Statistical Analysis Plan

Comparison of Midazolam (Versed) and Distraction on Anxiety, Emergence Delirium, Sedation/Agitation, and Vomiting in Pre-operative Patients ages 3 to 5

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Outcome Measures

1. Pre-induction anxiety as measured by the mYPAS scale after having received either pre-operative:
    a. Medication with PO midazolam and parental presence during induction.
    b. Interactive tablet-like electronic distraction device (ITEDD) and parental presence during induction.
2. Sedation/Agitation score via the RASS tool.
3. Incidence of post-operative emergence delirium (ED) as measured by the Pediatric Anesthesia Emergence Delirium (PAED scale.
4. Incidence of post-operative vomiting. If POV occurred was pharmacological intervention required.

	Induction OR	Admit to PACU	Wake-up from anesthesia
Anxiety	m-YPAS		
Emergence Delirium			PAED
Sedation/Agitation	RASS	RASS	

Instruments/Tools/Measurement Methods:

Anxiety

Anxiety will be assessed using modified Yale Preoperative Anxiety Scale (m-YPAS) to measure anxiety in children during induction of anesthesia. The m-YPAS has been found to be a useful and valid tool for measuring anxiety in pediatric patients ages 2-6 (Kain et al. 1997). The m-YPAS has 22 numerically weighted items separated into five categories, scores range from 22 (no anxiety) to 100 (high level of anxiety).

Sedation/Agitation

Sedation/agitation will be assessed using the Richmond Agitation Sedation Score (RASS). This tool will be administered in pre-operative holding area, at induction, and on admission to the PACU postoperatively. The RASS is a 10-item tool completed by the nurse and based on nursing observations of behavior. Scores on the RASS can range from -5 (unarousable) to +4 (highly agitated and combative). The RASS tool has demonstrated excellent validity, reliability and is used at the Cleveland Clinic to evaluate patients in the recovery room (Ely et al., 2003).

Emergence Delirium

The Pediatric Anesthesia Emergence Delirium Scale (PAED) will be used to assess patients for presence of emergence delirium in the PACU. The PAED is an observational tool used by the

nurse/evaluator. Previous studies suggest this is a valid measure of ED in pediatric patients (Sikich et al., 2004). The PAED tool contains 5 items on the patients' behavior. The first 3 questions are reverse scored (4 = not at all; 3=just a little; 2=quite a bit; and 1=very much) and the last 2 questions are scored as follows (0=not at all; 1=just a little; 2=quite a bit; 3=very much; and 4=extremely). Scores on the PAED scale can range from 0 to 20. The authors of the PAED scale reported scores of >10 correspond to a "sensitivity of 0.64 and a 1-specificity of 0.14". Inter-observer reliability of the PAED was noted at 0.84 and deemed an acceptable instrument of emergence delirium (Sikich et al., 2004). Bajwa (2010) reported sensitivity of 100% and specificity of 94.5% for a score of >12 for the PAED when used by an experienced observer; thus, for purposes of this study scores >12 will be considered evidence of ED.

Vomiting

Vomiting will be assessed as a positive occurrence when child is actively vomiting and will be recorded on the data collection instrument as present or absent during the PACU stay.

Statistical methods

Categorical variables will be described using frequencies and percentages and comparisons between groups will be made with Pearson's chi-square tests or Fisher's exact tests. Normally distributed continuous variables will be presented with means and standard deviations, and comparisons will be made with independent sample t-tests. Continuous variables with a non-normal distribution will be described using medians and quartiles and compared using Wilcoxon Rank Sum tests. Ordered categorical variables with Wilcoxon Rank Sum tests to make comparisons between groups. Analyses will be performed using SAS® Software (version 9.4; Cary, NC).