Oxygen delivery using neonatal self-inflating resuscitation bags without a reservoir

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ABSTRACT

Background Guidelines recommend avoidance of excessive oxygen administration during neonatal resuscitation. Blenders are used in some but not all hospitals. It has been suggested that self-inflating bags without a reservoir deliver around 40% oxygen and could be used to provide an inexpensive and effective technique of avoiding oxygen toxicity.

Objective To explore how much oxygen is delivered when using two different brands of neonatal self-inflating resuscitation bags without a reservoir.

Methods In a benchtop setting, the smallest non-disposable self-inflating bags from the Laerdal and Ambu ranges were tested. Oxygen concentration delivered by these devices under a variety of conditions was measured. 108 combinations of oxygen flow rates (10; 5 to 1 litre/min), ventilation rates (30, 60, 100 inflations/min) and peak inspiratory pressure ranges (20 to 25 cm H_2O, 35 to 40 cm H_2O or pop-off valve range, 55 to 60 cm H_2O) were tested.

Results Delivered oxygen concentration varied depending on three parameters: gas flow rate, ventilatory rate and pressure. At a pressure of 20 to 25 cm H_2O, mean oxygen concentration delivered by both bags exceeded 70% at any gas flow rate except for 1 litre/min (where delivered oxygen concentration was 60% to 70%). When the pop-off valve was opened at 35 to 40 cm H_2O, oxygen concentrations fell to 30% to 45% at gas flow rates $\leq$2 litres/min. The Ambu bag delivered a lower oxygen concentration than the Laerdal bag but this difference was not clinically important.

Conclusion When using the Laerdal and Ambu infant resuscitation self-inflating bags without a reservoir, delivered oxygen concentration is >70% for currently recommended flow and pressure settings.

What is already known on this topic

- Excess tissue oxygenation should be avoided during neonatal resuscitation, especially in the premature infant.
- Delivered oxygen concentration when using a self-inflating bag without a reservoir has been suggested to be approximately 40%.

What this study adds

- Oxygen delivery, when bagging with a self-inflating bag without a reservoir, varies with gas flow rate, ventilatory rate, peak inspiratory pressure and tidal volume.
- In this study, self-inflating bags without a reservoir delivered oxygen at a considerably higher concentration than the previously reported level of 40%.

The use of high concentrations of oxygen for newborn resuscitation may be harmful. ILCOR's 2006 guidelines state that there is growing evidence from both animal and human studies that air is as effective as 100% oxygen for the resuscitation of most infants at birth and that excessive tissue oxygenation should be avoided, especially in the premature infant. However, they did not recommend an optimal initial inspiratory fraction of oxygen (Fio_2).[1] The American Heart Association's 2006 guidelines recommend supplementary oxygen whenever positive-pressure ventilation is indicated for resuscitation.[2] More recently, some international guidelines and experts in the field have recommended the use of air-oxygen blenders to better titrate Fio_2 delivery,[3 4] but these have not been universally implemented.[5–9] Barriers for implementation include the cost and difficulty of changing the delivery room setup and the expense of the blender.[7 8] In the absence of a blender and a dual gas supply, some international guidelines have suggested that by removing the reservoir from self-inflating bags, 40% oxygen may be delivered.[10 11]

In the era when operators aimed to deliver 100% oxygen, studies of self-inflating bags explored whether it was possible to deliver close to this concentration with those devices.[12–15] Investigators reported oxygen concentration at different oxygen gas flows, up to 15 litres/min and described that at lower flows (5 litres/min or less), delivered oxygen concentration could be as low as 40% without the presence of a reservoir. Following from this, international guidelines recommended setting at least 5 litres/min of oxygen gas flow when using self-inflating bags with a reservoir, aiming to deliver oxygen concentrations close to 100%. More recently, some practitioners responded to the air/oxygen debate by attempting to deliver around 40% by using self-inflating bags without a reservoir.[16]

We sought to determine the oxygen concentrations delivered by two manufacturers' self-inflating bags when used without a reservoir under a range of conditions.

MATERIALS AND METHODS

Self-inflating bags

We tested two non-disposable self-inflating bags provided by two different manufacturers

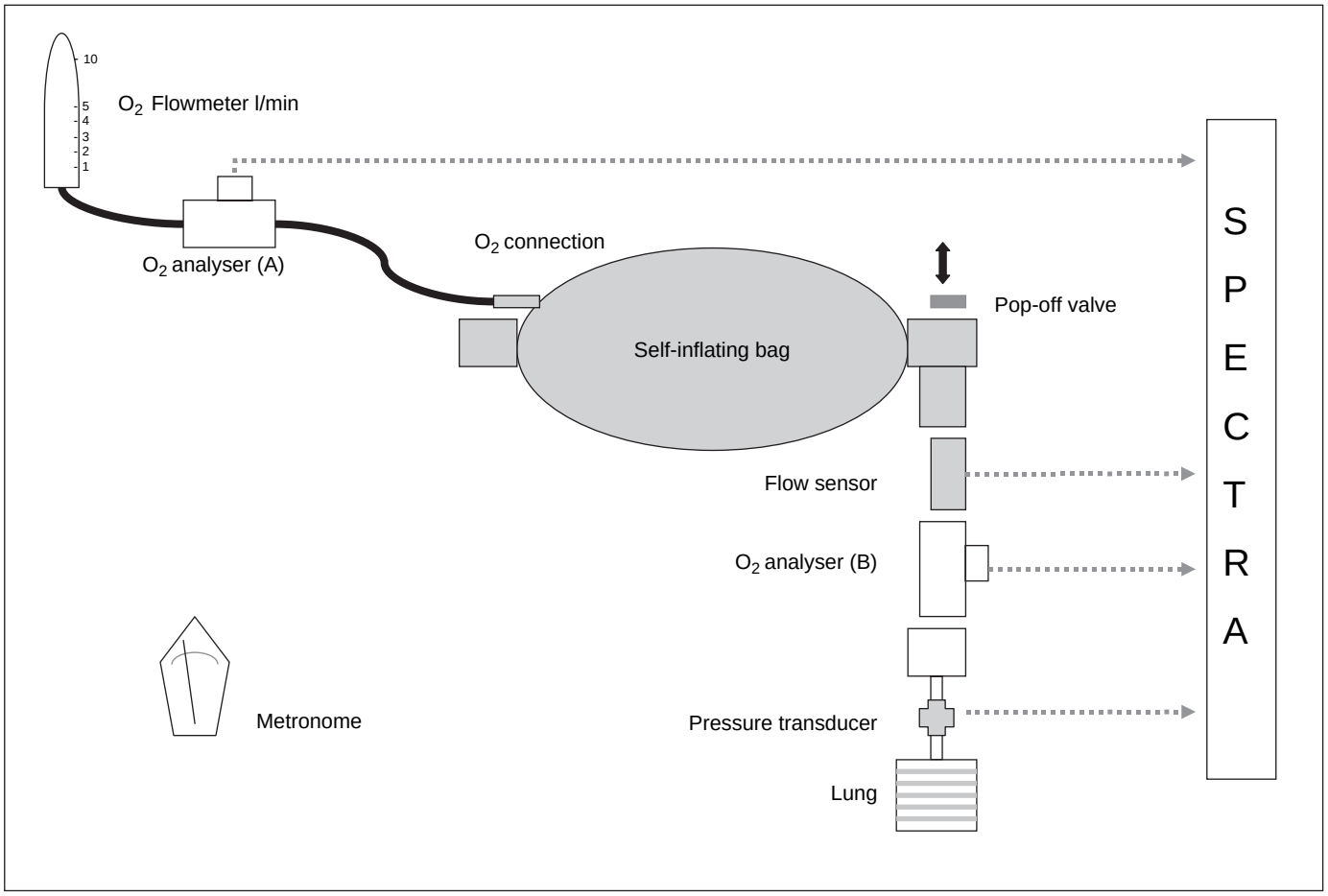

Figure 1 Diagram illustrating the experimental setup.

commonly used during neonatal resuscitation. These were the Laerdal infant resuscitator (LR), with a 240 ml capacity (Laerdal Medical, Stavanger, Norway) and Ambu Mark IV Baby resuscitator (AR) with a 450 ml capacity (Ambu A/S, Ballerup, Denmark).

In vitro experimental conditions were created to assess delivered oxygen concentration with different combinations of oxygen flow rates, pressure ranges and ventilatory rates, when the reservoir was not connected to the self-inflating bags.

Procedure

Both bags were visually inspected for any defects or leaks. Performance was tested according to manufacturer recommendations to ensure that the valve systems were functioning properly. Figure 1 shows a diagram of the experimental circuit.

The bags were connected to the wall pure (100%) oxygen flow source. A laboratory flowmeter (1 to 10 litres/min; Platon, London, UK) was used to verify that the wall source was delivering the set flow. Two oxygen analysers (MX300-I portable oxygen monitor; Teledyne Analytical Instruments, City of Industry, California, USA) were placed to measure oxygen entering the bag and exiting at the patient outlet flow (A and B in fig 1). They were calibrated before recording data with 21% and 100% oxygen. A flow sensor and a pressure transducer were connected to a Florian respiratory function monitor (Acutronic Medical Systems, Zug, Switzerland) and were used to target pressure ranges as well as measure leaks. The flow sensor was calibrated each time it was disconnected. All testing was performed using a 50 ml test lung (Dräger, Lubeck, Germany). This test lung has a compliance of 0.6 ml/cm H_2O and resistance 85 cm H_2O/l/s). Data were recorded using Spectra software (Grove Medical, London, UK) at 200 Hz.

Baseline measurements were made with the reservoir connected to the self inflating bag with the following combination of parameters:

- Oxygen flow: 5 litres/min.
- Ventilation rate: 60 inflations/min.
- Targeted peak inspiratory pressure (PIP): 20 to 25 cm H_2O, 35 to 40 cm H_2O and 55 to 60 cm H_2O.

The reservoir was then removed and the following combinations were tested:

- Oxygen flow: 10, 5, 4, 3, 2 and 1 litre/min.
- Ventilation rates: 30, 60 and 100 inflations/min.
- Targeted PIP: 20 to 25 cm H_2O, 35 to 40 cm H_2O or pop-off valve range, 55 to 60 cm H_2O.

After measuring with the reservoir, these 54 combinations were tested for each bag (from higher to lower flow rates, lower to higher ventilation rates, lower to higher pressures). These measurements were then repeated with the order of combinations reversed. All manoeuvres were performed by a single operator (RB).

During measurements, a metronome was used to pace the rate of manual inflations. The researcher used the pressure displayed on the computer screen to target PIP within the desired ranges. To allow steady state measurements to be reached, each combination was performed for a minimum of 1 min and until oxygen concentration stability was achieved for a period of at least 30 s.

Table 1 Mean (SD) oxygen concentration in the pretest condition (reservoir connected to the self-inflating bag, gas flow rate 5 litres/min, ventilatory rate 60 inflations/min, at each targeted peak inspiratory pressure range)

	Delivered oxygen concentration (%)	
Targeted PIP (cm H_2O)	LR	AR
20–25	99.9 (0.19)	99.3 (0.34)
35–40	99.1 (0.55)	83.7 (0.37)
55–60*	100 (0.8)	100 (0.94)

LR, Laerdal infant resuscitator; AR, Ambu Mark IV Baby resuscitator; PIP, peak inspiratory pressure.
*Pressure limit valve occluded.

Table 2 Median (IQR) delivered peak inspiratory pressure (PIP) and tidal volume at targeted PIP ranges using the Laerdal resuscitator and Ambu resuscitator.

Targeted PIP (cm H_2O)	LR		AR	
	Actual PIP	Vt (ml)	Actual PIP	Vt (ml)
20–25	21.6 (20.6–23.0)	15.0 (14.2–15.9)	21.6 (20.1–23.0)	17.6 (16.5–18.7)
35–40	35.6 (35.1–36.1)	20.9 (20.4–22.3)	36.1 (35.6–37.0)	24.6 (23.4–26.7)
55–60	62.1 (57.8–67.0)	32.5 (30.4–35.3)	58.3 (55.4–60.7)	34.0 (31.4–36.3)

LR, Laerdal infant resuscitator; AR, Ambu Mark IV Baby resuscitator; PIP, peak inspiratory pressure; Vt tidal volume.

Data analysis

Delivered oxygen concentration for each test condition was expressed as mean and SD. PIP and tidal volume (Vt) were expressed as medians with IQR at each targeted pressure and for each self-inflating bag.

A two-sample t test was used to compare mean delivered oxygen concentration, gas flow rate and pressure ranges, for the two devices.

Data were analysed using Stata (Intercooled 10; Stata Corporation, College Station, Texas, USA).

RESULTS

A total of 216 combinations were analysed. When the reservoir was attached to both self-inflating bags, oxygen delivery was 99% to 100%. A difference was seen only in the Ambu resuscitator when the pop-off valve was opened, when the delivered oxygen concentration dropped to 83.7% (SD 0.37) (table 1).

Measured pressure and Vt at each targeted pressure range are displayed in table 2. PIPs were generally within the targeted ranges, but this was more difficult to achieve in the 55- to 60-cm H_2O range.

Figure 2 shows delivered oxygen concentration at targeted pressure ranges. Without the reservoir, mean oxygen delivery was stable once steady state was achieved. This occurred well within the 1-min time specified in the methods. The SDs shown on fig 2A–C are all small, ranging from 0.0% to 1.26%. Delivered oxygen concentration varied depending on all three variables: gas flow rate, ventilatory rate and pressure. At a pressure range of 20 to 25 cm H_2O (fig 2A), the oxygen concentration delivered by both self-inflating bags was >70% at any gas flow rate except 1 litre/min, when it was between 60% and 70% depending on ventilation rate. When the pop-off valve was opened at 35 to 40 cm H_2O (fig 2B), delivered oxygen concentration fell significantly due to leak through the opened valve, particularly at gas flow rates ≤5 litres/min ($p<0.001$). It was only at gas flow rates ≤2 litres/min that oxygen concentration fell to between 30% and 45%. Once the valve was occluded to increase the pressure to 55 to 60 cm H_2O (fig 2C), oxygen concentration increased but did not reach that achieved when bagging at the lowest targeted pressure range. This pattern was observed at all gas flow rates ≤5 litres/min.

The number of recorded observations was high; therefore, when a two-sample t test was used to compare the bags, all differences were statistically significant ($p<0.001$) even when the differences in oxygen concentration were <10%, that is, not clinically important.

DISCUSSION

LR and AR devices differ in bag volume (240 ml in LR vs 450 ml in AR). They were chosen for testing because they are the most popular self-inflating bags currently used internationally.[6 8 14] Although they have different volume capacities, it was possible to accurately target PIPs as per the experimental protocol and, therefore, achieve similar Vt's, as shown in table 1. The difference in delivered oxygen concentration may be explained by their different capacities, the design of the resuscitation device (oxygen inlet connection and valve) and the amount of leak through the pop-off valve. In this benchtop setting, oxygen delivery is influenced by the mixture of oxygen and air entering the bag, the minute volume and leak through the pop-off valve. If oxygen flow is lower than the minute volume plus the leak, the Fio_2 decreases. For example, when oxygen gas flow rate is 1 litre/min, a combination of 20 ml Vt and 60 bpm produces 1200 ml/min (>1 litre of oxygen) and, therefore, oxygen delivery will be <100%. Our results are consistent with the explanation of Diependaele *et al*.[14] This shows why a high flow ≥5 litres/min and a reservoir are needed to deliver an oxygen concentration close to 100%.

Reise *et al* analysed delivered oxygen concentration at gas flow rates of 10, 8, 5, 3 and 1 litre/min, combining them with ventilatory rates of 30, 40 and 60 inflations/min at Vt's of 20 and 40 ml.[17] In our study, we tested the oxygen concentration a baby might receive depending on three targeted pressure ranges and three ventilatory rates, within a comparable gas flow range. Peak pressure ranges and ventilatory rates were chosen to reflect those commonly used and recommended in international guidelines.[18] In addition, we also included a higher rate following our observations from video recordings that operators frequently exceeded recommended ventilation rates during high risk resuscitations. In our study, a Vt of 20 ml was delivered at targeted peak pressures of 20 to 40 cm H_2O, whereas 40 ml could not be achieved even by targeting 55 to 60 cm H_2O. Our results were consistent with those of Reise *et al*, that is, the delivered oxygen concentration falls only when "aggressive" parameters are chosen and oxygen flows are <5 litres/min. Although our Vt are not comparable with those reported by Reise *et al*, oxygen delivery was consistent with their results at ventilation rates of 30 to 60 inflations/min, when pressures of 20 to 25 cm H_2O and 55 to 60 cm H_2O were used. When a rate of 100 inflations/min was tested, we observed a further decrease in oxygen delivery (of more than 10%) only at the lower oxygen flow rates. This occurred with the LR but not with the AR and can be explained by their different volume capacity and the design of the resuscitation device, as previously described.

A Vt <8 ml/kg is considered adequate in the delivery room, at least in preterm infants.[19] Therefore, a PIP of 20 to 25 cm

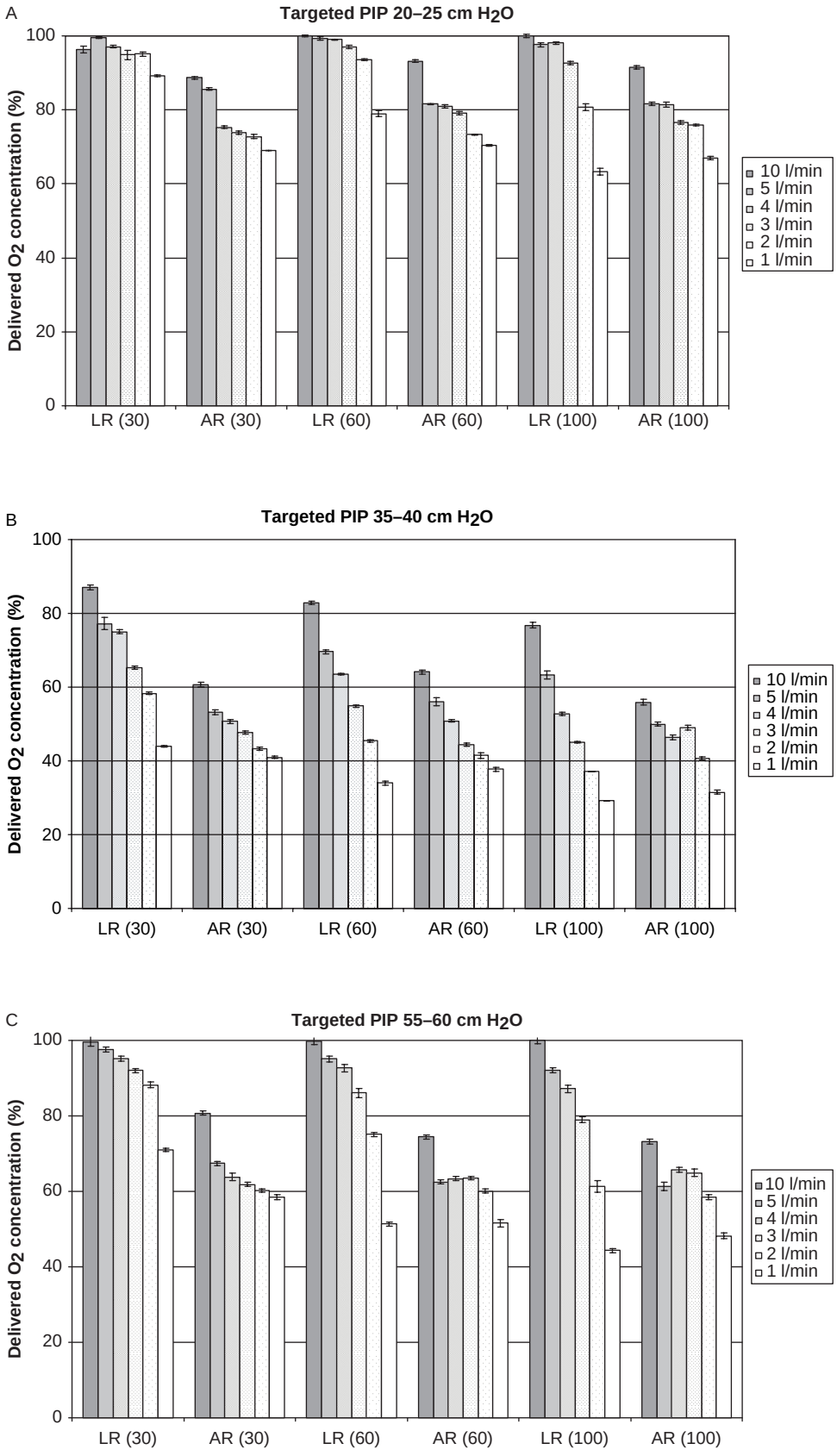

Figure 2 Mean (SD) delivered oxygen concentration at targeted peak inspiratory pressure (PIP) ranges of 20 to 25 cm H_2O (A), 35 to 40 cm H_2O (B) and 55 to 60 cm H_2O (C). Oxygen flow (litre/min) and ventilatory rates (30, 60, 100 inflations/min) are displayed for Laerdal resuscitator (LR) and Ambu resuscitator (AR).

H_2O would be a reasonable target pressure range for a newborn baby needing ventilatory support.[20] Our findings when testing the LR and the AR were consistent with Reise *et al*'s evaluation of the LR. They found that at their lowest Vt (20 ml), the delivered oxygen concentration was at least 70% at all oxygen flows and ventilatory rates.

Our study was designed to reflect clinical practice, using recommended pressures and increasing the PIP to reflect difficult resuscitations. This clinical approach showed that as pressure was increased and the pop-off valve was released (35 to 40 cm H_2O), the delivered oxygen concentration decreased due to leak through the opened valve. When the valve was occluded to increase the pressure to 55 to 60 cm H_2O, oxygen concentration increased again. This explains why our results show lower oxygen concentrations than those of Reise *et al*.

Self-inflating bags may be used without any flow. However, a flow of 5 litres/min is an easy figure to remember and has been widely used in teaching programs for both testing the self-inflating bag and setting the gas flow rate for resuscitation.[10] Following the concerns about oxygen toxicity in the delivery room, this practice needs to be reviewed. A recent systematic review by Saugstad *et al* points out that resuscitation of term or near-term newborn infants with room air seems to be safe. However, the authors recommend that oxygen should be readily available for use in infants who do not respond to initial resuscitative efforts.[21] Saugstad *et al* also points out that extremely low birthweight infants also frequently receive supplemental oxygen in the delivery room. Using typical flow and pressure settings, even if the reservoir is removed from the self-inflating bag, oxygen concentration remains between 80% and 99%. Moreover, even decreasing the flow to 1 litre/min, oxygen concentration remains within a range (70% to 90%) that may be considered harmful. In our study, the only way to provide <50% oxygen using a self-inflating bag with pure oxygen flow was by using pressures and rates which may be excessive and potentially damaging.

CONCLUSION

When using a self-inflating bag connected to a pure oxygen flow source without a reservoir, delivered oxygen concentration remains higher than previously suggested at pressure ranges recommended by international guidelines. The use of a self-inflating bag without a reservoir can no longer be recommended to provide the intermediate range oxygen concentrations now thought to be most appropriate for neonatal resuscitation.

There is a need for the implementation of air-oxygen mixture gas flow in the delivery room to deliver oxygen concentrations <100%. Blenders facilitate accurate and rapid changes in oxygen concentration. Many delivery room settings provide a supply of medical air for maternal use. If clinicians do not have access to a blender but have access to supplies of medical air and oxygen in the resuscitation area, then the use of separate flow meters and a Y-connector may achieve intermediate concentrations of oxygen.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

Contributors M Thió designed the study, carried out the experiments, analysed the data and wrote the manuscript. R Bhatia assisted with the experiments and contributed to the preparation of the manuscript. JA Dawson contributed to study design, statistical analysis and manuscript preparation. PG Davis supervised all stages of the study design, carrying out the experiments and preparation of the manuscript.

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