The effectiveness of computerized anesthesia in primary mandibular molar pulpotomy: A randomized controlled trial

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Objective: The technique of local anesthetic administration is an important consideration in the behavior guidance of a pediatric patient. The study hypothesized that there is no difference in the pain effectiveness in the experimental subjects with the use of single tooth anesthesia and the controls with the use of conventional technique (traditional inferior alveolar nerve block [IANB]). The purpose of this study was to compare the anesthesia effectiveness of traditional IANB; IANB using a computer-controlled local anesthetic delivery system (CCLAD); and intraligamental anesthesia (ILA) using CCLAD in pulpotomy of the primary mandibular second molars.

Method and Materials: Ninety-one healthy 5- to 9-year-old children underwent pulpotomy of the mandibular second molars. They were randomly assigned into Group A (traditional IANB), Group B (IANB using CCLAD), or Group C (ILA injection using CCLAD). The effectiveness of anesthesia was measured during different steps of pulpotomy using the sounds, eyes, and motor (SEM) scale. The postoperative complications were recorded after 24 hours.

Results: For all five pulpotomy steps, the anesthesia effectiveness was similar among the three anesthesia techniques. Anesthesia effectiveness was not significantly different (based on SEM scores) between the three groups during clamp application, drilling of the tooth, entering the pulp, pulp extirpation, and removal of the clamp ($P = .635$, $P = .996$, $P = .630$, $P = .945$, and $P = .101$, respectively). There was no significant difference in postoperative complications between the three groups.

Conclusion: The IANB anesthesia using CCLAD and periodontal ligament anesthesia using CCLAD were as effective as traditional IANB in anesthetizing the primary mandibular molars during pulpotomy. (Quintessence Int 2016;47:217–224; doi: 10.3290/j.qi.a34977)

Key words: anesthesia, computerized, effectiveness, mandibular, primary molars, pulpotomy

The dental treatment of pediatric patients is challenging in two important respects: anesthesia and painless treatment. Several aspects of delivering dental care may be hazardous for clinicians and patients. If the child is unrestrained during the injection of local anesthesia, injuries to the eye, cheek, lip, or limb can sometimes occur.1
The most widely used anesthetic technique is the inferior alveolar nerve block (IANB), and this is the gold standard technique for blocking the hemimandible.\textsuperscript{2,3} This technique is used in everyday dental and oral surgical practice. When it is combined with lingual nerve and long buccal nerve block, it provides adequate anesthesia of a wide anatomical area; this includes all of one side of the mandibular teeth and gingivae, the body and inferior ramus of the mandible, and the anterior two-thirds of the tongue and floor of the mouth.

High pressure periodontal ligament injection (ie, intraligamental anesthesia [ILA]) has also been employed, primarily as a mean of achieving complete anesthesia in a tooth in which regional block anesthesia had previously failed. The technique of this approach is to insert the needle through the gingival sulcus into the periodontal ligament between the tooth and the alveolar bone. The operator slowly injects a small volume of anesthetic solution under high pressure to control the pain of the associated tooth.\textsuperscript{4}

In 2006, a new concept of drug delivery was introduced to the dental profession: the computer-controlled local anesthetic delivery (CCLAD) system. A new version is called the single tooth anesthesia (STA) system. It is combined with dynamic pressure-sensing technology and is specifically engineered for dental applications.\textsuperscript{5}

Limited studies in children have compared the effectiveness of the ILA using CCLAD and the IANB using CCLAD to the gold standard IANB technique. The purpose of this study was to compare the anesthesia effectiveness of traditional IANB; IANB using a CCLAD; and ILA using CCLAD in pulpotomy of the primary mandibular second molars. The study also aimed to assess which technique provides the least postoperative pain and lip biting by the patient.

**METHOD AND MATERIALS**

**Patients**
The ethical committee of King Abdulaziz University (Jeddah, Saudi Arabia) approved the study. This study has been registered under NCT 02025140 identifier at http://clinicaltrial.gov. Consent forms were signed by the parents before starting the procedure, after they had been provided verbal and written information concerning the study.

The sample was selected from newly screened patients in the electronic filing system in the pediatric dentistry specialty clinics at King Abdulaziz University Hospital from November 2012 to April 2013. The children’s inclusion criteria were:

- age, which ranged from 5 to 9 years
- a child who was physically and mentally healthy
- a child who had no contraindications to local anesthesia
- a child who was cooperative with a behavioral rating of “positive” or “definitely positive,” according to the Frankl behavior classification scale\textsuperscript{6}
- a child who was diagnosed with carious primary mandibular second molars that required treatment by pulpotomy.

The exclusion criteria were:

- a child who was medically compromised
- a child who was uncooperative, or
- parents who did not provide consent.

Sample size calculation was based on the major outcome “pain effectiveness” using the sounds, eyes, and motor (SEM) scale, which states that calculation of sample size was based on the hypothesis that there is no true difference in means of the reported pain in the experimental subjects with the use of STA and the controls with the use of conventional technique (traditional IANB). The sealed envelope sample size equivalence trial calculator was used for sample size calculation (available at: https://www.sealedenvelope.com/power/continuous-equivalence).

The sample size calculation revealed that if there is truly no difference between the conventional and experimental groups, then 27 patients are required in each experimental group and 27 control subjects with probability (power) = 0.95. The Type I error probability associated with the test of this null hypothesis is $\alpha = .05$. In this time period, 2,100 patients were screened; only 1,043 patients were between 5 and 9
years. Of the 1,043 patients, only 120 patients fulfilled the inclusion criteria. Of the 120 patients, 100 patients agreed to participate in the study.

**Procedure**

The study methodology was a controlled, randomized, double-blind clinical trial. Block randomization technique was applied to assign participants to one of the three study groups. The study was performed by two investigators. The primary investigator performed the anesthesia technique and pulpotomy and assured concealment allocation. The second investigator (evaluator) who was blinded to the anesthesia technique evaluated the effectiveness of the anesthesia during the procedure by using the SEM scale.7

The SEM scale is an objective method that observes sounds, eyes and motor pain reactions. The reactions were classified on a scale from 1 to 4 into four categories; comfort, mild discomfort, moderately painful, and painful for each of the S, E, and M codes.7 The minimum and maximum scores of pain reaction would be 3 and 12 respectively. Study subjects were not informed about the group allocation.

Assurance of patient blindness was done using two steps: first, the children were blinded with a commonly used sun eyeglass so they could not distinguish the anesthetic delivery system. Second, the audible sounds were produced during both injection methods (ie, with the wand or the traditional syringe) so the children were unaware of the method being used.

Patients were randomly assigned to one of three groups (Fig 2). Group A underwent the traditional IANB, which was performed according to the standard technique.11 In everyday practice, an operator takes approximately 80 to 90 seconds to administer an IANB block.10

Group B underwent IANB using a computer-regulated device performed with the STA system. The IANB injection was administered in accordance with the manufacturer’s instruction. The model used was the STA system produced by Milestone Scientific. The handpiece was rotated when inserting the needle to avoid deflection. The foot pedal was set on slow delivery, and the rotating needle was slowly advanced through the tissue. The machine was adjusted in the aspiration mode. After negative aspiration, the cartridge was emptied at what is labeled as the “turbo mode” on the instrument. The time to administer a mandibular block with the wand is 90 seconds, as indicated in the manufacturer’s instructions.10

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**Figs 1a and 1b** The equipment used in the study. (a) (top to bottom) The traditional short needle, the extra-short needle single tooth anesthesia (STA), and the short needle STA. (b) The STA system.
Group C underwent ILA using CCLAD performed with the STA system using STA mode. During interligamental injection the automatic cruise was used to allow the operator to engage the control-flow without continuously depressing on the foot control. The needle was inserted in the sulcus parallel to the long axis of the tooth with the bevel facing the tooth. As the needle entered the sulcus (approximately 2 mm below the crest of the bone), the foot switch was activated at low rate and maintained at that rate throughout the entire injection. The technique described by the manufacturer for mandibular teeth recommends using two insertion sites. Pulpal anesthesia is provided with the administration of 1.2 mL of lidocaine (0.6 mL mesiolingually and 0.6 mL distolingually; for a mandibular molar, the administration always starts on the distal side and then proceeds to the mesial side).12

The tooth was approached at an approximately 45-degree angle to the vertical. The needle was placed in the gingival sulcus with the bevel toward the tooth lingually. The needle was then slowly moved down toward the root of the tooth until there was resistance. The needle was held in place without excessive pressure and was monitored for the sound and light prompts. When the light prompt arrived at the middle of the yellow zone, there was a good chance that the needle was in the correct site; if the light prompt arrived at the green zone, there was an excellent chance that the needle was in the correct injection site.5 All children anesthetized by ILA reached the correct site; if any single patient does not reach the yellow zone the first time, the needle should be removed and re-entered to the position until the yellow light prompt arrives.

Measurements of the effectiveness of anesthesia

The research evaluator, who was blind to the injection technique, observed all treatment sessions and was able to evaluate the effectiveness of the injection techniques during the five steps of pulpotomy. Pain reaction and behavior were recorded at the following steps:

- during the placement of the clamp
- during the drilling of the tooth
- on entering into the pulp
- on pulp extirpation
- at rubber dam removal.

The reactions were classified on a scale from 1 to 4 into four categories; comfort, mild discomfort, moderately painful, and painful for each of the S, E, and M codes. For sound this varies from 1 (no sounds) to 4 (screaming and sobbing). For eyes this varies from 1 (no eye signs) to 4 (crying and tears). For motor this varies from 1 (hand relaxed) to 4 (aggressive physical contact). The minimum and maximum scores of pain reaction would be 3 and 12 respectively.7

The intraexaminer reliability of the SEM scale was performed using a recorded video of the procedure. The effectiveness of anesthesia in 10 patients was evaluated twice: the first time during the procedure and
the second time after 24 hours using a video tape. After administering anesthesia, the equipment and needles were removed before the assistant observer’s entrance to the clinic. The parent was contacted by phone the day after the child received the anesthesia to check the child’s postoperative pain and postoperative lip biting.

**Statistical analysis**

The data were subjected to analysis using SPSS, version 16 (SPSS). Numeric data were described using the mean and the standard deviation (SD). Qualitative data were described by the frequencies and percentages. The interclass correlation test was used to measure the intraexaminer reliability. The analysis of variance (ANOVA) test and t test were used for group comparisons between the anesthesia groups in quantitative variables, and the chi-square test was used for qualitative variables. The level of statistical significance was set at $P < .05$.

**RESULTS**

The intraexaminer reliability of the effectiveness of anesthesia was assessed using the SEM scores. The intraexaminer reliability for the effectiveness of anesthesia was measured using the interclass correlation test, which indicated strong agreement in all five steps of pulpotomy: placement of the clamp, 0.987 (confidence interval [CI], 0.952–0.997); drilling of the tooth, 0.934 (CI, 0.771–0.983); pulp entry, 0.962 (CI, 0.864–0.990); pulp extirpation, 0.976 (CI, 0.913–0.994); and clamp removal, 0.890 (CI, 0.703–0.944).

The sample included 100 patients who gave signed informed consent. They were randomized to three groups. However, seven patients were excluded because of failure of the anesthesia technique or because of uncontrolled bleeding of the pulp, which is indicated for pulpectomy or extraction. Two patients were excluded because they refused application of rubber dam. The final sample comprised 91 children with ages ranging between 5 and 9 years. The sample consisted of 39 (42.9%) boys and 52 (57.1%) girls. The procedure was completed in 25 to 30 minutes. In nearly 50% of the patients (45 patients [49.5%]), pulpotomy was performed on the mandibular left second molar, whereas in the remaining 46 (50.5%) patients, it was performed on the mandibular right second molar.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>The effectiveness of the three anesthesia techniques during each pulpotomy step</th>
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<tbody>
<tr>
<td>Pulpotomy steps</td>
<td>Anesthesia technique</td>
</tr>
<tr>
<td>Clamp placement</td>
<td>3.354 ± 0.984</td>
</tr>
<tr>
<td>Drilling of the tooth</td>
<td>4.032 ± 1.923</td>
</tr>
<tr>
<td>Pulp entry</td>
<td>5.225 ± 2.348</td>
</tr>
<tr>
<td>Pulp extirpation</td>
<td>5.516 ± 2.541</td>
</tr>
<tr>
<td>Clamp removal</td>
<td>3.387 ± 0.989</td>
</tr>
</tbody>
</table>

*The statistical significance is $P < .05$, using the ANOVA test.
Table 2 shows the correlation between the mean score of SEM and patient age. We found an insignificant correlation between the mean SEM score and different age groups ($r = .095, P = .371$). In each step of the pulpotomy, there was a weak correlation between the effectiveness of the anesthesia and age. During clamp placement, drilling of the tooth, pulp entry, pulp extirpation, and clamp removal, the $r$ values were $r = .006, r = .145, r = .079, r = .073$, and $r = .013$, respectively. The mean SEM score during the whole pulpotomy procedure in males was 3.9436 and in females was 4.4346. However, there was no significant difference between the sexes ($P = .073$).

**Postoperative complications**

All parents were contacted after 24 hours to record if their child complained of postoperative pain or lip biting after the procedure. ILA was associated with the highest percentage (46.7%) of postoperative pain, but the difference was not statistically significant ($P = .396$) (Fig 3). Only two patients in the IANB group anesthetized by CCLAD showed lip biting; however, the difference in comparison to the other groups was not statistically significant ($P = .125$).

**DISCUSSION**

Very few studies have been conducted comparing CCLAD using STA-system to the IANB in the mandible. The design of this study was a double-blinded, randomized, controlled clinical trial that addressed three different anesthetic techniques in mandibular second molar pulpotomy. Traditional IANB was compared to IANB using CCLAD and to ILA using CCLAD.

IANB using CCLAD and periodontal ligament injection using CCLAD were as effective as the traditional IANB with no statistical difference between the groups. This is in contrast to the findings of Öztaş et al.\(^\text{12}\) who stated that the effectiveness of anesthesia with periodontal ligament injection during pulpotomy treatment was significantly lower than the effectiveness of anesthesia with IANB. This can be explained by the fact that the former study was performed before the intro-
duction of the STA system and the pressure-detecting sensor of the system, which made ILA more reliable, more predictable, and a more comfortable anesthesia. It was reported that injection is easier, faster, and more reliable when clinicians apply the STA concept to dental injections.5,13

The results compared the effectiveness of traditional IANB at the five steps during the pulpotomy procedure. The comparison showed that the pulp entering step and the pulp extirpation step were significantly more painful (based on the SEM scale), compared to rubber dam application and removal. Similar findings were found with the effectiveness of IANB using CCLAD and ILA using CCLAD. These results were supported by Amoudi et al,14 who concluded that the highest mean SEM scores were recorded on entering the pulp and on pulp extirpation, whereas during clamp removal the SEM mean score was very low when using the traditional infiltration method or the CCLAD method.

After 24 hours, the postoperative complications of the anesthesia were assessed by a phone call to the parents who were asked about the presence of postoperative pain at the site of the injection or postoperative lip biting because of numbness from the IANB. The data showed greater postoperative pain was associated with the ILA technique than with the other techniques; however, this difference was not statistically significant. The ILA technique is applied under high pressure, which is responsible for the postoperative pain. ILA, if delivered by a high-pressure syringe, can result in trauma to the periodontal tissue and prolong postoperative pain, which can persist up to 4 weeks.15,16 In the present study, the slow moderate pressures used in the STA system could explain the low postoperative discomfort.5 In the study of Öztas et al,12 no comparison was made between the postoperative pain of the intraligamental injection and IANB; however most patients stated that they preferred the ILA more than the IANB.12

Furthermore, developmental disturbances in the underlying permanent tooth buds are another complication of using ILA in primary dentition. A study that examined the spread of the solutions injected into the periodontal ligament found no concerns regarding slow delivery injection to the periodontal ligament.17

According to a study by Ashkenazi et al9 on the effect of computerized delivery intraligamental injection in primary molars on their corresponding permanent tooth buds, the CCLAD intraligamental injection does not increase the danger of any developmental disturbances to the underlying tooth buds.

CONCLUSION

The IANB and the ILA using CCLAD were as effective as the gold standard techniques for anesthetizing mandibular second primary molars during all five steps of pulpotomy and could be used as an alternative technique.

During the pulpotomy procedures, the data showed that the ILA using CCLAD provided more anesthesia to the main nerve supply of the tooth; however, a lower amount of anesthesia was used compared to IANB. This difference was not statistically significant.

Postoperative pain was more associated with intraligamental injection than both IANB anesthesia techniques, but the difference was not statistically significant.

Further research is needed in order to evaluate the anesthesia effectiveness of different techniques using the CCLAD.

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