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A Comparison of Leak Synchronized Nasal SIMV Methods and Leak Compensated Nasal SIMV in Newborns with Respiratory Distress Syndrome

Author (s)

Ahmet Özdemir[1], Mustafa Ali Akın[2], Osman Baştuğ[1], Tamer Güneş[3]

Affiliation (s)

[1]University of Health Sciences, Kayseri City Hospital, Neonatal Unit, Kayseri, Turkey
[2]Ondokuz Mayis University Medical Faculty, Department of Neonatology, Samsun, Turkey
[3]Erciyes University Medical Faculty, Department of Neonatology, Kayseri, Turkey

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Abstract

The aim of the present study was to compare the efficacy of leak compensated nasal SIMV (LCnSIMV) and leak synchronized nasal SIMV (LSnSIMV) modes in order to reduce the need for endotracheal intubation and associated complications in newborns with respiratory distress. This randomized, prospective study was conducted on 50 infants (25 per group) with gestational age below 34 weeks and/or below 2000 grams who have been admitted to NICU of Erciyes University Hospital because of respiratory distress syndrome (RDS) and need for mechanical ventilation. Infants with congenital heart disease, nasopharyngeal pathology (coanal atresia and cleft palate-lip) were excluded. Infants monitored on mechanical ventilator after surfactant were randomly assigned to LCnSIMV and LSnSIMV groups before extubation. SPO_2/FiO_2 (S/F), peak heart rate (PHR), respiration rate per minute (RRM), and arterial blood pressure (aBP) values of patients were recorded. Gestational age, birth weight, gender, RDS, patent ductus arteriosus (PDA) requiring treatment, presence of intraventricular bleeding (IVH), retinopathy of prematurity (ROP), bronchopulmonary dysplasia (BPD), necrotizing enterocolitis (NEC) were recorded. The patients enrolled in the study were female by 48% and male by 52%. There was not any statistically significant difference between groups for gender, postnatal age and birth weight. There was detected statistically significant difference between LCnSIMV and LSnSIMV groups for non-invasive ventilation period and re-intubation rate (p=0.04 and p=0.03, respectively). There was detected statistically significant difference between LCnSIMV and LSnSIMV groups for SpO_2 and S/F rates at 60 minutes (p=0.03 and p=0.01, respectively). There was not any difference between groups for blood pressure, PDA, IVH, ROP, BPD, NEC, sepsis and air leak. It may be appropriate to prefer the LSnSIMV method in patients with respiratory distress syndrome who need non-invasive ventilation in the pre-extubation period by considering the patient-ventilator compliance for positive effect in terms of mechanical clinical variables.

Keywords: Prematurity, respiratory distress syndrome, surfactant, mechanical ventilation, leak compensation, leak synchronization

Correspondence: Ahmet Özdemir, University of Health Sciences, Kayseri City Hospital, Neonatal Unit, Kayseri, Turkey
E-mail: dr.ozdemir@yahoo.com

Introduction

Mechanical ventilation (MV) is associated with increased survival in preterm babies; however, it may also play a role in the development of bronchopulmonary dysplasia (BPD) in living babies. Non-invasive ventilation (NIV) both reduces the need for invasive MV and decreases the incidence of BPD in preterm babies with RDS.[1-5]

Different ventilators differ significantly in their ability to compensate for leaks and achieve patient synchronization for patient-ventilator compliance. Ventilator performance, ventilator settings, and leak size play an important role in determining trigger and respiratory compliance. The aim of the study was to compare the efficacy of leak compensated nasal SIMV (LC nSIMV) and leak synchronized nasal SIMV (LS nSIMV) in order to prevent complications associated with invasive mechanical ventilation in preterm infants with RDS since there are limited and conflicting data about use of NIV methods in infants with RDS.

Highlights

- The adverse effects of invasive mechanical ventilation in infants are known, especially premature babies with respiratory distress syndrome.
- Considering patient-ventilator compatibility in premature infants, providing non-invasive ventilation is extremely important for patient comfort.
- In patients diagnosed with respiratory distress, it would be more appropriate to prefer non-invasive ventilation method with leak synchronization to leak-compensated method.

Material and Method

Approval of Erciyes University Faculty of Medicine Ethics Committee was obtained for this study (date:19.06.2015, number:2015/303), and the informed consent form was filled out by parents and their consents were obtained. Our study was supported by Scientific Research Projects unit of Erciyes University by project code TSG-2015-5873.

This prospective and randomized study included 50 preterm infants (25 per group) with gestational age below 34 weeks and/or body weight below 2000 grams who were admitted because of RSD and connected to a mechanic ventilator after consents of the parents; infants were randomly assigned to LC nSIMV and LS nSIMV groups. Exclusion Criteria were congenital heart disease, respiratory and nervous system malformation and nasopharyngeal pathology (coanal atresia and cleft palate-lip), and major congenital/chromosomal abnormality. Surfactan was administered to preterm infants enrolled due to RDS. Before extubation, intravenous caffeine was started in all patients according to our clinic's protocol, and noninvasive respiratory support was provided using short binasal prongs. LC nSIMV ventilation support was performed through Nellcor Puritan Bennett™ 840 Ventilatory System; LS nSIMV ventilator support was provided by Nellcor Puritan Bennett™ 980 Ventilatory System. Blood gas parameters, SPO_2/FiO_2 (S/F) rate, peak heart rate of the patients, respiration count per minute and duration for separation from mechanical ventilator at 1st hour following extubation and at 4 to 6-hour intervals were recorded. Maternal variables, delivery type, antenatal steroid use, gestational age, birth weight, gender, extubation failure and the status of premature babies in terms of common comorbid problems such as PDA, IVH, ROP, BPD, Pneumothorax, and NEC were followed. Reintubation criteria included respiratory acidosis in the blood gas (pH <7.25, PCO_2> 60 mm Hg); frequent apnea (<100/min heart rate along with respiratory arrest for >10 sec or >20 sec), FiO>0.6 to preserve SpO_2 at 90% to 95% and occurrence of frequent desaturation.

Statistical Analysis

Statistical analyses were performed by SPSS ver 22.0. Shapiro-Wilk test was used to review if data distributed normally; values were expressed in mean±standard deviation. Chi-square test was used for comparison of categorical data. In comparison of LC NSIMV and LS NSIMV groups, the difference between dependent samples was determined by paired t sample test. Any p value below 0.05 ($p<0.05$) was accepted as statistically significant. Statistical analysis between repeated measurements was done by repeated measure method.

Results

24 (48%) females and 26 (52%) males were enrolled in the study. There was not any statistically significant difference between LCnSIMV and LSnSIMV groups for gender, postnatal age and birth weight (**Table 1**). There was not any statistically significant difference between LCnSIMV and LSnSIMV groups for APGAR score minutes 1 and 5 (**Table 1**). There was detected statistically significant difference between LCnSIMV and LSnSIMV groups for non-invasive ventilation period and re-intubation rate (p=0.04 and p=0.03, respectively) (**Table 1**).

Table 1.
Demographic characteristics and primary neonatal outcomes between groups

Demographic characteristics and primary neonatal outcomes	Groups		p value
	LC nSIMV	LS nSIMV	
Gestational age, weeks	29.6±1.8	29.4±1.7	0.72
Birth weight, g	1355±220	1370±231	0.96
Cesarean section, n (%)	12 (48)	13 (52)	0.83
Male gender, n (%)	14 (56)	15 (60)	0.92
Antenatal steroid, n (%)	8 (32)	9 (36)	0.79
APGAR score minute 1	6.8±1.5	7.3±1.5	0.65
APGAR score minute 5	8.6±0.7	8.7±0.9	0.98
NIV period, hours	48.1±10	40.2±8.1	0.04
Re-intubation, n (%)	5 (20)	2 (8)	0.03

NIV: Non-invasive ventilation, LC nSIMV: Leak compensated nasal SIMV, LS nSIMV: Leak synchronized nasal SIMV

There was detected statistically significant difference between LCnSIMV and LSnSIMV groups for SpO_2 and S/F rates at 60 minutes (p=0.03 and p=0.01, respectively) (**Table 2**). There was not any statistically significant difference between LCnSIMV and LSnSIMV groups for respiratory rate per minute, heart rate and PCO_2 (**Table 2**).

Table 2.
Clinical and laboratory data in NIV process

Variables	Time			
	Min. 15	Min. 30	Min. 60	Hour 6
SpO_2	91.5±1.2	92.7±1.5	95.6±0.8	94.3±0.7
	90.6±1.4	92.3±1.3	93.0±0.5	94.2±0.4
p value	0.41	0.64	0.03	0.1
S/F rate	240±7	258±5.4	276±6.9	290±5.3
	236±6	255±4.6	260±7.2	288±4.4
p value	0.74	0.56	0.01	0.1
RRM	50.4±2.2	48±1.5	44±1.1	40.2±1.2
(/min)	50.1±2.0	48.3±0.9	43.6±1.0	41.3±0.8
p value	0.82	0.87	0.59	0.63
HR	146±5	140±6	135±4	131±3
(/min)	144±4	141±5	136±3	130±4
p value	0.54	0.58	0.61	0.47
PCO_2			40±5	40±4
(mmHg)	-	-	40±4	39±4
p value			0.52	0.18

* Upper line LS nSIMV, lower line LC nSIMV, S/F rate: Saturation / FiO_2 rate, RRM: Respiratory rate per minute, HR: Heart rate

There was not any statistically significant difference between LCnSIMV and LSnSIMV groups for pneumothorax, patent ductus arteriosus, intraventricular bleeding, necrotizing enterocolitis, prematurity retinopathy, bronchopulmonary dysplasia rates and hospitalization periods (**Table 3**).

Table 3.
Evaluation of groups for secondary neonatal outcomes

Secondary neonatal outcomes	Groups		p value
	LC nSIMV	LS nSIMV	
Pneumothorax, n (%)	2 (8)	1 (4)	0.12
Patent ductus arteriosus, n (%)	1 (4)	2 (8)	0.18
Intraventricular bleeding, n (%)	3 (12)	4 (16)	0.36
Necrotizing enterocolitis, n (%)	2 (8)	1 (4)	0.15
Prematurity retinopathy, n (%)	2 (8)	3 (12)	0.27
Bronchopulmonary dysplasia, n (%)	3 (12)	2 (8)	0.46
Hospitalization period	41.2±4.2	40.5±4.6	0.59

LC nSIMV: Leak compensated nasal SIMV, LS nSIMV: Leak synchronized nasal SIMV

Discussion

Our study is the first study evaluating the effectiveness of LC nSIMV and LS nSIMV modes in preterm babies with RDS.

Gas leakage is inevitable in non-invasive positive pressure ventilation when compared to invasive positive pressure ventilation. The space between the mask/cannula and nose and/or mouth is the main factor of air leakage. NIPPV (Nasal Intermittent Positive Pressure Ventilation) is a non-invasive ventilation method which has similar effects with invasive ventilation with pressures applied in addition to CPAP (Continious Positive Airway Pressure). NIPPV facilitates ventilation (CO_2 excretion) and oxygenization. It may be synchronized or non-synchronized. Mechanical ventilators providing effective synchronization using flow sensors are not very common and difficult due to large leaks during CPAP, and it is not clear whether unsynchronized NIPPV is effective. Synchronized NIPPV may reduce extubation failure if delivered via a ventilator rather than a two-stage CPAP device, but may not provide long-term benefits such as reduction in BPD.[6,7] In our study, we compared leak compensation and leak synchronization in patients with RDS. Our results revealed the importance of leak synchronization of which we have shown the superiority for patient compliance.

When compared with NIPPV and CPAP in the initial treatment of RDS; NIPPV appears to be superior to CPAP in terms of the need for intubation and reducing the rate of respiratory failure. Many studies indicating the superiority of NIPPV to other NIV methods performed synchronization. When synchronized NIPPV and CPAP are compared, it was emphasized that synchronized NIPPV is superior to CPAP in terms of extubation failure, need for oxygen support, and the risk of BPD development.[8-10] It was emphasized in a meta-analysis on avoiding endotracheal intubation for protection from BPD that this strategy has significantly lower mortality and BPD (p=0.01).[11,12] In our study, high-level mechanical ventilators were used as the mechanical ventilation mode in which the compensation and synchronization features of the NSIMV mode were tested in non-invasive ventilation. We did not detect any difference between groups for BPD which is one of the secondary diseases when compared with the study conducted by Jasani et al.[8] This may be explained with limited number of patients.

The results of the meta-analysis investigating whether synchronization is a necessary factor in premature infants indicated that synchronized CMV (Continuous mandatory ventilation) NIPPV is more beneficial in terms of extubation failure. Furthermore, small clinical studies have emphasized that although it has been observed to reduce the symptoms of prematurity apnea in infants treated with sNIPPV, there is little evidence of the effect of synchronization on important outcomes such as BPD and mortality.[13] Another study evaluating the effect of synchronization of NCPAP vs NIMV (Non-invasive Mechanic Ventilation) vs S-NIMV (Infant Star 950; Infrasonics, Inc., San Diego, CA) in clinically stable premature infants showed that groups were similar for ventilation and gas exchange; however, synchronized nasal ventilation has a positive effect on ventilation effort.[14] Another recent meta-analysis including 10 studies and 1061 preterm infants reported that although a significant decrease was found in respiratory failure and intubation need with NIPPV, there was not any significant decrease in the development of chronic lung disease, BPD, and further studies were needed.[15] Positive effect of synchronization was also demonstrated in our study with clinical parameters. However, in parallel with the cochrane database, no positive effect was found in terms of BPD development. An important study comparing the leak compensation in pediatric NIV simulation through 7 top-quality ventilators (Maquet Servo-i, Drager V500, Drager Carina, Covidien PB840, Respironics V60, Respironics Vision, GE Healthcare/Engstrom Carestation, CareFusion Avea, Hamilton C3, Hamilton G5) stated that compensations of ventilators would change depending on patient weights and pulmonary mechanics. PB840 and C3 have compensation rates of over 90% on all body weights, whole lung mechanics

profiles and all leak levels; however, although PB840 and C3 show better triggering and compensation than other ventilators, the clinical significance of these differences is uncertain.[16] Although the compensation of Covidien PB840 that we have used in our study was good, more positive results were obtained in terms of patient compliance with Covidien PB980 synchronization in the other study group.

The main limitation of our study was limited number of patients in groups. Studies with larger numbers of patients comparing noninvasive compensation and synchronization in preterm babies are needed.

Conclusion

Consequently, in consideration of the positive effect on clinical parameters in patients with RDS who need noninvasive ventilation in the pre-extubation period and patient-ventilator compliance, we believe that it would be more appropriate to prefer the LS nSIMV method to the LC nSIMV method.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

Conflict of Interest: The authors have no conflict of interest to declare.

Ethics Committee Approval: Ethical approval of Erciyes University Faculty of Medicine Ethics Committee was obtained for this study (date:19.06.2015, number:2015/303).

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Informed Consent: Informed consent form was filled out by parents and their consents were obtained.

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