Evaluation of two NIV-NAVA interfaces: the Medin nasal prongs and the RAM nasal cannula

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Evaluation of Two NIV-NAVA Interfaces:
The Medin Nasal Prongs and the RAM Nasal Cannula

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2012
Dedication

I would dedicate this paper to my family and friends who supported me through this journey.
Acknowledgements

I would like to thank my mentor Dr. Howard Stein for his endless support and guidance through my research project. He challenged me to expand my thinking and encouraged my professional and personal growth. I would also like to thank Stacey Fisher for her support and counsel. I lastly would like to thank the respiratory therapists and nurses in the NICCU at The Toledo Children’s Hospital for assisting in the trials and completing the surveys.
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Introduction

Noninvasive ventilation (NIV) is a modality of ventilation that does not require the neonate to be intubated. It provides more support than CPAP alone and has been shown to increase dynamic lung compliance and tidal volume and has improved arterial blood gas when compared to CPAP (Kallet & Diaz, 2009). Because NIV provides ventilation without an endotracheal tube it is associated with lower incidence of ventilator assisted bacterial pneumonia from chronic intubation (Antonelli et al., 2000).

Noninvasive positive pressure ventilation is the most commonly used method of NIV. The health care provider sets the tidal volume or pressure and determines a minimum rate. The limitation of this type of ventilation arises when the neonate needs to take a deeper inspiration but the ventilator only delivers the set tidal volume or pressure. This results in compromised ventilatory support that is exacerbated by poor synchrony from lack of reliable flow trigger. Asynchrony seen in positive pressure ventilation consists of: poor timing between inspiratory effort and assist delivery, and poor adjustment of the magnitude of assist in relation to the patient’s needs and poor termination of breath (Sinderby & Beck, 2007). Asynchronous ventilation can result in complications as diaphragmatic dysfunction, pneumonia, higher ventilator weaning failure, increased use of analgesics and sedation, and other co-morbidities associated with increased ICU time (Rowley, Lowson, & Caruso, 2009). Asynchrony has also shown to cause sleep disruption in mechanically ventilated patients (Sinderby & Beck). Sleep disruption can further complicate the underlying disease process and cause increased hospital stay. These complications are even more evident in situations where the goal is to assist spontaneous respiratory effort. A synchronized ventilatory assist is now available that allows a neonate’s diaphragmatic electrical signal (the primary inspiratory muscle for inspiration) to
communicate with a ventilator. These signals to the diaphragm are referred to as the electrical activity of the diaphragm (Edi). Edi is a reflection of the phrenic nerve activity and thus a reflection of the respiratory neural drive. Variations in respiratory drive are controlled by the body’s respiratory physiologic feedback system, which aid in maintaining appropriate spontaneous breathing.

A new type of mechanical ventilation known as neurally adjusted ventilatory assist (NAVA) provides positive pressure ventilation in proportion to Edi. Edi is measured via transesophageal electrodes positioned at the level of the crural diaphragm, which has been shown to accurately represent the global diaphragmatic activity during respiration. Edi values provide a more comprehensive understanding of breathing patterns, the control of breathing, and the mechanisms underlying tidal breathing (Hutten, van Thujil, van Bellegem, van Eykern, & van Aalderen, 2009). An increase in Edi is the trigger for the ventilator to initiate an inspiratory assist and once triggered, will deliver a peak pressure (PIP) in proportion to the strength of Edi signal. Therefore, the PIP will be adjusted on a breath-by-breath basis using physiologic feedback mechanisms according to the changing needs of the neonate. NAVA can be used both invasively and non-invasively (NIV-NAVA). The NAVA level determines the amount of airway pressure delivered per unit of EAdi. The higher the NAVA level the more the load on respiratory muscles during maximum inspiration is decreased (Sinderby, Beck, Spahija, et al., 2007). When NAVA is used non-invasively (NIV-NAVA) the ventilator is able to adjust flow to compensate for variable air leaks around the nasal interface (Sinderby & Beck, 2007). This decreases the load on respiratory muscles during maximum inspiration.

NIV-NAVA is delivered by a nasal interface to provide non-invasive positive pressure ventilation to the neonate. The neonate presents a special challenge with interfaces due to their
small size and small tidal volumes (Deakins, 2009). Although there are multiple neonatal interfaces available for non-invasive ventilation, all of these are cumbersome and uncomfortable and put the neonate at risk for side effects such as nasal septal erosion and pressure sores around the face (Deakins). Two interfaces routinely used for NIV-NAVA in our NICU are Medin nasal prongs (Medin) and RAM nasal cannula (RAM). The Medin nasal prongs (Medin Medical Innovations, Munich, Germany) is a device that fits over the nose and mouth and contains a strap that fits over the head (Figure 2). A tube is connected from the mask to the ventilator that administers flow of air and oxygen. Medin is approved for CPAP bilevel CPAP and synchronous non-invasive positive pressure (SNIPP).

The RAM nasal cannula (Neotech, Valencia, CA.), is approved for CPAP use in neonates, and looks similar to the traditional nasal cannula used to deliver oxygen, but its stiffer design allows for a higher flow and pressure delivery similar to the Medin nasal prongs (Figure 2). NIV is currently an off label use for the RAM nasal cannula. Although their company has done studies to show that the RAM nasal cannula delivers CPAP effectively (Ramanathan, Crotwell, & DiBlasi 2010), there are no studies that show the efficacy of the RAM nasal cannula to deliver the high pressures needed for non-invasive ventilation.

No study has been done to compare the effects of these two interfaces using NIV-NAVA. The current study sought to discover if a difference between the two interfaces exists with regard to efficacy and comfort.
Methods

This was a prospective, single factorial, case series of ten neonates comparing two interfaces for non-invasive ventilation: Medin nasal prongs and RAM nasal cannula. The population for this study was a convenience sample of neonates who were admitted to the NICU at The Toledo Children’s Hospital and who required non-invasive mechanical ventilation with NIV-NAVA. Participation occurred once the inclusion criteria were met and informed consent was obtained. The neonate was first monitored on the interface (RAM or Medin) that was currently being used and was chosen by the treating physician. Measurement of vital signs and ventilator parameters were collected for a period of 20 minutes. The neonate was then switched to the other interface (RAM or Medin). Again, after a 10-minute stabilization period, measurements of vital signs and ventilator parameters were collected for 20 minutes. The neonate was then switched back to the original interface and, after a 10-minute stabilization period a final 20 minutes of data was obtained. After the study, the neonate was left on the original interface. Other than FiO₂, which was adjusted to keep the oxygen saturation (Sat) in the range of 88-96%, all other ventilator parameters were kept constant.

Edi was measured by electrodes within a nasogastric tube positioned at the level of the crural diaphragm. Proper positioning was confirmed by on-line analysis on SERVO-I software. The nasogastric tube was connected to SERVO-I ventilator software for Edi recording. Data output included peak and minimum Edi, respiratory rate (RR), FiO₂, and Sat stored in one-minute increments in the SERVO-I software, downloaded to a flash drive, and imported into Microsoft Excel for data analysis.

After the study, bedside nurses and respiratory therapists were asked to fill out a “comfort scale” questionnaire (see appendix) to access neonate comfort on each modality. The
questionnaire was a 10-question survey with responses ranging from strongly agree to strongly disagree.

Independent variable for this study was the type of ventilatory interface. The dependent variables were: heart rate (HR), RR, Sat, blood pressure (BP) (measured every 5 minutes), Edi peak (Edi P) and Edi min (Edi M), peak pressure (Peak P), FiO₂, percent leakage, and the comfort scale questionnaire. Comparisons of vital signs and ventilatory parameters were done using ANOVA and Kruskal-Wallis test was performed for data that had extreme outliers. Pearson Chi-Square test and Fisher’s exact test were used to compare survey data. The null hypothesis was that there was no statistical difference between the Medin nasal prongs and RAM nasal cannula for vital signs, ventilatory parameters, or comfort scale with. A p < 0.05 was considered significant.
Results

Ten neonates were enrolled in the study. 60% were males, 90% were delivered via cesarean section, and 40% received maternal steroids, and 90% received surfactant. Table 1 lists other neonate demographics. When the study was designed both Medin and RAM were in use in the NICU. By the time the study started, RAM was used almost exclusively by the treating physicians so all neonates started out on RAM. The NAVA level ranged from 1-3 msV/cmH2O and did not vary throughout any study. The PIP alarm was set at 40 cmH2O, apnea time at 10 seconds and Edi trigger at 0.5.

Figures 3-5 compare the vital signs and ventilatory parameters for the RAM and Medin interfaces. Differences between Medin and RAM were significant for PIP and mean BP. PIP was lower for neonates on the Medin compared to the RAM. Mean BP was lower for the neonates starting on the RAM cannula compared to the Medin and the second RAM cannula set. There was no difference in Edi Peak, RR, HR, FiO2, PEEP, Sat and Edi min. The leakages between the two trials on RAM were not different, but there was less leakage on RAM than when on Medin (Figure 4).

Survey data was divided into 3 sections: evaluation of bedside care, function of the nasal interface, and neonate comfort on each interface. Twenty-eight surveys were obtained 17 from respiratory therapists and 11 from nurses. Overall more bedside caregivers thought it was easier to take care of a neonate on the RAM compared to the Medin. It was easier to apply (Question 1) and maintain (Question 2) the nasal interface, to suction the nares (Question 3) and to provide non respiratory support (question 4) with the RAM (Figure 6). Figure 7 shows the perception of the caregivers in the functionality of the nasal interface. Overall, the RAM appeared to have a better seal (Question 5) and remained in place better (Question 6) than Medin. However, these
differences were noted only amongst the respiratory therapists and not the nurses (Figure 9, Question 5 and 6). Both interfaces resulted in minimal ventilator alarms (Figure 7, Question 7). Figure 8 shows the difference in perceived neonate comfort by the care givers. Neonates appeared to have no or minimal work of breathing (Question 8), and did not appear in pain (Question 9) more often than Medin. However, these differences were only seen among respiratory therapists and not the nurses (Figure 9, Question 8 and 9). Both groups of care givers agreed that both interfaces had minimal or not retractions at the end of the study period (Question 10).
Discussion

We compared the efficacy, functionality, and comfort of two nasal interfaces with the use of NIV-NAVA. The advantages of NIV include the decrease use of sedation and less complications of intubation, such as nosocomial infections and ventilator-associated pneumonia. Compared to CPAP, NIV increases tidal volume and functional residual capacity, and improves lung compliance. The biggest disadvantage is asynchrony. Neonates are unable to take a deeper inspiration when needed due to the set tidal volume and pressure. This asynchrony can lead to diaphragmatic dysfunction, pneumonia, higher ventilatory weaning failure, increases use of analgesics and sedation, and other co-morbidities associated with increased ICU time (Rowley et al., 2009). NIV-NAVA provides all the advantages of NIV and overcomes the disadvantage of asynchrony. NIV-NAVA initiates a proportional assisted breath in accordance to changes in the Edi signal.

We found that although these neonates ventilated equally well on both RAM and Medin the care givers felt that the RAM cannula was easier to use, functioned better, and the neonates were more comfortable compared to Medin.

With NIV-NAVA the actual value of peak pressure delivered to the lungs depends on the leak at the interface, the leak through the mouth and into the stomach. Seeing there is no accurate way to measure transpulmonary pressure with NIV-NAVA we chose to measure peak pressure in the ventilator and not at the nares knowing that any inaccuracies in measurements would be constant between both interfaces. Peak pressure was about 20% higher when on RAM. This is most likely due to RAM being narrower and having stiffer tubing than Medin requiring higher peak pressures to achieve the same flow at the nares. Since the neonate appeared to detect similar flows and get adequate respiratory support from both interfaces, there was no need to increase
respiratory drive and hence no change in Edi Peak. Although we did not measure flow directly, we assumed the flow was comparable because clinical stability assessed by vital signs, Sat, FiO₂, on both interfaces were similar.

Caregivers felt that the RAM cannula was easier to use, functioned better, and the neonates were more comfortable on RAM compared to Medin. The Medin nasal prongs appeared more cumbersome for the neonate and the extra straps around the head and face offered more areas of discomfort and could increase the risk of skin irritation for the neonate. Also, the extra straps made the interface more time-consuming to put on.

Both nurses and respiratory therapists felt RAM was superior for bedside care, resulted in minimal bedside alarms, and minimal or no retractions at the end of the study period. Respiratory therapists, but not nurses, felt RAM provided a better seal, remained in place better, and resulted in neonates with less work of breathing and pain than when on Medin. This is most likely due to respiratory therapists maintaining the interface and assessing neonate respiratory status and comfort, whereas the registered nurses maintained non-respiratory care.

This study was limited by only comparing the Medin and RAM; other interfaces used in the NICU were not evaluated. The study had few patients with similar diagnoses limiting the ability to determine if the interfaces would function differently in various disease states. Another limitation of the study was unequal survey responses from the nurses and respiratory therapists. This may have affected the data with regards to differences between nurses and respiratory therapists. However, the difference in survey responses should not affect the overall outcome responses for RAM and Medin.
Conclusion

In our study the RAM nasal cannula (not FDA approved for NIV-NAVA) functioned equally to the Medin nasal prongs with NIV-NAVA. In addition caregivers felt the RAM was superior to Medin in comfort, care, and function. From our studies the RAM nasal cannula is an acceptable alternative to the Medin nasal prongs.
References


Breatnach, C., Conlon, N. P., Stack, M., Healy, M., & O'Hare, B. P. A prospective crossover comparison of neurally adjusted ventilatory assist and pressure-support ventilation in a pediatric and neonatal intensive care unit population. *Pediatric Critical Care Medicine, 11*(1), 7-11. doi: 10.1097/PCC.0b013e3181b0630f


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### Tables

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**Diagnosis:**

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Table 1: Patient Demographics: Persistent Pulmonary Hypertension (PPHN), Respiratory Distress Syndrome (RDS), Pulmonary Insufficiency of Prematurity (PIP).
Figures

Figure 1: Images of Medin nasal prongs.

Figure 2: Images of the RAM nasal cannula.

Figure 3: Comparison of peak pressure, Edi peak, and Edi minimum for RAM and Medin. * p < 0.05
Figure 4: Comparison heart rate (HR), mean blood pressure (MBP), and percent leakage for RAM and Medin. * p < 0.05

Figure 5: Comparison respiratory rate (RR), oxygen saturation (Sat), and fraction of inspired oxygen (FiO₂) for RAM and Medin. * p < 0.05
Figure 6: Survey responses (n=28) for care questions and comparing RAM vs. Medin. Care questions were: #1 It was easy to apply the nasal interface, #2 It was easy to maintain the nasal interface, #3 Nasal suctioning was easily performed, and #4 It was easy to apply non-respiratory care to neonates. * p < 0.05.

Figure 7: Survey responses (n=28) for interface function questions comparing RAM and Medin. Function questions were: #5 The prongs provided an acceptable seal at the nares, #6 The nasal interface did not dislodge from the nares, and #7 There were minimal vent alarms. * p < 0.05.
Figure 8: Survey responses (n=28) for comfort questions comparing RAM and Medin. Comfort questions were: #8 Neonate appeared comfortable (no or minimal work of breathing), #9 Neonate did not appear to be in pain, and #10 At the end of the study period, retractions were not present or mild. * p < 0.05.

Figure 9: Survey responses (n=28) for the questions (#5, #6, #8, #9) that showed differences between respiratory therapists and nurses (RTn=17, Nn=11). * p < 0.05 (RT RAM vs RT Medin). There was no statistical difference between N interfaces.
Appendix

**Comfort Scale Survey Regarding NIV/NAVA Interfaces**

By filling out this survey you give permission to have your responses used anonymously as part of data combined from all the surveys.

**Please circle who you are:** Nurse   RT

**Please circle the interface being evaluated:** Medin   RAM

**Please circle a response for the following 9 questions using this scale:**

1) **Strongly Agree**

2) **Agree**

3) **Disagree**

4) **Strongly Disagree**

1) It was easy to apply the nasal interface  
   1  2  3  4

2) It was easy to maintain the nasal interface  
   1  2  3  4

3) Nasal Suctioning was easily performed  
   1  2  3  4

4) It was easy to apply non-respiratory care to neonate  
   1  2  3  4

5) The prongs provided an acceptable seal at the nares  
   1  2  3  4

6) Nasal interface did not dislodge from the nares  
   1  2  3  4

7) There minimal vent alarms  
   1  2  3  4

8) Neonate appeared comfortable (work of breathing)  
   1  2  3  4

9) Neonate did not appear to be in pain  
   1  2  3  4

**For question 10 please circle one of the following choices:**

10) At the end of the study period, retractions were:

   Not Present   Mild   Moderate   Severe
Abstract

Objective: This study compared the functionality and efficacy of two interfaces used in NIV-NAVA: Medin nasal prongs and RAM nasal cannula.

Method: A prospective, single factorial, case series from March 2012 to September 2012. Ten neonates on NAVA were examined on each interface. Efficacy of each interface was measured via vital signs and ventilator parameters that were collected for a period of 20 minutes on each interface. The functionality of each interface was a measured through a 10 question survey that was given to registered nurses and respiratory therapists. Statistical analysis was performed using ANOVA, Kruskal-Wallis test, Pearson Chi-Square test, and Fisher’s exact test. (p < 0.05).

Results: Neonates ventilated equally on both interfaces. Bedside care givers felt the RAM was easier to use, functioned better, and the neonates were more comfortable compared to Medin.

Conclusion: RAM nasal cannula is an acceptable alternative to the Medin nasal prongs.