

**Original Article**

# Intraoperative Pain during Restorative Treatment of Maxillary First Permanent Molars Using Artpharma versus Artinibsa in Children after Infiltration Technique: A Randomized Controlled Clinical Trial

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## Abstract

**Aim:** The aim of this study is to assess intraoperative pain during restorative treatment of maxillary first permanent molars using Artpharma versus Artinibsa in children after infiltration technique.

**Subjects and methods:** This study is a randomized controlled clinical trial in which 46 children aged from 8-10 years old with maxillary permanent molars indicated for Class I restorative treatment were recruited from the outpatient diagnostic clinic in Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, and randomly assigned to intervention and control groups. Each child received a maxillary infiltration anesthesia using a 4% Articaine (Artpharma) 1:100000 anesthetic solution, while in the control group, they received a 4% Articaine (Artinibsa) 1:100000 solution. The pain scale was used to record intra-operative pain during the procedure.

**Results:** Regarding frequency and percentage values for Wong-Baker Faces Pain Rating Scales there was no statistically significant difference between both groups ( $p=0.135$ ). Success rate results showed single case failed in control group, while in the intervention group all cases were successful and the difference between both groups was not statistically significant difference ( $p=1$ ).

**Conclusion:** Both Artpharma and Artinibsa are successful in controlling intraoperative pain during restorative treatment of maxillary first permanent molars.

**Keywords:** Local anesthesia, Pediatric, Artpharma, Artinibsa, Pain.

## Introduction

The primary cause of dental phobia especially in children is pain during dental treatment, pain is always subjective<sup>1</sup>. Pain is defined as "an unpleasant sensory and emotional experience connected with existing or potential tissue damage or explained in terms of such damage" by the International Association for the Study of Pain (IASP)<sup>2</sup>. It's crucial to manage pain during dental operations, as pain could lead to noncompliance and treatment avoidance<sup>3</sup>.

Local anesthesia (LA) is one of the most important processes used in management of pain in dental procedures<sup>4</sup>. There are no local anesthetic techniques that guarantee 100% successful local anesthetic rates. Favorably, the advancements of recent local anesthetic and injectable technologies are offering us new ideas for how to deal with this issue<sup>4</sup>. However, local anesthetics have several drawbacks, such as low anesthetic efficacy, short duration, and adverse effects<sup>5</sup>.

There are numerous varieties of local anesthetic solutions in the market. Artpharma, a local Egyptian brand, was recently launched. Articaine is one of the most modern LA agents<sup>6</sup>. It is a safe and efficacious LA for all routine dental procedures in patients in maxillary and mandibular infiltration anaesthesia, and mandibular block anaesthesia for asymptomatic and symptomatic teeth, and has no higher association with anaesthetic-related adverse effects<sup>7</sup>.

Some authors advised the use of 2% articaine in pediatric dentistry because of the lower Cmax and the shorter half-life<sup>8</sup>. They showed a shorter time to maximum concentration and increased clearance compared to investigations in adults. However, one of the adverse event that might be directly related to articaine was accidental lip injury; no pharmacokinetic investigation was performed<sup>9</sup>.

Also, prolonged numbness appears to be the most frequent adverse event after articaine for dental intervention, occurring primarily in children younger than 7 years old<sup>10</sup>. Moreover, paraesthesia is a rare but unwanted adverse effect attributed to the use of this LA

in dentistry, particularly following the administration of a nerve block injection. There is no evidence to support the opinion that the use of articaine carries a greater associated risk of paraesthesia than with the use of any other local anaesthetic<sup>11</sup>.

Therefore, the assessment of intraoperative pain for restorative treatment of maxillary first permanent molars utilizing Artpharma versus Artinibsa in children during infiltration technique is the aim of this study. The null hypothesis was the fact that there is no significant difference between using 4% articaine (artpharma) 1:100000 in maxillary infiltration anesthetic technique and using 4% articaine (artinibsa) 1:100000 in maxillary infiltration anesthetic technique.

## Subjects and Methods

Review and approval of this study were conducted by the Research ethics committee (REC), Faculty of Dentistry, Cairo university, with respect to the scientific content compliance with applicable rehearse and human subjects and regulation, with an approval number: [32-7-20]. Also, this randomized clinical trial was registered on clinicaltrials.gov with ID: NCT 04303234.

## Study design:

This study was a randomized controlled clinical trial performed in the outpatient diagnostic clinic in Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University to screen all children and check their chief complaints and refer them. Inclusion criteria comprised: children aged 8-10 years old, mentally capable of communication, and cooperative children [rating  $\geq 3$  according to Frankl's behavior rating scale<sup>12</sup> i.e., 3 = the child has good acceptance of treatment, cautious behavior at times, willingness to comply with the dentist, at times with reservation, but patient follows the dentist's directions cooperatively, and 4 = the child has good rapport with the dentist, is interested in the dental procedures, and laughs and enjoys the situation], with class I initial caries in their maxillary first permanent molar.

Clinical photograph was taken before and after the restoration. No radiographic images were taken in this study. Exclusion criteria involved: medically compromised patients,

children reporting spontaneous or elicited pain from caries or showing any signs of pulpal infection, swelling or abscess and guardians who refused to participate in the study.

### Sample size determination:

A power analysis was designed to have adequate power to apply a 2-sided statistical test of the research hypothesis (null hypothesis) that there is no statistical difference regarding intraoperative pain using 4% Articaine (Artinibsa) and Articaine (Artpharma) solution. Revision and approval of the sample size were carried out by the Medical Biostatistics Unit (MBU), Faculty of Dentistry, Cairo University, Egypt

According to the results of **Coté et al.**<sup>13</sup> in which the (mean±SD) value for the control group was (0.95 ± 0.65) and based on the expert's opinion which estimated the difference between the control and the intervention to be (0.55). The effect size (d) was figured out to be (0.846). By adopting an alpha ( $\alpha$ ) level of 0.05 (5%), and beta ( $\beta$ ) level of 0.20 (20%) i.e. power=80; the predicted sample size (n) was found to be a total of (46) samples i.e. (23) for each group. Sample size calculation was performed using G\*Power version 3.1.9.4.

### Study setting:

The study was conducted on 46 cases that were randomly and equally allocated to each of the tested groups (i.e. 23 cases each). Sequence generation and allocation concealment were used to avoid selection bias in determining the groups similar to **Kahan et al.**<sup>14</sup>, who performed a sequence generation and allocation concealment by simple randomization and dividing the patients into two parallel groups. The co-supervisor of the current study assigned the participants to either intervention or control group via a random sequence using the web ([www.random.org](http://www.random.org)).

Once the parent signed the consent, the investigator made a phone call to the co-supervisor to allocate the child to either intervention or control group according to the generated random sequence. Only the participants and the statistician were blinded. But, the investigator was not blinded because

it would be difficult to determine the amount of anesthesia that should be given to the patient if the carpule was covered.

Dental unit (Night, Safwan Company, Egyptian brand), Artpharma anesthetic carpule 1.7 ml (4% articaine, 1:100,000 epinephrine, Artpharmadent, Egypt), Artinibsa anesthetic carpule 1.8 ml (4% articaine, 1:100,000 epinephrine, Inibsa, Spain), and 20% benzocaine topical anesthetic gel (Sky Dent, USA) were used.

### Study setting:

Personal, Medical and Past dental history were recorded for the diagnostic procedure. Children were divided into two equal groups: group A (intervention), and group B (control). The child was accompanied to the clinic in a friendly manner and then seated on the dental chair. Topical anesthesia was applied after dryness, then left for 3 to 5 minutes to ensure effectiveness. The tooth was anesthetized via infiltration in the buccal vestibule. The child's eyes were concealed by the principal investigator's palm. Content of 1 carpule was injected at 1 ml depth of the buccal vestibule. The needle was inserted at the depth of the muco-buccal fold and was targeted at the apical region of the tooth to be anesthetized.

After ensuring successful anesthesia, caries removal was performed using a high-speed dental handpiece fitted with a round and 330 burs. Phosphoric Acid etch (37%), was applied for 20 seconds and then the tooth was washed and dried. Bond was applied using a small brush after thorough dryness and light cured for 20 seconds. Composite was applied using incremental technique, with 2 ml thickness for each increment until filling the whole cavity with the composite, Finishing and polishing were carried out and occlusion was checked using articulating paper to remove any high spots. Clinical photograph was taken before and after the restoration.

### Outcome's assessment:

Intraoperative pain was recorded by using Wong-baker pain rating scale **Coté et al.**<sup>13</sup>. A set of six cartoon faces were shown to the children with different facial expression

starting from a smile/happy to tears. Verbal explanation to the child was given before the treatment, the children selected the face which represents what they felt at the time of treatment. Success was determined if the child pointed out on a scale from 0-2, while failure if the child pointed out on a scale from 3-5 according to **Alzahrani et al.**<sup>15</sup>.

Onset of anesthesia was recorded by using a stopwatch and the unit was minutes<sup>16</sup>. Sensation after injection: was checked by probing of mucosa<sup>17</sup>. Time of disappearance of numbness was recorded after 2 hours by phone call.

## Results

Categorical and ordinal were presented as frequency and percentage values. Categorical data were analyzed using Fisher's exact test. Ordinal data were analyzed using Mann-Whitney U test. Numerical data were tested for normality using Shapiro-Wilk. They were normally distributed so they were presented as mean and standard deviation values and were analyzed using independent t-test. The level of significance was determined at  $p \leq 0.05$  within all tests. R statistical analysis software version 4.1.3 for Windows was used to perform statistical analysis.

The study was conducted on 46 cases that were randomly and equally allocated to each of the tested groups (i.e. 23 cases each). There was no statistically significant difference between both groups regarding sex ( $p=1$ ) and age ( $p=0.866$ ), as described in table (1).

In the intervention group, 21 children had "No hurt" score while in the control group, 16 children, and the difference between both groups was not statistically significant ( $p=0.135$ ), as observed in figure (1). For the intervention group, all cases were successful while for the control group, a single case failed and the difference between both groups was not statistically significant ( $p=1$ ), as shown in table (2).

All cases in both groups showed anesthetic effect after the injection. The onset of the anesthesia in the control group was ( $0.65 \pm 0.06$ ) which had later onset of anesthesia than intervention group which was ( $0.63 \pm 0.04$ ) yet the difference was not

statistically significant ( $p=0.395$ ), as illustrated in figure (2). Numbness disappeared in 7 cases (30.4%) in intervention group and in 2 cases (8.7%) in control group and the difference between both groups was not statistically significant ( $p=0.135$ ), as shown in figure (3).

## Discussion

Deep carious primary teeth are usually treated with pulpotomy, pulp therapy is the most common procedure done for children<sup>18</sup>. Artpharma is a new local product in the Egyptian market containing 4% articaine with a remarkable affordable cost compared to the Artinibsa which also contain 4% articaine that is why we compared between 4% articaine (Artpharma) and 4% articaine (Artinibsa)<sup>19</sup>.

Children who are mentally capable of communication were included to ensure their ability to properly understand the procedures and cooperate with the dentist. This was also in accordance with **Alzahrani et al.**<sup>15</sup>. Medically compromised patients and guardians or parents who refused to participate in the study were excluded similar to **Alzahrani et al.**<sup>15</sup> and **Elheeny**<sup>20</sup>.

Buccal infiltration was the preferred method of anesthesia in comparison with others as it is the least painful. This was in accordance with **Angelo and Polyvios**<sup>21</sup>, and **Hosseini et al.**<sup>22</sup>. The onset of anesthesia after the injection was recorded by a stopwatch and the unit was minutes as per **McNicol et al.**<sup>23</sup>. Sensation after injection was checked by probing the mucosa according to **Mittal et al.**<sup>17</sup>.

The intraoperative pain was recorded by Wong-Baker Faces Pain Rating scale similar to **Erfanparast et al.**<sup>24</sup>, but they used it during pulpotomy treatment in secondary primary molar. The child was instructed to fill in a Wong-Baker Scale for rating the pain experienced due to the needle prick in both techniques.

There were no statistically significant differences between both groups regarding sex and age this is in accordance with **Coté et al.**<sup>13</sup> and **Jain et al.**<sup>3</sup> as they found no statistically significant differences in the outcomes of the two solutions (Articaine & lidocaine) regarding the gender. **Martin et al.**<sup>7</sup> clarified that there was no statistical difference between articaine and

lidocaine treatment groups with respect to age, sex, weight, race distribution, or the proportion of subjects undergoing simple or complex procedures.

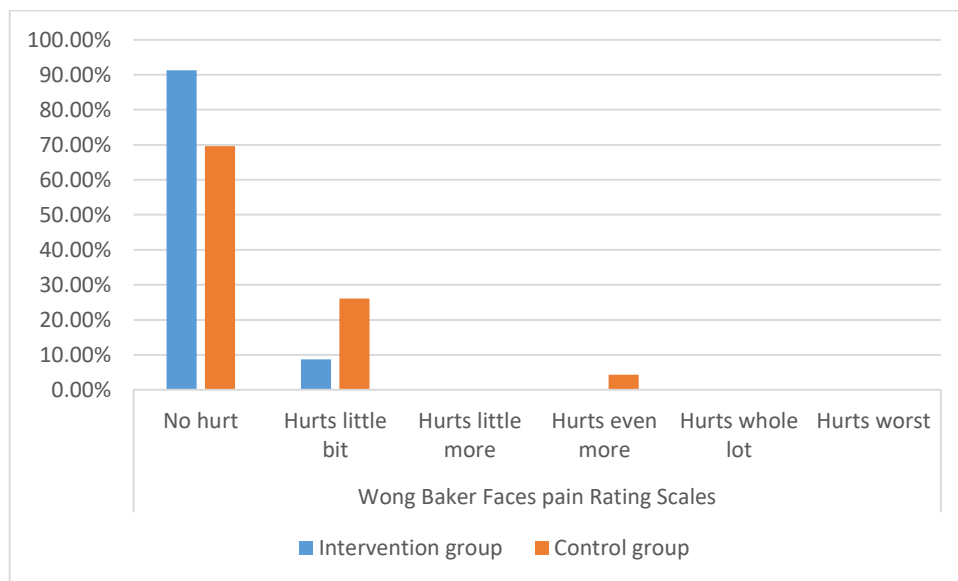
was not statistically significant as reported by **Strazar et al.**<sup>25</sup>, **Kim et al.**<sup>26</sup>, and **Alzahrani et al.**<sup>15</sup>.

The majority of both groups had “No hurt” score and the difference between both groups

**Table (1):** Intergroup comparisons for demographic data

Parameter		Intervention group	Control group	p-value	
Sex	Male	N	6	6	<b>1</b>
		%	26.1%	26.1%	
	Female	N	17	17	
		%	73.9%	73.9%	
Age	Mean±SD	9.26±0.92	9.30±0.82	<b>0.866</b>	

\*The significance level was set at  $p \leq 0.05$



**Figure 1:** A bar chart showing percentage of Wong Baker Faces pain Rating Scales in different groups.

Single case failed in control group, in this study as the child pointed out on the face that denotes “hurt even more” but upon probing the gums revealed no sensation and this may be due to the feeling of numbness which the child did not differentiate between it and pain. While in intervention group, all cases were successful and the difference between both groups was not statistically significant this was similar to **Alzahrani et al.**<sup>15</sup>. They showed equivalence in success rates for both anesthetic techniques infiltration and inferior alveolar nerve block during treatment. On the contrary, **Coté et al.**<sup>13</sup> complete anesthesia was achieved in most of the participants while they reported that nine patients needed additional local anesthesia for both articaine and lidocaine.

No difference in onset time between both solutions as both are articaine because they have the same pKa 7.8 which means they have fast onset **Coté et al.**<sup>13</sup>. Having a low pKa will result in short latency period and lead to fast onset<sup>27</sup>.

**Martin et al.**<sup>7</sup> did not find any difference between articaine and lignocaine, both with 1:100,000 epinephrine, concluding that both solutions were appropriate for clinical use and comparable with respect to the onset and duration of anesthesia. The pain relief provided by both solutions was similar. **Kim et al.**<sup>26</sup> found no statistically significant differences between articaine and lignocaine regarding their onset of action.

In our study, both anesthetics succeeded in preventing pain sensation after injection and pain during the treatment, similar to **Hosseini et al.**<sup>22</sup> who reported that there was no statistically significant difference between 4% articaine and 2% lidocaine on anesthetic success following an infiltration injection for maxillary first molars with irreversible pulpitis.

However, success rate was affected by the root length where the palatal root length significantly affected the anesthetic success, whereas the mesiobuccal and distobuccal root lengths had no significant influence on anesthesia. In **Martin et al.**<sup>7</sup> study, there was no statistically significant difference in pain relief observed between articaine and lidocaine. The numbness disappearance sensation after 2 hours between both groups was not statistically significant difference similar to **Nagendrababu**

**et al.**<sup>28</sup>, there was no statistical significance difference between articaine and lignocaine regarding duration of anesthesia.

A study conducted by **Martin et al.**<sup>7</sup>, stated that the average duration of both anesthesia in simple and complex dental procedures was comparable between the articaine and lidocaine groups. The range of duration was wide, from twenty minutes to more than three hours. **Elbay et al.**<sup>29</sup> stated that the mean duration of the anesthesia of soft tissue was 139.68 min for 3% mepivacaine and 149.10 min for 2% lidocaine-epinephrine, without a clinically significant difference.

### Conclusion:

From the results of this study, the following can be concluded:

- 1) Both local anesthetic Artipharma and Artinibsa proved to be successful in pain management during restorative treatment of upper maxillary first permanent molar.
- 2) Gender and age had no effect on the anesthetized group.
- 3) All cases in both groups had lost pain sensation after injection.
- 4) No statistically significant difference in the subjective pain reaction (Wong Baker Faces Pain Rating Scale) was observed between both solutions.
- 5) Artipharma proved to be a successful anesthetic agent to be used in dental practice.

### Conflict of Interest:

The authors declare no conflict of interest.

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This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors

### Ethics:

This study protocol was approved by the ethical committee of the Faculty of Dentistry-Cairo University with an approval number: [32-7-20]. Also, this randomized clinical trial was registered on clinicaltrials.gov with ID: NCT 04303234.

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