

A Randomized Trial of Non-Synchronized Nasopharyngeal Intermittent Mandatory Ventilation (nsNIMV) vs. Nasal Continuous Positive Airway Pressure (NCPAP) in the Prevention of Extubation Failure in Pre-term < 1,500 Grams

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Objective: To compare the rate of reintubation within 7 days after extubation and study the complications in premature infants who were randomized in the immediate postextubation period to either nsNIMV or NCPAP.

Material and Method: This study was conducted in the neonatal unit of Queen Sirikit National Institute of Child Health between June 1 and November 30, 2006. Intubated premature infants born at GA ≤ 34 weeks or with birth weight ≤ 1500 gm, ready to be extubated before 4 weeks of age were recruited. Infants were randomized to either nsNIMV or NCPAP after extubation. Non-synchronized NIMV setting was the same as ventilator setting before extubation and NCPAP pressure was set at the same mean airway pressure of pre extubation ventilator value. Extubation was performed after intravenous loading dose of aminophylline. Primary outcome measurement was reintubation within 7 days of initial extubation and the secondary outcome was possible complications such as apnea, abdominal distension, gastrointestinal (GI) perforation, necrotizing enterocolitis (NEC), sepsis and death.

Results: A total of 70 VLBW infants were admitted to the neonatal unit during the study period. A total of 57 infants were intubated of which 48 infants were recruited for the study; 24 were in the nsNIMV group and 24 were in the NCPAP group. Infants in the nsNIMV group had mean birth weight and body weight at the start of study less than that in the NCPAP group (984.8 ± 218 vs. 1067 ± 214 and 1185 ± 219 vs. 1205 ± 191 , $p = 0.003$, 0.02). The nsNIMV group also had a higher rate of RDS and antenatal steroid used when compared to the NCPAP group ($19/24$ vs. $12/24$ and $17/24$ vs. $8/24$, $p = 0.03$, 0.01). The nsNIMV group had fewer males than in the NCPAP group ($8/24$ vs. $17/24$, $p = 0.01$). Reintubation was similar in both groups but atelectasis and sepsis were statistically significant risk factor for reintubation in NCPAP group.

There were no significant differences in treatment related complications between the two groups, with respect to incidence of apnea (41.7% in nsNIMV vs. 62.5% in NCPAP), abdominal distensions (8.3% in nsNIMV vs. 16.7% in NCPAP), NEC (4.2% in nsNIMV vs. 12.5 in NCPAP), sepsis (4.2% in nsNIMV vs. 8.3% NCPAP). No GI perforation was observed in both groups.

Conclusion: Non-invasive mode of ventilation, both NIMV and NCPAP, for weaning of pre-term infants from ventilator may reduce the rate of reintubation in this group. Both modes seem to be equally safe. We believe that the use of non-invasive ventilator techniques will significantly reduce neonatal morbidity in the future. Additional prospective evaluation of these approaches should be conducted in the future.

Keywords: Non-synchronized nasopharyngeal intermittent mandatory ventilation (nsNIMV), Nasal continuous positive airway pressure (NCPAP), Extubation failure

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Respiratory problems are major causes of morbidity and mortality in premature infants. Over the past few decades, endotracheal intubation and conventional mechanical ventilation have dramatically increased survival in these very tiny babies. However, despite being potentially lifesaving, they are associated with increased pulmonary morbidity⁽¹⁾: subglottic stenosis, respiratory infection, ventilator induced lung injury, and increased risk for bronchopulmonary dysplasia. Minimizing the duration of endotracheal intubation or avoiding it completely is the goal of neonatal intensive care. Since it may not be possible to avoid invasive endotracheal intubation in some very tiny babies, it may be more feasible to wean them early to a more noninvasive mode of respiratory support. Two such modes are the Nasopharyngeal Intermittent Mandatory Ventilation (NIMV) or Nasal intermittent Positive Pressure Ventilation (NIPPV) and Nasal Continuous Positive Airway Pressure (NCPAP).

Neonatal CPAP was first used as an alternative to ventilation in 1971⁽²⁾. Since then it has been shown to reduce extubation failure, treat respiratory distress syndrome (RDS)⁽³⁾ and apnea of prematurity. Unfortunately, studies have also shown that 25-40% of low birth weight infants fail extubation⁽³⁾. Neonatal NIMV was introduced in an effort to reduce extubation failure rate.

Neonatal NIMV is a mode of ventilation that combines NCPAP with superimposed ventilation breaths. It can be administered using the same systems used to deliver NCPAP at either the nasal or nasopharyngeal level. In pediatric intensive care, it has been shown to improve oxygenation and reduce dyspnea, tachypnea, and tachycardia⁽⁴⁾. The mechanism of action of NIMV remains uncertain, but the hypothesis includes improving respiratory drive, increasing mean airway pressure allowing recruitment of alveoli, decreasing work of breathing, increasing functional residual capacity, and increasing tidal and minute ventilation⁽¹⁾.

To our knowledge, there have been no reports of the use of NIMV in the neonates in Thailand.

Objectives

To compare the rate of reintubation within 7 days after extubation and study the complications in premature infants who were randomized in the immediate postextubation period to either nsNIMV or NCPAP.

Material and Method

This study was a prospectively randomized clinical trial conducted in the neonatal unit of Queen

Sirikit National Institute of Child Health from June 1 to November 31, 2006. The study was approved by the Institute's Review Board. Written informed consent was obtained from the parents of each patient prior to enrollment.

Study population and protocol: Intubated premature infants born at gestational age (GA) ≤ 34 weeks or with birth weight of $\leq 1,500$ grams, ready to be extubated before 4 weeks of age were recruited. The decision to extubate was at the discretion of the attending physician, but the ventilator settings before extubation were $\text{FiO}_2 \leq 0.4$, IMV rate ≤ 15 bpm, PIP ≤ 15 cm H₂O and PEEP ≤ 5 cm H₂O. All patients were clinically stable and had no other significant non-respiratory conditions at the time of study entry. The infants were randomized by block of 4 to either nsNIMV or NCPAP after extubation. The nsNIMV setting was the same as the ventilator setting before extubation and the NCPAP pressure was set to obtain the same mean airway pressure of the pre-extubation ventilator setting. Most of the neonates were on aminophylline at the time of extubation; those who were not, received an intravenous loading dose of 8 mg/kg/ dose and maintained at 1.5 mg/kg/dose q 12 hr. Binasopharyngeal prongs and Bear 750 ventilators were used during the study. Blood gases were obtained just before extubation, 1, 12 hours after extubation, and when clinically indicated thereafter. Chest x-ray was obtained 4 hours postextubation and when clinically indicated. At least one cranial ultrasound was performed on the infants within 7 days of life. The neonates' condition was monitored daily.

The primary outcome was the rate of reintubation (extubation failure) within 7 days of extubation. The secondary outcome was to see the complications such as abdominal distension, necrotizing enterocolitis (NEC), gastrointestinal perforation, apnea, atelectasis, and sepsis. Presence of any of the following criteria was considered as extubation failure: (1) respiratory failure: $\text{pH} \leq 7.25$, $\text{PaCO}_2 \geq 25\%$ above pre extubation value or $\text{PaCO}_2 \geq 60$ mmHg, $\text{FiO}_2 \geq 0.6$ to maintain O_2 saturation $\geq 92-95\%$; (2) increased setting: IMV rate ≥ 20 bpm, PIP ≥ 20 cmH₂O, mean airway pressure ≥ 8 cmH₂O; (3) apnea episode with bradycardia < 100 beat/min that did not resolve with stimulation and required bag and mask ventilation; (4) the need for re-intubation as deemed necessary by the attending neonatologist. Demographic data, the duration of endotracheal intubation prior to study entry, the rate of extubation failure within 7 days, and the rate of complications were recorded.

Infants with major congenital malformations, cleft lip/cleft palate, symptomatic patent ductus arteriosus (PDA), necrotizing enterocolitis (NEC), sepsis, and intraventricular hemorrhage (IVH) grade III and IV were excluded from the study.

Sample size and statistics: A sample of 24 infants in each group were randomly selected using an α error of 0.05 and 80% power of test ($\beta = 0.2$). We calculated our sample size to detect a 50% reduction in the number of re-intubation with nsNIMV compared with NCPAP. Statistical analysis was performed with the use of SPSS. Continuous data were analyzed with Student-t-test; proportionate data analyzed using of Pearson Chi-square test and Fisher's Exact test. Subgroup analysis was performed with Repeated Measures Analysis of Variance. A p-value of ≤ 0.05 was considered as a significant difference.

Results

Seventy very low birth weight (VLBW) infants were admitted to neonatal unit between June 1

and November 31, 2006. A total of 57 infants were intubated, of which 48 were recruited for the study. The nine infants excluded were one case of IVH grade IV, one with bronchopulmonary dysplasia and seven infants who died. Twenty-four infants were randomized to nsNIMV and the other twenty-four to NCPAP.

The mean gestational age (GA) in the nsNIMV group was 28.33 ± 2.65 weeks and that in the NCPAP group was 29 ± 2.19 weeks. Infants in the nsNIMV group had a mean birth weight of 984.83 ± 218.05 grams and those in the NCPAP group had a mean birth weight of 1185 ± 219.64 grams, p-value = 0.003. There were 33.3% males in the nsNIMV group and 70.8% in the NCPAP group, p-value = 0.01. Antenatal steroid was used in 70.8% of the nsNIMV group and 33.3% in NCPAP group, p = 0.01. There were no significant differences in chorioamnionitis, pregnancy induced hypertension, cesarean section rate, and Apgar scores between the groups as shown in Table 1.

At the time of study entry, infants in the nsNIMV group had a mean body weight less than that

Table 1. Demographic data

Parameter	nsNIMV (n = 24)	NCPAP (n = 24)	p-value
BW (g) (mean \pm SD)	984.83 \pm 218.05	1185.25 \pm 219.64	0.003*
GA (wk) (mean \pm SD)	28.33 \pm 2.65	29.25 \pm 2.19	0.19
Male gender [n (%)]	8 (33.3)	17 (70.8)	0.01*
Chorioamnionitis [n (%)]	1 (4.2)	0	0.31
ANS** [n (%)]	17 (70.8)	8 (33.3)	0.01*
PIH*** [n (%)]	7 (29.2)	12 (50)	0.14
Caesarean section [n (%)]	12 (50)	15 (62.5)	0.38
Apgar score 1 min	5.20 \pm 2.41	6.42 \pm 2.5	0.09
Apgar score 5 min	7.41 \pm 1.67	8 \pm 1.41	0.19
Inborn [n(%)]	15 (66.67)	13 (54.17)	0.41

* p-value < 0.05

** ANS: antenatal steroid

*** PIH: pregnancy-induced hypertension

Table 2. Infants profile at the start of study

Parameter	nsNIMV (n = 24)	NCPAP (n = 24)	p-value
Weight at study (g) (mean \pm SD)	1067.33 \pm 214.00	1205.00 \pm 191.07	0.02*
Days of ventilator	12.96 \pm 9.90	6.90 \pm 6.00	0.26
PIE [n (%)]	1 (4.2)	0	0.31
Pneumothorax [n (%)]	0	0	
IVH [n (%)]	7 (29.16)	3 (12.5)	0.16
RDS [n (%)]	19 (79.2)	12 (50)	0.03*
Surfactant [n (%)]	9 (37.5)	3 (12.5)	0.05
HFOV [n (%)]	3 (12.5)	0	0.23

in the NCPAP group (1067 ± 213 grams vs 1205 ± 191 grams, p -value = 0.02). There was a higher incidence of RDS in the nsNIMV group when compared to the NCPAP group (19/24 vs. 12/24, p -value = 0.03). There were no statistically significant differences between the two groups in the days on ventilator, pulmonary interstitial emphysema (PIE), IVH, and number of infants who were given surfactant and high frequency oscillation ventilation (HFOV) (Table 2).

There were no statistically significant differences between the two groups in the rate of reintubation (Table 3). Two of 24 (8.3%) in the nsNIMV group were reintubated; 1 each for pneumonia and sepsis. Four out of 24 (16.7%) were reintubated in the NCPAP group; 2 neonates for atelectasis and 2 for sepsis. There were no significant differences in the rates of respiratory failure, apnea, abdominal distension, NEC, GI perforation, sepsis, and death in both groups (Table 3).

There were no significant differences in the pre-extubation and 1, 12 hour post-extubation blood gases (Table 4).

In nsNIMV group there were no significant risk factors for reintubation, but sepsis and atelectasis were statistically significant risk factor for reintubation in NCPAP group (Table 5).

Discussion

Extubation failure is a common problem in the neonates, occurring in approximately 40% of premature infants. These failures are due to apnea, hypoventilation, atelectasis, or intercurrent illnesses like sepsis or PDA. In this study the combined extubation failure rate was 12.5%. The authors found that sepsis and atelectasis were significant risk factors for extubation failure in the CPAP group while there were no significant risk factors for failure in the nsNIMV group.

Even though there was a trend towards lower extubation failure in the nsNIMV group compared to the NCPAP group, it was not significant and the rate of extubation failure was similar in both the groups. This result was unlike those that have been published

Table 3. Clinical outcome after extubation

Parameter	nsNIMV (n = 24)	NCPAP (n = 24)	p-value
Primary outcome			
Re-intubations [n (%)]	2 (8.3)	4 (16.7)	0.38
Secondary outcome			
Respiratory failure (%)	2 (8.3)	2 (8.3)	1
Death [n (%)]	0	0	-
Apnea [n (%)]	10 (41.7)	15 (62.5)	0.15
Atelectasis [n (%)]	0	2 (8.3)	0.15
Abdominal distension [n (%)]	2 (8.3)	4 (16.7)	0.66
NEC [n (%)]	1 (4.2)	3 (12.5)	0.61
Gut perforation	0	0	-
Sepsis [n (%)]	1 (4.2)	2 (8.3)	1.00

Table 4. Comparison of blood gas pre and post extubation*

BLOOD GAS	nsNIMV			NCPAP			p-value
	Pre-extubation	Post-extubation (1 hr)	Post-extubation (12 hrs)	Pre-extubation	Post-extubation (1 hrs)	Post-extubation (12 hrs)	
pH	7.32 ± 0.08	7.37 ± 0.06	7.36 ± 0.04	7.35 ± 0.08	7.39 ± 0.05	7.38 ± 0.05	0.14
PCO ₂ (mmHg)	43.50 ± 9.90	42.67 ± 8.53	42.55 ± 9.7	40.72 ± 0.62	38.49 ± 9.1	38.30 ± 8.01	0.82
HCO ₃ (mmol/L)	21.49 ± 2.72	23.75 ± 3.87	23.71 ± 3.38	20.98 ± 4.48	22.70 ± 3.9	23.38 ± 3.03	0.55
BE (mmol/L)	-3.34 ± 2.97	-1.27 ± 3.75	-1.22 ± 3.7	-4.21 ± 4.44	-0.78 ± 3.23	-1.75 ± 3.03	0.66

* Analysis with repeated measured analysis of variance
Values mean \pm SD

Table 5. Risk for reintubation

Risk	nsNIMV			NCPAP		
	Success (22) n (%)	Failure (2) n (%)	p-value	Success (20) n (%)	Failure (4) n (%)	p-value
IVH	6 (21.3)	1 (50)	0.51	2 (10)	1 (25)	0.44
Sepsis	0	1 (50)	0.08	0	2 (50)	0.02*
NEC	1 (45)	0	1	1 (5)	2 (50)	0.6
Abdominal distension	2 (9.1)	0	1	4 (18.2)	2 (50)	0.11
Apnea	8 (36.4)	2 (100)	0.16	11 (56)	4 (100)	0.26
Atelectasis	0	0	-	0	2 (50)	0.02*
PIE	1 (45)	0	1	0	0	-

previously by Barrington 2001⁽⁵⁾, Khalef 2000⁽⁶⁾ and Friedlich 1999⁽⁷⁾ which showed that synchronized NIMV increases the likelihood of successful extubation. In a meta-analysis study⁽⁸⁾, comparing extubation of infants to NIMV and NCPAP, there was a significant benefit for infant extubated to NIMV in terms of prevention of extubation failure. The effect was clinically important, with an absolute risk reduction for extubation failure of 32% using NIMV, with a number needed to treat of 3. However, all the studies were conducted using synchronized NIMV unlike our study where nsNIMV was used. Up to date, there have been no studies that have compared synchronized with non-synchronized NIMV. We opted to use the non-synchronized mode due to lack of availability of ventilators with options for synchronization in a lot of the neonatal units in our country.

In the present study, two infants were re-intubated in nsNIMV group; one due to pneumonia and the other due to sepsis. On the other hand, four infants were reintubated in NCPAP group; two for atelectasis at 6 hours and 8 hours after extubation and two cases for sepsis due to *Acinetobacter baumannii* and *Staphylococcus coagulase negative*. Both these cases were reintubated because the attending neonatologist felt it necessary due to the infant's condition.

Secondary outcomes of respiratory failure were similar in both groups (8.3%), while apnea and bradycardia were seen less often in nsNIMV group compared to the NCPAP group (41% vs. 62.5%, p-value = 0.15). Barrington et al⁽⁵⁾ and Friedlich et al⁽⁷⁾ compared sNIMV with NCPAP at time of extubation of VLBW infants and found apnea and bradycardia also occurred less often in the sNIMV group. Khalaf et al⁽⁶⁾ found no difference between both groups. Other secondary outcomes such as abdominal distension, NEC, GI perforation, IVH and sepsis did not differ

significantly between the groups. Earlier studies in the past have raised concerns about excessive GI perforations that occurred with noninvasive modes using face mask or nasal prongs but they have not been reported in recent studies⁽⁹⁾. Jackson et al⁽¹⁰⁾ have described excessive abdominal distension with incorrect nasopharyngeal prong position, until they changed their practice and started using shorter prongs with smaller infants. Other complications that have been reported with CPAP (nasal trauma⁽¹¹⁾, pneumothorax⁽¹²⁾) could also be expected with NIMV but none have been formally reported so far. Our study was not designed to evaluate long-term outcomes, which would require a much larger number of infants.

Conclusion

Non-invasive mode of ventilation, both NIMV and NCPAP, for weaning of pre-term infants from the ventilator may reduce the rate of reintubation in these patients. Both modes seem to be equally safe. The authors believe that the use of non-invasive ventilator techniques will significantly reduce neonatal morbidity and hope that additional prospective evaluation of these approaches will be conducted in the future.

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การศึกษาการใช้เครื่องช่วยหายใจชนิด nsNIMV เปรียบเทียบกับ NCPAP ภายหลังการนำท่อช่วยหายใจออกในทารกเกิดก่อนกำหนด

มिरา โครนา, หทัยทิพย์ ภารตวิสุทธิ, วราภรณ์ แสงทวีสิน, วิบูลย์ กาญจนพัฒนกุล, อุไรวรรณ โชติเกียรติ, จินตกานต์ เกษมศรี ณ อยุธยา

วัตถุประสงค์: เพื่อทำการศึกษาเปรียบเทียบอัตราการใส่ท่อช่วยหายใจคืนและความปลอดภัย จากการใช้ nsNIMV กับ NCPAP ภายหลังการนำท่อช่วยหายใจออก 7 วัน ในทารกที่เกิดก่อนกำหนด

วัสดุและวิธีการ: เริ่มทำการศึกษาตั้งแต่ 1 มิถุนายน - 30 พฤศจิกายน พ.ศ. 2549 ในทารกที่มีอายุครรภ์น้อยกว่าหรือเท่ากับ 34 สัปดาห์ และมีน้ำหนักตัวน้อยกว่า 1,500 กรัม ที่เข้ารับการรักษาที่หอผู้ป่วยทารกแรกเกิดของสถาบันสุขภาพเด็กแห่งชาติมหาราชินี ที่ใช้เครื่องช่วยหายใจน้อยกว่า 4 สัปดาห์ ทารกทุกรายต้องได้รับ aminophylline loading dose ทางหลอดเลือดก่อนนำท่อช่วยหายใจออกและภายหลังที่นำท่อช่วยหายใจออก ทารกจะใช้ nsNIMV หรือ NCPAP แยกตามกลุ่มที่ randomized ไว้ โดยในกลุ่ม nsNIMV ใช้เครื่องช่วยหายใจ setting เท่ากับก่อนนำท่อช่วยหายใจออก และ NCPAP ใช้ MAP เท่าเดิมเช่นกัน โดยผลลัพธ์หลักที่ศึกษาคือ อัตราการใส่ท่อช่วยหายใจคืนภายหลังการนำท่อช่วยหายใจออก 7 วัน และผลลัพธ์รอง คือความปลอดภัยและภาวะแทรกซ้อนที่เกิดขึ้น

สถิติที่ใช้ Pearson Chi-Square, Fisher's Exact test, Student t- test, Repeated measures analysis of variance

ผลการศึกษา: จำนวนทารกที่มีอายุครรภ์น้อยกว่าหรือเท่ากับ 34 สัปดาห์ หรือมีน้ำหนักตัวน้อยกว่า 1,500 กรัม มีจำนวน 70 ราย ใส่ท่อช่วยหายใจ 57 ราย ไม่ได้ใส่ท่อช่วยหายใจ 13 ราย เข้าเกณฑ์การคัดเลือกจำนวน 48 ราย แบ่งเป็น nsNIMV 24 ราย NCPAP 24 ราย ข้อมูลทั่วไปในกลุ่ม nsNIMV พบว่ามีน้ำหนักเฉลี่ยแรกคลอดและน้ำหนักขณะที่นำท่อช่วยหายใจออกน้อยกว่ากลุ่ม NCPAP อย่างมีนัยสำคัญ (984.8 ± 218 กรัม เทียบกับ $1,067 \pm 214$ กรัม และ $1,185 \pm 219$ กรัม เทียบกับ $1,205 \pm 191$ กรัม, $p = 0.003$, 0.02 ตามลำดับ) ในกลุ่ม nsNIMV พบภาวะ RDS และมีการใช้ antenatal steroid มากกว่า NCPAP (19/24 เทียบกับ 12/24 และ 17/24 เทียบกับ 8/24 $p = 0.03$, 0.01 ตามลำดับ) พบทารก เพศชายในกลุ่ม NCPAP มากกว่า (8/24 เทียบกับ 17/24 $p = 0.01$) ส่วนข้อมูลทั่วไปด้านอื่น ๆ ไม่แตกต่างกัน

ในกลุ่ม nsNIMV มีอัตราการใส่ท่อช่วยหายใจคืน 2/24 ราย คิดเป็นร้อยละ 8.3 เทียบกับกลุ่ม NCPAP มีอัตราการใส่ท่อช่วยหายใจคืน 4/24 ราย คิดเป็นร้อยละ 16.7 ซึ่งไม่แตกต่างทางสถิติโดยพบว่า ทารกที่ต้องใส่ท่อช่วยหายใจคืนในกลุ่ม nsNIMV มีภาวะ pneumonia และ sepsis 2 ราย ในกลุ่ม NCPAP ทารกที่ต้องใส่ท่อช่วยหายใจคืน 4 ราย จากภาวะ atelectasis 2 ราย และ sepsis 2 ราย

พบภาวะ apnea ในกลุ่ม nsNIMV ร้อยละ 41.7 ในกลุ่ม NCPAP พบร้อยละ 62.5 ภาวะ abdominal distension ในกลุ่ม nsNIMV ร้อยละ 8.3 ในกลุ่ม NCPAP พบร้อยละ 16.7 ภาวะ NEC ในกลุ่ม nsNIMV พบร้อยละ 4.2 กลุ่ม NCPAP พบร้อยละ 12.5 ภาวะ sepsis ในกลุ่ม nsNIMV พบร้อยละ 4.2 กลุ่ม NCPAP พบร้อยละ 8.3 ไม่พบภาวะลำไส้ทะลุในทั้งสองกลุ่ม

สรุป: ไม่พบความแตกต่างของการใส่ท่อช่วยหายใจคืนและภาวะการหายใจล้มเหลว ทั้งในกลุ่ม nsNIMV และ NCPAP แต่จะพบว่าทารกในกลุ่ม NCPAP มีภาวะ atelectasis มากกว่า nsNIMV ดังนั้น nsNIMV และ NCPAP น่าจะมีประสิทธิภาพในการป้องกันภาวะการหายใจล้มเหลว ภาวะ atelectasis และมีความปลอดภัยในการนำมาใช้ภายหลังจากการนำท่อช่วยหายใจออก ในทารกที่เกิดก่อนกำหนด
