To date, 271 publications have described the science of NAVA and Edi monitoring. In this document, the studies that were published on PubMed on NAVA and Edi during 2016 are summarized. The use of NAVA was investigated in studies with invasive or non-invasive ventilation and in adults and children (including neonates) and animals.

Studies on the use of Edi monitoring are also included. Edi was used in studies to test the responsiveness to different interventions, such as neuromuscular blockade, bronchodilators, sedatives and feeding.

In the 10 adult clinical studies in 2016, including a total of 356 patients, plus one meta-analysis, the vast majority examined differing patient outcomes comparing NAVA versus conventional ventilation. These studies involved patients with varying respiratory illnesses and challenges, such as ARDS, COPD, multiple weaning failure and ECMO. Some of the results demonstrated that patients who received NAVA had preserved diaphragmatic function, received protective tidal volumes, showed improved synchrony and comfort and required less post-extubation NIV when compared with patients who received conventional ventilation.

With respect to infants, eight clinical studies comparing NAVA with conventional ventilation and involving 183 infants and preterm babies were published. The studies looked at patients who had bronchopulmonary dysplasia, acute respiratory failure, underdeveloped lungs, undergone cardiac surgery, and different methods of enteral feeding. Overall, these studies found advantages of NAVA, such as improved blood gases, oxygenation, synchrony, cerebral blood flow and PIP using NAVA when compared with conventional ventilation techniques.

Four animal studies were published examining the physiological interpretation and clinical application of expiratory Edi and the potential use of NAVA during anesthesia.

The studies and main results are explained in more detail below.
In 2016, on PubMed, there were 35 new publications on NAVA and Edi, including 23 original scientific papers, 5 case reports, 3 editorials and 4 reviews.

Studies in Adults:

Multi-center randomized trial: NAVA vs. PSV
2016 marked the first publication of a multi-center trial to evaluate clinical outcomes with NAVA in adult patients. Demoule et al (Intensive Care Med 42(11):1723–1732) included 128 intubated patients recovering from ARF (i.e., in the weaning phase). They were randomized to receive either PSV or NAVA with the primary objective being the probability of remaining on a partial ventilator mode throughout the first 48 hours without any return to assist/control ventilation. They found equal probability in both groups; however, improved synchrony, improved comfort and less post-extubation NIV were found in the NAVA patients. An editorial (Navalesi, 42(11):1770–1771), as well as a commentary letter (Sinderby, Demoule, Similowski, Intensive Care Med, 2017), accompanied the study where the design and power were debated.

ARDS patients on NAVA control ventilator support during ECMO
Mauri et al (Anesthesiology 125:159–167) studied eight spontaneously breathing ARDS patients undergoing venovenous ECMO. During both PSV and NAVA, they manipulated the ECMO gas flow at four different levels (decreased from a defined baseline) for 20-minute periods in each mode. With increasing gas flow, they observed reductions in all measured variables: Edi, P 0.1, transpulmonary pressure, tidal volume and airway pressure. Contrary to PSV, the ventilator support increased during NAVA as gas flow was reduced (and Edi increased). The authors suggested that when increasing the NAVA level, the patient would downregulate the Edi further in order to protect the lungs.

NAVA improved diaphragm efficiency compared to PSV
The impact of prolonged assisted ventilation on diaphragmatic efficiency was evaluated by Di Mussi et al (Critical Care, 20:1–12) for patients ventilated on NAVA or PSV. Twenty-five patients who had received controlled mechanical ventilation for at least 72 hours were randomized to receive either NAVA (n = 13) or PSV (n = 12) for a 48-hour period. Neumechanical efficiency (NME) and neuroventilatory efficiency (NVE) were measured 3 times: baseline (0 hours), 24 and 48 hours during a spontaneous breathing trial. NVE and NME were similar at baseline, but after 48 hours, the values were significantly higher in the NAVA group. The results imply better preservation of diaphragm function with NAVA.
Edi peak values were on average higher during NAVA (~10 uV) compared to PSV (~6 uV), suggesting a lower suppression of diaphragmatic activation in NAVA.

**Lung protective ventilation enabled by partial neuromuscular blockade during NAVA**

Doorduin et al (AJRCCM October 2016) performed a proof-of-concept study aiming to show if a low dose of rocuronium (partial neuromuscular blockade) could facilitate lung protective ventilation during spontaneous breathing by allowing a reduction in muscular activity. In 10 sedated ARDS patients with lung injury and tidal volumes > 8 ml/kg, rocuronium was administered to target a tidal volume of 6 ml/kg during NAVA. Respiratory and hemodynamic measures were taken while patients were ventilated with either PSV or NAVA (2 hours for each mode) under continuous infusion of rocuronium. They demonstrated significant reductions in tidal volume, transpulmonary pressure and Edi, however, with increased hemodynamic consequences, such as mean arterial pressure and increased heart rate.

**NAVA and neural PSV improved comfort scores with helmet interfaces**

In 15 hypoxemic patients ventilated non-invasively after extubation, Cammarota et al (Anesthesiology 125(6):1181–1189) studied 3 modes of ventilation delivered through two different “helmets,” (i) PSV; (ii) NAVA and (iii) neural PSV (i.e., NAVA mode set with highest NAVA level while limiting the upper pressure). Their outcomes included patient comfort, Edi, patient-ventilator interaction and blood gases. The two helmets (standard fixation straps vs. new helmet) were randomized, and then the three modes were randomized and applied for 30 minutes each. The comfort score, accompanied by a decrease in Edi peak, significantly improved with both helmets from standard PSV to NAVA and from NAVA to neural PSV with neural PSV receiving the highest comfort score. Blood gases were similar for all ventilation periods. They found the pressurization rate was fastest with neural PSV. Synchrony was improved with NAVA and neural PSV compared to pneumatic PSV.

**EAdi for assessment of response to bronchodilator therapy in COPD patients**

Li et al (J Thoracic Dis 8(5):958–965) described an exploratory study on 36 non-ventilated mild-to-moderate COPD patients, where the Edi signal was used to evaluate the responsiveness to bronchodilator therapy. Half the patients (Group A) were randomized to receive a placebo, Salbutamol then Ipratropium; whereas the other half (Group B) received a placebo and a reversed order of Ipratropium and Salbutamol. Pulmonary function tests and Edi and dyspnea measurements were performed at the end of each period (15–30 minutes, depending on the provided drug). Bronchodilators significantly improved the pulmonary function tests and reduced both dyspnea and the Edi signal compared to the placebo. The authors found that the ratio of minute ventilation to the Edi amplitude had the greatest sensitivity to detect bronchodilator efficacy. They concluded that neural respiratory drive seems to be a promising and sensitive index to evaluate patient responsiveness to bronchodilators.

**NAVA showed trend of improved outcomes for difficult to wean COPD patients**

In a randomized clinical trial, Kuo et al (International J of COPD 11:945–951) studied 33 COPD patients with ventilator dependency (defined as > 21 days in a weaning center). They compared NAVA patients (n = 14) to conventional ventilation (PSV or AOV; n = 19) in terms of weaning outcomes and asynchrony in patients who had been ventilated for more than 21 days. Spontaneous breathing trials (PS of 8, PEEP 5) were performed every 24 hours and if successful, patients were extubated to NIV. Their results are in line with previous research that shows the asynchrony index was lower in NAVA compared to the two other conventional types of ventilation, and that the Edi helped to improve detection of asynchrony. The authors claimed that the clinical outcomes (mortality and weaning outcomes), though not statistically significant, were improved with NAVA.

**Systematic review: NIV NAVA significantly reduced risk of asynchrony**

In a systematic review and meta-analysis in seven studies including 85 adult patients who were ventilated non-invasively with NAVA, Sehgal et al (Intensive Care Med 42(11):1813–1815) created Forest plots of the mean difference of the asynchrony index between PSV and NAVA. This summary showed the improved synchrony with NIV NAVA, and that the risk of asynchrony for those ventilated in NIV PSV was 3.4 times higher. In the article, three studies on children were also reviewed and analyzed.

**Edi-based index analyzed for outcome evaluation**

In a retrospective study, Bellani et al (Respir Care 61(4):495–501) used a previously published index (ratio of inspiratory muscle pressure, Pmus, and the electrical activity of the diaphragm, EAdi) and compared values of the index over time during an ICU stay. Forty-one adult (mean age 60) participants were included with a four-day mean duration of controlled ventilation and a six-day mean duration of deep sedation. The mean Pmus/EAdi was 1.04 cm H2O per uV, similar to the values obtained in their validation paper in 10 ventilated ICU patients (Bellani et al Critical Care Med 41(6):1483–1491, 2013). No trends were observed in Pmus/EAdi over the course of the ICU stay, and no differences in clinical outcomes were correlated to the index.

**NIV NAVA improved patient-ventilator synchrony in COPD**

In a study involving 40 patients with acute exacerbation of COPD, Wang et al (Zhonghua Yi Xue Za Zhi 15:96(42):3375–3378) studied the impact of NIV NAVA and NIV PSV on synchrony and gas exchange. The authors report similar improvements in gas exchange with the two modes, but synchrony was improved with NIV NAVA, i.e. shorter trigger delay, shorter cycling-off delay, less ineffective efforts along with auto-triggering and double triggering).
Synchrony was improved during sedation with Dexmedetomidine (DEX) vs. Propofol

In a multi-center, prospective, open label randomized clinical trial, Conti et al (Critical Care 20:206–214) studied patient-ventilator interaction with two types of sedatives: dexmedetomidine (DEX) and standard Propofol sedation at similar RASS scores. Twenty adult ICU patients who had failed their first weaning trial were included. While ventilated in the PSV mode, the Edi and ventilator signals were recorded for 10 minutes at varying intervals over a 24-hour period. The asynchrony index was found to be lower for DEX patients than with Propofol from 2 hours onwards, reaching significance at 12 hours. At similar levels of PSV, the two groups had no significant differences for time in synchrony, tidal volume, respiratory rate and blood gases. Edi peak tended to be lower with Propofol (~10 µV), compared to DEX (~16 µV), but this was not significant. The authors concluded that the use of DEX sedation may offer an advantage in terms of patient-ventilator synchrony.

Case Reports and “Letter to the Editor” in Adults

- A case report by Sangha and Whitacre (J Intensive Care Med. 32(2):170–173) showed the importance of Edi monitoring to detect ventilator auto-triggering.

- Another case report by Goto et al (J Intensive Care. 4: 26–32) described an ARDS patient who was ventilated with NAVA after failing weaning with (asynchronous) conventional ventilation. The authors described improved gas exchange and lung aeration in dorsal and mid-dorsal regions with NAVA (using EIT).

- The first Indian case report by Baldi et al (Indian Journal of Crit Care Med 20:364–367) was published and described a 55-year old patient with ARDS and difficult weaning (> 30 days of invasive conventional ventilation) believed to be a result of poor patient-ventilator interaction. The patient was placed on NAVA and gradually weaned and extubated 2 days later.

- In a Letter to the Editor, Schellekens and Heunks (Intensive Care Med 42:633–634) responded to a paper reporting inappropriate Edi catheter placement complicated by hydropneumothorax. The letter states that the authors should have used additional criteria, such as esophageal ECG pattern, to verify the position.

Studies in Children (including neonates)

Randomized trial of NAVA vs. conventional ventilation in preterm infants

Kallio et al (Eur J Pediatrics 175:1175–1183) performed a randomized controlled trial in 60 preterm infants (28–36 + 6 weeks GA with at least 4 hours of invasive ventilation). The babies were randomized to either NAVA or conventional ventilation, and the primary outcome was duration of invasive ventilation. The extubation criteria were: FIO2 < 0.4 and PIP < 16 cm H2O, satisfactory rate and tidal volume with lowering of support. The investigators found no difference in the median times to extubation or length of NICU stay between the two groups. Despite similar tidal volumes, the patients in the NAVA group had lower peak inspiratory pressures than in the conventional study arm. Sixty percent of the NAVA group had reached the extubation criteria of < 16 cm H2O PIP during the first data collection period, but the preterm infants were not extubated as it was still deemed they needed invasive ventilation and additional doses of surfactant. The amount of administered opiates did not differ between groups. The authors suggested that due to improved synchrony in NAVA, adequate transpulmonary pressure will be obtained at a lower peak inspiratory pressure. This led to the conclusion that traditional extubation criteria should be developed for NAVA as a prerequisite for reliable performance of future trials.

NAVA improved oxygenation and lowered pressures and work of breathing in BPD

In a retrospective study, Jung et al (Ped Crit Care 17(12): 1142–1146) examined ventilatory data from 29 preterm infants (median GA 25 weeks, BW 680 g) with bronchopulmonary dysplasia (ventilated invasively for at least 4 weeks and with a respiratory severity score > 4), as they were transitioned from SIMV to NAVA over 24 hours. They found significantly lower PIP, mean airway pressure, Edi and work of breathing during NAVA compared to SIMV. As well, there was a significant improvement in arterial blood gases and less oxygenation requirements over a 24-hour period of NAVA. No adverse effects were observed during NAVA ventilation, which, as a median value, lasted 18.5 days after the transition from SIMV.

NAVA and NIV NAVA limited tidal volumes and pressures in preterm infants

A recent paper by LoVerde, Firestone and Stein (J Perinatology. 36(12):1097–1100) supported that NAVA is appropriate for the respiratory control system in preterms. In a group of 15 premature infants (mean birth weight 950 g; mean gestational age 26.8 weeks), the authors showed a downregulation of respiratory drive (Edi) with increasing levels of NAVA (“breakpoint”), thereby limiting increases in tidal volume and peak inspiratory pressure. This physiological response was demonstrated before (invasive NAVA) and after extubation (non-invasive NAVA). The authors found that the downregulation of respiratory drive during the NAVA level titration occurred at slightly higher pressures (~ 5 cm H2O) during NIV NAVA.

NIV NAVA provided significantly improved synchrony in pediatric patients

Chidini et al (Ped Crit Care Med 17:e487-e495) studied 18 children with acute respiratory failure needing non-invasive ventilation upon admission to the PICU. All consecutively
admitted patients were eligible if they had P/F ratio < 300 and at least two of the following: High respiratory rate, use of accessory muscles, paradoxical abdominal motion and in a need of a feeding tube and an indwelling arterial line. The children were randomized to undergo 60-minutes of NIV PSV or NIV NAVA first and then undergo the other mode for an additional 60 minutes. A full-face mask was used throughout both modes. The results were measured as an asynchrony index, which was significantly lower during NIV NAVA mode. All types of asynchrony measures were lower with NIV NAVA, but they found the majority of asynchrony was due mainly to ineffective efforts. The authors also found that patients had similar blood gases and required similar amounts of sedation during both modes.

NAVA benefited hemodynamics after cardiac surgery
Zhu et al (Pediatr Cardiology 37:1064–1071) evaluated cerebral blood flow and arterial oxygenation in 21 pediatric patients (median age 10 months; mean weight 7.5 kg) after Bidirectional Superior Cavopulmonary Anastomosis (BCPA). After cardiac surgery, the following interventions were studied: (i) PC before waking from anesthesia at lower (10 ml/kg) and higher tidal volume (15 ml/kg); (ii) 2 minutes of CPAP to establish if a high Edi can be tolerated; and (iii) PSV or NAVA which were randomly assigned at low and high levels of assist. The main differences between NAVA and PSV at high levels of assist were higher VT, PIP, and MAP in PSV. Blood gases were improved with NAVA at both the low and high levels of assist compared to PSV. Increasing NAVA levels did not alter VT (~10 ml/kg), differing from PSV, where VT increased at the higher assist. Cerebral blood flow was more optimal during NAVA.

NAVA vs. conventional ventilation and hemodynamics after cardiac surgery
Liet et al (BMC Pediatrics 16:180–186) examined the physiological, mainly hemodynamic, effects of NAVA versus conventional ventilation (a combination of volume control and PSV) in patients who had undergone cardiac surgery. Six infants (mean age 7.8 months) were studied for 30 minutes with data being recorded in the last 10 minutes of each period, either on NAVA or conventional ventilation. The clinicians attempted to maintain minute volumes constant during both modes. Four of the infants had an initially low central venous oxygenation which tended to increase their cardiac index with NAVA compared to those who received conventional ventilation. For the group of six infants, the mean cardiac index did not change significantly; there were no differences in tidal volume, minute ventilation or pH, PIP was lower with NAVA. The authors concluded that their pilot study suggests that NAVA could have a beneficial effect on hemodynamics in children.

Edi as predictor of feeding method efficiency in preterm infants
The role of feeding methods (slow feed vs. bolus feed) on neural breathing patterns was recently described by Ng et al (Early Human Development 101:33–37) in the FEAdi Trial. In a prospective randomized, cross-over trial, 10 non-ventilated infants (mean birth weight 1,050 g; mean study weight 1,480 g; mean study age 27.5 days) were fed by bolus feed or slow infusion feed over 90 minutes. There was high variability in terms of the responses to the feeding methods (e.g., Edi min, Edi pk, neural respiratory rate, central apnea) with no group mean differences for the two feeding methods. The authors concluded that the feeding method does not affect breathing patterns, and that in particular, a bolus feed does not seem to induce increased central apnea.

NIV NAVA promoted efficient post-extubation support in preterms
In a retrospective study of 24 newly extubated preterm neonates (mean birth weight 814 g), Colaizy et al describe the capacity of NIV NAVA to provide efficient ventilator support, as defined by a reduction in PCO2, with an increase in NAVA levels (Perinatol. 2016 Dec 5 [Epub ahead of print]). In 83% of the babies, an increase in the NAVA level demonstrated a decrease in PCO2 (“responders”); while in the remaining patients, the increase in assist had no impact (“non-responders”). There were no differences between groups in term of age, weight or days since extubation. The median decrease in PCO2 for the entire cohort was 4 mm Hg, and was 5 mm Hg for the responders. Of note, the responders had higher levels of NAVA (1.4 vs. 0.6 cm H2O/uV). The authors concluded that NIV NAVA can produce efficient and synchronized support after extubation as measured by PCO2.

Case Reports in Infants

• From Roosens et al (Ped Pulm 51:E37–E39): after admission to the NICU for neonatal resuscitation, a 2.5 kg baby (one of twins) was sedated and ventilated for 6 days with conventional ventilation and extubated to CPAP, which was not a satisfactory support. X-ray revealed elevation of the right hemi-diaphragm: the infant had unilateral diaphragm paralysis. The infant was switched to NIV NAVA and ventilated with a nasal mask and with acceptable Edi values (6-20 uV) and NAVA level (1.5 cm H2O/uV). CO2 and feeding tolerance improved. The diaphragm paralysis recovered after 3 months, and the child was discharged home without needing additional ventilatory support.

• Cosi et al (Pediatrics. Nov;138(5)) reported a case of a 4-month-old infant with asphyxiating thoracic dystrophy and respiratory failure who was successfully ventilated with NAVA. The investigators noted marked improvement in feeding tolerance with NAVA, allowing for weight gain and eligibility for thoracic surgery.

• One editorial, titled NAVA: Beyond the best synchronization, appeared in 2016 in relation to NAVA in children (Piasta and Conti. Minerva Anestesiologia 82(8):818–20). The authors concluded that NAVA may probably represent an optimal tool to achieve an early shift from invasive to noninvasive ventilation, as it represents a virtually leak-insensitive form of ventilator support.
Studies in Animals

NAVA is feasible during anesthesia
In an animal model (juvenile pigs ~27 kg), the feasibility of NAVA was tested during sedation and anesthesia (Campoccia Jalde et al, Eur J of Anesthesiology, 33:283–291). During NAVA ventilation, animals received either Sevoflurane or Propofol with or without remifentanil, each for 15 minutes with extra washout periods. Blood gases, as well as neuroventilatory (NVE) and neuromechanical efficiency (NME) measures, were collected at the end of each period. The last 5 minutes of the ventilator data was analyzed off-line. The Edi was well-preserved with both sedation and anesthesia. However, they found a lower Edi value during Sevoflurane, resulting in lower tidal volume and delivered pressure compared to Propofol. Variability in tidal volume was also preserved with Sevoflurane. NME and NVE were higher with Sevoflurane. The authors suggest that Edi and NAVA could be useful tools in the operating room.

Role of NAVA and PSV on gastroesophageal reflux
Cantin et al (PLOSone 11(1):e0146742) examined the role of non-invasive positive pressure ventilation (NIPPV), using nasal PSV, nasal NAVA or no nasal ventilation as a control on gastroesophageal reflux in non-sedated spontaneously breathing newborn lambs (mean weight 4.6 kg). Gastroesophageal reflux, esophageal insufflations, states of alertness and ventilator and breathing pattern variables were continuously and wirelessly recorded for 3 consecutive days, where the animals were ventilated (or not) for 6 hours. The main findings were similar reductions (inhibition) in gastroesophageal reflux and similar insufflations into the esophagus in both modes compared to the control condition. These findings are similar to what the investigators previously reported for nasal CPAP.

Continuous NAVA provided lung protection during the expiratory breathing phase
Brander et al (Respir Physiol Neurobiol. Mar;237:57–67) performed a study using continuous NAVA, where Edi controls pressure continuously and provides neurally adjusted PEEP in rabbits (3–4 kg) with acute lung injury. Using CT imaging, the authors demonstrated, in an open-chest model, that lung protective reflexes were integrated during continuous NAVA as evidenced by improved aeration and prevention of over-distension during titrations of the NAVA level. This was confirmed to be vagally mediated, as vagotomy resulted in a lack of expiratory Edi (no control of PEEP) and cyclic lung collapse. With NIV NAVA, removal of the expiratory assist was compensated by increased tonic Edi and PEEP or by increased upper airway braking of expiratory flow.

Expiratory Edi, PEEP and lung aeration in an ARDS animal model
Pellegrini et al (Am J Resp Crit Care Med, Dec 6, Epub ahead of print) report the role of expiratory Edi on lung aeration in 10 pigs with mild ARDS (target P/F-ratio 250). The pigs were on CPAP, which was gradually reduced from 15 cm H2O to zero in 3 cm H2O incremental steps. The investigators used dynamic CT scan images and repeated the procedure during paralysis in five of the animals. The investigators found a linear correlation between expiratory Edi and transdiaphragmatic pressure (Pdi); the correlation being stronger at lower lung volumes. Edi and Pdi during expiration were elevated with decreasing CPAP. Atelectasis was observed during paralysis and mechanical ventilation at low PEEP levels, which was not observed during spontaneous breathing. The authors concluded that the results demonstrated a central role of the diaphragm during breath-by-breath maintenance of alveolar
inflation and protection against lung collapse.

**Reviews**

Four reviews, which discuss NAVA and NIV NAVA, were published (one in adults, 3 in neonates):


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