Comparative Evaluation of Intraligamentary Injection and Traditional Inferior Alveolar Nerve Block in Patients with Irreversible Pulpitis

Dissertation Submitted to

Maharashtra University of Health Sciences,
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In The Partial Fulfillment of Regulations
for the Award of the Degree of
MDS

In

CONSERVATIVE DENTISTRY AND ENDODONTICS
BRANCH - IV
2019

Appendix 'B'

COMPARATIVE EVALUATION OF INTRALIGAMENTARY INJECTION AND TRADITIONAL INFERIOR ALVEOLAR NERVE BLOCK IN PATIENTS WITH IRREVERSIBLE PULPITIS

By
DR. DEEPASHRI A. TEKAM

Under the guidance of
DR. CHETANA S. MAKADE

THROUGH
VSPM Dental College and Research Centre, Nagpur

Dissertation Submitted to

Maharashtra University of Health Sciences, Nashik

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Certificate

This is to certify that the ***Dissertation entitled***

COMPARATIVE EVALUATION OF INTRALIGAMENTARY INJECTION AND TRADITIONAL INFERIOR ALVEOLAR NERVE BLOCK IN PATIENTS WITH IRREVERSIBLE PULPITIS

has been prepared by **DR. DEEPASHRI A. TEKAM** *under my direct supervision and guidance in partial fulfilment of the regulations for the award of the*

DEGREE OF MDS

IN

CONSERVATIVE DENTISTRY AND ENDODONTICS

Her work on the subject has been checked by me from time to time. I am satisfied regarding the authenticity of her observations, clinical material and experimentation in this dissertation and it confirms to the standards of Maharashtra University of Health Sciences, Nashik.

I have great pleasure in forwarding it to

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Appendix 'D'

Certificate

This is to certify that the ***Dissertation Entitled***

COMPARATIVE EVALUATION OF INTRALIGAMENTARY INJECTION AND TRADITIONAL INFERIOR ALVEOLAR NERVE BLOCK IN PATIENTS WITH IRREVERSIBLE PULPITIS

is a bonafide work by **DR. DEEPASHRI A. TEKAM**

under the guidance of

DR. CHETANA S.MAKADE

as partial fulfilment of regulations for the award of the

DEGREE OF MDS

IN

CONSERVATIVE DENTISTRY AND ENDODONTICS

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of Maharashtra University of Health Sciences, Nashik and has not been submitted previously for the award of any Diploma or Degree from any University.

Date: 21/12/2018

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LIST OF ABBREVIATIONS

SR. NO	ABBREVIATIONS	FULL FORM
1.	IANB	Inferior alveolar nerve block
2.	STA	Single Tooth Anesthesia
3.	ILA	Intra-ligamentary
4.	HP-VAS	Heft-Parker Visual Analog Scale
5.	EPT	Electric pulp test
6.	EDTA	Ethylene Diamine Tetra-acetic Acid
7.	NaOCl	Sodium Hypochlorite
8.	GG	Gates Glidden
9.	mins	Minutes
10.	WL	Working Length
11.	sec	Seconds
12.	SPSS	Statistical Package for the Social Sciences
13.	ANOVA	Analysis of Variance
14.	SD	Standard Deviation
15.	S	Significant
16.	NS	Not Significant
17.	HS	Highly Significant
18.	N	Number of specimens
19.	p-value	Probability of obtaining a test statistic at least as extreme as the one that was actually observed
20.	Max.	Maximum
21.	Min.	Minimum
22.	No.	Number
23.	CI	Confidence Interval

INTRODUCTION

"The threat and fear of pain constitutes one of the great obstacles to the acceptance of dental services".

-National Institute of Health, USA.

The perception of endodontic pain is strongly related to the subjectivity of the patient. Its management using effective pain control measures is essential for successful endodontic treatment. The experience of unpleasant sensation of pain or the related fear and anxiety during treatment procedures is one of the most common reasons for the patient to put off their dental visits.[1] Hence, to accomplish this various measures like appropriate use of local anesthetic technique, analgesics, anxiety reduction techniques are required. Successful local anesthesia plays a cardinal role in painless endodontic treatment. However, achieving successful pulpal anesthesia in irreversible pulpitis is still a challenge.[2]

Irreversible pulpitis is a localized inflammatory response to the bacterial invasion of the pulp-dentin complex leading to hyperalgesia and allodynia, preventing profound anesthesia during the endodontic procedure. The most possible reasons can be activation of nociceptors by inflammation leading to sprouting the nerve fibers, increasing expression of neuropeptide, release of inflammatory mediator and tumor necrosis factor. In addition, altered resting potential of nerve reduces the amount of anesthetic solution penetrating into the membrane, tetrodotoxin resistant sodium channels and accessory innervation leading to variation in success rate of anesthesia.

Local anesthetics are the drugs that decrease the permeability of ion channels to sodium ions thus producing a nerve conduction blockade. Lidocaine, an amide anesthetic is most commonly used anesthetic agent. The clinical use and various studies prove lidocaine to be a safest drug due to its low allergenicity, and minimal toxicity. Thus, making it a "gold standard" to which all new local anesthetics can be compared. Other local anesthetic agents like mepivacaine, articaine, and bupivacaine are also commercially available.[3]

Rusching and colleagues in 1969 [4,5] introduced an amide anesthetic, Articaine which later entered the clinical practice in 1976. It is characterized by increased liposolubility and presence of thiophene ring which proves to be effective in producing pulpal anesthesia **Malamed SF et al in 2000** [5] studied efficacy of articaine and reported it to be equally effective in nerve block and infiltration techniques. **Potonik I et al in 2006**[6] reported the effectiveness of articaine by depressing the compound action potential of the A fibers when compared with 2% or 4% lidocaine or 3% mepivacaine. **Matthews et al in 2009**[7] used 4% articaine as a supplemental buccal infiltration after

standard IANB in patient with inflamed pulp with a success rate of 58%. Similarly, **Aggarwal et al in 2009**[8] have shown that supplemental buccal and lingual infiltration of 4% articaine increases the success rate of IANB in patients with irreversible pulpitis.

Anesthesia can be achieved by nerve block, local infiltration; supplementary injection (intraosseous injection, intraligamentary injections, intrapulpal injections) and using advanced anesthetic techniques like pressure anesthesia, computer-controlled local anesthetic delivery system.The inferior alveolar nerve block (IANB) is the most commonly used technique for achieving anesthesia for endodontic procedures of mandibular teeth. Several clinical studies have reported IANB is effective in 30-80% of patients diagnosed with irreversible pulpitis.[9-10] The overall failure rates of IANB for healthy lower molars have ranged from 15% to 35%.[10, 11] **Hargreaves and Keiser in 2001**[9] reviewed causes of failure of IANB; few of these were anatomical consideration (nature of bone in the adult mandible), injection speed, patient's psychological characteristics, needle gauge and the use of local anesthetics. **Costa FA et al in 2013**[12.] reported pain induced during penetration (the moment when the needle perforates the mucosa) was higher with the IANB technique (7% to 47%). **Moon S et al in 2012** [13] reported hypoesthesia after IAN block anesthesia caused by a hematoma formation near the Inferior Alveolar Nerve which resulted in pressure to the nerve. **Le Claire et al in 1988**[14] surveyed on reasons for endodontic fear and showed that local anesthetic injection, sensation of files introduced in root canals and tapping or pushing on a sore tooth were ranked as the most unpleasant or anxiety arousing aspects of root canal therapy .

To enhance the success rate of IANB various supplementary injection technique were advocated to achieve adequate pulpal anesthesia when convention IANB technique fails. With the advent of 20th century, Intraligamentary anesthesia (ILA) was introduced as a novel and effective method of dental local anesthesia. The injected anesthetic in ILA is distributed by passing through the cribriform plate and the medullary bone spaces into the vasculature in and around adjacent teeth. The sensitive nerve ending of nervus mandibularis passes through the apical foramen into the pulp; however, the endings of these nerves are also located in the periodontal tissues. The ILA injection thus produces an immediate desensitization of these nerve endings surrounding the tooth and of the pulpal nerves. According to **Lin S et al in 2017**[15], ILA injections succeeded for more than 90% of the cases of mandibular molars diagnosed with asymptomatic irreversible pulpitis, with no side effects or severe postoperative pain. **Schleder et al in 1988** [16] reported a success rate of 86.7% and 20 min of profound pulpal anesthesia when 2% lidocaine with 1:100 000 epinephrine was used for ILA injections for asymptomatic mandibular posterior teeth. ILA injections proved to be safe and effective anesthetic technique when used as supplementary injection. However, **Malamed S in 1982** [17] reported that the PDL injection to be a successful alternative to the conventional nerve block techniques for mandibular anesthesia. In addition, systemic condition like hemophilia or other bleeding disorder, mentally and physically handicapped patients who are more prone to post injection soft tissue trauma due convention block technique and cases where anesthesia is require for only one or two teeth without anesthetizing entire quadrant and soft tissue PDL injection proves to be effective anesthetic technique.

The search for newer device and technique to minimize patient's anxiety and the discomfort by traditional anesthetic techniques is judicious. Computerized anesthesia is an innovative prospective technique toward pain control. Single tooth anesthesia system (2006), is a computer controlled device with dynamic pressure sensing (DPS) technology, which enabled fluid pressure and flow rate at the needle tip to be precisely controlled and monitored in real-time during all phases of the injection process.Successful pulpal anesthesia was obtained 86% of the time with the articaine solution and 74% of the time with the lidocaine solution using Wand system [18].

Although the literature reveals various clinical trials on the anesthetic efficacy of articaine and failure of IANB in irreversible pulpitis, there is no current literature reporting effectiveness of intraligamentary injection using STA system as a primary technique for anesthetizing teeth with irreversible pulpitis. Hence, the current clinical trial was undertaken to test the same in irreversible pulpitis using articaine and compare it with that of IANB. Thus, the null hypothesis was formulated that ILA using STA System will prove to be equally effective as that of IANB anesthetic technique in patients with irreversible pulpitis. The aim of this preliminary, prospective, randomized, double-blind study (patient and observer) is to compare the effectiveness of ILA using STA System and Traditional IANB injection technique using 4% articaine with 1:100,000epinephrine, on mandibular 1st and/or 2nd molars, with irreversible pulpitis.

AIM & OBJECTIVES

AIM

To compare the effectiveness of intraligamentary injection using STA System and Traditional inferior alveolar nerve block injection technique in irreversible pulpitis patients.

OBJECTIVES

1. To compare the onset of intraligamentary and traditional IANB injection techniques.
2. To compare the duration of intraligamentary and traditional IANB injection techniques.

3. To compare pain perception, by the participants during treatment procedure under intraligamentary and traditional IANB injection techniques.

4. To compare acceptability of intraligamentary and traditional IANB injection techniques by patients.

REVIEW OF LITERATURE

Anesthetics are a diverse group of drugs that are used in the management of pain.The achievement of good local anesthesia requires knowledge of the agents being used, the neuroanatomy involved, and best techniques and devices available. The review of literature represents anesthetic techniques and agents used during various operative procedures requiring pulpal anesthesia.

Malamed S (1982)[17]**,**evaluated effectiveness of periodontal ligament (PDL) injection for mandibular anesthesia using both a conventional syringe and two new local anesthetic devices-the Peri-Press and the Ligmaject. The PDL injection was employed for 71 restorative procedures (tooth preparation for alloy or gold restorations)

on mandibular posterior teeth and successful pulpal anesthesia was achieved in 65 cases. When used for periodontal procedures, such as curettage and root planing, all seven PDL injections proved successful, as was the case for two extractions of mandibular teeth.The only significant degree of difficulty in achieving clinically adequate pain control occurred in endodontic cases. The duration for achieving adequate pulpal anesthesia was approximately 30 to 45 minutes. The study concluded that both the newer devices and the conventional syringe techniques proved effective, with fewer side effects.

Cowans et al (1986)[19]**,** clinically assessed the effectiveness of intraligamentary injection during operative procedure and reported limited application for simple procedure in single teeth in presence of healthy periodontium.

Walton RE (1990)[20]**,**reviewed the clinical and experimental literature for determining the efficacy of periodontal ligament (PDL) injection as an primary injection. The advantages of PDL injection are; rapid onset of anesthesia, localized anesthetic effect, minor periodontal and pulpal injury from the injection. However, their certain disadvantages associated with PDL injection are unpredictable depth and duration of anesthesia and discomfort during the PDL injection, is more painful in anterior teeth than posterior teeth.

Hoffmeister et al (1991)[21]**,**studied morphological changes of peripheral nerves following intraneural injection of local anesthetic. They used 4% articaine solution in the ischiadic nerve of Wistar rats and the lingual nerve of cats. Neurosensory disturbances are caused by intraneural local-anesthetic injection and are the result of intraneural hematomas with consecutive fibrosis was assumed. They concluded that 4%

anesthetic solutions are not capable of damaging the nerve, even when injected directly into it.

Vahatalo K et al (1993)[22]**,** compared the anesthetic properties of articaine hydrochloride with 1:200,000 epinephrine and lidocaine with 1:80,000 epinephrine for maxillary infiltration anesthesia.Infiltration anesthesia was performed on the upper lateral incisor; each participant received 0.6 mL of each test solution at different times. The onset and duration of anesthesia were monitored using an electric pulp tester. The latency time of articaine solution reported by them was 14sec shorter and 45 sec longer in duration than lidocaine preparation for anesthesia.They reported no statistically significant differences between the articaine and lidocaine solutions with respect to the onset and duration of anesthesia.

Potocnik I et al (1999)[11]**,** studied failure of inferior alveolar nerve block in endodontics and they reported that IANB failed in approximately 30% to 45% of cases. They defined the reasons for failure of IANB, to be anatomical considerations and abnormal physiological responses in the presence of inflammation.

Oliveira PC et al (2004)[23]**,** evaluate the onset of action of pulpal and soft tissue anesthesia, and pain experience after buccal and palatal infiltrative injections with 4% articaine with 1:100,000 adrenaline, and 2% lignocaine with 1:100,000 adrenaline. Twenty healthy adult subjects received buccal and palatal infiltrationin the buccal and palatal regions of the upper right canine.The pain experience caused by palatal injection was verified by the visual analogue scale (VAS). They analyzed data using Wilcoxons test (α= 0.05) and found no significant statistical differences between the solutions with respect to VAS (p= 0.45), onset of action (p= 0.80) and pulpal (p= 0.08) and soft tissue

(p= 0.18) anesthesia duration. They concluded that both anesthetic solutions showed similar pain experience.

Elizabeth C et al (2004)[24]**,** compared the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine to 2% lidocaine with 1:100,000 epinephrine for inferior alveolar nerve blocks in patients experiencing irreversible pulpitis in mandibular posterior teeth.Seventy-two patients diagnosed with irreversible pulpitis of a mandibular posterior tooth randomly received, 2.2 ml of 4% articaine with 1:100,000 epinephrine or 2.2 ml of 2% lidocaine with 1:100,000 epinephrine using a conventional inferior alveolar nerve block. Success was as defined as none or mild pain (Visual Analogue Scale recordings) on endodontic access or initial instrumentation which was initiated after 15 min after solution deposition and all patients were required to have profound lip numbness.They reported success rate of 24% for inferior alveolar nerve block using articaine and 23% for the lidocaine solution.There was no significant differencebetween the articaine and lidocaine solutions and neither solution resulted in an acceptable rate of anesthetic success in patients with irreversible pulpitis.

Berlin J et al (2005)[18]**,** designeda prospective, randomized, double-blind studycomparing the anesthetic efficacy of the intraligamentary injection of 4% articaine with 1:100,000 epinephrine and of 2% lidocaine with 1:100,000 epinephrine, administered with computer-controlled local anesthetic delivery system (CCLADS), in mandibular posterior teeth.1.4 mL of 4% articaine with 1:100,000 epinephrine solution and of 1.4 mL of 2% lidocaine with 1:100,000 epinephrine solution was administered, at 2 separate appointments to 51 subjects using CCLADS. Pulp tester was used to test effectiveness of anesthesia, in 2-minute cycles for 60 minutes, of the mandibular

posterior teeth.Anesthesia was considered successful when 2 consecutive 80 readings (highest output) were obtained within 20 minutes. The study success rate of 86% for pulpal anesthesia using articaine and 74% with lidocaine solution. In addition, they found that the mean onset of pulpal anesthesia for the first molar were 1.3 minutes with articaine solution and 2.2 minutes with lidocaine solution; whereas duration of pulpal anesthesia was reported to be 34 minutes and 31 minutes for the articaine and lidocaine solution respectively.They concluded that the efficacy of 4% articaine with 1:100,000epinephrine was similar to the efficacy of 2% lidocaine with 1:100,000epinephrine for intraligamentary injections.

Kanaa MD et al (2006)[25]**,**in their randomized double blind cross-over study investigated the efficacy and discomfort associated with slow (60 seconds) and rapid (15 seconds) inferior alveolar nerve blocks (IANB) using 2.0 ml of 2% lidocaine with 1:80,000 epinephrine for securing pulpal anesthesia in mandibular first molar, premolar and lateral incisor. The study reported slow IANB injection produced significantly more episodes of no pulp response than rapid IANB injection in first molars, premolars and lateral incisors. In addition, they suggested that slow IANB may allow deeper penetration of the nerve trunk with anesthetic agent than rapid injection and also found that IANB injections were significantly more comfortable when given slowly than rapidly.

Aggarwal V et al (2009)[8]**,**in their prospective, randomized, double-blinded study to evaluate anesthetic efficacy of supplemental buccal and lingual infiltrations of articaine and lidocaine after an inferior alveolar nerve block in patients with irreversible pulpitis.Eighty-four patients received standard IANB of 2% lidocaine with 1:200,000

epinephrine. Twenty-four patients did not receive supplemental infiltrations (control). Thirty patients received supplemental buccal and lingual infiltrations of 2% articaine with 1:200,000epinephrine, and 30 patients received buccal and lingual infiltrations of 2% lidocaine with 1:200,000 epinephrine at 2 minutes after the IANB. Endodontic access preparation was initiated after 15 minutes of initial IANB. Pain during treatment was recorded by using a Heft Parker visual analog scale. Success was recorded as ‘‘none’’ or ‘‘mild’’ pain. They demonstrated that supplementary buccal and lingual infiltration of 2% lidocaine with 1:200,000 epinephrine or 4% articaine with 1:200,000 epinephrine improved the success rate from 33% to 47% and 67%, respectively andalso the success rate of 4% articaine with 1:200,000 epinephrine was significantly more than 2%lidocaine with 1:200,000 epinephrine.

Srinivasan N et al (2009)[26], in their prospective, randomized, double-blind study compared the anesthetic efficacy of 4% articaine and 2% lidocaine (both with 1:100,000 epinephrine) for buccal infiltration in patients experiencing irreversible pulpitis in maxillary posterior teeth.After receiving buccal infiltration, endo access opening was done.Success was defined as no or mild discomfort (VAS recordings) during the endodontic procedure. They reported success rate of 100% for maxillary buccal infiltration to produce pulpal anesthesia using articaine, and for the lidocaine solution, success rate was 80% in first premolar and 30% in first molar. The study reported efficacy of 4% articaine to be superior to 2% lidocaine for maxillary buccal infiltration in posterior teeth.

Garisto GA et al (2010)[27] conducted a retrospective analysis on cases of paresthesia involving dental local anesthetics for the period from 1997 to 2008from the

U.S. Food and Drug Administration Adverse Event Reporting System.Chi square analysis was used to compare expected frequencies, on the basis of U.S. local anesthetic sales data, with observed reports of oral paresthesia.Paresthesia was reported in cases involving mandibular nerve block (94.5%),the lingual nerve block (89.0%). In addition anesthetic formulations 4% prilocaine(7.3%) and 4% articaine(3.6%) proved to report paresthesia.The study suggested that paresthesia occurs more commonly after use of 4 %local anesthetic formulations.

Poorni S et al (2011)[28] designed a randomized double-blind trial to evaluate the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine in inferior alveolar nerve block (IANB) and infiltration anesthetic techniques to anesthetize mandibular molars with irreversible pulpitis. Subject's self-reported pain response was recorded on Heft Parker Visual Analogue Scale after local anesthetic administration during access preparation and pulp extirpation. They observed that although Buccal Infiltration and IANB of 4% articaine were equally effective, Buccal Infiltrationcould be considered as an viable alternative to IANB for pulpal anesthesia in mandibular molars with irreversible pulpitis.

Ashraf H et al (2013)[29] compared the anesthetic success rate of buccal infiltration injections of articaine and lidocaine when supplemented with an IANB.One hundred twenty-five patients diagnosed with irreversible pulpitis participated received the IANB by using either 2% lidocaine with 1:100,000epinephrine or 4% articaine with 1:100,000 epinephrine. The patients reporting moderate-to severe pain upon initiation of their endodontic treatment during instrumentation received supplemental buccal infiltration injections. After the block or the supplemental buccal infiltration injections,

success was achieved with no or mild pain during instrumentation of the root canals. The success rate after the administration of the infiltration injections after an incomplete IANB by using lidocaine was 29%, whereas by using articaine it was 71% and no statistical differences were detected in the success rates between the 2 anesthetics after the block injections. They concluded that supplementing an incomplete IANB with articaine infiltration increases the anesthetic success effectively when compared with lidocaine in mandibular molars with irreversible pulpitis.

Saxena P et al (2013) [30] reviewed advances in local anesthesia technique, overviewed newer devices and methods of rendering pain control. The article discussed local anesthesia delivery devices like vibrotactile devices, computer-controlled local anesthetic delivery (CCLAD) systems, jet injectors, safety dental syringes and devices for Intra-Osseous (IO) anesthesia and various local anesthesia techniques. They advocated that there is still room for the improvement of painless techniques in administrating local anesthetics andit is important for clinicians to be familiar with all the local anesthesia devices and techniques available for dental procedures to best exploit them.

Tortamano PI et al (2013)[31]**,** compared the onset and duration periods of pulpal anesthesia using 2% lidocaine with 1:100,000epinephrine, 4% articaine with 1:100,000epinephrine. Thirty subjects received 1.8 mL of each of the three local anesthetic solutions in IANB. Onset and duration periods of pulpal anesthesia were determined using electric pulp stimulation. They found that the mean time of onset of pulpal anesthesia was 8.7, 7.4 and 7.7 min and the mean duration of pulpal anesthesia was 61.8, 106.6 and 88.0 min for 2% lidocaine with 1:100,000 epinephrine, 4%

articaine with 1:100,000 epinephrine and 4% articaine with 1:200,000 epinephrine, respectively. They concluded that 4% articaine with 1:100,000 epinephrine exhibits faster onset and also had longest duration of pulpal anesthesia in IANB.

Kambalimath HD et al (2013)[32] compared the anesthetic properties of 4 % articaine hydrochloride and 2 % lidocaine both with 1:100,000 epinephrine for mandibular inferior alveolar nerve anesthesia.Thirty healthy patients received each test solution at different times. Inferior alveolar nerve block anesthesia was used for extraction of bilateral impacted mandibular third molar on different occasions. The time of onset of action, duration of anesthesia, efficacy of anesthesia, hemodynamic parameters and oxygen saturation were monitored during the procedure. A visual analog scale was used to assess pain during surgery, and thus subjectively evaluate the anesthetic efficacy of the two solutions. They reported no statistically significant difference in the onset and duration of anesthesia between the Articaine and Lidocaine solutions.

Fowler S (2013)[33] studied the success of the inferior alveolar nerve (IAN) block using either 3.6 mL or 1.8 mL 2% lidocaine with 1:100,000 epinephrine in patients presenting with symptomatic irreversible pulpitis. 319 patients presenting with symptomatic irreversible pulpitis received either a 1.8-mL volume or 3.6-mL volume of 2% lidocaine with 1:100,000epinephrine in an IAN block. Endodontic emergency treatment was completed on each subject. Success was defined as the ability to access and instrument the tooth without pain (visual analog scale score of 0) or mild pain (VAS rating #54 mm). The success of 1.8-mL volume was 28%, and for the 3.6-mL volume it was 39% and no statistically significant difference between the 2 volumes. They

concluded the success rates (28%–39%) with either volume are not high enough to ensure complete pulpal anesthesia.

Jing Q et al (2014)[34] evaluated the effectiveness and safety of a computer-controlled periodontal ligament (PDL) injection system to the local soft tissues as the primary technique in mandibular posterior teeth with irreversible pulpitis. They divided patients into 3 groups according to the position of the involved tooth: the premolar group (PM, n=38), first molar group (FM, n=66), and second molar group (SM, n=58). All the patients received computer-controlled PDL injection with 4% articaine with 1:100,000epinephrine. Immediately after the injection, endodontic access was performed, and the degree of pain during the treatment was evaluated by the patients using Visual Analogue Scale for pain.Theoverall success rate reported was 76.5% and significant difference in success rates among the PM, FM, and SM groups (92.1%, 53.0%, and 93.1%, respectively. They didn't observe any adverse effects on the periodontal soft tissues at the injection sites in the follow-up visits in any of the groups.They concluded that the computer-controlled PDL injection system demonstrates both satisfactory anesthetic effects and safety in local soft tissues as primary anesthetic technique for mandibular posterior teeth with irreversible pulpitis.

AtasoyUlusoy OI et al (2014)[35] executed a single-blind randomized clinical trial,to evaluateefficacy of buccal infiltrations for maxillary first molars in patients with irreversible pulpitis.After administration of 1.5 mL 4% articaine with 1 : 100 000 epinephrine (n = 25) or 1.5 mL 4% articaine with 1 : 100 000 epinephrine bitartrate (n = 25),visual analoguescale (VAS) scores and pulse rate measurements were recorded during access cavity preparation and initial file placement into the mesiobuccal,

distobuccal canal. They analyzed data using Duncan and t-tests and found no significant difference between the two anesthetic solutions regarding the VAS scores and pulse rate measurements during endodontic procedures. The heart rates during negotiation of palatal canals to be significantly higher than when negotiating the mesiobuccal and distobuccal canals ($P < 0.0001$). They concluded that buccal infiltration did not achieve adequate pulpal anesthesia in the palatal root canal of the maxillary first molars associated with irreversible pulpitis.

Ahmad ZH et al (2014)[36]**,** determined the anesthetic efficacy of inferior alveolar nerve block (IANB) using 4% articaine and 2% lidocaine supplemented with buccal infiltration.Forty five patients, diagnosed with irreversible pulpitis of a mandibular posterior tooth were included in the study. The first group of 15 patients received 2% lidocaine with 1:200000 epinephrine, the second group 2% lidocaine with 1: 80,000 epinephrine and the third group of 15 subjects received 4% articaine with 1:100000 epinephrine. During the access cavity preparation those patients who complained of pain received an additional buccal infiltration. The percentage of subjects who got profound anesthesia and failure to achieve anesthesia were calculated and tabulated using a visual analog scale. 87% of subjects who received 4% Articaine with 1:100,000 epinephrine got satisfactory anesthesia with inferior alveolar nerve block alone and only 13% subjects received an additional buccal infiltration and none of the patients failed to obtain complete anesthesia with articaine. They concluded that 4% articaine can be used effectively for obtaining profound anesthesia for endodontic procedures in patients with irreversible pulpitis.

Pendse G et al (2014)[37] determined the effect of preoperative ibuprofen on the success of inferior alveolar nerve block in patients with irreversible pulpitis. Forty five patients were diagnosed with irreversible pulpitis randomly received identical capsules of either 400mg ibuprofen or placebo 45 minutes before the administration of a convention-al IAN block. Access was begun after 15 minutes and profound lip numbness. They reported the success rate to be 77.27% for ibuprofen group and 47.82% for placebo group with no significant statistical difference between them. (p=.065).

Darawade DA et al (2014)[38] compared the efficacy of 4% articaine hydrochloride and 2% lignocaine hydrochloride in dentistry. They carried out study in 50 patients by injecting 0.5-1 ml of 4% articaine HCL containing 1:100000adrenaline, incrementally in the buccal vestibule without palatal anesthesia at experimental site and at the control site they injected 0.8-1 ml of 2% lignocaine HCL containing 1:100000adrenaline. They concluded that articaine to be useful with regard to its usefulness, its safety and effectiveness making it an ideal anesthetic agent to be used in dentistry.

Dhamodharan YKT et al (2015)[39] compared the pain perception, behavioral response and the associated change in physiological parameters while receiving local anesthesia injection with cartridge syringe and computer controlled local anesthetic delivery system (CCLAD) over two consecutive visits. 120 children aged 7 – 11 years were randomly divided into group A: receiving injections with CCLAD during first visit; group B: receiving injections with cartridge syringe during first visit. The physiological parameters (heart rate and blood pressure) were recorded before and during injection procedure. Objective evaluation of disruptive behavior and subjective

evaluation of pain perceived were done using Face Legs Activity Cry Consolability (FLACC) scale and modified facial image scale (FIS) respectively.They reported no statistical difference in pain response (p = 0.164) and disruptive behavior (p = 0.120) between cartridge syringe and CCLAD injections during the first visit although the latter showed lesser scores. However,during the second visit there were significant increase in pain response (p = 0.004) and disruptive behavior (p =0.006) in cartridge syringe group with an associated increase in heart rate.They concluded that injections with CCLAD produced lesser pain ratings and disruptive behavior than cartridge syringe in children irrespective of order of visit.

Zain M et al (2015)[40] evaluated the pulpal anesthesia of mandibular 1st molar by using 4% articaine buccal infiltration and inferior alveolar nerve block anesthetic technique. Ninety subjects experiencing moderate to severe pain in mandibular 1st molar were enrolled.Group I consisted of subjects who received a standard IANB of 4% Articaine with 1:100,000 epinephrine and Group II Group 2 consisted of subjects who received BI of 4% Articaine with 1:100,000epinephrine. Thirty two subjects experienced anesthetic success (71.11%) after Buccal Infiltration of 4% Articaine compare to 29 subjects (64.4%) who received IANB of 4% articaine. No significant difference was found between success rates of buccal infiltration with 4% articaine as compared to inferior alveolar nerve block of 4% articaine and they concluded that 4% articaine buccal infiltration to be a viable alternative for inferior alveolar nerve block in securing successful pulpal anesthesia for endodontic therapy.

Kohale et al (2016)[41]compared pain perception when injection administered using the CCLAD system and conventional technique in patients requiring oral surgical

procedure in maxillary anterior region using randomized split mouth design. Computerized single tooth anesthesia with a 30 gauge needle was used to give nasopalatine nerve block by same operator, over minimum gap of 7 days. Patient's pain perception was assessed using numeric rating scale. Computerized single tooth anesthesia showed lesser pain score than conventional group Their study confirmed the theory of controlled flow rate and fluid pressure can lessen the pain perception which is nearly difficult in conventional technique.

Allegretti CE et al (2016)[42]compared the anesthetic efficacy of 4% articaine, 2% lidocaine and 2% mepivacaine, all in combination with 1:100,000 epinephrine, in patients with irreversible pulpitis of permanent mandibular molars during a pulpectomy procedure. Sixty-six volunteers received 3.6 mL of local anesthetic as a conventional inferior alveolar nerve block (IANB). The subjective signal of lip numbness, pulpal anesthesia and absence of pain during the pulpectomy procedure were evaluated respectively, by questioning the patient, stimulation using an electric pulp tester and a verbal analogue scale. Their study reported the success rate to be 68.2% for mepivacaine, 63.6% for articaine and 63.6% for lidocaine and for patients who reported no pain or mild pain during the pulpectomy; the success rate was 72.7% for mepivacaine, 63.6% for articaine and 54.5% for lidocaine.They concluded that neither of the solutions resulted in 100% anesthetic success in patients with irreversible pulpitis of mandibular molars.

Su N et al (2016)[43] assessed the efficacy and safety of articaine and compared articaine with lidocaine for irreversible pulpitis (IP) treatment.They explored thedatabases electronically; relevant journals as well as the references of the included

studies were hand-searched for comparing the efficacy and safety of articaine with lidocaine in treatment of IP. They observed thatin comparison with 2% lidocaine with 1:100 000 epinephrine, 4% articaine with 1:100 000 epinephrine showed a higher success rate in anesthesia of IP ,lower VAS scores during injection phase and treatment phase, shorter onset time of pulpal anesthesia and lower percentage of patients undergoing adverse events.

Drum M et al (2017)[44] reviewed the literature related to the anesthesia necessary for endodontic therapy with irreversible pulpitis. They concluded that no single drug, solution, or technique will allow dentists to comfortably treat every patient with symptomatic irreversible pulpitis. However, there are some supplemental techniques and adjuncts that can be used to increase the success rates of pulpal anesthesia that will benefit both dentists and their patients.

González-Castro O et al (2017)[45] review set out to describe current devices for a controlled flow of dental anesthesia solution to reduce pain and anxiety during its administration and address the supported evidence. Although few studies analyze the topic in detail so far, the present review found some support to the use of computerized anesthetic delivery systems to reduce the anxiety and pain during anesthetic injections. Computer-controlled anesthetic delivery seemed to be statistically superior to traditional dental injectionsin terms of patient comfort. The use of computer controlled anesthetic may be considered a strategy to reduce patient´s fear and create a positive attitude towards dental treatment in the future.

Hopman AJG (2017)[46] carried out a literature review on neurotoxicity after use of articaine and summarized that paresthesia is observed after administration of 4%

articaine, the tongue (lingual nerve) was the most frequently affected than lip and chin after IANB.

Alzahrani F et al (2018)[47] compared the anesthetic efficacy for pain and behavior during treatment with mandibular infiltration using 4% articaine (BI) with inferior alveolar nerve block (IANB) using 2% lidocaine for extraction or pulp therapy in mandibular primary molars. BI supplemented by buccal intrapapillary infiltration with 4% articaine; IANB with 2% lidocaine supplemented with long buccal infiltration. Behavior during the injection and treatment procedures was assessed using Wong-Baker Facial Rating Scale (W-BFRS), Visual Analogue Scale (VAS), and Frankl Behavior Rating Scale (FBRS). They reported that during the injection phase, the absolute differences in success rates between the two techniques were 0.06 for VAS and 0.08 for the behavior of the child (FBRS). They suggested equivalence in success rates for both anesthetic techniques during treatment.

MATERIALS & METHOD

The present study was conducted in the Department of Conservative dentistry and Endodontics, with the objective to evaluate and compare the effectiveness of intraligamentary injection using Single Tooth Anesthesia (STA) System and Traditional Inferior Alveolar Nerve Block (IANB) injection technique in patients with irreversible pulpitis in mandibular molars.

ETHICS COMMITTEE APPROVAL:

The ethical committee approval for this clinical trial was requested and granted by the registered ethics board of institution. This clinical trial was also registered and approved with Clinical Trial Registry of India.

STUDY PARTICIPANTS:

All patients visiting OPD of the Department of Conservative Dentistry and Endodontics with history of acute pain associated with mandibular molars were evaluated for the following criteria:

SELECTION CRITERIA:

Inclusion Criteria:

1. Age (18-50yrs).
2. Presence of acute pain in a mandibular first or/and second molar.
3. Prolonged response to cold testing.
4. Grade ≥ 54 mm on Heft-Parker Visual Analog Scale (HP-VAS) in mandibular molars

Exclusion Criteria:

1. Large periapical radiolucency with mandibular 1^{st} and/or 2^{nd} molars.
2. Periodontal disease other than acute apical periodontitis.
3. History of any medication that would alter pain perception.
4. History of allergy or sensitivity to local anesthetic drug or suspected drug abuse.
5. History of bleeding disorders.
6. Patients who were pregnant or breast-feeding.

ARAMAMENTARIUM:

Instruments and Equipment:

- Front surface mouth mirror (GDC, India) (PLATE–I)
- Straight probe (GDC, India) (PLATE–I)
- Explorer (GDC, India) (PLATE–I)
- Pair of Tweezers (GDC, India) (PLATE–I)
- Excavator (GDC, India) (PLATE–I)
- Cotton holder (GDC, India) (PLATE–I)
- Waste receiver (GDC India) (PLATE–I)
- Electric pulp tester (Gentle Pulse Analog Pulp Tester, Parkell) (PLATE–I)
- Endo frost (ROEKO Endo-Frost, Langenau, Germany) (PLATE–II)
- Self-aspirating syringes (Septodont, Saint-Maur-des-Fosses Cedex, France). (PLATE–II)
- 27-gauge long needles (Septoject; Septodont,Saint-Maur-des-Fosses Cedex, France). (PLATE–II)
- Single Tooth Anesthesia System (Milestone Scientific) (PLATE–III)
- 30 gauge ½ inch needle. (PLATE–III)
- 5ml syringe with 24 gauge needle (Nirlife, India)
- Rubber dam kit: (Hygenic Dental Dam Kit, Coltene) (PLATE–III)
- Suction tips (PLATE–III)
- Dental Floss (Colgate) (PLATE–III)
- Digital radiovisiography system (Kodak 5100 RVG, France)
- Air rotor hand piece (NSK, Japan) (PLATE–IV)

- Rotary burs: (PLATE–IV)
  - Round Bur (BR-41,Mani ,Japan)
  - Safe end bur (Ex-24,Mani ,Japan)
- Standard 2% files # 10-20(Sybron Endo ,Mexico) (PLATE–V)
- X-Smart Endomotor (DENTSPLY, Maillefer, Switzerland) (PLATE–V)
- Gates Glidden drills (Mani, Japan) (PLATE–V)

  Pro Taper Next Rotary files.(DENTSPLY, Maillefer, Switzerland) (PLATE–V)
- Endo Bloc (DENTSPLY, Maillefer, Switzerland) (PLATE–V)

Materials:

- 1.7 mL 4% articaine with 1:100,000 epinephrine (Septocaine®) (PLATE–II)
- Root canal irrigation solutions (PLATE–VI)
  - Sodium hypochlorite (NaOCl) (5.25%) (Hyposept UPS Hygienes, India)
  - Normal saline (0.9 % w/v, Nirlife, India)
- Chelating agent for smear layer removal
  - 17% liquid Ethylene Diamine Tetra Acetic acid (EDTA) (DentWash, Prime Dental, India) (PLATE–VII)
- RC Help (Prime Dental Products, India) (PLATE–VI)
- Cavit (3M ESPE, Germany) (PLATE–VII)]

PATIENT CONSENT:

In all eighty patients were assessed, out of which eighteen patients did not fulfill the inclusion criteria whereas two of them declined to participate in the study. Thus,

sixty patients (N=60) diagnosed with irreversible pulpitis in need of root canal treatment were selected for the study. The purpose of the study was explained to them in detail and further informed that such treatments in dental practice requires anesthesia & does not involve any additional risks. Patients were also informed about the confidentiality of data to be collected and their participation was entirely on voluntary basis, following this informed written consent was signed by them and was kept as a record. Patients were also given option to abandon their participation.

PREOPERATIVE EVALUATION:

Radiographic evaluation:

A brief case history of all the participants was recorded by a single clinician. Preoperative Intraoral periapical radiographs were obtained to evaluate the presence and severity of caries, deep restorations in relation to the dental pulp as well as root fractures and periapical changes.

Cold testing:

The patient was guided about the application of cold stimulus and if the patient felt it, they were instructed to raise their hands. The cold testing was done using Endo Frost (ROEKO Endo-Frost, Langenau, Germany). The cotton pellet sprayed with Endo Frost was placed towards the cervical one third of a tooth on either the buccal or lingual aspect. The pellet was placed for 2-5 sec and response was recorded according to reaction of patient ;no response indicated irreversible pulpitis. (PLATE–VIII)

Electric pulp testing:

The patients were given similar instruction prior to Electric pulp testing as that in cold testing. Electric pulp testing was performed before administrating anesthesia by

placing the tip at the occlusal third of the buccal surface of the suspected tooth to be tested and the response was recorded. The electric pulp testing response was used to confirm the diagnosis of irreversible pulpitis. (PLATE–VIII)

Heft-Parker Visual Analogue Scale:

A 170-mm Heft-Parker visual analog scale was used in the study for evaluation pain perception and anesthetic effectiveness. Patient was given a thorough explanation of the HP-VAS scale which was divided into 5 categories: no pain corresponded to 0 mm; faint pain was defined as 0 to 23mm, mild pain was defined as 23 to 54 mm, moderate pain was defined as 54 to 114 mm strong/intense pain was defined as greater than 114 mm.[66]

The operator rendered the treatment to all patients to eliminate or minimize interpersonal variability in the treatment procedure. A blinded investigator assisted patients to mark their rating on the Heft-Parker Visual Analog Scale pre-operatively & post- operatively.

PREANESTHETIC EVALUATION:

- A thorough medical history (detail as possible about allergies and drug reactions) was noted.
- The patient's past anesthetic experience including any complications were evaluated.

Sensitivity Test:

The intradermal (intracutaneous) injection was given by inserting the needle tip, bevel up, just underneath the surface of the skin and injecting 0.1 mL of the anesthetic

agent. A "bleb" was formed. Injection site was kept under observation for 15-20 minutes any visible change at injection site was observed. No changes indicated no allergy to anesthetic solution.

TREATMENT GROUPS:

Simple randomization of samples was done by the open Epi random program. According to the block number generated the participants were allocated into two groups:

Group I *(n=30):* Patients receiving anesthesia using Traditional Inferior Alveolar Nerve Block (IANB)

Group II *(n=30):* Patients receiving Intraligamentary injection anesthesia using Single Tooth Anesthesia (STA) system.

Group I received standard IANB injections using 1.7 mL 4% articaine with 1:100,000 epinephrine (Septocaine®). The direct technique also known as the Halstead approach was used for IANB. (PLATE–IX)

1. Operators position:
   - Right IANB and right handed operator 8‘O’clock position facing the patient was used.
   - Left IANB and right handed operator 10‘O’clock position facing in same direction as that of patient was used.
2. Patient position:
   - Semi-Supine position was used.
3. The patient was requested to open the mouth wide and the ramus was held between the thumb and index finger.

4. The thumb was placed in the mandibular retro molar region in the coronoid notch of the ascending ramus.
5. Before reaching the final resting point; with the help of thumb the mucosa was stretched over the ramus and by doing so two important functions were achieved: First, with the thumb we can palpate the internal oblique ridge of the mandible. Secondly, it assists in easier needle penetration in the mucosa.
6. The index or middle finger was placed extra orally on the posterior aspect of the ramus at the same height as the thumb.
7. The self-aspirating syringes (Septodont, Saint-Maur-des-Fosses Cedex, France) and 27-gauge long needles (Septoject; Septodont) was then introduced across the premolars of the opposite side aiming to enter mucosa at the level of halfway up the thumbnail.
8. The point of entry is midway between the internal oblique ridge (which was palpated by the thumb) and the pterygomandibular raphe (which is visualized)
9. The needle was advanced through the tissue until bony contact was made.
10. When the needle contacted bone in the correct position it was withdrawn slightly, aspiration was performed and 1.7 mL of solution deposited slowly at a rate of 1 mL/min.
11. Slowly syringe was withdrawn and when approximately half its length was within the tissue, re-aspiration was done if negative, remaining solution was deposited so to anesthetize lingual nerve.

Group II received Intraligamentary injection with Single Tooth Anesthesia (STA) System (Milestone Scientific) using 0.9 mL (per side) 4% articaine with

1:100,000epinephrine by 30 gauge ½ inch needle. STA system drug administration is done using the following steps: (PLATE–IX)

1. Turn the STA drive unit to "On". The system will default to the STA mode.
2. Load and attach the STA bonded handpiece with the pre-attached bonded 30 gauge ½ inch needle and the anesthetic drug.
3. The unit automatically purges the air from the system.
4. Rest the handpiece in the cap holder.
5. Hold the STA handpiece in a pen-like grasp; place the needle into the gingival sulcus of the tooth to be anesthetized.
6. Simultaneously, activate the ControlFlo™ rate by depressing the foot control. Finger rest was used to control and stabilize needle movements; gently and slowly the needle was advanced within the sulcus.
7. The STA System unit provides a continuous audible and visual feedback to guide the needle tip to the periodontal ligament.
8. As the foot control is depressed, the device initially says "sensing". Then the word "Cruise" is heard at which time the cruise control function is engaged by removing one's foot from the pedal.
9. In the STA mode, the DPS technology provides real time pressure feedback via:
    a. The visual Pressure Sensing Scale (Gauge) comprised of a series of orange, yellow and green LED lights.
    b. The orange LED's indicate minimal pressure, the yellow LED indicate mild pressure and the green LED's indicate moderate pressures indicative of the periodontal ligament tissue.

c. The auditory Pressure Sensing Scale is composed of a series of triple ascending tones “beep, beep, beep”. Increasing pressure is indicated by the triple ascending sequence.

d. When the periodontal ligament is identified, the user will hear the letters “PDL” spoken three times, followed by a series of extended tones “beeeep, beeeep” indicating correct needle positioning.

ANESTHETIC EVALUATION:

The electric pulp tester (Gentle Pulse Analog Pulp Tester, Parkell) was used as described earlier to confirm the effect of local anesthesia for both the groups. The time of onset was recorded as a time till no response on EPT was seen in both groups. The subjective symptoms like profound lip numbness were evaluated for time of onset in Group I. Whereas, in Group II as subjective symptoms were absent, the gums adjacent to tooth structure was probed every 10 minutes and the response was evaluated on HP-VAS score. The patient were asked to rate their pain during anesthetic administration using HPVAS score for both techniques.

Root canal treatment procedure was carried out under magnification and using rubber dam isolation. Access opening was done using diamond round burs (BR-40,Mani,Japan). 10 no.K file (SybronEndo, Mexico) was used as a path finder file followed by 15no. K file (SybronEndo , Mexico) for working length determination (PLATE–X). Biomechanical preparation was done using Protaper next files (Dentsply Maillefer,USA) with intermittent irrigation with sodium hypochlorite and normal saline.

After the completion of endodontic treatment, patients were asked to rate their pain during endodontic procedure on HP-VAS score for both groups. The patients requiring supplementary injection for achieving anesthesia were excluded from the study.

POST-ANESTHETIC EVALUATION:

The duration of anesthesia for Group I, was evaluated by wearing off subjective symptoms. The subjective symptoms of Group II, was evaluated by asking patient to press the gums with fingernail every 10 minutes until feeling normal pressure returned and the responses was recorded. The effectiveness was evaluated by recording the time of onset, and duration of anesthesia using subjective symptoms and EPT readings before and after anesthetic procedure.

The Evaluation of pain perception was done as per the HP-VAS grading system. For evaluating acceptability; whether the anesthesia procedure was comfortable; the grading was done as follows:

- Agree -1
- Partially agree -2
- Partially disagree-3
- Disagree-4

Evaluating post anesthetic pain at an interval of 3hrs, 24hrs and 1 week was done using HP VAS score.

All relevant data regarding effectiveness, pain perception and acceptability, was collected and evaluated using descriptive analytic statistics.

ALGORITHM FOR METHODOLOGY:

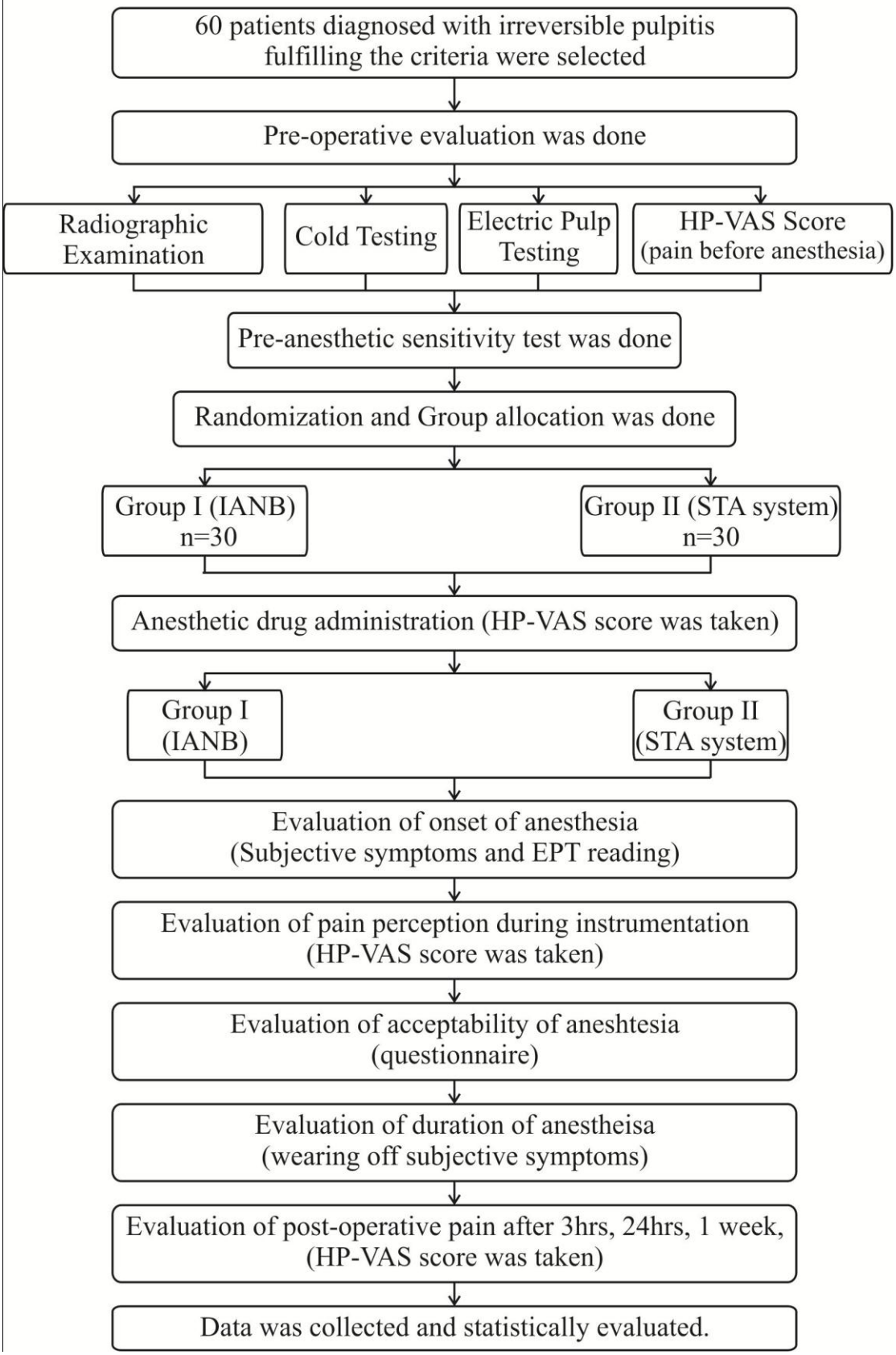
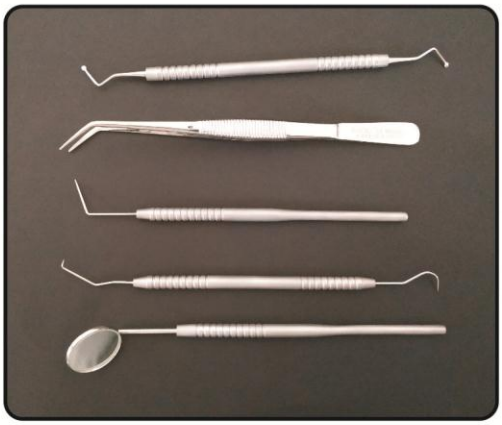


PLATE - I

ARMAMENTARIUM



Hand instruments (GDC, India)

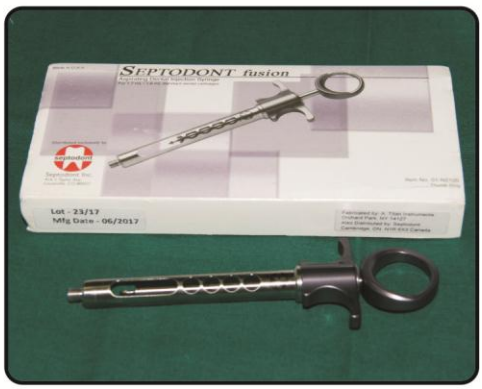
Cotton Holder & Waste Receiver (GDC, India)

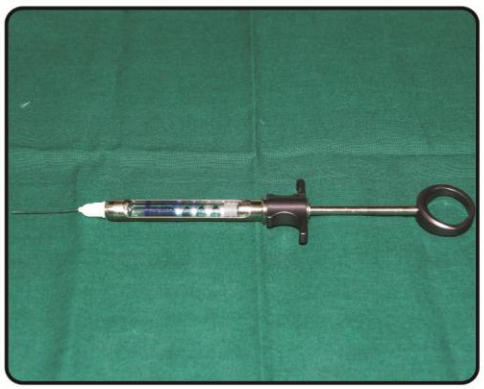
Electric Pulp Tester (Gentle Pulse Analog Pulp Tester, Parkell)

PLATE - II

ARMAMENTARIUM

Endo Frost
(ROEKO Endo-Frost, Langenau, Germany)



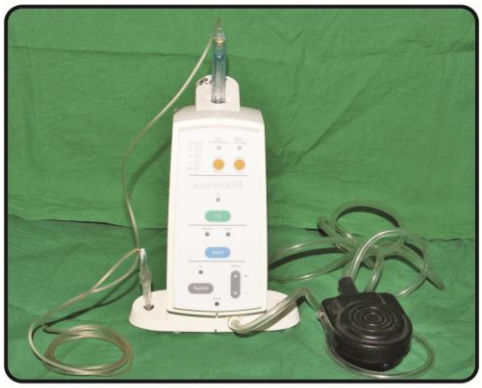


Self-Aspirating Syringes 27 Gauge Long Needles
(Septodont, Saint-Maur-des-Fosses Cedex, France)

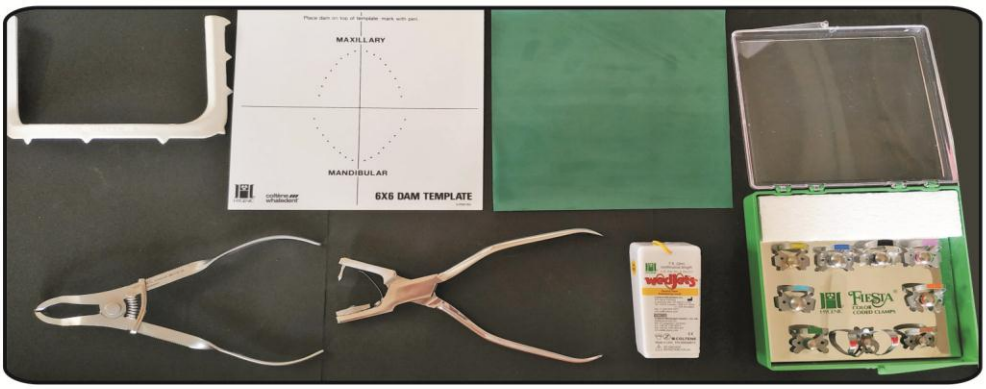
1.7 mL 4% Articaine with 1:100,000 Epinephrine (Septocaine®)

PLATE - III

ARMAMENTARIUM



Single Tooth Anesthesia System 30 ½ Inch Gauge Needle (Milestone Scientific)



Rubber Dam Kit (Hygenic Dental Dam Kit, Coltene)

Dental Floss (Colgate)

PLATE - IV

ARMAMENTARIUM

Suction Tips

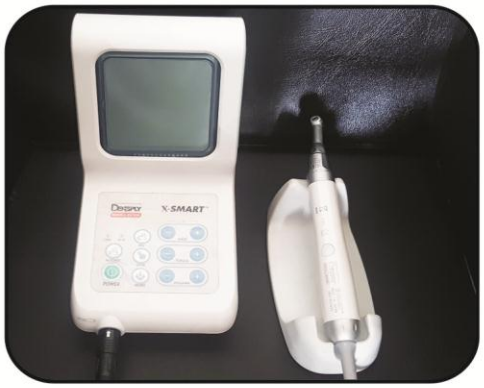
Air Rotor Hand Piece (NSK, Japan)

Round Bur (BR-40, Mani, Japan) &
Safe End Bur (Ex-24, Mani, Japan)

PLATE - V

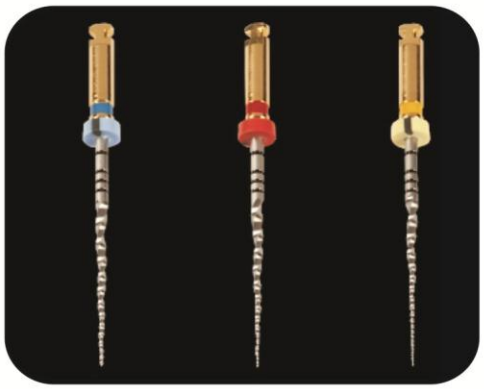
ARMAMENTARIUM

Standard 2% Files # 10-20 (SybronEndo, Mexico)

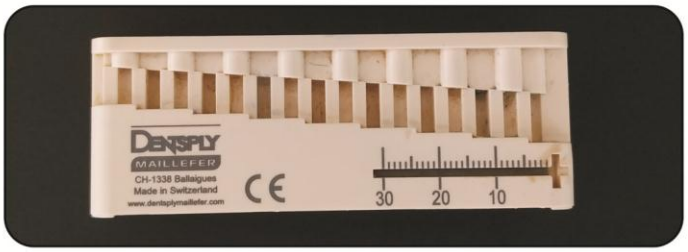


Endodontic Motor X-Smart (DENTSPLY, Maillefer, Ballaigues, Switzerland)

Gates Glidden Drills (Mani, Japan)



Pro Taper Next Rotary Files (DENTSPLY, Maillefer, Ballaigues, Switzerland)

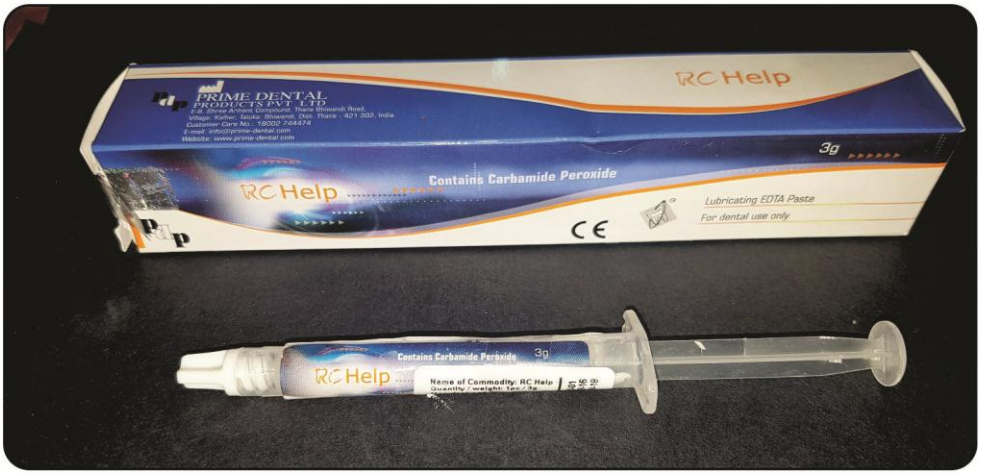


Endobloc (DENTSPLY, Maillefer, Switzerland)

PLATE - VI

MATERIALS

Sodium hypochlorite (NaOCl) (5.25%) (Hyposept UPS Hygienes, India) & Normal saline (0.9 % w/v, Nirlife, India)



RC Help (Prime Dental Products, India)

PLATE - VII

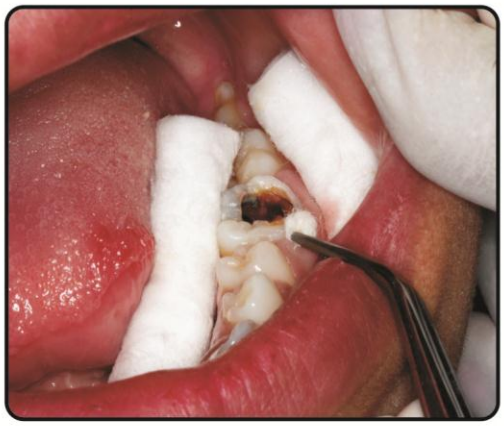
MATERIALS

17% liquid Ethylene Diamine Tetra Acetic acid (EDTA)
(DentWash, Prime Dental, India)

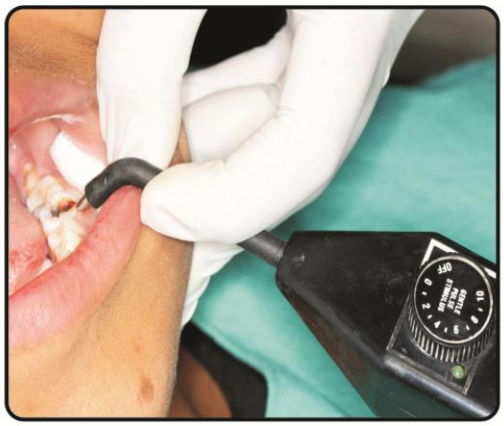
Cavit (3M ESPE, Germany)

PLATE - VIII

PRE-OPERATIVE EVALUATION



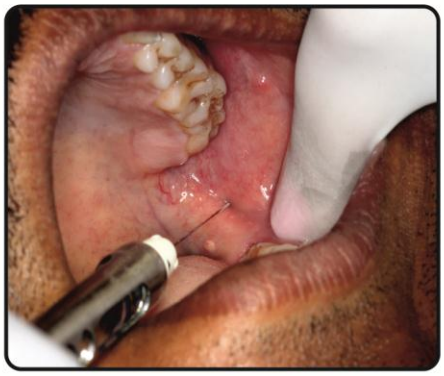
Cold Testing



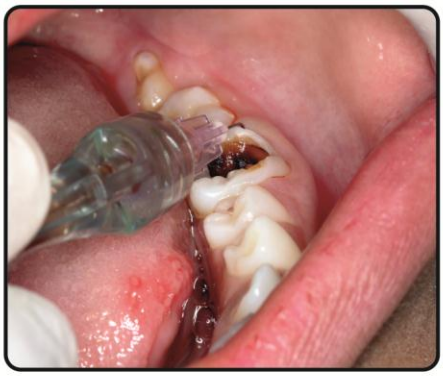
Electric Pulp Testing

PLATE - IX

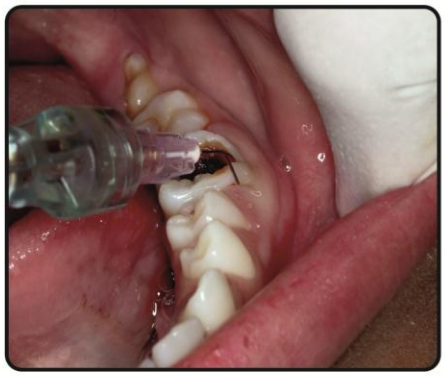
ANESTHETIC TECHNIQUE



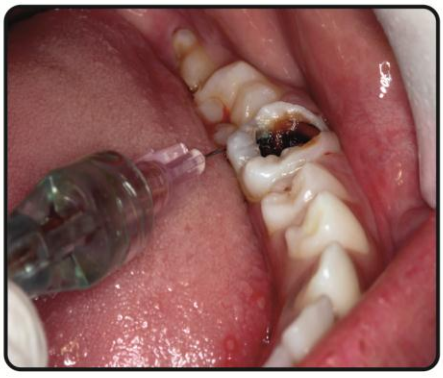
Group I- Inferior Alveolar Nerve Block



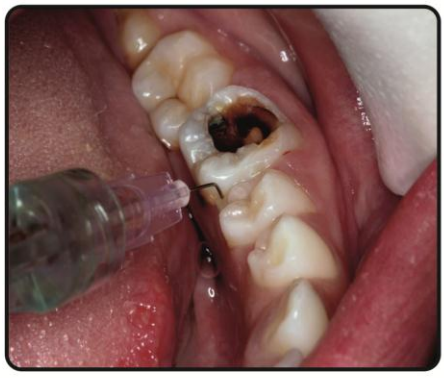
a) Distobuccal Line Angle



b) Mesiobuccal Line Angle



c) Mesio Lingual Line Angle



d) Disto Lingual Line Angle

Group II- Intraligamentary Injection with
Single Tooth Anesthesia (STA) System

PLATE - X

INSTRUMENTATION

Access Cavity Preparation and Instrumentation

RESULTS

The present in vivo study was carried out to compare the effectiveness of Intraligamentary injection using Single Tooth Anesthesia (STA) System and Traditional Inferior Alveolar Nerve Block (IANB) injection technique using 4% articaine with 1:100,000epinephrine, on mandibular 1st and/or 2nd molars, with irreversible pulpitis.

SAMPLE SIZE CALCULATION:

Sample size calculation was done using paired t-test with 95% confidence level and 80% power of test.

STATISTICAL ANALYSIS:

Descriptive and inferential statistical analysis was performed using SPSS ver. 20.0 (IBM Corp). Descriptive statistics such as mean, median, mode, standard deviation and range (maximum, minimum) were used to describe the continuous variables in the study viz. age of patients, time of onset of anesthesia and effectiveness measurement by electric pulp testing procedure between two treatment groups i.e. IANB and STA system. Although, age variable is on continuous scale, was transformed into categories in order to understand the distribution of patients in two groups. Thus, categorical variables like age, gender, severity of pain on different conditions and response of patients on anesthesia procedure were described using frequency and percentages. The t-test was used to compare difference in mean time of onset and duration of anesthesia between two groups. It was also used to determine the mean effectiveness between two groups before and after electric pulp testing. Paired test was performed for evaluating mean difference of effectiveness before and after electric pulp testing in two groups. To determine whether the distribution of patients in two groups was statistically significantly different or not, a Pearson's Chi-square test of independence was used. A P-value < 0.05 was considered statistically significant for all tests

Brief description of methods is given below:

If $x_1, x_2, \ldots x_n$ are the observations on random variable X, then

A) Sample mean for a set of observations is given by

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

B) **Standard deviation** for a set of observations in given by

$$s = \sqrt{\frac{1}{(n-1)} \sum_{i=1}^{n} (x_i - \bar{x})^2}$$

wherex_i = observation on each object

n = number of objects

C) **Median**: It is the middle value of a set of values when arranged in the increasing order of magnitude.

D) **Range** is the difference between maximum and minimum value of the variable.

E) **Student's t-test for independent samples**

The test is used for comparing the statistical significance of difference in the means of two samples. It compares the sample difference between two means in relation to the variation in the data (expressed as the standard deviation of the difference between the means).

It is given by the formula:

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{s_{(\bar{x}_1 - \bar{x}_2)}}$$

where $\bar{x}_1$ and $\bar{x}_2$ are the means of sample observations of two different groups, μ_1 and μ_2 are the means of the respective populations from which the samples are derived, and $s_{(\bar{x}_1 - \bar{x}_2)}$ is the pooled sample standard deviation, which is given by:

$$s(\bar{x}_1 - \bar{x}_2) = \sqrt{\frac{s^2_{pooled}}{n_1} + \frac{s^2_{pooled}}{n_2}}$$

where

$$s^2_{pooled} = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

here s_1^2 and s_2^2 are the variance of two samples and n_1 and n_2 are the sample sizes in two groups.

If the test statistic results in a *P*-value > 0.05 (level of significance), then the null hypothesis H_0: *There is insignificant difference in the means of two groups* is accepted and the alternative hypothesis H_1: *There is significant difference in the means* is rejected. On the other hand if *P*-value < 0.05, then the H_1 is accepted and $H_0$is rejected.

F) Chi-square test

Let *X* and *Y* be two variables under study with *r* and *s* levels respectively; and the data on *r*×*s* levels be in the form of counts. Let the null hypothesis be that the two variables are independent. That is, knowing the levels of *X* does not help in predicting the levels of *Y*; against the alternative hypothesis that the two factors are not independent. That is, knowing the level of *X* can help in predicting levels of *Y*. To decide about the acceptance of hypothesis, the Chi-square test statistic is used which is defined as:

$$\chi^2 = \sum_{i=1}^{r}\sum_{j=1}^{s} \frac{(O_{ij} - E_{ij})^2}{E_{ij}}$$

where O_{ij} is the observed frequency count for i^{th} level of variable X and j^{th} level of variable Y. E_{ij} is the expected frequency count for same cell. The expected count is given by

$$E_{ij} = \frac{n_i \times n_j}{n}$$

where n_i and n_j are the total counts for i^{th} level of variable X and j^{th} level of variable Y; and n is the total count. The calculated Chi-square value is compared with the tabulated one for $(r\text{-}1)\times(s\text{-}1)$ degrees of freedom. If the corresponding p-value is smaller than the pre-decided significance level, say 0.05, then we reject the null hypothesis and accept the alternative one. If the p-value is more than 0.05, then we accept null hypothesis.

G) Fisher's exact test

Fisher's exact test is a statistical test to determine if there are any non-random associations between two categorical variables.

If X and Y are the two categorical variables with m and n observed states respectively, then a m x n matrix can be generated with a_{ij} as the number of observations for i^{th} state of X and j^{th} state of Y. Accordingly, the row and the column sums R_i and C_j are

$$N = \sum_i Ri = \sum_j Cj$$

The conditional probability of getting the actual matrix given the particular row and column sums is given by

$$P_{cutoff} = \frac{R_1!R_2!...R_m!)(C_1!C_2!...C_n!)}{N!\prod a_{ij}!}$$

This is a multivariate generalization of hypergeometric distribution. All possible matrices of non-negative integers consistent with rows and column sums are determined, and for each matrix the conditional probability using above expression is determined, such that the sum of probabilities is 1.

To determine the P-value of the test, the tables needs to be ordered by some criterion that measures dependence, and those tables that represent equal or greater deviation from independence than the observed table are the ones whose probabilities are added together.In a typical 2 x 2 case, the P-value of the test is simply the sum of P-values of matrices that are less than P_{cutoff}.

H) Paired t-test

The method is typically used for assessing the effectiveness of an experimental procedure that makes used of related observations resulting from dependent samples. The hypothesis test based on this type of data is known as *paired comparison test*. Its formulation is given by:

For *n* sample differences computed from *n* pairs of measurements, which are distributed normally, the test statistic for testing hypothesis about population mean difference μ_d is given by:

$$t = \frac{\bar{d} - \mu_d}{s_d / \sqrt{n}}$$

where $\bar{d}$ is the sample mean, μ_d is the hypothesized population mean difference, s_d is the standard deviation of sample difference. Under the assumption that H_0 is true, the test statistic is distributed as *Student'st* with *n*-1 degrees of freedom.

OVERALL RESULT:

Table 1 shows the distribution of patients between both groups. Out of 30 patients in Inferior Alveolar Nerve Block (IANB) group, maximum i.e.10 (33.33%) belong to age group > 45 years, followed by 9 (30%) patients belong to age group 26-35 years and 36-45 years each. Out of 30 patients in Single Tooth Anesthesia System (STA), maximum i.e. 11 (36.67%) belong to age group 26-35 years, followed by 10 (33.33%) patients in age group ≤ 25 years. Table 1also provide group wise mean age of patients. In IANB group, it was 39.10 ± 9.76 years, which was significantly higher than STA group (31.73 ± 8.87 years) as indicated by a p-value of 0.0034, obtained using t-test for independent samples.

Table 2 presents the gender distribution of patients between both groups. Out of 30 patients in IANB group, 17 (56.67%) were female and 13 (43.33%) were male, while in STA group, out of 30 patients, 14 (46.67%) were female and 16 (53.33%) were male. The distribution of patients according to gender was insignificant in two treatment groups as indicated by a p-value of 0.6054, obtained using Pearson's chi-square test.

Table 3 provides the pain perception before anesthesia in both groups. Out of 30 patients in the IANB group, maximum 23 (76.67%) patients experienced moderate pain, followed by 6 (20%) with mild pain. While in the STA group, maximum 16 (53.33%) patients experienced mild pain, followed by 14 (46.67%) with moderate pain. The distribution of patients according to severity of pain before anesthesia was significant in two treatment groups as revealed by a p-value of 0.0209 (p-value < 0.05), obtained using Pearson's Chi-square test.

Table 4 describes the mean electric pulp testing reading before anesthesia in both groups. The mean reading before electric pulp testing in IANB group was 6.47 ± 0.86 and 6.63 ± 0.61 in STA group; however, the difference in mean was statistically insignificant (p-value > 0.05).

Table 5 explains the pain perception during anesthetic administration in both groups. Out of 30 patients in the IANB group, maximum 11 (36.67%) experienced no pain and mild pain, followed by 6 (20%) with faint pain. While in STA group, maximum 21 (70%) patients experienced no pain, followed by 6 (20%) patients with mild pain. The distribution of patients according to severity of pain at the site of injection was insignificant in both groups, as indicated by a p-value of 0.0552 (p-value > 0.05), obtained using Pearson's Chi-square test.

Table 6 describes the mean electric pulp testing reading after anesthesia in both groups.. For both IANB and STA group, the test resulted into a p-value < 0.0001, indicating that the mean difference between the effectiveness after electric pulp testing (IANB: 10.00 ± 0.00; STA: 9.87 ± 0.35) was statistically significantly as compared to before testing (IANB: 6.47 ± 0.86; STA: 6.63 ± 0.61).

Table 7 depicts the descriptive statistics for mean time of onset of anesthesia (in min) between two treatment groups. The mean time in STA group was 2.93 ± 1.80 min, which was significantly higher than IANB group 1.40 ± 0.86 min, as indicated by p-value of 0.0001, obtained using t-test for independent samples. Other statistical parameters like median, mode and range were also shown in the table.

Table 8 elucidates pain perception during endodontic procedure in both groups. Out of 30 patients in the IANB group, maximum 25 (83.33%) patients experienced no pain, followed by 4 (13.33%) patients who went through mild pain. While in STA group, maximum 25 (83.33%) patients experienced mild pain, followed by 4 (13.33%) patients who suffered from no pain condition. The distribution of patients according to severity of pain during root canal procedure was significant in both groups as indicated by a p-value < 0.0001, obtained using Fisher's exact test.

Table 9 summarizes the response to the questionnaire. In the IANB group, maximum 21 (70%) patients responded that the anesthesia procedure was comfortable, while 9 (30%) partially agreed to the question. In the STA group, 26 (86.67) agreed that the procedure was comfortable and only 4 (13.33%) patients partially agreed to the question. The distribution of patients in both groups according to the response type was insignificant as indicated by p-value of 0.21 using Chi-square test of homogeneity.

Table 10 summarize the descriptive statistics for mean duration of anesthesia (in min) for two treatment groups. The mean duration in STA group was 33.17 ± 5.94 min, which was significantly lower than IANB group 161.83 ± 15.28 min, as indicated by p-value < 0.0001, as obtained using t-test for independent samples.

Table 11 describes pain perception at the site of injection after completion of endodontic procedure at different time interval. In the IANB group, at 3 hours, the presence of pain at the site was experienced by 8 patients, while at 24 hours and 1 week, none of the patient experienced the pain. On the other hand, in STA group, not a single patient experienced pain at these three-time intervals.

DISCUSSION

Management of pain is essential in reducing fear and anxiety of patients during endodontic procedures for positive reinforcement of patients towards the treatment. The local anesthetic technique is the most consistently used technique for endodontic pain management.[48]

The choice of **anesthetic injection techniques** is also important for treating the teeth affected with irreversible pulpitis. Various injection techniques like IANB, Gow-Gates technique, Vazirani-Akinosi technique, local infiltration, intraosseous injections, intraligamentary injection, intrapulpal anesthesia, pressure anesthesia, computer controlled local drug delivery system have been studied during endodontic treatment of

teeth with irreversible pulpitis. To achieve pulpal anesthesia, IANB is the most frequently used anesthetic technique. The conventional IANB technique, involves blocking the inferior alveolar nerve, which includes the insertion of the needle near the area of the mandibular foramen, where the inferior alveolar nerve is located before it enters the foramen. **Aggarwal V et al in 2010**[49], reported no statistically significant differences in anesthetic efficiencybetween IANB, Gow-Gates,Vazirani-Akinosi and infiltrations. However, few researchers **(Potocnik I et al in 1999**[11]**, Tortamano IP et al** [50]**, Aggarwal V et al in 2009**[8]**)** have reported a higher IANB failure rate, mainly in teeth with irreversible pulpitis.[1]

Literature reports various mechanisms to explain the high failure rate of IANB; fewer to mention are altered resting potentials, decreased excitability thresholds of inflamed nerves, tetrodotoxin-resistant sodium channels (TTX-R) (resistant to anesthetics), increased expression of sodium channels in irreversibly inflamed pulps, and apprehensive patients with lower pain thresholds[51-54]. Nav1.7, Nav1.8 and Nav1.9 are predominant amongst the nine distinct units of voltage-gated sodium channel. Nav1.8 is a TTX-R sodium channel plays an important role in pain associated with inflammation and the onset of neuropathic pain. **Ines Drenjanevi-Peri in 2009**[55] explained that to reduce inflammation-induced sensitization of high-threshold primary afferent neurons the modulation of TTX-R voltage-gated sodium current is required. **Becker DE in 2006**[56] reported that the local anesthetic agents acts on Tetrodotoxin (TTX)-sensitive sodium channels in the peripheral nervous system. However, one of the reason for local anesthetic failures is presence of prostaglandin E2 as it increases the peak current by two-fold and reduces the threshold voltage for activation of the sodium current generated from TTX-R. The inflammation and bacterial insult leads to

sprouting of nerve fibers, increased expression of neuropeptide (substance P and calcitonin gene-related peptide) and the release of inflammatory mediators (prostaglandins E2, prostaglandins F2a, interleukins 1 and 6, and tumor necrosis factor). This leads to excitability of nociceptor isoforms giving rise to the clinical conditions like neuronal plasticity, allodynia and hyperalgesia. The inflammation- induced tissue acidosis causes 'ion trapping' of local anesthetics making it unable to cross the cell membranes. **Apkarian AV in 2009**[57] reported that the central sensitization was associated with increased excitability of central neurons and resulting in hyperalgesia. This exaggerated response to the peripheral stimuli may lead to the perception of pain, thus causing failure of local anesthesia.

Supplemental injections are essential when, anesthesia from conventional injections is inadequate, and the pain is too severe for the endodontist to proceed. In early 1900's Intraligamentary injections were earlier referred as peridental or periodontal injections and were considered very unconventional. However, the increased use of Intraligamentary injections began in 1970's with the introduction of specialized syringes that allowed operator the ease to administer the anesthetic solution. The success rate reported for intraligamentary injection for patients with irreversible pulpitis are in range of 63% to 74 %[17, 44]. A second resurgence occurred early in 2000's with the introduction of computer controlled local anesthetic delivery system[58].

The **computer controlled local anesthetic delivery system(CCLAD)** provided a high level of injection control. The core technology is an automatic delivery of local anesthetic solution at a fixed pressure:volume ratio regardless of variations in tissue resistance. This results in a controlled, highly effective, and comfortable

injection even in the resistant tissues such as the palate and periodontal ligament [42]. The first of this computer-controlled system, the Wand was introduced in1997. The core technology is an automatic delivery of local anesthetic solution at a fixed pressure:volume ratio regardless of variations in tissue resistance. The recent advancement is the introduction of **Single Tooth Anesthesia (STA) system** (2007). It has advantage of proper placement of needle via real-time visual and audible feedback, which provides information about the pressure of anesthetic solution and tissue when compared to Wand system.[58]

The use of STA system as a primary injection reported good success rates for restorative procedures. **Malamed S in 1982**[17] reported that the primary Intraligamentary injection appears to be a successful alternative to the conventional IANB techniques for mandibular anesthesia. However, till date no literature reports the primary use of STA system for endodontic procedures. Hence, in the present study the effectiveness of STA system as primary anesthetic technique was evaluated in cases with irreversible pulpitis requiring endodontic treatment.

The choice of **anesthetic drugs** depends on the volume of anesthetic solution, and its concentration that may alter the anesthetic efficacy. The most commonly used local anesthetics solution is lidocaine (1942) which is considered as a gold standard for comparing new local anesthetic drugs. The other important anesthetic solution is Articaine (1969), which is 4-methyl-3(2-[propylamino] propionamido)-2-thiophene carboxylic acid, methyl ester hydrochloride) is a amide local anesthetic containing thiophene ring and an additional ester ring [59]. **Robertson et al in 2007** [60.] **and Corbett et al in 2008**[61] reported that 4% articaine with 1:100000epinephrine was more efficient

than 2% lidocaine with 1:100000epinephrine in producing pulpal anesthesia in mandibular molars. **Poorni S etal in 2011**[28]concluded that buccal infiltration with 4% articaine to be effective in producing pulpal anesthesia in mandibular molars with irreversible pulpitis. **Malamed SF et al in 2000** reported that 4% articaine with epinephrine 1:100,000 to be safe, effective local anesthetic and the time of onset and duration of anesthesia are appropriate for performing clinical procedure[5]. Hence, in the current study articaine was used as anesthetic drug of choice for endodontic procedure.

In this study eighty patients were evaluated, out of which eighteen patients did not fulfill the inclusion criteria whereas two of them declined to participate in the study. Thus, sixty patients (N=60) diagnosed with irreversible pulpitis in need of endodontic treatment were selected for the study and informed consent was obtained from the patients prior to treatment procedure. The appropriate diagnosis was made using Radiographs, EPT, and Cold test.

The radiographic examination provides information about the presence and severity of caries, deep restorations in relation to the dental pulp as well as root fractures and periapical changes. **Talabani et al in 2016**[64] performed radiographic evaluation of tooth in need of endodontic treatment and reported irreversible pulpitis to be most difficult condition for carrying out endodontic procedure. Hence in the current study radiographic examination was used for diagnosis of irreversible pulpitis.

Brannstrom in 1966[66] postulated that cold testing causes contraction and rapid movement of dentinal fluid results in 'hydrodynamic forces' acting on the A (delta)δ nerve fibers within the pulp–dentine complex. The cold test assists in diagnosis of reversible and irreversible pulpitis. The application of cold stimulus may either produce

a lingering effect or the pain subsides immediately on removal of the stimulus from the tooth. If the patient feels a lingering pain, even after the removal of cold stimulus, a final diagnosis of irreversible pulpitis can be confirmed. Hence, in the current study cold testing was used to confirm the final diagnosis of irreversible pulpitis.

The objective of EPT is to stimulate A delta (δ) nerve in pulp dentin complex. A positive result is due to ionic shift in the dentinal fluid causing depolarization and subsequent generation of action potential from A delta (δ) nerve. Literature reports that for conducting studies on dental anesthesia electric stimuli should be a preferred option owing to its resemblance to physiologic circumstances, noninvasive nature and ease in application[65]. Hence, in the present study electric pulp testing technique was used for diagnosis of irreversible pulpitis

The pre anesthetic evaluation for identification of allergy to anesthetic solution was done by performing sensitivity test. It was performed by inserting the needle tip, bevel up, just underneath the surface of the skin and injecting 0.1 mL of the agent. A "bleb" was formed after injection was given and the injection site was kept under observation for 15-20 minutes for any visible change at injection site. No visible change indicating no allergy of anesthetic drug. The advantage of sensitivity test, its reproducibility, and the reaction is localized presenting less danger to patients[67].

Pain measurement is difficult to establish, because of its subjective characteristic. The traditional methods used for measuring pain are numeric and verbal self-rating scales. The HP-VAS score method used in the present study is a noninvasive, easy for the respondent to understand and it validates anesthetic efficiency. It integrates spacing of six categorical scale descriptive words onto 170-

mm horizontal line for measuring pain[68.]The HP-VAS score was taken prior to anesthetic procedure to evaluate pain before anesthesia and equalize the patient of same pain threshold.

A randomized double blinded (patient and observer) clinical trial was designed in which patients were recruited from the regular OPD visiting the Department of Conservative dentistry and Endodontics. Simple randomization of study subjects were done by the open Epi random program. Random allocation ensures no systematic differences between intervention groups in terms of known and unknown factors that may affect outcome. According to the block number generated, the patients were allocated into Group I(IANB) & Group II (STA system). Patients and the observer were blinded in the study. Double blinding ensures that the different views of subjects and clinicians cannot systematically bias the assessment of outcomes [62.]

For sample size estimation, a study by **Shah M et al in 2012** [63] was referred. They evaluated pain perception using VAS score between groups treated with Wand and Traditional system, the standardized difference between the mean VAS scores of two groups was 0.29 that is the estimated effect size. Considering the largest acceptable effect size of 0.8, a sample size of 52 (26 in each group) provided the desired difference with 80% power and 95% confidence interval. A sample size of 25 per group was proposed for the study. Considering the dropouts around 20% of 25 i.e. 5 added to each group making sample of 30 per group.

Group I received standard IANB injections. The direct technique also known as the Halstead approach was used for IANB[69]. The operator was standing in front of the patient and with help of thumb palpated the mucobuccal fold, then moved

posteriorly until contact was made with the external oblique ridge on the anterior border of ramus of mandible and coronoid notch was identified. The buccal sucking pad was moved bucally which gave better exposure to internal oblique ridge, pterygomandibular raphe and pterygotemporal depression. The needle was inserted parallel to occlusal plane of mandibular teeth from opposite at the level bisecting the finger, penetrating the tissue pterygotemporal depression and entering pterygomandibular space. Patient was asked to keep mouth wide open. The needle was penetrated into tissue until it gently contacts the bone on internal surface of ramus of mandible. The needle was withdrawn 1mm and the solution was deposited slowly.

The IANB technique provides effective anesthesia, by acting directly on the nerves that run through the pterygomandibular space. Furthermore, as the anesthetic solution administered near the nerve, makes it less susceptible to the local inflammatory changes. It is therefore an extremely effective method of mandibular molar anesthesia. Hence, in the current study IANB technique has been used for mandibular anesthesia.

Group II received Intraligamentary injection with Single Tooth Anesthesia (STA) System. The anesthetic administration was performed according to manufacturer's instruction. After turning on the STA drive unit; the handpiece with the pre-attached bonded 30 gauge ½ inch needle and the anesthetic drug was attached to the unit. The STA handpiece grasped in a pen-like position; and the needle was placed into the gingival sulcus of the tooth to be anesthetized. Simultaneously, the ControlFlo™ rate was activated by depressing the foot control. Finger rest was used to control and stabilize needle movements; gently and slowly, the needle was advanced within the sulcus. The STA System unit provided a continuous audible and visual

feedback to guide the needle tip to the periodontal ligament. In the STA mode, the DPS technology provided a real time pressure feedback via:visual Pressure Sensing Scale (Gauge) comprised of a series of orange, yellow, and green LED lights. The orange LED's indicate minimal pressure, the yellow LED indicates mild pressure and the green LED's indicate moderate pressures. When the periodontal ligament was identified, the operator hears the letters "PDL" spoken three times; followed by a series of extended tones "beep, beep" indicating correct needle positioning and drug administration was performed [70].

The onset of anesthesia for Group I was evaluated with subjective symptom of IANB like profound lip numbness followed by EPT reading. The subjective symptoms were absent in STA system i.e. Group II, hence the gums adjacent to tooth structure was probed every 10 minutes and the response was evaluated on HP-VAS score followed by EPT reading to confirm the anesthetic effectiveness[23]. After anesthetic administration, HP-VAS score was recorded to evaluated pain during anesthetic procedure for both anesthetic techniques.

Isolation was done using rubber dam and access cavity preparation was done. After the extirpation procedure, standard biomechanical protocol was followed[71]. After the endodontic treatment HP-VAS score was taken to evaluate pain during endodontic procedure for both anesthetic technique. If the patients complained of pain supplementary injection was given to achieve anesthesia, and these patients were excluded from the study.

After the completion of procedure patient were asked to rate the pain on HP-VAS score for evaluating the acceptability of both anesthetic techniques.

The duration of anesthesia for Group I was evaluated by wearing-off lip numbness in IANB. Whereas, for Group II the patients were asked to press the gums with fingernail every 10 minutes until normal feeling returned[19].

Säkkinen J et al in 2005 reviewed various post-operative complication associated with IANB [72]. **Froum SJ et al in 2000,** after 24 hours reported limited localized inflammation in the periodontal ligament when intraligamentary injection was given[73.]Hence, in the present study for both anesthetic techniques the patients follow up was done after 3hrs, 24hrs, and 1 week to rule out any complication and post anesthetic pain. If pain was reported patient were asked to rate their pain using HP VAS score.

The results were statistically analyzed with descriptive and inferential statistics using SPSS ver. 20.0 (IBM Corp). Descriptive statistics such as mean, median, mode, standard deviation and range were used to describe the continuous variables in the study viz. age of patient, time of onset of anesthesia by using electric pulp test procedure for both groups. The t-test was used to compare difference in mean time of onset of anesthesia between two groups. Paired test was performed for evaluating mean difference of effectiveness of anesthesia before and after electric pulp testing in both groups. Pearson's Chi-square test of independence was used to determine whether the distribution of patients in both groups was statistically significantly different or not. A P-value < 0.05 was considered statistically significant for all tests. The overall results are discussed under following section.

1. Demographic variation:

In current study, the range of mean age for both groups was 31-39 years and equal gender distribution was reported.

2. Effectiveness of anesthesia:

The mean EPT value recorded before administration of anesthesia for Group I was 6.47, and for Group II 6.63. This suggests that the pain threshold of both the group was same, suggesting equal distribution or normalization of the sample size. After administration of anesthesia, EPT were recorded for both the groups. The mean values calculated for Group I was 10, and for Group II 9.87 respectively. This suggests that both the techniques were effective. The current study is in accordance with **Reader &Nusstein in 2002** who used the EPT to monitor pulpal anesthesia and they reported that the lack of response of the EPT indicates pulpal anesthesia obtained clinically[74].

The time of onset of anesthesia for both groups was evaluated by subjective symptoms and EPT readings before and after anesthetic procedures. The mean time of onset of Group II was higher than Group I. The anatomical position of mandibular molars and bone density can alter the success rate of STA system[75].The findings of our study are in accordance with **Waikakul and Punwutikorn in 1991 and Haghighat A et al in 2015** whoreported similar the time of onset for IANB [69, 76.]

3. Evaluation of Pain perception and acceptance of anesthetic technique:

The pre anesthetic pain in irreversible pulpitis in our study was moderate and lingering in nature requiring endodontic treatment; the findings of our study were in accordance with **Pak and White in 2011**[77] who reported 80% of patients experiencing severe pain before endodontic treatment.

The pain perceptions, during anesthetic administration in both groups, were similar. In this study, the smaller gauge needles were used i.e. for IANB 27 gauge and for STA system 30 ½ gauge, which reported mild pain during anesthetic administration. According to **Wågø KJ in 2015** [78]there is a direct proportional relation between gauge of the needle and pain perception that may possibly be a reason for acceptability of both the technique in current study.

The pain perception may vary among patients as they express different emotional responses to similar levels of stimulus intensity. **Segura-Egea et al** reported a significant relationship between pulp status and pain level experienced during root canal treatment and more pain in teeth with irreversible pulpitis and acute apical periodontitis [79]. In our study, both groups reported mild pain during endodontic procedures. However, on HP-VAS score Group I reported less pain when compared to Group II.

In the present study, the acceptance of anesthetic technique was analyzed by patient's feedback; both groups reported no significant difference regarding acceptability of anesthetic techniques. This suggests that both techniques were acceptable to the patients.

The post anesthetic pain is an unpleasant sensory, perpetual, and emotional experience of the patients. The needle perforating the mucosa, rate of deposition of anesthetic solution, might be an attributing factor for post anesthetic pain at site of injection [75]. In present study, Group I reported mild pain after 3 hours in eight patients, while no pain was reported at 24 hours and 1 week time intervals. On the other hand, in Group II, not a single patient experienced post anesthetic pain at the site of injection.

In **Group I** the mean duration of anesthesia was161.83 min whereas, **Tortamano IP in 2013**[31] reported the mean duration of anesthesia for IANB to be106.6 min which is shorter when compared with the current study. **Group II** reported the mean duration of anesthesia 33.17 min that is in accordance with **Cowan et al in 1986**who reported duration of anesthesia for intraligamentary injection 30-45 mins[19]. The mean duration of anesthesia in STA group was significantly lower than IANB group that suggests that Group II reported shorter duration of anesthesia than Group I.

Dhanrajani PJ in 2002[80] reported that IANB is the second-most common cause of permanent altered sensation of trigeminal nerve and is associated with other post-operative complication. Hence, in our study the patients were on follow up for 3hr, 24hrs, and 1 week. However, none of the patients reported any **complication** for both groups**.**

Both groups reported no significant difference in anesthetic effectiveness, pain perception, and acceptability. Thus, the hypothesis, Intraligamentary injection using STA System will prove an effective anesthetic technique as IANB in patients with irreversible pulpitis was accepted. Hence, to conclude, STA system can be used as a primary anesthetic agent for mandibular molars in patients with irreversible pulpitis. However, further clinical trials are required for evaluating the effectiveness of Intraligamentary injection using STA System.

LIMITATIONS

1. Pain is subjective phenomena hence it is difficult to assess accuracy of pain.
2. The anatomical variation and absorption of local anaesthesia might influence the effectiveness of anaesthesia.
3. Study with larger sample size is needed to evaluate benefits of STA system and its clinical implementation.

SUMMARY AND CONCLUSION

The pain free endodontic treatment is primarily important for achieving a positive attitude and acceptability of the treatment among the patients. Many methods have been evolved for achieving this goal, amongst them effective local anesthetic techniques is of utmost importance. Inferior alveolar nerve block (IANB) is one of the most frequently used mandibular injection technique for achieving local anesthesia for endodontic treatment. However, considering the complex nature of oral and dental tissues, achieving effective local anesthesia may be challenging in certain circumstances.

The intraligamentary injection techniques can be helpful in carrying out the pain-free dental treatment. It produces an immediate desensitization of the nerve endings surrounding the tooth and of the pulpal nerves. Single tooth anesthesia system introduced in 2007, incorporates dynamic pressure sensing (DPS) technology which assist in proper needle placement and controlled flow of anesthetic solution.

The **aim** of this study was to compare the effectiveness of intraligamentary injection using STA System and Traditional inferior alveolar nerve block injection technique in irreversible pulpitis patients.

Sample Distribution

In this, randomized double blinded (patient and observer)clinical trial patients were recruited from the regular OPD visiting the Department of Conservative dentistry and Endodontics. Sixty patients (N=60) diagnosed with irreversible pulpitis in need of endodontic treatment were selected for the study. Simple randomization of study subjects was done by the open Epi random program. According to the block number generated, the patients were allocated into Group I (IANB) & Group II (STA system).

Treatment groups

Group I *(n=30):* Patients receiving anesthesia using Inferior Alveolar Nerve Block (IANB)

Group II *(n=30):* Patients receiving Intraligamentary injection anesthesia using Single Tooth Anesthesia (STA) system.

A single clinician recorded a brief case history of all the participants. Preoperative Intraoral periapical radiographs , cold test and EPT were obtained to diagnose irreversible pulpitis. **Group I** traditional inferior alveolar nerve block was

given and for **Group II** Intraligamentary injection anesthesia, using Single Tooth Anesthesia (STA) system was administered. For evaluation onset of anesthesia EPT reading were considered. The subjective symptom was evaluated for onset and duration of anesthesia. For pain perception, HP- VAS score was taken. Isolation was done using rubber dam and access cavity preparation was done. After the extirpation procedure, standard biomechanical protocol was followed. Patients were instructed to report and rate their post anesthetic pain after 3hrs, 24 hrs. & 1 week interval. After appropriate data collection and statistical analysis the following results were obtained:

The mean time of onset of Group II was higher than Group I. The effectiveness of anesthesia for both groups were similar. In our study, pre anesthetic pain in irreversible pulpitis was moderate and lingering in nature requiring endodontic treatment**.** The pain perceptions, during anesthetic administration in both groups, were similar in both the groups. They reported no significant difference regarding acceptability of anesthetic technique. Group I reported mild pain after 3 hours in eight patients, while no pain was reported at 24 hours and 1 week time intervals. On the other hand, in Group II, not a single patient experienced post anesthetic pain at the site of injection. Though the mean duration of anesthesia in STA group (33 minutes) was significantly lower than IANB group (160 minutes); STA system proved efficient for performing endodontic treatment.

Thus, the hypothesis of this study that Intraligamentary injection using STA System will prove to be an effective anesthetic technique as IANB in patients with irreversible pulpitis was accepted.

Within the limitation of the study, both the Groups reported similar effectiveness of anesthesia, pain perception by participants and acceptability of anesthesia technique. Hence, to conclude; "Intraligamentary injection using STA system may be used as a primary anesthetic technique for patients with irreversible pulpitis." However, further clinical trials are required for the same.

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TABLES

Table 1: Age distribution of patients amongst both the groups

AGE (years)	**GROUP I** IANB (%)	**GROUP II** STA System (%)
≤ 25	2 (6.67)	10 (33.33)
26-35	9 (30)	11 (36.67)
36-45	9 (30)	6 (20)
> 45	10 (33.33)	3 (10)
Total	30 (100)	30 (100)
Mean ± SD*	39.10 ± 9.76	31.73 ± 8.87

****Mean ±standard deviation***

Table 2: Gender distribution of patients amongst both the groups

GENDER	**GROUP I** IANB (%)	**GROUP II** STA System (%)
Female	17 (56.67)	14 (46.67)
Male	13 (43.33)	16 (53.33)
Total	30 (100)	30 (100)

Table 3: The pain perception in both groups before anesthesia

SEVERITY OF PAIN (HP-VAS SCALE)	**GROUP I** IANB	**GROUP II** STA System
Mild	6 (20.00)	16 (53.33)
Moderate	23 (76.67)	14 (46.67)
Intense	1 (3.33)	0
Total	30	30

P-value: 0.0209 (Significant) as obtained using Pearson's Chi-square test

Table 4: Comparison of mean reading by electric pulp testing before anesthesia between both groups

GROUPS	BEFORE ANESTHESIA	
	Mean	Standard Deviation
GROUP I: IANB	6.47	0.86
GROUP II: STA System	6.63	0.61
P-value*	0.3920 (NS)	

Obtained using t-test for independent samples; †Obtained using Paired t-test;
NS: Non-significant; S: Significant; HS: Highly Significant

Table 5: The pain perception in both groups during anesthetic administration

SEVERITY OF PAIN (HP-VAS SCALE)	GROUP I IANB	GROUP II STA System
No Pain	11 (36.67)	21 (70.00)
Faint	6 (20.00)	3 (10.00)
Mild	11 (36.67)	6 (20.00)
Moderate	2 (6.67)	0
Total	30	30

P-value: 0.0552 (Not Significant) as obtained using Pearson's Chi-square test

Table 6: Comparison of mean reading by electric pulp testing after anesthesia between both groups

GROUPS	AFTER ANESTHESIA	
	Mean	Standard Deviation
GROUP I: IANB	10.00	0.00
GROUP II: STA System	9.87	0.35
P-value*	0.0434 (S)	

Obtained using t-test for independent samples; †Obtained using Paired t-test;
NS: Non-significant; S: Significant; HS: Highly Significant

Table 7: Comparison of mean time of onset of anesthesia (in min) amongst both groups.

GROUPS	Mean	Standard Deviation	Median	Mode	Minimum	Maximum
GROUP I: IANB	1.40	0.86	1	1	1	5
GROUP II :STA System	2.93	1.80	2	2	1	10

P-value: 0.0001 (Significant) as obtained using t-test for independent samples

Table 8: The pain perception during endodontic procedure (RCT) in both groups

SEVERITY OF PAIN (HP-VAS SCALE)	**GROUP I** IANB	**GROUP II** STA System
No Pain	25 (83.33)	4 (13.33)
Faint	1 (3.33)	0
Mild	4 (13.33)	25 (83.33)
Moderate	0	1
Total	30	30

P-value: < 0.0001 (Highly Significant) as obtained using Fisher's exact test

Table 9: The response to question: *Was anesthesia procedure comfortable*?

ANESTHESIA PROCEDURE WAS COMFORTABLE	**GROUP I** IANB	**GROUP II** STA System
Agree	21 (70)	26 (86.67)
Partially Agree	9 (30)	4 (13.33)

P-value: 0.2100(Not Significant) as obtained using Pearson's Chi-square test

Table 10: Comparison of mean duration of anesthesia (in min) between both groups.

Parameter	**Groups [Mean ± SD]**	
	GROUP I IANB	**GROUP II** STA System
Duration of Anesthesia (in minutes)	161.83 ± 15.28	33.17 ± 5.94

Table 11: Pain perception at site of injection after completion of endodontic procedure at different time points in both groups

PAIN AT SITE	**LEVELS**	**GROUP I** IANB	**GROUP II** STA System
3 hours	*Yes*	8 (26.67)	0
	No	22 (73.33)	30 (100)
24 hours	*No*	30 (100)	30 (100)
1 week	*No*	30 (100)	30 (100)

GRAPHS:

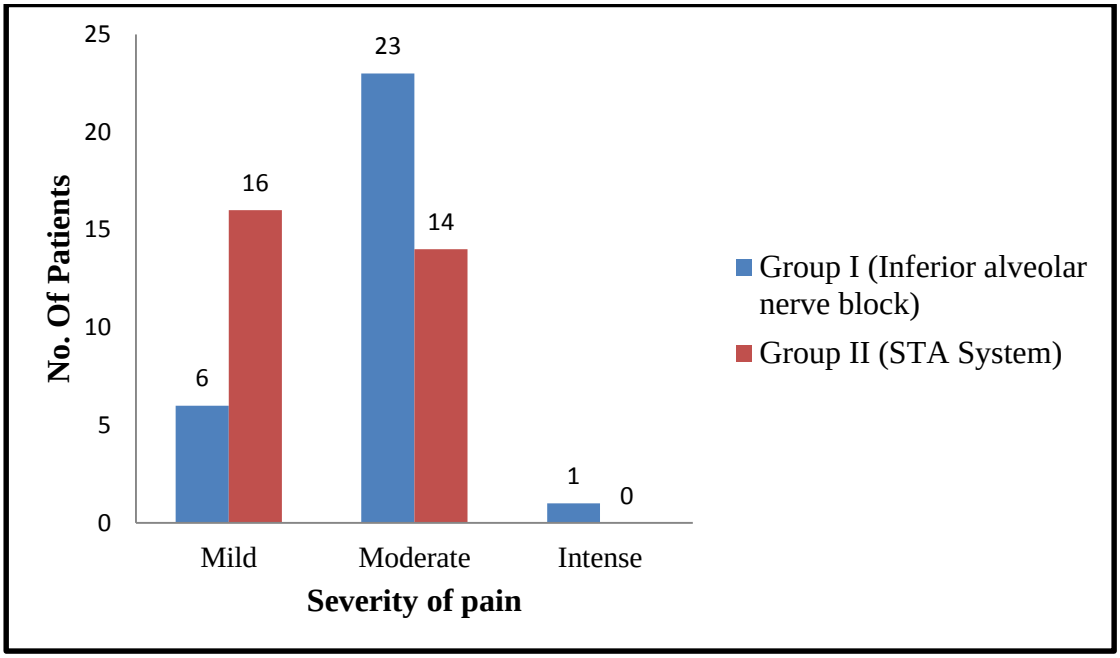


Figure 1: Bar chart showing the pain perception in both groups before anesthesia.

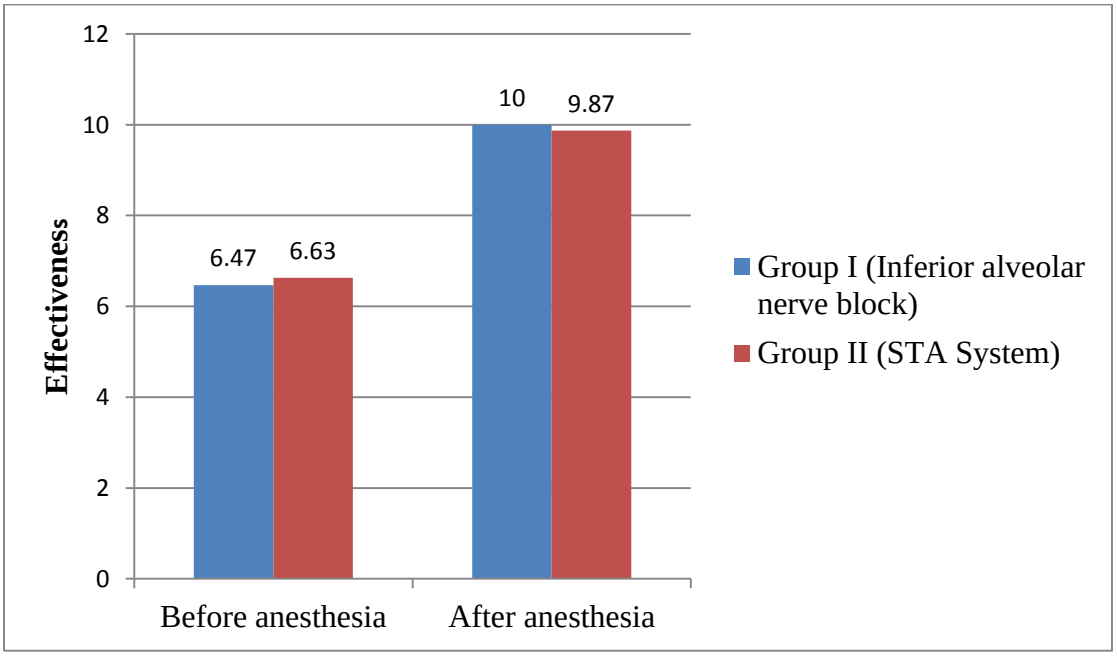


Figure 2: Bar chart showing the mean reading before and after electric pulp testing in both groups.

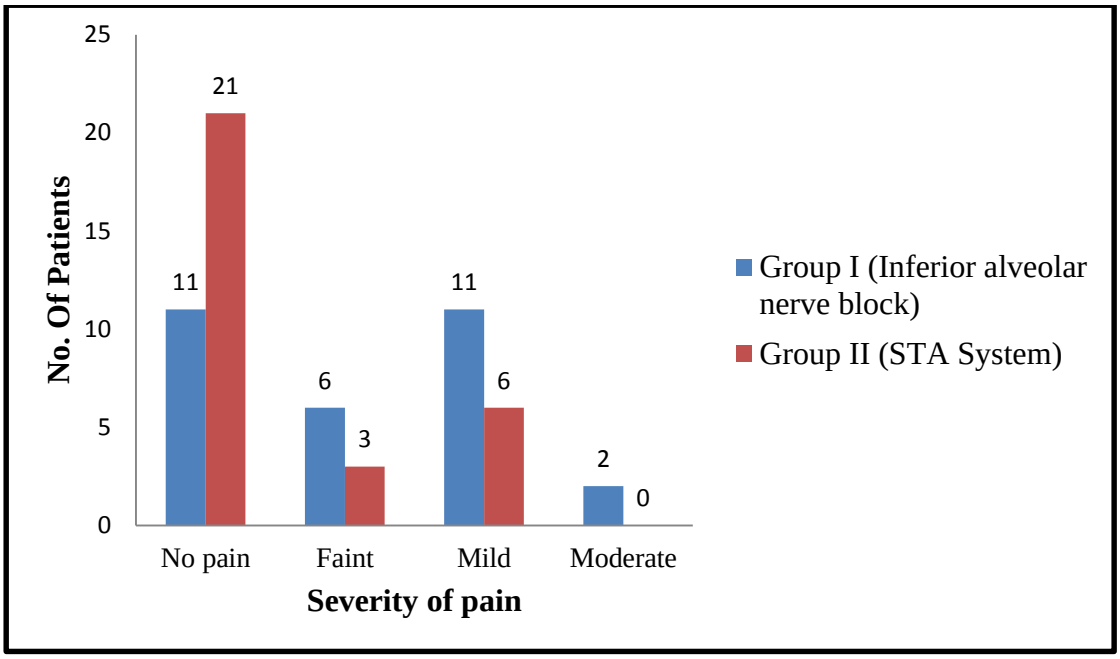


Figure 3: Bar chart showing the pain perception in both groups during anesthetic administration.

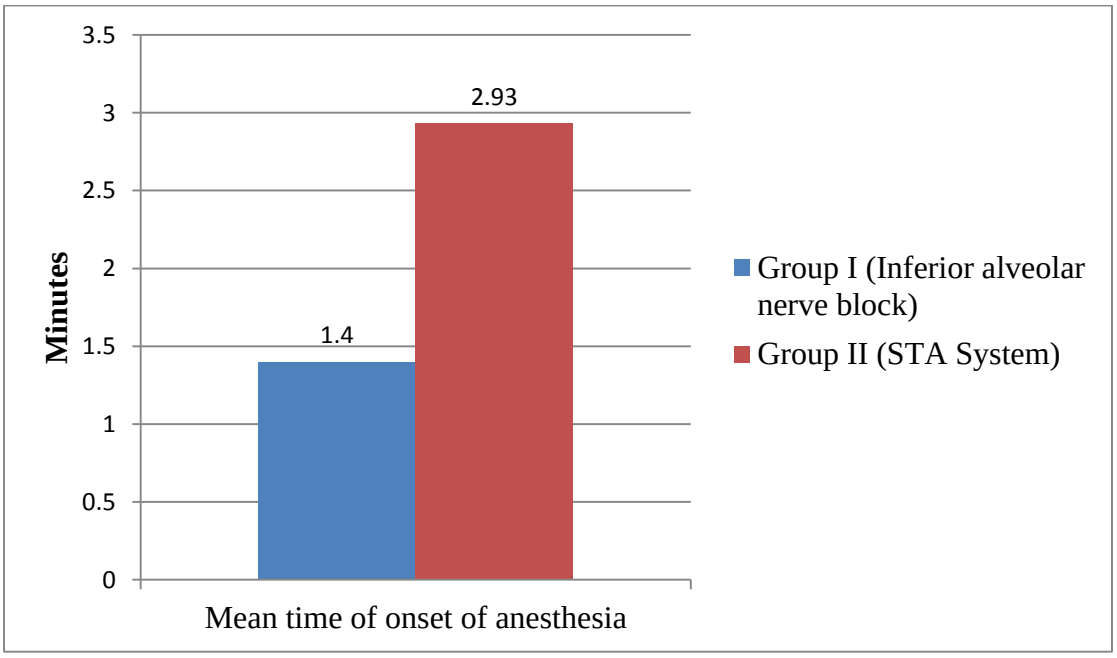


Figure 4: Bar chart showing the mean time of anesthesia (in min) in both groups.

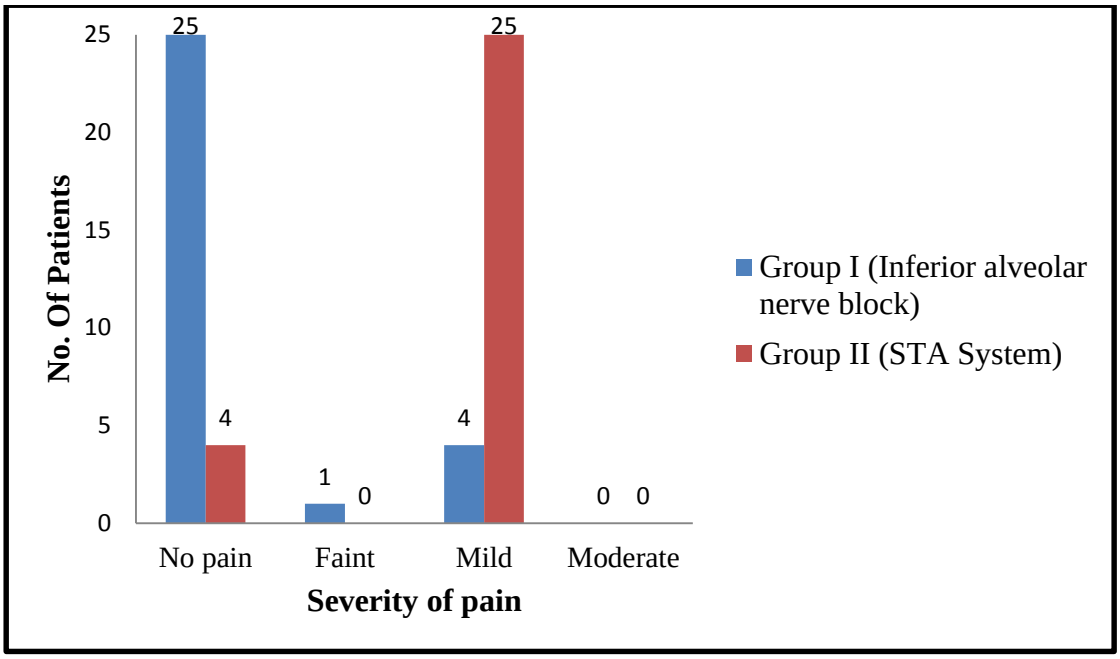


Figure 5: Bar chart showing the pain perception in both groups during endodontic procedure.

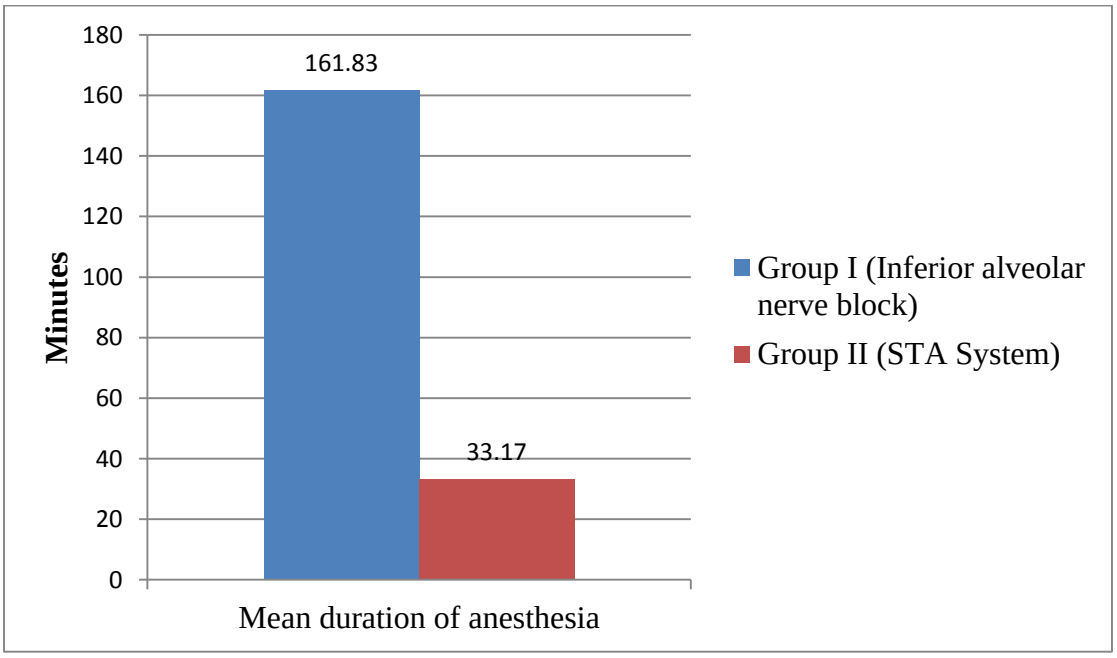


Figure 6: Bar chart showing the mean duration of anesthesia (in min) in both groups.

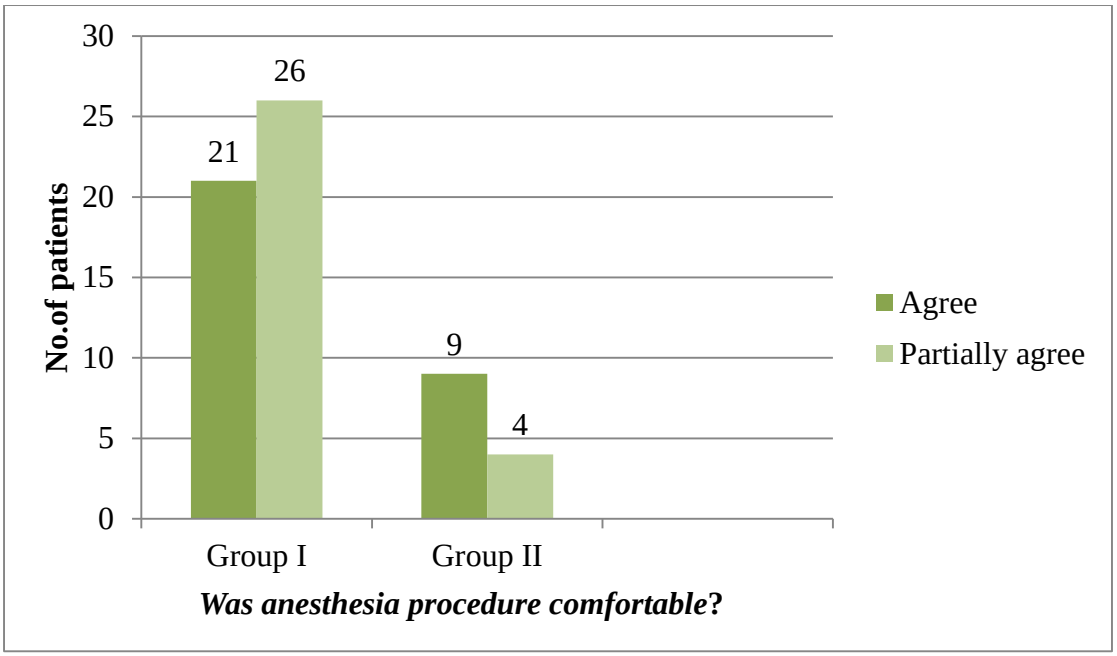


Figure 7: Bar chart showing the response to question: *Was anesthesia procedure comfortable*?

(Confidential)
INFORMED CONSENT FORM

COMPARATIVE EVALUATION OF INTRALIGAMENTARY INJECTION AND TRADITIONAL INFERIOR ALVEOLAR NERVE BLOCK IN PATIENTS WITH IRREVERSIBLE PULPITIS.

Patients ID:

I, Mr./Mrs/Miss_____ Resident of: _____

_____

_____aged _____years, exercising my free will/ choice , without anypressure/lure of incentive in any form, hereby give my consent for the research project.I acknowledge that doctor has informed me about this research project suitably and sufficiently to my satisfaction. I agree to let my X –rays, photographs, impression and other investigations to be taken as required. I agree to take part in this project and will not mix any other projects during the period of this trials. I shall report to the dental hospital or other place where called on given appointment dates and time. I shall inform the doctor on any adverse effect or unusual symptoms noticed by me. I shall co-operate with the doctors and paramedical staff, in all respects. I permit to publishing the results of my participation in this study. I shall not be given any reimbursement or compensation. I have been informed of my right to opt out of this research project at any time without giving any reason for doing so.

I hereby record my consent without giving any reason for doing so.

1.....	.....	.....	.....
Patient's name	Signature	Date	Time
2.....	.....	.....	.....
Witness's name	Signature	Date	Time
3.....	.....	.....	.....
Investigator's name	Signature	Date	Time

PATIENTS EVALUATION FORM

Date:_____

Name:.....Registration No.....

Age/sex: .....

Address & Contact no.....

Medical history: .....

Past dental history.....

Past dental anesthesia history: .....

Diagnosis : .....

Tooth no:.....

Group: ..... I / II .....

1) **EFFECTIVENESS:**

Time of onset of anesthesia		
Electric pulp testing	Before administration of anesthesia	After administration of anesthesia

2) **PAIN PERCEPTION**

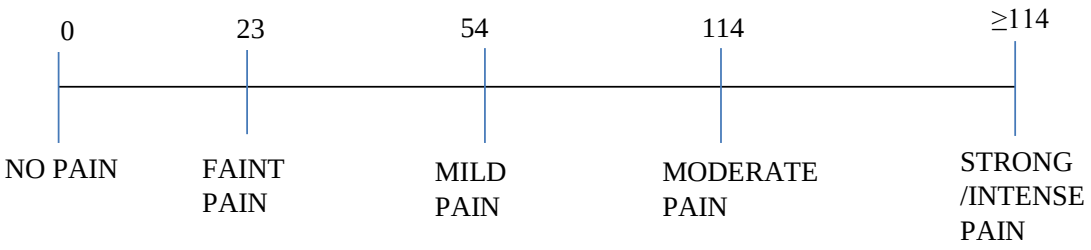
SYMPTOMS	**HP-VAS SCORE**		
Pain before anesthesia			
Pain at the site of anesthesia during administration of anesthesia			
Pain during pulpectomy			
Pain at site of injection after completion of root canal procedure.	3hrs	24hrs	1 week

3) **ACCEPTIBILITY:**

SYMPTOMS	Agree	Partially agree	Partially disagree	Disagree
Was the anesthetic procedure comfortable				
Was the recovery from anesthesia comfortable	3hrs	24 hrs	1 week	

Signature of patient Signature of operator

HEFT PARKER VISUAL ANALOGUE SCLAE



ACCEPTIBILITY

AGREE	PARTIALLY AGREE	PARTIALLY DISAGREE	DISAGREE
1	2	3	4

Group I: INFERIOR ALVEOLAR NERVE BLOCK

SR NO.	AGE (YRS)	GENDER	EFFECTIVENESS		
			Time of onset of anesthesia (min)	*Electric pulp testing*	
				Before	*After*
1.	34	F	2	7	10
2.	50	F	1	7	10
3.	27	F	2	7	10
4.	45	F	1	8	10
5.	31	F	1	7	10
6.	42	M	1	7	10
7.	50	M	1	7	10
8.	49	F	5	6	10
9.	41	M	1	5	10
10.	32	M	1	6	10
11.	50	M	3	6	10
12.	45	F	2	7	10
13.	29	M	2	6	10
14.	50	F	1	5	10
15.	26	M	1	5	10
16.	26	M	1	7	10
17.	24	F	2	6	10
18.	48	M	2	6	10
19.	18	M	1	7	10
20.	38	F	1	5	10
21.	43	F	1	5	10
22.	50	F	1	6	10
23.	50	F	1	7	10
24.	28	F	1	7	10
25.	36	F	1	7	10
26.	48	M	1	7	10
27.	40	M	1	7	10
28.	50	F	1	7	10
29.	33	M	1	8	10
30.	40	F	1	6	10

SR. NO.	PAIN PERCEPTION (HP-VAS SCORE)					
	Pain before anesthesia	*Pain at site of injection*	*Pain during rct*	*Pain at site of injection after completion of root canal treatment*		
				3HRS	24HRS	1 WEEK
1.	85	23	54	0	1	1
2.	85	54	23	1	1	1
3.	85	23	00	1	1	1
4.	85	54	00	0	1	1
5.	85	23	00	1	1	1
6.	85	54	00	1	1	1
7.	85	54	00	1	1	1
8.	54	54	00	0	1	1
9.	54	00	00	1	1	1
10.	85	00	00	1	1	1
11.	85	54	00	1	1	1
12.	85	23	00	0	1	1
13.	85	54	00	0	1	1
14.	85	54	00	1	1	1
15.	85	85	54	0	1	1
16.	54	54	00	1	1	1
17.	144	85	54	0	1	1
18.	85	00	00	1	1	1
19.	85	23	00	0	1	1
20.	85	23	00	1	1	1
21.	54	00	00	1	1	1
22.	54	00	00	1	1	1
23.	85	54	00	1	1	1
24.	85	00	00	1	1	1
25.	85	54	00	1	1	1
26.	85	00	00	1	1	1
27.	85	00	54	1	1	1
28.	85	00	00	1	1	1
29.	85	00	00	1	1	1
30.	54	00	00	1	1	1

SR NO.	ACCEPTIBILITY			
	Was anesthesia procedure comfortable	*Was recover from anesthesia comfortable*		
		3HRS	24HRS	1 WEEK
1.	2	1	1	1
2.	2	1	1	1
3.	2	1	1	1
4.	2	1	1	1
5.	2	1	1	1
6.	2	1	1	1
7.	2	1	1	1
8.	1	3	1	1
9.	1	1	1	1
10.	1	1	1	1
11.	1	1	1	1
12.	1	1	1	1
13.	1	1	1	1
14.	1	1	1	1
15.	2	1	1	1
16.	1	1	1	1
17.	2	1	1	1
18.	1	1	1	1
19.	1	1	1	1
20.	1	1	1	1
21.	1	1	1	1
22.	1	1	1	1
23.	1	1	1	1
24.	1	1	1	1
25.	1	1	1	1
26.	1	1	1	1
27.	1	1	1	1
28.	1	1	1	1
29.	1	1	1	1
30	1	1	1	1

Group I: ILA INJECTION USING STA SYSTEM

SR NO.	AGE (YRS)	GENDER	EFFECTIVENESS		
			Time of onset of anesthesia (min)	*Electric pulp testing*	
				Before	*After*
	49	M	3	7	10
	42	F	2	6	10
	45	F	2	6	9
	25	F	2	7	9
	23	F	3	7	10
	28	F	2	8	10
	32	M	2	8	10
	31	F	3	7	10
	26	M	10	7	10
	32	M	7	6	10
	42	M	4	6	9
	32	F	5	6	10
	24	F	5	7	10
	21	M	2	6	10
	25	F	1	6	10
	27	M	2	6	9
	28	F	2	7	10
	20	M	3	7	10
	48	M	3	6	10
	24	M	2	6	10
	24	M	3	7	10
	50	M	2	6	10
	38	F	3	7	10
	23	F	2	7	10
	22	F	3	7	10
	28	M	2	7	10
	32	F	2	7	10
	38	M	2	7	10
	35	M	2	6	10
	49	M	3	7	10

SR NO	PAIN PERCEPTION (HP-VAS SCORE)					
	Pain before anesthesia	*Pain at site of injection*	*Pain during rct*	*Pain at site of injection after completion of root canal treatment.*		
				3HRS	24HRS	1 WEEK
1.	54	54	54	1	1	1
2.	54	00	54	1	1	1
3.	54	00	54	1	1	1
4.	54	00	54	1	1	1
5.	54	00	00	1	1	1
6.	54	00	54	1	1	1
7.	54	00	00	1	1	1
8.	85	00	54	1	1	1
9.	85	23	00	1	1	1
10.	54	00	54	1	1	1
11.	85	54	54	1	1	1
12.	54	23	54	1	1	1
13.	85	54	85	1	1	1
14.	54	00	54	1	1	1
15.	54	54	54	1	1	1
16.	85	54	54	1	1	1
17.	85	23	54	1	1	1
18.	54	00	00	1	1	1
19.	85	54	54	1	1	1
20.	54	00	54	1	1	1
21.	85	00	54	1	1	1
22.	54	00	54	1	1	1
23.	85	00	54	1	1	1
24.	85	00	54	1	1	1
25.	85	00	54	1	1	1
26.	85	00	54	1	1	1
27.	85	00	54	1	1	1
28.	85	00	54	1	1	1
29.	54	00	54	1	1	1
30	54	54	54	1	1	1

SR NO.	ACCEPTIBILITY			
	Was anesthesia procedure comfortable	*Was recover from anesthesia comfortable*		
		3HRS	24HRS	1 WEEK
1.	2	1	1	1
2.	1	1	1	1
3.	1	1	1	1
4.	1	1	1	1
5.	1	1	1	1
6.	1	1	1	1
7.	1	1	1	1
8.	1	1	1	1
9.	2	1	1	1
10.	1	1	1	1
11.	2	1	1	1
12.	1	1	1	1
13.	2	1	1	1
14.	1	1	1	1
15.	1	1	1	1
16.	1	1	1	1
17.	1	1	1	1
18.	1	1	1	1
19.	1	1	1	1
20.	1	1	1	1
21.	1	1	1	1
22.	1	1	1	1
23.	1	1	1	1
24.	1	1	1	1
25.	1	1	1	1
26.	1	1	1	1
27.	1	1	1	1
28.	1	1	1	1
29.	1	1	1	1
30	2	1	1	1

DURATION OF ANESTHETIC TECHNIQUE:		
Sr. no.	***Group I (in mins)***	***Group II (in mins)***
1.	180	30
2.	180	35
3.	150	35
4.	140	30
5.	140	25
6.	180	30
7.	170	40
8.	160	35
9.	160	40
10.	150	45
11.	170	30
12.	160	25
13.	130	30
14.	175	30
15.	180	35
16.	170	40
17.	185	45
18.	180	40
19.	170	30
20.	160	35
21.	150	25
22.	140	25
23.	150	25
24.	180	30
25.	170	35
26.	155	35
27.	160	35
28.	170	35
29.	150	40
30.	140	25