Original Article

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Buffered articaine infiltration for primary maxillary molar extractions: a randomized controlled study

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Background: Dental pain management is an important aspect of patient management in pediatric dentistry. Articaine is considered the most successful anesthetic agent for infiltration anesthesia. Buffered articaine has been observed to have faster onset and longer duration of action with less pain on injection. The aim of this study was to evaluate and compare pain on injection, onset of action, and pain during extraction using buffered (using Sodium bicarbonate ($NaHCO_3$)) and non-buffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4–10-year-old children.

Methods: Seventy children who required extraction of maxillary primary molars were enrolled in this triple-blind randomized study. Children undergoing extraction were randomly divided into two groups, with 35 in each group. The study group was the buffered articaine group; the control group was the non-buffered articaine group. Buccal and palatal infiltrations were administered with either buffered or non-buffered articaine. Subjective evaluation was done for pain on injection, pain during extraction using Wong–Baker Faces Pain Rating Scale (WBFPR) and onset of anesthesia in seconds. Pain on injection, pain during extraction were objectively evaluated using Sound Eye Motor (SEM) scale and onset of anesthesia was also evaluated objectively by pricking with sharp dental probe.

Results: The outcome was, significantly less pain on injection and significantly faster onset of anesthesia with significantly less pain during extraction for both subjective and objective evaluations in the buffered articaine group. Subgroup analysis was also performed and it showed variable results, with only significant difference for WBFPR scores in age subgroup 4–7 years for palatal infiltration.

Conclusion: Less pain on injection, faster onset of anesthesia, and less pain during extraction were observed when buffered articaine was used for maxillary primary molar extraction.

Keywords: Articaine; Buffers; Local Infiltration; Primary Molars; Tooth Extraction.

INTRODUCTION

Pain management is an extremely important step in patient management in pediatric dentistry [1]. Local anesthesia (LA) is the transient loss of sensation in a specific area of the body caused by the depression of nerve ending excitation or inhibition of conduction in the peripheral nerves [2]. Although local anesthetic injections cause pain and anxiety in children, they are an integral part of dental treatment for comfortable, cooperative, and pain-free dental treatment [3]. The site and speed of injection and the pH of the anesthetic solution have all been linked to pain during LA administration [4].

Articaine is a local anesthetic agent with potency one-and-a-half times that of lidocaine, which is widely used. Articaine is more reliable than other local anesthetics for diffusion through soft and hard tissue [5].

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The pH of most dental local anesthetic formulations ranges from 3.0 to 6.5 [6]. Articaine with adrenaline generally enters the body at a lower pH (3.5-4.0) than the physiological pH of 7.4. At this lower pH, the ionized charged form predominates, requiring the body to buffer and convert enough anesthetic to the active de-ionized form to produce anesthesia [7]. It has been proposed that alkalization of the acidic solution can reduce the pain caused by LA administration without compromising the onset of anesthesia [8,9].

Buffering of the anesthetic solution can be easily accomplished by adding a small amount of sodium bicarbonate ($NaHCO_3$) to the solution [2]. The addition of NaHCO3 to local anesthetics has been useful in the reduction of pain on injection and faster onset of anesthesia in various studies [1,10,11]. A literature search showed several studies on the use of buffered lidocaine for infiltration and block anesthesia during dental procedures in adults [11,12], but there is a paucity of literature on the use of buffered articaine solution in children.

Thus, aim of this study was to evaluate and compare pain on injection, onset, and efficiency of anesthesia during primary maxillary molar extraction using buffered and non-buffered 4% articaine (with 1:100000 adrenaline) infiltration in 4–10-year-old children.

METHODS

This triple-blind, parallel arm, randomized study was carried out in the Department of Pediatric and Preventive Dentistry after ethical clearance was obtained from the ethics committee of the institution (IEC/VSPMDCRC/09/2019) and signed informed consent from parents and children's assent were obtained for the treatment from January 2022 to April 2022.

Sample size was estimated based on the following assumptions: alpha error = 10% and study power 80%. The difference in proportion of pain on injection was considered as one of the major outcome for determining the effect size. Based on the results of the study by Shurtz et al, 2015 [13] where the proportions for buffered and unbuffered group were 71.25% and 91.25%, the effect size was determined to be 20%, The minimum sample require was calculated to be 33 per group. Taking into account dropouts a total of 70 children were enrolled in the trial with 35 in each group (Fig. 1).

Healthy and cooperative ([positive or definitely positive] according to Frankl's behavior rating scale) children aged 4–10 years with at least one primary maxillary molar indicated for extraction were included in the study. Children with an active dentoalveolar infection at the site of injection, known history of allergy to any local anesthetic agent, and/or history of dental treatment in the last 6 months were excluded.

Randomization was performed using random allocation computer software, according to the intervention to be used. Each child received a unique identification code generated by the software; these codes were placed in opaque, numbered, and sealed envelopes for concealment. Allocation of children in a 1:1 ratio to either the study group (buffered 4% articaine (with 1:100000 adrenaline) infiltration) or control group (non-buffered 4% articaine (with 1:100000 adrenaline) infiltration) was performed. Investigator 1 performed enrolment, randomization, and envelope sealing for allocation to the intervention. All local anesthetic infiltrations and extractions were performed by a single operator. The operator, evaluator, and children were blinded to the intervention allotted. The trial was completed after all enrolled children underwent treatment according to group allocation.

1. Preparation of buffered articaine

Under sterile conditions, 0.18 ml from a 1.8-ml cartridge of 4% articaine (with 1:100000 adrenaline) (Septanest, Septodont, France) was taken out and replaced with 0.18 ml, 8.4% $NaHCO_3$ [8.4% weight / volume] (SODAC, Neon Uttaranchal Biotech Ltd, India) using an insulin syringe. The insulin syringe was used to replace the LA solution with the buffered solution [14]. The cartridge was then inverted five times to mix the solution

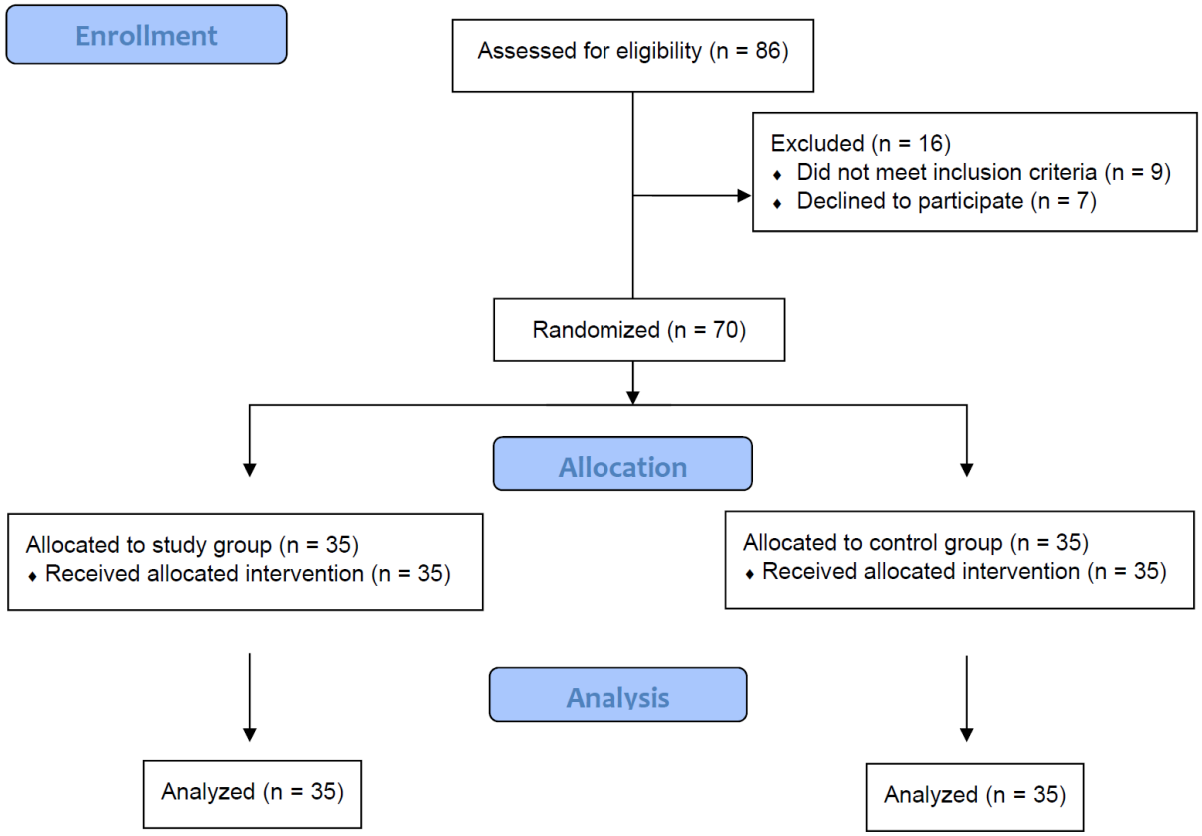

Fig. 1. CONSORT flowchart. CONSORT, consolidated standards of reporting trials; n, sample size.

such that there was no precipitation.

For non-buffered LA solution, 0.18 ml of a 1.8-ml cartridge of 4% articaine (with 1:100000 adrenaline) was taken out and replaced with the same amount of distilled water [13].

2. Technique of LA administration

The LA sensitivity test was performed prior to the injection procedure by injecting intradermal 0.1 ml of the respective LA solution. The intraoral injection site was dried using a gauze. A cotton-tip applicator that contained approximately 0.2 ml of topical anesthetic (LOX* 10% spray, Lignocain-100mg, Neon Laboratories Ltd, India) was applied at injection site and left for 1 min. Buccal infiltration was performed by administering 1.5 ml of solution at the depth of the mucobuccal fold opposite to the maxillary molar. Palatal infiltration was performed with 0.2–0.3 ml of the respective LA solution in each group [15]. The injection rate was approximately 1 ml/min in both the study and control groups. Both anesthetic drugs were administered using a self-aspirating fusion syringe (Septodont Fusion Syringe, Cambridge, ON, Canada) and 30 gauge short needle (Septoject, Septodont, France).

After confirmation of all signs and symptoms of profound LA, the extraction procedure was performed following the standard protocol [2]. The complete procedure was videotaped, and recording was performed from a fixed distance from the dental chair with a video recorder.

Pain on injection was assessed subjectively using the Wong-Baker Faces Pain Rating Scale (WBFPR) and objectively using the Sound, Eye and Motor (SEM) scale. The WBFPR scale consists of six faces with an increasing degree of pain from left to right and has a numerical scale from 0 to 10 corresponding to each face. The SEM scale is designed to measure subjects' comfort or pain. The rating of comfort considers three types of observations:

Table 1. Distribution of children according to age and replace word sex with gender

		Study group	Control group	P-value
Age	4-7 Years	13 (37.14%)	18 (51.40%)	0.33
	8-10 Years	22 (62.86%)	17 (48.60%)	
	Mean ± SD (years)	8.29 ± 1.29 (5.07 - 10.27)	7.86 ± 1.30 (5.79 - 10.35)	
Gender	Boys	18 (51.40%)	18 (51.40%)	1.00
	Girls	17 (48.60%)	17 (48.60%)	

SD, standard deviation.

Table 2. Intergroup analysis of WBFPR and SEM scores for pain on injection

		Group	N	Mean	SD	P-value
WBFPR score	Buccal infiltration	Study	35	1.20	1.47	< 0.0001*
		Control	35	3.71	3.07	
	Palatal infiltration	Study	35	1.94	1.84	< 0.0001*
		Control	35	4.62	3.02	
SEM score	Buccal infiltration	Study	35	1.17	0.28	< 0.0001*
		Control	35	1.81	0.67	
	Palatal infiltration	Study	35	1.25	0.30	< 0.0001*
		Control	35	2.43	0.92	

*significant (Mann Whitney U test); N, sample size; SD, standard deviation; SEM, Sound, Eye and Motor; WBFPR, Wong-Baker Faces Pain Rating.

sounds, eyes, and motor. The level of response for each observation was assigned a numerical value, and these values were averaged to obtain the comfort level.

Subjective assessment of the onset of anesthesia was performed using a stopwatch from the moment of retrieval of the needle immediately after the injection up to the first symptom of anesthesia for both buccal infiltration and palatal infiltration. The time of onset was evaluated objectively by checking the presence or absence of pain to prick of a sharp dental probe applied to the gingival margin. Pain during extraction was also assessed subjectively using the WBFPR and objectively using the SEM scale.

Results were recorded in an Excel sheet and the analysis of statistics was carried out using descriptive and inferential statistics, with the use of chi-square test for age distribution, student's t test for onset of anesthesia, Man Whitney U test for WBFPRS and SEM score. Software used for the analysis was SPSS 24.0 and Graph Pad Prism 7.0; $P < 0.05$ was considered as the level of significance.

RESULTS

All 70 children underwent the extraction procedure with no dropouts; thus, data of 35 children in each group were analyzed. In the study group and control group, 37.14% and 51.40% of children were aged 4–7 years and 62.86% and 48.60% of children were aged 8–10 years, respectively, with no statistically significant difference between the distribution in age subgroups. In both groups, 51.40% of patients were boys and 48.60% were girls (Table 1).

Analysis of pain on injection assessed with the WBFPR and SEM scales for buccal and palatal infiltration showed that it was significantly less in the study group than in the control groups (Table 2). The subjective and objective assessment of onset of anesthesia for buccal and palatal infiltration was significantly faster in the study group (Table 3).

Subgroup analysis for subjective and objective pain on injection using the WBFPR and SEM scales for the age subgroups of 4–7 years and 8–10 years showed no

Table 3. Intergroup comparison of time (s) of onset of anesthesia

		Group	N	Mean in seconds	SD	P-value
Subjective	Buccal infiltration	Study	35	49.22	4.24	< 0.0001*
		Control	35	78.48	7.35	
	Palatal infiltration	Study	35	46.00	3.97	< 0.0001*
		Control	35	75.91	7.71	
Objective	Buccal infiltration	Study	35	58.80	5.30	< 0.0001*
		Control	35	87.91	7.57	
	Palatal infiltration	Study	35	54.88	4.40	< 0.0001*
		Control	35	86.57	7.06	

*significant (Student's t test); N, sample size; SD, standard deviation.

Table 4. Subgroup analysis of WBFPR and SEM scores for pain on injection

		Buccal infiltration		P-value	Palatal infiltration		P-value
		Study group	Control group		Study group	Control group	
WBFPR score	Age 4 - 7 (37.14%)	1.07 ± 1.32	1.33 ± 1.68	0.65	1.23 ± 1.01	5.44 ± 2.63	< 0.0001*
	Age 8 - 10 (62.86%)	1.27 ± 1.57	1.05 ± 1.24	0.64	2.36 ± 2.10	3.76 ± 3.23	0.11
SEM Score	Age 4 - 7 (37.14)	1.12 ± 0.25	1.09 ± 0.22	0.68	1.20 ± 0.25	1.20 ± 0.23	0.98
	Age 8 - 10 (62.86)	1.21 ± 0.29	1.27 ± 0.31	0.53	1.28 ± 0.32	1.31 ± 0.36	0.81

*significant (Mann Whitney U test); SEM, Sound, Eye, and Motor; WBFPR, Wong–Baker Faces Pain Rating.

Table 5. Subgroup analysis of time (s) of onset of anesthesia

Analysis	Age group	Buccal infiltration		P-value	Palatal infiltration		P-value
		Study group	Control group		Study group	Control group	
Subjective	Age 4 - 7 (37.14%)	49.30 ± 3.40	75.22 ± 7.47	< 0.0001*	45.92 ± 3.79	79.00 ± 5.62	< 0.0001*
	Age 8 - 10 (62.86%)	49.18 ± 4.74	81.94 ± 5.55	< 0.0001*	46.04 ± 4.16	72.64 ± 8.41	< 0.0001*
Objective	Age 4 - 7 (37.14%)	58.46 ± 3.64	84.83 ± 6.17	< 0.0001*	54.46 ± 3.40	87.88 ± 5.87	< 0.0001*
	Age 8 - 10 (62.86%)	59.00 ± 6.15	91.17 ± 7.69	< 0.0001*	55.13 ± 4.95	85.17 ± 8.08	< 0.0001*

*significant (Student's t test).

statistically significant differences between the study group and control group for both buccal and palatal infiltration, except for the WBFPR scale for the subgroup of 4–7 years, which showed significantly less pain in the study group for palatal infiltration (Table 4). Subgroup analysis for the subjective and objective assessment of the onset of anesthesia for both age subgroups showed that it was significantly faster in the study group (Table 5).

Pain during extraction assessed using the WBFPR and SEM scales showed significantly less pain in the study group (Table 6). Analysis for pain during extraction for subgroups of 4-7 years and 8-10 years showed significantly less pain in study group for both buccal and palatal infiltrations (Table 7).

DISCUSSION

Articaine with epinephrine generally enters the body at a lower pH (3.5-4.0) than the physiologic pH of 7.4. At this lower pH, the ionized charged form predominates, requiring the body to buffer and convert enough anesthetic to the active de-ionized form to produce anesthesia [7]. It has been proposed that alkalizing this acidic solution can reduce pain caused by local anesthesia administration without compromising anesthesia onset [8,9]. There is little literature on the use of buffered articaine solution in children. When used in adult for maxillary infiltration buffered articaine injection have been observed to be less painful [10]. Buffered articaine

Table 6. Intergroup analysis of WBFPR and SEM scores for pain during extraction

	Group	N	Mean	SD	P-value
WBFPR score	Study	35	1.77	2.31	< 0.0001*
	Control	35	5.14	3.15	
SEM Score	Study	35	1.22	0.34	< 0.0001*
	Control	35	2.39	0.95	

*significant (Mann Whitney U test); N, sample size; SD, standard deviation; SEM, Sound, Eye and Motor; WBFPR, Wong–Baker Faces Pain Rating.

Table 7. Subgroup analysis of WBFPR and SEM scores for pain during extraction

	Subgroup	Study group	Control group	P-value
WBFPR score	Age 4 - 7 (37.14%)	0.66 ± 1.03	5.55 ± 2.87	< 0.001*
	Age 8 - 10 (62.86%)	2.00 ± 2.44	4.70 ± 3.45	< 0.003*
SEM Score	Age 4 - 7 (37.14%)	1.11 ± 0.17	2.55 ± 0.53	< 0.0001*
	Age 8 - 10 (62.86%)	1.25 ± 0.37	2.23 ± 1.25	< 0.0001*

*significant (Mann Whitney U test); SEM, Sound, Eye, and Motor; WBFPR, Wong–Baker Faces Pain Rating.

solutions have a greater efficiency in respect to onset, duration of action and pain experienced by the patient during treatment procedure than the conventional articaine [1]. Thus buffering 4% articaine formulation may increase the success of LA [13]. In present study, less pain on injection, faster onset of action and less pain during extraction was observed with buffered articaine.

WBFPR and SEM scores were significantly lower in the study group for buccal and palatal infiltration. Amorim et al. compared pain during injection of buffered and non-buffered articaine for supra-periosteal buccal anesthesia in the upper canine apex and concluded that pain was lower when buffered 2% articaine was used [10]. The possible reason for this may be elevated pH of buffered articaine. Kurien et al. and Afsal et al. evaluated efficacy and pain reaction using buffered lidocaine for pulp therapy and efficacy and pain perception for inferior alveolar nerve block (IANB) for pulp therapy or extraction, respectively, and found significantly less pain on injection in the buffered lidocaine group than in the non-buffered lidocaine group [11,12]. However, no added advantage was observed when Shurtz et al. evaluated pain on injection of buffered articaine infiltration buccally for the mandibular first molar for pulpal anesthesia in adults compared with plain articaine [13]. The possible reason for this may be the density of mandible. Chopra et al. and Meincken et al. evaluated pain on injection during IANB administration with buffered lidocaine and found statistically non-significant differences in pain on injection between the buffered and non-buffered lidocaine groups [4,16].

The subjective assessment of the onset of anesthesia showed that it was significantly faster in the study group for both buccal and palatal infiltration. Kurien et al. and Afsal et al. evaluated onset of anesthesia using buffered lidocaine for pulp therapy in children using buffered and non-buffered 2% lignocaine for IANB and observed significantly faster onset with buffered lignocaine [11,12]. However, Chopra et al. and Meincken et al. evaluated the onset of anesthesia with buffered lidocaine during IANB administration and found no statistically significant difference in the onset time between buffered and non-buffered lidocaine [4,16]. In addition, Amorim et al. evaluated the onset of anesthesia for buffered and non-buffered articaine for supraperiosteal buccal anesthesia in the upper canine apex and found no statistically significant difference between the buffered and non-buffered groups [10]. In study carried out to evaluate buffered articaine for IANB in adults for root canal treatment, no significant difference was observed for onset of anesthesia compared to nonbuffered articaine [1]. Shurtz used buffered articaine buccal infiltration to anaesthetize mandibular molar in adults and found no significant difference in onset of anesthesia [13].

The effectiveness of anesthesia was evaluated subjectively and objectively using pain during extraction, and pain scores were significantly lower in the study group. Kurien et al. compared anesthetic efficacy of buffered and non-buffered lignocaine in pulp therapy requiring IANB and observed significantly less pain with buffered lignocaine [11]. However, Hemmanur and Nasim compared the efficacy of buffered and non-buffered articaine during root canal treatment and reported no statistically significant difference [1]. Saatchi et al. evaluated the efficacy of buffered lidocaine for IANB for pulp therapies in children below 18 years of age and found no statistically significant difference when compared to non-buffered lidocaine [17]. In the present study none of the children reported adverse effects in any of the groups. Sparse data are available regarding the use of buffered articaine in children, making comparison of the results of the present study difficult.

The broad age group of 4-10 years old children enrolled for the present study could be a limitation as abstract thinking skills of a 4 and a 10 year old can vary significantly. In conclusion, buffered articaine anesthetic solution resulted in less pain on injection, faster onset of action, and better efficiency in reducing pain during extraction. Since there are only a few studies and varying evidence regarding the effectiveness of buffered articaine in adults and, to the best of our knowledge, the present study was the only study that used buffered articaine in children, more randomized controlled trials are needed.

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AUTHOR CONTRIBUTIONS

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Devendra Nagpal: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Validation, Writing - review & editing
Purva Chaudhari: Data curation, Investigation, Supervision, Validation, Writing - review & editing
Gagandeep Lamba: Supervision, Writing - review & editing
Kavita Hotwani: Supervision, Validation
Prabhat Singh: Supervision, Validation

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