Conventional Direct Laryngoscopy Vs. Video Laryngoscopy With The C-MAC For Pyloromyotomy

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1.0 Background

Infantile hypertrophic pyloric stenosis is a condition caused by marked hypertrophy and hyperplasia of the muscular layers of the pylorus. Pyloric stenosis occurs in approximately 1 out of every 300 live births in the United States. The highest incidence is in first born male children, specifically those who had an affected parent. The age of presentation ranges from 3 to 12 weeks, with 95% presenting at 8 weeks. Infants exhibit symptoms of non-bilious, projectile vomiting shortly after feeding. Pyloric stenosis can mimic failure to thrive and results in a hypochloremic, hyponatremic, metabolic alkalosis, and in severe cases of dehydration, metabolic acidosis. Treatment requires surgical pyloromyotomy.

During induction of anesthesia for the surgical pyloromyotomy, direct laryngoscopy is the primary method for securing an airway in the operating room. Any infant with the diagnosis of pyloric stenosis is considered to be at risk for aspiration of gastric contents, and therefore, requires a rapid sequence intubation for securing the airway. Rapid sequence intubation is challenging in infants and leads to frequent oxygen desaturation, perhaps even more frequent at a teaching institution, where resident anesthesiologists are securing the airway. With the introduction of the video laryngoscope, the staff anesthesiologist is able to have direct vision as the resident anesthesiologist secures the airway. This allows for early advice and intervention by the staff anesthesiologist. We hypothesize that the video laryngoscope will have a decreased incidence of oxygen desaturation when compared to conventional laryngoscopy in this patient population.

2.0 Rationale and Specific Aims

Specific Aims of this study include determining if there is a difference in the desaturation rates of the two different intubation techniques. Also, is there is a difference in intubation success between the two techniques, does intubation success vary with different training levels, and does desaturation rate differ amongst training levels.

3.0 Inclusion/Exclusion Criteria

Inclusion Criteria:

- Need general anesthesia for pyloromyotomy procedure
- Have been informed of the nature of the study and informed consent has been obtained from the legally responsible guardian

Exclusion Criteria:

- Abnormal/difficult airway
- Allergy to succinylcholine and/or propofol

5.0 Enrollment/Randomization

Patients will be enrolled in the study on the day of surgery, in a private setting- including but not limited to: pre-operative waiting area, pre-operative holding, or patient's hospital

room. The study will be explained by a member of the research team with extensive knowledge of the protocol. Randomization will occur for each patient using a computer randomized list to one of two groups. One group will be conventional laryngoscopy and the other will be video laryngoscopy. The study seeks to enroll 36 subjects to each group.

4.0 Study Procedures

1. **Study design:** The study will be randomized, controlled, and prospective in design.
2. **Comparison groups** The two comparison groups will be:
    a. **Conventional Laryngoscopy (DL), N = 35**
    Endotracheal intubation will be performed by conventional direct laryngoscopy.
    b. **Video Laryngoscopy (CMAC), N = 37**
    Endotracheal intubation will be performed by video laryngoscopy with the C-MAC.
3. **Study and timeline of interventions**
    a. **Preoperative:** All patients enrolled in this study will receive an intravenous catheter preoperatively.
    b. **Intraoperative:** Subjects will all undergo induction of anesthesia by rapid sequence intubation. Upon arrival to the operating room, a new pulse oximeter probe will be placed on the patient's big toe. Orogastric suctioning with a 10 French Salem sump will be done with the patient supine, right and left lateral positions. Preoxygenation with 100% oxygen will be undertaken for approximately one minute. After pre-oxygenation, a rapid sequence induction will occur with Propofol 2.5mg/kg and Succinylcholine 2.5mg/kg IV. The resident will two- hand mask the patient and the staff anesthesiologist will manually ventilate the patient maintaining airway pressures less than 15mmHG. Approximately twenty seconds after administration of succinylcholine, direct laryngoscopy with a Miller 1 blade or a CMAC 0 blade with be undertaken. The patient will be intubated with a 3.0 cuffed endotracheal tube that has been loaded with a stylet. If the resident is having difficulty securing the airway, the staff may intervene at any point. The airway will be deemed secure when end tidal CO2 x 3 is seen, chest rise is adequate, and bilateral and equal breath sounds are heard. Anesthesia will be maintained with sevoflurane. The patient will be extubated at the conclusion of the case when he/she meets extubation criteria.
    c. **Postoperative:** All patients will receive routine PACU care. Pain and anxiety scores will be recorded according to routine PACU practice. Medication for pain, nausea, and anxiety will be given according to the judgment of the anesthesiologist.
    d. **Measured end-points:**
        i. Level of resident training
        ii. Desaturation below 80% during induction

iii. Staff intervention needed for intubation
iv. Number of intubation attempts

5.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Adverse events, other than those measured as end points, should be reported to the principal investigator, Dr. Nicole Horn at **317-944-9981**.

6.0 Study Withdrawal/Discontinuation

Participants may withdraw at any time before the procedure, and parents will have the ability to request that their child's data be withdrawn at any time prior to data analysis.

7.0 Statistical Considerations

The primary outcome of the study will be desaturation below 80%. Resident training level, staff intervention required, number of intubation attempts and any adverse events will also be recorded. Our hypothesis is a significantly smaller percentage of patients in the CMAC group will desaturate below 80% compared to the DL group. A two group chi-square test with a 0.05 two-sided significance level will have 80% power to detect the difference between 30% vs. 5% proportion of O2sat dropping below 80% (odds ratio of 0.123) when the sample size in each group is 36.

8.0 Privacy/Confidentiality Issues

Participant privacy is an important goal of the researchers. Only members of the research team will have access to identifiable data. Data will be stored in a secure REDCap database. Only members of the research team will have access to REDCap data. Paper copies of PHI will be kept with study charts and paperwork in the locked anesthesiology offices until data analysis is completed and the paperwork is no longer needed, or for 7 years per Indiana law.

9.0 Follow-up and Record Retention

The participation in the study begins with induction of anesthesia, and ends when the patient is discharged from recovery room. There will be no patient follow-up after the day of the procedure.

The patient data related to the study will be entered into a secure REDCap database. Paper copies of study data will be kept in the locked anesthesiology offices. Following completion of the study, all copies of data collected will be stored for the required amount of time (min. 7 years) and then will be physically destroyed.