Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) Use in Pediatric Populations

Statistical Analysis Plan

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After IRB approval, patients were randomized to control or THRIVE. Controls received 100% oxygen via the side port of a Parson's laryngoscope to insufflate the oropharynx at 6-10 L/min, titrated by the anesthesiologist. THRIVE received 100% oxygen via HFNC at 2L/kg/min using an Optiflow machine. Inclusion criteria were all patients from birth to 18 years old. Exclusion criteria included papillomatosis, tracheostomy, or unrepaired heart disease.

The primary aim was surgical interruptions. A priori power calculation based on 15 pilot surgeries demonstrated the frequency of interruptions in the control to be 0.93 and 0.33 in THRIVE. Assuming a Poisson regression, 80% power, and 95% confidence interval, 27 patients in each group (54 total) were needed to demonstrate a significant difference. To account for incomplete data and dropouts, an additional 20 patients (74 total) were targeted for consent. The secondary aims were to compare differences in oxygen desaturation index (ODI), desaturations below 90%, transcutaneous carbon dioxide (tCO_2), and adverse events.

Demographics and postoperative diagnoses in control and THRIVE were collected. Interruptions were defined as the need to pause surgery to provide airway support, such as mask ventilation or intermittent intubation. Pulse oximetry was recorded by second in the electronic medical record. ODI was defined as a 4% decrease in saturation from a 120 second rolling mean for greater than 10 seconds.[2] TCO_2 was recorded at procedure start and end. Adverse events (nausea, vomiting, sinus pain, throat pain, epistaxis) were recorded prior to discharge.

Outcomes were calculated using negative binomial regression with case duration as an offset in the unadjusted and adjusted models, with the exception of tCO_2. Models were adjusted for postoperative diagnoses. As a result of interim analysis, it was determined that analysis of the outcome measure Absolute Incidence of Oxygen Desaturation Less than 90% would not would not provide statistically meaningful results when comparing the two groups, and this outcome was removed from the analysis plan.