Original article

Graded oxygen delivery using low flow rotameter during positive pressure ventilation using self-inflating bag with a leak - an experimental study

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Abstract

Introduction: Bag-mask ventilation does not always guarantee 100% seal around airway opening and hence delivered fraction of oxygen (FDO_2) may vary. **Aim:** To determine the FDO_2 *via* a standard neonatal self-inflating bag with and without application of leak, without a reservoir bag with flow rates of 0.1, 0.2, 0.4, 0.6, 0.8, 1, 2, 4 and 6 L/min. **Method:** A test lung with a three way rotator to produce 0%, 30%, 50% and 75% leak was connected to a 3.5 mm ID endotracheal tube (ETT) connected to a VBM standard preterm self-inflating bag of 250 mL without a reservoir. The ETT was connected to ENVENTEC oxygen analyser and the bag inlet to a 100% oxygen source. Ventilation was done to a peak pressure of 15-20 cm H_2O, at 40 bpm. FDO_2 was recorded every 30 s, until the difference between two consecutive values was ≤ 1%. **Result:** The change in FDO_2 was maximum when compared between 0.1 L/min and 6 L/min. For all leak percentages, the delivered oxygen showed an increasing trend from 0.1 to 0.6 L/min, a plateau from 0.6 to 1 L/min after which it increased. The change in FDO_2 was different for different flow rates among various leak percentages. The highest delivered oxygen without leak was 56.15 ± 3.45% with 4 L/min flow. The oxygen delivered with 70% leak was considerably lower when compared to values with different leaks with respective flow rates. **Conclusion:** FDO_2 increases with oxygen flow rates greater than 1 L/min. Leak around the mask has no effect of FDO_2. Equilibration of FDO_2 is achieved with in 60-90 s.

Keywords: Oxygen delivery, self-inflating bag, positive pressure ventilation

Introduction

About 10% of infants require certain degree of support to start their breathing, and less than 1% requires comprehensive resuscitation.[1] Ventilation is the key to neonatal resuscitation. Ventilation alone is sufficient in most newborns with no further therapies such as chest compressions or medications required. Data from the 1970s and 1980s suggested that multiple sustained inflations immediately after birth would expand the lungs to functional residual capacity and result in a quicker response, with spontaneous respirations.[1] Effective bag-mask ventilation (BMV) should be carried out at appropriate time in nonvigorous or asphyxiated neonates to prevent hypoxic ischaemic encephalopathy and other harmful effects due to deprivation of oxygen. However, it is also important to monitor the proportion of oxygen delivered *via* self-inflating bag to prevent the toxic effects of oxygen in neonates as they have an underdeveloped antioxidant system. The North American Neonatal

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Resuscitation program manual states that the use of a self-inflating bag without a reservoir during resuscitation, delivers air when no gas source is connected. When connected to 100% oxygen source, it delivers 80% - 100% of oxygen with a reservoir and approximately 40% oxygen without a reservoir. However, Kathy *et al* proved that at any flow within 5-10 L/min, the FDO_2 always exceeded 95% with the minimum FDO_2 being 59% at 1 L/min.[2]

Any leak produced during bag and mask ventilation around the seal is difficult to quantify and it has not been studied if a leak around the airway would alter the oxygen concentration delivered to the neonate. Any discrepancy can be important because of the increased sensitivity of neonate for oxygen as well as in context of resuscitation scenario.

Methodology

This study was conducted in the neonatal intensive care unit (NICU) of Kasturba Medical College, Manipal. The equipment required for this study included a low flow oxygen flow meter (calibrated at a flow scale of 0.1 L/min from 0.1-1 L/min and 1 L/min from 1-10 L/min), a VBM standard preterm self-inflating bag of 250 mL attached to a pressure gauge without using a reservoir, an oxygen tubing, a 3.5 mm ID endotracheal tube (ETT tube) connected to a test lung which has a 3-way rotator to produce leak of 30%, 50% and 70%, ENVITEC oxygen analyser, metronome software to pace the ventilation rate and to record oxygen delivered at 30 second interval. The personnel involved in the study were two observers and the principal investigator. The person who performed manual ventilation trials was blinded to the values on oxygen analyser. The same person performed the ventilations throughout the whole experiment.

The oxygen analyser was calibrated each time before the test to 21% oxygen. The oxygen analyser was placed in between the self-inflating bag and the ETT tube with the test lung. The bag inlet in turn was connected to a 100% oxygen source using the oxygen tubing. Manual ventilation using the self-inflating bag was done, to reach a PIP of 15-20 cmH_2O and at 40 bpm. The analyser recorded the oxygen delivered and the metronome was used to count the 40 breaths to deliver as well as alert the 30 second off-time. The concentration of delivered oxygen (FDO_2) was measured at oxygen flow rates of 0, 0.1, 0.2, 0.4, 0.6, 0.8, 1, 2, 4 and 6 L/min. FDO_2 was recorded every 30 seconds and the trial was terminated when two consecutive values were obtained with a difference ≤ 1%. Each test group was tested four times. The test was done for each flow without a reservoir bag attached. Each test was done without leak and with leaks of 30%, 50% and 70% respectively. The statistical analysis was done using 16.0 version of SPSS and comparison of FDO_2 at different flow rates for each leak percentage was compared using univariate general linear model. The delivered oxygen was expressed in mean (SD) for different flow rates among different leak percentages. The time of equalisation was also expressed in mean (SD).

Results

The study has 36 combinations with different leaks and different flow rates. With each combination repeated four times, there were 144 readings for the whole study.

The test showed that the change in delivered oxygen was maximum when compared between 0.1 L/min and 6 L/min. In general for all leak percentages, the delivered oxygen showed an increasing trend from 0.1 L/min to 0.6 L/min, a plateau from 0.6 L/min to 1 L/min after which there was an increase. The effect of different amounts of leak on the FDO_2 was inconsistent *(Figure 1)*.

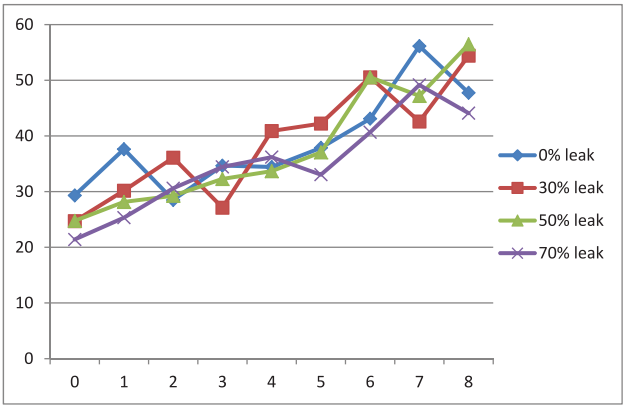

Figure 1: FDO_2 (Mean±SD) with VBM resuscitator with rate of40 breaths/min and a pressure range of 15-20 cm H_2O.

Table 1: FDO_2 (mean± SD) with PIP 15- 20 cm of H_2O and rate 40 breaths/min

Leak (%)	Flow rates (L/min)								
	0.1	0.2	0.4	0.6	0.8	1	2	4	6
0	29.32 (2.39)	37.62 (2.83)	28.54 (0.33)	34.67 (2.32)	34.42 (0.67)	37.87 (1.99)	43.12 (0.45)	56.15 (3.45)	47.75 (4.06)
30	24.72 (0.2)	30.17 (1.92)	36.12 (1.62)	27.12 (2.88)	40.92 (2.75)	42.22 (1.76)	50.55 (3.34)	42.62 (7.58)	54.42 (4.99)
50	24.75 (1.04)	28.15 (2.17)	29.25 (0.64)	32.27 (1.01)	33.67 (2.20)	37.05 (1.43)	50.55 (1.04)	47.23 (5.25)	56.47 (2.80)
70	21.41 (0.21)	25.325 (0.95)	30.60 (1.70)	34.45 (2.64)	36.23 (1.00)	33.05 (2.38)	40.67 (1.35)	49.17 (2.52)	44.12 (3.41)

Table 2: Time to equalisation (s) (mean± SD) for different flow rates and different leaks

Leak (%)	Flow rates (L/min)								
	0.1	0.2	0.4	0.6	0.8	1	2	4	6
0	97.5 (15)	105 (17.32)	82.5 (15)	105 (17.32)	90 (24.49)	90 (0)	105 (51.9)	120 (42.42)	82.5 (28.72)
30	60 (0)	82.5 (15)	120 (42.42)	97.5 (28.72)	112.5 (15)	127.5 (78.89)	135 (51.96)	112.5 (15)	120 (42.42)
50	67.5 (15)	82.5 (15)	75 (17.32)	90 (24.49)	75 (17.32)	82.5 (15)	90 (0)	90 (0)	90 (0)
70	30 (0)	75 (17.32)	105 (51.96)	120 (42.42)	105 (57.44)	82.5 (15)	82.5 (15)	90 (24.49)	82.5 (15)

The highest delivered oxygen without leak was 56.15 ± 3.45% with 4 L/min flow, with 30% leak was 54.42 ± 4.99% with 6 L/min flow, with 50% leak was 56.475 ± 2.80% with 6 L/min flow and with a leak of 70% was 49.17 ± 2.52% with 4 L/min flow. The oxygen delivered with 70% leak was considerably lower when compared to values with different leaks with respective flow rates while the delivered oxygen is inconsistent with leaks of 0%, 30% and 50% until 0.6 L/min *(Figure 1)*.

The time to equalisation took 60 - 90 s (with a frequency of 21.5 and 52.8% respectively) *(Table 2)* showing that there is adequate delivery of oxygen within 2 minutes of bag and mask ventilation

Discussion

Oxygen concentration delivered by self-inflating bag without oxygen reservoir has been shown to vary depending upon bag size, flow rate of oxygen, peak pressure used and ventilation rate while oxygen concentration delivered by blow-by oxygen depends upon flow rate and distance between the distal end of the oxygen-flow tubing and the infant's face. Thio *et al* have shown that an oxygen flow rate of 1–2 L/min for PPV using a 240 mL bag without oxygen reservoir provides oxygen concentration of approximately 30–40%. For a limited-resource setting with no oxygen blender, lower oxygen concentration could probably be obtained by adjusting the oxygen flow using a low-flow meter or a Y connector to mix oxygen with air.[3]

Kathy *et al* proved that when used with neonates, a Laerdal-style self-inflating bag can deliver a very high oxygen concentration, even without a reservoir. They found that with a pre-term-size resuscitator (240 mL) and a test lung set to mimic a low-birth-weight infant, as little as 2 L/min of oxygen into the bag, maintained the fraction of delivered oxygen (FDO_2) at 0.95.[2] They found that delivered oxygen even at low inlet flows of 100% oxygen (1 L/min), FDO_2 is 0.60 or more.[2] The study matched with the manufacturer specifications mentioned. They concluded that even with low flow rates as 1 L/min the Laerdal Infant Resuscitator could deliver high oxygen concentrations without reservoir. They mentioned that discrepancy in oxygen delivery exists between resuscitation devices which caused considerable variation with the delivered oxygen.[2] In this study, VBM resuscitator was used to ventilate and in a leak free scenario, the delivered oxygen did not exceed 65% even with flow rates of 6 L/min, the

highest delivered O_2 being 56.15 ± 3.45% with 4 L/min flow.

Dawson *et al* found that when the mask is held at 5 mm distance from the infant's mouth without squeezing the Laerdal Infant Resuscitator in spontaneously breathing infants, more than 50% oxygen is delivered with flow rates greater than 5 L/min.[5] They concluded that free flow oxygen can be delivered even when the mask is held at a distance of 5 mm from infant mouth with a flow of at least 5 L/min. The mean (range) FiO_2 measured after 30 seconds when the oxygen was delivered at 5 L/min from oxygen tubing held inside a cupped hand at 1, 2, 3, 4 or 5 cm above the mouth, was 96% (90–100%), 85% (68–100%), 79% (51–99%), 69% (50–100%) and 64% (36–98%) respectively. It showed a decrement in delivered oxygen when distance increased from mouth. In our study, delivered oxygen was less with 70% leak when compared to no leak, 30% and 50% leak scenarios in general for different flow rates. The delivered oxygen below flow rates of 1 L/min seems to be not consistent but shows a considerable increase after 2 L/min. The time to equalisation was about 90 s in most cases, which implies that a stable fraction of oxygen was delivered within a considerably short span of time.

The limitations of this study was that only one brand of resuscitation bag was tested with the attached manometer. Testing with the other types of self-inflating bag was not noted. Manual ventilation for a longer time may affect the set rate and FDO_2 due to hand fatigue. This can result in a lower FDO_2. This test was not done with a reservoir bag attached to assess the delivered oxygen.

Conclusion

The highest oxygen delivered during graded oxygen delivery using low flow rotameter during positive pressure ventilation using self-inflating bag in a leak free scenario is 56.15 ± 3.45% with 4 L/min oxygen flow. The delivered oxygen is not consistent among flow rates with different leak percentages. The delivered oxygen is the least with 70% leak among flow rates. The time to equalisation is 60 – 90 s showing adequate delivery of oxygen within 2 minutes of bag and mask ventilation.

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