A COMPARATIVE EVALUATION OF ARTICAINE (4%) FOR BUCCAL INFILTRATION VS LIDOCAINE (2%) FOR NERVE BLOCK AS LOCAL ANESTHETIC AGENT IN CHILDREN.

Dissertation

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MASTER OF DENTAL SURGERY

In

PEDODONTICS AND PREVENTIVE DENTISTRY

By

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

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I hereby declare that this dissertation entitled **"A COMPARATIVE EVALUATION OF ARTICAINE (4%) FOR BUCCAL INFILTRATION VS LIDOCAINE (2%) FOR NERVE BLOCK AS LOCAL ANESTHETIC AGENT IN CHILDREN"** is a bonafide and genuine research work carried out by me under the guidance of ***Dr. Neerja Singh***, Professor and Head, Department of Pedodontics and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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Dr. Shaifali Agrawal

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S.NO	ABBREVIATIONS	FULL FORM
1.	IANB	Inferior alveolar nerve block
2.	BI	Buccal infiltration
3.	AI	Articaine Infiltration
4.	BI	Buccal Infiltration
5.	VAS	Visual Analogue Scale
6.	ASA	American Society of Anesthesiologists
7.	EPT	Electric Pulp Tester
8.	A100	Articaine with 1:100,000 epinephrine
9.	A200	Articaine with 1:200,000 epinephrine

Aim: To evaluate and compare efficacy of articaine (4%) buccal infiltration and lidocaine (2%) nerve block as local anesthetic agent for painful dental procedures in children.

Materials and Method: The present in-vivo study was carried out in children with the age group between 6 to 18 years including both the genders with a sample size of 40. The subjects were randomly divided into two groups on the basis of arch involved: Group A & Group B. Group A consist of 20 patients randomly receiving both the anesthetic agents (4% articaine infiltration and 2% lidocaine nerve block) at an interval of 1 week in the maxillary arch and Group B consist of 20 patients randomly receiving the two anesthetic agents (4% articaine infiltration or 2% lidocaine nerve block) in the mandibular arch at an interval of 1 week. Pain during administration of anesthetic agents and intra-operative pain was assessed by VAS in both the arches. Onset of anesthesia for both the agents was recorded from the time of injection to the start of objective sign in both the arches.

Results: Pain during administration of lignocaine as nerve block was more in maxillary arch than articaine with buccal infiltration, which was statistically significant (p=0.001) while pain score was more with lignocaine in mandibular arch (p=0.06) but not statistically significant. Intra-operative pain score was similar for both the anesthetic agents in maxillary (p=1.00) and mandibular arch (p=1.00) respectively. Articaine showed significantly shorter onset of anesthesia in both the arches i.e. maxillary arch (p=0.0009) and mandibular arch (p=0.0001).

Conclusion: Anesthetic efficacy of 4% articaine with infiltration and 2% lidocaine with nerve block was found to be similar. Hence, articaine infiltration can be used as an alternative to lignocaine nerve block.

Keywords: Articaine, Lignocaine, Local anesthetic agent.

One of the important aspects for the successful treatment in pediatric dentistry is the control of pain. If a child experiences pain during the dental procedure, he/she might develop reluctance or phobia towards future dental treatment. Therefore, it is important at each visit to reduce discomfort and to control painful situation. Local anesthesia is a technique that prevents discomfort, eliminates pain and renders the dental treatment to be carried out effectively and comfortably. 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 nerve [1]. Painless dentistry and local anesthesia are the two different terms which are interlinked and plays a key role towards successful management of an individual during dental procedures.

Adequate local anesthesia is essential for the painless dental procedures and it can be achieved by administration of local anesthetic agent. According to the historical review, before the discovery of local anesthetic agents people used uncomfortable and intolerable methods for dental treatment. Introduction of local anesthetic agent is a boon which has revolutionized the field of dentistry. The era of local anesthetics started with the discovery of cocaine in 1860, following which range of anesthetic drugs was introduced, which forms the backbone of pain control in dentistry. [2]

In 1943, first amide local anesthetic lidocaine hydrochloride was synthesized and was introduced to the dental market in 1948, this advancement brought a transformation in clinical practice and within few years it became the most popular and widely used local anesthetic agent.[2] Lidocaine is also considered as the "gold standard" for comparison with other anesthetic drugs.[1] Lidocaine has minimal adverse drug reactions and is considered to be the safest anesthetic agent but in case of unintentional intravascular injections plasma concentration of the drug increases leading to systemic toxicity.[3] Other drawbacks like limited diffusibilty, need for multiple injections and complex biotransformation has led to the discovery of an agent which has few advantages over lidocaine.

Articaine is an amide type of local anesthetic agent which possesses clinical actions similar to lidocaine but has unique physicochemical properties. Articaine has thiophene ring instead of benzene ring, which accords for the lipid solubility of the drug resulting in high tissue penetration and diffusion. Articaine is the only amide

local anesthetic agent which has an ester linkage rendering the drug to undergo biotransformation not only in liver but also in plasma, consequently reducing its half life to 20 min contrary to lidocaine which undergoes biotransformation only in liver and has a half life of 90 min[1]. Articaine gets rapidly hydrolyzed in blood into its inactive metabolite which reduces the systemic toxicity of drug in blood even on repeated injections. Articaine's superior reputation has been primarily based on clinician's opinion that it possesses enhanced diffusion properties and better anesthetic efficacy.

Recent evidences have shown that buccal infiltration with articaine produces palatal and lingual anesthesia, thus, eliminating the need of block anesthesia and multiple injections which are uncomfortable and painful to children. Use of articaine achieves successful pain control and is considered to be safer anesthetic agent than lidocaine[4].

Despite its popularity, articaine is not routinely used as an anesthetic agent by clinicians in their practice may be because of limited literature. Present study is formulated to compare the anesthetic efficacy of 4% articaine as buccal infiltration with 2% lidocaine as nerve block to contribute to a more profound knowledge about the quality of articaine as local anesthetic agent.

AIM

To evaluate and compare efficacy of articaine (4%) buccal infiltration and lidocaine (2%) nerve block as local anesthetic agent for painful dental procedures in children.

OBJECTIVES

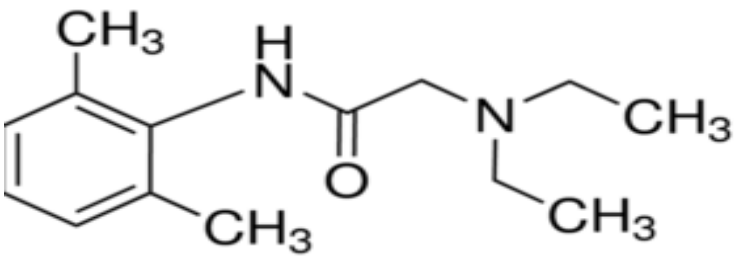
1. To compare the pain perceived by the patients while administering articaine (4%, buccal infiltration) and lidocaine (2%, nerve block) as an anesthetic agent.
2. To assess and compare the effectiveness of articaine (4%, buccal infiltration) and lidocaine (2%, nerve block) as local anesthetic agent in maxillary arch.
3. To assess and compare the effectiveness of articaine (4%, buccal infiltration) and lidocaine (2%, nerve block) as local anesthetic agent in mandibular arch.

Local anesthesia is an essential part in dentistry for pain control during treatment. Many researches have been conducted in search for an ideal local anesthetic agent which can relieve pain effectively without having any adverse effects. Till date, wide range of anesthetics have been synthesized out of which lidocaine is most popular[5]. Lidocaine has been widely used to produce local anesthesia in pediatric and adult patients. Articaine is an amide type of local anesthetic agent that has been used since 1976 due to enhanced safety and efficacy. Articaine when administered as buccal infiltration has the potential to diffuse through the soft and hard tissue eliminating the need for palatal/lingual nerve block as in case of lidocaine. Clinical studies have been conducted for comparing articaine and lidocaine in terms of anesthetic concentration, technique of anesthetic administration, onset and duration of anesthesia, anesthetic efficacy etc, but the results were contradictory[6,7,8]. Therefore, the purpose of this study is to evaluate and compare efficacy of articaine (4%) infiltration and lidocaine (2%) nerve block as local anesthetic agent for painful dental procedures in children.

Lidocaine

Lidocaine was discovered in 1943 by Lofgren and his assistant Lundqvist. Official clinical trial of lidocaine started in 1944 and it lasted for 3 years. After completion of trial on May 11, 1948, the patent for lidocaine was granted under the brand name Xylocaine. In November 1948, Xylocaine was approved by the Food and Drug Administration for use in the United States[9]. It is the first amide local anesthetic agent which has replaced procaine for the use in dentistry.

Chemical Structure



3, 2- Diethylamino 2′, 6-acetoxylidide Hydrochloride

Formulations Used in Dentistry

It is available in three formulations: 2% without a vasoconstrictor, 2% with epinephrine 1:50,000 and 2% with epinephrine 1:100,000. The only recommended use of 2% with epinephrine 1:50,000 are for hemostasis where small volumes of the drug molecules are infiltrated directly into the surgical site.

Pharmacokinetics:

Lignocaine is metabolised in the liver by the cytochrome P450 system forming monoethylglycerine and xylidide; xylidide is a local anesthetic and potentially toxic.[10] **Puente NW et al** in their study reported metabolite 2, 6-xylidine of lignocaine to be carcinogenic in a rat model. Excretion of lignocaine occurs via the kidneys[11]. **A. H. Beckett et al** conducted a study on metabolism and excretion of lignocaine in man in 1966 and observed that less than 10% of lignocaine is excreted in urine without being metabolized**[12]**. The half-life of lignocaine has been shown to be approximately 90 min.[1]

Dosage:

According to most manufacturers recommendations, the maximum dose of lignocaine for infiltration and regional nerve block techniques is 300 mg (approximately 4.5 mg/kg) without a vasoconstrictor and 500 mg (7 mg/kg) with 1:200000 adrenalin (based on a 70 kg patient).

Toxicity:

Central nervous System and Cardiovascular system are affected by lidocaine toxicity. Lignocaine toxicity can result when either the correct dose of lignocaine is inadvertently administered or delivered via the intravascular route, or when high doses of the drug have been administered[13]. First symptoms and signs of lidocaine toxicity are usually neurological with numbness of the mouth and tongue. Shortly afterwards, there is the onset of tinnitus, confusion, seizures, and potentially coma. Cardiovascular toxicity usually manifests itself as tachycardia and hypertension but with increasing toxicity bradycardia and hypotension occur. Ventricular arrhythmias and cardiac arrest are also known side effects[14]. According to a case report

published by **R Jayanthi et al in 2016,**[15] 3 healthy individuals developed tonic clonic seizures almost instantly after administration of Lidocaine hydrochloride with adrenaline 1:100,000 for dental extraction of maxillary tooth.

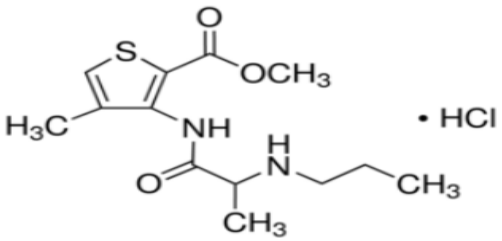
Efficacy and Failure:

Lidocaine has been used in dentistry over decades for controlling pain and producing profound anesthesia. It is characterized by rapid onset of action, produces profound anesthesia and is a potent drug[1]. It binds to the protein receptor sites rapidly and produces intermediate duration of action. In 1943 **Lofgren** by his experiments stated "*LL30 is superior to the usually used local anesthetic Novocain (procaine)"*. Effective dental concentration is 2%, which is considered the most efficacious for use in pediatric and adult patients.[16] Lidocaine in dentistry is indicated for topical anesthetic action, infiltration or nerve block. Despite producing successful anesthesia, lidocaine is associated with anesthetic failure especially after an inferior alveolar nerve block, **Madan et al.** suggested a number of reasons for high failure rate of the IAN block which includes (1) accessory nerve supply (mylohyoid nerve, cervical cutaneous nerve C1, C2, auriculotemporal nerve); (2) variable course of IAN; (3) variation in foramen position; and (4) bifid alveolar nerve of bifid mandibular canal[7]. Clinical studies have shown the failure of IANB to be approximately 44-84% and failure of infiltrations to be approximately 0-36%[17].

Articaine

Articaine hydrochloride was initially named as Carticaine hydrochloride, it was first synthesized in 1969 by Rusching et al[17]. The drug was approved for use in Germany and Europe in 1976. Carticaine was renamed as Articaine in 1984, later on in the same year articaine became available in Canada[1]. In 2000, FDA approved articaine for use in the market of U.S. Articaine possesses many physicochemical properties of other anesthetic agents but has few additional properties which make this drug highly popular.

Chemical Structure:



4-methyl-3(2-[propylamino]propionamido)-2-thiophenecarboxylic acid, methyl ester hydrochloride.

Pharmacokinetics:

About 90% - 95% of articaine is metabolized quickly in the blood by plasma esterases and 5-10% is broken down in the liver by hepatic microsomal enzymes which is relatively a slow process[2]. Once rapidly hydrolysed, articaine reaches the systemic circulation not as an active substance but as an inactive metabolite, articainic acid. Articaine has a plasma half life of 20 minutes[18].

Jakobs et al.[19] evaluated the pharmacokinetics of both 2% and 4% articaine in children and found plasma half-lives of 18.5 min and 23.6 minutes, respectively. **Muller et al**.[20] studied the pharmacokinetics of articaine by administering it as mandibular nerve block anesthesia using 2 mL of 4% articaine with 1:200,000 epinephrine in 10 alert patients and 10 patients under general anesthesia. Blood samples were collected from peripheral veins and a half-life of approximately 20 minutes was found. Muller concluded that compared to other local anesthetics, whose plasma half-lives may vary between 1 and 3.6 hours, the 20 minute value found for articaine was very low.

Articaine is largely excreted in urine as the metabolite articainic acid, followed by articainic acid glucuronide and the parent drug.

Pharmacodynamics:

Articaine is unique among all local anesthetics, it is the only amide type of local anesthetic agent which contains thiophene ring instead of an aromatic benzene ring and an additional ester group[17]. Thiophene ring present in the structure is responsible for increased liposolubility and high protein binding. Increased lipid solubility allows more anesthetic molecule of articaine to diffuse across the lipid

nerve membrane thereby increasing the drug potency. Articaine is 95% plasma protein bound, this high degree of protein binding increases the tendency for articaine to attach securely to the protein receptor site, providing longer duration of clinical activity[4]. Ester group present in the structure allows it to get hydrolysed both by plasma esterases and by hepatic microsomal enzymes.

In the U.S. many claims were made by dentists, some good (faster onset, increased success rates; "don't miss as often"); some bad (increased risk of parasthesia)[1]. Clinically it has been claimed that maxillary buccal infiltration of articaine provides palatal soft tissue anesthesia, obviating the need for palatal injection which, in many hands is traumatized[21]. Articaine can also provide pulpal and lingual anesthesia when administered by infiltration in the adult mandible[22]. A review article on articaine's clinical pharmacology reported, "In dentistry, articaine is the drug of choice in vast majority of literature.[23]

Dosage:

According to manufacturer's recommendation articaine has a maximum safe dose of 7.0mg/kg of body weight (upto 500mg) for the adult patients and for children it is 5mg/kg of body weight[1,5]. A 1.7 mL cartridge of 4% articaine contains 68 mg of the drug which is almost twice the amount of drug (68mg) as a 1.8 mL cartridge of 2% lidocaine (36 mg). The maximum number of cartridges of articaine that a patient can be safely given would therefore be about half the number of cartridges that the same patient could receive if lidocaine were selected[24].

Concentration of Articaine:

FDA approved use of 4% articaine HCL with epinephrine 1:100,000 in 2000 and with epinephrine 1:200,000 in 2006.

Efficacy:

Anesthetic concentration of articaine either 2% or 4%, has no effect on clinical efficacy.

Hintze A, Paessler L[25] did a comparative randomized double-blind study to investigate the efficacy of articaine 4% (epinephrine 1:200,000) and articaine 2%

(epinephrine 1:200,000), both the concentration of articaine (4% and 2%) was used as infiltration for extractions of maxillary and mandibular teeth. After the statistical analysis it was found that 2% and 4% articaine with 1:200,000 adrenaline have same anaesthetic effect.

Articaine should always be used in association with a vasoconstrictor because of its vasodilatation properties, but vasoconstrictor concentrations have little effect on clinical properties of articaine.

Tófoli G R et al[26] did a randomized double blind-study to compare the effectiveness of 4% articaine with 1:100,000 and 4% articaine with 1:200,000 epinephrine as an inferior alveolar nerve block in mandibular first premolars. No significant differences in the duration of anesthesia, and ability to induce pulp and soft tissue anesthesia, as determined by electric pulp tester (EPT) were observed between 4% articaine with 1:100,000 adrenaline (A100) and 4% articaine with 1:200,000 adrenaline (A200).

Similarly, **Moore et al** [27] conducted a study and found no significant differences in the level of pulpal anesthesia between 4% articaine with 1:100,000 adrenaline (A100) and 4% articaine with 1:200,000 adrenaline (A200) for maxillary infiltration and IANB anesthesia. **Hersh et al**.[28] carried out a study and concluded similar plasma concentration curves in patients receiving both 4% A100 and 4% A200 and concluded that 4% A200 is as safe as 4% A100.

Toxicity:

Various instances of local anesthetic toxicity have been reported. The earliest and most common response to any local anesthetic agent at high dose is by CNS; at even higher dose CVS is also affected. Since articaine undergoes rapid hydrolysis in plasma into its inactive metabolite, articainic acid, the risk of systemic toxicity is less compared with other local anesthetics, especially if repeated injection is performed. Presence of inactive metabolite lowers the systemic toxicity of articaine because active metabolite of a drug is responsible for causing systemic toxicity and desirable effects.

Oertel and Rahn[18] in their study concluded that the rapid breakdown of articaine to its inactive metabolite articainic acid results in a very low systemic toxicity, giving articaine a wide therapeutic range. Thus, articaine can be safely administered using repeated doses because the use of articaine in higher doses is safer than other amide-type local anesthetics. **Isen et al.** carried out a study and observed that re-injection with articaine, if required, is safe after 30 minutes, since the majority of the initial dose would already be metabolized[29].

Although articaine is a safe anesthetic agent yet it has some adverse effects. In 2005, FDA required a new paraesthesia warning in the package insert[1]. A retrospective study of paresthesia following the injection of local anaesthetic in mandibular arch was conducted in Ontario by **Mikesell P et al,** from 1973 to 1993, 143 reports of paresthesia was reported most often following the injection of articaine and prilocaine[3]. Till date, there is only one report in the literature of maxillary paresthesia involving articaine following an extraction.[30]

Contraindications:

Articaine is contraindicated in patients with known sensitivity to amide-type local anesthetics and person with sulphite sensitivity (asthmatics). Articaine should not be used in patients with liver diseases because of its metabolism. In patients with renal failure, accumulation of articainic metabolites occurs leading to local anesthetic systemic toxicity (LAST)[31]. In patients with impaired cardiovascular functions articaine possess myocardial depressant properties.

Use of Articaine in children:

Available literature shows that use of articaine in children is safe and effective for clinical procedures[32,33]. Common adverse effects reported in children are numbness and soft tissue injuries when administering block anesthesia, most common being prolonged numbness mainly occurring in children younger than 7 years[30].

Jakobs et al.[19] performed a study to measure the serum levels of articaine 2% and 4%. The study was carried out on a total of 27 children, aged 3 to 12 years, undergoing general anesthesia. Venous blood samples were collected before local anesthesia and then 2, 5, 10, and 20 minutes after infiltration with either 2% articaine

with 1:200,000 epinephrine or 4% articaine with 1:200,000 epinephrine. It was observed that the 2 % articaine has lower serum concentration and shorter half life. Thus, it was concluded that use of 2% articaine was particularly advantageous in pediatric dentistry. **Brickhouse TH et al**[32] found articaine 4% to be effective and safe for use in pediatric dentistry. **Wright GZ et al.**[33] conducted a retrospective survey and provided initial evidence for the use of articaine in children less than 4 years of age.

Comparison between 4% articaine as infiltration and 2% lidocaine as nerve block:

Ram D, Amir E (2006)[5] designed a cross over study for comparing the reaction of children receiving articaine 4% with 1:200 000 epinephrine and lidocaine 2% with 1:100 000 epinephrine. 62 children of age between 5-13 years were included in the study. Children randomly received local anesthesia with either lidocaine 2% with 1:100,000 epinephrine or articaine 4% with 1:200, 000 epinephrine at two separate visits. Modified Taddio's behavioural pain scale was used to evaluate pain reaction during injection and treatment. Time of onset was evaluated by asking the child when the numbness started. Wong-Baker FACES pain rating scale was used to rate the pain after the injection. Duration of anesthesia was recorded when the feeling of local anesthesia in soft tissues disappeared. After all the scores were analysed they deduced that articaine 4% with 1:200 000 epinephrine is as effective as lidocaine 2% with 1:100 000 epinephrine and the duration of numbness of soft tissues was more with articaine than with lidocaine.

Corbett IP, Kanaa MD, Whitworth JM, Meechan JG (2008)[34] conducted a double blind randomized, controlled trial to compare efficacy of 4% articaine with 1:100,000 epinephrine buccal infiltration to 4% articaine with 1:100,000 epinephrine buccal plus lingual infiltration of the same dose in mandibular first molar teeth. 31 subjects were included in the study. The results of the study were compared with 2% lidocaine 1:80,000 epinephrine administered as an inferior alveolar nerve block in 27 volunteers. Each volunteer received each treatment over 2 visits separated by at least

1 week. Onset and duration of anesthesia was determined using electronic pulp tester. Onset of subjective signs was also recorded. After the statistical analysis they observed that buccal and buccal plus lingual infiltrations of articaine with epinephrine did not differ in efficacy in obtaining pulpal anesthesia for mandibular permanent first molars ($p = 0.17$) and efficacy of 4% articaine as buccal infiltrations with epinephrine for first molar pulp anesthesia was similar to that of an Inferior alveolar nerve block using 2% lidocaine with epinephrine over a 30-minute study period.

Sherman MG, Flax M, Namerow K, Murray PE (2008)[7] conducted a double blinded study to compare the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine (AE) and 2% lidocaine with 1:100,000 epinephrine (LE) for Gow-Gates blocks and maxillary infiltrations in patients experiencing irreversible pulpitis in mandibular and maxillary posterior teeth. Forty two patients were included in the study who received either AE (1.7 ml) or LE (1.8 ml) by using either a Gow-Gates injection or maxillary infiltration. After the anesthetic agent administration Endo Ice was used every minute for 5 minutes to check the pulpal response, endodontic access was initiated after no pulpal response was found. Pre-injection pain and intra-operative pain were measured by asking the patient rate their pain intensity on a visual analogue scale (VAS). After the complete evaluation, the results demonstrated similar anesthetic effectiveness of 4% articaine and 2% lidocaine when used during the endodontic treatment of teeth diagnosed with irreversible pulpitis and similar anesthetic success in both the dental arches.

Abdulwahab M, Boynes S, Moore P, Seifikar S, Al-Jazzaf A, Alshuraidah A et al (2009)[35] formulated a randomized, double-blind clinical trial to assess the efficacy of 0.9 ml of six local anesthetic formulations for posterior mandibular buccal infiltration anesthesia in 18 healthy participants of age between 18-65 years.. Six anesthetics included in the study are: 2 % lidocaine with 1:100,000 epinephrine (L100), 4 % articaine with 1:100,000 epinephrine (A100), 4 % articaine with 1:200,000 epinephrine (A200), 4 % prilocaine with 1:200,000 epinephrine (P200), 3 % mepivacaine without vasoconstrictor and 0.5 % bupivacaine with 1:200,000 epinephrine (B200). Each participant received mandibular infiltration of 6 anesthetic

agents at 6 visits. Anesthetic efficacy was determined by measuring changes in sensory threshold of the dental pulp with Electric Pulp Tester. Participants rated the pain experienced induced by the injection procedure on a Visual Analgue Scale (VAS). It was found that mandibular infiltration with 0.9 mL of the tested dental anesthetics could induce only partial pulpal anesthesia, a level likely to be inadequate for most dental procedures. When 2 % lidocaine with 1:100,000 epinephrine was compared with 4 % articaine with 1:100,000 epinephrine, it was observed that articaine induced statistically greater pulpal anesthesia after mandibular buccal infiltration.

Poorni S, Veniashok B, Senthilkumar A D, Indira R, Ramchandranan R(2011)[6] conducted a randomized double-blind trial to evaluate the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine as inferior alveolar nerve block (IANB) and as infiltration anesthetic techniques to anesthetize mandibular molars with irreversible pulpitis. The study included 156 healthy volunteers aged 18-30 years and composed of 2 test arms and 1 control arm. Test arm A consisted of subjects who received IANB of 4% articaine, test arm B consisted of subjects who received buccal infiltration (B Infil) of 4% articaine, whereas the subjects in the control arm received a standard IANB of 2% lidocaine with 1:100,000 epinephrine. Heft Parker Visual Analogue Scale was used to rate the pain experienced by the patient after local anesthetic administration and during the treatment. After the statistical analysis no significant difference was found in the success rates among the 3 arms of the trial and it was also found that the buccal Infiltration and IANB of 4% articaine were equally effective. Hence, they came to a conclusion that buccal infiltration of 4% articaine can be considered a viable alternative in IANB for pulpal anesthesia in mandibular molars with irreversible pulpitis.

Arrow P (2012)[36] carried out a study to compare the efficacy of articaine 4% with 1:100 000 adrenaline (test) and lignocaine 2% with 1:80 000 adrenaline (control), delivered either through an inferior alveolar nerve block (IANB) or buccal infiltration (BI) for routine restorative procedures in mandibular posterior teeth. 57 children were randomly allocated to test and control techniques, and to the type of local anesthetic. Faces pain scale was used to report the pain during anesthetic

administration and during dental treatment. Success of local anesthesia was determined by subjective soft tissue symptom and patient report of pain during the treatment. Analgesia success and pain scores were compared for anesthetic technique and type of agent used. They found that there was a higher success and less painful treatment with IANB than BI technique and there was no statistically significant difference in success of local analgesia between articaine and lignocaine when delivered via buccal infiltration.

Powell V (2012)[37] did a systematic review to analyse whether articaine is superior to lidocaine in providing pulpal anesthesia. Two databases and tables of contents in relevant journals were searched. They included 13 studies resulting in a combined study population of 560 participants. These were peer-reviewed articles that were clinical trials, published between January 1970 and December 2009. The trials' investigators used electric pulp tester (EPT), visual analog scales (VAS), or a combination of the two to measure pulpal anesthesia. After the completion of the study it was concluded that 4% articaine was more likely to produce successful pulpal anesthesia than was 2% lidocaine and success rate was improved if the method of administration was infiltration.

Monteiro M R, Groppo F C, Haiter-Neto F, Volpato, M. C. Volpato and J.F.A. Almeida (2015)[38] conducted a randomized controlled trial to compare the anesthetic efficacy of inferior alveolar nerve blocks (IANB) of 1.8 ml of 2% lidocaine (LI) to a buccal infiltration (BI) of 1.8 ml of 4% articaine (AR), both with 1:100 000 epinephrine, in patients with symptomatic irreversible pulpits. 50 volunteers were randomly divided into two groups (30 for AR and 20 for LI). Visual analogue scales (VAS) was used by the patient to record their pain perception before treatment, after cold testing and 5 or 10 min after injection. Success was recorded when complete pain-free treatment was achieved after a single injection (IANB or BI) or when one supplemental injection was needed for emergency endodontic procedures. There was a significant difference between the groups concerning the primary injections. No significant difference was found when a supplemental injection was performed. However, supplemental injection increased the anesthetic success rates within groups. Thus, it was concluded that a single anesthesia

techniques (IANB or BI) were not able to achieve pain-free emergency endodontic treatment and supplemental anesthetic techniques should be considered prior to treatment procedures in order to increase success rate.

Arali V, Mytri P (2015)[16] formulated a randomized double-blind cross over trial to compare the anesthetic efficacy of 4% articaine buccal infiltration with 1:100,000 epinephrine and 2% lignocaine inferior alveolar nerve block in children of 5-8 years with irreversible pulpitis. 50 subjects were randomly divided into two groups, Group 1 constituted of 4% articaine group, while Group 2, of 2% lignocaine group. All the interventions were performed at two separate visits at an interval of 1 week in mandibular primary molar area. Onset of anesthesia, pain during the procedure and the duration of anesthesia were evaluated. Taddio's behavior modified pain scale and visual analogue pain scale was used to analyze behavior of the child during the injection procedure and pain experienced by the subject during the treatment respectively. After statistical analysis it was suggested that the onset of anesthesia with 4% articaine was faster as compared to 2% lignocaine and the duration of anesthesia with articaine infiltration was shorter. Therefore, they concluded that 4% articaine infiltration can be used in children with irreversible pulpitis and it can be used to replace the IAN block in children thereby reducing the post anesthetic complications like lip biting.

Chopra R, Marwaha M, Bansal K, Mittal M (2016)[39] carried out a study to compare the efficacy of buccal infiltration with articaine in achieving pulpal anesthesia of primary molars as compared to inferior alveolar nerve block with lignocaine. 30 Patients were randomly assigned to receive nerve block with either 2 % lignocaine with 1:80,000 adrenaline or infiltration with 4% articaine with 1:200,000 adrenaline on first appointment and the other solution on second appointment. Pain during the injection and treatment was recorded by SEM score. After completion of the procedure patient self-assessed their experience by rating the Facial Image Score scores and Heft-Parker Visual Analogue Score (HP-VAS). Pain Score recorded at the time of injection showed significantly more movements of patient with block as compared to infiltration. SEM scores during the treatment were also higher for block than infiltration. Based on the results it was proved that

articaine infiltration has the potential to replace inferior alveolar nerve block for primary mandibular molars.

Muhammad Zain, Shakeel Ur Rehman Khattak, Huma Sikandar, Shafqat Ali Shah and Fayyaz (2016)[40] evaluated the success of pulpal anesthesia of mandibular 1st molar by using 4% articaine as buccal infiltration versus 2% lidocaine as inferior alveolar nerve block. 156 patients, who participated in the study, were divided into 2 groups with 78 subjects in each group. Group 1 received 4% articaine buccal infiltration and the group 2 received inferior alveolar nerve block of 2% lidocaine. Anesthesia was evaluated 10 min after administration of local anesthetic agent by lip numbness and Electric Pulp Tester (EPT). Visual Analogue Scale (VAS) was used to assess preoperative pain and pain during the procedure. No significant difference was found between the success rates of two groups. Hence, it was concluded that 4% articaine buccal infiltration can be considered a viable alternative to 2% lidocaine inferior alveolar nerve block in securing successful pulpal anaesthesia for endodontic therapy.

Naveen Kumar Reddy Kolli, S. V. S. G. Nirmala, and Sivakumar Nuvvula (2017)[41] conducted a prospective randomized triple blinded study to compare the pain experienced during extraction of maxillary primary molars with conventional lignocaine anesthesia (group I) versus buccal infiltration of lignocaine (group II) and buccal infiltration of articaine (group III) in 90 children between the age of 6-14 years. In all groups following maxillary primary molar extraction, self-report of pain and behavioral measure were recorded on FPS-R (faces pain scale-revised) and FLACC (face legs activity cry consolability scale) respectively. After statistical analysis they found that the articaine group had significantly lower pain scores for self-report and behavioral measures, while there was no significant difference between the conventional and articaine groups with FPS-R and FLACC during primary maxillary molar extraction. Therefore, they concluded that the maxillary primary molar extraction procedure can be successfully accomplished by bypassing the palatal injection and articaine buccal infiltration can be considered as an alternative to conventional local anesthesia for the extraction of maxillary primary molars.

Manali R Srinivasan, S Poorni, Y Nitharshikha, D Diana, Duraivel D (2017)[42] designed a randomized double blinded cross over trial to compare the anaesthetic efficacy of buccal infiltration of 4% articaine with 1:100,000 epinephrine with that of 2% lignocaine with 1:200,000 epinephrine as inferior alveolar nerve block (IANB) in mandibular second premolars. 54 subjects between the age group of 20-40 years were included in the study. Each subject received both the (articaine and lignocaine) anesthetic agents at a separate appointment of 1 week apart. Pulp sensibility measures were recorded using EPT. After completion of the study they did not find any significant difference between the success rates of 4% articaine as buccal infiltration and 2% lignocaine as IANB. Thus, they concluded that the buccal infiltration of 4% articaine can be used as a viable alternative anaesthetic technique for inferior alveolar nerve block of 2% lignocaine in mandibular second premolars.

Sara Ghadimi, Mahdi Shahrabi, Zahra Khosravi, Rooholah Behroozi (2018)[8] carried out a randomized cross-over clinical trial to compare the anesthetic efficacy of inferior alveolar nerve block using 2% lidocaine and buccal infiltration using 4% articaine for pulpotomy of mandibular primary second molars. Trial was performed on 23 children of age between 5-8 years. Participants were divided into two groups, group A and B. Group A consisted of 11 subjects receiving 4%articaine as infiltration and Group B consisted of 12 subjects receiving 2%lidocaine as nerve block. Each subject received both the anesthetic agent (lidocaine and articaine) at an interval of 1 week. Patients' feeling during injection and their behavior during pulpotomy was assessed by Wong Bakers Faces pain scale and Taddio's Modified behavior pain scale respectively. No significant difference of discomfort was found between articaine and lidocaine groups during injection. Patients' behavior during pulpotomy was significantly better in the articaine group. Based on the results of this study it was concluded that articaine buccal infiltration could be a valuable alternative to the inferior alveolar nerve block of lidocaine for pulpotomy of mandibular second primary molars.

The present study was conducted in the Department of Pedodontics and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences (BBDCODS). After obtaining clearance from institutional ethical committee of BBDCODS, Lucknow **(Appendix II)**, 40 patients, who fulfilled the inclusion and exclusion criteria, were enrolled in the study. A written informed consent **(Appendix III)** was obtained from the parents/ guardian before the treatment. Additionally, assent **(Appendix IV)** was taken from children above seven years of age.[43] The study was done with an aim to evaluate and compare efficacy of articaine (4%) buccal infiltration and lidocaine (2%) nerve block as a local anesthetic agent.

SAMPLE SIZE CALCULATION:

The minimum sample size was calculated to be 36 by using the following formula[44]:- **(Appendix IX)**

$$n = (Z\alpha_{/2} + Z_{\beta})^2 \times P(1-P)/(p1-p2)^2$$

p1: Prevalence in group.

p2: Prevalence in group.

P: Pooled prevalence = (p1+p2)/2.

$Z\alpha_{/2:}$ Significance level.

$Z_{\beta:}$ Power of the study.

ELIGIBILITY CRITERIA:

Inclusion criteria:

- ✓ Children of both the gender (male and female) with an age group of 6-18 years.
- ✓ Children requiring pulp therapy or extraction.
- ✓ Subjects categorised as ASA class 1. **(Appendix XIII)**

- ✓ Children who are co-operative and can be managed by non-pharmacological means of behaviour management; Frankl III and IV **(Appendix XI).**

Exclusion criteria:

- ✓ Patients who are known allergic to the local anesthetic agent to be used.
- ✓ Evidence of soft tissue infection near the proposed injection site.
- ✓ Children whose parents are not willing to give informed consent.

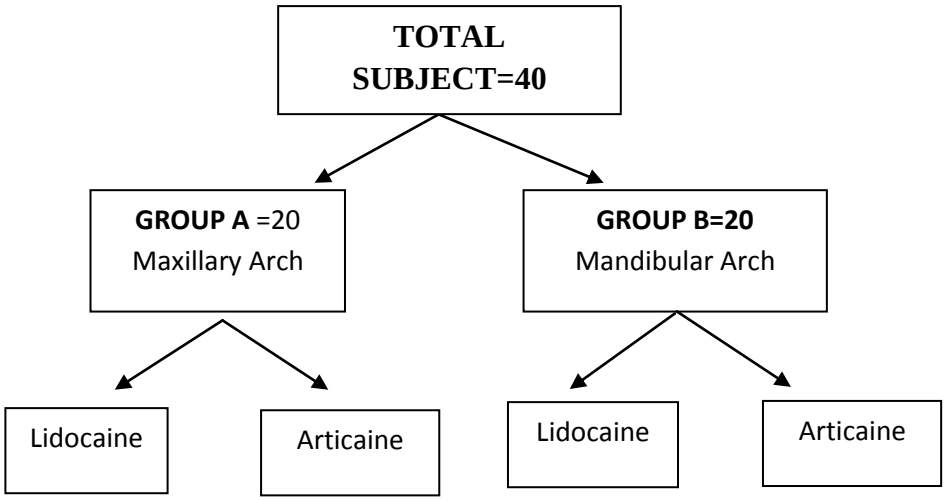
MATERIALS USED: (PLATE I)

- Diagnostic instrument- Mouth mirror, Probe, Tweezer (API).
- Cotton.
- Conventional syringe with needle. (Dispovan) – 24 guage
- **Topical anesthetic agent:**
  Lidoacine Topical Aerosol USP (Nummit Spray) – ICPA Health Products Ltd
- **Local anesthetic agents:**
  1. Lidocaine Hydrochloride 2% with Epinephrine 1:80,000 (Xicaine)
  2. Articaine Hydrochloride 4% with Epinephrine 1:100,000 (Septodont)
- Stop watch.
- Instruments required for the procedure.

STUDY DESIGN :

- The present in-vivo study was carried out in children with the age group between 6 to 18 years including both the genders with a sample size of 40.
- The subjects were randomly divided into two groups on the basis of arch involved: Group A & Group B.
- Group A consist of 20 patients randomly receiving both the anesthetic agents (4% articaine infiltration and 2% lidocaine nerve block) at an interval of 1

week in the maxillary arch and Group B consist of 20 patients randomly receiving the two anesthetic agents (4% articaine infiltration or 2% lidocaine nerve block) in the mandibular arch at an interval of 1 week.



METHODOLOGY:

- Forty patients who fulfilled the inclusion criteria were enrolled for the study. Visual examination and thorough medical history followed by dental history was taken. The patients/ parents were explained in detail the purpose and method of the treatment procedure to be performed. A written informed consent was obtained from the parents/ guardian before the treatment. Additionally, assent was taken from children above seven years of age.

- Procedure was performed by two investigators; investigator 1 who performed the administration of anesthesia and investigator 2 who was for observing the administration technique and measurement of pain scale.

- In the first appointment, the patients falling into either Group A or Group B were randomly selected to receive either 2% lidocaine with 1:80,000 epinephrine as nerve block or 4% articaine with 1:100,000 epinephrine as infiltration. In the second appointment, the local anesthetic agent not used previously was then administered.

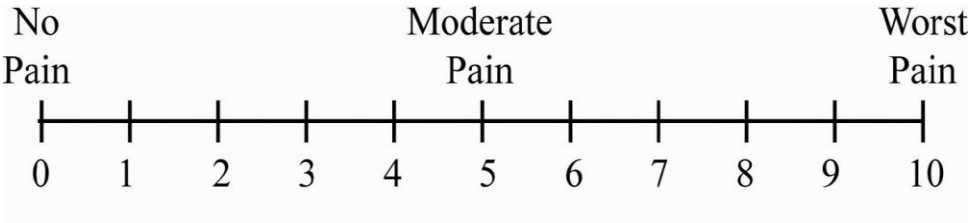
- The concerned area where the anesthetic solution has to be deposited was dried with gauge piece followed by application of topical anesthetic agent-

Lidoacine Topical Aerosol USP. 1.7 ml of either of the anesthetic solution was deposited at a rate of 1.8 ml/min. All the anesthetic injections were administered by a single operator.

- Pain during administration of anesthetic agents and anesthetic efficacy was assessed on Visual Analogue Scale (VAS) **(Appendix XII).** The method of marking the scale was explained to the child. To determine the *pain experienced during the deposition of anesthetic solution*, subjects were asked to rate the pain immediately after the lidocaine nerve block or articaine infiltration, on the pain scale (VAS) which best describe their feeling. *Anesthetic efficacy* was assessed by having subject rate the intra-operative pain following the treatment procedure on the VAS. Each subject placed a mark on the scale where it best described their pain level. *Onset of anesthesia* was recorded from the time of injection to the start of objective sign, which was assessed after every 15 seconds with a probe, first on the contralateral side followed by the anesthetised tooth.

SCORING:

Visual Analogue Scale:



The VAS is widely used to measure the pain intensity. The use of the VAS pain scale was first reported by Woodforde and Merskey. This scale requires little training to score and has been found to be acceptable to patients. It is a 10 cm horizontal line that is labeled as "no pain" at one end and "worst pain possible" at the other end. The numbers on the scale are interpreted as, 0=no pain, 1-4 = mild pain, 5-7= moderate pain and 8-10 = severe pain.[45] When using a VAS to assess pain, subjects are asked to indicate their pain intensity by marking on the 10 cm line.

The present study was conducted in the Department of Pedodontics and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Lucknow with an aim to evaluate and compare efficacy of articaine (4%) buccal infiltration and lidocaine (2%) nerve block as local anesthetic agent for painful dental procedures in children.

The study was carried out in children with the age group between 6 to 18 years including both the genders with a sample size of 40. The subjects were randomly divided into two groups on the basis of arch involved: Group A & Group B. Group A consist of 20 patients randomly receiving both the anesthetic agents (4% articaine infiltration and 2% lidocaine nerve block) at an interval of 1 week in the maxillary arch and Group B consist of 20 patients randomly receiving the two anesthetic agents (4% articaine infiltration or 2% lidocaine nerve block) in the mandibular arch at an interval of 1 week.

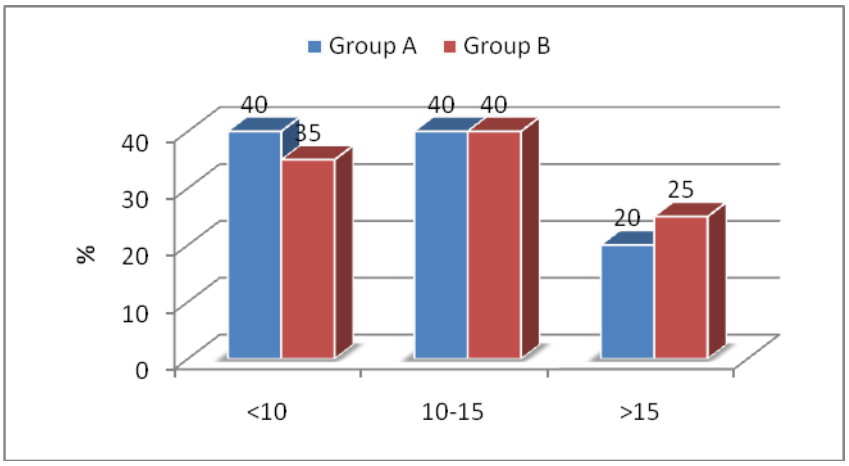
Statistical analysis

The results are presented in frequencies, percentages and mean±SD. The Chi-square test was used to compare categorical variables between the groups. The Unpaired t-test was used to compare continuous variables between the groups. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

Table-1: Distribution of patients according to age between the groups

Age in years	Group A (n=20)		Group B (n=20)		p-value[1]
	No.	%	No.	%	
<10	8	40.0	7	35.0	0.91
10-15	8	40.0	8	40.0	
>15	4	20.0	5	25.0	
Mean±SD	11.15±3.97		11.80±4.22		

[1]Chi-square test



Graph. 1: Distribution of patients according to age between the groups

Table-1 & Graph.1 shows the distribution of patients according to age between the groups. More than one third of patients in Group A (40%) and in Group B (35%) were <10 years. The mean age of patients of Group A and Group B was 11.15±3.97 and 11.80±4.22 years respectively. There was no significant (p>0.05) difference in age among the groups showing comparability of the groups in terms of age.

Table-2: Distribution of patients according to gender between the groups

Gender	Group A (n=20)		Group B (n=20)		p-value[1]
	No.	%	No.	%	
Male	7	35.0	6	30.0	0.73
Female	13	65.0	14	70.0	

[1]Chi-square test

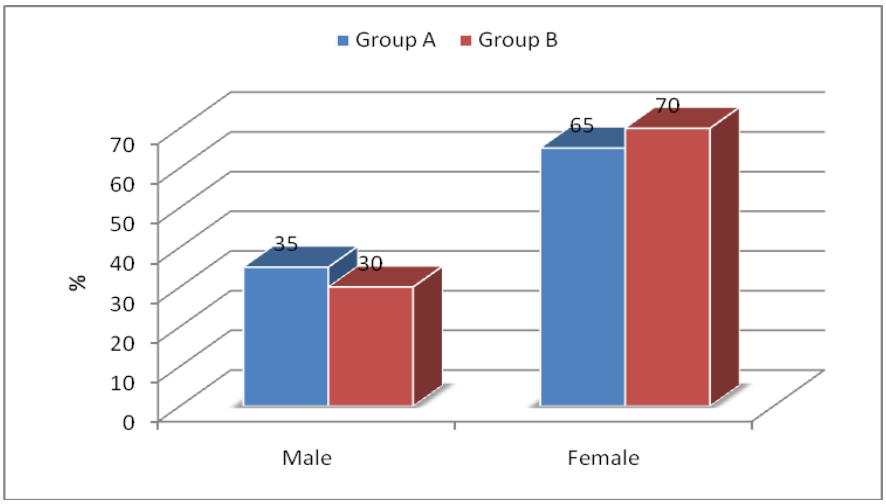


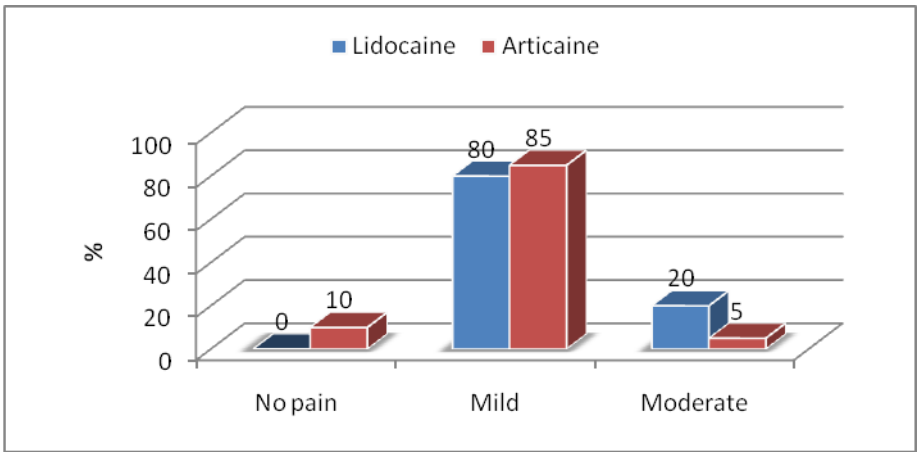
Fig. 2: Distribution of patients according to gender between the groups

Table-2 & Fig.2 shows the distribution of patients to according gender between the groups. More than one third of patients in Group A (35%) and in Group B (30%) were males. There was no significant (p>0.05) difference in gender between the groups showing comparability of the groups in terms of gender.

Table-3: Comparison of Visual Analogue Scale (VAS) Score during deposition between Lidocaine and Articaine in Group A (maxillary arch)

VAS	Lidocaine (n=20)		Articaine (n=20)		p-value[1]
	No.	%	No.	%	
No pain	0	0.0	2	10.0	0.001*
Mild	16	80.0	17	85.0	
Moderate	4	20.0	1	5.0	

[1]Chi-square test, *Significant



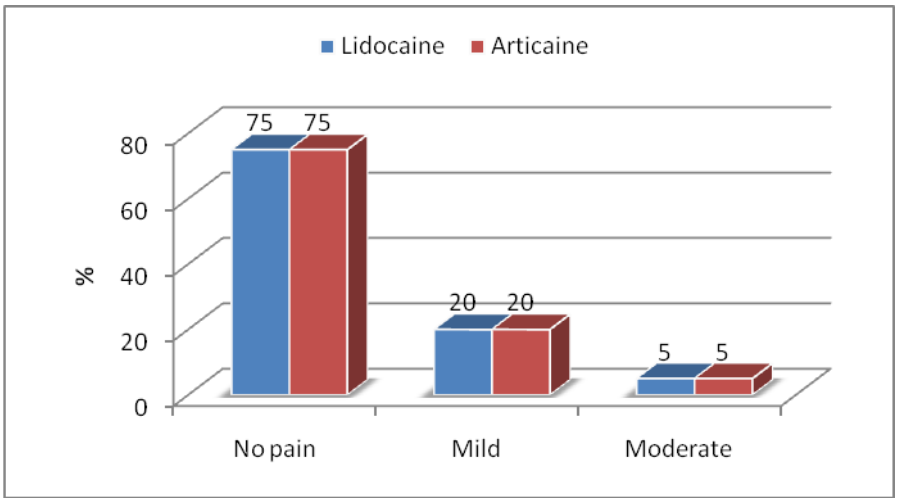
Graph- 3: Comparison of VAS during deposition between Lidocaine and articaine in Group A

Table-3 & Graph-3 shows the comparison of VAS after deposition of lidocaine and articaine in Group A. *Mild pain score* was observed in majority of the patients after deposition of lidocaine (80%) and articaine (85%). None of the patient reported *no pain score* after administration of lidocaine while 10% of patients reported the same score after administration of articaine. *Moderate pain score* was found to be in 20% of patients with lidocaine whereas the same pain score was found only in 5% of patients with articaine. This difference was statistically significant. ($p<0.05$)

Table-4: Comparison of intra-operative VAS (Visual Analogue Scale) Score between Lidocaine and Articaine in Group A (maxillary arch)

VAS	Lidocaine (n=20)		Articaine (n=20)		p-value[1]
	No.	%	No.	%	
No pain	15	75.0	15	75.0	1.00
Mild	4	20.0	4	20.0	
Moderate	1	5.0	1	5.0	

[1]Chi-square test



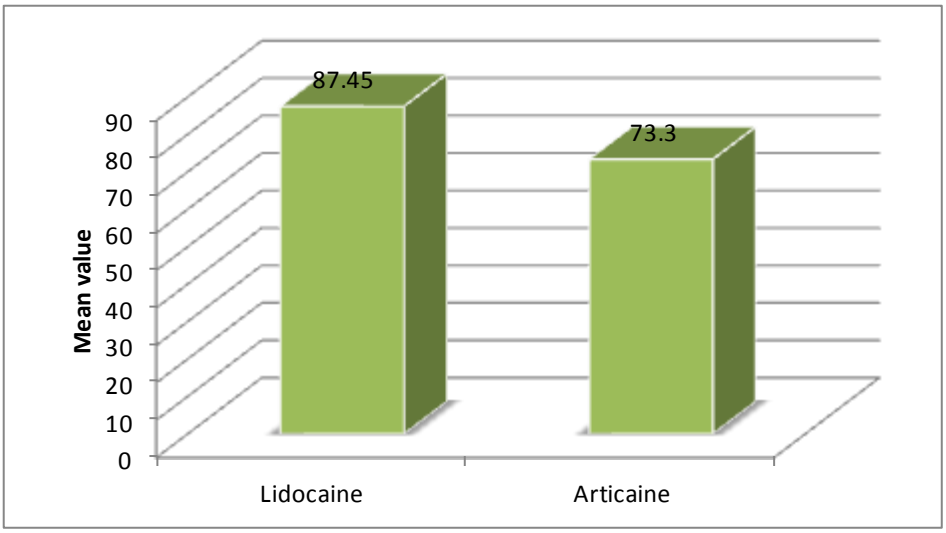
Graph-4: Comparison of intra-operative VAS between Lidocaine and articaine in Group A

Table-4 & Graph-4 depicts comparison of VAS score during the treatment (intra-operatively) between lidocaine and articaine in Group A (maxillary arch). *No pain score* was reported in 75% of the patients during the treatment with both lidocaine and articaine. *Mild* and *moderate pain score* was reported by equal number of patients when compared between articaine and lidocaine. No statistical significant difference was observed.

Table-5: Comparison of onset of anesthesia between Lidocaine and articaine in Group A (maxillary arch)

Groups	**Onset of anesthesia in seconds (Mean±SD)**
Lidocaine	87.45±11.90
Articaine	73.30±12.79
p-value[1]	0.0009*

[1]Unpaired t-test, *Significant



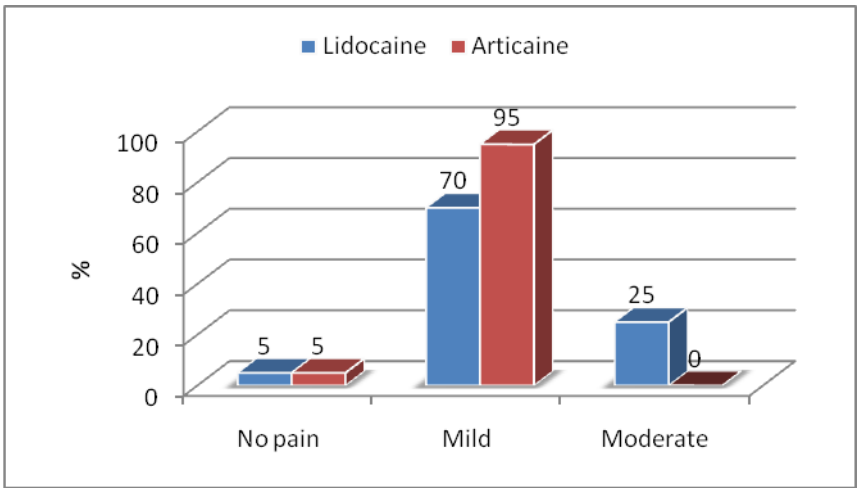
Graph-5: Comparison of onset of anesthesia between Lidocaine and articaine in Group A

Table-5 & Graph-5 shows the comparison of onset of anesthesia between lidocaine and articaine in Group A. The onset of anesthesia of lidocaine was 87.45±11.90 sec while of articaine it was 73.30±12.79 sec. This difference was statistically significant (p=0.0009).

Table-6: Comparison of VAS (Visual Analogue Scale) during deposition between Lidocaine and articaine in Group B (mandibular arch)

VAS	Lidocaine (n=20)		Articaine (n=20)		p-value[1]
	No.	%	No.	%	
No pain	1	5.0	1	5.0	0.06
Mild	14	70.0	19	95.0	
Moderate	5	25.0	0	0.0	

[1]Chi-square test



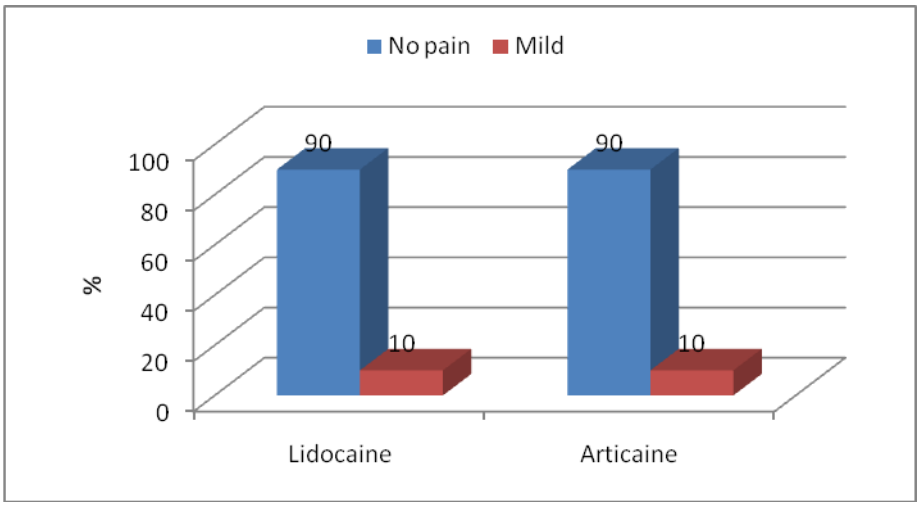
Graph-6: Comparison of VAS during deposition between Lidocaine and articaine in Group B

Table-6 & Graph-6 shows the comparison of VAS score after deposition of lidocaine and articaine in Group B. 5% of the patients reported *no pain score* with articaine and lidocaine. *Mild pain score* was found to be in only 70% of the patient with lidocaine while articaine showed 95% with the same score. 25% of the patients reported *moderate pain score* after deposition of lidocaine whereas none of them reported the same pain score after deposition of articaine. These differences were significant but not statistically significant (p>0.05).

Table-7: Comparison of intra-operative VAS (Visual Analogue Scale) score between Lidocaine and articaine in Group B (mandibular arch)

VAS	Lidocaine (n=20)		Articaine (n=20)		p-value[1]
	No.	%	No.	%	
No pain	18	90.0	18	90.0	1.00
Mild	2	10.0	2	10.0	

[1]Chi-square test



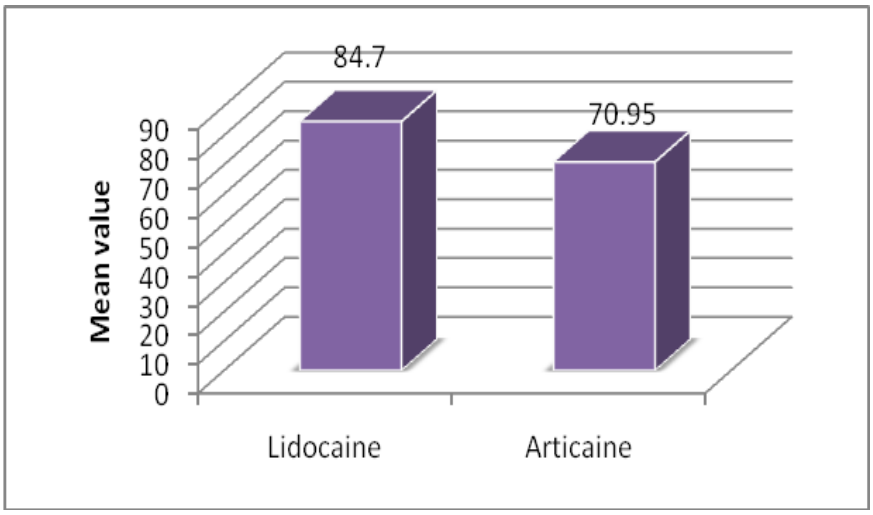
Graph-7: Comparison of intra-operative VAS between Lidocaine and articaine in Group B

Table-7 & Graph-7 shows the intra-operative comparison of VAS score between lidocaine and articaine in Group B. Maximum number of patients reported *no pain score* during the treatment with lidocaine (90%) and articaine (90%). *Mild pain score (10%)* was reported by equal number of patients with both the anesthetic agents, this difference was not statistically significant (p>0.05).

Table-8: Comparison of onset of anesthesia between Lidocaine and articaine in Group B (mandibular arch)

Groups	Onset of anesthesia in seconds (Mean±SD)
Lidocaine	84.70±8.56
Articaine	70.95±6.14
p-value[1]	0.0001*

[1]Unpaired t-test, *Significant



Graph-8: Comparison of onset of anesthesia between Lidocaine and articaine in Group B

Table-8 & Graph-8 shows the comparison of onset of anesthesia between lidocaine and articaine in Group B. Statistically significant (p=0.0001) difference was found in the onset of anesthesia between lidociane (84.70±8.56) and articaine (70.95±6.14) in the Group B.

Local anesthesia is the safest method to achieve pain free treatment. Lignocaine is the gold standard anesthetic agent used in dentistry till date due to its minimal toxicity and better efficacy[42]. Hence, lignocaine was used in the study for comparison. However, clinical studies have reported that anesthetic failure by lignocaine nerve block especially during inferior alveolar nerve block can occur upto 25% of the time[7]. **Meechan (2005)** suggested that poor operator technique, variations in the position of the foramina, accessory innervations, accuracy of the injection and variable course of the inferior alveolar nerve might explain why local anesthesia does not work in all cases. Low success rate of inferior alveolar nerve block have been observed (23% and 39%) in studies conducted by **Claffey et al (2004)** and **Aggarwal et al (2009)** respectively during the treatment of patients with irreversible pulpitis[46][47].

Infiltrations are easier to perform, do not require perforation of cortical bone, comfortable to the patient and operator and avoid lingual numbness and possible damage to the nerve. Thus, to achieve anesthesia, infiltrations can be used as a primary injection technique or as a supplemental injection to enhance the effectiveness of primary injection. Recent evidences have shown that use of articaine in dentistry can be an effective measure to provide local anesthesia either by block or by infiltration[39]. Articaine is an amide with an additional ester group, and its chemical structure makes the drug more fat-soluble and enhances its ability to diffuse through hard and soft tissues, which makes it a useful anesthetic agent in dentistry.

Available literature indicates that articaine is equally effective in nerve block and infiltration anesthetic techniques when compared with other local anesthetics including lidocaine with epinephrine[48] and prilocaine with epinephrine[49]. **Ribeiro et al (2011)** found successful and effective diffusion of 4% articaine into the pulp of maxillary teeth and to the palate when administered as posterior superior alveolar nerve block without any palatal injections[50]. Four percent articaine with 1:100,000 epinephrine has been found to produce successful anesthesia as suggested by the study of **Lima et al (2009)** where they administered articaine through buccal vestibule without any palatal injection during extraction of impacted maxillary third molar[51]. Hence, based on the finding of the above studies supporting articaine's

efficacy as local anesthetic agent in dentistry, it was selected in this study as local anesthetic agent.

Use of articaine as buccal infiltration to obtain analgesia has been tested predominantly on adults and the results suggested that articaine is better at obtaining pulpal analgesia than lignocaine as buccal infiltration[36]. Articaine infiltration has been found to be significantly better than lidocaine buccal infiltration for achieving pulpal analgesia in mandibular molars with the success rate of 87%[52], 76.9%[40] and 64%[34]. **Kanna D et al (2006)** found buccal infiltration with 4% articaine to be more effective than buccal infiltration with 2% lidocaine in securing mandibular first molar anesthesia[22]. In a study conducted by **Silva-Junior et al (2017),** combination of buccal infiltration of 2% articaine and inferior alveolar nerve block of 2% lidocaine with epinephrine 1:100,000 showed increased efficacy during impacted mandibular third molar surgery in comparison to combination of buccal infiltration of 2% lidoacine and inferior alveolar nerve block of 2% lidocaine[53]. These observations on infiltration of articaine led us to use articaine as infiltration for comparison with lignocaine nerve block.

Not all studies agree on articaine's ability as infiltration to produce better anesthetic properties than lignocaine nerve block. Studies conducted by **Sharman et al (2008)[7]** and **Kambalimath et al(2013)[54]** showed equal efficacy of articaine infiltration and lidocaine nerve block in securing anesthesia during treatment procedures. On the other hand, **Abdulwahab et al (2009)** compared six different local anesthetic agents and found that articaine was the only one which has better pulpal anesthesia than lignocaine after mandibular infiltration[35]. Thus, the mixed findings on the efficacy of articaine pointed to the need of further search which led us to formulate our study with the purpose ***to compare anesthetic efficacy of 2% lignocaine block with 4% articaine infiltration for dental procedures in children.***

Anesthetic efficacy is determined when the procedure can be performed without any pain. Patients' pain complaints are subjective reports of an immeasurable stimulus. Pain measurement is difficult to establish, because its perception and intensity are multifactorial which encompasses sensorial and effective factors[6].

In the present study, evaluation of pain was done on Visual Analogue Scale (VAS) which provided validated and meaningful measure of anesthetic efficacy. VAS is a 10 cm metric scale with the two endpoints labeled as ”no pain” and “worst pain ever” for assessing individual pain perceptions in which patient is asked to rate the scale according to intensity of pain experienced by him. VAS has been found to be methodologically sound, conceptually simple, easy to administer, and unobtrusive to the respondent[6].**Huskisson EC (1983)** stated that the VAS is ideal for crossover experiments, enabling one patient to express an opinion about the relative value of different treatments[55]. **Katz J et al (1999)** conducted a study in which they suggested visual analogue pain scale to be reliable, valid, and have ratio scale properties and suggested it be the optimal tool for describing pain severity or intensity[56].

Within the limitations of the present study, there was no significant difference according to age (p=0.91) and gender (p=0.73) between the groups i.e. Group A (maxillary arch) and Group B (mandibular arch). **(Table 1 and Table 2).** The results are in accordance with the study conducted by **Kanaa D et al (2006)[22] and Naveen Kumar et al (2017)[41],** in which they did not find any significant difference according to age and gender.

The results of the present study depict *comparison of VAS pain score after deposition of 2% lidocaine and 4% articaine solutions in the maxillary arch and mandibular arch respectively*. Pain score was more with 2% lignocaine than 4% articaine in the maxillary arch, which was statistically significant **(p=0.001)** and the pain score was more with lignocaine in mandibular arch **(p=0.06**) but not statistically significant. **(Table 3 and Table 6)**

Similar results were obtained by **Chopra et al (2016)[39]** in which pain score after administration of lignocaine as nerve block was more when compared to articaine as infiltration during pulp therapy of mandibular primary molars. **Srinivasan et al (2008)[57]** and **Kanaa et al (2012)[58]** reported articaine buccal infiltration to be more comfortable than lidocaine infiltration in the maxillary teeth with irreversible pulpitis. Contrary to the results obtained, **Mikesell P et al (2005)[59], Poorni S et al**

(2011)[6] and **Sara Ghadimi et al (2018)[8]** reported no difference in the discomfort experienced by the patients during the administration of articaine as infiltration and lidocaine as nerve block for the routine treatment procedures in the mandibular arch. Higher pain score with lignocaine nerve block than articaine infiltration may be explained by the fact that the depth of penetration is more in block than infiltration, and moreover, for the nerve block additional palatal/lingual injections are required to achieve anesthesia on buccal as well as lingual/palatal side which is uncomfortable to patients whereas single injection of articaine buccal infiltration produces lingual/palatal anesthesia.

The result of the present study show *comparison of intra-operative VAS (Visual Analogue Scale) score between Lidocaine and articaine in the maxillary arch and mandibular arch respectively.* Intra-operative pain score obtained was same for both the solutions (4% articaine infiltration and 2% lignocaine block) in maxillary **(p=1.00)** and mandibular arch **(p=1.00)** respectively, which suggests that articaine buccal infiltration alone could provide similar comfort during treatment to lignocaine group where both buccal and palatal/lingual injections were given. **(Table 4 and Table 7)**

The above results are in accordance with the study conducted by **Sherman et al (2008)[7] and Poorni S et al (2011)[6]** in which similar pain score was observed for buccal infiltration of 4% articaine with 1:100,000 epinephrine and 2% lidocaine with 1:100,000 epinephrine as nerve block during treatment procedures in the mandibular and maxillary arch. Anesthetic success rate as suggested by **Peng M et al (2008)[60], Hassan S et al (2015)[61], Luqman et al (2015)[62]** and **Bansal S et al(2018)[32]** was found to be similar for buccal infiltration of articaine and conventional buccal plus palatal injections of lidocaine during extraction of permanent maxillary premolar and molar. Contradictory to the above results, **Chopra et al (2016)[39]** and **Muhammad Zain et al (2016)[40]** reported high pain score with lignocaine nerve block as compared to articaine as infiltration for pulp therapy in mandibular molars. **Veena Arali and Mytri P (2015)[16]** and **Sara Ghadimi et al (2018)[8]** also reported significantly better patients' behavior with articaine during dental treatment. In a systematic review by **Virginia Powell (2012)[37]** articaine infiltration was found to be

2.44 times more likely to produce successful pulpal anesthesia than lidocaine nerve block. Significantly less pain score was observed with 4% articaine in a study conducted by **Naveen Kumar et al (2017)[41]** during extraction of maxillary molars as determined by Faces Pain Scale-Revised.

The results of the present study depict *onset of anesthesia in maxillary arch and mandibular arch respectively*. The onset of anesthesia in the maxillary arch was significantly faster **(p=0.0009)** for articaine group (73.30+-12.79 sec) than lidocaine group (87.45+-11.90 sec) and in mandibular arch also onset of anesthesia was significantly faster **(p=0.0001)** for articaine group (70.95 +- 6.14 sec) than lidocaine group(84.70 +_8.56 sec) (**Table 5 and table 8).**

In accordance with the results obtained in table 5 and table 8, **Veena Arali and Mytri P (2015)[16]** found shorter mean time of onset of anesthesia with 4% articaine as infiltration as compared to 2% lignocaine as mandibular nerve block in children with irreversible pulpitis. **Costa et al (2005)[64]** assessed the onset of anesthesia and found that the mean onset time with both 4% articaine with 1:100,000 epinephrine as maxillary infiltrations and 4% articaine with 1:200,000 epinephrine as maxillary infiltrations were superior to 2% lidocaine with 1:100,000 epinephrine when administered as maxillary infiltrations. **Malamed et al (2000)[17] and D. Ram et al (2006)[5]** found similar onset time after treatment with 4% articaine with 1:200,000 epinephrine and 2% lidocaine with 1:100,000 epinephrine in the mandibular arch and there was no association with the type of LA agent and LA technique used which is contrary to the results obtained in the present study. **Kimmo Vahatalo (1993)[48]** compared the anesthetic properties of the articaine and lidocaine with different epinephrine concentration when administered as infiltration and found no significant difference with respect to onset between the two agents when monitored using electric pulp tester. Shorter onset of anesthesia of articaine as observed in the present study could be attributed to the increased liposolubility of articaine which helps in greater diffusion of the anesthetic solution in the tissues, leading to the faster action.

Statistical analysis of the data obtained from the present study suggests that articaine can be successfully used through infiltration method as a local anesthetic agent for

pulp therapy and extraction procedures in children. The present study also provided an insight that due to shorter onset of articaine and similar efficacy of articaine as infiltration and lignocaine as nerve block, single infiltration of articaine can be used an alternative for achieving anesthesia to conventional buccal plus lingual/palatal injections of lignocaine.

The present study was conducted in the Department of Pedodontics and Preventive Dentistry, BBDCODS, Lucknow, in which 40 children were included to evaluate and compare efficacy of articaine (4%) buccal infiltration and lidocaine (2%) nerve block as local anesthetic agent for pulp therapy and extraction procedures in children.

On the basis of observations made during the course of study and their analysis, the following conclusions have been drawn:

1. Buccal infiltration of 4% articaine was better tolerated by children during administration in both maxillary and mandibular arch.
2. Lidocaine 2% as nerve block and articaine 4% as buccal infiltration are equally effective local anesthetic agents in both the arches during the treatment.
3. Articaine as infiltration showed significantly faster onset in comparison to lignocaine as nerve block in maxillary and mandibular arches.

The present study indicates that with the use of 4% articaine as buccal infiltration, dental treatment can be performed without the need for palatal/lingual nerve block. Hence, it can be suggested that buccal infiltration of 4% articaine can be a useful alternative to 2% lidocaine as nerve block during treatment procedures in dentistry.

1) Stanley F. Malamed, DDS. Handbook of local anesthesia fifth edition.
2) Narasimhan Srinivasan, Mahendran Kavitha, Chandarasekaran S. Loganathan, Govindasamy Padmini. Comparison of anesthetic efficacy of 4% articaine and 2% lidocaine for maxillary buccal infiltration in patients with irreversible pulpitis. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics 2009;107(1):133 – 13
3) Deepashri H. Kambalimath, R. S. Dolas, H. V. Kambalimath, S. M. Agrawal. Efficacy of 4 % Articaine and 2 % Lidocaine: A clinical study. J. Maxillofac. Oral Surg. Jan-Mar 2013; 12(1):3–10
4) S. Thaminee. Articaine in Dentistry. J. Pharm. Sci. & Res. 2015;7(9):792-794
5) Ram D, Amir E. Comparison of articaine 4% and lidocaine 2% in paediatric dental patients. Int J Paediatr Dent. Jul 2006; 16(4):252-6.
6) Poorni S, Veniashok B, Senthilkumar A D, Indira R, Ramachadran S. Anaesthetic efficacy of four percent articaine for pulpal anaesthesia by using inferior alveolar nerve block and buccal infiltration techniques in patients with irreversible pulpitis: A prospective randomized double-blind clinical trial. J Endod. 2011; 37: 1603–160.
7) Michael G. Sherman, Michael Flax, MS, Kenneth Namerow, Peter E. Murray, Anesthetic Efficacy of the Gow-Gates Injection and Maxillary Infiltration with Articaine and Lidocaine for Irreversible Pulpitis. JOE, June 2008;34(6):656-659.
8) Sara Ghadimi, Mahdi Shahrabi, Zahra Khosravi, Rooholah Behroozi. Efficacy of articaine infiltration versus lidocaine inferior alveolar nerve block for pulpotomy in mandibular primary second molars: A randomized clinical trial. J Dent Res Dent Clin Dent Prospects. 2018 Spring; 12(2): 97–101.
9) Torsten Gordh, Torsten E. Gordh, Kjell Lindqvist. Lidocaine: The Origin of a Modern Local Anesthetic. Anesthesiology 2010; 113:1433–7
10) Astra Standard times, Westborough, Mass, 1988, Astra Pharmaceutical Products.
11) Nell W. Puente and E David losephy. Analysis of the tidocaine Metabolite 2,6-Dimethylaniline in Bovine and Human Milk. Journal of Analytical Toxicology, November/December 2001;25.
12) A. H. Beckett, R. N. Boyes And P. J. Appleton. The metabolism and excretion of lignocaine in man. J. Pharm. Pharmac., 1966; 18, Suppl., 76s-81s

13) Laurence Weinberg, Benjamin Peake, Chong Tan, Mehrdad Nikfarjam. Pharmacokinetics and pharmacodynamics of lignocaine: A Review. J Anesthesiol 2015 July 27; 4(2): 17-29

14) Brown DL, Skiendzielewski J J: Lidocaine toxicity. Ann Emerg Med, December 1980; 9:627-629,

15) R Jayanthi, KSGA Nasser, K Monica. Local Anesthetics Systemic Toxicity. Journal of The Association of Physicians of India. March 2016; 64,

16) Veena Arali, Mytri P. Anaesthetic Efficacy of 4% Articaine Mandibular Buccal Infiltration Compared To 2% Lignocaine Inferior Alveolar Nerve Block in Children with Irreversible Pulpitis. J Clin Diagn Res. 2015 Apr; 9(4): ZC65–ZC67.

17) Stanley F. Malamed, Suzanne Gagnon, Dominique Leblanc. A comparison between Articaine HCl and Lidocaine HCl in pediatric dental patients. American Academy of Pediatric Dentistry, 2000;22(4): 307-311

18) Oertel R, Rahn R, Kirch W. Clinical pharmacokinetics of articaine. Clin Pharmacokinet, 1997; 33:417-25.

19) Jakobs W, Ladwig B, Cichon P, Ortel R, Kirch W. Serum levels of articaine 2% and 4% in children. Anesth Prog, 1995;42:113-5.

20) Muller WP, Weiser P, Scholler KL. Pharmacokinetics of articaine in mandibular nerve block. Reg Anesth, 1991;14:52-5.

21) Artur de Oliveira Ribeiro, Carlos Emanoel Silva da Silveira, Liane Maciel de Almeida Souza. Study of articaine diffusion into the pulp of maxillary teeth and to the palate. RGO - Rev Gaúcha Odontol, Porto Alegre, Jul 2011;.59(3):373-378,

22) Mohammad Dib Kanaa, John Martin Whitworth, Ian Porter Corbett and John Gerard Mechan. Articaine and Lidocaine Mandibular Buccal Infiltration Anesthesia: A Prospective Randomized Double-Blind Cross-Over Study. JOE, April 2006; 32(4):296-298.

23) Kellie Paxton, David E. Thome. Efficacy of Articaine Formulations:Quantitative Reviews. Dent Clin N Am, 2010; 54:643–653

24) Weaver JM. Articaine, a new local anesthetic for American dentists: will it supercede lidocaine? Anesth Prog 1999;46:111-2.

25) Hintze A, Paessler L. Comparative investigations on the efficacy of articaine 4% (epinephrine 1:200,000) and articaine 2% (epinephrine 1:200,000) in

local infiltration anaesthesia in dentistry – a randomised double-blind study. Clin Oral Investig 2006;10: 145–150

26) Tófoli G R, Ramacciato J C, de Oliveira P C, Volpato M C, Groppo F C, Ranali J. Comparison of effectiveness of 4% articaine associated with 1:100,000 or 1:200,000 epinephrine in inferior alveolar nerve block. Anesth Prog 2003; 50**:**164–168.
27) Moore PA, Boynes SG, Hersh EV, DeRossi SS, Sollecito TP, Goodson JM, Leonel JS, Floros C, Peterson C, Hutcheson M. The anesthetic efficacy of 4 percent articaine 1:200,000 epinephrine: two controlled clinical trials. J Am Dent Assoc. 2006 Nov; 137(11):1572-81.
28) Hersh E V, Giannakopoulos H, Levin L M et al. The pharmacokinetics and cardiovascular effects of high-dose articaine with 1:100,000 and 1:200,000 epinephrine. J Am Dent Assoc 2006; 137: 1562–1571.
29) Isen D. Articaine: Pharmacology and clinical use of a recently approved local anesthetic. Dent Today 2000;19:72-7.
30) K. E. Yapp, M. S. Hopcraft, P. Parashos. Articaine: a review of the literature. British Dental Journal. Apr 9 2011; 210(7)
31) Seema Malhotra, Vinay Kumar Gupta, Swastika Suvirya, Nitin Singh, Rachana Bahuguna and Suleman Abbas Khan. Articaine: An Alternative to Lignocaine. Asian Journal of Oral Health & Allied Sciences 2013; 3(1)
32) Brickhouse TH, Unkel JH, Webb MD, Best AM, Hollowell RL. Articaine use in children among dental practitioners. Pediatr Dent. 2008 Nov-Dec;30(6):516-21
33) Wright GZ, Weinberger SJ, Friedman CS, Plotzke OB. Use of articaine local anesthesia in children under 4 years of age – a retrospective report. Anesth Prog 1989; 36:268-71.
34) Corbett IP, Kanaa MD, Whitworth JM, Meechan JG. Articaine infiltration for anesthesia of mandibular first molars. J Endod. 2008 May; 34(5):514-8.
35) Abdulwahab M, Boynes S, Moore P, Seifikar S, Al-Jazzaf A, Alshuraidah A, Zovko J, Close J. The efficacy of six local anesthetic formulations used for posterior mandibular buccal infiltration anesthesia. JADA, August 2009;140:1018-1024
36) Arrow P. A comparison of articaine 4% and lignocaine 2% in block and infiltration analgesia in children. Aust Dent J 2012; 57: 325–333.

37) Powell V. Articaine is superior to lidocaine in providing pulpal anesthesia. J Am Dent Assoc. 2012 Aug;143(8):897-8.

38) Monteiro M R, Groppo F C, Haiter-Neto F, Volpato M C, Almeida JF. 4% articaine buccal infiltration versus 2% lidocaine inferior alveolar nerve block for emergency root canal treatment in mandibular molars with irreversible pulpits: a randomized clinical study. Int Endod J 2015; 48: 145–152

39) Chopra R, Marwaha M, Bansal K, Mittal M Evaluation of Buccal Infiltration with Articaine and Inferior Alveolar Nerve Block with Lignocaine for Pulp Therapy in Mandibular Primary Molars. J Clin Pediatr Dent. 2016; 40(4):301-5

40) Muhammad Zain, Shakeel Ur Rehman Khattak, Huma Sikandar, Shafqat Ali Shah and Fayyaz1Comparison of Anaesthetic Efficacy of 4% Articaine Primary Buccal Infiltration Versus 2% Lidocaine Inferior Alveolar Nerve Block in Symptomatic Mandibular First Molar Teeth. Journal of the College of Physicians and Surgeons Pakistan 2016; 26 (1): 4-8

41) Naveen Kumar Reddy Kolli, S.V. S. G. Nirmala, Sivakumar Nuvvula. The Effectiveness of Articaine and Lidocaine Single Buccal Infiltration versus Conventional Buccal and Palatal Injection Using Lidocaine during Primary Maxillary Molar Extraction: A Randomized Control Trial. Anesth Essays Res. 2017 Jan-Mar; 11(1): 160–164

42) Manali Ramakrishnan Srinivasan , Saravanan Poorni , Yogeshwaran Nitharshika, Davidson Diana, Dasarathan Duraivel. Articaine buccal infiltration versus lignocaine inferior alveolar block for pulpal anaesthesia in mandibular second premolars – Randomized control double blinded clinical trial. June 2017; 31(2)

43) Indian pediatrics 2010;47: 1039-1046

44) Charan J and Biswas Tamoghna. How to Calculate Sample Size for Different Study Designs in Medical Research? Indian J Psychol Med. Apr-Jun 2013; 35(2): 121–126.

45) Gillian A. Hawker, Samra Mian, Tetyana Kendzerska, And Melissa French. Measures of Adult Pain. Arthritis Care & Research. November 2011;63(11): S240–S252

46) Claffey E, Reader A, Nusstein J, Beck M, Weaver J. Anaesthetic efficacy of articaine for inferior alveolar nerve blocks in patients with irreversible pulpitis. J Endod. 2004; 30:568–71.

47) Aggarwal V, Jain A, Debipada K. Anesthetic efficacy of supplemental buccal and lingual infiltrations of articaine and lidocaine following an inferior alveolar nerve block in patients with irreversible pulpitis. J Endod 2009;35:925–9

48) Vahatalo K, Antila H, Lehtinen R. Articaine and lidocaine for maxillary infiltration anaesthesia. Anesth Prog 1993; 40:114–6.

49) Hass DA, Harper DG, Saso MA, Young ER. Comparison of articaine and prilocaine anesthesia by infiltration in maxillary and mandibular arches. Anesth Prog 1990;37: 230–7.

50) Artur de Oliveira RIBEIRO, Carlos Emanoel Silva da SILVEIRA, Liane Maciel de Almeida SOUZA. Study of articaine diffusion into the pulp of maxillary teeth and to the palate. RGO - Rev Gaúcha Odontol., Porto Alegre, jul./set., 2011;59(3):373-378.

51) José-Lacet Lima-Júnior, Eduardo Dias-Ribeiro, Túlio-Neves de Araújo, Julierme Ferreira-Rocha, Evaldo-Sales Honfi-Júnior, Carlos-Frederico de Moraes Sarmento, Flávio-Roberto-Guerra Seabra, Maria do Socorro-Cirilo de Sousa. Evaluation of the buccal vestibule-palatal diffusion of 4% articaine hydrochloride in impacted maxillary third molar extractions. Med Oral Patol Oral Cir Bucal. 2009 Mar 1;14 (3):E129-32.

52) Robertson D, Nusstein J, Reader A, Beck M, McCartney M. The anesthetic efficacy of articaine in buccal infiltration of mandibular posterior teeth. J Am Dent Assoc. 2007 Aug;138(8):1104-12.

53) Geraldo Prisco da Silva-Junior, Liane Maciel de Almeida Souza, and Francisco Carlos Groppo, Comparison of Articaine and Lidocaine for Buccal Infiltration After Inferior Alveolar Nerve Block For Intraoperative Pain Control During Impacted Mandibular Third Molar Surgery. Anesth Prog, 2017; 64:80–84

54) Deepashri H. Kambalimath, R. S. Dolas, H. V. Kambalimath, S. M. Agrawal. Efficacy of 4 % Articaine and 2 % Lidocaine: A clinical study. J. Maxillofac. Oral Surg. Jan-Mar 2013; 12(1):3–10

55) Huskisson EC. Pain Measurment and Assessment, Raven Press. New York, NY 1983.

56) Joel Katz and Ronald Melzack. Measurement of Pain. Surgical Clinics of North America. April 1999;79(2)

57) Narasimhan Srinivasan, Mahendran Kavitha, Chandarasekaran S. Loganathan,Govindasamy Padmini**.**Comparison of anesthetic efficacy of 4% articaine and 2% lidocaine for maxillary buccal infiltration in patients with irreversible pulpitis. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics, January 2009; 107(1) ,133 – 136

58) Kanaa MD, Whitworth JM, Meechan JG. A comparison of the efficacy of 4% articaine with 1:100,000 epinephrine and 2% lidocaine with 1:80,000 epinephrine in achieving pulpal anesthesia in maxillary teeth with irreversible pulpitis. J Endod. 2012 Mar; 38(3):279-82.

59) Philip Mikesell, John Nusstein, Al Reader, Mike Beck and Joel Weaver. A Comparison of Articaine and Lidocaine for Inferior Alveolar Nerve Blocks. JOE, April 2005;31(4).

60) Peng M, Zhu ZM, Yang XM. [Feasibility of permanent maxillary tooth removal using articaine anesthesia without palatal injection]. Hua Xi Kou Qiang Yi Xue Za Zhi. 2008 Aug;26(4):416-8.

61) Dr. Shahid Hassan; Dr. Ajaz Shah, Dr. Manzoor Dar, Dr. Tajamul Hakeem, Dr. Zahoor Teli Comparison of Articaine and Lidocaine Used As Dental Local Anesthetics-A Research Article. IOSR-JDMS. Aug. 2015;14(8) Ver. II.

62) Luqman U, Majeed Janjua OS, Ashfaq M, Irfan H, Mushtaq S, Bilal A. Comparison of articaine and lignocaine for uncomplicated maxillary exodontia. J Coll Physicians Surg Pak. 2015 Mar; 25(3):181-4.

63) Bansal SK, Kaura S, Sangha PK, Kaur P, Bahl R, Bansal S. Comparison of anesthetic efficacy of 4% articaine versus 2% lignocaine. Indian J Dent Sci 2018;10:92-7.

64) Costa CG, Tortamano IP, Rocha RG, Francischone CE, Tortamano N. Onset and duration periods of articaine and lidocaine on maxillary infiltration. Qiuntessence Int 2005; 36:197-207.

APPENDIX-I

Institutional Research Committee Approval

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **A Comparative Evaluation of Articaine (4%) for Buccal Infiltration v/s Lidocaine (2%) for Nerve Block as Local Anesthetic Agent in Children** submitted by **Dr.Shaifali Agrawal** Post graduate student from the Department of **Pedodontics and preventive Dentistry** as part of MDS Curriculum for the academic year **2016-2019** with the Accompanying proforma was reviewed by the institutional research committee present on **7th and 8th December2016** 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. (Dr).Vivek Govila
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
Principal

Chairperson Institutional Research Committee

APPENDIX-II

Institutional Ethical Committee Approval

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 Vth Institutional Ethics Sub-Committee

IEC Code: 13 **BBDCODS/03/2017**

Title of the Project: A Comparative Evaluation of Articaine (4%) for Buccal Infiltration v/s Lidocaine (2%) for never block as Local Anesthetic Agent in Children.

Principal Investigator: Dr. Shaifali Agrawal **Department:** Pedodontics and Preventive Dentistry

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Shaifali Agrawal

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 02nd March, 2017.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Neerja Singh Member	Prof. & Head, Department of Pedodontics, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Manu Narayan Member	Reader, Department of Public Health Dentistry, BBDCODS, Lucknow

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

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

Lakshmi Bala 01/05/2017
Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Forwarded by:

(Dr. Vivek Govila)
Principal
BBDCODS

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

APPENDIX- III

Consent Form

Title of the Study: *"A Comparative Evaluation of Articaine (4%) for Buccal Infiltration vs Lidocaine (2%) for Nerve Block as Local Anesthetic Agent in Children".*

Title of the Study.....

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 been explained 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 such a 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 [ ]**

6. I agree to participate in the above study. I have been explained about the complications and side 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 Acceptable

Representative:……..

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 consent form

Signature/thumb impression of the subject or legally

acceptable representative Date……..

APPENDIX- IV

Babu Banarasi Das College of Dental Sciences

(A Constituent Institution of Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow — 227105 (INDIA)

Child Assent Form

Study Number……
subject's Full Name……
Date of
Address……
Birth/Age……
……

I……., exercising my free power of choice, hereby give my consent for participation in the study entitled:

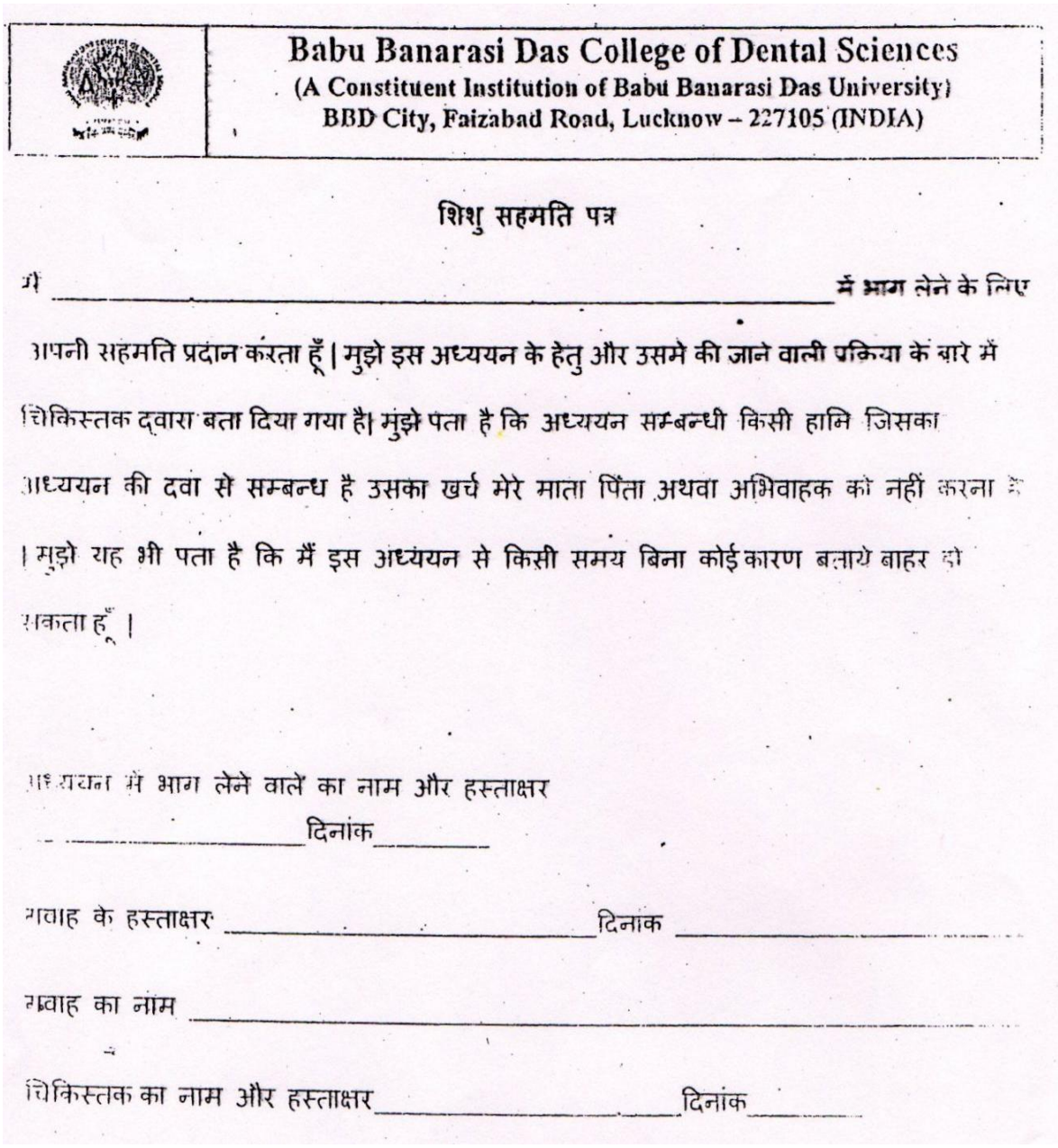
"……"

I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any procedure related injury, which has causal relationship with the said study. I am also aware of right to opt out of the study, at any time during the course -of the study, without having to give reasons for doing so

Signature of the study participant…… Date:……
Name of the study participant……

- Signature of the Witness…….. Date……
  Name of the Witness……

Signature of the attending Pl4sician……
Name ofthe attending Physician……..



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

शिशु सहमति पत्र

मैं _____ में भाग लेने के लिए

आपनी सहमति प्रदान करता हूँ | मुझे इस अध्ययन के हेतु और उसमे की जाने वाली प्रक्रिया के बारे में चिकित्सक द्वारा बता दिया गया है| मुझे पता है कि अध्ययन सम्बन्धी किसी हानि जिसका अध्ययन की दवा से सम्बन्ध है उसका खर्च मेरे माता पिता अथवा अभिवाहक को नहीं करना है | मुझे यह भी पता है कि मैं इस अध्ययन से किसी समय बिना कोई कारण बताये बाहर हो सकता हूँ |

अध्ययन में भाग लेने वाले का नाम और हस्ताक्षर
_____ दिनांक _____

अभिवाह के हस्ताक्षर _____ दिनांक _____

अभिवाह का नाम _____

चिकित्सक का नाम और हस्ताक्षर _____ दिनांक _____

APPENDIX- V

Participation Information Document (PID)-English

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

A COMPARITIVE EVALUATION OF ARTICAINE (4%) FOR BUCCAL INFILTRATION VS LIDOCAINE (2%) FOR NERVE BLOCK AS LOCAL ANESTHETIC AGENT IN CHILDREN.

You are being invited to take part in this research study. Please read all the information carefully. Kindly discuss all your doubts before giving your consent.

The aim of this study is to evaluate and compare efficacy of articaine (4% buccal infiltration) and lidocaine (2% nerve block) as local anesthetic agent for painful procedures in children.

Your cooperation is needed for the study. There are no such interventions, risk and adverse effects related to the study.

You have been chosen for this study as he /she is fulfilling the required criteria for the study participant. Taking part in this research is entirely voluntary. It is up to you to decide whether you want to participate or not. If you take part in this study, you will be given this information sheet and will be asked to sign a consent form. Additional information will become available to you during the course of study.

The information collected about you will be kept confidential though it may be looked by people from IEC to check that the study is being carried out correctly. The result of the study will be published in the indexed journal without revealing your identity. There is no sponsorship for the study.

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

I thank you for allowing your child to participate.

Contact address-

Dr. Shaifali Agrawal

Department of Pedodontics and Preventive Dentistry

BBDCOS, Lucknow

Email: - agrshaifali@gmail.com

Member Secretary Ethics Committee

Dr. Laxmi Bala

Email: - bbdcods.ice@gmail.com

Name of the principal investigator-

Signature of principal investigator Date:

APPENDIX- VI

Participation Information Document (PID)- Hindi

डेंटल साइंसेज के बाबू बनारसी दास कॉलेज (बाबू बनारसी दास विश्वविद्यालय के एक घटक संस्थान)बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

भागीदारी जानकारी दस्तावेज (पीआईडी)

नसों को सुन करने के लिए मुँह मे दिये गये स्थानीय संवेदनाहारी के रूप में अर्टीकेन 4% और लीडोकेन 2% की एक तुल्यात्मक मुल्यांकन

आपको इस शोध अध्ययन मे भाग लेने के लिए आमंत्रित किया जा रहा है। सभी जानकारी को ध्यान पूर्वक पढ़े। कृपया अपनी सहमती देने से पहले सभी संदेहों पर चर्चा करें।

इस अध्ययन का उद्देश्य बच्चों के मुँह मे दिये गये स्थानीय संवेदनाहारी के रूप में अर्टीकेन 4% और लीडोकेन 2% की तुलना करना।

आपका सहयोग अध्ययन के लिए आवश्यक है। ऐसा कोई भी जोखिम और प्रतिकूल प्रभाव इस अध्ययन से आप पर नही पड़ेगा।

आपको इस अध्ययन के लिए चुना गया है। क्योकि यह अध्ययन भागीदार के लिए आवश्यक मानदंडों को पूरा कर रहा है। इस शोध में भाग लेने के लिए आप पूरी तरह स्वत्रंत है तथा इस अध्ययान मे भाग लेना या नही लेना आप पर निर्भर करता है। अगर आप इस अध्ययन मे भाग लेते है तो आपको सूचना पत्र दिया जायेगा तथा एक सहमति पत्र पर हस्ताक्षर करने के लिए कहॉ जायेगा। इसके अतिरिक्त जानकारी अध्ययन के दौरान आप के लिए उपलब्ध हो जाएगी।

आप के बारे मे ली गयी जानकारी गोपनीय रखी जायेगी। इस अध्ययन की आई ई सी के लोगो द्वारा की जा सकती है। अध्ययन के परिणाम के लिए अपनी पहचान का खुलासा किए बिना अनुक्रमित जर्नल में प्रकाशित किया जाएगा। वहॉ अध्ययन के लिए कोई प्रायोजन है।

संस्था के विभागाध्यक्ष / आई0ई0सी0 की समीक्षा की और अध्ययन को मंजूरी दी है।

आप द्वारा इस अध्ययन में अनुमति देने के लिए धन्यवाद।

संपर्क पता :–

डॉ0 शेफाली अग्रवाल

पीडोडोनटिक्स और निवारक दंत चिकित्सा विभाग

बी0बी0डी0सी0ओ0डी0एस0, लखनऊ

ई मेल:- agrshaifali@gmail.com

सदस्य सचिव आचार समिति

डॉ0 लक्ष्मीबाला

ई मेल:- bbdcods.ice@gmail.com

प्रमुख अन्वेषक का नामः

प्रमुख अन्वेषक के हस्ताक्षर : तारीखः

APPENDIX- VII

Guardian Information Document (GID)- English

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

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Your child's cooperation is needed for the study. There are no such interventions, risk and adverse effects related to the study.

Your child has been chosen for this study as he /she is fulfilling the required criteria for the study participant. Taking part in this research is entirely voluntary. It is up to you to decide whether you want your child to participate or not. If you allow your child to take part in this study, you will be given this information sheet and will be asked to sign a consent form. Additional information will become available to you during the course of study.

The information collected about you and your child will be kept confidential though it may be looked by people from IEC to check that the study is being carried out correctly. The result of the study will be published in the indexed journal without revealing your identity. There is no sponsorship for the study.

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

I thank you for allowing your child to participate.

Contact address-

Dr. Shaifali Agrawal

Department of Pedodontics and Preventive Dentistry

BBDCOS, Lucknow

Email: - agrshaifali@gmail.com

Member Secretary Ethics Committee

Dr. Laxmi Bala

Email: - bbdcods.ice@gmail.com

Name of the principal investigator-

Signature of principal investigator Date:

APPENDIX- VIII

Guardian Information Document (GID)- Hindi

डेंटल साइंसेज के बाबू बनारसी दास कॉलेज (बाबू बनारसी दास विश्वविद्यालय के एक घटक संस्थान)बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

अभिभावक जानकारी दस्तावेज (जी0आईडी)

नसों को सुन करने के लिए मुँह मे दिये गये स्थानीय संवेदनाहारी के रूप में अर्टीकेन 4% और लीडोकेन 2% की एक तुल्यात्मक मुल्यांकन

आपका और आपके बच्चे को इस शोध अध्ययन मे भाग लेने के लिए आमंत्रित किया जा रहा है। सभी जानकारी को ध्यान पूर्वक पढ़े। कृपया अपनी सहमती देने से पहले सभी संदेहों पर चर्चा करें।

इस अध्ययन का उद्देश्य बच्चों के मुँह मे दिये गये स्थानीय संवेदनाहारी के रूप में अर्टीकेन 4% और लीडोकेन 2% की तुलना करना।

आपका और आपके बच्चे का सहयोग अध्ययन के लिए आवश्यक है। ऐसा कोई भी जोखिम और प्रतिकूल प्रभाव इस अध्ययन से आप पर नही पड़ेगा।

आपके बच्चे को इस अध्ययन के लिए चुना गया है। क्योकि यह अध्ययन भागीदार के लिए आवश्यक मानदंडों को पूरा कर रहा है। इस शोध में भाग लेने के लिए आपका बच्चा/बच्ची पूरी तरह स्वत्रंत है तथा इस अध्ययन मे भाग लेना या नही लेना आप पर निर्भर करता है। अगर आपका बच्चा इस अध्ययन मे भाग लेता है तो आपको सूचना पत्र दिया जायेगा तथा एक सहमति पत्र पर हस्ताक्षर करने के लिए कहाँ जायेगा। इसके अतिरिक्त जानकारी अध्ययन के दौरान उपलब्ध हो जाएगी।

आपके बच्चे के बारे मे ली गयी जानकारी गोपनीय रखी जायेगी। इस अध्ययन की आई ई सी के लोगो द्वारा की जा सकती है। अध्ययन के परिणाम के लिए अपनी पहचान का खुलासा किए बिना अनुक्रमित जर्नल में प्रकाशित किया जाएगा। वहाँ अध्ययन के लिए कोई प्रायोजन है।

संस्था के विभागाध्यक्ष / आई0ई0सी0 की समीक्षा की और अध्ययन को मंजूरी दी है।

आप द्वारा इस अध्ययन में अनुमति देने के लिए धन्यवाद।

संपर्क पता :–

डॉ0 शेफाली अग्रवाल

पीडोडोनटिक्स और निवारक दंत चिकित्सा विभाग

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सदस्य सचिव आचार समिति

डॉ0 लक्ष्मीबाला

ई मेल:- bbdcods.ice@gmail.com

प्रमुख अन्वेषक का नाम:

प्रमुख अन्वेषक के हस्ताक्षर : तारीख:

APPENDIX- IX

Formula Used

The sample size was calculated using the following formula (Charan and Biswas, 2013):

$n= (Z_{\alpha/2}+Z_{\beta})^2 \text{ X } P(1-P)/(p1-p2)^2$

Where n: Sample size per group

p1: Prevalence in Group 1,

p2: Prevalence in group 2,

P: Pooled prevalence=(p1+p2)/2

$Z_{\alpha/2}$: Significance level,

Z_{β} : Power of the study

APPENDIX- X, XI And XII

CASE SHEET (Appendix X)

Patient Record

OPD NO.: Date :

Name :

Age/Sex :

Address :

Contact No :

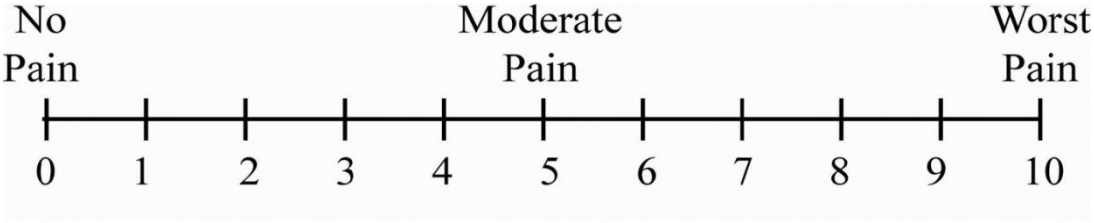
Guardian's Name : Relation to the patient:

Behaviour Rating Scale : (Appendix XI)

FRANKEL'S BEHAVIOUR RATING SCALE	
RATING	BEHAVIOUR
1. Definitely Negative (--)	Refuses treatment, cries forcefully, extremely negative behaviour associated with fear.
2. Negative (-)	Reluctant to accept treatmemt and displays evidence of slight negativism.
3. Positive (++)	Accepts treatment, but if the child has a bad experience during treatment, may become uncooperative.
4. Definitely Positive (+)	Unique behaviour,looks forward to and understands the importance of good preventive care.

Rating :

Visual Analogue Scale: (Appendix XII)



Tooth Number	Procedure	Drug	Vas Score after L.A. administration	Intra Operative Vas Score	Onset Of Anesthesia (sec)

APPENDIX- XIII

ASA Physical Status classification (Appendix XIII)

ASA Physical Status classification	Definition
ASA I	Normal healthy patient
ASA II	Patient with mild systemic disease
ASA III	Patient with severe systemic disease
ASA IV	Patient with severe systemic disease that is constant threat to life
ASA V	A moribund patient who is not expected to survive without operation
ASA VI	A declared brain-dead patient whose organs are being removed for donor purpose

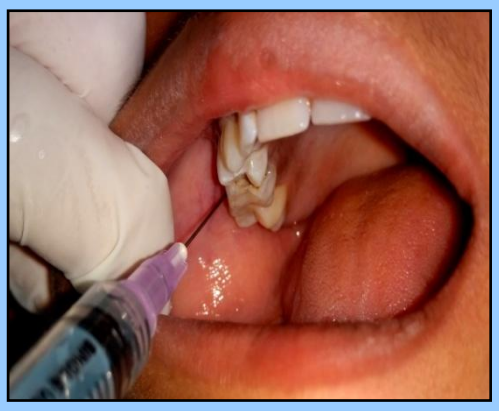
LIDOCAINE

Figure No. 1

ARTICAINE

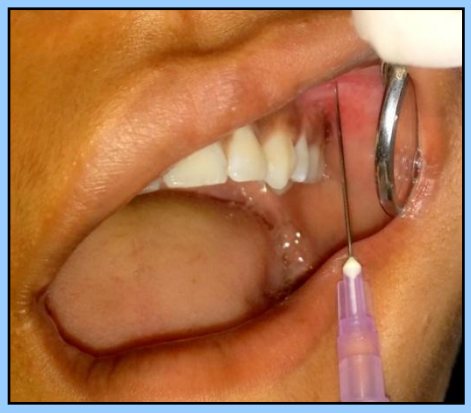
Figure No. 2

LOCAL ANESTHETIC AGENTS



NERVE BLOCK BY LIDOCAINE

Figure No. 3



INFILTRATION BY ARTICAINE

Figure No. 4

ADMINISTRATION TECHNIQUES OF LOCAL ANESTHETIC AGENTS

PLATE NO. 1