



ASSESSMENT OF VIBRAJECT AND DENTALVIBE COMFORT SYSTEMS EFFICACY IN RELIEVING OF PAIN ASSOCIATED WITH LOCAL INJECTION IN CHILDREN

Mohamed Nagy Hamdy Khalil^{1*}, Alaa Nabil Abbas², Alaa Eldeen Abd Allah³

ABSTRACT

Objective: This study was directed to compare the efficacy of VibraJect (VJ) and DentalVibe (DV) comfort systems and Topical anesthesia (TA) (20% benzocaine) in relieving of pain associated with local injection in children. **Subjects and methods:** This study was conducted as a prospective blind randomized controlled clinical trial. A total of 150 children, who were attending dental treatment in the pediatric dental clinic, were selected. Subjects were equally divided according to used method into three groups (50 each). Fifty Subjects received into local anesthetic injections with VJ; fifty subjects received into local anesthetic (LA) injections with DV comfort system; fifty subjects received into local anesthetic injections with TA. Pain during injection was evaluated subjectively using Wong-Baker FACES pain rating scale by showing the scale to the child and asking him/her to choose a face that best described his/her feeling. Pain also had been objectively evaluated using face, leg, activity, cry and consolability (FLACC) scale by observing the child behavior during anesthesia administration. **Results:** This study revealed that vibration applied using the VJ and DV decreased pain associated with a LA injection delivered via infiltration and nerve block. Subjects in the VJ and DV groups had significantly lower pain scores than those in the control (TA) group. **Conclusion:** In this study, VJ and DV reduced pain during LA injection without causing anxiety in comparison to conventional injection.

KEYWORDS: pain, dental local anesthesia, topical anesthesia, DentalVibe, VibraJect.

INTRODUCTION

Fear-related behavior has been recognized as one of the most difficult challenge in the dental office. Patient's fear may be acquired through many experiences and threatening information. Direct experience is one of the most common sources of dental fear^(1,2).

Local anesthetics are the most important and safest drugs for pain control in dentistry⁽³⁾. Unfortunately, local anesthetic injection considered one of the most anxiety-provoking procedures for

both the dental patients as well as the dentists⁽⁴⁾.

Topical anesthetic reduces the slight discomfort associated with insertion of the needle. It is affective to a depth of 2-3mm. It is available in gel, liquid, ointment, patch and pressurized spray forms⁽⁵⁾. The most common topical anesthetics used in dentistry are those containing benzocaine or lidocaine. Benzocaine 20% is an ester based local anesthetic⁽⁶⁾.

Many techniques had been suggested to decrease the pain during local anesthetic injection including

1. Master's candidate, Faculty of Dental Medicine, Boys, Assiut, Al-Azhar University.
2. Lecturer of Pedodontics and Oral Health Department, Faculty of Dental Medicine, Boys, Cairo, Al-Azhar University.
3. Assistant Professor of Pedodontics and Oral Health, Faculty of Dental Medicine, Boys, Cairo, Al Azhar University.

• **Corresponding author:** mohamednagydentist.1986@gmail.com

physical techniques as pressure or vibration and psychological techniques as distraction⁽⁷⁾. Vibration is a physical technique based on “Gate control theory” of pain, which states that physical pain is not a direct outcome of activation of pain receptor neurons; rather, its perception is modulated by the interactions between different neurons⁽⁸⁾.

Lately, several studies were done to investigate the effect of vibration on pain during local anesthesia injections but the results are equivocal. DentalVibe is a cordless, rechargeable, handheld device that delivers soothing, pulsed, percussive micro-oscillations to the site of injection. Its U-shaped vibrating tip attached to a microprocessor-controlled Vibra-Pulse motor, which gently stimulates the sensory receptors at the injection site. It also lights the injection area and has a U-shaped tip attachment to retract the lip or cheek⁽⁹⁾. Vibraject is a small, vibratory, battery operated device which has an attachment that snaps on to the standard dental syringe producing vibrations at high frequency on to the needle to block pain sensation during local anesthetic injections⁽¹⁰⁾. If effective, these devices may represent a time-efficient, non-pharmacological technique to improve the experience of children receiving local anesthetic during dental procedures⁽¹¹⁾.

Therefore, the purpose of this study was to

compare the efficacy of VJ, DV comfort systems and TA (20% benzocaine) in relieving of pain associated with local injection in children.

SUBJECTS AND METHODS

This a prospective blind randomized controlled clinical study was conducted on 150 children, who were selected from an Outpatient Clinic of the Department of Pedodontics and Oral Health, Faculty of Dental Medicine, Al-Azhar University and was taken informed consent from parents. Their selection based on their need for infiltration or nerve block anesthesia for operative procedures.

Children were equally divided according to used method into three groups as following:

- **Group A:** The fifty children of this group were submitted to VibraJect system (MiltexInc LLC., York, PA, USA) during local anesthetic injection (figure 1, a).
- **Group B:** The fifty children in this group received local anesthetic injection with the help of Dental Vibe system (BING Innovations LLC, Crystal Lake, IL, USA) (figure 1, b).
- **Group C:** The fifty children group received local anesthetic injection after application of the TA (20% benzocaine).



FIG (1) (a) Anesthesia in the VibraJect group; (b) DentalVibe group

Patient Selection

Selection of patients was based on specific inclusion and exclusion criteria as the follow:

Inclusion Criteria

Children aged 4-12 years old, apparently healthy Children, cooperative children and children with carious primary molars indicated for procedures that require LA injections.

Exclusion Criteria:

Very young patients under 3 years, uncooperative children, handicapped patients, presence of infection at injection site and children who are allergic to local anesthesia.

Patient Consent

Each parent/caregiver was signed an informed consent having details about the whole treatment procedure before starting of the study.

Intervention

- Child history taking, including personal, medical, and dental history.
- Clinical screening and examination was made using mirror and probe in addition to radiograph if needed to assess inclusion criteria.

Each child included in the study received 1 mL of local anesthetic solution (Artinibsa articaine hypochloride 4% with 1:100.000 epinephrine, Inibsa, Spain) injected using a short, 27-gauge needle (Septoject®, Septodont., France) which was delivered over 1 min.

Observation

Both subjective and objective assessment was made using Wong-Baker FACES and the FLACC scale.

Wong-Baker Faces Scale (WBFS) ⁽¹²⁾:

The WBFS combines pictures and numbers to enable the user to rate pain. It includes 6 colored

cartoon faces which values from 0 to 10. Where “0” = no hurt, “2” = hurts little bit, “4”= hurts little more, “6”= hurts even more, “8”= hurts whole lot and “10”= hurts worst.

FLACC Behavioral Pain Assessment Scale ⁽¹³⁾:

This scale includes five categories: face, leg, activity, cry and consolability. Each one of these points has a record of “0, 1, or 2”.

Ethical Consideration

This study was carried out after approval of ethical committee, Faculty of Dental Medicine, Al-Azhar University, Cairo, Boys (EC Ref No. 156/022019/146G).

Statistical analysis

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, data showed non-parametric (not-normal) distribution. Qualitative data were presented as frequencies and percentages. Chi-square and Fisher’s Exact tests were used to compare between the two groups. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20.

RESULTS

1- Relation between upper and lower arches results

Wong-Baker Faces scale

Regarding upper and lower arches, there were statistically significant differences between VJ, DV and TA groups. There was a statistically significant difference between TA and each of VJ and DV groups where $p < 0.001$. No statistically significant difference was found between VJ and DV groups. Also, there was no statistically significant difference between upper and lower groups regarding VJ, DV and TA.

TABLE (1) The mean, standard deviation (SD) values of Wong-Beker Faces scale of different groups

Variables	Wong - Beker Faces Scale				p-value	
	Upper		Lower			
	N= 25	%	N= 25	%		
VibraJect system (VJ)	No Hurt	18	72%	14	56%	0.480ns
	Hurts Little bit	3	12%	3	12%	
	Hurts Little more	2	8%	2	8%	
	Hurts even more	0	0%	0	0%	
	Hurts whole lot	2	8%	4	16%	
	Hurts worst	0	0%	2	8%	
Dental Vibe system (DV)	No Hurt	15	60%	18	72%	0.869ns
	Hurts Little bit	3	12%	4	16%	
	Hurts Little more	4	16%	2	8%	
	Hurts even more	1	4%	0	0%	
	Hurts whole lot	1	4%	1	4%	
	Hurts worst	1	4%	0	0%	
Topical anesthesia system (TA)	No Hurt	0	0%	0	0%	0.405ns
	Hurts Little bit	8	32%	5	20%	
	Hurts Little more	5	20%	3	12%	
	Hurts even more	1	4%	2	8%	
	Hurts whole lot	2	8%	4	16%	
	Hurts worst	9	36%	11	44%	
p-value	<0.001*		<0.001*			

*, significant ($p < 0.05$) ns; non-significant ($p > 0.05$)

FLACC scale:

Regarding upper and lower arches, there were statistically significant differences between VJ, DV and TA groups where $p < 0.001$. There was a statistically significant difference between TA and each of VJ and DV groups where $p < 0.001$. No statistically significant difference was found between VJ and DV groups. Also, there was no statistically significant difference between upper and lower groups regarding VJ, DV and TA.

2- Relation between male and female results:

Wong-Beker Faces scale:

Regarding male and female gender, there were statistically significant differences between VJ, DV and TA groups. There was a statistically significant

difference between TA and each of VJ and DV groups where $p < 0.001$. No statistically significant difference was found between VJ and DV groups. Also, there was no statistically significant difference between male and female groups regarding VJ, DV and TA.

FLACC scale:

Regarding male and female gender, there were statistically significant differences between VJ, DV and TA groups where $p < 0.001$. There was a statistically significant difference between TA and each of VJ and DV groups where $p < 0.001$. No statistically significant difference was found between VJ and DV groups. Also, there was no statistically significant difference between male and female groups regarding VJ, DV and TA.

TABLE (3) The mean, standard deviation (SD) values of Wong-Beker Faces scale of different groups

Variables		Wong - Beker Faces Scale				p-value
		Male		Female		
		N = 87	%	N = 63	%	
VibraJect system (VJ)	No Hurt	21	65.6%	11	61.1%	0.077ns
	Hurts Little bit	4	12.5%	2	11.1%	
	Hurts Little more	3	9.4%	1	5.6%	
	Hurts even more	0	0%	0	0%	
	Hurts whole lot	4	12.5%	2	11.1%	
	Hurts worst	0	0%	2	0%	
Dental Vibe system (DV)	No Hurt	19	63.3%	14	70%	0.384ns
	Hurts Little bit	5	16.7%	2	10%	
	Hurts Little more	4	13.3%	2	10%	
	Hurts even more	1	3.3%	0	0%	
	Hurts whole lot	0	0%	2	10%	
	Hurts worst	1	3.3%	0	0%	
Topical anesthesia system (TA)	No Hurt	0	0%	0	0%	0.480ns
	Hurts Little bit	6	24%	6	24%	
	Hurts Little more	4	16%	3	12%	
	Hurts even more	5	20%	3	12%	
	Hurts whole lot	2	8%	3	12%	
	Hurts worst	8	32%	10	40%	
p-value		<0.001*		<0.001*		

* significant ($p < 0.05$) ns; non-significant ($p > 0.05$)

TABLE (4) The mean, standard deviation (SD) values of FLACC scale of different groups

Variables		FLACC Scale				p-value
		Male		Female		
		N = 87	%	N = 63	N = 87	
VibraJect system (VJ)	No Pain	20	62.5%	11	61.1%	0.106ns
	Mild discomfort	5	15.6%	4	22.2%	
	Moderate pain	3	9.4%	1	5.6%	
	Sever pain	4	12.5%	2	11.1%	
Dental Vibe system (DV)	No Pain	24	80%	14	70%	0.150ns
	Mild discomfort	2	6.7%	4	20%	
	Moderate pain	2	6.7%	1	5%	
	Sever pain	2	6.7%	1	5%	
Topical anesthesia system (TA)	No Pain	0	0%	0	0%	0.197ns
	Mild discomfort	6	24%	6	24%	
	Moderate pain	10	40%	5	20%	
	Sever pain	9	36%	14	56%	
p-value		<0.001*		<0.001*		

* significant ($p < 0.05$) ns; non-significant ($p > 0.05$)

DISCUSSION

Dental local anesthesia considered the most effective way to control pain during dental procedures, but unfortunately it may become itself a source of pain and anxiety especially for children⁽³⁾. The aim of the study was to compare the efficacy of VibraJect and DentalVibe comfort systems and Topical anesthesia (20% benzocaine) in relieving of pain associated with local injection in children.

One hundred and fifty children aged 4-12 years old were included. Subjects equally divided according to used method into three groups (50 each). Fifty Subjects received local anesthetic injections with VibraJect. Fifty Subjects received local anesthetic injections with DentalVibe comfort system. Fifty Subjects received local anesthetic injections with Topical anesthesia. In each group, twenty-five subjects received one inferior alveolar injection and another twenty-five subjects received one upper buccal infiltration injections.

In the current study, all local anesthetic injections were administered by the same dentist in order to control operator-related variables such as gender, technical expertise, and previous experience. Wong-Baker Faces Scale was employed to subjectively assess the perceived pain during anesthetic solution administration; it could be used for children aged 3 years or more. FLACC scale was used to objectively assess the pain perception by the operator during the injection. It could be used to assess pain for children aged 1 year or older.

Some studies have evaluated the pain upon needle insertion and solution deposition together and others have evaluated each pain separately in children⁽¹⁴⁾. In the current study, evaluation of pain was performed together since needle insertion was defined for the children as the first time he/she felt discomfort and solution deposition as the later time he/she felt discomfort during injection, this still might create a doubt whether they could discern

the difference and reported pain accurately. The use of two different scales reduced this risk, as the observer rated the pain first with the FLACC Scale so as not to be biased by the children's self-report. Eventually, the pain scores gathered from both the patients and the observer were highly concordant.

Our study showed that there was no relationship between the perceived pain during injection and the age of the child, which comes in contrast to studies done by Ching et al.⁽¹⁵⁾ and Elbay et al.⁽¹⁶⁾ who showed that the pain decreased as the age of the child increased, which may be attributed to using a wider age range of the subjects compared to our study.

The current study revealed that injection with DentalVibe has significantly lower pain scores than those in the control group and most of subjects found that injection with the DentalVibe to be less painful than the injection with the traditional technique and preferred the injection with the DentalVibe more than the control injection.

This finding was in agreement with another study who indicated decreased pain with the use of DV. In This previous study a randomized block, split-mouth design was used to determinethe effectiveness of a vibratory device with topical anesthetic compared to topical anesthetic only in reducing the pain experienced during an inferior alveolar nerve block. They found that the use of the vibratory device and topical anesthetic significantly reduced the pain experienced during the administration of a local anesthetic injection compared with the use of topical anesthetic alone⁽¹⁷⁾.

In another randomized control trial done by Shilpapiya et al.⁽¹⁸⁾, 30 patients aged 6-12 years who needed dental treatment in both sides of the maxilla or the mandible had received 2 injections, one using the DentalVibe and the other without it. They compared the pain during both injections using Frankel's behavior rating scale. The results showed significantly less pain perceived during local

anesthetic injections using DentalVibe compared to the injections which was done without the use of DentalVibe.

Furthermore, randomized clinical trial conducted by Dak-Albab et al. ⁽¹⁹⁾, on 30 patients aged 8-12 years, who needed an Inferior Alveolar Nerve Block anesthesia in both sides. They compared the pain during injection with the aid of DentalVibe and injection with the application of topical anesthetic gel. Results showed that patients received injections with the aid of DentalVibe experienced less pain than those with topical anesthetic gel. Where the assessment of pain done using FLACC scale.

This current study is not in agreement with other studies who indicated no significant reduced pain with the use of DV.

Elbay et al. ⁽²⁰⁾ conducted a randomized, control, crossover clinical trial, comprising 60 children requiring an operative procedure with supra-periosteal anesthesia on both their mandibular and maxillary molars, bilaterally. One of the molars was treated with a traditional syringe, and the contralateral tooth was treated with the aid of DentalVibe. On each visit, pain was evaluated using the Wong-Baker FACES Pain Rating Scale and the FLACC scale. The results showed no statistical significant difference between TS and DV for pain during injection and needle insertion for supra-periosteal anesthesia in either the maxillary and mandibular operative procedures.

In a randomized clinical trial by Raslan and Masri ⁽²¹⁾, evaluating the pain perceived during injection with a 3 different injections on both jaws with the aid of DentalVibe and compare it to that perceived during injection using the traditional method, without the application of topical anesthesia in both groups. 40 children aged 6-12 years were enrolled in this study that needed different local anesthetic injections (maxillary infiltration injection, palatal infiltration injection and Inferior Alveolar Nerve Block injection). Pain assessment was done using FLACC scale and the Wong-Baker Faces Pain

Rating Scale. They found that there was no statically difference regarding pain perception between the 2 groups during dental LA injections.

The current study revealed that injection with VibraJect has significantly lower pain scores than those in the control group and most of subjects found the injection with the VibraJect to be less painful than the injection with the traditional technique, and preferred the injection with the VibraJect more than the control injection.

These results were in accordance with these were published by Chaudhry et al. ⁽²²⁾ who also evaluated the efficacy of Vibraject in decreasing pain during local anesthetic injection in children. Also, in 2014 Chandrasekaran et al stated that Vibraject has significantly reduced pain during delivery of local anesthesia in adults ⁽²³⁾.

On the other hand, a single-blind randomized controlled study was done by Roeber et al. ⁽¹⁴⁾ among children. They also were in disagreement with our results. The possible explanation for this disagreement is that Roeber et al. ⁽¹⁴⁾ did not compare a Vibraject assisted injection and a conventional injection within the same patient.

When comparing pain score of males and females in each group of this study, no statistically significant difference was found. This came in agreement with a study done by Almeida et al. ⁽²⁴⁾ where they evaluated sex-related differences in dental pain perception in children aged 4-9 years, where they find no statistically significant difference between the males and females.

This finding may be due to using vibration as a physical mean to decrease the pain during injection, which based on the "Gate control theory" of pain, which states that the physical pain is due to interactions between different neurons. As stimulating the large diameter A-beat fibers by the application of vibration can interrupt nociceptive signals which lead to closing the gate which reduce the pain perception ⁽⁸⁾.

CONCLUSION

1. The VibraJect and DentalVibe reduced pain during LA injection without causing anxiety.
2. Gender do not affect pain perception during injection using VibraJect and DentalVibe comfort system when compared to traditional method.

REFERENCES

1. Appukkuttan D. Strategies to manage patients with dental anxiety and dental phobia: literature review. *Clinical, Cosmetic and Investigational Dentistry* 2016; 8: 35.
2. Fayad M, Elbieh A, Baig M, Alruwaili S. Prevalence of dental anxiety among dental patients in Saudi Arabia. *J Int Soc Prev Community Dent* 2017; 7: 100.
3. Chopra R, Jindal G, Sachdev V, Sandhu M. Double-Blind Crossover Study to Compare Pain Experience During Inferior Alveolar Nerve Block Administration Using Buffered Two Percent Lidocaine in Children. *Pediatr Dent.* 2016; 38: 25-9.
4. Malamed SF, Reed K, Okundaye A, Fonner A. *Local and Regional Anesthesia in Dental and Oral Surgery. Complications of Regional Anesthesia*: Springer 2017; 341-58.
5. Kumar M, Chawla R, Goyal M. Topical anesthesia. *J. Anaesthesiol. Clin. Pharmacol.* 2015; 31: 450-6.
6. Malamed S. *Handbook of local anesthesia-e-book*: Elsevier Health Sciences, 2014.
7. Ram D, Hermida B L, Amir E. Reaction of children to dental injection with 27G or 30G gauge needles. *Int J Pediatr Dent.* 2007; 17: 383-7.
8. Campbell T, Johnson, J and Zernicke, K. Gate Control Theory of Pain, in *Encyclopedia of Behavioral Medicine*, M.D. Gellman and J.R. Turner, Editors 2013; 832-4.
9. Kumar S. Newer delivery systems for local anesthesia in dentistry. *J Pharm Sci Res* 2015; 7: 252-5.
10. Saxena P, Gupta S, Newaskar V, Chandra A. Advances in dental local anesthesia techniques and devices: An update. *Nati J of Maxillofacial Surgery* 2013; 4: 19.
11. Saijo M, Ito E, Ichinohe T, Kaneko Y. Lack of pain reduction by a vibrating local anesthetic attachment: a pilot study. *Anesth Prog.* 2005;52:62-4.
12. Baker C, Wong D. QUEST: A process of pain assessment in children. *OrthopNurs* 1987; 6: 11-21.
13. Blount R, Loiselle K. Behavioural assessment of pediatric pain. *Pain Research and Management* 2009; 14: 47-52.
14. Roeber B, Wallace D, Rothe V, Salama F, Allen KD. Evaluation of the effects of the VibraJect attachment on pain in children receiving local anesthesia. *Pediatric Dentistry* 2011; 33: 46-50.
15. Ching, D., Finkelman, M., and Loo, C. Effect of the Dental-Vibe injection system on pain during local anesthesia injections in adolescent patients. *Pediatr Dent* 2014; 36: 51-5.
16. Elbay, M., SermetElbay, U., Yildirim, S., Ugurluel, C., Kaya, C. and Baydemir, C. Comparison of injection pain caused by the DentalVibe Injection System versus a traditional syringe for inferior alveolar nerve block anaesthesia in paediatric patients. *Eur J Paediatr Dent* 2015; 16: 123-128.
17. Momin M, Hashimoto K, Honda K, Yosue T. The Effects of Vibration on Pain and Anxiety during Local Anesthesia Administration. *JSM Dent* 2014; 2: 1022.
18. Shilpapiya, M., Jayanthi, M., Reddy, V. N., Sakthivel, R., Selvaraju, G. and Vijayakumar, P. Effectiveness of new vibration delivery system on pain associated with injection of local anesthesia in children. *J Indian Soc Pedod Prev Dent.* 2015; 33: 173-6.
19. Dak-Albab, R., Al-Monaqel, M., Koshha, R., Shakhshero, H. and Soudan, R. A comparison between the effectiveness of vibration with Dentalvibe and benzocaine gel in relieving pain associated with mandibular injection: A randomized clinical trial. *Anaesth Pain & Intensive Care* 2016; 20: 43-9.
20. Elbay, U., Elbay, M., Yildirim, S., Kaya, E., Kaya, C., Ugurluel, C., et al. Evaluation of the injection pain with the use of DentalVibe injection system during supraperiosteal anesthesia in children: a randomised clinical trial. *Int J Paediatr Dent* 2016; 26: 336-45.
21. Raslan, N. and Masri, R. A randomized clinical trial to compare pain levels during three types of oral anesthetic injections and the effect of Dentalvibe® on injection pain in children. *Int J Paediatr Dent.* 2017; 28: 102-10.
22. Chaudhry K, Shishodia M, Singh C, Tuli A. Comparative evaluation of pain perception by vibrating needle (Vibraject™) and conventional syringe anesthesia during various dental procedures in pediatric patients: A short study. *Int Dent Med J Adv Res* 2015; 1: 1-5.
23. Chandrasekaran J, DP, S, MS, Ahmed A, Kumarasamy B. Efficacy of painless injection technique – Vibraject – Clinical trial in Chennai, India. *Int J Med and Dent Sci* 2014; 3:250-6.
24. Almeida, G, Longo, D, Trevizan, M, deCarvalho, F, Nelson-Filho, P, Kuchler, E, et al. Sex Differences in Pediatric Dental Pain Perception. *J Dent Child* 2016; 83: 120-4.