Implementation of Nasal Non-Invasive Ventilation with a RAM Cannula in the Inpatient / Outpatient Setting

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PROTOCOL

Implementation of Nasal Non-Invasive Ventilation with a RAM Cannula in the Inpatient / Outpatient Setting

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Background:

Nasal Non-invasive ventilator (NIV) can be a useful mode of respiratory support in the acute setting preventing endotracheal intubation [9]. It may also be use for long-term respiratory support in patients with chronic respiratory failure in an enhanced medical home setting [1]. Non-invasive continuous positive pressure can be delivery using several devices and modes including High-Flow Nasal Cannula (HFNC), Continuous Positive Airway Pressure (CPAP) and Bi-level positive airway pressure (BIPAP). The use of Nasal NIV has been associated with better outcomes in the intensive care setting in neonates to prevent invasive procedures [2-3]. Nasal NIV, using a RAM Cannula interface [Neotech], has been demonstrated to decrease the use of mechanical ventilation and endotracheal intubation in neonates[4].

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Dr. Ramanathan introduced the concept of RAM Cannula as a Nasal NIV device in 2011 for infants in the neonatal intensive care unit. Although, the current FDA indication for RAM – NC is for oxygen delivery, positive pressure can be deliver at discretion and experience of the medical practitioner.

[redacted]

RAM Cannula can be used as a Nasal NIV device to improve tidal volumes, decrease the work of breathing, improve ventilation and oxygenation in the pediatric population[5]. In comparison with a regular nasal cannula [Hudson Cannula], RAM Cannulas are made of softer material and thinner walled prongs. Due to the increase diameter on the inner nasal prongs, a decrease in airflow resistance is achieved. These characteristics support the RAM Cannula as an optimal interface for positive pressure delivery.

Our division has recently described the feasibility and utility of the use NIV using a RAM Nasal Cannula (NIV/RAM-NC) in the outpatient setting [1]. NIV/RAM-NC inpatient initiation has become more common as more data are available about the use of this new technology. Standardized protocols of how NIV/RAM-NC should be implemented and monitored are lacking here at both the inpatient and outpatient site in Children's Memorial Hermann Hospital.

Rationale:

NIV/RAM-NC has the potential to improve transition from invasive ventilation to NIV. In the process of weaning and depending on the underline pulmonary pathophysiologic disorder, patients may require positive pressure for long-term management in order to be discharged from hospital. At this time, the availability of NIV interfaces that can be used in the outpatient setting are limited to BIPAP and CPAP with nasal or full-face mask. These approaches restrict the use of positive pressure delivery devices in the pediatric setting due

to several factors, including: patient age, weight, mask fitness, tolerability of the interface, facial developmental and skin irritation and breakdowns [7-8]. We propose the implementation of a standardized protocol to initiate NIV/RAM-NC with Trilogy mechanical ventilator at the Children Memorial Hospital inpatient and outpatient site.

Objectives:

Primary Aims:

- Implement a standardized protocol to initiate NIV/RAM-NC with Trilogy mechanical ventilator at the Children Memorial Hospital inpatient and outpatient site.

Secondary Aims:

- Explore the side effects and complications associated with the use of NIV/RAM-NC in children.

Study Design and Methods

***Overview*:** A one-year prospective study will be conducted in order to enroll subjects to start NIV/RAM-NC. Demographic data, clinical diagnosis, NIV RAM Cannula mode and parameters, associated complications, side effects and mortality information will be collected from the electronic medical record at the end of the year. Descriptive statistics will be obtained and presented in percentage and averages.

Study Population:

Children from 0 to 21 years admitted to the Children Memorial Hermann Hospital and consulted to Pediatric Pulmonary Service for initiation of NIV/RAM-NC both at the inpatient and outpatient.

Inclusion Criteria:

Children who fail to wean from chronic respiratory support (CPAP, BiPAP, HFNC) in whom long-term ventilation is considered between 10/2016 – 10/2017 will be included.

Exclusion Criteria:

Children with minimal setting (CPAP < 5cmH2O, HFNC < 3LPM) able to be weaned to

regular nasal cannula and patients with upper airway obstruction that may be candidates for surgical procedure will be excluded.

Study Procedures:

Patient Risks: Risk related to the use of NIV/RAM-NC include:

- Ulceration and pressure necrosis due to the interface long-term use.
- Skin breakdown and ulceration of the nasal septum
- Abdominal distension due to aerophagia
- Aspiration of gastric content
- Nasal sinus congestion
- Air trapping and risk of pneumothorax (air leak)
- Need of further procedures (ex. chest tube)

Patient Benefits:

- Prevent invasive procedures like tracheostomy tube cannulation
- Avoid the use of traditional facial interfaces for positive pressure delivery and their complications
- Potential decrease the length of the total hospitalization

Study Outcomes

Our goal is to safely initiate and monitor the use of NIV/RAM-NC implementation in the inpatient and outpatient setting at Children Memorial Hospital and promote an adequate transition to home NIV ventilation with Pediatric Pulmonary follow up.

Data Analysis Plan

At the end of the study, data will be extracted from the electronic medical record (Care4) McGovern Medical School, UT Health. Statistical collaboration from UT will be used for data analysis, if needed. Data analysis will be encrypted with a password that will be known by the principal investigator and research co-workers. Percentage analysis for the epidemiology and risk factors information from the EMR will be analyzed for each variable. Graphical analysis from multiple variables for hypothesis testing will be part of the study.

Sample size and power

Based on our experience about the use of NNIV with RAM Cannula, we expect to enroll around 50 subjects to be part of the study. No power known at this time due to the limited use of NIV/RAM-NC in the pediatric population and the scant literature on this topic. Our sample will depend on the number of patients consulted to initiate NIV/RAM-NC at the inpatient and outpatient setting.

Limitations

Limited use of NIV/RAM-NC in the pediatric population may affect our enrollment and observations. We expect to implement a protocol and describe our experience with our NIV/RAM-NC children cohort.

Confidentiality

Every effort will be made to protect the privacy of the subjects. Unique identifiers will not be stored in the final database that will be used for analytic purposes. Information such as age, sex, and ethnicity will be collected to examine the patterns of interaction, if any, among demographic subgroups. Collected data will be encrypted on a password protected USB. We will minimize the need to collect information about research subjects. Data will be collected using a linking log (saved in a different password protected USB) to avoid the use of identifiers and destroyed after 2 years. The need to access to research data should be based on a “need to know” and "minimum necessary" standard.

Upon completion of the study, electronic data will be retained by the principal investigator (Wilfredo De Jesus Rojas, MD) at the University of Texas Medical School office ([redacted]) All data forms will be kept in a locked file cabinet and electronic files will be password protected. Subjects will not be directly identifiable. The PI, co-investigators, and designated study staff will use the information for data analysis and manuscript preparation.

NIV/RAM-NC Implementation Inpatient Protocol:

Where will this initiative be implemented?

This quality improvement project will be implemented in Children Memorial Hermann Hospital inpatient site (Pediatric Intensive care unit [PICU] and Intermediate care unit

[IMU]) in the TMC plus at the Pediatric Pulmonary Clinics and High Risk Clinics at UTMB outpatient sites.

How will we implement this project?

INPATIENT:

- Pediatric Pulmonary Team will be consulted on patients that fail to wean from chronic respiratory support (CPAP, BiPAP, High flow Nasal Cannula in whom long-term ventilation is considered.
- Pediatric Pulmonary Team, as a consultant, will consider patient history, physical examination, previous imaging and laboratories and previous attempts to wean from respiratory support and causes of failure to wean.
- The Pulmonary team will determine which patients would potentially benefit from use of NIV/RAM-NC for long-term respiratory support and will recommend initiation of NIV/RAM-NC.
- Baseline pulmonary pathophysiology to consider NIV/RAM-NC Initiation include inability to wean from conventional ventilator support and one or combination of the following:
    - Chest Wall weakness
    - Central control abnormalities
    - Obstructive lung disease
    - Restrictive lung disease

    - Indications for NIV/RAM-NC initiation can include:
        - Inability to tolerate weaning from HFNC or hospital CPAP/BPAP without sedation
        - Inability to tolerate conventional CPAP/BPAP mask interface
        - Dyspnea secondary to chest wall weakness
        - Parental desire to avoid tracheostomy tube placement
        - Obstructive sleep apnea

    - Baseline workup requested before NIV/RAM-NC initiation (these would be standard elements of patient evaluation regardless of evaluation for NIV/RAM-NC)

- Blood Gas (Assess baseline hypercapnea)
- Pulse oximetry monitoring (Assess baseline hypoxemia)
- Chest X-ray (CXR), (Evaluate baseline pulmonary disease)
- ENT evaluation to evaluate for upper airway anomalies that can be fixed surgically (if apply)

OUTPATIENT:

- Pediatric Pulmonary Team will be consulted as an outpatient on patients in whom long-term ventilation is considered.
- Pediatric Pulmonary Team, as a outpatient consultant, will evaluate patient history, physical examination, previous imaging and laboratories.
- The Pulmonary team will determine which patients would potentially benefit from use of NIV/RAM-NC for long-term respiratory support and will recommend initiation of NIV/RAM-NC in the outpatient setting.
- Baseline pulmonary pathophysiology to consider NIV/RAM-NC initiation could include one of the following or combination:
    - Chest Wall weakness
    - Central control abnormalities
    - Obstructive lung disease
    - Restrictive lung disease

    - Indications for NIV/RAM-NC initiation can include:
        - Inability to tolerate conventional CPAP/BPAP mask interface
        - Dyspnea secondary to chest wall weakness
        - Parental desire to avoid tracheostomy tube placement
        - Obstructive sleep apnea

    - Baseline workup requested before NIV/RAM-NC initiation (these would be standard elements of patient evaluation regardless of evaluation for NIV/RAM-NC)
        - Blood Gas (Assess baseline hypercapnea)
        - Pulse oximetry monitoring (Assess baseline hypoxemia)
        - Chest X-ray (CXR), (Evaluate baseline pulmonary disease)

- ENT evaluation to evaluate for upper airway anomalies that can be fixed surgically (if apply)

What will we measure?

- Monitoring success of NIV/RAM-NC implementation will include
  - Work of breathing improvement (clinically)
  - Tachypnea improvement (Monitoring respiratory rate)
  - Hypercapnea (Monitor Blood gases)
  - Hypoxemia (Monitor pulse oximetry)
  - CXR (Evaluation of air trapping / hyperexpansion)

Interpretation and Potential Importance of Findings

We expect to implement and describe the safeness of NIV/RAM-NC initiation in the pediatric population along with the epidemiology, side effect and complications associated with the device. The introduction of NIV/RAM-NC in the inpatient/outpatient setting is a consideration to avoid the invasive procedures like tracheostomies for long term ventilation and decrease the length of hospitalization in an enhanced medical home with adequate outpatient follow up.

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