Efficacy of Lidocaine Hydrochloride 2% Gel as a topical anaesthetic agent in Children

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ABSTRACT:
Objective: Injection of local anesthesia is one of the most common reasons of dental fear and anxiety in children. Topical anesthetics reduce the slight uneasiness that might be experienced due to insertion of the needle. The aim of this study was to evaluate the efficacy of Lidocaine Hydrochloride 2% Gel in reducing the pain during injection. Material and methods: 42 healthy children between 6-10 years of age who received lidocaine Hydrochloride 2% Gel for two minutes prior to buccal infiltration. The pain responses were self-rated by the participants before and after injection using Wong-Baker FACES Scale and heart rate was also noted using Pulse Oximeter. Result: Heart Rate and Wong-Baker FACES Pain Rating Scale gave statistically insignificant differences between data recorded the before and after the injection. Conclusion: The use of Lidocaine Hydrochloride 2% Gel before the administration of local anesthesia will minimized pain perceived. Further study needed to be compared with other types of topical anesthesia.

Key words: Pain, Infiltration, Local anesthesia, Topical, Anesthesia Injection, Lidocaine Hydrochloride 2%.

INTRODUCTION:
Pain is one of the most important factor the children are afraid of, the result for this is crying because of fear and anxiety. As a pediatric dentist we need to overcome this crying by reducing the pain by various techniques to promote a positive dental attitude. The most fearful aspect for all the children is painful nature of injection which can be overcome by various techniques, one among them is use of topical anesthetics [1-4]. Behavior management and pain control is an important part the management of children at the dental chair, therefore, reducing the pain during the dental appointment should reduce fear and anxiety, and promote a positive dental attitude. Moreover, most clinicians consider dental fear and anxiety to be an extremely relevant dimension of their practice. [1]. Several studies show that the dental injection is the most common cause of dental fear and anxiety[2, 3], many methods were introduced to reduce the painful nature of the injection, and find a more comfortable and pleasant means of achieving local anesthesia before dental procedures. [4] Topical anesthetics (TA) being widely used now a days in numerous medical and surgical specialties such as Anesthesia, Ophthalmology, Dermatology, Dentistry etc. It is defined as superficial loss of sensation which produced by direct application of local anesthetic solutions, ointments, gels or sprays [5, 6]. The benefits of TA are not only pharmacological but also psychological [7-9] which played an important role in minimizing patient apprehension. [4] Lidocaine being approved and one of the most effective topical anesthetic which is used in dentistry to curb pain temporarily for various oral lesions like like aphthous ulcers, blisters, teething, or gingivitis. [10] Lidocaine is a well-established and approved local anesthetic alone and in combination used in a variety of topically applied preparations, mostly as a medicinal product. It is also used to treat painful oral conditions in children, like aphthous ulcers, blisters, teething, or gingivitis. [10]
Lidocaine Hydrochloride 2% is also used as a topical anesthetic for certain skin conditions (e.g., scrapes, minor burns, eczema, insect bites). Studies show a positive effect when it was used on skin [11], however, there are no current intra-oral dental uses listed for this type of topical anesthesia. Therefore, the objectives of this randomized clinical study were to determine the efficacy of Lidocaine Hydrochloride 2% as a topical anesthesia in children. The aim of the study was to evaluate the efficacy of Lidocaine Hydrochloride 2% gel in the reduction of pain during local infiltration in pediatric patients.

**METHODOLOGY**

The study was conducted at the University Hospital of Riyadh Elm University, Riyadh, KSA after the ethical approval from the research center (No: FRP/2016/116). The study was conducted for patients attending the university hospitals of Riyadh Elm University during the period between September 2016 and March 2017 were seeking dental treatment and who required dental anesthesia.

Based on inclusion and exclusion criteria, only 43 children participated after informed consent was obtained from parents.

Inclusion criteria were patients aged between 6-10 years of both the genders who were physically and mentally fit, categorized their physical status as I according to American Society of Anesthesiologists (ASA). Exclusion criteria were those participants not adhering to the above mentioned age limits, physically and psychologically abled individuals [Physical status II, III, or IV according to American Society of Anesthesiologists (ASA)], children allergic to local anesthesia, chronic habit of taking analgesics or anti-inflammatory medications, children with signs of inflammation or ulceration of the oral mucosa.

A test was done by applying Lidocaine Hydrochloride 2% gel in the oral cavity in the to confirm that none of the ten volunteers had allergic reaction to topical anesthetics by monitoring them for one hour post application.

**Topical anesthetic application**

A Lidocaine Hydrochloride 2% topical anesthetic was applied in to the maxillary buccal fold at the molar region the selected area of needle infiltration for administering local anesthesia, the topical anesthetic was applied to a dry mucosa by isolating that zone with gauze and also using a saliva ejector as required. Lidocaine Hydrochloride 2% gel was placed in the isolated area and made this product stayed in contact with the mucosa for a period of 2 minutes. Next, the local anesthesia was administered. The same anesthetic agent (Lidocaine hydrochloride (HCl) 2% with 1:100,000 epinephrine) and the same syringe (a Breech-loading, metallic, cartridge-type, and aspirating syringe), 25 gauge needle (Dentsply Inc, Canada) were used for every administration of local anesthesia. The technique was used advocated by Malamed [12].

**Pain and Behavior assessment**

Child’s cooperation was evaluated before any intervention using the Frankel scale. Only one investigator was selected to conduct the study to avoid from subjective variations and the others recording the findings.

After injecting anesthetic agent into the gingival sulcus, pain perception was evaluated, The Wong-Baker FACES Pain Rating Scale (WBS) [13, 14] was used that had six faces with different expressions, with 0 being “no hurt” marked on the left and 10 being “hurts worse” marked on the right, and heart rate was evaluated by using a Pulse Oximeter on the patient’s index finger.

**Statistical analysis:**

It was performed using SPSS software (version 19.0 data processing software (IBM Corp. Armonk, NY, USA). Apart from the Demographic Data, pair t-test was done to compare the HR and Face pain rating scale before and after the injection.

**RESULTS:**

The research comprised 43 patients (26 girls and 17 boys) with a mean age of 8.1 ± 1.38 years (range: 6-10 years). One of the participants was excluded due to uncooperative behavior. More than half of the participants (60.5%) were girls and (39.5%) were boys. No statistically significant difference was observed between the heart rate before and after the local anesthetic injection, neither for The Wong-Baker FACES Pain Rating Scale (WBS) before and after the local anesthetic injection. (P > 0.05) (Table 1).

**Table 1:** Heart rate and the pain perception score before and after injection.

**DISCUSSION:**

The present study was conducted to evaluate the effectiveness of Lidocaine Hydrochloride 2% Gel in children concerning pain reaction during injection. The age group participated in this present study would possess sufficient verbal and cognitive skills to communicate well and understand the instructions and explanation given about the treatment. It is clinically important to note that uncooperative children can give inaccurate pain assessment; all the children selected for this study were cooperative (positive or definitely positive according to the Frankel's Behavior rating scale) except for one who was excluded from the test.

Since pain is extremely difficult to quantify in children, two different methods were used to assess pain. The objective method was a Pulse oximeter used to assess the patient’s heart rate before and after the injection and subjective method was the Wong-Baker FACES Pain Rating Scale (WBS) used in children to rate pain severity where patients were instructed to indicate their pain by pointing to one of the faces before and after the injection.

Lidocaine is a well-known product for local pain reduction [15]. It is a well-established and approved local anesthetic alone and in combination, mostly as a...
medicinal product. In different clinical studies conducted with children, the efficacy of topically applied lidocaine could be demonstrated [16]. It is also used to treat painful oral conditions in children, like ulcers, blisters, teething, or gingivitis [17]. Therefore, excluding its toxicity. The result evinced the safety and effectiveness of the Lidocaine Hydrochloride 2% Gel in controlling and minimizing the pain of the injection, thus improving the behavior of the child and it will allow the dentist to give the best quality of treatment.

CONCLUSION:
The application of the Lidocaine Hydrochloride 2% Gel is adequate to reduce or prevent pain on the oral mucosa or gingivae. And it is most effective in pediatric patients with dental fear and anxiety in which injection of local anesthesia is deemed necessary. Further studies needed to compare with other types of topical anesthesia.

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