

In vivo Evaluation of 4% Articaine and 2% Lignocaine Intraligamentary Injection Administered with Single Tooth Anesthesia-Wand

Abstract

Background: The available literature confirms the effectiveness of intraligamentary injections equal to nerve blocks and articaine equal to lignocaine with better depth of penetration for single tooth pulpectomy procedures with less postoperative soft tissue trauma. An advancement in the field of local anesthesia delivery is the Single Tooth Anesthesia-Wand (STA-Wand) which is relatively pain-free and offers comfort to the child. **Aims:** This study aims to evaluate and compare the anesthetic effectiveness and postoperative complications of 4% articaine and 2% lignocaine intraligamentary injection administered as single tooth anesthesia using a computer-controlled local anesthetic delivery system, the STA-Wand. **Settings and Design:** Using a randomized, split-mouth, cross-over study design, twenty children aged 4–10 years who required bilateral mandibular pulpectomies were administered intraligamentary injections with 4% articaine and 2% lidocaine in two appointments using STA-Wand. Pain, anxiety, and cooperation levels were scored by an operator and an observer at four phases of treatment using Wong-Baker Faces Pain Rating Scale and Two-6 point Co-operation Anxiety Rating Scale. Results were tabulated and analyzed. **Statistical Analysis:** Mann-Whitney U-test, paired *t*-test, and Student's *t*-test. **Results:** Both the local anesthetic agents were equally effective with no significant difference ($P > 0.05$) throughout rest of the treatment procedure compared to injection phase in minimizing pain, anxiety, and gaining the cooperation levels of children whereas during injection phase, 4% articaine showed superior effectiveness in minimizing pain compared to 2% lignocaine ($P = 0.054$). **Conclusion:** Both the local anesthetic agents delivered using STA-Wand is clinically acceptable, effective, and safe for usage in children.

Keywords: Articaine, intraligamentary injection, lignocaine, Single Tooth Anesthesia-Wand

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Introduction

“Although the operative dentistry may be perfect, the appointment is a failure if the child departs in tears,” stated Mc Elroy (1895). The appointment can be made successful by controlling the factors responsible for child's fear and anxiety. One such stimuli reported to be responsible is the fear of injection.^[1] This can be eliminated by administering an anesthetic agent that has the ability to work efficiently in controlling pain with an effective technique and also through a drug delivery system that has the potentiality to deliver an anesthetic agent absolutely pain-free.

There are advancements in local anesthetic drug delivery systems which claim to deliver local anesthesia in a relatively painless manner. The choice of an anesthetic agent plays a significant role in achieving full potency of the anesthetic action to

control pain. The local anesthetic agent lignocaine hydrochloride has been widely used for dental local anesthesia due to its proven efficacy with low allergenicity and toxicity. At the same time, articaine is the only amide anesthetic containing an ester group. It contains a thiopentene ring that enables greater lipid solubility and potency as a greater portion of an administered dose can enter neurons and thereby providing enhanced diffusion properties and better anesthetic efficacy. Furthermore, the lower systemic toxicity of articaine allows it to be used in a concentration (4% solution) higher than other amide local anesthetics.^[2] Wright *et al.* reported the successful use of articaine with epinephrine in children with less incidence of complications and side effects.^[3]

The management of disruptive and uncooperative children receiving one of the

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Access this article online

Website:

www.contempclindent.org

DOI: 10.4103/ccd.ccd_882_16

Quick Response Code:



How to cite this article: Chenchugopal M, Mungara J, Venumbaka NR, Elangovan A, Vijayakumar P, Rajendran S. *In vivo* evaluation of 4% articaine and 2% lignocaine intraligamentary injection administered with single tooth anesthesia-wand. *Contemp Clin Dent* 2017;8:315-20.

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most stressful dental procedures like pulpectomy of lower molar teeth continues to represent a special challenge to pediatric dentists since it depends on their ability or skill in delivering the local anesthesia in a painless manner with effective local anesthetic agents that can work effectively throughout the treatment procedures.

Clinical studies on articaine and lignocaine have focused on the time to onset of clinical anesthesia, dose, duration, depth of anesthesia along with the safety and efficacy profile, and mean time of onset in children versus adults, infiltrations and nerve blocks, conventional syringe versus computer-controlled drug delivery system Single Tooth Anesthesia-Wand (STA-Wand) administered for restorative procedures and extractions.^[4,5] The available literature on articaine confirms the effectiveness of conventional single buccal infiltrations in maxillary primary molar extractions replacing the need of painful palatal injections which is usually required whenever conventional infiltration anesthesia with lignocaine is preferred.^[6] Interestingly, the literature available on the efficacy of articaine intraligamentary injections administered with Wand for pulpectomy procedures on primary molar teeth seems to be limited, and sometimes, the intraligamentary injections have also been considered to overcome the drawbacks of nerve block particularly when there is a need for treatment procedures in bilateral quadrants at the same appointment.^[7,8]

With this background, the present study was undertaken to assess and compare the efficacy and postoperative complications of 4% articaine hydrochloride with 1:100,000 epinephrine and 2% lignocaine hydrochloride with 1:100,000 epinephrine delivered by STA-Wand as intraligamentary injections in pediatric patients by evaluating the level of pain, anxiety, and cooperation at various intervals of the single visit primary mandibular molar pulpectomy procedure.

Methods

Twenty children aged 4–10 years who required at least one tooth on each side of the mandibular arch indicated for single sitting pulpectomy procedure under local anesthesia were selected after eliminating the medically compromised children and children with significant behavior management problems. Selected children were randomly allocated to receive either 1.8 ml of 2% lignocaine or 0.9 ml of 4% articaine local anesthetic agent during the first appointment of the treatment procedure on one side of the arch with the other agent being delivered during the second appointment of the treatment procedure on the other side of the arch by a split mouth, cross-over, computer-generated random permuted block design.

The study design was approved by the Institutional Review Board, Ragas Dental College, Chennai. The parents of all selected children were clearly explained

about the procedure with a written consent obtained. Each child served as his/her own control. A minimum of 1 week time difference was maintained between the two appointments to avoid the effect of carry-over phenomenon in children. During the second appointment, exactly the same type of protocol was followed with only change being the local anesthetic agent delivered with the specified amount. The operative procedure carried out was similar for all children and was completed in the same appointment.

Based on the study design, the anesthetic effectiveness and postoperative complications of both the LA agents were assessed and compared at various intervals during mandibular molar single visit pulpectomy procedure by evaluating the pain, anxiety, and cooperation levels of children using Wong-Baker Faces Pain Rating Scale, Two-6 point Co-operation Anxiety Rating Scale and also by evaluating the postoperative adverse events through telephone follow-up and recall examination at 24 and 48 h following the operative procedure.

During the initial appointment, basic treatment procedures such as fluoride application, oral prophylaxis, atraumatic restoration of shallow pits and fissure carious lesions were completed as per the requirement for each child using basic behavior management techniques to relieve child's fear and anxiety as well as to desensitize the child for the dental environment. Behavior analysis was done during these prior visits only for the purpose of subject inclusion and exclusion. The method of correlating the faces of the Wong Bakers Faces Pain Rating Scale with child's pain experience was explained to the child before the scoring so that the operator could be assured that the child thoroughly understood what he/she was being asked to do during the procedure. An independent observer was equally well trained and familiarized regarding the scoring criteria of Two-6 point Co-operation Anxiety Rating Scale. During initial appointments, baseline pain, anxiety, and cooperation scores were not considered for comparison as the selected children were requiring bilateral treatment procedures and pain intensity may vary based on the individual tooth's pulp status.

On the day of appointment for the pulpectomy procedure, 20% benzocaine topical anesthetic gel was applied on the sulcal area of the lingual gingiva for 1 min before the delivery of intraligamentary injection at the mesiobuccal and distobuccal line angle of the tooth with the needle directed at an approximately 30° angle to the long axis of the tooth in the buccal-lingual plane in an attempt to numb the intraoral soft tissue mucous membrane of the gingiva to prevent mild pain/discomfort during needle prick if at all caused. The working field was isolated with a rubber dam following which the pulpectomy procedure was carried out as per guidelines by a single operator and pain, anxiety, and cooperation were observed and scored by both the operator and the observer during local anesthetic administration,

rubber dam application, access cavity preparation, and pulp extirpation. If any disparity between scores were noticed, then final scores were given after arriving at a conclusion in consensus at the end of each interval of the treatment procedure.

Following pulpectomy, children were examined at 24 and 48 h through periodic telephonic calls made to the parent to assess the occurrence of any adverse events. The placement of stainless steel crowns was purposefully postponed to the next appointment for eliminating any impact of it on the assessment of the postoperative complications that could probably occur due to anesthesia. Scores recorded were tabulated and statistically analyzed with SPSS software version 19.0 (Unicom Systems, Inc., Beverly Hills, CA, United States) using Mann–Whitney U-test, Paired *t*-test, and Student’s *t*-test.

Results

Pain scores

Even though both 4% articaine (18 [90%] children with score 0 and 2 [10%] with score 2), ($P = 0.637$, $P = 1.000$ Table 1) and 2% lignocaine (15 [75%] children with score 0, 4 [20%] with score 2 and 1 [5%] with score 4), ($P = 0.308$, $P = 1.000$), were equally effective throughout rest of the treatment procedure following injection phase, 4% articaine (17 [85%] children with score 0 and 3 [15%] with score 2) was showing slightly better effectiveness in minimizing pain levels of children during injection phase compared to 2% lignocaine (12 [60%] children with score 0, 6 [30%] with score 2 and 2 [10%] with score 4), ($P = 0.066$). However, there was no statistically significant difference in the pain scores between the two anesthetic agents during rest of the treatment procedure compared to the injection phase ($P = 0.204$).

Anxiety scores

Even though both 4% articaine (20 [100%] children with score 1) and 2% lignocaine (18 [90%] children with score 1 and 2 [10%] with score 2) were equally effective throughout rest of the treatment procedure following injection phase ($P = 1.000$), their effectiveness increased during rest of the treatment procedure compared to injection phase and that difference was not statistically significant with 4% articaine ($P = 0.317$) whereas, with 2% lignocaine, it was statistically significant ($P = 0.024$).

During injection phase, 4% articaine (19 [95%] children with score 1 and 1 [5%] with score 2) was significantly effective in minimizing the child’s anxiety compared to 2% lignocaine (12 [60%] children with score 1, 5 [25%] with score 2 and 3 [15%] with score 3), ($P = 0.012$), However, there was no statistically significant difference in the anxiety scores between the two anesthetic agents during rest of the treatment procedure following injection phase ($P = 0.152$).

Table 1: The mean pain, anxiety, and cooperation scores of children during local anesthetic injection and treatment

	Mean pain score with SD				Mean anxiety score with SD				Mean co-operation score with SD				
	Phase I	Phase II	Phase III	Phase IV	Phase I	Phase II	Phase III	Phase IV	Phase I	Phase II	Phase III	Phase IV	P
4% articaine (n=20)	0.30±0.733	0.20±0.616	0.20±0.616	0.20±0.616	0.948	1.05±0.224	1.00±0.000	1.00±0.000	0.398	1.05±0.224	1.00±0.000	1.00±0.000	0.398
2% lignocaine (n=20)	1.00±1.376	0.60±1.142	0.60±1.142	0.60±1.142	0.649	1.55±0.759	1.10±0.308	1.10±0.308	0.005	1.50±0.688	1.10±0.308	1.10±0.308	0.008
P	0.054	0.179	0.179	0.179	0.010*	0.163	0.163	0.163	0.011*	0.163	0.163	0.163	0.163

Paired *t*-test and Student’s *t*-test. Pain score of 4% articaine (Phase I versus Phase II, III, IV) - $P=0.948$, Pain score of 2% lignocaine (Phase I versus II, III, IV) - $P=0.649$, Pain score of 4% articaine (Phase I) versus 2% lignocaine (Phase I) - $P=0.054$, Pain score of 4% articaine (Phase II, III, IV) versus 2% lignocaine (Phase II, III, IV) - $P=0.054$, Anxiety and cooperation score of 4% articaine (Phase I vs. Phase II, III, IV) $P=0.398$. *Anxiety score of 2% lignocaine (Phase I vs. II, III, IV) $P=0.005$. *Anxiety score of 4% articaine (Phase I) versus 2% lignocaine (Phase I) $P=0.010$. *Co-operation score of 2% lignocaine (Phase I vs. II, III, IV) $P=0.008$. *Cooperation score of 4% articaine (Phase I) versus 2% lignocaine (Phase I) - $P=0.011$. Anxiety and cooperation score of 4% articaine (Phase II, III, IV) versus 2% lignocaine (Phase II, III, IV) - $P=0.163$. SD: Standard deviation

Cooperation scores

Even though both 4% articaine (20 [100%] children with score 1) and 2% lignocaine (18 [90%] children with score 1 and 2 [10%] with score 2) were equally effective throughout rest of the treatment procedure following injection phase ($P = 1.000$), their effectiveness increased during rest of the treatment procedure compared to injection phase and that difference was not statistically significant with 4% articaine ($P = 0.317$) whereas with 2% lignocaine, it was statistically significant ($P = 0.026$).

During injection phase, 4% articaine (19 [95%] children with score 1 and 1 [5%] with score 2) was significantly effective in gaining the cooperation of children compared to 2% lignocaine (12 [60%] children with score 1, 6 [30%] with score 2 and 2 [10%] with score 3), ($P = 0.008$). However, there was no statistically significant difference in the cooperation scores between the two anesthetic agents during rest of the treatment procedure following injection phase ($P = 0.152$).

Mean pain, anxiety, and cooperation scores

Four percent articaine was consistently effective throughout rest of the treatment period following the injection phase of the procedure in minimizing the pain [$P = 0.948$ Table 1], anxiety [$P = 0.398$ Table 1], and gaining the cooperation [$P = 0.398$ Table 1] levels of children compared to injection phase with a difference that was statistically nonsignificant.

Two percent lignocaine was consistently effective throughout rest of the treatment period following the injection phase of the procedure in minimizing the pain [$P = 0.649$ Table 1] levels of children compared to injection phase with a difference that was statistically nonsignificant and was significantly effective throughout rest of the treatment period following the injection phase of the procedure in minimizing the child's anxiety [$P = 0.005$ Table 1] and gaining the cooperation levels of children [$P = 0.008$ Table 1] compared to injection phase with a difference that was statistically significant. During injection phase, 4% articaine was significantly superior in minimizing the pain [$P = 0.054$ Table 1], anxiety [$P = 0.010$ Table 1] and gaining the cooperation [$P = 0.011$ Table 1] levels of children compared to 2% lignocaine. However, both the local anesthetic agents were equally effective in minimizing pain [$P = 0.179$ Table 1], anxiety [$P = 0.163$ Table 1] and gaining the Child's cooperation [$P = 0.163$ Table 1] during rest of the treatment procedure following the injection phase of the procedure.

Safety

None of the children had an incidence of postoperative soft tissue trauma, paresthesia (prolonged numbness), pain at the site of injection, and allergic reactions of any kind following the administration of either 4% articaine or 2% lignocaine ($P = 1.000$).

Discussion

Anxiety about dental injection is a common obstacle in that it causes many patients to delay or avoid the dental treatment. It is important to take appropriate measures to relieve child's fear and anxiety by utilizing the advancements in agents and techniques for local anesthesia to give maximum possible comfort to the child with a minimal amount of pain. Hence, the present study was done to check the efficacy of 4% articaine and intraligamentary injections delivered by STA-Wand and to compare with that of 2% lignocaine.

Despite the delivery of the local anesthetic agent using a pain-free delivery system, the application of topical anesthetic was usually considered in this study as an attempt to reduce discomfort associated with needle penetration and it had no effect on either the injection technique or the delivery system at all. The amount of the topical anesthetic applied was kept very minimal in the present study keeping in mind the systemic absorption of the topical anesthetic drug when calculating the total amount of local anesthetic dosage administered. However, the benzocaine (ester) topical anesthetic was used in this study as they are poorly absorbed into the cardiovascular system and less likely causes an overdose.

Literature has proven STA-Wand's efficacy and safety in delivering the local anesthetic agent in a relatively painless manner in pediatric population. STA-Wand significantly offers less pain and reduced behavior disruption and possibly increased safety in young children, making it a potential asset to any practitioner's armamentarium.^[9] In a study done by Ram and Peretz,^[10] children displayed better behavior and showed no signs of discomfort when they received local anesthesia with STA-Wand compared to conventional infiltration. Palm *et al.*^[11] showed that Wand offers less painful mandibular block injections than using traditional methods. Previous studies on the computerized system of anesthesia seemed to provide less painful injections compared to the traditional syringe in children.^[12,13] Interestingly, Asarch *et al.*^[14] reported that "There was no significant differences in pain ratings and disruptive behavior of children between the computerized and the traditional method of administering local anesthetic injections."

Numerous studies have shown STA as effective as mandibular nerve block for carrying single tooth treatment procedures. Malamed^[15] showed periodontal ligament injection as a successful alternative to the conventional nerve block techniques for mandibular anesthesia. Oztas *et al.*^[8] showed significantly lower pain scores during the periodontal ligament injection using STA-Wand compared to traditional inferior alveolar nerve injection.

The available literature on articaine use in children shows that it is safe and effective for clinical procedures in

children of all ages and it also has an anesthetic potency 1.5 times that of lignocaine and 5 times that of procaine.^[16] In the present study, 0.9 ml (Half the cartridge) of 4% articaine was used as it was recommended by Malamed in the year 1997 that when using any local anesthetic with 4% concentration, the drug volume should be reduced to half for multi-rooted teeth. Articaine provides enhanced diffusion with deeper penetration and has been proven as an effective replacement for conventional palatal injections with local anesthetic agent like lignocaine usually during primary maxillary molar extractions in children.^[6] Hence, in the present study, articaine was compared with its predecessor lignocaine when delivered as intraligamentary injections by a computer-controlled local anesthetic delivery system.

In the present study, children requiring bilateral pulp therapy procedures were selected based on their treatment requirement. In that case, pain severity may vary from one side to the other side based on the pulp status. Hence, baseline pain, anxiety, and cooperation scoring of the initial appointment were not considered for comparison. Following a randomized, split-mouth, cross-over study design, either of the local anesthetic agent were delivered to the ascertained group, and the pulpectomy procedure was carried out as per the guidelines.

The anesthetic efficacy of the agent depends on its ability to control pain. Pain evaluation is hard to measure because of a subjective component and a multidimensional character of its perception. Hence, the efficacy of the anesthetic agent was evaluated using Wong-Baker Faces Pain Rating Scale introduced by Wong and Baker (1988). It measures the unpleasantness or affective dimension of a child's pain experience after injection and has been considered a reliable tool for subjective evaluation of pain perception regarding the experience of the local anesthetic injection with STA-Wand or the conventional technique in children of age group 3–17 years.^[4] Two-6 point Co-operation Anxiety Rating Scale which was developed by Allard, Stokes and Kennedy in the year 1980 was refined and reused in several studies and was proven to be effective even in children of younger age group.^[9] Hence, it was used in the present study to measure the anxiety and cooperation levels of children.

Pain, anxiety, and cooperation levels were evaluated during injection and subsequent treatment. Parents were asked by phone about the occurrence of adverse effects, and follow-up examination was done at 24 and 48 h. The present study results showed that both 4% articaine and 2% lignocaine were constantly effective throughout the treatment in minimizing the pain, anxiety and gaining the cooperation of children whereas 2% lignocaine showed a significant difference in pain, anxiety and cooperation levels of children during the injection phase compared to rest of the treatment period. This can be attributed to the

delay in the onset of anesthetic effect with 2% lignocaine compared to 4% articaine.

The study by Berlin *et al.*^[17] reported that “mean onset times of pulpal anesthesia with 4% articaine is 1.3 min and with 2% lignocaine is 2.2 min when delivered as an intraligamentary injection using a computer-controlled local anesthetic delivery system.” In contrary, Ram and Amir^[18] reported no difference in the onset time between 4% articaine and 2% lignocaine. Furthermore, it has been proven that mean onset time of anesthesia with 4% articaine was generally shorter for children than adults.^[19]

While comparing the overall anesthetic efficacy of 4% articaine and 2% lignocaine, both the agents were equally effective in minimizing the pain levels of children [Table 1] which was in accordance to the findings of Malamed^[15] Berlin *et al.*,^[17] Amir^[18] who had reported similar anesthetic efficacy between 4% articaine and 2% lignocaine when delivered as maxillary infiltrations, mandibular blocks, and intraligamentary injections.

In the present study, 4% articaine showed significantly superior results compared to 2% lignocaine in minimizing the anxiety and gaining the cooperation levels of children during injection phase which can be explained by delay in the onset of action to minimize pain that could have resulted in an anxious child. Similar results were attained by Lopez *et al.*^[20] who showed significant superior anesthetic effectiveness of 4% articaine over 2% lignocaine during restorative dental care in young children. This present study findings were in contrary to the findings of Ram and Amir^[18] who concluded that both 4% articaine and 2% lignocaine showed similar efficacy.

The skill of the operator in delivering a local anesthetic injection through a technique sensitive drug delivery system like STA-Wand holds a greater concern among clinicians as this requires much experience to achieve the actual potency of the anesthetic agent.^[21] In the present study, the skill factor has been overcome as single, well-trained, postgraduate dentist delivered the injection for all children following several trials of success during the pilot study of research. None of the children in the present study reported any adverse events in contrary to some of the reported adverse events such as postprocedural dental pain, accidental lip and/or cheek injury and prolonged numbness and enamel hypoplasia of underlying permanent tooth with 4% articaine and 2% lignocaine delivered as maxillary infiltrations, mandibular nerve blocks and intraligamentary injections.^[22] However, Ashkenazi *et al.*^[23] confirmed the safety of the underlying permanent dental bud when their corresponding primary tooth was exposed to intraligamentary injection delivered by STA-Wand in children 4.1 years or older.

The present study findings suggest that using either 4% articaine or 2% lignocaine is clinically acceptable, effective

and safe for usage in children. Thus, considering pain as a complex phenomenon which is impacted by wide variety of contextual variables, and taking into account the perception of the child and anticipated discomfort as a critical factor, the skill of the dentist in administering a painless injection with an efficacious local anesthetic agent is of utmost importance. Further clinical studies are required to assess the role of confounding factors which can affect pain and distress behavior following local anesthesia such as site of injection and area to be anesthetized, rate of injection, child preference, physical appearance of injection, presence of parents in the operatory, age of the child, experience of the operator, rate of injection with larger sample size to confirm the present study outcome.

Conclusion

Based on the results of the present study, it can be concluded that 4% articaine intraligamentary injection delivered by STA-Wand can be considered as safe and effective alternative for nerve block without any postoperative complications in young children during multiple pulpectomies planned on both the quadrants of the mandible in a single visit.

Acknowledgment

The authors would like to thank Dr. Jayanthi Mungara, Professor and Head, Department of Pedodontics and Preventive Dentistry, Ragas Dental College, Chennai, for her constant support and motivation in conducting the study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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