

The Effects of Operating Room Virtual Tour on Preoperative Anxiety, Emergence Delirium and Postoperative Behavioral Changes of Pediatric Patients: Prospective, Randomized, and Controlled Trial

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Study

The protocol of this prospective, randomized and controlled clinical trial was approved by the institutional review board of Seoul National University Bundang Hospital (B-1705-396-302) and registered at Clinical Trials Registry (registration number NCT 03172182, <https://clinicaltrials.gov>). All children and parents/guardians received appropriate explanation of this study prior to admission. Written informed consent was obtained from parents/guardians of all children, and assent was also obtained from children older than the age of 7 years. This study was performed at Seoul National University Bundang Hospital, between June and October of 2017.

Virtual reality tour of the operating theater

The 4-min video of the VR tour, a 360° movie, introduced and explained the perioperative preparation process. In this video, Pororo, the famous little penguin character, acts as a pediatric patient who is scheduled be on a tour of the operating theater before surgery. After admission, Pororo changes into a theater gown and intravenous catheter is placed in his forearm. Then, he is transported to the operating theater after confirming his identity in the reception area of the operating theater. Monitoring devices, including ECG, non-invasive blood pressure cuff and pulse oximeter are placed. A facial mask is applied for induction of general anesthesia. During the tour, Pororo explains the preoperative procedure in detail and emphasized that all children can undergo this same process without difficulty.

The script of the VR video was written by an anesthesiologist from Seoul National University Bundang Hospital, and doctors and nurses of this hospital acted in the movie, wearing costumes of animation characters. The VR video was produced in collaboration with

IONIX (Seongnam, Korea) and VR producing company (The VR Co, Seoul, Korea). Seoul National University Bundang Hospital signed a memorandum of understanding with ICONIX to use the animation character Pororo and other characters from the animated film 'Pororo The Little Penguin' (©ICONIX/OCON/EBS/SKBroadband). Filming was carried out using three adapted GoPro Hero4® VR cameras (GoPro, San Mateo, California, USA) by a professional VR company (The VR Co.) in the operating theater of the hospital. The video was then turned into an application for mobile devices. The VR tour was provided using smartphones (Galaxy S6®; Samsung, Suwon, Korea) and VR headsets (VR Gear®; Samsung).

Patients

A total of 86 children, aged 4-10 years with the American Society of Anesthesiologist (ASA) physical status of I or II, undergoing general anesthesia and elective surgery were enrolled for this study. The exclusion criteria included the following: children requiring major surgery or postoperative intensive care; those with a history of prematurity or congenital disease; those with hearing impairment; those with cognitive deficits or cognitive and intellectual developmental disabilities; those who had an experience of anesthesia previously; those taking psychoactive medications; and those with a history of epilepsy or seizure.

Randomization

Randomization was conducted by an independent anesthesiologist who was in charge of patient allocation at 2 h prior to arrival at the preoperative reception area of the operating theater. A computer-generated randomized code (Random Allocation Software version 1.0; University of Medical Sciences, Isfahan, Iran) with nontransparent envelopes that contained sequential

numbers was used. The allocation ratio was 1: 1. The outcome assessor and an anesthesiologist were blinded to group assignment, although children and their parents/guardians were not blinded.

Intervention

Enrolled children were randomly assigned into either the control (n = 43) or VR group (n = 43), and the intervention was done by a researcher in a separate empty room 1 h prior to entering the operating theater to exclude any possible external interferences. Children and parents/guardians in the control group received conventional informative education regarding the perioperative process. Those in the VR group received a VR-guided tour of the operating theater via a smartphone application with a VR headset. After the intervention, an anesthesiologist asked each child and accompanying parent/guardian if they had any questions regarding the perioperative procedures.

Anesthesia

Children were transported from the pre-anesthetic reception are to the operating theater accompanied by their parent/guardian without premedication. Induction of anesthesia was performed by an anesthesiologist with at least 2 years of experience. Standard monitoring devices, including ECG, non-invasive blood pressure cuff, and pulse oximeter, were placed; 5 mg/kg thiopental sodium was administered intravenously while oxygenation was carried out using a facial mask. Upon confirming the disappearance of the eyelid reflex, parent/guardian was guided to the waiting room. Mask ventilation with sevoflurane in oxygen (5 l/min) in increments was commenced to reach the maximum vaporizer setting within a few breaths, and

rocuronium 0.3–0.6mg/kg was given for endotracheal intubation. Anesthesia was maintained with sevoflurane with medical air in oxygen (fraction of inspired oxygen 0.5). At the end of the operation, sevoflurane was discontinued, and glycopyrrolate and neostigmine were given to reverse the neuromuscular blockade. Children were transferred to the postanesthesia care unit (PACU) after extubation.

Outcomes

The primary outcome was the incidence and degree of ED. The degree of ED was measured using Pediatric Anesthesia Emergence Delirium (PAED) scale (Appendix 1) by the blinded assessor at 5 min after the arrival of PACU.

Secondary outcomes included the preoperative anxiety scores and postoperative behavior disturbances. Preoperative anxiety was measured using the validated Korean version of m-YPAS (Appendix 2) by the blinded single assessor to exclude any interrater biases. The m-YPAS score was evaluated on each child twice: baseline (at the time of admission before the study intervention) and just prior to the induction of anesthesia (when the child was placed on the stretcher for transportation from the bed to the operating theater). Postoperative behavior disturbances were recorded using Post-Hospitalization Behavior Questionnaire for Ambulatory Surgery (PHBQ-AS) (Appendix 3) by calling to their parents/guardians on 1 and 14 days after surgery.

Sample size

Power analyses were undertaken using G*Power 3.1.2 (Heinrich-Heine University,

Düsseldorf, Germany). The sample size of the current study was based on the previous investigation on the emergence delirium. The incidence of emergence delirium of the control group (without intervention) was 40.6%, and the reduction of 30% in the incidence of delirium was considered to be clinically significant. A sample size of 43 children per group was determined with a significance level of 0.05 ($\alpha = 0.05$) and a power of 80 percent ($\beta = 0.20$), allowing for a 10 % dropout rate.

Statistical analysis

All data in this study are presented as the median (interquartile range) or numbers (%). SPSS 21.0 for Windows (IBM, Armonk, New York, USA) was used for all statistical analyses. The test of normal distribution was assessed using Shapiro–Wilk test. Mann–Whitney U test was used for analyses of continuous variables (age, weight, height, induction time, m-YPAS, PAED scale and PHBQ-AS) and χ^2 test was used for categorical variables (gender, ASA physical class and incidence of ED). A full analysis set was used for data analysis. P of less than 0.050 was considered statistically significant.

Appendix 1. The Pediatric Anesthesia Emergence Delirium (PAED) scale.

Behaviour	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

Total score :

Appendix 2. mYPAS (modified Yale preoperative anxiety scale)

A. Activity _____

B. Vocalizations _____

C. Emotional Expressivity _____

D. State of Arousal _____

E. Use of Parent _____

A. Activity

0. Can't code (child not visible)
1. Looking around, curious, playing with toys, reading (or other age appropriate behavior); moves around holding area/ treatment room to get toys or go to parent; may move toward OR equipment
2. Not exploring or playing, may look down, may fidget with hands or suck thumb (blanket); may sit close to parent while waiting, or play has a definite manic quality
3. Moving from toy to parent in unfocused manner, nonactivity derived movements; frenetic/frenzied movement or play; squirming, moving on table, may push mask away or clinging to parent
4. Actively trying to get away, pushes with feet and arms, may move whole body; in waiting room, running around unfocused, not looking at toys or will not separate from parent, desperate clinging

B. Vocalizations

0. Can't code (child not visible or can't hear audio)
1. Reading (nonvocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but may be generally quiet; child too young to

talk in social situations or too engrossed in play to respond

2. Responding to adults but whispers, "baby talk", only head nodding
3. Quiet, no sounds or responses to adults
4. Whimpering, moaning, groaning, silently crying
5. Crying or may be screaming "no"
6. Crying, screaming loudly, sustained (audible through mask)

C. Emotional Expressivity

0. Can't code (can't see face or child not visible)
1. Manifestly happy, smiling, or concentrating on play
2. Neutral, no visible expression on face
3. Worried (sad) to frightened, sad, worried, or tearful eyes
4. Distressed, crying, extreme upset, may have wide eyes

D. State of Apparent Arousal

0. Can't Code (child not visible)
1. Alert, looks around occasionally, notices watches what anesthesiologist does with him/her (could be relaxed)
2. Withdrawn child sitting still and quiet, may be sucking on thumb or face turned into adult
3. Vigilant looking quickly all around, may startle to sounds, eyes wide, body tense
4. Panicked whimpering, may be crying or pushing others away, turns away

E. Use of Parents

0. Can't code (child not visible)
1. Busy playing, sitting idle, or engaged in age appropriate behavior and doesn't need parent; may interact with parent if parent initiates the interaction
2. Reaches out to parent(approaches parent and speaks to otherwise silent parent), seeks and accepts comfort, may lean against parent

3. Looks to parents quietly, apparently watches actions, doesn't seek contact or comfort, accepts it if offered or clings to parent
4. Keeps parent at distance or may actively withdraw from parent, may push parent away or desperately clinging to parent and will not let parent go

Total adjusted score = $(A/4 + B/6 + C/4 + D/4 + E/4) \times 100/5$

Appendix 3. Post Hospitalization Behavior Questionnaire for Ambulatory Surgery (PHBQ-AS)

Does your child make a fuss about eating?

Does your child spend time just sitting or lying and doing nothing?

Is your child uninterested in what goes on around him (or her)?

Does your child get upset when you leave him (or her) alone for a few minutes?

Does your child need a lot of help doing things?

Is it difficult to get your child interested in doing things (like playing games with toys)?

Does your child have temper tantrums?

Is it difficult to get your child to talk to you?

Does your child have bad dreams at night or wake up and cry?

Does your child have trouble getting to sleep at night?

Does your child have a poor appetite?

Total Score (Each 1):