Clinical comparison of pain perception rates between computerized local anesthesia and conventional syringe in pediatric patients

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The purpose of this study was to evaluate pain perception rates in pediatric patients by comparing computerized injection device and traditional injection procedure. In a clinical trial, by using a crossover design, sixty-four patients were randomly assigned to receive, in consecutive sessions, dental anesthetic techniques with either traditional or computerized device. Visual Analogue Scale qualification and heart rate monitoring as physiologic indicator of pain response were used for the evaluation. Results showed that traditional syringe injections were more painful than computerized injection device ($p<0.001$). Results suggested that computerized injection device reduces pain perception compared to the traditional syringe during the dental anesthetic management.
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INTRODUCTION

The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[1] It can be conceptualized as a psychobiological phenomenon having both physiological and psychological components of perception and reaction to it. [2]

Pain evaluation is hard to measure because of a subjective component and a multidimensional character of its perception.[3] Even though today several methods exist, the assessment by self report is considered the "gold standard" for pain qualification.[4] Visual Analogue Scale (VAS) seems to be the most reliable and sensitive of this kind of techniques.[5] The VAS is a 100 mm line anchored at each extreme from "no pain" to "pain as bad as it could be"[3-6] and coloring graduated from blue to red. Therefore, the VAS is comprehensible and reliable for 8 years and older children.[4,7,8]

Local anesthetic injection is the most anxiety-provoking procedure for both children and adults dentistry patients.[9-10] Thus, it is necessary to search for techniques that minimize/reduce pain in patients in order for them to report greater satisfaction with treatment.[11,12]

There are many studies conducted to achieve a painless injection such as: the use of topical anesthetic,[13-15] warming anesthesia solution to body temperature[16,17] or increasing injection time by the administration of local anesthesia.[11,18] None of these techniques have eliminated anxiety and fear in patients.[19]

During the last three decades, researchers have demonstrated interest in dental fear.[20] The achievement of successful local anesthesia is a continuous challenge in dentistry.[21] North American national surveys have shown that between 1987 and 1999, dentists in private practice were obtaining up to date high technology equipment to decrease anxiety during the treatment. [22]

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Among this years, equipment such as: Needleless jet-injection systems,[21,23-25] electronic dental anesthesia,[26] intraosseus injection systems[21,27-30] and computer controlled system for local anesthetic delivery has been offered for clinical use.

The Council on Scientific Affairs evaluated the computer system for safety and efficacy according to the ADA Acceptance Program Guidelines for Instruments and Accessory Products and the American National Standards Institute/ADA Specification No. 34 for Dental Aspirating Syringes. The U.S Food and Drug Administration (FDA) through a 510 (k) application.27 The anesthetic cartridge is placed in a disposable plastic sleeve, which docks with the pump that delivers anesthetic solution through a micro-intravenous tube connected to a pen-like hand piece, cleared the local anesthetic delivery system, for marketing. This hand piece places a Lure lock of any size or a gauge needle. A foot pedal, with two flow-rate settings, controls injection. Slow injections regulated by this computerized system should be better than the traditional syringe, so the children would report less pain,[19,31,32] some studies showed significantly reduced disruptive behaviors[36,41] and some studies found no differences in disruptive behaviors.[42,43]

The computerized system delivers anesthetic at a constant pressure and controlled volume, regardless of the resistance in the tissues. The regulation of pressure and volume is directly related to pain. Dentists have tried to regulate pressure and volume by slowly pushing the anesthetic with their thumbs, but manual gauging is not perfect. Gauging pressure and volume of the anesthetic injection is not easy because the amount of resistance and pressure needle varies with each individual. A computerized system, however, offers considerable promises of reducing pain precisely because it can control pressure and volume.[23,33,34] In conjunction with this new technology, two new palatal injections that can anesthetize multiple maxillary teeth have been defined. A palatal approach to the Anterior Superior Alveolar nerve (P-ASA), a palatal approach to the Anterior and Middle Superior Alveolar nerves (AMSA) and new insertion methods are now possible.[35] Furthermore, all the same injection sites and techniques that we have previously used with a syringe can also be employed.[33, 34]

Only a few controlled clinic reports have evaluated the efficacy of this computerized anesthesia system in children. They have evaluated pain response by subjective self-report using VAS. However, heart rate, blood pressure, respiration or galvanic skin response can provide indirect measures of pain and anxiety, and could provide elements for further investigations. In addition, these measurements are not subject to observer bias and could provide important validation to direct observation measures.[36] The purpose of this study was to evaluate pain perception rates in pediatric patients by comparing a computerized injection device and the traditional injection procedure.

MATERIALS AND METHODS

The Institutional Review Board at San Luis Potosi University approved this protocol. The medical history of each patient was reviewed previous to treatment. A detailed informed consent form was signed by each his/her parents.

Sixty-four children, age 9 to 12 years programmed to operative dentistry procedure using local anesthesia participated in this study. There were no gender, race, or ethnic restrictions criteria for inclusion study. Patients that had a significant behavioral management problem were excluded from the study.

The tissues were dried with a 2x2 gauze. The topical anesthetic was applied and left in place for 1 minute. Then, the injection was administrated. Vestibular and palatal infiltrations were the only injections given. The same operator was used throughout the study. The local anesthetic was given using either the computerized system or the traditional syringe. All injections consisted in 2% Xylocaine with 1:100,000 epinephrine, administered with a 30-gauge needle. The amount of anesthetic administrated depended on the location of the injection, buccal infiltration (0.90 ml) or palatal infiltrations (0.45 ml).

The computerized system used in this study is a U.S. FDA approved device and it is a Milestone Scientific product. The computerized system injections were given according to the instructions of the manufacturer. This equipment has 2 delivery speeds controlled by an air-activated foot pedal. Only the slower speed mode was used. The traditional syringe injection was given according to the standard technique. Before the initiation of the study, the dentist took a technique course to perform the use of local anesthesia by a computerized system.

Each child, who used a 10-point VAS, provided the perception of pain. Prior to starting the dental treatment, a researcher explained the VAS to the patient. Heart rate, as a physiological indicator of pain response, was recorded by using a pulse oximeter (Nonin 9500). It was placed on the right finger of the patient and given continuous pulse rate. This type of oximeter is secure, easy to apply and does not interfere with the dental procedure.

Each subject was his own control. The computerized injection system and the traditional metal aspirating syringe injection were used on opposite side of each control group. A total of 4 injections were given to each child: 2 injections with the computerized system on one side and 2 injections with syringe on the other side.

Patients were blindfolded. The computerized system produces an audible beep during the administration of the injection. Because the beeping tone cannot be turned off, we produced the same beeping tone during

both injection methods so that the children would not be aware of which method was being used. During the injection, the heart rate was recorded. Immediately after each injection, we asked the children about the amount of pain they had perceived during the injection.

Statistical significance was tested with the use of the Student's t-test and the Kolmogorov-Smirnov test when appropriated. A probability value <0.05 was considered statistically significant. The statistical program was R version 6.2.[37]

RESULTS

Before injections, the two groups were comparable in age, gender, and previous experience with dental injections and heart rate. The average age was 10.5 years old with a range of 9 to 12 years old. Thirty-four were girls and 30 were boys. Mean scores of heart rate before injections were 84.72 and 78.51 for computerized and conventional respectively (p>0.05, Student's t test).

Table 1 shows the difference in heart rate between previous and trans-buccal infiltration in both methods of local anesthesia. Results indicated a statistically significant difference (p<0.001, Student's t test) between groups of treatment; the difference mean heart rate by using the computerized device was lower than conventional infiltration, indicating less painful injections.

Table 1. Difference mean in heart rate previous and trans-buccal infiltration.

	Conventional	Computerized
Difference mean heart rate	3.66±1.50	-1.03±0.31

p<0.001, Student´s t test

We compared the perception of pain by using VAS. Table 2 shows the distribution of the VAS scores. Patients experienced significantly less pain of injection with the computerized method (p<0.001, Kolmogorov-Smirnov test).

Table 2. VAS scores for conventional and computerized methods.

	Conventional	Computerized
Median (cm)	0.77	0.35
Minimum value	0.10	0.10
Maximum value	3.45	2.00

p<0.001, Kolmogorov-Smirnov test

The differences in hearth rate between previous and trans-palatal injection with both methods are show in the Table 3. The difference in the mean heart rate by using a computerized device was lower than conventional infiltration (p<0.01, Student's t test), indicating less painful injections.

Table 3. Difference mean in heart rate previous and trans- palatal infiltration.

	Conventional	Computerized
Difference mean heart rate	5.74±2.15	1.61±0.72

p<0.01, Student´s t test

Table 4 shows the comparison of the perception of pain when using both methods. Significant difference was found. Children experienced less pain with the computerized method (p<0.001, Kolmogorov-Smirnov test).

Table 4. VAS scores for conventional and computerized methods.

	Conventional	Computerized
Median (cm)	1.55	0.75
Minimum value	0.10	0.10
Maximum value	3.60	2.75

p<0.001, Kolmogorov-Smirnov test

DISCUSSION

Asarch *et al.*[19] did the first controlled clinic report in 1999. Fifty-seven children between 5 and 13 years old were used in this study. Inferior alveolar block injections, palatal, and buccal infiltrations were the only injections administered throughout this study. They found no significant difference in pain ratings or disruptive behavior between injections with the computerized system and injections with a traditional syringe. However, despite how well the study was executed, there were some problems with the wide age range. Children under 8 years old could not use the VAS with precision and these children did not serve as their own controls, so there were inadequate comparisons of anesthesia techniques.

Gibson *et al.*[37] did another investigation in 2000. Sixty-two healthy pediatric patients between 5 and 13 years old were used in this study. They explored the efficacy of the computerized system with children by extending and improving the limitations of Asarch *et al.*[19] They assessed disruptive pain behavior and pain ratings by children, comparing Wand-specific injections with traditional buccal infiltration/palatal injections. Slower injection speeds were used with the Wand, as recommended by the manufacturer. However, there were a few limitations to this study. First, as well as the Asarch *et al.,* [19] they selected children between 5 and 13 years old. Second, each child was randomly assigned to either the Wand or traditional syringe technique. Therefore, children did not have a good comparative control between themselves and injection sites.

Saloum *et al.*[38] did a controlled clinical report in 2000. Forty volunteers between 21 and 36 years old participated. Volunteers evaluated pain with a pain description scale (no pain, mild, moderate, and severe). This study had many advantages over the others. Patients were blindfolded so they would not be aware of the method being used. Three different injections were evaluated in this study: (1) MSA in the mucobuccal fold of the maxillary right and left first premolars; (2) palatal infiltration in the attached gingival of the maxillary right and left first premolars; and (3) bilateral mandibular IAN. All 3 injections were administrated in one side. The 3 injections on opposite side were administrated with the traditional aspirating syringe (control group). The Wand generally seemed to provide less painful injections when compared to the traditional syringe.

Allen *et al.*,[36] in 2002, used 40 healthy patients between 2 and 5 years old. Pain behavior was measured by using an established code. Buccal infiltration and palatal injection were administered with the traditional technique; a P-ASA and a palatal approach to the AMSA were used with the Wand injections. They demonstrated that the Wand could significantly reduce disruptive behaviors in children.

Primosch and Brooks[40] in 2002 compared pain response between two different flow rates (slow versus fast) of local anesthetic solution injected into palatal tissue using Wand device. Twenty adult people received bilateral palatal injections. VAS self reported was used to measure intensity and heart rate was used as a physiological indicator of pain response. The slow injection rate statistically had a minor pain response than the one with fast velocity. However, there was not a significant difference in mean heart rate between the two flow rates.

In 2003, Ram and Peretz[41] studied children reaction by comparing the use of local anesthesia in upper incisors with a conventional buccal infiltration, and a periodontal ligament injection with a computerized device (Wand). Ninety-eight children aged from 2 to 4 years old participated in this study. They found that more children reacted negatively while receiving the conventional infiltrative injection, whereas children who received the Wand anesthetic solution reacted positively. Children were sedated with hydroxyzine and nitrous oxide, so this could have produced a different result.

CONCLUSION

Under the conditions of this study, the computerized system of anesthesia seemed to provide less painful injections when compared to the traditional syringe in pediatric patients.

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