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Non-invasive neurally adjusted ventilatory assist (NIV-NAVA) in the neonatal intensive care unit (NICU): an Australian NICU experience

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Abstract

Background Preterm infants often require non-invasive breathing support while their lungs and control of respiration are still developing. Non-invasive neurally adjusted ventilatory assist (NIV-NAVA) is an emerging technology that allows infants to breathe spontaneously while receiving support breaths proportional to their effort. This study describes the first Australian Neonatal Intensive Care Unit (NICU) experience of NIV-NAVA.

Methods Retrospective cohort study of infants admitted to a major tertiary NICU between October 2017 and April 2021 supported with NIV-NAVA. Infants were divided into three groups based on the indication to initiate NIV-NAVA (post-extubation; apnoea; escalation). Successful application of NIV-NAVA was based on the need for re-intubation within 48 h of application.

Results There were 169 NIV-NAVA episodes in 122 infants (82 post-extubation; 21 apnoea; 66 escalation). The median (range) gestational age at birth was 25 + 5 weeks (23 + 1 to 43 + 3 weeks) and median (range) birthweight was 963 g (365–4320 g). At NIV-NAVA application, mean (SD) age was 17 days (18.2), and median (range) weight was 850 g (501–4310 g). Infants did not require intubation within 48 h in 145/169 (85.2%) episodes [72/82 (87.8%) extubation; 21/21 (100%) apnoea; 52/66 (78.8%) escalation).

Conclusion NIV-NAVA was successfully integrated for the three main indications (escalation; post-extubation; apnoea). Prospective clinical trials are still required to establish its effectiveness versus other modes of non-invasive support.

Keywords Neurally adjusted ventilatory assist, Non-invasive ventilation, Ventilation weaning, Premature infant, Interactive ventilatory support

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Background

Advancing medical knowledge and improving technology over the past decades has seen consistent increases in survival rates for extreme preterm infants. Despite these improvements, there continues to be high rates of ventilator-associated complications with little reduction in rates of bronchopulmonary dysplasia (BPD). This has resulted an increased use of non-invasive ventilation (NIV), including more sophisticated methods of achieving patient-triggered ventilation [1, 2]. Systems that synchronise respiratory effort with lung inflation may help mitigate the long-term consequences of asynchrony including lung injury via volutrauma or hyperoxia [3]. Consequently, the use of NIV continues to increase, however, there are a paucity of data demonstrating clinical benefit [2, 4].

Neonatal non-invasive ventilation is used for a variety of indications which include respiratory failure, prevention of extubation failure and persistent, severe apnoea of prematurity [4–7]. Well-established non-invasive modes of respiratory support range from nasal continuous positive airway pressure (NCPAP), nasal intermittent positive pressure ventilation (NIPPV) and high-flow nasal cannula (HFNC). These all have varying volume and quality of supporting literature [4–6, 8]. Indeed, NCPAP, NIPPV and HFNC have respective benefits with regard to safety, efficacy, and ease of clinical use [1, 9]. However, there are limitations to these modalities particularly in terms of synchrony with infants breathing efforts for NIPPV and infants with absent or insufficient respiratory drive [4, 10, 11].

Neurally adjusted ventilatory assist (NAVA) differs from traditional ventilatory support, which adjusts ventilation according to pressure or flow changes, as NIV-NAVA delivers synchronised and scaled inspiratory support based upon the electrical diaphragmatic signal (Edi) activity [12, 13]. Minute sensors are embedded within standard feeding tubes to detect Edi [3, 12, 14]. This has no impact on feeding whilst monitoring the overall respiratory drive [15]. A computer algorithm analyses a filtered and amplified Edi signal to trigger the ventilation system. The system detects the start of a breath as it is being initiated in the diaphragm and provides synchronised support during inspiration. The level of support changes during inspiration in proportion to the detected Edi [13, 14]. Inspiratory support discontinues as the system detects the Edi signal decreasing to allow expiration. With adequate support, neural feedback mechanisms theoretically result in a decrease in respiratory drive with subsequent lower levels of inspiratory support [15]. However, this is not always seen in preterm infants due to immature neural feedback mechanisms [16].

The aim of this study was to evaluate our experience with NIV-NAVA by describing the intubation rate at 48 h following the initiation of NIV-NAVA for the following indications:

- Post-extubation as a weaning mode from invasive ventilation.
- As an escalation mode from NCPAP.
- NCPAP therapy with a backup breath facility to treat apnoeas.

Methods

This was a retrospective cohort study conducted at the Royal Hospital for Women Neonatal Intensive Care Unit (NICU). Infants admitted to this unit between 4 October 2017 and 20 April 2021 who received NIV-NAVA during their admission were included in the study. Standard demographic maternal, perinatal, and neonatal data variables were extracted. Inclusion criteria included: inpatient, complete electronic medical records, indications for NIV-NAVA applications including post-extubation, escalation and apnoea (NIV-NAVA is not currently used as a primary mode of respiratory support in this unit). Exclusion criteria included: application of NIV-NAVA at another hospital or for other indications and if the patient had known congenital malformations of the lungs, airways or chest wall. All infants were managed using the Royal Hospital for Women's, "NAVA (Neurally Adjusted Ventilatory Assist", clinical guidelines (Appendix 1). Indications for the initiation of NIV-NAVA and typical settings for these indications can be found in the clinical guidelines.

The primary outcome was the need for intubation within 48 h of NIV-NAVA initiation. The decision for intubation was at the discretion of the treating neonatologist. Infants were stratified by indication and analysed in subgroups. We also investigated change in FiO_2 and PCO_2 when NIV-NAVA was used as an escalation mode. Infants may have required NIV-NAVA multiple times and subsequently appear across multiple indication groups or record more than one episode for the same indication.

The Respiratory Severity Score (RSS) was calculated prior to initiation of NIV-NAVA to indicate level of respiratory illness upon study entry point. This was calculated as either:

$$RSS\ (invasively\ ventilated\ infants) = \left(\frac{PIP}{3} + \frac{2\times\ PEEP}{3}\right) \times\ FiO2\%$$

OR

$$RSS\ (non-invasively\ supported\ infants) = \frac{MAP}{PEEP} \times\ FiO2\%$$

MAP, *mean arterial pressure;* PIP, *Peak inspiratory pressure in cm;* PEEP, *Positive end-expiration pressure in cm H2O;* FiO_2, *fraction of inspired oxygen*.

All statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY: IBM Corp). Descriptive statistics were used to present the results of the study and summarised to the indication for NIV-NAVA. Data was inspected for normality before further analysis. Continuous demographic variables including the outcomes of FiO_2 and pCO_2 were summarised by mean and standard deviation if normally distributed and by median and range if not. Differences between initial and subsequent FiO_2 and pCO_2 were analysed by a paired samples test across all three indications. Statistical significance was set at $p<0.05$.

The study was approved by the South Eastern Sydney Local Health District (Northern Sector) Human Research Ethics Committee (2020/ETH02488).

Results

122 infants were included in the study period; there were 169 episodes of NIV-NAVA use for the three different indications. The average age of the infants commencing NIV-NAVA therapy was 17.2 days with a median weight of 839 g. The median respiratory severity score was 2.6. The perinatal clinical characteristics of included infants is summarised in Table 1.

Of the infants requiring extubation from invasive ventilation, 72 (87.8%) did not require intubation after 48 h. 52 (78.8%) infants were successfully escalated from NCPAP to NIV-NAVA. 21 (100%) of those requiring NIV-NAVA for apnoea treatment were not intubated at 48 h. The overall rate of not requiring intubation following NIV-NAVA use was 145/169 (86%). There were 110 infants < 1000 g at the time of application of NIV-NAVA. 90/110 (82%) in this subgroup did not require intubation. The reason for intubation was not consistently reported but was usually for oxygenation and/or ventilation failure. There were no significant changes in mean FiO_2 (33.8% before; 32.7% after [$p=0.353$]) or pCO_2 (49.4 mmHg before; 48.8 mmHg after [$p=0.547$]) with application of NIV-NAVA in the escalation group. The clinical characteristics of the infants whilst on NIV-NAVA in addition to their prior ventilation modes is summarised in Table 2. There were no adverse events documented related to either the use of the NAVA catheter or the ventilation system.

Discussion

This retrospective cohort study describes the first experience of NIV-NAVA in an Australian NICU and represents the largest reported cohort of NIV-NAVA infants [9, 10, 16–18]. Within 48 h of application of NIV-NAVA for all indications, the majority of infants did not require intubation (86%). This is encouraging as these infants were at high risk of intubation, as evidenced by the cohort's Respiratory Severity Scores (RSS) [19, 20]. The particularly high rate of success in infants with apnoeas highlights the effectiveness of the back-up support that is activated when the system detects an apnoeic episode. These results are consistent with other studies that have shown low intubation rates following the application of NIV-NAVA [21–27].

As a surrogate marker of respiratory status, we compared FiO_2 and pCO_2 before and after the application of NIV-NAVA in the escalation group and found no significant differences. Previous similar studies have shown that the application of NIV-NAVA in this setting either has no effect or improves these parameters [18, 22, 25, 28, 29]. The blood gases in this study were based on clinical need and were not timed. As a result, there was significant variability in the timing of FiO2 and pCO2 measurements both before and after the application of NIV-NAVA as well as the overall time between blood gases. In some circumstances, the two gases may not have been optimally timed to accurately capture the change in respiratory status [30, 31].

There are a number of important limitations to acknowledge in this study. Although it is reassuring that the rate of intubation in this cohort was low, there was no way of determining how many of these infants would have required intubation if alternative modes of non-invasive respiratory support were used. It was not possible to find a suitable control group of infants in whom NIV-NAVA was not used as the infants in this cohort were at significantly higher risk of needing intubation in which case their respiratory support was escalated to NIV-NAVA. They were also not representative of a typical cohort of infants requiring non-invasive respiratory support. The study is also inherently limited by its opportunistic nature, particularly with respect to finding objective measures of clinical change before and after the application of NIV-NAVA. While it is reassuring that infants in the escalation group had stable blood gas parameters, the lack of control in the timing of blood collection limits what we can conclude.

NCPAP has a well-established, evidenced-based role in the NICU environment and is the most widely used non-invasive mode of support for infants with respiratory distress. However, there are clinical circumstances where NCPAP alone does not provide adequate support and other forms of NIPPV may not be synchronised.

Table 1 Perinatal clinical characteristics

	Extubation (*n* = 62)	**Escalation (*n* = 55)**	**Apnoeas (*n* = 18)**	**Overall (*n* = 113)**
Male sex *(%)*	41 (62%)	39 (67%)	13 (65%)	78 (64%)
Gestational age, median *age in weeks and days (minimum-maximum)*	25 + 2 weeks (23 + 1 to 37 + 5)	26 + 1 weeks (23 + 1 to 41 + 3)	26 + 6 weeks (23 + 6 to 34 + 3)	25 + 5 weeks (23 + 1 to 43 + 3)
Birthweight (BW)				
Median BW in grams (minimum-maximum)	708 (365–4310)	810 (365–3740)	894 (498–2324)	963 (365–4310)
BW number < 10th percentile (%)	12 (18%)	9 (16%)	1 (5.0%)	18 (15%)
BW < 3rd percentile (%)	6 (9.1%)	3 (5.2%)	1 (5.0%)	8 (6.6%)
Plurality				
Singleton (%)	53 (86%)	44 (80%)	11 (65%)	93/112* (83%)
Twins (%)	8 (13%)	10 (18%)	5 (28%)	18/112* (16%)
Triplets (%)	1 (1.6%)	1 (1.8%)	1 (5.6%)	1/112* (0.9%)
Antenatal steroids				
Complete (%)	45 (73%)	40 (73%)	19 (56%)	78 (69%)
Incomplete (%)	5 (8.1%)	4 (7.3%)	3 (17%)	23 (20%)
Nil (%)	12 (19%)	11 (20%)	5 (28%)	12 (11%)
Chorioamnionitis *(%)*	22 (36%)	18 (33%)	3/17* (18%)	34/112* (30%)
Delivery mode				
Normal vaginal	15 (23%)	12 (21%)	4 (20%)	30 (25%)
Breech vaginal	10 (15%)	6 (10%)	0 (0.0%)	14 (12%)
Instrumental vaginal	3 (4.5%)	3 (5.2%)	1 (5.0%)	5 (4.1%)
Lower segment caesarean section	38 (58%)	37 (64%)	15 (75%)	73 (60%)
Apgar score				
Median Apgar 1 min (minimum-maximum)	5 (1–9)	6 (1–9)	5 (2–9)	5 (1–9)
Median Apgar 5 min (minimum-maximum)	7 (1–9)	8 (4–10)	8 (4–9)	8 (1–10)
Sepsis				
Early onset sepsis (%)	1/65* (1.5%)	0 (0.0%)	1/19* (5.3%)	2/120* (1.7%)
Late onset sepsis (%)	27/65* (42%)	25 (43%)	7/19* (37%)	48/120* (40%)
Respiratory distress syndrome (RDS) *(%)*	65 (99%)	57 (98%)	19/19* (100%)	119/121* (98%)
Surfactant, *number receiving surfactant (%)*	63 (95%)	55 (95%)	19 (95%)	115 (94%)
Caffeine use, *number who received caffeine (%)*	59 (89%)	50/57* (88%)	19/20* (95%)	109/121* (90%)
Intraventricular haemorrhage (IVH)	18 (27%)	8 (14%)	2/17* (12%)	25/119* (21%)
All IVH (%)	7 (10.6%)	3 (5.2%)	1/17* (5.9%)	11/119* (9.2%)
Major IVH (Grade 3/4) (%)				
Necrotising enterocolitis (NEC) *(%)*	7/65* (11%)	4/57* (7.0%)	1/17* (5.9%)	11/117* (9.4%)
Postnatal steroids *(%)*	48 (73%)	31 (53%)	8 (44%)	71 (59%)
Bronchopulmonary dysplasia (BPD) *(%)*	49 (74%)	43 (74%)	12 (60%)	88 (72%)
Retinopathy of prematurity (ROP) requiring laser or intra-vitreal injection *(%)*	10 (15%)	6 (10%)	1/18* (5.6%)	15/120* (13%)
Survival (%)	61 (92%)	54 (93%)	20 (100%)	113 (93%)

***Incomplete data**

List of Abbreviations

BW, *birthweight;* **RDS,** *respiratory distress syndrome;* **IVH,** *intraventricular haemorrhage;* **NEC,** *necrotising enterocolitis;* **BPD,** *bronchopulmonary dysplasia;* **ROP,** *retinopathy of prematurity*

NIV-NAVA has the theoretical advantages of optimising synchrony with breathing and providing support that is proportional to infants' breathing efforts. Cohort studies such as this continue to show the stability that can be achieved with the application of NIV-NAVA in high-risk infants and adds to the growing body of evidence that supports its use in the NICU environment in selected clinical circumstances. Large, high-quality randomised trials are currently lacking but are essential to help further establish where NIV-NAVA fits into clinical practice [12, 32].

This study has shown that NIV-NAVA can be successfully integrated into the NICU environment for three main indications (escalation; post-extubation; apnoea).

Table 2 NIV-NAVA clinical characteristics

	Extubation (*n* = 82)	**Escalation (*n* = 66)**	**Apnoeas (*n* = 21)**	**Overall (*n* = 169)**
Age when on NIV-NAVA, *age in days (SD)*	18.8 (19.2)	17.3 (18.8)	10.4 (9.6)	17.2 (18.2)
Corrected gestational age on NIV-NAVA, *median corrected gestational age in weeks and days (minimum-maximum)*	27 + 5 weeks (23 + 6 to 42 + 0)	28 + 3 weeks (25 + 3 to 44 + 4)	28 + 0 weeks (24 + 6 to 34 + 3)	28 + 1 weeks (23 + 6 to 44 + 4)
Weight when on NIV-NAVA, *median weight in grams (minimum-maximum)*	827 (490–4310)	901 (575–3740)	847 (575–2350)	839 (490–4310)
Previous Ventilation				
Conventional ventilation *(%)*	80 (98%)	N/A	N/A	80 (47%)
NCPAP *(%)*	N/A	65 (99%)	20 (95%)	85 (50%)
High flow *(%)*	N/A	1 (1.5%)	1 (4.8%)	2 (1.2%)
HFOV *(%)*	2 (2.4%)	N/A	N/A	2 (1.2%)
Respiratory Severity Score (RSS)**, *median RSS (minimum-maximum)*	2.8 (1.72–6.90)	2.5 (0.8-7.0)	1.8 (1.3–3.2)	2.6 (0.8-7.0)
Intubation not required within 48 h of initiation of NIV-NAVA *(%)*	72/82 (88%)	52/66 (79%)	21/21 (100%)	145/169 (86%)
Weight on NAVA ≤ 1000 g	48/58 (83%)	30/40 (75%)	12/12 (100%)	90/110 (82%)

**Calculated by RSS = MAP/PEEP x FiO_2% or (PIP/3 + PEEPx2/3) x FiO_2%

List of Abbreviations

NIV-NAVA, *non-invasive neurally adjusted ventilatory assist;* **SD,** *standard deviation;* **NCPAP,** *nasal continuous positive airway pressure;* **HFOV,** *high frequency oscillatory ventilation;* **RSS,** *Respiratory Severity Score;* **MAP,** *mean arterial pressure;* **PEEP,** *Positive end-expiration pressure;* **FiO_2,** *fraction of inspired oxygen;* **PIP,** *Peak inspiratory pressure;* **Rate,** *rate in breaths per minute;* **Ti,** *total inspiratory time in seconds;*

Although promising, it is important to note that prospective clinical trials are still required to establish the effectiveness of NIV-NAVA by comparing it to other modes of non-invasive support.

Supplementary Information

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Supplementary Material 1

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Author contributions
TS developed the original concept for the study. TP, JS, SB, and KL provided important intellectual input into the development of the study protocol. TS and TP performed a preliminary analysis to establish feasibility. JC was responsible for all data collection. JC performed statistical analysis with the assistance of Dr Kylie-Ann Mallit (acknowledgements). JC drafted the initial manuscript and all authors provided editorial input and approved the final manuscript.

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Data availability
The datasets used and analysed during the study are available from the corresponding author (Dr Tim Schindler) on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the South Eastern Sydney Local Health District (Northern Sector) Human Research Ethics Committee (2020/ETH02488) who deemed that individual consent was not required due to the nature of the study, being a retrospective study of de-identified data. All data was handled as per the New South Wales Information Privacy Commission Statutory Guidelines for Research and the study was conducted in accordance with applicable Privacy Acts and Regulations.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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