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Anesthetic Effect of EMLA Occluded with Orahesive Oral Bandages on Oral Mucosa. A Placebo-Controlled Study

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The efficiency of a topical anesthetic occluded with Orahesive Oral Bandage was investigated. Experimental pain was provoked by needle insertions into two palatal test areas in 20 healthy subjects. Pain, estimated on a 100-mm visual analogue scale (VAS), decreased significantly from 23.5 mm to 10.5 mm at the greater palatine foramen and from 51.5 mm to 35.0 mm at the incisive foramen after application of a eutectic mixture of local anesthetics (EMLA). No significant change in pain perception was obtained after placebo application. The EMLA cream and the Orahesive Oral Bandages were well accepted by the subjects, as only two out of 20 subjects experienced slight gagging reflexes and only three considered the taste unpleasant. No other adverse reactions were observed. Occlusion of topical anesthetics seems to be a useful technique for achieving superficial mucosal anesthesia.

Topical anesthetics are applied to alleviate pain during many clinical procedures, such as subgingival scaling, removal of sutures, gingival retraction, and injection of local anesthetics. Topical anesthetics are therefore valuable adjuncts to the dental armamentarium.[1] Lidocaine and benzocaine are among the most commonly used topical anesthetics on the oral mucosa.[2,3] Though effective, these agents are not ideal, and topical anesthetics may still be improved.

Within the last decade, a new, eutectic mixture of local anesthetics (EMLA, Astra Läkemedel AB, Södertälje Sweden) has been developed and shown to be highly effective for anesthetizing the skin prior to venipuncture and minor dermatologic surgery.[4] EMLA consists of an equal mixture of 2.5% lidocaine and 2.5% prilocaine in an aqueous solution. EMLA has also been found to be effective on the genital mucosa.[5] Recently, EMLA has been applied on the oral mucosa.[6,7] A significant reduction in pain scores was found during needle insertion into the mucosa of the hard palate and into the buccal fold after application of EMLA for 5 min.[6] The viscosity and retention ability of the EMLA cream were, however, described as unsuitable for clinical application in the oral cavity.[6] Occlusion of the EMLA cream may be a simple solution to this problem.

The Orahesive Oral Bandage (ConvaTec, Princeton, NJ) was developed to provide mechanical, physical, and chemical protection for wounds in the oral cavity. The bandage consists primarily of carboxymethylcellulose, which sticks to the oral mucosa after humidification. The aim of the present study was to determine the anesthetic effect of EMLA occluded with Orahesive on pain provoked by needle insertion into the palatal mucosa.

METHODS

Subjects

Twenty healthy dental students (12 women and eight men aged 21–42 yr, mean age 26 yr) participated in the study. Informed consent according to the II Helsinki declaration was obtained.

Test Procedure

Baseline and test values of pain intensity during standard needle (27-ga) insertion into the palatal test areas were determined (1) on a 100-mm visual analog scale (VAS) with a left endpoint of "no pain" and a right endpoint of "worst imaginable pain," and (2) on a simple verbal pain rating scale (0 = no pain, 1 = slight pain, 2 = moderate pain, 3 = strong pain, and 4 = very strong pain). The needle insertions were performed at the left and right

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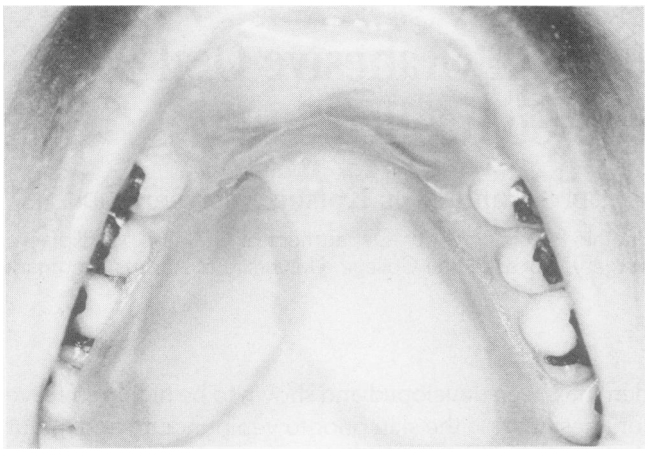

Figure 1. Occlusion of EMLA and placebo creams with three Orahesive Oral Bandages on the hard palate.

greater palatine foramens 0.5 to 1.0 cm above the gingival margin and at right angles to the palatal mucosa. Insertions at the incisive foramen were made at the edge of the incisive papilla according to the description by Haglund and Evers.[8] The sequence of the three palatal insertions was randomized in a balanced way. After baseline needle insertions, a double-blind study regimen was used to apply the EMLA and a placebo cream (similar in appearance, viscosity, and other characteristics to the EMLA cream but without analgesic activity) at the left and right greater palatine foramens. A double-blind parallel group regimen was used at the incisive foramen, where EMLA or placebo was applied to each subject according to a randomized table. The exact amount of 0.4 g EMLA and placebo was determined on a Mettler balance and placed on an Orahesive Oral Bandage (round, 30-mm diameter). The EMLA and placebo were gently applied to the dried palatal test areas and left for 5 min (Figure 1). After removal of the EMLA and placebo, the oral mucosa was cleaned with a gauze swab. Needle insertions were repeated at the three test areas, and the intensity of perceived pain was registered.

Taste of the EMLA cream and discomfort caused by the Orahesive Oral Bandages were registered by the subjects immediately after the test.

Orahesive Oral Bandages were on a separate occasion applied on the hard palate, the lower lip mucosa, and on the buccal mucosa in nine subjects and left until spontaneous discharge. The time was noted by the subject and reported to the investigators.

Statistics

Wilcoxon's signed-rank test, the sign test, and the Mann-Whitney U test were used for statistical analysis. A significant difference was accepted at $P < 0.05$.

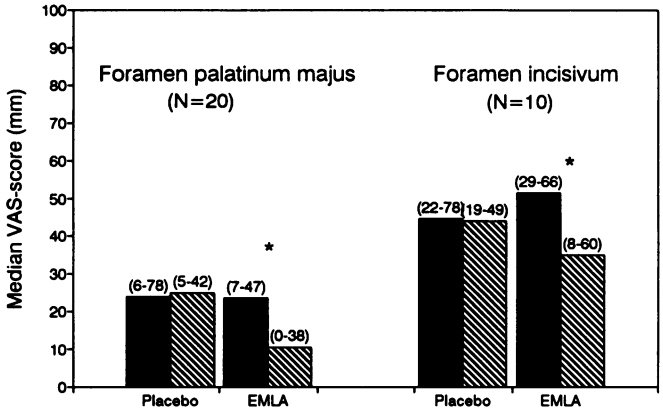

Figure 2. Pre- (■) and postapplication (▨) values of needle pain estimated on VAS (mm). EMLA or placebo applied on the greater palatine foramen (foramen palatinum majus) and incisive foramen (foramen incisivum). The range of observations are given in parenthesis. Asterisks (*) indicate significant differences (Wilcoxon: $P < 0.05$) between pre- and postapplication values.

RESULTS

The pain elicited by needle insertion into the hard palate was significantly reduced after application of EMLA but not after placebo (Figure 2). The median pain intensity estimated on the VAS was reduced from 23.5 mm to 10.5 mm at the greater palatine foramen and from 51.5 mm to 35.0 mm at the incisive foramen after EMLA application. No significant difference in pain on the VAS was found between preapplication values at either test site. Postapplication values of pain were significantly different at the greater foramen palatine (Wilcoxon: $P < 0.001$) but not at the incisive foramen (Mann-Whitney: $P > 0.325$). A simple pain rating scale also showed significant reduction in pain perception after EMLA application but not after placebo (Figure 3). Eleven out of 20

Figure 3. Frequency distribution of needle pain estimated on verbal rating scales. Pre- (■) and postapplication (▨) of EMLA or placebo. Asterisks (*) indicate significant differences (Sign test, $P < 0.05$) between pre- and postapplication values.

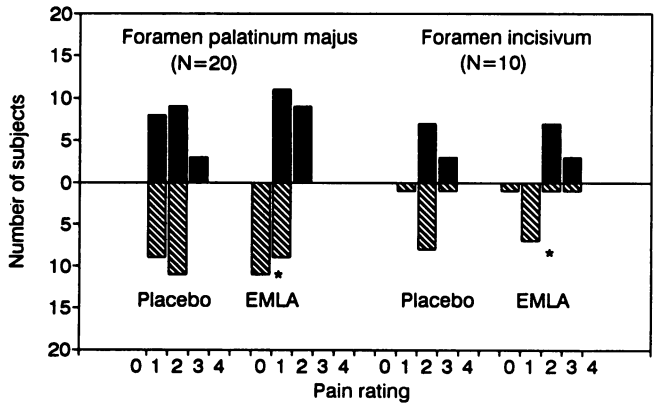

Table 1. Anesthetic Effects of EMLA and Placebo Creams on the Hard Palate Estimated by Questions

	Greater Palatine Foramen (n = 20)		*Incisive Foramen (n = 10)*	
Question	*Yes*	*No*	*Yes*	*No*
Difference between EMLA and placebo?	17	3	—	—
Difference before and after placebo?	5	15	1	9
Difference before and after EMLA?	16	4	9	1

subjects experienced no pain at all during needle insertion at the greater palatine foramen after EMLA application, but only one subject indicated no pain at the incisive foramen. Table 1 summarizes the anesthetic effect of EMLA by questions to the subjects. Generally, the subjects were able correctly to locate the test areas where EMLA had been applied.

The overall subjective acceptance of the combination of EMLA and Orahesive Oral Bandages was good, as only two subjects considered the application to be slightly unpleasant due to gagging reflexes. Three out of 20 subjects stated that the taste was bad. No other adverse reactions were noted on the oral mucosa. Both the application and removal of the Orahesive Oral Bandages were considered by the investigators to be easy and caused no problems in all 20 subjects.

On the hard palate, the median adhesion duration of Orahesive was 10.1 hr (range 2.5 to 24.0 hr); on the lower lip mucosa, 5.2 hr (range 1.0 to 21.5 hr); and on the buccal mucosa, 2.5 hr (range 0.5 to 9.5 hr) as tested in nine subjects.

DISCUSSION

The anesthetic effect of EMLA occluded by Orahesive Oral Bandages was investigated by needle insertion into the palatal mucosa in the present double-blind, placebo-controlled study. Previously, most studies on the efficacy of oral topical anesthetics have been conducted in the mucobuccal fold.[1,3,9] However, palatal injections are considered the most painful, and efficacy studies of topical anesthetics should preferentially be conducted in this region. Gill and Orr[10] were not able to find any significant difference in needle pain perception after application of active topical anesthetics or placebo on the hard palate. However, they calculated mean pain ratings from an ordinal scale (1 to 5), which may not be statistically appropriate, and hence, information could have been lost.[11]

The EMLA cream significantly reduced the perception of pain during needle insertion into the palatal mucosa in the present study, especially at the greater palatine foramen. The relatively high and persistent pain rating at the incisive foramen may be due to the very dense innervation of the anterior part of the hard palate.[12] A similar reduction in pain perception was demonstrated by Holst and Evers,[6] but only five out of their 20 subjects experienced completely pain-free needle insertion into the palatal mucosa, whereas in the present study 11 out of 20 subjects were totally pain free. This difference could be due to the effect of occlusion, which may secure optimal retention and absorption of the anesthetic agents left undisturbed by tongue movements and saliva. The use of Orahesive Oral Bandages is an easy and practical technique to occlude topical anesthetics on the oral mucosa. Furthermore, the rather long adhesion period observed in the present study would indicate a possibility of using the Orahesive as an occluding, supporting oral bandage for medical ointments for treatment of superficial mucosal lesions.

In conclusion, the present study indicates that occlusion of topical anesthetics may be a new well-controlled technique for obtaining mucosal anesthesia. It also indicates the need for still more effective topical anesthetic agents in the oral cavity.

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