

## ORIGINAL ARTICLE

# A comparison between the effectiveness of vibration with Dentalvibe and benzocaine gel in relieving pain associated with mandibular injection: a randomized clinical trial

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## ABSTRACT

**Introduction:** Mandibular nerve block injection (MNBI) is considered as one of the most painful injections, especially in children. Various recent studies have compared the use of pharmaceutical drugs, including some non-pharmaceutical methods applied to relieve pain in dental practice. This study aims to investigate the effectiveness of the use of a drugless method by applying vibration at the injection site to reduce pain associated with (MNBI).

**Methodology:** A cross-over, double-blind randomized clinical trial was carried out during 2014 to 2015 at Pediatric Dentistry department in the Dental College, Damascus University, where 60 MNBI were given to 30 children, aged 8 to 12 years. Each child received 2 MNBI in both right and left side of mandibular jaw, with 1-2 weeks apart. Topical analgesic (benzocaine 20%) gel was applied in 15 children, while 15 children received MNBI with vibration using DentalVibe at the injection side. Two high quality digital cameras were used to record children's reactions to pain during injections, on face in particular and the whole body in general. Two external evaluators were also employed to assess the pain reaction using FLACC scale for pain assessment.

**Results:** Pain intensity decreased from 5.57 when used topical gel into (3.36) when used vibration with DentalVibe device. Significant differences were recorded ( $P=0.002$ ) for the benefit of vibration technique with DentalVibe in the injection site compared with the topical benzocaine 20% gel.

**Conclusion:** Our study proves that vibration technique with DentalVibe device can be used as a simple and effective method to alleviate pain associated with dental injections as compared to traditional topical analgesic gels.

**Key words:** Vibration; DentalVibe; Gel; Pain; Anesthesia, Local

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## INTRODUCTION

Local anesthetic administration is considered a painful procedure in the awake patients,<sup>1</sup> and it is more difficult in pediatric dentistry; especially as a child's reaction to local injection at earlier visits affects his attitude at all subsequent sessions.<sup>2</sup> Some statistics in United States indicate that 4-6% of the population avoids dental visit due to fear of pain only,<sup>3</sup> therefore many studies have been carried out to come up with new methods to relieve injection pain.<sup>4-7</sup> Many researchers studied the effect of using topical anesthetic drugs on the injection site to relieve pain,<sup>8-14</sup> however, non-drug methods are still under research and development.<sup>4-7</sup> So we felt a real need to study the

effectiveness of one of those methods, which is vibration on the tissues at injection site, for relieving pain, associated with mandibular nerve block injection in comparison with traditional topical gel (Benzocaine 20%).

## METHODOLOGY

The sample consisted of 30 children, aged between 8 and 12 years, presented to the Pediatric Dentistry Department at the Faculty of Dentistry at Damascus University. The sample size was calculated using G-Power 3.1 statistical program with ( $\alpha=0.05$ , and Power=0.95). The informed consent was taken from parents or legal guardians before the procedures was carried out. CONSORT Statement

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was taken in mind when the current randomized clinical trial (RCT) was designed and conducted. All unhealthy children or those who had taken any sedative or analgesic drugs in the past 24 hours of the dental visit were excluded from our study. Similarly, we excluded all cases with acute or chronic inflammation or abscesses at injection site or subjects with previous traumatic painful dental experience. All children of the sample needed symmetric dental treatment in both lower sides. Cooperative children were classified as absolute positive or positive on Frankel's classification scale (Table 1).

**Table 1: Frankl's scale used to evaluate a child's cooperation**

Cooperation level	Attitude or reaction observed
Definitely negative	Refusal of treatment; crying forcefully, fearful, or any other evidence of extreme negativism.
Negative	Reluctance to accept treatment; uncooperative; some evidence of negative attitude but not pronounced, i.e., sudden withdrawal.
Positive	Acceptance of treatment; at time of cautious; willingness to comply with the dentist, at time with reservation, but patient follows the dentist's directions cooperatively.
Definitely positive	Good rapport with dentist; interested in the dental procedures; laughing and enjoying the situation.

A disposable oral examination kit and a traditional oral local anesthesia kit were used for each subject. In addition, a dental vibrating device (DentalVibe - Injection Comfort System) manufactured by BING Innovations Co., a high definition digital camera (14 Megapixel) manufactured by Sony, two digital cameras 3-point stands, and benzocaine 20% topical gel were also utilized in this study.

**Study design:** This study was designed as cross-over, double-blinded randomized clinical trial, and conducted from 24-2-2014 to 15-5-2015 in at Pediatric Dentistry Department, Damascus University. Neither the patients nor external evaluators could discriminate between two applied technique groups.

Two mandibular nerve block injections were conducted in two separate treatment sessions 1-2 weeks apart. The order of using vibration or gel technique was under randomized distribution; we started with topical gel, as stated above, for injection (Technique A) on 15 children in their first visits, whereas the rest of the sample (15 subjects), received injections with vibration that was applied in their visits as well (Technique B).

Technique A was achieved by using benzocaine 20% gel being applied using a sterilized cotton roll on the retro-

molar pad for two minutes after drying the oral mucosa at the site by a piece of sterilized gauze. However, in Technique B we applied vibrating device (DentalVibe) on the injection site for 30 seconds.

Children's behavioral reaction against stimulated pain alarm was recorded by two high quality digital cameras (14 Mega pixel), one of them focused on the face, while the other was used to record the whole body response during the procedure.

Two external evaluators were trained previously, and they evaluated the pain sensation for each patient. To gain reliable results, the evaluators proper work was tested by Kappa coefficient test.<sup>33</sup>

**Statistical Analysis:** FLACC scale values ranged between 0-10, the result is the sum of its five partial values; each one ranged between 0-2. As FLACC rises, pain degree increases too. Each child had two results on FLACC – a result from each evaluator, according to the method used for pain relief (topical gel then vibration or vice versa). Pain scale results for topical gel method were coded by FLACC (A), whereas the scale values for vibrating method were coded by FLACC (B). The mean of FLACC scale value was calculated when there was a difference between evaluators' results. For paired samples student's t-test was applied to compare differences between pain degrees when the two methods were applied on all subjects (A: Topical gel – B: Vibration). To assess gender effect the first method used in each child, student's t-test in independent samples were used. The differences were considered statistically significant when P-value was less than 0.05.

## RESULTS

High concurrence between both evaluator's results was indicated when Kappa coefficient test values were about 0.952 and 0.893 for the first and second evaluator respectively. In addition, this test recorded around 1.00 for both evaluators.

Moreover, significant differences were noticed between topical gel and vibrating methods (P=0.002) (Table 3); the pain level rose on FLACC scale in the first method to 5.57, while it was only 3.36 with DentalVibe during injection. Likewise, significant differences were reported between all FLACC scale partial values except activity (A) and (C) consolability as shown in Table 3. Regarding gender influence, only some females experienced pain more than males (5.8:5.3) with the use of benzocaine, while just slightly more than half the number of males (4:2.8) felt more pain with DentalVibe. However, differences were not significant as shown in Table 4. Similarly, no significant differences were noted between the two methods in terms of the application order as Table 5 clarifies.

Table 2: The distribution of pain intensity using (FLACC) non-self-evaluating scale in both applied methods.

child's number	(A) Topical gel Technique						(B) Vibrating technique					
	F	L	A	C	C	FLACC(A)	F	L	A	C	C	FLACC(B)
1	3	3	2	1	1.5	10.5	2	1.5	1.5	1	1	7
2	0.5	0	0	0	0	0.5	0.5	0	0	0	0	0.5
3	1.5	0	0	0	0	1.5	0	0	0	0	0	0
4	2	1.5	1.5	1	1	7	1	1.5	2	1	1	6.5
5	2	1.5	0.5	1	1	6	2.5	1.5	1	1	1	7
6	3	2.5	1.5	3	2	12	1.5	1	0	1	1	4.5
7	2	1.5	1.5	1	1	7	0.5	0.5	0.5	0	1	2.5
8	0.5	0	0	0	0	0.5	0.5	0	0	0	0	0.5
9	0	0	0	0	0	0	1.5	0	0	0	0	1.5
10	1.5	1.5	1.5	0	1	5.5	2	1.5	1	0	1	5.5
11	2	2	3	1	1	9	1	0.5	0	0	1	2.5
12	0.5	1.5	0.5	0	0	2.5	0.5	1.5	0.5	0	0	2.5
13	2.5	1.5	0	0	1	5	1.5	0.5	0	0	0	2
14	1	0	0	0	0	1	1	0	0	0	0	1
15	1	1.5	0	0	0	3	0	0	0	0	0	0
16	3	1.5	1.5	3	3	12	3	1.5	1.5	3	2.5	11.5
17	1.5	0	0	1.5	1.5	4.5	0	0	0	0	0	0
18	3	1.5	1	1	1	7.5	2	0.5	0	0	1	3.5
19	2	2	2	3	1.5	10.5	2	0.5	1	1	0.5	5
20	0.5	1.5	1.5	0	0	3.5	0.5	1.5	0.5	0	0	2.5
21	3	1.5	1.5	1.5	1.5	9	2	2	3	3	3	13
22	1.5	0.5	0	0	0	2	0.5	0.5	0	0	0	1
23	3	1.5	1	3	1.5	10	1	1.5	0.5	0	0	3
24	1	0	0	0	0	1	0	0	0	0	0	0
25	1.5	1.5	0.5	1	0	4.5	2.5	1.5	1.5	2	1	8.5
26	1.5	0	0	1	1	3.5	1.5	0	0	0	0	1.5
27	2	1.5	3	1	1	8.5	0.5	1.5	2	1	0	5
28	2	3	3	1.5	1.5	11	0.5	0.5	1	0	0	2
29	1	0	0	0	0	1	1	0	0	0	0	1
30	1	0	0	0	0	1	1	0	0	0	0	1

Table 3: The differences between the means of FLACC non-self-evaluating scale's values using paired samples student's t-test.

Scale	Method	Mean	standard deviation (SD)	t-value	P-value
(FLACC) the whole non-self-evaluating scale	FLACC(A)	5.57	3.15	3.36	<b>*0.002</b>
	FLACC(B)	3.36			
(Face (F	F(A)	1.7	0.9	3.42	<b>*0.002</b>
	F(B)	1.08			
Legs (L)	L(A)	1.25	0.76	3.19	<b>*0.004</b>
	L(B)	0.76			
Action (A)	A(A)	0.98	0.92	2.01	0.054
	A(B)	0.61			
Crying ("c")	C(A)	0.86	0.97	2.31	<b>*0.029</b>
	C(B)	0.42			
("Consolability ("C	C (A)	0.76	0.72	2.03	0.53
	C (B)	0.48			

(A) Topical gel, (B) vibrating. \* P-value<0.05

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**Table 4: Gender effect on pain response using independent samples student's t-test**

Means of pain	Gender	children's number	Mean	(SD)	t-value	P-value
FLACC (A)	Male	13	5.36	3.71	0.308	0.761
	Female	17	5.82	4.06		
FLACC (B)	Male	13	2.86	3.62	0.858	0.401
	female	17	4.03	3.33		

(A) Topical gel, (B) Vibrating.

**Table 5: The effect of the two techniques order using independent samples student's t-test**

Means of pain	Gender	Number	Mean	(SD)	t-value	P-value
FLACC(A)	A	15	6.15	3.8	0.646	0.524
	B	15	5.2	3.99		
FLACC(B)	A	15	3.69	3.73	0.169	0.868
	B	15	3.47	3.27		

(A) Topical gel, (B) Vibrating.

## DISCUSSION

Use of topical gel has been crucially discussed in different studies regardless of the wide range of various drugs used to form it and their different concentrations. So its positive effect on relieving injection pain and its advantage comparing with placebo was proved by a lot of randomized controlled trials.<sup>8,13,15-17</sup> Tuga et al indicated that benzocaine 20% was better than three other anesthetic drugs used as topical gels on injection site, due to its fast and long effect on the oral mucosa and biocompatibility in comparison with some other less effective drugs.<sup>18</sup> Therefore, it is considered as the first choice drug for topical anesthesia and it is available in many pharmaceutical gel products.<sup>19</sup>

In 1965, gate control theory was developed by Melzack and Wall, which suggests that stimulated nerve pulses in the thick myelinated fibers are triggered by non-harmful stimulants (such as vibration or pressure), whereas thin fibers are more likely to be stimulated by harmful stimulants (pain). The speed of transportation in non-myelinated fibers is 1.2 m/s in comparison with 14.8-120 m/s in myelinated fibers. The pain and other sensations are transmitted as nerve pulses through various gates before reaching the brain. Normally, these gates are opened to allow pain signals to pass easily, but if various other stimuli were applied (such as vibration and pressure) then tremendous amounts of non-painful signals will be sent via myelinated nerve fibers. However, the traffic of nerve pulses might lead to pain gate closure, which pauses transition of the sense caused by applying painful alarm and coming from this region of the body.<sup>20-22</sup> Many recent studies in general medicine and dentistry relied on gate control theory to relieve the injection pain with children,

such as Nanitsos et al in 2009,<sup>4</sup> Shahidi in Iran 2011,<sup>5</sup>

Aminabad and Farahani in 2009,<sup>6</sup> and Lee and Lee study in Korya 2013.<sup>7</sup>

On the other side, a number of recent studies have used the Sound–Eye–Motor scale (SEM),<sup>7,9,23-26</sup> which assess changes occurring in a patient's voice, eyes, and movement to evaluate patient's discomfort during treatment.<sup>27</sup> Another scale 'Face–Leg–Activity–Cry–Consolability' (FLACC), has also been used in many other studies,<sup>28-31</sup> and the Royal College for Nursing recommends its use to evaluate the pain on over 3-year-old children regardless of their cooperation level<sup>32</sup>. This means that it can be used in both normal children and those who have learning disabilities as shown by Malviya et al's study in 2006.<sup>30</sup>

Many researchers studied the pain fear associated with intra-oral injections, which is considered one of important factors that make patients avoid visiting a dental practice.<sup>37,38</sup> Children also perceive this feeling through their parents,<sup>39</sup> which makes intra-oral injections a big issue. Therefore, many studies aimed to find different ways to relieve pain by drugs; using traditional topical anesthetics, or non-drugs methods; such as vibration, application of cold, or pressure on injection site.<sup>5-9,40</sup>

As this study was a double blinded, the external evaluator, which used to calculate pain levels, was not aware of the method applied in distraction. In addition, to ensure blinding we selected two external evaluators (both of them were not related to dental field) to avoid being biased to any of the methods used, unlike some of other studies that could not get out of blinding issue, especially when the external evaluator was with the dentist while doing the injections.<sup>40</sup> In our study, We relied on two evaluators instead of one to gain more reliable results like what Hesselgard et al and Nilsson et al did in their studies of

2007 and 2008 respectively.<sup>29,35</sup>

Some studies indicate that children's evaluation of their pain may be exaggerated especially immediately after the procedure, which makes the observational pain scales more reliable than self-evaluating scales,<sup>41</sup> like Stinson et al's systematic review in 2009. They found no typical scale for it and suggested further studies to develop a self-evaluating pain scale designed according to a child's age, mental development and pain types.<sup>42</sup> For this reason, we avoided self-evaluating scales in our study and relied on non-self-evaluating scales, which assess observation and behaviors. FLACC scale is considered as a good and reliable scale according to many studies,<sup>28-31</sup> due to its five parts which give specific numbers representing pain levels unlike, SEM scale whose evaluator is restricted to only four pain levels. Consequently, FLACC is more accurate and detailed to register response levels of different parts of the body.

This study found a noticeable positive effect on reducing pain associated with vibration technique by DentalVibe, which agrees with Ching et al study results in which they noticed a reduction in mean pain level with the use of DentalVibe<sup>43</sup>. However, no positive influence was recorded for the same technique by Vibraject in a study by Roebra et al in 2011. These results might be due to the small surface that was stimulated by vibrating with this device, which causes no stirring in thick myelinated fibers.<sup>44</sup> Nevertheless, our study findings disagree with the pilot study done by Saijo et al in 2005,<sup>45</sup> in which the subjects received injections in maxilla's both sides, and pain-relieving technique distributed randomly. In that study, no differences were recorded between vibrating using Vibraject and topical gel. This disagreement can be justified by the differences in both of the devices applied, and also the differences in the injection types. The reduction in pain sensation with

vibration technique during injection could be interpreted by gate control theory as mentioned earlier

In terms of gender affect, males, in comparison with females, could have a higher pain threshold as other experimental studies suggest that women have lower pain tolerance than men and the pain experience may also be related to cultural and psychological status<sup>46</sup>. These results are similar to findings by Coulthard et al,<sup>47</sup> but are unlike what Elias study concluded.<sup>48</sup>

All in all, we may say that vibrating technique had better results on reducing pain sensation than topical gel, as it may have been a distraction for some children especially those who do not prefer flavored materials that may, stimulate nausea or could have harmful effects if swallowed. In addition, vibrating technique is a time-saving method in comparison to applying topical gels and easier as there is no need to dry the injection site like in the other method.

## CONCLUSION

In conclusion, these results indicate that using vibration with mandibular nerve block injection was significantly better able to relieve pain than the use of topical gel during the procedure and therefore, it could be an easy convenient alternative. Further studies are required to detect the efficacy of DentalVibe device in other types of intra-oral dental injections; and a comparison of this device with other vibration machines is also suggested to provide further beneficial results.

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**Author contribution:** All of the authors took part in the conduct of study.

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