A New Method of Topical Anesthesia by Using Anesthetic Solution in a Patch

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Abstract

Introduction: We investigated the effects of topical anesthesia of the oral mucosa by using an adhesive patch instilled with 2% lidocaine hydrochloride solution. **Methods:** The subjects were 20 healthy adult volunteers who gave written informed consent. Each patient was treated in a randomized crossover fashion with a hemostatic adhesive patch instilled with one of the following agents: 2% lidocaine hydrochloride with 12.5 μg/mL epinephrine, 2% lidocaine hydrochloride, 20% ethyl aminobenzoate, or physiological saline solution. A cotton ball containing 20% ethyl aminobenzoate was also tested. The adhesive patch or cotton ball was placed on the gingivobuccal fold of the maxillary right canine for 2 or 5 minutes. Then, a 33-gauge or 30-gauge needle was inserted to a depth of 2 mm. Insertion pain was evaluated with a visual analog scale (VAS) and a 4-level verbal rating scale immediately after needle removal. Efficacy of analgesia was calculated from the verbal rating scale. **Results:** The VAS was lower and the efficacy of analgesia was higher on 33-gauge needle insertion than on 30-gauge needle insertion in all treatments. The VAS was also significantly lower and the efficacy of analgesia was higher in the lidocaine groups than in the other groups. Adding epinephrine did not enhance the anesthetic effect of lidocaine hydrochloride. **Conclusions:** Topical mucosal anesthesia with an adhesive patch containing 2% lidocaine hydrochloride solution is simple and may be more effective than conventional methods. *(J Endod 2013;39:1369–1373)*

Key Words

Adult, benzocaine, lidocaine, mouth mucosa, pain, pain threshold

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Local anesthesia is a fundamental method of pain control during dental treatment. However, the pain that accompanies the process of local anesthesia itself frequently causes fear of dental treatment and may provoke vasovagal syncope (1, 2), hyperventilation attack (3), and other adverse events. There are 2 types of pain during local anesthesia. One is at needle insertion, and the other is during agent injection. Topical anesthetics are generally used for analgesia during needle insertion (4, 5), but they have no effect on the pain felt during anesthetic injection (6). Several reports have suggested that application of a 20% lidocaine hydrochloride patch is more effective than other topical anesthetic methods (7, 8). Various methods that enhance the tissue absorption of local anesthetics to achieve better topical mucosal anesthesia have also been reported. Examples are iontophoresis, which uses a small electric current to accelerate the permeation of local anesthetics into the gingiva, phonophoresis, which uses ultrasonic waves (9–11), and needle-free local anesthesia systems (Injex; Pharma AG, Berlin, Germany) (12). However, all of these methods require specialized equipment and complex techniques. The dental topical anesthetics currently available in Japan are tetracaine hydrochloride and ethyl aminobenzoate (benzocaine). These are classified as ester-type anesthetics, and their anesthetic potency is weaker (13) than that of lidocaine hydrochloride, an amide-type anesthetic most widely used for infiltration anesthesia. In addition, allergies to local anesthetics are more frequently reported with ester-type anesthetics (14). Here, we investigated a new and simple method of topical anesthesia by using an adhesive patch instilled with a small volume of 2% lidocaine hydrochloride solution.

Materials and Methods

This study was approved by the Ethics Committee of Tokyo Dental College (Approval No. 307) and undertaken in accordance with the provisions of the Declaration of Helsinki. The subjects were 20 healthy adult volunteers (12 men, 8 women) who gave written informed consent. The sample size was calculated on the basis of data obtained by using a visual analog scale (VAS) in our pilot study. A power analysis ($\alpha = 0.05$, $\beta = 0.20$) suggested that at least 15 subjects would be required to detect a 15% difference in the mean VAS; we therefore enrolled 20 subjects and used them for all of the treatments. None of the subjects had a history of neurologic disease or poisoning that could have affected normal sensation, and none had received surgical treatment or other trauma to the area of the alveolar mucosa where we intended to insert the needles.

The agents used were 2% lidocaine hydrochloride (Xylocaine Polyamp 2%; AstraZeneca K.K., Osaka, Japan), 2% lidocaine hydrochloride with 12.5 μg/mL epinephrine (Xylocaine Cartridge for Dental Use; Dentsply Sankin, Tokyo, Japan), 20% benzocaine (Hurricaine Gel Dental 20%; Agsa Japan, Osaka, Japan), and physiological saline solution. We used a hemostatic adhesive patch (Medipatch; Hakujuji, Tokyo, Japan). The gauze portion (10 $\times$ 10 mm) of the patch was instilled with 0.06 mL (15 drops from a 33-gauge [G] needle) of 2% lidocaine hydrochloride solution (Lido treatment, 1.2 mg lidocaine hydrochloride), 2% lidocaine hydrochloride with 12.5 μg/mL epinephrine solution (Lido/Epi treatment, 1.2 mg lidocaine hydrochloride with 0.75 μg epinephrine), or physiological saline solution (Control treatment), or it was spread with 0.06 g 20% benzocaine (Benzo/Patch treatment). In an additional treatment (Benzo/Cotton treatment), 0.06 g 20% benzocaine (Hurricaine Gel Dental 20%) was applied to a 3-mm-diameter cotton ball (Cotton Ball No. 3; Hakujuji). This treatment served as the control for the Benzo/Patch treatment; it is used widely in routine dental practice.

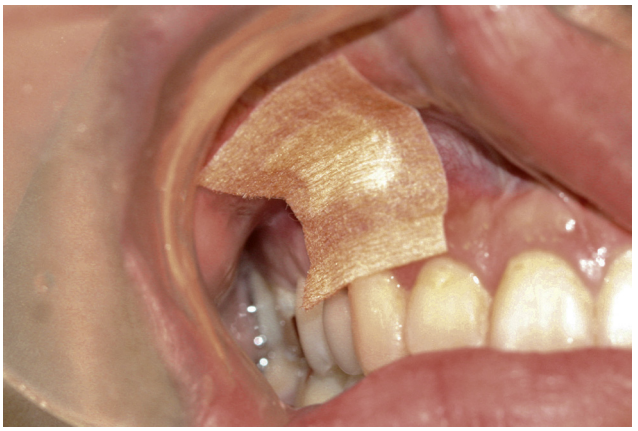

Figure 1. An adhesive patch was applied for 2 or 5 minutes to the dried gingivobuccal fold of the maxillary right canine.

Subjects were placed in a supine position on a dental chair and given 5 minutes to rest. The patch or the cotton ball was then applied for 2 or 5 minutes to the dried gingivobuccal fold of the maxillary right canine (Fig. 1). Within 15 seconds after removal of the agent, the upper lip was extended sufficiently for exposure of the injection site. A 30G Short dental injection needle (0.32 mm in diameter; Dentsply Sankin) or a 33G Super Short dental injection needle (0.26 mm in diameter; Dentsply Sankin) was inserted perpendicular to the mucosal surface to a depth of 2 mm and held in place for 10 seconds. Immediately after removal of the needle, the pain on needle insertion was assessed by using a VAS and a 4-level verbal rating scale (VRS). Presence or absence of numbness of the tongue and pharyngeal discomfort were also assessed.

To maintain consistency of the anesthesia technique, one individual (S.N.) administered all anesthetics. In the 4 treatments in which the patch was used, the experimental agents were randomly prepared by another person to ensure double blindness. A total of 5 needle insertions were performed on each subject in a randomized crossover manner. Each participant underwent all 5 treatments, with an interval of at least 3 days between experiments. The VRS was evaluated by using 4 levels of pain severity: 0 for no pain, 1 for slight pain, 2 for mild or moderate pain, and 3 for severe pain. In addition, efficacy of analgesia was calculated from the VRS as (Number of patients with no pain or slight pain)/(Total no. of patients) $\times$ 100.

The Friedman h test and Wilcoxon t test with Bonferroni correction were used for intergroup comparisons. A P value less than .05 was considered significant. The Wilcoxon t test was also used to compare VAS scores by using the 2 different durations of agent application and the same diameter needle and by using different diameter needles with the same duration of agent application.

Results

The average subject age was 27.7 $\pm$ 1.0 years, average height was 168.1 $\pm$ 6.8 cm, and average weight was 61.7 $\pm$ 12.3 kg. Vasovagal reflex, hyperventilation attack, allergies to local anesthetic, or other adverse events were not observed. The results of VAS and VRS and the efficacy of analgesia are presented in Figure 2 and Table 1.

VAS and VRS were significantly lower in the Lido and Lido/Epi treatments than in the Control treatment with both 2- and 5-minute application, as well as with both 33G and 30G needles. The efficacy of analgesia applied for 2 or 5 minutes before 33G needle insertion was 95% in the Lido treatment and 100% in the Lido/Epi treatment. VAS was significantly lower in the Benzo/Patch treatment than in the Control treatment in all intertreatment comparisons, but VRS was significantly lower with this treatment only after 5-minute application. The efficacy of Benzo/Patch analgesia for 2 or 5 minutes before 33G needle insertion was 70%. Both VAS and VRS were significantly lower in the Benzo/Cotton treatment than in the Control treatment only in the case of 5-minute application before 33G needle insertion; the efficacy of analgesia under these treatment conditions was limited to 65%. On the VAS and VRS, no differences were observed in all intergroup comparisons between the Benzo/Cotton treatment and the Benzo/Patch treatment.

Comparisons between the Lido and Lido/Epi treatments revealed no differences in either VAS or VRS under any of the 4 conditions. In the comparison of different durations of anesthetic application, followed by the insertion of identical-gauge needles, no differences in VAS were observed in the respective treatments. In the 2-minute application treatment, although the VAS values for Lido treatment and Lido/Epi treatment followed by 33G needle insertion were significantly lower than those with 30G needle insertion, no differences were observed in all other comparisons (data not shown).

Although 17 subjects complained of tongue numbness when given the Benzo/Cotton treatment and 8 complained of pharyngeal discomfort, no subjects complained of these complications when they were given the other treatments.

Discussion

We found here that topical anesthesia was more effective with an adhesive patch containing a small volume of 2% lidocaine hydrochloride (1.2 mg) than with a cotton ball containing 20% benzocaine, which is a conventional method. Application of 2% lidocaine hydrochloride via an adhesive patch for 2 minutes effectively prevented the pain of insertion of a 33G needle, and the pain from a 30G needle was prevented by 5-minute application. Adding epinephrine to the local anesthetic solution did not enhance the anesthetic effect.

Combined formulations of 2.5% lidocaine hydrochloride and 2.5% prilocaine hydrochloride (Oraqix, Dentsply Pharmaceutical, York, PA; EMLA 5%, AstraZeneca, London, United Kingdom) are commercially available outside Japan and are reported to be more effective than 20% benzocaine (15). High-concentration lidocaine patches such as DentiPatch (20% lidocaine mucoadhesive patch; Noven, Miami, FL) and Penles (60% lidocaine tape; Japan Lederle, Osaka, Japan) are also reported to be effective topical mucosal anesthetics (16, 17). However, in Japan the former has not received pharmaceutical approval, and the latter is not indicated for intraoral use. Consequently, none of these products are available here as a dental topical anesthetic. Although 2% lidocaine hydrochloride with 12.5 μg/mL epinephrine is widely used for infiltration or conduction anesthesia in Japan, to our knowledge there has been no research into the use of this agent as a topical mucosal anesthetic.

We used a widely used VAS (18) and a 4-level VRS to evaluate pain at needle insertion. The average VAS score in the Control treatment under the 4 experimental settings ranged from 17.3–23.1 mm. These scores suggest that the insertion pain was light to moderate (19). In a clinical setting, in addition to pain at needle insertion, pain may arise during the injection of local anesthetic solutions. Because it is difficult to completely eliminate pain during injection when topical anesthetics are used (6), sufficient topical anesthesia for maximum effect is at least required.

The pain that accompanies local anesthesia itself can cause fear of dental treatment, and highly anxious or phobic patients may feel more pain than others during injection (20). Pain during local anesthesia may provoke vasovagal syncope, hyperventilation attack, and other adverse events in phobic dental patients or patients with cardiovascular disease. In addition, children or disabled individuals may become