Oxygen Delivery Using a Neonatal Self-inflating Resuscitation Bag: Effect of Oxygen Flow

WHAT’S KNOWN ON THIS SUBJECT: Excess tissue oxygenation should be avoided during neonatal resuscitation, especially in premature infants. Delivered oxygen concentrations when using a self-inflating bag (SIB) at oxygen flows <1 L/min remain to be established.

WHAT THIS STUDY ADDS: Low oxygen concentrations (30%–40%) can be delivered with a SIB at an oxygen flow <1 L/min. A practical scheme has been developed correlating the oxygen flow rate and the corresponding delivered fraction of oxygen when using a neonatal SIB.

abstract

OBJECTIVE: We evaluated the effect of oxygen (O2) flow rate on the corresponding delivered fraction of oxygen (FiO2) during positive pressure ventilation (PPV) when using a neonatal self-inflating bag (SIB).

METHODS: Fifteen health care professionals administered PPV at a respiratory rate of 40 to 60 breaths per minute and at peak inspiratory pressures of 25 and 35 cm H2O to a manikin by using a SIB with reservoir connected to an O2 source equipped with a flowmeter (flow rates: 0–10 L/min). The FiO2 corresponding to each flow rate was measured at the inflow to the facial mask for 60 seconds.

RESULTS: In total, 2520 FiO2 data points were collected. At every O2 flow rate, the FiO2 gradually increased from time 0 seconds to time 60 seconds, both at 25 cm H2O and at 35 cm H2O. After 1 minute of PPV at 25 cm H2O, the delivered FiO2 was 31.5% ± 2.1% and 43.1% ± 3.1% at O2 flow rates of 0.1 and 0.5 L/min, respectively. After 1 minute of PPV at 35 cm H2O, the delivered FiO2 was 29.4% ± 2.0% and 42.1% ± 4.6% at O2 flow rates of 0.1 and 0.5 L/min, respectively. At all O2 flow rates >5 L/min, the delivered FiO2 was >85% and >95%, after 1 minute of PPV at 25 and 35 cm H2O, respectively.

CONCLUSIONS: Delivered FiO2 during PPV depends on 3 factors: oxygen flow rate, peak inspiratory pressures, and time elapsed. These data can be used to develop a scheme correlating the oxygen flow rate and the corresponding delivered FiO2 when using a neonatal SIB.

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KEY WORDS: fraction of oxygen, neonatal resuscitation, oxygen flow rate, positive pressure ventilation, self-inflating bag

ABBREVIATIONS:

FiO2—fraction of oxygen
O2—oxygen
PIP—peak inspiratory pressures
PPV—positive pressure ventilation
SIB—self-inflating bag

Dr Trevisanuto designed the study, participated in the interpretation of data, and participated in drafting the manuscript; Dr Dal Cengio collected the data and participated in drafting the manuscript; Dr Dogliioni participated in the collection and interpretation of data and the drafting of the manuscript; Mr Cavallin participated in the analysis and interpretation of data; Dr Zanardo participated in the concept, design, and interpretation of data; Dr Parotto participated in the design of the study, interpretation of the data, and drafting of the manuscript; Dr Weiner participated in the concept, design, and manuscript preparation; and all authors are responsible for the reported research, have revised the manuscript, and have approved the manuscript as submitted.

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Effective PPV is the most important single intervention in neonatal resuscitation. PPV can be achieved with a flow-inflating bag, a self-inflating bag (SIB), or a T-piece mechanical device. Although an SIB may not be the ideal device for neonatal resuscitation, given the inability to deliver positive end expiratory pressure, it is commonly used in both high- and low-resource countries. Despite this limitation, the ability to titrate oxygen delivery with an SIB is still necessary. SIBs do not require a compressed gas source. When attached to a pure oxygen source, the fraction of oxygen (FiO₂) at the mask depends on the amount of admixture between the oxygen in-flow and ambient air drawn into the bag. This design allows the opportunity to adjust the mask FiO₂ by simply adjusting the inflow rate of oxygen without requiring a separate blender and compressed air. The most recent international guidelines for neonatal resuscitation recommend beginning resuscitation with air rather than 100% oxygen (O₂) in term infants and with an FiO₂ between 30% to 90% in preterm infants with gestational age <32 weeks. Administration of supplemental O₂ should be regulated by blending O₂ and air, and the concentration delivered should be guided by oximetry. Pulse oximeters are portable, relatively inexpensive, and widely available even in resource-limited settings. Compressed air and blenders, however, are not available in many neonatal resuscitation settings in both high- and low-resource countries. This limits the ability to control the administered FiO₂. On the basis of the most recent recommendations, this may result in suboptimal care, especially when low FiO₂ is needed.

It is known that when using an SIB (with reservoir) supplied with an O₂ flow of 5 to 10 L/min the FiO₂ delivered to the patients corresponds to ~90% to 100%. The oxygen concentration delivered when using an SIB without a reservoir has been suggested to be ~40%; however, recent studies have shown that oxygen concentrations are higher than previously suggested at pressure ranges recommended by international guidelines. In these studies, O₂ flow ranged from 1 to 10 L/min and the measurement of delivered FiO₂ was made after 1 minute of ventilation. The FiO₂ obtained by using an unaltered SIB supplied with low O₂ flow rates (<1 L/min) remains to be established. Furthermore, the actual FiO₂ reached with a SIB supplied with O₂ during the first minute of PPV has not been previously assessed.

From a practical point of view, the ability to use a well-defined oxygen flow-FiO₂ relationship with an SIB may become an essential tool for clinicians in settings without compressed air and blenders.

In this bench study, we aimed to construct a scheme correlating the O₂ flow rate and the corresponding delivered FiO₂ when using a neonatal SIB under conditions simulating real-world mask resuscitation.

**METHODS**

Institutional review board approval was obtained. The study was conducted at the Department of Woman and Child Health, Azienda Ospedaliera, University of Padova, Italy.

**Subjects**

Health care professionals involved in neonatal resuscitation, skilled in the use of the SIB, were invited to participate in the study.

**Study Design**

This bench study was conducted on a full-term manikin model (Laerdal ALS Baby Trainer, Laerdal Medical, Stavanger, Norway). Each participant was required to administer PPV to the manikin using an SIB with a 300 mL capacity (Ambu, Mark IV Baby Resuscitator, Glen Burnie, MD) connected to an O₂ source equipped with a flowmeter (Flowmeter, Levate, Italy). The flowmeter was marked at 0.1 L/min increments between 0 L/min and 1 L/min and 0.5 L/min increments from 1 L/min to 10 L/min. The SIB was equipped with the supplied reservoir. Before any procedures, the SIB was visually inspected for any defects, connections were tightened, and performance was tested according to the manufacturer’s recommendations to ensure proper functioning of the valve systems.

Participants were asked to ventilate the manikin at a rate between 40 and 60 breaths per minute following the rhythm (breath . . . two . . . three . . . breath . . . two . . . three) as reported in the *Textbook of Neonatal Resuscitation*. Ventilation was administered at a peak inspiratory pressure (PIP) of 25 or 35 cm H₂O, in a randomized order. PIP was measured in a continuous fashion by means of a manometer (Mallinckrodt Medical, Athlone, Ireland) connected to the SIB allowing constant monitoring by the participant.

Each participant was asked to ventilate the manikin for 1 minute at each of the following flow rates: 0.1, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 L/min. The sequence of flow rates for each participant was chosen in a randomized fashion (closed, opaque envelops). Participants were blinded to the delivered flow rate as well as the corresponding FiO₂. These parameters were set and manually recorded by 2 of the authors (VDC and ND). The author setting the flow rate was blinded to the corresponding...
measured FiO₂, and vice versa. FiO₂ was measured using an oximeter (Oxygen Analyzer, Criterion Oxichek, Respirronics, Herrsching, Germany) positioned between the facial mask and the SIB. On the basis of the user’s manual, the linearity error is <3% of reading, and the response time is <5 seconds to 90% of the final value. The instrument was calibrated before recording data with 21% and 100% oxygen.

To reproduce a real-world clinical scenario, the steps in the procedure were as follows: (1) open the O₂ flow at the randomized rate, (2) wait 15 seconds, (3) position the facial mask (Infant Face Mask, size 2, GE Medical Systems, Buc, France) on the manikin, and (4) start PPV at the preselected parameters (PIP at 25 or 35 cm H₂O). FiO₂ values were recorded at the time of the first administered breath and after 10, 20, 30, 40, 50, 60 seconds. Each trial lasted 1 minute. After each 1-minute trial of PPV at a specific O₂ flow rate, the system was allowed to return to the baseline FiO₂ of 21%.

Statistics
Continuous data are expressed as mean ± SD. The coefficient of variation (CV) of FiO₂ values was calculated for each combination of time and flow rate, using the formula for small or moderately sized sample.

RESULTS
Fifteen health-care professionals participated in the study. All the trials were completed. In total, 2520 FiO₂ data points were collected. The summary of FiO₂ values with a PIP of 25 cm H₂O and 35 cm H₂O at the different time points are shown in Tables 1 and 2, respectively. At every O₂ flow rate, the FiO₂ gradually increased from time 0 seconds to time 60 seconds, both at 25 cm H₂O and at 35 cm H₂O (Tables 1 and 2).

After 1 minute of PPV at 25 cm H₂O, FiO₂ values were 31.5% ± 2.1% and 43.1% ± 3.1% at O₂ flow rates of 0.1 and 0.5 L/min, respectively. After 1 minute of PPV at 35 cm H₂O, FiO₂ values were 29.4% ± 2.0% and 42.1% ± 4.6% at O₂ flow rates of 0.1 and 0.5 L/min, respectively. At all O₂ flow rates >5 L/min, FiO₂ values were >85% and >95%, after 1 minute of PPV at 25 and 35 cm H₂O, respectively (Tables 1 and 2).

Figures 1 and 2 show the FiO₂ values obtained at different O₂ flow rates (range 0–10 L/min) over time during PPV at a respiratory rate of 40 to 60 per minute and PIP of 25 and 35 cm H₂O, respectively. At a PIP of 25 cm H₂O, the CV had a maximum of 0.280 and a minimum of 0.004, whereas at a PIP of 35 cm H₂O the maximum was equal to 0.260 and the minimum to 0.012.

DISCUSSION
Our study shows the relationship between O₂ flow rate and delivered FiO₂ over time during PPV with a neonatal SIB and reservoir. The delivered FiO₂ depends on 3 factors: O₂ flow rate, PIP, and time elapsed. These results allow the construction of a simple scheme showing the actual FiO₂ delivered with variable O₂ flow at a given time (Figs 1 and 2). Such a scheme may represent a useful and inexpensive tool for neonatal resuscitation when a compressed air source and blender are not available. Effective PPV is of utmost importance during neonatal resuscitation.1,3,5 Two meta-analyses comparing neonatal resuscitation initiated with room air versus 100% O₂ showed increased

<table>
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<tr>
<th>TABLE 1</th>
<th>FiO₂ Values Obtained at Different Oxygen Flow Rates (Range 0–10 L/min) Over Time During PPV at a Respiration Rate of 40 to 60 per Minute and PIP of 25 cm H₂O</th>
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<tbody>
<tr>
<td>Flow rate (L/min)</td>
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<td>Time (s)</td>
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<td>0.1</td>
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Data expressed as mean ± SD.

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<th>FiO₂ Values Obtained at Different Oxygen Flow Rates (Range 0–10 L/min) Over Time During PPV at a Respiration Rate of 40 to 60 per Minute and PIP of 35 cm H₂O</th>
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survival when resuscitation was initiated with air.\textsuperscript{12,13} There are no studies in term infants comparing outcomes when resuscitations are initiated with \( \text{FiO}_2 \) other than 100% or room air.\textsuperscript{1} One study in preterm infants showed that initiation of resuscitation with a blend of \( \text{O}_2 \) and air resulted in less hypoxemia or hyperoxia, as defined by the investigators, than when resuscitation was initiated with air or 100% \( \text{O}_2 \).\textsuperscript{14} Current guidelines recommend starting PPV with 21\% \( \text{FiO}_2 \) for term infants and 30\% to 90\% \( \text{FiO}_2 \) for infants delivered \(<32 \text{ weeks’ gestation}. The guidelines recommend adjusting the \( \text{FiO}_2 \) based on pulse oximetry.\textsuperscript{4} Two previous surveys have shown that the SIB is the most commonly used device for PPV in the newborn.\textsuperscript{15,16} For this reason, it is important to have the ability to adjust the \( \text{FiO}_2 \) across a wide range when using an SIB. Unfortunately, in many areas where newborns are resuscitated, pulse oximetry is available, but compressed air and oxygen blenders are not.\textsuperscript{4,7,8} A low-cost and easy-to-use scheme for adjusting the \( \text{FiO}_2 \) when using an SIB without a blender may play a key role in these settings. A source of oxygen and a flowmeter capable of accurately delivering flow between 0.1 to 8 L/min would be required.

Other bench studies have attempted to examine this question.\textsuperscript{9–11} These investigators measured the ventilating \( \text{FiO}_2 \) in a closed system, with the reservoir removed, and varied the oxygen flow between 1 and 10 L/min. Although using a closed system may result in a more precise \( \text{FiO}_2 \) measurement, our study was specifically designed to reflect actual clinical practice by ventilating a manikin with a face-mask and an intact SIB. Similar to our results, these investigators found that the delivered oxygen concentration exceeded 60\% within 1 minute using a flow rate >1 L/min. On the basis of these studies, it appeared that adjusting the oxygen flow rate had little effect on the delivered \( \text{FiO}_2 \). The current study, however, shows that by using lower oxygen flows (0.1 to 1 L/min), resuscitators can achieve a clinically relevant range of \( \text{FiO}_2 \) without requiring compressed air and a blender. We found that the delivered \( \text{FiO}_2 \) was 30\% to 40\% at flow rates of 0.1 and 0.5 L/min. These \( \text{FiO}_2 \) values corresponded to those reported by Reise et al when using a blender (\( \text{FiO}_2 \) 40\%) at flow rates ranging from 1 to 10 L/min.\textsuperscript{11} When compressed air and a blender are not available, the resuscitator can adjust the effective \( \text{FiO}_2 \) from 21\% to 85\% or 95\% by using a low-flowmeter and simply adjusting the oxygen flow progressively from 0 L/min (“off”) to 5 L/min as needed based on pulse oximetry.
On the basis of statements in the *Textbook of Neonatal Resuscitation* it would be expected that previous investigators would have found a lower FiO2 at similar flow rates because they removed the reservoir from the SIB. Interestingly, there was little difference in the delivered FiO2 between our study and previous studies when the flow rate exceeded 1 L/min. This suggests that the reservoir has no effect on the delivered FiO2 probably because the tidal volume used for a neonate is so low that the residual volume in the bag itself maintains the FiO2 and does not need the reservoir. The same findings were demonstrated by Reise et al, who conducted the same experiment with and without a reservoir.

This study raises additional questions about the time required to achieve high concentrations of oxygen. The *Textbook of Neonatal Resuscitation* states that an FiO2 of 90% to 100% is administered during PPV with a SIB, when using an O2 flow rate of 5 to 10 L/min. This is confirmed by our findings, but this FiO2 is reached only after 30 seconds of constant flow rate and PPV at high PIP values (35 cm H2O). When PPV is administered at a PIP of 25 cm H2O, the maximal FiO2 is 90% and this is reached after 60 seconds of ventilation. During the first 30 seconds of PPV, the delivered FiO2 never reaches high concentrations even at high O2 flow rates. This has important implications for providers evaluating the efficacy of assisted ventilation. We need to keep in mind that the FiO2 reaching the patient at the initiation of ventilation may be considerably lower than expected. Based on these data, we might speculate that infants randomized to resuscitation with 100% O2 in recent milestone clinical trials could have actually received significantly lower, but nonetheless potentially harmful, FiO2. If seen in light of these considerations, our findings appear to confirm that effective PPV instead of FiO2 is the major determinant of successful neonatal resuscitation and further support the recommendation to use room air during initial PPV.

There are some limitations to our study that must be considered in the interpretation of these results. This study was conducted with a manikin model in a laboratory setting. We chose to use an “open” system by ventilating the manikin with a face mask compared with previous studies that used a more controlled “closed” system with an endotracheal tube and test lung. This may have decreased the precision of our FiO2 measurements but more accurately reflects clinical practice in real-world conditions. We tested only 1 manufacturer’s neonatal SIB. Other neonatal SIB models and sizes could have different performance characteristics, including the administered FiO2. On the basis of our clinical practice and textbook recommendations, we chose PIP values of 25 and 35 cmH2O for this study. It would be reasonable to expect a different FiO2 if a different target PIP is used. The target PIP was achieved by participants guided by a manometer. This well represents clinical practice, but a mechanical system, such as an automatic piston, could more constantly and precisely maintain the target PIP. FiO2 values were only recorded during the first 60 seconds of ventilation. Although previous investigators, using higher flow rates, found that FiO2 stabilized after 60 seconds, it is possible that FiO2 would have continued to increase with the lower flows used in the current study.

**CONCLUSIONS**

In this study, we evaluated the relationship between O2 flow rate and delivered FiO2 over time during PPV with a neonatal SIB. Our data show that the delivered FiO2 depends on 3 factors: O2 flow rate, PIP, and time elapsed. These data can be used to develop a scheme correlating the oxygen flow rate and the corresponding delivered FiO2. The provider can adjust the effective FiO2 from 21% to 85% to 95% by using a low-flowmeter and simply adjusting the oxygen flow progressively from 0 L/min ("off") to 5 L/min as needed based on pulse oximetry. This scheme may be a useful and inexpensive tool for neonatal resuscitation when a compressed air source and blender are not available.

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