Original Article

Comparative evaluation of the efficacy of two anesthetic gels (2% lignocaine and 20% benzocaine) in reducing pain during administration of local anesthesia – A randomized controlled trial

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Abstract

Background and Aims: Topical anesthetic agents are widely used in the field of pediatric dentistry to reduce pain and apprehension during administration of local anesthesia. Various topical anesthetic agents are available, among which the most commonly used ones are lignocaine and benzocaine. Hence we planned this study to compare and evaluate the effectiveness of topical anesthesia on needle insertion pain during administration of inferior alveolar nerve block.

Material and Methods: This double blind clinical study included 30 children of 4–8 years of age who were divided equally into two groups: Group A-2% lignocaine hydrochloride gel (Lox 2%) and Group B-20% benzocaine gel (ProGel-B). The intervention involved assessment of pain perception by the child during administration of inferior alveolar nerve block. The child's pain assessment was done using modified Wong–Baker pain rating scale. The ratings were subjected to statistical analysis.

Results: In Group A, 6.7% (N = 1) showed slight pain, 66.7% (N = 10) showed moderate pain, and 26.7% (N = 4) showed severe pain. In Group B, 46.7% (N = 7) showed no pain, 46% (N = 7) showed slight pain, and 6.7% (N = 1) showed moderate pain on needle insertion. (P value –0.000).

Conclusion: This study demonstrates that there is a highly significant difference between the topical anesthetic effectiveness of 2% lignocaine and 20% benzocaine on needle insertion pain in inferior alveolar nerve block. Twenty percent benzocaine showed better results than 2% lignocaine in reducing the needle insertion pain.

Keywords: Precaine, progel, topical anesthesia

Introduction

Anxiety is defined as a state of obnoxiousness with an associated fear of danger from within or a learned process of one's own environment. It mostly depends on the capability to imagine.[1] Anxiety is the most common issue stumbled upon by pedodontists in the dental operatory. Children tend to refuse dental treatment because of which dental anxiety becomes the major source of challenge for pediatric dentists. Dental anxiety is defined as state anxiety as it arises because of the treatment procedure and is associated with negative prospects that are often associated to earlier traumatic experiences, negative outlook of the family, fear of pain and trauma, and perceptions of an unsuccessful previous dental treatment.[2] Few studies claim that there is a significant effect of topical anesthetics

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on dental anxiety. A randomized clinical trial by Cho *et al.*, stated that highly anxious participants reported higher pain scores, however, topical anesthetic agents reduced the effect of anxiety on needle insertion pain.[3]

Injecting local anesthesia in children is in itself an anxiety evoking procedure.[4] In addition, pain management is the vital aspect in pediatric dentistry. The dentist can overcome the issue of injection pain by altering the pH and temperature of local anesthetic solution and by reducing the speed of injecting the solution into the tissues.[5] Another technique is to prepare the tissues before injection, i.e., surface anesthesia, which includes refrigeration,[6] transcutaneous electronic nerve stimulation (TENS),[7] and topical anesthesia.

Topical anesthetic gel/ointment is easily available and is not technique sensitive. Hence, topical anesthetic gel/ointment has become the "holy grail" of painless technique of local anesthesia in pediatric dentistry.

They have the ability to cross the oral mucosal membrane and produce analgesia.[8,9] They block the conduction of signals from the terminal fibers of the sensory nerves, thereby producing surface anesthesia for a depth of 2–3 mm. This change takes place secondary to an alteration in transmission through voltage-sensitive sodium channels, resulting in an increment in the action-potential threshold. This trait of topical anesthesia enables it to minimize needle insertion pain effectively.

There are various topical anesthetic agents available ranging from gels to sprays. Benzocaine is most widely used by dentists, and it is rapidly absorbed on the mucosal membrane. It is less soluble in water and is long acting with less toxicity. Topical benzocaine is commercially marketed in 10% and 20% concentrations. It is acknowledged as safe and effective as an external source for temporary pain relief owing to minor trauma in mucosa or gingiva, minor dental procedures, teething, etc. Despite its well-documented literature of innocuous use, there have been rare cases of adverse effects such as methemoglobinemia.

Lignocaine is most commonly used topical anesthetic agent (Gold Standard)[10] followed by benzocaine. However, there are side effects such as allergic skin reactions, blisters, ulcers, and rarely methemoglobinemia. This research was conducted to evaluate the effectiveness of 2% lignocaine gel and 20% benzocaine gel as a topical anesthetic agent prior to administration of local anesthesia. Twenty percent benzocaine gel, i.e., ProGel-B is a new topical anesthetic agent marketed by Septodont Healthcare India Pvt Ltd.

Material and Methods

The study was a double-blind, randomized, controlled clinical trial. This randomized controlled trial compared the effectiveness of two topical anesthetic agents, i.e., 2% lignocaine gel and 20% benzocaine gel. For sample size calculation, a sampling error of 5% was considered, the power was set to 85% and minimum sample size of 26 was obtained. The study comprised of 30 healthy children (12 males and 18 females) in the age group of 4–8 years. Prior to the participation in this study, a medical history was acquired from all the participants, and a brief oral examination was done.

Inclusion criteria

- The children were required to present with at least one tooth indicated for pulpectomy
- 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
- Recent trauma to oral tissues
- Children taking medications which suppress the CNS such as diazepam, chlordiazepoxide HCl, alprazolam, etc.

Metabolism of lignocaine in the liver gets inhibited by midazolam non-competitively and possesses the risk of potential toxicity.[11]

The trial was carried out in the second dental visit. The initial phase of treatment involved measures taken to ensure the child's adaptability to the dental office (first visit).

An informed consent was obtained from the parents/guardians of the participants. Randomization was done for the included participants using computer-generated sequence. The mandibular posterior areas such as retromandibular raphe and the buccal vestibule were chosen for application of the respective topical anesthetic agent. The site of application of the topical anesthetic agent and the needle were dried with 2 × 2 inch gauze. Additionally, the tongue and buccal surfaces of lips were isolated using cotton rolls to prevent the topical agent from anesthetizing these tissues.

The children were randomly divided into two groups: Group A being 2% lignocaine gel and Group B being 20% benzocaine gel. The topical anesthetic gel was applied to the test area using cotton swab applicator that was completely dipped in the gel by investigator A. Following this, 1.2 ml of local anesthetic agent was administered preceded by aspiration

through inferior alveolar nerve block onto the areas that were surface anesthetized. The needle was concealed to avoid fear/anxiety-provoking situation in the child as that will alter the pain perception. In a clinical trial, 25 children were randomly divided into two groups: i.e., "show the Local Anaesthesia syringe group" and "do not show the LA syringe group," and the results revealed that the show group participants had a tendency to be more anxious than the no-show group both before and after the administration of local anesthesia.[12] All efforts were taken to avoid the usage of fear/anxiety provoking statements or portrayal of fear promoting situation.

During the administration of local anesthesia, the response of the child was constantly observed by investigator B, who was blinded of the topical anesthetic agent used. 1.2 ml of local anesthesia was administered using 2 ml syringe (needle size 0.4538 mm/261½) (Hindustan Unlock [AU: Advise on edit] 2mL syringe). Following this, each participant was advised to quantify the pain perception four point pain intensity scale [Figure 1].

The child was advised to choose the emoticon that best described the amount of pain he/she had experienced at the time of needle insertion, and his/her response was recorded by the investigator B. The clinical trial for each child was accomplished in a single visit. All the data acquired were analyzed using SPSS software.

Results

A total of 30 children (12 males and 18 females) with 15 in each group were included in the study [Table 1]. Mean and standard deviation of pain scores in Group A was found to be 2.20 ± 0.561 and Group B was found to be 0.60 ± 0.632 [Table 2]. In Group A, 6.7% (N = 1) showed slight pain, 66.7% (N = 10) showed moderate pain, and 26.7% (N = 4) showed severe pain. In Group B, 46.7% (N = 7) showed no pain, 46.7% (N = 7) showed slight pain, and 6.7% (N = 1) showed moderate pain on needle insertion [Table 3]. The P value was found to be 0.000, which shows highly significant difference between the two groups. The graph shows comparison of pain scores between both the groups [Figure 2].

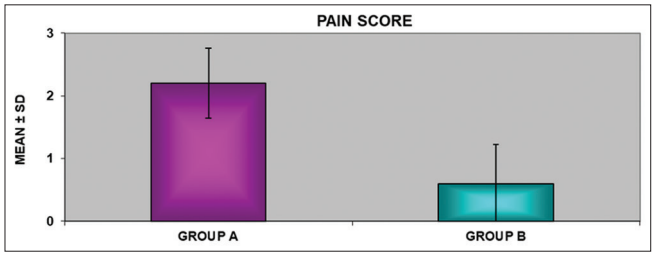

Figure 1: Graph depicting pain scores between both the groups

Discussion

Local anesthesia is a combination of two Greek words "an" (without) and "aesthesis" (sensation). In dentistry, local anesthesia is classified on the basis of their effects as (a) Conduction anesthesia, (b) Infiltration anesthesia, and (c) Topical anesthesia.[13]

Local anesthetics are classified into ester linkage agents (benzocaine) and amide linkage agents (lignocaine) and are the most widely used topical anesthetic agents.[14] Topical anesthesia can be defined as loss of sensation on the mucous membrane that is produced by direct application. The first local anesthetic was a topical anesthetic, that is, cocaine and was discovered in 1860 by Albert Niemann.[15]

Benzocaine is para-aminobenzoic acid ester. Because it has low systemic toxicity, it is safe to use. However, there are rare cases of methemoglobinemia in the literature. Lignocaine is most widely used local anesthetic agent and is an antiarrhythmic drug. It is eliminated from the body through liver; hence, its metabolism is compromised in patients with liver dysfunction. Lidocaine acts by blocking the sodium channels, and topical administration of the same blocks ectopic discharges from afferent fibers. Topical application of lidocaine slows down the peripheral nociceptor sensitization and central hyperexcitability.[16]

Topical anesthesia targets the free nerve-endings that reversibly blocks nerve conduction near the site of administration, which in turn induces a temporary loss of sensation in that area. The permeability of cell membrane to sodium ions is decreased, and therefore, nerve conduction is blocked. This eventually decreases the depolarization and increases excitability threshold until the capacity to induce action potential is completely lost.[17] Topical anesthesitic agents do not contain vasoconstrictor as it weakens the mucosal permeability. In addition, topical anesthetics are more concentrated than injectable ones to promote diffusion within the mucosa.

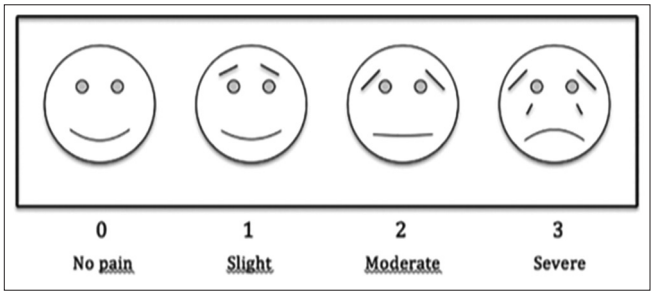

Figure 2: Four-point pain scale

Table 1: Demographic data depicting number of males and females in the study

	n=30
Males	12
Females	18

Table 2: Pain Score (Mean and standard deviation)

Group	*n*	Mean	Std. Deviation	Std. Error Mean
Pain Score Group A	15	2.20	0.561	0.145
Group B	15	0.60	0.632	0.163

Table 3: Level of pain perception in each group

	Group A	Group B	Total
Pain Score No Pain Count % within group	0 0.0%	7 46.7%	7 23.3%
Slight Count % within group	1 6.7%	7 46.7%	8 26.7%
Moderate Count % within group	10 66.7%	1 6.7%	11 36.7%
Severe Count % within group	4 26.7%	0 0%	4 13.3%
Total Count % within group	15 100%	15 100%	30 100%

The present study was conducted among 30 children (12 males and 18 females) in the age range of 4–8 years to evaluate the efficacy of 2% lignocaine and 20% benzocaine as a topical anesthetic agent. Topical anesthesia was used prior to administration of nerve block. To standardize the protocol, only mandibular arch and therefore inferior alveolar nerve block were included. This study showed a significant difference between the mean pain scores in Group A and Group B. Both the topical anesthetic agents were rubbed with moderate pressure over the surface for 30 s and left for 1 min.[18]

Giddon *et al.* compared topical anesthetic agents in dosage forms and reported that there was no statistical difference among 20% benzocaine, 5% lidocaine, and placebo when applied for 30 s on palate using 25gauge needle.[19] In a study, benzocaine gel and lignocaine spray were compared, and the results revealed that benzocaine gel had the least VAS score than lignocaine spray,[20] which corresponds to the findings of the present study. A clinical study of 510 extractions (Grade II and III) were carried out with lignocaine hydrochloride gel 5% and bupivacaine hydrochloride gel 5% as topical agents, and it was concluded that 5% lignocaine hydrochloride gel was better than 5% bupivacaine hydrochloride gel.[21] In a clinical trial, 2% lignocaine gel and 20% benzocaine gel were compared with placebo, and it was concluded that the effectiveness of both 2% lignocaine and 20% benzocaine were similar.[18]

Another topical anesthetic agent introduced in the 1980s was Eutectic Mixture of Local Anesthetics (EMLA) 5%. The first clinical study using EMLA was done by Holst and Evers in 1985.[22] Nayak *et al.* compared EMLA 5%, benzocaine 18%, and lignocaine 5% in 6–12 years aged children and found out that EMLA 5% was the best agent in pain reduction than lignocaine and benzocaine. However, taste acceptance was favorable for benzocaine.[23]

Di Marco *et al.* compared the effectiveness of fast acting refrigerant topical agent with 20% benzocaine in a split mouth study and concluded that both refrigerant and 20% benzocaine gave similar benefits, however, the refrigerant had a fast onset of action.[24] Vongsavan *et al.* stated that 20% benzocaine gel was more effective than the placebo in reducing needle insertion pain in palatal injections.[25] Another clinical trial revealed that 2.5% lignocaine + 2.5% prilocaine gave better results than 20% benzocaine in reducing needle insertion pain in maxillary vestibule.[26]

There are various alternatives to topical anesthesia, but they are much technique sensitive, for example computer-controlled local anesthetic delivery (CCLAD) and TENS. CCLAD works on the idea of slow delivery of local anesthesia. The speed of the delivery of solution is under computer control. In a clinical trial, comparing CCLAD with conventional method in pediatric patients showed that CCLAD gave better results than the traditional technique.[27] TENS device stimulates the neurons that in turn activates the descending inhibitory system, and hence, hyperalgesia is reduced.

Conclusion

This study demonstrates that there is a high significant difference between the topical anesthetic effectiveness of lignocaine 2% and benzocaine 20% on needle insertion pain in inferior alveolar nerve block.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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