Investigation of Pupillometry as Guide for Extubation Readiness in Anesthetized Children

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Aims/Objectives
1/ Increase the safety of tracheal extubation in pediatric anesthesia.
2/ Define an objective, quantitative metric to guide extubation in anesthetized pediatric patients.
3/ Demonstrate a method to decrease anesthetic vapor requirements for extubation and thereby decrease the time interval that patients are subject to the risks of anesthetic vapor.
4/ Compare pupillometry method to a traditional extubation method.

Study Protocol
In pediatric patients undergoing general anesthesia for surgery, subjects will be randomized to two groups: Group 1/ Deep vapor extubation group, and Group 2/ Pupillometry group.

For subjects randomized to Group 1, the protocol is as follows:
At the conclusion of surgery and in preparation for tracheal extubation, spontaneous ventilation will be reinitiated and a deep plane of anesthesia will be established with anesthetic vapor set at 1.5 MAC (sevoflurane ~3.75%) for 8 minutes. This follows a traditional method for deep extubation. The subject will then be extubated. Immediately following extubation, 100% O_2 will be given via an anesthesia mask together with 5 cm H_2O CPAP and a gentle jaw thrust, which is the standard practice of the authors. Following standard practice, anesthetics and equipment necessary to manage any extubation issue will be prepared and immediately available. Ventilation will be monitored in a standard manner, using chest wall movement, capnography, reservoir bag movement, condensation of anesthetic mask and auscultation. Oxygenation will be monitored by continuous pulse oximetry and skin color.

For subjects randomized to Group 2, the protocol is as follows:
1/ At the conclusion of surgery and in preparation for tracheal extubation, spontaneous ventilation will be reinitiated and a deep plane of anesthesia will be established with anesthetic vapor set at < 0.5 MAC together with titrated increments of propofol and fentanyl as appropriate at discretion of anesthesiologist.
2/ Pre-stimulus pupillometry: Measure pupil with portable infrared pupillometer. 2 measurements will be made to establish a stable baseline.
3/ Perform standardized laryngeal stimulus (deflate ETT cuff, withdraw ETT 1 cm, readvance ETT 1cm, reinflate ETT cuff).
4/ Post-stimulus pupillometry. Measure pupil size. 2 measurements will be made, the first within 30 seconds of laryngeal stimulus, the second within 30 seconds of the 1st measurement. PRD = Post-stimulus pupil size - pre-stimulus pupil size.
5/ Decision analysis. If PRD < or = 0.10 mm, extubate. If PRD > 0.10 mm, deepen patient with increments of propofol and/or fentanyl at anesthesiologist discretion, then repeat sequence of

pre-stimulus pupillometry, standardized laryngeal stimulus, post-stimulus pupillometry, decision analysis.
6/ If protocol iterates 3 times, the anesthesiologist will extubate when clinically appropriate irrespective of PRD.
7/ Immediately following extubation, 100% O_2 will be given via an anesthesia mask together with 5 cm H_2O CPAP and a gentle jaw thrust, which is the standard practice of the authors.
Following standard practice, anesthetics and equipment necessary to manage any extubation issue will be prepared and immediately available. Ventilation will be monitored in a standard manner, using chest wall movement, capnography, reservoir bag movement, condensation of anesthetic mask and auscultation. Oxygenation will be monitored by continuous pulse oximetry and skin color.

Statistical Analysis Plan

Calculation of descriptive statistics (mean, median, standard deviation) for parameters:

- -Age
- -Sevoflurane concentration
- -Pupillometry

Estimation of differences between Groups on Outcome #1 with comparison by T test.