Original Article

Comparison of the Effectiveness of Two Different Methods of Alleviating Pain and Anxiety during Local Anaesthesia Administration in Children: A Split-mouth Study

Seema Jabeen, Anshika Dixit, Suleman Abbas Khan, Saumya Navit, Shaifali Agrawal, Rudrani Roy
Department of Pediatric Dentistry, Saraswati Dental College and Hospital, Lucknow, Uttar Pradesh, India

Abstract

Introduction: This study aimed to compare the effectiveness of two different methods, a custom-designed mucosal vibrator and topical benzocaine gel, in alleviating pain and anxiety during local anaesthesia (LA) administration in paediatric patients. **Materials and Methods:** A randomised, split-mouth controlled trial was conducted with 30 paediatric patients aged 5–10 years. Each child received LA with a custom-designed mucosal vibrator in one session and with topical benzocaine gel in another. Pain perception and anxiety were assessed using the Wong-Baker FACES Pain Rating Scale, Sound–Eye–Motor Scale and pulse rate measurements. The sequence of interventions was randomised using the sequentially numbered, opaque, sealed envelope technique. **Results:** The study found that the custom-designed mucosal vibrator significantly reduced pain perception compared to the benzocaine gel, as evidenced by both subjective and objective pain scores ($P < 0.05$). However, the two methods showed no significant difference in anxiety levels, as indicated by similar pulse rate changes ($P > 0.05$). **Conclusion:** The custom-designed mucosal vibrator offers a cost-effective and efficient alternative to topical benzocaine for reducing pain during LA in children, though it does not significantly alter anxiety levels. This device could be a valuable tool for paediatric dental practitioners to improve the comfort of their patients during dental procedures.

Keywords: Anxiety reduction, local anaesthesia, mucosal vibrator, pain management, Sound–Eye–Motor Scale, topical benzocaine, Wong-Baker FACES Pain Scale

Introduction

Dental anxiety and fear are well-known elements that have a detrimental effect on a patient's willingness to receive dental care.[1] While they can afflict persons of all ages, this state appears to be most prevalent in children.[2] Anxiety is a state of dread, trepidation or unease brought on by impending events or by anything with an unpredictable outcome.[3] It is suggested that children who are extremely worried about treatment procedures report more pain than usual.[4]

On the other hand, pain is a subjective experience.[5] It is defined by the International Association for the Study of Pain as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.'[5] Taddio *et al*. reported that 68% of children aged 6–8 years, 65% of children aged 9–12 years and 51% of adolescents aged 13–17 years have a strong phobia of needles.[6]

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Hence, effective pain control and anxiety management during the dental treatment of paediatric patients is the cornerstone for successful behaviour guidance. Although local anaesthesia (LA) is considered the backbone of pain prevention and control in dentistry, it is connected with pain. This pain is further aggravated by the fear and anxiety caused by the sight of the needle, a condition referred to as needle phobia or trypanophobia.[7]

The application of topical anaesthetic agents – available in gel, liquid, ointment, patch and pressurised spray forms – is the

Address for correspondence: Dr. Seema Jabeen, Department of Pediatric Dentistry, Saraswati Dental College and Hospital, Lucknow, Uttar Pradesh, India.
E-mail: drsimlko@gmail.com

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most commonly practised method to control the pain of needle insertion. Topical anaesthetics with benzocaine or lidocaine are the most often used in dentistry.[8] Benzocaine, having a long-lasting effect, is comparatively safe and poses a minimal risk during topical application.[9] Nevertheless, depending on the amount of anaesthetic substance absorbed by the mucosa and the relative toxicity of its components, this method could have complications or side effects.[8]

Research continually seeks newer and better methods for pain management while administering LA that can alleviate both the patient's fear and the discomfort caused by the needle. Contributions include buffering LA, intranasal and inhalational anaesthesia, using cold spray, applying pressure, employing a mechanical delivery system, vibrating the tissue or using non-injectable anaesthesia. Over the past decade, vibrating devices have demonstrated efficacy in distracting paediatric patients and numbing the pain associated with injections.[10] Melzack and Wall's Gate Control Theory serves as the foundation for vibratory stimulation.[11] According to Gate Control Theory, the dorsal horn of the spinal cord contains a 'gate' that regulates the transmission of pain from the peripheral nervous system to the central nervous system.[12] As a result, the brain perceives vibration stimuli, which are used as a counter-stimulant to an anaesthetic injection before the pain associated with the injection.[13]

Certain commercially available mucosal vibratory systems have posed an innovative breakthrough in dentistry. These devices reduce discomfort at the injection site by producing vibrations at a sustained frequency as a counter-stimulation. However, these mucosal vibrating devices are not readily available in India and are expensive. These devices' high cost and unavailability motivated us to design a cost-effective device to benefit dental practitioners.

Aim

The current clinical study aims to analyse and compare the efficacy of a custom-made mucosal vibrating device and benzocaine gel in reducing pain perception and anxiety levels during local anaesthetic administration, to lower the unpleasant experience of needle pricks for paediatric patients.

Materials and Methods

The present study was carried out in the Department of Pediatric Dentistry, Saraswati Dental College and Hospital, Lucknow, with the approval of the Institutional Human Ethics Research Committee and the Institutional Research and Development Committee. Informed consent was obtained from the parents of the patients, along with the child's brief medical and dental history. The sample size was calculated using G Power software (version 3.1.9.4). Based on previous studies, with standard values of alpha error set at 0.05 and the power of the study at 80%, the minimum sample size required was 30 patients. Thus, 30 patients aged between 5 and 10 years were selected, fulfilling the inclusion criteria. Each patient served as their own control owing to the split-mouth crossover study design.

The present *in vivo* split-mouth randomised controlled trial aimed to fairly compare the effectiveness of benzocaine gel and a custom-designed mucosal vibrator on pain perception and anxiety levels in paediatric dental patients during local anaesthetic administration. Based on the intervention used on the same thirty patients, the following groups were formed:

- Group A (Experimental group): A custom-designed mucosal vibrator was used while administering LA
- Group B (Control group): In this group, topical benzocaine gel was used while administering LA.

The samples were randomised in terms of the order of intervention. The sequence of interventions, i.e., which intervention was to be used first, was generated using the sequentially numbered, opaque, sealed envelope (SNOSE) technique. Intervention A (custom-designed mucosal vibrator) was written on 15 pieces of paper, and Intervention B (topical benzocaine gel) was on another 15 pieces of paper, placed in non-transparent, enclosed envelopes. Each participant was permitted to choose an envelope. The investigator then unsealed the envelope, and the participant was treated accordingly. Intervention A received vibration with the custom-designed mucosal vibrator followed by a local anaesthetic injection, whereas Intervention B received topical benzocaine gel application followed by a local anaesthetic injection at the first appointment. Fifteen children who received LA injection with the vibrator device at the first appointment were treated with the topical gel in the second appointment and vice versa for the remaining 15 children.

During the first visit, an oral screening/examination was conducted along with the case history. Frankl's behaviour rating and baseline pulse rate were recorded, and the treatment procedure was explained in detail to the child. Behaviour modification of the child was done, and the SNOSE technique was performed to choose the intervention to be used first. The subsequent visits were the treatment visits under LA.

In the next appointment, the chosen intervention (vibrations or topical anaesthetic) through the SNOSE technique was utilised before injecting the anaesthesia. During the administration of LA, the dental operatory assistant recorded the Sound–Eye–Motor Scale. After administering LA and before commencing the treatment procedure, the Wong-Baker FACES Pain Rating Scale (WBFPRS) chart [Figures 1 and 2] was shown to the child to record the prick pain, and the pulse rate was recorded again to assess anxiety.

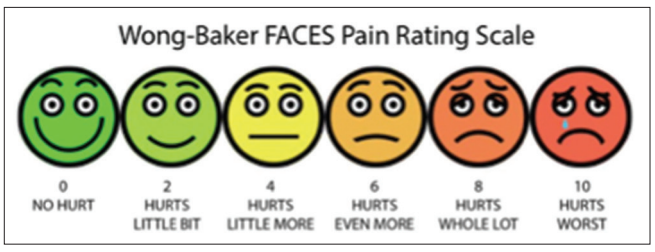

Figure 1: Wong Baker FACES Pain Reading Scale

In the subsequent visit, which occurred after 3–5 days, the other intervention was utilised on the contralateral side within the same arch. The pulse rate, WBFPRS and Sound–Eye–Motor Scale were recorded as done previously. The following intervention techniques were applied before and during the treatment.

Custom-designed mucosal vibrator group

In the mucosal vibrator group (Group A), after employing the tell-show-do technique, vibrations were applied through the custom-designed mucosal vibrator to the injection site for 10 s before and during the entire administration of the local anaesthetic solution. While administering the LA, the needle was kept in close proximity to the mucosal vibrator [Figure 3]. This helped the local anaesthetic solution dissipate and provided a soothing effect. The procedure was performed after cleaning the mucosa of saliva near the area of needle penetration. The custom-designed vibration device was prepared by attaching an amalgam condenser to a vibrating gadget (Envilife Quality Products), made of acrylonitrile butadiene styrene, operated on an AAA battery with a vibrating speed of 10 Hz [Figure 4].

Figure 2: Child depicting Wong-Baker FACES Pain Rating Scale

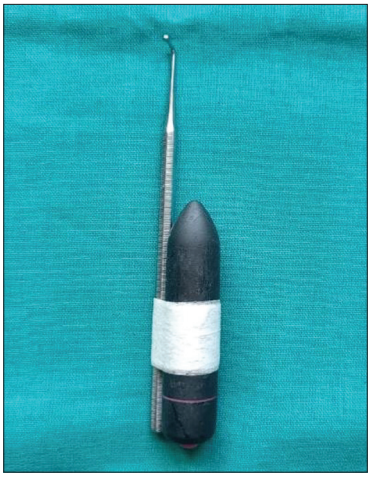

Figure 4: Custom-designed mucosal vibrator

Topical benzocaine group

In the topical gel application group (Group B), the site of injection was isolated using cotton rolls, and sterile cotton applicators were used to apply the topical benzocaine anaesthetic gel for 30 s at the site of injection. The gel was left for 1–2 min after briefing the child [Figure 5]. Following the intervention, 1.5 mL of LA solution was administered (1 mL/min) using a 24-G sterile syringe needle [Figure 6], and the dental treatment was carried out in both groups.

Results

The results of the study revealed notable differences in pain perception and anxiety levels between the two intervention groups. In Group A (mucosal vibrator), the mean pulse rate at baseline was 89.20 ± 8.54, and post-intervention, it was 89.87 ± 9.11, showing a minimal and statistically insignificant change (P = 0.349), as shown in Table 1. Similarly, in Group B (topical benzocaine), the baseline pulse rate was 89.20 ± 8.54, which slightly increased to 90.60 ± 8.92 post-intervention, but this change was also not statistically significant (P = 0.057), as presented in Table 2. When comparing the post-intervention pulse rates between Group A and Group B, the difference was 0.73 ± 1.93, which was not

Figure 3: Application of custom designed mucosal vibrator and local anaesthesia administration

Figure 5: Application of topical benzocaine gel

Figure 6: Application of local anaesthesia

significant (P = 0.754), as shown in Table 3. These findings suggest that neither intervention significantly impacted anxiety levels, as indicated by the pulse rate.

However, the pain perception outcomes measured by the Wong-Baker FACES Pain Scale and the Sound–Eye–Motor Scale showed significant differences between the groups. Group A (mucosal vibrator) demonstrated lower pain scores (1.00 ± 0.98) compared to Group B (topical benzocaine) with a score of 1.60 ± 1.13, with the difference being statistically significant (P = 0.023), as shown in Table 4. In addition, the Sound–Eye–Motor Scale scores were also lower in Group A (1.73 ± 0.83) compared to Group B (2.27 ± 0.74), with a significant difference (P = 0.007), as presented in Table 5. These results indicate that the custom-designed mucosal vibrator was more effective in reducing pain perception and improving patient comfort compared to the topical benzocaine gel during local anaesthetic administration in paediatric patients.

Discussion

Getting into the good graces of a child can be instrumental in achieving the needed patient cooperation, which eventually gets half of the work done for the paediatric dentist. Making good memories for children during dental visits is one of the most important aims of paediatric dentistry. However, contradictory to it, the most cumbersome aspect for a pedodontist is treating child patients with dental anxiety and fear-related behaviours. A study by Colares *et al*. on 970 children aged between 5 and 12 years old showed a 14.4% prevalence of dental fear and anxiety.[14] According to the American Academy of Pediatric Dentistry, the greatest barrier to preventing children from seeing a dentist is their fear of pain.[15] The study conducted by Hmud and Walsh[16] determined the '4S factors' that contribute to children's dental anxiety. These factors include sights (of dental operatory), sounds (of suction and airotor), sensations (like high-frequency vibrations) and smells (of dental materials).[16]

Table 1: Comparative evaluation of mean pulse rate at baseline and post-anaesthesia among Group A (mucosal vibrator) paediatric patients

Characteristics	Mean±SD (bpm)
Baseline	89.20±8.54
At intervention	89.87±9.11
Post-intervention change	0.67±3.84
Significance of change (paired *t*-test)	t=0.952; P=0.349 NS

NS: Non-significant (P<0.05), SD: Standard deviation

Table 2: Comparative evaluation of mean pulse rate at baseline and post-anaesthesia among Group B (topical benzocaine) paediatric patients

Characteristics	Mean±SD (bpm)
Baseline	89.20±8.54
At intervention	90.60±8.92
Post-intervention change	1.40±3.87
Significance of change (paired *t*-test)	t=1.984; P=0.057 NS

NS: Non-significant (P<0.05), SD: Standard deviation

Table 3: Comparative evaluation of post-intervention pulse rate between Group A and Group B paediatric patients

Characteristics	Mean±SD (bpm)
Group A	89.87±9.11
Group B	90.60±8.92
Difference between two groups (Group B - Group A)	0.73±1.93
Significance of difference (independent samples *t*-test)	t=0.315; P=0.754 NS

NS: Non-significant (P<0.05), SD: Standard deviation

Table 4: Comparative evaluation of post-intervention wrong bakers

Characteristics	Mean±SD (bpm)
Group A	1.00±0.98
Group B	1.60±1.13
Difference between two groups (Group B - Group A)	0.60±0.72
Significance of difference under independent non-parametric considerations (Mann–Whitney *U*-test)	Z=2.274; P=0.023 significant

Significant (P<0.05). SD: Standard deviation

Table 5: Comparative evaluation of post-intervention sound eye motor scale scores between Group A and Group B paediatric patients

Characteristics	Mean±SD (bpm)
Group A	1.73±0.83
Group B	2.27±0.74
Difference between two groups (Group B - Group A)	0.53±0.82
Significance of difference under independent considerations for non-parametric scalar data (Mann–Whitney *U*-test)	Z=2.713; P=0.007 significant

Significant (P<0.05). SD: Standard deviation

However, apprehension associated with trypanophobia and the needle prick pain experienced by children while administering LA serves as the major obstacle for paedodontists.[17] The American Academy of Paediatrics (2001) states that children ought to undergo painful procedures as little as possible.[18] Therefore, alleviating anxiety, controlling pain and preventing negative responses while administering local anaesthetic injections have clinical importance in dental practice. The most often employed approach for alleviating the discomfort of inserting a needle is the prior application of topical anaesthesia over the soft tissue.[19] Investigators have found that 20% benzocaine works better than other anaesthetics when applied topically at the injection site because of its quick and prolonged effects on the oral mucosa and its biocompatibility when compared to some other less potent medications.[20] Unfortunately, topical anaesthetics typically prevent deep tissues from getting anaesthetised by pharmacologically affecting superficial tissues (2–4 mm).[21] Furthermore, a lot of patients find topical anaesthetic gels and sprays uncomfortable due to their negative taste.[22]

Due to these issues, a dependable method of pain management during injection is required. Among all the techniques available, non-invasive, non-pharmacological techniques are the ones that different paediatric dental organisations recommend.[23] Among these, distraction is considered one of the safest and least expensive behaviour control strategies; it draws the patient's attention away from painful stimuli.[24,25] Studies by Alanazi *et al*.,[26] Sahithi *et al*.[27] and Hegde *et al*.[28] have demonstrated that cold and vibration can alleviate pain and stress while administering infiltration anaesthesia. The vibrating mucosa on the injection site before LA might be a distraction for children. In addition, the vibration approach is considered to be a time-saving technique in comparison to local anaesthetic gels. It is easier as it eliminates the need to dry the injection site. Using commercially available vibrating devices while administering dental anaesthesia has shown mixed results in dentistry. However, the higher cost of these vibrating devices and lack of availability in the Indian market motivated us to design a custom-made mucosal vibrator that is cost-effective and easy to assemble in the clinic. In the present study, an innovative, simple and child-friendly gadget that combines the effects of vibration with distraction was designed. This device comes with the advantages of being easily assembled and affordable. The device runs on batteries and is reusable. The present study demonstrated that using a mucosal vibrator while injecting local anaesthetic alleviates patient discomfort, and the broad tip of the ball burnisher used as a vibrator can have a massaging effect, which also helps in the dissolution of solution faster, which is in accordance with the study executed by Tandon *et al*.[29] There is no need to alter the conventional anaesthetic method in any way. It is lightweight and readily manipulated with the non-operative hand, freeing up the operative hand to deliver the injection.

As in children, the subjective gauging may vary in opinion of one's pain threshold level; thus, using a single parameter to quantify anxiety and pain may not yield an accurate result. Therefore, as suggested by Cardinal *et al*.[30] and Beltramini *et al*.,[31] a combination of physiological (pulse rate), self-reported (WBFPRS) and objective (Sound–Eye–Motor Scale) parameters were employed in this study. The autonomic nerve system, which is responsible for regulating blood pressure, heart rate and respiration rate, is particularly important in controlling the pulse rate.[32] There is additional evidence in the literature that the patient's level of fear is directly correlated with their heart rate (Kilinç *et al*. 2016;[33] Pani *et al*. 2016[34] and Raghav e*t al.*, 2016),[26] revealing the value of pulse oximeters in assessing levels of stress and anxiety in patients receiving dental care.

As per the findings of this study, significantly less pain on both subjective and objective scales was observed during local anaesthetic administration in patients using a custom-designed mucosal vibrator compared to the application of topical benzocaine gel. Thus, children in the custom-designed mucosal vibrator group showed a greater degree of compliance in comparison to the topical benzocaine group while receiving LA. The probable reason for the significantly less pain observed in the mucosal vibrator group can be attributed to the gate control theory.[28] Another reason for the reduced pain during local anaesthetic administration in the mucosal vibrator group could be the distraction of the child's attention from the syringe by applying vibratory stimuli mucosa.

However, the results were not in line with the clinical trial executed by Saijo *et al*.,[35] who concluded that vibration did not positively affect the pain threshold while administering LA. This could be attributed to Saijo *et al*.'s[35] different device use. They used VibraJect™, which incorporates vibrations within the syringe itself, while we used a dedicated mucosal vibrator with a traditional syringe. Elbay *et al*.[36] also did not find any decrease in pain perception using vibrations. Another possible reason may be that the children choose higher-scale faces on the pain scales due to disappointment with dental procedures. Although significantly less pain while administering local anaesthetic was observed in the mucosal vibrator group compared to the topical benzocaine group, no significant difference in pulse rate or anxiety was noted. Thus, in the present study, pain and anxiety remain independent of each other, and the increase in pain, as observed in the benzocaine group, did not result in an increase in anxiety. The similar anxiety levels in both groups could be attributed to the appropriate behaviour management and conditioning of children by the operator before and during the procedure. Another factor could be including children with a Frankl positive behaviour rating in this study. In the present study, while comparing the anxiety levels at baseline and after intervention (i.e. LA administration), a marginal increase in pulse rate was observed in both the topical benzocaine group and the mucosal vibrator group after local anaesthetic administration; however, no statistically significant increase in pulse rate (or anxiety) was noted between the two groups. This

could be justified based on the behaviour modification of the child by the operator since the entire treatment procedure was conducted over two visits. The child was well-acclimatised to the dental setting and the operator, resulting in similar levels of apprehension at both visits. Supporting our study is the research conducted by Jain *et al*.,[37] who reported no significant change/increase in pulse rate before and after administration of LA using the lignocaine hydrochloride topical gel and the mucosal vibrator. Similarly, Suohu *et al*.[38] also found no significant difference in the pulse rate before and post-administration of LA in the Buzzy (vibration) and conventional syringe groups. Likewise, Faghihian *et al*.[39] also found no significant difference in the mean heart rate before and while administering anaesthesia.

Conclusion

The novel custom-designed mucosal vibrator used in the present study may provide an economical alternative to the existing commercially available expensive mucosal vibratory devices and can be widely used in the future to ensure painless local anaesthetic delivery to a larger population. Within the limitations of the study, the following conclusions can be drawn:

Mean pain perception among children was significantly less with a custom-designed mucosal vibrator as compared to the topical benzocaine during LA administration. No significant difference in pulse rate was observed between the mucosal vibrator group and the topical benzocaine group during local anaesthetic administration. This showed that children faced the same level of anxiety with both interventions.

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Conflicts of interest

There are no conflicts of interest.

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