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Comparative Evaluation of Two Topical Anaesthetic Gels to Reduce Pain During Local Anaesthesia Administration

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ABSTRACT

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. This double blind clinical study included 50 children of 7-9 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 visual analog scale. The ratings were subjected to statistical analysis. Student paired t- test showed statistically significant difference in the VAS score between Progel B and the LOX in males as well as females. Independent Student t-test showed no statistically significant difference in VAS score between males and females. 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.

KEY WORDS: BENZOCAINE; CHILDREN; LIGNOCAINE; PAIN SCALE; PROGEL-B.

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience arising from actual or potential tissue damage or described in terms of such damage.(Zacny et al., 2002) In pediatric dentistry, pain sensation is generated by stimuli like sound of the drill or touch of the needle at the time of local anesthetic administration and is not necessarily dependent on tissue damage.(Taani and Quteish, 2001) Ointments, anesthetic sprays, gels, or adhesive patch are topical application of local anesthetic which are utilized to reduce pain of local anesthetic injections, but these methods have their own limitations. (Cho et al., 2017)

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. (Nair and Gurunathan, 2019)Anxiety is the most common issue stumbled upon

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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 with earlier traumatic experiences, negative outlook of the family, fear of pain and trauma, and perceptions of an unsuccessful previous dental treatment. Few studies claim that there is a significant effect of topical anesthetics 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. (Cho et al., 2017)

Injecting local anesthesia in children is in itself an anxiety evoking procedure. (Fiset et al., 1985) 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.(Courtney, Agrawal and Revington, 1999) Another technique is to prepare the tissues before injection, i.e., surface anesthesia, which includes refrigeration, (Ghaderi, Banakar and Rostami, 2013) transcutaneous electronic nerve stimulation (TENS), (Choudhari et al., 2017) 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. (Ship, Williams and Osheroff, 1960; Adriani et al., 1964) 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 the most commonly used topical anesthetic agent (Vickers and Punnia-Moorthy, 1992) 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.

Our department is passionate about child care, we have published numerous high quality articles in this domain over the past 3 years (Govindaraju, Jeevanandan and Subramanian, 2017a, 2017b; Nagaveni et al., 2017; Panchal, Gurunathan and Shanmugaavel, 2017; Ravikumar, Jeevanandan and Subramanian, 2017; Jeevanandan and Govindaraju, 2018; Nair et al., 2018; Ravikumar et al., 2018, 2019; Ravindra et al., 2018, 2019; Subramanyam et al., 2018; Vishnu Prasad et al., 2018; Jeevanandan, Ganesh and Arthilakshmi, 2019; Ramadurai et al., 2019; Ramakrishnan, Dhanalakshmi and Subramanian, 2019; Veerale Panchal, Jeevanandan and Subramanian, 2019; Vignesh et al., 2019; V. Panchal, Jeevanandan and Subramanian, 2019; Mathew, Roopa, et al., 2020; Mathew, Samuel, et al., 2020; Samuel, Acharya and Rao, 2020). With this inspiration we planned to pursue research on comparison and evaluation of two anesthetic gels to reduce pain during local anesthesia administration.

MATERIAL AND METHODS

The study was a double-blinded 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 a minimum sample size of 50 was obtained. The study consisted of 50 healthy children (22 males and 28 females) in the age group of 7-9 years who had bilateral molars that required local anesthesia for dental treatment. Prior to the participation in this study, a medical history was acquired from all the participants, and a brief oral examination was done.

Each child would receive both topical anesthetic agents. To decide which agent each child would get at at the first appointment was decided by coin toss. The other topical agent would be used in the next appointment on the opposite tooth . Group A was 2% lignocaine gel and Group B was20% benzocaine gel. The topical anesthetic gel was applied to the test area using a cotton swab applicator that was completely dipped in the gel by the investigator. 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 situations in the child as that will alter the pain perception. The child was advised to choose the emoticon that best describes the amount of pain he/she had experienced at the time of needle insertion, and his/her response was recorded by the investigator. The clinical trial for each child was accomplished in a single visit. All the data acquired were analyzed using SPSS software.

RESULTS AND DISCUSSION

The total number of participant was 50 and male to female ratio was 22 males (44%) and 28 females (56%), their age ranged from 7 -10 years(8±1.2) years

Table 1. Comparison of LOX gel and ProGel-B based on the gender.

Gender	Number	Mean±SD VAS (ProgelB)	Mean±SD VAS (LOX)	P Value
Male	22	12.5±8.07	25.3±11.3	0.000
Female	28	15.1±10.2	22.2±10.1	0.011

Student paired t- test showed statistically significant difference in the VAS score between Progel B and the LOX in males as well as females.

Table 2. Comparison of Visual Analogue Scale in male and female in both injection methods

Injection Method	Mean±SD VAS in Male	Mean±SD VAS in Female	p Value
Progel B	12.5±8.07	15.1±10.2	0.420
LOX	25.3±11.3	22.2±10.1	0.450

Independent Student t-test showed no statistically significant difference in VAS score between males and females 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. (Boyce, Kirpalani and Mohan, 2016) Local anesthetics are classified into ester linkage agents (benzocaine) and amide linkage agents (lignocaine) and are the most widely used topical anesthetic agents.(Stewart et al., 1982) 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. (Wulf et al., 1999)

Benzocaine is a 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 the most widely used local anesthetic agent and is an antiarrhythmic drug. It is eliminated from the body through the 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. (Jorge, Feres and Teles, 2011)

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.(Kumar, Chawla and Goyal, 2015) 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.

In a study conducted by Garg et al., 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 blocks. To standardize the protocol, only mandibular arch and therefore inferior alveolar nerve blocks 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. 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.(Garg et al., 2016)

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.(Giddon et al., 1968)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,(Koppolu et al., 2016) 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.(Satya Bhushan and Nayak, 2010).

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.(Holst and Evers, 1985) 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.(Nayak and Sudha, 2006) 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.(DiMarco and Wetmore, 2016) Vongsavan et al. stated that 20% benzocaine gel was more effective than the placebo in reducing needle insertion pain in

palatal injections.(Nakrathok et al., 2020)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.(Al-Melh, Abu Al-Melh and Andersson, 2017).

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 the 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.(Mittal et al., 2015) 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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