
**“EVALUATION OF THE EFFICACY OF
LOCAL BUFFERED LOCAL ANESTHETIC IN
EXTRACTION OF INFECTED TEETH –
RANDOMIZED DOUBLE BLIND STUDY”**

By

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Dissertation

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LIST OF ABBREVIATIONS

Pre-op	:	Pre-operative
Post-op	:	Post-operative
Intra-op	:	Intra-operative
M	:	Male
F	:	Female
Hb	:	Hemoglobin
BT	:	Bleeding time
CT	:	Clotting time
RBS	:	Random Blood Sugar
IOPA	:	Intra-oral peri-apical radiograph
OPG	:	Orthopantomogram
VAS	:	Visual Analog Scale
EPT	:	Electric Pulp Tester

ABSTRACT

Background and Objectives:

Successful pain control is an integral part of clinical practice, and anesthetising an area of interest or teeth associated with infection can be challenging. Many factors contribute to the reduction of clinical efficiency of LA, including the increased vascularity of the inflamed tissues. This reduces the local anaesthetic effect, thereby increasing the sensitivity of the tissues. It has also been reported that the pH of inflamed tissues is lowered slightly, which in turn interferes with the dissociation of local anaesthetics.

Lignocaine is one of the most commonly used agents to anaesthetize an area preoperatively. It can however cause undesirable effects such as burning on injection, relatively slow onset and lack of numbness when injected into infected tissues as a result of the acidic pH of commercial preparations (pH is between 3.5 and 7.0 compared with physiological pH, which is between 7.35 and 7.45).

Buffered local anaesthetics can be more efficient in controlling pain in such cases. The reason for buffering local anaesthetics is substantiated by the Henderson-Hasselbalch equation; if a local anaesthetic solution is buffered to a pH that is closer to its pKa, more of the free base form will be available on injection to enter the nerve sheath. This can be achieved by the addition of sodium bicarbonate (8.4% NaHCO₃), which will increase the pH of the solution.

Thus the objective of this study is to compare efficacy of buffered lignocaine in extraction of infected tooth in terms of pain reduction, onset of action and burning sensation while infiltration.

Materials and Method:

A total of 70 patients were included in study after fulfilling eligibility criteria and were divided in two equal group (Study group and control group). Study group received buffered lignocaine (8.4% sodium bicarbonate added to 2%lignocaine mixture) while control received commercial lignocaine preparation (2% lignocaine with 1:80000 adrenaline). Pain was evaluated using VAS scale preoperatively and during procedure. Tooth pain was evaluated using EPT (Electric Pulp Tester).

Results:

The mean age of population included in study was 40.41 + 10.96. Only 1/3rd of control group experienced burning sensation while 2/3rd of study group population experienced burning sensation. There was statistical difference in pain reduction score in study group compared to control group.

Conclusion:

Buffered lignocaine is more effective compared to commercial lignocaine preparation in extraction of infected teeth.

Keywords: Buffered lignocaine, Infected tooth, Extraction, Pain, VAS

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INTRODUCTION

Tooth extraction is the commonest procedure performed by dentist in routine practice. Tooth extraction reasons vary, but the most common one is pain. Pain is mostly due to infected tooth or some periapical pathology. Most of the patients avoid visiting dentist due to fear of pain. For smoother extraction experience the procedure should be pain free to reduce anxiety or fear of procedure.

Local anesthetics drugs were introduced to control pain during operative procedures. Increased vascularity of inflamed tissues leads to failure of action of Local anesthesia. Literature suggests change in pH in inflamed tissues, which in turn interferes with the dissociation of local anaesthetics. When the pH of tissue fluids was measured in the presence of inflammation it was found to be in acidic range and in pus cases pH was around 5.0¹.

Lignocaine is the most common anesthetic agent used, however has unwanted effects such as burning on infiltration, relatively slow onset and lack of numbness when injected into infected tissue because of acidic pH of tissue and commercial preparation(pH -3.5 to 7.0)

Buffered local anesthetics may provide better results in relieving pain in such cases. Henderson-Hasselbalch equation provides reason for buffering local anesthetic. Alkalisng local anesthetic to a pH that is closer to its pKa, results in more of free bases. Free bases enter nerve sheath and anesthetize nerve. This can be attained by the addition of sodium bicarbonate (8.4% NaHCO₃), which will increase the pH of the solution.

This study is conducted to evaluate and compare the efficacy of Buffered Local Anesthetic in extraction of infected Maxillary teeth and Mandibular anterior teeth by changing the pH with 8.4% Sodium Bicarbonate.

AIM AND OBJECTIVES OF THE STUDY

AIM OF THE STUDY:

To Evaluate and Compare the efficacy of Buffered Local anaesthetic in Extraction of infected Maxillary teeth and mandibular anterior teeth by altering the pH with 8.4% Sodium Bicarbonate.

OBJECTIVES:

- Pain was evaluated before administration of local anaesthesia and after every 1 min after administration of anesthesia till onset of action.
- To evaluate and compare the burning sensation caused during infiltration of lignocaine and buffered lignocaine.
- To evaluate the onset of action of lignocaine and buffered lignocaine.

NULL HYPOTHESIS:

There will be no difference in efficacy of commercial lignocaine and buffered lignocaine in achieving anesthesia for extraction of infected teeth.

ALTERNATE HYPOTHESIS:

There will be difference in efficacy of commercial lignocaine and buffered lignocaine in achieving anesthesia for extraction of infected teeth.

REVIEW OF LITERATURE

- **G. Arora, S. Degala and S. Dasukil et al (2019)** in their study of “**Efficacy of buffered local anaesthetics in head and neck infections**” on 60 patients found that there was reduction of pain and painless infiltration can be achievable in cases of localized acute infections by the addition of sodium bicarbonate to local anaesthetics so that the resultant ratio of local anaesthetic to NaHCO₃ equals 10:1. In doing so, the efficacy of the local anaesthetic is not compromised. It is recommended that local anaesthetic buffering should be done immediately before the local anaesthetic is given, to eliminate concerns about the shortened shelf-life of the anaesthetic caused by the buffering. The results of this study confirm that the routine use of alkalinized local anaesthetic solution in cases of acute head and neck infections may improve patients’ comfort and speed up the time of onset of anaesthesia.²
- **Pandian Senthooor, Krishnamachari Janani and C. Ravindran et al (2019)** in their study on “**A Prospective, Randomized Double-Blinded Study to Evaluate the Efficacy of Buffered Local Anesthetics in Infected and Inflamed Pulp and Periapical Tissues**” concluded buffered 2% lignocaine with 1:200,000 epinephrine had early onset of anesthesia when compared to unbuffered form. Injecting 2% buffered lignocaine, pain was significantly reduced during extraction of the teeth.³
- **Savina Gupta and Ashok Kumar et al (2018)** in their study “**Sodium bicarbonate: an adjunct to painless palatal anesthesia**” concluded that by

adding 7.4% sodium bicarbonate to 2% lignocaine with 1:80,000 adrenaline resulted in decreased pain perseverance while infiltrating maxillary palatal region.⁴

- **P. V. Aulestia-Viera , M. M. Braga and M. A. Borsatti et al (2018)** did a systematic review on “ **The effect of adjusting the pH of local anaesthetics in dentistry: a systematic review and meta-analysis** ” and concluded that there was not much significant difference in onset of action of local anaesthetic in normal tissue but inflamed tissue showed better results.⁵
- **Paul Hobeich, Stephen Simon, Emit Schneiderman and Jianing et al (2013)** in their study on “ **A Prospective, Randomized, Double- blind Comparison of the Injection Pain And Anesthetic Onset of 2% Lidocaine with 1:100,000 Epinephrine Buffered with 5% and 10% Sodium Bicarbonate in Maxillary Infiltrations**” concluded that needle penetration pain, anaesthetic deposition pain, and onset of anaesthesia did not differ significantly between the buffered and nonbuffered solutions in healthy maxillary canine infiltrations.⁶
- **Matthew Balasco and Melissa Drum et al (2013)** in their study “**Buffered Lidocaine for Incision and Drainage: A Prospective, Randomized Double-blind Study**” noticed that by buffering lidocaine (addition of sodium bicarbonate to 2% lidocaine with 1:100,000 epinephrine) didn't result in reduction of pain during infiltration and during incision and drainage in acute cases.⁷

- **Stanley F Malamed et al (2013)** in his study “**Faster onset and more comfortable injection with alkalinized 2% lidocaine with epinephrine 1:100,000**” concluded that by alkalinizing lidocaine just before infiltration resulted in faster onset of action and increased comfort to the patient.⁸
- **Vinay Mohan Kashyap and Rajendra Desai et al (2011)** in their study on “**Effect of alkalinisation of lignocaine for intraoral nerve block on pain during injection, and speed of onset of anaesthesia**” confirmed the efficacy of the alkalinised local anaesthetic solution in reducing pain on injection and quicker onset of anaesthesia while administrating nerve block namely inferior alveolar, lingual and long buccal nerve block.⁹
- **Jalil Modaresi et al (2008)** in his study on “**Effect of Pulp Inflammation on Nerve Impulse Quality with or without Anesthesia** ” concluded that there was significant changes in the impulse quality of dental afferent fibers originating from inflamed pulps including a decrease in conduction velocity and an increase in intensity of impulse were noted. Also, a resistance to local anesthetic and the transmission of the impulse, even distant from the inflamed area, were apparent.¹⁰
- **Robert Davies et al (2003)** in his study “**Buffering the pain of local anaesthetics: A systematic review**” concluded that sodium bicarbonate buffering does not affect efficacy of local anaesthetic solution and reduces pain.¹¹

- **KENNETH B. COLARIC et al (1998)** in his study on “ **Pain Reduction in Lidocaine Administration Through Buffering and Warming** ” found out that warming unbuffered lidocaine did not significantly decrease the pain of infiltration when compared with room-temperature, unbuffered lidocaine. However, the combination of warming and buffering lidocaine had a greater effect on the reduction of infiltration pain than either warming or buffering alone.¹²
- **J. E. Masters et al (1998)** in his study on “**Randomised control trial of pH buffered lignocaine with adrenaline in outpatient operations**” noticed that bicarbonate buffering of local anaesthetic decrease pain during administration.¹³
- **R. Fitton, M. Ragbir and M. A. P. Milling et al (1996)** in their study on “ **The use of pH adjusted lignocaine in controlling operative pain in the day surgery unit: a prospective, randomised trial** ” found that buffered lignocaine imparts a significant reduction in pain on infiltration, compared to the commercial preparation at both room and body temperature. They established practice to buffer an ampoule of 1% lignocaine and adrenaline with 8.4% sodium bicarbonate, by a ratio of 9 to 1, at the start of the day surgical list and found that such pH adjustment is a safe and simple method of improving the degree of comfort for patients undergoing local anaesthetic procedures and had a distinct advantage over warmed lignocaine.¹⁴

- **Christoph RA and Buchanan L et al (1988)** in their study on “ **Pain Reduction in Local Anesthetic Administration Through pH Buffering** ” found out effects of three local anaesthetic drugs namely 1% lidocaine, 1% lidocaine with 1:100,000 epinephrine and 1% mepivacaine. They concluded that buffering significantly reduced mean quantitative pain.¹⁵

- **Michele Curatolo et al (1998)** in his study on “**Adding Sodium Bicarbonate to Lidocaine Enhances the Depth of Epidural Blockade** ” found bicarbonate added to lidocaine hydrochloride resulted in higher pain threshold, faster onset of action and higher degree of motor block as compared to conventional lidocaine hydrochloride.¹⁶

- **Joel M Bartifield et al (1994)** in his study “ **The effect of Warming and Buffering on pain of Infiltration of Lidocaine**” concluded that buffering was more effective compared to warming in reduction of pain while giving infiltration.¹⁷

MATERIAL AND METHODS

The study was conducted in the Department of Oral and Maxillofacial Surgery, KLE VK Institute of Dental Sciences, K.A.H.E.R, Belagavi, Karnataka.

Surgical Armamentarium

Surgical gloves

Mouth mirror

2% lignocaine with 1:80000 adrenaline (Commercial preparation)

8.4% Sodium bicarbonate

2ml disposable syringe

Micropipette

Probe

Electric pulp tester (EPT)

Periosteal elevator

Tooth extraction forceps

Gauze

Pre-operative assessment

Hb

BT

CT

RBS

Any systemic conditions

Allergy to lignocaine

Tenderness to percussion (TOP)

IOPA or OPG

Electric pulp tester reading of infected tooth

Study design

Prospective, Double Blind, Randomized Controlled Trial.

Duration of study

January 2022 - November 2022.

Sample size

70 subjects, who fulfilled the eligibility criteria and gave consent to participate.

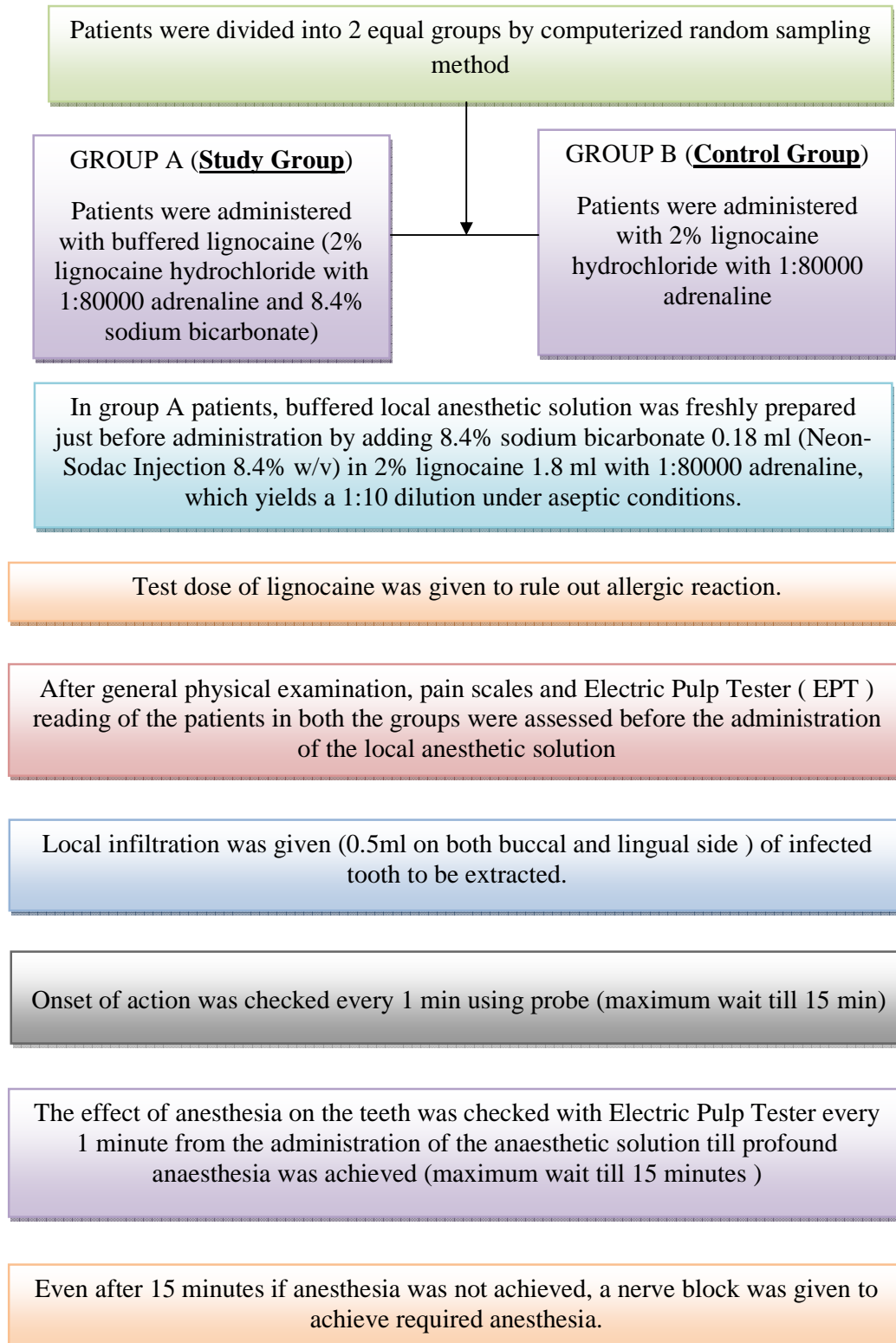
Inclusion criteria

- Patients with complaint of pain in maxillary teeth and mandibular anteriors and diagnosed to have inflamed or infected pulp and periapical tissues for which extraction is indicated.
- Age between 16-65 years.

Exclusion criteria

- Allergy to lignocaine
- Patients who are taking medications that might influence anesthetic assessment.
- Medically compromised patients.
- Patients unable to give informed consent.

Methodology



EVALUATION OF PARAMETERS

- Pain was assessed using both VAS and EPT.
- Pain was evaluated before administration of local anesthesia and after every 1 min after administration of anesthseia till onset of action.
- Onset of Anesthesia in teeth was checked by using Electric Pulp Tester (EPT).
- Burning sensation while giving local anaesthetic was evaluated as YES / NO.



**Figure 1 :
Micropipette**



**Figure 2 : 2% lignocaine
with 1:80000 adrenaline**



**Figure 3 : 8.4%
sodium
bicarbonate
(SODAC)**

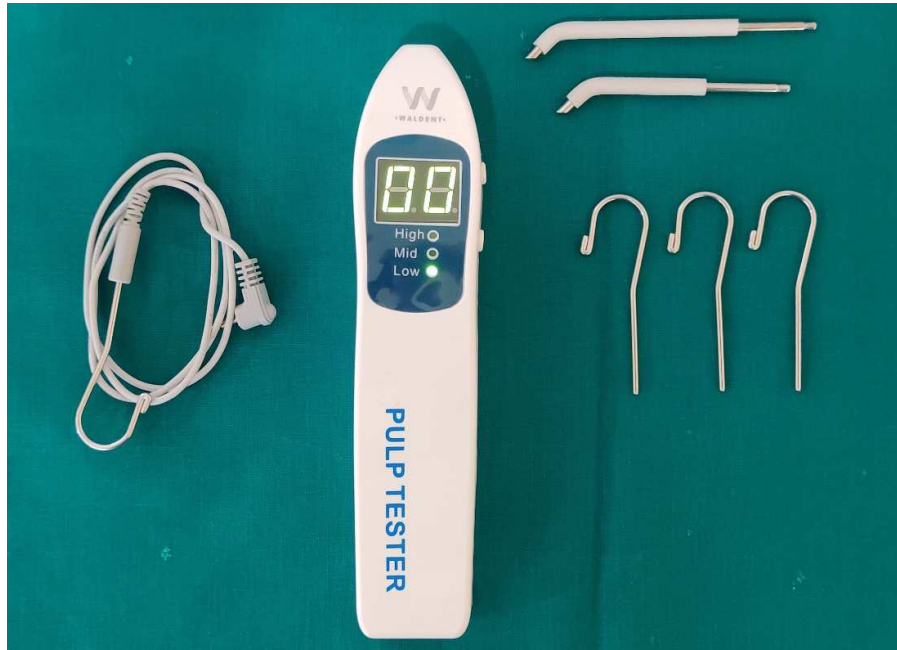


Figure 4 : Electric Pulp Tester



Figure 5 : IOPA of Infected teeth



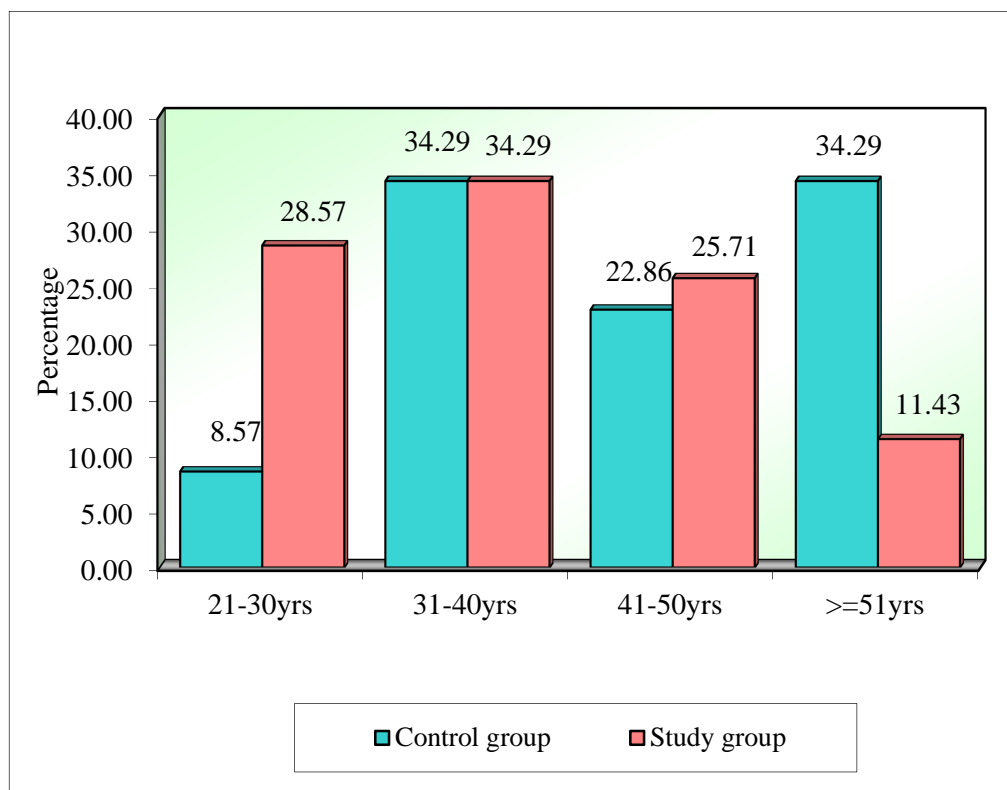
Figure 6 : EPT reading in patient

RESULTS**Table 1: Comparison of control group and study group according to age groups**

Age groups	Control group	%	Study group	%	Total	%
21-30yrs	3	8.57	10	28.57	13	18.57
31-40yrs	12	34.29	12	34.29	24	34.29
41-50yrs	8	22.86	9	25.71	17	24.29
>=51yrs	12	34.29	4	11.43	16	22.86
Mean age	43.86		36.97		40.41	
SD age	10.96		9.97		10.96	
Total	35	100.00	35	100.00	70	100.00
Chi-square=7.8280, p=0.0500*						

*p<0.05

Figure 1: Comparison of control group and study group according to age groups



Observation

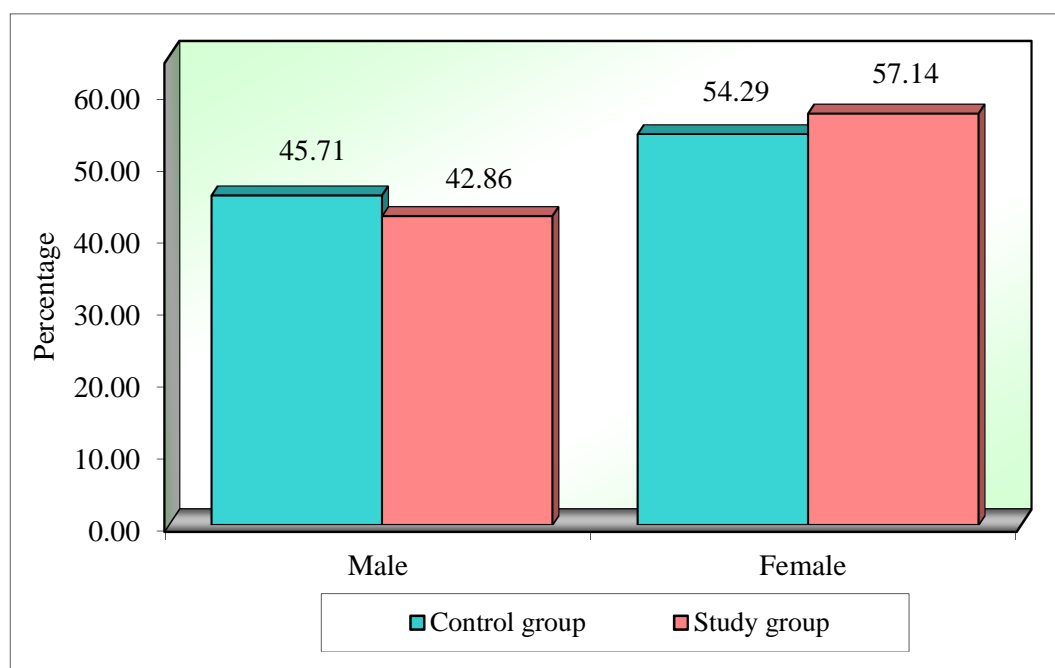
Table 1 shows age distribution among study and control group, with mean age in study group 36.97 ± 9.97 and in control group 43.86 ± 10.96 . Thus, the mean age of population participated in overall study was 40.41 ± 10.96 . Each group consisted of equal participant of 35 each.

Table 2: Comparison of control group and study group according to gender

Gender	Control group	%	Study group	%	Total	%
Male	16	45.71	15	42.86	31	44.29
Female	19	54.29	20	57.14	39	55.71
Total	35	100.00	35	100.00	70	100.00

Chi-square=0.0580, p=0.8100

Figure 2: Comparison of control group and study group according to gender



Observations

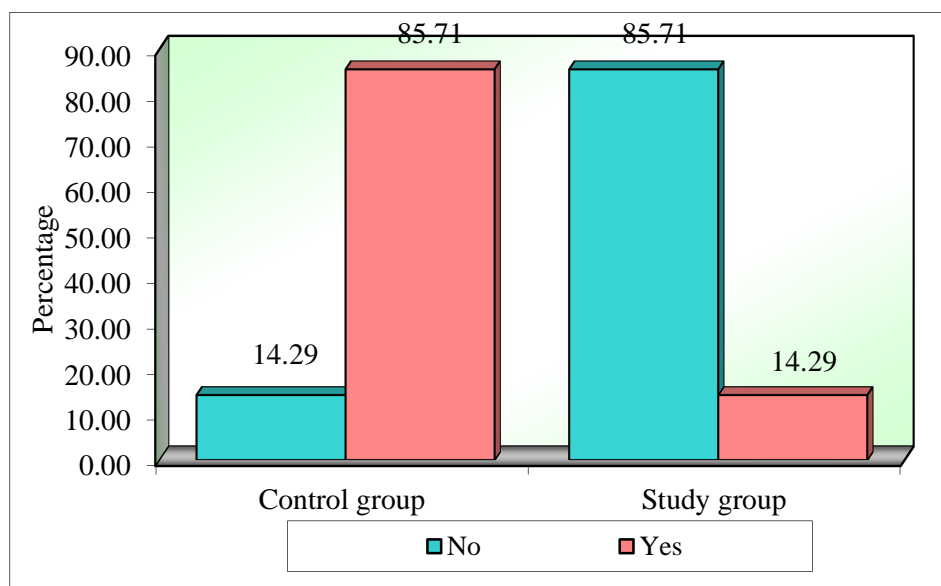
Table 2 shows study group having 42.86% male and 57.14 % female while control having 45.71% male and 54.29% female. P value (> 0.810) indicates statically insignificant.

Table 3: Comparison of control group and study group according to Burning Sensation while injecting LA

Burning Sensation	Control group	%	Study group	%	Total	%
No	5	14.29	30	85.71	35	50.00
Yes	30	85.71	5	14.29	35	50.00
Total	35	100.00	35	100.00	70	100.00
Chi-square=35.7140, p=0.0001*						

*p<0.05

Figure 3: Comparison of control group and study group according to Burning Sensation while injecting LA



Observations

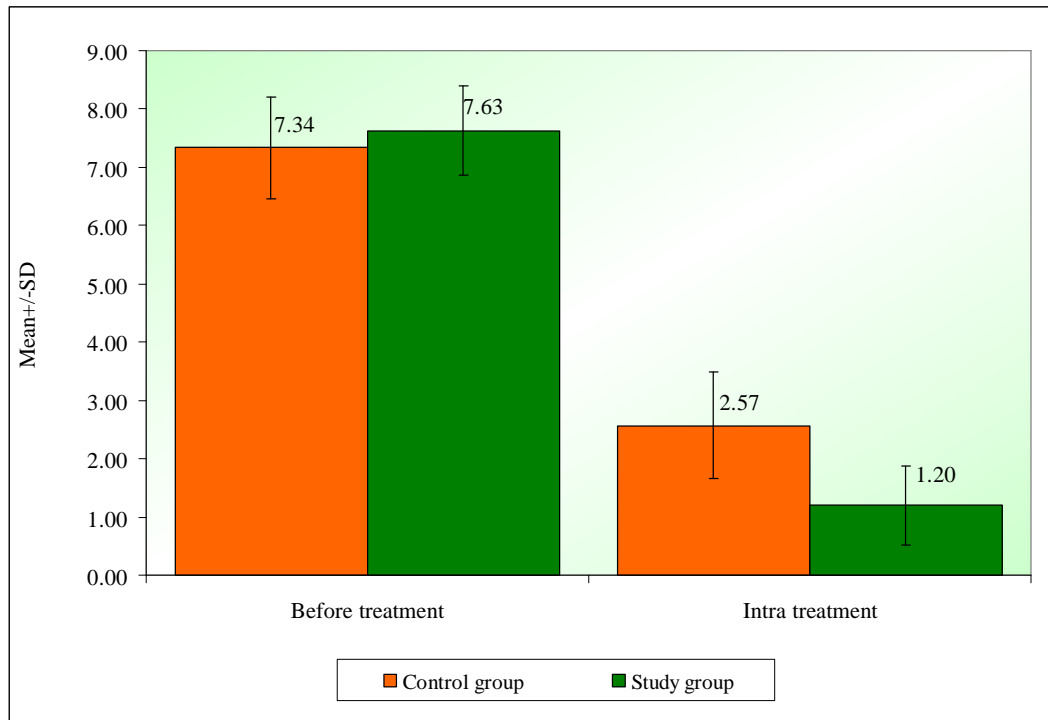
Table 3 represents burning sensation while injecting LA which was 14.29 % in study group and 85.71 % of total patients in control group with highly statically significant p value of 0.0001. Thus, indicating that more than 2/3rd of patient in control group experienced discomfort while injecting LA.

Table 4: Comparison of control group and study group with before and intra treatment pain scores by Mann-Whitney U test

Time points	Groups	Mean	SD	Mean rank	U-value	Z-value	P-value
Before treatment	Control group	7.34	0.87	32.29	500.00	-1.3156	0.1883
	Study group	7.63	0.77	38.71			
Intra treatment	Control group	2.57	0.92	48.29	165.00	5.2505	0.0001*
	Study group	1.20	0.68	22.71			

*p<0.05

Figure 4: Comparison of control group and study group with before and intra treatment pain scores



Observations

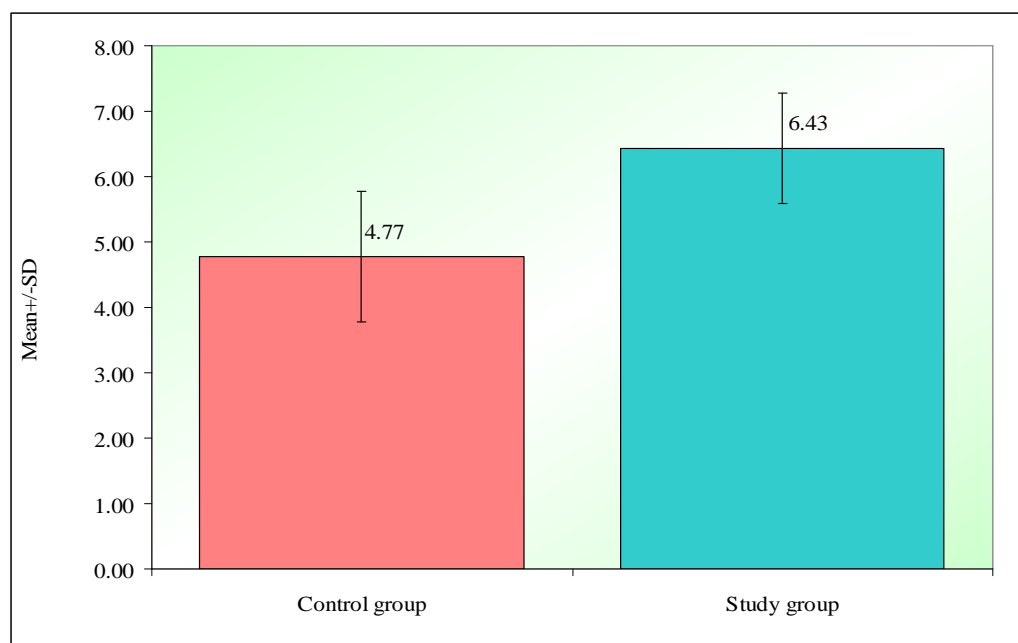
Table 4 represents pain in both study and control group, before treatment and during treatment. During treatment pain score in study group was $1.20 + 0.68$ and control group was $2.57 + 0.92$. Thus, indicating that there was no pain in study group while mild pain in control group.

Table 5: Comparison of control group and study group with changes in pain scores from before to intra treatment by Mann-Whitney U test

Groups	Mean	SD	Mean rank	U-value	Z-value	P-value
Control group	4.77	1.00	21.87	135.50	-5.5970	0.0001*
Study group	6.43	0.85	49.13			

*p<0.05

Figure 5: Comparison of control group and study group with changes in pain scores from before to intra treatment



Observations

Table 5 represents pain reduction in both group which was 6.43 + 0.85 in study group and 4.77 + 1.0 in control group. P value of 0.0001 indicates statistically significance between both groups. Thus, indicating more pain reduction in study group as compared to control group.

Table 6: Comparison of before and intra treatment pain scores in control group and study group by Wilcoxon matched pairs test

Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Control group	Before treatment	7.34	0.87	4.77	1.00	64.98	5.1594	0.0001*
	After treatment	2.57	0.92					
Study group	Before treatment	7.63	0.77	6.43	0.85	84.27	5.1598	0.0001*
	After treatment	1.20	0.68					

*p<0.05

Figure 6: Comparison of before and intra treatment pain scores in control group and study group

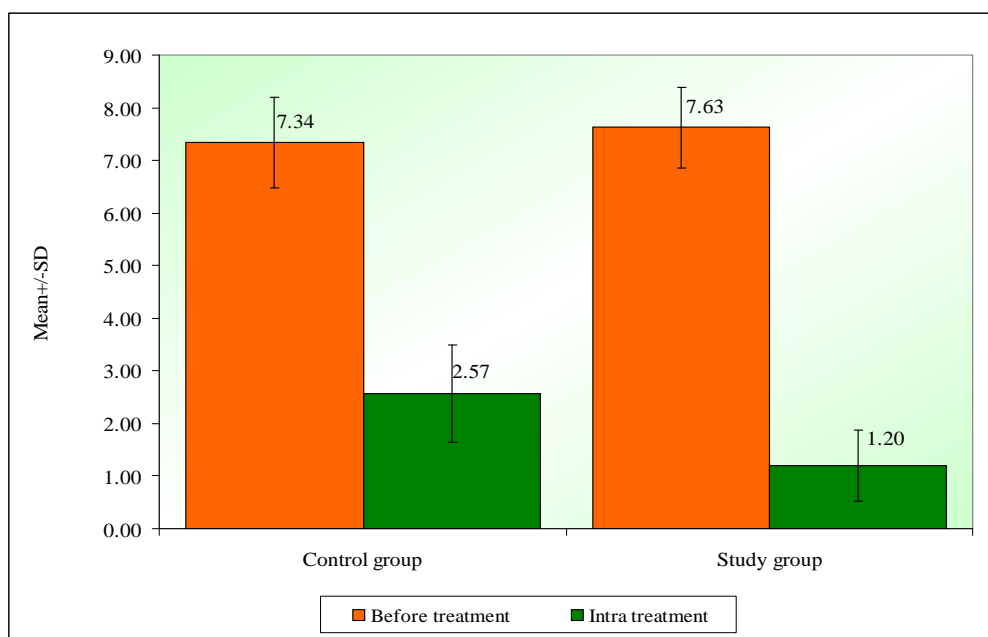
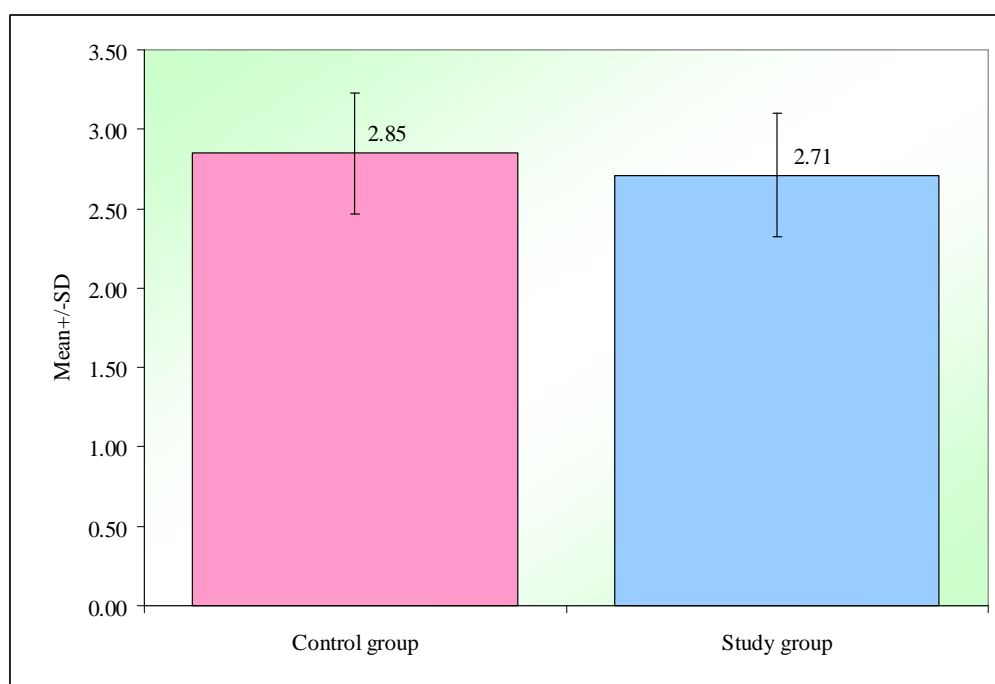


Table 7: Comparison of control group and study group with mean initial Electric Pulp tester scores by Independent t test

Groups	Mean	SD	SE	t-value	P-value
Control group	2.85	0.38	0.06	1.4612	0.1486
Study group	2.71	0.39	0.07		

Figure 7: Comparison of control group and study group with mean initial Electric Pulp tester scores



Observations

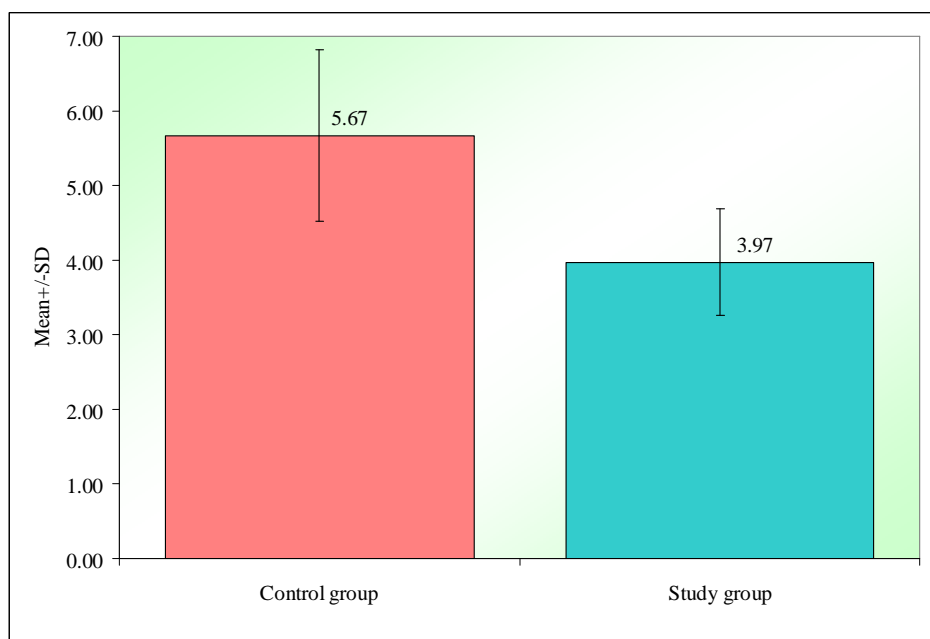
Table 7 represents Initial Pulp tester score of 2.71 + 0.39 of study group and 2.85 + 0.38 of control group. The p value of 0.1486 indicates that there is not much significant difference in initial reading thus eliminating bias.

Table 8: Comparison of control group and study group with mean time taken to achieve anesthesia (min) by Independent t test

Groups	Mean	SD	SE	t-value	P-value
Control group	5.67	1.15	0.21	7.2502	0.0001*
Study group	3.97	0.71	0.12		

*p<0.05

Figure 8: Comparison of control group and study group with mean time taken to achieve anesthesia (min)



Observations

Table 8 shows mean time taken to achieve anesthesia (min) in control group which is 5.67 + 1.15 and in study group which is 3.97 + 0.71. Thus, indicating a faster onset of action in case of study group. The p value of 0.0001 indicates significant difference between two groups.

DISCUSSION

Tooth extraction is most common procedure performed by an “Oral and Maxillofacial Surgeon” in their daily practice. Pain is the most common symptom reported by the patient requiring tooth extraction. Due to lack of screening and no regular dental visits, dental caries prevalence in India is about 54.16%¹⁸. Further consequences of dental caries led to pulpitis and periapical pathology causing pain.

pH of tissue was measured in a study in the presence of inflammation (pus) which was 5.0¹. This pH change interferes with the dissociation of LA.

Commercial LA (2% lignocaine containing 1:80000 adrenaline) have pH around 3.3²⁸ or in range of 3.5 to 4.4³³. Although acidic pH extends shelf life of solution and prevents oxidation of adrenaline but in return results in burning sensation on infiltration and has slower onset of action²⁹.

Total of 70 patients were taken in this study which were equally divided into two groups control and study after fulfilling eligibility criteria. Mean age of patient was 40.41 + 10.96. Both groups had similar age distribution, thus bias based on pain perception in different age group which was reported by Stephen Gibson et al and Farrell et al was nullified¹⁹.

Alkalisiation of local anesthetic solution was done just before procedure to avoid precipitation of lipids due to lower water solubility, decrease stability because of more uncharged base form and adrenaline present in LA is unstable at physiological pH. Clouding of solution after adding sodium bicarbonate denotes

precipitation making solution ineffective. As precipitation increases with time buffered solution should be freshly prepared²³.

Paul Larson et al in his study “Stability of Buffered Lidocaine and Epinephrine used for Local Anaesthesia” noticed deterioration of buffered lidocaine at room temperature, 26.95% in 2 weeks and 1.34% at 4 weeks³⁰. To encounter this drawback in our study freshly prepared buffered solution was used. In this study, 8.4% sodium bicarbonate was added to 2% lignocaine with 1:80000 epinephrine in ratio of 10:1, thus obtaining buffered solution. This solution was stable (did not precipitate) as reported by Fitton el al¹⁴. Buffered solution was freshly prepared just before administration to increase its efficacy. This was also supported by Christoph R A et al in his study³¹.

In a study by Vent el al, stated that buffering the solution by adding sodium bicarbonate in ratio of 3:1 was more effective as compared to 9:1 ratio³². While study by G Arora et al² and Gupta et al⁴ reported dilution ratio of 10:1 to be more beneficial. Thus in our study sodium bicarbonate was added in 10:1 ratio in accordance to literature.

Pre operative pain was evaluated by VAS and EPT for both groups (Table 4), which suggested that there was not much difference between two groups preoperatively thus removing the selection bias. Both the group patient mostly presented moderate to severe initial pain as infected (TOP +ve) tooth were taken. EPT reading was also lower suggestive of lower pain threshold (Table 7).

The acidity of commercial LA is responsible for pain or burning sensation (discomfort) during infiltration for infected tooth removal (acidic environment)²⁰. Buffering the conventional solution by adding sodium bicarbonate should reduce the pain or burning sensation theoretically. This result was supported by study done by G Arora et al². In our study burning sensation was evaluated while infiltration (Table 3) which suggested that majority of study group patient didn't report any burning sensation.

Alkalinization of LA results in increased pH and also formation of carbon dioxide and water. Condouris et al noticed that carbon dioxide increased the efficacy of LA and conduction blockage was significantly higher as compared to commercial LA preparation²⁴. Bromage et al suggested that carbon dioxide acts by increasing flow of LA into nerve membrane thus, shortening the time of onset of action and increased spread of analgesia by 20% - 30% in epidural anesthesia²⁵.

Vinay Kashyap et al in his study found out quicker onset of action of buffered lignocaine compared to commercial lignocaine even in normal tooth extraction cases while giving mandibular nerve blocks (inferior alveolar, lingual and long buccal)²¹. Similar results were obtained in our study in which onset of action in study group was $3.97 + 0.71$ and in control group was $5.67 + 1.15$. This result was also supported by study by G Arora et al, which compared the onset of action in both group and mean difference was 2.96 min ². There were five patient in control group (Non buffered) in which LA was ineffective, while other 20 patients in which soft tissue anesthesia was achieved but while attempting extraction patient experienced pain. For all such patients nerve block was given for pain control and extraction was done. While buffered lignocaine was effective in each and every patient.

After administration of local anesthetic, faster formation of a mixture of charged and uncharged forms results rapid drug diffusion across nerve membrane and quicker onset of action²³.

J M Ritchie et al (1965) in his article on effect of local anesthesia on nerve fibres found out that alkaline anesthetic solution acts more effectively on all type of nerve fibres (myelinated and non myelinated). Thus, have better pain relieving action²².

Dissociation constant (pKa) determine the onset of action of LA. A lower pKa increases tissue uptake and hastens the onset of action²⁶. Thus, in cases of inflammation, decreased pH may reduce onset of action while increasing in pH results in faster onset of action.

James A Phero et al compared effect of Buffered and Non-Buffered lidocaine with Epinephrine in Mandibular Nerve Block and concluded that buffered LA required less time to induce lip numbness as compared to hard tissue. But in our study as local infiltration was given, no such discrepancies were noticed²⁷.

Split mouth technique would have given more appropriate results as pain threshold varies from patient to patient.

SUMMARY AND CONCLUSION

The current randomized prospective study evaluated the efficacy of buffered lignocaine in extraction of infected tooth.

It was evident from our study that buffered lignocaine was more effective as compared to commercial lignocaine (2% lignocaine hydrochloride with 1:80000 adrenaline) in controlling pain in extraction of infected tooth and also burning sensation was significantly lower while infiltration. Onset of action was quicker in buffered lignocaine thus relieving the symptoms rapidly as compared to control group (commercial lignocaine).

This study concluded that buffered lignocaine was more effective compared to commercial nonbuffered lignocaine in extraction of infected tooth while giving local infiltration.

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ANNEXURE I – CONSENT FORM

KAHER’s KLE VK Institute of Dental Sciences

Department of Oral and Maxillofacial Surgery Belagavi

CONSENT FORM

**EVALUATION OF THE EFFICACY OF BUFFERED LOCAL ANESTHETICS
IN EXTRACTION OF INFECTED TEETH - RANDOMIZED DOUBLE BLIND
STUDY**

OPERATOR: DR. TOLE NINAD NIKHIL

I, _____ aged _____
have been informed about my involvement in the study:

- 1) I agree to give my personal details like name, age, sex, address and the details required for the study to the best of my knowledge.
- 2) I agree and give my consent to the oral surgeon for this procedure.
- 3) I have been informed about the possible complications following local anesthetic administration.
- 4) I permit the dentist to utilize the information given by me and results obtained from this study for presentation and publication purpose.
- 5) I will not claim any returns for my cooperation in the study, even if it is being sponsored by any agency. I am participating with my own will and wish.
- 6) I will follow the instructions given by the doctor.
- 7) During the study, if I wish to resign from the study, I am free to do so and my treatment will still be completed in the department.

In my full consciousness and presence of mind, after understanding all the procedure in my vernacular language, I am willing and give my consent to participate in this study.

Date:

Place:

Subject's Signature

Signature of witness

ANNEXURE II – BIostatISTICS CLEARANCE CERTIFICATE



KLE V.K. Institute of Dental Sciences

(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA

Re-Accredited 'A' grade by NAAC (2nd Cycle) & Placed in Category 'A' by MHRD (GoI)

TEL : 0831-2470362
FAX: 0831-2470640

Web: <http://www.kledental-bgm.edu.in>
E-mail: principal@kledental-bgm.edu.in



Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of **REG.NO. - IF0220006** , Post Graduate Student, under the guidance of **Professor, Department of ORAL AND MAXILLOFACIAL SURGERY**, entitled “**EVALUATION OF THE EFFICACY OF BUFFERED LOCAL ANESTHETICS IN EXTRACTION OF INFECTED TEETH – RANDOMIZED DOUBLE BLIND STUDY**” has been done under my guidance and considered satisfactory.

Place: Belagavi

Date: *09/12/2022*

Name & Signature of Biostatistician

Dr. S.B. Jawali
Sr. Asst. prof. in statistics
Dept. of com. medicine
CSM KLE DMP, Belagavi.

ANNEXURE III – ETHICAL CLEARANCE CERTIFICATE



Research and Ethics Committee
KLE V K INSTITUTE OF DENTAL SCIENCES
KLE University



Accredited 'A' Grade by NAAC

Placed in Category 'A' by MHRD (Govt)

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SI. No. : 1468

CERTIFICATE

This is to Certify that the synopsis titled

*Evaluation of the efficacy of Buffered Local
Anesthetics in extraction of Infected teeth*

- Randomized Double Blind Study . Submitted by

Dr. _____ REG.NO. - IF0220006 _____ P. G. Student /

Staff, Guided by _____ from Department of
and maxillofacial
Oral Surgery _____ has been critically evaluated by
committee members and granted ethical clearance to conduct the above
mentioned study

Date : 5/5/21

[Signature]
Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

[Signature]
Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Research and Ethical Committee
KLE V K Institute of Dental Sciences

Research and Ethical Committee
KLE V K Institute of Dental Sciences

ANNEXURE IV

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi

Department of Oral and Maxillofacial Surgery

Patient Information Sheet

**“Evaluation of the efficacy of buffered local anesthetics in extraction of
infected teeth - Randomized double blind study”**

Dear Patient,

You are invited to take part in a research to evaluate efficacy of buffered local anaesthetics in extraction of infected teeth. I would like to evaluate parameters before and after extraction of infected teeth. This research is a part of a MDS, main dissertation at KLE Academy of Higher Education and Research.

Before you decide whether to take part in the study it is important that you understand what the research is for and what you will be asked to do. Please take time to read the following information and discuss it with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep. You will be also asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving any reason. The standard of care you receive will not change whether or not you decide to participate in this study.

Since traditional local anaesthetic sometimes fail to act completely in infected cases, we are using buffered local anaesthetic in which 8.4% NaHCO₃ will be added to increase pH of local anaesthetic which can act better in infected cases and help in painless removal of the teeth.

You have been chosen because you have been diagnosed with infected teeth. The study will involve minimum 68 participants who will be examined and randomly divided into study and control group. According to the group intervention will be done and different parameters will be evaluated.

The information gained from this research will be used to publish in scientific platforms/ journals without revealing your identity to make recommendations for the best practice and the results of the study may also lead onto further studies into the management of infected teeth with buffered local anaesthetic.

PG Student (MDS)

Dept. of Oral and Maxillofacial Surgery,

KLEVKIDS, Belagavi

संमती पत्र

संक्रमित दात काढण्यासाठी बफर्ड लोकल अनेस्थेटिक्सच्या कार्यक्षमतेचे मूल्यांकन -
रॅडोमिज्ड डबल ब्लॅंड अभ्यास

ऑपरेटर: डॉ. टोले निनाद निखिल

मला, _____ वयाची _____ मला माझ्या
अभ्यासामध्ये सामील असल्याची माहिती दिली आहे:

- 1) मी माझे वैयक्तिक तपशील जसे की नाव, वय, लिंग, पत्ता आणि अभ्यासासाठी आवश्यक असलेल्या तपशीलांना माझ्या सर्वोत्तम माहिती देण्यास सहमत आहे.
- 2) मी सहमत आहे आणि या प्रक्रियेसाठी तोंडी शल्य चिकित्सकांना माझी संमती देतो.
- 3) स्थानिक अनेस्थेटिक प्रशासनानंतर मला संभाव्य गुंतागुंतांविषयी माहिती देण्यात आली आहे.
- 4) मी दंतचिकित्सकांकडून माझ्याद्वारे दिलेली माहिती आणि या अभ्यासामधून प्राप्त झालेल्या सादरीकरणासाठी आणि प्रकाशनाच्या उद्देशाने वापरण्यास परवानगी देतो.
- 5) मी अभ्यासासाठी केलेल्या सहकार्यासाठी कोणत्याही परताव्याचा दावा करणार नाही, जरी ती कोणत्याही एजन्सीने प्रायोजित केली असेल. मी माझ्या स्वतःच्या इच्छेने आणि इच्छेने सहभाग घेत आहे.
- 6) मी डॉक्टरांनी दिलेल्या सूचनांचे पालन करेन.
- 7) अभ्यासादरम्यान, मला अभ्यासाचा राजीनामा द्यायचा असल्यास मी असे करण्यास मोकळे आहे आणि माझे उपचार अद्याप विभागात पूर्ण होतील.

माझ्या पूर्ण चेतने आणि मनाच्या उपस्थितीत, माझ्या स्थानिक भाषेतील सर्व प्रक्रिया समजल्यानंतर मी इच्छुक आहे आणि या अभ्यासामध्ये भाग घेण्यास मी संमती देतो.

तारीख:

ठिकाण:

विषयाची स्वाक्षरी

साक्षीची सही

ಒಪ್ಪಿಗೆ ಪತ್ರ

ಸೋಂಕಿತ ಹಲ್ಲುಗಳನ್ನು ಹೊರತೆಗೆಯುವಲ್ಲಿ ಬರ್ಲಿನ್ ಸ್ಥಳೀಯ ಅರಿವಳಿಕೆಗಳ ಪರಿಣಾಮಕಾರಿತ್ವದ ಮೌಲ್ಯಮಾಪನ -
ಯಾದ್ಯತ್ ಿzed ಿಕ ಡಬಲ್ ಬ್ಲೈಂಡ್ ಅಧ್ಯಯನ

ಅಪರೇಟರ್: ಡಿ.ಆರ್. ಟೋಲ್ ನಿನಾಡ್ ನಿಖಿಲ್

ನಾನು, _____ ವಯಸ್ಸಿನ _____ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ
ವಾಲ್ವಿಕ್ಟಿವಿಟಿಯ ಬಗ್ಗೆ ತಿಳಿಸಲಾಗಿದೆ:

- 1) ನನ್ನ ವೈಯಕ್ತಿಕ ವಿವರಗಳಾದ ಹೆಸರು, ವಯಸ್ಸು, ಲಿಂಗ, ವಿಳಾಸ ಮತ್ತು ಅಧ್ಯಯನಕ್ಕೆ ಬೇಕಾದ ವಿವರಗಳನ್ನು ನನ್ನ
ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮವಾಗಿ ನೀಡಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ.
- 2) ಈ ವಿಧಾನಕ್ಕಾಗಿ ಮೌಖಿಕ ಶಸ್ತ್ರಚಿಕಿತ್ಸಕನಿಗೆ ನಾನು ಒಪ್ಪುತ್ತೇನೆ
- 3) ಸ್ಥಳೀಯ ಅರಿವಳಿಕೆ ಅಡಳಿತವನ್ನು ಅನುಸರಿಸಿ ಸಂಭವನೀಯ ತೊಂದರೆಗಳ ಬಗ್ಗೆ ನನಗೆ ತಿಳಿಸಲಾಗಿದೆ.
- 4) ದಂತವೈದ್ಯರಿಗೆ ನಾನು ನೀಡಿದ ಮಾಹಿತಿ ಮತ್ತು ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಸ್ತುತಿ ಮತ್ತು ಪ್ರಕಟಣೆ
ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಿಕೊಳ್ಳಲು ನಾನು ಅನುಮತಿ ನೀಡುತ್ತೇನೆ.
- 5) ಯಾವುದೇ ವಿಜ್ಞಾನಿಯಿಂದ ಪ್ರಾಯೋಜಿಸಲ್ಪಟ್ಟಿದ್ದರೂ ಸಹ, ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಸಹಕಾರಕ್ಕಾಗಿ ಯಾವುದೇ ಆದಾಯವನ್ನು
ನಾನು ಪಡೆಯುವುದಿಲ್ಲ. ನಾನು ನನ್ನ ಸ್ವಂತ ಇಚ್ಛೆ ಮತ್ತು ಆಶಯದೊಂದಿಗೆ ಭಾಗವಹಿಸುತ್ತಿದ್ದೇನೆ.
- 6) ವೈದ್ಯರು ನೀಡಿದ ಸೂಚನೆಗಳನ್ನು ನಾನು ಅನುಸರಿಸುತ್ತೇನೆ.
- 7) ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ, ನಾನು ಅಧ್ಯಯನಕ್ಕೆ ರಾಜೀನಾಮೆ ನೀಡಲು ಬಯಸಿದರೆ, ನಾನು ಅದನ್ನು ಮಾಡಲು
ಮುಕ್ತನಾಗಿರುತ್ತೇನೆ ಮತ್ತು ನನ್ನ ಚಿಕಿತ್ಸೆಯು ಇನ್ನೂ ಇಲಾಖೆಯಲ್ಲಿ ಪೂರ್ಣಗೊಳ್ಳುತ್ತದೆ.

ನನ್ನ ಪೂರ್ಣ ಪ್ರಜ್ಞೆ ಮತ್ತು ಮನಸ್ಸಿನ ಉಪಸ್ಥಿತಿಯಲ್ಲಿ, ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿನ ಎಲ್ಲಾ ಕಾರ್ಯವಿಧಾನಗಳನ್ನು
ಅರ್ಥಮಾಡಿಕೊಂಡ ನಂತರ, ನಾನು ಸಿದ್ಧನಾಗಿದ್ದೇನೆ ಮತ್ತು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು
ನೀಡುತ್ತೇನೆ.

ದಿನಾಂಕ:

ಸ್ಥಳ:

ವಿಷಯದ ಸಹಿ

ಸಾಕ್ಷಿಯ ಸಹಿ

ANNEXURE VI – MAIN SHEET

Sr No	Name	Age	Gender	Group	Teeth extracted	Burning Sensation while injecting LA	Pain Score		Electric Pulp tester reading	Time taken to achieve anesthesia (min)
							Before	Intra Op		
1	Dananjay Adiler	32	Male	C	26	Yes	8	3	2.4	6
2	Lellavati	27	Female		26	Yes	8	1	2.1	3
3	Vishnu P	46	Male	C	26	Yes	7	3	2.6	5
4	Nirmala Y P	33	Female	C	24	Yes	6	3	3.1	5
5	Nirmala S G	32	Female		31 32 41 42	No	7	1	2.8	3
6	Veena N	36	Female	C	21 23	Yes	7	2	3.2	6
7	Muntazheja Khatib	52	Female	C	16	Yes	6	2	2.1	5
8	Pooja Bhatia	26	Female		16	No	7	1	2.3	4
9	Deepa Narasagol	45	Female	C	17	Yes	9	3	2.7	7
10	Mahish Ginde	45	Male		25	No	8	0	2.9	4
11	Ritu Choughale	43	Female	C	15	Yes	9	4	3.1	Not acted
12	Ritu R	21	Female		42	yes	8	0	2.6	3
13	Talasava Shinageri	55	Female	C	21	Yes	7	1	2.9	5
14	Naseem A B	47	Male		13	No	8	1	2.4	4
15	Nayab A	36	Male	C	15	yes	7	2	2.1	7
16	Sonam	33	Female		25	No	7	1	3.4	4
17	Ayush P	28	Male	C	21	Yes	6	2	2.3	6
18	Suresh Patil	42	Male		25	Yes	9	1	2	3
19	Pavan G	58	Male	C	16	Yes	7	2	3.3	7

20	Abduleashid Sanadi	31	Male		25	No	6	0	2.9	4
21	Shantavva S	60	Female	C	21	No	7	2	3.5	6
22	Arjun M	22	Male		21	No	8	1	2.4	6
23	Sulochana P	59	Female	C	25	Yes	6	3	3.2	6
24	Laxmi S	39	Female		15	No	8	2	2.9	4
25	Girija N	48	Female	C	41	No	8	3	2.3	Not acted
26	Nagendra L	46	Male	C	14	No	7	2	3.1	6
27	Vidhya S	31	Female	C	26	Yes	7	2	2.9	7
28	Geeta N	52	Female	C	16	Yes	6	1	2.8	7
29	Maseera Kittur	27	Female		15	No	8	2	3	3
30	Shivakka Patil	62	Female	C	14 15	Yes	7	1	2.4	7
31	Albert Lobo	37	Male	C	13	Yes	6	2	3.2	6
32	Varsha V	40	Female		15	No	8	2	2.9	5
33	Mallavva	57	Female	C	24	Yes	8	1	3.3	6
34	Mohan Adhikeri	38	Male		15	No	9	1	2.1	4
35	Nitin Badmarji	41	Male		15	No	7	2	2.4	5
36	Bhavani Shingavi	57	Female		24 25	No	6	0	2.8	4
37	Anand C	34	Male	C	16	Yes	8	1	3.2	8
38	Poonam Kowadkar	22	Female		41	Yes	7	1	2.9	4
39	Aishwarya P	25	Female		17	No	7	1	2.7	4
40	Kashappa B K	59	Male	C	17	Yes	8	3	2.6	8
41	Sultan Hirani	52	Male		23	Yes	7	1	2.8	3
42	Rohit Kerkar	34	Male		21	No	8	1	3.3	5
43	Laxmi Lohar	38	Female	C	32	Yes	8	3	3.6	6
44	Supreeta Mulimani	41	Female		24	No	8	1	3.4	4
45	Nilamma P	53	Female		25	No	7	2	2.8	4
46	Yallappa K	60	Female	C	24	Yes	7	4	2.6	Not acted

47	Rashmi Bani	36	Female		24	No	7	0	2.7	4
48	Albert M	42	Male	C	26	Yes	8	4	2.8	Not acted
49	Arnav Savant	31	Male	C	15	Yes	7	3	3.2	7
50	Poonam Kowadkar	23	Female		22	No	7	2	2.7	4
51	Manoj K	45	Male	C	24	Yes	8	4	2.9	7
52	Nirmala P	51	Female		25 26	No	7	1	3.1	4
53	Kasturi Badmarji	49	Female		23	No	8	2	2.4	4
54	Manohar Jha	36	Male	C	14	Yes	7	3	2.7	7
55	Kailash Patil	38	Male		17	No	8	2	3.4	4
56	Kanakya V	41	Female	C	15	Yes	7	3	3.2	8
57	Mohsin Pathan	28	Male	C	14	Yes	9	3	2.4	7
58	Bibi Jahan	43	Female		24	No	9	2	2.6	5
59	Saurav B	29	Male		26	No	7	1	2.8	4
60	Kamlesh K	50	Male		26	No	8	2	3.3	5
61	Devansh Patil	36	Male	C	24	Yes	8	3	2.9	8
62	Kshama K	31	Female		27	No	9	1	2.5	4
63	Muskan Khan	24	Female	C	25	No	7	3	2.8	7
64	Kaishav Pudalik	37	Male		26	No	8	2	2.2	4
65	Rahil P	39	Male	C	24 25	No	8	2	2.9	8
66	Gangu P	53	Female	C	16	Yes	8	3	2.8	7
67	Kusum S	29	Female		23	No	7	1	2.9	3
68	Aslam S	36	Male		15	No	8	2	2.3	4
69	Tasleem	53	Female	C	26	Yes	8	4	2.6	Not acted
70	Rishi P	47	Male		16	No	8	1	2.3	3

CONTROL GROUP

Sr No	Name	Age	Gender	Group	Teeth extracted	Burning Sensation while injecting LA	Pain Score		Electric Pulp tester reading	Time taken to achieve anesthesia (min)
							Before	Intra Op		
1	Dananjay Adiler	32	Male	C	26	Yes	8	3	2.4	6
2	Vishnu P	46	Male	C	26	Yes	7	3	2.6	5
3	Nirmala Y P	33	Female	C	24	Yes	6	3	3.1	5
4	Veena N	36	Female	C	21 23	Yes	7	2	3.2	6
5	Muntazheja Khatib	52	Female	C	16	Yes	6	2	2.1	5
6	Deepa Narasagol	45	Female	C	17	Yes	9	3	2.7	7
7	Ritu Choughale	43	Female	C	15	Yes	9	4	3.1	Not acted
8	Talasava Shinageri	55	Female	C	21	Yes	7	1	2.9	6
9	Nayab A	36	Male	C	15	yes	7	2	2.1	7
10	Ayush P	28	Male	C	21	Yes	6	2	2.3	6
11	Pavan G	58	Male	C	16	Yes	7	2	3.3	7
12	Shantavva S	60	Female	C	21	No	7	2	3.5	6
13	Sulochana P	59	Female	C	25	Yes	6	3	3.2	6
14	Girija N	48	Female	C	41	No	8	3	2.3	Not acted
15	Nagendra L	46	Male	C	14	No	7	2	3.1	6
16	Vidhya S	31	Female	C	26	Yes	7	2	2.9	7
17	Geeta N	52	Female	C	16	Yes	6	1	2.8	7
18	Shivakka Patil	62	Female	C	14 15	Yes	7	1	2.4	7
19	Albert Lobo	37	Male	C	13	Yes	6	2	3.2	6
20	Mallavva	57	Female	C	24	Yes	8	1	3.3	6
21	Anand C	34	Male	C	16	Yes	8	3	3.2	8

22	Kashappa B K	59	Male	C	17	Yes	8	3	2.6	8
23	Laxmi Lohar	38	Female	C	32	Yes	8	1	3.6	6
24	Yallappa K	60	Female	C	24	Yes	7	4	2.6	Not acted
25	Albert M	42	Male	C	26	Yes	8	4	2.8	Not acted
26	Arnav Savant	31	Male	C	15	Yes	7	3	3.2	7
27	Manoj K	45	Male	C	24	Yes	8	4	2.9	7
28	Manohar Jha	36	Male	C	14	Yes	7	3	2.7	7
29	Kanakya V	41	Female	C	15	Yes	7	3	3.2	8
30	Mohsin Pathan	28	Male	C	14	Yes	9	3	2.4	7
31	Devansh Patil	36	Male	C	24	Yes	8	3	2.9	8
32	Muskan Khan	24	Female	C	25	No	7	3	2.8	7
33	Rahil P	39	Male	C	24 25	No	8	2	2.9	8
34	Gangu P	53	Female	C	16	Yes	8	3	2.8	7
35	Tasleem	53	Female	C	26	Yes	8	4	2.6	Not acted

STUDY GROUP

Sr No	Name	Age	Gender	Group	Teeth extracted	Burning Sensation while injecting LA	Pain Score		Electric Pulp tester reading	Time taken to achieve anesthesia (min)
							Before	Intra Op		
1	Lellavati	27	Female		26	Yes	8	1	Initial 2.1	3
2	Nirmala S G	32	Female		31 32 41 42	No	7	1	2.8	3
3	Pooja Bhatia	26	Female		16	No	7	1	2.3	4
4	Mahish Ginde	45	Male		25	No	8	0	2.9	4
5	Ritu R	21	Female		42	yes	8	0	2.6	3
6	Naseem A B	47	Male		13	No	8	1	2.4	4
7	Sonam	33	Female		25	No	7	1	3.4	4
8	Suresh Patil	42	Male		25	Yes	9	1	2	3
9	Abduleashid Sanadi	31	Male		25	No	6	0	2.9	4
10	Arjun M	22	Male		21	No	8	1	2.4	6
11	Laxmi S	39	Female		15	No	8	2	2.9	4
12	Maseera Kittur	27	Female		15	No	8	2	3	3
13	Varsha V	40	Female		15	No	8	2	2.9	5
14	Mohan Adhikeri	38	Male		15	No	9	1	2.1	4
15	Nitin Badmarji	41	Male		15	No	7	2	2.4	5
16	Bhavani Shingavi	57	Female		24 25	No	6	0	2.8	4
17	Poonam Kowadkar	22	Female		41	Yes	7	1	2.9	4
18	Aishwarya P	25	Female		17	No	7	1	2.7	4
19	Sultan Hirani	52	Male		23	Yes	7	1	2.8	3
20	Rohit Kerkar	34	Male		21	No	8	1	3.3	5
21	Supreeta Mulimani	41	Female		24	No	8	1	3.4	4
22	Nilamma P	53	Female		25	No	7	2	2.8	4

23	Rashmi Bani	36	Female		24	No	7	0	2.7	4
24	Poonam Kowadkar	23	Female		22	No	7	2	2.7	4
25	Nirmala P	51	Female		25 26	No	7	1	3.1	4
26	Kasturi Badmarji	49	Female		23	No	8	2	2.4	4
27	Kailash Patil	38	Male		17	No	8	2	3.4	4
28	Bibi Jahan	43	Female		24	No	9	2	2.6	5
29	Saurav B	29	Male		26	No	7	1	2.8	4
30	Kamlesh K	50	Male		26	No	8	2	3.3	5
31	Kshama K	31	Female		27	No	9	1	2.5	4
32	Kaishav Pudalik	37	Male		26	No	8	2	2.2	4
33	Kusum S	29	Female		23	No	7	1	2.9	3
34	Aslam S	36	Male		15	No	8	2	2.3	4
70	Rishi P	47	Male		16	No	8	1	2.3	3