

The Effect of 20% Benzocaine Gel on the Pain of Needle Insertion in Inferior Alveolar Nerve Block Injection: A Randomized Double-Blind Clinical Trial

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Abstract

Background and objectives: Dental phobia is a widespread issue that impacts a large portion of the world's population. As a result, various solutions have been proposed, such as applying topical anesthesia before the injection. However, there are paradoxical findings in different studies regarding the significance of pain control in dentistry. This study aims to evaluate the effect of Benzocaine Gel 20% on reducing pain for inferior alveolar nerve block.

Materials and methods: In the current double-blinded clinical trial, patients were randomly divided into two groups: the study group received 20% Benzocaine Gel (Master Dent) while the control negative group received Fluoride Gel (Master Dent AFP). An inferior alveolar nerve block injection was done afterward. The level of pain was assessed using Visual Analogue Scale (VAS). Data were analyzed using SPSS version 16.

Results: 329 patients were included of which, 149 (45.3%) and 180 (54.7%) individuals were in the control negative and intervention groups, respectively. The VAS was 73.97 ± 14.01 in the control negative and 60.68 ± 19.1 in the intervention group, which was significantly different ($P = 0.001$).

Conclusion: This investigation suggests that topical anesthetic substance 20% Benzocaine Gel can efficiently reduce injection pain and patients can become more comfortable during the procedure.

Keywords: Topical anesthesia, Benzocaine, Inferior alveolar nerve block.

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1. Introduction

An international problem that has impacted oral and dental health is dental fear and anxiety. The patient frequently feels uncomfortable while visiting the dentist, whether they are in the office or lying on the unit. According to epidemiological studies, 20 - 30% of people are concerned about the failure of dental procedures. About 40% of people in Western societies worry about visiting the dentist, and 20% of them are really terrified of it. The dread and anxiety related to dental treatments persist despite technological advancements in the

field of dental equipment and the development of dental science (1,2).

Pain is the most common clinical experience of the patient in the dental office. Therefore, it is crucial for the dentist to be aware of the right methods of pain control in order to implement his treatment plan with tenacity and earn the patient's trust during conventional dental treatments (3).

Pain management is thus the key strategy for patient behavioral guidance. The most popular form of pain relief, anesthetic, also results in pain and anxiety (4). Consequently, it is feasible to make reference to a variety of measures, including psychologically preparing the patient, taking some

anti-anxiety medications before visiting the doctor's office, employing a correct and gentle injection technique, and applying superficial anesthetic prior to the injection (5).

Using topical anesthetic before injection is one of the most crucial tactics, as was previously indicated (6,7). Moreover, using superficial anesthetic has a number of contradictions. Some feel there are alternatives to other procedures such that there is no need for superficial anesthetic, while others emphasize its usefulness prior to injection (8,9).

Topical anesthetics come in a variety of forms that can be applied using a cotton tip to the mucous membranes of the mouth, such as gels, liquids, ointments, and sprays under pressure. Ethyl Aminobenzoate (Benzocaine), Butacaine Sulfate, Cocaine, Diclonin, Lidocaine, and Tetracaine are a few of the several anesthetics used in topical anesthetics (10). The most effective method for topical anesthetic of the oral mucosa during dental treatments is probably Ethylaminobenzoate (Benzocaine) liquid solutions, ointments, or gels. Compared to other superficial anesthetics, this drug has a quicker onset of action and a longer duration of anesthesia. Oral anesthetics have also not been linked to any systemic effects (7).

In light of the significance of pain management and the discrepancies in previous research, this study has established the impact of 20% benzocaine gel on the discomfort associated with inferior alveolar nerve block injections.

2. Materials and Methods

In the present double-blinded clinical trial 329 patients referred to the Tooba dental faculty were included.

The inclusion criteria were as follows:

- 1) Patients who needed inferior alveolar nerve block anesthesia
- 2) Absence of systemic diseases
- 3) Absence of a history of dental pain in the last month

The exclusion criteria were as follows:

- 1) Patients who had contraindications to lidocaine use
- 2) Patients with a history of mental illness which made them unable to answer the questions
- 3) Smoking and alcohol-consuming patients

The sample size was calculated to be 70 individuals in each group based on Koppolu et al.' study (11).

The demographic and clinical features such as age, sex, medical history, and procedure of removal of the tooth were recorded. Patients were randomly divided into two groups; the intervention group received 20% benzocaine gel (master dent) while the control negative group received APF (master dent) flavored gel. Both gels had the same odor so the patients would be unaware of their group.

Prior to the procedure, the injection site was dried for 5 seconds with air spray; benzocaine gel) intervention group) or fluoride gel (control negative group) was applied for 2 minutes based on the manufacturer's instructions. Afterward, the inferior alveolar nerve block of 2% Lidocaine with 1:100,000 epinephrine (Master Dent) was done using a 27-gauge needle (12,13).

At the end of the injection, the patients were instructed to rate their pain from each needle insertion on a horizontal 100-mm

visual analog scale (VAS). Their level of pain was categorized as without/mild pain (scoring 0 - 49 mm), moderate pain (scoring 50 - 74 mm), and severe pain (scoring 75 - 100 mm) (14). All examinations and injections were performed by a final-year dental student. The injector as well as the patients were not aware of the type of anesthetic.

In this study, confounding factors such as patient anxiety, previous dental experience, pre-referral analgesia, and other factors that affected the patient's perception of pain were ignored.

Data analysis was performed in SPSS Ver.16 (SPSS Inc., Chicago, IL, USA). The normality hypothesis was checked with the Kolmogorov-Smirnov test. Independent t-test (compare mean VAS in two groups), and ANCOVA regression (control confounder variables for compare mean VAS in two groups) were used to test the hypotheses. P-value of < 0.05 was considered statistically significant.

3. Results

The present investigation consisted of 329 subjects who were randomly divided into two groups intervention (180 patients) and control negative (149 patients). The patients had a mean age of 42.26 ± 15.19 years old (Figure 1). There was a statistically significant difference between the patients in terms of their age and those in the intervention group were on average 3.66 years older than the control negative group ($P = 0.029$).

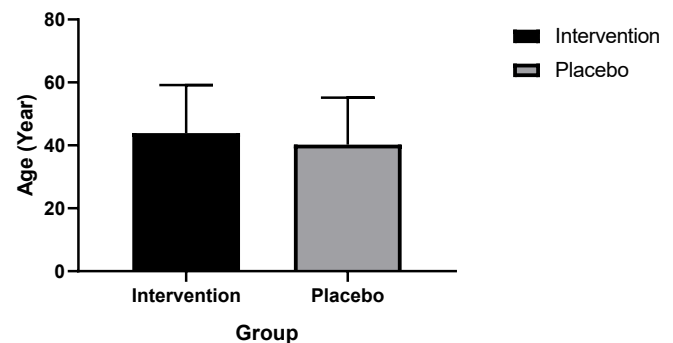


Figure 1. The mean age of the patients based on their group.

The mean visual pain intensity scale (VAS) in both groups was 66.7 ± 18.21 after the injection; the control negative group had a VAS of 73.97 ± 14.01 , while the intervention group had a mean of 60.68 ± 19.1 (Figure 2). The mean VAS was 13.28 levels lower in the intervention group compared to the control negative group, which was statistically significant ($P = 0.001$).

As demonstrated in Table 1, there was no significant difference in the mean VAS of the patients in terms of their sex in both intervention and control negative groups ($P = 0.198$ and $P = 0.932$, respectively). However, a statistically significant difference was observed in the men's pain score between the intervention and control negative group ($P < 0.001$). The pain score was 15.6 times higher in the control negative group compared to the intervention group. Further-

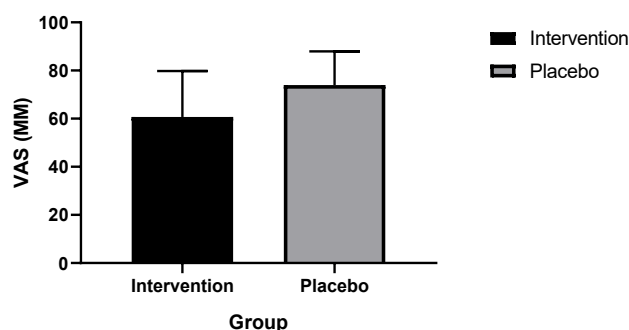


Figure 2. The visual analog scale (VAS) of the patients based on their group.

more, the average pain score in women in the control negative group was 11.7 times higher than the intervention group, which was also statistically significant (Table 2).

Owing to the fact that the age variable was statistically significant between the two groups, its effect was adjusted using ANOVA. Findings after the required adjustments

suggested that pain in the intervention group was 0.4 units less than the control negative group, which was statistically significant ($P > 0.001$).

4. Discussion

Inserting a needle during local anesthesia has often been reported as a fearful stimulus for anxious patients. The two components of a local anesthetic injection that may lead to pain are the needle insertion and the injection of the solution. Reducing fear and anxiety can improve the dentist-patient relationship and allow the patients to have a favorable attitude toward dental procedures (15).

The anesthetic gel was applied for two minutes in this investigation, but the exact duration is controversial in different studies ranging from 30 seconds to 2 minutes (16-18). IAN (inferior alveolar nerve) block injection was used in the present study; however, some authors have suggested topical anesthesia is ineffective in some injection modalities (13,19). Moreover, some studies have also inserted the needle without any injection in order to differentiate the pain level between injection and inserting a needle (20).

Table 1. Comparison of mean pain scores between men and women by treatment group and in general.

Variable	Treatment group	Descriptive values	Independent t-student test results	
		Mean $\pm$ SD	95% confidence interval	P-Value
VAS in the intervention group	Men	67.12 $\pm$ 18.2	1.98 – 9.49	0.198
	Women	66.13 $\pm$ 18.27		
VAS in the control group	Men	73.88 $\pm$ 14.35	4.76 – 4.35	0.932
	Women	74.07 $\pm$ 13.71		

Table 2. Evaluation of the difference in pain score in men and women according to treatment group.

Variable	Treatment group	Descriptive values	Independent t-student test results	
		Mean $\pm$ SD	95% confidence interval	P-Value
Pain in men	Control negative	74.07 $\pm$ 13.71	21.2 – 10,13	< 0.001
	Intervention	58.41 $\pm$ 18.92		
Pain in women	Control negative	73.88 $\pm$ 14.35	6.9 – 16.5	< 0.001
	Intervention	62.17 $\pm$ 19.17		

The results of the current investigation indicated that the mean pain after injection in the benzocaine group was significantly lower than the control negative group. Cho et al. Conducted a study assessing the effect of local anesthesia on pain from needle insertion and injection and its relationship with anxiety in apical surgery patients and found that the use of local

anesthesia with lidocaine significantly reduced the pain of needle entry and injection in patients. They also stated that the amount of pain between the local anesthesia group and the placebo group was significantly higher during the needle insertion than the injection. Finally, they suggested that the use of local anesthesia is significantly effective in pain

reduction (21). The results of their study were in line with the present study. Therefore, it can be concluded that lidocaine and benzocaine, despite the differences in their molecular structure, showed similar superficial effects on pain control in patients.

Furthermore, Garg et al. investigated the effectiveness of 2% lidocaine gel and 20% benzocaine gel for local anesthesia. They reported the mean VAS scores of 1.2 in the lidocaine group, 1.12 in the benzocaine group, and 3.6 in the placebo group. They found that lidocaine and benzocaine are equally effective which is similar to Cho et al and this study (21,22). Since the VAS scale is not numerically valid and is only suggested when comparing the differences in one study, the controversies in VAS scores reported in these studies are not of great importance.

In 2016, Shavit et al. Examined the effect of two local anesthetics, tetracaine gel 2% and benzocaine gel 20% in children with phrenectomy. They acknowledged that the mean Neonatal Facial Coding System (NFCS) in the Tetracaine and Benzocaine groups was 4.5 and 3.5, respectively. Moreover, the VAS score was 57.2 and 58.2 in the Tetracaine and Benzocaine groups, respectively. Finally, they stated that these two anesthetics were not effective in controlling pain in these patients which is in contrast with the findings of the current study (23).

Another study also investigated the effect of 5% benzocaine gel in alleviating pain caused by fixed orthodontic appliances in a double-blind clinical trial. They reported the average VAS score of 0.89 and 1.15 in the benzocaine and placebo groups, respectively. However, the difference was not statistically significant (14). The controversy between their findings and the present study might be explained by the difference in benzocaine concentration, which was 5% in their study and 20% in the present study. Furthermore, the type of treatment was different which can affect the results.

Generally, various factors are effective in pain perception, which is effective in the accuracy of the results and the cause discrepancies with the present study. Age, sex, number of samples, time of application of superficial anesthesia gel, type of injection, injection site, duration of injection, distance between two injections in case and control groups, treatments performed between injections in groups, type of anesthetic substance, type of substance used as a placebo, measurement methods in both behavioral control and patients' anxiety can all be among these cases (24,25).

Sex is one of the factors associated with the level of fear, which is more frequent among children. A study examined dental anxiety in children and reported 16.8% mild, 58.5% moderate, and 24.8% of severe anxiety among them. They also stated that the rate of dental anxiety in women, especially housewives, was more common and had an inverse association with age and literacy level. Based on this study, it can be concluded that the 20% benzocaine gel as a topical anesthetic before injection is probably more indicated in women and children (26).

5. Limitations

One of the major limitations of the present study is that pain perception is inherently subjective and can be influenced by numerous factors such as individual tolerance levels, psychological state, and prior experiences with dental procedures. Ignoring confounding factors like anxiety or previous experiences may impact reliability of the obtained findings.

6. Conclusion

The results of this study demonstrated that the mean pain level; after injection in the benzocaine superficial anesthesia group was significantly lower than the control negative group. In other words, benzocaine superficial anesthetic can effectively reduce the pain of injection and make the patient feel more comfortable.

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Ethics

The current clinical trial was registered in the Iranian Registry of Clinical Trials (IRCT) and obtained the confirmation code (IRCT20151017024573N8). Written consent was taken from the patients and the study protocol was approved by the ethics committee of Mazandaran University of Medical Sciences (IR.MAZUMS.REC.1398.1181).

Using artificial intelligence (AI)

It is declared by the authors of this manuscript that no generative artificial intelligence (AI) or AI-assisted technologies were used to generate content, ideas, or theories during the writing process of this work.

Author contributions

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Niloofar Modarresi: Investigation

Melika Mollaei: Methodology, Writing - Original draft

Conflict of interest

The authors declare no conflict of interest.

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