Evaluation of Effect of Distraction Techniques Using Virtual Reality and Eight-dimension Audio Analgesia Methods on Pain Perception and Anxiety Levels in Children During Restorative Procedures: A Comparative *In Vivo* Study

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ABSTRACT

Introduction: Dental pain and dental anxiety are the most common determinants of negative dental experience, the reason for broken appointments and ignored oral health care affecting the quality of life.

Aim: To evaluate the effects of distraction techniques using virtual reality and eight-dimension (8D) audio analgesia method on pain perception and anxiety levels in children during restorative procedures.

Materials and methods: A total of 120 children between the ages of 4 and 10 years old who visited for the first time to a pediatric dental department were grouped equally between three interventional groups. Group I was treated with conventional tell-show-do (TSD) method; patients selected for group II (8D audio analgesia) and group III (virtual reality method) underwent two-step procedure that initially involved the TSD technique, by explaining the distraction techniques method conditioned for restoration treatment. Clinical evaluation of anxiety levels was measured by using the Chotta Bheem–Chutki (CBC), face, legs, activity, cry, consolability (FLACC) scale, and recording pulse and oxygen saturation rate. One-way analysis of variance (ANOVA) followed by *post hoc* Tukey's test was done to compare all the parameters between the three groups.

Results: In comparison to the conventional TSD method, both 8D audio analgesia and virtual reality method showed statistically better results. One-way ANOVA followed by *post hoc* Tukey's test showed no significant difference between the virtual reality group and 8D audio analgesic group.

Conclusion: Both 8D audio analgesia and virtual reality box distraction techniques can be used as an efficient distraction technique for TSD during dental procedures in children.

Keywords: 8D audio analgesia, Anxiety, Behavior management techniques, Virtual reality.

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INTRODUCTION

Pain is a distressing sensation and is one of the four cardinal signs of inflammation by "Celsus." As pain is perceived only by the patient, it is more often regarded as a symptom than sign. According to the International Association of Pain, pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[1] Dental anxiety is a universal human phenomenon, a feeling of tension associated with dental procedure or dental setup. Anxious patients anticipate more pain than they actually experience. The negative consequences of dental fear and anxiety lead to uncooperative child behavior, unresponsiveness, and lack of satisfaction with dental procedures.[2]

Various behavior management have evolved, and the noninvasive method has been highly appreciated and welcomed by parents and children. The noninvasive method includes psychological techniques, that is, a distraction which is a nondrug pain control technique (audio–video, audio analgesia, eye-ball movement, thaumaturgy).[3]

Recently, studies have shown proven effects of masking the dental procedure (sound of drill) to eliminate "conditioned anxiety." Anxiety and apprehension magnify the pain, and by masking it prevents the magnification. The methods that effectively give these masking effects are virtual reality (VR) distraction and audio analgesia.[4] Virtual reality analgesia is a technique where the patient's mind enters a 3D computer-generated world. In this

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virtual world, the brain gets flooded with information, allowing the patient to process less of the pain signals.[3]

Also, audio analgesia since its introduction in 1959 by Gardner and Licklider, is the production of insensitivity to pain by the use of pleasant loud music with a white noise that requires two parallel devices one to play the pleasant music and the other to play the white noise.[4] Past months, there has been an introduction of eight-

dimension (8D) music that lets the music revolve around the brain creating an effect that the music can be felt in brain rather than just heard through ears. 8D music is nothing but a stereo track with spatial reverb effect that lets the music circle around the brain. This can be an effective audio analgesic distraction technique.

Since there is limited literature on VR analgesia methods and no literature on 8D audio analgesia. The purpose of the current study was to assess and compare the effects of 8D audio analgesia method and VR-based distraction techniques on children undergoing restorative procedures.

MATERIALS AND METHODS

Patient Selection

The study protocol was approved by the Institutional Ethics Committee. The study was conducted on children aged 4–10 years (male and female) who reported to the Department of Pedodontics and Preventive Dentistry, Sri Siddhartha Dental College and Hospital, Tumakuru. A total of 120 children who fulfilled the inclusion criteria were included in the present study. The child was subjected to a brief medical and dental history, and informed consent was obtained from the parents. The duration of the present study was 6 months, and the samples were collected using selective sampling method during the outpatient department (OPD) hours.

Inclusion Criteria

Children between 4 and 10 years, children with no past history of dental treatment, and children who need a simple dental procedure (restorative).

Exclusion Criteria

Presence of any systemic disorders, special healthcare children, presence of any infections, dentoalveolar abscess, a sinus tract, or an obvious interradicular radiolucency.

Materials Used

Audio–visual eye apparatus—(VR glasses 3D VR box headset, China), mobile phones (iPhone, Apple, United States), wireless earphones (air pods, Apple, United States), fingertip pulse oximeter (Dr Trust Signature Series), Chotta Bheem–Chutki (CBC) pictorial scale.

Randomization

This research study was a simple random sampling randomized controlled trial using the lottery method. A computer-generated table of random numbers assigned the participants into three groups. Control group was allocated as group I, 8D audio analgesia was allocated as group II and VR distraction method was allocated to group III. Allocation concealment was performed using the sequencing number opaque sealed envelope (SNOSE) technique. A Consolidated standards of reporting trials (CONSORT) flow diagram is shown in Figure 1.

Clinical Procedure

Group I (control group): The participant was not given any type of distraction technology, and would be treated with conventional behavior methods like tell-show-do (TSD).

Patients selected for group II and III underwent two-step procedure that initially involved the TSD technique by explaining
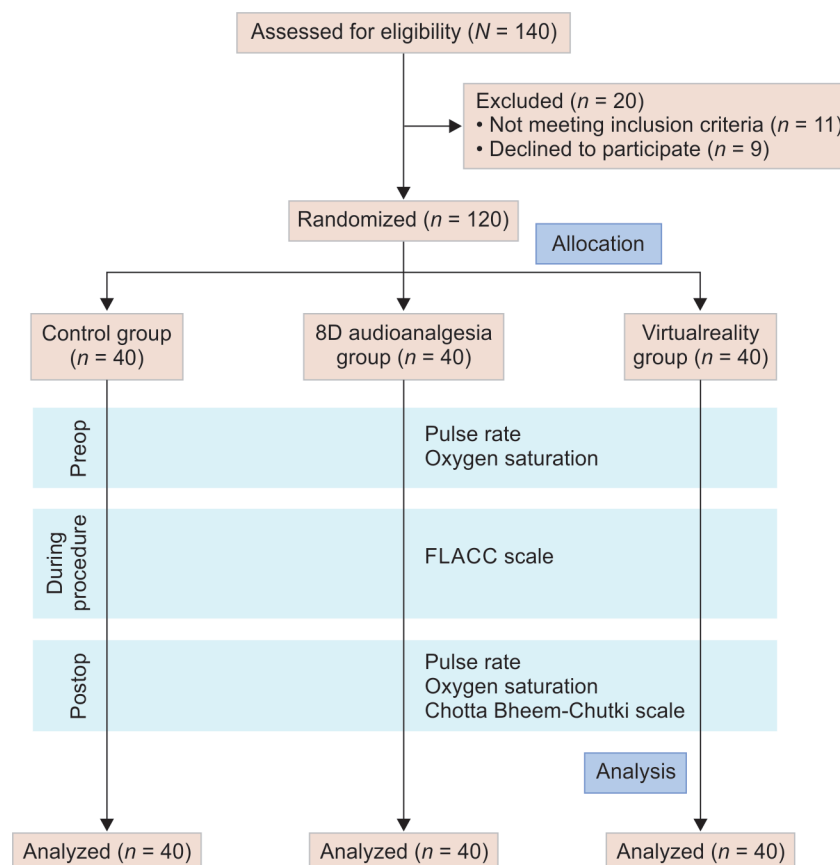

Fig. 1: Consolidated Standards of Reporting Trails (CONSORT) diagram

the distraction techniques used and showing them the devices to touch, feel, and see. Followed by second procedure where the child was asked to wear the devices during the restorative procedures. To maintain the communication between the dentist and the child "intercom app" was installed on two mobile phones (iPhone, Apple, United States) one that was connected to either of the devices with distraction technology and the other for the communication between the dentist and child. The voice commands passed irrespective of the video and audio playing.

Group II (8D audio analgesia): The earphones were connected to the audio player of mobile phone. The 8D audios from popular rhyme/music: "Coco Melon 8D," "Baby Shark 8D," "Frozen 8D," "Moana 8D," and "Movie Songs 8D," were played during the restorative procedure. 8D audio is an effect that when applied to a stereo track, the music will be felt like being revolving around your head (Fig. 2).

Group III [Audio–visual (AV) eyeglasses (VR box)]: The AV eyeglasses reduced the visual interference of the child completely and the auditory interference from the environment was reduced by in-ear headphones. The device was connected to a mobile phone (iPhone, Apple, United States) in which MP4 audio–visual files were played. A cartoon episode selected by the patient from one of the following popular cartoon series ("Tom and Jerry," "Chotta Bheem," "Motu Patlu") was played throughout the restorative procedure. The commands by the operator to the child were delivered through intercom app (Fig. 3).

After conditioning each participant, class 1 cavity was prepared using high-speed handpiece with water spray and then the teeth were properly isolated and restored with type II glass ionomer cement (GIC).[5]

Clinical Evaluation

Pain assessment scale: The CBC pictorial scale was used in this study to analyze pain after the restorative procedure. Children were first asked to choose their favorite character between Chotta Bheem and Chutki. Then the 6-scale pictorial representation, either Chotta Bheem or Chutki was shown to the children, and they were asked to choose the one that best described their emotions during the restorative procedure. It's an observational self-measurement that permits the child to respond nonverbally. A happy face received a score of 1 and an unhappy face received a score of 6.[6]

Behavior assessment scale: The behavior of the child during the procedure was assessed with the help of the face, legs, activity, cry, consolability (FLACC) scale in this study which was a reliable scale proved by Dak-Albab et al.[7] in the Syrian Arab Republic.

Pulse rate measure: Pulse rate and oxygen saturation were recorded twice during the study, once before the restorative procedure and then immediately after the completion of restorative procedure. The difference between the two measures was taken as the final value.[8]

Statistical Analysis

The statistical analysis was done using Statistical Package for the Social Sciences (SPSS) (IBM version 23). The descriptive statistics included mean, standard deviation, frequency, and percentages. The inferential statistics included one-way analysis of variance (ANOVA) followed by a *post hoc* Tukey's test. The level of significance was set at 0.05 at a 95% confidence interval.

RESULTS

Among 120 participants, majority of the participants were males in control group (80%), 8D audio analgesia group (60%), and VR (67.5%). There was no statistically significant difference among genders when Chi-squared test was applied ($p = 0.147$). The mean ages in groups I, II, and III were 5.70 ± 1.98, 7.32 ± 1.98, and 8.05 ± 1.77, respectively. There was significant difference statistically in the mean age of the population when one-way ANOVA test was performed ($p = 0.001$) (Table 1).

Table 1: Distribution of the study participants among the study groups

Study characteristics		Control n (%)	8D audio analgesia n (%)	VR n (%)	p-value
Gender[a]	Male	32 (80%)	24 (60%)	27 (67.5%)	0.147
	Female	8 (20%)	16 (40%)	13 (32.5%)	
Total		40 (100%)	40 (100%)	40 (100%)	
Age in year[b] (mean ± SD)		5.70 ± 1.98	7.32 ± 1.98	8.05 ± 1.77	0.001*

All values are expressed as frequency with percentages (in parentheses); SD, standard deviation; The statistical test used: [a]Chi-squared test and [b]one-way ANOVA: *$p \leq 0.05$ is considered statistically significant

Fig. 2: Distraction using 8D audio analgesia earphones

Fig. 3: Distraction using VR box and mobile phone

Oxygen saturation among the three study groups is depicted in Table 2. It was found that VR group had the lowest mean O_2 saturation values (96.20 ± 3.15). When ANOVA test was performed it was found that there was significant difference in O_2 saturation values among the three groups ($p = 0.019$). When pairwise Tukey *post hoc* test was performed, it was found that statistically there was a significant difference in O_2 saturation value among the control group and VR group ($p = 0.015$).

The pulse rate among the three study groups is depicted in Table 3. It was found that VR group had the lowest mean pulse rate values (84.73 ± 5.70). When ANOVA test was performed it was found that there was a significant difference statistically in O_2 saturation values among the three groups ($p = 0.001$). When pairwise Tukey *post hoc* test was performed, it was found that there was a significant difference in the mean pulse rate values between group I and group II ($p = 0.001$) and also between group I and group III ($p = 0.001$).

Figure 4 compares the O_2 saturation before and after intervention between the three groups. Figure 5 compares the pulse rate before and after intervention between the three groups.

Table 4 presents the posttreatment pain scale readings among the three study groups. It was found that in the control group, majority (62.50%) of the participants were sad, whereas in 8D audio analgesia (72.5%) and VR (62.5%) group majority of them were happy. Statistically, there was a significant difference in the

pain scale readings between the three study groups when the Chi-squared test was applied.

Table 5 presents the posttreatment FLACC scale readings among the three study groups. It was found that in the control group, majority (60%) of the participants had mild discomfort, whereas in 8D audio analgesia (97.5%) and VR (97.5%) groups
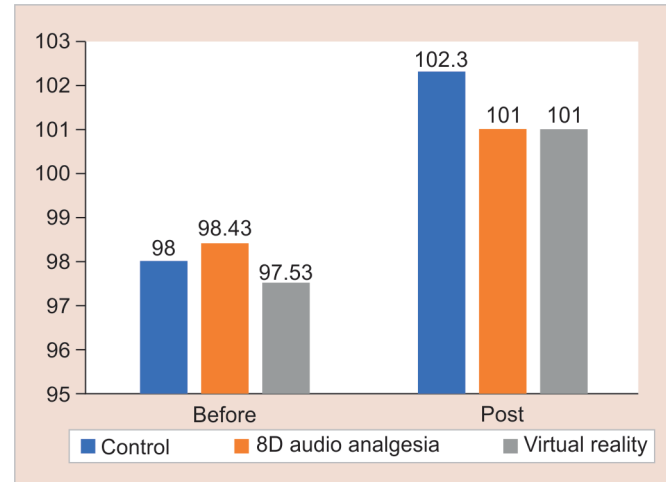

Fig. 4: Comparison of O_2 saturation before and after intervention among the three groups

Table 2: Comparison of treatment values of O_2 among the study groups

Group	Mean ± SD	N	f	p	Post hoc test Pair	Mean difference	p
Control (I)	102.30 ± 15.23	40	4.087	0.019*	A and B	3.125	0.437
8D audio analgesia (II)	99.18 ± 5.59	40			A and B	6.100	0.015*
VR (III)	96.20 ± 3.15	40			A and B	2.975	0.498

All values are expressed as mean ± standard deviation (SD); The statistical test used: one-way ANOVA followed by Tukey's *post hoc* test; level of significance: *$p ≤ 0.05$ is considered statistically significant

Table 3: Comparison of treatment values of pulse rate among the study groups

Group	Mean ± SD	N	f	p	Post hoc test Pair	Mean difference	p
Control (I)	111.00 ± 22.74	40	38.146	0.001*	A and B	19.425	0.001*
8D audio analgesia (II)	91.57 ± 5.89	40			A and B	26.275	0.001*
VR (III)	84.73 ± 5.70	40			A and B	6.850	0.080

All values are expressed as mean ± standard deviation (SD). The statistical test used: one-way ANOVA followed by Tukey's *post hoc* test; level of significance: *$p ≤ 0.05$ is considered statistically significant

Table 4: Comparison of posttreatment pain scale scores among the groups

Pain scale	Control n = 40	8D audio analgesia n = 40	VR n = 40	p-value
Happy	8 (20%)	29 (72.50%)	25 (62.50%)	0.001*
Sad	25 (62.50%)	9 (22.50%)	14 (35%)	
Crying	1 (2.50%)	1 (2.50%)	1 (2.50%)	
Angry	1 (2.50%)	1 (2.50%)	0 (0%)	
Shouting	4 (10%)	0 (0%)	0 (0%)	
Running	1 (2.50%)	0 (0%)	0 (0%)	

All values are expressed as frequency with percentages (in parentheses). The statistical test used: Chi-squared test: *$p ≤ 0.05$ is considered statistically significant

Table 5: Comparison of posttreatment FLACC scale scores among the groups

FLACC scale	Control n = 40	8D audio analgesia n = 40	Virtual reality n = 40	p-value
Relaxed and comfortable	11 (27.5%)	39 (97.5%)	39 (97.5%)	0.001*
Mild discomfort	24 (60%)	0 (0%)	1 (2.5%)	
Moderate pain	4 (10%)	1 (2.5%)	0 (0%)	
Severe pain	1 (2.5%)	0 (0%)	0 (0%)	

All values are expressed as frequency with percentages (in parentheses). The statistical test used: Chi-squared test: *$p \leq 0.05$ is considered statistically significant
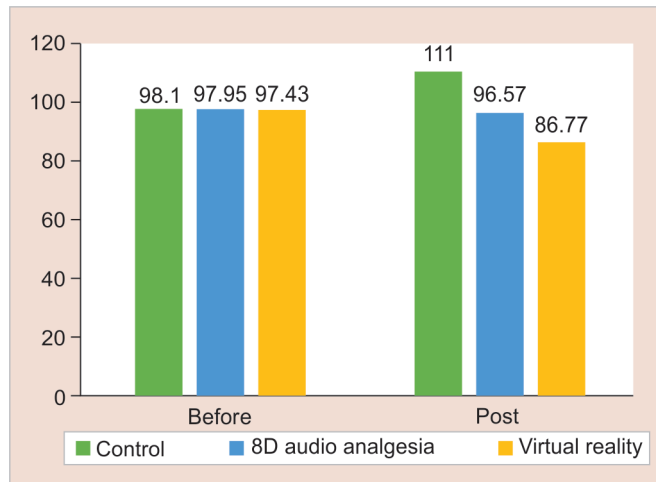
Fig. 5: Comparison of pulse rate before and after intervention among the three groups

majority of them were relaxed and comfortable. Significant difference was seen in the FLACC scale readings between the three study groups when Chi-squared test was applied.

Discussion

Any pediatric dentist who successfully manages apprehensive children has a challenging yet rewarding experience.[9] Due to the dynamic nature of dental anxiety and its combination of social, perceptual, and psychological components, assessing it with a single parameter may produce unreliable results. Hence, a combination of subjective (self-assessment report) CBC scale, objective FLACC scale, and physiologic measurement using fingertip pulse oximeter is used in the study as each child perceives dental pain depending upon their cognitive abilities.[2]

The study included 120 children with equal number of participants allocated to each of the three interventional groups. None of the children in the present study was reported with any previous dental experience. They typically perceive dental situations as stressful because of the fear of the unknown.[10]

According to Aitken et al.,[11] a self-reported estimate of pain gives a quick emotional response to dental therapy.[1] The CBC scale, considered a relevant scale in assessing subjective pain in children undergoing dental procedures because of children's identification with the well-known cartoon character, is being used in the present study. In contrast to the Venham picture test (VPT) scale, this scale has the potential to assess both the child's level of positive and negative feelings as reported by Sadana et al.[6]

Several researchers have used the FLACC pain scale during treatment to report pain. According to The Royal College for Nursing, the scale can be used in children older than 3 years old, whether they cooperate or not.[8]

Various studies reported on fear and anxiety in dental patients have employed pulse rate and oxygen saturation as an end metric. The autonomic nerve system (ANS), which controls heart rate and respiration rate as well as body temperature, is also responsible for controlling pulse rate. In order to determine whether a person is experiencing stress or anxiety, the ANS' physiological reactions are employed as indications. The anticipation of a dental procedure acts as a stress stimulus, stimulates the sympathetic nervous system, and may raise heart rate.[12]

According to McCaul and Mallot's theory,[13] when a patient is diverted from an unpleasant stimulus, their experience of pain is lessened. It's obvious sense that a patient's attention to an unpleasant stimulus has a direct correlation with their perception of pain.[14]

In accordance with our study results, AV eyeglasses "VR box" and 8D audio analgesia have significant advantages over the conventional behavior management of TSD technique during dental restorative procedures. Pulse rate and oxygen saturation level were significantly reduced in the VR group, with the mean postdistraction pulse rate and oxygen saturation measuring 84.73 and 96.20, respectively. The subjective pain scale using CBC scale reported that a majority of 62.5% participants were happy and that of FLACC scale revealed about 97.5% of participants were relaxed and comfortable. This above finding could be attributed to the fact that children are more likely to accept VR that blocks the view of the real world and utilizes fantastical realms and 3D virtual landscapes that have considerable ecological validity. This method by which the sensory input from the VR distractions shields the child from the pain stimulus is called sensory shielding as defined by McCaffery and Pasero.[15] Many researchers have already stated that the AV eyeglasses "VR box" cause less fear to the patient during both invasive and noninvasive procedure.[8]

On the other hand, it was duly noted that the AV eyeglasses "VR box" was difficult to use due to its size and weight of the box; in some cases, the child had to hold the box to keep it from sliding to sometimes it blocked the operator's vision, thereby hindering the dental procedure.[8] Wismeijer et al.[16] in their review pointed out "simulator sickness" due to close contact and poor-quality visuals shown *via* the VR device. No children who used the VR equipment in our study reported feeling queasy, which is expected to make sensitive people nauseous.[17]

Nonetheless, 8D audio analgesia using just the earphones was superior to AV eyeglasses and conventional group in managing the child during dental restorative procedure. Audio analgesia has already proven to be the best among other distraction techniques which was also concluded in the studies carried out by Sivakumar et al.[18] and Lehmann et al.[19] it is an effective technique due to relaxation effect of the calm sound over the noise created by the dental procedures.

Our current study showed significant reduction in pulse rate and oxygen saturation, the mean values interpreted as 91.57 and 99.18, respectively, in the 8D audio analgesia group. CBC scale recorded a majority of 72.5% reported being happy with the

treatment while FLACC scale revealed 97.5% of them were as relaxed and comfortable as the VR group participants. The 8D audio analgesia used in our study upgraded the conventional audio analgesic procedure by creating binaural beats, where each ear hears tones at different frequencies. This means it unlocks the benefit of a state of relaxation and induction of the mental state associated with meditation. The limitation to this method was that 8D music could be only appreciated when using earphones and some children may be apprehensive to wear phones as it can create dizziness and/or nausea. None of the kids in our study denied wearing earphones throughout the procedure. We maintained the volume between 70 and 75 dB for kids wearing earphones as indicated by the World Health Organization (WHO) and the treatment procedure did not last >30 minutes.

The conventional group with TSD technique and no distraction technology, though it remains a universal method used for behavior management by the dentists of the world. It showed to be disadvantageous over both VR group and 8D audio analgesia group. The mean pulse rate and oxygen saturation rate remained high, and CBC revealed that 62.5% of participants were sad while the FLACC scale revealed that 60% of group experienced mild discomfort. This could be due to overexplanation and the fact that the noise and sound of dental procedures do not get masked in the process and perception of the child toward TSD technique varied depending on their cognitive characteristic.

Children were most comfortable in the 8D audio analgesia group followed by the VR group, according to the overall results determined by all the parameters. The fact that the children were given the option to choose video/song played elicited positive behavior thereby instilling a reduced anxiety and fear of unknown. According to Wismeijer and Vingerhoets, the gate control theory, which suggests that when a person is distracted by pleasurable stimuli, some areas of the brain process less pain-related stimuli, explains why distractions can reduce the sense of pain.[2]

However, the limitations of the research were that both the distraction technology was used only in single-visit procedures, involving just the restorative procedure. Hence, further research is required involving various age-group and larger sample size with multiple visit procedures involving invasive procedures such as local anesthesia administration and/or extraction procedures.

CONCLUSION

The result of our study concludes that both distraction technologies used were superior to the conventional group. We also observed that children were most comfortable using headphones rather than VR box. And just the use of earphones with YouTube songs is more cost-effective and readily available than VR box. Hence, active distraction technologies like 8D audio and VR are recommended in pediatric dental practice.

Clinical Significance

This study is important as it helps reduce dental anxiety in children during the first dental visit. Once a positive behavior is inculcated in the patient, their fear and anxiety will reduce and they will come with more dental treatments in the future.

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