EVALUATION OF EFFECTIVENESS OF VIBRAJECT INJECTION TECHNIQUE IN PATIENTS UNDERGOING ORTHODONTIC EXTRACTION OF BILATERAL MAXILLARY PREMOLAR - A PROSPECTIVE SPLIT MOUTH STUDY.

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LIST OF ABBREVIATIONS

Abbreviations	Full form
LA	Local Anaesthesia
CCLAD	Computer controlled local anaesthetics delivery
VAS	Visual Analogue Scale
Na+	Sodium
OMFS	Oral and maxillofacial surgery
n	No of injection sites
p	Probability value
Std.	Standard

INTRODUCTION

The history of discovery of anaesthesia dates back from 1750 to 1850 in the Western European countries which admitted the change in culture within the society.[1] Prior to this phase, pain was believed to be related with the sin of an individual. Thus no efforts were ever made by the society to accept pain as a suffering of disease or a condition which can be minimized by medical innovations. As the society started progressing in industrial, democracy and humanity area ,scientist went far beyond to discover various aspects of medical era which also led to discovery of anaesthesia by the two dentists named Horace Wells in 1815 to 1848[2] and William Thomas Green Morton in 1819 to 1868.[3] Before the discovery of anaesthesia used in medical practice, the coco leaf and its properties were revealed by tribal people residing in Negro river region, one of it being numbness[4]which was later officially documented by a European researcher.[5]In the 16th century, it was made known through a report by

Jesuit Bernabe Cobo that coco leaves when chewed can help lighten tooth pain.[6]Soon after its discovery, it was smacked by the reports of abuse due to uncontrolled use of cocaine as it was believed to alter central nervous system giving a feeling of euphoria.[7] In the year 1865 the active ingredient from cocaine leaf was discovered and molecular formula of $C_{17}H_{21}NO_4$ was determined[8] which later supported for synthesizing artificial cocaine of alkaloid form in 1923. [9-14]

Local anaesthesia is defined as "a local state of loss of sensation without loss of consciousness in a circumscribed area of the body due to a depression of excitation in nerve endings or an inhibition of the conduction process in peripheral nerves".[15]In ideal cases, after any stimulus, there is a shift in resting membrane potential of nerve because of increased sodium influx through the membrane. This increased influx of sodium ions which bind to the sodium channels cause depolarization and ultimately pain.[11]The basic principle by which the local anaesthesia causes loss of pain sensation at the site is explained by two step mechanisms. The first step elucidates that as soon as the anaesthetic solution is injected in unionised form, it passes through the membrane post which it is converted into ionised form and binds to sodium channels i.e., Na^+ on the nerve membrane and averts depolarization gaining control over pain. The second step includes the expansion of nerve membrane for the passage of local anaesthetic drugs to cause Na+ channel deactivation.[13]

Howmuch ever perfect the mechanism and the drug is in delivering its action it cannot be overlooked with the fact that the procedure of administration of local anaesthesia itself is agonizing and needs a thorough research to overcome this biggest disadvantage. Needle prick fear is considered to be the most common anxiety that

aggravates the pain and fear during dental procedures.[16]The feeling of needle being penetrated into the mucosa has a negative psychological impact on many patients. A study reports of about 13-14% of patients experiencing needle phobia which confines them from undergoing any kind of dental treatment thereby deteriorating their dental health.[17]Various investigations were carried out to find the actual cause of phobia and it was found that patients fear the thought of injection because of their previous painful experience with any of the medical events that included needle penetration.[18]while few cases were reported to have phobia without any previous exposure to the needle but had their relatives visiting medical professionals for the treatments[19]suggesting the pain being a word of mouth for those who haven't even experienced it. A multicentre study by Appukuttan DP et al[20] stated that patient with prior history of dental visits and those who have undergone local anaesthesia injection were 3.34 times more likely to avoid the dentists in future. Thus this fear became a hurdle for those with past experience and also for those visiting the dentist for the first time leading to avoiding the dental visits.

Pain during injection is associated with various variables like site of injection, rate of depositing anaesthetic solution into the tissues,[21] health of the patient,[22] the gauge of the needle,[23] temperature of the anaesthetic solution,[24]dispensability of the tissues[15] and the experience of the dentist. When it comes to the blocks administered for anaesthetizing the oral tissues, the maxillary blocks and infiltrations especially palatal report to be more painful over mandibular blocks and infiltrations. Infra orbital nerve block, posterior superior nerve blocks is administered on labial or buccal aspect while incisive nerve block and greater palatine nerve blocks are administered from palatal aspect. From the above cited blocks the ones which are injected in palatal

mucosa are more painful over the ones in buccal mucosa.[25]The tissues of palatal mucosa are tightly attached to underlying periosteum. There is very limited space between the palatal tissue and palatal bone and thus when anaesthetic solution is injected in this region it creates excessive pressure as these is no space for the solution to spread easily because of the resilient tissues thus the inbuilt pressure causes discomfort and pain to the patients regardless of application of topical anaesthetic gels and sprays.[26] When the same is compared with buccal nerve blocks or infiltrations, the mucosa expands with the amount of solution deposited thus eliminating the pressure and causing less discomfort and pain to the patient.[26]

To overcome this issue researchers have come up with various techniques of administrating local anaesthesia and advancements in devices which can be attached to the syringe in order to limit injection associated pain. Computer controlled local anaesthetic delivery (CCLAD) system is one of the techniques which is determined on the flow rate of LA from the syringe.[27] Since rapid flow rate is associated with pain, the rate is controlled by computer aided software delivering a fixed slow deposition of solution into the tissues to limit discomfort. Few of the systems jotted in literature include Comfort control syringe,[28] Wand Compudent system.[29]Jet injection is another concept wherein a solution is mechanically pushed through a miniature opening with pressure such that it creates a small column of solution which penetrates into the tissues at the injection site.[30] The advantage is, since the column of solution formed is extremely small it causes least damage to the tissues and consequently minimal or no pain to the patient. Jet injectors include some like, MED-JET H III[31] and Syrijet.[29] Vibrotactile devices are the newest among these which work on gate control theory of pain.[27] Since the theory states that the non-noxious stimuli can block the gates for

noxious stimuli and thus control pain, these devices infuse vibrations either machine initiated or mechanically through touch at the site of injection and prevents the pain stimuli reaching the cerebral cortex for creating discomfort.[32]Vibraject, Accupal and Dental Vibe are few of the Vibrotactile devices enlisted in the literature.[27]

VIBRAJECT

Taking into consideration the disadvantages like time consumption, easy of portability of all these devices, tissue blanching post-use.[28]Vibraject was developed with an anticipation to overcome the shortcomings of other devices. Vibraject was first introduced in the year 1995 in United States of America.[33] It is a small device which is attached to the syringe. It consists of a clip bracket which it attached near the syringe barrel and provides attachment arms for stable grasp to the clinicians. The clip bracket helps to prevent cross contamination between patients since it can be autoclaved.[33] This device works on Gate control theory, wherein the perception of vibrating stimulus is amplified preventing the blockage of pain perception through the dorsal horn of spinal cord. In addition to this, the motor of the device also produces a 'hum' sound during injecting the solution which gives calm and soothing effect to the patients.[34]Looking into the advantages of this device from patient's aspect, it has a physiological effect as it provides pain relief via Gate control theory and also acts psychologically wherein the patients get inclined towards and tend to believe in the modern technology. The advantage to the clinicians is;[35] though the device produces vibration, they are of high frequency and low altitude which does not interfere with the dexterity of the clinician while injecting anaesthesia and thus the clinician can still focus on the pin point site of the injection. Secondly, apart from the needle

penetration, ballooning of mucosa while injecting local anaesthesia is another reason for pain. The vibrations of this device not just alleviates pain while insertion but also curtails balloon formation due to micro vibration and enhances a smooth spread of the solution within the tissue.

Chaudhry K et al[36]reported that Vibraject when compared with other injection techniques provides lesser pain and discomfort to the patient while on the other side. Saijo M et al[37] found no significant difference in pain reduction by comparing Vibraject with electrical injection device. In an attempt to carry out evidence based practice in dentistry the dentist needs to be up-to-date with the new knowledge, best technique and the latest devices available. The literature is sparse with regard to this newer device; moreover the available literature has not given a concrete decision regarding the use of Vibraject in reducing pain. Thus the split mouth study was undertaken with an aim to evaluate the effectiveness of Vibraject injection technique in patients undergoing extraction of bilateral premolar for orthodontic treatment.

AIMS AND OBJECTIVES

Aim of the Study

To evaluate the pain perception by Vibraject injection technique while giving Infraorbital and Greater palatine nerve block by VAS and Wong-Baker scale.

Objectives of the study

1. To evaluate the pain perception by conventional injection technique while giving Infraorbital and Greater palatine nerve block by VAS and Wong-Baker scale.

2. To compare pain perception between Vibraject injection technique and conventional injection technique.

REVIEW OF LITERATURE

1. History of local anaesthesia

The development of anaesthesia in general and local anaesthetics, in particular, required a cultural change. The concept of pain (especially obstetric pain) was linked to the concept of original sin, and the ability to endure pain was regarded as a sign of character and in men was even associated with virility. The change that took place in Western Europe between 1750 and 1850, encompassing the industrialization, progressive humanization and democratization of society, created an atmosphere favourable to the discovery of anaesthetics. Nothing comparable occurred in Asia, Russia or the Islamic countries, where feudalism persisted in a variety of forms. This general process altered the cultural, political and religious climate, affecting a significant number of individuals.[1]

Dentists, not doctors, were responsible for the discovery of anaesthesia, given their close day-to-day contact with pain and hence their motivation to seek the means to alleviate it. Doctors focused more on infections than pain because people were dying of pneumonia, diphtheria, gangrene, tuberculosis, tetanus, puerperal fever, and so on. It was two dentists, then, who first introduced anaesthesia: Horace Wells (1815–1848), with nitrous oxide in 1844 and William Thomas Green Morton (1819–1868), with ether in 1846.[3,38,39]

Ruetsch YA *et al* in their published article reported about the journey of anaesthesia from cocaine to Ropivacaine. In 1850, around three centuries after the triumph of Peru by Pizzaro, the Austrian von Scherzer brought an adequate quantum of coca leaves to Europe to allow the separation of cocaine. As proposed by his companion Sigmund Freud, depictions of the properties of the coca provoked the Austrian Koller to perform in 1884 the primary clinical activity under local anaesthesia by organization of cocaine on the eye. The utilization of cocaine for local and peripheral anaesthesia quickly spread all through Europe and America. The lethal impacts of cocaine were before long distinguished bringing about numerous passing among the two patients and dependent therapeutic staff. Local anaesthesia was in a significant emergency until the advancement of present day natural science which prompted the combination of unadulterated cocaine in 1891. New amino ester local anaesthetics were combined somewhere in the range of (1891-1930), for example, Tropocaine, Eucaine, Holocaine, Orthoform, Benzocaine and Tetracaine. Furthermore, amino amide neighbourhood soporifics were set up somewhere in the range of (1898-1972) including Nirvaquine, procaine, Chloroprocaine, Cinchocaine, Lidocaine, Mepivacaine, Prilocaine, Efocaine, Bupivacaine, Etidocaine and Articaine.

These medications were apparently less dangerous than cocaine, however they had contrasting measures of sensory nervous system (CNS) and cardiovascular (CV) health. Bupivacaine proved to be of unique intrigue as a result of its long length of activity and history of clinical application.[40]

In 1901, Braun demonstrated the "chemical tourniquet" property of Epinephrine. **In 1904-1905,** procaine was synthesized by German chemist **Einhorn** and **Uhfelder** in Germany. When adrenaline was added, this agent was found to be effective and safe as a local anaesthetic agent for most patients. Procaine was widely used by physicians and dentists till the 1950's. **In 1943, Swedish chemist, Nils Lofgren** synthesized Lignocaine, an amine anaesthetic. It revolutionized the use of local anaesthesia in dentistry as it was less allergic and more potent than procaine. By the 1950's it became widely accepted.[15]

Combined in 1957, the presentation of Bupivacaine available in 1965 paralleled the dynamic and aggregate reports of CNS and CVS effects, prompting the limitation of its utilization and the distinguishing proof of a unique treatment safe CV lethality. Various exploratory investigations were led to distinguish the fine cell system of this effect which refined comprehension of the activity of local analgesics. The distinguishing proof of optically dynamic isomers of the Mepivacaine family prompted the choice of Ropivacaine, an unadulterated S-(-) enantiomer whose toxicology was specifically and widely contemplated before its presentation available in 1996. During the fast and broad utilization of Ropivacaine in the facility, undesirable reactions have been seen as constrained.[41]

Chriptopher A too published an article discussing about the history of local anaesthetic agents. The historical backdrop of local anaesthesia began in 1859, when cocaine was detached by Niemann. In 1884, the ophthalmologist Koller was the primary, who utilized cocaine for topical anaesthesia in ophthalmological medical procedure. In 1884, local anaesthesia in the oral depression was first performed by the specialist Halsted, when he expelled an intelligence tooth without agony. In many cases, various unfavourable impacts were seen with the clinical utilization of cocaine. In 1905, Einhorn revealed the amalgamation of procaine, which was the main ester-type local anaesthetic agent. Procaine was the most usually utilized local anaesthesia for over four decades. In 1943, Löfgren incorporated Lidocaine, which was the first "present day" local anaesthetic agent, since it is an amide-derivate of diethyl amino acidic corrosive. Lidocaine was showcased in 1948 and is up to now the most generally utilized sedative in dentistry around the world; however other amide local anaesthetics were brought into clinical use: Mepivacaine 1957, Prilocaine 1960, and Bupivacaine 1963. In 1969, Articaine was combined by the scientist Muschaweck and was affirmed in 1975 as a nearby sedative in Germany. Today Articaine is the most ordinarily utilized nearby sedative in dentistry in Germany, Switzerland, Austria, France, Poland and the Czech Republic.[42]

2. Pharmacology of local anaesthesia

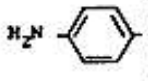
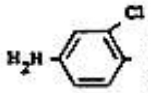
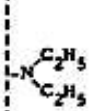
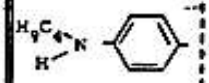
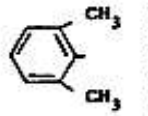
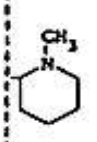
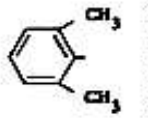
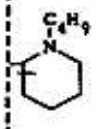
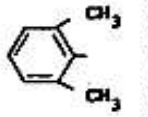
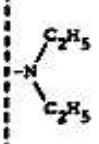
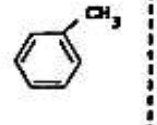
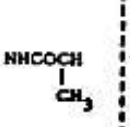
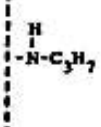
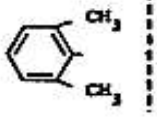
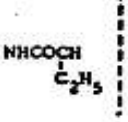
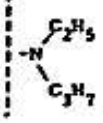
Local anaesthetic drugs may be defined as pharmacological agents who are capable of producing a loss of sensation in a circumscribed area of the body. This localized form of anaesthesia is due to an inhibition of excitation at nerve endings or to a blockade of the conduction process in peripheral nervous tissue.

Regional anaesthesia originated **in 1884** when **Koller** described the topical anaesthetic properties of cocaine, an alkaloid that has been isolated from the leaves of the Erythroxylin coca bush. Procaine, which was synthesized by **Einhorn in 1905,** was the first injectable agent of clinical value for the production of local anaesthesia. Following the introduction of procaine numerous compounds of similar chemical structure were developed. Tetracaine and Chloroprocaine are the procaine-like agents which have persisted to this day as clinically useful local anaesthetic drugs.[43]

In 1943, Lofgren synthesized Lidocaine which represented a new chemical class of local anaesthetic compounds. Whereas the procaine-like drugs are ester derivatives of Para-aminobenzoic acid, Lidocaine is an amide derivative of diethyl amino acetic acid. Since the advent of Lidocaine, many other amide substances such as Mepivacaine, Prilocaine, Bupivacaine and Etidocaine have been introduced into clinical practice as local anaesthetic agents each with its own pharmacological profile.[44]

In 1981 Benjamin G and Covino discussed about the structure and mechanism of local anaesthesia. Chemical compounds that demonstrate local anaesthetic activity usually possess the following chemical arrangement.[45]

Aromatic portion----Intermediate chain ----Amine portion

AGENT	CHEMICAL CONFIGURATION			PRIMARY ANESTHETIC USE
	Aromatic Lipophilic	Intermediate Chain	Amine Hydrophilic	
A. Esters				
PROCAINE				Infiltration
CHLOROPROCAINE				Obstetrical Epidural
TETRACAINE				Spinal
B. Amides				
MEPIVACAINE				Infiltration Peripheral nerve block Surgical epidural
BUPIVACAINE				Peripheral nerve blocks Surgical and Obstetrical epidural
LIDOCAINE				Infiltration Peripheral nerve blocks Surgical epidural Obstetrical spinal
PRILOCAINE				Infiltration Peripheral nerve blocks Surgical epidural
ETIDOCAINE				Peripheral nerve blocks Surgical epidural

The reported action of duration of local anaesthesia is as follows:

Agent	Relative In Vivo Potency	Approximate Lipid Solubility	Duration (Min)	Approximate Protein Binding
LOW POTENCY — SHORT DURATION				
Procaine	1	< 1	60-90	5
INTERMEDIATE POTENCY/DURATION				
Mepivacaine	2	1	120-240	75
Prilocaine	2	1.5	100-240	55
Lidocaine	2	4	90-200	65
HIGH POTENCY — LONG DURATION				
Bupivacaine	8	30	180-600	95
Tetracaine	8	80	180-600	85
Etidocaine	6	140	180-600	94

Covino BG in (1986) in his study reported that the most important clinical properties of local anaesthetic agents are potency, onset and duration of action and relative blockade of sensory and motor fibres. These qualities are related primarily to the physicochemical properties of the various compounds. In general, lipid solubility determines the relative intrinsic potency of the various agents, while protein binding influences the duration of anaesthesia and *pKa* is correlated with the onset of action. In general, the local anaesthetics for infiltration, peripheral nerve blockade and extradural anaesthesia can be classified into three groups: (1) agents of low potency and short duration for example- Procaine and Chloroprocaine; (2) agents of moderate potency and duration for example- Lignocaine, Mepivacaine and Prilocaine; and (3) agents of high potency and long duration for example- Amethocaine, Bupivacaine and

Etidocaine. These local anaesthetics also vary in terms of onset: Chloroprocaine, Lignocaine, Mepivacaine, Prilocaine and Etidocaine have a rapid onset, while procaine, Amethocaine and Bupivacaine are characterized by a longer latency period.[4]

Moore PA and Hersh EV in (2010) reported that the amide local anaesthetic agents currently available in dentistry were extremely safe and effective. The availability of various formulations of Lidocaine, Mepivacaine, Prilocaine, Articaine and Bupivacaine permits a practitioner to select agents that can meet treatment requirements. Many advances in local anaesthesia therapeutics and armamentarium have become available to the dental practitioner in recent years. Through careful selection of agents and proper adjustment of dosing most serious adverse reactions associated with dental local anaesthetic agents can be prevented.[46]

Becker DE and Reed KL in (2012) reported that local anaesthetics have an impressive history of efficacy and safety in medical and dental practice. Their use is so routine and adverse effects are so infrequent that providers may understandably overlook many of their pharmaco-therapeutic principles. In their review they discussed about onset of anaesthesia, duration of action, metabolism and elimination of the agent from the body, toxicity associated with local anaesthesia and interaction of these agents with other drugs. The review helped to update essential pharmacology for the various local anaesthetic formulations.[14]

Mumba JM *et al* in (2017) presented a summary of the findings which jotted few points that local anaesthetics block the transmission of pain from the nerve endings into the central nervous system. Chemically, they are classified as esters and amides depending on the intermediate chain between the lipophilic aromatic ring and

the hydrophilic amine group. The primary mode of action is blockade of the fast voltage-gated sodium channels. To achieve this effect, the unionised fraction of the drug crosses the lipid bi-layer of the axoplasm and blocks the channel intracellularly. The duration and density of the block depend on both the volume and concentration of the agent used. Factors that influence the efficacy of local anaesthetics are the pH, pKa, lipid solubility, protein binding and the length of the intermediate chain. Efficacy can be augmented by use of adjuncts such as Adrenaline, opioids, alpha 2- adrenergic agonists (Clonidine) and alkalinisation. Toxicity is related to the site of injection, the vascularity of the site and the injected dose. The use of vasoconstrictors may reduce toxicity due to reduction in systemic absorption. From the local anaesthetics in clinical use, racemic Bupivacaine has the highest affinity for the sodium channels and is the most difficult to manage in the event of systemic toxicity.[47]

Giovannitti JA *et al* in (2013) provided a comprehensive review of the pharmacology of local anaesthetics as a class and provided details of the individual drugs available in dental cartridges. Maximum recommended doses of local anaesthetics and vasoconstrictors are presented for healthy adult and paediatric patients and for patients with cardiovascular system impairments. Various complications and reasons for failure of local anaesthesia effectiveness were discussed and current and future trends in local anaesthesia were presented to provide an overview of current researches in local anaesthesia. It was reported that local anaesthesia remained the foundation of pain control in dentistry especially when combined with moderate-deep sedation for invasive and painful procedures in the contemporary oral and maxillofacial surgical model. Local anaesthetics also are the

safest and most effective drugs in medicine and dentistry to relieve intraoperative and postoperative pain. It is only with a thorough understanding of pharmacology and anatomy that clinicians have the basic clinical foundation to enhance the care of patients.[48]

3. Local anaesthesia implications

Ribotsky BM *et al* in (1996) conducted a study to assess the advantages of using a 50/50 mixture of Lidocaine and Bupivacaine with respect to onset and duration of local anaesthesia instead of using the solutions independently were evaluated. In a double-blind randomized experiment, 12 subjects each volunteering both feet was studied. One foot was injected with 1 ml of one of the following three solutions: 1% plain Lidocaine, 0.25% plain Bupivacaine (Marcaine), or a 50/50 mixture of 1% Lidocaine and 0.25% Bupivacaine; and in the other foot, a 1-ml injection of normal saline as a blinded control. A 5.07 (10 g) Semmes-Weinstein monofilament wire was used for testing for sensory blockade and the onset and duration of anaesthesia was recorded for each subject. It was determined that there was no significant difference in the mean onset times for the three solutions and no significant difference between the durations of anaesthesia of plain Lidocaine and the 50/50 mixture. Additionally, it was determined that Bupivacaine had a prolonged duration of anaesthesia compared with the other two solutions. The results of this preliminary study suggest that there is no clinical advantage with respect to onset and duration of local blockade to using a 50/50 mixture of plain Lidocaine and plain Bupivacaine in place of their independent use.[49]

OZMEN O *et al* in (2013) conducted a study to investigate whether a 2% Lidocaine addition to 0.5% Bupivacaine that is used in a lateral sagittal infraclavicular block, when administered in an upper extremity surgery, decreases the block onset time, drug effect time and drug activity when compared with Bupivacaine alone. This study was performed on 120 American Society of Anaesthesiology classification I–II patients who were 18–65 years old and scheduled to undergo an upper extremity surgery. The group testing in the study was as follows: 20 mL (5 mg/mL) Bupivacaine, 10 mL (5 mg/mL) Bupivacaine + 10 mL (20 mg/mL) Lidocaine and 20 mL (20 mg/mL) Lidocaine were used respectively in the Bupivacaine group, Bupivacaine + Lidocaine group and Lidocaine groups. It was found that the block onset time was very long in the Bupivacaine group. Motor block developed the fastest in the Lidocaine group and the Bupivacaine + Lidocaine group. Motor block regression was the fastest in the Lidocaine group and the slowest in the Bupivacaine + Lidocaine group. Loss of cold and touch sense was the fastest in the Bupivacaine + Lidocaine group and the Lidocaine group. Loss of sense of pain was the fastest in the Bupivacaine + Lidocaine group. Postoperative analgesia requirement time was the longest in the Bupivacaine + Lidocaine group. There were no differences among the satisfaction scores. It was concluded that Lidocaine addition to Bupivacaine significantly lowered the block onset time and extended the postoperative analgesia requirement time compared to Bupivacaine alone and had no effect.[50]

Yadav A et al in (2013) aimed to demonstrate if 2% Lidocaine hydrochloride with 1: 2,00,000 epinephrine could provide palatal anaesthesia in maxillary tooth removal with a single buccal injection. The subjects included in the clinical study were those requiring extraction of the maxillary third molar of either side. For the

purpose of comparison, the sample was randomly divided into 2 main groups: group 1 (study group) included 100 subjects who were to receive a single injection before extraction, and group 2 (control group) included 100 subjects who were to receive a single buccal injection and a single palatal injection before extraction. After 5 minutes the extraction was performed. All patients were observed for Faces Pain Scale during extraction and asked for the same on a 100-mm visual analogue scale after extraction. According to visual analogue scale and Faces Pain Scale scores when maxillary third molar removal without palatal injection (study group) and with palatal injection (control group) were compared the difference was not statistically significant. It was concluded that removal of maxillary third molars without palatal injection is possible by depositing 2 mL of 2% Lidocaine hydrochloride with 1: 2,00,000 epinephrine to the buccal vestibule of the tooth.[51]

Balakrishnan K *et al* in (2015) conducted a literature review which discussed about the analgesic and anaesthetic abilities of the Bupivacaine versus Lignocaine during surgical removal of impacted third molars. It was found that both Bupivacaine and Lignocaine have their merits and demerits but beyond any doubt it has been proven by the clinical trials that Bupivacaine provides better and prolonged analgesia and anaesthesia post operatively during minor surgical procedures done at chair side along with surgical removal of impacted third molars. Hence, Bupivacaine can be regularly used as the anaesthetic solution along with adrenaline 1:2,00,000 for surgical removal of impacted third molars provided care being taken regarding the dosage and the cardio depressant property of Bupivacaine. Right now, further studies are going on.[52]

Dhanrajani P and Chung P in 2016 conducted a study to compare the effectiveness and duration of action of two concentrations of Bupivacaine with adrenaline for postoperative pain in patients undergoing surgical removal of four third molars under general anaesthesia.

60 patients undergoing surgical removal of four wisdom teeth received Bupivacaine 0.5% (n = 30) or 0.25% (n = 30). The severity of pain in the immediate recovery period and at 2 and 24 hours after surgery was recorded using the visual analogue scale. Differences were assessed by box and whisper plot and the Student's *t*-test. It was found that the analgesic effects of the 0.25% and 0.5% doses were significantly different at 30 min after surgery but not after 2 and 24 hours. The difference of mean of 0.25% and 0.5% was much higher after 0.5 h but less after 2 and 24 hours. The study concluded that Bupivacaine 0.5% was statistically better for pain control during the immediate postoperative period, but there was no significant difference in pain control between the two dose strengths at 2 and 24 hours after surgery.[53]

Agarwal P *et al* in 2017 conducted a study to compare Bupivacaine and Lignocaine use in surgical extraction of impacted mandibular third molars. This was a prospective, randomized, double blind study. 50 patients requiring surgical removal of impacted mandibular third molars were randomly divided into two equal groups. 0.5% Bupivacaine without any vasoconstrictor and 2% Lignocaine with 1:80,000 Adrenaline were used in a double blind manner. All required parameters were noted during surgery and questionnaires given to all patients to assess onset of anaesthesia, the time of complete disappearance of numbness, pain perception and postoperative

analgesic requirement. It was found that longer duration of action and longer painless period postoperatively, lesser pain intensity and decreased postoperative analgesic requirement were observed for Bupivacaine with statistical significance. However, the onset of anaesthesia was earlier for Lignocaine as compared to Bupivacaine. Study concluded that Bupivacaine has better pain control, increased duration of anaesthesia, lesser postoperative pain and decreased analgesic requirement postoperatively than Lignocaine. The application of Bupivacaine to minor oral surgical procedures like removal of impacted teeth is desirable.[54]

Adelusi EA *et al* in 2019 conducted a study to evaluate the post-extraction pain control of 0.5% Bupivacaine compared with 2% Lidocaine following intra-alveolar tooth extraction. This study was a double blind randomized controlled trial on patients who underwent intra-alveolar tooth extraction. There were two groups of 126 subjects per Bupivacaine and Lidocaine group respectively. Pain experience was assessed using Numeric Rating Scale (NRS). Data were analysed using SPSS and $P<0.05$ was considered statistically significant. When post-operative pain was recorded in Lidocaine group between 3 to 12 hours post-extraction there was a significant improvements afterward while in the Bupivacaine group, there was almost pain-free period for the first 8 to 9 hours postoperatively. A significant reduction in the need for post-operative analgesics was noted in the Bupivacaine group. Overall patient satisfaction was significantly higher for the Bupivacaine group.

The study concluded that Bupivacaine appears to offer more effective post-operative pain control following intra-alveolar tooth extraction.[55]

4. Fear of local anaesthesia

Willershausen B *et al* in 1999 conducted a study to assess fear relation to dental treatment in 59 ambulant patients at Dental Clinic of the University of Mainz. Questions were asked regarding fear of treatment and answers were compared with clinical findings on the status of oral health and with habits of oral hygiene. 65% of the patients reported some level of fear of dental treatment. Younger patients had significantly more fear of treatment than older patients. Patients reported the noise and vibration of the drill (56%), the sight of the injection needle (47%) and sitting at the treatment chair (42%) as especially fear provoking. As subjective elements of their fear, the patients reported muscle tension (64%), higher heart-beat (59%), accelerated breathing (37%), sweating (32%), and stomach cramps (28%). Among fearful patients, greater changes in pulse rate (>10 beats/min) and changes in blood pressure were measured. Oral health correlated with levels of fear only for younger patients. Although the frequency of caries (DMF/T) and the degree of treatment need (CPITN) showed a significant correlation with subjective fear of treatment among patients under 35 years of age, the correlation weakens with increasing age of the patients studied. Thus study findings strongly suggested that there is a need for more prophylactic measures to lower the levels of fear of dental treatment.[56]

Oosterink FM *et al* in 2008 conducted a study to establish a hierarchy of anxiety-provoking capacities of a large set of dental stimuli and to determine the differences in relation to gender, age, ethnicity, and level of dental trait anxiety. Along with this, the study also aimed to derive an estimate of the number of stimuli to be presented to anxious patients in order to obtain full coverage of their dental fears.

For the same, a questionnaire describing 67 potentially anxiety-provoking stimuli was constructed and presented to 960 adults. The results indicated that invasive stimuli (e.g. surgical procedures) were rated as the most anxiety provoking and that non-invasive stimuli (e.g. the dentist as a person) were the least anxiety provoking. The fear-evoking capacity of the dental stimuli varied with gender, age, ethnicity, and level of dental trait anxiety, whereas the rank order of these stimuli appeared to be independent of these factors. Furthermore, it appeared that the top 25 most anxiety-provoking objects and situations found in the current study contained only eight (28%) stimuli. [57]

Van Wijk AJ and Hogstraten J in 2009 conducted a study to check the relationship between anxiety and pain felt during a dental injection in a sample of 'normal' patients about to undergo 'invasive' dental treatment. Duration and intensity of pain during a dental injection were measured within a sample of 247 patients. In addition, data on dental anxiety, fear of dental pain, type of treatment, amount of anaesthetic fluid, injection location and the use of surface anaesthesia were also collected. The result showed that anxious patients felt more pain and of longer duration than less anxious patients. 28% of variance on the duration of pain felt could be accounted for by fear of dental pain. For the intensity of pain felt, 22% of variance could be accounted for by anxiety felt for the injection and dental anxiety. The result conclude that some patients are expected to feel elevated levels of pain during dental injection and would benefit from extra attention and care from the dentist.[58]

Siddiqui TM *et al* in 2016 conducted a study to assess the intensity of needle phobia and to evaluate the different dimensions of fear of dental injections to help provide better care to the patients. 250 adult patients above 18 years of age were selected who attended outpatients Department of Operative Dentistry, Baqai Dental College. A modified form of the structured questionnaire used by Milgrom *et al*. was generated. The items were scored based on the 5-point traditional Likert scale ranging from strongly disagrees to strongly agree. The results reported that there was a statistically significant difference in fear of dental injections among male and female subjects. The most fearful aspect of dental injection was found to be fear of cross-infection. Fears associated with local anaesthesia, for example, inadequate numbness, adverse reaction, and trouble in breathing or swallowing were the least common fears reported by the patients. It was concluded that understanding the nature and extent of patients' fear of injection is important for dentists to expand their knowledge of the association of fear of dental needles for the impact on the treatment outcome and reluctance of the patients intervene.[59]

Cianetti S *et al* in 2017 reported a systematic review to quantify the prevalence and mean score of dental fear/anxiety (DFA) in children/adolescents and its variation according to several variables. The studies included were Cross- sectional and cohort studies published from 2000 to 2014, that measured DFA in children /adolescents (aged 0-19 years), in the general population, or visiting private or public dental services (general or paediatric) or attending school and kindergarten, The database searched were Medline, Embase, Web Of Science. After screening 743 abstracts and evaluating 164 full-text publications, 36 articles were selected. Dental fear/anxiety prevalence rates were 12.2%, 10.0%, 12.2%,11.0% and

20.0% for the CFSS-DS, DAS, MDAS, DFS, and DFSS-SF scores, respectively. In the studies that used MCDAS Dental fear/prevalence rates varied from 13.3% to 29.3%. In the studies that used CFSS-DS ratings. The review concluded that dental fear/anxiety is a common problem in children and adolescents worldwide, therefore, new strategies to overcome this condition should be encouraged.[60]

Vanhee T *et al* in 2019 conducted a study to determine the nature of dental anxiety-provoking stimuli in young patients. A questionnaire was submitted to 566 children between 3 to 18 years in health institutions and schools in Brussels, Belgium. The items were divided into 3 groups: environment (ENV), local anaesthesia (LA), and intervention (INT) and summarized through averaging per group. The response of the questionnaire was, 7.2% of the respondents expressed high to severe dental anxiety. Several items presented a clear bimodal distribution dividing the population in fearless and fearing patients, for example, sight and feel of the syringe, sight and taste of blood and extraction. Others presented with a gradually lower incidence with increasing fear level. Fear for the environment was generally low. The study inferred that while the dental environment is in general not causing fear, the invasive part of the anaesthesia and the invasive dental procedures are involved.[61]

5. Techniques to reduce pain during local anaesthesia administration

Tan PY *et al* in 2001 conducted a clinical study to assess whether WAND will provide greater comfort during anaesthesia delivery while achieving the same anaesthetic effect as traditional syringe technique. 20 patients with painless anal

pathology were randomized to receive anal anaesthesia using either the WAND or traditional syringe technique to a randomly selected half of the anoderm (right or left). The opposite side was then anesthetized by the alternate method, allowing patients to act as their own control. Objective and subjective pain scores were obtained from the patient after each mode of delivery. It was found that 80 % patients preferred the use of the WAND. Objective and subjective pain scores per patients and subjective pain scores per the observer were significantly lower for the WAND than for traditional syringe technique. The mean volume of local anaesthetic used with the WAND was 1.7 ml compared with 3.2 ml for traditional syringe technique. Anaesthesia achieved with the WAND was as good as that achieved with traditional syringe technique when the pinch test was used. The study concluded that WAND is as effective as the traditional syringe technique in the delivery of anal anaesthesia while providing a more comfortable experience for the patient.[62]

Yesilyurt C *et al* in 2008 conducted a study to compare a computerised device (the Wand) with a conventional syringe in terms of the pain of needle insertion and injection during inferior alveolar nerve (IAN) block injection. 40 patients between the ages of 18 and 30 years requiring local anaesthesia for dental restoration in the mandible were included in the study. Contra lateral IAN injections were administrated at two separate appointments with random use of either the Wand or a conventional syringe. Following the injection, the patients used both the pain rating score (PRS) and a visual analogue scale (VAS) to assess the intensity of pain. In results, Wand was found to be less painful than the syringe for the pain of both needle insertion and injection concluding that the Wand technique resulted in significantly

lower pain scores during the IAN block injections. Most of the patients preferred the IAN injection with the Wand for future dental injections.[63]

Tahmassebi JF *et al* in 2009 conducted a study to compare the sensation of pain when injections were given using the Wand computer controlled local analgesia (LA) system and a conventional technique in children of pre-school and school age. 38 children were randomly assigned to either a treatment or control group. The treatment (Wand) group consisted of 20 children, while the control group (conventional LA technique) consisted of 18 children. The children were aged between 39.0 and 120.0 months with a mean age of 81.9 months (SD-23.2). Pain sensation was rated using the VAS scale. The results showed no statistical difference in pain sensation and anxiety when the Wand was used, compared with the conventional technique. The study concluded that there was no difference in the pain or anxiety experienced by the children in the conventional and Wand group.[64]

Shah M *et al* in 2012 conducted a study to compares the pain response of a group of 10 subjects to the Wand (®) with the response to traditional syringe injections and also compares the extent of the area anesthetized. 10 subjects were selected for the study and 20 injections were given contra-laterally to them, 10 with Wand(®) and rest with the traditional aspirating syringe. Each subject received 2 injections on the palate, Left side with Wand(®) (test) and Right side with Traditional syringe (control). Pain perception levels were recorded with a visual analogue scale. The results showed injections with the syringe were more painful than injections with the Wand(®) in 2 of 10 subjects. Also the extent of the area anesthetized by both the techniques was similar except in 2 patients. It was concluded that Wand(®) results in

less painful injections; however, mean ratings of pain for both the groups were mostly below the annoying level of pain.[65]

Langthasa M *et al* in 2012 conducted a study to evaluate and compare the pain perception by the paediatric patients, while experiencing computerized injection device comfort control syringe (CCS) and the conventional injection technique during dental clinical procedures. Fifty patients aged 6-14 years requiring local anaesthesia on both sides of the dental arch for various treatment procedures were selected for this study. The patients served as their own control and on the appointed day CCS was used on one side of the dental arch and on the subsequent appointment, i.e., the very next day conventional injection technique was used. Visual analogue scale (VAS) and faces pain rating scale (FRS) were used to assess the child's pain perception to each of the techniques immediately after the injection. Results reported a statistically significant difference in the pain perception by children using VAS and FRS between computerized and conventional technique. No statistically significant difference was observed when physiological parameters (heart rate, blood pressure and temperature) were compared at various intervals between the computerized and the conventional technique concluding that computerized injection device (CCS) provides less painful injections when compared to the conventional injection technique.[66]

Shilpapriya M *et al* in 2015 conducted a study to investigate the effects of vibration stimuli on pain experienced during local anaesthetic injections. Thirty patients aged 6-12 years old of both the genders with Frankel's behaviour rating scale as positive and definitely positive requiring bilateral local anaesthesia injections for

dental treatment were included in the split-mouth cross over design. Universal pain assessment tool was used to assess the pain with and without vibration during the administration of local anaesthesia. Results reported that local anaesthetic administration with vibration resulted in significantly less pain compared to the injections without the use of vibe. It was concluded that vibration can be used as an effective method to decrease pain during dental local anaesthetic administration.[67]

Pradhan R *et al* in 2017 conducted a prospective study to determine pain, duration, profoundness and complications associated with administration of Intraligamentary Injection Technique (ILT). The study was conducted on 194 patients (male=122, female=72) who reported for dental extractions in mandibular posteriors. The ILT was administered with Ligajet Intraligamentary jet injector using cartridge containing lignocaine hydrochloride 2% with adrenaline 1:80000 and a 30 gauge needle at buccal (mesiobuccal), lingual, mesial and distal aspect of the mandibular molars. Parameters assessed were Pain on Injection (PI) and Pain during Procedure (PP). Mean and standard deviation was derived for Duration of Anaesthesia (DA). Results showed that localized soft tissue anaesthesia, decreased PI (SD=0.83), and minimal PP (SD=0.94). The DA (SD=4.62) and mean value of 24.06 minutes. It was concluded that the Intraligamentary injection technique can be used effectively to anaesthetize mandibular molars as a primary technique for extraction of mandibular posterior teeth.[68]

Garret-BernardinA ***et al* in 2017** conducted a study to evaluate the pain experience and behaviour during dental injection using the Wand computerized delivery system versus conventional local anaesthesia in children and adolescents. An

observational crossover split mouth study was performed on 67 patients requiring local anaesthesia for dental treatments in both sides of the dental arch. Patients received both types of injections in two separate appointments, one with the use of a Computer Delivery System (the Wand STA system) and one with the traditional syringe. Parameters recorded were pain rating; changes in heart rate; level of collaboration and patient satisfaction. It was observed that the use of the Wand system determined significantly lower pain ratings and lower increase of heart rate than the traditional syringe. During injection, the number of patients showing a relaxed behaviour was higher with the Wand than with the traditional local anaesthesia. The patient level of satisfaction was higher with the Wand compared to the conventional local anaesthesia. Study concluded that Wand system may provide a less painful injection when compared to the conventional local anaesthesia and it seemed to be better tolerated with respect to a traditional syringe.[69]

Raslan N and Masri R in 2017 conducted a randomized controlled trial to compare pain levels caused by three types of anaesthesia injections and the effect of the Dental vibe on reducing the injection pain. The study included 40 children and each one received six injections. The injections were divided randomly into two methods: experimental (DV): buccal and palatal infiltration on the maxilla and inferior alveolar nerve block (IANB) with vibration and traditional (TR): receiving the same previous injections without vibration. Moreover, pain was assessed using the FLACC and Wong-Baker faces pain scales. The result showed no statistically significant differences regardless of the injection site in subjective and objective evaluation in the (TR) method. Although the pain scores in (DV) method were less than the traditional in most injections, the differences were not statistically significant.

The study inferred that the Dentalvibe did not decrease discomfort and was not accepted more by children.[70]

Ghaderi F and Ahmadbeigi M in 2018 conducted a study to compare pain perception in dental injection by Smart-ject with conventional technique. The study was a randomized single-blind crossover clinical trial. The participants consisted of 50 healthy volunteer dental students. They received a topical anaesthetic agent plus injection in maxillary premolar buccal mucosa via conventional technique on one side (control) and a topical anaesthetics agent plus injection in maxillary premolar buccal mucosa by Smart-ject on the other side (experimental). It was found that there was a statistically significant difference in VAS score between Smart-ject and the conventional technique. The mean of VAS scores for Smart-ject and the conventional technique were 14.5±7.4 and 24±12.1, respectively. The study concluded that needle penetration is not the main reason of pain during injection. Inconsistent fluid pressure created by injected anaesthetic solution on nerve fibres is more impressive in pain development. Hence, Smart-ject as a CCLAD can be considered as an appropriate device for dental.[71]

Yamashita Y *et al* in 2020 conducted a clinical study to assess the clinical effect of virtual reality (VR) to relieve anxiety during impacted mandibular third molar extraction under local anaesthesia. VR to alleviate anxiety concerning surgical treatment for 51 patients undergoing impacted mandibular third molar extraction under local anaesthesia. Fear and anxiety before and after treatment were evaluated by a questionnaire that included a visual analogue scale (VAS). The post-treatment questionnaire asked patients to evaluate their satisfaction on a 5-level Likert scale.

The results found were, anxiety had decreased among the patients who had used VR (VR group), with a difference of -13.3 ± 28.7 mm in anxiety measured using a VAS before and during treatment. In contrast, it had increased by 4.0 ± 22.3 mm in the 49 patients who had not used VR. Furthermore, the post-treatment questionnaire administered to the VR group revealed that 92% had reported that their anxiety had decreased. It was concluded that the use of VR could be valuable during dental treatment, especially extractions and surgical treatment.[72]

Smolarek PC *et al* in 2020 reported a systematic review and meta-analysis to analyse whether pain and disruptive behaviour can be decreased by the use of computerized local dental anaesthesia (CDLA) in children. Randomized clinical trials that compared computerized and conventional anaesthesia were included. The primary outcome was pain perception during anaesthesia; the secondary, disruptive behaviour. The risk of bias of individual papers and the quality of the evidence were evaluated. After search, 8389 records were found and 20 studies remained for the qualitative and quantitative syntheses. High heterogeneity was detected for both outcomes. For the pain perception, the overall analysis showed a standard mean difference of -0.78 (-1.31, -0.25) favouring CDLA; however, when only studies at low risk of bias were analysed (subgroup analysis), there was no difference between the two techniques [-0.12(-0.46, 0.22)]. It is concluded that there is no difference in the pain perception in children subjected to computerize or conventional dental local anaesthesia. Notwithstanding, the quality of the available evidence is low.[73]

Rizzo-Lorenzo A *et al* in 2020 conducted a single-blinded randomized controlled trial among patients requiring an upper third molar extraction was

performed to evaluate the anxiety degree after receiving information or not, about the functioning of The Wand system. Secondarily, perceived pain and the need of re-anaesthesia were assessed. Patients were randomly assigned to the experimental group (detailed explanation about The Wand) or control group (no specific information). Local anaesthesia with The Wand consisted in a supraperiosteal infiltrative technique injection 1.6 mL at the buccal and 0.2 mL at the palatal side. The study concluded that patients that received a detailed explanation of The Wand did not have a significant reduction of the anxiety degree and perceived pain during the anaesthetic act compared to patients that received no information. The need of re-anaesthesia was not related to the anxiety level but was significantly related to increasing operative time.[74]

Bilsin E *et al* in 2020 conducted a randomized controlled trial study to assess the efficacy of external cooling and vibration devices on the pain of injections applied to the site of local anaesthesia in children during dental treatment. 60 children requiring mandibular deciduous teeth extraction were included. The children in the experimental group were anesthetized after cold application, and a vibration device was administered on the application site 2 minutes before and during the anaesthesia process, whereas those in the control group were only given local mandibular anaesthesia without any other procedure. It was found that the mean pain score was lower in the experimental group with a significant difference between the groups. The study concluded that application of external cooling and vibration on the site of local anaesthesia had a significant effect on the injection pain experienced by children during dental treatment.[75]

Ocak H *et al* in 2020 conducted a study to evaluate the effectiveness of the needleless injection for infiltrative anaesthesia and compare the acceptance and efficacy between jet injection with INJEX and local infiltration anaesthesia. 28 adult patients admitted for tooth extraction were included in the study. Two symmetrical teeth in the same jaw were extracted from each of the patients. Jet injection with the INJEX® was performed on one side and classical (needle) infiltration anaesthesia on the other side with 0.3 cc Ultracain DS forte (Sanofi Aventis, İstanbul, Türkiye) on buccal and lingual aspects and 0.1 cc on palatal aspects of the teeth. Results showed that the difference between pain and discomfort scores experienced during tooth extraction was statistically significant (P = 0.026). The pain or discomfort score of the INJEX® method during tooth extraction was significantly higher. Jet injection with the INJEX® was not found to be effective for local infiltrative anaesthesia especially teeth extractions. The study concluded that jet injection may be more acceptable when using for previously classical local infiltration anaesthesia by patients. The main problem with jet injection was the "pop" sound when the INJEX® device was pressed, and also inadequate supplying the anaesthesia.[76]

Use of Vibraject in dental practice

Saijo M *et al* in 2005 conducted a pilot study to evaluate the injection pain when Vibraject was applied with an automated electric syringe with a 33-gauge dental needle under single-blind randomized conditions. Ten healthy adults were included in the study. Volunteers underwent intraoral injections with and without Vibraject application at a sufficient interval. Intraoral injection was given into the alveolar mucosa adjacent to the root apex of the maxillary lateral incisor using a computer-

controlled electric syringe with a 33-gauge needle. After the injection was finished, participants evaluated the degree of pain at needle insertion and anaesthetic injection on a visual analogue scale (VAS; 0–100 mm) and a pain rating score (PRS; painless, pressure sensation, slight pain, painful). The result reported that the PRS at needle insertion decreased in 2 participants and increased in 3 participants when applying Vibraject. At anaesthetic injection, the PRS increased in 4 participants and decreased in 1 participant when applying Vibraject. It was concluded that Vibraject reduces patient discomfort if the patient markedly fears undergoing injection and also state that the hum of the motor seems to have a calming effect.[37]

Murray P *et al* in 2010 conducted a study to assess if a commercially available vibrating dental syringe attachment, Vibraject LLC (USA), could reduce pain experienced by patients having intraoral injections for dental treatment. The patients were divided into two groups. Group A received one injection using the vibrating dental syringe attachment. Group B, the control group, received one injection using conventional methods. The patients were then asked to grade the injection pain using a visual analogue scale from 0-10. Zero was marked as no pain up to 10 as unbearable pain. The site of injection, the type of injection (infiltration or IDB), the operator and the pain score were all noted for each patient. No other pain relief adjuncts, such as topical anaesthetic gels were used on any of the patients. Result showed that Subjects receiving the conventional injection methods had a mean pain score of 4.6 (± 0.414) The VibraJect group had a mean pain score of 1.71 (±0.235)($P<0.05$). Certain sites had larger decrease in the mean pain score using the VibraJect. It was concluded that the vibrating syringe attachment resulted in reduced pain levels on receiving intraoral injections.[77]

Roeber B *et al* in 2011 conducted a randomized, controlled, single-blinded study to evaluate the effectiveness of VibraJect, a vibrating attachment for a traditional syringe, in reducing pain related disruptive behaviour and self-reported pain in children receiving local anaesthesia. 90 children receiving local anaesthesia for routine restorative procedures were included in the study. Participants were randomly assigned to either a control (injection as usual) or experimental (injection using the VibraJect) group. Participants were recruited from a large urban paediatric dental clinic within a university medical centre. The results reported that there was no significant difference between injection with and without the Vibraject on any measures of pain, including self-reported intensity, independent direct observations of pain related disruptive behaviour, and subjective dentist ratings. It was concluded that Vibraject did not provide any benefits over a conventional approach to anaesthesia injection for children in this study.[78]

Chandrasekaran J *et al* in 2014 conducted a study to evaluate the efficacy if Vibraject versus conventional injection technique in reducing pain and discomfort. Prospective, randomized, cross- over, single blinded design was carried out among 37 adults above 18 years of age in private hospital in Chennai city, Tamil Nadu, India using a split mouth technique. Calibrated single examiner used an appropriate amount of anaesthetic solution, 2% Lidocaine with 1:1,00,00 dilution of epinephrine was injected slowly and then patient was asked to report their discomfort and pain was noted using verbal descriptor scale. Sign test was calculated to check the efficacy of vibraject to that of conventional injection technique. It was found that 35 subjects reported increased pain score while using conventional injection technique than using vibraject with a significant difference.

Similarly, four subjects reported increased pain score while using conventional injection technique than using Vibraject with a significant difference. The study concluded that Vibraject can significantly reduce pain both during insertion of needle and during deposition of solution when compared to the conventional injection technique.[33]

Chaudhry K *et al* in 2015 conducted a study to evaluate the pain perception through Vibraject™ and comparing it with traditional injection technique during dental procedures in clinical paediatric dentistry. 20 children aged between 8 and 14 years, visited the Department of Pedodontics, K.D. Dental College and Hospital, Mathura, for some dental treatment were selected. In the first appointment, local anaesthesia using a conventional syringe was administered. The procedure was repeated with Vibraject™ on the opposite side of the same dental arch on the subsequent visit. The child side of the same age was assessed through visual analogue scale (VAS) and faces pain rating scale (FRS) for both the techniques. Various physiological parameters were also assessed and compared between conventional and vibrating injection techniques. The results reported that there was a statistically significant difference in VAS and FRS found between the two techniques whereas when physiological parameters (heart rate, blood pressure and temperature) were compared at various intervals, the difference was not statistically significant. The study inferred that Vibraject provides less pain while giving local anaesthetic injections in comparison to the conventional injection technique in clinical dental procedures.[36]

Saad NM *et al* in 2017 conducted a prospective randomized controlled clinical trial to evaluate the effect of the vibration-assisted syringe on pain perception in children during different intra-oral injections of local anaesthesia, as well as, assessment of anxiety expressed by children receiving different intra-oral injections using vibration-assisted syringe. A total number of 120 children aged 4-8 years were selected from patients visiting the paediatric dental clinic at Mansoura University. The children were assigned into four equal groups (30 children each) according to the type of intra-oral injection needed for their treatment; Group I: children underwent upper posterior buccal infiltration, Group II: children underwent inferior alveolar nerve block, Group III: children underwent upper anterior infiltration and Group IV: children underwent posterior palatal infiltration. Each child was subjected to both anaesthetic injections; the conventional and the vibration-assisted (Vibraject) in two separate dental visits with two weeks apart. Pain perception by VAS was significantly lower in Vibraject-assisted injections in groups I, III and IV. On comparing the difference in anxiety by FAS it was significantly lower in Vibraject-assisted injections only in group IV subjects. The study concluded that Vibraject provides less pain in comparison to conventional injection. Some of the children were less anxious when injected by Vibraject-assisted syringe in comparison to the conventional syringe. Thus Vibraject may be a promising method of delivering local anaesthesia in children.[79]

Bhawana *et al* in 2019 conducted a study to evaluate and compare pain experienced during insertion of needle and administration of local anaesthesia on the palate with Vibraject (a vibrating attachment to the conventional syringe) and conventional syringe. A total of 50 patients with bilaterally posterior teeth were enrolled in this split mouth randomized controlled clinical study. The pain relief was

recorded by the patient on the Facial Visual Analogue Scale at the postoperative hour, 2nd, 4th and 8th hour and on postoperative day 1. The time of when the patient first complains of unbearable pain was noted postoperatively and then the patient was given 20 mg of oral piroxicam as a rescue medication. Results reported that patients in both the groups reported no statistically significant decrease in pain score at needle insertion and local anaesthesia deposition. The study inferred that traditional procedure can be preferred to the Vibraject as it does not require accessory attachment to conventional syringe and neither does these techniques show any difference in pain perceived.[80]

Quarnstrom F and Bang-Pastore SH conducted unblinded randomized controlled trial to determine if a new vibrating device, Vibraject is effective to control pain caused by local anaesthetic injections. 36 patients needing local anaesthesia injection were included in the study. The injections were divided into two phases. Phase 1 included piercing the tissue through quick jerk with needle before anaesthesia is injected. The VAS was recorded before injection and again before the solution was administered (with needle pierced in the tissue). The results showed that the pain for needle puncture for Vibraject was mean 14.6 and for wand was 12.6. The overall evaluation of unpleasantness was less for the Vibraject group compared to wand but no significant difference was seen between the techniques. The study concluded that there is a little difference in pain perceived by dental patients when injected using Vibraject as opposed to injecting with the Wand.[81]

MATERIAL AND METHODS

An interventional study was conducted to evaluate and compare the effectiveness of Vibraject injection technique with conventional injection technique for achieving local anaesthesia in patients undergoing orthodontic extraction of bilateral maxillary premolar.

STUDY DESIGN:

A randomized double blind prospective and comparative study

SOURCE OF DATA:

For recruiting patients in the study, the patients reporting to Out Patients Department of Oral and Maxillofacial Surgery indicated for maxillary premolar extraction for orthodontic purpose.

STUDY AREA:

The study was conducted in the Department of Oral and Maxillofacial Surgery.

DURATION OF STUDY:

The study was performed for a period of 18 months from January 2019 to July 2020

SCIENTIFIC AND ETHICAL CONSIDERATION:

Before staring the study, approval was obtained from BORS and Institutional Ethics Committee of Maharashtra University of Health Sciences, Nasik.

INFORMED CONSENT:

For conducting the study an informed written consent was obtained from the patients prior to start of the study. The consent gave a brief description about the study and also mentions about maintaining the confidentiality of the patients in regard with all study parameters and that their photographs will to be obtained for the study report.

ELIGIBILITY CRITERIA

Inclusion criteria

1. Patients falling in the age group of 14-25 years.

2. Patients with no serious illness or underlying diseases

3. Patients requiring bilateral maxillary premolar extractions for orthodontic purpose

Exclusion criteria

1. Pregnant women.
2. Mentally challenged patients
3. Patients who were known to have allergy to any medication or local anaesthesia.
4. Patients with gross oral pathology.
5. Patients not willing to give informed consent.

SAMPLE SIZE CALCULATION:

A total of 34 patients visiting OMFS department for extraction of bilateral maxillary premolar for orthodontic purpose were selected for the study. The sample size was calculated using the below formula. Power of the study as kept at 80%, significance was kept at 5% with a confidence interval of 95% the following calculations were made:

$$n = \frac{[DEFF \times Np(1-p)]}{[(d^2/Z^2_{1-\alpha/2} \times (N-1)+p \times (1-p)]}$$

Where,

N=Population size (for finite population)

(p)= Hypothesized % frequency of outcome factor in the population

Confidence limits as % of 100(absolute ± %) (d): 5%

Design effect: 1

Substituting the values in the formula, a sample size of 34 was derived

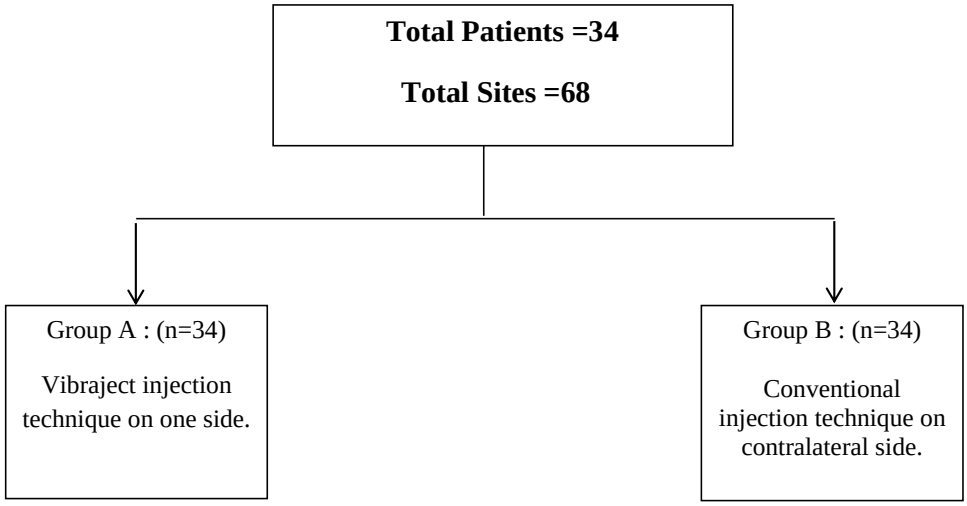
No. of sites= 68

SAMPLING TECHNIQUE

The patients were selected according to the inclusion and exclusion criteria and were then divided randomly into two groups. The randomization for site was done using computer generated random list.

Group A (n=34): Patients were given Vibraject injection technique for delivering local anaesthesia on one side.

Group B (n=34): Patients were given conventional injection technique for delivering local anaesthesia on contra-lateral side.



Flowchart showing distribution of subjects in the study

RANDOMIZATION

Numbers were assigned to patients visiting Department of Oral and Maxillofacial surgery falling into inclusion criteria of the study and site randomization was done through computer generated system as seen in Table no.1 below.

Subject	Group Assigned	Side
1	Group B	Right
2	Group B	Left
3	Group B	Right
4	Group A	Left
5	Group A	Left
6	Group B	Left
7	Group B	Left
8	Group A	Right
9	Group A	Left
10	Group B	Right
11	Group A	Right
12	Group A	Left
13	Group B	Left
14	Group B	Left
15	Group A	Right
16	Group B	Right
17	Group A	Right

18	Group B	Left
19	Group B	Right
20	Group B	Right
21	Group B	Right
22	Group B	Left
23	Group A	Right
24	Group B	Left
25	Group A	Right
26	Group B	Left
27	Group B	Right
28	Group A	Left
29	Group B	Right
30	Group B	Right
31	Group A	Left
32	Group B	Left
33	Group A	Left
34	Group B	Right

ALLOCATION CONCEALMENT

In both the groups, the same type of syringe was used for administering local anaesthesia.

BLINDING:

To avoid bias in the study a double blinding was performed. The patients were not aware to which group they belonged because of allocation concealment. Secondly,

the person recording the parameters of pain due to administration of local anaesthesia was kept unaware about the group he is recording for.

ARMAMENTARIUM REQUIRED

- Mouth mask
- Head cap
- Surgical Gloves
- Sterile Cotton
- Kidney tray
- 2 ml short needle syringe
- 2 % Lignocaine with 1:2,00,000 epinephrine (fig 1)
- Vibraject device (fig 2)
- Standard armamentarium for maxillary premolar orthodontic extractions (fig 4 and 5)
- Emergency drug kit

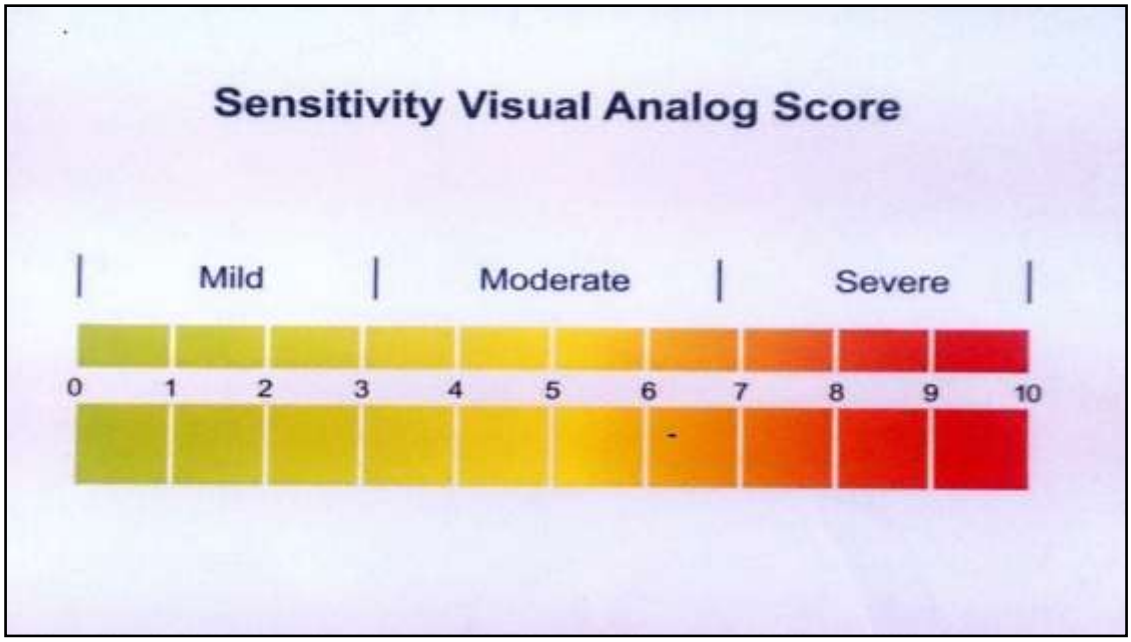
CLINICAL PARAMETERS ASSESSED:

1. Sensitivity Visual Analogue Scale
2. Wong-Baker FACES Pain Rating Scale

1. Sensitivity Visual Analogue Scale

- The pain VAS is a continuous scale comprised of a horizontal or vertical line, usually 10 centimeters (100 mm) in length, anchored by 2 verbal descriptors, one for each symptom extreme.

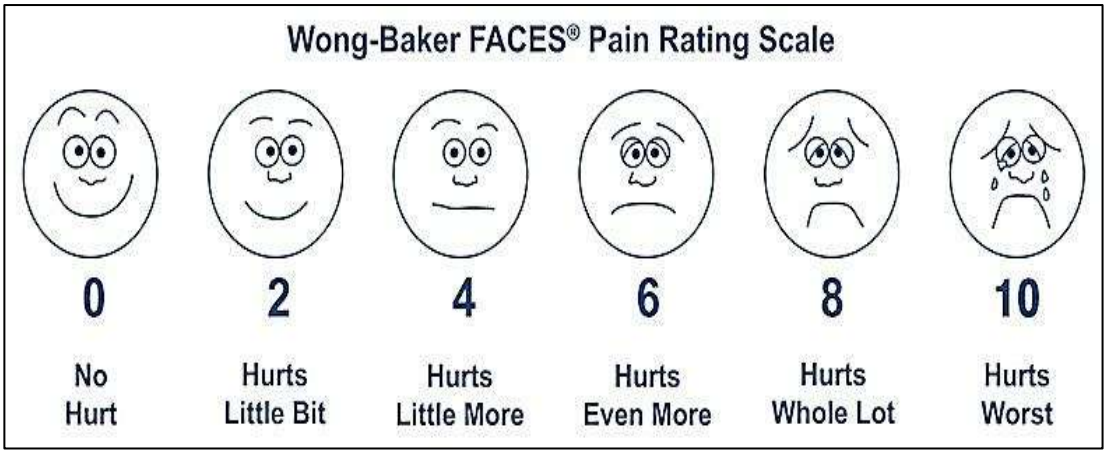
- For pain intensity, the scale is most commonly anchored by “no pain” (score of 0) and “pain as bad as it could be” or “worst imaginable pain” (score of 10 [10- mm scale]).
- A higher score indicates greater pain intensity. Based on the distribution of pain VAS scores in postsurgical patients pain intensity is described as none, mild, moderate, or severe.
- The following cut points on the pain VAS were kept:
    - Mild pain (0-3 point)
    - Moderate pain (3-7 point)
    - Severe pain (7-10 point)



2. Wong-Baker FACES Pain Rating Scale

- Each face represents a person who has no pain (hurt), or some, or a lot of pain.

- Face 0 doesn't hurt at all, Face 2 hurts just a little bit, Face 4 hurts a little bit more, Face 6 hurts even more, Face 8 hurt a whole lot, Face 10 hurts as much as patient can imagine.



CLINICAL PROCEDURE:

- Patients visiting Oral and Maxillofacial Surgery Department for bilateral maxillary orthodontic extractions under the inclusion criteria were divided into two groups and received local anaesthesia to respective site as per randomization.

Group A – (Study group)

Vibraject injection technique for delivering local anaesthesia on one side of maxillary arch.

Group B – (Control Group)

Conventional injection technique for delivering local anaesthesia on the contra-lateral side of maxillary arch.

- After obtaining written informed consent both the groups were operated for maxillary extraction by same operator under all aseptic conditions.
- Prior to procedure, self-reported questionnaire with details of age, gender, address and date of procedure were recorded.
- Under all aseptic precautions, Infraorbital and Greater palatine nerve block was achieved on one side with Vibraject attachment in Group A patients (fig 8 and 9) and on contra-lateral side with Conventional injection technique in Group B patients.(fig 6 and 7)
- Keeping the speed of injection same for every patient, local anaesthetic solution, 2% Lignocaine containing 2, 00,000 epinephrine was deposited for desired nerve block and pain was evaluated while insertion of needle into tissue and while deposition of solution.
- Pain on needle insertion was noted for every patient using Visual Analogue Scale (VAS) and Wong-Baker Scale. Pain during deposition of local anaesthesia was defined as pain described by the patient on Visual Analogue Scale (VAS) during deposition of the solution and not on the needle- prick and also on Wong-Baker Scale by person blinded to the study as expression of patient during pain while pain is experienced by patient .

STATISTICAL ANALYSIS:

The data regarding responses of the patients on Visual Analog Scale and Wong-Baker scale were recorded and transferred onto an Excel Spreadsheet 2010. The data checked for normality using Kolmogorov- Smirnov test.

- For comparing the data between groups for Visual Analog Scale - Unpaired t test is used.
- For comparison the data between groups for Wong-Baker Scale - Mann Whitney U test is used.
- The significance was set at $p<0.05$.

COLOUR PLATE 1

Fig 1 - 2% Lignocaine with 1:200,000 Epinephrine.

Fig 2 -Vibraject Device.

COLOUR PLATE 2

Fig 3 -Vibraject device attached to syringe with short needle.

Fig 4 - Armamentarium for orthodontic extraction of maxillary premolar using conventional injection technique.

COLOUR PLATE 3

Fig 5 - Armamentarium for orthodontic extraction of maxillary premolar using Vibraject injection technique.

Fig 6 - Infraorbital Nerve Block Using Conventional Injection technique.

COLOUR PLATE 4

Fig 7 -Greater palatine Nerve Block Using Conventional Injection technique.

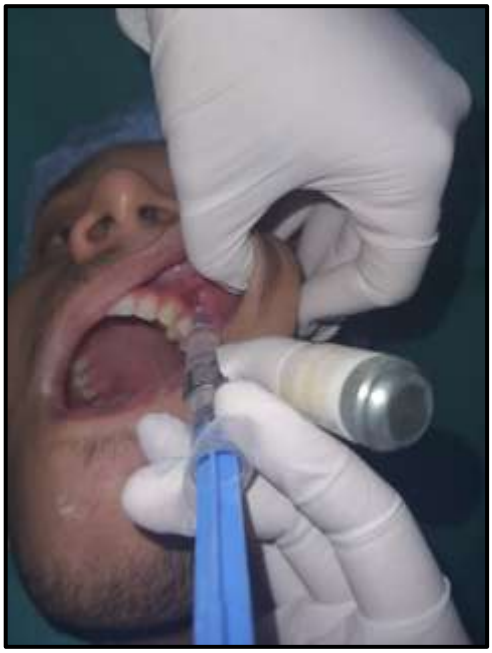


Fig 8 - Infraorbital Nerve Block Using Vibraject Injection technique.

COLOUR PALATE 5

Fig 9 - Greater palatine Nerve Block Using Vibraject Injection technique.

RESULTS

The present study was conducted to assess the difference between Vibraject and conventional technique towards pain perception while insertion of the needle and deposition of anaesthetic solution. Unpaired t-test was applied to assess the difference between VAS scores. Mann-Whitney U test was applied to assess the difference between Wong-Baker scale scores. The results obtained are as follows:

Table no.1

The table represents the distribution of patients according to the gender in the present study. A total of 18 males accounting to 52.94% and 16 females accounting to 47.05% were present in the study.

Graph no.1

The pie chart represents the distribution of patients in the study according to gender. Number of males and females in the study were almost same.

Table no.2

The table represents the distribution of patients according to age group in the present study. Seven patients accounting to 20.58% belonged to 14-16 years age group, six patients accounting to 17.64% belonged to 17-19 years age group, eight patients accounting to 23.52% belonged to 20-22 years of age group and thirteen patients accounting to 38.23% belonged to 23-25 years of age group. Maximum patients were from 23-25 years age group followed by 20-22 years, 14-16 years and 17-19 years.

Graph no.2

The pie chart represents the distribution of patients in the study according to the age groups. The maximum patients were present in 23-25 age groups which were followed by 20-22 years, 17-19 years and least in 14-16 years age group.

Table no.3

The table represents the mean values of Visual Analogue Scale (VAS) scores for pain perception in Group A while insertion of the needle for administering local anaesthesia. The mean pain score was 3.76 with a minimum of score 1 and maximum of score 6 reported by the patients in the group. In case of pain perception during deposition of local anaesthetic solution, the mean VAS score was 4.76 with a minimum of 2 and maximum of 8 score.

Table no.4

The table represents the mean values of Visual Analogue Scale (VAS) scores for pain perception in Group B while insertion of the needle for administering local

anaesthesia. The mean pain score was 7.03 with a minimum of score 4 and maximum of score 10 reported by the patients in the group. In case of pain perception during deposition of local anaesthetic solution, the mean VAS score was 7.82 with a minimum of 6 and maximum of 10 score.

Graph no.3

The bar diagram represents the pain perception associated with Vibraject and conventional technique while insertion of the needle. Technique is presented on x-axis and the pain perception is presented on y-axis. The pain perception can be seen higher among the conventional technique as compared to Vibraject.

Graph no.4

The bar diagram represents the pain perception associated with Vibraject and conventional technique during deposition of anaesthetic solution. The technique is presented on x-axis and the pain perception is presented on y-axis. The pain perception can be seen higher among the conventional technique as compared to Vibraject.

Table no.5

The table represents the distribution of patients in Group A based on the Wong-Baker score reported for pain perception during insertion of the needle while administering local anaesthesia. Score 0 was reported by 2 (5.9%) patients, score 2 was reported by 5 (14.7%) patients, score 4 by 14 (41.2%) patients, score 6 by 12 (35.3%) patients, and score 8 by 1 (2.9%) patient. None of the patients in this group reported score of 10 for pain perception.

Table no.6

The table represents the distribution of patients in Group A based on the Wong-Baker score reported for pain perception during deposition of local anaesthetic solution. None of the patients reported with score 0 and 2 in this group. Score 4 was reported by 15 (44.1%) patients, score 6 by 19 (55.9%) patients. Even score 8 and score 10 was not reported by any of the patients in this group for pain perception.

Table no.7

The table represents the distribution of patients in Group B based on the Wong-Baker score reported for pain perception during insertion of the needle while administering local anaesthesia. Score 0, 2 and 4 was not reported by any of the patients in this group. Score 6 was reported by 11 (32.4%) patients, score 8 by 16 (47.1%) patient and score 10 by seven (20.6%) patients. Maximum patients reported with score of 8 followed by 6 and 10.

Table no.8

The table represents the distribution of patients in Group B based on the Wong-Baker score reported for pain perception during deposition of local anaesthetic solution. None of the patients reported with score 0 and 2 and 4 in this group. Score 6 was reported by five (14.7%) patients, score 8 by 13 (38.2%) patients and score 10 by 16 (47.1%) patients. Maximum patients reported score 10 followed by 8 and 6.

Graph no.5

The bar diagram represents the distribution of patients as per their response to pain perception when measured through Wong-Baker scale. The scores from 0 to 10

are presented on x-axis and percentage of patients responding to the scores on y-axis. The percentage of patients are presented to be highest for score 6 followed by 4, 2 and 10.

Graph no.6

The bar diagram represents the distribution of patients as per their response to pain perception when measured through Wong-Baker scale. The scores from 0 to 10 are presented on x-axis and percentage of patients responding to the scores on y-axis. The percentage of patients are presented to be highest for score 6 followed by 4, followed by others.

Table no.9

The table represents the difference in the VAS scores between Group A and Group B for needle insertion and anaesthesia deposition. Unpaired t-test was applied to assess the difference between the two groups and it was found that there was statistically significant difference in VAS scores between Group A (Vibraject) and Group B (Conventional technique) while insertion of needle. The difference between the score was 3.26 with $t=9.07$ and $p<0.0001$ for pain perception during the deposition of anaesthetic solution, the difference between the two groups was also found to be statistically significant with a mean difference of 3.05 in VAS scores, $t=11.10$ and $p<0.0001$. The pain perception was significantly less in patients who were administered local anaesthesia with Vibraject as compared to conventional technique.

Table no.10

The table represents the difference in the Wong-Baker scores between Group A and Group B for needle insertion. Mann-Whitney U test was applied to assess the difference between the two groups and it was found that there was statistically significant difference in Wong-Baker scores between Group A (Vibraject) and Group B (Conventional technique) while insertion of needle with Mann-Whitney U value of 85.00 and $p<0.0001$. The pain perception in patients administered with conventional technique had significantly higher scores than the Vibraject technique.

Table no.11

The table represents the difference in the Wong-Baker scores between Group A and Group B while anaesthetic solution deposition. Mann-Whitney U test was applied to assess the difference between the two groups and it was found that there was statistically significant difference in Wong-Baker scores between Group A (Vibraject) and Group B (Conventional technique) while local anaesthesia deposition with Mann-Whitney U value of 47.50 and $p<0.0001$. The pain perception in patients administered with conventional technique had significantly higher scores than the Vibraject technique.

Overall, use of Vibraject showed significantly less pain perception as compared to conventional technique during needle insertion as well as during local anaesthetic solution deposition. The lower scores of pain were reported by the patients in Vibraject group while the patients in conventional technique group reported higher scores of pain. Thus null hypothesis is rejected and there is significant difference between vibraject injection technique and conventional injection technique for delivering local anaesthesia.

DISCUSSION

Perception towards dental pain is influenced by various factors like gender, the speed of injecting local anaesthesia, force of anaesthetic flow, fear towards the numbness sensation, sharp objects like needles and anxiety within the patient before injecting anaesthesia. It has been reported in the study conducted by Milgrom that, 25% of the patients avoid going to the dentist because of the fear associated with dental injection. Among these there exists certain percentage of patients who have fear towards dental injection because of the past traumatic experience in the dental clinic.[82] The fear associated with dental treatment unfortunately becomes a hurdle towards long term dental and in turn general health for the patients.

Thus, various studies have been reported in the literatures that aimed at reducing the pain associated with dental anaesthetic procedure in both adults as well as children. Few clinicians shake the lip of the patients while delivering local anaesthetic injection to reduce pain perception for the patients. This technique has been reported to be effective in reducing pain and it work on the principle of Gate Control Theory which is described by Melzack and Wall[83] in the year 1962. According to this theory, the lip shaking activates the nerves hat sends a non painful impulse to the brain while the needle prick sends painful impulse to the brain. The impulses generated by lip shaking travel faster to the brain over the needle prick impulse and thus it reduced the pain felt during injection technique.

There are certain mechanical devices that have also been reported to show a positive effect in reduction of pain during anaesthetic procedure. These mechanical adjuncts that can be used are classified into intraosseous techniques, vibratactile devices and needleless or jet injections.[84]

Other techniques which have been in use are use of warm buffered local anaesthesia, application of topical local anaesthesia before injecting the anaesthesia via needle and administration of conscious sedations through medications like nitrous oxide or benzodiazepine which is a short acting.[85]The intraosseous devices reported in the literature are X-tip and Stabident by Dentsply Maillefer, Tulsa, OK and Fairfax Dental, Miami, FL respectively. These devices are especially useful in the cases of hot tooth wherein local infiltration or a traditional nerve block does not cause the required numbness around the tooth. These techniques enable intraosseous injection directly into the bone. Both the devices have shown comparable onset of action, increase in

heart rate and duration of anaesthesia. The needle is inserted through the attached gingiva and directed towards the bone. The technique has not been in use largely because of the limitation that, the intraosseous devices cannot be used in the patients with periodontal diseases and in the areas interproximal space is minimal.[86]Moreover, these injections have shown less success in providing profound anaesthesia for mandibular 1st molars with a success rate of 75%. Additionally, these devices are invasive and require gingival followed by cortical and alveolar bone perforation.[87]

The needleless jet injection system was dated back to 1866 and was introduced first for immunization and vaccinations. Later the use became evident in dentistry with further modifications in the techniques. This technique provides rapid onset of anaesthesia without the fear of needle stick injury. But they too come with disadvantages of pressure sensation felt by the patient during anaesthesia administration, increase in the chance of hematoma formation, loud noise associated with the device which can be a major disadvantage in case of paediatric patients as it may increase the fear amongst them toward the procedure and equivocal pulpal anaesthesia.[88]

With regards to the use of vibratactile devices for injecting local anaesthesia, four devices have been in use by the practitioners namely, Wand by Milestone Scientific, Livingston, NJ; Accupal by Advance Design, Little Rock, AR; Vibe by Bing Innovations, Crystal Lake, IL and the forth being Vibraject by Irvine, CA.[84,89]The Wand device is a computer controlled delivery system for local anaesthesia. It performs all the scopes as that of traditional local anaesthesia administration done by the dentists. The anaesthesia flow is controlled by computer

via a foot pedal allowing a painless injection to the patients.[90] certain disadvantages associated with Wand system is the cost of this device. The cost of Wand is not compatible with the cost of traditional injection needles. Moreover, the Wand requires a complete set that includes handpieces, disposable needles, injection tubings as well as anaesthetic cartridge holders which adds on to the pre-existing high cost of the device. The medical waste generated with this device is more compared to the traditional syringes.[84]

DentalVibe is a device that is attached to the mucosa while the local anaesthesia is being administered. The devices vibrated the mucosa and thus the clinician has to hold the device touching the mucosa with one hand and perform the administration of local anaesthesia procedure with other hand. The vibrations generated, works through Gate Control theory and reduces the pain perception among patients. Another device which has been reported in the literature is Accupal. This device is a palatal injection system and is a cordless device. The vibrations produced work via Gate Control theory to minimize pain perception. The non-nociceptive mechanoreceptors are activated by vibrations and these have a lower threshold and inhibitory effect on the nociceptive receptors thereby minimizing perception of pain.

Another device which is in use by the clinicians is Vibraject. This device is attached to the conventional syringes while administrating local anaesthesia. When the device is activated, it causes the injecting needle to vibrate at a frequency of 10,000 cycles per minute. These vibrations help in minimizing pain perception during local anaesthesia procedures. The advantage with this device is it does not require any change in the administrative procedure from that of conventional one. Vibraject

device is lately introduced into the field and thus does not have enough literature to support or confute the effectiveness of this device in reducing pain. The present study used Vibraject device to assess the pain perception using both Visual Analogue Scale and Wong Baker scale and compare it with the conventional technique.

In the present study, the pain was assessed at the time of insertion of needle and during the deposition of local anaesthesia. The mean pain scored obtained by Visual analogue scale during insertion of the needle was found reported to be 3.76 while during the deposition of local anaesthesia it was 4.76 in the patients among whom Vibraject device was used. When the same was assessed in the patients after administrating local anaesthesia through a conventional technique, the pain by visual analogue scale during the time of insertion was 7.03 while it was 7.82 during the deposition of anaesthetic solution. When the pain was noted using Wong-baker scale, the maximum patients reported to have a score of 4 followed by 6 indicating little more to even more pain by using of Vibraject device while the same that is 44.1% and 55.9% patients reported with score 4 and 6 during deposition of anaesthetic solution. In the group administered with conventional technique, the maximum patients accounting to 47.1% and 32.4% reported score 8 and 6 respectively during insertion of needle and 47.1% and 38.2% with score 10 and 8 respectively during anaesthetic solution deposition indicating worst pain.

The difference in the pain perception in the present study between the two techniques assessed by Visual analogue scale as well as Wong-Baker scale was found to be significant with Vibraject device showing better minimization of pain over conventional technique during insertion of needle. A study reports the responses of

patients after administering local anaesthesia using Vibraject device.[91] Kosinski T, during his routine practice when used Vibraject device, received a positive response from his patients. Patients reported that they did not feel any pain while needle insertion and had a great experience. The discomfort was neither felt in infiltration nor in blocks including palatal nerve blocks. The results of the present study were in accordance with the study results demonstrated by Chaudhry K et al[36] with mean score of 51.50 using visual analogue scale of 1-100 in the patients administered with conventional technique while it was 36.5 in the patients administered local anaesthesia using Vibraject. Similar was noted with the pain scoring using Wong Baker scale. The score for conventional technique was 3.05 while it was 2.25 for the Vibraject group. For both the scales the difference between the techniques was reported to be significant with Vibraject being superior in minimizing pain.

A verbal descriptor scale was used to assess the signs of discomfort and pain of patients while insertion and deposition of local anaesthesia in Chandrasekaran J et al[33] study and provided a supporting a result to that of the present study with a significant difference between the conventional technique and use of Vibraject in pain minimization. 94.59% of patients reported to have increased pain during needle insertion while using conventional technique over Vibraject. Likewise, 37.83% patients reported increased pain while anaesthetic solution deposition by conventional injection technique, two patients reported a decrease in pain while 21 stated that there was no difference in the pain perception between conventional and Vibraject technique. Report[34] states that Vibraject is effective in patient showing extreme fear towards injection. The hum sound made by the device has a soothing effect on the patients making them relaxed.

Literature report various other vibrating devices used in controlling pain perception while administrating local anaesthesia. One such device is used as a massager and has three vibrating spheres. For inferior alveolar nerve block the device is to be placed on the ramus of mandible or on zygomatic arch on ipsilateral side of injection while in case of maxillary injections the device is applied against zygomatic arch. Nanitsos E et al[92] reported a significant difference between the reporting of pain by administering local anaesthesia through conventional technique and by use of vibrating device for inferior alveolar nerve block but not for infiltrations. It can be noted that along with the action of vibrations on the nerve impulses the vibrating devices also act as a distracter during the local anaesthesia administration procedure thereby providing a synergistic effect for pain minimization.

A contrast was reported in the study conducted by Roeber B et al[93] wherein the assessment was done with respect to disruptive behaviour due to pain, pain intensity and pain behaviour through dentist's perspective. It was noted in their study that around 28% children presented with disruptive behaviour associated with pain after injecting without the use of Vibraject while it was 26% by the use of Vibraject device. Thus both the groups displayed comparable behaviours related to pain during anaesthesia. Similar was noted with pain intensity reported by the patients. Patients administered with and without Vibraject device reported average pain intensity. Even through the dentist's perception the behaviour of the patient while administering local anaesthesia was found to be same in both the groups. The insignificant results as explained by Roeber B et al[93] was accounted to the fact that, even though Vibraject work on Gates Control theory but the vibrations produced by the device are extremely

small to cause any effect in activation of large nerve fibres in that area for reducing pain perception.

Alike results were also reported by Bhawana et al[80]with no significant difference in the pain intensity by using conventional technique or use of Vibraject device while administering local anaesthesia. The contrast results can be accounted to the type of nerve block given to the patients. In this study, greater palatine nerve block was given to the patients while in the present study infra-orbital along with greater palatine nerve block was given. This study too explained the reason that the vibrations produced by Vibraject are too small to bring activation in the large nerve fibres for minimizing pain perception. Another reason can be because of the injection site. Since palatal mucosa has tough adherence to the underlying periosteum, the administration of anaesthetic solution causes tension in the tissues leading to exacerbated pain during deposition that may be slightly higher than during the needle insertion.

The results of the present study were not in accordance with Saijo M et al[37] study that assessed the difference in pain perception between conventional technique and Vibraject technique. 24.6 was the mean pain score recorded using visual analogue scale among patients receiving injection through Vibraject device attached while it was 22.4 when using conventional technique. While deposition of anaesthesia, the pain score recorded was 26.2 when using Vibraject device and 22.7 when using conventional injection technique. During both, the insertion of needle and deposition of anaesthetic solution the difference in the pain perception was reported to be insignificant with Vibraject better in controlling pain among patients. Though not

significant but the advantages of using Vibraject was reported as a computer controlled system with slowest injection rate and use of fine 33 gauge needle for anaesthesia deposition.

The use of vibrating devices is not restricted to the administration of local anaesthesia but has also been studied in the branch of orthodontics. A significant difference was noted in the pain perception among patients provided with a vibrating device that as to be held in the mouth between the maxillary and mandibular teeth for 15 minutes immediately after placement of archwires. The group with use of Vibrating devices had less pain perceived than the group who did not receive any vibrating device. It was also noted that the vibratory devices worsened if used when pain was already present. The pain in such cases would become intolerable to the patients thus stressing the use of the device immediately after archwire placements.[94]

Thus, literature presents information on the Vibraject device which supports its use by few researchers also confutes its use as a device for reducing pain perception while administrating local anaesthesia. The variation in the results can be a consequence of difference in the sample size across the studies. Many of the studies have been conducted as a pilot study and thus have a smaller sample size. Apart from this, the assessment tools used in the studies differ. Few have used Visual analogue scale, Wong Baker scale while few have used verbal expression of the pain perception. Moreover, the samples on which the studies have been conducted are not same. There are studies that are conducted among children while there are few studies conducted among adults accounting to further variations in the results. The methodological part also contributes to the variations observed in the studies. It was

noted that, few studies have made use of headphones among patients to limit the sound of 'hum' associated with the device that itself has a calming effect. Along with this, patients were also blindfolded to restrict the bias in reporting pain perception after visualizing the use of device in a particular site. Further variation can be accounted by the site if injection chosen, the palatal tissues being more tensed and attachment to the periosteum may show difference in the pain perception than the inferior alveolar nerve block.

Overall, the study provides a useful data in deciding the use of Vibraject device for minimizing the pain perception among patients during needle insertion as well as local anaesthetic solution deposition. The vibratory action of the device activates the large nerve impulses thereby limiting the pain response as supported by the Gates Control theory.

SUMMARY

Pain perception becomes one of the hurdles in dental treatment for the patients. The feeling of needle being penetrated into the mucosa has a negative psychological impact on many patients. When it comes to the blocks administered for anaesthetizing the oral tissues, the maxillary blocks and infiltrations especially palatal report to be more painful over mandibular blocks and infiltrations. The tissues of palatal mucosa are tightly attached to underlying periosteum. There is very limited space between the palatal tissue and palatal bone and thus when anaesthetic solution is injected in this region it creates excessive pressure as there is no space for the solution to spread easily because of the resilient tissues. Various techniques of administrating local anaesthesia and advancements in devices have been reported which can be attached to the syringe in order to limit injection associated pain. Vibraject is one of the device attached to the syringes. It consists of a clip bracket which it attached near the syringe barrel and provides attachment arms for stable

grasp to the clinicians. Since the literature is sparse with regard to this newer device the present study was conducted to evaluate the effectiveness of Vibraject injection technique in patients undergoing extraction of bilateral premolar for orthodontic treatment.

A total of 34 patients falling between 14-25 years requiring bilateral maxillary premolar extractions for orthodontic purpose were included in the present study with 68 sites. Group A patients were given Vibraject injection technique for delivering local anaesthesia on one side while Group B patients were given conventional injection technique for delivering local anaesthesia on contra-lateral side. It was a split mouth study and randomization was done using computer generated randomization method. Clinical parameters assessed were pain using Sensitivity Visual Analogue Scale and Wong-Baker FACES Pain Rating Scale. Pain on needle insertion was noted for every patient using Visual Analogue Scale (VAS) and Wong-Baker Scale. Pain during deposition of local anaesthesia was defined as pain described by the patient on Visual Analogue Scale (VAS) during deposition of the solution and not on the needle- prick and also on Wong-Baker Scale. Analysis of the data was done using unpaired t-test and Mann-Whitney U test.

The results showed that there was statistically significant difference in VAS scores between Group A (Vibraject) and Group B (Conventional technique) while insertion of needle as well as during deposition of local anaesthetic solution. A statistically significant difference in Wong-Baker scores was also found between Group A (Vibraject) and Group B (Conventional technique) while needle insertion and local anaesthesia deposition.

The study concluded that, use of Vibraject significantly reduces pain perception in the patients undergoing administration of local anaesthesia. The perception is significantly less in Vibraject at the time of insertion of needle as well as during deposition of local anaesthetic solution and thus can be used in patients with dental anxiety and in children along with routine patients.

CONCLUSION

Within the limitations of the study it can be concluded that use of Vibraject significantly reduces pain perception in the patients undergoing administration of local anaesthesia. The perception is significantly less in Vibraject at the time of insertion of needle as well as during deposition of local anaesthetic solution. Use of Vibraject can be important especially in patients having anxiety towards dental treatment as well as in paediatric patients.

Limitations of the study include,

- The participants were not assessed for their pre-injection dental anxiety and thus there may be few patients who would have perceived greater pain due to anxiety and fear.
- The vibrations of the device can be felt by the patients within the tissues which may have created a bias in their responses.

Future recommendations,

- Addition of pre-injection apprehension scores can be useful in determining pain perception among anxious patients.
- Studies on larger sample size are recommended.

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TABLES AND GRAPHS

Table no.1- Distribution of patients according to gender

Gender	Number	Percentage
Males	18	52.94
Females	16	47.05
Total	34	100.00

Table no.2- Distribution of patients according to age group

Age group	Number	Percentage
14-16years	7	20.58
17-19 years	6	17.64
20-22 years	8	23.52
23-25 years	13	38.23
Total	34	100.00

Table no.3- Descriptive data on pain in Group A measured by VAS scale

	N	Minimum	Maximum	Mean	Std. Deviation
Pain on Insertion of needle	34	1	6	3.76	1.208
Pain during Deposition of LA solution	34	2	8	4.76	1.208

Table no.4- Descriptive data on pain in Group B measured by VAS scale

	N	Minimum	Maximum	Mean	Std. Deviation
Pain on Insertion of needle	34	4	10	7.03	1.714
Pain during Deposition of LA solution	34	6	10	7.82	1.058

Table no.5- Descriptive data on pain on insertion of needle in Group A measured by Wong-Baker scale

Scores	Frequency	Percentage
0	2	5.9
2	5	14.7
4	14	41.2
6	12	35.3
8	1	2.9
10	0	0.0
Total	34	100.0

Table no.6- Descriptive data on pain during deposition of LA solution in Group A measured by Wong-Baker scale

Scores	Frequency	Percentage
0	0	0.0
2	0	0.0
4	15	44.1
6	19	55.9
8	0	0.0
10	0	0.0
Total	34	100.0

Table no.7- Descriptive data on pain during insertion of needle in Group B measured by Wong-Baker scale

Scores	Frequency	Percentage
0	0	0.0
2	0	0.0
4	0	0.0
6	11	32.4
8	16	47.1
10	7	20.6
Total	34	100.0

Table no.8- Descriptive data on pain during deposition of LA solution in Group B measured by Wong-Baker scale

Scores	Frequency	Percentage
0	0	0.0
2	0	0.0
4	0	0.0
6	5	14.7
8	13	38.2
10	16	47.1
Total	34	100.0

Table no.9- Comparison of pain during insertion of needle and deposition of LA solution amongst patients administered with Vibraject and conventional technique as measured by VAS scale

Pain	Groups	Mean	Mean difference	t-value	Significance (p)
Pain on Insertion of needle	Vibraject	3.76	3.26	9.07	**<0.0001***
	Conventional technique	7.03			
Pain during Deposition of LA solution	Vibraject	4.76	3.05	11.10	**<0.0001***
	Conventional technique	7.82			

*Significance at p<0.05

A significant difference was observed between the groups with respect to pain during insertion and deposition of local anaesthesia. A significantly less pain was felt with Vibraject use.

Table no.10- Comparison of pain during insertion of needle amongst patients administered with Vibraject and conventional technique as measured by Wong-Baker scale

Scores	Vibraject (n)	Conventional technique(n)	Mann-Whitney U test	Significance (p)
0	2	0	85.00	**<0.0001***
2	5	0		
4	14	0		
6	12	11		
8	1	16		
10	0	7		

*Significance at p<0.05

A significant difference was observed between the two groups with respect to pain perceived during insertion of needle for local anaesthesia. Vibraject technique showed significantly less pain as compared to conventional technique.

Table no.11- Comparison of pain during deposition of LA solution amongst patients administered with Vibraject and conventional technique as measured by Wong-Baker scale

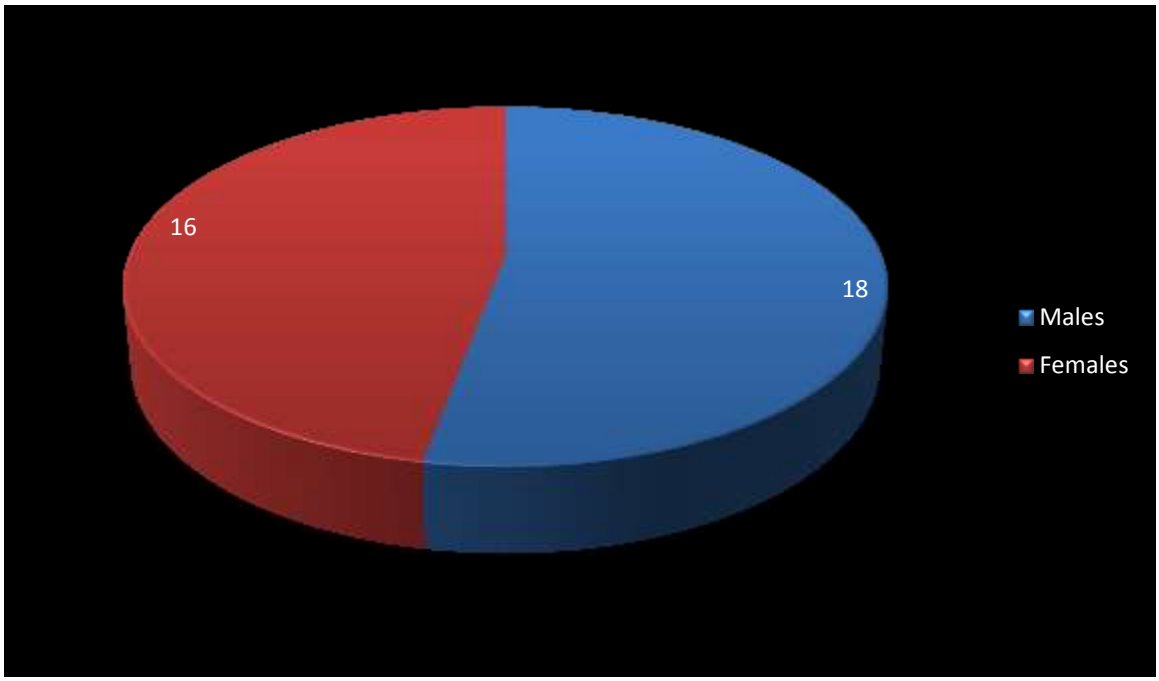
Scores	Vibraject (n)	Conventional technique(n)	Mann-Whitney U test	Significance (p)
0	0	0	47.50	**<0.0001***
2	0	0		
4	15	0		
6	19	5		
8	0	13		
10	0	16		

*Significance at $p<0.05$

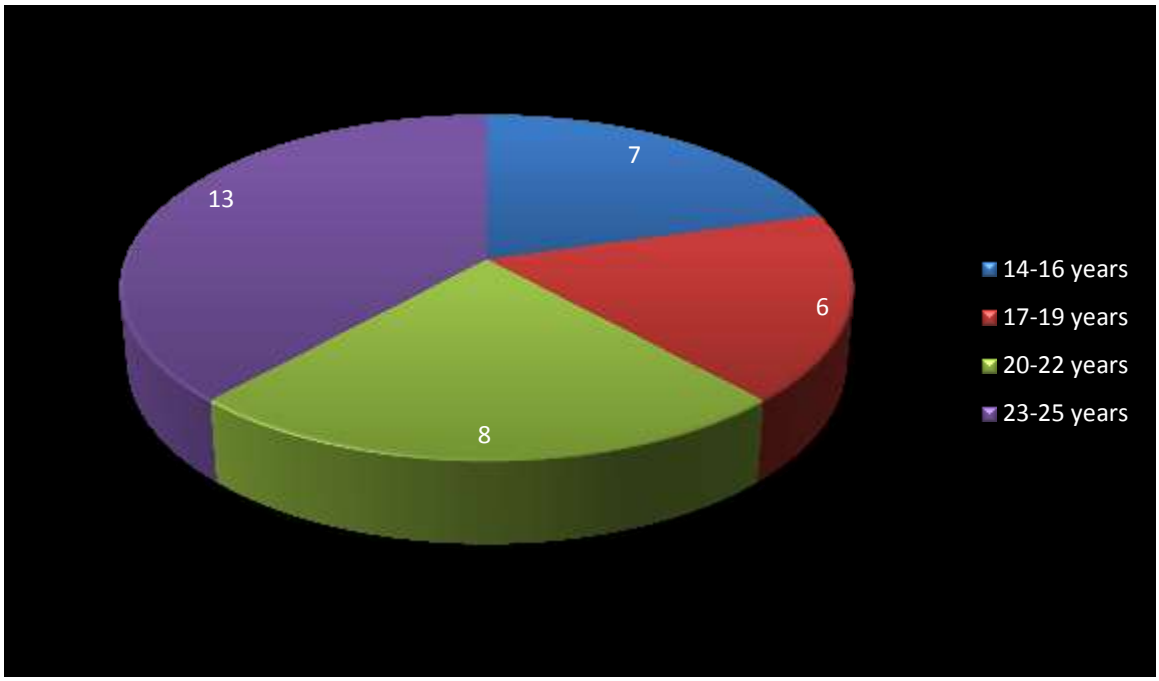
A significant difference was observed between the two groups with respect to pain perceived during deposition of local anaesthesia. Vibraject technique showed significantly less pain as compared to conventional technique.

GRAPHS

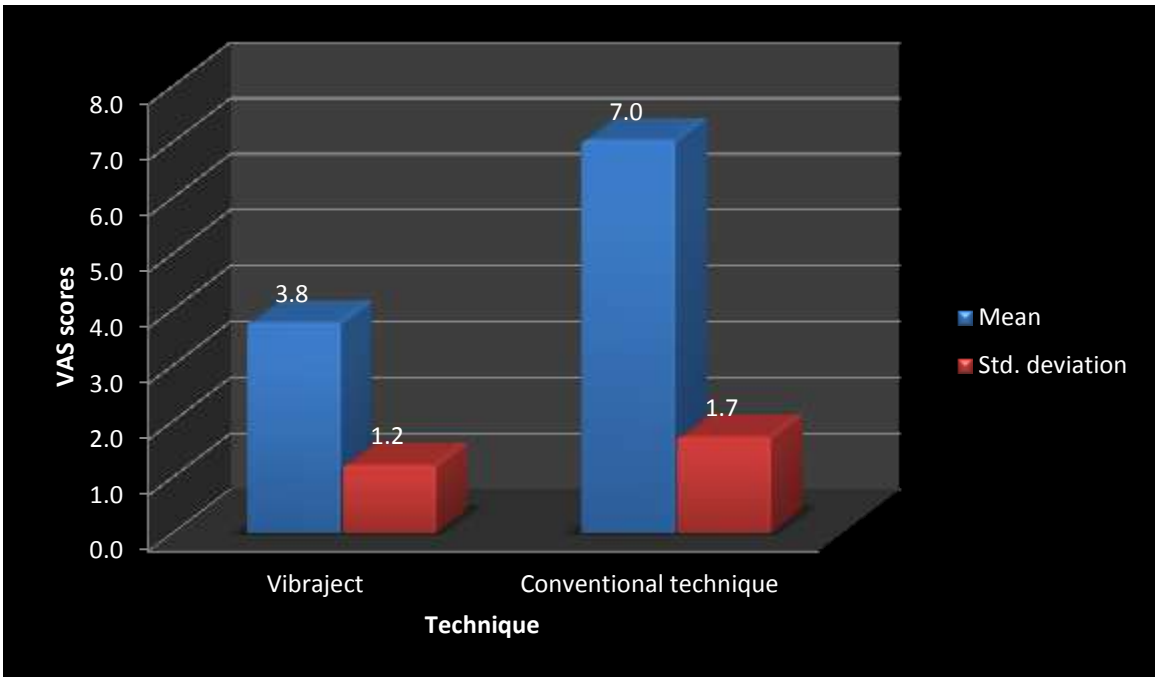
Graph no.1- Pie chart representing distribution of patients according to gender



Graph no.2- Pie chart representing distribution of patients according to age group



Graph no.3- Bar diagram representing pain perception during insertion of needle in Vibraject and Conventional technique group measured by VAS scale



Graph no.4- Bar diagram representing pain perception during deposition of LA solution during Vibraject and Conventional technique group measured by VAS scale

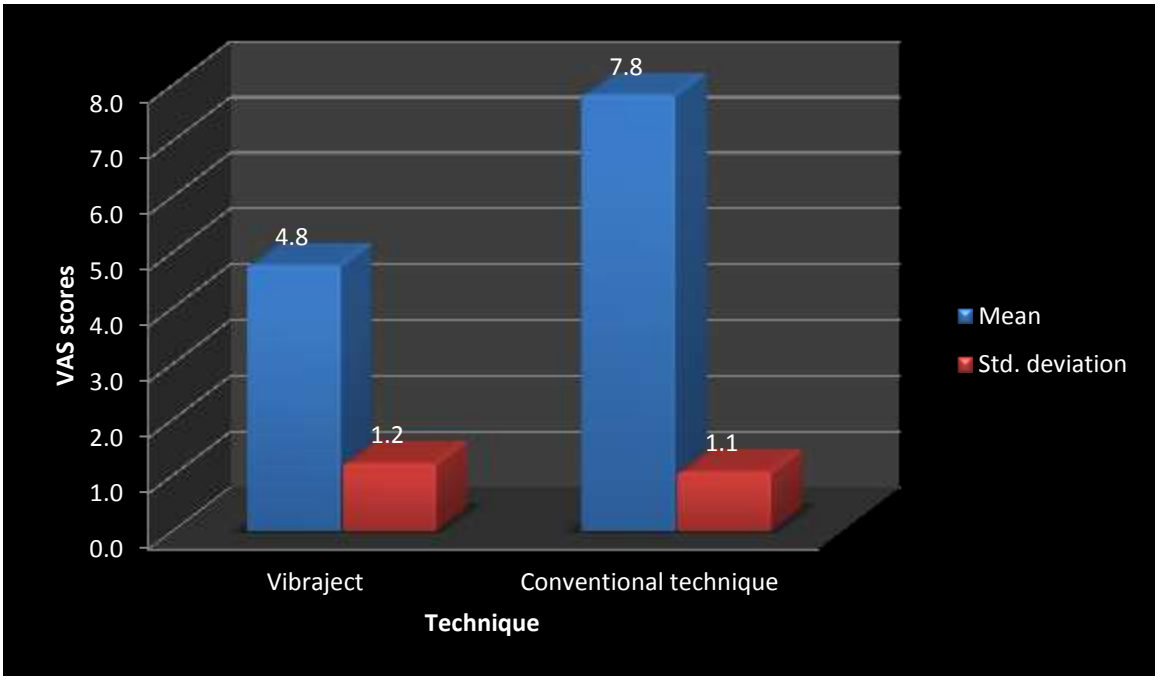


Table no.5- Bar diagram representing pain perception during insertion of needle as measured by Wong-Baker scale in Vibraject and Conventional technique group

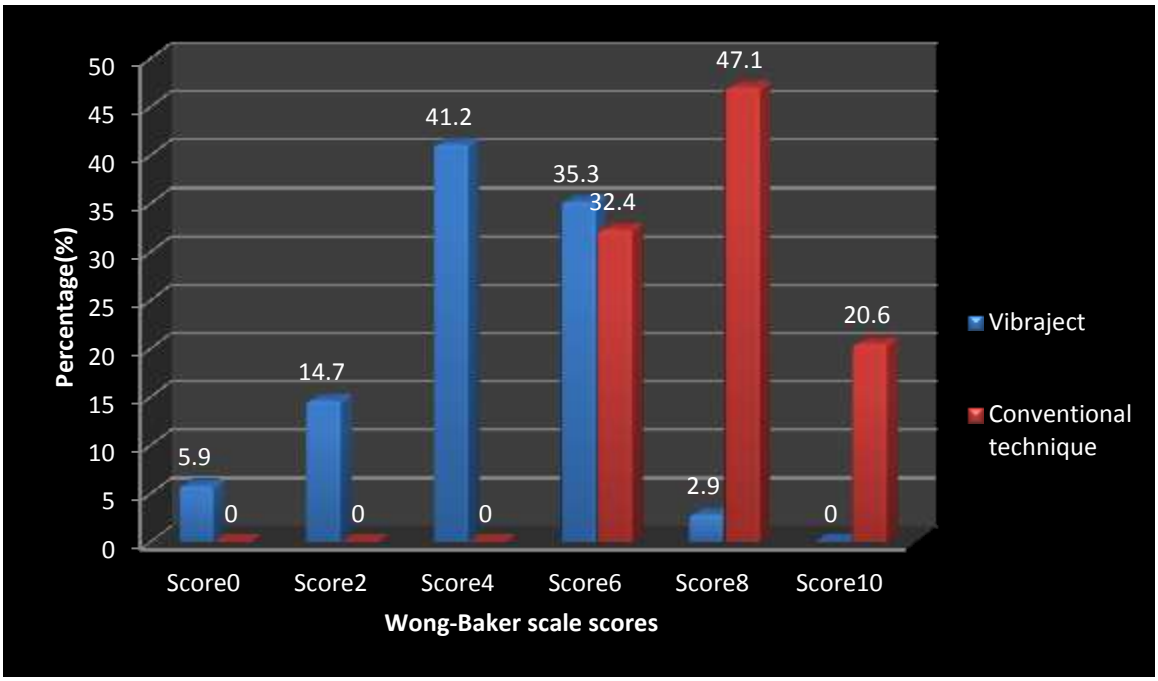
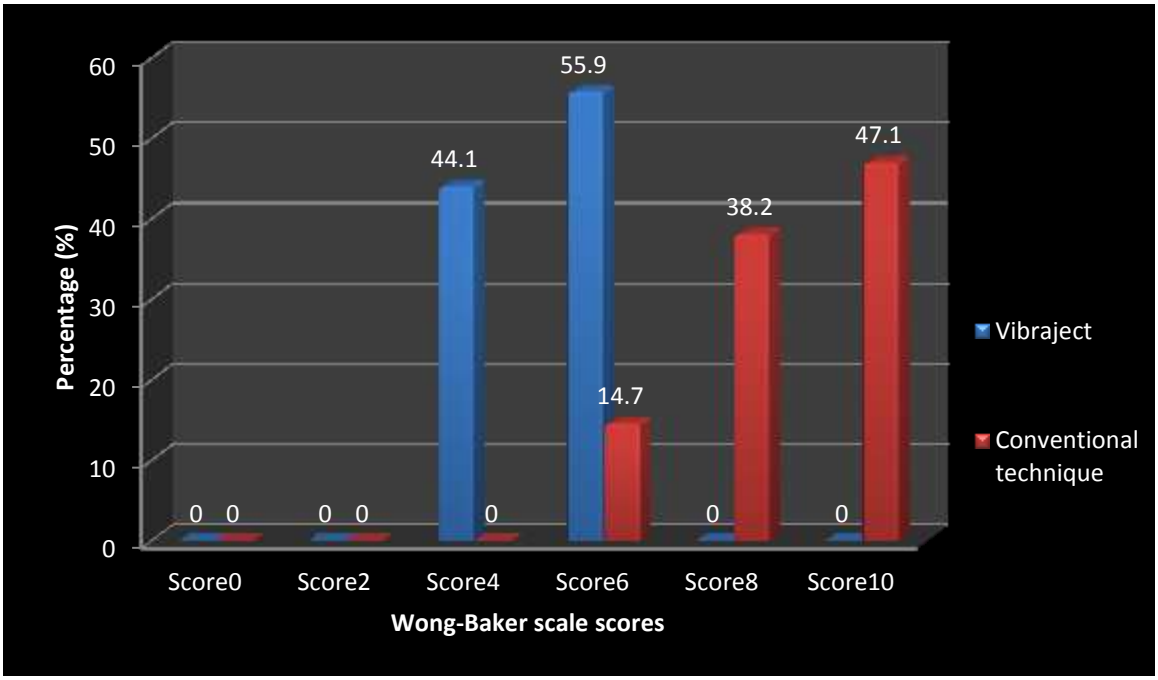


Table no.6- Bar diagram representing pain perception during deposition of LA solution as measured by Wong-Baker scale in Vibraject and Conventional technique group



ANNEXURE- I

CASE HISTORY PROFORMA

Case number- Date-

Name- Age/Sex-

Registration No- Address- Education- Occupation- Chief Complaint-

History of present illness –

Past Medical History-

Past Dental History-

Drug Allergy

History- Family

History

Personal History-

- Diet
- Oral habits
- Sleep
- Oral hygiene Examination-

Extra-oral examination:

- Facial Symmetry
- TMJ
- Lymph nodes

Intra-oral Examination:

- Teeth present
- Missing teeth
- Occlusion
- Caries/attrition/abrasion/erosion/abfraction
- Others

Diagnosis-

Radiographic investigations:

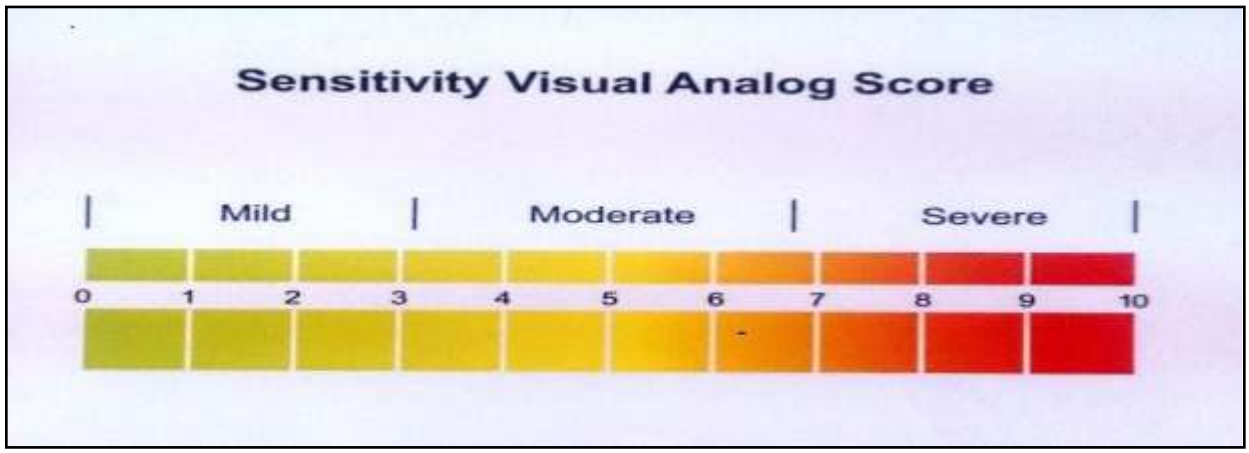
Other investigations:

Advice:

-

ANNEXURE - II

ASSESSMENT FORM



ANNEXURE-III

INFORMED CONSENT FORM

(Confidential)

"Evaluation of effectiveness of Vibraject injection technique in patients undergoing orthodontic extraction of bilateral maxillary premolar –

A prospective split mouth study"

वैयक्तीक माहिती

रूग्णाचे नाव :
वय/लिंग :
पत्ता :

दिनांक :

मोबाईल नंबर :

मी कबूल करतो की डॉक्टरांनी मला या संशोधन प्रकल्पाबद्दल समाधानकारक माहिती दिली आहे. मी माझ्या एक्स-रे, छायाचित्रे, इंप्रेशन आणि आवश्यकतेनुसार अन्य तपासण्या करण्यास सहमत आहे. मी या प्रकल्पात भाग घेण्यास सहमती देतो आणि या चाचणीच्या कालावधीत कोणतेही अन्य प्रकल्प एकत्रित करणार नाही. मला डेन्टल हॉस्पिटल किंवा इतर ठिकाणी दिलेल्या भेटीची तारीख आणि वेळ सांगितली आहे. मी डॉक्टर आणि पॅरामेडिकल कर्मचा-यांना सर्व बाबतीत सहकार्य करेल. या अभ्यासात मी माझ्या सहभागाचे निकाल प्रकाशित करण्यास परवानगी देतो. मला कोणतीही नुकसान भरपाई दिली जाणार नाही. असे करण्यासाठी कोणतेही कारण न देता मला कोणत्याही वेळी या संशोधन प्रकल्पातून बाहेर पडण्याचा अधिकार मिळालेला आहे. मी या अन्वये केलेल्या चाचणीत सहभागासाठी माझी संमती नोंदवित आहे.

_____	_____	_____	_____
१) रूग्णाचे नाव	स्वाक्षरी	तारीख	वेळ
_____	_____	_____	_____
२) साक्षीदाराचे नाव	स्वाक्षरी	तारीख	वेळ
_____	_____	_____	_____
३) डॉक्टरचे नाव	स्वाक्षरी	तारीख	वेळ

Master Sheet

			Group A				Group B			
Sr.No	**Age**	**Gender**	**Pain on insestion**		**Pain during deposition of LA**		**Pain on insestion**		**Pain during deposition of LA**	
			VAS	Wong Baker	VAS	Wong Baker	VAS	Wong Baker	VAS	Wong Baker
1	14	M	4	6	5	6	7	8	7	6
2	18	F	3	4	6	6	6	8	6	6
3	25	F	5	4	6	4	8	8	8	8
4	20	M	4	6	4	4	9	8	9	10
5	24	F	3	4	5	6	10	8	10	10
6	20	F	5	6	3	4	5	6	9	8
7	23	M	4	2	3	4	4	6	8	8
8	18	F	5	4	5	6	6	6	7	8
9	21	M	3	6	4	4	4	6	6	6
10	23	M	2	4	4	6	7	6	8	8
11	24	F	4	6	6	4	8	8	7	10
12	25	M	3	4	4	6	5	6	8	10
13	18	F	2	4	4	6	7	6	8	10
14	15	M	6	6	5	4	8	8	6	8
15	16	F	4	2	5	6	9	6	8	8
16	22	F	3	2	5	6	10	10	10	10
17	24	F	5	4	4	4	5	6	8	8
18	16	M	4	6	5	6	7	6	8	10
19	15	F	3	4	4	6	6	8	8	8
20	22	M	6	6	7	6	6	8	9	10
21	23	F	5	8	8	6	8	8	7	6
22	14	M	4	4	4	6	7	10	8	6
23	20	M	5	4	6	6	9	10	7	8
24	25	M	4	6	5	6	7	10	8	8
25	22	F	3	4	5	4	7	10	8	10
26	24	M	3	4	2	4	8	8	7	10
27	17	F	5	6	5	4	5	8	8	8
28	21	M	3	2	5	4	7	8	9	10
29	18	F	1	0	3	6	6	6	7	10
30	23	M	2	0	4	4	5	8	7	10
31	19	F	4	2	4	4	6	8	8	8
32	14	M	2	4	5	6	7	8	6	10
33	23	M	4	6	6	6	10	10	9	10
34	25	M	5	6	6	4	10	10	9	10