"COMPARISON OF PAIN ON INJECTION AND ONSET OF ANESTHESIA OF 2 % BUFFERED LIDOCAINE (WITH 1 :2,00,000 ADRENALINE) AND 2 % NONBUFFERED LIDOCAINE (WITH 1:2,00,000 ADRENALINE) IN INFERIOR ALVEOLAR NERVE BLOCK FOR PRIMARY MOLARS: A RANDOMIZED DOUBLE BLIND STUDY"

Dissertation submitted to

Maharashtra University of Health Sciences, Nashik

in the Partial Fulfillment of Regulations

for the award of the Degree of

MDS IN

PAEDODONTICS AND PREVENTIVE DENTISTRY

BRANCH VIII

2018-2021

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LIST OF ABBREVIATIONS

LA	Local anesthesia
IANB	Inferior alveolar nerve block
IAN	Inferior alveolar nerve
HCl	Hydrochloride
CO2	Carbon dioxide
PIV	Peripheral intravenous line
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 Scores
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
APF	Acidulated phosphate fluoride
S	Statistically significant
NS	Non significant
SD	Standard deviation

INTRODUCTION

"Although operative dentistry may be perfect, the appointment is a failure if the patient departs in tears."

- Mc Elroy 1895

Reduction in pain is one of the most important aspects of behaviour management in children undergoing dental treatment. Local anesthesia (LA) administration is a prerequisite for pain reduction while performing various restorative, endodontic and minor surgical procedures in children. [(1)] Fear associated with dental injections have been considered to be a factor for avoiding dental appointments. Although short-lived, the perceived pain of the local anesthetic injection is extreme enough in some children to decline further treatment under local anesthesia. Inferior alveolar nerve block (IANB) is the most routinely used injection technique for achieving local anesthesia for endodontic treatment and extraction of

mandibular teeth. [2] Pain caused during LA administration has been attributed to various factors like the site of injection, speed of injection and pH of the anesthetic solution. [1]

Lignocaine is the most frequently used local anesthetic (LA). It is a local anesthetic agent of the amide class. It is a weak organic base consisting of uncharged and charged fractions when in solution. [3] It is considered that only the uncharged or nonionized form of the local anesthetic solution is capable of diffusing through interstitial tissues, the perineural tissues and the nerve membrane. [3] Once within the nerve axoplasm, the nonionized molecule recalibrates into its ionized and nonionized portions, according to the pH of the axoplasm. The ionized form attaches itself within the sodium channel of the nerve, blocking neurotransmission. [4] Most amides, unfortunately, are chemically unstable in the uncharged form, being subject to photodegradation, aldehyde formation, and other denaturing reactions.[5] Therefore, an acidic medium with a pH of 6.4 is used for stabilization and preservation. The addition of epinephrine requires further lowering of the pH ranging from 2.9 and 4.4 by adding antioxidant .[2] This prevents its early oxidation and increases the shelf life of the solution. However, a lower pH can produce a burning sensation on the injection site, a slow time to onset of anesthesia, and a decreased clinical efficacy.[2,6]

It has been suggested that alkalizing this acidic solution can reduce pain caused during administration of local anesthesia without compromising onset of anesthesia .[7,8] It fastens the onset of anesthesia by increasing the concentration of uncharged basic form, thus facilitating the penetration of lidocaine into the nerve cell. Buffered lidocaine has been used in various fields of surgery and medicine to reduce

the pain and onset of anesthesia. Buffering or alkalinization can be readily accomplished by the addition of small amount of sodium bicarbonate to the anesthetic solution just prior to its use. Sodium bicarbonate is an alkalinizing agent, which is most commonly used for the management of metabolic acidosis.[2] It increases the plasma bicarbonate ion concentration, buffers the excess hydrogen ions, and leads to the rise in pH of the blood, thereby reversing clinical signs of acidosis.

The addition of sodium bicarbonate to LA also result in the production of carbon dioxide and water. Carbon dioxide potentiates local anesthesia by 3 mechanisms. Firstly, by having direct depressant effect on the axon. Secondly, by concentrating LA inside the nerve trunk and lastly by converting LA to the active cation through its effect on pH at the site of action inside the nerve. [2,9]

Most of the studies have been conducted to assess the use of buffered lidocaine for infiltration and block anesthesia during dental procedures in adults, but literature on the use of buffered lidocaine solution in children is sparse.

The purpose of study is to compare pain on injection and onset of anesthesia of 2 % buffered lidocaine (with 1 :2,00,000 adrenaline) and 2 % nonbuffered lidocaine (with 1:2,00,000 adrenaline) in inferior alveolar nerve block for primary molars: a randomized double blind study.

AIM AND OBJECTIVE

AIM OF THE STUDY

To compare pain on injection and onset of anesthesia of 2 % buffered lidocaine (with 1 :2,00,000 adrenaline) and 2 % nonbuffered lidocaine (with 1:2,00,000 adrenaline) in inferior alveolar nerve block for primary molars: a randomized double-blind study.

PRIMARY OBJECTIVE:

1. To compare pain on injection and onset of anesthesia of 2%buffered (with 1:2,00,000 adrenaline) with 2 %nonbuffered lidocaine (with 1:2,00,000 adrenaline) in inferior alveolar nerve block for primary molars.

SECONDARY OBJECTIVE:

1. To evaluate pain on injection and onset of anesthesia of 2% nonbuffered lidocaine (with 1:2,00,000 adrenaline) in inferior alveolar nerve block for primary molars.

2. To evaluate pain on injection and onset of anesthesia of 2% buffered lidocaine (with 1:2,00,000adrenaline) in inferior alveolar nerve block for primary molars.

REVIEW OF LITERATURE

De jong R and Cullen S (1963) [10] studied the buffer demand and ph. of local anaesthetic solutions containing epinephrine. 10 or 20 aliquots of random shelf samples of three widely used local anaesthetics (lidocaine HCl,2-chlorprocaine HCl and mepivacaine HCl) were titrated for changes in ph with heparinized fasting human venous blood at room temperature. Ph was recorded with Beckmann zeromatic glass electrode ph. meter which was allowed to equilibrate overnight and was standardized with laboratory buffer at ph. 7. Ph values observed during titration were averaged and plotted as blood titration curve of 10ml aliquot of LA solution. From this curve the volume of blood required to bring a 10 ml aliquot of local anaesthetic to a ph of 7.0 was measured which was designated as buffer demand of the local anaesthetic. Results had shown that the ph and buffer demand of lidocaine with freshly mixed epinephrine was 6.7 was 6.5 respectively and that for commercially prepared lidocaine with epinephrine containing sodium metabisulfide was 4.2 and 10.8

respectively. They concluded that LA to which epinephrine and a preservative (sodium metabisulfite) have been added have ph lower than the initial solution and buffer demand is nearly double the 2% lidocaine.

Catchlove (1972) [9] studied the influence of ph and carbon dioxide (CO2) on local anaesthesia. These solutions with different combinations of pCO2 and pH were applied to desheathed and sheathed frog nerves and their compound action potential was recorded. CO2 (1-50%) and local anaesthetic (1.0 mM) had caused a much greater block when given together than when applied separately. The effect was maximum at a relatively high pH (7.3). The permeability of the nerve sheath to radioactive lidocaine and sucrose was measured by perfusing these substances through a segment of isolated sheath. Apparent permeability to the anaesthetic was seen as a linear function of the fraction of nonionized lidocaine. This permeability was not changed by varying pCO2 or pH. The study concluded that CO2 potentiates the action of local anaesthetics by 1) a direct depressant effect of CO2 on the axon, 2) concentrating local anaesthetic inside the nerve trunk and 3) through its effect on pH, converting local anaesthetic to the active cation at the site of action inside the nerve.

Rood J (1977) [11] carried out a study to evaluate the use of buffered lignocaine solution in the presence of acute inflammation. A total of 34 patients with acute inflammation associated with the extracted teeth received either commercial or buffered lignocaine (groups 1 and 2) and 40 patients received the same preparations in the absence of inflammation (groups 3 and 4). A labial or buccal supraperiosteal infiltration was given using an aspirating syringe, and 1 ml of analgesic solution was deposited near to the apical region of the tooth to be extracted. About 0.5 ml of

solution was administered palatally. All of the injections were administered by a single operator to achieve uniformity of technique. One series of injections was given using commercial 2 per cent lignocaine solution, with 1 in 80 000 adrenaline (pH 3.5). A second group of patients received 2 per cent lignocaine solution, with 1 in 80 000 adrenaline, buffered to pH 6.75. Control series of patients were subjected to the same procedures using the same solutions. Absolute analgesia was taken as a successful result following a completely painless extraction. This was assessed by the operator and confirmed by questioning the patient. Commercial lignocaine solution used in the presence of acute inflammation showed a statistically marked reduction of efficiency when compared with its use when no inflammation was apparent. Also, the buffered solution was less efficient in the presence of inflammation. When comparing the success rate of each solution in the presence of inflammation neither proved to be more efficient. The study concluded that there was no significant improvement in successful analgesia produced by buffering the solution.

Moore DC (1981) [(12)] carried out a study to report the pH values of the commonly used commercially prepared local anaesthetic drugs like bupivacaine, mepivacaine, chloroprocaine, etidocaine, lidocaine and prilocaine with and without epinephrine 1:200,000 as well as the additives that they contain. Also, the effect on pH when epinephrine is added to plain solutions of these drugs, was studied. pH was determined by the Beckman model 3560 digital pH meter. After the pH values of the plain solutions were determined, 0.1 mg of 1: l0000 epinephrine was withdrawn from a 1-ml ampule and added to the 20-ml samples, creating a final epinephrine concentration of 1:200,000. Results had shown that with the exception of chloroprocaine, all solutions of the local anaesthetic drugs without epinephrine that

did not contain additives had pH values of 4.4 or greater than 5. Furthermore, solutions with epinephrine containing additives had pH values less than 4. The pH of epinephrine was 3.3. He concluded that the use of solutions with low pH values can be circumvented by using single dose ampules or vials with no epinephrine, adding 0.25 mg of sodium bisulfide to the local anaesthetic solution and also, by adding epinephrine immediately before injection, except in the case of chloroprocaine.

McKay W, Morris R, Mushlin P (1987)[13] carried out a double-blind, randomized study in twenty-four young, healthy volunteers to determine the relation between pH of anaesthetic solutions and pain associated with intracutaneous injection (skin infiltration) of the local anaesthetic, lidocaine. Each subject had received an intradermal injection of normal saline solution and five preparations of lidocaine like plain 1% lidocaine; plain 1% lidocaine plus epinephrine (added by investigator); commercial 1% lidocaine with epinephrine already added; sodium bicarbonate added to commercial 1% lidocaine with epinephrine; and sodium bicarbonate added to plain 1% lidocaine. One ml of sodium bicarbonate (1 mEq/ml) was added to each 10 ml of local anaesthetic to give a final concentration of 0.1 mEq/ml. For each test 0.1 ml was injected intradermally in six discrete areas on the volar surface of the left forearm and then 0.2 ml injected subcutaneously via a 26-gauge hypodermic needle and 1 ml tuberculin syringe in one injection. All six injections were made at 15 sec intervals covering approximately a 2-min period. Immediately after all six injections, subjects were asked to score a pain-free injection as 0 and the most pain imaginable as 10, using a 10 cm linear analog pain scale. Results had shown that commercial preparation of lidocaine with epinephrine had the highest mean pain score (43 ± 5); this was more painful than was plain lidocaine (38 ± 5), plain lidocaine with added

epinephrine (30 ± 4), normal saline solution (29 ± 4), commercial preparation of lidocaine and epinephrine with sodium bi- carbonate (24 ± 4), or lidocaine with sodium bicarbonate (15 ± 3) .The study concluded that addition of sodium bicarbonate significantly reduces pain produced by infiltration of lidocaine with or without epinephrine which relates to the alkalinity of solutions of local anaesthetic.

Christoph RA, Buchanan L, Begalla K et al. (1988) [(7)] carried out randomized, prospective, double-blind study to assess the effects of pH buffering on the pain on injection and efficacy of 1% lidocaine, 1% lidocaine with 1:100,000 epinephrine, and 1% mepivacaine. Plain and buffered solutions of the three local anaesthetics were prepared, and a 0.5 intradermal injection of each was administered to the 25 adult volunteers included in the study. Pain of anaesthetic infiltration was rated from 0 to 10. The area of anesthetized skin surrounding each injection site was measured at time intervals following each of the injection. The mean pain estimates were significantly reduced on buffering the local anaesthetics compared to the nonbuffered controls: 1) 1% lidocaine compared with buffered 1% lidocaine, 4.9 ± 0.4 versus 1.1 ± 0.2 ($P < 10 -6$); 2) 1% lidocaine with epinephrine compared with buffered 1% lidocaine with epinephrine, 5.1 ± 0.4 versus 1.8 ± 0.4 ($P < 10-6$); and 3) 1% mepivacaine compared with buffered 1% mepivacaine, 5.1 ± 0.4 versus 0.9 ± 0.2 ($P < 10-6$). Onset, extent, and duration of skin anaesthesia were not statistically altered on pH buffering. It was concluded that the pain of local anaesthetic administration can be dramatically reduced by buffering the local anaesthetic prior to its infiltration. Anaesthetic efficacy was not compromised, and patient acceptance might be significantly increased.

Eppley B, Sadove M (1989) [8] in their study had used buffered anaesthetics for multiple local orofacial procedures. The anaesthetic solution was diluted in a 1:10 ratio with one-part sodium bicarbonate NaHC03 (1mEq/mL) per ten of standard lidocaine or bupivacaine (with or without epinephrine). 50-mL vial of, lidocaine required 5mL of NaHC03 and a cartridge required 0.2 mL NaHC03. They consistently came up with the reduction of injection pain without any observed decrease in anaesthetic effectiveness They concluded that buffering local anaesthetic solution is a useful technique for very apprehensive or paediatric patient, as well as for those procedures that necessitate significant volumes of injected local anaesthetics.

Laserson P, Ragi G, Swandby M, et al. (1991) [14] carried out a study to measure the concentrations of buffered lidocaine and epinephrine in order to evaluate their stability with chromatography. Buffered lidocaine dropped to 66.1% of initial concentrations after 4 weeks when stored at 25°C. Buffered epinephrine fell to 1.34% of its initial concentration under similar conditions. Buffered lidocaine and epinephrine maintained 94.54% and 82.04%, respectively, of their initial concentrations after 4 weeks when refrigerated at 0-4°C. Both lidocaine and epinephrine maintained greater than 90% concentration 2 weeks after buffering when stored at 0-4°C. They concluded that buffered lidocaine with epinephrine may be stored for upto 2 weeks if kept refrigerated.

Chaney M, Kerby R, Reader Al et al. (1991) [15] carried out a randomized control study in 30 subjects to measure the degree of anaesthesia obtained with 2.2% lidocaine hydrocarbonate with and without 1:100,000 epinephrine, and 2% of

lidocaine hydrochloride with 1: 100,000 epinephrine for inferior alveolar nerve block over the course of three successive appointments. The first molar, first premolar, lateral incisor, and contralateral canine (control) was tested blindly with an analytic technology pulp tester at 3-min cycles for 60 min. Anaesthetic success was defined as no subject response to the utmost output (80 reading) of the pulp tester within 16 min and maintenance of this reading for the rest of the testing period. Anaesthetic success ranged from 3% to 10% for the plain lidocaine hydrocarbonate; from 37% to 63%for the lidocaine hydrocarbonate and lidocaine hydrochloride solutions with epinephrine. It was concluded that 2.2% lidocaine hydrocarbonate without vasoconstrictor was not as effective as the other two preparations for inferior alveolar nerve block. The other two preparations were equivalent for inferior alveolar nerve block of 60-min duration

Orlinsky M, Hudson C, Chan L et al. (1992) [16] studied and compared the pain of infiltration between unbuffered lidocaine and buffered lidocaine in a traumatic laceration in a total of 61 patients. Each patient's wound was divided into two sample injection sites, with Site I (for longitudinally oriented wounds, the most central aspect of the medial wound edge; for transverse wounds, the medial corner) always receiving the first injection and Site II (for longitudinally oriented wounds corresponding segment of the lateral wound edge; for transverse wounds, lateral corner) receiving the second. In irregularly shaped wounds, similar sites were chosen and were far enough apart so that no crossover would occur. For each subject, solutions of buffered and unbuffered 1% lidocaine were randomly assigned to Site I or Site II of a single laceration, with the patient serving as self-control. Pain scores were recorded for each site, along with an anaesthetic preference for each patient. It was observed that buffered lidocaine had a preference ratio of 3.0 over unbuffered

lidocaine (95% confidence interval, 1.86 to 4.84; P < 0.0001). It was also observed that Site I was preferred more often than Site II regardless of which medication was used. They concluded that buffered lidocaine is preferred over unbuffered lidocaine and that the order of injection is an important factor in studies that involve multiple sequential injections in the same patient.

Janer L, Padial M, Sánchez JL (1993)[17]carried out a double-blinded comparison study to compare the degree of pain of intradermal infiltration and the duration of anaesthesia for 1% lidocaine with epinephrine 1:100,000, 1% lidocaine with epinephrine 1:100,000 with 80 meq/L sodium bicarbonate, bacteriostatic saline solution with 1% lidocaine with epinephrine 1:300,000, and bacteriostatic saline solution with 1% lidocaine with epinephrine 1:100,000. Results had shown that bacteriostatic saline solution with epinephrine 1:300,000 is significantly less painful on intradermal infiltration than lidocaine with epinephrine 1:100,000 with sodium bicarbonate 80 meq/mL. The saline preparation is an effective anaesthetic alternative for superficial surgical procedures such as shave and scissors excision, light curettage and electrodesiccation, and superficial CO2 laser vaporization. The study concluded that pH values of bacteriostatic saline solution with epinephrine 1:300,000 and lidocaine with epinephrine diluted with bacteriostatic saline solution were 5.3 and 4.2, respectively. Both were found to be less painful than 1% lidocaine with epinephrine with sodium bicarbonate 84 meq/mL, which had a pH of 7.4.

Brogan G, Giarrusso E, Hollander J et al. (1995) [18] carried out a randomized, prospective, single-blinded study in 45 patients with traumatic lacerations to compare pain on infiltration, need for additional anaesthesia, and pain

on suturing using plain, warm, and buffered lidocaine solution. Standard injection technique was used. Pain of infiltration was recorded for each margin by using visual-analogue pain scale. Need for additional anaesthesia and pain on suturing were secondary outcome parameters. Pain on injection varied by the type of lidocaine used (mean pain scores: plain, 8.2; buffered, 4.7 [P<0.05 versus plain]; warm, 4.9 [P<0.05 versus plain]). There was no significant difference between the mean pain scores of the groups given warm and buffered lidocaine (P=NS). Need for additional anaesthesia and pain on suturing did not vary by the type of anaesthesia. The order of injection was not found to influence results. Mean pain scores were not different for margins 1 and 2 in any of the groups (P=NS). It was concluded that both buffered and warmed lidocaine were as efficacious as plain lidocaine, and they had significantly less pain associated with infiltration than did plain lidocaine.

Xia Y, Chen E, David L et al. (2002) [(19)]carried out a randomized, double-blinded, placebo-controlled study in 40 adult volunteers to evaluate pain and the spread of analgesia when local anaesthetics are given as an intradermal injection into the dorsal aspect of the hand. Volunteers were randomly assigned to receive a 0.25-mL injection of lignocaine hydrochloride (1%), buffered lignocaine, diphenhydramine (1%), or placebo (0.9% sodium chloride solution) into the dorsal aspect of both hands. The volunteers used a visual analog scale to compare the pain of needle insertion and solution injection. The extent of the analgesic area was marked on a strip of tape placed horizontally across hand. Then at 32 minutes after intradermal injection, the extent of the analgesic area was marked on a strip of tape placed vertically across the hand. The result showed that Buffered lignocaine during intradermal infiltration was found to be significantly less painful than either lignocaine hydrochloride or

diphenhydramine and equivalent to placebo. Diphenhydramine showed significantly larger diameter of anaesthesia followed by Buffered lignocaine.

Davies RJ (2003) [20] reviewed the evidence that buffering of local anaesthetics with sodium bicarbonate reduces the pain of injection whilst not affecting efficacy. Medline search from 1966 to December 2001 was done and 63 publications were identified. The study concluded that buffering with sodium bicarbonate significantly reduces the pain of local anaesthetic injection. The buffered solutions retain the efficacy of local anaesthetics and are stable in the mixtures used in the trials. Adrenaline-containing buffered solutions need refrigeration in closed containers for storage. Buffering will be particularly useful where pain of local anaesthetic injection may not be well tolerated such as in large areas of infiltration, sensitive areas such as the face and in children.

Luhmann J, Hurt S, Shootman M et al. (2004) [21] carried out a randomized controlled study in 69 children aged 4 to 17 years old undergoing PIV insertion with 22-gauge catheters to compare the reduction of pain and anxiety during PIV insertion provided by subcutaneous buffered 1% lidocaine or topical ELA-Max in children. Children received either buffered lidocaine or ELA-Max. Buffered lidocaine was administered by using 30-gauge needles to inject 0.1 to 0.2 mL subcutaneously just before PIV insertion. ELA-Max was applied to the skin and occluded with Tegaderm 30 minutes before PIV insertion. Self-reported Visual Analog Scale (VAS) questionnaires (rating on a scale of 1–10; 1 no pain, anxiety) were completed by patients and their parents before PIV insertion to assess baseline perceptions about pain and anxiety associated with PIV insertion and immediately after PIV insertion to

assess pain and anxiety associated with the experience. After PIV insertion, the nurse who inserted the PIV also completed a VAS questionnaire assessing technical difficulty and satisfaction with the local anaesthesia. A blinded observer also completed a VAS questionnaire to assess pain and anxiety associated with the PIV insertion. Data were analyzed by using t tests. There were no differences for buffered lidocaine and ELA-Max groups in age, gender, race, prior IV experience, or baseline pain and anxiety. There were no significant differences between buffered lidocaine and ELA-Max in mean pain and anxiety after PIV insertion by patient, parent, and blinded observer ratings. Nurse ratings of technical difficulty, number of PIV-insertion attempts, and satisfaction with local anaesthesia also were not significantly different for buffered lidocaine and ELA-Max groups. They concluded that ELA-Max provides similar pain and anxiety reduction during PIV insertion in children compared with injected buffered lidocaine. Technical difficulty and satisfaction by nurses inserting the PIV also were similar.

Faiz A, Fathie WK, Hamid RS et al. (2006) [(22)] evaluated the effect of alkalization of local anaesthetic solution in 80 patients in periapical surgery on one or more of their upper anterior teeth. For the purpose of comparison, the sample was randomly divided into two groups based on the local anaesthetic solution that they were to receive before surgery. The first group(control) included those patients who received the commercially available local anaesthetic solution with a standard pH of 3.5. The patients in second group (trial group) received a pH adjusted local anaesthetic solution at 7.2 (using sodium bicarbonate). Prior to, and at the completion of intended surgery, pain during injection, onset of achievement of surgical anaesthesia, pain during operation and the duration of operation itself were recorded.

Faster onset of anaesthesia was seen in group two when compared to control group. Also, in second group less pain was recorded on deposition of solution and during operation. They found that pH adjusted local anaesthetic solutions may provide certain advantages when compared to the commercially available local anaesthetic solutions regarding enhancement of anaesthetic efficiency, reduced pain on injection as well as during surgery.

Burns C, Ferris G, Feng C et al. (2006) [23] carried out a prospective, double-blind study in 60 volunteers to compare the pain induced by infiltration of the skin (intradermal injection) with 1% lidocaine with epinephrine 1:100,000 buffered with sodium bicarbonate and 1% lidocaine freshly mixed with epinephrine. Volunteers rated the pain of infiltration on a 100-mm visual analog scale immediately after injection. The pain scores for the anaesthetic solutions were compared using the paired t test. Results had shown that the pain score for the buffered solution and fresh solution was 18.3 ± 20.3 and 23.5 ± 19.1 (P = .0543) respectively. 65% of volunteers found that the fresh solution was more painful than the buffered solution. The results did not reach statistical significance. They finally concluded that buffered lidocaine with epinephrine caused less pain on intradermal injection than lidocaine freshly mixed with epinephrine, but the results were not statistically significant.

Whitcomb M, Drum M, Reader A et al. (2010) [24] carried out a randomized cross over study in 40 blinded subjects to compare the anaesthetic efficacy of sodium bicarbonate buffered 2% lidocaine with 1: 100,000 epinephrine in inferior alveolar nerve blocks at 2 separate appointments spaced at least 1 week apart. An electric pulp tester was used in 4-minute cycles for 60 minutes to test for anaesthesia of central

incisors, lateral, premolars, first and second molars. For the buffered 2% lidocaine with 1: 100,000 epinephrine/sodium bicarbonate formulation, successful pulpal anaesthesia ranged from 10-71% and for the unbuffered 2% lidocaine with 1: 100,000 epinephrine formulation, it ranged from 10-72%. No significant differences between the 2 anaesthetic formulations were noted. The buffered lidocaine group did not statistically result in less pain or faster onset of anaesthesia during injection than did the unbuffered lidocaine formulation. The study concluded that for an IAN block buffering a 2% lidocaine with epinephrine with sodium bicarbonate, did not statistically increase anaesthetic success, provide faster onset, or result in less pain of injection when compared with unbuffered 2% lidocaine with epinephrine.

Kashyap VM, Desai R, Reddy PB et al. (2011) [25] conducted a randomized prospective study in 100 patients aged 18-55 years to study the effect of alkalinization of lignocaine for intraoral nerve block on pain during injection, and speed of onset of anaesthesia. 3 nerve blocks (inferior alveolar, lingual, and long buccal) were given**.** Visual analogue scale (VAS) was used to measure pain by the patient. The patients who received injection with sodium bicarbonate reported no pain compared to 39/50 (78%) patients who did not receive sodium bicarbonate ($p < 0.0001$). The mean (SD) time (seconds) to onset of local anaesthesia in the sodium bicarbonate group was 34.4 (9.8) and was 109.8 (31.6) in the control group ($p < 0.001$). Results had shown the efficacy of the alkalinized local anaesthetic solution in reducing pain on injection and fastening the onset of anaesthesia.

Welch M, Czyz C, Kalwerisky K et al. (2012) [26] carried out a double-blind, prospective, randomized study in fifty-four consecutive patients to determine the pain

perception during periocular, subcutaneous anaesthesia on raising the pH of 2% lidocaine with epinephrine 1:100 000 to a physiologic level. Patients were given simultaneous injections of buffered and unbuffered 2% lidocaine with epinephrine 1:100 000. The needles were inserted simultaneously and the anaesthesia was injected for a 20-second count for a total volume of 1.0 ml per injected side. The patients were asked to rate the pain on each side on a Likert-type visual analog scale of 0 to 10. Results had shown that 65 percent of patients preferred the buffered lidocaine with a scaled pain reduction of 0.9 (P _0.0005). Additionally, for the patients who believed that the buffered solution was less painful, the mean decrease in scaled pain rating was 2, for a 51% reduction in pain level (P _ 0.001). No gender differences were noted. They concluded that buffering 2% lidocaine with epinephrine 1:100 000 with sodium bicarbonate 8.4% offers a clinically and statistically significant reduction in pain experienced by two-thirds of patients receiving periocular subcutaneous anaesthesia.

Balasco M, Drum M, Reader A, et al (2013) [27] carried out a prospective, randomized, double-blind study in 81 adult patients to compare the pain of infiltration and pain of an incision and drainage procedure by using a buffered and a nonbuffered 2% lidocaine with 1:100,000 epinephrine solution in symptomatic patients with a diagnosis of pulpal necrosis and associated acute swelling. Patients used 170-mm visual analog scale to rate pain of needle insertion, placement, and solution deposition for each infiltration. The procedure of incision and drainage was performed, and the pain of incision, drainage, and dissection was recorded. No significant differences were found between the 2-anaesthetic solution for pain of solution deposition for either the mesial or distal site infiltrations. Majority of patients experienced moderate-

to-severe pain with the incision and drainage procedure. No significant differences were found between the 2 preparations. It was concluded that the addition of a sodium bicarbonate buffer to 2% lidocaine with 1:100,000 epinephrine did not result in significantly decreased pain of infiltrations or significantly decreased pain of the incision and drainage procedure when compared with 2% lidocaine with 1:100,000 epinephrine in symptomatic patients with a diagnosis of pulpal necrosis and associated acute swelling.

Hobeich P, Simon S, Schneiderman E et al. (2013) [28] carried out a prospective, randomized, double-blind study in 30 patients to compare injection pain and anaesthetic onset of 2% lidocaine with 1:100,000 epinephrine buffered with 5% and 10% sodium bicarbonate in maxillary infiltrations at 3 separate appointments. Pain on needle penetration and deposition of anaesthetic solution was recorded by using a Heft-Parker visual analogue scale. Anaesthetic onset was determined by 2 consecutive negative responses to electronic pulp test. The mean anaesthetic onset for nonbuffered anaesthetics was 119 seconds, 116 seconds for the 5% buffered solutions, and 121 seconds for the 10% buffered solutions. There was no significant difference between the 3 groups and in pain on needle penetration or anaesthetic deposition between the 3 anaesthetic solutions tested. The study concluded that two percent lidocaine with 1:100,000 epinephrine buffered with 5% or 10% sodium bicarbonate did not differ from nonbuffered solutions in anaesthetic onset or injection pain in maxillary infiltrations of canines with healthy pulps.

Malamed SF, Tavana S, Falkel M. (2013) [29] carried out a split mouth study in 20 patients to compare the anaesthetic latency and injection pain for alkalinized

versus non-alkalinized anaesthetic in inferior alveolar nerve blocks (IANBs) measured using electric pulp tester (EPT), and injection pain was measured using a visual analog scale (VAS). The study buffered the anaesthetic directly in the cartridges using a mixing pen device. The control solution was non-alkalinized 2% lidocaine/epinephrine 1:100,000 at pH 3.85. The test solution was 2% lidocaine/ epinephrine 1:100,000 alkalinized to pH 7.31. Onset time with the alkalinize anaesthetic was, 71% of participants achieved pulpal analgesia in 2 minutes or less. With non-alkalinized anaesthetic, it was12% achieved pulpal analgesia in 2 minutes or less (P = 0.001). The average time to pulpal analgesia for the non-alkalinized anaesthetic was 6:37 (range 0:55 to 13:25). Average time to pulpal analgesia for alkalinized anaesthetic was 1:51 (range 0:11 to 6:10) (P = 0.001). 72% of the participants rated the alkalinized injection as more comfortable, 11% rated the non-alkalinized injection as more comfortable, and 17% reported no preference (P = 0.013). 44% of the patients receiving alkalinized anaesthetic solution rated the injection pain as zero ("no pain") on a 100-mm VAS, compared to 6% of the patients who received non-alkalinized anaesthetic solution (P = 0.056). They concluded that alkalinizing lidocaine with epinephrine toward physiologic pH immediately before injection significantly reduced anaesthetic onset time and increases the comfort of the injection.

Gupta S, Mandlik G, Padhye MN, et al. (2014) [30] conducted a double-blind study in 200 subjects with 100 subjects in each group to validate the addition of sodium bicarbonate in local anaesthetics to increase its effectiveness as local infiltrations in teeth associated with periapical infections. One group received local infiltration with 2 % lignocaine and 1:80,000 adrenaline, and the other group received

local infiltration with sodium bicarbonate as an adjunct to the mentioned local anaesthetic solution. All extractions were carried by a single operator. Subjective pain during extraction was recorded using two pain scales namely, the visual analog scale and the verbal response scale. The data related to the onset of action of local anaesthesia and any requirement of repeated injections during the procedure was also recorded. Clinical and statistical data confirmed that the addition of sodium bicarbonate in local anaesthetics increased the efficacy of local anaesthesia in inflamed tissues. It was concluded that the action of sodium bicarbonate in local anaesthetics increases the pH levels of these solutions, thus possibly making them more effective in an acidic environment.

Comerci AW, Maller SC, Townsend RD (2015) [31] carried out a double-blind, split-mouth, randomized human clinical study in 20 patients to evaluate the effectiveness of a new sodium bicarbonate LA buffering device (Onset) in reducing pain related with dental injections. Patients were asked to quantify the pain experienced during injection on a visual analog scale (0, no pain; 10, worst possible pain). One side of the mouth received standard-of-care injections of 2% lidocaine with 1:100,000 epinephrine. On the opposite side, after the buffering device was used to mix the components within the anaesthetic carpule, patients received injections of 2% lidocaine with 1:100,000 epinephrine buffered 9:1 with 8.4% sodium bicarbonate. The mean pain scores were 2.7 for buffered and 2.7 for unbuffered IA injections and mean pain scores were 2.0 for buffered and 2.7 for unbuffered LB injections. The data were analyzed with a paired t test ($\alpha = 0.05$), and no statistically significant difference was found between groups for IA ($P = 0.94$) or LB ($P = 0.17$) nerve block injections. They concluded that patients receiving common dental nerve block injections, local

anaesthetic buffering technology did not significantly lessen pain compared to that experienced during a standard unbuffered injection

Agarwal A, KD J, Sinha A et al. (2015) [32] carried out a prospective, randomized controlled, double-blind study in a crossover design to evaluate the anaesthetic efficacy of sodium bicarbonate buffered 2% lidocaine with 1:1000000 epinephrine in Inferior Alveolar Nerve Blocks (IAN). Thirty subjects randomly received 2 IAN blocks using 3 ml of 2% lidocaine with 1:100,000 epinephrine and 2% lidocaine with 1: 100,000 epinephrine/ 0.17 mEq/ml sodium bicarbonate at 2 separate appointments spaced at least 1 week apart, in a crossover design. Results had shown that buffering of local anaesthetic solution made the experience of injection more comfortable to the patient with 70% marked no pain on solution deposition. 2% lidocaine with 1:100000 epinephrine with sodium bicarbonate has faster onset i.e. 74% of nerve blocks showed less than 1 minute of time while 2% lidocaine with 1:100000 epinephrine showed 67% of nerve blocks were effective after 2 minutes. They concluded that buffering of anaesthetic solution significantly decreased the pain of injection, provide faster onset when compared to unbuffered anaesthetic solution for IAN block.

Harreld TK, Fowler S, Drum M et al. (2015) [33] carried out prospective, randomized, double-blind study in 88 patients to compare the pain of infiltration and the pain of an incision and drainage procedure of a buffered using the Onpharma buffering system versus a nonbuffered 4% lidocaine formulation in symptomatic emergency patients presenting with a diagnosis of pulpal necrosis, associated periapical area, and an acute clinical swelling. Patients rated the pain of needle

insertion, needle placement, and solution deposition for each injection using a 170-mm visual analog scale. Patients rated the pain of incision, drainage, and dissection on a 170-mm visual analog scale. No significant differences between the buffered and nonbuffered 4% lidocaine formulations were found for needle insertion, placement, and solution deposition of the infiltration injections or for the treatment phases of incision, drainage, and dissection. The study concluded that buffering a 4% lidocaine formulation did not significantly decreased the pain of infiltrations or pain of the incision and drainage procedure when compared with a nonbuffered 4% lidocaine formulation in symptomatic patients with a diagnosis of pulpal necrosis and associated acute swelling.

Schellenberg J, Drum M, Reader A et al. (2015) [(34)] conducted a randomized controlled, double blind study to determine the effect of 4% buffered lidocaine on the anaesthetic success of the inferior alveolar nerve (IAN) block in 100 emergency patients experiencing symptomatic irreversible pulpitis. For the buffered solution, each cartridge was buffered with 8.4% sodium bicarbonate using the OnPharma system. 15 minutes after IAN block, profound lip numbness was confirmed, and endodontic access was initiated. No or mild pain on access or instrumentation of the root canal was considered as success. The success rate for the IAN block was 32% and 40% for the buffered group and the nonbuffered group respectively, with no significant difference (P = .4047) between the groups. Ratings of injection pain for the IAN block were not significantly (P = .9080) different between the 2 formulations. They concluded that for in patients with symptomatic irreversible pulpitis, a 4% buffered lidocaine formulation did not result in a statistically significant increase in the success rate or a decrease in injection pain of the IAN block.

Saatchi M, Khademi A, Baghaei B, et al. (2015) [2] carried out a prospective, randomized, double-blind study to compare the anaesthetic efficacy of buffered with nonbuffered 2% lidocaine with 1:80,000 epinephrine solution for inferior alveolar nerve (IAN) block in 80 adult subjects with mandibular posterior teeth experiencing symptomatic irreversible pulpitis. The subjects had received 2 cartridges of either 2% lidocaine with 1:80,000 epinephrine buffered with 0.18 mL 8.4% sodium bicarbonate or 2% lidocaine with 1:80,000 epinephrine with 0.18 mL sterile distilled water using conventional IAN block injections. 15 minutes after injection, endodontic access preparation was initiated. Lip numbness was required for all the subjects. Success was determined as no or mild pain on basis of recordings of Heft-Parker visual analog scale upon access cavity preparation or initial instrumentation. The t, Mann-Whitney, and chi-square tests were used to analyze data. The success rates were 62.5% and 47.5% for buffered and nonbuffered groups, respectively, with no significant differences between the two groups (P = .381). The study concluded that buffering the 2% lidocaine with 1:80,000 epinephrine with 8.4% sodium bicarbonate did not improve the success of the IANB in subjects with symptomatic irreversible pulpitis.

Chopra R, Jindal G, Sachdev V et al. (2016) [1] carried out a double-blind crossover study to assess the reduction in pain on injection during inferior alveolar nerve block administration in children aged 6 to 12-years. 30 patients received two sessions of inferior alveolar nerve block scheduled one week apart. 2% lidocaine with 1:200,000 epinephrine was given during one appointment, and a buffered solution was given during the other. Pain on injection was assessed using the SEM scale, and the time to onset of anesthesia was assessed after gingival probing. The Heft-Parker visual analogue scale (HP-VAS) was self-recorded by the patient after administration

of local anaesthesia. No significant differences were found between the SEM scores (P=0.71) and HP-VAS scores (P=0.93) for the two solutions used using Mann-Whitney analysis. Student's t test was used to assess the difference in the onset of anaesthesia, which was also found to be statistically insignificant (P=0.824). They concluded that buffered lidocaine did not reduced the pain on injection or time to onset of anaesthesia for inferior alveolar nerve block in children.

Saatchi M, Farhad AR, Shenasa N et al. (2016) [35] carried out a prospective, randomized, double-blind study in 100 patients to evaluate the effect of a buccal infiltration of sodium bicarbonate on the anaesthetic success of the IANB in patients with symptomatic irreversible pulpitis. The participants received a buccal infiltration injection of either 0.7 mL 8.4% sodium bicarbonate with 0.3 mL 2% lidocaine containing 1:80,000 epinephrine or 0.7 mL sterile distilled water with 0.3 mL 2% lidocaine containing 1:80,000 epinephrine. After 15 minutes, all the participants received conventional IANB injection using 3.6 mL 2% lidocaine with 1:80,000 epinephrine. Access cavity preparation was started 15 minutes after the IANB injection. Lip numbness was a requisite for all the participants. Success was determined as no or mild pain on the basis of HP- VAS recordings on access cavity preparation or initial instrumentation. Data was analysed using the t, chi-square and Mann-Whitney U tests. The success rate after the buccal infiltration of sodium bicarbonate was 78%, whereas without the buccal infiltration of sodium bicarbonate it was 44% ($P < .001$). It was concluded that buccal infiltration of 0.7 mL 8.4% sodium bicarbonate increased the success rate of IANBs in mandibular first molars with symptomatic irreversible pulpitis.

Phero JA, Nelson B, Davis B et al. (2016) [36] carried out a prospective, randomized, double-blinded, cross over study to assess the outcomes for peak blood levels (clinical outcomes) for buffered 2% lidocaine with 1:100,000 epinephrine compared with non-buffered 2% lidocaine with 1:100,000 epinephrine. 30 minutes after a mandibular nerve block with 80 mg of the buffered or unbuffered drug, venous blood samples for lidocaine were obtained. After two weeks, the same subjects were tested with the alternate drug combinations. Subjects reported on pain on injection with a 10-point Likert-type scale and time to lower lip numbness. Outcome variables were subjects' peak blood lidocaine levels, responses to pain on injection, and time to lower lip numbness i.e onset. Serum lidocaine levels were analysed with liquid chromatography-mass spectrometry. Statistical significance was set at a P value < 0.05 for all outcomes. Median blood levels (44 blood samples) at 30 minutes were 1.19 μg/L /kg of body weight whereas, mean blood level differences of lidocaine for each patient were significantly lower after nerve block using the buffered drug compared with the non-buffered agent (P < .01). Mean score for pain on injection (n = 46 scores) was 3.3 (SD, 0.9). Seventy-eight percent of subjects reported lower or the same pain scores with the buffered drug; 61% of subjects reported a shorter time to lower lip numbness with the buffered drug. They concluded that buffering 2% lidocaine with epinephrine can produce clinical outcomes favorable for subjects and clinicians without clinically detrimental peak blood lidocaine levels.

Phero JA, Warren VT, Fisher AG (2017) [37] carried out a randomized, crossover design study in adult volunteers to assess the outcomes for pulpal anaesthesia, pain on injection, and midface numbness time for buffered 1% lidocaine with 1:100,000 Epinephrine versus nonbuffered 2% lidocaine with 1:100,000

Epinephrine. The outcome variables were volunteer's responses to cold and electric pulp testing (EPT) stimulation of the maxillary first molar and canine, pain levels during the injection, and time to midface numbness. After maxillary field blocks with 40 mg of buffered lidocaine or 80 mg of nonbuffered lidocaine, volunteers reported pain on injection and responses of the maxillary first molar and canine after cold and EPT stimulation. Teeth were tested before block and at 30-minute intervals until a positive response was noted. After 2 weeks, volunteers were tested with the alternate drug combinations. For all outcome variables, assessment of treatment difference, calculated as 1% buffered minus 2% nonbuffered, was performed with the Wilcoxon rank sum test with significance at $P < .05$. Pain levels during the injection were significantly lower for 1% buffered lidocaine, with $P = .04$. The time to response after injection were not significantly different for the 2 drug formulations for the cold test on a molar, with $P = .08$, or the cold test on a canine, with $P = .22$. But, time to response were significantly longer for nonbuffered drugs for EPT on the molar and canine, both with $P = .01$. The study concluded that buffering 1% lidocaine with 1:100,000 Epinephrine reduces the pain on injection with a maxillary field block and results in similar lengths of pulpal anaesthesia tested with a cold stimulus as compared with nonbuffered 2% lidocaine with 1:100,000 Epinephrine.

Warren VT, Fisher AG, Rivera EM et al. (2017) [38] carried out a randomized cross-over study to assess the outcomes for pulpal anaesthesia and pain on injection for buffered 1% lidocaine with 1:100,000 epinephrine (EPI) and non-buffered 2% lidocaine with 1:100,000 EPI. After mandibular nerve block responses at the mandibular first molar and canine were checked after cold and electrical pulp testing (EPT). The patients reported pain on injection with a 10-point Likert-type

scale. The teeth were tested before nerve block and at 30-minute intervals until a positive response returned. After two weeks, patients were tested with the alternate drug combinations. Significance was set at a P value < 0.05. After the cold test and EPT, duration of anaesthesia was not statistically different between the 2 drug formulations. Also, patients reported significantly lower pain scores with the buffered than non-buffered drug (P < .01). They concluded that buffered 1% lidocaine with EPI produced lower pain on injection and similar duration of pulpal anaesthesia as non-buffered 2% lidocaine with EPI and lower pain on injections.

Aminah M, Nagar P, Singh P et al. (2017) [39] carried out a randomized controlled study in 40 children aged between 7 to 13 years to compare the effect of topical anaesthetic gel, pre-cooling, vibration and buffered local anaesthesia on the pain perception during the administration of local anaesthesia in routine dental procedures. Application of topical anaesthesia at the site of administration of local anaesthesia, pre-cooling the anaesthetic site prior to the administration of local anaesthesia, vibratory stimulus at the site of administration of local anaesthesia, buffering the local anaesthetic agent were the groups from 1 to 4 respectively. During the administration of infiltration anaesthesia, the pain perception was assessed using Wong-Baker Faces Pain Rating Scale. The statistical analysis was performed using SPSS software. Greatest pain reduction was observed in the pre-cooling group with mean pain score 2.4 followed by vibration group with mean pain score 2.6 then buffered local anaesthesia with mean score of 5.6 and lastly topical anaesthesia with 6.2 mean score. Mann-Whitney test showed that pre-cooling was statistical significance compared with topical anaesthesia and buffered local anaesthesia (P<0.001). The study concluded that pre-cooling of the injection site before

infiltration anaesthesia was an easy, reliable and effective technique with no additional cost and was found to reduce discomfort and facilitate clinical management.

Kurien R, Goswami M, Sanjay Singh S (2018)[40] conducted a randomized, split-mouth clinical trial study to compare and evaluate the anaesthetic efficacy and the patient's pain reaction to pre-warmed, buffered and conventional 2% lignocaine for the success of the inferior alveolar nerve block technique in mandibular primary molars undergoing pulp therapy. They included sixty children of age 6−12 years, indicated for bilateral pulp therapy on mandibular primary molars, and administered conventional, buffered or pre-warmed 2% lignocaine on two separate visits. Parameters were assessed using objective and subjective scales. Pre-warmed and buffered anaesthetics resulted in less pain on injection ($P<0.001$) and during pulp therapy, faster onset of action, lower SEM Sound, Eye and Motor scores ($P<0.001$) and shorter duration of action ($P<0.001$). No significant difference was found between them. It was concluded that buffering or pre-warming the anaesthetic solution reduced pain on administration and during the procedures in children.

Meincken M, Norman CA, Arevalo O et al. (2019) [41] carried out a prospective, randomized, single-blind, split-mouth design study in 65 children aged 7 to 11-year-olds to compare injection pain and onset of anaesthesia of alkalinized and non- alkalinized local anaesthetic solutions. The control agent was nonalkalinized two percent lidocaine 1:100,000 with epinephrine, and the test agent was two percent lidocaine 1:100,000 with epinephrine alkalinized. Injection pain was measured using the image result for the Wong-Baker Faces Pain Rating Scale and the Ohio State

University Behavior Rating Scale. Onset of anaesthesia was measured using endodontic ice and a timer after two minutes. They concluded that no significant differences between the test and control groups for either onset time or injection pain.

METHODOLOGY

The present randomized, double-blind split mouth study was carried out in the Department of Paediatric and Preventive dentistry of the concerned dental college to evaluate and compare pain on injection and onset of anesthesia of 2 % buffered lidocaine (with 1 :2,00,000 adrenaline) and 2 % nonbuffered lidocaine (with 1:2,00,000 adrenaline) in inferior alveolar nerve block (IANB) for primary molars. The study was carried out after obtaining ethical clearance from the institutional ethics committee (IEC).

Parents of the child selected for the study were explained the purpose and methodology of the study in local vernacular language and a signed informed consent with child's assent was obtained.

SAMPLE SIZE: The sample size was calculated in consultation with the statistician and based on previous studies. The formula used for estimation of sample size was:

$$n=(Z_{1-\alpha}+Z_{1-\beta})^2 (s1+s2)^2 /(\mu_1 - \mu_2)^2$$

Where $\mu_1 - \mu_2 = 25$ is the mean difference, s1 and s2 are the standard deviations of 1st and 2nd group respectively, $Z_{1-\alpha}$ and $Z_{1-\beta}$ are values of standardized normal variate for specified α and β respectively.

α^{error} – 5% ; power of the study ($1-\beta$)- 80%

So, the required sample size (n) was 26. Therefore, considering possible dropouts of 10 %, total 30 children (60 primary molars) were included in this study and equally allocated.

SAMPLING METHOD: Convenience sampling

A total of 30 children under the age group 5 to 10 years visiting Department of Paediatric and Preventive Dentistry for routine dental care were screened and selected for the study as per following selection criteria.

INCLUSION CRITERIA:

1. Healthy children in age group 5 to 10 year.
2. Children indicated for same type of bilateral dental procedures requiring inferior alveolar nerve block.

3. Children who exhibited Frankl ‘s behaviour rating grade three or four i.e positive and definitely positive.[42]

4. Children whose parents/caretakers have given consent of participation.

5. Children who gave assent for treatment

EXCLUSION CRITERIA:

1. Active infection at the site of injection.

2. Children with known history of allergy to any local anesthetic agent.

3. History of dental treatment in last 6 months.

STUDY DESIGN: A randomized, double-blind split mouth study

(Patient and second investigator (I2) were blinded to the allocation of local anaesthetic solution)

TREATMENT ALLOCATION: The children were randomly divided into two groups based on Simple randomization by lottery method. 15 chits of buffered and 15 chits of nonbuffered were made and mixed in a fish bowl. The children were asked to pick one of these chits. This determined the anaesthetic solution to be administered on first visit (either buffered or nonbuffered).

CLINICAL METHODOLOGY

During initial screening visit the child had undergone non invasive treatment like fluoride application/oral prophylaxis to acclimatize to dental environment and to evaluate their behaviour. Also, the Wong Baker scale was introduced to child to familiarize with it.

In second and third visit the child had undergone the needed dental treatment as per standard protocol under IANB with the allocated LA solution either buffered or nonbuffered (with 1:2,00,000 adrenaline) for that visit. There was a gap of one week between second and third visit. Before giving LA, allergy testing was done with respective solution.

All IANB injections were administered by a same operator. The injection site was dried with gauze. Topical anesthetic solution was applied at the injection site for one minute before IANB administration. IANB was performed using the conventional technique as described in Handbook of Local Anaesthesia.[6] Injection time was approximately 1.5 mL/minute[3] with an average duration of nearly 2 minutes. Following this the surgical site was checked for the subjective symptoms and objective signs of anesthesia.[6]

Video was recorded in second and third visit from the time, the child, sat on the dental chair until the subjective symptoms and objective signs of LA started to appear. The recording was done from a fixed distance from the dental chair with a video recorder ensuring complete visibility of the child.

Pain on injection and onset of anaesthesia was assessed both subjectively and objectively.

At the end of visit 2nd and 3rd visit, parents were informed about the possible postoperative complications and were advised to report if any were observed.

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 consists of 6 faces with increasing degree of pain from left to right and has a numerical scale from 0-10 corresponding to each face.

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

A. ASSESSMENT OF PAIN ON INJECTION:

Subjective assessment of pain on injection: Pain on injection during the administration of LA solutions was recorded by asking the children to self asses the pain experienced by Wong-Baker FACES Pain Rating Scale (FPS) [43,44] just after the IANB administration .

Objective assessment of pain on injection: Pain on injection during administration of IANB was assessed in the child by second investigator (I2) by playing back the video recordings of each visit and rated them according to the Sound, Eye & Motor (SEM) scale. [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 ANESTHESIA (Measured in Seconds):

The time of onset of anesthesia 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 anesthesia (numbness or tingling in lower lip of respective side). Objectively, it was assessed by the presence /absence of pain on gingival probing. A straight probe was used to assess the onset of anesthesia by inserting it in the gingival sulcus of the teeth in the area of anesthesia and repeating it every 20 seconds by the operator (investigator 1).

Recording of data:

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

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 videographed during administration of IANB. 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:

The first 10 patients' injections procedures of the mandible were videotaped and same videos were reassessed by the same rater (I2) at 1 month's time for intra examiner reliability.[45]

MATERIALS –

1. Mouthmask, headcap and gloves **(colour plate no.1, fig. 1)**
2. Oral examination diagnostic instruments – a. mouth mirror b. probe c. tweezer. **(colour plate no.1, fig. 2)**
3. Other Materials –
    - **a.** Upper and lower foam trays and APF topical fluoride gel (Fluorolgel. Azure laboratories pvt ltd.) **(colour plate no.2, fig.3)**
    - b. Topical anesthetic solution **(colour plate no.2, fig.4)**

c. Disposable syringe with 24-gauge needle (Dispo Van) **(colour plate no.3, fig.5)**

d. 2% lignocaine HCl (with adrenaline1: 200000). **(colour plate no.3, fig.6)**

e. 8.4%sodium bicarbonate **(colour plate no.3, fig.7)**

4. For measuring pain on injection and onset of anaesthesia –

a. Sound, Eye, Motor (SEM) scale

b. Wong Baker faces pain rating scale.

c. Stop watch.

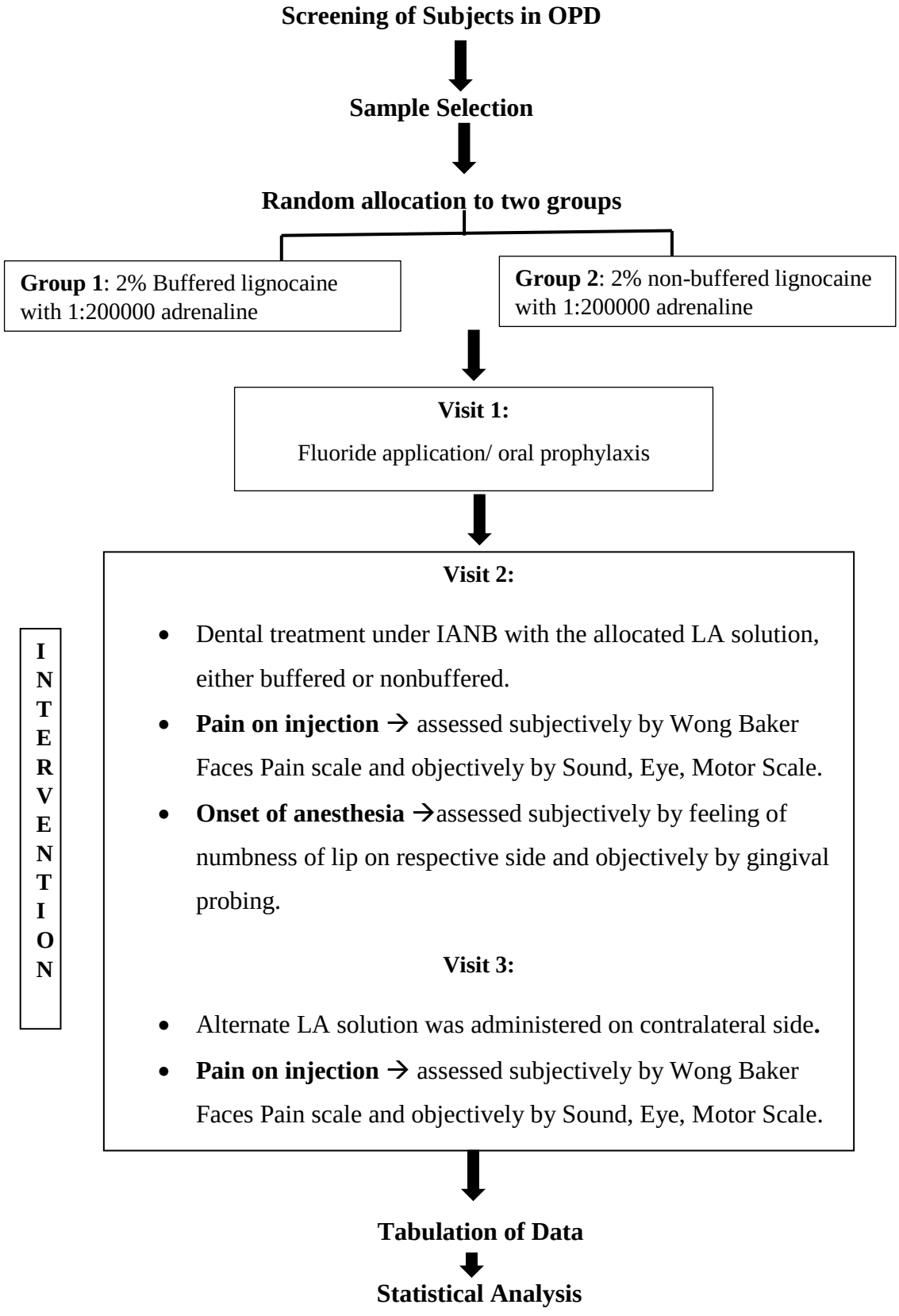
Buffered lidocaine solution was prepared as follows:

A 30-mL vial of 2% lidocaine with 1: 200,000 adrenaline (Lox two percent, Neon Laboratories Ltd., Mumbai, India) was taken and from it 3 mL of solution was removed using a sterile disposable syringe. To this, 3 mL of 8.4% sodium bicarbonate (Neon Laboratories Ltd) was added, using a sterile, disposable syringe to achieve a dilution of 1:10. It was shaken until the solution was clear, to ensure that sodium bicarbonate dissolved completely.[1,40]

3ml of lidocaine was replaced with 3ml of distilled water in the control group to compensate for the amount of lidocaine that was replaced by buffer solution in the experimental group.[2]

Bottle containing buffered lidocaine solution was stored in a refrigerator for one week and was discarded later.

Procedures and Protocol



COLOUR PLATE NO. 1

Fig 1: Disposable Gloves, Head Cap And Facemask

Fig.2 Diagnostic instruments

COLOUR PLATE NO. 2

Fig 3. Upper and lower foam trays and APF topical fluoride gel

Fig 4: Topical anesthetic solution

COLOUR PLATE NO. 3

Fig 5: Disposable syringe with 24 gauge needle

Fig 6: 2% Lignocaine with 1:200000 adrenaline

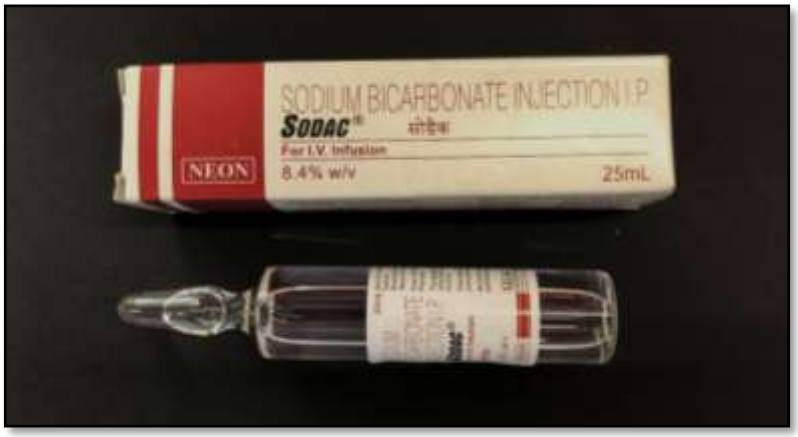


Fig 7: 8.4% Sodium Bicarbonate

COLOUR PLATE NO:4

Fig.8

Fig. 9

Fig. 10

Fig 8, fig 9 and fig 10 : Intra operative photographs

RESULTS

A total of thirty 5 to 10-year-old children (17 males and 13 females; mean age equals 7.47±1.51 years for boys and 7.14±1.41 years for girls) participated in the study, and each received IANB injection on two separate appointments. Thus, a total of 60 IANB injections were given. Intergroup comparison of Pain on injection by Wong baker scale and SEM scale and objective and subjective Onset of anesthesia (seconds) between buffered and unbuffered group was done along with the subgroup analysis (age and gender wise).

Statistical methods:

Statistical analysis of the study to compare pain experience during inferior alveolar nerve block administration and onset of anesthesia using buffered and unbuffered two percent lidocaine in children was carried out to find the significant difference between those values. Statistical analysis of the data in the present study

was done by using both descriptive and inferential statistics. Wong-Baker (WB) faces ratings, Sound Eye Motor (SEM) scores and onset of anesthesia using buffered and unbuffered two percent lidocaine in children were compared using student unpaired t-test. The age wise and gender wise subgroup analysis was performed using the same respective test (student unpaired t-test).

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.

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

Inferential Statistics :

Students unpaired t test

Assumption:

1. The samples (n_1 and n_2) from two normal populations are independent.
2. One or both sample sizes are less than 30
3. The appropriate sampling distribution of the test statistic is the t distribution
4. The unknown variances of the two populations are not equal

To compute the two-sample t-test two major computations are needed before computing the t-test. First, you need to estimate the pooled standard deviation of the two samples. The pooled standard deviation gives an weighted average of the standard deviations of the two samples. The ***pooled standard deviation*** is going to be between the two standard deviations, with greater weight given to the standard deviation from a larger sample. The equation for the pooled standard deviation is:

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

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

$$df = n_1 + n_2 - 2$$

The formula for the two sample t-test is:

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

Results

Distribution of children according to their age, gender and weight

The descriptive statistics for distribution of children according to demographic characteristics of age, gender and weight in the present study is given in **Table 1 and Graph 1, Graph 2 and Graph 3.** 46.67% of the children were in the age group of 5-7 years and 53.33% were in the age group of 8-10 years. 56.67% of the children were boys and 43.33% were girls. Mean weight of boys was 23±4.56 kg and mean age of girls was 21.53±3.30 kg. There was a non-significant difference (p value= 0.33) seen in the distribution of children according to their age, gender and weight.

Pain on injection:

a. Wong baker Scale score

On comparing **Wong Baker Scale Score** for the pain on injection during administration of LA in both groups **(Table 2 & Graph 4),** mean Wong Baker Scale score in buffered lidocaine group was 1.60±1.77 and in unbuffered lidocaine group it was 3.46±2.40. By using student's unpaired t test, a statistically significant difference was found in Wong Baker Scale scores of two groups(t=3.42,p=0.001).

b. Sound Eye Motor (SEM) Scale score

On comparing mean Sound Eye Motor (SEM) Scale score for pain on injection between two groups, mean SEM score in buffered lidocaine group was

1.19±0.34 and in unbuffered lidocaine group it was 1.92±0.71 **(Table 3 and Graph 5).** A statistically significant difference was found in Sound Eye Motor Scale scores of two groups (t=5.04, p=0.0001) by using student's unpaired t test.

Onset of anesthesia:

a. Objective sign

On comparing time to onset of anesthesia (objective sign) between two groups **(Table 4 and Graph 6),** mean onset of anesthesia score in buffered lidocaine group was found to be 83.33±27.11 seconds and in unbuffered lidocaine group it was 128.83±34.78 seconds. By using student's unpaired t test statistically significant difference was found in onset of anesthesia score between two groups (t=5.65, p=0.0001).

b. Subjective sign

On comparing time to onset of anaesthesia (subjective sign) between two groups **(Table 5 and Graph 7**), Mean onset of anesthesia score in buffered lidocaine group was 101.50±37.85 and in unbuffered lidocaine group it was 156.66±40.11. By using student's unpaired t test statistically significant difference was found in onset of anesthesia score between two groups (t=5.47, p=0.0001).

Subgroup analysis :

Subgroups were made according to age (5 to 7 years and 8 to 10 years) and gender (boys and girls) to test the difference in mean values of parameters across the buffered and unbuffered lidocaine group.

1. Pain on injection

i. *Wong baker Scale Score*

Subgroup analysis of Wong Baker Scale Score **(Table 6 and Graph 8)** showed that mean Wong Baker Scale score for boys of buffered lidocaine group was 1.52±1.66 and in unbuffered lidocaine group it was 3.52±2.87. By using student's unpaired t test statistically significant difference was found in Wong Baker Scale score in boys of two groups (t=2.48, p=0.010).

Mean Wong Baker Scale score for girls of buffered lidocaine group was 1.69±1.97 and in unbuffered lidocaine group it was 3.38±1.700. A statistically significant difference was found in Wong Baker Scale score in girls of two groups (t=2.33, p=0.028) by using student's unpaired t test.

Mean Wong Baker Scale score for children age 5-7 years of buffered lidocaine group was 1.71±1.54 and in unbuffered lidocaine group it was 3.28±2.67. By using student's unpaired t test statistically significant difference was found in Wong Baker Scale score in children age group 5-7 years of two groups(t=1.98,p=0.045).

Mean Wong Baker Scale score for children age 8-10 years of buffered lidocaine group was 1.50±0 and in unbuffered lidocaine group it was 3.62±2.21 By using student's unpaired t test statistically significant difference was found in Wong Baker Scale score in children age group 8-10 years of two groups(t=2.84,p=0.008).

ii. Sound Eye Motor (SEM) Scale score

Subgroup analysis of Sound Eye Motor (SEM) Scale **(Table 7 and Graph 9)** showed that the mean Sound Eye Motor score for boys of buffered lidocaine group

was 1.25±0.38 and in unbuffered lidocaine group it was 1.92±0.74. A statistically significant difference was found in Sound Eye Motor score in boys of two groups(t=3.30,p=0.002) by using student's unpaired t test.

Mean Sound Eye Motor score for girls of buffered lidocaine group was 1.12±0.28 and in unbuffered lidocaine group it was 1.93±0.70. By using student's unpaired t test statistically significant difference was found in Sound Eye Motor score in girls of two groups(t=3.83,p=0.001).

Mean Sound Eye Motor score for children age 5-7 years of buffered lidocaine group was 1.23±0.35 and in unbuffered lidocaine group it was 1.98±0.79. On using student's unpaired t test, statistically significant difference was found in Sound Eye Motor score in children age group 5-7 years of two groups (t=3.20, p=0.004).

Mean Sound Eye Motor score for children age 8-10 years of buffered lidocaine group was 1.16±0.34 and in unbuffered lidocaine group it was 1.87±0.65. By using student's unpaired t test, statistically significant difference was found in Sound Eye Motor score in children age group 8-10 years of two groups (t=3.86, p=0.001).

1. Onset of anesthesia:

i. Objective

Subgroup analysis of onset of anesthesia (objective sign) **(Table 8 and Graph 10)** showed that the mean time of onset of anesthesia score for boys of buffered lidocaine group was 84.41±28.11 and in unbuffered lidocaine group it was

130.58±33.86. A statistically significant difference was found in onset of anesthesia score in boys of two groups (t=4.32, p=0.0001) by using student's unpaired t test.

Mean onset of anesthesia score for girls of buffered lidocaine group was 81.92±26.81 and in unbuffered lidocaine group it was 126.53±37.21. A statistically significant difference was found in onset of anesthesia score in girls of two groups (t=3.50, p=0.002) on using student's unpaired t test.

Mean onset of anesthesia score for children age 5-7 years of buffered lidocaine group was 99.28±24.79 and in unbuffered lidocaine group it was 131.78±28.66. On using student's unpaired t test statistically significant difference was found in onset of anesthesia score in children age group 5-7 years of two groups (t=3.20, p=0.004).

Mean onset of anesthesia score for children age 8-10 years of buffered lidocaine group was 69.37±21.04 and in unbuffered lidocaine group it was 126.25±40.14. By using student's unpaired t test statistically significant difference was found in onset of anesthesia score in children age group 8-10 years of two groups(t=5.01,p=0.0001).

ii. Subjective

Subgroup analysis of onset of anesthesia (subjective sign) (**Table 9 and Graph 11)** showed that the mean time of onset of anesthesia score for boys in buffered lidocaine group was 100.88±35.40 and in unbuffered lidocaine group it was 157.05±38.69. By using student's unpaired t test statistically significant difference was found in onset of anesthesia score in boys of two groups(t=4.41,p=0.0001).

Mean onset of anesthesia score for girls of buffered lidocaine group was 102.30±42.30 and in unbuffered lidocaine group it was 156.15±43.50. By using student's unpaired t test statistically significant difference was found in onset of anesthesia score in girls of two groups(t=3.19,p=0.004).

Mean onset of anesthesia score for children age 5-7 years of buffered lidocaine group was 124.64±38.15 and in unbuffered lidocaine group it was 164.28±29.53. By using student's unpaired t test statistically significant difference was found in onset of anesthesia score in children age group 5-7 years of two groups(t=3.07,p=0.005).

Mean onset of anesthesia score for children age 8-10 years of buffered lidocaine group was 81.25±23.90 and in unbuffered lidocaine group it was 150±47.46 By using student's unpaired t test statistically significant difference was found in onset of anesthesia score in children age group 8-10 years of two groups(t=5.17,p=0.0001)

Intra rater reliability

Intra-rater reliability was assessed using by using Cronbach alpha method of reliability (as depicted in **Table 10.)** The intra-rater evaluation of investigator 2 was alpha=0.791& p-value=0.0001 for evaluations of pain on injection. Thus, showing good reliability of investigator 2.

Adverse effects:

None of the children in the study showed any adverse reactions to buffered or unbuffered lidocaine.

DISCUSSION

Pain is an unavoidable factor during various dental procedures because of which a patient especially pediatric patient may fear dental treatments. The management of pain is a crucial factor in pediatric dentistry since it dictates the behavior of the children during the present appointment, as well as ensures their compliance for future visits. In dentistry, the introduction of local anesthesia (LA) as a means of pain control has been one of the medical marvels of the twentieth century. The administration of LA is a prerequisite for reducing pain during various dental procedures like restorative, endodontic and minor surgical procedures and is more necessary in children than in adults. However, the very means which is employed to reduce pain in itself might be a source of both pain and anxiety in children. Increased anxiety can lead to increased pain perception in children and may create a barrier in receiving optimal and necessary dental care; thus, several procedural, behavioral, and

pharmacological strategies have been proposed to alleviate pain and discomfort during pediatric dental treatment. [1,46]

Lignocaine is one of the most commonly used local anesthetics in dentistry. The drawbacks associated with the administration of local anesthetics are burning sensation, its unreliability in areas of inflammation and infection and its relatively slow onset of action. The burning and stinging of injections due to the acidic anesthetic agents is the most common complaint by the patients in dentistry. This is because the commercially available synthetic local anesthetics are prepared as weak bases and might precipitate as insoluble powdered unstable solids. Thus, they have to be combined with an acid to form a salt which is water-soluble; these can be dissolved in sterile water or saline, creating a stable, injectable anesthetic solution.[47] The pH of our body is maintained at 7.4. Injectable local anesthetics 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 anesthetics to improve both the depth and the duration of anesthesia. 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 anesthetic 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 anesthetic solution at pH=2.9 can create a significant amount of pain.[29,40]

However, it has been shown in the studies that the pain on injection between different anesthetics 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 anesthetics is responsible for the decrease in pain, by increasing the speed of onset of anesthesia.[7] 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 anesthetic 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:

$$RN + H+ \longleftrightarrow RNH+$$

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.[6] 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 anesthetic solution to a pH closer to the physiologic range (7.35 to 7.45), enough of the anesthetic will enter into the nerve to effectively block nerve conduction. The time required for this transformation is a key factor in anesthetic latency (e.g., 5 to 10-minute onset for most vasopressor-containing local anesthetic 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 anesthesia. 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 anesthesia is achieved.[6,29,47] Therefore , based on knowledge of the mechanism of action of local anesthetics, studies were carried out to determine whether a more rapidly acting local anesthetic could be developed simply by adjusting the pH of the injected solution upward (i.e., alkalinization) towards the pKa of the local anesthetic 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 addition of sodium bicarbonate to the anesthetic solution and the addition of carbon dioxide have been used to achieve this effect.[7,8] The most common method for buffering local anesthetics (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 anesthetics increases the pH of the solution and results in the production of some carbon dioxide.[48] 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 anesthetic inside the nerve trunk through ion trapping, and lastly by changing the charge of the local anesthetic inside the nerve axon. **Condouris and Shakalis** showed that CO2 possesses an independent anesthetic effect and caused a sevenfold potentiation in anesthetic action. [9,15]

This "anesthetic buffering" process results in several clinical advantages, like greater patient comfort during injection and more rapid onset of anesthesia. Sodium bicarbonate has been added to various local anesthetics 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. [(2)]

In the present study we aimed to compare the effectiveness of 2 % buffered lidocaine (with 1:2,00,000 adrenaline) and 2 % nonbuffered lidocaine (with 1:2,00,000 adrenaline) on pain during injection and onset of anesthesia during in inferior alveolar nerve block for primary molars. 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.

The present study was a randomized, bilateral split-mouth, double-blind study. The split- mouth study design offers homogeneity between the study groups regarding individual variables like age, gender, behavior etc.

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 anesthetic injection. [(1,2,40)] Excessive alkalinization causes precipitation which decreases the bioavailability of the local anesthetic and interferes with its activity. A 10:1 ratio is recommended for lignocaine buffering, mainly due to the concern about precipitation of the solution. In our study we added 3 ml of 8.4%

sodium bicarbonate to a 30ml vial containing 2% lignocaine hydrochloride with 1:2,00,000 adrenaline solution which yielded a ratio of 1:10.

Unfortunately, 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. Buffered lignocaine can remain "active" for 1 week when stored at room temperature and a few weeks when refrigerated.[9,15,48] **Larson et al**, evaluated the effect of refrigeration on the stability of buffered lignocaine with adrenaline. The author stored buffered 2% lignocaine with epinephrine 1:100,000 with sodium bicarbonate, at room temperature, and refrigerated temperatures; and measured lignocaine and epinephrine concentrations with chromatography at weekly intervals. **Larson et al** had concluded that the buffered lignocaine with adrenaline can be stored for up to 2 weeks if kept refrigerated. The solution should be warmed to room temperature before injection; as previous studies have suggested that warmer solutions may cause less pain on infiltration.[16,40]

In our study, in the control group same amount of removed lidocaine i.e 3ml was replaced with distilled water to compensate for the amount of lidocaine that was replaced by buffer solution in the experimental group. This was in accordance with the study by **Saatchi et al**. [2] However , all other studies [1,40,41,46] had unbalanced dosage of lidocaine in experimental and control groups, which may affect the outcome of IANB.

Since, pain is extremely difficult to quantify in children, in the present study pain on injection was assessed during administration of inferior alveolar nerve block using two different scales (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 has good construct validity, adequate psychometric properties, and it is easy and quick to use, and inexpensive to reproduce which was with accordance **Alzarani et al 2018**. [49] 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.[50] 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) . [40]

In the present study, 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. Moreover, this scale has 90% inter- rater reliability.[42] 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 at measuring the SEM scores for pain on injection, intra-rater reliability was established which was found to be good (alpha=0.791 & p-value=0.0001) **(as depicted in Table 10)**

On comparing Wong Baker Scale Score **(Table 2 & Graph 4)** and SEM score **(Table 3 & Graph 5)** for the pain on injection during administration of LA in both groups, mean for pain on injection in patients of group 1 (buffered lidocaine) was less

than in group 2 (unbuffered lidocaine) showing a statistically significant difference in pain on injection between two groups, both subjectively using WBFPS (t=3.42,p=0.001) and objectively using SEM scale (t=5.04, p=0.0001). These results are in accordance with **Kurien et al 2018** [40] and **Afsal M.M, et al 2019** [46] where they found a statistically significant difference for the pain on injection between buffered and unbuffered lidocaine groups during administration of inferior alveolar nerve block. However, this was in contrast to studies by **Chopra R et al (2016) and Meincken M et al (2019)** who found a statistically non-significant difference for the pain on injection between buffered and unbuffered lidocaine groups. [1,41]

In the current study, a straight probe was used to assess the onset of anesthesia (objectively) by inserting it in the gingival sulcus of the teeth in the area of anesthesia at an interval of every 15 seconds [40,42] and subjectively assed based on the subjective signs like numbness of lip, tongue .[6,46]

In our study, we found the mean time for onset of anesthesia (objective) for IANB in buffered lidocaine group was comparatively less than that for unbuffered lidocaine group (Table 4 and Graph 6). The difference in mean onset between the groups was found to be statistically significant (t=5.65, p=0.0001). This was in accordance with **Kurien et al**, who conducted a randomized, split-mouth clinical trial study to compare and evaluate the time to onset of anesthesia and the child's pain reaction to buffered and conventional 2% lignocaine for the success of the inferior alveolar nerve block technique in 60 mandibular primary molars. The result showed faster onset of anesthesia in buffered lignocaine group with a statistically significant difference between two groups (P=0.001).

In our study, the subjective mean time for onset of anesthesia was also found to be less in buffered lidocaine group than that in unbuffered lidocaine group **(Table 5 and Graph 7)** and found a statistically significant difference between two groups (t=5.47, p=0.0001).This was in accordance with the randomized, double-blind, crossover study (N = 48) carried by **Afsal M.M et al**, who compared pain perception and anesthetic 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 anesthesia (both subjective and objective) was lowest for buffered lidocaine, with a statistically significant difference between buffered lidocaine and lidocaine (P < 0.001). [46] In contrast, **Chopra R et al and Meincken M et al** in their study, found statistically non-significant difference in onset time between buffered lidocaine and unbuffered lidocaine.[1,41]

In the current study, all LA administrations in children 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. Inferior alveolar nerve block was chosen in our study to compare between two anesthetic solutions, as **Kaufman et al** have found that IABN is the most painful and results in more discomfort than infiltration, intra-ligamentary injection and mental nerve block. Therefore, reduction in injection pain for IANB was still needed. [51]

In the present study, pain on injection (subjective and objective) and onset of anesthesia (subjective and objective) scores according to age and gender of children were compared to evaluate buffered vs unbuffered groups in the results across this subgroup. On comparing pain on injection (subjective and objective) and onset of

anesthesia (subjective and objective) scores according to the gender of children, the differences between the subjective onset time (P= 0.0001, P=0.004), objective onset time (P=0.0001, P=0.002), SEM scores (P=0.002, P=0.001) as well as WBFPS scores (P=0.010, P=0.028) were found to be statistically significant for both boys and girls children. Similarly, when the subjects were divided into two age groups (i.e., five to seven years old and eight to ten years old), both the age groups showed a statistically significant difference between the two anesthetic solutions for all the parameters tested (P< 0.05). However, this was in contrast to study by **Chopra R et al (2016)** who found no statistically significant differences of pain scores and onset of anesthesia between two anesthetic solutions according to the age and gender of the pediatric patient. [(2)]

In the current study, none of the children reported adverse effects in any of the groups because the 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)** [(52)], where adverse effects like facial edema, paresthesia 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 anesthetic solutions is not associated with any adverse effects.[(1)] It was noted that during the study children better tolerated IANB using the buffered lidocaine as an anesthetic solution than unbuffered lidocaine.

SUMMARY AND CONCLUSION

Pain control is the most important part in pediatric dentistry, as it dictates the behavior of the patient for the rest of the treatment procedure. Local anesthesia administration is essential for pain reduction while performing various endodontic and minor surgical procedures in children. Ambiguously, administration of LA itself becomes a source of pain and anxiety for children. Unpleasant treatment experiences negatively influence the child's behavior towards dental treatment. Pain caused during LA administration has been attributed to many factors like the speed of injection, pH of LA solution, site of injection etc. The inferior alveolar nerve block, is considered typically to be more painful especially in children. Lignocaine, a commercially available LA solution used in dentistry is acidic (pH= 3.5-5). Injecting such acidic LA solution results in burning sensation and pain which can lead to unpleasant treatment experiences that negatively influences the child's behavior towards dental treatment. From physiological standpoint, increasing the ph of the

anesthetic solution decreases the injection pain and onset time of anesthesia.LA solutions are not stable at alkaline pH, so no such solutions are commercially manufactured. For this reason, many researchers recommend buffering the LA solution using sodium bicarbonate just before injection.

Buffering lidocaine with sodium bicarbonate can increase the pH approximately to 7.4. Hence, a prospective double blinded, randomized control study was planned to compare pain on injection and onset of anesthesia of 2 % buffered lidocaine (with 1 :2,00,000 adrenaline) and 2 % nonbuffered lidocaine (with 1:2,00,000 adrenaline) in inferior alveolar nerve block for primary molars.

Following findings were observed:

Statistically significant difference was found for pain on injection in children of both the groups both subjectively and objectively observed using WB and SEM scale respectively. Mean WB scores revealed that buffered lidocaine group (1.60±1.77) was more effective than unbuffered lidocaine group (3.46±2.40). Mean SEM scores revealed that buffered lidocaine group (1.19±0.34) was more effective than unbuffered lidocaine group (1.92±0.71).

Significantly lower time to onset of anesthesia of 83.33±27.11 seconds was seen in buffered lidocaine group than in the unbuffered lidocaine group which was 128.83±34.78 seconds. Thus, significantly reducing the clinical time of onset of anesthesia.

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

1. Buffered 2% lidocaine with 1:200000 adrenaline was more effective in reducing the pain on injection during inferior alveolar nerve block injection in children aged 5 – 10 years compared with the unbuffered lidocaine.

2. Buffered lidocaine provided a significant clinical advantage in relation to time to onset of anaesthesia for inferior alveolar nerve blocks in children aged 5 – 10 years compared with the unbuffered lidocaine.

3. Since, there are few studies and varied evidences regarding effectiveness of buffered lidocaine in children, more randomized controlled trials should be carried out.

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TABLES

Table1: Distribution of children according to their age, gender and weight

		Number of children (N)	Percentage (%)	p-value
Age	5-7 Years	14	46.67	0.33, NS
	8-10 Years	16	53.33	
Gender	Boys	17	56.67	
	Girls	13	43.33	
Mean weight (kg)	Boys	23 ± 4.56		
	Girls	21.53 ± 3.30		

NS-statistically non-significant

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

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value
Buffered lidocaine	30	1.60	1.77	0.32	3.42 p=0.001,S
Unbuffered lidocaine	30	3.46	2.40	0.43	

S-statistically significant

Table 3: 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
Buffered lidocaine	30	1.19	0.34	0.06	5.04 p=0.0001,S
Unbuffered lidocaine	30	1.92	0.71	0.13	

S-statistically significant

Table 4: Comparison of mean onset of anesthesia between two groups (Objective sign)

Group	N	Mean (seconds)	Std. Deviation	Std. Error Mean	t-value
Buffered lidocaine	30	83.33	27.11	4.94	5.65 p=0.0001, S
Unbuffered lidocaine	30	128.83	34.78	6.35	

S-statistically significant

Table 5: Comparison of mean onset of anaesthesia between two groups (subjective sign)

Group	N	Mean (seconds)	Std. Deviation	Std. Error Mean	t-value
Buffered lidocaine	30	101.50	37.85	6.91	5.47 p=0.0001, S
Unbuffered lidocaine	30	156.66	40.11	7.32	

S-statistically significant

Table 6: Subgroup analysis of Wong Baker Scale Score in buffered and unbuffered lidocaine groups

	Buffered lidocaine	Unbuffered lidocaine	t value
Boys (n=17)	1.52±1.66	3.52±2.87	2.48,p=0.010,S
Girls (n=13)	1.69±1.97	3.38±1.70	2.33,p=0.028,S
Age 5-7 years (n=14)	1.71±1.54	3.28±2.67	1.98,p=0.045,S
Age 8-10 years (n=16)	1.50±0	3.62±2.21	2.84,p=0.008,S

S-statistically significant

Table 7: Subgroup analysis of Sound Eye Motor (SEM) Scale score in buffered and unbuffered lidocaine groups

	Buffered lidocaine	Unbuffered lidocaine	P-value (t- statistic)
Boys (n=17)	1.25±0.38	1.92±0.74	3.30,p=0.002,S
Girls (n=13)	1.12±0.28	1.93±0.70	3.83,p=0.001,S
Age 5-7 years (n=14)	1.23±0.35	1.98±0.79	3.20,p=0.004,S
Age 8-10 years (n=16)	1.16±0.34	1.87±0.65	3.86,p=0.001,S

S-statistically significant

Table 8: Subgroup analysis of time to onset of anesthesia in buffered and unbuffered lidocaine groups (objective)

	Buffered lidocaine	Unbuffered lidocaine	t value
Boys (n=17)	84.41±28.11	130.58±33.86	4.32, p=0.0001, S
Girls (n=13	81.92±26.81	126.53±37.21	3.50, p=0.002, S
Age 5-7 years (n=14)	99.28±24.79	131.78±28.66	3.20, p=0.004, S
Age 8-10 years (n=16)	69.37±21.04	126.25±40.14	5.01, p=0.0001, S

S-statistically significant

Table 9: Subgroup analysis of time to onset of anesthesia in buffered and unbuffered lidocaine groups (Subjective)

	Buffered lidocaine	Unbuffered lidocaine	t value
Boys (n=17)	100.88±35.40	157.05±38.69	4.41,p=0.0001,S
Girls (n=13)	102.30±42.30	156.15±43.50	3.19,p=0.004,S
Age 5-7 years (n=14)	124.64±38.15	164.28±29.53	3.07,p=0.005,S
Age 8-10 years (n=16)	81.25±23.90	150±47.46	5.17,p=0.0001,S

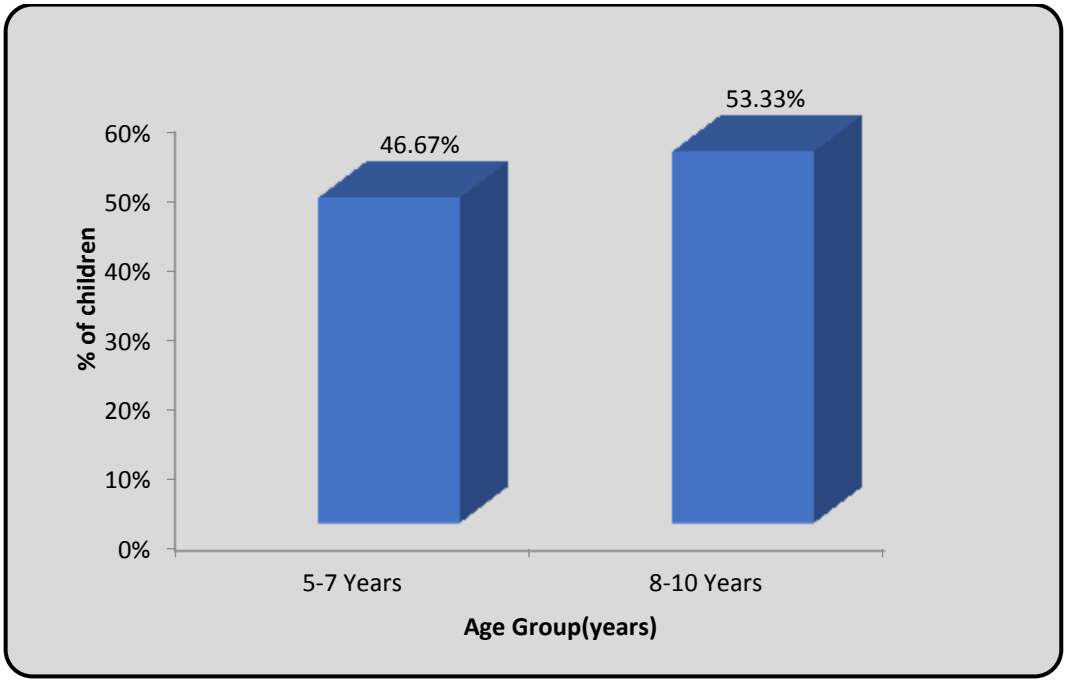
S-statistically significant

Table 10: Intra rater reliability

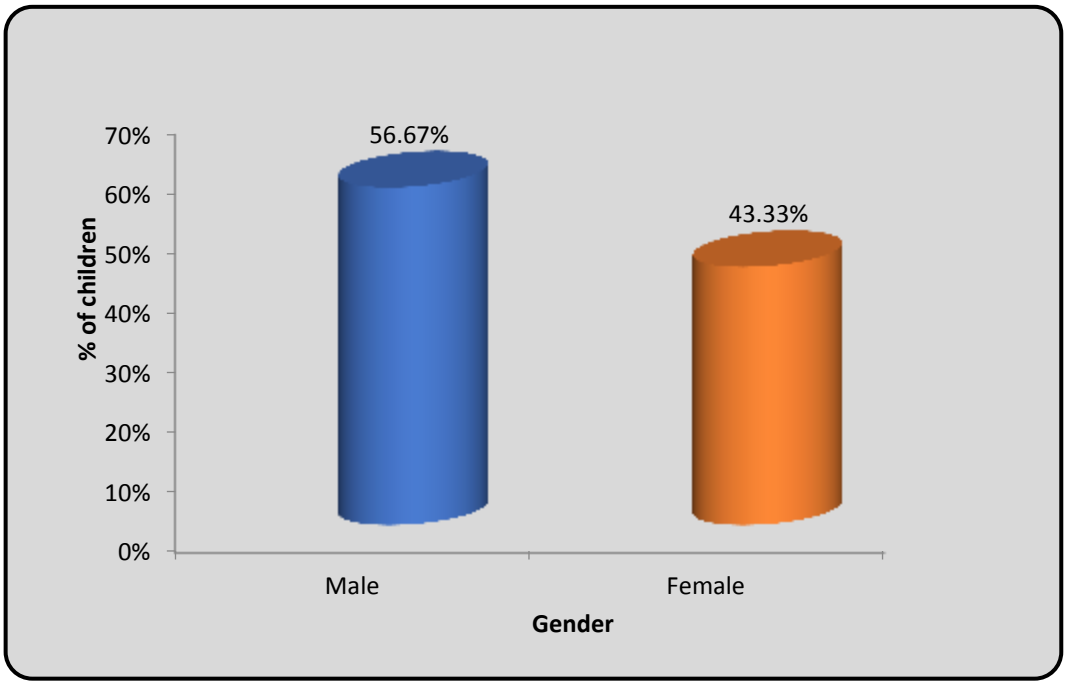
	Statistics
Alpha	0.791
p-value	0.0001,S
Result	Reliable

GRAPHS

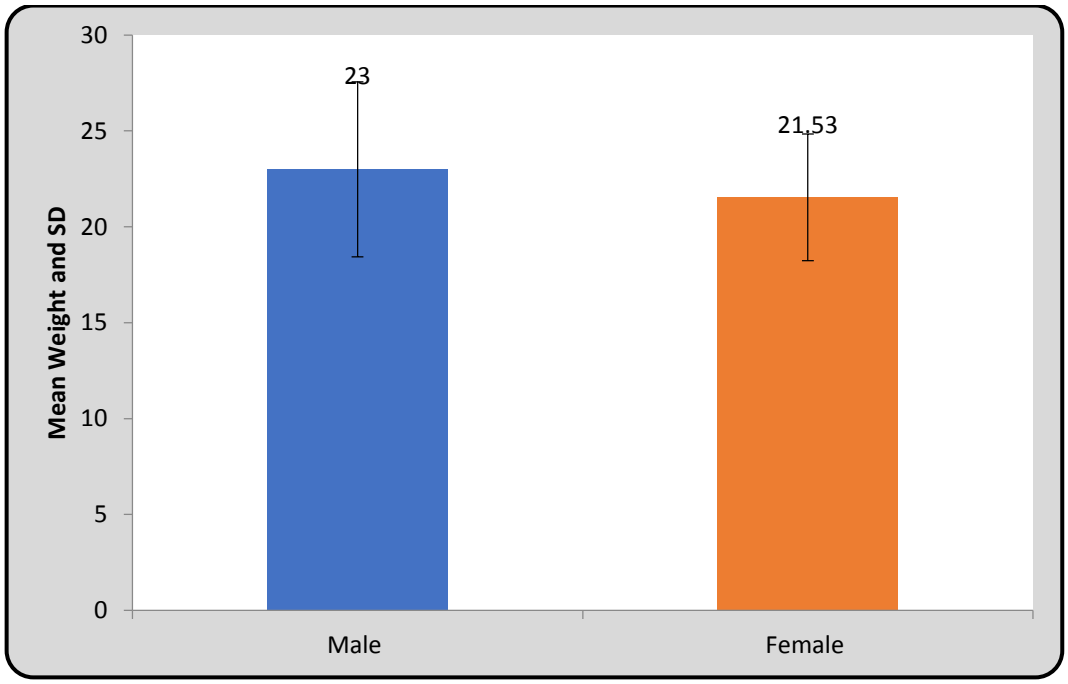
Graph 1: Distribution of children according to their age



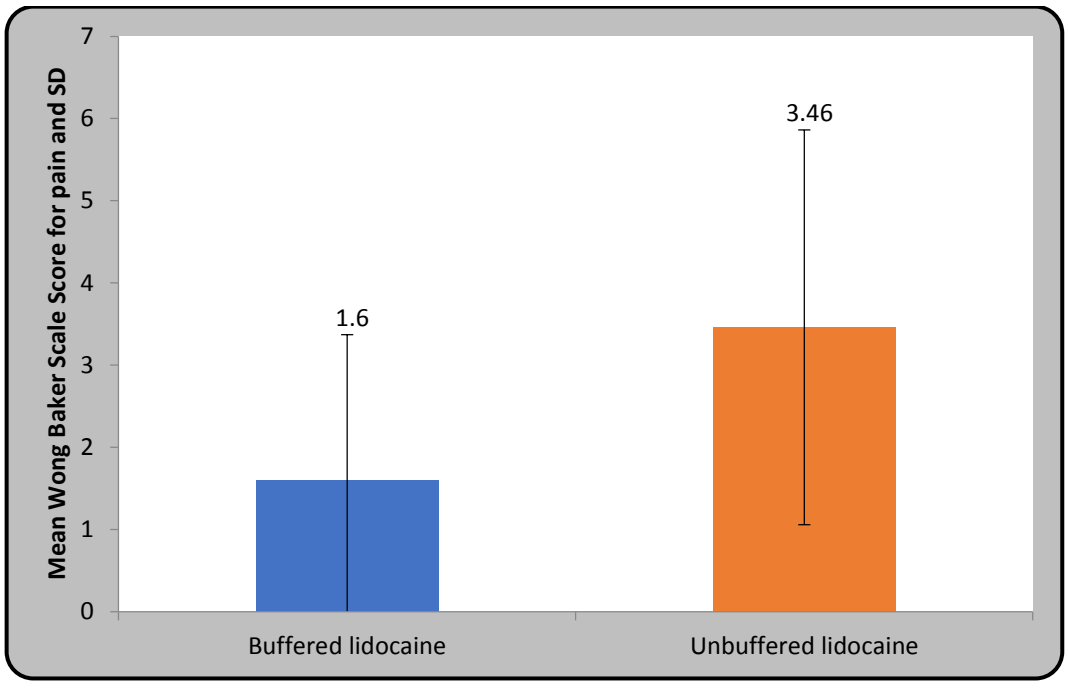
Graph 2: Distribution of children according to their gender



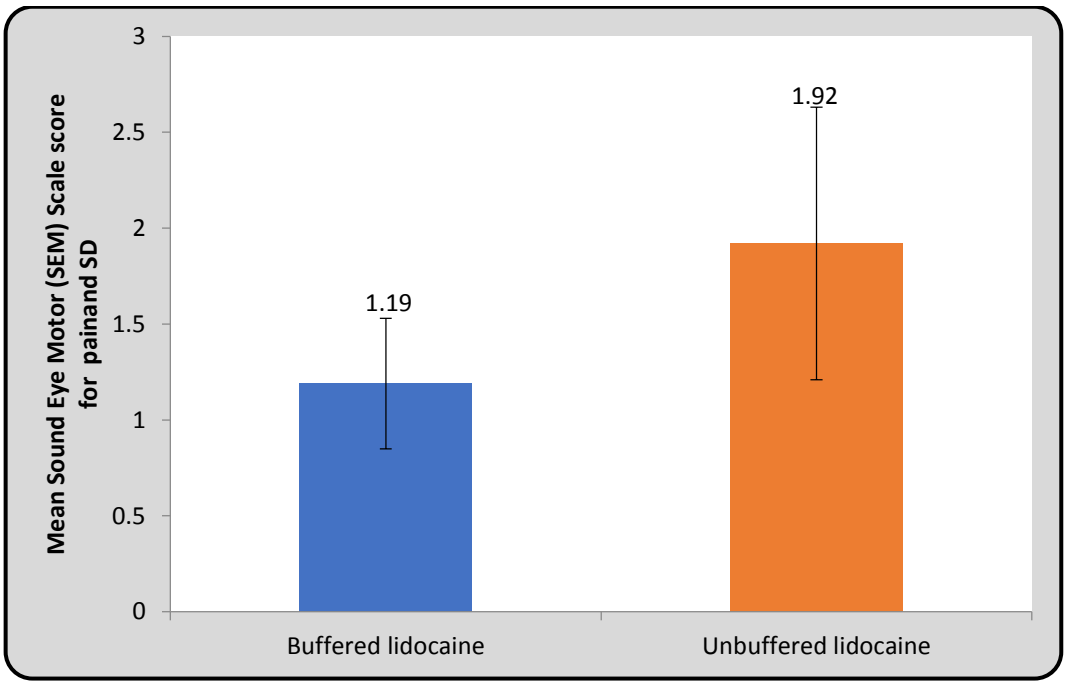
Graph 3: Distribution of children according to their weight(kg)



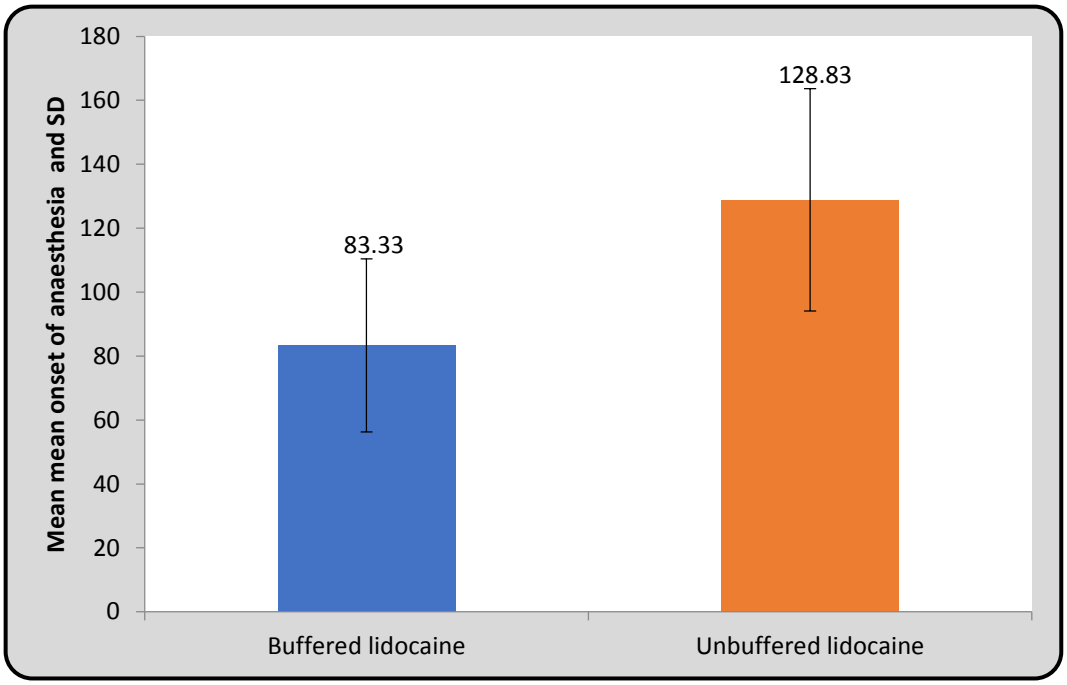
Graph 4: Comparison of mean Wong Baker Scale Score for pain on injection between two groups



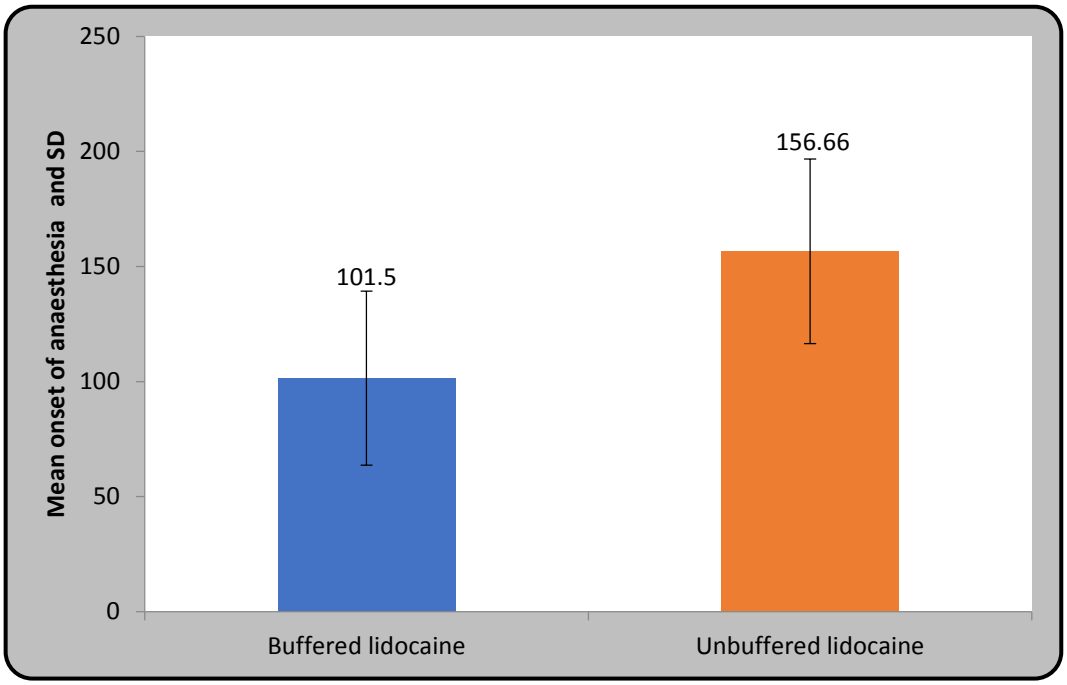
Graph 5 : Comparison of mean Sound Eye Motor (SEM) Scale score for pain on injection between two groups



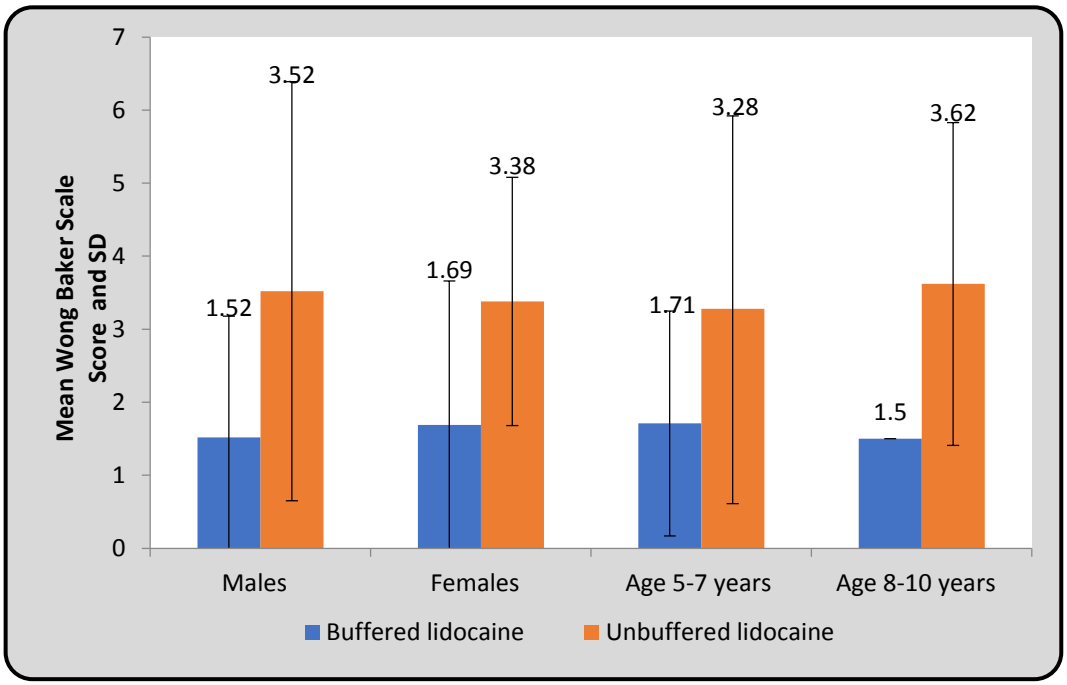
Graph 6: Comparison of mean onset of anaesthesia between two groups (Objective sign)



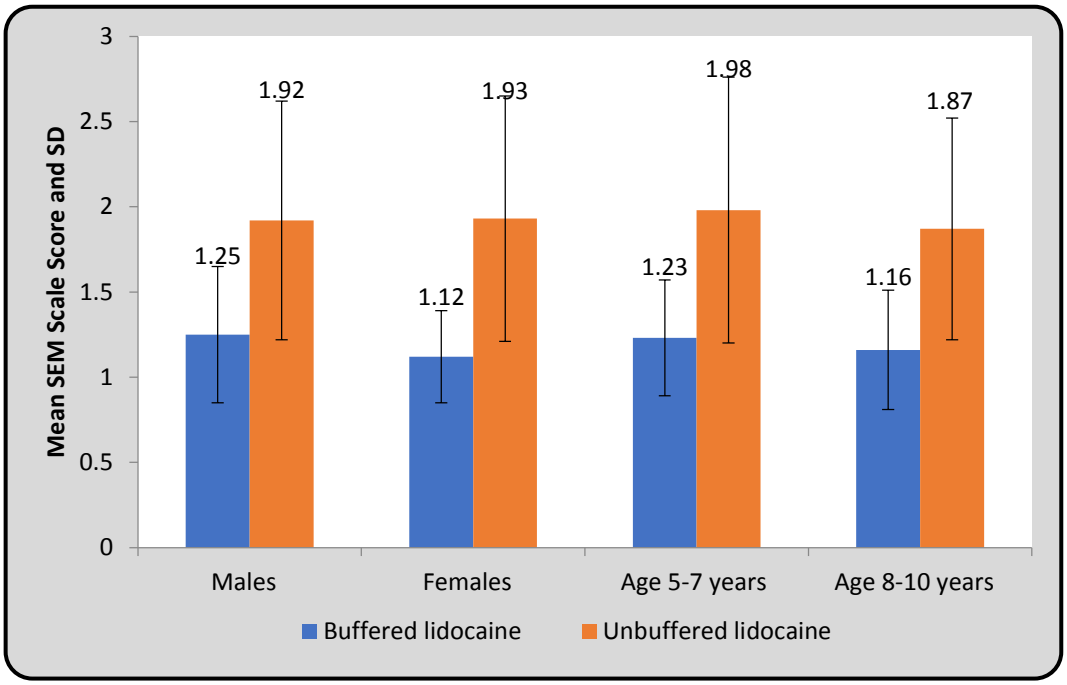
Graph 7: Comparison of mean onset of anaesthesia between two groups (subjective sign



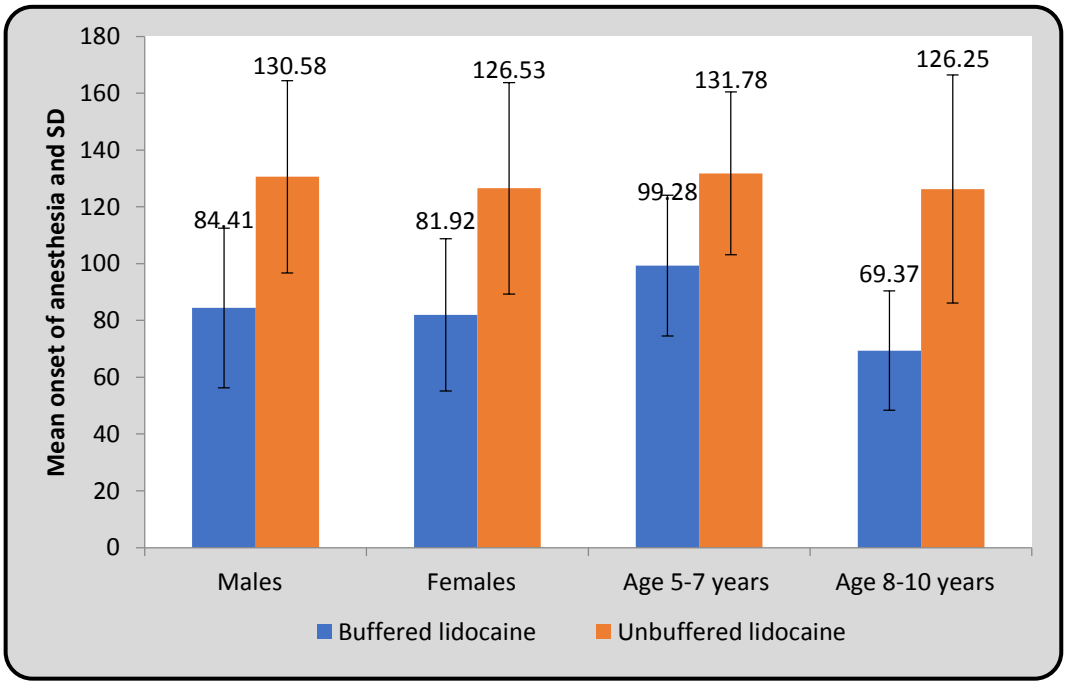
Graph 8: Subgroup analysis of Wong Baker Scale Score in buffered and unbuffered lidocaine groups



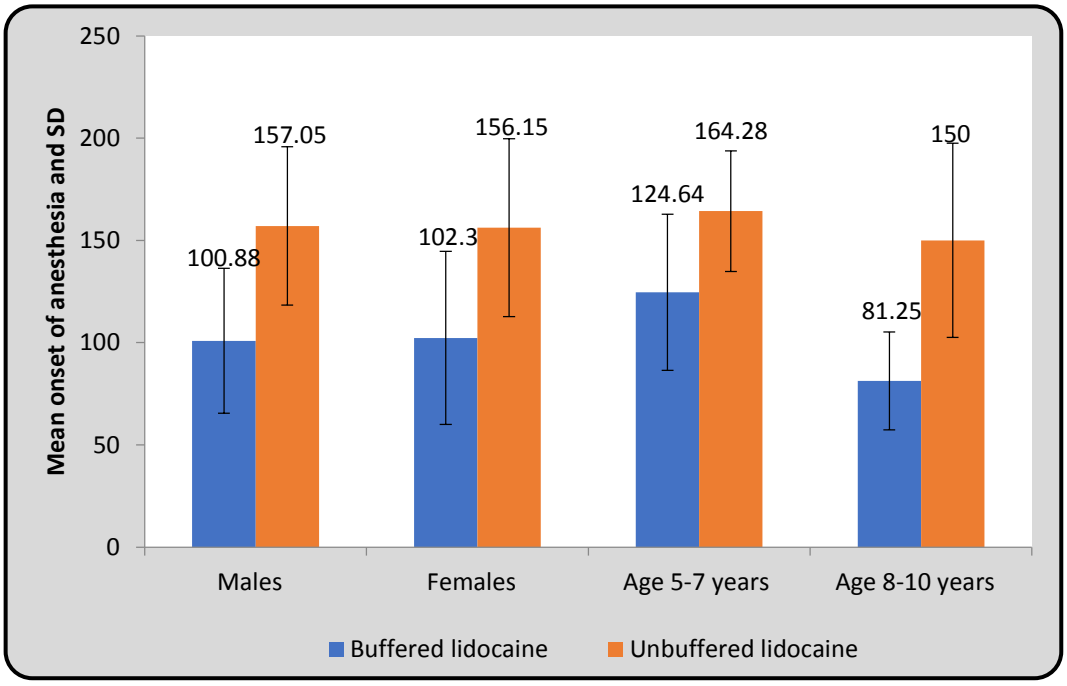
Graph 9: Subgroup analysis of Sound Eye Motor (SEM) Scale score in buffered and unbuffered lidocaine groups



Graph 10: Subgroup analysis of time to onset of anesthesia in buffered and unbuffered lidocaine groups (objective)



Graph 11: Subgroup analysis of time to onset of anesthesia in buffered and unbuffered lidocaine groups (Subjective)



ANNEXURE 1

DEPARTMENT OF PEDIATRIC & 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 _____

Thumb print of participant

Day/month/year

ANNEXURE 2

DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY

Comparison of pain on injection and onset of anesthesia of 2 % buffered lidocaine (with 1 :2,00,000 adrenaline) and 2 % nonbuffered lidocaine (with 1:2,00,000 adrenaline) in inferior alveolar nerve block for primary molars: a randomized double blind 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

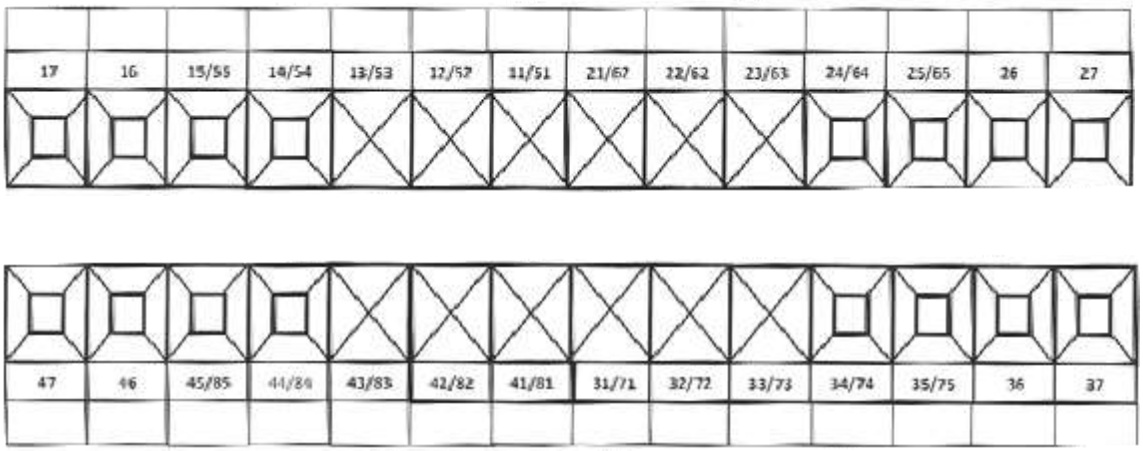
A. Examination of Soft tissues

- 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 anesthesia (seconds)**	
	Subjective (Wong Baker Faces Pain scale)	Objective (Sound Eye Motor)	Subjective	Objective
Visit 2				
Visit 3				

Adverse Effects (If Any)

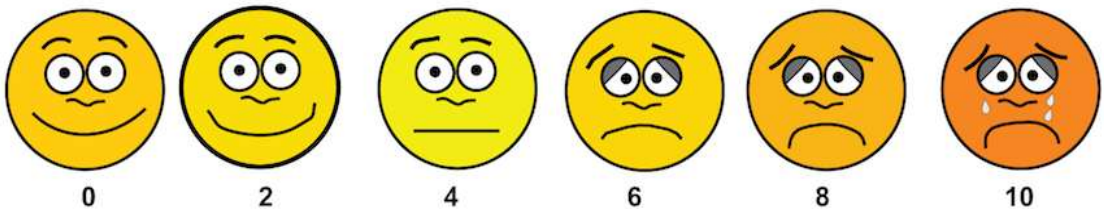
- **Allergy to local anesthesia :**
- **Paresthesia :**
- **Postoperative soft tissue injury :**
    - **Cheek bite**
    - **Lip bite**

ANNEXURE 3

Visit 2

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.

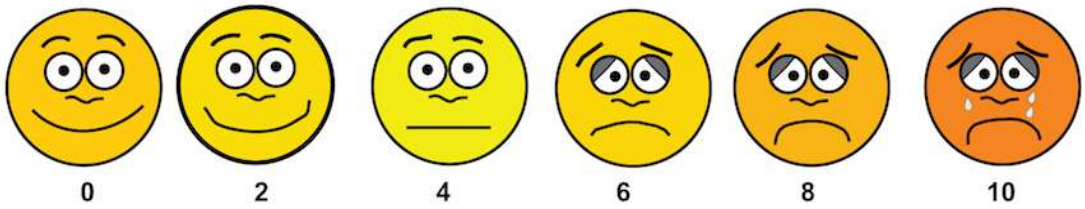
*Wong, D. and Baker, C.: Pain in children: comparison of assessment scales, Pediatric Nursing1988;14(1)

Procedure	**Score**
Pain on injection	

Visit 3

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 on injection	

ANNEXURE 4

Visit 2

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	Comfort	Mild discomfort	Moderate discomfort	Severe discomfort	Pain on injection
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 defense, turning the head to the opposite side	

Pain on injection	Total	
	Average	

Visit 3

ID no:

SOUND, EYE, AND MOTOR (SEM) SCORING CRITERIA

Parameter	**Comfort**	**Mild discomfort**	**Moderate discomfort**	**Severe discomfort**	**Pain on injection**
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 defense, turning the head to the opposite side	

Pain on injection	Total	
	Average	

MASTER CHART

DEMOGRAHIC DETAILS							ASSESMENT							
							visit 2 (buffered)				visit 3 (nonbuffered)			
ID no	gender	DOB	age	frankl	weight	pain on injection		onset of anesthesia		pain on injection		onset of anesthesia		
						subjective (Wong Baker Faces Pain Scale)	objective(Sound Eye Motor)	subjective	objective	subjective (Wong Baker Faces Pain Scale)	objective (Sound Eye Motor)	subjective	objective	
I-01	1	08/05/2011	8.32	3	19	2	1.3	80	90	2	1.3	160	180	0
I-02	2	01/03/2011	8.43	3	20	0	1	50	55	2	1.3	55	60	0
I-03	1	14/12/2009	9.18	4	27	2	2	50	60	4	2	160	180	0
I-04	1	11/09/2009	9.4	4	24	2	1	80	90	4	2	170	180	0
I-05	2	25/08/2010	9.06	4	24	6	1.33	45	50	6	3	80	90	0
I-06	2	29/10/2010	8.66	4	25	0	1	40	45	2	1.3	160	180	0
I-07	2	23/03/2014	5.48	4	26	0	1	120	180	2	1.3	160	180	0
I-08	2	02/03/2014	5.61	3	15	2	1	95	110	4	2	120	180	0
I-09	2	21/05/2013	6.4	4	23	2	1	85	90	4	2.3	170	180	0
I-10	1	24/01/2014	5.72	3	16	2	1	80	85	2	3	100	180	0
I-11	1	24/09/2014	5.07	4	18	0	2	150	180	2	1.6	160	180	0
I-12	2	21/09/2011	8.11	3	18	2	1	80	90	4	2	175	180	0
I-13	1	11/02/2013	6.3	4	22	0	1	90	120	2	1	110	120	0
I-14	2	28/06/2013	5.89	3	21	4	1.3	120	180	6	3	110	200	0
I-15	2	29/03/2013	6.35	4	20	2	1	90	120	2	1.3	165	180	0

MASTER CHART

DEMOGRAPHIC DETAILS							ASSESMENT							
							visit 2 (nonbuffered)				visit 3 (buffered)			
ID no	gender	DOB	age	frankl	weight	Pain on injection		Onset of anesthesia		Pain on injection		Onset of anesthesia		
						Subjective (Wong Baker Faces Pain Scale)	Objective(Soun d Eye Motor)	Subjective	Objective	Subjective (Wong Baker Faces Pain Scale)	Objective(Sound Eye Motor)	Subjective	Objective	
II-01	1	29/10/2010	8.66	3	20	2	1.3	120	180	0	1	60	90	0
II-02	1	22/10/2010	9	4	20	2	1.3	110	120	0	1	70	90	0
II-03	1	20/09/2011	8.14	4	23	4	2	200	240	2	1	90	120	0
II-04	1	21/09/2011	8.11	3	20	2	2.3	95	100	0	1	80	90	0
II-05	2	23/03/2014	5.48	3	21	6	3	120	180	4	2	60	90	0
II-06	1	29/10/2010	8.66	3	25	4	1.6	105	110	0	1	45	60	0
II-07	1	20/01/2011	8.79	3	35	10	3	90	120	6	2	50	55	0
II-08	1	03/03/2014	5.1	3	27	0	1	160	180	2	1.33	140	180	0
II-09	2	25/08/2010	9.06	4	24	2	1.33	120	180	0	1	110	120	0
II-10	2	22/01/2013	6.37	3	18	2	2	110	120	0	1	80	100	0
II-11	1	14/06/2011	8.15	4	20	6	3	120	180	2	1	90	95	0
II-12	2	29/03/2013	6.35	3	28	0	1	90	120	0	1	100	120	0
II-13	2	11/04/2011	7.92	4	25	2	1.3	100	120	0	1	90	100	0
II-14	1	18/08/2013	6.19	3	24	4	2.3	160	180	2	1.33	95	100	0
II-15	1	28/06/2013	5.89	4	23	10	3	110	120	4	1.33	85	90	0