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Extubation Success in Premature Infants With Respiratory Distress Syndrome Treated With Bi-Level Nasal Continuous Positive Airway Pressure Versus Nasal Intermittent Positive Pressure Ventilation

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ABSTRACT

Infants born prematurely with respiratory distress syndrome are at high risk for complications from mechanical ventilation. Strategies are needed to minimize their days on the ventilator. The purpose of this study was to compare extubation success rates in infants treated with 2 different types of continuous positive airway pressure devices. A retrospective cohort study design was used. Data were retrieved from electronic medical records for patients in a large, metropolitan, level III neonatal intensive care unit. A sample of 194 premature infants with respiratory distress syndrome was selected, 124 of whom were treated with nasal intermittent positive pressure ventilation and 70 with bi-level variable flow nasal continuous positive airway pressure (bi-level nasal continuous positive airway pressure). Infants in both groups had high extubation success rates (79% of nasal intermittent positive pressure ventilation group and 77% of bi-level nasal continuous positive airway pressure group). Although infants in the bi-level nasal continuous positive airway pressure group were extubated sooner, there was no difference in duration of oxygen therapy between the 2 groups. Promoting early extubation and extubation success is a vital strategy to reduce complications of mechanical ventilation that adversely affect premature infants with respiratory distress syndrome.

Key Words: bi-level, continuous positive airway pressure, extubation, nasal intermittent positive pressure ventilation, respiratory distress syndrome

Premature infants are at high risk for complications after birth; therefore, providers seek to minimize complications associated with prolonged ventilation. Fewer days on the ventilator may result in fewer complications such as chronic lung disease[1] and ventilator-associated pneumonia.[2] In addition, infants requiring prolonged ventilation are also at risk for poor neurodevelopmental outcomes.[3] Minimizing ventilator days may decrease overall lengths of stay,[4] which may translate into lower costs of hospitalization. The most effective postextubation ventilatory strategies are not yet known. The purpose of this study was to compare the effectiveness of 2 types of continuous positive airway pressure (CPAP) on extubation success and duration of oxygen therapy.

Factors affecting extubation success include birth weight, gestation, postextubation respiratory support, and methylxanthine therapy. Low-birth-weight and short gestation are known contributors to extubation failure.[5,6] Infants weighing less than 1250 g at birth are at highest risk for extubation failure.[7] In a study

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of infants weighing less than 1000 g, Stefanescu et al[8] found that 40% of infants failed extubation. Apnea is often the cause of extubation failure. Both CPAP[9] and methylxanthine therapy[10] have been shown to be effective therapies to manage apnea postextubation.

CONTINUOUS POSITIVE AIRWAY PRESSURE

All types of CPAP are designed to provide positive pressure to the airways of a spontaneously breathing infant.[11] Continuous positive airway pressure aids in maintaining functional residual capacity, which helps prevent atelectasis. Nasal CPAP can be categorized by the type of flow used to generate the positive pressure.

Continuous flow nasal CPAP

Continuous flow nasal CPAP (NCPAP) is commonly delivered using a time-cycled, pressure-limited ventilator paired with nasal prongs and can be referred to as conventional NCPAP. Conventional NCPAP has been a popular method of delivering CPAP, as the same ventilator can be used for initial management of the intubated infant as well as postextubation care. During conventional NCPAP, the ventilator supplies a continuous flow of pressure during the inspiratory and expiratory phases of the breathing cycle. A limitation of conventional NCPAP is that the infant must exhale against the continuous flow of gas, which increases imposed work of breathing.[12] Other types of continuous flow CPAP include bubble CPAP and that which may be delivered with high-flow nasal cannula. These 2 types of continuous flow CPAP were not evaluated in this study because they were not being used regularly during both time periods in the unit from which the data were obtained.

Nasal intermittent positive pressure ventilation

In addition to a baseline of CPAP, infants may be given intermittent, time-cycled positive pressure breaths. These additional breaths may help combat apnea and improve extubation success. In a meta-analysis, Davis et al[13] reported that infants who received synchronized nasal intermittent positive pressure ventilation (NIPPV) were less likely to require reintubation than those treated with continuous flow CPAP alone. These results may not translate to infants treated with a nonsynchronized mode of NIPPV.

Variable flow CPAP

Variable flow CPAP has been available in the United States since 1995. Both nasal prongs and a nasal mask can be used to administer variable flow CPAP. The variable flow device entrains gas during the inspiratory phase, maintaining a more stable mean airway pressure that can improve alveolar recruitment and minimize atelectasis.[14] Because the variable flow device diverts gas flow away from the infant at exhalation, patients receiving variable flow CPAP have decreased work of breathing compared with those treated with continuous flow CPAP.[15]

Bi-level variable flow CPAP

The newest generation of variable flow CPAP adds a bi-level mode. In the bi-level mode, infants receive 2 levels of airway pressure. In the bi-level variable flow mode, intermittent breaths are delivered at lower peak pressures than with NIPPV and usually with longer inspiratory times.[16] CareFusion,[17] manufacturer of the bi-level variable flow Infant Flow SiPAP (San Diego, California), reports that this new mode improves oxygenation and ventilation and can help decrease extubation failures and days on the ventilator. At present, insufficient evidence exists to support those claims.

REVIEW OF LITERATURE

Conventional versus variable flow NCPAP

In a MEDLINE search of the combined terms, "continuous positive airway pressure" and "newborn" and "extubation," 3 studies comparing variable flow NCPAP to conventional NCPAP with an outcome of extubation success were identified. Results of these trials were conflicting. In the largest of the studies, Stefanescu et al[8] recruited 162 infants with birth weights of 1000 g or less and randomized them to receive either variable flow NCPAP ($n = 78$) or conventional NCPAP ($n = 84$). There were no statistical differences between the 2 groups on maternal or infant characteristics. Infants in the conventional NCPAP group had a mean birth weight of 755 g (SD = 155) and a mean gestation of 25.7 weeks (SD = 2). Infants who received variable flow NCPAP had a mean birth weight of 744 g (SD = 123) with a mean gestation of 25.9 weeks (SD = 1.5). Stefanescu et al[8] defined extubation success as avoiding reintubation for 168 hours (7 days). They found no significant differences in extubation success rates between the 2 groups (61.5% of variable flow group, 61.9% of conventional NCPAP group). However, they did find a secondary benefit of variable flow NCPAP, with the variable flow group having fewer total days on oxygen ($P = .03$) and shorter lengths of stay ($P = .017$).

Conversely, 2 groups of researchers showed better extubation success in infants receiving variable flow NCPAP than in those receiving conventional NCPAP. Roukema et al[18] randomized 93 infants weighing 1250 g

or less at birth to receive either variable flow or conventional NCPAP. The mean birth weight of their entire sample was 852 g, with a mean gestation of 26.2 weeks. They defined extubation success as ≤ 7 days. They found that infants in the variable flow group were 2.5 times more likely to be successfully extubated at 7 days of age than were the infants in the conventional NCPAP group (odds ratio, 2.5; 95% confidence interval, 1.1-5.8).

Sun and Tien[19] randomized 73 patients weighing 1250 g or less to receive either variable flow NCPAP ($n = 38$) or conventional NCPAP ($n = 35$). The infants in the conventional NCPAP group had a mean birth weight of 857 g (SD = 200) and a mean gestation of 26.3 weeks (SD = 1.8). Infants randomized to variable flow NCPAP had a mean birth weight of 800 g (SD = 193) and a mean gestation of 26.3 weeks (SD = 2). There were no significant differences in birth weight or gestation between the 2 groups. They measured extubation failure both at 24 hours or less and at 7 days or less. They found that infants in the variable flow NCPAP group were less likely to fail extubation at 24 hours or less ($P < .001$) and at 7 days or less ($P < .001$). Extubation success rates at 7 days or less were 84% for the variable flow group and 46% for the conventional NCPAP group. The improved extubation success rates seen by Roukema et al[18] and Sun and Tien[19] may have been due, in part, to the larger mean birth weight of their subjects than those of Stefanescu et al.[8]

Variable flow versus bi-level variable flow NCPAP

In a MEDLINE search combining the terms "continuous positive airway pressure" and "bi-level or bi-level" and "newborn," 2 relevant studies were retrieved. Both were studies comparing variable flow NCPAP with bi-level variable flow NCPAP. No studies comparing bi-level variable flow NCPAP with conventional NCPAP or NIPPV were found. Both of the studies that compared variable flow NCPAP with bi-level variable flow NCPAP showed that bi-level variable flow NCPAP improved respiratory outcomes more than variable flow NCPAP alone.

In a crossover study, Migliori et al[20] compared the effects of variable flow NCPAP and bi-level variable flow NCPAP. They recruited 20 infants born at 32 weeks of gestation or less. Their sample had a mean postconceptual age of 29.6 weeks and a mean weight of 1033 g at the time of study. They studied all infants over four 1-hour time periods of alternating variable flow and bi-level variable flow NCPAP. During periods of bi-level variable flow NCPAP, infants had higher transcutaneous oxygen levels ($P < .001$), lower transcutaneous carbon dioxide levels ($P < .001$), and reduced respiratory rates ($P < .001$).

Lista et al[21] recruited 40 infants born at less than 35 weeks and randomized them to receive either variable flow NCPAP ($n = 20$) or bi-level variable flow NCPAP ($n = 20$) after extubation. Infants in the variable flow NCPAP group had a mean birth weight of 1429 g (SD = 545) and mean gestation of 30.3 weeks (SD = 2). Infants who received bi-level variable flow NCPAP had a mean birth weight of 1411 g (SD = 560) and a mean gestation of 30.2 weeks (SD = 2). There were no significant differences between the groups on birth weight or gestation. They found that infants in the bi-level variable flow NCPAP group had fewer days on respiratory support, with the bi-level variable flow NCPAP group having a mean duration of 3 days (SD = 1) and the variable flow CPAP group having a mean duration of 6.2 days (SD = 2). The difference in days on respiratory support was significant ($P = .025$). Infants in the bi-level variable flow NCPAP group also had fewer total days on oxygen ($P = .027$) and were discharged sooner ($P = .02$).

METHODS

Data for this study were abstracted from the BabySteps database for a metropolitan, 93-bed, level III neonatal intensive care unit, with more than 700 admissions per year. BabySteps is an electronic health record used by the physicians and nurse practitioners of Pediatrix Medical Group. The dependent variable of extubation success was defined as avoiding reintubation for 7 days after initial extubation from mechanical ventilation. The following data were collected: type of CPAP at extubation, gestation, gender, maternal race, caffeine administration, and duration of oxygen therapy (days).

Study inclusion criteria were premature infants (<37 weeks of gestation) with a diagnosis of respiratory distress syndrome (RDS) who required mechanical ventilation on the first day of life. Infants with any of the following conditions were excluded: airway anomalies, neuromuscular disease, major chromosomal and/or congenital anomalies, and infants who were transported in or out or died prior to extubation. Inclusion and exclusion criteria were the same for both groups. Institutional review board approval was obtained from the hospital and the University of Texas at Arlington.

All consecutively born premature infants in 2006-2007 with a diagnosis of RDS extubated to NIPPV were selected for group 1. The Dräger Babylog (Dräger Medical Inc, Telford, Pennsylvania) was used to deliver NIPPV. The interface for the NIPPV was nasal prongs. Infants in group 2 were born in 2010 and extubated to bi-level NCPAP delivered by the Infant Flow SiPAP

system. The interface for the bi-level NCPAP was nasal prongs alternating with nasal mask. The years 2006-2007 were chosen for the NIPPV group, as the 2 years prior to the acquisition of the bi-level NCPAP device. Data from 2010 were the most recent data available. No significant changes in medical or nursing care occurred between 2006 and 2010 in this unit.

SPSS Statistics (17.0) was used to analyze the study data (SPSS; IBM, Armonk, New York). Descriptive statistics were used to compare the groups. Two-tailed Fisher exact test was used to compare extubation success between the groups, and nonparametric tests were used to compare duration of oxygen therapy and day of life extubated. A logistic regression model was created to evaluate the contributions of the independent variables (gestation, gender, type of CPAP, maternal race, and caffeine administration) on the dependent variable of extubation success. The adjusted odds ratio represented the effect size.

RESULTS

Sample demographics

The sample included 194 premature infants, 124 infants in the NIPPV group, and 70 infants in the bi-level NCPAP group. The proportions of infants by gender and maternal race are presented in Table 1. There was no difference in gender $\chi^2_1 = 0.08$, $P = .784$. There was no difference in maternal race between the 2 groups when race was categorized as white, black, Hispanic, and Other, $\chi^2_1 = 5.94$, $P = .114$. However, when the maternal race variable was collapsed into 2 categories (white and ethnic minority), there were significantly more minority infants in the bi-level NCPAP group than in the NIPPV group, $\chi^2_1 = 4.70$, $P = .03$.

Both birth weight and gestation were comparable between the 2 groups. Infants in the bi-level NCPAP group had a mean birth weight of 931 g (SD = 351) compared with infants in the NIPPV group with a mean birth weight of 894 g (SD = 304). An independent-samples *t* test showed no significant difference between the 2 groups on birth weight ($P = .439$). The bi-level NCPAP group had a median gestation of 26 weeks (range, 23-32 weeks) and the NIPPV group had a median gestation of 27 weeks (range, 23-32 weeks). An independent-samples *t* test comparing mean gestational age showed no significant difference between the 2 groups on gestation ($P = .409$).

The majority of infants (100% of those in the bi-level NCPAP group and 96% of those in the NIPPV group) received bovine surfactant, either calfactant (Infasurf) or beractant (Survanta). Most infants received caffeine, as well (87% in bi-level NCPAP group and 76% of those in NIPPV group, with no significant difference between the 2 groups, $\chi^2_1 = 3.42$, $P = .064$).

Table 1. **Demographic characteristics of infants (*N* = 194)**

	NIPPV *n* (%)	Bi-level NCPAP *n* (%)	*P*
Gender			
Male	61 (49.2%)	33 (47.1%)	NS
Female	63 (50.8%)	37 (52.9%)	
Maternal race			
White	55 (44.4%)	20 (28.6%)	NS
Black	45 (36.3%)	37 (52.9%)	
Hispanic	18 (14.5%)	9 (12.9%)	
Other	6 (4.8%)	4 (5.7%)	
Maternal race (collapsed)			
White	55 (44.4%)	20 (28.6%)	.03
Other	69 (55.6%)	50 (71.4%)	

Abbreviations: NCPAP, nasal continuous positive airway pressure; NIPPV, nasal intermittent positive pressure ventilation; NS, not significant.

EXTUBATION SUCCESS

Comparison of bi-level NCPAP and NIPPV groups

There was no difference in extubation success between the NIPPV group and the bi-level NCPAP group ($P = .856$, 2-tailed Fisher exact test). Both groups had high extubation success rates (79% of the NIPPV group and 77.1% of the bi-level NCPAP group).

Logistic regression model of extubation success

Logistic regression analysis with extubation success as the dependent variable and gender, maternal race, gestation, caffeine administration, and type of CPAP as predictors indicated that extubation success increased with increasing gestation, $\chi^2_5 = 13.10$, $P = .022$. The odds ratio for gestation was 1.37 (95% confidence interval, 1.14-1.65), indicating that for every additional week of gestation, the infants were 1.3 times more likely to be successfully extubated. Results of the analysis with all of the model predictors are provided in Table 2.

DURATION OF OXYGEN THERAPY

The distribution of the variable days on oxygen was significantly skewed; therefore, nonparametric tests were chosen. The Mann-Whitney *U* test on total days on oxygen revealed no significant difference between the NIPPV and bi-level NCPAP groups, $U = 4121$, $z = -0.58$, $P = .561$.

Table 2. **Results of logistic regression model of extubation success**

	Unadjusted OR (95% CI)	*P*	Adjusted OR (95% CI)	*P*
Gender (female)	1.08 (0.55-2.14)	.821	1.08 (0.53-2.19)	.841
Maternal race (ethnic minority)	1.10 (0.55-2.21)	.785	1.64 (0.75-3.56)	.214
Caffeine (yes)	1.33 (0.59-3.00)	.499	1.63 (0.68-3.91)	.277
Type CPAP (bi-level NCPAP)	0.90 (0.44-1.81)	.759	0.80 (0.38-1.71)	.572
Gestation (in weeks)	1.31 (1.10-1.57)	.002	1.37 (1.14-1.65)	.001

Abbreviations: CI, confidence interval; CPAP, continuous positive airway pressure; NCPAP, nasal continuous positive airway pressure; OR, odds ratio.

DAY OF LIFE EXTUBATED

During data analysis, an additional finding related to extubation was found. Infants who were extubated to bi-level NCPAP were extubated sooner than those extubated to NIPPV. The distribution of the variable day of life extubated was significantly skewed, so nonparametric tests were used. A Mann-Whitney *U* test on day of life extubated revealed that infants in the bi-level NCPAP group were extubated significantly sooner than infants in the NIPPV group, $U = 3373$, $z = -2.58$; $P = .01$.

A Kaplan-Meier survival analysis was subsequently performed to analyze time to extubation for the bi-level NCPAP and NIPPV groups. The median days to extubation for the bi-level NCPAP group were 7, compared with 23 days for the NIPPV group.

DISCUSSION

The purpose of this study was to compare bi-level NCPAP with NIPPV on extubation success and oxygen duration. The definition of extubation success (7 days) was chosen because it was the most commonly used definition in the literature review. Low birth weight, short gestation, and male gender are predictors of RDS mortality.[22] These factors may negatively affect extubation success and, therefore, were controlled for in the analysis. Extubation success rates were equally high in both study groups.

This is the first study to compare NIPPV with bi-level variable flow NCPAP. Because there are no studies that are directly comparable, the findings are compared with those of researchers who studied other forms of CPAP on the outcome of extubation success. Stefanescu et al[8] compared infants treated with variable flow NCPAP with those treated with conventional NCPAP. They found no significant difference in extubation success rates between the 2 groups. However, their extubation success rates (61.5% of those treated with conventional NCPAP and 61.9% of those treated with variable flow NCPAP) were lower than those in this study.

In this study, the extubation success rates of 77% in the bi-level NCPAP group and 79% in the NIPPV group are higher than expected. This may be due to the addition of intermittent breaths to the baseline CPAP in both of the study groups. Davis et al[13] reported that NIPPV can reduce extubation failure more than CPAP alone. However, all of the studies included in that meta-analysis compared synchronized NIPPV with CPAP. It is unknown whether these findings translate to infants treated with a nonsynchronized mode of NIPPV. In addition, the majority of infants in both groups received caffeine, which has been shown to promote extubation success.[10] The inability to show a difference in extubation success between the 2 groups may have been due to a ceiling effect. A ceiling effect occurs when the values of the outcome variable are clustered near the top of the range.[23] When that occurs, it becomes difficult to elucidate a difference between 2 treatments.

DURATION OF OXYGEN THERAPY

Infants treated with bi-level NCPAP did not have a shorter duration of oxygen therapy than infants treated with NIPPV. This is in contrast to the findings of Stefanescu et al,[8] who found that infants treated with variable flow versus conventional NCPAP had significantly fewer days on supplemental oxygen. Their conventional NCPAP group had a mean duration of oxygen therapy of 77.2 days compared with 65.7 days for the variable flow NCPAP group.

Analysis also revealed that infants in the bi-level NCPAP group were extubated sooner than infants in the NIPPV group, a statistically significant finding. Infants who are able to be extubated sooner would be expected to have a shorter duration of oxygen therapy. Many respiratory therapies that hold promise in improving respiratory outcomes have failed to reduce long-term oxygen need. Examples of these therapies include NIPPV,[13] synchronized mechanical ventilation,[24] and high-frequency ventilation.[25] Prolonged oxygen need is the defining characteristic of the chronic lung disease of prematurity, bronchopulmonary dysplasia (BPD). Evidence has shown that BPD is a multifactoral disease. Not only are there neonatal predictors of BPD such as low birth weight, short gestation, prolonged

need for mechanical ventilation, and postnatal infection, but there are also maternal factors including antenatal steroid administration and antenatal infection.[26] The contradictory finding of reduced duration of mechanical ventilation in the bi-level NCPAP group without a resulting decrease in duration of oxygen need may have been due to a confounder that was not identified in this study such as antenatal or postnatal infection.

LIMITATIONS

A retrospective cohort study design limits the variables for study to those that are available in the database. In this study, no data were available on levels of CPAP, nor on the rate of positive pressure breaths administered. Additional comparisons of the bi-level NCPAP and NIPPV groups could have been made with stratification of levels of treatment, which would have provided additional information regarding the contribution of NIPPV and bi-level NCPAP to extubation success and oxygen dependency. Another limitation of the retrospective cohort design is lack of control over confounders that may have impacted the outcomes. There were no protocols or guidelines for extubation readiness or extubation failure in this neonatal intensive care unit. In a randomized controlled trial design, protocols could be established so that uniform criteria exist for both extubation and the need for reintubation, which would limit variability because of differences in provider practice patterns. Although the known confounders of gestation, gender, and caffeine were identified, other confounders may have affected extubation success that have yet to be determined.

The infants included in this retrospective cohort study were selected from a convenience sample of premature infants born in one hospital. Although the sample drawn from this neonatal intensive care unit was diverse, it may not be representative of the larger population of premature infants with RDS. This limits the generalizability of the findings.

CONCLUSIONS

This study is the first to compare bi-level NCPAP and NIPPV on the outcome of extubation success. The study showed that high extubation success rates are possible with the use of bi-level NCPAP and NIPPV postextubation. Another promising finding was that infants treated with bi-level NCPAP were extubated sooner than those treated with NIPPV. Promoting early extubation and extubation success are vital strategies to reduce complications of mechanical ventilation that adversely affect premature infants with RDS.

Additional research is needed to explore the variables that contribute to oxygen dependency in premature infants with RDS. In this study, infants in the bi-level NCPAP group were extubated sooner than those in the NIPPV group. However, there were no differences in the duration of oxygen therapy between the 2 groups. This finding suggests that there are additional factors that affect long-term oxygen need. Previous studies of promising therapies such as high frequency ventilation and synchronized mechanical ventilation have failed to demonstrate reduction in oxygen dependence and BPD. However, as providers develop expertise in using these new ventilators and modes of ventilation, additional well-designed studies may provide insight into strategies that may reduce oxygen dependence and BPD.

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- Within 3–4 weeks after your CE enrollment form is received, you will be notified of your test results.
- If you pass, you will receive a certificate of earned contact hours and answer key. If you fail, you have the option of taking the test again at no additional cost.
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- Need CE STAT? Visit www.nursingcenter.com for immediate results, other CE activities and your personalized CE planner tool.
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Registration Deadline: October 31, 2015

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Disclosure Statement:
The authors and CE planners have disclosed that they have no financial relationships related to this article.

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