Original article

An addition of tidal volume (volume guarantee) to synchronised intermittent mandatory ventilation in neonates with respiratory distress syndrome – A randomised controlled trial

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Abstract

Background: Volume guarantee is a synchronised mode with time-cycled, pressure-limited ventilation, developed to maintain minimal preset mechanical tidal volume. **Objective**: To compare the effects of synchronised intermittent mandatory ventilation plus volume guarantee (SIMV+VG) with conventional synchronised intermittent mandatory ventilation (SIMV) in preterm neonates with respiratory distress syndrome (RDS). **Method:** This prospective study included preterm neonates admitted in Neonatal Intensive Care Unit (NICU) from October, 2010 to March, 2011. A total of 28 neonates were randomised in the study with the SIMV and SIMV+VG during initial ventilation and weaning phase. The outcome measures were to compare peak inspiratory pressure (PIP), mean airway pressure (MAP), oxygenation (PaO_2/FiO_2) and ventilation in both the groups. **Result:** During the initial ventilation, the oxygenation (based on PaO_2/FiO_2 ratio) was considerably better in the SIMV+VG (285.6±154) as compared to the SIMV group (156.8±92.9) and it was statistically significant (p=0.025).The compliance in SIMV+VG group was higher than SIMV group but it did not reach statistically significant difference. During the weaning phase, the SIMV+VG group showed hypocarbia (33 mm Hg) whereas the SIMV group showed normocarbia (44 mm Hg); (p=0.025). The compliance was better in the SIMV+VG (2.7 ± 1.8 mL/mbar) as compared to the SIMV (0.7 ± 0.6 mL/mbar). This was statistically significant (p value=0.042). **Conclusion:** The SIMV+VG is relatively better for weaning from ventilatory support and it enhances the spontaneous respiratory effort.

Keywords: Respiratory distress syndrome, synchronised intermittent mandatory ventilation, volume guarantee, preterm, weaning.

Introduction

The Respiratory Distress Syndrome (RDS) is the most common cause of respiratory distress in premature infants, correlating with structural and functional lung maturity. The RDS is a dynamic condition where the underlying pathophysiology keeps constantly changing, either as a part of the natural progression or in response to the treatment. Therefore, it is necessary to match the therapy to changing disease status. Monitoring the pulmonary mechanics and waveforms enables the detection of events such as hyperinflation and air trapping. [1]

The ventilator dependent neonate varies from minute to minute because of the spontaneous inspiratory effort and sudden change in respiratory compliance and resistance associated with breath holding and

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active expiration. The volume guarantee (VG) option available on the (Dräger Babylog 8000 plus - Dräger Medical Inc., Lübeck, Germany) ventilator is the most widely used and most extensively studied type of volume guarantee ventilation. In VG, the inspiratory pressure is regulated in response to the change in lung compliance and patient effort using exhaled tidal volume measurements.

During VG ventilation, the ventilator adjusts the peak inflation pressure within the set limits to achieve a target tidal volume ($V_{Ttarget}$). A guaranteed volume is aimed at stabilising the minute volume and reducing the volutrauma and atelectrauma.[2] Despite increased acceptance of VG, there is limited data to guide the clinician in selecting the optimal settings in this unique group of infants. The selection of optimal volume is critical in ensuring the success of all volume guarantee modes of mechanical ventilation.[3] In this study, an attempt has been made to compare the effect of SIMV+VG with conventional SIMV during weaning in preterm neonates with RDS.

Methodology

This prospective, randomised study included preterm neonates admitted in Neonatal Intensive Care Unit (NICU) with RDS that required ventilator support. Approval was obtained from the Institutional Ethics Committee.

The inclusion criteria were clinical and radiographic evidence of respiratory distress syndrome in preterm neonates, need for mechanical ventilation and surfactant replacement therapy. Preterm neonates with congenital anomalies, perinatal asphyxia, sepsis, endotracheal tube leak > 60% of the inspiratory tidal volume and those requiring reintubation were excluded from the study.

Drager Babylog 8000 plus is a pneumatically and electrically powered infant ventilator which can be used as a pressure or flow controlled ventilator. Mandatory breaths are volume or time triggered, pressure or flow limited and time cycled. Continuous flow is available for spontaneous breathing. Alternatively, the spontaneous breaths can be volume triggered, pressure limited and flow cycled.[4] This ventilator has volume guarantee as an addition to the synchronised mode. Calibration before initiation as per the manufacturer's guidelines was done before initiation. The ventilator parameters used during SIMV and SIMV+VG included peak inspiratory pressure (PIP), positive end expiratory pressure (PEEP), inspiratory time (Ti), expiratory time (T_e), respiratory rate (RR) and flow rate. The guaranteed tidal volume was initially set at 4-6mL/kg.

Neonates were randomly allocated to one of two groups. Group 1 was preterm neonates ventilated with SIMV and Group 2 was preterm neonates ventilated with SIMV+VG. Randomisation was done by lottery method using cards in a sealed box. Unknown to clinical investigators, the cards were picked up for a neonate to assign to either of two groups. The ventilator parameters were monitored periodically and decision to suspend VG was made if any unforeseen side effect was observed during the period.

The outcome measure was to compare the effects of SIMV and SIMV+VG based on the following parameters: mean airway pressure (MAP), minute ventilation ($\dot{V}_E$), oxygenation (PaO_2/FiO_2), ($PaCO_2$) carbon dioxide elimination oxygenation index (OI) and lung compliance (C_L). Descriptive statistics were used to define the patient population and the respiratory variables. Independent t-test was used to locate the association between SIMV and SIMV+VG. Data were analysed using SPSS 16, SPSS, Chicago, Illinois for windows V.15, p value <0.05 was considered statistically significant.

Results

A total of 32 preterm neonates were eligible during the six months period from October 2010 to March 2011, of which 28 were included. Out of four excluded neonates, two neonates were switched to other modes of ventilation and the other two neonates had endotracheal tube leak > 60 % (*Figure 1*).

The demographic data of neonates included in the study is presented in (*Table 1*). The mean gestation

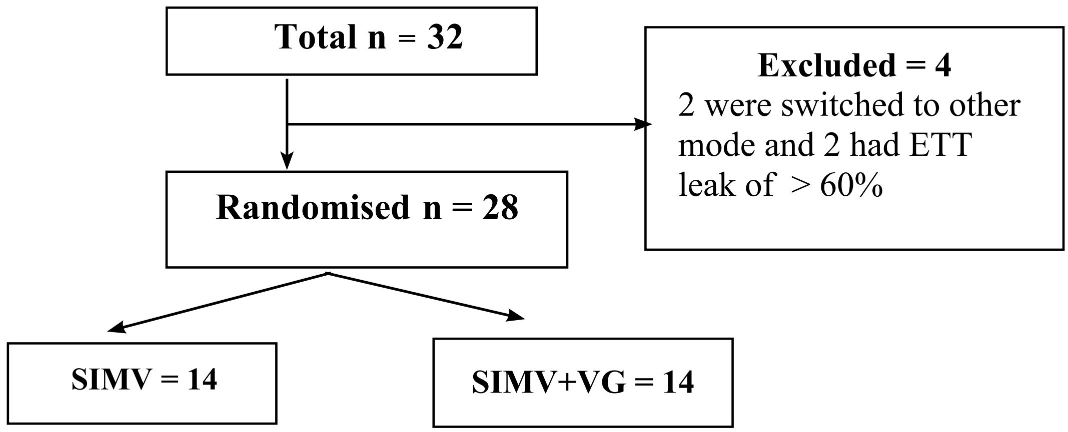

Figure 1: Consort statement of the study

and weight were not different in both groups. A total of 10 out of 14 neonates required surfactant in SIMV group and 11 out of 14 in SIMV+VG group.

In the first six hours of ventilation, the maximum pressure requirement was 20 cm H_2O in SIMV group and 18 cm H_2O in SIMV+VG group. Mean baseline spontaneous respiratory rate was 34 breaths/min in SIMV group and 36 breaths per minute in SIMV+VG group. Mean airway pressure was 9.9 cm H_2O in SIMV group and 8.8 cm H_2O in SIMV+VG group. Compliance in SIMV+VG group was higher than SIMV group but there was no significant difference. Comparison of parameters such as peak inspiratory pressure, mean airway pressure, compliance and respiratory rate in the first six hours of ventilation has been listed in (*Table 2*). Oxygenation index was 9.4 in SIMV and 5.6 in SIMV + VG.

Table 1: Baseline characteristics of neonates and surfactant requirement

Variable	**SIMV n = 14**	**SIMV+VG n = 14**
Birth weight (g) (Mean ± SD)	1524 ± 39.0	1389 ± 36.7
Gestational age (weeks) (Mean ± SD)	31.0 ± 2.8	31.9 ± 2.3
Gender - Male: Female (n)	10 : 4	11 : 3
Surfactant requirement (n)	10	11

During the first six hours of ventilation, oxygenation (based on PaO_2/FiO_2 ratio) was considerably better in SIMV+VG group (285.6 ± 154) compared to SIMV group (156.8 ± 92.9) and it was statistically significant (p=0.025). Oxygenation index was 9.4 ± 7.4 in SIMV group and 5.6 ± 5.0 in SIMV+VG group and this showed no significant difference. The partial pressure of carbon dioxide in SIMV group was 36.5 ± 8.4 mmHg and 35.2 ± 8.4 mmHg in SIMV+VG group. This also showed no significant difference *(Figure 2)*.

During weaning phase, as shown in *Table 3*, the pressure requirement was 15 ± 1.2 cm H_2O in SIMV and 15.5 ± 2.01 cm of H_2O in SIMV+VG. There was no significant difference in the mean airway

Table 2: Comparison of peak inspiratory pressure, mean airway pressure, compliance and respiratory rate during the first six hours of ventilation

	SIMV (Mean ± SD)	**SIMV+VG (Mean ± SD)**
Peak inspiratory pressure [PIP] (cm H_2O)	20.3 ± 3.5	18.6 ± 3.2
Mean airway pressure [MAP] (mbar)	9.9 ± 1.4	8.8 ± 2.0
Compliance (mL/mbar)	0.8 ± 0.7	1.26 ± 1.06
Respiratory rate [RR] (breaths/ min)	34 ± 8.0	36.0 ± 5.4

Independent t-test

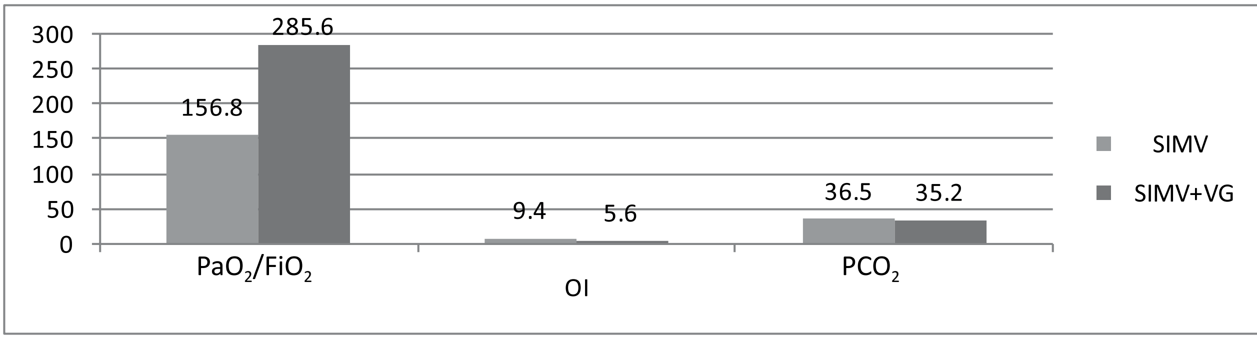

Figure 2: Effect on Oxygenation (PaO_2/ FiO_2), Oxygenation Index (OI) and ventilation ($PaCO_2$) during first six hours of ventilation.

pressure. The mean spontaneous respiratory rate was equal in both the groups (35 ± 4.3 breaths/min in SIMV and 36 ± 6.3 breaths/min in SIMV+VG). The spontaneous tidal volumes in both groups were 6 mL/kg. The PaO_2/FiO_2 ratio was (276 ± 126) in SIMV group and (274 ± 113) in SIMV+VG group and there was no significant difference. The oxygenation index (OI) was 4 ± 2.9 in SIMV group and 3 ± 0.7 in SIMV+VG group. There was better compliance in SIMV+VG as compared to SIMV during weaning phase (0.7 ± 0.6 mL/mbar in SIMV and 2.7 ± 1.8 mL/mbar in SIMV+VG) which was statistically significant (P = 0.042).

Discussion

The present study was aimed at analysing the addition of tidal volume (VG mode) with a synchronised mode of ventilation to support faster weaning and attain spontaneous effort in preterm neonates with respiratory distress syndrome. Limited information is available to guide the clinician's choice of tidal volume setting in volume targeted modes, especially in extremely low birth weight (ELBW) infants, who often remained ventilator dependent for many weeks. Although there is general consensus that a tidal volume of 4-5 mL/kg is an appropriate starting point for VG, there is no systematic attempt to determine these values. Hence they remained optimal as the underlying pulmonary condition evolves. Weaning infants from mechanical ventilation has always been inexact science with no consensus regarding optimal strategies even when the standard pressure-limited modes are used. In general, weaning has been accomplished by lowering inspiratory pressure and allowing infant's own effort to gradually take over the work of breathing. With improved lung compliance and spontaneous respiratory effort, the infant is able to maintain adequate tidal volume and minute ventilation as the inspiratory pressure is reduced.[5] The study published by Herrera showed that short term use (60 minute interval) of SIMV+VG resulted in automatic weaning of the mechanical support. Nine infants have been studied for two consecutive 60-min intervals in a crossover trial. A short term use of SIMV+VG resulted in automatic reduction of the mechanical support and enhancement of spontaneous respiratory effort. Although they found

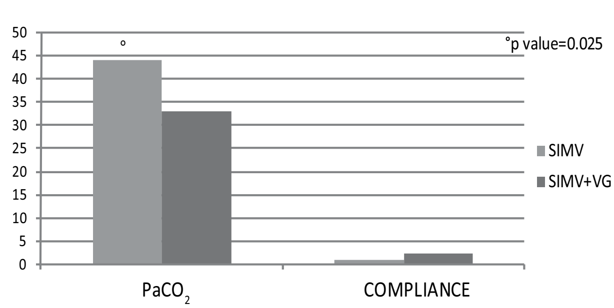

Figure 3: Ventilation and compliance during weaning phase

Table 3: Effect on weaning phase

Parameters	SIMV (n = 14)	SIMV+VG (n = 14)
Peak inspiratory pressure (PIP) in mbar	15.1 ± 1.2	15.5±2.01
Mean airway pressure (MAP) in mbar	7.84 ± 1.09	7.63 ± 2.2
Tidal volume spontaneous ($V_{T\ spont}$) in mL/kg	6.5 ± 2	6.3 ± 1.8
Respiratory rate (RR) in breaths/min	35.07 ±4.3	36.6 ± 3.6

Independent t-test

relatively no change in compared to SIMV alone.[6] A Cochrane review of volume guarantee versus pressure targeted ventilation showed a significant reduction in the duration of ventilation[7]. In present study, long term use (12 hours) of SIMV+VG and SIMV was compared. Both the modes helped in weaning from mechanical ventilatory support. However, the duration of weaning was less in SIMV+VG as compared to SIMV.

Keszler M [8,9] studied automatic weaning of peak inspiratory pressure in response to changing lung compliance and respiratory effort[8,9]. More consistent tidal volume, fewer excessively large breaths, lower peak pressure, less hypocapnea shorter duration of mechanical ventilation and lower levels of inflammatory cytokines have been documented.

When SIMV-volume guarantee was compared with the SIMV mode of ventilation, initially and subsequently during weaning phase in neonates with respiratory distress syndrome, there was better oxygenation and higher compliance noted in SIMV+VG as compared to SIMV alone. However, maximum inspiratory pressure, mean airway pressure and breath rate characteristics, as oxygenation and ventilation during weaning phase.

Another trial by Cheema and colleagues evaluated initial arterial blood gases in infants with RDS shortly after they were placed on SIMV ventilation *versus* SIMV+VC.[10] Stratified analysis revealed that infants >25 weeks gestation had significantly less hypocarbia when volume guarantee was used (27% vs 61%,p<0.05). In this study also, it has been shown that the addition of the volume guarantee to SIMV compared to SIMV alone could result in hypocarbia. There was statistically significant difference in carbon dioxide levels between the modes (p=0.0247). A larger study would be required to confirm these findings.

Conclusion

SIMV+VG mode is relatively better for weaning from ventilatory support and it enhances spontaneous respiratory effort. Better compliance has been observed during the weaning phase. An optimal guarantee tidal volume of 4-6 mL/kg can be initiated if the VG is used.

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