Improving neonatal resuscitation at birth: technique and devices
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Compressive force applied to a manikin’s head during mask ventilation

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Abstract

Objective
To investigate the compressive force applied to the head during mask ventilation and determine whether this force increases in response to an attempt to correct mask leak.

Methods
The authors asked 24 participants (consultants, fellows and nurses) to administer positive pressure ventilation to a modified leak-free, term newborn manikin using a self-inflating bag (SIB) and a Neopuff T-piece device. Recordings were made before and after the participants were informed about their percentage of mask leak and asked to correct this. Airway pressure and flow were measured using a Florian monitor, and the force applied to the head was measured using a concealed custom-made load cell weighing scale.

Results
There were no differences in mean (SD) force applied to the head between devices used and before or after the attempt to correct the mask leak (SIB before 2215 (892) and after 2195 (989) g; Neopuff before 1949 (957) and after 2028 (909) g). There was a large variation in force with both devices before and after the attempt (coefficient of variation: SIB before 40% and after 45%; Neopuff before 50% and after 45%). There was no correlation between mask leak and the difference in force used before and after the attempt to correct the mask leak using both devices.

Conclusion
During mask ventilation of a manikin, the authors observed that large forces were exerted on the head with either an SIB or a Neopuff, but these forces did not increase during the attempt to minimise the mask leak.
Introduction

Approximately 10% of infants, particularly preterm infants, will need some form of resuscitation at birth at which time adequate ventilation is crucial and is usually applied using a facemask. An appropriate mask technique is essential for establishing effective ventilation. However, leak between mask and face is common, even for experienced operators, and it reduces the efficacy of resuscitation. Airway obstruction is also common in preterm infants receiving mask ventilation immediately after birth, especially in very low birth weight infants as they have a relatively large tongue and small mandibles. During mask ventilation of infants, obstruction can be caused by liquid in the oropharynx, positioning of the head, neck and tongue or by pressing down on the mask too hard, leading to obstruction of the nose and mouth. While investigating mask ventilation techniques using manikins, we observed that when the resuscitator was notified of mask leak, airway obstruction often accompanied the corrective action. Specifically, we observed that the participants pressed harder on the mask with the intention to reduce mask leak. However, there are no data available on how much force is applied to the head of infants during mask ventilation and whether it depends on the device used. This prompted us to investigate the compressive force applied to the head of a manikin during mask ventilation and determine whether this force increases in response to an attempt to correct mask leak, leading to obstruction. We also investigated whether different devices lead to different compressive forces to the head.

Methods

The study was performed in the neonatal intensive care centre of the Leiden University Medical Center (LUMC), Leiden, the Netherlands. Neonatal staff members, registrars and nurses of the unit were asked to administer positive pressure ventilation to a modified, leak-free manikin (Laerdal Resusci Baby; Laerdal, Stavanger; Norway) representing a term newborn. In this manikin, the original lung was replaced with a 50 mL leak-free test lung (Dräger, Lübeck, Germany) that was positioned so that inflation caused a visible chest rise. Non-distensible tubing connected the lung and mouth, which ensured that all connections were airtight. The mandible of the manikin was adapted to cause obstruction when too much downward pressure was given without an efficient chin lift. Positive pressure ventilation was applied using a size 0/1 Laerdal round mask (Laerdal, Stavanger, Norway) in combination with a Neopuff T-piece infant resuscitator (Fisher & Paykel Healthcare, Auckland, New-Zealand) or an Ambu mark IV self-inflating bag (SIB) (Ambu, Copenhagen; Denmark) with a positive end expiratory pressure (PEEP) valve and manometer attached. The
Neopuff was set to a peak inflating pressure (PIP) of 30 cm H₂O and a PEEP of 5 cm H₂O; gas flow was set to 8 L/min. The PEEP valve of the Ambu was also set to 5 cm H₂O.

All recordings were made using a Florian respiratory monitor (Acutronic Medical Systems, AG, Switzerland), which uses a hot-wire anemometer as a flow sensor and has a dead space of < 1 mL. The flow sensor was placed distally between the T-piece of the Neopuff and the facemask or between the end of the SIB and the facemask, and the output signal was integrated to provide inspired and expired tidal volumes. The difference in inspired and expired volumes equals facemask leak. This was calculated by expressing the volume of the gas that did not return through the flow sensor during expiration as a percentage of the volume that passed through the flow sensor during inflation. The Florian remained on to minimise the drift and was zeroed by the researchers each time recordings were made.

Measuring obstruction is complicated by the confounding effect of the leak as large leaks make it difficult to determine the presence of an obstruction. Therefore, we only noted obstruction from inflations with less than 30% leak. We defined obstruction as a typical flattening of the flow wave and a measured tidal volume < 50% of expected values.

The compressive force was measured using a custom-made load cell weighing scale (van Loenen, LUMC, the Netherlands). This was composed of a spring-loaded rigid platform, which measured the force in grams independently from the surface area it was applied over. The weighing scale was zeroed before every measurement with the head of the manikin on the scale (figure 1).
Before starting the measurements, the device was zeroed and the calibration was rechecked by measuring a known weight. The accuracy and reproducibility of the device was tested by measuring different known weights (250 and 500 g, 1, 2 and 5 kg), and a combination of the weights, in triplicate. The scale constantly measured the force applied to the head of the manikin and the mean force was calculated.

The signals of airway flow, tidal volumes, airway pressure and force applied to the head were digitised and recorded at 200 Hz using a data acquisition program (Spectra, Grove Medical Limited, Hampton, UK).

All participants were informed that we were investigating the effect of leak reduction and were not aware that they participated in a study in which the compressive force exercised on the head was recorded. The weighing scale was concealed by a blanket under the head of the manikin. Also, the screen of the Florian and the laptop were not visible for the participants.

Participants were experienced using T-piece and SIB. All participants were asked to give mask ventilation using both devices, but they were randomised to start with either the SIB or the T-piece. After one minute, they were informed of the average mask leak that occurred and they were asked to improve their technique in order reduce the mask leak. The average mask leak was calculated and reported to the participant. A total of two minutes of mask ventilation was recorded.

**Statistical analysis**

Data was analysed using SPSS for Windows version 17.0.0. The results are given as mean (SD). To quantify the difference between compressive force applied to the head and leak before and after the attempt to correct the mask leak, a paired t test was used. A comparison of all forces applied to the head was made using an analysis of variance.

Correlations between pressure and leak were analysed using a Pearson correlation test. Correlations of the difference in the pressure between both measurements in Neopuff and SIB, and leak were also analysed using a Pearson correlation test. The coefficient of variation (CV) was calculated as (SD/mean)x100, and a CV < 5% was regarded to reflect good agreement and a CV < 10% to reflect acceptable agreement. A p value < 0.05 was considered statistically significant. Reported p values are two-sided.

**Results**

**Participants**

We obtained all four recordings from 24 participants, of whom 10 were consultants, 5 registrars and 9 neonatal intensive care unit nurses. All participants were trained and experienced in neonatal resuscitation.
Compressive force applied to the head

There was a large variation in the compressive force applied to the manikin’s head, which ranged between 606 and 3717 g (figure 2). The mean force applied during resuscitation was similar for both devices (SIB and T-piece, respectively: 2205 (932) and 1989 (925) g) and the variation in force applied was also similar between devices (SIB and T-piece, respectively: CV of 40 % and 50%) (figure 2). The variation in the force did not change after the correction of the leak (SIB and T-piece: CV both 45%; figure 2) and primarily arose due to variation in the force applied between operators, irrespective of the device used. The mean CV in the force applied by each operator using each device and before and after leak correction was 18.2% (12.4), with six operators having a CV of < 5%. There was no change in force during either the PIP or the PEEP phases of inflation.

Figure 2. Box plots representing the median (IQR) force in g for both devices and for attempts before and after correction of leak. Self-inflating bag (SIB)/Neopuff before and SIB/Neopuff after represent the attempts before and after the effort to correct the mask leak by all participants using an SIB and Neopuff.

During mask ventilation, there was no difference in the compressive force on the head between SIB and T-piece before (means (SD) SIB vs. Neopuff: 2215 (892) vs. 1949 (957) g; NS) and after (2195 (989) vs. 2028 (909) g; NS) the effort to correct the mask leak.

During ventilation with the SIB, there was no difference in the compressive force before and after the effort to correct mask leak (means (SD) before vs. after: 2215 (892) vs. 2195
Compressive force during mask ventilation

(989) g; NS). The compressive force increased in 14 participants (by 14.0% (18.2)) and decreased in 10 participants (by 19.5% (17.4)). The median (IQR) difference in the force applied between before and after (before to after) mask placement correction was 19 (-200 to 177) g (figure 3).

Figure 3. The δ force (= force first attempt–force second attempt) in g against the percentage of mask leak notified to the participant after the first attempt, ventilating with a self-inflating bag. (Pearson correlation test: r = -0.10; NS.)

During ventilation with the T-piece, there was no difference in the compressive force between before and after the effort to correct the mask leak during ventilation (mean (SD) before vs. after: 1949 (957) vs. 2028 (909) g; NS). However, the majority (15% (63)) of participants increased (by 21.5% (23.8)) compressive force, whereas only 9 (37%) participants decreased (by 12.5% (11.8)) the amount of compressive force applied. The median (IQR) difference in the force applied between before and after (before to after) mask placement correction was -79 (-304 to 95) g (figure 4).
Correlation of leak and force applied to the head after correction of facemask position.

There was no correlation between the amount of facemask leak and the difference in compressive force applied before and after attempting to correct the facemask position using an SIB ($r = -0.10$; NS) or a T-piece ($r = -0.27$; NS) (figures 3 and 4).

Leak and airway obstruction

Using the SIB, the mean (SD) amount of facemask leak was similar before correction (47% (33%)) compared with after correction of facemask leak (36% (35.3%)). Using the T-piece, the mask leak was 42.3% (31%) before correction and 38.0% (33.6%) (NS) after correction of facemask positioning.

During inflations that were associated with minimal leak, occasionally airway obstruction was observed, but the occurrence of airway obstruction was not increased by an attempt to correct the mask leak using both devices (table 1). There was no difference in compressive force applied to the head in the presence (2141 (866) g) or absence (2205 (920) g; NS) of an airway obstruction.
Table 1. Number of occurrence of obstruction for all participants, no obstruction or obstruction could not be evaluated due to high mask leak (N = 24) during the attempts of participants

<table>
<thead>
<tr>
<th></th>
<th>Obstruction</th>
<th>No obstruction</th>
<th>Obstruction cannot be judged</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIB before</td>
<td>2</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>SIB after</td>
<td>1</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Neopuff before</td>
<td>1</td>
<td>17</td>
<td>6</td>
</tr>
<tr>
<td>Neopuff after</td>
<td>2</td>
<td>15</td>
<td>7</td>
</tr>
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SIB, self-inflating bag.

**Discussion**

This is the first study evaluating the compressive force that is potentially applied to an infant's head during mask ventilation. Although we observed a large variation in compressive force applied by the participants during mask ventilation, even the minimum force (606 g) applied equates to a very significant pressure on a newborn infant’s skull (see below). This variation was not associated with the type of device used nor was it associated with attempts to minimise facemask leak. Instead, the large variation was mostly associated with differences between operators, with 25% of participants displaying a CV of less than 5% across all four test conditions (two devices, before and after leak correction). Although there are no normal values available for comparison, the application of force required to ensure a good seal between the mask and the face should be countered by lifting from under the chin (‘squeezing’ the mask), and so the net force on the skull should be minimal. However, the amount of compressive force applied to the skull in these studies were significant, but was not be correlated to the amount of mask leak before or after leak correction or whether obstruction occurred or not. It is likely that other factors in the mask technique play a role in how much force is pressed on the head.

Airway obstruction can occur when more force is exerted on the mask during an attempt to reduce the leak. However, in this manikin study, we could not confirm the compressive force increased during the attempt to correct for facemask leak. In addition, no correlation was found between the compressive force and the occurrence of leak and obstruction. However, as we only observed obstruction occasionally, it is difficult to draw conclusions. Although the participants were blinded for the aim of this study, it is possible that our previous study created more awareness of facemask leak and the possibility of airway obstruction, which may have influenced our results. Furthermore, as the participants were familiar with the use of manikins, it is possible that they applied greater force than they would apply to an infant. Nevertheless, the average force measured was considerable and even if it was markedly reduced, we would expect it to have a major impact on cerebral physiology (see below).
When translating our measurements into approximate pressures (mm Hg) that could be applied to preterm infants during mask ventilation, we first measured the area of the occiput of a preterm infant making contact with the underlying surface. To calculate this, a print of the area was made from a preterm infant of 29 weeks of gestation using washable ink (permission was received from the parents before making this measurement). The measured weight force (in g) was then divided by this surface area (9.1 cm²) and converted into mm Hg using the equation; 1g/cm² = 0.735561273 mm Hg. With a surface area of 9.1 cm² (see methods), we calculated that a mean (SD) pressure of 170 (75) mm Hg was applied to the head. During ventilation with an SIB a mean (SD) pressure of 179 (72) mm Hg was applied before and 177 (79) mm Hg after the attempt to correct the mask leak, during Neopuff 157 (77) mm Hg and 164 (73) mm Hg.

We found no difference in the compressive force when an SIB or a Neopuff was used. Apparently, the force is predominantly determined by the way the mask is held and not by the device used to administer the inflations. This is supported by our observation that during inflations, the compressive force did not change with either device and that the primary source of variation was between participants.

This study has been performed with a manikin and it is difficult to extrapolate our findings to human infants. There are no clinical data available about the possible adverse effect that can occur when a large force is pressed on a head of a newborn infant. The manikin’s head is considerably less compliant than the head of a newborn infant, and it is possible that the participants were more concerned with reducing facemask leak rather than the force applied in this study. Thus, we would expect that the force applied to the head of an infant be considerably less, would be applied over a much greater area (≥ 9.1 cm²) and would be mitigated by any structural rigidity and force dispersement provided by the scalp and skull. Nevertheless, the pressures exerted were considerable (averaging 150–180 mm Hg) and even if the real pressures exerted were a quarter of this, we would expect it to have a very significant physiological impact. Indeed, as the systemic arterial pressures are only 50–60 mm Hg (at best), we would expect cerebral capillary blood flow to effectively cease in regions exposed to the greatest force. If the pressures persist, this may cause hypoxic/ischaemic injury as well as increasing the risk of hyperperfusion injury following the release of the force. The associated increase in the intracranial pressure may also cause cerebral tissue damage and contribute to a reflex bradycardia, which is often already present in a newborn infant requiring resuscitation. Although it has been described that when a resuscitation mask is jammed on the face of a newborn, this can mould the back of the head and can bruise the face,¹ there are no reports describing the influence of the force on cerebral perfusion. Clearly, the exertion of too great a force on an infant’s skull is undesirable and this study is the first to measure and highlight the risks of
applying large compressive forces during facemask resuscitation.

In conclusion, during mask ventilation of a manikin, we observed that large forces were exerted on the head, but these forces did not increase during the attempt to minimise the mask leak. Using an SIB or a Neopuff made no difference in how much force was applied. More experimental and observational studies are needed to see whether large forces are used during resuscitation and what their effect is on a newborn infant’s head and especially the cerebral circulation.
Chapter 4

References
