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Original Article

Effect of virtual reality distraction on pain and anxiety during local anesthesia injection in children – a randomized controlled cross-over clinical study

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***ABSTRACT*:**
Background: Pain control is essential in treating child patients. One of the most commonly used behavior management techniques to manage anxiety and pain during dental procedures in children is distraction. **Aim:** The aim of the present study was to evaluate the effect of virtual reality (VR) eyeglasses on pain and anxiety during local anesthesia (LA) administration in four to eight year old children. **Material and method:** Forty healthy co-operative children requiring restorative treatment under local anesthesia were recruited for the study. Children were randomly divided into two groups based on the sequence in which VR was introduced during the treatment sessions. Baseline anxiety was assessed using the physiologic parameters – Heart rate (HR), S_{PO2}, and subjective self-reported scale - Venham's picture test (VPT). During LA injection, anxiety was assessed using physiologic parameters. After LA, the anxiety was assessed using the physiologic parameters, subjective self-reported scale and observational scale – Venham's clinical anxiety rating scale {VRS}. Pain on injection was measured using Wong Baker {WB} faces pain rating scale. **Results** – For descriptive purpose, the mean values of the anxiety and pain parameters of all children were clubbed in two groups – VR group and without VR distraction group. Mean HR was less in VR distraction after IANB injection than no distraction with statistically significant difference {p=0.0180}. Pain on IANB injection was lower in VR group as compared to no distraction with no statistically significant difference {p=0.9447}. **Conclusion**: VR distraction helps in reducing anxiety during LA administration. Also it helps in reducing pain perception during LA administration.

Keywords: Pain; Anxiety; Children; Virtual reality goggle distraction.

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INTRODUCTION

Fear and anxiety in dentistry particularly in pediatric dentistry are triggered by painful procedures. This might lead to difficulties in persuading patients to accept certain types of treatment, especially which induce pain. Pain control is essential in treating children. Unfortunately, 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.[1]

After understanding the need to reduce anxiety and pain in anxious children, many behavior management techniques have been developed based on pharmacological and non-pharmacological approach.[2]

Distraction, a non-pharmacological behavior management technique, appears to be safe and inexpensive and leads to an effective relaxed experience in short painful dental procedure. Conventional distraction techniques include counting the breath, listening to music or stories and watching videos. Distraction techniques in managing anxious children or managing pain in medical and dental settings are generally categorized into interactive, passive and active distraction. Interactive distraction requires cognitive engagement with a distracting stimulus. In passive distraction, the child receives the distracting stimuli from watching television or listening to music. In active distraction, interactive devices like virtual reality (VR) eyeglasses, virtual reality that plays movies or videogames at close proximity which blocks the peripheral vision of the child are used. [3]

Occlusive VR eyewear projects 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.[4]

Because of the success of distraction techniques in medical settings and in adult patients, many dentists believe that these techniques may be successful and fruitful in the management of anxious pediatric dental patients.[5]

There are only a few studies done to see the effect of virtual reality goggle distraction technique on management of dental anxiety and pain during LA injection in children. Hence this clinical study was done with the aim to evaluate the effect of virtual reality distraction technique on dental anxiety and pain in children during LA administration.

MATERIAL AND METHODS

This crossover clinical study was conducted in the department of pediatric and preventive dentistry after obtaining ethical clearance from institutional ethics committee.

Children aged 4-8 years reporting to the department of pediatric and preventive dentistry for dental treatment were screened from OPD based on the SCARED (Screen for child anxiety related disorders) questionnaire**.** 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 selected. Informed consent was taken from the parents of the children selected. A child was selected based on the criteria. that consists of no previous history of dental visit or treatment,[2] children in category 3 and 4 according to frankle behavior rating scale,[2,3] children with no anxiety disorders according to the scared questionnaire,[2] children having decayed mandibular molars[2] and children willing to wear the VR goggles and the headphones.[3] Exclusion criteria was children suffering from any systemic diseases, children having physically and mentally handicapping conditions[3] and children having visual and hearing impairment.[4] Statistical consultation was done to calculate the sample size. The minimum number of subjects was calculated to be 40 in order to achieve a type I error = 5%, type II error = 15%, power = 85%.

The subjects were randomized into two groups based on the sequence of the distraction method used during the dental treatment. In the first session, all the children in both groups received fluoride therapy without any distraction. Children in group 1 underwent restorative treatment under LA without any distraction in session 2 and with VR distraction in session 3. Children in group 2 underwent restorative treatment under LA with VR distraction in session 2 and without distraction in session 3 (table 1).

VR device (figure 1) was introduced to the subjects during respective treatment sessions using tell-show-do technique before treatment. Once VR device was adopted on the child's eyes, the cartoon was started. Then, topical anesthetic agent (LOX) was placed by a piece of cotton roll on the injection site and inferior alveolar block injection was administered using 2 ml LOX 2% with 1:2,00,000 conc. adrenaline by a 24gauge needle over a span of 1 min, followed by a primary mandibular molar restoration. Subjects in group 1 received similar procedures without the use of VR distraction, where child was explained the procedure using tell-show-do technique and involvement technique (counting to 10) during the IANB injection.[6] In the third appointment which took place 1 to 2 weeks after the second session, primary mandibular molar restoration with inferior alveolar nerve block injection was performed with and without VR distraction in groups 1 and 2, respectively. Each therapeutic session lasted about half a hour.[3]

All clinical examination and dental procedures were performed by a single pediatric dentist.

Child's anxiety levels in all visits were assessed using a combination of heart rate (HR), Oxygen saturation (S_{PO2})[7], Venham's picture test (VPT)[8] and Venham's clinical anxiety rating scale (VRS).[9] Pain was assessed using the Wong Baker faces pain rating scale.[10] 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 LA procedure on the dental chair.[3]

Venham's picture test was administered in the waiting room to assess baseline anxiety, in the dental chair and immediately after LA injection. 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.[8]

VRS was assessed by an independent pediatric dentist by playing back the video recordings of each visit and rated them according to the Venham's 6- point scale to assess clinical anxiety.[9] The recording was done from a fixed distance from the dental chair with a 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. Pain felt by the child was rated using the Wong-Baker Faces pain raing scale after giving LA. 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. 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.[10]

The parameters were measured at different times across the treatment - baseline scores were taken at two times- in the waiting room and when the child sat on the dental chair, during the LA injection and after the injection. All the

parameters were recorded and appropriate statistical analysis was carried out.
The demographic parameter age was summarized in terms of mean and standard deviation and compared across the 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 pictures test (VPT), and Wong-Baker (WB) faces ratings were compared using Kruskal-Wallis test. All the analyses were performed using SPSS version 20.0 (IBM Corp) software and statistical significance was tested at 5% level.

RESULTS

8 patients out of 40 in both groups failed to attend the second and third sessions, leaving a total of 32 patients in the present study (table 2). The mean ages of the subjects in groups 1 and 2 were 7.35 ± 0.93and 6.40± 1.73 years, respectively. No significant difference was seen in the means of ages between the two groups (P = 0.075) The subjects comprised 12 boys and 4 girls in group 1 and 8 boys and 8 girls in group 2, with no statistically significant differences between the two groups regarding gender (P = 0.306) (table 3).
Anxiety scores as measured with heart rate (HR), S_{PO2} , VPT and VRS is shown in table 4 and 5. In group 1 the mean HR during local anesthesia in the second (without VR distraction) and third (with VR distraction) treatment sessions were 99.69 ± 13.37 and 99.27 ± 9.84 respectively. The mean HR decreased to 97.81 ± 14.15 and 95.93 ± 10.16 respectively after Local anesthesia injection. The difference between the mean HR was not statistically significant. In group 2, the mean HR during local anesthesia was 112.07 ± 10.36 in the second treatment session (with VR distraction), which decreased to 102.29 ± 9.67 in the third treatment session (without VR distraction). The difference was statistically significant {p=0.021}. After LA injection the mean HR was 109.27 ± 9.65 in the second treatment session (with VR distraction), which decreased to 98.64 ± 98.41 in the third treatment session (without VR distraction). The difference was statistically significant {p=0.006}

In group 1 the mean VPT at baseline, in dental chair in the second (without VR distraction) and third (with VR distraction) treatment sessions were 1.63 ± 1.50 and 0.87 ± 0.92 respectively. The mean VPT after local anesthesia was 2.31 ± 1.82 and 1.93 ± 1.39 respectively. The difference between the mean HR was not statistically significant. In group 2, VPT at baseline, in dental chair was 0.67 ± 1.05 in the second treatment session (with VR distraction), which decreased to 0.43 ± .094 in the third treatment session (without VR distraction). The difference was statistically significant {p=0.008}. After LA injection the mean VPT was 1.67 ± 1.18 in the second treatment session (with VR distraction), which decreased to 1.07 ± 0.62 in the third treatment session (without VR distraction). The difference was not statistically significant.
In group 1, mean the VRS scores were less for the session with VR distraction {0.88 ± 0.49} than the session with no distraction {0.95 ± 0.39} and the difference was statistically significant {p=0.001}. Also in group 2, mean the VRS scores were less for the session with VR distraction {1.06 ± 0.83} than the session with no distraction {1.24 ± 0.44} and the difference was statistically significant {p=0.001}.
In group 1, the mean faces scale pain scores in the second (without VR distraction) and third (with VR distraction) treatment sessions were 5.38± 2.60 and 4.93 ± 2.12, respectively. There was a decrease in pain scores with use of VR distraction, but the difference was not statistically significant. In group 2, the mean of faces scale pain score was 5.33 ± 2.35 in the second treatment session (with VR distraction), which decreased to 4.29 ± 1.54 in the third session (without VR distraction).
The values obtained while comparing two distraction techniques is given in table 6. There was no difference of baseline HR in the two visits for both groups. HR was lower when the anesthetic injection was performed while wearing VR eyeglasses, but the difference was not statistically significant. After local anesthesia the mean HR was less while wearing VR eyeglasses as compared to no distraction and the difference was statistically significant (p= 0.0180). There was no difference of baseline in waiting room and in dental chair, VPT for both groups. After local anesthesia the mean of VPT was more while wearing VR eyeglasses as compared to no distraction but the difference was not statistically significant. Pain scores were lower when the children had the anesthetic injection using VR distraction. Group A (VR distraction) shows a lower injection pain score (5.02 ± 2.32) as compare to Group B {no distraction} (5.04 ± 2.45) but the difference was not statistically significant {p=0.9447}.

Table 1 sequence of the treatment in each group across sessions

Treatment Sessions	Group 1	Group 2
Visit 1	Fluoride application without any distraction	Fluoride application without any distraction
Visit 2	Treatment under LA without any intervention	Treatment under LA with VR goggle distraction
Visit 3	Treatment under LA with VR goggle distraction	Treatment under LA without any intervention

Figure 1: Virtual reality (VR) Goggles with earphones

Table 2: The distribution of patients completing the treatment in both groups over session

	Session 1 {fluoride}	Session 2	Session3	Total final sample
Group 1 {n = 20}	20	17	16	16
Group 2 {n = 20}	20	17	16	16

Table 3: Descriptive statistics for children characteristics in study groups

Characteristics	Levels	Groups		
		I (n = 16)	II (n = 16)	P-value
Age		7.35 ± 0.93	6.40± 1.73	0.075 (NS)
Gender	Male	12 (75.00)	8 (50.00)	0.306 (NS)†
	Female	4 (25.00)	8 (50.00)	

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

Table 4: Descriptive statistics and their comparisons for different parameters before, during and after LA injection for group 1 across sessions

Group 1	*Levels*	Sessions						P-value
		1		2 {no D}		3 {VR}		
Baseline		Mean	SD	Mean	SD	Mean	SD	
In waiting room	*Heart Rate*	83.24	10.62	83.19	23.20	85.13	9.46	0.780 (NS)*
	*VPT**	1.65	1.69	1.38	1.02	0.93	1.03	0.575 (NS) †
On dental chair								
	Heart Rate	87.35	9.97	92.38	13.77	89.60	9.31	0.142 (NS)*
	*VPT**	1.53	1.70	1.63	1.50	0.87	0.92	0.682 (NS) †
During								
Local Anesthesia	*Heart Rate*	-	-	99.69	13.37	99.27	9.84	0.523 (NS)*
After								
Local Anesthesia	*Heart Rate*	-	-	97.81	14.15	95.93	10.16	0.685 (NS)*
	*VPT**	-	-	2.31	1.82	1.93	1.39	0.519 (NS) †
	WB‡	-	-	5.38	2.60	4.93	2.12	0.599 (NS) †
	VRS	0.00	0.00	0.95	0.39	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 5: Descriptive statistics for different parameters before, during and after LA injection for group 2 across sessions

Group 2	Level	Sessions						P-value
		1		2 {VR}		3 {no D}		
		Mean	SD	Mean	SD	Mean	SD	
Baseline								
In waiting room	*Heart Rate*	90.94	12.15	96.07	10.80	91.71	12.07	0.146 (NS)*
	*VPT**	1.65	1.73	0.67	0.90	0.71	0.91	0.697 (NS) †
On dental chair								
	Heart Rate	93.71	11.74	99.60	10.15	94.50	11.95	0.116 (NS)*
	*VPT**	1.82	1.85	0.67	1.05	0.43	0.94	**0.008 (S) †**
During								
Local Anaesthesia	*Heart Rate*	-	-	112.07	10.36	102.29	9.67	**0.021 (S)***
After								
Local Anaesthesia	*Heart Rate*	-	-	109.27	9.65	98.64	8.41	**0.006 (S)***
	*VPT**	-	-	1.67	1.18	1.07	0.62	0.146 (NS) †
	WB‡	-	-	5.33	2.35	4.29	1.54	**0.007 (S) †**
	VRS	0.00	0.00	1.06	0.83	1.24	0.44	**<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
		VR (n = 32)	None (n = 32)	
Baseline				
	Heart Rate	90.58 ± 11.63	91.59 ± 17.10	0.8418(NS)*
	VPT	1.04 ± 1.28	0.98 ± 1.11	0.7113(NS)†
	SPO2	98.89 ± 14.74	98.91 ± 0.28	0.3686(NS)*
Measure				
	Heart Rate	94.80 ± 10.99	96.89 ± 12.74	0.0961(NS)*
	VPT	1.13 ± 1.22	1.17 ± 1.37	0.2701(NS)†
	SPO2	98.98 ± 0.15	98.98 ± 0.15	0.1353(NS)*
During				
Local Anaesthesia	*Heart Rate*	104.62 ± 11.60	105.89 ± 12.49	0.0717(NS)*
	SPO2	98.93 ± 0.25	98.87 ± 0.34	0.5345(NS)*
After				
Local Anaesthesia	*Heart Rate*	102.18 ± 11.44	103.70 ± 12.31	0.0180(S)*
	VPT	1.89 ± 1.56	1.74 ± 1.45	0.6039(NS)†
	WB	5.02 ± 2.32	5.04 ± 2.45	0.9447(NS)†
	SPO2	98.89 ± 0.38	98.87 ± 0.34	0.7451(NS)*
	VRS	1.06±0.54	0.76±0.56	0.801 {NS}

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

DISCUSSION

Pain and anxiety are unpleasant feelings and emotional experiences. 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.[2]

Distraction, a non-pharmacological behavior management technique is the most effective and easy to use technique. 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.[2]

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.[3]

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 virtual reality goggle distraction with no 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 virtual reality distraction and no 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. 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.[11]

The children of age group 4-8 years are difficult to treat as they exhibit more disruptive behavior. Hence this age group was selected for the study.[3,5,12]

Anxiety in an individual may broadly be classified as trait anxiety and state anxiety. 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.[2]

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. 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.[12]

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.[13]

Pain can be measured by self-report, biological markers, and behaviour. Because pain is subjective; self-report is the best if available. The Wong Baker Faces pain scale is used to assess pain perceived during dental procedures. It has been used in the study as it is easy to understand for children.[14]

In VR, 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.[3]

In both groups the mean anxiety and pain scores were more in session 2, as compared to session 3 irrespective of the distraction technique used. It could be because the child was exposed to the LA injection procedure for the 1st time in session 2.

The mean HR, SPO2 and VPT scores at baseline, in waiting room, were not significantly different in the groups A and B. The mean HR score during and after LA was more in group B {no distraction} as compared to group A {VR distraction}. The mean WB pain scores after LA was least in Group A {VR group} as compared to Group B {no distraction} but the difference was not statistically significant among the three groups.

It shows that VR distraction was more effective in reducing anxiety and pain during LA injection than no distraction technique. Similar results were found in study done by Aminabadi et al, who found 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.

Same results were obtained in studies done by Asvanund et al[3], Fakhruddin et al[4], Ram D et al[15], Wiedherhold et al[16], and Panda et al[11], who found that VR distraction technique was effective in reducing pain and anxiety in children during dental treatment.

CONCLUSION

Results of this study showed that VR as distraction technique was effective in reducing pain and anxiety during LA injection as seen on Wong Baker Pain scale. VR can be effectively used as a distraction technique. Further studies to assess the impact of VR distraction on anxiety and pain perception across multiple sequential visits must be carried out.

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