Ice vs Benzocaine 20% gel as a Topical Anesthesia for the Oral Mucosa: A Randomized Clinical Study

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Abstract

Topical anesthesia is used to minimize the pain produced by the needle. Therefore, it is essential to use topical anesthesia during dental treatments to provide the best pain control. Ice was introduced as a safe method of local anesthesia. This study aimed to assess the patient's perception of pain and the efficacy of Benzocaine 20% gel and ice as a topical anesthetic agent applied to the oral mucosa before injecting local anesthesia. Healthy patients without any expression of dental fear were invited to participate in this study. Randomization was applied by using sealed envelopes according to inclusion criteria. Before the process begins, an envelope was opened to reveal which side and type of topical application (lignocaine or ice) were used at the first and second appointments. A (VAS) of 100 mm was used for patients to rate their intensity of pain to needle prick with the application of topical lignocaine or ice. Following the application of ice and Benzocaine 20% gel, the VAS ratings among 30 subjects. VAS pain ratings were higher for topical gel (1 min Ice10.0 ± 11.5 gel 20.1 ± 16.7) and (2.5 min: ice 6.0 ± 7.5 gel 12.1 ± 16.3) there were significant differences between ratings at 1 min (p=0.003) and 2.5 min (p = 0.032). There were no correlations between age and VAS pain. The suggested approach of employing ice on the oral mucosa before the dental injection is a cost-effective alternative to Benzocaine 20% oral gel.

Keywords: Topical anesthesia, Ice, Benzocaine 20% gel, VAS pain

INTRODUCTION

Despite the ongoing development of new dental injection procedures, many patients continue to endure pain and discomfort, which has been linked to dental anxiety [1-3]. To eliminate or lessen needle pain, a topical anesthetic should be applied. Topical anesthetic gels are commonly used in dentistry [4], although their effects are unknown. Topical anesthetic does not guarantee painless injections, and its success is based on time (injection speed) and needle gauge [5]. Some authors claim that lidocaine 5 percent gel only improves needle insertion pain, not injection discomfort unless topical anesthetic has been applied for 10 minutes [6]. Some studies even question whether topical anesthetic reduces discomfort during needle insertion or injection [7]. Various gels are now used for topical anesthetic before dental injections (e.g. lidocaine, prilocaine, or benzocaine) [8, 9]. Because of a lack of bio adhesion, these gels tend to spread in the mouth, resulting in a decreased anesthetic effect [10] an unpleasant taste, and/or patient discomfort [11]. Several ingredients in topical anesthetic gels have been linked to adverse responses [12].

These parameters are critical for creating and testing new topical anesthetics. A safe type of local anesthesia, ice has been used for many years to reduce injection pain in the skin [13]. It's rare to find published research on ice as a topical

anesthetic in dentistry [14]. Application of Ice on the palatal surface before and after local infiltration anesthesia relieved discomfort in a trial but did not compare to other topical anesthesia [15]. However, this trial did not test ice as a sole topical anesthetic agent [16]. The use of ice as a topical anesthesia is not common practice in dentistry [14].

The anesthetic effect of cooling has been described in many ways [17]. Topical cold application activated the myelinated A fibers, by inhibition of pain pathways [18], presumably as part of the spinal cord gate control system [17]. Cold-induced

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neuropraxia is caused by a reduction in the activation threshold of tissue nociceptors as well as the conduction velocity of pain signals [19, 20]. This study aims to compare the effect of two topical anesthetic agents applied on the oral mucosa, to evaluate the efficacy of topical anesthesia at 1, 2.5, and 5 minutes with Benzocaine 20% gel and ice on the oral mucosa before administering local anesthesia injection and to observe the perception of pain by patients after local anesthesia injection using a visual analog scale.

MATERIALS AND METHODS

This study is a A Randomized Clinical Study performed from November 2021- May 2022 in Ar Rass College of Dentistry Dental Clinics. The study consists of 30 Saudi adults.

Sampling Technique (With Inclusion and Exclusion Criteria)

Healthy patients 14 years and above without expression of any dental fear were included in this study. Medical disorders that could jeopardize patient safety, such as a known allergy to local anesthetics agents or any of the other ingredients, will exclude patients.

Patient compliance according to the study protocol in terms of two topical anesthesia comparisons, not followed will lead to exclusion of the patient from the study.

To compare the anesthetic effects and subjective experiences of two topical anesthetic agents, the participant was excluded from the trial if the study protocol was not followed.

Participants unable to give signed consent were excluded. If a patient refuses to participate further, he or she was removed from the study without being asked any questions.

Data Collection Methods First Appointment

At the initial visit, randomization was conducted in blocks of four utilizing a set of envelopes consecutively numbered by a statistician based on their enrolment in this study. Before the process begins, an envelope was opened to determine which side and kind of topical anesthetic (Benzocaine 20% gel or ice) were used at the initial and subsequent appointments.

Technique for Application of Topical Anesthesia

The oral mucosa was dried before the application of 0.2 mL Benzocaine 20% gel by using a cotton roll. Ice was prepared by filling a 2.5 ml plastic syringe halfway with mineral water and freezing it in the freezer. To prevent frostbite, the ice temperature was maintained between 4 and 0 degrees Celsius. Before application, the tip of the plastic syringe was slit using a knife which results in allowing the ice to be pushed against the mucosa as it melts. After each procedure, the patient was asked to complete the questionnaire.

Buccal Side Assessment

The effect of topical anesthesia on the buccal mucosa was evaluated by using a 30-gauge 12-inch short needle penetrating 1 mm in the mucosa without bone contact, the patient response was recorded at 1 and 2.5 minutes, counting from the time topical anesthesia was first applied to the mucosa. The patient will grade his or her pain on a 100 mm visual analog scale (VAS) following each stick and injection (**Figure 1**).

Second Appointment

A two-week time was allowed to ensure that no pain persisted at the second visit and that all symptoms have entirely subsided. On the second visit, the premolar on the contralateral side was treated with topical anesthesia (Benzocaine 20% gel or cold). The same protocol was followed as the first one.

Pilot Study

A pilot study was performed on 5 patients.

Data Management and Analysis Plan

Based on prior findings, a statistical power calculation determined that 50 participants would be required to achieve 80% power of the study at the 0.05 level of significance. The paired t-test was used to evaluate repeated measures, the chisquare test was used to compare association, and the Pearson correlation test was used to analyze the correlation of concerned variables. Data were expressed as mean and standard deviation.

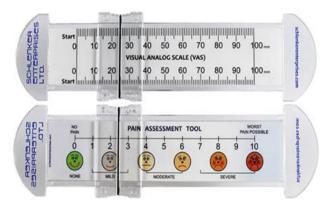


Figure 1. Visual analog scale (VAS).

RESULTS AND DISCUSSION

Amongst 30 participants in the age range of 18 to 55 years, the VAS ratings following the application of ice and Benzocaine 20% gel are presented in **Table 1**. When comparing VAS pain ratings following needle insertion at different times after the application of the topical gel and ice. VAS pain ratings were higher for topical gel (1 min Ice10.0 \pm 11.5 gel 20.1 \pm 16.7) and (2.5 min: ice 6.0 \pm 7.5 gel 12.1 \pm 16.3) there were significant differences between ratings at 1 min (p=0.003) and 2.5 min (p = 0.032). There were no correlations between age and VAS pain (**Figure 1**).

 Table 1. Comparing VAS pain ratings following needle insertion at different times after application of the topical gel and ice

Variables measured	lce mean ± SD (mm)	Benzocaine 20% gel mean ± SD (mm)	Paired t-test (p-value)
VAS pain needle insertion (1 min)	10.0 ± 11.5	20.1 ± 16.7	.003
VAS pain needle insertion (2.5 min)	6.0 ± 7.5	12.1 ± 16.3	.032

Of the 24 patients who wrote comments in their final questionnaire, twelve preferred that ice was better than topical gel whereas ten participants complain of sensitivity and discomfort caused by ice. Similarly, two reported that they dislike the usage of ice. No unintended side effects were found.

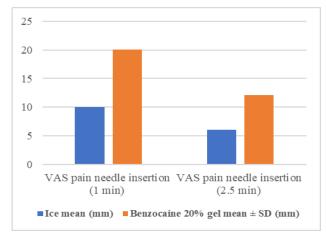


Figure 2. Comparing VAS pain ratings following needle insertion at different times after application of the topical gel and ice (1 min Ice 10.0 ± 11.5 gel 20.1 ± 16.7) and (2.5 min: ice 6.0 ± 7.5 gel 12.1 ± 16.3).

By definition, pain is "an unpleasant sensory and emotional experience connected with existing or potential tissue damage, or described in terms of such damage," according to the International Association for the Study of Pain [21]. Before dental injections, topical anesthesia is used as efficiently and non-invasively as possible to remove or lessen pain. Although earlier authors questioned the impact of topical anesthesia before oral cavity injection [22], Numerous research has indicated a positive impact [23-26]. Only one earlier study [27] had looked into the effects of local mucosal cooling before infiltration of local anesthesia in dentistry, according to Aminabadi and Farahani [28]. Even though results from later studies have indicated that pre-cooling is effective, pre-cooling can be applied in a variety of ways and conjunction with a variety of other strategies. Even though the use of cryo-anesthesia to lessen injection pain had been considered to be promising, very scant literature reviews concerning the clinical efficacy of these agents were found, according to a 2015 article [29].

Our results state that there is an obvious improvement of the VAS number after 2.5min than 1min on both the ice and the Benzocaine 20% which is supported by a previous study [16]. Also, our finding suggested that a significantly higher proportion of the participants reported a bad or very bad taste following treatment with Benzocaine 20% gel on the buccal site, in comparison to when ice was used on the same site. Previous studies have also emphasized the bad taste experience associated with anesthetic gels [8, 9, 13].

The present study suggests that simple methods like precooling the injection site with ice can be used as an effective non-pharmacological technique to reduce injection pain. The results of the present study are supported by other studies conducted previously by [5, 10-12] who also found similar results from their studies. Further research on a large sample size is required to confirm our findings.

CONCLUSION

The suggested approach of employing ice on the oral mucosa before the dental injection is a cost-effective alternative to Benzocaine 20% oral gel.

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CONFLICT OF INTEREST: The authors declare that there are no conflicts of interests.

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ETHICS STATEMENT: The research proposal was approved by the Regional Research and Ethics committee. The PI ensured that the patient have received and comprehended the information provided, and participated in this study with their full consent.

References

- Hindocha N, Manhem F, Bäckryd E, Bågesund M. Ice versus lidocaine 5% gel for topical anaesthesia of oral mucosa-a randomized cross-over study. BMC Anesthesiol. 2019;19(1):1-11.
- Amruthavarshini I, Vinay C, Uloopi KS, Rojaramya KS, Chandrasekhar R, Penmatsa C. Effectiveness of pre-cooling the injection site, laser biostimulation, and topical local anesthetic gel in reduction of local anesthesia injection pain in children. Int J Clin Pediatr Dent. 2021;14(1):81-3.
- 3. Joshi S, Bhate K, Kshirsagar K, Pawar V, Kakodkar P. DentalVibe reduces pain during the administration of local anesthetic injection in comparison to 2% lignocaine gel: results from a clinical study. J Dent Anesth Pain Med. 2021;21(1):41.
- Gouthaman SS, Kandamani J, Ramakrishnan DS, PU AW. Comparative Evaluation of Clinical Anaesthetic Efficacy of 15 % Lidocaine Spray and 20 % Benzocaine Gel during Removal of Arch Bars. J Evol Med Dent Sci. 2020;9(38):2791-5.
- Rehman N, Qazi SR. Efficacy of topical benzocaine in maxilla: A randomized controlled trial. Anesth Prog. 2019;66(1):24-9.
- Havale R, Rao DG, Shrutha SP, Tuppadmath KM, Tharay N, Mathew I, et al. Comparative evaluation of pain perception following topical application of clove oil, betel leaf extract, lignocaine gel, and ice prior

to intraoral injection in children aged 6–10 years: a randomized control study. J Dent Anesth Pain Med. 2021;21(4):329.

- Kanthaswamy AC, Poojashree B, Vignesh. Efficacy of application of ice pack before. Int J Sci Dev Res. 2020;5(1):193-7.
- 8. Mohammed MA. Comparative analysis of the efficacy of Paracetamol and Naproxen as a preemptive analgesia following surgical dental extraction. J Adv Pharm Educ Res. 2021;11(1):178-81.
- Harouak H, Ibijbijen J, Nassiri L. Comparison between Medicinal Plants Used Against Oral Diseases and Pharmaceutical Dental Products in Morocco. Ann Dent Spec. 2019;7(2):1-4.
- Aksoy F, Tosun S. Effects of different topical anesthetics on pain from needle insertion and injection, and the influence of anxiety in patients awaiting endodontic treatment. Restor Dent Endod. 2022;47(3):e25. doi:10.5395/rde.2022.47.e25
- Fathima HM. Comparative Evaluation of Two Topical Anaesthetic Gels to Reduce Pain During Local Anaesthesia Administration. Biosci Biotechnol Res Commun. 2020;13(7):354-9.
- De Alencar Gondim DG, Montagner AM, Pita-Neto IC, Bringel RJDS, Sandrini FAL, Moreno EFC, et al. Comparative Analysis of the Effectiveness of the Topical Administration of Benzocaine and EMLA® on Oral Pain and Tactile Sensitivity. Int J Dent. 2018;2018.
- Pranati T, Anjaneyulu K. Comparative evaluation of application of cold stimulus versus topical anaesthesia to control pain caused during injection of local anaesthetic solution-a preliminary study. Int J Dent Oral Sci. 2021;8(2):1515-9.
- 14. Soni HK, Saha R, Prajapati R, Pathak S. The Effectiveness of Pre-Cooling the Injection Site in Alleviating the Pain of Oral Injections in Pediatric Subjects. Acta Sci Dent Sci. 2020;4(2):1-5.
- 15. Tirupathi SP, Rajasekhar S. Effect of precooling on pain during local anesthesia administration in children: a systematic review. J Dent Anesth Pain Med. 2020;20(3):119.
- Ghaderi F, Ahmadbeigi M, St G. Cite this article as: Ghaderi F., Ahmadbeigi M. Pain Perception Due to Dental Injection by Smartject: Split Mouth Design Study. J Dent Shiraz Univ Med Sci. 2018;19(1):57-62.
- Menon VD, Muthusekhar MR. Comparison of Precooled Tetrafluoroethane Versus Lidocaine Topical Anesthetic as A Pre-Injection Anesthetic for Inferior Alveolar Nerve Block-A Split Mouth Study. Int J Dentistry Oral Sci. 2021;8(9):4222-5.

- Mohammed MA. Comparative analysis of the efficacy of Paracetamol and Naproxen as a preemptive analgesia following surgical dental extraction. J Adv Pharm Educ Res. 2021;11(1):178-81.
- Harouak H, Ibijbijen J, Nassiri L. Comparison between Medicinal Plants Used Against Oral Diseases and Pharmaceutical Dental Products In Morocco. Ann Dent Spec. 2019;7(2):1-4.
- Prathyusha P, Adyanthaya A, Raheema M, Nair SS, Sivaraman A, Risana K, et al. Assessment of Pain Perception in Paediatric Patients on Application of Cooled and Uncooled Topical Anaesthetic Gel before Infiltration Anaesthesia--A Pilot Study. J Evol Med Dent Sci. 2021;10(23):1751-6.
- Sluka KA, George SZ. A new definition of pain: Update and implications for physical therapist practice and rehabilitation science. Phys Ther. 2021;101(4):pzab019.
- Parirokh M, Sadeghi AS, Nakhaee N, Pardakhty A, Abbott PV, Yosefi MH. Effect of topical anesthesia on pain during infiltration injection and success of anesthesia for maxillary central incisors. J Endod. 2012;38(12):1553-6.
- Meechan JG. Intra-oral topical anaesthetics: a review. J Dent. 2000;28(1):3-14.
- Bhalla J, Meechan JG, Lawrence HP, Grad HA, Haas DA. Effect of time on clinical efficacy of topical anesthesia. Anesth Prog. 2009;56(2):36-41.
- Yaacob HB, Noor GM, Malek SN. The pharmacological effect of xylocaine topical anaesthetic--a comparison with a placebo. Singap Dent J. 1981;6(2):55-7.
- Rosivack RG, Koenigsberg SR, Maxwell KC. An analysis of the effectiveness of two topical anesthetics. Anesth Prog. 1990;37(6):290-2.
- Harbert H. Topical ice: a precursor to palatal injections. J Endod. 1989;15(1):27-8.
- Aminabadi NA, Farahani RMZ. The effect of pre-cooling the injection site on pediatric pain perception during the administration of local anesthesia. J Contemp Dent Pract. 2009;10(3):43-50.
- Lathwal G, Pandit IK, Gugnani N, Gupta M. Efficacy of different precooling agents and topical anesthetics on the pain perception during intraoral injection: a comparative clinical study. Int J Clin Pediatr Dent. 2015;8(2):119-22.