Intraligamentary and Supraperiosteal Anesthesia Efficacy Using a Computer Controlled Delivery System in Mandibular Molars

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Purpose: *The purpose of this study was to compare pain, efficacy and postoperative complications of anesthesia in first primary mandibular molars anesthetized with either intraligamentary (IL) or supraperiosteal (SP) anesthesia using a computer-controlled delivery system (CCDS).* ***Study design:*** *This randomized, controlled-crossover, blind clinical trial was conducted with 90 children requiring bilateral extraction, pulpotomy or restorative treatment of first mandibular primary molars. A CCDS was used to deliver IL anesthesia to 1 deciduous tooth and SP anesthesia to the contralateral tooth in each patient. Severity of pain and efficacy of anesthesia during the treatments were evaluated using the Wong-Baker Faces Pain Rating Scale (PRS) and comfort and side effects were assessed using post-injection and post-treatment questionnaires. Data were analyzed using $\chi 2$ and Mann-Whitney U tests.* ***Results:*** *According to PRS scores, pain levels during extraction were significantly higher with IL when compared to SP. Patients reported significantly less pain during needle insertion with SP when compared to IL; however, rates of postoperative complications were significantly higher with SP when compared to IL.* ***Conclusions:*** *CCDS-administered IL anesthesia and SP anesthesia were similarly effective when used during restorative treatment and pulpotomy of primary mandibular molars; however, SP was more effective than IL when used during extraction procedures.*

Key words: intraligamentary, supraperiosteal anesthesia, computer-controlled delivery system.

INTRODUCTION

Local anesthesia and pain control are two of the most important elements of dentistry, particularly pediatric dentistry. Poorly controlled pain can result in adverse short or long-term consequences.[1,2] Although pain management during dental treatments has progressed greatly over the past several decades, local anesthesia delivery can still create problems, mainly in terms of needle phobia which is usually ranked first or second among the most common dental phobias and has been recognized as the most difficult aspect of patient management and a potential barrier to good dental care, especially in children.[3,5]

CCDS was developed to improve pain control during delivery of local anesthesia. The delivery device itself resembles a pen, which gives it an important advantage over traditional anesthesia techniques for child patients and others who are afraid of a conventional needle [6]. CCDS has been recommended for infiltration, nerve-block, intraosseous and intraligamentary injections. [3,6,7] According to the manufacturer, the computer-controlled anesthesia device maintains constant pressure and volume ratios, delivering local anesthetic solutions at a constant rate, regardless of tissue resistance. Previous studies indicate that CCDS injection seems less painful than injection with traditional anesthesia-delivery system. A study by Sumer et al. [8] reported that when compared to traditional systems, CCDS used with pediatric patients resulted in significantly less pain during needle insertion and injection. By contrast, a study by Ram et al. [9] reported that anesthesia-delivery systems had no effect on pain

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response; [10] however, another study by the same authors showed fewer negative reactions to CCDS and no signs of discomfort after treatment, and both Klein et al. [11] and Allen et al. [12] reported significantly less disruptive behavior in children during the injection phase with CCDS.

There are several methods for obtaining pain control using local anesthetics [13, 14] that vary according to the site of anesthetic solution deposition relative to the area of operative intervention. Intraligamentary anesthesia (IL), or 'periodontal ligament injection', is one of the main injection techniques used in the mandible. The technique saw a resurgence in popularity in the early 1980s with the manufacture of new syringe devices designed to facilitate injection.[13,15,16] While it can be used successfully in either the maxilla or mandible, it is most useful in the mandible, where it can provide pulpal anesthesia of a single tooth without the concurrent lingual and facial soft-tissue anesthesia produced by other mandibular nerve-blocking techniques.[16] As a result, IL plays a significant role in preventing possible postoperative trauma such as lip- or tongue-biting due to residual soft-tissue anesthesia, which lasts significantly longer than pulpal anesthesia. This is particularly important in pediatric dentistry, as most children may have difficulty coping with problems related to prolonged soft tissue anesthesia.[16-18]

Several studies have recommended IL anesthesia primarily for use in pediatric dentistry, with delivery administered using either a conventional or high-pressure syringe, or by CCDS.[13,15,16,19] Although one study [20] has recommended against the use of IL injection in primary teeth in order to avoid damage to the underlying dental bud, a recent study by Ashkenazi et al.[21] reported that a local anesthetic solution administered slowly using CCDS caused no damage to the periodontal apparatus or the permanent dental bud in children. However, the authors still warned against the use of both traditional and high-pressure syringes, suggesting instead CCDS for anesthesia delivery to primary molars.

Supraperiosteal (SP) infiltration is another anesthesia injection technique, the aim of which is to deposit local anesthesia solutions as close as possible to the apex of the tooth of interest.[22-24] Infiltration anesthesia often produces pulpal analgesia in the primary dentition, even in mandibular molars that are to undergo restorative treatment;[25,26] however, success rates for mandibular infiltration anesthesia of primary mandibular molars have been widely reported to decrease with age as a result of increases in mandible density.[17, 27, 28] In spite of the common belief that a thick cortical plate prevents liquid anesthesia from diffusing into the cancellous bone and, therefore, to the nerves supplying the dental pulp, a number of studies have suggested that holes in the mandible, including the mental foramen as well as multiple minor perforations, allow solution to diffuse into the cancellous space, making it possible to achieve pulpal anesthesia using infiltration techniques.[17,27,28] Several studies have reported on the effectiveness of local anesthetic solution injected into the mucobuccal fold between primary or permanent mandibular molar roots.[28-33] However, infiltration anesthesia has the drawback of producing soft-tissue anesthesia in conjunction with pulpal anesthesia and thus carries the potential risk of postoperative trauma in children.[17, 27]

The literature contains a number of studies [10, 34, 35] comparing the results of IL and SP anesthesia used for primary incisors and maxillary primary molars; however, there are no published reports comparing the use of IL and SP anesthesia in mandibular primary molars. Therefore, this study aimed to clinically evaluate IL and SP anesthesia delivered using CCDS for anesthesia of primary mandibular molars requiring extraction, pulpotomy or restorative treatment in terms of efficacy, injection pain, postoperative complications and patient preference.

MATERIALS AND METHOD

The study protocol was approved by the Ethics Committee of Kocaeli University (#73/2012), and written consent was obtained from parents and patients before any treatment. Based on data from a previous study[36], a minimum sample size of 66 subjects was calculated using the G*Power software program (Ver 3.1.9.2; power 0.80, α=0.05, β=0.20). Therefore, taking into account possible requirements for additional anesthesia or other events, this study was conducted with 90 children aged 6-12 years who were the first to meet the inclusion criteria and agree to participation from among those patients applying for routine dental treatment.

All patients required similar operative procedures (bilateral primary first molar pulpotomy, restorative treatment, or extraction) with similar levels of operative difficulty. Patients demonstrated either positive or definitely positive behavior during preoperative behavioral assessments (rankings of 3 or 4 on the Frankl Scale)[37], and none required a sedative or other pharmacological therapy to receive dental treatment. Patients with significant medical or dental history, allergies to local anesthetics or sulfites, or active pathosis in the area of the injection as well as patients taking any medication that might affect anesthetic assessment were excluded.

The study was conducted using a randomized, controlled crossover, blind design. Similar procedures were performed on both the left and right primary mandibular first molars of each patient using two different anesthesia techniques, with a minimum interval of at least 1 week between procedures, and the anesthesia used in the first procedure in a patient randomly selected using a computer-generated list. A total of 180 procedures were performed, with teeth divided into 3 equal groups according to procedure and 2 equal subgroups according to anesthesia technique.

All dental injections were administrated with a CCDS (Sleeper ONE, Dental Hi Tec, BP 30051, 49308 Cholet–Cedex, France) by the same operator who had two months' experience using the CCDS.

In preparation for treatment, the injection site was dried with a cotton-tip applicator, and topical anesthetic spray (Hurricaine, Beutlich, 1541 Shields Drive Waukegan IL 60085, USA) was applied to the injection area for 60 seconds before injection for both anesthesia techniques. Both SP and IL anesthesia techniques were performed using a short needle and Articaine Hydrochloride with 1/100,000 epinephrine (Ultracaine D-S forte, Hoechst Canada Inc., Montreal Quebec, Canada) as an anesthetic agent.

CCDS administration of local anesthesia was performed using the device's slow setting for anesthesia delivery. SP injections were performed according to the manufacturer's instructions for injection technique and time, with a single 1.0 ml dose delivered per tooth, requiring an average of 52 seconds. IL injections were performed according to the method described previously,[15] with 0.2 ml of solution deposited interproximally at both the mesial and distal roots, requiring approximately 15 seconds per injection. All pulpotomy and restorative procedures were performed using a rubber dam.

Pain levels were subjectively evaluated using the Wong-Baker FACES pain rating scale (PRS) [38] (Fig. 1), which measures the unpleasantness or affective dimension of a child's pain experience. 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 anesthesia injection, patients were asked to use the PRS to indicate how they felt during needle insertion and solution injection. Patients were also asked to provide PRS ratings at various stages of restorative treatment, pulpotomy and extraction procedures, as follows: For restorative procedures, during (1) use of the high-speed handpiece on enamel (HSHP), (2) use of the low-speed handpiece on dentine (LSHP), (3) placement of the matrix band (PM) and (4) tooth restoration (TR); for pulpotomy procedures, during (1) use of the high-speed handpiece on enamel (HSHP), (2) use of the low-speed handpiece on dentine (LSHP), (3) removal of coronal pulp (RCP), (4) placement of the matrix band (PM) and (5) tooth restoration (TR); and for extraction procedures, (1) during probing on the vestibular and palatal sides of the gingival sulcus for anesthesia control (P), (2) Gingival elevation and elevation (GE) and (3) extraction (E). Although patients were aware of the anesthesia technique being tested, the PRS was administered to patients and the data recorded by a trained dental assistant blinded to the anesthesia technique and who did not otherwise participate in treatment.

Postoperative complications were evaluated using information gathered from patients' parents. At the end of each procedure, parents were given cards listing possible postoperative complications (hematoma, swelling, infection and bleeding, lip biting) and asked to contact the clinic and note down on the cards if any of these complications were observed. Cards were collected at the subsequent appointments, and the data recorded. In addition, following the second appointment, patients were asked which of the 2 anesthesia techniques they preferred.

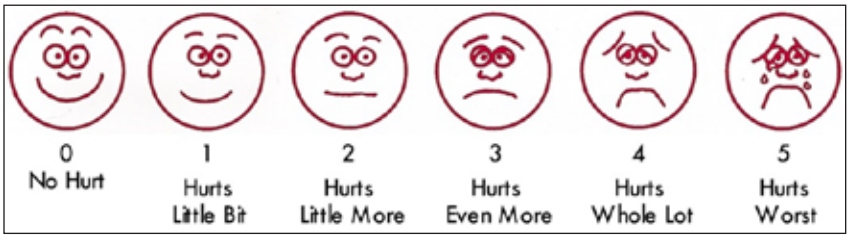
Statistical analysis was performed using a commercially available software program (SPSS 18.0; SPSS, Chicago, IL). Data were analyzed using $\chi 2$ and Mann-Whitney U tests.

RESULTS

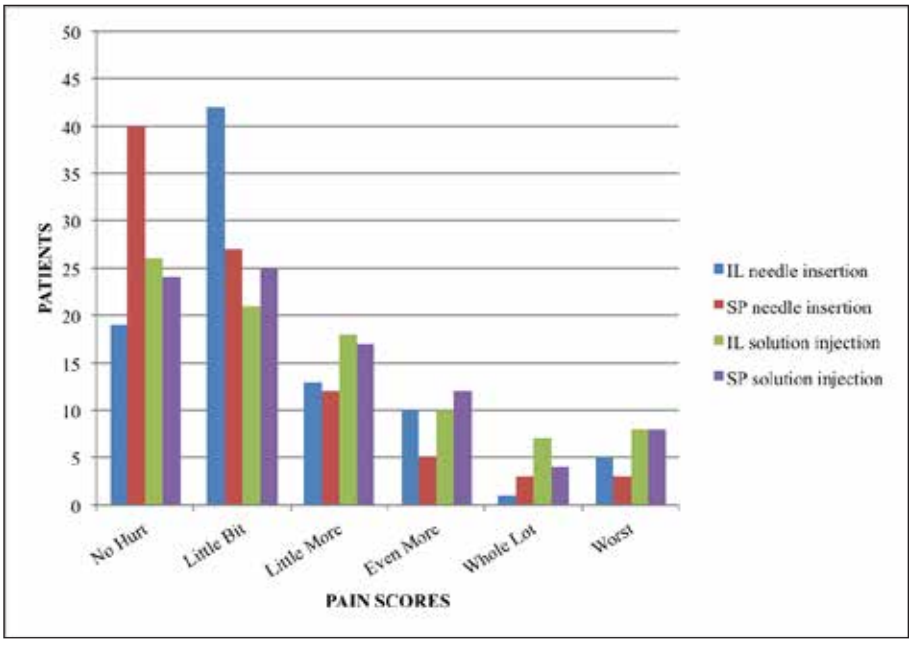
The study was conducted with 90 children [48 girls (53.3%), 42 boys (46.7%)] ranging in age between 6-12 years (mean age: 7.62±1.05 years). Both techniques were performed on each patient, for a total of 180 operative procedures.

Graph 1 shows the scores for pain during needle insertion and solution injection. Patients reported significantly less pain on needle insertion with the SP technique (P=.004). However, no significant difference in pain during solution injection was observed between the two anesthesia techniques (P=.822). Moreover, no significant

Figure 1: Wong-Baker FACES pain rating scale



Graph 1: PRS pain response scores during needle insertion and solution injection with intraligamentary and supraperiosteal technique



gender differences were observed in pain levels during needle insertion or solution injection (P=.264).

Graph 2 shows the scores for pain during pulpotomy. Overall, the SP group had a higher number of subjects reporting "no hurt" than the IL group, and the IL group had a higher number of subjects reporting "hurts worst" than the SP group. The majority of subjects in both groups reported "no hurt" during the use of HSHP (SP: n=21, 70%; IL: n=19, 63.3%). "No hurt" was also reported by 21 subjects (70%) in the SP group and 12 subjects (40%) in the IL group during use of LSHP, by 20 subjects (66.7%) in the SP group and 16 subjects (53.3%) in the IL group during RCP, by 13 subjects (43.3%) in the SP group and by 12 subjects (40%) in the IL group during PM, and by the majority of subjects in both groups (SP: n= 24, 80%; IL: n= 23, 76.7%) during TR. None of the subjects in the SP group reported "hurts worst" during any of the first 3 stages of pulpotomy, whereas in the IL group, "hurts worst" was reported by 2 subjects (6.7%) during the use of HSHP, by 3 subjects (10%) during use of LSHP, and by 4 subjects (13.3%) during RCP. Furthermore, "hurts worst" during PM was reported by 4 subjects (13.3%) in the SP group as well as 4 subjects (13.3%) in the IL group, and "hurts worst" during TR was reported by 1 subject (3.3 %) in the SP group as well as 1 subject (3.3%) in the IL group. Pain scores were higher for the IL group when compared to the SP group for all stages of the pulpotomy treatment procedures. However, no statistically significant difference in pain during pulpotomy was observed between the two anesthesia techniques (P=.577)

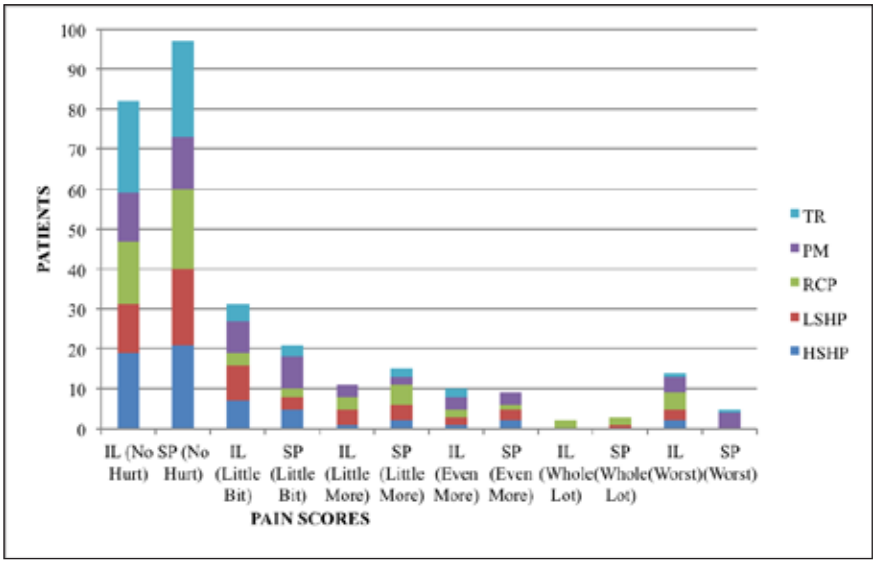
Graph 3 shows the scores for pain during restorative procedures. "No hurt" was reported by 21 subjects (70%) in the SP group and 16 subjects (53.3%) in the IL group during use of HSHP, by 16 subjects (53.3%) in the SP group and 17 subjects (56.7%) in the IL group during use of LSHP, by 18 subjects (60%) in the SP group and by 17 subjects (56.7%) in the IL group during PM, and by the majority of subjects in both groups (SP:n=23, 76.7%; IL:22=73.3%) during TR. By contrast, "hurts worst" was reported by only 1 (3.3%) subject in the SP group during use of HSHP and by only 1 (3.3%) subject in the SP group during use of LSHP and by only 1 (3.3%) subject in IL group during PM. Differences in pain scores between groups were not statistically significant for any of the stages of the restoration treatment procedures (P=.551)

Graph 4 shows the scores for pain during extraction. "No hurt" was reported by the majority of patients in both groups during P (SP:n=26, 86.7%; IL:N=24, 80%) during GE (SP:N=19 63.3%; IL:n=18 60%) and during E (SP:n=16, 53.3%; IL:n=8, 26%7). By contrast, "hurts worst" was reported by only 1 (3.3%) subject in IL group during E. Pain scores were higher for the IL group when compared to the SP group for all stages of the extraction procedures. But there was only statically significant difference for the extraction stage (P=.002).

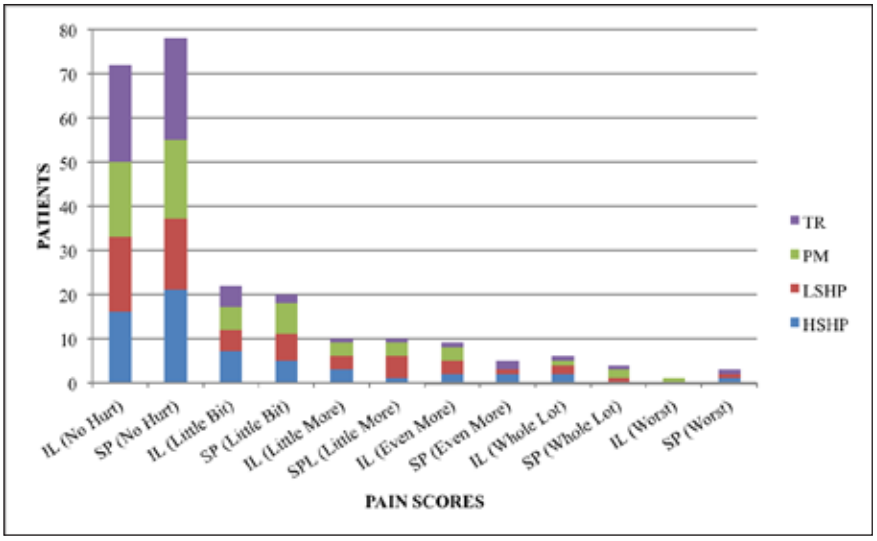
In terms of postoperative complications, overall, no significant differences were found between the two techniques. None of the patients reported postoperative complications severe enough to require clinical treatment. In total, post-operative pain was reported by 18 subjects (20%) treated with SP and by 23 subjects (26%) treated with IL; hematoma was reported by 20 subjects (22.2%) treated with SP and by 26 subjects (28.9%) treated with IL; and lip-biting was reported by 12 subjects (13.3%) treated with SP and by 2 subjects (2.2%) treated with IL. Intraoral bruising was evaluated as hematoma and none of the detected hematomas were visible extraorally. Also there was no report related to swelling or infection. Whereas the differences in rates between groups were not significant for post-operative pain and hematoma, the difference in lip-biting was significantly higher in the SP group when compared to the IL group.

With regard to patient preferences for anesthesia technique, more subjects preferred the SP technique (n=51, 56.7%) over the IL technique (n=39, 43.3%), but the difference was not statistically significant for gender. Preferences were similar for boys and girls.

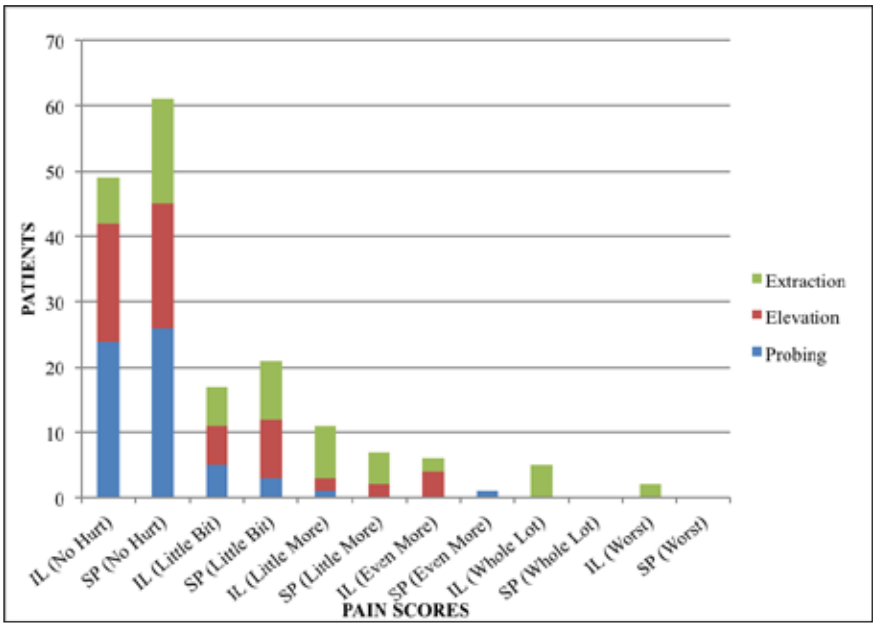
Graph 2: PRS pain response scores during the stages of pulpotomy with intraligamentary and supraperiosteal technique (HSHP: High speed hanpiece, LSHP: Low speed handpiece, RCP: Removal of coronal pulp, PM: Placement of matrix band, TR: Tooth restoration)



Graph 3: PRS pain response scores during the stages of restorative procedure with intraligamentary and supraperiosteal technique(HSHP: High speed hanpiece, LSHP: Low speed handpiece, , PM: Placement of matrix band, TR: Tooth restoration)



Graph 4: PRS pain response scores during the stages of extraction procedure with intraligamentary and supraperiosteal technique



DISCUSSION

The present study compared the effectiveness of SP and IL injection delivered by CCDS to primary mandibular molars. Given the wide range of variables involved (e.g. differences in anesthetic agents, anesthetic techniques, patient groups, evaluation methods), it is difficult to assess differences in anesthesia effects reported by different studies. To the best of our knowledge, this is the first study to compare the use of SP and IL anesthesia delivered using CCDS to mandibular primary molars.

In the present study, all injections were administrated by a single operator who had two months' experience using the CCDS, and all procedures were evaluated by a single clinician who was blinded to the anesthesia technique used. Previous studies have been conducted with one operator[39] or with multiple operators.[5,40] The present study conducted preoperative behavioral assessments using the Frankl Scale, and only patients who demonstrated 'positive' or 'definitely positive' behavior were included in the study. A literature review found that some, but not all studies included pretreatment behavioral assessments,[39-41] and Yılmaz et al.[40] also included behavioral assessment during restoration treatment that did not require local anesthesia. In the present study, due to lack of time, behavioral assessments were based only on observation during preliminary examinations.

While most studies evaluating the effectiveness of anesthesia

in adults use pulp testing to assess pain,[15,42] studies conducted with children commonly rely on subjective assessment of pain using PRS, both for its simplicity and in order to avoid possible cooperation problems. Despite the fact that self-reporting, as the most accurate way to evaluate pain, is considered to be the gold standard in pediatric pain assessment, it is not always reliable in young children,[2] since not all children under 6 years of age have reached a level of cognitive development necessary for understanding the pain scale.[19] Moreover, young children tend to assign higher intensity scores to pain descriptors than older children, possibly because young children have had fewer pain experiences to draw on as reference points.[43] In the present study, in order to improve the reliability of reported pain scores, only children aged 6-12 were included in the study. Similarly, a study by Koyuturk et al.[44] that evaluated the use of infiltrative anesthesia in mandibular and maxillary treatment limited participation to children aged 6-12 years.

Previous studies comparing injection pain have been conducted with either traditional syringes or CCDSs.[19] Sumer et al.[8] reported that patients who received anesthesia using a CCDS experienced significantly less pain on needle insertion and during injection. Yenisey [45] also reported pain levels during needle insertion and anesthetic delivery to be lower with CCDS than with conventional injection. Similarly, Zhao et al.[46] found children had lower pain scores at injection with CCDS than with a conventional syringe, although pain scores during treatment were not found to vary by injection system. This study used a CCDS for both IL and SP for a number of reasons. First of all, CCDS in general seems to result in less painful injections when compared to traditional syringes. Second, a traditional syringe may provoke fear in some children. Finally, a conventional syringe poses a potential risk to the underlying permanent tooth bud when IL anesthesia is used, whereas slow administration of a local anesthetic solution using CCDS has been shown not to increase the possibility of developmental disturbances during IL anesthesia delivery in primary dentition.[21]

This study found pain during needle insertion to be greater with IL anesthesia than with SP anesthesia. This conflicts with Ram and Peretz, [10] who reported modified Behavioral Pain Scale scores that indicated a more positive reaction from patients receiving IL using a CCDS when compared to those receiving SP anesthesia using a traditional syringe. The lower levels of pain observed in our study with SP may attributed to the fact that all anesthesia in our study was delivered using CCDS, which utilizes needles that are shorter and thinner than conventional injectors. Differences in findings between the two studies may also be related to the different scales used to evaluate pain as well as the different teeth evaluated (molars vs incisors).

Whereas the present study found IL and SP to perform similarly for pulpotomies and restorative treatment, IL was found to be less effective than SP for extraction. While no statistically significant differences in pain scores were found during gingival probing or during decolation and elevation, a significant difference was observed during tooth extraction. These results are inconsistent with the findings of Ashkenazi et al.[35] who concluded that the effectiveness of anesthesia using a CCDS (infiltration and intrasulcular) had a downward trend, but was not significantly different for restoration, pulpotomy and preformed crowns, or extraction. Differences in findings between two studies may be attributed to the the area in the oral cavity being injected. While they performed the study on maxillary primary molar teeth, the present study was conducted on mandibular primary molars. In the present study, also, it is possible that children interpret the pressure required for extraction as a type of pain or discomfort, which would explain why IL anesthesia was found to be less effective than SP during extraction. Moreover, teeth requiring extraction are usually affected by inflammation or periapical abscess, and, as reported by Ashkenazi et al.,[18,35] local anesthesia may be less effective in cases where acute local inflammation or other symptoms are present.

Our study also found post-operative complications to be affected by anesthesia technique; specifically, the SP group had a significantly higher rate of lip-biting than the IL group. This finding is expected, given that accidental biting or chewing of the lip, tongue or cheek is a common complication of residual soft-tissue anesthesia that occurs with the SP technique. Moreover, this finding is in line with Sammons et al.,[47] who reported fewer post-operative complications such as lip-biting, tongue-biting and postoperative pain among patients receiving IL delivery of local anesthesia in addition to general anesthesia when compared to controls.

A surprising result in the present study is that the rate of hematoma is higher compared to the literature. The result of this study showed that hematoma was reported for the 20 (22.2%) of the 90 injections with SP and 26 (28.9%) of the 90 injections with IL. Although Kuster and Udin[48], reported hematoma frequency as 0.1% in 4134 patients, they defined hematoma as a rapid swelling which caused an asymmetry of the face and small intraoral "bruise" at the injection site was not considered to be a hematoma in their investigation. As intraoral bruising was considered to be a hematoma in this study, the incidence rates in the results are in contrast with their report.

With regard to gender differences, the present study found no significant differences in terms of pain reported by boys and by girls, which is in line with the findings of a previous study.[40]

CONCLUSIONS

1. Pain scores were higher during needle insertion with IL than with SP.
2. IL and SP anesthesia administered by CCDS to be similarly effective in restorative treatment and pulpotomies of primary mandibular molars,
3. IL anesthesia appeared to be less effective than SP in extraction procedures.
4. Overall postoperative complications were similar, with the exception of lip biting, which was observed at a significantly higher rate with SP when compared to IL anesthesia delivery.

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