

The Self-Inflating Resuscitation Bag Delivers High Oxygen Concentrations When Used Without a Reservoir: Implications for Neonatal Resuscitation

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OBJECTIVE: To measure the delivered fractional oxygen concentration (F_{DO_2}) from preterm-size Laerdal silicone resuscitators (PLSR) without a reservoir. **BACKGROUND:** The North American Neonatal Resuscitation Program manual states that self-inflating bags without a reservoir deliver approximately 40% oxygen, differing from the PLSR manufacturer's specifications. **METHODS:** A neonatal test lung was manually ventilated using PLSRs *without* a reservoir. A 50 psi 100% oxygen source and an oxygen flow meter were used to provide desired oxygen inlet flows. F_{DO_2} was measured using 3 different PLSRs after 4 min of manual ventilation of a neonatal test lung, at differing inspired tidal volumes (5 mL or 20 mL), respiratory rates (40 breaths/min or 60 breaths/min), and oxygen inlet flows (1 to 4, 5, and 10 L/min). **RESULTS:** In all tests using 5 or 10 L/min, F_{DO_2} exceeded 0.95. The lowest F_{DO_2} was 0.59, at 1 L/min. **CONCLUSIONS:** The F_{DO_2} measured during this study did not differ from PLSR specifications. The F_{DO_2} did, however, differ from information contained in the North American Neonatal Resuscitation Program manual regarding use of a self-inflating bag without a reservoir. Care should be taken when selecting a self-inflating resuscitation device to provide blended air and oxygen, as high concentrations of oxygen may be delivered by these devices even when the reservoir is removed. American and Canadian recommendations for the provision of supplemental oxygen with self-inflating bags require reevaluation. *Key words:* infant-preterm, infant-newborn, resuscitator, F_{DO_2} , neonatal resuscitation, positive-pressure ventilation, oxygen, blender. [Respir Care 2009;54(12):1665–1670. © 2009 Daedalus Enterprises]

Introduction

The recent paradigm shift toward the acceptability of “room air” for the initial resuscitation of newly born babies, followed by “supplemental” oxygen if required, has led to a reexamination of methods of providing positive-pressure ventilation across the world.

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Ms Johnston and Dr Aziz have disclosed a relationship with the Canadian Neonatal Resuscitation Program. Dr Aziz has disclosed a relationship with the Laerdal Foundation, Stavanger, Norway.

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The North American Neonatal Resuscitation Program is the recommended educational tool for North American health-care providers who are required to care for newly born babies.¹ The program endorses 3 devices for providing positive-pressure ventilation: the T-piece resuscitator, the flow-inflating bag, and the self-inflating bag. The first 2 devices require a pressurized gas source to operate, making blended gases essential for the provision of air and

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supplemental oxygen less than 100%. However, the North American Neonatal Resuscitation Program provider manual states that the self-inflating resuscitator can deliver air when no gas source is connected; and when connected to a 100% oxygen source, using a recommended flow of 5–10 L/min into the inlet of the self-inflating bag, it is stated that the self-inflating bag can deliver 80–100% ox-

Table 1. Manufacturer's Observed Delivered Oxygen Concentrations, Using a Preterm Ventilation Bag* and a Tidal Volume of 20 mL

Oxygen Flow (L/min)	Fraction of Delivered Oxygen (%)			
	At 40 breaths/min		At 60 breaths/min	
	With Reservoir	Without Reservoir	With Reservoir	Without Reservoir
3	100	98	100	97
8	100	100	100	100
15	100	100	100	100

* 240-mL Laerdal silicone resuscitator
From Reference 6

xygen when a reservoir is attached, and approximately 40% oxygen without the reservoir.²

With the Canadian adaptation of the North American Neonatal Resuscitation Program guidelines recommending that oxygen blending devices be used to deliver a range of fractions of inspired oxygen ($F_{I_{O_2}}$) during resuscitation,³ the self-inflating bag may be seen as an option for health centers or care areas without a high-pressure medical air source. Laerdal (Stavanger, Norway) is the manufacturer of a commonly used self-inflating resuscitator.⁴ IWK Health Centre, in Halifax, Nova Scotia, Canada, uses the 240-mL preterm-size Laerdal silicone resuscitator (PLSR) during neonatal resuscitation in the birth unit and in the neonatal intensive care unit. This size of Laerdal silicone resuscitator was previously referred to as a Laerdal infant resuscitator (LIR).⁵

Table 1 shows the manufacturer's description of the fraction of oxygen delivered (F_{DO_2}) with and without the reservoir at differing oxygen inlet flow rates, ventilation rates, and tidal volumes (V_T). According to the manufacturer's specifications, the F_{DO_2} from the PLSR without a reservoir is 0.97–1.0 when the 100% oxygen inlet flow is 3 L/min or greater.⁶ This differs considerably from the F_{DO_2} of 0.40 described in the North American Neonatal Resuscitation Program textbook.

Reise et al described a bench test where the F_{DO_2} was similar to the oxygen concentration of the inlet gas, whether that be 100% oxygen or 40% oxygen, when the reservoir of the PLSR was removed.⁵ Again, their findings differ from the information found in the North American Neonatal Resuscitation Program manual regarding the oxygen delivery capacity of the self-inflating bag.² Similar data have been reported from other Canadian centers (personal communication, R John Baier MD, Department of Pediatrics, University of Manitoba, Winnipeg, Manitoba, Canada, 2007). Given the identified discrepancy between the North American Neonatal Resuscitation Program text² and the manufacturer's specifications,⁶ there is a need to eval-

uate PLSR with respect to F_{DO_2} . This evaluation would be particularly important in the care of very-low-birth-weight babies who require small V_T and may be at risk from oxygen toxicity.

Objectives

Two objectives were identified for this bench test. The first was to determine the F_{DO_2} from a preterm-size Laerdal resuscitator with the reservoir removed, using a 100% oxygen inlet flow of 5 and 10 L/min under the following conditions:

1. Ventilation with a lung simulator, using a 2.5-mm endotracheal tube (ETT), V_T of 5 mL, and respiratory rates of 40 and 60 breaths/min to simulate ventilation of a preterm baby.

2. Ventilation with a lung simulator, using a 3.5-mm ETT, V_T of 20 mL, and respiratory rates of 40 and 60 breaths/min, to simulate ventilation of a term baby.

The second objective was to determine the F_{DO_2} as the 100% oxygen inlet flow was decreased from 4 L/min to 1 L/min.

Methods

This study was conducted at the IWK Health Centre, Halifax, Nova Scotia, Canada

Three new PLSRs (Laerdal, Stavanger, Norway) were tested. The reservoirs were removed for this bench test. For continuity of test performance, the same person performed each set of tests. Prior to each test, the PLSR was pressure-tested and leak-tested according to the operator's manual.⁶ Each PLSR was tested using the same passive lung simulator (Neonatal Demonstration Lung Model, Ing-Mar Medical, Pittsburgh, Pennsylvania) and oxygen analyzer (INOvent, INO Therapeutics/Datex Ohmeda, Madison, Wisconsin). The oxygen analyzer was calibrated to room air and 100% oxygen before each test.

The PLSR was connected to the passive lung simulator using an ETT (Mallinckrodt, Hazelwood, Missouri). A 2.5-mm inner-diameter ETT was used to simulate ventilation of a preterm baby, and a 3.5 mm inner-diameter ETT to simulate ventilation of a term baby. A standard connector with side port (Portex, Keene, New Hampshire) of the same size as the ETT was used to facilitate the connection to the sample tubing of the INOvent oxygen analyzer in all tests.

Oxygen was connected to the inlet of the PLSR using a standard 6-foot length of oxygen tubing. The oxygen source was a 50 psi 100% oxygen wall outlet and pressure-compensated oxygen flow meter (Ohmeda, Durnlee, Illinois). Flow was verified using a gas flow analyzer (VT Plus, BioTek Instruments, Winooski, Vermont).

Table 2. Using a Self-Inflating Bag Without a Reservoir, and With 100% Oxygen

Series	Target V_T (mL)	V_T Range (mL)	Target Rate (breaths/min)	Rate Range (breaths/min)	Oxygen Inlet Flow (L/min)	Mean F_{DO_2} *			
						At 1 min	At 2 min	At 3 min	At 4 min
1	5	4.8–6.0	40	36–42	5	0.97	0.97	0.98	0.99
2	5	4.5–6.1	60	57–64	5	0.99	0.97	0.97	0.97
3	5	4.8–5.9	40	37–43	10	0.99	0.99	1.00	1.00
4	5	4.4–5.7	60	57–63	10	0.99	0.99	0.99	0.99
5	20	18–22	40	37–44	5	0.98	0.97	0.98	0.98
6	20	19–23	60	57–63	5	0.97	0.96	0.97	0.98
7	20	18–22	40	38–43	10	0.98	0.99	0.99	0.99
8	20	18–23	60	56–64	10	0.97	0.97	0.98	0.98

* $n = 3$ for each test. Maximum standard deviation 0.01.

F_{DO_2} = fraction of delivered oxygen

For the first objective, testing was performed using oxygen flows of 5 and 10 L/min. The neonatal test lung was manually ventilated with the PLSR, and V_T was measured using a new neonatal flow sensor connected to a ventilator (Avea, Viasys Healthcare, Palm Springs, California). Measurement of V_T using a proximally placed pneumotachometer during neonatal ventilation has been shown to be accurate.^{7,8} The ventilator's flow sensor is a hot-wire anemometer capable of detecting flows as low as 0.4 L/min, and has an accuracy of $\pm 10\%$.⁹ There is some evidence that the accuracy of the Avea's flow sensor may be greater than that of other flow sensors currently in use.⁸ The flow sensor was zeroed prior to each test, using the zero-flow sensor feature, software version 3.9A.⁹ Data were collected by a "frame grabber" (VGA2USB, Epiphan Systems, Ottawa, Ontario) connecting the Avea's video output to a laptop computer. The PLSR were tested using combinations of V_T values (5 and 20 mL) and respiratory rates (40 and 60 breaths/min). The lung simulator was manually ventilated with each combination of V_T and respiratory rate for a period of 4 minutes to allow the F_{DO_2} to equilibrate.¹⁰ Inspiratory V_T and respiratory rate were recorded by the VGA2USB frame grabber at intervals of one minute. F_{DO_2} was measured continuously throughout the test. At the end of each minute the F_{DO_2} was recorded.

For the second objective, the following protocol was used. Using the same equipment and the same pre-test calibrations for all equipment, the lung simulator was manually ventilated with each resuscitator at each of the oxygen inlet flows, decreasing from 4 L/min to 1 L/min. The F_{DO_2} was measured at the end of 4 minutes and recorded for each oxygen inlet flow. The data from each test were pooled and the means recorded.

F_{DO_2} at flow rates of 1 to 4 L/min for each scenario were compared using independent measures, two-tailed t-tests using statistical software (Microsoft Office Excel 2003, Redmond, Washington).

Results

The 3 PLSRs performed similarly during testing. In all the tests the oxygen concentration measured by the INO-vent oxygen analyzer did not fluctuate outside of the 3% tolerance specified by the manufacturer.¹¹ Mean F_{DO_2} for the 3 bags in each simulation were slightly lower at the beginning of testing, although clinically insignificant and within the tolerance of the oxygen analyzer (Table 2).

For the first objective, the F_{DO_2} measured in all tests at 5 and 10 L/min exceeded 0.95, with a maximum standard deviation of 0.01 (see Table 2). This was comparable to the specifications listed in the manufacturer's manual (see Table 1), at both 5 and 20 mL V_T and respiratory rates of 40 and 60 breaths/min.⁶

For the second objective, the mean F_{DO_2} measured did not decrease below 0.90 until the oxygen inlet flow was decreased below 2 L/min (Fig. 1). Mean F_{DO_2} at 1 and 2 L/min were significantly lower than at 3 and 4 L/min under most conditions ($P < .05$) (see Fig. 1; Table 3).

Discussion

This bench test is consistent with the manufacturer's description of device function, and indicates that, even at low inlet flows of 100% oxygen (1 L/min), F_{DO_2} is 0.60 or more.

All self-inflating resuscitators must incorporate a gas inlet and reservoir for the provision of supplemental oxygen. The variability of oxygen delivery by these devices has been previously documented^{10,12}; however, information on the effectiveness of resuscitators used in neonatal ventilation is scarce.¹³ Differences in the mechanism controlling the delivery of oxygen during manual ventilation and the position of the gas inlet, air intake valve, and reservoir may contribute to the variability of oxygen delivery with different resuscitators.^{10,12} Therefore, it would

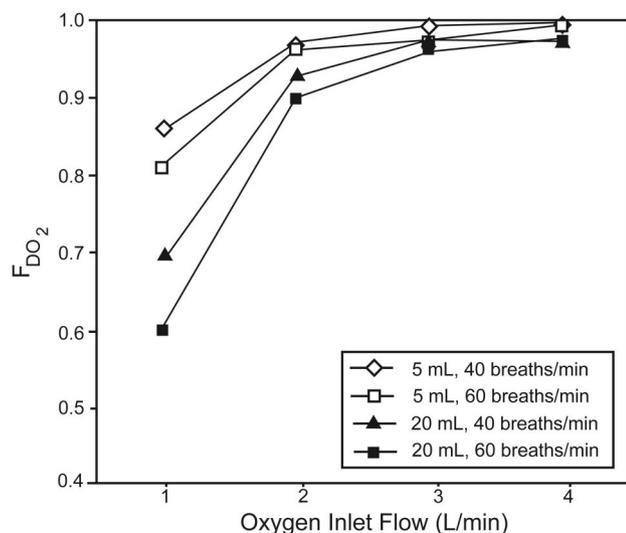


Fig. 1. Mean fraction of delivered oxygen (F_{DO_2}) when oxygen inlet flow is decreased from 4 L/min to 1 L/min, with 3 different self-inflating bags and with 4 different tidal-volume and ventilation-rate scenarios. Mean F_{DO_2} at 1 L/min and 2 L/min differed significantly in each scenario from those at 3 L/min and 4 L/min ($P < .05$).

be difficult to generalize the F_{DO_2} across the various self-inflating resuscitators, with or without the use of the reservoir. However, for any self-inflating resuscitator to deliver a fraction of oxygen of 0.40, a sufficient quantity of room air must be drawn into the resuscitator to provide the 3:1 air:oxygen ratio needed to deliver a fraction of oxygen of 0.40.¹⁴ In the case of the PLSR, the room air would be drawn into the resuscitator through the intake reservoir valve at the bottom of the ventilation bag. This valve allows gas flow into the bag from the inlet gas source and the reservoir, when one is attached. When the oxygen flow through the gas inlet is substantially higher than the minute ventilation required to ventilate the patient, there is little chance that room air will be drawn in through the intake reservoir valve to create a blended air/oxygen mixture. Therefore, a higher fraction of oxygen is delivered to the patient.

V_T of 4–6 mL/kg has been cited for neonatal ventilation, and avoidance of overinflation, hyperventilation, and hyperoxygenation are considered critical in the premature baby.^{15,16} With this low V_T range, the F_{DO_2} approximated 0.99 when using oxygen inlet flows of 5 and 10 L/min, as specified by the North American Neonatal Resuscitation Program, demonstrating that little air was drawn into the resuscitation bag through the intake reservoir valve. The plastic housing distal to the intake reservoir valve has a volume of approximately 40 mL by water displacement. It could be hypothesized that the valve housing creates a small, open-end reservoir that contributes to the high F_{DO_2} when ventilating with very small V_T .

All of the questions surrounding oxygen administration during neonatal resuscitation have not been answered definitively.¹⁷ However, it has been cited that use of oxygen concentrations between room air and 100% can be successfully used to resuscitate newborns and that the use of 100% oxygen may result in adverse sequelae.^{17,18} The use of oxygen blenders to provide variable oxygen concentrations is one option that may allow normal oxygen levels to be achieved more quickly.¹⁸ As well, the North American Neonatal Resuscitation Program provider manual states that blenders should be available for resuscitation of pre-term neonates < 32 weeks gestation in those centers that routinely deliver babies of this gestational age.² The Canadian adaptation of the North American Neonatal Resuscitation Program guidelines is in agreement with this statement.³ Reise et al recommended the use of an air/oxygen blender to ensure accuracy of F_{DO_2} when using a PLSR.⁵ Their data showed that an F_{DO_2} of 0.40 could be delivered using a source gas supply from an air/oxygen blender set at an F_{IO_2} of 0.40. This recommendation would appear appropriate in light of the high oxygen concentrations delivered using a 100% oxygen source without a blender.

Most oxygen blenders require both high-pressure oxygen and medical air sources. If the neonatal resuscitation area is not currently equipped with high-pressure medical air, the cost related to installation is not insignificant. The topic of the pros and cons of oxygen blenders is beyond the scope of this paper. Our concern with regard to the results of this bench test is that clinicians may see the option of providing 40% oxygen via the self-inflating resuscitation bag without a reservoir as a possible alternative to refitting resuscitation areas. We have demonstrated that this is not accurate for the PLSR. As well, the manufacturer's information for oxygen concentration delivered by the PLSR⁶ is in conflict with that stated in the North American Neonatal Resuscitation Program provider manual.² This conflict may result in the unintentional administration of high concentrations of oxygen during neonatal resuscitation.

Despite an increase in the use of other resuscitation devices, such as the T-piece resuscitator, the self-inflating bag remains a widely used resuscitation device. In a 2004 study of resuscitation practices throughout the world, including Canada and the United States, the self-inflating bag was the most popular resuscitation device, with the Laerdal resuscitator being the most popular model.¹⁴ The results of our bench test may affect how clinicians view the oxygen administration ability of this device.

We are unaware of exactly which self-inflating resuscitation devices were tested by the North American Neonatal Resuscitation Program. There are a wide variety of self-inflating infant and premature resuscitators, both reusable and disposable, on the market today. A test of other resuscitators to determine oxygen delivery capacity would

Table 3. Fraction of Delivered Oxygen*

	Fraction of Delivered Oxygen			
	Oxygen Inlet Flow 4 L/min	Oxygen Inlet Flow 3 L/min	Oxygen Inlet Flow 2 L/min	Oxygen Inlet Flow 1 L/min
Target 5 mL (mean 4.9 mL) and 40 breaths/min (mean 38.6 breaths/min)				
F _{DO₂} range	0.98–1.00	0.98–0.99	0.96–0.97	0.80–0.87
F _{DO₂} mean ± SD†	0.99 ± 0.01	0.99 ± 0.01	0.97 ± 0.01	0.86 ± 0.03
Target 5 mL (mean 5.2 mL) and 60 breaths/min (mean 61.3 breaths/min)				
F _{DO₂} range	0.98–0.99	0.96–0.99	0.94–0.98	0.79–0.83
F _{DO₂} mean ± SD‡	0.99 ± 0.01	0.97 ± 0.01	0.96 ± 0.01	0.81 ± 0.02
Target 20 mL (mean 20.8 mL) at 40 breaths/min (mean 40.6 breaths/min)				
F _{DO₂} range	0.97–.98	0.96–0.97	0.92–0.94	0.68–0.73
F _{DO₂} mean ± SD§	0.97 ± 0.01	0.97 ± 0.01	0.93 ± 0.01	0.70 ± 0.02
Target 20 mL (mean 21.1 mL) at 60 breaths/min (mean 59.2 breaths/min)				
F _{DO₂} range	0.97–0.98	0.94–0.97	0.88–0.92	0.59–0.64
F _{DO₂} mean ± SD¶	0.97 ± 0.01	0.96 ± 0.01	0.90 ± 0.02	0.60 ± 0.02

* P values calculated via 2-tailed independent t test, and assuming unequal variances.

† 4 L/min versus 3 L/min, P = .68; 4 L/min versus 2 L/min, P = .02; 4 L/min versus 1 L/min, P = .002; 3 L/min versus 2 L/min, P = .004; 3 L/min versus 1 L/min, P = .003; 2 L/min versus 1 L/min, P = .005.

‡ 4 L/min versus 3 L/min, P = .18; 4 L/min versus 2 L/min, P = .10; 4 L/min versus 1 L/min, P < .001; 3 L/min versus 2 L/min, P = .52; 3 L/min versus 1 L/min, P < .001; 2 L/min versus 1 L/min, P < .001.

§ 4 L/min versus 3 L/min, P = .10; 4 L/min versus 2 L/min, P < .001; 4 L/min versus 1 L/min, P < .001; 3 L/min versus 2 L/min, P < .001; 3 L/min versus 1 L/min, P < .001; 2 L/min versus 1 L/min, P < .001.

¶ 4 L/min versus 3 L/min, P = .18; 4 L/min versus 2 L/min, P = .002; 4 L/min versus 1 L/min, P < .001; 3 L/min versus 2 L/min, P = .002; 3 L/min versus 1 L/min, P < .001; 2 L/min versus 1 L/min, P < .001.

F_{DO₂} = fraction of delivered oxygen

be warranted in light of the new North American Neonatal Resuscitation Program guidelines for oxygen administration during resuscitation. It is important to understand that there are differences in oxygen delivery among the various self-inflating resuscitators or any other device used for positive-pressure ventilation.

Limitations

This bench test did not test factors such as added water vapor and carbon dioxide, both of which may influence F_{DO₂} in vivo. However, this bench test was not constructed to replicate a physiologic state. The purpose of the bench test was to determine the oxygen concentration delivered from the PLSR. This measurement is in keeping with the unit of measurement cited by the North American Neonatal Resuscitation Program and the manufacturer.^{2,6} The addition of exhaled CO₂ and water vapor would certainly reduce the amount of oxygen that is actually available at the alveolar level. Despite this reduction, the alveolar oxygen level (P_{AO₂}) would be significantly higher when 100% oxygen is delivered, as opposed to 40% oxygen.

The modified alveolar air equation is:

$$P_{AO_2} = F_{IO_2}(P_{bar} - P_{H_2O}) - (P_{aCO_2}/R)$$

in which P_{bar} is the barometric pressure, P_{H₂O} is the water vapor pressure at 37°C, and R is the respiratory exchange ratio (CO₂ excretion/oxygen uptake).

Using an F_{DO₂} of 1.0, the P_{AO₂} would be:

$$638 \text{ mm Hg} = 1.0(760 \text{ mm Hg} - 47 \text{ mm Hg}) - (60 \text{ mm Hg}/0.8)$$

Using an F_{DO₂} of 0.40, the P_{AO₂} would be:

$$210 \text{ mm Hg} = 0.40 (760 \text{ mm Hg} - 47 \text{ mm Hg}) - (60 \text{ mm Hg}/0.8)$$

Using the modified alveolar air equation¹³ and a P_{aCO₂} reflecting that of a newborn who exhibited fetal distress in utero,¹⁹ the P_{AO₂} is close to 3 times higher when 100% oxygen is delivered. Physiologic dead space and shunt will further decrease the amount of oxygen that transfers into the pulmonary capillaries; however, these deficiencies

would have to be considerable to impact on the difference in oxygen delivery.

Only one brand of self-inflating resuscitation bag was tested. Because of the popularity of the PLSR and its use in the IWK Health Centre, it was decided to test only this brand. Testing of other types of self-inflating neonatal resuscitators is warranted, in light of the results of this bench test.

Conclusions

This bench test demonstrated a considerable difference between the F_{DO_2} measured during this study and the reference from the North American Neonatal Resuscitation Program provider manual for oxygen delivery from a self-inflating resuscitation bag without a reservoir. Until this issue is resolved for all self-inflating bags, it would be wise to reconsider which device is optimal for the delivery of supplemental oxygen during positive-pressure ventilation in newly born infants, and to be familiar with the manufacturer's specifications for the chosen device.

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