

EFFECT OF VIRTUAL REALITY GLASSES DISTRACTION ON THE ANXIETY OF PRESCHOOL CHILDREN DURING PULPOTOMY TREATMENT (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: Controlling child's dental anxiety is an integral part in pediatric dentistry. Numerous methods are used to control dental anxiety in children. Audiovisual distraction using virtual reality (VR) glasses is a non-pharmacological intervention that can be used to manage child's anxiety during dental treatment.

OBJECTIVES: To evaluate and compare the effect of VR glasses to conventional behavior management techniques on child's anxiety during pulpotomy.

METHODOLOGY: The study was a randomized controlled clinical trial. The sample consisted of twenty preschool children of age ranging from 4 to 5 years old presented to the Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Alexandria University. The selected children had at least one mandibular primary molar indicated for pulpotomy. The eligible participants were randomly and equally divided into an experimental group, where VR glasses distraction was used for child behavior management and a control group, where conventional behavior management techniques were used. Pre and post-operative assessment of child's dental anxiety was done using (a) Venham clinical anxiety rating scale (b) Changes in salivary cortisol level.

STATISTICAL METHOD: Mann-Whitney test, Friedman test, and Wilcoxon signed rank test were used. Significance level was set at P value < 0.05.

RESULTS: The VR group showed significantly lower scores for Venham clinical anxiety rating scale than the control group during intraoral examination (P=0.02). However, there were no significant changes in salivary cortisol level in any of the groups.

CONCLUSION: VR glasses were useful in managing dental anxiety in preschool children especially during intraoral examination.

KEYWORDS: Dental anxiety, virtual reality, audiovisual, distraction, salivary cortisol.

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INTRODUCTION

The key of success of any pediatric dental treatment is highly dependable on the child's cooperative behavior during the dental visit (1). Dental anxiety has been always considered as an obstacle facing pediatric dentists, and greatly compromising both the quality and efficacy of the dental treatment provided (2,3). Therefore, the main goal of a pediatric dentist

is to reduce or eliminate the child's dental anxiety by understanding the underlying causes (4).

Management of child's dental anxiety can be done either non-pharmacologically or pharmacologically, or by using a combination of both (5–7). Non-pharmacological management techniques are more favored by both professionals and parents for eliminating the risks associated with pharmacological

interventions (8). Distraction is one of the non-pharmacological behavior management techniques commonly used by pediatric dentists, especially when carrying out painful dental procedures to withdraw the patient's attention from unpleasant stimuli. The ideal distractor requires optimal amount of attention involving multiple sensory modalities to ensure patient's participation, and compete with the noxious signals. Virtual reality (VR) glasses are one of the types of audiovisual distraction tools, consisting of head-mounted display and headphones (9,10).

Several studies have investigated the effect of audiovisual glasses distraction on children of different age groups during different dental procedures, and found a significant decrease in dental anxiety, as well as, improvement of behavior with the use of audiovisual glasses (11–13).

Literature is still investigating the effectiveness of the application of VR glasses distraction in pediatric dental setting. This study was designed to evaluate and compare the effect of VR glasses distraction to the conventional behavior management techniques on child's dental anxiety during pulpotomy treatment.

The null hypothesis of this study was that there would be no significant difference in child's dental anxiety with or without VR glasses distraction.

MATERIALS AND METHODS

The approval of research ethics committee in the Faculty of Dentistry, Alexandria University was obtained before the beginning of the study (IORG0008839), and was registered in ClinicalTrials.gov (NCT04110379) - (IRB00010556). The parents of all the participating children signed informed consents after full explanation of the objectives, as well as, the benefits and the risks of the study. The study was a randomized controlled clinical trial with two parallel groups. It was set up and recorded according to the CONSORT guidelines (14). It was carried out in the Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Alexandria University and the Department of Clinical Pathology, Faculty of Medicine, Alexandria University. The PICO question for this study was: Do preschool children receiving pulpotomy treatment (Population:P) using either VR glasses distraction (Intervention:I) or conventional behavioral management techniques (Control:C) show lower level of dental anxiety during different dental procedures (Outcome:O)?

Sample size Estimation (13)

The lowest required sample size was twenty children, ten per each group. The Sample size was based on the following assumptions: alpha error =5%, study power=80%, mean modified Venham's clinical rating of anxiety and cooperative behavior scale (MVARs) score for the children in the audiovisual distraction group = 0.14, standard deviation = 0.36, mean MVARs score for children in the control group = 0.75, standard deviation = 0.52. Sample size was calculated using MedCalc Statistical Software version 18.2.1 (15).

Study sample

Twenty healthy children of age ranging from four to five years old, with ASA category I (16), and Frankl behavior rating score 2(negative) or 3(positive) (17), requiring pulpotomy in one of their mandibular primary molars were included in this study, in order to standardize the local anesthesia technique and the dental treatment received by all the participating children, and for standardization of the length of dental session, which would affect the outcome. The tooth selection for pulpotomy treatment was done according to the guidelines of the American Academy of Pediatric Dentistry (AAPD) (18), where all the selected teeth were vital with deep caries that resulted in carious exposure, exhibiting signs and symptoms of reversible pulpitis, with a healthy periodontium, and no radiographic signs of infection or pathologic resorption. Children taking medications that interfere with measures of salivary cortisol (19), requiring emergency treatment, and with any systemic or mental diseases were excluded.

Randomization, Allocation Concealment, and Grouping

Subjects fitting the inclusion criteria were randomly assigned using a computer – generated list to one of the two groups (experimental or control group). Allocation was performed by using permuted block technique, where participants were allocated in blocks of two and the allocation ratio was equal. Allocation was performed by a trial independent individual (20). Each child was given a serial number written in identical sheets of paper with the group to which the child was allocated and placed inside opaque envelopes carrying the respective names of the children. A trial-independent personnel was assigned to keep the envelopes and unfold them only at the time of the dental visit so that the group to which the child is allocated is concealed from the operator/outcome evaluator.

The eligible participants were randomly divided into 2 groups where group I (experimental): consisted of 10 children where behavior management was done using the VR glasses (Remax Fantasy Land by Schenzen Remax Co., Ltd) as a distraction method and group II (control): consisted of 10 children where behavior management was done using the conventional techniques as Tell-Show-Do (TSD), distraction, and positive reinforcement. The operator and the child could not be blinded to intervention done to each group since the behavior management technique used for each group was different. However, the Clinical Pathology laboratory technician who carried out the salivary cortisol samples' analysis was blinded about the studied groups.

Intervention and Outcome Assessment

The child's first dental visit was a non-invasive visit for preparation of the patient before intervention. This visit included taking medical and dental history, preoperative periapical radiograph to ensure tooth is indicated for pulpotomy treatment (18), and dental prophylaxis. In the Second visit, the child was assigned to one of the behavior management groups according to the randomization process. In group I, the VR glasses were introduced to the child using TSD technique, and he/she was given the choice of the age appropriate cartoon episodes to view during the whole dental treatment. The child took five minutes to get familiar with the glasses before starting the dental treatment (21). In group II, Conventional behavior management techniques were done to relieve the child's dental anxiety during the dental treatment, which included: TSD technique (5), distraction by speaking to the child or counting, and positive verbal and social reinforcement (6).

Operative procedure

For all the participating children ferric sulfate (Quick-Stat, Vista Dental Products, USA) pulpotomy was performed for mandibular primary molars where, the injection site was dried and 20% Benzocaine topical anesthesia gel (Iolite, Dharma research, INC, Miami, Florida) was applied to the tissue for thirty seconds using cotton swab. Inferior alveolar nerve block anesthesia was administrated. Mepivacaine HCL 2% with 1:20000 Levonordefrin (Mepecaine-L, Alexandria Co. For Pharmaceuticals, Egypt) was used. Profoundness of local anesthesia was checked by gently probing the gingival tissue adjacent to the tooth being restored. All primary molars were treated with rubber dam isolation followed by caries removal, and coronal access

using a sterile high speed #330 carbide bur. Coronal pulp tissue amputation was done using a sterile sharp spoon excavator. Pulpal hemorrhage was controlled using a sterile moist cotton pellet under pressure for two to three minutes. A cotton pellet moistened with 15.5% of ferric sulfate gel (Quick-Stat, Vista Dental Products, USA) was applied to the pulp stumps for 15 seconds. Pulpal stumps were then rinsed, dried with cotton pellets and a thick paste of hard setting zinc oxide eugenol (Pyrax, India) was packed gently. Then teeth were restored with a preformed stainless steel crowns (Kids Crown, India) (22,23).

Outcome assessment:

In the present study two methods were used to assess dental anxiety:

A. Venham Clinical Anxiety Rating Scale (24)

All Assessments were done by the same investigator (Dentist) who provided the dental treatment to all the participating children. Before assessing the child's dental anxiety, the investigator was trained and calibrated. The dental sessions of ten patients were videotaped and re-evaluated by the investigator for the assessment of intra-examiner reliability of Venham clinical anxiety rating scale by using Weighted Kappa test, and the values ranged from 0.70 to 1.00 indicating good reliability (25). Those patients were not included in the study. This scale consisted of 6 categories (range from 0 to 5) where 0= relaxed, 1=uneasy, 2= tense, 3= reluctant, 4= interference, 5= out of contact. Each category describes the patient status in the dental chair when a particular dental procedure was performed. The child's dental anxiety was evaluated preoperatively by Venham clinical anxiety rating scale once the child was seated on the dental chair, and during each of the following steps (intraoral examination, local anesthesia administration, rubber dam application, and pulpotomy procedure) respectively (13).

B. Estimation of Salivary cortisol level

Two salivary samples were collected from each child. The first preoperative sample was collected before intraoral examination and the second postoperative sample was collected immediately after completion of the pulpotomy procedure. For standardization of the salivary sample, 2 ml of unstimulated saliva was collected during the morning hours due to circadian rhythm. Eating, drinking and chewing gums or brushing teeth were avoided for 30 minutes before sampling. Otherwise, it was recommended to rinse the mouth thoroughly with cold water 5 minutes prior to sample collection. In case of any visible blood

contamination in the patient's sample, it was discarded, and a new sample was taken after 10 minutes. Each child was asked to pool saliva in his/her mouth for 5 minutes and then passively drool it in a sterile container. The plastic containers containing the saliva samples were tightly closed, placed with ice gel pack, and immediately taken to the laboratory of the Clinical Pathology Department, Faculty of Medicine Alexandria University. Whole unstimulated saliva samples were then transferred to Eppendorf tubes, centrifuged and stored at -20°C till being assayed (26,27).

Assay procedure

The salivary samples were analyzed for salivary cortisol using solid phase enzyme linked immunosorbent assay using salivary cortisol ELISA kit (DRG International, Inc., USA). The procedure was done as per manufacturer's instructions. The mean absorbance values of each set of standards, controls, and patient's samples were calculated, and the corresponding concentration of each sample was determined from a standard curve created from known salivary cortisol concentrations provided in the kit. Salivary cortisol values obtained for baseline and postoperatively were compared to assess the changes, where elevation of salivary cortisol level from baseline following the pulpotomy procedure would suggest increased level of dental anxiety in children, which is a reflection of hypothalamic pituitary adrenal cortex axis (HPA axis), activation in response to stress accompanying dental treatment (28,29).

Statistical Analysis

Data were analyzed using SPSS for Windows version 23.0 (30), and significance level was set at P value < 0.05 . Normality was checked for quantitative variables using descriptive statistics, plots, and normality tests. Median and interquartile range (IQR) were calculated for non-normally distributed and qualitative ordinal variables (salivary cortisol level and Venham's clinical anxiety rating scale). Comparisons between the two study groups were done using Mann-Whitney test for quantitative non-normally distributed variables and qualitative ordinal variables. Comparison of different time points (procedures) within each group were done using Friedman test and Wilcoxon signed rank test according to the number of time points. Post-hoc pairwise comparisons were done using Bonferroni adjusted significance levels.

RESULTS

Twenty-four patients were examined to be enrolled in the present study, twenty patients aging four to five years old with a mean (\pm SD) age $4.6 (\pm 0.52)$ were selected according to the inclusion criteria and were equally divided into two groups, and four patients were excluded, three of them were not meeting the inclusion criteria, and one declined to participate in the study. There were no dropouts or missing data from the participants (Figure 1) (14). There was no significant difference between the experimental and control groups regarding age, gender, and previous dental experience where ($P=1.00$) respectively. Regarding Frankl behavior rating score, 50% of the children had score 3 (positive) in both groups and 50% had score 2 (negative) with no significant difference between the groups ($P=1.00$). As for the tooth restored, the mandibular primary first molars were the majority in both the experimental and control groups (80 and 70 %) respectively, and the mandibular primary second molars were 20 and 30% in the experimental and control groups respectively with no significant difference between the groups ($P=1.00$). (Table 1)

There was no significant difference in the scores of Venham clinical anxiety rating scale between the two groups preoperatively ($P=1.00$). There was a significant difference between the two groups during intraoral examination ($P=0.02$). In the experimental group, 100% of the patients were relaxed during Intra oral examination. In the control group only 40% of patients were relaxed, 50% were uneasy, and 10% were tense. There was no significant difference between the two groups during Local anesthesia administration, Rubber dam application, nor pulpotomy procedure ($P=0.32$, 0.17 , and 0.12 respectively). According to Friedman test, there was a significant difference in the level of dental anxiety during different dental procedures within each group, where in the experimental group ($P<0.001$), and in the control group ($P=0.001$).

The post-hoc comparisons between different dental procedures within each of the experimental group and the control groups separately revealed significant elevation in the level of dental anxiety with local anesthesia administration when compared to intraoral examination in the same group ($P=0.03$ and 0.02) respectively. (Table 2)

There was no significant difference in salivary cortisol level between the two groups preoperatively ($P=0.44$) and postoperatively ($P=0.80$). No significant difference in salivary

cortisol level was found at different time points within experimental and control groups (P=0.96, and 0.58 respectively). (Figure 2)

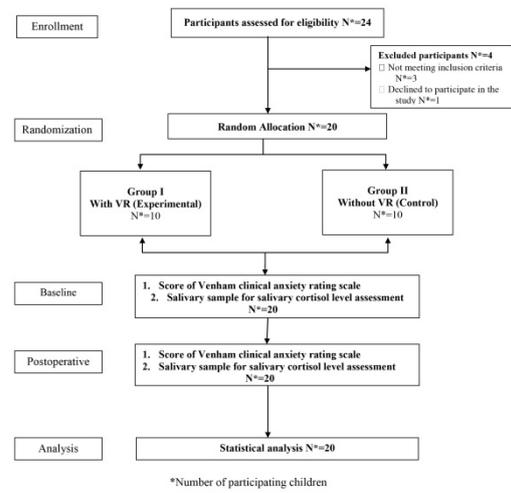


Figure (1): CONSORT flow diagram of the study design (14).

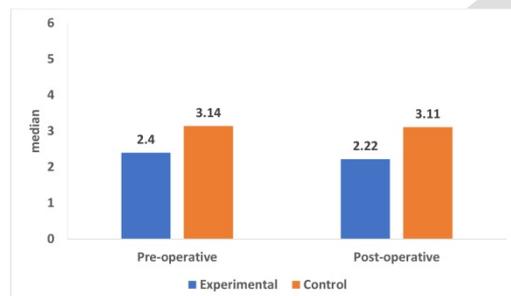


Figure (2): Comparison of salivary cortisol between the two study groups.

Table (1): Characteristics of the two study groups

		Experimental (N* =10)	Control (N* =10)	P value
Age (mean ± SD)		4.60 ± 0.52	4.60 ± 0.52	1.00
Gender: N* (%)	Male	6 (60%)	5 (50%)	1.00
	Female	4 (40%)	5 (50%)	
Previous dental visits: N* (%)	Yes	3 (30%)	2 (20%)	1.00
	No	7 (70%)	8 (80%)	
Frankl behavior rating score: N* (%)	2 (Negative)	5 (50%)	5 (50%)	1.00
	3 (Positive)	5 (50%)	5 (50%)	
Tooth restored: N* (%)	Mandibular primary first molar	8 (80%)	7 (70%)	1.00
	Mandibular primary second molar	2 (20%)	3 (30%)	

T-test and Fisher exact tests were used
*Number of participating children

Table (2): Comparison of Venham's anxiety scale between the two study groups

		Experimental (N**=10)	Control (N**=10)	Mann-Whitney P value
Pre-operative ^{a,b}	Relaxed (0)	5 (50%)	4 (40%)	1.00
	Uneasy (1)	2 (20%)	4 (40%)	
	Tense (2)	3 (30%)	2 (20%)	
	Median (IQR)	0.50 (2.00)	1.00 (1.25)	
Intra-oral examination ^a	Relaxed (0)	10 (100%)	4 (40%)	0.02*
	Uneasy (1)	0 (0%)	5 (50%)	
	Tense (2)	0 (0%)	1 (10%)	
	Median (IQR)	0.00 (0.00)	1.00 (1.00)	
Local Anesthesia administration ^b	Relaxed (0)	2 (20%)	3 (30%)	0.32
	Uneasy (1)	3 (30%)	1 (10%)	
	Tense (2)	5 (50%)	1 (10%)	
	Reluctant (3)	0 (0%)	5 (50%)	
	Median (IQR)	1.50 (1.25)	2.50 (3.00)	
Rubber dam application ^{a,b}	Relaxed (0)	6 (60%)	4 (40%)	0.17
	Uneasy (1)	3 (30%)	1 (10%)	
	Tense (2)	1 (10%)	2 (20%)	
	Median (IQR)	0.00 (1.00)	1.50 (3.00)	
Pulpotomy ^{a,b}	Relaxed (0)	7 (70%)	4 (40%)	0.12
	Uneasy (1)	3 (30%)	2 (20%)	
	Tense (2)	0 (0%)	4 (40%)	
	Median (IQR)	0.00 (1.00)	1.00 (2.00)	
Friedman test		<0.001*	0.001*	
P value Intraoral examination vs. Local anesthesia administration		0.03*	0.02*	

*statistically significant at p value <0.05

**Number of participating children

^{a,b} different superscripted letters denote statistically significant differences between different procedures in each group using Bonferroni adjustments for multiple comparisons

DISCUSSION

The findings of the present study showed that VR glasses significantly reduced dental anxiety during intraoral examination in comparison to conventional behavior management techniques, thus rejecting the tested null hypothesis. Whereas, during rubber dam application, local anesthesia administration, and pulpotomy, the effect of VR glasses was comparable to conventional behavior management technique, thus accepting the null hypothesis.

Children using VR glasses showed significantly lower scores of Venham clinical anxiety rating scale during intraoral examination, this might be due to getting more indulged in watching cartoons that blocked their vision to the dental surroundings, and the headphones that prevented the sounds of the hand piece. On the other hand, the children in the control group were more aware of the dental settings and tools, when using TSD technique with distraction by counting and talking to them were not enough to divert their attention. These findings were in agreement with Al-Khotani et al., who also showed that audiovisual glasses distraction was effective during intraoral examination. However, the authors stated that they observed significant difference between the experimental and control groups during local anesthesia administration, rubber dam application, and dental restoration, unlike the current study where there was no significant difference between the two groups during these procedures, as well as during the pulpotomy treatment (13). The justification for this disagreement might be due to the difference in age groups between the two studies. It is well known that younger children- especially preschool age group – tend to be more anxious during dental treatment than older ones owing to the differences in their cognitive ability, and the inability to master their emotions, unlike schoolers who can utilize life tasks more efficiently (31,32).

Post hoc analysis within each of the experimental and control groups separately, revealed that dental anxiety level increased during local anesthesia administration. This might be due to centration, which refers to the child's tendency to focus on only one aspect of a situation (32); in this case it was the painful stimulus, which might have compromised the effect of VR glasses distraction. In this study, only children of age ranging from four to five years were included, however, different age groups possess different cognitive and behavioral characteristics (31,32), therefore,

including wider range in age group is recommended in future studies as it might yield more expanded results on the efficacy of VR glasses in reducing child's dental anxiety. In the present study, there was no significant difference in salivary cortisol level between the experimental and control groups preoperatively and postoperatively. These results disagree with those of Shetty et al., who found a significant decrease in salivary cortisol level postoperatively with the use of VR glasses distraction (21). This disagreement could be due to the difference in saliva sampling techniques, where adsorbent cotton rolls were used for collection, while in the present study saliva sampling was done by passive drooling. Previous studies showed that the method of saliva collection has an influence on the analytical measurement and the accuracy of salivary cortisol concentration (29,33). The results of the present study also disagree with those of Yogita et al., who found an increase in salivary cortisol level following dental extraction in children (34). This disagreement is assumed to be due to the difference in the dental procedure carried out. In the present study pulpotomy treatment was done, whereas a more invasive procedure such as dental extraction might have caused more pronounced changes in salivary cortisol level.

Dental anxiety has a multi-dimensional concept including both cognitive and physiological components. The strength of the present study was using more than one technique for measuring dental anxiety to achieve a more successful assessment of preschool age children whose cognitive ability is still limited. Venham clinical anxiety rating scale has been used as a cognitive measure of child's anxiety. The findings of the present study, as well as, previous studies that used the same scale proved that it was a good indicator of child's anxiety during dental treatment (13). The salivary cortisol is highly correlated to serum cortisol (33), and it was used as a physiological measure of child's dental anxiety. Saliva sampling done during the study was non-painful; unlike blood sampling that could induce additional stress and elicit a false rise in cortisol level (35).

The limitations of this study were, the unavailability of VR glasses customized for children, and having to place a smart phone inside it in order to play the cartoons, rendering it a bit heavy for children with small head size. This might have affected the comfortability of the child during the dental treatment. Moreover, VR glasses' size

increased the difficulty for rubber dam application. Another limitation was not assessing the effectiveness of VR glasses distraction during stainless steel crown preparation due to the fear of saliva sample being contaminated with blood, thus affecting the final outcome (27). Stainless steel crown preparation would have increased the duration of the dental treatment, which might have increased dental anxiety in preschool children whose attention span is short, thus affecting the salivary cortisol values obtained (32).

The clinical implications of the findings of the present study are that VR glasses have shown to be beneficial as a form of distraction and acclimatization. They can be efficiently used for child's preparation during first dental visit. If children can be suitably acclimatized to accept examination and treatment on dental chair, a number of treatments under general anesthesia can be avoided.

CONCLUSION

Based on the results and within the limitations of the present study:

VR glasses distraction was a useful tool for managing dental anxiety in preschool children especially during intraoral examination, while it showed no difference from conventional behavior management techniques during local anesthesia administration, rubber dam application, and pulpotomy treatment.

CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest.

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