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Comparison of injection pain caused by the DentalVibe Injection System versus a traditional syringe for inferior alveolar nerve block anaesthesia in paediatric patients

ABSTRACT

Aim To compare paediatric patients' pain during needle insertion and injection in inferior alveolar nerve block (IANB) anaesthesia injected by either a traditional syringe (TS) or the DentalVibe Injection Comfort System (DV).

Materials and methods Study Design: the study was a randomised controlled crossover clinical trial, comprised of 60 children aged 6–12 requiring an operative procedure with IANB anaesthesia on their mandibular molars bilaterally. One of the molar teeth was treated with TS and the contralateral tooth was treated with DV. On each visit, subjective and objective pain was evaluated using the Wong-Baker Faces Pain Rating Scale (PRS) and the Face, Legg, Cry, Consolability Scale (FLACC Scale). Patients were asked which anaesthesia technique they preferred. Data were analysed using Wilcoxon signed rank, Spearman correlation, and Mann-Whitney U tests.

Results There were no statistically significant differences for pain evaluation during needle insertion and injection of each injection system. However, a negative correlation was found on the FLACC between age and pain scores during injection after using DV.

Conclusion Paediatric patients experienced similar pain during IANB anaesthesia administered with TS and DV. With increased age, pain values reduced during anaesthetic agent injection with DV according to FLACC. The traditional procedure was preferred to DV in paediatric patients.

Keywords Inferior alveolar nerve block; Injection; Pain.

Introduction

Inferior alveolar nerve block anaesthesia (IANB) is the most frequently used technique for achieving local anaesthesia for restorative and surgical procedures in mandibular primary and permanent molar teeth [Wilson and Montgomery, 2005]. The main advantage of alveolar inferior nerve block injection is the depth of anaesthesia. The ability to achieve anaesthesia of all molars, premolars and canines on the side of the injection makes it possible to treat multiple teeth in the same quadrant at one appointment [Oulis et al., 1996]. On the other hand, IANB anaesthesia has some disadvantages for paediatric patients, particularly the fact that it is more painful than infiltration anaesthesia in the mandible, which sometimes affects children's behaviour [Jones et al., 1995]. Oulis et al. [1996] and Jones et al. [1995] demonstrated that a mandibular block was more painful than buccal infiltration and Sharaf [1997] also stated that block anaesthesia had a negative impact on the behaviours of 3- to 5-year-old children. An unpleasant treatment experience can have a negative influence on a child's attitude toward subsequent operative procedures [Sharaf, 1997]. Therefore, numerous methods have been developed to reduce discomfort and pain perceptions associated with dental injections [Kaufman et al., 2005; Friedman and Hochman, 2001].

One new technique aimed at reducing injection pain and anxiety during intraoral injection is the use of computer-controlled injection systems (CCDS) developed as alternatives to the conventional syringe [Palm, 2004]. In the literature, several studies have been conducted related to CCDS usage in children. A study by Yenisey [2009] reported that when compared to traditional systems, CCDS used with paediatric patients resulted in significantly less pain during needle insertion and injection. By contrast, a study by Asarch et al. [1999] reported that CCDS had no effect on pain response. Similarly, Ram et al. [2003] concluded that there was no difference between the two systems in terms of pain and behaviour in children.

Another local anaesthetic delivery method is

used to decrease patients' fear of injection by taking advantage of the gate control theory of pain management, suggesting that pain can be reduced by the simultaneous activation of nerve fibers through the use of vibration [Dickenson, 2002]. An important component of the theory, proposed by Melzack and Wall, is that stimulation of the larger diameter A fibers with proper pressure or vibration can close a neural "gate" to nociceptive signals and, as a result, decrease the perception of pain [Melzack and Wall, 1965]. This gate is believed to lie inside the spinal cord/brainstem, and it blocks the transmission of nociceptive action potentials to higher centers in the nervous system. The exploitation of the theory can be significant, particularly in the sensitive oral region where more than a third of the cells in the somatosensory cortex of the brain are allocated to sensorial inputs from the mouth [Barr, 1979]. Vibration stimuli are easily administered in the orofacial region and can be used with the aim of increasing the pain threshold. Nanitsos et al. [2009] researched the effect of vibrations on pain during local anaesthesia injections. Their results indicated that injections with vibration resulted in decreased pain and lower pain ratings than no vibration-stimulus injections.

DentalVibe (DV) is a recently introduced technology, developed to stimulate the mechanoreceptors with vibration during the delivery of dental injections to decrease injection pain [Ching et al., 2014; Ungor et al., 2014]. The device provides a hand-held cordless injection method and includes a U-shaped vibrating tip that delivers percussive micro-oscillations to the injection administration site. Ching et al. [2014] stated that DV significantly decreased self-reported pain in local anaesthesia (LA) injections for adolescent patients in comparison to the traditional approach. According to their study, 83% of patients found DV injections to be less painful than those with traditional syringes. Ungor et al. [2014] evaluated the effects of DV on pain and anxiety levels during LA injections in adult patients. They found that DV reduced pain during LA injections without causing anxiety. To the best of our knowledge, there has been no study published on the effectiveness of DV in paediatric dentistry patients.

The purpose of this study was to compare the pain between an exposure group (injections with the aid of the DV Injection Comfort System) and a control group (traditional injections without the aid of the DV) in paediatric patients during needle insertion and injection in IANB for both sides of mandibular molar teeth.

Materials and methods

Sixty children who were receiving dental treatment in a paediatric dental clinic were selected due to requiring IANB for the operative procedure on their mandibular

molars bilaterally in this study. The number of necessary subjects for the study was determined after a power calculation (power=0.80, $\alpha=0.05$, $\beta=0.20$, 'G*Power Ver: 3.1.9.2'). The protocol of this study was approved by the Ethics Committee of Kocaeli University (KOU KAEK 2014/197). Written consent was obtained from the parents and patients before each treatment.

The inclusion criteria were as follows: being 6 to 12 years old, no medically or developmentally compromising conditions, and having positive or definitely positive behaviour during preoperative behavioural assessments. The exclusion criteria were as follows: the presence of medically or developmentally compromising conditions, a history of chronic disease, and currently taking medication that contraindicated the use of local anaesthetic.

The "tell-show-do" technique was used for all patients. Reframing techniques (for example, using euphemistic phrases such as "putting the tooth to sleep") were used to describe the injection to all the children. None of them needed a sedative or other pharmacological therapy prior to receiving dental treatment.

The study was conducted using a randomised, controlled cross-over design. Operative procedures were performed on both the left and right mandibular teeth of each patient with IANB using two different anaesthesia systems [Traditional syringe or DV (BING Innovations, Florida, USA)] with a minimum interval of at least 1 week between procedures, and the anaesthesia system used in the first procedure in patients randomly selected using a computer-generated list. A total of 120 IANB injections were performed with patients divided into 2 equal groups, according to anaesthesia systems, as follows:

- > I (n=60): Traditional Syringe Group (TS Group)
- > II (n=60): Traditional Syringe+ DentalVibe Group (DV Group)

Before initiating all the treatments, the site of the injection was dried with a cotton tip applicator, and topical anaesthetic spray (Hurracaine, Beutlich, 1541 Shields Drive Waukegan IL 60085, USA) was applied for 60 seconds. For all injections, 1 ml of Articaine Hydrochloride with 1/100.000 epinephrine (Ultracaine D-S forte, Hoechst Canada Inc., Montreal Quebec, Canada) was injected through a 27 G dental needle.

In both TS and DV groups, the DV device was placed on the oral mucosa to enclose the injection site before administering local anaesthesia. The device was located medial to the mandibular ramus for IANB injections. To control for potential subject-expectancy effects and pressure from the placement of the DV, the device was placed near the injection site for all injections; however, it was not turned on for the TS group. The device was used as a retractor in the same manner as a dental mirror.

In the TS group, during the anaesthesia injection,

injections were administered using TS for IANB. For the IANB, each child was requested to open his/her mouth as wide as possible while the operator positioned the ball of the thumb on the coronoid notch of the anterior border of the ramus, and the needle was inserted between the internal oblique ridge and the pterygomandibular raphe. When the bone was contacted, the needle was withdrawn approximately 1 mm to prevent subperiosteal injection. After a negative aspiration, solution was deposited. In the DV group, all procedures were similar, except the DV was turned on to stimulate the area of intended needle penetration. After five seconds of vibration, the needle was inserted. The DV continued vibration during needle insertion and anaesthetic injection. All dental injections were administered by the same practitioner who had 2 months of experience in using the DV. During the study, both injection techniques were evaluated by a single rater who was not the practitioner of treatment.

Both subjective and objective evaluations were performed to measure each child's pain in this study. For subjective evaluation, the Wong-Baker FACES pain rating scale (PRS) was used [Wong and Baker, 1998]. The PRS measures the unpleasantness or affective dimension of a child's pain experience and is used in children aged 3–17 years old. The PRS consists of a set of cartoon faces with varying facial expressions ranging from a smile/laughter to tears, and each child is asked to select the facial expression that best represents 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"). Immediately after the anaesthesia injection, patients were asked to use the PRS to indicate how they felt during needle insertion and solution injection. The data were recorded.

Objective assessment was performed by observing the patients' behaviour using the Face, Legg, Cry, Consolability Scale (FLACC Scale) during the anaesthetic injection and needle insertion. The scale comprised the following parameters: (1) Face, (2) Legs, (3) Activity, (4) Cry, and (5) Consolability. Each of the five categories is scored from 0–2, which results in a minimum total score of 0 and maximum of 10. According to this scale: 0=Relaxed and comfortable (no pain); 1–3=Mild discomfort; 4–6=Moderate pain; and 7–10=Severe discomfort or pain [Willis et al., 2003]. Behavioural parameters were recorded.

Statistical analysis was performed using a commercially available software programme (SPSS 20.00; SPSS, Chicago, IL) to compare the measurements of both scale scores. In order to evaluate the differences between groups, Spearman's correlation, Mann-Whitney U, and Wilcoxon tests were used. To examine gender differences, the data were analyzed with Monte Carlo chi-square and Fisher exact tests; the level of significance was set at 0.05.

Results

Sixty children consisting of 33 girls (55%) and 27 boys (45%) who were 6–12 years of age (8.37 ± 1.99) were included in this study. Both injection methods (DV and TS) allowed the 120 mandibular nerve block anaesthesia procedures to be completed and carried out in all 60 patients.

The data showed there was no statistically significant difference in the self-reported pain (PRS) between DV and TS techniques during needle insertion ($P=0.188$) and anaesthetic injection according to the Wilcoxon signed-rank test ($P=0.274$).

For needle insertion, 19 (31.7%) of the 60 subjects in the DV group and 21 (35%) of 60 subjects in the TS group reported "no pain," 21 (35%) of 60 subjects in the DV group and 23 (38.3%) of 60 subjects in the TS group reported it "hurts just a little bit," 7 (11.7%) of 60 subjects in the DV group and 10 (16.7%) of 60 subjects in the TS group reported it "hurts a little more," 9 (15%) of 60 subjects in the DV group and 3 (5%) subjects in the TS group reported it "hurts even more," 1 (1.7%) subject in the TS group reported it "hurts a whole lot," 4 (6.7%) subjects in the DV group and 2 (3.3%) subjects in the TS group reported it "hurts the worst," according to the PRS (Fig. 1).

For anaesthetic injection, 11 (18.3%) of the 60 subjects in the DV group and 13 (21.7%) of 60 subjects in the TS group reported "no hurt," 16 (26.7%) of 60 subjects in the DV group and 18 (30%) of 60 subjects in the TS group reported it "hurts just a little bit," 14 (23.3%) of 60 subjects in the DV group and 13 (21.7%) of 60 subjects in the TS group reported it "hurts a little more," 12 (20%) of 60 subjects in the DV group and 13 (21.7%) subjects in the TS group reported it "hurts even more," 3 (5%) subjects in the DV group and 1 (1.7%) subject in the TS group reported it "hurts a whole lot," 4 (6.7%) subjects in the DV group and 2

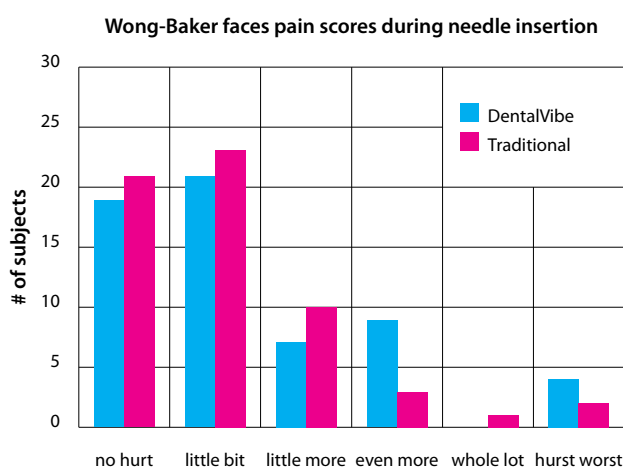


FIG. 1 PRS pain response scores during needle insertion.

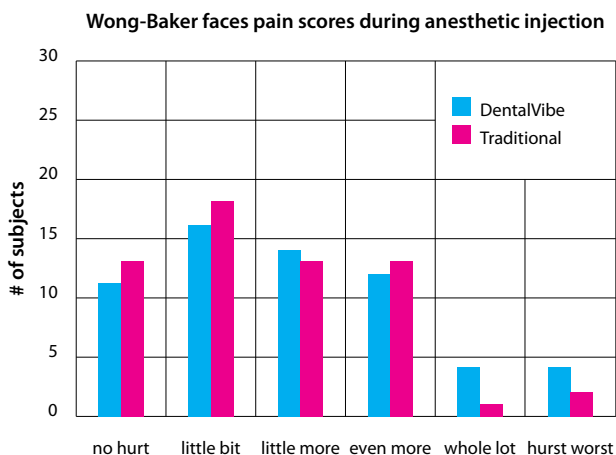


FIG. 2 PRS pain response scores during anesthetic injection.

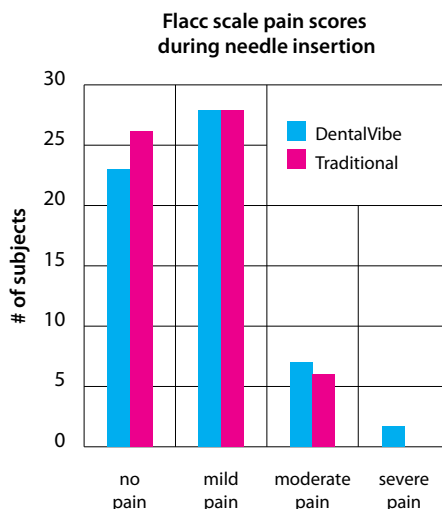


FIG. 3 Pain rating scores according to FLACC during needle insertion.

(3.3%) subjects in the TS group reported it “hurts the worst,” according to the PRS (Fig. 2).

No statistically significant difference in FLACC pain response scores was found between the DV and TS groups during needle insertion ($P= 0.514$) and anaesthetic injection, according to the Wilcoxon signed-rank test ($P= 0.314$).

For needle insertion, 23 (38.3%) of 60 subjects in the DV group and 26 (43.3%) of 60 subjects in the TS group showed “no pain,” 28 (46.7%) of 60 subjects showed “mild pain” for both injection systems, 7 (11.7%) subjects in the DV group and 6 (10%) subjects in the TS group showed “moderate pain,” and 2 (3.4%) subjects in the DV group showed “severe discomfort or pain.” In the TS group, none showed “severe discomfort or pain,” according to the FLACC scale (Fig. 3).

For anaesthetic injection, 14 (23.3%) of 60 subjects in the DV group and 21 (35%) of 60 subjects in the TS group showed “no pain,” 31 (51.7%) of 60 subjects showed “mild pain” for both injection systems, 11 (18.3%) subjects in the DV group and 7 (11.7%) subjects in the TS group showed “moderate pain,” 4 (6.7%) subjects in the DV group and 1 (1.7%) subject in the TS group showed “severe discomfort or pain” (Fig. 4).

The Mann-Whitney U test, used to determine whether there was a statistically significant association between the difference in pain ratings and gender, found no significant effect in both the DV and the TS groups during needle insertion and anaesthetic injection according to the FLACC and PRS.

Although more patients preferred the TS over the DV method, there was no statically significant difference for patient preference. While 22 (36.7%) subjects found the injection with the DV to be less painful than the TS, 38 (63.3%) found the injection with the DV to be more painful. No significant gender difference was observed in terms of preference. Thirteen (39.3%)

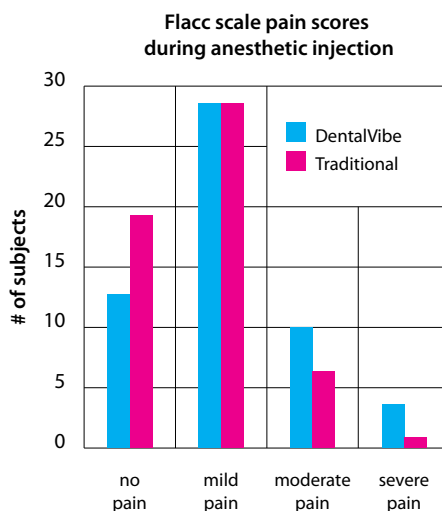


FIG. 4 Pain rating scores according to FLACC during anesthetic injection.

of 33 girls preferred the use of the DV during local anaesthesia administration, while 9 (33.3%) of 27 boys chose the DV.

According to the Spearman’s correlation coefficient, a negative correlation was found between age and pain rating scores with the FLACC after using DentalVibe during anaesthetic injection (Spearman’s correlation coefficient= $- 0.302$; $P= 0.019$). However, there was no statistically significant correlation between age and pain scores with the FLACC during needle insertion with the DV (Spearman’s correlation coefficient= -0.153 ; $P=0.243$). There was also no correlation for pain scores with PRS between age and both DV and TS techniques during needle insertion-anaesthetic injection.

Discussion

The purpose of this study was to compare the pain experienced during needle insertion with either a TS or

the DV in IANB injection. To the best of our knowledge, this is the first study aiming to evaluate the effectiveness of the DentalVibe in paediatric dentistry patients.

The progression of a child's physical, psychological, and cognitive development is important when examining his or her experiences of pain. These factors make pain assessment in children a particularly complex process [Bieri et al., 1990]. Since paediatric patients' subjective evaluation of pain may affect the reliability of the results, both subjective and objective evaluations were performed to measure pain in this study. The PRS, developed with the aim of subjective evaluation, has adequate psychometric properties, and it is easy and quick to use [Wong and Baker, 1998]. Chambers et al. [1999] stated that the PRS was preferred by a majority of children in their study. Furthermore, it was also the preferred pain assessment instrument of children 3 to 7, 8 to 12, and 13 to 18 years of age in another study by Keck et al. [1996]. However, it is not always reliable in young children, since not all children have reached the level of cognitive development necessary for understanding the pain scale [Versloot et al., 2005]. Moreover, young children have demonstrated a tendency to select faces at the extremes of the scale during procedure-related pain. The FLACC scale, which was developed with the aim of objective evaluation, has been shown to have excellent validity and reliability for pain assessment in young, cognitively intact children [Merkel et al., 1997; Breau et al., 2000]. Merkel et al. [2002] used the FLACC scale to assess post-operative pain in a post-anaesthesia care unit. Their conclusion was that the FLACC scale is reliable and valid in quantifying pain in children who have difficulties expressing severe pain. In the presented study, the PRS and FLACC were used concurrently to use the advantages of both assessment scales.

There are several devices used to decrease patients' fear of injection by taking advantage of the gate control theory of pain management [Dickenson, 2002]. VibraJect is one of those devices and has controversial performance. Nanitsos et al. [2009] and Blair [2002] have recommended the use of VibraJect for painless injections. Their results indicate that injections with vibration resulted in decreased pain. In contrast, Yoshikawa et al. [2003], Saijo et al. [2005], and Roeber et al. [2011] found no significant pain reduction when Vibraject was applied with a conventional dental syringe. They concluded that one possible reason is that the vibrations were extremely small and did not activate the large nerve fibers in that area for many individuals [Roeber et al., 2011]. Furthermore, according to them, the design of the device may be an important factor in pain perception. Vibraject was applied with an automated electric syringe with a dental needle. Since the dental needle is integrated in Vibraject and both of them are applied simultaneously, it was difficult to hide the needle from paediatric patients. This makes it more

complicated to apply for local anaesthesia. A similar device described in the literature is the DentalVibe, which was used in the present study. In contrast to VibraJect, the DentalVibe looks like a retractor similar to a dental mirror, and the needle is not integrated into the device, making it easier to hide the syringe from paediatric patient. The vibration is applied before the needle insertion and continues during the anaesthetic injection. Since initially applied vibrations attract paediatric patients' perceptions of pain, dental needles can be managed more easily.

The findings of the present study indicate that there was no statistically significant difference between DV and traditional injection techniques during needle insertion and anaesthetic injection. This result was inconsistent with previous studies that suggested decreased pain with DV use [Ching et al., 2014; Ungor et al., 2014]. In addition, it may not be suitable to compare the results of previous studies with those of the current study because the previous investigations were done using adolescents and adults, not in paediatric patients.

The present study found a negative correlation between age and pain scores on the FLACC after use of the DV during anaesthetic agent injection. It has been reported that, compared to older children, young children tend to assign higher intensity scores to pain, possibly because they have fewer pain experiences to use as reference points [Merkel et al., 1997]. The negative correlation could also be attributed to the young patients' discomfort with the sensation of vibration experienced with the DV system, which they reported as a higher pain rating. In addition, the DV required an injection time longer than traditional injections. Following the manufacturer's instructions, the needle was inserted after 5 seconds of vibration, and the DV continued to operate during needle insertion and anaesthetic injection. In the present study, the negative correlation found between age and pain scores might also be related to the longer duration of DV use compared to the conventional method, which might cause impatience and stress among children. That young children might become restless during the lengthy duration of injection required by the DV could be considered a disadvantage of the DV.

Moreover, a higher number of patients preferred traditional injections in the present study. To control for potential subject-expectancy effects and pressure from placement of the DV, it was placed near the injection side for all injections; however, it was not turned on for the TS group. A limitation of this study is that patients could not be completely blinded because of the vibration resulting from the DV. It is likely that the children did not feel comfortable with the vibration sensation caused by the DV and thus selected the traditional injection without the DV.

On the other hand, no significant gender difference

was found in both anaesthesia methods for pain scores during needle insertion and injection. The findings are consistent with a previous study in which boys and girls showed the same reaction while receiving local anaesthesia [Ram et al., 2002].

Conclusion

The results of this study showed that paediatric patients experienced similar levels of pain during IANB anaesthesia administered with a traditional syringe and with the DV. As patients' age increased, pain values reduced during anaesthetic agent injections with the DV according to the FLACC. The traditional procedure was preferred to the DentalVibe in children.

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