Comparing Intubation rates in the delivery room by interface

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Research Proposal
Department of Pediatrics

Project Title: Comparing intubation rates in the delivery room by interface

7-19-2022

Study Personnel:

Name, degree	Role	Employer
Ashley Fischer, MD	Co-PI	UICOMP
Gretchen Kopec, MD	Co-PI	UICOMP
M. Jawad Javed, MD	Investigator	UICOMP
Praveen Kumar, MD	Mentor	UICOMP
Kamlesh Macwan, MD	Collaborator	UICOMP

Study Sites:

x OSF - St. Francis Medical Center - Peoria ☐St. Jude Midwest Affiliate

☐ Unity Point Methodist/Proctor ☐UICOMP

☐Other:

Anticipated study duration after start: 1 year

Needed services:

x Statistician ☐Healthcare Analytics

Funding source:

☐The research specified in this protocol will not be funded.

☐The research specified in this protocol is funded by a pharmaceutical/device company.

☐The research specified in this protocol is funded through NIH

X Other: applying for department and CHOI grant funding

x This study has been reviewed with the relevant division(s) or division head(s).

☐ I request detailed feedback/mentorship from the Research Facilitation Committee for this project.

Background and rationale

Although the majority of premature neonates < 30 weeks gestion require positive pressure ventilation (PPV) at birth, the optimal interface to provide PPV has not been determined. Preferably this support would be provided by non-invasive means to prevent the development of bronchopulmonary dysplasia. Resuscitation with a face mask, single nasal tube, nasal prongs, and/or LMA are all approved methods of resuscitation per NRP as of 2010. Face masks have been associated with more dead space, air leak and airway obstruction however are the most commonly used interface. Recently, the Trigeminal Cardiac Reflex has been described, which can be induced with the placement of a facemask, resulting in bradycardia and apnea. Bi-nasal prongs (RAM cannula) have been found in studies to be associated with lower intubation rates in the delivery room (down to 24 weeks gestation), less need for epinephrine, chest compressions, and subsequent invasive ventilation. In addition to the potential practical advantages of bi-nasal prong resuscitation, there is evidence to suggest that ventilation through the nose may stimulate the subepithelial receptors of the upper airways causing an increase in respiratory rate and depth.

Both binasal prongs and face masks are acceptable by NRP and have been utilized for neonatal resuscitation at OSF SFMC since 2016, however the choice is by provider preference with rare use of the bi-nasal prongs. Also, historically we have provided constant positive airway pressure (CPAP) during delayed cord clamping with a facemask by the OB team who needs to remain sterile during a C/S (majority of premature deliveries). Thus, nearly all babies have had some exposure to a facemask during the initial resuscitation period.

For our prospective study we will sterilize facemasks, bi-nasal prongs, and tubing. A neonatal provider will scrub and don sterile gown and gloves to be able to provide the infant with the CPAP utilizing the study interface during delayed cord clamping. That same interface will be continued during resuscitation measures after delayed cord clamping is complete.

The interface utilized in the delivery room to provide resuscitation has been recorded in the Vermont Oxford Database since 2018. On retrospective review of patients born < 30 weeks' gestation, 7/30 of neonates resuscitated with bi-nasal prongs were intubated in the delivery room (23%) and 114/136 of neonates resuscitated with facemask were intubated in the delivery room (84%). There were 33 infants in which both a facemask and bi-nasal prongs were utilized during initial resuscitation as well, 13 of required intubation (39%). However, we are unable to determine from the database which interface was utilized first. Also, prior to 2021, only one neonatologist was utilizing bi-nasal prongs thus it is difficult to determine if the difference is entirely due to the interface alone.

Specific Aims/Objectives

We hypothesize that there will be at least a 40% reduction in the rate of intubation for patients born < 30 weeks' gestation when bi-nasal prongs are utilized for neonatal resuscitation vs face mask.

Research Design and Methods

1. Subject population

Subject identification/recruitment:

All patients born at OSF SFMC < 30 weeks' gestation

Inclusion/exclusion criteria, including age:

Inclusion: all resuscitated infants < 30 weeks' gestation born at OSF SFMC

Exclusion: diagnosis of congenital diaphragmatic hernia, no PPV needed, or no resuscitation desired due to major congenital anomalies or peri-viable status

Estimated sample size:

Hypothesis: 40% reduction in intubations in the delivery room

Baseline intubation rate for facemask resuscitation in neonates < 30 weeks from 2018-2020: ~80% (retrospective intubation rate for ram cannula resuscitation 23%)

alpha 0.05, beta 80%

Estimated sample size = 42 patients

Estimated M:F ratio:

1:1

2. Study design (specify study type, any randomization or control groups)

Prospective stratified randomization with separate blocks for neonates with a gestational age < 25 0/7 weeks and those 25 1/7 weeks to 29 6/7 weeks gestation.

3. Procedures (step by step description of each part of the study, tools to be used, any subject compensation)

1) Consent would be obtained prior to birth by neonatologist
2) Randomization would occur prior to delivery
3) Patients receiving non-randomized apparatus will be considered a protocol violation.
4) CPAP will be set up prior to either c/s or vaginal delivery utilizing either an appropriately sized face mask or ram cannula. Sterile packets with tubing and prongs or a facemask will be supplied for C/S.
    a) **Bi-nasal prong Resuscitation**
        i) Settings on T-piece are set to PIP of 22, PEEP of 6, Flow of 10 L, FiO2 30%. (Settings are slightly higher than facemask to account for known leak with RAM cannula so the pressure seen by the lungs should be equivalent between the nasal prongs and facemask.)
        ii) Immediately after delivery, place the RAM cannula in correct position with the prongs in the nares (prongs should face down into the nasopharynx) and tighten the strap around the head.
        iii) If the neonate is actively breathing, provide CPAP via the RAM cannula and T piece
        iv) If the neonate is apneic or ineffectively breathing, provide PPV via the RAM cannula and T piece at a rate of 40-60 breaths per minute by holding the cannula with your thumb and closing the mouth with your middle finger to ensure a proper seal
        v) If the heart rate starts to increase, continue with resuscitation per NRP guidelines
        vi) If the heart rate does not increase appropriately, troubleshoot the RAM cannula:
            (1) Suction nares and mouth
            (2) Maintain Closed mouth
            (3) Adjust RAM Cannula in nose to ensure seal
            (4) Reposition head and neck to open airway
            (5) Increase pressure by increments of 2 until adequate chest rise is seen or at a PIP of 30
            (6) Alternative Airway (intubation)
        vii) When 60 seconds of delayed cord clamping is complete (if appropriate to perform delayed cord clamping) - Patient will move on the bed to the resuscitation room to complete resuscitation as above. Pulse oximeter to be placed on the right wrist and EKG leads placed in the appropriate position.
    a. **Face mask resuscitation**
        i. Settings on T-piece are set to PIP of 20, PEEP of 5, Flow of 10 L, FiO2 30%.
        ii. After delivery, place the face mask in the correct position on the face, bringing the chin to the mask

iii. If the neonate is actively breathing, provide CPAP via the Face Mask and T piece
iv. If the neonate is apneic or ineffectively breathing, provide PPV via the Face Mask and T piece at a rate of 40-60 breaths per minute
v. If the heart rate starts to increase, continue with resuscitation per NRP guidelines
vi. If the heart rate does not increase appropriately, troubleshoot the Face Mask:
    1. Adjust the Face Mask
    2. Reposition the head and neck to open airway
    3. Suction mouth, then nares
    4. Open Mouth
    5. Increase pressure by increments of 2 until adequate chest rise is seen or at a PIP of 30
    6. Alternative airway (intubation)
vii. When 60 seconds of delayed cord clamping is complete (if appropriate to perform delayed cord clamping) - Patient will move on the bed to the resuscitation room to complete resuscitation as above. Pulse oximeter to be placed on the right wrist and EKG leads placed in the appropriate position.

4. Statistical Analysis Plan (sample size, power justification, specific tests to compare variables)

Primary objective: 40% reduction in intubation rate from resuscitation with facemask vs binasal prongs.

Secondary objectives: incidence of chest compressions and epinephrine in the delivery room, incidence of chronic lung disease, mortality, severe IVH (grade 3-4), severe ROP (stage 3-5) - all would be compared with chi-square testing. Would also analyze average hematocrit and base deficit (if a blood gas is obtained) after admission to the NICU and compare groups via student t-test.

5. Consent procedures (if applicable, or rationale for waiver of consent; list study personnel responsible for consent)

Parents would be consented prior to birth. If parents do not consent for inclusion in the study, the neonate would be resuscitated per routine by NRP guidelines utilizing the interface of provider preference.

6. Risks to subjects/Minimization of Risks (including alternatives to treatment, and

any benefits to participation)

Patients would have minimal risk. Both interfaces are acceptable for use by NRP. Thus, only risk would be in regards to the storage of patient information.

7. Measurement

Data to be collected:

See excel spreadsheet attached

List any additional data elements that will need to be accessed for the study, but not collected (eg when selecting patients from the EMR): None

If specimens/sample will be obtained, described how they will be labelled including any patient identifiers: N/A

8. Data Storage Plan (where/how will data be stored, accessed, and protected; paper records vs Excel/REDCap)

Data will be stored on REDCap

Duration of data storage after study completion: 3 years

Plan for deletion of data or removal of identifiers: Patient ID will be removed once all data is collected and finalized

9. Alignment (How does this project align with or add value to department/institutional objectives?)

The project is well aligned with multiple division goals - reducing intubation rates in the delivery room has the potential of avoiding CPR, allowing for LISA administration which has been associated with lower rates of severe IVH and chronic lung disease than other modes of surfactant administration. The project would also contribute significantly to the literature regarding the optimal interface device in the delivery room.

10. Goals for Publication/Presentation of Results (include plans for authorship, guidelines can be found here)

Will plan to publish results and present at conferences such as PAS and AAP.

References

Aziz, Khalid, et al. “Part 5: Neonatal Resuscitation 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.” *Pediatrics*, vol. 147, no. Supplement 1, 2020, doi:10.1542/peds.2020-038505e.

Biniwale, Manoj, and Fiona Wertheimer. “Decrease in Delivery Room Intubation Rates after Use of Nasal Intermittent Positive Pressure Ventilation in the Delivery Room for Resuscitation of Very Low Birth Weight Infants.” *Resuscitation*, vol. 116, 2017, pp. 33–38., doi:10.1016/j.resuscitation.2017.05.004.

Capasso, Letizia, et al. “A Randomized Trial Comparing Oxygen Delivery on Intermittent Positive Pressure with Nasal Cannulae versus Facial Mask in Neonatal Primary Resuscitation.” *Acta Paediatrica*, vol. 94, no. 2, 2007, pp. 197–200., doi:10.1111/j.1651-2227.2005.tb01890.x.

Gaertner, Vincent D, et al. “Physiological Responses to Facemask Application in Newborns Immediately after Birth.” *Archives of Disease in Childhood - Fetal and Neonatal Edition*, 2020, doi:10.1136/archdischild-2020-320198.

“Kattwinkel, Et Al. Special Report: Neonatal Resuscitation: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Pediatrics. 2010;126(5):e1400-e1413.” *PEDIATRICS*, vol. 128, no. 1, 2011, pp. 176–176., doi:10.1542/peds.2011-1260.

Kuypers, Kristel L.A.M., et al. “The Effect of a Face Mask for Respiratory Support on Breathing in Preterm Infants at Birth.” *Resuscitation*, vol. 144, 2019, pp. 178–184., doi:10.1016/j.resuscitation.2019.08.043.

Machumpurath, Smitha, et al. "Interfaces for Non-Invasive Neonatal Resuscitation in the Delivery Room: A Systematic Review and Meta-Analysis." *Resuscitation*, vol. 156, 2020, pp. 244–250., doi:10.1016/j.resuscitation.2020.08.008.

McCarthy, Lisa K, et al. "Nasal Airways (Single or Double Prong, Long or Short) for Neonatal Resuscitation." *Cochrane Database of Systematic Reviews*, 2011, doi:10.1002/14651858.cd009102.

Schmolzer, G. M., et al. "Airway Obstruction and Gas Leak during Mask Ventilation of Preterm Infants in the Delivery Room." *Archives of Disease in Childhood - Fetal and Neonatal Edition*, vol. 96, no. 4, 2010, doi:10.1136/adc.2010.191171.