RESEARCH
O&G Forum 2024; 34 – 2s: 98 - 102

EFFECTS OF LIDOCAINE HYDROCHLORIDE BUFFERED WITH 8.4% SODIUM BICARBONATE ON THE PAIN EXPERIENCED, ONSET AND DURATION OF ACTION OF ANESTHETIC EFFECT IN PATIENTS UNDERGOING BILATERAL SURGICAL EXTRACTION OF MANDIBULAR THIRD MOLARS: SPLIT MOUTH, PROSPECTIVE OBSERVATIONAL STUDY

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Abstract
Background: Local anesthesia plays a crucial role in minimizing patient discomfort during dental extractions. Lignocaine, a commonly used local anesthetic, is typically buffered with sodium bicarbonate to reduce injection pain. The purpose of this study was to compare the effectiveness of lignocaine buffered with 8.4% sodium bicarbonate in the ratio of 4:1 versus 9:1 versus unbuffered lignocaine during surgical extraction of impacted mandibular molars with a history of Pericoronitis.
Aim and Objectives: This study aims to study the effects of using buffered local anesthesia as opposed to conventional local anesthesia for surgical extraction of impacted mandibular molars. The objectives include measurement of pain experienced by the patient during administration of local anesthesia and during the procedure, and the measurement of onset and duration of action of anesthesia.
Materials and Methods: This is a prospective, split-mouth study. 56 patients requiring bilateral surgical extraction of mandibular third molars were given conventional local anesthesia on one side and the procedure was done, and local anestheisa buffered with 8.4% Sodium Bicarbonate in the ratio 5:1 on the opposite side, after a period of 7 days. The VAS score was recorded after administration of LA and after completion of the procedure, the onset and duration of action of local anesthesia was recorded and compared on both sides.
Results: Results showed that local anethesia buffered with sodium bicarbonate showed was significantly reduced pain at the time of administration and during the procedure. ($P< 0.05$). the onset and duration of action was also lower for buffered local anesthesia.
Conclusion: Local anesthesia buffered with sodium bicarbonate significantly reduces the pain experienced, and the onset of action of the anesthetic agent. The duration of action is also increased. This data can be safely used to advocate for the use of buffered LA over conventional LA for the extraction of mandibular third molars.
Keyword: Dental Pain, Local Anesthesia, Pain on Administration, Onset of Action, Duration of Action, Surgical Extraction, Alkalization

INTRODUCTION

Ophthalmologist Carl Koller first introduced the concept of local anesthetics when he used cocaine to anesthetise his patient's eyes in 1884. [1]. Over the century, use of local anestheisa has increased drastically, owing heavily to its transient effect and easy of use. Lidocaine is a commonly used anesthetic agent, with its average onset being less than one minute, and its duration of action lasting over an hour. [2]. This can be further increased by the addition of epinephrine into the solution.

Lignocaine is the most commonly used anesthetic that is used in dentistry today. Commercially available local anesthethia contains 2% Lignocaine with epinephrine 1:80,000. Other agents are added to this solution to stabilze the solution and to bring it to the required pH. Commercially available Lignocaine solution has a pH of 3.49 -+ 0.29 [3].

While such an acidic pH is essential to maintain the efficacy of the solution and to prevent of oxidation of adrenaline present in the local anesthesia, this also causes severe pain and burning sensation on administration of the drug. This can be countered by the addition of a buffering agent, such as sodium bicarbonate. While such a change can help decrease the associated burning sensation, addition of a base will cause oxidation of adrenaline. Hence, the addition of a buffering agent is done immediately before the injection of local anesthesia into the tissues.

The rapid onset of action is credited to the low dissociation constant (pKa) and high lipid solubility of lignocaine [3]. A concept proposed to counter this problem is the alkalization of lignocaine, through the addition of lignocaine. This idea was put forth to counteract the burning feeling and lessen injection pain [4].

Lignocaine is the most commonly used anesthetic agent for dental treatment. While administration can be uncomfortable, it is highly effective and has only a few reported side effects. [5]

Some of the factors influencing pain during injection are: the velocity with which the solution is injected into the tissues, the route of drug administration, the pH and temperature of the solution [6,7]. While several of these factors are beyond the control of the clinician, The pH of the solution can be altered to benefit the patient and to alter the characteristics of the anesthetic agent.

This is done by a process called buffering, which includes addition of 8.4% sodium bicarbonate to the anesthetic agent [9]. Buffering of local anesthetics has been the subject of numerous investigations, and the existing literature points to a possible reduction in discomfort during injection and a quicker onset of action [10]. This study compared the effectiveness of an 8.4% sodium bicarbonate buffered local anesthetic to a traditional 2% lignocaine with 1:80,000 adrenaline in terms of the pain experienced by the patient, the onset and duration of anesthesia.

AIM:

This study aims to study the effects of using buffered local anesthesia as opposed to conventional local anesthesia for surgical extraction of impacted mandibular molars.

OBJECTIVES:

Primary Objectives: To determine average VAS score in buffered versus unbuffered local anaesthetic solution

Secondary Objectives: To determine the average onset and duration of action of local anaesthesia

METHODOLOGY:

This is a prospective, double -blinded randomised control clinical trial with the cases to controls allocation ratio as 1:1. This study was carried out at the Department of Oral and Maxillofacial Surgery at Saveetha Dental College and hospital.

Based on previous studies evaluating similar characteristics, G power version 3.1 0. software was used to calculate the sample size for the power of the study to be 95%.

Originally, 70 patients were recruited for the study, however, 14 patients did not return after the surgical extraction of ipsilateral side, and data regarding extraction of contra-lateral side could not be collected. These patients were removed from the study.

A total of 56 patients requiring inferior alveolar nerve block for the surgical extraction of impacted mandibular third molars were taken up for the study. All participants were systemically healthy adults, without any co-morbidities who were diagnosed with bilaterally impacted mandibular third molars. Surgical extraction of teeth was done at two different appointments, one week apart.

Inclusion criteria:

Patient requiring bilateral surgical extraction of impacted mandibular third molars (Pell and Gregory classification- Position A,B,C and Class I,II,III)

Patients within 18 years to 40 years of age.

Patient with no active infection/ associated abscess/ active pus discharge/ trismus

Systemically healing patients without any comorbidities, such as diabetes, hypertension, hepatic or renal disorders, history of peptic ulcers, patients with a history of cardiac disorders.

Exclusion criteria:

Patients with single sided-impacted mandibular molars, not requiring extraction of the opposite side.

Patients with soft-tissue impactions, not requiring any bone-guttering.

Patient requiring non-surgical extraction of mandibular third molars

Patient below 18 years of age or above 40 years of age

Patient with active infection/ associated abscess/ active pus discharge/ trismus

Systemically healing patients without any comorbidities, such as diabetes, hypertension, hepatic or renal disorders, history of peptic ulcers, patients with a history of cardiac disorders.

METHODOLOGY:

As the patients entered the clinic, they underwent a preliminary examination by a dentist and a thorough medical history and necessary radiographs were taken.

In case the eligibility criterion was met, the patient was explained about the ongoing study and informed consent was taken.

The dentists handed the participants a sealed envelope with a number inside. The numbers were generated and then randomly allocated to the cases or control group using Random Allocation Software (RAS version 3.0)

This study was double blinded and neither the patient, nor the clinician was aware of the group the patient was being allocated to.

Intervention:

At the first appointment, the participants were given conventional local anaesthetic solution as inferior alveolar, long buccal, and lingual nerve block. immediately after the nerve block was given, the participants were asked to rate the pain experienced on a VAS scale. The onset of action of anesthesia was measured by probing the buccal mucosa on the region of the

mandibular first molar and the vermillion border of the ipsilateral side of the lower lip using a blunt periodontal probe by applying gentle pressure. Probing was started 30 seconds after administration of local anaesthesia and done every 5 seconds, till the patient reported complete numbness of both the sites. This time was measured as the time of onset of action of local anesthesia. The procedure was carried out. After the completion of the procedure, patient was asked to rate the pain experienced during the procedure on the Visual-Analogue Scale.

The patient was discharged from the clinic with strict instructions to call and inform the clinician as soon as the effects of the anesthetic agent wear-off and the need for rescue analgesics is felt. This time period was noted as the duration of anesthesia.

The exact same procedure was repeated on the contralateral side after one week. The VAS score during injection of local ansethetic agent, the VAS score during the procedure and the onset and duration of action of local anesthetic agent was recorded.

Outcomes measured:

Primary Outcome Measured:

Pain experienced by the participants at the time of injection.

Pain experienced during the procedure.

Secondary Outcomes Measured:

Onset of action of local anesthesia

Duration of Action of local anesthesia.

The Visual Analog Scale (VAS) was used for the measurement of pain.

The VAS is a validated tool for measuring pain intensity, with scores ranging from 0 to 10, where 0 represents no pain and 10 represents the worst pain imaginable. Participants were instructed to mark their pain intensity on a 10 cm horizontal line corresponding to their perceived level of pain.

STATISTICAL ANALYSIS:

IBM SPSS statistics version 23 was used to analyse the collected data. Descriptive statistics were used to summarize the demographic characteristics of the participants. The mean VAS scores at each time point were compared between the experimental and control groups using independent t-tests. The significance level was set at $p < 0.05$.

Mann-Whitney U Test was done to analyse the data and draw out conclusions.

RESULTS

Table 1: VAS score after LA administration

Group	Minimum	Maximum	Mean	SD
Cases	3.00	6.00	4.8	1.62
Controls	4.00	8.00	5.2	1.81

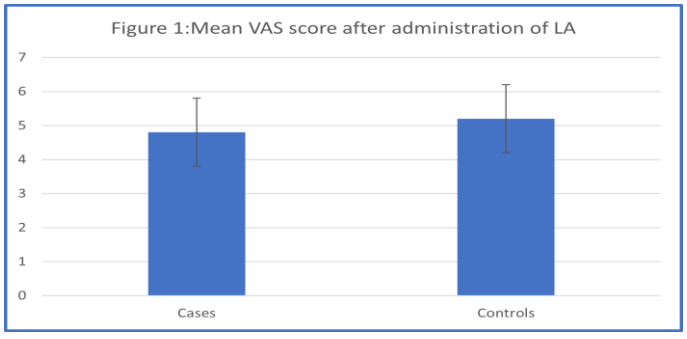

Table 1 shows us the average pain experienced by the subjects. The minimum VAS score for the cases group was 3 while for the control group, it was 4. The maximum VAS score for the cases group was 6 while it went up to 8 in the control group. The mean and SD were 4.80 and 1.62 respectively for the cases group and 5.2 and 1.81 respectively for the control group. The figure 1 shows the Mean VAS score after administration of LA

Table 2: VAS score after completion of procedure

Group	Minimum	Maximum	Mean	SD
Cases	1.00	6.00	3.3	1.51
Controls	1.00	7.00	4.7	1.54

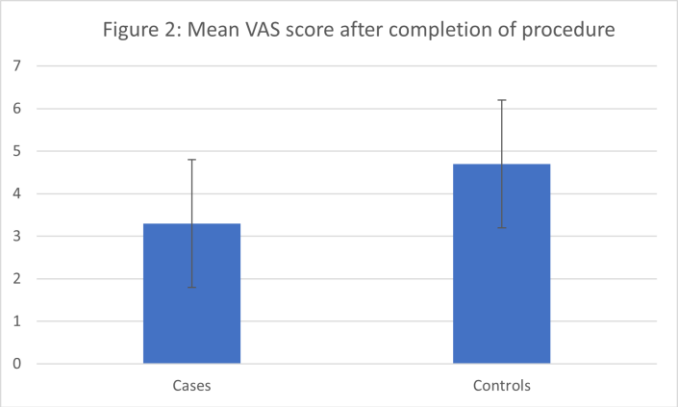

Table 2: The minimum VAS score was 1 while for the cases as well as the control. The maximum VAS score for the cases group was 6 while increased to 7 in the control group. The mean VAS score was 3.3 for the cases group and 4.7 for the control group (Figure 2).

Table 3: Onset of action (in seconds)

Group	Minimum	Maximum	Mean	SD
Cases	25	180	68.70	24.80
Controls	35	235	148.28	36.78

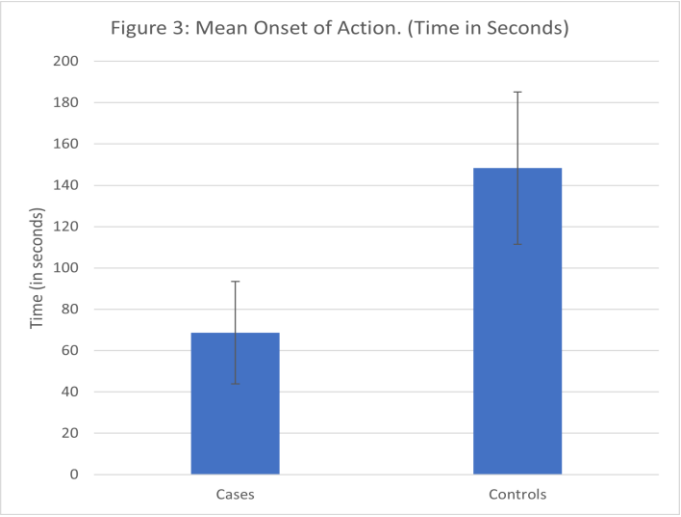

Table 3: The minimum onset of action of the cases group was 25 seconds and the maximum was 180 seconds. For the control group, the minimum onset of action was 35 seconds and maximum was 235 seconds. The mean for cases group was 68.70, while it was 148.28 for the controls. The figure 3 shows the Mean Onset of Action in seconds.

Table 4: Duration of action (in minutes)

Group	Minimum	Maximum	Mean	SD
Cases	120	280	234.68	30.24
Controls	140	250	185.00	14.80

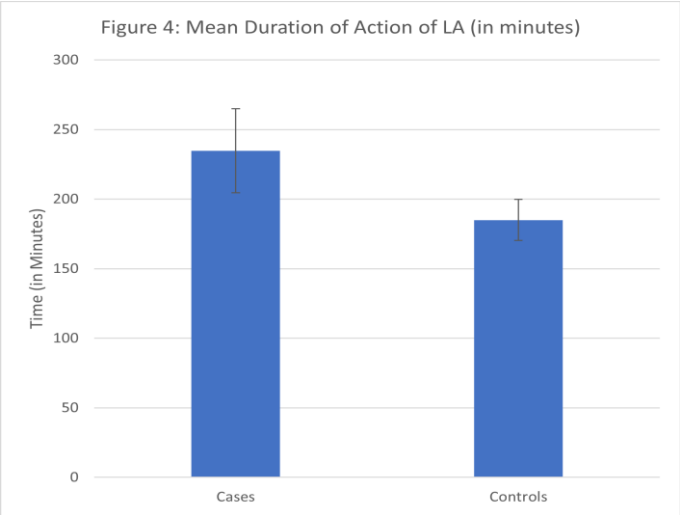

Table 4: The minimum and maximum values for cases group was 120 minutes and 280 minutes respectively, while for the control group, it was 140 minutes and 250 minutes. The mean duration was 234.68 for cases and 185.00 for the control group respectively (Figure 4).

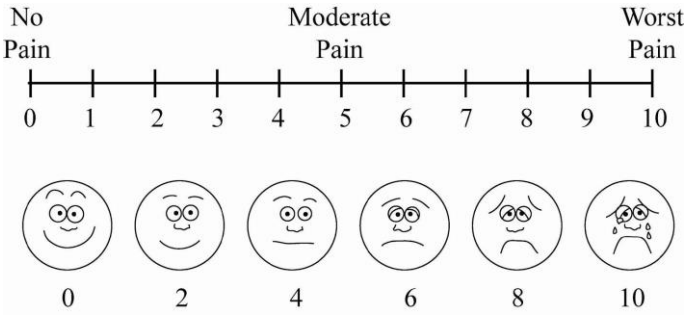

Figure5: The Visual Analog Scale (VAS) was used for the measurement of pain

The Visual Analog Scale (VAS) was used for the measurement of pain was shown in figure 5.

TABLE 5: Comparison between study and control groups using Mann-Whitney U test

Parameter	Mean Difference	Mann-Whitney U test	Z-value	p-value
VAS score during anesthesia	-0.4	1375	6.778	<0.001
VAS score during procedure	-1.4	2390	6.316	<0.001
Onset of Action (in seconds)	-79.58	468	8.564	<0.001
Duration of Anesthesia (in minutes)	49.68	1576	10.378	<0.001

Table 5 shows the Comparison between study and control groups using Mann-Whitney U test

DISCUSSION:

Commercially available lignocaine, is a weak basic that exists in its salt form, dissolved in distilled water. These salts have both hydrophiillic, and hydrophobic ends that remain in equilibrium when the solution is at the ideal pH.

The pKa or the dissociation constant of an anesthetic agent determines if the anesthetic agent exists as its ionised or unionized form within the solution. When the pH of the solution is close to the pka of the solution, the salts exists equally in both of its forms; charged cation (BNH+) and its uncharged base form (BN). The basic form (BN) can penetrate the outmost layer of the nerve fibre, that is the epineurium. Upon entering the nerve, the anesthetic salt changes to its charged form, BNH+, which bind to the existing sodium channels and block them.

This normal mechanism may be disrupted by the presence of infection. Active infection and presence of pus will lower the normal pH of the tissues, hence disturbing the equilibrium and moving away from the pKa. This will cause an increase in the number of charged cations (BNH+) and a decrease in the salt form of the agent (BN). This will result in reduced penetration of the drug into the epineurium, and hence an over-all decrease in the effect of anesthesia. [11-15]

This can result in increased discomfort and pain experienced by the patient. Additionally, local anesthesia vials are acidic in nature to prevent oxidation of the adrenaline present in the solution. This causes several patients to experience the presence of a burning sensation upon injection, and a general sense of discomfort. [11,13]

Amide anesthetics are weak basis. Commercially produced amides are often combined with an acid to stabilize them. Lignocaine is commercially available as lignocaine hydrochloride, which converts it into a water-soluble salt.

An artcle published by Davies at al found that addition of sodium bicarbonate as a buffering agent reduced pain on injection [14]. The most commonly used method for buffering LA is the addition of 1ml of 8.4% sodium chloride to 10 ml of local anesthetic. [15]

Catchlove previously confirmed that the presence of CO2 reduces the pH of interstitial fluid in the nerve sheath, which causes increased ionization of the anesthetic solution.[16].

In our study, the use of a split-mouth technique helped neutralize the confounding factors, and formed the basis of a more comprehensive system of pain evaluation. The mean VAS score after LA administration was 4.8 in the cases group, while it was 5.2 in the control group.

The mean VAS score after the completion of the procedure was 3.3 for the cases group and 4.7 for the control group. Both of these numbers indicate an overall decrease in the pain perceived by the patient when buffered LA solution is used.

Similarly, the mean onset of action was 180 seconds for Cases group, and 235 seconds for Control group, thus indicating an overall reduction in the onset of action. This can be explained by the increased ability of the anesthetic agent to enter the epineurium due to the presence of the buffering agent.

The mean duration of action was 280 minutes for cases and 250 for controls. The increased duration of action can be explained

due to the presence of more ionized molecules that bind to, and inactivate the sodium channels.

CONCLUSION:

In conclusion, Buffered local anesthesia shows superior results because of its lesser painful injection, quicker onset and longer duration of action, buffered local anesthetia can be considered superior than conventional local anesthetic, according to our study. Therefore, buffered LA in dentistry should be investigated as a potential remedy to lessen patient discomfort during injection and provide a quicker anesthetic effect.

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