Best Evidence Statement (BESt)

Date: 7-28-2010

Title: Clinical Utility of Neurally Adjusted Ventilatory Assist (NAVA) in decreasing the use of sedation

Clinical Question

P (population/problem)	Among pediatric patients who are mechanically ventilated
I (intervention)	does NAVA mode of ventilation
C (comparison)	compared to conventional modes of ventilation
O (outcome)	decreased need for sedation?

Target Population

Any pediatric patients requiring mechanical ventilation and already have an NG tube in place. Modality is not limited by age.

Exclusion criteria: patient unable to spontaneously breathe, continuous neuromuscular blockade, known impairment of neural signal, or contraindication for nasal or orogastric tube

Recommendation: There is insufficient evidence and lack of consensus at this point, to make a recommendation regarding the use of NAVA for decreasing the need for sedation.

Research agenda Further research is needed that specifically relates the use of the NAVA mode of ventilation to use/need of sedation levels and titration.

Discussion

No studies were identified that directly examined the sedation needs of children being mechanically ventilated using NAVA mode compared to traditional modes. A prospective cohort study examined the frequency of asynchrony and the relationship of asynchrony to sedation levels in adult mechanically ventilated patients. This study (N=20) showed all patients to have at least one asynchrony. Asynchrony was present in 31 out of 35 breaths. (DeWit, 2009[3A]). This leads to the hypothesis that the presence of asynchrony has the potential to impact patient comfort. Patient comfort then in turn may impact sedation level. Further research relating the NAVA mode of ventilation itself with patient comfort scores and various levels of sedation needs to be conducted to further explore this clinical question.

Health Benefits, Side Effects and Risks: potential for improved patient comfort, improved patient ventilator breath cycle synchrony

Minimal Risk associated with NG tube insertion

References/citations

Allo, J., Beck, J. C. P., Brander, L. M., Brunet, F. M., Slutsky, A. S., MD, & Sinderby, C., PhD. (2006). Influence of neurally adjusted ventilatory assist and positive end-expiratory pressure on breathing pattern in rabbits with acute lung injury *Crit Care Med, 34*(12), 2997. [Animal Study]

Beck, J., Brander, L., Slutsky, A. S., Reilly, M. C., Dunn, M. S., & Sinderby, C. (2008). Non-invasive neurally adjusted ventilatory assist in rabbits with acute lung injury. *Intensive Care Medicine, 34*(2), 316-323. [Animal study]

Bengtsson, Jan A., MD, PhD, & Edberg, Karl E. MD, PhD. (2010). Neurally adjusted ventilatory assist in children: An observational study *11*(1). *Pediatric Critical Care Medicine*,11,(1). [4a].

Brander, L., MD, Leong-Poi, H., MD, Beck, J. P., Brunet, F., MD, Hutchison, S. J.,MD, Slutsky, A. S. '., et al. (2009). Titration and implementation of neurally adjusted ventilatory assist in critically ill patients. *Chest, 135*, 695-703. [3a]

Breathnach, C., Conlanc, N., Stack, M., Healy, M., & O'Hare, B., P. (2010). **A** prospective crossover comparison of neurally adjusted ventilatory assist and pressure-support ventilation in a pediatric and neonatal intensive care unit population *11*(1). *Pediatric Critical Care Medicine*,11(1). [3a]

Colombo, D., Cammarota, G., Bergamaschi, V., De Lucia, M., Corte, F. D., & Navalesi, P. (2008). Physiologic response to varying levels of pressure support and neurally adjusted ventilatory assist in patients with acute respiratory failure. *Intensive Care Medicine, 34*(11), 2010-2018. [2b]

DeWit, M., Pedram, S., Best, A. M., & Epstein, S. K. (2009). Observational study of patient-ventilator asynchrony and relationship to sedation level. *Journal of Critical Care, 24*(1), 74-80. [2a]

Rowley, D. D., & Lowson, S. M. (2009). Diaphragmatic electrical signaling unmasks asynchrony and improves patient ventilator interaction *Respiratory Therapy, 4*(4), 51. [5a]

Stein, H., & Howard, D. (1999). Neonates Ventilated with NAVA have Better Blood Gases than Those Ventilated with SIMV/PC with Pressure Support [Abstract]. *Respiratory Care, 54*(11). [5a]

Note: Full tables of evidence grading system available in separate document:

- Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality (abbreviated table below)
- Grading a Body of Evidence to Answer a Clinical Question
- Judging the Strength of a Recommendation (abbreviated table below)

Table of Evidence Levels (see note above)

Quality level	***Definition***
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	Other: General review, expert opinion, case report, consensus report, or guideline

†a = good quality study; b = lesser quality study

Table of Recommendation Strength (see note above)

Strength	***Definition***
"Strongly recommended"	There is consensus that benefits clearly outweigh risks and burdens (or visa-versa for negative recommendations).
"Recommended"	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is lack of consensus to direct development of a recommendation.

Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.

1. Grade of the Body of Evidence (see note above)
2. Safety / Harm
3. Health benefit to patient *(direct benefit)*
4. Burden to patient of adherence to recommendation *(cost, hassle, discomfort, pain, motivation, ability to adhere, time)*
5. Cost-effectiveness to healthcare system *(balance of cost / savings of resources, staff time, and supplies based on published studies or onsite analysis)*
6. Directness *(the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome])*
7. Impact on morbidity/mortality or quality of life

Supporting information

Introductory/background information

Neurally Adjusted Ventilatory Assist(NAVA), is a relatively new Federal Drug Administration (FDA) approved mode of ventilation that has been shown to improve patient ventilator interaction, and decrease the incidence of both inspiratory and expiratory asynchrony with mechanical ventilation (Bengtsson, 2010[4b], Brander, 2009, [3a], Breathnach, 2010, [3a], Rowley, 2009[5a], Stein, 2009 [5a]). The mode works by utilizing a specialized gastric tube with electrodes attached to detect the electrical activity of the diaphragm (EAdi or edi). The early detection of the edi signal allows the ventilator to administer the breath more rapidly in comparison to triggering based on pressure or flow.

Several studies have been performed to show safety and improved synchrony in adult, pediatric, and neonatal patients (Bengtsson, 2010[4b], Brander, 2009, [4b], Breathnach, 2010, [3a], Rowley, 2009[5a], Stein, 2009 [5a]). The ability of the NAVA to improve patient ventilator synchrony and patient comfort led to the clinical question relating improved synchrony to sedation level. Two studies published in 2010 focused specifically on the use of NAVA in pediatric patients. Breathnach, et al performed a prospective crossover comparison of NAVA in comparison to PSV mode of ventilation. Sixteen patients ranging in age from 2d/o to 4y/o were enrolled. No power analysis was reported. All patients were in NAVA mode for a minimal period of thirty minutes and then switched to NAVA. Continuous variables of minute ventilation, peak inspiratory pressure, mean airway pressure, respiratory rate were reported as mean with standard deviation after 30 minutes in pressure support mode, and after one and three hours after switching to NAVA mode. Recorded waveform analysis reported 65% improved inspiratory triggering in NAVA, and an 85% improvement in inspiratory cycling off of the breath. Additionally, there was a significant decrease in measured Peak Inspiratory Pressure (PIP), after the patients were switched to NAVA. PIP decreased 28% after 30 minutes (p=0026), and a 32% decrease after 3 hours (p=.001) (Breathnach, 2010, [3a]).

Bengtsson et al published an observational study (N=21), that also compared NAVA to pressure support. Patients enrolled ranged in age from 2d/o to 15 y/o. Patients were ventilated in Pressure Support Centilation (PSV) mode for 30 minutes, switched to NAVA for 30 minutes, then switched back to PSV mode. The authors did report decreased Peak Inspiratory Pressure (PIP), decreased tidal volume compared to PSV mode, and increased Respiratory rate, but neither an exact percentage of change, nor a p value was reported. Power analysis was also not reported (Bengtsson, 2010[4b]).

Stein looked at NAVA in the neonatal population and presented 2 posters regarding this work at the American Association for Respiratory Care Conference in San Antonio, TX in 2009. Stein compared 87 infants in NAVA compared to conventional ventilation prior to switching to NAVA. Stein reported better blood gases for infants ventilating in NAVA (Stein 2009 [5a]). Stein also evaluated 180 premature infants, under 31 wks gestation or weighing less than 1500g. Stein reported no increased incidence in the rate of pneumothorax, IVH, or the development of NEC in infants ventilated by NAVA mode compared to conventional ventilation (Stein 2009 [5a]). The evidence demonstrates that NAVA can to be safe to utilize as a mode of mechanical ventilation in the pediatric population.

Group/team members

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Susan McGee, RN, MSN, Center for Professional Excellence, POC scholar mentor

Search strategy:

Ovid Medline Pubmed, Ovid Cinahl data bases used,
No criteria set for search limitations.
Search Terms: Neurally Adjusted Ventilatory Assist, NAVA, synchrony, mechanical ventilation, sedation, and patient ventilator synchrony

No conflicts of interest, NAVA catheters are currently being purchased from Maquet Critical Care, Inc. for half price.

Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Reviewed against quality criteria by two independent reviewers

