RESEARCH ARTICLE

Comparative Evaluation of Two Different Topical Anesthetic Agents in Controlling Pain during Intraoral Local Anesthetic Administration in Children: A Split-mouth Triple-blinded Randomized Clinical Trial

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Abstract

Aim: To compare the efficacy of lignocaine and benzocaine when applied as a topical anesthetic before intraoral local anesthetic administration in children.

Materials and methods: Forty-four patients aged between 4 years and 10 years indicated for pulp therapy of primary teeth under inferior alveolar nerve block were selected for this study. The participants were randomly allocated into two groups of 22 each. Group I (lignocaine gel) and group II (benzocaine gel) were applied before inferior alveolar nerve block. The pain scale was assessed by a trained examiner using the visual analog scale (VAS) and sound eye motor scale.

Results: Lignocaine when used as a topical anesthetic agent showed lower mean scores under both the pain scales when compared with benzocaine but the results were statistically insignificant.

Conclusion: Lignocaine and benzocaine are equally effective when applied as a topical anesthetic agent. But lignocaine was more preferred in taste when compared with benzocaine.

Keywords: Benzocaine, Lignocaine, Randomized trial, Sound eye motor scale, Topical anesthetics, Visual analog scale.

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Introduction

Fear is the most difficult aspect of patient management and also is a barrier to good dental care. Dentists adapt to pharmacological and psychological strategies to reduce pain and anxiety in patients with dental phobia. The prevalence of dental anxiety is more in children compared with adults. Anxiety and fear can affect the quality of care rendered to children by pediatric dentists. The control of pain during administration of local anesthesia is essential for the prevention of dental caries at the primary level in children. Hence, topical anesthetics plays a major role in eliminating the anxiety and fear in children before injecting local anesthesia and thereby helping in primary care and prevention of dental caries. Therefore, it has an important role to play in the comprehensive healthcare of children.

Children are usually reluctant toward any dental treatment as they suffer from fear and anxiety associated with pain.[1] Local anesthesia is required before any dental procedures such as extractions, pulpotomies, root canal treatments/pulpectomies, drainage of abscesses, and minor oral surgical procedures. However, the irony of the situation is that local anesthetics which are the most effective drugs for the prevention and management of pain are themselves associated with pain and this pain gets further aggravated due to the fear and anxiety caused by the sight of the needle. Behavior management may help in reducing the fear and anxiety of the patient but it will not help in reducing pain while administration of local anesthesia.

Topical or surface anesthesia is an important prerequisite for many pediatric dental procedures. Topical anesthetics not only provide anesthesia but also provide relief from pain before the introduction of local anesthesia.[2] Depending on the invasiveness of the dental procedure, the clinician must choose the right amount of anesthesia. The pediatric dentist should be well versed with type, duration, the quantity of topical anesthesia to be administered in achieving maximum efficiency, without the risk of toxicity.

Many factors affect the efficacy of topical anesthetics including their concentration, area of application, and duration of application.[3] Topical anesthetics may not only affect an individual pharmacologically but also psychologically.[4] Topical anesthesia is achieved on the application of the agent on the surface of the tissues. They block signaling in terminal fibers of sensory nerves.[5] The topical anesthetic is effective only up to a depth of 2–3 mm.[6,7] Topical anesthetics may not be palatable; however, the addition of flavoring agents has made it more acceptable for children.[8] Topical

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anesthetics are effective on oral tissues because of the ability of mucosal membranes for absorption.

Various agents are commercially available today for topical analgesia. While lignocaine serves as the gold standard, benzocaine is also known for its excellent surface anesthetic properties.[5] Lignocaine is known to have comparatively fewer allergic reactions when compared with benzocaine.[6] Commercially, topical anesthetics are available in the forms of aerosols, gels, ointments, pastes, powder, and patches. The ingredients are the same, but they are used for different purposes. The spray is used when the patients are prone to gagging and can be used before X-rays. Gels are more effective in anesthetizing the mucosa when compared with other forms.

The purpose of this study was to evaluate and compare the efficacy of lignocaine gel and benzocaine gel in reducing pain while administration of local anesthesia.

Materials and Methods

The present study was conducted in accordance with the guidelines given by the CONSORT checklist. The present study is a randomized double-blinded clinical trial including 44 patients of age group 4–10 years attending Outpatient Department of Pediatric Dentistry of Saveetha Dental College, Chennai. The study design was reviewed and approved by the institutional review board with ethical number SRB/MDS/PEDO/18-19/0005. Sample size calculation was determined from a previous study by Deepika et al.[7] using G-Power with 85% power. Forty-four patients were allotted in both groups.

Inclusion Criteria

Cooperative children (Frankl Behavior scale: Definitely positive) who required local anesthesia administration in the mandibular arch bilaterally.

Children falling under the category of ASA I and ASA II were included in the trial.

Exclusion Criteria

Children with a history of hypersensitivity reactions to anesthetic agents.

Pre-cooperative or lacking cooperative abilities children.

Randomization was done using the chit pick box method. A box containing 22 chits labeled "group I" and 22 chits labeled "group II" was prepared and kept ready at the start of the study. The chit was picked by the patient from the box and was assigned to the group according to the chit picked. The participant was blinded regarding the treatment protocol. The evaluator and the operator of the treatment procedure were also blinded. Informed consent was taken from the parents of all the children who were participating in the study. The participants of the study were indicated either for an inferior alveolar nerve block or infiltration anesthesia.

The children requiring each of the above-mentioned local anesthesia techniques were tested for two different flavored topical anesthetic agents. Product 1 (Septodont, Lignospan-O, lignocaine 5%) and Product 2 (Septodont, Progel-B, benzocaine 20%) using split mouth design. In the first visit, half of the children received lignocaine (Septodont, Lignospan-O, lignocaine 5%) and the other half received benzocaine (Septodont, Progel-B, benzocaine 20%). In the subsequent visit, children who received lignocaine (Septodont, Lignospan-O, lignocaine 5%) received benzocaine (Septodont, Progel-B, benzocaine 20%) on the contralateral side and *vice versa*.

Each child was assessed using visual analog scale (VAS) and sound eye motor scale. The procedure was performed by a single operator. The mucosa was dried before the application of the topical anesthetic. The topical anesthetic was taken on a cotton applicator tip and was applied on the mucosa for about 30 seconds. The applicator tip was inserted into the gel container and rotated clockwise three times to standardize the amount of drug applied, this was in accordance with the manufacturer's instructions. The excess topical anesthetic was cleaned with gauze and then 1 mL of 2% lignocaine with 1:200,000 adrenaline (Astra Zeneca Pharma, India Ltd.) was injected using a 30-gauge short needle syringe.

Pain response was assessed after the needle prick. The pain response was assessed by a well-trained examiner who was standing at a distance of 5 feet from the operator. The examiner recorded the child's pain response using VAS and sound eye motor scale. Before the main study, for calibration of the procedure, a pilot study was conducted in the Department.

The VAS is a unidimensional measure of pain intensity, which has been widely used in children as well as adults. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms, e.g., the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. The patient marked on the VAS, the point that they felt represents their perception of pain.

Sounds, eyes, and motor (SEM) scale is used to assess the observed pain. It is divided into two categories of comfort and discomfort. The discomfort response is further divided into three subscales: mild pain, moderate pain, and severe pain. The obtained responses from both visits were subjected to statistical analysis without revealing the identity of the products.

Statistical Analysis

The scores obtained from VAS and SEM pain scales of 44 children were entered in an excel spreadsheet. Statistical analysis was carried out using SPSS version 17 software (SPSS, Inc., Chicago, IL, USA). A comparison was made between both the test products using Wilcoxon test.

Results

Out of 44 children included in the study, 25 were girls and 19 were boys in the age group of 4–10 years with a mean age of 6.27 years (Table 1).

Tables 2 and 3 show a comparison between both the test groups under VAS and SEM scales. The mean scores obtained for the lignocaine group were lower than the benzocaine group under both pain scales. However, the mean scores under both the pain scales were statistically not significant ($p > 0.05$).

Discussion

The local anesthetics are classified into amide group and an ester group. Lignocaine contains an amide linkage and benzocaine an

Table 1: Summary of demographic variables describing sample size and number of males and females participants in each group (split-mouth clinical trial)

Groups	*Sample size*	*Female*	*Male*
Lignocaine	44	25	19
Benzocaine	44	25	19

Table 2: Comparison between both test products using VAS

Groups	*No. of children*	*Mean ± SD*	*p value*
Lignocaine	44	0.41 ± 0.503	1.000
Benzocaine	44	0.59 ± 0.503	1.000

p value < 0.05

Table 3: Comparison between both test groups using SEM

Groups	*No. of children*	*Mean ± SD*	*p value*
Lignocaine	44	0.27 ± 0.456	1.000
Benzocaine	44	0.64 ± 0.492	1.000

p value < 0.05

ester linkage.[9] Lignocaine is considered to have a faster onset of action and less allergic reaction.[10] Benzocaine when compared with lignocaine has a slower onset of action and is known to cause a few allergic reactions leading to burning or itching sensation.[2]

Topical anesthetics have both pharmacological and psychological effects. Before the administration of local anesthesia, the participants, as well as their parents, were informed about the benefits of the study. It was observed that patients were more cooperative in accepting a treatment that required administration of local anesthesia when they were informed about the benefits of topical anesthetics before their usage.[11] Based on a principle, it is proved that the duration of the application has an influence on the amount of penetration of the anesthetic. In the present study, topical anesthetics were applied for about 30 seconds and left for a minute so as to increase the depth of penetration.[12] Application of topical anesthetic agents for 1 minute helped in the reduction of sensation of pain.[7] Pain is dependent on various physiological and psychological factors. It is difficult to assess pain as it is experienced on an individual level.[13]

In the present study, VAS and SEM scales were used to measure pain. The VAS was used due to its simplicity as no training is required other than the ability to use a ruler to measure the distance to determine a score. It takes less than a minute to complete; however, the assessment is clearly highly subjective. Sounds, eyes, and motor was used as there are many factors in the scale that help to elicit pain, e.g., verbal responses and movement of the eyes and limbs.

It was observed that lignocaine had a lower mean pain score than benzocaine when measured with both the pain scales. The study is a split-mouth study compared the use of both the topical anesthetics in subsequent visits in the same participant. It was observed that children were more comfortable during local anesthesia administration when lignocaine was applied on the mucosa as topical anesthetic as compared to benzocaine as lignocaine has lower mean pain scores as compared to benzocaine.

Before the treatment procedure, the children and their guardians were made familiar with the advantages of topical anesthesia which helped in reducing fear and anxiety. Filmed videos of topical as well as local anesthesia administration in a child were showed to them.

The order of injection has an effect on anticipated as well as experienced pain intensity.[14] Generally more pain is observed in the first injection as compared to the second. In the present study, though lignocaine had lower mean scores in both the pain scales, the results were statistically not significant proving benzocaine to be as effective as lignocaine. Another similar study by Nair and Gurunathan in 2019 demonstrated superior results with benzocaine compared with lignocaine.[15]

Taste preference was also observed in the present study. Lignocaine that was used was raspberry flavored and benzocaine has a mint flavoring agent. It was found that lignocaine was better accepted by the patients as out of 44 children 30 preferred it over benzocaine which was similar to the study performed by Kohli et al.[16]

Conclusion

The following was observed in the present study:

- Lignocaine and benzocaine are equally effective in controlling pain during the administration of local anesthesia.
- Lignocaine was more preferred in taste when compared with benzocaine.
- Surface anesthesia before needle penetration has got a positive result in reducing pain and anxiety in young children.

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