

**COMPARISON OF AUDIO-VISUAL AND VIRTUAL REALITY
GOGGLE DISTRACTION TECHNIQUES IN MANAGING DENTAL
ANXIETY AND PAIN IN PEDIATRIC DENTAL PATIENTS - A
RANDOMIZED CONTROLLED CLINICAL TRIAL.**

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CONTENTS



Chapter no.	TITLES	PAGE NO.
1	INTRODUCTION	1
2	AIM AND OBJECTIVES	4
3	REVIEW OF LITERATURE	5
4	MATERIALS AND METHOD	26
5	RESULTS	42
6	DISCUSSION	55
7	SUMMARY AND CONCLUSION	68
8	BIBLIOGRAPHY	71
9	TABLES AND GRAPHS	i-xi
10	ANNEXURES	
	1. Consent form	xi
	2. SCARED questionnaire	xv
	3. Case record form	xviii
	4. Venham's Picture test	xxii
	5. Venham's clinical anxiety rating scale	xxiii
	6. Wong Baker faces rating scale.	xxiv
	7. Master chart	

LIST OF COLOUR PLATES



PLATE NO.	TITLES	PAGE NO.
I	Instruments – diagnostic and restorative	33
II	Materials and Pulse oxymeter	34
III	Camera and AV set-up	35
IV	VR goggles	36
V	Representative IOPA of patients	37
VI	Representative of treatment session without any distraction	38
VII	Representative of treatment session with AV distraction	39
VIII	Representative of treatment session with VR distraction	40
IX	Administration of VPT and WB scales	41

LIST OF TABLES



Table No.	Description of Tables	Page No.
1	Distribution of children and treatment sequence in groups.	i
2	Descriptive statistics for children characteristics in three study groups	i
3	Descriptive statistics and their comparisons for different parameters before, during and after restoration for group 1 across sessions	ii
4	Descriptive statistics and their comparisons for different parameters before, during and after restoration for group 2 across sessions	iii
5	Descriptive statistics for different parameters before, during and after restoration for group 3 across sessions	iv
6	comparison among the various variables using AV, VR and no distraction	v

LIST OF GRAPHS



Graph No.	Title	Page No.
1	Column chart showing mean age of children in each group	vi
2	Column chart showing distribution of children as per gender in three groups	vi
3	Bar chart showing mean heart rate according to stages and sessions for Group 1	vii
4	Bar chart showing mean VPT according to stages and sessions for Group 1	vii
5	Bar chart showing mean WB according to stages and sessions for Group 1	viii
6	Bar chart showing mean heart rate according to stages and sessions for Group 2	viii
7	Bar chart showing mean VPT according to stages and sessions for Group 2	ix
8	Bar chart showing mean WB according to stages and sessions for Group 2	ix
9	Bar chart showing mean heart rate according to stages and sessions for Group 3	x
10	Bar chart showing mean VPT according to stages and sessions for Group 3	x
11	Bar chart showing mean WB according to stages and sessions for Group 3	xi

LIST OF ABBREVIATIONS



Sr. No.	Short Form	Full Form
1.	AV	Audio-Visual
2.	CDSIS	Computerized delivery system – intra-sulcular
3.	CFSS	Child fear survey schedule
4.	FIS	Facial image scale
5.	FLACC	Face legs activity cry consolability scale
6.	FPS - R	Faces pain scale revised
7.	GR	Global rating
8.	HF- VAS	Heft parker Visual analogue scale
9.	HR	Heart rate
10.	LA	Local anesthetic
11.	MCDAS	Modified child dental anxiety scale
12.	OHI	Oral hygiene index
13.	PFS	Pain faces scale
14.	SCARED	Screen for Child Anxiety Related Disorders
15.	SEM	Sound eye motor
16.	SPO ₂	Oxygen saturation
17.	STAI	State trait anxiety inventory
18.	VAS	Visual analogue scale
19.	VPT	Venham's Picture Test
20.	VR	Virtual reality
21.	VRS	Venham's clinical anxiety rating scale
22.	WB	Wong Baker

INTRODUCTION

Dentistry exposes patients to an environment and particular experiences that trigger a natural response of fear in many people. This might lead to difficulties in persuading patients to accept certain types of treatment. Managing the behavior of pediatric patients requires continuous interaction with the patient and their parents for the purpose of communication. The key aim of any pediatric dentist when managing child patient behavior is to reduce fear and anxiety, along with promoting good dental health and strategies to achieve this.¹

According to Wright et al., all dental health teams should have two main objectives: to carry out dental treatment effectively and efficiently; and to encourage a positive attitude in children. It is important that dentists are able to evaluate anxiety in their patients, in order to identify children who require special care with regard to fear.

Pain control is essential in treating child patients. Unfortunately, an intraoral local anesthesia injection during dental treatment is associated with some level of

pain. Painless injections and relevant behavior management techniques are needed for creating a positive dental experience when treating child patients. Research has shown that approximately 14% of 4- to 11-year-old children are anxious when attending a dental clinic, and their strongest fears are associated with injections. Inadequate measures to help cope with the pain from local anesthesia could lead to a negative dental experience which might develop into dental fear and anxiety and eventually avoidance of dental treatment in the future.

It is essential to identify anxious children at the earliest age possible in order to institute a precocious behavioral treatment. For this purpose, four kinds of anxiety measuring parameters have been used to assess dental anxiety like physiological means, psychological/psychometric means, projective means, and behavioral means.²

Given the need to reduce anxiety and pain in anxious children, many techniques have been developed with this consideration in mind. These management techniques are broadly classified into two main headings. First are the behavioral techniques including the tell-show-do technique, distraction, inspiration, modeling, and also aversive techniques like hand over mouth technique and physical restraints. The second category consists of pharmacologic techniques.³

With the changing attitude of parents and dental professional towards the aversive techniques, non-aversive techniques like distraction are becoming more popular.

Distraction appears to be safe and inexpensive and gives rise to an effective relaxed experience in short painful dental procedure. Distraction operates on the assumption that by shifting a child's focus to something engaging and attractive, his or her capacity to attend to painful stimuli is hindered, thereby reducing pain, distress, and anxiety. Conventional distraction techniques include counting the breath,

listening to music or stories, etc. Distraction techniques in managing anxious children or managing pain in medical and dental settings are generally categorized into active, interactive and passive distraction.⁴

Inter-active distraction requires the cognitive engagement of the child with a distracting stimulus. In passive distraction, the child receives the distracting stimuli from watching TV or listening to music. In active distraction, interactive devices like Audio-visual (AV) eyeglasses, virtual reality that plays movies or videogames at close proximity which blocks the peripheral vision of the child.

The video eyewear may be better distraction than watching video projected on the screen as due to the occlusive eyewear that project the images right in front of the eyes of the user and, blocking out real world's visual and auditory stimuli. The child's attention will be more or less “diverted” from the real world, leaving them less attentive to the real world activities. To be effective, the cognitive behavioral intervention that diverts attention from a stressful stimulus and focuses it onto a more pleasant experience has to be age appropriate and appealing.⁵

Because of the success of distraction techniques in medical settings and in adult patients, many dentists believe that this technique may be successful and fruitful in the management of anxious pediatric dental patients.²

Few studies have been done to compare audiovisual and virtual reality goggle distraction technique on management of dental anxiety and pain in children aged 4-8 years of age. Hence this clinical study was done to compare audiovisual and virtual reality distraction techniques in managing dental anxiety and pain in children.

AIM AND OBJECTIVES

Aim of the study –

To compare audio-visual and virtual reality goggles as distraction techniques in managing dental anxiety and pain in pediatric dental patient.

Objectives –

1. To evaluate the effect of audio-visual distraction technique using chair mounted monitor on dental anxiety and pain in children.
2. To evaluate the effect of virtual reality distraction technique using virtual reality goggles on dental anxiety and pain in children.
3. To compare the effect of audio-visual and virtual reality distraction techniques on dental anxiety and pain in children.

REVIEW OF LITERATURE

The main goal of all dental health teams in pediatric dentistry is to carry out dental treatment effectively and efficiently; and also instill positive attitude in children. Dental anxiety and pain are the main reasons for un-co-operative behavior of the child during dental treatment. With the changing attitude of parents and pediatric dentist, aversive techniques to manage an anxious child have fallen out of favor and distraction in various forms have gained popularity. Distraction is the technique of diverting the patient's attention from what may be perceived as an unpleasant procedure. This distraction can be done through audio, audio-visual or with the recent advances like virtual reality (VR). The VR refers to a human-computer interface that enables the user to interact dynamically with the computer generated environment. This application may be superior to traditional distraction because it offers more immersive images due to the occlusive headsets that project the images right in front of the eyes of the user and, depending on the model used, block out real-world (visual, auditory, or both) stimuli. The VR even combines the audio, visual, and kinesthetic sensory modalities.⁶

Studies are done to study the effect of various distraction techniques on dental anxiety and pain in children, using different measures to assess anxiety and pain, out of which few relevant studies concerning the present study are quoted here.

The review has been categorized under –

- 1) Studies on Dental anxiety and its assessment.
- 2) Studies on Dental pain and its assessment.
- 3) Studies on different techniques of distraction in management of anxiety and pain.

Dental Anxiety and Its Assessment –

Due to anxiety to dental treatment, patients often avoid visiting the dentist until the moment they feel pain or discomfort. Anxious children need to be diagnosed early and this can be achieved with the help of various anxiety measure scales.

Venham L L, Gaulin-Krem E(1979)⁷ developed a self-reported measure to assess situational anxiety for young children. He used stylized cartoon figures (male character) as a stimulus. The cartoon figure portrayed various states of emotional arousal like happiness, fear, sadness and anger. Three studies were conducted after which the final picture test was formed, which contained eight pairs of cartoon figures with varying emotions. The picture test were checked for its validity and reliability in two more studies, in which children were asked to select the picture from each pair with which they could easily relate to. Children as young as 3 yrs were able to use the modified picture test.

Venham L L, Gaulin-Kremer E, Munster E, Bengston-Audia D, Cohan J (1980)⁸ developed an interval rating scale for children's dental anxiety and unco-

operative behavior. The rating scales were 6-point scale used to rate anxiety and un-co-operative behavior of the child. A series of stimuli chosen from video-tapes of 45 sec duration of children undergoing dental treatment were shown to observers in pairs. The observers were asked to produce comparative judgment of each pair. Six segments were chosen for anxiety and six for un-co-operative behavior. Fourteen naïve observers were asked to rate the anxiety and un-co-op-erative behavior and make paired comparison judgments. The results showed that the anxiety rating scale is an interval scale whose neighboring categories are approximately equidistant and gives reliable result.

Hosey M T, Blinkhorn A S (1995)⁹, did a study to evaluate four behavioral scales - The Frankl (F), Houpt (**H**), Visual Analogue (VAS) and Global Rating (**GR**) scales, to assess anxious children during dental treatment. Twenty-nine anxious children aged 3-16 years who had been referred to a specialist clinic were included in the study, and 64 separate visits were recorded on videotape. The videotapes were evaluated by two separate panels of independent observers (judges): a two-judge panel (the two authors) and a four-judge panel (four other dentists). Two-judge panel evaluated the children's behavior on all 64 visits, and the four-judge panel evaluated a 12-visit segment. They found that there was significant correlation between the Global Rating scale and the Visual Analogue, Houpt and Frankl scales.

Rayen R, Muthu M S, Cahndrashekhar Rao R, Sivakumar N (2006)¹⁰, evaluated the physiologic and behavioral measures in relation to dental anxiety during sequential dental visits in children. They selected children who would require minimum 3 visits for the dental treatment. The anxiety was assessed using heart rate, blood pressure, oxygen saturation and co-operative behavior at various different stages during the treatment visits. They came to the conclusion there is a direct co-relation between the

pulse rate and blood pressure during anxiety producing dental situations. Also it was proved that the extent of anxiety a child experiences does not co-relate directly to dental knowledge, but is an amalgamation of personal experiences, family concerns, disease levels and general personality traits.

Guinot Jimeno F, Yuste Bielsa S, Cuadros Fernández C, Lorente Rodríguez A I, Mercadé Bellido M (2011)¹¹, reviewed literature to analyze the objective and subjective scales that are most commonly to assess the degree of anxiety of children in dental setting. Heart rate, blood pressure, electro-dermal activity and cortisol concentrations in saliva were found as objective measures for measuring anxiety in children undergoing dental treatment. Under subjective measures for measuring dental anxiety they categorized Venham's picture test, Children's fear survey schedule- dental subscale, Corah's dental anxiety scale, etc. From the literature the authors found that, Venham's picture test, a pictorial scale, can be easily performed, takes only one or two minutes to perform making it the scale of choice for children. It is reliable and can be understood by a wide age group.

Nigam A G. Marwah N. Goenka P, Chaudhary A(2013)¹², undertook a survey to see the co-relation of general anxiety and dental anxiety in children aged 3-5 years. General anxiety was measured using Pre-school anxiety scale which was filled by parents. Dental anxiety was measured using Venham's picture test and pulse rate. The children were divided into three groups based on general anxiety- mild, moderate and severe. Under the dental anxiety heading the children were grouped as co-operative, tense cooperative and un-co-operative. They concluded that there is positive correlation of general anxiety with dental anxiety which signifies that although dental anxiety can be seen in any child, there is more probability of dental anxiety in children who are generally more anxious.

Agarwal M, Das UM(2013)¹³, did a cross-sectional study to predict dental anxiety using Venham's Picture test and to determine if a relationship exists between prior dental experience and children's dental anxiety. They studied 200 children of 8-10 year age group who were divided in two groups based on the history of dental experience. They concluded that there was no significant difference in the mean Venham's picture test anxiety scores between the children of different age group with or without previous dental experience.

Killinc G, Akay A, Eden E, Sevinc N, Elliidokuz H(2016)¹⁴, did a study to evaluate children's dental anxiety levels at a kindergarten and a dental clinic. Ninety children between 4-6yr of age, enrolled at the kindergarten were selected and their anxiety was assessed using Facial image scale (FIS), Venham's picture test (VPT) and pulse rate in the classroom. 10 children visited a dental clinic a day, where their anxiety was assessed during dental checkup and fluoride varnish application using the above mentioned parameters and also the behavior of the child was assessed using Frankl's behavior rating scale. The mother of the children enrolled in the study were asked to fill a state-trait anxiety inventory (STAI) form 1 and 2, which helped in measuring children's transient and continuous anxiety levels. The results showed statistically significant difference in the pulse rate of the children at the KG and dental clinic. They concluded that children were more anxious at the dental clinic than at the kindergarten.

Dental Pain and its Assessment

One of the reasons for dental anxiety in children is pain caused due to local anesthesia injection. The mere name of an injection can cause the child to become un-co-operative. The pain can be assessed using various scales.

Wong D, Baker C (1988)¹⁵ did a study to compare validity, reliability, and preference of scales to assess pain intensity. 150 hospitalized children were divided in three age groups – 3 to 7 yrs, 8 to 12 yrs, and 13-18 yrs. Pain was assessed using six different scales – the simple descriptive scale, the numeric scale, the faces scale, the glasses scale, the chips scale and the color scale. The results of the study showed that children aged 3-18 yrs clearly preferred the faces scale over the other scales. From the study they came to the following important conclusions – 1) the perception of pain is very individualized, 2) children do not become accustomed to pain, 3) procedures involving needle are considered painful by children and 4) children's pain is not effectively managed in the effort to relieve their pain.

Loggia M, Schweinhardt P, Villemure C, Bushnell M C (2008)¹⁶, reviewed the effects of psychological state on pain perception in the dental environment. It showed that the most important factor affecting the person's pain experience is the individual's psychological state at the time of the experience. They found that the factors which alter the pain perception are attention of the patients, their emotions, social influences and placebo effects. They concluded that it is important for the patient and the clinician to be aware of the psychological effects on pain so that the clinician can create an environment that helps the patient reduce anxiety, improve mood and focus attention away from pain.

Garra G, Singer A J, Taira B R, Chohan J, Cardoz H, Chisena H et al (2010)¹⁷, did an observational study to validate of Wong-Baker FACES pain rating scale in pediatric emergency department patients. The study was done in children aged 8-17 yrs in pediatric emergency department. Children were asked to rate their pain severity on the 6-point ordinal faces scale (Wong Baker scale). They concluded that the Wong-Baker scale had an excellent correlation in older children with acute pain in the emergency department.

Srouji R, Ratnapalan S, And Schneeweiss S (2010)¹⁸, reviewed Pain Assessment and non-pharmacological management in children. He stated that pain perception in children is complex and often difficult to assess. For assessment of pain in children three methods are most commonly used – self-report, behavioral and psychological. Different pain assessment scales are used in different age groups. The author has reviewed scales used for pain assessment in neonates and infants, toddlers, pre-schoolers - by this age most children are able to use 4-5 scale discrimination item scale like Wong Baker faces pain scale, school aged children and adolescents.

Khatri A, Kalra N(2012)¹⁹, did a clinical study to compare two pain scales to assess dental pain in East Delhi children. Children aged 3-14 yrs of age were divided in 3 groups based on age and gender. The children were asked to rate their pain after extraction on Visual analogue scale and Wong-baker pain rating scale, which were presented sequentially. They concluded that Wong-Baker faces pain scale was more sensitive as compared to VAS. They also found that pain threshold tends to decline and pain management becomes more effective with increasing age.

Jain A, Yeluri R, Munshi A K. (2012)²⁰, reviewed pain measurement and assessment in children. He stated that measurement refers to the assignment of a number or value and is commonly associated with the dimension of pain intensity. Assessment describes a more complex process in which information about pain, its meaning, and its effect on the person is considered along with quantitative values. The pain measures were classified as self-report, behavioral, or physiological measures. They found that self-report measures are considered to be the gold-standard method of pain measurement. It requires sufficient cognitive and language development of the child to understand the task of reporting pain. For children with cognitive or developmental impairments, behavioral measures are used. Physiological responses to pain like changes in heart rate,

blood pressure, respiratory rate, oxygen saturation are used in physiological measures. Also they have categorized pain assessment tools according to the age group. They found that Pre-schoolers i.e children around 4 years of age are usually able to use 4-5 item pain discrimination scales. The commonly used scales in this age group are – the child facial coding system (CFCS), poker chip tool, Faces pain scale, the OUCHER scale. They concluded that children present a unique challenge that necessitates consideration at each age, developmental level, cognitive and communication skills, previous pain experiences, and associated beliefs. Selection of appropriate measures requires a thorough understanding of pain, measurement, and child development.

Belcheva A, Shindova M(2014)²¹, studied the pain perception of pediatric patients during cavity preparation with Er-Yag laser and conventional rotary instruments. Ninety 6-12 yr old children were divided in two groups. In each group after cavity preparation and before restoration pain felt by the child was assessed using the universal pain assessment tool, which is a combination of Wong-Baker faces rating scale and the visual analogue scale. They used this scale as it is easy for the children to rate their pain

Chopra R, Jindal G, Sachdev V, Sandhu M (2016)²² did a double-blind crossover study to compare the pain perception in children during inferior alveolar nerve block administration using buffered 2% lidocaine. Thirty 6- 12 year old patients requiring two sessions of operative procedures under local anesthesia were selected. The pain was assessed using Sound, Eye, Motor scale (SEM) and Heft-Parker Visual analogue scale (HP- VAS). An independent observer assessed the child from a distance of 1.5 meters and recorded the pain perception of the child on SEM scale during anesthetic deposition. SEM scale is divided into two categories of comfort and discomfort. The discomfort response is further divided into three subscales: mild pain, moderate pain and severe pain. The patient then reported the pain felt on a self-report

scale, the HP-VAS scale. HP-VAS scale is a 170-mm scale divided into four categories. On this scale, the zero mm point indicated no pain. Mild, faint, or weak pain corresponded to marking between zero to 54 mm. Moderate pain was defined as greater than 54 mm and less than 114 mm. Strong, intense, and maximum pain was any marking above 114 mm. The patient was instructed to place a mark on the line that corresponded to his/her current assessment of pain. The results showed that there was no significant difference between the SEM score and HP-VAS score during LA administration.

Management of Anxiety and Pain

Management of dental anxiety and pain can be done by behavior management. Behavior management is as fundamental to the successful treatment of children. Disruptive behavior can interfere significantly with providing quality dental care, resulting in increased delivery time and risk of injury to the child. Communicative management and appropriate use of commands are used universally in pediatric dentistry with both the cooperative and uncooperative child. Rather than being a collection of singular techniques, communicative management is an ongoing subjective process that becomes an extension of the personality of the dentist. Associated with this process are the specific techniques of tell-show-do, voice control, nonverbal communication, positive reinforcement, and distraction.

Distraction is the technique of diverting the patient's attention from what may be perceived as an unpleasant procedure. Giving the patient a short break during a stressful procedure can be an effective use of distraction prior to considering more advanced behavior guidance techniques.

Armfield J M, Heaton L J(2013)²³, reviewed management of fear and anxiety in dental clinic. From the various studies he reviewed he found that, there are various methods to manage fear and anxiety in dental clinic which include making good rapport and communication with the patient, providing control via TSD, signaling and psychological means like distraction, positive reinforcement, relaxation breathing, guided imagery etc. Regarding distraction, they got sufficient evidence which said that focusing attention on specific alternative visual or auditory stimuli in the dental clinic might be beneficial for patients with mild to moderate dental anxiety. Several options are available for the clinician, ranging from background music to television sets to computer games to 3D video glasses for watching movies. They concluded that managing anxiety and fear in dental setting can be achieved by effectively applying the mentioned behavior management techniques.

Abdelmoniem S A, Mahmoud S A (2016)²⁴, did a comparative evaluation of passive, active and passive-active distraction techniques on pain perception during local anesthesia administration in children. Ninety children of 4-9 years of age requiring inferior alveolar nerve block for primary molar extraction were selected and randomly divided into three groups. Different distraction techniques ie passive, active and passive-active were implemented during LA administration. The children in passive distraction group were instructed to listen to a song on headphones. Children in active distraction group were asked to move their legs up and down alternatively. While, children in passive-active distraction group were asked to use the combination of both the techniques. Pain perception during LA injection was evaluated with the help of Sound, Eye and Motor scale (SEM) and Wong Baker Faces Pain Rating scale. They concluded that all the examined distraction techniques were equally effective in reducing pain perception during LA administration.

Music Distraction

Aitken J C, Wilson S, Coury D, Moursi A(2002)²⁵, studied the effect of music distraction on pain, anxiety and behavior in pediatric dental patients. Forty five children aged 4-6 yrs were selected who required two visits each involving restorative treatment with local anesthesia in a mandibular quadrant. Visit 1 was a baseline session for all patients. During visit 2, the children were assigned to an upbeat music group, a relaxing music group or a no music group. Variables measured were: parent-reported anxiety via the Modified Corah Anxiety Scale, self-reported anxiety via the Venham picture scale, heart rate, behavior via the North Carolina Behavior Rating Scale and pain via a visual analogue scale. They concluded that audio distraction was not an effective means for reducing pain, anxiety or unco-operative behavior in children during restorative procedure.

Marwah N, Prabhakar A R, Raju O S(2005)²⁶, did a study to evaluate the efficacy of music distraction in management of anxious pediatric dental patients. Forty children aged between 4 and 8 years were selected for the study. The assessment of anxiety was done using Venham's picture test, Venham's anxiety rating scale, pulse rate, and oxygen saturation during different treatment visits. They concluded that audio distraction did decrease the anxiety level in pediatric dental patients, but not to a very significant level.

Yamini.V. Bailwad S, Sivakumar. N(2010)²⁷, studied the effect of music distraction in the management of anxious pediatric dental patients. Children aged 6-12 yrs were selected and were divided in two groups- a control group and music group. Each child had 3 dental visits. The choice of music was left to the patients because playing familiar music which might have helped the child gain control over the unpleasant stimulus and give them a feeling of being in familiar environment. They

concluded that Audio distraction did decrease the level of anxiety in anxious pediatric dental patients although not to a significant level.

Jindal R, Kaur R(2011)²⁸, did a study to see the comparison between the effect of audio distraction with the normal dental set-up. Thirty patients of age between 4 and 8 years were included in the study. Each patient had gone through four dental visits. Anxiety was measured using Venham's picture test. They concluded that audio distraction did decrease the level of anxiety in anxious pediatric dental patients to a significant level during the restorative procedure and invasive procedure.

Singh D, Samadi F, Jaiswal JN, Tripathi AM (2014)²⁹, did a clinical study to see the stress reduction through audio distraction in anxious pediatric dental patients. Sixty children were randomly selected and equally divided into two groups of thirty each. The first group was control group and the second group was music group. The dental procedure employed was extraction for both the groups. The children included in music group were allowed to hear audio presentation throughout the treatment procedure. Anxiety was measured by using Venham's picture test, pulse rate, blood pressure and oxygen saturation. They concluded that audio distraction did decrease the anxiety in pediatric patients to a significant extent.

Audio-Visual Distraction Technique

With the increasing popularity of television or the audio-visual aids, this technique was introduced in 1981 as distraction technique.

Venham LL, Goldstien M, Gaulin-Kremer E, Cohan J, Fairbanks J(1981)³⁰, conducted a study on fifty-five dentally naïve children, ranging in age from two to six years. They were studied over a series of four dental visits. Patients in the distraction group viewed familiar children's television programs throughout their dental visits; patients in control group had no exposure to this distraction stimulus. The children's

response to dental care was assessed using a combination of physiological, behavioral, and self-report measures. They observed that young children responded more adversely to dental care, which confirms previous suggestions that children's dental anxiety declines with age. They concluded that passive television viewing procedure is ineffective in reducing the stress that very young children experience during dental visits.

Seyerek S K, Corah N L, Pace L F(1984)³¹ compared 3 distraction techniques in reducing stress in dental patients. 80 college students – 40 men and 40 women requiring minimum two amalgam restorations were included in the study and were divided into four groups of 20 each. The first visit was same for all the patients. In second visit, patients in group 2 listened to comedy clips through earphones, patients in group 3 saw the comedy video with the help of television and patients in group 4 played a video ping-pong game. The anxiety and physiologic parameters were recorded with the help of rating scales and a polygraph before and after the procedure. The results showed that both video comedy and video-game successfully distracted patients during dental procedures.

Prabhakar A R, Marwah N, Raju OS(2007)³², did a study to evaluate and compare the two distraction techniques, viz, audio distraction and audiovisual distraction, in management of anxious pediatric dental patients. Sixty children aged between 4-8 years were divided into three groups. Each child had four dental visits - screening visit, prophylaxis visit, cavity preparation and restoration visit, and extraction visit. Child's anxiety level in each visit was assessed using a combination of four measures: Venham's picture test, Venham's rating of clinical anxiety, pulse rate, and oxygen saturation. They concluded that audiovisual distraction technique was more effective in managing anxious pediatric dental patient as compared to audio distraction technique.

Jimeno F G, Bellido M, Fernandes C, Rodriguez A I, Perez J, Quesada JR(2014)¹, did a study to evaluate the effect of audiovisual distraction on children's behavior, pain and anxiety in the dental setting. It was a non-randomized crossover trial performed on 34 patients aged 6–8 years, who required a minimum of two treatment visits for restorative therapy. During the last visit, the patient was shown a cartoon film. The anxiety was measured by asking the parents to fill the Modified Corah anxiety scale. Also anxiety was measured with the help of Venham's picture test, heart rate. Wong Baker faces pain rating scale was used to assess the pain felt by children. The behavioral aspect was recorded on the Frankl' behavior rating scale after each visit. They concluded that the use of the audiovisual material used as a method of distraction improves the global behavior of children aged 6–8 years but did not reduce their parent's perception of the patients' anxiety, or the patient's self-reported anxiety, pain or heart rate according to the measurement scales used. This type of product is widely accepted among pediatric patients.

Naithani M, Viswanath D(2014)³³, did a comparative study on management of child's dental anxiety by audio and audio-visual distraction technique. 75 children aged between 4-8 years divided into 3 groups of 25 each. The children were then subjected to 4 visits and at the end of each visit the anxiety levels were assessed using a combination of Venham Picture Test (VPT), Venham Rating of Clinical Anxiety (VRCA), Child Fear Survey Schedule (CFSS), Pulse Rate and Oxygen Saturation. The results showed that VPT was significant when compared to other parameters during all visits in both inter and intra group comparisons. They concluded that audio-visual distraction was much better than audio distraction alone in managing child's dental anxiety.

Shrivastva M, Lal A, Mishra S, Fatima S, Siddiqui S R (2015)³⁴, reviewed the use of audiovisual distraction techniques in managing pediatric patients during dental

treatment. They stated that among the non-pharmacological method of behavior management techniques comes distraction. Distraction technique intends to move the patient's attention away from the treatment. Audio-visual distraction is a promising and most effective distraction technique offering non pharmacological mode of sedation conceived to decrease the unpleasantness often associated with dental procedures in children. Audiovisual distraction is powerful distraction tool as it takes control in an enjoyable way over two types of sensations of hearing and visual. They stated that cartoon distraction works on the principle of ACCEPTS. Activities, Contributing, Comparisons, Emotions, Pushing away, Thoughts and Sensations. They concluded that the audio-visual distraction technique can provide additional good quality methods to decrease unpleasant situation for child undergoing dental treatment.

Kaur R, Jindal R, Dua R, Mahajan S, Sethi K, Garg S (2015)², did a study to evaluate and compare audio and audiovisual distraction aids in management of anxious pediatric dental patients of different age groups. Children were divided in two age groups, that is, 4-6 years and 6-8 years with 30 patients in each age group on their first dental visit. The children of both the age groups were divided into 3 subgroups, the control group, audio distraction group, audio-visual distraction group with 10 patients in each subgroup. Each child in all the subgroups had gone through three dental visits. Child anxiety level at each visit was assessed by using a combination of anxiety measuring parameters – heart rate, dental sub-scale of children's fear survey schedule-short scale, clinical anxiety rating scale and co-operative behavior rating scale. They concluded that audiovisual distraction aids perform better than audio distraction aids to manage anxious dental patient.

Agarwal N. Dhawan J, Kumar D, Anand A, Tangri K(2017)³⁵, did a study to evaluate the effectiveness of two topical anesthetic agents used along with audio-visual

aids in pediatric dental patients. 120 children in the age range of 3-14 years were selected. EMLA and benzocaine gel (20%) were assessed for their effectiveness in reducing the pain on needle insertion during local anesthesia administration. Children requiring local anesthesia for the dental treatment were randomly divided into four equal groups of 30 children based upon whether AV aids were used or not. AV aids were given using Sony Vaio laptop with earphones with nursery rhymes and cartoon movies DVD. The pain assessment was done by using the Visual Analogue Scale (VAS) scale and measurement of the physiological responses of pulse rate and oxygen saturation were done by pulse oximeter. They concluded that EMLA with AV aids was better when compared with EMLA without AV aids followed by benzocaine with AV aids. Benzocaine topical anesthetic agent without AV aids was least effective in reducing the pain scores

Virtual Reality Distraction Technique

Since 2000, new distraction techniques involving 2D, 3D videos or the virtual reality have been introduced. Virtual reality distraction is unique in that it is immersive and engaging, integrating many sensory experiences and thus capturing a greater degree of attention. VR refers to a human computer interface that enables the user to interact dynamically with the computer generated environment. Many systems can be used like head mounted, 3D displays (HMDs), VR goggles etc.

Bentsen B, Svensson P, Wenzel A(2001)³⁶, did a study to evaluate the effect of 3D video glasses on perceived pain and unpleasantness induced by restorative dental treatment. Twenty-three patients (17 female and six male, age range 20±49 years) with a need for an occlusal dental restoration in two homologous teeth participated in the study. In this split-mouth design, the patient received the dental treatment wearing 3D video

glasses and without video glasses (control situation) in a randomized order. The tooth cavities were prepared in accordance with conventional techniques after mounting the video glasses. The patient rated the intensity of pain and unpleasantness on 100mm visual analogue scales (VASs) after preparation of the first cavity; immediately after, the opposite tooth was prepared and again the volunteer rated the intensity of pain and unpleasantness. The cavities were then filled using a routine composite technique. Eventually, the patient indicated whether s/he would prefer video glasses or not if s/he were to have another filling and what the expectations of the effect had been. The results showed that patients preferred to wear 3D glasses during the treatment. They concluded that the 3D glasses is an effective distraction technique.

Touzy L Z, Lamontagne P, Smith BE(2004)³⁷, did a study to assess pain and anxiety reduction using a manual stimulation distraction device when administering local analgesia oro-dental injections. Hundred patients from different dental clinics were identified by their practitioners as requiring dental procedures under local anesthesia, in the same area on both sides of the mouth. A local anesthetic solution was injected on either the left or right side at different times by random selection; one side using manual simulation distraction device, while the opposite side used a solution without manual distraction simulation device. Using 10-point visual analogue nominal and ordinal scales, pain and stress were recorded by the patient each time after receiving the injection. Results showed significant reductions in perceived pain and stress from local analgesia injections ($p < 0.001$) when MSDD was used. They concluded that manual simulation distraction device was effective at reducing pain and stress experienced with local regional analgesic injections.

Ram D. Shapira J, Holan G, Magora F, Cohen S, Davodovich E.(2010)³⁸, studied the effect of Audio-visual eyeglass distraction on behavior during restorative

treatment in children. 61 children wore wireless audiovisual eyeglasses with earphones, and 59 received dental treatment under nitrous oxide sedation. A Frankl behavior rating score was assigned to each child. After each treatment, a Houpt behavior rating score was recorded by an independent observer. A visual analogue scale (VAS) score was obtained from children who wore AVD eyeglasses, their parents, and the clinician. The results showed that the behavior of children using AVD was excellent and the satisfaction of the parents and clinicians were also high. They concluded that audiovisual eyeglasses offer an effective distraction tool for the alleviation of the unpleasantness and distress that arises during dental restorative procedures.

Florella M, Sarale C, Ram RD(2010)³⁹ reported four cases which used audiovisual I atrosedation with video eyeglasses distraction method in pediatric patients. The children wore the AVD eyeglasses before the local anesthetic injection and throughout the whole dental procedure. All four children were rated as uncooperative (Frankl 1) before the treatment. During the whole dental procedure pulse, respiration and oxygen saturation were monitored every few minutes and the child's behavior, limb and body movements and crying were observed and a summed score was obtained according to the Houpt scale 1-6. During treatment with Audiovisual distraction (AVD) ratings on the Houpt behavior scale showed that the children were very good or excellent (Houpt 5-6) during all the dental sessions. Satisfaction VAS ratings 0-10 given separately by the children, parents and dentists were between 8-10. They concluded that AVD method may contribute an additional good quality mode to reduce the unpleasantness for every child undergoing dental treatment

El-Sharkawi H, El-Housseiny A, Aly A M(2012)⁴⁰, did a study to evaluate the effect of a distraction technique using audiovisual (A/V) glasses on pain perception during administration of local anesthesia for children. Forty-eight healthy, cooperative 5-

to 7-year-olds were selected on the basis of existence of bilateral carious primary mandibular molars, which necessitated an inferior alveolar nerve block anesthesia before treatment. Treatment was done on 2 visits 1 week apart. Children had been randomly assigned to receive the A/V glasses at one visit and no distraction during the other visit. Two different pain assessment scales were used: the pain faces scale (PFS) and the face, legs, activity, cry, and consolability scale (FLACC) scale. They concluded that Distraction induced by audiovisual (A/V) glasses significantly reduces pain associated with injection of local anesthesia.

Kerimoglu B, Meuman A, Paul J, Stefanov D G, Twersky R(2013)⁴¹, did a study to evaluate the anesthesia induction using video glasses as a distraction tool for the management of pre-operative anxiety in children. Ninety six children aged 4 to 9 years undergoing outpatient surgery were recruited to one of 3 intervention groups receiving midazolam, video glasses, or both. The Modified Yale Preoperative Anxiety Scale was the primary dependent measure used to assess anxiety at baseline before intervention, 20 minutes later at transport to the operating room (OR), and during mask induction. The secondary measure used to assess anxiety was heart rate. They concluded that the use of video glasses and midazolam alone or in combination maintains baseline levels of anxiety at time of transport to the OR and prevents significantly increased anxiety during induction of anesthesia in children.

Tanja-Dijkstra K, Pahl S, White MP, Andrade J, Qain C(2014)⁴², did a simulation study to check whether using virtual reality distraction improves dental experience. Sixty nine participants took part in the simulated dental experience and were randomly divided into 3 groups- active, passive and control. Along with that they were also categorized into high and low dental anxiety groups. The patients were called 1 week later to recall the memories of the simulated dental experience. They found that VR

distraction had a profound effect on the memories of the patient. Patients with higher dental anxiety showed a greater reduction in the memory vividness than lower-anxiety patients. They concluded that VR distractions can be considered as a relevant intervention for anxiety.

Asvanund Y, Mitrakul K, Juhong R, Arunakul M(2015)⁴, did a study to evaluate the effectiveness of audiovisual (AV) eyeglasses on pain reduction during local anesthetic injection in children who are 5 to 8 years old. Forty-nine healthy, cooperative children with bilateral carious molars requiring treatment under local anesthesia were recruited in this crossover study. Treatments were done in two visits, 1 to 4 weeks apart. Subjects were randomly divided into two groups according to the sequence of AV eyeglasses used. Group I received the injection without wearing AV eyeglasses in the first visit and then wearing AV eyeglasses in a second visit. Group II was vice versa. Self-reporting pain using the Faces Pain Scale-Revised (FPS-R), face, legs, activity, crying, and consolability scale (FLACC), and heart rate (HR), were measured to assess the injection pain. They conclude that AV eyeglasses successfully reduced pain, physical distress, and HR during local anesthesia injection.

Fakhruddin KS, El Batawi H, Gordus M O(2015)⁵, did a study to assess the effectiveness of audiovisual distraction technique with video eyewear and computerized delivery system-intrasulcular (CDSIS) during the application of local anesthetic in phobic pediatric patients undergoing pulp therapy of primary molars. randomized, crossover clinical study includes 60 children, aged between 4 and 7yearold (31 boys and 29 girls). Children were randomly distributed equally into two groups as A and B. This study involved two treatment sessions of pulp therapy, 1week apart. During treatment session I, group A had an audiovisual distraction with video eyewear, whereas group B had audiovisual distraction using projector display only without video eyewear.

During treatment session II, group A had undergone pulp therapy without video eyewear distraction, whereas group B had the pulp treatment using video eyewear distraction. Each session involved the pulp therapy of equivalent teeth in the opposite sides of the mouth. At each visit scores on the Modified Child Dental Anxiety Scale (MCDAS) (f) were used to evaluate the level of anxiety before treatment. After the procedure, children were instructed to rate their pain during treatment on the Wong Bakers' faces pain scale. Changes in pulse oximeter and heart rate were recorded in every 10 min. they concluded that the use of audiovisual distraction with video eyewear and the use of CDSIS system for anesthetic delivery was demonstrated to be effective in improving children's cooperation.

Panda A (2017)⁶, did a study to determine the effect of virtual reality (VR) distraction on pain perception during dental treatment in children. Thirty pediatric patients, aged 6 to 8 years, whose treatment plan consisted of pulp therapy in the mandibular primary molars, were randomly divided into an experimental and a control group. Children in the experimental group were shown a VR video during treatment, which consisted of administration of inferior alveolar nerve block followed by pulp therapy. Subjects in the control group received similar procedures without the use of VR distraction. At the end of the treatment, children in both groups were shown faces pain scale-revised and asked to point out the face which best showed the amount of pain perceived by them. They concluded that VR eyewear can be successfully used to distract children and decrease the amount of pain perceived by them during dental procedures.

MATERIALS AND METHOD

The present randomized cross-over clinical study was carried out in the department of pediatric and preventive dentistry of the concerned dental college to compare the effect of audio-visual and virtual reality goggle distraction technique in managing dental anxiety and pain in pediatric dental patients. The study was carried out after obtaining ethical clearance from the local ethics committee. Parents of the child selected for the study were explained the purpose and methodology of the study in local vernacular language and a signed informed consent was obtained. (**Annexure 1; Page no xii**)

Statistician consultation was done before the sample size was calculated (formula given by Minn M. Soe and Kevin M. Sullivan, Emory University from Andrew G. Dean, EpiInformatics.com). The minimum number of subjects was calculated to be 48 in order to achieve a type I error = 5%, type II error = 20%, power = 80%. The total number of subjects required was calculated as 60 in order to make up for lost cases (20%) while the study was being conducted⁴.

Subject Selection

Children in 4-8 years age group coming to the department of pediatric and preventive dentistry for dental treatment were screened based on the SCARED questionnaire (**Annexure 2; page no. xv**). The parents of the children were asked to fill a SCARED questionnaire to assess general anxiety status of the child. A child having score below 25 was considered without any anxiety disorder and was further examined on the dental chair. The child was examined on the dental chair and intra-oral examination was carried out with the help of mouth mirror and probe. The dentition status, the caries status according to WHO criteria, the oral hygiene status according to the OHI simplified index and the radiographic interpretation along with the treatment plan were recorded on the case record form prepared for the study. (**Annexure 3; page no. xviii**). A child was selected to be included in the study based on the following criteria.^{3,2}

Inclusion Criteria –

- 1) No previous history of dental visit or treatment.³
- 2) Children in category 3 and 4 according to Frankl behavior rating scale.^{3,4}
- 3) Children with no anxiety disorders according to the SCARED questionnaire.³
- 4) Children having decayed mandibular molars requiring restorative treatment.³
- 5) Children willing to wear the VR goggles and the headphones.⁴

Exclusion Criteria –

- 1) Children suffering from any systemic diseases.⁴

- 2) Children having physically and mentally handicapping conditions.⁴
- 3) Children having visual and hearing impairment.⁵

Study Design –

This was a randomized controlled clinical trial with crossover design. The subjects were randomly divided into three groups based on the sequence of the distraction method used during the dental treatment. The treatment phase consisted of four treatment visits. At the first visit children in all the 3 groups underwent appropriate topical fluoride application without any intervention. The visits 2, 3 and 4 were at one to two weeks interval and the treatment done in each group was as mentioned below⁴:

Treatment Sessions	Group 1	Group 2	Group 3
Visit 1	Fluoride application without any distraction	Fluoride application without any distraction	Fluoride application without any distraction
Visit 2	Restoration under LA without any intervention	Restoration under LA with AV distraction	Restoration under LA with VR goggles
Visit 3	Restoration under LA with AV distraction	Restoration under LA with VR goggles	Restoration under LA without any intervention
Visit 4	Restoration under LA with VR goggles	Restoration under LA without any intervention	Restoration under LA with AV distraction

The dental procedure to be carried out was explained to the child using tell-show-do technique. For the visits that included use of either AV distraction or wearing of VR goggle with headphones as distraction technique, the child was introduced to the chair mounted monitor and the virtual reality goggles. The child was given few minutes to get used to the distraction technique before starting the dental procedure. All subjects were presented with choice of cartoon movie. The VR goggle is a device composed of head

mounted display and in-ear headphones, which provides a close proximity device aimed at reducing visual and auditory interferences from the environment.

Each treatment visit was completed under 30 minutes. All clinical examination and dental procedures were performed by a single pediatric dentist as per the established guidelines for pediatric dentistry.

Clinical Methodology

Local anesthesia technique

An inferior alveolar nerve block was used to anaesthetize the mandibular primary molars. The injection site was dried with gauze. A cotton-tip applicator that contained approximately 0.2 mL of topical anesthesia gel was applied for 1 minute. A short gauge needle and the administration of 1.5 mL of 2% lignocaine with 1:100,000 epinephrine was used for all injection procedures. Injection time was approximately 1 mL/minute with an average duration of nearly 2 minutes.⁴

Assessment of Anxiety and Pain –³²

Child's anxiety levels in all visits were assessed using a combination of four measures: Heart rate, Oxygen saturation,⁴³ Venham's picture test⁷, and Venham's rating of clinical anxiety⁸.

Pain was assessed using the Wong Baker faces pain rating scale¹⁵.

1) Heart Rate (HR) and Oxygen Saturation (SPO₂) –

Heart rate and oxygen saturation was measured with the help of finger pulse oximeter. The pulse oximeter was introduced to the child using TSD technique. HR and SPO₂ were recorded at baseline in waiting room, during and after the procedure on the dental chair.⁴

During the restorative procedure, the HR and SPO₂ were recorded every 10 min. The values were noted down and the average of the value measured was calculated and noted down as the final value of HR and SPO₂ during the restorative procedure.⁵

2. Venham's Picture Test - (Annexure 4; page no xxii)

Venham's picture test was administered in the waiting room to assess baseline anxiety, in the dental chair immediately after LA injection and after completion of restorative procedure. The child was asked to point out the figure in each pair of 8 set to which he/she could most relate to and the scores thus assigned were totaled and noted.⁷

2) Venham's Clinical Anxiety rating –

An independent pediatric dentist assessed the clinical anxiety of the child by playing back the video recordings of each visit and rated them according to the Venham's 6-point scale to assess clinical anxiety.⁸(Annexure 5; page no xxiii)

The recording was done from a fixed distance from the dental chair with a Sony Point and Shoot camera such that the complete torso of the child would be seen. The recording started from the moment the child sat in the dental chair during each session continued till the procedure was complete.

The videos were reassessed by the pediatric dentist at 1 month's time for intra examiner reliability

3) Wong Baker Faces Pain Rating Scale –

Pain felt by the child was rated using the Wong-Baker Faces pain rating scale after giving LA and at the end of the restorative procedure. The Wong Baker Faces pain rating scale consists of 6 faces with increasing degree of pain from left to right and had a numerical scale from 0-10 corresponding to each face.¹⁵(Annexure 6; page no. xxiv)

The child was asked to point out the face to which he can most relate to in terms of the pain he felt after LA and at the end of the restorative procedure.

MATERIALS –

- A. Oral examination of the child was done on the dental chair with the help of diagnostic instruments - mouth mirror, probe, and tweezer. (**colour plate 1 fig.1**)
- B. Restorative instruments - Spoon excavator, cement carrier, condensers, burnisher, plastic filling instruments (API Ashoons, India), Airtor Hand Piece (Mini-head Hand piece, Dentmark. India) Round, inverted cone, straight fissure diamond burs. (**color plate 1 fig 2**)
- C. Materials -Upper and lower foam trays,APF topical fluoride gel (Fluorogel. Azure laboratories pvt ltd.), Topical anesthetic solution. (LOX 10% spray), Lignocaine with 2% adrenaline (LOX 2%) and syringe (Nirlife Oneuse 24 gauge disposable syringe). GIC restorative cement (Pyrax) (**color plate 2 fig 1**)
- D. For measuring anxiety and pain –
 - 1) SCARED questionnaire for parent. (**annexure 2**)
 - 2) Venham's picture test. (**annexure 4**)
 - 3) Venham's clinical anxiety rating scale. (**annexure 5**)
 - 4) Pulse oxymeter to measure pulse rate and oxygen saturation. (**color plate 2 fig.2**)
 - 5) Wong Baker faces pain rating scale. (**annexure 6**)
 - 6) Sony Point and shoot camera (**color plate 3 fig 1**)
- E. For distraction techniques –

- 1) Chair mounted monitor with headphones (AOC LCD monitor) (**color plate 3 fig 2**)
- 2) Virtual reality goggles with headphones (WideView XL edition) (**color plate 4 fig 1**)
- 3) Collection of cartoon movies and story videos.

The representative IOPA of the dentinal caries lesion selected for the study are shown in **color plate 5**. The representative treatment of injecting LA and restorative treatment without any distraction have been annexed in **color plate 6**. The representative treatment of injecting LA and restorative treatment with audio-visual distraction have been annexed in **color plate 7**. The representative treatment of injecting LA and restorative treatment with virtual reality goggle distraction have been annexed in **color plate 8**. The administration of the Venham's picture test and the Wong Baker scale has been represented in **color plate 9**.

Color Plate 1



Fig 1. Diagnostic instruments



Fig 2. Instruments for restorative procedure

Color Plate 2



Fig. 1 Materials



Fig 2. Pulse Oxymeter

Color Plate 3



Fig 1. Sony point and shoot camera.



Fig 2. Audio-visual set-up

Color Plate 4



Fig 1. VR Goggles with earphones

Color plate 5

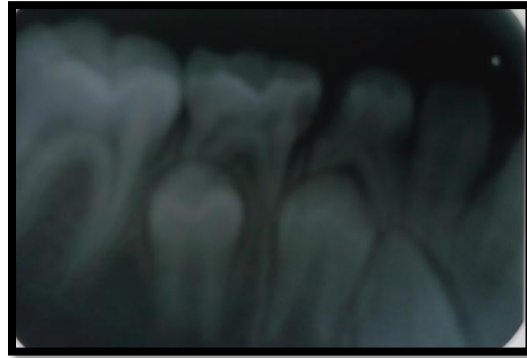


Fig 1. Pt 21 Dentinal caries with 75

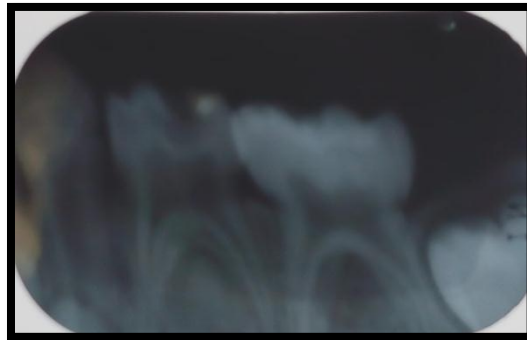


Fig 2. Pt 34 occlusal dentinal caries with 85



Fig 3. Pt 41 dentinal caries with 74.

Color plate 6



Fig 1. Administration of LA without any Distraction.



Fig 2. Restorative treatment without distraction

Color Plate 7



Fig 1. Administration of LA using Audio-visual distraction.



Fig 2. Restorative treatment using Audio-visual distraction.

Color Plate 8



Fig 1. Administration of LA using VR Goggle distraction.



Fig 2. Restorative treatment using VR goggle distraction.

Color Plate 9



Fig 1. Administering VPT test



Fig 2. Administering Wong Baker pain scale.

RESULTS

This was a randomized controlled clinical trial with crossover design. 60 children selected based on the inclusion criteria were randomly divided into three groups of 20 each. The treatment phase consisted of four treatment visits. At the first visit, children in all the 3 groups underwent appropriate topical fluoride application without any intervention. The visits 2, 3 and 4 were at one to two weeks interval and sequence of distraction method according to the group was as mentioned below and in **table 1** {page no. i} –

Sequence in Group 1 for restorative treatment under LA: No distraction – AV distraction – VR distraction. {N- AV-VR}

Sequence in Group 2 for restorative treatment under LA: AV distraction – VR distraction -No distraction. {AV-VR-N}

Sequence in Group 3 for restorative treatment under LA: VR distraction -No distraction – AV distraction. {VR-N-AV}

Each child was supposed to undergo four treatment sessions. In group 1, 3 patients failed to report back in 2nd session and 1 failed to report back for 4th session, leaving a total of 16 patients who completed all 4 sessions. In group 2, 2 patients failed to report back for 2nd session and 1 failed to report back for 3th session, and 1 failed to report back for 4th session, leaving a total of 16 patients who completed all 4 sessions. In group 3, 3 patients failed to report back in 2nd session and 1 failed to report back for 4th session, leaving a total of 16 patients who completed all 4 session. Hence, the final total sample included 48 children, 16 in each group.

The parameters were measured at different times across the treatment. Baseline scores were taken at two times- 1st in the waiting room and 2nd when the child sat on the dental chair. The parameters were measured during Local anesthetic injection and during restorative treatment and also after completing the treatment. All the parameters were recorded and appropriate statistical analysis was carried out.

Statistical tests -

The demographic parameter age was summarized in terms of mean and standard deviation and compared across three groups using one-way analysis of variance (ANOVA). Gender distribution was compared across groups using Pearson's chi-square test of homogeneity. Heart rate across groups was compared using one-way ANOVA, while Venham's picture test (VPT), and Wong-Baker (WB) faces ratings were compared using Kruskal-Wallis test. The comparison of these parameters across groups at different times, i.e. baseline, during treatment and post-treatment were performed using the same respective tests. Further, each parameter was compared across times in each group. Heart

rate was compared using repeated measure analysis of variance, while VPT and WB faces readings were compared using Friedman test. All the analyses were performed using SPSS ver 20.0 (IBM Corp) software and statistical significance was tested at 5% level.

A brief description of methods used is given below:

The details of the methods used are as below:

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

Sample mean for a set of observations is given by

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

Standard deviation for a set of observations is given by

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

where x_i = observation on each object

n = number of objects

A) Analysis of variance

Analysis of variance (ANOVA) is used to test the significance of difference in the mean of three or more groups. The basic assumption is that the variable of interest is normally distributed in the population under study.

Method

Here the interest is to test the null hypothesis that the population means are same, i.e.

$$H_0 : \mu_1 = \mu_2 = \dots \mu_m$$

against the alternative H_1 that they are not same.

Some of the statistics computed to test the hypothesis are as below:

i) Grand mean: It is the mean of set of all observations in the studied groups and is given by:

$$\bar{x}_{GM} = \frac{1}{N} \sum_{i=1}^N x_i$$

ii) Total sum of squares: It is the sum of squares of each observation from the grand mean and is given by:

$$TSS = \sum_{i=1}^N (x_i - \bar{x}_{GM})^2$$

Total sums of squares is the sum of two components i.e., variation between groups and within groups.

iii) Between group sum of squares

$$SSB = \sum_{j=1}^m n_j (\bar{x}_j - \bar{x}_{GM})^2$$

iv) Within group sum of squares

$$SSW = \sum_{j=1}^m \sum_{i=1}^n (x_{ij} - \bar{x}_j)^2$$

The mean sum of squares is obtained by dividing the above sum of squares with the respective degrees of freedom, i.e. $N-1$, $p-1$ and $p(n-1)$.

v) **F-statistic:** It is the ratio of between and within mean sum of squares

$$F = \frac{MS_{Between}}{MS_{Within}}$$

If the p -value based on F-statistic is greater than 0.05, H_0 is accepted, otherwise H_1 is accepted.

B) Chi-square test

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

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

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

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

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

accept the alternative one. If the p -value is more than 0.05, then we accept null hypothesis.

C) Kruskal-Wallis test – A non-parametric equivalent of ANOVA

The test is a non-parametric equivalent of one-way analysis of variance for comparing three or more groups. It is used for testing if the samples originate from same or different populations. The procedure for determining significance of difference across groups using the test is as below:

i) The n_1, n_2, \dots, n_k observations from k samples are combined into a single series of size n and arranged in order of magnitude from smallest to largest. The observations are then replaced by ranks from 1 assigned to smallest observation to n assigned to largest observation. When two or more observations have same value, each observation is given a mean of the ranks for which it is tied.

ii) The ranks assigned to observations in each of the k groups are added separately to give k rank sums.

iii) The test statistic is defined as:

$$H = \frac{12}{n(n+1)} \sum_{j=1}^k \frac{R_j^2}{n_j} - 3(n+1)$$

where k is the number of groups; n_j is the number of observation in j^{th} group; n is the total number of samples from all the groups and R_j is the sum of ranks from j^{th} group.

iv) When there are more than 5 observations in one or more groups, H is compared with the tabulated value of χ^2 with $k-1$ degrees of freedom.

D) Friedman's test

The test is a non-parametric equivalent of parametric repeated measures ANOVA and typically used to detect the differences in observations across multiple test attempts. The procedure mainly involves ranking each row and then considering the values of ranks by columns.

- Given data $\{x_{ij}\}_{n \times k}$ as a matrix of n rows (repeated measurements) and k columns (treatments), calculate the ranks within each row. If there are tied ranks, then assign an average rank that would have been assigned without ties. Replace the data with the new matrix of ranks $\{r_{ij}\}_{n \times k}$ where r_{ij} is the rank of entry x_{ij} within i^{th} row.

- Find values:

$$\bar{r}_{.j} = \frac{1}{n} \sum_{i=1}^n r_{ij}$$

$$\bar{r} = \frac{1}{nk} \sum_{i=1}^n \sum_{j=1}^k r_{ij}$$

$$SS_t = n \sum_{j=1}^k (\bar{r}_{.j} - \bar{r})^2$$

$$SS_e = \frac{1}{n(k-1)} \sum_{i=1}^n \sum_{j=1}^k (r_{ij} - \bar{r})^2$$

- The test statistic Q is given by

$$Q = \frac{SS_t}{SS_e}$$

When n or k is large ($n > 15$; $k > 4$), the probability distribution of Q can be approximated by chi-squared distribution. In this case, p -value is given by $P(\chi^2_{k-1} \geq Q)$, else p -values can be obtained from Q tables.

Table 2 {page no i} provides the descriptive statistics for children characteristics in three study groups. The mean age of children was found higher in Group I (7.35 ± 0.93 years) as compared to that of Group II and III (Group II: 6.90 ± 1.07 years and Group III: 6.40 ± 1.73 years); however, the difference in the mean age of children across groups was statistically insignificant as revealed by p-value of 0.075. In regards to gender, the number of males and females in Group I was 12 (75.00%) and 4 (25%) respectively. Group II had 11 (68.75%) males and 5 (31.25%) females, and Group III had 8 (50%) males and 8 (50%) females. The difference in proportions of gender across groups was statistically insignificant as indicated by p-value of 0.306. **Graph 1 and 2 {page no vi}** show the distribution of children according to mean age and gender across groups.

Table 3 {page no ii} provides the descriptive statistics and comparisons of different parameters before, during and after restoration for Group I {N-AV-VR}, across 4 treatment sessions. The mean heart rate at baseline in waiting room, in session 3 was highest (85.73 ± 10.70 bpm) as compared to session 1 (83.24 ± 10.62 bpm), session 2 (83.19 ± 23.20 bpm) and session 4 (85.13 ± 9.46 bpm); however, the difference across sessions was statistically insignificant as revealed by a p-value of 0.780. The difference in baseline VPT scores between different sessions was also statistically insignificant as indicated by a p-value of 0.575. The mean heart rate and VPT scores at baseline on dental chair across sessions were statistically insignificant with p-values of 0.142 and 0.682 respectively. The mean heart rate of children during local anesthesia was statistically insignificant across 3 sessions as indicated by a p-value of 0.523. Similarly, during restoration, the difference in the mean heart rate was statistically insignificant as revealed by p-value of 0.188. After the effect of local anesthesia, the difference in the mean heart rate, VPT scores and WB pain scores were statistically insignificant with p-values 0.685, 0.519 and 0.599 respectively. **Maximum heart rate (97.81 ± 14.15 bpm) was observed**

at session 2, maximum mean VPT (2.31 ± 1.82) was observed at the same session and maximum mean WB (5.38 ± 2.60) was also obtained at the same session 2 as compared to other sessions. Further, after restoration, the difference of mean heart rate of children in Group I was statistically insignificant as revealed by p-value of 0.151. The mean VPT scores and WB pain scores was statistically insignificant across 4 sessions with p-value of 0.361 and 0.072 respectively. **Further VRS score is highly significant across the sessions with p-value < 0.001.** A bar chart showing mean Heart rate according to stages and sessions is shown in **Graph 3 {page no vii}**. A bar chart showing mean VPT according to stages and sessions is shown in **Graph 4 {page no vii}**. A bar chart showing mean Wong Baker according to stages and sessions is shown in **Graph 5 {page no viii}**.

Table 4 {page no. iii } provides the descriptive statistics and comparisons for different parameters before, during and after restoration for Group II {AV-VR-N}, across 4 sessions of treatment. **The mean heart rate at baseline in waiting room for session 4 was highest (96.20 ± 12.33 bpm) as compared to session 1 (93.67 ± 9.91 bpm), session 2 (96.07 ± 11.10 bpm) and session 3 (95.94 ± 10.42 bpm); however, the difference in the mean heart rate across 4 sessions was statistically insignificant as revealed by a p-value of 0.932.** The difference in baseline VPT scores across sessions was statistically insignificant as indicated by p-value of 0.827. The difference in the mean heart rate and VPT scores at baseline on dental chair was statistically insignificant as indicated by p-values of 0.942 and 0.455 respectively. The highest mean heart rate was 99.00 ± 13.38 bpm and mean VPT was 1.20 ± 1.42 in session 2. The mean heart rate of children during local anesthesia was statistically insignificant across 3 sessions as indicated by p-value of 0.636. Similarly, during restoration, the difference in the mean heart rate was statistically insignificant as revealed by p-value of 0.985. After local anesthesia, the difference in the

mean heart rate was found to be statistically insignificant (p-value of 0.378) across sessions. **The mean VPT scores in session 3 showed significantly higher value (1.94 ± 1.06) as compared to other sessions with p-value of 0.015.** The WB pain scores of children showed statistically significant difference across 3 sessions with a p-value of 0.013, where the maximum mean was observed in session 3 of treatment (6.22 ± 2.26) as compared to other sessions. Further, after restoration, the mean heart rate of children was observed, where the difference between the means was statistically insignificant as revealed by p-value of 0.781. The difference of mean VPT scores was statistically insignificant with a p-value of 0.727. Furthermore, the mean WB pain scores was statistically insignificant across 4 sessions with a p-value 0.134, where the highest mean score was observed in session 4 (0.53 ± 0.83) of treatment. **However, VRS score is highly significant across three groups with p-value < 0.001.** A bar chart showing mean Heart rate according to stages and sessions is shown in **Graph 6 {page no viii}**. A bar chart showing mean VPT according to stages and sessions is shown in **Graph 7 {page no ix}**. A bar chart showing mean Wong Baker according to stages and sessions is shown in **Graph 8 {page no ix}**.

Table 5{page no iv} provides the descriptive statistics and comparisons for different parameters before, during and after restoration for Group III {VR-N-AV}, across 4 sessions of treatment. The mean heart rate at baseline in waiting room in session 2 was highest (96.07 ± 10.80 bpm) as compared to session 1 (90.94 ± 12.15 bpm), session 3 (91.71 ± 12.07 bpm) and session 4 (90.40 ± 10.87 bpm), however the difference in the mean heart rate across 4 sessions was statistically insignificant as revealed by a p-value of 0.146. The difference in mean baseline VPT scores across different sessions was statistically insignificant as indicate by p-value of 0.697. **The difference of mean heart rate of children at baseline on dental chair in different**

sessions was statistically insignificant as indicated by p-value 0.116. The highest mean heart rate 99.60 ± 10.15 bpm was observed in session 2. The highest mean VPT scores was observed in session 4 (1.87 ± 1.55) and the difference was statistically significant across 4 sessions with p-value of 0.008. The difference between mean heart rate of children during local anesthesia was statistically significant across 3 sessions as indicated by p-value of 0.021. Similarly, during restoration, the difference in the mean heart rate was statistically significant as revealed by a p-value of 0.004. After local anesthesia, the difference in the mean heart rate and WB pain scores were statistically significant across sessions (p-value- 0.006 and 0.007 respectively), while mean VPT scores were statistically insignificant with p-value of 0.146. Further, after restoration, the mean heart rate of children was statistically significant as revealed by a p-value of 0.002. The difference in mean VPT scores was statistically significant with p-value of 0.022, where the highest score was observed in session 1 (1.82 ± 1.70). Furthermore, the mean WB pain scores of children was statistically significant across 4 sessions with p-value 0.032, where the highest mean score was observed in session 4 (0.93 ± 1.49) of treatment. However, VRS score is highly significant across three groups with p-value < 0.001 . A bar chart showing mean Heart rate according to stages and sessions is shown in **Graph 9** {page no x}. A bar chart showing mean VPT according to stages and sessions is shown in **Graph 10** {page no x}. A bar chart showing mean Wong Baker according to stages and sessions is shown in **Graph 11** {page no xi}.

For descriptive purpose, the values for the parameters used to assess anxiety and pain of all the 48 children, irrespective of the sequence of introduction of distraction method, were clubbed together as –

Group A – AV distraction.

Group B – VR distraction.

Group C – without distraction.

So finally Group A, B and C had 48 children who underwent treatment with respective distraction or no distraction at various sessions.

Table 6{page no v} gives the comparison of the AV, VR and no distraction modes on all parameters of anxiety and pain.

HR - The mean HR at baseline in waiting room in groups A, B and C was 91.43 ± 11.61 , 90.58 ± 11.63 and 91.59 ± 17.10 respectively and the difference was not statistically significant. On the dental chair the mean of the HR in groups A, B and C was 93.32 ± 11.83 , 94.80 ± 10.99 and 96.89 ± 12.74 respectively and the difference was not statistically significant. During local anesthesia the mean of the HR in groups A, B and C was 101.49 ± 10.99 , 104.62 ± 11.60 and 105.89 ± 12.49 respectively and the difference was not statistically significant. **During restorative treatment the mean of the HR in groups A, B and C was 94.66 ± 9.83 , 97.02 ± 8.68 and 99.52 ± 10.85 respectively and the difference was statistically significant {p=0.0011}. After local anesthesia the mean of the HR in groups A, B and C was 98.55 ± 10.64 , 102.18 ± 11.44 and 103.70 ± 12.31 respectively and the difference was statistically significant {p= 0.0180}. After restorative treatment the mean of the HR in groups A, B and C was 91.00 ± 10.28 , 93.76 ± 9.08 and 96.35 ± 10.60 respectively and the difference was statistically significant {p= 0.0003}. fig 12 is a bar chart showing mean heart rate according to stages and type of distraction.**

SpO₂- At baseline in waiting room, the mean SpO₂ in groups A, B and C was 98.87 ± 0.34 , 96.69 ± 14.74 and 98.91 ± 0.28 respectively and the difference was not statistically significant. On the dental chair the mean of the SpO₂ in groups A, B and C

was 98.94 ± 0.25 , 98.98 ± 0.15 and 98.98 ± 0.15 respectively and the difference was not statistically significant. During local anesthesia the mean of the SpO₂ in groups A, B and C was 98.89 ± 0.31 , 98.93 ± 0.25 and 98.87 ± 0.34 respectively and the difference was not statistically significant. During restorative treatment the mean of the SpO₂ in groups A, B and C was 98.91 ± 0.28 , 98.91 ± 0.29 and 98.93 ± 0.25 respectively and the difference was not statistically significant. After local anesthesia the mean of the SpO₂ in groups A, B and C was 98.91 ± 0.28 , 98.89 ± 0.38 and 98.87 ± 0.34 respectively and the difference was not statistically significant. During restorative treatment the mean of the SpO₂ in groups A, B and C was 98.94 ± 0.25 , 98.93 ± 0.258 and 98.87 ± 0.34 respectively and the difference was not statistically significant. **fig 15 is a bar chart showing mean SpO₂ according to stages and type of distraction.**

VPT - At baseline in waiting room, the mean VPT in groups A, B and C was 1.09 ± 1.10 , 1.04 ± 1.28 and 0.98 ± 1.11 respectively and the difference was not statistically significant. On the dental chair the mean of the VPT in groups A, B and C was 0.94 ± 1.15 , 1.13 ± 1.22 and 1.17 ± 1.37 respectively and the difference was not statistically significant. After local anesthesia the mean of the VPT in groups A, B and C was 1.79 ± 1.27 , 1.89 ± 1.56 and 1.74 ± 1.45 respectively and the difference was not statistically significant. During restorative treatment the mean of the SpO₂ in groups A, B and C was 0.60 ± 0.88 , 0.76 ± 0.96 and 0.72 ± 1.19 respectively and the difference was not statistically significant. **fig 13 is a bar chart showing mean SpO₂ according to stages and type of distraction.**

WB - After local anesthesia the mean of the WB in groups A, B and C was 5.28 ± 2.22 , 5.02 ± 2.32 and 5.04 ± 2.45 respectively and the difference were not statistically significant. After restorative treatment the mean of the WB in groups A, B and C was 0.34 ± 0.76 , 0.62 ± 1.09 and 0.43 ± 0.83 respectively and the difference was not

statistically significant. **fig 14 is a** bar chart showing mean SpO₂ according to stages and type of distraction.

DISCUSSION

Pain and anxiety are unpleasant feelings and emotional experiences, which are associated with real or possible traumas to tissues. Management strategies have been proposed to reduce distress during dental treatment in children and are mainly divided into two broad categories. The first module consists of behavioral techniques including the tell-show-do technique, distraction, inspiration, modeling and hypnotism. The second category consists of pharmacologic techniques.³

According to the published guidelines for the clinical management of children by the American Academy of Pediatric Dentistry, distraction, diverting patient's attention

from perceived unpleasant procedure to decrease the likelihood of unpleasantness perception and/or threshold is indicated for pediatric patient of any age.⁵

Distraction appears to be safe and inexpensive and gives rise to an effective relaxed experience in short painful dental procedure. The application of distraction is based on the assumption that pain perception has a large psychological component in that the amount of attention directed to the noxious stimuli which modulates the perceived pain. Previous techniques to distract a child include watching television, listening to music, counting the furniture in the room and non-medical dialogs, which serve to distract the child's attention from anxiety-provoking stimuli.³

Audiovisual distraction is powerful distraction tool as it takes control in an enjoyable way over two types of sensations of hearing and visual. It partially isolates the child patient from the sounds and the sight of the unfriendly dental environment. Audiovisual distraction techniques potential in managing the child patient has led many dental practitioners to install television screens in the dental environment. Audio-visual distraction methods like cartoon distraction is a simple, labor saving and easy to administer therapy that relieves pain and distress in child patients during intravenous injection procedures as equally and effectively as other common psychological procedures.³⁴

The development of wireless audiovisual eyeglasses which are easy to use, comfortable and inexpensive for the dental practitioner and the child has opened further opportunities for its use in dental treatment. In recent years, there has been an increase in behavioral research in virtual reality (VR) and virtual world. This application may be superior to traditional distraction because it offers more immersive images due to the occlusive head-sets that project the images right in front of the eyes of the user and, depending on the model used, block out real-world (visual, auditory, or both) stimuli.

Depending on how immersive the presented stimuli are, the person's attention will be more or less "drained" from the real world, leaving less attention available to real-world processes, including painful stimuli.

From the review of literature it was seen that many studies have been carried out to compare various distraction techniques in children, but few have been done to compare audiovisual and virtual reality goggle distraction technique on management of dental anxiety and pain in children aged 4-8years of age. Hence this cross-over clinical study was carried out to compare audiovisual and virtual reality distraction techniques in managing dental anxiety and pain in children.

As different individuals have different pain thresholds, this study was designed to be a crossover study so that each individual would be acting as his/her own control in different situations and, therefore the differences in anxiety and pain threshold would not result in bias in reporting the results. Moreover, unpleasant pain experience can increase pain perception and anxiety during the next sessions, resulting, in turn, to perceive more pain. It has also been demonstrated that distraction techniques are less effective in individuals who have a previous bitter pain experience. Therefore, in the present study subjects were excluded if they had previous invasive painful medical or dental history in the recent past.⁶

The children of age group 4-8 years are difficult to treat as they exhibit more disruptive behavior as was observed by **Prabhakar et al{2007}**³², **Aswanund et al {2015}**⁴, **Kaur et al {2015}**² in their study. Hence this age group was selected for the study.

The children were treated in four dental visits which include one visit for fluoride application and three visits for restorations under local anesthesia. The visits were in accordance with **Prabhakar et al.{2007}**³². In the study done by **Yamini et al.{2010}**²⁷ three visits were conducted. Where as in another study conducted by **Venham et al.**

{1977}⁴³, six dental visits were carried out to know the child response to sequential dental visit.

Anxiety in an individual may broadly be classified as trait anxiety and state anxiety. This study aimed at assessing dental anxiety, which is considered a type of state anxiety, and pain perception in children during short invasive dental treatment. The presence of trait anxiety, which is related to the personality and temperament of a child, was assessed using the SCARED questionnaire, to screen those children who had a predilection for childhood anxiety disorders, during their initial examination. This was done to limit the confounding effect that a child's anxious personality trait might have over dental anxiety. It was also suggested by **Dahlquist LM et al (2010)**⁴⁴, that patients with higher levels of anxiety may not respond well to distraction techniques.

The SCARED was initially developed by **Birmaher et al {1995}**⁴⁵ and his collaborators. It comprises of 38-items questionnaire. The parent version of this questionnaire was designed to evaluate symptoms as a result of separation anxiety, overall anxiety, phobic disorders, compulsive disorders, fear of trauma, social phobia, specific phobia and fear of school in children below 8 years of age. The questionnaire was used to evaluate the presence of childhood background anxiety disorders in the subjects. In this questionnaire, scores above 25 indicate the presence of childhood anxiety disorders and were excluded from the study.³. The SCARED questionnaire was translated in local language for ease in understanding for the patient's parents.

To measure anxiety in a patient, various measures have been reported in the literature. In children the choice is based on age and intellectual development. These measures can be objective or subjective, depending on the method used to quantify the degree of anxiety.

The objective measures include the measurement of physiological function. The psycho-physiological responses produced by anxiety are associated in general with an increase in the activity of the sympathetic branch of the autonomic nervous system. Changes occur in the cardiovascular system causing increased blood pressure and pulse rate. Studies carried out by **Messer et al. {1977}**⁴⁶ and **Myers et al. {1972}**⁴⁷ confirmed that the physiological changes occur in the body as a result of the stress and anxiety suffered by patients during dental procedures, who concluded that heart rate can be used as a reliable indicator of anxiety.¹¹

A study carried out by **Rayen et al. [2006]**¹⁰ concluded that heart rate and blood pressure increase simultaneously as a result of stress and anxiety in the dental clinic.

Pulse oximeter which measures the pulse rate and oxygen saturation is one of the most acceptable methods for measuring the physiologic changes as it gives continuous percentage measurements of the patient's arterial hemoglobin and oxygenation as well as the pulse rate. Hence it was used in the study.³²

Among the subjective measures, the most commonly used is the Venham's picture scale. It is a self-report measure that permits measurement of the state of anxiety of children when visiting a dentist. Children are presented with eight pairs of images that show various emotions and they are asked to select the ones that reflect their emotional state best. The scores range from 0 (no anxiety) to 8 (very anxious). The test is easy to perform and only takes one or two minutes, which makes it one of the scales of choice for children.¹¹

Venham's Clinical anxiety rating scale is a valid and reliable rating scale and has been proven useful for assessing children's responses to dental stress.² It is a six-point interval rating scale to measure anxiety.⁸

A pediatric dentist assessed anxiety by playing back the video record from the visits. Scores were assigned using VARS to determine the clinical ratings of anxiety and cooperative behaviour at intervals when a specific dental procedure is performed. Intra-examiner reliability was assessed by reviewing the videotapes again after 1 week and scoring them. (Cohen's Kappa = 0.85).⁴⁸

Pain can be measured by self-report, biological markers, and behaviour. Because pain is subjective; self-report is the best if available. The various self-report scales available are the Visual analogue scale, Wong Baker Faces pain rating scale, Faces pain scale, universal pain assessment tool. The Wong Baker Faces pain scale is used to assess pain perceived during dental procedures. It consists of a number of faces ranging from happy to crying. **Hockenberry et al.** and **Sheller et al.** determine high sensitivity and validity of Wong-Baker Faces Pain Scale in children over 3 years of age.⁴⁹ It has been used in the study as it is easy to understand for children. The children were asked to indicate the level of pain they perceived on this pictorial index. The scale was shown to the children immediately after administering local anaesthesia and after completing the treatment.³

Audio-visual distraction is a promising and effective distraction technique offering non-pharmacological mode of sedation conceived to decrease the unpleasantness often associated with dental procedures in children.³⁴ The children were shown a cartoon or a film on a chair mounted screen with earphones attached for music. It blocks the sound of the Airtor to some extent but still the child is able to see what treatment is being rendered. While the Audio-visual distraction technique is not meant to replace the trust-building communication that is inherent to good child patient–clinician relationships **Ram D et al**³⁸ recommend introducing audio-visual distraction at dental

appointments after trust is established, to enhance the positive patient attitude toward the dental experience.

In the recent years, new distraction technique using Virtual reality eyeglasses have been used. VR distraction is unique in that it is immersive and engaging, integrating many sensory experiences, and thus capturing a greater degree of attention. It blocks the peripheral vision of the child. It was noted that the use of a new device, such as the Virtual Reality eyeglasses could provoke anxiety; and thus, instead of producing relaxation and reduction in anxiety, can stimulate it. Thus, it was decided that the children in the study group during VR session, once seated in the dental operatory would be allowed to use the VR device for approximately 5 minutes before beginning the dental treatment and administering the local anesthetic. This strategy may increase the children's acceptance of VR distraction and improved patient experience resulting in greater anxiety reduction and an overall increase in the effectiveness of the VR distraction procedure in these children.

The children included in the present study were also provided with a list of choices from the selected playlist and those cartoons were played both on audio-visual and VR eyeglasses. Several authors have reflected on the importance of children choosing audiovisual material themselves and how this influences their behaviour.¹ It is possible that, if they are allowed to choose the audiovisual material, they feel that they have some control over the dentist's behaviour, which reduces their level of stress. Normally children do not have any control over what occurs when they are in the dental chair; hence, having control over the music and/or film can be beneficial. The studies done by **Venham et al., 1981³⁰**; **Sullivan et al., 2000⁵⁰**; **Aitken et al., 2002²⁵** who did not give any opportunity to children to select audiovisual materials did not find an improvement in patient behaviour during treatment sessions.

60 patients were enrolled in the study, 20 in each group. Each child was supposed to undergo four treatment sessions. In group 1, 3 patients failed to report back in 2nd session and 1 failed to report back for 4th session, leaving a total of 16 patients who completed all 4 sessions. In group 2, 2 patients failed to report back for 2nd session and 1 failed to report back for 3th session, and 1 failed to report back for 4th session, leaving a total of 16 patients who completed all 4 sessions. In group 3, 3 patients failed to report back in 2nd session and 1 failed to report back for 4th session, leaving a total of 16 patients who completed all 4 sessions. Hence, the final total sample was 48 children, 16 in each group.

In the present study, in intra-group comparisons across 4 sessions it was seen that in Group 1{N-AV-VR}, the mean HR at baseline in all the sessions was statistically insignificant. The maximum HR was observed during 2nd session {treatment with no distraction} after LA injection.

The difference in mean in Group 2{AV-VR- N} was statistically insignificant across all sessions at all times.

In Group 3{VR-N-AV}, difference in mean of HR during LA injection was statistically significant with the highest scores seen in treatment using VR distraction. Also after restoration HR was high in VR session.

The results from the present study indicate that although there was a no change in the oxygen saturation and the pulse rate increased, there was no statistically significant difference. This was in conjunction with the earlier studies done by **Yelderman et al**⁵¹. and **Prabhakar et al**³² who had observed a similar kind of pattern. The fact that the pulse rate was maximum during the injection phase indicates that increase is psychosomatic in origin. Possibly, the anticipation of injection provides sympathetic stimulation and catecholamine release, which accounts for greater increase in pulse rate (prabhakar et al).

Where as in a study done by **Asvanund et al⁴2015**, who evaluated the effect of audio-visual eyeglasses, there was significant reduction in heart rate while wearing eyeglasses during LA injection.

The mean VPT scores in intra-group comparisons – in Group 2 {AV-VR- N}, the mean VPT score after LA in session 3{with VR} showed a significantly higher value as compared with other sessions. In Group 3{VR-N-AV}, the highest mean VPT scores when the child sat in dental chair was observed in session 4{with AV distraction} (1.87 ± 1.55) and the difference was statistically significant across 4 sessions with p-value of 0.008. After restoration the difference in mean VPT scores was statistically significant with p-value of 0.022, where the highest score was observed in session 1 (1.82 ± 1.70) {with VR distraction.}

In study done by **Jimeno G et al {2014}¹**, 2014; 79% of the sample scored 0 in the Venham Picture Test at the end of the control visit. Perhaps, during the test, the children were guided more by their personal preferences than by their feelings at that moment (i.e., they chose those figures in the test that looked happier and more relaxed).

In a study done by **Naithani et al{2014}³³**, the decrease in anxiety over a span of four appointments was more for the audio- visual group as compared to the audio group alone. This inference was in accordance with **Mungara et al.{2013}⁵²**, as well as **Prabhakar et al{2007}³²**.

The Venham's Clinical Anxiety rating scores - in intra-group comparisons – the VRS scores in Group 1 {N-AV-VR} across sessions were statistically significant with not much difference in mean scores in sessions 2, 3, 4. The VRS scores in Group 2 across sessions were statistically significant with highest scores in session 2 {AV-VR- N}with AV distraction. The VRS scores in Group 3 {VR-N-AV} across sessions were statistically significant with highest scores in session 3 {without any distraction}. The

overall findings show that the children were more anxious on the beginning of restorative treatment under local anesthesia for the 1st treatment visit and were more relaxed in the next visits. The ratings of Venham's anxiety scale in study done by **Prabhakar et al{2007}**³² were less in audiovisual distraction group as compared to control groups and audio distraction groups, but these were not statistically significant.. In study done by **Kaur et al{2015}**², results regarding clinical anxiety rating indicated children were most relaxed in audiovisual followed by audio group and were least relaxed in control group during three dental visits.

In regards to pain - in intra-group comparisons in group 2 {AV-VR- N}, the WB pain scores after LA, of children showed statistically significant difference across 3 sessions with a p-value of 0.013, where the maximum mean was observed in session 3 [with VR distraction] of treatment (6.22 ± 2.26) as compared to other sessions. In group 3 {VR-N-AV}, the mean WB score after LA injection was statistically significant with the highest score in session 4 [with AV distraction]. In the same group, after restoration, the mean WB pain scores of children was statistically significant across 4 sessions with p-value 0.032, where the highest mean score was observed in session 4 (0.93 ± 1.49) [with AV distraction]of treatment.

The results observed in the study carried out by **Aminabadi et al {2012}**³, showed a significant decrease in pain perception (using Wong-Baker faces pain rating scale) and state anxiety scores (using faces version of the modified child dental anxiety scale) with the use of VR eyeglasses during dental treatment in 120 children aged 4 to 6 years. The results of **Aitken et al. [2002]**²⁵, who used music with younger children (4–6 years), the results of **Hoge et al. [2012]**⁵³, who used a video eyewear as a distraction method with children aged 4–16 years, and **Jimeno G et al [2014]**¹ who used audiovisual distraction in 6-8 year old children did not find any significant results in pain scales in the

experimental. In contrast, **Baghdadi et al [2000]**⁵⁴ found a difference in self-reported pain during dental treatment between exposure-to-audio analgesia and a control situation. This difference might be explained by the fact that the children in the earlier study were aged 9–12 years, and were able to distinguish the sensation of pain more clearly than the younger children described herein.¹

For descriptive purpose, the values for the parameters used to assess anxiety and pain of all the 48 children, irrespective of the sequence of introduction of distraction method, were clubbed together as –

Group A – AV distraction.

Group B –VR distraction.

Group C – without distraction.

So finally Group A, B and C had 48 children who underwent treatment with respective distraction or no distraction at various sessions.

The mean HR, S_{PO2} and VPT scores at baseline, in waiting room, were not significantly different in the groups A, B and C. The mean HR during and after LA was highest in group C {no distraction}, then group B {VR distraction} and least in group A {AV distraction}. The VPT scores at baseline, on dental chair were less in Group A {AV distraction} and more in Group B and group C. The mean VPT scores before after LA and restoration were not significantly different. The mean WB pain scores after LA was not different among the three groups, but after restoration the WB scores were less in group A {AV distraction} and more in Group B {VR distraction}.

It shows that AV distraction was more effective in reducing anxiety and pain than VR and no distraction technique. **Jimeno G et al {2014}**¹, did a study to evaluate the effect of audio-visual distraction on pain and anxiety in children and found that AV distraction technique is effective in reducing pain and anxiety in children. **Aminabadi et**

al {2012}³, did a study to see the impact of virtual reality distraction on pain and anxiety during dental treatment in 4-6 yr old children, who divided the children in groups – one with distraction and one without. They assessed the pain using Wong Baker faces pain scale and anxiety using Faces version of Modified Child Dental Anxiety Scale. They found that VR distraction is effective in reducing pain perception and anxiety. **Prabhakar et al. (2007)**³² reported results coinciding with the present study. They found that the use of AV distraction during dental treatment was more effective in managing the children than using audio distraction alone.

Khotani A et al {2016}⁵⁵, did a study to evaluate the effect of audio-visual eyeglasses as distraction technique on child's behavior. They concluded that AV eyeglasses seems to be an effective method in reducing fear and anxiety in children during dental treatment. Further, children who used eyeglass goggle as a distraction tool during dental treatment reported not only less anxiety than control groups but also showed more positive responses after injection with local anesthesia.

Studies have been done to study the effect of AV or VR with no distraction, but this is the first to compare all three in a cross-over design.

In the present study, audiovisual distraction did have a favorable effect on reducing anxiety as seen on heart rate, Venham's picture test and Venham's rating scale. A significant difference in the reduction of anxiety as assessed by the pre- treatment and post treatment of all the patients in the AV distraction than the VR distraction. The reason for reduction in Audio-visual distraction could be that the children are more familiar with Audio-visual distraction as it similar to watching cartoons on a TV. The VR distraction was effective in reducing anxiety and pain but not significantly. This could be because even though VR is said to block all the surrounding

sight and sound as its advantage, it can also lead the child to get startled by the dental procedure due to the same.

VR was more effective after LA in reducing pain as seen on Wong Baker Pain scale as compared to AV. After restorative procedure AV was more effective in pain as assessed by same scale compared to VR.

A study wherein a child undergoes restoration with VR as distraction across multiple sessions could help child getting used to being cut-off from the surroundings and then assess the impact of VR distraction on child's anxiety and pain perception.

SUMMARY AND CONCLUSION

Dental anxiety can lead to an unavoidable stressful condition, which can be a matter of concern for dentist. Majority of the patients present to the clinic with some amount of fear. This fear or anxiety prevents many patients from seeking dental treatment at an early stage. Noise of dental equipments can really be an unpleasant stimulus that leads to fear especially in children. For past many years researchers have been trying to understand the exact cause that leads to un-cooperation. Efforts have been made to study the psychology of children and eliminate the fear.

Various behavior management techniques are used to calm the patient so that desired behavior can be obtained from the patient. Initially it was Tell Show Do that

helped dentist to eliminate the unpleasant stimulus that could lead to fear in a child. Over years distraction has gained a lot of importance in behavior management. AV distraction seems to be an effective method in reducing fear and anxiety in children during dental treatment. Distracting children with audio visual technique have proven to minimize the discomfort caused to children during injection and various other dental treatments.

In present study children were divided into three groups based on the sequence of introduction of distraction method; AV, VR goggles and No distraction.

The following observations were made – the HR after LA administration increased from baseline values in all three AV, VR and No distraction group, but the increase was highest in group in which no distraction was used and least in AV group. The heart rate measured after completing the procedure reduced in all three groups and was significantly reduced in AV group as compared to VR and no distraction group.

There was no significant difference between the mean S_{PO_2} value at baseline – in waiting room and on dental chair, during and after the LA administration and the restorative treatment procedure.

The difference between the mean VPT scores was not statistically significant when measured at baseline – in waiting room and on dental chair and after LA administration and completing the restorative procedure.

In regards to pain the difference between the Mean WB scores revealed that VR distraction was more effective than AV in reducing pain perception on LA administration. But pain scores after the restorative procedure showed that AV distraction was more effective in reducing pain than VR distraction. However the differences were not statistically significant.

From the present study it can be concluded that

1. Audiovisual distraction technique is more effective in reducing pain and anxiety during restorative treatment under local anesthesia in- 4-8 year old children.
2. VR distraction was effective in reducing pain perception during LA administration but not during restorative procedure.

A study to assess the impact of VR distraction on anxiety and pain perception across multiple sequential visits must be carried out.

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Table 1 showing distribution of children and treatment sequence in groups.

Treatment Sessions	Group 1 [n=20]	Group 2 [n=20]	Group 3 [n=20]
Visit 1	Fluoride application without any distraction	Fluoride application without any distraction	Fluoride application without any distraction
Visit 2	Restoration under LA without any intervention	Restoration under LA with AV distraction	Restoration under LA with VR goggles
Visit 3	Restoration under LA with AV distraction	Restoration under LA with VR goggles	Restoration under LA without any intervention
Visit 4	Restoration under LA with VR goggles	Restoration under LA without any intervention	Restoration under LA with AV distraction

Table 2: Descriptive statistics for children characteristics in three study groups

Characteristics	Levels	Groups			P-value
		I (n = 16)	II (n = 16)	III (n = 16)	
Age		7.35 ± 0.93	6.90 ± 1.07	6.40 ± 1.73	0.075 (NS)
Gender	Male	12 (75.00)	11 (68.75)	8 (50.00)	0.306 (NS) [†]
	Female	4 (25.00)	5 (31.25)	8 (50.00)	

*Obtained using one-way ANOVA; [†]Obtained using Pearson's Chi-square test; NS: Non-Significant; S: significant

Table 3: Descriptive statistics and their comparisons for different parameters before, during and after restoration for group 1 across sessions

Group 1	Levels	Sessions								P-value
		1		2		3		4		
Baseline		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
In waiting room	Heart Rate	83.2 4	10.6 2	83.1 9	23.2 0	85.7 3	10.7 0	85.1 3	9.46	0.780 (NS)*
	VPT*	1.65	1.69	1.38	1.02	1.27	1.33	0.93	1.03	0.575 (NS) †
On dental chair										
	Heart Rate	87.3 5	9.97	92.3 8	13.7 7	86.7 3	12.3 0	89.6 0	9.31	0.142 (NS)*
	VPT*	1.53	1.70	1.63	1.50	1.33	1.45	0.87	0.92	0.682 (NS) †
During										
Local Anesthesia	Heart Rate	-	-	99.6 9	13.3 7	96.8 0	12.1 9	99.2 7	9.84	0.523 (NS)*
Restorative	Heart Rate	91.3 5	12.3 5	95.0 6	11.7 3	90.3 3	10.7 3	92.9 3	9.51	0.188 (NS)*
After										
Local Anesthesia	Heart Rate	-	-	97.8 1	14.1 5	95.4 0	13.0 4	95.9 3	10.1 6	0.685 (NS)*
	VPT*	-	-	2.31	1.82	2.27	1.67	1.93	1.39	0.519 (NS) †
	WB‡	-	-	5.38	2.60	5.07	2.37	4.93	2.12	0.599 (NS) †
Restorative	Heart Rate	88.0 6	11.4 9	91.6 9	9.62	87.2 0	11.0 3	89.5 3	9.64	0.151 (NS)*
	VPT*	1.24	1.64	1.19	1.56	0.67	1.05	0.87	1.25	0.361 (NS) †
	WB‡	0.00	0.00	0.63	0.96	0.53	0.92	0.40	0.83	0.072 (NS) †
	VRS	0.00	0.00	0.95	0.39	0.95	0.78	0.88	0.49	< 0.001 (S)

*Venham's picture test; ‡Wong baker faces

*Obtained using one-way repeated measures ANOVA; †Obtained using Friedman test; HS: Highly Significant; S: Significant; NS: Non-Significant

Table 4: Descriptive statistics and their comparisons for different parameters before, during and after restoration for group 2 across sessions

Group 2	Levels	Sessions								P-value
		1		2		3		4		
Baseline		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
In waiting room	Heart Rate	93.67	9.91	96.07	11.10	95.94	10.42	96.20	12.33	0.932 (NS)*
	VPT*	1.06	0.94	0.87	1.30	1.22	1.00	0.73	0.88	0.827 (NS)†
On dental chair										
	Heart Rate	96.56	9.36	99.00	13.38	97.89	9.13	98.87	11.37	0.942 (NS)*
	VPT*	0.94	1.00	1.20	1.42	1.00	0.91	0.67	0.72	0.455 (NS)†
During										
Local Anesthesia	Heart Rate	-	-	106.33	10.86	104.78	10.08	108.67	11.67	0.636 (NS)*
Restorative	Heart Rate	99.22	7.30	100.13	7.69	99.22	8.14	100.07	8.06	0.985 (NS)*
After										
Local Anesthesia	Heart Rate	-	-	104.40	10.28	101.11	9.82	105.80	10.26	0.378 (NS)*
	VPT*	-	-	1.20	1.08	1.94	1.06	1.07	1.03	0.015 (S)†
	WB‡	-	-	4.40	2.41	6.22	2.26	4.00	2.00	0.013 (S)†
Restorative	Heart Rate	95.39	8.17	96.47	7.35	95.39	9.04	96.47	7.76	0.781 (NS)*
	VPT*	0.83	0.79	0.53	0.99	0.78	0.81	0.47	0.64	0.727 (NS)†
	WB‡	0.00	0.00	0.40	0.83	0.33	0.77	0.53	0.83	0.134 (NS)†
	VRS	0.00	0.00	1.06	0.54	0.65	0.49	0.38	0.50	< 0.001 (S)†

‡Venham's picture test; †Wong baker faces

*Obtained using one-way repeated measures ANOVA; †Obtained using Friedman test; HS: Highly Significant; S: Significant; NS: Non-Significant

Table 5: Descriptive statistics for different parameters before, during and after restoration for group 3 across sessions

Group 3	Level	grp3								P-value
		1		2		3		4		
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Baseline										
In waiting room	<i>Heart Rate</i>	90.94	12.15	96.07	10.80	91.71	12.07	90.40	10.87	0.146 (NS)*
	<i>VPT*</i>	1.65	1.73	0.67	0.90	0.71	0.91	1.47	1.73	0.697 (NS)†
On dental chair										
	<i>Heart Rate</i>	93.71	11.74	99.60	10.15	94.50	11.95	95.93	10.76	0.116 (NS)*
	<i>VPT*</i>	1.82	1.85	0.67	1.05	0.43	0.94	1.87	1.55	0.008 (S)†
During										
Local Anaesthesia	<i>Heart Rate</i>	-	-	112.07	10.36	102.29	9.67	105.93	11.82	0.021 (S)*
Restorative	<i>Heart Rate</i>	99.88	10.28	103.67	11.42	93.43	8.89	98.07	7.25	0.004 (S)*
After										
Local Anaesthesia	<i>Heart Rate</i>	-	-	109.27	9.65	98.64	8.41	104.80	11.83	0.006 (S)*
	<i>VPT*</i>	-	-	1.67	1.18	1.07	0.62	2.67	1.80	0.146 (NS)†
	<i>WB‡</i>	-	-	5.33	2.35	4.29	1.54	6.13	2.45	0.007 (S)†
Restorative	<i>Heart Rate</i>	95.71	12.07	101.20	12.57	89.43	9.48	95.27	8.75	0.002 (S)*
	<i>VPT*</i>	1.82	1.70	0.40	0.74	0.29	0.73	0.93	0.88	0.022 (S)†
	<i>WB‡</i>	0.00	0.00	0.27	0.70	0.14	0.53	0.93	1.49	0.032 (S)†
	<i>VRS</i>	0.00	0.00	1.06	0.83	1.24	0.44	0.76	0.56	< 0.001 (S)†

‡Venham's picture test; †Wong baker faces

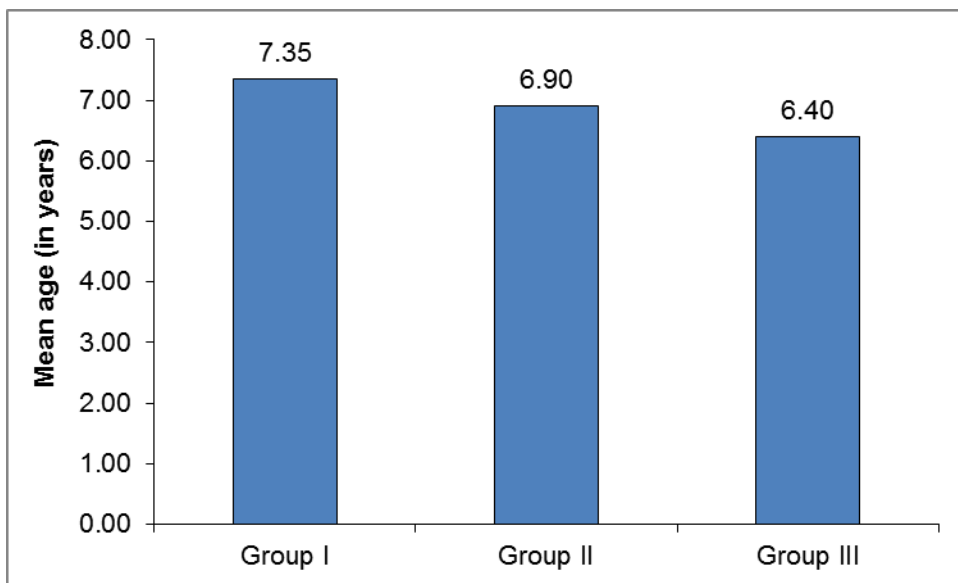
*Obtained using one-way repeated measures ANOVA; †Obtained using Friedman test; S: Significant; NS: Non-Significant

Table 6: Descriptive statistics for parameters according to stages and type of distraction

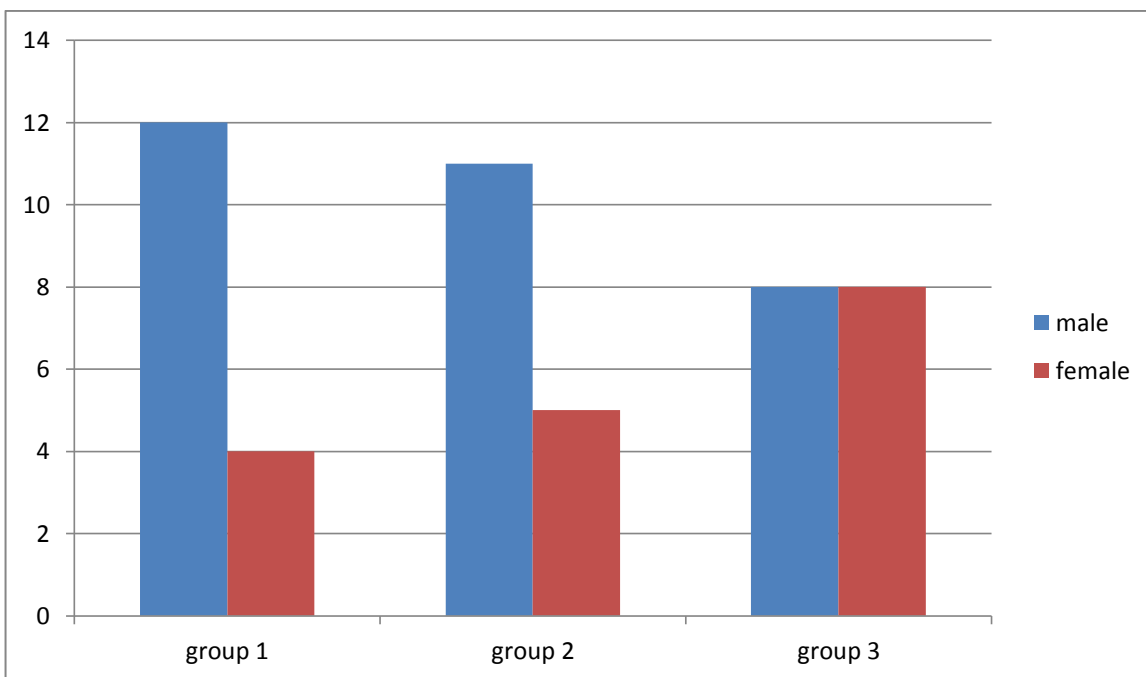
Stages	Parameters	Distraction			P-Value
		AV (n = 48)	VR (n = 48)	None (n = 48)	
Baseline					
	<i>Heart Rate</i>	91.43 ± 11.61	90.58 ± 11.63	91.59 ± 17.10	0.8418(NS)*
	<i>VPT</i>	1.09 ± 1.10	1.04 ± 1.28	0.98 ± 1.11	0.7113(NS)†
	<i>SPO2</i>	98.87 ± 0.34	96.69 ± 14.74	98.91 ± 0.28	0.3686(NS)*
Measure					
	<i>Heart Rate</i>	93.32 ± 11.83	94.80 ± 10.99	96.89 ± 12.74	0.0961(NS)*
	<i>VPT</i>	0.94 ± 1.15	1.13 ± 1.22	1.17 ± 1.37	0.2701(NS)†
	<i>SPO2</i>	98.94 ± 0.25	98.98 ± 0.15	98.98 ± 0.15	0.1353(NS)*
During					
Local Anaesthesia	<i>Heart Rate</i>	101.49 ± 10.99	104.62 ± 11.60	105.89 ± 12.49	0.0717(NS)*
	<i>SPO2</i>	98.89 ± 0.31	98.93 ± 0.25	98.87 ± 0.34	0.5345(NS)*
Restorative	<i>Heart Rate</i>	94.66 ± 9.83	97.02 ± 8.68	99.52 ± 10.85	0.0011(S)*
	<i>SPO2</i>	98.91 ± 0.28	98.91 ± 0.29	98.93 ± 0.25	0.8695(NS)*
After					
Local Anaesthesia	<i>Heart Rate</i>	98.55 ± 10.64	102.18 ± 11.44	103.70 ± 12.31	0.0180(S)*
	<i>VPT</i>	1.79 ± 1.27	1.89 ± 1.56	1.74 ± 1.45	0.6039(NS)†
	<i>WB</i>	5.28 ± 2.22	5.02 ± 2.32	5.04 ± 2.45	0.9447(NS)†
	<i>SPO2</i>	98.91 ± 0.28	98.89 ± 0.38	98.87 ± 0.34	0.7451(NS)*
Restorative	<i>Heart Rate</i>	91.00 ± 10.28	93.76 ± 9.08	96.35 ± 10.60	0.0003(S)*
	<i>VPT</i>	0.60 ± 0.88	0.76 ± 0.96	0.72 ± 1.19	0.2196(NS)†
	<i>WB</i>	0.34 ± 0.76	0.62 ± 1.09	0.43 ± 0.83	0.3123(NS)†
	<i>SPO2</i>	98.94 ± 0.25	98.93 ± 0.25	98.87 ± 0.34	0.2794 (NS)*

*Obtained using one-way repeated measures ANOVA; †Obtained using Friedman test; S: Significant; NS: Non-Significant

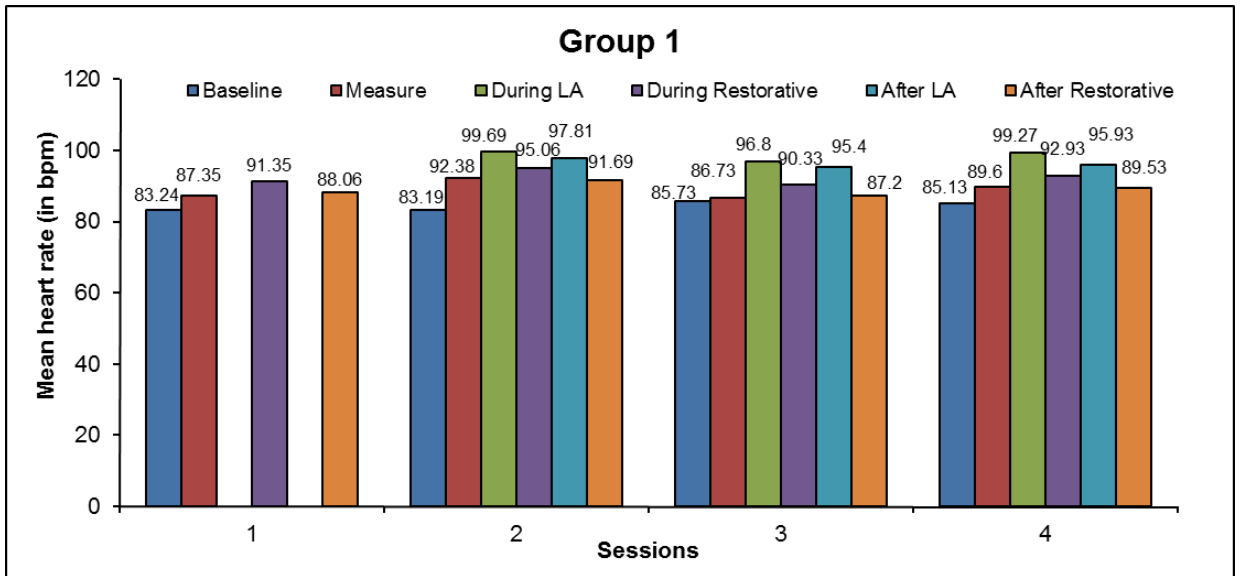
Graphs



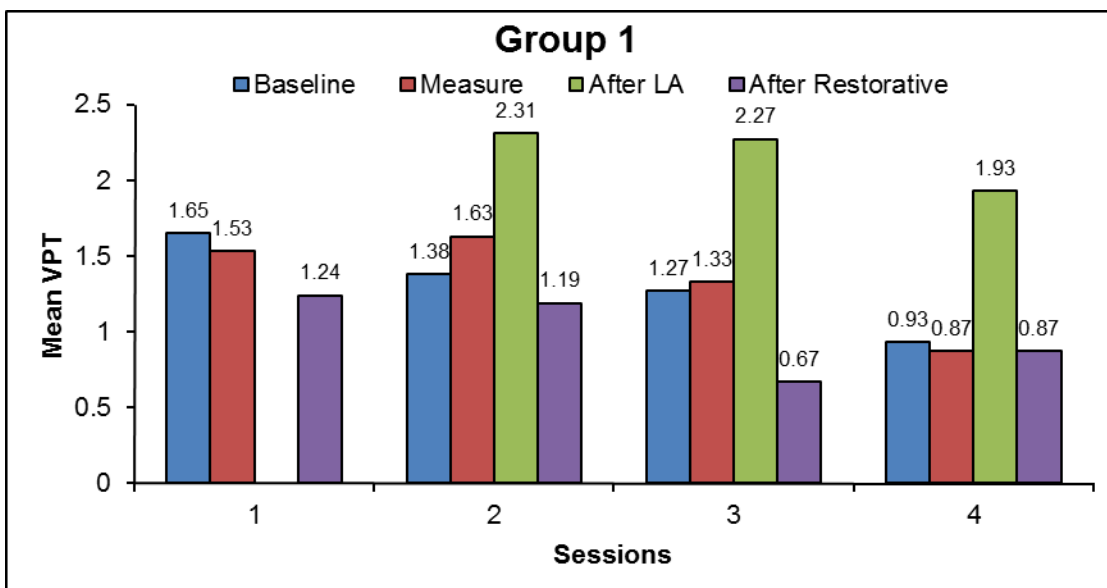
Graph 1: Column chart showing mean age of children in each group



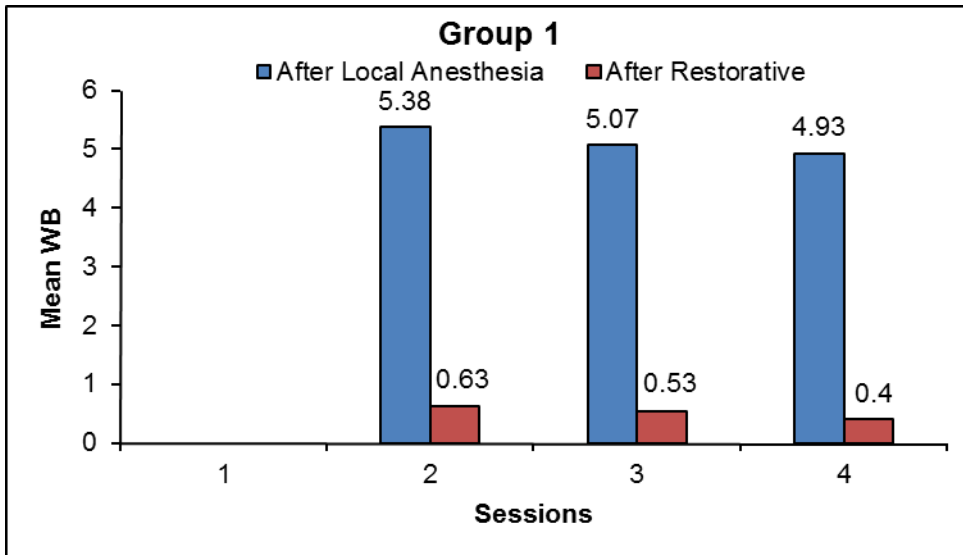
Graph 2: Distribution of children as per gender in three groups



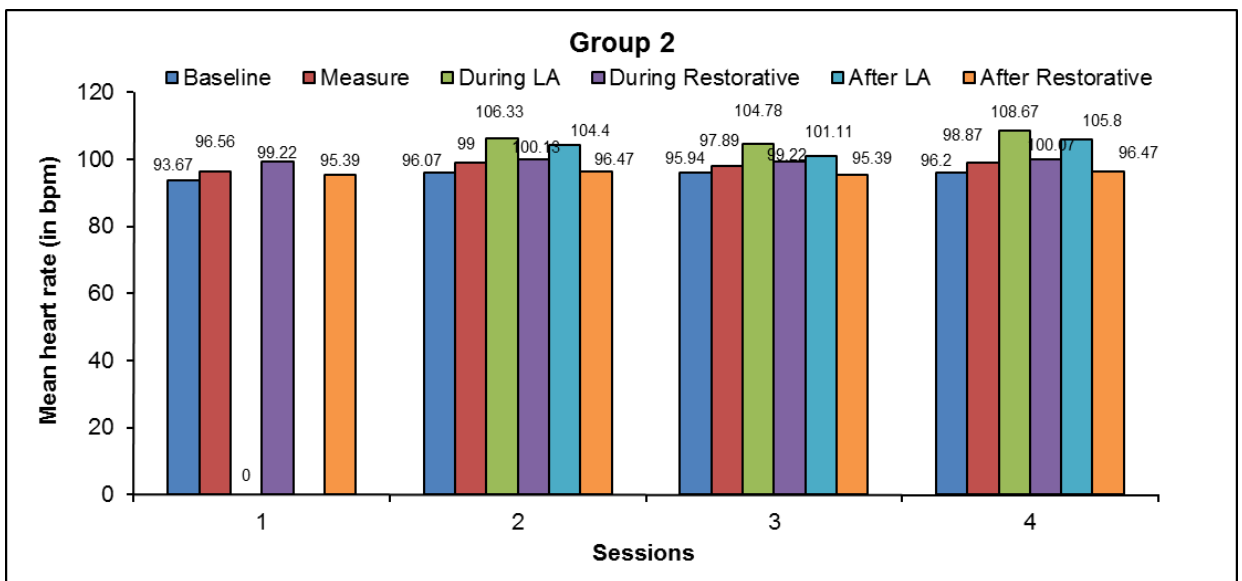
Graph 3: Bar chart showing mean heart rate according to stages and sessions for Group 1



Graph 4: Bar chart showing mean VPT according to stages and sessions for Group 1

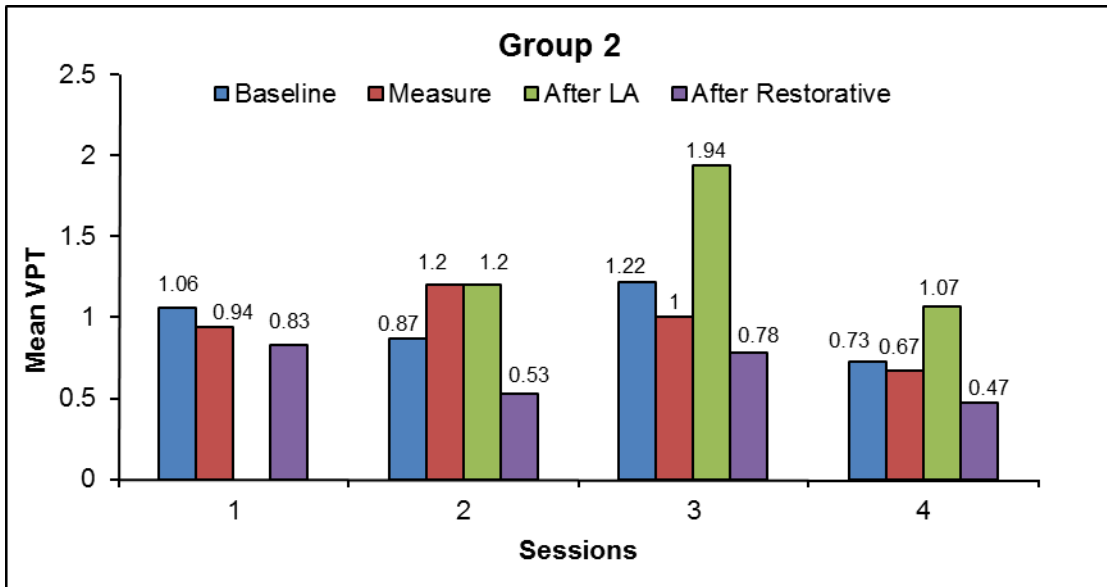


Graph 5: Bar chart showing mean WB according to stages and sessions for Group 1

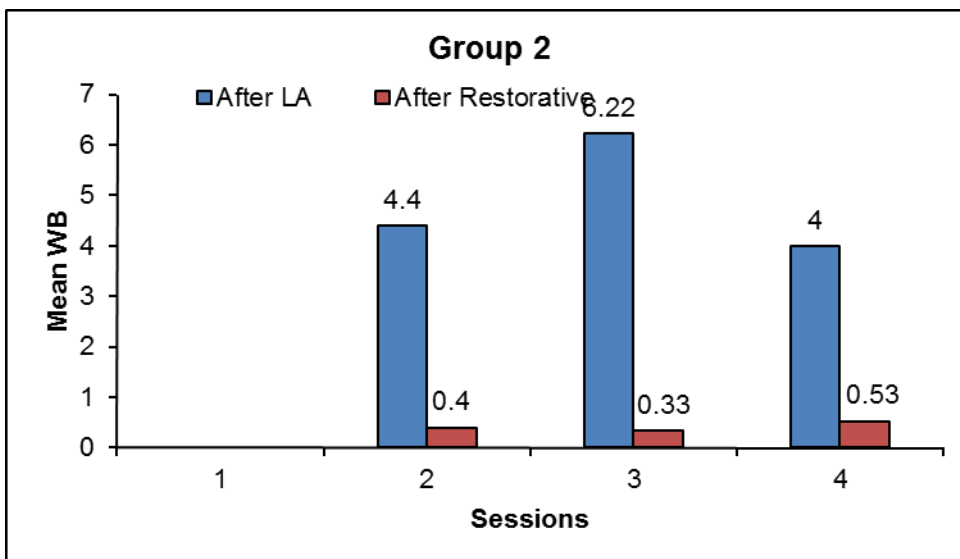


Graph 6: Bar chart showing mean heart rate according to stages and sessions for Group 2

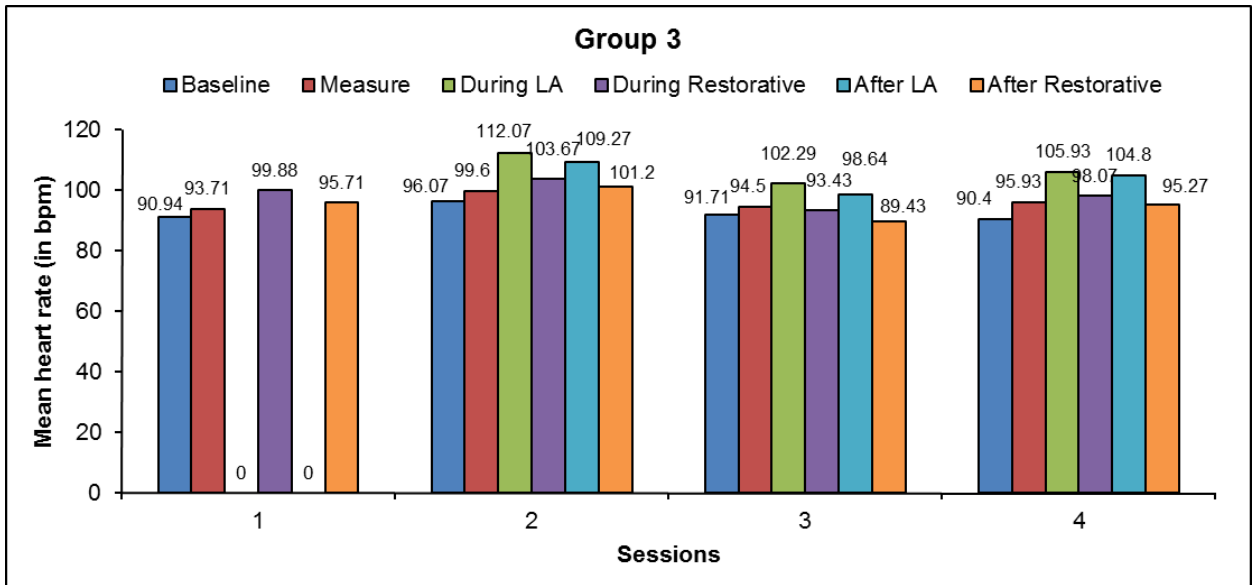
2



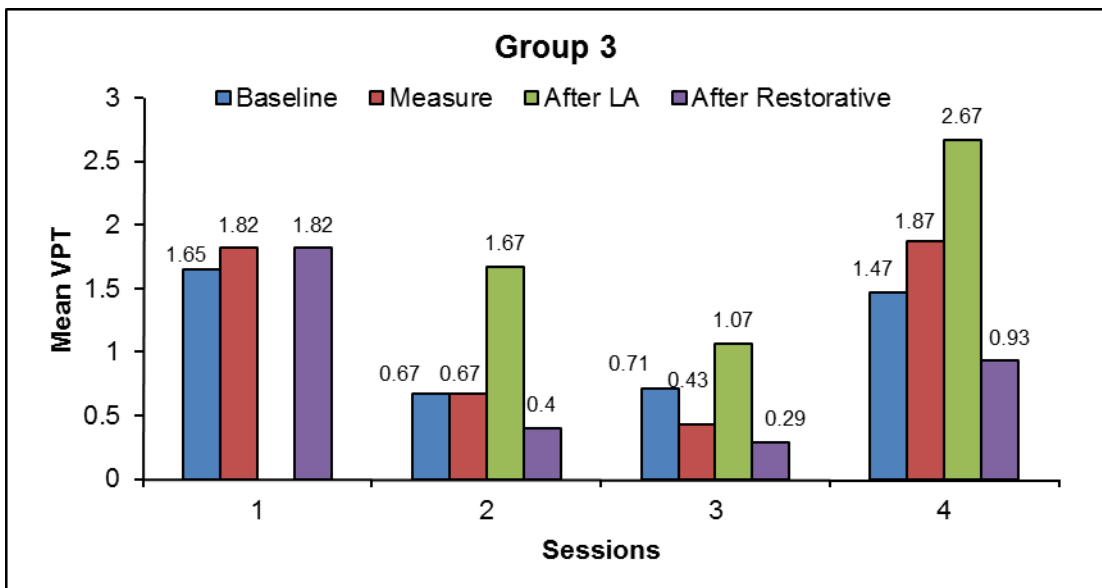
Graph 7: Bar chart showing mean VPT according to stages and sessions for Group 2



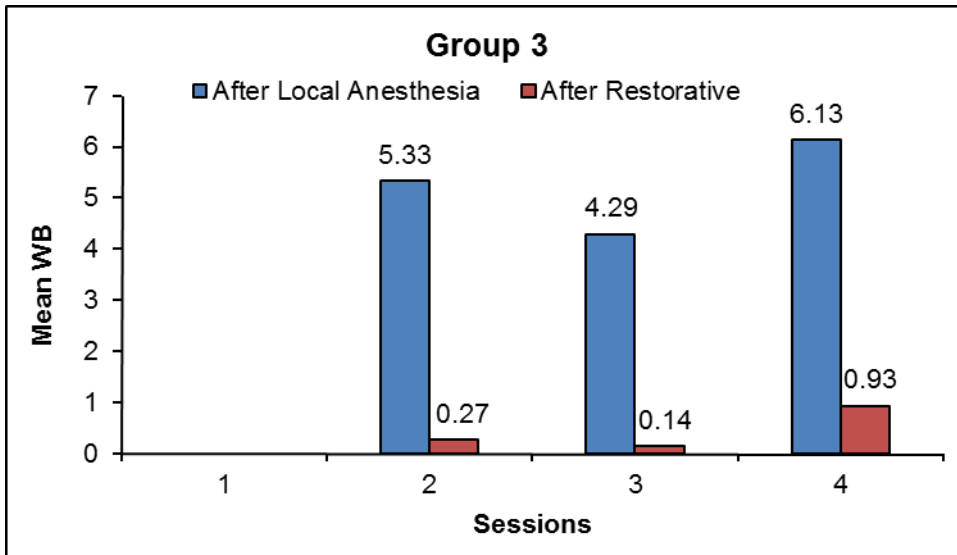
Graph 8: Bar chart showing mean WB according to stages and sessions for Group 2



Graph 9: Bar chart showing mean heart rate according to stages and sessions for Group 3



Graph 10: Bar chart showing mean VPT according to stages and sessions for Group 3



Graph 11: Bar chart showing mean WB according to stages and sessions for Group 3

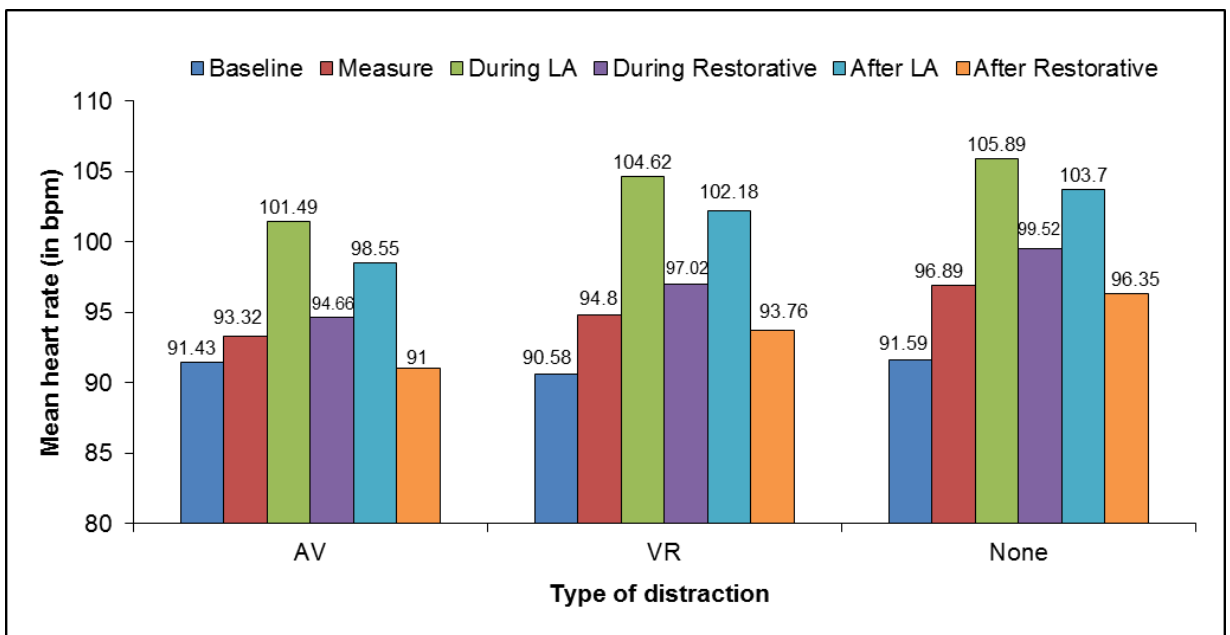


Figure 12: Bar chart showing mean heart rate according to stages and type of distraction

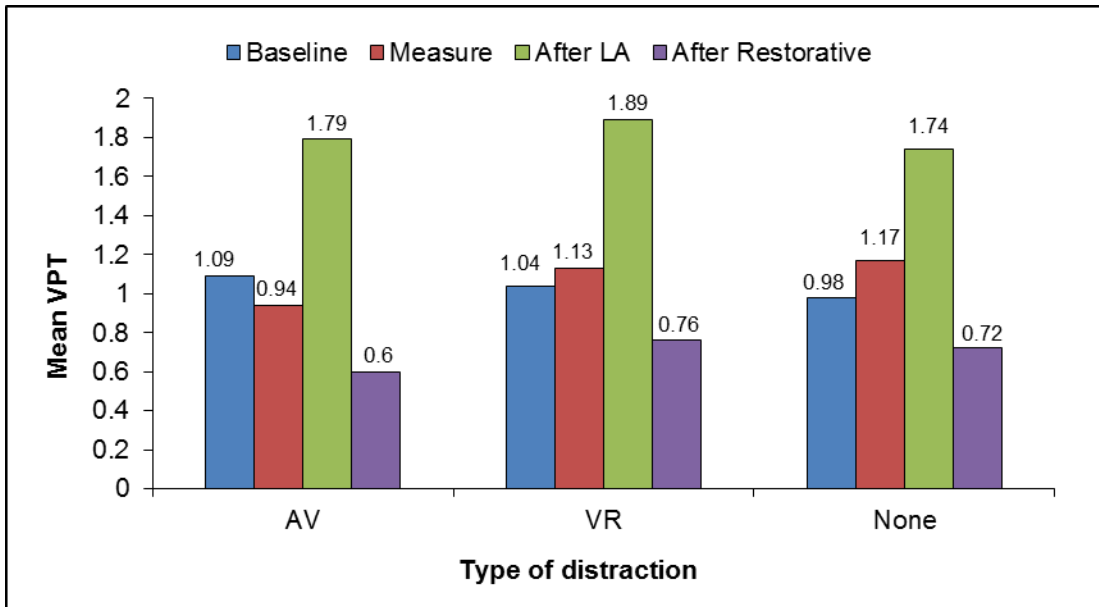


Figure 13: Bar chart showing mean VPT according to stages and type of distraction

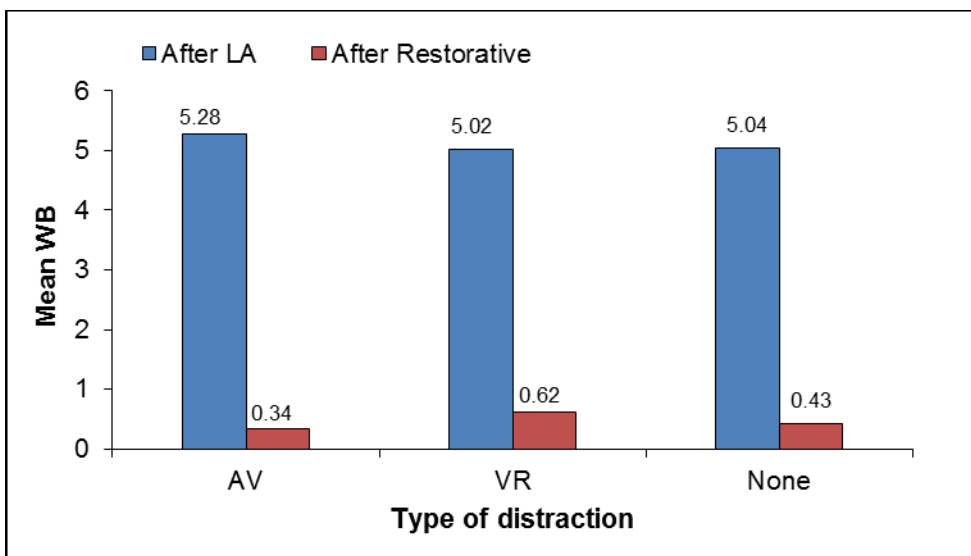


Figure 14: Bar chart showing mean WB according to stages and type of distraction

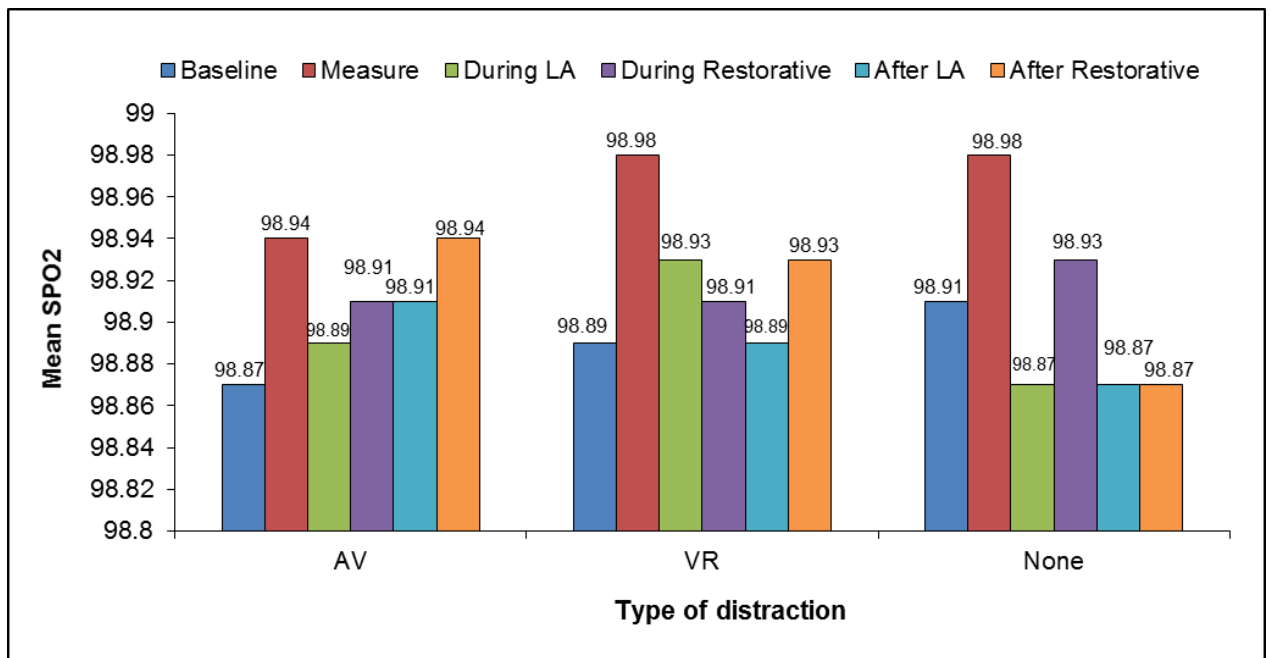


Figure 15: Bar chart showing mean SPO2 according to stages and type of distraction

ANNEXURE 1

Department of Pedodontics & Preventive Dentistry

सहमति पत्र

मैंने निचे दी गयी जानकारी पढ़ ली है , या मुझे पढ़वा दी गयी है। मुझे सवाल पूछने का अवसर दिया गया था और जो सवाल मैंने पूछे थे वह मेरे संतुष्टि तक दिए गए हैं। मैं स्व-इच्छा से इस रिसर्च में सहभागी होने की अनुमति देता/देती हूँ।

मैं इस "खास तरह की फॉर्म को स्वीकार करता/करती हूँ, और मुझे डॉक्टर ने इस रिसर्च के बारे में अच्छे से मेरे संतुष्टि तक समझाया है। मैं मेरे बच्चे के मुह के उचित चेक-उप करवाने के लिए राजी हूँ। मैं इस प्रोजेक्ट में भाग लेने को राजी हूँ। मैं हर तरह से डॉक्टर्स को सहयोग करूँगा/करूँगी। मैं मेरे सहभाग के बारे में प्रकाशन करने के लिए अनुमति देता/देती हूँ। मुझे कोई भी मुआवज़ा नहीं दिया जायेगा। मुझे इस रिसर्च प्रोजेक्ट को किसी भी वक्त छोड़ के जाने के मेरे हक के बारे में बताया गया है। मैं मेरे सहभाग के लिए की अनुमति का रिकॉर्ड देता/देती हूँ।

माता/पिता / संरक्षक का नाम	दस्तखत/ अंगूठे का निशान	दिनांक	समय
जाच करने वाले का नाम	दस्तखत	दिनांक	समय

अगर अशिक्षित है, तो एक शिक्षित गवाह ने दस्तखत करना चाहिए। जो भाग लेने वाले अशिक्षित हैं उन्होंने अंगूठे का निशान भी लगाना चाहिए।

मैंने अनुमति पत्र का इस सहभागी को पूरा पढ़के और समझके देना देखा है, और इस व्यक्ति को सारे सवाल पूछने का अवसर मिला है। मैं पुष्टि करता हूँ किस व्यक्ति ने खुद की इच्छा से अनुमति दी है।

गवाह का नाम:

निशान

गवाह की दस्तखत:

दिनांक:

सहभागी के अंगूठे का

ANNEXURE 1

CERTIFICATE OF CONSENT

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I acknowledge the “Specially designed proforma”, and also the doctor has informed me about this research project suitably and sufficiently to my satisfaction. I agree to let my child’s oral examination to be taken as required. I agree to take part in this project. I shall co-operate with the doctors, in all respects. I permit to publishing the results of my participation in this study. I shall not be given any reimbursement or compensation. I have been informed of my right to opt out of this research project at any time without giving any reason for doing so. I hereby record my consent for participation in the said project.

.....
Parent’s/guardian’s name	Signature/thumbprint	Date	Time
.....
Investigator’s name	Signature	Date	Time

If illiterate a literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness _____ Thumb print of participant

Signature of witness _____



Date _____

Day/month/year

ANNEXURE 2

बच्चो के उत्कंठा से सम्बंधित विकारों की छानबीन (SCARED)

माता पिता के भरने के लिए फॉर्म

नाम:

तारीख:

सूचना:

निचे कुछ वाक्य दिए गए हैं जो लोगों के भावना दर्शाते हैं। हर वाक्या को पढ़े और तय करिए की आपके बच्चो के लिए यह वाक्य " गलत है ", "कभीकबार सही है" या "हमेशा सही है " । फिर हर वाक्य के लिए, आपके बच्चो को पीछे ३ महीनो में लक्षण बताने वाला विकल्प चुने और आपके सुनिश्चित जवाब के निचे (V) ये निशान डाले।

	0 गलत है	1 कभीकबार सही है	2 हमेशा सही है
१) जब मेरे बच्चे को डर लगता है, तो उसे सांस लेने में तकलीफ होती है।			
२)मेरे बच्चे को स्कूल में सिरदर्द होता है।			
३)मेरे बच्चे को ऐसे लोगों के संग रहना पसंद नहीं, जिन्हें वह अच्छे से जानते नहीं।			
४)मेरा बच्चा अगर घर से दूर कही सोता है तो उसे बोहोत डर लगता है।			
५)मेरा बच्चा उसे दूसरे लोग पसंद करेंगे या नहीं इस बारे में सोचके चिंतित होता है।			
६)जब मेरे बच्चे को डर लगता है, तोह उसे चक्कर आये जैसा लगता है।			
७)मेरा बच्चा/बच्ची बेचैन है।			
८)में जहा भी जाती/जाता हूँ, मेरा बच्चा मेरे पीछे आता/आती है।			
९)लोग मुझे बताते हैं की मेरा बच्चा बेचैन दिखता है।			
१०)मेरा बच्चा अपरिचित लोगो के साथ बेचैनी महसूस करता/करती है।			
११)मेरे बच्चे को स्कूल में पेट में दर्द होता है।			
१२)जब मेरे बच्चे को डर लगता है, तो उसे लगता है की वह पागल हो रहा है।			

१३)मेरे बच्चा अकेले सोने से चिंतित होता है।			
१४)मेरा बच्चा दूसरे बच्चों जैसा अच्छा बनने के लिए चिंतित रहता/रहती है।			
१५)जब मेरे बच्चे को डर लगता है, तो उसे लगता है की चीजे असली नहीं हैं।			
१६)मेरे बच्चे को अपने माता/पिता के साथ कुछ बुरा हो रहा है ऐसे डरावने ख्वाब आते हैं।			
१७)मेरे बच्चे को स्कूल जाने से चिंतित होता है।			
१८)जब मेरा बच्चा घबराता है, उसकी दिल की धड़कन बढ़ जाती है।			
१९)मेरा बच्चा अस्थिर हो जाता /जाती है।			
२०)मेरे बच्चे को उसके साथ कुछ बुरा हो रहा है ऐसे डरावने सपने आते हैं।			
२१)मेरा बच्चा उसके साथ घट रही चीजों के लिए चिंतित रहता है।			
२२)जब मेरे बच्चे को डर लगता है, तो उसे बोहोत पसीना आता है।			
२३)मेरा बच्चा बोहोत चिंता करने वाला है।			
२४)मेरा बच्चा बिना किसी वजह के बोहोत घबरा जाता है।			
२५)मेरा बच्चा घर पे अकेले रहने से डरता है।			
२६)मेरे बच्चे को अपरिचित लोगो से बात करने में मुश्किल होती है।			
२७)जब मेरे बच्चे को डर लगता है, तोह उसे डैम घुटने जैसा लगता है।			
२८)लोग मुझे बताते हैं की मेरा बच्चा बोहोत ज्यादा चिंता करता है।			
२९)मेरे बच्चे को परिवार से दूर रहना पसंद नहीं है।			
३०)मेरे बच्चे को चिंता का दौरा पड़ने का डर लगता है।			
३१)मेरा बच्चा अपने माता पिता के साथ कुछ बुरा हो जायेगा ऐसे चिंता करता/करती है।			
३२)मेरा बच्चा, जिन लोगो को अच्छे से नहीं जनता, उनके सामने समाता है।			
३३)मेरा बच्चा आगे भविष्य में क्या होगा इसको सोचके चिंतित होता है।			
३४)मेरा बच्चा जब डरता है, तो उसे उलटी करने जैसा लगता है।			
३५)मेरा बच्चा, वह सारी चीजे कैसे कर रहा है, ये सोचके चिंतित होता है।			

३६)मेरे बच्चे को स्कूल में जाने से डर लगता है।			
३७)मेरा बच्चा जो घटनाये घट चुकी ही उनके बारे में चिंतित रहता है।			
३८)जब मेरा बच्चे को डर लगता है, तो उसे चक्कर आए जैसा लगता है।			
३९)मेरा बच्चा जब दूसरे बच्चो या बड़ों के साथ रहता है, या फिर उसे जब दुसरो के सामने कुछ कला प्रदर्शित करनी रहती है, तो बेचैनी महसूस करता है।			
४०)जब मेरे बच्चे को कोई पार्टी, या ऐसी जगह जाना पड़ता है जहा वह लोगो को अच्छे से नहीं जनता/जानती, तोह उसे बेचैनी महसूस होती है।			
४१) मेरा बच्चा शर्मीले किस्म का है।			

ANNEXURE 3

DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY

COMPARISON OF AUDIO-VISUAL AND VIRTUAL REALITY GOGGLE DISTRACTION TECHNIQUES IN MANAGING DENTAL ANXIETY AND PAIN IN PEDIATRIC DENTAL PATIENTS- A RANDOMIZED CONTROLLED CLINICAL STUDY.

EXAMINATION PROFORMA/CASE RECORD FORM

Identification No. Day Month Year ExaminerOrig/Dupl
Group

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

1 2 3 4 5 6 7 8 9 10 11 12 13

General information:

Name of child _____

Gender 1=M, 2=F

14

Age in years

15 16

Name and Address of parent:

_____ **Contact No. of Parent:** _____

Frankl behavior rating:

1. Definitely positive

17 **2. Positive**

SCARED Score(parental):

18

Intra-Oral Examination:

1. Teeth present(FDI)

2. Dental caries status –

DMFT/dmft index –

17	16	15/55	14/54	13/53	12/52	11/51	21/62	22/62	23/63	24/64	25/65	26	27
47	46	45/85	44/84	43/83	42/82	41/81	31/71	32/72	33/73	34/74	35/75	36	37

Total score =

3. OHI assessment –

55/16

51/11

65/26

Debris Score

Good: 0.0=0.6

Fair: 0.7-1.8

75/46

71/31

85/36

Poor: 1.9-3.0

55/16

51/11

65/26

Calculus Score

Treatm ent	Distra ction	Baseline Measure	Measures (before	LA procedure	Restorative procedure	VRS
---------------	-----------------	---------------------	---------------------	--------------	--------------------------	-----

75/46

71/31

85/36

Good: 0.0-0.6

Fair: 0.7-1.8

Poor: 1.9-3.0

Simplified oral hygiene index = Debris Index – Simplified +Calculus Index - Simplified

=

4. Radiographic interpretation:

5. Treatment plan

session	technique	s (in waiting room)			starting procedure after TSD)												
								During		After		During		After			
		HR	SP O ₂	VPT	HR	SP O ₂	VPT	HR	SP O ₂	HR	SP O ₂	HR	SP O ₂	HR	SP O ₂		VPT
I. Fluoride application																	
II. Restoration under LA																	
III. Restoration under LA																	
IV. Restoration under LA																	

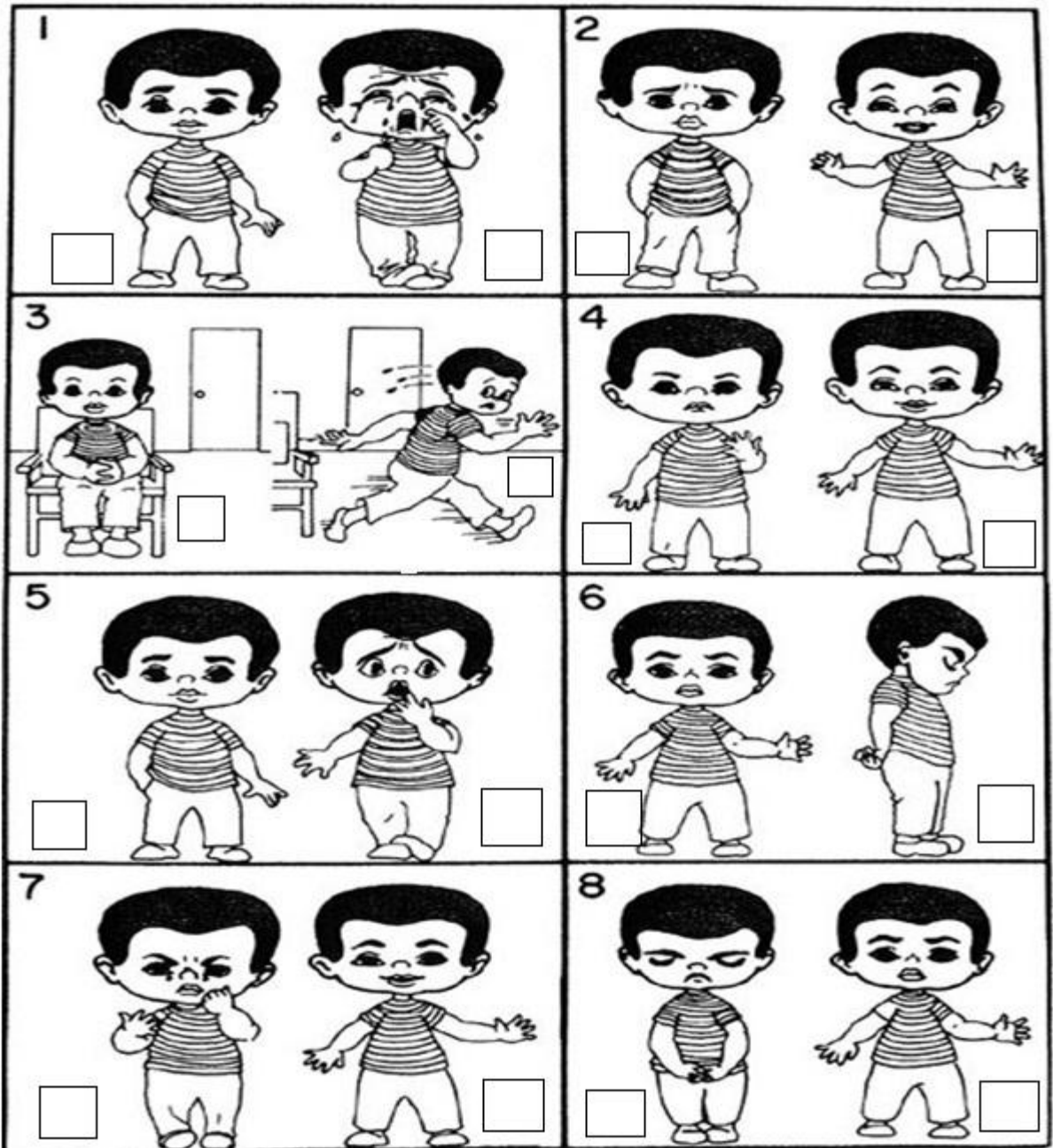
VRS Assessment observers: - 1

ANNEXURE 4

Venham's picture test (self-reported anxiety scale)

Name of the patient:-

Age/sex:-



ANNEXURE 5

Venham's Clinical anxiety rating scale

0.	Relaxed smilingwilling and able to converse.	
1.	Uneasy concerned. During stressful procedure may protest briefly and quietly to indicate discomfort. Hands remain down or partially raised to signal discomfort. Child willing and able to interpret experience as requested. Tense facial expressionmay have tears in eyes.	
2.	Child appears scared. Tone of voice questions and answers reflect anxiety. During stressful procedureverbal protest(quiet) cryinghands tense and raised(not interfering much -- may touch dentist's hand or instrumentbut not pull at it). Child interprets situation with reasonable accuracy andcontinues to work to cope with his/her anxiety.	
3.	Shows reluctance to enter situation difficulty in correctly assessing situational threat. Pronounced verbal protestcrying. Using hands to try to stop procedure. Protest out of proportion to threat. Copes with situation with great reluctance.	
4.	Anxiety interferes with ability to assess situation. General crying not related to treatment. More prominent body movement. Child can be reached through verbal communication and eventually with reluctance and great effort he or she begins the work of coping with the threat.	
5.	Child out of contact with the reality of the threat. Generally crying unabled o listen to verbal communication makes no effort to cope with threat. Actively involved in escape behavior. Physical restraint required.	

ANNEXURE 6

Wong-Baker FACES™ Pain Rating Scale



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MASTER CHART 1

Sl. no	Name of the patient	Age/Sex	Treatment1_None_Baseline_SPO2	Treatment1_None_Baseline_VPT	Treatment1_None_Measure_HR	Treatment1_None_Measure_SPO2	Treatment1_None_Measure_VPT	Treatment1_None_Restorative_During_HR	Treatment1_None_Restorative_During_SPO2	Treatment1_None_Restorative_After_HR	Treatment1_None_Restorative_After_SPO2	Treatment1_None_Restorative_After_VPT	Treatment1_None_Restorative_After_WB	Treatment1_None_VHS
1	Milind Raj	8y/M	96 bpm 95%	2	88 bpm 95%	2	80 bpm 95%	2	105 bpm 95%	102 bpm 95%	0	0	0	0
2	nishant ninge	8y/M	105 bpm 95%	4	103 bpm 95%	2	108 bpm 95%	2	108 bpm 95%	107 bpm 95%	2	2	0	0
3	Sujal Deshpande	8y/M	90 bpm 95%	3	84 bpm 95%	3	80 bpm 95%	3	100 bpm 95%	110 bpm 95%	3	3	0	0
4	Rohit Deshpande	7y/M	90 bpm 95%	3	85 bpm 95%	2	80 bpm 95%	2	108 bpm 95%	108 bpm 95%	3	3	0	0
5	shrut Deshpande	6y/F	98 bpm 95%	2	100 bpm 95%	2	95 bpm 95%	2	108 bpm 95%	108 bpm 95%	3	3	0	0
6	hritvik Kumar	7y/M	88 bpm 95%	4	80 bpm 95%	4	80 bpm 95%	4	104 bpm 95%	104 bpm 95%	4	4	0	0
7	divyanshu Dhanur	6y/M	87 bpm 95%	4	78 bpm 95%	1	84 bpm 95%	1	102 bpm 95%	100 bpm 95%	4	4	0	0
8	naishk Gopalale	6y/M	100 bpm 95%	4	103 bpm 95%	4	109 bpm 95%	4	108 bpm 95%	111 bpm 95%	5	5	0	0
9	Rohit Sharma	8y/M	83 bpm 95%	3	72 bpm 95%	2	84 bpm 95%	2	87 bpm 95%	83 bpm 95%	4	4	0	0
10	sidhant paril	7y/M	98 bpm 95%	2	100 bpm 95%	2	100 bpm 95%	2	102 bpm 95%	100 bpm 95%	2	2	0	0
11	Kunal Singh	8y/M	75 bpm 95%	0	85 bpm 95%	0	88 bpm 95%	1	105 bpm 95%	107 bpm 95%	0	0	0	0
12	ashish wante	5y/F	78 bpm 95%	2	72 bpm 95%	2	88 bpm 95%	2	104 bpm 95%	102 bpm 95%	5	5	0	0
13	amogh Chauhan	8y/M	87 bpm 95%	0	92 bpm 95%	0	90 bpm 95%	0	105 bpm 95%	104 bpm 95%	0	0	0	0
14	Saralika	7y/M	98 bpm 95%	0	100 bpm 95%	0	105 bpm 95%	1	112 bpm 95%	108 bpm 95%	3	3	0	0
15	aditi adhav	8y/F	85 bpm 95%	1	88 bpm 95%	0	85 bpm 95%	0	104 bpm 95%	104 bpm 95%	1	1	0	0
16	roshan galavde	8y/M	80 bpm 95%	0	78 bpm 95%	0	82 bpm 95%	2	104 bpm 95%	104 bpm 95%	2	2	0	0
17	soyama Inavale	8y/M	85 bpm 95%	1	80 bpm 95%	1	85 bpm 95%	0	100 bpm 95%	100 bpm 95%	0	0	0	0
18	Jayashree Patil	8y/M	75 bpm 95%	0	80 bpm 95%	0	84 bpm 95%	0	104 bpm 95%	104 bpm 95%	0	0	0	0
19	tamara dhole	8y/M	65 bpm 95%	0	70 bpm 95%	0	74 bpm 95%	0	104 bpm 95%	104 bpm 95%	2	2	0	0
20	laxsha Deshmukh	8y/F	90 bpm 95%	0	92 bpm 95%	0	88 bpm 95%	0	108 bpm 95%	106 bpm 95%	1	1	0	0

