Perioperative Virtual Reality for Pediatric Anesthesia

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Protocol and Statistical Analysis

In this pragmatic, randomized controlled, parallel-group study, children aged 5 to 12 years scheduled for elective surgery with general anesthesia are randomly allocated to a virtual reality group (VR group) or a non-virtual reality control group (No VR group. Parental written informed consent and, for children aged 7 years or greater, pediatric assent are obtained prior to enrollment. Following baseline measurement, participants are randomized using a secure, web-based application and the aid of a statistician. The simple randomization sequence is concealed from study staff until completion of baseline assessment. Patients in the VR group receive audiovisual distraction with a VR headset during inhaled mask induction of general anesthesia in the operating room. The No VR group serves as the control group and receives standard medical care without any audiovisual devices.

Patients assigned to the VR group receive a customized Samsung Gear VR headset that displays a pre-selected, interactive game designed for pediatric perioperative use featuring an animated animal character moving through a landscape. In the preoperative area, patients in the VR group receive a five-minute orientation to the headset that includes instructions, an opportunity to temporarily wear the headset, adjust headset fit to the patient, and operate the controller. The VR headsets are then administered immediately before induction of GA. The headsets are non-disposable and cleaned between uses with disposable antimicrobial wipes.

Anesthesia providers conduct routine anesthetic care at their medical discretion independent of VR use, including the use of pre-medication for anxiolysis or parental presence during induction. The standard inhaled mask induction of general anesthesia

consists of using an age appropriate mask and circle system to administer oxygen (3 L/min) and nitrous oxide (7 L/min) for approximately one minute followed by an incremental increase in sevoflurane to a maximum vaporizer setting of 8%. An intravenous catheter is placed after inhaled induction of anesthesia and the elective surgery or procedure is performed.

The primary outcome is preoperative pediatric anxiety as measured by the Modified Yale Preoperative Anxiety Scale (mYPAS). The mYPAS is administered at three time points: in the preoperative holding area (baseline, or T0), on entering the operating room (T1), and during induction of general anesthesia (T2). An independent anesthesiologist who is not part of the anesthesia team delivering care records all measurements. Secondary outcomes are perioperative parental anxiety, pediatric induction compliance, and parental and patient satisfaction. Perioperative parental anxiety is measured using the State-Trait Anxiety Inventory (STAI) at two time points: in the preoperative holding area (baseline, or T0) and after induction of general anesthesia (T3). Pediatric induction compliance is measured by the Induction Compliance Checklist (ICC) during induction of general anesthesia (T2). Parental and patient satisfaction with the perioperative experience is measured with a previously reported 21-item parental and patient satisfaction questionnaire after induction of general anesthesia (T3).

For analysis, data is visualized using histograms and the Shapiro-Wilk test is used to determine whether continuous data are normally distributed. The Wilcoxon rank sum test is used for univariate comparisons for all continuous and ordinal data between the VR and No VR groups, and Fisher's exact test is used to compare categorical data. The mYPAS score has three repeated measurements over time (T0, T1, and T2) and

the between-group effect for the use of VR. The primary analysis is a univariate comparison of mYPAS scores from T0 to T1 and T0 to T2 using Wilcoxon rank sum tests. The effect size corresponding to the primary analysis is the difference in medians, with the confidence limits calculated by bootstrapping with replacement with 200,000 repetitions. The mYPAS scores are also modeled using linear mixed-effects regression to address the within-subject correlation of mYPAS scores and the two repeated-measures time points (T1 and T2). The model incorporates random slopes (i.e., trend over time from T1 to T2) and intercepts for each patient, and adjusts for baseline mYPAS score (T0), which is obtained prior to randomization.