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Original Article

Behavioral response and pain perception to computer controlled local anesthetic delivery system and cartridge syringe

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Abstract

Aim: The present study evaluated and compared the pain perception, behavioral response, physiological parameters, and the role of topical anesthetic administration during local anesthetic administration with cartridge syringe and computer controlled local anesthetic delivery system (CCLAD). **Design:** A randomized controlled crossover study was carried out with 120 children aged 7-11 years. They were randomly divided into Group A: Receiving injection with CCLAD during first visit; Group B: Receiving injection with cartridge syringe during first visit. They were further subdivided into three subgroups based on the topical application used: (a) 20% benzocaine; (b) pressure with cotton applicator; (c) no topical application. Pulse rate and blood pressure were recorded before and during injection procedure. Objective evaluation of disruptive behavior and subjective evaluation of pain were done

using face legs activity cry consolability scale and modified facial image scale, respectively. The washout period between the two visits was 1-week. **Results:**Injections with CCLAD produced significantly lesser pain response, disruptive behavior ($P < 0.001$), and pulse rate ($P < 0.05$) when compared to cartridge syringe injections. Application of benzocaine produced lesser pain response and disruptive behavior when compared to the other two subgroups, although the result was not significant. **Conclusion:**Usage of techniques which enhance behavioral response in children like injections with CCLAD can be considered as a possible step toward achieving a pain-free pediatric dental practice.

Keywords: Behavior, cartridge syringe, computer controlled local anesthetic delivery system, local anesthesia, pain perception

Introduction

Dental anxiety and fear are a matter of concern for the treating dentist. The use of local anesthetic injections is one of the most anxiety-provoking procedure in dentistry. [1] Though it produces pain and anxiety, [2] its proper administration provides a relatively painless treatment and also helps in gaining the child′s cooperation.

The present study was planned to assess the pain perception, behavioral response, physiological parameters, and role of topical anesthetic administration during local anesthetic administration with cartridge syringe and computer controlled local anesthetic delivery systems (CCLAD).

Materials and Methods

This randomized controlled trial with crossover design was carried out in the children who had reported as outpatients in Department of Pediatric Dentistry. The study protocol was approved by the institutional review board and ethical committee consent (ref 011/KSRIDSR/EC/2011) was obtained. Written consent was obtained from parents of participating children.

Inclusion and exclusion criteria

One hundred and twenty children were included in the study based on the following inclusion criteria:

1. Age 7-11 years;
2. Children with American Society of Anesthesiologists I status;

3. No previous history of dental treatment and, who needed at least two clinical sessions of operative procedures preceded by local anesthetic injection, one on either side of the maxilla or mandible, neither of which was due to emergency.

Exclusion criteria were:

1. Children allergic to local anesthetics (lignocaine);
2. Children under medications that could alter the pain perception;
3. Medically compromised and special children;
4. Uncooperative patients (Frankl behavior rating 1-definitely negative).

Randomization

The children were randomly divided into two groups: Group A - receiving injections with CCLAD (Single Tooth Anesthesia [STA] Wand, Milestone Scientific Pvt. Ltd., Livingston, USA) during first visit and then cartridge injections; Group B - receiving injections with cartridge syringe (conventional) during first visit followed by CCLAD injections. Randomization pattern was generated using computer software (Random allocation software). Both the groups were further randomly divided into three subgroups: Subgroup one-children receiving 20% topical benzocaine (Mucopain, IPCA Laboratories, Bangalore, India) gel, subgroup two children receiving pressure using a cotton applicator; subgroup three children receiving no topical gel.

Measurement of baseline data

Before commencement of the treatment procedure, pulse oximeter probe (FTP-101, SCure Pvt. Ltd., Gujarat, India) and blood pressure (BP) cuff of digital BP monitor (Omron Healthcare Pvt. Ltd., Singapore) were fixed on the right hand index finger and on the left arm respectively. The baseline data of pulse rate and BP were obtained in the counseling room 10 min before procedure with the patient seated on a chair in an erect position. Three readings were taken and the mean score was calculated.

Injection procedure and interpretation

Children were familiarized with the interpretation of modified facial image scale (FIS) after being seated on the dental chair. The injection procedure was explained to all the children using standard and similar euphemisms. The injection site was dried with cotton and topical anesthetic gel was applied and allowed to remain for 30 s. In subgroup two, the cotton applicator stick was

pressed firmly to the tissue near the injection site as a counter-stimulation during the injection procedure. All injections which consisted of 2% lignocaine with 1:1,00,000 epinephrine were then administered with a one inch 30 gauge needle using the bi-rotational technique to minimize needle deflection. [3] In Group A, injections were administered with STA mode (1 cc per 207 s) was used initially till 1/4 th of cartridge was administered followed by the normal mode (1 cc per 35 s). In Group B, injections were given slowly at approximately 1 ml/min with an aspirating cartridge syringe (Septodont, France). All the injections were given by the same operator/primary investigator, to ensure that the results were not influenced by inter-operator variability. Objective evaluation of disruptive behavior was done using face legs activity cry consolability (FLACC) scale by a calibrated dental assistant. The physiological parameters (pulse rate, BP) were recorded during the injection procedure. Subjective evaluation of pain was rated using a modified FIS after the injection procedure. The washout period between the visits was 1-week. [4] During the next appointment, the child was administered local anesthetic injection using the alternative technique on other side of the jaw.

Statistical analysis

The data obtained were statistically analyzed using SPSS software (15.0, SPSS Inc., Chicago Ill, USA). *t*-test, Mann-Whitney test were used for comparing mean scores of FIS, FLACC of both modes of local anesthetic administration. ANOVA and Kruskal-Wallis test were used for comparing quantitative variables between the three subgroups. Tukey honestly significant difference test was used with ANOVA to compare the means of three subgroups that were found to be statistically significant. $P \leq 0.05$ was considered as statistically significant.

Results

One hundred and twenty children, 71 boys and 49 girls (mean age = 9.23 ± 1.52 years) were included in the study. The attrition rate was 4.5% ($n = 10$) as they did not report for the second appointment. 110 children were subjected to both computerized and conventional (cartridge syringe) injection technique.

Computer controlled local anesthetic delivery system versus cartridge syringe

Children who received injections with CCLAD showed a significant decrease ($P < 0.002$) in pain perception as seen by FIS scores when compared to cartridge group. There was a significant decrease ($P < 0.001$) in the disruptive

behavior on comparing the two groups [Table - 1]. Pulse rate was significantly increased ($P = 0.04$) in cartridge group. There were no significant differences in systolic and diastolic BP ($P > 0.05$) among the groups during injection [Table - 2].

Comparison between topical subgroups

There was a statistically significant difference between the three topical subgroups based on FIS and FLACC scores. Children who were given 20% benzocaine topical gel application showed lesser pain response and disruptive behavior when compared to applicator pressure and no topical gel subgroups, although it was not significant. This was evident while receiving injections with cartridge syringe and CCLAD [Table - 3].

On comparing the topical subgroups with each other, children who received injections with CCLAD showed no significant difference in FIS ($P = 0.94$) and FLACC ($P = 0.99$) scores between benzocaine and applicator pressure subgroups. Whereas, both benzocaine and applicator pressure subgroup was significantly better than no topical gel group [Table - 4]. In children receiving injections with cartridge syringe, there was a significant difference between benzocaine and no topical gel group when FIS ($P = 0.01$) and FLACC ($P = 0.001$) scores were compared. There was a significant difference between FLACC ($P = 0.04$) scores of benzocaine and applicator pressure group, whereas, FIS ($P = 0.407$) scores showed no significant differences [Table - 4]. There were no significant differences in physiological parameters irrespective of topical application method used for both modes of local anesthetic administration.

Patient behavior

The children receiving cartridge syringe injections showed more facial expressions, leg movements and were difficult to console when compared to CCLAD injections. On assessing the overall children′s behavior, 71 children (64%) showed better behavioral response while receiving CCLAD injections. 13 children (12%) demonstrated better behavioral response with cartridge syringe injections. 26 children (26%) showed similar behavioral response during both modes of local anesthetic administration.

Patient preference

Thirty-eight children preferred receiving local anesthesia with CCLAD while only 6 children preferred cartridge syringe injections. 66 children found both methods to be similar.

Discussion

Pediatric dentists prefer techniques and strategies that help to enhance the behavior of the children in the dental office. Dental anxiety and fear are strongly related to the impairment of having a quality oral health care in an individual′s life. Successful dental treatment in a child depends not only on the quality of treatment, but also in instilling a positive attitude toward dental care.

Various methods like usage of topical anesthesia and prolonged injection time, [5] distraction techniques, counter-stimulation, warming the anesthetic solution, [6] varying the rates of infiltration, buffering the local anesthesia, reduced speed of injection, [7] cooling of soft tissue injection site, [8] and change in appearance of anesthetic delivery system [9] have been used to eliminate/minimize pain during injections.

Studies by Asarch *et al*., Gibson *et al*., Allen *et al*., Ram and Peretz, Tahmassebi *et al*., have compared the pain response during local anesthetic delivery with cartridge and CCLAD. [2],[10],[11],[12] Asarch *et al*., Ram and Peretz and Tahmassebi *et al*. found no significant differences in pain response and disruptive behavior between both the techniques of administration. [2],[12],[13] Asarch *et al*., Ram and Peretz concluded that CCLAD produced lesser disruptive behavior than traditional syringe. [2],[12] Palm *et al*. stated that the measurement of associated change in physiological parameters during injection procedure would have minimized observer bias and provided validation for direct observation measures. [14] These parameters were assessed by San Martin-Lopez *et al*., Langthasa *et al*. [15],[16] However, the results were contradictory and not conclusive. There is minimal evidence which supports the role of topical anesthetic while administering injections with cartridge and CCLAD, which provided the rationale for conducting the present study.

In the studies by Asarch *et al*., Gibson *et al*., Allen *et al.* parallel study design was followed where the children were subjected to injection either by traditional syringe or CCLAD.[2],[10],[11] The possible demerit of this study design is that, in behavioral research the comparison of pain responses between individuals may be inappropriate as pain threshold differs in each person. Hence, in the present study crossover design was followed where the children served as his/her control. This was in accordance with the studies done by Ram*et al*., Palm *et al*., Langthasa *et al*. [12],[14],[16]

The children aged 7-11 years belong to concrete operational period according to Jean Piaget′s cognitive theory. The children in this age group become capable of reasoning logically when the problem is displayed before them which would help them in making the decision regarding pain perception. [17] Children who had a previous history of dental treatment were excluded as their previous experiences might influence the results of the study. In the present study, no attempt was made to sex match as the studies by Ram and Peretz, Tahmassebi *et al*. suggests there was no significant difference in pain reaction between girls and boys. [12],[13] However, Chapman HR, Kirby Turner NC stated that girls in general report more fear than boys. [18]

Asarch *et al*., Gibson *et al*., Allen *et al*. in their studies blindfolded the patients and switched on the sound of CCLAD during both injection procedures to reduce bias. [2],[10],[11]However, in our study we did not practice this as we believed blindfolding a child during the first visit for treatment might increase his/her anxiety level and alter the pain perception and physiological parameters. Standard and similar euphemisms and distraction techniques were used as alternative methods to reduce anxiety in both the groups.

Facial image scale was used to assess the subjective pain response. This scale is a valid and reliable measure of dental anxiety for employment with young children in clinical settings. [19] Ideally a scale should be short in length to maximize response from children and minimize time for administration; easy to hold the attention of child and be simple to score and interpret. [20] In this study, the scale was modified to three faces signifying:

1. No discomfort,
2. Mild discomfort,
3. Severe discomfort.

This was done to reduce the confusion among children while assessing pain.

Objective evaluation provides better information about the discomfort experienced by the child during injection procedure. The subjective evaluation can also differ according to child′s pain threshold level. In this study, FLACC scale was used to assess the behavior of the child during injection procedure. FLACC pain assessment tool incorporates five categories of pain behaviors: Facial expression; leg movement; activity; cry; and consolability. FLACC scale is a validated and a reliable scale used in assessing pain in acutely ill adults and children postgeneral anesthesia. [21] FLACC scale can be used for quantifying pain behaviors in children who cannot verbalize the presence or severity of pain.

The present study suggests that children who received injections with CCLAD showed significantly less pain and disruptive behavior when compared to children who received injection by cartridge. Gibson *et al*. compared CCLAD and traditional syringe in children of 5-13 years and concluded that no significant difference in pain ratings between them.[10] Palm *et al*. compared the pain perception while administering mandibular block with CCLAD and traditional method in children aged 7-18 years and concluded that mandibular block was less painful with the CCLAD. [14] Langthasa *et al*. compared pain perception while experiencing injections with a comfort control syringe (CCS) and conventional syringe in children aged 6-14 years. Injections with CCS were less painful and produced significantly less disruptive behaviors than a conventional syringe. [16] The age of patients and site of injection varied in all the above studies. Thus, the use of CCLAD produced less pain ratings irrespective of age and site of injection when compared to the traditional technique.

In the present study, children who received injections with cartridge showed more disruptive behavior as measured by FLACC scale. Gibson *et al*. reported that significantly fewer children cried or exhibited body movements while receiving injections with CCLAD during first 15 s. [10] Allen *et al*. reported a gradual increase in disruptive behavior in CCLAD group after the initial 15 s contrary to the above results. [11] This may be due to increased injection time with CCLAD, which might result in restless behavior particularly in preschool children. [14] Asarch *et al*., Ram and Peretz reported no significant differences in disruptive behavior while receiving injections with CCLAD and a traditional method respectively. [2],[12]

Pulse rate was significantly increased in children receiving cartridge injection. This may be due to increased and uncontrolled injection pressure while using cartridge syringe. The infiltration of injection fluid leads to increased pressure built up causing pain. [22] Kudo found a positive correlation between pressure at the start of injection and intensity of pain.[23] San Martin-Lopez *et al*. showed a significant difference in heart rate on comparing computerized device and conventional syringe. [15] Langthasa *et al*. found no significant differences in pulse rate, BP and body temperature while administering injections with CCLAD and traditional syringe. There were no significant differences in systolic and diastolic BP between both the techniques in the present study which were in accordance with Langthasa *et al*. [16]

In this study, benzocaine gel application produced lesser pain response and disruptive behavior than the other 2 topical subgroups in children receiving both CCLAD and cartridge syringe injections, although it was not statistically

different. Nayak and Sudha showed 18% benzocaine gel had the most rapid onset of action and was superior in pain reduction when compared to 5% lignocaine ointment and 5% eutectic mixture of local anesthetics cream due to its low dissociation constant. [24]

In children who received CCLAD injections, the pain perception and behavioral response was nearly similar while using benzocaine and topical applicator pressure and was significantly better than no topical gel application. Thus, the injections with CCLAD were less painful irrespective of the topical application method (benzocaine and counter-stimulation) used. Children who received injections with cartridge showed the significantly lesser disruptive behavior when benzocaine topical application was used. The subjective pain response showed no statistically significant difference irrespective of whether benzocaine or topical pressure was used. Subjective evaluations may have differed due to variations in pain threshold among the children. However, children may show a change in their behavior in the presence of pain.

The children who received cartridge syringe injections showed more facial expressions, leg movements and were difficult to console when compared to CCLAD group. Ram and Peretz showed that there was no significant difference in crying, facial expression, hands, legs, and torso movements while receiving injections with CCLAD and conventional syringe. This was seen irrespective of the age group (3-5 years, 6-10 years) being compared. [12] Body movements, crying and application of restraints occurred more frequently while using a traditional syringe. [25]

There were a few limitations in this study that need to be considered. The operator and subjects were not blinded to the mode of local anesthetic delivery. An attempt was made to minimize this bias by using an independent observer for coding the behaviors. The reliability of these results could have been further improved by videotaping the injection procedure and allowing a third investigator to evaluate it.

Techniques which enhance the behavioral response in children should be considered for a better pediatric dental practice. Use of CCLAD can be considered as a possible step toward achieving a relatively pain-free and successful pediatric dental practice.

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