A new suction mask to reduce leak during neonatal resuscitation: a manikin study

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ABSTRACT
Objective Leak around the face mask is a common problem during neonatal resuscitation. A newly designed face mask using a suction system to enhance contact between the mask and the infant’s face might reduce leak and improve neonatal resuscitation. The aim of the study is to determine whether leak is reduced using the suction mask (Resusi-sure mask) compared with a conventional mask (Laerdal Silicone mask) in a manikin model.
Methods Sixty participants from different professional categories (neonatal consultants, fellows, registrars, nurses, midwives and students) used each face mask in a random order to deliver 2 min of positive pressure ventilation to a manikin. Delivered airway pressures were measured using a pressure line. Inspiratory and expiratory flows were measured using a flow sensor, and inspiratory tidal volumes and mask leaks were derived from these values.
Results A median (IQR) leak of 12.1 (0.6–39.0)‰ was found with the conventional mask compared with 0.7 (0.2–4.6)‰ using the suction mask (p=0.002). 50% of the participants preferred to use the suction mask and 38% preferred to use the conventional mask. There was no correlation between leak and operator experience.
Conclusions A new neonatal face mask based on the suction system reduced leak in a manikin model. Clinical studies to test the safety and effectiveness of this mask are needed.

BACKGROUND
Around 3%–6% of newborn infants require positive pressure ventilation (PPV) in the delivery room (DR).1 This is most commonly delivered using a round or anatomically shaped face mask attached to a T-piece device, self-inflating bag or flow-inflating bag.2 However, delivering effective mask ventilation can be challenging, because of large leak around the mask. Studies report variable leak, sometimes >50% of inspiratory volume, during mask PPV in preterm infants in the DR.1 4
In order to perform PPV, the operator must hold the mask onto the infant’s face, applying downward pressure on the mask and upward pressure with fingers under the chin to create a seal, while stabilising the infant’s head to keep the airway open.5 Many operators find it difficult to maintain a good seal between the mask and face while keeping the head in the correct position and without causing obstruction to the airway.6 A two-person technique seems to reduce leak compared with a single operator.7 However, in some settings there may not be sufficient staff available to perform this technique.

A new face mask called Resusi-sure (LSR Healthcare, Sydney, NSW, Australia) uses a suction system to generate negative pressure to create a seal between the mask and the infant’s face. The mask has Australian Therapeutic Goods Administration (TGA) approval. There have been no studies comparing its effectiveness with other widely used face masks.

Our aim was to compare the leak measured during ventilation using the suction mask with that measured using the conventional mask in a manikin model. Subjects ranged from experienced neonatal consultants to medical and midwifery students with limited or no experience in ventilating a newborn infant.

METHODS
Setting and participants
The study was undertaken in a tertiary perinatal centre, The Royal Women’s Hospital in Melbourne, Australia and staff from different professional categories were invited to participate. All participants except the medical and midwifery students had annual inhouse training in neonatal resuscitation.

Equipment
The conventional mask (Laerdal Silicone mask, Laerdal, Stavanger, Norway) size 0/1 mask, outer diameter=65 mm, inner diameter=40 mm, internal...
volume 41 mL, was compared with the suction mask (Resusi-sure mask), outer diameter 60 mm, inner diameter 40 mm, internal volume 25 mL (figure 1) which has a side port with an internal diameter of 7 mm. The port is designed to connect to standard tubing used by suction apparatus on the resuscitation trolley. The mask is designed to form a vacuum chamber between the inner and the outer rim (figure 2). The suction mask is manufactured by Romar Engineering (Sefton, NSW, Australia). We performed the study using a prototype mask in June 2015. In the final quarter of 2015, the production mask was released by LSR Healthcare. The Australian TGA approved the mask for neonatal resuscitation.

During the design of the study and prior to commencement, the suction mask was tested in our laboratory across a range of negative suction pressures to determine the minimum pressure required to achieve an adequate seal. The adequate seal was defined by the rise of the indicator arrow on the suction gauge with a corresponding change in the sound of the suction. This optimal pressure was 100 mm Hg and used throughout the study.

The suction mask only forms a seal with skin or a prosthetic equivalent of skin. In order to test the suction mask in a manikin we used a silicon ‘seal skin’ layer to mimic the skin on the baby’s face (figure 3). This removable silicon layer, PlatSil Gel-10 (Polytek, Easton, Pennsylvania, USA), was provided by the mask manufacturer. Both masks were tested with the silicon layer in situ. A Laerdal Resusci Baby manikin (Laerdal) was modified by inserting a test lung, creating a leak-free circuit as previously described. A Florian respiratory monitor (Acutronic Medical Systems, Zug, Switzerland) detected gas flow via a flow sensor placed between the Neopuff T piece and the mask. The flow sensor has an accuracy of ±8%. Tidal volumes were obtained by integration of the flow signal and airway pressure was measured via a pressure line connected immediately proximal to the test lung. Leak was calculated as the difference between inspiratory and expiratory tidal volumes expressed as a percentage of the inspired volume. Spectra software (Grove Medical, London, UK) was used to capture and record data.

**Study protocol**

All participants received a standardised educational session provided by one researcher (LL). The scripted session included a standardised description of the objectives of the study, the mechanism of action of the suction mask and the manikin including the silicone layer on the face. This was followed by a demonstration of how to place both masks onto the face (by rolling the mask from the chin to cover the mouth and nares) and how to maintain this position using the two-point top hold. All participants had the opportunity to practice with both masks before formal recordings were made. In order to allow comparison with other studies, participants were requested to deliver PPV for 2 min with each mask at a respiratory rate (RR) of 40–60 inflations/min. They did not wear gloves when ventilating the manikin, they were not able to view the measurements and none had previously used the suction mask. Mask order was allocated randomly (using variable block randomisation). At completion of the study participants were asked to state their preferred mask and their experience in neonatology.

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**Figure 1** Photograph showing the suction mask (A) and the conventional mask (B).

**Figure 2** Photograph of the suction mask from below showing the inner and outer rims that form the vacuum chamber.

**Figure 3** Photograph of the silicon ‘seal skin’ layer attached to the manikin’s face.
Power calculation and statistical analysis

The sample size was calculated using the results of a previous study which reported a mean (SD) leak of 35 (27)%.[10] To detect a reduction in mean leak from 35% to 25% using a paired Student’s t test with an $\alpha$-value of 0.05 and a power of 80%, at least 60 participants were required.

Normally distributed data are shown as mean and SD and skewed data as median and IQR. Differences in ventilation parameters between the two masks were assessed using a sign test due to skewed distribution. The difference in medians and its 95% CI was calculated using a quantile regression analysis. The strength of relationship between leak and years of experience was estimated using the Spearman correlation coefficient. Data were analysed using Stata software (Intercooled V.13, Stata, Texas, USA). The first and the last in flations were excluded from the analysis. In flations with an RR of $>100$/min and a leak less than $-10\%$ were excluded from further analyses due to suspected artefacts. Leak values between $-10\%$ and 0% were assigned the value 0%.

RESULTS

Sixty participants were enrolled in the study: 10 neonatal consultants, 10 fellows, 10 registrars, 10 nurses, 10 midwives and 10 students (5 medical and 5 midwifery students). Participant’s neonatal experience was median (IQR) 19 (15–25) years for consultants, 4 (3–7) years for fellows, 0.7 (0.5–1) years for registrars, 4 (3–13) years for midwives, 5.7 (4–9) years for nurses and 0 (0–0.3) years for students.

Thirty participants started PPV with the conventional mask and 30 with the suction mask. After excluding 91 in flations, 5411 in flations obtained with the conventional mask and 5327 with the suction mask were averaged for each operator before further analysis. Measured leak using the suction mask was significantly lower than that with the conventional mask (table 1 and figure 4A).

Leak and the variability in leak using the suction mask were less compared with the conventional mask for all professional categories (figure 4B). There was no correlation between leak and years of experience using either mask (conventional mask: r=$-0.06$, p=0.56; suction mask: r=$0.08$, p=0.36).

Thirty (50%) participants preferred to use the suction mask because they felt that it gave a better seal or that the mask was easier to hold to achieve better ventilation. Operators reported that they felt they used less downward pressure to keep the suction mask in place and could focus on maintaining the neutral position of the head. Nineteen participants (32%) preferred the conventional mask due to familiarity. Some operators were worried about the possible negative side effects of the suction mask in infants. Eleven (18%) participants had no preference between the two masks.

DISCUSSION

To the best of our knowledge, this is the first study testing the new suction mask in a neonatal manikin model.

In contrast to other masks previously tested in manikin models" or infants' this is the first mask showing a reduction in leak compared with the conventional mask. This might be due to the sealing effect of the negative pressure between the inner and outer rims of the suction mask. In our study, there were lower levels of leak measured during PPV with the

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Table 1 | Comparison of ventilation parameters according to the two different masks in 60 participants

<table>
<thead>
<tr>
<th></th>
<th>Conventional mask</th>
<th>Suction mask</th>
<th>Difference in medians</th>
<th>p Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak (%)</td>
<td>12.1 (0.6 to 39.0)*</td>
<td>0.7 (0.2 to 4.6)*</td>
<td>$-12.0 (-19.5 to -4.5)&lt;/i&gt;†</td>
<td>0.002</td>
</tr>
<tr>
<td>PIP</td>
<td>24.9 (24.5 to 25.3)*</td>
<td>25.2 (24.6 to 25.7)*</td>
<td>0.2 (-0.2 to 0.6)†</td>
<td>0.25</td>
</tr>
<tr>
<td>PEEP</td>
<td>3.5 (2.9 to 4.1)*</td>
<td>3.2 (2.8 to 3.7)*</td>
<td>$-0.4 (-0.8 to -0.0)†</td>
<td>0.046</td>
</tr>
<tr>
<td>RR</td>
<td>44.9 (39.7 to 50.4)*</td>
<td>44.8 (40.5 to 49.5)*</td>
<td>$-0.6 (-4 to 2.8)†</td>
<td>0.73</td>
</tr>
</tbody>
</table>

*Median (IQR).
†Coefficient (95% CI).
PEEP, positive end expiratory pressure; PIP, peak inspiratory pressure; RR, respiratory rate.

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Figure 4 | Comparison of leak (%) between conventional mask (CM) and suction mask (SM) for all participants (A) and divided by professional categories sorted by median order (B). The bottom and top of the box represent the 25th and 75th percentile and the band inside the box represents the median. The ends of the whiskers represent the adjacent values (most extreme values within 1.5 IQR of the nearer quartile) and data not included between the whiskers are plotted as outliers.

higher pressures.\textsuperscript{13} We observed a painless red mark on the face of the manikin’s face. Among all professional categories the suction mask resulted in less leak compared with the conventional mask. We included students in our study to determine whether inexperienced operators could achieve a better seal with the suction mask compared with the conventional mask. Equally important is that there is reduced variability in leak using the suction mask which is likely to result in more consistent ventilation. This should be formally evaluated in the DR using this mask on newborn infants. Our findings were consistent with other studies which found no correlation between leak and years of experience.\textsuperscript{10}

Half of the participants preferred to use the suction mask, mainly because they felt more confident in its seal. However, two concerns were highlighted. First, the negative pressure could potentially lead to discomfort, bruising and excoriation, especially when applied to the wet skin of a preterm infant. Applying the suction mask to adult human forearms, less pressure (\textasciitilde75 mm Hg) was sufficient to form an adequate seal. In comparison, other devices in clinical practice such as vacuum-assisted vaginal delivery (150–600 mm Hg) use much higher pressures.\textsuperscript{13} We observed a painless red mark on the forearm that disappeared within a few seconds independently of how long (30 s, 1 min, 5 min) the negative pressure was applied to the forearm. Second, if the only available suction system is being used by the suction mask, disconnection would be necessary when the suction system is needed to clear the airway. This may be a limitation for its use, especially in low-resource settings. Finally, the optimal mask leak is not known. The advantage of minimising leak is to better target appropriate tidal volumes using lower peak inflating pressures.

As with all manikin studies, ours also has certain important limitations. Although we attempted to provide an accurate model of a term infant’s face, the same improvement in the effectiveness of the suction mask may not be seen during actual clinical use. In addition, we were unable to test the safety of this mask with this model. A clinical study is needed to test this mask in the term infant population.

**CONCLUSION**

This is the first study showing a significant difference in leak between two different resuscitation masks. There is less variability in leak using the suction mask among all professional categories. The suction mask may improve neonatal resuscitation but needs further investigation in clinical trials to explore the feasibility, efficacy and safety of its use to support the transitioning newborn infant.

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**Competing interests** LSR Healthcare provided the suction mask for the study.

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**REFERENCES**

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