Original Article

pISSN 2383-9309 ▮ eISSN 2383-9317
J Dent Anesth Pain Med 2020;20(6):397-402 ▮ https://doi.org/10.17245/jdapm.2020.20.6.397

DentalVibe® versus lignocaine hydrochloride 2% gel in pain reduction during inferior alveolar nerve block in children

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Background: Inferior alveolar nerve block (IANB) is the most common, painful, and anxiety-provoking procedure involving needle insertion for anesthetic solution deposition. DentalVibe® (DV) delivers vibration at a sustained frequency as a counter-stimulation to the site of injection, thereby alleviating pain. The aim of this study was to evaluate and compare the effectiveness of DV and lignocaine hydrochloride 2% gel (Lox 2% jelly) in pain reduction during IANB in children.

Methods: A split-mouth randomized clinical trial was designed with a sample of 60 children (age, 6 to 12 years) requiring bilateral IANB for various dental procedures; DV was used while administering IANB and Lox 2% jelly was used as the topical anesthetic before administering IANB at subsequent appointments. During both appointments, pain perception was measured using the sound, eye, motor (SEM) scale and Wong-Baker faces pain rating scale (WBFPRS); oxygen saturation (SpO2) and pulse rate were measured using a pulse oximeter before, during, and after the IANB procedure. The obtained values were tabulated and subjected to statistical analysis. Wilcoxon test was used for intergroup comparison, and Friedman test, for intragroup comparison of measured variables at different treatment phases.

Results: The medians and interquartile ranges of the WBFPRS scores recorded during the IANB procedure for DV and Lox 2% jelly were 2 (2–4) and 2 (0–2), respectively ($P < 0.05$). The SEM scale scores, mean SpO_2, and pulse rate did not show any significant differences during the IANB procedure between both treatments.

Conclusion: Both DV and Lox 2% jelly were found to be effective in pain reduction during IANB in children.

Keywords: DentalVibe®; Inferior Alveolar Nerve; Lignocaine Hydrochloride Gel; Nerve Block; Pain; Topical Gel.

INTRODUCTION

Dental fear and anxiety are well-recognized factors that have a negative impact on patient willingness to undergo dental treatment. Many dental procedures induce inevitable emotions of fear and anxiety as a response [1]. When children experience pain during dental treatment, they may exhibit behavioral problems during subsequent visits, resulting in the need for behavioral guidance [2]. Dental procedures, such as local anesthesia administration, are associated with pain and discomfort and one of the main reasons for dental fear and anxiety, with severe consequences for the individual's future dental health [2].

Pain relief and avoiding trauma during treatment play a major role in the successful clinical management of patients. Bothe children and adults experience needle phobia. The pain induced by the injection of local anesthetic agents can be reduced by several complementary methods, including application of topical

Received: December 13, 2020 • Revised: June 12, 2020 • Accepted: August 4, 2020
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analgesics, use of distraction techniques, varying the rates of infiltration, buffering and warming the anesthesia solution, reduce the speed of injection, use of fine needles with improved syringes, precooling of the injection site, and use of vibration tools [3].

For controlling the pain due to local anesthetic injections, topical analgesia continues to be the most commonly used agent. Topical gels can be applied locally, allow control over systemic drug absorption, and help in dosage reduction. Lignocaine hydrochloride 2% gel (Lox 2% jelly; Neon Laboratories Ltd., Delhi, India) is a topical anesthetic with excellent anesthetic efficacy and limited allergenicity [4]. Owing to the low viscosity of topical anesthetics, they have a short retention time at the site of application.

Vibratory stimulation is one of the several non-pharmacological techniques used to reduce pain [3]. DentalVibe® ([DV] BING Innovations, FL, USA) was introduced recently in the field of dentistry by Dr. Steven Goldberg; this intraoral device delivers vibration in a sustained frequency as a counter-stimulation to the site of injection, thereby alleviating pain [3]. The DV system, was introduced for pain reduction during local anesthetic injections; it is a cordless, rechargeable, hand-held device that delivers soothing, pulsed, percussive micro-oscillations to the site where the injection is being administered and gently stimulates the sensory nerves [5]. DV was found to be effective in reducing pain in children who had a phobia of intraoral injections as it also has a provision for auditory distraction (70–75 dB) [3].

The present study aimed to evaluate and compare the efficacy of the new vibratory device, DV, and Lox 2% jelly in pain reduction during the inferior alveolar nerve block (IANB) procedure in children

METHODS

The present split-mouth randomized clinical trial involved 60 children of both sexes (22 boys and 38 girls) who required bilateral IANBs for various dental procedures and visited the outpatient Department of Pediatric and Preventive Dentistry. A consent form was provided before the procedure to the guardians/parents of the participants in the local language to ensure they understood the contents and granted informed consent. The study was approved by the Ethical Committee of the Institution (protocol/IRB/21/ 2015–18).

Inclusion criteria:

1. Children who required bilateral IANB injections.
2. Medically and mentally healthy children aged 6–12 years.

Exclusion criteria:

1. Children with a systemic illness.
2. Children with a history of eventful dental experiences during local anesthesia injection.
3. Children with special health care needs.

Before the IANB procedure, DV and Lox 2% jelly were used on either side randomly at two different appointments. The children were examined using basic diagnostic instruments and preoperative radiographs to determine the need for local anesthesia, such as extractions and pulp therapies. The children were informed of the procedure. Subsequently, the site of injection of IANB was determined and isolated.

1. DV procedure

Using basic behavior management techniques such as communication and tell-show-do method, DV (Fig. 1) was introduced to the injection site with a light touch when contacting the tissue and applied for about 1 min before IANB and continued for 5 s after injecting 2.0 mL of 2% lidocaine with 1:80000 epinephrine (LIGNOX 2% A, Warren) at a rate of 1 mL/min to help spread the solution. The IANB was administered using a 2 mL syringe with a 24-gauge needle (Unolok, Hindustan Syringes and Medical Devices Ltd., India) by keeping the needle as close as possible to one of the prongs of the vibrating tip.

2. Lox 2% jelly procedure

Using the same basic behavior management techniques

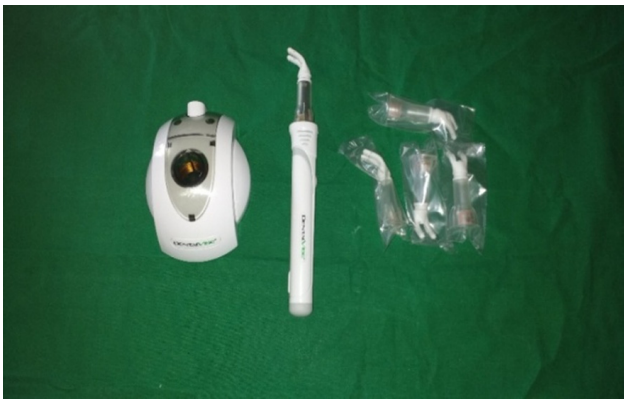

Fig. 1. DENTALVIBE®

Fig. 2. Lignocaine Hydrochloride 2% Gel

as in the DV procedure, Lox 2% jelly (Fig. 2) was applied to the opposite side of the same arch. The site of injection was cleaned and dried with a gauze piece before the application of topical Lox 2% jelly for 2 min, followed by the administration of 2.0 mL of 2% lidocaine with 1:80000 epinephrine (LIGNOX 2% A, Warren) at a rate of 1 mL/min IANB, using a 2 mL syringe with a 24-gauge needle.

Before, during, and after the IANB procedure at both the appointments, each child's pain perception was measured using the following:

1. The sound, eye, motor (SEM) scale [6] of pain level takes into account three types of responses: sounds, eyes, and motor responses. The level of response was given a numerical value ranging from 1 (comfort) to 4 (painful), and these values were averaged to obtain the comfort level at the time of rating.
2. For subjective evaluation, the Wong-Baker faces pain rating scale (WBFPRS) [7] was used. The WBFPRS measures the unpleasantness of a child's experience using a set of cartoon faces with varying facial expressions, ranging from smile/laughter to tears, and each child was asked to select the facial expression that best represented his/her experience of discomfort. Each face has a numerical value ranging from 0 (smiling face, "no hurt") to 5 (crying/screaming face, "hurts worst").
3. Blood oxygen saturation, as measured by the pulse oximeter, was used for monitoring the patient's condition during the dental procedures. The pulse oximeter was turned on throughout the IANB procedure to display the oxygen saturation (SpO_2) and pulse rate that appeared on the screen for the children to see. The changes in SpO_2 and pulse rate were recorded before, during, and 5 min after the IANB procedure.

3. Statistical analysis

The data obtained from the two groups were subjected to statistical analysis using the SPSS software version 21. Wilcoxon test, a paired nonparametric test, was used for intergroup comparison, and Friedman test, an extension of the paired non-parametric test, was used for intragroup comparison of pain, oxygen saturation, and pulse rate at different time phases.

RESULTS

The patient group consisted of 22 (36.66%) boys and 38 girls (63.34%), with ages ranging from 18 to 37 years (mean, 21.9 years).

The SEM scale scores demonstrated no significant difference in pain level when the before, during, and after the IANB procedure using either DV or Lox 2% jelly (Table 1). Intergroup comparison between the treatment groups for the SEM scores revealed no difference in pain

Table 1. Comparison of Pain Level, SpO_2 Level, and Pulse Rate at Different Treatment Phases of both DV and Lox 2% jelly Treatments

Parameters	Agent used		Before	During	After
			mean ± SD (range)		
Pulse rate	DV		100.9 ± 16.6 (68-158)	114.5 ± 17.1 (80-170)*	110.5 ± 15.4 (75-150)
	Lox 2% Jelly		101.2 ± 15.8 (71-160)	115.8 ± 17 (83-167)*	111.6 ± 15.8 (77-170)
	P-value (paired test)		0.874	0.903	0.936
SpO_2	DV		97.8 ± 3.1 (83-99)	98 ± 3.2 (77-99)	98.2 ± 2.2 (86-99)
	Lox 2% Jelly		98 ± 4.4 (65-99)	98.6 ± 0.8 (93-99)	98.2 ± 2.1 (86-99)
	P-value (paired test)		0.617	0.588	0.691
			median (mean) min-Q1-Q3-max		
WBFPR	DV		0 (1) 0-0-2-10	2 (2.9) 0-2-4-10*	0 (1) 0-0-2-8
	Lox 2% Jelly		0 (0.7) 0-0-0-8	2 (1.7) 0-0-2-10*	0 (0.3) 0-0-0-8
	P-value (paired test)		0.148	<0.01	0.012
SEM	DV	Sound	1 (1) 1-1-1-2	2 (1.6) 1-1-2-4*	1 (1) 1-1-1-2
		Eye	1 (1) 1-1-1-3	1 (1.5) 1-1-2-3	1 (1.1) 1-1-1-3
		Motor	1 (1) 1-1-1-2	1 (1.2) 1-1-1-3	1 (1) 1-1-1-2
	Lox 2% Jelly	Sound	1 (1) 1-1-1-2	1 (1.3) 1-1-2-3	1 (1) 0-1-1-2
		Eye	1 (1) 1-1-1-3	1 (1.3) 1-1-2-3	1 (1) 0-1-1-2
		Motor	1 (1) 1-1-1-2	1 (1.1) 1-1-1-3	1 (1) 0-1-1-2
	P-value (paired test)	Sound	0.346	0.012	1.00
		Eye	0.772	0.021	0.09
		Motor	0.345	0.093	1.00

*, $P < 0.05$ compared to Before (Friedmann test)
SEM, Sound Eye Motor; WBFPRS, Wong-Baker faces pain rating scale; SpO_2, oxygen saturation; DV, Dental Vibe®; Lox 2% jelly, lignocaine hydrochloride 2% gel.

levels before, during, and after the IANB procedure, with the same variables.

The WBFPRS scores demonstrated a significant increase ($P < 0.05$) in both the DV and Lox 2% jelly groups from before to during the IANB procedure. The medians and interquartile ranges of the WBFPRS scores for DV and Lox 2% jelly were 2 (2–4) and 2 (0–2), respectively ($P < 0.05$, pairwise comparison). SpO_2 rate and pulse rate exhibited no statistically significant differences ($P > 0.05$).

DISCUSSION

Pain control is considered one of the most challenging aspects of behavior management during IANB procedures in children. There has been much advancement in anesthetic agents and techniques to achieve pain-free local anesthesia [8]. These include altering the pH or temperature of the anesthetic solution and administering the injection at a low speed. Another effective method is to anesthetize the surface mucosa before needle insertion. The methods by which surface anesthesia can be achieved include refrigeration, transcutaneous electric nerve stimulation, and topical anesthesia [9].

According to Ronald Melzack and Patric Wall's Gate Control' theory, pain can be reduced by activating large-diameter nerve fibers to carry non-painful stimuli (touch and vibration). Because the brain can receive only one sensation at the same time, the application of vibration as a counter-stimulation to the anesthetic injection will reach the brain first and will be recognized before the pain sensation [10]. DV sends intermittent micro-sonic oscillations to the brain's neurological pain sensors, closing the pain gate, and blocking the pain of injections. Additionally, the comfort tip gently massages the injection site, causing rapid dissipation of the solution and producing a profound anesthetic effect [5].

In the current study, when the pain scores on the SEM scale were compared between DV and Lox 2% jelly use, no significant difference was observed before, during, and after the IANB procedure. Our study results are in

agreement with those of previous studies that affirmed that vibration does not reduce pain in children who undergo local anesthesia [11,12].

The WBFPRS demonstrated a significant difference in pain experience during the IANB procedure with both DV and Lox 2% jelly treatment compared to before and after the procedure, suggesting that both agents were equally efficient in pain reduction during the IANB procedure. The efficacy of DV can be attributed to the distraction it causes with the counter-stimulation of vibration during the IANB procedure. Lox 2% jelly's efficacy could be attributed to the deep penetration of the anesthesia injection it affords and localization of the drug [13].

The WBFPRS scores before and after the IANB procedure showed no significant difference between the two treatments, which can be attributed to the child's unawareness of what will take place at the dental visit before the procedure. The absence of significant differences in the scores recorded after the procedure readings might be attributed to the continued application of DV for 5 seconds after the IANB and in the case of Lox 2% Jelly, it could be attributed to its high bioavailability resulting in prolonged anesthetizing effect in the selected area [13].

The pulse rate was higher during the IANB procedure than before and after with both DV and Lox 2% jelly, indicating that discomfort and anxiety were felt more during the IANB procedure, which may be due to the sequelae of increased heart rate attributed to vaso-constriction and decreased oxygen-carrying capacity as a consequence of decreased oxygen saturation values. Dental operative procedures with the administration of local anesthetic agents may cause stress, resulting in anxiety and behavioral problems [2,8,9]. The inspiration and expiration of air are vital processes that make oxygen available to the cells and eliminate carbon dioxide from the lungs. Impairment of this process causes a reduction in oxygen supply to the tissues, leading to hypoxia [14]. The present result was similar to that of Belcheva and Shindova, who demonstrated that the sensation of high-frequency vibrations during conventional preparation was a stress-triggering factor in the majority of children in the control group [15].

In our study, the mean pulse rate and the mean SpO_2 rate before, during, and after the IANB procedure between DV and Lox 2% jelly treatments showed no statistically significant difference, suggesting that the efficacy of both agents in pain reduction was identical throughout the IANB procedure. The present study results were in accordance with the study conducted by Yoshikawa et al., who found no significant pain reduction when the Vibraject™ was attached to a conventional dental syringe [12].

We observed that a few children were reluctant to accept DV, which could be due to the vibratory sound made by the device and also due to their increased apprehension of allowing a new object into the oral cavity. Despite these disadvantages, DV showed acceptable efficacy in pain reduction during the IANB procedure. In contrast to our study results, in a randomized clinical trial conducted by Raslan et al., DV was found to be ineffective in decreasing the pain resulting from dental anesthetic injections in children [5].

The limitations of the present study were the small sample size, inability to differentiate sex-based responses to DV, and the inclusion of only one type of block anesthesia (IANB). Future investigations should include clinical trials involving large sample sizes of different age groups with the inclusion of various local anesthesia administration techniques, and the use of DV devices should be evaluated with different categories of behavior to further determine the acceptability and efficacy of DV in pain and anxiety reduction among children.

In conclusion, this study revealed that DV and Lox 2% jelly were equally effective in reducing pain during inferior alveolar nerve block in children. However, further studies are recommended to determine the efficacy of DV and its practical applicability in pediatric dentistry for reducing pain during local anesthetic procedures.

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AUTHOR CONTRIBUTIONS

Alekhya Chowdary Menni: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing
Ambati Naga Radhakrishna: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing
M. Ghanashyam Prasad: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing

NOTE: There are no conflicts of interest to declare.

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