Neonatal resuscitation 2: An evaluation of manual ventilation devices and face masks

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Abstract

**Background:** The key to successful neonatal resuscitation is effective ventilation. Little evidence exists to guide clinicians in their choice of manual ventilation device or face mask. The expiratory tidal volume measured at the mask [$V_{TE(mask)}$] is a good estimate of the tidal volume delivered during simulated neonatal resuscitation.

**Aim:** To compare the efficacy of (i) the Laerdal Infant Resuscitator and the Neopuff Infant Resuscitator, used with (ii) round and anatomically shaped masks in a model of neonatal resuscitation.

**Methods:** 34 participants gave positive pressure ventilation to a mannequin at specified pressures with each of the four device-mask combinations. Flow, inspiratory tidal volume at the face mask [$V_{TI(mask)}$], $V_{TE(mask)}$ and airway pressure were recorded. Leak from the mask was calculated from $V_{TI(mask)}$ and $V_{TE(mask)}$.

**Results:** 10,780 inflations were recorded and analysed. Peak inspiratory pressure targets were achieved equally with the Laerdal and Neopuff. Positive end-expiratory pressure was delivered with the Neopuff but not the Laerdal. Despite similar peak pressures, $V_{TE(mask)}$ varied widely. Mask leak was large for each combination of device and mask. There were no differences between the masks.

**Conclusion:** During face mask ventilation of a neonatal resuscitation mannequin there are large leaks around the face mask. Airway pressure is a poor proxy for volume delivered during positive pressure ventilation via a mask.
Background
International consensus statements\textsuperscript{1, 2} and guidelines from various bodies advise how to resuscitate newly born infants.\textsuperscript{3-7} All agree that the key is effective ventilation and recommend giving positive pressure ventilation (PPV) with manual ventilation devices via face masks. Self-inflating bags, flow-inflating bags\textsuperscript{1-7} and T-pieces\textsuperscript{4, 6, 7} are recommended, but a preference for one type of device is not expressed. It is recommended that the face mask used, whether round or anatomically shaped, should have a cushioned rim.\textsuperscript{1-7}

While the manual ventilation devices used to resuscitate newborns vary within countries and worldwide, the Laerdal Infant Resuscitator\textsuperscript{TM} (Laerdal Medical, Victoria, Australia) appears to be the most frequently used.\textsuperscript{8, 9} Though not described in consensus statements, use of a T-piece - the Neopuff Infant Resuscitator\textsuperscript{TM} (Fisher & Paykel Healthcare, Auckland, New Zealand) - appears common.\textsuperscript{8, 9} There is more uniformity in the masks used, a clear preference being shown for round masks.\textsuperscript{8, 9}

There is a dearth of evidence as to which device is superior for resuscitating newborns. The only prospective quasi-randomised trial compared two self-inflating bags.\textsuperscript{10} The few studies of newborns given mask ventilation at delivery reported that tidal volumes sufficient for gas exchange were rarely delivered.\textsuperscript{12, 13, 14} An in-vitro study reported self-inflating bags to be more effective than flow-inflating bags in delivering an adequate minute volume.\textsuperscript{15} A further in-vitro study reported that more consistent airway pressures were delivered with a T-piece than with a flow-inflating bag.\textsuperscript{16}

In the only examination of face masks to date, participants had little or no experience of neonatal resuscitation, a mechanical ventilator was used to give inflations to well, spontaneously breathing infants and leak was not measured.\textsuperscript{16} This study suggested that round masks with a cushioned rim leak less than anatomically shaped masks without a cushioned rim.

We have described a system for measuring the leak from masks and estimating tidal volumes delivered during simulated neonatal resuscitation.\textsuperscript{17} We used this system to evaluate the two ventilation devices and two face masks. The aims of this study were (i) to compare the Laerdal and the Neopuff in terms of operators’ ability to deliver PPV at specified pressures; (ii) to compare the Laerdal and the Neopuff in their ability to deliver tidal volume; (iii) to compare the leak during PPV with a round face mask and an anatomically shaped mask; (iv) to determine whether greater experience of neonatal resuscitation predicted better tidal volume delivery and less mask leak; and (v) to assess whether preference for a manual ventilation device predicted appropriate tidal volumes and low leak with that device.

Materials and Methods

Setting
Staff at the Intensive Care Nursery of the Royal Women’s Hospital were invited to participate. All had completed the hospital’s neonatal resuscitation training program prior to the study. Participants were in four groups: consultants, fellows, residents and neonatal nurses. The experience in neonatology of each participant was recorded. At
completion of the study, each participant was asked to state their preferred device and mask.

**Manual ventilation devices**
The Laerdal Infant Resuscitator™ is a 240 mL silicone self-inflating bag. Though not supplied as standard with this device, manometers are attached at our hospital and operators are encouraged to use them. A manometer was used for this study. The Neopuff is a T-piece device that requires a gas source, which was set at 8L/min for this study, as is standard in our delivery rooms. This device has a manometer built in and a valve on the outlet which allows for a positive end-expiratory pressure (PEEP) to be set for a given flow rate. Occlusion of this valve generates a preset peak inspiratory pressure (PIP). Both of these devices are routinely used at our hospital and all participants were accredited to use both. Flow-inflating bags are not routinely used at our hospital and were not used in this study.

**Face masks**
Each device was used with both a size 0/1 round Laerdal face mask (Laerdal Medical, Oakleigh, Australia) and a size 1 anatomically shaped face mask with a partially air-filled cushioned rim (Intersurgical, Wokingham, UK). We routinely use the Laerdal mask at our hospital. Participants had not used the anatomically shaped mask prior to this study.

**Model**
We modified a Laerdal Resusci Baby™ mannequin (Laerdal Medical, Oakleigh, Australia) by placing a test lung (Dräger, Lubeck, Germany) with a baseline volume of 50 mL in its “thorax”. It was connected via an airtight seal to the mannequin’s “oropharynx”, so that its’ inflation and deflation caused “chest” excursion similar to that of the unaltered mannequin. A pressure monitoring line was connected immediately proximal to the test lung. This system had a compliance of 0.46 mL/cm H2O.

**Recording equipment**
We used the Florian Respiratory Monitor (Acutronic Medical Systems, Zug, Switzerland) to measure pressures and gas flow. This monitor measures airway pressures directly and was calibrated against a column of water. It uses a flow sensor to detect gas flow and calculates the volume of gas passing through the sensor by integration of the flow signal. The volume measurement was calibrated with a fixed volume syringe. The output from the Florian monitor was connected via an analog-digital converter to a computer and acquired using the Spectra software program (Grove Medical, London, UK), a program specifically designed for the acquisition and analysis of respiratory signals.

**Values measured**
The airway pressures delivered were measured directly. The flow sensor from the Florian monitor was placed between each ventilation device and mask. The monitor thus calculated the volume of gas passing from the device through the mask – the inspiratory tidal volume at the mask \([V_{Ti(mask)}]\) – and the volume of gas returning from the mannequin through the mask – the expiratory tidal volume at the mask \([V_{TE(mask)}]\). We have demonstrated that \([V_{TE(mask)}]\) is a good estimate of the tidal volume delivered to the test lung in this model.\(^{17}\) The flow, volume and pressure signals for each
inflation were examined using LabView (National Instruments, Austin TX, USA) software and a program specifically developed by one of the investigators (PAD) for detailed analysis of neonatal respiratory signals.

**Values calculated**
The volume of gas leaking at the mask was determined as a percentage of the inspiratory tidal volume at the mask \[\text{leak (\%)} = (V_{TI(mask)} - V_{TE(mask)})/ V_{TI(mask)} \times 100\].

**Instructions**
Participants gave PPV to the mannequin with combinations of the Laerdal bag, the Neopuff and both masks. The order in which the four combinations were used was allocated randomly. Participants were requested to ventilate the mannequin for 2 minutes with PIP 25 cm H$_2$O, PEEP 5 cm H$_2$O and to ensure adequate chest excursion. The instructions given were the same for each device-mask combination. Participants could not see the flow, volume or pressure traces on the Florian monitor or computer.

**Statistics**
Data were analysed using SPSS, version 11.5 (SPSS Inc. Illinois, USA). Data from participants were averaged for each device and mask combination, yielding data for 136 participant-device-mask combinations. Differences between means were determined by analysis of variance (ANOVA), with the main analyses comparing the 2 devices, the 2 masks, and the 4 participant groups (consultants, fellows, residents and nurses), allowing for all interactions between participant-device-mask combinations. If there were significant differences on overall ANOVA for participant group, data were analysed post hoc by the least significant difference method to determine between which participant groups the significant differences occurred.

Mean differences and 95% confidence intervals (CIs) were calculated where appropriate. P-values < 0.05 were considered statistically significant.

**Results**

**Participants**
Thirty-four staff members - 7 consultants, 10 fellows, 8 residents, and 9 neonatal nurses - participated in this study (years’ of experience shown in Table 1).

**Measurements**
A total of 10,780 inflations were recorded from the 34 participants using each of the four device-mask combinations. The data for each participant group are shown as mean (SD) in Table 2.

**Peak inspiratory pressure (PIP)**
Overall, the mean (SD) PIP was 26.4 (2.6) cm H$_2$O. The mean (SD) for the PIP is shown for each participant group, device and mask in Table 2. There was no significant difference for devices ($F_{1, 130} = 0.02, P = 0.88$), participant groups ($F_{3, 130} = 0.82, P = 0.48$), or masks ($F_{1, 130} = 0.08, P = 0.78$) (Table 2).
Positive end expiratory pressure (PEEP)
Participants delivered PEEP with the Neopuff (mean 4.5 cm H2O, SD 1.1), but not the Laerdal bag (mean 0.0 cm H2O, SD 1.0).

Expiratory tidal volume at the mask \( V_{TE(mask)} \)
There was marked variability in \( V_{TE(mask)} \), ranging from 0 to 29 mL. Overall, the mean (SD) \( V_{TE(mask)} \) was 7.6 (4.9) mL. The mean \( V_{TE(mask)} \) for each participant group, device and mask is shown in Table 2. The overall \( V_{TE(mask)} \) with the Neopuff was lower than with the Laerdal bag (\( F_{1, 130} = 50.0, P <0.001; \) Table 2, Fig 1). There was variation between the different participant groups, but this variation was not statistically significant overall (\( F_{3, 130} = 2.1, P = 0.10; \) Table 2). There was no significant difference between masks (\( F_{1,130} = 0.3, P = 0.60; \) Table 2).

Pressure and expired tidal volume
Although there was a significant positive relationship between the mean \( V_{TE(mask)} \) delivered and mean PIP used (% of variance explained = 13.7, \( P < 0.001 \)), the relationship between the two variables was weak. For example between delivered peak pressures of 20 – 30 cm H2O the \( V_{TE(mask)} \) ranged from as low as zero, to as high as 17 mL (Fig. 2).

Percentage of gas leak from the face masks
Overall, the mean (SD) leak between the mask and the mannequin’s face was 65% (33%). The mean (SD) leak from the face mask is shown for each participant group, device and mask in Table 2. The leak was higher for the Neopuff than the Laerdal (\( F_{1, 130} = 10.9, P = 0.001; \) Table 2, Fig. 3). There was variation between the participant groups (\( F_{3, 130} = 4.1, P = 0.008; \) Table 2, Fig. 3). On post hoc analysis, the residents had more leak than the consultants (mean difference 19.2%, 95% CI 3.5%, 34.9%), the fellows (mean difference 22.3%, 95% CI 7.9%, 36.6%), and the nurses (mean difference 22.7%, 95% CI 7.9%, 37.4%). There was no statistically significant difference between masks (\( F_{1,130} = 3.1, P = 0.08; \) Table 2).

Interactions
There were no statistically significant interactions between participant group, device or mask for any variable (data not shown).

Participants’ preferences
The Neopuff was preferred by 32 of 34 participants and the majority preferred the round mask (Table 1). As so few preferred the Laerdal we decided against comparing performance with the preferred combination of device and mask.

Discussion
Our study shows that while giving PPV via a mask, it is possible to deliver highly variable volumes despite generating very similar airway pressures (Fig. 3). This illustrates that airway pressure is a very crude proxy for the volume of gas delivered during ventilation via a mask. Thus clinicians may be falsely reassured that effective ventilation is occurring because the desired pressures are achieved. The aim of
ventilation is to provide a volume of gas to the lung adequate for gas exchange. A direct measure of the parameter of interest (volume) would be more valuable than the current poor substitute (inflating pressure).

An important difference between the two ventilation devices is the provision of PEEP with the Neopuff. While there are no current recommendations about the use of PEEP during resuscitation, there are many reasons to believe that it may be beneficial, particularly for very premature infants.18 The provision of PEEP with the Neopuff partially explains the smaller VTE(mask) delivered with this device, as the inflating pressure (difference between peak and trough pressure – 20 cm H2O here) is smaller than that with the Laerdal (25 cm H2O).

This study demonstrates substantial leak from the mask during simulated neonatal resuscitation, even in the most experienced hands. In the sole study of face masks, the absence of significant leak was inferred from the achievement of set mechanical ventilator pressures.16 Our finding that a target PIP may be achieved with large leaks suggests that this inference is not correct. It has been suggested that resuscitation bags of 240 mL are too small to resuscitate newborns and that larger paediatric (at least 450 mL) bags should be used.12 Given that an infant’s tidal volume is about 4 - 8 mL/kg, a 240 mL bag should be more than adequate. That these devices have been demonstrated to be inadequate13 suggests there was considerable leak in the system, most likely at the mask. We were surprised that the anatomical mask was no different to the round mask, as this was the first time participants had used it. It is possible that with experience, performance could improve with this model.

Our findings that a target pressures can be delivered accurately by operators of varying levels of experience using a Neopuff are similar to those of Finer.16 Somewhat surprisingly, participants also achieved the target PIP accurately with the Laerdal bag. The Laerdal bag is often not used with a manometer and it may have improved the participants’ ability to deliver this target PIP. The manometer of the Neopuff is built into the control box and is some distance from the T-piece. Some participants remarked that they tended to concentrate on the pressures being delivered rather than the mannequin’s chest excursion. The manometer in the Laerdal circuit seemed less of a distraction, as most participants placed it alongside the mannequin’s chest, allowing simultaneous observation of both the manometer and chest excursion. This may help to explain the smaller leak and larger VTE(mask) delivered with the Laerdal.

All but two participants expressed a preference for the Neopuff. This precluded meaningful statistical analysis of the effect of operator preference. However, such a marked preference combined with inferior performance suggests that personal preference for a device is not a reliable way to discern the most effective tool for resuscitation.

**Conclusion**

During face mask ventilation of a neonatal resuscitation mannequin there are large leaks around the face mask. Widely varying volumes may be delivered with similar target peak airway pressures regardless of the device and mask used or the experience
of the resuscitator. This shows that airway pressure is a poor proxy for the tidal volume delivered during positive pressure ventilation via a face mask. Specified peak airway pressures may be generated accurately using a Laerdal bag with a manometer and a Neopuff Infant Resuscitator, though only the Neopuff produces PEEP. Larger tidal volumes were delivered with the Laerdal bag and less leak was seen from the face mask than with the Neopuff. Clinical studies to determine the most effective devices and techniques to give PPV to newborns at delivery are urgently needed.

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Competing interests
None

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Figure legends

Figure 1
Expiratory tidal volume at the mask [V_{TE(mask)}] by device and group. Boxplots show median values (solid bar), interquartile range (margins of box), range of data, and any extreme values (indicated by an asterisk).

Figure 2
Scatterplot showing relationship between mean peak inspiratory pressure and mean expiratory tidal volume at the mask [V_{TE(mask)}].

Figure 3
Percentage leak by device and group. Boxplots show median 0values (solid bar), interquartile range (margins of box), range of data, any outliers (indicated by a circle) and extreme values (indicated by an asterisk).
References
17. O'Donnell CPF, Kamlin COF, Davis PG, Morley CJ. Neonatal resuscitation 1: evaluating face mask leak and estimating tidal volume in a model.
Table 1. Years’ of experience in neonatal paediatrics, and device and mask preferences in each group.

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Years’ Experience*</th>
<th>Device Preference</th>
<th>Mask Preference</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Laerdal/Neopuff</td>
<td></td>
</tr>
<tr>
<td>Consultants</td>
<td>7</td>
<td>17 (5, 33)</td>
<td>1/6</td>
<td>3/4</td>
</tr>
<tr>
<td>Fellows</td>
<td>10</td>
<td>3 (2, 20)</td>
<td>1/9</td>
<td>8/2</td>
</tr>
<tr>
<td>Residents</td>
<td>8</td>
<td>0.6 (0.5, 2)</td>
<td>0/8</td>
<td>6/2</td>
</tr>
<tr>
<td>Nurses</td>
<td>9</td>
<td>7.5 (2.8, 13)</td>
<td>0/9</td>
<td>6/3</td>
</tr>
</tbody>
</table>

*Values are median (range)

Table 2. Peak inspiratory pressure, expired tidal volume and leak from the face mask for each participant group, device and mask.

<table>
<thead>
<tr>
<th>Overall n=136</th>
<th>Mean PIP (cm H₂O)</th>
<th>Expiratory tidal volume at the mask [Vₑ(mask)] (mL)</th>
<th>Leak from the face mask [% of Vₑ(mask)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall n=136</td>
<td>26.4 (2.6)</td>
<td>7.6 (4.9)</td>
<td>64.6 (33.1)</td>
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</table>

Participant groups

<table>
<thead>
<tr>
<th>Consultants n=28</th>
<th>Mean PIP (cm H₂O)</th>
<th>Expiratory tidal volume at the mask [Vₑ(mask)] (mL)</th>
<th>Leak from the face mask [% of Vₑ(mask)]</th>
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<tr>
<td>Consultants n=28</td>
<td>26.0 (1.8)</td>
<td>8.2 (4.4)</td>
<td>62.2 (34.0)</td>
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<td>Fellows n=40</td>
<td>26.2 (1.3)</td>
<td>7.5 (5.1)</td>
<td>59.1 (35.2)</td>
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<tr>
<td>Residents n=32</td>
<td>27.1 (5.0)</td>
<td>6.2 (5.4)</td>
<td>81.4 (22.9)</td>
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<tr>
<td>Nurses n=36</td>
<td>26.3 (1.7)</td>
<td>8.6 (4.5)</td>
<td>58.7 (33.6)</td>
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</table>

Device

<table>
<thead>
<tr>
<th>Laerdal n=68</th>
<th>Mean PIP (cm H₂O)</th>
<th>Expiratory tidal volume at the mask [Vₑ(mask)] (mL)</th>
<th>Leak from the face mask [% of Vₑ(mask)]</th>
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</thead>
<tbody>
<tr>
<td>Laerdal n=68</td>
<td>26.3 (3.4)</td>
<td>10.2 (3.6)</td>
<td>56.2 (31.8)</td>
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<tr>
<td>Neopuff n=68</td>
<td>26.5 (2.2)</td>
<td>5.1 (4.8)</td>
<td>73.5 (32.1)</td>
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Mask

<table>
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<tr>
<th>Round n=68</th>
<th>Mean PIP (cm H₂O)</th>
<th>Expiratory tidal volume at the mask [Vₑ(mask)] (mL)</th>
<th>Leak from the face mask [% of Vₑ(mask)]</th>
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</thead>
<tbody>
<tr>
<td>Round n=68</td>
<td>26.5 (2.9)</td>
<td>7.5 (5.0)</td>
<td>69.6 (30.1)</td>
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<tr>
<td>Anatomical n=68</td>
<td>26.3 (2.8)</td>
<td>7.8 (4.9)</td>
<td>60.2 (35.2)</td>
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</table>

Data are mean (SD). PIP = peak inspiratory pressure;
Expired tidal volume at mask
[VT_{e(mask)}] (mL)