



Effect of Using Virtual Reality Headset on Children Perioperative Anxiety: A Randomized Clinical Trial

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ARTICLE INFO

Received: 20 October 2023

Revised: 11 November 2022

Available Online: 15 Nov 2023

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ABSTRACT

Background:

Perioperative anxiety can affect up to 75% of children, which is more harmful than it is for adults. One of the appealing methods for diverting children's attention from difficult situations is virtual reality technology. The purpose of this study is to determine how well a virtual reality headset reduces preoperative anxiety and other undesirable postoperative behaviors in children.

Materials And Methods:

Eighty children aged five to twelve, who were scheduled for elective day surgery were randomly divided into two groups, each with 40 children. The virtual reality group (VRG) and the non-virtual reality control group, but with parental presence (NVRG). The Visual Facial Analogue Scale (VFAS) was used to measure preoperative anxiety in the holding area and in the operation room during anesthesia induction. Emergency delirium, unfavorable behavioral development, and the parents' satisfaction were also evaluated postoperatively.

Results:

The demographic and social parameters of children in both groups were comparable. Most children in VRG showed lower rates of moderate anxiety than NVRG (8% vs. 44%) at the holding area ($P < 0.05$). At the time of anesthesia induction, the NVRG developed the highest level of anxiety than VRG (8% vs. 0%). However, there were no significant intergroup differences in postoperative emergency delirium or the onset of new negative behavior ($P = 0.32$).

Conclusion:

Children's participation during the induction of general anesthesia can be improved by using virtual reality distraction technology as a simple, non-invasive, and enjoyable alternative to parental presence.

Keywords: Virtual reality headset; Children; Perioperative; Anxiety; Distraction technology.

Introduction

Perioperative anxiety, which is more harmful in children than it is in adults, affects 41.7% to 75.44% of children who were scheduled for surgery due to the immense mental suffering that may result from being separated from their parents, being in unfamiliar environments, or undergoing traumatic and painful procedures (1,2). Children are more likely than adults to have higher levels of autonomic nervous activity, which can lead to longer anesthesia induction times, anesthesia durations, recovery times, and a higher risk of emergence delirium (3,4).

Some children who experience anxiety may exhibit disruptive behaviors that last for a long time after the event (5). Many healthcare organizations have implemented policies and procedures to lessen children's perioperative stress and anxiety and improve their emotional reactions to operating rooms (6). Preoperative sedatives, training programs, and family involvement are some of the techniques that may help some groups of children and the parent to reach contentment (7). The effect of parental or child guardian attendance at the time of anesthetic induction to lessen children anxiety has not been proven in studies (7).

One of the appealing methods for diverting children's attention from difficult situations, easing their fear, and gaining their cooperation during medical procedures is the use of virtual reality technology (8,9). Additionally, using distraction technologies during surgery with or without sedatives prevents increases in children's perioperative anxiety (11,12). In our study, we predicted that perioperative anxiety and the emergence of other atypical postoperative behaviors would be decreased by the use of virtual reality distraction technology, and it will aid anesthesiologists in smoothly inducing general anesthesia in young school age children utilizing a safe, easy, non-invasive, and enjoyable manner.

Materials and Methods

Ethical approval

Approval was obtained from the institutional review board (22-152E) at King Fahad Medical City, Riyadh, Saudi Arabia on May 17, 2022. The study was carried out between May and October 2022. IRB Registration Number with KACST, KSA: H-01-R-012, IRB Registration Number with OHRP/NIH, USA: IRB00010471, Approval Number Federal Wide Assurance NIH, USA: FWA00018774.

Recruitment

Eighty children aged between five to twelve years at Maternity Children Hospital, Riyadh, Saudi Arabia, were recruited for a randomized, clinical trial. All

children were American Society of Anesthesiologists (ASA) Physical Status I and II, undergoing an elective day surgery under general anesthesia. It was decided before trial enrollment that it would not be possible to include children under the age of five due to the size of the VR headset and VR software content.

Exclusion criteria included Cognitively challenged patients, those unable to understand the study's goals, those with current or previous diagnoses of epilepsy, seizure disorder, dementia, migraines, or any neurological conditions that would prevent the use of VR were all excluded. Additionally, children with medical condition that causes nausea or dizziness, hypersensitivity to flashing light or motion, children with stereoscopic vision or severe hearing impairment, injury to the eyes, face, or neck that prohibits comfortable use of VR.

All children had their parents' written informed permission obtained in the preoperative area prior to enrolment. The Declaration of Helsinki was incorporated into the study.

Randomization

Children were assigned using computer-generated randomization codes to place them in the VRG and the NVRG. We employed participant observation techniques, behavior analysis, and instrument design in this randomized investigation. The randomization codes were concealed in consecutively numbered and sealed envelopes.

Sample size calculation

The sample size was estimated to detect a difference of 0.8 standard deviation (SD) of the preoperative anxiety between the two study groups (VR and NVR). The sample size for the present study was deduced to be 34 patients per group at a power of 90%, type I error of 0.05, and confidence interval of 95% (13). Two patients in the VR group had unexpected hardware failure due to battery depletion; and one patient in NVR group had sedation, as a result the patients were excluded from the analysis. Analysis was performed on 77 individuals in total, 38 in the VR group and 39 in the NVR group. There were no unfollowed patients.

Procedure

During the pre-operative screening clinic, the anesthesiologist discussed the study to the family members and advised that any additional information should be provided on the day of surgery before consent and intervention.

Patients in the VR group were given an American-made Oculus Quest 2 VR headset (Fig 1) that displayed a pre-selected cartoon (The Boss Baby). The images were three-dimensional and continuously adjusted to the child's head movements to give them the feeling of being present in the virtual environment. In preliminary testing, the headsets were confirmed not to interfere with anesthesia face mask fit. Patients in the VR group first got orientation to the headset in the preoperative holding room. Parents were subsequently removed from their children while the children continued to wear the VR headsets as they were taken to the operation room and during the induction of anesthesia. The headsets were not disposable, and they were cleaned with antimicrobial disposable wipes in between uses. Induction of anesthesia was either by inhalational (Sevoflurane + 50% N₂O/O₂) or intravenous induction (Propofol 2mg/kg+ fentanyl 2mic/kg). No pharmacological sedatives were administered preoperatively; oxygen saturation monitoring was simply utilized to guarantee minimum child irritation. As soon as the child starts to be sleepy or inactive the headset removed and anesthesiologist starts anesthesia care with ASA monitoring as usual. Immediately

following extubation, the child received pethidine 0.25–0.5 mg/kg or Dexmedetomidine 0.25–0.5mic/kg intravenously, per standard procedure at our facility, before being transferred to the recovery room. The parent's satisfaction was assessed prior to the child's discharge home for both groups using satisfaction questionnaire, and they were informed they will receive phone contact survey after 24 hours and two weeks post-surgery for screening of post-operative new negative behavioral changes in their child.



Figure 1: Oculus Quest 2 VR headset.

Anxiety Level	None	Mild	Mild-Moderate	Moderate	Moderate-High	Highest
Faces						

Figure 2: The proposed Visual Facial Anxiety Scale (VFAS) [15].

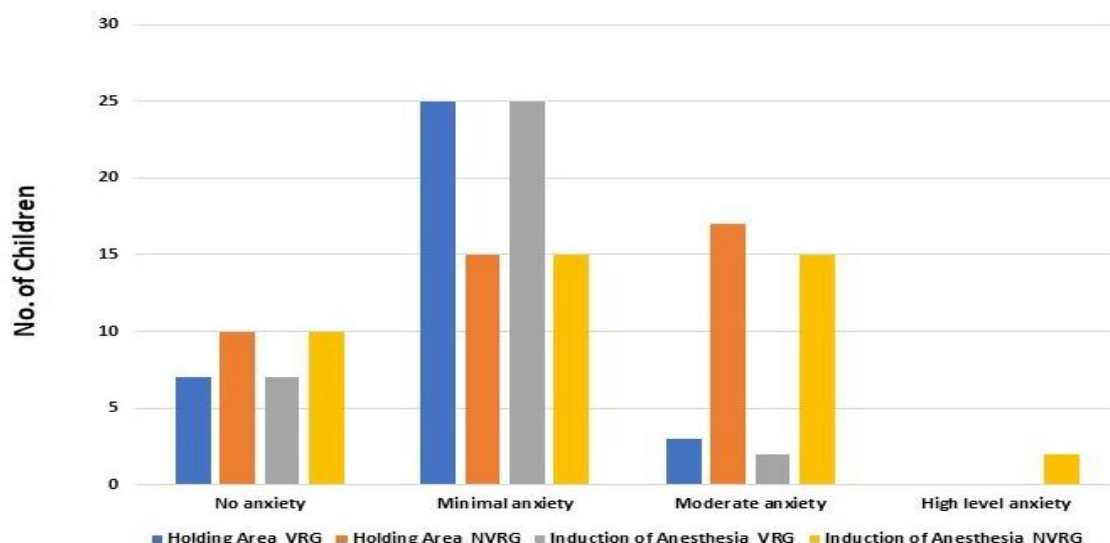


Figure 3: Level of anxiety in holding area and during induction of anesthesia.

Along with clinical information, each patient's sociodemographic information, including age, gender, and educational level, was acquired. The child's preoperative anxiety and postoperative delirium level were the primary outcomes. The Visual Facial Analogue Scale (VFAS) (Fig 2) was used to measure and record the preoperative anxiety in children. We select VFAS for anxiety assessment instead of Modified Yale Preoperative Anxiety Scale (mYPAS), because it is a useful and simple valid tool to assess preoperative anxiety in children and doesn't need specific training (14). The VFAS was developed by adapting the Wong-Baker Faces Pain Scale. The far-left face of the VFAS was chosen to represent no anxiety, while the far-right face was chosen to represent the amount of anxiety that was the highest. The remaining facial expressions ranged from mild anxiety to moderate (mild moderate, moderate, high moderate) anxiety.

Both in the preoperative holding area and during the induction of general anesthesia, the VFAS was given. Based on the child's anxious facial expression, an independent anesthesiologist who was not a member of the anesthesia team providing care recorded all measurements.

The Pediatric Anesthesia Emergence Delirium Scale (Table 1) (16), which evaluates for delirium score including eye contact with the caregiver, awareness of the surroundings, intentional behaviors, restlessness, and inconsolability, was used to assess the child's post-operative delirium degree. A score of nine or more is consistent with hyperactive delirium, also known as emerging delirium. All measurements were made by recovery nurses after they had received orientation from an anesthesiologist, and they were made ten and twenty minutes after arrival.

Table 1: Pediatric Anesthesia Emergence Delirium Scale (16).

Behavior	Not at all	Just a little	Quite a bit	Very much	Extremely
Makes eye contact with caregiver	4	3	2	1	0
Actions are purposeful	4	3	2	1	0
Aware of surroundings	4	3	2	1	0
Restless	0	1	2	3	4
Inconsolable	0	1	2	3	4

Postoperative parent satisfaction and postoperative new unfavorable behavioral changes were the secondary outcomes. The satisfaction of the parent is determined before the child is sent home using a parental satisfaction survey which was limited to five questions to make it simpler for parents to complete the survey

(17). Two phone contact surveys will be used to measure the post-operative new negative behavioral changes: one after 24 hours and one after two weeks. The survey questions concern the emergence of sleep disturbance, nocturnal enuresis, and doctor anxiety (18).

Table 2: Demographic and basic characteristics of the enrolled patients.

Basic characteristics	Stratification	VRG n=38	NVRG n=39
Age (y)	6-5	26 (68%)	28 (72%)
	7-8	7 (20%)	6 (15%)
	9-10	4 (10%)	3 (8%)
	11-12	1 (2%)	2 (5%)
Gender (M/F)	M	22 (58%)	24 (61%)
	F	16 (42%)	15 (39%)
Education	Kindergarten	17 (45%)	16 (41%)
	Elementary school	21 (55%)	23 (59%)
Types of surgery	Minor surgery	15 (39%)	13 (33%)
	Intermediate surgery	23 (61%)	26 (67%)

Table 3. VFAS (Visual Facial Analogue Scale) Anxiety level developed in both groups.

Location	Anxiety level using VFAS	VRG n=38	NON VRG Parent n=39
Holding area	Non	10 (26%)	18 (7%)
	Mild	25 (66%)	38.5 (15%)
	MODERATE (mild)	1 (2.6%)	5 (12.8%)
	MODERATE	2 (5.2%)	10 (25.6%)
	MODERATE(High)	0	2 (5.1%)
	Highest	0	0
Induction time in operating room	Anxiety level using VFAS	VRG n=38	Non-VRG Parent n=39
	Non	12 (31%)	8 (20%)
	Mild	25 (66%)	13 (33.3%)
	MODERATE (mild)	0	2 (5.1%)
	MODERATE	1 (3%)	13 (33.3%)
	MODERATE(High)	0	0
	Highest	0	3 (8%)

Statistical analysis

Descriptive statistics were used to summarize quantitative data from patient observational scales. Data from measurements are presented as mean standard deviation, while data from counts are presented as rate with a 95% confidence level, a standard deviation of 0.5, and a confidence interval (margin of error) of $\pm 5\%$. The t-test, rank sum test, and chi-square test were all utilized, depending on the type of data. The generalized estimating equation model was used to examine the factors influencing preoperative anxiety in children. A P value less than 0.05 was considered to be significant.

Results

There were no significant changes in the demographic and basic data among study groups all Ps >0.05 (Table 2).

In the holding area, according to the results of the anxiety measurement using the VFAS, ten children (26%) in the VRG and seven children in the NVRG (18%) had no anxiety ($P<0.05$) (Fig 3), while 66% of children in the VRG had mild anxiety compared to 39%

in the NVRG ($P<0.05$), and only 8% in the VRG and 43% in the NVRG ($P<0.001$) developed moderate level anxiety. However, none of the children in either group had the highest-level anxiety (Table 3).

During the induction of anesthesia in the operating room, children in VRG and NVRG continue to experience similar levels of anxiety, but the moderate level anxiety decreased in VRG to 3% from 8% registered in holding area. 8% of NVRG children experienced the highest levels of anxiety, which is significantly different from VRG (0%) ($P<0.001$) (Fig 3).

Ten minutes after arriving at the post anesthesia care unit, 50% of both groups developed a score of less than nine, which is considered to represent the absence of delirium ($P=0.32$), and after 20 minutes, these percentages increased to 97% and 94% in the VRG and NVRG groups, respectively ($P=0.12$).

In the first 24 hours following surgery, postoperative new unfavorable behavioral changes were observed in 34% of children in the VR group versus 36% in the NVR group, but these numbers dropped to 25% in the VR group versus 28% in the NVR group after two weeks ($P=0.14$) (Fig 4).

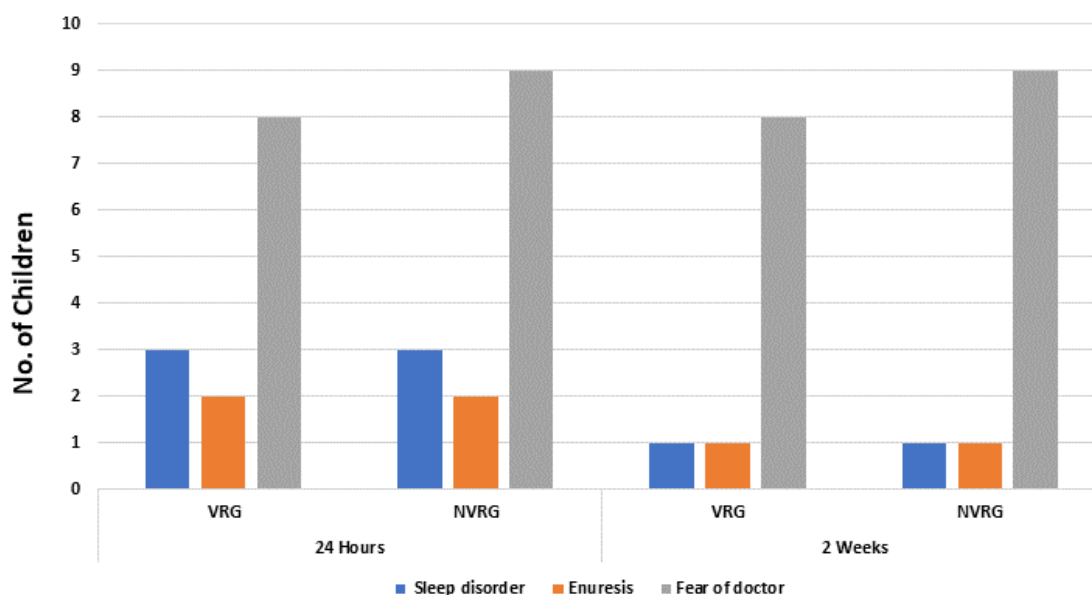


Figure 4: Incidence of postoperative new negative behavioral changes.

Fear of doctors was reported as the most frequent negative behavior in both groups in the first 24 hours, followed by sleep difficulties after two weeks, and finally enuresis.

High parental satisfaction with anesthesia services was found in both groups according to a survey of parents. The majority (38%) chose communication from the anesthesia team as the best anesthesia service, followed by giving the child no sedative (28%), and 9% preferred the way anesthesia was administered in the operating room. The parents who participated in the VR group thought it was an amazing experience, and all of the parents are completely delighted with VR.

Discussion

Technology is now popular among children around the world, making it an appealing technique to distract child anxiety and gain their cooperation during medical procedures. Various non pharmacological distraction methods have been used to minimize preoperative stress in children (2,19). Prior studies on VR's potential to enhance health outcomes showed that it reduced children's anxiety in perioperative settings, whether or not sedatives were used (12).

The purpose of this clinical study, which included 77 children, was to determine whether virtual reality distraction technology can help anesthesiologists induce general anesthesia in young school-age children safely and comfortably while also reducing perioperative anxiety and other abnormal postoperative behaviors.

There were statistically significant variations in anxiety levels between groups. The results of the present study support previous findings that preoperative anxiety was

significantly lower in the VR groups compared to the control groups. VR helped children undergoing surgery under general anesthesia feel less anxious before their procedures (20). The interaction of children with the VR, which became familiar to them and favorable, may have contributed to the decrease in the percentage of children who experienced moderate anxiety during anesthesia induction in the operating room.

Emergence Delirium (ED) after anesthesia is still a problem that needs to be resolved (21). Children that are affected make un purposeful movements and are unaware of their surroundings. Emergence delirium is associated with early postoperative negative behavior within two weeks following outpatient surgery, in addition to its involvement immediately following surgery (22). The incidences of ED reported in the literature vary dramatically from 20% to 80% depending on risk variables including age and the type of surgery that was performed (23).

Both groups experienced a 50% incidence of emergence delirium as a result of our anesthesia regimen; this reported incidence of ED is consistent with some published data (22,24) and shows that neither group had any effect on lowering the delirium score during the first 10 minutes of recovery.

Children's recovery from ED increases to 97% and 94% in VRG and NVRG respectively, after 20 minutes. These fundamental conclusions are in line with studies that found no variations in the emerging delirium response (22). Anxiety before surgery can increase the likelihood of undesirable behavioral changes following surgery (1,4).

After 24 hours, our research indicated little change in the incidence of negative behavior between VR and

NVR; 34% and 36%, respectively. These instances started to decline after two weeks. This result is aggravated by a number of factors, including age less than three years, which is not included in our study. Other studies have shown that negative behavior can occur up to 50% before dropping to 20% after one week (26).

The frequency of reported undesirable behavior, such as enuresis and sleep issues, did not change between the two groups, according to our analysis; however, doctor dread was cited most frequently in both groups. A meta-analysis study on 2020 corroborated the benefit of VR in reducing preoperative anxiety in pediatric patients, but there was no noticeable impact on postoperative behavior (10).

In our study, both groups scored anesthetic services with high parental satisfaction, and all the parents in the VR group favor its use, and think it was a great experience. The parent in the VR group prefers to utilize VR. These results are in line with those of other research that have found that parents of participants would be open to VR use in the future (25).

Strengths and weaknesses

The use of internationally recognized, standardized evaluation methods, the use of a simple method to assess anxiety without additional training, covering many aspects of perioperative anxiety effect on children and the first use of a virtual reality headset to reduce perioperative anxiety for pediatric surgical fields at KSA-based on our knowledge-are among the study's strengths.

This study also has some limitations which include, the subjective assessment of the anxiety level, and emergence delirium, lack of using physiological parameter for assessing child anxiety also using passive fewer interactive forms of VR, which may affect our research result, as the degree of immersion may have an impact on the effectiveness of VR interventions, therefore, the role of immersion using different virtual real games or videos should be a focus of future research, other limitation include narrow list of negative behaviors that was screened and the need to investigate more new psychological postoperative behaviors in future research.

In conclusion, our study supports the useful effects of using virtual reality headset for reducing preoperative separation anxiety and improve children cooperation during general anesthesia induction. It has also similar parental effect on postoperative behaviors outcome in young school aged children, with high parental satisfaction response. Larger sample sizes should be

used in future studies considering using highly immersive system with active distraction which may produce greater effect.

Conflict of Interest

None

Funding

None to declare.

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