzzy with the conventional syringe.

While conducting the study, it was observed that some children, though they were comfortable playing with Buzzy, got frightened when the cold and vibration of Buzzy were applied to their cheeks during the administration of IANB. It might have been the failure to distract those children that could have been reflected as the inappreciable reduction in the values of subjective parameters. Though the change in pulse rate (objective parameter) was lowest in the Buzzy group when compared to counterstimulation and control, the effectiveness of Buzzy in reducing pain perception and anxiety couldn't be substantiated, as that change was not statistically significant.

Based on the observations of the present study, the null hypothesis was rejected, as it was found that the counterstimulation method was effective in reducing pain perception and anxiety in children during the delivery of local anesthesia when compared to Buzzy (the external cooling and vibrating device) and the conventional technique.

The possible limitations of the study are:

- Only single blinding was done in this study. Only the independent observer was blinded. Neither the child nor the clinician could be blinded in this study.
- The subjective and objective parameters were not assessed during the intervention, as it was of short duration. The scores were taken only before and after the intervention.

## Conclusion

Counterstimulation was found to be more effective in comparison with the control, with a statistically significant difference in both subjective parameters (WBFPRS and FLACC).

Counterstimulation was found to be more effective in comparison with the external cooling and vibrating device (Buzzy), with a statistically significant difference in one subjective parameter (FLACC).

The external cooling and vibrating device (Buzzy), in comparison with the control, had no statistically significant difference in any of the subjective or objective parameters.

To conclude, within the limitations of the present study,

- Counterstimulation was the most effective method in decreasing the discomfort during IANB in pediatric dental patients aged 5–7 years, as compared to the external cooling and vibrating device and conventional technique.

- The effectiveness of the external cooling and vibrating device (Buzzy) in alleviating the discomfort of IANB in pediatric dental patients was found to be similar to the conventional technique.

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