“COMPARATIVE EVALUATION OF CLINICAL EFFECTIVENESS OF BUFFERED AND NONBUFFERED 4% ARTICAINE (WITH ADRENALINE 1:100000) INFILTRATION FOR PRIMARY MAXILLARY MOLAR EXTRACTIONS : AN EXPERIMENTAL STUDY.”.

Dissertation submitted to

Maharashtra University of Health Sciences, Nashik

in the Partial Fulfilment of Regulations

for the award of the Degree of

MDS IN

PAEDODONTICS AND PREVENTIVE DENTISTRY

BRANCH VIII

2019-2022

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LIST OF ABBREVIATIONS

LA	Local anesthesia
IANB	Inferior alveolar nerve block
HCl	Hydrochloride
CO2	Carbon dioxide
ELA	Eutectic mixture of local anesthetic
NaHCO3	Sodium bicarbonate
IV	Intravenous
FPS	Faces Pain Scale
HP-VAS	Heft-Parker Visual Analogue Score
SEM	Sound, Eye, Motor
VAS	Visual analogue scale
WBS	Wong Baker Scale
WBFRS	Wong- Baker Facial Rating Scale
WBFPS	Wong- Baker Faces Pain Scale
WB	Wong-Baker
FBRS	Frankl Behavior Rating Scale
EPT	Electric pulp tester
I1	Investigator 1
I2	Investigator 2
S	Statistically significant
NS	Non significant
SD	Standard deviation

INTRODUCTION

"The method of scientific investigation is nothing but the expression of the necessary mode of working the human mind."

- **Thomas Henry Huxley**

Pain is one of the most common reason that a patient seeks treatment from a dentist. As a result, pain management is an extremely important step in patient management [1]. Local anaesthesia is the transient loss of sensation in a specific area of the body caused by the depression of nerve ending excitation or the inhibition of conduction in the peripheral nerves [2]. The foundation of clinical dentistry is local anaesthesia (LA). Local anaesthetic solutions were used for dental procedures as early as the nineteenth century to manage pain during treatment [3]. Fear of dental injections has been identified as a factor in avoiding dental appointments. Although it is only temporary, the perceived pain of the local anaesthetic injection is severe enough in

some children to refuse further treatment under local anaesthesia [4]. The site of injection, speed of injection, and pH of the anaesthetic solution have all been linked to pain during LA administration [5]. Despite the fact that local anaesthetic injections cause pain and anxiety in children, they are an integral part of dental treatment for the comfort, cooperation, and pain-free dental treatment [6].

Articaine was first synthesised as carticaine in 1969 and entered clinical use in Germany in 1976. It was first released in the United Kingdom in 1998, in the United States in 2000, and in Australia in 2005. It is currently available as a 4% solution containing 1:100,000 or 1:200,000 adrenaline [7]. Articaine is the only amide local anaesthetic with an ester group. Because of its distinct chemistry, it undergoes biotransformation in both plasma (via hydrolysis by plasma esterases) and the liver (by hepatic microsomal enzymes). As a result, articaine has an elimination half-life of 20 to 40 minutes, as compared to more than 90 minutes for lidocaine and other amides that require hepatic clearance. The risk of systemic toxicity with articaine is thus reduced, especially during lengthy appointments requiring additional doses of anaesthetic [8]. The potency of articaine hydrochloride is one and half times that of lidocaine. It differs from other amide local anaesthetics in that it has a thiophene group rather than a benzene ring, which increases its lipo-solubility. Uckan claimed that articaine is more reliable than other local anaesthetics at diffusing through soft and hard tissues [9].

The pH of most dental local anaesthetic formulations ranges from 3.0 to 6.5 [10]. Articaine HCl formulation contains epinephrine as a vasoactive agent, causing the pH to range between 3.5 and 4.0. Articaine exists in two molecular forms in this formulation: a de-ionized, uncharged free base form and an ionised, charged cationic

form [11]. The active lipid soluble form of the local anaesthetic is the de-ionized form, which enters the nerve membrane and blocks nerve conduction [12]. Adequate anaesthesia requires a sufficient amount of de-ionized free base anaesthetic.

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 ionised charged form predominates, requiring the body to buffer and convert enough anaesthetic to the active de-ionized form to produce anaesthesia [13]. It has been proposed that alkalizing this acidic solution can reduce pain caused by local anaesthesia administration without compromising anaesthesia onset [14,15].

Buffering or alkalinization of an anaesthetic solution can be easily accomplished by adding a small amount of sodium bicarbonate to the solution just prior to use. Sodium bicarbonate is an alkalinizing agent that is commonly used to treat metabolic acidosis [2]. The addition of sodium bicarbonate to LA produces both carbon dioxide and water. Carbon dioxide enhances local anaesthesia through three mechanisms. Firstly, it has a direct depressant effect on the axon. Secondly, by concentrating LA within the nerve trunk, and finally, by converting LA to the active cation via its effect on pH at the site of action within the nerve [2,16]. Literature search shows several studies on the use of buffered lidocaine for infiltration and block anaesthesia during dental procedures in adults, but there is little literature on the use of buffered articaine solution in children.

So the aim of this study was to compare pain on injection and clinical effectiveness of buffered 4% articaine (with 1:100000 adrenaline) and nonbuffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

AIM AND OBJECTIVE

AIM OF THE STUDY

To evaluate and compare clinical effectiveness of buffered 4% articaine (with 1:100000 adrenaline) and nonbuffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

PRIMARY OBJECTIVE

1) To evaluate clinical effectiveness (pain on injection and pain during extraction) of buffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

2) To evaluate clinical effectiveness (pain on injection and pain during extraction) of nonbuffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

3) To compare clinical effectiveness (pain on injection and pain during extraction) of buffered 4% articaine (with 1:100000 adrenaline) and nonbuffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

SECONDARY OBJECTIVE

1) To evaluate onset of anaesthesia of buffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

2) To evaluate onset of anaesthesia of nonbuffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

3) To compare onset of anaesthesia of buffered 4% articaine (with 1:100000 adrenaline) and nonbuffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions in 4 – 10 year old children.

REVIEW OF LITERATURE

de Jong RH, Cullen SC (1963) [16] investigated the buffering requirement and ionic strength of epinephrine-containing local anaesthetic formulation. With heparinized fasting human venous blood at room temperature, 10 or 20 aliquots of random shelf samples of three frequently used local anaesthetics (lidocaine HCl, 2-chlorprocaine HCl, and mepivacaine HCl) were titrated for changes in ph. Ph was measured using a Beckmann zeromatic glass electrode ph. metre that was allowed to equilibrate overnight before being calibrated with laboratory buffer at ph. 7. The averaged ph values observed during titration were shown as a blood titration curve of a 10ml aliquot of LA solution. The volume of blood required to get a 10 ml aliquot of local anaesthetic to a ph of 7.0 was calculated from this curve, and the buffer demand of the local anaesthetic was named after it. The ph and buffer demand of lidocaine with freshly mixed epinephrine were 6.7 and 6.5, respectively, while the ph and buffer demand of commercially manufactured lidocaine with epinephrine including sodium

metabisulfide were 4.2 and 10.8. They came to the conclusion that LA containing epinephrine and a preservative (sodium metabisulfite) has a lower ph than the original solution and has a buffer requirement about double that of 2 percent lidocaine.

Rood JP (1977) [17] Studied the use of commercial two percent lignocaine formulation (with 1:80000 adrenalin) and buffered two percent lignocaine formulation (with 1:80000 adrenalin) in presence and absence of acute inflammation. Results showed as when a commercialized lignocaine formulation was administered in the presence of acute inflammatory condition, its effectiveness was much lower than when it was administered when inflammatory condition was not there. Similar results obtained with buffered solution that it's efficiency was lower in inflammatory condition. Then they concluded that two percent lignocaine formulation (with 1:80000 adrenalin) is often ineffective for analgesia in dental tissue with acute inflammation and buffering the solution makes it less acidic but does not change clinical efficiency of local analgesia.

Moore DC (1981) [18] performed a study to describe the pH values of regularly used commercially made local anaesthetic medications like bupivacaine, mepivacaine, chloroprocaine, etidocaine, lidocaine, and prilocaine, as well as the additives they include, with and without epinephrine 1:200,000. The effect of epinephrine added to simple solutions of these medications on pH was also investigated. In this study, digital pH metre of the Beckman (model no. 3560) was used to determine the pH. Following the determination of the pH of the simple solutions, 0.1 mg of 1:10000 epinephrine was extracted from a ampule of 1-milliliter and added to the samples of 20-milliliter, yielding a ultimate concentration of 1:200,000 epinephrine. All formulations of local anaesthetic medicines that did not contain epinephrine were

shown to be safe except chloroprocaine,. All formulations of local anaesthetic medicines with epinephrine on present that did not contain additives had pH (ionic strength) values of 4.4 or more than 5, with the exception of chloroprocaine. Furthermore, the pH of solutions with epinephrine-containing additions was less than 4. Epinephrine has a pH of 3.3. He found that utilising ampules or vials in a single dose without epinephrine and addition of 0.25 milligram of sodium bisulfide to LA formulation, and addition of epinephrine shortly before administration, apart from chloroprocaine, can avoid low pH formulations usage.

Christoph RA, Buchanan L, Begalla K, Schwartz S (1988) [14] evaluated the effects of pH alkalinization on the efficacy of 1% lidocaine, 1% lidocaine combined with epinephrine, and 1% mepivacaine and injection pain in a randomized, prospective, double-blinded study. The three local anaesthetics were made in both plain and buffered solutions, and each was given a 0.5 intradermal injection to the 25 adult volunteers who took part in the study. Anaesthetic infiltration pain was graded on a scale of 0 to 10. At time intervals after each injection, the site of each administration site's anaesthetized skin surface was measured. The mean pain estimates were significantly reduced when the local anaesthetics were buffered in comparison with non-buffered control group: 1) 1 percent lidocaine in comparison with 1 percent buffered lidocaine, 2) 1 percent lidocaine with epinephrine in comparison with 1 percent buffered lidocaine with epinephrine, On pH buffering, the onset, range, and longevity of cutaneous anaesthetic weren't significantly different. The pain during local anaesthetic administration may be significantly decreased by alkalization of the local anaesthetic before administration. The anaesthetic's efficacy was not jeopardised, and patient acceptance may have improved dramatically.

Eppley BL and Sadove AM (1989) [15] **s**tudied decrease in pain on injection by alkalizing local anaesthetic formulations. Pain of injection was considered to be the main cause of anxiety for local anaesthesia and acidic pH of the anaesthetic solution increases its unavoidable effect. Mechanism of local anaesthetic solution shows more rapid dispersement of unionized molecules to effect transport across nerve membrane. Buffering the local anaesthetic solution does not only reduce pain but also enhance depth and duration of anaesthesia. Sodium bicarbonate can be effectively use as a buffer despite its drawback of reduced half-life of local anaesthetic solution. Pain and irritation of local anaesthesia could be tolerated by adult patient so buffering could be very beneficial in paediatric patients.

Orlinsky M, Hudson C, Chan L, Deslauriers R (1992) [19] compared the infiltration pain between nonbuffered along with buffered lidocaine in severely lacerated injury. For investigation two wound sites were selected in which site I always received the first administration, and site II always received the second administration. Similar locations were chosen in irregularly shaped wounds and were spaced far enough apart to prevent crossing. The patient served as self-control, and for each participant, solutions of buffered and nonbuffered 1 percent lidocaine was randomly allocated to either Site I or Site II of a particular lacerated injury. Anaesthetic preference as well as their pain levels for each site was documented for every patient. The preference ratio of buffered lidocaine to unbuffered lidocaine was found to be 3:1. Site I was likewise found to be chosen more frequently than Site II, regardless of the medicine utilised. They concluded, lidocaine which was buffered was preferable to lidocaine which was unbuffered in studies involving numerous sequential injections in the same patient, the order of administration was crucial.

Vahatalo K, Antila H, Lehtinen R (1993) [20] compared the anaesthetic characteristics of articaine hydrochloride combined with epinephrine and xylocaine-adrenalin for infiltration anaesthesia in maxillary region. This double-blinded study included twenty healthy dental student volunteers (12 females, 8 males) with age of mean of 23.8 years. At different periods, each individual received 0.6 ml of each test solution. All subjects were given infiltration anaesthetic of the upper lateral incisor twice, so that they received both test solutions. The time between infiltrations was roughly two weeks. The onset of pulpal anaesthesia was monitored with the use of an electric pulp stimulator. The electro-conducting medium was sodium fluoride gel. Pulpal responsiveness was measured every 5 minutes. Every single one of the 40 infiltrations resulted in full anaesthesia. There were no clinically significant adverse effects. The latency time was 14 seconds shorter and the duration of anaesthesia 45 seconds longer with the articaine solution than with the lidocaine preparation, but the differences were not statistically significant.

Brogan GX, Giarrusso E, Hollander JE, Cassara G, Maranga MC, Thode HC (1995) [21] compared infiltration anaesthetic pain, if further anaesthetic deposition needed, and pain while suturing using nonbuffered, heated and buffered lidocaine formulation in 45 patients with traumatic lacerations in a randomised, prospective, single-blinded research. The injection technique was standard. The infusion administration pain was measured with the use of visual analogue scoring pain scale for each margin. Secondary outcome measures were the need for further anaesthesia and suturing pain. The type of lidocaine used had an effect on pain after injection (average scores of pain → for plain LA - 8.2; for buffered LA - 4.7 [$P<0.05$ versus plain]; for heated LA 4.9 [$P<0.05$ versus plain]). The average scores for pain of

heated and buffered lidocaine groups were not significantly different. Further anaesthetic needed and pain while suturing did not differ based on the anaesthesia used. There was no effect on the outcome for order of injections given. In all of the groups, the average scores for pain for 1st and 2nd margins were not different. Among the three formulations, buffered and heated lidocaine formulations were shown to be equally effective than plain LA, and they caused much lower pain during infiltration anaesthesia compared to plain LA.

Davies RJ (2003) [22] carried out a review for which a Medline search was conducted from 1966 to December 2001, yielding 63 papers. The researchers found that adjusting pH with sodium bicarbonate lowers local anaesthetic injections pain substantially. The pH adjusted formulations keep the LA's potency and are chemically stable as employed in the studies. For storage, adrenalin-containing buffered formulations must be kept refrigerated in sealed vessel. Adjusting pH would be especially effective in situations where LA injection pain is rarely well tolerated, especially in large zones of infiltration, sensitive sites like the face, and in children.

Al–Sultan AF (2004) [23] investigated the effectiveness of pH adjusted lidocaine against commercial lidocaine for maxillary infiltration anaesthesia. Sodium bicarbonate was utilised to modify the pH of the LA formulations, that had demonstrated the acceleration of anaesthetic molecule dissociation. This study comprised 200 patients with maxillary teeth that needed to be extracted. The pain associated with injection was much lesser with pH adjusted lidocaine group compared to the commercial lidocaine group, according to the findings. The study group had decreased pain related with extraction, but statistically non-significant. The difference was statistically significant for pain observed during extraction in favour of

study groups for teeth with periapical lesions. As a result, they found that while pH adjusted lidocaine anaesthetic solution has limited benefits, it was useful in situations of periapical lesion and can be used efficiently in places where local anaesthesia delivery was problematic, such as palatal injections.

Oliveira PC, Volpato MC, Ramacciato JC, Ranali J (2004) [24] evaluated and compared anaesthetic efficacy as well as pain experience after not only maxillary buccal infiltration but also palatal infiltration with 2 percent lignocaine and 4 percent articaine, both containing 1:100000 adrenalin. In this double-blinded, split mouth trial twenty healthy individuals of age twenty to thirty nine year old (16 women, 4 males) (mean age 26 years). The individuals were given 1.8 millilitre of 2 percent lignocaine combined with adrenalin and 4 percent articaine containing 1:100000 adrenalin during two different sessions. Short needles 30g along with self-aspiration syringe were employed. With 1.8 ml of the solution, a buccal infiltration in the maxillary right canine region was conducted, followed by 0.35 ml in the palate after 5 minutes. The discomfort generated by palatal injection (palatal pain sensitivity) was measured with the help of visual analogue scale (VAS), which ranged from zero to ten (greatest imaginable pain). Wilcoxon test used to analyse nonparametrically the onset of pulpal anaesthesia and the data from VAS values. In terms of start of action, pulpal anaesthetic duration, and anaesthetic duration of soft tissues, the differences were nonsignificant between articaine formulations and lignocaine formulations. Articaine and lignocaine exhibit similar behaviour according to the average VAS values.

Costa CG, Tortamano IP, Rocha RG, Francischone CE, Tortamano N (2005) [25] compared the effects of 2% lidocaine containing 1:100000 adrenalin, 4% articaine containing 1:200000 adrenalin, and 4% articaine containing 1:100000

adrenalin on the start and extent of pulpal analgesia for infiltration in maxilla. 20 healthy individuals, randomly given 1.8 millilitre of any one out of three LA formulations for operative dental procedures on three upper back teeth. To evaluate the start and extent of pulpal analgesia, a pulp testing unit that was powered by electricity was utilised. For 2% lidocaine containing 1:100000 adrenalin, 4% articaine containing 1:200000 adrenalin, and 4% articaine containing 1:100000 adrenalin, the average values for start of pulpal analgesia were around three, one and half, and one and half minutes, respectively, and that for duration of pulpal analgesia were around forty, fiftyseven, and sixtysix minutes. The differences for Kruskal- Wallis non-parametric test were significant in both articaine formulations compared to the lidocaine formulations, with superior results. In spite of the fact that 4% articaine containing 1:100000 adrenalin produced the quickest onset of action and prolonged duration of action of pulpal anaesthesia for infiltration in maxilla, the difference between the articaine formulations the were statistically insignificant. Statistically present study found no evidence that 4% articaine containing 1:100000 adrenalin produced superior clinical results than 4% articaine containing 1:200000 adrenalin.

Uckan S, Dayangac E, Araz K (2006) [9] tested articaine HCL to see if it may deliver palatal anaesthetic not requiring for a second injection palatally during upper arch tooth extraction. 23 individuals with extractions needed bilaterally and 30 individuals with extractions needed unilaterally extractions out of a total of 53. Test group consisted 2 milliliter of 4% articaine containing 1:100000 adrenalin, administered into the buccal vestibule of associated tooth. Then extraction was completed after 5 minutes. 27 patients were used as controls and were given the identical palatal injection technique. Following extraction, all individuals filled out a

Faces Pain scoring scale (FPS) and a 100-millimeter Visual Analogue scoring scale (VAS). When permanent upper arch tooth extraction by administering injection in palatal region (97.5%) and not administering injection in palatal region (96.8%) were evaluated using VAS and FPS scores, the differences were statistically insignificant. By injecting 2 millilitre articaine HCL into the maxillary arch buccal vestibule, it is possible to remove it permanently without palatal injection.

Al-Sultan AF, Fathie W, Hamid R (2006) [26] investigated **t**he buffering effect of LA formulations on its efficacy in periapical surgery. 80 patients requiring periapical surgery on one or more of their upper anterior teeth were decided to enrol in study. Then participants were placed into either of the two groups at random for comparison based on the local anaesthetic solution they would receive prior to surgery. Patients in the control group were given a commercially available local anaesthetic solution with a standard pH of 3.5. Patients who received a pH-adjusted local anaesthetic solution at 7.2 (using sodium bicarbonate) were included in the study. Pain during the injection, the onset of surgical anaesthetic, pain during the procedure, and the length of the operation were all documented. There was a substantial dissimilarity in the onset of surgical anaesthetic when both groups were compared, with the trial group having a speedier onset than the group which was controlled. In trial group, minimum discomfort observed during the deposition of the solution, as well as lower pain score levels observed during the surgery. As a result, the researchers concluded that pH adjusted local anaesthetic solutions may have some advantages over commercially available local anaesthetic solutions in terms of improving anaesthetic efficiency and reducing pain during injection and surgery.

Burns CA, Ferris G, Feng C, Cooper JZ, Brown MD (2006) [27] compared discomfort generated by intradermal injection with one percent lidocaine containing 1:100000 epinephrine alkalinized using sodium bicarbonate and one percent lidocaine mixed with epinephrine just prior in a prospective, double-blind research in 60 participants. Immediately after injection, volunteers judged the discomfort of infiltration on a 100-mm visual analogue scoring scale. They utilised the paired t test to compare the pain values for various anaesthetic solutions. The pain values for the buffered and fresh formulations were 18.3 20.3 and 23.5 19.1 (P =.0543), respectively. The fresh solution was determined to be more unpleasant by 65 percent of volunteers than the buffered solution. The findings were not statistically significant. They eventually found that intradermal injections of alkalinized lidocaine containing epinephrine caused minimum pain compared to lidocaine combined with epinephrine just priorly, although the difference was statistically insignificant.

Corbett IP, Kanaa MD, Whitworth JM, Meechan JG (2008) [28] compared 4 percent articaine combined with 1:100000 adrenalin for administration in buccal region to buccal plus lingual administration of the equal dose of medication for both group in order to achieve pulpal analgesia of lower arch first molar tooth. For a group of 27 volunteers, the results were compared to the efficacy of a nerve block in inferior alveolar nerve using two percent lidocaine combined with 1:80,000 adrenalin. Pulp tester which works electrically was used for determination of analgesia. The efficacy for administration in buccal region to buccal plus lingual administration of articaine anaesthetic combined with adrenalin in obtaining pulpal analgesia for lower arch permanent first tooth did not differ. Over a 30-minute trial period, the effectiveness of four percent articaine combined with adrenalin administration for pulp analgesia of

first molar tooth was comparable to a nerve block in inferior alveolar nerve using two percent lidocaine combined with 1:80,000 adrenalin (96 and 80 no-response events at maximum activation, respectively). Subjective dental numbing was more prevalent after IANB than buccal infiltrate. Buccal administration using articaine caused discomfort that was dependant on volume and similar to that of an IANB.

Srinivasan N, Kavitha M, Loganathan CS, Padmini G (2009) [29] examined the anaesthetic efficacy of four percent articaine and two percent lidocaine both containing 1:100000 adrenalin for buccal administration in patients with pulpal inflammation in upper arch posterior teeth to conduct randomized, double-blinded study. Endo access was opened after getting buccal infiltration. During the endodontic operation, effectiveness was determined as nil or minor discomfort (VAS values). They reported a 100 percent effectiveness rate for upper arch infiltration in buccal region to create pulpal anaesthesia with articaine, and an 80 percent success rate for the lidocaine solution in the first bicuspid and 30% in the first molar tooth. The research For maxillary buccal infiltration in posterior teeth, four percent articaine was discovered more effective than two percent lidocaine anaesthesia.

Whitcomb M, Drum M, Reader A, Nusstein J, Beck M (2010) [30] compared the anaesthetic success of a buffered 2 percent lignocaine with adrenalin and alkalinized with sodium bicarbonate formulation and nonbuffered 2 percent lignocaine with adrenalin formulation nerve block given in inferior alveolar space in two different visits and the gap between two visits was at least 7 days. All teeth except canines and third molars were tested for anaesthesia using pulp tester which electrically handled in 4 min cycles for one hour. When two consecutive eighty readings scores were acquired within 15 min and the eighty reading was sustained for

one hour, anaesthesia was judged successful. Successful pulpal anaesthesia ranged from 10-71 percent in buffered 2 percent lignocaine with adrenalin. Success for anaesthesia of pulp ranging from 10-72 percent in the nonbuffered 2 lignocaine with adrenalin formulation The differences were insignificant between the two anaesthetic compositions. In comparison to the unbuffered lidocaine formulation, the buffered lignocaine formulation did not result in a quicker onset of analgesia of pulp or reduced pain and discomfort during administration. As a result, they concluded that using sodium bicarbonate to buffer a 2 lignocaine with adrenalin for a nerve block in inferior alveolar space did not increase success of analgesia, give quicker onset, or result in minimum pricking pain of administration when comparison was made with nonbuffered 2 percent lignocaine with adrenalin.

Kashyap VM, Desai R, Reddy PB, Menon S (2011) [31] investigated the outcome of alkalinizing lignocaine with sodium bicarbonate for nerve anaesthetization intraorally on injection pain and start time of anaesthesia. For this research, middle aged 100 individuals included who were administered three nerve anaesthetization in inferior alveolar space, lingual space, and long buccal space to test the outcome of alkalinization. All the individuals were administered with double percentage of lignocaine hydrochloride combined with adrenalin dose, and half of individuals were administered 8.4 percent sodium bicarbonate with 0.1 dilution at random. Then on a scoring of visual analogue scale (VAS) scores, no patient who received formulation with sodium bicarbonate injection made complain of pain, when compared with more than three quarter who didn't receive formulation with sodium bicarbonate. In sodium bicarbonate group, the average time to starting off local anaesthetization was around just more than a half minute, when comparison was made

with control group in which it was nearly closed to two minutes. As a result, they proved that alkalinized local anaesthetic formulation's efficacy for lowering pricking pain of injection and resulted in quicker onset of anaesthetization.

Kalia V, Supreet, Kaur R (2011) [32] compared onset and duration of forth percent of articaine combined with adrenalin to double percentage of lidocaine combined with adrenalin by kalia et al for anaesthetization during exodontia. A total of 100 people were decided to be enrol in this randomised, controlled, single-blinded, cross-over trial based on the inclusion and exclusion criteria. Each patient required bilateral extractions of a similar sort, which were completed in two sessions. They were given 4 percent articaine with 1:100000 epinephrine on either side and anaesthetization of lidocaine with 1:100000 epinephrine on another side during single appointment. Onset of anaesthesia and the length of post-operative anaesthesia were both assessed and compared. In terms of the beginning of subjective and objective symptoms, as well as the onset of pulpal anaesthesia, substantial difference among 4 percent articaine and double percentage of lidocaine was observed. This indicates that 4 percent articaine has a shorter onset of anaesthesia than 2 percent lidocaine. The mean anaesthetic duration difference between the two agents was 1.19760 hour, which was statistically and clinically significant, indicating that forth percent of articaine has prolonged period of anaesthesia than the 2 percent lidocaine.

Hobeich P, Simon S, Schneiderman E, He J (2013) [33] compared injection penetration pain and anaesthetic onset of doubled percentage of lidocaine combined with adrenalin alkalinized with fifth percentage and tenth percentage of sodium bicarbonate in upper arch infiltrations at three distinct sessions in a prospective, randomised, double-blind research in 30 patients. A scoring of Heft-Parker visual

analogue scale scores were utilized to record pain during penetration of needle and deposition of anaesthetic solution. Two recurrent negative answers to pulp testing unit which was electrically driven were used to determine anaesthetic onset. The average time it took for nonbuffered anaesthetics to start working was almost around 2 minutes for all the three formulations. The differences were insignificant for pain of penetration of needle and deposition of anaesthetic formulation for all three anaesthetics. In infiltrations of upper arch for canines with healthy pulps, all the three formulations didn't vary from one another in terms of anaesthetic onset or discomfort of injection.

Malamed SF, Tavana S, Falkel M (2013) [34] compared the anaesthetic onset and pricking pain of injection of alkalinized anaesthetics with non-alkalinized anaesthetics in nerve block in inferior alveolar space which were measured using pulp testing unit which is electrically driven, and pricking pain of injection was evaluated with use of a visual analogue scale scores in 20 patients in a split mouth study. Using a mixing pen gadget, the researchers buffered the anaesthesia directly in the cartridges. Non-alkalinized two percent lidocaine combined with adrenalin at pH of 3.85 was used as control group solution. The test solution's pH was alkalinized to 7.31 with two percent lidocaine combined with adrenalin. With the alkalinize anaesthetic, 71 percent of individuals had pulpal analgesia in less than 2 minutes. Pulpal analgesia was induced in 12 percent of cases with non-alkalinized anaesthetics in 2 minutes or less. The alkalinized injection was rated as more comfortable by 72 percent of the subjects, 11 percent preferred the nonalkalinized injection, and 17 percent had no preference. On a 100-mm VAS, 44% of patients received alkalinized anaesthetic solution and assessed injection discomfort as 0 ("no pain"), compared to

only 6% of patients getting non-alkalinized anaesthetic solution. They concluded that alkalinizing lidocaine up to the pH of physiologic pH just before administration of injection dramatically decreased time of onset of anaesthetic and improved comfort of injection.

Agarwal A, Jithendra KD, Sinha A, Garg M, Sharma S, Singh A (2015) [35] assessed the anaesthetic effectiveness of two percent lidocaine combined with adrenalin and alkalinized with sodium bicarbonate for nerve blocks in inferior alveolar space in a crossover trial. In a crossover design, thirty individuals were given two blocks using 3 millilitre of 2 percent lidocaine combined with adrenalin and 2 millilitre of 2 percent lidocaine combined with adrenalin with a fixed amount of sodium bicarbonate at two different sessions spaced at least 1 week apart. The results showed that buffering the local anaesthetic solution made the injection experience more pleasant for the patient, with 70% reporting no pain during solution deposition. 2 percent of lidocaine combined with adrenalin and sodium bicarbonate has speedier onset, with 74 percent of nerve blocks taking less than 1 minute, whereas 2 of percent lidocaine combined with adrenalin only had 67 percent success rate after 2 minutes. When compared to unbuffered anaesthetic solution for IAN block, they found that buffering the anaesthetic solution greatly reduced injection pain and provided faster onset.

Shurtz R, Nusstein J, Reader A, Drum M, Fowler S, Beck M (2015) [36] investigated the effect of 4 percent buffered articaine for primary infiltration in buccal region of first molar of the mandibular arch. Primary goal of the randomised trial was comparing degree of pulpal analgesia achieved with a buffered 4% articaine combined with epinephrine formulation and nonbuffered 4% articaine combined with

epinephrine formulation for primary infiltration in buccal region of first molar of the mandibular arch. In this study, 80 participants were given infiltrations in mandibular buccal region using 4% articaine combined with epinephrine and buffered using 8.4 percent sodium bicarbonate and 4 percent articaine combined with epinephrine at two separate sessions in a double-blind fashion. The first molar was tested for pulpal anaesthesia with an electric pulp tester every half minute for the first five minutes and then every one minute for the following fiftyfive minutes. Two back to back 80 out of 80 results on electric pulp testing unit were considered successful pulpal anaesthesia. The start time of pulpal anaesthetic as well as ratings for pain of each injection were noted. The rate of anaesthesia success for buffered and nonbuffered articaine were found to be 71% and 65%, respectively. For injection pain or anaesthetic onset, the difference was insignificant when two formulations compared. As a result of their observations, they found that buffered articaine had no advantage over nonbuffered articaine in terms of anaesthetic success, anaesthesia onset, or injection pain for primary infiltration in buccal region of first molar of the mandibular arch.

Arali V and Mytri P (2015) [3] compared the anaesthetizing success of 4 percent articaine for infiltration in mandibular buccal region with 2 percent lignocaine nerve block in inferior alveolar space, in children with irreversible pulpitis. 40 children aged 5-8 years old were participated in this trial. The participants and the paediatric dentist who performed pulpectomy were blinded. Then one of the treatments listed below was applied. For buccal infiltration, 1.8 millilitre of 4 percent articaine combined with epinephrine was injected into the muco-buccal fold near to a mandibular first primary molar of one side. For IAN block, 1.8 millilitre of 2 percent lignocaine combined with epinephrine was utilised for another side. When compared

with 2 percent lignocaine, the onset of anaesthesia of 4 percent articaine was faster. With articaine infiltration, anaesthesia lasted less time. In the articaine group, there was less need for additional injection. In children with irreversible pulpitis and as an alternative for nerve block in inferior alveolar space, infiltration with 4 percent articaine could be employed.

Saatchi M, Khademi A, Baghaei B, Noormohammadi H (2015) [4] studied the effectiveness of nerve block in inferior alveolar space for teeth with irreversible pulpal inflammation with symptoms using sodium bicarbonate–buffered lidocaine. For that total of 80 patients with earlier specified criteria were chosen for this study. Using typical IAN block injections, the patients received either 2 percent lidocaine combined with epinephrine which was buffered with 0.18 millilitre 8.4 percent sodium bicarbonate as buffer solution or 2 percent lidocaine combined with epinephrine with 0.18 millilitre distilled water. 15 minutes following injection, endodontic access preparation began. All of the patients required lip numbing. Visual analogue scale recordings taken during cavity preparation and no or minor pain was considered as success. The differences were insignificant for success rate between two groups. Conclusion was made based on the results that buffering didn't enhance effectiveness of local anaesthetics for IAN block in specified criteria.

Luqman U, Majeed Janjua OS, Ashfaq M, Irfan H, Mushtaq S, Bilal A (2015) [37] compared single buccal articaine injections to traditional lignocaine buccal and palatal injections for maxillary tooth extractions. Maxillary teeth were separated into three groups, and the faces pain scoring scale (FPS) and visual analogue scoring scale (VAS) were utilized to quantify per operation pain objectively and subjectively. A total of 194 patients took part in the research. The VAS scores of all teeth showed a

statistically significant difference. In addition, both groups' FPS scores were statistically insignificant. For maxillary exodontia, researchers found that infiltration in buccal region with a solitary injection of articaine and infiltration in both buccal region and palatal region for lignocaine were both similarly efficient.

Chopra R, Jindal G, Sachdev V, Sandhu M (2016) [5] compared experience of pain during nerve block administration in inferior alveolar space using 2% buffered lidocaine in child patients. For that thirty 6 - 12 years old children underwent two visits of nerve block in inferior alveolar space which was scheduled with gap of seven days. 2% lidocaine combined with adrenalin was administered in one appointment, and prepared buffered formulation was administered during the other. The sound, eye, and motor (SEM) scoring scale, was utilized to assess pain on injection and time to start of anaesthesia was assessed when probing was done in gingiva. Visual analogue scale scores was self-recorded by a child patient after local anaesthetics administered. The observations revealed that the differences were insignificant between the two formulations for both SEM and HP-VAS scores. The difference in the start of anaesthesia was likewise shown to be statistically not significant using the Student's t test. They concluded that buffering of lidocaine didn't help to reduce injection discomfort time to start of anaesthesia for nerve block in inferior alveolar space in children.

Kolli NKR, Nirmala SVSG, Nuvvula S (2017) [38] evaluated and compared, the pain levels during exodontia of deciduous molars of upper arch with the use of conventional lignocaine anaesthetic against lignocaine plus articaine in buccal infusion. For that, ninety children using randomization, were assigned to undergo lignocaine conventional anaesthesia which was control group, articaine in buccal

infusion as group II, and lignocaine in buccal infusion as group III. Following maxillary primary molar extraction, a combine score of self-reported (facial legs activity cry consolability scale score) and pulse rate were evaluated. During primary maxillary molar extraction, they discovered that group II had pain scores significantly reduced for self-reported and behavioural measures and the differences were insignificant group 2 and control group.

M M A, Khatri A, Kalra N, Tyagi R, Khandelwal D (2019) [39] compared the perception of pain and anaesthetic efficacy of 2 percent lignocaine combined with adrenalin, buffered lignocaine anaesthetic, and 4 percent articaine combined with adrenalin for the nerve block in inferior alveolar space. For that 48 children of aged 5 to 10 years old who got three nerve block administration of injection spaced one week apart in three sessions were included. The Wong-Baker Faces pain scoring scale and the sound eye motor scoring scale were used to assess pain after injection. Subjective and objective markers were used to determine anaesthetic efficacy (pain on probing). The outcomes revealed pain perception measured by the Wong-Baker scoring scale after injection differed considerably when buffered lignocaine compared with lignocaine and also with articaine. Buffered lignocaine anaesthetic had the earliest onset of anaesthesia, with a substantial statistical difference when buffered and only lignocaine compared. The efficacy of local analgesia was substantially different between buffered lignocaine and only lignocaine, as well as lignocaine and articaine, as measured by objective signs. The authors concluded that buffered lignocaine was minimally painful and greater effective anaesthetic agent during nerve block in inferior alveolar space injections in 5 to 10 year old kids based on the findings.

Rathi NV, Khatri AA, Agrawal AG, M. SB, Thosar NR, Deolia SG (2019)[40] evaluated and compared the efficacy of articaine vs lidocaine, both of which contain adrenalin, using a solo infiltration in buccal region for deciduous molar exodontia. Children aged seven to twelve years who needed deciduous molar exodontia were enrolled in the study and received infiltration buccal region with either articaine or lidocaine, both with epinephrine, with fifty children in each group. Strong construct and valid Wong-Baker Facial Pain scoring scale, was used in subjective estimation of perception of pain during exodontia. The values of heart rates and blood pressures were objectively examined as an indirect indicator of physiologic pain perception. In all children who received articaine, a solo infiltration in buccal region was sufficient to provide anaesthesia in palatal or lingual region, but all of the children who received lidocaine required additional anaesthetic. The lidocaine group had a higher mean FPS value, which was statistically significant. In the articaine group, the average heart rate noted during the use was lower than average baseline values, which was statistically significant. The researchers determined that a solo infiltration in buccal region using 4 percent articaine containing adrenalin produced appropriate palatal or lingual local anaesthetic for deciduous molar exodontia in paediatric patients aged 7 to 12 years, when comparison was made with 2 percent lidocaine containing adrenalin.

Amorim KS, Fontes VTS, Gercina AC, Groppo FC, Souza LMA (2020) [41] evaluated and compared start, depth of pulp and soft tissue anaesthetization, success of anaesthetization and discomfort of 2 percent buffered articaine and 4 percent non-buffered articaine formulations during injection. Volunteers were chosen for this randomised, triple-blind, crossover clinical experiment, and each got two maxillary

supra-periosteal anaesthetic administrations in the canine area region. The administration of injections were carried out in two visits, with each session utilising a different local anaesthetic solution and a 1 mL/min anaesthetic injection speed. The electrical pulp testing unit and the esthesiometer kit were used to evaluate the start, depth of pulp and soft tissue anaesthetization, respectively. On a visual analogue scale, volunteers rated their pain during injections. The pH of the anaesthetic solutions was determined using pH metre equipment. Except for pain or discomfort during administration of the injection, which was minimum when buffered 2 percent articaine was utilized and the pH, they found no difference between the two anaesthetizing solutions. The pH study showed that the solutions were not identical. They concluded that a 2 percent buffered articaine solution had the same anaesthetic characteristics as a 4 percent unbuffered articaine solution, but with a significant reduction in discomfort during injection.

Hemmanur S and Nasim I (2020) [1] investigated the anaesthetic success of buffered versus conventional local anaesthetic agents in patient with irreversible pulpal inflammation with symptoms. They looked at when local anaesthetic started working, how long it lasted, and how much pain the patient felt during the course of action. Patients identified with irreversible pulpal inflammation with symptoms and intact periapical tissues appropriate for endodontic therapy were enrolled in this double-blind randomized clinical research. 32 teeth with irreversible pulpal inflammation allocated randomly eight teeth into four groups. Control group was teeth treated with traditional 2 percent lignocaine that was group I and group III treated with traditional 4 percent Articaine hydrochloride. In experimental group, group II treated with buffered 2 percent lignocaine and group IV treated by buffered 4 percent

articaine hydrochloride. Based on the findings, they concluded that buffered articaine is statistically considerably better than conventional or buffered lignocaine as an anaesthetic agent. The researchers came to the conclusion that buffering local anaesthetic agents improves their efficacy, start of action, and longevity. As a result, buffered local anaesthetics can be utilised instead of traditional anaesthetics.

Tirupathi SP and Rajasekhar S (2020) [42] investigated the success of a single infusion in buccal region of 4 percent articaine to minimize pain during procedure that was exodontia of upper and lower deciduous molar teeth. They wanted to see if they could get rid of palatal administration of injections and nerve block in inferior alveolar space by using a single infusion in buccal region with 4 percent articaine to extract deciduous molars. The authors used PROSPERO to record this systematic review and followed PRISMA principles for reporting it. For that published research between 1990 and 2020, searched electronically in three databases: PubMed, Ovid SP, and Cochrane. All of the papers included were randomised control trials with children ranging in age from five to fourteen. Systematic review included studies that compared single infusion in buccal region with 4 percent articaine to one of comparison groups including: a) solitary infusion in buccal region with 2 percent lignocaine; b)buccal with palatal or lingual infiltration anaesthesia with 2 percent lignocaine; c) nerve block in inferior alveolar space with 2% lignocaine. The FLACC (Face, Legs, Arms, Cry, Consolability) values for solitary infusion in buccal region with 4 percent articaine was substantially lower when compared with FLACC values for solitary infusion in buccal region with 2 percent lignocaine. The single infusion in buccal region of 4 percent articaine had considerably lower FLACC ratings than the twice infiltration of 2 percent lignocaine group. The efficacy of rates of single infusion in buccal region of 4 percent articaine and nerve block in inferior alveolar space with 2 percent lignocaine were not significantly different during extraction. Despite the fact that the majority of studies favour single infusion in buccal region

with 4% articaine for minimizing pain during deciduous molar exodontia, the proof was not sufficient to made conclusion that it is superior to single infusion in buccal region, double infusion administration (buccal with palatal or lingual), or nerve block in inferior alveolar space with 2% lignocaine.

METHODOLOGY

The present randomized control study was carried out in the department of paediatric and preventive dentistry of the concerned dental college to evaluate and compare clinical effectiveness of buffered and nonbuffered 4% articaine (with 1:100000 adrenaline) infiltration for primary maxillary molar extractions in 4 to 10 year old children. The study was carried out after obtaining ethical clearance from the institutional ethics committee. Parents of the children selected for the study were explained the purpose and methodology of the study in local vernacular language and a signed informed consent was obtained. Children's assent for the treatment procedure was also acquired.

Sample size was determined considering the difference in proportion of pain on injection as one of the outcome major.

Following assumptions were made from study by Shurtz R et al, 2015 [36]

1) Proportions in buffered group was 71.25 %

2) Proportion in nonbuffered group was 91.25 %

3) Difference in proportion (effect size) was 20 %

4) Power (1-β) was 80 %

5) An α error is 10 % (1 sided)

Required sample size ; n = 33 per group

Therefore, 35 children per group were selected in two groups considering 10% dropouts.

$$n = \frac{\{Z_{1-\alpha}\sqrt{2P(1-P)} + Z1-\beta\sqrt{P1(1-P1)} + P2(1-P2)\}2}{(P1-P2)2}$$

Where P is mean of two sample proportions = $\frac{P1+P2}{2}$

SAMPLING

A total of 70 children were selected from the outpatient department of paediatric dentistry by using a convenience sampling procedure based on following selection criteria.

INCLUSION CRITERIA

- Healthy children of 4-10 years of age.
- Children cooperative enough to follow the instructor's directions. (Frankl's definitely positive and positive) [43].
- Children having at least one primary maxillary molar indicated for extraction under local anaesthetic.
- Children whose parents/caretakers sign the consent letter of participation.
- Children who gave assent for the treatment.

EXCLUSION CRITERIA

- Children with an active infection at the site of injection.
- Children with a known history of allergy to any local anaesthetic agent.
- History of major dental treatment in last 6 months.

STUDY DESIGN:

A randomized, double-blind study (Patient and second investigator (I2) were blinded to the allocation of local anaesthetic solution)

Calibration of a researcher:

Calibration of a researcher for the sound, eye, and motor (SEM) scale was done prior to the commencement of the study. Ten patients, not included in the study, were video-graphed during buccal and palatal infiltration. One researcher and one independent observer rated the SEM motor responses on these recorded videos. Next, the values for both the observers were calibrated until full agreement was achieved.

Intra-rater reliability:

First 10 videos were reassessed by investigator 2 & rated separately for evaluations of pain on injection and profoundness of anaesthesia during procedures to establish intra-rater reliability [44].

TREATMENT ALLOCATION:

The children were randomly divided into two groups based on simple randomization by envelope method. A total of 70 sealed envelopes were prepared, containing one card each having the names of either of the buffered or nonbuffered

local anaesthetic drug, accordingly 35 envelopes of group 1 and 35 envelopes of group 2 were prepared.

Exact equal gender wise distribution in each group was not possible due to unequal number of participants in each group. But for nearly equal distribution, 2 blocks were prepared by thoroughly shuffling, 18 envelopes in block 1 and 17 envelopes in block 2. The series of envelopes thus formed were numbered from 1- 35 in each block. For male patient an envelope was drawn from block 1 and for female patient envelope was drawn from block 2 sequentially by investigator 1 in first visit. The randomized sequence of envelopes was prepared by the individual who was not involved in the study [45].

CLINICAL METHODOLOGY

After random allocation into 2 groups by withdrawing one envelope from either of blocks. Each child underwent 2 visits for treatment completion.

Visit 1: Children in both group underwent non-invasive treatment in the form oral prophylaxis to get them acclimatized to the dental environment and also confirm their cooperative behavior. Wong-Baker Faces Pain Rating Scale (FPS) [46] was introduced and explained to the children.

Visit 2: During the second visit, each child received a single anaesthetic dose by respective group protocol, group 1 [buffered 4% articaine (with adrenalin 1:100000) infiltration] and group 2 [nonbuffered 4% articaine (with adrenalin 1:100000) infiltration] for the maxillary tooth to be extracted.

LA sensitivity test was done prior to injection procedure by injecting intradermal 0.1 ml of respective drug. The intraoral injection site was dried with gauze. A cotton-tip applicator that contained approximately 0.2 ml of topical anaesthesic (LOX* 10% spray) was applied at injection site and left for one minute.

Buffered articaine solution was prepared as follows :

Under sterile conditions, 0.18 mL from a 1.8-mL cartridge of 4% articaine (with 1:100000 adrenalin) was drawn and replaced with 0.18 mL 8.4% sodium bicarbonate (8.4% weight/volume) using an insulin syringe. The insulin syringe was used to replace the LA solution with buffered solution [47]. The cartridge was then inverted 5 times to mix the solution such that no precipitation should be present. For nonbuffered LA solution, 0.18 mL from a 1.8-mL cartridge of 4% articaine (with 1:100000 adrenalin) was drawn and replaced with 0.18 mL of sterile distilled water [36].

For group 1 [buffered 4% articaine (with adrenalin 1:100000) infiltration] (Septanest, Septodont), buccal infiltration was performed with 1.5 ml of solution. The solution was administered in the depth of the mucobuccal fold opposite to the maxillary molar and palatal infiltration was performed with approximately 0.2-0.3 ml of solution which was administered in palatal mucosa of the maxillary molar to be extracted [48,49]. Rate of injection was approximately 1.5 ml / minute. For group 2 [nonbuffered 4% articaine (with adrenalin 1:100000) infiltration] (Septanest, Septodont) same procedure followed as group 1. Both anaesthetic drugs were administered by self-aspirating needle (Wal-Syringes - walldent syringe) & 30 gauge short needle (Septoject, Septodont). The lowest effective dose of anaesthesia was administered as submucosal infiltration. Up to one cartridge of articaine (maximum

dose: 7 mg/kg body weight) was administered as infiltration. After confirming all signs & symptoms of profound LA, extraction procedure was carried out following the standard protocol [2]. A child was not included in the study, if he /she expressed signs & symptoms of pain after 5 min of local anaesthesia administered or during extraction.

Complete procedure was videotaped & recording was done from a fixed distance from the dental chair with a video recorder such as to provide complete visual of child. The recording started from the moment the child sat in the dental chair during second visit and ended when the extraction procedure was completed. All local anaesthesia and extractions procedure were performed by an investigator 1 in all patients. Training and calibration for local anaesthesia technique and extraction procedure was done with subject expert prior to start of clinical procedure of the study. Calibration of investigator 2 for objective evaluation of pain and discomfort by Sound Eye Motor (SEM) scale was done before study.

TOOLS OF MEASUREMENT:

Tools used for measuring pain on injection were as follows:

1. Wong Baker Faces Pain Rating Scale:

The Wong Baker Faces pain rating scale consisted of 6 faces with increasing degree of pain from left to right and had a numerical scale from 0-10 corresponding to each face.

2. Sound, Eye & Motor (SEM) scale:

This scale was designed to measure subject comfort or pain. The rating of comfort takes into account three types of observations -sounds, eyes, and motor. The level of response for each observation was given a numerical value and these values are averaged to obtain the comfort level.

Observations of possible indications of pain	Comfort or pain level			
	1-comfort	2- mild discomfort	3- moderately painful	4- painful
Sound	No sounds indicating pain	Nonspecific sounds; possible indication of pain	Specific verbal complaints (such as "OW"), raises voice	Verbal complaint indicate intense pain (such as screaming, sobbing)
Eye	No eye signs of discomfort	Eyes wide, show of concern, no tears	Watery eyes, eyes flinching	Crying tears running down face
Motor	Hands relaxed; no apparent body tension	Hands showing some distress or tension; grasping of chair owing to discomfort, muscular tension	Random movement of arms or body without aggressive intention of physical contact, grimacing, twitching	Movement of hands to make aggressive physical contact (such as pushing, pulling head away)

Tools for measuring onset of anaesthesia:

1. Stop watch

2. Straight probe

METHODS OF MEASUREMENT

During visit 2, parameters recorded were pain on injection, onset of anaesthesia (measured in seconds) for buccal and palatal infiltration and efficacy of anaesthesia.

A) Assessment of pain on injection:

Subjective assessment of pain on injection: The pain experienced by patient during the administration of the injections was recorded by investigator 2, asking child to select the facial expression that best represented by his/her experience of pain or discomfort by Wong-Baker Faces Pain Rating Scale (WBFPS) [46] for both buccal infiltration and palatal infiltration.

Objective assessment of pain on injection: The pain experienced by patient during the administration of the injections was recorded by investigator 2 objectively by, watching videotape of injection procedure from patient sitting on chair till the end of LA procedure by using the Sound Eye Motor Scale (SEM) [43]. The level of response for each observation was given a numerical value and these values were averaged to obtain to asses pain on injection in children objectively.

B) Assessment of onset of anaesthesia (measured in seconds):

The time of onset of anaesthesia was defined as the first sensation of numbness or tingling in the anesthetized region. It was calculated using a stop watch from the point of retrieval of the needle after the injection up to the 1st symptom of anaesthesia subjectively for both the buccal infiltration and the palatal infiltration. The time of onset was evaluated objectively by, operator (investigator 1) by the presence

/absence of pain to prick of sharp dental probe applied on gingival margin on the attached gingiva surrounded to the tooth to be extracted.

C) Assessment of clinical effectiveness of anaesthesia:

Subjective and objective assessment of pain during extraction

Profoundness of anaesthesia assessed by evaluating pain during extraction, immediately after extraction, the patients were questioned by investigator 2 about the pain they had perceived during the extractions & asked to select the facial expression that best represented by his/her experience of pain /discomfort by Wong-Baker Faces Pain Rating Scale (WBFPS) [46] and objectively by investigator 2 watching videotape of procedure from start of LA procedure till end of extraction by using the Sound Eye Motor Scale (SEM) [43].

Recording of data:

Respective parameter data (subjective and objective measurement) was recorded in the customized case record proforma.

MATERIALS –

A. Mouthmask, headcap and gloves

B. **Oral examination diagnostic instruments** –

a. Mouth mirror

b. Probe

c. Tweezer.

C. Materials –

a. Topical anaesthetic solution

b. 4% articaine (with adrenaline 1:100000)

c. 8.4% sodium bicarbonate buffering solution (8.4% weight/volume)

d. Self-aspirating syringe
e. 30 gauge needle
f. Personal protective equipment (PPE) kit
g. Insulin syringe

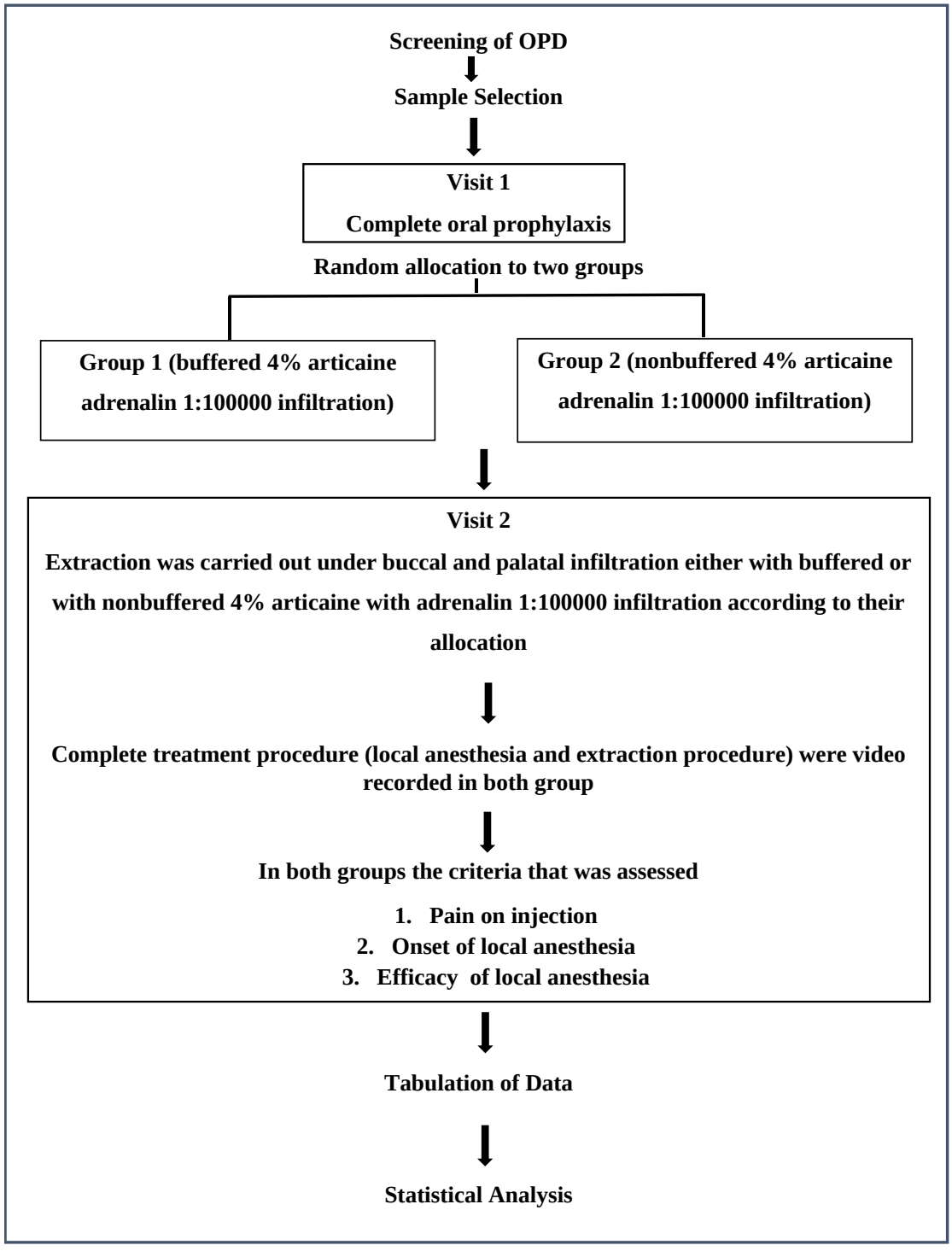
D. Extraction instruments –

a. Maxillary molar extraction forceps (Rotex Germany)
b. Moon's probe
c. Periosteal elevator

E. For measuring pain on injection, onset of anaesthesia and effectiveness of anaesthesia –

1) Sound Eye Motor (SEM) scale
2) Wong baker faces pain rating scale.
3) Stopwatch

Procedures and Protocol



COLOR PLATE NO. 1

Fig 1: Surgical Gloves, Head Cap And FFP 2 Facemask

Fig.2 : Personal Protective Equipment (PPE) Kit

COLOR PLATE NO. 2

Fig.3 Diagnostic Instruments

Fig 4: Topical Anaesthetic Solution

COLOR PLATE NO. 3

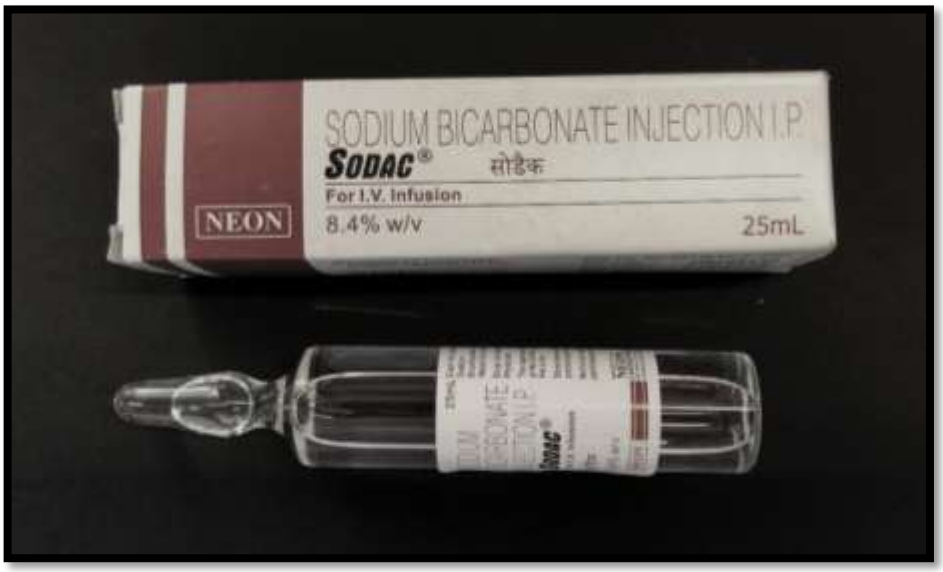


Fig.5 : 8.4% Sodium Bicarbonate

Fig.6 : Articaine with Adrenaline 1:100,000 (Septanest)

COLOR PLATE NO. 4

Fig 7 : Waldent Wal-syringes Self-aspirating Syringe

Fig 8 : Self-aspirating Syringe Adapted with 30 Guage Needle

Fig 9: Insulin Syringe

COLOR PLATE NO. 5

Fig 10 : Instruments For Extraction Procedure

Fig 11: Intra Operative Photographs

RESULTS

A total of seventy 4 to 10-year-old children (36 males and 34 females; in which 35 in each group; mean age for buffered articaine group equals 8.29±1.29 years and mean age for nonbuffered articaine group equals 7.86±1.30 years) participated in the study, and each received buccal and palatal infiltration and underwent extraction of primary maxillary molars. Comparison of pain on injection for buccal and palatal infiltration and pain during extraction by Wong Baker scale and SEM scale and objective and subjective onset of anaesthesia (seconds) between buffered and nonbuffered group was done along with the subgroup analysis for age of children.

STATISTICAL FORMULAS

Analysis of the data was done by using both descriptive and inferential statistics. Descriptive statistics used for distribution of children in the present study. Together with simple graphics analysis, it was used for quantitative analysis of data in the present study. Inferential statistics used to make judgments of the probability that

an observed difference between groups was a dependable one or one that might have happened by chance in this study. Thus, inferential statistics use to make inferences from our data to more general conditions.

The software used in the analysis were SPSS 24.0 and Graph Pad Prism 7.0 version and $p<0.05$ is considered as level of significance.

The statistical tests used for the analysis of the results were:

1. Student's unpaired t test
2. Chi square Test

Descriptive Statistics :

1. **Arithmetic Mean** :The arithmetic mean, or average, is the sum of the values divided by the number of values.

Formula:

$$\overline{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

Where:

$\overline{X}$ = Sample arithmetic mean

n = Sample size

$X_i = i^{th}$ Observation of the random variable X

$\sum_{i=1}^{n} X_i$ = Summation of all the X_i values in the sample

2. Standard Deviation (SD) =

$$\sqrt{\frac{\Sigma(X - \bar{X})^2}{(n - 1)}}$$

where:

X = each score
$\bar{X}$ = the mean or average
n = the number of values
Σ means we sum across the values

<u>Inferential Statistics</u> :

1. Student's unpaired t test

Assumption:

1. The samples (n_1 and n_2) from two normal populations were independent.
2. The appropriate sampling distribution of the test statistic was the t distribution
3. The unknown variances of the two populations were not equal

To compute the two-sample t-test two major computations were needed before computing the t-test. First, we estimated the pooled standard deviation of the two samples. The pooled standard deviation gives weighted average of the standard deviations of the two samples. The ***pooled standard deviation*** was between the two standard deviations, with greater weight given to the standard deviation from a larger sample. The equation for the pooled standard deviation was:

$$S_P = \sqrt{\frac{(n_1 - 1)S_1^2 + (n_2 - 1)S_2^2}{n_1 + n_2 - 2}}$$

In all work with two-sample t-test the degrees of freedom or df was:

$$df = n_1 + n_2 - 2$$

The formula for the two sample t-test was:

$$T = \frac{\overline{X} - \overline{Y}}{S_p \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

2. Chi square Test

- Formula
  - o = observed data in each category
  - e = observed data in each category based on the experimenter's hypothesis
  - ∑ = Sum of the calculations for each category

$$X^2 = \sum \frac{(o - e)^2}{e}$$

Reliability Analysis:

Intra-rater reliability was assessed by using Cronbach alpha method of reliability (as depicted in **Table 1**). The intra-rater evaluation of investigator 2 was alpha=0.900 & p-value=0.0001 for evaluations of pain on injection and pain during extraction. Thus, showing good reliability of investigator 2.

Inter-rater reliability was assessed with Pearson's Correlation Coefficient which was 0.832 and reliability was 0.9082 (as depicted in **Table 2**).

Results

Distribution of children according to their age and gender

The descriptive statistics for distribution of children according to demographic characteristics of age and gender in the present study as depicted in **Table 3 and Graph 1**. 37.14% of the children in buffered articaine group and 51.4% in nonbuffered articaine group were in the age group of 4-7 years, 62.86% in buffered articaine group and 48.6% in nonbuffered articaine group were in the age group of 8-10 years and the distribution was statistically not significant (p-value=0.33). In both the groups 51.4% of the patients were boys and 48.6% were girls.

Pain on injection:

a. Wong Baker Scale score

On comparing WBS score for the pain on injection during administration of buccal and palatal infiltration in both groups **(Table 4, Graph 2)** Mean WBS score for buccal infiltration in buffered articaine group was 1.20±0.24 and in nonbuffered group it was 3.07±0.51. By using student's unpaired t test **statistically significant difference** was found in WBS score for **buccal infiltration** among patients of two groups (t=4.36, p=0.0001).

Mean WBS score for palatal infiltration in buffered articaine group was 1.94±1.84 and in nonbuffered group was 4.62±3.02. By using student's unpaired t test **statistically significant difference** was found in WBS score for **palatal infiltration** among patients of two groups (t=4.48, p=0.0001).

b. Sound Eye Motor (SEM) Scale score

On comparing mean SEM Scale score for **pain on injection** between two groups **(Table 5, Graph 3)**, mean SEM score for buccal infiltration in buffered articaine group was 1.17±0.28 and in nonbuffered group it was 1.81±0.67. By using Student's unpaired t test **statistically significant difference** was found in SEM score for **buccal infiltration** among patients of two groups (t=5.13, p=0.0001).

Mean SEM score for palatal infiltration in buffered articaine group was 1.25±0.30 and in nonbuffered group it was 2.43±0.93. By using student's unpaired t test **statistically significant difference** was found in SEM score for **palatal infiltration** among patients of two groups (t=7.20, p=0.0001).

Onset of anaesthesia:

a. Subjective sign

On comparing time to **onset of anaesthesia** (subjective sign) between two groups **(Table 6, Graph 4)** mean onset of anaesthesia score for buccal infiltration in buffered articaine group was 49.22±4.24 and in nonbuffered group it was 78.48±7.35. By using student's unpaired t test **statistically significant difference** was found for onset of anaesthesia score for **buccal infiltration** among patients of two groups (t=20.38, p=0.0001).

Mean onset of anaesthesia score for palatal infiltration in buffered articaine group was 46±3.97 and in nonbuffered group it was 75.91±7.71. By using student's unpaired t test **statistically significant difference** was found in onset of anaesthesia score for **palatal infiltration** among patients of two groups (t=20.39, p=0.0001).

b. Objective sign

On comparing time to **onset of anaesthesia** (objective sign) between two groups **(Table 7, Graph 5)**, mean onset of anaesthesia score for buccal infiltration in buffered articaine group was 58.80±5.30 and in nonbuffered group it was 87.91±7.57. By using student's unpaired t test **statistically significant difference** was found in onset of anaesthesia score for **buccal infiltration** among patients of two groups (t=18.63, p=0.0001).

Mean onset of anaesthesia score for palatal infiltration in buffered articaine group was 54.88±4.40 and in nonbuffered group it was 86.57±7.06. By using student's unpaired t test **statistically significant difference** was found for onset of anaesthesia score for **palatal infiltration** among patients of two groups (t=22.51, p=0.0001).

Subgroup analysis :

Subgroups were made according to age (4 to 7 years and 8 to 10 years) to test the difference in mean values of parameters across the buffered and nonbuffered articaine group.

1. Pain on injection :

i. Wong Baker Scale Score

Subgroup analysis of WBS score **(Table 8, Graph 6 and Graph 7)** showed mean WBS score among **4-7 years** of age group for buccal infiltration in buffered articaine group was 1.07±1.32 and in nonbuffered articaine group it was 1.33±1.68. By using student's unpaired t test **no statistical significant difference** was found in WBS score among 4-7 years of age group in both the groups (t=0.45, p=0.65). Mean

WBS score among **8-10 years** of age group for buccal infiltration in buffered articaine group was 1.27±1.57 and in nonbuffered articaine group it was 1.05±1.24. By using student's unpaired t test **no statistical significant difference** was found in WBS Score among 8-10 years of age group in both the groups (t=0.45, p=0.64).

Mean WBS score among **4-7 years** of age group for palatal infiltration in buffered articaine group was 1.23±1.01 and in nonbuffered articaine group it was 5.44±2.63. By using student's unpaired t test **statistically significant difference** was found in WBS score among 4-7 years of age group in both the groups (t=5.45, p=0.0001). Mean WBS score among **8-10 years** of age group for palatal infiltration in buffered articaine group was 2.36±2.10 and in nonbuffered articaine group it was 3.76±3.23. By using student's unpaired t test **no statistical significant difference** was found in WBS score among 8-10 years of age group in both the groups (t=1.63, p=0.11).

ii. Sound Eye Motor (SEM) Scale score

Subgroup analysis of SEM Scale **(Table 9, Graph 8 and Graph 9)** showed mean SEM score among **4-7 years** of age group for buccal infiltration in buffered articaine group was 1.12±0.25 and in nonbuffered articaine group it was 1.09±0.22. By using student's unpaired t test **no statistical significant difference** was found in SEM score among 4-7 years of age group in both the groups (t=0.41, p=0.68). Mean SEM score among **8-10 years** of age group for buccal infiltration in buffered articaine group was 1.21±0.29 and in nonbuffered articaine group it was 1.27±0.31. By using student's unpaired t test **no statistical significant difference** was found in SEM score among 8-10 years of age group in both the groups (t=0.62, p=0.53).

Mean SEM score among **4-7 years** of age group for palatal infiltration in buffered articaine group was 1.20±0.25 and in nonbuffered articaine group it was 1.20±0.23. By using student's unpaired t test **no statistical significant difference** was found in SEM score among 4-7 years of age group in both the groups (t=0.01, p=0.98). Mean SEM score among **8-10 years** of age group for palatal infiltration in buffered articaine group was 1.28±0.32 and in nonbuffered articaine group it was 1.31±0.36. By using student's unpaired t test **no statistical significant difference** was found in SEM score among 8-10 years of age group in both the groups (t=0.23, p=0.81).

2. Onset of anaesthesia :

i. Subjective sign

Subgroup analysis of onset of anaesthesia (subjective sign) **(Table 10, Graph 10 and Graph 11)** showed that mean time of onset of anaesthesia score among **4-7 years** of age group for buccal infiltration in buffered articaine group was 49.30±3.40 and in nonbuffered articaine group it was 75.22±7.47. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 4-7 years of age group in both the groups (t=11.61, p=0.0001). Mean time of onset of anaesthesia score among **8-10 years** of age group for buccal infiltration in buffered articaine group was 49.18±4.74 and in nonbuffered articaine group it was 81.94±5.55. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 8-10 years of age group in both the groups (t=19.85, p=0.0001).

Mean time of onset of anaesthesia score among **4-7 years** of age group for palatal infiltration in buffered articaine group was 45.92±3.79 and in nonbuffered articaine group it was 79±5.62. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 4-7 years of age group in both the groups (t=18.35, P=0.0001). Mean time of onset of anaesthesia score among **8-10 years** of age group for palatal infiltration in buffered articaine group was 46.04±4.16 and in nonbuffered articaine group it was 72.64±8.41. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 8-10 years of age group in both the groups (t=12.95, P=0.0001).

ii) Objective sign

Subgroup analysis of onset of anaesthesia (objective sign) **(Table 11 and Graph 12, Graph 13)** showed that mean time of onset of anaesthesia score among **4-7 years** of age group for buccal infiltration in buffered articaine group was 58.46±3.64 and in nonbuffered articaine group it was 84.83±6.17. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 4-7 years of age group in both the groups (t=13.72, P=0.0001). Mean time of onset of anaesthesia score among **8-10 years** of age group for buccal infiltration in buffered articaine group was 59±6.15 and in nonbuffered articaine group it was 91.17±7.69. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 8-10 years of age group in both the groups (t=14.51, P=0.0001).

Mean time of onset of anaesthesia score among **4-7 years** of age group for palatal infiltration in buffered articaine group was 54.46±3.40 and in nonbuffered articaine group it was 87.88±5.87. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 4-7 years of age group in both the groups (t=18.36, P=0.0001). Mean time of onset of anaesthesia score among **8-10 years** of age group for palatal infiltration in buffered articaine group was 55.13±4.95 and in nonbuffered articaine group it was 85.17±8.08. By using student's unpaired t test **statistically significant difference** was found in mean time of onset of anaesthesia score among 8-10 years of age group in both the groups (t=14.31, P=0.0001).

3. Pain during extraction

i. Wong Baker Scale Score

On comparing WBS score for **pain during extraction**, **(Table 12 and Graph 14)** showed mean WBS score for pain during extraction in buffered articaine group was 1.77±2.31 and in nonbuffered group it was 5.14±3.15. By using student's unpaired t test **statistically significant difference** was found in WBS score among patients of two groups (t=5.09, p=0.0001).

ii. Sound Eye Motor (SEM) Scale score :

On comparing SEM scale for **pain during extraction (Table 13 and Graph 15)** showed mean WBS score for pain during extraction in buffered articaine group was 1.22±0.34 and in nonbuffered group it was 2.39±0.95. By using Student's unpaired t test **statistically significant difference** was found in WBS Score among patients of two groups (t=6.80, p=0.0001).

Subgroup analysis :

1. Pain during extraction

i. Wong Baker Scale Score :

Subgroup analysis of **pain during extraction (Table 14 and Graph 16)** showed that the mean WBS score for patients in the age group of **4-7 years** for buffered articaine group was 0.66±1.03 and in nonbuffered articaine group it was 5.55±2.87. By using student's unpaired t test **statistically significant difference** was found in WBS score among patients of two groups (t=4.02, p=0.001). Mean WBS score for patients in the age group of **8-10 years** for buffered articaine group was 2±2.44 and in nonbuffered articaine group it was 4.70±3.45. By using student's unpaired t test **statistically significant difference** was found in WBS score among patients of two groups (t=3.09, p=0.003).

ii. Sound Eye Motor (SEM) Scale score

Subgroup analysis of SEM Scale **(Table 15 and Graph 17)** showed mean SEM score for patients in the age group of **4-7 years** for buffered articaine group was 1.11±0.17 and in nonbuffered articaine group it was 2.55±0.53. By using Student's unpaired t test **statistically significant difference** was found in SEM score among patients of two groups (t=6.38, p=0.0001). Mean SEM score for patients in the age group of **8-10 years** for buffered articaine group was 1.25±0.37 and in nonbuffered articaine group it was 2.23±1.25. By using student's unpaired t test **statistically significant difference** was found in SEM score among patients of two groups (t=3.94, p=0.0001).

Adverse effects:

As sodium bicarbonate was routinely used for intravenous infusions, its addition to anaesthetic solutions was not associated with any adverse effects. None of the children in the study showed any adverse reactions to buffered or nonbuffered articaine.

DISCUSSION

The local anaesthetic can prevent discomfort that may be associated with any minor dental procedure. Even the youngest child treated in the dental office normally has no contraindications for the use of a local anaesthetic [50]. Thus, an adequate local anaesthesia is essential for successful patient management. Nowadays, different anaesthetic solutions with various chemical adjuncts are commercially available such as lignocaine and articaine [51]. Articaine (4-methyl-3-[2-(propylamino)-propionamido]-2-thiophene-carboxylic acid, methyl ester hydrochloride) differs from the other amide local anaesthetics due to its unique thiophene ring. Articaine is a common LA agent with low allergic and toxic potential [51]. The unique composition of articaine with both an ester group and a thiophene ring, it allows greater lipid solubility and potency, facilitating greater diffusion across the lipid-rich nerve membrane to access target receptors. Thus, it can diffuse through soft and hard tissues in a more dependable manner when compared to other LA agents [40].

Ironically, the administration of local anaesthesia itself becomes a source of pain and anxiety for children. Pain caused during local anaesthesia administration has been attributed to many factors, including the speed of injection, site of injection, and pH of the anaesthetic solution. It has been suggested that alkalizing this acidic solution can lead to reduced pain caused during administration of local anaesthesia [5].

Buffered local anaesthetics have been purported to improve anaesthetic onset and success. The physiological/ biologic basis for increased efficacy is as follows: when an anaesthetic formulation is buffered to a pH that is closer to its pKa (7.9), more of the nonionized form theoretically will be accessible to enter the nerve sheath, thereby increasing the onset of anaesthesia and success. Therefore, buffering a 4% articaine formulation may increase the success of LA agent [36].

The pH of our body is maintained at 7.4. Injectable LA without vasoconstrictors have a pH of around 6.4 (slight acidic) which is relatively close to the physiologic pH of the body. Vasoconstrictors like adrenaline are added to anaesthetics to improve both the depth and the duration of anaesthesia. However, the adrenaline oxidizes rapidly at or near physiologic pH, so an antioxidant (most commonly sodium bisulfite) is added to the solution, which lowers the pH to approximately 3.5. Studies have reported that, the anaesthetic pH generally ranges from 2.86 to 4.16. On comparison, lemon juice has a pH range of 2.2 to 2.6. Thus it is expected that bathing a needle in the patient's mouth with an anaesthetic solution at pH=2.9 can create a significant amount of pain [34,52].

However, it has been shown in the studies that the pain on injection between different anaesthetics does not correlate with acidity per se (e.g. etidocaine pH 4.7 is

more painful than chloroprocaine pH 3.4), it is likely the increased ratio of uncharged to charged molecules of any given anaesthetics is responsible for the decrease in pain, by increasing the speed of onset of anaesthesia [14].

As at acidic pH, lignocaine forms ionized water soluble salts, they are extremely stable and have a long shelf-life. The recently accepted mechanism of action of lignocaine by most of the investigators postulates that two ionic forms of the LA exist in equilibrium within the anaesthetic cartridge: RN (which is the uncharged, de-ionized, "active" free base form of the drug, lipid soluble) and RNH+ (the "charged" or ionized cationic form, and is not lipid soluble). Only the lipid-soluble de-ionized form i.e. RN can cross the nerve membrane. The equilibrium between the two is illustrated as follows:

$$RN + H+ \leftrightarrow RNH+$$

In accordance with the Henderson-Hasselbalch equation , the relative amounts of de-ionized and ionized forms of LA are dependent on the pH of the solution [2]. Once within the nerve, the RN picks up an H+ thus forming RNH+ enters Na+ channel to block nerve conduction. Only after the body buffers the injected anaesthetic solution to a pH closer to the physiologic range (7.35 to 7.45), enough of the anaesthetic will enter into the nerve to effectively block nerve conduction. The time required for this transformation is a key factor in anaesthetic latency (e.g., 5 to 10- minute onset for most vasopressor-containing local anaesthetic solutions). Thus, in case of commercially available preparations, the majority of lignocaine will be in the ionized state and will not be capable of immediately diffusing through the nerve sheath to affect anaesthesia. The pain experienced during administration of LA ,

mostly results from a combination of the local irritative effects of the acidic solution and the time required for the above-mentioned dissociations to take place before anaesthesia is achieved [2,34,53].

Therefore, based on knowledge of the mechanism of action of local anaesthetics, studies were carried out to determine whether a more rapidly acting local anaesthetic could be developed simply by adjusting the pH of the injected solution upward (i.e., alkalinization) towards the pKa of the local anaesthetic so that a greater percentage of the drug would be unionized and can immediately be available to diffuse through the nerve membrane. Two strategies like the addition of sodium bicarbonate to the anaesthetic solution and the addition of carbon dioxide have been used to achieve this effect [14,15].

The most common method for buffering local anaesthetics (alkalinization) is by the addition of sodium bicarbonate. Sodium bicarbonate is a systemic alkalinizing agent which is commonly used to treat metabolic acidosis. It buffers excess hydrogen ions by increasing the plasma bicarbonate concentration, and raises the pH of the blood, thereby reversing clinical signs of acidosis. The addition of sodium bicarbonate to local anaesthetics increases the pH of the solution and results in the production of some carbon dioxide [54]. When sodium bicarbonate (NaHCO3) solution is mixed with an LA, it interacts with the hydrochloric acid in the LA to create water and carbon dioxide (CO2). **Catchlove (1972)** concluded that CO2 in combination with lignocaine HCl potentiates the action of lignocaine HCl by providing a direct depressant effect of CO2 on the axon, by concentrating the local anaesthetic inside the nerve trunk through ion trapping, and lastly by changing the charge of the local anaesthetic inside the nerve axon [55,56].

This "anaesthetic buffering" process resulted in several clinical advantages, like greater patient comfort during injection and more rapid onset of anaesthesia. Sodium bicarbonate has been added to various local anaesthetics to increase the proportion of the nonionized form of the drug and allow more molecules to cross cell membranes so as to shorten the latency and increase the potency of the solution [4].

In the present study we aimed to compare pain on injection and clinical effectiveness of buffered and nonbuffered 4% articaine (with 1:100000 adrenaline) in infiltration for primary maxillary molar extractions in 4 – 10 year old children. Age group of 4-10 years, was selected for the study, as it was the age at which extraction is the choice of treatment in non-restorable primary molars. Larger age group provided feasibility in this study and to compensate bias due to age, evaluation was done by dividing it in two subgroups of age 4-7 and age 8-10. The present study was a randomized, double-blind study. All patients were randomly divided in two group by simple unrestricted randomization (envelope method) [57].

Treatment was carried out in 2 visits, in first visit, children in both groups underwent non-invasive treatment like oral prophylaxis to get them acclimatized to the dental environment and also confirm their cooperative behavior. All the children selected in our study were cooperative (positive or definitely positive) according to the Frankl's Behavior Rating scale as the uncooperative children can give inaccurate pain assessment. During the second visit, each child received buccal and palatal infiltration by respected group protocol, group 1 (buffered 4% articaine) or group 2 (nonbuffered 4% articaine) for the maxillary tooth to be extracted. This protocol was followed in the study by **Chopra et al 2016** [58].

The ratio of LA to bicarbonate in published studies has varied significantly, from 2:1 (LA-to-bicarbonate) to 3:1, 5:1, 6:1, 10:1, 30:1, and 33:1, having their results, from "no positive effect" to "excellent results" to "the formation of a precipitate" within the solution. From studies, it appears that LA-to-bicarbonate ratio of between 5:1 and 10:1 provides best opportunity of achieving a more comfortable and more rapid-acting local anaesthetic injection [1,4,5,52]. Excessive alkalinization causes precipitation which decreases the bioavailability of the LA and interferes with its activity. A 10:1 ratio is recommended for LA buffering, mainly due to the concern about precipitation of the solution. In our study we added 0.18 ml of 8.4% sodium bicarbonate to a 1.8 ml cartridge containing 4% articaine hydrochloride with 1:100000 adrenaline solution which yielded a ratio of 1:10.

However, buffering decreases shelf life. Most amides and amines are chemically unstable in the post buffered uncharged form and are subject to photo degradation and aldehyde formation. Therefore, all buffered formulations were prepared immediately before each injection by primary investigator.

In our study, in the control group same amount of removed articaine i.e. 0.18ml was replaced with distilled water to compensate for the amount of articaine that was replaced by buffer solution in the experimental group. In the study by Saatchi et al 2015 1:10 ratio was followed for buffering [4]. However, all other studies [5,39,52,59] had unbalanced dosage of LA in experimental and control groups, which may affect the outcome of buccal and palatal infiltration.

Since, pain is extremely difficult to quantify in children, in the present study pain on injection was assessed during buccal and palatal infiltration and during

extraction using two different methods (subjective and objective). The Wong-Baker Faces pain scale was used as a self-report pain measurement (subjective measurement) by the children. For pain evaluation the self-report of a child for pain assessment is generally considered a "gold standard". The Wong Baker Faces Scale (WBFS) was chosen because it had good construct validity, adequate psychometric properties, and it was easy and quick to use, and inexpensive to reproduce [60].

A systematic review identified WBFS as one of the scales that is has undergone extensive psychometric testing and been used in the assessment of both acute and disease-related pain in children [61]. It has been reported to be effective in children 3–16 years of age and can be more easily understood than the visual analogue scale (VAS) [52] .

Sound Eye Motor (SEM) scale was used as an objective scale that measures the pain or discomfort taking into account the SEM components of child's response to stimulation [43]. An investigator 2 assessed the pain on injection by playing back the video record of the treatment. The level of response for each sound, eye and motor observation was given a numerical value and these values were averaged to determine the clinical ratings for pain. To measure the consistency of investigator 2 by using Cronbach alpha method of reliability at measuring the SEM scores for pain on injection, intra-rater reliability was established which was found to be good (as depicted in **Table 1**). Inter-rater reliability was assessed with Pearson's Correlation Coefficient which was 0.832 and reliability was 0.9082 (as depicted in **Table 2**).

On comparing Wong Baker Scale Score **(Table 4 & Graph 2)** and SEM score **(Table 5 & Graph 3)** for the pain on injection during buccal and palatal

infiltration of articaine in both groups, mean for pain on injection in patients of group 1 (buffered articaine) was less than in group 2 (nonbuffered articaine). Results showing a statistically significant difference in pain on injection between two groups in buccal as well as palatal infiltration, both subjectively using WBFP Scale and objectively using SEM scale. The results for pain on injection were in accordance with the studies by **Hemmanur and Nasim 2020** and **Amorim et al 2020** (p=0.001) in which buffered articaine showed much less pain during injection when compared to conventional articaine [1,41]. The study done by **Shurtz et al 2015** also shows contrast results with the present study where they have used buffered articaine buccal infiltration of the mandibular first molar in adult [36]. The results in the studies by **Kurien et al 2018** and **Afsal M.M et al 2019** found a statistically significant difference for the pain on injection between buffered and nonbuffered lidocaine groups during administration of inferior alveolar nerve block [39,52]. However, the studies by **Chopra R et al 2016** and **Meincken M et al 2019** found a statistically non-significant difference for the pain on injection between buffered and nonbuffered lidocaine groups [5,59].

A straight probe was used in this study to assess the onset of anaesthesia (subjectively) based on the subjective signs like numbness of lip, tongue [2,39] and objectively assessed by probing in the gingival sulcus of the teeth in the area of anaesthesia at an interval of every 15 seconds [43,52]. The subjective mean time for onset of anaesthesia was also found to be less in buffered articaine group than that in nonbuffered articaine group **(Table 6 and Graph 4)** and found a statistically significant difference between two groups for both buccal and palatal infiltration. In the randomized, double-blind, crossover study carried by **Afsal M.M et al**, who

compared pain perception and anaesthetic efficacy of 2% lignocaine with 1:200,000 epinephrine and buffered lignocaine for the inferior alveolar nerve block , found that the time to onset of anaesthesia (both subjective and objective) was lowest for buffered lidocaine, with a statistically significant difference between buffered lidocaine and lidocaine ($P < 0.001$) [39]. In another studies, **Chopra R et al** and **Meincken M** et al found statistically non-significant difference for onset time between buffered and nonbuffered lidocaine [5,59].

The mean time for onset of anaesthesia (objectively) for buccal and palatal infiltration in buffered articaine group was comparatively less than that for nonbuffered articaine group **(Table 7 and Graph 5)**. The difference in mean onset between the groups was found to be statistically significant both in buccal and palatal infiltration. The results of the present study were in contrast with study done in adult using buffered articaine by **Shurtz et al 2015** and **Hemmanur and Nasim 2020**, where the difference for onset of anaesthesia was statistically insignificant ($p=1.00$, $p=0.136$ respectively) [1,36]. In a study by **Kurien et al 2018**, who conducted a randomized, split-mouth clinical trial to evaluate and compare the time for onset of anaesthesia and the child's pain reaction to buffered and conventional 2% lignocaine for the success of the inferior alveolar nerve block technique in mandibular primary molars. The result showed faster onset of anaesthesia in buffered lignocaine group with a statistically significant difference between two groups ($P=0.001$) [52].

All infiltration administered in children in this study were carried out by the same operator to eliminate inter-examiner variability while pain perception was assessed by investigator 2 in order to provide accurate comparison between the two group. Buccal and palatal infiltration were chosen for extraction of maxillary primary

molars, as a systematic review by **Tirupati and Rajasekhar** concluded that there is insufficient evidence to justify the statement that a single buccal infiltration of 4% articaine alone is sufficient for the extraction of primary molars. Therefore they suggested that further evidence is required to justify the claim that palatal infiltrations and IANB can be replaced with the use of 4% articaine single buccal infiltration for the extraction of primary molars in children [42].

Subgroup analysis was done on basis of age of children because of larger age group used in the study in present study with age 4-7 and age 8-10 as two subgroups. Pain on injection (WBFPS scale and SEM scale) and onset of anaesthesia (subjective and objective) scores according to age of children were compared to evaluate effect of buffering in the results across subgroups. On comparing pain on injection for buccal infiltration according to the age of children, WBFPS score **(Table 8, Graph 6 and Graph 7)** showed the differences that were statistically insignificant and for palatal infiltration according to the age of children, the differences were statistically significant except at age 8-10 year.

On comparing pain on injection for buccal infiltration according to the age of children, SEM scale **(Table 9, Graph 8 and Graph 9)** in subgroup analysis score showed the differences that were statistically insignificant and for palatal infiltration according to the age of children, the differences were also statistically insignificant. However, the results in the study by **Chopra R et al 2016** who found no statistically significant differences of scores for pain on injection for WBFPS score and for SEM scale score between two anaesthetic solutions according to the age of the paediatric patient except for higher age group 8-10 year [5].

Onset of anaesthesia (subjective and objective) scores according to the age of children, the differences between the subjective onset time **(Table 10, Graph 10 and Graph 11)** for buccal infiltration showed the differences were statistically significant and for palatal infiltration also showed the differences were statistically significant. The differences between the objective onset time **(Table 11 and Graph 12, Graph 13)** for buccal infiltration were statistically significant and also for palatal infiltration were statistically significant. The results in study by **Chopra R et al 2016** showed statistically significant differences for onset of anaesthesia between buffered and nonbuffered lidocaine solutions according to the age of the paediatric patient [5].

Effectiveness of anaesthesia evaluated for pain during extraction (subjectively and objectively). In subjective evaluation, pain scores were much less in buffered articaine group than nonbuffered articaine group with statistically significant difference. **(Table 12 and Graph 14)** In objective evaluation, pain scores were lower in buffered articaine group than nonbuffered articaine group with statistically significant difference. **(Table 13 and Graph 15)** In the study done by **Hemmanur and Nasim 2020**, they compared anaesthetic efficacy of buffered and conventional local anaesthetic agent for root canal treatment. They reported no statistical significant difference was found between the buffered and nonbuffered articaine group for anaesthetic efficacy [1]. In the study done by **Kurien et al 2018**, in which they compared anaesthetic efficacy of buffered and nonbuffered lignocaine in pulp therapy and they noted a statistically significant difference between the two solutions ($p=0.014$) [52]. Also **Saatchi et al 2015** compared buffered lidocaine in IANB for pulp therapies in children below 18 years of age and showed results with no statistical significant differences [4].

Subgroup analysis of WBS scores, on comparing buffered and nonbuffered articaine group for pain during extraction according to the age of children **(Table 14 and Graph 16)** showed the differences that were statistically significant. Subgroup analysis of SEM scores when buffered and nonbuffered articaine group for pain during extraction according to the age of children (**Table 15 and Graph 17)** showed the statistically significant difference.

None of the children reported adverse effects in any of the groups because the safety of local anaesthetic agent used in this study and children and the parents were given proper post treatment instructions and also, instructions were repeated during telephonic contact. This was in accordance with the study done by **Rathi et al 2019** [40], where adverse effects like facial edema, paraesthesia or accidental lip injury were not reported in both the groups children and parents accompanying them were properly instructed against lips biting, post treatment. Also, sodium bicarbonate is routinely used for intravenous infusions, so its addition to anaesthetic solutions is not associated with any adverse effects [5]. It was noted that during the study children better tolerated buccal and palatal infiltration using the buffered articaine as an anaesthetic solution than nonbuffered articaine.

Limitations :

1) Present study was not a split mouth study, because pain perception may be different for different person, so cross over design would have given more appropriate results.

2) Sparse data was available in the literature for use of buffered articaine in children, therefore less comparing studies were available.

SUMMARY AND CONCLUSION

A prospective double blinded, randomized controlled study was planned to evaluate and compare pain on injection, onset of anaesthesia and pain during extraction of buffered and nonbuffered 4% articaine (with 1:100000 adrenaline) infiltrations for primary maxillary molar extractions. Pain on injection and pain during injection evaluated subjectively and objectively using WBS and SEM scale respectively. Onset of anaesthetic solution also evaluated subjectively and objectively after buccal and palatal infiltrations.

The following findings were observed :

1. There was **no statistically significant difference** found in distribution of children according to their age and gender.
2. There was **statistically significant difference** between buffered and nonbuffered articaine group for **pain on injection** for buccal and palatal infiltration when assessed subjectively using WBS and objectively using SEM

scale. The mean WBS scores and mean SEM scale scores pain on injection were less in buffered articaine group.

3. There was **statistically significant difference** between buffered and nonbuffered articaine group for **onset of anaesthesia** (subjectively and objectively) for buccal and palatal infiltration. Onset time of anaesthesia was observed to be shorter in buffered than nonbuffered articaine group when assessed both subjectively and objectively.
4. There was **statistically significant difference** between buffered and nonbuffered articaine group for **pain during extraction** when assessed subjectively using WBS and objectively using SEM scale. The mean WBS scores and mean SEM scale scores for pain during extraction of primary maxillary molars were less in buffered articaine group.

From observation of the results of the present study, following conclusions can be made:

Pain on injection during buccal and palatal infiltration was less with buffered articaine and also the onset of anaesthesia was faster with buffered articaine when compared with nonbuffered articaine. Also, clinically the profoundness of anaesthesia was greater with buffered articaine as can be judged by the pain scores using WBS and SEM scale for primary maxillary molars extraction.

Since, there were only few studies and varied evidences regarding effectiveness of buffered articaine in adults and as per best of our knowledge, present study was the only research that made use of buffered articaine in children, more randomized controlled trials should be carried out.

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TABLES

Table 1 : Intra-rater method of reliability

Cronbach alpha	0.900
p-value	0.0001,S
Result	Reliable

S-significant

Table 2 :Inter-rater method of reliability

Pearson's Correlation Coefficient	0.832
Reliability	0.9082
Result	Reliable

Table 3 : Distribution of children according to their age and gender

		Buffered Articaine	Non Buffered Articaine	χ^2-value
Age	4-7 Years	13(37.14%)	18(51.4%)	0.33,NS
	8-10 Years	22(62.86%)	17(48.6%)	
	Mean±SD	8.29±1.29 (5.07-10.27 yrs)	7.86±1.30 (5.79-10.35 yrs)	
Gender	Boys	18(51.4%)	18(51.4%)	-
	Girls	17(48.6%)	17(48.6%)	

NS-Nonsignificant

Table 4: Comparison of mean Wong Baker Scale Score for pain on injection between two groups

Group		N	Mean	Std. Deviation	Std. Error Mean	t-value
Buccal Infiltration	Buffered articaine	35	1.20	1.47	0.24	4.36 P=0.0001,S
	Nonbuffered articaine	35	3.71	3.07	0.51	
Palatal Infiltration	Buffered articaine	35	1.94	1.84	0.31	4.48 P=0.0001,S
	Nonbuffered articaine	35	4.62	3.02	0.51	

S-significant

Table 5: Comparison of mean Sound Eye Motor (SEM) Scale score for pain on injection between two groups

Group		N	Mean	Std. Deviation	Std. Error Mean	t-value
Buccal Infiltration	Buffered articaine	35	1.17	0.28	0.04	5.13 P=0.0001,S
	Nonbuffered articaine	35	1.81	0.67	0.11	
Palatal Infiltration	Buffered articaine	35	1.25	0.30	0.05	7.20 P=0.0001,S
	Nonbuffered articaine	35	2.43	0.92	0.15	

S-significant

Table 6: Comparison of mean onset of anaesthesia between two groups (Subjective sign)

Group		N	Mean in seconds	Std. Deviation	Std. Error Mean	t-value
Buccal Infiltration	Buffered articaine	35	49.22	4.24	0.71	20.38 P=0.0001,S
	Nonbuffered articaine	35	78.48	7.35	1.24	
Palatal Infiltration	Buffered articaine	35	46	3.97	0.67	20.39 P=0.0001,S
	Nonbuffered articaine	35	75.91	7.71	1.30	

S-significant

Table 7 : Comparison of mean onset of anaesthesia between two groups (Objective sign)

Group		N	Mean in seconds	Std. Deviation	Std. Error Mean	t-value
Buccal Infiltration	Buffered articaine	35	58.80	5.30	0.89	18.63 P=0.0001,S
	Nonbuffered articaine	35	87.91	7.57	1.27	
Palatal Infiltration	Buffered articaine	35	54.88	4.40	0.74	22.51 P=0.0001,S
	Nonbuffered articaine	35	86.57	7.06	1.19	

S-significant

Table 8 : Subgroup analysis of Wong Baker Scale Score in buffered and nonbuffered articaine groups

Gender	Buccal Infiltration		t-value	Palatal Infiltration		t-value
	Buffered articaine	Non buffered articaine		Buffered articaine	Non buffered articaine	
Age 4-7 (37.14%)	1.07±1.32	1.33±1.68	0.45 P=0.65,NS	1.23±1.01	5.44±2.63	5.45 P=0.0001,S
Age 8-10 (62.86%)	1.27±1.57	1.05±1.24	0.45 P=0.64,NS	2.36±2.10	3.76±3.23	1.63 P=0.11,NS

S-significant, NS-Nonsignificant

Table 9 : Subgroup analysis of Sound Eye Motor (SEM) Scale score in buffered and nonbuffered articaine groups

	Buccal Infiltration		t-value	Palatal Infiltration		t-value
	Buffered articaine	Non buffered articaine		Buffered articaine	Non buffered articaine	
Age 4-7 (37.14)	1.12±0.25	1.09±0.22	0.41 P=0.68,NS	1.20±0.25	1.20±0.23	0.01 P=0.98,NS
Age 8-10 (62.86)	1.21±0.29	1.27±0.31	0.62 P=0.53,NS	1.28±0.32	1.31±0.36	0.23 P=0.81,NS

NS-Nonsignificant

Table 10 : Subgroup analysis of time to onset of anaesthesia in buffered and nonbuffered articaine groups (Subjective)

	Buccal Infiltration		t-value	Palatal Infiltration		t-value
	Buffered articaine	Non buffered articaine		Buffered articaine	Non buffered articaine	
Age 4-7 (37.14%)	49.30±3.40	75.22±7.47	11.61 P=0.0001,S	45.92±3.79	79±5.62	18.35 P=0.0001,S
Age 8-10 (62.86%)	49.18±4.74	81.94±5.55	19.85 P=0.0001,S	46.04±4.16	72.64±8.41	12.95 P=0.0001,S

S-significant

Table 11 : Subgroup analysis of time to onset of anaesthesia in buffered and nonbuffered articaine groups (Objective)

	Buccal Infiltration		t-value	Palatal Infiltration		t-value
	Buffered articaine	Non buffered articaine		Buffered articaine	Non buffered articaine	
Age 4-7 (37.14%)	58.46±3.64	84.83±6.17	13.72 P=0.0001,S	54.46±3.40	87.88±5.87	18.36 P=0.0001,S
Age 8-10 (62.86%)	59±6.15	91.17±7.69	14.51 P=0.0001,S	55.13±4.95	85.17±8.08	14.31 P=0.0001,S

S-significant

Table 12 : Comparison of mean Wong Baker Scale Score for pain during extraction between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Buffered articaine	35	1.77	2.31	0.39	5.09 P=0.0001,S
Non buffered articaine	35	5.14	3.15	0.53	

S-significant

Table 13 : Comparison of mean Sound Eye Motor (SEM) Scale score for pain during extraction between two groups

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Buffered articaine	35	1.22	0.34	0.05	6.80
Nonbuffered articaine	35	2.39	0.95	0.16	P=0.0001,S

S-significant

Table 14: Subgroup analysis of Wong Baker Scale Score in buffered articaine and nonbuffered articaine groups for pain during extraction.

	Buffered Articaine	Non Buffered Articaine	t-value
Age 4-7 (37.14%)	0.66±1.03	5.55±2.87	4.02,p=0.001,S
Age 8-10 (62.86%)	2±2.44	4.70±3.45	3.09,p=0.003,S

S-significant

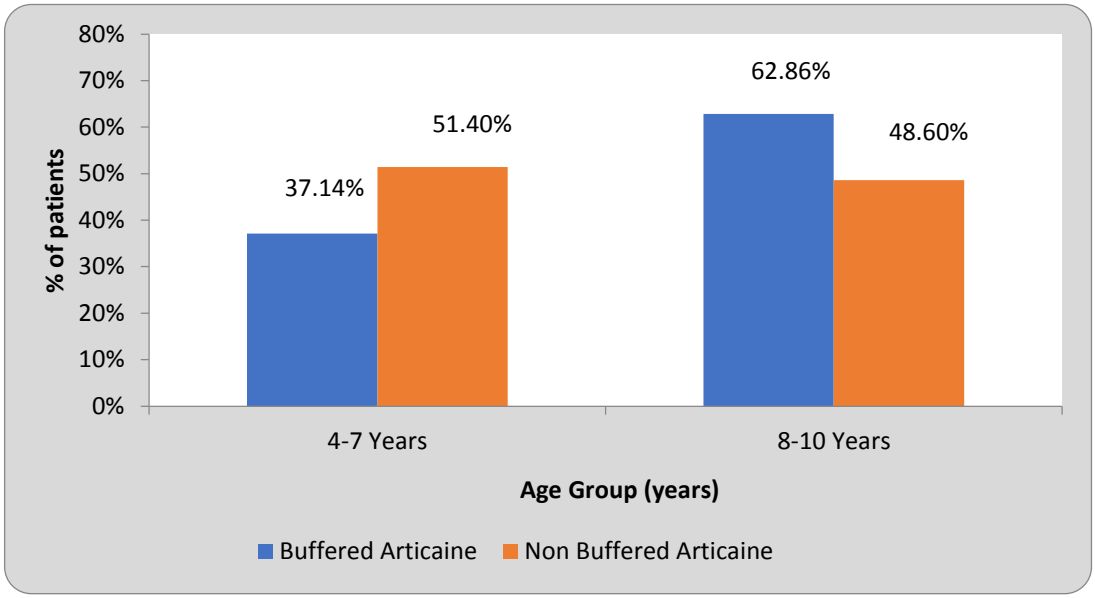
Table 15: Subgroup analysis of Sound Eye Motor(SEM) score in buffered articaine and nonbuffered articaine groups for pain during extraction.

	Buffered Articaine	Non Buffered Articaine	t-value
Age 4-7 (37.14%)	1.11±0.17	2.55±0.53	6.38,p=0.0001,S
Age 8-10 (62.86%)	1.25±0.37	2.23±1.25	3.94,p=0.0001,S

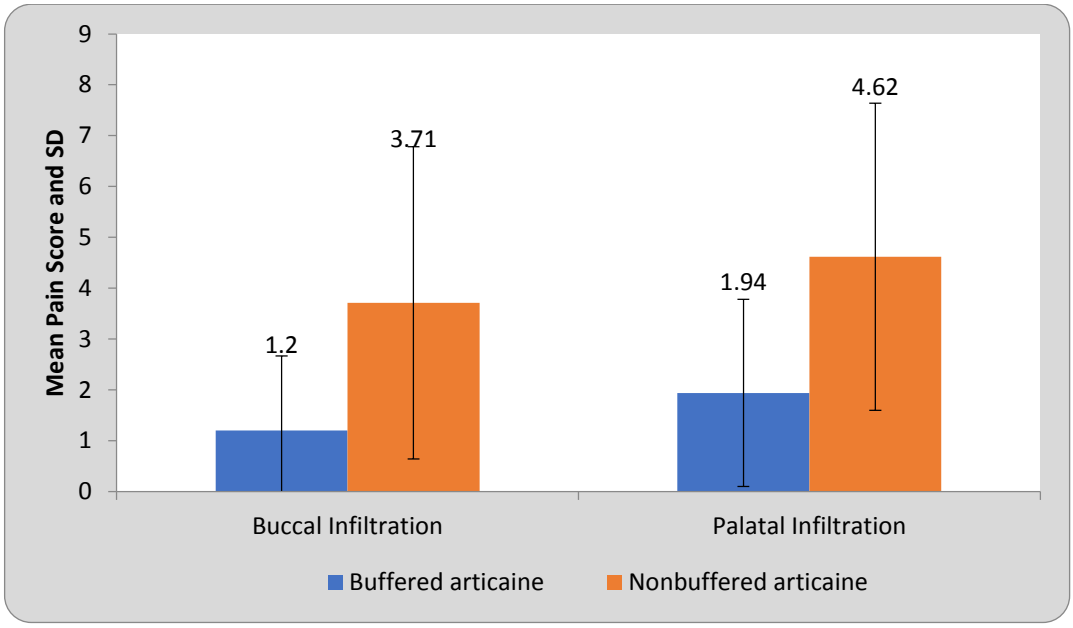
S-significant

GRAPHS

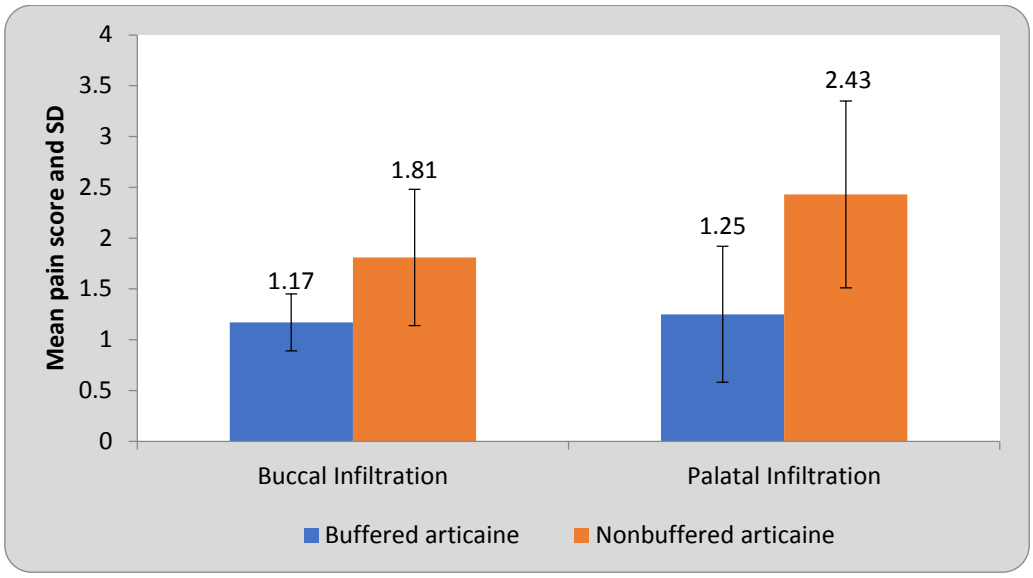
Graph 1: Distribution of children according to their age



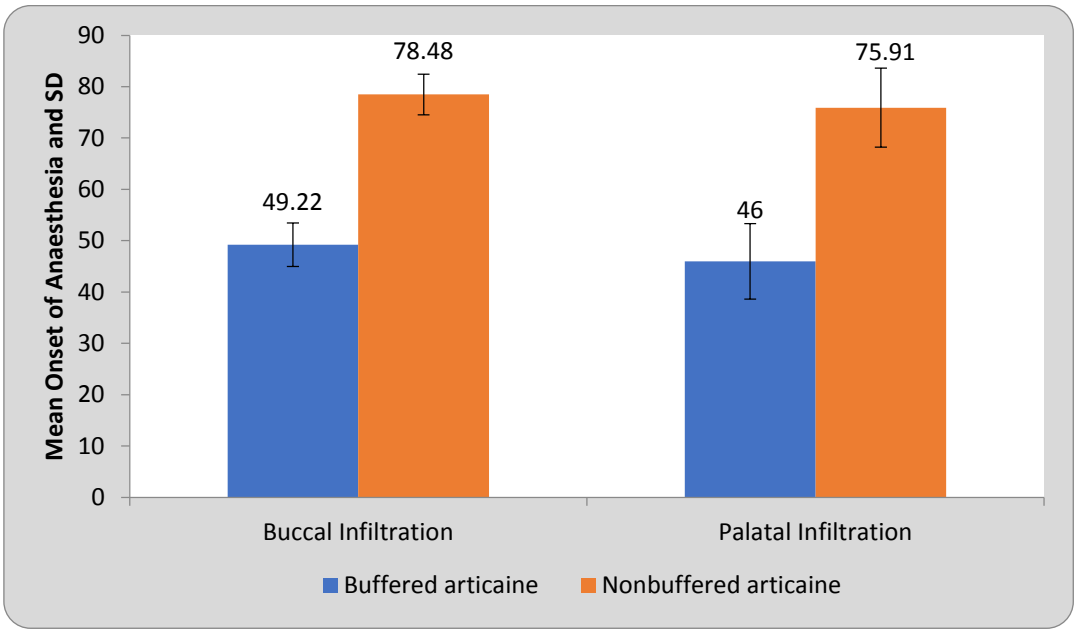
Graph 2: Comparison of mean Wong Baker Scale Score for pain on injection between two groups



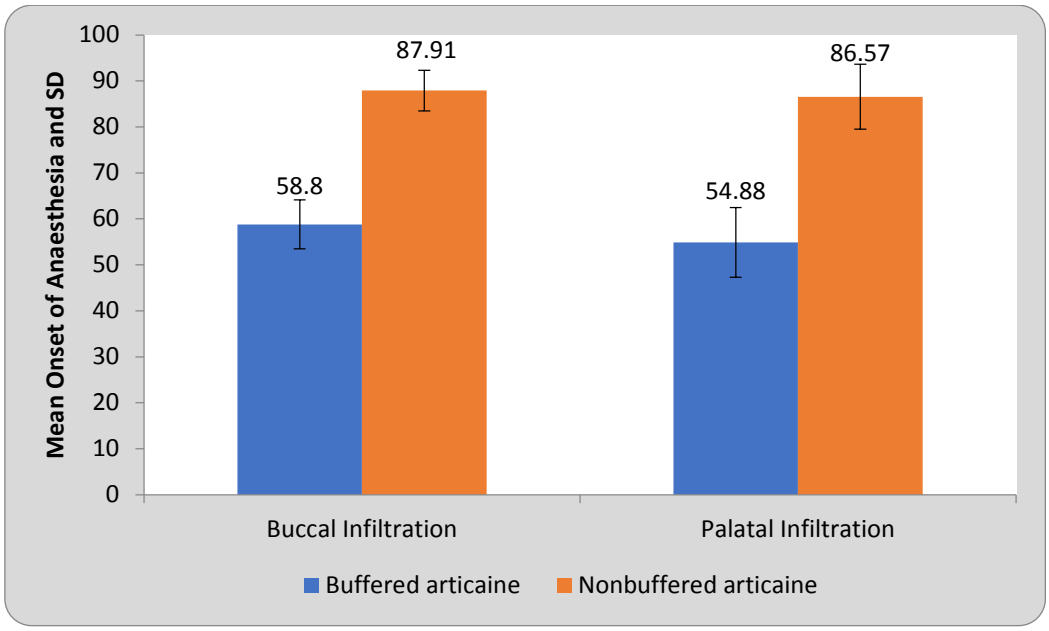
Graph 3: Comparison of mean Sound Eye Motor (SEM) Scale score for pain on injection between two groups



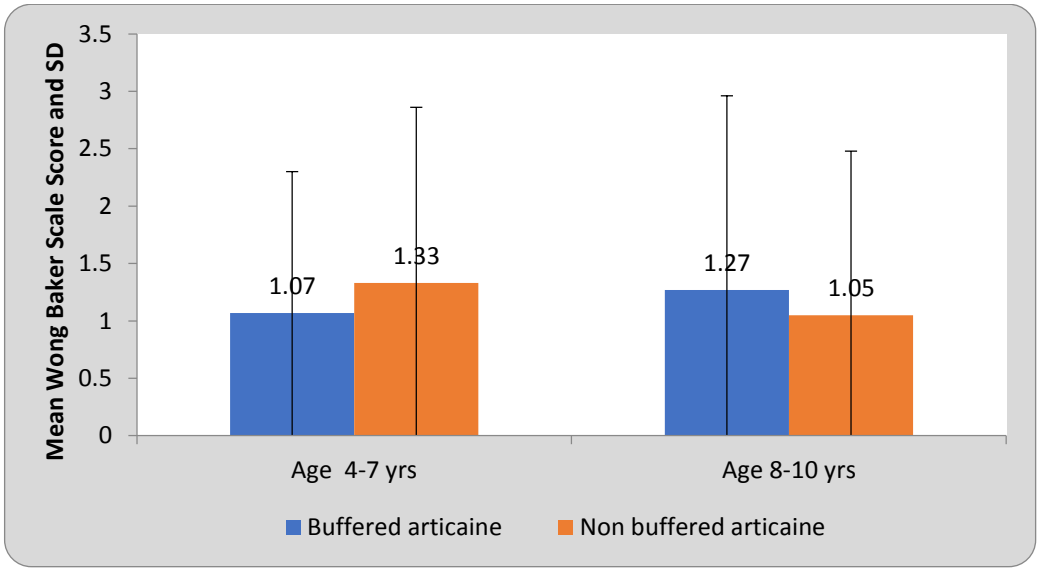
Graph 4: Comparison of mean onset of anaesthesia between two groups (Subjective sign)



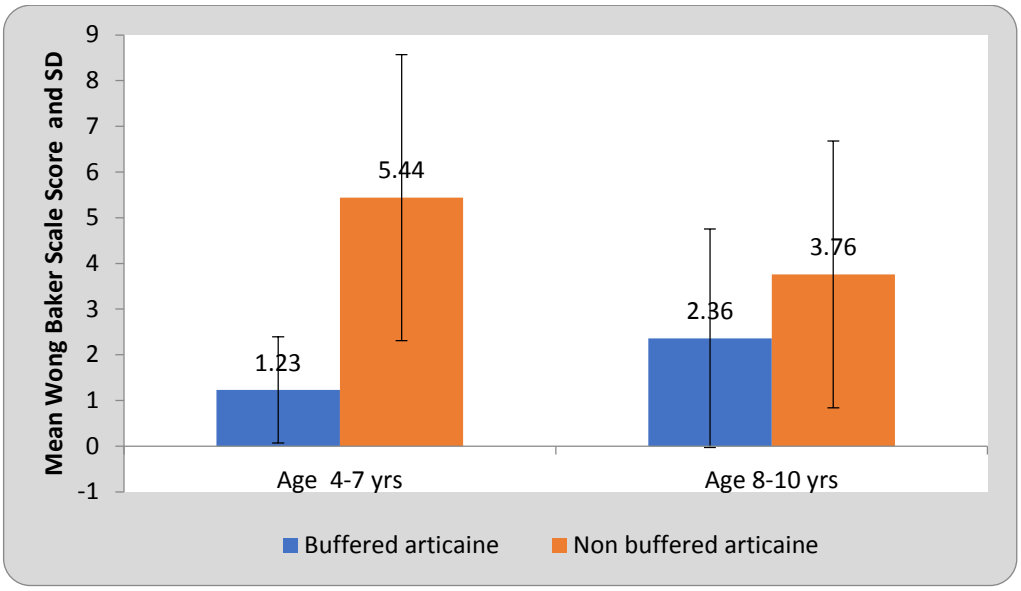
Graph 5 : Comparison of mean onset of anaesthesia between two groups (Objective sign)



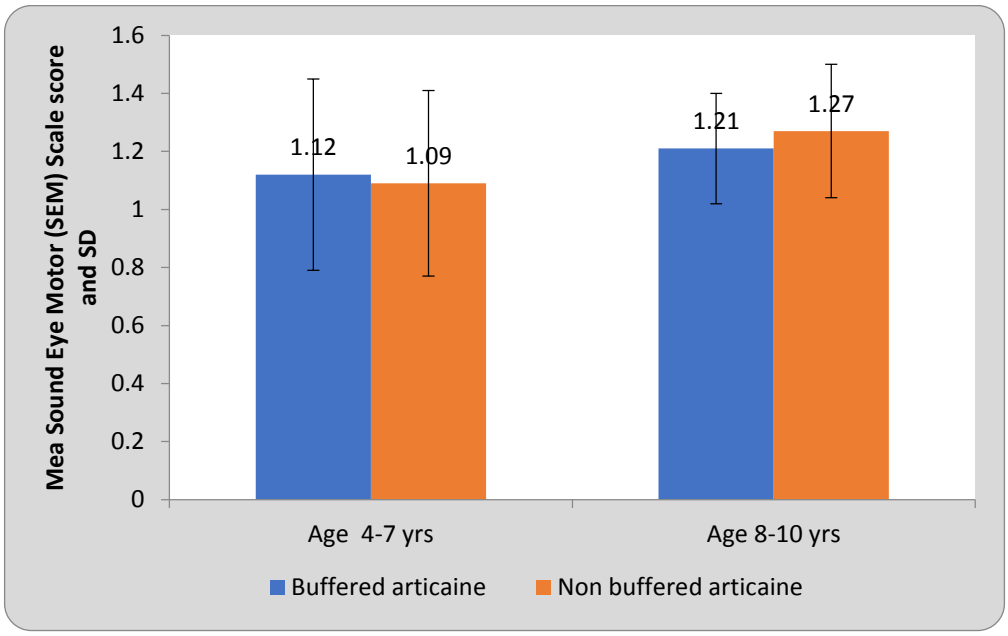
Graph 6 : Subgroup analysis of Wong Baker Scale Score in buffered and nonbuffered articaine groups for buccal infiltration



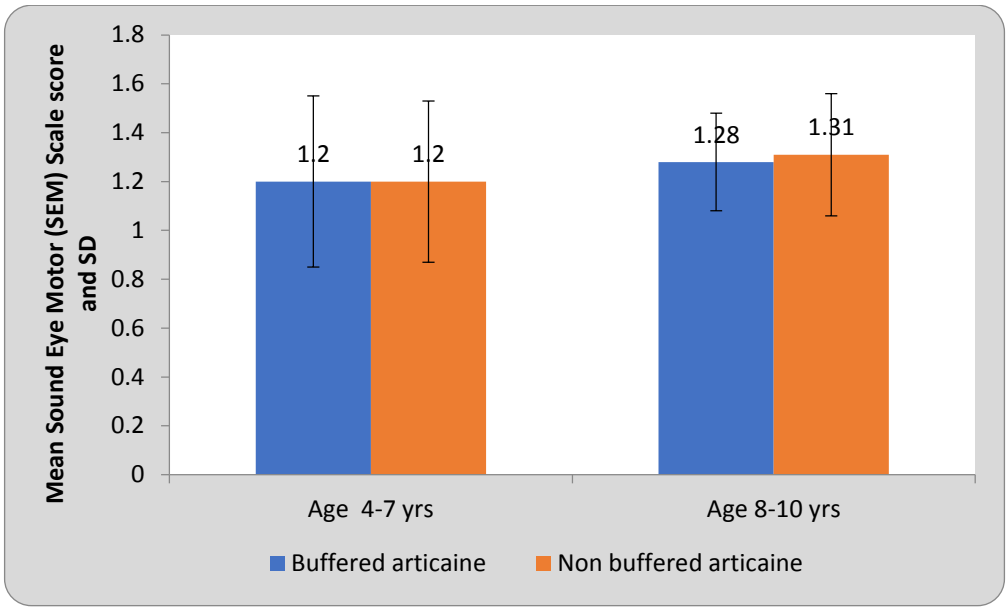
Graph 7 : Subgroup analysis of Wong Baker Scale Score in buffered and nonbuffered articaine groups for palatal infiltration



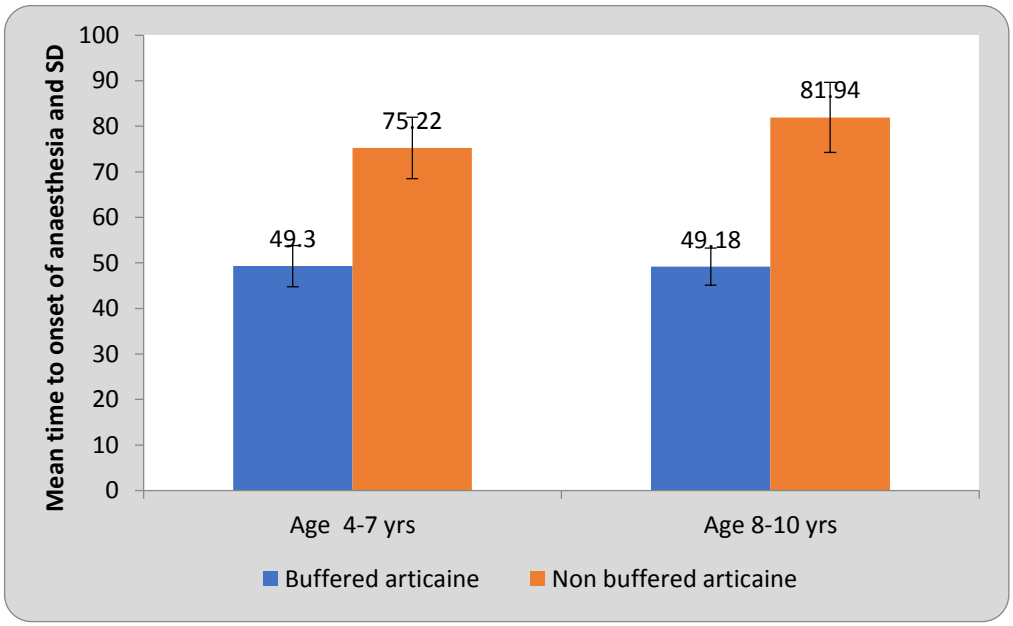
Graph 8 : Subgroup analysis of Sound Eye Motor (SEM) Scale score in buffered and nonbuffered articaine groups for buccal infiltration



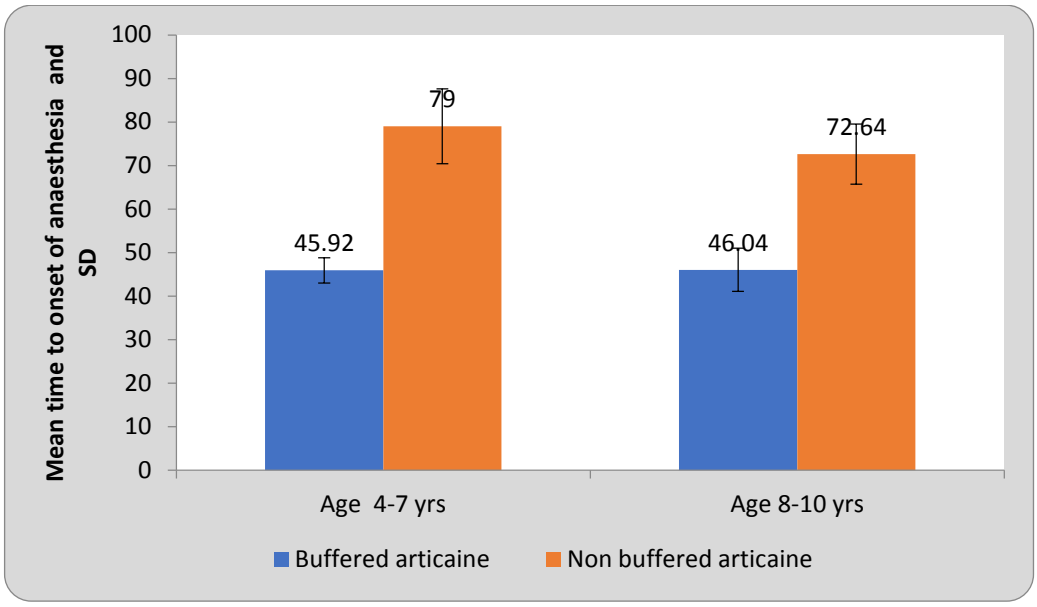
Graph 9 : Subgroup analysis of Sound Eye Motor (SEM) Scale score in buffered and nonbuffered articaine groups for palatal infiltration



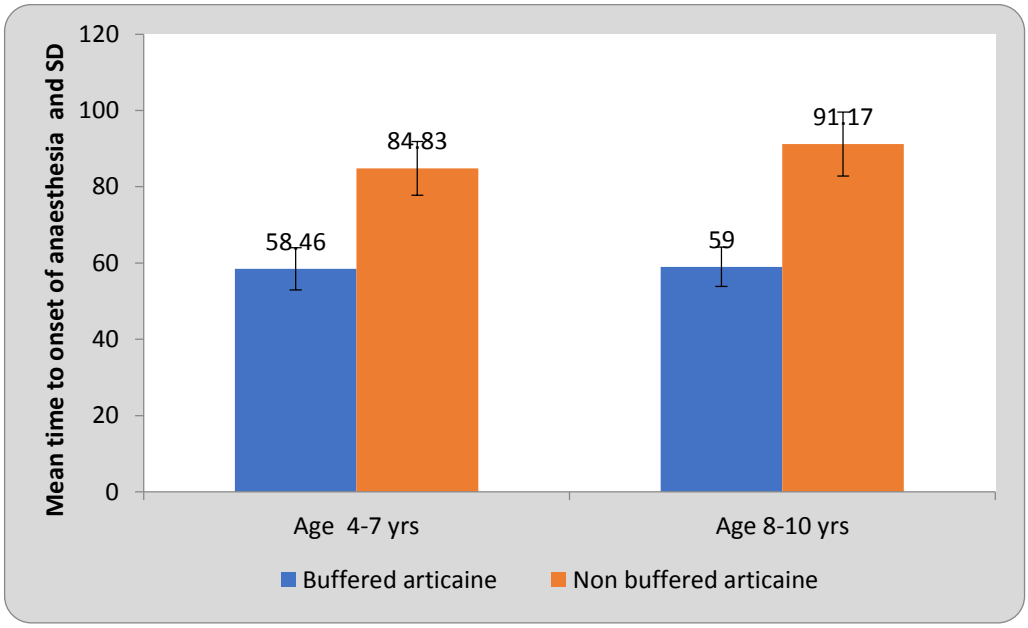
Graph 10 : Subgroup analysis of time to onset of anaesthesia in buffered and nonbuffered articaine groups (Subjective) for buccal infiltration



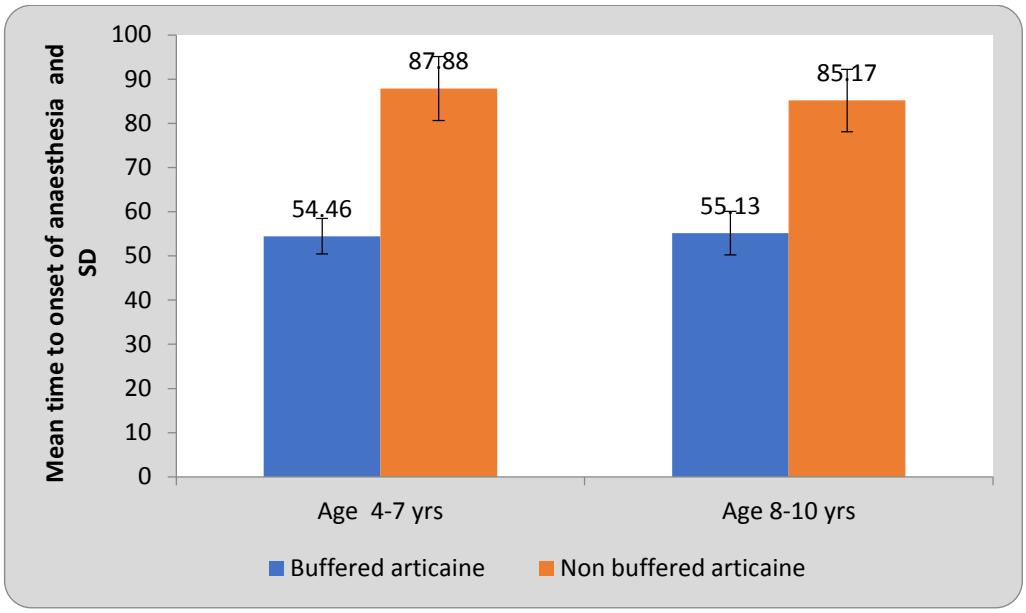
Graph 11 : Subgroup analysis of time to onset of anaesthesia in buffered and nonbuffered articaine groups (Subjective) for palatal infiltration



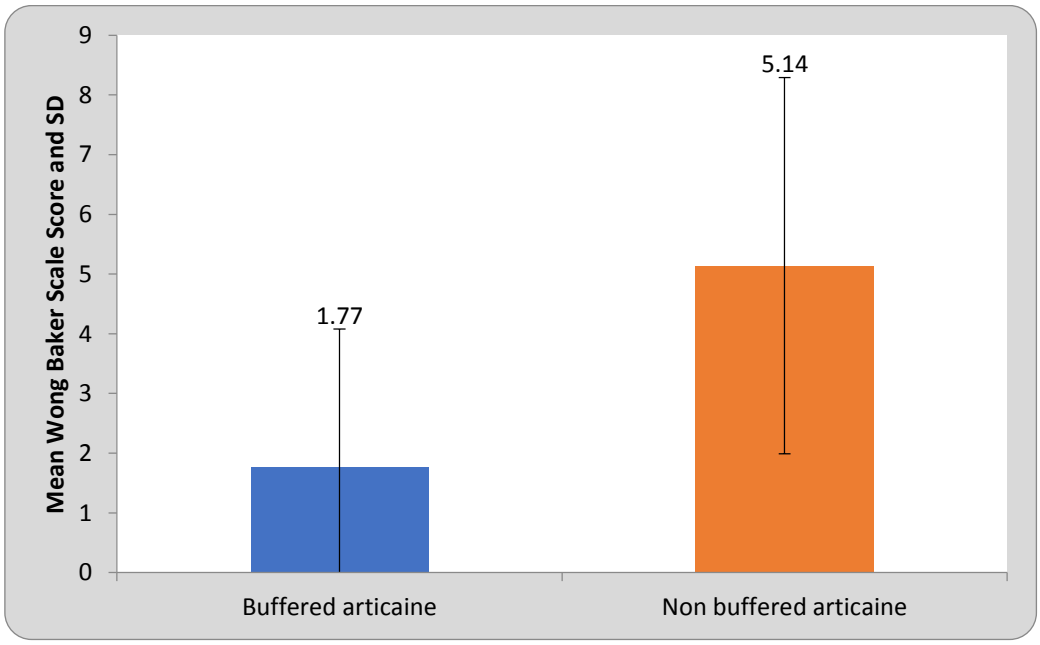
Graph 12 : Subgroup analysis of time to onset of anaesthesia in buffered and nonbuffered articaine groups (Objective) for buccal infiltration



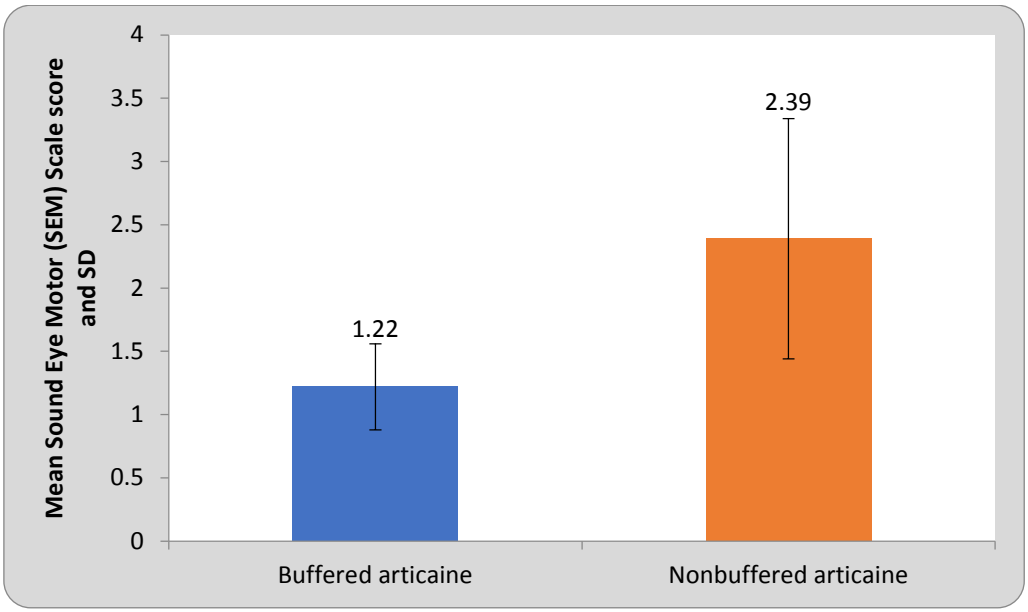
Graph 13 : Subgroup analysis of time to onset of anaesthesia in buffered and nonbuffered articaine groups (Objective) for palatal infiltration



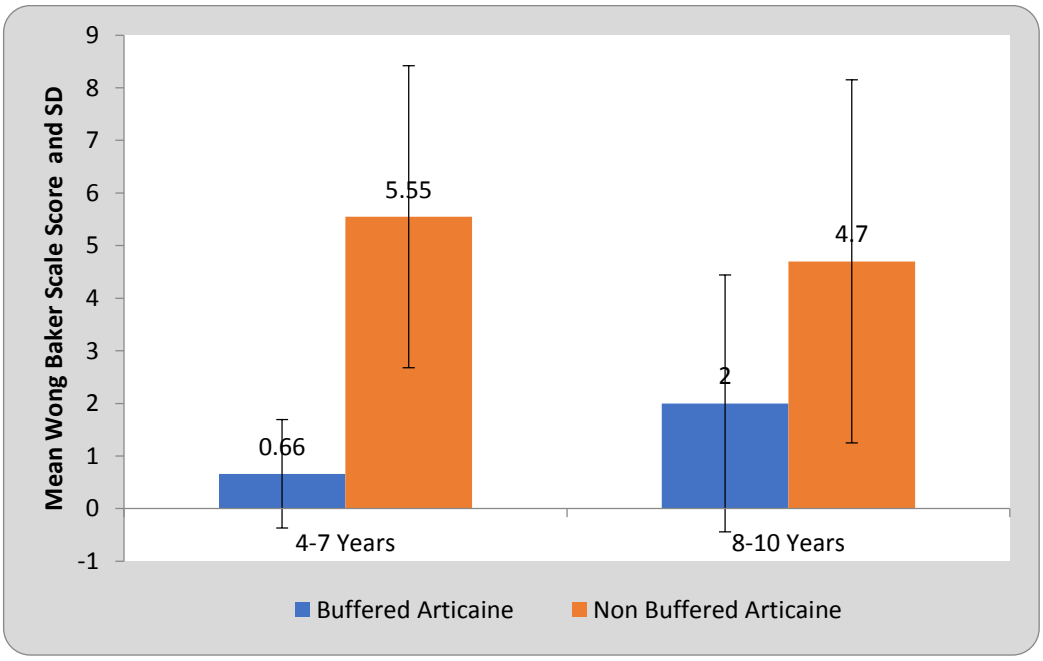
Graph 14 : Comparison of mean Wong Baker Scale Score for pain during extraction between two groups



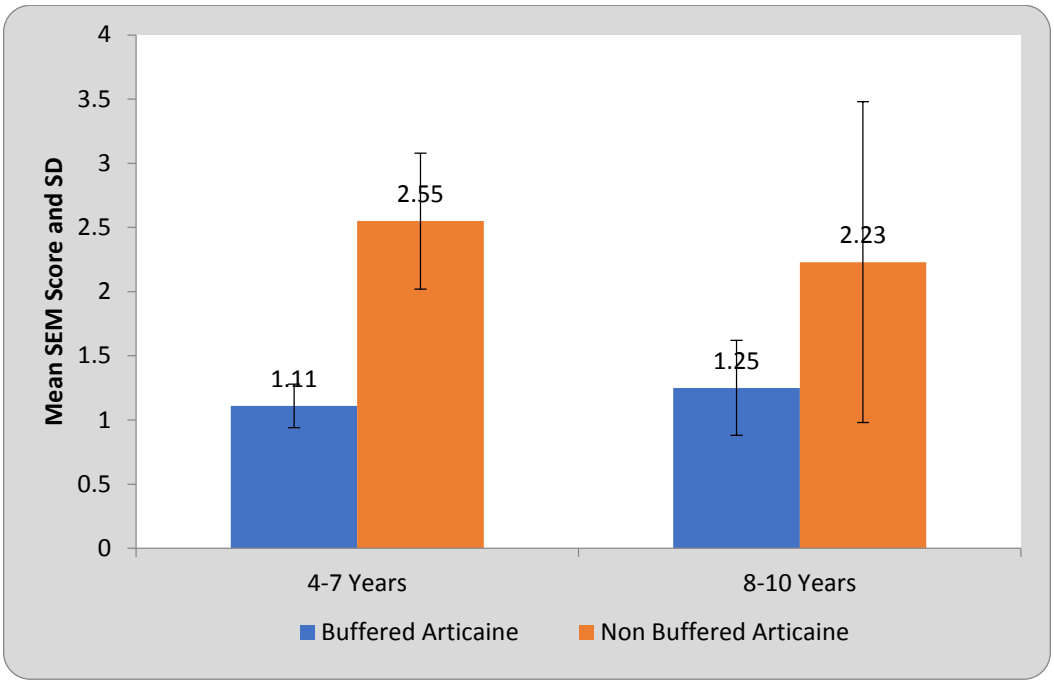
Graph 15 : Comparison of mean Sound Eye Motor (SEM) Scale score for pain during extraction between two groups



Graph 16 : Subgroup analysis of Wong Baker Scale Score in buffered articaine and nonbuffered articaine groups for pain during extraction.



Graph 17 : Subgroup analysis of Sound Eye Motor (SEM) score in buffered articaine and nonbuffered articaine groups for pain during extraction.



ANNEXURE 1

DEPARTMENT OF PAEDIATRIC & PREVENTIVE DENTISTRY

Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I acknowledge the "Specially designed proforma", and also the doctor has informed me about this research project suitably and sufficiently to my satisfaction. I agree to let my child's oral examination to be taken as required. I agree to take part in this project. I shall co-operate with the doctors, in all respects. I permit to publishing the results of my participation in this study. I shall not be given any reimbursement or compensation. I have been informed of my right to opt out of this research project at any time without giving any reason for doing so. I hereby record my consent for participation in the said project.

.....	.....	.....	.....
Parent's/guardian's name	Signature/thumbprint	Date	Time

.....	.....	.....	.....
Investigator's name	Signature	Date	Time

If illiterate a literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____

Signature of witness _____

Date _____

Day/month/year

Thumb print of participant

ANNEXURE 2

DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY

Comparative evaluation of clinical effectiveness of buffered and nonbuffered 4% articaine (with adrenaline 1:100000) infiltration for primary maxillary molar extractions: an experimental study.

EXAMINATION PROFORMA/CASE RECORD FORM

Identification No.		Day		Month		Year				Examiner Orig/Dupl		Group
1	2	3	4	5	6	7	8	9	10	11	12	13

GENERAL INFORMATION:

Name of child: _____

Gender: ☐ 1=M, 2=F

14

Age ☐ years

15

Studying in class: ☐

16

Name and Address of parent:

_____

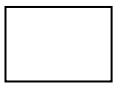
_____Contact No. of Parent: _____

Chief Complaint:

H/O Present illness:

Past Medical History:

Past Dental History:

Behaviour Assessment as per Frankl Behavior rating scale: 

18

General examination

- **Weight** 

19

- **Height** 

20

I. Extra Oral examination

- Swelling on face and jaws:
- Lymph nodes:

II. Intra oral examination

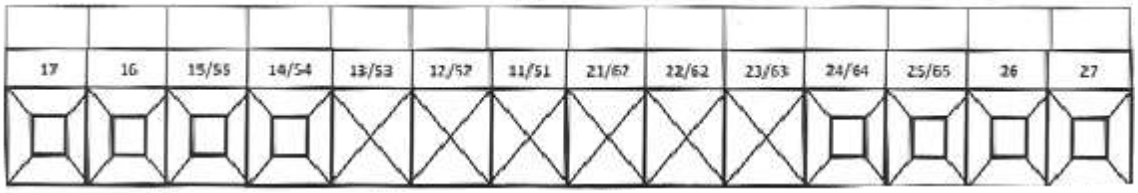
A. Examination of Soft tissues

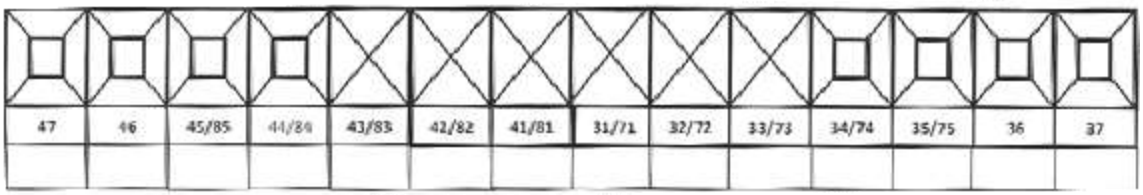
- Gingiva
- Oral mucosa
- Floor of mouth

B. Examination of Hard tissues:

- Teeth Present (FDI notation)

III. Dentition Status & Treatment Need:





DMFT score :

Primary teeth Crown	Permanent teeth Crown	Status	Treatment
A	0	Sound	0= none
B	1	Decayed	P= Preventive, caries arresting care
C	2	Filled, with decay	F= Fissure sealant
D	3	Filled, no decay	1= One surface filling
E	4	Missing, as a result of caries	2= Two or more surfaces filling
—	5	Missing, any other reason	3= Crown for any reason
F	6	Fissure sealant	4= Veneer or laminate
G	7	Crown	5= Pulp care and restoration
—	8	Unerupted tooth (crown)or exposed root	6= Extraction
			7= Need for other care (specify)
T	T	Trauma (fracture)	8= Need for other care (specify)
—	9	Not recorded	9= not recorded

IV. Radiograph:

V. Diagnosis:

VI. Treatment Plan:

VII. Assessment

Patient Identity No ( )	**Pain On Injection**		**Onset of anaesthesia (seconds)**	
	Subjective (Wong Baker Faces Pain scale)	Objective (Sound Eye Motor)	Subjective	Objective
After buccal infiltration				
After palatal infiltration				
After extraction				

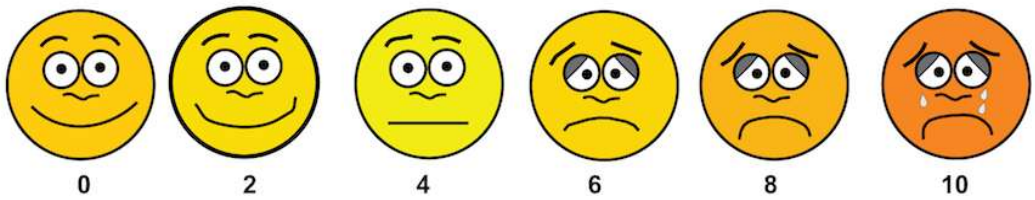
Adverse Effects (If Any)

- **Allergy to local anaesthesia :**
- **Paresthesia :**
- **Postoperative soft tissue injury :**
  - **Cheek bite**
  - **Lip bite**

After Buccal Infiltration

ID no:

WONG BAKER SCALE



Instructions for Usage

Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

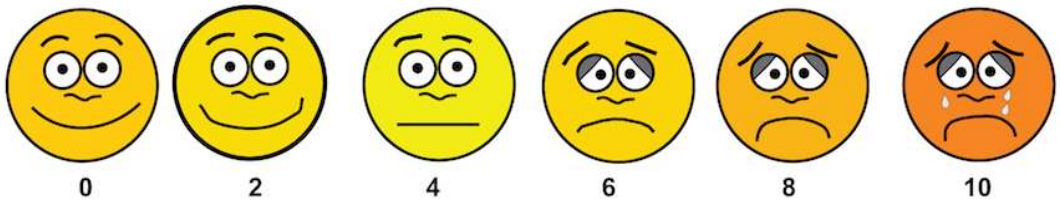
*Wong, D. and Baker, C.: Pain in children: comparison of assessment scales, Pediatric Nursing1988;14(1)

Procedure	**Score**
Pain on injection	

After Palatal Infiltration

ID no:

WONG BAKER SCALE



Instructions for Usage

Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

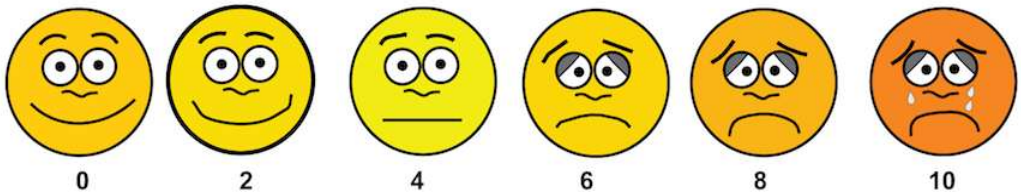
*Wong, D. and Baker, C.: Pain in children: comparison of assessment scales, Pediatric Nursing1988;14 (1)

Procedure	**Score**
Pain on injection	

After Extraction Procedure

ID no:

WONG BAKER SCALE



कोई दर्द नहीं | थोड़ा-सा दर्द होता है | थोड़ा अधिक दर्द होता है | थोड़ा और अधिक दर्द होता है | बहुत दर्द होता है | बेहद दर्द होता है

Instructions for Usage

Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

*Wong, D. and Baker, C.: Pain in children: comparison of assessment scales, Pediatric Nursing1988;14(1)

Procedure	**Score**
Pain during extraction	

After Buccal Infiltration

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	**Comfort**	**Mild discomfort**	**Moderate discomfort**	**Severe discomfort**	**Score**
Grade	1	2	3	4	
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint, shouting, crying	
Eye	No sign	Dilated eye without tear (anxiety sign	Tears, sudden eye movements	Crying, tears all over the face	
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side	

Pain on injection	Total	
	Average	

After Palatal Infiltration

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	**Comfort**	**Mild discomfort**	**Moderate discomfort**	**Severe discomfort**	**Score**
Grade	1	2	3	4	
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint, shouting, crying	
Eye	No sign	Dilated eye without tear (anxiety sign	Tears, sudden eye movements	Crying, tears all over the face	
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side	

Pain on injection	Total	
	Average	

After Extraction Procedure

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	**Comfort**	**Mild discomfort**	**Moderate discomfort**	**Severe discomfort**	**Score**
Grade	1	2	3	4	
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint, shouting, crying	
Eye	No sign	Dilated eye without tear (anxiety sign	Tears, sudden eye movements	Crying, tears all over the face	
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side	

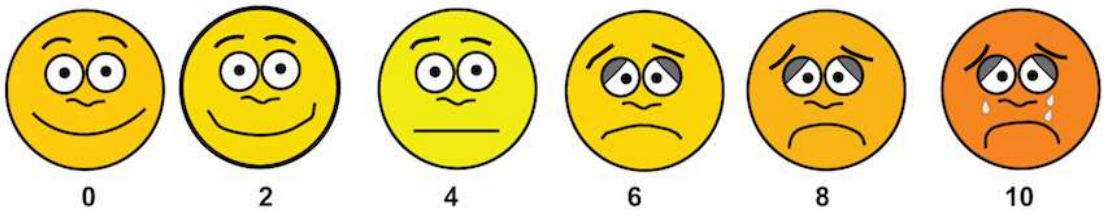
Pain during extraction	Total	
	Average	

ANNEXURE 3

After Buccal Infiltration

ID no:

WONG BAKER SCALE



Instructions for Usage

Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

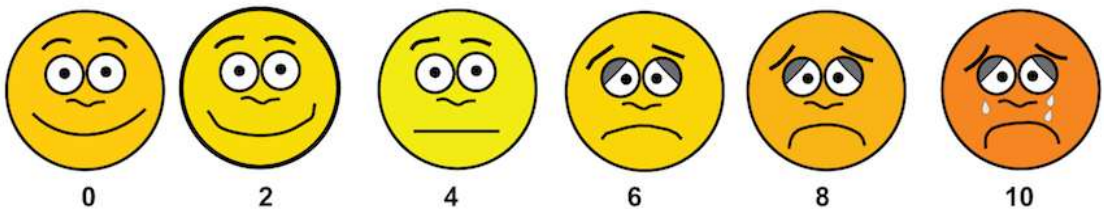
*Wong, D. and Baker, C.: Pain in children: comparison of assessment scales, Pediatric Nursing1988;14(1)

Procedure	**Score**
Pain on injection	

After Palatal Infiltration

ID no:

WONG BAKER SCALE



Instructions for Usage

Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

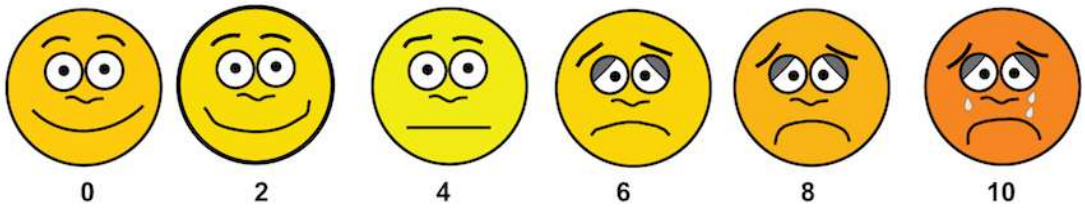
*Wong, D. and Baker, C.: Pain in children: comparison of assessment scales, Pediatric Nursing1988;14(1)

Procedure	**Score**
Pain on injection	

After Extraction Procedure

ID no:

WONG BAKER SCALE



कोई दर्द नहीं	थोड़ा-सा दर्द होता है	थोड़ा अधिक दर्द होता है	थोड़ा और अधिक दर्द होता है	बहुत दर्द होता है	बेहद दर्द होता है

Instructions for Usage

Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

*Wong, D. and Baker, C.: Pain in children: comparison of assessment scales, Pediatric Nursing1988;14(1)

Procedure	**Score**
Pain during extraction	

ANNEXURE 4

After Buccal Infiltration

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	**Comfort**	**Mild discomfort**	**Moderate discomfort**	**Severe discomfort**	**Score**
Grade	1	2	3	4	
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint, shouting, crying	
Eye	No sign	Dilated eye without tear (anxiety sign	Tears, sudden eye movements	Crying, tears all over the face	
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side	

Pain on injection	Total	
	Average	

After Palatal Infiltration

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	**Comfort**	**Mild discomfort**	**Moderate discomfort**	**Severe discomfort**	**Score**
Grade	1	2	3	4	
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint, shouting, crying	
Eye	No sign	Dilated eye without tear (anxiety sign	Tears, sudden eye movements	Crying, tears all over the face	
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side	

Pain on injection	Total	
	Average	

After Extraction Procedure

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	**Comfort**	**Mild discomfort**	**Moderate discomfort**	**Severe discomfort**	**Score**
Grade	1	2	3	4	
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint, shouting, crying	
Eye	No sign	Dilated eye without tear (anxiety sign	Tears, sudden eye movements	Crying, tears all over the face	
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side	

Pain during extraction	Total	
	Average	

MASTER CHART

	DEMOGRAHIC DETAILS				ASSESMENT										Adverse effect
Sr. No.	ID no	gender	DOB	age	pain on injection (buccal infiltration)		onset of anesthesia (buccal infiltration)		pain on injection (palatal infiltration)		onset of anesthesia (palatal infiltration)		pain during extraction		
					subjective	objective	subjective (Sec)	objective(Sec)	subjective	objective	subjective(Sec)	objective(Sec)	subjective	objective	
1	1	1	11/08/2011	9.86	2	1	50	58	2	1	46	50	4	2	0
2	5	2	31/09/2011	9.92	0	1	46	52	0	1	44	50	0	1	0
3	6	1	23/07/2012	9.04	0	1.33	48	60	0	1.33	44	58	0	1	0
4	9	1	24/09/2011	9.9	0	1	55	60	4	1.33	50	56	6	1.66	0
5	10	1	29/03/2012	9.4	2	1	50	62	2	1.33	48	58	4	1	0
6	11	2	11/02/2014	7.52	0	1	48	56	2	1	47	55	2	1	0
7	12	1	28/06/2014	7.17	0	1.66	52	64	2	1.66	40	53	4	2	0
8	14	2	21/05/2013	8.43	2	1.66	45	54	4	1.66	45	49	6	1.33	0
9	15	2	12/01/2012	9.79	2	1	48	54	2	1	53	59	0	1.66	0
10	17	2	15/10/2014	5.07	0	1	55	60	0	1	45	52	0	1	0
11	19	1	17/11/2013	8	0	1	45	58	0	1	48	58	0	1	0
12	21	1	15/08/2011	10.27	0	1	47	59	0	1	48	55	2	1	0
13	24	1	04/01/2012	9.9	0	1	52	63	2	1.33	39	55	0	1	0
14	25	1	01/07/2014	7.43	0	1	54	65	2	1.33	45	58	0	1.33	0
15	27	1	15/01/2020	6.9	0	1	46	58	2	1.33	48	50	2	1.33	0
16	30	1	27/05/2013	8.57	2	1	58	62	2	1.33	45	54	0	1	0
17	31	1	13/04/2013	8.7	0	1	45	48	0	1	47	55	0	1	0
18	32	2	24/03/2014	7.77	2	1	48	60	0	1	49	58	0	1	0
19	34	2	13/02/2014	7.92	2	1	58	70	0	1	50	65	2	1.33	0
20	35	2	18/09/2012	9.36	0	1	57	65	0	1	48	63	2	1	0
21	40	1	02/07/2014	7.52	4	1.66	50	62	2	1.66	42	58	0	1	0
22	41	1	15/10/2013	8.25	2	1.33	55	72	4	1.33	46	52	2	1.33	0
23	43	2	29/01/2015	6.8	0	1	45	52	0	1.33	48	57	0	1	0
24	45	2	25/04/2014	7.65	2	1.33	49	58	2	1	45	50	0	1	0
25	48	1	02/12/2013	8.11	2	1.66	46	55	2	1.33	58	60	0	1.33	0
26	49	2	08/10/2015	6.25	0	1	53	69	0	1	42	48	2	1.33	0
27	51	1	19/06/2013	8.57	2	1.33	50	56	2	1.66	45	52	2	1	0
28	54	2	25/07/2012	9.45	0	1	49	58	4	1	40	52	4	1.66	0
29	56	2	17/02/2013	8.71	0	1	46	55	2	1.33	41	48	2	1	0
30	57	1	04/08/2013	8.41	0	1	44	54	2	1.33	51	62	0	1	0
31	61	2	04/09/2012	9.35	6	2	46	58	6	2.33	44	56	4	1.33	0
32	64	2	23/11/2013	8.13	4	1.66	42	52	8	1.33	41	57	10	2.33	0
33	66	2	09/02/2012	9.9	2	1.33	46	55	4	1.66	42	48	2	1	0
34	68	1	11/08/2015	6.41	2	1.33	50	58	2	1	50	58	0	1	0
35	69	2	01/01/2016	6	2	1	45	56	2	1	46	52	0	1	0

MASTER CHART II

	DEMOGRAHIC DETAILS				ASSESMENT										Adverse effect
Sr. No.	ID no	gender	DOB	age	pain on injection (buccal infiltration)		onset of anesthesia (buccal infiltration)		pain on injection (palatal infiltration)		onset of anesthesia (palatal infiltration)		pain during extraction		
					subjective	objective	subjective (Sec)	objective (Sec)	subjective	objective	subjective(Sec)	objective(Sec)	subjective	objective	
1	2	1	11/06/2011	10	0	1	73	83	0	1	72	80	2	1	0
2	3	1	23/03/2011	9.54	0	1	75	85	0	1	78	90	2	1	0
3	4	2	29/03/2009	9.05	2	1	80	87	0	1	76	82	2	1	0
4	7	1	14/11/2012	8.7	2	1.66	72	79	2	2.33	75	83	4	1.33	0
5	8	1	21/05/2014	7.19	4	2.33	73	80	6	2.66	76	85	10	3	0
6	13	1	21/09/2014	7.04	0	1	77	82	2	2	82	95	4	2.66	0
7	16	2	28/06/2010	9.28	4	2	70	84	4	1.66	78	90	4	1.33	0
8	18	1	24/09/2013	8.14	2	1.33	88	92	2	1.33	82	98	4	1	0
9	20	2	21/11/2011	9.9	0	1	83	95	0	1	88	92	0	1	0
10	22	1	15/07/2013	10.35	2	1.66	73	80	2	1.33	78	85	6	2.66	0
11	23	1	11/01/2022	9.88	2	1.66	60	75	4	2	88	93	2	1.66	0
12	26	1	12/10/2015	7.16	2	1.66	73	85	4	2	68	80	4	2.33	0
13	28	2	10/02/2013	8.83	10	3.33	84	92	10	3.66	85	92	10	4	0
14	29	1	26/08/2013	8.3	6	3.33	80	85	4	3.33	88	95	10	4	0
15	33	2	10/04/2013	6.8	2	2.34	82	95	4	3	78	82	6	3.34	0
16	36	1	16/03/2013	8.87	2	1	75	90	4	2	80	92	0	1.33	0
17	37	2	14/10/2014	7.3	4	2.33	77	84	6	3.33	75	88	2	3	0
18	38	1	21/06/2014	7.6	10	2.33	59	74	10	3.66	75	80	10	2.66	0
19	39	2	23/05/2014	7.68	10	2.66	82	98	10	4	79	88	10	2.66	0
20	42	2	14/04/2015	6.75	6	1.33	89	110	8	2.66	77	93	6	2.33	0
21	44	2	12/10/2015	6.08	2	1.66	86	93	4	2.33	75	95	8	3	0
22	46	1	09/06/2015	6.57	4	1	84	89	6	2.66	62	73	4	2.33	0
23	47	2	17/07/2015	6.45	4	2.33	72	78	6	3.33	68	75	6	3.33	0
24	50	1	01/03/2015	6.85	8	2	80	85	10	3	84	90	10	3.33	0
25	52	1	24/06/2014	7.54	4	1.66	78	80	4	2.66	60	75	4	2.33	0
26	53	2	02/10/2013	8.27	2	2.66	85	88	6	3.33	62	73	8	3.66	0
27	55	2	17/03/2016	5.82	0	1.33	75	84	4	1.66	65	82	4	1.66	0
28	58	1	16/10/2015	6.24	4	1.66	79	87	4	2.66	72	85	2	2	0
29	59	2	02/04/2016	5.79	6	1.33	83	92	6	1.66	66	79	4	2.33	0
30	60	2	28/02/2016	5.86	2	2.33	87	93	2	3	68	85	4	1.66	0
31	62	1	31/10/2014	7.2	0	2.66	89	98	2	4	73	89	2	2	0
32	63	2	16/11/2013	8.16	2	1	79	95	4	1.66	75	83	6	3.33	0
33	65	2	24/12/2012	9.02	6	1.66	89	95	8	2.33	85	93	10	4	0
34	67	1	05/08/2013	8.43	10	1.66	72	88	10	2	88	99	8	3.66	0
35	70	2	22/07/2013	8.46	6	2.66	84	97	4	4	76	91	2	2	0