"A COMPARATIVE EVALUATION OF 0.5% LEVOBUPIVACAINE, 2%LIDOCAINE & 4% ARTICAINE AS LOCAL ANESTHETIC AGENTS IN PEDIATRIC DENTAL PATIENTS "

DISSERTATION

Submitted to

BABU BANARASI DAS UNIVERSITY,

LUCKNOW, UTTAR PRADESH

In the partial fulfilment of the requirements for the degree

of

MASTER OF DENTAL SURGERY

In

PEDIATRIC AND PREVENTIVE DENTISTRY

By

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ACKNOWLEDGEMENT

"The beginning of all wisdom is acknowledgement of facts." The three years of my post-graduation have been a voyage of discovery for me. Thank you are two little words which would probably never convey the sense of gratitude and regards which I feel for all the wonderful people who have made this research a reality. Thus I humbly take this opportunity to acknowledge them for their varied contributions in so many ways that helped me during the making of this dissertation.

I acknowledge my gratitude to my guide and mentor **Dr. Subash Singh** for the continuous support that he has shown. His advice and invaluable guidance helped me to sail through all the troubles during this research project. I am also immensely grateful to him for sharing his patience, motivation and knowledge with me. Above all, I thank him for his unwavering support, collegiality and mentorship throughout these 3 years.

Above all, I would like to thank the head of the family **Dr. Monika Rathore**, Professor and Head of the Department for her unflinching support, advice and brilliant supervision.

Her valuable suggestions and her instructions has served as the major contributor towards the completion of this project.

I am extremely thankful to **Dr. Neerja Singh** and **Dr. Somya Govil** for their kind cooperation and helping me with the conductance of my dissertation, without whose constant support this dissertation would not have been possible.

Finally, I would like to acknowledge with gratitude, the support and love of my mother, **Mrs Sanjana Sahu** and father, **Mr. Pradeep Sahu** who have been the pillars of my strength. Also the constant help and the unlashing support of my brother, **Pratik Sahu** has always motivated me to work.

I would also like to enormously thank to **Dr. Monisha Moses**, **Dr. Mansi Semwal**, **Dr. Khyati Kaushal**, **Dr. Sharlin Ahmad**, **Dr. Anu Bhat and Dr. Naina Agrawal** for their valuable time, knowledge and guidance throughout these three years. Their

incessant encouragement and professional insight has helped me to learn in the right direction by leaps and bounds.

Finally, I will be failing in my duty if I do not thank whose profound help, support and sincerity has helped me in completing my thesis. I deeply appreciate the undying support from my dear collegues**, Dr. Saheli Basu, Dr. Akash Roy Chowdhury**, **Dr. Needhi Singh** and **Dr. Bibhav Dubey**. My journey in this department would be incomplete without their encouragement and patience through the constant highs and lows.

I also extend my heartfelt gratefulness to **Mr. Rajesh Shukla, Dr. Aayushi Bharadwaj**, **Dr. Ajay Yadav**, **Dr. Sadia Salman**, **Dr. Ninapyari Ahanthem**, **Dr. Sarwani Mishra, Dr. Spandan Dey, Dr. Anushka Banerjee, Dr. Shreeja Anand, Dr. Sushmita Gupta, Dr. Shifa Amir** A special thanks to my friends **Shubham Chaturvedi**, **Biswajit Bagchi**, **Dr. Aman Kumar**, **Dr. Rajatava Paria**, **Dr. Pratik Maity** who have always been my side and supported me throughout my journey.

It is a pleasure at this point to thank my principal, **Dr. Puneet Ahuja** for providing me with the opportunity to conduct the research and use the facilities of this college.

I want to convey my deepest appreciation to all non- teaching staff at the Department of Pedodontics for their kind and helpful nature.

This is dedicated to my family, friends and teachers who supported me on this journey and without them this would have been only a dream.

Dr. Raunaq Pradeep Sahu

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S.NO	ABBREVIATED FORM	FULL FORM
1.	%	Percentage
2.	IANB	Inferior Alveolar Nerve Block
3.	WBFPS	Wong Baker's Faces Pain Scale
4.	ASA	American Society Of Anaesthesiologists
5.	BI	Buccal Infiltration

ABSTRACT

Aim. To compare pain perception & anesthetic efficacy of 0.5% Levobupivacaine, 2% Lidocaine & 4% Articaine in pediatric dental patients.

Materials and Methods. The present in-vivo study was carried out in children of both the genders categorized as ASA I (American Society of Anesthesiologists) and Frankl III and IV with an age group of 5-16 years, requiring complex dental treatments. The patients were allocated to three treatment groups, Group I (0.5% Levobupivacaine), Group II (2% Lidocaine), and Group III (4% Articaine). The study was performed by two investigators; investigator 1 performed procedure of administering local anesthesia & investigator 2 recorded the scores of pain scale. In Group 1 patients received injections of 0.8mL of 0.5% Levobupivacaine infiltration. Group 2 patients received 0.8mL of 2% Lidocaine with epinephrine 1:100000 infiltration. Group 3 patients received 0.8mL of 4% Articaine with adrenaline 1:100000 infiltration. Supplemental block was given if required in all the three groups. The allocations of the subjects to the groups were randomly done. The pain experienced during the injection of various anesthetic agents was asked and recorded immediately by the investigator as told by the subjects on the pain rating scale. Anesthetic efficacy of the various anesthetic agents was recorded by the investigator on the basis of pain described by the subjects on pain rating scale (Won Baker's Pain rating scale) during complex dental procedures i.e. Pulp therapy, Extractions and Surgical procedures.

Results. Pain scores during administration of anesthesia was significantly less in Group I as compared to Group II and Group III, (P=0.001). There was no statistically significant difference in pain scores during complex dental treatment among the three

groups, suggestive of equivalent efficacy. Safety of anesthetic agent was assessed on the basis of incidence of Bleeding (12.5%), Trismus (7.5%), Vomiting and Dizziness (2.5%) post-operatively. Safety scores were higher with Levobupivacaine followed by Articaine and Lidocaine.

Conclusion. The present study concluded that 0.5% Levobupivacaine proved to be least painful, more safer and efficacious anesthetic agent as compared to 4% Articaine and 2% Lidocaine. Hence 0.5% Levobupivacaine is a better alternative and can be recommended for pediatric patients requiring complex dental procedures.

INTRODUCTION

Pain is defined as "an unpleasant sensory and emotional experience linked with existing or potential tissue damage, or explained in terms of such damage" by the **International Association for the Study of Pain** (IASP)[1]. Sensory refers to the senses of touch, hearing, taste, smell, and sight, which create an experience that is transferred per se from the sensory organs to the nerve centres through a nerve impulse. Dental pain is an inflammatory condition that can be classified as either somatic (periodontal, alveolar, or mucosal) or visceral i.e., pulpal. All patients should be assessed for pain by dental professionals. Patients may have substantial physical and psychological effects as a result of poor pain management.

Local anesthesia is defined as loss of sensation in circumscribed area of the body caused by depression of excitation of nerves endings or inhibition of conduction process in peripheral [2]

Dental procedures can cause discomfort and pain, which can be exacerbated by fear and anxiety, especially in children who need dental care. The child's expectation of pain can further complicate the situation. To treat young patients effectively, it is crucial to use the right amount and method of administering local anesthesia and provide behavior counseling. Local anesthesia can be administered to individual either through a nerve block approach or infiltration approach. Adequate local anesthesia is necessary for pain-free dental procedures and is achieved through the use of local anesthetic drugs. Before the advent of local anesthetic drugs, dental procedures were often unbearable and painful. The introduction of local anesthetics has revolutionized dentistry, beginning with the discovery of cocaine in 1860. Since then, a range of anesthetic medications have been developed and serve as the cornerstone for managing pain in dentistry.

In 1943, the first amide-type local anesthetic called lidocaine hydrochloride was synthesized in the field of dentistry. Lidocaine was later discovered in 1946 and became available for use in 1948. It is a commonly used local anesthetic, especially when combined with epinephrine, as it provides fast pain relief and can numb dental tissue for 60 to 90 minutes. Lidocaine is used for minor surgical procedures and dental surgeries, and can be administered through injection, inhalation, or topical application. However, it is important to monitor the amount given to prevent potential toxic effects on the body.

Another commonly used local anesthetic is 4 percent articaine combined with adrenaline. Articaine is a modern anesthetic that was synthesized in 1969 and became available in dental practices in the UK in 1998. It is an amide-type anesthetic that has improved lipid solubility due to its thiophene ring instead of a benzene ring. Although in most trials, 4 percent articaine was not found to be more effective than 2 percent lidocaine for inferior alveolar nerve block, it has been shown to be a potent nerve block when delivered through infiltration.

Bupivacaine is available in a racemic solution in which the two enantiomers, R (+) dextrorotatory and S (-) levorotatory stereoisomers, are present in equal proportions. Levobupivacaine is a S (-) isomer derivative that was created as a safer alternative to bupivacaine. Levobupivacaine was found to offer benefits over bupivacaine in terms of cardiotoxicity and CNS toxicity in human volunteer studies, and it can be utilised in paediatric patients. In dentistry, one human volunteer study compared the anaesthetic properties of 0.5% Bup and 0.5% Lbup, both associated with epinephrine (1: 200,000), and found no significant differences between the two anaesthetics in achieving onset time and duration of soft tissue and pulpal anaesthesia for an inferior alveolar nerve

block [3]. Despite the fact that Levobupivacaine has lower cardiotoxicity and CVS toxicity, dentists do not consistently employ it in their practise, possibly due to a lack of evidence. Hence, the present study was conducted with the aim to assess and analyse the local anaesthetic agents 0.5% Levobupivacaine, 2% Lidocaine, and 4% Articaine in pediatric dentistry patients.

Aim & Objectives.

AIM

To compare pain perception & anesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients.

OBJETIVES

1. To assess the pain perception during administration of 0.5% Levobupivacaine, 2% Lidocaine & 4% Articaine as a local anesthetic agent.
2. To assess and compare efficacy and safety of 0.5% Levobupivacaine, 2% Lidocaine & 4% Articaine as local anesthetic agents in pediatric patients undergoing dental procedures.

REVIEW OF LITERATURE

Wilson TG, Primosch RE, Melamed B and **Courts FJ (1990)**[4] studied clinical effectiveness of 1 and 2% lidocaine in pediatric dental patients. This effectiveness was measured by changes in the child's heart rate, the child's self-report of pain, and the operator's assessment of the anesthesia's effectiveness. Although the incidence of anesthetic failure was higher for the 1% solution (31.3%) than for the 2% solution (11.1%), no statistically significant difference between the solutions was found.

Baghdadi ZD (2000)[5] compared parenteral and electronic dental anesthesia during operative procedures in children. One tooth was treated with LA and another with EDA at the same appointment. The pain levels during restorative treatment were assessed using a color scale. Behavior was also assessed using sound, eye, and motor (SEM) scale. Although the success rate of EDA was less than that of LA, there was no significant difference between the two methods.

Malamed SF, Gagnon S and **Leblanc D (2000)**[6] compared safety and efficacy between articaine HCl and lidocaine HCl in pediatric dental patients. Three identical single-dose, randomized, double-blind, parallel-group, active-controlled multicenter studies were conducted to compare the safety and efficacy of articaine HCl (4% with epinephrine 1: 100,000) to that of lidocaine HCl (2% with epinephrine 1: 100,000) in patients aged 4 years to 79 years, with subgroup analysis on subjects 4 to < 13 years. VAS scores indicate that articaine is an effective local anesthetic in children and that articaine is as effective as lidocaine when measured on this gross scale. Articaine 4% with epinephrine 1:100,000 is a safe and effective local anesthetic for use in pediatric dentistry.

Berlin J, Nusstein J, Reader A, Beck M and **Weaver J (2005)**[7] evaluated the efficacy of articaine and lidocaine in a primary intraligamentary injection administered with a computer-controlled local anesthetic delivery system. Using a crossover design, intraligamentary injections of 1.4 mL of 4% articaine with 1: 100,000 epinephrine and of 1.4 mL of 2% lidocaine with 1: 100,000 epinephrine was

randomly administered with a computer-controlled local anesthetic delivery system, in a double-blind manner on the mesial and distal aspects of a mandibular first molar, at 2 separate appointments to 51 subjects. The study concluded that the efficacy of 4% articaine with 1:100,000 epinephrine was similar to the efficacy of 2% lidocaine with 1: 100,000 epinephrine for intraligamentary injections.

D. RAM (2006)[8] conducted a study to assess the time of onset, efficacy, duration of numbness of the soft tissues, children's sensation after treatment with both anesthetic solutions, as well as the occurrence of adverse epinephrine reactions in children who received local anesthesia with lidocaine 2 percent with 1: 100 000 epinephrine and articaine 4 percent with 1: 200 000 epinephrine. They found that articaine 4% with 1:200 000 epinephrine is just as effective as lidocaine 2% with 1:100 000 epinephrine. With articaine, the numbing effect on soft tissues lasted longer than with lidocaine

Batista da Silva C et al. (2010)[9] evaluated the anesthetic efficacy of articaine and lidocaine for incisive/mental nerve block. This prospective randomized double-blind crossover study compared the anesthetic efficacy of 0.6 mL 4% articaine and 2% lidocaine, both with 1:100.000 epinephrine administered as IANB to 40 volunteers in two sessions. In the study Articaine promoted higher anesthesia success and longer duration of anesthesia than lidocaine for most of the teeth after IANB although anesthesia success could be considered clinically appropriated only for premolars.

Srisurang S, Narit L and **Prisana P (2011)**[10] studied the clinical efficacy of lidocaine, mepivacaine, and articaine for local infiltration. The patients were randomly allocated into one of three groups, according to the local anesthetic agent used: 2% lidocaine, 2% mepivacaine, or 4% articaine, all with 1:100 000 epinephrine, and were blinded to the anesthetic used. They found that local anesthetization using 4% articaine with 1:100 000 epinephrine covers a wider area of soft tissue and adjacent teeth than 2% lidocaine or 2% mepivacaine with 1:100 000 epinephrine, which is sufficient for the extraction of one or two teeth.

Poorni S, Veniashok B, Senthilkumar AD, Indira R and **Ramachandran S (2011)** evaluated anesthetic efficacy of four percent articaine for pulpal anesthesia by using inferior alveolar nerve block and buccal infiltration techniques in patients with irreversible pulpitis. The study was composed of 2 test arms and 1 control arm. Subjects in the test arms received either a standard IANB or a buccal infiltration (B Infil) of 4% articaine with 1:100,000 epinephrine, whereas the subjects in the control arm received a standard IANB of 2% lidocaine with 1: 100,000 epinephrine. Although Buccal Infil and IANB of 4% articaine were equally effective, Buccal Infil can be considered a viable alternative in IANB for pulpal anesthesia in mandibular molars with irreversible pulpitis.

Arrow P. A (2012)[11] compared 4% articaine and 2% lignocaine in block and infiltration analgesia in children. Using the faces pain scale, pain reports from analgesia administration and from dental treatment were elicited. Analgesia success and pain reports were compared by anaesthetic technique and type. There was higher success and less painful treatment with IANB. There was no statistically significant difference in local analgesia success between articaine and lignocaine when delivered via buccal infiltration.

Kanaa MD, Whitworth JM and **Meechan JG (2012)**[12] did a prospective randomized trial of different supplementary local anesthetic techniques after failure of inferior alveolar nerve block in patients with irreversible pulpitis in mandibular teeth. This randomized clinical trial included 182 patients diagnosed with irreversible pulpitis in mandibular teeth. Patients received 2.0 mL of 2% lidocaine with 1: 80,000 epinephrine as an IANB injection. Of the 182 patients, 122 achieved successful pulpal anesthesia within 10 minutes after initial IANB injection; 82 experienced pain-free treatments.

Somuri AV, Rai AB and **Pillai M (2013)**[13] conducted a study on the extraction of permanent maxillary teeth by only buccal infiltration of articaine. The aim of this

study was to demonstrate whether articaine hydrochloride administered alone as a single buccal infiltration in maxillary tooth removal, can provide favourable palatal anesthesia as compared to buccal and palatal injection of lidocaine. According to the VAS and FPS scores, the pain on extraction between buccal infiltration of articaine and the routine buccal and palatal infiltration of lignocaine was statistically insignificant. They concluded that the routine use of a palatal injection for the removal of permanent maxillary premolar teeth may not be required when articaine/HCl is used as the local anesthetic.

Atasoy Ulusoy Öİ and **Alaçam T (2013)**[14] did a study to evaluate the efficacy of a single buccal infitration using 4% articaine hydrochloride (HCl) with 1: 100,000 epinephrine or 4% articaine HCl with 1: 100 000 epinephrine bitartrate for obtaining adequate pulpal anaesthesia in the palatal roots of maxillary first molars associated with irreversible pulpitis. There was no significant difference between the two anaesthetic solutions regarding the VAS scores and pulse rate measurements during endodontic procedures. Single buccal infiltration did not achieve adequate pulpal anaesthesia in the palatal root canal of the maxillary first molars associated with irreversible pulpitis.

Ashraf H, Kazem M, Dianat O and **Noghrehkar F (2013)**[15] evaluated the efficacy of articaine versus lidocaine in block and infiltration anesthesia administered in teeth with irreversible pulpitis. One hundred twenty-five emergency patients who had their first or second mandibular molar diagnosed with irreversible pulpitis participated in the study and received the IANB by using either 2% lidocaine with 1:100,000 epinephrine or 4% articaine with 1: 100,000 epinephrine. The success rate after the administration of the infiltration injections after an incomplete IANB by using lidocaine was 29%, whereas by using articaine it was 71%

Darawade DA, Kumar S, Budhiraja S, Mittal M and **Mehta TN (2014)**[16]did a clinical study on the efficacy of 4% articaine hydrochloride versus 2% lignocaine hydrochloride in extraction. The study was carried out in 50 patients who needed the

orthodontic extraction in the age group from 15 to 25 years. Experimental sites were injected with 0.5-1 ml of 4% articaine HCL containing 1:100000 adrenaline, incrementally in the buccal vestibule without palatal anaesthesia. Control sites were injected with 0.8-1 ml of 2% lignocaine HCL containing 1:100000 adrenaline, incrementally in the buccal vestibule. Articaine has proved its usefulness in all regards.

Brajkovic D, Antonijevic D, Milovanovic P and **Kisic D (2014)**[17] conducted a double-blind, randomized study to evaluate anesthetic parameters, postoperative analgesia and vasoactive properties of levobupivacaine and bupivacaine for lower third molar surgery. Sixty patients (ASA I) were scheduled for lower third molar surgery under inferior alveolar nerve block, lingual nerve block and buccal nerve block (mandibular nerve blocks) obtained with 3 ml of 0.5 % levobupivacaine and 3 ml of 0.5 % bupivacaine. Success rate, onset and duration of three nerve bocks were evaluated by electrical pulp testing, pinprick testing and signs of soft tissue anesthesia. Levobupivacaine 0.5 % achieved superiority over bupivacaine 0.5 % in the intensity of intraoperative anesthesia and duration of postoperative analgesia for lower third molar surgery under the mandibular nerve blocks.

Rogers BS, Botero TM, McDonald NJ, Gardner RJ and **Peters MC (2014)**[18] evaluated efficacy of articaine versus lidocaine as a supplemental buccal infiltration in mandibular molars with irreversible pulpitis. One hundred emergency patients diagnosed with Irreversible Pulpitis of a mandibular molar were selected and received an IANB with 4% articaine. All injections were 1.7 mL with 1: 100,000 epinephrine. Seventy-four patients failed to achieve pulpal anesthesia after IANB with 4% articaine, resulting in IANB success rate of 26%. Supplemental Buccal Infiltration with articaine was significantly more effective than lidocaine.

Brajkovic D, Brkovic B, Milic M, Biocanin V, Krsljak E and **Stojic D (2015)**[19] conducted a study to investigate analgesic parameters and patient satisfaction after using 0.5% levobupivacaine (Lbup), 0.5% bupivacaine (Bup) and 2% lidocaine with

epinephrine 1: 80,000 (Lid + Epi) for an inferior alveolar nerve block following lower third molar surgery. The use of a new and long-acting local anesthetic 0.5% levobupivacaine is clinically relevant and effective for an inferior alveolar nerve block and postoperative pain control after third molar surgery. In our study Lbup and Bup controlled postoperative pain more efficiently after lower third molar surgery compared to Lid + Epi.

Kung J, McDonagh M and **Sedgley CM (2015)**[20] evaluated whether Articaine provide an advantage over Lidocaine in patients with symptomatic irreversible pulpitis or not. Two hundred seventy-five studies were initially identified from the search; 10 double-blind, randomized clinical trials met the inclusion criteria. For combined studies, articaine was more likely than lidocaine to achieve successful anesthesia (odds ratio [OR], 2.21; 95% CI, 1.41-3.47; P = .0006; I (2) = 40%). Maxillary infiltration subgroup analysis showed no significant difference between articaine and lidocaine.

Mittal M, Sharma S, Kumar A, Chopra R 4 and **Srivastava D (2015)**[21] The purpose of this study was to evaluate the efficacy of articaine compared to lidocaine for extraction of primary maxillary molars and assess whether palatal anesthesia could be achieved with buccal infiltration injection but without the need for palatal infiltration. One hundred and two children requiring primary maxillary molar extraction were randomly selected to receive buccal infiltration using either articaine or lidocaine. During extraction, The Wong Baker Facial Pain Scale (FPS) was employed for subjective evaluation and Modified Behavior Pain Scale (MBPS) values, heart rate, and blood pressure were recorded for objective evaluation. Effectiveness of anesthesia was checked using subjective symptoms and probing Statistically significantly higher MBPS pain scale values were seen with lidocaine as compared to articaine. FPS, heart rate, and blood pressure values presented no statistically significant difference in the two groups.

Kumaresan R, Srinivasan B and **Pendayala S (2015)**[22] compared the effectiveness of lidocaine in permanent maxillary teeth removal performed with single buccal infiltration versus routine buccal and palatal injection. One hundred and fifty patients requiring extraction of maxillary teeth were included in the study. Patients were randomly allotted to two groups, study and control. Patients in study group received a single buccal infiltration of 1.5 mL of lidocaine with epinephrine for extraction of maxillary teeth. Patients in control group received 1.5 mL of buccal and 0.3 mL of palatal infiltration of lidocaine with epinephrine for the extraction. The study concluded that the extraction of permanent maxillary anterior teeth and premolars is possible by depositing local anesthesia to the buccal vestibule of the tooth without palatal supplementation.

Zurfluh MA, **Daubländer M** and **van Waes HJ (2015)**[23] conducted a study to determine if using a solution of articaine with a reduced amount of epinephrine could decrease the amount of time soft tissue anesthesia lasts, and therefore decrease the chance of self-inflicted soft tissue damage, while still providing adequate anesthesia. The study involved children and adolescents who received routine dental treatment, and compared the effects of two different solutions: one with articaine 4% and a reduced amount of epinephrine), and the other with a conventional amount of epinephrine in terms of the duration of soft tissue anesthesia.The study concluded that articaine 4% solution with the reduced epinephrine concentration (1:400,000) was considered a safe and suitable drug for routine treatments in pediatric dentistry.

Luqman U, Majeed Janjua OS, Ashfaq M, Irfan H, Mushtaq S and **Bilal A (2015)**[24]compared articaine and lignocaine for uncomplicated maxillary exodontia. Patients aged 20 - 60 years under simple extraction in the maxillary arch were included in the study.Maxillary teeth were divided into three groups; group-1 (posterior teeth) including first, second and third molars on either side, group-2 (middle teeth) including the premolars and group-3 (anterior teeth) including incisors and canines. Group-A (study group) received buccal infiltration of 4% articaine with 1:200,000 adrenaline and Group-B (control group) received buccal and palatal infiltration of 2% lignocaine/HCl with 1: 100,000 adrenaline. Faces Pain Scale (FPS)

and a Visual Analogue Score (VAS) was used for objective and subjective assessment of per operative pain respectively. It was found buccal infiltration with a single articaine injection and lignocaine buccal and palatal infiltration were equally effective for maxillary exodontia.

Chopra R, Marwaha M, Bansal K and **Mittal M (2016)**[25] evaluation the Buccal Infiltration with Articaine and Inferior Alveolar Nerve Block with Lignocaine for Pulp Therapy in Mandibular Primary Molars. 30 patients (4-8 years) with indication of pulp therapy in at least two mandibular primary molars were selected. Patients were randomly assigned to receive nerve block with lignocaine or infiltration with articaine on first appointment and the other solution on second appointment. All the pulpotomies and pulpectomies were performed by a pediatric dentist. They concluded that Articaine infiltration has the potential to replace inferior alveolar nerve block for primary mandibular molars.

Aggarwal V, Singla M, Miglani S and **Kohli S (2017)**[26] did a comparative evaluation of anesthetic efficacy of 2% Lidocaine, 4% Articaine, and 0.5% Bupivacaine on Inferior Alveolar Nerve Block in Patients with Symptomatic Irreversible Pulpitis. 91 adult patients were randomly divided into three groups on the basis of the anesthetic solution used. The first group received IANB with 1.8 mL of 2% lidocaine with 1:200,000 epinephrine, the second group received IANB with 4% articaine with 1:100,000 epinephrine, and the third group received IANB with 0.5% bupivacaine with 1:200,000 epinephrine. After 15 minutes of IANB, conventional endodontic access preparation was started. The pain during the treatment was noted on a Heft-Parker visual analog scale (HP VAS). The study concluded that 2% lidocaine solution used for IANB had similar success rates when compared with 4% articaine and 0.5% bupivacaine.

Tong HJ, Alzahrani FS, Sim YF, Tahmassebi JF and **Duggal M (2018)**[27] evaluated the available evidence on the efficacy of lidocaine and articaine, used in paediatric dentistry. The available evidence indicates that the efficacy of both

lidocaine and articaine in routine dental procedures for children is comparable, as per low quality data. Patients reported similar levels of pain during treatment for both anesthetic types, whether administered through articaine infiltration or lidocaine IAD nerve blocks. However, post-treatment pain was significantly lower with articaine injections. Additionally, there was no noticeable difference in adverse event occurrence between the two anesthetic methods in pediatric patients.

Majid OW and **Ahmed AM (2018)**[28] studied the Anesthetic Efficacy of Articaine and Lidocaine in Equivalent Doses as Buccal and Non-Palatal Infiltration for Maxillary Molar Extraction. This randomized, double-blinded, placebo-controlled clinical trial included patients requiring extraction of 1 maxillary molar under local anesthesia. Patients were randomly distributed into 1 of 3 groups: group A received 4% articaine 1.8 mL as a buccal injection and 0.2 mL as a palatal injection, group B received 4% articaine 1.8 mL plus normal saline 0.2 mL as a palatal injection, and group C received 2% lidocaine 3.6 mL plus normal saline 0.2 mL as a palatal injection. Pain was measured during injection, 8 minutes afterward, and during extraction using a visual analog scale. Although the anesthetic effects of single placebo-controlled buccal injections of 4% articaine and 2% lidocaine were comparable, the level of anesthetic adequacy was statistically less than that achieved by 4% articaine given by the standard technique.

Ashwath B, Subramoniam S, Vijayalakshmi R, Shanmugam M, Priya BM and **Anitha V (2018)**[29] did a randomized double-blind split-mouth study on anesthetic efficacy of 4% articaine and 2% lignocaine in achieving palatal anesthesia following a single buccal infiltration during periodontal therapy. The success rate for maxillary buccal infiltration to induce palatal anesthesia using articaine was 90% during scaling and root planing and 82.5% during AFS and for lignocaine solution was 20% and 15%, respectively.Finally it was observed that the efficacy of 4% articaine was superior to 2% lignocaine to induce palatal anesthesia following maxillary buccal infiltration in maxillary posterior sextants.

Sandilya V, Andrade NN, Mathai PC, Aggarwal N, Sahu V and **Nerurkar S (2019)**[30] did a Randomized Control Trial Comparing Buccal Infiltration of 4%

Articaine with Buccal and Palatal Infiltration of 2% Lignocaine for the Extraction of Maxillary Premolar Teeth. A double-blind randomized clinical trial with a split-mouth design, where each patient (n = 100) was part of two groups, was conducted. Experimental Group 1: single buccal infiltration of 4% articaine with 1:100,000 adrenaline (Septanest™ with adrenaline 1: 100,000 by Septodont). Control Group 2: routine buccal and palatal infiltrations of 2% lignocaine with 1:200,000 adrenaline (Lox™ 2% with adrenaline 1: 200,000 by Neon). The parameters studied were time to onset of anesthesia, pain during the extraction procedure (not during the injecting of the local anesthetic), and frequency of extra amount of local anesthetic injected.The difference was not statistically significant (P > 0.05) between the two groups with respect to all three parameters. This proves that a single buccal infiltration of articaine can be used as an alternative to lignocaine for the extraction of the maxillary premolar teeth in most of the cases.

M M A, Khatri A, Kalra N, Tyagi R and **Khandelwal D (2019)**[31] studied the pain perception and efficacy of local analgesia using 2% lignocaine, buffered lignocaine, and 4% articaine in pediatric dental procedures. 48 children aged 5-10 years, who received three inferior alveolar nerve block injections in three appointments scheduled one week apart from the next. Pain on injection was assessed using the Wong-Baker Faces pain scale and the sound eye motor scale (SEM). Efficacy of anesthesia was assessed by subjective (tingling or numbness of the lip, tongue, and corner of mouth) and objective signs (pain on probing). Buffered lignocaine was the least painful and the most efficacious anesthetic agent during the inferior alveolar nerve block injection in 5-10-year-old patients.

Tirupathi SP and **Rajasekhar S (2020)**[32] evaluated whether single buccal infiltration with 4% articaine induce sufficient analgesia for the extraction of primary molars in children. Five articles were included for this systematic review. Of the five studies that evaluated subjective pain during extraction, two reported no significant difference between the articaine and lignocaine groups, and the remaining three reported lower subjective pain during extraction in the articaine group. Only two

studies evaluated objective pain scores during extraction, and both studies reported lower pain scores in the articaine group.

Monteiro J, Tanday A, Ashley PF, Parekh S and **Alamri H (2020)**[33] did interventions for increasing acceptance of local anaesthetic in children and adolescents having dental treatment. Parallel randomised controlled trials (RCTs) of interventions used to increase acceptance of dental LA in children and adolescents under the age of 18 years.Authors did not find sufficient evidence to draw firm conclusions as to the best interventions to increase acceptance of LA in children due to variation in methodology and nature/timing of outcome measures. We recommend further parallel RCTs, reported in line with the CONSORT Statement. Care should be taken when choosing outcome measures.

Chandrasekaran D, Chinnaswami R, Shanthi K, Sargunam A, Kumar S and **Tharini S (2021)**[34] conducted a Prospective Study to Assess the Efficacy of 4% Articaine, 0.5% Bupivacaine and 2% Lignocaine using a Single Buccal Supraperiosteal Injection for Maxillary Tooth Extraction. According to the VAS and FPS scores, the pain on extraction between buccal infiltration of articaine and the routine buccal and palatal infiltration of lignocaine was statistically significant.It concluded that the routine use of a palatal injection for extraction of maxillary teeth may not be required when articaine is used as a local anesthetic solution.

Liew AKC, Yeh YC, Abdullah D and **Tu YK (2021)**[35] studied the anesthetic efficacy in vital asymptomatic teeth using different local anesthetics. Randomized controlled trials comparing pulpal anesthesia of various LA on vital asymptomatic teeth were included in this review. For maxillary buccal infiltration, articaine 4% with epinephrine 1:100,000 was more efficacious than lidocaine 2% with epinephrine 1:100,000. For mandibular buccal infiltration, articaine 4% with epinephrine 1:100,000 was more efficacious than various lidocaine solutions. The study concluded articaine 4% with epinephrine is superior when maxillary or mandibular infiltration is required in vital asymptomatic teeth.

Gholami M, Banihashemrad A, Mohammadzadeh A and **Ahrari F. (2021)**[36]checked the Efficacy of 4% Articaine Versus 2% Lidocaine in Inducing Palatal Anesthesia for Tooth Extraction in Different Maxillary Regions. 300 patients were categorized into 3 strata according to the extraction area (anterior, premolar, molar), and then randomly assigned to 2 groups based on the administered medication. The first group received buccal infiltration by 0.6 mL of 2% lidocaine, whereas the second group was buccally administered using 0.6 mL of 4% articaine. Articaine can be considered as a suitable alternative to lidocaine for eliminating painful palatal infiltration in the extraction of maxillary teeth.

Yu J, Liu S and **Zhang X (2021)**[37] evaluated whether buccal infiltration of articaine replace traditional inferior alveolar nerve block for the treatment of mandibular molars in pediatric patients. PubMed, Embase, ScienceDirect, CENTRAL, and Google Scholar databases were searched for randomized controlled trials (RCTs) comparing the two techniques in pediatric patients and reporting the success of anesthesia and/or pain during treatment. PRISMA guidelines were followed. Results suggested that buccal infiltration of articaine is a viable alternative to IANB with lignocaine in pediatric patients for treating mandibular molars.

Grant R, Brown T, Young L and **Lamont T (2021)**[38] conducted a study to determine the most effective method or substance for achieving pulpal anesthesia in irreversible pulpitis, for both the maxilla and mandible. After comparing the results directly, it was found that the most effective treatments for achieving pulpal anesthesia in the mandible with irreversible pulpitis were pre-medication with aceclofenac and paracetamol followed by IANB, or IANB with 2% lidocaine with buccal infiltration with 4% articaine, compared to the control alone. However, when comparing the treatments indirectly, pre-medication with ibuprofen and paracetamol followed by IANB was found to be the best intervention compared to the control. On the other hand, no significant differences were observed between the interventions in the maxilla.

Kijsamanmith K, et al.(2022)[39] evaluated the effect of single buccal infiltration anesthesia of 4% articaine with either 1:100,000 or 1:200,000 epinephrine on pulpal blood flow and anesthesia of maxillary first molars and second premolars in humans. Fifteen healthy volunteers with intact maxillary first molars and second premolars received an infiltration of 4% articaine with either EP100 or EP200 at buccal aspect of maxillary first molars. The PBF, pulpal anesthesia and soft tissue anesthesia were assessed with a laser Doppler flowmeter (LDF), an electric pulp tester (EPT) and Aesthesiometer II, respectively. Single buccal infiltration to maxillary first molar produced PBF reduction and successful pulpal anesthesia, evaluated by EPT, in both first molar and second premolar. This anesthetic technique also produced high success of buccal tissue anesthesia, but demonstrated very low success for palatal tissue anesthesia.

Chen S, Xiang J and **Ji Y (2022)**[40] studied the efficacy of Articaine vs Lignocaine for infiltration anaesthesia during primary molar extractions. The electronic databases of PubMed, Embase, Scopus, BioMed Central, CENTRAL, and Google Scholar were searched up to August 2020. Randomized controlled trials on paediatric patients comparing the infiltration of articaine with lignocaine for extraction of primary molar were included. Pain of extraction and successful palatal/lingual anaesthesia with single buccal infiltration was evaluated. The study concluded that Articaine may have a better anaesthetic effect compared to lignocaine but the difference may not be clinically relevant.

Syed GA and **Mulay SA (2022)**[41] did a comparative evaluation of Anesthetic Efficacy of 4% Articaine and 2% Lidocaine for Buccal Infiltration in Adult Patients with Irreversible Pulpitis of Maxillary First Molar. Two hundred patients with irreversible pulpitis of the maxillary first molar were divided into four study groups and received only buccal infiltration of either 0.8 ml of 4% articaine or 1.6 ml of 2% lidocaine. Endodontic access was begun 7 min after the solution deposition. The success was defined as "no pain (0 mm)" or "weak/mild pain (>0 mm and ≤54 mm)" during access opening, and during the first file insertion till working length. The

efficacy of 4% articaine with 1:100,000 epinephrine has been found to be better than 2% lidocaine with 1:80,000 epinephrine.

Habib MFOM et al. (2022)[42] evaluated the Inferior alveolar nerve block success of 2% mepivacaine versus 4% articaine in patients with symptomatic irreversible pulpitis in mandibular molars. Three hundred and thirty patients with moderate-to-severe pain in mandibular molars with SIP randomly received either 3.6 ml 2% mepivacaine hydrochloride with 1:100 000 adrenalin or 3.4 ml 4% articaine hydrochloride with 1:100 000 adrenaline (n = 165). Intraoperative pain (IOP) intensity was assessed during access cavity preparation and canal instrumentation using 11-point Numerical Rating Scale (NRS). 2% mepivacaine and 4% articaine demonstrate similar IANB success rates for mandibular molars with SIP. Intraoperative pain experience during endodontic treatment can be associated with preoperative pain, tooth type and age.

MATERIALS & METHODOLOGY

The present study was conducted in the Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences (BBDCODS) after obtaining clearance from Instituitional Ethical Committee of BBDCODS, Lucknow. The study included 120 patients on the basis of inclusion and exclusion criteria. Written informed consent was obtained from the parents' or guardians. Additionally, assent was also obtained from children older than seven years of age. The purpose of the study was to assess perception of pain, safety and efficacy of 0.5% Levubupivacaine ,2% Lidocaine & 4% Articaine.

SAMPLE SIZE CALCULATION

The minimum sample size was calculated to be 120 by using the following criteria.

Sample size estimation was done by using G power (v3.1.9.4)

F tests - ANOVA: Fixed effects, main effects and interactions

Analysis: A priori: Compute required sample size

Input: Effect size f = 0.48

α err prob = 0.05

Power (1-β err prob) = 0.95

Numerator df = 10

Number of groups = 5

Number of covariates = 1

Output: Noncentrality parameter λ = 26.4960000

Critical F = 1.9186393

Denominator df = 109

Total sample size = 115

Actual power = 0.9501391

ELIGIBILITY CRITERIA:

Inclusion criteria-

- Children of both the gender (male and female) with an age group of 5-16 years.
- Children requiring complex dental procedures.
- Children categorized as ASA I and Frankl III and IV

Exclusion criteria-

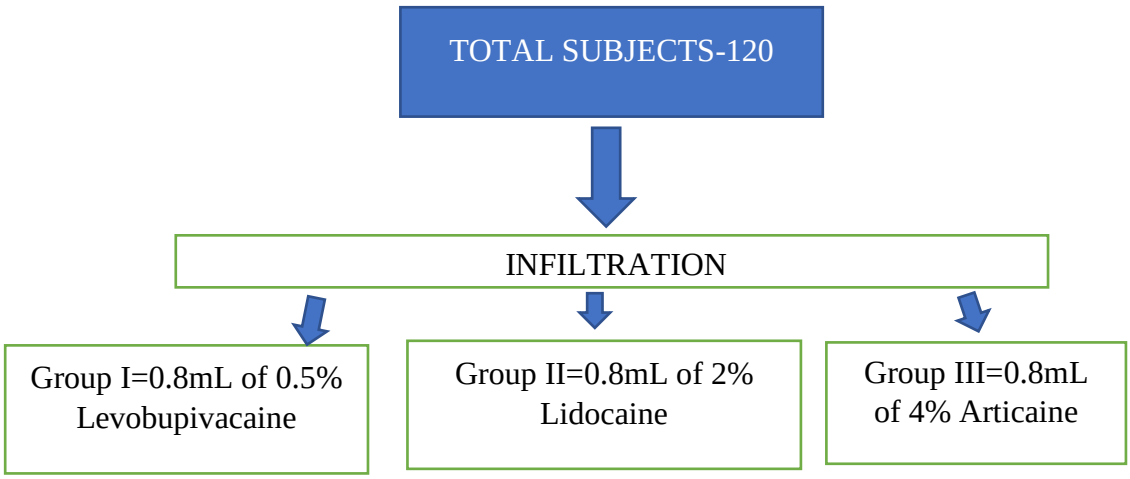
- Children who were allergic to the local anesthetic agent to be used.
- Presence of soft tissue infection near the proposed injection (infiltration) site were excluded from the study.
- Children/Guardian who were not willing to give informed consent or assent.

MATERIALS USED-

- Diagnostic instruments- Mouth mirror, Probe, Tweezers
- Cotton
- Conventional syringe with needle (27 gauge)
- Local anesthetic agent:
  - ✓ Levobupivacaine 0.5% (Levo-anawin, Neon laboratories., INDIA)
  - ✓ Lidocaine Hydrochloride 2% with epinephrine
  - ✓ Articaine Hydrochloride 4% with epinephrine (Septanest, Septodont., FRANCE)
- Stop watch
- Gloves

STUDY DESIGN

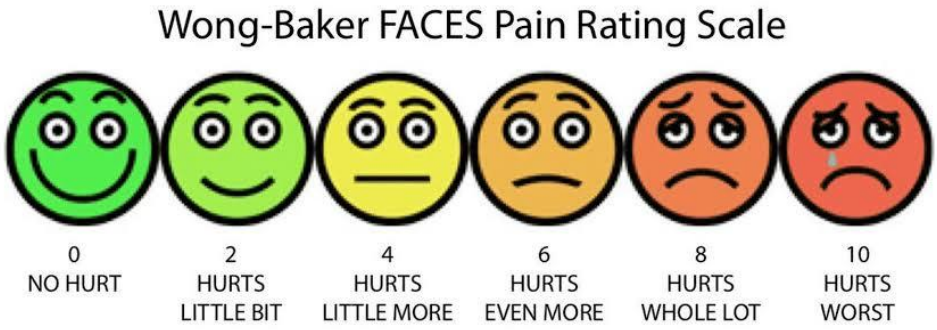
- The present *in-vivo* study was carried out in children of both the genders with age group of 5-16 years, requiring complex dental procedures (pulp therapy, extraction and surgical procedures),
- Children included were categorized as ASA I (American Society of Anesthesiology) and Frankl III and IV (Behaviour Rating Scale).
- The subjects were randomly divided into three treatment groups, Group I, Group II and Group III.
- Patients in Group I received 0.8mL of 0.5% Levobupivacaine infiltration, in Group II received 0.8mL of 2% Lidocaine with 1:100000 epinephrine and Group III received 0.8 ml of 4% Articaine with 1:10000 epinephrine.
- The study is a single blind study in which the evaluator is blinded to avoid bias.



METHODOLOGY

- The study included 120 children aged 5 to 16 of both the genders, who required complex dental treatments like pulp therapy, extraction or surgical procedures, and were classified as ASA I and Frankl III and IV. The procedure of the treatment was thoroughly communicated to the patients and their guardians. Written informed consent was sought from parents/ Guardian. Children below the age of seven also gave their assent.
- The evaluation process was single-blind in order to prevent any bias.

- The infiltration procedure was carried out in patients undergoing pulp therapy, extraction and surgical procedures, with a supplemental nerve block if required.
- The subjects were asked to rate the pain score immediately after infiltration i.e the pain experienced during infiltration with 2% lidocaine, 4% articaine and 0.5% levobupivacaine as discussed by Wong-Baker Pain rating scale.
- Anesthetic safety was assessed by the incidence of adverse effects such as dizziness, vomiting, bleeding and trismus after the procedure.
- Anesthetic efficacy was assessed on the basis of pain rating scores rated by the subjects during intra-operative treatment procedure.



SCORING

The Wong–Baker Faces Pain Rating Scale is a pain scale that was developed by Donna Wong and Connie Baker. The scale shows a series of faces ranging from a happy face at 0, or "no hurt" to a crying face at 10. The Wong-Baker Pain Scale has six faces. The first face signifies "no hurt" and has a pain value of 0. The second face indicates that it "hurts a little bit" and has a pain score of 2. The third face signifies "hurts a little more" and corresponds to a pain level of 4. The fourth face signifies "hurts even more," with a pain level of 6. The sixth face, which represents a pain score of 10, denotes "hurts worst," while the fifth face represents an 8 and says "hurts a lot."

The above Pain Rating Scale is for children but can also be used for older age group between 6 and 15 years.

LOCAL ANESTHETIC AGENTS

Figure no. 1**: 0.5%LEVOBUPIVACAINE**

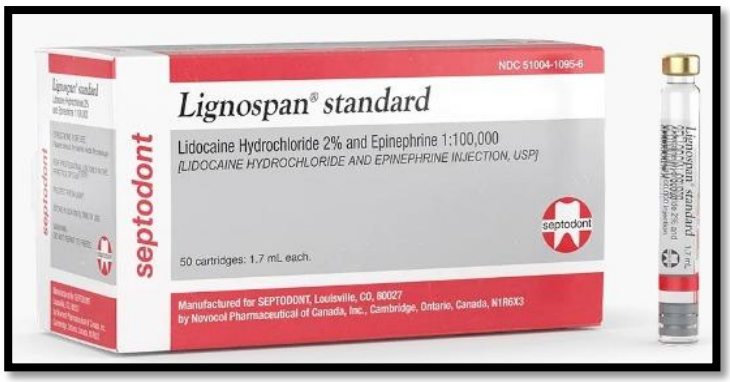


Figure no. 2: **2% LIDOCAINE**

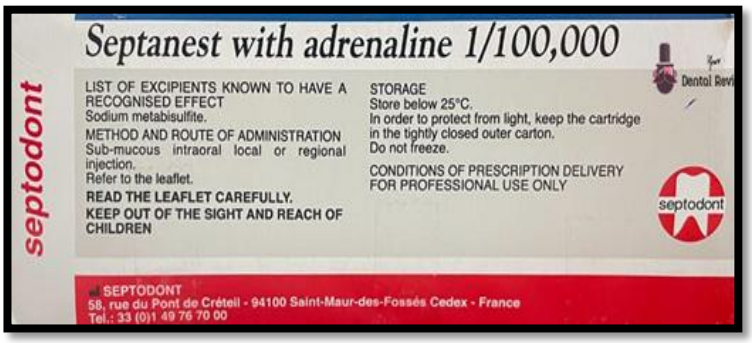


Figure no. 3: **4% ARTICAINE**

Plate-I

ADMINISTRATION OF LOCAL ANESTHETIC AGENTS

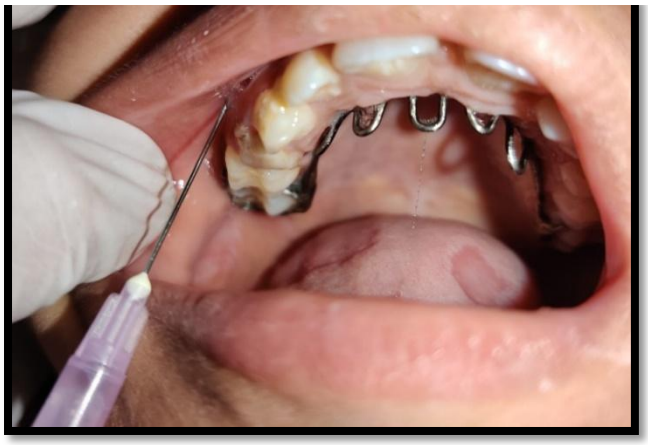


Figure no. 4: **INFILTRATION WITH 0.5% LEVOBUPIVACAINE**

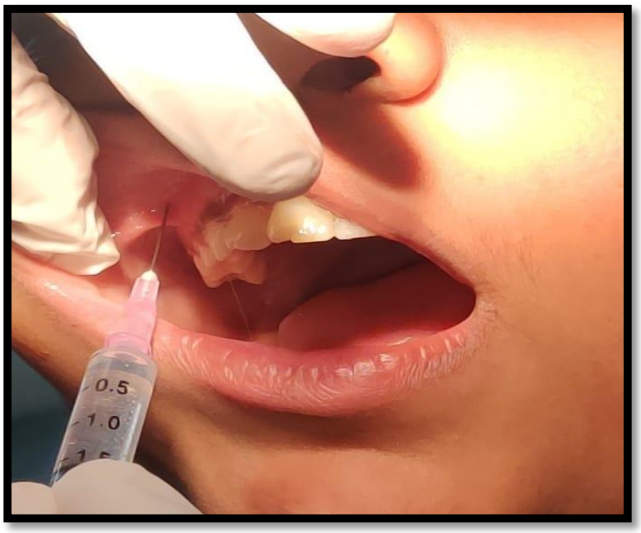


Figure no. 5: **INFILTRATION WITH 2% LIDOCAINE**

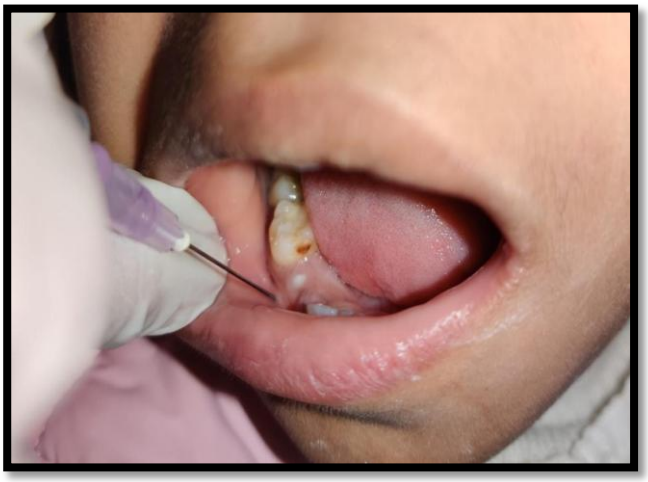


Figure no. 6: **INFILTRATION WITH 4% ARTICAINE**

Plate-II

RESULTS & OBSERVATIONS

Data was entered into Microsoft Excel spreadsheet and was checked for any discrepancies. Summarized data was presented using Tables and Graphs. The data was analysed by SPSS (21.0 version). Shapiro Wilk test was used to check which all variables were following normal distribution. Data was normally distributed therefore; bivariate analyses were performed using the parametric tests i.e One-way ANOVA followed by post hoc tukey's test. Chi sqaure test was used for categorical variables. Level of statistical significance was set at p-value less than 0.05

Table 1: Intergroup comparison of mean age

Groups	N=120 subjects	Mean age	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum age	Maximum Age
					Lower Bound	Upper Bound		
Group I	**40**	8.40	2.540	.402	7.59	9.21	5	16
Group II	**40**	9.2	3.364	.532	8.24	10.39	5	16
Group III	**40**	9.25	2.436	.385	8.47	10.03	5	15
Total	**120**	8.99	2.818	.257	8.48	9.50	5	16
P value								**0.272**

Graph 1: Intergroup comparison of mean age

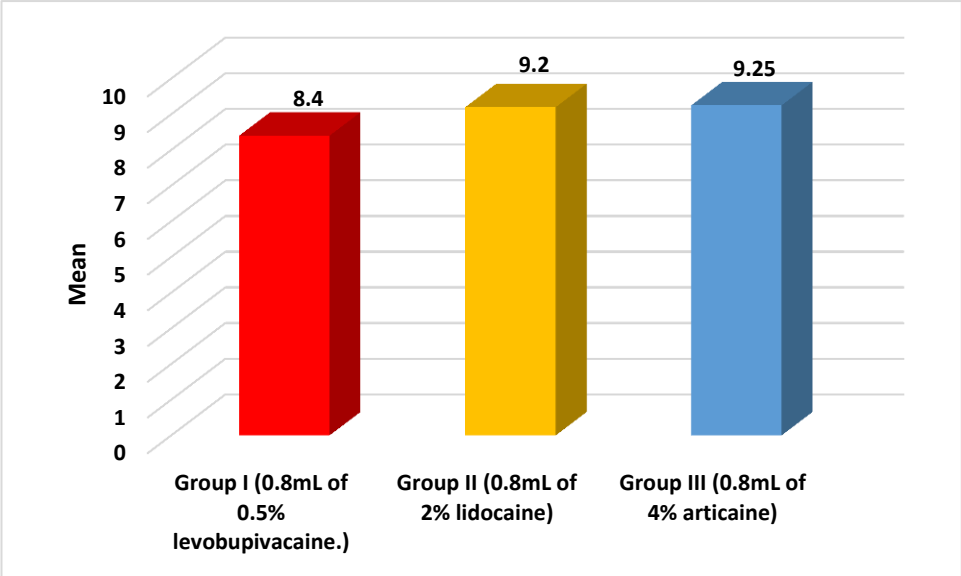


Table1 and Graph 1 depicts intergroup comparison of mean ages. Group I, Group II and Group III consisted of 40 subjects each. In Group I and Group II, the minimum age of patient was 5 years and the maximum age was 16 years with a mean age of 8.40 and 9.2 respectively. In Group III minimum age was 5 years and maximum age was 15 years with a mean age of 9.25. No significant difference was seen in the mean ages of subjects included in the present study. (p= 0.272).

Table 2: Gender-wise distribution of study subjects among the three study groups

Study Groups			Gender		Total
			Female	Male	
	Group I (0.8mL of 0.5% levobupivacaine.)	N	19	21	40
		%	47.5%	52.5%	100.0%
	Group II (0.8mL of 2% lidocaine)	N	15	25	40
		%	37.5%	62.5%	100.0%
	Group III (0.8mL of 4% articaine)	N	24	16	40
		%	60.0%	40.0%	100.0%
Total		N	58	62	120
		%	48.3%	51.7%	100.0%
P value					0.131

Graph 2: Gender-wise distribution of study subjects among the three study groups

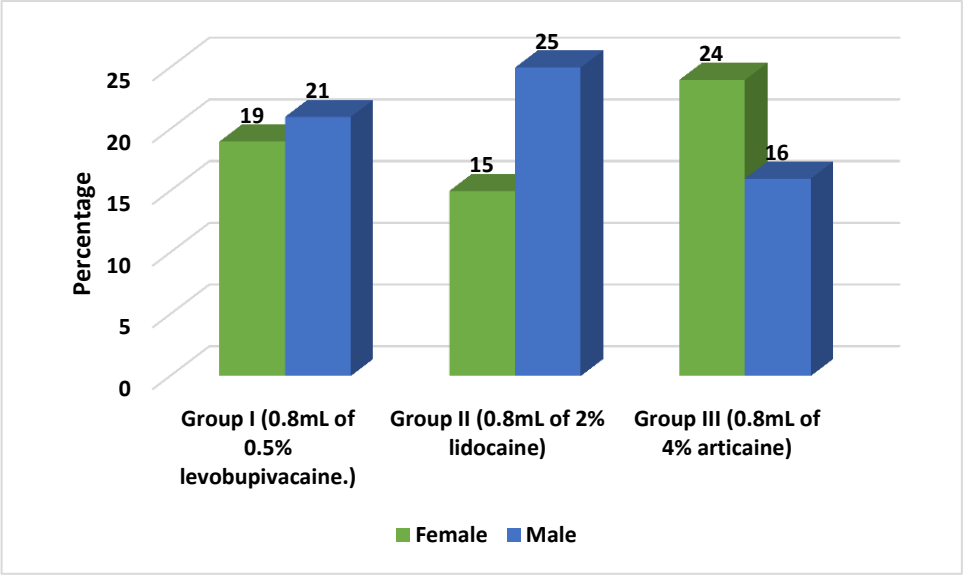


Table 2 and Graph 2 shows Gender-wise distribution of study subjects. In Group I out of 40 subjects, 19(47.5%) were females and 21(52.5%) were male. In Group II ,15(37.5%) were females and 25(62.5%) were males out of 40 subjects and in Group III 24(60%) were females and 16(40%) were males. No significant difference was seen in distribution of males and females when compared among 3 study groups. (p= 0.131).

Table 3: Intergroup comparison of Mean pain score during administration of anaesthetic agents (WONG-BAKERS SCALE)

Study Groups	N=120 subjects	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum Pain score	Maximum Pain score
					Lower Bound	Upper Bound		
Group I (0.8mL of 0.5% levobupivacaine.)	40	1.80	1.418	.224	1.35	2.25	0	4
Group II (0.8mL of 2% lidocaine)	40	2.20	1.418	.224	1.75	2.65	0	4
Group III (0.8mL of 4% articaine)	40	2.00	1.657	.262	1.32	2.38	0	6
Total	120	1.95	1.500	.137	1.68	2.22	0	6
P value	0.001*							
Post hoc	2>3>1							

Graph 3: Intergroup comparison of Mean pain score during administration of anaesthetic agents (WONG-BAKERS SCALE)

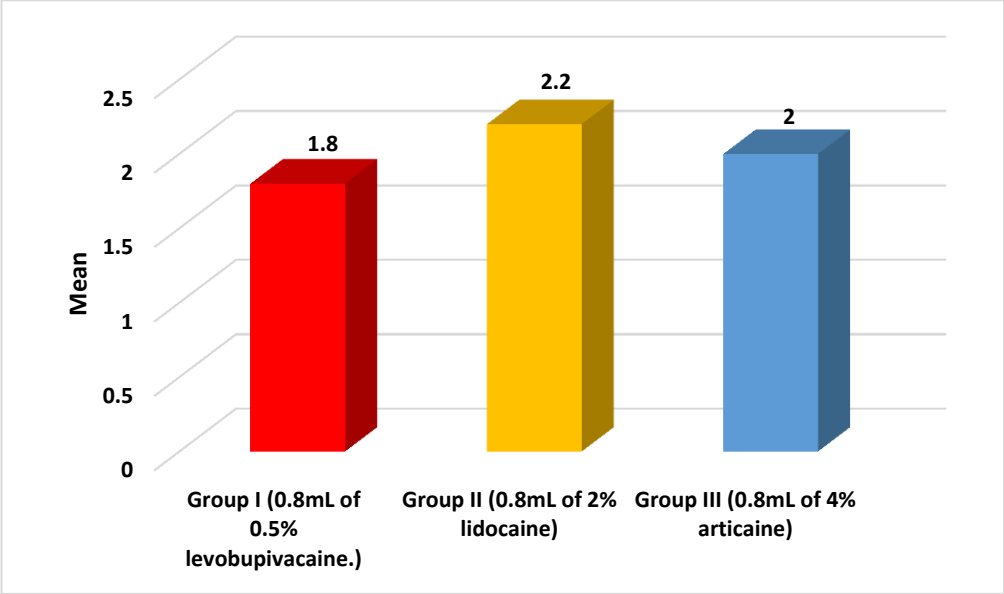


Table 3 and Graph 3 describes intergroup comparison of pain scores during administration of anesthetic agent. In Group I, minimum pain score of 0 and a maximum of 4 was recorded with a mean pain score of 1.80. In Group II, minimum pain score was 0 and a maximum of 4 with a mean pain score of 2.20. While in Group III, minimum pain score was 0 and a maximum score of 6 was recorded with a mean pain score of 2.00. Post hoc values showed that mean pain score was found to be more in Group II subjects followed by Group III and Group I subjects. Statistically significant difference in mean values of pain score was observed using Wong Bakers Scale among subjects of three study groups (*$p>0.05$).*

Table 4: Intergroup comparison of safety of local anaesthetic agents.

Study groups			Variables					Total
			No post op complication	Dizziness	Vomiting	Bleeding	Trismus	
	Group I (0.8mL of 0.5% levobupivacaine.)	N	37	0	0	2	1	40
		%	92.50%	0.00%	0.00%	5.00%	2.50%	100.00%
	Group II (0.8mL of 2% lidocaine)	N	30	1	1	5	3	40
		%	75.00%	2.50%	2.50%	12.50%	7.50%	100.00%
	Group III (0.8mL of 4% articaine)	N	30	1	2	3	4	40
		%	75.00%	2.50%	5.00%	7.50%	10.00%	100.00%
Total		N	97	2	3	10	8	120
		%	80.80%	1.70%	2.50%	8.30%	6.70%	100.00%
P value								0.519

Graph 4: Intergroup comparison of safety of local anaesthetic agents.

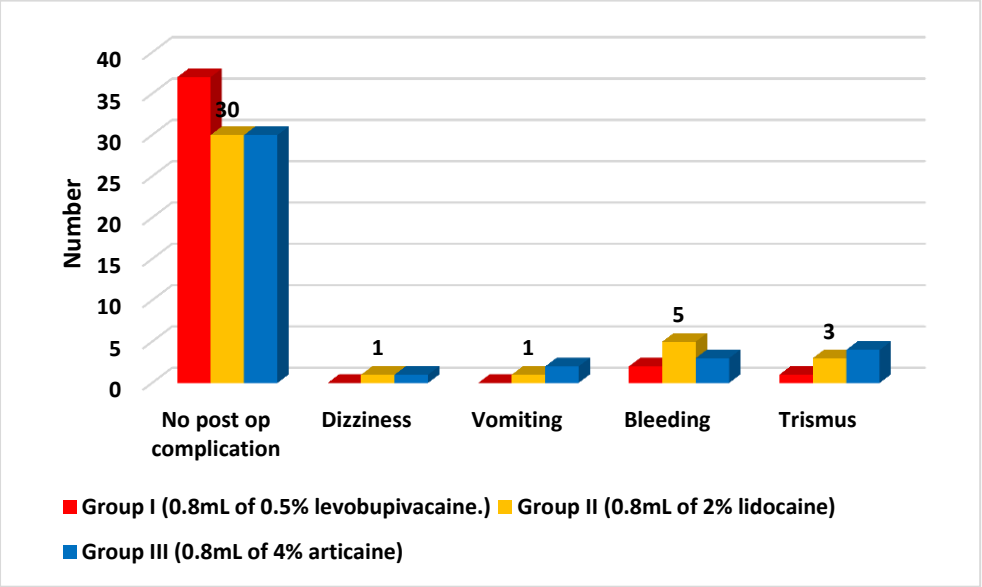


Table and Graph 4 shows intergroup comparison of safety of local anaesthetic agents. 37 (92.5%) of the 40 patients in Group I had no post-operative problems. Two of the individuals had bleeding, and one experienced trismus. Out of 40 patients in Group II, 30 (or 75%) did not exhibit any post-operative symptoms, whereas 1 subject had dizziness, 1 subject had vomiting, 5 subjects had bleeding and 3 subjects had trismus. In Group III, 30 patients (or 75%), out of 40 patients did not have any post-operative side effects, whereas 1 subject had dizziness, 2 subjects had vomiting, 3 subjects had bleeding, and 4 subjects had trismus.

According to the results, it can be concluded that levobupivacaine outperformed lidocaine and articaine in terms of safety of local anaesthetic agents.

No significant difference was observed in the post op complications observed in three study groups as p>0.05.

Table 5.1: Intergroup comparison of efficacy of anaesthetic agents while performing extraction (WONG-BAKERS SCALE)

Study groups	N=87 subjects	Mean Pain Score	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum Pain score	Maximum Pain score
					Lower Bound	Upper Bound		
Group I (0.8mL of 0.5% levobupivacaine.)	31	1.9355	1.31493	.23617	1.4532	2.4178	.00	4.00
Group II (0.8mL of 2% lidocaine)	27	2.0741	1.51723	.29199	1.4739	2.6743	.00	4.00
Group III (0.8mL of 4% articaine)	29	1.6552	1.69613	.31496	1.0100	2.3003	.00	4.00
Total	87	1.8851	1.50523	.16138	1.5643	2.2059	.00	4.00
P VALUE	0.572							

Graph 5.1: Intergroup comparison of efficacy of test agents while performing extraction (WONG-BAKERS SCALE)

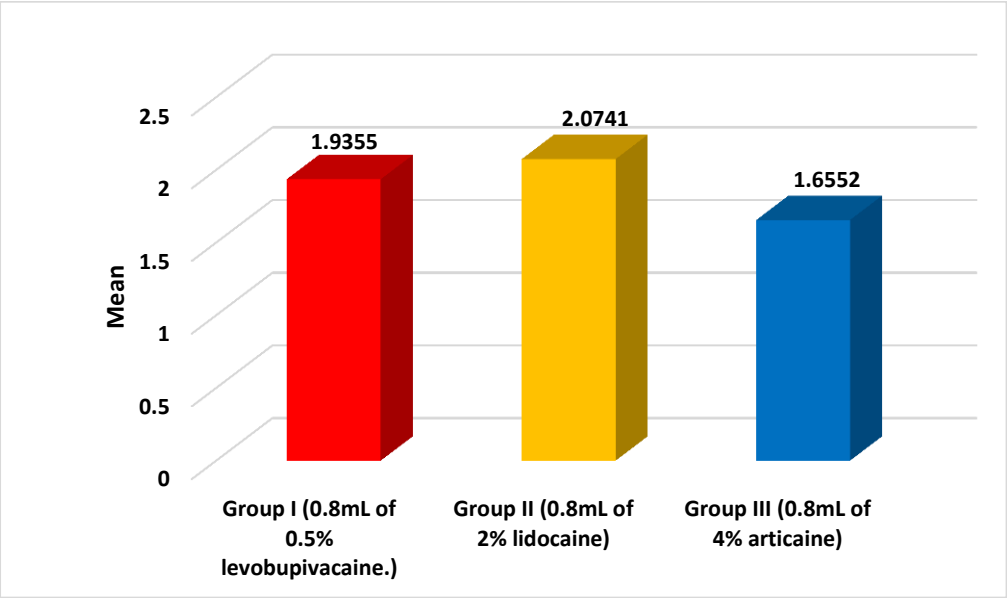


Table5.1 and Graph 5.1 depicts intergroup comparison of Mean pain scores while performing extraction. Out of total 87 subjects who underwent extraction; total of 31 subjects had a minimum pain score of 0 and a maximum pain score of 4 with a mean of 1.9355 was recorded in Group I. In Group II, 27 subjects were with a minimum pain score of 0 and a maximum pain score of 4 with a mean pain score value of 2.0741. Group III consisted of 29 subjects with a minimum pain score of 0 and a maximum score of 4 with a mean pain score of 1.6552. No significant difference was seen in the efficacy of test agents while performing extraction (*p= 0.572).*

In Group I (Levobupivacaine) out of 31 subjects, 9 subjects had a pain score of 4, 8 subjects had a pain score of 2, and 12 subjects had a pain score of 0 according to Wong Baker's pain rating scale.

In Group II (Lidocaine) out of 27 subjects, 7 subjects had a pain score of 4, 18 subjects had a pain score of 2 and 6 subjects had a pain score of 0 according to Wong Baker's pain rating scale.

In Group III (Articaine) out of 29 subjects, 8 subjects had a pain score of 4, 14 subjects had a pain score of 2 and 5 subjects had a pain score of 0 according to Wong Baker's pain rating scale.

TABLE 5.2: Intergroup comparison of efficacy of anaesthetic agents while performing vital pulp therapy (WONGBAKERSCALE)

Study groups	N=29 subjects	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum pain score	Maximum pain score
					Lower Bound	Upper Bound		
Group I (0.8mL of 0.5% levobupivacaine.)	8	1.7500	1.66905	0.59010	.3546	3.1454	0.00	4.00
Group II (0.8mL of 2% lidocaine)	11	2.5455	1.29334	0.38996	1.6766	3.4143	0.00	4.00
Group III (0.8mL of 4% articaine)	10	2.2000	1.75119	0.55377	0.9473	3.4527	0.00	6.00
Total	29	2.2069	1.54410	0.28673	1.6196	2.7942	0.00	6.00
P VALUE								0.558

Graph 5.2: Intergroup comparison of efficacy of anaesthetic agents while performing vital pulp therapy (WONG-BAKERS SCALE)

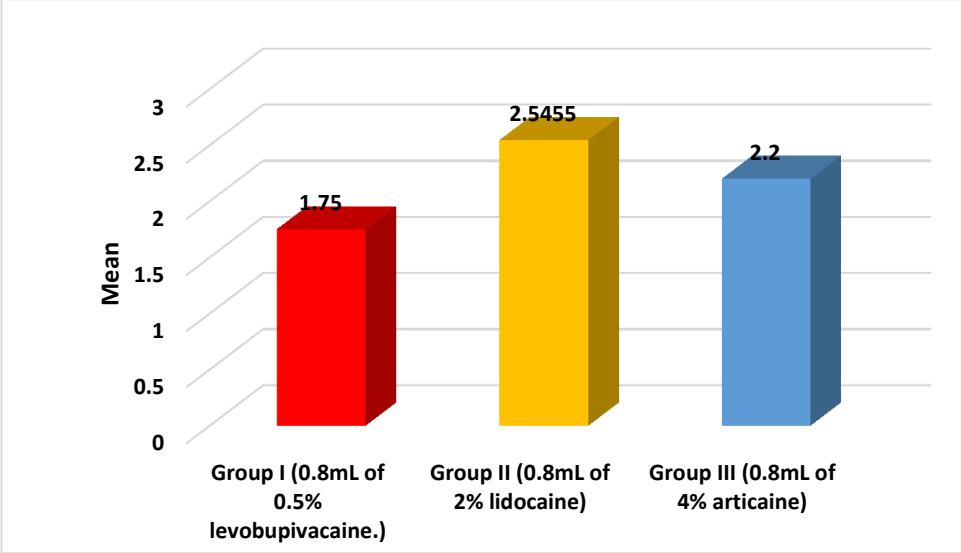


Table 5.2 and Graph 5.2 depicts intergroup comparison of Mean pain scores while performing pulp therapy. Out of 29 subjects who underwent pulp therapy, a total of 8 subjects with a minimum pain score of 0 and a maximum pain score of 4 with a mean of 1.7500 was recorded in Group I. In Group II 11 subjects had minimum pain score of 0 and a maximum pain score of 4 with a mean pain score of 2.5455 and in Group III,10 subjects were with a minimum score of 0 and a maximum score of 6 with a mean pain score of 2.2000. No significant difference was seen in the efficacy of test agents while performing extraction (*p>0.05).*

In Group I out of 8 subjects 2 subjects had a pain score of 4, 3 subjects had a pain score of 2 and 3 subjects had a pain score of 0 according to Wong Baker's pain rating scale.

In Group II out of 11 subjects 4 subjects had a pain score of 4, 5 subjects had a pain score of 2 and 2 subjects had a pain score of 0 according to Wong Baker's pain rating scale.

In Group III out of 10 subjects 1 subject had a pain score of 6, 7 subjects had a pain score of 2 and 2 subjects had a pain score of 0 according to Wong Baker's pain rating scale.

TABLE 5.3: Intergroup comparison of efficacy of anaesthetic agents while performing surgical procedure (WONGBAKERSCALE)

Study groups	N=4 subjects	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum pain score	Maximum pain score
					Lower Bound	Upper Bound		
Group I (0.8mL of 0.5% levobupivacaine.)	1	0.0000	.	.	.	.	0.00	0.00
Group II (0.8mL of 2% lidocaine)	2	2.0000	0.00000	0.00000	2.0000	2.0000	2.00	2.00
Group III (0.8mL of 4% articaine)	1	2.0000	.	.	.	.	2.00	2.00
Total	4	1.5000	1.00000	0.50000	0.0912	3.0912	0.00	2.00
P VALUE	-							

Graph 5.3: Intergroup comparison of efficacy of anaesthetic agents while performing surgical procedure (WONG-BAKERS SCALE)

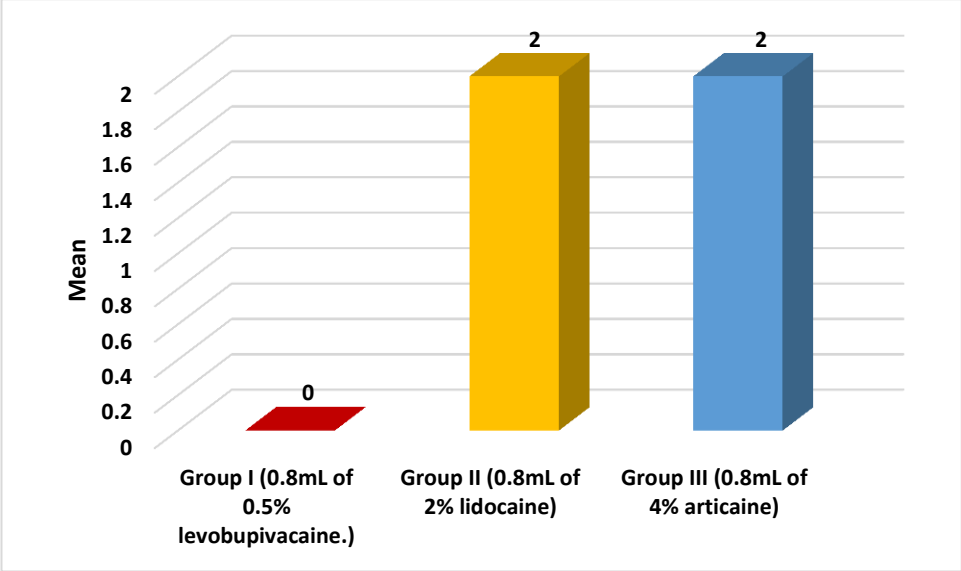


Table 5.3 and Graph 5.3 depicts intergroup comparison of Mean pain scores while performing surgical procedures. Out of 4 subjects who underwent surgical procedures, a total of 1 subject with a minimum pain score of 0.00 and a maximum pain score of 0.00 with a mean of 0.0000 was recorded in Group I. In Group II 2 subjects had minimum pain score of 2.00 and a maximum pain score of 2.00 with a mean pain score of 2.0000 and in Group III,1 subject was with a minimum score of 2.00 and a maximum score of 2.00 with a mean pain score of 2.00. No significant difference was seen in the efficacy of test agents while performing surgical procedures (*p>0.05).*

In Group I, 1 subject had a pain score of 2 according to Wong Baker's pain rating scale.

In Group II, 1 subject had a pain score of 2 and another subject had a pain score of 0 according to Wong Baker's pain rating scale.

In Group III, 1 subject had a pain score of 2 according to Wong Baker's pain rating scale.

DISCUSSION

The present *in-vivo* randomized control trial study was conducted to compare pain perception & anesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients, in the Department of Pediatric and Preventive Dentistry, BBDCODS, BBDU, Lucknow.

International Association for the Study of Pain **(IASP)**[1] stated that pain is "an unpleasant sensory and emotional experience connected with existing or potential tissue damage or defined in terms of such damage". It is one of the main reasons why pediatric patients seek dental care, particularly in the case of an emergency. The safest way to ensure pain-free therapy is through local anaesthesia.

According to American Academy of Pediatric dentistry **AAPD (2020)**[43] "Local anesthesia is the temporary loss of sensation including pain in one part of the body produced by a topically-applied or injected agent without depressing the level of consciousness". Effects like analgesia (loss of pain sensation) and paralysis (loss of muscular strength) can be induced when it is applied on specific nerve pathways (nerve block). It lowers the pain and discomfort associated with surgical and dental treatments for patients.

The first known LA agent, Procaine, an amino ester, was created from the application of cocaine in 1884, which first became popular. Lidocaine and Mepivacaine were two of the amide LA agents that were first introduced in the 1940s to 1950s. These were thought to be superior LA agents than Procaine because they were more powerful and had less allergic responses. Thereafter, Lidocaine became the new "gold standard". Lidocaine, also known as lignocaine and sold under the trade name Xylocaine, is an amino amide type local anaesthetic[65]. According to **Gordh T et al. (2010)**[44], Lidocaine normally starts functioning within few minutes when used for local anaesthesia or in nerve blocks, and it lasts for 30 minutes to three hours. Because of its low toxicity and higher effectiveness, lignocaine is still the preferred anaesthetic agent in dentistry. Thus, lignocaine was included in the study as a means of comparison.

Bupivacaine, a local anaesthetic agent that is more soluble in lipids and attaches to protein more readily than lignocaine. It accumulates in nerve membranes in a

relatively high concentration and stays bound for a longer period of time than lignocaine[66]. This results in a longer duration of action than lignocaine. Bupivacaine provides effective post-operative pain control and lasts better than any other regularly used anesthetic agents after the surgical procedures. Despite the fact that bupivacaine is often well tolerated, there have been sporadic instances of significant cardiovascular and nervous system side effects, including some fatalities, following an unintentional intravascular injection during obstetric analgesia and intravenous regional anaesthesia[59].

Levobupivacaine, the S-enantiomer of bupivacaine, is a brand-new anaesthetic agent with an improved safety profile compared to racemic bupivacaine and comparable effectiveness[58]. Additionally, it has been hypothesised that the clinical parameters of regional anaesthesia produced with 0.5% levobupivacaine may be comparable to or even superior to those produced with an equivalent dose of bupivacaine based on comparative clinical studies evaluating levobupivacaine (LBUP) for peripheral nerve blocks. According to **Aronson J et al. (2016)**[45], studies on animals and human volunteers, levobupivacaine showed to have benefits in terms of cardiotoxicity and CNS toxicity. Because of its less CNS and CVS toxicity 0.5% Levobupivacaine was included in this present study.

Articaine was introduced to the market in 1969 and is considered a "hybrid" amide due to its combination of an ester-group thiophene ring[57]. This thiophene ring enhances the potency and lipid solubility of the substance, allowing it to penetrate through the myelin sheath and cortical bone more effectively. In a study by **Joshi et al. (2020)**[46], Articaine was used for buccal infiltration and the results suggested that it is more effective in providing pulpal analgesia than Lignocaine as a buccal infiltration. Based on the effectiveness of Articaine used for buccal infiltration in providing analgesia for complex dental procedures on adults, Articaine was used in the present study for pediatric patients.

Anesthetic efficacy can be determined when a complex procedure is performed without any pain and discomfort. Patient’s pain complaints are subjective reports of an immeasurable stimulus.

There are few reported literatures about the pain perception, safety and efficacy of 0.5% Levobupivacaine and the mixed findings on the pain perception, safety and

efficacy on 2% Lidocaine with 1:100000 epinephrine and 4% Articaine with 1:100000 in pediatric age groups, this led to formulate the present study to compare anaesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine for complex dental procedures in children.

In the present study, evaluation of pain was done by Wong-Bakers pain rating scale (WBFPS). The Wong–Baker Faces Pain Rating Scale is a pain scale that was developed by **Donna Wong and Connie Baker**[47]. The scale shows a series of faces ranging from a happy face at 0, or "no hurt" to a crying face at 10. The Wong-Baker Pain Scale has six faces. Research by **Donna Wong and Connie Baker** identified that children had difficulty rating their pain with numbers yet responded well to facial expressions. Consequently, they developed the scale to help children better communicate their pain. Though , the assessment of pain can be done by the other pain rating scales like, Visual Analog Scale, the numeric rating scale, the graphic rating scale, and the Color Analog Scale, but the Faces pain rating scale is the scale with the largest support for its validity as discussed by the studies of **Malviya S et al. (2009)**[48] and **Walker B et al. (2019)**[49] conducted a study where they compared various pain rating scales and concluded that, Wong-Baker scale was preferred by children over the numeric rating scale, the graphic rating scale, the Pieces of Hurt tool, and the Color Analog Scale **.** The Wong Baker Faces Pain Scale has been extensively studied and its reliability and validity confirmed in children aged 3 to 18 years. **Khatri A et al. (2012)**[50] stated that Wong-Baker faces pain rating scale (WBFPS) was found to be more sensitive as compared to visual analogue scale (VAS). This Pain Rating Scale is used for children but can also be used for older age group between 6 and 15 years. This led to the inclusion of Wong Baker's pain rating scale in the present study for pain perception.

Infiltrations are more pleasant for the patient and the operator, easier to do, and prevent lingual numbness and potential nerve injury. They also do not need perforating the cortical bone. Hence Infiltrations can therefore be advantageous over nerve block if used to produce anaesthesia for complex dental procedures.

In the present study, subjects were in the age range of 5-16 with mean age of 8.40 in group I and 9.20 in Group II, while in Group III the mean age of the subjects was 9.25 **(Table 1 and Graph 1).** Out of 40 subjects in each group i.e. I &II, males were

more as compared to females (21 males and 19 females in Group I), (25 males & 15 females). Group III had more number of females than males (24 females &16 males)**.** The present study had a total sample size of 120 and there was no significant gender difference in this study **(Table 2 and Graph 2).** The study done by **Erfanparast L et al. (2020)**[51] which included the sample size of 48 children, aged 4 to 6, of both genders, with a mean age of 3.5 years showed no statistically significant difference in t which is in accordance to the result of the present study.

Results of the present study **(Table 3 and Graph 3)** reveals that, during administration of anesthetic agents, all the studied agents showed minimum score of 0 and a maximum score of 6. Pain perception was seen least in 0.5% Levobupivacaine (1.80) followed by 4% Articaine (2.00), 2% Lidocaine showed maximum value of pain (2.20). Result observed suggests that there was a statistical significant difference in perception of pain during administration of the anaesthetic agents. The findings of the present study are in accordance to a study by **Tirumalasetty S.S.M (2021)**[53] where the pain perception of 0.5% Bupivacaine and 2% lidocaine in periodontal surgery was compared and found that 0.5% Bupivacaine was less painful than 2% Lidocaine[53]. In contrast to the findings of the present study, **Afsal M.M et al. in 2019**, found that buffered lignocaine caused less pain compared to 4% articaine when administered as inferior alveolar nerve block (IANB) in children between the ages of 5 and 10.[52].

In the present study, safety parameters were assessed in terms of dizziness, vomiting, bleeding and trismus **(Table 4 and Graph 4)**. The incidence of bleeding was the highest followed by Trismus, Vomiting and Dizziness. These findings are in contrast to the findings of **J.K. Aronson (2016)**[54] where they compared safety between lidocaine and articaine and concluded that they both had a similar incidence of adverse effects. These effects included headache, paresthesia/hyperesthesia after injection, infection, and rash, and there was also one reported case of mouth ulceration. Another study conducted by **Doc.Y et al. (2006**)[55] concluded that there were no significant harmful effects such as bleeding, swelling, pain, jaw stiffness, headache, nausea, or dizziness associated with the use of articaine or prilocaine injections. The only adverse effect that was attributed to articaine was two instances of accidental lip numbness in patients. These findings were in accordance to the

findings of the present study. **M.F Stanley et al (2000)**[56] stated that in the lidocaine group the most common minor adverse event was post-procedural pain.

The present study revealed that there were differences in the effectiveness of the test agents used during extraction, pulp therapy and surgical procedures, but it was not statistically significant. Articaine was found to be the most effective anesthetic for extraction followed by Levobupivacaine and Lidocaine **(Table 5.1 and Graph 5.1)**. During pulp therapy, Levobupivacaine was determined to be the most effective anesthetic agent than Articaine and Lidocaine **(Table 5.2)**. For surgical procedures, again Levobupivacaine proved to be the most potent anesthetic agent than the other two local anaesthetics. **(Table 5.3)**.The present findings are in concordance with the study conducted by **Rood J et al (2002)**[61] where they compared the efficacy of 0.75% levobupivacaine (without vasoconstrictor) with 2% lignocaine (with adrenaline 1:80,000) and with placebo for postoperative pain relief in 93 patients having day surgery under general anaesthesia for the removal of impacted mandibular third molars and concluded that levobupivacaine had lower visual analogue pain scores (VAS) and seems to be a suitable alternative local anaesthetic to lignocaine with adrenaline for pain control after oral operations. Findings of the present study i.e Articaine is more effective than Lidocaine is supported by the systematic review 'conducted by **Kammerer et al. (2014)**[62] and **Fan et al. (2014)**[63], where they stated that articaine infiltration was 2.44 times more likely to produce successful pulpal anaesthesia than lidocaine nerve block.

The current study evaluated that only one patient out of 40 patients, who received Articaine for pulp therapy needed to adjunct with a supplementary nerve block for the completion of the procedure. The reason for need of supplementary nerve block may may be attributed due to the variations in the location of foramina and precision of injection etc. The same reasoning was explained by the study conducted by **Meechan et al (2005)**[64]**,** where they stated that local anaesthetic may not always be effective due to ineffective operator skill, variances in the location of the foramina, accessory innervations, precision of the injection, and variations in the course of the inferior alveolar nerve when given as a posterior superior alveolar nerve block without any palatal injections.

Anxiety management in pediatric dental treatment is crucial since it is frequently linked to the induction of pain and worsens pain perception. As a result, people feel more pain, and that suffering lasts longer and is remembered more vividly.

When the treatment can be completed painlessly, anaesthesia is considered effective. It is important to minimize or avoid pain during dental treatment for adults and children. Safe and effective local anesthetic agents can be used to prevent the sensation of pain during dental procedures, which can help establish trust and a positive relationship between the patient and dentist.This can also help to reduce anxiety and fear in patients and promote a positive outlook toward dental care.

The uniqueness of this study lies in the fact that it is one of the few *in- vivo* study performed to evaluate the anaesthetic efficacy and pain perception of Lidocaine, Articaine and Levobupivacaine together in pediatric dental patients.

Statistical analysis of the data obtained from the present study suggests that Levobupivacaine was found to be significantly more effective, safe and less painful when compared to Articaine and Lidocaine during anaesthetic solution administration.

CONCLUSIONS

The present *in-vivo* study made an attempt to determine the pain perception & anesthetic efficacy of 0.5% Levobupivacaine, 2% Lidocaine & 4% Articaine in pediatric dental patients. The findings of the study and the analysis of the observations lead to the following conclusions:

1) Pain associated during administration of anesthetic agents was minimum with 0.5% Levobupivacaine followed by 4% Articaine and maximum with 2% Lidocaine.

2) 0.5% Levobupivacaine showed fewer side effects than 4% Articaine and 2% Lidocaine. No major adverse effects were seen with any of the agents.

3) All three agents provided effective anesthesia for routine dental invasive procedures. The anesthetic efficacy of 0.5% Levobupivacaine was comparatively higher than 4% Articaine and 2% Lidocaine.

4) From the results of present study, it can be concluded that 0.5% Levobupivacaine is a safer and more efficacious alternative to 4% Articaine and 2% Lidocaine for painful dental procedures in fearful and anxious pediatric patients.

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ANNEXURE I

Ethical Clearance Form

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 14 **BBDCODS/04/2022**

Title of the Project: A Comparitive Evaluation of 0.5% Levobupivacaine, 2% Lidocaine & 4% Articaine as Local Anesthetic Agents in Pediatric Dental Patients.

Principal Investigator: Dr Raunaq Pradeep Sahu **Department:** Pediatric and Preventive Dentistry

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Raunaq Pradeep Sahu,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Puneet Ahuja)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

ANNEXURE II

Institutional Research Committee Approval

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"A Comparitive Evaluation of 0.5% Levobupivacaine, 2% Lidocaine & 4% Articaine as Local Anesthetic Agents in Pediatric Dental Patients"** submitted by **Dr Raunaq Pradeep Sahu** Post graduate student from the **Department of Pediatric and Preventive Dentistry** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **12th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

ANNEXURE III

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

PARTICIPANT INFORMATION DOCUMENT

1. Study Title

A comparative evaluationof 0.5% levobupivacaine, 2%lidocaine & 4% articaine as local anesthetic agents in pediatric dental patients.

2. Invitation Paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. What is the purpose of the study?

This study aims to compare pain perception & anesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients.

4**. Why have I been chosen?**

You have been chosen for this study as you are fulfilling the required criteria for this study.

5. **Do I have to take part?**

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you are still free to withdraw at any time and without giving a reason.

6. **What will happen to me if I take part?**

The participant will be benefited as the required dental treatment will be carried out once the local anaesthesia is effective. This will also help the patients to get the treatment done without pain, fear and anxiety.

7**. What do I have to do?**

This study requires treatment to be carried out only after the parent has given consent, and assent from the patient for the administration of local anaesthesia. Children of both the gender (male and female) with an age group of 5-16 years, requiring dental treatment categorized as ASA I and Frankl III and IV will be included in the study.

8. What is the procedure that is being tested?

The study will be carried out to evaluate and compare pain perception & anesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients. Patient selection will be done on basis of Frankl's Behaviour Rating scale and ASA I status.

9. What are the interventions for the study?

Dental procedures requiring administration of local anaesthesia.

10. What are the side effects of taking part?

Although there are no reports of serious side effects of the procedure, but the participant may have minimum side effects of the drugs like nausea or post-operative vomiting. If anything happens during the procedure we have skilled personnel and specialized equipments to manage any emergency.

If the participant suffers any other symptom post operatively, the guardian should immediately talk to the doctor.

11. What are the possible disadvantages and risks of taking part?

There are no disadvantages of taking part in this study, there can be minimum side effects of the drug.

12. What are the possible benefits of taking part?

The participant will be benefited as the required dental treatment will be carried out once the local anaesthesia is effective.This will also help the patients to get the treatment done without pain, fear and anxiety.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

Nothing will happen to the participants.

15. What if something goes wrong?

The problems/complaint will be handled by the HOD or the IRC.If something serious happens the institute will take care of the problems.

16. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The results of the study will be used to compare the pain perception and anaesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients. Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

The research is been done in the DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY, BBDCODS. The research is self -funded. The participants will have to pay for procedural charges as given by the institution.

19. Will the results of the study be made available after study is over?

Yes

20. Who has reviewed the study?

The HOD and the members of IRC/ IEC of the institution has reviewed and approved the study.

21. Contact for further information

Dr. Raunaq pradeep sahu

Department of Pediatric and Preventive Dentistry

Babu Banarasi College of Dental Sciences.

Lucknow-227105

Mob- 7869830026

Dr. LaxmiBala

Member Secretary of Ethics Committee of the institution,

Babu Banarasi College of Dental Sciences.

Lucknow

bbdcods.iec@gmail.com

THANK YOU FOR TAKING OUT YOUR PRECIOUS TIME FOR READING THE DOCUMENTS AND PARTICIPATING IN THE STUDY.

Signature of PI……

Name…….

Date……..

बाबूबनारसीदासकॉलेजऑफडेंटलसाइंसेज

(बाबूबनारसीदासविश्वविद्यालय)

बीबीडीसिटी, फैजाबादरोड, लखनऊ - 227105 (भारत)

प्रतिभागी के लिए सूचना पत्र

1. अध्ययनशीर्षक

बाल चिकित्सा दंत रोगियों में स्थानीय संवेदनाहारी एजेंटों के रूप में 0.5% लेवोबुपिवाकेन , 2% लिडोकेन और 4% आर्टिकाइन का तुलनात्मक मूल्यांकन।

2. निमंत्रण अनुच्छेद

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो दोस्तों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक के साथ इस पर चर्चा करें। किसी भी स्पष्टीकरण या अधिक जानकारी के लिए हमसे पूछें। आप भाग लेना चाहते हैं या नहीं, यह आपका निर्णय है।

3. **अध्ययन का उद्देश्य क्या है**?

इस अध्ययन का उद्देश्य बाल चिकित्सा दंत रोगियों में 0. 5% लेवोबुपिवाकेन, 2% लिडोकेन और 4% आर्टिकाइन की दर्द धारणा और संवेदनाहारी प्रभावकारिता की तुलना करना है।

4. मुझे क्यों चुना गया है?

आपको इस अध्ययन के लिए चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

5. क्यामुझेभागलेनाहै?

अनुसंधान में आप की भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैं, तो आपको रखने के लिए यह सूचना पत्र दिया जाएगा और सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप बिना किसी कारण के किसी भी समय वापस लेने के लिए स्वतंत्र हैं।

6. अगर मैं भाग लूंगा तो मेरा क्या होगा?

प्रतिभागी को लाभ होगा क्योंकि स्थानीय संज्ञाहरण प्रभावी होने के बाद आवश्यक दंत चिकित्सा उपचार किया जाएगा। इससे मरीजों को बिना दर्द, डर और चिंता के इलाज कराने में भी मदद मिलेगी।

7. मुझे क्या करना है?

इस अध्ययन के लिए माता-पिता की सहमति के बाद ही उपचार किया जाना आवश्यक है, और स्थानीय संज्ञाहरण के प्रशासन के लिए रोगी से सहमति प्राप्त करना आवश्यक है। अध्ययन में 5-16 वर्ष के आयु वर्ग के लिंग (पुरुष और महिला) दोनों के बच्चों को शामिल किया जाएगा, जिन्हें एएसए I और फ्रैंकल III और IV के रूप में वर्गीकृत दंत चिकित्सा उपचार की आवश्यकता होती है।

8. **वह प्रक्रिया क्या है जिसका परीक्षण किया जा रहा है**?

बाल चिकित्सा दंत रोगियों में 0.5% लेवोबुपिवाकेन, 2% लिडोकेन और 4% आर्टिकाइन की दर्द धारणा और संवेदनाहारी प्रभावकारिता का मूल्यांकन और तुलना करने के लिए अध्ययन किया जाएगा। रोगी का चयन फ्रैंकल के व्यवहार रेटिंग पैमाने और एएसए I स्थिति के आधार पर किया जाएगा।

9. **अध्ययन के लिए हस्तक्षेप क्या हैं**?

स्थानीय संज्ञाहरण के प्रशासन की आवश्यकता वाली दंत प्रक्रियाएं।

10. **भाग लेने के दुष्प्रभाव क्या हैं**?

हालांकि प्रक्रिया के गंभीर दुष्प्रभावों की कोई रिपोर्ट नहीं है, लेकिन प्रतिभागी को मतलीया पोस्ट-ऑपरेटिव उल्टी जैसी दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं। यदि प्रक्रिया के दौरान कुछ भी होता है तो हमारे पास किसी भी आपात स्थिति के प्रबंधन के लिए कुशल कर्मचारी और विशेष उपकरण हैं।

यदि प्रतिभागी किसी अन्य लक्षण पोस्टकोऑपरेटिव रूप से पीड़ित करता है, तो अभिभावक को तुरंत डॉक्टर से बात करनी चाहिए ।

11. **भाग लेने के संभावित नुकसान और जोखिम क्या हैं**?

इस अध्ययन में भाग लेने के कोई नुकसान नहीं हैं, दवा के न्यूनतम दुष्प्रभाव हो सकते हैं।

12. **भाग लेने के संभावित लाभ क्या हैं**?

प्रतिभागी को लाभ होगा क्योंकि स्थानीय संज्ञाहरण के प्रभावी होने के बाद आवश्यक दंत चिकित्सा उपचार किया जाएगा। इससे रोगियों को दर्द, भय और चिंता के बिना उपचार करने में भी मदद मिलेगी।

13. **यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा** ?

यदि अनुसंधान के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है, तो आपको इनके बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र हैं, आपका शोधकर्ता आपको बताएगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. **जब शोध अध्ययन रुक जाता है तो क्या होता है**?

प्रतिभागियों को कुछ नहीं होगा।

15. **अगर कुछ गलत हो जाए तो क्या होगा**?

समस्याओं / शिकायतको HOD या IRC द्वारा नियंत्रित किया जाएगा। अगर कुछ गंभीर होता है तो संस्थान समस्याओं का ध्यान रखेगा।

16. **क्या इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा** ?

हां इसे गोपनीय रखा जाएगा।

17. **शोध अध्ययन के परिणामों का क्या होगा** ?

अध्ययन के परिणामों का उपयोग बाल चिकित्सा दंत रोगियों में 0.5% लेवोबुपिवाकेन, 2% लिडोकेन और 4% आर्टिकाइन की दर्द धारणा और संवेदनाहारी प्रभावकारिता की तुलना करने के लिए किया जाएगा। किसी भी रिपोर्ट/प्रकाशन के मामले में आपकी पहचान गोपनीय रखी जाएगी।

18. **अनुसंधान का आयोजन कौन कर रहा है ?**

अनुसंधान को समर्पित और पूर्व दंत चिकित्सा, बी बी डी सी ओ डी एस के विभाग में किया गया है । अनुसंधानस्व-आधारित है। प्रतिभागियों को संस्था द्वारा दिए गए प्रक्रियात्मक शुल्क के लिए भुगतान करना होगा।

19. **क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे**?

हाँ

20. **अध्ययन की समीक्षा किसने की ?**

संस्था के एच ओ डी और आई आर सी / आई ई सी के सदस्यों ने अध्ययन की समीक्षा और अनुमोदन किया है।

21. **अधिक जानकारी के लिए संपर्क करें**

डॉ। रौनक प्रदीप साहू

बालरोग और निवारक दंत चिकित्सा विभाग

बाबू बनारसी कॉलेज ऑफडेंट लसाइंसेज।

लखनऊ-**227105**

मोब- **7869830026**

डॉ लक्ष्मी बाला

संस्था की आचार समिति के सदस्य सचिव,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ

bbdcods.iec@gmail.com

अध्ययन के दौरान दस्तावेजों और साझेदारी के लिए आपका समय निकालने के लिए धन्यवाद।

प्रमुख अन्वेषक के हस्ताक्षर……

नाम. . . . . .

दिनांक……

डॉ. लक्ष्मीबाला

संस्था की आचार समिति के सदस्य सचिव,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ

bbdcods.iec@gmail.com

दस्तावेजों को पढ़ने और अध्ययन में भाग लेने के लिए अपना कीमती समय निकालने के लिए धन्यवाद।

पी आई के हस्ताक्षर .....

नाम……।

तारीख……..

ANNEXURE IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi DasUniversity)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

CHILD INFORMATION DOCUMENT

Study title:— To compare pain perception & anesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients.

Introduction

This study aims to compare pain perception & anesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients.We invite you to participate in this study.

What will you have to do?

To participate in this research study, patient must be fall in Frankl III and IV and ASA I , if found to fulfill pre-specified criteria, you will be eligible to be enrolled in this research study.

Since you are in the age group of 5-16 years we ask your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

Risks and discomforts

There is no foreseen significant risk / hazard to your health, if you wish to participate in the study. If you follow the directions of the dentist in charge of this study and you are injured due to any procedure given under the study plan, the institute will take care.

Benefits

The participant will be benefited as the required dental treatment will be carried out once the participant gets anaesthetized.This will help the patients to get the treatment done without pain, fear and anxiety.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study. Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority. Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent / guardian can take away your authorization to collect process and disclose data about you at any time.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. You may stop participating in the research at any time you wish. The study investigator may decide to withdraw you from the study if he/she considers it is in your best interest

You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information.

Parents responsibilities

It is the responsibility of your parent / guardian to come along with you to the centre during the study period for all the visits unless you withdraw or are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report any expected or unexpected reactions (side effects) that you notice during the studyperiod.

We expect your co-operation throughout the study.

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

के लिए सूचना पत्र

अध्ययन का शीर्षक: - बाल चिकित्सा दंत रोगियों में 0.5% लेवोबुपिवाकेन, 2% लिडोकेन और 4% आर्टिकाइन की दर्द धारणा और संवेदनाहारी प्रभावकारिता की तुलना करने के लिए।

परिचय

इस अध्ययन का उद्देश्य बाल चिकित्सा दंत रोगियों में %0.5लेवोबुपिवाकेन, %2लिडोकेन और %4आर्टिकाइन की दर्द धारणा और संवेदनाहारी प्रभावकारिता की तुलना करना है। हम आपको इस अध्ययन में भाग लेने के लिए आमंत्रित करते हैं।

आपको क्या करना होगा?

इस शोध अध्ययन में भाग लेने के लिए, रोगी को फ्रैंकल III और IV और एएसए I में होना चाहिए, यदि पूर्वनिर्धारित मानदंडों को पूरा करना पाया जाता है-, तो आप इस शोध अध्ययन में नामांकित होने के पात्र होंगे।

चूंकि आप वर्ष के आयु वर्ग 16-5में हैं, इसलिए हम आपके साथ जाने वाले माता-अभिभावक से भी इसी तरह के फॉर्म पर हस्ताक्षर करने के लिए कहते हैं/पिता, जिसे पेरेंट इंफॉर्मेड कंसेंट फॉर्म कहा जाता है।

जोखिम और असुविधाएँ

यदि आप अध्ययन में भाग लेना चाहते हैं, तो आपके स्वास्थ्य के लिए कोई महत्वपूर्ण खतरा / खतरा नहीं है। यदि आप इस अध्ययन के प्रभारी दंत चिकित्सक के निर्देशों का पालन करते हैं और अध्ययन योजना के तहत दी गई किसी भी प्रक्रिया के कारण आप घायल हो जाते हैं, तो संस्थान ध्यान रखेगा।

लाभ

प्रतिभागी को लाभान्वित किया जाएगा क्योंकि एक बार प्रतिभागी को एनेस्थेटाइज किए जाने के बाद आवश्यक दंत चिकित्सा की जाएगी। इससे रोगियों को दर्द, भय और चिंता के बिना उपचार करने में मदद मिलेगी।

गोपनीयता

आपके मौजूदा मेडिकल रिकॉर्ड तक पहुँचा जा सकता है; आपके स्वास्थ्य संबंधी व्यक्तिगत जानकारी को अध्ययन करने के उद्देश्य से अध्ययन जांचकर्ताओं द्वारा एकत्र और संसाधित किया जा सकता है। आपके बारे में जानकारी एकत्र की जाएगी और एक निर्दिष्ट नंबर के साथ फाइलों में संग्रहीत की जाएगी, और सीधे आपके नाम के साथ नहीं। अध्ययन से संबंधित सभी दस्तावेज केवल अध्ययन अन्वेषक, प्रायोजक, आचार समिति और नियामक प्राधिकरण द्वारा एक्सेस किए जाएंगे।आपके माता-पिता / अभिभावक प्रक्रिया को एकत्र करने और किसी भी समय आपके बारे में डेटा का खुलासा करने के लिए आपके प्राधिकरण को दूर कर सकते हैं।

मना करने या वापस लेने का अधिकार

यदि आप ऐसा नहीं करना चाहते हैं तो आपको इस शोध में भाग लेने की आवश्यकता नहीं है। आप किसी भी समय अपनी इच्छानुसार शोध में भाग लेना बंद कर सकते हैं। अध्ययन अन्वेषक आपको अध्ययन से पीछे हटने का निर्णय ले सकता है यदि वह समझता है कि यह आपके सर्वोत्तम हित में है

आपको अध्ययन के दौरान विकसित महत्वपूर्ण नए निष्कर्षों से अवगत कराया जाएगा ताकि आप नई जानकारी के प्रकाश में अध्ययन में अपनी भागीदारी पर विचार कर सकें।

माता-पिता की जिम्मेदारियां

यह आपके माता-पिता / अभिभावक की जिम्मेदारी है कि आप सभी यात्राओं के लिए अध्ययन अवधि के दौरान केंद्र में तब तक साथ आए जब तक कि आप वापस नहीं आते या अध्ययन से समय से पहले ही बंद नहीं हो जाते। अध्ययन अवधि के दौरान किसी भी अपेक्षित या अप्रत्याशित प्रतिक्रियाओं (दुष्प्रभाव) की रिपोर्ट करना आपकी जिम्मेदारी और आपके माता-पिता / अभिभावक की भी जिम्मेदारी है।

हम पूरे अध्ययन में आपके सहयोग की अपेक्षा करते हैं।

ANNEXURE V

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study- To compare pain perception & anesthetic efficacy of 0.5% levobupivacaine, 2% lidocaine & 4% articaine in pediatric dental patients.

Study Number……..

Subject's Full Name…….
Date of Birth/Age ……
Address of the Subject…….
Phone no. and e-mail address……
Qualification ……
Occupation: Student / Self Employed / Service /
Housewife/Other (Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject.....(For the purpose of
compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. **OR** I have beenexplained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided sucha use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [✓] No [ ] Not Applicable [ ]**

I agree to participate in the above study. I have been explained about the complications andside effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally AcceptableRepresentative:……..
Signatory's Name…….
Date …….
Signature of the Investigator……
Date……..
Study Investigator's Name**.....**
Date……..
Signature of the witness……
Date……..
Name of the witness……
Received a signed copy of the PID and duly filled consent form Signature/thumb impression of the subject or legally acceptable representative Date……..

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

सहमति प्रपत्र (अंग्रेज़ी)

बाल चिकित्सा दंत रोगियों में स्थानीय संवेदनाहारी एजेंटों के रूप में 0.5% लेवोबुपिवाकेन, 2% लिडोकेन और 4% आर्टिकाइन का तुलनात्मक मूल्यांकन।

स्टडी नंबर……..

विषय का पूरा नाम …….

जन्म तिथि/आयु ……

विषय का पता…….

फोन नंबर। और ई-मेल पता ……

योग्यता ……

व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)

विषय की वार्षिक आय……

नाम और नामांकित व्यक्ति (ओं) और विषय के साथ उसका संबंध (के प्रयोजन के लिए)

मुकदमे से संबंधित मौत के मामले में मुआवजा)।

1. मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया है

……..उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे

स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी। इसके संबंध में आयोजित किया जा सकता है, भले ही मैं परीक्षण से हट जाऊं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएगी।

4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।

5. मैं भविष्य के शोध के लिए संग्रहीत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमति देता हूं। हाँ [] नहीं [ ]

लागू नहीं [ ]

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने प्रतिभागी/स्वयंसेवक के मुझे दिए गए सूचना दस्तावेज को भी पढ़ और समझ लिया है।

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):.....

हस्ताक्षरकर्ता का नाम……. तारीख .....।

अन्वेषक के हस्ताक्षर ..... तारीख……..

अध्ययन अन्वेषक का नाम ..... तारीख……

गवाह के हस्ताक्षर…… तारीख……..

गवाह का नाम .....

पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से स्वीकार्य प्रतिनिधि

दिनांक……..

ANNEXURE VI

American Society of Anaesthesiologists Classification

Classification	Description
ASA 1	Healthy patients
ASA 2	Mild to moderate systemic disease caused by the surgical condition or by other pathological processes, and medically well controlled
ASA 3	Severe disease process which limits activity but is not incapacitating
ASA 4	Severe incapacitating disease process that is a constant threat to life
ASA 5	Moribund patient not expected to survive 24 hours with or without an operation
ASA 6	Declared brain-dead patient whose organs are being removed for donor purposes

ANNEXURE VII

ANNEXURE VIII

CASE HISTORY PROFORMA
DEPARTMENT OF ORAL MEDICINE AND RADIOLOGY
BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

OPD NO. **CASE NO.** **DATE:**

NAME: **AGE:** **GENDER:**
OCCUPATION:
ADDRESS:

CONTACT NO:

CHIEF COMPLAINT:

PAST MEDICAL HISTORY:

DRUG ALLERGY:

PAST DENTAL HISTORY:

FAMILY HISTORY:

DELETERIOUS HABITS:

GENERAL PHYSICAL EXAMINATION:

BLOOD PRESSURE - PULSE - RESPIRATION RATE -

EXTRAORAL EXAMINATION:

INTRAORAL EXAMINATION:

Hard Tissue Examination:

Soft Tissue Examination:

PROVISIONAL DIAGNOSIS:

RADIOGRAPHIC INVESTIGATION:

1. **Orthopantomogram**
2. **Lateral Cephalogram**

Plagiarism Report

Document Information

Analyzed document	A Comparative Evaluation Of 0.5% Levobupivacaine, 2%Lidocaine & 4% Articaine As Local Anesthetic Agents In Pediatric Dental Patients (D158502493)
Submitted	2023-02-13 10:24:00
Submitted by	
Submitter email	1180327004@bbdu.ac.in
Similarity	5%
Analysis address	1180327004.bbduni@analysis.urkund.com

Sources included in the report

SA	plaigairism.docx Document plaigairism.docx (D88145154)	1
SA	Main thesis of Dr. Liza Mohanty, MDS, Ist submission.pdf Document Main thesis of Dr. Liza Mohanty, MDS, Ist submission.pdf (D91479027)	3
SA	02-ALL-CHAPTERS-NEW.docx Document 02-ALL-CHAPTERS-NEW.docx (D151472809)	1
W	URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7220965/ Fetched: 2020-09-11 12:17:55	1
SA	IDBs vs Infiltrations for anaesthesia of mandibular teeth.docx Document IDBs vs Infiltrations for anaesthesia of mandibular teeth.docx (D56235206)	1
SA	PLAGIARISM CHECK.docx Document PLAGIARISM CHECK.docx (D35070978)	2
SA	Sakthi Final thesis PALAGRAIRSM.docx Document Sakthi Final thesis PALAGRAIRSM.docx (D153086101)	1

Entire Document

INTRODUCTION
Pain is defined

73% MATCHING BLOCK 1/10 SA plaigairism.docx (D88145154)

as "an unpleasant sensory and emotional experience linked with existing or potential tissue damage, or explained in terms of such damage" by the

International Association for the Study of Pain (IASP)1.