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A prospective, randomized, double-blinded, cross over comparison of buffered versus non-buffered 2% lidocaine with 1:80,000 adrenaline for dental extraction

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Abstract
Aim: To compare pain during injection, onset of anesthesia and effectiveness of anesthesia using buffered versus non- buffered 2% lidocaine with 1:80,000 adrenaline in dental extraction.
Patients and Methods: The investigator implemented a prospective, randomized, double-blinded, cross over study. The sample was composed of 200 extractions on 100 patients who needed bilateral extraction on same jaw. The predictable variable was buffered 2% lidocaine with 1:80,000 adrenaline and plain 2% lidocaine with 1:80,000 adrenaline. 100 patients on one side of the jaw received buffered and on the other side received plain or non buffered 2% lidocaine with adrenaline according to random number table. The outcome variable was pain during injection, onset of anesthesia and effectiveness of anesthesia on buffered and non-buffered group. Descriptive and bivariate statistics were computed and the P value was significant at 0.05.
Results: The sample was composed of 200 extractions on 100 patients. The mean pain score and efficacy of effectiveness was significantly significant in buffered when compared with non buffered 2% lidocaine with adrenaline. No significant difference was found in the onset of anesthesia between buffered and non buffered group.
Conclusion: The results of this study suggest that addition of sodium bicarbonate as a buffering agent with 2% lignocaine and 1:80,000 adrenaline reduces pain felt by the patient during injection of local anesthetics thus providing comfort to the patient. It also maintains the efficacy of effectiveness till the end of the procedure without supplemental injection.

Keywords: Buffered lidocaine, extraction, sodium bicarbonate

Introduction
Comfort of the patient is mandatory during minor surgical procedures. As it has apparent benefit for both patient and surgeon. Pain control during extraction is achieved through the administration of local anesthetics commonly lidocaine, an amide group. Although it remains as the backbone for pain control, the perceived pain during lidocaine administration due to its acidic pH can lead some patients to defer needed dental work.
As a vasoconstrictor, adrenaline is an important addition to lidocaine to reduce the rate of absorption, to decrease the risk of local anesthetic toxicity and to reduce bleeding during procedure because of perfusion [1]. When compared with plain lidocaine, adrenaline increases the duration of anesthesia at lower dose [2]. These solutions are merchandised as acidic solutions to extend the shelf life. This acidic nature causing injection painful during administration [3]. Neutralizing lidocaine to tissue pH reduces pain during injection. Sodium bicarbonate, a regular buffering agent which is effective in reducing pain during administration of lidocaine with adrenaline [4].
"Davies RJ *et al*. [5] reviewed the literature on buffering local anesthetics to decrease the pain on injection and found that buffering local anesthetics with sodium bicarbonate significantly reduced injection pain". "Galindo *et al*. [6] used pH-adjusted local anesthetic solutions (pH 7.4) in epidurals and peripheral nerve blocks to accomplish profound regional anesthesia." "Primosch and Robinson [7] showed no significant difference in pain on maxillary infiltrations between buffered and standard lidocaine with epinephrine".
Though studies have been done related to buffering of local anesthesia, cross over comparison

Studies for tooth extraction are very few in English literatures. This study adds evidence for the use of buffered anesthesia in dental extraction. The purpose of this prospective, randomized, double-blind cross over clinical trial is to compare pain during injection, onset of anesthesia and effectiveness of anesthesia using buffered versus non-buffered 2% lidocaine with 1:80,000 adrenaline in dental extraction.

Materials and methods

A total of 200 extractions, in 100 patients who needed bilateral extraction on same jaw (either maxillary or mandibular arch) were participated in this study with a written informed consent from each patient. The study was approved by Institutional Ethics Committee (ECI). Ethics clearance number: 1230/IEC/2017.

Patients above 18 years under ASA I and II category who needed bilateral extraction and patients who are not allergic to local anesthesia were included. Patients not willing to be a part of the study, medically compromised patients, pediatric patients and patients with a history of allergic /hypersensitivity reaction were excluded.

The teeth extracted were grossly decayed with poor prognosis to root canal treatment, roots stumps and orthodontic or therapeutic extraction.

100 patients on one side of the jaw received 2ml of buffered 2% lidocaine with 1: 80,000 adrenaline and on the other side received plain or non-buffered 2ml of 2% lidocaine with 1:80,000 adrenaline on the same appointment according to random-number table. Out of 100 injections, 84 infiltration and 16 Inferior Alveolar nerve block (IANB) were given in both groups. First operator who were blinded to anesthetic solution administered both buffered and non- buffered injections. Second operator who blended the buffering agent with lidocaine using mixing pen choose the anesthetic solution using randomized convenient sampling. Volume of solution in the anesthetic cartridge on the mixing pen was 2ml, which contains 0.2 ml of 8.4% sodium bicarbonate and 1.8ml of 2% lidocaine with adrenaline. For Non-buffered group 2 ml of 2% lidocaine with 1:80,000 adrenaline was administered using sterile syringe with 26-G disposable needle. Equal amount of anesthetic solution was delivered on both sides for a period of 1 minute. Prior to injection, each subject was given a thorough explanation of verbal rating scale (VRS) [8]. Verbal rating scale has markings beginning zero to three; with zero being “no pain” to three being “severe pain”. Immediately after injection, the subject rated the pain for injection on VRS for both buffered and non- buffered side. After these injections, onset of anesthesia was evaluated every 30 seconds by probing the marginal gingiva around the tooth to be extracted. Effectiveness of anesthesia was calculated by the requirement of supplemental anesthesia (i.e) number of additional injections given till the end of the procedure on both sides.

Statistical analysis

Data related to pain during injection, onset of anesthesia and effectiveness of anesthesia for buffered and non- buffered group was recorded, compared and subjected to different types of statistical analysis such as Chi- Square Test, Randomization test and T-Test. Comparisons were considered significant at $P < 0.05$.

Results

Pain during injection is sufficiently less in buffered group than non-buffered group. The mean value for buffered group on pain during injection is significantly reduced when compared with non-buffered group, which is statistically significant with P value 0.001 (<0.05) (Table 1).

Among 100 patients who were extracted under buffered 2% lidocaine with adrenaline, 71 patients encountered no pain, 24 patients encountered mild pain, 5 patients encountered moderate pain and no patients encountered severe pain during injection. Among 100 patients who were extracted under 2% lidocaine with 1:80,000 adrenaline (non-buffered group), only 10 patients encountered no pain, 70 patients encountered mild pain, 15 patients encountered moderate pain and 5 patients encountered severe pain during injection (Table 2).

The mean value for effectiveness of anesthesia for buffered group is 1.75 and non-buffered is 2.52 with T test value = -8.581 (df=99) and P value 0.0001 (< 0.05). Effectiveness of anesthesia between the buffered and non- buffered group is statistically significant (Table 3).

The mean anesthetic onset for buffered group is 2.00 and non-buffered group is 1.99 with T test value = 1.00 (df=99) and P value 0.320 (> 0.05). No statistical difference between the buffered and non- buffered group for onset of anesthesia (Table 4).

Discussion

The data from the result indicated that administration of buffered 2% lidocaine with 1:80,000 adrenaline reduces pain during injection and maintains efficacy of effectiveness till the end of the procedure without supplemental injection.

In this study 200 extractions were performed by a single operator. The techniques used are inferior alveolar nerve blocks and infiltrations. Same tooth in the same arch on both sides were extracted for all 100 patients with 84 infiltration and 16 Inferior Alveolar nerve block (IANB) were given with one side buffered and other side non buffered lidocaine with adrenaline. More number of patients experienced less pain in buffered group (Fig 1).

Pain is defined as “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” [9]. Patients experiencing pain during lidocaine injection is mainly due to rate of injection and acidity of solution [10]. In this study, the pH of the solutions were measured using a standard pH meter. The pH of 2% lidocaine with 1:80,000 adrenaline was found to be 3.6 pH. But the pH of normal tissue is 7.4 [11] This acidic 3.6 pH decreases the availability of deionized form of anesthetics and increase in volume in the tissue that causes pressure. Lesser the acidic nature more the deionized form more the availability of free base form more the desired anesthetic effect [12].

Sodium bicarbonate is an alkalinizing agent. It is an effective drug to correct acidosis commonly in chronic kidney disease patient [13]. Route of administration includes oral and intravenous. It is available as tablets, effervescent powders, liquids/ampules. When sodium bicarbonate mixed with acidic solution that is lidocaine with adrenaline, it increases the lipophilic or uncharged molecule availability of lidocaine which penetrates lipid bilayer of cell membrane and enter into the axoplasm of neuron. It also have prompt action on the binding of local anesthetics to sodium channel. Thereby hastens the onset of anesthesia.

Sodium bicarbonate used in this study is 8.4%. It is blended with 2% lidocaine with 1:80,000 adrenaline under sterile condition using mixing pen. The pH of this buffered solution is 7.2 nearly tissue pH. Buffered lidocaine using sodium

bicarbonate can be used for pain reduction [14]. Buffering using sodium bicarbonate is empirical and inexpensive. But should be used with caution to avoid complications in patients with systemic acidosis [15, 16]. According to literature, buffered lidocaine solution containing epinephrine can be stored for seven days without losing its stability [17, 18].

"Thompson [19] demonstrated that bicarbonate buffering lidocaine enhances its bactericidal effects. These properties should be borne in mind when taking biopsies for bacteriological culture using bicarbonate buffered local anesthetic. Gupta *et al*. [20] validate the addition of sodium bicarbonate in local anesthetics to increase its effectiveness in teeth with peri-apical infection. Data confirmed that the addition of sodium bicarbonate in local anesthetics did increase its efficacy in inflamed tissue. Vinay Mohan Kashyap *et al* [21] showed reduced pain on injection and faster onset when buffered anesthetics were used in intraoral nerve blocks as well as in infiltrations."

On contrary "Aulestia-Viera PV *et al*. [22] conducted a systematic review and meta- analysis to investigate the efficacy of buffering local anesthetics in reducing infiltration pain and anaesthesia onset time in dentistry. Data confirmed that onset of anesthesia and pain reduction with buffered lidocaine was not evident in normal or inflamed tissue".

"Oluwatola Afolabi *et al*. [23] explained the use of sodium bicarbonate and its effect on pain during injection in the upper lip. Decrease in the pain of the injection by buffering the lidocaine was not evident but the study did show that buffering increases the duration of lidocaine effect in the face".

In our study, data confirmed that buffering lidocaine with sodium bicarbonate reduces the pain during injection. Sodium bicarbonate buffering is a successful method in retaining comfort of the patient. It can be used in routine clinical practice during extraction and also other procedures under local anesthesia.

Table 1: Pain ratings during injection on buffered versus non-buffered group were measured using VRS and tabulated.

Variable	No Pain (Mean ± SD)	Mild Pain (Mean ± SD)	Moderate Pain (Mean ± SD)	Severe Pain (Mean ± SD)	P-Value
Buffered	0.93 ±0.38	1.87± 0.626	1.80± 1.095	0.00 ±0.00	0.0001*
Non-Buffered	0.00 ± 0.001	0.17 ±0.481	1.40±0.548	1.40 ±0.548	

* – Statistically significant (P value < 0.05)
SD – Standard Deviation

Table 2: No of patients experienced pain during injection on buffered and non-buffered group.

Variable	No Pain (no of patients)	Mild Pain (no of patients)	Moderate Pain (no of patients)	Severe Pain (no of patients)
Buffered	71	24	5	0
Non-Buffered	10	70	15	5

Table 3: Comparison of effectiveness of anesthesia on buffered versus non-buffered group.

Variable	Buffered (Mean ± SD) In minutes	Non-Buffered (Mean ±SD) In minutes	T- Test Value	P- Value
Effectiveness	1.75±0.796	2.52±0.948	-8.581 df= 99	0.0001*

* – Statistically significant (P value < 0.05)
SD – Standard Deviation

Table 4: Comparison of onset of anesthesia on buffered versus non- buffered group.

Variable	Buffered (Mean ± SD)	Non-Buffered (Mean ±SD)	T- Test	P- Value
Onset	2.00 ±0.167	1.99± 0.948	1.00 df= 99	0.320

SD – Standard Deviation

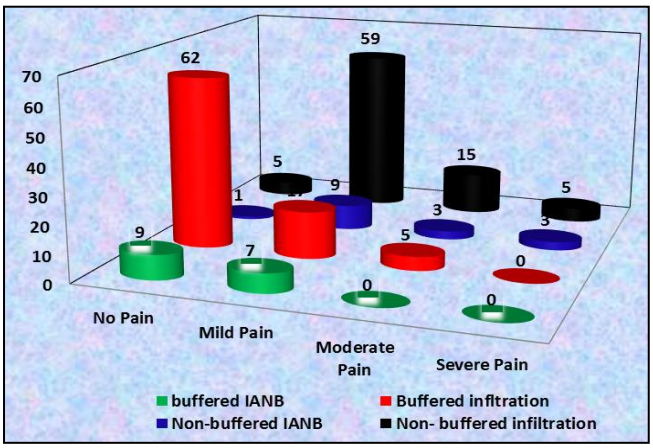

Fig 1: Data representation of pain during IANB (Inferior Alveolar Nerve Block) and infiltration on buffered and non-buffered group. Numeral indicates the number of patients on each group. Of 16 IANB and 84 infiltrations none of the patients experienced severe pain on buffered group.

Conclusions

We concluded that addition of 8.4% sodium bicarbonate with 2% lignocaine and 1:80,000 adrenaline reduces pain and burning sensation felt by the patient during injection of local anesthetics thus providing comfort to the patient. It also eliminates the supplemental or additional injection of local anesthetic agents by maintaining the effectiveness of anesthesia.

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