ORIGINAL ARTICLE

Comparison of three manual ventilation devices using an intubated mannequin

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Objective: To compare three devices for manual neonatal ventilation.
Design: Participants performed a two minute period of ventilation using a self inflating device, an anaesthesia bag with attached manometer, and a Neopuff device. An intubated neonatal mannequin, approximating a 1 kg infant with functional lungs, was used for the study. Target ventilation variables included a rate of 40 breaths per minute, peak inspiratory pressure (PIP) of 20 cm H_2O, and positive end expiratory pressure (PEEP) of 4 cm H_2O. The circuit was attached to a laptop computer for data recording.
Results: Thirty five participants were enrolled, including consultant neonatologists, paediatricians, and anaesthetists, paediatric and anaesthetic registrars, and neonatal nurses. The maximum PIP recorded using the self inflating bag, anaesthetic bag, and Neopuff device were 75.9, 35.5, and 22.4 cm H_2O respectively. There were significant differences between the devices for mean PIP (30.7, 18.1, and 20.1 cm H_2O), mean PEEP (0.2, 2.8, and 4.4 cm H_2O), mean airway pressure (7.6, 8.5, and 10.9 cm H_2O), % total breaths $\leqslant$ 21 cm H_2O PIP (39%, 92%, and 98%), and % total breaths $\geqslant$ 30 cm H_2O PIP (45%, 0, and 0). There was no difference between doctors and allied health professionals for the variables examined.
Conclusion: The anaesthetic bag with manometer and Neopuff device both facilitate accurate and reproducible manual ventilation. Self inflating devices without modifications are not as consistent by comparison and should incorporate a manometer and a PEEP device, particularly when used for resuscitation of very low birthweight infants.

The reported need for positive pressure ventilation in newborn infants has varied from about 2% in the 1970s to 1% in the early 1990s.[1–3] Infants receiving ventilatory support often require brief periods of manual ventilation for reasons including acute deterioration, equipment failure, patient transfer, and clinical assessment.[4] Loss of face mask seal and loss of pressure in the ventilation bag can lead to inadequate resuscitation.[5] Although ventilation is essential for resuscitation, excessive inspiratory pressures can lead to volutrauma, particularly in very low birthweight infants.[6–8] Inadequate positive end expiratory pressure (PEEP) and the resultant inadequate end expiratory lung volume augments lung injury by allowing repetitive expansion and collapse of the terminal airways and alveolar units (atelectrauma).[9]

There are several methods of providing manual ventilation. Self inflating devices are operated by squeezing and releasing a semirigid silicone bag to deliver each breath to the patient. They are portable and easy to use. They usually include a pressure limiting safety valve and can deliver room air without an independent gas flow. Flow dependent anaesthesia bags are squeezed to deliver each breath, and pressure release valves can be attached to limit peak pressures. Their accurate use requires training and skill but they can facilitate both prolonged inspirations and PEEP. The Neopuff (Fisher & Paykel, Auckland, New Zealand) is a flow controlled, pressure limited mechanical device specifically designed for neonatal resuscitation. Breaths are delivered by occluding a T piece. Peak inspiratory pressure (PIP) is preset, and PEEP can be adjusted using the twist valve at the top of the T piece.

The aim of our study was to compare the effectiveness of and consistency in manual ventilation by trained healthcare professionals using three devices: a self inflating bag, a disposable flow dependent anaesthesia bag with attached manometer, and a Neopuff device.

METHODS

Participants were recruited at in-service training days. They included 10 neonatal nurses, 11 consultant paediatricians and anaesthetists, 11 junior and middle grade paediatricians and anaesthetists, an emergency medical technician, a public health physician, and a midwife. A specially developed neonatal mannequin (approximating a 1 kg infant) with an endotracheal tube, functional lungs, and incorporated pressure transducer was used for this study (Fisher & Paykel). Air flow of 5 litres/min was delivered using a portable air compressor. The circuit was connected to an analogue to digital converter. Pressure waves were recorded continuously for each two minute study period on a dedicated laptop computer (Toshiba, USA). Information compiled for each participant included maximum PIP, mean PIP, mean airway pressure, mean PEEP, and ventilation rate.

Three devices were compared: an infant size, silicone, self inflating bag (Laerdal Medical, Stavanger, Norway); a disposable, flow dependent, latex free anaesthesia bag attached to a manometer (Intersurgical, Wokingham, UK); a Neopuff device. The self inflating bag had a pop off valve set to activate at PIPs in excess of 40 cm H_2O. The anaesthetic bag circuit did not incorporate a flow control valve. The operator could control the volume and pressure of the bag by adjusting the egress at the open end of the bag with their thumb and forefinger. The Neopuff settings were preset by each participant before testing. Participants were asked to provide positive pressure ventilation for a period of two minutes with each of the three devices, aiming to achieve 40 breaths per minute, delivering a PIP and PEEP of 20 cm H_2O and 4 cm H_2O respectively. Each operator was able to observe chest movements during ventilation in addition to a

Abbreviations: PEEP, positive end expiratory pressure; PIP, peak inspiratory pressure

Table 1 Summary of data from doctors group

	Self inflating bag			Anaesthetic bag			Neopuff device		
Subject	Max PIP	Mean PIP	Mean PEEP	Max PIP	Mean PIP	Mean PEEP	Max PIP	Mean PIP	Mean PEEP
PCons1	26.9	16.6	0.0	23.1	18.1	3.6	20.4	20.2	4.7
PCons2	49.6	26.9	0.2	22.4	18.3	3.5	21.1	20.9	4.2
PCons3	54.4	40.9	0.3	21.9	18.9	1.6	21.1	20.2	4.2
PCons4	48.6	44.9	0.4	35.5	23.4	3.9	20.1	20.0	4.6
PCons5	35.1	28.8	0.1	20.1	17.7	2.8	20.1	20.1	4.8
PCons6	43.4	32.9	0.1	19.8	18.1	5.5	20.1	20.1	4.6
PCons 7	51.0	48.6	0.5	20.1	19.6	5.3	20.1	20.1	4.6
PReg1	36.7	21.3	0.1	19.8	16.4	2.9	19.7	19.5	3.9
PReg2	75.9	48.7	0.5	25.2	18.7	2.6	20.9	20.6	4.8
PReg3	66.4	50.3	0.0	24.9	17.9	0.5	20.6	20.4	3.8
PReg4	40.6	29.4	0.0	18.6	16.5	2.9	20.3	20.1	5.1
PReg 5	32.5	21.2	0.0	21.8	17.5	3.0	20.4	20.2	4.1
PReg6	20.1	18.5	0.1	23.7	18.7	1.7	20.1	20.1	5.2
PSHO1	55.3	37.5	0.1	29.7	23.7	6.1	22.4	21.9	4.5
PSHO2	29.2	17.5	0.0	17.4	14.2	4.0	19.6	19.2	4.1
PSHO 3	18.5	11.9	0.1	20.6	17.3	2.9	19.8	19.6	4.1
ACons 1	61.7	41.9	0.1	27.5	20.8	2.4	20.6	20.4	4.8
ACons 2	57.2	39.4	0.0	26.4	20.4	2.8	20.5	20.3	4.1
ACons3	39.1	27.3	0.1	19.9	14.5	0.7	20.0	19.8	5.2
ACons 4	41.6	16.5	0.1	24.6	18.4	1.5	20.0	19.8	4.1
AReg1	58.5	40.9	0.1	25.1	20.8	3.8	20.7	20.5	4.2
AReg 2	66.8	48.5	0.3	24.1	18.4	0.3	20.2	20.1	4.1
PHD1	46.3	21.0	0.9	25.4	19.3	3.45	20.9	20.6	5.3

Values were recorded in cm H_2O.
PCons, Paediatric consultant; PReg, paediatric registrar; P SHO, paediatric senior house officer; ACons, anaesthetic consultant; AReg, anaesthetic registrar; PHD, public health doctor.

manometer while using either the anaesthesia bag or the Neopuff. A timer clock was not visible to participants. Candidates were not allowed to view their continuous recordings and were only shown a graphic representation of their performance at the end of the entire assessment.

The data were analysed with analysis of variance and one sample *t* testing using SPSS version 11 for Windows. Data were reported as mean (SEM). For each measured response, a 3 × 2 repeated measures analysis of variance was conducted to investigate the effects of device type (self inflating bag, anaesthetic bag, Neopuff), operator (medical, non-medical), and the interaction between these two factors. One sample *t* tests were performed to investigate if the target PIP, PEEP, and ventilation rates were achieved. Post hoc testing was performed using the Bonferroni test.

RESULTS

Thirty five healthcare workers participated in the study. There were insufficient participants to allow accurate statistical comparison between either individuals or subspecialists. Candidates were therefore designated as either doctors (n = 23) or allied health professionals (n = 12) (tables 1 and 2 respectively). There were no significant differences between the doctors and the allied health professionals ($p > 0.05$) for all variables examined. The maximum PIP values recorded using the self inflating bag, anaesthetic bag, and Neopuff device were 75.9 cm H_2O, 35.5 cm H_2O, and 22.4 cm H_2O respectively. The median value for mean maximum PIP was 46.3 cm H_2O, 22.0 cm H_2O, and 20.2 cm H_2O for the self inflating, anaesthetic, and Neopuff devices. Significant differences were found between the three devices for several variables (table 3).

The self inflating bag produced greater mean and maximum PIP and negligible PEEP values than the anaesthetic bag and Neopuff. Mean PEEP values for the anaesthetic bag were significantly lower than for Neopuff. Mean airway pressure was significantly greater using Neopuff compared with the anaesthetic and self inflating bags.

The recordings of each participant were further analysed to determine how many breaths remained within our target parameter of 20 cm H_2O PIP; 61% of breaths with the self

Table 2 Summary of data from allied health professional group

	Self inflating bag			Anaesthetic bag			Neopuff device		
Subject	Max PIP	Mean PIP	Mean PEEP	Max PIP	Mean PIP	Mean PEEP	Max PIP	Mean PIP	Mean PEEP
NeoNur 1	47.1	41.6	0.1	22.8	19.8	2.5	20.7	20.5	4.2
NeoNur 2	39.9	36.5	0.0	23.1	18.8	2.2	20.4	20.3	3.5
NeoNur3	50.0	31.4	0.0	20.9	17.3	2.3	20.5	19.9	3.5
NeoNur 4	54.5	40.2	0.0	22.1	18.2	3.9	20.6	20.4	4.1
NeoNur 5	50.3	30.1	0.2	18.7	16.8	3.8	20.1	19.8	3.9
NeoNur 6	36.9	24.4	0.1	16.8	12.9	1.5	19.8	19.4	4.2
NeoNur 7	28.3	18.6	0.1	21.4	18.1	4.0	19.8	19.6	3.8
NeoNur 8	27.6	18.8	0.1	19.8	17.1	1.9	19.9	19.5	5.1
NeoNur 9	47.0	13.8	0.1	20.2	16.2	2.4	20.1	19.9	4.6
NeoNur 10	39.4	21.9	0.1	24.7	17.8	4.1	20.3	20.1	4.7
MW1	61.7	41.9	0.1	27.5	20.8	2.4	20.6	20.4	4.7
EMT 1	25.5	21.6	0.1	13.9	10.8	0.7	20.1	20.1	5.2

Values were recorded in cm H_2O.
NeoNur, Neonatal nurse; MW, midwife; EMT, emergency medical technician.

Table 3 Ventilatory variables

Response	Self inflating bag	Anaesthetic bag	Neopuff	p Value
Mean max PIP	44.7 (2.3)	22.6 (0.7)	20.4 (0.5)	<0.001
Mean PIP	30.7 (1.9)	18.1 (0.4)	20.1 (0.1)	<0.001
Mean PEEP	0.15 (0.03)	2.83 (0.23)	4.41 (0.08)	<0.001
Mean airway pressure	7.6 (0.8)*	8.5 (0.3)*	10.9 (0.3)	<0.001
Mean rate	47.1 (3.0)*	47.3 (2.7)*	39.7 (1.8)	<0.05
% total breaths ⩽21 cm H_2O PIP	39 (0.07)	92 (0.02)*	98 (0.02)*	<0.001
% total breaths ⩾30 cm H_2O PIP	45 (0.07)	0 *	0*	<0.001

Values are mean (SEM). Values followed by an asterisk within the same row are not significantly different ($p > 0.05$).
PEEP, Positive end expiratory pressure; PIP, peak inspiratory pressure.

inflating bag exceeded 21 cm H_2O and 45% exceeded 30 cm H_2O, which was significantly different from the anaesthetic bag and Neopuff.

The one sample *t* tests performed for each device showed significant deviations from the set target parameters of PIP and PEEP for both the self inflating and anaesthetic bag devices ($p < 0.001$) and also for target rate ($p < 0.05$). The Neopuff device was more consistent and reliable in its performance by comparison.

DISCUSSION

Recent studies have highlighted the diversity of resuscitation equipment in routine use at maternity hospitals. A UK survey showed the T piece device to be the most popular device for resuscitation, with just 12% of maternity units using a self inflating bag.[10] O'Donnell *et al*,[11] in contrast, report the self inflating bag as the device of choice for most resuscitations in 17 of 29 tertiary hospitals in Australia and New Zealand.

The ability to perform consistent manual ventilation has been shown in this study to be equipment dependent and independent of professional grouping. The Neopuff and anaesthesia bags were comparable in terms of delivery of appropriate PIP and PEEP. Although there was a significant statistical difference between the Neopuff device and anaesthesia bag relating to mean and maximum PIP and mean PEEP, these differences are probably negligible in clinical practice. Self inflating devices without a manometer and possibly a PEEP valve should not be considered as first choice for manual ventilation of very low birthweight infants as they facilitate excessively high PIP and minimal PEEP.

This is the first study, to our knowledge, that compares all three resuscitation devices using an intubated model. Inaccurate face mask application resulting in air leakage is a major reason for failure of infants to respond to bag and mask ventilation at resuscitation.[5] In this study, we used an intubated mannequin to minimise leak complications when using the various devices. Finer *et al*[12] compared the resuscitation performance of 27 healthcare professionals using the Neopuff device, a disposable anaesthesia bag, and Jackson-Rees anaesthesia bag with attached manometers. That study used bag and mask ventilation rather than endotracheal tube ventilation and concluded that Neopuff was superior to both anaesthesia bags. Respiratory therapists were consistently better at delivering PIP and PEEP than the other professional groups studied. Neonatal resuscitation in Ireland and Europe principally involves trained doctors and nurses. Our study did not show any difference between these professional groups, but did show differences between all three devices for several variables.

Appropriate use of an anaesthetic bag is dependent on adequate training and practice with the device, otherwise its advantages are redundant and the device itself potentially dangerous. Mondolfi *et al*[13] described more ventilation failures and less operator confidence when using the anaesthesia bag compared with the self inflating bag in a paediatric emergency department. Kanter[14] also reported technical difficulties with anaesthesia bags resulting in underventilation coupled with a tendency to both overventilate and use excessive pressures with self inflating bags.[14] Advocates of the anaesthesia bag often cite the ability to ''feel'' the changes in lung compliance as an advantage. However, this has not been shown to any reliable extent and is rooted more in anecdote than evidence.[15] What has been shown to enhance ventilation performance with the anaesthesia bag is the attachment of a manometer, allowing more controlled ventilation in terms of peak pressures generated and overall mean airway pressure and thus oxygenation.[16 17] Zmora and Merritt[16] examined manual ventilation of a mannequin by paediatric staff both with and without a manometer. Target inspiratory pressures were achieved by 72% using a manometer in contrast with 18% without.

The appeal of the self inflating resuscitation bag lies in its simplicity of use such that even the most junior staff present can operate the device. However, from several perspectives the self inflating bag is not ideal. Kain *et al*[18] described unrecordable tidal volumes for self inflating bags that would result in clinically significant hypoventilation during actual resuscitation. Different studies by Martel and Soder[19] and Finer *et al*[20] have highlighted the limitations of self inflating devices in terms of oxygen delivery. Although the use of 100% oxygen at resuscitation is now questioned by some, the current Neonatal Resuscitation Programme guidelines still recommend resuscitation with 100% oxygen.[21–24] There is also growing evidence to support the use of prolonged initial ventilations at newborn resuscitation, which can easily be delivered with the Neopuff and anaesthesia bags.[25 26] Self inflating devices may not facilitate as adequate a prolonged inflation as these devices, although our study did not test the ability to provide prolonged individual ventilations with each device.

Anaesthesia bag circuits, by convention, have manometers attached for safety. Self inflating bags have pressure release safety valves set to activate at predetermined pressures. In designing this study, we considered using a manometer with the self inflating bag. Manometer attachment is optional on some self inflating bags but is not in widespread practice to the best of our knowledge. In any event, this study reaffirms the findings of previous studies that the pop off valves are not reliable as the sole pressure limiting mechanism.[21] Use of manometers attached to self inflating bags should therefore be strongly considered for neonatal resuscitation, especially in very low birthweight infants.

The ability to provide a consistent predetermined rate of ventilation has been studied previously.[27] Whyte *et al* described how none of 33 individual resuscitators were able to deliver 40 breaths per minute during a simulated resuscitation, whereas of 18 pairs of rescuers, four achieved 40 breaths per minute. Our results show that, overall, there was no significant deviation from the target rate of 40 per

minute while using the Neopuff device, unlike the other two devices studied.

When designing this study we used an air compressor to generate flow of 5 litres/min, in keeping with Neonatal Resuscitation Programme guidelines.[24] A PEEP of 4 cm H_2O was possible at this flow setting with both the anaesthetic bag and the Neopuff device. Add on PEEP apparatus for self inflating bags are available but are currently not widely used. O'Donnell *et al*[11] reported that only two of 29 tertiary neonatal units used PEEP devices on self inflating bags. In order to reflect clinical practice on the ground, we did not use a PEEP valve adaptation on the self inflating bag in this study.

CONCLUSION

The anaesthetic bag with manometer and Neopuff device both facilitate accurate and reproducible manual ventilation by healthcare professionals, irrespective of professional background. Neonatal resuscitation training programmes should incorporate the Neopuff (or a similar device) or the anaesthesia bag with attached manometer to provide PEEP and controlled PIP. Units using self inflating devices should attach at least a manometer and possibly a PEEP valve mechanism for newborn resuscitation, particularly for very low birthweight infants.

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