

# The efectiveness of topical anesthesia on pain during oral injections - A randomized clinical trial

**S** Crossref **6** https://doi.org/10.56238/sevened2023.005-021

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#### ABSTRACT

The aim of this study was to evaluate the efficacy of a topical anesthetic in pain and anxiety control during oral injections. The experimental design was

a randomized, double-blind, split mouth model. Anesthesia was performed in the infraorbital and posterior superior alveolar nerves in 10 healthy and patients. Before normotensive anesthesia randomization was performed on one side to apply the topical anesthetic (benzocaine 20%) and the other placebo. The pulse and blood pressure were assessed before, during and after anesthesia injection, and the pain in puncture was measured using a visual analog scale (VAS). The results showed statistically significant difference (p = 0.04) in pain of the needle puncture between the groups at the infraorbital nerve. In the posterior superior alveolar nerve no statistically significant difference was found between groups (p = 0.39). In the evaluation of systolic and diastolic blood pressure no significant diferences showed between groups in any of the times evaluated. In assessing the pulse was no statistically significant difference (p = 0.02) between the topical anesthetic and placebo only for the infraorbital nerve at the time of puncture. In conclusion, the topical anesthetic decreased the pain in anesthesia of the infraorbital nerve when compared to placebo.

Keywords: Anesteshics, Placebos, Benzocaine.

#### **1 INTRODUCTION**

Topical anesthetics are used to eliminate the pain of the needle puncture during local anesthesia. When topical anesthetics are applied, a decrease of pain stimulus occurs through the reversible block of nerve impulse transmission<sup>1</sup>.

Local topical anesthetic may present in the form of ester or amide, the most popular compositions are Benzocaine, Lidocaine and EMLA (Eutectic Mixture of Local Anesthetics)<sup>2</sup>. Benzocaine is a ester topical anesthetics, has poor solubility in water and low systemic absorption, toxicity reactions are rare <sup>3</sup>. Topical anesthetics are diffused to a depth of two to three millimeters from mucosa. To have adequate efficacy should be left in contact with the mucosa for 2-3 minutes <sup>4</sup>.



The issue of using topical anesthetics in control of pain during local anesthesia is a very controversial subject<sup>5,6,7,8</sup>. Most professionals dispense this step, because there are no studies proving the efficacy of topical anesthetics. Therefore, due to the lack of studies in the literature, this study aims to compare the efficacy of topical anesthetic (benzocaine 20%) compared to placebo in reduction of pain perception, in anxiety and blood pressure at the needle puncture.

## **2 MATERIALS AND METHODS**

This study was characterized by a pilot study, with the experimental design a randomized clinical trial, double-blind, split-mouth model.

Patients greater than 18 years old, healthy, with no history of allergic reaction to anesthetics or their components sensitivity. The maximum blood pressure to consider normotensive patients was 139/89 mmHg (Brazilian Guidelines on Hypertension) in measurement prior to anesthesia. Patients who have local and / or systemic changes that no indicate the procedures, smokers and pregnant women were excluded from the study.

Patients were informed about the objectives of the study and those who agreed to participate signed a consent term. This study was approved by the Ethics Committee of UNIFRA, protocol 398.375. As this is a pilot study sample size was not calculated, so 10 patients participated in each group.

Eligible patients participated in both groups, on one side of the patient was used topical anesthetic benzocaine 20% Benzotop® (DFL, São Paulo, Brazil) (test group) and in other side placebo (Novaderme, Santa Maria, Brazil). The products had their packages covered and the codes were revealed after statistical analysis. Due topain difference between the anterior and posterior maxilla by the presence of more nerve branches in the anterior region, the anesthetics were performed in the same anatomical region, two blocks in the same patient's infraorbital nerve and two of the posterior superior alveolar nerve. Randomization was performed by a second examiner who made the draw through coin toss, determining if the topical anesthetic or placebo was used first.

Anesthesia was performed by a single operator previously trained. After randomization, the mucosal was dried whith sterile gauze and a topical anesthetic (test group) or placebo (control group) were deposited with a swab in the region of puncture needle. Two minutes was awaited for the anesthetic technique. The needle used for anesthetic technique was a short, 30-gauge Injex® (Ourinhos, São Paulo, Brazil). 100.00 (DFL, São Paulo, Brazil). The use of one cartridge of 2% lidocaine with epinephrine at a concentration of 1 was advocated.

Heart rate and blood pressure were assessed 10 minutes before, during needle puncture and 10 minutes after anestethic infiltration by digital sphygmomanometer Omron® HEM 742 Automatic INT



(Kyoto, Japan). The painful sensation was evaluated during needle puncture through the Visual Analogue Scale (VAS).

Data normality was tested using the Shapiro-Wilk test. Descriptive measures were evaluated using mean and standard deviation. Differences between groups were evaluated using the Student t test. The level of significance was set at 5%.

### **3 RESULTS**

Ten patients were included and completed the study, 5 male and 5 female. The average age was 30 years of age with a range of 18-45 A total of 40 sites were included, 20 for the infraorbital nerve and 20 for posterior superior alveolarnerve.

Corresponding to the level of pain reported by patients on the VAS results were shown in Table I.

Table I: Mean and standard deviation of the reported pain as assessed by a Visual Analogue Scale (VAS) after puncturing the posterior superior alveolar nerve and infraorbital. n=10

	Nervo Alveolar Superior Posterior		Nervo Infraorbitário		
	Anestésico Tópico	Placebo	Anestésico Tópico	Placebo	
VAS (Mean ± S.D.)	3,1 ± 1,19	$3,4 \pm 1,07$	2,8 ± 1,31	3,8 ± 1,31	
p*	0,39		0,04		
e T de Student.					

\* Teste T de <u>Student</u>. Diferença estatisticamente significante p<0,05.

Statistically significant difference was observed between the topical anesthetic and placebo for the infraorbital nerve (p = 0.04). There was no statistically significant difference between groups for the posterior superior alveolar nerve (p = 0.39). It was observed that the pain perception reported by patients was similar between the infraorbital nerve, and the posterior superior alveolar nerve.

In the evaluation of pulse, the results were divided into before, during and after the puncture and are shown in Table II.



Table II - Mean and standard deviation of Pulse reported, assessed before, during and after the puncture in the posterior superior alveolar and infraorbital nerves. n = 10

	Nervo Alveo Post Anestésico		р	Nervo Infraort Anestésico	oitário	p
Pulso	Tópico	Placebo		Tópico	Placebo	
Prévia (Mean $\pm$ S.D.)	84,70±11,85	84,40±7,47	<mark>,</mark> 929	83,00±9,59	85,00±7,22	0,225
Durante (Mean ± S.D.)	86,10±12,60	87,10±8,44	,736	82,30±10,91	89,00±8,90	0,020
Após (Mean ± S.D.) * Teste T de Student.	84,00±11,28	86,40±8,40	.539	83,70±10,70	88,80±8,54	0,101

Diferença estatisticamente significante p<0.05.

Statistically significant differences were found during the pulse between the punch and placebo topical anesthetic to the infraorbital nerve (p = 0.02). There was no statistically significant difference between the previous period and after the puncture of the needle to the infraorbital nerve. In the posterior superior alveolar nerve no statistically significant difference was observed in both seasons.

The results corresponding to blood pressure (BP) of patients were divided into systolic and diastolic blood pressure are shown in Tables III and IV.

**Tabela 3** – Média e desvio-padrão da PA sistólica reportada, avaliada Antes durante e após punção nos nervos alveolar superior posterior e infraorbitário. n=10

Nervo Alveo	lar Superior	p			p
Poste	erior		Nervo Infraorb	itário	
Anestésico			Anestésico		
Tópico	Placebo		Tópico	Placebo	<u>-</u> 20
130,30±13,19	130,60±10,14	0,909	132,10±12,03	137,00±9,10	0,144
132,90±12,35	134,30±11,43	0,549	135,90±10,74	140,40±13,62	<mark>0,16</mark> 7
131,10±10,02	133,30±10,41	0,158	136,20±11,08	139,20±9,77	0,402
	Poste Anestésico Tópico 130,30±13,19 132,90±12,35	Tópico Placebo   130,30±13,19 130,60±10,14   132,90±12,35 134,30±11,43	Posterior   Anestésico   Tópico Placebo   130,30±13,19 130,60±10,14 0,909   132,90±12,35 134,30±11,43 0,549	Posterior Nervo Infraorb   Anestésico Anestésico   Tópico Placebo Tópico   130,30±13,19 130,60±10,14 0,909 132,10±12,03   132,90±12,35 134,30±11,43 0,549 135,90±10,74	Posterior Nervo Infraorbitário   Anestésico Anestésico   Tópico Placebo Tópico Placebo   130,30±13,19 130,60±10,14 0,909 132,10±12,03 137,00±9,10   132,90±12,35 134,30±11,43 0,549 135,90±10,74 140,40±13,62

Diferença estatisticamente significante p<0,05.



Tabela 4 - Média e desvio-padrão, avaliada através da Pa diastólica. Antes, durante e após punção nos nervos	
alveolar superior posterior e infraorbitário. n=10	

Nervo Alveo	lar Superior	р			p
Posterior			Nervo Infraorbitário		
Anestésico			Anestésico		
Tópico	Placebo	-	Tópico	Placebo	
79,50±11,81	83,00±11,36	0,079	80,90±11,80	85,50±11,16	0,086
83,20±11,90	81,30±13,42	0,3 <mark>4</mark> 8	84,10±12,96	86,80±12,37	0,281
81,20±11,09	82,60±12,55	0,396	85,30±11,51	85,90±10,60	0,809
	Poste Anestésico Tópico 79,50±11,81 83,20±11,90	Anestésico Tópico Placebo   79,50±11,81 83,00±11,36   83,20±11,90 81,30±13,42	Posterior   Anestésico   Tópico Placebo   79,50±11,81 83,00±11,36 0,079   83,20±11,90 81,30±13,42 0,348	Posterior Nervo Infraort   Anestésico Anestésico   Tópico Placebo   79,50±11,81 83,00±11,36   83,20±11,90 81,30±13,42   0,348 84,10±12,96	Posterior Nervo Infraorbitário   Anestésico Anestésico   Tópico Placebo Tópico Placebo   79,50±11,81 83,00±11,36 0,079 80,90±11,80 85,50±11,16   83,20±11,90 81,30±13,42 0,348 84,10±12,96 86,80±12,37

Diferença estatisticamente significante p<0,05.

There was no statistically significant difference in blood pressure (BP) and diastolic BP between the topical anesthetic and placebo in all evaluated periods.

No adverse effects were observed in the use of topical anesthetic, placebo and anesthetic cartridges.

#### **4 DISCUSSION**

The present study showed less pain during needle puncture when the 20% Benzocaine topical anesthetic was used for the infraorbital nerve.

The advantages related to the use of topical anesthetic in reduction of pain during needle insertion and anxiety control are not consolidated in the literature, since there are many studies with conflicting results on this topic <sup>7,9,10</sup>.

Importantly, the anesthetic technique, the deposition rate of the anesthetic, the temperature of local anesthetic and anatomical region are factors that influence directly on the pain sensation the patient <sup>4</sup>. Caring cited in the literature for control and predictability of anesthetic technique were used during the study. Previously the use of topical anesthetic and placebo, the mucosa was properly dried to prevent solubilization by saliva and the time of application of the product was monitored <sup>4</sup>.

Regarding pain puncture, was statistically significant difference only for the anterior maxilla, agreeing with data obtained in previous studies <sup>6,8</sup>.

Topical anesthetic showed superior result to placebo in the infraorbital nerve region, which can be explained by this site has more nerve branches<sup>11</sup>, which highlights the importance of using topical anesthetic. The results showed that despite being a pilot study, sample was sufficient to show a statistically significant difference between groups.

For the evaluation of the pulse of patients before, during and after the puncture needle, Rosivack et al.<sup>12</sup> showed that values ranged from an average of 2.2 beats per minute, and that these values do not have clinical relevance. In the present study, during the evaluation of pulse, statistically significant



difference was found only for the infraorbital nerve during needle puncture, however the differences between mean values has minimal clinical relevance.

It was observed that independent of the anesthetized region there was no significant difference in blood pressure at any of the time points analyzed, which would occur in a situation of pain in the puncture needle. In these situations the endogenous catecholamine release could lead to increased blood pressure<sup>13,14</sup>.

## **5 CONCLUSION**

The prior application of topical anesthetic causes a decrease in pain and reduction of pulse during needle puncture in the infraorbital nerve region, and this reduction in the anterior maxila isprobably associated with the presence of more nerve branches in that region. The application of topical anesthetic is a procedure that should be performed in the anterior maxila to reduce the pain during anesthetic procedures.

In posterior superior alveolar nerve no statistically significant differences between the topical anesthetic and placebo were observed. Prospective studies are needed to prove the advantages of the use of topical anesthetic.



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