Vol: 8 Issue: 1

EDJ

Comparative Efficacy of Lidocaine, Benzocaine, and Combination Topical Therapy for Pain Reduction in Pediatric Local Anesthesia: A Randomized Clinical Trial Study

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ABSTRACT

Background and objective: Topical anesthetics are highly used in the field of pediatric dentistry such as (Lidocaine and Benzocaine) which are used to relieve pain during needle insertion. The aim of this study to compare and evaluate the effectiveness of multiple topical anesthetic agents prior to anesthetic delivery undergoing pediatric and minor oral procedures .

Material and Methods: This study included 60 children of 6-12 years of age, the total number of the samples were divided into 3 groups; Group I: 20 cases (lidocaine gel 20%), Group II: 20 cases (benzocaine gel 20%), and Group III: 20 cases both lidocaine gel 20% and benzocaine gel 20%) were applied before needle insertion during inferior alveolar nerve block and infiltration. In addition, the child's pain assessment was done using the Visual Analog Scale (VAS).

Results: 33 boys (55%) and 27 girls (45%) of 6-12 years old participated in the study, the two-step application of both (20% Benzocaine and 20% Lidocaine) showed lower mean scores when it was compared with Benzocaine and Lidocaine, but the results were statistically insignificant. Lidocaine and Benzocaine alone or together are equivalent in efficiency when used as a topical anesthetic agent. The results showed that females and males have no difference in Visual Analogue Scale scores, and with increasing age the VAS score decreased.

Conclusion: This study concluded the two-step application of both (20% Benzocaine and 20% Lidocaine) is more effective in reducing pain upon needle penetration into the oral mucosa than each agent used alone, and 20% benzocaine demonstrated better results than 20% lidocaine in reducing pain upon needle penetration. But it was statistically non-significant. The findings highlight the potential benefit of combining topical anesthetics for improved pain management in pediatric dental procedures.

Keywords: Needle insertion pain, Pediatric patients, Visual analog scale, Topical anesthesia, inferior alveolar nerve block.

Article Information

Submission Date: 13/8/2024
Revision date: 27/10/2024
Acceptance date: 30/1/2025
Publishing date: Jun 2025

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DOI: doi.org/10.15218/edj.2025.7

INTRODUCTION

Pain is an irritating sensation that is initiated by any noxious stimulus that passes through a specific neural network and reaches the central nervous system where it is interpreted as the feeling of pain. The word anesthesia originates from 2 Greek words (an) which means without and (aesthesis) which means sensation.[1]

Dental injections are highly used during clinical procedures not only on children but also on adults to obtain local anesthesia. Fear of syringes is quite noticeable among pediatric patients this is where the role of topical anesthetics starts which reduces the pain or discomfort that is associated with the initial penetration of the needle into the mucosa by anesthetizing a 2-3 mm depth of surface tissue at the area of needle insertion that act by stopping any signal from transmitting through the terminal fibers of sensory nerves. However, their effects are limited to in or just below the mucosa. For this reason, topical anesthesia has been utilized to reduce pain to the patient.[2]

When it comes to the health and safety of the user, it is of special interest to gain knowledge about the benefits and efficiency of different topical anesthetics to help in the control of pain not only during needle insertion but also in the treatment of wounds as an option alternative to dental infiltration injections.[3]

Up to our knowledge there has been no published clinical trials to assess and compare the efficacy of intraoral topical anesthetics (lidocaine and benzocaine) agents in gel form both alone and in mixture in reducing the pain resulting from needle insertion during injections of local anesthetic among pediatric patients aged 6-12 years old, and its contribution to a more cooperative and calm child during dental procedures by assessing the child's facial expression during needle insertion using the visual analogue scale as the children's facial expressions could be a stable indication of pain management since they may exaggerate their pain perception verbally. and to find out which one of these agents is more effective than other and whether using them together will increase the efficiency of pain reduction or not.[4]

PATIENTS AND METHODS

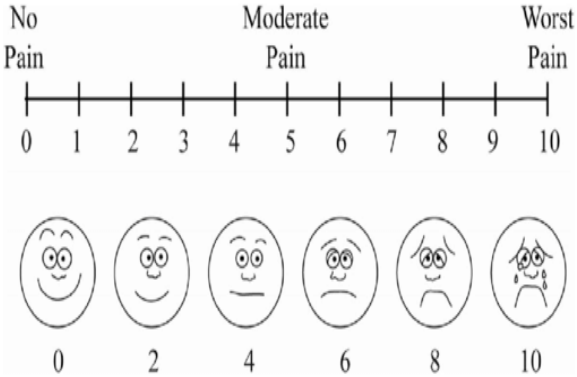
The study was carried out in Hawler Medical university, Collage of Dentistry from 5th of October 2021 to 7th of April 2022.

The inclusion criteria were cooperative children (children who could collaborate with our work and accepted the given treatment modalities with obedience) who needed local anesthesia administration, children fell under the category of ASA I (normal healthy patient) and ASA II (A patient with a mild systemic disease).

Randomization was carried out using a computer-generated random number sequence in Microsoft Excel. The group assignments were placed into opaque, sealed, and sequentially numbered envelopes to ensure allocation concealment. As each eligible child was enrolled, an envelope was drawn in order and opened to determine the group assignment. The samples were collected in the Teaching Polyclinics at College of Dentistry, Hawler Medical University, Erbil, Iraq was accepted as a sample) and in total 60 cases were collected in children whom their ages fell between (6 -12) years.

The total number of the samples were divided into 3 groups and their number of samples were as the following: 20 for %20 lidocaine gel, 20 for %20 benzocaine gel, and another 20 samples using two -step application of both (lidocaine and benzocaine).

The procedure started first by evaluating the patients in Pedodontics Department to confirm the patient's indication for local anesthesia, after that the site to be injected was identified then the area of in injection was dried with a triple air syringe, then the topical anesthesia was applied, for every sample a standardized scoop (Shofu company) was used to measure out 1 scoop (1 scoop= 0.2gram) of topical anesthesia and a piece of cotton was dipped in it then it was applied on the desired site and was left over the site for one and a half minute after that the local anesthesia was



injected, during the needle penetration the patient's facial reaction was documented using VAS (visual analogue scale).

Fig.1 Standardized scoop.

Fig.3 topical anesthesia was applied by using (Cotton and tweezer).

For the third group (two-step application of Lidocaine and Benzocaine) a slightly different approach was used first both Lidocaine and Benzocaine gels were placed inside a standardized

Fig.2 area was dried by using (Triple air syringe).

scoop to make sure that they were the same amount then the Lidocaine was applied first, then after 1 minute the Benzocaine was applied as shown in (Figures 1, 2 and 3).

Two-step application of Lidocaine and Benzocaine

For the third group (two-step application of Lidocaine and Benzocaine) first, both the Lidocaine and the Benzocaine were placed inside a standardized scoop (each one /1 scoop) (1 scoop of gel = 0.2 gram) to make sure that they were the same amount then firstly the Lidocaine was applied (for 1 min) followed by the application of Benzocaine (for 1min).

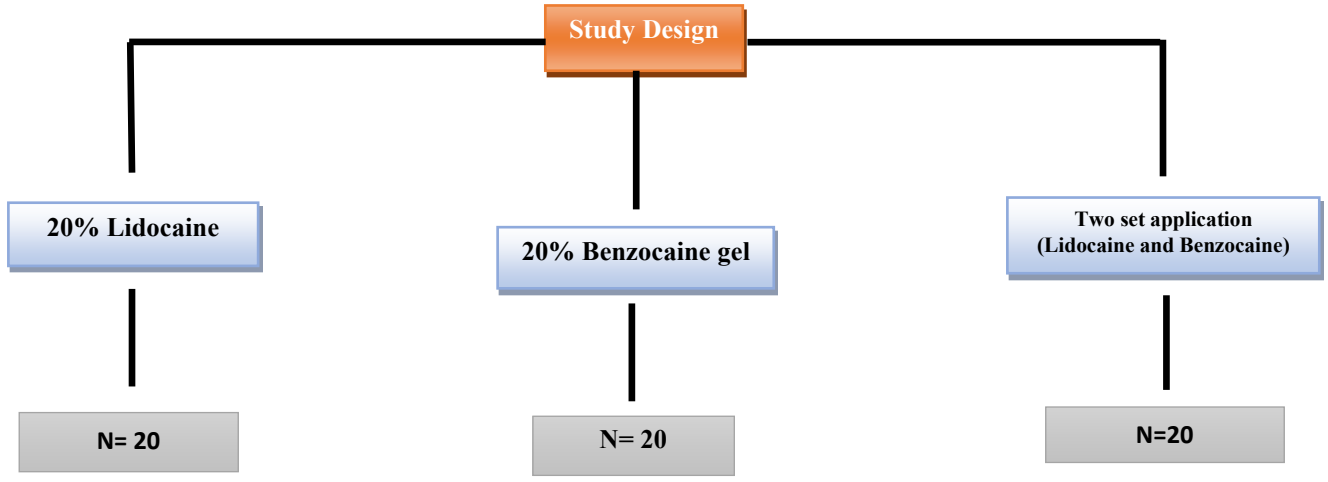


Fig 4. A schematic diagram showing sample grouping.

DOI: doi.org/10.15218/edj.2025.7

Group design

Three groups of samples denoted. Each of these groups was subjected to evaluation of severity of pain at the site of penetration of needle (Figures 4).

Ethical approval was obtained by the Ethical Committee of the College of Dentistry, Hawler Medical University, Erbil, Iraq. The research adhered to globally recognized standards for the protection of human research participants, aligning with key international guidelines such as the Declaration of Helsinki. Prior to the commencement of the study, explicit informed consent was obtained from each participating following the following

-Children must have an understanding of the research and their participation within it.

-Consent should be an explicit agreement (typically involving the researchers (s), the child, their -parents/carers.

-Children's consent must be given voluntarily.-Consent should be renegotiable, so that children can withdraw at any stage of the research process.

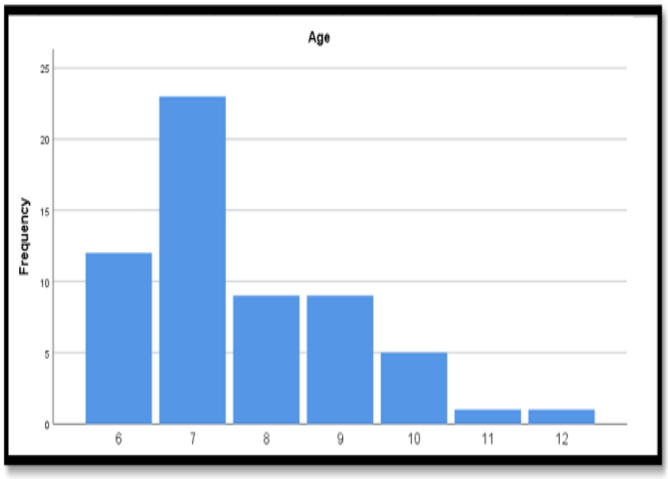


Fig 5. Frequency of samples according to Age differences

were statistically insignificant. Lidocaine and benzocaine and are almost equally effective when applied as a topical anesthetic agent.

The result showed that most of the sites were for the purpose of infiltration either palatal/lingual or buccal which is about 34% and for inferior alveolar nerve block (IANB) is about 26% as seen in (Table 1).

DATA ANALYSIS:

The statistical analysis was done using Statistical Package for Social Sciences (SPSS) Version 30 Statistical Analysis Software. The values were represented in mean ± SD, and t-test was used to compare between different groups.

RESULTS

This study included 60 subjects aged between (6-12) years, 33 boys (55%) and 27 girls (45%) (Figure 5); the participants were randomly assigned into three groups, Group I: 20 cases (lidocaine gel 20%), Group II: 20 cases (benzocaine gel 20%), and Group III: 20 cases both lidocaine gel 20% and benzocaine gel 20%) were applied before needle insertion during inferior alveolar nerve block and infiltration. The pain scale was assessed by a trained assessor using the Visual Analog Scale (VAS).

+as a result, lidocaine gel 20% and benzocaine gel 20% (experimental group) when used together as a topical anesthetic agent demonstrated lower mean scores than the other two agents (lidocaine and benzocaine) used alone, the results

Table 1. Percentage of site of application of topical anesthetics.

	Frequency	Percent	Valid Percent
IANB	26	43.3	43.3
infiltration	34	56.7	56.7
Total	60	100.0	100.0

Statistical comparison was performed according to the severity of pain among samples of the study, demonstrate that there is difference among the tested topical anesthetic gels. Hurts even more group showed the highest values 31.7%, followed by Hurts Little More (25%), Hurts Little Bit (18.3%), Hurts Whole Lot (16.7%) and Hurts Worst (8.3%) respectively, as shown in Table (3.5%) (Table 2).

Table 2. Severity of pain according to Visual Analogue Score (VAS).

	Frequency	Percent	Valid Percent
Hurts Little Bit	11	18.3	18.3
Hurts Little More	15	25.0	25.0
Hurts Even More	19	31.7	31.7
Hurts Whole Lot	10	16.7	16.7
Hurts Worst	5	8.3	8.3
Total	60	100.0	100.0

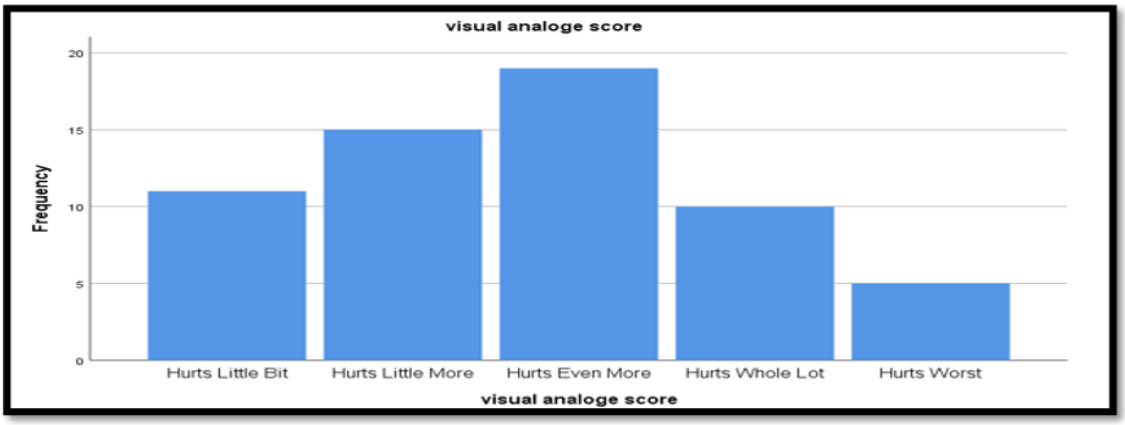


Fig 6. The severity of pain by visual analogue scale.

Student paired t- test showed that statistically non-significant differences in all the results of the VAS score, age, site of application as well as in the type of topical anesthetic agent used in relation to gender (Table 3). All the relationships are non-causal.

Table 3. Student paired T-test for age, type and site of topical anesthesia, VAS in relation to gender.

	Gender	N	Mean	Std. Deviation	Std. Error Mean	t -test P - Value	Decision
Age	Male	33	7.64	1.496	0.260	0.934	NS
	Female	27	7.67	1.330	0.256		
Type of topical anesthesia	Male	33	2.00	0.829	0.144	0.862	NS
	Female	27	2.04	0.808	0.155		
Site	Male	33	1.55	0.506	0.088	0.719	NS
	Female	27	1.59	0.501	0.096		
Visual Analogue Score	Male	33	2.85	1.093	0.190	0.358	NS
	Female	27	2.56	1.311	0.252		

DOI: doi.org/10.15218/edj.2025.7

Table 4 shows the statistical analysis of data by using independent student t-test revealed that, there was statistically insignificant difference ($P<0.05$) in the VAS score only in relation to the age of the patient, this significance is shown in this equation (VAS= 0.336 age) which states that each time we have a specific age we can multiply it by 0.336 to get the expected VAS score, thus this also helps us predict the VAS score of future patients.

Table 4. Independent samples test of tested materials.

		Leven's Test for Equality of Variances		t-Test for Equality of Means						
									95%Confidence interval of the Difference	
		F	Sig.	t	Df	Sig.(2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Age	Equal variances assumed	0.658	0.421	0.940	58	0.351	0.346	0.358	-0.391	1.083
	Equal variances not assumed			0.920	48.900	0.352	0.346	0.376	-0.410	1.103
Type of Topical Anesthesia	Equal variances assumed	0.000	0.991	-0.456	58	0.650	-0.097	0213	-0524	0.329
	Equal variances not assumed			-0.456	53.637	0.651	-0.097	0214	-0.525	0.331
Visual Analogue Scale	Equal variances assumed	0.033	0.857	2.101	58	0.040	0.636	0.303	0.030	1.241
	Equal variances not assumed			2.100	53.852	0.040	0.636	0.303	0.029	1.243
Gender	Equal variances assumed	0.486	0.489	-0.351	58	0.720	-0.048	0.132	-0.311	0.216
	Equal variances not assumed			-0.351	54.103	0.719	-0.048	0.132	-0.311	0.216

The result of the descriptive statistical test for the VAS according to type of the tested materials are shown in (Figure 7), which revealed that the highest value of Hurts Little More observed in group Mixture while the highest value of Hurts Even More was observed in Lidocaine and Benzocaine groups followed by Mixture group.

Fig 7. Comparison between percentage mean values of the VAS score of the three topical anesthetic agents.

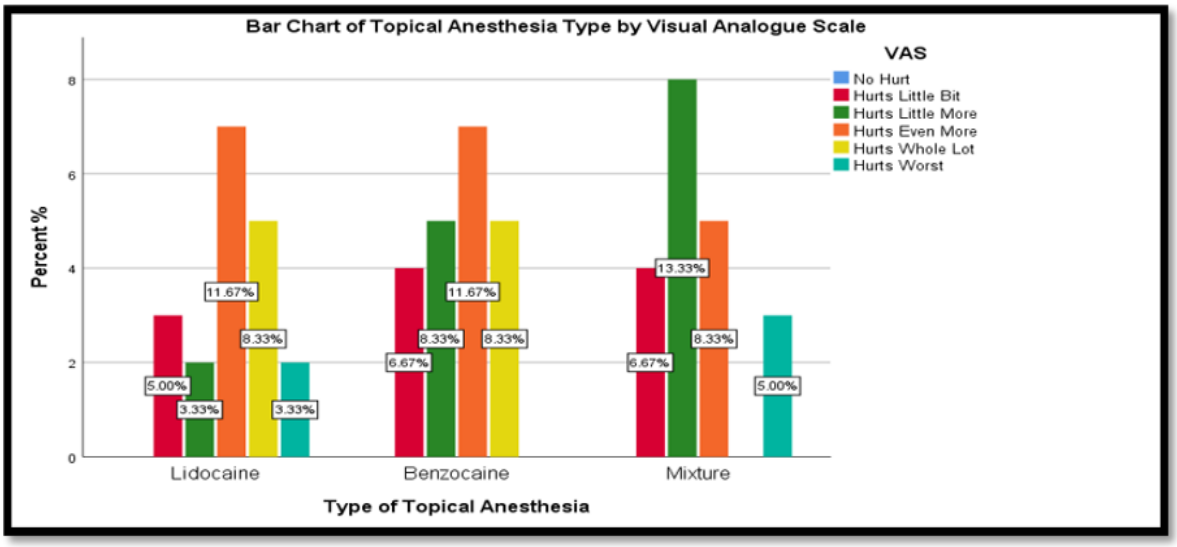
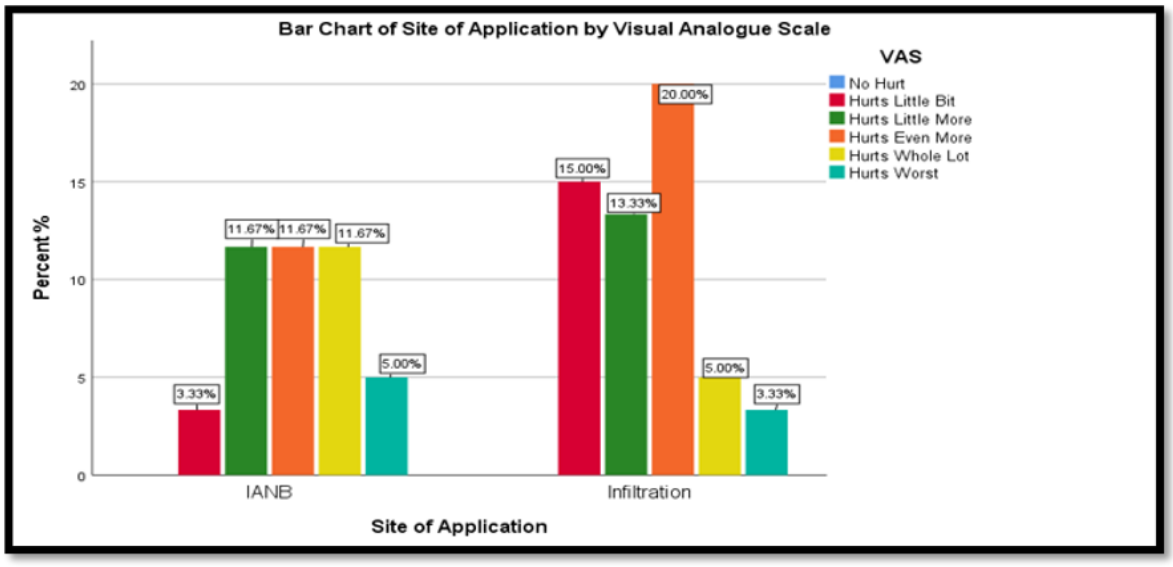


Fig 8. Bar chart for comparison between values of the VAS score in relation to the site of application.



DISCUSSION

Based on a principle, it is proven that the longer the duration of application the deeper the anesthetizing agent penetrates the mucosa, therefore in this study the topical anesthesia used was applied for about 30 seconds and was left on the mucosa for 1 minute to increase the depth of penetration. Application of topical anesthesia for 1 minute reduces the sensation of pain. It is important to mention that pain is affected by vari-

DOI: doi.org/10.15218/edj.2025.7

ous physiological and psychological factors and pain evaluation can be difficult since it is experienced on an individual level.[5]

Lidocaine and benzocaine are almost equal in effectiveness when applied as a topical anesthetic agent. In addition, during this study with increasing age there was a noticeable decrease in VAS score, and this could be due to psychological reasons such as with increasing age the child becomes more educated and more comprehensive to pain perception and dental procedures making the child more cooperative and calmer therefore becomes less fearful when it comes to needle injections.[6]

The VAS values obtained in this study considerably had equal effects for both group I and II, while the effectiveness increased in group III, this finding may be attributed to the fact that there is increasing in the constituent of the gel, and the severity of pain decreased with increasing age of the patient, this result is in agreement with the study done by Garg and Kaur (2016)[9] to assess the pain resulting from needle pricks at bilateral labial sites following the application of topical treatments (2% lidocaine gel, 20% benzocaine gel, and a placebo paste) in subsequent sessions on the same individual. A total of forty healthy participants, aged between 18-30 years, were subjected to three separate sessions where 2% lidocaine gel, 20% benzocaine gel, and a placebo paste were applied on them. During each session, a 26-gauge needle was inserted into the maxillary labial mucosa both before and 1 minute after the application of the respective treatment. Subsequently, participants immediately rated the intensity of pain on a visual analogue scale (VAS) following the needle insertion.[7]

Results demonstrated that lidocaine and benzocaine were equal in effectiveness, and both were better than placebo in reducing the pain of needle insertion. their lidocaine gel was only 2% while ours was 20% which makes the percentage of anesthetic agent in a gel a potential factor which may affect the results of efficacy, the scale of pain was self-reported by the patients themselves rather than by a trained examiner which affects the accuracy of the VAS score obtained by the patients. In addition, the subjects in this study are much older (18-30 years of age) than the subjects in our study which are aged between (6-11) years which indicates that age could be a factor affecting the VAS scores.[8]

On the other hand, the results obtained from our study disagreed with the results obtained by Castro-Rodriquez et al (2010), while comparing the efficiency of 20% lidocaine patches and topically anesthetizing gel in decreasing injection pain in children at the same visit. Injections followed a 15-minute application of Denti Patch TM (20% lidocaine) or a 1-minute application of topical anesthetic gel (Topex, 20% benzocaine). [9]

Each child filled a Faces Pain Scale and Visual Analog Scale after each injection and was asked which injection hurt more. Injections were recorded with videos and two independent assessors, using the Sounds, Eyes, and Motor Scale, rated observed pain-related behavior. As a result, significant difference was seen in observed pain sounds favoring use of the DentiPatch. This disagreement could be due to 2 reasons firstly because a patch has a more prolonged time of application (15min) which allows for penetration of the anesthetic agent to deeper layers of the mucosa and spread more which makes it more effective. secondly it could be due to the different constituents of 2 different anesthetic agents since Lidocaine contains substances which prolong the action of anesthesia, substances such as: (Hydroxypropyl Methylcellulose) and (Lactic Acid). Thus, these substances could increase the efficacy of Lidocaine since Benzocaine does not contain these substances. [10]

The result of the present study is in agreement with the study performed by Kotian et al (2021) which involved Forty-four individuals aged between 4 years and 10 years indicated for root canal therapy of primary teeth under inferior alveolar nerve block were selected for this study. The participants were randomly assigned into two groups of 22 each. Group I (lidocaine gel) and group II (benzocaine gel) were applied prior to inferior alveolar nerve block. The pain scale was evaluated by a trained examiner using the visual analog scale (VAS) and sound eye motor scale. As a result, Lidocaine when utilized as a topical anesthetic agent demonstrated reduced mean scores under both the pain scales when compared with benzocaine but the results were statistically insignificant. Lidocaine and benzocaine are equal in effectiveness when applied as a topical anesthetic agent. But lidocaine was more preferred over Benzocaine in terms of taste, but we must

consider that in this study the topical anesthetic agents were applied only at one site for the purpose of inferior alveolar nerve block injection not infiltration which could indicate the site of application a critical point in affecting the VAS score.[11]

It is important to mention that too little of literature is found talking about using two different materials of topical anesthesia for the same patient at the same time. In addition, after collecting results from various studies about the usage of topical anesthetics on pediatric patients it was noticed that the results were contrary to one another, and this could be due to the reason that acute pain can be influenced by other factors such as psychological factors, and this may lead to different results regarding the efficiency of different topical anesthetic agents among different studies. On the other hand, the sight of needle itself may create fear in children. Similarly, injection rate, solution volume, agent pH, and tissue buffering capacity are additional factors affecting the reports of pain experience. Let us not also forget that a child dentally uneducated or in other words not familiar with the nature of the dental work could induce a fear from the unknown and exaggerate the perception of pain.[12]

Future research should include larger, multicenter studies with diverse populations and expanded age ranges. Incorporating objective pain assessment methods and evaluating other anesthetic agents, such as sprays or patches, could provide deeper insights. Studies on long-term outcomes, alternative application techniques, and the role of psychological interventions in pain management are also recommended to optimize the use of topical anesthetics in pediatric dentistry.

CONCLUSION

This study concludes that the two-step application of both 20% benzocaine and 20% lidocaine is more effective in reducing pain during needle penetration into the oral mucosa compared to using either topical anesthetic agent alone. Additionally, 20% benzocaine demonstrated better results than 20% lidocaine in minimizing pain. The findings highlight the potential benefit of combining topical anesthetics for improved pain management in pediatric dental procedures. Future studies could further explore the clinical significance of these differences.

CONFLICT OF INTEREST

The authors reported no conflict of interests.

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