Evaluating the efficacy of commonly used topical anesthetics

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Abstract

Purpose: *This study compared the efficacy of commonly used topical anesthetics using an objective measuring scale.*

Methods: *The following were tested: 5% EMLA cream, 10% cocaine, 10% lidocaine, 10% benzocaine, 1% dyclonine, and a placebo. A special instrument was designed to serve the purpose of pressure application on the gingiva to obtain a threshold discomfort level in grams before and after the topical delivery. The medicaments, in the quantity of 20 μL (2–3 drops) were placed on the maxillary anterior region using Beckman paper wicks in the form of discs. The topical anesthetics were left on the gingiva for 3 min and off for another 3 min. The instrument applied pressure progressively, and the pressure application was stopped when the subjects reported the initial feeling of discomfort.*

Results: *5% EMLA cream significantly reduced the pain threshold level followed by 1% dyclonine and 10% benzocaine. However, there was no significant difference between 10% cocaine, 10% lidocaine, and the placebo. The placebo effect was observed.*

Conclusions: *5% EMLA cream was superior in performance to all other topical anesthetics. The remainder of the agents had no statistically different effect than the saline.(Pediatr Dent 21:197–200, 1999)*

With the new technologies in dentistry such as the new tooth-cutting, laser device, and the air abrasion unit, the need for local anesthetic is reduced or eliminated. Placement of a rubber dam clamp, however, may cause significant discomfort. A topical anesthetic would be beneficial to aid in rubber dam placement for this purpose. This would also allow better isolation for purposes of sealant application and preventive resin restoration (PRR).

Review of literature

Several studies have evaluated the efficacy of topical anesthetics using subjective measuring scales. However, no current studies have used an objective measuring scale. Visual analogue scales are regarded as the most sensitive measurements of pain experience in adults.[1] Manner et al.[2] found a good agreement between visual analogue scales and a verbal scale in assessing pain experience in children as young as four years of age. Meechan and Donaldson,[3] used a visual analogue scale with caricature of a smiling child at one end and a tearful child at the other in children five years and younger. They compared the response and rate of discomfort between 5% EMLA cream and 5% Lidocaine topical anesthetics. There was no significant difference between EMLA and Lidocaine in reducing pain of anesthetic injection. The amount of pulpal anesthesia obtained with 5% EMLA cream was also measured. It was found to be insufficient. The first study investigating the application of EMLA cream in the oral cavity was performed in Sweden by comparing its pain reduction effect during a needle insertion to a placebo. EMLA was found to be very effective in reducing pain experience.[4]

Rosivack et al.[5] used a visual analogue scale in adult patients to compare 20% Benzocaine, 5% Lidocaine, and a placebo (saline) in reducing pain when a needle was inserted. In this study both 5% Lidocaine and 20% Benzocaine were found to be more effective topical anesthetic agents than a placebo. However, there was no statistical difference between the two topical agents. Kincheloe et al.[6] used a post-treatment questionnaire to rate the subject's pain experience after the application of either a topical anesthetic or a placebo before local anesthetic injection. They found no indication that the topical anesthetic had any effect compared to a placebo in reducing pain threshold.

In a study by Vickers et al.[7] a visual analogue test to measure the efficacy of topical anesthetics such as 5% EMLA cream, 5% Xylocaine, and NUM (Lignocaine 5%, Amethocaine 1.7%) was used. When compared to a placebo, all three topical agents were found to be effective in pain reduction during needle insertion, with EMLA being the most effective agent.

This study determined the comparative efficacy of various commonly used topical anesthetics on normal mucosa using an objective measuring scale.

Methods

This study was approved by the Medical Human Subject Protection Committee of UCLA. Twenty-four volunteer subjects, 12 males, and 12 females, ranging in age from 21 to 34 were selected from pre- and postdoctoral students at the UCLA School of Dentistry.

Subject selection was based on the following:

1. Normal healthy gingiva
2. No history of allergy
3. No history of periodontal surgery
4. No history of abcess in area being tested
5. No bleeding disorders
6. Not immunocompromised
7. No systemic or genetic diseases that may compromise the health of the oral mucosa.

A signed informed consent form was received from each subject. The testing was done in a double-blind manner in which one investigator randomly delivered the topical anes-

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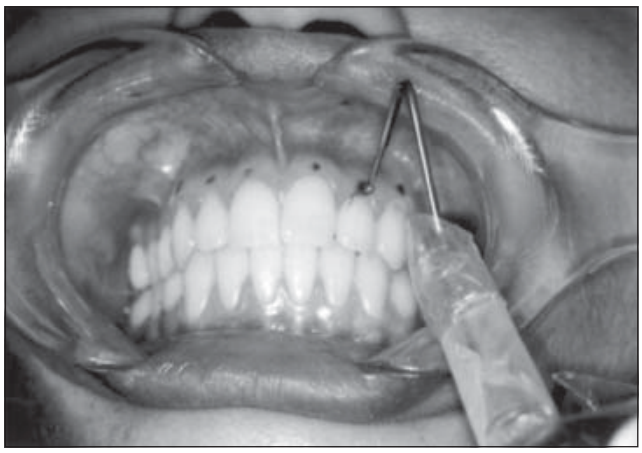

Fig 1. Method of threshold measurement. Pressure is applied progressively on gingiva before and after the topical agent application and it is stopped when the subject reports initial feeling of discomfort.

Fig 2. Pressure gauge instrument. This instrument has three different parts; handle, shank, and replacable stainless steel tip.

thetic agents onto discs and then placed them on test sites while the other investigator applied the pressure device to the test sites. The second investigator was unaware of the type of topical placed on each site.

The maxillary anterior keratinized gingiva, from canine to canine, was used for the six different test sites on each subject.

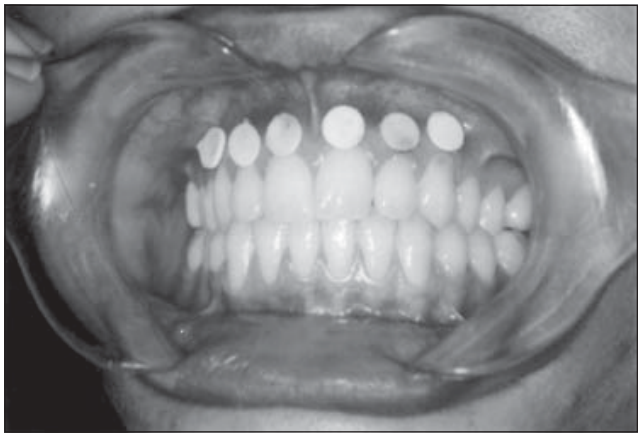

Fig 3. Method of topical delivery. Using discs prepared from Beckman paper wicks, the agents were delivered to the gingival tissue in the quantity of 20 micoliters.

The area was wiped dry with a gauze. An indelible pen was used to mark the test sites. A special instrument was constructed for the purposes of this study. This instrument was pre-calibrated with the Instron machine. It allowed a progressive force to be applied to gingiva and the subjects were instructed to inform the investigator when they first perceived the pressure as uncomfortable (Fig 1). This baseline threshold discomfort level was recorded in grams for each subject.

This instrument has three different parts (Fig 2):

1. Handle/measuring device. Headgear force-analyzing gauge (1000 grams max)
2. Shank. Orthodontic 0.028 stainless-steel tubing fixed to headgear gauge with stainless-steel ligature and acrylic.
3. Tip. Replaceable stainless-steel ball clasp with a ball 1.8 mm in diameter that fits tightly onto the shank tube.

The following topical anesthetics were used:

A. 1% Dyclonine, Dyclonine HCL , Astra Inc.
B. 5% EMLA cream, 2.5% Lidocaine and 2.5% Prilocaine, Prilocaine,Astra Inc.
C. 10% Cocaine, Astra Inc.
D. 10% Benzocaine, Hurricaine 20%, Bentlich Lp.
E. 10% Lidocaine, Xylocaine oral spray, Astra Inc.
F. Saline (placebo)

The drugs being tested were alphabetically marked as listed above and were delivered to the test sites using a 6.8-mm diameter disc that contained 20 µL (2–3 drops) of one of the six solutions. These discs were created from Beckman paper wicks with an attached water impervious backing (Fig 3). A different topical anesthetic was placed on each disc and was applied on a different gingival site. The discs were left on the test sites for 3 min, and then taken off for 3 min, prior to retesting. After the topical agents were applied, the threshold discomfort level was remeasured by applying pressure with the instrument on a separate point under the disc from the original test. The criteria that was used originally to measure the discomfort level was applied again for the retesting. The maximum force allowed on the test site was limited to 600 g.

The samples were randomly placed on six different test sites by a separate investigator as shown in Fig 4. The investigator

Table 1. Mean Pre/Post-Threshold Comparison

	Topical Anesthetic					
	A	B	C	D	E	F
Mean Threshold (Grms)						
Pre	304	298	329	322	332	321
Post	347	388	346	358	360	350

Table 2. Kruskal Wallis Test

Topical	N	Sum Of Scores Post-Pre	Mean Score Post-Pre
A	24	1881	78.4
B	24	2392	99.7
C	24	1481	61.7
D	24	1704	71.0
E	24	1495	62..0
F	24	1486	62.0

who applied the instrument on the test sites was blind to the solution under each disc. The data was collected and analyzed using the Kruskal-Wallis and paired-wise *t*-test.

Results

Table 1 and Fig 4 illustrate threshold levels before and after topical application for 24 subjects. Topical anesthetic B (5% EMLA) was significantly different when compared to the remainder of the agents.

Table 2 illustrates the Kruskal-Wallis test results. This test is a nonparametric measure of the data and it gives a ranking based on the measurements. The *P* value was measured to be 0.092. The chi-square was measured to be 15.289 indicating significant differences among groups.

Topical B (EMLA cream) had the highest difference between pre and post-threshold levels. There were no significant differences between topical anesthetics C (10%cocaine), E (10% lidocaine), and F (saline).

Table 3. Paired-Wise Test

Bonferroni Grouping		Mean Post-Pre	N	Topical Type
	A	99.7	24	B
B	A	78.4	24	A
B	A	71	24	D
B		62	24	E
B		62	24	F
B		62	24	C

Table 3 and Fig 5 illustrates the paired-wise *t*-test results. This test uses the Bonferroni grouping method. The topical agents placed in one group (based on their mean pre- and post-difference) are significantly different from the agents not placed in the same group. Therefore, topical B (EMLA) was significantly different when compared to the rest of the agents in the Bonferroni grouping type B. All the other agents were not significantly different in that same grouping. However, in grouping A, topical anesthetics B (EMLA), A (Dyclonine), and D (Benzocaine) are not significantly different from each other; however, they are significantly different from agents E (Lidocaine), F (saline), and C (Cocaine).

Discussion

There are procedures in dentistry where there is no need for local anesthetic application. Use of the new laser device and the air abrasion unit often reduces or eliminates the need for pulpal anesthesia. Sealants and preventive restorative resins may not require application of a local anesthetic. However, there is a need for soft tissue anesthesia since a rubber dam would be recommended when performing the above procedures for improved isolation. Developing a potent, yet low dosage, topical anesthetic patch for use in children would be very helpful for rubber dam application and other uncomfortable procedures procedures.

In this study, all five topical anesthetics, as well as the placebo, showed some degree of soft-tissue anesthesia. When they were compared to the placebo however, 10% cocaine and 10% lidocaine had the same result as the placebo, and 5% EMLA was superior to the rest of the agents.

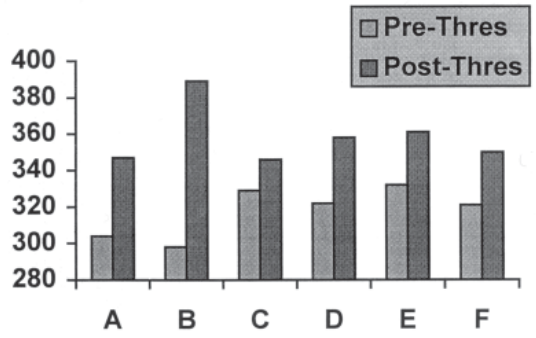

Fig 4. Mean pre/post threshold Comparison.

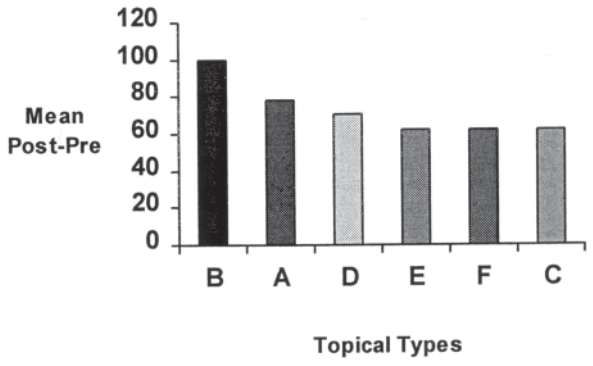

Fig 5. Topical anesthetic B has the highest pre-post theshold difference peak.

There are variables that need to be considered when the result of this study is reviewed. Although the study was double-blind in nature and the topical agents were applied randomly on different test sites, there could have been an overlapping effect due to close proximity of discs to each other. The amount of keratinized tissue and variable gingival sensitivity at the test sites (i.e., canine eminence area is a more sensitive tissue site), could have influenced the results. In addition, the state of mind the subjects were in at the time of testing could have been a variable. Three subjects were extremely nervous and the smallest amount of pressure from the measuring device was perceived as uncomfortable to them. Those subjects were eliminated from the study. Research has shown that the perception of pain is as individualized as each personality.[8] The magnitude, intensity, and/or quality of a painful stimulus is not simply a function of degree of injury alone.[9] The literature also reveals five main variables that can affect the psychological perception of pain: culture, personal history (previous experiences), personality, emotion, and cognitive.[9]

All the subjects were aware of receiving several types of topical anesthetics. We did observe a placebo effect with an increase in threshold discomfort level when using saline on the paper discs. Although we selected the application and waiting times to be comparable with the time used in a practice setting, increasing the length of application or waiting time might have caused an increase in the pre- and post-threshold test results. This might have also affected the ranking order of the topical anesthetic agents.

Use of topical anesthetics could be especially beneficial to pediatric patients and young adults who are needle phobic. Development of an EMLA patch with the proper pediatric dosages to prevent possible overdosage and side effects should be the aim of future research. Studies should be performed to determine the optimal time needed for maximum effect.

Conclusions

1. 5% EMLA cream was superior in performance to all other topical anesthetics.
2. The remainder of the agents had no statistically different effect than the saline.

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Abstract of the Scientific Literature

Alternatives to silver amalgam and resin composite in pediatric dentistry

Silver amalgam is waning as a restorative material, not because of its mercury content but because more suitable materials have been developed. Glass-ionomers have three major limitations: difficult handling properties, poor wear resistance, and poor fracture strength. Glass-ionomer silver cermet has low fracture strength and cannot be used to replace cusps and marginal ridges but has good wear resistance (due to the silver component) and it has been shown to release fluoride to the approximating tooth surface and to deter *Streptococcus mutans* colonization interproximally. New improved self-setting traditional glass-ionomers harden by acid-base neutralization reaction and have less early sensitivity to moisture and low solubility in oral fluids. The light-setting resin-modified glass-ionomers as bases/liners and restoratives combine glass-polyalkenoate cement with a light-polymerizing resin component. These are valuable as enamel and dentin replacements for use in non-stress bearing restorations in primary teeth with less than five year's duration. The resin increases fracture strengths and wear resistance. Resin-modified glass-ionomers perform well in primary teeth in Class I, II, III, and V restorations. Brands differ considerably in physical properties. Compomers do not undergo a significant acid-base reaction; polymerization is light-initiated free-radical polymerization. The author speculates on their use for high caries patients and Class II sandwich preparations.

Comments: This article provides a concise review of the development and use of glass-ionomer silver-cermet cements, resin-modified glass-ionomer cements, and polyacrylic acid-modified resin composites (compomers) for the restoration of primary teeth. The author refers to the early definitions of McLean to avoid confusion over nomenclature. Useful guidelines are presented which should assist the clinician in appropriate selection of the newest materials for use in children. The author closes with a wise recommendation for the clinician and assistant to practice placing the new materials in prepared cavities in extracted teeth before attempting treatment in a child's mouth. **LBM**

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Alternatives to silver amalgam and resin composite in pediatric dentistry. Croll, TP. Quintessence Int 29:697-703, 1998.

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